VITEK 2™ — technology

AST-GN90

IVD

Карта для определения чувствительности к антимикробным препаратам грамотрицательных бактерий

КРАТКОЕ ОПИСАНИЕ

Данная карта предназначена для использования с системами VITEK® 2 в клинических лабораториях для лабораторного определения чувствительности к антимикробным препаратам **клинически значимых аэробных грамотрицательных палочек**. Используйте, как указано в руководстве "Расходные материалы".

ПРИМЕНЕНИЕ

Инструкция по применению предоставляется в наборе или может быть загружена с сайта **www.biomerieux.com/techlib**

Для получения дополнительных инструкций по применению смотрите руководство по расходным материалам.

ХРАНЕНИЕ

Хранить при температуре от 2° до 8° C.

СОСТАВ КАРТЫ

Антимикробный препарат	Код	Концентрация §	Диапазон определения ≤	≥	Указания к применению FDA (Управление по контролю за продуктами и лекарствами, США)
Амикацин	AN	8, 16, 64	2	64	CSAGNB**
Амоксициллин/Клавулановая кислота	AMC	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Ампициллин	AM	4, 8, 32	2	32	CSAGNB**
Ампициллин/Сульбактам	SAM	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Азтреонам	ATM	2, 8, 32	1	64	CSAGNB**
Цефазолин	CZ	4, 16, 64	4	64	CSAGNB**
Цефепим	FEP	2, 8, 16, 32	1	64	CSAGNB**
Цефтриаксон	CRO	1, 2, 8, 32	1	64	CSAGNB**
Ципрофлоксацин	CIP	0.5, 2, 4	0.25	4	CSAGNB**
Эртапенем	ETP	0.5, 1, 6	0.5	8	*E. coli*, *K. pneumoniae*, *C. freundii*, *C. koseri*, *E. aerogenes*, *E. cloacae*, Kox(-ESBL)**, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *S. marcescens*
Гентамицин	GM	4, 16, 32	1	16	CSAGNB**
Имипенем	IPM	1, 2, 6, 12	0.25	16	*Acinetobacter* spp., *Citrobacter* spp., *Enterobacter* spp., *E. coli*, *Klebsiella* spp., *M. morganii*, *P. vulgaris*, *Pv. rettgeri*, *P. aeruginosa*, *S. marcescens*, *Pv. stuartii*
Левофлоксацин	LEV❷	0.25, 0.5, 2, 8	0.12	8	*E. cloacae*, *E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *S. marcescens*, *A. baumannii*, *A. lwoffii*, *C. koseri*, *C. freundii*, *E. aerogenes*, *E. sakazakii*, *K. oxytoca*, *M. morganii*, *P. agglomerans*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *P. fluorescens*, *C. sakazakii*
Меропенем	MEM❷	0.5, 2, 6, 12	0.25	16	*E. coli*, *K. pneumoniae*, *P. aeruginosa*, *P. mirabilis*, *Acinetobacter* spp., *C. freundii*, *E. cloacae*, *K. oxytoca*, *M. morganii*, *P. vulgaris*, *S. marcescens*, *A. hydrophila*, *C. diversus*, *H. alvei*, *P. multocida*, *Salmonella* spp., *Shigella* spp.
Нитрофурантоин	FT	16, 32, 64	16	512	CSAGNB**

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Пиперациллин/тазобактам	TZP	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. enterica*
Тетрациклин	TE	2, 4, 8	1	16	CSAGNB**
Триметоприм/Сульфаметоксазол	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

Численные значения выражены в µг/мл.
§ Эквивалентна по эффективности концентрации стандартного метода.
**CSAGNB = Клинически значимые аэробные грамотрицательные палочки.
**Kox(-ESBL) = *K. oxytoca* (кроме штаммов, продуцирующих БЛРС).
❶,❷ пр. = См. рабочие характеристики с кодом препарата и данным символом в колонке комментариев в руководстве к расходным материалам.
**Eco(+ETEC) = *E. coli* (в т. ч. чувствительные энтеротоксигенные штаммы, вызывающие диарею).

КОНТРОЛЬ КАЧЕСТВА

		Контрольные штаммы CLSI®, результаты в системе VITEK 2		
Антимикробный препарат	Код	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™
Амикацин	AN	≤2 – 4	≤2 – 4	-
Амоксициллин/Клавулановая кислота	AMC	≤2/1 – 8/4	-	4/2 – 16/8
Ампициллин	AM	≤2 – 8	-	-
Ампициллин/Сульбактам	SAM	≤2/1 – 8/4	-	8/4 – ≥32/16
Азтреонам	ATM	≤1	2 – 8	-
Цефазолин	CZ	≤4	-	-
Цефепим	FEP	≤1	≤1 – 8	-
Цефтриаксон	CRO	≤1	8 – ≥64	-
Ципрофлоксацин	CIP	≤0.25	≤0.25 – 1	-
Эртапенем	ETP	≤0.5	2 – ≥8	-
Гентамицин	GM	≤1	≤1 – 2	-
Имипенем	IPM	≤0.25	1 – 4	-
Левофлоксацин	LEV	≤0.12	0.5 – 4	-
Меропенем	MEM	≤0.25	≤0.25 – 1	-
Нитрофурантоин	FT	≤16	-	-
Пиперациллин/тазобактам	TZP	≤4/4	≤4/4 – 8/4	≤4/4
Тетрациклин	TE	≤1 – 2	8 – ≥16	-
Триметоприм/Сульфаметоксазол	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-

Численные значения выражены в µг/мл.

ОГРАНИЧЕНИЯ

Для следующих сочетаний микроорганизм / антимикробный препарат результат следует подтверждать альтернативным методом:
- Амикацин: *Acinetobacter baumannii*
- Амоксициллин/Клавулановая кислота: *Providencia* spp.
- Ампициллин: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Ампициллин/Сульбактам: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Азтреонам: *Pseudomonas* spp.
- Имипенем: *Serratia marcescens*
- Пиперациллин/тазобактам: *Serratia marcescens*

Для следующих сочетаний микроорганизм / антимикробный препарат результат следует подтверждать альтернативным методом при получении результата "умеренно устойчивый" или "устойчивый":

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- Амоксициллин/Клавулановая кислота: *Proteus* spp.

Для следующих сочетаний микроорганизм / антимикробный препарат результат следует подтверждать альтернативным методом при получении результата "устойчивый":
- Имипенем: *Aeromonas* spp.
- Меропенем: *Aeromonas* spp.
- Пиперациллин/тазобактам: *Pseudomonas aeruginosa*

Возможность определения устойчивости на данной карте для следующих сочетаний микроорганизм / антимикробный препарат неизвестна, поскольку на момент сравнительного тестирования при определении рабочих характеристик устойчивые штаммы не были доступны:
- Эртапенем: *E. coli, K. pneumoniae, C. freundii, C. koseri, E. aerogenes, E. cloacae, K. oxytoca* (кроме штаммов, продуцирующих БЛРС), *M. morganii, P. mirabilis, P. vulgaris, S. marcescens*

ПРИМЕЧАНИЕ: Результаты для сочетаний антимикробный препарат / микроорганизм, для которых существуют ограничения, можно исключить из лабораторного отчета. Для получения подробной информации смотрите руководство по программному обеспечению.

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⇩ Перед первым использованием данной карты ⇩ НЕОБХОДИМО ввести приведенные в данной инструкции штрих-коды в программу “Flex Panel Entry”.

01 A310IE0K---R

02 BAST-GN9001B

03 C---Z010702B

04 D00080E1C0H8

05 E0L1N0320 1WY

06 F2G0Y2P0-230

ТАБЛИЦА СИМВОЛОВ И ОБОЗНАЧЕНИЙ

Символ	Обозначение
REF	Номер по каталогу
IVD	Для лабораторной диагностики
	Произведено
	Дата производства
	Температурные ограничения
	Использовать до
LOT	Номер партии
	Перед использованием прочтите инструкцию
Σ	Содержимого достаточно для <n> тестов
EC REP	Уполномоченный представитель в Европейском Сообществе

ПАТЕНТЫ

Продукт защищен одним или более патентов США: D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 и 6,340,573; и иностранными аналогами. Прочие патенты в процессе регистрации.

BIOMÉRIEUX, голубой логотип, VITEK и bioLiaison являются используемыми, зарегистрированными и/или находящимися в процессе регистрации торговыми марками, принадлежащими компании bioMérieux SA, или одному из ее филиалов или одной из ее компаний. ATCC товарный знак и фирменное наименование и любые номера по каталогу ATCC являются торговыми марками, принадлежащими Американской Коллекции Типовых Культур. Другие названия и торговые марки являются собственностью их соответствующих владельцев.

BIOMÉRIEUX

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VITEK 2™ — technology

AST-GN91

IVD

Карта для определения чувствительности к антимикробным препаратам грамотрицательных бактерий

КРАТКОЕ ОПИСАНИЕ

Данная карта предназначена для использования с системами VITEK® 2 в клинических лабораториях для лабораторного определения чувствительности к антимикробным препаратам **клинически значимых аэробных грамотрицательных палочек**. Используйте, как указано в руководстве "Расходные материалы".

ПРИМЕНЕНИЕ

Инструкция по применению предоставляется в наборе или может быть загружена с сайта **www.biomerieux.com/techlib**

Для получения дополнительных инструкций по применению смотрите руководство по расходным материалам.

ХРАНЕНИЕ

Хранить при температуре от 2° до 8° C.

СОСТАВ КАРТЫ

Антимикробный препарат	Код	Концентрация §	Диапазон определения ≤	≥	Указания к применению FDA (Управление по контролю за продуктами и лекарствами, США)
Ампициллин/Сульбактам	SAM	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Азтреонам	ATM	2, 8, 32	1	64	CSAGNB**
Цефазолин	CZ	4, 16, 64	4	64	CSAGNB**
Цефепим	FEP	2, 8, 16, 32	1	64	CSAGNB**
Цефтазидим	CAZ	1, 2, 8, 32	1	64	CSAGNB**
Цефтриаксон	CRO	1, 2, 8, 32	1	64	CSAGNB**
Цефуроксим	CXM	2, 8, 32	1	64	CSAGNB**
Ципрофлоксацин	CIP	0.5, 2, 4	0.25	4	CSAGNB**
Эртапенем	ETP	0.5, 1, 6	0.5	8	*E. coli*, *K. pneumoniae*, *C. freundii*, *C. koseri*, *E. aerogenes*, *E. cloacae*, Kox(-ESBL)**, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *S. marcescens*
БЛРС '	ESB	FEP 1, CTX 0.5, CAZ 0.5, FEP/CA 1/10, CTX/CA 0.5/4, CAZ/CA 0.5/4	NEG	POS	*E. coli*, *K. pneumoniae*, *K. oxytoca*
Гентамицин	GM	4, 16, 32	1	16	CSAGNB**
Левофлоксацин	LEV❷	0.25, 0.5, 2, 8	0.12	8	*E. cloacae*, *E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *S. marcescens*, *A. baumannii*, *A. lwoffii*, *C. koseri*, *C. freundii*, *E. aerogenes*, *E. sakazakii*, *K. oxytoca*, *M. morganii*, *P. agglomerans*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *P. fluorescens*, *C. sakazakii*
Меропенем	MEM❷	0.5, 2, 6, 12	0.25	16	*E. coli*, *K. pneumoniae*, *P. aeruginosa*, *P. mirabilis*, *Acinetobacter* spp., *C. freundii*, *E. cloacae*, *K. oxytoca*, *M. morganii*, *P. vulgaris*, *S. marcescens*, *A. hydrophila*, *C. diversus*, *H. alvei*, *P. multocida*, *Salmonella* spp., *Shigella* spp.
Пиперациллин/тазобактам	TZP	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. enterica*

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Тайгециклин	TGC	0.75, 2, 4	0.5	8	*C. freundii*, *C. koseri*, *E. coli*, *E. cloacae*, *E. aerogenes*, *K. oxytoca*, *K. pneumoniae*, *S. marcescens*
Тобрамицин	TM	8, 16, 64	1	16	CSAGNB**
Триметоприм/Сульфаметоксазол	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

Численные значения выражены в µг/мл.
§ Эквивалентна по эффективности концентрации стандартного метода.
**CSAGNB = Клинически значимые аэробные грамотрицательные палочки.
**Kox(-ESBL) = *K. oxytoca* (кроме штаммов, продуцирующих БЛРС).
Прим.: БЛРС FEP = Цефепим, CTX = Цефотаксим, CAZ = Цефтазидим, CA = Клавулановая кислота. Штаммы, продуцирующие БЛРС, устойчивы ко всем пенициллинам, цефалоспоринам, азтреонаму.
NEG = Отрицательный.
POS = Положительный.
Отрицательный результат теста на БЛРС не исключает наличия БЛРС, скрытых бета-лактамазой класса AmpC.
❶,❷ пр. = См. рабочие характеристики с кодом препарата и данным символом в колонке комментариев в руководстве к расходным материалам.
**Eco(+ETEC) = *E. coli* (в т. ч. чувствительные энтеротоксигенные штаммы, вызывающие диарею).

КОНТРОЛЬ КАЧЕСТВА

		Контрольные штаммы CLSI®, результаты в системе VITEK 2			
Антимикробный препарат	Код	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™	*K. pneumoniae* ssp *pneumoniae* ATCC® 700603™
Ампициллин/Сульбактам	SAM	≤2/1 – 8/4	-	8/4 – ≥32/16	-
Азтреонам	ATM	≤1	2 – 8	-	-
Цефазолин	CZ	≤4	-	-	-
Цефепим	FEP	≤1	≤1 – 8	-	-
Цефтазидим	CAZ	≤1	≤1 – 4	-	-
Цефтриаксон	CRO	≤1	8 – ≥64	-	-
Цефуроксим	CXM	2 – 8	-	-	-
Ципрофлоксацин	CIP	≤0.25	≤0.25 – 1	-	-
Эртапенем	ETP	≤0.5	2 – ≥8	-	-
БЛРС	ESB	NEG	-	-	POS
Гентамицин	GM	≤1	≤1 – 2	-	-
Левофлоксацин	LEV	≤0.12	0.5 – 4	-	-
Меропенем	MEM	≤0.25	≤0.25 – 1	-	-
Пиперациллин/тазобактам	TZP	≤4/4	≤4/4 – 8/4	≤4/4	-
Тайгециклин	TGC	≤0.5	-	-	-
Тобрамицин	TM	≤1	≤1	-	-
Триметоприм/Сульфаметоксазол	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-	-

Численные значения выражены в µг/мл.
Прим.: БЛРС FEP = Цефепим, CTX = Цефотаксим, CAZ = Цефтазидим, CA = Клавулановая кислота. Штаммы, продуцирующие БЛРС, устойчивы ко всем пенициллинам, цефалоспоринам, азтреонаму.
NEG = Отрицательный.
POS = Положительный.
Отрицательный результат теста на БЛРС не исключает наличия БЛРС, скрытых бета-лактамазой класса AmpC.

ОГРАНИЧЕНИЯ

Для следующих сочетаний микроорганизм / антимикробный препарат результат следует подтверждать альтернативным методом:
- Ампициллин/Сульбактам: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Азтреонам: *Pseudomonas* spp.
- Пиперациллин/тазобактам: *Serratia marcescens*

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Для следующих сочетаний микроорганизм / антимикробный препарат результат следует подтверждать альтернативным методом при получении результата "устойчивый":
- Меропенем: *Aeromonas* spp.
- Пиперациллин/тазобактам: *Pseudomonas aeruginosa*

Возможность определения устойчивости на данной карте для следующих сочетаний микроорганизм / антимикробный препарат неизвестна, поскольку на момент сравнительного тестирования при определении рабочих характеристик устойчивые штаммы не были доступны:
- Эртапенем: *E. coli, K. pneumoniae, C. freundii, C. koseri, E. aerogenes, E. cloacae, K. oxytoca* (кроме штаммов, продуцирующих БЛРС), *M. morganii, P. mirabilis, P. vulgaris, S. marcescens*
- Тайгециклин: *C. freundii, E. cloacae, E. coli, K. oxytoca, K. pneumoniae, C. koseri, E. aerogenes, S. marcescens*

ПРИМЕЧАНИЕ: Результаты для сочетаний антимикробный препарат / микроорганизм, для которых существуют ограничения, можно исключить из лабораторного отчета. Для получения подробной информации смотрите руководство по программному обеспечению.

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⇩ Перед первым использованием данной карты ⇩ НЕОБХОДИМО ввести приведенные в данной инструкции штрих-коды в программу “Flex Panel Entry”.

01 A310IF0J---P

02 BAST-GN9101K

03 C---Z00080EH

04 D1C0G0H0I0LE

05 E1N11031W2GF

06 F2P1R052300F

ТАБЛИЦА СИМВОЛОВ И ОБОЗНАЧЕНИЙ

Символ	Обозначение
REF	Номер по каталогу
IVD	Для лабораторной диагностики
	Произведено
	Дата производства
	Температурные ограничения
	Использовать до
LOT	Номер партии
	Перед использованием прочтите инструкцию
Σ	Содержимого достаточно для <n> тестов
EC REP	Уполномоченный представитель в Европейском Сообществе

ПАТЕНТЫ

Продукт защищен одним или более патентов США: D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 и 6,340,573; и иностранными аналогами. Прочие патенты в процессе регистрации.

BIOMÉRIEUX, голубой логотип, VITEK и bioLiaison являются используемыми, зарегистрированными и/или находящимися в процессе регистрации торговыми марками, принадлежащими компании bioMérieux SA, или одному из ее филиалов или одной из ее компаний. ATCC товарный знак и фирменное наименование и любые номера по каталогу ATCC являются торговыми марками, принадлежащими Американской Коллекции Типовых Культур. Другие названия и торговые марки являются собственностью их соответствующих владельцев.

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VITEK 2™ — technology

AST-GP74

IVD

S. pneumoniae Susceptibility

SUMMARY AND EXPLANATION

The VITEK® 2 Gram Positive Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of ***Streptococcus pneumoniae*** to antimicrobial agents when used as instructed in the Product Information manual.

INSTRUCTIONS FOR USE

A package insert is provided in the kit or downloadable from **www.biomerieux.com/techlib**

See the Product Information manual for additional Instructions for Use.

STORAGE CONDITIONS

Store at 2° to 8° C.

CONTENTS OF THE CARD

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Amoxicillin	AMX❷	0.06, 0.25, 1, 2	0.06	8	*S. pneumoniae*
Benzylpenicillin	P	0.06, 0.25, 1, 2, 4	0.06	8	SP(P&M)**
Cefotaxime	CTX	0.06, 0.25, 0.5, 1	0.06	4	*S. pneumoniae*
Ceftriaxone	CRO	0.06, 0.25, 0.5, 1	0.06	4	*S. pneumoniae*
Chloramphenicol	C	2, 8, 16	2	32	*S. pneumoniae*
Ertapenem	ETP	0.5, 1, 4	0.5	8	Spn except P(R)**
Erythromycin [c]	E❷	0.06, 0.125, 0.25	0.25	1	*S. pneumoniae*
Levofloxacin	LEV	0.5, 1, 2	0.5	8	*S. pneumoniae*
Linezolid	LNZ	1	2	4	*S. pneumoniae*
Meropenem	MEM	0.125, 0.25, 0.5, 1	0.06	4	*S. pneumoniae*
Moxifloxacin	MXF	0.25, 1, 2	0.25	4	*S. pneumoniae*
Ofloxacin	OFL	1, 2, 4	1	8	*S. pneumoniae*
Telithromycin	TEL	0.06, 0.25, 1, 4	0.25	4	*S. pneumoniae*
Tetracycline	TE	0.5, 1, 2	1	16	*S. pneumoniae*
Trimethoprim/Sulfamethoxazole	SXT	2/38, 8/152, 16/304, 32/608	10 (0.5/9.5)	320 (16/304)	*S. pneumoniae*
Vancomycin	VA	0.5, 1	1	2	*S. pneumoniae*

Numerical values are expressed in µg/ml.
§ Equivalent standard method concentration by efficacy.
❶,❷ etc. = See performance characteristics identified by the drug code with this symbol in the Comment column in Systems Product Information.
**SP(P&M) = *S. pneumoniae* (pneumonia and meningitis)
**Spn except P(R) = *S. pneumoniae* (excluding penicillin-resistant strains)
[c] = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.

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QUALITY CONTROL

		CLSI® Quality Control Organisms VITEK 2 Results
Antimicrobic	Code	*S. pneumoniae* ATCC® 49619™
Amoxicillin	AMX	≤0.06 – 0.12
Benzylpenicillin	P	0.25 – 1
Cefotaxime	CTX	≤0.06 – 0.12
Ceftriaxone	CRO	≤0.06 – 0.12
Chloramphenicol	C	≤2 – 8
Ertapenem	ETP	≤0.5
Erythromycin[c]	E	≤0.25
Levofloxacin	LEV	≤0.5 – 2
Linezolid	LNZ	≤2
Meropenem	MEM	≤0.06 – 0.25
Moxifloxacin	MXF	≤0.25
Ofloxacin	OFL	≤1 – 4
Telithromycin	TEL	≤0.25
Tetracycline	TE	≤1
Trimethoprim/Sulfamethoxazole	SXT	≤10 (0.5/9.5) – 20 (1/19)
Vancomycin	VA	≤1

Numerical values are expressed in µg/ml.
[c] = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.

LIMITATIONS

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:
- Amoxicillin: *Streptococcus pneumoniae*
- Benzylpenicillin: *S. pneumoniae* (based on the breakpoints for pneumonia)
- Linezolid: *Streptococcus pneumoniae*
- Telithromycin: *Streptococcus pneumoniae*

The ability of the VITEK 2 System to detect **intermediate isolates of *Streptococcus pneumoniae*** with **erythromycin** is unknown because intermediate organisms were not available at the time of comparative testing. Erythromycin-intermediate strains of *Streptococcus pneumoniae* are very rare.

NOTE: A result for an antibiotic/organism combination which may have a limitation may be suppressed from reporting. Refer to the software user manual for instructions.

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⇩ MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.

01 A3207F0H---V

02 BAST-GP74018

03 C--39440102-

04 D082Y3F222M5

05 E3C2Q0A380CB

06 F0506000000N

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
	Temperature limitation
	Use by
LOT	Batch code
	Consult Instructions for Use
Σ	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community

PATENTS

Product covered by one or more of U.S. Patent Nos. D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 and 6,340,573; and Foreign Counterparts. Other Patents Pending.

WARRANTY

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VITEK 2™ — technology

AST-GP71

IVD

Карта для определения чувствительности *Staphylococcus* spp., *Enterococcus* spp., *S. agalactiae* к антимикробным препаратам

КРАТКОЕ ОПИСАНИЕ

Данная карта предназначена для использования с системами VITEK® 2 в клинических лабораториях для лабораторного определения чувствительности к антимикробным препаратам ***Staphylococcus* spp., *Enterococcus* spp. и *S. agalactiae***. Используйте, как указано в руководстве "Расходные материалы".

ПРИМЕНЕНИЕ

Инструкция по применению предоставляется в наборе или может быть загружена с сайта **www.biomerieux.com/techlib**

Для получения дополнительных инструкций по применению смотрите руководство по расходным материалам.

ХРАНЕНИЕ

Хранить при температуре от 2° до 8° C.

СОСТАВ КАРТЫ

Антимикробный препарат	Код	Концентрация §	Диапазон определения ≤	Диапазон определения ≥	Указания к применению FDA (Управление по контролю за продуктами и лекарствами, США)
Бензилпенициллин	P	0.125, 0.25, 1	0.03	0.5	*Staphylococcus* spp.
Цефокситин скрининг	OXSF	6	NEG	POS	*Staphylococcus* spp.
Ципрофлоксацин	CIP	1, 2, 4	0.5	8	*Staphylococcus* spp., *Enterococcus* spp.
Клиндамицин	CM	0.5, 1, 2	0.25	8	*Staphylococcus* spp., *S. agalactiae*
Даптомицин NS	DAP	0.5, 1, 2, 4, 16	0.12	8	*S. aureus*, VSEfaeca**
Эритромицин	E❶	0.25, 0.5, 2	0.25	8	*Staphylococcus* spp., *Enterococcus* spp., *S. agalactiae*
Гентамицин	GM	8, 16, 64	0.5	16	*Staphylococcus* spp.
Клиндамицин (индуцибельная устойчивость)	ICR❷	CM 0.5, CM/E 0.25/0.5	NEG	POS	*Staphylococcus* spp.
Левофлоксацин	LEV	0.25, 2, 8	0.12	8	*Staphylococcus* spp., *Enterococcus* spp., *S. agalactiae*
Линезолид	LNZ	0.5, 1, 2	0.5	8	*S. agalactiae*, *E. faecalis*, *E. faecium*, *S. aureus*, *S. epidermidis*, *S. haemolyticus*
Миноциклин	MNO	0.12, 0.5, 1	0.5	16	*Staphylococcus* spp., *Enterococcus* spp.
Моксифлоксацин	MXF	0.25, 2, 8	0.25	8	MSSA**
Нитрофурантоин	FT	16, 32, 64	16	512	*Staphylococcus* spp., *Enterococcus* spp.
Оксациллин	OX1	0.5, 1, 2	0.25	4	*Staphylococcus* spp.
Хинупристин/Дальфопристин	QDA	0.25, 0.5, 2	0.25	16	MSSA**, *S. epidermidis*, VREF**, *S. agalactiae*
Рифампицин	RA	0.25, 0.5, 2	0.5	32	*Staphylococcus* spp.
Тетрациклин	TE	0.5, 1, 2	1	16	*Staphylococcus* spp., *Enterococcus* spp., *S. agalactiae*
Тайгециклин NS	TGC	0.25, 0.5, 1	0.12	2	*E. faecalis*, *E. faecium*, *S. aureus*, *S. epidermidis*, *S. haemolyticus*, *S. agalactiae*, *E. casseliflavus*
Триметоприм/Сульфаметоксазол	SXT❶	2/38, 8/152, 16/304	10 (0.5/9.5)	320 (16/304)	*S. aureus*
Ванкомицин	VA❷	1, 2, 4, 8, 16	0.5	32	*Enterococcus* spp., *Staphylococcus* spp., *S. agalactiae*

Численные значения выражены в µг/мл.

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§ Эквивалентна по эффективности концентрации стандартного метода.
NEG = Отрицательный.
POS = Положительный.
NS = В настоящее время устойчивые штаммы отсутствуют, что исключает получение какого-либо результата, кроме "чувствительный". При получении МИК, соответствующих другой категории чувствительности ("умеренно устойчивый", "устойчивый") следует отправить штамм в референсную лабораторию для дальнейшего анализа.
**VSEfaeca = *E. faecalis* (чувствительные к ванкомицину штаммы).
❶,❷ пр. = См. рабочие характеристики с кодом препарата и данным символом в колонке комментариев в руководстве к расходным материалам.
**MSSA = чувствительные к метициллину штаммы *S. aureus*
**VREF = устойчивые к ванкомицину штаммы *E. faecium*

КОНТРОЛЬ КАЧЕСТВА

		Контрольные штаммы CLSI®, результаты в системе VITEK 2				
Антимикробный препарат	Код	*E. faecalis* ATCC® 29212™	*S. aureus* ATCC® 29213™	*S. aureus* ATCC® BAA-1026™	*S. aureus* ATCC® BAA-976™	*S. aureus* ATCC® BAA-977™
Бензилпенициллин	P	-	0.25 – ≥0.5	-	-	-
Цефокситин скрининг	OXSF	-	NEG	POS	-	-
Ципрофлоксацин	CIP	≤0.5 – 2	≤0.5	-	-	-
Клиндамицин	CM	4 – ≥8	≤0.25	-	-	-
Даптомицин[NS]	DAP	1 – 4	0.25 – 1	-	-	-
Эритромицин	E	1 – 4	≤0.25 – 1	-	-	-
Гентамицин	GM	-	≤0.5 – 1	-	-	-
Клиндамицин (индуцибельная устойчивость)	ICR	-	-	-	NEG	POS
Левофлоксацин	LEV	0.25 – 2	≤0.12 – 0.5	-	-	-
Линезолид	LNZ	1 – 4	1 – 4	-	-	-
Миноциклин	MNO	1 – 4	≤0.5	-	-	-
Моксифлоксацин	MXF	≤0.25 – 0.5	≤0.25	-	-	-
Нитрофурантоин	FT	≤16	≤16 – 32	-	-	-
Оксациллин	OX1	-	≤0.25 – 0.5	-	-	-
Хинупристин/Дальфопристин	QDA	2 – 8	≤0.25 – 1	-	-	-
Рифампицин	RA	-	≤0.5	-	-	-
Тетрациклин	TE	8 – ≥16	≤1	-	-	-
Тайгециклин[NS]	TGC	≤0.12	≤0.12 – 0.25	-	-	-
Триметоприм/Сульфаметоксазол	SXT	-	≤10 (0.5/9.5)	-	-	-
Ванкомицин	VA	1 – 4	≤0.5 – 2	-	-	-

Численные значения выражены в µг/мл.
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ОГРАНИЧЕНИЯ

Для следующих сочетаний микроорганизм / антимикробный препарат результат следует подтверждать альтернативным методом:
- Даптомицин: *Streptococcus agalactiae*
- Эритромицин: *Streptococcus agalactiae*
- Миноциклин: *Enterococcus faecium*

Для следующих сочетаний микроорганизм / антимикробный препарат результат следует подтверждать альтернативным методом при получении результата "положительный":
- Цефокситин скрининг: *Staphylococcus saprophyticus*

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Возможность определения устойчивости на данной карте для следующих сочетаний микроорганизм / антимикробный препарат неизвестна, поскольку на момент сравнительного тестирования при определении рабочих характеристик устойчивые штаммы не были доступны:

- Линезолид: *Enterococcus* spp., *Staphylococcus* spp., *Streptococcus agalactiae*
- Миноциклин: *Staphylococcus* spp.
- Тайгециклин: *Enterococcus* spp., *Staphylococcus* spp., *Streptococcus* spp.

ПРИМЕЧАНИЕ: Результаты для сочетаний антимикробный препарат / микроорганизм, для которых существуют ограничения, можно исключить из лабораторного отчета. Для получения подробной информации смотрите руководство по программному обеспечению.

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⇩ Перед первым использованием данной карты ⇩ НЕОБХОДИМО ввести приведенные в данной инструкции штрих-коды в программу “Flex Panel Entry”.

01 A3207C0W---M

02 BAST-GP7101I

03 C---Z0G370H9

04 D0P3X0I193I5

05 E132N1Y2R0VU

06 F201W0X1H3KB

07 G343L-V-U-T8

08 H-S-P-K-J-I2

09 I-F-60000000D

ТАБЛИЦА СИМВОЛОВ И ОБОЗНАЧЕНИЙ

Символ	Обозначение
REF	Номер по каталогу
IVD	Для лабораторной диагностики
	Произведено
	Дата производства
	Температурные ограничения
	Использовать до
LOT	Номер партии
	Перед использованием прочтите инструкцию
Σ	Содержимого достаточно для <n> тестов
EC REP	Уполномоченный представитель в Европейском Сообществе

ПАТЕНТЫ

Продукт защищен одним или более патентов США: D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 и 6,340,573; и иностранными аналогами. Прочие патенты в процессе регистрации.

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VITEK 2™ — technology

AST-N263

IVD

Карта для определения чувствительности к антимикробным препаратам грамотрицательных бактерий

КРАТКОЕ ОПИСАНИЕ

Данная карта предназначена для использования с системами VITEK® 2 в клинических лабораториях для лабораторного определения чувствительности к антимикробным препаратам **клинически значимых аэробных грамотрицательных палочек**. Используйте, как указано в руководстве "Расходные материалы".

ПРИМЕНЕНИЕ

Инструкция по применению предоставляется в наборе или может быть загружена с сайта **www.biomerieux.com/techlib**

Для получения дополнительных инструкций по применению смотрите руководство по расходным материалам.

ХРАНЕНИЕ

Хранить при температуре от 2° до 8° C.

СОСТАВ КАРТЫ

Антимикробный препарат	Код	Концентрация §	Диапазон определения ≤	≥	Указания к применению FDA (Управление по контролю за продуктами и лекарствами, США)
Ампициллин	AM	4, 8, 32	2	32	CSAGNB**
Ампициллин/Сульбактам	SAM	4, 16, 32	2	32	N/A**
Цефотаксим	CTX	1, 4, 16, 32	1	64	CSAGNB**
Цефподоксим	CPD	0.5, 1, 4	0.25	8	CSAGNB**
Цефтазидим	CAZ	1, 2, 8, 32	1	64	CSAGNB**
Цефуроксим	CXM	2, 8, 32	1	64	CSAGNB**
Ципрофлоксацин	CIP	0.5, 2, 4	0.25	4	CSAGNB**
БЛРС '	ESB	FEP 1, CTX 0.5, CAZ 0.5, FEP/CA 1/10, CTX/CA 0.5/4, CAZ/CA 0.5/4	NEG	POS	*E. coli*, *K. pneumoniae*, *K. oxytoca*
Фосфомицин	FOS	8, 16, 32	16	256	N/A**
Гентамицин	GM	4, 16, 32	1	16	CSAGNB**
Имипенем	IPM	1, 2, 6, 12	0.25	16	*Acinetobacter* spp., *Citrobacter* spp., *Enterobacter* spp., *E. coli*, *Klebsiella* spp., *M. morganii*, *P. vulgaris*, *Pv. rettgeri*, *P. aeruginosa*, *S. marcescens*, *Pv. stuartii*
Левофлоксацин	LEV❷	0.25, 0.5, 2, 8	0.12	8	*E. cloacae*, *E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *S. marcescens*, *A. baumannii*, *A. lwoffii*, *C. koseri*, *C. freundii*, *E. aerogenes*, *E. sakazakii*, *K. oxytoca*, *M. morganii*, *P. agglomerans*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *P. fluorescens*, *C. sakazakii*
Меропенем	MEM❷	0.5, 2, 6, 12	0.25	16	*E. coli*, *K. pneumoniae*, *P. aeruginosa*, *P. mirabilis*, *Acinetobacter* spp., *C. freundii*, *E. cloacae*, *K. oxytoca*, *M. morganii*, *P. vulgaris*, *S. marcescens*, *A. hydrophila*, *C. diversus*, *H. alvei*, *P. multocida*, *Salmonella* spp., *Shigella* spp.
Нитрофурантоин	FT	16, 32, 64	16	512	CSAGNB**

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Пиперациллин/тазобактам	TZP	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. enterica*
Тайгециклин	TGC	0.75, 2, 4	0.5	8	*C. freundii*, *C. koseri*, *E. coli*, *E. cloacae*, *E. aerogenes*, *K. oxytoca*, *K. pneumoniae*, *S. marcescens*
Триметоприм/Сульфаметоксазол	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

Численные значения выражены в µг/мл.
§ Эквивалентна по эффективности концентрации стандартного метода.
**CSAGNB = Клинически значимые аэробные грамотрицательные палочки.
**N/A = Специфические указания к применению FDA отсутствуют.
Прим.: БЛРС FEP = Цефепим, CTX = Цефотаксим, CAZ = Цефтазидим, CA = Клавулановая кислота. Штаммы, продуцирующие БЛРС, устойчивы ко всем пенициллинам, цефалоспоринам, азтреонаму.
NEG = Отрицательный.
POS = Положительный.
Отрицательный результат теста на БЛРС не исключает наличия БЛРС, скрытых бета-лактамазой класса AmpC.
❶,❷ пр. = См. рабочие характеристики с кодом препарата и данным символом в колонке комментариев в руководстве к расходным материалам.
**Eco(+ETEC) = *E. coli* (в т. ч. чувствительные энтеротоксигенные штаммы, вызывающие диарею).

КОНТРОЛЬ КАЧЕСТВА

		Контрольные штаммы CLSI®, результаты в системе VITEK 2			
Антимикробный препарат	Код	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™	*K. pneumoniae* ssp *pneumoniae* ATCC® 700603™
Ампициллин	AM	≤2 – 8	-	-	-
Ампициллин/Сульбактам	SAM	≤2 – 8	-	8 – ≥32	-
Цефотаксим	CTX	≤1	8 – 32	-	-
Цефподоксим	CPD	≤0.25 – 1	-	-	-
Цефтазидим	CAZ	≤1	≤1 – 4	-	-
Цефуроксим	CXM	2 – 8	-	-	-
Ципрофлоксацин	CIP	≤0.25	≤0.25 – 1	-	-
БЛРС·	ESB	NEG	-	-	POS
Фосфомицин	FOS	≤16	≤16	-	-
Гентамицин	GM	≤1	≤1 – 2	-	-
Имипенем	IPM	≤0.25	1 – 4	-	-
Левофлоксацин	LEV	≤0.12	0.5 – 4	-	-
Меропенем	MEM	≤0.25	≤0.25 – 1	-	-
Нитрофурантоин	FT	≤16	-	-	-
Пиперациллин/тазобактам	TZP	≤4/4	≤4/4 – 8/4	≤4/4	-
Тайгециклин	TGC	≤0.5	-	-	-
Триметоприм/Сульфаметоксазол	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-	-

Численные значения выражены в µг/мл.
Прим.: БЛРС FEP = Цефепим, CTX = Цефотаксим, CAZ = Цефтазидим, CA = Клавулановая кислота. Штаммы, продуцирующие БЛРС, устойчивы ко всем пенициллинам, цефалоспоринам, азтреонаму.
NEG = Отрицательный.
POS = Положительный.
Отрицательный результат теста на БЛРС не исключает наличия БЛРС, скрытых бета-лактамазой класса AmpC.

ОГРАНИЧЕНИЯ

Для следующих сочетаний микроорганизм / антимикробный препарат результат следует подтверждать альтернативным методом:

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- Ампициллин: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Ампициллин/Сульбактам: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Цефподоксим: *Morganella morganii, Serratia* spp.
- Имипенем: *Serratia marcescens*
- Пиперациллин/тазобактам: *Serratia marcescens*

Для следующих сочетаний микроорганизм / антимикробный препарат результат следует подтверждать альтернативным методом при получении результата "устойчивый":
- Имипенем: *Aeromonas* spp.
- Меропенем: *Aeromonas* spp.
- Пиперациллин/тазобактам: *Pseudomonas aeruginosa*

Возможность определения устойчивости на данной карте для следующих сочетаний микроорганизм / антимикробный препарат неизвестна, поскольку на момент сравнительного тестирования при определении рабочих характеристик устойчивые штаммы не были доступны:
- Тайгециклин: *C. freundii, E. cloacae, E. coli, K. oxytoca, K. pneumoniae, C. koseri, E. aerogenes, S. marcescens*

ПРИМЕЧАНИЕ: Результаты для сочетаний антимикробный препарат / микроорганизм, для которых существуют ограничения, можно исключить из лабораторного отчета. Для получения подробной информации смотрите руководство по программному обеспечению.

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⇩ Перед первым использованием данной карты ⇩ НЕОБХОДИМО ввести приведенные в данной инструкции штрих-коды в программу “Flex Panel Entry”.

01 A310HY0J---N

02 BAST-N26301K

03 C---Z020P0FR

04 D100G0I0L110

05 E100320I1W2GZ

06 F0Y2P1R23007

ТАБЛИЦА СИМВОЛОВ И ОБОЗНАЧЕНИЙ

Символ	Обозначение
REF	Номер по каталогу
IVD	Для лабораторной диагностики
	Произведено
	Дата производства
	Температурные ограничения
	Использовать до
LOT	Номер партии
	Перед использованием прочтите инструкцию
	Содержимого достаточно для <n> тестов
EC REP	Уполномоченный представитель в Европейском Сообществе

ПАТЕНТЫ

Продукт защищен одним или более патентов США: D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 и 6,340,573; и иностранными аналогами. Прочие патенты в процессе регистрации.

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CE

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VITEK 2™ — technology

AST-P632

IVD

Staphylococcus spp., *Enterococcus* spp. and *S. agalactiae* Susceptibility

SUMMARY AND EXPLANATION

The VITEK® 2 Gram Positive Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of ***Staphylococcus* spp., *Enterococcus* spp., and *S. agalactiae*** to antimicrobial agents when used as instructed in the Product Information manual.

INSTRUCTIONS FOR USE

A package insert is provided in the kit or downloadable from **www.biomerieux.com/techlib**

See the Product Information manual for additional Instructions for Use.

STORAGE CONDITIONS

Store at 2° to 8° C.

CONTENTS OF THE CARD

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Benzylpenicillin	P	0.125, 0.25, 1	0.03	0.5	*Staphylococcus* spp.
Cefoxitin Screen	OXSF	6	NEG	POS	*Staphylococcus* spp.
Clindamycin	CM	0.06, 0.25, 1	0.125	4	MSSA**, MSSE**
Daptomycin [NS]	DAP	0.5, 1, 2, 4, 16	0.12	8	*S. aureus*, VSEfaeca**
Erythromycin	E❷	1, 2, 4, 8	0.25	8	
Fosfomycin	FOS	8, 32	8	128	N/A**
Fusidic Acid	FA	0.5, 1, 4	0.5	32	N/A**
Gentamicin	GM	8, 16, 64	0.5	16	*Staphylococcus* spp.
Inducible Clindamycin Resistance	ICR❷	CM 0.5, CM/E 0.25/0.5	NEG	POS	*Staphylococcus* spp.
Levofloxacin	LEV	0.25, 2, 8	0.12	8	*Staphylococcus* spp., *Enterococcus* spp., *S. agalactiae*
Linezolid	LNZ	0.5, 1, 2	0.5	8	*S. agalactiae*, *E. faecalis*, *E. faecium*, *S. aureus*, *S. epidermidis*, *S. haemolyticus*
Mupirocin	MUP❷	2, 4	2	512	
Oxacillin	OX1	0.5, 1, 2	0.25	4	*Staphylococcus* spp.
Rifampicin	RA	0.015, 0.03, 0.125, 0.5	0.03	4	N/A**
Teicoplanin	TEC	1, 4, 8, 16	0.5	32	N/A**
Tetracycline	TE	0.5, 1, 2	1	16	*Staphylococcus* spp., *Enterococcus* spp., *S. agalactiae*
Tigecycline [NS]	TGC	0.25, 0.5, 1	0.12	2	*E. faecalis*, *E. faecium*, *S. aureus*, *S. epidermidis*, *S. haemolyticus*, *S. agalactiae*, *E. casseliflavus*
Trimethoprim/Sulfamethoxazole	SXT❷	8/152, 16/304, 32/608	10 (0.5/9.5)	320 (16/304)	N/A**
Vancomycin	VA❷	1, 2, 4, 8, 16	0.5	32	*Enterococcus* spp., *Staphylococcus* spp., *S. agalactiae*

Numerical values are expressed in µg/ml.
§ Equivalent standard method concentration by efficacy.
NEG = Negative
POS = Positive
**MSSA = Methicillin-susceptible *S. aureus*
**MSSE = Methicillin-susceptible *S. epidermidis*
[NS] = The current absence of resistant isolates precludes defining any results other than susceptible. Isolates yielding MIC results suggestive of Nonsusceptible category should be submitted to a reference laboratory for further testing.
**VSEfaeca = *E. faecalis* (vancomycin susceptible strains)

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❶,❷ etc. = See performance characteristics identified by the drug code with this symbol in the Comment column in Systems Product Information.
**N/A = No specific FDA Indications for Use available

QUALITY CONTROL

		CLSI® Quality Control Organisms VITEK 2 Results				
Antimicrobic	Code	*E. faecalis* ATCC® 29212™	*S. aureus* ATCC® 29213™	*S. aureus* ATCC® BAA-1026™	*S. aureus* ATCC® BAA-976™	*S. aureus* ATCC® BAA-977™
Benzylpenicillin	P	-	0.25 – ≥0.5	-	-	-
Cefoxitin Screen	OXSF	-	NEG	POS	-	-
Clindamycin	CM	≥4	≤0.12 – 0.25	-	-	-
Daptomycin[NS]	DAP	1 – 4	0.25 – 1	-	-	-
Erythromycin	E	1 – 4	≤0.25 – 1	-	-	-
Fosfomycin	FOS	-	≤8	-	-	-
Fusidic Acid	FA	-	≤0.5	-	-	-
Gentamicin	GM	-	≤0.5 – 1	-	-	-
Inducible Clindamycin Resistance	ICR	-	-	-	NEG	POS
Levofloxacin	LEV	0.25 – 2	≤0.12 – 0.5	-	-	-
Linezolid	LNZ	1 – 4	1 – 4	-	-	-
Mupirocin	MUP	-	≤2	-	-	-
Oxacillin	OX1	-	≤0.25 – 0.5	-	-	-
Rifampicin	RA	0.5 – ≥4	≤0.03	-	-	-
Teicoplanin	TEC	≤0.5	≤0.5 – 1	-	-	-
Tetracycline	TE	8 – ≥16	≤1	-	-	-
Tigecycline[NS]	TGC	≤0.12	≤0.12 – 0.25	-	-	-
Trimethoprim/Sulfamethoxazole	SXT	≤10 (0.5/9.5)	≤10 (0.5/9.5)	-	-	-
Vancomycin	VA	1 – 4	≤0.5 – 2	-	-	-

Numerical values are expressed in µg/ml.
NEG = Negative
POS = Positive
[NS] = The current absence of resistant isolates precludes defining any results other than susceptible. Isolates yielding MIC results suggestive of Nonsusceptible category should be submitted to a reference laboratory for further testing.

LIMITATIONS

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):
- Daptomycin: *Streptococcus agalactiae*
- Rifampicin: *Streptococcus agalactiae*

Perform an alternative method of testing prior to reporting of results when a Positive (+) result is obtained with the following antibiotic/organism combination(s):
- Cefoxitin Screen: *Staphylococcus saprophyticus*

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:
- Linezolid: *Enterococcus* spp., *Staphylococcus* spp., *Streptococcus agalactiae*
- Tigecycline: *Enterococcus* spp., *Staphylococcus* spp., *Streptococcus* spp.

NOTE: A result for an antibiotic/organism combination which may have a limitation may be suppressed from reporting. Refer to the software user manual for instructions.

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⇩ MUST enter the following barcodes into “Flex Panel Entry” program before first use of this Susceptibility Card.

01 A320JT0U---K

02 BAST-P63201R

03 C---ZY20G37I

04 D473X300T0UY

05 E193I132N3Q8

06 F20480Y1H3KL

07 G0K3L-V-U-TD

08 H-P-K-J-I-65

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
	Temperature limitation
	Use by
LOT	Batch code
	Consult Instructions for Use
Σ	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community

PATENTS

Product covered by one or more of U.S. Patent Nos. D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 and 6,340,573; and Foreign Counterparts. Other Patents Pending.

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VITEK 2™ — technology

AST-N204

IVD

Gram Negative Susceptibility Card

SUMMARY AND EXPLANATION

The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of **clinically significant aerobic gram-negative bacilli** to antimicrobial agents when used as instructed in the Product Information manual.

INSTRUCTIONS FOR USE

A package insert is provided in the kit or downloadable from **www.biomerieux.com/techlib**

See the Product Information manual for additional Instructions for Use.

STORAGE CONDITIONS

Store at 2° to 8° C.

CONTENTS OF THE CARD

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Amikacin	AN	8, 16, 64	2	64	CSAGNB**
Amoxicillin/Clavulanic Acid	AMC	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Ampicillin	AM	4, 8, 32	2	32	CSAGNB**
Cefepime	FEP	2, 8, 16, 32	1	64	CSAGNB**
Cefotaxime	CTX	1, 4, 16, 32	1	64	CSAGNB**
Ceftazidime	CAZ	1, 2, 8, 32	1	64	CSAGNB**
Ciprofloxacin	CIP	0.5, 2, 4	0.25	4	CSAGNB**
Ertapenem	ETP	0.5, 1, 6	0.5	8	*E. coli*, *K. pneumoniae*, *C. freundii*, *C. koseri*, *E. aerogenes*, *E. cloacae*, Kox(-ESBL)**, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *S. marcescens*
ESBL '	ESB	FEP 1, CTX 0.5, CAZ 0.5, FEP/CA 1/10, CTX/CA 0.5/4, CAZ/CA 0.5/4	NEG	POS	*E. coli*, *K. pneumoniae*, *K. oxytoca*
Fosfomycin	FOS	8, 16, 32	16	256	N/A**
Gentamicin	GM	4, 16, 32	1	16	CSAGNB**
Imipenem	IPM	1, 2, 6, 12	0.25	16	*Acinetobacter* spp., *Citrobacter* spp., *Enterobacter* spp., *E. coli*, *Klebsiella* spp., *M. morganii*, *P. vulgaris*, *Pv. rettgeri*, *P. aeruginosa*, *S. marcescens*, *Pv. stuartii*
Meropenem	MEM❷	0.5, 2, 6, 12	0.25	16	*E. coli*, *K. pneumoniae*, *P. aeruginosa*, *P. mirabilis*, *Acinetobacter* spp., *C. freundii*, *E. cloacae*, *K. oxytoca*, *M. morganii*, *P. vulgaris*, *S. marcescens*, *A. hydrophila*, *C. diversus*, *H. alvei*, *P. multocida*, *Salmonella* spp., *Shigella* spp.
Nitrofurantoin	FT	16, 32, 64	16	512	CSAGNB**
Norfloxacin	NOR	1, 8, 32	0.5	16	CSAGNB**
Piperacillin/Tazobactam	TZP	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. enterica*

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Trimethoprim/Sulfamethoxazole	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

Numerical values are expressed in µg/ml.
§ Equivalent standard method concentration by efficacy.
**CSAGNB = Clinically significant aerobic gram negative bacilli
**Kox(-ESBL) = *K. oxytoca* (excluding ESBL producing strains)
Note: For ESBL, FEP is Cefepime, CTX is Cefotaxime, CAZ is Ceftazidime and CA is Clavulanic Acid. For ESBL positive strains, the test interpretation should be reported as resistant for all penicillins, cephalosporins, and aztreonam.
NEG = Negative
POS = Positive
A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.
**N/A = No specific FDA Indications for Use available
❶,❷ etc. = See performance characteristics identified by the drug code with this symbol in the Comment column in Systems Product Information.
**Eco(+ETEC) = *E. coli* (including susceptible enterotoxigenic strains implicated in traveler's diarrhea)

QUALITY CONTROL

		CLSI® Quality Control Organisms VITEK 2 Results			
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™	*K. pneumoniae* ssp *pneumoniae* ATCC® 700603™
Amikacin	AN	≤2 – 4	≤2 – 4	-	-
Amoxicillin/Clavulanic Acid	AMC	≤2/1 – 8/4	-	4/2 – 16/8	-
Ampicillin	AM	≤2 – 8	-	-	-
Cefepime	FEP	≤1	≤1 – 8	-	-
Cefotaxime	CTX	≤1	8 – 32	-	-
Ceftazidime	CAZ	≤1	≤1 – 4	-	-
Ciprofloxacin	CIP	≤0.25	≤0.25 – 1	-	-
Ertapenem	ETP	≤0.5	2 – ≥8	-	-
ESBL'	ESB	NEG	-	-	POS
Fosfomycin	FOS	≤16	≤16	-	-
Gentamicin	GM	≤1	≤1 – 2	-	-
Imipenem	IPM	≤0.25	1 – 4	-	-
Meropenem	MEM	≤0.25	≤0.25 – 1	-	-
Nitrofurantoin	FT	≤16	-	-	-
Norfloxacin	NOR	≤0.5	1 – 4	-	-
Piperacillin/Tazobactam	TZP	≤4/4	≤4/4 – 8/4	≤4/4	-
Trimethoprim/Sulfamethoxazole	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-	-

Numerical values are expressed in µg/ml.
Note: For ESBL, FEP is Cefepime, CTX is Cefotaxime, CAZ is Ceftazidime and CA is Clavulanic Acid. For ESBL positive strains, the test interpretation should be reported as resistant for all penicillins, cephalosporins, and aztreonam.
NEG = Negative
POS = Positive
A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.

LIMITATIONS

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):
- Amikacin: *Acinetobacter baumannii*
- Amoxicillin/Clavulanic Acid: *Providencia* spp.
- Ampicillin: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Imipenem: *Serratia marcescens*
- Piperacillin/Tazobactam: *Serratia marcescens*

Perform an alternative method of testing prior to reporting of results when an intermediate or resistant result is obtained with the following antibiotic/organism combination(s):

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- Amoxicillin/Clavulanic Acid: *Proteus* spp.

Perform an alternative method of testing prior to reporting results when a resistant result is obtained with the following antibiotic/organism combination(s):
- Imipenem: *Aeromonas* spp.
- Meropenem: *Aeromonas* spp.
- Piperacillin/Tazobactam: *Pseudomonas aeruginosa*

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:
- Ertapenem: *E. coli, K. pneumoniae, C. freundii, C. koseri, E. aerogenes, E. cloacae, K. oxytoca* (excluding ESBL producing strains), *M. morganii, P. mirabilis, P. vulgaris, S. marcescens*

NOTE: A result for an antibiotic/organism combination which may have a limitation may be suppressed from reporting. Refer to the software user manual for instructions.

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⇩ MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.

01 A310FJ0J---Y

02 BAST-N20401I

03 C---Z010702B

04 D1C0F0G0L1NO

05 E111003202G0

06 F0Y0T2P2300B

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
	Temperature limitation
	Use by
LOT	Batch code
	Consult Instructions for Use
Σ	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community

PATENTS

Product covered by one or more of U.S. Patent Nos. D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 and 6,340,573; and Foreign Counterparts. Other Patents Pending.

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REF 21342

043900- 03 - 2019-03 EN

VITEK® 2 GP

℞ only IVD

INTENDED USE

These Instructions for Use correspond to the VITEK® 2 Systems 7.01 or higher software. If you are not using VITEK® 2 Systems 7.01 or higher software, please refer to the VITEK® 2 Systems Product Information that you received with your current software version.

The VITEK® 2 Gram-Positive identification card (GP) is intended for use with VITEK® 2 Systems for the automated identification of most significant Gram-positive organisms. The VITEK® 2 GP identification card is a single-use disposable. For a list of claimed species, see the Organisms Identified section.

DESCRIPTION

The GP identification card is based on established biochemical methods[2,3,7,8,9,10,11,14,20,21,22,23,27,32,37,39] and newly developed substrates. There are 43 biochemical tests measuring carbon source utilization, enzymatic activities and resistance. Final identification results are available in approximately eight hours or less.

For a list of well contents, see the GP Well Contents table.

Table 1: GP Well Contents

Well	Test	Mnemonic	Amount/Well
2	D-AMYGDALIN	AMY	0.1875 mg
4	PHOSPHATIDYLINOSITOL PHOSPHOLIPASE C	PIPLC	0.015 mg
5	D-XYLOSE	dXYL	0.3 mg
8	ARGININE DIHYDROLASE 1	ADH1	0.111 mg
9	BETA-GALACTOSIDASE	BGAL	0.036 mg
11	ALPHA-GLUCOSIDASE	AGLU	0.036 mg
13	Ala-Phe-Pro ARYLAMIDASE	APPA	0.0384 mg
14	CYCLODEXTRIN	CDEX	0.3 mg
15	L-Aspartate ARYLAMIDASE	AspA	0.024 mg
16	BETA GALACTOPYRANOSIDASE	BGAR	0.00204 mg
17	ALPHA-MANNOSIDASE	AMAN	0.036 mg
19	PHOSPHATASE	PHOS	0.0504 mg
20	Leucine ARYLAMIDASE	LeuA	0.0234 mg
23	L-Proline ARYLAMIDASE	ProA	0.0234 mg
24	BETA GLUCURONIDASE	BGURr	0.0018 mg
25	ALPHA-GALACTOSIDASE	AGAL	0.036 mg
26	L-Pyrrolydonyl-ARYLAMIDASE	PyrA	0.018 mg
27	BETA-GLUCURONIDASE	BGUR	0.0378 mg
28	Alanine ARYLAMIDASE	AlaA	0.0216 mg
29	Tyrosine ARYLAMIDASE	TyrA	0.0276 mg
30	D-SORBITOL	dSOR	0.1875 mg
31	UREASE	URE	0.15 mg
32	POLYMIXIN B RESISTANCE	POLYB	0.00093 mg
37	D-GALACTOSE	dGAL	0.3 mg

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Well	Test	Mnemonic	Amount/Well
38	D-RIBOSE	dRIB	0.3 mg
39	L-LACTATE alkalinization	lLATk	0.15 mg
42	LACTOSE	LAC	0.96 mg
44	N-ACETYL-D-GLUCOSAMINE	NAG	0.3 mg
45	D-MALTOSE	dMAL	0.3 mg
46	BACITRACIN RESISTANCE	BACI	0.0006 mg
47	NOVOBIOCIN RESISTANCE	NOVO	0.000075 mg
50	GROWTH IN 6.5% NaCl	NC6.5	1.68 mg
52	D-MANNITOL	dMAN	0.1875 mg
53	D-MANNOSE	dMNE	0.3 mg
54	METHYL-B-D-GLUCOPYRANOSIDE	MBdG	0.3 mg
56	PULLULAN	PUL	0.3 mg
57	D-RAFFINOSE	dRAF	0.3 mg
58	O/129 RESISTANCE (comp.vibrio.)	O129R	0.0084 mg
59	SALICIN	SAL	0.3 mg
60	SACCHAROSE/SUCROSE	SAC	0.3 mg
62	D-TREHALOSE	dTRE	0.3 mg
63	ARGININE DIHYDROLASE 2	ADH2s	0.27 mg
64	OPTOCHIN RESISTANCE	OPTO	0.000399 mg

Note: Other well numbers between 1 and 64 not designated in this table are empty.

PRECAUTIONS

Note: For industry customers that need assistance on selecting the correct VITEK® 2 identification card, please refer to the VITEK® 2 Compact Instrument User Manual chapter, "Guidance to Select a VITEK® 2 Identification Card."

- For *In Vitro* Diagnostic Use Only.
- For US Only: Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- For professional use only.
- Suspensions not within the appropriate zone on the VITEK® 2 DENSICHEK™ Plus or the VITEK® 2 DENSICHEK™ may compromise card performance.
- Do not use the card after the expiration date shown on the package liner.
- Store the card unopened in the package liner. Do not use the card if the protective package liner is damaged or if no desiccant is present.
- Allow the card to come to room temperature before opening the package liner.
- Do not use powdered gloves. Powder may interfere with the optics.
- Use of culture media other than the recommended types must be validated by the customer laboratory for acceptable performance.
- A Gram stain should be performed to determine an organism’s Gram reaction and morphology prior to selecting the identification card to inoculate.
- The card performs as intended only when used in conjunction with VITEK® 2 Systems, following the instructions contained in these Instructions for Use.
- **Do not use glass test tubes**. Use clear plastic (polystyrene) tubes only. Variation exists among test tubes of standard diameter. Carefully place the tube into the cassette. If resistance is encountered, discard and try another tube that does not require pressure to insert.
- Prior to inoculation, inspect cards for tape tears or damage to the tape and discard any that are suspect. Check the saline level in the tubes after the cassette has been processed to ensure proper filling of card.
  - VITEK® 2 60 or VITEK® 2 XL: Eject improperly filled cards.
  - VITEK® 2 Compact: Do not load improperly filled cards.
- Give special consideration to specimen source and patient drug or antimicrobic regimen.

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- Interpretation of test results requires the judgment and skill of a person knowledgeable in microbial identification testing. Additional testing may be required. (See the Supplemental Tests section.)
- Do not clean saline dispenser with chemical agents. The use of chemical agents may impact card performance.

Warning: All patient specimens, microbial cultures, and inoculated VITEK® 2 cards, along with associated materials, are potentially infectious and should be treated with universal precautions.[30,35]

Warning: All hazardous waste must be disposed of by following your local inspecting agency's guidelines.

STORAGE CONDITIONS

Upon receipt, store VITEK® 2 GP cards unopened in their original package liner at 2°C to 8°C.

SPECIMEN PREPARATION

For specimen preparation information, see the Culture Requirements Table.

Table 2: Culture Requirements Table

VITEK® 2 Card	Media	Age of Culture[1]	Incubation Conditions	Inoculum Density	Dilution for AST	Age of Suspension Before Loading Instrument
GP	TSAB[2,3] CBA[2,3] TSA[2,3] BP CHBA CHOC CHOC PVX CNT CPS ID MRSA ID MSA SAID TSAHB TSAL VRE	12 to 48 hours	35°C to 37°C 5% to 10% CO_2 or aerobic, non CO_2	0.50 to 0.63 McFarland Standard	N/A[4]	≤30 minutes
GP and AST GP pair	TSAB CBA CPS ID	18 to 24 hours	35°C to 37°C 5% to 10% CO_2 or aerobic, non-CO_2	0.50 to 0.63 McFarland Standard	280 µL in 3.0 mL saline	< 30 minutes
GP and AST ST pair	TSAB CBA	18 to 24 hours	35°C to 37°C 5% to 10% CO_2	0.50 to 0.63 McFarland Standard	280 µL in 3.0 mL saline	< 30 minutes

[1]Cultures with scant or poor growth may give unidentified or incorrect results even when the Age of Culture requirements are met.

[2]These media were used in the identification product database development and will give optimal performance.

[3]OMA Official Methods of Analysis validated medium.

[4]N/A = not applicable

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Culture Requirements Table — Media Abbreviations

BP = Baird Parker

CBA = Columbia Blood Agar with 5% Sheep Blood

CHBA = Columbia Horse Blood Agar

CHOC = Chocolate Agar

CHOC PVX = Chocolate Polyvitex

CNT = Count-TACT® (irradiated) Trypticase Soy Agar

CPS ID = chromID™ CPS (CPS ID agar)

MRSA ID = chromID™ (MRSA ID Agar)

MSA = Mannitol Salt Agar

SAID = chromID™ S. aureus (S. aureus ID Agar)

TSA = Trypticase Soy Agar

TSAB = Trypticase Soy Agar with 5% Sheep Blood

TSAHB = Trypticase Soy Agar with 5% Horse Blood

TSAL = TSA with Lecithin and P80

VRE = chromID™ VRE

TEST PROCEDURE

Materials

When used with VITEK® 2 instrumentation, the GP card is a complete system for routine identification testing of most clinically significant Gram-positive organisms.

Required materials are:

- VITEK® 2 GP Card
- DENSICHEK™ Plus Kit or VITEK® DENSICHEK® Kit
- DENSICHEK™ Plus Standards Kit or DENSICHEK® Standards Kit
- VITEK® 2 Cassette
- Sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- 12 mm x 75 mm clear plastic (polystyrene) disposable test tubes
- Sterile sticks or swabs
- Appropriate agar medium (see Culture Requirements table).

Optional accessories:

- Adjustable volume saline dispenser
- Loops
- Pre-dispensed saline test tubes (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Test tube caps
- Vortex

Procedure

Warning: Failure to follow instructions and recommendations provided in this section for performing laboratory tasks may cause erroneous or delayed results.

For product-specific information, see the Culture Requirements table.

Note: Prepare the inoculum from a pure culture, according to good laboratory practices. In case of mixed cultures, a re-isolation step is required. It is recommended that a purity check plate be done to ensure that a pure culture was used for testing.

1. Do one of the following:
   - Select isolated colonies from a primary plate if culture requirements are met.
   - Subculture the organism to be tested to appropriate agar medium and incubate accordingly.

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2. Aseptically transfer 3.0 mL of sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0) into a clear plastic (polystyrene) test tube (12 mm x 75 mm).
3. Use a sterile stick or swab to transfer a sufficient number of morphologically similar colonies to the saline tube prepared in step 2. Prepare a homogenous organism suspension with a density equivalent to a McFarland No. 0.50 to 0.63 using a calibrated VITEK® 2 DENSICHEK™ Plus or VITEK® 2 DENSICHEK™.
   Note: Age of suspension must not exceed 30 minutes before inoculating card.
4. Place the suspension tube and GP card in the cassette.
5. Refer to the appropriate Instrument User Manual for instructions on data entry and how to load the cassette into the instrument.
6. Follow your local inspecting agency's guidelines for disposal of hazardous waste.

RESULTS

Identification Analytical Techniques

VITEK® 2 Systems identify an organism by using a methodology based on the characteristics of the data and knowledge about the organism and reactions being analyzed. Sufficient data have been collected from known strains to estimate the typical reactions of the claimed species to a set of discriminating biochemicals. If a unique identification pattern is not recognized, a list of possible organisms is given, or the strain is determined to be outside the scope of the database.

The printed lab report contains suggestions for any supplemental tests necessary to complete the identification. If the tests are not sufficient to complete the identification, then standard microbiology references and literature should be consulted.

Certain species may belong to slashline (mixed) taxa identification. This occurs when the biopattern is the same for the taxa listed. Supplemental tests may be used to separate slashline taxa. The species in the GP Slashline Taxa table belong to the GP slashline taxa.

Table 3: GP Slashline Taxa

Slashline Name	Species Belonging to the Slashline
For 7.01 Software Users	
Micrococcus luteus/lylae	*Micrococcus luteus* *Micrococcus lylae*
For 7.01 or Higher Software Users	
Dermacoccus nishinomiyaensis/ *Kytococcus sedentarius*	*Dermacoccus nishinomiyaensis* *Kytococcus sedentarius*
Listeria ivanovii	*Listeria ivanovii* ssp. *ivanovii* *Listeria ivanovii* ssp. *londoniensis*
Streptococcus mitis/ *Streptococcus oralis*	*Streptococcus mitis* *Streptococcus oralis*

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Table 4: Identification Card Qualifying Messages

ID Message Confidence Level	Choices	% Probability	Comments
Excellent	1	96 to 99	N/A
Very Good	1	93 to 95	N/A
Good	1	89 to 92	N/A
Acceptable	1	85 to 88	N/A
Low Discrimination	2 to 3	Sum of choices = 100; after resolution to one choice, percent probability reflects the number associated with selected choice.	Two to three taxa exhibit same biopattern. Separate by supplemental testing.
Inconclusive or Unidentified Organism	> 3 or 0	N/A	Either > 3 taxa exhibit same biopattern or Very atypical biopattern. Does not correspond to any taxon in the database. Check Gram stain and purity.

PERCENT PROBABILITY

As part of the identification process, the software compares the test set of reactions to the expected set of reactions of each organism, or organism group, that can be identified by the product. A quantitative value, the percent probability, is calculated and relates to how well the observed reactions compare to the typical reactions of each organism. A perfect match between the test reaction pattern and the unique reaction pattern of a single organism, or organism group, would provide a percent probability of 99. When a perfect match is not obtained, it is still possible for the reaction pattern to be sufficiently close to that of an expected reaction pattern such that a clear decision can be provided about the organism identification. The range of percent probabilities in the one-choice case is 85 to 99. Values closer to 99 indicate a closer match to the typical pattern for the given organism.

When the reaction pattern is not sufficient to discriminate between two to three organisms, the percent probabilities reflect this ambiguity. The reported probability values indicate, relatively, the order in which the reaction pattern best corresponds to the listed possibilities. The order does not, however, suggest that the pattern match to one of the possible identifications is clearly superior to another. The probability characteristic of an overall sum of 100 is retained through the calculation process. After resolution to one choice, the probability characteristic of the single choice is retained.

ADDITIONAL INFORMATION ON LAB REPORT

Supplemental test — External (offline) test that allows the user to resolve a slashline or Low Discrimination identification. Numbers in parentheses indicate percent positive reaction for the species/test listed.

Contraindicating test — Test result that is unusual for a reported taxon.

Table 5: Notes Associated with Certain Taxa

Taxa	Note
For 7.01 or Higher Software Users	
Enterococcus durans	Possibility of *Enterococcus villorum* if veterinary.
Listeria monocytogenes	Critical pathogen, check CAMP test and beta hemolysis. The species identified may have significance to patient or sample outcome and can be stopped for review.
Staphylococcus warneri	Possibility of *Staphylococcus pasteuri* if yellow pigmented.
For 8.01 or Higher Software Users	

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Taxa	Note
Listeria innocua	Possibility of *Listeria monocytogenes*. Check for beta hemolysis. *Listeria innocua* strains are non-hemolytic.

Notes Associated with an Improperly Filled Card or with a Negative Profile (Biopattern)

- For the case where the time between two readings is greater than 40 minutes: “CARD ERROR — Missing data.”
- For the case where there is a negative profile: “Organism with low reactivity biopattern — please check viability.”
- When a biopattern is calculated for an unknown organism that is completely negative or consists of both negative tests and tests that fall within the uncertainty zone, the identification call will be “Non or low reactive biopattern.”

The following non-reactive species could potentially trigger this note if a test was atypical or fell within the uncertainty zone:

- *Alloiococcus otitis*
- *Dermacoccus nishinomiyaensis*
- *Gemella bergeri*
- *Kocuria rosea*
- *Kocuria varians*
- *Kytococcus sedentarius*
- *Leuconostoc mesenteroides* ssp. *cremoris*
- *Micrococcus lylae*
- *Staphylococcus auricularis*
- *Streptococcus pluranimalium*

QUALITY CONTROL

Quality control organisms and their expected results are listed in the VITEK® 2 GP Quality Control Tables. Process these according to the procedure for test isolates outlined in this document.

Certification Statement

This is to certify that bioMérieux complies with ISO 13485 and FDA Quality System Regulation (QSR) requirements for design, development, and manufacture of microbial identification systems.

Frequency of Testing

Currently, it is recommended that you use your most stringent inspecting agency’s guidelines for frequency of identification product testing.

Common practice is to perform QC upon receipt of shipment of the test kits. Reactions must follow Instructions for Use results.

If the results do not meet the criteria, subculture for purity and repeat the test. If discrepant results are repeated, perform an alternate identification method and contact bioMérieux.

Testing and Storage of QC Organisms

1. Rehydrate the organism according to the manufacturer's instructions.
2. Use Trypticase Soy with 5% sheep blood agar (TSAB) and incubate at 35°C to 37°C in 5% to 10% CO_2 for approximately 18 to 24 hours.
3. Check for purity. Perform second subculture for testing.
4. Use Trypticase Soy with 5% sheep blood agar (TSAB) and incubate at 35°C to 37°C in 5% to 10% CO_2 for approximately 18 to 24 hours.

Short-Term Storage Conditions

1. Subculture to a TSAB plate or slant.
2. Incubate for 24 hours at 35°C to 37°C in 5% to 10% CO_2.
3. Refrigerate at 2°C to 8°C for up to two weeks.
4. Subculture once as described above and use for QC.

Long-Term Storage Conditions

1. Make a heavy suspension in Tryptic Soy Broth (TSB) with 15% glycerol.

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2. Freeze at -70°C.
3. Subculture to TSAB twice before running QC.

Note: Avoid repeated thawing and refreezing by either freezing in single-use aliquots or removing a small portion of frozen organism preparation with a sterile applicator stick.

STREAMLINED QUALITY CONTROL

Note: Industrial Use Only laboratories should perform quality control following the Streamlined Quality Control section. No additional testing is required for these users.

As there are no substrates that are consistently sensitive to degradation during shipping conditions, streamlined quality control may be conducted by testing two strains: one that is mostly positive and the other, which is mostly negative for reactions on GP. (See GP Quality Control tables for more details.)

COMPREHENSIVE QUALITY CONTROL

Customers who do not qualify for streamlined quality control testing are required to perform comprehensive quality control testing, which entails demonstration of a positive and negative reaction for each substrate of an identification product.[6]

In order to qualify initially for streamlined quality control testing, the CLSI® M50-A standard requires that the user perform and document either of the following:[5]

- Verification testing to show that performance is equivalent to the manufacturer's claims.
- Comprehensive quality control testing of at least three lots over at least three different seasons.

Refer to the complete CLSI® M50-A standard for information regarding continued qualification and further details of requirements and responsibilities for both the user and the manufacturer related to streamlined quality control testing.

GP Quality Control Tables:

***Enterococcus casseliflavus* ATCC® 700327™** (for streamlined or comprehensive quality control)

***Streptococcus salivarius* ssp. *thermophilus* ATCC® 19258™** (for comprehensive quality control)

***Kocuria kristinae* ATCC® BAA-752™** (for comprehensive quality control)

***Listeria monocytogenes* ATCC® BAA-751™** (for comprehensive quality control)

***Streptococcus pneumoniae* ATCC® 49619™** (for comprehensive quality control)

***Staphylococcus saprophyticus* ATCC® BAA-750™** (for streamlined or comprehensive quality control)

***Staphylococcus sciuri* ATCC® 29061™** (for comprehensive quality control)

***Streptococcus equi* ssp. *zooepidemicus* ATCC® 43079™** (for comprehensive quality control)

***Enterococcus saccharolyticus* ATCC® 43076™** (for comprehensive quality control)

The GP card typically identifies the quality control organisms as one-choice or within a low discrimination or slashline identification. However, strains are chosen for reaction performance over identification performance. Therefore, an unidentified or misidentified result may occur when all expected quality control reactions are correct.

Table 6: QC Organism: *Enterococcus casseliflavus* ATCC® 700327™ (for streamlined or comprehensive quality control)

AMY	+	CDEX	-	BGURr	-	URE	-	dMAL	+	PUL	-
PIPLC	-	AspA	v[1]	AGAL	+	POLYB	+	BACI	+	dRAF	+
dXYL	+	BGAR	+	PyrA	+	dGAL	+	NOVO	+	O129R	+
ADH1	v[2]	AMAN	v	BGUR	-	dRIB	+	NC6.5	+	SAL	+
BGAL	+	PHOS	-	AlaA	v	ILATk	-	dMAN	+	SAC	+
AGLU	v	LeuA	v	TyrA	+	LAC	+	dMNE	+	dTRE	+
APPA	v	ProA	-	dSOR	v	NAG	+	MBdG	+	ADH2s	v
										OPTO	+

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

[1]Reaction is mostly positive although occasional negative reaction may occur.

[2]Reaction updated to variable but will not appear in QC software until 9.02.

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Table 7: QC Organism: *Streptococcus salivarius* ssp. *thermophilus* ATCC® 19258™ (for comprehensive quality control)

AMY	v	CDEX	v	BGURr	v	URE	v	dMAL	-	PUL	v
PIPLC	v	AspA	v	AGAL	v	POLYB	v	BACI	v	dRAF	v
dXYL	v	BGAR	v	PyrA	v	dGAL	v	NOVO	v	O129R	v
ADH1	v	AMAN	v	BGUR	v	dRIB	v	NC6.5	v	SAL	v
BGAL	v	PHOS	v	AlaA	v	lLATk	v	dMAN	v	SAC	v
AGLU	-	LeuA	v	TyrA	v	LAC	v	dMNE	v	dTRE	v
APPA	v	ProA	v	dSOR	v	NAG	-	MBdG	v	ADH2s	v
										OPTO	v

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 8: QC Organism: *Kocuria kristinae* ATCC® BAA-752™ (for comprehensive quality control)

AMY	v	CDEX	v	BGURr	v	URE	v	dMAL	v	PUL	v
PIPLC	v	AspA	–	AGAL	–	POLYB	v	BACI	–	dRAF	v
dXYL	v	BGAR	v	PyrA	v	dGAL	v	NOVO	–	O129R	v
ADH1	v	AMAN	v	BGUR	v	dRIB	v	NC6.5	v	SAL	v
BGAL	–	PHOS	v	AlaA	v	lLATk	+	dMAN	v	SAC	v
AGLU	+	LeuA	+	TyrA	v	LAC	–	dMNE	v	dTRE	v
APPA	–	ProA	+	dSOR	v	NAG	v	MBdG	v	ADH2s	v
										OPTO	v

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 9: QC Organism: *Listeria monocytogenes* ATCC® BAA-751™ (for comprehensive quality control)

AMY	+	CDEX	+	BGURr	v	URE	v	dMAL	v	PUL	v
PIPLC	+	AspA	v	AGAL	v	POLYB	+	BACI	v	dRAF	–
dXYL	v	BGAR	–	PyrA	v	dGAL	–	NOVO	v	O129R	v
ADH1	–	AMAN	+	BGUR	v	dRIB	v	NC6.5	+	SAL	v
BGAL	–	PHOS	v	AlaA	v	lLATk	v	dMAN	–	SAC	–
AGLU	+	LeuA	v	TyrA	v	LAC	v	dMNE	v	dTRE	v
APPA	v	ProA	v	dSOR	v	NAG	+	MBdG	v	ADH2s	v
										OPTO	v

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 10: QC Organism: *Streptococcus pneumoniae* ATCC® 49619™ (for comprehensive quality control)

AMY	v	CDEX	v	BGURr	v	URE	v	dMAL	v	PUL	v
PIPLC	v	AspA	v	AGAL	v	POLYB	v	BACI	–	dRAF	v[1]
dXYL	v	BGAR	v	PyrA	v	dGAL	v	NOVO	v	O129R	–
ADH1	v	AMAN	–	BGUR	v	dRIB	–	NC6.5	–	SAL	v[1]
BGAL	v	PHOS	v	AlaA	+	lLATk	v	dMAN	v	SAC	v
AGLU	v	LeuA	v	TyrA	v	LAC	v	dMNE	v	dTRE	v
APPA	v[1]	ProA	v	dSOR	v	NAG	v	MBdG	v	ADH2s	v
										OPTO	–

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+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

[1]Reaction updated to variable but will not appear in QC software until 9.02

Table 11: QC Organism: *Staphylococcus saprophyticus* ATCC® BAA-750™ (for streamlined or comprehensive quality control)

AMY	-	CDEX	-	BGURr	-	URE	+	dMAL	+	PUL	-
PIPLC	-	AspA	-	AGAL	-	POLYB	-	BACI	v	dRAF	-
dXYL	-	BGAR	-	PyrA	v	dGAL	v	NOVO	+	O129R	v
ADH1	v	AMAN	-	BGUR	-	dRIB	v	NC6.5	+	SAL	-
BGAL	+	PHOS	v	AlaA	-	lLATk	v	dMAN	+	SAC	+
AGLU	v	LeuA	-	TyrA	-	LAC	+	dMNE	v[1]	dTRE	+
APPA	v	ProA	-	dSOR	-	NAG	v	MBdG	-	ADH2s	-
										OPTO	+

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

[1]Reaction is mostly negative although occasional positive reaction may occur.

Table 12: QC Organism: *Staphylococcus sciuri* ATCC® 29061™ (for comprehensive quality control)

AMY	v	CDEX	v	BGURr	+	URE	–	dMAL	v	PUL	v
PIPLC	v	AspA	v	AGAL	v	POLYB	–	BACI	v	dRAF	–
dXYL	–	BGAR	v	PyrA	v	dGAL	v	NOVO	v	O129R	v
ADH1	+	AMAN	v	BGUR	+	dRIB	v	NC6.5	v	SAL	v
BGAL	v	PHOS	+	AlaA	–	lLATk	v	dMAN	v	SAC	v
AGLU	v	LeuA	–	TyrA	–	LAC	–	dMNE	v	dTRE	+
APPA	–	ProA	v	dSOR	v	NAG	v	MBdG	+	ADH2s	–
										OPTO	v

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 13: QC Organism: *Streptococcus equi* ssp. *zooepidemicus* ATCC® 43079™ (for comprehensive quality control)

AMY	v	CDEX	v	BGURr	v	URE	v	dMAL	v	PUL	v[1]
PIPLC	v	AspA	v	AGAL	v	POLYB	v	BACI	v	dRAF	v
dXYL	v	BGAR	v	PyrA	v	dGAL	+	NOVO	v	O129R	v
ADH1	+[2]	AMAN	v	BGUR	v	dRIB	v[3]	NC6.5	v	SAL	v
BGAL	v	PHOS	+	AlaA	v	lLATk	v	dMAN	v	SAC	v
AGLU	v	LeuA	v	TyrA	v	LAC	v	dMNE	v	dTRE	–
APPA	+[2]	ProA	v	dSOR	v	NAG	v	MBdG	v	ADH2s	+
										OPTO	v

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

[1]Reaction is mostly positive although occasional negative reaction may occur.

[2]Reaction updated to positive but will not appear in QC software until 9.02.

[3]Reaction updated to variable but will not appear in QC software until 9.02.

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Table 14: QC Organism: *Enterococcus saccharolyticus* ATCC® 43076™ (for comprehensive quality control)

AMY	v	CDEX	+	BGURr	v	URE	v	dMAL	v	PUL	v
PIPLC	v	AspA	v	AGAL	+	POLYB	v	BACI	v	dRAF	v
dXYL	v	BGAR	v	PyrA	–	dGAL	v	NOVO	v	O129R	v
ADH1	v	AMAN	v	BGUR	v	dRIB	v	NC6.5	v	SAL	v
BGAL	v	PHOS	v	AlaA	v	lLATk	v	dMAN	+	SAC	v
AGLU	v	LeuA	v	TyrA	v	LAC	v	dMNE	v	dTRE	v
APPA	v	ProA	v	dSOR	+	NAG	v	MBdG	v	ADH2s	v
										OPTO	v

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

LIMITATIONS

The VITEK® 2 GP card cannot be used with a direct clinical specimen or sample or other sources containing mixed flora. Any change or modification in the procedure may affect the results.

Newly described or rare species may not be included in the GP database. Selected species will be added as strains become available.

Warning: Testing of unclaimed species may result in an unidentified result or a misidentification.

PERFORMANCE CHARACTERISTICS

For 7.01, 8.01, and 9.01 Software Users

In a multi-site clinical study*, the performance of the VITEK® 2 GP identification card was evaluated using 457 clinical and stock isolates of both commonly and rarely observed species of gram-positive cocci. The reference identification was determined with API® STAPH and API® 20 STREP identification kits. Overall, the VITEK® 2 GP correctly identified 96.1% of the isolates, including 3.9% low discrimination with the correct species listed. Misidentifications occurred at 3.5% and no identifications occurred at 0.4%.

For 9.02 Software Users

In a multi-site clinical study*, the performance of the VITEK® 2 GP identification card was evaluated using 457 clinical and stock isolates of both commonly and rarely observed species of gram-positive cocci. The reference identification was determined with API® STAPH and API® 20 STREP identification kits. Overall, the VITEK® 2 GP correctly identified 95.8% of the isolates, including 3.5% low discrimination with the correct species listed. Misidentifications occurred at 3.5% and no identifications occurred at 0.7%.

*Data on file at bioMérieux, Inc.

ORGANISMS IDENTIFIED

Claims are for all software users unless otherwise stated.

- *Abiotrophia defectiva*
- *Aerococcus urinae*
- *Aerococcus viridans*
- *Alloiococcus otitis*
- *Dermacoccus nishinomiyaensis/Kytococcus sedentarius*
- *Enterococcus avium*
- *Enterococcus casseliflavus*
- *Enterococcus cecorum*
- *Enterococcus columbae*
- *Enterococcus durans*
- *Enterococcus faecalis*
- *Enterococcus faecium*
- *Enterococcus gallinarum*
- *Enterococcus hirae*
- *Enterococcus raffinosus*
- *Enterococcus saccharolyticus*

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- *Erysipelothrix rhusiopahiae*
- *Facklamia hominis*
- *Gardnerella vaginalis*
- *Gemella bergeri*
- *Gemella haemolysans*
- *Gemella morbillorum*
- *Gemella sanguinis*
- *Globicatella sanguinis*
- *Globicatella sulfidifaciens*
- *Granulicatella adiacens*
- *Granulicatella elegans*
- *Helcococcus kunzii*
- *Kocuria kristinae*
- *Kocuria rhizophila*
- *Kocuria rosea*
- *Kocuria varians*
- *Lactococcus garvieae*
- *Lactococcus lactis* ssp. *cremoris*
- *Lactococcus lactis* ssp. *lactis*
- *Lactococcus raffinolactis*
- *Leuconostoc citreum*
- *Leuconostoc lactis*
- *Leuconostoc mesenteroides* ssp. *cremoris*
- *Leuconostoc mesenteroides* ssp. *dextranicum*
- *Leuconostoc mesenteroides* ssp. *mesenteroides*
- *Leuconostoc pseudomesenteroides*
- *Listeria grayi*+
- *Listeria innocua*+
- *Listeria ivanovii*+
- *Listeria monocytogenes*+
- *Listeria seeligeri*+
- *Listeria welshimeri*+
- *Micrococcus luteus*
- *Micrococcus lylae*
- *Pediococcus acidilactici*
- *Pediococcus pentosaceus*
- *Rothia dentocariosa*
- *Rothia mucilaginosa*
- *Staphylococcus arlettae*
- *Staphylococcus aureus* *+
- *Staphylococcus auricularis*
- *Staphylococcus capitis*
- *Staphylococcus caprae*
- *Staphylococcus carnosus* ssp. *carnosus*
- *Staphylococcus chromogenes*
- *Staphylococcus cohnii* ssp. *cohnii*
- *Staphylococcus cohnii* ssp. *urealyticus*
- *Staphylococcus epidermidis*+
- *Staphylococcus equorum*
- *Staphylococcus gallinarum*
- *Staphylococcus haemolyticus*
- *Staphylococcus hominis* ssp. *hominis*

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- *Staphylococcus hominis* ssp. *novobiosepticus*
- *Staphylococcus hyicus*+
- *Staphylococcus intermedius*+
- *Staphylococcus kloosii*
- *Staphylococcus lentus*
- *Staphylococcus lugdunensis*
- *Staphylococcus pseudintermedius*
- *Staphylococcus saprophyticus*
- *Staphylococcus schleiferi*
- *Staphylococcus sciuri*
- *Staphylococcus simulans*
- *Staphylococcus vitulinus*
- *Staphylococcus warneri*
- *Staphylococcus xylosus*
- *Streptococcus agalactiae*
- *Streptococcus alactolyticus*
- *Streptococcus anginosus*
- *Streptococcus canis*
- *Streptococcus constellatus* ssp. *constellatus*
- *Streptococcus constellatus* ssp. *pharyngis*
- *Streptococcus cristatus*
- *Streptococcus downei*
- *Streptococcus dysgalactiae* ssp. *dysgalactiae*
- *Streptococcus dysgalactiae* ssp. *equisimilis*
- *Streptococcus equi* ssp. *equi*
- *Streptococcus equi* ssp. *zooepidemicus*
- *Streptococcus equinus*
- *Streptococcus gallolyticus* ssp. *gallolyticus*
- *Streptococcus gallolyticus* ssp. *pasteurianus*
- *Streptococcus gordonii*
- *Streptococcus hyointestinalis*
- *Streptococcus infantarius* ssp. *coli* (formerly known as *Streptococcus lutetiensis*)
- *Streptococcus infantarius* ssp. *infantarius*
- *Streptococcus intermedius*
- *Streptococcus mitis/Streptococcus oralis*
- *Streptococcus mutans*
- *Streptococcus ovis*
- *Streptococcus parasanguinis*
- *Streptococcus pluranimalium*
- *Streptococcus pneumoniae*
- *Streptococcus porcinus*
- *Streptococcus pseudoporcinus*
- *Streptococcus pyogenes*
- *Streptococcus salivarius* ssp. *salivarius*
- *Streptococcus salivarius* ssp. *thermophilus*
- *Streptococcus sanguinis*
- *Streptococcus sobrinus*
- *Streptococcus suis* I
- *Streptococcus suis* II
- *Streptococcus thoraltensis*
- *Streptococcus uberis*
- *Streptococcus vestibularis*

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- *Vagococcus fluvialis*

Additional Claims For 8.01 or Higher Software Users

- *Listeria fleischmannii*
- *Listeria rocourtiae*
- *Streptococcus iniae*

Taxonomy Changes For 9.02 Software Users

- *Streptococcus suis* (formerly *Streptococcus suis* I and II)

**Staphylococcus aureus* claim contains only the subspecies *aureus.*

+ OMA Official Methods of Analysis validated claim.

SUPPLEMENTAL TESTS

Table 15: GP Supplemental Tests

Abbreviation	Test Name	Description	Comments	Reference
For 7.01 or Higher Software Users				
A-HEM	ALPHA HEMOLYSIS	Certain species produce incomplete hemolysis resulting in a green zone around colonies on blood based media.	N/A	21, 22, 23, 26, 27
	Acidification of:	Acidification of carbon source observed with pH indicators (e.g., phenol red, bromcresol purple).	Some tests also appear on the GP card but are recommended as supplemental tests since results of conventional macromethods may differ from rapid commercial micromethods.	2, 3, 4, 8, 10, 14, 16, 17, 21, 22, 23, 26 , 27, 28, 31, 32, 33, 34, 36, 40, 42
AMD/STARCH	AMIDON/STARCH			
GLYCOGENac	GLYCOGEN			
lARABINOSE	L-ARABINOSE acid.			
INULIN	INULIN			
MdG	METHYL-A-DGLUCOPYRANOSIDE			
MdM	METHYL-A-DMANNOPYRANOSIDE			
PULLULAN	PULLULAN			
SACCHAROSE	SACCHAROSE (SUCROSE)			
dGALACTOSE	D-GALACTOSE			
dMALTOSE	D-MALTOSE			
dMANNITOL	D-MANNITOL			
dMANNOSE	D-MANNOSE			
dMELEZIT	D-MELEZITOSE			
dMELIBIOSE	D-MELIBIOSE			
dRAFFINOSE	D-RAFFINOSE			
dRIBOSE	D-RIBOSE			
dSORBITOL	D-SORBITOL			
dTREHALOSE	D-TREHALOSE			
dXYLOSE	D-XYLOSE			
lRHAMNOSE	L-RHAMNOSE			
ANANE	ALPHA-D-N-ACETYLNEURAMINIDASE	Presence of respective enzyme cleaves substrate generating detectable leaving group (e.g., p-nitrophenol, methyl umbelliferone, beta-naphthylamide, beta-naphthol, p-nitroaniline, 7-amidomethyl-coumarin).	Presence of enzyme is indicated by generation of a colored or fluorescent product, or a noncolored product that forms color upon addition of a specific reagent.	7, 11, 21, 22, 23, 27, 28, 29, 31, 34, 39
AIFUC	ALPHA-L-FUCOSIDASE			
BGLU	BETA-GLUCOSIDASE			
BGURase	BETA-GLUCURONIDASE			
BNAG	BETA-N-ACETYLGLUCOSAMINIDASE			
BNAGA	BETA-N-ACETYLGALACTOSAMINIDASE			
BdFUC	BETA-D-FUCOSIDASE			
PAL	ALKALINE PHOSPHATASE			
Pyrro. Ary.	Pyrrolidonyl ARYLAMIDASE			

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Abbreviation	Test Name	Description	Comments	Reference
Adherence	Adherence to agar	Sticking of colonies to the agar surface	Characteristic of *Rothia mucilaginosa*	27
AER.GROWTH	AEROBIC GROWTH	Growth in air	N/A	22
Arg.hydr.	ARGININE dihydrolase	Hydrolysis of arginine releases an amine resulting in alkalinization of the medium observed with a pH indicator (e.g., purple color formation in the presence of bromcresol purple).	N/A	2, 21, 22, 27, 36
B-HEM	BETA HEMOLYSIS	Certain species possess hemolysins that give a transparent zone around colonies on blood-based agars.	N/A	21, 22, 27, 37
BILE SOL	BILE SOLUBILITY	Pneumococcal colonies completely lyse and disappear when exposed to a 10% solution of deoxycholate.	Rapid test for *Streptococcus pneumoniae*	27
CAMP (S.au)	CAMP TEST (*Staph. aureus*)	Synergistic hemolysis of *Listeria monocytogenes* colonies by beta-toxin producing colonies of *Staphylococcus aureus*.	N/A	27
CAT	CATALASE	Colony placed on a drop of 3% hydrogen peroxide produces gas bubbles. The bacteria that contain cytochrome enzyme are catalase positive.	Differentiation of *Micrococcaceae* (+) from *Streptococcaceae* (–)	21, 22, 27, 38
CLINDA.S	Clindamycin susceptible	Zone of inhibition around the clindamycin disk > 20mm	Used to differentiate *Lactococcus lactis* and *Lactococcus garvieae*.	15
ESCULIN	ESCULIN hydrolysis	Hydrolysis of esculin forms esculetin which produces a black pigment in the presence of iron salts.	N/A	3, 18, 21, 22, 24, 27
Gas prod.	Gas production	Production of CO_2 from degradation carbohydrate (e.g., glucose) metabolism.	N/A	27
HIP	HIPPURATE hydrolysis	Hydrolysis of sodium hippurate releases glycine that produces a blue colored product after addition of ninhydrin.	N/A	12, 21, 22, 26, 27
LAP	LEUCINE AMINOPEPTIDASE	The substrate leucine-beta-naphthylamide is hydrolyzed by the enzyme leucine aminopeptidase and released beta-naphthylamide combines with the cinnamaldehyde reagent to form a bright pink to cherry red pigment.	N/A	19
LitmusMILK	Litmus Milk Medium	Acid production in Litmus Milk	N/A	16

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Abbreviation	Test Name	Description	Comments	Reference
NaCl 6.5%	GROWTH IN 6.5% NaCl	Growth in 6.5% NaCl broth	N/A	16, 19
NO3	NITRATE REDUCTION	Test for the ability to reduce nitrate to nitrite or nitrogen gas.	N/A	21, 22, 38
NOVO_R OPTO_R VANCO_R	NOVOBIOCIN_RESISTANCE OPTOCHIN_RESISTANCE VANCOMYCIN_RESISTANCE	Ability of certain species to grow in the presence of specific antibacterial compounds	N/A	20, 21, 22, 27, 40, 41
NaCl 7.5%	GROWTH IN 7.5% NACL	Ability of certain species to grow in the presence of a high concentration of NaCl	N/A	22
PI/OR/RED	PINK/ORANGE/RED PIGMENT	Ability of certain species to produce pink, orange, or red colonies on nondifferential media	Characteristic of *Kocuria rosea*	22, 27, 28
PVATE	PYRUVATE	Ability to use pyruvate as a sole carbon source	N/A	28
SATELLITE	SATELLITE behavior	Appearance of satellite colonies of nutritionally deficient *Streptococcaceae* around colonies of *Staphylococcus epidermidis*.	Nutritionally deficient *Streptococcaceae* require nutritional factors supplied by metabolism of colonies of *Staphylococcus epidermidis*.	9, 27
Str.sero.A Str.sero.B Str.sero.C Str.sero.D Str.sero.G	Strepto Serology A Strepto Serology B Strepto Serology C Strepto Serology D Strepto Serology G	Agglutination tests for *Streptococcus* groups A,B,C,D, and G	N/A	1, 13, 18, 21, 22, 24, 27, 28, 36
UREASE	Urease	Hydrolysis of urea releases ammonia, resulting in alkalinization of the medium observed with a pH indicator (e.g., red color formation in the presence of phenol red).	N/A	21, 22, 25, 27
VP	VOGES PROSKAUER	Ability of some species to produce acetoin from glucose fermentation.	N/A	20, 21, 27, 34
YELLOW	YELLOW PIGMENT	Ability of certain species to produce yellow pigmented colonies on nondifferential media.	For example, used to differentiate *E. casseliflavus* (+) from *E. gallinarum* (–).	21, 22, 27, 28
For 7.01 Software Users Only				
BILE ESC	BILE ESCULIN	Bile-esculin positive organisms are able to grow in the presence of 40% bile and to hydrolyze esculin.	N/A	18, 24
CAROTENOID	CAROTENOID PIGMENT	Presence of red, pink, or orange pigment	N/A	28

REFERENCES

1. Balows A, Hausler Jr. WJ, Herrmann KL, Isenberg HD, Shadomy HJ. *Manual of Clinical Microbiology* 5th edition. American Society of Microbiology, Washington, D.C.1991.

2. Barros RR, Carvalho GS, Peralta JM, Facklam RR, Teixeira LM. Phenotypic and Genotypic Characterization of *Pediococcus* Strains Isolated from Human Clinical Sources. J. Clin. Microbiol. 2001. 39:1241- 1246.

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3. Bille J, Catimel B, Bannerman E, Jacquet C, Yersin MN, Caniaux I, Monget D, Rocourt J. API *Listeria*, a New and Promising One-Day System to Identify *Listeria* Isolates. Appl. Environ. Microbiol. 1992. 58:1857-1860.
4. Christensen JJ, Facklam RR. *Granulicatella* and *Abiotrophia* Species from Human Clinical Specimens. J. Clin. Microbiol. 2001. 39:3520-3523.
5. Clinical and Laboratory Standards Institute, M50-A, Quality Control for Commercial Microbial Identification Systems; Approved Guideline, Vol. 28 No. 23.
6. Clinical Laboratory Improvement Amendments of 1988. 42 U.S.C 263a. PL 100-578. 1988.
7. Collins MD, Farrow JAE, Katic V, Kandler O. Taxonomic studies on streptococci of serological groups E, P, U and V: description of *Streptococcus porcinus* sp. nov. Syst. Appl. Microbiol. 1984. 5:402-413.
8. Collins MD, Jones D, Farrow JAE, Kilpper-Bälz R, Schleifer KH. *Enterococcus avium* nom. rev., comb. nov.; *E.casseliflavus* nom. rev., comb. nov.; *E. durans* nom. rev., comb. nov.; *E.gallinarum* comb. nov.; and *E. malodoratus* sp.nov. Int. J. Syst. Bacteriol. 1984. 34:220-223.
9. Collins MD, Lawson PA. The genus *Abiotrophia* (Kawamura et al.) is not monophiletic: proposal of *Granulicatella* gen. nov., *Granulicatella adiacens* comb.nov., *Granulicatella elegans* comb. nov.and *Granulicatella balaenopterae* comb. nov. Int. J. Syst. Evol. Microbiol. 2000. 50:365-369.
10. Collins MD, Hutson RA, Hoyles L, Falsen E, Nikolaitchouk N, Foster G. *Streptococcus ovis* sp. nov. isolated from sheep. Int. J. Syst. Evol. Microbiol. 2001. 51:1147-1150.
11. Coykendall AL. Classification and Identification of the Viridans Streptococci. Clin. Microbiol. Rev. 1989. 2:315-328.
12. Duarte, R.S., R.R. Barros, R.R. Facklam and L.M. Teixeira. Phenotypic and Genotypic Characteristics of *Steptococcus porcinus* J. Clin.Microbiol. 2005 43(9): 4592-4601.
13. Devriese LA, Ceyssens K, Rodrigues UM, Collins MD. *Enterococcus columbae*, a species from pigeon intestines. FEMS Microbiol Lett. 1990. 59(3):247-51.
14. Devriese LA, Kilpper-Bälz R, Schleifer KH. *Streptococcus hyointestinalis* sp.nov. from the gut of swine. Int. J. Syst. Bacteriol. 1988. 38:440-441.
15. Elliot JA, Facklam RR. Antimicrobial susceptibilities of *Lactococcus lactis* and *Lactococcus garvieae* and a proposed method to discriminate between them. J. Clin. Microbiol. 1996. 34(5): 1296-1298.
16. Elliot JA, Facklam RR. Identification of *Leuconostoc* spp. by analysis of soluble whole-cell protein patterns. J. Clin. Microbiol. 1993. 31(5):1030- 1033
17. Euzéby. Dictionnaire de Bactériologie Vétérinaire. Autres fichier : voir Accueil. Mise à jour : 02 février 2000. Principaux caractéres permettant de différencier les espèces du genre Listeria. D'après :. BILLE (J.), ROCOURT (J).
18. Facklam RR. What Happened to the Streptococci: Overview of Taxonomic and Nomenclature Changes. Clin. Microbiol. Rev. 2002.15:613-630.
19. Facklam R.R. and J.A. Elliott, Identification, Classification and Clinical Relevance of Catalast-Negative, Gram-Positive Cocci, Excluding the Streptococci and Enterococci. Clin. Microbiol. Rev. 1995. 8(4): 479-495.
20. Farrow JAE, Facklam RR, Collins MD. Nucleic acid homologies of some vancomycin-resistant leuconostocs and description of *Leuconostoc citreum* sp. nov. and *Leuconostoc pseudomesenteroides* sp. nov. Int. J. Syst. Bacteriol. 1989. 39:279-283.
21. Freney J, Renaud F, Hansen W, Bollet C. *Précis de bactériologie clinique*, ESKA, Paris, France. 2000.
22. Holt JG, Krieg NR, Sneath PHA, Staley JT, Williams ST, (editors) *Bergey's Manual of Determinative Bacteriology*, 9th edition. Williams and Wilkins, Baltimore, Maryland. 1994.
23. Kilpper-Bälz R, Schleifer KH. *Streptococcus suis* sp. nov., nom. rev. Int. J. Syst. Bacteriol. 1987. 37:160-162.
24. Koneman EW, Allen SD, Janda WM, Schreckenberger PC, Winn WC Jr. *Color Atlas and Textbook of Diagnostic Microbiology*, 5th edition. Lippincott-Raven, Philadelphia, PA.1997.
25. Kovács G., J. Burghardt, S. Pradella, P. Schumann, E. Stackebrandt and K. Màrialigeti. *Kocuria palusris* sp. nov. and *Kocuria rhizophilia* sp. nov., isolated from the rhizoplane of the narrow-leaved cattail (*Typha angustifolia*). Int. J. Syst. Bacteriol., 1999, 49, 167-173.
26. Mahlen, S.D. and J.E. Clarridge III. Thumb Infection Caused by *Streptococcus pseudoporcinus*. J.Clin.Microbiol. 2009. 47(9): 3041-3042.
27. Murray PR, Baron EJ, Pfaller MA, Tenover FC, Yolken RH, editors. *Manual Of Clinical Microbiology*, 7th edition. American Society for Microbiology, Washington, D.C. 1999.
28. Murray PR, Baron EJ, Jorgensen JH, Pfaller MA, Yolken RH, editors. Manual Of Clinical Microbiology, Volume 1, 8th edition. American Society for Microbiology, Washington, D.C. 2003.
29. Murray, P.R., E.J. Baron, M.L. Landry, J.H. Jorgensen and M.A. Pfaller. 2007. *Manual of Clinical Microbiology*, 9th edition. American Society for Microbiology, Washington, D.C.

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30. National Committee for Clinical Laboratory Standards, M29-A, *Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissue* — Approved Guideline, 1997.
31. Poyart C, Quesne G, Trieu-Cuot P. Taxonomic dissection of the *Streptococcus bovis* group by analysis of manganese-dependent superoxide dismutase gene (sodA) sequences: reclassification of *Streptococcus infantarius* subsp. *coli* as *Streptococcus lutetiensis* sp.nov. and of *Streptococcus bovis* biotype II.2 as *Streptococcus pasteurianus* sp nov. Int. J. Syst. Evol. Microbiol. 2002. 52:1247-1255.
32. Schlegel L, Grimont F, Collins MD, Regnault B, Grimont PAD, Bouvet A. *Streptococcus infantarius* sp. nov., *Streptococcus infantarius* subsp *infantarius* subsp. nov. and *Streptococcus infantarius* subsp *coli* subsp. nov., isolated from humans and food. Int. J. Syst. Evol. Microbiol. 2000. 50:1425-1434.
33. Schlegel, L., F. Grimont, E. Ageron, P. A. D. Grimont, and A. Bouvet. Reappraisal of the taxonomy of the *Streptococcus bovis/Streptococcus equinus* complex and related species: description of *Streptococcus gallolyticus* subsp. *gallolyticus* subsp. nov., *S. gallolyticus* subsp. *macedonicus* subsp. nov. and *S. gallolyticus* subsp. *pasteurianus* subsp. nov. Int. J. Syst. Evol. Microbiol. 2003. 53:631-645.
34. Takashi, S., K. Kikuchi, Y. Tanaka, N. Takahashi, S. Kamata and K. Hiramatsu. Reclassification of Phenotypically Identified *Staphylococcus intermedius* Strains. J.Clin.Microbiol. 2007. 45(9): 2770-2778.
35. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health, Office of Health and Safety, Biosafety in Microbiological and Biomedical Laboratories, 1988.
36. Versalovic J, Carroll KC, Funke G, Jorgensen JH, Landry ML, Warnock DW, editors. Manual Of Clinical Microbiology, Volume 1, 10th edition. American Society for Microbiology, Washington, D.C. 2011.
37. Viera VV, Teixeira LM, Zahner V, Momen H, Facklam RR, Steigerwalt AG, Brenner DJ, Castro ACD. Genetic relationships among the different phenotypes of *Streptococcus dysgalactiae* strains. Int. J. Syst. Bacteriol. 1998. 48:1231-1243.
38. Von Graevenitz, A. *Rothia dentocariosa*: taxonomy and differential diagnosis. Clin.Microbiol. and Infection, 2004. 10:399-402.
39. Whiley RA, Hall LMC, Hardie JM, Beighton D. A study of small colony beta hemolytic, Lancefield group C streptococci within the anginosus group: description of *Streptococcus constellatus* subsp. *pharyngis* subsp.nov., associated with the human throat and pharyngitis. Int. J. Syst. Bacteriol. 1999. 49:1443-1449.
40. Whiley, R.A. & Hardie ,J.M. 2009. *Streptococcaceae*. In *Bergey's Manual of Systematic Bacteriology,* 2nd ed., Volume 3. DeVos, P., Garrity, G., Jones, D., Krieg, N.R., Ludwig, W., Rainey, F.A., Schleifer, K.-H., and Whitman, W.B. (eds), Springer, New York, pp. 707-708.
41. Jorgensen, JH., Pfaller, M., Carroll, K., Funke, G., Landry, ML., Richter, S., Warnock, D. *Manual of Clinical Bicrobiology*, Volume 1, 11th edition. American Society for Microbiology, Washington, D.C., 2015.
42. Winn, W.C., S. Allen, W. Janda, E. Koneman, G. Procop, P. Schreckenberger, G. Woods. *Color Atlas and Textbook of Diagnostic Microbiology*, 6th ed., 2006, Lippincott Williams & Wilkins, Philadelphia, Baltimore.

Use this Instructions for Use with VITEK® 2 Product No. 21342.

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalog number
IVD	In Vitro Diagnostic Medical Device
	Legal Manufacturer
	Temperature limitation
	Use by date
LOT	Batch code
	Consult Instructions for Use

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Symbol	Meaning
	Date of manufacture
	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community
℞ only	For US Only : Caution : US Federal Law restricts this device to sale by or on the order of a licensed practitioner

Instructions for Use provided in the kit or downloadable from www.biomerieux.com/techlib

LIMITED WARRANTY

bioMérieux warrants the performance of the product for its stated intended use provided that all procedures for usage, storage and handling, shelf life (when applicable), and precautions are strictly followed as detailed in the instructions for use (IFU).

Except as expressly set forth above, bioMérieux hereby disclaims all warranties, including any implied warranties of merchantability and fitness for a particular purpose or use, and disclaims all liability, whether direct, indirect or consequential, for any use of the reagent, software, instrument and disposables (the “System”) other than as set forth in the IFU.

WASTE DISPOSAL

All hazardous waste must be disposed of by following your local inspecting agency's guidelines.

REVISION HISTORY TABLE

Change type categories	
N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user
Note :	Minor typographical, grammar, and formatting changes are not included in the revision history.

Release Date	Part Number	Change Type	Change Summary
2019-03	043900-03	Technical change	Updated for 9.02 software release. Updated sections: • Intended Use • Precautions • Additional Information on Lab Report • Testing of QC Organisms • Performance Characteristics • Organisms Identified • References
2016-10	043900-02	Technical change	• Updated content to reflect the 8.01 Product Information Manual

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Release Date	Part Number	Change Type	Change Summary
2016-05	043900-01	Administrative	• Formatting changes do not affect the fit, form, or function of the product
		Technical change	• New IFU derived from product chapter in the Product Information Manual • Updated Limited Warranty section • Updated with RX only information

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REF 21346

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VITEK® 2 NH

℞ only IVD

INTENDED USE

These Instructions for Use correspond to the VITEK® 2 Systems 7.01 or higher software. If you are not using VITEK® 2 Systems 7.01 or higher software, please refer to the VITEK® 2 Systems Product Information that you received with your current software version.

The VITEK® 2 Neisseria-Haemophilus identification card (NH) is intended for use with the VITEK® 2 Systems for the automated identification of most clinically significant fastidious organisms. The VITEK® 2 NH identification card is a single-use disposable. For a list of claimed species, see the Organisms Identified section.

DESCRIPTION

The NH Card is based on established biochemical methods and newly developed substrates measuring carbon source utilization and enzymatic activities. There are 30 biochemical tests. Final identification results are available in approximately six hours.

For a list of well contents, see the NH Well Contents table.

Table 1: NH Well Contents

Well	Test	Mnemonic	Amount/Well
1	Arginine ARYLAMIDASE	ArgA	0.0324 mg
2	GAMMA-GLUTAMYL-TRANSFERASE	GGT	0.0228 mg
3	L-Lysine-ARYLAMIDASE	LysA	0.0228 mg
4	D-GALACTOSE	dGAL	0.3 mg
5	Leucine ARYLAMIDASE	LeuA	0.023 mg
6	ELLMAN	ELLM	0.03 mg
7	Phenylalanine ARYLAMIDASE	PheA	0.026 mg
8	L-Proline ARYLAMIDASE	ProA	0.023 mg
10	L-Pyrrolidonyl-ARYLAMIDASE	PyrA	0.018 mg
13	Tyrosine ARYLAMIDASE	TyrA	0.0279 mg
15	Ala-Phe-Pro-ARYLAMIDASE	APPA	0.038 mg
18	D-GLUCOSE	dGLU	0.3 mg
19	GLYCOGENE	GLYG	0.18 mg
20	D-MANNOSE	dMNE	0.3 mg
22	D-MALTOSE	dMAL	0.3 mg
28	SACCHAROSE/SUCROSE	SAC	0.3 mg
33	N-ACETYL-D-GLUCOSAMINE	NAG	0.3 mg
36	UREASE	URE	0.15 mg
39	BETA-GALACTOPYRANOSIDASE Indoxyl	BGALi	0.006 mg
40	ORNITHINE DECARBOXYLASE	ODC	0.15 mg
41	ALPHA-ARABINOSIDASE	AARA	0.0324 mg
45	PYRUVATE	PVATE	0.15 mg
46	PHOSPHORYL CHOLINE	PHC	0.0366 mg
47	D-MALATE	dMLT	0.15 mg

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Well	Test	Mnemonic	Amount/Well
51	MALTOTRIOSE	MTE	0.3 mg
52	L-GLUTAMINE	IGLM	0.15 mg
59	PHOSPHATASE	PHOS	0.05 mg
61	d-Ribose 2	dRIB2	0.3 mg
62	Phenylphosphonate	OPS	0.024 mg
64	D-XYLOSE	dXYL	0.3 mg

Note: Other well numbers between 1 and 64 not designated in this table are empty.

PRECAUTIONS

Note: For industry customers that need assistance on selecting the correct VITEK® 2 identification card, please refer to the VITEK® 2 Compact Instrument User Manual chapter, "Guidance to Select a VITEK® 2 Identification Card."

- For *In Vitro* Diagnostic Use Only.
- For US Only: Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- For professional use only.
- Suspensions not within the appropriate zone on the VITEK® 2 DENSICHEK™ Plus or the VITEK® 2 DENSICHEK™ may compromise card performance.
- Do not use the card after the expiration date shown on the package liner.
- Store the card unopened in the package liner. Do not use the card if the protective package liner is damaged or if no desiccant is present.
- Allow the card to come to room temperature before opening the package liner.
- Do not use powdered gloves. Powder may interfere with the optics.
- Use of culture media other than the recommended types must be validated by the customer laboratory for acceptable performance.
- A Gram stain should be performed to determine an organism's Gram reaction and morphology prior to selecting the identification card to inoculate.
- The card performs as intended only when used in conjunction with VITEK® 2 Systems, following the instructions contained in these Instructions for Use.
- **Do not use glass test tubes**. Use clear plastic (polystyrene) tubes only. Variation exists among test tubes of standard diameter. Carefully place the tube into the cassette. If resistance is encountered, discard and try another tube that does not require pressure to insert.
- Prior to inoculation, inspect cards for tape tears or damage to the tape and discard any that are suspect. Check the saline level in the tubes after the cassette has been processed to ensure proper filling of card.
  - VITEK® 2 60 or VITEK® 2 XL: Eject improperly filled cards.
  - VITEK® 2 Compact: Do not load improperly filled cards.
- Give special consideration to specimen source and patient drug or antimicrobic regimen.
- Give special consideration to sample source.
- Interpretation of test results requires the judgment and skill of a person knowledgeable in microbial identification testing. Additional testing may be required. (See the Supplemental Tests section.)
- Do not clean saline dispenser with chemical agents. The use of chemical agents may impact card performance.

Warning: All patient specimens, microbial cultures, and inoculated VITEK® 2 cards, along with associated materials, are potentially infectious and should be treated with universal precautions.[18,20]

Warning: All hazardous waste must be disposed of by following your local inspecting agency's guidelines.

STORAGE CONDITIONS

Upon receipt, store VITEK® 2 NH cards unopened in their original package liner at 2°C to 8°C.

SPECIMEN PREPARATION

For specimen preparation information, see the Culture Requirements Table.

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Table 2: Culture Requirements Table

VITEK® 2 Card	Media	Age of Culture[1]	Incubation Conditions	Inoculum Density	Dilution for AST	Age of Suspension Before Loading Instrument
NH	*Campylobacter*: TSAB[2] CBA CHBA TSAHB	*Campylobacter*: 18 to 24 hours	*Campylobacter*: 35°C to 37°C or 40°C to 42°C microaerobic conditions	2.70 – 3.30 McFarland Standard	N/A [5]	≤ 30 minutes
	Haemophilus: CHOC[2] CHOC PVX[2] CBA CHOC + B	Fastidious: 18 to 24 hours	Fastidious: 35°C to 37°C with 5% to 10% CO_2			
	Neisseria: CHOC[2] CHOC PVX[2] CHOC VCAT CHBA ML[3] NYC[4] TM[3] TSAB					
	Other Fastidious: CHOC[2] CHOC PVX[2] CBA CHBA ML[3] TM[3] TSAB TSAHB					

[1]Cultures with scant or poor growth may give unidentified or incorrect results even when the Age of Culture requirements are met.

[2]These media were used in the identification product database development and will give optimal performance.

[3]These media were validated for *Neisseria gonorrhoeae*, *Neisseria meningitidis* and *Moraxella catarrhalis*.

[4]This medium was validated for *Neisseria gonorrhoeae*.

[5]N/A = not applicable

Culture Requirements Table — Media Abbreviations

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CBA = Columbia Blood Agar with 5% Sheep Blood

CHBA = Columbia Horse Blood Agar

CHOC = Chocolate Agar

CHOC + B = Chocolate Agar with Bacitracin

CHOC PVX = Chocolate Polyvitex Agar

CHOC VCAT = Chocolate Polvitex Agar with VCAT

ML = Martin-Lewis Agar

NYC = New York City Medium

TM = Thayer-Martin Agar

TSAB = Trypticase Soy Agar with 5% Sheep Blood

TSAHB = Trypticase Soy Agar with 5% Horse Blood

TEST PROCEDURE

Materials

When used with VITEK® 2 instrumentation, the NH Card is a complete system for routine identification testing of most significant fastidious organisms.

Required materials are:

- VITEK® 2 NH Card
- DENSICHEK™ Plus Kit or VITEK® DENSICHEK® Kit
- DENSICHEK™ Plus Standards Kit or DENSICHEK® Standards Kit
- VITEK® 2 Cassette
- Sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- 12 mm x 75 mm clear plastic (polystyrene) disposable test tubes
- Sterile sticks or swabs
- Appropriate agar medium (see Culture Requirements table).

Optional accessories:

- Adjustable volume saline dispenser
- Loops
- Pre-dispensed saline test tubes (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Test tube caps
- Vortex

Procedure

Warning: Failure to follow instructions and recommendations provided in this section for performing laboratory tasks may cause erroneous or delayed results.

For product-specific information, see the Culture Requirements table.

Note: Prepare the inoculum from a pure culture, according to good laboratory practices. In case of mixed cultures, a re-isolation step is required. It is recommended that a purity check plate be done to ensure that a pure culture was used for testing.

1. Do one of the following:
   - Select isolated colonies from a primary plate if culture requirements are met.
   - Subculture the organism to be tested to appropriate agar medium and incubate accordingly.
2. Aseptically transfer 3.0 mL of sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0) into a clear plastic (polystyrene) test tube (12 mm x 75 mm).
3. Use a sterile stick or swab to transfer a sufficient number of morphologically similar colonies to the saline tube prepared in step 2. Prepare a homogenous organism suspension with a density equivalent to a McFarland No. 2.70 to 3.30 using a calibrated VITEK® 2 DENSICHEK™ Plus or VITEK® 2 DENSICHEK™.
   Note: Age of suspension must not exceed 30 minutes before inoculating card.
4. Place the suspension tube and NH card in the cassette.

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5. Refer to the appropriate Instrument User Manual for instructions on data entry and how to load the cassette into the instrument.
6. Follow your local inspecting agency's guidelines for disposal of hazardous waste.

RESULTS

Identification Analytical Techniques

VITEK® 2 Systems identify an organism by using a methodology based on the characteristics of the data and knowledge about the organism and reactions being analyzed. Sufficient data have been collected from known strains to estimate the typical reactions of the claimed species to a set of discriminating biochemicals. If a unique identification pattern is not recognized, a list of possible organisms is given, or the strain is determined to be outside the scope of the database.

The printed lab report contains suggestions for any supplemental tests necessary to complete the identification. If the tests are not sufficient to complete the identification, then standard microbiology references and literature should be consulted.

Table 3: Identification Card Qualifying Messages

ID Message Confidence Level	Choices	% Probability	Comments
Excellent	1	96 to 99	N/A
Very Good	1	93 to 95	N/A
Good	1	89 to 92	N/A
Acceptable	1	85 to 88	N/A
Low Discrimination	2 to 3	Sum of choices = 100; after resolution to one choice, percent probability reflects the number associated with selected choice.	Two to three taxa exhibit same biopattern. Separate by supplemental testing.
Inconclusive or Unidentified Organism	> 3 or 0	N/A	Either > 3 taxa exhibit same biopattern or Very atypical biopattern. Does not correspond to any taxon in the database. Check Gram stain and purity.

PERCENT PROBABILITY

As part of the identification process, the software compares the test set of reactions to the expected set of reactions of each organism, or organism group, that can be identified by the product. A quantitative value, the percent probability, is calculated and relates to how well the observed reactions compare to the typical reactions of each organism. A perfect match between the test reaction pattern and the unique reaction pattern of a single organism, or organism group, would provide a percent probability of 99. When a perfect match is not obtained, it is still possible for the reaction pattern to be sufficiently close to that of an expected reaction pattern such that a clear decision can be provided about the organism identification. The range of percent probabilities in the one-choice case is 85 to 99. Values closer to 99 indicate a closer match to the typical pattern for the given organism.

When the reaction pattern is not sufficient to discriminate between two to three organisms, the percent probabilities reflect this ambiguity. The reported probability values indicate, relatively, the order in which the reaction pattern best corresponds to the listed possibilities. The order does not, however, suggest that the pattern match to one of the possible identifications is clearly superior to another. The probability characteristic of an overall sum of 100 is retained through the calculation process. After resolution to one choice, the probability characteristic of the single choice is retained.

ADDITIONAL INFORMATION ON LAB REPORT

Supplemental test — External (offline) test that allows the user to resolve a slashline or Low Discrimination identification. Numbers in parentheses indicate percent positive reaction for the species/test listed.

Contraindicating test — Test result that is unusual for a reported taxon.

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Table 4: Notes Associated with Certain Taxa

Taxa	Note			
For 7.01 or Higher Software Users				
Haemophilus influenzae	*Haemophilus aegyptius* is a recognized species, but there is controversy as to whether it should be retained as a legitimate species. *Haemophilus aegyptius* is indistinguishable from *H. influenzae* by either DNA/DNA hybridization or by any single phenotypic test. Isolates of *H. aegyptius* exhibit distinct pathogenicity and are associated with cases of acute purulent conjunctivitis. *Haemophilus influenzae* biogroup *Aegyptius* is also indistinguishable from *H. aegyptius* and *H. influenzae*, but is considered the etiologic agent of Brazilian purpuric fever, which is a systemic pediatric infection that is typically preceded by purulent conjunctivitis that resolves before the onset of the systemic infection. Consequently, isolates of *H. aegyptius*, *H. influenzae* biogroup *Aegyptius*, and other biogroups of *H. influenzae* will all identify as *H. influenzae* when tested with the NH card.			
Neisseria gonorrhoeae *Neisseria meningitidis*	Critical pathogen The species identified may have significance to patient or sample outcome and can be stopped for review.			
Neisseria sicca	Possibility of *N. flavescens* or *N. mucosa*. Isolates of these species may be misidentified as *N. sicca*. In order to rule them out, perform the following tests:			
		YELLOW	GLU	NO3
	N. flavescens	+	-	-
	N. mucosa	+	+	+
	N. sicca	-	+	-
For 9.02 Software Users				
Neisseria cinerea	Possibility of *Neisseria gonorrhoeae*			

Notes Associated with an Improperly Filled Card or with a Negative Profile (Biopattern)

- For the case where the time between two readings is greater than 40 minutes: “CARD ERROR — Missing data.”
- For the case where there is a negative profile: “Organism with low reactivity biopattern — please check viability.”
- When a biopattern is calculated for an unknown organism that is completely negative or consists of both negative tests and tests that fall within the uncertainty zone, the identification call will be “Non or low reactive biopattern.”

Campylobacter jejuni ssp. *jejuni* could potentially trigger “Non or low reactive biopattern” if a test was atypical or fell within the uncertainty zone.

QUALITY CONTROL

Quality control organisms and their expected results are listed in the VITEK® 2 NH Quality Control Tables. Process these according to the procedure for test isolates outlined in this document.

Note: *Staphylococcus epidermidis* ATTC® 12228™ needs to be tested at a McFarland Standard No. 0.5 to 0.63. All other QC strains are tested at a McFarland Standard No. 2.70 to 3.30.

Certification Statement

This is to certify that bioMérieux complies with ISO 13485 and FDA Quality System Regulation (QSR) requirements for design, development, and manufacture of microbial identification systems.

Frequency of Testing

Currently, it is recommended that you use your most stringent inspecting agency’s guidelines for frequency of identification product testing.

Common practice is to perform QC upon receipt of shipment of the test kits. Reactions must follow Instructions for Use results.

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If the results do not meet the criteria, subculture for purity and repeat the test. If discrepant results are repeated, perform an alternate identification method and contact bioMérieux.

Testing and Storage of QC Organisms

1. Rehydrate the organism according to the manufacturer's instructions.
2. Use Chocolate agar and incubate at 35°C to 37°C in 5% to 10% CO_2. Incubate for 18 to 24 hours or until sufficient growth is obtained.
3. Check for purity. Perform second subculture for testing.
4. Use Chocolate agar and incubate at 35°C to 37°C in 5% to 10% CO_2. Incubate for 18 to 24 hours.

Short-Term Storage Conditions

Short-term storage is not recommended. Cultures maintained by other methods, specifically those maintained on agar plates or slants for long periods of time at room temperature or at 2°C to 8°C are subject to loss or change of important biochemical characteristics.

Long-Term Storage Conditions

1. Make a heavy suspension in Tryptic Soy Broth (TSB) with 15% glycerol.
2. Freeze at -70°C.
3. Subculture twice to Chocolate agar before running QC.

Note: Avoid repeated thawing and refreezing by either freezing in single-use aliquots or removing a small portion of frozen organism preparation with a sterile applicator stick.

STREAMLINED QUALITY CONTROL

Note: Industrial Use Only laboratories should perform quality control following the Streamlined Quality Control section. No additional testing is required for these users.

Streamlined quality control may be used to confirm acceptable performance of the NH card after shipping/storage. This methodology may be performed with the NH card by following the instructions for quality control testing as described in the NH Instructions for Use and meeting the criteria stated in the CLSI® M50-A Quality Control for Commercial Microbial Identification Systems.

Testing may be conducted using *Eikenella corrodens* ATCC® BAA-1152™ and evaluating the performance of the PHOS well. Testing at bioMérieux, Inc. has shown that the PHOS well is the most labile well on the NH card and *E. corrodens* ATCC® BAA-1152™ is the most sensitive strain for detecting degradation of this well with a false positive reaction. (See NH Quality Control table for more details).

COMPREHENSIVE QUALITY CONTROL

Customers who do not qualify for streamlined quality control testing are required to perform comprehensive quality control testing, which entails demonstration of a positive and negative reaction for each substrate of an identification product.[4]

In order to qualify initially for streamlined quality control testing, the CLSI® M50-A standard requires that the user perform and document either of the following:[3]

- Verification testing to show that performance is equivalent to the manufacturer's claims.
- Comprehensive quality control testing of at least three lots over at least three different seasons.

Refer to the complete CLSI® M50-A standard for information regarding continued qualification and further details of requirements and responsibilities for both the user and the manufacturer related to streamlined quality control testing.

NH Quality Control Tables:

***Eikenella corrodens* ATCC® BAA-1152™** (for streamlined or comprehensive quality control)

***Aggregatibacter aphrophilus* ATCC® 33389™** (for comprehensive quality control)

***Haemophilus influenzae* ATCC® 9007™** (for comprehensive quality control)

***Neisseria gonorrhoeae* ATCC® 19424™** (for comprehensive quality control)

***Neisseria lactamica* ATCC® 23970™** (for comprehensive quality control)

***Oligella urethralis* ATCC® 17960™** (for comprehensive quality control)

***Enterobacter aerogenes* ATCC® 13048™** (for comprehensive quality control)

***Paenibacillus polymyxa* ATCC® 7070™** (for comprehensive quality control)

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***Staphylococcus epidermidis* ATCC® 12228™** (for comprehensive quality control)

The NH card typically identifies the quality control organisms as one-choice or within a low discrimination or slashline identification. However, strains are chosen for reaction performance over identification performance. Therefore, an unidentified or a misidentified result may occur when all expected quality control reactions are correct.

Note: The NH card uses unclaimed taxa for quality control testing. These strains will give an unidentified or a misidentified result.

Table 5: QC Organism: *Eikenella corrodens* ATCC® BAA-1152™ (for streamlined or comprehensive quality control)

ArgA	-	PheA	-	GLYG	-	BGALi	-	MTE	-
GGT	-	ProA	+	dMNE	-	ODC	+	IGLM	v
LysA	-	PyrA	-	dMAL	-	AARA	-	*PHOS**	-
dGAL	-	TyrA	-	SAC	-	PVATE	-	dRIB2	-
LeuA	+	APPA	+	NAG	-	PHC	-	OPS	-
ELLM	+	dGLU	-	URE	-	dMLT	v	dXYL	-

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive.

*Key well for streamlined quality control.

Table 6: QC Organism *Aggregatibacter aphrophilus* ATCC® 33389™ (for comprehensive quality control)

ArgA	v	PheA	v	GLYG	v	BGALi	+	MTE	+
GGT	+	ProA	–	dMNE	+	ODC	–	IGLM	–
LysA	v	PyrA	v	dMAL	+	AARA	v	PHOS	+
dGAL	v	TyrA	v	SAC	+	PVATE	–	dRIB2	v
LeuA	v	APPA	–	NAG	v	PHC	v	OPS	v
ELLM	v	dGLU	+	URE	–	dMLT	v	dXYL	v

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive.

Table 7: QC Organism: *Haemophilus influenzae* ATCC® 9007™ (for comprehensive quality control)

ArgA	v	PheA	+	GLYG	v	BGALi	–	MTE	v
GGT	–	ProA	–	dMNE	v	ODC	v	IGLM	v
LysA	v	PyrA	–	dMAL	–	AARA	v	PHOS	+
dGAL	+	TyrA	v	SAC	v	PVATE	v	dRIB2	+
LeuA	+	APPA	–	NAG	v	PHC	+	OPS	+
ELLM	v	dGLU	+	URE	+	dMLT	+	dXYL	+

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive.

Table 8: QC Organism: *Neisseria gonorrhoeae* ATCC® 19424™ (for comprehensive quality control)

ArgA	+	PheA	v	GLYG	v	BGALi	v	MTE	v
GGT	v	ProA	v	dMNE	v	ODC	–	IGLM	–
LysA	v	PyrA	v	dMAL	v	AARA	–	PHOS	v
dGAL	v	TyrA	v	SAC	v	PVATE	v	dRIB2	v
LeuA	v	APPA	+	NAG	v	PHC	–	OPS	v
ELLM	–	dGLU	v	URE	v	dMLT	–	dXYL	v

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive.

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Table 9: QC Organism: *Neisseria lactamica* ATCC® 23970™ (for comprehensive quality control)

ArgA	v	PheA	v	GLYG	v	BGALi	+	MTE	v
GGT	v	ProA	v	dMNE	v	ODC	v	IGLM	v
LysA	-	PyrA	v	dMAL	v	AARA	+	PHOS	v
dGAL	v	TyrA	v	SAC	v	PVATE	v	dRIB2	v
LeuA	v	APPA	v	NAG	v	PHC	v	OPS	-
ELLM	v	dGLU	v	URE	v	dMLT	v	dXYL	v

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive.

Table 10: QC Organism: *Oligella urethralis* ATCC® 17960™ (for comprehensive quality control)

ArgA	–	PheA	+	GLYG	–	BGALi	v	MTE	–
GGT	+	ProA	+	dMNE	–	ODC	v	IGLM	+
LysA	v	PyrA	v	dMAL	v	AARA	v	PHOS	–
dGAL	–	TyrA	+	SAC	–	PVATE	+	dRIB2	–
LeuA	v	APPA	v	NAG	–	PHC	v	OPS	v
ELLM	+	dGLU	–	URE	v	dMLT	+	dXYL	–

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive.

Table 11: QC Organism: *Enterobacter aerogenes* ATCC® 13048™ (for comprehensive quality control)

ArgA	v	PheA	v	GLYG	v	BGALi	v	MTE	v
GGT	v	ProA	v	dMNE	v	ODC	v	IGLM	v
LysA	+	PyrA	+	dMAL	v	AARA	v	PHOS	v
dGAL	v	TyrA	v	SAC	v	PVATE	v	dRIB2	v
LeuA	v	APPA	v	NAG	+	PHC	v	OPS	v
ELLM	v	dGLU	v	URE	v	dMLT	v	dXYL	v

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive.

Note: *Enterobacter aerogenes* is an unclaimed taxa for the NH card.

Table 12: QC Organism: *Paenibacillus polymyxa* ATCC® 7070™ (for comprehensive quality control)

ArgA	v	PheA	v	GLYG	+	BGALi	v	MTE	v
GGT	v	ProA	v	dMNE	v	ODC	v	IGLM	v
LysA	v	PyrA	v	dMAL	v	AARA	v	PHOS	v
dGAL	v	TyrA	v	SAC	v	PVATE	v	dRIB2	v
LeuA	v	APPA	v	NAG	v	PHC	v	OPS	v
ELLM	v	dGLU	v	URE	v	dMLT	v	dXYL	v

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive.

Note: *Paenibacillus polymyxa* is an unclaimed taxa for the NH card.

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Table 13: QC Organism: *Staphylococcus epidermidis* ATCC® 12228™ (for comprehensive quality control)

ArgA	v	PheA	v	GLYG	v	BGALi	v	MTE	v
GGT	v	ProA	v	dMNE	v	ODC	v	IGLM	v
LysA	v	PyrA	v	dMAL	v	AARA	v	PHOS	v
dGAL	v	TyrA	v	SAC	v	PVATE	v	dRIB2	v
LeuA	–	APPA	v	NAG	v	PHC	v	OPS	v
ELLM	v	dGLU	v	URE	v	dMLT	v	dXYL	v

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive.

Note: *Staphylococcus epidermidis* is an unclaimed taxa for the NH card.

LIMITATIONS

The VITEK® 2 NH card cannot be used with a direct clinical specimen or sample or other sources containing mixed flora. Any change or modification in the procedure may affect the results.

Newly described or rare species may not be included in the NH database. Selected species will be added as strains become available.

Warning: Testing of unclaimed species may result in an unidentified result or a misidentification.

PERFORMANCE CHARACTERISTICS

For 7.01 Software Users

In a multi-site clinical study*, the performance of the VITEK® 2 NH identification card was evaluated using 371 clinical and stock isolates of both commonly and rarely observed species of fastidious organisms. The reference identification was determined by 16S rRNA gene sequencing. Overall, the VITEK® 2 NH correctly identified 96.5% of these isolates, including 10.2% low discrimination with the correct species listed. Misidentifications occurred at 2.7% and no identifications occurred at 0.8%.

For 8.01, 9.01, and 9.02 Software Users

In a multi-site clinical study*, the performance of the VITEK® 2 NH identification card was evaluated using 371 clinical and stock isolates of both commonly and rarely observed species of fastidious organisms. The reference identification was determined by 16S rRNA gene sequencing. Overall, the VITEK® 2 NH correctly identified 95.7% of these isolates, including 10.5% low discrimination with the correct species listed. Misidentifications occurred at 3.2% and no identifications occurred at 1.1%.

*Data on file at bioMérieux, Inc.

ORGANISMS IDENTIFIED

Claims are for all software users unless otherwise stated.

- *Actinobacillus ureae*
- *Aggregatibacter actinomycetemcomitans*
- *Aggregatibacter aphrophilus*
- *Aggregatibacter segnis*
- *Campylobacter coli*
- *Campylobacter fetus* ssp. *fetus*
- *Campylobacter jejuni* ssp. *jejuni*
- *Capnocytophaga* spp.
- *Cardiobacterium hominis*
- *Eikenella corrodens*
- *Gardnerella vaginalis*
- *Haemophilus haemolyticus*
- *Haemophilus influenzae*
- *Haemophilus parahaemolyticus*
- *Haemophilus parainfluenzae*
- *Kingella denitrificans*
- *Kingella kingae*

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- *Moraxella (Branhamella) catarrhalis*
- *Neisseria cinerea*
- *Neisseria elongata*
- *Neisseria gonorrhoeae*
- *Neisseria lactamica*
- *Neisseria meningitidis*
- *Neisseria sicca*
- *Oligella urethralis*
- *Suttonella indologenes*

Additional Claims For 8.01 or Higher Software Users

- *Actinobacillus pleuropneumoniae*
- *Actinobacillus suis*
- *Histophilus somni*
- *Moraxella (Neisseria) ovis*
- *Neisseria weaveri*
- *Riemerella anatipestifer*

SUPPLEMENTAL TESTS

Table 14: NH Supplemental Tests

Abbreviation	Test Name	Description	Comments	Reference
For 7.01 or Higher Software Users				
25C	GROWTH AT 25degC	Ability of certain species to grow at 25°C.	N/A	14, 17
42C	GROWTH AT 42degC	Ability of certain species to grow at 42°C.	N/A	17
AGAR 35	GROWTH AT 35C (NUTRIENT AGAR)	Ability of certain species to grow at 35°C on nutrient agar.	N/A	16, 17
CAT	CATALASE	Colony placed on a drop of hydrogen peroxide produces gas bubbles. The bacteria that contain cytochrome enzyme are catalase positive.	N/A	11, 12, 14, 17
COCCI	COCCUS SHAPE	Coccus (round) shape of the bacterial cell examined with gram stain.	N/A	11, 14, 17
DNAse	DNAse	Ability of certain species to produce DNAse resulting in the degradation of DNA.	N/A	12, 16, 17
ESCULIN	ESCULIN hydrolysis	Hydrolysis of esculin forms esculetin that produces a black pigment in the presence of iron salts.	N/A	11, 17, 21
HEMO-horse	Horse blood hemolysis	Certain species possess hemolysins that give a transparent zone around the colonies on blood-based agars.	Hemolysis on horse blood is used as a differential test in the identification of *Haemophilus* spp.	17
HIP	HIPPURATE hydrolysis	Hydrolysis of sodium hippurate releases glycine that produces a blue colored product after addition of ninhydrin.	Of the *Campylobacter* species, only *Campylobacter jejuni* gives a positive hippurate reaction.	17

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Abbreviation	Test Name	Description	Comments	Reference
IND	INDOLE	Ability of certain species to split indole from tryptophan detected by a colored product revealed with a specific reagent (e.g., Kovacs, Ehrlichs, DMAC reagents).	N/A	11, 17, 22
MOB	MOTILITY	Test for motility using hanging drop procedure or wet mount.	Bacterial motility can be observed by placing a drop of bacterial suspension on a slide and viewing it under a microscope.	17, 22
NO3	NITRATE REDUCTION	Test for the ability to reduce nitrate to nitrite or nitrogen gas.	N/A	11, 12, 17, 22
ONPG	BETA-GALACTOSIDASE	Presence of beta-galactosidase cleaves o-nitrophenol-beta-D-galactopyranoside to produce a yellow colored product.	N/A	10, 11, 16, 17
OX	OXIDASE	Detection of the presence of cytochrome C.	N/A	11, 17, 19
THAYER M.	Thayer Martin Agar	Growth on selective medium used in the differentiation of *Neisseria* spp.	Thayer Martin Agar, New York City Agar, or Chocolate Polyvitex Agar with VCAT can be used for this test.	11, 17
UREASE	Urease	Hydrolysis of urea releases ammonia resulting in alkalinization of the medium observed with a pH indicator (e.g., red color formation in the presence of phenol red).	Some tests also appear on the NH card but are recommended as supplemental tests since results of conventional macromethods often differ from rapid commercial micromethods.	11, 17
V FACTOR	V FACTOR (NAD) REQUIREMENT	NAD required for growth.	N/A	16, 17, 19
X FACTOR	X FACTOR (HEMIN) REQUIREMENT	Hemin required for growth.	N/A	11, 17, 19
dFRUCTOSE	D-FRUCTOSE acidification	Acidification of carbon source observed with pH indicator (e.g., phenol red, bromcresol purple).	Some tests also appear on the NH card but are recommended as supplemental tests since results of conventional macromethods often differ from rapid commercial micromethods.	8, 9, 11, 12, 14, 17, 19, 21, 22
dGALACTOSE	D-GALACTOSE acidification			
dGLUCOSE	D-GLUCOSE acidification			
LACTOSE	LACTOSE acidification			
dMALTOSE	D-MALTOSE acidification			
dMANNITOL	D-MANNITOL acidification			
dMANNOSE	D-MANNOSE acidification			
dRAFFINOSE	D-RAFFINOSE acidification			
SACCHAROSE	SACCHAROSE/SUCROSE acidification			
dTREHALOSE	D-TREHALOSE acidification			
For 8.01 or Higher Software Users				
22C	GROWTH AT 22degC	Ability of certain species to grow at 22 °C.	N/A	12
A-HEM	ALPHA HEMOLYSIS	Certain species produce incomplete hemolysis resulting in a green zone around colonies on blood based media.	N/A	3

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Abbreviation	Test Name	Description	Comments	Reference
MICROAER.	MICROAEROBIC GROWTH	Growth requiring a lower concentration of oxygen than is present in the atmosphere.	N/A	14
NO2	NITRITE REDUCTION	Test for the ability to reduce nitrite to nitrogen gas (NO2), nitrate to nitrite, and/or nitrogen gas from nitrate (NO3 to N2).	N/A	12
YELLOW	YELLOW PIGMENT	Ability of certain species to produce yellow pigmented colonies on non-differential media.	N/A	3
dXYLOSE	D-XYLOSE acidifcation	Acidification of carbon source observed with pH indicator (e.g., phenol red, bromcresol purple).	Some tests also appear on the NH card but are recommended as supplemental tests since results of conventional macromethods often differ from rapid commercial micromethods.	8, 9, 11, 12, 14, 17, 19, 21, 22

REFERENCES

1. Balows A, Hausler WJ, Herrmann KL, Isenberg HD, Shadomy HJ, editors. Manual of Clinical Microbiology, 5th ed. American Society for Microbiology, Washington, D.C. 1991.
2. Balows A, Truper HG, Dworkin M, Harder W, and Schleifer K-H, editors. The Prokaryotes - a Handbook on the Biology of Bacteria: Exophysiologoy, Isolation, Identification, Applications, 2nd ed., Volume II. Springer-Verlag, New York 1992.
3. Brenner DJ, Krieg NR, Staley JT, Garrity GM, editors. *Bergey's Manual of Systematic Bacteriology*, 2nd Edition. Springer, New York, NY. 2005.
4. Clinical and Laboratory Standards Institute, M50-A, Quality Control for Commercial Microbial Identification Systems; Approved Guideline, Vol. 28 No. 23.
5. Clinical Laboratory Improvement Amendments of 1988. 42 U.S.C 263a. PL 100-578. 1988.
6. Difco Manual Dehydrated Culture Media and Reagents for Microbiology. 10th ed. 1984.
7. Holmes B, Costas M, On SL, Vandamme P, Falsen E, Kersters K. Neisseria weaveri sp. nov. (formerly CDC group M-5), from dog bite wounds of humans. Int J Syst Bacteriol. 1993 Oct; 43(4):687-93.
8. Holt JG, Krieg NR, Sneath PHA, Staley JT, Williams ST, editors. Bergey's Manual of Determinative Bacteriology, 9th ed. Williams and Wilkins, Baltimore 1994.
9. Kilian M, Nicolet J, Biberstein EL, Biochemical and Serological Characterization of Haemophilus pleuropneumoniae (Matthews and Pattison 1961) Shope 1964 and Proposal of a Neotype Strain. Int J Syst Bacteriol. 1978. 28:20-26.
10. Koneman EW, Allen SD, Janda WM, Schreckenberger PC, Winn WC, editors. Color Atlas and Textbook of Diagnostic Microbiology 4th ed. Lippincott, Philadelphia, PA 1992.
11. Koneman EW, Allen SD, Janda WM, Schreckenberger PC, Winn WC, editors. Color Atlas and Textbook of Diagnostic Microbiology 5th ed. Lippincott, Philadelphia, PA. 1997.
12. Koneman EW, Allen SD, Janda WM, Procop GW, Schreckenberger PC, Winn WC, Woods GL, editors. Color Atlas and Textbook of Diagnostic Microbiology 6th ed. Lippincott, Philadelphia, PA. 2006.
13. Krieg NR, Holt JG, editors. *Bergey's Manual of Systematic Bacteriology*, 9th ed. Williams and Wilkins, Baltimore 1984.
14. Lindqvist, K., A Neisseria Species Associated with Infectious Keratoconjunctivitis of Sheep: Neisseria ovis nov. spec. *The Journal of Infectious Diseases*. 1960. 106:162-165.
15. Manafi M, Kneifel W, Bascomb S. Fluorogenic and chromogenic substrates used in bacterial diagnostics. Microbiol. 1991; Rev. 55:335- 348.
16. Murray PR, Baron EJ, Pfaller MA, Tenover FC, Yolken RH, editors. Manual of Clinical Microbiology, 7th ed. American Society for Microbiology, Washington, D.C. 1999.
17. Murray PR, Baron EJ, Jorgensen JH, Pfaller MA and Yolken RH, editors. Manual of Clinical Microbiology, 8th ed. American Society for Microbiology, Washington, D.C. 2003.
18. National Committee for Clinical Laboratory Standards, M29-A, Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissue — Approved Guideline, 1997.

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19. Nørskov-Lauritsen N, Kilian M. 2006. Reclassification of Actinobacillus actinomycetemcomitans, Haemophilus aphrophilus, Haemophilus paraphrophilus, and Haemophilus segnis as Aggregatibacter actinomycetemcomitans gen. nov., comb. nov., Aggregatibacter aphrophilus comb. nov., and Aggregatibacter segnis comb. nov., and emended description of Aggregatibacter aphrophilus to include V factor dependent and V factor-independent isolates. IJSEM. 2006. 56:2135- 2146.

20. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health, Office of Health and Safety, Biosafety in Microbiological and Biomedical Laboratories, 1988.

21. Versalovic, J., K.C. Carroll, G. Funke, J.H. Jorgensen, M.L. Landry and D.W. Warnock. 2011. *Manual of Clinical Microbiology*, 10th edition. American Society for Microbiology, Washington, D.C.

22. Weyant RS, Moss CW, Weaver RE, Hollis DG, Jordon JG, Cook EC, and Daneshvar MI. Identification of Unusual Pathogenic and Gram-Negative Aerobic and Facultatively Anaerobic Bacteria 2nd ed. Williams & Wilkins, Philadelphia, PA 1996.

Use this Instructions for Use with VITEK® 2 Product No. 21346.

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalog number
IVD	In Vitro Diagnostic Medical Device
	Legal Manufacturer
	Temperature limitation
	Use by date
LOT	Batch code
	Consult Instructions for Use
	Date of manufacture
	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community
Rx only	For US Only : Caution : US Federal Law restricts this device to sale by or on the order of a licensed practitioner

Instructions for Use provided in the kit or downloadable from www.biomerieux.com/techlib

LIMITED WARRANTY

bioMérieux warrants the performance of the product for its stated intended use provided that all procedures for usage, storage and handling, shelf life (when applicable), and precautions are strictly followed as detailed in the instructions for use (IFU).

Except as expressly set forth above, bioMérieux hereby disclaims all warranties, including any implied warranties of merchantability and fitness for a particular purpose or use, and disclaims all liability, whether direct, indirect or consequential, for any use of the reagent, software, instrument and disposables (the “System”) other than as set forth in the IFU.

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WASTE DISPOSAL

All hazardous waste must be disposed of by following your local inspecting agency's guidelines.

REVISION HISTORY TABLE

Change type categories	
N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user
Note :	Minor typographical, grammar, and formatting changes are not included in the revision history.

Release Date	Part Number	Change Type	Change Summary
2019-03	043902-03	Technical change	Updated for 9.02 software release. Updated sections: • Intended Use • Precautions • Testing of QC Organisms • Organisms Identified
2016-10	043902-02	Technical change	• Updated content to reflect the 8.01 Product Information Manual
2016-05	043902-01	Administrative	• Formatting changes do not affect the fit, form, or function of the product
		Technical change	• New IFU derived from product chapter in the Product Information Manual • Updated Limited Warranty section • Updated with RX only information

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REF 21347

043907- 03 - 2019-03 EN

VITEK® 2 ANC

℞ only IVD

INTENDED USE

These Instructions for Use correspond to the VITEK® 2 Systems 7.01 or higher software. If you are not using VITEK® 2 Systems 7.01 or higher software, please refer to the VITEK® 2 Systems Product Information that you received with your current software version.

The VITEK® 2 Anaerobic and Corynebacteria identification card (ANC) is intended for use with VITEK® 2 Systems for the automated identification of most clinically significant anaerobic organisms and *Corynebacterium* species. The VITEK® 2 ANC identification card is a single-use disposable. For a list of claimed species, see the Organisms Identified section.

DESCRIPTION

The ANC card is based on established biochemical methods and newly developed substrates. There are 36 biochemical tests measuring carbon source utilization and enzymatic activities. Final results are available in approximately six hours.

For a list of well contents, see the ANC Well Contents table.

Table 1: ANC Well Contents

Well	Test	Mnemonic	Amount/Well
4	D-GALACTOSE	dGAL	0.3 mg
5	Leucine ARYLAMIDASE	LeuA	0.023 mg
6	ELLMAN	ELLM	0.03 mg
7	Phenylalanine ARYLAMIDASE	PheA	0.026 mg
8	L-Proline ARYLAMIDASE	ProA	0.023 mg
10	L-Pyrrolidonyl-ARYLAMIDASE	PyrA	0.018 mg
11	D-CELLOBIOSE	dCEL	0.3 mg
13	Tyrosine ARYLAMIDASE	TyrA	0.0279 mg
15	Ala-Phe-Pro-ARYLAMIDASE	APPA	0.038 mg
18	D-GLUCOSE	dGLU	0.3 mg
20	D-MANNOSE	dMNE	0.3 mg
22	D-MALTOSE	dMAL	0.3 mg
28	SACCHAROSE/SUCROSE	SAC	0.3 mg
30	ARBUTIN	ARB	0.1875 mg
33	*N*-ACETYL-D-GLUCOSAMINE	NAG	0.3 mg
34	5-Bromo-4-chloro-3-indoxyl-beta-glucoside	BGLUi	0.006 mg
36	UREASE	URE	0.15 mg
37	5-Bromo-4-chloro-3-indoxyl-beta-glucuronide	BGURi	0.006 mg
39	BETA-GALACTOPYRANOSIDASE Indoxyl	BGALi	0.006 mg
41	ALPHA-ARABINOSIDASE	AARA	0.0324 mg
42	5-Bromo-4-chloro-3-indoxyl-alpha-galactoside	AGALi	0.006 mg
43	BETA-MANNOSIDASE	BMAN	0.036 mg
44	ARGININE GP	ARG	0.15 mg
45	PYRUVATE	PVATE	0.15 mg
51	MALTOTRIOSE	MTE	0.3 mg

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Well	Test	Mnemonic	Amount/Well
53	ESCULIN hydrolysis	ESC	0.0225 mg
54	BETA-D-FUCOSIDASE	BdFUC	0.0342 mg
55	5-Bromo-4-chloro-3-indoxyl-beta- *N*-acetyl-glucosamide	BNAGi	0.006 mg
56	5-Bromo-4-chloro-3-indoxyl-alpha-mannoside	AMANi	0.006 mg
57	ALPHA-L-FUCOSIDASE	AlFUC	0.0342 mg
59	PHOSPHATASE	PHOS	0.05 mg
60	L-ARABINOSE	lARA	0.3 mg
61	d-Ribose 2	dRIB2	0.3 mg
62	Phenylphosphonate	OPS	0.024 mg
63	ALPHA-L-ARABINOFURANOSIDE	AARAF	0.015 mg
64	D-XYLOSE	dXYL	0.3 mg

Note: Other well numbers between 1 and 64 not designated in this table are empty.

PRECAUTIONS

Note: For industry customers that need assistance on selecting the correct VITEK® 2 identification card, please refer to the VITEK® 2 Compact Instrument User Manual chapter, "Guidance to Select a VITEK® 2 Identification Card."

- For *In Vitro* Diagnostic Use Only.
- For US Only: Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- For professional use only.
- Suspensions not within the appropriate zone on the VITEK® 2 DENSICHEK™ Plus or the VITEK® 2 DENSICHEK™ may compromise card performance.
- Do not use the card after the expiration date shown on the package liner.
- Store the card unopened in the package liner. Do not use the card if the protective package liner is damaged or if no desiccant is present.
- Allow the card to come to room temperature before opening the package liner.
- Do not use powdered gloves. Powder may interfere with the optics.
- Use of culture media other than the recommended types must be validated by the customer laboratory for acceptable performance.
- A Gram stain should be performed to determine an organism's Gram reaction and morphology prior to selecting the identification card to inoculate.
- The card performs as intended only when used in conjunction with VITEK® 2 Systems, following the instructions contained in these Instructions for Use.
- **Do not use glass test tubes**. Use clear plastic (polystyrene) tubes only. Variation exists among test tubes of standard diameter. Carefully place the tube into the cassette. If resistance is encountered, discard and try another tube that does not require pressure to insert.
- Prior to inoculation, inspect cards for tape tears or damage to the tape and discard any that are suspect. Check the saline level in the tubes after the cassette has been processed to ensure proper filling of card.
  - VITEK® 2 60 or VITEK® 2 XL: Eject improperly filled cards.
  - VITEK® 2 Compact: Do not load improperly filled cards.
- Give special consideration to specimen source and patient drug or antimicrobic regimen.
- Interpretation of test results requires the judgment and skill of a person knowledgeable in microbial identification testing. Additional testing may be required. (See the Supplemental Tests section.)
- Do not clean saline dispenser with chemical agents. The use of chemical agents may impact card performance.

Warning: All patient specimens, microbial cultures, and inoculated VITEK® 2 cards, along with associated materials, are potentially infectious and should be treated with universal precautions.[17,18]

Warning: All hazardous waste must be disposed of by following your local inspecting agency's guidelines.

STORAGE CONDITIONS

Upon receipt, store VITEK® 2 ANC cards unopened in their original package liner at 2°C to 8°C.

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SPECIMEN PREPARATION

For specimen preparation information, see the Culture Requirements Table.

Table 2: Culture Requirements

VITEK® 2 Card	Media	Age of Culture[1]	Incubation Conditions	Inoculum Density	Dilution for AST	Age of Suspension Before Loading Instrument
ANC	Corynebacteria: CBA[2] CNA TSAB TSAHB	Corynebacteria: 18 to 24 hours	Corynebacteria: 35°C to 37°C CO_2 or non-CO_2	2.70 to 3.30 McFarland Standard	N/A[3]	≤ 30 minutes
	Anaerobes: CBA[2] CDC[2] BRU CHBA TSAB TSAHB	Anaerobes: 18 to 72 hours	Anaerobes: 35°C to 37ºC anaerobic environment			
	Gram-Positive Anaerobes ONLY: CNA CDC PEA PEA					

[1]Cultures with scant or poor growth may give unidentified or incorrect results even when the Age of Culture requirements are met.

[2]These media were used in the identification product database development and will give optimal performance.

[3]N/A = not applicable

Culture Requirements Table — Media Abbreviations

BRU = Brucella Agar with 5% Sheep Blood, Hemin, and Vitamin K

CBA = Columbia Blood Agar with 5% Sheep Blood

CDC = CDC Anaerobe Agar with 5% Sheep Blood

CDC PEA = CDC Blood Agar with PEA

CHBA = Columbia Horse Blood Agar

CNA = Columbia CNA Agar with 5% Sheep Blood

PEA = Phenylethyl Alcohol Agar with 5% Sheep Blood

TSAB = Trypticase Soy Agar with 5% Sheep Blood

TSAHB = Trypticase Soy Agar with 5% Horse Blood

Materials

When used with VITEK® 2 instrumentation, the ANC card is a complete system for routine identification testing of most clinically significant anaerobic organisms and *Corynebacterium* species.

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Required materials are:

- VITEK® 2 ANC Card
- DENSICHEK™ Plus Kit or VITEK® DENSICHEK® Kit
- DENSICHEK™ Plus Standards Kit or DENSICHEK® Standards Kit
- VITEK® 2 Cassette
- Sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- 12 mm x 75 mm clear plastic (polystyrene) disposable test tubes
- Sterile sticks or swabs
- Appropriate agar medium (see Culture Requirements table).

Optional accessories:

- Adjustable volume saline dispenser
- Loops
- Pre-dispensed saline test tubes (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Test tube caps
- Vortex

Procedure

Warning: Failure to follow instructions and recommendations provided in this section for performing laboratory tasks may cause erroneous or delayed results.

For product-specific information, see the Culture Requirements table.

Note: Prepare the inoculum from a pure culture, according to good laboratory practices. In case of mixed cultures, a re-isolation step is required. It is recommended that a purity check plate be done to ensure that a pure culture was used for testing.

1. Do one of the following:
   - Select isolated colonies from a primary plate if culture requirements are met.
   - Subculture the organism to be tested to appropriate agar medium and incubate accordingly.
2. Aseptically transfer 3.0 mL of sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0) into a clear plastic (polystyrene) test tube (12 mm x 75 mm).
3. Use a sterile stick or swab to transfer a sufficient number of morphologically similar colonies to the saline tube prepared in step 2. Prepare a homogenous organism suspension with a density equivalent to a McFarland No. 2.70 to 3.30 using a calibrated VITEK® 2 DENSICHEK™ Plus or VITEK® 2 DENSICHEK™.
   Note: Age of suspension must not exceed 30 minutes before inoculating card.
4. Place the suspension tube and ANC card in the cassette.
5. Refer to the appropriate Instrument User Manual for instructions on data entry and how to load the cassette into the instrument.
6. In addition to the internal tests included on the card, three offline tests are required in the ANC ID algorithm. The offline tests selected for use in the ANC ID product are Gram stain, morphology, and aerotolerance. The ANC Offline Test results can be entered at the Smart Carrier Station (VITEK® 2 60 or VITEK® 2 XL only) or the workstation.

Table 3: ANC Offline Tests

Test Name	Test	Result	Definition
AERO	Aerotolerance	–	Anaerobe
		+	Aerobe
		?	Facultative
GRAM	Gram stain results	–	Gram Negative
		+	Gram Positive
		?	Gram Variable

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Test Name	Test	Result	Definition
MORPH	Morphology	–	Bacilli
		+	Cocci
		?	Coccobacilli

7. Follow your local inspecting agency's guidelines for disposal of hazardous waste.

RESULTS

Identification Analytical Techniques

VITEK® 2 Systems identify an organism by using a methodology based on the characteristics of the data and knowledge about the organism and reactions being analyzed. Sufficient data have been collected from known strains to estimate the typical reactions of the claimed species to a set of discriminating biochemicals. If a unique identification pattern is not recognized, a list of possible organisms is given, or the strain is determined to be outside the scope of the database.

The printed lab report contains suggestions for any supplemental tests necessary to complete the identification. If the tests are not sufficient to complete the identification, then standard microbiology references and literature should be consulted.

Certain species may belong to a slashline (mixed) taxa identification. This occurs when the biopattern is the same for the taxa listed. Supplemental tests may be used to separate slashline taxa. The species in the ANC Slashline Taxa table belong to the ANC slashline taxa.

Table 4: ANC Slashline Taxa

Slashline Name	Species Belonging to the Slashline
For 7.01, 8.01, and 9.01 Software Users	
Clostridium group	*Clostridium innocuum* *Clostridium limosum* *Clostridium novyi*
For 9.02 Software Users	
Clostridium group	*Clostridium innocuum* *Hathewaya limosa* (formerly known as *Clostridium limosum*) *Clostridium novyi* *Clostridium sporogenes* *Colstridium subterminale*

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Table 5: Identification Card Qualifying Messages

ID Message Confidence Level	Choices	% Probability	Comments
Excellent	1	96 to 99	N/A
Very Good	1	93 to 95	N/A
Good	1	89 to 92	N/A
Acceptable	1	85 to 88	N/A
Low Discrimination	2 to 3	Sum of choices = 100; after resolution to one choice, percent probability reflects the number associated with selected choice.	Two to three taxa exhibit same biopattern. Separate by supplemental testing.
Inconclusive or Unidentified Organism	> 3 or 0	N/A	Either > 3 taxa exhibit same biopattern or Very atypical biopattern. Does not correspond to any taxon in the database. Check Gram stain and purity.

PERCENT PROBABILITY

As part of the identification process, the software compares the test set of reactions to the expected set of reactions of each organism, or organism group, that can be identified by the product. A quantitative value, the percent probability, is calculated and relates to how well the observed reactions compare to the typical reactions of each organism. A perfect match between the test reaction pattern and the unique reaction pattern of a single organism, or organism group, would provide a percent probability of 99. When a perfect match is not obtained, it is still possible for the reaction pattern to be sufficiently close to that of an expected reaction pattern such that a clear decision can be provided about the organism identification. The range of percent probabilities in the one-choice case is 85 to 99. Values closer to 99 indicate a closer match to the typical pattern for the given organism.

When the reaction pattern is not sufficient to discriminate between two to three organisms, the percent probabilities reflect this ambiguity. The reported probability values indicate, relatively, the order in which the reaction pattern best corresponds to the listed possibilities. The order does not, however, suggest that the pattern match to one of the possible identifications is clearly superior to another. The probability characteristic of an overall sum of 100 is retained through the calculation process. After resolution to one choice, the probability characteristic of the single choice is retained.

ADDITIONAL INFORMATION ON LAB REPORT

Supplemental test — External (offline) test that allows the user to resolve a slashline or Low Discrimination identification. Numbers in parentheses indicate percent positive reaction for the species/test listed.

Contraindicating test — Test result that is unusual for a reported taxon.

Table 6: Notes Associated with Certain Taxa

Taxa	Note
For 7.01 or Higher Software Users	
Actinomyces israelii	*Actinomyces israelii* represents a complex of two closely related species, *A. israelii* and *A. gerencseriae* (formerly known as *A. israelii serotype II*).
Corynebacterium diphtheriae	Critical pathogen. The species identified may have significance to patient or sample outcome and can be stopped for review.
For 9.02 Software Users	

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Taxa	Note
Rhodococcus hoagii *Turicella otitidis*	*Rhodococcus hoagii* and *Turicella otitidis* can be differentiated from each other by pigment and body site. *R. hoagii* produces a salmon color and *T. otitidis* is only found in the region of the ear. In addition, *R. hoagii* is most commonly found as a veterinary pathogen while *T. otitidis* is found as human pathogen.

Notes Associated with an Improperly Filled Card or with a Negative Profile (Biopattern)

- For the case where the time between two readings is greater than 40 minutes: “CARD ERROR — Missing data.”
- For the case where there is a negative profile: “Organism with low reactivity biopattern — please check viability.”
- When a biopattern is calculated for an unknown organism that is completely negative or consists of both negative tests and tests that fall within the uncertainty zone, the identification call will be “Non or low reactive biopattern.”

The following non-reactive species could potentially trigger this note if a test was atypical or fell within the uncertainty zone:

- *Clostridium clostridioforme*
- *Fusobacterium nucleatum*
- *Fusobacterium mortiferum*

QUALITY CONTROL

Quality control organisms and their expected results are listed in the VITEK® 2 ANC Quality Control Tables. Process these according to the procedure for test isolates outlined in this document.

Certification Statement

This is to certify that bioMérieux complies with ISO 13485 and FDA Quality System Regulation (QSR) requirements for design, development, and manufacture of microbial identification systems.

Frequency of Testing

Currently, it is recommended that you use your most stringent inspecting agency’s guidelines for frequency of identification product testing.

Common practice is to perform QC upon receipt of shipment of the test kits. Reactions must follow Instructions for Use results.

If the results do not meet the criteria, subculture for purity and repeat the test. If discrepant results are repeated, perform an alternate identification method and contact bioMérieux.

Testing and Storage of QC Organisms

1. Rehydrate the organism according to the manufacturer's instructions.
2. *Corynebacterium*: Use Columbia Blood agar with 5% sheep blood (CBA) and incubate at 35°C to 37°C in non-CO_2 aerobic conditions. Incubate for 18 to 24 hours or until sufficient growth is obtained.
3. Anaerobes: Use Columbia Blood agar with 5% sheep blood and incubate at 35°C to 37°C in anaerobic conditions for 18 to 24 hours or until sufficient growth is obtained.
4. Check for purity. Perform second subculture for testing.
5. *Corynebacterium*: Use Columbia Blood agar with 5% sheep blood and incubate at 35°C to 37°C in non-CO_2 aerobic conditions. Incubate for 18 to 24 hours.
6. Anaerobes: Use Columbia Blood agar with 5% sheep blood and incubate at 35°C to 37°C in anaerobic conditions for 18 to 24 hours.

Short-Term Storage Conditions - *Corynebacterium*

1. Streak to a CBA plate or slant.
2. Incubate at 35°C to 37°C in non-CO_2 aerobic conditions. Incubate for 18 to 24 hours.
3. Refrigerate at 2°C to 8°C for up to five days.
4. Subculture to CBA. Incubate at 35°C to 37°C in non-CO_2 aerobic conditions for 18 to 24 hours. Use for QC.

Short-Term Storage Conditions - Anaerobes

1. Streak to a CBA plate or slant.
2. Incubate at 35°C to 37°C in anaerobic conditions for 18 to 24 hours or until sufficient growth is obtained.

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3. Store at room temperature in anaerobic conditions for up to five days.
4. Subculture to CBA. Incubate at 35°C to 37°C in anaerobic conditions for 18 to 24 hours. Use for QC.

Long-Term Storage Conditions

1. Make a heavy suspension in Tryptic Soy Broth (TSB) with 15% glycerol.
2. Freeze at -70°C.
3. Subculture to CBA twice before running QC.

Note: Avoid repeated thawing and refreezing by either freezing in single-use aliquots or removing a small portion of frozen organism preparation with a sterile applicator stick.

STREAMLINED QUALITY CONTROL

Note: Industrial Use Only laboratories should perform quality control following the Streamlined Quality Control section. No additional testing is required for these users.

As there are no substrates that are consistently sensitive to degradation during shipping conditions, streamlined quality control may be conducted by testing two strains: one that is mostly positive and the other, which is mostly negative for reactions on ANC. (See ANC Quality Control tables for more details).

COMPREHENSIVE QUALITY CONTROL

Customers who do not qualify for streamlined quality control testing are required to perform comprehensive quality control testing, which entails demonstration of a positive and negative reaction for each substrate of an identification product.[4]

In order to qualify initially for streamlined quality control testing, the CLSI® M50-A standard requires that the user perform and document either of the following:[3]

- Verification testing to show that performance is equivalent to the manufacturer's claims.
- Comprehensive quality control testing of at least three lots over at least three different seasons.

Refer to the complete CLSI® M50-A standard for information regarding continued qualification and further details of requirements and responsibilities for both the user and the manufacturer related to streamlined quality control testing.

ANC Quality Control Tables:

***Clostridium septicum* ATCC® 12464™** (for streamlined or comprehensive quality control)

***Bacteroides ovatus* ATCC® BAA-1296™** (for streamlined or comprehensive quality control)

***Bacteroides vulgatus* ATCC® 8482™** (for comprehensive quality control)

***Clostridium perfringens* ATCC® 13124™** (for comprehensive quality control)

***Corynebacterium striatum* ATCC® BAA-1293™** (for comprehensive quality control)

***Parabacteroides distasonis* ATCC® BAA-1295™** (for comprehensive quality control)

For 7.01, 8.01, and 9.01 Software Users

***Clostridium sordellii* ATCC® 9714™** (for comprehensive quality control)

For 9.02 Software Users

***Paeniclostridium sordellii* ATCC® 9714™** (formerly known as ***Clostridium sordellii* ATCC® 9714™**) for comprehensive quality control

The ANC card typically identifies the quality control organisms as one-choice or within a low discrimination or slashline identification. However, strains are chosen for reaction performance over identification performance. Therefore, an unidentified or misidentified result may occur when all expected quality control reactions are correct.

Table 7: QC Organism: *Clostridium septicum* ATCC® 12464™ (for streamlined or comprehensive quality control)

dGAL	-	dCEL	-	SAC	-	BGALi	+	MTE	-	PHOS	-	GRAM	+
LeuA	-	TyrA	-	ARB	-	AARA	v	ESC	-	IARA	-	MORPH	-
ELLM	-	APPA	-	NAG	-	AGALi	-	BdFUC	+	dRIB2	-	AERO	-
PheA	-	dGLU	-	BGLUi	-	BMAN	-	BNAGi	-	OPS	+		
ProA	-	dMNE	-	URE	-	ARG	-	AMANi	v	AARAF	-		
PyrA	v	dMAL	-	BGURi	-	PVATE	-	AIFUC	-	dXYL	-		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

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Table 8: QC Organism: *Bacteroides ovatus* ATCC® BAA-1296™ (for streamlined or comprehensive quality control)

dGAL	+	dCEL	+	SAC	v	BGALi	+	MTE	+	PHOS	v	GRAM	-
LeuA	-	TyrA	-	ARB	v	AARA	+	ESC	+	IARA	+	MORPH	-
ELLM	+	APPA	+	NAG	+	AGALi	+	BdFUC	v	dRIB2	+	AERO	-
PheA	-	dGLU	+	BGLUi	v	BMAN	v	BNAGi	-	OPS	v		
ProA	-	dMNE	+	URE	-	ARG	-	AMANi	v[1]	AARAF	+		
PyrA	-	dMAL	+	BGURi	v	PVATE	v	AIFUC	v	dXYL	v		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive.

[1]Reaction is mostly positive although occasional negative reaction may occur.

Table 9: QC Organism: *Bacteroides vulgatus* ATCC® 8482™ (for comprehensive quality control)

dGAL	v	dCEL	v	SAC	v	BGALi	v	MTE	v	PHOS	+	GRAM	–
LeuA	v	TyrA	v	ARB	v	AARA	+	ESC	v	IARA	v	MORPH	–
ELLM	+	APPA	+	NAG	v	AGALi	v	BdFUC	+	dRIB2	v	AERO	–
PheA	v	dGLU	v	BGLUi	v	BMAN	v[1]	BNAGi	v[1]	OPS	v		
ProA	v	dMNE	v	URE	v	ARG	v	AMANi	-	AARAF	+		
PyrA	v	dMAL	v	BGURi	v[1]	PVATE	v	AIFUC	+	dXYL	+		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

[1]Reaction is mostly positive although occasional negative reaction may occur.

Table 10: QC Organism: *Clostridium perfringens* ATCC® 13124™ (for comprehensive quality control)

dGAL	v	dCEL	v	SAC	+	BGALi	v	MTE	+	PHOS	+	GRAM	+
LeuA	v	TyrA	v	ARB	v	AARA	v	ESC	v	IARA	v	MORPH	–
ELLM	–	APPA	–	NAG	v	AGALi	+	BdFUC	v	dRIB2	+	AERO	–
PheA	v	dGLU	v	BGLUi	v	BMAN	v	BNAGi	v	OPS	+		
ProA	v	dMNE	v	URE	v	ARG	+	AMANi	v	AARAF	–		
PyrA	+	dMAL	+	BGURi	v	PVATE	–	AIFUC	v	dXYL	v		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 11: QC Organism: *Clostridium sordellii ATCC® 9714™ (for comprehensive quality control)**

dGAL	–	dCEL	v	SAC	–	BGALi	–	MTE	v	PHOS	v	GRAM	+
LeuA	v	TyrA	v	ARB	v	AARA	–	ESC	–	IARA	v	MORPH	–
ELLM	v	APPA	v	NAG	v	AGALi	–	BdFUC	–	dRIB2	v	AERO	–
PheA	v	dGLU	v	BGLUi	–	BMAN	–	BNAGi	v	OPS	–		
ProA	+	dMNE	-	URE	+	ARG	v	AMANi	–	AARAF	v		
PyrA	v	dMAL	v	BGURi	v	PVATE	v	AIFUC	v	dXYL	–		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

*For 7.01, 8.01, and 9.01 software users, *Clostridium sordellii*

*For 9.02 software users, *Paeniclostridium sordellii*, formerly known as *Clostridium sordellii*

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Table 12: QC Organism: *Corynebacterium striatum* ATCC® BAA-1293™ (for comprehensive quality control)

dGAL	+	dCEL	–	SAC	+	BGALi	–	MTE	–	PHOS	–	GRAM	+
LeuA	+	TyrA	+	ARB	–	AARA	v	ESC	v	IARA	–	MORPH	–
ELLM	v	APPA	v	NAG	–	AGALi	v	BdFUC	–	dRIB2	–	AERO	+
PheA	v	dGLU	+	BGLUi	v	BMAN	v	BNAGi	v	OPS	v		
ProA	+	dMNE	+	URE	v	ARG	v	AMANi	v	AARAF	v		
PyrA	–	dMAL	–	BGURi	v	PVATE	+	AIFUC	v	dXYL	v		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 13: QC Organism: *Parabacteroides distasonis* ATCC® BAA-1295™ (for comprehensive quality control)

dGAL	v	dCEL	v	SAC	v	BGALi	v	MTE	v	PHOS	v	GRAM	–
LeuA	v	TyrA	v	ARB	+	AARA	v	ESC	+	IARA	v	MORPH	–
ELLM	v	APPA	v	NAG	+	AGALi	v	BdFUC	v	dRIB2	v	AERO	–
PheA	v[1]	dGLU	v	BGLUi	+	BMAN	v	BNAGi	v	OPS	v		
ProA	v	dMNE	v	URE	v	ARG	v	AMANi	v	AARAF	v		
PyrA	+	dMAL	v	BGURi	–	PVATE	v	AIFUC	–	dXYL	v		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

[1]Reaction is mostly positive although occasional negative reaction may occur.

LIMITATIONS

The VITEK® 2 ANC card cannot be used with a direct clinical specimen or sample or other sources containing mixed flora.

Newly described or rare species may not be included in the ANC database. Selected species will be added as strains become available.

Warning: Testing of unclaimed species may result in an unidentified result or a misidentification.

PERFORMANCE CHARACTERISTICS

For 7.01 Software Users

In a multi-site clinical study*, the performance of the VITEK® 2 ANC identification card was evaluated using 365 clinical and stock isolates of both commonly and rarely observed species. The reference identification was determined using 16S rRNA gene sequencing. Overall, the VITEK® 2 ANC correctly identified 93.9% of these isolates, including 9.0% low discrimination with the correct species listed. Misidentifications occurred at 5.8% and no identifications occurred at 0.3%.

For 8.01 and 9.01 Software Users

In a multi-site clinical study*, the performance of the VITEK® 2 ANC identification card was evaluated using 365 clinical and stock isolates of both commonly and rarely observed species. The reference identification was determined using 16S rRNA gene sequencing. Overall, the VITEK® 2 ANC correctly identified 94.0% of these isolates, including 9.0% low discrimination with the correct species listed. Misidentifications occurred at 5.8% and no identifications occurred at 0.3%.

For 9.02 Software Users

In a multi-site clinical study*, the performance of the VITEK® 2 ANC identification card was evaluated using 365 clinical and stock isolates of both commonly and rarely observed species. The reference identification was determined using 16S rRNA gene sequencing. Overall, the VITEK® 2 ANC correctly identified 94.3% of these isolates, including 10.4% low discrimination with the correct species listed. Misidentifications occurred at 5.5% and no identifications occurred at 0.3%.

*Data on file at bioMérieux, Inc.

ORGANISMS IDENTIFIED

Claims are for all software users unless otherwise stated.

- *Actinobaculum schaalii*
- *Actinomyces bovis*
- *Actinomyces israelii*
- *Actinomyces meyeri*

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- *Actinomyces naeslundii*
- *Actinomyces neuii*
- *Actinomyces odontolyticus*
- *Actinomyces turicensis*
- *Anaerococcus prevotii*
- *Arcanobacterium haemolyticum*
- *Atopobium vaginae*
- *Bacteroides caccae*
- *Bacteroides eggerthii*
- *Bacteroides fragilis*
- *Bacteroides ovatus*
- *Bacteroides stercoris*
- *Bacteroides thetaiotaomicron*
- *Bacteroides uniformis*
- *Bacteroides vulgatus*
- *Bifidobacterium* spp.
- *Campylobacter ureolyticus* (formerly known as *Bacteroides ureolyticus*)
- *Clostridium baratii*
- *Clostridium bifermentans*
- *Clostridium butyricum*
- *Clostridium cadaveris*
- *Clostridium chauvoei*
- *Clostridium clostridioforme*
- *Clostridium difficile*
- *Clostridium glycolicum*
- *Clostridium* group
- *Clostridium histolyticum*
- *Clostridium paraputrificum*
- *Clostridium perfringens*
- *Clostridium ramosum*
- *Clostridium septicum*
- *Clostridium sordellii*
- *Clostridium sporogenes*
- *Clostridium subterminale*
- *Clostridium tertium*
- *Collinsella aerofaciens*
- *Corynebacterium amycolatum*
- *Corynebacterium diphtheriae*
- *Corynebacterium jeikeium*
- *Corynebacterium minutissimum*
- *Corynebacterium pseudodiphtheriticum*
- *Corynebacterium striatum*
- *Corynebacterium ulcerans*
- *Corynebacterium urealyticum*
- *Eggerthella lenta*
- *Eggerthia catenaformis* (formerly known as *Lactobacillus catenaformis*)
- *Eubacterium limosum*
- *Finegoldia magna*
- *Fusobacterium mortiferum*
- *Fusobacterium necrophorum*
- *Fusobacterium nucleatum*
- *Fusobacterium varium*

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- *Lactobacillus acidophilus*
- *Lactobacillus buchneri*
- *Lactobacillus casei*
- *Lactobacillus fermentum*
- *Lactobacillus gasseri*
- *Lactobacillus hilgardii*
- *Lactobacillus parabuchneri*
- *Lactobacillus paracasei*
- *Lactobacillus plantarum*
- *Microbacterium flavescens*
- *Microbacterium* spp.
- *Parabacteroides distasonis*
- *Parabacteroides merdae*
- *Parvimonas micra*
- *Peptoniphilus asaccharolyticus*
- *Peptoniphilus indolicus*
- *Peptostreptococcus anaerobius*
- *Porphyromonas gingivalis*
- *Prevotella bivia*
- *Prevotella buccae*
- *Prevotella disiens*
- *Prevotella denticola*
- *Prevotella intermedia*
- *Prevotella melaninogenica*
- *Prevotella oralis*
- *Prevotella oris*
- *Propionibacterium acnes*
- *Propionibacterium granulosum*
- *Propionibacterium propionicum* (formerly known as *Propionibacterium propionicus*)
- *Staphylococcus saccharolyticus*
- *Trueperella pyogenes* (formerly known as *Arcanobacterium pyogenes*)
- *Turicella otitidis*
- *Veillonella* spp.

Taxonomy Changes For 8.01 or Higher Software Users

- *Terrisporobacter glycolicus* (formerly known as *Clostridium glycolicum*)

Additional Claims and Taxonomy Changes For 9.02 Software Users

- *Actinotignum schaalii* (formerly known as*Actinobaculum schaalii*)
- *Actinomyces canis*
- *Bacteroides pyogenes*
- *Bacteroides xylanisolvens*
- *Corynebacterium glucuronolyticum*
- *Hathewaya histolytica* (formerly known as *Clostridium histolyticum*)
- *Hathewaya limosa* (formerly known as *Clostridium limosum*)
- *Paeniclostridium sordellii* (formerly known as *Clostridium sordellii*)
- *Paraclostridium bifermentans* (formerly known as *Clostridium bifermentans*)
- *Porphyromonoas asaccharolytica*
- *Porphyromonas gulae*
- *Porphyromonas uenonus*
- *Prevotella nanceiensis*
- *Prevotella salivae*

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- *Prevotella timonensis*
- *Rhodococcus hoagii*

SUPPLEMENTAL TESTS

Table 14: ANC Supplemental Tests

Abbreviation	Test Name	Description	Comments	Reference
For 7.01 or Higher Software Users				
AFUC	Alpha-Fucosidase	Presence of enzyme cleaves substrate generating detectable leaving group (e.g., p-nitrophenol, methyl umbelliferone, beta-naphthylamide, p-nitroaniline, 7-amino-methyl-coumarin).	Presence of enzyme is indicated by generation of a colored or fluorescent product, or a non-colored product that forms color upon addition of a specific reagent.	9, 16, 25, 28
BNAG	BETA-N-ACETYL-GLUCOSAMINIDASE	Presence of respective enzyme cleaves substrate generating detectable leaving group (e.g., p-nitrophenol, methyl umbelliferone, beta-naphthylamide, beta-naphthol, p-nitroaniline, 7-amidomethyl-coumarin).	Presence of enzyme is indicated by generation of a colored or fluorescent product, or a noncolored product that forms color upon addition of a specific reagent.	16, 27
Branch.flt	BRANCHING FILAMENTS	Appearance of branching filaments on microscopic examination.	N/A	8, 9, 15
CAT	CATALASE	Colony placed on a drop of hydrogen peroxide produces gas bubbles. The bacteria that contain cytochrome enzyme are catalase positive.	N/A	7, 9, 15, 16, 23, 25
ESCULIN	ESCULIN hydrolysis	Hydrolysis of esculin forms esculetin, which produces a black pigment in the presence of iron salts.	Some tests also appear on the ANC card but are recommended as supplemental tests since results of conventional macromethods may differ from rapid commercial micromethods.	5, 8, 9, 15, 16, 28, 30
GELATIN	Gelatin hydrolysis	Mediated by a gelatinase enzyme. A positive reaction is evidenced by liquefaction of the gelatin substrate.	N/A	7, 9, 15, 16,20, 28, 30
IND	INDOLE	Ability of certain species to split indole from tryptophan detected by a colored product revealed with a specific reagent (e.g., Kovacs, Ehrlichs, DMAC reagents).	N/A	7, 15, 16, 24
LECITHIN.	LECITHINASE	A precipitate surrounding the colony on egg yolk agar indicates lecithinase activity of alphatoxin produced by the organism.	N/A	7, 9, 16
LIP	LIPASE	An iridescent pearly sheen on the surface of the colony on egg yolk agar indicates lipase activity.	N/A	7, 9, 16

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Abbreviation	Test Name	Description	Comments	Reference
LIPOPHILY	LIPOPHILY	Lipophilic	Enhanced growth in the presence of lipids in the culture medium.	16
NO3	NITRATE REDUCTION	Test for the ability to reduce nitrate to nitrite or nitrogen gas.	N/A	7, 9, 15, 16
PAL	ALKALINE PHOSPHATASE	Presence of enzyme cleaves substrate generating detectable leaving group.	Presence of enzyme is indicated by generation of a colored or fluorescent product, or a non-colored product that forms color upon addition of a specific reagent.	16
PIGMENT	Pigment	Ability of certain species to produce pigmented colonies on nondifferential media.	N/A	16, 28, 29, 30
Point.ends	POINTED ENDS	Appearance of thin gram-negative rods with pointed ends is a microscopic characteristic for *Fuscobacterium nucleatum*.	N/A	9
PYRAZINAM.	PYRAZINAMIDASE	Test for the activity of the enzyme pyrazinamidase, which hydrolyses pyrazinamide to pyrazinoic acid.	N/A	16
SPOR	SPORE	Microscopic examination for spores. Phase-contrast microscopy is recommended.	N/A	9, 16
UREASE	Urease	Hydrolysis of urea releases ammonia resulting in alkalinization of the medium observed with a pH indicator (e.g., red color formation in the presence of phenol red).	Some tests also appear on the ANC card but are recommended as supplemental tests since results of conventional macromethods often differ from rapid commercial micromethods.	7, 8, 9, 15, 16
lARABINOSE	L-ARABINOSE acidification	Anaerobe: PRAS* method *Corynebacterium*: acid from carbohydrate. Acidification of carbon source observed with pH indicator (e.g., phenol red, bromcresol purple).	Some tests also appear on the ANC card but are recommended as supplemental tests since results of conventional macromethods often differ from rapid commercial micromethods.	7, 8, 9, 15, 16, 19, 20, 23, 25, 27, 28, 30
dCELLOB	DCELLOBIOSE acidification			
dFRUCTOSE	D-FRUCTOSE acidification			
dGALACTOSE	DGALACTOSE acidification			
dGLUCOSE	D-GLUCOSE acidification			
LACTOSE	Lactose acidification			
dMALTOSE	D-MALTOSE acidification			
dMANNITOL	D-MANNITOL acidification			
dMANNOSE	D-MANNOSE acidification			
dRAFFINOSE	dRAFFINOSE acidification			
lRHAMNOSE	L-RHAMNOSE acidification			
dRIBOSE	dRIBOSE acidification			
SACCHAROSE	SACCHAROSE/SUCROSE acidification			
SALICIN	SALICIN			
STARCHac	STARCH acidification			
dTREHALOSE	dTREHALOSE acidification			
XYL	XYLOSE			
XYLAN	XYLAN acidification			
For 9.02 Software Users				

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Abbreviation	Test Name	Description	Comments	Reference
CASEIN	CASEIN hydrolysis	Mediated by an exoenzyme casease. A positive reaction is evidenced by liquefaction of the casein substrate.	N/A	21, 26

*PRAS: Pre-reduced anaerobically sterilized media

REFERENCES

1. Balows, A., W.J. Hausler, K.L. Herrmann, H.D. Isenberg, H.J. Shadomy (ed.). 1991. *Manual of Clinical Microbiology*, 5th ed. American Society for Microbiology, Washington, D.C.
2. Balows, A., H.G. Truper, M. Dworkin, W. Harder, and K-H. Schleifer (ed.). 1992. *The Prokaryotes- a Handbook on the Biology of Bacteria: Exophysiology, Isolation, Identification, Applications*, 2nd ed., Volume II. Springer-Verlag, New York.
3. Clinical and Laboratory Standards Institute, M50-A, Quality Control for Commercial Microbial Identification Systems; Approved Guideline, Vol. 28 No. 23.
4. Clinical Laboratory Improvement Amendments of 1988. 42 U.S.C 263a. PL 100-578. 1988.
5. De Vos, P., Garrity, G., Jones, D., Krieg, N., Ludwig, W., Rainey, F., Schleifer, K., Whitman, W. Bergey's' Manual of Systematic Bacteriology, Second Edition, Volume Three the Firmicutes, Springer Publishing Dordrecht, 2009.
6. Difco Manual Dehydrated Culture Media and Reagents for Microbiology. 10th ed. 1984
7. Holdeman, L.V., Cato, E.P., Moore, W.E.C., Anaerobe Laboratory Manual 4th ed. Blacksburg VA.: VPI Anaerobe Laboratory, 1977.
8. Holt, J.G., N.R. Krieg, P.H.A. Sneath, J.T. Staley, S.T. Williams (ed.). 1994. *Bergey's Manual of Determinative Bacteriology*, 9th ed. Williams and Wilkins, Baltimore.
9. Jousimies-Somer, H., P. Summanen, D. M. Citron, E.J. Baron, H.M. Wexler, S.M. Finegold (ed) 2002 *Wadsworth - KTL Anaerobic Bacteriology Manual*, 6th ed. Star Publishing Belmont California.
10. Koneman, E.W., S.D. Allen, W. M. Janda, P.C. Schreckenberger, W.C. Winn (ed.). 1992. *Color Atlas and Textbook of Diagnostic Microbiology*, 4th ed. Lippincott Publishing Company, Philadelphia,PA.
11. Koneman, E.W., S.D. Allen, W.M. Janda, P.C. Schreckenberger, W.C. Winn (ed.). *Color Atlas and Textbook of Diagnostic Microbiology*, 5th ed. 1997 Lippincott, Philadelphia, New York.
12. Krieg, N.R., and J.G. Holt. (ed.) 1984. *Bergey's Manual of Systematic Bacteriology*, 9th ed. Williams and Wilkins, Baltimore.
13. Manafi, M., W. Kneifel, and S. Bascomb. 1991. Fluorogenic and chromogenic substrates used in bacterial diagnostics. Microbiol. Rev. 55:335-348.
14. Murray, P.R., E.J. Baron, M.A. Pfaller, F.C. Tenover and R.H. Yolken (ed.) 1999. *Manual of Clinical Microbiology*, 7th ed. American Society for Microbiology, Washington, D.C.
15. Murray, P.R., E.J. Baron, J.H. Jorgensen, M.A. Pfaller, and R.H. Yolken (ed.) 2003. *Manual of Clinical Microbiology*, 8th ed. American Society for Microbiology, Washington, D.C.
16. Murray, P.R., Baron, E., Jorgensen, J.H., Landry, M.L., Pfaller, M.A. *Manual of Clinical Microbiology*. 9th ed. Washington D.C.: ASM Press, 2007.
17. National Committee for Clinical Laboratory Standards, M29-A, *Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissue* - Approved Guideline, 1997.
18. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health, Office of Health and Safety, *Biosafety in Microbiological and Biomedical Laboratories*, 1988.
19. Winn, W.C. Jr, Allen, S.D., Janda, W.M., Koneman, E.W., Propcop, G.W., Schreckenberger, P.C., Woods, G.L. *Koneman's Color Atlas and Textbook of Diagnostic Microbiology 6th* ed. Philadelphia: Lippincott Williams & Wilkins, 2006.
20. Alauzet, C., Mory, F., Carlier, J.-P., Marchandin, H., Jumas-Bilak, E., & Lozniewski, A., 2007. *Prevotella nanceiensi*s sp. nov., isolated from human clinical samples. Int J Syst Evol Microbiol 57, 2216-2220.
21. Benno, Y., Watabe, J. & Mitsuoka, T. 1983. *Bacteroides pyogenes* sp. nov., *Bacteroides suis* sp. nov., and *Bacteroides helcogenes* sp. nov., New Species from Abscesses and Feces of Pigs. System. Appl. Microbiol. 4, p. 396-407.
22. Chassard, C., Delmas, E., Lawson, P.A. & Bernalier-Donadille, A. 2008. *Bacteroides xylanisolvens* sp. nov., a Xylan Degrading Bacterium Isolated from Human Faeces. Int J Syst Evol Microbiol 58, 1008-1013.
23. Devriese, L.A., Riegel, P., Hommez, J., Vaneechoutte, M., De Baere, T. & Haesebrouck, F. 2000. Identification of *Corynebacterium glucuronolyticum* Strains from the Urogenital Tract of Humans and Pigs. J. Clin. Microbiol. 38, p. 4657-4659.
24. Finegold, S.M., Vaisanen, M.-L., Rautio, M., Eerola, E., Summanen, P., Molitoris, D., Song, Y., Liu, C., & Jousimies-Somer, H. 2004. *Porphyromonas uenonis* sp. nov., a Pathogen for Humans Distinct from *P. asaccharolytica* and *P. endodontalis*. J. Clin. Microb, 42, p. 5298-5301.

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25. Fournier, D., Mouton, C., Lapierre, P., Kato, T., Okuda, K., & Ménard, C. 2001. Porphyromonas gulae sp. nov., an anaerobic, Gram-negative coccobacillus from the gingival sulcus of various animal hosts. Int J Syst Evol Microbiol 51, 1179-1189.
26. Holdeman, L.V. and Johnson, J.L. 1977. *Bacteroides disiens* sp. nov. and *Bacteroides bivius* sp. nov. from Human Clinical Infections. Int. J. Syst. Bacteriol. 27, p. 337-345.
27. Hoyles, L., Falsen, E., Foster, G., Pascual, C., Greko, C. & Collins, M.D. 2000. *Actinomyces canis* sp. nov., isolated from dogs. Int J Syst Evol Microbiol 50, 1547-1551.
28. Jorgensen, J.H., M. A Phaller, K.C. Carroll, G. Funke, M.L. Landry, S.S. Richter, and D.W. Warnock. 2015. Manual of Clinical Microbiology, 11th edition. American Society for Microbiology, Washington, D.C.
29. Kedlaya, I., Ing, M.B. & Wong, S.S. 2001. *Rhodococcus equi* Infections and Immunocompetent Hosts: Case Report and Review. Clinical Infectious Disease, 32, p. e39-e47.
30. Love, D.N., Johnson, J.L., Jones, R.F., Bailey, M. & Calverley, A. 1986. *Bacteroides tectum* sp. nov. and Characteristics of Other Nonpigmented *Bacteroides* Isolates from Soft-Tissue Infections from Cats and Dogs. Int J Syst Bacteriol. 36, 123-128.

Use this Instructions for Use with VITEK® 2 Product No. 21347.

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalog number
IVD	In Vitro Diagnostic Medical Device
	Legal Manufacturer
	Temperature limitation
	Use by date
LOT	Batch code
	Consult Instructions for Use
	Date of manufacture
	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community
Rx only	For US Only : Caution : US Federal Law restricts this device to sale by or on the order of a licensed practitioner

Instructions for Use provided in the kit or downloadable from www.biomerieux.com/techlib

LIMITED WARRANTY

bioMérieux warrants the performance of the product for its stated intended use provided that all procedures for usage, storage and handling, shelf life (when applicable), and precautions are strictly followed as detailed in the instructions for use (IFU).

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REVISION HISTORY TABLE

Change type categories	
N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user
Note :	Minor typographical, grammar, and formatting changes are not included in the revision history.

Release Date	Part Number	Change Type	Change Summary
2019-03	043907-03	Technical change	Updated for 9.02 software release. Updated sections: • Intended Use • Precautions • Culture Requirements • Additional Information on Lab Report • Testing of QC Organisms • Performance Characteristics • Organisms Identified • References
2016-10	043907-02	Technical change	• Updated content to reflect the 8.01 Product Information Manual
2016-05	043907-01	Administrative	• Formatting changes do not affect the fit, form, or function of the product
		Technical change	• New IFU derived from product chapter in the Product Information Manual • Updated Limited Warranty section • Updated with RX only information

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043908- 03 - 2019-03 EN

VITEK® 2 YST

Rx only IVD

INTENDED USE

These Instructions for Use correspond to the VITEK® 2 Systems 7.01 or higher software. If you are not using VITEK® 2 Systems 7.01 or higher software, please refer to the VITEK® 2 Systems Product Information that you received with your current software version.

The VITEK® 2 Yeast identification card (YST) is intended for use with VITEK® 2 Systems for the automated identification of most clinically significant yeasts and yeast-like organisms. The VITEK® 2 YST identification card is a single-use disposable. For a list of claimed species, see the Organisms Identified section.

DESCRIPTION

The YST card is based on established biochemical methods[1,6,8,10,11] and newly developed substrates. There are 46 biochemical tests measuring carbon source utilization, nitrogen source utilization, and enzymatic activities. Final results are available in approximately 18 hours.

For a list of well contents, see the YST Well Contents table.

Table 1: YST Well Contents

Well	Test	Mnemonic	Amount/Well
3	L-Lysine-ARYLAMIDASE	LysA	0.0228 mg
4	L-MALATE assimilation	IMLTa	0.15 mg
5	Leucine-ARYLAMIDASE	LeuA	0.0234 mg
7	ARGININE	ARG	0.15 mg
10	ERYTHRITOL assimilation	ERYa	0.3 mg
12	GLYCEROL assimilation	GLYLa	0.16 µL
13	Tyrosine ARYLAMIDASE	TyrA	0.0276 mg
14	BETA-N-ACETYL-GLUCOSAMINIDASE	BNAG	0.0408 mg
15	ARBUTIN assimilation	ARBa	0.3 mg
18	AMYGDALIN assimilation	AMYa	0.3 mg
19	D-GALACTOSE assimilation	dGALa	0.3 mg
20	GENTOBIOSE assimilation	GENa	0.3 mg
21	D-GLUCOSE assimilation	dGLUa	0.3 mg
23	LACTOSE assimilation	LACa	0.96 mg
24	METHYL-A-D-GLUCOPYRANOSIDE assimilation	MAdGa	0.3 mg
26	D-CELLOBIOSE assimilation	dCELa	0.3 mg
27	GAMMA-GLUTAMYL-TRANSFERASE	GGT	0.0228 mg
28	D-MALTOSE assimilation	dMALa	0.3 mg
29	D-RAFFINOSE assimilation	dRAFa	0.3 mg
30	PNP-N-acetyl-BD-galactosaminidase 1	NAGA1	0.0306 mg
32	D-MANNOSE assimilation	dMNEa	0.3 mg
33	D-MELIBIOSE assimilation	dMELa	0.3 mg
34	D-MELEZITOSE assimilation	dMLZa	0.3 mg
38	L-SORBOSE assimilation	ISBEa	0.3 mg

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Well	Test	Mnemonic	Amount/Well
39	L-RHAMNOSE assimilation	IRHAa	0.3 mg
40	XYLITOL assimilation	XLTa	0.3 mg
42	D-SORBITOL assimilation	dSORa	0.1875 mg
44	SACCHAROSE/SUCROSE assimilation	SACa	0.3 mg
45	UREASE	URE	0.15 mg
46	ALPHA-GLUCOSIDASE	AGLU	0.036 mg
47	D-TURANOSE assimilation	dTURa	0.3 mg
48	D-TREHALOSE assimilation	dTREa	0.3 mg
49	NITRATE assimilation	NO3a	0.03 mg
51	L-ARABINOSE assimilation	lARAa	0.3 mg
52	D-GALACTURONATE assimilation	dGATa	0.15 mg
53	ESCULIN hydrolysis	ESC	0.225 mg
54	L-GLUTAMATE assimilation	lGLTa	0.15 mg
55	D-XYLOSE assimilation	dXYLa	0.3 mg
56	DL-LACTATE assimilation	LATa	0.15 mg
58	ACETATE assimilation	ACEa	0.15 mg
59	CITRATE (SODIUM) assimilation	CITa	0.15 mg
60	GLUCURONATE ASSIMILATION	GRTas	0.15 mg
61	L-PROLINE assimilation	lPROa	0.15 mg
62	2-KETO-D-GLUCONATE assimilation	2KGa	0.15 mg
63	N-ACETYL-GLUCOSAMINE assimilation	NAGa	0.15 mg
64	D-GLUCONATE assimilation	dGNTa	0.15 mg

Note: Other well numbers between 1 and 64 not designated in this table are empty.

PRECAUTIONS

Note: For industry customers that need assistance on selecting the correct VITEK® 2 identification card, please refer to the VITEK® 2 Compact Instrument User Manual chapter, "Guidance to Select a VITEK® 2 Identification Card."

- For *In Vitro* Diagnostic Use Only.
- For US Only: Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- For professional use only.
- Suspensions not within the appropriate zone on the VITEK® 2 DENSICHEK™ Plus or the VITEK® 2 DENSICHEK™ may compromise card performance.
- Do not use the card after the expiration date shown on the package liner.
- Store the card unopened in the package liner. Do not use the card if the protective package liner is damaged or if no desiccant is present.
- Allow the card to come to room temperature before opening the package liner.
- Do not use powdered gloves. Powder may interfere with the optics.
- Use of culture media other than the recommended types must be validated by the customer laboratory for acceptable performance.
- A Gram stain should be performed to determine an organism’s Gram reaction and morphology prior to selecting the identification card to inoculate.
- The card performs as intended only when used in conjunction with VITEK® 2 Systems, following the instructions contained in these Instructions for Use.
- **Do not use glass test tubes**. Use clear plastic (polystyrene) tubes only. Variation exists among test tubes of standard diameter. Carefully place the tube into the cassette. If resistance is encountered, discard and try another tube that does not require pressure to insert.

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- Prior to inoculation, inspect cards for tape tears or damage to the tape and discard any that are suspect. Check the saline level in the tubes after the cassette has been processed to ensure proper filling of card.
  - VITEK® 2 60 or VITEK® 2 XL: Eject improperly filled cards.
  - VITEK® 2 Compact: Do not load improperly filled cards.
- Give special consideration to specimen source and patient drug or antimicrobic regimen.
- Interpretation of test results requires the judgment and skill of a person knowledgeable in microbial identification testing. Additional testing may be required. (See the Supplemental Tests section.)
- Do not clean saline dispenser with chemical agents. The use of chemical agents may impact card performance.

Warning: All patient specimens, microbial cultures, and inoculated VITEK® 2 cards, along with associated materials, are potentially infectious and should be treated with universal precautions.[13,17]

Warning: All hazardous waste must be disposed of by following your local inspecting agency's guidelines.

STORAGE CONDITIONS

Upon receipt, store VITEK® 2 YST cards unopened in their original package liner at 2°C to 8°C.

SPECIMEN PREPARATION

For specimen preparation information, see the Culture Requirements Table.

Table 2: Culture Requirements Table

VITEK® 2 Card	Media	Age of Culture[1]	Incubation Conditions	Inoculum Density	Dilution for AST	Age of Suspension Before Loading Instrument
YST	SDA[2] SDA-E[2] TSAB[2] CBA IMA TSA TSAHB CHBA CID CPS ID	18 to 72 hours	30°C to 37°C aerobic, non-CO_2 (or 25°C to 30°C for species that do not tolerate 30°C to 37°C)	1.80 to 2.20 McFarland Standard	N/A[3]	≤ 30 minutes
YST and AST-YST Pair	SDA SDA-E TSAB CBA TSA CHBA CID CPS ID	18 to 72 hours	35°C to 37°C aerobic, non-CO_2	1.80 to 2.20 McFarland Standard	280 µL in 3.0 mL saline	≤ 30 minutes

[1]Cultures with scant or poor growth may give unidentified or incorrect results even when the Age of Culture requirements are met.

[2]These media were used in the identification product database development and will give optimal performance.

[3]N/A = not applicable

Culture Requirements Table — Media Abbreviations

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CBA = Columbia Blood Agar with 5% Sheep Blood

CHBA = Columbia Horse Blood Agar

CID = chromID™Candida (Candida ID2 agar)

CPS ID = chromID™ CPS (CPS ID agar)

IMA = Inhibitory Mould Agar

SDA = Sabouraud Dextrose Agar

SDA-E = Sabouraud Dextrose Agar (Emmons)

TSA = Trypticase Soy Agar

TSAB = Trypticase Soy Agar with 5% Sheep Blood

TSAHB = Trypticase Soy Agar with 5% Horse Blood

Materials

When used with VITEK® 2 instrumentation, the YST card is a complete system for routine identification testing of most clinically significant yeasts and yeast-like organisms.

Required materials are:

- VITEK® 2 YST Card
- DENSICHEK™ Plus Kit or VITEK® DENSICHEK® Kit
- DENSICHEK™ Plus Standards Kit or DENSICHEK® Standards Kit
- VITEK® 2 Cassette
- Sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- 12 mm x 75 mm clear plastic (polystyrene) disposable test tubes
- Sterile sticks or swabs
- Appropriate agar medium (see Culture Requirements table).

Optional accessories:

- Adjustable volume saline dispenser
- Loops
- Pre-dispensed saline test tubes (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Test tube caps
- Vortex

Procedure

Warning: Failure to follow instructions and recommendations provided in this section for performing laboratory tasks may cause erroneous or delayed results.

For product-specific information, see the Culture Requirements table.

Note: Prepare the inoculum from a pure culture, according to good laboratory practices. In case of mixed cultures, a re-isolation step is required. It is recommended that a purity check plate be done to ensure that a pure culture was used for testing.

1. Do one of the following:
   - Select isolated colonies from a primary plate if culture requirements are met.
   - Subculture the organism to be tested to appropriate agar medium and incubate accordingly.
2. Aseptically transfer 3.0 mL of sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0) into a clear plastic (polystyrene) test tube (12 mm x 75 mm).
3. Use a sterile stick or swab to transfer a sufficient number of morphologically similar colonies to the saline tube prepared in step 2. Prepare the homogenous organism suspension with a density equivalent to a McFarland No. 1.80 to 2.20 using a calibrated VITEK® 2 DENSICHEK™ Plus or VITEK® 2 DENSICHEK™.
   Note: Filamentous species may pick up small amounts of glucose from the isolation media. This has the potential for causing false positive reactions. Avoid scraping or rubbing the agar when preparing the organism suspension. For strains

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that do not readily form a smooth suspension in saline, it is recommended that a wet swab be used to make the suspension. Do not rub the agar surface when preparing a suspension using a wet swab.

Note: Age of suspension must not exceed 30 minutes before inoculating card.

4. Place the suspension tube and YST card in the cassette.
5. Refer to the appropriate Instrument User Manual for instructions on data entry and how to load the cassette into the instrument.
6. Follow your local inspecting agency's guidelines for disposal of hazardous waste.

RESULTS

Identification Analytical Techniques

VITEK® 2 Systems identify an organism by using a methodology based on the characteristics of the data and knowledge about the organism and reactions being analyzed. Sufficient data have been collected from known strains to estimate the typical reactions of the claimed species to a set of discriminating biochemicals. If a unique identification pattern is not recognized, a list of possible organisms is given, or the strain is determined to be outside the scope of the database.

The printed lab report contains suggestions for any supplemental tests necessary to complete the identification. If the tests are not sufficient to complete the identification, then standard microbiology references and literature should be consulted.

Certain species may belong to a slashline (mixed) taxa identification. This occurs when the biopattern is the same for the taxa listed. Supplemental tests may be used to separate slashline taxa. The species in the Slashline (Mixed) Taxa Identification table belong to the YST slashline taxa.

Table 3: Slashline (Mixed) Taxa Identification

Slashline Name	Species Belonging to the Slashline
C. inconspicua/C. lambica	*Candida inconspicua* *Candida lambica*
Kloeckera spp.	*Kloeckera apiculata* *Kloeckera apis* *Kloeckera japonica*
*Rhodotorula glutinis/mucilaginosa/(Crypto. laurentii)**	*Rhodotorula glutinis* *Rhodotorula mucilaginosa*

*This is also a pseudoslashline.

Certain species may belong to a pseudoslashline (mixed) taxa identification. A pseudoslashline indicates a rare isolate or rare occurrence of the same biopattern. Supplemental tests may be used to separate pseudoslashline taxa. The species in Pseudoslashline Taxa Table belong to the pseudoslashline taxa.

Table 4: Pseudoslashline Taxa

Pseudoslashline name	Species Belonging to Pseudoslashline
Candida sake/(C. famata/C. lipolytica)	*Candida famata* *Candida lipolytica*
*Rhodotorula glutinis/mucilaginosa/(Crypto. laurentii)**	*Cryptococcus laurentii*

*This is also a slashline.

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Table 5: Identification Card Qualifying Messages

ID Message Confidence Level	Choices	% Probability	Comments
Excellent	1	96 to 99	N/A
Very Good	1	93 to 95	N/A
Good	1	89 to 92	N/A
Acceptable	1	85 to 88	N/A
Low Discrimination	2 to 3	Sum of choices = 100; after resolution to one choice, percent probability reflects the number associated with selected choice.	Two to three taxa exhibit same biopattern. Separate by supplemental testing.
Inconclusive or Unidentified Organism	> 3 or 0	N/A	Either > 3 taxa exhibit same biopattern or Very atypical biopattern. Does not correspond to any taxon in the database. Check Gram stain and purity.

PERCENT PROBABILITY

As part of the identification process, the software compares the test set of reactions to the expected set of reactions of each organism, or organism group, that can be identified by the product. A quantitative value, the percent probability, is calculated and relates to how well the observed reactions compare to the typical reactions of each organism. A perfect match between the test reaction pattern and the unique reaction pattern of a single organism, or organism group, would provide a percent probability of 99. When a perfect match is not obtained, it is still possible for the reaction pattern to be sufficiently close to that of an expected reaction pattern such that a clear decision can be provided about the organism identification. The range of percent probabilities in the one-choice case is 85 to 99. Values closer to 99 indicate a closer match to the typical pattern for the given organism.

When the reaction pattern is not sufficient to discriminate between two to three organisms, the percent probabilities reflect this ambiguity. The reported probability values indicate, relatively, the order in which the reaction pattern best corresponds to the listed possibilities. The order does not, however, suggest that the pattern match to one of the possible identifications is clearly superior to another. The probability characteristic of an overall sum of 100 is retained through the calculation process. After resolution to one choice, the probability characteristic of the single choice is retained.

ADDITIONAL INFORMATION ON LAB REPORT

Supplemental test — External (offline) test that allows the user to resolve a slashline or Low Discrimination identification. Numbers in parentheses indicate percent positive reaction for the species/test listed.

Contraindicating test — Test result that is unusual for a reported taxon.

Table 6: Notes Associated with Certain Taxa

Taxa	Note			
For 7.01 or Higher Software Users				
Candida krusei	Possibility of *C. inconspicua* or *C. lambica*. Isolates of these infrequent species may be misidentified as *C. krusei*; in order to rule them out, perform the following tests:			
		HYPH/PH	dGLUf	dXYLOSEa
	C. inconspicua	-	-	-
	C. krusei	+	+	-
	C. lambica	+	+	+

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Taxa	Note
Rhodotorula glutinis/ mucilaginosa *Cryptococcus laurentii*	Possibility of *Cryptococcus albidus*
Geotrichum klebahnii	Possibility of *Geotrichum candidum*
Cryptococcus neoformans	Critical pathogen The species identified may have significance to patient or sample outcome and can be stopped for review.
For 8.01 or Higher Software Users	
Candida glabrata	*Candida nivariensis* and *Candida bracarensis* have similar morphology and biochemical utilization patterns compared to *Candida glabrata*, and they exhibit similar multi-resistance to anti-fungals. These three species may be differentiated from each other by molecular methods, such as MALDI-TOF, since phenotypic tests do not differentiate them. Retrospective studies of culture collections showed that up to 0.1% of isolates previously identified as *C. glabrata* were strains of *C. nivariensis* and that 0.2-2.2% of isolates previously identified as *C. glabrata* were strains of *C. bracarensis*.[3,9]
For 9.02 Software Users	
Candida parapsilosis	*Candida metapsilosis* and *Candida orthopsilosis* have similar morphology and biochemical utilization patterns compared to *Candida parapsilosis*. Although data are limited, antifungal susceptibility testing of both species show a similar profile to that of *C. parapsilosis*. These three species may be differentiated from each other by molecular methods, such as MALDI-TOF, since phenotypic tests do not differentiate them. *C.orthopsilosis* and *C. metapsilosis* are rare clinical isolates but are reported emerging pathogens associated with candidemia.

Notes Associated with an Improperly Filled Card or with a Negative Profile (Biopattern)

- For the case where the time between two readings is greater than 40 minutes: “CARD ERROR — Missing data.”
- For the case where there is a negative profile: “Organism with low reactivity biopattern — please check viability.”
- When a biopattern is calculated for an unknown organism that is completely negative or consists of both negative tests and tests that fall within the uncertainty zone, the identification call will be “Non or low reactive biopattern.”

The following non-reactive species could potentially trigger this note if a test was atypical or fell within the uncertainty zone:

- *Candida sake*
- *Candida zeylanoides*
- *Malassezia furfur*
- *Malassezia pachydermatis*

For 7.01 Software Users

- *Zygosaccharomyces bailii*

For 8.01 or Higher Software Users

- *Zygosaccharomyces* species

QUALITY CONTROL

Quality control organisms and their expected results are listed in the VITEK® 2 YST Quality Control Tables. Process these according to the procedure for test isolates outlined in this document.

Note: *Staphylococcus epidermidis* ATCC® 12228™ needs to be tested at a McFarland Standard No. 0.5 to 0.63. All other QC strains are tested at a McFarland Standard No. 1.80 to 2.20.

Certification Statement

This is to certify that bioMérieux complies with ISO 13485 and FDA Quality System Regulation (QSR) requirements for design, development, and manufacture of microbial identification systems.

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Frequency of Testing

Currently, it is recommended that you use your most stringent inspecting agency's guidelines for frequency of identification product testing.

Common practice is to perform QC upon receipt of shipment of the test kits. Reactions must follow Instructions for Use results.

If the results do not meet the criteria, subculture for purity and repeat the test. If discrepant results are repeated, perform an alternate identification method and contact bioMérieux.

Testing and Storage of QC Organisms

1. Rehydrate the organism according to the manufacturer's instructions.
2. Yeast: Streak onto Sabouraud dextrose agar (SDA) or SDA (Emmons) and incubate aerobically at 35°C to 37°C for 18 to 24 hours, or until sufficient growth is achieved, except for:
   - *Prototheca wickerhamii* ATCC® 16529™, *Zygosaccharomyces parabailii* ATCC® MYA-4549™, and *Kloeckera japonica* ATCC® 58370™,which are incubated at 28°C to 30°C.
   - *Sporobolomyces salmonicolor* ATCC® MYA-4550™, which is incubated at 25°C to 27°C.
3. Bacteria: Use trypticase soy agar with 5% sheep blood (TSAB). Incubate aerobically at 35°C to 37°C for 18 to 24 hours.
4. Check for purity. Perform second subculture for testing.
5. Yeast: Streak onto SDA or SDA (Emmons) and incubate aerobically at 35°C to 37°C for 18 to 24 hours, or until sufficient growth is achieved, except for:
   - *Prototheca wickerhamii* ATCC® 16529™, *Zygosaccharomyces parabailii* ATCC® MYA-4549™, and *Kloeckera japonica* ATCC® 58370™, which are incubated at 28°C to 30°C.
   - *Sporobolomyces salmonicolor* ATCC® MYA-4550™, which is incubated at 25°C to 27°C.
6. Bacteria: Use trypticase soy agar with 5% sheep blood (TSAB). Incubate aerobically at 35°C to 37°C for 18 to 24 hours.

Short-Term Storage Conditions

1. Streak to a SDA or SDA (Emmons) plate or slant for yeast QC organisms and TSAB for bacteria QC organisms.
2. Incubate for 24 hours at the appropriate temperature.
3. Refrigerate at 2°C to 8°C for up to one week.
4. Subculture once as described above and use for QC.

Long-Term Storage Conditions

1. Make a heavy suspension in Tryptic Soy Broth (TSB) with 15% glycerol.
2. Freeze at -70°C.
3. Subculture to appropriate medium twice before running QC.

Note: Avoid repeated thawing and refreezing by either freezing in single-use aliquots or removing a small portion of frozen organism preparation with a sterile applicator stick.

STREAMLINED QUALITY CONTROL

Note: Industrial Use Only laboratories should perform quality control following the Streamlined Quality Control section. No additional testing is required for these users.

Streamlined quality control may be used to confirm acceptable performance of the YST card after shipping/storage. This methodology may be performed with the YST card by following the instructions for quality control testing as described in the YST Instructions for Use and meeting the criteria stated in CLSI® M50-A Quality Control for Commercial Microbial Identification Systems.

Testing may be conducted using *Candida albicans* ATCC® 14053™ and evaluating the performance of the NAGA1 well. Testing at bioMérieux, Inc. has shown that the NAGA1 well is the most labile well on the YST card and *Candida albicans* ATCC® 14053™ is the most sensitive strain for detecting degradation of this well with a false negative reaction. (See YST Quality Control table for more details).

COMPREHENSIVE QUALITY CONTROL

Customers who do not qualify for streamlined quality control testing are required to perform comprehensive quality control testing, which entails demonstration of a positive and negative reaction for each substrate of an identification product.[5]

In order to qualify initially for streamlined quality control testing, the CLSI® M50-A standard requires that the user perform and document either of the following:[4]

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- Verification testing to show that performance is equivalent to the manufacturer's claims.
- Comprehensive quality control testing of at least three lots over at least three different seasons.

Refer to the complete CLSI® M50-A standard for information regarding continued qualification and further details of requirements and responsibilities for both the user and the manufacturer related to streamlined quality control testing.

YST Quality Control Tables:

***Candida albicans* ATCC® 14053™** (for streamlined or comprehensive quality control)

***Candida glabrata* ATCC® MYA-2950™** (for comprehensive quality control)

***Candida lusitaniae* ATCC® 34449™** (for comprehensive quality control)

***Candida utilis* ATCC® 9950™** (for comprehensive quality control)

***Kloeckera japonica* ATCC® 58370™** (for comprehensive quality control)

***Prototheca wickerhamii* ATCC® 16529™** (for comprehensive quality control)

***Sporobolomyces salmonicolor* ATCC® MYA-4550™** (for comprehensive quality control)

***Trichosporon mucoides* ATCC® 204094™** (for comprehensive quality control)

***Oligella ureolytica* ATCC® 43534™** (for comprehensive quality control)

***Staphylococcus epidermidis* ATCC® 12228™** (for comprehensive quality control)

***Zygosaccharomyces parabailii*ATCC® MYA-4549™** (for comprehensive quality control)

Note: The comprehensive quality control strain *Zygosaccharomyces bailii* ATCC® MYA-4549™ had a taxonomic update to *Zygosaccharomyces parabailii* ATCC® MYA-4549™. This strain identifies as *Zygosaccharomyces bailii* in the 7.01 software and as *Zygosaccharomyces* species in the 8.01 software.

The YST card typically identifies the quality control organisms as one-choice or within a low discrimination or slashline identification. However, strains are chosen for reaction performance over identification performance. Therefore, an unidentified or misidentified result may occur when all expected quality control reactions are correct.

Note: The YST card uses unclaimed taxa for quality control testing. These strains will give an unidentified or a misidentified result.

Table 7: QC Organism: *Candida albicans* ATCC® 14053™ (for streamlined or comprehensive quality control)

LysA	-	ARBa	-	GGT	v	IRHAa	-	NO3a	-	CITa	+
IMLTa	+	AMYa	v	dMALa	+	XLTa	+	IARAa	v	GRTas	v
LeuA	+	dGALa	+	dRAFa	-	dSORa	+	dGATa	v	IPROa	+
ARG	+	GENa	-	NAGA1	+	SACa	+	ESC	-	2KGa	+
ERYa	-	dGLUa	+	dMNEa	+	URE	-	IGLTa	+	NAGa	+
GLYLa	v	LACa	-	dMELa	-	AGLU	+	dXYLa	+	dGNTa	+
TyrA	v	MAdGa	+	dMLZa	-	dTURa	+	LATa	+		
BNAG	-	dCELa	-	ISBEa	-	dTREa	+	ACEa	+		

+ = 95% to100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Note: The NAGA1 well is used for streamlined quality control.

Table 8: QC Organism: *Candida glabrata* ATCC® MYA-2950™ (for comprehensive quality control)

LysA	–	ARBa	–	GGT	–	IRHAa	–	NO3a	v	CITa	–
IMLTa	–	AMYa	v	dMALa	–	XLTa	v	IARAa	–	GRTas	–
LeuA	v	dGALa	–	dRAFa	v	dSORa	–	dGATa	–	IPROa	v
ARG	–	GENa	v	NAGA1	–	SACa	–	ESC	–	2KGa	–
ERYa	–	dGLUa	v	dMNEa	v	URE	–	IGLTa	v	NAGa	–
GLYLa	–	LACa	–	dMELa	–	AGLU	–	dXYLa	–	dGNTa	v
TyrA	–	MAdGa	–	dMLZa	v	dTURa	–	LATa	–		

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BNAG	v	dCELa	v	ISBEa	–	dTREa	+	ACEa	v		

+ = 95% to100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 9: QC Organism: *Candida lusitaniae* ATCC® 34449™ (for comprehensive quality control)

LysA	v	ARBa	+	GGT	v	lRHAa	+	NO3a	v	CITa	+
lMLTa	+	AMYa	+	dMALa	v	XLTa	v	lARAa	–	GRTas	v
LeuA	+	dGALa	v	dRAFa	–	dSORa	+	dGATa	v	lPROa	+
ARG	v	GENa	+	NAGA1	v	SACa	v	ESC	+	2KGa	v
ERYa	v	dGLUa	v	dMNEa	v	URE	v	lGLTa	+	NAGa	+
GLYLa	v	LACa	v	dMELa	v	AGLU	v	dXYLa	v	dGNTa	v
TyrA	v	MAdGa	v	dMLZa	v	dTURa	+	LATa	v		
BNAG	v	dCELa	+	ISBEa	+	dTREa	v	ACEa	+		

+ = 95% to100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 10: QC Organism: QC Organism *Candida utilis* ATCC® 9950™ (for comprehensive quality control)

LysA	v	ARBa	v	GGT	v	lRHAa	v	NO3a	+	CITa	v
lMLTa	v	AMYa	+	dMALa	v	XLTa	–	lARAa	v	GRTas	v
LeuA	v	dGALa	v	dRAFa	+	dSORa	–	dGATa	v	lPROa	v
ARG	v	GENa	v	NAGA1	–	SACa	+	ESC	v	2KGa	–
ERYa	v	dGLUa	+	dMNEa	+	URE	v	lGLTa	v	NAGa	–
GLYLa	+	LACa	v	dMELa	v	AGLU	v	dXYLa	v	dGNTa	v
TyrA	v	MAdGa	v	dMLZa	+	dTURa	v	LATa	v		
BNAG	v	dCELa	v	ISBEa	v	dTREa	v	ACEa	v		

+ = 95% to100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 11: QC Organism: *Kloeckera japonica* ATCC® 58370™ (for comprehensive quality control)

LysA	v	ARBa	v	GGT	v	lRHAa	v	NO3a	v	CITa	v
lMLTa	v	AMYa	v	dMALa	–	XLTa	v	lARAa	v	GRTas	v
LeuA	v	dGALa	v	dRAFa	v	dSORa	v	dGATa	v	lPROa	v
ARG	v	GENa	v	NAGA1	v	SACa	v	ESC	v	2KGa	v
ERYa	v	dGLUa	v	dMNEa	v	URE	v	lGLTa	v	NAGa	v
GLYLa	v	LACa	v	dMELa	v	AGLU	v	dXYLa	v	dGNTa	v
TyrA	v	MAdGa	v	dMLZa	v	dTURa	v	LATa	v		
BNAG	v	dCELa	v	ISBEa	v	dTREa	v	ACEa	–		

+ = 95% to100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 12: QC Organism: *Prototheca wickerhamii* ATCC® 16529™ (for comprehensive quality control)

LysA	v	ARBa	v	GGT	–	lRHAa	v	NO3a	–	CITa	–
lMLTa	–	AMYa	–	dMALa	v	XLTa	v	lARAa	v	GRTas	v
LeuA	v	dGALa	v	dRAFa	v	dSORa	v	dGATa	v	lPROa	v
ARG	v	GENa	–	NAGA1	v	SACa	–	ESC	v	2KGa	v
ERYa	v	dGLUa	v	dMNEa	v	URE	v	lGLTa	v	NAGa	v
GLYLa	+	LACa	v	dMELa	v	AGLU	v	dXYLa	v	dGNTa	v

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TyrA	–	MAdGa	–	dMLZa	–	dTURa	–	LATa	v		
BNAG	–	dCELa	–	ISBEa	v	dTREa	v	ACEa	v		

+ = 95% to100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 13: QC Organism: *Sporobolomyces salmonicolor* ATCC® MYA-4550™ (for comprehensive quality control)

LysA	+	ARBa	v	GGT	v	lRHAa	v	NO3a	v	CITa	v
lMLTa	v	AMYa	v	dMALa	v	XLTa	v	lARAa	v	GRTas	v
LeuA	v	dGALa	v	dRAFa	v	dSORa	v	dGATa	v	lPROa	v
ARG	v	GENa	v	NAGA1	v	SACa	v	ESC	v	2KGa	v
ERYa	v	dGLUa	v	dMNEa	v	URE	v	lGLTa	v	NAGa	v
GLYLa	v	LACa	v	dMELa	v	AGLU	v	dXYLa	v	dGNTa	v
TyrA	v	MAdGa	v	dMLZa	v	dTURa	v	LATa	v		
BNAG	v	dCELa	v	ISBEa	v	dTREa	v	ACEa	v		

+ = 95% to100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 14: QC Organism: *Trichosporon mucoides* ATCC® 204094™ (for comprehensive quality control)

LysA	v	ARBa	+	GGT	+	lRHAa	+	NO3a	v	CITa	v
lMLTa	v	AMYa	–	dMALa	+	XLTa	+	lARAa	+	GRTas	+
LeuA	v	dGALa	+	dRAFa	+	dSORa	v	dGATa	+	lPROa	v
ARG	+	GENa	+	NAGA1	+	SACa	v	ESC	+	2KGa	+
ERYa	+	dGLUa	v	dMNEa	v	URE	+	lGLTa	v	NAGa	v
GLYLa	v	LACa	+	dMELa	+	AGLU	+	dXYLa	+	dGNTa	+
TyrA	+	MAdGa	+	dMLZa	+	dTURa	v	LATa	+		
BNAG	+	dCELa	+	ISBEa	v	dTREa	v	ACEa	v		

+ = 95% to100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 15: QC Organism: *Oligella ureolytica* ATCC® 43534™ (for comprehensive quality control)

LysA	v	ARBa	v	GGT	v	lRHAa	v	NO3a	v	CITa	v
lMLTa	v	AMYa	v	dMALa	v	XLTa	v	lARAa	v	GRTas	v
LeuA	v	dGALa	v	dRAFa	v	dSORa	v	dGATa	v	lPROa	v
ARG	v	GENa	v	NAGA1	v	SACa	v	ESC	v	2KGa	v
ERYa	v	dGLUa	–	dMNEa	–	URE	v	lGLTa	v	NAGa	v
GLYLa	v	LACa	v	dMELa	v	AGLU	v	dXYLa	v	dGNTa	v
TyrA	v	MAdGa	v	dMLZa	v	dTURa	v	LATa	v		
BNAG	v	dCELa	v	ISBEa	v	dTREa	v	ACEa	v		

+ = 95% to100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Note: *Oligella ureolytica* is an unclaimed taxa for the YST card.

Table 16: QC Organism: *Staphylococcus epidermidis* ATCC® 12228™ (for comprehensive quality control)

LysA	v	ARBa	v	GGT	v	lRHAa	v	NO3a	v	CITa	v
lMLTa	v	AMYa	v	dMALa	v	XLTa	v	lARAa	v	GRTas	v
LeuA	–	dGALa	v	dRAFa	v	dSORa	v	dGATa	v	lPROa	v
ARG	v	GENa	v	NAGA1	v	SACa	v	ESC	v	2KGa	v

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ERYa	v	dGLUa	v	dMNEa	v	URE	v	lGLTa	v	NAGa	v
GLYLa	v	LACa	v	dMELa	v	AGLU	v	dXYLa	v	dGNTa	v
TyrA	v	MAdGa	v	dMLZa	v	dTURa	v	LATa	v		
BNAG	v	dCELa	v	ISBEa	v	dTREa	v	ACEa	v		

+ = 95% to100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Note: *Staphylococcus epidermidis* is an unclaimed taxa for the YST card.

Table 17: QC Organism: *Zygosaccharomyces parabailii* ATCC® MYA-4549™ (for comprehensive quality control)

LysA	v	ARBa	v	GGT	v	lRHAa	v	NO3a	v	CITa	v
lMLTa	v	AMYa	v	dMALa	v	XLTa	v	lARAa	v	GRTas	v
LeuA	v	dGALa	v	dRAFa	v	dSORa	v	dGATa	v	lPROa	–
ARG	v	GENa	v	NAGA1	v	SACa	v	ESC	v	2KGa	v
ERYa	v	dGLUa	v	dMNEa	v	URE	v	lGLTa	–	NAGa	v
GLYLa	v	LACa	v	dMELa	v	AGLU	v	dXYLa	v	dGNTa	–
TyrA	v	MAdGa	v	dMLZa	v	dTURa	v	LATa	v		
BNAG	v	dCELa	v	ISBEa	v	dTREa	–	ACEa	v		

+ = 95% to100% positive; v = 6% to 94% positive; – = 0% to 5% positive

For 7.01 Software Users

Zygosaccharomyces parabailii ATCC® MYA-4549™ identifies as *Zygosaccharomyces bailii*.

For 8.01 or Higher Software Users
Zygosaccharomyces parabailii ATCC® MYA-4549™ identifies as *Zygosaccharomyces* species.

LIMITATIONS
The VITEK® 2 YST card cannot be used with a direct clinical specimen, sample, or another source containing mixed flora. Any change or modification in the procedure may affect the results.

Newly described or rare species may not be included in the YST database. Selected species will be added as strains become available.

Warning: Testing of unclaimed species may result in an unidentified result or a misidentification.

PERFORMANCE CHARACTERISTICS
For 7.01 Software Users

In a multi-site clinical study*, the performance of the VITEK® 2 YST identification card was evaluated using 623 clinical and stock isolates of both commonly and rarely observed species of yeast and yeast-like organisms. The reference identification was determined with API® 20C AUX identification kits. Overall, the VITEK® 2 YST correctly identified 98.2% of the isolates, including 8.1% low discrimination with the correct species listed. Misidentifications occurred at 1.5% and no identifications occurred at 0.3%.

For 8.01 and 9.01 Software Users

In a multi-site clinical study*, the performance of the VITEK® 2 YST identification card was evaluated using 621 clinical and stock isolates of both commonly and rarely observed species of yeast and yeast-like organisms. The reference identification was determined with API® 20C AUX identification kits. Overall, the VITEK® 2 YST correctly identified 97.9% of the isolates, including 7.2% low discrimination with the correct species listed. Misidentifications occurred at 1.8% and no identifications occurred at 0.5%.

For 9.02 Software Users

In a multi-site clinical study*, the performance of the VITEK® 2 YST identification card was evaluated using 621 clinical and stock isolates of both commonly and rarely observed species of yeast and yeast-like organisms. The reference identification was determined with API® 20C AUX identification kits. Overall, the VITEK® 2 YST correctly identified 97.6% of the isolates, including 6.0% low discrimination with the correct species listed. Misidentifications occurred at 1.9% and no identifications occurred at 0.5%.

*Data on file at bioMérieux, Inc.

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ORGANISMS IDENTIFIED

Claims are for all software users unless otherwise stated.

- *Candida albicans*
- *Candida boidinii*
- *Candida catenulata*
- *Candida colliculosa*
- *Candida dubliniensis*
- *Candida famata*
- *Candida freyschussii*
- *Candida glabrata*
- *Candida guilliermondii*
- *Candida haemulonii*
- *Candida inconspicua/Candida lambica*
- *Candida intermedia*
- *Candida kefyr*
- *Candida krusei*
- *Candida lipolytica*
- *Candida lusitaniae*
- *Candida magnoliae*
- *Candida norvegensis*
- *Candida parapsilosis*
- *Candida pelliculosa*
- *Candida pulcherrima*
- *Candida rugosa*
- *Candida sake*
- *Candida spherica*
- *Candida tropicalis*
- *Candida utilis*
- *Candida zeylanoides*
- *Cryptococcus albidus*
- *Cryptococcus laurentii*
- *Cryptococcus neoformans*
- *Cryptococcus terreus*
- *Cryptococcus uniguttulatus*
- *Geotrichum klebahnii*
- *Kloeckera* spp.
- *Kodamaea ohmeri*
- *Malassezia furfur*
- *Malassezia pachydermatis*
- *Millerozyma farinosa* (formerly known as *Pichia farinosa*)
- *Prototheca wickerhamii*
- *Prototheca zopfii*
- *Rhodotorula glutinis/Rhodotorula mucilaginosa*
- *Rhodotorula minuta*
- *Saccharomyces cerevisiae*
- *Saprochaete capitata* (formerly known as *Geotrichum capitatum*)
- *Sporobolomyces salmonicolor*
- *Stephanoascus ciferrii*
- *Trichosporon asahii*
- *Trichosporon inkin*
- *Trichosporon mucoides*
- *Zygosaccharomyces bailii*

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Additional Claims For 8.01 or Higher Software Users

- *Candida auris*
- *Candida ciferrii* (formerly known as *Stephanoascus ciferrii*)
- *Candida duobushaemulonii*
- *Candida haemulonii* var *vulnera*
- *Cryptococcus gattii*
- *Zygosaccharomyces* species (includes *Zygosaccharomyces bailii*; *Zygosaccharomyces bailii* is no longer a single species claim)

SUPPLEMENTAL TESTS

Table 18: YST Supplemental Tests

Abbreviation	Test Name	Description	Comment	Reference
For 7.01 or Higher Software Users				
2KG	2-KETO-D-GLUCONATE	Ability to use 2-keto-D-gluconate as a sole carbon source.	N/A	2, 6, 10
4ASCOSPOR.	4 Ascospores	Microscopic examination for the presence of four ascospores per ascus.	N/A	2, 6, 10
Apic.CELLS	APICULATE CELLS	Microscopic examination for the presence of apiculate (lemon-drop shaped) cells.	N/A	2, 6, 10
Arthro.	Arthroconidia	Microscopic examination for the presence of arthroconidia (fragmentation of hyphae into rectangular cells) on morphology agar (e.g., cornmeal agar).	N/A	2, 6, 10
CAROTENOID	CAROTENOID PIGMENT	Presence of red, pink, or orange pigment on Sabouraud dextrose agar.	N/A	2, 6, 7, 10, 15, 16
dCELLOB.a	D-CELLOBIOSE Assimilation	Ability to use cellobiose as the sole carbon source.	N/A	2, 6, 7, 10, 15, 16
CHLS	Chlamydospores	Microscopic examination for the presence of chlamydospores on morphology agar (e.g., cornmeal agar).	N/A	2, 6, 10
DULCITOLa	DULCITOL Assimilation	Ability to use dulcitol (galactitol) as the sole carbon source.	N/A	2, 6, 10

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Abbreviation	Test Name	Description	Comment	Reference
ERYTHRIT.a	ERYTHRITOL Assimilation	Ability to use erythritol as the sole carbon source.	N/A	2, 6, 10
dGALACT.a	D-GALACTOSE Assimilation	Ability to use galactose as the sole carbon source.	N/A	2, 6, 10, 15
dGALf	D-GALACTOSE Fermentation	Production of gas from fermentation of galactose.	N/A	2, 6, 10
dGLUf	D-GLUCOSE Fermentation	Production of gas from fermentation of glucose.	N/A	2, 6, 10
w/o OIL	GROWTH WITHOUT OIL	Ability to grow on Sabouraud dextrose agar without the addition of a fatty acid source (e.g., olive oil).	N/A	2, 6, 7, 10, 16
HYPH/PH	HYPHAE/ PSEUDOHYHPAE	Microscopic examination for the presence of filaments on morphology agar (e.g., cornmeal agar).	N/A	2, 6, 7, 10, 16
INOSITOLa	myo-INOSITOL Assimilation	Ability to use inositol as the sole carbon source.	N/A	2, 6, 10, 15
NITRATEa	NITRATE Assimilation	Ability to use potassium nitrate as the sole nitrogen source.	N/A	2, 6, 7, 10, 14, 16
LACTOSEa	LACTOSE Assimilation	Ability to use lactose as the sole carbon source.	N/A	2, 6, 10
lARABIN.a	L-ARABINOSE Assimilation	Ability to use arabinose as the sole carbon source.	N/A	2, 6, 10
dMALTOSEa	D-MALTOSE Assimilation	Ability to use maltose as the sole carbon source.	N/A	2, 6, 10
dMALf	D-MALTOSE Fermentation	Production of gas from fermentation of maltose.	N/A	2, 6, 10
dMELIBIO.a	D-MELIBIOSE Assimilation	Ability to use melibiose as the sole carbon source.	N/A	2, 6, 10
OX_Phe	Phenol Oxidase	Ability to produce brown to black pigment from phenol oxidase activity on phenolic substrates (e.g., caffeic acid or birdseed agar).	N/A	12

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Abbreviation	Test Name	Description	Comment	Reference
dRAFFIN.a	D-RAFFINOSE Assimilation	Ability to use raffinose as the sole carbon source.	N/A	2, 6, 7, 10, 16
lRHAMNOSEa	L-RHAMNOSE Assimilation	Ability to use rhamnose as the sole carbon source.	N/A	2, 6, 10
SACCHAR.a	SACCHAROSE/ SUCROSE Assimilation	Ability to use sucrose as the sole carbon source.	N/A	2, 6, 10
SACf	SACCAROSE/ SUCROSE Fermentation	Production of gas from fermentation of sucrose.	N/A	2, 6, 10
SATELLITE	SATELLITE behavior	Formation of satellite colonies on Sabouraud dextrose agar.	N/A	2, 6, 10
Sphe.CELLS	Spherical CELLS	Microscopic examination for the presence of spherical cells.	*Candida famata* can be differentiated from *Candida guilliermondii* by the shape of the cells. *Candida famata* has mostly spherical cells while *Candida guilliermondii* has mostly ovoid cells.	2, 6, 10
SPORANGE	SPORANGE	Microscopic examination for the presence of sporangia.	N/A	11
dTREHAL.a	D-TREHALOSE Assimilation	Ability to use trehalose as the sole carbon source.	N/A	2, 6, 10
dTREf	D-TREHALOSE Fermentation	Production of gas from fermentation of trehalose.	N/A	2, 6, 10
UREASE	Urease	Hydrolysis of urea releases ammonia resulting in alkalinization of the medium observed with a pH indicator (e.g., red color formation in the presence of phenol red).	N/A	2, 6, 10
dXYLOSEa	D-XYLOSE Assimilation	Ability to use xylose as the sole carbon source.	N/A	2, 6, 10
For 8.01 or Higher Software Users				
37C	GROWTH AT 37C	Ability to grow at 37°C.	N/A	15
42C	Growth at 42degC	Ability to grow at 42°C.	N/A	2, 15
Cser.AorD	Capsular Serotype A or D	Agglutination tests for capsular serotype A , D or AD.	N/A	18

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Abbreviation	Test Name	Description	Comment	Reference
Cser.BorC	Capsular Serotype B or C	Agglutination tests for capsular serotype B or C.	N/A	18
GLYCEROLa	Glycerol assim.	Ability to use glycerol as the sole carbon source.	N/A	2, 15
INUa	INULIN assimilation	Ability to use inulin as the sole carbon source.	N/A	15
RAFf	RAFFINOSE fermentation	Production of gas from fermentation of raffinose.	N/A	2, 15

REFERENCES

1. Atlas RA. *Handbook of Microbiological Media.* CRC Press, Ann Arbor. 1993.
2. Barnett JA, Payne RW, Yarrow D, editors. *Yeasts: Characteristics and Identification,* 3rd ed. Cambridge University Press, New York. 2000.
3. Bishop JA, Chase N, Magill SS, Kurtzman CP, Fiandaca MJ, Merz WG. *Candida bracarensis* detected among isolates of *Candida glabrata* by peptide nucleic acid fluorescence in situ hybridization: susceptibility data and documentation of presumed infection. J Clin Microbial. 2008; 46:443-446.
4. Clinical and Laboratory Standards Institute, M50-A, Quality Control for Commercial Microbial Identification Systems; Approved Guideline, Vol. 28 No. 23.
5. Clinical Laboratory Improvement Amendments of 1988. 42 U.S.C 263a. PL 100-578. 1988.
6. Kreger-van Rij NJW, editor. *The yeasts — a taxonomic study,* 3rd ed. Elsevier Science Publishers B.V. Amsterdam. 1984.
7. Kurtzman, CP, JW Fell, T Boekhout, editors. *The Yeasts, a Taxonomic Study,* 5th ed. Elsevier, San Diego, CA. 2011.
8. Larone DH. *Medically Important Fungi — a guide to identification.* 3rd ed. ASM Press. American Society for Microbiology. Washington, D.C. 1995.
9. Lockhart SR, Messer SA, Gherna M, Bishop JA, Merz WG, Pfaller MA, Diekema DJ. Identification of *Candida nivariensis* and *Candida bracarensis* in a large global collection of *Candida glabrata* isolates: comparison to the literature. J Clin Microbial. 2009; 47: 1216-1217.
10. Lodder J. *The Yeasts,* Second Edition. North Holland Publishing Company, Netherlands. 1971.
11. McGinnis MR. *Laboratory Handbook of Medical Mycology,* Academic Press, New York. 1980.
12. Murray PR, Baron EJ, Pfaller MA, Tenover FC, Yolken RH, editors. *Manual of Clinical Microbiology,* 7th Edition. American Society for Microbiology, Washington, D.C. 1999.
13. National Committee for Clinical Laboratory Standards, M29-A, Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissue—Approved Guideline. 1997.
14. Pincus DH, Salkin IF, Hurd NH, Levy IL, Kemna MA. Modification of Potassium Nitrate Assimilation Test for Identification of Clinically Important Yeasts. J. Clin. Microbiol. 1988; 26:366-368.
15. Satoh K., K. Makimura, Y.Hasumi, Y.Nishiyama, K. Uchida and H. Yamaguchi. *Candida auris* sp.nov., a novel ascomycetous yeast isolated from the external ear canal of an inpatient in a Japanese hospital. Microbiol Immunol 2009; 53: 41-44.
16. Suh S-O., P. Gujjari, C. Beres, B.Beck and J. Zhou. Proposal of Zygosaccharomyces parabailii sp. nov. and Zygosaccharomyces pseudobailii sp. nov., novel species closely related to Zygosaccharomyces bailii. Int. J. Syst. Evol. Microbial., May 2013; 63: 1922-1929.
17. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health, Office of Health and Safety, Biosafety in Microbiological and Biomedical Laboratories. 1988.
18. Versalovic, J., G. Funke, K.C. Carroll, J.H. Jorgensen, M.L. Landry and D.W. Warnock. 2011. *Manual of Clinical Microbiology*, 10th edition. American Society for Microbiology, Washington, D.C.
19. Kurtzman, C.P., Fell, J.W., Boekhout, T. (eds.) *The Yeasts - A Taxonomic Study*, 5th edn. Amsterdam: Elsevier Science B.V., 2011.
20. Lockhart, S.R., Messer, S.A., Pfaller, M.A., Diekema, D.J. Geographic distribution and antifungal susceptibility of the newly described specied *Candida orthopsilosis* and *Candida metapsilosis* in comparison to the closely related species *Candida parapsilosis*. J Clin Microbiol. 2008; 46:2659-2664.

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Use this Instructions for Use with VITEK® 2 Product No. 21343.

INDEX OF SYMBOLS

Symbol	Meaning
	Catalog number
	In Vitro Diagnostic Medical Device
	Legal Manufacturer
	Temperature limitation
	Use by date
	Batch code
	Consult Instructions for Use
	Date of manufacture
	Contains sufficient for <n> tests
	Authorized representative in the European Community
	For US Only : Caution : US Federal Law restricts this device to sale by or on the order of a licensed practitioner

Instructions for Use provided in the kit or downloadable from www.biomerieux.com/techlib

LIMITED WARRANTY

bioMérieux warrants the performance of the product for its stated intended use provided that all procedures for usage, storage and handling, shelf life (when applicable), and precautions are strictly followed as detailed in the instructions for use (IFU).

Except as expressly set forth above, bioMérieux hereby disclaims all warranties, including any implied warranties of merchantability and fitness for a particular purpose or use, and disclaims all liability, whether direct, indirect or consequential, for any use of the reagent, software, instrument and disposables (the “System”) other than as set forth in the IFU.

WASTE DISPOSAL

All hazardous waste must be disposed of by following your local inspecting agency's guidelines.

REVISION HISTORY TABLE

Change type categories	
N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user

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Note : Minor typographical, grammar, and formatting changes are not included in the revision history.

Release Date	Part Number	Change Type	Change Summary
2019-03	043908-03	Technical change	Updated for 9.02 software release. Updated sections: • Intended Use • Precautions • Culture Requirements • Additional Information on Lab Report • Testing of QC Organisms • Performance Characteristics • Organisms Identified • References
2016-10	043908-02	Technical change	• Updated content to reflect the 8.01 Product Information Manual
2016-05	043908-01	Administrative	• Formatting changes do not affect the fit, form, or function of the product
		Technical change	• New IFU derived from product chapter in the Product Information Manual • Updated Limited Warranty section • Updated with RX only information

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REF 21341

044066- 03 - 2019-03 EN

VITEK® 2 GN

Rx only IVD

INTENDED USE

These Instructions for Use correspond to the VITEK® 2 Systems 7.01 or higher software. If you are not using VITEK® 2 Systems 7.01 or higher software, please refer to the VITEK® 2 Systems Product Information that you received with your current software version.

The VITEK® 2 Gram-Negative identification card (GN) is intended for use with VITEK® 2 Systems for the automated identification of most clinically significant fermenting and non-fermenting Gram-negative bacilli. The VITEK® 2 GN identification card is a single-use disposable. For a list of claimed species, see the Organisms Identified section.

DESCRIPTION

The GN card is based on established biochemical methods[1,2,4,8,9,10,11,12,17,18,20,21,24,25,27] and newly developed substrates measuring carbon source utilization, enzymatic activities, and resistance. There are 47 biochemical tests and one negative control well. The Decarboxylase Negative Control Well (well 52) is used as a baseline reference for the Decarboxylase test wells. Final results are available in approximately 10 hours or less.

For a list of well contents, see the GN Well Contents table.

Table 1: GN Well Contents

Well	Test	Mnemonic	Amount/Well
2	Ala-Phe-Pro-ARYLAMIDASE	APPA	0.0384 mg
3	ADONITOL	ADO	0.1875 mg
4	L-Pyrrolydonyl-ARYLAMIDASE	PyrA	0.018 mg
5	L-ARABITOL	lARL	0.3 mg
7	D-CELLOBIOSE	dCEL	0.3 mg
9	BETA-GALACTOSIDASE	BGAL	0.036 mg
10	H2S PRODUCTION	H2S	0.0024 mg
11	BETA-N-ACETYL-GLUCOSAMINIDASE	BNAG	0.0408 mg
12	Glutamyl Arylamidase pNA	AGLTp	0.0324 mg
13	D-GLUCOSE	dGLU	0.3 mg
14	GAMMA-GLUTAMYL-TRANSFERASE	GGT	0.0228 mg
15	FERMENTATION/ GLUCOSE	OFF	0.45 mg
17	BETA-GLUCOSIDASE	BGLU	0.036 mg
18	D-MALTOSE	dMAL	0.3 mg
19	D-MANNITOL	dMAN	0.1875 mg
20	D-MANNOSE	dMNE	0.3 mg
21	BETA-XYLOSIDASE	BXYL	0.0324 mg
22	BETA-Alanine arylamidase pNA	BAlap	0.0174 mg
23	L-Proline ARYLAMIDASE	ProA	0.0234 mg
26	LIPASE	LIP	0.0192 mg
27	PALATINOSE	PLE	0.3 mg
29	Tyrosine ARYLAMIDASE	TyrA	0.0276 mg
31	UREASE	URE	0.15 mg

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Well	Test	Mnemonic	Amount/Well
32	D-SORBITOL	dSOR	0.1875 mg
33	SACCHAROSE/SUCROSE	SAC	0.3 mg
34	D-TAGATOSE	dTAG	0.3 mg
35	D-TREHALOSE	dTRE	0.3 mg
36	CITRATE (SODIUM)	CIT	0.054 mg
37	MALONATE	MNT	0.15 mg
39	5-KETO-D-GLUCONATE	5KG	0.3 mg
40	L-LACTATE alkalinization	ILATk	0.15 mg
41	ALPHA-GLUCOSIDASE	AGLU	0.036 mg
42	SUCCINATE alkalinization	SUCT	0.15 mg
43	Beta-N-ACETYL-GALACTOSAMINIDASE	NAGA	0.0306 mg
44	ALPHA-GALACTOSIDASE	AGAL	0.036 mg
45	PHOSPHATASE	PHOS	0.0504 mg
46	Glycine ARYLAMIDASE	GlyA	0.012 mg
47	ORNITHINE DECARBOXYLASE	ODC	0.3 mg
48	LYSINE DECARBOXYLASE	LDC	0.15 mg
52	DECARBOXYLASE BASE	0DEC	N/A
53	L-HISTIDINE assimilation	IHISa	0.087 mg
56	COUMARATE	CMT	0.126 mg
57	BETA-GLUCURONIDASE	BGUR	0.0378 mg
58	O/129 RESISTANCE (comp.vibrio.)	O129R	0.0105 mg
59	Glu-Gly-Arg-ARYLAMIDASE	GGAA	0.0576 mg
61	L-MALATE assimilation	IMLTa	0.042 mg
62	ELLMAN	ELLM	0.03 mg
64	L-LACTATE assimilation	ILATa	0.186 mg

Note: Other well numbers between 1 and 64 not designated in this table are empty.

PRECAUTIONS

Note: For industry customers that need assistance on selecting the correct VITEK® 2 identification card, please refer to the VITEK® 2 Compact Instrument User Manual chapter, "Guidance to Select a VITEK® 2 Identification Card."

- For *In Vitro* Diagnostic Use Only.
- For US Only: Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- For professional use only.
- Suspensions not within the appropriate zone on the VITEK® 2 DENSICHEK™ Plus or the VITEK® 2 DENSICHEK™ may compromise card performance.
- Do not use the card after the expiration date shown on the package liner.
- Store the card unopened in the package liner. Do not use the card if the protective package liner is damaged or if no desiccant is present.
- Allow the card to come to room temperature before opening the package liner.
- Do not use powdered gloves. Powder may interfere with the optics.
- Use of culture media other than the recommended types must be validated by the customer laboratory for acceptable performance.
- A Gram stain should be performed to determine an organism’s Gram reaction and morphology prior to selecting the identification card to inoculate.
- The card performs as intended only when used in conjunction with VITEK® 2 Systems, following the instructions contained in these Instructions for Use.

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- **Do not use glass test tubes**. Use clear plastic (polystyrene) tubes only. Variation exists among test tubes of standard diameter. Carefully place the tube into the cassette. If resistance is encountered, discard and try another tube that does not require pressure to insert.
- Prior to inoculation, inspect cards for tape tears or damage to the tape and discard any that are suspect. Check the saline level in the tubes after the cassette has been processed to ensure proper filling of card.
  - VITEK® 2 60 or VITEK® 2 XL: Eject improperly filled cards.
  - VITEK® 2 Compact: Do not load improperly filled cards.
- Give special consideration to specimen source and patient drug or antimicrobic regimen.
- Interpretation of test results requires the judgment and skill of a person knowledgeable in microbial identification testing. Additional testing may be required. (See the Supplemental Tests section.)
- Do not clean saline dispenser with chemical agents. The use of chemical agents may impact card performance.

Warning: All patient specimens, microbial cultures, and inoculated VITEK® 2 cards, along with associated materials, are potentially infectious and should be treated with universal precautions.[23,26] It is suggested that highly pathogenic species such as *Brucella melitensis*, *Burkholderia mallei*, *Burkholderia pseudomallei*, *Escherichia coli O157*, *Francisella tularensis*, and *Yersinia pestis* be sent to your state health laboratory or other suitable reference laboratory for confirmation.

Warning: All hazardous waste must be disposed of by following your local inspecting agency's guidelines.

STORAGE CONDITIONS

Upon receipt, store VITEK® 2 GN cards unopened in their original package liner at 2°C to 8°C.

SPECIMEN PREPARATION

For specimen preparation information, see the Culture Requirements Table.

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Table 2: Culture Requirements Table

VITEK® 2 Card	Media	Age of Culture[1]	Incubation Conditions	McFarland Standards	Dilution for AST	Age of Suspension Before Loading Instrument
GN	TSA[2,3] CBA[2,3] MAC[2,3] BCP CET CLED CHOC CHOC PVX CHBA CNT CPS ID DENA DRIG HEK SM ID TSAHB TSAB TSAL VRBG XLD	18 to 24 hours	35°C to 37°C Aerobic, non-CO_2	0.50 to 0.63 McFarland Standard	N/A[4]	≤ 30 minutes
GN and AST GN pair	CBA MAC TSAB CPS ID	18 to 24 hours	35°C to 37°C Aerobic, non-CO_2	0.50 to 0.63 McFarland Standard	145 µL in 3.0 mL saline	< 30 minutes

[1]Cultures with scant or poor growth may give unidentified or incorrect results even when the Age of Culture requirements are met.

[2]These media were used in the identification product database development and will give optimal performance.

[3]OMA Official Methods of Analysis validated medium.

[4]N/A = not applicable

Culture Requirements Table — Media Abbreviations

BCP = Bromcresol Purple Agar

CBA = Columbia Blood Agar with 5% Sheep Blood

CET = Cetrimide Agar

CHBA = Columbia Horse Blood Agar

CHOC = Chocolate Agar

CHOC PVX = Chocolate Polyvitex

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CLED = Cystine Lactose Electrolyte Deficient Agar

CNT = Count-TACT® (irradiated) Trypticase Soy Agar

CPS ID = chromID™ CPS (CPS ID agar)

DENA = DE Neutralizing Agar

DRIG = Drigalski Agar

HEK = Hektoen Agar

MAC = MacConkey Agar

SM ID = chromID™Salmonella (SM ID2 Agar)

TSA = Trypticase Soy Agar

TSAB = Trypticase Soy Agar with 5% Sheep Blood

TSAHB = Trypticase Soy Agar with 5% Horse Blood

TSAL = TSA with Lecithin and P80

VRBG = Violet Red Bile Glucose Agar

XLD = Xylose Lysine Desoxycholate

Materials

When used with VITEK® 2 instrumentation, the GN card is a complete system for routine identification testing of most significant fermenting and non-fermenting Gram-negative bacilli.

Required materials are:

- VITEK® 2 GN Card
- DENSICHEK™ Plus Kit or VITEK® DENSICHEK® Kit
- DENSICHEK™ Plus Standards Kit or DENSICHEK® Standards Kit
- VITEK® 2 Cassette
- Sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- 12 mm x 75 mm clear plastic (polystyrene) disposable test tubes
- Sterile sticks or swabs
- Appropriate agar medium (see Culture Requirements table).

Optional accessories:

- Adjustable volume saline dispenser
- Loops
- Pre-dispensed saline test tubes (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Test tube caps
- Vortex

Procedure

Warning: Failure to follow instructions and recommendations provided in this section for performing laboratory tasks may cause erroneous or delayed results.

For product-specific information, see the Culture Requirements table.

Note: Prepare the inoculum from a pure culture, according to good laboratory practices. In case of mixed cultures, a re-isolation step is required. It is recommended that a purity check plate be done to ensure that a pure culture was used for testing.

1. Do one of the following:
   - Select isolated colonies from a primary plate if culture requirements are met.
   - Subculture the organism to be tested to appropriate agar medium and incubate accordingly.
2. Aseptically transfer 3.0 mL of sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0) into a clear plastic (polystyrene) test tube (12 mm x 75 mm).

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3. Use a sterile stick or swab to transfer a sufficient number of morphologically similar colonies to the saline tube prepared in step 2. Prepare a homogenous organism suspension with a density equivalent to a McFarland No. 0.50 to 0.63 using a calibrated VITEK® 2 DENSICHEK™ Plus or VITEK® 2 DENSICHEK™.
   Note: Age of suspension must not exceed 30 minutes before inoculating card.
4. Place the suspension tube and GN card in the cassette.
5. Refer to the appropriate Instrument User Manual for instructions on data entry and how to load the cassette into the instrument.
6. Follow your local inspecting agency's guidelines for disposal of hazardous waste.

RESULTS

Identification Analytical Techniques

VITEK® 2 Systems identify an organism by using a methodology based on the characteristics of the data and knowledge about the organism and reactions being analyzed. Sufficient data have been collected from known strains to estimate the typical reactions of the claimed species to a set of discriminating biochemicals. If a unique identification pattern is not recognized, a list of possible organisms is given, or the strain is determined to be outside the scope of the database.

The printed lab report contains suggestions for any supplemental tests necessary to complete the identification. If the tests are not sufficient to complete the identification, then standard microbiology references and literature should be consulted.

Certain species may belong to a slashline (mixed) taxa identification. This occurs when the biopattern is the same for the taxa listed. Supplemental tests may be used to separate slashline taxa. The species in the GN Slashline Taxa table belong to the GN slashline taxa.

Table 3: GN Slashline Taxa

Slashline Name	Species Belonging to the Slashline
For 7.01 or Higher Software Users	
Acinetobacter baumannii complex	*Acinetobacter baumannii* *Acinetobacter calcoaceticus* *Acinetobacter pittii* (*Acinetobacter* genomospecies 3) *Acinetobacter nosocomialis* (*Acinetobacter* genomospecies TU13)
Brevundimonas diminuta/vesicularis	*Brevundimonas diminuta* *Brevundimonas vesicularis*
Burkholderia cepacia group	*Burkholderia cepacia* *Burkholderia multivorans* *Burkholderia stabilis* *Burkholderia vietnamiensis*
Enterobacter cloacae complex	*Enterobacter cloacae* ssp. *cloacae* *Enterobacter hormaechei* *Enterobacter kobei* *Enterobacter ludwigii* *Enterobacter cloacae* ssp. *dissolvens*
Moraxella group	*Moraxella lacunata* *Moraxella nonliquefaciens* *Moraxella osloensis*
Neisseria animaloris/zoodegmatis	*Neisseria animaloris* *Neisseria zoodegmatis*

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Slashline Name	Species Belonging to the Slashline
Salmonella group	*Salmonella enterica* ssp. *enterica* *Salmonella* ser. Enteritidis *Salmonella* ser. Paratyphi B *Salmonella* ser. Paratyphi C *Salmonella* spp. *Salmonella* ser. Typhimurium
Serratia liquefaciens group	*Serratia grimesii* *Serratia liquefaciens* *Serratia proteamaculans*
Shigella group	*Shigella boydii* *Shigella dysenteriae* *Shigella flexneri*
Yersinia enterocolitica/frederiksenii	*Yersinia enterocolitica* *Yersinia frederiksenii*
For 7.01, 8.01, and 9.01 Software Users	
Aeromonas hydrophila/caviae	*Aeromonas caviae* *Aeromonas hydrophila*
Cronobacter sakazakii group	*Cronobacter genomospecies 1* *Cronobacter dublinensis* ssp. *dublinensis* *Cronobacter dublinensis* ssp. *lausannensis* *Cronobacter dublinensis* ssp. *lactaridi* *Cronobacter malonaticus* *Cronobacter sakazakii* *Cronobacter turicensis* *Cronobacter muytjensii*
For 9.02 Software Users	
Aeromonas hydrophila/punctata (caviae)	*Aeromonas punctata (caviae)* *Aeromonas hydrophila*
Cronobacter sakazakii group	*Cronobacter universalis* *Cronobacter dublinensis* ssp. *dublinensis* *Cronobacter dublinensis* ssp. *lausannensis* *Cronobacter dublinensis* ssp. *lactaridi* *Cronobacter malonaticus* *Cronobacter sakazakii* *Cronobacter turicensis* *Cronobacter muytjensii*

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Table 4: Identification Card Qualifying Messages

ID Message Confidence Level	Choices	% Probability	Comments
Excellent	1	96 to 99	N/A
Very Good	1	93 to 95	N/A
Good	1	89 to 92	N/A
Acceptable	1	85 to 88	N/A
Low Discrimination	2 to 3	Sum of choices = 100; after resolution to one choice, percent probability reflects the number associated with selected choice.	Two to three taxa exhibit same biopattern. Separate by supplemental testing. Must resolve to mate with susceptibility card.
Inconclusive or Unidentified Organism	>3 or 0	N/A	Either > 3 taxa exhibit same biopattern or Very atypical biopattern. Does not correspond to any taxon in the database. Check Gram stain and purity.

PERCENT PROBABILITY

As part of the identification process, the software compares the test set of reactions to the expected set of reactions of each organism, or organism group, that can be identified by the product. A quantitative value, the percent probability, is calculated and relates to how well the observed reactions compare to the typical reactions of each organism. A perfect match between the test reaction pattern and the unique reaction pattern of a single organism, or organism group, would provide a percent probability of 99. When a perfect match is not obtained, it is still possible for the reaction pattern to be sufficiently close to that of an expected reaction pattern such that a clear decision can be provided about the organism identification. The range of percent probabilities in the one-choice case is 85 to 99. Values closer to 99 indicate a closer match to the typical pattern for the given organism.

When the reaction pattern is not sufficient to discriminate between two to three organisms, the percent probabilities reflect this ambiguity. The reported probability values indicate, relatively, the order in which the reaction pattern best corresponds to the listed possibilities. The order does not, however, suggest that the pattern match to one of the possible identifications is clearly superior to another. The probability characteristic of an overall sum of 100 is retained through the calculation process. After resolution to one choice, the probability characteristic of the single choice is retained.

ADDITIONAL INFORMATION ON LAB REPORT

Supplemental test — External (offline) test that allows the user to resolve a slashline or Low Discrimination identification. Numbers in parentheses indicate percent positive reaction for the species/test listed.

Contraindicating test — Test result that is unusual for a reported taxon.

Table 5: Notes Associated with Certain Taxa

Taxa	Note
For 7.01 or Higher Software Users	

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Taxa	Note
Brucella melitensis	**Important!** Presumptive Identification Highly pathogenic organism. The following are included in an identification of Brucella melitensis: *Brucella melitensis abortus* *Brucella melitensis canis* *Brucella melitensis melitensis* *Brucella melitensis neotamae* *Brucella melitensis ovis* *Brucella melitensis suis*
Burkholderia mallei	**Important!** Presumptive Identification Highly pathogenic organism.
Burkholderia pseudomallei	Highly pathogenic organism. Isolates of *Burkholderia thailandensis* are biochemically similar to *Burkholderia pseudomallei.* Since the possibility of *Burkholderia thailandensis* exists, the user should send the isolate to their state lab or other suitable reference laboratory for confirmation.
Escherichia coli O157	Confirm by serological tests. Highly pathogenic organism.
Francisella tularensis	Confirm by serological tests. Highly pathogenic organism.
Salmonella enterica ssp. *arizonae* *Salmonella enterica* ssp. *diarizonae* *Salmonella* group *Salmonella* ser. Gallinarum *Salmonella* ser. Paratyphi A *Salmonella* ser. Typhi	Confirm by serological tests.
Shigella group *Shigella sonnei*	Confirm by serological tests.
Vibrio cholerae	Critical pathogen. The species identified may have significance to patient or sample outcome and can be stopped for review.
Yersinia pestis	**Important!** Presumptive Identification Highly pathogenic organism.
For 9.02 Software Users	
Ochrobactrum anthropi	Possibility of *Brucella* spp.

Notes Associated with an Improperly Filled Card or with a Negative Profile (Biopattern)

- For the case where the time between two readings is greater than 40 minutes: “CARD ERROR — Missing data.”
- For the case where there is a negative profile: “Organism with low reactivity biopattern — please check viability.”
- When a biopattern is calculated for an unknown organism that is completely negative or consists of both negative tests and tests that fall within the uncertainty zone, the identification call will be “Non or low reactive biopattern.”

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The following species could potentially trigger this note if a test was atypical or fell within the uncertainty zone:

- *Acinetobacter haemolyticus*
- *Acinetobacter lwoffii*
- *Actinobacillus ureae*
- *Aeromonas salmonicida*
- *Brucella melitensis*
- *Francisella tularensis*
- *Methylobacterium* spp.
- *Moraxella lacunata*
- *Moraxella nonliquefaciens*
- *Moraxella osloensis*
- *Pasteurella multocida*
- *Pseudomonas alcaligenes*
- *Pseudomonas fluorescens*
- *Pseudomonas stutzeri*

QUALITY CONTROL

Quality control organisms and their expected results are listed in the VITEK® 2 GN Quality Control Tables. Process these according to the procedure for test isolates outlined in this document.

Certification Statement

This is to certify that bioMérieux complies with ISO 13485 and FDA Quality System Regulation (QSR) requirements for design, development, and manufacture of microbial identification systems.

Frequency of Testing

Currently, it is recommended that you use your most stringent inspecting agency's guidelines for frequency of identification product testing.

Common practice is to perform QC upon receipt of shipment of the test kits. Reactions must follow Instructions for Use results.

If the results do not meet the criteria, subculture for purity and repeat the test. If discrepant results are repeated, perform an alternate identification method and contact bioMérieux.

Testing and Storage of QC Organisms

1. Rehydrate the organism according to the manufacturer's instructions.
2. Use Trypticase Soy agar with 5% sheep blood agar (TSAB). Incubate aerobically at 35°C to 37°C for approximately 18 to 24 hours.
3. Check for purity. Perform second subculture for testing.
4. Use Trypticase Soy agar with 5% sheep blood agar (TSAB). Incubate aerobically at 35°C to 37°C for approximately 18 to 24 hours.

Short-Term Storage Conditions

1. Streak to a TSAB plate or slant.
2. Incubate for 24 hours at 35°C to 37°C.
3. Refrigerate at 2°C to 8°C for up to two weeks.
4. Subculture once as described above and use for QC.

Long-Term Storage Conditions

1. Make a heavy suspension in Tryptic Soy Broth (TSB) with 15% glycerol.
2. Freeze at -70°C.
3. Subculture to TSAB twice before running QC.

Note: Avoid repeated thawing and refreezing by either freezing in single-use aliquots or removing a small portion of frozen organism preparation with a sterile applicator stick.

STREAMLINED QUALITY CONTROL

Note: Industrial Use Only laboratories should perform quality control following the Streamlined Quality Control section. No additional testing is required for these users.

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As there are no substrates that are consistently sensitive to degradation during shipping conditions, streamlined quality control may be conducted by testing two strains: one that is mostly positive and the other which is mostly negative for reactions on GN. See the GN Quality Control tables.

COMPREHENSIVE QUALITY CONTROL

Customers who do not qualify for streamlined quality control testing are required to perform comprehensive quality control testing, which entails demonstration of a positive and negative reaction for each substrate of an identification product.[6]

In order to qualify initially for streamlined quality control testing, the CLSI® M50-A standard requires that the user perform and document either of the following:[5]

- Verification testing to show that performance is equivalent to the manufacturer's claims.
- Comprehensive quality control testing of at least three lots over at least three different seasons.

Refer to the complete CLSI® M50-A standard for information regarding continued qualification and further details of requirements and responsibilities for both the user and the manufacturer related to streamlined quality control testing.

GN Quality Control Tables:

***Enterobacter hormaechei* ATCC® 700323™** (for streamlined or comprehensive quality control)

***Stenotrophomonas maltophilia* ATCC® 17666™** (for streamlined or comprehensive quality control)

***Acinetobacter baumannii* ATCC® BAA-747™** (for comprehensive quality control)

***Elizabethkingia meningoseptica* ATCC® 13253™** (for comprehensive quality control)

***Klebsiella oxytoca* ATCC® 700324™** (for comprehensive quality control)

***Ochrobactrum anthropi* ATCC® BAA-749™** (for comprehensive quality control)

***Proteus vulgaris* ATCC® 6380™** (for comprehensive quality control)

***Pseudomonas aeruginosa* ATCC® 9721™** (for comprehensive quality control)

***Pseudomonas aeruginosa* ATCC® BAA-1744™** (for comprehensive quality control)

Note: *Pseudomonas aeruginosa* ATCC® BAA-1744™ may contain two morphologically distinct colony types; however, either will provide proper expected reactions when tested for quality control.

For 7.01 Software Users

***Shigella sonnei* ATCC® 25931™** (for comprehensive quality control)

For 8.01 or Higher Software Users

***Escherichia coli* ATCC® 25922™** (for comprehensive quality control)

The GN card typically identifies the quality control organisms as one-choice or within a low discrimination or slashline identification. However, strains are chosen for reaction performance over identification performance. Therefore, an unidentified or misidentified result may occur when all expected quality control reactions are correct.

Table 6: QC Organism: *Enterobacter hormaechei* ATCC® 700323™ (for streamlined or comprehensive quality control)

APPA	-	AGLTp	-	BXYL	+	SAC	+	SUCT	v	CMT	-
ADO	+	dGLU	+	BAlap	-	dTAG	-	NAGA	+	BGUR	v
PyrA	-	GGT	+	ProA	v	dTRE	+	AGAL	+	O129R	+
IARL	-	OFF	+	LIP	v	CIT	+	PHOS	v	GGAA	-
dCEL	+	BGLU	-	PLE	+	MNT	+	GlyA	v	IMLTa	-
BGAL	+	dMAL	+	TyrA	v	5KG	-	ODC	+	ELLM	-
H2S	-	dMAN	+	URE	-	ILATk	v	LDC	-	ILATa	-
BNAG	+	dMNE	+	dSOR	+	AGLU	-	IHISa	-		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 7: QC Organism: *Stenotrophomonas maltophilia* ATCC® 17666™ (for streamlined or comprehensive quality control)

APPA	+	AGLTp	-	BXYL	-	SAC	-	SUCT	v	CMT	-

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ADO	-	dGLU	-	BAlap	-	dTAG	-	NAGA	-	BGUR	-
PyrA	-	GGT	v	ProA	+	dTRE	-	AGAL	-	0129R	-
lARL	-	OFF	-	LIP	+	CIT	v	PHOS	+	GGAA	+
dCEL	-	BGLU	v	PLE	-	MNT	v	GlyA	-	IMLTa	-
BGAL	-	dMAL	-	TyrA	v	5KG	-	ODC	-	ELLM	-
H2S	-	dMAN	-	URE	-	ILATk	v	LDC	v	ILATa	-
BNAG	v	dMNE	-	dSOR	-	AGLU	v	lHISa	-		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 8: QC Organism: *Acinetobacter baumannii* ATCC® BAA-747™ (for comprehensive quality control)

APPA	v	AGLTp	v	BXYL	v	SAC	v	SUCT	+	CMT	v
ADO	v	dGLU	v	BAlap	v	dTAG	v	NAGA	v	BGUR	v
PyrA	v	GGT	v	ProA	v	dTRE	v	AGAL	v	O129R	v
lARL	v	OFF	v	LIP	v	CIT	+	PHOS	–	GGAA	v
dCEL	v	BGLU	v	PLE	v	MNT	+	GlyA	v	IMLTa	v
BGAL	v	dMAL	v	TyrA	+	5KG	v	ODC	v	ELLM	v
H2S	v	dMAN	v	URE	v	ILATk	+	LDC	v	ILATa	v
BNAG	v	dMNE	v	dSOR	v	AGLU	v	lHISa	+		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 9: QC Organism: *Elizabethkingia meningoseptica* ATCC® 13253™ (for comprehensive quality control)

APPA	+	AGLTp	+	BXYL	v	SAC	v	SUCT	–	CMT	v
ADO	v	dGLU	–	BAlap	v	dTAG	v	NAGA	+	BGUR	v
PyrA	+	GGT	v	ProA	v	dTRE	v	AGAL	v	O129R	v
lARL	v	OFF	–	LIP	v	CIT	v	PHOS	v	GGAA	+
dCEL	v	BGLU	v	PLE	v	MNT	v	GlyA	+	IMLTa	v
BGAL	v	dMAL	v	TyrA	v	5KG	v	ODC	v	ELLM	v
H2S	v	dMAN	v	URE	v	ILATk	–	LDC	v	ILATa	v
BNAG	+	dMNE	v	dSOR	v	AGLU	+	lHISa	v		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 10: QC Organism: *Klebsiella oxytoca* ATCC® 700324™ (for comprehensive quality control)

APPA	–	AGLTp	v	BXYL	v	SAC	v	SUCT	v	CMT	v
ADO	+	dGLU	+	BAlap	v	dTAG	+	NAGA	v	BGUR	–
PyrA	v	GGT	–	ProA	–	dTRE	+	AGAL	+	O129R	v
lARL	+	OFF	+	LIP	–	CIT	v	PHOS	v	GGAA	–
dCEL	+	BGLU	+	PLE	+	MNT	v	GlyA	–	IMLTa	v
BGAL	+	dMAL	v	TyrA	v[2]	5KG	v[1]	ODC	–	ELLM	v
H2S	v	dMAN	+	URE	+	ILATk	v	LDC	+	ILATa	v
BNAG	–	dMNE	+	dSOR	v	AGLU	–	lHISa	v		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

[1]Reaction is mostly positive although occasional negative reaction may occur.

[2]Reaction is mostly negative although occasional positive reaction may occur.

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Table 11: QC Organism: *Ochrobactrum anthropi* ATCC® BAA-749™ (for comprehensive quality control)

APPA	v	AGLTp	v	BXYL	v	SAC	v	SUCT	v	CMT	v
ADO	v	dGLU	v	BAlap	v	dTAG	v	NAGA	v	BGUR	v
PyrA	+	GGT	v	ProA	+	dTRE	v	AGAL	v	O129R	–
lARL	v	OFF	v	LIP	v	CIT	v	PHOS	–	GGAA	v
dCEL	v	BGLU	v	PLE	v	MNT	v	GlyA	+	IMLTa	v
BGAL	v	dMAL	v	TyrA	v	5KG	v	ODC	v	ELLM	+
H2S	v	dMAN	v	URE	v	ILATk	v	LDC	v	ILATa	v
BNAG	v	dMNE	v	dSOR	v	AGLU	v	lHISa	v		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 12: QC Organism: *Proteus vulgaris* ATCC® 6380™ (for comprehensive quality control)

APPA	v	AGLTp	v	BXYL	v	SAC	+	SUCT	v	CMT	v
ADO	–	dGLU	v	BAlap	v	dTAG	v	NAGA	v	BGUR	v
PyrA	v	GGT	v	ProA	–	dTRE	–	AGAL	–	O129R	v
lARL	v	OFF	v	LIP	–	CIT	v	PHOS	+	GGAA	v
dCEL	–	BGLU	+	PLE	v	MNT	–	GlyA	v	IMLTa	v
BGAL	–	dMAL	v	TyrA	v	5KG	v	ODC	v	ELLM	+
H2S	+	dMAN	–	URE	+	ILATk	v	LDC	–	ILATa	v
BNAG	v	dMNE	–	dSOR	–	AGLU	v	lHISa	v		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 13: QC Organism: *Pseudomonas aeruginosa* ATCC® 9721™ (for comprehensive quality control)

APPA	v	AGLTp	v	BXYL	v	SAC	v	SUCT	v	CMT	v
ADO	v	dGLU	v	BAlap	+	dTAG	v	NAGA	v	BGUR	v
PyrA	v	GGT	v	ProA	v	dTRE	v	AGAL	v	O129R	v
lARL	v	OFF	v	LIP	v	CIT	v	PHOS	v	GGAA	v
dCEL	v	BGLU	v	PLE	v	MNT	v	GlyA	v	IMLTa	v
BGAL	v	dMAL	–	TyrA	v	5KG	v	ODC	v	ELLM	v
H2S	v	dMAN	v	URE	v	ILATk	+	LDC	v	ILATa	v
BNAG	v	dMNE	v	dSOR	v	AGLU	v	lHISa	v		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 14: QC Organism: *Pseudomonas aeruginosa* ATCC® BAA-1744™ (for comprehensive quality control)

APPA	v	AGLTp	v	BXYL	v	SAC	v	SUCT	v	CMT	+
ADO	v	dGLU	v	BAlap	v	dTAG	v	NAGA	v	BGUR	v
PyrA	v	GGT	v	ProA	v	dTRE	v	AGAL	v	O129R	v
lARL	v	OFF	v	LIP	v	CIT	v	PHOS	v	GGAA	v
dCEL	v	BGLU	v	PLE	v	MNT	v	GlyA	v	IMLTa	+
BGAL	v	dMAL	v	TyrA	v	5KG	v	ODC	v	ELLM	v
H2S	v	dMAN	v	URE	v	ILATk	v	LDC	v	ILATa	v[1]
BNAG	v	dMNE	v	dSOR	v	AGLU	v	lHISa	v		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

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[1]Reaction is mostly positive although occasional negative reaction may occur.

Note: Culture may contain two morphologically distinct colony types; however, either will provide proper expected reactions when tested for quality control.

For 7.01 Software Users

Table 15: QC Organism: *Shigella sonnei* ATCC® 25931™ (for comprehensive quality control)

APPA	v	AGLTp	v	BXYL	–	SAC	–	SUCT	v	CMT	+
ADO	v	dGLU	v	BAlap	v	dTAG	v	NAGA	–	BGUR	+
PyrA	v	GGT	–	ProA	v	dTRE	v	AGAL	v	O129R	v
lARL	v	OFF	v	LIP	v	CIT	–	PHOS	v	GGAA	v
dCEL	v	BGLU	–	PLE	–	MNT	–	GlyA	v	IMLTa	v
BGAL	v	dMAL	+	TyrA	+	5KG	v	ODC	+	ELLM	v
H2S	v	dMAN	v	URE	v	lLATk	v	LDC	v	lLATa	v
BNAG	–	dMNE	v	dSOR	v	AGLU	v	lHISa	v		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

For 8.01 or Higher Software Users

Table 16: QC Organism: *Escherichia coli* ATCC® 25922™ (for comprehensive quality control)

APPA	v	AGLTp	v	BXYL	–	SAC	–	SUCT	v	CMT	+
ADO	v	dGLU	v	BAlap	v	dTAG	v	NAGA	–	BGUR	+
PyrA	v	GGT	–	ProA	v	dTRE	v	AGAL	v	O129R	v
lARL	v	OFF	v	LIP	v	CIT	–	PHOS	v	GGAA	v
dCEL	v	BGLU	–	PLE	–	MNT	–	GlyA	v	IMLTa	v
BGAL	v	dMAL	+	TyrA	+	5KG	v	ODC	+	ELLM	v
H2S	v	dMAN	v	URE	v	lLATk	v	LDC	v	lLATa	v
BNAG	–	dMNE	v	dSOR	v	AGLU	v	lHISa	v		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

LIMITATIONS

The VITEK® 2 GN card cannot be used with direct clinical samples or other sources containing mixed flora. Any change or modification in the procedure may affect the results.

Newly described or rare species may not be included in the GN database. Selected species will be added as strains become available.

Warning: Testing of unclaimed species may result in an unidentified result or a misidentification.

PERFORMANCE CHARACTERISTICS

For 7.01 Software Users

In a multi-site clinical study*, the performance of the VITEK® 2 GN identification card was evaluated using 562 clinical and stock isolates of both commonly and rarely observed species of gram-negative bacilli, including 153 non-fermentative strains. The reference identification was determined with API® 20 E and API® 20 NE identification kits. Overall, the VITEK® 2 GN correctly identified 96.2% of the isolates, including 6.8% low discrimination with the correct species listed. Misidentifications occurred at 3.4% and no identifications occurred at 0.4%.

For 8.01 and 9.01 Software Users

In a multi-site clinical study*, the performance of the VITEK® 2 GN identification card was evaluated using 562 clinical and stock isolates of both commonly and rarely observed species of gram-negative bacilli, including 153 non-fermentative strains. The reference identification was determined with API® 20 E and API® 20 NE identification kits. Overall, the VITEK® 2 GN correctly identified 95.4% of the isolates, including 6.6% low discrimination with the correct species listed. Misidentifications occurred at 4.1% and no identifications occurred at 0.5%.

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For 9.02 Software Users

In a multi-site clinical study*, the performance of the VITEK® 2 GN identification card was evaluated using 562 clinical and stock isolates of both commonly and rarely observed species of gram-negative bacilli, including 153 non-fermentative strains. The reference identification was determined with API® 20 E and API® 20 NE identification kits. Overall, the VITEK® 2 GN correctly identified 95.2% of the isolates, including 6.4% low discrimination with the correct species listed. Misidentifications occurred at 4.3% and no identifications occurred at 0.5%.

*Data on file at bioMérieux, Inc.

ORGANISMS IDENTIFIED

Claims are for all software users unless otherwise stated.

Enterobacteriaceae

- *Budvicia aquatica*
- *Buttiauxella agrestis*
- *Cedecea davisae**
- *Cedecea lapagei**
- *Citrobacter amalonaticus**
- *Citrobacter braakii**
- *Citrobacter farmeri**
- *Citrobacter freundii**
- *Citrobacter koseri**
- *Citrobacter sedlakii*
- *Citrobacter youngae**
- *Cronobacter sakazakii* group+
- *Edwardsiella hoshinae**
- *Edwardsiella tarda**
- *Enterobacter aerogenes**
- *Enterobacter amnigenus* 1*
- *Enterobacter amnigenus* 2*
- *Enterobacter asburiae**
- *Enterobacter cancerogenus**
- *Enterobacter cloacae* complex+
- *Escherichia coli**
- *Escherichia coli* O157*
- *Escherichia fergusonii**
- *Enterobacter gergoviae**
- *Escherichia hermannii**
- *Escherichia vulneris**
- *Ewingella americana**
- *Hafnia alvei**
- *Klebsiella oxytoca **
- *Klebsiella pneumoniae* ssp. *ozaenae*
- *Klebsiella pneumoniae* ssp. *pneumoniae**
- *Klebsiella pneumoniae* ssp. *rhinoscleromatis*
- *Kluyvera ascorbata**
- *Kluyvera cryocrescens*
- *Kluyvera intermedia** (formerly known as *Enterobacter intermedius*)
- *Leclercia adecarboxylata**
- *Moellerella wisconsensis**
- *Morganella morganii* ssp. *morganii**
- *Morganella morganii* ssp. *sibonii*
- *Pantoea agglomerans**
- *Pantoea* spp.

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- *Plesiomonas shigelloides*
- *Proteus hauseri*
- *Proteus mirabilis**
- *Proteus penneri**
- *Proteus vulgaris*
- *Providencia alcalifaciens**
- *Providencia rettgeri*
- *Providencia rustigianii*
- *Providencia stuartii**
- *Rahnella aquatilis**
- *Raoultella ornithinolytica*
- *Raoultella planticola*
- *Salmonella enterica* ssp. *arizonae**
- *Salmonella enterica* ssp. *diarizonae*
- *Salmonella* group*
- *Salmonella* ser. *Gallinarum**
- *Salmonella* ser. Paratyphi A*
- *Salmonella* ser. *Typhi**
- *Serratia ficaria**
- *Serratia fonticola**
- *Serratia liquefaciens* group*
- *Serratia marcescens**
- *Serratia odorifera**
- *Serratia plymuthica**
- *Serratia rubidaea**
- *Shigella* group*
- *Shigella sonnei**
- *Yersinia aldovae*
- *Yersinia enterocolitica/frederiksenii**
- *Yersinia intermedia**
- *Yersinia kristensenii**
- *Yersinia pestis*
- *Yersinia pseudotuberculosis**
- *Yersinia ruckeri**
- *Yokenella regensburgei*

Additional Claims and Taxonomy Changes For 8.01 or Higher Software Users

- *Hafnia paralvei*
- *Lelliottia amnigena* 1* (formerly known as *Enterobacter amnigenus* 1)
- *Lelliottia amnigena* 2* (formerly known as *Enterobacter amnigenus* 2)
- *Pandoraea* spp.
- *Pluralibacter gergoviae** (formerly known as *Enterobacter gergoviae*)
- *Ralstonia insidiosa*
- *Tatumella ptyseos*

Additional Claims For 9.02 Software Users

- *Citrobacter werkmanii*

Non-*Enterobacteriaceae*

- *Achromobacter denitrificans*
- *Achromobacter xylosoxidans*
- *Acinetobacter baumannii* complex
- *Acinetobacter haemolyticus*

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- *Acinetobacter junii*
- *Acinetobacter lwoffii*
- *Acinetobacter radioresistens*
- *Acinetobacter ursingii*
- *Actinobacillus ureae*
- *Aeromonas hydrophila/Aeromonas caviae*
- *Aeromonas salmonicida*
- *Aeromonas sobria*
- *Aeromonas veronii*
- *Alcaligenes faecalis* ssp. *faecalis*
- *Bordetella bronchiseptica*
- *Bordatella hinzii*
- *Bordetella trematum*
- *Brevundimonas diminuta/vesicularis*
- *Brucella melitensis*
- *Burkholderia cepacia* group+
- *Burkholderia gladioli**
- *Burkholderia mallei*
- *Burkholderia pseudomallei*
- *Chromobacterium violaceum*
- *Chryseobacterium gleum*
- *Chryseobacterium indologenes*
- *Comamonas testosteroni*
- *Cupriavidus pauculus*
- *Delftia acidovorans*
- *Elizabethkingia meningoseptica*
- *Francisella tularensis*
- *Grimontia hollisae*
- *Mannheimia haemolytica*
- *Methylobacterium* spp.
- *Moraxella* group
- *Myroides* spp.
- *Neisseria animaloris/zoodegmatis*
- *Ochrobactrum anthropi*
- *Oligella ureolytica*
- *Paracoccus yeei*
- *Pasteurella aerogenes*
- *Pasteurella canis*
- *Pasteurella dagmatis*
- *Pasteurella multocida*
- *Pasteurella pneumotropica*
- *Pasteurella testudinis*
- *Photobacterium damselae*
- *Pseudomonas aeruginosa**
- *Pseudomonas alcaligenes*
- *Pseudomonas fluorescens**
- *Pseudomonas luteola*
- *Pseudomonas mendocina*
- *Pseudomonas oleovorans*
- *Pseudomonas oryzihabitans*
- *Pseudomonas putida*
- *Pseudomonas stutzeri*

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- *Ralstonia mannitolilytica*
- *Ralstonia pickettii*
- *Rhizobium radiobacter*
- *Roseomonas gilardii*
- *Shewanella algae*
- *Shewanella putrefaciens*
- *Sphingobacterium multivorum*
- *Sphingobacterium spiritivorum*
- *Sphingobacterium thalpophilum*
- *Sphingomonas paucimobilis*
- *Stenotrophomonas maltophilia*
- *Vibrio alginolyticus**
- *Vibrio cholerae**
- *Vibrio fluvialis**
- *Vibrio metschnikovii**
- *Vibrio mimicus**
- *Vibrio parahaemolyticus**
- *Vibrio vulnificus**

Additional Claims For 8.01 or Higher Software Users

- *Pandoraea* species
- *Ralstonia insidiosa*

Additional Claims and Taxonomy Changes For 9.02 Software Users

- *Aeromonas hydrophila/Aeromonas punctata* (formerly known as *Aeromonas caviae*)
- *Bergeyella zoohelcum*

Highly Pathogenic Organisms

- *Brucella melitensis**
- *Burkholderia mallei**
- *Burkholderia pseudomallei**
- *Escherichia coli* O157*
- *Francisella tularensis**
- *Yersinia pestis**

* OMA Official Methods of Analysis validated claim.

+ Species within this group or complex that are OMA Official Methods of Analysis validated claims are *Burkholderia cepacia*, *Cronobacter sakazakii*, and *Enterobacter cloacae*.

SUPPLEMENTAL TESTS

Table 17: GN Supplemental Tests

Abbreviation	Test Name	Description	Comments	Reference
For 7.01 or Higher Software Users				
41C	GROWTH AT 41°C	Ability of certain species to grow at 41°C.	N/A	18, 20
42C	GROWTH AT 42°C	Ability of certain species to grow at 42°C.	N/A	20, 22
44C	GROWTH AT 44°C	Ability of certain species to grow at 44°C.	N/A	21

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Abbreviation	Test Name	Description	Comments	Reference
ADONITOL dCELLOB dMALTOSE dMANNITOL dMELIBIOSE dSORBITOL dTREHALOSE dTURANOSE DUL INOSITOL LACTOSE IRHAMNOSE SACCHAROSE SALICIN	ADONITOL acidification D-CELLOBIOSE acidification D-MALTOSE acidification D-MANNITOL acidification D-MELIBIOSE acidification SORBITOL acidification D-TREHALOSE acidification TURANOSE acidification DULCITOL acidification INOSITOL acidification LACTOSE acidification L-RHAMNOSE acidification SACCHAROSE/SUCROSE acidification SALICIN acidification	Acidification of carbon source observed with pH indicator (e.g., phenol red, bromcresol purple, etc.).	Some tests also appear on the GN card but are recommended as supplemental tests since results of conventional macromethods may differ from rapid commercial micromethods.	2, 8, 10, 12, 13, 14, 16, 17, 19, 21, 22, 27, 28
Arg.hydr.	ARGININE dihydrolase	Hydrolysis of arginine releases an amine resulting in alkalinization of the medium observed with a pH indicator (e.g., red color formation in the presence of phenol red).	N/A	7, 10, 12, 17, 18, 19, 20, 22, 25, 27
B-HEM	BETA HEMOLYSIS	Certain species possess hemolysins that give a transparent zone around colonies on blood-based agar.	N/A	3, 9, 20, 27
DNAse	DNAse test	Ability of certain species to produce DNAse resulting in the degradation of DNA.	N/A	17, 20, 27
ESCULIN	ESCULIN hydrolysis	Hydrolysis of esculin forms esculetin that produces a black pigment in the presence of iron salts.	N/A	12, 17, 19, 20, 27
GELATIN	GELATIN hydrolysis	Mediated by a gelatinase enzyme, a positive reaction is observed by liquefaction of the gelatin substrate.	N/A	3, 9, 18, 19, 20, 22, 24
dGLUf	Glucose fermentation	Fermentation of glucose observed with pH indicators (e.g. phenol red, bromcresol purple, etc.).	Some tests also appear on the GN card but are recommended as supplemental tests since results of conventional macromethods may differ from rapid commercial micromethods.	29
IND	INDOLE	Ability of certain species to split indole from tryptophan detected by a colored product revealed with a specific reagent (e.g., Kovacs, Ehrlich's, DMAC reagents, etc.).	N/A	10, 12, 16, 17, 19, 20, 27
JordanTART	Jordan_Tartrate	Fermentation of tartrate results in acidification of the medium observed with a pH indicator (e.g., yellow color formation in the presence of phenol red).	N/A	19
Lysine dec.	Lysine decarboxylase	Hydrolysis of lysine releases an amine resulting in alkalinization of the medium observed with a pH indicator (e.g., purple color formation in the presence of bromcresol purple).	Some tests also appear on the GN card but are recommended as supplemental tests since results of conventional macromethods may differ from rapid commercial micromethods.	21, 22

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Abbreviation	Test Name	Description	Comments	Reference
MNTka	MALONATE alkalinization	Utilization of malonate as sole carbon source.	N/A	15, 16, 30
MOB	MOTILITY	Test for motility using hanging drop procedure or wet mount.	Bacterial motility can be observed by placing a drop of bacterial suspension on a slide and viewing it under a microscope.	4, 12, 17, 19, 20, 25, 27, 28, 30
NAT	SODIUM-ACETATE alkalinization	Ability of certain species to utilize acetate as a sole source of carbon.	N/A	29
NO2 NO3 NO3→N2	NITRITE REDUCTION NITRATE REDUCTION NITROGEN PRODUCTION FROM NO3	Test for the ability to reduce nitrite to nitrogen gas (NO2) nitrate to nitrite and/ or nitrogen gas from nitrate (NO3→N2)	N/A	10, 20, 22, 29, 30
NaCl 0% NaCl 6%	GROWTH IN 0% NaCl GROWTH IN 6% NaCl	Ability of certain species to grow in the presence or absence of 6.0% NaCl.	N/A	7, 8, 20, 21, 22
O/129 R	O/129 RESISTANCE	Ability of certain species to grow in the presence of the vibriostatic compound O/129.	Some tests also appear on the GN card but are recommended as supplemental tests since results of conventional macromethods may differ from rapid commercial micromethods.	8, 11
ONPG	BETA_ GALACTOSIDASE	Presence of beta-galactosidase cleaves o-nitrophenol-beta-D-galactopyranoside to produce a yellow colored product.	N/A	8, 12, 17, 19, 20
Ornith.dec	Ornithine decarboxylase	Hydrolysis of ornithine releases an amine resulting in alkalinization of the medium observed with a pH indicator (e.g., purple color formation in the presence of bromcresol purple).	Some tests also appear on the GN card but are recommended as supplemental tests since results of conventional macromethods may differ from rapid commercial micromethods.	8, 10, 17, 19, 20, 27
OX	OXIDASE	Detection of the presence of cytochrome C.	Characteristic useful in identifying many species of non-fermenters. All members of *Enterobacteriaceae* are oxidase negative.	10, 12, 17, 18, 19, 20, 21, 22, 25, 27, 28
PURPLE	PURPLE PIGMENT	Ability of certain species to produce purple colonies on non-differential media.	Characteristic of *Chromobacterium violaceum*.	19, 20
PYOCYANIN	PYOCYANIN pigment	Ability of species to produce blue pigment (pyocyanin) or fluorescent pigment (pyoverdin).	Presence of both pyocyanin and pyoverdin is characteristic of *Pseudomonas aeruginosa* producing greenish fluorescent colonies.	1, 20
PYOVERDIN	PYOVERDIN pigment			
RM	Methyl Red	Test for acid production, requiring positive organisms to produce acid from glucose.	N/A	21
UREASE	Urease	Hydrolysis of urea releases ammonia resulting in alkalinization of the medium observed with a pH indicator (e.g., red color formation in the presence of phenol red).	N/A	10, 12, 17, 19, 20, 25, 27
VP	VOGES PROSKAUER	Ability of some species to produce acetoin from glucose fermentation.	N/A	12, 17, 19, 20, 25, 30

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Abbreviation	Test Name	Description	Comments	Reference
YELLOW	YELLOW PIGMENT	Ability of certain species to produce yellow pigmented colonies on nondifferential media.	N/A	12, 17, 19, 20, 29
For 7.01 Software Users Only				
dFRUCTOSEa dGLUCOSEa dMANNITOLa dMELa lSORBOSEa	D-FRUCTOSE assimilation D-GLUCOSE assimilation D-MANNITOL assimilation D-MELIBIOSE assimilation L-SORBOSE assimilation	Capability of organisms to grow using a specific sole carbon source.	N/A	2, 4, 17, 18
dMLZ	MELEZITOSE acidification	Acidification of carbon source observed with pH indicator (e.g., phenol red, bromcresol purple, etc.).	Some tests also appear on the GN card but are recommended as supplemental tests since results of conventional macromethods may differ from rapid commercial micromethods.	8, 10, 12, 13, 14, 16, 17, 19, 21, 22, 27
For 8.01 or Higher Software Users				
dGLUCOSE dMELEZIT. dXYLOSE lSORBOSE	D-GLUCOSE acidification MELEZITOSE acidification D-XYLOSE acidification L-SORBOSE acidification	Acidification of carbon source observed with pH indicator (e.g., phenol red, bromcresol purple, etc.).	Some tests also appear on the GN card but are recommended as supplemental tests since results of conventional macromethods may differ from rapid commercial micromethods.	2, 8, 10, 12, 13, 14, 16, 17, 19, 21, 22, 27, 28
COL R	COLISTIN RESISTANCE	Ability of certain species to grow in the presence of the colistin.	N/A	28

REFERENCES

1. American Society for Microbiology. 98th General Meeting Workshop Program. Practical Approach to the Identification of the Medically Important Glucose Non-Fermenting Gram-Negative Bacilli. American Society for Microbiology, Washington, D.C. 1998.
2. Brenner DJ, Grimont PAD, Steigerwalt AG, Fanning GR, Ageron E, Riddle CF. Classification of Citrobacteria by DNA Hybridization: Designation of *Citrobacter farmeri* sp.nov., *Citrobacter youngae* sp.nov., *Citrobacter braakii* sp.nov., *Citrobacter werkmanii* sp.nov., *Citrobacter sedlakii* sp.nov., and Three Unnamed Citrobacter Genomospecies. Int. J. Syst. Bacteriol. 1993;43:645-658.
3. Brenner DJ, Krieg NR, Staley JT, Garrity GM, editors. Bergey's Manual of Systematic Bacteriology, 2nd Edition. Springer, New York, NY. 2005
4. Chang YH, Han J, Chun J, Lee KC, Rhee MS, Kim YB, Bae KS. *Comamonas koreensis* sp.nov., a non-motile species from wetland in Woopo, Korea. Int. J. Syst. Evol. Microbiol. 2002;52:377-381.
5. Clinical and Laboratory Standards Institute, M50-A, Quality Control for Commercial Microbial Identification Systems; Approved Guideline, Vol. 28 No. 23.
6. Clinical Laboratory Improvement Amendments of 1988. 42 U.S.C. 263a. PL 100-578.1988.
7. Coenye, T., Falsen, E., Hoste, B., Ohlen, M., Goris, J., Govan, J.R.W., Gillis, M. and Vandamme, P. Description of *Pandoraea* gen. nov. with *Pandoraea apista* sp. nov., *Pandoraea pulmonicola* sp. nov., *Pandoraea pnomenusa* sp. nov., *Pandoraea sputorum* sp. nov. and *Pandoraea norimbergensis* comb. nov. Int. J . Syst. Evol. Microbial. 2000; 50:887-889.
8. Coenye T, Mahenthiralingam E, Henry D, Lipuma JJ, Laevens S, Gillis M, Speert DP, Vandamme P. Burkholderia ambifaria sp nov., a novel member of the *Burkholderia cepacia* complex including biocontrol and cystic fibrosis-related isolates. Int. J. Syst. Evol. Microbiol. 2001; 51:1481-1490.
9. Coenye T, Vandamme P, Gowan JRW, Lipuma JJ. Taxonomy and Identification of the *Burkholderia cepacia* Complex. J. Clin. Microbiol. 2001;39:3427-3436.
10. De Baere T, Steyaert, Wauters G, De Vos P, Goris J, Coenye T, Suyama T, Verschraegen G, Vaneechoutte M. Classification of *Ralstonia pickettii* biovar 3/ 'thomasii' strains (Pickett 1994) and of new isolates related to nosocomial recurrent meningitis as Ralstonia mannitolytica sp.nov. Int. J. Syst. Evol. Microbiol. 2001;51:547-558.
11. Freney J, Renaud F, Hansen W, Bollet C. *Précis de bactériologie clinique*. ESKA, Paris, France. 2000.

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12. Gavini F, Mergaert J, Beji A, Mielcarek C, Izard D, Kersters K, DeLey J. Transfer of *Enterobacter agglomerans* (Beijerinck 1888) Ewing and Fife to Pantoea gen. Nov. as Pantoea agglomerans comb.nov. and Description of *Pantoea dispersa* sp. Nov. Int. J. Syst. Bacteriol. 1989;39:337-345.

13. Hoffman, H., S. Stindl, A. Stump, A,. Mehlen, D. Monget, J. Heesemann, K. Schleifer, and A. Roggenkamp. 2005. Description of *Enterobacter ludwigii* sp. nov., a novel *Enterobacter* species of clinical relevance. Syst. Appl. Microbiol. 28: 206-212.

14. Hoffman, H., S. Stindl, Wolfgang, A. Stump, A. Mehlen, D. Monget, J. Heesemann, K. Schleifer, and A. Roggenkamp. 2005. Reeassignment of *Enterobacter dissolvens* to *Enterobacter cloacae* as *E.cloacae* subspecies *dissolvens* comb.nov. and emended description of *Enterobacter asburiae* and *Enterobacter kobei*. Syst. Appl. Microbiol. 28: 196-205.

15. Huys, G., Cnockaert, M., Abbott, S.L., Janda, M. and Vandamme, P. *Hafnia paralvei* sp. nov., formerly known as *Hafnia alvei* hybridization group 2. Int. J . Syst. Evol. Microbial. 2010; 60:1725-1728.

16. Iversen, C., N. Mullan, B. McCardell, B. Tall, A. Lehnen, S. Fanning, R. Stephan, and H. Joosten. 2008. *Cronobacter* gen. nov., a new genus to accommodate the biogroups of *Enterobacter sakazakii*, and proposal of *Cronobacter sakazakii* gen. nov., comb., *Cronobacter malonaticus* sp. nov., *Cronobacter turicensis* sp. nov., *Cronobacter muytjensii* sp. nov., *Cronobacter dublinensis* sp. nov., *Cronobacter genomospecies* 1, and of three subspecies, *Cronobacter dubinensis* subsp. *dublinensis* subsp. nov., *Cronobacter dulinensis* subsp. *lausannensis* subsp.nov. and *Cronobacter dublinensis* subsp. *lactaridi* subsp. nov. Int. J. Syst. Evol. Microbiol. 58: 1442-1447.

17. Holt J.G., Krieg N.R., Sneath P.H., Staley J.T., Williams S.T. *Bergey's Manual of Determinative Bacteriology*, 9th Edition. William and Wilkins, Baltimore, Maryland. 1994.

18. Krieg NR, Holt JG. *Bergey's Manual of Systematic Bacteriology, volume 1*. William & Wilkins, Baltimore, Maryland. 1984.

19. Mohr O'Hara, C., Brenner, F.W., Steigerwalt, A.G., Hill, B.C., Holmes, B., Grimont, P.A.D., Hawkey, P.M., Penner, J.L., Miller, J.M. and Brenner, D.J. 2000. Classification of *Proteus vulgaris* biogroup 3 with recognition of *Proteus hauseri* sp. nov., nom. Rev. and unnamed *Proteus* genomospecies 4, 5, and 6. Int J Syst Evol Microbiol. 50, 1869-1875.

20. Murray P.R., Baron E.J., Pfaller M.A., Tenover F.C., Yolken R.H., editors. *Manual of Clinical Microbiology*, 7th Edition. American Society for Microbiology, Washington, D.C. 1999.

21. Murray P.R., Baron E.J., Jorgensen J.H., Pfaller M.A. and Yolken R.H., editors. *Manual of Clinical Microbiology*, Volume 1, 8th Edition. American Society for Microbiology, Washington, DC. 2003.

22. Murray, P.R., E.J. Baron, M.L. Landry, J.H. Jorgensen and M.A. Pfaller. 2007. *Manual of Clinical MIcrobiology*, 9th edition. American Society for Microbiology, Washington, D.C.

23. National Committee for Clinical Laboratory Standards, M29-A, *Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissue* — Approved Guideline, 1997.

24. Richard C, Kiredjian M. *Laboratory methods for the Identification of the Medically Important Glucose Nonfermenting Gram-Negative Bacilli*. Institut Pasteur, Paris, France. 1992.

25. Smith S.K., Sutton D.C., Fuerst J.A., Reichelt J.L.. Evaluation of the Genus *Listonella* and the reassignment of *Listonella damsela* (Love et al.) MacDonell and Colwell to the Genus *Photobacterium* as *Photobacterium damsela* comb. nov. with an Emended Description. Int. J. Syst. Bacteriol. 1991;41:529-534.

26. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health, Office of Health and Safety, *Biosafety in Microbiological and Biomedical Laboratories*, 1988.

27. Vandamme P, Goris J, Coenye T, Hoste B, Janssens D, Kersters K, DeVos P, Falsen E. Assignment of Centers for Disease Control group Ivc-2 to the genus *Ralstonia* as *Ralstonia paucula* sp.nov. Int. J. Syst. Bacteriol. 1999;49:663-669.

28. Versalovic, J., K.C. Carroll, G. Funke, J.H. Jorgensen, M.L. Landry and D.W. Warnock. 2011. *Manual of Clinical Microbiology*, 10th edition. American Society for Microbiology, Washington, D.C.

29. Weyant R.S., Moss C.W., Weaver R.E., Hollis D.G., Jordan J.G., Cook E.C., and Daneshvar M.I. *Identification of Unusual Pathogenic Gram-Negative Aerobic and Facultatively Anaerobic Bacteria*. 2nd Edition. Williams & Wilkins. Baltimore, Maryland. 1996.

30. J.H. Jorgensen, M.A. Phaller, K.C. Carroll, G. Funke, M.L. Landry, S.S. Richter, and D.W. Warnock. 2015. *Manual of Clinical Microbiology*, 11th edition. American Society for Microbiology, Washington, D.C.

Use this Instructions for Use with VITEK® 2 Product No. 21341.

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalog number
IVD	In Vitro Diagnostic Medical Device

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Symbol	Meaning
	Legal Manufacturer
	Temperature limitation
	Use by date
	Batch code
	Consult Instructions for Use
	Date of manufacture
	Contains sufficient for <n> tests
	Authorized representative in the European Community
	For US Only : Caution : US Federal Law restricts this device to sale by or on the order of a licensed practitioner

Instructions for Use provided in the kit or downloadable from www.biomerieux.com/techlib

LIMITED WARRANTY

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WASTE DISPOSAL

All hazardous waste must be disposed of by following your local inspecting agency's guidelines.

REVISION HISTORY TABLE

Change type categories	
N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user
Note :	Minor typographical, grammar, and formatting changes are not included in the revision history.

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Release Date	Part Number	Change Type	Change Summary
2019-03	044066-03	Technical change	Updated for 9.02 software release. Updated sections: • Intended Use • Precautions • Culture Requirements • Additional Information on Lab Report • Testing of QC Organisms • Performance Characteristics • Organisms Identified • References
2016-10	044066-02	Technical change	• Updated content to reflect the 8.01 Product Information Manual
		Correction	• Performance Characteristics
2016-05	044066-01	Administrative	• Formatting changes do not affect the fit, form, or function of the product
		Technical change	• New IFU derived from product chapter in the Product Information Manual • Updated Limited Warranty section • Updated with RX only information

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VITEK® 2 AST-N233

Rx only IVD

INTENDED USE

The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.

SUMMARY AND EXPLANATION

Susceptibility testing is indicated for any organism that contributes to an infectious process warranting antimicrobial chemotherapy. Susceptibility tests are most often indicated when the causative organism is thought to belong to a species capable of exhibiting resistance to commonly used agents. Isolated colonies of each type of organism that may play a pathogenic role are selected from an agar plate and tested for susceptibility. These tests are then examined and the Minimum Inhibitory Concentration (MIC) is determined. The MIC obtained using a dilution test may tell the physician the concentration of an antimicrobial agent needed at the site of infection to inhibit the infecting organism.

MICs have traditionally been determined using antimicrobial concentrations derived from serial twofold dilutions.[2] The MIC is then determined from the lowest concentration that exhibits inhibition of growth. An interpretive criterion (Susceptible, Intermediate, or Resistant) can then be assigned to MIC results to aid in the direction of therapy.

For some antimicrobials (e.g., high-level gentamicin, high-level streptomycin) a qualitative result is generated.

The standard and reference procedures are based on susceptibility tests requiring 16 to 24 hours of incubation for bacteria. Various manufacturers have now developed automated procedures designed to generate results more rapidly by using shortened incubation times. Laboratories worldwide use either variations of the standard reference procedure or a commercially available product to determine the MICs of infectious organisms.

Extended-Spectrum Beta Lactamases (ESBLs)

ESBLs are enzymes that arise by mutations in genes for common plasmid-mediated beta-lactamases. Strains of *Klebsiella* spp. and *E. coli* that produce ESBLs may be clinically resistant to therapy with penicillins, cephalosporins, or aztreonam despite apparent *in vitro* susceptibility to some of these agents. Some of these strains will show MICs above the normal susceptible population but below the standard breakpoints for certain extended-spectrum cephalosporins or aztreonam. Before reporting a strain as an ESBL producer, a confirmatory method may be performed. The VITEK® 2 ESBL Test is a confirmatory test for those ESBLs inhibited by clavulanic acid, and it utilizes cefepime, cefotaxime, and ceftazidime, with and without clavulanic acid, to determine a positive or negative result.

STORAGE CONDITIONS

Upon receipt, store VITEK® 2 AST cards unopened in their original package liner at 2°C to 8°C.

PRINCIPLE OF THE TEST

The AST card for VITEK® 2 Systems is an automated test methodology based on the MIC technique reported by MacLowry and Marsh and Gerlach.[15,16] The AST card is essentially a miniaturized and abbreviated version of the doubling dilution technique for MICs determined by the microdilution method.[1]

Each AST card contains a control well containing only microbiological culture medium. The remaining microwells contain premeasured amounts of specific antimicrobials combined with culture medium.

The organism suspension to be tested must be diluted to a standardized concentration in 0.45% saline before being used to rehydrate the antimicrobial medium within the card. The card is then filled, sealed, and placed into the instrument incubator/reader, either automatically (as with VITEK® 2 60 or VITEK® 2 XL) or manually (as with VITEK® 2 Compact). The instrument monitors the growth of each well in the card over a defined period of time (up to 18 hours for Gram-negatives). At the completion of the incubation cycle, MIC values (or test results, as appropriate) are determined for each antimicrobial contained on the card.

PRECAUTIONS

- For *In Vitro* Diagnostic Use Only.
- For US Only: Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- For professional use only.

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- Suspensions not within the appropriate zone on the VITEK® 2 DensiCHEK™ Plus or VITEK® 2 DensiCHEK™ may compromise card performance.
- Do not use the card after the expiration date shown on the package liner.
- Store the card unopened in the package liner. Do not use the card if the protective package liner is damaged or if no desiccant is present.
- Allow the card to come to room temperature before opening the package liner.
- Do not use powdered gloves. Powder may interfere with the optics.
- Use of culture media other than the recommended types must be validated by the customer laboratory for acceptable performance.
- The card performs as intended only when used in conjunction with VITEK® 2 Systems, following the instructions contained in the Instructions for Use.
- It is highly recommended that Good Laboratory Practices (e.g., FDA, CLSI, ISO, etc.) also be followed, according to local guidelines or requirements.
- **Do not use glass test tubes**. Use clear plastic (polystyrene) tubes only. Variation exists among test tubes of standard diameter. Carefully place the tube into the cassette. If resistance is encountered, discard and try another tube that does not require pressure to insert.
- Prior to inoculation, inspect cards for tape tears or damage to the tape and discard any that are suspect. Check the saline level in the tubes after the cassette has been processed to ensure proper filling of card.
  - VITEK® 2 60 or VITEK® 2 XL: Eject improperly filled cards.
  - VITEK® 2 Compact: Do not load improperly filled cards.
- Give special consideration to specimen source and patient therapy regimen. AST cards may contain some antimicrobials that are not proven to be effective for treatment of infections due to all organisms that may be tested. For interpreting and reporting of antimicrobial results that have been shown to be active against organism groups both *in vitro* and in clinical infections, refer to the individual pharmaceutical antimicrobial labeling or local therapy guidelines.
- Interpretation of test results requires the judgment and skill of a person knowledgeable in AST. Additional testing may be required.[17]

Warning: All patient specimens, microbial cultures, and inoculated VITEK® 2 cards, along with associated materials, are potentially infectious and should be treated with universal precautions [18,20]

REAGENTS

When used with VITEK® 2 instrumentation, the AST card is a complete system for routine susceptibility testing. Each AST card contains selected antimicrobials in varying concentrations, dried with a microbiological culture medium.

Contents of the Card

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Amikacin	an01n	8, 16, 64	2	64	**CSAGNB
Amoxicillin/ Clavulanic Acid	amc01n	4/2, 16/8, 32/16	2/1	32/16	**CSAGNB
Ampicillin	am01n	4, 8, 32	2	32	**CSAGNB
Cefalotin	cf01n	2, 8, 32	2	64	**CSAGNB
Cefotaxime	ctx01n	1, 4, 16, 32	1	64	**CSAGNB
Cefoxitin	fox01n	8, 16, 32	4	64	**CSAGNB
Ceftazidime	caz01n	1, 2, 8, 32	1	64	**CSAGNB
Ciprofloxacin	cip01n	0.5, 2, 4	0.25	4	**CSAGNB
Ertapenem	etp01n[c]	0.5, 1, 6	0.5	8	*E. coli*, *K. pneumoniae*, *C. freundii*, *C. koseri*, *E. aerogenes*, *E. cloacae*, **Kox(-ESBL), *M. morganii*, *P. mirabilis*, *P. vulgaris*, *S. marcescens*

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Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Gentamicin	gm01n	4, 16, 32	1	16	**CSAGNB
Imipenem	ipm04n	1, 2, 6, 12	0.25	16	*Acinetobacter* spp., *Citrobacter spp.*, *Enterobacter* spp., *E. coli*, *Klebsiella* spp., *M. morganii*, *P. vulgaris*, *P. rettgeri*, *P. aeruginosa*, *S. marcescens*, *P. stuartii*
Nalidixic Acid	na01n	8, 16, 32	2	32	**CSAGNB
Nitrofurantoin	ft01n	16, 32, 64	16	512	**CSAGNB
Ofloxacin	ofl01n	0.5, 1, 4	0.25	8	**N/A
Piperacillin/ Tazobactam	tzp03n[c]	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *P. rettgeri*, *P. stuartii*, *S. enterica*
Ticarcillin	tic01n	16, 32, 64	8	128	**CSAGNB
Tobramycin	tm01n	8, 16, 64	1	16	**CSAGNB
Trimethoprim/ Sulfamethoxazole	sxt02n❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, **Eco(+ETEC), *C. sakazakii*

Numerical values are expressed in µg/mL.

§ Equivalent standard method concentration by efficacy.

**CSAGNB = Clinically significant aerobic gram-negative bacilli

[c] = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.

**Kox(-ESBL) = *K. oxytoca* (excluding ESBL producing strains)

**N/A = No specific FDA Indications for Use available

❶, ❷ etc. = See performance characteristics identified by the drug code with this symbol.

**Eco(+ETEC) = E. coli (including susceptible enterotoxigenic strains implicated in traveler's diarrhea)

INSTRUMENT

The VITEK® 2 instruments are a family of *in vitro* diagnostic devices intended to rapidly assess the antimicrobial susceptibility of bacterial and yeast pathogens to available antimicrobial agents. For detailed information on the use and operation of these devices, refer to the appropriate Instrument User Manual.

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SPECIMEN PREPARATION

Culture Requirements Table

VITEK® 2 Card	Media	Age of Culture	Incubation Conditions	McFarland Standards	Dilution for AST	Age of Suspension Before Loading Instrument
AST Gram-Negative	TSAB CBA MAC CPS ID	8 to 24 hours	35°C to 37°C aerobic, non-CO_2	0.50 to 0.63	145 µL in 3.0 mL 0.45% saline	VITEK® 2 Compact: ≤ 30 minutes VITEK® 2: ≤ 1 hour
GN and AST GN pair	CBA[1] MAC[1] TSAB CPS ID	18 to 24 hours	35°C to 37°C aerobic, non-CO_2	0.50 to 0.63	145 µL in 3.0 mL 0.45% saline	≤ 30 minutes

[1] These media were used in the identification product database developments and will give optimal performance.

Culture Requirements Table — Media Abbreviations

CBA = Columbia Sheep Blood Agar

MAC = MacConkey Agar

CPS ID = chromID™ CPS (CPS ID Agar)

TSAB = Trypticase Soy Agar with 5% Sheep Blood

TEST PROCEDURE

Warning: Failure to properly follow instructions and recommendations provided in this section for performing laboratory tasks may cause erroneous or delayed results.

Materials

Materials provided are:

- VITEK® 2 DensiCHEK™ Plus Kit
- DensiCHEK™ Plus Standards Kit
- VITEK® 2 Cassette
- Adjustable volume saline dispenser
- 12 mm x 75 mm clear plastic (polystyrene) disposable test tubes
- VITEK® 2 60 or VITEK® 2 XL only: VITEK® 2 Pipettor/Diluter Accessory Kit (containing instrument pipette tips and saline hookup) and 0.45% saline bag

Materials required, but not provided are:

- Sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Loops, sterile sticks or swabs
- Appropriate agar medium (See the Culture Requirements Table.)
- QC isolates
- VITEK® 2 AST Cards
- Micropipettors to deliver 145 µL

Optional Accessories:

- Pre-dispensed saline test tubes (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Test tube caps
- Vortex

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Test Card Setup Procedure

The following procedure contains general information applicable to all susceptibility products. (See the Culture Requirements Table for product-specific information.)

Note: Prepare the inoculum from a pure culture, according to good laboratory practices. In case of mixed cultures, a re-isolation step is required. It is recommended that a purity check plate be done to ensure that a pure culture was used for testing.

1. Do one of the following:
   - Select isolated colonies from a primary plate if culture requirements are met.
   - Subculture the organism to be tested to appropriate agar medium and incubate accordingly.
2. Aseptically transfer 3.0 mL of sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0) into a clear plastic (polystyrene) test tube (12 mm x 75 mm).
3. Use a sterile stick or swab to transfer a sufficient number of morphologically similar colonies to the saline tube prepared in step 2. Prepare a homogenous organism suspension with a density equivalent to the appropriate McFarland standard using the VITEK® 2 DensiCHEK™ Plus (see the Culture Requirements Table). The inoculum density required for the GN, GP, ST, or YST can be diluted automatically for AST cards by the VITEK® 2 instrument (VITEK® 2 60 or VITEK® 2 XL). **Note:** The age of the suspension before loading the instrument for AST testing must be less than one hour when using VITEK® 2 60 or VITEK® 2 XL, and less than 30 minutes when using VITEK® 2 Compact.
4. Choose one of the following:
   - **For an automatic dilution (VITEK® 2 60 or VITEK® 2 XL only):** Place the suspension tube prepared in step 3 into the cassette with or without an identification card. In the next cassette slot, place an empty tube and an AST card. The instrument will automatically dilute the bacterial suspension to prepare an inoculum suitable for the susceptibility card.
   - **For a manual dilution (VITEK® 2 Compact, VITEK® 2 60 or VITEK® 2 XL):** In a second tube containing 3.0 mL of saline, transfer 145 µL of the suspension prepared in step 3. Then place this tube in the cassette with a susceptibility card. The tube with the initial bacterial suspension can also be used for inoculation of an identification card.

   Note: Check the saline level in the tubes after filling. When it is evident by the saline level in the tube that a card has been improperly filled, do not load the card if using VITEK® 2 Compact; **or**, eject the card if using VITEK® 2 60 or VITEK® 2 XL.

   Note: Refer to the appropriate Instrument User Manual for detailed information regarding data entry, processing, etc.
5. Follow your local inspecting agency's guidelines for disposal of hazardous waste.

QUALITY CONTROL

Quality Control organisms should be processed according to the Test Card Setup Procedure.

Quality Control

CLSI® Quality Control Organisms VITEK® 2 Results					
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™	*K. pneumoniae* ssp. *pneumoniae* ATCC® 700603™
Amikacin	an01n	≤ 2 - 4	≤ 2 - 4	-	-
Amoxicillin/ Clavulanic Acid	amc01n	≤ 2/1 - 8/4	-	4/2 - 16/8	-
Ampicillin	am01n	≤ 2 - 8	-	≥ 32†	-
Cefalotin	cf01n	4 - 16	-	-	-
Cefotaxime	ctx01n	≤ 1	8 - 32	-	-
Cefoxitin	fox01n	≤ 4 - 8	-	-	-
Ceftazidime	caz01n	≤ 1	≤ 1 - 4	-	-
Ciprofloxacin	cip01n	≤ 0.25	≤ 0.25 - 1	-	-
Ertapenem	etp01n	≤ 0.5	2 - ≥ 8	-	-
Gentamicin	gm01n	≤ 1	≤ 1 - 2	-	-

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CLSI® Quality Control Organisms VITEK® 2 Results					
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™	*K. pneumoniae* ssp. *pneumoniae* ATCC® 700603™
Imipenem	ipm04n	≤ 0.25	1 - 4	-	-
Nalidixic Acid	na01n	≤ 2 - 4	-	-	-
Nitrofurantoin	ft01n	≤ 16	-	-	-
Ofloxacin	ofl01n	≤ 0.25	1 - ≥ 8	-	-
Piperacillin/ Tazobactam	tzp03n	≤ 4/4[1]	≤ 4/4 - 8/4[2]	≤ 4/4[3]	-
Ticarcillin	tic01n	≤ 8 - 16	≤ 8 - 32	≥ 128†	-
Tobramycin	tm01n	≤ 1	≤ 1	-	-
Trimethoprim/ Sulfamethoxazole	sxt02n	≤ 20 (1/19)	160 (8/152) - ≥ 320 (16/304)	-	-

Numerical values are expressed in µg/mL.

† *Escherichia coli* ATCC® 35218™ is not intended for routine QC testing of ampicillin, piperacillin, or ticarcillin. This organism is recommended only for routine QC of ß-lactamase inhibitor combinations. However, since this strain contains a plasmid-encoded ß-lactamase (non-ESBL), it is resistant to many penicillinase-labile antimicrobials, but susceptible to ß-lactamase/ß-lactamase inhibitor combinations. To ensure that the plasmid is present, testing of the ß-lactam alone (e.g., AM, PIP, TIC), in addition to the ß-lactamase/ß-lactamase inhibitor combination (e.g., AMC, SAM, TZP, TCC), can be performed. If the strain has lost its plasmid, it will be susceptible to the ß-lactam alone (i.e., AM, PIP, TIC), indicating that the QC test is invalid, and a new culture of *Escherichia coli* ATCC® 35218™ must be used.

[1]FDA/CLSI Broth Microdilution expected QC range = 1/4 - 4/4 µg/mL

[2]FDA/CLSI Broth Microdilution expected QC range = 1/4 - 8/4 µg/mL

[3]FDA/CLSI Broth Microdilution expected QC range = 0.5/4 - 2/4 µg/mL

Certification Statement

This is to certify that bioMérieux complies with ISO 13485 and FDA Quality System Regulation (QSR) requirements for design, development, and manufacture of antimicrobial susceptibility systems.

Frequency of QC Testing

Refer to *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically,* CLSI® and/or your local guidelines.[2]

Preparation of QC Organisms

1. Rehydrate the organism according to the manufacturer's instructions.
2. Subculture to Trypticase Soy Agar with 5% sheep blood (TSAB).
3. Incubate at 35°C for 24 hours.
4. Check for purity.
5. Subculture to a TSAB plate.
6. Incubate 16 to 18 hours at 35°C.

Short-Term Storage Conditions

1. Streak to a TSAB plate or slant.
2. Incubate for 24 hours.
3. Refrigerate at 2°C to 8°C for up to two weeks.
4. Subculture once as described above and use for QC.

Long-Term Storage Conditions

1. Make a heavy suspension in Tryptic Soy Broth (TSB) with 15% glycerol.
2. Freeze at -70°C.
3. Subculture to TSAB twice before running QC.

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Note: Avoid repeated thawing and refreezing by either freezing in single-use aliquots or removing a small portion of frozen organism preparation with a sterile applicator stick.

RESULTS

Susceptibility Analytical Techniques

The system evaluates each organism's growth pattern in the presence of the antimicrobial in relation to the growth control well. Several parameters based on the growth characteristics are used to determine the MIC or qualitative result (for example, ESBL POS/NEG). The MIC result must be linked to an organism identification to determine a category interpretation. Accurate identification is critical, especially with certain organism/antimicrobial combinations (e.g., *Staphylococcus aureus*/oxacillin).

In cases where the identification of an organism is in question, confirmatory testing is necessary to ensure correct interpretation of susceptibility results.

A category interpretation will be reported along with a MIC, according to the interpretations defined by the Food and Drug Administration (FDA), CLSI®, Comité de l'Antibiogramme de la Société Française de Microbiologie (CASFM), European Committee for Antimicrobial Susceptibility Testing (EUCAST), or to an adaptation of the global settings according to other local guidelines.

Note: When FDA and CLSI® breakpoints differ, VITEK® 2 Systems AST tests are cleared for use with FDA breakpoints applied.

Combination Antimicrobials

The MICs for the combination antimicrobials are listed on the laboratory and patient reports as the first concentration (e.g., ampicillin/sulbactam ≤ 8/4 µg/mL is reported as ≤ 8 µg/mL.). The actual concentrations for each value in the antimicrobial calling range are as follows:

- amoxicillin/clavulanic acid (amc01n) (µg/mL) 2/1, 4/2, 8/4, 16/8, 32/16
- piperacillin/tazobactam (µg/mL) 4/4, 8/4, 16/4, 32/4, 64/4, 128/4
- trimethoprim/sulfamethoxazole: **Note exception** — This drug is listed on the laboratory and patient reports as the sum of the two antimicrobial concentrations: 20 µg/mL = 1/19, 40 µg/mL = 2/38, 80 µg/mL = 4/76, 160 µg/mL = 8/152, 320 µg/mL = 16/304

Antimicrobial Deduction

Antimicrobials that have been deduced will only report an interpretive result and will be noted with a **+**.

Clinical Efficacy and Indications for Use

AST cards may contain some antimicrobials that are not proven to be effective for treatment of infections caused by all organisms that may be tested. For interpreting and reporting of antimicrobial results that have shown to be active against organism groups both *in vitro* and in clinical infections, refer to the individual pharmaceutical antimicrobial labeling or the local therapy guidelines.

Indications for use specific to the FDA are found in each VITEK® 2 AST card package insert in the column labeled, "FDA Indications for Use". This list contains the antimicrobial/organism combinations that have been cleared by the FDA for testing and reporting on the VITEK® 2 System. FDA clearance has been granted according to the FDA approved pharmaceutical labeling and the VITEK® 2 AST clinical trial data. To report only organisms listed in the FDA Indications for Use section of the package insert, enable bioART Indications for Use suppression rules.

Urinary Use Only Antimicrobials

Certain antimicrobial agents are limited to use in treating urinary tract infections. Accordingly, these agents should not be reported against pathogens recovered from infection sites other than the urinary tract (except as noted). Please refer to the current *CLSI Performance Standards for Susceptibility Testing, M100* and/or local guidelines for additional information.[3]

For urine only, per CLSI®:[3]

- *Enterobacteriaceae*: lomefloxacin or ofloxacin, norfloxacin, nitrofurantoin, sulfisoxazole, trimethoprim, cefazolin
- *Pseudomonas aeruginosa*: lomefloxacin or ofloxacin, norfloxacin
- Other non-*Enterobacteriaceae*: lomefloxacin or ofloxacin, norfloxacin, sulfisoxazole, tetracycline
- *Staphylococcus* spp.: lomefloxacin, norfloxacin, nitrofurantoin, sulfisoxazole, trimethoprim
- *Enterococcus* spp.: ciprofloxacin, levofloxacin, norfloxacin, nitrofurantoin, tetracycline

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LIMITATIONS

A VITEK® 2 AST card cannot be used with a direct clinical specimen or sample or other sources containing mixed flora. Any change or modification in the procedure may affect the results.

A result for an antibiotic/organism combination, which may have a limitation, may be suppressed from reporting. This can be accomplished through the use of bioART rules in the VITEK® 2 Systems software. Refer to the software user manual for instructions.

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

- Amikacin (an01n): *Acinetobacter baumannii*
- Amoxicillin/Clavulanic Acid (amc01n): *Providencia* spp.
- Ampicillin (am01n): *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Imipenem (ipm04n): *Serratia marcescens*
- Piperacillin/Tazobactam (tzp03n): *Serratia marcescens*

Perform an alternative method of testing prior to reporting of results when an intermediate or resistant result is obtained with the following antibiotic/organism combination(s):

- Amoxicillin/Clavulanic Acid (amc01n): *Proteus* spp.

Perform an alternative method of testing prior to reporting results when a resistant result is obtained with the following antibiotic/organism combination(s):

- Imipenem (ipm04n): *Aeromonas* spp.
- Piperacillin/Tazobactam (tzp03n): *Pseudomonas aeruginosa*

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:

- Ertapenem (etp01n): *E. coli, K. pneumoniae, C. freundii, C. koseri, E. aerogenes, E. cloacae, K. oxytoca* (excluding ESBL producing strains), *M. morganii, P. mirabilis, P. vulgaris, S. marcescens*

EUCAST Limitations

It is recommended that the existing bioART suppression rules be enabled, or new rules created and enabled, for these limitations if the EUCAST breakpoints are applied.

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

- Amikacin (an01n): *Acinetobacter* spp.
- Amoxicillin/Clavulanic Acid (amc01n): *Providencia* spp.
- Ampicillin (am01n): *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Imipenem (ipm04n): *Serratia marcescens*
- Ticarcillin (tic01n): *Pseudomonas* spp.

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:

- Ertapenem (etp01n): *Enterobacteriaceae*

EXPECTED VALUES

Expected results for susceptibility tests will vary based on location and institution. VITEK® 2 Systems were tested at several geographically diverse locations to ensure that trends that occurred by location were integrated into the performance characteristics of the system. Organism resistance patterns will differ by institution; therefore, expected values will be directly related to the population of organisms at each site.

PERFORMANCE CHARACTERISTICS

The performance characteristics of the antimicrobial agents included in VITEK® 2 AST cards were established using the manual and autodilution modes (on a VITEK® 2 System) at multiple clinical laboratories. The VITEK® 2 AST card results were compared to results from a CLSI® reference method. Essential agreement (EA) represents VITEK® 2 results which agree exactly or are within a ± twofold dilution (± two doubling dilutions for antifungal) of the reference result.

Category agreement (CA) occurs when the VITEK® 2 and the reference interpretative results agree (Susceptible, Intermediate, and Resistant). There are instances when the category agreement for an antimicrobial falls below the essential

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agreement. This can occur when a significant number of MICs cluster around a category breakpoint during clinical trial testing, resulting in interpretative errors. For a description of interpretive errors, refer to the footnotes below the table that follows (Performance Characteristics). When the majority of the errors are of the minor type, a high corresponding essential agreement percentage demonstrates that the antimicrobial retains an acceptable overall performance.

There are instances when the performance is based solely on category agreement (CA) because at the time performance was established, less than five discrete twofold dilutions were evaluated. A minimum of five dilutions is necessary to calculate essential agreement (EA) based on ± one twofold dilution. These instances are designated by a "c" footnote in the Contents of the Card table. The following performance tables have values for CA only when EA was not established at the time of FDA clearance.

The reproducibility of the VITEK® 2 system was established by testing a set of on-scale organisms.*

*Data on file at bioMérieux, Inc

Performance Characteristics for Gram-Negative Antimicrobial Susceptibility Testing

Antimicrobial	Antimicrobial Code	Antibiotic Version	Bp[1]	Comment[2]	Essential Agreement				Category Agreement				% Reproducibility
					% Error				% Error				
					% EA	VME	ME	mE	% CA	VME	ME	mE	
Amikacin	AN	an01n	CLSI	#, E	98.0	0.0	0.4	0.0	96.5	0.0	0.4	2.9	100
			CA-SFM	I	96.1	4.2	0.6	1.4	–	–	–	–	
Amoxicillin/Clavulanic Acid	AMC	amc01n	CLSI	#, E	96.3	0.8	0.0	2.4	92.1	0.8	0.0	6.5	100
Ampicillin	AM	am01n	CLSI	#, E	93.3	1.3	0.0	0.8	90.9	1.3	0.0	7.8	99.3
			CA-SFM	I	94.9	0.6	2.2	4.3	–	–	–	–	
Cefalotin (Cephalothin)	CF	cf01n	CLSI	#, E	97.3	0.8	0.0	1.2	89.4	0.8	0.0	10.6	96.7
			CA-SFM	I	95.7	0.2	0.4	3.3	–	–	–	–	
Cefotaxime	CTX	ctx01n	CLSI	#, E	95.8	1.1	0.2	2.6	92.9	1.1	0.2	6.7	98.1
			CA-SFM	I	94.0	0.4	0.1	3.5	–	–	–	–	
Cefoxitin	FOX	fox01n	CLSI	#, E	97.2	0.9	0.0	1.5	92.2	0.9	0.0	8.7	98.9
			CA-SFM	I	95.1	0.5	0.2	3.4	–	–	–	–	
Ceftazidime	CAZ	caz01n	CLSI	#, E	97.5	1.1	0.2	1.0	97.3	1.1	0.2	3.5	95.4
			CA-SFM	I	92.3	5.1	0.0	4.1	–	–	–	–	
Ciprofloxacin	CIP	cip01n	CLSI	#, E	97.9	0.0	0.0	0.5	96.6	0.0	0.0	3.8	98.9
			CA-SFM	E	97.9	0.0	0.0	0.5	96.6	0.0	0.0	3.8	
Ertapenem	ETP	etp01n	CLSI	#, E	–	–	–	–	98.8	0.0	0.0	1.2	97.8
Gentamicin	GM	gm01n	CLSI	#, E	97.1	1.9	0.0	0.6	96.4	1.9	0.0	2.9	100
			CA-SFM	E	97.1	1.9	0.0	0.6	96.4	1.9	0.0	2.9	
Imipenem	IPM	ipm04n	CLSI	#, E ❷	95.7	2.4	0.3	0.4	94.8	2.4	0.3	4.4	99.6
Nalidixic Acid	NA	na01n	CLSI	#, E	98.4	0.0	0.0	N/A	98.9	0.9	0.9	N/A	100
Nitrofurantoin	FT	ft01n	CLSI	#, E	93.6	0.0	0.0	4.3	78.8	0.0	0.0	17.9	100
			CA-SFM	I	94.8	0.2	0.4	4.0	–	–	–	–	
Ofloxacin	OFL	ofl01n	CLSI	I	96.9	2.1	0.3	0.7	93.6	2.1	0.3	5.8	100
			CA-SFM	I	96.7	0.9	0.0	2.6	91.1	0.9	0.0	8.8	
Piperacillin/ Tazobactam*	TZP	tzp03n	CLSI	#, E	N/A	N/A	N/A	N/A	93.2	0.9	2.2	5.0	96.7

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Antimicrobial	Antimicrobial Code	Antibiotic Version	Bp[1]	Comment[2]	Essential Agreement				Category Agreement				% Reproducibility
					% Error				% Error				
					% EA	VME	ME	mE	% CA	VME	ME	mE	
Ticarcillin	TIC	tic01n	CLSI	#, E	97.2	0.0	0.5	1.4	91.7	0.4	2.6	7.5	97.8
			CA-SFM	I	92.6	1.4	0.2	4.5	–	–	–	–	
Tobramycin	TM	tm01n	CLSI	#, E	98.0	0.0	0.0	1.2	94.7	0.0	0.0	5.6	100
			CA-SFM	E	98.0	0.0	0.0	1.2	94.7	0.0	0.0	5.6	
Trimethoprim/ Sulfamethoxazole	SXT	sxt02n	CLSI	#, E ❷	–	–	–	–	100	0.0	0.0	N/A	100
			CA-SFM	E ❷	99.5	0.0	0.0	0.0	100	0.0	0.0	0.0	
Trimethoprim/ Sulfamethoxazole	SXT	sxt02n	CLSI[3]	#, E ❷ Applies to V2S SW PC version 5.02 and above	-	-	-	-	100	0.0	0.0	N/A	97.8

[1] Abbreviations — Bp = breakpoint committee; EA = essential agreement; CA = category agreement; VME = Very Major Error (susceptible result with resistant reference result); ME = Major Error (resistant result with susceptible reference result); mE = minor Error (susceptible or resistant result with an intermediate reference result, or an intermediate result with a susceptible or resistant reference result).

[2] Comment — Specific organism groups are designated as P. aeurg. for *Pseudomonas aeruginosa*, others for species other than *Pseudomonas aeruginosa*, and Acineto. for *Acinetobacter*.

[3] FDA breakpoints are used in the CLSI Interpretation Standard (breakpoint committee) in the VITEK® 2 Systems software.

* The overall essential agreement for VITEK® 2 piperacillin/tazobactam was not calculated since the test contains less than five discrete concentrations. However, of the 2453 isolates tested, 348 (14.2%) yielded on-scale VITEK® 2 MIC values (i.e., results of 8, 16, 32, and 64 µg/ml). Those results were evaluated for MIC trends and the following results were obtained when VITEK® 2 was compared to CLSI broth microdilution method; 74.4% (259/348) of the VITEK® MICs were within +/- one doubling dilution; 18.4% (64/348) of the VITEK® MICs were higher by more than one doubling dilution; and 7.2% (25/348) of the VITEK® MICs were lower by more than one doubling dilution.

Key:

= US Food and Drug Administration 510(k) cleared
CLSI® = Clinical and Laboratory Standards Institute
CA-SFM = Comité de l'Antibiogramme de la Société Française de Microbiologie
E = External performance data
I = Internal performance data
– = Not available
❶ ❷ = Symbol identifies the performance characteristics for a specific antimicrobial version.
Ref. = Reference method for clinical performance study.

EUCAST Performance Characteristics for Gram-Negative Antimicrobial Susceptibility Testing

Antimicrobial	Antimicrobial Code	Antibiotic Version	Comment[1]	Essential Agreement				Category Agreement			
				% Error				% Error			
				%EA[2]	VME	ME	mE	%CA	VME	ME	mE
Amikacin	AN	an01n	(excludes: *Acinetobacter*)	98.5	0.0	0.0	0.6	96.7	0.0	0.0	3.3
Amoxicillin/Clavulanic Acid	AMC	amc01n	*Enterobacteriaceae* (excludes: *Providencia*)	90.0	9.4	3.5	0.0	93.1	10.6	4.0	0.0

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Antimicrobial	Antimicrobial Code	Antibiotic Version	Comment[1]	Essential Agreement				Category Agreement			
				% Error				% Error			
				%EA[2]	VME	ME	mE	%CA	VME	ME	mE
Ampicillin	AM	am01n	*Enterobacteriaceae* (excludes: *Citrobacter, Enterobacter, Pantoea, Serratia* spp.)	93.2	2.7	0.9	0.0	96.6	4.3	1.8	0.0
Cefotaxime	CTX	ctx01n	*Enterobacteriaceae*	95.9	7.4	0.8	0.9	94.1	7.4	0.8	3.8
Ceftazidime	CAZ	caz01n	*Enterobacteriaceae, Pseudomonas*	96.7	3.0	0.3	0.8	97.9	3.0	1.0	1.3
Ciprofloxacin	CIP	cip01n	N/A	98.1	0.0	0.3	0.2	95.3	0.0	0.3	4.5
Ertapenem	ETP	etp01n	*Enterobacteriaceae*	99.5	0.0	0.0	0.5	98.9	0.0	0.0	1.1
Gentamicin	GM	gm01n	N/A	98.3	0.4	0.0	0.8	96.8	0.0	0.0	3.2
Imipenem	IPM	ipm04n	N/A	95.8	1.0	0.4	0.8	92.2	1.0	0.4	7.3
Nitrofurantoin	FT	ft01n	*E. coli* only	95.7	3.8	0.6	0.0	96.6	7.7	2.6	0.0
Ofloxacin	OFL	ofl01n	*Enterobacteriaceae*	99.5	0.0	0.6	0.0	98.0	0.0	0.6	1.5
Piperacillin/Tazobactam	TZP	tzp03n	*Enterobacteriaceae, Pseudomonas*	96.2	0.8	0.9	1.0	94.8	1.2	1.5	3.8
Ticarcillin	TIC	tic01n	*Enterobacteriaceae*	96.5	2.0	0.7	1.0	94.9	2.0	0.7	3.5
Tobramycin	TM	tm01n	N/A	98.9	0.0	0.5	0.0	94.7	0.0	0.8	4.6
Trimethoprim/ Sulfamethoxazole	SXT	sxt02n	(also includes *S. maltophilia*) ❷	98.4	0.0	0.0	0.4	99.5	0.0	0.0	0.5

[1] Comment — Unless stated otherwise, performance is for *Enterobacteriaceae*, *Pseudomonas*, and *Acinetobacter*.

[2] Abbreviations — Bp = breakpoint committee; EA = essential agreement; CA = category agreement; VME = Very Major Error (susceptible result with resistant reference result); ME = Major Error (resistant result with susceptible reference result); mE = minor Error (susceptible or resistant result with an intermediate reference result, or an intermediate result with a susceptible or resistant reference result).

Key:

= EUCAST = European Committee on Antimicrobial Susceptibility

❶ ❷ = Symbol identifies the performance characteristics for a specific antimicrobial version.

LIST OF CLAIMS

Note: If the organism is not in the VITEK® 2 susceptibility database, results will not be reported.

Note: Organisms listed with an asterisk (*) indicate an AES claimed organism. No asterisk is displayed for a group; however, when an individual species (with an asterisk) is contained within a group, it is expertised.

Gram-Negative Organisms Claimed for AST-GN (keyID)

- *Achromobacter denitrificans*
- *Achromobacter xylosoxidans*
- *Acinetobacter baumannii**
- *Acinetobacter baumannii complex**
- *Acinetobacter calcoaceticus**
- *Acinetobacter haemolyticus*
- *Acinetobacter johnsonii*
- *Acinetobacter junii*
- *Acinetobacter lwoffii*
- *Acinetobacter pittii**
- *Acinetobacter* spp.
- *Aeromonas caviae*
- *Aeromonas hydrophila*
- *Aeromonas hydrophila/caviae*
- *Aeromonas sobria*

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- *Alcaligenes faecalis* ssp. *faecalis*
- *Bordetella avium*
- *Bordetella bronchiseptica*
- *Brevundimonas diminuta*
- *Brevundimonas diminuta/vesicularis*
- *Brevundimonas vesicularis*
- *Burkholderia cepacia**
- *Cedecea davisae**
- *Cedecea lapagei**
- *Cedecea neteri**
- *Chryseobacterium gleum*
- *Chryseobacterium indologenes*
- *Citrobacter amalonaticus**
- *Citrobacter braakii**
- *Citrobacter farmeri**
- *Citrobacter freundii**
- *Citrobacter koseri**
- *Citrobacter youngae**
- *Comamonas testosteroni*
- *Cronobacter muytjensii**
- *Cronobacter sakazakii* group*
- *Cronobacter sakazakii**
- *Delftia acidovorans*
- *Edwardsiella hoshinae**
- *Edwardsiella tarda**
- *Elizabethkingia meningoseptica* (formerly known as *Chryseobacterium meningosepticum*)
- *Enterobacter aerogenes**
- *Enterobacter asburiae**
- *Enterobacter cancerogenus**
- *Enterobacter cloacae**
- *Enterobacter cloacae* complex*
- *Enterobacter cloacae* ssp. *cloacae**
- *Enterobacter cloacae* ssp. *dissolvens* *
- *Escherichia coli**
- *Escherichia coli* ATCC® 25922™
- *Escherichia coli* ATCC® 35218™
- *Escherichia fergusonii*
- *Escherichia hermannii**
- *Escherichia vulneris**
- *Ewingella americana*
- *Hafnia alvei**
- *Hafnia paralvei**
- *Klebsiella oxytoca**
- *Klebsiella pneumoniae**
- *Klebsiella pneumoniae* ssp. *ozaenae**
- *Klebsiella pneumoniae* ssp. *pneumoniae**
- *Klebsiella pneumoniae* ssp. *pneumoniae* ATCC® 700603 ™
- *Klebsiella pneumoniae* ssp. *rhinoscleromatis**
- *Klebsiella* spp.*
- *Kluyvera ascorbata**
- *Kluyvera cryocrescens**
- *Kluyvera intermedia* (formerly known as *Enterobacter intermedius*)*

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- *Leclercia adecarboxylata**
- *Lelliottia amnigena* (formerly known as Enterobacter amnigenus)*
- *Lelliottia amnigena 1* (formerly known as Enterobacter amnigenus 1)*
- *Lelliottia amnigena 2* (formerly known as Enterobacter amnigenus 2)
- *Mannheimia haemolytica*
- *Moraxella* group
- *Moraxella lacunata*
- *Moraxella nonliquefaciens*
- *Moraxella osloensis*
- *Morganella morganii**
- *Morganella morganii* ssp. *morganii**
- *Morganella morganii* ssp. *sibonii**
- *Myroides* ssp.
- *Pantoea agglomerans*
- *Pantoea dispersa*
- *Pasteurella aerogenes*
- *Pasteurella multocida**
- *Pasteurella pneumotropica*
- *Plesiomonas shigelloides*
- *Pluralibacter gergoviae* (formerly known as *Enterobacter gergoviae*)*
- *Proteus hauseri**
- *Proteus mirabilis**
- *Proteus penneri**
- *Proteus vulgaris**
- *Providencia alcalifaciens**
- *Providencia rettgeri**
- *Providencia rustigianii**
- *Providencia stuartii**
- *Pseudomonas aeruginosa**
- *Pseudomonas aeruginosa* ATCC® 27853™
- *Pseudomonas alcaligenes*
- *Pseudomonas fluorescens*
- *Pseudomonas luteola*
- *Pseudomonas mendocina*
- *Pseudomonas oleovorans*
- *Pseudomonas oryzihabitans*
- *Pseudomonas putida*
- *Pseudomonas* spp.
- *Pseudomonas stutzeri*
- *Ralstonia pickettii*
- *Raoultella ornithinolytica**
- *Raoultella planticola**
- *Raoultella terrigena**
- *Salmonella enterica* ssp. *arizonae*
- *Salmonella enterica* ssp. *enterica**
- *Salmonella* group*
- *Salmonella* ser. Enteritidis*
- *Salmonella* ser. Paratyphi A*
- *Salmonella* ser. Paratyphi B*
- *Salmonella* ser. Paratyphi C*
- *Salmonella* ser. Typhi*
- *Salmonella* ser. Typhimurium*

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- *Salmonella* spp.*
- *Serratia ficaria**
- *Serratia fonticola**
- *Serratia grimesii**
- *Serratia liquefaciens**
- *Serratia liquefaciens* group*
- *Serratia marcescens**
- *Serratia odorifera**
- *Serratia plymuthica**
- *Serratia proteamaculans*
- *Serratia rubidaea**
- *Shewanella putrefaciens*
- *Shewanella putrefaciens* group
- *Shigella boydii**
- *Shigella dysenteriae**
- *Shigella flexneri**
- *Shigella* group*
- *Shigella sonnei**
- *Shigella* spp.
- *Sphingobacterium multivorum*
- *Sphingobacterium spiritivorum*
- *Sphingomonas paucimobilis*
- *Stenotrophomonas maltophilia**
- *Vibrio alginolyticus*
- *Vibrio fluvialis*
- *Vibrio harveyi*
- *Vibrio metschnikovii*
- *Vibrio mimicus*
- *Vibrio parahaemolyticus*
- *Vibrio vulnificus*
- *Yersinia aldovae*
- *Yersinia enterocolitica**
- *Yersinia enterocolitica* group*
- *Yersinia frederiksenii**
- *Yersinia intermedia**
- *Yersinia kristensenii**
- *Yersinia pseudotuberculosis**
- *Yersinia ruckeri*

REFERENCES

1. Barry, AL The Antimicrobic Susceptibility Test, Principles and Practices, Lea and Febiger, Philadelphia, PA. 1976.
2. Clinical Laboratory Standards Institute (CLSI®), Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically, M7- A7, Wayne, Pennsylvania, January 2006.
3. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Eighteenth Informational Supplement, M100-S18, Vol. 27, No. 1, January 2008.
4. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-third Informational Supplement, M100-S22, January 2012.
5. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-fourth Informational Supplement; M100-S24, January 2014.
6. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-fifth Informational Supplement, M100-S25, January 2015.
7. Comité de l'Antibiogramme de la Société Française de Microbiologie. Communiqué 1996. Path Biol, 1996, 44, n° 8, I-VIII.
8. Comité de l'Antibiogramme de la Société Française de Microbiologie, Communiqué 2007.

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9. Comite de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM), Recommendations 2012.
10. Comité de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM). Communiqué 2014.
11. Comité de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM). Communiqué 2015.
12. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 2.0, January 2012.
13. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 4.0, January 2014.
14. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 5.0, January 2015.
15. Gerlach, EH Microdilution 1: A Comparative Study, p. 63-76, In: Balows, A. (ed.), Current Techniques for Antibiotic Susceptibility Testing, Charles C. Thomas, Springfield, IL. 1974.
16. MacLowry, JD, and HH Marsh. 1968. Semi-automatic microtechnique for serial dilution antibiotic sensitivity testing in the clinical laboratory. J. Lab. Clin. Med. 1968;72:685-687.
17. Murray, PR, Baron EJ, Pfaller MA, Tenover FC, and Yolken RH, editors. Manual of Clinical Microbiology, 8th ed. American Society for Microbiology, Washington, D.C. 2003.
18. National Committee for Clinical Laboratory Standards, M29-A, Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissue – Approved Guideline (1997).
19. National Committee for Clinical Laboratory Standards, Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Approved Standard — Third Edition, M27-A3, Vol. 22, No. 15, 2008.
20. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health, Office of Health and Safety, Biosafety in Microbiological and Biomedical Laboratories, 1988.

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INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalog number
IVD	In Vitro Diagnostic Medical Device
	Legal Manufacturer
	Temperature limitation
	Use by date
LOT	Batch code
	Consult Instructions for Use
	Date of manufacture
	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community
Rx only	For US Only : Caution : US Federal Law restricts this device to sale by or on the order of a licensed practitioner

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Instructions for Use provided in the kit or downloadable from www.biomerieux.com/techlib

BARCODES

User MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.

01 A310H40L---7

02 BAST-N233116

03 C---Z010702B

04 D0D0F0K0G0LD

05 E1N03200S0YI

06 F0M2P0N0523T

07 G-O000000000C

08 H0T-NS1308HF

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WASTE DISPOSAL

All hazardous waste must be disposed of by following your local inspecting agency's guidelines.

REVISION HISTORY TABLE

Change type categories	
N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user
Note:	Minor typographical, grammar, and formatting changes are not included in the revision history.

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Release Date	Part Number	Change Type	Change Summary
2018-01	045516-01	Administrative	• Formatting changes do not affect the fit, form, or function of the product
		Technical change	• Combined product package insert content with VITEK® 2 Product Information Manual AST content • Updated Limited Warranty section • Updated with RX only information • Updated with EUCAST limitations

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VITEK® 2 AST-P580

Rx only IVD

INTENDED USE

The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of *Staphylococcus* spp., *Enterococcus* spp., and *S. agalactiae* to antimicrobial agents when used as instructed.

SUMMARY AND EXPLANATION

Susceptibility testing is indicated for any organism that contributes to an infectious process warranting antimicrobial chemotherapy. Susceptibility tests are most often indicated when the causative organism is thought to belong to a species capable of exhibiting resistance to commonly used agents. Isolated colonies of each type of organism that may play a pathogenic role are selected from an agar plate and tested for susceptibility. These tests are then examined and the Minimum Inhibitory Concentration (MIC) is determined. The MIC obtained using a dilution test may tell the physician the concentration of an antimicrobial agent needed at the site of infection to inhibit the infecting organism.

MICs have traditionally been determined using antimicrobial concentrations derived from serial twofold dilutions.[2] The MIC is then determined from the lowest concentration that exhibits inhibition of growth. An interpretive criterion (Susceptible, Intermediate, or Resistant) can then be assigned to MIC results to aid in the direction of therapy.

For some antimicrobials (e.g., high-level gentamicin, high-level streptomycin) a qualitative result is generated.

The standard and reference procedures are based on susceptibility tests requiring 16 to 24 hours of incubation for bacteria. Various manufacturers have now developed automated procedures designed to generate results more rapidly by using shortened incubation times. Laboratories worldwide use either variations of the standard reference procedure or a commercially available product to determine the MICs of infectious organisms.

Methicillin-Resistant Staphylococci (MRS)

Resistance to oxacillin is used to detect the presence of MRS. Most MRS are also usually resistant to multiple antimicrobials, including other beta-lactams, aminoglycosides, macrolides, clindamycin, and tetracycline. However, a “community-acquired methicillin-resistant *S. aureus*” phenotype has been described. These are not multi-drug resistant strains, but are typically resistant to penicillin and oxacillin, susceptible or resistant to erythromycin, and susceptible to gentamicin, clindamycin, and tetracycline.

Oxacillin (OX1)

This test provides an MIC determination and category interpretation for oxacillin. Interpretive results for MRS are reported as resistant to all beta-lactams (except anti-MRSA beta-lactams) when the instrument is operating in the CLSI® mode or the User-Defined (based on CLSI®) mode. The results from this test correlate to results that would be obtained from standard dilution testing of oxacillin. The calling range is 0.25 µg/mL to 4.0 µg/mL.

Cefoxitin Screen

This test may be used to predict *mec*A-mediated oxacillin resistance, and it is based on the cefoxitin disk screen test. The cefoxitin screen and oxacillin work in combination to determine the final interpretation reported for oxacillin.

Synergy Screen

Since the use of penicillin or ampicillin alone often results in treatment failure of serious enterococcal endocarditis, combination therapy is usually indicated to enhance bactericidal activity. The synergy between a cell wall active agent (such as penicillin, ampicillin, or vancomycin) and an aminoglycoside (such as gentamicin, kanamycin or streptomycin) is best predicted for enterococci by screening for high-level resistance to the aminoglycoside. When enterococci are susceptible *in vitro* to the high-level aminoglycoside and a cell wall active agent, this is predictive of the effectiveness of this combination therapy. Results are reported as SYN-S (high-level synergy screen is susceptible) and SYN-R (high-level synergy screen is resistant).

Inducible Clindamycin Resistance Test (ICR)

A positive ICR test is indicative of inducible MLS_b resistance, which confers resistance to macrolides, lincosamides, and type B streptogramin. An isolate with a positive ICR test should be reported as resistant to clindamycin; however, clindamycin may

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still be effective in some patients. If the ICR test is positive and the clindamycin result is susceptible or intermediate, the clindamycin result will be forced resistant by the ICR test (in CLSI® mode or User-defined based on CLSI®).

STORAGE CONDITIONS

Upon receipt, store VITEK® 2 AST cards unopened in their original package liner at 2°C to 8°C.

PRINCIPLE OF THE TEST

The AST card for VITEK® 2 Systems is an automated test methodology based on the MIC technique reported by MacLowry and Marsh and Gerlach.[15,16] The AST card is essentially a miniaturized and abbreviated version of the doubling dilution technique for MICs determined by the microdilution method.[1]

Each AST card contains a control well containing only microbiological culture medium. The remaining microwells contain premeasured amounts of specific antimicrobials combined with culture medium.

The organism suspension to be tested must be diluted to a standardized concentration in 0.45% saline before being used to rehydrate the antimicrobial medium within the card. The card is then filled, sealed, and placed into the instrument incubator/reader, either automatically (as with VITEK® 2 60 or VITEK® 2 XL) or manually (as with VITEK® 2 Compact). The instrument monitors the growth of each well in the card over a defined period of time (up to 18 hours for *Staphylococcus, Enterococcus* and *S. agalactiae*). At the completion of the incubation cycle, MIC values (or test results, as appropriate) are determined for each antimicrobial contained on the card.

REAGENTS

When used with VITEK® 2 instrumentation, the AST card is a complete system for routine susceptibility testing. Each AST card contains selected antimicrobials in varying concentrations, dried with a microbiological culture medium.

Contents of the Card

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Benzylpenicillin	p04n	0.125, 0.25, 1	0.03	0.5	*Staphylococcus* spp.
Cefoxitin Screen	oxsf01n	6	NEG	POS	*Staphylococcus* spp.
Clindamycin	cm01n	0.5, 1, 2	0.25	8	*Staphylococcus* spp., *S. agalactiae*
Erythromycin	e02n❶	0.25, 0.5, 2	0.25	8	*Staphylococcus* spp., *Enterococcus* spp., *S. agalactiae*
Fosfomycin	fos01n	8, 32	8	128	**N/A
Fusidic Acid	fa01n	0.5, 1, 4	0.5	32	**N/A
Gentamicin	gm01n	8, 16, 64	0.5	16	*Staphylococcus* spp.
Inducible Clindamycin Resistance	icr02n❷	CM 0.5, CM/E 0.25/0.5	NEG	POS	*Staphylococcus* spp.
Levofloxacin	lev01n	0.25, 2, 8	0.12	8	*Staphylococcus* spp., *Enterococcus* spp., *S. agalactiae*
Linezolid	lnz02n	0.5, 1, 2	0.5	8	*S. agalactiae*, *E. faecalis*, *E. faecium*, *S. aureus*, *S. epidermidis*, *S. haemolyticus*
Moxifloxacin	mxf02n	0.25, 2, 8	0.25	8	**MSSA
Mupirocin	mup01n❶	1	2	8	**N/A
Nitrofurantoin	ft01n	16, 32, 64	16	512	*Staphylococcus* spp., *Enterococcus* spp.
Oxacillin	ox101n	0.5, 1, 2	0.25	4	*Staphylococcus* spp.
Rifampicin	ra01n	0.25, 0.5, 2	0.5	32	*Staphylococcus* spp.
Teicoplanin	tec01n	1, 4, 8, 16	0.5	32	**N/A

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Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Tetracycline	te03n	0.5, 1, 2	1	16	*Staphylococcus* spp., *Enterococcus* spp., *S. agalactiae*
Tigecycline	tgc02n[NS]	0.25, 0.5, 1	0.12	2	*E. faecalis*, *E. faecium*, *S. aureus*, *S. epidermidis*, *S. haemolyticus*, *S. agalactiae*, *E. casseliflavus*
Tobramycin	tm01n	16, 32, 64	1	16	**N/A
Trimethoprim/ Sulfamethoxazole	sxt02n❷	8/152, 16/304, 32/608	10 (0.5/9.5)	320 (16/304)	**N/A
Vancomycin	va04n❷	1, 2, 4, 8, 16	0.5	32	*Enterococcus* spp., *Staphylococcus* spp., *S. agalactiae*

Numerical values are expressed in µg/mL.

§ Equivalent standard method concentration by efficacy.

NEG = Negative

POS = Positive

❶, ❷ etc. = See performance characteristics identified by the drug code with this symbol.

**N/A = No specific FDA Indications for Use available

**MSSA = Methicillin-susceptible *S. aureus*

[NS] = The current absence of resistant isolates precludes defining any results other than susceptible. Isolates yielding MIC results suggestive of Nonsusceptible category should be submitted to a reference laboratory for further testing.

PRECAUTIONS

- For *In Vitro* Diagnostic Use Only.
- For US Only: Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- For professional use only.
- Suspensions not within the appropriate zone on the VITEK® 2 DensiCHEK™ Plus or VITEK® 2 DensiCHEK™ may compromise card performance.
- Do not use the card after the expiration date shown on the package liner.
- Store the card unopened in the package liner. Do not use the card if the protective package liner is damaged or if no desiccant is present.
- Allow the card to come to room temperature before opening the package liner.
- Do not use powdered gloves. Powder may interfere with the optics.
- Use of culture media other than the recommended types must be validated by the customer laboratory for acceptable performance.
- The card performs as intended only when used in conjunction with VITEK® 2 Systems, following the instructions contained in the Instructions for Use.
- It is highly recommended that Good Laboratory Practices (e.g., FDA, CLSI, ISO, etc.) also be followed, according to local guidelines or requirements.
- **Do not use glass test tubes**. Use clear plastic (polystyrene) tubes only. Variation exists among test tubes of standard diameter. Carefully place the tube into the cassette. If resistance is encountered, discard and try another tube that does not require pressure to insert.
- Prior to inoculation, inspect cards for tape tears or damage to the tape and discard any that are suspect. Check the saline level in the tubes after the cassette has been processed to ensure proper filling of card.
  - VITEK® 2 60 or VITEK® 2 XL: Eject improperly filled cards.
  - VITEK® 2 Compact: Do not load improperly filled cards.

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- Give special consideration to specimen source and patient therapy regimen. AST cards may contain some antimicrobials that are not proven to be effective for treatment of infections due to all organisms that may be tested. For interpreting and reporting of antimicrobial results that have been shown to be active against organism groups both *in vitro* and in clinical infections, refer to the individual pharmaceutical antimicrobial labeling or local therapy guidelines.
- Interpretation of test results requires the judgment and skill of a person knowledgeable in AST. Additional testing may be required.[17]

Warning: All patient specimens, microbial cultures, and inoculated VITEK® 2 cards, along with associated materials, are potentially infectious and should be treated with universal precautions [18,20]

INSTRUMENT

The VITEK® 2 instruments are a family of *in vitro* diagnostic devices intended to rapidly assess the antimicrobial susceptibility of bacterial and yeast pathogens to available antimicrobial agents. For detailed information on the use and operation of these devices, refer to the appropriate Instrument User Manual.

SPECIMEN PREPARATION

Culture Requirements Table

VITEK® 2 Card	Media	Age of Culture	Incubation Conditions	McFarland Standards	Dilution for AST	Age of Suspension Before Loading Instrument
AST Gram-Positive	TSAB CBA CPS ID	18 to 24 hours	35°C to 37°C 5% to 10% CO_2 or aerobic, non-CO_2	0.50 to 0.63	280 µL in 3.0 mL 0.45% saline	VITEK® 2 Compact: ≤30 minutes VITEK® 2: ≤ 1 hour
GP and AST GP pair	TSAB[1] CBA[1] CPS ID	18 to 24 hours	35°C to 37°C 5% to 10% CO_2 or aerobic, non-CO_2	0.50 to 0.63	280 µL in 3.0 mL 0.45% saline	≤ 30 minutes

[1] These media were used in the identification product database developments and will give optimal performance.

Culture Requirements Table — Media Abbreviations

CBA = Columbia Sheep Blood Agar

CPS ID = chromID™ CPS (CPS ID Agar)

TSAB = Trypticase Soy Agar with 5% Sheep Blood

TEST PROCEDURE

Warning: Failure to properly follow instructions and recommendations provided in this section for performing laboratory tasks may cause erroneous or delayed results.

Materials

Materials provided are:

- VITEK® 2 DensiCHEK™ Plus Kit
- DensiCHEK™ Plus Standards Kit
- VITEK® 2 Cassette
- Adjustable volume saline dispenser
- 12 mm x 75 mm clear plastic (polystyrene) disposable test tubes
- VITEK® 2 60 or VITEK® 2 XL only: VITEK® 2 Pipettor/Diluter Accessory Kit (containing instrument pipette tips and saline hookup) and 0.45% saline bag

Materials required, but not provided are:

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- Sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Loops, sterile sticks or swabs
- Appropriate agar medium (See the Culture Requirements Table.)
- QC isolates
- VITEK® 2 AST Cards
- Micropipettors to deliver 280 µL
- Disposable pipette tips

Optional Accessories:

- Pre-dispensed saline test tubes (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Test tube caps
- Vortex

Test Card Setup Procedure

The following procedure contains general information applicable to all susceptibility products. (See the Culture Requirements Table for product-specific information.)

Note: Prepare the inoculum from a pure culture, according to good laboratory practices. In case of mixed cultures, a re-isolation step is required. It is recommended that a purity check plate be done to ensure that a pure culture was used for testing.

1. Do one of the following:
   - Select isolated colonies from a primary plate if culture requirements are met.
   - Subculture the organism to be tested to appropriate agar medium and incubate accordingly.
2. Aseptically transfer 3.0 mL of sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0) into a clear plastic (polystyrene) test tube (12 mm x 75 mm).
3. Use a sterile stick or swab to transfer a sufficient number of morphologically similar colonies to the saline tube prepared in step 2. Prepare a homogenous organism suspension with a density equivalent to the appropriate McFarland standard using the VITEK® 2 DensiCHEK™ Plus (see the Culture Requirements Table). The inoculum density required for the GN, GP, ST, or YST can be diluted automatically for AST cards by the VITEK® 2 instrument (VITEK® 2 60 or VITEK® 2 XL).
   Note: The age of the suspension before loading the instrument for AST testing must be less than one hour when using VITEK® 2 60 or VITEK® 2 XL, and less than 30 minutes when using VITEK® 2 Compact.
4. Choose one of the following:
   - **For an automatic dilution (VITEK® 2 60 or VITEK® 2 XL only):** Place the suspension tube prepared in step 3 into the cassette with or without an identification card. In the next cassette slot, place an empty tube and an AST card. The instrument will automatically dilute the bacterial suspension to prepare an inoculum suitable for the susceptibility card.
   - **For a manual dilution (VITEK® 2 Compact, VITEK® 2 60 or VITEK® 2 XL):** In a second tube containing 3.0 mL of saline, transfer 280 µL of the suspension prepared in step 3. Then place this tube in the cassette with a susceptibility card. The tube with the initial bacterial suspension can also be used for inoculation of an identification card.

   Note: Check the saline level in the tubes after filling. When it is evident by the saline level in the tube that a card has been improperly filled, do not load the card if using VITEK® 2 Compact; **or**, eject the card if using VITEK® 2 60 or VITEK® 2 XL.

   Note: Refer to the appropriate Instrument User Manual for detailed information regarding data entry, processing, etc.
5. Follow your local inspecting agency's guidelines for disposal of hazardous waste.

QUALITY CONTROL

Quality Control organisms should be processed according to the Test Card Setup Procedure.

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Quality Control

CLSI® Quality Control Organisms VITEK® 2 Results									
Antimicrobic	Code	*E. faecalis* ATCC® 29212™	*S. aureus* ATCC® 29213™	*E. coli* ATCC® 35218™	*S. pneumoniae* ATCC® 49619™	*E. faecalis* ATCC® 51299™	*S. aureus* ATCC® BAA-1026™	*S. aureus* ATCC® BAA-976™	*S. aureus* ATCC® BAA-977™
Benzylpenicillin	p04n	-	0.25 - ≥ 0.5	-	-	-	-	-	-
Cefoxitin Screen	oxsf01n	-	NEG	-	-	-	POS	-	-
Clindamycin	cm01n	4 - ≥ 8	≤ 0.25	-	-	-	-	-	-
Erythromycin	e02n	1 - 4	≤ 0.25 - 1	-	-	-	-	-	-
Fosfomycin	fos01n	-	≤ 8	-	-	-	-	-	-
Fusidic Acid	fa01n	-	≤ 0.5	-	-	-	-	-	-
Gentamicin	gm01n	-	≤ 0.5 - 1	-	-	-	-	-	-
Inducible Clindamycin Resistance	icr02n	-	-	-	-	-	-	NEG	POS
Levofloxacin	lev01n	0.25 - 2	≤ 0.12 - 0.5	-	-	-	-	-	-
Linezolid	lnz02n	1 - 4	1 - 4	-	-	-	-	-	-
Moxifloxacin	mxf02n	≤ 0.25 - 0.5	≤ 0.25	-	-	-	-	-	-
Mupirocin	mup01n	-	≤ 2	-	-	-	-	-	-
Nitrofurantoin	ft01n	≤ 16	≤ 16 - 32	-	-	-	-	-	-
Oxacillin	ox101n	-	≤ 0.25 - 0.5	-	-	-	-	-	-
Rifampicin	ra01n	-	≤ 0.5	-	-	-	-	-	-
Teicoplanin	tec01n	≤ 0.5	≤ 0.5 - 1	-	-	-	-	-	-
Tetracycline	te03n	8 - ≥ 16	≤ 1	-	-	-	-	-	-
Tigecycline[NS]	tgc02n	≤ 0.12	≤ 0.12 - 0.25	-	-	-	-	-	-
Tobramycin	tm01n	-	≤ 1	-	-	-	-	-	-
Trimethoprim/ Sulfamethoxazole	sxt02n	≤ 10 (0.5/9.5)	≤ 10 (0.5/9.5)	-	-	-	-	-	-
Vancomycin	va04n	1 - 4	≤ 0.5 - 2	-	-	-	-	-	-

Numerical values are expressed in µg/mL.

NEG = Negative

POS = Positive

[NS] = The current absence of resistant isolates precludes defining any results other than susceptible. Isolates yielding MIC results suggestive of Nonsusceptible category should be submitted to a reference laboratory for further testing.

Certification Statement

This is to certify that bioMérieux complies with ISO 13485 and FDA Quality System Regulation (QSR) requirements for design, development, and manufacture of antimicrobial susceptibility systems.

Frequency of QC Testing

Refer to *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically,* CLSI® and/or your local guidelines.[2]

Preparation of QC Organisms

1. Rehydrate the organism according to the manufacturer's instructions.
2. Subculture to Trypticase Soy Agar with 5% sheep blood (TSAB).
3. Incubate at 35°C for 24 hours.
   Note: Gram-positive organisms may require an atmosphere of CO_2. (Refer to the Culture Requirements Table).
4. Check for purity.

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5. Subculture to a TSAB plate.
6. Incubate 16 to 18 hours at 35°C.

Short-Term Storage Conditions

1. Streak to a TSAB plate or slant.
2. Incubate for 24 hours.
3. Refrigerate at 2°C to 8°C for up to two weeks.
4. Subculture once as described above and use for QC.

Long-Term Storage Conditions

1. Make a heavy suspension in Tryptic Soy Broth (TSB) with 15% glycerol.
2. Freeze at -70°C.
3. Subculture to TSAB twice before running QC.
   Note: Avoid repeated thawing and refreezing by either freezing in single-use aliquots or removing a small portion of frozen organism preparation with a sterile applicator stick.

RESULTS

Susceptibility Analytical Techniques

The system evaluates each organism's growth pattern in the presence of the antimicrobial in relation to the growth control well. Several parameters based on the growth characteristics are used to determine the MIC or qualitative result (for example, ESBL POS/NEG). The MIC result must be linked to an organism identification to determine a category interpretation. Accurate identification is critical, especially with certain organism/antimicrobial combinations (e.g., *Staphylococcus aureus*/oxacillin).

In cases where the identification of an organism is in question, confirmatory testing is necessary to ensure correct interpretation of susceptibility results.

A category interpretation will be reported along with a MIC, according to the interpretations defined by the Food and Drug Administration (FDA), CLSI®, Comité de l'Antibiogramme de la Société Française de Microbiologie (CASFM), European Committee for Antimicrobial Susceptibility Testing (EUCAST), or to an adaptation of the global settings according to other local guidelines.

Note: When FDA and CLSI® breakpoints differ, VITEK® 2 Systems AST tests are cleared for use with FDA breakpoints applied.

Combination Antimicrobials

The MICs for the combination antimicrobials are listed on the laboratory and patient reports as the first concentration (e.g., ampicillin/sulbactam ≤ 8/4 µg/mL is reported as ≤ 8 µg/mL.). The actual concentrations for each value in the antimicrobial calling range are as follows:

- trimethoprim/sulfamethoxazole: **Note exception** — This drug is listed on the laboratory and patient reports as the sum of the two antimicrobial concentrations: 20 µg/mL = 1/19, 40 µg/mL = 2/38, 80 µg/mL = 4/76, 160 µg/mL = 8/152, 320 µg/mL = 16/304

Antimicrobial Deduction

Antimicrobials that have been deduced will only report an interpretive result and will be noted with a **+**.

Clinical Efficacy and Indications for Use

AST cards may contain some antimicrobials that are not proven to be effective for treatment of infections caused by all organisms that may be tested. For interpreting and reporting of antimicrobial results that have shown to be active against organism groups both *in vitro* and in clinical infections, refer to the individual pharmaceutical antimicrobial labeling or the local therapy guidelines.

Urinary Use Only Antimicrobials

Certain antimicrobial agents are limited to use in treating urinary tract infections. Accordingly, these agents should not be reported against pathogens recovered from infection sites other than the urinary tract (except as noted). Please refer to the current *CLSI Performance Standards for Susceptibility Testing, M100* and/or local guidelines for additional information.[3]

For urine only, per CLSI®.[3]

- *Staphylococcus* spp.: lomefloxacin, norfloxacin, nitrofurantoin, sulfisoxazole, trimethoprim

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- *Enterococcus* spp.: ciprofloxacin, levofloxacin, norfloxacin, nitrofurantoin, tetracycline

LIMITATIONS

A VITEK® 2 AST card cannot be used with a direct clinical specimen or sample or other sources containing mixed flora. Any change or modification in the procedure may affect the results.

A result for an antibiotic/organism combination, which may have a limitation, may be suppressed from reporting. This can be accomplished through the use of bioART rules in the VITEK® 2 Systems software. Refer to the software user manual for instructions.

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

- Erythromycin (e02n): *Streptococcus agalactiae*
- Cefoxitin Screen (oxsf01n): *Staphylococcus pseudintermedius* (specific to VITEK® 2 Systems 8.01 software or higher)

Perform an alternative method of testing prior to reporting of results when a Positive (+) result is obtained with the following antibiotic/organism combination(s):

- Cefoxitin Screen (oxsf01n): *Staphylococcus saprophyticus*

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:

- Linezolid (lnz02n): *Enterococcus* spp., *Staphylococcus* spp., *Streptococcus agalactiae*
- Tigecycline (tgc02n): *Enterococcus* spp., *Staphylococcus* spp., *Streptococcus* spp.

EUCAST Limitations

It is recommended that the existing bioART suppression rules be enabled, or new rules created and enabled, for these limitations if the EUCAST breakpoints are applied.

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

- Erythromycin (e02n): *Streptococcus agalactiae, Staphylococcus* spp.
- Teicoplanin (tec01n): *Staphylococcus epidermidis, Staphylococcus haemolyticus*
- Cefoxitin Screen (oxsf01n): *Staphylococcus pseudintermedius* (specific to VITEK® 2 Systems 8.01 software or higher)

Perform an alternative method of testing prior to reporting of results when a Positive (+) result is obtained with the following antibiotic/organism combination(s):

- Cefoxitin Screen (oxsf01n): *Staphylococcus saprophyticus*

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:

- Linezolid (lnz02n): *Streptococcus agalactiae*
- Nitrofurantoin (ft01n): *Staphylococcus saprophyticus*
- Tigecycline (tgc02n): *Streptococcus agalactiae, Staphylococcus* spp.

EXPECTED VALUES

Expected results for susceptibility tests will vary based on location and institution. VITEK® 2 Systems were tested at several geographically diverse locations to ensure that trends that occurred by location were integrated into the performance characteristics of the system. Organism resistance patterns will differ by institution; therefore, expected values will be directly related to the population of organisms at each site.

PERFORMANCE CHARACTERISTICS

The performance characteristics of the antimicrobial agents included in VITEK® 2 AST cards were established using the manual and autodilution modes (on a VITEK® 2 System) at multiple clinical laboratories. The VITEK® 2 AST card results were compared to results from a CLSI® reference method. Essential agreement (EA) represents VITEK® 2 results which agree exactly or are within a ± twofold dilution (± two doubling dilutions for antifungal) of the reference result.

Category agreement (CA) occurs when the VITEK® 2 and the reference interpretative results agree (Susceptible, Intermediate, and Resistant). There are instances when the category agreement for an antimicrobial falls below the essential agreement. This can occur when a significant number of MICs cluster around a category breakpoint during clinical trial testing, resulting in interpretative errors. For a description of interpretive errors, refer to the footnotes below the table that

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follows (Performance Characteristics). When the majority of the errors are of the minor type, a high corresponding essential agreement percentage demonstrates that the antimicrobial retains an acceptable overall performance.

There are instances when the performance is based solely on category agreement (CA) because at the time performance was established, less than five discrete twofold dilutions were evaluated. A minimum of five dilutions is necessary to calculate essential agreement (EA) based on ± one twofold dilution. These instances are designated by a "c" footnote in the Contents of the Card table. The following performance tables have values for CA only when EA was not established at the time of FDA clearance.

The reproducibility of the VITEK® 2 system was established by testing a set of on-scale organisms.*

*Data on file at bioMérieux, Inc

Performance Characteristics for Gram-Positive Antimicrobial Susceptibility Testing

Antimicrobial	Antimicrobial Code	Antibiotic Version	Bp[1]	Comment[2]	Essential Agreement				Category Agreement				% Reproducibility
					% Error				% Error				
					% EA	VME	ME	mE	% CA	VME	ME	mE	
Benzylpenicillin (Penicillin)	P	p04n	CLSI	#, E	97.4	0.4	0.3	N/A	98.5	0.9	1.0	N/A	99.3
Cefoxitin Screen	OXSF	oxsf01n	CLSI	E, Ref. = CLSI Disk Diffusion	–	–	–	–	98.3	2.0	1.4	N/A	100
				E, Ref. = mecA PCR	–	–	–	–	97.2	2.3	3.2	N/A	
Oxacillin + Cefoxitin Screen			CLSI	#, Ref. = CLSI Cefoxitin Disk Diffusion	–	–	–	–	98.5	0.4	2.8	N/A	–
Oxacillin + Cefoxitin Screen			CLSI	E, Ref. = mecA PCR	–	–	–	–	97.8	1.2	3.2	N/A	–
Clindamycin	CM	cm01n	CLSI	#, E	98.7	2.3	0.0	0.7	99.1	2.3	0.0	0.9	98.5
			CA-SFM	I	96.1	2.5	4.3	0.0	-	-	-	-	
Erythromycin	E	e02n	CLSI	#, E ❶	95.9	0.4	0.4	5.1	92.8	0.4	0.4	7.5	95.2
			CA-SFM	I ❶	94.7	9.4	0.0	0.3	95.0	9.4	0.0	0.3	
Fosfomycin	FOS	fos01n	CA-SFM	I, Staph	97.1	6.5	0.3	N/A	95.8	11.8	1.7	N/A	100
Fusidic Acid	FA	fa01n	CA-SFM	I, Staph	100	0.0	0.0	0.0	99.2	0.0	0.0	0.8	100
Gentamicin	GM	gm01n	CLSI	#, E, Staph	99.2	0.0	0.0	0.8	95.1	0.0	0.0	4.9	100
			CA-SFM	E, Staph	99.2	0.0	0.0	0.8	95.1	0.0	0.0	4.9	
Inducible Clindamycin Resistance	ICR	icr02n	CLSI	#, E	N/A	N/A	N/A	N/A	99.5	2.0	0.4	N/A	100
Levofloxacin	LEV	lev01n	CLSI	#, E	99.3	0.0	0.0	0.2	95.8	0.0	0.0	4.2	100
Linezolid	LNZ	lnz02n	CLSI	#, E	98.7	0.0	0.1	0.1	98.9	0.0	0.1	1.0	100
			CA-SFM	E	98.7	0.0	0.1	0.7	92.6	0.0	0.1	7.3	
Moxifloxacin	MXF	mxf02n	CLSI	#, E	99.2	0.0	0.0	0.0	83.3	0.0	0.0	16.7	100
			CA-SFM	E	98.5	0.0	0.0	0.1	92.4	0.0	0.0	7.6	
Mupirocin	MUP	mup01n	CA-SFM	E ❶	99.7	0.0	0.0	0.0	100	0.0	0.0	0.0	100
			Global	E ❶	99.7	0.0	0.3	0.0	99.2	0.0	0.9	0.0	
Nitrofurantoin	FT	ft01n	CLSI	#, E	98.3	0.0	1.4	0.0	91.7	0.0	1.4	7	100
Oxacillin	OX1	ox101n	CLSI	#, E, Staph	97.4	1.6	1.1	0.0	97.1	2.2	3.4	0.0	98.1
Rifampicin (Rifampin)	RA	ra01n	CLSI	#, E	100	0.0	0.0	0.0	100	0.0	0.0	0.0	100
			CA-SFM	I, Staph	99.5	0.0	0.0	0.3	–	–	–	–	

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Antimicrobial	Antimicrobial Code	Antibiotic Version	Bp[1]	Comment[2]	Essential Agreement				Category Agreement				% Reproducibility
					% Error				% Error				
					% EA	VME	ME	mE	% CA	VME	ME	mE	
Teicoplanin	TEC	tec01n	CLSI	I	96.6	3.3	0.3	0.4	95.7	3.3	0.3	2.7	99.4
			CA-SFM	I	96.9	1.6	0.0	1.1	95.9	1.6	0.3	3.2	
Tetracycline	TE	te03n	CLSI	#, E	99.1	1.2	0.4	0.5	99.3	1.2	0.5	0.8	94.8
Tigecycline	TGC	tgc02n	CLSI	#, E	–	–	–	–	99.4	66.7†	0.4	N/A	100
Tobramycin	TM	tm01n	CLSI	E, Staph	99.5	0.0	0.0	0.3	95.1	0.0	0.0	4.9	100
			CA-SFM	E, Staph	99.5	0.0	0.0	0.3	95.1	0.0	0.0	4.9	
Trimethoprim/ Sulfamethoxazole	SXT	sxt02n	CLSI	I ❷	97.3	1.6	1.5	0.0	–	–	–	–	97.6
			CA-SFM	I ❷	97.3	0.0	0.8	1.8	–	–	–	–	
Vancomycin	VA	va04n	CLSI[3]	#, E ❷	99.9	0.0	0.0	0.1	99.7	0.0	0.0	0.3	100
			CA-SFM	E ❷	99.9	0.0	0.0	0.1	99.7	0.0	0.0	0.3	

[1] Abbreviations — Bp = breakpoint committee; EA = essential agreement; CA = category agreement; VME = Very Major Error (susceptible result with resistant reference result); ME = Major Error (resistant result with susceptible reference result); mE = minor Error (susceptible or resistant result with an intermediate reference result, or an intermediate result with a susceptible or resistant reference result).

[2] Comment — Specific organism groups are designated as Staph for *staphylococci*, Enc for *enterococci*, S aga for Group B *streptococci*, Sau for *Staphylococcus aureus*.

[3] FDA breakpoints are used in the CLSI Interpretation Standard (breakpoint committee) in the VITEK® 2 Systems software.

For all gram-positive Beta-lactams with indications for *Staphylococcus* spp., with the exception of Benzylpenicillin (Penicillin), performance in this table represents forcing-resistance based on oxacillin resistance.

† Non-defined error; susceptible (S) breakpoints only, no I or R breakpoints exist.

Key:

= US Food and Drug Administration 510(k) cleared
CLSI® = Clinical and Laboratory Standards Institute
CA-SFM = Comité de l'Antibiogramme de la Société Française de Microbiologie
E = External performance data
I = Internal performance data
– = Not available
N/A = Not applicable
Ref. = Reference method for clinical performance study.
❶ ❷ = Symbol identifies the performance characteristics for a specific antimicrobial version.

EUCAST Performance Characteristics for Gram-Positive Antimicrobial Susceptibility Testing

Antimicrobial	Antimicrobial Code	Antibiotic Version	Comment[1]	Essential Agreement				Category Agreement			
				% Error				% Error			
				%EA[2]	VME	ME	mE	%CA	VME	ME	mE
Benzylpenicillin	P	p04n	*Staphylococcus, S. agalactiae*	98.3	0.8	1.9	0.0	98.3	0.8	3.9	0.0
Clindamycin	CM	cm01n	*Staphylococcus, S. agalactiae*	98.1	3.3	0.3	0.0	98.1	3.3	0.3	0.7
Erythromycin	E	e02n	*Staphylococcus* ❶	94.7	9.4	0.0	0.0	95.3	9.4	0.0	0.0
Fosfomycin	FOS	fos01n	*Staphylococcus*	97.1	6.5	0.3	N/A	95.8	11.8	1.7	N/A
Fusidic Acid	FA	fa01n	*Staphylococcus*	100.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0
Gentamicin	GM	gm01n	*Staphylococcus*	99.2	0.0	0.0	0.0	99.7	0.0	0.4	0.0
Levofloxacin	LEV	lev01n	N/A	99.7	1.4	0.0	0.0	98.4	1.4	0.0	1.3

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Antimicrobial	Antimicrobial Code	Antibiotic Version	Comment[1]	Essential Agreement				Category Agreement			
				% Error				% Error			
				%EA[2]	VME	ME	mE	%CA	VME	ME	mE
Linezolid	LNZ	lnz02n	N/A	98.7	0.0	0.1	0.0	99.5	0.0	0.5	0.0
Moxifloxacin	MXF	mxf02n	*Staphylococcus, S. agalactiae*	99.0	0.7	0.0	0.5	95.2	0.7	0.0	4.6
Nitrofurantoin	FT	ft01n	*S. saprophyticus*	98.2	0.0	0.0	0.0	100	0.0	0.0	0.0
Rifampicin	RA	ra01n	*Staphylococcus*, *S. agalactiae*	96.0	0.0	0.0	3.5	88.4	0.0	0.0	11.6
Teicoplanin	TEC	tec01n	*S. agalactiae, S. aureus, Enterococcus*, coagulase-negative *Staphylococcus* except *S. epidermidis* and *S. haemolyticus*	98.9	4.8	0.2	0.0	99.4	4.8	0.2	0.0
Tetracycline	TE	te03n	*Staphylococcus, S. agalactiae*	98.5	1.0	1.4	0.3	96.0	1.0	1.4	2.8
Tigecycline	TGC	tgc02n	N/A	99.0	0.0	0.0	0.3	99.5	66.7	0.0	0.3
Tobramycin	TM	tm01n	*Staphylococcus*	98.9	0.8	0.4	0.0	99.4	0.8	0.4	0.0
Trimethoprim/ Sulfamethoxazole	SXT	sxt02n	*Staphylococcus, S. agalactiae* ❷	92.9	6.7	4.1	2.2	89.8	6.7	4.1	6.2
Vancomycin	VA	va04n	*Staphylococcus, S. agalactiae, Enterococcus* ❷ (EUCAST v1.3 breakpoints)	99.8	2.0	0.0	0.0	99.7	4.1	0.1	0.0
			Staphylococcus, S. agalactiae, Enterococcus ❷ (EUCAST v2.0 breakpoints)	99.8	2.1	0.0	0.0	99.7	8.3	0.0	0.0

[1] Comment — Unless stated otherwise, performance is for *Staphylococcus*, *Enterococcus*, and *S. agalactiae*.

[2] Abbreviations — Bp = breakpoint committee; EA = essential agreement; CA = category agreement; VME = Very Major Error (susceptible result with resistant reference result); ME = Major Error (resistant result with susceptible reference result); mE = minor Error (susceptible or resistant result with an intermediate reference result, or an intermediate result with a susceptible or resistant reference result).

Key:

= EUCAST = European Committee on Antimicrobial Susceptibility
❶ ❷ = Symbol identifies the performance characteristics for a specific antimicrobial version.

LIST OF CLAIMS

Note: If the organism is not in the VITEK® 2 susceptibility database, results will not be reported.

Note: Organisms listed with an asterisk (*) indicate an AES claimed organism. No asterisk is displayed for a group; however, when an individual species (with an asterisk) is contained within a group, it is expertised.

Gram-Positive Organisms Claimed for AST-GP (keyID)

- *Coagulase-negative Staphylococcus**
- *Coagulase-positive Staphylococcus**
- *Enterococcus avium*
- *Enterococcus casseliflavus**
- *Enterococcus durans*
- *Enterococcus faecalis**
- *Enterococcus faecalis* ATCC® 29212™
- *Enterococcus faecalis* ATCC® 51299™
- *Enterococcus faecium**

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- *Enterococcus gallinarum**
- *Enterococcus hirae*
- *Enterococcus malodoratus*
- *Enterococcus mundtii*
- *Enterococcus* spp.*
- *Escherichia coli* ATCC® 35218™
- *Staphylococcus aureus**
- *Staphylococcus aureus* ATCC® 29213™
- *Staphylococcus aureus* ATCC® BAA-976™
- *Staphylococcus aureus* ATCC® BAA-977™
- *Staphylococcus aureus* ATCC® BAA-1026™
- *Staphylococcus auricularis**
- *Staphylococcus capitis**
- *Staphylococcus chromogenes**
- *Staphylococcus cohnii**
- *Staphylococcus cohnii* ssp. *cohnii**
- *Staphylococcus cohnii* ssp. *urealyticus**
- *Staphylococcus epidermidis**
- *Staphylococcus haemolyticus**
- *Staphylococcus hominis**
- *Staphylococcus hominis* ssp. *hominis**
- *Staphylococcus hyicus**
- *Staphylococcus intermedius**
- *Staphylococcus kloosii**
- *Staphylococcus lentus**
- *Staphylococcus lugdunensis**
- *Staphylococcus pseudintermedius*
- *Staphylococcus saprophyticus**
- *Staphylococcus schleiferi**
- *Staphylococcus sciuri**
- *Staphylococcus simulans**
- *Staphylococcus warneri**
- *Staphylococcus xylosus**
- *Streptococcus agalactiae**
- *Streptococcus pneumoniae**
- *Streptococcus pneumoniae* ATCC® 49619™

REFERENCES

1. Barry, AL The Antimicrobic Susceptibility Test, Principles and Practices, Lea and Febiger, Philadelphia, PA. 1976.

2. Clinical Laboratory Standards Institute (CLSI®), Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically, M7- A7, Wayne, Pennsylvania, January 2006.

3. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Eighteenth Informational Supplement, M100-S18, Vol. 27, No. 1, January 2008.

4. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-third Informational Supplement, M100-S22, January 2012.

5. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-fourth Informational Supplement; M100-S24, January 2014.

6. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-fifth Informational Supplement, M100-S25, January 2015.

7. Comité de l'Antibiogramme de la Société Française de Microbiologie. Communiqué 1996. Path Biol, 1996, 44, n° 8, I-VIII.

8. Comité de l'Antibiogramme de la Société Française de Microbiologie, Communiqué 2007.

9. Comite de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM), Recommendations 2012.

10. Comité de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM). Communiqué 2014.

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11. Comité de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM). Communiqué 2015.
12. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 2.0, January 2012.
13. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 4.0, January 2014.
14. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 5.0, January 2015.
15. Gerlach, EH Microdilution 1: A Comparative Study, p. 63-76, In: Balows, A. (ed.), Current Techniques for Antibiotic Susceptibility Testing, Charles C. Thomas, Springfield, IL. 1974.
16. MacLowry, JD, and HH Marsh. 1968. Semi-automatic microtechnique for serial dilution antibiotic sensitivity testing in the clinical laboratory. J. Lab. Clin. Med. 1968;72:685-687.
17. Murray, PR, Baron EJ, Pfaller MA, Tenover FC, and Yolken RH, editors. Manual of Clinical Microbiology, 8th ed. American Society for Microbiology, Washington, D.C. 2003.
18. National Committee for Clinical Laboratory Standards, M29-A, Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissue – Approved Guideline (1997).
19. National Committee for Clinical Laboratory Standards, Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Approved Standard — Third Edition, M27-A3, Vol. 22, No. 15, 2008.
20. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health, Office of Health and Safety, Biosafety in Microbiological and Biomedical Laboratories, 1988.

Permission to incorporate portions of M100 (Performance Standards for Antimicrobial Susceptibility Testing: Informational Supplement) in the bioMérieux clinical microbiology instrumentation and System has been granted by CLSI®. The current standard and supplements to it may be obtained from CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

BARCODES

User MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.

01 A3209R0X---J

02 BAST-P580015

03 C---Z0G370PN

04 D0I0T0U193I-

05 E132N2R300VB

06 F200X0Y1H3KJ

07 G2T0K3L-V-U1

08 H-T-S-P-K-J1

09 I-I-F-60000T

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INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalog number
IVD	In Vitro Diagnostic Medical Device
	Legal Manufacturer
	Temperature limitation
	Use by date
LOT	Batch code
	Consult Instructions for Use
	Date of manufacture
	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community
Rx only	For US Only : Caution : US Federal Law restricts this device to sale by or on the order of a licensed practitioner

Instructions for Use provided in the kit or downloadable from www.biomerieux.com/techlib

LIMITED WARRANTY

bioMérieux warrants the performance of the product for its stated intended use provided that all procedures for usage, storage and handling, shelf life (when applicable), and precautions are strictly followed as detailed in the instructions for use (IFU).

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WASTE DISPOSAL

All hazardous waste must be disposed of by following your local inspecting agency's guidelines.

REVISION HISTORY TABLE

Change type categories	
N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user
Note:	Minor typographical, grammar, and formatting changes are not included in the revision history.

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Release Date	Part Number	Change Type	Change Summary
2018-01	045573-01	Administrative	• Formatting changes do not affect the fit, form, or function of the product
		Technical change	• Combined product package insert content with VITEK® 2 Product Information Manual AST content • Updated Limited Warranty section • Updated with RX only information • Updated with EUCAST limitations

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045610- 01 - 2018-01 EN

VITEK® 2 AST-P592

Rx only IVD

INTENDED USE

The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of *Staphylococcus* spp., *Enterococcus* spp., and *S. agalactiae* to antimicrobial agents when used as instructed.

SUMMARY AND EXPLANATION

Susceptibility testing is indicated for any organism that contributes to an infectious process warranting antimicrobial chemotherapy. Susceptibility tests are most often indicated when the causative organism is thought to belong to a species capable of exhibiting resistance to commonly used agents. Isolated colonies of each type of organism that may play a pathogenic role are selected from an agar plate and tested for susceptibility. These tests are then examined and the Minimum Inhibitory Concentration (MIC) is determined. The MIC obtained using a dilution test may tell the physician the concentration of an antimicrobial agent needed at the site of infection to inhibit the infecting organism.

MICs have traditionally been determined using antimicrobial concentrations derived from serial twofold dilutions.[2] The MIC is then determined from the lowest concentration that exhibits inhibition of growth. An interpretive criterion (Susceptible, Intermediate, or Resistant) can then be assigned to MIC results to aid in the direction of therapy.

For some antimicrobials (e.g., high-level gentamicin, high-level streptomycin) a qualitative result is generated.

The standard and reference procedures are based on susceptibility tests requiring 16 to 24 hours of incubation for bacteria. Various manufacturers have now developed automated procedures designed to generate results more rapidly by using shortened incubation times. Laboratories worldwide use either variations of the standard reference procedure or a commercially available product to determine the MICs of infectious organisms.

Methicillin-Resistant Staphylococci (MRS)

Resistance to oxacillin is used to detect the presence of MRS. Most MRS are also usually resistant to multiple antimicrobials, including other beta-lactams, aminoglycosides, macrolides, clindamycin, and tetracycline. However, a “community-acquired methicillin-resistant *S. aureus*” phenotype has been described. These are not multi-drug resistant strains, but are typically resistant to penicillin and oxacillin, susceptible or resistant to erythromycin, and susceptible to gentamicin, clindamycin, and tetracycline.

Oxacillin (OX1)

This test provides an MIC determination and category interpretation for oxacillin. Interpretive results for MRS are reported as resistant to all beta-lactams (except anti-MRSA beta-lactams) when the instrument is operating in the CLSI® mode or the User-Defined (based on CLSI®) mode. The results from this test correlate to results that would be obtained from standard dilution testing of oxacillin. The calling range is 0.25 µg/mL to 4.0 µg/mL.

Cefoxitin Screen

This test may be used to predict *mec*A-mediated oxacillin resistance, and it is based on the cefoxitin disk screen test. The cefoxitin screen and oxacillin work in combination to determine the final interpretation reported for oxacillin.

Synergy Screen

Since the use of penicillin or ampicillin alone often results in treatment failure of serious enterococcal endocarditis, combination therapy is usually indicated to enhance bactericidal activity. The synergy between a cell wall active agent (such as penicillin, ampicillin, or vancomycin) and an aminoglycoside (such as gentamicin, kanamycin or streptomycin) is best predicted for enterococci by screening for high-level resistance to the aminoglycoside. When enterococci are susceptible *in vitro* to the high-level aminoglycoside and a cell wall active agent, this is predictive of the effectiveness of this combination therapy. Results are reported as SYN-S (high-level synergy screen is susceptible) and SYN-R (high-level synergy screen is resistant).

Inducible Clindamycin Resistance Test (ICR)

A positive ICR test is indicative of inducible MLS_b resistance, which confers resistance to macrolides, lincosamides, and type B streptogramin. An isolate with a positive ICR test should be reported as resistant to clindamycin; however, clindamycin may

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still be effective in some patients. If the ICR test is positive and the clindamycin result is susceptible or intermediate, the clindamycin result will be forced resistant by the ICR test (in CLSI® mode or User-defined based on CLSI®).

STORAGE CONDITIONS

Upon receipt, store VITEK® 2 AST cards unopened in their original package liner at 2°C to 8°C.

PRINCIPLE OF THE TEST

The AST card for VITEK® 2 Systems is an automated test methodology based on the MIC technique reported by MacLowry and Marsh and Gerlach.[15,16] The AST card is essentially a miniaturized and abbreviated version of the doubling dilution technique for MICs determined by the microdilution method.[1]

Each AST card contains a control well containing only microbiological culture medium. The remaining microwells contain premeasured amounts of specific antimicrobials combined with culture medium.

The organism suspension to be tested must be diluted to a standardized concentration in 0.45% saline before being used to rehydrate the antimicrobial medium within the card. The card is then filled, sealed, and placed into the instrument incubator/reader, either automatically (as with VITEK® 2 60 or VITEK® 2 XL) or manually (as with VITEK® 2 Compact). The instrument monitors the growth of each well in the card over a defined period of time (up to 18 hours for *Staphylococcus, Enterococcus* and *S. agalactiae*). At the completion of the incubation cycle, MIC values (or test results, as appropriate) are determined for each antimicrobial contained on the card.

REAGENTS

When used with VITEK® 2 instrumentation, the AST card is a complete system for routine susceptibility testing. Each AST card contains selected antimicrobials in varying concentrations, dried with a microbiological culture medium.

Contents of the Card

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Ampicillin	am01n	0.5, 4, 8, 32	-	-	*Enterococcus* spp., *S. agalactiae*
Enterococcus spp.			2	32	
S. agalactiae			0.25	16	
Benzylpenicillin	p04n	0.125, 0.25, 1	0.03	0.5	*Staphylococcus* spp.
Cefoxitin Screen	oxsf01n	6	NEG	POS	*Staphylococcus* spp.
Ciprofloxacin	cip01n	1, 2, 4	0.5	8	*Staphylococcus* spp., *Enterococcus* spp.
Clindamycin	cm01n	0.5, 1, 2	0.25	8	*Staphylococcus* spp., *S. agalactiae*
Erythromycin	e02n❶	0.25, 0.5, 2	0.25	8	*Staphylococcus* spp., *Enterococcus* spp., *S. agalactiae*
Fosfomycin	fos01n	8, 32	8	128	**N/A
Fusidic Acid	fa01n	0.5, 1, 4	0.5	32	**N/A
Gentamicin	gm01n	8, 16, 64	0.5	16	*Staphylococcus* spp.
Gentamicin High Level (synergy)	hlg01n	500	S	R	*Enterococcus* spp.
Imipenem	ipm02n	2, 4, 8	1	16	**N/A
Inducible Clindamycin Resistance	icr02n❷	CM 0.5, CM/E 0.25/0.5	NEG	POS	*Staphylococcus* spp.
Linezolid	lnz02n	0.5, 1, 2	0.5	8	*S. agalactiae*, *E. faecalis*, *E. faecium*, *S. aureus*, *S. epidermidis*, *S. haemolyticus*
Moxifloxacin	mxf02n	0.25, 2, 8	0.25	8	**MSSA

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Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Oxacillin	ox101n	0.5, 1, 2	0.25	4	*Staphylococcus* spp.
Rifampicin	ra01n	0.25, 0.5, 2	0.5	32	*Staphylococcus* spp.
Streptomycin High Level (synergy)	hls01n	1000	S	R	*Enterococcus* spp.
Teicoplanin	tec01n	1, 4, 8, 16	0.5	32	**N/A
Tetracycline	te03n	0.5, 1, 2	1	16	*Staphylococcus* spp., *Enterococcus* spp., *S. agalactiae*
Tigecycline	tgc02n[NS]	0.25, 0.5, 1	0.12	2	*E. faecalis*, *E. faecium*, *S. aureus*, *S. epidermidis*, *S. haemolyticus*, *S. agalactiae*, *E. casseliflavus*
Trimethoprim/ Sulfamethoxazole	sxt02n❷	8/152, 16/304, 32/608	10 (0.5/9.5)	320 (16/304)	**N/A
Vancomycin	va04n❷	1, 2, 4, 8, 16	0.5	32	*Enterococcus* spp., *Staphylococcus* spp., *S. agalactiae*

Numerical values are expressed in µg/mL.

§ Equivalent standard method concentration by efficacy.

NEG = Negative

POS = Positive

❶, ❷ etc. = See performance characteristics identified by the drug code with this symbol.

**N/A = No specific FDA Indications for Use available

**MSSA = Methicillin-susceptible *S. aureus*

[NS] = The current absence of resistant isolates precludes defining any results other than susceptible. Isolates yielding MIC results suggestive of Nonsusceptible category should be submitted to a reference laboratory for further testing.

PRECAUTIONS

- For *In Vitro* Diagnostic Use Only.
- For US Only: Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- For professional use only.
- Suspensions not within the appropriate zone on the VITEK® 2 DensiCHEK™ Plus or VITEK® 2 DensiCHEK™ may compromise card performance.
- Do not use the card after the expiration date shown on the package liner.
- Store the card unopened in the package liner. Do not use the card if the protective package liner is damaged or if no desiccant is present.
- Allow the card to come to room temperature before opening the package liner.
- Do not use powdered gloves. Powder may interfere with the optics.
- Use of culture media other than the recommended types must be validated by the customer laboratory for acceptable performance.
- The card performs as intended only when used in conjunction with VITEK® 2 Systems, following the instructions contained in the Instructions for Use.
- It is highly recommended that Good Laboratory Practices (e.g., FDA, CLSI, ISO, etc.) also be followed, according to local guidelines or requirements.

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- **Do not use glass test tubes**. Use clear plastic (polystyrene) tubes only. Variation exists among test tubes of standard diameter. Carefully place the tube into the cassette. If resistance is encountered, discard and try another tube that does not require pressure to insert.
- Prior to inoculation, inspect cards for tape tears or damage to the tape and discard any that are suspect. Check the saline level in the tubes after the cassette has been processed to ensure proper filling of card.
  - VITEK® 2 60 or VITEK® 2 XL: Eject improperly filled cards.
  - VITEK® 2 Compact: Do not load improperly filled cards.
- Give special consideration to specimen source and patient therapy regimen. AST cards may contain some antimicrobials that are not proven to be effective for treatment of infections due to all organisms that may be tested. For interpreting and reporting of antimicrobial results that have been shown to be active against organism groups both *in vitro* and in clinical infections, refer to the individual pharmaceutical antimicrobial labeling or local therapy guidelines.
- Interpretation of test results requires the judgment and skill of a person knowledgeable in AST. Additional testing may be required.[17]

Warning: All patient specimens, microbial cultures, and inoculated VITEK® 2 cards, along with associated materials, are potentially infectious and should be treated with universal precautions [18,20]

INSTRUMENT

The VITEK® 2 instruments are a family of *in vitro* diagnostic devices intended to rapidly assess the antimicrobial susceptibility of bacterial and yeast pathogens to available antimicrobial agents. For detailed information on the use and operation of these devices, refer to the appropriate Instrument User Manual.

SPECIMEN PREPARATION

Culture Requirements Table

VITEK® 2 Card	Media	Age of Culture	Incubation Conditions	McFarland Standards	Dilution for AST	Age of Suspension Before Loading Instrument
AST Gram-Positive	TSAB CBA CPS ID	18 to 24 hours	35°C to 37°C 5% to 10% CO_2 or aerobic, non-CO_2	0.50 to 0.63	280 µL in 3.0 mL 0.45% saline	VITEK® 2 Compact: ≤30 minutes VITEK® 2: ≤ 1 hour
GP and AST GP pair	TSAB[1] CBA[1] CPS ID	18 to 24 hours	35°C to 37°C 5% to 10% CO_2 or aerobic, non-CO_2	0.50 to 0.63	280 µL in 3.0 mL 0.45% saline	≤ 30 minutes

[1] These media were used in the identification product database developments and will give optimal performance.

Culture Requirements Table — Media Abbreviations

CBA = Columbia Sheep Blood Agar

CPS ID = chromID™ CPS (CPS ID Agar)

TSAB = Trypticase Soy Agar with 5% Sheep Blood

TEST PROCEDURE

Warning: Failure to properly follow instructions and recommendations provided in this section for performing laboratory tasks may cause erroneous or delayed results.

Materials

Materials provided are:

- VITEK® 2 DensiCHEK™ Plus Kit
- DensiCHEK™ Plus Standards Kit

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- VITEK® 2 Cassette
- Adjustable volume saline dispenser
- 12 mm x 75 mm clear plastic (polystyrene) disposable test tubes
- VITEK® 2 60 or VITEK® 2 XL only: VITEK® 2 Pipettor/Diluter Accessory Kit (containing instrument pipette tips and saline hookup) and 0.45% saline bag

Materials required, but not provided are:

- Sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Loops, sterile sticks or swabs
- Appropriate agar medium (See the Culture Requirements Table.)
- QC isolates
- VITEK® 2 AST Cards
- Micropipettors to deliver 280 µL
- Disposable pipette tips

Optional Accessories:

- Pre-dispensed saline test tubes (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Test tube caps
- Vortex

Test Card Setup Procedure

The following procedure contains general information applicable to all susceptibility products. (See the Culture Requirements Table for product-specific information.)

Note: Prepare the inoculum from a pure culture, according to good laboratory practices. In case of mixed cultures, a re-isolation step is required. It is recommended that a purity check plate be done to ensure that a pure culture was used for testing.

1. Do one of the following:
   - Select isolated colonies from a primary plate if culture requirements are met.
   - Subculture the organism to be tested to appropriate agar medium and incubate accordingly.
2. Aseptically transfer 3.0 mL of sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0) into a clear plastic (polystyrene) test tube (12 mm x 75 mm).
3. Use a sterile stick or swab to transfer a sufficient number of morphologically similar colonies to the saline tube prepared in step 2. Prepare a homogenous organism suspension with a density equivalent to the appropriate McFarland standard using the VITEK® 2 DensiCHEK™ Plus (see the Culture Requirements Table). The inoculum density required for the GN, GP, ST, or YST can be diluted automatically for AST cards by the VITEK® 2 instrument (VITEK® 2 60 or VITEK® 2 XL). **Note:** The age of the suspension before loading the instrument for AST testing must be less than one hour when using VITEK® 2 60 or VITEK® 2 XL, and less than 30 minutes when using VITEK® 2 Compact.
4. Choose one of the following:
   - **For an automatic dilution (VITEK® 2 60 or VITEK® 2 XL only):** Place the suspension tube prepared in step 3 into the cassette with or without an identification card. In the next cassette slot, place an empty tube and an AST card. The instrument will automatically dilute the bacterial suspension to prepare an inoculum suitable for the susceptibility card.
   - **For a manual dilution (VITEK® 2 Compact, VITEK® 2 60 or VITEK® 2 XL):** In a second tube containing 3.0 mL of saline, transfer 280 µL of the suspension prepared in step 3. Then place this tube in the cassette with a susceptibility card. The tube with the initial bacterial suspension can also be used for inoculation of an identification card.

   Note: Check the saline level in the tubes after filling. When it is evident by the saline level in the tube that a card has been improperly filled, do not load the card if using VITEK® 2 Compact; **or**, eject the card if using VITEK® 2 60 or VITEK® 2 XL.

   Note: Refer to the appropriate Instrument User Manual for detailed information regarding data entry, processing, etc.
5. Follow your local inspecting agency's guidelines for disposal of hazardous waste.

QUALITY CONTROL

Quality Control organisms should be processed according to the Test Card Setup Procedure.

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Quality Control

CLSI® Quality Control Organisms VITEK® 2 Results									
Antimicrobic	Code	*E. faecalis* ATCC® 29212™	*S. aureus* ATCC® 29213™	*E. coli* ATCC® 35218™	*S. pneumoniae* ATCC® 49619™	*E. faecalis* ATCC® 51299™	*S. aureus* ATCC® BAA-1026™	*S. aureus* ATCC® BAA-976™	*S. aureus* ATCC® BAA-977™
Ampicillin	am01n	≤ 2	0.5 - 2	-	-	-	-	-	-
Benzylpenicillin	p04n	-	0.25 - ≥ 0.5	-	-	-	-	-	-
Cefoxitin Screen	oxsf01n	-	NEG	-	-	-	POS	-	-
Ciprofloxacin	cip01n	≤ 0.5 - 2	≤ 0.5	-	-	-	-	-	-
Clindamycin	cm01n	4 - ≥ 8	≤ 0.25	-	-	-	-	-	-
Erythromycin	e02n	1 - 4	≤ 0.25 - 1	-	-	-	-	-	-
Fosfomycin	fos01n	-	≤ 8	-	-	-	-	-	-
Fusidic Acid	fa01n	-	≤ 0.5	-	-	-	-	-	-
Gentamicin	gm01n	-	≤ 0.5 - 1	-	-	-	-	-	-
Gentamicin High Level (synergy)	hlg01n	S	-	-	-	R	-	-	-
Imipenem	ipm02n	≤ 1 - 2	≤ 1	-	-	-	-	-	-
Inducible Clindamycin Resistance	icr02n	-	-	-	-	-	-	NEG	POS
Linezolid	lnz02n	1 - 4	1 - 4	-	-	-	-	-	-
Moxifloxacin	mxf02n	≤ 0.25 - 0.5	≤ 0.25	-	-	-	-	-	-
Oxacillin	ox101n	-	≤ 0.25 - 0.5	-	-	-	-	-	-
Rifampicin	ra01n	-	≤ 0.5	-	-	-	-	-	-
Streptomycin High Level (synergy)	hls01n	S	-	-	-	R	-	-	-
Teicoplanin	tec01n	≤ 0.5	≤ 0.5 - 1	-	-	-	-	-	-
Tetracycline	te03n	8 - ≥ 16	≤ 1	-	-	-	-	-	-
Tigecycline[NS]	tgc02n	≤ 0.12	≤ 0.12 - 0.25	-	-	-	-	-	-
Trimethoprim/ Sulfamethoxazole	sxt02n	≤ 10 (0.5/9.5)	≤ 10 (0.5/9.5)	-	-	-	-	-	-
Vancomycin	va04n	1 - 4	≤ 0.5 - 2	-	-	-	-	-	-

Numerical values are expressed in µg/mL.

NEG = Negative

POS = Positive

[NS] = The current absence of resistant isolates precludes defining any results other than susceptible. Isolates yielding MIC results suggestive of Nonsusceptible category should be submitted to a reference laboratory for further testing.

Certification Statement

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This is to certify that bioMérieux complies with ISO 13485 and FDA Quality System Regulation (QSR) requirements for design, development, and manufacture of antimicrobial susceptibility systems.

Frequency of QC Testing

Refer to *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically,* CLSI® and/or your local guidelines.[2]

Preparation of QC Organisms

1. Rehydrate the organism according to the manufacturer's instructions.
2. Subculture to Trypticase Soy Agar with 5% sheep blood (TSAB).
3. Incubate at 35°C for 24 hours.
   Note: Gram-positive organisms may require an atmosphere of CO_2. (Refer to the Culture Requirements Table).
4. Check for purity.
5. Subculture to a TSAB plate.
6. Incubate 16 to 18 hours at 35°C.

Short-Term Storage Conditions

1. Streak to a TSAB plate or slant.
2. Incubate for 24 hours.
3. Refrigerate at 2°C to 8°C for up to two weeks.
4. Subculture once as described above and use for QC.

Long-Term Storage Conditions

1. Make a heavy suspension in Tryptic Soy Broth (TSB) with 15% glycerol.
2. Freeze at -70°C.
3. Subculture to TSAB twice before running QC.
   Note: Avoid repeated thawing and refreezing by either freezing in single-use aliquots or removing a small portion of frozen organism preparation with a sterile applicator stick.

RESULTS

Susceptibility Analytical Techniques

The system evaluates each organism's growth pattern in the presence of the antimicrobial in relation to the growth control well. Several parameters based on the growth characteristics are used to determine the MIC or qualitative result (for example, ESBL POS/NEG). The MIC result must be linked to an organism identification to determine a category interpretation. Accurate identification is critical, especially with certain organism/antimicrobial combinations (e.g., *Staphylococcus aureus*/oxacillin).

In cases where the identification of an organism is in question, confirmatory testing is necessary to ensure correct interpretation of susceptibility results.

A category interpretation will be reported along with a MIC, according to the interpretations defined by the Food and Drug Administration (FDA), CLSI®, Comité de l'Antibiogramme de la Société Française de Microbiologie (CASFM), European Committee for Antimicrobial Susceptibility Testing (EUCAST), or to an adaptation of the global settings according to other local guidelines.

Note: When FDA and CLSI® breakpoints differ, VITEK® 2 Systems AST tests are cleared for use with FDA breakpoints applied.

Combination Antimicrobials

The MICs for the combination antimicrobials are listed on the laboratory and patient reports as the first concentration (e.g., ampicillin/sulbactam ≤ 8/4 µg/mL is reported as ≤ 8 µg/mL.). The actual concentrations for each value in the antimicrobial calling range are as follows:

- trimethoprim/sulfamethoxazole: **Note exception** — This drug is listed on the laboratory and patient reports as the sum of the two antimicrobial concentrations: 20 µg/mL = 1/19, 40 µg/mL = 2/38, 80 µg/mL = 4/76, 160 µg/mL = 8/152, 320 µg/mL = 16/304

Antimicrobial Deduction

Antimicrobials that have been deduced will only report an interpretive result and will be noted with a **+**.

Clinical Efficacy and Indications for Use

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AST cards may contain some antimicrobials that are not proven to be effective for treatment of infections caused by all organisms that may be tested. For interpreting and reporting of antimicrobial results that have shown to be active against organism groups both *in vitro* and in clinical infections, refer to the individual pharmaceutical antimicrobial labeling or the local therapy guidelines.

Urinary Use Only Antimicrobials

Certain antimicrobial agents are limited to use in treating urinary tract infections. Accordingly, these agents should not be reported against pathogens recovered from infection sites other than the urinary tract (except as noted). Please refer to the current *CLSI Performance Standards for Susceptibility Testing, M100* and/or local guidelines for additional information.[3]

For urine only, per CLSI®:[3]

- *Staphylococcus* spp.: lomefloxacin, norfloxacin, nitrofurantoin, sulfisoxazole, trimethoprim
- *Enterococcus* spp.: ciprofloxacin, levofloxacin, norfloxacin, nitrofurantoin, tetracycline

LIMITATIONS

A VITEK® 2 AST card cannot be used with a direct clinical specimen or sample or other sources containing mixed flora. Any change or modification in the procedure may affect the results.

A result for an antibiotic/organism combination, which may have a limitation, may be suppressed from reporting. This can be accomplished through the use of bioART rules in the VITEK® 2 Systems software. Refer to the software user manual for instructions.

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

- Erythromycin (e02n): *Streptococcus agalactiae*
- Cefoxitin Screen (oxsf01n): *Staphylococcus pseudintermedius* (specific to VITEK® 2 Systems 8.01 software or higher)

Perform an alternative method of testing prior to reporting of results when a Positive (+) result is obtained with the following antibiotic/organism combination(s):

- Cefoxitin Screen (oxsf01n): *Staphylococcus saprophyticus*

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:

- Ampicillin (am01n): *Streptococcus agalactiae*
- Linezolid (lnz02n): *Enterococcus* spp., *Staphylococcus* spp., *Streptococcus agalactiae*
- Tigecycline (tgc02n): *Enterococcus* spp., *Staphylococcus* spp., *Streptococcus* spp.

EUCAST Limitations

It is recommended that the existing bioART suppression rules be enabled, or new rules created and enabled, for these limitations if the EUCAST breakpoints are applied.

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

- Erythromycin (e02n): *Streptococcus agalactiae, Staphylococcus* spp.
- Teicoplanin (tec01n): *Staphylococcus epidermidis, Staphylococcus haemolyticus*
- Cefoxitin Screen (oxsf01n): *Staphylococcus pseudintermedius* (specific to VITEK® 2 Systems 8.01 software or higher)

Perform an alternative method of testing prior to reporting of results when a Positive (+) result is obtained with the following antibiotic/organism combination(s):

- Cefoxitin Screen (oxsf01n): *Staphylococcus saprophyticus*

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:

- Linezolid (lnz02n): *Streptococcus agalactiae*
- Tigecycline (tgc02n): *Streptococcus agalactiae, Staphylococcus* spp.

EXPECTED VALUES

Expected results for susceptibility tests will vary based on location and institution. VITEK® 2 Systems were tested at several geographically diverse locations to ensure that trends that occurred by location were integrated into the performance

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characteristics of the system. Organism resistance patterns will differ by institution; therefore, expected values will be directly related to the population of organisms at each site.

PERFORMANCE CHARACTERISTICS

The performance characteristics of the antimicrobial agents included in VITEK® 2 AST cards were established using the manual and autodilution modes (on a VITEK® 2 System) at multiple clinical laboratories. The VITEK® 2 AST card results were compared to results from a CLSI® reference method. Essential agreement (EA) represents VITEK® 2 results which agree exactly or are within a ± twofold dilution (± two doubling dilutions for antifungal) of the reference result.

Category agreement (CA) occurs when the VITEK® 2 and the reference interpretative results agree (Susceptible, Intermediate, and Resistant). There are instances when the category agreement for an antimicrobial falls below the essential agreement. This can occur when a significant number of MICs cluster around a category breakpoint during clinical trial testing, resulting in interpretative errors. For a description of interpretive errors, refer to the footnotes below the table that follows (Performance Characteristics). When the majority of the errors are of the minor type, a high corresponding essential agreement percentage demonstrates that the antimicrobial retains an acceptable overall performance.

There are instances when the performance is based solely on category agreement (CA) because at the time performance was established, less than five discrete twofold dilutions were evaluated. A minimum of five dilutions is necessary to calculate essential agreement (EA) based on ± one twofold dilution. These instances are designated by a "c" footnote in the Contents of the Card table. The following performance tables have values for CA only when EA was not established at the time of FDA clearance.

The reproducibility of the VITEK® 2 system was established by testing a set of on-scale organisms.*

*Data on file at bioMérieux, Inc

Performance Characteristics for Gram-Positive Antimicrobial Susceptibility Testing

Antimicrobial	Antimicrobial Code	Antibiotic Version	Bp[1]	Comment[2]	Essential Agreement				Category Agreement				% Reproducibility
					% Error				% Error				
					% EA	VME	ME	mE	% CA	VME	ME	mE	
Ampicillin	AM	am01n	CLSI	#, E	97.6	1.1	0.3	0.2	99.5	2.2	0.6	0.2	97
Benzylpenicillin (Penicillin)	P	p04n	CLSI	#, E	97.4	0.4	0.3	N/A	98.5	0.9	1.0	N/A	99.3
Cefoxitin Screen	OXSF	oxsf01n	CLSI	E, Ref. = CLSI Disk Diffusion	–	–	–	–	98.3	2.0	1.4	N/A	100
				E, Ref. = mecA PCR	–	–	–	–	97.2	2.3	3.2	N/A	
Oxacillin + Cefoxitin Screen			CLSI	#, Ref. = CLSI Cefoxitin Disk Diffusion	–	–	–	–	98.5	0.4	2.8	N/A	–
Oxacillin + Cefoxitin Screen			CLSI	E, Ref. = mecA PCR	–	–	–	–	97.8	1.2	3.2	N/A	–
Ciprofloxacin	CIP	cip01n	CLSI	#, E	99.3	1.4	0.0	0.2	96.7	1.4	0.0	2.9	100
			CA-SFM	E	99.3	1.4	0.0	0.2	96.7	1.4	0.0	2.9	
Clindamycin	CM	cm01n	CLSI	#, E	98.7	2.3	0.0	0.7	99.1	2.3	0.0	0.9	98.5
			CA-SFM	I	96.1	2.5	4.3	0.0	-	-	-	-	
Erythromycin	E	e02n	CLSI	#, E ❶	95.9	0.4	0.4	5.1	92.8	0.4	0.4	7.5	95.2
			CA-SFM	I ❶	94.7	9.4	0.0	0.3	95.0	9.4	0.0	0.3	
Fosfomycin	FOS	fos01n	CA-SFM	I, Staph	97.1	6.5	0.3	N/A	95.8	11.8	1.7	N/A	100
Fusidic Acid	FA	fa01n	CA-SFM	I, Staph	100	0.0	0.0	0.0	99.2	0.0	0.0	0.8	100
Gentamicin	GM	gm01n	CLSI	#, E, Staph	99.2	0.0	0.0	0.8	95.1	0.0	0.0	4.9	100
			CA-SFM	E, Staph	99.2	0.0	0.0	0.8	95.1	0.0	0.0	4.9	

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Antimicrobial	Antimicrobial Code	Antibiotic Version	Bp[1]	Comment[2]	Essential Agreement				Category Agreement				% Reproducibility
					% Error				% Error				
					% EA	VME	ME	mE	% CA	VME	ME	mE	
Gentamicin High Level	HLG	hlg01n	CLSI	#, E	N/A	N/A	N/A	N/A	100	N/A	N/A	N/A	100
			CA-SFM	E, Enc	N/A	N/A	N/A	N/A	100	N/A	N/A	N/A	
Imipenem	IPM	ipm02n	CLSI	E	–	–	–	–	99.2	0.4	0.5	0.3	100
			CA-SFM	E	–	–	–	–	99.2	0.4	0.5	0.3	
Inducible Clindamycin Resistance	ICR	icr02n	CLSI	#, E	N/A	N/A	N/A	N/A	99.5	2.0	0.4	N/A	100
Linezolid	LNZ	lnz02n	CLSI	#, E	98.7	0.0	0.1	0.1	98.9	0.0	0.1	1.0	100
			CA-SFM	E	98.7	0.0	0.1	0.7	92.6	0.0	0.1	7.3	
Moxifloxacin	MXF	mxf02n	CLSI	#, E	99.2	0.0	0.0	0.0	83.3	0.0	0.0	16.7	100
			CA-SFM	E	98.5	0.0	0.0	0.1	92.4	0.0	0.0	7.6	
Oxacillin	OX1	ox101n	CLSI	#, E, Staph	97.4	1.6	1.1	0.0	97.1	2.2	3.4	0.0	98.1
Rifampicin (Rifampin)	RA	ra01n	CLSI	#, E	100	0.0	0.0	0.0	100	0.0	0.0	0.0	100
			CA-SFM	I, Staph	99.5	0.0	0.0	0.3	–	–	–	–	
Streptomycin High Level	HLS	hls01n	CLSI	#, E, Enc	N/A	N/A	N/A	N/A	100	N/A	N/A	N/A	100
			CA-SFM	E, Enc	–	–	–	–	100	0.0	0.0	–	
Teicoplanin	TEC	tec01n	CLSI	I	96.6	3.3	0.3	0.4	95.7	3.3	0.3	2.7	99.4
			CA-SFM	I	96.9	1.6	0.0	1.1	95.9	1.6	0.3	3.2	
Tetracycline	TE	te03n	CLSI	#, E	99.1	1.2	0.4	0.5	99.3	1.2	0.5	0.8	94.8
Tigecycline	TGC	tgc02n	CLSI	#, E	–	–	–	–	99.4	66.7†	0.4	N/A	100
Trimethoprim/ Sulfamethoxazole	SXT	sxt02n	CLSI	I ❷	97.3	1.6	1.5	0.0	–	–	–	–	97.6
			CA-SFM	I ❷	97.3	0.0	0.8	1.8	–	–	–	–	
Vancomycin	VA	va04n	CLSI[3]	#, E ❷	99.9	0.0	0.0	0.1	99.7	0.0	0.0	0.3	100
			CA-SFM	E ❷	99.9	0.0	0.0	0.1	99.7	0.0	0.0	0.3	

[1] Abbreviations — Bp = breakpoint committee; EA = essential agreement; CA = category agreement; VME = Very Major Error (susceptible result with resistant reference result); ME = Major Error (resistant result with susceptible reference result); mE = minor Error (susceptible or resistant result with an intermediate reference result, or an intermediate result with a susceptible or resistant reference result).

[2] Comment — Specific organism groups are designated as Staph for *staphylococci*, Enc for *enterococci*, S aga for Group B *streptococci*, Sau for *Staphylococcus aureus*.

[3] FDA breakpoints are used in the CLSI Interpretation Standard (breakpoint committee) in the VITEK® 2 Systems software.

For all gram-positive Beta-lactams with indications for *Staphylococcus* spp., with the exception of Benzylpenicillin (Penicillin), performance in this table represents forcing-resistance based on oxacillin resistance.

† Non-defined error; susceptible (S) breakpoints only, no I or R breakpoints exist.

Key:

= US Food and Drug Administration 510(k) cleared
CLSI® = Clinical and Laboratory Standards Institute
CA-SFM = Comité de l'Antibiogramme de la Société Française de Microbiologie
E = External performance data
I = Internal performance data
– = Not available
N/A = Not applicable

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Ref. = Reference method for clinical performance study.

❶ ❷ = Symbol identifies the performance characteristics for a specific antimicrobial version.

EUCAST Performance Characteristics for Gram-Positive Antimicrobial Susceptibility Testing

Antimicrobial	Antimicrobial Code	Antibiotic Version	Comment[1]	Essential Agreement				Category Agreement			
				% Error				% Error			
				%EA[2]	VME	ME	mE	%CA	VME	ME	mE
Ampicillin	AM	am01n	*Enterococcus*	97.7	1.4	0.4	1.0	97.7	1.4	0.4	1.6
Benzylpenicillin	P	p04n	*Staphylococcus, S. agalactiae*	98.3	0.8	1.9	0.0	98.3	0.8	3.9	0.0
Ciprofloxacin	CIP	cip01n	*Staphylococcus*	99.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0
Clindamycin	CM	cm01n	*Staphylococcus, S. agalactiae*	98.1	3.3	0.3	0.0	98.1	3.3	0.3	0.7
Erythromycin	E	e02n	*Staphylococcus* ❶	94.7	9.4	0.0	0.0	95.3	9.4	0.0	0.0
Fosfomycin	FOS	fos01n	*Staphylococcus*	97.1	6.5	0.3	N/A	95.8	11.8	1.7	N/A
Fusidic Acid	FA	fa01n	*Staphylococcus*	100.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0
Gentamicin	GM	gm01n	*Staphylococcus*	99.2	0.0	0.0	0.0	99.7	0.0	0.4	0.0
Imipenem	IPM	ipm02n	*Enterococcus*	91.9	3.1	0.8	0.0	98.0	3.1	0.8	0.5
Linezolid	LNZ	lnz02n	N/A	98.7	0.0	0.1	0.0	99.5	0.0	0.5	0.0
Moxifloxacin	MXF	mxf02n	*Staphylococcus, S. agalactiae*	99.0	0.7	0.0	0.5	95.2	0.7	0.0	4.6
Rifampicin	RA	ra01n	*Staphylococcus*, *S. agalactiae*	96.0	0.0	0.0	3.5	88.4	0.0	0.0	11.6
Teicoplanin	TEC	tec01n	*S. agalactiae, S. aureus, Enterococcus*, coagulase-negative *Staphylococcus* except *S. epidermidis* and *S. haemolyticus*	98.9	4.8	0.2	0.0	99.4	4.8	0.2	0.0
Tetracycline	TE	te03n	*Staphylococcus, S. agalactiae*	98.5	1.0	1.4	0.3	96.0	1.0	1.4	2.8
Tigecycline	TGC	tgc02n	N/A	99.0	0.0	0.0	0.3	99.5	66.7	0.0	0.3
Trimethoprim/ Sulfamethoxazole	SXT	sxt02n	*Staphylococcus, S. agalactiae* ❷	92.9	6.7	4.1	2.2	89.8	6.7	4.1	6.2
Vancomycin	VA	va04n	*Staphylococcus, S. agalactiae, Enterococcus* ❷ (EUCAST v1.3 breakpoints)	99.8	2.0	0.0	0.0	99.7	4.1	0.1	0.0
			Staphylococcus, S. agalactiae, Enterococcus ❷ (EUCAST v2.0 breakpoints)	99.8	2.1	0.0	0.0	99.7	8.3	0.0	0.0

[1] Comment — Unless stated otherwise, performance is for *Staphylococcus*, *Enterococcus*, and *S. agalactiae*.

[2] Abbreviations — Bp = breakpoint committee; EA = essential agreement; CA = category agreement; VME = Very Major Error (susceptible result with resistant reference result); ME = Major Error (resistant result with susceptible reference result); mE = minor Error (susceptible or resistant result with an intermediate reference result, or an intermediate result with a susceptible or resistant reference result).

Key:

= EUCAST = European Committee on Antimicrobial Susceptibility

❶ ❷ = Symbol identifies the performance characteristics for a specific antimicrobial version.

LIST OF CLAIMS

Note: If the organism is not in the VITEK® 2 susceptibility database, results will not be reported.

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Note: Organisms listed with an asterisk (*) indicate an AES claimed organism. No asterisk is displayed for a group; however, when an individual species (with an asterisk) is contained within a group, it is expertised.

Gram-Positive Organisms Claimed for AST-GP (keyID)

- *Coagulase-negative Staphylococcus**
- *Coagulase-positive Staphylococcus**
- *Enterococcus avium*
- *Enterococcus casseliflavus**
- *Enterococcus durans*
- *Enterococcus faecalis**
- *Enterococcus faecalis* ATCC® 29212™
- *Enterococcus faecalis* ATCC® 51299™
- *Enterococcus faecium**
- *Enterococcus gallinarum**
- *Enterococcus hirae*
- *Enterococcus malodoratus*
- *Enterococcus mundtii*
- *Enterococcus* spp.*
- *Escherichia coli* ATCC® 35218™
- *Staphylococcus aureus**
- *Staphylococcus aureus* ATCC® 29213™
- *Staphylococcus aureus* ATCC® BAA-976™
- *Staphylococcus aureus* ATCC® BAA-977™
- *Staphylococcus aureus* ATCC® BAA-1026™
- *Staphylococcus auricularis**
- *Staphylococcus capitis**
- *Staphylococcus chromogenes**
- *Staphylococcus cohnii**
- *Staphylococcus cohnii* ssp. *cohnii**
- *Staphylococcus cohnii* ssp. *urealyticus**
- *Staphylococcus epidermidis**
- *Staphylococcus haemolyticus**
- *Staphylococcus hominis**
- *Staphylococcus hominis* ssp. *hominis**
- *Staphylococcus hyicus**
- *Staphylococcus intermedius**
- *Staphylococcus kloosii**
- *Staphylococcus lentus**
- *Staphylococcus lugdunensis**
- *Staphylococcus pseudintermedius*
- *Staphylococcus saprophyticus**
- *Staphylococcus schleiferi**
- *Staphylococcus sciuri**
- *Staphylococcus simulans**
- *Staphylococcus warneri**
- *Staphylococcus xylosus**
- *Streptococcus agalactiae**
- *Streptococcus pneumoniae**
- *Streptococcus pneumoniae* ATCC® 49619™

REFERENCES

1. Barry, AL The Antimicrobic Susceptibility Test, Principles and Practices, Lea and Febiger, Philadelphia, PA. 1976.

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2. Clinical Laboratory Standards Institute (CLSI®), Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically, M7- A7, Wayne, Pennsylvania, January 2006.
3. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Eighteenth Informational Supplement, M100-S18, Vol. 27, No. 1, January 2008.
4. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-third Informational Supplement, M100-S22, January 2012.
5. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-fourth Informational Supplement; M100-S24, January 2014.
6. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-fifth Informational Supplement, M100-S25, January 2015.
7. Comité de l'Antibiogramme de la Société Française de Microbiologie. Communiqué 1996. Path Biol, 1996, 44, n° 8, I-VIII.
8. Comité de l'Antibiogramme de la Société Française de Microbiologie, Communiqué 2007.
9. Comite de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM), Recommendations 2012.
10. Comité de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM). Communiqué 2014.
11. Comité de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM). Communiqué 2015.
12. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 2.0, January 2012.
13. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 4.0, January 2014.
14. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 5.0, January 2015.
15. Gerlach, EH Microdilution 1: A Comparative Study, p. 63-76, In: Balows, A. (ed.), Current Techniques for Antibiotic Susceptibility Testing, Charles C. Thomas, Springfield, IL. 1974.
16. MacLowry, JD, and HH Marsh. 1968. Semi-automatic microtechnique for serial dilution antibiotic sensitivity testing in the clinical laboratory. J. Lab. Clin. Med. 1968;72:685-687.
17. Murray, PR, Baron EJ, Pfaller MA, Tenover FC, and Yolken RH, editors. Manual of Clinical Microbiology, 8th ed. American Society for Microbiology, Washington, D.C. 2003.
18. National Committee for Clinical Laboratory Standards, M29-A, Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissue – Approved Guideline (1997).
19. National Committee for Clinical Laboratory Standards, Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Approved Standard — Third Edition, M27-A3, Vol. 22, No. 15, 2008.
20. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health, Office of Health and Safety, Biosafety in Microbiological and Biomedical Laboratories, 1988.

Permission to incorporate portions of M100 (Performance Standards for Antimicrobial Susceptibility Testing: Informational Supplement) in the bioMérieux clinical microbiology instrumentation and System has been granted by CLSI®. The current standard and supplements to it may be obtained from CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

BARCODES

User MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.

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01 A320A20W---E

02 BAST-P59201V

03 C---Z0D0G372

04 D0H0P0I0T0UI

05 E19182J3I2NP

06 F2R200X1E0YX

07 G1H3K0K3L-VE

08 H-T-S-P-K-J1

09 I-I-F000000U

INDEX OF SYMBOLS

Symbol	Meaning
	Catalog number
	In Vitro Diagnostic Medical Device
	Legal Manufacturer
	Temperature limitation
	Use by date
	Batch code
	Consult Instructions for Use
	Date of manufacture

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Symbol	Meaning
	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community
Rx only	For US Only : Caution : US Federal Law restricts this device to sale by or on the order of a licensed practitioner

Instructions for Use provided in the kit or downloadable from www.biomerieux.com/techlib

LIMITED WARRANTY

bioMérieux warrants the performance of the product for its stated intended use provided that all procedures for usage, storage and handling, shelf life (when applicable), and precautions are strictly followed as detailed in the instructions for use (IFU).

Except as expressly set forth above, bioMérieux hereby disclaims all warranties, including any implied warranties of merchantability and fitness for a particular purpose or use, and disclaims all liability, whether direct, indirect or consequential, for any use of the reagent, software, instrument and disposables (the “System”) other than as set forth in the IFU.

WASTE DISPOSAL

All hazardous waste must be disposed of by following your local inspecting agency's guidelines.

REVISION HISTORY TABLE

Change type categories	
N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user
Note:	Minor typographical, grammar, and formatting changes are not included in the revision history.

Release Date	Part Number	Change Type	Change Summary
2018-01	045610-01	Administrative	• Formatting changes do not affect the fit, form, or function of the product
		Technical change	• Combined product package insert content with VITEK® 2 Product Information Manual AST content • Updated Limited Warranty section • Updated with RX only information • Updated with EUCAST limitations

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REF 413110

045611- 01 - 2018-11 EN

VITEK® 2 AST-N223

Rx only IVD

INTENDED USE

The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.

SUMMARY AND EXPLANATION

Susceptibility testing is indicated for any organism that contributes to an infectious process warranting antimicrobial chemotherapy. Susceptibility tests are most often indicated when the causative organism is thought to belong to a species capable of exhibiting resistance to commonly used agents. Isolated colonies of each type of organism that may play a pathogenic role are selected from an agar plate and tested for susceptibility. These tests are then examined and the Minimum Inhibitory Concentration (MIC) is determined. The MIC obtained using a dilution test may tell the physician the concentration of an antimicrobial agent needed at the site of infection to inhibit the infecting organism.

MICs have traditionally been determined using antimicrobial concentrations derived from serial twofold dilutions.[2] The MIC is then determined from the lowest concentration that exhibits inhibition of growth. An interpretive criterion (Susceptible, Intermediate, or Resistant) can then be assigned to MIC results to aid in the direction of therapy.

For some antimicrobials (e.g., high-level gentamicin, high-level streptomycin) a qualitative result is generated.

The standard and reference procedures are based on susceptibility tests requiring 16 to 24 hours of incubation for bacteria. Various manufacturers have now developed automated procedures designed to generate results more rapidly by using shortened incubation times. Laboratories worldwide use either variations of the standard reference procedure or a commercially available product to determine the MICs of infectious organisms.

Extended-Spectrum Beta Lactamases (ESBLs)

ESBLs are enzymes that arise by mutations in genes for common plasmid-mediated beta-lactamases. Strains of *Klebsiella* spp. and *E. coli* that produce ESBLs may be clinically resistant to therapy with penicillins, cephalosporins, or aztreonam despite apparent *in vitro* susceptibility to some of these agents. Some of these strains will show MICs above the normal susceptible population but below the standard breakpoints for certain extended-spectrum cephalosporins or aztreonam. Before reporting a strain as an ESBL producer, a confirmatory method may be performed. The VITEK® 2 ESBL Test is a confirmatory test for those ESBLs inhibited by clavulanic acid, and it utilizes cefepime, cefotaxime, and ceftazidime, with and without clavulanic acid, to determine a positive or negative result.

STORAGE CONDITIONS

Upon receipt, store VITEK® 2 AST cards unopened in their original package liner at 2°C to 8°C.

PRINCIPLE OF THE TEST

The AST card for VITEK® 2 Systems is an automated test methodology based on the MIC technique reported by MacLowry and Marsh and Gerlach.[15,16] The AST card is essentially a miniaturized and abbreviated version of the doubling dilution technique for MICs determined by the microdilution method.[1]

Each AST card contains a control well containing only microbiological culture medium. The remaining microwells contain premeasured amounts of specific antimicrobials combined with culture medium.

The organism suspension to be tested must be diluted to a standardized concentration in 0.45% saline before being used to rehydrate the antimicrobial medium within the card. The card is then filled, sealed, and placed into the instrument incubator/reader, either automatically (as with VITEK® 2 60 or VITEK® 2 XL) or manually (as with VITEK® 2 Compact). The instrument monitors the growth of each well in the card over a defined period of time (up to 18 hours for Gram-negatives). At the completion of the incubation cycle, MIC values (or test results, as appropriate) are determined for each antimicrobial contained on the card.

PRECAUTIONS

- For *In Vitro* Diagnostic Use Only.

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- For US Only: Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- For professional use only.
- Suspensions not within the appropriate zone on the VITEK® 2 DensiCHEK™ Plus or VITEK® 2 DensiCHEK™ may compromise card performance.
- Do not use the card after the expiration date shown on the package liner.
- Store the card unopened in the package liner. Do not use the card if the protective package liner is damaged or if no desiccant is present.
- Allow the card to come to room temperature before opening the package liner.
- Do not use powdered gloves. Powder may interfere with the optics.
- Use of culture media other than the recommended types must be validated by the customer laboratory for acceptable performance.
- The card performs as intended only when used in conjunction with VITEK® 2 Systems, following the instructions contained in the Instructions for Use.
- It is highly recommended that Good Laboratory Practices (e.g., FDA, CLSI, ISO, etc.) also be followed, according to local guidelines or requirements.
- **Do not use glass test tubes**. Use clear plastic (polystyrene) tubes only. Variation exists among test tubes of standard diameter. Carefully place the tube into the cassette. If resistance is encountered, discard and try another tube that does not require pressure to insert.
- Prior to inoculation, inspect cards for tape tears or damage to the tape and discard any that are suspect. Check the saline level in the tubes after the cassette has been processed to ensure proper filling of card.
  - VITEK® 2 60 or VITEK® 2 XL: Eject improperly filled cards.
  - VITEK® 2 Compact: Do not load improperly filled cards.
- Give special consideration to specimen source and patient therapy regimen. AST cards may contain some antimicrobials that are not proven to be effective for treatment of infections due to all organisms that may be tested. For interpreting and reporting of antimicrobial results that have been shown to be active against organism groups both *in vitro* and in clinical infections, refer to the individual pharmaceutical antimicrobial labeling or local therapy guidelines.
- Interpretation of test results requires the judgment and skill of a person knowledgeable in AST. Additional testing may be required.[17]

Warning: All patient specimens, microbial cultures, and inoculated VITEK® 2 cards, along with associated materials, are potentially infectious and should be treated with universal precautions [18,20]

REAGENTS

When used with VITEK® 2 instrumentation, the AST card is a complete system for routine susceptibility testing. Each AST card contains selected antimicrobials in varying concentrations, dried with a microbiological culture medium.

Table 1: Contents of the Card

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Ampicillin	am01n	4, 8, 32	2	32	**CSAGNB
Ampicillin/ Sulbactam	sam02n	4, 16, 32	2	32	**N/A
Cefotaxime	ctx01n	1, 4, 16, 32	1	64	**CSAGNB
Cefpodoxime	cpd01n	0.5, 1, 4	0.25	8	**CSAGNB
Ceftazidime	caz01n	1, 2, 8, 32	1	64	**CSAGNB
Cefuroxime	cxm01n	2, 8, 32	1	64	**CSAGNB
Ciprofloxacin	cip01n	0.5, 2, 4	0.25	4	**CSAGNB

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Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Ertapenem	etp01n[c]	0.5, 1, 6	0.5	8	*E. coli*, *K. pneumoniae*, *C. freundii*, *C. koseri*, *E. aerogenes*, *E. cloacae*, **Kox(-ESBL), *M. morganii*, *P. mirabilis*, *P. vulgaris*, *S. marcescens*
ESBL	esb01n	FEP 1, CTX 0.5, CAZ 0.5, FEP/CA 1/10, CTX/CA 0.5/4, CAZ/CA 0.5/4	NEG	POS	*E. coli*, *K. pneumoniae*, *K. oxytoca*
Gentamicin	gm01n	4, 16, 32	1	16	**CSAGNB
Imipenem	ipm04n	1, 2, 6, 12	0.25	16	*Acinetobacter* spp., *Citrobacter spp.*, *Enterobacter* spp., *E. coli*, *Klebsiella* spp., *M. morganii*, *P. vulgaris*, *P. rettgeri*, *P. aeruginosa*, *S. marcescens*, *P. stuartii*
Meropenem	mem02n❷	0.5, 2, 6, 12	0.25	16	*E. coli*, *K. pneumoniae*, *P. aeruginosa*, *P. mirabilis*, *Acinetobacter* spp., *C. freundii*, *E. cloacae*, *K. oxytoca*, *M. morganii*, *P. vulgaris*, *S. marcescens*, *A. hydrophila*, *C. diversus*, *H. alvei*, *P. multocida*, *Salmonella* spp., *Shigella* spp.
Moxifloxacin	mxf01n	0.25, 1, 4	0.25	8	*K. pneumoniae*, *C. freundii*, *E. cloacae*, *E. coli*, *K. oxytoca*, *P. mirabilis*
Piperacillin	pip02n❷	4, 16, 32, 64	4	128	*Acinetobacter* spp., *Enterobacter* spp., *E. coli*, *Klebsiella* spp., *M. morganii*, *P. rettgeri*, *P. mirabilis*, *P. vulgaris*, *P. aeruginosa*, *Serratia* spp., *B. cepacia*, *C. koseri*, *C. freundii*, *P. fluorescens*, *C. sakazakii*

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Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Piperacillin/ Tazobactam	tzp03n[c]	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *P. rettgeri*, *P. stuartii*, *S. enterica*
Tigecycline	tgc01n[c]	0.75, 2, 4	0.5	8	*C. freundii*, *C. koseri*, *E. coli*, *E. cloacae*, *E. aerogenes*, *K. oxytoca*, *K. pneumoniae*, *S. marcescens*
Trimethoprim/ Sulfamethoxazole	sxt02n❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, **Eco(+ETEC), *C. sakazakii*

Numerical values are expressed in µg/mL.

§ Equivalent standard method concentration by efficacy.

NEG = Negative

POS = Positive

[c] = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.

**N/A = No specific FDA Indications for Use available

**CSAGNB = Clinically significant aerobic gram-negative bacilli

**Kox(-ESBL) = *K. oxytoca* (excluding ESBL producing strains)

A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.

Note: For ESBL, FEP is Cefepime, CTX is Cefotaxime, CAZ is Ceftazidime and CA is Clavulanic Acid.

❶, ❷ etc. = See performance characteristics identified by the drug code with this symbol.

**Eco(+ETEC) = E. coli (including susceptible enterotoxigenic strains implicated in traveler's diarrhea)

INSTRUMENT

The VITEK® 2 instruments are a family of *in vitro* diagnostic devices intended to rapidly assess the antimicrobial susceptibility of bacterial and yeast pathogens to available antimicrobial agents. For detailed information on the use and operation of these devices, refer to the appropriate Instrument User Manual.

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SPECIMEN PREPARATION

Table 2: Culture Requirements Table

VITEK® 2 Card	Media	Age of Culture	Incubation Conditions	McFarland Standards	Dilution for AST	Age of Suspension Before Loading Instrument
AST Gram-Negative	TSAB CBA MAC CPS ID	8 to 24 hours	35°C to 37°C aerobic, non-CO_2	0.50 to 0.63	145 µL in 3.0 mL 0.45% saline	VITEK® 2 Compact: ≤ 30 minutes VITEK® 2: ≤ 1 hour
GN and AST GN pair	CBA[1] MAC[1] TSAB CPS ID	18 to 24 hours	35°C to 37°C aerobic, non-CO_2	0.50 to 0.63	145 µL in 3.0 mL 0.45% saline	≤ 30 minutes

[1] These media were used in the identification product database developments and will give optimal performance.

Culture Requirements Table — Media Abbreviations

CBA = Columbia Sheep Blood Agar

MAC = MacConkey Agar

CPS ID = chromID™ CPS (CPS ID Agar)

TSAB = Trypticase Soy Agar with 5% Sheep Blood

TEST PROCEDURE

Warning: Failure to properly follow instructions and recommendations provided in this section for performing laboratory tasks may cause erroneous or delayed results.

Materials

Materials provided are:

- VITEK® 2 DensiCHEK™ KitVITEK® 2 DensiCHEK™ Plus KitVITEK® 2 DensiCHEK® Kit
- VITEK® 2 DensiCHEK™ Standards KitVITEK® 2 DensiCHEK™ Plus Standards KitVITEK® 2 DensiCHEK® Plus Standards Kit
- VITEK® 2 Cassette
- Adjustable volume saline dispenser
- 12 mm x 75 mm clear plastic (polystyrene) disposable test tubes
- VITEK® 2 60 or VITEK® 2 XL only: VITEK® 2 Pipettor/Diluter Accessory Kit (containing instrument pipette tips and saline hookup) and 0.45% saline bag

Materials required, but not provided are:

- Sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Loops, sterile sticks or swabs
- Appropriate agar medium (See the Culture Requirements Table.)
- QC isolates
- VITEK® 2 AST Cards
- Micropipettors to deliver 145 µL
- Micropipettors to deliver 280 µL
- Disposable pipette tips

Optional Accessories:

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- Pre-dispensed saline test tubes (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Test tube caps
- Vortex

Test Card Setup Procedure

The following procedure contains general information applicable to all susceptibility products. (See the Culture Requirements Table for product-specific information.)

Note: Prepare the inoculum from a pure culture, according to good laboratory practices. In case of mixed cultures, a re-isolation step is required. It is recommended that a purity check plate be done to ensure that a pure culture was used for testing.

1. Do one of the following:
   - Select isolated colonies from a primary plate if culture requirements are met.
   - Subculture the organism to be tested to appropriate agar medium and incubate accordingly.
2. Aseptically transfer 3.0 mL of sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0) into a clear plastic (polystyrene) test tube (12 mm x 75 mm).
3. Using sterile technique, prepare a homogenous organism suspension with a density equivalent to the appropriate McFarland standard or McFarland Reference using a compatible benchtop densitometer (see the Culture Requirements Table).
   Note: The age of the suspension before loading the instrument for AST testing must be less than one hour when using VITEK® 2 60 or VITEK® 2 XL, and less than 30 minutes when using VITEK® 2 Compact.
4. Choose one of the following:
   - **For an automatic dilution (VITEK® 2 60 or VITEK® 2 XL only):** Place the suspension tube prepared in step 3 into the cassette with or without an identification card. In the next cassette slot, place an empty tube and an AST card. The instrument will automatically dilute the bacterial suspension to prepare an inoculum suitable for the susceptibility card.
   - **For a manual dilution (VITEK® 2 Compact, VITEK® 2 60 or VITEK® 2 XL):** In a second tube containing 3.0 mL of saline, transfer 145 µL of the suspension prepared in step 3. Then place this tube in the cassette with a susceptibility card. The tube with the initial bacterial suspension can also be used for inoculation of an identification card.

   Note: Check the saline level in the tubes after filling. When it is evident by the saline level in the tube that a card has been improperly filled, do not load the card if using VITEK® 2 Compact; **or**, eject the card if using VITEK® 2 60 or VITEK® 2 XL.

   Note: Refer to the appropriate Instrument User Manual for detailed information regarding data entry, processing, etc.
5. Follow your local inspecting agency's guidelines for disposal of hazardous waste.

QUALITY CONTROL

Quality Control organisms should be processed according to the Test Card Setup Procedure.

Table 3: Quality Control

CLSI® Quality Control Organisms VITEK® 2 Results					
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™	*K. pneumoniae* ssp. *pneumoniae* ATCC® 700603™
Ampicillin	am01n	≤ 2 - 8	-	≥ 32†	-
Ampicillin/ Sulbactam	sam02n	≤ 2 - 8	-	8 - ≥ 32	-
Cefotaxime	ctx01n	≤ 1	8 - 32	-	-
Cefpodoxime	cpd01n	≤ 0.25 - 1	-	-	-
Ceftazidime	caz01n	≤ 1	≤ 1 - 4	-	-
Cefuroxime	cxm01n	2 - 8	-	-	-
Ciprofloxacin	cip01n	≤ 0.25	≤ 0.25 - 1	-	-
Ertapenem	etp01n	≤ 0.5	2 - ≥ 8	-	-

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CLSI® Quality Control Organisms VITEK® 2 Results					
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™	*K. pneumoniae* ssp. *pneumoniae* ATCC® 700603™
ESBL	esb01n	NEG	-	-	POS
Gentamicin	gm01n	≤ 1	≤ 1 - 2	-	-
Imipenem	ipm04n	≤ 0.25	1 - 4	-	-
Meropenem	mem02n	≤ 0.25	≤ 0.25 - 1	-	-
Moxifloxacin	mxf01n	≤ 0.25	1 - 8	-	-
Piperacillin	pip02n	≤ 4	≤ 4 - 8	≥ 128†	-
Piperacillin/ Tazobactam	tzp03n	≤ 4/4[1]	≤ 4/4 - 8/4[2]	≤ 4/4[3]	-
Tigecycline	tgc01n	≤ 0.5	-	-	-
Trimethoprim/ Sulfamethoxazole	sxt02n	≤ 20 (1/19)	160 (8/152) - ≥ 320 (16/304)	-	-

Numerical values are expressed in µg/mL.

[1]FDA/CLSI Broth Microdilution expected QC range = 1/4 - 4/4 µg/mL

[2]FDA/CLSI Broth Microdilution expected QC range = 1/4 - 8/4 µg/mL

[3]FDA/CLSI Broth Microdilution expected QC range = 0.5/4 - 2/4 µg/mL

NEG = Negative

POS = Positive

Note: For ESBL, FEP is Cefepime, CTX is Cefotaxime, CAZ is Ceftazidime and CA is Clavulanic Acid.

A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.

† *Escherichia coli* ATCC® 35218™ is not intended for routine QC testing of ampicillin, piperacillin, or ticarcillin. This organism is recommended only for routine QC of ß-lactamase inhibitor combinations. However, since this strain contains a plasmid-encoded ß-lactamase (non-ESBL), it is resistant to many penicillinase-labile antimicrobials, but susceptible to ß-lactamase/ß-lactamase inhibitor combinations. To ensure that the plasmid is present, testing of the ß-lactam alone (e.g., AM, PIP, TIC), in addition to the ß-lactamase/ß-lactamase inhibitor combination (e.g., AMC, SAM, TZP, TCC), can be performed. If the strain has lost its plasmid, it will be susceptible to the ß-lactam alone (i.e., AM, PIP, TIC), indicating that the QC test is invalid, and a new culture of *Escherichia coli* ATCC® 35218™ must be used.

Certification Statement

This is to certify that bioMérieux complies with ISO 13485 and FDA Quality System Regulation (QSR) requirements for design, development, and manufacture of antimicrobial susceptibility systems.

Frequency of QC Testing

Refer to *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically,* CLSI® and/or your local guidelines.[2]

Preparation of QC Organisms

1. Rehydrate the organism according to the manufacturer's instructions.
2. Subculture to Trypticase Soy Agar with 5% sheep blood (TSAB).
3. Incubate at 35°C for 24 hours.
4. Check for purity.
5. Subculture to a TSAB plate.
6. Incubate 16 to 18 hours at 35°C.

Short-Term Storage Conditions

1. Streak to a TSAB plate or slant.
2. Incubate for 24 hours.

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3. Refrigerate at 2°C to 8°C for up to two weeks.
4. Subculture once as described above and use for QC.

Long-Term Storage Conditions

1. Make a heavy suspension in Tryptic Soy Broth (TSB) with 15% glycerol.
2. Freeze at -70°C.
3. Subculture to TSAB twice before running QC.
   Note: Avoid repeated thawing and refreezing by either freezing in single-use aliquots or removing a small portion of frozen organism preparation with a sterile applicator stick.

RESULTS

Susceptibility Analytical Techniques

The system evaluates each organism's growth pattern in the presence of the antimicrobial in relation to the growth control well. Several parameters based on the growth characteristics are used to determine the MIC or qualitative result (for example, ESBL POS/NEG). The MIC result must be linked to an organism identification to determine a category interpretation. Accurate identification is critical, especially with certain organism/antimicrobial combinations (e.g., *Staphylococcus aureus*/oxacillin).

In cases where the identification of an organism is in question, confirmatory testing is necessary to ensure correct interpretation of susceptibility results.

A category interpretation will be reported along with a MIC, according to the interpretations defined by the Food and Drug Administration (FDA), CLSI®, Comité de l'Antibiogramme de la Société Française de Microbiologie (CASFM), European Committee for Antimicrobial Susceptibility Testing (EUCAST), or to an adaptation of the global settings according to other local guidelines.

Note: When FDA and CLSI® breakpoints differ, VITEK® 2 Systems AST tests are cleared for use with FDA breakpoints applied.

Combination Antimicrobials

The MICs for the combination antimicrobials are listed on the laboratory and patient reports as the first concentration (e.g., ampicillin/sulbactam ≤ 8/4 µg/mL is reported as ≤ 8 µg/mL.). The actual concentrations for each value in the antimicrobial calling range are as follows:

- piperacillin/tazobactam (µg/mL) 4/4, 8/4, 16/4, 32/4, 64/4, 128/4
- trimethoprim/sulfamethoxazole: **Note exception** — This drug is listed on the laboratory and patient reports as the sum of the two antimicrobial concentrations: 20 µg/mL = 1/19, 40 µg/mL = 2/38, 80 µg/mL = 4/76, 160 µg/mL = 8/152, 320 µg/mL = 16/304

Antimicrobial Deduction

Antimicrobials that have been deduced will only report an interpretive result and will be noted with a **+**.

Clinical Efficacy and Indications for Use

AST cards may contain some antimicrobials that are not proven to be effective for treatment of infections caused by all organisms that may be tested. For interpreting and reporting of antimicrobial results that have shown to be active against organism groups both *in vitro* and in clinical infections, refer to the individual pharmaceutical antimicrobial labeling or the local therapy guidelines.

Urinary Use Only Antimicrobials

Certain antimicrobial agents are limited to use in treating urinary tract infections. Accordingly, these agents should not be reported against pathogens recovered from infection sites other than the urinary tract (except as noted). Please refer to the current *CLSI Performance Standards for Susceptibility Testing, M100* and/or local guidelines for additional information.[3]

For urine only, per CLSI®.[3]

- *Enterobacteriaceae*: lomefloxacin or ofloxacin, norfloxacin, nitrofurantoin, sulfisoxazole, trimethoprim, cefazolin
- *Pseudomonas aeruginosa*: lomefloxacin or ofloxacin, norfloxacin
- Other non-*Enterobacteriaceae*: lomefloxacin or ofloxacin, norfloxacin, sulfisoxazole, tetracycline

LIMITATIONS

A VITEK® 2 AST card cannot be used with a direct clinical specimen or sample or other sources containing mixed flora. Any change or modification in the procedure may affect the results.

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A result for an antibiotic/organism combination, which may have a limitation, may be suppressed from reporting. This can be accomplished through the use of bioART rules in the VITEK® 2 Systems software. Refer to the software user manual for instructions.

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

- Ampicillin (am01n): *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Ampicillin/Sulbactam (sam02n): *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Cefpodoxime (cpd01n): *Morganella morganii, Serratia* spp.
- Imipenem (ipm04n): *Serratia marcescens*
- Piperacillin/Tazobactam (tzp03n): *Serratia marcescens*

Perform an alternative method of testing prior to reporting results when a resistant result is obtained with the following antibiotic/organism combination(s):

- Imipenem (ipm04n): *Aeromonas* spp.
- Meropenem (mem02n): *Aeromonas* spp.
- Piperacillin/Tazobactam (tzp03n): *Pseudomonas aeruginosa*

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:

- Ertapenem (etp01n): *E. coli, K. pneumoniae, C. freundii, C. koseri, E. aerogenes, E. cloacae, K. oxytoca* (excluding ESBL producing strains), *M. morganii, P. mirabilis, P. vulgaris, S. marcescens*
- Tigecycline (tgc01n): *C. freundii, E. cloacae, E. coli, K. oxytoca, K. pneumoniae, C. koseri, E. aerogenes, S. marcescens*

EUCAST Limitations

It is recommended that the existing bioART suppression rules be enabled, or new rules created and enabled, for these limitations if the EUCAST breakpoints are applied.

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

- Ampicillin (am01n): *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Cefpodoxime (cpd01n): *Serratia* spp.
- Imipenem (ipm04n): *Serratia marcescens*
- Tigecycline (tgc01n): *Serratia* spp., *Enterobacter* spp., *Morganella* spp., *Proteus* spp., *Providencia* spp., *Cronobacter sakazakii*

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:

- Ertapenem (etp01n): *Enterobacteriaceae*

EXPECTED VALUES

Expected results for susceptibility tests will vary based on location and institution. VITEK® 2 Systems were tested at several geographically diverse locations to ensure that trends that occurred by location were integrated into the performance characteristics of the system. Organism resistance patterns will differ by institution; therefore, expected values will be directly related to the population of organisms at each site.

PERFORMANCE CHARACTERISTICS

The performance characteristics of the antimicrobial agents included in VITEK® 2 AST cards were established using the manual and autodilution modes (on a VITEK® 2 System) at multiple clinical laboratories. The VITEK® 2 AST card results were compared to results from a CLSI® reference method. Essential agreement (EA) represents VITEK® 2 results which agree exactly or are within a ± twofold dilution (± two doubling dilutions for antifungal) of the reference result.

Category agreement (CA) occurs when the VITEK® 2 and the reference interpretative results agree (Susceptible, Intermediate, and Resistant). There are instances when the category agreement for an antimicrobial falls below the essential agreement. This can occur when a significant number of MICs cluster around a category breakpoint during clinical trial testing, resulting in interpretative errors. For a description of interpretive errors, refer to the footnotes below the table that follows (Performance Characteristics). When the majority of the errors are of the minor type, a high corresponding essential agreement percentage demonstrates that the antimicrobial retains an acceptable overall performance.

There are instances when the performance is based solely on category agreement (CA) because at the time performance was established, less than five discrete twofold dilutions were evaluated. A minimum of five dilutions is necessary to calculate

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essential agreement (EA) based on ± one twofold dilution. These instances are designated by a "c" footnote in the Contents of the Card table. The following performance tables have values for CA only when EA was not established at the time of FDA clearance.

The reproducibility of the VITEK® 2 system was established by testing a set of on-scale organisms.*

*Data on file at bioMérieux, Inc

Table 4: Performance Characteristics for Gram-Negative Antimicrobial Susceptibility Testing

Antimicrobial	Antimicrobial Code	Antibiotic Version	Bp[1]	Comment[2]	Essential Agreement				Category Agreement				% Reproducibility
					% Error				% Error				
					% EA	VME	ME	mE	% CA	VME	ME	mE	
Ampicillin	AM	am01n	CLSI	#, E	93.3	1.3	0.0	0.8	90.9	1.3	0.0	7.8	99.3
			CA-SFM	I	94.9	0.6	2.2	4.3	–	–	–	–	
Cefotaxime	CTX	ctx01n	CLSI	#, E	95.8	1.1	0.2	2.6	92.9	1.1	0.2	6.7	98.1
			CA-SFM	I	94.0	0.4	0.1	3.5	–	–	–	–	
Cefpodoxime	CPD	cpd01n	CLSI	#, E	96.0	0.0	0.4	0.8	96.3	0.0	0.4	3.5	100
			CA-SFM	I	94.1	1.2	2.9	1.3	–	–	–	–	
Ceftazidime	CAZ	caz01n	CLSI	#, E	97.5	1.1	0.2	1.0	97.3	1.1	0.2	3.5	95.4
			CA-SFM	I	92.3	5.1	0.0	4.1	–	–	–	–	
Cefuroxime	CXM	cxm01n	CLSI	#, E	95.3	1.5	1.0	1.6	93.9	1.5	1.0	4.8	99.6
Ciprofloxacin	CIP	cip01n	CLSI	#, E	97.9	0.0	0.0	0.5	96.6	0.0	0.0	3.8	98.9
			CA-SFM	E	97.9	0.0	0.0	0.5	96.6	0.0	0.0	3.8	
Ertapenem	ETP	etp01n	CLSI	#, E	–	–	–	–	98.8	0.0	0.0	1.2	97.8
Extended-Spectrum Beta-Lactamase (ESBL)	ESBL	esb01n	CLSI	#, E	N/A	N/A	N/A	N/A	97.7	2.7	1.9	N/A	100
Gentamicin	GM	gm01n	CLSI	#, E	97.1	1.9	0.0	0.6	96.4	1.9	0.0	2.9	100
			CA-SFM	E	97.1	1.9	0.0	0.6	96.4	1.9	0.0	2.9	
Imipenem	IPM	ipm04n	CLSI	#, E ❷	95.7	2.4	0.3	0.4	94.8	2.4	0.3	4.4	99.6
Meropenem	MEM	mem02n	CLSI	#, E ❷	97.6	1.4	0.0	0.3	96.8	1.4	0.0	2.8	99.6
			Global	#, E ❷	97.6	0.0	0.0	0.5	97.7	0.0	0.0	2.3	
Moxifloxacin	MXF	mxf01n	CLSI	#, E	98.7	0.0	0.0	0.0	97.8	2.2	0.0	0.0	100
Piperacillin	PIP	pip02n	CLSI	#, E ❷	94.6	2.0	0.2	3.7	92.4	2.7	0.2	6.8	99.3
			CA-SFM	E ❷	94.6	2.0	0.3	2.5	91.0	2.0	0.3	8.1	
			Global	#, E ❷	94.9	1.2	0.5	3.8	91.9	1.2	0.5	7.4	
Piperacillin/ Tazobactam*	TZP	tzp03n	CLSI	#, E	N/A	N/A	N/A	N/A	93.2	0.9	2.2	5.0	96.7
Tigecycline	TGC	tgc01n	Global	#, E	94.4	0.0	2.0	0.0	90.1	0.0	2.0	8.5	100
Trimethoprim/ Sulfamethoxazole	SXT	sxt02n	CLSI	#, E ❷	–	–	–	–	100	0.0	0.0	N/A	100
			CA-SFM	E ❷	99.5	0.0	0.0	0.0	100	0.0	0.0	0.0	
Trimethoprim/ Sulfamethoxazole	SXT	sxt02n	CLSI[3]	#, E ❷ Applies to V2S SW PC version 5.02 and above	-	-	-	-	100	0.0	0.0	N/A	97.8

[1] Abbreviations — Bp = breakpoint committee; EA = essential agreement; CA = category agreement; VME = Very Major Error (susceptible result with resistant reference result); ME = Major Error (resistant result with susceptible reference result); mE =

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minor Error (susceptible or resistant result with an intermediate reference result, or an intermediate result with a susceptible or resistant reference result).

[2] Comment — Specific organism groups are designated as P. aeurg. for *Pseudomonas aeruginosa*, others for species other than *Pseudomonas aeruginosa*, and Acineto. for *Acinetobacter*.

[3] FDA breakpoints are used in the CLSI Interpretation Standard (breakpoint committee) in the VITEK® 2 Systems software.

* The overall essential agreement for VITEK® 2 piperacillin/tazobactam was not calculated since the test contains less than five discrete concentrations. However, of the 2453 isolates tested, 348 (14.2%) yielded on-scale VITEK® 2 MIC values (i.e., results of 8, 16, 32, and 64 µg/ml). Those results were evaluated for MIC trends and the following results were obtained when VITEK® 2 was compared to CLSI broth microdilution method; 74.4% (259/348) of the VITEK® MICs were within +/- one doubling dilution; 18.4% (64/348) of the VITEK® MICs were higher by more than one doubling dilution; and 7.2% (25/348) of the VITEK® MICs were lower by more than one doubling dilution.

Key:

= US Food and Drug Administration 510(k) cleared
CLSI® = Clinical and Laboratory Standards Institute
CA-SFM = Comité de l'Antibiogramme de la Société Française de Microbiologie
E = External performance data
I = Internal performance data
– = Not available
❶ ❷ = Symbol identifies the performance characteristics for a specific antimicrobial version.
Ref. = Reference method for clinical performance study.

Table 5: EUCAST Performance Characteristics for Gram-Negative Antimicrobial Susceptibility Testing

Antimicrobial	Antimicrobial Code	Antibiotic Version	Comment[1]	Essential Agreement				Category Agreement			
				% Error				% Error			
				%EA[2]	VME	ME	mE	%CA	VME	ME	mE
Ampicillin	AM	am01n	*Enterobacteriaceae* (excludes: *Citrobacter, Enterobacter, Pantoea, Serratia* spp.)	93.2	2.7	0.9	0.0	96.6	4.3	1.8	0.0
Cefotaxime	CTX	ctx01n	*Enterobacteriaceae*	95.9	7.4	0.8	0.9	94.1	7.4	0.8	3.8
Cefpodoxime	CPD	cpd01n	*Enterobacteriaceae* excluding *Serratia* spp.	93.8	3.8	2.2	0.0	94.1	6.3	5.8	0.0
Ceftazidime	CAZ	caz01n	*Enterobacteriaceae, Pseudomonas*	96.7	3.0	0.3	0.8	97.9	3.0	1.0	1.3
Cefuroxime	CXM	cxm01n	*Enterobacteriaceae*	94.0	2.8	2.6	0.0	93.7	3.7	7.8	0.0
Ciprofloxacin	CIP	cip01n	N/A	98.1	0.0	0.3	0.2	95.3	0.0	0.3	4.5
Ertapenem	ETP	etp01n	*Enterobacteriaceae*	99.5	0.0	0.0	0.5	98.9	0.0	0.0	1.1
Gentamicin	GM	gm01n	N/A	98.3	0.4	0.0	0.8	96.8	0.0	0.0	3.2
Imipenem	IPM	ipm04n	N/A	95.8	1.0	0.4	0.8	92.2	1.0	0.4	7.3
Meropenem	MEM	mem02n	❷	97.6	0.5	0.0	0.6	95.9	0.5	0.0	3.9
Moxifloxacin	MXF	mxf01n	*Enterobacteriaceae*	98.7	0.0	0.6	0.2	95.4	0.0	0.6	4.1
Piperacillin	PIP	pip02n	*Enterobacteriaceae, Pseudomonas* ❷	93.9	2.4	1.6	1.9	88.5	4.3	2.9	8.5
Piperacillin/Tazobactam	TZP	tzp03n	*Enterobacteriaceae, Pseudomonas*	96.2	0.8	0.9	1.0	94.8	1.2	1.5	3.8
Tigecycline	TGC	tgc01n	(excludes: *Serratia, Morganella/Proteus/ Providencia*, and *Enterobacter*)	96.9	0.0	0.4	0.8	94.6	0.0	0.4	5.0
Trimethoprim/ Sulfamethoxazole	SXT	sxt02n	(also includes *S. maltophilia*) ❷	98.4	0.0	0.0	0.4	99.5	0.0	0.0	0.5

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[1] Comment — Unless stated otherwise, performance is for *Enterobacteriaceae*, *Pseudomonas*, and *Acinetobacter*.

[2] Abbreviations — Bp = breakpoint committee; EA = essential agreement; CA = category agreement; VME = Very Major Error (susceptible result with resistant reference result); ME = Major Error (resistant result with susceptible reference result); mE = minor Error (susceptible or resistant result with an intermediate reference result, or an intermediate result with a susceptible or resistant reference result).

Key:

= EUCAST = European Committee on Antimicrobial Susceptibility

❶ ❷ = Symbol identifies the performance characteristics for a specific antimicrobial version.

LIST OF CLAIMS

Note: If the organism is not in the VITEK® 2 susceptibility database, results will not be reported.

Note: Organisms listed with an asterisk (*) indicate an AES claimed organism. No asterisk is displayed for a group; however, when an individual species (with an asterisk) is contained within a group, it is expertised.

Gram-Negative Organisms Claimed for AST-GN (keyID)

- *Achromobacter denitrificans*
- *Achromobacter xylosoxidans*
- *Acinetobacter baumannii**
- *Acinetobacter baumannii complex**
- *Acinetobacter calcoaceticus**
- *Acinetobacter haemolyticus*
- *Acinetobacter johnsonii*
- *Acinetobacter junii*
- *Acinetobacter lwoffii*
- *Acinetobacter pittii**
- *Acinetobacter* spp.
- *Aeromonas caviae*
- *Aeromonas hydrophila*
- *Aeromonas hydrophila/caviae*
- *Aeromonas sobria*
- *Alcaligenes faecalis* ssp. *faecalis*
- *Bordetella avium*
- *Bordetella bronchiseptica*
- *Brevundimonas diminuta*
- *Brevundimonas diminuta/vesicularis*
- *Brevundimonas vesicularis*
- *Burkholderia cepacia**
- *Cedecea davisae**
- *Cedecea lapagei**
- *Cedecea neteri**
- *Chryseobacterium gleum*
- *Chryseobacterium indologenes*
- *Citrobacter amalonaticus**
- *Citrobacter braakii**
- *Citrobacter farmeri**
- *Citrobacter freundii**
- *Citrobacter koseri**
- *Citrobacter youngae**
- *Comamonas testosteroni*
- *Cronobacter muytjensii**
- *Cronobacter sakazakii* group*
- *Cronobacter sakazakii**
- *Delftia acidovorans*

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- *Edwardsiella hoshinae**
- *Edwardsiella tarda**
- *Elizabethkingia meningoseptica* (formerly known as *Chryseobacterium meningosepticum*)
- *Enterobacter aerogenes**
- *Enterobacter asburiae**
- *Enterobacter cancerogenus**
- *Enterobacter cloacae**
- *Enterobacter cloacae* complex*
- *Enterobacter cloacae* ssp. *cloacae**
- *Enterobacter cloacae* ssp. *dissolvens* *
- *Escherichia coli**
- *Escherichia coli* ATCC® 25922™
- *Escherichia coli* ATCC® 35218™
- *Escherichia fergusonii*
- *Escherichia hermannii**
- *Escherichia vulneris**
- *Ewingella americana*
- *Hafnia alvei**
- *Hafnia paralvei**
- *Klebsiella oxytoca**
- *Klebsiella pneumoniae**
- *Klebsiella pneumoniae* ssp. *ozaenae**
- *Klebsiella pneumoniae* ssp. *pneumoniae**
- *Klebsiella pneumoniae* ssp. *pneumoniae* ATCC® 700603 ™
- *Klebsiella pneumoniae* ssp. *rhinoscleromatis**
- *Klebsiella* spp.*
- *Kluyvera ascorbata**
- *Kluyvera cryocrescens**
- *Kluyvera intermedia* (formerly known as *Enterobacter intermedius*)*
- *Leclercia adecarboxylata**
- *Lelliottia amnigena* (formerly known as Enterobacter amnigenus)*
- *Lelliottia amnigena 1* (formerly known as Enterobacter amnigenus 1)*
- *Lelliottia amnigena 2* (formerly known as Enterobacter amnigenus 2)
- *Mannheimia haemolytica*
- *Moraxella* group
- *Moraxella lacunata*
- *Moraxella nonliquefaciens*
- *Moraxella osloensis*
- *Morganella morganii**
- *Morganella morganii* ssp. *morganii**
- *Morganella morganii* ssp. *sibonii**
- *Myroides* ssp.
- *Pantoea agglomerans*
- *Pantoea dispersa*
- *Pasteurella aerogenes*
- *Pasteurella multocida**
- *Pasteurella pneumotropica*
- *Plesiomonas shigelloides*
- *Pluralibacter gergoviae* (formerly known as *Enterobacter gergoviae*)*
- *Proteus hauseri**
- *Proteus mirabilis**
- *Proteus penneri**

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- *Proteus vulgaris**
- *Providencia alcalifaciens**
- *Providencia rettgeri**
- *Providencia rustigianii**
- *Providencia stuartii**
- *Pseudomonas aeruginosa**
- *Pseudomonas aeruginosa* ATCC® 27853™
- *Pseudomonas alcaligenes*
- *Pseudomonas fluorescens*
- *Pseudomonas luteola*
- *Pseudomonas mendocina*
- *Pseudomonas oleovorans*
- *Pseudomonas oryzihabitans*
- *Pseudomonas putida*
- *Pseudomonas* spp.
- *Pseudomonas stutzeri*
- *Ralstonia pickettii*
- *Raoultella ornithinolytica**
- *Raoultella planticola**
- *Raoultella terrigena**
- *Salmonella enterica* ssp. *arizonae*
- *Salmonella enterica* ssp. *enterica**
- *Salmonella* group*
- *Salmonella* ser. Enteritidis*
- *Salmonella* ser. Paratyphi A*
- *Salmonella* ser. Paratyphi B*
- *Salmonella* ser. Paratyphi C*
- *Salmonella* ser. Typhi*
- *Salmonella* ser. Typhimurium*
- *Salmonella* spp.*
- *Serratia ficaria**
- *Serratia fonticola**
- *Serratia grimesii**
- *Serratia liquefaciens**
- *Serratia liquefaciens* group*
- *Serratia marcescens**
- *Serratia odorifera**
- *Serratia plymuthica**
- *Serratia proteamaculans*
- *Serratia rubidaea**
- *Shewanella putrefaciens*
- *Shewanella putrefaciens* group
- *Shigella boydii**
- *Shigella dysenteriae**
- *Shigella flexneri**
- *Shigella* group*
- *Shigella sonnei**
- *Shigella* spp.
- *Sphingobacterium multivorum*
- *Sphingobacterium spiritivorum*
- *Sphingomonas paucimobilis*
- *Stenotrophomonas maltophilia**

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- *Vibrio alginolyticus*
- *Vibrio fluvialis*
- *Vibrio harveyi*
- *Vibrio metschnikovii*
- *Vibrio mimicus*
- *Vibrio parahaemolyticus*
- *Vibrio vulnificus*
- *Yersinia aldovae*
- *Yersinia enterocolitica**
- *Yersinia enterocolitica* group*
- *Yersinia frederiksenii**
- *Yersinia intermedia**
- *Yersinia kristensenii**
- *Yersinia pseudotuberculosis**
- *Yersinia ruckeri*

REFERENCES

1. Barry, AL The Antimicrobic Susceptibility Test, Principles and Practices, Lea and Febiger, Philadelphia, PA. 1976.
2. Clinical Laboratory Standards Institute (CLSI®), Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically, M7- A7, Wayne, Pennsylvania, January 2006.
3. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Eighteenth Informational Supplement, M100-S18, Vol. 27, No. 1, January 2008.
4. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-third Informational Supplement, M100-S22, January 2012.
5. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-fourth Informational Supplement; M100-S24, January 2014.
6. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-fifth Informational Supplement, M100-S25, January 2015.
7. Comité de l'Antibiogramme de la Société Française de Microbiologie. Communiqué 1996. Path Biol, 1996, 44, n° 8, I-VIII.
8. Comité de l'Antibiogramme de la Société Française de Microbiologie, Communiqué 2007.
9. Comite de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM), Recommendations 2012.
10. Comité de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM). Communiqué 2014.
11. Comité de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM). Communiqué 2015.
12. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 2.0, January 2012.
13. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 4.0, January 2014.
14. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 5.0, January 2015.
15. Gerlach, EH Microdilution 1: A Comparative Study, p. 63-76, In: Balows, A. (ed.), Current Techniques for Antibiotic Susceptibility Testing, Charles C. Thomas, Springfield, IL. 1974.
16. MacLowry, JD, and HH Marsh. 1968. Semi-automatic microtechnique for serial dilution antibiotic sensitivity testing in the clinical laboratory. J. Lab. Clin. Med. 1968;72:685-687.
17. Murray, PR, Baron EJ, Pfaller MA, Tenover FC, and Yolken RH, editors. Manual of Clinical Microbiology, 8th ed. American Society for Microbiology, Washington, D.C. 2003.
18. National Committee for Clinical Laboratory Standards, M29-A, Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissue – Approved Guideline (1997).
19. National Committee for Clinical Laboratory Standards, Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Approved Standard — Third Edition, M27-A3, Vol. 22, No. 15, 2008.
20. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health, Office of Health and Safety, Biosafety in Microbiological and Biomedical Laboratories, 1988.

Permission to incorporate portions of M100 (Performance Standards for Antimicrobial Susceptibility Testing: Informational Supplement) in the bioMérieux clinical microbiology instrumentation and System has been granted by CLSI®. The current standard and supplements to it may be obtained from CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

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INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalog number
IVD	In Vitro Diagnostic Medical Device
	Legal Manufacturer
	Temperature limitation
	Use by date
LOT	Batch code
	Consult Instructions for Use
	Date of manufacture
	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community
Rx only	For US Only : Caution : US Federal Law restricts this device to sale by or on the order of a licensed practitioner

Instructions for Use provided in the kit or downloadable from www.biomerieux.com/techlib

BARCODES

User MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.

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01 A310GV0J---0

02 BAST-N22301P

03 C---Z020P0FR

04 D100G0I0L1N7

05 E11032O2G1KC

06 F202P1R2300K

LIMITED WARRANTY

bioMérieux warrants the performance of the product for its stated intended use provided that all procedures for usage, storage and handling, shelf life (when applicable), and precautions are strictly followed as detailed in the instructions for use (IFU).

Except as expressly set forth above, bioMérieux hereby disclaims all warranties, including any implied warranties of merchantability and fitness for a particular purpose or use, and disclaims all liability, whether direct, indirect or consequential, for any use of the reagent, software, instrument and disposables (the “System”) other than as set forth in the IFU.

WASTE DISPOSAL

All hazardous waste must be disposed of by following your local inspecting agency's guidelines.

REVISION HISTORY TABLE

Change type categories	
N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user
Note:	Minor typographical, grammar, and formatting changes are not included in the revision history.

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Release Date	Part Number	Change Type	Change Summary
2018-11	045611-01	Administrative	• Formatting changes do not affect the fit, form, or function of the product
		Technical change	• Combined product package insert content with VITEK® 2 Product Information Manual AST content • Updated Limited Warranty section • Updated with RX only information • Updated with EUCAST limitations

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REF 22330

045616- 01 - 2018-01 EN

VITEK® 2 AST-P606

Rx only IVD

INTENDED USE

The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of *Staphylococcus* spp., *Enterococcus* spp., and *S. agalactiae* to antimicrobial agents when used as instructed.

SUMMARY AND EXPLANATION

Susceptibility testing is indicated for any organism that contributes to an infectious process warranting antimicrobial chemotherapy. Susceptibility tests are most often indicated when the causative organism is thought to belong to a species capable of exhibiting resistance to commonly used agents. Isolated colonies of each type of organism that may play a pathogenic role are selected from an agar plate and tested for susceptibility. These tests are then examined and the Minimum Inhibitory Concentration (MIC) is determined. The MIC obtained using a dilution test may tell the physician the concentration of an antimicrobial agent needed at the site of infection to inhibit the infecting organism.

MICs have traditionally been determined using antimicrobial concentrations derived from serial twofold dilutions.[2] The MIC is then determined from the lowest concentration that exhibits inhibition of growth. An interpretive criterion (Susceptible, Intermediate, or Resistant) can then be assigned to MIC results to aid in the direction of therapy.

For some antimicrobials (e.g., high-level gentamicin, high-level streptomycin) a qualitative result is generated.

The standard and reference procedures are based on susceptibility tests requiring 16 to 24 hours of incubation for bacteria. Various manufacturers have now developed automated procedures designed to generate results more rapidly by using shortened incubation times. Laboratories worldwide use either variations of the standard reference procedure or a commercially available product to determine the MICs of infectious organisms.

Methicillin-Resistant Staphylococci (MRS)

Resistance to oxacillin is used to detect the presence of MRS. Most MRS are also usually resistant to multiple antimicrobials, including other beta-lactams, aminoglycosides, macrolides, clindamycin, and tetracycline. However, a “community-acquired methicillin-resistant *S. aureus*” phenotype has been described. These are not multi-drug resistant strains, but are typically resistant to penicillin and oxacillin, susceptible or resistant to erythromycin, and susceptible to gentamicin, clindamycin, and tetracycline.

Oxacillin (OX1)

This test provides an MIC determination and category interpretation for oxacillin. Interpretive results for MRS are reported as resistant to all beta-lactams (except anti-MRSA beta-lactams) when the instrument is operating in the CLSI® mode or the User-Defined (based on CLSI®) mode. The results from this test correlate to results that would be obtained from standard dilution testing of oxacillin. The calling range is 0.25 µg/mL to 4.0 µg/mL.

Cefoxitin Screen

This test may be used to predict *mec*A-mediated oxacillin resistance, and it is based on the cefoxitin disk screen test. The cefoxitin screen and oxacillin work in combination to determine the final interpretation reported for oxacillin.

Synergy Screen

Since the use of penicillin or ampicillin alone often results in treatment failure of serious enterococcal endocarditis, combination therapy is usually indicated to enhance bactericidal activity. The synergy between a cell wall active agent (such as penicillin, ampicillin, or vancomycin) and an aminoglycoside (such as gentamicin, kanamycin or streptomycin) is best predicted for enterococci by screening for high-level resistance to the aminoglycoside. When enterococci are susceptible *in vitro* to the high-level aminoglycoside and a cell wall active agent, this is predictive of the effectiveness of this combination therapy. Results are reported as SYN-S (high-level synergy screen is susceptible) and SYN-R (high-level synergy screen is resistant).

Inducible Clindamycin Resistance Test (ICR)

A positive ICR test is indicative of inducible MLS_b resistance, which confers resistance to macrolides, lincosamides, and type B streptogramin. An isolate with a positive ICR test should be reported as resistant to clindamycin; however, clindamycin may

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still be effective in some patients. If the ICR test is positive and the clindamycin result is susceptible or intermediate, the clindamycin result will be forced resistant by the ICR test (in CLSI® mode or User-defined based on CLSI®).

STORAGE CONDITIONS

Upon receipt, store VITEK® 2 AST cards unopened in their original package liner at 2°C to 8°C.

PRINCIPLE OF THE TEST

The AST card for VITEK® 2 Systems is an automated test methodology based on the MIC technique reported by MacLowry and Marsh and Gerlach.[15,16] The AST card is essentially a miniaturized and abbreviated version of the doubling dilution technique for MICs determined by the microdilution method.[1]

Each AST card contains a control well containing only microbiological culture medium. The remaining microwells contain premeasured amounts of specific antimicrobials combined with culture medium.

The organism suspension to be tested must be diluted to a standardized concentration in 0.45% saline before being used to rehydrate the antimicrobial medium within the card. The card is then filled, sealed, and placed into the instrument incubator/reader, either automatically (as with VITEK® 2 60 or VITEK® 2 XL) or manually (as with VITEK® 2 Compact). The instrument monitors the growth of each well in the card over a defined period of time (up to 18 hours for *Staphylococcus, Enterococcus* and *S. agalactiae*). At the completion of the incubation cycle, MIC values (or test results, as appropriate) are determined for each antimicrobial contained on the card.

REAGENTS

When used with VITEK® 2 instrumentation, the AST card is a complete system for routine susceptibility testing. Each AST card contains selected antimicrobials in varying concentrations, dried with a microbiological culture medium.

Contents of the Card

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Ampicillin	am01n	0.5, 4, 8, 32	-	-	*Enterococcus* spp., *S. agalactiae*
Enterococcus spp.			2	32	
S. agalactiae			0.25	16	
Benzylpenicillin	p02n	0.125, 0.25, 1, 2, 8, 64	0.12	64	*Enterococcus* spp., *S. agalactiae*
Chloramphenicol	c03n	2, 8, 16	4	64	*Staphylococcus* spp., *Enterococcus* spp., *S. agalactiae*
Clindamycin	cm01n	0.5, 1, 2	0.25	8	*Staphylococcus* spp., *S. agalactiae*
Erythromycin	e05n❷	1, 2, 4, 8	0.25	8	**N/A
Gentamicin High Level (synergy)	hlg01n	500	S	R	*Enterococcus* spp.
Kanamycin High Level (synergy)	hlk01n	200	S	R	**N/A
Levofloxacin	lev01n	0.25, 2, 8	0.12	8	*Staphylococcus* spp., *Enterococcus* spp., *S. agalactiae*
Linezolid	lnz02n	0.5, 1, 2	0.5	8	*S. agalactiae*, *E. faecalis*, *E. faecium*, *S. aureus*, *S. epidermidis*, *S. haemolyticus*
Moxifloxacin	mxf02n	0.25, 2, 8	0.25	8	**MSSA
Nitrofurantoin	ft01n	16, 32, 64	16	512	*Staphylococcus* spp., *Enterococcus* spp.

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Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Quinupristin/ Dalfopristin	qda01n	0.25, 0.5, 2	0.25	16	**MSSA, *S. epidermidis*, Vancomycin-resistant *E. faecium*, *S. agalactiae*
Streptomycin High Level (synergy)	hls01n	1000	S	R	*Enterococcus* spp.
Teicoplanin	tec01n	1, 4, 8, 16	0.5	32	**N/A
Tetracycline	te03n	0.5, 1, 2	1	16	*Staphylococcus* spp., *Enterococcus* spp., *S. agalactiae*
Trimethoprim/ Sulfamethoxazole	sxt02n❷	8/152, 16/304, 32/608	10 (0.5/9.5)	320 (16/304)	**N/A
Vancomycin	va04n❷	1, 2, 4, 8, 16	0.5	32	*Enterococcus* spp., *Staphylococcus* spp., *S. agalactiae*

Numerical values are expressed in µg/mL.

§ Equivalent standard method concentration by efficacy.

❶, ❷ etc. = See performance characteristics identified by the drug code with this symbol.

**N/A = No specific FDA Indications for Use available

**MSSA = Methicillin-susceptible *S. aureus*

PRECAUTIONS

- For *In Vitro* Diagnostic Use Only.
- For US Only: Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- For professional use only.
- Suspensions not within the appropriate zone on the VITEK® 2 DensiCHEK™ Plus or VITEK® 2 DensiCHEK™ may compromise card performance.
- Do not use the card after the expiration date shown on the package liner.
- Store the card unopened in the package liner. Do not use the card if the protective package liner is damaged or if no desiccant is present.
- Allow the card to come to room temperature before opening the package liner.
- Do not use powdered gloves. Powder may interfere with the optics.
- Use of culture media other than the recommended types must be validated by the customer laboratory for acceptable performance.
- The card performs as intended only when used in conjunction with VITEK® 2 Systems, following the instructions contained in the Instructions for Use.
- It is highly recommended that Good Laboratory Practices (e.g., FDA, CLSI, ISO, etc.) also be followed, according to local guidelines or requirements.
- **Do not use glass test tubes**. Use clear plastic (polystyrene) tubes only. Variation exists among test tubes of standard diameter. Carefully place the tube into the cassette. If resistance is encountered, discard and try another tube that does not require pressure to insert.
- Prior to inoculation, inspect cards for tape tears or damage to the tape and discard any that are suspect. Check the saline level in the tubes after the cassette has been processed to ensure proper filling of card.
  - VITEK® 2 60 or VITEK® 2 XL: Eject improperly filled cards.
  - VITEK® 2 Compact: Do not load improperly filled cards.
- Give special consideration to specimen source and patient therapy regimen. AST cards may contain some antimicrobials that are not proven to be effective for treatment of infections due to all organisms that may be tested. For interpreting and reporting of antimicrobial results that have been shown to be active against organism groups both *in vitro* and in clinical infections, refer to the individual pharmaceutical antimicrobial labeling or local therapy guidelines.

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- Interpretation of test results requires the judgment and skill of a person knowledgeable in AST. Additional testing may be required.[17]

Warning: All patient specimens, microbial cultures, and inoculated VITEK® 2 cards, along with associated materials, are potentially infectious and should be treated with universal precautions [18,20]

INSTRUMENT

The VITEK® 2 instruments are a family of *in vitro* diagnostic devices intended to rapidly assess the antimicrobial susceptibility of bacterial and yeast pathogens to available antimicrobial agents. For detailed information on the use and operation of these devices, refer to the appropriate Instrument User Manual.

SPECIMEN PREPARATION

Culture Requirements Table

VITEK® 2 Card	Media	Age of Culture	Incubation Conditions	McFarland Standards	Dilution for AST	Age of Suspension Before Loading Instrument
AST Gram-Positive	TSAB CBA CPS ID	18 to 24 hours	35°C to 37°C 5% to 10% CO_2 or aerobic, non-CO_2	0.50 to 0.63	280 µL in 3.0 mL 0.45% saline	VITEK® 2 Compact: ≤30 minutes VITEK® 2: ≤ 1 hour
GP and AST GP pair	TSAB[1] CBA[1] CPS ID	18 to 24 hours	35°C to 37°C 5% to 10% CO_2 or aerobic, non-CO_2	0.50 to 0.63	280 µL in 3.0 mL 0.45% saline	≤ 30 minutes

[1] These media were used in the identification product database developments and will give optimal performance.

Culture Requirements Table — Media Abbreviations

CBA = Columbia Sheep Blood Agar

CPS ID = chromID™ CPS (CPS ID Agar)

TSAB = Trypticase Soy Agar with 5% Sheep Blood

TEST PROCEDURE

Warning: Failure to properly follow instructions and recommendations provided in this section for performing laboratory tasks may cause erroneous or delayed results.

Materials

Materials provided are:

- VITEK® 2 DensiCHEK™ Plus Kit
- DensiCHEK™ Plus Standards Kit
- VITEK® 2 Cassette
- Adjustable volume saline dispenser
- 12 mm x 75 mm clear plastic (polystyrene) disposable test tubes
- VITEK® 2 60 or VITEK® 2 XL only: VITEK® 2 Pipettor/Diluter Accessory Kit (containing instrument pipette tips and saline hookup) and 0.45% saline bag

Materials required, but not provided are:

- Sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Loops, sterile sticks or swabs
- Appropriate agar medium (See the Culture Requirements Table.)
- QC isolates

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- VITEK® 2 AST Cards
- Micropipettors to deliver 280 µL
- Disposable pipette tips

Optional Accessories:

- Pre-dispensed saline test tubes (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Test tube caps
- Vortex

Test Card Setup Procedure

The following procedure contains general information applicable to all susceptibility products. (See the Culture Requirements Table for product-specific information.)

Note: Prepare the inoculum from a pure culture, according to good laboratory practices. In case of mixed cultures, a re-isolation step is required. It is recommended that a purity check plate be done to ensure that a pure culture was used for testing.

1. Do one of the following:
   - Select isolated colonies from a primary plate if culture requirements are met.
   - Subculture the organism to be tested to appropriate agar medium and incubate accordingly.
2. Aseptically transfer 3.0 mL of sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0) into a clear plastic (polystyrene) test tube (12 mm x 75 mm).
3. Use a sterile stick or swab to transfer a sufficient number of morphologically similar colonies to the saline tube prepared in step 2. Prepare a homogenous organism suspension with a density equivalent to the appropriate McFarland standard using the VITEK® 2 DensiCHEK™ Plus (see the Culture Requirements Table). The inoculum density required for the GN, GP, ST, or YST can be diluted automatically for AST cards by the VITEK® 2 instrument (VITEK® 2 60 or VITEK® 2 XL). **Note:** The age of the suspension before loading the instrument for AST testing must be less than one hour when using VITEK® 2 60 or VITEK® 2 XL, and less than 30 minutes when using VITEK® 2 Compact.
4. Choose one of the following:
   - **For an automatic dilution (VITEK® 2 60 or VITEK® 2 XL only):** Place the suspension tube prepared in step 3 into the cassette with or without an identification card. In the next cassette slot, place an empty tube and an AST card. The instrument will automatically dilute the bacterial suspension to prepare an inoculum suitable for the susceptibility card.
   - **For a manual dilution (VITEK® 2 Compact, VITEK® 2 60 or VITEK® 2 XL):** In a second tube containing 3.0 mL of saline, transfer 280 µL of the suspension prepared in step 3. Then place this tube in the cassette with a susceptibility card. The tube with the initial bacterial suspension can also be used for inoculation of an identification card.

   Note: Check the saline level in the tubes after filling. When it is evident by the saline level in the tube that a card has been improperly filled, do not load the card if using VITEK® 2 Compact; **or**, eject the card if using VITEK® 2 60 or VITEK® 2 XL.

   Note: Refer to the appropriate Instrument User Manual for detailed information regarding data entry, processing, etc.
5. Follow your local inspecting agency's guidelines for disposal of hazardous waste.

QUALITY CONTROL

Quality Control organisms should be processed according to the Test Card Setup Procedure.

Quality Control

CLSI® Quality Control Organisms VITEK® 2 Results									
Antimicrobic	Code	*E. faecalis* ATCC® 29212™	*S. aureus* ATCC® 29213™	*E. coli* ATCC® 35218™	*S. pneumoniae* ATCC® 49619™	*E. faecalis* ATCC® 51299™	*S. aureus* ATCC® BAA-1026™	*S. aureus* ATCC® BAA-976™	*S. aureus* ATCC® BAA-977™
Ampicillin	am01n	≤ 2	0.5 - 2	-	-	-	-	-	-
Benzylpenicillin	p02n	1 - 4	-	-	-	-	-	-	-
Chloramphenicol	c03n	≤ 4 - 16	≤ 4 - 16	-	-	-	-	-	-
Clindamycin	cm01n	4 - ≥ 8	≤ 0.25	-	-	-	-	-	-

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CLSI® Quality Control Organisms VITEK® 2 Results									
Antimicrobic	Code	*E. faecalis* ATCC® 29212™	*S. aureus* ATCC® 29213™	*E. coli* ATCC® 35218™	*S. pneumoniae* ATCC® 49619™	*E. faecalis* ATCC® 51299™	*S. aureus* ATCC® BAA-1026™	*S. aureus* ATCC® BAA-976™	*S. aureus* ATCC® BAA-977™
Erythromycin	e05n	1 - 4	≤ 0.25 - 1	-	-	-	-	-	-
Gentamicin High Level (synergy)	hlg01n	S	-	-	-	R	-	-	-
Kanamycin High Level (synergy)	hlk01n	S	-	-	-	-	-	-	-
Levofloxacin	lev01n	0.25 - 2	≤ 0.12 - 0.5	-	-	-	-	-	-
Linezolid	lnz02n	1 - 4	1 - 4	-	-	-	-	-	-
Moxifloxacin	mxf02n	≤ 0.25 - 0.5	≤ 0.25	-	-	-	-	-	-
Nitrofurantoin	ft01n	≤ 16	≤ 16 - 32	-	-	-	-	-	-
Quinupristin/Dalfopristin	qda01n	2 - 8	≤ 0.25 - 1	-	-	-	-	-	-
Streptomycin High Level (synergy)	hls01n	S	-	-	-	R	-	-	-
Teicoplanin	tec01n	≤ 0.5	≤ 0.5 - 1	-	-	-	-	-	-
Tetracycline	te03n	8 - ≥ 16	≤ 1	-	-	-	-	-	-
Trimethoprim/ Sulfamethoxazole	sxt02n	≤ 10 (0.5/9.5)	≤ 10 (0.5/9.5)	-	-	-	-	-	-
Vancomycin	va04n	1 - 4	≤ 0.5 - 2	-	-	-	-	-	-

Numerical values are expressed in µg/mL.

Certification Statement

This is to certify that bioMérieux complies with ISO 13485 and FDA Quality System Regulation (QSR) requirements for design, development, and manufacture of antimicrobial susceptibility systems.

Frequency of QC Testing

Refer to *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically,* CLSI® and/or your local guidelines.[2]

Preparation of QC Organisms

1. Rehydrate the organism according to the manufacturer's instructions.
2. Subculture to Trypticase Soy Agar with 5% sheep blood (TSAB).
3. Incubate at 35°C for 24 hours.
   Note: Gram-positive organisms may require an atmosphere of CO_2. (Refer to the Culture Requirements Table).
4. Check for purity.
5. Subculture to a TSAB plate.
6. Incubate 16 to 18 hours at 35°C.

Short-Term Storage Conditions

1. Streak to a TSAB plate or slant.
2. Incubate for 24 hours.
3. Refrigerate at 2°C to 8°C for up to two weeks.
4. Subculture once as described above and use for QC.

Long-Term Storage Conditions

1. Make a heavy suspension in Tryptic Soy Broth (TSB) with 15% glycerol.
2. Freeze at -70°C.
3. Subculture to TSAB twice before running QC.
   Note: Avoid repeated thawing and refreezing by either freezing in single-use aliquots or removing a small portion of frozen organism preparation with a sterile applicator stick.

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RESULTS

Susceptibility Analytical Techniques

The system evaluates each organism's growth pattern in the presence of the antimicrobial in relation to the growth control well. Several parameters based on the growth characteristics are used to determine the MIC or qualitative result (for example, ESBL POS/NEG). The MIC result must be linked to an organism identification to determine a category interpretation. Accurate identification is critical, especially with certain organism/antimicrobial combinations (e.g., *Staphylococcus aureus*/oxacillin).

In cases where the identification of an organism is in question, confirmatory testing is necessary to ensure correct interpretation of susceptibility results.

A category interpretation will be reported along with a MIC, according to the interpretations defined by the Food and Drug Administration (FDA), CLSI®, Comité de l'Antibiogramme de la Société Française de Microbiologie (CASFM), European Committee for Antimicrobial Susceptibility Testing (EUCAST), or to an adaptation of the global settings according to other local guidelines.

Note: When FDA and CLSI® breakpoints differ, VITEK® 2 Systems AST tests are cleared for use with FDA breakpoints applied.

Combination Antimicrobials

The MICs for the combination antimicrobials are listed on the laboratory and patient reports as the first concentration (e.g., ampicillin/sulbactam ≤ 8/4 µg/mL is reported as ≤ 8 µg/mL.). The actual concentrations for each value in the antimicrobial calling range are as follows:

- trimethoprim/sulfamethoxazole: **Note exception** — This drug is listed on the laboratory and patient reports as the sum of the two antimicrobial concentrations: 20 µg/mL = 1/19, 40 µg/mL = 2/38, 80 µg/mL = 4/76, 160 µg/mL = 8/152, 320 µg/mL = 16/304

Antimicrobial Deduction

Antimicrobials that have been deduced will only report an interpretive result and will be noted with a **+**.

Clinical Efficacy and Indications for Use

AST cards may contain some antimicrobials that are not proven to be effective for treatment of infections caused by all organisms that may be tested. For interpreting and reporting of antimicrobial results that have shown to be active against organism groups both *in vitro* and in clinical infections, refer to the individual pharmaceutical antimicrobial labeling or the local therapy guidelines.

Urinary Use Only Antimicrobials

Certain antimicrobial agents are limited to use in treating urinary tract infections. Accordingly, these agents should not be reported against pathogens recovered from infection sites other than the urinary tract (except as noted). Please refer to the current *CLSI Performance Standards for Susceptibility Testing, M100* and/or local guidelines for additional information.[3]

For urine only, per CLSI®:[3]

- *Staphylococcus* spp.: lomefloxacin, norfloxacin, nitrofurantoin, sulfisoxazole, trimethoprim
- *Enterococcus* spp.: ciprofloxacin, levofloxacin, norfloxacin, nitrofurantoin, tetracycline

LIMITATIONS

A VITEK® 2 AST card cannot be used with a direct clinical specimen or sample or other sources containing mixed flora. Any change or modification in the procedure may affect the results.

A result for an antibiotic/organism combination, which may have a limitation, may be suppressed from reporting. This can be accomplished through the use of bioART rules in the VITEK® 2 Systems software. Refer to the software user manual for instructions.

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:

- Ampicillin (am01n): *Streptococcus agalactiae*
- Benzylpenicillin (p02n): *Streptococcus agalactiae*
- Chloramphenicol (c03n): *Streptococcus agalactiae*
- Linezolid (lnz02n): *Enterococcus* spp., *Staphylococcus* spp., *Streptococcus agalactiae*

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EUCAST Limitations

It is recommended that the existing bioART suppression rules be enabled, or new rules created and enabled, for these limitations if the EUCAST breakpoints are applied.

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

- Teicoplanin (tec01n): *Staphylococcus epidermidis, Staphylococcus haemolyticus*

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:

- Benzylpenicillin (p02n): *Streptococcus agalactiae*
- Chloramphenicol (c03n): *Streptococcus agalactiae*
- Linezolid (lnz02n): *Streptococcus agalactiae*
- Nitrofurantoin (ft01n): *Staphylococcus saprophyticus*

EXPECTED VALUES

Expected results for susceptibility tests will vary based on location and institution. VITEK® 2 Systems were tested at several geographically diverse locations to ensure that trends that occurred by location were integrated into the performance characteristics of the system. Organism resistance patterns will differ by institution; therefore, expected values will be directly related to the population of organisms at each site.

PERFORMANCE CHARACTERISTICS

The performance characteristics of the antimicrobial agents included in VITEK® 2 AST cards were established using the manual and autodilution modes (on a VITEK® 2 System) at multiple clinical laboratories. The VITEK® 2 AST card results were compared to results from a CLSI® reference method. Essential agreement (EA) represents VITEK® 2 results which agree exactly or are within a ± twofold dilution (± two doubling dilutions for antifungal) of the reference result.

Category agreement (CA) occurs when the VITEK® 2 and the reference interpretative results agree (Susceptible, Intermediate, and Resistant). There are instances when the category agreement for an antimicrobial falls below the essential agreement. This can occur when a significant number of MICs cluster around a category breakpoint during clinical trial testing, resulting in interpretative errors. For a description of interpretive errors, refer to the footnotes below the table that follows (Performance Characteristics). When the majority of the errors are of the minor type, a high corresponding essential agreement percentage demonstrates that the antimicrobial retains an acceptable overall performance.

There are instances when the performance is based solely on category agreement (CA) because at the time performance was established, less than five discrete twofold dilutions were evaluated. A minimum of five dilutions is necessary to calculate essential agreement (EA) based on ± one twofold dilution. These instances are designated by a "c" footnote in the Contents of the Card table. The following performance tables have values for CA only when EA was not established at the time of FDA clearance.

The reproducibility of the VITEK® 2 system was established by testing a set of on-scale organisms.*

*Data on file at bioMérieux, Inc

Performance Characteristics for Gram-Positive Antimicrobial Susceptibility Testing

Antimicrobial	Antimicrobial Code	Antibiotic Version	Bp[1]	Comment[2]	Essential Agreement				Category Agreement				% Reproducibility
					% Error				% Error				
					% EA	VME	ME	mE	% CA	VME	ME	mE	
Ampicillin	AM	am01n	CLSI	#, E	97.6	1.1	0.3	0.2	99.5	2.2	0.6	0.2	97
Chloramphenicol	C	c03n	CLSI	#, E	99.7	3.1	0.1	0.3	97.8	3.1	0.1	2.7	100
			CA-SFM	E	99.7	3.1	0.1	0.3	97.8	3.1	0.1	2.7	
Clindamycin	CM	cm01n	CLSI	#, E	98.7	2.3	0.0	0.7	99.1	2.3	0.0	0.9	98.5
			CA-SFM	I	96.1	2.5	4.3	0.0	-	-	-	-	
Erythromycin	E	e05n	CLSI	E ❷	92.6	0.0	0.0	4.7	84.2	0.0	0.0	15.8	100
			CA-SFM	E ❷	92.6	0.4	0.3	3.6	93.0	0.4	0.3	6.6	

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Antimicrobial	Antimicrobial Code	Antibiotic Version	Bp[1]	Comment[2]	Essential Agreement				Category Agreement				% Reproducibility
					% Error				% Error				
					% EA	VME	ME	mE	% CA	VME	ME	mE	
Gentamicin High Level	HLG	hlg01n	CLSI	#, E	N/A	N/A	N/A	N/A	100	N/A	N/A	N/A	100
			CA-SFM	E, Enc	N/A	N/A	N/A	N/A	100	N/A	N/A	N/A	
Kanamycin High Level	HLK	hlk01n	CA-SFM	I, Enc	N/A	N/A	N/A	N/A	100	N/A	N/A	N/A	99.3
Levofloxacin	LEV	lev01n	CLSI	#, E	99.3	0.0	0.0	0.2	95.8	0.0	0.0	4.2	100
Linezolid	LNZ	lnz02n	CLSI	#, E	98.7	0.0	0.1	0.1	98.9	0.0	0.1	1.0	100
			CA-SFM	E	98.7	0.0	0.1	0.7	92.6	0.0	0.1	7.3	
Moxifloxacin	MXF	mxf02n	CLSI	#, E	99.2	0.0	0.0	0.0	83.3	0.0	0.0	16.7	100
			CA-SFM	E	98.5	0.0	0.0	0.1	92.4	0.0	0.0	7.6	
Nitrofurantoin	FT	ft01n	CLSI	#, E	98.3	0.0	1.4	0.0	91.7	0.0	1.4	7	100
Quinupristin/dalfopristin	QDA	qda01n	CLSI	#, E	96.6	1.2	0.0	0.2	94.8	1.2	0.0	4.9	100
			CA-SFM	E	96.1	0.0	0.0	2.3	86.5	0.0	0.0	13.5	
Streptomycin High Level	HLS	hls01n	CLSI	#, E, Enc	N/A	N/A	N/A	N/A	100	N/A	N/A	N/A	100
			CA-SFM	E, Enc	–	–	–	–	100	0.0	0.0	–	
Teicoplanin	TEC	tec01n	CLSI	I	96.6	3.3	0.3	0.4	95.7	3.3	0.3	2.7	99.4
			CA-SFM	I	96.9	1.6	0.0	1.1	95.9	1.6	0.3	3.2	
Tetracycline	TE	te03n	CLSI	#, E	99.1	1.2	0.4	0.5	99.3	1.2	0.5	0.8	94.8
Trimethoprim/ Sulfamethoxazole	SXT	sxt02n	CLSI	I ❷	97.3	1.6	1.5	0.0	–	–	–	–	97.6
			CA-SFM	I ❷	97.3	0.0	0.8	1.8	–	–	–	–	
Vancomycin	VA	va04n	CLSI[3]	#, E ❷	99.9	0.0	0.0	0.1	99.7	0.0	0.0	0.3	100
			CA-SFM	E ❷	99.9	0.0	0.0	0.1	99.7	0.0	0.0	0.3	

[1] Abbreviations — Bp = breakpoint committee; EA = essential agreement; CA = category agreement; VME = Very Major Error (susceptible result with resistant reference result); ME = Major Error (resistant result with susceptible reference result); mE = minor Error (susceptible or resistant result with an intermediate reference result, or an intermediate result with a susceptible or resistant reference result).

[2] Comment — Specific organism groups are designated as Staph for *staphylococci*, Enc for *enterococci*, S aga for Group B *streptococci*, Sau for *Staphylococcus aureus*.

[3] FDA breakpoints are used in the CLSI Interpretation Standard (breakpoint committee) in the VITEK® 2 Systems software.

For all gram-positive Beta-lactams with indications for *Staphylococcus* spp., with the exception of Benzylpenicillin (Penicillin), performance in this table represents forcing-resistance based on oxacillin resistance.

Key:

= US Food and Drug Administration 510(k) cleared
CLSI® = Clinical and Laboratory Standards Institute
CA-SFM = Comité de l'Antibiogramme de la Société Française de Microbiologie
E = External performance data
I = Internal performance data
– = Not available
N/A = Not applicable
Ref. = Reference method for clinical performance study.
❶ ❷ = Symbol identifies the performance characteristics for a specific antimicrobial version.

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EUCAST Performance Characteristics for Gram-Positive Antimicrobial Susceptibility Testing

Antimicrobial	Antimicrobial Code	Antibiotic Version	Comment[1]	Essential Agreement				Category Agreement			
				% Error				% Error			
				%EA[2]	VME	ME	mE	%CA	VME	ME	mE
Ampicillin	AM	am01n	*Enterococcus*	97.7	1.4	0.4	1.0	97.7	1.4	0.4	1.6
Chloramphenicol	C	c03n	*Staphylococcus, S. agalactiae*	99.6	6.5	0.0	0.0	97.8	31.3	0.0	0.0
Clindamycin	CM	cm01n	*Staphylococcus, S. agalactiae*	98.1	3.3	0.3	0.0	98.1	3.3	0.3	0.7
Erythromycin	E	e05n	*Staphylococcus, S. agalactiae* ❷	93.8	0.6	0.0	0.7	98.7	0.6	0.0	1.0
Levofloxacin	LEV	lev01n	N/A	99.7	1.4	0.0	0.0	98.4	1.4	0.0	1.3
Linezolid	LNZ	lnz02n	N/A	98.7	0.0	0.1	0.0	99.5	0.0	0.5	0.0
Moxifloxacin	MXF	mxf02n	*Staphylococcus, S. agalactiae*	99.0	0.7	0.0	0.5	95.2	0.7	0.0	4.6
Nitrofurantoin	FT	ft01n	*S. saprophyticus*	98.2	0.0	0.0	0.0	100	0.0	0.0	0.0
Quinupristin/Dalfopristin	QDA	qda01n	*Staphylococcus, Enterococcus*	97.4	0.0	0.0	0.8	93.3	0.0	0.0	6.7
Teicoplanin	TEC	tec01n	*S. agalactiae, S. aureus, Enterococcus*, coagulase-negative *Staphylococcus* except *S. epidermidis* and *S. haemolyticus*	98.9	4.8	0.2	0.0	99.4	4.8	0.2	0.0
Tetracycline	TE	te03n	*Staphylococcus, S. agalactiae*	98.5	1.0	1.4	0.3	96.0	1.0	1.4	2.8
Trimethoprim/ Sulfamethoxazole	SXT	sxt02n	*Staphylococcus, S. agalactiae* ❷	92.9	6.7	4.1	2.2	89.8	6.7	4.1	6.2
Vancomycin	VA	va04n	*Staphylococcus, S. agalactiae, Enterococcus* ❷ (EUCAST v1.3 breakpoints)	99.8	2.0	0.0	0.0	99.7	4.1	0.1	0.0
			Staphylococcus, S. agalactiae, Enterococcus ❷ (EUCAST v2.0 breakpoints)	99.8	2.1	0.0	0.0	99.7	8.3	0.0	0.0

[1] Comment — Unless stated otherwise, performance is for *Staphylococcus*, *Enterococcus*, and *S. agalactiae*.

[2] Abbreviations — Bp = breakpoint committee; EA = essential agreement; CA = category agreement; VME = Very Major Error (susceptible result with resistant reference result); ME = Major Error (resistant result with susceptible reference result); mE = minor Error (susceptible or resistant result with an intermediate reference result, or an intermediate result with a susceptible or resistant reference result).

Key:

= EUCAST = European Committee on Antimicrobial Susceptibility

❶ ❷ = Symbol identifies the performance characteristics for a specific antimicrobial version.

LIST OF CLAIMS

Note: If the organism is not in the VITEK® 2 susceptibility database, results will not be reported.

Note: Organisms listed with an asterisk (*) indicate an AES claimed organism. No asterisk is displayed for a group; however, when an individual species (with an asterisk) is contained within a group, it is expertised.

Gram-Positive Organisms Claimed for AST-GP (keyID)

- *Coagulase-negative Staphylococcus**
- *Coagulase-positive Staphylococcus**

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- *Enterococcus avium*
- *Enterococcus casseliflavus**
- *Enterococcus durans*
- *Enterococcus faecalis**
- *Enterococcus faecalis* ATCC® 29212™
- *Enterococcus faecalis* ATCC® 51299™
- *Enterococcus faecium**
- *Enterococcus gallinarum**
- *Enterococcus hirae*
- *Enterococcus malodoratus*
- *Enterococcus mundtii*
- *Enterococcus* spp.*
- *Escherichia coli* ATCC® 35218™
- *Staphylococcus aureus**
- *Staphylococcus aureus* ATCC® 29213™
- *Staphylococcus aureus* ATCC® BAA-976™
- *Staphylococcus aureus* ATCC® BAA-977™
- *Staphylococcus aureus* ATCC® BAA-1026™
- *Staphylococcus auricularis**
- *Staphylococcus capitis**
- *Staphylococcus chromogenes**
- *Staphylococcus cohnii**
- *Staphylococcus cohnii* ssp. *cohnii**
- *Staphylococcus cohnii* ssp. *urealyticus**
- *Staphylococcus epidermidis**
- *Staphylococcus haemolyticus**
- *Staphylococcus hominis**
- *Staphylococcus hominis* ssp. *hominis**
- *Staphylococcus hyicus**
- *Staphylococcus intermedius**
- *Staphylococcus kloosii**
- *Staphylococcus lentus**
- *Staphylococcus lugdunensis**
- *Staphylococcus pseudintermedius*
- *Staphylococcus saprophyticus**
- *Staphylococcus schleiferi**
- *Staphylococcus sciuri**
- *Staphylococcus simulans**
- *Staphylococcus warneri**
- *Staphylococcus xylosus**
- *Streptococcus agalactiae**
- *Streptococcus pneumoniae**
- *Streptococcus pneumoniae* ATCC® 49619™

REFERENCES

1. Barry, AL The Antimicrobic Susceptibility Test, Principles and Practices, Lea and Febiger, Philadelphia, PA. 1976.
2. Clinical Laboratory Standards Institute (CLSI®), Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically, M7- A7, Wayne, Pennsylvania, January 2006.
3. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Eighteenth Informational Supplement, M100-S18, Vol. 27, No. 1, January 2008.
4. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-third Informational Supplement, M100-S22, January 2012.

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5. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-fourth Informational Supplement; M100-S24, January 2014.

6. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-fifth Informational Supplement, M100-S25, January 2015.

7. Comité de l'Antibiogramme de la Société Française de Microbiologie. Communiqué 1996. Path Biol, 1996, 44, n° 8, I-VIII.

8. Comité de l'Antibiogramme de la Société Française de Microbiologie, Communiqué 2007.

9. Comite de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM), Recommendations 2012.

10. Comité de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM). Communiqué 2014.

11. Comité de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM). Communiqué 2015.

12. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 2.0, January 2012.

13. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 4.0, January 2014.

14. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 5.0, January 2015.

15. Gerlach, EH Microdilution 1: A Comparative Study, p. 63-76, In: Balows, A. (ed.), Current Techniques for Antibiotic Susceptibility Testing, Charles C. Thomas, Springfield, IL. 1974.

16. MacLowry, JD, and HH Marsh. 1968. Semi-automatic microtechnique for serial dilution antibiotic sensitivity testing in the clinical laboratory. J. Lab. Clin. Med. 1968;72:685-687.

17. Murray, PR, Baron EJ, Pfaller MA, Tenover FC, and Yolken RH, editors. Manual of Clinical Microbiology, 8th ed. American Society for Microbiology, Washington, D.C. 2003.

18. National Committee for Clinical Laboratory Standards, M29-A, Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissue – Approved Guideline (1997).

19. National Committee for Clinical Laboratory Standards, Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Approved Standard — Third Edition, M27-A3, Vol. 22, No. 15, 2008.

20. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health, Office of Health and Safety, Biosafety in Microbiological and Biomedical Laboratories, 1988.

Permission to incorporate portions of M100 (Performance Standards for Antimicrobial Susceptibility Testing: Informational Supplement) in the bioMérieux clinical microbiology instrumentation and System has been granted by CLSI®. The current standard and supplements to it may be obtained from CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

BARCODES

User MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.

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01 

02 

03 

04 

05 

06 

07 

08 

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalog number
IVD	In Vitro Diagnostic Medical Device
	Legal Manufacturer
	Temperature limitation
	Use by date
LOT	Batch code
	Consult Instructions for Use
	Date of manufacture
Σ	Contains sufficient for <n> tests

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Symbol	Meaning
EC REP	Authorized representative in the European Community
Rx only	For US Only : Caution : US Federal Law restricts this device to sale by or on the order of a licensed practitioner

Instructions for Use provided in the kit or downloadable from www.biomerieux.com/techlib

LIMITED WARRANTY

bioMérieux warrants the performance of the product for its stated intended use provided that all procedures for usage, storage and handling, shelf life (when applicable), and precautions are strictly followed as detailed in the instructions for use (IFU).

Except as expressly set forth above, bioMérieux hereby disclaims all warranties, including any implied warranties of merchantability and fitness for a particular purpose or use, and disclaims all liability, whether direct, indirect or consequential, for any use of the reagent, software, instrument and disposables (the “System”) other than as set forth in the IFU.

WASTE DISPOSAL

All hazardous waste must be disposed of by following your local inspecting agency's guidelines.

REVISION HISTORY TABLE

Change type categories	
N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user
Note:	Minor typographical, grammar, and formatting changes are not included in the revision history.

Release Date	Part Number	Change Type	Change Summary
2018-01	045616-01	Administrative	• Formatting changes do not affect the fit, form, or function of the product
		Technical change	• Combined product package insert content with VITEK® 2 Product Information Manual AST content • Updated Limited Warranty section • Updated with RX only information • Updated with EUCAST limitations

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REF 413434

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VITEK® 2 AST-GN77

Rx only IVD

INTENDED USE

The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.

SUMMARY AND EXPLANATION

Susceptibility testing is indicated for any organism that contributes to an infectious process warranting antimicrobial chemotherapy. Susceptibility tests are most often indicated when the causative organism is thought to belong to a species capable of exhibiting resistance to commonly used agents. Isolated colonies of each type of organism that may play a pathogenic role are selected from an agar plate and tested for susceptibility. These tests are then examined and the Minimum Inhibitory Concentration (MIC) is determined. The MIC obtained using a dilution test may tell the physician the concentration of an antimicrobial agent needed at the site of infection to inhibit the infecting organism.

MICs have traditionally been determined using antimicrobial concentrations derived from serial twofold dilutions.[2] The MIC is then determined from the lowest concentration that exhibits inhibition of growth. An interpretive criterion (Susceptible, Intermediate, or Resistant) can then be assigned to MIC results to aid in the direction of therapy.

For some antimicrobials (e.g., high-level gentamicin, high-level streptomycin) a qualitative result is generated.

The standard and reference procedures are based on susceptibility tests requiring 16 to 24 hours of incubation for bacteria. Various manufacturers have now developed automated procedures designed to generate results more rapidly by using shortened incubation times. Laboratories worldwide use either variations of the standard reference procedure or a commercially available product to determine the MICs of infectious organisms.

Extended-Spectrum Beta Lactamases (ESBLs)

ESBLs are enzymes that arise by mutations in genes for common plasmid-mediated beta-lactamases. Strains of *Klebsiella* spp. and *E. coli* that produce ESBLs may be clinically resistant to therapy with penicillins, cephalosporins, or aztreonam despite apparent *in vitro* susceptibility to some of these agents. Some of these strains will show MICs above the normal susceptible population but below the standard breakpoints for certain extended-spectrum cephalosporins or aztreonam. Before reporting a strain as an ESBL producer, a confirmatory method may be performed. The VITEK® 2 ESBL Test is a confirmatory test for those ESBLs inhibited by clavulanic acid, and it utilizes cefepime, cefotaxime, and ceftazidime, with and without clavulanic acid, to determine a positive or negative result.

STORAGE CONDITIONS

Upon receipt, store VITEK® 2 AST cards unopened in their original package liner at 2°C to 8°C.

PRINCIPLE OF THE TEST

The AST card for VITEK® 2 Systems is an automated test methodology based on the MIC technique reported by MacLowry and Marsh and Gerlach.[15,16] The AST card is essentially a miniaturized and abbreviated version of the doubling dilution technique for MICs determined by the microdilution method.[1]

Each AST card contains a control well containing only microbiological culture medium. The remaining microwells contain premeasured amounts of specific antimicrobials combined with culture medium.

The organism suspension to be tested must be diluted to a standardized concentration in 0.45% saline before being used to rehydrate the antimicrobial medium within the card. The card is then filled, sealed, and placed into the instrument incubator/reader, either automatically (as with VITEK® 2 60 or VITEK® 2 XL) or manually (as with VITEK® 2 Compact). The instrument monitors the growth of each well in the card over a defined period of time (up to 18 hours for Gram-negatives). At the completion of the incubation cycle, MIC values (or test results, as appropriate) are determined for each antimicrobial contained on the card.

PRECAUTIONS

- For *In Vitro* Diagnostic Use Only.

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- For US Only: Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- For professional use only.
- Suspensions not within the appropriate zone on the VITEK® 2 DensiCHEK™ Plus or VITEK® 2 DensiCHEK™ may compromise card performance.
- Do not use the card after the expiration date shown on the package liner.
- Store the card unopened in the package liner. Do not use the card if the protective package liner is damaged or if no desiccant is present.
- Allow the card to come to room temperature before opening the package liner.
- Do not use powdered gloves. Powder may interfere with the optics.
- Use of culture media other than the recommended types must be validated by the customer laboratory for acceptable performance.
- The card performs as intended only when used in conjunction with VITEK® 2 Systems, following the instructions contained in the Instructions for Use.
- It is highly recommended that Good Laboratory Practices (e.g., FDA, CLSI, ISO, etc.) also be followed, according to local guidelines or requirements.
- **Do not use glass test tubes**. Use clear plastic (polystyrene) tubes only. Variation exists among test tubes of standard diameter. Carefully place the tube into the cassette. If resistance is encountered, discard and try another tube that does not require pressure to insert.
- Prior to inoculation, inspect cards for tape tears or damage to the tape and discard any that are suspect. Check the saline level in the tubes after the cassette has been processed to ensure proper filling of card.
  - VITEK® 2 60 or VITEK® 2 XL: Eject improperly filled cards.
  - VITEK® 2 Compact: Do not load improperly filled cards.
- Give special consideration to specimen source and patient therapy regimen. AST cards may contain some antimicrobials that are not proven to be effective for treatment of infections due to all organisms that may be tested. For interpreting and reporting of antimicrobial results that have been shown to be active against organism groups both *in vitro* and in clinical infections, refer to the individual pharmaceutical antimicrobial labeling or local therapy guidelines.
- Interpretation of test results requires the judgment and skill of a person knowledgeable in AST. Additional testing may be required.[17]

Warning: All patient specimens, microbial cultures, and inoculated VITEK® 2 cards, along with associated materials, are potentially infectious and should be treated with universal precautions [18,20]

REAGENTS

When used with VITEK® 2 instrumentation, the AST card is a complete system for routine susceptibility testing. Each AST card contains selected antimicrobials in varying concentrations, dried with a microbiological culture medium.

Table 1: Contents of the Card

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Amikacin	an01n	8, 16, 64	2	64	**CSAGNB
Amoxicillin/ Clavulanic Acid	amc01n	4/2, 16/8, 32/16	2/1	32/16	**CSAGNB
Ampicillin	am01n	4, 8, 32	2	32	**CSAGNB
Aztreonam	atm01n	2, 8, 32	1	64	**CSAGNB
Cefazolin	cz01n	4, 16, 64	4	64	**CSAGNB
Cefepime	fep02n	2, 8, 16, 32	1	64	**CSAGNB
Cefoxitin	fox01n	8, 16, 32	4	64	**CSAGNB
Ceftriaxone	cro01n	1, 2, 8, 32	1	64	**CSAGNB
Ciprofloxacin	cip01n	0.5, 2, 4	0.25	4	**CSAGNB

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Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Ertapenem	etp01n[c]	0.5, 1, 6	0.5	8	*E. coli*, *K. pneumoniae*, *C. freundii*, *C. koseri*, *E. aerogenes*, *E. cloacae*, **Kox(-ESBL), *M. morganii*, *P. mirabilis*, *P. vulgaris*, *S. marcescens*
Gentamicin	gm01n	4, 16, 32	1	16	**CSAGNB
Imipenem	ipm04n	1, 2, 6, 12	0.25	16	*Acinetobacter* spp., *Citrobacter spp.*, *Enterobacter* spp., *E. coli*, *Klebsiella* spp., *M. morganii*, *P. vulgaris*, *P. rettgeri*, *P. aeruginosa*, *S. marcescens*, *P. stuartii*
Levofloxacin	lev02n❷	0.25, 0.5, 2, 8	0.12	8	*E. cloacae*, *E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *S. marcescens*, *A. baumannii*, *A. lwoffii*, *C. koseri*, *C. freundii*, *E. aerogenes*, *E. sakazakii*, *K. oxytoca*, *M. morganii*, *P. agglomerans*, *P. vulgaris*, *P. rettgeri*, *P. stuartii*, *P. fluorescens*, *C. sakazakii*
Nitrofurantoin	ft01n	16, 32, 64	16	512	**CSAGNB
Piperacillin/ Tazobactam	tzp03n[c]	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *P. rettgeri*, *P. stuartii*, *S. enterica*
Tigecycline	tgc01n[c]	0.75, 2, 4	0.5	8	*C. freundii*, *C. koseri*, *E. coli*, *E. cloacae*, *E. aerogenes*, *K. oxytoca*, *K. pneumoniae*, *S. marcescens*
Tobramycin	tm01n	8, 16, 64	1	16	**CSAGNB
Trimethoprim/ Sulfamethoxazole	sxt02n❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, **Eco(+ETEC), *C. sakazakii*

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Numerical values are expressed in µg/mL.

§ Equivalent standard method concentration by efficacy.

**CSAGNB = Clinically significant aerobic gram-negative bacilli

[c] = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.

**Kox(-ESBL) = *K. oxytoca* (excluding ESBL producing strains)

❶, ❷ etc. = See performance characteristics identified by the drug code with this symbol.

**Eco(+ETEC) = E. coli (including susceptible enterotoxigenic strains implicated in traveler's diarrhea)

INSTRUMENT

The VITEK® 2 instruments are a family of *in vitro* diagnostic devices intended to rapidly assess the antimicrobial susceptibility of bacterial and yeast pathogens to available antimicrobial agents. For detailed information on the use and operation of these devices, refer to the appropriate Instrument User Manual.

SPECIMEN PREPARATION

Table 2: Culture Requirements Table

VITEK® 2 Card	Media	Age of Culture	Incubation Conditions	McFarland Standards	Dilution for AST	Age of Suspension Before Loading Instrument
AST Gram-Negative	TSAB CBA MAC CPS ID	8 to 24 hours	35°C to 37°C aerobic, non-CO_2	0.50 to 0.63	145 µL in 3.0 mL 0.45% saline	VITEK® 2 Compact: ≤ 30 minutes VITEK® 2: ≤ 1 hour
GN and AST GN pair	CBA[1] MAC[1] TSAB CPS ID	18 to 24 hours	35°C to 37°C aerobic, non-CO_2	0.50 to 0.63	145 µL in 3.0 mL 0.45% saline	≤ 30 minutes

[1] These media were used in the identification product database developments and will give optimal performance.

Culture Requirements Table — Media Abbreviations

CBA = Columbia Sheep Blood Agar

MAC = MacConkey Agar

CPS ID = chromID™ CPS (CPS ID Agar)

TSAB = Trypticase Soy Agar with 5% Sheep Blood

TEST PROCEDURE

Warning: Failure to properly follow instructions and recommendations provided in this section for performing laboratory tasks may cause erroneous or delayed results.

Materials

Materials provided are:

- VITEK® 2 DensiCHEK™ KitVITEK® 2 DensiCHEK™ Plus KitVITEK® 2 DensiCHEK® Kit
- VITEK® 2 DensiCHEK™ Standards KitVITEK® 2 DensiCHEK™ Plus Standards KitVITEK® 2 DensiCHEK® Plus Standards Kit
- VITEK® 2 Cassette
- Adjustable volume saline dispenser
- 12 mm x 75 mm clear plastic (polystyrene) disposable test tubes

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- VITEK® 2 60 or VITEK® 2 XL only: VITEK® 2 Pipettor/Diluter Accessory Kit (containing instrument pipette tips and saline hookup) and 0.45% saline bag

Materials required, but not provided are:

- Sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Loops, sterile sticks or swabs
- Appropriate agar medium (See the Culture Requirements Table.)
- QC isolates
- VITEK® 2 AST Cards
- Micropipettors to deliver 145 µL
- Micropipettors to deliver 280 µL
- Disposable pipette tips

Optional Accessories:

- Pre-dispensed saline test tubes (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Test tube caps
- Vortex

Test Card Setup Procedure

The following procedure contains general information applicable to all susceptibility products. (See the Culture Requirements Table for product-specific information.)

Note: Prepare the inoculum from a pure culture, according to good laboratory practices. In case of mixed cultures, a re-isolation step is required. It is recommended that a purity check plate be done to ensure that a pure culture was used for testing.

1. Do one of the following:
   - Select isolated colonies from a primary plate if culture requirements are met.
   - Subculture the organism to be tested to appropriate agar medium and incubate accordingly.
2. Aseptically transfer 3.0 mL of sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0) into a clear plastic (polystyrene) test tube (12 mm x 75 mm).
3. Using sterile technique, prepare a homogenous organism suspension with a density equivalent to the appropriate McFarland standard or McFarland Reference using a compatible benchtop densitometer (see the Culture Requirements Table).
   Note: The age of the suspension before loading the instrument for AST testing must be less than one hour when using VITEK® 2 60 or VITEK® 2 XL, and less than 30 minutes when using VITEK® 2 Compact.
4. Choose one of the following:
   - **For an automatic dilution (VITEK® 2 60 or VITEK® 2 XL only):** Place the suspension tube prepared in step 3 into the cassette with or without an identification card. In the next cassette slot, place an empty tube and an AST card. The instrument will automatically dilute the bacterial suspension to prepare an inoculum suitable for the susceptibility card.
   - **For a manual dilution (VITEK® 2 Compact, VITEK® 2 60 or VITEK® 2 XL):** In a second tube containing 3.0 mL of saline, transfer 145 µL of the suspension prepared in step 3. Then place this tube in the cassette with a susceptibility card. The tube with the initial bacterial suspension can also be used for inoculation of an identification card.

   Note: Check the saline level in the tubes after filling. When it is evident by the saline level in the tube that a card has been improperly filled, do not load the card if using VITEK® 2 Compact; **or**, eject the card if using VITEK® 2 60 or VITEK® 2 XL.

   Note: Refer to the appropriate Instrument User Manual for detailed information regarding data entry, processing, etc.
5. Follow your local inspecting agency's guidelines for disposal of hazardous waste.

QUALITY CONTROL

Quality Control organisms should be processed according to the Test Card Setup Procedure.

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Table 3: Quality Control

CLSI® Quality Control Organisms VITEK® 2 Results					
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™	*K. pneumoniae* ssp. *pneumoniae* ATCC® 700603™
Amikacin	an01n	≤ 2 - 4	≤ 2 - 4	-	-
Amoxicillin/ Clavulanic Acid	amc01n	≤ 2/1 - 8/4	-	4/2 - 16/8	-
Ampicillin	am01n	≤ 2 - 8	-	≥ 32†	-
Aztreonam	atm01n	≤ 1	2 - 8	-	-
Cefazolin	cz01n	≤ 4	-	-	-
Cefepime	fep02n	≤ 1	≤ 1 - 8	-	-
Cefoxitin	fox01n	≤ 4 - 8	-	-	-
Ceftriaxone	cro01n	≤ 1	8 - ≥ 64	-	-
Ciprofloxacin	cip01n	≤ 0.25	≤ 0.25 - 1	-	-
Ertapenem	etp01n	≤ 0.5	2 - ≥ 8	-	-
Gentamicin	gm01n	≤ 1	≤ 1 - 2	-	-
Imipenem	ipm04n	≤ 0.25	1 - 4	-	-
Levofloxacin	lev02n	≤ 0.12	0.5 - 4	-	-
Nitrofurantoin	ft01n	≤ 16	-	-	-
Piperacillin/ Tazobactam	tzp03n	≤ 4/4[1]	≤ 4/4 - 8/4[2]	≤ 4/4[3]	-
Tigecycline	tgc01n	≤ 0.5	-	-	-
Tobramycin	tm01n	≤ 1	≤ 1	-	-
Trimethoprim/ Sulfamethoxazole	sxt02n	≤ 20 (1/19)	160 (8/152) - ≥ 320 (16/304)	-	-

Numerical values are expressed in µg/mL.

† *Escherichia coli* ATCC® 35218™ is not intended for routine QC testing of ampicillin, piperacillin, or ticarcillin. This organism is recommended only for routine QC of ß-lactamase inhibitor combinations. However, since this strain contains a plasmid-encoded ß-lactamase (non-ESBL), it is resistant to many penicillinase-labile antimicrobials, but susceptible to ß-lactamase/ß-lactamase inhibitor combinations. To ensure that the plasmid is present, testing of the ß-lactam alone (e.g., AM, PIP, TIC), in addition to the ß-lactamase/ß-lactamase inhibitor combination (e.g., AMC, SAM, TZP, TCC), can be performed. If the strain has lost its plasmid, it will be susceptible to the ß-lactam alone (i.e., AM, PIP, TIC), indicating that the QC test is invalid, and a new culture of *Escherichia coli* ATCC® 35218™ must be used.

[1]FDA/CLSI Broth Microdilution expected QC range = 1/4 - 4/4 µg/mL

[2]FDA/CLSI Broth Microdilution expected QC range = 1/4 - 8/4 µg/mL

[3]FDA/CLSI Broth Microdilution expected QC range = 0.5/4 - 2/4 µg/mL

Certification Statement

This is to certify that bioMérieux complies with ISO 13485 and FDA Quality System Regulation (QSR) requirements for design, development, and manufacture of antimicrobial susceptibility systems.

Frequency of QC Testing

Refer to *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically,* CLSI® and/or your local guidelines.[2]

Preparation of QC Organisms

1. Rehydrate the organism according to the manufacturer's instructions.

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2. Subculture to Trypticase Soy Agar with 5% sheep blood (TSAB).
3. Incubate at 35°C for 24 hours.
4. Check for purity.
5. Subculture to a TSAB plate.
6. Incubate 16 to 18 hours at 35°C.

Short-Term Storage Conditions

1. Streak to a TSAB plate or slant.
2. Incubate for 24 hours.
3. Refrigerate at 2°C to 8°C for up to two weeks.
4. Subculture once as described above and use for QC.

Long-Term Storage Conditions

1. Make a heavy suspension in Tryptic Soy Broth (TSB) with 15% glycerol.
2. Freeze at -70°C.
3. Subculture to TSAB twice before running QC.
   Note: Avoid repeated thawing and refreezing by either freezing in single-use aliquots or removing a small portion of frozen organism preparation with a sterile applicator stick.

RESULTS

Susceptibility Analytical Techniques

The system evaluates each organism's growth pattern in the presence of the antimicrobial in relation to the growth control well. Several parameters based on the growth characteristics are used to determine the MIC or qualitative result (for example, ESBL POS/NEG). The MIC result must be linked to an organism identification to determine a category interpretation. Accurate identification is critical, especially with certain organism/antimicrobial combinations (e.g., *Staphylococcus aureus*/oxacillin).

In cases where the identification of an organism is in question, confirmatory testing is necessary to ensure correct interpretation of susceptibility results.

A category interpretation will be reported along with a MIC, according to the interpretations defined by the Food and Drug Administration (FDA), CLSI®, Comité de l'Antibiogramme de la Société Française de Microbiologie (CASFM), European Committee for Antimicrobial Susceptibility Testing (EUCAST), or to an adaptation of the global settings according to other local guidelines.

Note: When FDA and CLSI® breakpoints differ, VITEK® 2 Systems AST tests are cleared for use with FDA breakpoints applied.

Combination Antimicrobials

The MICs for the combination antimicrobials are listed on the laboratory and patient reports as the first concentration (e.g., ampicillin/sulbactam ≤ 8/4 µg/mL is reported as ≤ 8 µg/mL.). The actual concentrations for each value in the antimicrobial calling range are as follows:

- amoxicillin/clavulanic acid (amc01n) (µg/mL) 2/1, 4/2, 8/4, 16/8, 32/16
- piperacillin/tazobactam (µg/mL) 4/4, 8/4, 16/4, 32/4, 64/4, 128/4
- trimethoprim/sulfamethoxazole: **Note exception** — This drug is listed on the laboratory and patient reports as the sum of the two antimicrobial concentrations: 20 µg/mL = 1/19, 40 µg/mL = 2/38, 80 µg/mL = 4/76, 160 µg/mL = 8/152, 320 µg/mL = 16/304

Antimicrobial Deduction

Antimicrobials that have been deduced will only report an interpretive result and will be noted with a **+**.

Clinical Efficacy and Indications for Use

AST cards may contain some antimicrobials that are not proven to be effective for treatment of infections caused by all organisms that may be tested. For interpreting and reporting of antimicrobial results that have shown to be active against organism groups both *in vitro* and in clinical infections, refer to the individual pharmaceutical antimicrobial labeling or the local therapy guidelines.

Urinary Use Only Antimicrobials

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Certain antimicrobial agents are limited to use in treating urinary tract infections. Accordingly, these agents should not be reported against pathogens recovered from infection sites other than the urinary tract (except as noted). Please refer to the current *CLSI Performance Standards for Susceptibility Testing, M100* and/or local guidelines for additional information.[3]

For urine only, per CLSI®.[3]

- *Enterobacteriaceae*: lomefloxacin or ofloxacin, norfloxacin, nitrofurantoin, sulfisoxazole, trimethoprim, cefazolin
- *Pseudomonas aeruginosa*: lomefloxacin or ofloxacin, norfloxacin
- Other non-*Enterobacteriaceae*: lomefloxacin or ofloxacin, norfloxacin, sulfisoxazole, tetracycline

LIMITATIONS

A VITEK® 2 AST card cannot be used with a direct clinical specimen or sample or other sources containing mixed flora. Any change or modification in the procedure may affect the results.

A result for an antibiotic/organism combination, which may have a limitation, may be suppressed from reporting. This can be accomplished through the use of bioART rules in the VITEK® 2 Systems software. Refer to the software user manual for instructions.

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

- Amikacin (an01n): *Acinetobacter baumannii*
- Amoxicillin/Clavulanic Acid (amc01n): *Providencia* spp.
- Ampicillin (am01n): *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Aztreonam (atm01n): *Pseudomonas* spp.
- Imipenem (ipm04n): *Serratia marcescens*
- Piperacillin/Tazobactam (tzp03n): *Serratia marcescens*

Perform an alternative method of testing prior to reporting of results when an intermediate or resistant result is obtained with the following antibiotic/organism combination(s):

- Amoxicillin/Clavulanic Acid (amc01n): *Proteus* spp.

Perform an alternative method of testing prior to reporting results when a resistant result is obtained with the following antibiotic/organism combination(s):

- Imipenem (ipm04n): *Aeromonas* spp.
- Piperacillin/Tazobactam (tzp03n): *Pseudomonas aeruginosa*

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:

- Ertapenem (etp01n): *E. coli, K. pneumoniae, C. freundii, C. koseri, E. aerogenes, E. cloacae, K. oxytoca* (excluding ESBL producing strains), *M. morganii, P. mirabilis, P. vulgaris, S. marcescens*
- Tigecycline (tgc01n): *C. freundii, E. cloacae, E. coli, K. oxytoca, K. pneumoniae, C. koseri, E. aerogenes, S. marcescens*

EUCAST Limitations

It is recommended that the existing bioART suppression rules be enabled, or new rules created and enabled, for these limitations if the EUCAST breakpoints are applied.

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

- Amikacin (an01n): *Acinetobacter* spp.
- Amoxicillin/Clavulanic Acid (amc01n): *Providencia* spp.
- Ampicillin (am01n): *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Imipenem (ipm04n): *Serratia marcescens*
- Tigecycline (tgc01n): *Serratia* spp., *Enterobacter* spp., *Morganella* spp., *Proteus* spp., *Providencia* spp., *Cronobacter sakazakii*

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:

- Ertapenem (etp01n): *Enterobacteriaceae*

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EXPECTED VALUES

Expected results for susceptibility tests will vary based on location and institution. VITEK® 2 Systems were tested at several geographically diverse locations to ensure that trends that occurred by location were integrated into the performance characteristics of the system. Organism resistance patterns will differ by institution; therefore, expected values will be directly related to the population of organisms at each site.

PERFORMANCE CHARACTERISTICS

The performance characteristics of the antimicrobial agents included in VITEK® 2 AST cards were established using the manual and autodilution modes (on a VITEK® 2 System) at multiple clinical laboratories. The VITEK® 2 AST card results were compared to results from a CLSI® reference method. Essential agreement (EA) represents VITEK® 2 results which agree exactly or are within a ± twofold dilution (± two doubling dilutions for antifungal) of the reference result.

Category agreement (CA) occurs when the VITEK® 2 and the reference interpretative results agree (Susceptible, Intermediate, and Resistant). There are instances when the category agreement for an antimicrobial falls below the essential agreement. This can occur when a significant number of MICs cluster around a category breakpoint during clinical trial testing, resulting in interpretative errors. For a description of interpretive errors, refer to the footnotes below the table that follows (Performance Characteristics). When the majority of the errors are of the minor type, a high corresponding essential agreement percentage demonstrates that the antimicrobial retains an acceptable overall performance.

There are instances when the performance is based solely on category agreement (CA) because at the time performance was established, less than five discrete twofold dilutions were evaluated. A minimum of five dilutions is necessary to calculate essential agreement (EA) based on ± one twofold dilution. These instances are designated by a "c" footnote in the Contents of the Card table. The following performance tables have values for CA only when EA was not established at the time of FDA clearance.

The reproducibility of the VITEK® 2 system was established by testing a set of on-scale organisms.*

*Data on file at bioMérieux, Inc

Table 4: Performance Characteristics for Gram-Negative Antimicrobial Susceptibility Testing

Antimicrobial	Antimicrobial Code	Antibiotic Version	Bp[1]	Comment[2]	Essential Agreement				Category Agreement				% Reproducibility
					% Error				% Error				
					% EA	VME	ME	mE	% CA	VME	ME	mE	
Amikacin	AN	an01n	CLSI	#, E	98.0	0.0	0.4	0.0	96.5	0.0	0.4	2.9	100
			CA-SFM	I	96.1	4.2	0.6	1.4	–	–	–	–	
Amoxicillin/Clavulanic Acid	AMC	amc01n	CLSI	#, E	96.3	0.8	0.0	2.4	92.1	0.8	0.0	6.5	100
Ampicillin	AM	am01n	CLSI	#, E	93.3	1.3	0.0	0.8	90.9	1.3	0.0	7.8	99.3
			CA-SFM	I	94.9	0.6	2.2	4.3	–	–	–	–	
Aztreonam	ATM	atm01n	CLSI	#, E	98.9	1.6	0.3	0.3	96.6	1.6	0.3	0.3	100
			CA-SFM	I	93.7	0.8	0.2	5.2	–	–	–	–	
Cefazolin	CZ	cz01n	CLSI	#, E	96.8	1.2	3.0	2.8	95.8	1.2	3.0	4.1	97.4
Cefepime	FEP	fep02n	CLSI	#, E	94.2	4.0	1.4	6.3	92.1	–	–	–	98.6
Cefoxitin	FOX	fox01n	CLSI	#, E	97.2	0.9	0.0	1.5	92.2	0.9	0.0	8.7	98.9
			CA-SFM	I	95.1	0.5	0.2	3.4	–	–	–	–	
Ceftriaxone	CRO	cro01n	CLSI	#, E	95.8	1.1	0.5	3.0	90.2	1.1	0.5	9.3	98.5
			CA-SFM	I	93.0	0.4	0.6	4.2	–	–	–	–	
Ciprofloxacin	CIP	cip01n	CLSI	#, E	97.9	0.0	0.0	0.5	96.6	0.0	0.0	3.8	98.9
			CA-SFM	E	97.9	0.0	0.0	0.5	96.6	0.0	0.0	3.8	
Ertapenem	ETP	etp01n	CLSI	#, E	–	–	–	–	98.8	0.0	0.0	1.2	97.8
Gentamicin	GM	gm01n	CLSI	#, E	97.1	1.9	0.0	0.6	96.4	1.9	0.0	2.9	100
			CA-SFM	E	97.1	1.9	0.0	0.6	96.4	1.9	0.0	2.9	

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Antimicrobial	Antimicrobial Code	Antibiotic Version	Bp[1]	Comment[2]	Essential Agreement				Category Agreement				% Reproducibility
					% Error				% Error				
					% EA	VME	ME	mE	% CA	VME	ME	mE	
Imipenem	IPM	ipm04n	CLSI	#, E ❷	95.7	2.4	0.3	0.4	94.8	2.4	0.3	4.4	99.6
Levofloxacin	LEV	lev02n	CLSI	#, E ❷	98.6	0.5	0.2	0.3	95.8	0.5	0.2	3.9	100
			CA-SFM	E ❷	98.6	0.0	0.7	0.1	96.5	0.0	0.7	3.0	
Nitrofurantoin	FT	ft01n	CLSI	#, E	93.6	0.0	0.0	4.3	78.8	0.0	0.0	17.9	100
			CA-SFM	I	94.8	0.2	0.4	4.0	–	–	–	–	
Piperacillin/ Tazobactam*	TZP	tzp03n	CLSI	#, E	N/A	N/A	N/A	N/A	93.2	0.9	2.2	5.0	96.7
Tigecycline	TGC	tgc01n	Global	#, E	94.4	0.0	2.0	0.0	90.1	0.0	2.0	8.5	100
Tobramycin	TM	tm01n	CLSI	#, E	98.0	0.0	0.0	1.2	94.7	0.0	0.0	5.6	100
			CA-SFM	E	98.0	0.0	0.0	1.2	94.7	0.0	0.0	5.6	
Trimethoprim/ Sulfamethoxazole	SXT	sxt02n	CLSI	#, E ❷	–	–	–	–	100	0.0	0.0	N/A	100
			CA-SFM	E ❷	99.5	0.0	0.0	0.0	100	0.0	0.0	0.0	
Trimethoprim/ Sulfamethoxazole	SXT	sxt02n	CLSI[3]	#, E ❷ Applies to V2S SW PC version 5.02 and above	-	-	-	-	100	0.0	0.0	N/A	97.8

[1] Abbreviations — Bp = breakpoint committee; EA = essential agreement; CA = category agreement; VME = Very Major Error (susceptible result with resistant reference result); ME = Major Error (resistant result with susceptible reference result); mE = minor Error (susceptible or resistant result with an intermediate reference result, or an intermediate result with a susceptible or resistant reference result).

[2] Comment — Specific organism groups are designated as P. aeurg. for *Pseudomonas aeruginosa*, others for species other than *Pseudomonas aeruginosa*, and Acineto. for *Acinetobacter*.

[3] FDA breakpoints are used in the CLSI Interpretation Standard (breakpoint committee) in the VITEK® 2 Systems software.

* The overall essential agreement for VITEK® 2 piperacillin/tazobactam was not calculated since the test contains less than five discrete concentrations. However, of the 2453 isolates tested, 348 (14.2%) yielded on-scale VITEK® 2 MIC values (i.e., results of 8, 16, 32, and 64 µg/ml). Those results were evaluated for MIC trends and the following results were obtained when VITEK® 2 was compared to CLSI broth microdilution method; 74.4% (259/348) of the VITEK® MICs were within +/- one doubling dilution; 18.4% (64/348) of the VITEK® MICs were higher by more than one doubling dilution; and 7.2% (25/348) of the VITEK® MICs were lower by more than one doubling dilution.

Key:

= US Food and Drug Administration 510(k) cleared
CLSI® = Clinical and Laboratory Standards Institute
CA-SFM = Comité de l'Antibiogramme de la Société Française de Microbiologie
E = External performance data
I = Internal performance data
– = Not available
❶ ❷ = Symbol identifies the performance characteristics for a specific antimicrobial version.
Ref. = Reference method for clinical performance study.

Table 5: EUCAST Performance Characteristics for Gram-Negative Antimicrobial Susceptibility Testing

Antimicrobial	Antimicrobial Code	Antibiotic Version	Comment[1]	Essential Agreement				Category Agreement			
				% Error				% Error			
				%EA[2]	VME	ME	mE	%CA	VME	ME	mE
Amikacin	AN	an01n	(excludes: *Acinetobacter*)	98.5	0.0	0.0	0.6	96.7	0.0	0.0	3.3

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Antimicrobial	Antimicrobial Code	Antibiotic Version	Comment[1]	Essential Agreement				Category Agreement			
				% Error				% Error			
				%EA[2]	VME	ME	mE	%CA	VME	ME	mE
Amoxicillin/Clavulanic Acid	AMC	amc01n	*Enterobacteriaceae* (excludes: *Providencia*)	90.0	9.4	3.5	0.0	93.1	10.6	4.0	0.0
Ampicillin	AM	am01n	*Enterobacteriaceae* (excludes: *Citrobacter, Enterobacter, Pantoea, Serratia* spp.)	93.2	2.7	0.9	0.0	96.6	4.3	1.8	0.0
Aztreonam	ATM	atm01n	*Enterobacteriaceae, Pseudomonas*	98.1	0.0	0.9	1.0	97.4	0.0	0.9	1.9
Cefepime	FEP	fep02n	*Enterobacteriaceae, Pseudomonas*	97.0	2.0	1.3	0.8	93.9	9.0	2.6	2.4
Ceftriaxone	CRO	cro01n	*Enterobacteriaceae*	98.0	0.0	0.4	1.3	98.0	0.0	0.4	1.6
Ciprofloxacin	CIP	cip01n	N/A	98.1	0.0	0.3	0.2	95.3	0.0	0.3	4.5
Ertapenem	ETP	etp01n	*Enterobacteriaceae*	99.5	0.0	0.0	0.5	98.9	0.0	0.0	1.1
Gentamicin	GM	gm01n	N/A	98.3	0.4	0.0	0.8	96.8	0.0	0.0	3.2
Imipenem	IPM	ipm04n	N/A	95.8	1.0	0.4	0.8	92.2	1.0	0.4	7.3
Levofloxacin	LEV	lev02n	❷	99.4	0.0	1.3	0.2	96.7	0.0	0.7	2.9
Nitrofurantoin	FT	ft01n	*E. coli* only	95.7	3.8	0.6	0.0	96.6	7.7	2.6	0.0
Piperacillin/Tazobactam	TZP	tzp03n	*Enterobacteriaceae, Pseudomonas*	96.2	0.8	0.9	1.0	94.8	1.2	1.5	3.8
Tigecycline	TGC	tgc01n	(excludes: *Serratia, Morganella/Proteus/ Providencia*, and *Enterobacter*)	96.9	0.0	0.4	0.8	94.6	0.0	0.4	5.0
Tobramycin	TM	tm01n	N/A	98.9	0.0	0.5	0.0	94.7	0.0	0.8	4.6
Trimethoprim/ Sulfamethoxazole	SXT	sxt02n	(also includes *S. maltophilia*) ❷	98.4	0.0	0.0	0.4	99.5	0.0	0.0	0.5

[1] Comment — Unless stated otherwise, performance is for *Enterobacteriaceae*, *Pseudomonas*, and *Acinetobacter*.

[2] Abbreviations — Bp = breakpoint committee; EA = essential agreement; CA = category agreement; VME = Very Major Error (susceptible result with resistant reference result); ME = Major Error (resistant result with susceptible reference result); mE = minor Error (susceptible or resistant result with an intermediate reference result, or an intermediate result with a susceptible or resistant reference result).

Key:

= EUCAST = European Committee on Antimicrobial Susceptibility

❶ ❷ = Symbol identifies the performance characteristics for a specific antimicrobial version.

LIST OF CLAIMS

Note: If the organism is not in the VITEK® 2 susceptibility database, results will not be reported.

Note: Organisms listed with an asterisk (*) indicate an AES claimed organism. No asterisk is displayed for a group; however, when an individual species (with an asterisk) is contained within a group, it is expertised.

Gram-Negative Organisms Claimed for AST-GN (keyID)

- *Achromobacter denitrificans*
- *Achromobacter xylosoxidans*
- *Acinetobacter baumannii**
- *Acinetobacter baumannii complex**
- *Acinetobacter calcoaceticus**
- *Acinetobacter haemolyticus*
- *Acinetobacter johnsonii*
- *Acinetobacter junii*
- *Acinetobacter lwoffii*

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- *Acinetobacter pittii**
- *Acinetobacter* spp.
- *Aeromonas caviae*
- *Aeromonas hydrophila*
- *Aeromonas hydrophila/caviae*
- *Aeromonas sobria*
- *Alcaligenes faecalis* ssp. *faecalis*
- *Bordetella avium*
- *Bordetella bronchiseptica*
- *Brevundimonas diminuta*
- *Brevundimonas diminuta/vesicularis*
- *Brevundimonas vesicularis*
- *Burkholderia cepacia**
- *Cedecea davisae**
- *Cedecea lapagei**
- *Cedecea neteri**
- *Chryseobacterium gleum*
- *Chryseobacterium indologenes*
- *Citrobacter amalonaticus**
- *Citrobacter braakii**
- *Citrobacter farmeri**
- *Citrobacter freundii**
- *Citrobacter koseri**
- *Citrobacter youngae**
- *Comamonas testosteroni*
- *Cronobacter muytjensii**
- *Cronobacter sakazakii* group*
- *Cronobacter sakazakii**
- *Delftia acidovorans*
- *Edwardsiella hoshinae**
- *Edwardsiella tarda**
- *Elizabethkingia meningoseptica* (formerly known as *Chryseobacterium meningosepticum*)
- *Enterobacter aerogenes**
- *Enterobacter asburiae**
- *Enterobacter cancerogenus**
- *Enterobacter cloacae**
- *Enterobacter cloacae* complex*
- *Enterobacter cloacae* ssp. *cloacae**
- *Enterobacter cloacae* ssp. *dissolvens* *
- *Escherichia coli**
- *Escherichia coli* ATCC® 25922™
- *Escherichia coli* ATCC® 35218™
- *Escherichia fergusonii*
- *Escherichia hermannii**
- *Escherichia vulneris**
- *Ewingella americana*
- *Hafnia alvei**
- *Hafnia paralvei**
- *Klebsiella oxytoca**
- *Klebsiella pneumoniae**
- *Klebsiella pneumoniae* ssp. *ozaenae**
- *Klebsiella pneumoniae* ssp. *pneumoniae**

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- *Klebsiella pneumoniae* ssp. *pneumoniae* ATCC® 700603 ™
- *Klebsiella pneumoniae* ssp. *rhinoscleromatis**
- *Klebsiella* spp.*
- *Kluyvera ascorbata**
- *Kluyvera cryocrescens**
- *Kluyvera intermedia* (formerly known as *Enterobacter intermedius*)*
- *Leclercia adecarboxylata**
- *Lelliottia amnigena* (formerly known as Enterobacter amnigenus)*
- *Lelliottia amnigena 1* (formerly known as Enterobacter amnigenus 1)*
- *Lelliottia amnigena 2* (formerly known as Enterobacter amnigenus 2)
- *Mannheimia haemolytica*
- *Moraxella* group
- *Moraxella lacunata*
- *Moraxella nonliquefaciens*
- *Moraxella osloensis*
- *Morganella morganii**
- *Morganella morganii* ssp. *morganii**
- *Morganella morganii* ssp. *sibonii**
- *Myroides* ssp.
- *Pantoea agglomerans*
- *Pantoea dispersa*
- *Pasteurella aerogenes*
- *Pasteurella multocida**
- *Pasteurella pneumotropica*
- *Plesiomonas shigelloides*
- *Pluralibacter gergoviae* (formerly known as *Enterobacter gergoviae*)*
- *Proteus hauseri**
- *Proteus mirabilis**
- *Proteus penneri**
- *Proteus vulgaris**
- *Providencia alcalifaciens**
- *Providencia rettgeri**
- *Providencia rustigianii**
- *Providencia stuartii**
- *Pseudomonas aeruginosa**
- *Pseudomonas aeruginosa* ATCC® 27853™
- *Pseudomonas alcaligenes*
- *Pseudomonas fluorescens*
- *Pseudomonas luteola*
- *Pseudomonas mendocina*
- *Pseudomonas oleovorans*
- *Pseudomonas oryzihabitans*
- *Pseudomonas putida*
- *Pseudomonas* spp.
- *Pseudomonas stutzeri*
- *Ralstonia pickettii*
- *Raoultella ornithinolytica**
- *Raoultella planticola**
- *Raoultella terrigena**
- *Salmonella enterica* ssp. *arizonae*
- *Salmonella enterica* ssp. *enterica**
- *Salmonella* group*

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- *Salmonella* ser. Enteritidis*
- *Salmonella* ser. Paratyphi A*
- *Salmonella* ser. Paratyphi B*
- *Salmonella* ser. Paratyphi C*
- *Salmonella* ser. Typhi*
- *Salmonella* ser. Typhimurium*
- *Salmonella* spp.*
- *Serratia ficaria**
- *Serratia fonticola**
- *Serratia grimesii**
- *Serratia liquefaciens**
- *Serratia liquefaciens* group*
- *Serratia marcescens**
- *Serratia odorifera**
- *Serratia plymuthica**
- *Serratia proteamaculans*
- *Serratia rubidaea**
- *Shewanella putrefaciens*
- *Shewanella putrefaciens* group
- *Shigella boydii**
- *Shigella dysenteriae**
- *Shigella flexneri**
- *Shigella* group*
- *Shigella sonnei**
- *Shigella* spp.
- *Sphingobacterium multivorum*
- *Sphingobacterium spiritivorum*
- *Sphingomonas paucimobilis*
- *Stenotrophomonas maltophilia**
- *Vibrio alginolyticus*
- *Vibrio fluvialis*
- *Vibrio harveyi*
- *Vibrio metschnikovii*
- *Vibrio mimicus*
- *Vibrio parahaemolyticus*
- *Vibrio vulnificus*
- *Yersinia aldovae*
- *Yersinia enterocolitica**
- *Yersinia enterocolitica* group*
- *Yersinia frederiksenii**
- *Yersinia intermedia**
- *Yersinia kristensenii**
- *Yersinia pseudotuberculosis**
- *Yersinia ruckeri*

REFERENCES

1. Barry, AL The Antimicrobic Susceptibility Test, Principles and Practices, Lea and Febiger, Philadelphia, PA. 1976.
2. Clinical Laboratory Standards Institute (CLSI®), Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically, M7- A7, Wayne, Pennsylvania, January 2006.
3. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Eighteenth Informational Supplement, M100-S18, Vol. 27, No. 1, January 2008.
4. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-third Informational Supplement, M100-S22, January 2012.

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5. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-fourth Informational Supplement; M100-S24, January 2014.
6. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-fifth Informational Supplement, M100-S25, January 2015.
7. Comité de l'Antibiogramme de la Société Française de Microbiologie. Communiqué 1996. Path Biol, 1996, 44, n° 8, I-VIII.
8. Comité de l'Antibiogramme de la Société Française de Microbiologie, Communiqué 2007.
9. Comite de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM), Recommendations 2012.
10. Comité de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM). Communiqué 2014.
11. Comité de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM). Communiqué 2015.
12. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 2.0, January 2012.
13. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 4.0, January 2014.
14. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 5.0, January 2015.
15. Gerlach, EH Microdilution 1: A Comparative Study, p. 63-76, In: Balows, A. (ed.), Current Techniques for Antibiotic Susceptibility Testing, Charles C. Thomas, Springfield, IL. 1974.
16. MacLowry, JD, and HH Marsh. 1968. Semi-automatic microtechnique for serial dilution antibiotic sensitivity testing in the clinical laboratory. J. Lab. Clin. Med. 1968;72:685-687.
17. Murray, PR, Baron EJ, Pfaller MA, Tenover FC, and Yolken RH, editors. Manual of Clinical Microbiology, 8th ed. American Society for Microbiology, Washington, D.C. 2003.
18. National Committee for Clinical Laboratory Standards, M29-A, Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissue – Approved Guideline (1997).
19. National Committee for Clinical Laboratory Standards, Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Approved Standard — Third Edition, M27-A3, Vol. 22, No. 15, 2008.
20. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health, Office of Health and Safety, Biosafety in Microbiological and Biomedical Laboratories, 1988.

Permission to incorporate portions of M100 (Performance Standards for Antimicrobial Susceptibility Testing: Informational Supplement) in the bioMérieux clinical microbiology instrumentation and System has been granted by CLSI®. The current standard and supplements to it may be obtained from CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

INDEX OF SYMBOLS

Symbol	Meaning
	Catalog number
	In Vitro Diagnostic Medical Device
	Legal Manufacturer
	Temperature limitation
	Use by date
	Batch code
	Consult Instructions for Use
	Date of manufacture
	Contains sufficient for <n> tests

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Symbol	Meaning
EC REP	Authorized representative in the European Community
Rx only	For US Only : Caution : US Federal Law restricts this device to sale by or on the order of a licensed practitioner

Instructions for Use provided in the kit or downloadable from www.biomerieux.com/techlib

BARCODES

User MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.

01 A310G50K---0

02 BAST-GN7701L

03 C---Z010702B

04 D080E1C0K0H9

05 E0L1N0320O1WY

06 F0Y2P1R0523P

LIMITED WARRANTY

bioMérieux warrants the performance of the product for its stated intended use provided that all procedures for usage, storage and handling, shelf life (when applicable), and precautions are strictly followed as detailed in the instructions for use (IFU).

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WASTE DISPOSAL

All hazardous waste must be disposed of by following your local inspecting agency's guidelines.

REVISION HISTORY TABLE

Change type categories	
N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user
Note:	Minor typographical, grammar, and formatting changes are not included in the revision history.

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Release Date	Part Number	Change Type	Change Summary
2018-11	045751-01	Administrative	• Formatting changes do not affect the fit, form, or function of the product
		Technical change	• Combined product package insert content with VITEK® 2 Product Information Manual AST content • Updated Limited Warranty section • Updated with RX only information • Updated with EUCAST limitations

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REF 413205

046017- 01 - 2018-01 EN

VITEK® 2 AST-N240

Rx only IVD

INTENDED USE

The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.

SUMMARY AND EXPLANATION

Susceptibility testing is indicated for any organism that contributes to an infectious process warranting antimicrobial chemotherapy. Susceptibility tests are most often indicated when the causative organism is thought to belong to a species capable of exhibiting resistance to commonly used agents. Isolated colonies of each type of organism that may play a pathogenic role are selected from an agar plate and tested for susceptibility. These tests are then examined and the Minimum Inhibitory Concentration (MIC) is determined. The MIC obtained using a dilution test may tell the physician the concentration of an antimicrobial agent needed at the site of infection to inhibit the infecting organism.

MICs have traditionally been determined using antimicrobial concentrations derived from serial twofold dilutions.[2] The MIC is then determined from the lowest concentration that exhibits inhibition of growth. An interpretive criterion (Susceptible, Intermediate, or Resistant) can then be assigned to MIC results to aid in the direction of therapy.

For some antimicrobials (e.g., high-level gentamicin, high-level streptomycin) a qualitative result is generated.

The standard and reference procedures are based on susceptibility tests requiring 16 to 24 hours of incubation for bacteria. Various manufacturers have now developed automated procedures designed to generate results more rapidly by using shortened incubation times. Laboratories worldwide use either variations of the standard reference procedure or a commercially available product to determine the MICs of infectious organisms.

Extended-Spectrum Beta Lactamases (ESBLs)

ESBLs are enzymes that arise by mutations in genes for common plasmid-mediated beta-lactamases. Strains of *Klebsiella* spp. and *E. coli* that produce ESBLs may be clinically resistant to therapy with penicillins, cephalosporins, or aztreonam despite apparent *in vitro* susceptibility to some of these agents. Some of these strains will show MICs above the normal susceptible population but below the standard breakpoints for certain extended-spectrum cephalosporins or aztreonam. Before reporting a strain as an ESBL producer, a confirmatory method may be performed. The VITEK® 2 ESBL Test is a confirmatory test for those ESBLs inhibited by clavulanic acid, and it utilizes cefepime, cefotaxime, and ceftazidime, with and without clavulanic acid, to determine a positive or negative result.

STORAGE CONDITIONS

Upon receipt, store VITEK® 2 AST cards unopened in their original package liner at 2°C to 8°C.

PRINCIPLE OF THE TEST

The AST card for VITEK® 2 Systems is an automated test methodology based on the MIC technique reported by MacLowry and Marsh and Gerlach.[15,16] The AST card is essentially a miniaturized and abbreviated version of the doubling dilution technique for MICs determined by the microdilution method.[1]

Each AST card contains a control well containing only microbiological culture medium. The remaining microwells contain premeasured amounts of specific antimicrobials combined with culture medium.

The organism suspension to be tested must be diluted to a standardized concentration in 0.45% saline before being used to rehydrate the antimicrobial medium within the card. The card is then filled, sealed, and placed into the instrument incubator/reader, either automatically (as with VITEK® 2 60 or VITEK® 2 XL) or manually (as with VITEK® 2 Compact). The instrument monitors the growth of each well in the card over a defined period of time (up to 18 hours for Gram-negatives). At the completion of the incubation cycle, MIC values (or test results, as appropriate) are determined for each antimicrobial contained on the card.

PRECAUTIONS

- For *In Vitro* Diagnostic Use Only.
- For US Only: Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- For professional use only.

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- Suspensions not within the appropriate zone on the VITEK® 2 DensiCHEK™ Plus or VITEK® 2 DensiCHEK™ may compromise card performance.
- Do not use the card after the expiration date shown on the package liner.
- Store the card unopened in the package liner. Do not use the card if the protective package liner is damaged or if no desiccant is present.
- Allow the card to come to room temperature before opening the package liner.
- Do not use powdered gloves. Powder may interfere with the optics.
- Use of culture media other than the recommended types must be validated by the customer laboratory for acceptable performance.
- The card performs as intended only when used in conjunction with VITEK® 2 Systems, following the instructions contained in the Instructions for Use.
- It is highly recommended that Good Laboratory Practices (e.g., FDA, CLSI, ISO, etc.) also be followed, according to local guidelines or requirements.
- **Do not use glass test tubes**. Use clear plastic (polystyrene) tubes only. Variation exists among test tubes of standard diameter. Carefully place the tube into the cassette. If resistance is encountered, discard and try another tube that does not require pressure to insert.
- Prior to inoculation, inspect cards for tape tears or damage to the tape and discard any that are suspect. Check the saline level in the tubes after the cassette has been processed to ensure proper filling of card.
  - VITEK® 2 60 or VITEK® 2 XL: Eject improperly filled cards.
  - VITEK® 2 Compact: Do not load improperly filled cards.
- Give special consideration to specimen source and patient therapy regimen. AST cards may contain some antimicrobials that are not proven to be effective for treatment of infections due to all organisms that may be tested. For interpreting and reporting of antimicrobial results that have been shown to be active against organism groups both *in vitro* and in clinical infections, refer to the individual pharmaceutical antimicrobial labeling or local therapy guidelines.
- Interpretation of test results requires the judgment and skill of a person knowledgeable in AST. Additional testing may be required.[17]

Warning: All patient specimens, microbial cultures, and inoculated VITEK® 2 cards, along with associated materials, are potentially infectious and should be treated with universal precautions [18,20]

REAGENTS

When used with VITEK® 2 instrumentation, the AST card is a complete system for routine susceptibility testing. Each AST card contains selected antimicrobials in varying concentrations, dried with a microbiological culture medium.

Contents of the Card

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Amikacin	an01n	8, 16, 64	2	64	**CSAGNB
Aztreonam	atm01n	2, 8, 32	1	64	**CSAGNB
Cefepime	fep02n	2, 8, 16, 32	1	64	**CSAGNB
Ceftazidime	caz01n	1, 2, 8, 32	1	64	**CSAGNB
Ciprofloxacin	cip01n	0.5, 2, 4	0.25	4	**CSAGNB
Colistin	cs01n	4, 16, 32	0.5	16	**N/A
Gentamicin	gm01n	4, 16, 32	1	16	**CSAGNB
Imipenem	ipm04n	1, 2, 6, 12	0.25	16	*Acinetobacter* spp., *Citrobacter spp.*, *Enterobacter* spp., *E. coli*, *Klebsiella* spp., *M. morganii*, *P. vulgaris*, *P. rettgeri*, *P. aeruginosa*, *S. marcescens*, *P. stuartii*

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Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Levofloxacin	lev02n❷	0.25, 0.5, 2, 8	0.12	8	*E. cloacae*, *E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *S. marcescens*, *A. baumannii*, *A. lwoffii*, *C. koseri*, *C. freundii*, *E. aerogenes*, *E. sakazakii*, *K. oxytoca*, *M. morganii*, *P. agglomerans*, *P. vulgaris*, *P. rettgeri*, *P. stuartii*, *P. fluorescens*, *C. sakazakii*
Meropenem	mem02n❷	0.5, 2, 6, 12	0.25	16	*E. coli*, *K. pneumoniae*, *P. aeruginosa*, *P. mirabilis*, *Acinetobacter* spp., *C. freundii*, *E. cloacae*, *K. oxytoca*, *M. morganii*, *P. vulgaris*, *S. marcescens*, *A. hydrophila*, *C. diversus*, *H. alvei*, *P. multocida*, *Salmonella* spp., *Shigella* spp.
Piperacillin	pip02n❷	4, 16, 32, 64	4	128	*Acinetobacter* spp., *Enterobacter* spp., *E. coli*, *Klebsiella* spp., *M. morganii*, *P. rettgeri*, *P. mirabilis*, *P. vulgaris*, *P. aeruginosa*, *Serratia* spp., *B. cepacia*, *C. koseri*, *C. freundii*, *P. fluorescens*, *C. sakazakii*
Piperacillin/ Tazobactam	tzp03n[c]	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *P. rettgeri*, *P. stuartii*, *S. enterica*
Rifampicin	ra01n	2, 4, 16	2	32	**N/A
Ticarcillin	tic01n	16, 32, 64	8	128	**CSAGNB
Ticarcillin/ Clavulanic Acid	tcc01n	8/2, 32/2, 64/2	8/2	128/2	**CSAGNB
Tobramycin	tm01n	8, 16, 64	1	16	**CSAGNB

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Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Trimethoprim/ Sulfamethoxazole	sxt02n❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, **Eco(+ETEC), *C. sakazakii*

Numerical values are expressed in µg/mL.

§ Equivalent standard method concentration by efficacy.

**CSAGNB = Clinically significant aerobic gram-negative bacilli

**N/A = No specific FDA Indications for Use available

❶, ❷ etc. = See performance characteristics identified by the drug code with this symbol.

c = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.

**Eco(+ETEC) = E. coli (including susceptible enterotoxigenic strains implicated in traveler's diarrhea)

INSTRUMENT

The VITEK® 2 instruments are a family of *in vitro* diagnostic devices intended to rapidly assess the antimicrobial susceptibility of bacterial and yeast pathogens to available antimicrobial agents. For detailed information on the use and operation of these devices, refer to the appropriate Instrument User Manual.

SPECIMEN PREPARATION

Culture Requirements Table

VITEK® 2 Card	Media	Age of Culture	Incubation Conditions	McFarland Standards	Dilution for AST	Age of Suspension Before Loading Instrument
AST Gram-Negative	TSAB CBA MAC CPS ID	8 to 24 hours	35°C to 37°C aerobic, non-CO_2	0.50 to 0.63	145 µL in 3.0 mL 0.45% saline	VITEK® 2 Compact: ≤ 30 minutes VITEK® 2: ≤ 1 hour
GN and AST GN pair	CBA[1] MAC[1] TSAB CPS ID	18 to 24 hours	35°C to 37°C aerobic, non-CO_2	0.50 to 0.63	145 µL in 3.0 mL 0.45% saline	≤ 30 minutes

[1] These media were used in the identification product database developments and will give optimal performance.

Culture Requirements Table — Media Abbreviations

CBA = Columbia Sheep Blood Agar

MAC = MacConkey Agar

CPS ID = chromID™ CPS (CPS ID Agar)

TSAB = Trypticase Soy Agar with 5% Sheep Blood

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TEST PROCEDURE

Warning: Failure to properly follow instructions and recommendations provided in this section for performing laboratory tasks may cause erroneous or delayed results.

Materials

Materials provided are:

- VITEK® 2 DensiCHEK™ Plus Kit
- DensiCHEK™ Plus Standards Kit
- VITEK® 2 Cassette
- Adjustable volume saline dispenser
- 12 mm x 75 mm clear plastic (polystyrene) disposable test tubes
- VITEK® 2 60 or VITEK® 2 XL only: VITEK® 2 Pipettor/Diluter Accessory Kit (containing instrument pipette tips and saline hookup) and 0.45% saline bag

Materials required, but not provided are:

- Sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Loops, sterile sticks or swabs
- Appropriate agar medium (See the Culture Requirements Table.)
- QC isolates
- VITEK® 2 AST Cards
- Micropipettors to deliver 145 µL

Optional Accessories:

- Pre-dispensed saline test tubes (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Test tube caps
- Vortex

Test Card Setup Procedure

The following procedure contains general information applicable to all susceptibility products. (See the Culture Requirements Table for product-specific information.)

Note: Prepare the inoculum from a pure culture, according to good laboratory practices. In case of mixed cultures, a re-isolation step is required. It is recommended that a purity check plate be done to ensure that a pure culture was used for testing.

1. Do one of the following:
   - Select isolated colonies from a primary plate if culture requirements are met.
   - Subculture the organism to be tested to appropriate agar medium and incubate accordingly.
2. Aseptically transfer 3.0 mL of sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0) into a clear plastic (polystyrene) test tube (12 mm x 75 mm).
3. Use a sterile stick or swab to transfer a sufficient number of morphologically similar colonies to the saline tube prepared in step 2. Prepare a homogenous organism suspension with a density equivalent to the appropriate McFarland standard using the VITEK® 2 DensiCHEK™ Plus (see the Culture Requirements Table). The inoculum density required for the GN, GP, ST, or YST can be diluted automatically for AST cards by the VITEK® 2 instrument (VITEK® 2 60 or VITEK® 2 XL). **Note:** The age of the suspension before loading the instrument for AST testing must be less than one hour when using VITEK® 2 60 or VITEK® 2 XL, and less than 30 minutes when using VITEK® 2 Compact.
4. Choose one of the following:
   - **For an automatic dilution (VITEK® 2 60 or VITEK® 2 XL only):** Place the suspension tube prepared in step 3 into the cassette with or without an identification card. In the next cassette slot, place an empty tube and an AST card. The instrument will automatically dilute the bacterial suspension to prepare an inoculum suitable for the susceptibility card.
   - **For a manual dilution (VITEK® 2 Compact, VITEK® 2 60 or VITEK® 2 XL):** In a second tube containing 3.0 mL of saline, transfer 145 µL of the suspension prepared in step 3. Then place this tube in the cassette with a susceptibility card. The tube with the initial bacterial suspension can also be used for inoculation of an identification card.

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Note: Check the saline level in the tubes after filling. When it is evident by the saline level in the tube that a card has been improperly filled, do not load the card if using VITEK® 2 Compact; **or**, eject the card if using VITEK® 2 60 or VITEK® 2 XL.

Note: Refer to the appropriate Instrument User Manual for detailed information regarding data entry, processing, etc.

5. Follow your local inspecting agency's guidelines for disposal of hazardous waste.

QUALITY CONTROL

Quality Control organisms should be processed according to the Test Card Setup Procedure.

Quality Control

CLSI® Quality Control Organisms VITEK® 2 Results					
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™	*K. pneumoniae* ssp. *pneumoniae* ATCC® 700603™
Amikacin	an01n	≤ 2 - 4	≤ 2 - 4	-	-
Aztreonam	atm01n	≤ 1	2 - 8	-	-
Cefepime	fep02n	≤ 1	≤ 1 - 8	-	-
Ceftazidime	caz01n	≤ 1	≤ 1 - 4	-	-
Ciprofloxacin	cip01n	≤ 0.25	≤ 0.25 - 1	-	-
Colistin	cs01n	≤ 0.5 - 1	≤ 0.5 - 2	-	-
Gentamicin	gm01n	≤ 1	≤ 1 - 2	-	-
Imipenem	ipm04n	≤ 0.25	1 - 4	-	-
Levofloxacin	lev02n	≤ 0.12	0.5 - 4	-	-
Meropenem	mem02n	≤ 0.25	≤ 0.25 - 1	-	-
Piperacillin	pip02n	≤ 4	≤ 4 - 8	≥ 128†	-
Piperacillin/ Tazobactam	tzp03n	≤ 4/4[1]	≤ 4/4 - 8/4[2]	≤ 4/4[3]	-
Rifampicin	ra01n	4 - 16	16 - ≥ 32	-	-
Ticarcillin	tic01n	≤ 8 - 16	≤ 8 - 32	≥ 128†	-
Ticarcillin/ Clavulanic Acid	tcc01n	≤ 8/2 - 16/2	≤ 8/2 - 32/2	≤ 8/2 - 32/2	-
Tobramycin	tm01n	≤ 1	≤ 1	-	-
Trimethoprim/ Sulfamethoxazole	sxt02n	≤ 20 (1/19)	160 (8/152) - ≥ 320 (16/304)	-	-

Numerical values are expressed in µg/mL.

† *Escherichia coli* ATCC® 35218™ is not intended for routine QC testing of ampicillin, piperacillin, or ticarcillin. This organism is recommended only for routine QC of ß-lactamase inhibitor combinations. However, since this strain contains a plasmid-encoded ß-lactamase (non-ESBL), it is resistant to many penicillinase-labile antimicrobials, but susceptible to ß-lactamase/ß-lactamase inhibitor combinations. To ensure that the plasmid is present, testing of the ß-lactam alone (e.g., AM, PIP, TIC), in addition to the ß-lactamase/ß-lactamase inhibitor combination (e.g., AMC, SAM, TZP, TCC), can be performed. If the strain has lost its plasmid, it will be susceptible to the ß-lactam alone (i.e., AM, PIP, TIC), indicating that the QC test is invalid, and a new culture of *Escherichia coli* ATCC® 35218™ must be used.

[1]FDA/CLSI Broth Microdilution expected QC range = 1/4 - 4/4 µg/mL

[2]FDA/CLSI Broth Microdilution expected QC range = 1/4 - 8/4 µg/mL

[3]FDA/CLSI Broth Microdilution expected QC range = 0.5/4 - 2/4 µg/mL

Certification Statement

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This is to certify that bioMérieux complies with ISO 13485 and FDA Quality System Regulation (QSR) requirements for design, development, and manufacture of antimicrobial susceptibility systems.

Frequency of QC Testing

Refer to *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically,* CLSI® and/or your local guidelines.[2]

Preparation of QC Organisms

1. Rehydrate the organism according to the manufacturer's instructions.
2. Subculture to Trypticase Soy Agar with 5% sheep blood (TSAB).
3. Incubate at 35°C for 24 hours.
4. Check for purity.
5. Subculture to a TSAB plate.
6. Incubate 16 to 18 hours at 35°C.

Short-Term Storage Conditions

1. Streak to a TSAB plate or slant.
2. Incubate for 24 hours.
3. Refrigerate at 2°C to 8°C for up to two weeks.
4. Subculture once as described above and use for QC.

Long-Term Storage Conditions

1. Make a heavy suspension in Tryptic Soy Broth (TSB) with 15% glycerol.
2. Freeze at -70°C.
3. Subculture to TSAB twice before running QC.
   Note: Avoid repeated thawing and refreezing by either freezing in single-use aliquots or removing a small portion of frozen organism preparation with a sterile applicator stick.

RESULTS

Susceptibility Analytical Techniques

The system evaluates each organism's growth pattern in the presence of the antimicrobial in relation to the growth control well. Several parameters based on the growth characteristics are used to determine the MIC or qualitative result (for example, ESBL POS/NEG). The MIC result must be linked to an organism identification to determine a category interpretation. Accurate identification is critical, especially with certain organism/antimicrobial combinations (e.g., *Staphylococcus aureus*/oxacillin).

In cases where the identification of an organism is in question, confirmatory testing is necessary to ensure correct interpretation of susceptibility results.

A category interpretation will be reported along with a MIC, according to the interpretations defined by the Food and Drug Administration (FDA), CLSI®, Comité de l'Antibiogramme de la Société Française de Microbiologie (CASFM), European Committee for Antimicrobial Susceptibility Testing (EUCAST), or to an adaptation of the global settings according to other local guidelines.

Note: When FDA and CLSI® breakpoints differ, VITEK® 2 Systems AST tests are cleared for use with FDA breakpoints applied.

Combination Antimicrobials

The MICs for the combination antimicrobials are listed on the laboratory and patient reports as the first concentration (e.g., ampicillin/sulbactam ≤ 8/4 µg/mL is reported as ≤ 8 µg/mL.). The actual concentrations for each value in the antimicrobial calling range are as follows:

- piperacillin/tazobactam (µg/mL) 4/4, 8/4, 16/4, 32/4, 64/4, 128/4
- ticarcillin/clavulanic acid (µg/mL) 8/2, 16/2, 32/2, 64/2, 128/2
- trimethoprim/sulfamethoxazole: **Note exception** — This drug is listed on the laboratory and patient reports as the sum of the two antimicrobial concentrations: 20 µg/mL = 1/19, 40 µg/mL = 2/38, 80 µg/mL = 4/76, 160 µg/mL = 8/152, 320 µg/mL = 16/304

Antimicrobial Deduction

Antimicrobials that have been deduced will only report an interpretive result and will be noted with a **+**.

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Clinical Efficacy and Indications for Use

AST cards may contain some antimicrobials that are not proven to be effective for treatment of infections caused by all organisms that may be tested. For interpreting and reporting of antimicrobial results that have shown to be active against organism groups both *in vitro* and in clinical infections, refer to the individual pharmaceutical antimicrobial labeling or the local therapy guidelines.

Urinary Use Only Antimicrobials

Certain antimicrobial agents are limited to use in treating urinary tract infections. Accordingly, these agents should not be reported against pathogens recovered from infection sites other than the urinary tract (except as noted). Please refer to the current *CLSI Performance Standards for Susceptibility Testing, M100* and/or local guidelines for additional information.[3]

For urine only, per CLSI®:[3]

- *Enterobacteriaceae*: lomefloxacin or ofloxacin, norfloxacin, nitrofurantoin, sulfisoxazole, trimethoprim, cefazolin
- *Pseudomonas aeruginosa*: lomefloxacin or ofloxacin, norfloxacin
- Other non-*Enterobacteriaceae*: lomefloxacin or ofloxacin, norfloxacin, sulfisoxazole, tetracycline

LIMITATIONS

A VITEK® 2 AST card cannot be used with a direct clinical specimen or sample or other sources containing mixed flora. Any change or modification in the procedure may affect the results.

A result for an antibiotic/organism combination, which may have a limitation, may be suppressed from reporting. This can be accomplished through the use of bioART rules in the VITEK® 2 Systems software. Refer to the software user manual for instructions.

Ticarcillin/Clavulanic Acid (tcc01n) has been approved for use only with *Pseudomonas aeruginosa*. An alternative method of testing must be performed prior to reporting of results for all other organisms.

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

- Amikacin (an01n): *Acinetobacter baumannii*
- Aztreonam (atm01n): *Pseudomonas* spp.
- Imipenem (ipm04n): *Serratia marcescens*
- Piperacillin/Tazobactam (tzp03n): *Serratia marcescens*

Perform an alternative method of testing prior to reporting results when a resistant result is obtained with the following antibiotic/organism combination(s):

- Imipenem (ipm04n): *Aeromonas* spp.
- Meropenem (mem02n): *Aeromonas* spp.
- Piperacillin/Tazobactam (tzp03n): *Pseudomonas aeruginosa*

Perform an alternative method of testing prior to reporting of susceptible results for the following antibiotic/organism combination(s):

- Colistin (cs01n): Clinically-significant, aerobic, Gram-negative bacilli

EUCAST Limitations

It is recommended that the existing bioART suppression rules be enabled, or new rules created and enabled, for these limitations if the EUCAST breakpoints are applied.

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

- Amikacin (an01n): *Acinetobacter* spp.
- Imipenem (ipm04n): *Serratia marcescens*
- Ticarcillin (tic01n): *Pseudomonas* spp.
- Ticarcillin/Clavulanic Acid (tcc01n): *Serratia* spp.

Perform an alternative method of testing prior to reporting of susceptible results for the following antibiotic/organism combination(s):

- Colistin (cs01n): Clinically-significant, aerobic, Gram-negative bacilli

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EXPECTED VALUES

Expected results for susceptibility tests will vary based on location and institution. VITEK® 2 Systems were tested at several geographically diverse locations to ensure that trends that occurred by location were integrated into the performance characteristics of the system. Organism resistance patterns will differ by institution; therefore, expected values will be directly related to the population of organisms at each site.

PERFORMANCE CHARACTERISTICS

The performance characteristics of the antimicrobial agents included in VITEK® 2 AST cards were established using the manual and autodilution modes (on a VITEK® 2 System) at multiple clinical laboratories. The VITEK® 2 AST card results were compared to results from a CLSI® reference method. Essential agreement (EA) represents VITEK® 2 results which agree exactly or are within a ± twofold dilution (± two doubling dilutions for antifungal) of the reference result.

Category agreement (CA) occurs when the VITEK® 2 and the reference interpretative results agree (Susceptible, Intermediate, and Resistant). There are instances when the category agreement for an antimicrobial falls below the essential agreement. This can occur when a significant number of MICs cluster around a category breakpoint during clinical trial testing, resulting in interpretative errors. For a description of interpretive errors, refer to the footnotes below the table that follows (Performance Characteristics). When the majority of the errors are of the minor type, a high corresponding essential agreement percentage demonstrates that the antimicrobial retains an acceptable overall performance.

There are instances when the performance is based solely on category agreement (CA) because at the time performance was established, less than five discrete twofold dilutions were evaluated. A minimum of five dilutions is necessary to calculate essential agreement (EA) based on ± one twofold dilution. These instances are designated by a "c" footnote in the Contents of the Card table. The following performance tables have values for CA only when EA was not established at the time of FDA clearance.

The reproducibility of the VITEK® 2 system was established by testing a set of on-scale organisms.*

*Data on file at bioMérieux, Inc

Performance Characteristics for Gram-Negative Antimicrobial Susceptibility Testing

Antimicrobial	Antimicrobial Code	Antibiotic Version	Bp[1]	Comment[2]	Essential Agreement				Category Agreement				% Reproducibility
					% Error				% Error				
					% EA	VME	ME	mE	% CA	VME	ME	mE	
Amikacin	AN	an01n	CLSI	#, E	98.0	0.0	0.4	0.0	96.5	0.0	0.4	2.9	100
			CA-SFM	I	96.1	4.2	0.6	1.4	–	–	–	–	
Aztreonam	ATM	atm01n	CLSI	#, E	98.9	1.6	0.3	0.3	96.6	1.6	0.3	0.3	100
			CA-SFM	I	93.7	0.8	0.2	5.2	–	–	–	–	
Cefepime	FEP	fep02n	CLSI	#, E	94.2	4.0	1.4	6.3	92.1	–	–	–	98.6
Ceftazidime	CAZ	caz01n	CLSI	#, E	97.5	1.1	0.2	1.0	97.3	1.1	0.2	3.5	95.4
			CA-SFM	I	92.3	5.1	0.0	4.1	–	–	–	–	
Ciprofloxacin	CIP	cip01n	CLSI	#, E	97.9	0.0	0.0	0.5	96.6	0.0	0.0	3.8	98.9
			CA-SFM	E	97.9	0.0	0.0	0.5	96.6	0.0	0.0	3.8	
Colistin	CS	cs01n	CA-SFM	I	96.1	3.4	0.7	0.0	97.3	5.4	1.4	N/A	99.2
Gentamicin	GM	gm01n	CLSI	#, E	97.1	1.9	0.0	0.6	96.4	1.9	0.0	2.9	100
			CA-SFM	E	97.1	1.9	0.0	0.6	96.4	1.9	0.0	2.9	
Imipenem	IPM	ipm04n	CLSI	#, E ❷	95.7	2.4	0.3	0.4	94.8	2.4	0.3	4.4	99.6
Levofloxacin	LEV	lev02n	CLSI	#, E ❷	98.6	0.5	0.2	0.3	95.8	0.5	0.2	3.9	100
			CA-SFM	E ❷	98.6	0.0	0.7	0.1	96.5	0.0	0.7	3.0	
Meropenem	MEM	mem02n	CLSI	#, E ❷	97.6	1.4	0.0	0.3	96.8	1.4	0.0	2.8	99.6
			Global	#, E ❷	97.6	0.0	0.0	0.5	97.7	0.0	0.0	2.3	

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Antimicrobial	Antimicrobial Code	Antibiotic Version	Bp[1]	Comment[2]	Essential Agreement				Category Agreement				% Reproducibility
					% Error				% Error				
					% EA	VME	ME	mE	% CA	VME	ME	mE	
Piperacillin	PIP	pip02n	CLSI	#, E ❷	94.6	2.0	0.2	3.7	92.4	2.7	0.2	6.8	99.3
			CA-SFM	E ❷	94.6	2.0	0.3	2.5	91.0	2.0	0.3	8.1	
			Global	#, E ❷	94.9	1.2	0.5	3.8	91.9	1.2	0.5	7.4	
Rifampicin (Rifampin)	RA	ra01n	CA-SFM	E Acineto.	96.6	0.0	0.0	3.4	80.0	0.0	0.0	20.0	100
Piperacillin/ Tazobactam*	TZP	tzp03n	CLSI	#, E	N/A	N/A	N/A	N/A	93.2	0.9	2.2	5.0	96.7
Ticarcillin	TIC	tic01n	CLSI	#, E	97.2	0.0	0.5	1.4	91.7	0.4	2.6	7.5	97.8
			CA-SFM	I	92.6	1.4	0.2	4.5	–	–	–	–	
Ticarcillin/Clavulanic Acid	TCC	tcc01n	CLSI	#, E	98.9	0.0	1.9	0.6	92.7	0.0	1.9	19.6	100
			CA-SFM	I	94.8	2.2	0.3	4.1	–	–	–	–	
Tobramycin	TM	tm01n	CLSI	#, E	98.0	0.0	0.0	1.2	94.7	0.0	0.0	5.6	100
			CA-SFM	E	98.0	0.0	0.0	1.2	94.7	0.0	0.0	5.6	
Trimethoprim/ Sulfamethoxazole	SXT	sxt02n	CLSI	#, E ❷	–	–	–	–	100	0.0	0.0	N/A	100
			CA-SFM	E ❷	99.5	0.0	0.0	0.0	100	0.0	0.0	0.0	
Trimethoprim/ Sulfamethoxazole	SXT	sxt02n	CLSI[3]	#, E ❷ Applies to V2S SW PC version 5.02 and above	-	-	-	-	100	0.0	0.0	N/A	97.8

[1] Abbreviations — Bp = breakpoint committee; EA = essential agreement; CA = category agreement; VME = Very Major Error (susceptible result with resistant reference result); ME = Major Error (resistant result with susceptible reference result); mE = minor Error (susceptible or resistant result with an intermediate reference result, or an intermediate result with a susceptible or resistant reference result).

[2] Comment — Specific organism groups are designated as P. aeurg. for *Pseudomonas aeruginosa*, others for species other than *Pseudomonas aeruginosa*, and Acineto. for *Acinetobacter*.

[3] FDA breakpoints are used in the CLSI Interpretation Standard (breakpoint committee) in the VITEK® 2 Systems software.

* The overall essential agreement for VITEK® 2 piperacillin/tazobactam was not calculated since the test contains less than five discrete concentrations. However, of the 2453 isolates tested, 348 (14.2%) yielded on-scale VITEK® 2 MIC values (i.e., results of 8, 16, 32, and 64 µg/ml). Those results were evaluated for MIC trends and the following results were obtained when VITEK® 2 was compared to CLSI broth microdilution method; 74.4% (259/348) of the VITEK® MICs were within +/- one doubling dilution; 18.4% (64/348) of the VITEK® MICs were higher by more than one doubling dilution; and 7.2% (25/348) of the VITEK® MICs were lower by more than one doubling dilution.

Key:

= US Food and Drug Administration 510(k) cleared
CLSI® = Clinical and Laboratory Standards Institute
CA-SFM = Comité de l'Antibiogramme de la Société Française de Microbiologie
E = External performance data
I = Internal performance data
– = Not available
❶ ❷ = Symbol identifies the performance characteristics for a specific antimicrobial version.
Ref. = Reference method for clinical performance study.

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EUCAST Performance Characteristics for Gram-Negative Antimicrobial Susceptibility Testing

Antimicrobial	Antimicrobial Code	Antibiotic Version	Comment[1]	Essential Agreement				Category Agreement			
				% Error				% Error			
				%EA[2]	VME	ME	mE	%CA	VME	ME	mE
Amikacin	AN	an01n	(excludes: *Acinetobacter*)	98.5	0.0	0.0	0.6	96.7	0.0	0.0	3.3
Aztreonam	ATM	atm01n	*Enterobacteriaceae, Pseudomonas*	98.1	0.0	0.9	1.0	97.4	0.0	0.9	1.9
Cefepime	FEP	fep02n	*Enterobacteriaceae, Pseudomonas*	97.0	2.0	1.3	0.8	93.9	9.0	2.6	2.4
Ceftazidime	CAZ	caz01n	*Enterobacteriaceae, Pseudomonas*	96.7	3.0	0.3	0.8	97.9	3.0	1.0	1.3
Ciprofloxacin	CIP	cip01n	N/A	98.1	0.0	0.3	0.2	95.3	0.0	0.3	4.5
Colistin	CS	cs01n	*Pseudomonas, Acinetobacter, Enterobacteriaceae*	96.3	4.7	0.6	0.0	97.8	5.0	0.7	0.0
Gentamicin	GM	gm01n	N/A	98.3	0.4	0.0	0.8	96.8	0.0	0.0	3.2
Imipenem	IPM	ipm04n	N/A	95.8	1.0	0.4	0.8	92.2	1.0	0.4	7.3
Levofloxacin	LEV	lev02n	❷	99.4	0.0	1.3	0.2	96.7	0.0	0.7	2.9
Meropenem	MEM	mem02n	❷	97.6	0.5	0.0	0.6	95.9	0.5	0.0	3.9
Piperacillin	PIP	pip02n	*Enterobacteriaceae, Pseudomonas* ❷	93.9	2.4	1.6	1.9	88.5	4.3	2.9	8.5
Piperacillin/Tazobactam	TZP	tzp03n	*Enterobacteriaceae, Pseudomonas*	96.2	0.8	0.9	1.0	94.8	1.2	1.5	3.8
Ticarcillin	TIC	tic01n	*Enterobacteriaceae*	96.5	2.0	0.7	1.0	94.9	2.0	0.7	3.5
Ticarcillin/Clavulanic Acid	TCC	tcc01n	*Enterobacteriaceae* (excludes: *Serratia*), *Pseudomonas*	94.7	2.9	0.8	1.7	87.0	6.9	1.9	8.9
Tobramycin	TM	tm01n	N/A	98.9	0.0	0.5	0.0	94.7	0.0	0.8	4.6
Trimethoprim/ Sulfamethoxazole	SXT	sxt02n	(also includes *S. maltophilia*) ❷	98.4	0.0	0.0	0.4	99.5	0.0	0.0	0.5

[1] Comment — Unless stated otherwise, performance is for *Enterobacteriaceae*, *Pseudomonas*, and *Acinetobacter*.

[2] Abbreviations — Bp = breakpoint committee; EA = essential agreement; CA = category agreement; VME = Very Major Error (susceptible result with resistant reference result); ME = Major Error (resistant result with susceptible reference result); mE = minor Error (susceptible or resistant result with an intermediate reference result, or an intermediate result with a susceptible or resistant reference result).

Key:

= EUCAST = European Committee on Antimicrobial Susceptibility

❶ ❷ = Symbol identifies the performance characteristics for a specific antimicrobial version.

LIST OF CLAIMS

Note: If the organism is not in the VITEK® 2 susceptibility database, results will not be reported.

Note: Organisms listed with an asterisk (*) indicate an AES claimed organism. No asterisk is displayed for a group; however, when an individual species (with an asterisk) is contained within a group, it is expertised.

Gram-Negative Organisms Claimed for AST-GN (keyID)

- *Achromobacter denitrificans*
- *Achromobacter xylosoxidans*
- *Acinetobacter baumannii**
- *Acinetobacter baumannii complex**
- *Acinetobacter calcoaceticus**
- *Acinetobacter haemolyticus*
- *Acinetobacter johnsonii*
- *Acinetobacter junii*

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- *Acinetobacter lwoffii*
- *Acinetobacter pittii**
- *Acinetobacter* spp.
- *Aeromonas caviae*
- *Aeromonas hydrophila*
- *Aeromonas hydrophila/caviae*
- *Aeromonas sobria*
- *Alcaligenes faecalis* ssp. *faecalis*
- *Bordetella avium*
- *Bordetella bronchiseptica*
- *Brevundimonas diminuta*
- *Brevundimonas diminuta/vesicularis*
- *Brevundimonas vesicularis*
- *Burkholderia cepacia**
- *Cedecea davisae**
- *Cedecea lapagei**
- *Cedecea neteri**
- *Chryseobacterium gleum*
- *Chryseobacterium indologenes*
- *Citrobacter amalonaticus**
- *Citrobacter braakii**
- *Citrobacter farmeri**
- *Citrobacter freundii**
- *Citrobacter koseri**
- *Citrobacter youngae**
- *Comamonas testosteroni*
- *Cronobacter muytjensii**
- *Cronobacter sakazakii* group*
- *Cronobacter sakazakii**
- *Delftia acidovorans*
- *Edwardsiella hoshinae**
- *Edwardsiella tarda**
- *Elizabethkingia meningoseptica* (formerly known as *Chryseobacterium meningosepticum*)
- *Enterobacter aerogenes**
- *Enterobacter asburiae**
- *Enterobacter cancerogenus**
- *Enterobacter cloacae**
- *Enterobacter cloacae* complex*
- *Enterobacter cloacae* ssp. *cloacae**
- *Enterobacter cloacae* ssp. *dissolvens* *
- *Escherichia coli**
- *Escherichia coli* ATCC® 25922™
- *Escherichia coli* ATCC® 35218™
- *Escherichia fergusonii*
- *Escherichia hermannii**
- *Escherichia vulneris**
- *Ewingella americana*
- *Hafnia alvei**
- *Hafnia paralvei**
- *Klebsiella oxytoca**
- *Klebsiella pneumoniae**
- *Klebsiella pneumoniae* ssp. *ozaenae**

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- *Klebsiella pneumoniae* ssp. *pneumoniae**
- *Klebsiella pneumoniae* ssp. *pneumoniae* ATCC® 700603 ™
- *Klebsiella pneumoniae* ssp. *rhinoscleromatis**
- *Klebsiella* spp.*
- *Kluyvera ascorbata**
- *Kluyvera cryocrescens**
- *Kluyvera intermedia* (formerly known as *Enterobacter intermedius*)*
- *Leclercia adecarboxylata**
- *Lelliottia amnigena* (formerly known as Enterobacter amnigenus)*
- *Lelliottia amnigena 1* (formerly known as Enterobacter amnigenus 1)*
- *Lelliottia amnigena 2* (formerly known as Enterobacter amnigenus 2)
- *Mannheimia haemolytica*
- *Moraxella* group
- *Moraxella lacunata*
- *Moraxella nonliquefaciens*
- *Moraxella osloensis*
- *Morganella morganii**
- *Morganella morganii* ssp. *morganii**
- *Morganella morganii* ssp. *sibonii**
- *Myroides* ssp.
- *Pantoea agglomerans*
- *Pantoea dispersa*
- *Pasteurella aerogenes*
- *Pasteurella multocida**
- *Pasteurella pneumotropica*
- *Plesiomonas shigelloides*
- *Pluralibacter gergoviae* (formerly known as *Enterobacter gergoviae*)*
- *Proteus hauseri**
- *Proteus mirabilis**
- *Proteus penneri**
- *Proteus vulgaris**
- *Providencia alcalifaciens**
- *Providencia rettgeri**
- *Providencia rustigianii**
- *Providencia stuartii**
- *Pseudomonas aeruginosa**
- *Pseudomonas aeruginosa* ATCC® 27853™
- *Pseudomonas alcaligenes*
- *Pseudomonas fluorescens*
- *Pseudomonas luteola*
- *Pseudomonas mendocina*
- *Pseudomonas oleovorans*
- *Pseudomonas oryzihabitans*
- *Pseudomonas putida*
- *Pseudomonas* spp.
- *Pseudomonas stutzeri*
- *Ralstonia pickettii*
- *Raoultella ornithinolytica**
- *Raoultella planticola**
- *Raoultella terrigena**
- *Salmonella enterica* ssp. *arizonae*
- *Salmonella enterica* ssp. *enterica**

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- *Salmonella* group*
- *Salmonella* ser. Enteritidis*
- *Salmonella* ser. Paratyphi A*
- *Salmonella* ser. Paratyphi B*
- *Salmonella* ser. Paratyphi C*
- *Salmonella* ser. Typhi*
- *Salmonella* ser. Typhimurium*
- *Salmonella* spp.*
- *Serratia ficaria**
- *Serratia fonticola**
- *Serratia grimesii**
- *Serratia liquefaciens**
- *Serratia liquefaciens* group*
- *Serratia marcescens**
- *Serratia odorifera**
- *Serratia plymuthica**
- *Serratia proteamaculans*
- *Serratia rubidaea**
- *Shewanella putrefaciens*
- *Shewanella putrefaciens* group
- *Shigella boydii**
- *Shigella dysenteriae**
- *Shigella flexneri**
- *Shigella* group*
- *Shigella sonnei**
- *Shigella* spp.
- *Sphingobacterium multivorum*
- *Sphingobacterium spiritivorum*
- *Sphingomonas paucimobilis*
- *Stenotrophomonas maltophilia**
- *Vibrio alginolyticus*
- *Vibrio fluvialis*
- *Vibrio harveyi*
- *Vibrio metschnikovii*
- *Vibrio mimicus*
- *Vibrio parahaemolyticus*
- *Vibrio vulnificus*
- *Yersinia aldovae*
- *Yersinia enterocolitica**
- *Yersinia enterocolitica* group*
- *Yersinia frederiksenii**
- *Yersinia intermedia**
- *Yersinia kristensenii**
- *Yersinia pseudotuberculosis**
- *Yersinia ruckeri*

REFERENCES

1. Barry, AL The Antimicrobic Susceptibility Test, Principles and Practices, Lea and Febiger, Philadelphia, PA. 1976.

2. Clinical Laboratory Standards Institute (CLSI®), Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically, M7- A7, Wayne, Pennsylvania, January 2006.

3. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Eighteenth Informational Supplement, M100-S18, Vol. 27, No. 1, January 2008.

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4. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-third Informational Supplement, M100-S22, January 2012.
5. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-fourth Informational Supplement; M100-S24, January 2014.
6. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-fifth Informational Supplement, M100-S25, January 2015.
7. Comité de l'Antibiogramme de la Société Française de Microbiologie. Communiqué 1996. Path Biol, 1996, 44, n° 8, I-VIII.
8. Comité de l'Antibiogramme de la Société Française de Microbiologie, Communiqué 2007.
9. Comite de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM), Recommendations 2012.
10. Comité de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM). Communiqué 2014.
11. Comité de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM). Communiqué 2015.
12. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 2.0, January 2012.
13. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 4.0, January 2014.
14. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 5.0, January 2015.
15. Gerlach, EH Microdilution 1: A Comparative Study, p. 63-76, In: Balows, A. (ed.), Current Techniques for Antibiotic Susceptibility Testing, Charles C. Thomas, Springfield, IL. 1974.
16. MacLowry, JD, and HH Marsh. 1968. Semi-automatic microtechnique for serial dilution antibiotic sensitivity testing in the clinical laboratory. J. Lab. Clin. Med. 1968;72:685-687.
17. Murray, PR, Baron EJ, Pfaller MA, Tenover FC, and Yolken RH, editors. Manual of Clinical Microbiology, 8th ed. American Society for Microbiology, Washington, D.C. 2003.
18. National Committee for Clinical Laboratory Standards, M29-A, Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissue – Approved Guideline (1997).
19. National Committee for Clinical Laboratory Standards, Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Approved Standard — Third Edition, M27-A3, Vol. 22, No. 15, 2008.
20. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health, Office of Health and Safety, Biosafety in Microbiological and Biomedical Laboratories, 1988.

Permission to incorporate portions of M100 (Performance Standards for Antimicrobial Susceptibility Testing: Informational Supplement) in the bioMérieux clinical microbiology instrumentation and System has been granted by CLSI®. The current standard and supplements to it may be obtained from CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

INDEX OF SYMBOLS

Symbol	Meaning
	Catalog number
	In Vitro Diagnostic Medical Device
	Legal Manufacturer
	Temperature limitation
	Use by date
	Batch code
	Consult Instructions for Use
	Date of manufacture

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Symbol	Meaning
	Contains sufficient for <n> tests
	Authorized representative in the European Community
	For US Only : Caution : US Federal Law restricts this device to sale by or on the order of a licensed practitioner

Instructions for Use provided in the kit or downloadable from www.biomerieux.com/techlib

BARCODES

User MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.

01 

02 

03 

04 

05 

06 

LIMITED WARRANTY

bioMérieux warrants the performance of the product for its stated intended use provided that all procedures for usage, storage and handling, shelf life (when applicable), and precautions are strictly followed as detailed in the instructions for use (IFU).

Except as expressly set forth above, bioMérieux hereby disclaims all warranties, including any implied warranties of merchantability and fitness for a particular purpose or use, and disclaims all liability, whether direct, indirect or consequential, for any use of the reagent, software, instrument and disposables (the “System”) other than as set forth in the IFU.

WASTE DISPOSAL

All hazardous waste must be disposed of by following your local inspecting agency's guidelines.

REVISION HISTORY TABLE

Change type categories	
N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user
Note:	Minor typographical, grammar, and formatting changes are not included in the revision history.

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Release Date	Part Number	Change Type	Change Summary
2018-01	046017-01	Administrative	• Formatting changes do not affect the fit, form, or function of the product
		Technical change	• Combined product package insert content with VITEK® 2 Product Information Manual AST content • Updated Limited Warranty section • Updated with RX only information • Updated with EUCAST limitations

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BIOMÉRIEUX

REF 413230

046028- 01 - 2018-01 EN

VITEK® 2 AST-XN05

Rx only IVD

INTENDED USE

The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.

SUMMARY AND EXPLANATION

Susceptibility testing is indicated for any organism that contributes to an infectious process warranting antimicrobial chemotherapy. Susceptibility tests are most often indicated when the causative organism is thought to belong to a species capable of exhibiting resistance to commonly used agents. Isolated colonies of each type of organism that may play a pathogenic role are selected from an agar plate and tested for susceptibility. These tests are then examined and the Minimum Inhibitory Concentration (MIC) is determined. The MIC obtained using a dilution test may tell the physician the concentration of an antimicrobial agent needed at the site of infection to inhibit the infecting organism.

MICs have traditionally been determined using antimicrobial concentrations derived from serial twofold dilutions.[2] The MIC is then determined from the lowest concentration that exhibits inhibition of growth. An interpretive criterion (Susceptible, Intermediate, or Resistant) can then be assigned to MIC results to aid in the direction of therapy.

For some antimicrobials (e.g., high-level gentamicin, high-level streptomycin) a qualitative result is generated.

The standard and reference procedures are based on susceptibility tests requiring 16 to 24 hours of incubation for bacteria. Various manufacturers have now developed automated procedures designed to generate results more rapidly by using shortened incubation times. Laboratories worldwide use either variations of the standard reference procedure or a commercially available product to determine the MICs of infectious organisms.

Extended-Spectrum Beta Lactamases (ESBLs)

ESBLs are enzymes that arise by mutations in genes for common plasmid-mediated beta-lactamases. Strains of *Klebsiella* spp. and *E. coli* that produce ESBLs may be clinically resistant to therapy with penicillins, cephalosporins, or aztreonam despite apparent *in vitro* susceptibility to some of these agents. Some of these strains will show MICs above the normal susceptible population but below the standard breakpoints for certain extended-spectrum cephalosporins or aztreonam. Before reporting a strain as an ESBL producer, a confirmatory method may be performed. The VITEK® 2 ESBL Test is a confirmatory test for those ESBLs inhibited by clavulanic acid, and it utilizes cefepime, cefotaxime, and ceftazidime, with and without clavulanic acid, to determine a positive or negative result.

STORAGE CONDITIONS

Upon receipt, store VITEK® 2 AST cards unopened in their original package liner at 2°C to 8°C.

PRINCIPLE OF THE TEST

The AST card for VITEK® 2 Systems is an automated test methodology based on the MIC technique reported by MacLowry and Marsh and Gerlach.[15,16] The AST card is essentially a miniaturized and abbreviated version of the doubling dilution technique for MICs determined by the microdilution method.[1]

Each AST card contains a control well containing only microbiological culture medium. The remaining microwells contain premeasured amounts of specific antimicrobials combined with culture medium.

The organism suspension to be tested must be diluted to a standardized concentration in 0.45% saline before being used to rehydrate the antimicrobial medium within the card. The card is then filled, sealed, and placed into the instrument incubator/reader, either automatically (as with VITEK® 2 60 or VITEK® 2 XL) or manually (as with VITEK® 2 Compact). The instrument monitors the growth of each well in the card over a defined period of time (up to 18 hours for Gram-negatives). At the completion of the incubation cycle, MIC values (or test results, as appropriate) are determined for each antimicrobial contained on the card.

PRECAUTIONS

- For *In Vitro* Diagnostic Use Only.
- For US Only: Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- For professional use only.

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- Suspensions not within the appropriate zone on the VITEK® 2 DensiCHEK™ Plus or VITEK® 2 DensiCHEK™ may compromise card performance.
- Do not use the card after the expiration date shown on the package liner.
- Store the card unopened in the package liner. Do not use the card if the protective package liner is damaged or if no desiccant is present.
- Allow the card to come to room temperature before opening the package liner.
- Do not use powdered gloves. Powder may interfere with the optics.
- Use of culture media other than the recommended types must be validated by the customer laboratory for acceptable performance.
- The card performs as intended only when used in conjunction with VITEK® 2 Systems, following the instructions contained in the Instructions for Use.
- It is highly recommended that Good Laboratory Practices (e.g., FDA, CLSI, ISO, etc.) also be followed, according to local guidelines or requirements.
- **Do not use glass test tubes**. Use clear plastic (polystyrene) tubes only. Variation exists among test tubes of standard diameter. Carefully place the tube into the cassette. If resistance is encountered, discard and try another tube that does not require pressure to insert.
- Prior to inoculation, inspect cards for tape tears or damage to the tape and discard any that are suspect. Check the saline level in the tubes after the cassette has been processed to ensure proper filling of card.
  - VITEK® 2 60 or VITEK® 2 XL: Eject improperly filled cards.
  - VITEK® 2 Compact: Do not load improperly filled cards.
- Give special consideration to specimen source and patient therapy regimen. AST cards may contain some antimicrobials that are not proven to be effective for treatment of infections due to all organisms that may be tested. For interpreting and reporting of antimicrobial results that have been shown to be active against organism groups both *in vitro* and in clinical infections, refer to the individual pharmaceutical antimicrobial labeling or local therapy guidelines.
- Interpretation of test results requires the judgment and skill of a person knowledgeable in AST. Additional testing may be required.[17]

Warning: All patient specimens, microbial cultures, and inoculated VITEK® 2 cards, along with associated materials, are potentially infectious and should be treated with universal precautions [18,20]

REAGENTS

When used with VITEK® 2 instrumentation, the AST card is a complete system for routine susceptibility testing. Each AST card contains selected antimicrobials in varying concentrations, dried with a microbiological culture medium.

Contents of the Card

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Ampicillin/ Sulbactam	sam02n	4, 16, 32	2	32	**N/A
Aztreonam	atm01n	2, 8, 32	1	64	**CSAGNB
Cefepime	fep02n	2, 8, 16, 32	1	64	**CSAGNB
Cefixime	cfm01n	0.25, 1, 2	0.25	4	**N/A
Ceftriaxone	cro01n	1, 2, 8, 32	1	64	**CSAGNB
Cefuroxime	cxm01n	2, 8, 32	1	64	**CSAGNB
Chloramphenicol	c01n	4, 16, 32	2	64	**N/A
Colistin	cs01n	4, 16, 32	0.5	16	**N/A
ESBL	esb01n	FEP 1, CTX 0.5, CAZ 0.5, FEP/CA 1/10, CTX/CA 0.5/4, CAZ/CA 0.5/4	NEG	POS	*E. coli*, *K. pneumoniae*, *K. oxytoca*

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Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Levofloxacin	lev02n❷	0.25, 0.5, 2, 8	0.12	8	*E. cloacae*, *E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *S. marcescens*, *A. baumannii*, *A. lwoffii*, *C. koseri*, *C. freundii*, *E. aerogenes*, *E. sakazakii*, *K. oxytoca*, *M. morganii*, *P. agglomerans*, *P. vulgaris*, *P. rettgeri*, *P. stuartii*, *P. fluorescens*, *C. sakazakii*
Meropenem	mem02n❷	0.5, 2, 6, 12	0.25	16	*E. coli*, *K. pneumoniae*, *P. aeruginosa*, *P. mirabilis*, *Acinetobacter* spp., *C. freundii*, *E. cloacae*, *K. oxytoca*, *M. morganii*, *P. vulgaris*, *S. marcescens*, *A. hydrophila*, *C. diversus*, *H. alvei*, *P. multocida*, *Salmonella* spp., *Shigella* spp.
Minocycline	mno01n	2, 4, 8	1	16	**N/A
Moxifloxacin	mxf01n	0.25, 1, 4	0.25	8	*K. pneumoniae*, *C. freundii*, *E. cloacae*, *E. coli*, *K. oxytoca*, *P. mirabilis*
Piperacillin	pip02n❷	4, 16, 32, 64	4	128	*Acinetobacter* spp., *Enterobacter* spp., *E. coli*, *Klebsiella* spp., *M. morganii*, *P. rettgeri*, *P. mirabilis*, *P. vulgaris*, *P. aeruginosa*, *Serratia* spp., *B. cepacia*, *C. koseri*, *C. freundii*, *P. fluorescens*, *C. sakazakii*
Tetracycline	te01n	2, 4, 8	1	16	**CSAGNB
Ticarcillin/ Clavulanic Acid	tcc01n	8/2, 32/2, 64/2	8/2	128/2	**CSAGNB
Tigecycline	tgc01n[c]	0.75, 2, 4	0.5	8	*C. freundii*, *C. koseri*, *E. coli*, *E. cloacae*, *E. aerogenes*, *K. oxytoca*, *K. pneumoniae*, *S. marcescens*
Trimethoprim	tmp01n	0.5, 2, 8	0.5	16	**N/A

Numerical values are expressed in µg/mL.

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§ Equivalent standard method concentration by efficacy.

**N/A = No specific FDA Indications for Use available

**CSAGNB = Clinically significant aerobic gram-negative bacilli

Note: For ESBL, FEP is Cefepime, CTX is Cefotaxime, CAZ is Ceftazidime and CA is Clavulanic Acid.

NEG = Negative

POS = Positive

A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.

❶, ❷ etc. = See performance characteristics identified by the drug code with this symbol.

c = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.

INSTRUMENT

The VITEK® 2 instruments are a family of *in vitro* diagnostic devices intended to rapidly assess the antimicrobial susceptibility of bacterial and yeast pathogens to available antimicrobial agents. For detailed information on the use and operation of these devices, refer to the appropriate Instrument User Manual.

SPECIMEN PREPARATION

Culture Requirements Table

VITEK® 2 Card	Media	Age of Culture	Incubation Conditions	McFarland Standards	Dilution for AST	Age of Suspension Before Loading Instrument
AST Gram-Negative	TSAB CBA MAC CPS ID	8 to 24 hours	35°C to 37°C aerobic, non-CO_2	0.50 to 0.63	145 µL in 3.0 mL 0.45% saline	VITEK® 2 Compact: ≤ 30 minutes VITEK® 2: ≤ 1 hour
GN and AST GN pair	CBA[1] MAC[1] TSAB CPS ID	18 to 24 hours	35°C to 37°C aerobic, non-CO_2	0.50 to 0.63	145 µL in 3.0 mL 0.45% saline	≤ 30 minutes

[1] These media were used in the identification product database developments and will give optimal performance.

Culture Requirements Table — Media Abbreviations

CBA = Columbia Sheep Blood Agar

MAC = MacConkey Agar

CPS ID = chromID™ CPS (CPS ID Agar)

TSAB = Trypticase Soy Agar with 5% Sheep Blood

TEST PROCEDURE

Warning: Failure to properly follow instructions and recommendations provided in this section for performing laboratory tasks may cause erroneous or delayed results.

Materials

Materials provided are:

- VITEK® 2 DensiCHEK™ Plus Kit
- DensiCHEK™ Plus Standards Kit
- VITEK® 2 Cassette
- Adjustable volume saline dispenser

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- 12 mm x 75 mm clear plastic (polystyrene) disposable test tubes
- VITEK® 2 60 or VITEK® 2 XL only: VITEK® 2 Pipettor/Diluter Accessory Kit (containing instrument pipette tips and saline hookup) and 0.45% saline bag

Materials required, but not provided are:

- Sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Loops, sterile sticks or swabs
- Appropriate agar medium (See the Culture Requirements Table.)
- QC isolates
- VITEK® 2 AST Cards
- Micropipettors to deliver 145 µL

Optional Accessories:

- Pre-dispensed saline test tubes (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Test tube caps
- Vortex

Test Card Setup Procedure

The following procedure contains general information applicable to all susceptibility products. (See the Culture Requirements Table for product-specific information.)

Note: Prepare the inoculum from a pure culture, according to good laboratory practices. In case of mixed cultures, a re-isolation step is required. It is recommended that a purity check plate be done to ensure that a pure culture was used for testing.

1. Do one of the following:
   - Select isolated colonies from a primary plate if culture requirements are met.
   - Subculture the organism to be tested to appropriate agar medium and incubate accordingly.
2. Aseptically transfer 3.0 mL of sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0) into a clear plastic (polystyrene) test tube (12 mm x 75 mm).
3. Use a sterile stick or swab to transfer a sufficient number of morphologically similar colonies to the saline tube prepared in step 2. Prepare a homogenous organism suspension with a density equivalent to the appropriate McFarland standard using the VITEK® 2 DensiCHEK™ Plus (see the Culture Requirements Table). The inoculum density required for the GN, GP, ST, or YST can be diluted automatically for AST cards by the VITEK® 2 instrument (VITEK® 2 60 or VITEK® 2 XL).
   Note: The age of the suspension before loading the instrument for AST testing must be less than one hour when using VITEK® 2 60 or VITEK® 2 XL, and less than 30 minutes when using VITEK® 2 Compact.
4. Choose one of the following:
   - **For an automatic dilution (VITEK® 2 60 or VITEK® 2 XL only):** Place the suspension tube prepared in step 3 into the cassette with or without an identification card. In the next cassette slot, place an empty tube and an AST card. The instrument will automatically dilute the bacterial suspension to prepare an inoculum suitable for the susceptibility card.
   - **For a manual dilution (VITEK® 2 Compact, VITEK® 2 60 or VITEK® 2 XL):** In a second tube containing 3.0 mL of saline, transfer 145 µL of the suspension prepared in step 3. Then place this tube in the cassette with a susceptibility card. The tube with the initial bacterial suspension can also be used for inoculation of an identification card.

   Note: Check the saline level in the tubes after filling. When it is evident by the saline level in the tube that a card has been improperly filled, do not load the card if using VITEK® 2 Compact; **or**, eject the card if using VITEK® 2 60 or VITEK® 2 XL.

   Note: Refer to the appropriate Instrument User Manual for detailed information regarding data entry, processing, etc.
5. Follow your local inspecting agency's guidelines for disposal of hazardous waste.

QUALITY CONTROL

Quality Control organisms should be processed according to the Test Card Setup Procedure.

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Quality Control

CLSI® Quality Control Organisms VITEK® 2 Results					
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™	*K. pneumoniae* ssp. *pneumoniae* ATCC® 700603™
Ampicillin/ Sulbactam	sam02n	≤ 2 - 8	-	8 - ≥ 32	-
Aztreonam	atm01n	≤ 1	2 - 8	-	-
Cefepime	fep02n	≤ 1	≤ 1 - 8	-	-
Cefixime	cfm01n	≤ 0.25 - 1	-	-	-
Ceftriaxone	cro01n	≤ 1	8 - ≥ 64	-	-
Cefuroxime	cxm01n	2 - 8	-	-	-
Chloramphenicol	c01n	≤ 2 - 8	-	-	-
Colistin	cs01n	≤ 0.5 - 1	≤ 0.5 - 2	-	-
ESBL	esb01n	NEG	-	-	POS
Levofloxacin	lev02n	≤ 0.12	0.5 - 4	-	-
Meropenem	mem02n	≤ 0.25	≤ 0.25 - 1	-	-
Minocycline	mno01n	≤ 1	-	-	-
Moxifloxacin	mxf01n	≤ 0.25	1 - 8	-	-
Piperacillin	pip02n	≤ 4	≤ 4 - 8	≥ 128†	-
Tetracycline	te01n	≤ 1 - 2	8 - ≥ 16	-	-
Ticarcillin/ Clavulanic Acid	tcc01n	≤ 8/2 - 16/2	≤ 8/2 - 32/2	≤ 8/2 - 32/2	-
Tigecycline	tgc01n	≤ 0.5	-	-	-
Trimethoprim	tmp01n	≤ 0.5 - 2	≥ 16	-	-

Numerical values are expressed in µg/mL.

Note: For ESBL, FEP is Cefepime, CTX is Cefotaxime, CAZ is Ceftazidime and CA is Clavulanic Acid.

NEG = Negative

POS = Positive

A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.

† *Escherichia coli* ATCC® 35218™ is not intended for routine QC testing of ampicillin, piperacillin, or ticarcillin. This organism is recommended only for routine QC of ß-lactamase inhibitor combinations. However, since this strain contains a plasmid-encoded ß-lactamase (non-ESBL), it is resistant to many penicillinase-labile antimicrobials, but susceptible to ß-lactamase/ß-lactamase inhibitor combinations. To ensure that the plasmid is present, testing of the ß-lactam alone (e.g., AM, PIP, TIC), in addition to the ß-lactamase/ß-lactamase inhibitor combination (e.g., AMC, SAM, TZP, TCC), can be performed. If the strain has lost its plasmid, it will be susceptible to the ß-lactam alone (i.e., AM, PIP, TIC), indicating that the QC test is invalid, and a new culture of *Escherichia coli* ATCC® 35218™ must be used.

Certification Statement

This is to certify that bioMérieux complies with ISO 13485 and FDA Quality System Regulation (QSR) requirements for design, development, and manufacture of antimicrobial susceptibility systems.

Frequency of QC Testing

Refer to *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically,* CLSI® and/or your local guidelines.[2]

Preparation of QC Organisms

1. Rehydrate the organism according to the manufacturer's instructions.

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2. Subculture to Trypticase Soy Agar with 5% sheep blood (TSAB).
3. Incubate at 35°C for 24 hours.
4. Check for purity.
5. Subculture to a TSAB plate.
6. Incubate 16 to 18 hours at 35°C.

Short-Term Storage Conditions

1. Streak to a TSAB plate or slant.
2. Incubate for 24 hours.
3. Refrigerate at 2°C to 8°C for up to two weeks.
4. Subculture once as described above and use for QC.

Long-Term Storage Conditions

1. Make a heavy suspension in Tryptic Soy Broth (TSB) with 15% glycerol.
2. Freeze at -70°C.
3. Subculture to TSAB twice before running QC.
   Note: Avoid repeated thawing and refreezing by either freezing in single-use aliquots or removing a small portion of frozen organism preparation with a sterile applicator stick.

RESULTS

Susceptibility Analytical Techniques

The system evaluates each organism's growth pattern in the presence of the antimicrobial in relation to the growth control well. Several parameters based on the growth characteristics are used to determine the MIC or qualitative result (for example, ESBL POS/NEG). The MIC result must be linked to an organism identification to determine a category interpretation. Accurate identification is critical, especially with certain organism/antimicrobial combinations (e.g., *Staphylococcus aureus*/oxacillin).

In cases where the identification of an organism is in question, confirmatory testing is necessary to ensure correct interpretation of susceptibility results.

A category interpretation will be reported along with a MIC, according to the interpretations defined by the Food and Drug Administration (FDA), CLSI®, Comité de l'Antibiogramme de la Société Française de Microbiologie (CASFM), European Committee for Antimicrobial Susceptibility Testing (EUCAST), or to an adaptation of the global settings according to other local guidelines.

Note: When FDA and CLSI® breakpoints differ, VITEK® 2 Systems AST tests are cleared for use with FDA breakpoints applied.

Combination Antimicrobials

The MICs for the combination antimicrobials are listed on the laboratory and patient reports as the first concentration (e.g., ampicillin/sulbactam ≤ 8/4 µg/mL is reported as ≤ 8 µg/mL.). The actual concentrations for each value in the antimicrobial calling range are as follows:

- ticarcillin/clavulanic acid (µg/mL) 8/2, 16/2, 32/2, 64/2, 128/2

Antimicrobial Deduction

Antimicrobials that have been deduced will only report an interpretive result and will be noted with a **+**.

Clinical Efficacy and Indications for Use

AST cards may contain some antimicrobials that are not proven to be effective for treatment of infections caused by all organisms that may be tested. For interpreting and reporting of antimicrobial results that have shown to be active against organism groups both *in vitro* and in clinical infections, refer to the individual pharmaceutical antimicrobial labeling or the local therapy guidelines.

Urinary Use Only Antimicrobials

Certain antimicrobial agents are limited to use in treating urinary tract infections. Accordingly, these agents should not be reported against pathogens recovered from infection sites other than the urinary tract (except as noted). Please refer to the current *CLSI Performance Standards for Susceptibility Testing, M100* and/or local guidelines for additional information.[3]

For urine only, per CLSI®:[3]

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- *Enterobacteriaceae*: lomefloxacin or ofloxacin, norfloxacin, nitrofurantoin, sulfisoxazole, trimethoprim, cefazolin
- *Pseudomonas aeruginosa*: lomefloxacin or ofloxacin, norfloxacin
- Other non-*Enterobacteriaceae*: lomefloxacin or ofloxacin, norfloxacin, sulfisoxazole, tetracycline

LIMITATIONS

A VITEK® 2 AST card cannot be used with a direct clinical specimen or sample or other sources containing mixed flora. Any change or modification in the procedure may affect the results.

A result for an antibiotic/organism combination, which may have a limitation, may be suppressed from reporting. This can be accomplished through the use of bioART rules in the VITEK® 2 Systems software. Refer to the software user manual for instructions.

Ticarcillin/Clavulanic Acid (tcc01n) has been approved for use only with *Pseudomonas aeruginosa*. An alternative method of testing must be performed prior to reporting of results for all other organisms.

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

- Ampicillin/Sulbactam (sam02n): *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Aztreonam (atm01n): *Pseudomonas* spp.

Perform an alternative method of testing prior to reporting results when a resistant result is obtained with the following antibiotic/organism combination(s):

- Meropenem (mem02n): *Aeromonas* spp.

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:

- Tigecycline (tgc01n): *C. freundii, E. cloacae, E. coli, K. oxytoca, K. pneumoniae, C. koseri, E. aerogenes, S. marcescens*

Perform an alternative method of testing prior to reporting of susceptible results for the following antibiotic/organism combination(s):

- Colistin (cs01n): Clinically-significant, aerobic, Gram-negative bacilli

EUCAST Limitations

It is recommended that the existing bioART suppression rules be enabled, or new rules created and enabled, for these limitations if the EUCAST breakpoints are applied.

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

- Chloramphenicol (c01n): *Serratia* spp.
- Ticarcillin/Clavulanic Acid (tcc01n): *Serratia* spp.
- Tigecycline (tgc01n): *Serratia* spp., *Enterobacter* spp., *Morganella* spp., *Proteus* spp., *Providencia* spp., *Cronobacter sakazakii*

Perform an alternative method of testing prior to reporting of susceptible results for the following antibiotic/organism combination(s):

- Colistin (cs01n): Clinically-significant, aerobic, Gram-negative bacilli

EXPECTED VALUES

Expected results for susceptibility tests will vary based on location and institution. VITEK® 2 Systems were tested at several geographically diverse locations to ensure that trends that occurred by location were integrated into the performance characteristics of the system. Organism resistance patterns will differ by institution; therefore, expected values will be directly related to the population of organisms at each site.

PERFORMANCE CHARACTERISTICS

The performance characteristics of the antimicrobial agents included in VITEK® 2 AST cards were established using the manual and autodilution modes (on a VITEK® 2 System) at multiple clinical laboratories. The VITEK® 2 AST card results were compared to results from a CLSI® reference method. Essential agreement (EA) represents VITEK® 2 results which agree exactly or are within a ± twofold dilution (± two doubling dilutions for antifungal) of the reference result.

Category agreement (CA) occurs when the VITEK® 2 and the reference interpretative results agree (Susceptible, Intermediate, and Resistant). There are instances when the category agreement for an antimicrobial falls below the essential agreement. This can occur when a significant number of MICs cluster around a category breakpoint during clinical trial

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testing, resulting in interpretative errors. For a description of interpretive errors, refer to the footnotes below the table that follows (Performance Characteristics). When the majority of the errors are of the minor type, a high corresponding essential agreement percentage demonstrates that the antimicrobial retains an acceptable overall performance.

There are instances when the performance is based solely on category agreement (CA) because at the time performance was established, less than five discrete twofold dilutions were evaluated. A minimum of five dilutions is necessary to calculate essential agreement (EA) based on ± one twofold dilution. These instances are designated by a "c" footnote in the Contents of the Card table. The following performance tables have values for CA only when EA was not established at the time of FDA clearance.

The reproducibility of the VITEK® 2 system was established by testing a set of on-scale organisms.*

*Data on file at bioMérieux, Inc

Performance Characteristics for Gram-Negative Antimicrobial Susceptibility Testing

Antimicrobial	Antimicrobial Code	Antibiotic Version	Bp[1]	Comment[2]	Essential Agreement				Category Agreement				% Reproducibility
					% Error				% Error				
					% EA	VME	ME	mE	% CA	VME	ME	mE	
Aztreonam	ATM	atm01n	CLSI	#, E	98.9	1.6	0.3	0.3	96.6	1.6	0.3	0.3	100
			CA-SFM	I	93.7	0.8	0.2	5.2	–	–	–	–	
Cefepime	FEP	fep02n	CLSI	#, E	94.2	4.0	1.4	6.3	92.1	–	–	–	98.6
Cefixime	CFM	cfm01n	CLSI	I	96.3	0.3	1.5	1.1	92.3	0.4	1.5	6.8	99.8
			CA-SFM	I	96.3	0.3	1.5	1.1	92.3	0.4	1.5	6.8	
Ceftriaxone	CRO	cro01n	CLSI	#, E	95.8	1.1	0.5	3.0	90.2	1.1	0.5	9.3	98.5
			CA-SFM	I	93.0	0.4	0.6	4.2	–	–	–	–	
Cefuroxime	CXM	cxm01n	CLSI	#, E	95.3	1.5	1.0	1.6	93.9	1.5	1.0	4.8	99.6
Chloramphenicol	C	c01n	CLSI	I	95.3	0.8	0.0	3.0	86.2	0.8	0.0	13.4	96.1
			CA-SFM	I	95.3	0.8	0.0	3.0	86.2	0.8	0.0	13.4	
Colistin	CS	cs01n	CA-SFM	I	96.1	3.4	0.7	0.0	97.3	5.4	1.4	N/A	99.2
Extended-Spectrum Beta-Lactamase (ESBL)	ESBL	esb01n	CLSI	#, E	N/A	N/A	N/A	N/A	97.7	2.7	1.9	N/A	100
Levofloxacin	LEV	lev02n	CLSI	#, E ❷	98.6	0.5	0.2	0.3	95.8	0.5	0.2	3.9	100
			CA-SFM	E ❷	98.6	0.0	0.7	0.1	96.5	0.0	0.7	3.0	
Meropenem	MEM	mem02n	CLSI	#, E ❷	97.6	1.4	0.0	0.3	96.8	1.4	0.0	2.8	99.6
			Global	#, E ❷	97.6	0.0	0.0	0.5	97.7	0.0	0.0	2.3	
Minocycline	MNO	mno01n	CLSI	I	94.7	0.3	1.3	2.3	84.8	0.3	1.3	14.3	98
			CA-SFM	I	94.7	0.3	1.3	2.3	84.8	0.3	1.3	14.3	
Moxifloxacin	MXF	mxf01n	CLSI	#, E	98.7	0.0	0.0	0.0	97.8	2.2	0.0	0.0	100
Piperacillin	PIP	pip02n	CLSI	#, E ❷	94.6	2.0	0.2	3.7	92.4	2.7	0.2	6.8	99.3
			CA-SFM	E ❷	94.6	2.0	0.3	2.5	91.0	2.0	0.3	8.1	
			Global	#, E ❷	94.9	1.2	0.5	3.8	91.9	1.2	0.5	7.4	
Tetracycline	TE	te01n	CLSI	#, E	95.5	1.0	0.0	1.4	93.0	1.0	0.0	6.6	100
Ticarcillin/Clavulanic Acid	TCC	tcc01n	CLSI	#, E	98.9	0.0	1.9	0.6	92.7	0.0	1.9	19.6	100
			CA-SFM	I	94.8	2.2	0.3	4.1	–	–	–	–	
Tigecycline	TGC	tgc01n	Global	#, E	94.4	0.0	2.0	0.0	90.1	0.0	2.0	8.5	100

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Antimicrobial	Antimicrobial Code	Antibiotic Version	Bp[1]	Comment[2]	Essential Agreement				Category Agreement				% Reproducibility
					% Error				% Error				
					% EA	VME	ME	mE	% CA	VME	ME	mE	
Trimethoprim	TMP	tmp01n	CLSI	I	93.7	1.6	1.0	N/A	96.4	3.0	4.0	0.0	100
			CA-SFM	I	93.7	1.0	1.1	1.2	93.4	1.0	1.1	5.7	

[1] Abbreviations — Bp = breakpoint committee; EA = essential agreement; CA = category agreement; VME = Very Major Error (susceptible result with resistant reference result); ME = Major Error (resistant result with susceptible reference result); mE = minor Error (susceptible or resistant result with an intermediate reference result, or an intermediate result with a susceptible or resistant reference result).

[2] Comment — Specific organism groups are designated as P. aeurg. for *Pseudomonas aeruginosa*, others for species other than *Pseudomonas aeruginosa*, and Acineto. for *Acinetobacter*.

Key:

= US Food and Drug Administration 510(k) cleared
CLSI® = Clinical and Laboratory Standards Institute
CA-SFM = Comité de l'Antibiogramme de la Société Française de Microbiologie
E = External performance data
I = Internal performance data
– = Not available
❶ ❷ = Symbol identifies the performance characteristics for a specific antimicrobial version.
Ref. = Reference method for clinical performance study.

EUCAST Performance Characteristics for Gram-Negative Antimicrobial Susceptibility Testing

Antimicrobial	Antimicrobial Code	Antibiotic Version	Comment[1]	Essential Agreement				Category Agreement			
				% Error				% Error			
				%EA[2]	VME	ME	mE	%CA	VME	ME	mE
Aztreonam	ATM	atm01n	*Enterobacteriaceae, Pseudomonas*	98.1	0.0	0.9	1.0	97.4	0.0	0.9	1.9
Cefepime	FEP	fep02n	*Enterobacteriaceae, Pseudomonas*	97.0	2.0	1.3	0.8	93.9	9.0	2.6	2.4
Cefixime	CFM	cfm01n	*Enterobacteriaceae*	95.6	2.5	1.6	0.0	96.4	8.6	2.3	0.0
Ceftriaxone	CRO	cro01n	*Enterobacteriaceae*	98.0	0.0	0.4	1.3	98.0	0.0	0.4	1.6
Cefuroxime	CXM	cxm01n	*Enterobacteriaceae*	94.0	2.8	2.6	0.0	93.7	3.7	7.8	0.0
Chloramphenicol	C	c01n	*Enterobacteriaceae* (excludes: *Serratia*)	97.2	2.3	3.1	0.0	89.1	4.1	14.8	0.0
Colistin	CS	cs01n	*Pseudomonas, Acinetobacter, Enterobacteriaceae*	96.3	4.7	0.6	0.0	97.8	5.0	0.7	0.0
Levofloxacin	LEV	lev02n	❷	99.4	0.0	1.3	0.2	96.7	0.0	0.7	2.9
Meropenem	MEM	mem02n	❷	97.6	0.5	0.0	0.6	95.9	0.5	0.0	3.9
Moxifloxacin	MXF	mxf01n	*Enterobacteriaceae*	98.7	0.0	0.6	0.2	95.4	0.0	0.6	4.1
Piperacillin	PIP	pip02n	*Enterobacteriaceae, Pseudomonas* ❷	93.9	2.4	1.6	1.9	88.5	4.3	2.9	8.5
Ticarcillin/Clavulanic Acid	TCC	tcc01n	*Enterobacteriaceae* (excludes: *Serratia*), *Pseudomonas*	94.7	2.9	0.8	1.7	87.0	6.9	1.9	8.9
Tigecycline	TGC	tgc01n	(excludes: *Serratia, Morganella/Proteus/Providencia*, and *Enterobacter*)	96.9	0.0	0.4	0.8	94.6	0.0	0.4	5.0
Trimethoprim	TMP	tmp01n	*Enterobacteriaceae*	94.2	3.8	0.5	1.3	93.5	3.8	0.5	5.0

[1] Comment — Unless stated otherwise, performance is for *Enterobacteriaceae*, *Pseudomonas*, and *Acinetobacter*.

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[2] Abbreviations — Bp = breakpoint committee; EA = essential agreement; CA = category agreement; VME = Very Major Error (susceptible result with resistant reference result); ME = Major Error (resistant result with susceptible reference result); mE = minor Error (susceptible or resistant result with an intermediate reference result, or an intermediate result with a susceptible or resistant reference result).

Key:

= EUCAST = European Committee on Antimicrobial Susceptibility

❶ ❷ = Symbol identifies the performance characteristics for a specific antimicrobial version.

LIST OF CLAIMS

Note: If the organism is not in the VITEK® 2 susceptibility database, results will not be reported.

Note: Organisms listed with an asterisk (*) indicate an AES claimed organism. No asterisk is displayed for a group; however, when an individual species (with an asterisk) is contained within a group, it is expertised.

Gram-Negative Organisms Claimed for AST-GN (keyID)

- *Achromobacter denitrificans*
- *Achromobacter xylosoxidans*
- *Acinetobacter baumannii**
- *Acinetobacter baumannii complex**
- *Acinetobacter calcoaceticus**
- *Acinetobacter haemolyticus*
- *Acinetobacter johnsonii*
- *Acinetobacter junii*
- *Acinetobacter lwoffii*
- *Acinetobacter pittii**
- *Acinetobacter* spp.
- *Aeromonas caviae*
- *Aeromonas hydrophila*
- *Aeromonas hydrophila/caviae*
- *Aeromonas sobria*
- *Alcaligenes faecalis* ssp. *faecalis*
- *Bordetella avium*
- *Bordetella bronchiseptica*
- *Brevundimonas diminuta*
- *Brevundimonas diminuta/vesicularis*
- *Brevundimonas vesicularis*
- *Burkholderia cepacia**
- *Cedecea davisae**
- *Cedecea lapagei**
- *Cedecea neteri**
- *Chryseobacterium gleum*
- *Chryseobacterium indologenes*
- *Citrobacter amalonaticus**
- *Citrobacter braakii**
- *Citrobacter farmeri**
- *Citrobacter freundii**
- *Citrobacter koseri**
- *Citrobacter youngae**
- *Comamonas testosteroni*
- *Cronobacter muytjensii**
- *Cronobacter sakazakii* group*
- *Cronobacter sakazakii**
- *Delftia acidovorans*
- *Edwardsiella hoshinae**

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- *Edwardsiella tarda**
- *Elizabethkingia meningoseptica* (formerly known as *Chryseobacterium meningosepticum*)
- *Enterobacter aerogenes**
- *Enterobacter asburiae**
- *Enterobacter cancerogenus**
- *Enterobacter cloacae**
- *Enterobacter cloacae* complex*
- *Enterobacter cloacae* ssp. *cloacae**
- *Enterobacter cloacae* ssp. *dissolvens* *
- *Escherichia coli**
- *Escherichia coli* ATCC® 25922™
- *Escherichia coli* ATCC® 35218™
- *Escherichia fergusonii*
- *Escherichia hermannii**
- *Escherichia vulneris**
- *Ewingella americana*
- *Hafnia alvei**
- *Hafnia paralvei**
- *Klebsiella oxytoca**
- *Klebsiella pneumoniae**
- *Klebsiella pneumoniae* ssp. *ozaenae**
- *Klebsiella pneumoniae* ssp. *pneumoniae**
- *Klebsiella pneumoniae* ssp. *pneumoniae* ATCC® 700603 ™
- *Klebsiella pneumoniae* ssp. *rhinoscleromatis**
- *Klebsiella* spp.*
- *Kluyvera ascorbata**
- *Kluyvera cryocrescens**
- *Kluyvera intermedia* (formerly known as *Enterobacter intermedius*)*
- *Leclercia adecarboxylata**
- *Lelliottia amnigena* (formerly known as Enterobacter amnigenus)*
- *Lelliottia amnigena 1* (formerly known as Enterobacter amnigenus 1)*
- *Lelliottia amnigena 2* (formerly known as Enterobacter amnigenus 2)
- *Mannheimia haemolytica*
- *Moraxella* group
- *Moraxella lacunata*
- *Moraxella nonliquefaciens*
- *Moraxella osloensis*
- *Morganella morganii**
- *Morganella morganii* ssp. *morganii**
- *Morganella morganii* ssp. *sibonii**
- *Myroides* ssp.
- *Pantoea agglomerans*
- *Pantoea dispersa*
- *Pasteurella aerogenes*
- *Pasteurella multocida**
- *Pasteurella pneumotropica*
- *Plesiomonas shigelloides*
- *Pluralibacter gergoviae* (formerly known as *Enterobacter gergoviae*)*
- *Proteus hauseri**
- *Proteus mirabilis**
- *Proteus penneri**
- *Proteus vulgaris**

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- *Providencia alcalifaciens**
- *Providencia rettgeri**
- *Providencia rustigianii**
- *Providencia stuartii**
- *Pseudomonas aeruginosa**
- *Pseudomonas aeruginosa* ATCC® 27853™
- *Pseudomonas alcaligenes*
- *Pseudomonas fluorescens*
- *Pseudomonas luteola*
- *Pseudomonas mendocina*
- *Pseudomonas oleovorans*
- *Pseudomonas oryzihabitans*
- *Pseudomonas putida*
- *Pseudomonas* spp.
- *Pseudomonas stutzeri*
- *Ralstonia pickettii*
- *Raoultella ornithinolytica**
- *Raoultella planticola**
- *Raoultella terrigena**
- *Salmonella enterica* ssp. *arizonae*
- *Salmonella enterica* ssp. *enterica**
- *Salmonella* group*
- *Salmonella* ser. Enteritidis*
- *Salmonella* ser. Paratyphi A*
- *Salmonella* ser. Paratyphi B*
- *Salmonella* ser. Paratyphi C*
- *Salmonella* ser. Typhi*
- *Salmonella* ser. Typhimurium*
- *Salmonella* spp.*
- *Serratia ficaria**
- *Serratia fonticola**
- *Serratia grimesii**
- *Serratia liquefaciens**
- *Serratia liquefaciens* group*
- *Serratia marcescens**
- *Serratia odorifera**
- *Serratia plymuthica**
- *Serratia proteamaculans*
- *Serratia rubidaea**
- *Shewanella putrefaciens*
- *Shewanella putrefaciens* group
- *Shigella boydii**
- *Shigella dysenteriae**
- *Shigella flexneri**
- *Shigella* group*
- *Shigella sonnei**
- *Shigella* spp.
- *Sphingobacterium multivorum*
- *Sphingobacterium spiritivorum*
- *Sphingomonas paucimobilis*
- *Stenotrophomonas maltophilia**
- *Vibrio alginolyticus*

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- *Vibrio fluvialis*
- *Vibrio harveyi*
- *Vibrio metschnikovii*
- *Vibrio mimicus*
- *Vibrio parahaemolyticus*
- *Vibrio vulnificus*
- *Yersinia aldovae*
- *Yersinia enterocolitica**
- *Yersinia enterocolitica* group*
- *Yersinia frederiksenii**
- *Yersinia intermedia**
- *Yersinia kristensenii**
- *Yersinia pseudotuberculosis**
- *Yersinia ruckeri*

REFERENCES

1. Barry, AL The Antimicrobic Susceptibility Test, Principles and Practices, Lea and Febiger, Philadelphia, PA. 1976.
2. Clinical Laboratory Standards Institute (CLSI®), Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically, M7- A7, Wayne, Pennsylvania, January 2006.
3. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Eighteenth Informational Supplement, M100-S18, Vol. 27, No. 1, January 2008.
4. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-third Informational Supplement, M100-S22, January 2012.
5. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-fourth Informational Supplement; M100-S24, January 2014.
6. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-fifth Informational Supplement, M100-S25, January 2015.
7. Comité de l'Antibiogramme de la Société Française de Microbiologie. Communiqué 1996. Path Biol, 1996, 44, n° 8, I-VIII.
8. Comité de l'Antibiogramme de la Société Française de Microbiologie, Communiqué 2007.
9. Comite de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM), Recommendations 2012.
10. Comité de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM). Communiqué 2014.
11. Comité de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM). Communiqué 2015.
12. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 2.0, January 2012.
13. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 4.0, January 2014.
14. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 5.0, January 2015.
15. Gerlach, EH Microdilution 1: A Comparative Study, p. 63-76, In: Balows, A. (ed.), Current Techniques for Antibiotic Susceptibility Testing, Charles C. Thomas, Springfield, IL. 1974.
16. MacLowry, JD, and HH Marsh. 1968. Semi-automatic microtechnique for serial dilution antibiotic sensitivity testing in the clinical laboratory. J. Lab. Clin. Med. 1968;72:685-687.
17. Murray, PR, Baron EJ, Pfaller MA, Tenover FC, and Yolken RH, editors. Manual of Clinical Microbiology, 8th ed. American Society for Microbiology, Washington, D.C. 2003.
18. National Committee for Clinical Laboratory Standards, M29-A, Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissue – Approved Guideline (1997).
19. National Committee for Clinical Laboratory Standards, Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Approved Standard — Third Edition, M27-A3, Vol. 22, No. 15, 2008.
20. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health, Office of Health and Safety, Biosafety in Microbiological and Biomedical Laboratories, 1988.

Permission to incorporate portions of M100 (Performance Standards for Antimicrobial Susceptibility Testing: Informational Supplement) in the bioMérieux clinical microbiology instrumentation and System has been granted by CLSI®. The current standard and supplements to it may be obtained from CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

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INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalog number
IVD	In Vitro Diagnostic Medical Device
	Legal Manufacturer
	Temperature limitation
	Use by date
LOT	Batch code
	Consult Instructions for Use
	Date of manufacture
	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community
Rx only	For US Only : Caution : US Federal Law restricts this device to sale by or on the order of a licensed practitioner

Instructions for Use provided in the kit or downloadable from www.biomerieux.com/techlib

BARCODES

User MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.

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LIMITED WARRANTY

bioMérieux warrants the performance of the product for its stated intended use provided that all procedures for usage, storage and handling, shelf life (when applicable), and precautions are strictly followed as detailed in the instructions for use (IFU).

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WASTE DISPOSAL

All hazardous waste must be disposed of by following your local inspecting agency's guidelines.

REVISION HISTORY TABLE

Change type categories	
N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user
Note:	Minor typographical, grammar, and formatting changes are not included in the revision history.

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Release Date	Part Number	Change Type	Change Summary
2018-01	046028-01	Administrative	• Formatting changes do not affect the fit, form, or function of the product
		Technical change	• Combined product package insert content with VITEK® 2 Product Information Manual AST content • Updated Limited Warranty section • Updated with RX only information • Updated with EUCAST limitations

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VITEK® 2 AST-N232

℞only IVD

INTENDED USE

The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.

SUMMARY AND EXPLANATION

Susceptibility testing is indicated for any organism that contributes to an infectious process warranting antimicrobial chemotherapy. Susceptibility tests are most often indicated when the causative organism is thought to belong to a species capable of exhibiting resistance to commonly used agents. Isolated colonies of each type of organism that may play a pathogenic role are selected from an agar plate and tested for susceptibility. These tests are then examined and the Minimum Inhibitory Concentration (MIC) is determined. The MIC obtained using a dilution test may tell the physician the concentration of an antimicrobial agent needed at the site of infection to inhibit the infecting organism.

MICs have traditionally been determined using antimicrobial concentrations derived from serial twofold dilutions.[2] The MIC is then determined from the lowest concentration that exhibits inhibition of growth. An interpretive criterion (Susceptible, Intermediate, or Resistant) can then be assigned to MIC results to aid in the direction of therapy.

For some antimicrobials (e.g., high-level gentamicin, high-level streptomycin) a qualitative result is generated.

The standard and reference procedures are based on susceptibility tests requiring 16 to 24 hours of incubation for bacteria. Various manufacturers have now developed automated procedures designed to generate results more rapidly by using shortened incubation times. Laboratories worldwide use either variations of the standard reference procedure or a commercially available product to determine the MICs of infectious organisms.

Extended-Spectrum Beta Lactamases (ESBLs)

ESBLs are enzymes that arise by mutations in genes for common plasmid-mediated beta-lactamases. Strains of *Klebsiella* spp. and *E. coli* that produce ESBLs may be clinically resistant to therapy with penicillins, cephalosporins, or aztreonam despite apparent *in vitro* susceptibility to some of these agents. Some of these strains will show MICs above the normal susceptible population but below the standard breakpoints for certain extended-spectrum cephalosporins or aztreonam. Before reporting a strain as an ESBL producer, a confirmatory method may be performed. The VITEK® 2 ESBL Test is a confirmatory test for those ESBLs inhibited by clavulanic acid, and it utilizes cefepime, cefotaxime, and ceftazidime, with and without clavulanic acid, to determine a positive or negative result.

STORAGE CONDITIONS

Upon receipt, store VITEK® 2 AST cards unopened in their original package liner at 2°C to 8°C.

PRINCIPLE OF THE TEST

The AST card for VITEK® 2 Systems is an automated test methodology based on the MIC technique reported by MacLowry and Marsh and Gerlach.[15,16] The AST card is essentially a miniaturized and abbreviated version of the doubling dilution technique for MICs determined by the microdilution method.[1]

Each AST card contains a control well containing only microbiological culture medium. The remaining microwells contain premeasured amounts of specific antimicrobials combined with culture medium.

The organism suspension to be tested must be diluted to a standardized concentration in 0.45% saline before being used to rehydrate the antimicrobial medium within the card. The card is then filled, sealed, and placed into the instrument incubator/reader, either automatically (as with VITEK® 2 60 or VITEK® 2 XL) or manually (as with VITEK® 2 Compact). The instrument monitors the growth of each well in the card over a defined period of time (up to 18 hours for Gram-negatives). At the completion of the incubation cycle, MIC values (or test results, as appropriate) are determined for each antimicrobial contained on the card.

PRECAUTIONS

- For *In Vitro* Diagnostic Use Only.

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- For US Only: Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- For professional use only.
- Suspensions not within the appropriate zone on the VITEK® 2 DensiCHEK™ Plus or VITEK® 2 DensiCHEK™ may compromise card performance.
- Do not use the card after the expiration date shown on the package liner.
- Store the card unopened in the package liner. Do not use the card if the protective package liner is damaged or if no desiccant is present.
- Allow the card to come to room temperature before opening the package liner.
- Do not use powdered gloves. Powder may interfere with the optics.
- Use of culture media other than the recommended types must be validated by the customer laboratory for acceptable performance.
- The card performs as intended only when used in conjunction with VITEK® 2 Systems, following the instructions contained in the Instructions for Use.
- It is highly recommended that Good Laboratory Practices (e.g., FDA, CLSI, ISO, etc.) also be followed, according to local guidelines or requirements.
- **Do not use glass test tubes**. Use clear plastic (polystyrene) tubes only. Variation exists among test tubes of standard diameter. Carefully place the tube into the cassette. If resistance is encountered, discard and try another tube that does not require pressure to insert.
- Prior to inoculation, inspect cards for tape tears or damage to the tape and discard any that are suspect. Check the saline level in the tubes after the cassette has been processed to ensure proper filling of card.
  - VITEK® 2 60 or VITEK® 2 XL: Eject improperly filled cards.
  - VITEK® 2 Compact: Do not load improperly filled cards.
- Give special consideration to specimen source and patient therapy regimen. AST cards may contain some antimicrobials that are not proven to be effective for treatment of infections due to all organisms that may be tested. For interpreting and reporting of antimicrobial results that have been shown to be active against organism groups both *in vitro* and in clinical infections, refer to the individual pharmaceutical antimicrobial labeling or local therapy guidelines.
- Interpretation of test results requires the judgment and skill of a person knowledgeable in AST. Additional testing may be required.[17]

Warning: All patient specimens, microbial cultures, and inoculated VITEK® 2 cards, along with associated materials, are potentially infectious and should be treated with universal precautions [18,20]

REAGENTS

When used with VITEK® 2 instrumentation, the AST card is a complete system for routine susceptibility testing. Each AST card contains selected antimicrobials in varying concentrations, dried with a microbiological culture medium.

Table 1: Contents of the Card

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Ampicillin	am01n	4, 8, 32	2	32	**CSAGNB
Ampicillin/ Sulbactam	sam02n	4, 16, 32	2	32	**N/A
Cefepime	fep02n	2, 8, 16, 32	1	64	**CSAGNB
Cefotaxime	ctx01n	1, 4, 16, 32	1	64	**CSAGNB
Cefpodoxime	cpd01n	0.5, 1, 4	0.25	8	**CSAGNB
Ceftazidime	caz01n	1, 2, 8, 32	1	64	**CSAGNB
Cefuroxime	cxm01n	2, 8, 32	1	64	**CSAGNB
Ciprofloxacin	cip01n	0.5, 2, 4	0.25	4	**CSAGNB
Gentamicin	gm01n	4, 16, 32	1	16	**CSAGNB

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Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Imipenem	ipm04n	1, 2, 6, 12	0.25	16	*Acinetobacter* spp., *Citrobacter spp.*, *Enterobacter* spp., *E. coli*, *Klebsiella* spp., *M. morganii*, *P. vulgaris*, *P. rettgeri*, *P. aeruginosa*, *S. marcescens*, *P. stuartii*
Levofloxacin	lev02n❷	0.25, 0.5, 2, 8	0.12	8	*E. cloacae*, *E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *S. marcescens*, *A. baumannii*, *A. lwoffii*, *C. koseri*, *C. freundii*, *E. aerogenes*, *E. sakazakii*, *K. oxytoca*, *M. morganii*, *P. agglomerans*, *P. vulgaris*, *P. rettgeri*, *P. stuartii*, *P. fluorescens*, *C. sakazakii*
Meropenem	mem02n❷	0.5, 2, 6, 12	0.25	16	*E. coli*, *K. pneumoniae*, *P. aeruginosa*, *P. mirabilis*, *Acinetobacter* spp., *C. freundii*, *E. cloacae*, *K. oxytoca*, *M. morganii*, *P. vulgaris*, *S. marcescens*, *A. hydrophila*, *C. diversus*, *H. alvei*, *P. multocida*, *Salmonella* spp., *Shigella* spp.
Piperacillin	pip02n❷	4, 16, 32, 64	4	128	*Acinetobacter* spp., *Enterobacter* spp., *E. coli*, *Klebsiella* spp., *M. morganii*, *P. rettgeri*, *P. mirabilis*, *P. vulgaris*, *P. aeruginosa*, *Serratia* spp., *B. cepacia*, *C. koseri*, *C. freundii*, *P. fluorescens*, *C. sakazakii*
Piperacillin/ Tazobactam	tzp03n[c]	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *P. rettgeri*, *P. stuartii*, *S. enterica*

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Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Tigecycline	tgc01n[c]	0.75, 2, 4	0.5	8	*C. freundii*, *C. koseri*, *E. coli*, *E. cloacae*, *E. aerogenes*, *K. oxytoca*, *K. pneumoniae*, *S. marcescens*
Tobramycin	tm01n	8, 16, 64	1	16	**CSAGNB
Trimethoprim/ Sulfamethoxazole	sxt02n❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, **Eco(+ETEC), *C. sakazakii*

Numerical values are expressed in µg/mL.

§ Equivalent standard method concentration by efficacy.

**CSAGNB = Clinically significant aerobic gram-negative bacilli

**N/A = No specific FDA Indications for Use available

❶, ❷ etc. = See performance characteristics identified by the drug code with this symbol.

[c] = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.

**Eco(+ETEC) = E. coli (including susceptible enterotoxigenic strains implicated in traveler's diarrhea)

INSTRUMENT

The VITEK® 2 instruments are a family of *in vitro* diagnostic devices intended to rapidly assess the antimicrobial susceptibility of bacterial and yeast pathogens to available antimicrobial agents. For detailed information on the use and operation of these devices, refer to the appropriate Instrument User Manual.

SPECIMEN PREPARATION

Table 2: Culture Requirements Table

VITEK® 2 Card	Media	Age of Culture	Incubation Conditions	McFarland Standards	Dilution for AST	Age of Suspension Before Loading Instrument
AST Gram-Negative	TSAB CBA MAC CPS ID	8 to 24 hours	35°C to 37°C aerobic, non-CO_2	0.50 to 0.63	145 µL in 3.0 mL 0.45% saline	VITEK® 2 Compact: ≤ 30 minutes VITEK® 2: ≤ 1 hour
GN and AST GN pair	CBA[1] MAC[1] TSAB CPS ID	18 to 24 hours	35°C to 37°C aerobic, non-CO_2	0.50 to 0.63	145 µL in 3.0 mL 0.45% saline	≤ 30 minutes

[1] These media were used in the identification product database developments and will give optimal performance.

Culture Requirements Table — Media Abbreviations

CBA = Columbia Sheep Blood Agar

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MAC = MacConkey Agar

CPS ID = chromID™ CPS (CPS ID Agar)

TSAB = Trypticase Soy Agar with 5% Sheep Blood

TEST PROCEDURE

Warning: Failure to properly follow instructions and recommendations provided in this section for performing laboratory tasks may cause erroneous or delayed results.

Materials

Materials provided are:

- VITEK® 2 DensiCHEK™ KitVITEK® 2 DensiCHEK™ Plus KitVITEK® 2 DensiCHEK® Kit
- VITEK® 2 DensiCHEK™ Standards KitVITEK® 2 DensiCHEK™ Plus Standards KitVITEK® 2 DensiCHEK® Plus Standards Kit
- VITEK® 2 Cassette
- Adjustable volume saline dispenser
- 12 mm x 75 mm clear plastic (polystyrene) disposable test tubes
- VITEK® 2 60 or VITEK® 2 XL only: VITEK® 2 Pipettor/Diluter Accessory Kit (containing instrument pipette tips and saline hookup) and 0.45% saline bag

Materials required, but not provided are:

- Sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Loops, sterile sticks or swabs
- Appropriate agar medium (See the Culture Requirements Table.)
- QC isolates
- VITEK® 2 AST Cards
- Micropipettors to deliver 145 µL
- Micropipettors to deliver 280 µL
- Disposable pipette tips

Optional Accessories:

- Pre-dispensed saline test tubes (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Test tube caps
- Vortex

Test Card Setup Procedure

The following procedure contains general information applicable to all susceptibility products. (See the Culture Requirements Table for product-specific information.)

Note: Prepare the inoculum from a pure culture, according to good laboratory practices. In case of mixed cultures, a re-isolation step is required. It is recommended that a purity check plate be done to ensure that a pure culture was used for testing.

1. Do one of the following:
   - Select isolated colonies from a primary plate if culture requirements are met.
   - Subculture the organism to be tested to appropriate agar medium and incubate accordingly.
2. Aseptically transfer 3.0 mL of sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0) into a clear plastic (polystyrene) test tube (12 mm x 75 mm).
3. Using sterile technique, prepare a homogenous organism suspension with a density equivalent to the appropriate McFarland standard or McFarland Reference using a compatible benchtop densitometer (see the Culture Requirements Table).
   Note: The age of the suspension before loading the instrument for AST testing must be less than one hour when using VITEK® 2 60 or VITEK® 2 XL, and less than 30 minutes when using VITEK® 2 Compact.
4. Choose one of the following:
   - **For an automatic dilution (VITEK® 2 60 or VITEK® 2 XL only):** Place the suspension tube prepared in step 3 into the cassette with or without an identification card. In the next cassette slot, place an empty tube and an AST card.

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The instrument will automatically dilute the bacterial suspension to prepare an inoculum suitable for the susceptibility card.

- **For a manual dilution (VITEK® 2 Compact, VITEK® 2 60 or VITEK® 2 XL):** In a second tube containing 3.0 mL of saline, transfer 145 µL of the suspension prepared in step 3. Then place this tube in the cassette with a susceptibility card. The tube with the initial bacterial suspension can also be used for inoculation of an identification card.

Note: Check the saline level in the tubes after filling. When it is evident by the saline level in the tube that a card has been improperly filled, do not load the card if using VITEK® 2 Compact; **or**, eject the card if using VITEK® 2 60 or VITEK® 2 XL.

Note: Refer to the appropriate Instrument User Manual for detailed information regarding data entry, processing, etc.

5. Follow your local inspecting agency's guidelines for disposal of hazardous waste.

QUALITY CONTROL

Quality Control organisms should be processed according to the Test Card Setup Procedure.

Table 3: Quality Control

CLSI® Quality Control Organisms VITEK® 2 Results					
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™	*K. pneumoniae* ssp. *pneumoniae* ATCC® 700603™
Ampicillin	am01n	≤ 2 - 8	-	≥ 32†	-
Ampicillin/ Sulbactam	sam02n	≤ 2 - 8	-	8 - ≥ 32	-
Cefepime	fep02n	≤ 1	≤ 1 - 8	-	-
Cefotaxime	ctx01n	≤ 1	8 - 32	-	-
Cefpodoxime	cpd01n	≤ 0.25 - 1	-	-	-
Ceftazidime	caz01n	≤ 1	≤ 1 - 4	-	-
Cefuroxime	cxm01n	2 - 8	-	-	-
Ciprofloxacin	cip01n	≤ 0.25	≤ 0.25 - 1	-	-
Gentamicin	gm01n	≤ 1	≤ 1 - 2	-	-
Imipenem	ipm04n	≤ 0.25	1 - 4	-	-
Levofloxacin	lev02n	≤ 0.12	0.5 - 4	-	-
Meropenem	mem02n	≤ 0.25	≤ 0.25 - 1	-	-
Piperacillin	pip02n	≤ 4	≤ 4 - 8	≥ 128†	-
Piperacillin/ Tazobactam	tzp03n	≤ 4/4[1]	≤ 4/4 - 8/4[2]	≤ 4/4[3]	-
Tigecycline	tgc01n	≤ 0.5	-	-	-
Tobramycin	tm01n	≤ 1	≤ 1	-	-
Trimethoprim/ Sulfamethoxazole	sxt02n	≤ 20 (1/19)	160 (8/152) - ≥ 320 (16/304)	-	-

Numerical values are expressed in µg/mL.

† *Escherichia coli* ATCC® 35218™ is not intended for routine QC testing of ampicillin, piperacillin, or ticarcillin. This organism is recommended only for routine QC of ß-lactamase inhibitor combinations. However, since this strain contains a plasmid-encoded ß-lactamase (non-ESBL), it is resistant to many penicillinase-labile antimicrobials, but susceptible to ß-lactamase/ß-lactamase inhibitor combinations. To ensure that the plasmid is present, testing of the ß-lactam alone (e.g., AM, PIP, TIC), in addition to the ß-lactamase/ß-lactamase inhibitor combination (e.g., AMC, SAM, TZP, TCC), can be performed. If the strain has lost its plasmid, it will be susceptible to the ß-lactam alone (i.e., AM, PIP, TIC), indicating that the QC test is invalid, and a new culture of *Escherichia coli* ATCC® 35218™ must be used.

[1]FDA/CLSI Broth Microdilution expected QC range = 1/4 - 4/4 µg/mL

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[2]FDA/CLSI Broth Microdilution expected QC range = 1/4 - 8/4 µg/mL

[3]FDA/CLSI Broth Microdilution expected QC range = 0.5/4 - 2/4 µg/mL

Certification Statement

This is to certify that bioMérieux complies with ISO 13485 and FDA Quality System Regulation (QSR) requirements for design, development, and manufacture of antimicrobial susceptibility systems.

Frequency of QC Testing

Refer to *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically,* CLSI® and/or your local guidelines.[2]

Preparation of QC Organisms

1. Rehydrate the organism according to the manufacturer's instructions.
2. Subculture to Trypticase Soy Agar with 5% sheep blood (TSAB).
3. Incubate at 35°C for 24 hours.
4. Check for purity.
5. Subculture to a TSAB plate.
6. Incubate 16 to 18 hours at 35°C.

Short-Term Storage Conditions

1. Streak to a TSAB plate or slant.
2. Incubate for 24 hours.
3. Refrigerate at 2°C to 8°C for up to two weeks.
4. Subculture once as described above and use for QC.

Long-Term Storage Conditions

1. Make a heavy suspension in Tryptic Soy Broth (TSB) with 15% glycerol.
2. Freeze at -70°C.
3. Subculture to TSAB twice before running QC.
   Note: Avoid repeated thawing and refreezing by either freezing in single-use aliquots or removing a small portion of frozen organism preparation with a sterile applicator stick.

RESULTS

Susceptibility Analytical Techniques

The system evaluates each organism's growth pattern in the presence of the antimicrobial in relation to the growth control well. Several parameters based on the growth characteristics are used to determine the MIC or qualitative result (for example, ESBL POS/NEG). The MIC result must be linked to an organism identification to determine a category interpretation. Accurate identification is critical, especially with certain organism/antimicrobial combinations (e.g., *Staphylococcus aureus*/oxacillin).

In cases where the identification of an organism is in question, confirmatory testing is necessary to ensure correct interpretation of susceptibility results.

A category interpretation will be reported along with a MIC, according to the interpretations defined by the Food and Drug Administration (FDA), CLSI®, Comité de l'Antibiogramme de la Société Française de Microbiologie (CASFM), European Committee for Antimicrobial Susceptibility Testing (EUCAST), or to an adaptation of the global settings according to other local guidelines.

Note: When FDA and CLSI® breakpoints differ, VITEK® 2 Systems AST tests are cleared for use with FDA breakpoints applied.

Combination Antimicrobials

The MICs for the combination antimicrobials are listed on the laboratory and patient reports as the first concentration (e.g., ampicillin/sulbactam ≤ 8/4 µg/mL is reported as ≤ 8 µg/mL.). The actual concentrations for each value in the antimicrobial calling range are as follows:

- ampicillin/sulbactam (sam01n) (µg/mL) 2/1, 4/2, 8/4, 16/8, 32/16
- piperacillin/tazobactam (µg/mL) 4/4, 8/4, 16/4, 32/4, 64/4, 128/4

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- trimethoprim/sulfamethoxazole: **Note exception** — This drug is listed on the laboratory and patient reports as the sum of the two antimicrobial concentrations: 20 µg/mL = 1/19, 40 µg/mL = 2/38, 80 µg/mL = 4/76, 160 µg/mL = 8/152, 320 µg/mL = 16/304

Antimicrobial Deduction

Antimicrobials that have been deduced will only report an interpretive result and will be noted with a **+**.

Clinical Efficacy and Indications for Use

AST cards may contain some antimicrobials that are not proven to be effective for treatment of infections caused by all organisms that may be tested. For interpreting and reporting of antimicrobial results that have shown to be active against organism groups both *in vitro* and in clinical infections, refer to the individual pharmaceutical antimicrobial labeling or the local therapy guidelines.

Urinary Use Only Antimicrobials

Certain antimicrobial agents are limited to use in treating urinary tract infections. Accordingly, these agents should not be reported against pathogens recovered from infection sites other than the urinary tract (except as noted). Please refer to the current *CLSI Performance Standards for Susceptibility Testing, M100* and/or local guidelines for additional information.[3]

For urine only, per CLSI®.[3]

- *Enterobacteriaceae*: lomefloxacin or ofloxacin, norfloxacin, nitrofurantoin, sulfisoxazole, trimethoprim, cefazolin
- *Pseudomonas aeruginosa*: lomefloxacin or ofloxacin, norfloxacin
- Other non-*Enterobacteriaceae*: lomefloxacin or ofloxacin, norfloxacin, sulfisoxazole, tetracycline

LIMITATIONS

A VITEK® 2 AST card cannot be used with a direct clinical specimen or sample or other sources containing mixed flora. Any change or modification in the procedure may affect the results.

A result for an antibiotic/organism combination, which may have a limitation, may be suppressed from reporting. This can be accomplished through the use of bioART rules in the VITEK® 2 Systems software. Refer to the software user manual for instructions.

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

- Ampicillin (am01n): *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Ampicillin/Sulbactam (sam02n): *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Cefpodoxime (cpd01n): *Morganella morganii, Serratia* spp.
- Imipenem (ipm04n): *Serratia marcescens*
- Piperacillin/Tazobactam (tzp03n): *Serratia marcescens*

Perform an alternative method of testing prior to reporting results when a resistant result is obtained with the following antibiotic/organism combination(s):

- Imipenem (ipm04n): *Aeromonas* spp.
- Meropenem (mem02n): *Aeromonas* spp.
- Piperacillin/Tazobactam (tzp03n): *Pseudomonas aeruginosa*

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:

- Tigecycline (tgc01n): *C. freundii, E. cloacae, E. coli, K. oxytoca, K. pneumoniae, C. koseri, E. aerogenes, S. marcescens*

EUCAST Limitations

It is recommended that the existing bioART suppression rules be enabled, or new rules created and enabled, for these limitations if the EUCAST breakpoints are applied.

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

- Ampicillin (am01n): *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Cefpodoxime (cpd01n): *Serratia* spp.
- Imipenem (ipm04n): *Serratia marcescens*

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- Tigecycline (tgc01n): *Serratia* spp., *Enterobacter* spp., *Morganella* spp., *Proteus* spp., *Providencia* spp., *Cronobacter sakazakii*

EXPECTED VALUES

Expected results for susceptibility tests will vary based on location and institution. VITEK® 2 Systems were tested at several geographically diverse locations to ensure that trends that occurred by location were integrated into the performance characteristics of the system. Organism resistance patterns will differ by institution; therefore, expected values will be directly related to the population of organisms at each site.

PERFORMANCE CHARACTERISTICS

The performance characteristics of the antimicrobial agents included in VITEK® 2 AST cards were established using the manual and autodilution modes (on a VITEK® 2 System) at multiple clinical laboratories. The VITEK® 2 AST card results were compared to results from a CLSI® reference method. Essential agreement (EA) represents VITEK® 2 results which agree exactly or are within a ± twofold dilution (± two doubling dilutions for antifungal) of the reference result.

Category agreement (CA) occurs when the VITEK® 2 and the reference interpretative results agree (Susceptible, Intermediate, and Resistant). There are instances when the category agreement for an antimicrobial falls below the essential agreement. This can occur when a significant number of MICs cluster around a category breakpoint during clinical trial testing, resulting in interpretative errors. For a description of interpretive errors, refer to the footnotes below the table that follows (Performance Characteristics). When the majority of the errors are of the minor type, a high corresponding essential agreement percentage demonstrates that the antimicrobial retains an acceptable overall performance.

There are instances when the performance is based solely on category agreement (CA) because at the time performance was established, less than five discrete twofold dilutions were evaluated. A minimum of five dilutions is necessary to calculate essential agreement (EA) based on ± one twofold dilution. These instances are designated by a "c" footnote in the Contents of the Card table. The following performance tables have values for CA only when EA was not established at the time of FDA clearance.

The reproducibility of the VITEK® 2 system was established by testing a set of on-scale organisms.*

*Data on file at bioMérieux, Inc

Table 4: Performance Characteristics for Gram-Negative Antimicrobial Susceptibility Testing

Antimicrobial	Antimicrobial Code	Antibiotic Version	Bp[1]	Comment[2]	Essential Agreement				Category Agreement				% Reproducibility
					% Error				% Error				
					% EA	VME	ME	mE	% CA	VME	ME	mE	
Ampicillin	AM	am01n	CLSI	#, E	93.3	1.3	0.0	0.8	90.9	1.3	0.0	7.8	99.3
			CA-SFM	I	94.9	0.6	2.2	4.3	–	–	–	–	
Cefepime	FEP	fep02n	CLSI	#, E	94.2	4.0	1.4	6.3	92.1	–	–	–	98.6
Cefotaxime	CTX	ctx01n	CLSI	#, E	95.8	1.1	0.2	2.6	92.9	1.1	0.2	6.7	98.1
			CA-SFM	I	94.0	0.4	0.1	3.5	–	–	–	–	
Cefpodoxime	CPD	cpd01n	CLSI	#, E	96.0	0.0	0.4	0.8	96.3	0.0	0.4	3.5	100
			CA-SFM	I	94.1	1.2	2.9	1.3	–	–	–	–	
Ceftazidime	CAZ	caz01n	CLSI	#, E	97.5	1.1	0.2	1.0	97.3	1.1	0.2	3.5	95.4
			CA-SFM	I	92.3	5.1	0.0	4.1	–	–	–	–	
Cefuroxime	CXM	cxm01n	CLSI	#, E	95.3	1.5	1.0	1.6	93.9	1.5	1.0	4.8	99.6
Ciprofloxacin	CIP	cip01n	CLSI	#, E	97.9	0.0	0.0	0.5	96.6	0.0	0.0	3.8	98.9
			CA-SFM	E	97.9	0.0	0.0	0.5	96.6	0.0	0.0	3.8	
Gentamicin	GM	gm01n	CLSI	#, E	97.1	1.9	0.0	0.6	96.4	1.9	0.0	2.9	100
			CA-SFM	E	97.1	1.9	0.0	0.6	96.4	1.9	0.0	2.9	
Imipenem	IPM	ipm04n	CLSI	#, E ❷	95.7	2.4	0.3	0.4	94.8	2.4	0.3	4.4	99.6

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Antimicrobial	Antimicrobial Code	Antibiotic Version	Bp[1]	Comment[2]	Essential Agreement				Category Agreement				% Reproducibility
					% Error				% Error				
					% EA	VME	ME	mE	% CA	VME	ME	mE	
Levofloxacin	LEV	lev02n	CLSI	#, E ❷	98.6	0.5	0.2	0.3	95.8	0.5	0.2	3.9	100
			CA-SFM	E ❷	98.6	0.0	0.7	0.1	96.5	0.0	0.7	3.0	
Meropenem	MEM	mem02n	CLSI	#, E ❷	97.6	1.4	0.0	0.3	96.8	1.4	0.0	2.8	99.6
			Global	#, E ❷	97.6	0.0	0.0	0.5	97.7	0.0	0.0	2.3	
Piperacillin	PIP	pip02n	CLSI	#, E ❷	94.6	2.0	0.2	3.7	92.4	2.7	0.2	6.8	99.3
			CA-SFM	E ❷	94.6	2.0	0.3	2.5	91.0	2.0	0.3	8.1	
			Global	#, E ❷	94.9	1.2	0.5	3.8	91.9	1.2	0.5	7.4	
Piperacillin/ Tazobactam*	TZP	tzp03n	CLSI	#, E	N/A	N/A	N/A	N/A	93.2	0.9	2.2	5.0	96.7
Tigecycline	TGC	tgc01n	Global	#, E	94.4	0.0	2.0	0.0	90.1	0.0	2.0	8.5	100
Tobramycin	TM	tm01n	CLSI	#, E	98.0	0.0	0.0	1.2	94.7	0.0	0.0	5.6	100
			CA-SFM	E	98.0	0.0	0.0	1.2	94.7	0.0	0.0	5.6	
Trimethoprim/ Sulfamethoxazole	SXT	sxt02n	CLSI	#, E ❷	–	–	–	–	100	0.0	0.0	N/A	100
			CA-SFM	E ❷	99.5	0.0	0.0	0.0	100	0.0	0.0	0.0	
Trimethoprim/ Sulfamethoxazole	SXT	sxt02n	CLSI[3]	#, E ❷ Applies to V2S SW PC version 5.02 and above	-	-	-	-	100	0.0	0.0	N/A	97.8

[1] Abbreviations — Bp = breakpoint committee; EA = essential agreement; CA = category agreement; VME = Very Major Error (susceptible result with resistant reference result); ME = Major Error (resistant result with susceptible reference result); mE = minor Error (susceptible or resistant result with an intermediate reference result, or an intermediate result with a susceptible or resistant reference result).

[2] Comment — Specific organism groups are designated as P. aeurg. for *Pseudomonas aeruginosa*, others for species other than *Pseudomonas aeruginosa*, and Acineto. for *Acinetobacter*.

[3] FDA breakpoints are used in the CLSI Interpretation Standard (breakpoint committee) in the VITEK® 2 Systems software.

* The overall essential agreement for VITEK® 2 piperacillin/tazobactam was not calculated since the test contains less than five discrete concentrations. However, of the 2453 isolates tested, 348 (14.2%) yielded on-scale VITEK® 2 MIC values (i.e., results of 8, 16, 32, and 64 µg/ml). Those results were evaluated for MIC trends and the following results were obtained when VITEK® 2 was compared to CLSI broth microdilution method; 74.4% (259/348) of the VITEK® MICs were within +/- one doubling dilution; 18.4% (64/348) of the VITEK® MICs were higher by more than one doubling dilution; and 7.2% (25/348) of the VITEK® MICs were lower by more than one doubling dilution.

Key:

= US Food and Drug Administration 510(k) cleared
CLSI® = Clinical and Laboratory Standards Institute
CA-SFM = Comité de l'Antibiogramme de la Société Française de Microbiologie
E = External performance data
I = Internal performance data
– = Not available
❶ ❷ = Symbol identifies the performance characteristics for a specific antimicrobial version.
Ref. = Reference method for clinical performance study.

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Table 5: EUCAST Performance Characteristics for Gram-Negative Antimicrobial Susceptibility Testing

Antimicrobial	Antimicrobial Code	Antibiotic Version	Comment[1]	Essential Agreement				Category Agreement			
				% Error				% Error			
				%EA[2]	VME	ME	mE	%CA	VME	ME	mE
Ampicillin	AM	am01n	*Enterobacteriaceae* (excludes: *Citrobacter, Enterobacter, Pantoea, Serratia* spp.)	93.2	2.7	0.9	0.0	96.6	4.3	1.8	0.0
Cefepime	FEP	fep02n	*Enterobacteriaceae, Pseudomonas*	97.0	2.0	1.3	0.8	93.9	9.0	2.6	2.4
Cefotaxime	CTX	ctx01n	*Enterobacteriaceae*	95.9	7.4	0.8	0.9	94.1	7.4	0.8	3.8
Cefpodoxime	CPD	cpd01n	*Enterobacteriaceae* excluding *Serratia* spp.	93.8	3.8	2.2	0.0	94.1	6.3	5.8	0.0
Ceftazidime	CAZ	caz01n	*Enterobacteriaceae, Pseudomonas*	96.7	3.0	0.3	0.8	97.9	3.0	1.0	1.3
Cefuroxime	CXM	cxm01n	*Enterobacteriaceae*	94.0	2.8	2.6	0.0	93.7	3.7	7.8	0.0
Ciprofloxacin	CIP	cip01n	N/A	98.1	0.0	0.3	0.2	95.3	0.0	0.3	4.5
Gentamicin	GM	gm01n	N/A	98.3	0.4	0.0	0.8	96.8	0.0	0.0	3.2
Imipenem	IPM	ipm04n	N/A	95.8	1.0	0.4	0.8	92.2	1.0	0.4	7.3
Levofloxacin	LEV	lev02n	❷	99.4	0.0	1.3	0.2	96.7	0.0	0.7	2.9
Meropenem	MEM	mem02n	❷	97.6	0.5	0.0	0.6	95.9	0.5	0.0	3.9
Piperacillin	PIP	pip02n	*Enterobacteriaceae, Pseudomonas* ❷	93.9	2.4	1.6	1.9	88.5	4.3	2.9	8.5
Piperacillin/Tazobactam	TZP	tzp03n	*Enterobacteriaceae, Pseudomonas*	96.2	0.8	0.9	1.0	94.8	1.2	1.5	3.8
Tigecycline	TGC	tgc01n	(excludes: *Serratia, Morganella/Proteus/ Providencia*, and *Enterobacter*)	96.9	0.0	0.4	0.8	94.6	0.0	0.4	5.0
Tobramycin	TM	tm01n	N/A	98.9	0.0	0.5	0.0	94.7	0.0	0.8	4.6
Trimethoprim/ Sulfamethoxazole	SXT	sxt02n	(also includes *S. maltophilia*) ❷	98.4	0.0	0.0	0.4	99.5	0.0	0.0	0.5

[1] Comment — Unless stated otherwise, performance is for *Enterobacteriaceae*, *Pseudomonas*, and *Acinetobacter*.

[2] Abbreviations — Bp = breakpoint committee; EA = essential agreement; CA = category agreement; VME = Very Major Error (susceptible result with resistant reference result); ME = Major Error (resistant result with susceptible reference result); mE = minor Error (susceptible or resistant result with an intermediate reference result, or an intermediate result with a susceptible or resistant reference result).

Key:

= EUCAST = European Committee on Antimicrobial Susceptibility

❶ ❷ = Symbol identifies the performance characteristics for a specific antimicrobial version.

LIST OF CLAIMS

Note: If the organism is not in the VITEK® 2 susceptibility database, results will not be reported.

Note: Organisms listed with an asterisk (*) indicate an AES claimed organism. No asterisk is displayed for a group; however, when an individual species (with an asterisk) is contained within a group, it is expertised.

Gram-Negative Organisms Claimed for AST-GN (keyID)

- *Achromobacter denitrificans*
- *Achromobacter xylosoxidans*
- *Acinetobacter baumannii**
- *Acinetobacter baumannii complex**
- *Acinetobacter calcoaceticus**

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- *Acinetobacter haemolyticus*
- *Acinetobacter johnsonii*
- *Acinetobacter junii*
- *Acinetobacter lwoffii*
- *Acinetobacter pittii**
- *Acinetobacter* spp.
- *Aeromonas caviae*
- *Aeromonas hydrophila*
- *Aeromonas hydrophila/caviae*
- *Aeromonas sobria*
- *Alcaligenes faecalis* ssp. *faecalis*
- *Bordetella avium*
- *Bordetella bronchiseptica*
- *Brevundimonas diminuta*
- *Brevundimonas diminuta/vesicularis*
- *Brevundimonas vesicularis*
- *Burkholderia cepacia**
- *Cedecea davisae**
- *Cedecea lapagei**
- *Cedecea neteri**
- *Chryseobacterium gleum*
- *Chryseobacterium indologenes*
- *Citrobacter amalonaticus**
- *Citrobacter braakii**
- *Citrobacter farmeri**
- *Citrobacter freundii**
- *Citrobacter koseri**
- *Citrobacter youngae**
- *Comamonas testosteroni*
- *Cronobacter muytjensii**
- *Cronobacter sakazakii* group*
- *Cronobacter sakazakii**
- *Delftia acidovorans*
- *Edwardsiella hoshinae**
- *Edwardsiella tarda**
- *Elizabethkingia meningoseptica* (formerly known as *Chryseobacterium meningosepticum*)
- *Enterobacter aerogenes**
- *Enterobacter asburiae**
- *Enterobacter cancerogenus**
- *Enterobacter cloacae**
- *Enterobacter cloacae* complex*
- *Enterobacter cloacae* ssp. *cloacae**
- *Enterobacter cloacae* ssp. *dissolvens* *
- *Escherichia coli**
- *Escherichia coli* ATCC® 25922™
- *Escherichia coli* ATCC® 35218™
- *Escherichia fergusonii*
- *Escherichia hermannii**
- *Escherichia vulneris**
- *Ewingella americana*
- *Hafnia alvei**
- *Hafnia paralvei**

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- *Klebsiella oxytoca**
- *Klebsiella pneumoniae**
- *Klebsiella pneumoniae* ssp. *ozaenae**
- *Klebsiella pneumoniae* ssp. *pneumoniae**
- *Klebsiella pneumoniae* ssp. *pneumoniae* ATCC® 700603 ™
- *Klebsiella pneumoniae* ssp. *rhinoscleromatis**
- *Klebsiella* spp.*
- *Kluyvera ascorbata**
- *Kluyvera cryocrescens**
- *Kluyvera intermedia* (formerly known as *Enterobacter intermedius*)*
- *Leclercia adecarboxylata**
- *Lelliottia amnigena* (formerly known as Enterobacter amnigenus)*
- *Lelliottia amnigena 1* (formerly known as Enterobacter amnigenus 1)*
- *Lelliottia amnigena 2* (formerly known as Enterobacter amnigenus 2)
- *Mannheimia haemolytica*
- *Moraxella* group
- *Moraxella lacunata*
- *Moraxella nonliquefaciens*
- *Moraxella osloensis*
- *Morganella morganii**
- *Morganella morganii* ssp. *morganii**
- *Morganella morganii* ssp. *sibonii**
- *Myroides* ssp.
- *Pantoea agglomerans*
- *Pantoea dispersa*
- *Pasteurella aerogenes*
- *Pasteurella multocida**
- *Pasteurella pneumotropica*
- *Plesiomonas shigelloides*
- *Pluralibacter gergoviae* (formerly known as *Enterobacter gergoviae*)*
- *Proteus hauseri**
- *Proteus mirabilis**
- *Proteus penneri**
- *Proteus vulgaris**
- *Providencia alcalifaciens**
- *Providencia rettgeri**
- *Providencia rustigianii**
- *Providencia stuartii**
- *Pseudomonas aeruginosa**
- *Pseudomonas aeruginosa* ATCC® 27853™
- *Pseudomonas alcaligenes*
- *Pseudomonas fluorescens*
- *Pseudomonas luteola*
- *Pseudomonas mendocina*
- *Pseudomonas oleovorans*
- *Pseudomonas oryzihabitans*
- *Pseudomonas putida*
- *Pseudomonas* spp.
- *Pseudomonas stutzeri*
- *Ralstonia pickettii*
- *Raoultella ornithinolytica**
- *Raoultella planticola**

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- *Raoultella terrigena**
- *Salmonella enterica* ssp. *arizonae*
- *Salmonella enterica* ssp. *enterica**
- *Salmonella* group*
- *Salmonella* ser. Enteritidis*
- *Salmonella* ser. Paratyphi A*
- *Salmonella* ser. Paratyphi B*
- *Salmonella* ser. Paratyphi C*
- *Salmonella* ser. Typhi*
- *Salmonella* ser. Typhimurium*
- *Salmonella* spp.*
- *Serratia ficaria**
- *Serratia fonticola**
- *Serratia grimesii**
- *Serratia liquefaciens**
- *Serratia liquefaciens* group*
- *Serratia marcescens**
- *Serratia odorifera**
- *Serratia plymuthica**
- *Serratia proteamaculans*
- *Serratia rubidaea**
- *Shewanella putrefaciens*
- *Shewanella putrefaciens* group
- *Shigella boydii**
- *Shigella dysenteriae**
- *Shigella flexneri**
- *Shigella* group*
- *Shigella sonnei**
- *Shigella* spp.
- *Sphingobacterium multivorum*
- *Sphingobacterium spiritivorum*
- *Sphingomonas paucimobilis*
- *Stenotrophomonas maltophilia**
- *Vibrio alginolyticus*
- *Vibrio fluvialis*
- *Vibrio harveyi*
- *Vibrio metschnikovii*
- *Vibrio mimicus*
- *Vibrio parahaemolyticus*
- *Vibrio vulnificus*
- *Yersinia aldovae*
- *Yersinia enterocolitica**
- *Yersinia enterocolitica* group*
- *Yersinia frederiksenii**
- *Yersinia intermedia**
- *Yersinia kristensenii**
- *Yersinia pseudotuberculosis**
- *Yersinia ruckeri*

REFERENCES

1. Barry, AL The Antimicrobic Susceptibility Test, Principles and Practices, Lea and Febiger, Philadelphia, PA. 1976.
2. Clinical Laboratory Standards Institute (CLSI®), Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically, M7- A7, Wayne, Pennsylvania, January 2006.

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3. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Eighteenth Informational Supplement, M100-S18, Vol. 27, No. 1, January 2008.
4. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-third Informational Supplement, M100-S22, January 2012.
5. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-fourth Informational Supplement; M100-S24, January 2014.
6. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-fifth Informational Supplement, M100-S25, January 2015.
7. Comité de l'Antibiogramme de la Société Française de Microbiologie. Communiqué 1996. Path Biol, 1996, 44, n° 8, I-VIII.
8. Comité de l'Antibiogramme de la Société Française de Microbiologie, Communiqué 2007.
9. Comite de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM), Recommendations 2012.
10. Comité de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM). Communiqué 2014.
11. Comité de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM). Communiqué 2015.
12. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 2.0, January 2012.
13. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 4.0, January 2014.
14. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 5.0, January 2015.
15. Gerlach, EH Microdilution 1: A Comparative Study, p. 63-76, In: Balows, A. (ed.), Current Techniques for Antibiotic Susceptibility Testing, Charles C. Thomas, Springfield, IL. 1974.
16. MacLowry, JD, and HH Marsh. 1968. Semi-automatic microtechnique for serial dilution antibiotic sensitivity testing in the clinical laboratory. J. Lab. Clin. Med. 1968;72:685-687.
17. Murray, PR, Baron EJ, Pfaller MA, Tenover FC, and Yolken RH, editors. Manual of Clinical Microbiology, 8th ed. American Society for Microbiology, Washington, D.C. 2003.
18. National Committee for Clinical Laboratory Standards, M29-A, Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissue – Approved Guideline (1997).
19. National Committee for Clinical Laboratory Standards, Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Approved Standard — Third Edition, M27-A3, Vol. 22, No. 15, 2008.
20. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health, Office of Health and Safety, Biosafety in Microbiological and Biomedical Laboratories, 1988.

Permission to incorporate portions of M100 (Performance Standards for Antimicrobial Susceptibility Testing: Informational Supplement) in the bioMérieux clinical microbiology instrumentation and System has been granted by CLSI®. The current standard and supplements to it may be obtained from CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

INDEX OF SYMBOLS

Symbol	Meaning
	Catalog number
	In Vitro Diagnostic Medical Device
	Legal Manufacturer
	Temperature limitation
	Use by date
	Batch code
	Consult Instructions for Use
	Date of manufacture

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Symbol	Meaning
	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community
Rx only	For US Only : Caution : US Federal Law restricts this device to sale by or on the order of a licensed practitioner

Instructions for Use provided in the kit or downloadable from www.biomerieux.com/techlib

BARCODES

User MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.

01 
A 3 1 0 H 3 0 J - - - M

02 
B A S T - N 2 3 2 0 1 O

03 
C - - - Z 0 2 0 P 1 C 4

04 
D 0 F 1 0 0 G 0 I 0 L C

05 
E 0 3 2 O 1 W 2 G 2 0 6

06 
F 2 P 1 R 0 5 2 3 0 0 F

LIMITED WARRANTY

bioMérieux warrants the performance of the product for its stated intended use provided that all procedures for usage, storage and handling, shelf life (when applicable), and precautions are strictly followed as detailed in the instructions for use (IFU).

Except as expressly set forth above, bioMérieux hereby disclaims all warranties, including any implied warranties of merchantability and fitness for a particular purpose or use, and disclaims all liability, whether direct, indirect or consequential, for any use of the reagent, software, instrument and disposables (the “System”) other than as set forth in the IFU.

WASTE DISPOSAL

All hazardous waste must be disposed of by following your local inspecting agency's guidelines.

REVISION HISTORY TABLE

Change type categories	
N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user
Note:	Minor typographical, grammar, and formatting changes are not included in the revision history.

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Release Date	Part Number	Change Type	Change Summary
2019-01	046128-01	Administrative	• Formatting changes do not affect the fit, form, or function of the product
		Technical change	• Combined product package insert content with VITEK® 2 Product Information Manual AST content • Updated Limited Warranty section • Updated with RX only information • Updated with EUCAST limitations

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VITEK 2™ — technology

AST-N222

IVD

Gram Negative Susceptibility Card

SUMMARY AND EXPLANATION

The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of **clinically significant aerobic gram-negative bacilli** to antimicrobial agents when used as instructed in the Product Information manual.

INSTRUCTIONS FOR USE

A package insert is provided in the kit or downloadable from **www.biomerieux.com/techlib**

See the Product Information manual for additional Instructions for Use.

STORAGE CONDITIONS

Store at 2° to 8° C.

CONTENTS OF THE CARD

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Amikacin	AN	8, 16, 64	2	64	CSAGNB**
Aztreonam	ATM	2, 8, 32	1	64	CSAGNB**
Cefepime	FEP	2, 8, 16, 32	1	64	CSAGNB**
Ceftazidime	CAZ	1, 2, 8, 32	1	64	CSAGNB**
Ciprofloxacin	CIP	0.5, 2, 4	0.25	4	CSAGNB**
Colistin	CS	4, 16, 32	0.5	16	N/A**
Gentamicin	GM	4, 16, 32	1	16	CSAGNB**
Imipenem	IPM	1, 2, 6, 12	0.25	16	*Acinetobacter* spp., *Citrobacter* spp., *Enterobacter* spp., *E. coli*, *Klebsiella* spp., *M. morganii*, *P. vulgaris*, *Pv. rettgeri*, *P. aeruginosa*, *S. marcescens*, *Pv. stuartii*
Meropenem	MEM❷	0.5, 2, 6, 12	0.25	16	*E. coli*, *K. pneumoniae*, *P. aeruginosa*, *P. mirabilis*, *Acinetobacter* spp., *C. freundii*, *E. cloacae*, *K. oxytoca*, *M. morganii*, *P. vulgaris*, *S. marcescens*, *A. hydrophila*, *C. diversus*, *H. alvei*, *P. multocida*, *Salmonella* spp., *Shigella* spp.
Minocycline	MNO	2, 4, 8	1	16	N/A**
Pefloxacin	PEF	0.5, 2, 8	0.25	16	N/A**
Piperacillin	PIP❷	4, 16, 32, 64	4	128	*Acinetobacter* spp., *Enterobacter* spp., *E. coli*, *Klebsiella* spp., *M. morganii*, *Pv. rettgeri*, *P. mirabilis*, *P. vulgaris*, *P. aeruginosa*, *Serratia* spp., *B. cepacia*, *C. koseri*, *C. freundii*, *P. fluorescens*, *C. sakazakii*
Piperacillin/Tazobactam	TZP	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. enterica*
Rifampicin	RA	2, 4, 16	2	32	N/A**
Ticarcillin	TIC	16, 32, 64	8	128	CSAGNB**
Ticarcillin/Clavulanic Acid	TCC	8/2, 32/2, 64/2	8/2	128/2	CSAGNB**
Tobramycin	TM	8, 16, 64	1	16	CSAGNB**

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Trimethoprim/Sulfamethoxazole	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

Numerical values are expressed in µg/ml.
§ Equivalent standard method concentration by efficacy.
**CSAGNB = Clinically significant aerobic gram negative bacilli
**N/A = No specific FDA Indications for Use available
❶,❷ etc. = See performance characteristics identified by the drug code with this symbol in the Comment column in Systems Product Information.
**Eco(+ETEC) = *E. coli* (including susceptible enterotoxigenic strains implicated in traveler's diarrhea)

QUALITY CONTROL

		CLSI® Quality Control Organisms VITEK 2 Results		
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™
Amikacin	AN	≤2 – 4	≤2 – 4	-
Aztreonam	ATM	≤1	2 – 8	-
Cefepime	FEP	≤1	≤1 – 8	-
Ceftazidime	CAZ	≤1	≤1 – 4	-
Ciprofloxacin	CIP	≤0.25	≤0.25 – 1	-
Colistin	CS	≤0.5 – 1	≤0.5 – 2	-
Gentamicin	GM	≤1	≤1 – 2	-
Imipenem	IPM	≤0.25	1 – 4	-
Meropenem	MEM	≤0.25	≤0.25 – 1	-
Minocycline	MNO	≤1	-	-
Pefloxacin	PEF	≤0.25	0.5 – 4	-
Piperacillin	PIP	≤4	≤4 – 8	-
Piperacillin/Tazobactam	TZP	≤4/4	≤4/4 – 8/4	≤4/4
Rifampicin	RA	4 – 16	16 – ≥32	-
Ticarcillin	TIC	≤8 – 16	≤8 – 32	-
Ticarcillin/Clavulanic Acid	TCC	≤8/2 – 16/2	≤8/2 – 32/2	≤8/2 – 16/2 S/W ≤ VT2 4.01 & VT2compact 1.02 ≤8/2 – 32/2 S/W ≥ VT2 4.02 & VT2compact 2.01
Tobramycin	TM	≤1	≤1	-
Trimethoprim/Sulfamethoxazole	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-

Numerical values are expressed in µg/ml.

LIMITATIONS

Ticarcillin/Clavulanic Acid has been approved for use only with *Pseudomonas aeruginosa*. An alternative method of testing must be performed prior to reporting of results for all other organisms.

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):
- Amikacin: *Acinetobacter baumannii*
- Aztreonam: *Pseudomonas* spp.
- Imipenem: *Serratia marcescens*
- Piperacillin/Tazobactam: *Serratia marcescens*

Perform an alternative method of testing prior to reporting results when a resistant result is obtained with the following antibiotic/organism combination(s):
- Imipenem: *Aeromonas* spp.
- Meropenem: *Aeromonas* spp.
- Piperacillin/Tazobactam: *Pseudomonas aeruginosa*

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Perform an alternative method of testing prior to reporting of susceptible results for the following antibiotic/organism combination(s):

- Colistin: Clinically significant aerobic gram negative bacilli

NOTE: A result for an antibiotic/organism combination which may have a limitation may be suppressed from reporting. Refer to the software user manual for instructions.

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⇩ MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.

01 A310GU0K---2

02 BAST-N22201G

03 C---Z01081CT

04 D0G0L18032OL

05 E2G1B19202PO

06 F1M0N130523R

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
	Temperature limitation
	Use by
LOT	Batch code
	Consult Instructions for Use
Σ	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community

PATENTS

Product covered by one or more of U.S. Patent Nos. D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 and 6,340,573; and Foreign Counterparts. Other Patents Pending.

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VITEK 2™ — technology

AST-GP75

IVD

Карта для определения чувствительности *Staphylococcus* spp., *Enterococcus* spp., *S. agalactiae* к антимикробным препаратам

КРАТКОЕ ОПИСАНИЕ

Данная карта предназначена для использования с системами VITEK® 2 в клинических лабораториях для лабораторного определения чувствительности к антимикробным препаратам ***Staphylococcus* spp., *Enterococcus* spp., и *S. agalactiae***. Используйте, как указано в руководстве "Расходные материалы".

ПРИМЕНЕНИЕ

Инструкция по применению предоставляется в наборе или может быть загружена с сайта **www.biomerieux.com/techlib**

Для получения дополнительных инструкций по применению смотрите руководство по расходным материалам.

ХРАНЕНИЕ

Хранить при температуре от 2° до 8° C.

СОСТАВ КАРТЫ

Антимикробный препарат	Код	Концентрация §	Диапазон определения ≤	≥	Указания к применению FDA (Управление по контролю за продуктами и лекарствами, США)
Ampicillin *Enterococcus* spp. *S. agalactiae*	AM	0.5, 4, 8, 32	- 2 0.25	- 32 16	*Enterococcus* spp., *S. agalactiae*
Cefoxitin Screen	OXSF	6	NEG	POS	*Staphylococcus* spp.
Ciprofloxacin	CIP	1, 2, 4	0.5	8	*Staphylococcus* spp., *Enterococcus* spp.
Clindamycin	CM	0.06, 0.25, 1	0.125	4	MSSA**, MSSE**
Daptomycin NS	DAP	0.5, 1, 2, 4, 16	0.12	8	*S. aureus*, VSEfaeca**
Doxycycline	DO	0.25, 1, 2, 4	0.5	16	*S. aureus*
Erythromycin	E❶	0.25, 0.5, 2	0.25	8	*Staphylococcus* spp., *Enterococcus* spp., *S. agalactiae*
Gentamicin	GM	8, 16, 64	0.5	16	*Staphylococcus* spp.
Gentamicin High Level (synergy)	HLG	500	S	R	*Enterococcus* spp.
Inducible Clindamycin Resistance	ICR❷	CM 0.5, CM/E 0.25/0.5	NEG	POS	*Staphylococcus* spp.
Levofloxacin	LEV	0.25, 2, 8	0.12	8	*Staphylococcus* spp., *Enterococcus* spp., *S. agalactiae*
Linezolid	LNZ	0.5, 1, 2	0.5	8	*S. agalactiae*, *E. faecalis*, *E. faecium*, *S. aureus*, *S. epidermidis*, *S. haemolyticus*
Moxifloxacin	MXF	0.25, 2, 8	0.25	8	MSSA**
Nitrofurantoin	FT	16, 32, 64	16	512	*Staphylococcus* spp., *Enterococcus* spp.
Oxacillin	OX1	0.5, 1, 2	0.25	4	*Staphylococcus* spp.
Rifampicin	RA	0.25, 0.5, 2	0.5	32	*Staphylococcus* spp.
Streptomycin High Level (synergy)	HLS	1000	S	R	*Enterococcus* spp.
Tetracycline	TE	0.5, 1, 2	1	16	*Staphylococcus* spp., *Enterococcus* spp., *S. agalactiae*
Tigecycline NS	TGC	0.25, 0.5, 1	0.12	2	*E. faecalis*, *E. faecium*, *S. aureus*, *S. epidermidis*, *S. haemolyticus*, *S. agalactiae*, *E. casseliflavus*
Trimethoprim/Sulfamethoxazole	SXT❶	2/38, 8/152, 16/304	10 (0.5/9.5)	320 (16/304)	*S. aureus*
Vancomycin	VA❷	1, 2, 4, 8, 16	0.5	32	*Enterococcus* spp., *Staphylococcus* spp., *S. agalactiae*

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Численные значения выражены в µг/мл.
§ Эквивалентна по эффективности концентрации стандартного метода.
**MSSA = чувствительные к метициллину штаммы *S. aureus*
**MSSE = чувствительные к метициллину штаммы *S. epidermidis*
NS = В настоящее время устойчивые штаммы отсутствуют, что исключает получение какого-либо результата, кроме "чувствительный". При получении МИК, соответствующих другой категории чувствительности ("умеренно устойчивый", "устойчивый") следует отправить штамм в референсную лабораторию для дальнейшего анализа.
**VSEfaeca = *E. faecalis* (чувствительные к ванкомицину штаммы).
❶,❷ пр. = См. рабочие характеристики с кодом препарата и данным символом в колонке комментариев в руководстве к расходным материалам.

КОНТРОЛЬ КАЧЕСТВА

		Контрольные штаммы CLSI®, результаты в системе VITEK 2					
Антимикробный препарат	Код	*E. faecalis* ATCC® 29212™	*S. aureus* ATCC® 29213™	*E. faecalis* ATCC® 51299™	*S. aureus* ATCC® BAA-1026™	*S. aureus* ATCC® BAA-976™	*S. aureus* ATCC® BAA-977™
Ampicillin *Enterococcus* spp. *S. agalactiae*	AM	≤2	0.5 – 2	-	-	-	-
Cefoxitin Screen	OXSF	-	NEG	-	POS	-	-
Ciprofloxacin	CIP	≤0.5 – 2	≤0.5	-	-	-	-
Clindamycin	CM	≥4	≤0.12 – 0.25	-	-	-	-
Daptomycin[NS]	DAP	1 – 4	0.25 – 1	-	-	-	-
Doxycycline	DO	2 – 8	≤0.5	-	-	-	-
Erythromycin	E	1 – 4	≤0.25 – 1	-	-	-	-
Gentamicin	GM	-	≤0.5 – 1	-	-	-	-
Gentamicin High Level (synergy)	HLG	S	-	R	-	-	-
Inducible Clindamycin Resistance	ICR	-	-	-	-	NEG	POS
Levofloxacin	LEV	0.25 – 2	≤0.12 – 0.5	-	-	-	-
Linezolid	LNZ	1 – 4	1 – 4	-	-	-	-
Moxifloxacin	MXF	≤0.25 – 0.5	≤0.25	-	-	-	-
Nitrofurantoin	FT	≤16	≤16 – 32	-	-	-	-
Oxacillin	OX1	-	≤0.25 – 0.5	-	-	-	-
Rifampicin	RA	-	≤0.5	-	-	-	-
Streptomycin High Level (synergy)	HLS	S	-	R	-	-	-
Tetracycline	TE	8 – ≥16	≤1	-	-	-	-
Tigecycline[NS]	TGC	≤0.12	≤0.12 – 0.25	-	-	-	-
Trimethoprim/Sulfamethoxazole	SXT	-	≤10 (0.5/9.5)	-	-	-	-
Vancomycin	VA	1 – 4	≤0.5 – 2	-	-	-	-

Численные значения выражены в µг/мл.
NS = В настоящее время устойчивые штаммы отсутствуют, что исключает получение какого-либо результата, кроме "чувствительный". При получении МИК, соответствующих другой категории чувствительности ("умеренно устойчивый", "устойчивый") следует отправить штамм в референсную лабораторию для дальнейшего анализа.

ОГРАНИЧЕНИЯ

Для следующих сочетаний микроорганизм / антимикробный препарат результат следует подтверждать альтернативным методом:
- Daptomycin: *Streptococcus agalactiae*
- Erythromycin: *Streptococcus agalactiae*

Для следующих сочетаний микроорганизм / антимикробный препарат результат следует подтверждать альтернативным методом при получении результата "положительный":
- Цефокситин скрининг: *Staphylococcus saprophyticus*

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Возможность определения устойчивости на данной карте для следующих сочетаний микроорганизм / антимикробный препарат неизвестна, поскольку на момент сравнительного тестирования при определении рабочих характеристик устойчивые штаммы не были доступны:

- Ampicillin: *Streptococcus agalactiae*
- Linezolid: *Enterococcus* spp., *Staphylococcus* spp., *Streptococcus agalactiae*
- Tigecycline: *Enterococcus* spp., *Staphylococcus* spp., *Streptococcus* spp.

ПРИМЕЧАНИЕ: Результаты для сочетаний антимикробный препарат / микроорганизм, для которых существуют ограничения, можно исключить из лабораторного отчета. Для получения подробной информации смотрите руководство по программному обеспечению.

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⇩ Перед первым использованием данной карты ⇩ НЕОБХОДИМО ввести приведенные в данной инструкции штрих-коды в программу “Flex Panel Entry”.

01 A 3 2 0 7 G 0 P - - - R

02 B A S T - G P 7 5 0 1 H

03 C - - - Z 0 D 3 7 0 H P

04 D 4 7 3 X 3 Y 0 I 1 9 6

05 E 1 8 3 I 1 3 2 N 2 R 6

06 F 0 V 2 0 0 X 1 E 1 H C

07 G 3 K 3 4 3 L - S - F C

ТАБЛИЦА СИМВОЛОВ И ОБОЗНАЧЕНИЙ

Символ	Обозначение
REF	Номер по каталогу
IVD	Для лабораторной диагностики
	Произведено
	Температурные ограничения
	Использовать до
LOT	Номер партии
	Перед использованием прочтите инструкцию
Σ	Содержимого достаточно для <n> тестов
EC REP	Уполномоченный представитель в Европейском Сообществе

ПАТЕНТЫ

Продукт защищен одним или более патентов США: D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 и 6,340,573; и иностранными аналогами. Прочие патенты в процессе регистрации.

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VITEK 2™ — technology

AST-GP67

IVD

Staphylococcus spp., *Enterococcus* spp. and *S. agalactiae* Susceptibility

SUMMARY AND EXPLANATION

The VITEK® 2 Gram Positive Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of ***Staphylococcus* spp., *Enterococcus* spp., and *S. agalactiae*** to antimicrobial agents when used as instructed in the Product Information manual.

INSTRUCTIONS FOR USE

A package insert is provided in the kit or downloadable from **www.biomerieux.com/techlib**

See the Product Information manual for additional Instructions for Use.

STORAGE CONDITIONS

Store at 2° to 8° C.

CONTENTS OF THE CARD

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Ampicillin *Enterococcus* spp. *S. agalactiae*	AM	0.5, 4, 8, 32	- 2 0.25	- 32 16	*Enterococcus* spp., *S. agalactiae*
Benzylpenicillin *Enterococcus* spp. *Staphylococcus* spp. *S. agalactiae*	P	0.125, 0.25, 1, 2, 8, 64	- 0.12 0.03 0.12	- 64 0.5 64	*Staphylococcus* spp., *Enterococcus* spp., *S. agalactiae*
Cefoxitin Screen	OXSF	6	NEG	POS	*Staphylococcus* spp.
Ciprofloxacin	CIP	1, 2, 4	0.5	8	*Staphylococcus* spp., *Enterococcus* spp.
Clindamycin	CM	0.5, 1, 2	0.25	8	*Staphylococcus* spp., *S. agalactiae*
Erythromycin	E❶	0.25, 0.5, 2	0.25	8	*Staphylococcus* spp., *Enterococcus* spp., *S. agalactiae*
Gentamicin	GM	8, 16, 64	0.5	16	*Staphylococcus* spp.
Gentamicin High Level (synergy)	HLG	500	S	R	*Enterococcus* spp.
Inducible Clindamycin Resistance	ICR❷	CM 0.5, CM/E 0.25/0.5	NEG	POS	*Staphylococcus* spp.
Levofloxacin	LEV	0.25, 2, 8	0.12	8	*Staphylococcus* spp., *Enterococcus* spp., *S. agalactiae*
Linezolid	LNZ	0.5, 1, 2	0.5	8	*S. agalactiae*, *E. faecalis*, *E. faecium*, *S. aureus*, *S. epidermidis*, *S. haemolyticus*
Moxifloxacin	MXF	0.25, 2, 8	0.25	8	MSSA**
Nitrofurantoin	FT	16, 32, 64	16	512	*Staphylococcus* spp., *Enterococcus* spp.
Oxacillin	OX1	0.5, 1, 2	0.25	4	*Staphylococcus* spp.
Quinupristin/Dalfopristin	QDA	0.25, 0.5, 2	0.25	16	MSSA**, *S. epidermidis*, VREF**, *S. agalactiae*
Rifampicin	RA	0.25, 0.5, 2	0.5	32	*Staphylococcus* spp.
Streptomycin High Level (synergy)	HLS	1000	S	R	*Enterococcus* spp.
Tetracycline	TE	0.5, 1, 2	1	16	*Staphylococcus* spp., *Enterococcus* spp., *S. agalactiae*
Tigecycline [NS]	TGC	0.25, 0.5, 1	0.12	2	*E. faecalis*, *E. faecium*, *S. aureus*, *S. epidermidis*, *S. haemolyticus*, *S. agalactiae*, *E. casseliflavus*
Trimethoprim/Sulfamethoxazole [c]	SXT❶	2/38, 8/152, 16/304	10 (0.5/9.5)	320 (16/304)	*S. aureus*
Vancomycin	VA❷	1, 2, 4, 8, 16	0.5	32	*Enterococcus* spp., *Staphylococcus* spp., *S. agalactiae*

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Numerical values are expressed in µg/ml.
§ Equivalent standard method concentration by efficacy.
NEG = Negative
POS = Positive
❶,❷ etc. = See performance characteristics identified by the drug code with this symbol in the Comment column in Systems Product Information.
**MSSA = Methicillin-susceptible *S. aureus*
**VREF = Vancomycin-resistant *E. faecium*
[NS] = The current absence of resistant isolates precludes defining any results other than susceptible. Isolates yielding MIC results suggestive of Nonsusceptible category should be submitted to a reference laboratory for further testing.
[c] = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.

QUALITY CONTROL

		CLSI® Quality Control Organisms VITEK 2 Results					
Antimicrobic	Code	*E. faecalis* ATCC® 29212™	*S. aureus* ATCC® 29213™	*E. faecalis* ATCC® 51299™	*S. aureus* ATCC® BAA-1026™	*S. aureus* ATCC® BAA-976™	*S. aureus* ATCC® BAA-977™
Ampicillin *Enterococcus* spp. *S. agalactiae*	AM	≤2	0.5 – 2	-	-	-	-
Benzylpenicillin *Enterococcus* spp. *Staphylococcus* spp. *S. agalactiae*	P	1 – 4	0.25 – ≥0.5	-	-	-	-
Cefoxitin Screen	OXSF	-	NEG	-	POS	-	-
Ciprofloxacin	CIP	≤0.5 – 2	≤0.5	-	-	-	-
Clindamycin	CM	4 – ≥8	≤0.25	-	-	-	-
Erythromycin	E	1 – 4	≤0.25 – 1	-	-	-	-
Gentamicin	GM	-	≤0.5 – 1	-	-	-	-
Gentamicin High Level (synergy)	HLG	S	-	R	-	-	-
Inducible Clindamycin Resistance	ICR	-	-	-	-	NEG	POS
Levofloxacin	LEV	0.25 – 2	≤0.12 – 0.5	-	-	-	-
Linezolid	LNZ	1 – 4	1 – 4	-	-	-	-
Moxifloxacin	MXF	≤0.25 – 0.5	≤0.25	-	-	-	-
Nitrofurantoin	FT	≤16	≤16 – 32	-	-	-	-
Oxacillin	OX1	-	≤0.25 – 0.5	-	-	-	-
Quinupristin/Dalfopristin	QDA	2 – 8	≤0.25 – 1	-	-	-	-
Rifampicin	RA	-	≤0.5	-	-	-	-
Streptomycin High Level (synergy)	HLS	S	-	R	-	-	-
Tetracycline	TE	8 – ≥16	≤1	-	-	-	-
Tigecycline[NS]	TGC	≤0.12	≤0.12 – 0.25	-	-	-	-
Trimethoprim/Sulfamethoxazole[c]	SXT	-	≤10 (0.5/9.5)	-	-	-	-
Vancomycin	VA	1 – 4	≤0.5 – 2	-	-	-	-

Numerical values are expressed in µg/ml.
NEG = Negative
POS = Positive
[NS] = The current absence of resistant isolates precludes defining any results other than susceptible. Isolates yielding MIC results suggestive of Nonsusceptible category should be submitted to a reference laboratory for further testing.
[c] = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.

LIMITATIONS

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

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- Erythromycin: *Streptococcus agalactiae*

Perform an alternative method of testing prior to reporting of results when a Positive (+) result is obtained with the following antibiotic/organism combination(s):
- Cefoxitin Screen: *Staphylococcus saprophyticus*

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:
- Ampicillin: *Streptococcus agalactiae*
- Benzylpenicillin: *Streptococcus agalactiae*
- Linezolid: *Enterococcus* spp., *Staphylococcus* spp., *Streptococcus agalactiae*
- Tigecycline: *Enterococcus* spp., *Staphylococcus* spp., *Streptococcus* spp.

NOTE: A result for an antibiotic/organism combination which may have a limitation may be suppressed from reporting. Refer to the software user manual for instructions.

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⇩ MUST enter the following barcodes into “Flex Panel Entry” program before first use of this Susceptibility Card.

01 A3203L0W---J

02 BAST-GP6701R

03 C---Z0D1F371

04 D0H0P0I1918L

05 E3I132N2R0VF

06 F201W0X1E1H5

07 G3K343L-V-T8

08 H-S-P-K-J-I2

09 I-F-6000000D

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
	Temperature limitation
	Use by
LOT	Batch code
	Consult Instructions for Use
Σ	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community

PATENTS

Product covered by one or more of U.S. Patent Nos. D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 and 6,340,573; and Foreign Counterparts. Other Patents Pending.

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VITEK 2™ — technology

AST-GN69

IVD

Gram Negative Susceptibility Card

SUMMARY AND EXPLANATION

The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of **clinically significant aerobic gram-negative bacilli** to antimicrobial agents when used as instructed in the Product Information manual.

INSTRUCTIONS FOR USE

A package insert is provided in the kit or downloadable from **www.biomerieux.com/techlib**

See the Product Information manual for additional Instructions for Use.

STORAGE CONDITIONS

Store at 2° to 8° C.

CONTENTS OF THE CARD

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Amoxicillin/Clavulanic Acid	AMC	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Ampicillin	AM	4, 8, 32	2	32	CSAGNB**
Ampicillin/Sulbactam	SAM	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Cefazolin	CZ	4, 16, 64	4	64	CSAGNB**
Cefepime	FEP	2, 8, 16, 32	1	64	CSAGNB**
Ceftazidime	CAZ	1, 2, 8, 32	1	64	CSAGNB**
Ceftriaxone	CRO	1, 2, 8, 32	1	64	CSAGNB**
Ciprofloxacin	CIP	0.5, 2, 4	0.25	4	CSAGNB**
Ertapenem [c]	ETP	0.5, 1, 6	0.5	8	*E. coli*, *K. pneumoniae*, *C. freundii*, *C. koseri*, *E. aerogenes*, *E. cloacae*, Kox(-ESBL)**, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *S. marcescens*
ESBL [ı]	ESB	FEP 1, CTX 0.5, CAZ 0.5, FEP/CA 1/10, CTX/CA 0.5/4, CAZ/CA 0.5/4	NEG	POS	*E. coli*, *K. pneumoniae*, *K. oxytoca*
Gentamicin	GM	4, 16, 32	1	16	CSAGNB**
Imipenem	IPM	1, 2, 6, 12	0.25	16	*Acinetobacter* spp., *Citrobacter* spp., *Enterobacter* spp., *E. coli*, *Klebsiella* spp., *M. morganii*, *P. vulgaris*, *Pv. rettgeri*, *P. aeruginosa*, *S. marcescens*, *Pv. stuartii*
Levofloxacin	LEV❷	0.25, 0.5, 2, 8	0.12	8	*E. cloacae*, *E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *S. marcescens*, *A. baumannii*, *A. lwoffii*, *C. koseri*, *C. freundii*, *E. aerogenes*, *E. sakazakii*, *K. oxytoca*, *M. morganii*, *P. agglomerans*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *P. fluorescens*, *C. sakazakii*
Nitrofurantoin	FT	16, 32, 64	16	512	CSAGNB**
Piperacillin/Tazobactam [c]	TZP	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. enterica*
Tobramycin	TM	8, 16, 64	1	16	CSAGNB**

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Trimethoprim/Sulfamethoxazole	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

Numerical values are expressed in µg/ml.
§ Equivalent standard method concentration by efficacy.
**CSAGNB = Clinically significant aerobic gram negative bacilli
[c] = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.
**Kox(-ESBL) = *K. oxytoca* (excluding ESBL producing strains)
Note: For ESBL, FEP is Cefepime, CTX is Cefotaxime, CAZ is Ceftazidime and CA is Clavulanic Acid. For ESBL positive strains, the test interpretation should be reported as resistant for all penicillins, cephalosporins, and aztreonam.
NEG = Negative
POS = Positive
A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.
❶,❷ etc. = See performance characteristics identified by the drug code with this symbol in the Comment column in Systems Product Information.
**Eco(+ETEC) = *E. coli* (including susceptible enterotoxigenic strains implicated in traveler's diarrhea)

QUALITY CONTROL

		CLSI® Quality Control Organisms VITEK 2 Results			
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™	*K. pneumoniae* ssp *pneumoniae* ATCC® 700603™
Amoxicillin/Clavulanic Acid	AMC	≤2/1 – 8/4	-	4/2 – 16/8	-
Ampicillin	AM	≤2 – 8	-	-	-
Ampicillin/Sulbactam	SAM	≤2/1 – 8/4	-	8/4 – ≥32/16	-
Cefazolin	CZ	≤4	-	-	-
Cefepime	FEP	≤1	≤1 – 8	-	-
Ceftazidime	CAZ	≤1	≤1 – 4	-	-
Ceftriaxone	CRO	≤1	8 – ≥64	-	-
Ciprofloxacin	CIP	≤0.25	≤0.25 – 1	-	-
Ertapenem[c]	ETP	≤0.5	2 – ≥8	-	-
ESBL'	ESB	NEG	-	-	POS
Gentamicin	GM	≤1	≤1 – 2	-	-
Imipenem	IPM	≤0.25	1 – 4	-	-
Levofloxacin	LEV	≤0.12	0.5 – 4	-	-
Nitrofurantoin	FT	≤16	-	-	-
Piperacillin/Tazobactam[c]	TZP	≤4/4* *(*FDA/CLSI Broth Microdilution expected QC range = 1/4 – 4/4 µg/ml)*	≤4/4 – 8/4* *(*FDA/CLSI Broth Microdilution expected QC range = 1/4 – 8/4 µg/ml)*	≤4/4* *(*FDA/CLSI Broth Microdilution expected QC range = 0.5/4 – 2/4 µg/ml)*	-
Tobramycin	TM	≤1	≤1	-	-
Trimethoprim/Sulfamethoxazole	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-	-

Numerical values are expressed in µg/ml.
[c] = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.
Note: For ESBL, FEP is Cefepime, CTX is Cefotaxime, CAZ is Ceftazidime and CA is Clavulanic Acid. For ESBL positive strains, the test interpretation should be reported as resistant for all penicillins, cephalosporins, and aztreonam.
NEG = Negative
POS = Positive
A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.

LIMITATIONS

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):
- Amoxicillin/Clavulanic Acid: *Providencia* spp.

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- Ampicillin: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Ampicillin/Sulbactam: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Imipenem: *Serratia marcescens*
- Piperacillin/Tazobactam: *Serratia marcescens*

Perform an alternative method of testing prior to reporting of results when an intermediate or resistant result is obtained with the following antibiotic/organism combination(s):
- Amoxicillin/Clavulanic Acid: *Proteus* spp.

Perform an alternative method of testing prior to reporting results when a resistant result is obtained with the following antibiotic/organism combination(s):
- Imipenem: *Aeromonas* spp.
- Piperacillin/Tazobactam: *Pseudomonas aeruginosa*

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:
- Ertapenem: *E. coli, K. pneumoniae, C. freundii, C. koseri, E. aerogenes, E. cloacae, K. oxytoca* (excluding ESBL producing strains), *M. morganii, P. mirabilis, P. vulgaris, S. marcescens*

NOTE: A result for an antibiotic/organism combination which may have a limitation may be suppressed from reporting. Refer to the software user manual for instructions.

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⇩ MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.

01 A310FY0J---D

02 BAST-GN6901V

03 C---Z070200S

04 D0E1C0G0H0LN

05 E1N110320O1W6

06 F0Y2P052300W

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
	Temperature limitation
	Use by
LOT	Batch code
	Consult Instructions for Use
Σ	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community

PATENTS

Product covered by one or more of U.S. Patent Nos. D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 and 6,340,573; and Foreign Counterparts. Other Patents Pending.

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VITEK 2™ — technology

AST-N203

IVD

Gram Negative Susceptibility Card

SUMMARY AND EXPLANATION

The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of **clinically significant aerobic gram-negative bacilli** to antimicrobial agents when used as instructed in the Product Information manual.

INSTRUCTIONS FOR USE

A package insert is provided in the kit or downloadable from **www.biomerieux.com/techlib**

See the Product Information manual for additional Instructions for Use.

STORAGE CONDITIONS

Store at 2° to 8° C.

CONTENTS OF THE CARD

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Amikacin	AN	8, 16, 64	2	64	CSAGNB**
Amoxicillin/Clavulanic Acid	AMC	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Ampicillin	AM	4, 8, 32	2	32	CSAGNB**
Ampicillin/Sulbactam	SAM	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Cefepime	FEP	2, 8, 16, 32	1	64	CSAGNB**
Cefotaxime	CTX	1, 4, 16, 32	1	64	CSAGNB**
Cefoxitin	FOX	8, 16, 32	4	64	CSAGNB**
Ceftazidime	CAZ	1, 2, 8, 32	1	64	CSAGNB**
Cefuroxime	CXM	2, 8, 32	1	64	CSAGNB**
Ciprofloxacin	CIP	0.5, 2, 4	0.25	4	CSAGNB**
Ertapenem	ETP	0.5, 1, 6	0.5	8	*E. coli*, *K. pneumoniae*, *C. freundii*, *C. koseri*, *E. aerogenes*, *E. cloacae*, Kox(-ESBL)**, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *S. marcescens*
Fosfomycin	FOS	8, 16, 32	16	256	N/A**
Gentamicin	GM	4, 16, 32	1	16	CSAGNB**
Levofloxacin	LEV❷	0.25, 0.5, 2, 8	0.12	8	*E. cloacae*, *E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *S. marcescens*, *A. baumannii*, *A. lwoffii*, *C. koseri*, *C. freundii*, *E. aerogenes*, *E. sakazakii*, *K. oxytoca*, *M. morganii*, *P. agglomerans*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *P. fluorescens*, *C. sakazakii*
Meropenem	MEM❷	0.5, 2, 6, 12	0.25	16	*E. coli*, *K. pneumoniae*, *P. aeruginosa*, *P. mirabilis*, *Acinetobacter* spp., *C. freundii*, *E. cloacae*, *K. oxytoca*, *M. morganii*, *P. vulgaris*, *S. marcescens*, *A. hydrophila*, *C. diversus*, *H. alvei*, *P. multocida*, *Salmonella* spp., *Shigella* spp.
Nitrofurantoin	FT	16, 32, 64	16	512	CSAGNB**
Piperacillin/Tazobactam	TZP	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. enterica*

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Trimethoprim/Sulfamethoxazole	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

Numerical values are expressed in µg/ml.
§ Equivalent standard method concentration by efficacy.
**CSAGNB = Clinically significant aerobic gram negative bacilli
**Kox(-ESBL) = *K. oxytoca* (excluding ESBL producing strains)
**N/A = No specific FDA Indications for Use available
❶,❷ etc. = See performance characteristics identified by the drug code with this symbol in the Comment column in Systems Product Information.
**Eco(+ETEC) = *E. coli* (including susceptible enterotoxigenic strains implicated in traveler's diarrhea)

QUALITY CONTROL

		CLSI® Quality Control Organisms VITEK 2 Results		
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™
Amikacin	AN	≤2 – 4	≤2 – 4	-
Amoxicillin/Clavulanic Acid	AMC	≤2/1 – 8/4	-	4/2 – 16/8
Ampicillin	AM	≤2 – 8	-	-
Ampicillin/Sulbactam	SAM	≤2/1 – 8/4	-	8/4 – ≥32/16
Cefepime	FEP	≤1	≤1 – 8	-
Cefotaxime	CTX	≤1	8 – 32	-
Cefoxitin	FOX	≤4 – 8	-	-
Ceftazidime	CAZ	≤1	≤1 – 4	-
Cefuroxime	CXM	2 – 8	-	-
Ciprofloxacin	CIP	≤0.25	≤0.25 – 1	-
Ertapenem	ETP	≤0.5	2 – ≥8	-
Fosfomycin	FOS	≤16	≤16	-
Gentamicin	GM	≤1	≤1 – 2	-
Levofloxacin	LEV	≤0.12	0.5 – 4	-
Meropenem	MEM	≤0.25	≤0.25 – 1	-
Nitrofurantoin	FT	≤16	-	-
Piperacillin/Tazobactam	TZP	≤4/4	≤4/4 – 8/4	≤4/4
Trimethoprim/Sulfamethoxazole	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-

Numerical values are expressed in µg/ml.

LIMITATIONS

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):
- Amikacin: *Acinetobacter baumannii*
- Amoxicillin/Clavulanic Acid: *Providencia* spp.
- Ampicillin: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Ampicillin/Sulbactam: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Piperacillin/Tazobactam: *Serratia marcescens*

Perform an alternative method of testing prior to reporting of results when an intermediate or resistant result is obtained with the following antibiotic/organism combination(s):
- Amoxicillin/Clavulanic Acid: *Proteus* spp.

Perform an alternative method of testing prior to reporting results when a resistant result is obtained with the following antibiotic/organism combination(s):
- Meropenem: *Aeromonas* spp.
- Piperacillin/Tazobactam: *Pseudomonas aeruginosa*

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The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:

- Ertapenem: *E. coli, K. pneumoniae, C. freundii, C. koseri, E. aerogenes, E. cloacae, K. oxytoca* (excluding ESBL producing strains), *M. morganii, P. mirabilis, P. vulgaris, S. marcescens*

NOTE: A result for an antibiotic/organism combination which may have a limitation may be suppressed from reporting. Refer to the software user manual for instructions.

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⇩ MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.

01 A310FI0K----

02 BAST-N203019

03 C---Z010702B

04 D0O1C0F0K0GI

05 E0I0L1N1O035

06 F1W2G0Y2P23U

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
	Temperature limitation
	Use by
LOT	Batch code
	Consult Instructions for Use
Σ	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community

PATENTS

Product covered by one or more of U.S. Patent Nos. D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 and 6,340,573; and Foreign Counterparts. Other Patents Pending.

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CE

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VITEK 2™ — technology

AST-N214

IVD

Gram Negative Susceptibility Card

SUMMARY AND EXPLANATION

The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of **clinically significant aerobic gram-negative bacilli** to antimicrobial agents when used as instructed in the Product Information manual.

INSTRUCTIONS FOR USE

A package insert is provided in the kit or downloadable from **www.biomerieux.com/techlib**

See the Product Information manual for additional Instructions for Use.

STORAGE CONDITIONS

Store at 2° to 8° C.

CONTENTS OF THE CARD

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Ampicillin	AM	4, 8, 32	2	32	CSAGNB**
Ampicillin/Sulbactam	SAM	4, 16, 32	2	32	N/A**
Cefotaxime	CTX	1, 4, 16, 32	1	64	CSAGNB**
Cefpodoxime	CPD	0.5, 1, 4	0.25	8	CSAGNB**
Ceftazidime	CAZ	1, 2, 8, 32	1	64	CSAGNB**
Cefuroxime	CXM	2, 8, 32	1	64	CSAGNB**
Ciprofloxacin	CIP	0.5, 2, 4	0.25	4	CSAGNB**
Ertapenem	ETP	0.5, 1, 6	0.5	8	*E. coli*, *K. pneumoniae*, *C. freundii*, *C. koseri*, *E. aerogenes*, *E. cloacae*, Kox(-ESBL)**, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *S. marcescens*
ESBL '	ESB	FEP 1, CTX 0.5, CAZ 0.5, FEP/CA 1/10, CTX/CA 0.5/4, CAZ/CA 0.5/4	NEG	POS	*E. coli*, *K. pneumoniae*, *K. oxytoca*
Gentamicin	GM	4, 16, 32	1	16	CSAGNB**
Imipenem	IPM	1, 2, 6, 12	0.25	16	*Acinetobacter* spp., *Citrobacter* spp., *Enterobacter* spp., *E. coli*, *Klebsiella* spp., *M. morganii*, *P. vulgaris*, *Pv. rettgeri*, *P. aeruginosa*, *S. marcescens*, *Pv. stuartii*
Meropenem	MEM❷	0.5, 2, 6, 12	0.25	16	*E. coli*, *K. pneumoniae*, *P. aeruginosa*, *P. mirabilis*, *Acinetobacter* spp., *C. freundii*, *E. cloacae*, *K. oxytoca*, *M. morganii*, *P. vulgaris*, *S. marcescens*, *A. hydrophila*, *C. diversus*, *H. alvei*, *P. multocida*, *Salmonella* spp., *Shigella* spp.
Moxifloxacin	MXF	0.25, 1, 4	0.25	8	*K. pneumoniae*, *C. freundii*, *E. cloacae*, *E. coli*, *K. oxytoca*, *P. mirabilis*
Piperacillin/Tazobactam	TZP	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. enterica*
Tetracycline	TE	2, 4, 8	1	16	CSAGNB**
Tigecycline	TGC	0.75, 2, 4	0.5	8	*C. freundii*, *C. koseri*, *E. coli*, *E. cloacae*, *E. aerogenes*, *K. oxytoca*, *K. pneumoniae*, *S. marcescens*

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Trimethoprim/Sulfamethoxazole	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

Numerical values are expressed in µg/ml.
§ Equivalent standard method concentration by efficacy.
**CSAGNB = Clinically significant aerobic gram negative bacilli
**N/A = No specific FDA Indications for Use available
**Kox(-ESBL) = *K. oxytoca* (excluding ESBL producing strains)
Note: For ESBL, FEP is Cefepime, CTX is Cefotaxime, CAZ is Ceftazidime and CA is Clavulanic Acid. For ESBL positive strains, the test interpretation should be reported as resistant for all penicillins, cephalosporins, and aztreonam.
NEG = Negative
POS = Positive
A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.
❶,❷ etc. = See performance characteristics identified by the drug code with this symbol in the Comment column in Systems Product Information.
**Eco(+ETEC) = *E. coli* (including susceptible enterotoxigenic strains implicated in traveler's diarrhea)

QUALITY CONTROL

		CLSI® Quality Control Organisms VITEK 2 Results			
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™	*K. pneumoniae* ssp *pneumoniae* ATCC® 700603™
Ampicillin	AM	≤2 – 8	-	-	-
Ampicillin/Sulbactam	SAM	≤2 – 8	-	8 – ≥32	-
Cefotaxime	CTX	≤1	8 – 32	-	-
Cefpodoxime	CPD	≤0.25 – 1	-	-	-
Ceftazidime	CAZ	≤1	≤1 – 4	-	-
Cefuroxime	CXM	2 – 8	-	-	-
Ciprofloxacin	CIP	≤0.25	≤0.25 – 1	-	-
Ertapenem	ETP	≤0.5	2 – ≥8	-	-
ESBL'	ESB	NEG	-	-	POS
Gentamicin	GM	≤1	≤1 – 2	-	-
Imipenem	IPM	≤0.25	1 – 4	-	-
Meropenem	MEM	≤0.25	≤0.25 – 1	-	-
Moxifloxacin	MXF	≤0.25	1 – 8	-	-
Piperacillin/Tazobactam	TZP	≤4/4	≤4/4 – 8/4	≤4/4	-
Tetracycline	TE	≤1 – 2	8 – ≥16	-	-
Tigecycline	TGC	≤0.5	-	-	-
Trimethoprim/Sulfamethoxazole	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-	-

Numerical values are expressed in µg/ml.
Note: For ESBL, FEP is Cefepime, CTX is Cefotaxime, CAZ is Ceftazidime and CA is Clavulanic Acid. For ESBL positive strains, the test interpretation should be reported as resistant for all penicillins, cephalosporins, and aztreonam.
NEG = Negative
POS = Positive
A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.

LIMITATIONS

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):
- Ampicillin: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Ampicillin/Sulbactam: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Cefpodoxime: *Morganella morganii, Serratia* spp.
- Imipenem: *Serratia marcescens*
- Piperacillin/Tazobactam: *Serratia marcescens*

Perform an alternative method of testing prior to reporting results when a resistant result is obtained with the following antibiotic/organism combination(s):

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- Imipenem: *Aeromonas* spp.
- Meropenem: *Aeromonas* spp.
- Piperacillin/Tazobactam: *Pseudomonas aeruginosa*

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:

- Ertapenem: *E. coli, K. pneumoniae, C. freundii, C. koseri, E. aerogenes, E. cloacae, K. oxytoca* (excluding ESBL producing strains), *M. morganii, P. mirabilis, P. vulgaris, S. marcescens*
- Tigecycline: *C. freundii, E. cloacae, E. coli, K. oxytoca, K. pneumoniae, C. koseri, E. aerogenes, S. marcescens*

NOTE: A result for an antibiotic/organism combination which may have a limitation may be suppressed from reporting. Refer to the software user manual for instructions.

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⇩ MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.

01 A310GM0J---K

02 BAST-N21401Q

03 C---Z020P0FR

04 D100G0I0L1N7

05 E110320O2G1KC

06 F2P0-1R2300V

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
	Temperature limitation
	Use by
LOT	Batch code
	Consult Instructions for Use
Σ	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community

PATENTS

Product covered by one or more of U.S. Patent Nos. D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 and 6,340,573; and Foreign Counterparts. Other Patents Pending.

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VITEK 2™ — technology

AST-N215

IVD

Gram Negative Susceptibility Card

SUMMARY AND EXPLANATION

The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of **clinically significant aerobic gram-negative bacilli** to antimicrobial agents when used as instructed in the Product Information manual.

INSTRUCTIONS FOR USE

A package insert is provided in the kit or downloadable from **www.biomerieux.com/techlib**

See the Product Information manual for additional Instructions for Use.

STORAGE CONDITIONS

Store at 2° to 8° C.

CONTENTS OF THE CARD

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Amoxicillin/Clavulanic Acid	AMC	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Ampicillin	AM	4, 8, 32	2	32	CSAGNB**
Cefalotin	CF	2, 8, 32	2	64	CSAGNB**
Cefotaxime	CTX	1, 4, 16, 32	1	64	CSAGNB**
Cefoxitin	FOX	8, 16, 32	4	64	CSAGNB**
Cefpodoxime	CPD	0.5, 1, 4	0.25	8	CSAGNB**
Ceftazidime	CAZ	1, 2, 8, 32	1	64	CSAGNB**
Cefuroxime	CXM	2, 8, 32	1	64	CSAGNB**
Ciprofloxacin	CIP	0.5, 2, 4	0.25	4	CSAGNB**
Gentamicin	GM	4, 16, 32	1	16	CSAGNB**
Imipenem	IPM	1, 2, 6, 12	0.25	16	*Acinetobacter* spp., *Citrobacter* spp., *Enterobacter* spp., *E. coli*, *Klebsiella* spp., *M. morganii*, *P. vulgaris*, *Pv. rettgeri*, *P. aeruginosa*, *S. marcescens*, *Pv. stuartii*
Meropenem	MEM❷	0.5, 2, 6, 12	0.25	16	*E. coli*, *K. pneumoniae*, *P. aeruginosa*, *P. mirabilis*, *Acinetobacter* spp., *C. freundii*, *E. cloacae*, *K. oxytoca*, *M. morganii*, *P. vulgaris*, *S. marcescens*, *A. hydrophila*, *C. diversus*, *H. alvei*, *P. multocida*, *Salmonella* spp., *Shigella* spp.
Nitrofurantoin	FT	16, 32, 64	16	512	CSAGNB**
Norfloxacin	NOR	1, 8, 32	0.5	16	CSAGNB**
Piperacillin/Tazobactam	TZP	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. enterica*
Tetracycline	TE	2, 4, 8	1	16	CSAGNB**
Tobramycin	TM	8, 16, 64	1	16	CSAGNB**
Trimethoprim/Sulfamethoxazole	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

Numerical values are expressed in µg/ml.
§ Equivalent standard method concentration by efficacy.
**CSAGNB = Clinically significant aerobic gram negative bacilli

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❶,❷ etc. = See performance characteristics identified by the drug code with this symbol in the Comment column in Systems Product Information.
**Eco(+ETEC) = *E. coli* (including susceptible enterotoxigenic strains implicated in traveler's diarrhea)

QUALITY CONTROL

		CLSI® Quality Control Organisms VITEK 2 Results		
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™
Amoxicillin/Clavulanic Acid	AMC	≤2/1 – 8/4	-	4/2 – 16/8
Ampicillin	AM	≤2 – 8	-	-
Cefalotin	CF	4 – 16	-	-
Cefotaxime	CTX	≤1	8 – 32	-
Cefoxitin	FOX	≤4 – 8	-	-
Cefpodoxime	CPD	≤0.25 – 1	-	-
Ceftazidime	CAZ	≤1	≤1 – 4	-
Cefuroxime	CXM	2 – 8	-	-
Ciprofloxacin	CIP	≤0.25	≤0.25 – 1	-
Gentamicin	GM	≤1	≤1 – 2	-
Imipenem	IPM	≤0.25	1 – 4	-
Meropenem	MEM	≤0.25	≤0.25 – 1	-
Nitrofurantoin	FT	≤16	-	-
Norfloxacin	NOR	≤0.5	1 – 4	-
Piperacillin/Tazobactam	TZP	≤4/4	≤4/4 – 8/4	≤4/4
Tetracycline	TE	≤1 – 2	8 – ≥16	-
Tobramycin	TM	≤1	≤1	-
Trimethoprim/Sulfamethoxazole	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-

Numerical values are expressed in µg/ml.

LIMITATIONS

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):
- Amoxicillin/Clavulanic Acid: *Providencia* spp.
- Ampicillin: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Cefpodoxime: *Morganella morganii, Serratia* spp.
- Imipenem: *Serratia marcescens*
- Piperacillin/Tazobactam: *Serratia marcescens*

Perform an alternative method of testing prior to reporting of results when an intermediate or resistant result is obtained with the following antibiotic/organism combination(s):
- Amoxicillin/Clavulanic Acid: *Proteus* spp.

Perform an alternative method of testing prior to reporting results when a resistant result is obtained with the following antibiotic/organism combination(s):
- Imipenem: *Aeromonas* spp.
- Meropenem: *Aeromonas* spp.
- Piperacillin/Tazobactam: *Pseudomonas aeruginosa*

NOTE: A result for an antibiotic/organism combination which may have a limitation may be suppressed from reporting. Refer to the software user manual for instructions.

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⇩ MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.

01 A310GN0L---5

02 BAST-N21501Z

03 C---Z07020DI

04 D0F0K100G0IP

05 E0L0320O2G0YT

06 F0T2P0-0523U

07 G-O000000000C

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
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	Temperature limitation
	Use by
LOT	Batch code
	Consult Instructions for Use
Σ	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community

PATENTS

Product covered by one or more of U.S. Patent Nos. D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 and 6,340,573; and Foreign Counterparts. Other Patents Pending.

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VITEK 2™ — technology

AST-N340

IVD

Gram Negative Susceptibility Card

SUMMARY AND EXPLANATION

The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of **clinically significant aerobic gram-negative bacilli** to antimicrobial agents when used as instructed in the Product Information manual.

INSTRUCTIONS FOR USE

A package insert is provided in the kit or downloadable from **www.biomerieux.com/techlib**

See the Product Information manual for additional Instructions for Use.

STORAGE CONDITIONS

Store at 2° to 8° C.

CONTENTS OF THE CARD

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Amikacin	AN	8, 16, 64	2	64	CSAGNB**
Amoxicillin/Clavulanic Acid	AMC	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Ampicillin	AM	4, 8, 32	2	32	CSAGNB**
Cefixime	CFM	0.25, 1, 2	0.25	4	N/A**
Cefoxitin	FOX	8, 16, 32	4	64	CSAGNB**
Ceftazidime	CAZ	1, 2, 8, 32	1	64	CSAGNB**
Ceftriaxone	CRO	1, 2, 8, 32	1	64	CSAGNB**
Ciprofloxacin	CIP	0.5, 2, 4	0.25	4	CSAGNB**
Ertapenem	ETP	0.5, 1, 6	0.5	8	*E. coli*, *K. pneumoniae*, *C. freundii*, *C. koseri*, *E. aerogenes*, *E. cloacae*, Kox(-ESBL)**, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *S. marcescens*
Fosfomycin	FOS	8, 16, 32	16	256	N/A**
Gentamicin	GM	4, 16, 32	1	16	CSAGNB**
Mecillinam	MEC	1, 3, 8, 32	1	64	N/A**
Nalidixic Acid	NA	8, 16, 32	2	32	CSAGNB**
Nitrofurantoin	FT	16, 32, 64	16	512	CSAGNB**
Ofloxacin	OFL	0.5, 1, 4	0.25	8	N/A**
Piperacillin/Tazobactam	TZP	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. enterica*
Ticarcillin	TIC	16, 32, 64	8	128	CSAGNB**
Trimethoprim/Sulfamethoxazole	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

Numerical values are expressed in µg/ml.
§ Equivalent standard method concentration by efficacy.
**CSAGNB = Clinically significant aerobic gram negative bacilli
**N/A = No specific FDA Indications for Use available
**Kox(-ESBL) = *K. oxytoca* (excluding ESBL producing strains)
❶,❷ etc. = See performance characteristics identified by the drug code with this symbol in the Comment column in Systems Product Information.
**Eco(+ETEC) = *E. coli* (including susceptible enterotoxigenic strains implicated in traveler's diarrhea)

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QUALITY CONTROL

		CLSI® Quality Control Organisms VITEK 2 Results		
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™
Amikacin	AN	≤2 – 4	≤2 – 4	-
Amoxicillin/Clavulanic Acid	AMC	≤2/1 – 8/4	-	4/2 – 16/8
Ampicillin	AM	≤2 – 8	-	-
Cefixime	CFM	≤0.25 – 1	-	-
Cefoxitin	FOX	≤4 – 8	-	-
Ceftazidime	CAZ	≤1	≤1 – 4	-
Ceftriaxone	CRO	≤1	8 – ≥64	-
Ciprofloxacin	CIP	≤0.25	≤0.25 – 1	-
Ertapenem	ETP	≤0.5	2 – ≥8	-
Fosfomycin	FOS	≤16	≤16	-
Gentamicin	GM	≤1	≤1 – 2	-
Mecillinam	MEC	≤1	-	-
Nalidixic Acid	NA	≤2 – 4	-	-
Nitrofurantoin	FT	≤16	-	-
Ofloxacin	OFL	≤0.25	1 – ≥8	-
Piperacillin/Tazobactam	TZP	≤4/4	≤4/4 – 8/4	≤4/4
Ticarcillin	TIC	≤8 – 16	≤8 – 32	-
Trimethoprim/Sulfamethoxazole	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-

Numerical values are expressed in µg/ml.

LIMITATIONS

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):
- Amikacin: *Acinetobacter baumannii*
- Amoxicillin/Clavulanic Acid: *Providencia* spp.
- Ampicillin: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Piperacillin/Tazobactam: *Serratia marcescens*

Perform an alternative method of testing prior to reporting of results when an intermediate or resistant result is obtained with the following antibiotic/organism combination(s):
- Amoxicillin/Clavulanic Acid: *Proteus* spp.

Perform an alternative method of testing prior to reporting results when a resistant result is obtained with the following antibiotic/organism combination(s):
- Piperacillin/Tazobactam: *Pseudomonas aeruginosa*

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:
- Ertapenem: *E. coli, K. pneumoniae, C. freundii, C. koseri, E. aerogenes, E. cloacae, K. oxytoca* (excluding ESBL producing strains), *M. morganii, P. mirabilis, P. vulgaris, S. marcescens*

NOTE: A result for an antibiotic/organism combination which may have a limitation may be suppressed from reporting. Refer to the software user manual for instructions.

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⇩ MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.

01 A310L30K---D

02 BAST-N34001L

03 C---Z010702B

04 D090K0G0H0L7

05 E1N1O031J0SE

06 F0Y0M2P0N238

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
	Temperature limitation
	Use by
LOT	Batch code
	Consult Instructions for Use
Σ	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community

PATENTS

Product covered by one or more of U.S. Patent Nos. D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 and 6,340,573; and Foreign Counterparts. Other Patents Pending.

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VITEK 2™ — technology

AST-GN79

IVD

Карта для определения чувствительности к антимикробным препаратам грамотрицательных бактерий

КРАТКОЕ ОПИСАНИЕ

Данная карта предназначена для использования с системами VITEK® 2 в клинических лабораториях для лабораторного определения чувствительности к антимикробным препаратам **клинически значимых аэробных грамотрицательных палочек**. Используйте, как указано в руководстве "Расходные материалы".

ПРИМЕНЕНИЕ

Инструкция по применению предоставляется в наборе или может быть загружена с сайта **www.biomerieux.com/techlib**

Для получения дополнительных инструкций по применению смотрите руководство по расходным материалам.

ХРАНЕНИЕ

Хранить при температуре от 2° до 8° C.

СОСТАВ КАРТЫ

Антимикробный препарат	Код	Концентрация §	Диапазон определения ≤	≥	Указания к применению FDA (Управление по контролю за продуктами и лекарствами, США)
Амикацин	AN	8, 16, 64	2	64	CSAGNB**
Ампициллин	AM	4, 8, 32	2	32	CSAGNB**
Ампициллин/Сульбактам	SAM	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Цефазолин	CZ	4, 16, 64	4	64	CSAGNB**
Цефепим	FEP	2, 8, 16, 32	1	64	CSAGNB**
Цефокситин	FOX	8, 16, 32	4	64	CSAGNB**
Цефтазидим	CAZ	1, 2, 8, 32	1	64	CSAGNB**
Цефтриаксон	CRO	1, 2, 8, 32	1	64	CSAGNB**
Ципрофлоксацин	CIP	0.5, 2, 4	0.25	4	CSAGNB**
Эртапенем	ETP	0.5, 1, 6	0.5	8	*E. coli*, *K. pneumoniae*, *C. freundii*, *C. koseri*, *E. aerogenes*, *E. cloacae*, Kox(-ESBL)**, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *S. marcescens*
БЛРС	ESB	FEP 1, CTX 0.5, CAZ 0.5, FEP/CA 1/10, CTX/CA 0.5/4, CAZ/CA 0.5/4	NEG	POS	*E. coli*, *K. pneumoniae*, *K. oxytoca*
Гентамицин	GM	4, 16, 32	1	16	CSAGNB**
Меропенем	MEM❷	0.5, 2, 6, 12	0.25	16	*E. coli*, *K. pneumoniae*, *P. aeruginosa*, *P. mirabilis*, *Acinetobacter* spp., *C. freundii*, *E. cloacae*, *K. oxytoca*, *M. morganii*, *P. vulgaris*, *S. marcescens*, *A. hydrophila*, *C. diversus*, *H. alvei*, *P. multocida*, *Salmonella* spp., *Shigella* spp.
Нитрофурантоин	FT	16, 32, 64	16	512	CSAGNB**
Пиперациллин/тазобактам	TZP	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. enterica*
Тобрамицин	TM	8, 16, 64	1	16	CSAGNB**

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Триметоприм/Сульфаметоксазол	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

Численные значения выражены в µг/мл.
§ Эквивалентна по эффективности концентрации стандартного метода.
**CSAGNB = Клинически значимые аэробные грамотрицательные палочки.
**Kox(-ESBL) = *K. oxytoca* (кроме штаммов, продуцирующих БЛРС).
Прим.: БЛРС FEP = Цефепим, CTX = Цефотаксим, CAZ = Цефтазидим, CA = Клавулановая кислота. Штаммы, продуцирующие БЛРС, устойчивы ко всем пенициллинам, цефалоспоринам, азтреонаму.
NEG = Отрицательный.
POS = Положительный.
Отрицательный результат теста на БЛРС не исключает наличия БЛРС, скрытых бета-лактамазой класса AmpC.
❶,❷ пр. = См. рабочие характеристики с кодом препарата и данным символом в колонке комментариев в руководстве к расходным материалам.
**Eco(+ETEC) = *E. coli* (в т. ч. чувствительные энтеротоксигенные штаммы, вызывающие диарею).

КОНТРОЛЬ КАЧЕСТВА

		Контрольные штаммы CLSI®, результаты в системе VITEK 2			
Антимикробный препарат	Код	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™	*K. pneumoniae* ssp *pneumoniae* ATCC® 700603™
Амикацин	AN	≤2 – 4	≤2 – 4	-	-
Ампициллин	AM	≤2 – 8	-	-	-
Ампициллин/Сульбактам	SAM	≤2/1 – 8/4	-	8/4 – ≥32/16	-
Цефазолин	CZ	≤4	-	-	-
Цефепим	FEP	≤1	≤1 – 8	-	-
Цефокситин	FOX	≤4 – 8	-	-	-
Цефтазидим	CAZ	≤1	≤1 – 4	-	-
Цефтриаксон	CRO	≤1	8 – ≥64	-	-
Ципрофлоксацин	CIP	≤0.25	≤0.25 – 1	-	-
Эртапенем	ETP	≤0.5	2 – ≥8	-	-
БЛРС·	ESB	NEG	-	-	POS
Гентамицин	GM	≤1	≤1 – 2	-	-
Меропенем	MEM	≤0.25	≤0.25 – 1	-	-
Нитрофурантоин	FT	≤16	-	-	-
Пиперациллин/тазобактам	TZP	≤4/4	≤4/4 – 8/4	≤4/4	-
Тобрамицин	TM	≤1	≤1	-	-
Триметоприм/Сульфаметоксазол	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-	-

Численные значения выражены в µг/мл.
Прим.: БЛРС FEP = Цефепим, CTX = Цефотаксим, CAZ = Цефтазидим, CA = Клавулановая кислота. Штаммы, продуцирующие БЛРС, устойчивы ко всем пенициллинам, цефалоспоринам, азтреонаму.
NEG = Отрицательный.
POS = Положительный.
Отрицательный результат теста на БЛРС не исключает наличия БЛРС, скрытых бета-лактамазой класса AmpC.

ОГРАНИЧЕНИЯ

Для следующих сочетаний микроорганизм / антимикробный препарат результат следует подтверждать альтернативным методом:
- Амикацин: *Acinetobacter baumannii*
- Ампициллин: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Ампициллин/Сульбактам: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Пиперациллин/тазобактам: *Serratia marcescens*

Для следующих сочетаний микроорганизм / антимикробный препарат результат следует подтверждать альтернативным методом при получении результата "устойчивый":
- Меропенем: *Aeromonas* spp.

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- Пиперациллин/тазобактам: *Pseudomonas aeruginosa*

Возможность определения устойчивости на данной карте для следующих сочетаний микроорганизм / антимикробный препарат неизвестна, поскольку на момент сравнительного тестирования при определении рабочих характеристик устойчивые штаммы не были доступны:

- Эртапенем: *E. coli, K. pneumoniae, C. freundii, C. koseri, E. aerogenes, E. cloacae, K. oxytoca* (кроме штаммов, продуцирующих БЛРС), *M. morganii, P. mirabilis, P. vulgaris, S. marcescens*

ПРИМЕЧАНИЕ: Результаты для сочетаний антимикробный препарат / микроорганизм, для которых существуют ограничения, можно исключить из лабораторного отчета. Для получения подробной информации смотрите руководство по программному обеспечению.

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⇩ Перед первым использованием данной карты ⇩ НЕОБХОДИМО ввести приведенные в данной инструкции штрих-коды в программу “Flex Panel Entry”.

01 A310G70J---4

02 BAST-GN79012

03 C---Z010200N

04 D0E1C0K0G0HZ

05 E0L1N11032GP

06 F0Y2P052300W

ТАБЛИЦА СИМВОЛОВ И ОБОЗНАЧЕНИЙ

Символ	Обозначение
REF	Номер по каталогу
IVD	Для лабораторной диагностики
	Произведено
	Дата производства
	Температурные ограничения
	Использовать до
LOT	Номер партии
	Перед использованием прочтите инструкцию
Σ	Содержимого достаточно для <n> тестов
EC REP	Уполномоченный представитель в Европейском Сообществе

ПАТЕНТЫ

Продукт защищен одним или более патентов США: D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 и 6,340,573; и иностранными аналогами. Прочие патенты в процессе регистрации.

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VITEK 2™ — technology

AST-GN66

IVD

Gram Negative Susceptibility Card

SUMMARY AND EXPLANATION

The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of **clinically significant aerobic gram-negative bacilli** to antimicrobial agents when used as instructed in the Product Information manual.

INSTRUCTIONS FOR USE

A package insert is provided in the kit or downloadable from **www.biomerieux.com/techlib**

See the Product Information manual for additional Instructions for Use.

STORAGE CONDITIONS

Store at 2° to 8° C.

CONTENTS OF THE CARD

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Ampicillin	AM	4, 8, 32	2	32	CSAGNB**
Ampicillin/Sulbactam	SAM	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Cefazolin	CZ	4, 16, 64	4	64	CSAGNB**
Cefepime	FEP	2, 8, 16, 32	1	64	CSAGNB**
Cefoxitin	FOX	8, 16, 32	4	64	CSAGNB**
Ceftazidime	CAZ	1, 2, 8, 32	1	64	CSAGNB**
Ceftriaxone	CRO	1, 2, 8, 32	1	64	CSAGNB**
Ciprofloxacin	CIP	0.5, 2, 4	0.25	4	CSAGNB**
Ertapenem [c]	ETP	0.5, 1, 6	0.5	8	*E. coli*, *K. pneumoniae*, *C. freundii*, *C. koseri*, *E. aerogenes*, *E. cloacae*, Kox(-ESBL)**, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *S. marcescens*
ESBL [ı]	ESB	FEP 1, CTX 0.5, CAZ 0.5, FEP/CA 1/10, CTX/CA 0.5/4, CAZ/CA 0.5/4	NEG	POS	*E. coli*, *K. pneumoniae*, *K. oxytoca*
Gentamicin	GM	4, 16, 32	1	16	CSAGNB**
Imipenem	IPM	1, 2, 6, 12	0.25	16	*Acinetobacter* spp., *Citrobacter* spp., *Enterobacter* spp., *E. coli*, *Klebsiella* spp., *M. morganii*, *P. vulgaris*, *Pv. rettgeri*, *P. aeruginosa*, *S. marcescens*, *Pv. stuartii*
Levofloxacin	LEV❷	0.25, 0.5, 2, 8	0.12	8	*E. cloacae*, *E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *S. marcescens*, *A. baumannii*, *A. lwoffii*, *C. koseri*, *C. freundii*, *E. aerogenes*, *E. sakazakii*, *K. oxytoca*, *M. morganii*, *P. agglomerans*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *P. fluorescens*, *C. sakazakii*
Nitrofurantoin	FT	16, 32, 64	16	512	CSAGNB**
Piperacillin/Tazobactam [c]	TZP	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. enterica*
Tobramycin	TM	8, 16, 64	1	16	CSAGNB**

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Trimethoprim/Sulfamethoxazole	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

Numerical values are expressed in µg/ml.
§ Equivalent standard method concentration by efficacy.
**CSAGNB = Clinically significant aerobic gram negative bacilli
[c] = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.
**Kox(-ESBL) = *K. oxytoca* (excluding ESBL producing strains)
Note: For ESBL, FEP is Cefepime, CTX is Cefotaxime, CAZ is Ceftazidime and CA is Clavulanic Acid. For ESBL positive strains, the test interpretation should be reported as resistant for all penicillins, cephalosporins, and aztreonam.
NEG = Negative
POS = Positive
A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.
❶,❷ etc. = See performance characteristics identified by the drug code with this symbol in the Comment column in Systems Product Information.
**Eco(+ETEC) = *E. coli* (including susceptible enterotoxigenic strains implicated in traveler's diarrhea)

QUALITY CONTROL

		CLSI® Quality Control Organisms VITEK 2 Results			
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™	*K. pneumoniae* ssp *pneumoniae* ATCC® 700603™
Ampicillin	AM	≤2 – 8	-	-	-
Ampicillin/Sulbactam	SAM	≤2/1 – 8/4	-	8/4 – ≥32/16	-
Cefazolin	CZ	≤4	-	-	-
Cefepime	FEP	≤1	≤1 – 8	-	-
Cefoxitin	FOX	≤4 – 8	-	-	-
Ceftazidime	CAZ	≤1	≤1 – 4	-	-
Ceftriaxone	CRO	≤1	8 – ≥64	-	-
Ciprofloxacin	CIP	≤0.25	≤0.25 – 1	-	-
Ertapenem[c]	ETP	≤0.5	2 – ≥8	-	-
ESBL	ESB	NEG	-	-	POS
Gentamicin	GM	≤1	≤1 – 2	-	-
Imipenem	IPM	≤0.25	1 – 4	-	-
Levofloxacin	LEV	≤0.12	0.5 – 4	-	-
Nitrofurantoin	FT	≤16	-	-	-
Piperacillin/Tazobactam[c]	TZP	≤4/4* *(*FDA/CLSI Broth Microdilution expected QC range = 1/4 – 4/4 µg/ml)*	≤4/4 – 8/4* *(*FDA/CLSI Broth Microdilution expected QC range = 1/4 – 8/4 µg/ml)*	≤4/4* *(*FDA/CLSI Broth Microdilution expected QC range = 0.5/4 – 2/4 µg/ml)*	-
Tobramycin	TM	≤1	≤1	-	-
Trimethoprim/Sulfamethoxazole	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-	-

Numerical values are expressed in µg/ml.
[c] = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.
Note: For ESBL, FEP is Cefepime, CTX is Cefotaxime, CAZ is Ceftazidime and CA is Clavulanic Acid. For ESBL positive strains, the test interpretation should be reported as resistant for all penicillins, cephalosporins, and aztreonam.
NEG = Negative
POS = Positive
A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.

LIMITATIONS

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):
- Ampicillin: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*

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- Ampicillin/Sulbactam: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Imipenem: *Serratia marcescens*
- Piperacillin/Tazobactam: *Serratia marcescens*

Perform an alternative method of testing prior to reporting results when a resistant result is obtained with the following antibiotic/organism combination(s):
- Imipenem: *Aeromonas* spp.
- Piperacillin/Tazobactam: *Pseudomonas aeruginosa*

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:
- Ertapenem: *E. coli, K. pneumoniae, C. freundii, C. koseri, E. aerogenes, E. cloacae, K. oxytoca* (excluding ESBL producing strains), *M. morganii, P. mirabilis, P. vulgaris, S. marcescens*

NOTE: A result for an antibiotic/organism combination which may have a limitation may be suppressed from reporting. Refer to the software user manual for instructions.

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⇩ MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.

01 A310FV0J---W

02 BAST-GN6014

03 C---Z02000E7

04 D1C0K0G0H0LI

05 E1N110320O1W6

06 F0Y2P052300W

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
	Temperature limitation
	Use by
LOT	Batch code
	Consult Instructions for Use
Σ	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community

PATENTS

Product covered by one or more of U.S. Patent Nos. D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 and 6,340,573; and Foreign Counterparts. Other Patents Pending.

WARRANTY

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VITEK 2™ — technology

AST-GN68

IVD

Gram Negative Susceptibility Card

SUMMARY AND EXPLANATION

The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of **clinically significant aerobic gram-negative bacilli** to antimicrobial agents when used as instructed in the Product Information manual.

INSTRUCTIONS FOR USE

A package insert is provided in the kit or downloadable from **www.biomerieux.com/techlib**

See the Product Information manual for additional Instructions for Use.

STORAGE CONDITIONS

Store at 2° to 8° C.

CONTENTS OF THE CARD

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Amikacin	AN	8, 16, 64	2	64	CSAGNB**
Ampicillin	AM	4, 8, 32	2	32	CSAGNB**
Ampicillin/Sulbactam	SAM	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Cefazolin	CZ	4, 16, 64	4	64	CSAGNB**
Cefepime	FEP	2, 8, 16, 32	1	64	CSAGNB**
Ceftazidime	CAZ	1, 2, 8, 32	1	64	CSAGNB**
Ceftriaxone	CRO	1, 2, 8, 32	1	64	CSAGNB**
Ciprofloxacin	CIP	0.5, 2, 4	0.25	4	CSAGNB**
Doripenem [NS]	DOR	0.25, 0.5, 1, 4	0.12	8	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *C. freundii*, *E. cloacae*, *K. oxytoca*, *S. marcescens*
Ertapenem [c]	ETP	0.5, 1, 6	0.5	8	*E. coli*, *K. pneumoniae*, *C. freundii*, *C. koseri*, *E. aerogenes*, *E. cloacae*, Kox(-ESBL)**, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *S. marcescens*
ESBL [,]	ESB	FEP 1, CTX 0.5, CAZ 0.5, FEP/CA 1/10, CTX/CA 0.5/4, CAZ/CA 0.5/4	NEG	POS	*E. coli*, *K. pneumoniae*, *K. oxytoca*
Gentamicin	GM	4, 16, 32	1	16	CSAGNB**
Levofloxacin	LEV❷	0.25, 0.5, 2, 8	0.12	8	*E. cloacae*, *E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *S. marcescens*, *A. baumannii*, *A. lwoffii*, *C. koseri*, *C. freundii*, *E. aerogenes*, *E. sakazakii*, *K. oxytoca*, *M. morganii*, *P. agglomerans*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *P. fluorescens*, *C. sakazakii*
Nitrofurantoin	FT	16, 32, 64	16	512	CSAGNB**
Piperacillin/Tazobactam [c]	TZP	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. enterica*
Tobramycin	TM	8, 16, 64	1	16	CSAGNB**
Trimethoprim/Sulfamethoxazole	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

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Numerical values are expressed in µg/ml.
§ Equivalent standard method concentration by efficacy.
**CSAGNB = Clinically significant aerobic gram negative bacilli
NS = The current absence of resistant isolates precludes defining any results other than susceptible. Isolates yielding MIC results suggestive of Nonsusceptible category should be submitted to a reference laboratory for further testing.
c = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.
**Kox(-ESBL) = *K. oxytoca* (excluding ESBL producing strains)
Note: For ESBL, FEP is Cefepime, CTX is Cefotaxime, CAZ is Ceftazidime and CA is Clavulanic Acid. For ESBL positive strains, the test interpretation should be reported as resistant for all penicillins, cephalosporins, and aztreonam.
NEG = Negative
POS = Positive
A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.
❶,❷ etc. = See performance characteristics identified by the drug code with this symbol in the Comment column in Systems Product Information.
**Eco(+ETEC) = *E. coli* (including susceptible enterotoxigenic strains implicated in traveler's diarrhea)

QUALITY CONTROL

		CLSI® Quality Control Organisms VITEK 2 Results			
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™	*K. pneumoniae* ssp *pneumoniae* ATCC® 700603™
Amikacin	AN	≤2 – 4	≤2 – 4	-	-
Ampicillin	AM	≤2 – 8	-	-	-
Ampicillin/Sulbactam	SAM	≤2/1 – 8/4	-	8/4 – ≥32/16	-
Cefazolin	CZ	≤4	-	-	-
Cefepime	FEP	≤1	≤1 – 8	-	-
Ceftazidime	CAZ	≤1	≤1 – 4	-	-
Ceftriaxone	CRO	≤1	8 – ≥64	-	-
Ciprofloxacin	CIP	≤0.25	≤0.25 – 1	-	-
Doripenem[NS]	DOR	≤0.12	≤0.12 – 0.5	-	-
Ertapenem[c]	ETP	≤0.5	2 – ≥8	-	-
ESBL[·]	ESB	NEG	-	-	POS
Gentamicin	GM	≤1	≤1 – 2	-	-
Levofloxacin	LEV	≤0.12	0.5 – 4	-	-
Nitrofurantoin	FT	≤16	-	-	-
Piperacillin/Tazobactam[c]	TZP	≤4/4* *(*FDA/CLSI Broth Microdilution expected QC range = 1/4 – 4/4 µg/ml)*	≤4/4 – 8/4* *(*FDA/CLSI Broth Microdilution expected QC range = 1/4 – 8/4 µg/ml)*	≤4/4* *(*FDA/CLSI Broth Microdilution expected QC range = 0.5/4 – 2/4 µg/ml)*	-
Tobramycin	TM	≤1	≤1	-	-
Trimethoprim/Sulfamethoxazole	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-	-

Numerical values are expressed in µg/ml.
NS = The current absence of resistant isolates precludes defining any results other than susceptible. Isolates yielding MIC results suggestive of Nonsusceptible category should be submitted to a reference laboratory for further testing.
c = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.
Note: For ESBL, FEP is Cefepime, CTX is Cefotaxime, CAZ is Ceftazidime and CA is Clavulanic Acid. For ESBL positive strains, the test interpretation should be reported as resistant for all penicillins, cephalosporins, and aztreonam.
NEG = Negative
POS = Positive
A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.

LIMITATIONS

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):
- Amikacin: *Acinetobacter baumannii*
- Ampicillin: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*

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- Ampicillin/Sulbactam: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Piperacillin/Tazobactam: *Serratia marcescens*

Perform an alternative method of testing prior to reporting results when a resistant result is obtained with the following antibiotic/organism combination(s):
- Piperacillin/Tazobactam: *Pseudomonas aeruginosa*

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:
- Ertapenem: *E. coli, K. pneumoniae, C. freundii, C. koseri, E. aerogenes, E. cloacae, K. oxytoca* (excluding ESBL producing strains), *M. morganii, P. mirabilis, P. vulgaris, S. marcescens*

NOTE: A result for an antibiotic/organism combination which may have a limitation may be suppressed from reporting. Refer to the software user manual for instructions.

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⇩ MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.

01 A310FX0J---7

02 BAST-GN6801M

03 C---Z010200N

04 D0E1C0G0H0LN

05 E2A1N11031WE

06 F0Y2P052300W

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
	Temperature limitation
	Use by
LOT	Batch code
	Consult Instructions for Use
Σ	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community

PATENTS

Product covered by one or more of U.S. Patent Nos. D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 and 6,340,573; and Foreign Counterparts. Other Patents Pending.

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VITEK 2™ — technology

AST-GN71

IVD

Gram Negative Susceptibility Card

SUMMARY AND EXPLANATION

The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of **clinically significant aerobic gram-negative bacilli** to antimicrobial agents when used as instructed in the Product Information manual.

INSTRUCTIONS FOR USE

A package insert is provided in the kit or downloadable from **www.biomerieux.com/techlib**

See the Product Information manual for additional Instructions for Use.

STORAGE CONDITIONS

Store at 2° to 8° C.

CONTENTS OF THE CARD

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Amikacin	AN	8, 16, 64	2	64	CSAGNB**
Ampicillin	AM	4, 8, 32	2	32	CSAGNB**
Ampicillin/Sulbactam	SAM	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Aztreonam	ATM	2, 8, 32	1	64	CSAGNB**
Cefazolin	CZ	4, 16, 64	4	64	CSAGNB**
Cefepime	FEP	2, 8, 16, 32	1	64	CSAGNB**
Ceftriaxone	CRO	1, 2, 8, 32	1	64	CSAGNB**
Ciprofloxacin	CIP	0.5, 2, 4	0.25	4	CSAGNB**
Ertapenem [c]	ETP	0.5, 1, 6	0.5	8	*E. coli*, *K. pneumoniae*, *C. freundii*, *C. koseri*, *E. aerogenes*, *E. cloacae*, Kox(-ESBL)**, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *S. marcescens*
ESBL [ı]	ESB	FEP 1, CTX 0.5, CAZ 0.5, FEP/CA 1/10, CTX/CA 0.5/4, CAZ/CA 0.5/4	NEG	POS	*E. coli*, *K. pneumoniae*, *K. oxytoca*
Gentamicin	GM	4, 16, 32	1	16	CSAGNB**
Imipenem	IPM	1, 2, 6, 12	0.25	16	*Acinetobacter* spp., *Citrobacter* spp., *Enterobacter* spp., *E. coli*, *Klebsiella* spp., *M. morganii*, *P. vulgaris*, *Pv. rettgeri*, *P. aeruginosa*, *S. marcescens*, *Pv. stuartii*
Meropenem	MEM❷	0.5, 2, 6, 12	0.25	16	*E. coli*, *K. pneumoniae*, *P. aeruginosa*, *P. mirabilis*, *Acinetobacter* spp., *C. freundii*, *E. cloacae*, *K. oxytoca*, *M. morganii*, *P. vulgaris*, *S. marcescens*, *A. hydrophila*, *C. diversus*, *H. alvei*, *P. multocida*, *Salmonella* spp., *Shigella* spp.
Moxifloxacin	MXF	0.25, 1, 4	0.25	8	*K. pneumoniae*, *C. freundii*, *E. cloacae*, *E. coli*, *K. oxytoca*, *P. mirabilis*
Nitrofurantoin	FT	16, 32, 64	16	512	CSAGNB**
Tigecycline [c]	TGC	0.75, 2, 4	0.5	8	*C. freundii*, *C. koseri*, *E. coli*, *E. cloacae*, *E. aerogenes*, *K. oxytoca*, *K. pneumoniae*, *S. marcescens*
Tobramycin	TM	8, 16, 64	1	16	CSAGNB**

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Trimethoprim/Sulfamethoxazole	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

Numerical values are expressed in µg/ml.
§ Equivalent standard method concentration by efficacy.
**CSAGNB = Clinically significant aerobic gram negative bacilli
[c] = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.
**Kox(-ESBL) = *K. oxytoca* (excluding ESBL producing strains)
Note: For ESBL, FEP is Cefepime, CTX is Cefotaxime, CAZ is Ceftazidime and CA is Clavulanic Acid. For ESBL positive strains, the test interpretation should be reported as resistant for all penicillins, cephalosporins, and aztreonam.
NEG = Negative
POS = Positive
A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.
❶,❷ etc. = See performance characteristics identified by the drug code with this symbol in the Comment column in Systems Product Information.
**Eco(+ETEC) = *E. coli* (including susceptible enterotoxigenic strains implicated in traveler's diarrhea)

QUALITY CONTROL

		CLSI® Quality Control Organisms VITEK 2 Results			
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™	*K. pneumoniae* ssp *pneumoniae* ATCC® 700603™
Amikacin	AN	≤2 – 4	≤2 – 4	-	-
Ampicillin	AM	≤2 – 8	-	-	-
Ampicillin/Sulbactam	SAM	≤2/1 – 8/4	-	8/4 – ≥32/16	-
Aztreonam	ATM	≤1	2 – 8	-	-
Cefazolin	CZ	≤4	-	-	-
Cefepime	FEP	≤1	≤1 – 8	-	-
Ceftriaxone	CRO	≤1	8 – ≥64	-	-
Ciprofloxacin	CIP	≤0.25	≤0.25 – 1	-	-
Ertapenem[c]	ETP	≤0.5	2 – ≥8	-	-
ESBL'	ESB	NEG	-	-	POS
Gentamicin	GM	≤1	≤1 – 2	-	-
Imipenem	IPM	≤0.25	1 – 4	-	-
Meropenem	MEM	≤0.25	≤0.25 – 1	-	-
Moxifloxacin	MXF	≤0.25	1 – 8	-	-
Nitrofurantoin	FT	≤16	-	-	-
Tigecycline[c]	TGC	≤0.5	-	-	-
Tobramycin	TM	≤1	≤1	-	-
Trimethoprim/Sulfamethoxazole	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-	-

Numerical values are expressed in µg/ml.
[c] = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.
Note: For ESBL, FEP is Cefepime, CTX is Cefotaxime, CAZ is Ceftazidime and CA is Clavulanic Acid. For ESBL positive strains, the test interpretation should be reported as resistant for all penicillins, cephalosporins, and aztreonam.
NEG = Negative
POS = Positive
A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.

LIMITATIONS

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):
- Amikacin: *Acinetobacter baumannii*
- Ampicillin: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Ampicillin/Sulbactam: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*

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- Aztreonam: *Pseudomonas* spp.
- Imipenem: *Serratia marcescens*

Perform an alternative method of testing prior to reporting results when a resistant result is obtained with the following antibiotic/organism combination(s):
- Imipenem: *Aeromonas* spp.
- Meropenem: *Aeromonas* spp.

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:
- Ertapenem: *E. coli, K. pneumoniae, C. freundii, C. koseri, E. aerogenes, E. cloacae, K. oxytoca* (excluding ESBL producing strains), *M. morganii, P. mirabilis, P. vulgaris, S. marcescens*
- Tigecycline: *C. freundii, E. cloacae, E. coli, K. oxytoca, K. pneumoniae, C. koseri, E. aerogenes, S. marcescens*

NOTE: A result for an antibiotic/organism combination which may have a limitation may be suppressed from reporting. Refer to the software user manual for instructions.

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⇩ MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.

01 A310F-0J---P

02 BAST-GN71014

03 C--01020008Y

04 D0E1C0H0L1NO

05 E1103202G1KC

06 F0Y1R0523001

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
	Temperature limitation
	Use by
LOT	Batch code
	Consult Instructions for Use
Σ	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community

PATENTS

Product covered by one or more of U.S. Patent Nos. D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 and 6,340,573; and Foreign Counterparts. Other Patents Pending.

WARRANTY

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CE

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VITEK 2™ — technology

AST-GN73

IVD

Карта для определения чувствительности к антимикробным препаратам грамотрицательных бактерий

КРАТКОЕ ОПИСАНИЕ

Данная карта предназначена для использования с системами VITEK® 2 в клинических лабораториях для лабораторного определения чувствительности к антимикробным препаратам **клинически значимых аэробных грамотрицательных палочек**. Используйте, как указано в руководстве "Расходные материалы".

ПРИМЕНЕНИЕ

Инструкция по применению предоставляется в наборе или может быть загружена с сайта **www.biomerieux.com/techlib**

Для получения дополнительных инструкций по применению смотрите руководство по расходным материалам.

ХРАНЕНИЕ

Хранить при температуре от 2° до 8° C.

СОСТАВ КАРТЫ

Антимикробный препарат	Код	Концентрация §	Диапазон определения ≤	≥	Указания к применению FDA (Управление по контролю за продуктами и лекарствами, США)
Амикацин	AN	8, 16, 64	2	64	CSAGNB**
Ампициллин	AM	4, 8, 32	2	32	CSAGNB**
Ампициллин/Сульбактам	SAM	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Цефазолин	CZ	4, 16, 64	4	64	CSAGNB**
Цефепим	FEP	2, 8, 16, 32	1	64	CSAGNB**
Цефокситин	FOX	8, 16, 32	4	64	CSAGNB**
Цефтазидим	CAZ	1, 2, 8, 32	1	64	CSAGNB**
Цефтриаксон	CRO	1, 2, 8, 32	1	64	CSAGNB**
Ципрофлоксацин	CIP	0.5, 2, 4	0.25	4	CSAGNB**
БЛРС '	ESB	FEP 1, CTX 0.5, CAZ 0.5, FEP/CA 1/10, CTX/CA 0.5/4, CAZ/CA 0.5/4	NEG	POS	*E. coli*, *K. pneumoniae*, *K. oxytoca*
Гентамицин	GM	4, 16, 32	1	16	CSAGNB**
Левофлоксацин	LEV❷	0.25, 0.5, 2, 8	0.12	8	*E. cloacae*, *E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *S. marcescens*, *A. baumannii*, *A. lwoffii*, *C. koseri*, *C. freundii*, *E. aerogenes*, *E. sakazakii*, *K. oxytoca*, *M. morganii*, *P. agglomerans*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *P. fluorescens*, *C. sakazakii*
Меропенем	MEM❷	0.5, 2, 6, 12	0.25	16	*E. coli*, *K. pneumoniae*, *P. aeruginosa*, *P. mirabilis*, *Acinetobacter* spp., *C. freundii*, *E. cloacae*, *K. oxytoca*, *M. morganii*, *P. vulgaris*, *S. marcescens*, *A. hydrophila*, *C. diversus*, *H. alvei*, *P. multocida*, *Salmonella* spp., *Shigella* spp.
Нитрофурантоин	FT	16, 32, 64	16	512	CSAGNB**
Пиперациллин/тазобактам	TZP	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. enterica*
Тобрамицин	TM	8, 16, 64	1	16	CSAGNB**

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Триметоприм/Сульфаметоксазол	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

Численные значения выражены в µг/мл.
§ Эквивалентна по эффективности концентрации стандартного метода.
**CSAGNB = Клинически значимые аэробные грамотрицательные палочки.
Прим.: БЛРС FEP = Цефепим, CTX = Цефотаксим, CAZ = Цефтазидим, CA = Клавулановая кислота. Штаммы, продуцирующие БЛРС, устойчивы ко всем пенициллинам, цефалоспоринам, азтреонаму.
NEG = Отрицательный.
POS = Положительный.
Отрицательный результат теста на БЛРС не исключает наличия БЛРС, скрытых бета-лактамазой класса AmpC.
❶,❷ пр. = См. рабочие характеристики с кодом препарата и данным символом в колонке комментариев в руководстве к расходным материалам.
**Eco(+ETEC) = *E. coli* (в т. ч. чувствительные энтеротоксигенные штаммы, вызывающие диарею).

КОНТРОЛЬ КАЧЕСТВА

		Контрольные штаммы CLSI®, результаты в системе VITEK 2			
Антимикробный препарат	Код	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™	*K. pneumoniae* ssp *pneumoniae* ATCC® 700603™
Амикацин	AN	≤2 – 4	≤2 – 4	-	-
Ампициллин	AM	≤2 – 8	-	-	-
Ампициллин/Сульбактам	SAM	≤2/1 – 8/4	-	8/4 – ≥32/16	-
Цефазолин	CZ	≤4	-	-	-
Цефепим	FEP	≤1	≤1 – 8	-	-
Цефокситин	FOX	≤4 – 8	-	-	-
Цефтазидим	CAZ	≤1	≤1 – 4	-	-
Цефтриаксон	CRO	≤1	8 – ≥64	-	-
Ципрофлоксацин	CIP	≤0.25	≤0.25 – 1	-	-
БЛРС·	ESB	NEG	-	-	POS
Гентамицин	GM	≤1	≤1 – 2	-	-
Левофлоксацин	LEV	≤0.12	0.5 – 4	-	-
Меропенем	MEM	≤0.25	≤0.25 – 1	-	-
Нитрофурантоин	FT	≤16	-	-	-
Пиперациллин/тазобактам	TZP	≤4/4	≤4/4 – 8/4	≤4/4	-
Тобрамицин	TM	≤1	≤1	-	-
Триметоприм/Сульфаметоксазол	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-	-

Численные значения выражены в µг/мл.
Прим.: БЛРС FEP = Цефепим, CTX = Цефотаксим, CAZ = Цефтазидим, CA = Клавулановая кислота. Штаммы, продуцирующие БЛРС, устойчивы ко всем пенициллинам, цефалоспоринам, азтреонаму.
NEG = Отрицательный.
POS = Положительный.
Отрицательный результат теста на БЛРС не исключает наличия БЛРС, скрытых бета-лактамазой класса AmpC.

ОГРАНИЧЕНИЯ

Для следующих сочетаний микроорганизм / антимикробный препарат результат следует подтверждать альтернативным методом:
- Амикацин: *Acinetobacter baumannii*
- Ампициллин: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Ампициллин/Сульбактам: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Пиперациллин/тазобактам: *Serratia marcescens*

Для следующих сочетаний микроорганизм / антимикробный препарат результат следует подтверждать альтернативным методом при получении результата "устойчивый":
- Меропенем: *Aeromonas* spp.
- Пиперациллин/тазобактам: *Pseudomonas aeruginosa*

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ПРИМЕЧАНИЕ: Результаты для сочетаний антимикробный препарат / микроорганизм, для которых существуют ограничения, можно исключить из лабораторного отчета. Для получения подробной информации смотрите руководство по программному обеспечению.

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⇩ Перед первым использованием данной карты НЕОБХОДИМО ввести приведенные в данной инструкции штрих-коды в программу “Flex Panel Entry”.

01 A310G10J---5

02 BAST-GN7301M

03 C---Z010200N

04 D0E1C0K0G0HZ

05 E0L11031W2G7

06 F0Y2P052300W

ТАБЛИЦА СИМВОЛОВ И ОБОЗНАЧЕНИЙ

Символ	Обозначение
REF	Номер по каталогу
IVD	Для лабораторной диагностики
	Произведено
	Дата производства
	Температурные ограничения
	Использовать до
LOT	Номер партии
	Перед использованием прочтите инструкцию
Σ	Содержимого достаточно для <n> тестов
EC REP	Уполномоченный представитель в Европейском Сообществе

ПАТЕНТЫ

Продукт защищен одним или более патентов США: D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 и 6,340,573; и иностранными аналогами. Прочие патенты в процессе регистрации.

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VITEK 2™ — technology

AST-GN67

IVD

Gram Negative Susceptibility Card

SUMMARY AND EXPLANATION

The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of **clinically significant aerobic gram-negative bacilli** to antimicrobial agents when used as instructed in the Product Information manual.

INSTRUCTIONS FOR USE

A package insert is provided in the kit or downloadable from **www.biomerieux.com/techlib**

See the Product Information manual for additional Instructions for Use.

STORAGE CONDITIONS

Store at 2° to 8° C.

CONTENTS OF THE CARD

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Amikacin	AN	8, 16, 64	2	64	CSAGNB**
Ampicillin	AM	4, 8, 32	2	32	CSAGNB**
Ampicillin/Sulbactam	SAM	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Cefazolin	CZ	4, 16, 64	4	64	CSAGNB**
Cefepime	FEP	2, 8, 16, 32	1	64	CSAGNB**
Ceftazidime	CAZ	1, 2, 8, 32	1	64	CSAGNB**
Ceftriaxone	CRO	1, 2, 8, 32	1	64	CSAGNB**
Ciprofloxacin	CIP	0.5, 2, 4	0.25	4	CSAGNB**
Ertapenem [c]	ETP	0.5, 1, 6	0.5	8	*E. coli*, *K. pneumoniae*, *C. freundii*, *C. koseri*, *E. aerogenes*, *E. cloacae*, Kox(-ESBL)**, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *S. marcescens*
ESBL [ı]	ESB	FEP 1, CTX 0.5, CAZ 0.5, FEP/CA 1/10, CTX/CA 0.5/4, CAZ/CA 0.5/4	NEG	POS	*E. coli*, *K. pneumoniae*, *K. oxytoca*
Gentamicin	GM	4, 16, 32	1	16	CSAGNB**
Imipenem	IPM	1, 2, 6, 12	0.25	16	*Acinetobacter* spp., *Citrobacter* spp., *Enterobacter* spp., *E. coli*, *Klebsiella* spp., *M. morganii*, *P. vulgaris*, *Pv. rettgeri*, *P. aeruginosa*, *S. marcescens*, *Pv. stuartii*
Levofloxacin	LEV❷	0.25, 0.5, 2, 8	0.12	8	*E. cloacae*, *E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *S. marcescens*, *A. baumannii*, *A. lwoffii*, *C. koseri*, *C. freundii*, *E. aerogenes*, *E. sakazakii*, *K. oxytoca*, *M. morganii*, *P. agglomerans*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *P. fluorescens*, *C. sakazakii*
Nitrofurantoin	FT	16, 32, 64	16	512	CSAGNB**
Piperacillin/Tazobactam [c]	TZP	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. enterica*
Tobramycin	TM	8, 16, 64	1	16	CSAGNB**

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Trimethoprim/Sulfamethoxazole	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

Numerical values are expressed in µg/ml.
§ Equivalent standard method concentration by efficacy.
**CSAGNB = Clinically significant aerobic gram negative bacilli
[c] = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.
**Kox(-ESBL) = *K. oxytoca* (excluding ESBL producing strains)
Note: For ESBL, FEP is Cefepime, CTX is Cefotaxime, CAZ is Ceftazidime and CA is Clavulanic Acid. For ESBL positive strains, the test interpretation should be reported as resistant for all penicillins, cephalosporins, and aztreonam.
NEG = Negative
POS = Positive
A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.
❶,❷ etc. = See performance characteristics identified by the drug code with this symbol in the Comment column in Systems Product Information.
**Eco(+ETEC) = *E. coli* (including susceptible enterotoxigenic strains implicated in traveler's diarrhea)

QUALITY CONTROL

		CLSI® Quality Control Organisms VITEK 2 Results			
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™	*K. pneumoniae* ssp *pneumoniae* ATCC® 700603™
Amikacin	AN	≤2 – 4	≤2 – 4	-	-
Ampicillin	AM	≤2 – 8	-	-	-
Ampicillin/Sulbactam	SAM	≤2/1 – 8/4	-	8/4 – ≥32/16	-
Cefazolin	CZ	≤4	-	-	-
Cefepime	FEP	≤1	≤1 – 8	-	-
Ceftazidime	CAZ	≤1	≤1 – 4	-	-
Ceftriaxone	CRO	≤1	8 – ≥64	-	-
Ciprofloxacin	CIP	≤0.25	≤0.25 – 1	-	-
Ertapenem[c]	ETP	≤0.5	2 – ≥8	-	-
ESBL*	ESB	NEG	-	-	POS
Gentamicin	GM	≤1	≤1 – 2	-	-
Imipenem	IPM	≤0.25	1 – 4	-	-
Levofloxacin	LEV	≤0.12	0.5 – 4	-	-
Nitrofurantoin	FT	≤16	-	-	-
Piperacillin/Tazobactam[c]	TZP	≤4/4* *(*FDA/CLSI Broth Microdilution expected QC range = 1/4 – 4/4 µg/ml)*	≤4/4 – 8/4* *(*FDA/CLSI Broth Microdilution expected QC range = 1/4 – 8/4 µg/ml)*	≤4/4* *(*FDA/CLSI Broth Microdilution expected QC range = 0.5/4 – 2/4 µg/ml)*	-
Tobramycin	TM	≤1	≤1	-	-
Trimethoprim/Sulfamethoxazole	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-	-

Numerical values are expressed in µg/ml.
[c] = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.
Note: For ESBL, FEP is Cefepime, CTX is Cefotaxime, CAZ is Ceftazidime and CA is Clavulanic Acid. For ESBL positive strains, the test interpretation should be reported as resistant for all penicillins, cephalosporins, and aztreonam.
NEG = Negative
POS = Positive
A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.

LIMITATIONS

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):
- Amikacin: *Acinetobacter baumannii*

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- Ampicillin: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Ampicillin/Sulbactam: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Imipenem: *Serratia marcescens*
- Piperacillin/Tazobactam: *Serratia marcescens*

Perform an alternative method of testing prior to reporting results when a resistant result is obtained with the following antibiotic/organism combination(s):
- Imipenem: *Aeromonas* spp.
- Piperacillin/Tazobactam: *Pseudomonas aeruginosa*

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:
- Ertapenem: *E. coli, K. pneumoniae, C. freundii, C. koseri, E. aerogenes, E. cloacae, K. oxytoca* (excluding ESBL producing strains), *M. morganii, P. mirabilis, P. vulgaris, S. marcescens*

NOTE: A result for an antibiotic/organism combination which may have a limitation may be suppressed from reporting. Refer to the software user manual for instructions.

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⇩ MUST enter the following barcodes into “Flex Panel Entry” program before first use of this Susceptibility Card.

01 A310FW0J---1

02 BAST-GN6701D

03 C---Z010200N

04 D0E1C0G0H0LN

05 E1N110320O1W6

06 F0Y2P052300W

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
	Temperature limitation
	Use by
LOT	Batch code
	Consult Instructions for Use
Σ	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community

PATENTS

Product covered by one or more of U.S. Patent Nos. D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 and 6,340,573; and Foreign Counterparts. Other Patents Pending.

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VITEK 2™ — technology

AST-GN70

IVD

Gram Negative Susceptibility Card

SUMMARY AND EXPLANATION

The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of **clinically significant aerobic gram-negative bacilli** to antimicrobial agents when used as instructed in the Product Information manual.

INSTRUCTIONS FOR USE

A package insert is provided in the kit or downloadable from **www.biomerieux.com/techlib**

See the Product Information manual for additional Instructions for Use.

STORAGE CONDITIONS

Store at 2° to 8° C.

CONTENTS OF THE CARD

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Amikacin	AN	8, 16, 64	2	64	CSAGNB**
Ampicillin	AM	4, 8, 32	2	32	CSAGNB**
Ampicillin/Sulbactam	SAM	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Aztreonam	ATM	2, 8, 32	1	64	CSAGNB**
Cefazolin	CZ	4, 16, 64	4	64	CSAGNB**
Cefepime	FEP	2, 8, 16, 32	1	64	CSAGNB**
Ceftriaxone	CRO	1, 2, 8, 32	1	64	CSAGNB**
Ciprofloxacin	CIP	0.5, 2, 4	0.25	4	CSAGNB**
Ertapenem [c]	ETP	0.5, 1, 6	0.5	8	*E. coli*, *K. pneumoniae*, *C. freundii*, *C. koseri*, *E. aerogenes*, *E. cloacae*, Kox(-ESBL)**, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *S. marcescens*
ESBL [ı]	ESB	FEP 1, CTX 0.5, CAZ 0.5, FEP/CA 1/10, CTX/CA 0.5/4, CAZ/CA 0.5/4	NEG	POS	*E. coli*, *K. pneumoniae*, *K. oxytoca*
Gentamicin	GM	4, 16, 32	1	16	CSAGNB**
Meropenem	MEM❷	0.5, 2, 6, 12	0.25	16	*E. coli*, *K. pneumoniae*, *P. aeruginosa*, *P. mirabilis*, *Acinetobacter* spp., *C. freundii*, *E. cloacae*, *K. oxytoca*, *M. morganii*, *P. vulgaris*, *S. marcescens*, *A. hydrophila*, *C. diversus*, *H. alvei*, *P. multocida*, *Salmonella* spp., *Shigella* spp.
Nitrofurantoin	FT	16, 32, 64	16	512	CSAGNB**
Piperacillin/Tazobactam [c]	TZP	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. enterica*
Tigecycline [c]	TGC	0.75, 2, 4	0.5	8	*C. freundii*, *C. koseri*, *E. coli*, *E. cloacae*, *E. aerogenes*, *K. oxytoca*, *K. pneumoniae*, *S. marcescens*
Tobramycin	TM	8, 16, 64	1	16	CSAGNB**
Trimethoprim/Sulfamethoxazole	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

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Numerical values are expressed in µg/ml.
§ Equivalent standard method concentration by efficacy.
**CSAGNB = Clinically significant aerobic gram negative bacilli
[c] = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.
**Kox(-ESBL) = *K. oxytoca* (excluding ESBL producing strains)
Note: For ESBL, FEP is Cefepime, CTX is Cefotaxime, CAZ is Ceftazidime and CA is Clavulanic Acid. For ESBL positive strains, the test interpretation should be reported as resistant for all penicillins, cephalosporins, and aztreonam.
NEG = Negative
POS = Positive
A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.
❶,❷ etc. = See performance characteristics identified by the drug code with this symbol in the Comment column in Systems Product Information.
**Eco(+ETEC) = *E. coli* (including susceptible enterotoxigenic strains implicated in traveler's diarrhea)

QUALITY CONTROL

		CLSI® Quality Control Organisms VITEK 2 Results			
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™	*K. pneumoniae* ssp *pneumoniae* ATCC® 700603™
Amikacin	AN	≤2 – 4	≤2 – 4	-	-
Ampicillin	AM	≤2 – 8	-	-	-
Ampicillin/Sulbactam	SAM	≤2/1 – 8/4	-	8/4 – ≥32/16	-
Aztreonam	ATM	≤1	2 – 8	-	-
Cefazolin	CZ	≤4	-	-	-
Cefepime	FEP	≤1	≤1 – 8	-	-
Ceftriaxone	CRO	≤1	8 – ≥64	-	-
Ciprofloxacin	CIP	≤0.25	≤0.25 – 1	-	-
Ertapenem[c]	ETP	≤0.5	2 – ≥8	-	-
ESBL❶	ESB	NEG	-	-	POS
Gentamicin	GM	≤1	≤1 – 2	-	-
Meropenem	MEM	≤0.25	≤0.25 – 1	-	-
Nitrofurantoin	FT	≤16	-	-	-
Piperacillin/Tazobactam[c]	TZP	≤4/4* *(*FDA/CLSI Broth Microdilution expected QC range = 1/4 – 4/4 µg/ml)*	≤4/4 – 8/4* *(*FDA/CLSI Broth Microdilution expected QC range = 1/4 – 8/4 µg/ml)*	≤4/4* *(*FDA/CLSI Broth Microdilution expected QC range = 0.5/4 – 2/4 µg/ml)*	-
Tigecycline[c]	TGC	≤0.5	-	-	-
Tobramycin	TM	≤1	≤1	-	-
Trimethoprim/Sulfamethoxazole	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-	-

Numerical values are expressed in µg/ml.
[c] = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.
Note: For ESBL, FEP is Cefepime, CTX is Cefotaxime, CAZ is Ceftazidime and CA is Clavulanic Acid. For ESBL positive strains, the test interpretation should be reported as resistant for all penicillins, cephalosporins, and aztreonam.
NEG = Negative
POS = Positive
A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.

LIMITATIONS

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):
- Amikacin: *Acinetobacter baumannii*
- Ampicillin: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Ampicillin/Sulbactam: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Aztreonam: *Pseudomonas* spp.
- Piperacillin/Tazobactam: *Serratia marcescens*

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Perform an alternative method of testing prior to reporting results when a resistant result is obtained with the following antibiotic/organism combination(s):
- Meropenem: *Aeromonas* spp.
- Piperacillin/Tazobactam: *Pseudomonas aeruginosa*

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:
- Ertapenem: *E. coli, K. pneumoniae, C. freundii, C. koseri, E. aerogenes, E. cloacae, K. oxytoca* (excluding ESBL producing strains), *M. morganii, P. mirabilis, P. vulgaris, S. marcescens*
- Tigecycline: *C. freundii, E. cloacae, E. coli, K. oxytoca, K. pneumoniae, C. koseri, E. aerogenes, S. marcescens*

NOTE: A result for an antibiotic/organism combination which may have a limitation may be suppressed from reporting. Refer to the software user manual for instructions.

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⇩ MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.

01 A310FZ0J---J

02 BAST-GN7001W

03 C---Z010200N

04 D080E1C0H0LQ

05 E1N11032G0YK

06 F2P1R052300F

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
	Temperature limitation
	Use by
LOT	Batch code
	Consult Instructions for Use
Σ	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community

PATENTS

Product covered by one or more of U.S. Patent Nos. D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 and 6,340,573; and Foreign Counterparts. Other Patents Pending.

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VITEK 2™ — technology

AST-GN72

IVD

Gram Negative Susceptibility Card

SUMMARY AND EXPLANATION

The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of **clinically significant aerobic gram-negative bacilli** to antimicrobial agents when used as instructed in the Product Information manual.

INSTRUCTIONS FOR USE

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See the Product Information manual for additional Instructions for Use.

STORAGE CONDITIONS

Store at 2° to 8° C.

CONTENTS OF THE CARD

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Amoxicillin/Clavulanic Acid	AMC	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Ampicillin	AM	4, 8, 32	2	32	CSAGNB**
Cefalotin	CF	2, 8, 32	2	64	CSAGNB**
Cefazolin	CZ	4, 16, 64	4	64	CSAGNB**
Cefepime	FEP	2, 8, 16, 32	1	64	CSAGNB**
Cefoxitin	FOX	8, 16, 32	4	64	CSAGNB**
Cefpodoxime	CPD	0.5, 1, 4	0.25	8	CSAGNB**
Ceftazidime	CAZ	1, 2, 8, 32	1	64	CSAGNB**
Ceftriaxone	CRO	1, 2, 8, 32	1	64	CSAGNB**
Cefuroxime	CXM	2, 8, 32	1	64	CSAGNB**
Ciprofloxacin	CIP	0.5, 2, 4	0.25	4	CSAGNB**
Gentamicin	GM	4, 16, 32	1	16	CSAGNB**
Levofloxacin	LEV❷	0.25, 0.5, 2, 8	0.12	8	*E. cloacae*, *E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *S. marcescens*, *A. baumannii*, *A. lwoffii*, *C. koseri*, *C. freundii*, *E. aerogenes*, *E. sakazakii*, *K. oxytoca*, *M. morganii*, *P. agglomerans*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *P. fluorescens*, *C. sakazakii*
Nitrofurantoin	FT	16, 32, 64	16	512	CSAGNB**
Piperacillin/Tazobactam [c]	TZP	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. enterica*
Tetracycline	TE	2, 4, 8	1	16	CSAGNB**
Tobramycin	TM	8, 16, 64	1	16	CSAGNB**
Trimethoprim/Sulfamethoxazole	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

Numerical values are expressed in µg/ml.
§ Equivalent standard method concentration by efficacy.
**CSAGNB = Clinically significant aerobic gram negative bacilli
❶,❷ etc. = See performance characteristics identified by the drug code with this symbol in the Comment column in Systems Product Information.
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**Eco(+ETEC) = *E. coli* (including susceptible enterotoxigenic strains implicated in traveler's diarrhea)

QUALITY CONTROL

		CLSI® Quality Control Organisms VITEK 2 Results		
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™
Amoxicillin/Clavulanic Acid	AMC	≤2/1 – 8/4	-	4/2 – 16/8
Ampicillin	AM	≤2 – 8	-	-
Cefalotin	CF	4 – 16	-	-
Cefazolin	CZ	≤4	-	-
Cefepime	FEP	≤1	≤1 – 8	-
Cefoxitin	FOX	≤4 – 8	-	-
Cefpodoxime	CPD	≤0.25 – 1	-	-
Ceftazidime	CAZ	≤1	≤1 – 4	-
Ceftriaxone	CRO	≤1	8 – ≥64	-
Cefuroxime	CXM	2 – 8	-	-
Ciprofloxacin	CIP	≤0.25	≤0.25 – 1	-
Gentamicin	GM	≤1	≤1 – 2	-
Levofloxacin	LEV	≤0.12	0.5 – 4	-
Nitrofurantoin	FT	≤16	-	-
Piperacillin/Tazobactam[c]	TZP	≤4/4* *(*FDA/CLSI Broth Microdilution expected QC range = 1/4 – 4/4 µg/ml)*	≤4/4 – 8/4* *(*FDA/CLSI Broth Microdilution expected QC range = 1/4 – 8/4 µg/ml)*	≤4/4* *(*FDA/CLSI Broth Microdilution expected QC range = 0.5/4 – 2/4 µg/ml)*
Tetracycline	TE	≤1 – 2	8 – ≥16	-
Tobramycin	TM	≤1	≤1	-
Trimethoprim/Sulfamethoxazole	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-

Numerical values are expressed in µg/ml.
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LIMITATIONS

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):
- Amoxicillin/Clavulanic Acid: *Providencia* spp.
- Ampicillin: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Cefpodoxime: *Morganella morganii, Serratia* spp.
- Piperacillin/Tazobactam: *Serratia marcescens*

Perform an alternative method of testing prior to reporting of results when an intermediate or resistant result is obtained with the following antibiotic/organism combination(s):
- Amoxicillin/Clavulanic Acid: *Proteus* spp.

Perform an alternative method of testing prior to reporting results when a resistant result is obtained with the following antibiotic/organism combination(s):
- Piperacillin/Tazobactam: *Pseudomonas aeruginosa*

NOTE: A result for an antibiotic/organism combination which may have a limitation may be suppressed from reporting. Refer to the software user manual for instructions.

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01


02


03


04


05


06


07


INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
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	Temperature limitation
	Use by
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	Consult Instructions for Use
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VITEK 2™ — technology

AST-GN74

IVD

Gram Negative Susceptibility Card

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Ampicillin/Sulbactam	SAM	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Aztreonam	ATM	2, 8, 32	1	64	CSAGNB**
Cefazolin	CZ	4, 16, 64	4	64	CSAGNB**
Cefepime	FEP	2, 8, 16, 32	1	64	CSAGNB**
Cefoxitin	FOX	8, 16, 32	4	64	CSAGNB**
Ceftazidime	CAZ	1, 2, 8, 32	1	64	CSAGNB**
Ceftriaxone	CRO	1, 2, 8, 32	1	64	CSAGNB**
Ertapenem [c]	ETP	0.5, 1, 6	0.5	8	*E. coli*, *K. pneumoniae*, *C. freundii*, *C. koseri*, *E. aerogenes*, *E. cloacae*, Kox(-ESBL)**, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *S. marcescens*
Gentamicin	GM	4, 16, 32	1	16	CSAGNB**
Levofloxacin	LEV❷	0.25, 0.5, 2, 8	0.12	8	*E. cloacae*, *E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *S. marcescens*, *A. baumannii*, *A. lwoffii*, *C. koseri*, *C. freundii*, *E. aerogenes*, *E. sakazakii*, *K. oxytoca*, *M. morganii*, *P. agglomerans*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *P. fluorescens*, *C. sakazakii*
Meropenem	MEM❷	0.5, 2, 6, 12	0.25	16	*E. coli*, *K. pneumoniae*, *P. aeruginosa*, *P. mirabilis*, *Acinetobacter* spp., *C. freundii*, *E. cloacae*, *K. oxytoca*, *M. morganii*, *P. vulgaris*, *S. marcescens*, *A. hydrophila*, *C. diversus*, *H. alvei*, *P. multocida*, *Salmonella* spp., *Shigella* spp.
Nitrofurantoin	FT	16, 32, 64	16	512	CSAGNB**
Piperacillin/Tazobactam [c]	TZP	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. enterica*
Tetracycline	TE	2, 4, 8	1	16	CSAGNB**
Tigecycline [c]	TGC	0.75, 2, 4	0.5	8	*C. freundii*, *C. koseri*, *E. coli*, *E. cloacae*, *E. aerogenes*, *K. oxytoca*, *K. pneumoniae*, *S. marcescens*
Tobramycin	TM	8, 16, 64	1	16	CSAGNB**

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Trimethoprim/Sulfamethoxazole	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

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QUALITY CONTROL

		CLSI® Quality Control Organisms VITEK 2 Results		
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™
Amikacin	AN	≤2 – 4	≤2 – 4	-
Ampicillin/Sulbactam	SAM	≤2/1 – 8/4	-	8/4 – ≥32/16
Aztreonam	ATM	≤1	2 – 8	-
Cefazolin	CZ	≤4	-	-
Cefepime	FEP	≤1	≤1 – 8	-
Cefoxitin	FOX	≤4 – 8	-	-
Ceftazidime	CAZ	≤1	≤1 – 4	-
Ceftriaxone	CRO	≤1	8 – ≥64	-
Ertapenem[c]	ETP	≤0.5	2 – ≥8	-
Gentamicin	GM	≤1	≤1 – 2	-
Levofloxacin	LEV	≤0.12	0.5 – 4	-
Meropenem	MEM	≤0.25	≤0.25 – 1	-
Nitrofurantoin	FT	≤16	-	-
Piperacillin/Tazobactam[c]	TZP	≤4/4* *(*FDA/CLSI Broth Microdilution expected QC range = 1/4 – 4/4 µg/ml)*	≤4/4 – 8/4* *(*FDA/CLSI Broth Microdilution expected QC range = 1/4 – 8/4 µg/ml)*	≤4/4* *(*FDA/CLSI Broth Microdilution expected QC range = 0.5/4 – 2/4 µg/ml)*
Tetracycline	TE	≤1 – 2	8 – ≥16	-
Tigecycline[c]	TGC	≤0.5	-	-
Tobramycin	TM	≤1	≤1	-
Trimethoprim/Sulfamethoxazole	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-

Numerical values are expressed in µg/ml.
[c] = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.

LIMITATIONS

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):
- Amikacin: *Acinetobacter baumannii*
- Ampicillin/Sulbactam: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Aztreonam: *Pseudomonas* spp.
- Piperacillin/Tazobactam: *Serratia marcescens*

Perform an alternative method of testing prior to reporting results when a resistant result is obtained with the following antibiotic/organism combination(s):
- Meropenem: *Aeromonas* spp.
- Piperacillin/Tazobactam: *Pseudomonas aeruginosa*

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The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:

- Ertapenem: *E. coli, K. pneumoniae, C. freundii, C. koseri, E. aerogenes, E. cloacae, K. oxytoca* (excluding ESBL producing strains), *M. morganii, P. mirabilis, P. vulgaris, S. marcescens*
- Tigecycline: *C. freundii, E. cloacae, E. coli, K. oxytoca, K. pneumoniae, C. koseri, E. aerogenes, S. marcescens*

NOTE: A result for an antibiotic/organism combination which may have a limitation may be suppressed from reporting. Refer to the software user manual for instructions.

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⇩ MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.

01 A310G20K---J

02 BAST-GN7401V

03 C---Z0100088

04 D0E1C0K0G0HZ

05 E1N031W2G0YD

06 F2P0-1R0523C

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
	Temperature limitation
	Use by
LOT	Batch code
	Consult Instructions for Use
Σ	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community

PATENTS

Product covered by one or more of U.S. Patent Nos. D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 and 6,340,573; and Foreign Counterparts. Other Patents Pending.

WARRANTY

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CE

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VITEK 2™ — technology

AST-GN75

IVD

Gram Negative Susceptibility Card

SUMMARY AND EXPLANATION

The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of **clinically significant aerobic gram-negative bacilli** to antimicrobial agents when used as instructed in the Product Information manual.

INSTRUCTIONS FOR USE

A package insert is provided in the kit or downloadable from **www.biomerieux.com/techlib**

See the Product Information manual for additional Instructions for Use.

STORAGE CONDITIONS

Store at 2° to 8° C.

CONTENTS OF THE CARD

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Amikacin	AN	8, 16, 64	2	64	CSAGNB**
Ampicillin	AM	4, 8, 32	2	32	CSAGNB**
Ampicillin/Sulbactam	SAM	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Cefazolin	CZ	4, 16, 64	4	64	CSAGNB**
Cefepime	FEP	2, 8, 16, 32	1	64	CSAGNB**
Cefoxitin	FOX	8, 16, 32	4	64	CSAGNB**
Ceftazidime	CAZ	1, 2, 8, 32	1	64	CSAGNB**
Ceftriaxone	CRO	1, 2, 8, 32	1	64	CSAGNB**
Ciprofloxacin	CIP	0.5, 2, 4	0.25	4	CSAGNB**
Ertapenem [c]	ETP	0.5, 1, 6	0.5	8	*E. coli*, *K. pneumoniae*, *C. freundii*, *C. koseri*, *E. aerogenes*, *E. cloacae*, Kox(-ESBL)**, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *S. marcescens*
ESBL [ı]	ESB	FEP 1, CTX 0.5, CAZ 0.5, FEP/CA 1/10, CTX/CA 0.5/4, CAZ/CA 0.5/4	NEG	POS	*E. coli*, *K. pneumoniae*, *K. oxytoca*
Gentamicin	GM	4, 16, 32	1	16	CSAGNB**
Levofloxacin	LEV❷	0.25, 0.5, 2, 8	0.12	8	*E. cloacae*, *E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *S. marcescens*, *A. baumannii*, *A. lwoffii*, *C. koseri*, *C. freundii*, *E. aerogenes*, *E. sakazakii*, *K. oxytoca*, *M. morganii*, *P. agglomerans*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *P. fluorescens*, *C. sakazakii*
Meropenem	MEM❷	0.5, 2, 6, 12	0.25	16	*E. coli*, *K. pneumoniae*, *P. aeruginosa*, *P. mirabilis*, *Acinetobacter* spp., *C. freundii*, *E. cloacae*, *K. oxytoca*, *M. morganii*, *P. vulgaris*, *S. marcescens*, *A. hydrophila*, *C. diversus*, *H. alvei*, *P. multocida*, *Salmonella* spp., *Shigella* spp.
Nitrofurantoin	FT	16, 32, 64	16	512	CSAGNB**

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Piperacillin	PIP❷	4, 16, 32, 64	4	128	*Acinetobacter* spp., *Enterobacter* spp., *E. coli*, *Klebsiella* spp., *M. morganii*, *Pv. rettgeri*, *P. mirabilis*, *P. vulgaris*, *P. aeruginosa*, *Serratia* spp., *B. cepacia*, *C. koseri*, *C. freundii*, *P. fluorescens*, *C. sakazakii*
Tobramycin	TM	8, 16, 64	1	16	CSAGNB**
Trimethoprim/Sulfamethoxazole	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

Numerical values are expressed in µg/ml.
§ Equivalent standard method concentration by efficacy.
**CSAGNB = Clinically significant aerobic gram negative bacilli
[c] = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.
**Kox(-ESBL) = *K. oxytoca* (excluding ESBL producing strains)
Note: For ESBL, FEP is Cefepime, CTX is Cefotaxime, CAZ is Ceftazidime and CA is Clavulanic Acid. For ESBL positive strains, the test interpretation should be reported as resistant for all penicillins, cephalosporins, and aztreonam.
NEG = Negative
POS = Positive
A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.
❶,❷ etc. = See performance characteristics identified by the drug code with this symbol in the Comment column in Systems Product Information.
**Eco(+ETEC) = *E. coli* (including susceptible enterotoxigenic strains implicated in traveler's diarrhea)

QUALITY CONTROL

		CLSI® Quality Control Organisms VITEK 2 Results			
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™	*K. pneumoniae* ssp *pneumoniae* ATCC® 700603™
Amikacin	AN	≤2 – 4	≤2 – 4	-	-
Ampicillin	AM	≤2 – 8	-	-	-
Ampicillin/Sulbactam	SAM	≤2/1 – 8/4	-	8/4 – ≥32/16	-
Cefazolin	CZ	≤4	-	-	-
Cefepime	FEP	≤1	≤1 – 8	-	-
Cefoxitin	FOX	≤4 – 8	-	-	-
Ceftazidime	CAZ	≤1	≤1 – 4	-	-
Ceftriaxone	CRO	≤1	8 – ≥64	-	-
Ciprofloxacin	CIP	≤0.25	≤0.25 – 1	-	-
Ertapenem[c]	ETP	≤0.5	2 – ≥8	-	-
ESBL,	ESB	NEG	-	-	POS
Gentamicin	GM	≤1	≤1 – 2	-	-
Levofloxacin	LEV	≤0.12	0.5 – 4	-	-
Meropenem	MEM	≤0.25	≤0.25 – 1	-	-
Nitrofurantoin	FT	≤16	-	-	-
Piperacillin	PIP	≤4	≤4 – 8	-	-
Tobramycin	TM	≤1	≤1	-	-
Trimethoprim/Sulfamethoxazole	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-	-

Numerical values are expressed in µg/ml.
[c] = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.
Note: For ESBL, FEP is Cefepime, CTX is Cefotaxime, CAZ is Ceftazidime and CA is Clavulanic Acid. For ESBL positive strains, the test interpretation should be reported as resistant for all penicillins, cephalosporins, and aztreonam.
NEG = Negative
POS = Positive
A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.

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LIMITATIONS

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):
- Amikacin: *Acinetobacter baumannii*
- Ampicillin: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Ampicillin/Sulbactam: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*

Perform an alternative method of testing prior to reporting results when a resistant result is obtained with the following antibiotic/organism combination(s):
- Meropenem: *Aeromonas* spp.

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:
- Ertapenem: *E. coli, K. pneumoniae, C. freundii, C. koseri, E. aerogenes, E. cloacae, K. oxytoca* (excluding ESBL producing strains), *M. morganii, P. mirabilis, P. vulgaris, S. marcescens*

NOTE: A result for an antibiotic/organism combination which may have a limitation may be suppressed from reporting. Refer to the software user manual for instructions.

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⇩ MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.

01 A310G30J---H

02 BAST-GN75013

03 C--0102000EQ

04 D1C0K0G0H0LI

05 E1N11031W2GF

06 F0Y200523001

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
	Temperature limitation
	Use by
LOT	Batch code
	Consult Instructions for Use
Σ	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community

PATENTS

Product covered by one or more of U.S. Patent Nos. D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 and 6,340,573; and Foreign Counterparts. Other Patents Pending.

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VITEK 2™ — technology

AST-GN76

IVD

Gram Negative Susceptibility Card

SUMMARY AND EXPLANATION

The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of **clinically significant aerobic gram-negative bacilli** to antimicrobial agents when used as instructed in the Product Information manual.

INSTRUCTIONS FOR USE

A package insert is provided in the kit or downloadable from **www.biomerieux.com/techlib**

See the Product Information manual for additional Instructions for Use.

STORAGE CONDITIONS

Store at 2° to 8° C.

CONTENTS OF THE CARD

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Amikacin	AN	8, 16, 64	2	64	CSAGNB**
Ampicillin	AM	4, 8, 32	2	32	CSAGNB**
Cefazolin	CZ	4, 16, 64	4	64	CSAGNB**
Cefepime	FEP	2, 8, 16, 32	1	64	CSAGNB**
Cefoxitin	FOX	8, 16, 32	4	64	CSAGNB**
Ceftazidime	CAZ	1, 2, 8, 32	1	64	CSAGNB**
Ceftriaxone	CRO	1, 2, 8, 32	1	64	CSAGNB**
Ciprofloxacin	CIP	0.5, 2, 4	0.25	4	CSAGNB**
Ertapenem [c]	ETP	0.5, 1, 6	0.5	8	*E. coli*, *K. pneumoniae*, *C. freundii*, *C. koseri*, *E. aerogenes*, *E. cloacae*, Kox(-ESBL)**, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *S. marcescens*
ESBL [1]	ESB	FEP 1, CTX 0.5, CAZ 0.5, FEP/CA 1/10, CTX/CA 0.5/4, CAZ/CA 0.5/4	NEG	POS	*E. coli*, *K. pneumoniae*, *K. oxytoca*
Gentamicin	GM	4, 16, 32	1	16	CSAGNB**
Imipenem	IPM	1, 2, 6, 12	0.25	16	*Acinetobacter* spp., *Citrobacter* spp., *Enterobacter* spp., *E. coli*, *Klebsiella* spp., *M. morganii*, *P. vulgaris*, *Pv. rettgeri*, *P. aeruginosa*, *S. marcescens*, *Pv. stuartii*
Levofloxacin	LEV❷	0.25, 0.5, 2, 8	0.12	8	*E. cloacae*, *E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *S. marcescens*, *A. baumannii*, *A. lwoffii*, *C. koseri*, *C. freundii*, *E. aerogenes*, *E. sakazakii*, *K. oxytoca*, *M. morganii*, *P. agglomerans*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *P. fluorescens*, *C. sakazakii*
Nitrofurantoin	FT	16, 32, 64	16	512	CSAGNB**
Piperacillin/Tazobactam [c]	TZP	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. enterica*
Tigecycline [c]	TGC	0.75, 2, 4	0.5	8	*C. freundii*, *C. koseri*, *E. coli*, *E. cloacae*, *E. aerogenes*, *K. oxytoca*, *K. pneumoniae*, *S. marcescens*

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Trimethoprim/Sulfamethoxazole	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

Numerical values are expressed in µg/ml.
§ Equivalent standard method concentration by efficacy.
**CSAGNB = Clinically significant aerobic gram negative bacilli
[c] = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.
**Kox(-ESBL) = *K. oxytoca* (excluding ESBL producing strains)
Note: For ESBL, FEP is Cefepime, CTX is Cefotaxime, CAZ is Ceftazidime and CA is Clavulanic Acid. For ESBL positive strains, the test interpretation should be reported as resistant for all penicillins, cephalosporins, and aztreonam.
NEG = Negative
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A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.
❶,❷ etc. = See performance characteristics identified by the drug code with this symbol in the Comment column in Systems Product Information.
**Eco(+ETEC) = *E. coli* (including susceptible enterotoxigenic strains implicated in traveler's diarrhea)

QUALITY CONTROL

		CLSI® Quality Control Organisms VITEK 2 Results			
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™	*K. pneumoniae* ssp *pneumoniae* ATCC® 700603™
Amikacin	AN	≤2 – 4	≤2 – 4	-	-
Ampicillin	AM	≤2 – 8	-	-	-
Cefazolin	CZ	≤4	-	-	-
Cefepime	FEP	≤1	≤1 – 8	-	-
Cefoxitin	FOX	≤4 – 8	-	-	-
Ceftazidime	CAZ	≤1	≤1 – 4	-	-
Ceftriaxone	CRO	≤1	8 – ≥64	-	-
Ciprofloxacin	CIP	≤0.25	≤0.25 – 1	-	-
Ertapenem[c]	ETP	≤0.5	2 – ≥8	-	-
ESBL'	ESB	NEG	-	-	POS
Gentamicin	GM	≤1	≤1 – 2	-	-
Imipenem	IPM	≤0.25	1 – 4	-	-
Levofloxacin	LEV	≤0.12	0.5 – 4	-	-
Nitrofurantoin	FT	≤16	-	-	-
Piperacillin/Tazobactam[c]	TZP	≤4/4* *(*FDA/CLSI Broth Microdilution expected QC range = 1/4 – 4/4 µg/ml)*	≤4/4 – 8/4* *(*FDA/CLSI Broth Microdilution expected QC range = 1/4 – 8/4 µg/ml)*	≤4/4* *(*FDA/CLSI Broth Microdilution expected QC range = 0.5/4 – 2/4 µg/ml)*	-
Tigecycline[c]	TGC	≤0.5	-	-	-
Trimethoprim/Sulfamethoxazole	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-	-

Numerical values are expressed in µg/ml.
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NEG = Negative
POS = Positive
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LIMITATIONS

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):
- Amikacin: *Acinetobacter baumannii*

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- Ampicillin: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Imipenem: *Serratia marcescens*
- Piperacillin/Tazobactam: *Serratia marcescens*

Perform an alternative method of testing prior to reporting results when a resistant result is obtained with the following antibiotic/organism combination(s):
- Imipenem: *Aeromonas* spp.
- Piperacillin/Tazobactam: *Pseudomonas aeruginosa*

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:
- Ertapenem: *E. coli, K. pneumoniae, C. freundii, C. koseri, E. aerogenes, E. cloacae, K. oxytoca* (excluding ESBL producing strains), *M. morganii, P. mirabilis, P. vulgaris, S. marcescens*
- Tigecycline: *C. freundii, E. cloacae, E. coli, K. oxytoca, K. pneumoniae, C. koseri, E. aerogenes, S. marcescens*

NOTE: A result for an antibiotic/organism combination which may have a limitation may be suppressed from reporting. Refer to the software user manual for instructions.

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⇩ MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.

01 A310G40J---N

02 BAST-GN7601C

03 C---Z01020EO

04 D1C0K0G0H0LI

05 E1N110320O1W6

06 F0Y2P1R23007

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
	Temperature limitation
	Use by
LOT	Batch code
	Consult Instructions for Use
Σ	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community

PATENTS

Product covered by one or more of U.S. Patent Nos. D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 and 6,340,573; and Foreign Counterparts. Other Patents Pending.

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VITEK 2™ — technology

AST-GN80

IVD

Карта для определения чувствительности к антимикробным препаратам грамотрицательных бактерий

КРАТКОЕ ОПИСАНИЕ

Данная карта предназначена для использования с системами VITEK® 2 в клинических лабораториях для лабораторного определения чувствительности к антимикробным препаратам **клинически значимых аэробных грамотрицательных палочек**. Используйте, как указано в руководстве "Расходные материалы".

ПРИМЕНЕНИЕ

Инструкция по применению предоставляется в наборе или может быть загружена с сайта **www.biomerieux.com/techlib**

Для получения дополнительных инструкций по применению смотрите руководство по расходным материалам.

ХРАНЕНИЕ

Хранить при температуре от 2° до 8° C.

СОСТАВ КАРТЫ

Антимикробный препарат	Код	Концентрация §	Диапазон определения ≤	Диапазон определения ≥	Указания к применению FDA (Управление по контролю за продуктами и лекарствами, США)
Ампициллин	AM	4, 8, 32	2	32	CSAGNB**
Ампициллин/Сульбактам	SAM	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Азтреонам	ATM	2, 8, 32	1	64	CSAGNB**
Цефазолин	CZ	4, 16, 64	4	64	CSAGNB**
Цефепим	FEP	2, 8, 16, 32	1	64	CSAGNB**
Цефтазидим	CAZ	1, 2, 8, 32	1	64	CSAGNB**
Цефтриаксон	CRO	1, 2, 8, 32	1	64	CSAGNB**
Эртапенем	ETP	0.5, 1, 6	0.5	8	*E. coli*, *K. pneumoniae*, *C. freundii*, *C. koseri*, *E. aerogenes*, *E. cloacae*, Kox(-ESBL)**, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *S. marcescens*
БЛРС '	ESB	FEP 1, CTX 0.5, CAZ 0.5, FEP/CA 1/10, CTX/CA 0.5/4, CAZ/CA 0.5/4	NEG	POS	*E. coli*, *K. pneumoniae*, *K. oxytoca*
Гентамицин	GM	4, 16, 32	1	16	CSAGNB**
Левофлоксацин	LEV❷	0.25, 0.5, 2, 8	0.12	8	*E. cloacae*, *E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *S. marcescens*, *A. baumannii*, *A. lwoffii*, *C. koseri*, *C. freundii*, *E. aerogenes*, *E. sakazakii*, *K. oxytoca*, *M. morganii*, *P. agglomerans*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *P. fluorescens*, *C. sakazakii*
Меропенем	MEM❷	0.5, 2, 6, 12	0.25	16	*E. coli*, *K. pneumoniae*, *P. aeruginosa*, *P. mirabilis*, *Acinetobacter* spp., *C. freundii*, *E. cloacae*, *K. oxytoca*, *M. morganii*, *P. vulgaris*, *S. marcescens*, *A. hydrophila*, *C. diversus*, *H. alvei*, *P. multocida*, *Salmonella* spp., *Shigella* spp.
Нитрофурантоин	FT	16, 32, 64	16	512	CSAGNB**
Пиперациллин/тазобактам	TZP	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. enterica*

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Тайгециклин	TGC	0.75, 2, 4	0.5	8	*C. freundii*, *C. koseri*, *E. coli*, *E. cloacae*, *E. aerogenes*, *K. oxytoca*, *K. pneumoniae*, *S. marcescens*
Тобрамицин	TM	8, 16, 64	1	16	CSAGNB**
Триметоприм/Сульфаметоксазол	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

Численные значения выражены в µг/мл.
§ Эквивалентна по эффективности концентрации стандартного метода.
**CSAGNB = Клинически значимые аэробные грамотрицательные палочки.
**Kox(-ESBL) = *K. oxytoca* (кроме штаммов, продуцирующих БЛРС).
Прим.: БЛРС FEP = Цефепим, CTX = Цефотаксим, CAZ = Цефтазидим, CA = Клавулановая кислота. Штаммы, продуцирующие БЛРС, устойчивы ко всем пенициллинам, цефалоспоринам, азтреонаму.
NEG = Отрицательный.
POS = Положительный.
Отрицательный результат теста на БЛРС не исключает наличия БЛРС, скрытых бета-лактамазой класса AmpC.
❶,❷ пр. = См. рабочие характеристики с кодом препарата и данным символом в колонке комментариев в руководстве к расходным материалам.
**Eco(+ETEC) = *E. coli* (в т. ч. чувствительные энтеротоксигенные штаммы, вызывающие диарею).

КОНТРОЛЬ КАЧЕСТВА

		Контрольные штаммы CLSI®, результаты в системе VITEK 2			
Антимикробный препарат	Код	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™	*K. pneumoniae* ssp *pneumoniae* ATCC® 700603™
Ампициллин	AM	≤2 – 8	-	-	-
Ампициллин/Сульбактам	SAM	≤2/1 – 8/4	-	8/4 – ≥32/16	-
Азтреонам	ATM	≤1	2 – 8	-	-
Цефазолин	CZ	≤4	-	-	-
Цефепим	FEP	≤1	≤1 – 8	-	-
Цефтазидим	CAZ	≤1	≤1 – 4	-	-
Цефтриаксон	CRO	≤1	8 – ≥64	-	-
Эртапенем	ETP	≤0.5	2 – ≥8	-	-
БЛРС·	ESB	NEG	-	-	POS
Гентамицин	GM	≤1	≤1 – 2	-	-
Левофлоксацин	LEV	≤0.12	0.5 – 4	-	-
Меропенем	MEM	≤0.25	≤0.25 – 1	-	-
Нитрофурантоин	FT	≤16	-	-	-
Пиперациллин/тазобактам	TZP	≤4/4	≤4/4 – 8/4	≤4/4	-
Тайгециклин	TGC	≤0.5	-	-	-
Тобрамицин	TM	≤1	≤1	-	-
Триметоприм/Сульфаметоксазол	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-	-

Численные значения выражены в µг/мл.
Прим.: БЛРС FEP = Цефепим, CTX = Цефотаксим, CAZ = Цефтазидим, CA = Клавулановая кислота. Штаммы, продуцирующие БЛРС, устойчивы ко всем пенициллинам, цефалоспоринам, азтреонаму.
NEG = Отрицательный.
POS = Положительный.
Отрицательный результат теста на БЛРС не исключает наличия БЛРС, скрытых бета-лактамазой класса AmpC.

ОГРАНИЧЕНИЯ

Для следующих сочетаний микроорганизм / антимикробный препарат результат следует подтверждать альтернативным методом:
- Ампициллин: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Ампициллин/Сульбактам: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Азтреонам: *Pseudomonas* spp.

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- Пиперациллин/тазобактам: *Serratia marcescens*

Для следующих сочетаний микроорганизм / антимикробный препарат результат следует подтверждать альтернативным методом при получении результата "устойчивый":
- Меропенем: *Aeromonas* spp.
- Пиперациллин/тазобактам: *Pseudomonas aeruginosa*

Возможность определения устойчивости на данной карте для следующих сочетаний микроорганизм / антимикробный препарат неизвестна, поскольку на момент сравнительного тестирования при определении рабочих характеристик устойчивые штаммы не были доступны:
- Эртапенем: *E. coli, K. pneumoniae, C. freundii, C. koseri, E. aerogenes, E. cloacae, K. oxytoca* (кроме штаммов, продуцирующих БЛРС), *M. morganii, P. mirabilis, P. vulgaris, S. marcescens*
- Тайгециклин: *C. freundii, E. cloacae, E. coli, K. oxytoca, K. pneumoniae, C. koseri, E. aerogenes, S. marcescens*

ПРИМЕЧАНИЕ: Результаты для сочетаний антимикробный препарат / микроорганизм, для которых существуют ограничения, можно исключить из лабораторного отчета. Для получения подробной информации смотрите руководство по программному обеспечению.

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⇩ Перед первым использованием данной карты ⇩ НЕОБХОДИМО ввести приведенные в данной инструкции штрих-коды в программу “Flex Panel Entry”.

01 A310I40J---X

02 BAST-GN80013

03 C---Z020O08F

04 D0E1C0G0H1NI

05 E11031W2G0YL

06 F2P1R052300F

ТАБЛИЦА СИМВОЛОВ И ОБОЗНАЧЕНИЙ

Символ	Обозначение
REF	Номер по каталогу
IVD	Для лабораторной диагностики
	Произведено
	Дата производства
	Температурные ограничения
	Использовать до
LOT	Номер партии
	Перед использованием прочтите инструкцию
Σ	Содержимого достаточно для <n> тестов
EC REP	Уполномоченный представитель в Европейском Сообществе

ПАТЕНТЫ

Продукт защищен одним или более патентов США: D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 и 6,340,573; и иностранными аналогами. Прочие патенты в процессе регистрации.

BIOMÉRIEUX, голубой логотип, VITEK и bioLiaison являются используемыми, зарегистрированными и/или находящимися в процессе регистрации торговыми марками, принадлежащими компании bioMérieux SA, или одному из ее филиалов или одной из ее компаний. ATCC товарный знак и фирменное наименование и любые номера по каталогу ATCC являются торговыми марками, принадлежащими Американской Коллекции Типовых Культур. Другие названия и торговые марки являются собственностью их соответствующих владельцев.

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VITEK 2™ — technology

AST-GN81

IVD

Карта для определения чувствительности к антимикробным препаратам грамотрицательных бактерий

КРАТКОЕ ОПИСАНИЕ

Данная карта предназначена для использования с системами VITEK® 2 в клинических лабораториях для лабораторного определения чувствительности к антимикробным препаратам **клинически значимых аэробных грамотрицательных палочек**. Используйте, как указано в руководстве "Расходные материалы".

ПРИМЕНЕНИЕ

Инструкция по применению предоставляется в наборе или может быть загружена с сайта **www.biomerieux.com/techlib**

Для получения дополнительных инструкций по применению смотрите руководство по расходным материалам.

ХРАНЕНИЕ

Хранить при температуре от 2° до 8° C.

СОСТАВ КАРТЫ

Антимикробный препарат	Код	Концентрация §	Диапазон определения ≤	≥	Указания к применению FDA (Управление по контролю за продуктами и лекарствами, США)
Амикацин	AN	8, 16, 64	2	64	CSAGNB**
Амоксициллин/Клавулановая кислота	AMC	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Ампициллин	AM	4, 8, 32	2	32	CSAGNB**
Цефазолин	CZ	4, 16, 64	4	64	CSAGNB**
Цефепим	FEP	2, 8, 16, 32	1	64	CSAGNB**
Цефокситин	FOX	8, 16, 32	4	64	CSAGNB**
Цефтазидим	CAZ	1, 2, 8, 32	1	64	CSAGNB**
Цефтриаксон	CRO	1, 2, 8, 32	1	64	CSAGNB**
Ципрофлоксацин	CIP	0.5, 2, 4	0.25	4	CSAGNB**
Эртапенем	ETP	0.5, 1, 6	0.5	8	*E. coli*, *K. pneumoniae*, *C. freundii*, *C. koseri*, *E. aerogenes*, *E. cloacae*, Kox(-ESBL)**, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *S. marcescens*
Гентамицин	GM	4, 16, 32	1	16	CSAGNB**
Левофлоксацин	LEV❷	0.25, 0.5, 2, 8	0.12	8	*E. cloacae*, *E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *S. marcescens*, *A. baumannii*, *A. lwoffii*, *C. koseri*, *C. freundii*, *E. aerogenes*, *E. sakazakii*, *K. oxytoca*, *M. morganii*, *P. agglomerans*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *P. fluorescens*, *C. sakazakii*
Меропенем	MEM❷	0.5, 2, 6, 12	0.25	16	*E. coli*, *K. pneumoniae*, *P. aeruginosa*, *P. mirabilis*, *Acinetobacter* spp., *C. freundii*, *E. cloacae*, *K. oxytoca*, *M. morganii*, *P. vulgaris*, *S. marcescens*, *A. hydrophila*, *C. diversus*, *H. alvei*, *P. multocida*, *Salmonella* spp., *Shigella* spp.
Нитрофурантоин	FT	16, 32, 64	16	512	CSAGNB**
Пиперациллин/тазобактам	TZP	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. enterica*
Тетрациклин	TE	2, 4, 8	1	16	CSAGNB**

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Тобрамицин	TM	8, 16, 64	1	16	CSAGNB**
Триметоприм/Сульфаметоксазол	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

Численные значения выражены в µг/мл.
§ Эквивалентна по эффективности концентрации стандартного метода.
**CSAGNB = Клинически значимые аэробные грамотрицательные палочки.
**Kox(-ESBL) = *K. oxytoca* (кроме штаммов, продуцирующих БЛРС).
❶,❷ пр. = См. рабочие характеристики с кодом препарата и данным символом в колонке комментариев в руководстве к расходным материалам.
**Eco(+ETEC) = *E. coli* (в т. ч. чувствительные энтеротоксигенные штаммы, вызывающие диарею).

КОНТРОЛЬ КАЧЕСТВА

		Контрольные штаммы CLSI®, результаты в системе VITEK 2		
Антимикробный препарат	Код	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™
Амикацин	AN	≤2 – 4	≤2 – 4	-
Амоксициллин/Клавулановая кислота	AMC	≤2/1 – 8/4	-	4/2 – 16/8
Ампициллин	AM	≤2 – 8	-	-
Цефазолин	CZ	≤4	-	-
Цефепим	FEP	≤1	≤1 – 8	-
Цефокситин	FOX	≤4 – 8	-	-
Цефтазидим	CAZ	≤1	≤1 – 4	-
Цефтриаксон	CRO	≤1	8 – ≥64	-
Ципрофлоксацин	CIP	≤0.25	≤0.25 – 1	-
Эртапенем	ETP	≤0.5	2 – ≥8	-
Гентамицин	GM	≤1	≤1 – 2	-
Левофлоксацин	LEV	≤0.12	0.5 – 4	-
Меропенем	MEM	≤0.25	≤0.25 – 1	-
Нитрофурантоин	FT	≤16	-	-
Пиперациллин/тазобактам	TZP	≤4/4	≤4/4 – 8/4	≤4/4
Тетрациклин	TE	≤1 – 2	8 – ≥16	-
Тобрамицин	TM	≤1	≤1	-
Триметоприм/Сульфаметоксазол	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-

Численные значения выражены в µг/мл.

ОГРАНИЧЕНИЯ

Для следующих сочетаний микроорганизм / антимикробный препарат результат следует подтверждать альтернативным методом:
- Амикацин: *Acinetobacter baumannii*
- Амоксициллин/Клавулановая кислота: *Providencia* spp.
- Ампициллин: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Пиперациллин/тазобактам: *Serratia marcescens*

Для следующих сочетаний микроорганизм / антимикробный препарат результат следует подтверждать альтернативным методом при получении результата "умеренно устойчивый" или "устойчивый":
- Амоксициллин/Клавулановая кислота: *Proteus* spp.

Для следующих сочетаний микроорганизм / антимикробный препарат результат следует подтверждать альтернативным методом при получении результата "устойчивый":
- Меропенем: *Aeromonas* spp.
- Пиперациллин/тазобактам: *Pseudomonas aeruginosa*

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Возможность определения устойчивости на данной карте для следующих сочетаний микроорганизм / антимикробный препарат неизвестна, поскольку на момент сравнительного тестирования при определении рабочих характеристик устойчивые штаммы не были доступны:

- Эртапенем: *E. coli, K. pneumoniae, C. freundii, C. koseri, E. aerogenes, E. cloacae, K. oxytoca* (кроме штаммов, продуцирующих БЛРС), *M. morganii, P. mirabilis, P. vulgaris, S. marcescens*

ПРИМЕЧАНИЕ: Результаты для сочетаний антимикробный препарат / микроорганизм, для которых существуют ограничения, можно исключить из лабораторного отчета. Для получения подробной информации смотрите руководство по программному обеспечению.

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⇩ Перед первым использованием данной карты НЕОБХОДИМО ввести приведенные в данной инструкции штрих-коды в программу “Flex Panel Entry”.

01 A310I50K---A

02 BAST-GN8101C

03 C---Z010702B

04 D0E1C0K0G0HZ

05 E0L1N031W2G6

06 F0Y2P0-05238

ТАБЛИЦА СИМВОЛОВ И ОБОЗНАЧЕНИЙ

Символ	Обозначение
REF	Номер по каталогу
IVD	Для лабораторной диагностики
	Произведено
	Дата производства
	Температурные ограничения
	Использовать до
LOT	Номер партии
	Перед использованием прочтите инструкцию
Σ	Содержимого достаточно для <n> тестов
EC REP	Уполномоченный представитель в Европейском Сообществе

ПАТЕНТЫ

Продукт защищен одним или более патентов США: D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 и 6,340,573; и иностранными аналогами. Прочие патенты в процессе регистрации.

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VITEK 2™ — technology

AST-GN84

IVD

Gram Negative Susceptibility Card

SUMMARY AND EXPLANATION

The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of **clinically significant aerobic gram-negative bacilli** to antimicrobial agents when used as instructed in the Product Information manual.

INSTRUCTIONS FOR USE

A package insert is provided in the kit or downloadable from **www.biomerieux.com/techlib**

See the Product Information manual for additional Instructions for Use.

STORAGE CONDITIONS

Store at 2° to 8° C.

CONTENTS OF THE CARD

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Amoxicillin/Clavulanic Acid	AMC	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Ampicillin	AM	4, 8, 32	2	32	CSAGNB**
Aztreonam	ATM	2, 8, 32	1	64	CSAGNB**
Cefazolin	CZ	4, 16, 64	4	64	CSAGNB**
Cefepime	FEP	2, 8, 16, 32	1	64	CSAGNB**
Ceftriaxone	CRO	1, 2, 8, 32	1	64	CSAGNB**
Ciprofloxacin	CIP	0.5, 2, 4	0.25	4	CSAGNB**
Ertapenem [c]	ETP	0.5, 1, 6	0.5	8	*E. coli*, *K. pneumoniae*, *C. freundii*, *C. koseri*, *E. aerogenes*, *E. cloacae*, Kox(-ESBL)**, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *S. marcescens*
ESBL [ı]	ESB	FEP 1, CTX 0.5, CAZ 0.5, FEP/CA 1/10, CTX/CA 0.5/4, CAZ/CA 0.5/4	NEG	POS	*E. coli*, *K. pneumoniae*, *K. oxytoca*
Gentamicin	GM	4, 16, 32	1	16	CSAGNB**
Imipenem	IPM	1, 2, 6, 12	0.25	16	*Acinetobacter* spp., *Citrobacter* spp., *Enterobacter* spp., *E. coli*, *Klebsiella* spp., *M. morganii*, *P. vulgaris*, *Pv. rettgeri*, *P. aeruginosa*, *S. marcescens*, *Pv. stuartii*
Levofloxacin	LEV❷	0.25, 0.5, 2, 8	0.12	8	*E. cloacae*, *E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *S. marcescens*, *A. baumannii*, *A. lwoffii*, *C. koseri*, *C. freundii*, *E. aerogenes*, *E. sakazakii*, *K. oxytoca*, *M. morganii*, *P. agglomerans*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *P. fluorescens*, *C. sakazakii*
Meropenem	MEM❷	0.5, 2, 6, 12	0.25	16	*E. coli*, *K. pneumoniae*, *P. aeruginosa*, *P. mirabilis*, *Acinetobacter* spp., *C. freundii*, *E. cloacae*, *K. oxytoca*, *M. morganii*, *P. vulgaris*, *S. marcescens*, *A. hydrophila*, *C. diversus*, *H. alvei*, *P. multocida*, *Salmonella* spp., *Shigella* spp.
Nitrofurantoin	FT	16, 32, 64	16	512	CSAGNB**

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Piperacillin/Tazobactam [c]	TZP	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. enterica*
Tetracycline	TE	2, 4, 8	1	16	CSAGNB**
Trimethoprim/Sulfamethoxazole	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

Numerical values are expressed in µg/ml.
§ Equivalent standard method concentration by efficacy.
**CSAGNB = Clinically significant aerobic gram negative bacilli
[c] = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.
**Kox(-ESBL) = *K. oxytoca* (excluding ESBL producing strains)
Note: For ESBL, FEP is Cefepime, CTX is Cefotaxime, CAZ is Ceftazidime and CA is Clavulanic Acid. For ESBL positive strains, the test interpretation should be reported as resistant for all penicillins, cephalosporins, and aztreonam.
NEG = Negative
POS = Positive
A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.
❶,❷ etc. = See performance characteristics identified by the drug code with this symbol in the Comment column in Systems Product Information.
**Eco(+ETEC) = *E. coli* (including susceptible enterotoxigenic strains implicated in traveler's diarrhea)

QUALITY CONTROL

		CLSI® Quality Control Organisms VITEK 2 Results			
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™	*K. pneumoniae* ssp *pneumoniae* ATCC® 700603™
Amoxicillin/Clavulanic Acid	AMC	≤2/1 – 8/4	-	4/2 – 16/8	-
Ampicillin	AM	≤2 – 8	-	-	-
Aztreonam	ATM	≤1	2 – 8	-	-
Cefazolin	CZ	≤4	-	-	-
Cefepime	FEP	≤1	≤1 – 8	-	-
Ceftriaxone	CRO	≤1	8 – ≥64	-	-
Ciprofloxacin	CIP	≤0.25	≤0.25 – 1	-	-
Ertapenem[c]	ETP	≤0.5	2 – ≥8	-	-
ESBL'	ESB	NEG	-	-	POS
Gentamicin	GM	≤1	≤1 – 2	-	-
Imipenem	IPM	≤0.25	1 – 4	-	-
Levofloxacin	LEV	≤0.12	0.5 – 4	-	-
Meropenem	MEM	≤0.25	≤0.25 – 1	-	-
Nitrofurantoin	FT	≤16	-	-	-
Piperacillin/Tazobactam[c]	TZP	≤4/4* *(*FDA/CLSI Broth Microdilution expected QC range = 1/4 – 4/4 µg/ml)*	≤4/4 – 8/4* *(*FDA/CLSI Broth Microdilution expected QC range = 1/4 – 8/4 µg/ml)*	≤4/4* *(*FDA/CLSI Broth Microdilution expected QC range = 0.5/4 – 2/4 µg/ml)*	-
Tetracycline	TE	≤1 – 2	8 – ≥16	-	-
Trimethoprim/Sulfamethoxazole	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-	-

Numerical values are expressed in µg/ml.
[c] = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.
Note: For ESBL, FEP is Cefepime, CTX is Cefotaxime, CAZ is Ceftazidime and CA is Clavulanic Acid. For ESBL positive strains, the test interpretation should be reported as resistant for all penicillins, cephalosporins, and aztreonam.
NEG = Negative
POS = Positive

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A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.

LIMITATIONS

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):
- Amoxicillin/Clavulanic Acid: *Providencia* spp.
- Ampicillin: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Aztreonam: *Pseudomonas* spp.
- Imipenem: *Serratia marcescens*
- Piperacillin/Tazobactam: *Serratia marcescens*

Perform an alternative method of testing prior to reporting of results when an intermediate or resistant result is obtained with the following antibiotic/organism combination(s):
- Amoxicillin/Clavulanic Acid: *Proteus* spp.

Perform an alternative method of testing prior to reporting results when a resistant result is obtained with the following antibiotic/organism combination(s):
- Imipenem: *Aeromonas* spp.
- Meropenem: *Aeromonas* spp.
- Piperacillin/Tazobactam: *Pseudomonas aeruginosa*

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:
- Ertapenem: *E. coli, K. pneumoniae, C. freundii, C. koseri, E. aerogenes, E. cloacae, K. oxytoca* (excluding ESBL producing strains), *M. morganii, P. mirabilis, P. vulgaris, S. marcescens*

NOTE: A result for an antibiotic/organism combination which may have a limitation may be suppressed from reporting. Refer to the software user manual for instructions.

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⇩ MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.

01 A310I80J---K

02 BAST-GN84012

03 C---Z0702080

04 D0E1C0H0L1NO

05 E110320O1W2G3

06 F0Y2P0-2300R

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
	Temperature limitation
	Use by
LOT	Batch code
	Consult Instructions for Use
Σ	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community

PATENTS

Product covered by one or more of U.S. Patent Nos. D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 and 6,340,573; and Foreign Counterparts. Other Patents Pending.

WARRANTY

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VITEK 2™ — technology

AST-GN83

IVD

Gram Negative Susceptibility Card

SUMMARY AND EXPLANATION

The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of **clinically significant aerobic gram-negative bacilli** to antimicrobial agents when used as instructed in the Product Information manual.

INSTRUCTIONS FOR USE

A package insert is provided in the kit or downloadable from **www.biomerieux.com/techlib**

See the Product Information manual for additional Instructions for Use.

STORAGE CONDITIONS

Store at 2° to 8° C.

CONTENTS OF THE CARD

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Amikacin	AN	8, 16, 64	2	64	CSAGNB**
Amoxicillin/Clavulanic Acid	AMC	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Ampicillin	AM	4, 8, 32	2	32	CSAGNB**
Ampicillin/Sulbactam	SAM	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Aztreonam	ATM	2, 8, 32	1	64	CSAGNB**
Cefazolin	CZ	4, 16, 64	4	64	CSAGNB**
Cefepime	FEP	2, 8, 16, 32	1	64	CSAGNB**
Cefotaxime	CTX	1, 4, 16, 32	1	64	CSAGNB**
Cefoxitin	FOX	8, 16, 32	4	64	CSAGNB**
Ceftazidime	CAZ	1, 2, 8, 32	1	64	CSAGNB**
Ceftriaxone	CRO	1, 2, 8, 32	1	64	CSAGNB**
Cefuroxime	CXM	2, 8, 32	1	64	CSAGNB**
Ciprofloxacin	CIP	0.5, 2, 4	0.25	4	CSAGNB**
Gentamicin	GM	4, 16, 32	1	16	CSAGNB**
Meropenem	MEM❷	0.5, 2, 6, 12	0.25	16	*E. coli*, *K. pneumoniae*, *P. aeruginosa*, *P. mirabilis*, *Acinetobacter* spp., *C. freundii*, *E. cloacae*, *K. oxytoca*, *M. morganii*, *P. vulgaris*, *S. marcescens*, *A. hydrophila*, *C. diversus*, *H. alvei*, *P. multocida*, *Salmonella* spp., *Shigella* spp.
Nitrofurantoin	FT	16, 32, 64	16	512	CSAGNB**
Piperacillin/Tazobactam [c]	TZP	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. enterica*
Trimethoprim/Sulfamethoxazole	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

Numerical values are expressed in µg/ml.
§ Equivalent standard method concentration by efficacy.
**CSAGNB = Clinically significant aerobic gram negative bacilli
❶,❷ etc. = See performance characteristics identified by the drug code with this symbol in the Comment column in Systems Product Information.
[c] = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.

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**Eco(+ETEC) = *E. coli* (including susceptible enterotoxigenic strains implicated in traveler's diarrhea)

QUALITY CONTROL

		CLSI® Quality Control Organisms VITEK 2 Results		
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™
Amikacin	AN	≤2 – 4	≤2 – 4	-
Amoxicillin/Clavulanic Acid	AMC	≤2/1 – 8/4	-	4/2 – 16/8
Ampicillin	AM	≤2 – 8	-	-
Ampicillin/Sulbactam	SAM	≤2/1 – 8/4	-	8/4 – ≥32/16
Aztreonam	ATM	≤1	2 – 8	-
Cefazolin	CZ	≤4	-	-
Cefepime	FEP	≤1	≤1 – 8	-
Cefotaxime	CTX	≤1	8 – 32	-
Cefoxitin	FOX	≤4 – 8	-	-
Ceftazidime	CAZ	≤1	≤1 – 4	-
Ceftriaxone	CRO	≤1	8 – ≥64	-
Cefuroxime	CXM	2 – 8	-	-
Ciprofloxacin	CIP	≤0.25	≤0.25 – 1	-
Gentamicin	GM	≤1	≤1 – 2	-
Meropenem	MEM	≤0.25	≤0.25 – 1	-
Nitrofurantoin	FT	≤16	-	-
Piperacillin/Tazobactam[c]	TZP	≤4/4* *(*FDA/CLSI Broth Microdilution expected QC range = 1/4 – 4/4 µg/ml)*	≤4/4 – 8/4* *(*FDA/CLSI Broth Microdilution expected QC range = 1/4 – 8/4 µg/ml)*	≤4/4* *(*FDA/CLSI Broth Microdilution expected QC range = 0.5/4 – 2/4 µg/ml)*
Trimethoprim/Sulfamethoxazole	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-

Numerical values are expressed in µg/ml.
[c] = Category agreement was established at the time of FDA clearance. Essential agreement was not established since test contains less than five discrete dilutions.

LIMITATIONS

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):
- Amikacin: *Acinetobacter baumannii*
- Amoxicillin/Clavulanic Acid: *Providencia* spp.
- Ampicillin: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Ampicillin/Sulbactam: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Aztreonam: *Pseudomonas* spp.
- Piperacillin/Tazobactam: *Serratia marcescens*

Perform an alternative method of testing prior to reporting of results when an intermediate or resistant result is obtained with the following antibiotic/organism combination(s):
- Amoxicillin/Clavulanic Acid: *Proteus* spp.

Perform an alternative method of testing prior to reporting results when a resistant result is obtained with the following antibiotic/organism combination(s):
- Meropenem: *Aeromonas* spp.
- Piperacillin/Tazobactam: *Pseudomonas aeruginosa*

NOTE: A result for an antibiotic/organism combination which may have a limitation may be suppressed from reporting. Refer to the software user manual for instructions.

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⇩ MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.

01 A310I70K---M

02 BAST-GN8301U

03 C---Z010702B

04 D00080E1C0FN

05 E0K0G0H0I0L0

06 F032G0Y2P23F

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
	Temperature limitation
	Use by
LOT	Batch code
	Consult Instructions for Use
Σ	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community

PATENTS

Product covered by one or more of U.S. Patent Nos. D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 and 6,340,573; and Foreign Counterparts. Other Patents Pending.

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VITEK 2™ — technology

AST-GN93

IVD

Карта для определения чувствительности к антимикробным препаратам грамотрицательных бактерий

КРАТКОЕ ОПИСАНИЕ

Данная карта предназначена для использования с системами VITEK® 2 в клинических лабораториях для лабораторного определения чувствительности к антимикробным препаратам **клинически значимых аэробных грамотрицательных палочек**. Используйте, как указано в руководстве "Расходные материалы".

ПРИМЕНЕНИЕ

Инструкция по применению предоставляется в наборе или может быть загружена с сайта **www.biomerieux.com/techlib**

Для получения дополнительных инструкций по применению смотрите руководство по расходным материалам.

ХРАНЕНИЕ

Хранить при температуре от 2° до 8° C.

СОСТАВ КАРТЫ

Антимикробный препарат	Код	Концентрация §	Диапазон определения ≤	≥	Указания к применению FDA (Управление по контролю за продуктами и лекарствами, США)
Амикацин	AN	8, 16, 64	2	64	CSAGNB**
Ампициллин	AM	4, 8, 32	2	32	CSAGNB**
Ампициллин/Сульбактам	SAM	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Азтреонам	ATM	2, 8, 32	1	64	CSAGNB**
Цефазолин	CZ	4, 16, 64	4	64	CSAGNB**
Цефепим	FEP	2, 8, 16, 32	1	64	CSAGNB**
Цефтазидим	CAZ	1, 2, 8, 32	1	64	CSAGNB**
Цефтриаксон	CRO	1, 2, 8, 32	1	64	CSAGNB**
Ципрофлоксацин	CIP	0.5, 2, 4	0.25	4	CSAGNB**
Эртапенем	ETP	0.5, 1, 6	0.5	8	*E. coli*, *K. pneumoniae*, *C. freundii*, *C. koseri*, *E. aerogenes*, *E. cloacae*, Kox(-ESBL)**, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *S. marcescens*
БЛРС	ESB	FEP 1, CTX 0.5, CAZ 0.5, FEP/CA 1/10, CTX/CA 0.5/4, CAZ/CA 0.5/4	NEG	POS	*E. coli*, *K. pneumoniae*, *K. oxytoca*
Гентамицин	GM	4, 16, 32	1	16	CSAGNB**
Меропенем	MEM❷	0.5, 2, 6, 12	0.25	16	*E. coli*, *K. pneumoniae*, *P. aeruginosa*, *P. mirabilis*, *Acinetobacter* spp., *C. freundii*, *E. cloacae*, *K. oxytoca*, *M. morganii*, *P. vulgaris*, *S. marcescens*, *A. hydrophila*, *C. diversus*, *H. alvei*, *P. multocida*, *Salmonella* spp., *Shigella* spp.
Нитрофурантоин	FT	16, 32, 64	16	512	CSAGNB**
Пиперациллин/тазобактам	TZP	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. enterica*
Тайгециклин	TGC	0.75, 2, 4	0.5	8	*C. freundii*, *C. koseri*, *E. coli*, *E. cloacae*, *E. aerogenes*, *K. oxytoca*, *K. pneumoniae*, *S. marcescens*

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Триметоприм/Сульфаметоксазол	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

Численные значения выражены в µг/мл.
§ Эквивалентна по эффективности концентрации стандартного метода.
**CSAGNB = Клинически значимые аэробные грамотрицательные палочки.
**Kox(-ESBL) = *K. oxytoca* (кроме штаммов, продуцирующих БЛРС).
Прим.: БЛРС FEP = Цефепим, CTX = Цефотаксим, CAZ = Цефтазидим, CA = Клавулановая кислота. Штаммы, продуцирующие БЛРС, устойчивы ко всем пенициллинам, цефалоспоринам, азтреонаму.
NEG = Отрицательный.
POS = Положительный.
Отрицательный результат теста на БЛРС не исключает наличия БЛРС, скрытых бета-лактамазой класса AmpC.
❶,❷ пр. = См. рабочие характеристики с кодом препарата и данным символом в колонке комментариев в руководстве к расходным материалам.
**Eco(+ETEC) = *E. coli* (в т. ч. чувствительные энтеротоксигенные штаммы, вызывающие диарею).

КОНТРОЛЬ КАЧЕСТВА

		Контрольные штаммы CLSI®, результаты в системе VITEK 2			
Антимикробный препарат	Код	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™	*K. pneumoniae* ssp *pneumoniae* ATCC® 700603™
Амикацин	AN	≤2 – 4	≤2 – 4	-	-
Ампициллин	AM	≤2 – 8	-	-	-
Ампициллин/Сульбактам	SAM	≤2/1 – 8/4	-	8/4 – ≥32/16	-
Азтреонам	ATM	≤1	2 – 8	-	-
Цефазолин	CZ	≤4	-	-	-
Цефепим	FEP	≤1	≤1 – 8	-	-
Цефтазидим	CAZ	≤1	≤1 – 4	-	-
Цефтриаксон	CRO	≤1	8 – ≥64	-	-
Ципрофлоксацин	CIP	≤0.25	≤0.25 – 1	-	-
Эртапенем	ETP	≤0.5	2 – ≥8	-	-
БЛРС·	ESB	NEG	-	-	POS
Гентамицин	GM	≤1	≤1 – 2	-	-
Меропенем	MEM	≤0.25	≤0.25 – 1	-	-
Нитрофурантоин	FT	≤16	-	-	-
Пиперациллин/тазобактам	TZP	≤4/4	≤4/4 – 8/4	≤4/4	-
Тайгециклин	TGC	≤0.5	-	-	-
Триметоприм/Сульфаметоксазол	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-	-

Численные значения выражены в µг/мл.
Прим.: БЛРС FEP = Цефепим, CTX = Цефотаксим, CAZ = Цефтазидим, CA = Клавулановая кислота. Штаммы, продуцирующие БЛРС, устойчивы ко всем пенициллинам, цефалоспоринам, азтреонаму.
NEG = Отрицательный.
POS = Положительный.
Отрицательный результат теста на БЛРС не исключает наличия БЛРС, скрытых бета-лактамазой класса AmpC.

ОГРАНИЧЕНИЯ

Для следующих сочетаний микроорганизм / антимикробный препарат результат следует подтверждать альтернативным методом:
- Амикацин: *Acinetobacter baumannii*
- Ампициллин: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Ампициллин/Сульбактам: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Азтреонам: *Pseudomonas* spp.
- Пиперациллин/тазобактам: *Serratia marcescens*

Для следующих сочетаний микроорганизм / антимикробный препарат результат следует подтверждать альтернативным методом при получении результата "устойчивый":

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- Меропенем: *Aeromonas* spp.
- Пиперациллин/тазобактам: *Pseudomonas aeruginosa*

Возможность определения устойчивости на данной карте для следующих сочетаний микроорганизм / антимикробный препарат неизвестна, поскольку на момент сравнительного тестирования при определении рабочих характеристик устойчивые штаммы не были доступны:

- Эртапенем: *E. coli, K. pneumoniae, C. freundii, C. koseri, E. aerogenes, E. cloacae, K. oxytoca* (кроме штаммов, продуцирующих БЛРС), *M. morganii, P. mirabilis, P. vulgaris, S. marcescens*
- Тайгециклин: *C. freundii, E. cloacae, E. coli, K. oxytoca, K. pneumoniae, C. koseri, E. aerogenes, S. marcescens*

ПРИМЕЧАНИЕ: Результаты для сочетаний антимикробный препарат / микроорганизм, для которых существуют ограничения, можно исключить из лабораторного отчета. Для получения подробной информации смотрите руководство по программному обеспечению.

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⇩ Перед первым использованием данной карты НЕОБХОДИМО ввести приведенные в данной инструкции штрих-коды в программу “Flex Panel Entry”.

01 A310IH0J---0

02 BAST-GN93011

03 C---Z010200N

04 D080E1C0G0HA

05 E0L1N11032GP

06 F0Y2P1R23007

ТАБЛИЦА СИМВОЛОВ И ОБОЗНАЧЕНИЙ

Символ	Обозначение
REF	Номер по каталогу
IVD	Для лабораторной диагностики
	Произведено
	Дата производства
	Температурные ограничения
	Использовать до
LOT	Номер партии
	Перед использованием прочтите инструкцию
Σ	Содержимого достаточно для <n> тестов
EC REP	Уполномоченный представитель в Европейском Сообществе

ПАТЕНТЫ

Продукт защищен одним или более патентов США: D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 и 6,340,573; и иностранными аналогами. Прочие патенты в процессе регистрации.

BIOMÉRIEUX, голубой логотип, VITEK и bioLiaison являются используемыми, зарегистрированными и/или находящимися в процессе регистрации торговыми марками, принадлежащими компании bioMérieux SA, или одному из ее филиалов или одной из ее компаний. ATCC товарный знак и фирменное наименование и любые номера по каталогу ATCC являются торговыми марками, принадлежащими Американской Коллекции Типовых Культур. Другие названия и торговые марки являются собственностью их соответствующих владельцев.

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VITEK 2™ — technology

AST-GN82

IVD

Карта для определения чувствительности к антимикробным препаратам грамотрицательных бактерий

КРАТКОЕ ОПИСАНИЕ

Данная карта предназначена для использования с системами VITEK® 2 в клинических лабораториях для лабораторного определения чувствительности к антимикробным препаратам **клинически значимых аэробных грамотрицательных палочек**. Используйте, как указано в руководстве "Расходные материалы".

ПРИМЕНЕНИЕ

Инструкция по применению предоставляется в наборе или может быть загружена с сайта **www.biomerieux.com/techlib**

Для получения дополнительных инструкций по применению смотрите руководство по расходным материалам.

ХРАНЕНИЕ

Хранить при температуре от 2° до 8° C.

СОСТАВ КАРТЫ

Антимикробный препарат	Код	Концентрация §	Диапазон определения ≤	≥	Указания к применению FDA (Управление по контролю за продуктами и лекарствами, США)
Амикацин	AN	8, 16, 64	2	64	CSAGNB**
Ампициллин/Сульбактам	SAM	4/2, 16/8, 32/16	2/1	32/16	CSAGNB**
Азтреонам	ATM	2, 8, 32	1	64	CSAGNB**
Цефазолин	CZ	4, 16, 64	4	64	CSAGNB**
Цефепим	FEP	2, 8, 16, 32	1	64	CSAGNB**
Цефтазидим	CAZ	1, 2, 8, 32	1	64	CSAGNB**
Цефтриаксон	CRO	1, 2, 8, 32	1	64	CSAGNB**
Ципрофлоксацин	CIP	0.5, 2, 4	0.25	4	CSAGNB**
Эртапенем	ETP	0.5, 1, 6	0.5	8	*E. coli*, *K. pneumoniae*, *C. freundii*, *C. koseri*, *E. aerogenes*, *E. cloacae*, Kox(-ESBL)**, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *S. marcescens*
Гентамицин	GM	4, 16, 32	1	16	CSAGNB**
Имипенем	IPM	1, 2, 6, 12	0.25	16	*Acinetobacter* spp., *Citrobacter* spp., *Enterobacter* spp., *E. coli*, *Klebsiella* spp., *M. morganii*, *P. vulgaris*, *Pv. rettgeri*, *P. aeruginosa*, *S. marcescens*, *Pv. stuartii*
Левофлоксацин	LEV❷	0.25, 0.5, 2, 8	0.12	8	*E. cloacae*, *E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *S. marcescens*, *A. baumannii*, *A. lwoffii*, *C. koseri*, *C. freundii*, *E. aerogenes*, *E. sakazakii*, *K. oxytoca*, *M. morganii*, *P. agglomerans*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *P. fluorescens*, *C. sakazakii*
Меропенем	MEM❷	0.5, 2, 6, 12	0.25	16	*E. coli*, *K. pneumoniae*, *P. aeruginosa*, *P. mirabilis*, *Acinetobacter* spp., *C. freundii*, *E. cloacae*, *K. oxytoca*, *M. morganii*, *P. vulgaris*, *S. marcescens*, *A. hydrophila*, *C. diversus*, *H. alvei*, *P. multocida*, *Salmonella* spp., *Shigella* spp.

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Пиперациллин/тазобактам	TZP	2/4, 8/4, 24/4, 32/4, 32/8, 48/8	4/4	128/4	*A. baumannii*, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *C. koseri*, *M. morganii*, *P. mirabilis*, *P. vulgaris*, *Pv. rettgeri*, *Pv. stuartii*, *S. enterica*
Тайгециклин	TGC	0.75, 2, 4	0.5	8	*C. freundii*, *C. koseri*, *E. coli*, *E. cloacae*, *E. aerogenes*, *K. oxytoca*, *K. pneumoniae*, *S. marcescens*
Тобрамицин	TM	8, 16, 64	1	16	CSAGNB**
Триметоприм/Сульфаметоксазол	SXT❷	1/19, 4/76, 16/304	20 (1/19)	320 (16/304)	*Klebsiella* spp., *Enterobacter* spp., *M. morganii*, *P. vulgaris*, *P. mirabilis*, *S. sonnei*, *S. flexneri*, Eco(+ETEC)**, *C. sakazakii*

Численные значения выражены в µг/мл.
§ Эквивалентна по эффективности концентрации стандартного метода.
**CSAGNB = Клинически значимые аэробные грамотрицательные палочки.
**Kox(-ESBL) = *K. oxytoca* (кроме штаммов, продуцирующих БЛРС).
❶,❷ пр. = См. рабочие характеристики с кодом препарата и данным символом в колонке комментариев в руководстве к расходным материалам.
**Eco(+ETEC) = *E. coli* (в т. ч. чувствительные энтеротоксигенные штаммы, вызывающие диарею).

КОНТРОЛЬ КАЧЕСТВА

		Контрольные штаммы CLSI®, результаты в системе VITEK 2		
Антимикробный препарат	Код	*E. coli* ATCC® 25922™	*P. aeruginosa* ATCC® 27853™	*E. coli* ATCC® 35218™
Амикацин	AN	≤2 – 4	≤2 – 4	-
Ампициллин/Сульбактам	SAM	≤2/1 – 8/4	-	8/4 – ≥32/16
Азтреонам	ATM	≤1	2 – 8	-
Цефазолин	CZ	≤4	-	-
Цефепим	FEP	≤1	≤1 – 8	-
Цефтазидим	CAZ	≤1	≤1 – 4	-
Цефтриаксон	CRO	≤1	8 – ≥64	-
Ципрофлоксацин	CIP	≤0.25	≤0.25 – 1	-
Эртапенем	ETP	≤0.5	2 – ≥8	-
Гентамицин	GM	≤1	≤1 – 2	-
Имипенем	IPM	≤0.25	1 – 4	-
Левофлоксацин	LEV	≤0.12	0.5 – 4	-
Меропенем	MEM	≤0.25	≤0.25 – 1	-
Пиперациллин/тазобактам	TZP	≤4/4	≤4/4 – 8/4	≤4/4
Тайгециклин	TGC	≤0.5	-	-
Тобрамицин	TM	≤1	≤1	-
Триметоприм/Сульфаметоксазол	SXT	≤20 (1/19)	160 (8/152) – ≥320 (16/304)	-

Численные значения выражены в µг/мл.

ОГРАНИЧЕНИЯ

Для следующих сочетаний микроорганизм / антимикробный препарат результат следует подтверждать альтернативным методом:
- Амикацин: *Acinetobacter baumannii*
- Ампициллин/Сульбактам: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Азтреонам: *Pseudomonas* spp.
- Имипенем: *Serratia marcescens*
- Пиперациллин/тазобактам: *Serratia marcescens*

Для следующих сочетаний микроорганизм / антимикробный препарат результат следует подтверждать альтернативным методом при получении результата "устойчивый":

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- Имипенем: *Aeromonas* spp.
- Меропенем: *Aeromonas* spp.
- Пиперациллин/тазобактам: *Pseudomonas aeruginosa*

Возможность определения устойчивости на данной карте для следующих сочетаний микроорганизм / антимикробный препарат неизвестна, поскольку на момент сравнительного тестирования при определении рабочих характеристик устойчивые штаммы не были доступны:

- Эртапенем: *E. coli, K. pneumoniae, C. freundii, C. koseri, E. aerogenes, E. cloacae, K. oxytoca* (кроме штаммов, продуцирующих БЛРС), *M. morganii, P. mirabilis, P. vulgaris, S. marcescens*
- Тайгециклин: *C. freundii, E. cloacae, E. coli, K. oxytoca, K. pneumoniae, C. koseri, E. aerogenes, S. marcescens*

ПРИМЕЧАНИЕ: Результаты для сочетаний антимикробный препарат / микроорганизм, для которых существуют ограничения, можно исключить из лабораторного отчета. Для получения подробной информации смотрите руководство по программному обеспечению.

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⇩ Перед первым использованием данной карты ⇩ НЕОБХОДИМО ввести приведенные в данной инструкции штрих-коды в программу “Flex Panel Entry”.

01 A310I60J---8

02 BAST-GN8201L

03 C---Z0100088

04 D0E1C0G0H0LN

05 E1N0320O1W2GW

06 F2P1R0523O0F

ТАБЛИЦА СИМВОЛОВ И ОБОЗНАЧЕНИЙ

Символ	Обозначение
REF	Номер по каталогу
IVD	Для лабораторной диагностики
	Произведено
	Дата производства
	Температурные ограничения
	Использовать до
LOT	Номер партии
	Перед использованием прочтите инструкцию
Σ	Содержимого достаточно для <n> тестов
EC REP	Уполномоченный представитель в Европейском Сообществе

ПАТЕНТЫ

Продукт защищен одним или более патентов США: D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 и 6,340,573; и иностранными аналогами. Прочие патенты в процессе регистрации.

BIOMÉRIEUX, голубой логотип, VITEK и bioLiaison являются используемыми, зарегистрированными и/или находящимися в процессе регистрации торговыми марками, принадлежащими компании bioMérieux SA, или одному из ее филиалов или одной из ее компаний. ATCC товарный знак и фирменное наименование и любые номера по каталогу ATCC являются торговыми марками, принадлежащими Американской Коллекции Типовых Культур. Другие названия и торговые марки являются собственностью их соответствующих владельцев.

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BIOMÉRIEUX

REF **259790**

043260-01/9313397 **E** - 2016-03 **RU**

IVD

BacT/ALERT® SN
BacT/ALERT SN Anaerobic — Флаконы BacT/ALERT SN со средой для выделения анаэробных микроорганизмов из крови

НАЗНАЧЕНИЕ

BacT/ALERT SN Anaerobic — Флаконы BacT/ALERT SN со средой для выделения анаэробных микроорганизмов из крови (по тексту флаконы для культивирования BacT/ALERT SN, флаконы BacT/ALERT SN) используются с анализаторами культур крови и микобактерий автоматическими бактериологическими серии BacT/ALERT (по тексту анализаторы BacT/ALERT) для качественного обнаружения и выделения анаэробных и факультативных анаэробных микроорганизмов (бактерий) в крови и других в норме стерильных биологических жидкостях.

КРАТКОЕ ОПИСАНИЕ

Анализаторы BacT/ALERT используются для определения наличия микроорганизмов в крови и других в норме стерильных биологических жидкостях при подозрении на бактериемию. Анализатор BacT/ALERT в сочетании с флаконами для культивирования представляет собой как систему обнаружения микроорганизмов, так и среду с питательными и атмосферными условиями, подходящими для микроорганизмов, которые являются частыми возбудителями инфекций крови и других в норме стерильных биологических жидкостей. Флакон BacT/ALERT SN, в который предварительно производится посев образца, помещается в прибор, где осуществляется его инкубирование и непрерывный мониторинг наличия роста микроорганизмов во флаконе.

ПРИНЦИП ТЕСТА

Анализаторы BacT/ALERT основаны на использовании колориметрического датчика и светоотражения для регистрации наличия и накопления углекислого газа (CO_2) в питательной среде. Если в анализируемом образце присутствуют микроорганизмы, то в процессе роста и утилизации субстратов питательной среды они вырабатывают CO_2. Под действием вырабатываемого микроорганизмами углекислого газа цвет газопроницаемого датчика, встроенного в дно каждого флакона для культивирования, меняется с зелено-голубого на желтый[1]. В результате осветления датчика коэффициент отражения повышается. Мониторинг и регистрация отражения флакона производится прибором каждые 10 минут.

РЕАГЕНТЫ

Для диагностики *in vitro*.

ОСТОРОЖНО! С образцами и флаконами, в которые произведен посев, следует обращаться как с потенциально инфекционными материалами. Все флаконы, в которые был произведен посев, иглы для забора образцов и системы для взятия крови следует обеззараживать в соответствии с процедурой, используемой в вашем учреждении[2].

BacT/ALERT SN (цветовая кодировка: фиолетовая) — флаконы для культивирования BacT/ALERT SN, предназначенные для однократного использования, содержат 40 мл питательной среды и внутренний датчик углекислого газа, являющегося индикатором микробного роста. Питательная среда состоит из панкреатического гидролизата казеина (1,36 % вес/объем), папаинового гидролизата соевых бобов (0,24 % вес/объем), полианетолсульфоната натрия (SPS) (0,035 % вес/объем), менадиона (0,00005 % вес/объем), гемина (0,0005 % вес/объем), дрожжевого экстракта (0,376 % вес/объем), пиридоксина гидрохлорида (0,0008 % вес/объем), пировиноградной кислоты (натриевая соль, 0,08 % вес/объем), восстанавливающих агентов и других сложных аминокислот и углеводов в очищенной воде. Во флаконах создана атмосфера CO_2 в азоте под вакуумом. Состав среды может быть модифицирован для достижения необходимых функциональных характеристик.

ОСТОРОЖНО! Флаконы для культивирования BacT/ALERT изготовлены из поликарбоната. Некоторые дезинфицирующие средства нельзя использовать на поликарбонатных поверхностях, так как они могут вызвать повреждение флаконов. Проверьте, совместимо ли дезинфицирующее средство с поликарбонатом, перед тем как использовать его для дезинфекции поверхностей флаконов для культивирования BacT/ALERT.

ОСТОРОЖНО! Некоторые редко встречающиеся прихотливые микроорганизмы могут не расти или расти очень медленно в питательной среде флаконов для культивирования BacT/ALERT SN. При подозрении на наличие редко встречающихся, прихотливых микроорганизмов, требующих специфических питательных сред и условий культивирования, следует рассмотреть возможность использования альтернативных методов выделения или увеличения времени инкубации.

ОСТОРОЖНО! При культивировании во флаконах BacT/ALERT SN образцов, не являющихся кровью, (в норме стерильных биологических жидкостей) может понадобиться добавление в питательную среду крови или других добавок, например стерильной дефибринированной лошадиной крови (5 % объем/объем), для поддержания роста, особенно при выделении прихотливых микроорганизмов[3].

ОСТОРОЖНО! В редких случаях в образцах могут встречаться микроорганизмы, которые растут во флаконах для культивирования BacT/ALERT SN, но не производят достаточного количества углекислого газа для определения роста. Фактором, способствующим возникновению такой ситуации, является наличие в образце активных антибиотиков.

Необходимые дополнительные материалы

- Анализаторы BacT/ALERT
- Система забора крови
- Стерильные иглы для вентилирования и пересева из положительных флаконов
- Одноразовые перчатки
- Подходящий контейнер для биологически опасных отходов для утилизации материалов, которые могут быть загрязнены инфекционными материалами

Материалы, которые можно приобрести в компании bioMérieux

- BacT/ALERT Blood Collection Adapter Cap - Колпачок адаптера для взятия крови во флаконы BacT/ALERT (по тексту колпачок адаптера, колпачок адаптера для взятия крови во флаконы BacT/ALERT)
- Анализаторы BacT/ALERT
- Стерильные иглы для вентилирования и пересева из положительных флаконов

Инструкции по хранению

Флаконы для культивирования BacT/ALERT SN готовы к использованию. Их следует хранить в вертикальном положении в месте, защищенном от прямого солнечного света, при комнатной температуре (15-30 °C). Срок годности флаконов указан на этикетке каждого флакона. Запрещается осуществлять посев во флаконы для культивирования по окончании срока годности. При хранении флаконов при температуре ниже 15 °C возможно образование осадка, который растворяется при нагревании флакона до комнатной температуры. Перед использованием выдержите флакон до достижения комнатной температуры.

Химические или физические признаки нестабильности

Перед использованием флаконы для культивирования BacT/ALERT SN следует осмотреть на наличие признаков порчи или повреждения (обесцвечивание). Флаконы с признаками порчи, повреждения или протекания использовать нельзя. Среда должна быть прозрачной, хотя возможна небольшая опалесценция или следы осадка из-за наличия антикоагулянта — полианетолсульфоната натрия (SPS). Не путайте опалесценцию с помутнением. Не используйте флаконы при помутнении среды, пожелтении датчика или при наличии признаков повышенного давления газа во флаконе, так как все перечисленное свидетельствует о контаминации.

ПРИБОРЫ

Перед использованием прочтите руководство по эксплуатации анализатора BacT/ALERT.

ЗАБОР И ПОДГОТОВКА ОБРАЗЦОВ

ПРИМЕЧАНИЕ. Флаконы для культивирования BacT/ALERT SN должны использоваться специально обученным медицинским персоналом. Правильный забор образца имеет большую важность при работе с культурами крови. Предпочтительным методом для получения

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образцов крови для посева является венепункция. Рекомендованная процедура забора образцов приведена в документе Cumitech 1C[4].

ПРИМЕЧАНИЕ. Во время подготовки флакона и внесения образца пациента необходимо принять меры для предотвращения контаминации. Обязательной мерой для снижения частоты контаминации является надлежащая дезинфекция кожи.

ПРИМЕЧАНИЕ. Кровь можно брать непосредственно в пробирки, содержащие полианетолсульфонат натрия (SPS), хотя это не рекомендуется компанией bioMérieux. Пробирки с другими антикоагулянтами для культур крови использовать нельзя[5].

ПРИМЕЧАНИЕ. Компания bioMérieux рекомендует загружать флаконы для культивирования в анализатор BacT/ALERT как можно скорее после забора образцов. Если флаконы для культивирования невозможно загрузить в анализатор сразу после посева, то до загрузки их следует держать при комнатной температуре.

Подготовка флакона

1. Запишите на флаконе информацию о пациенте. Значки на этикетке флакона (☺, #, ◴) может определять пользователь.
2. Снимите пластиковую защитную пластину с верха пробки флакона для культивирования. Перед посевом продезинфицируйте верхнюю часть флакона для культивирования тампоном, пропитанным спиртом, или аналогичным материалом. Дайте ей высохнуть естественным образом.
3. Очистите выбранное для венепункции место в соответствии с утвержденной в вашем учреждении процедурой.

   Процедура посева при непосредственном заборе крови посредством венепункции

   ПРИМЕЧАНИЕ. При использовании техники непосредственного забора крови из кровотока пациента запрещено делать это из внутрисосудистых устройств и портов для гемодиализа из-за вероятности деформации просвета катетера или заброса содержимого флакона в кровоток пациента.

   ПРИМЕЧАНИЕ. При одновременном посеве во флаконы для культивирования крови BacT/ALERT нескольких типов с использованием системы забора крови с иглой-бабочкой и колпачка-адаптера для непосредственного взятия крови сначала нужно вносить образец во флакон для выделения аэробных микроорганизмов, а затем во флакон для выделения анаэробных микроорганизмов, чтобы кислород, скопившийся в трубке, не попал во флакон для выделения анаэробных микроорганизмов.

   а. Можно использовать меньший объем образца, но выделение можно повысить, если объем образца составляет приблизительно 10 мл[4,6] (рекомендованное значение).
   б. Чтобы избежать посева чрезмерного объема, отслеживайте объем забираемой во флакон крови. Для наполнения флакона приблизительно на 10 мл ориентируйтесь по линии уровня заполнения на этикетке флакона. Или используйте метки объема с шагом 5 мл на этикетке флакона для оценки объема внесенного образца.

   ПРИМЕЧАНИЕ. В ходе всей процедуры тщательно контролируйте процесс непосредственного забора, обеспечивая надлежащий поток и не допуская попадания содержимого флакона в трубку адаптера. Поскольку во флаконе для культивирования содержатся химические добавки, важно следовать указанной ниже пошаговой процедуре, чтобы не допустить возможный обратный поток и последующие нежелательные реакции.

   а. Держите флакон для культивирования ниже руки пациента в вертикальном положении (пробкой кверху).
   б. Возьмите кровь с помощью системы забора крови с иглой-бабочкой и колпачка адаптера для взятия крови во флаконы BacT/ALERT в соответствии с утвержденной в вашем учреждении процедурой и выполните посев непосредственно во флакон для культивирования у кровати пациента. Можно использовать меньший объем образца, но выделение можно повысить, если объем образца составляет приблизительно 10 мл (рекомендованное значение). Чтобы избежать посева чрезмерного объема, отслеживайте объем забираемой во флакон крови с помощью меток с шагом 5 мл, расположенных на этикетке флакона.
   в. Ослабьте жгут, как только кровь начнет поступать во флакон для культивирования или в течение 2 минут после его наложения.
   г. Проследите за тем, чтобы содержимое флакона не касалось пробки или конца иглы во время забора крови.

   В контаминированном флаконе для культивирования может быть создано избыточное давление, и при его непосредственном использовании для забора крови может произойти отток среды в вену пациента. Контаминация флакона для культивирования не всегда легко распознается. Во избежание оттока необходимо тщательно контролировать процесс непосредственного забора крови. Не используйте флаконы при помутнении среды, пожелтении датчика или при наличии признаков повышенного давления газа во флаконе, так как все перечисленное свидетельствует о контаминации.

   Процедура посева при заборе крови с помощью шприца

   ПРИМЕЧАНИЕ. При одновременном посеве во флаконы для культивирования крови BacT/ALERT нескольких типов с использованием шприца сначала следует вносить образец во флакон для выделения анаэробных микроорганизмов, а затем во флакон для выделения аэробных микроорганизмов, чтобы кислород, скопившийся в шприце, не попал во флакон для выделения анаэробных микроорганизмов. Используйте метки объема на этикетке флакона для оценки объема внесенного образца.

   а. Выполните венепункцию и перенос крови во флакон для культивирования BacT/ALERT в соответствии с утвержденной в вашем учреждении процедурой.

   ОСТОРОЖНО! Запрещается вдавливать поршень шприца с усилием при выполнении посева, так как может произойти разбрызгивание образца. При достижении необходимого объема заполнения удалите шприц, так как из-за вакуума автоматически отберется количество, превышающее рекомендуемый максимум. Во избежание нарушения вакуума прокалывайте пробку флакона вертикально. Не выполняйте посев во флакон с нарушенным вакуумом.

4. Незамедлительно доставьте флакон для культивирования, в который произведен посев, в лабораторию для исследований.

ПРОЦЕДУРА ПРОВЕДЕНИЯ ТЕСТА ДЛЯ ФЛАКОНОВ ДЛЯ КУЛЬТИВИРОВАНИЯ BacT/ALERT SN

Предварительные замечания и предостережения

1. Необходимо использовать одноразовые перчатки и обращаться с флаконами, в которые был произведен посев, как с потенциально инфекционными материалами. При попадании контаминированных веществ внутрь организма или при их контакте с открытыми ранами или поврежденными участками кожи следует немедленно обратиться к врачу.
2. Все проливы и утечки контаминированных веществ следует немедленно устранять, используя 5-процентный раствор натрия гипохлорита, разведенный в соотношении 1:10. Использованные для очистки материалы следует утилизировать с соблюдением соответствующих процедур.
3. Все флаконы, в которые был произведен посев, иглы для забора образцов и системы для взятия крови следует обеззараживать в соответствии с процедурой, используемой в вашем учреждении[2].
4. Использовать эти флаконы должен специально обученный персонал лаборатории.
5. Только для США. Осторожно! Согласно федеральному закону США данное устройство допускается к продаже только лицензированным врачам или по их заказу.

Замечания и предостережения к процедуре проведения теста

1. Следует приложить все усилия к недопущению контаминации образцов крови пациента при венепункции и во время посева во флаконы для культивирования. Контаминация может привести к положительному результату анализа образца при отсутствии в образце клинически значимого изолята.
2. Забор крови следует производить до начала антибиотикотерапии. Если это невозможно, забор крови следует производить непосредственно перед введением очередной дозы антибиотика.
3. Если флаконы для культивирования были доставлены в лабораторию не сразу после посева, а с задержкой или были предварительно инкубированы вне анализатора BacT/ALERT, осмотрите флаконы на наличие признаков микробного роста. При наличии явных признаков микробного роста не помещайте флаконы в анализатор BacT/ALERT для проведения мониторинга, а продолжайте работу с ними как с положительными флаконами.

Лабораторная процедура

ОСТОРОЖНО! При пересеве материала из положительных флаконов для культивирования следует соблюдать общие меры предосторожности. Внутри флакона может быть создано повышенное давление при внесении излишка жидкости или при наличии микроорганизмов, активно вырабатывающих газы. Положительные флаконы следует подвергать кратковременному вентилированию перед окрашиванием или утилизацией для удаления из них газов, вырабатываемых микроорганизмами.

1. Осмотрите флаконы перед началом работы. Не используйте флаконы при наличии повреждений и протечек. При помутнении

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среды, пожелтении датчика, наличии гемолиза, признаков избыточного газового давления или других признаков микробного роста флакон следует считать положительным. Возьмите материал для мазка и сделайте пересев. Инкубируйте флакон, только если мазок отрицательный.

2. После загрузки флаконов для культивирования в прибор они должны оставаться там от пяти до семи суток или до получения положительного результата.
3. Из всех флаконов, результаты анализа которых положительны, следует взять мазок и сделать пересев. При отсутствии микроорганизмов в мазке (что может указывать на ложноположительный результат) флакон следует повторно загрузить в прибор до получения роста на чашке, куда был произведен пересев, или повторной регистрации прибором роста во флаконе. При повторном определении роста культуры во флаконе, который первоначально был определен как ложноположительный, из него следует повторно выполнить мазок и сделать пересев.
4. Для проверки отрицательного результата также можно выполнять мазок и/или пересев из флакона перед его утилизацией.
5. Процедура загрузки флаконов для культивирования в анализатор и выгрузки из анализатора BacT/ALERT подробно описана в руководстве по эксплуатации.
6. **Не используйте флаконы для культивирования BacT/ALERT более одного раза.** Утилизируйте флаконы для культивирования BacT/ALERT, в которые был произведен посев, в соответствии с правилами вашей лаборатории. Автоклавирование и/или сжигание являются приемлемыми процедурами утилизации таких флаконов BacT/ALERT[2].
7. Использование средств сверления (например, тупых игл) для прокола пробки может привести к протечке флакона.

КОНТРОЛЬ КАЧЕСТВА

Сертификат соответствия предоставляется с каждой партией флаконов для культивирования. При желании лаборатории могут выполнить контроль качества флаконов для культивирования BacT/ALERT SN. См. руководство по эксплуатации анализатора BacT/ALERT и документ CLSI® M22-A3[6].

Прибор

Набор стандартов для калибровки ячеек анализатора BacT/ALERT предоставляется с каждым прибором для проведения процедур QC и калибровки. Любые процедуры контроля качества должны быть частью текущего профилактического обслуживания системы. Дополнительные сведения см. в руководстве по эксплуатации анализатора BacT/ALERT.

РЕЗУЛЬТАТЫ

Положительный или отрицательный результат определяется программным обеспечением принятия решений, являющимся частью анализатора BacT/ALERT. До получения положительного или отрицательного сигнала от анализатора BacT/ALERT никаких действий выполнять не требуется.

ОГРАНИЧЕНИЯ ТЕСТА

На результат теста влияет множество практически неконтролируемых факторов, связанных с кровью и другими в норме стерильными биологическими жидкостями, поэтому нельзя с уверенностью утверждать, что результат теста зависит только от правильного или неправильного использования питательной среды или работы системы обнаружения.

1. В образцах пациентов, определяемых как положительные анализатором BacT/ALERT, могут содержаться микроорганизмы, клетки которых видны в мазке, но которые не растут на обычно используемых для пересева средах. При подозрении на наличие таких микроорганизмов пересев следует выполнять на специальные среды. Кроме того, положительные флаконы BacT/ALERT могут содержать микроорганизмы, клетки которых не видны при обычной окраске мазка и для обнаружения и выделения которых могут требоваться специальные методы окрашивания мазков, а также специальные среды для пересева.
2. Некоторые штаммы *Peptostreptococcus anaerobius* могут быть чувствительны к антикоагулянту — полианетолсульфонату натрия (SPS), что может привести к слабому росту или слабому выделению углекислого газа (CO_2) этими штаммами при посеве во флаконы недостаточного объема образца крови.
3. Иногда при наличии в образце крови большого количества лейкоцитов анализатор BacT/ALERT может определить результат как положительный. Это может привести к тому, что из фактически отрицательных флаконов будет повторно взят мазок и сделан пересев.
4. Часто количество микроорганизмов незначительно, и они могут появляться в кровотоке периодически, поэтому необходимо последовательно выполнять забор нескольких образцов крови каждого пациента.
5. При получении положительного сигнала от анализатора BacT/ALERT настоятельно рекомендуется немедленно извлечь флакон из прибора. Это позволит избежать нежизнеспособности культур из-за автолиза или по другим причинам. В частности, для некоторых штаммов *Streptococcus pneumoniae* характерен автолиз, если флакон не извлекается из прибора немедленно после получения положительного сигнала.
6. В окрашенном по Граму мазке из отрицательного флакона могут в небольших количествах встречаться нежизнеспособные клетки микроорганизмов, попавшие в мазок из компонентов питательной среды, реагентов для окраски мазка, иммерсионного масла или с предметных стекол, что может привести к ложноположительному результату.
7. Не рекомендуется применять отсроченную загрузку флаконов для культивирования крови. Любая отсрочка в загрузке может привести к увеличению времени до обнаружения или получению ложноотрицательных результатов. В случае если избежать отсрочки не удается, то согласно внутренним и опубликованным данным флаконы следует хранить при комнатной температуре не более 24 часов.

РАБОЧИЕ ХАРАКТЕРИСТИКИ ТЕСТА

Компанией были проведены внутренние исследования посевов следующих микроорганизмов в концентрациях ≤ 10 КОЕ/флакон и ≤ 100 КОЕ/флакон на образцах человеческой крови, отобранных в популяции здоровых взрослых.

Таблица 1.

Микроорганизм	Посевной материал (КОЕ/флакон)	Время культивирования до определения статуса флакона (часы)* BacT/ALERT SN (пластик)
Грамположительные анаэробы (*C. perfringens, P. asaccharolyticus*, *P. micros*)	≤ 100 ≤ 10	11,6—41,8 13,3—46,6
Грамотрицательные анаэробы (*F. nucleatum, B. fragilis, B. vulgatus*)	≤ 100 ≤ 10	29,5—35,9 33,4—44,7
Грамположительные факультативные анаэробы (*S. aureus, S. pneumoniae*)	≤ 100 ≤ 10	13,8—16,4 15,2—19,3
Грамотрицательные факультативные анаэробы (*E. coli*)	≤ 100 ≤ 10	10,5 12,2

* Каждый микроорганизм исследовался в трех повторностях, получены средние значения. Приведен диапазон этих средних значений, за исключением данных для *E. coli*, которая была единственным исследованным грамотрицательным факультативным микроорганизмом.

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СПИСОК ЛИТЕРАТУРЫ

1. Thorpe TC, Wilson ML, Turner JE, DiGuiseppi JL, Willert M, Mirrett S, et al: BacT/ALERT: an Automated Colorimetric Microbial Detection System. *J Clin Micro* 1990;28(7), 1608-1612.
2. *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* 5th Edition. U.S. Department of Health and Human Services Centers for Disease Control and Prevention and National Institutes of Health. Fifth Edition. US Government Printing Office. Washington: Feb 2007.
3. Koneman EW, Allen SD, Janda WM, Schreckenberger PC, Winn WC. *Color Atlas and Textbook of Diagnostic Microbiology*, 6th ed. 2006, pp. 446,590.
4. Baron EJ, Weinstein MP, Dunne Jr. WM, Yagupsky P, Welch DF, Wilson DM. 2005. Cumitech 1C, Blood Cultures IV. Coordinating ed. Baron EJ. ASM Press, Washington, DC.
5. CLSI. *Principles and Procedures for Blood Cultures; Approved Guideline.* CLSI document M47-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2007.
6. CLSI/NCCLS. *Quality Control for Commercially Prepared Microbiological Culture Media*; Approved Standard—Third Edition. CLSI/NCCLS document M22-A3. Wayne, PA: NCCLS; 2004.

ОГРАНИЧЕННАЯ ГАРАНТИЯ

Компания bioMérieux гарантирует, что рабочие характеристики данного изделия соответствуют указанному предусмотренному назначению в течение всего срока эксплуатации при условии, что строго соблюдены все процедуры по использованию, хранению и обработке и меры безопасности, как подробно изложено в инструкциях по эксплуатации.

За исключением вышеуказанных случаев, компания bioMérieux не дает никаких гарантий, в том числе, подразумеваемых гарантий товарного качества и гарантий соответствия предполагаемому использованию, и не дает никаких обязательств, в том числе, явно выраженных, подразумеваемых или косвенных, в отношении использования какого-либо реагента, программного обеспечения, прибора и расходных материалов (далее — «Система»), отличного от указанного в инструкциях по эксплуатации.

ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ

bioMérieux
Флаконы BacT/ALERT SN

100 шт./уп. REF 259790

Для получения технической поддержки в США обращайтесь в службу технической поддержки компании bioMérieux по телефону 1-800-682-2666. За пределами США свяжитесь с местным представителем компании bioMérieux.

ТАБЛИЦА СИМВОЛОВ И ОБОЗНАЧЕНИЙ

Символ	Обозначение
REF	Номер по каталогу
	Официальный производитель
	Дата изготовления
	Температурный диапазон
	Использовать до
LOT	Номер партии
	Обратитесь к инструкции по применению
Σ	Содержимого достаточно для <n> тестов
EC REP	Уполномоченный представитель в Европейском сообществе
	Вверх
IVD	Изделие медицинское для диагностики in vitro
	Не использовать повторно
	Без латекса
Rx only	Только для США. Осторожно! Согласно федеральному закону США данное устройство допускается к продаже только лицензированным врачам или по их заказу.
	Уровень заполнения

Инструкция прилагается к набору. Кроме того, инструкцию можно загрузить с сайта www.biomerieux.com/techlib.

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ИСТОРИЯ ПЕРЕСМОТРОВ

В этом разделе содержится обзор изменений, внесенных в инструкцию по применению флаконов BacT/ALERT SN.

Дата выпуска	Номер версии	Тип изменений	Обзор изменений
2016-03	043260-01 /9313397 E	Изменение содержания	В раздел **«Ограничения теста»** добавлены сведения об отсроченной загрузке.
			Добавлено предупреждение Rx-only для пользователей в США.
		Административные изменения	В раздел **«Ограниченная гарантия»** добавлено указание.
			Раздел **«Таблица символов и обозначений»** обновлен с целью внесения обозначения символа Rx-only.
2015-05	9307043 C	Изменение содержания	В раздел **«Реагенты»** внесено разъяснение по дате истечения срока годности.
			Раздел «Забор и подготовка образцов»: - добавление предупреждения относительно вероятности высокого давления во флаконе; - добавление примечания касательно этикетки на флаконе с меткой уровня заполнения; - добавление примечаний с информацией о венепункции.
		Административные изменения	Раздел **«Таблица символов и обозначений»** обновлен с целью внесения новых символов для продукта.
			Добавление адреса технической библиотеки

ПРИМЕЧАНИЕ. Незначительные типографские, грамматические изменения и изменения в форматировании в историю пересмотров не включены.

Категории типов изменений:

- **Корректура** — исправление ошибок в документации.
- **Изменение содержания** — внесение новых и измененных (обновленных) данных по назначению и рабочим характеристикам продукта.
- **Административные изменения** — введение изменений нетехнического характера, заслуживающих внимания пользователя.

Для получения технической консультации и поддержки просьба обращаться к уполномоченному представителю производителя на территории Российской Федерации:

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В случае выявления побочных действий, не указанных в инструкции по применению или руководстве по эксплуатации медицинского изделия, нежелательных реакций при его применении, особенностей взаимодействия медицинских изделий между собой, фактов и обстоятельств, создающих угрозу жизни и здоровью граждан и медицинских работников при применении и эксплуатации медицинских изделий, необходимо направить сообщение, содержащее указанные сведения, в Федеральную службу по надзору в сфере здравоохранения в соответствии с действующим законодательством.

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Этот продукт может быть защищен одним или несколькими патентами; см. http://www.biomerieux-usa.com/patents.

CLSI является зарегистрированным товарным знаком, принадлежащим Clinical and Laboratory Standards Institute.

Другие названия и товарные знаки принадлежат их законным владельцам.

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BacT/ALERT FA Plus

℞ only IVD

НАЗНАЧЕНИЕ

Флаконы BacT/ALERT FA Plus со средой и адсорбентом для выделения аэробных микроорганизмов из крови и стерильных биологических жидкостей (далее по тексту флаконы BacT/ALERT FA Plus) используются с анализаторами культур крови и микобактерий автоматическими бактериологическими семействами BacT/ALERT для качественного обнаружения и выделения аэробных и факультативно анаэробных микроорганизмов (бактерий и дрожжевых грибов) из крови и других в норме стерильных биологических жидкостей.

КРАТКОЕ ОПИСАНИЕ

Анализаторы культур крови и микобактерий автоматические бактериологические семейства BacT/ALERT (по тексту анализаторы культур крови BacT/ALERT, система обнаружения микроорганизмов BacT/ALERT, анализатор BacT/ALERT, система BacT/ALERT, анализатор, система) используются для определения наличия микроорганизмов в образцах крови и других в норме стерильных биологических жидкостях, полученных от пациентов при подозрении на бактериемию или фунгемию. Анализатор BacT/ALERT в сочетании с флаконами для культивирования представляет собой как систему обнаружения микроорганизмов, так и среду с питательными и атмосферными условиями, подходящими для микроорганизмов, которые часто встречаются в крови и других в норме стерильных биологических жидкостях. Флакон BacT/ALERT FA Plus, в который предварительно производится посев образца, помещается в анализатор, где осуществляется культивирование и непрерывный мониторинг наличия роста микроорганизмов во флаконе.

ПРИМЕЧАНИЕ: Если не указано иное, предоставленная информация относится ко всем конфигурациям системы обнаружения микроорганизмов BacT/ALERT.

ПРИНЦИП МЕТОДА

В основе работы анализаторов культур крови BacT/ALERT лежит использование колориметрического датчика и светоотражения для регистрации наличия и накопления углекислого газа (CO_2) в питательной среде. Если в анализируемом образце присутствуют микроорганизмы, то в процессе роста и утилизации субстратов питательной среды они вырабатывают углекислый газ. Под действием вырабатываемого микроорганизмами углекислого газа (CO_2) цвет газопроницаемого датчика, встроенного в дно каждого флакона для культивирования, меняется с зелено-голубого на желтый.[1] В результате осветления датчика коэффициент отражения повышается. Мониторинг и регистрация отражения флакона производится анализатором каждые 10 минут.

РЕАГЕНТЫ

Для диагностики *in vitro*.

ОСТОРОЖНО! С образцами и флаконами, в которые произведен посев, следует обращаться как с потенциально инфекционными материалами. Все флаконы, в которые был произведен посев, иглы для сбора образцов и системы для взятия крови следует обеззараживать в соответствии с процедурой, используемой в вашем учреждении.[2]

Флако **BacT/ALERT FA Plus** (цветовая кодировка: бледно-зеленая) —флаконы BacT/ALERT FA Plus, предназначенные для однократного использования, содержат 30 мл комплексной питательной среды и ≥1,6 г адсорбирующих полимерных гранул. На момент изготовления питательная среда состоит из следующих компонентов: сочетание пептонов/биологических экстрактов (≥1,85 % масса/объем), масса (≥0,083 % вес/объем), витаминов и аминокислот (≥0,00145 % вес/объем), источников углерода (≥0,45 % масса/объем), следовых веществ (≥0,0005 % масса/объем) и прочих комплексных аминокислот и углеводных субстратов в очищенной воде. Во флаконах создана разреженная атмосфера, состоящая из N_2, O_2 и CO_2. Количественный/качественный состав среды может быть модифицирован для достижения необходимых функциональных характеристик.

ОСТОРОЖНО! Флаконы BacT/ALERT изготовлены из поликарбоната. Некоторые дезинфицирующие средства нельзя использовать на поликарбонатных поверхностях, так как они могут вызвать повреждение флаконов. Проверьте, совместимо ли дезинфицирующее средство с поликарбонатом, перед тем как использовать его для дезинфекции поверхностей флаконов BacT/ALERT.

ОСТОРОЖНО! При культивировании во флаконах BacT/ALERT FA Plus не кровяных образцов (в норме стерильных биологических жидкостей), или образцов крови очень малого объема (0,5 мл или менее) требуется добавление в питательную среду крови, например стерильной дефибринированной лошадиной крови (10,0 % объем/объем), для поддержания роста, особенно для выделения прихотливых микроорганизмов, таких как *Haemophilus influenzae, Streptococcus pneumoniae* и *Neisseria gonorrhoeae*.[3]

Необходимые дополнительные материалы

- Анализаторы культур крови BacT/ALERT
- Система взятия крови
- Стерильные иглы для вентилирования и высева из положительных флаконов
- Одноразовые перчатки
- Подходящий контейнер для биологически опасных отходов для сброса материалов, которые могут быть загрязнены инфекционными материалами.

Материалы, которые можно приобрести в компании bioMérieux

- BacT/ALERT Blood Collection Adapter Cap — Колпачок адаптера для взятия крови во флаконы BacT/ALERT (по тексту колпачок адаптера, колпачок адаптера для взятия крови во флаконы BacT/ALERT)
- Анализаторы культур крови BacT/ALERT
- Стерильные иглы для вентилирования и высева из положительных флаконов

Инструкции по хранению

Флаконы BacT/ALERT FA Plus готовы к использованию. Их следует хранить в вертикальном положении в месте, защищенном от прямого света, при комнатной температуре (15–30 °C). Срок годности флаконов указан на этикетке каждого флакона. Запрещается осуществлять посев во флаконы для культивирования по окончании срока годности. При хранении флаконов при температуре ниже 15 °C возможно образование осадка, который растворяется при нагревании флакона до комнатной температуры. Перед использованием выдержите флакон до достижения комнатной температуры.

Химические или физические признаки нестабильности

Перед использованием флаконы BacT/ALERT FA Plus следует осмотреть на наличие признаков порчи или повреждения (обесцвечивание). Нельзя использован флаконы с признаками порчи, повреждений или утечки. Среда в отстоявшемся флаконе должна быть прозрачной, хотя возможна небольшая опалесценция или следы осадка из-за наличия антикоагулянта полианетолсульфоната натрия (SPS) или адсорбирующих полимерных гранул . Не путайте эти изменения с помутнением, которое является признаком микробного роста. Не используйте флаконы при помутнении среды, пожелтении датчика или

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наличии признаков повышенного давления газа во флаконе, т. к. все перечисленное свидетельствует о контаминации.

ПРИБОРЫ

Перед использованием прочтите руководство по эксплуатации анализаторов культур крови BacT/ALERT.

ВЗЯТИЕ И ПОДГОТОВКА ОБРАЗЦОВ

Общие сведения

1. Флаконы BacT/ALERT FA Plus должны использоваться специально обученным медицинским персоналом. Правильный сбор образца имеет большое значение при работе с культурами крови. Предпочтительным методом для получения образцов крови для посева является венепункция. Рекомендованная процедура сбора образцов приведена в документе Cumitech 1C[4].
2. Во время подготовки флакона и внесения образца пациента необходимо принять меры для предотвращения контаминации. Обязательной мерой для снижения частоты контаминации является надлежащая дезинфекция кожи.
3. Кровь можно брать непосредственно в пробирки, содержащие полианетолсульфонат натрия (SPS), хотя это не рекомендуется компанией bioMérieux. Пробирки с другими антикоагулянтами для культур крови использовать нельзя.[5]
4. Компания bioMérieux рекомендует загружать флаконы для культивирования в анализаторы культур крови BacT/ALERT как можно скорее после взятия образцов. Если флаконы невозможно загрузить в анализатор сразу после посева, то до загрузки в анализатор их следует хранить при комнатной температуре не более 24 часов.
5. Оптимальное выделение изолятов достигается при внесении во флакон максимального объема образца. Использование меньшего объема образца может исказить результаты выделения и/или увеличить время обнаружения некоторых микроорганизмов. Не заполняйте флакон образца объемом более 10 мл. Вакуум во флаконе обычно превышает 10 мл. Следите за поступающим во флакон объемом с помощью меток объема с шагом 5 мл, расположенных на этикетке флакона.

Подготовка флакона

1. Запишите на флаконе информацию о пациенте. Условные обозначения на этикетке флакона (☺,#,🕑) могут быть определены пользователем.
2. Снимите пластиковую защитную пластину с верха пробки флакона для культивирования Перед посевом продезинфицируйте верхнюю часть флакона тампоном, пропитанным спиртом, или аналогичным материалом. Дайте ей высохнуть естественным способом.
3. Обработайте выбранное для венепункции место в соответствии с утвержденной в вашем учреждении процедурой.

Процедура посева при непосредственном взятии крови путем венепункции

ПРИМЕЧАНИЕ: При использовании техники непосредственного взятия крови из кровотока пациента запрещено делать это из внутрисосудистых устройств и портов для гемодиализа из-за вероятности деформации просвета катетера или заброса содержимого флакона в кровоток пациента.

ПРИМЕЧАНИЕ: При одновременном посеве во флаконы BacT/ALERT нескольких типов с использованием системы взятия крови с иглой-бабочкой и адаптера для непосредственного взятия крови сначала нужно вносить образец во флакон для выделения аэробных микроорганизмов, а затем — для выделения анаэробных микроорганизмов, чтобы кислород, скопившийся в трубке, не попал во флакон для выделения анаэробных микроорганизмов.

а. Можно использовать меньший объем образца, но высеваемость можно повысить, если объем образца составляет приблизительно 10 мл (рекомендованное значение).[4,6]

б. Чтобы избежать посева чрезмерного объема, отслеживайте объем во флакон крови. Для наполнения флакона приблизительно на 10 мл ориентируйтесь по линии уровня заполнения на этикетке. Или используйте метки объема с шагом 5 мл на этикетке флаконы для оценки объема внесенного образца.

ПРИМЕЧАНИЕ: В ходе всей процедуры тщательно контролируйте процесс непосредственного взятия, обеспечивая надлежащий поток и не допуская попадания содержимого флакона в трубку адаптера. Поскольку во флаконе для культивирования содержатся химические добавки, важно следовать указанной ниже пошаговой процедуре, чтобы не допустить возможный обратный поток и последующие нежелательные реакции.

а. Держите флакон для посева ниже руки пациента в вертикальном положении (пробкой кверху).

б. Возьмите кровь с помощью системы взятия крови с иглой-бабочкой и колпачка адаптера для взятия крови во флаконы, в соответствии с утвержденной в вашем учреждении процедурой, и выполните посев непосредственно во флакон для культур у кровати пациента. Можно использовать меньший объем образца, но высеваемость можно повысить, если объем образца составляет приблизительно 10 мл (рекомендованное значение). Чтобы избежать посева чрезмерного объема, отслеживайте объем поступающей во флакон крови с помощью меток с шагом 5 мл, расположенных на этикетке флакона.

в. Ослабьте жгут, как только кровь начнет поступать во флакон, или в течение 2 минут после его наложения.

d. Проследите за тем, чтобы содержимое флакона не касалось пробки или конца иглы во время взятия крови.

ОСТОРОЖНО! В контаминированном флаконе для культивирования может быть избыточное давление, и при его использовании для непосредственного взятия крови может произойти отток в вену пациента. Контаминация флакона для культивирования не всегда легко распознается. Во избежание оттока необходимо тщательно контролировать процесс непосредственного взятия крови. Не используйте флаконы при помутнении среды, пожелтении датчика или при наличии признаков повышенного давления газа во флаконе, т. к. все перечисленное свидетельствует о контаминации.

Процедура посева при взятии крови с помощью шприца

ПРИМЕЧАНИЕ: При одновременном посеве во флаконы BacT/ALERT нескольких типов с использованием шприца сначала следует вносить образец во флакон для выделения анаэробных микроорганизмов, а затем — для выделения аэробных микроорганизмов, чтобы кислород, скопившийся в шприце, не попал во флакон для выделения анаэробных микроорганизмов. Используйте метки объема на этикетке флакона для оценки объема внесенного образца.

а. Выполните венепункцию и перенос крови во флакон BacT/ALERT в соответствии с утвержденной в вашем учреждении процедурой.

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ОСТОРОЖНО! При выполнении посева запрещается вдавливать поршень шприца с усилием, так как может произойти разбрызгивание образца. При достижении необходимого объема заполнения удалите шприц, так как из-за вакуума автоматически будет набрано количество, превышающее рекомендованный максимум. Во избежание нарушения вакуума прокалывайте пробку флакона вертикально. Не выполняйте посев во флакон с нарушенным вакуумом.

4. Незамедлительно доставьте флакон для культивирования, в который произведен посев, в лабораторию для исследований.

ПРОЦЕДУРА ПРОВЕДЕНИЯ ТЕСТА ДЛЯ ФЛАКОНОВ BacT/ALERT FA PLUS

Предварительные замечания и меры предосторожности

1. Необходимо использовать одноразовые перчатки и обращаться с флаконами, в которые был произведен посев, как с потенциально инфекционными материалами. При попадании контаминированных веществ внутрь или при их контакте с поврежденными участками кожи и слизистых оболочек — следует немедленно обратиться к врачу.
2. Все протечки и контаминированные материалы следует немедленно устранять, используя 5% раствор гипохлорита натрия, разведенный в соотношении 1:10. Использованные для очистки материалы следует утилизировать с соблюдением соответствующих процедур.
3. Все флаконы, в которые был произведен посев, иглы для сбора образцов и системы для взятия крови следует обеззараживать в соответствии с процедурой, используемой в вашем учреждении.[2]
4. Утилизацию этих флаконов должен осуществлять специально обученный медицинский персонал.
5. Только для США: Внимание: Согласно федеральному закону США, данное изделие допускается к продаже только лицензированным врачам или по их заказу.

Замечания и меры предосторожности при выполнении процедуры

1. Необходимо принять все меры для предотвращения контаминации образца пациента во время венепункции и посева во флакон, поскольку контаминация может привести к получению положительного результата при отсутствии в образце клинически значимого изолята.
2. Взятие крови следует производить до начала антибиотикотерапии. Если это невозможно, взятие крови следует производить непосредственно перед введением очередной дозы препарата.
3. Если флаконы были доставлены в лабораторию не сразу после посева, а с задержкой, или были предварительно инкубированы вне анализатора BacT/ALERT, осмотрите флаконы на предмет наличия признаков микробного роста. При наличии явных признаков микробного роста не помещайте флаконы в анализатор культур крови BacT/ALERT для проведения мониторинга, а продолжайте работу с ними как с положительными флаконами.

Процедура лабораторного исследования

ОСТОРОЖНО! При высев материала из положительных флаконов следует соблюдать общие меры предосторожности. При внесении избыточного объема жидкости или наличии микроорганизмов, активно вырабатывающих газы, внутри флакона может быть создано повышенное давление. Положительные флаконы следует подвергать кратковременному вентилированию перед окрашиванием или утилизацией для удаления из них газов, вырабатываемых микроорганизмами.

1. Осмотрите флаконы перед началом работы. Не используйте флаконы при наличии повреждений и протечек. При помутнении среды, пожелтении датчика, наличии гемолиза, признаков избыточного давления газа или других признаков микробного роста флакон следует считать положительным. Возьмите материал для мазка и сделайте высев. Инкубируйте флакон только в том случае, если мазок положительный.
2. После загрузки флаконов в анализатор инкубируйте 5 суток или до получения положительного результата.
3. Мазок и высев следует выполнять из всех положительных флаконов. При отсутствии микроорганизмов в мазке (что может указывать на ложноположительный результат) флакон следует повторно загрузить в анализатор до получения роста на чашке, куда был произведен высев, или до повторной регистрации анализатором роста во флаконе. Из флаконов, результат которых первоначально был определен как ложноположительный и затем был классифицирован как положительный, следует повторно взять мазок и сделать высев.
4. Для проверки отрицательного результата также можно выполнять мазок и/или высев из флакона перед его утилизацией.
5. Процедура загрузки флаконов в анализатор и выгрузки из анализатора BacT/ALERT подробно описана в руководстве по эксплуатации.
6. **Не используйте флаконы BacT/ALERT повторно**. Утилизируйте флаконы BacT/ALERT, в которые произведен посев, в соответствии с правилами вашей лаборатории. Автоклавирование и/или сжигание являются приемлемыми процедурами утилизации таких флаконов, как BacT/ALERT.[2]
7. Использование средств сверления (например, тупых игл) для прокола пробки может привести к протечке флаконы.

КОНТРОЛЬ КАЧЕСТВА

Сертификат соответствия предоставляется с каждой партией флаконов для культур. При желании отдельные лаборатории могут выполнять дополнительный контроль качества флаконов BacT/ALERT FA Plus. См. соответствующее руководство пользователя анализатора BacT/ALERT и документ CLSI® M22-A3.[6]

Прибор

Комплект стандартов отражательной способности BacT/ALERT поставляется с каждым анализатором культур крови и микобактерий автоматическим бактериологическим семейством BacT/ALERT 3D с принадлежностями (по тексту анализатор BacT/ALERT 3D, система обнаружения микроорганизмов BacT/ALERT 3D, система BacT/ALERT 3D). Для получения дополнительной информации см. соответствующее руководство пользователя анализатора BacT/ALERT.

ОСТОРОЖНО! Если поставщик ЛИС вашего лечебного учреждения отправляет идентификационные номера флаконов и сокращенные обозначения типов флаконов в анализатор BacT/ALERT, используйте правильные сокращения типов флаконов во избежание возможного получения ложноположительных или ложноотрицательных результатов. Для получения более подробной информации свяжитесь с представителем компании bioMérieux.

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РЕЗУЛЬТАТЫ

Положительный или отрицательный результат определяется программным обеспечением для принятия решений, которое является частью анализаторов культур крови BacT/ALERT. До получения положительного или отрицательного сигнала от анализатора BacT/ALERT никаких действий выполнять не требуется.

ОГРАНИЧЕНИЯ МЕТОДА

На результат посева крови влияет множество факторов, которые практически не поддаются контролю, поэтому нельзя с уверенностью утверждать, что результат теста зависит только от правильного или неправильного использования питательной среды или работы системы обнаружения.

1. В образцах пациентов, определяемых анализатором BacT/ALERT как положительные, могут содержаться микроорганизмы, клетки которых видно в мазке, но которые не растут на обычно используемых для высева средах. При подозрении на наличие таких микроорганизмов высев следует выполнять на специальные среды. Кроме того, положительные флаконы BacT/ALERT могут содержать микроорганизмы, клеток которых не видно при обычной окраске мазка и для обнаружения и выделения которых могут требоваться специальные методы окрашивания мазков, а также специальные среды для высева.
2. Некоторые редко встречающиеся прихотливые микроорганизмы могут не вырасти или расти очень медленно в питательной среде флаконов BacT/ALERT FA Plus. Кроме этого, в редких случаях в образцах могут встречаться микроорганизмы, которые растут в питательной среде флаконов BacT/ALERT FA Plus, но не производят достаточного количества углекислого газа для определения роста. При подозрении на наличие редко встречающихся, прихотливых микроорганизмов, требующих специфических питательных сред и условий культивирования, следует рассмотреть возможность использования альтернативных методов выделения или увеличения времени инкубации.
3. Некоторые штаммы *Haemophilus influenzae, Neisseria meningitidis* и *Neisseria gonorrhoeae* могут быть чувствительны к антикоагулянту полианетолсульфонату натрия (SPS), что может привести к слабому росту или слабому выделению углекислого газа (CO_2) этими штаммами при посеве во флаконы недостаточного объема образца.
4. Иногда, при наличии в образце большого количества лейкоцитов, анализатор BacT/ALERT может определить результат как положительный. В этом случае результаты мазка и высева могут быть отрицательными.
5. Часто количество микроорганизмов незначительное, и они могут появляться в кровотоке периодически, поэтому необходимо последовательно выполнять взятие нескольких образцов крови каждого пациента.
6. При получении положительного сигнала от анализатора BacT/ALERT следует немедленно извлечь флакон из анализатора. Это позволит избежать ложноотрицательных результатов из-за аутолиза или по другим причинам. В частности, если флакон не извлекается из анализатора немедленно после получения положительного сигнала, для некоторых штаммов *Streptococcus pneumoniae* характерен аутолиз.
7. В окрашенном по Граму мазке из отрицательного флакона могут в небольших количествах встречаться нежизнеспособные клетки микроорганизмов, попавшие в мазок из компонентов питательной среды, реагентов для окраски, иммерсионного масла или с предметных стекол, что может привести к ложноположительному результату.
8. Компания bioMérieux рекомендует загружать флаконы для культивирования в анализаторы BacT/ALERT как можно скорее после взятия образца. Если неизбежна задержка доставки флаконов в лабораторию, следует принимать во внимание информацию по исследованиям образцов с отсроченной загрузкой, в разделе «Рабочие характеристики теста».
9. Нейтрализации цефтазидима и цефепима достичь не удалось.
10. Если флаконы хранились в течение 12 месяцев, для обнаружения *Stenotrophomonas maltophilia* в спинномозговой жидкости может потребоваться больше времени, или может быть получен отрицательный результат исследования.
11. Флаконы BacT/ALERT FA Plus не имеют соответствующих уровней CO_2 в свободном пространстве для поддержания роста капнофилов, таких, как *Capnocytophaga* spp.

ОЖИДАЕМЫЕ РЕЗУЛЬТАТЫ

1. Доля положительных посевов составляла 12,3 % (в диапазоне: 7,9–14,3 %) в целом, и в 9,4 % (в диапазоне: 5,0 %–11,2 %) для значимых изолятов в трех центрах проведения клинического исследования флаконов BacT/ALERT FA Plus с 6–10 мл крови с использованием анализатора BacT/ALERT 3D.
2. Доля положительных посевов составляла 20,2 % (в диапазоне: 16,4–24,3 %) в целом и в 15,4 % (в диапазоне: 8,2 %–21,6 %) для значимых изолятов в трех центрах проведения клинических исследований флаконов BacT/ALERT FA Plus, в которые были внесены образцы стерильных биологических жидкостей с использованием анализатора BacT/ALERT 3D.
3. Ожидаемая доля положительных результатов будет зависеть от таких факторов, как количество пациентов, распространенность значимых микроорганизмов, географическое расположение места проведения теста и уровень контаминации. Приведенные значения ожидаемых результатов основаны на данных, полученных в ходе нескольких клинических исследований.

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НЕЙТРАЛИЗАЦИЯ ПРОТИВОМИКРОБНЫХ ПРЕПАРАТОВ

Нейтрализация противомикробных препаратов с помощью адсорбирующих полимерных гранул различается в зависимости от уровня дозировки и времени взятия образца. Внутренние исследования, проведенные на системе обнаружения микроорганизмов BacT/ALERT 3D, показали, что противомикробные препараты эффективно нейтрализуются средой BacT/ALERT FA Plus на основании 100 % выделения тестируемых микроорганизмов. В этих исследованиях противомикробные препараты добавлялись в клинически значимых концентрациях непосредственно во флаконы для культур во время посева с чувствительными штаммами. Эффективность противомикробных препаратов была подтверждена параллельным тестированием с использованием среды без нейтрализующих свойств в качестве контрольного элемента. В среде были нейтрализованы противомикробные препараты, следующих групп: пенициллины, глицилциклины, полиены, макролиды, триазолы, эхинокандины, цефазолин, цефокситин, цефтаролин, аминогликозиды, фторхинолоны, линкозамиды, гликопептиды и оксазолидиноны.

Нейтрализации цефтазидима и цефепима достичь не удалось. Цефотаксим и цефтриаксон нейтрализовались не полностью. Цефотаксим нейтрализовался при концентрациях, составляющих от 2 до 50 % от его максимальной концентрации в сыворотке крови (PSL), в зависимости от микроорганизма. Цефтриаксон нейтрализовался при концентрациях, составляющих от 1 до 50 % от PSL, в зависимости от микроорганизма.

Свойства нейтрализации противомикробных препаратов зависят от состава материала флакона и не определяются алгоритмом анализа системы обнаружения микроорганизмов BacT/ALERT. Нейтрализация была продемонстрирована для амикацина (класс аминогликозидов), пиперациллина (класс пенициллинов), ванкомицина (класс гликопептидов) и вориконазола (класс триазолов). Испытания показали, что система анализатора не оказывала влияния на способность флакона к нейтрализации противомикробных препаратов.

За дополнительной информацией по противомикробным препаратам, которые нейтрализуются во флаконах BacT/ALERT FA Plus, обращайтесь к местному представителю компании bioMérieux.

РАБОЧИЕ ХАРАКТЕРИСТИКИ

Системы обнаружения микроорганизмов BacT/ALERT 3D

Вещества, которые могут помешать проведению теста

Были проведены внутренние исследования посевов с использованием спинномозговой, плевральной и синовиальной жидкостей, плазмы крови, цельной крови и кровяных сгустков. К аликвотам каждой из этих жидкостей были также добавлены лейкоциты в концентрациях, обычно наблюдаемых в каждой из перечисленных биологических жидкостей при бактериемии. Тест проводился в присутствии микроорганизмов или в их отсутствие. Данные вещества не мешали выделению и обнаружению микроорганизмов и не давали ложноположительных результатов в отсутствие микроорганизмов.

Аналитическая чувствительность: Предел обнаружения (LoD)

В таблице 1 представлены результаты внутренних исследований посевов. Для каждого вида микроорганизмов тест был выполнен как минимум в 30 повторностях. Данные в таблице 1 получены при использовании флаконов в конце срока годности. Во флаконы, засеянные *H. influenzae*, добавляли по 4 мл смешанной крови человека. На пределе обнаружения микроорганизмы были обнаружены не менее чем в 95 % случаев.

Таблица 1. Аналитическая чувствительность: Предел обнаружения (LoD)

Микроорганизм	Идентификационный номер штамма	Предел обнаружения (LoD) (КОЕ/флакон)
Candida albicans	ATCC® 14053™	6
Enterobacter aerogenes	ATCC® 13048™	8
Enterococcus faecalis	NCTC 12697	5
Escherichia coli	NCTC 12923	4
Haemophilus influenzae	ATCC® 10211™	6
Klebsiella pneumoniae	STL 104016	4
Listeria monocytogenes	ATCC® 15313™	6
Pseudomonas aeruginosa	NCTC 12924	4
Salmonella enterica	ATCC® 14028™	5
Staphylococcus aureus	NCTC 10788	5
Streptococcus pneumoniae	ATCC® 6305™	6

ПРИМЕЧАНИЕ: В 96,7 % случаев высев материала из флаконов, признанных положительными, был произведен не позднее, чем через 30 минут.
Штамм STL 104016 был получен из внутренней коллекции культур микроорганизмов компании bioMérieux.

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Аналитическая чувствительность: Ростовые свойства

В таблице 2 представлены результаты внутренних исследований посевов с использованием крови здоровых людей или без нее. Было проверено несколько штаммов каждого вида микроорганизмовпри целевой концентрации посевного материала 125 КОЕ/флакон. Фактическое количество микроорганизмов составило 3–298 КОЕ/флакон. В данном исследовании высев материала из флаконов BacT/ALERT FA Plus проводился как минимум через 24 часа после того, как система зарегистрировала рост во флаконе. Перечисленные виды микроорганизмов являются представителями клинически распространенных микроорганизмов, обычно выделяемых при посевах крови и стерильных биологических жидкостей.

Таблица 2. Аналитическая чувствительность: Показатели роста

Микроорганизм	Кровь				Без крови			
	% выделения (кол-во)	Концентрация посевного материала, КОЕ/флакон (диапазон)	Продолжительность культивирования до определения статуса флакона (часы)		% выделения* (кол-во=3)	Концентрация посевного материала, КОЕ/флакон (диапазон)	Продолжительность культивирования до определения статуса флакона (часы)	
			Среднее	Диапазон			Среднее	Диапазон
Staphylococcus aureus	100,0 (33/33)	54–150	13,4	12,2–15,6	100,0	116–150	16,7	14,6–18,2
Escherichia coli	100,0 (33/33)	71–254	11,3	10,3–12,4	100,0	73–176	11,4	10,6–11,9
Pseudomonas aeruginosa	100,0 (15/15)	74–148	16,0	13,7–18,6	100,0	74–148	20,8	17,8–25,6
Klebsiella pneumoniae	100,0 (15/15)	89–123	11,3	10,6–12,3	100,0	95–123	12,0	11,6–12,4
Candida albicans	100,0 (38/38)	88–298	28,9	19,2–52,8	100,0	88–298	27,1	22,1–30,1
Streptococcus pneumoniae	100,0 (33/33)	3–260	13,9	10,8–16,5	100,0	4–25	14,3	13,0–16,3
Staphylococcus epidermidis	100,0 (15/15)	44–135	17,6	14,3–36,0	100,0	45–105	21,4	19,0–24,8
Enterococcus faecalis	100,0 (15/15)	63–259	11,6	11,0–12,3	100,0	71–169	12,3	11,8–12,7
Enterococcus faecium	100,0 (15/15)	25–120	12,6	11,3–14,4	100,0	25–120	15,5	14,0–17,5
Enterobacter cloacae	100,0 (15/15)	111–200	12,0	10,8–15,7	100,0	111–185	11,7	11,3–12,0
Candida glabrata	100,0 (15/15)	118–281	44,8	27,3–64,8	100,0	118–194	39,9	30,9–50,4
Haemophilus influenzae	100,0 (15/15)	105–266	14,4	12,1–16,8	0	-	-	-
Proteus mirabilis	100,0 (15/15)	36–213	12,9	11,3–16,3	100,0	36–213	12,5	11,3–13,6

* При высеваемости менее 100,0 % рекомендуется добавить кровь, например стерильную дефибринированную лошадиную кровь (10,0 % объем/объем).[3]

Для некоторых видов, включая *Capnocytophaga ochracea, Cardiobacterium hominis, Eikenella corrodens, Haemophilus parainfluenzae, Granulicatella adiacens u Helicobacter cinaedi*, положительный сигнал был получен в менее, чем 100 % случаев.

Результаты клинических исследований (посевы крови)

Ниже приводятся результаты сравнения посевов крови во флаконы BacT/ALERT FA Plus и BacT/ALERT FA Aerobic — флаконы BacT/ALERT FA со средой с активированным углем для выделения аэробных микроорганизмов из крови (по тексту флаконы BacT/ALERT FA) (для всех соответствующих пар).

В трех разных центрах в США было проведено многоцентровое клиническое исследование, в котором сравнивали характеристики флаконов для посева крови BacT/ALERT FA Plus и BacT/ALERT FA при аэробном культивировании после добавления образцов крови объемом от 6 до 10 мл (соответствующие пары). Всего было получено 1656 пар флаконов от 728 взрослых пациентов с подозрением на бактериальные/дрожжевые инфекции крови. Если хотя бы для одного флакона в паре анализатор BacT/ALERT регистрировал положительный результат, производился высев материала из обоих флаконов. Считалось, что пара флаконов дала положительный результат, если результаты высева материала либо из флакона BacT/ALERT FA Plus, либо из флакона BacT/ALERT FA были положительными. Результат считался истинно положительным, если анализатором BacT/ALERT был зарегистрирован рост во флаконе и при высеве материала из этого флакона был получен рост микроорганизма. Для сравнения характеристик были рассчитаны доля истинно положительных результатов для флаконов BacT/ALERT FA Plus и для флаконов BacT/ALERT FA и соотношение количества истинно положительных результатов для обоих типов флаконов. Выделенные клинические изоляты относили к группе значимых, контаминантов или неизвестных по усмотрению центров, где проводилось исследование.

В общей сложности из всех соответствующих пар аэробных посевов крови, давших положительный результат, было выделено 267 изолятов. При высеве материала из флаконов BacT/ALERT FA Plus или BacT/ALERT FA в 238 парах флаконов был выделен, по крайней мере, один изолят. Из 214 пар флаконов был выделен один изолят, из 19 пар — два изолята и из 5 пар — три изолята. Общая выборка результатов, приведенных в таблице 3, включает 267 изолятов, выделенных из пар флаконов с положительным результатом, и 1418 пар флаконов с отрицательным результатом (всего было получено 1685 результатов). При использовании флаконов BacT/ALERT FA Plus было выявлено в общей сложности 208 изолятов, в то время как при использовании флаконов BacT/ALERT FA — 194 изолята. Что касается значимых изолятов, при использовании флаконов BacT/ALERT FA Plus было выявлено всего 159 изолятов, а при использовании флаконов BacT/ALERT FA — 135 изолятов. При высеве материала из флаконов BacT/ALERT FA Plus, давших положительный результат, было получено пять ложноположительных результатов, что составляет 0,30 % (5/1685) от всей исследуемой популяции.

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В нижеследующих таблицах сравниваются результаты, полученные для всех соответствующих флаконов BacT/ALERT FA Plus и BacT/ALERT FA для посевов крови, которые при высеве дали любое количество изолятов (таблица 3), единственный изолят (таблица 4) или несколько изолятов (таблица 5).

Таблица 3. Все соответствующие пары, давшие один или несколько изолятов (посевы крови)

Определение клинических изолятов	Флаконы BacT/ALERT FA Plus, истинно положительные результаты	% истинно положительных результатов, флаконы BacT/ALERT FA Plus	Флаконы BacT/ALERT FA, истинно положительные результаты	% истинно положительных результатов, флаконы BacT/ALERT FA	Соотношение количества истинно положительных результатов*
Значимые	159	9,4 (159/1685)	135	8,0 (135/1685)	1,178
Контаминанты	36	2,1 (36/1685)	47	2,8 (47/1685)	0,766
Неизвестные	13	0,8 (13/1685)	12	0,7 (12/1685)	1,083
Всего	208	12,3 (208/1685)	194	11,5 (194/1685)	1,072

* 135 (сто тридцать пять) изолятов было выявлено при использовании как флаконов BacT/ALERT FA Plus, так и флаконов BacT/ALERT FA; 73 изолята — только при использовании флаконов BacT/ALERT FA Plus и 59 изолятов — только при использовании флаконов BacT/ALERT FA. Соотношение количества истинно положительных результатов по всем изолятам составило 1,072 (208/194) с 95 % ДИ (0,952; 1,192).[7]

Таблица 4. Все соответствующие пары, давшие единственный изолят (посевы крови)

Клиническое определение	Флаконы BacT/ALERT FA Plus истинно положительные результаты	Флаконы BacT/ALERT FA, истинно положительные результаты	Соотношение количества истинно положительных результатов*
Значимые	138	111	1,243
Контаминанты	26	33	0,788
Неизвестные	8	9	0,889
Всего	172	153	1,124

***** 111 (сто одиннадцать) изолятов было выявлено при использовании как флаконов BacT/ALERT FA Plus, так и флаконов BacT/ALERT FA; 61 изолят — только при использовании флаконов BacT/ALERT FA Plus и 42 изолята — только при использовании флаконов BacT/ALERT FA. Соотношение количества истинно положительных результатов по единственным изолятам составило 1,124 (172/153) с 95 % ДИ (0,986; 1,262).[7]

Таблица 5. Все соответствующие пары, давшие несколько изолятов (посевы крови)

Клиническое определение	Флакон BacT/ALERT FA Plus истинно положительные результаты	Флакон BacT/ALERT FA, истинно положительные результаты	Соотношение количества истинно положительных результатов*
Значимые	21	24	0,875
Контаминанты	10	14	0,714
Неизвестные	5	3	1,667
Всего	36	41	0,878

* 24 (двадцать четыре) изолята было выявлено при использовании как флаконов BacT/ALERT FA Plus, так и флаконов BacT/ALERT FA; 12 изолятов — только при использовании флаконов BacT/ALERT FA Plus и 17 изолятов — только при использовании флаконов BacT/ALERT FA. Соотношение количества истинно положительных результатов по нескольким изолятам составило 0,878 (36/41) с 95 % ДИ (0,637; 1,119).[7]

В данном клиническом исследовании для 1413 пар флаконов BacT/ALERT FA Plus и BacT/ALERT FA после 5 дней инкубации были получены отрицательные результаты теста для обоих типов флаконов. Для 95 из этих пар был проведен заключительный высев материала из обоих флаконов, и в двух случаях выявлены ложноотрицательные результаты для обоих типов флаконов; высев материала только из флаконов BacT/ALERT FA Plus был проведен для 1312 пар, и выявлен один ложноотрицательный результат; для шести пар флаконов высевы не проводились. Результаты представлены в таблице 6.

Таблица 6. Количество ложноотрицательных результатов по соответствующим парам аэробных посевов крови, которые были отмечены системой в ходе теста как отрицательные для обоих флаконов

Высев из флаконов BacT/ALERT FA Plus	Высев из флаконов BacT/ALERT FA	% ложноотрицательных результатов для Флакон BacT/ALERT FA Plus	% ложноотрицательных результатов для Флакон BacT/ALERT FA
Да	Да	2,11 (2/95)	2,11 (2/95)
Да	Нет	0,08 (1/1312)	-

Общая частота ложноотрицательных результатов для флаконов BacT/ALERT FA Plus на основании высевов материала составила 0,2 % (3/1407).

Сравнение количества микроорганизмов (число изолятов), выделенных при высеве материала из флаконов BacT/ALERT FA Plus и BacT/ALERT FA, представлено в таблице 7.

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Таблица 7. Сравнение количества микроорганизмов из флаконов BacT/ALERT FA Plus и BacT/ALERT FA (число изолятов) — посевы крови

Группа	Флаконы BacT/ALERT FA Plus	Флаконы BacT/ALERT FA
Enterobacteriaceae	34	32
Enterococcus spp.	33	28
Дрожжевые грибы	17	18
Неферментирующие грамотрицательные бациллы	8	11
Другие грамотрицательные бактерии	4	3
Другие грамположительные бактерии	6	8
Коагулазоотрицательный *Staphylococcus*	37	53
Staphylococcus aureus	52	30
Streptococcus spp.	17	11

ПРИМЕЧАНИЕ: В таблицу изолятов включены полимикробные культуры.

Результаты клинических исследований (посевы стерильных биологических жидкостей)

В четырех разных центрах в США и Канаде было проведено многоцентровое клиническое исследование, в котором сравнивали характеристики флаконов BacT/ALERT FA Plus и BacT/ALERT FAпри посеве образцов стерильных биологических жидкостей. Всего было получено 404 пары флаконов от 369 взрослых пациентов с подозрением на бактериальные или дрожжевые инфекции стерильных биологических жидкостей. В исследовании использовались следующие типы стерильных биологических жидкостей: амниотическая жидкость, жидкость, полученная при проведении постоянного амбулаторного перитонеального диализа (ПАПД), спинномозговая жидкость (СМЖ), перитонеальная жидкость, плевральная жидкость и синовиальная жидкость. Выделенные клинические изоляты относили к группе значимых, контаминантов или неизвестных по усмотрению центров, где проводилось исследование.

В общей сложности из всех пар аэробных посевов стерильных биологических жидкостей, давших положительный результат, было выделено 92 изолята. При высеве материала из флаконов BacT/ALERT FA Plus или BacT/ALERT FA в 75 парах флаконов был выделен, по крайней мере, один изолят. Из 62 пар флаконов был выделен один изолят, из 9 пар — два изолята и из 4 пар — три изолята. Общая выборка результатов, приведенных в таблице 8, включает 92 изолята, выделенных из пар флаконов с положительным результатом, и 329 пар флаконов с отрицательным результатом (всего был получен 421 результат). При использовании флаконов BacT/ALERT FA Plus было выявлено в общей сложности 85 изолятов, в то время как при использовании флаконов BacT/ALERT FA — 67 изолятов. Что касается значимых изолятов, при использовании флаконов BacT/ALERT FA Plus всего было выявлено 65 изолятов, а при использовании флаконов BacT/ALERT FA — 59 изолятов. Ложноположительных результатов для материала из флаконов BacT/ALERT FA Plus в исследованной выборке не было (0/421).

В таблице 8 сравниваются результаты, полученные для флаконов BacT/ALERT FA Plus и BacT/ALERT FA с посевами стерильных биологических жидкостей, которые при высеве дали один или несколько изолятов.

Таблица 8. Все пары, давшие один или несколько изолятов (посевы стерильных биологических жидкостей)

Клиническое определение	Флаконы BacT/ALERT FA Plus, истинно положительные результаты	% истинно положительных результатов при использовании флаконов BacT/ALERT FA Plus в популяции	Флаконы BacT/ALERT FA, истинно положительные результаты	% истинно положительных результатов при использовании флаконов BacT/ALERT FA в популяции	Соотношение количества истинно положительных результатов*
Значимые	65	15,4 (65/421)	59	14,0 (59/421)	1,102
Контаминанты	13	3,1 (13/421)	2	0,5 (2/421)	6,500
Неизвестные	7	1,7 (7/421)	6	1,4 (6/421)	1,167
Всего	85	20,2 (85/421)	67	15,9 (67/421)	1,269

***** 60 (шестьдесят) изолятов было выявлено при использовании как флаконов BacT/ALERT FA Plus, так и флаконов BacT/ALERT FA; 25 изолятов — только при использовании флаконов BacT/ALERT FA Plus и 7 изолятов — только при использовании флаконов BacT/ALERT FA. Соотношение количества истинно положительных результатов по всем изолятам составило 1,269 (85/67) с 95 % ДИ (1,083; 1,455).[7]

ПРИМЕЧАНИЕ: Число образцов амниотической и спинномозговой жидкости, полученных в ходе клинического исследования, было ограниченным (соответственно 2 и 38 образцов).

В таблице 9 приводятся данные по минимальным объемам образцов, достигнутым в клиническом исследовании аэробных посевов стерильных биологических жидкостей.

Таблица 9. Номинальный объем (мл) образцов стерильных биологических жидкостей, флаконы BacT/ALERT FA Plus — положительный результат теста

Тип образца	Общее кол-во образцов	Кол-во положительных результатов	Минимальный объем образца (мл)
Амниотическая жидкость	2	1	1,0
Жидкость, полученная при постоянном амбулаторном перитонеальном диализе	94	26	1,0
СМЖ	38	4	0,1
Перитонеальная жидкость	116	19	1,0
Плевральная жидкость	106	17	0,5
Синовиальная жидкость	48	8	0,5
Всего	404	75	-

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В данном клиническом исследовании для 329 пар флаконов BacT/ALERT FA Plus и BacT/ALERT FA после 5 дней инкубации были получены отрицательные результаты теста для обоих типов флаконов. Для 297 из этих пар был проведен высев материала из обоих флаконов, BacT/ALERT FA Plus и BacT/ALERT FA, при этом ложноотрицательных результатов не выявлено. Высев материала только из флаконов BacT/ALERT FA Plus был проведен для 32 пар, при этом ложноотрицательных результатов не выявлено. Результаты представлены в таблице 10.

Таблица 10. Количество ложноотрицательных результатов по парам аэробных посевов стерильных биологических жидкостей, которые были отмечены системой в ходе теста как отрицательные для обоих флаконов

Высев из флаконов BacT/ALERT FA Plus	Высев из флаконов BacT/ALERT FA	% ложноотрицательных результатов для Флакон BacT/ALERT FA Plus	% ложноотрицательных результатов для Флакон BacT/ALERT FA
Да	Да	0,0 (0/297)	0,0 (0/297)
Да	Нет	0,0 (0/32)	-

Сравнение количества микроорганизмов (число изолятов), выделенных при высеве материала из флаконов BacT/ALERT FA Plus и BacT/ALERT FA, представлено в таблице 11.

Таблица 11. Сравнение количества микроорганизмов из флаконов BacT/ALERT FA Plus и BacT/ALERT FA (число изолятов) — посевы стерильных биологических жидкостей

Группа	Флаконы BacT/ALERT FA Plus	Флаконы BacT/ALERT FA
Enterobacteriaceae	8	7
Enterococcus spp.	12	10
Дрожжевые грибы	11	11
Неферментирующие грамотрицательные бациллы	8	3
Другие грамположительные бактерии	5	3
Другие грамотрицательные бактерии	-	-
Коагулазоотрицательный *Staphylococcus*	21	19
Staphylococcus aureus	12	9
Streptococcus spp.	8	5

ПРИМЕЧАНИЕ: В таблицу изолятов включены полимикробные культуры.

Контроль качества в ходе клинического исследования проводился со всеми 13 микроорганизмами (*Candida albicans, Candida krusei, Enterococcus faecalis, Escherichia coli, Haemophilus influenzae, Neisseria meningitidis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Stenotrophomonas maltophilia, Streptococcus agalactiae, Streptococcus pneumoniae и Streptococcus pyogenes*), которые были подготовлены путем последовательных разведений и посеяны во флаконы BacT/ALERT FA Plus в концентрации 100 КОЕ/флакон с приемлемым диапазоном 30–300 КОЕ/флакон. Общие результаты контроля качества были расценены как удовлетворительные. Случаи, когда результаты контроля качества были неприемлемыми, связаны с техническими ошибками (например, слишком малое или слишком большое число колоний, контаминация или неправильная маркировка флаконов). Повторные тесты давали приемлемые результаты.

Отсроченная загрузка

В таблице 12 представлены результаты исследований посевов 11 видов микроорганизмов (*Staphylococcus aureus, Candida albicans, Candida krusei, Escherichia coli, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa, Streptococcus pneumoniae, Enterococcus faecium, Haemophilus influenzae* и *Neisseria meningitidis)* в концентрациях 100 КОЕ/флакон (при допустимом диапазоне 30-300 КОЕ/флакон), выполненных в трех центрах. Фактическое количество микроорганизмов составило 35–290 КОЕ/флакон. Все флаконы были протестированы с кровью от здоровых добровольцев и хранились при заданных температурах, учитывая время перед загрузкой в анализатор BacT/ALERT 3D. Доля выделения отражает флаконы, которые анализатор пометил как положительные, и из которых при высеве были получены колонии с морфологией, соответствующей посеянному микроорганизму.

Таблица 12. Отсроченная загрузка

Вводимый образец	Температура инкубации (˚C)	Время хранения (часы)	% выделения	Продолжительность культивирования до определения статуса флакона с момента посева (время хранения + Продолжительность культивирования до определения статуса флакона анализатора в часах)	
				Среднее	Диапазон
Тестовые флаконы, в которые произведен посев	Контроль	Без задержки	100,0 (459/459)	14,3	8,5–84,0
	2–8	48	98,6 (292/296)	63,7	57,5–103,2
	20–25	24	98,0 (291/297)	31,8	26,2–74,4
	20–25	36	91,9 (272/296)	41,8	38,0–70,5
	35–37	8	98,9 (454/459)	16,1	10,2–53,8
	35–37	24	56,6 (259/458)*	28,3	26,0–74,4
Отрицательные контроли	Все условия		0,5 (1/221)†	-	-

* **ВНИМАНИЕ**: **Флаконы для культур, хранившиеся при 35–37 °C в течение 24 ч или дольше перед загрузкой в систему, могут не давать положительного сигнала и требуют высева.**

† При исследовании посевов был отмечен ложноположительный результат (1/221).

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Прецизионность в условиях одной лаборатории (повторяемость)

В таблице 13 представлены результаты внутренних исследований посевов, которые проводились в течение 12 дней несколькими операторами с использованием нескольких анализаторов. Микроорганизмы выращивались при добавлении клинически значимых концентраций противомикробных препаратов, к которым они чувствительны. В данном исследовании высев материала из флаконов BacT/ALERT FA Plus проводился как минимум через 24 ч после того, как система зарегистрировала рост во флаконе. Тестирование было выполнено не менее чем в 108 повторностях для каждого сочетания микроорганизма и противомикробного препарата.

Таблица 13. Прецизионность в условиях одной лаборатории (повторяемость)

Вводимый образец		Диапазон (КОЕ/флакон)	% выделения				Продолжительность культивирования до определения статуса флакона (часы)	
Микроорганизм	Противомикробный препарат		Партия 1	Партия 2	Партия 3	Всего	Среднее	Диапазон
C. albicans	Флюконазол	140–364	100,0	100,0	100,0	100,0	26,0	22,8–31,3
E. coli	Амикацин	26–156	100,0	100,0	100,0	100,0	12,0	11,2–13,0
K. pneumoniae	Левофлоксацин	108–170	100,0	100,0	100,0	100,0	13,4	11,7–15,2
P. aeruginosa	Пиперациллин	80–148	100,0	97,2	100,0	99,1	19,2	17,4–24,1
S. pneumoniae	Пенициллин G	9–505	100,0	100,0	100,0	100,0	13,2	11,6–15,5
S. aureus	Ванкомицин	94–158	100,0	100,0	100,0	100,0	16,9	14,6–20,3

Воспроизводимость

В таблице 14 представлены результаты исследований посевов, проведенных в трех центрах. В каждом центре тестирование было выполнено в 162 повторностях в течение 3 дней с участием не менее двух операторов на каждый центр. Воспроизводимость оценивалась для каждого из девяти микроорганизмов. Для двух микроорганизмов (*C. albicans* и *S. pneumoniae*) культуры готовили путем последовательных разведений, для остальных семи — с использованием образцов BioBall®. *C. albicans* и *S. pneumoniae* были посеяны во флаконы BacT/ALERT FA Plus в концентрации 100 КОЕ/флакон с приемлемым диапазоном 30–300 КОЕ/флакон, а остальные семь микроорганизмов — в концентрации 1–17 КОЕ/флакон. Фактическая концентрация микроорганизмов в посевном материале составила 6–700 КОЕ/флакон для диапазона 30–300 КОЕ/флакон и 1–270 КОЕ/флакон для диапазона 1–17 КОЕ/флакон. Доля выделения отражает положительный результат теста, отмеченный системой, и результаты окрашивания по Граму/высева, подтверждающие наличие микроорганизма.

Таблица 14. Воспроизводимость

Вводимый образец	% выделения				Продолжительность культивирования до определения статуса флакона (часы)		Диапазон концентраций посевного материала (КОЕ/флакон)
	Центр 1	Центр 2	Центр 3	Всего	Среднее	Диапазон	
S. aureus	100,0 % (18/18)	87,5 % (21/24)	100,0 % (30/30)	95,8 % (69/72)	15,6	14,6–16,7	2–11
C. albicans	100,0 % (18/18)	83,3 % (30/36)	100,0 % (33/33)	93,1 % (81/87)	36,6	24,6–76,8	14–700
E. coli	100,0 % (27/27)	77,8 % (21/27)	100,0 % (30/30)	92,9 % (78/84)	12,8	11,8–14,1	1–38
P. aeruginosa	100,0 % (24/24)	75,0 % (18/24)	97,0 % (32/33)	91,4 % (74/81)	18,4	17,1–21,1	1–11
E. faecalis	100,0 % (18/18)	79,2 % (19/24)	96,7 % (29/30)	91,7 % (66/72)	13,9	12,6–15,3	1–15
E. aerogenes	74,4 % (29/39)	72,2 % (26/36)	85,4 % (41/48)	78,1 % (96/123)	14,9	11,7–20,8	<1–270*
L. monocytogenes	100,0 % (18/18)	100,0 % (24/24)	100,0 % (30/30)	100,0 % (72/72)	24,1	20,4–36,4	1–14
S. enterica	100,0 % (24/24)	75,0 % (18/24)	100,0 % (33/33)	92,6 % (75/81)	13,5	2,3–14,8	1–13
S. pneumoniae	100,0 % (30/30)	100,0 % (36/36)	100,0 % (21/21)	100,0 % (87/87)	14,2	11,6–18,9	6–500
Всего	95,4 % (206/216) 95 %-ный ДИ: 91,7 %; 97,8 %	83,5 % (213/255) 95 %-ный ДИ: 78,4 %; 87,9 %	96,9 % (279/288) 95 %-ный ДИ: 94,2 %; 98,6 %	92,0 % (698/759) 95 % ДИ: 89,8 %; 93,8 %	-		

* Подсчет количества микроорганизмов на чашках при концентрации посевного материала 270 КОЕ/флакон проводили с использованием последовательных разведений.

Эти данные включают повторные тесты, выполнявшиеся вследствие технических ошибок в отдельно взятом центре (например, контаминация флаконов или реагентов, слишком малое или слишком большое количество колоний, не был изменен статус флакона после положительного сигнала от системы и положительного результата высева). Данные, из которых исключены лабораторные ошибки, демонстрируют 100-процентное выделение, за исключением *E. aerogenes* — частота выделения этого микроорганизма (суммарная для всех центров) составила 85 %.

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СПРАВОЧНАЯ ЛИТЕРАТУРА

1. Thorpe TC, Wilson ML, Turner JE, DiGuiseppi JL, Willert M, Mirrett S, et al: BacT/ALERT: an Automated Colorimetric Microbial Detection System. *J Clin Micro* 1990;28(7), 1608-1612.
2. *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* 5th Edition. U.S. Department of Health and Human Services Centers for Disease Control and Prevention and National Institutes of Health. Fifth Edition. US Government Printing Office. Washington: Feb 2007.
3. Koneman EW, Allen SD, Janda WM, Schreckenberger PC, Winn WC. *Color Atlas and Textbook of Diagnostic Microbiology*, 6th ed. 2006, pp. 446,590.
4. Baron EJ, Weinstein MP, Dunne Jr. WM, Yagupsky P, Welch DF, Wilson DM. 2005. Cumitech 1C, Blood Cultures IV. Coordinating ed. Baron EJ. ASM Press, Washington, DC.
5. CLSI. *Principles and Procedures for Blood Cultures; Approved Guideline*. CLSI document M47-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2007.
6. CLSI. *Quality Control for Commercially Prepared Microbiological Culture Media*; Approved Standard—Third Edition. CLSI/NCCLS document M22-A3. Wayne, PA: NCCLS; 2004.
7. Kondratovich M. Comparing Two Medical Tests When Results of Reference Standard Are Unavailable for Those Negative via Both Tests. *J. Biopharm Stat* 2008;18:1,145-166.

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ТАБЛИЦА СИМВОЛОВ И ОБОЗНАЧЕНИЙ

Символ	Обозначение
REF	Номер по каталогу
	Изготовитель
	Дата изготовления
	Температурный диапазон
	Использовать до
LOT	Код партии
	Обратитесь к инструкции по применению
	Содержимого достаточно для проведения n-количества тестов
EC REP	Уполномоченный представитель в Европейском сообществе
	Верх
IVD	Медицинское изделие для диагностики in vitro
	Запрет на повторное применение
	Без латекса
Rx only	Только для США: Внимание: Согласно федеральному закону США, данное изделие допускается к продаже только лицензированным врачам или по их заказу.
	Уровень заполнения

Инструкция прилагается к набору или ее можно загрузить с сайта www.biomerieux.com/techlib.

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ИСТОРИЯ ПЕРЕСМОТРОВ

В этом разделе содержится перечень изменений, внесенных в инструкцию по применению флаконов BacT/ALERT FA Plus.

Дата выпуска	Номер версии	Тип изменений	Обзор изменений
2016-04	043784-03/ 9312050 E	Изменение содержания:	В разделе **«Реагенты»** обновлена информация о составе
			Добавлено предупреждение Rx-only для пользователей в США.
		Административные изменения:	В раздел **«Ограниченная гарантия»**- добавлено положение
2015-05	9309503 D	Изменение содержания:	В раздел **«Реагенты»** внесено уточнение срока годности
			В раздел **«Взятие и подготовка образцов»** - добавление предупреждения относительно высокого давления во флаконе - добавление примечания относительно этикетки на флаконе с меткой уровня заполнения; - добавление примечаний с информацией о венепункции.
			В раздел **«Контроль качества»** добавлено предупреждение относительно ЛИС и сокращенных обозначений типов флаконов
		Административные изменения:	Раздел **«Таблица символов и обозначений»** обновлен с целью внесения новых символов для продукта
2013-04	9305048 C	Изменение содержания:	В разделах **«Назначение», «Взятие и подготовка образцов», «Ожидаемые результаты», «Нейтрализация противомикробных препаратов», «Рабочие характеристики»**, где пересмотренный текст включает дополнительную информацию по характеристикам продукта, основанную на данных клинических исследований
			В раздел **«Ограничения метода»** после оценки FDA добавлены пункты 2, 8, 9 и 10.
		Административные изменения:	Из раздела **«Реагенты»** текст о предупреждениях перенесен в раздел «Ограничения метода»

ПРИМЕЧАНИЕ: Незначительные типографские, грамматические изменения и изменения в форматировании в историю пересмотров не включены.

Категории типов изменений:

- **Корректура** — исправление ошибок в документации.
- **Изменение содержания** — внесение новых и измененных (обновленных) данных по назначению и рабочим характеристикам продукта.
- **Административные изменения** — введение изменений нетехнического характера, заслуживающих внимания пользователя.

Для получения технической консультации и поддержки просьба обращаться
к уполномоченному
представителю производителя на территории Российской Федерации:
ООО «биоМерье Рус»
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В случае выявления побочных действий, не указанных в инструкции по применению или руководстве по эксплуатации медицинского изделия, нежелательных реакций при его применении, особенностей взаимодействия медицинских изделий между собой, фактов и обстоятельств, создающих угрозу жизни и здоровью граждан и медицинских работников при применении и эксплуатации медицинских изделий, необходимо направить сообщение, содержащее указанные сведения, в Федеральную службу по надзору в сфере здравоохранения в соответствии с действующим законодательством.

bioMérieux, голубой логотип, BacT/ALERT, BioBall, FAN являются используемыми, зарегистрированными и/или находящимися в процессе регистрации товарными знаками, принадлежащими компании bioMérieux, одной из дочерних или входящих в ее группу компаний.

Этот продукт может быть защищен одним или несколькими патентами; см. http://www.biomerieux-usa.com/patents.

Товарный знак и товарное имя ATCC, а также любые номера по каталогу ATCC – товарные знаки компании American Type Culture Collection.

CLSI является зарегистрированным товарным знаком, принадлежащим Clinical and Laboratory Standards Institute.

Другие названия и товарные знаки принадлежат их законным владельцам.

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BacT/ALERT FN Plus

℞ only IVD

НАЗНАЧЕНИЕ

Флаконы BacT/ALERT FN Plus со средой и адсорбентом для выделения анаэробных микроорганизмов из крови и стерильных биологических жидкостей (далее по тексту флаконы BacT/ALERT FN Plus, флаконы для культивирования) используются с анализаторами культур крови и микобактерий автоматическими бактериологическими серии BacT/ALERT с принадлежностями для качественного обнаружения и выделения анаэробных и факультативно анаэробных микроорганизмов в крови и других в норме стерильных биологических жидкостях.

КРАТКОЕ ОПИСАНИЕ

Анализаторы культур крови и микобактерий автоматические бактериологические серии BACT/ALERT с принадлежностями (далее анализатор культур крови BacT/ALERT, анализатор BacT/ALERT, анализатор) используются для определения наличия микроорганизмов в образцах крови и других в норме стерильных биологических жидкостей при подозрении на септицемию. Анализатор BacT/ALERT в сочетании с флаконами для культивирования обеспечивает как систему обнаружения микроорганизмов, так и среду с питательными качествами и атмосферными условиями, подходящими для микроорганизмов, которые являются частыми возбудителями инфекций крови и других в норме стерильных биологических жидкостей. Флакон BacT/ALERT FN Plus, в который предварительно производится посев образца, помещается в анализатор, где осуществляется культивирование и непрерывный мониторинг наличия роста микроорганизмов во флаконе.

ПРИМЕЧАНИЕ: Предоставленная информация относится ко всем конфигурациям анализаторов культур крови BacT/ALERT, если не указано иное.

ПРИНЦИП

Анализаторы культур крови BacT/ALERT основаны на использовании колориметрического датчика, светоотражения для регистрации наличия и накопления углекислого газа (CO_2) в питательной среде. Если в анализируемом образце присутствуют микроорганизмы, то в процессе метаболизации субстратов питательной среды они вырабатывают углекислый газ. Под действием вырабатываемого микроорганизмами углекислого газа CO_2 цвет газопроницаемого датчика, встроенного в дно каждого флакона для культивирования, меняется с зелено-голубого на желтый[1]. В результате осветления датчика коэффициент отражения повышается. Мониторинг и регистрация отражения флакона производится прибором каждые 10 минут.

РЕАГЕНТЫ

Для диагностики *in vitro*.

ОСТОРОЖНО: С образцами и флаконами, в которые произведен посев, следует обращаться как с потенциально инфекционными материалами. Все флаконы, в которые был произведен посев, иглы для взятия образцов и системы для взятия крови следует обеззараживать в соответствии с процедурой, используемой в вашем учреждении[2].

BacT/ALERT FN Plus (цветная кодировка: оранжевая) — одноразовые флаконы BacT/ALERT FN Plus содержат 40 мл комплексной питательной среды и ≥1,6 г адсорбирующих полимерных гранул. На момент производства среда состоит из следующих компонентов: сочетание пептонов/биологических экстрактов (≥ 1,85 % вес/объем), антикоагулянтов (≥ 0,083 % вес/объем), витаминов и аминокислот (≥ 0,00145 % вес/объем), источников углерода (≥ 0,45 % вес/объем), следовых веществ (≥ 0,0005 % вес/объем) и прочих комплексных аминокислот и углеводных субстратов в очищенной воде. Атмосфера в вакуумных флаконах разреженная, N_2 и CO_2. Количественный/качественный состав среды может быть модифицирован для достижения необходимых функциональных характеристик.

ОСТОРОЖНО: Флаконы BacT/ALERT изготовлены из поликарбоната. Некоторые дезинфицирующие средства нельзя использовать на поликарбонатных поверхностях, так как они могут вызвать повреждение флаконов. Проверьте, совместимо ли дезинфицирующее средство с поликарбонатом, перед тем как использовать его для дезинфекции поверхностей флаконов для культивирования BacT/ALERT.

ОСТОРОЖНО: При культивировании во флаконах BacT/ALERT FN Plus некровяных образцов (в норме стерильных биологических жидкостей) или образцов крови очень малого объема (0,5 мл или менее) требуется добавление в питательную среду крови, например стерильной дефибринированной лошадиной крови (10,0 % объем/объем), для поддержания роста, особенно для выделения прихотливых микроорганизмов, таких как *Haemophilus influenzae* и *Streptococcus pneumoniae*[3].

Необходимые дополнительные материалы

- Анализаторы культур крови BacT/ALERT
- Система для взятия крови
- Стерильные иглы для вентилирования и высева из положительных флаконов
- Одноразовые перчатки
- Подходящий контейнер для биологически опасных отходов для сброса материалов, которые могут быть загрязнены инфекционными материалами.

Материалы, которые можно приобрести в компании bioMérieux

- BacT/ALERT Blood Collection Adapter Cap – Колпачок адаптера для взятия крови во флаконы BacT/ALERT
- Анализаторы культур крови BacT/ALERT
- Стерильные иглы для вентилирования и высева из положительных флаконов

Инструкции по хранению

Флаконы BacT/ALERT FN Plus готовы к использованию. Их следует хранить в вертикальном положении в месте, защищенном от прямого света, при комнатной температуре (15–30 °C). Срок годности флакона указан на его этикетке. Запрещается осуществлять посев во флаконы для культивирования по окончании срока годности. При хранении флаконов при температуре ниже 15 °C возможно образование осадка, который растворяется при нагревании флакона до комнатной температуры. Перед использованием выдержите флакон до достижения комнатной температуры.

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Химические или физические признаки нестабильности
Перед использованием флаконы BacT/ALERT FN Plus следует осмотреть на наличие признаков порчи или повреждения (обесцвечивание). Флаконы со следами порчи, повреждений или утечки нельзя использовать. Среда в отстоявшемся флаконе должна быть прозрачной, хотя возможна небольшая опалесценция или следы осадка из-за наличия антикоагулянта полианетолсульфоната натрия (SPS) или адсорбирующих полимерных гранул. Не путайте эти изменения с помутнением, которое является признаком микробного роста. Не используйте флаконы при помутнении среды, пожелтении датчика или наличии признаков повышенного давления газа во флаконе, т. к. все перечисленное свидетельствует о контаминации.

ПРИБОРЫ
Перед использованием прочтите руководство по эксплуатации анализаторов культур крови BacT/ALERT.

ВЗЯТИЕ И ПОДГОТОВКА ОБРАЗЦОВ
Общие сведения
1. Флаконы BacT/ALERT FN Plus должны использоваться специально обученным медицинским персоналом. Правильное взятие образца имеет большую важность при работе с культурами крови. Рекомендованная процедура сбора образцов приведена в документе Cumitech 1C[4].
2. Во время подготовки флакона и внесения образца пациента необходимо принять меры для предотвращения контаминации. Обязательной мерой для снижения частоты контаминации является надлежащая дезинфекция кожи.
3. Кровь можно брать непосредственно в пробирки, содержащие полианетолсульфонат натрия SPS, хотя это не рекомендуется компанией bioMérieux. Пробирки с другими антикоагулянтами для культур крови использовать нельзя[5].
4. Компания bioMérieux рекомендует загружать флаконы для культивирования в анализаторы культур крови BacT/ALERT как можно скорее после взятия крови. Если флаконы невозможно загрузить в анализатор сразу после посева, то до загрузки в анализатор их следует держать при комнатной температуре не более 24 часов.
5. Оптимальное выделение изолятов достигается при добавлении максимального объема образца. Использование меньшего объема образца может исказить результаты выделения и/или увеличить время обнаружения некоторых микроорганизмов. Не заполняйте флакон объемом образца более 10 мл. Вакуум во флаконе обычно превышает 10 мл. Следите за собранным объемом с помощью меток объема с шагом 5 мл, расположенных на этикетке флакона.

Подготовка флакона
1. Запишите на флаконе информацию о пациенте. Условные обозначения на этикетке флакона (☺,#,🕑) может определять пользователь.
2. Снимите пластиковую защитную пластину с верха пробки флакона для культивирования. Перед посевом продезинфицируйте верхнюю часть флакона пропитанным спиртом тампоном или аналогичным материалом. Дайте ей высохнуть естественным способом.
3. Очистите выбранное для венепункции место в соответствии с утвержденной в вашем учреждении процедурой.
4. Для посева используйте иглу размера 21G или большего (например, 22, 23 или 25-го) размера. При использовании игл меньшего, чем 21G, размера (например, 16G, 18G, 19G или 20G) возможен выход газа из флакона вследствие большего диаметра отверстия.

Процедура посева при непосредственном взятии крови
ПРИМЕЧАНИЕ: При одновременном посеве во флаконы BacT/ALERT нескольких типов с использованием системы взятия крови с иглой-бабочкой и адаптера для непосредственного взятия крови сначала нужно вносить образец во флакон для выделения аэробных микроорганизмов, а затем — для выделения анаэробных микроорганизмов, чтобы кислород, скопившийся в трубке, не попал во флакон для выделения анаэробных микроорганизмов.

a. Можно использовать меньший объем образца, но высеваемость можно повысить, если объем образца составляет приблизительно 10 мл (рекомендованное значение).[4,6]
b. Чтобы избежать посева чрезмерного объема, отслеживайте объем поступающей во флакон крови. Для наполнения флакона приблизительно на 10 мл ориентируйтесь по линии уровня заполнения на этикетке флакона. Или используйте метки объема на 5 мл на этикетке флакона для оценки объема внесенного образца.

ПРИМЕЧАНИЕ: В ходе всей процедуры тщательно контролируйте процесс непосредственного взятия крови, обеспечивая надлежащий поток и не допуская попадания содержимого флакона в трубку адаптера. Поскольку во флаконе для культивирования содержатся химические добавки, важно следовать указанной ниже пошаговой процедуре, чтобы не допустить возможный обратный поток и последующие нежелательные реакции.

a. Держите флакон для культивирования ниже уровня руки пациента в вертикальном положении (пробкой кверху).
b. Соберите кровь с помощью системы взятия крови с иглой-бабочкой и адаптера для взятия крови во флаконы в соответствии с утвержденной в вашем учреждении процедурой и выполните посев непосредственно во флакон для культивирования у кровати пациента. Можно использовать меньший объем образца, но высеваемость можно повысить, если объем образца составляет приблизительно 10 мл (рекомендованное значение). Чтобы избежать посева чрезмерного объема, отслеживайте объем забираемой во флакон крови с помощью меток с шагом 5 мл, расположенных на этикетке флакона.
c. Ослабьте жгут, как только кровь начнет поступать во флакон для культивирования или в течение 2 минут после его наложения.
d. Проследите за тем, чтобы содержимое флакона не касалось пробки или конца иглы во время взятия крови.

ОСТОРОЖНО: В контаминированном флаконе для культивирования крови может быть избыточное давление и при его использовании для непосредственного взятия крови может произойти отток среды в вену пациента. Контаминация флакона для культивирования не всегда легко распознается. Во избежание оттока необходимо тщательно контролировать процесс непосредственного взятия крови. Не используйте флаконы при помутнении среды, пожелтении датчика или наличии признаков повышенного давления газа во флаконе, т. к. все перечисленное свидетельствует о контаминации.

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Процедура посева при взятии крови с помощью шприца

ПРИМЕЧАНИЕ: При одновременном посеве во флаконы BacT/ALERT нескольких типов с использованием шприца сначала следует вносить образец во флакон для выделения анаэробных микроорганизмов, а затем — для выделения аэробных микроорганизмов, чтобы кислород, скопившийся в шприце, не попал во флакон для выделения анаэробных микроорганизмов. Используйте метки объема на этикетке флакона для оценки объема внесенного образца.

a. Выполните венепункцию и перенос крови во флакон BacT/ALERT в соответствии с утвержденной в вашем учреждении процедурой.

ОСТОРОЖНО: Запрещается вдавливать поршень шприца с усилием при выполнении посева, так как может произойти разбрызгивание образца. При достижении необходимого объема заполнения удалите шприц, так как из-за вакуума автоматически отберется количество больше рекомендуемого максимума. Во избежание нарушения вакуума прокалывайте пробку флакона вертикально. Не выполняйте посев во флакон с нарушенным вакуумом.

5. Незамедлительно доставьте флакон для культивирования, в который произведен посев, в лабораторию для исследований.

ПРОЦЕДУРА ПРОВЕДЕНИЯ ТЕСТА ДЛЯ ФЛАКОНОВ BacT/ALERT FN PLUS

Предварительные замечания и предостережения

1. Необходимо использовать одноразовые перчатки и обращаться с флаконами, в которые был произведен посев, как с потенциально инфекционными материалами. При попадании контаминированных веществ внутрь или при их контакте с поврежденными участками кожи и слизистых оболочек следует немедленно обратиться к врачу.
2. Все протечки и утечки контаминированных веществ следует немедленно устранять, используя 5 % раствор натрия гипохлорита, разведенный в соотношении 1:10. Использованные для очистки материалы следует утилизировать с соблюдением соответствующих процедур.
3. Все флаконы, в которые был произведен посев, иглы для взятия образцов и системы для взятия крови следует обеззараживать в соответствии с процедурой, используемой в вашем учреждении[2].
4. Утилизацию этих флаконов должен осуществлять специально обученный медицинский персонал.
5. Только для США. Осторожно: Согласно федеральному закону США данное изделие допускается к продаже только лицензированным врачам или по их заказу.

Замечания и предостережения к процедуре проведения теста

1. Необходимо принять все меры для предотвращения загрязнения образца пациента во время венепункции и посева во флакон, поскольку загрязнение может привести к получению положительного результата при отсутствии в образце клинически значимого изолята.
2. Взятие крови следует производить до начала антибиотикотерапии. Если это невозможно, взятие крови следует производить непосредственно перед введением очередной дозы препарата.
3. Если флаконы были доставлены в лабораторию не сразу после посева, а с задержкой или были предварительно инкубированы вне анализатора BacT/ALERT, визуально осмотрите флаконы на предмет наличия признаков микробного роста. При наличии явных признаков микробного роста не помещайте флаконы в анализатор культур крови BacT/ALERT для проведения мониторинга, а продолжайте работу с ними как с положительными флаконами.

Лабораторная процедура

ОСТОРОЖНО: При высеве материала из положительных флаконов следует соблюдать общие меры предосторожности. Внутри флакона может быть создано повышенное давление при внесении излишка жидкости или наличии микроорганизмов, активно вырабатывающих газы. Положительные флаконы следует подвергать кратковременному вентилированию перед окрашиванием или утилизацией для удаления из них газов, вырабатываемых микроорганизмами.

1. Визуально осмотрите флаконы перед началом работы. Не используйте флаконы при наличии повреждений и протечек. При помутнении среды, пожелтении датчика, наличии гемолиза, признаков избыточного давления газа или других признаков микробного роста считайте флакон положительным. Возьмите материал для мазка и сделайте высев. Инкубируйте флакон только если мазок отрицательный.
2. После загрузки флаконов в прибор инкубируйте 5 суток или до получения положительного результата.
3. Мазок и высев следует выполнять для всех положительных флаконов. При отсутствии микроорганизмов в мазке (что может указывать на ложноположительный результат) флакон следует повторно загрузить в прибор до получения роста во флаконе, из которого был произведен высев, или до повторной регистрации прибором роста во флаконе. При повторном определении роста во флаконе, который первоначально был определен как ложноположительный, из него следует повторно взять мазок и сделать высев.
4. Для проверки отрицательного результата также можно выполнять мазок и/или высев из флакона перед отбраковыванием его как отрицательного.
5. Процедура загрузки в анализатор и выгрузки из анализатора BacT/ALERT флаконов подробно описана в руководстве по эксплуатации.
6. **Не используйте флаконы BacT/ALERT более одного раза.** Утилизируйте флаконы BacT/ALERT, в которые произведен посев, в соответствии с правилами вашей лаборатории. Автоклавирование и/или сжигание являются приемлемыми процедурами утилизации флаконов BacT/ALERT[2].
7. Использование средств сверления (например, тупых игл) для прокола пробки может привести к протечке флакона.

КОНТРОЛЬ КАЧЕСТВА

Сертификат соответствия предоставляется с каждой партией флаконов для культивирования. При желании отдельные лаборатории могут выполнить контроль качества флаконов BacT/ALERT FN Plus. См. соответствующее руководство по эксплуатации BacT/ALERT и документ CLSI® M22-A3.[6]

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Прибор
Комплект стандартов отражающей способности BacT/ALERT Reflectance Standards поставляется с каждым анализатором BacT/ALERT 3D. Любые процедуры контроля качества должны быть частью текущего профилактического обслуживания системы. Дополнительные сведения см. в соответствующем руководстве по эксплуатации анализатора BacT/ALERT.

ОСТОРОЖНО: Если поставщик ЛИС вашего лечебного учреждения отправляет идентификационные номера флаконов и сокращенные обозначения типов флаконов в анализатор BacT/ALERT, используйте правильные сокращения типов флаконов во избежание возможного получения ложноположительных или ложноотрицательных результатов. Для получения более подробной информации свяжитесь с представителем компании bioMérieux.

РЕЗУЛЬТАТЫ

Положительный или отрицательный результат определяется программным обеспечением для принятия решений, являющимся частью анализаторов культур крови BacT/ALERT. До получения положительного или отрицательного сигнала от анализатора BacT/ALERT никаких действий выполнять не требуется.

ОГРАНИЧЕНИЯ МЕТОДА

На результат теста влияет множество факторов, которые практически не поддаются контролю, поэтому нельзя с уверенностью утверждать, что результат теста зависит только от правильного или неправильного использования питательной среды или работы анализатора.

1. В образцах пациентов, определяемых как положительные анализатором BacT/ALERT, могут содержаться микроорганизмы, клетки которых видно в мазке, но которые не растут на обычно используемых для высева средах. При подозрении на наличие таких микроорганизмов высев следует выполнять на специальные среды. Кроме того, положительные флаконы BacT/ALERT могут содержать микроорганизмы, клеток которых не видно при обычной окраске мазка и для обнаружения и выделения которых могут требоваться специальные методы окрашивания мазков, а также специальные среды для высева.
2. Некоторые редко встречающиеся прихотливые микроорганизмы могут не вырасти или расти очень медленно в питательной среде флаконов BacT/ALERT FN Plus. Кроме этого, в редких случаях в образцах могут встречаться микроорганизмы, которые растут в питательной среде флаконов BacT/ALERT FN Plus, но не производят достаточного количества углекислого газа для определения роста. При подозрении на наличие редко встречающихся, прихотливых микроорганизмов, требующих специфических питательных сред и условий культивирования, следует рассмотреть возможность использования альтернативных методов выделения или увеличения времени инкубации.
3. Некоторые штаммы *Peptostreptococcus anaerobius* могут быть чувствительны к антикоагулянту полианетолсульфонату натрия (SPS), что может привести к слабому росту или слабому выделению углекислого газа CO_2 этими штаммами при посеве во флаконы недостаточного объема образца.
4. Иногда при наличии в образце большого количества лейкоцитов анализатор BacT/ALERT может определить результат как положительный. В этом случае результаты мазка и высева могут быть отрицательными.
5. Часто количество микроорганизмов незначительное, и они могут появляться в кровотоке периодически, поэтому необходимо последовательно выполнять взятие образцов крови каждого пациента.
6. При получении положительного сигнала от анализатора BacT/ALERT следует немедленно извлечь флакон из прибора. Это позволит избежать нежизнеспособных культур из-за автолиза или по другим причинам. В частности, для некоторых штаммов *Streptococcus pneumoniae* характерен автолиз, если флакон не извлекается из прибора немедленно после получения положительного сигнала.
7. В окрашенном по Граму мазке из отрицательного флакона могут в небольших количествах встречаться нежизнеспособные клетки микроорганизмов, попавшие в мазок из компонентов питательной среды, реагентов для окраски, иммерсионного масла или с предметных стекол, что может привести к ложноположительному результату.
8. Компания bioMérieux рекомендует загружать флаконы для культивирования в анализаторы культур крови BacT/ALERT как можно скорее после взятия образца. Если неизбежна задержка доставки флаконов в лабораторию, следует принимать во внимание информацию по исследованиям образцов с отсроченной загрузкой, которая содержится в разделе «Рабочие характеристики теста».
9. Нейтрализации цефтазидима, цефтриаксона и цефепима достичь не удалось.

ОЖИДАЕМЫЕ РЕЗУЛЬТАТЫ

1. Положительные результаты были получены в 11,1 % случаев (диапазон 8,7 %–14,3 %) в целом и в 8,0 % случаев (диапазон 6,4 %–9,3 %) для значимых изолятов при внесении во флаконы BacT/ALERT FN Plus 6–10 мл крови по результатам клинического исследования флаконов BacT/ALERT FN Plus, проведенного с анализаторами BacT/ALERT 3D в трех исследовательских центрах.
2. Положительные результаты были получены в 20,3 % случаев (диапазон 17,0 %–25,3 %) в целом и в 14,6 % случаев (диапазон 6,1 %–24,1 %) для значимых изолятов при внесении во флаконы BacT/ALERT FN Plus стерильных биологических жидкостей по результатам клинического исследования флаконов BacT/ALERT FN Plus, проведенного с анализаторами BacT/ALERT 3D в трех исследовательских центрах.
3. Ожидаемый процент положительных результатов будет зависеть от таких факторов, как популяция пациентов, распространенность значимых микроорганизмов, географическое положение места проведения теста и уровень контаминации. Приведенные значения возможных результатов основаны на данных, полученных в ходе множества клинических исследований.

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НЕЙТРАЛИЗАЦИЯ ПРОТИВОМИКРОБНЫХ ПРЕПАРАТОВ

Нейтрализация противомикробных препаратов с помощью адсорбирующих полимерных гранул различается в зависимости от уровня дозировки и времени сбора образца. Внутренние исследования на анализаторе BacT/ALERT 3D показали, что среда флаконов BacT/ALERT FN Plus эффективно нейтрализует противомикробные препараты, о чем свидетельствовало выделение 100 % микроорганизмов. В этих исследованиях противомикробные препараты добавлялись в клинически значимых концентрациях непосредственно во флаконы для культивирования во время посева с чувствительными штаммами облигатных и факультативно анаэробных микроорганизмов. Эффективность противомикробных препаратов была подтверждена параллельным тестированием с использованием среды без нейтрализующих свойств в качестве контроля. Исследования показали, что в среде были нейтрализованы следующие антибиотики/группы антибиотиков: имипенем, меропенем, оксациллин, глицилциклины, макролиды, цефокситин, цефтаролин, аминогликозиды, фторхинолоны, линкозамиды, кетолиды и гликопептиды.

Нейтрализации цефтазидима, цефтриаксона и цефепима достичь не удалось. Цефотаксим, цефазолин, ампициллин, пенициллин и эртапенем нейтрализовались не полностью. Цефотаксим нейтрализовался при концентрациях, составляющих от 3 до 40 % от его максимальной концентрации в сыворотке (PSL), в зависимости от микроорганизма. Цефазолин нейтрализовался при концентрациях, составляющих от 5 до 25 % от PSL, в зависимости от микроорганизма. Эртапенем нейтрализовался при концентрации, составляющей 5 % от PSL. Ампициллин нейтрализовался в посевах *E. faecalis* при концентрации, составляющей 75 % от PSL. Пенициллин нейтрализовался в посевах *S. pneumoniae* при концентрации, составляющей 120 % от PSL. В посевах *C. perfringens* ни ампициллин, ни пенициллин не нейтрализовались при 100 % PSL.

Свойства нейтрализации противомикробных средств зависят от состава материала флакона и не определяются алгоритмами анализаторов BacT/ALERT. Нейтрализация была продемонстрирована для цефокситина, цефтаролина, имипенема, ванкомицина и пиперациллин-тазобактама. Тестирование показало, что система прибора не влияет на противомикробные нейтрализующие свойства флаконов.

За дополнительной информацией по противомикробным препаратам, которые нейтрализуются во флаконах BacT/ALERT FN Plus, обращайтесь к местному представителю компании bioMérieux.

РАБОЧИЕ ХАРАКТЕРИСТИКИ ТЕСТА

Анализаторы культур крови BacT/ALERT 3D

Вещества, которые могут помешать проведению теста

Были проведены внутренние исследования с использованием спинномозговой, плевральной и синовиальной жидкости, плазмы, цельной крови и кровяных сгустков. К аликвотам каждой из этих жидкостей были также добавлены лейкоциты в концентрациях, обычно наблюдаемых в каждой из перечисленных биологических жидкостей при бактериемии. Тест проводился в присутствии микроорганизмов или в их отсутствие. Данные вещества не мешали выделению и обнаружению микроорганизмов и не давали ложноположительных результатов в отсутствие микроорганизмов.

Аналитическая чувствительность: предел обнаружения (LoD)

Данные в таблице 1 представляют результаты внутренних исследований посевов. Для каждого вида было выполнено как минимум 30 повторений теста. Данные в таблице 1 получены при исследовании посевов во флаконы в конце срока годности. Во флаконы, засеянные *B. fragilis* и *S. pneumoniae*, добавляли по 1 мл пула человеческой крови. На пределе обнаружения (LoD) микроорганизмы обнаруживались не менее чем в 95 % случаев.

Таблица 1. Аналитическая чувствительность: предел обнаружения (LoD)

Микроорганизм	Идентификационный номер штамма	Предел обнаружения (LoD) (КОЕ/флакон)
Bacteroides fragilis	ATCC® 25285™	5
Clostridium perfringens	NCTC 8798	4
Enterobacter aerogenes	ATCC® 13048™	8
Enterococcus faecalis	NCTC 12697	4
Escherichia coli	NCTC 12923	4
Listeria monocytogenes	ATCC® 15313™	6
Salmonella enterica	ATCC® 14028™	5
Staphylococcus aureus	NCTC 10788	4
Streptococcus pneumoniae	ATCC® 6305™	6

ПРИМЕЧАНИЕ: В 86,6 % случаев высев материала из флаконов, признанных положительными, был произведен не позднее чем через 30 минут.

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Аналитическая чувствительность: питательные свойства среды

Данные в таблице 2 представляют результаты внутренних исследований посевов с использованием крови здоровых людей-добровольцев или без нее. Было проверено несколько штаммов каждого вида при целевой концентрации посевного материала 125 КОЕ/флакон. Фактическое количество микроорганизмов составило 3–299 КОЕ/флакон. В данном исследовании высев материала из флаконов BacT/ALERT FN Plus проводился как минимум через 24 ч после того, как система зарегистрировала рост во флаконе. Перечисленные виды являются представителями клинически распространенных микроорганизмов в культурах крови и стерильных биологических жидкостях.

Таблица 2. Аналитическая чувствительность: питательные свойства среды

Микроорганизм	Кровь				Без крови			
	% выделения (кол-во)	Концентрация посевного материала, КОЕ/флакон (диапазон)	Время до получения положительного сигнала (часы)		% выделения* (кол-во=3)	Концентрация посевного материала, КОЕ/флакон (диапазон)	Время до получения положительного сигнала (часы)	
			Среднее	Диапазон			Среднее	Диапазон
Staphylococcus aureus	100,0 (15/15)	54–150	14,6	12,9–16,7	100,0	116–150	21,8	21,3–22,0
Escherichia coli	100,0 (15/15)	73–254	10,9	10,4–12,4	100,0	73–176	11,6	10,4–12,9
Bacteroides fragilis	100,0 (18/18)	9–154	29,7	24,3–43,6	66,7 (2/3)	19–154	97,2	79,2–115,2
Streptococcus pneumoniae	100,0 (15/15)	4–260	16,5	11,5–43,8	100,0	4–25	17,5	16,0–19,3
Clostridium perfringens	100,0 (18/18)	58–210	17,3	12,0–40,1	100,0 (8/8)	76–210	27,1	14,1–35,7
Klebsiella pneumoniae	100,0 (15/15)	89–123	11,2	10,4–13,1	100,0	95–123	12,6	12,1–13,4
Fusobacterium nucleatum	70,6 (12/17)	19–204	74,4	36,0–108,0	75,0 (3/4)	19–116	56,1	41,2–64,8
Streptococcus agalactiae	100,0 (15/15)	14–194	16,9	12,7–28,9	100,0	21–34	25,9	20,5–33,4
Enterococcus faecalis	100,0 (15/15)	63–259	13,7	11,9–19,4	100,0	71–169	22,4	17,8–24,8
Parvimonas micra	80,0 (16/20)	46–154	51,4	37,3–69,6	0,0 (0/4)	46–154	–	–
Enterobacter cloacae	100,0 (15/15)	111–200	11,9	11,1–12,5	100,0	111–185	13,0	11,9–14,7
Proteus mirabilis	100,0 (15/15)	36–213	11,4	10,9–12,5	100,0	36–213	11,9	11,5–12,7
Eggerthella lenta	86,7 (13/15)	83–175	41,0	34,8–60,0	66,7 (2/3)	83–151	46,0	44,0–48,0
Staphylococcus epidermidis	100,0 (15/15)	44–135	21,0	17,4–25,3	100,0	44–105	29,3	24,5–36,8
Listeria monocytogenes	100,0 (15/15)	121–251	17,1	15,5–19,3	100,0	121–251	19,2	17,7–20,3
Clostridium tertium	100,0 (15/15)	24	12,5	11,4–13,5	100,0	24	14,8	14,1–16,0
Clostridium septicum	50,0 (20/40)	25–146	31,7	13,9–62,4	40,0 (2/5)	90–146	43,4	17,1–69,6
Peptoniphilus asaccharolyticus	60,0 (12/20)	49–296	50,9	34,4–79,2	25,0 (1/4)	81–296	44,7	–

* При выделении менее 100,0 % рекомендуется добавить кровь, например стерильную дефибринированную лошадиную кровь (10,0 % объем/объем)[3].

Для некоторых видов, включая *Capnocytophaga ochracea, Cardiobacterium hominis, Haemophilus parainfluenzae* и *Granulicatella adiacens*, положительный сигнал был получен в менее чем 100 % случаев.

Результаты клинических исследований (посевы крови)

Ниже приводятся результаты сравнения посевов крови во флаконы BacT/ALERT FN Plus и BacT/ALERT FN Anaerobic – Флаконы BacT/ALERT FN для культивирования с активированным углем для выделения анаэробных микроорганизмов из крови (по тексту — флаконы BacT/ALERT FN) (для всех соответствующих пар).

В трех разных центрах в США было проведено многоцентровое клиническое исследование, в котором сравнивали эффективность использования флаконов BacT/ALERT FN Plus и BacT/ALERT FN для посева на анаэробы после добавления образцов крови объемом от 6 до 10 мл (соответствующие пары). Всего было получено 2514 пар флаконов для посева на анаэробы от 1080 взрослых пациентов с подозрением на бактериальные или дрожжевые инфекции крови. Если хотя бы для одного флакона в паре анализатор BacT/ALERT регистрировал положительный результат, производился высев материала из обоих флаконов. Считалось, что пара флаконов дала положительный результат, если результаты высева материала либо из флакона BacT/ALERT FN Plus, либо из флакона BacT/ALERT FN были положительными. Положительный результат считался подтвержденным, если анализатором BacT/ALERT был зарегистрирован рост во флаконе для культивирования и при высеве материала из этого флакона был получен рост изолята. Была определена доля подтвержденных положительных результатов для флаконов BacT/ALERT FN Plus и для флаконов BacT/ALERT FN, и для сравнения их эффективности подсчитано соотношение количества подтвержденных положительных результатов для обоих типов флаконов. Выделенные клинические изоляты относили к группе значимых, контаминантов или неизвестных по усмотрению центров, где проводилось исследование.

В общей сложности из всех соответствующих пар анаэробных культур крови, давших положительный результат, было выделено 312 изолятов. При высеве материала из флаконов BacT/ALERT FN Plus или BacT/ALERT FN в 289 паре флаконов был выделен по крайней мере один изолят. Из 266 пар флаконов был выделен один изолят, а из 23 пар — два изолята. Общая выборка результатов, приведенных в таблице 3, включает 312 изолятов, выделенных из пар флаконов, давших положительный результат, и 2225 пар флаконов, давших отрицательный результат (всего 2537 результат теста). При использовании флаконов BacT/ALERT FN Plus было выявлено в общей сложности 282 изолята, в то время как при использовании флаконов BacT/ALERT FN — 192 изолята. Что касается значимых изолятов, при использовании флаконов BacT/ALERT FN Plus было выявлено всего 202 изолята, а при использовании флаконов BacT/ALERT FN — 150 изолятов. При высеве материала из флаконов BacT/ALERT FN Plus, давших положительный результат, было получено три ложноположительных результата, что составляет 0,12 % (3/2537) от всей исследованной выборки.

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В нижеследующих таблицах сравниваются результаты, полученные для всех соответствующих флаконов BacT/ALERT FN Plus и BacT/ALERT FN, которые при высеве дали любое количество изолятов (таблица 3), единственный изолят (таблица 4) или несколько изолятов (таблица 5).

Таблица 3. Все соответствующие пары флаконов, из которых был выделен один или несколько изолятов, в совокупности (посевы крови)

Группа клинических изолятов	BacT/ALERT FN Plus, подтвержденные положительные результаты	% подтвержденных положительных результатов BacT/ALERT FN Plus в выборке	BacT/ALERT FN, подтвержденные положительные результаты	% подтвержденных положительных результатов BacT/ALERT FN в выборке	Соотношение количества подтвержденных положительных результатов*
Значимые	202	8,0 (202/2537)	150	5,9 (150/2537)	1,347
Контаминанты	58	2,3 (58/2537)	30	1,2 (30/2537)	1,933
Неизвестные	22	0,9 (22/2537)	12	0,5 (12/2537)	1,833
Всего	282	11,1 (282/2537)	192	7,6 (192/2537)	1,469

* 162 (сто шестьдесят два) изолята было выявлено при использовании как флаконов BacT/ALERT FN Plus, так и флаконов BacT/ALERT FN; 120 изолятов — только при использовании флаконов BacT/ALERT FN Plus и 30 изолятов — только при использовании флаконов BacT/ALERT FN. Соотношение количества подтвержденных положительных результатов по всем изолятам составило 1,469 (282/192) с 95 % ДИ (1,317; 1,621)[7].

Таблица 4. Все соответствующие пары, из которых был выделен единственный изолят (посевы крови)

Клиническое определение	BacT/ALERT FN Plus, подтвержденные положительные результаты	BacT/ALERT FN, подтвержденные положительные результаты	Соотношение количества подтвержденных положительных результатов*
Значимые	177	133	1,331
Контаминанты	51	27	1,889
Неизвестные	15	9	1,667
Всего	243	169	1,438

* 146 (сто сорок шесть) изолятов было выявлено при использовании как флаконов BacT/ALERT FN Plus, так и флаконов BacT/ALERT FN; 97 изолятов — только при использовании флаконов BacT/ALERT FN Plus и 23 изолята — только при использовании флаконов BacT/ALERT FN. Соотношение количества подтвержденных положительных результатов по единственным изолятам составило 1,438 (243/169) с 95 % ДИ (1,286, 1,590)[7].

Таблица 5. Все соответствующие пары, давшие несколько изолятов (посевы крови)

Клиническое определение	BacT/ALERT FN Plus, подтвержденные положительные результаты	BacT/ALERT FN, подтвержденные положительные результаты	Соотношение количества подтвержденных положительных результатов*
Значимые	25	17	1,471
Контаминанты	7	3	2,333
Неизвестные	7	3	2,333
Всего	39	23	1,696

* 16 (шестнадцать) изолятов было выявлено при использовании как флаконов BacT/ALERT FN Plus, так и флаконов BacT/ALERT FN; 23 изолята — только при использовании флаконов BacT/ALERT FN Plus и 7 изолятов — только при использовании флаконов BacT/ALERT FN. Соотношение количества подтвержденных положительных результатов по множественным изолятам составило 1,696 (39/23) с 95 % ДИ (1,088, 2,304)[7].

В данном клиническом исследовании для 2218 соответствующих пар флаконов BacT/ALERT FN Plus и BacT/ALERT FN для выделения анаэробов из крови после 5 дней инкубации были получены отрицательные результаты теста для обоих типов флаконов. Для 63 из этих пар был проведен высев материала из обоих флаконов, и в семи случаях выявлены ложноотрицательные результаты для обоих типов флаконов; высев материала только из флаконов BacT/ALERT FN Plus был проведен для 848 пар, и выявлено четыре ложноотрицательных результата; для 1307 пар флаконов высевы не проводились. Результаты представлены в таблице 6.

Таблица 6. Количество ложноотрицательных результатов по соответствующим парам флаконов для посева крови на анаэробы, которые были отмечены системой в ходе теста как отрицательные для обоих флаконов

Высев из флаконов BacT/ALERT FN Plus	Высев из флаконов BacT/ALERT FN	% ложноотрицательных результатов для BacT/ALERT FN Plus	% ложноотрицательных результатов для BacT/ALERT FN
Да	Да	11,1 (7/63)	11,1 (7/63)
Да	Нет	0,5 (4/848)	–

Из этих 7 положительных результатов при высеве в 2 случаях были выделены строгие аэробы (*Acinetobacter baumannii* и *Pseudomonas aeruginosa*). Флаконы BacT/ALERT FN Plus не предназначены для обнаружения строгих аэробов в крови и других, в норме стерильных биологических жидкостей. Общая частота ложноотрицательных результатов для флаконов BacT/ALERT FN Plus по результатам высевов материала составила 1,2 % (11/911), а при исключении строгих аэробов — 1,0 % (9/911).

Сравнение количества микроорганизмов (число изолятов), выделенных при высеве материала из флаконов BacT/ALERT FN Plus и BacT/ALERT FN, представлено в таблице 7.

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Таблица 7. Сравнение количества микроорганизмов из флаконов BacT/ALERT FN Plus и BacT/ALERT FN (число изолятов) — посевы крови

Группа	BacT/ALERT FN Plus	BacT/ALERT FN
Анаэробы*	10	4
Enterobacteriaceae	50	43
Enterococcus spp.	28	19
Дрожжи	0	0
Другие грамотрицательные бактерии	6	3
Другие грамположительные бактерии	9	6
Коагулазоотрицательный *Staphylococcus*	93	53
Staphylococcus aureus	65	42
Streptococcus spp.	21	22

ПРИМЕЧАНИЕ: В таблицу изолятов входят полимикробные культуры.

* В этом клиническом исследовании выделены изоляты следующих анаэробов. *Bacteroides caccae* (4), *Bacteroides fragilis* (2), *Lactobacillus* spp. (1), *Peptostreptococcus micros* (1), *Prevotella denticola* (1), *Propionibacterium acnes* (1), *Propionibacterium* spp. (1)

Результаты клинических исследований (посевы стерильных биологических жидкостей)

В четырех разных центрах в США и Канаде было проведено многоцентровое клиническое исследование, в котором сравнивали эффективность флаконов BacT/ALERT FN Plus и BacT/ALERT FN при исследовании образцов стерильных биологических жидкостей. Всего было получено 339 пары флаконов от 310 взрослых пациентов с подозрением на бактериальные или дрожжевые инфекции стерильных биологических жидкостей. В исследовании использовались следующие типы стерильных биологических жидкостей: раствор для постоянного амбулаторного перитонеального диализа (ПАПД), спинномозговая жидкость (СМЖ), перитонеальная жидкость, плевральная жидкость и синовиальная жидкость. Выделенные клинические изоляты относили к группе значимых, контаминантов или неизвестных по усмотрению центров, где проводилось исследование.

В общей сложности из всех пар посевов стерильных биологических жидкостей на анаэробы, давших положительный результат, было выделено 77 изолятов. При высеве материала из флаконов BacT/ALERT FN Plus или BacT/ALERT FN в 61 паре флаконов был выделен по крайней мере один изолят. Из 50 пар флаконов был выделен один изолят, из 7 пар — два изолята, из 3 пар — три изолята и из 1 пары — четыре изолята. Общая выборка результатов, приведенных в таблице 8, включает 77 изолятов, выделенных из пар флаконов, давших положительный результат, и 278 пар флаконов, давших отрицательный результат (всего 355 результат теста). При использовании флаконов BacT/ALERT FN Plus было выявлено в общей сложности 72 изолята, в то время как при использовании флаконов BacT/ALERT FN — 59 изолятов. Что касается значимых изолятов, при использовании флаконов BacT/ALERT FN Plus было выявлено всего 52 изолята, а при использовании флаконов BacT/ALERT FN — 50 изолятов. Ложноположительных результатов для материала из флаконов BacT/ALERT FN Plus в исследованной выборке не было (0/355).

В таблице 8 сравниваются результаты, полученные для флаконов BacT/ALERT FN Plus и BacT/ALERT FN при посевах стерильных биологических жидкостей, которые при высеве дали один или несколько изолятов.

Таблица 8. Все пары, давшие один или несколько изолятов, в совокупности (культуры стерильных биологических жидкостей)

Клиническое определение	BacT/ALERT FN Plus, подтвержденные положительные результаты	% подтвержденных положительных результатов BacT/ALERT FN Plus в выборке	BacT/ALERT FN, подтвержденные положительные результаты	% подтвержденных положительных результатов BacT/ALERT FN в выборке	Соотношение количества подтвержденных положительных результатов*
Значимые	52	14,6 (52/355)	50	14,1 (50/355)	1,040
Контаминанты	12	3,4 (12/355)	2	0,6 (2/355)	6,000
Неизвестные	8	2,2 (8/355)	7	2,0 (7/355)	1,143
Всего	72	20,3 (72/355)	59	16,6 (59/355)	1,220

* 54 (пятьдесят четыре) изолята было выявлено при использовании как флаконов BacT/ALERT FN Plus, так и флаконов BacT/ALERT FN; 18 изолятов — только при использовании флаконов BacT/ALERT FN Plus и 5 изолятов — только при использовании флаконов BacT/ALERT FN. Соотношение количества подтвержденных положительных результатов по всем изолятам составило 1,220 (72/59) с 95 %-ным ДИ (1,044, 1,396)[7].

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В таблице 9 приводятся данные по минимальным объемам образцов, достигнутым в клиническом исследовании анаэробных культур стерильных биологических жидкостей.

Таблица 9. Номинальный объем (мл) образцов стерильных биологических жидкостей, флаконы BacT/ALERT FN Plus — положительный результат теста

Тип образца	Общее кол-во образцов	Кол-во положительных результатов	Минимальный объем образца (мл)
Раствор для постоянного амбулаторного перитонеального диализа	75	22	1,0
СМЖ	24	2	0,1
Перитонеальная жидкость	106	16	0,3
Плевральная жидкость	93	22	0,5
Синовиальная жидкость	41	10	0,2
Всего	339	72	–

В данном клиническом исследовании для 277 пар флаконов BacT/ALERT FN Plus и BacT/ALERT FN после 5 дней инкубации были получены отрицательные результаты теста для обоих типов флаконов. Для 166 из этих пар был проведен высев материала из обоих флаконов, при этом ложноотрицательные результаты были выявлены в 11 случаях как для флаконов BacT/ALERT FN Plus, так и для флаконов BacT/ALERT FN. Высев материала только из флаконов BacT/ALERT FN Plus был проведен для 111 пар, при этом ложноотрицательных результатов не выявлено. Результаты представлены в таблице 10.

Таблица 10. Количество ложноотрицательных результатов по парам посевов стерильных биологических жидкостей на анаэробы, которые были отмечены системой в ходе теста как отрицательные для обоих флаконов

Высев из флаконов BacT/ALERT FN Plus	Высев из флаконов BacT/ALERT FN	% ложноотрицательных результатов для BacT/ALERT FN Plus	% ложноотрицательных результатов для BacT/ALERT FN
Да	Да	6,6 (11/166)*	6,6 (11/166)*
Да	Нет	0,0 (0/111)	–

* Из этих 11 положительных результатов высева в 8 случаях были выделены строгие аэробы: *Acinetobacter baumannii* (2), *Candida albicans* (1), *Candida parapsilosis* (2), *Cryptococcus neoformans* (1), *Micrococcus* spp. (1), *Pseudomonas aeruginosa* (1).

ПРИМЕЧАНИЕ: Флаконы BacT/ALERT FN Plus не предназначены для обнаружения строгих аэробов в крови и других, в норме стерильных биологических жидкостей.

Общая частота ложноотрицательных результатов для флаконов BacT/ALERT FN Plus на основании высевов материала составила 4,0 % (11/277), а при исключении строгих аэробов — 1,1 % (3/277).

Сравнение количества микроорганизмов (число изолятов), выделенных при высеве материала из флаконов BacT/ALERT FN Plus и BacT/ALERT FN, представлено в таблице 11.

Таблица 11. Сравнение количества микроорганизмов из флаконов BacT/ALERT FN Plus и BacT/ALERT FN (число изолятов) — культуры стерильных биологических жидкостей

Группа	BacT/ALERT FN Plus	BacT/ALERT FN
Анаэробы*	6	6
Enterobacteriaceae	9	8
Enterococcus spp.	14	11
Дрожжи	4	2
Другие грамотрицательные бактерии	2	1
Другие грамположительные бактерии	1	0
Коагулазоотрицательный *Staphylococcus*	19	16
Staphylococcus aureus	9	9
Streptococcus spp.	8	6

ПРИМЕЧАНИЕ: В таблицу изолятов входят полимикробные культуры.

* В этом клиническом исследовании выделены следующие анаэробы. *Bacteroides fragilis* (2: 1 только из флаконов BacT/ALERT FN; 1 из флаконов BacT/ALERT FN Plus и BacT/ALERT FN)*, Clostridium ramosum* (1 из флаконов BacT/ALERT FN Plus и BacT/ALERT FN)*, Clostridium* spp. (1 из флаконов BacT/ALERT FN Plus и BacT/ALERT FN), *Prevotella loescheii* (1 из флаконов BacT/ALERT FN Plus и BacT/ALERT FN), *Prevotella melaninogenica* (1 только из флаконов BacT/ALERT FN Plus), *Veillonella* spp. (1 из флаконов BacT/ALERT FN Plus и BacT/ALERT FN).

Контроль качества в ходе клинического исследования проводился для всех 3 микроорганизмов (*Bacteroides fragilis, Bacteroides vulgatus* и *Clostridium perfringens)*, которые были приготовлены для посева путем последовательных разведений и посеяны во флаконы BacT/ALERT FN Plus в количестве 100 КОЕ/флакон с приемлемым диапазоном 30–300 КОЕ/флакон. В целом результаты контроля качества были расценены как удовлетворительные. Случаи, когда результаты контроля качества были неприемлемыми, связаны с техническими ошибками (например, не внесена добавка, слишком малое или слишком большое число колоний, использование неправильного растворителя, не был изменен статус флакона после положительного сигнала от системы и положительного результата высева, не использовались предварительно восстановленная среда или реагенты). Повторные тесты давали приемлемые результаты.

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Отсроченная загрузка

В таблице 12 представлены результаты исследований посевов 6 видов микроорганизмов (*Staphylococcus aureus, Escherichia coli, Streptococcus pneumoniae, Enterococcus faecium, Bacteroides fragilis* и *Clostridium perfringens*) в целевой концентрации 100 КОЕ/флакон (при допустимом диапазоне 30-300 КОЕ/флакон), выполненных в трех центрах. Фактическое количество микроорганизмов составило 41–253 КОЕ/флакон. Все флаконы были протестированы с кровью людей-добровольцев и хранились при определенной температуре определенное время перед загрузкой в анализатор BacT/ALERT 3D. Доля высеваемости соответствует флаконам с положительными результатами, определенными анализатором, из которых при высеве был получен рост колоний с морфологией соответствующей посеянному микроорганизму.

Таблица 12. Отсроченная загрузка

Вводимый образец	Температура инкубации (°C)	Время хранения (ч)	% выделения	Время до получения положительного сигнала с момента посева (время хранения + время до получения положительного сигнала анализатора в часах)	
				Среднее	Диапазон
Тестовые флаконы, в которые произведен посев	Контроль	Без задержки	100,0 (89/89)	15,9	9,5–52,8
	2–8	48	100,0 (65/65)	63,3	50,1–90,4
	20–25	24	100,0 (62/62)	34,7	26,0–79,2
	20–25	36	100,0 (62/62)	43,6	38,0–78,6
	35–37	8	100,0 (72/72)	17,7	10,0–53,4
	35–37	24	80,0 (64/80)*	28,6	26,0–52,3
Отрицательные контроли	Все условия		0,0 (0/51)	–	–

*** ОСТОРОЖНО: Флаконы для культивирования, хранившиеся при 35–37 °C в течение 24 ч или дольше перед загрузкой в систему, могут не давать положительного сигнала и требуют высева.**

Прецизионность в условиях одной лаборатории (повторяемость)

Данные в таблице 13 представляют результаты внутренних исследований посевов, которые проводились в течение 12 дней несколькими операторами с использованием нескольких анализаторов. Микроорганизмы выращивались при добавлении клинически значимых концентраций противомикробных препаратов, к которым они чувствительны. В данном исследовании высев материала из флаконов BacT/ALERT FN Plus проводился как минимум через 24 ч после того, как система зарегистрировала рост во флаконе. Было выполнено не менее 108 повторений тестов для каждого сочетания микроорганизма и противомикробного препарата.

Таблица 13. Прецизионность в условиях одной лаборатории (повторяемость)

Вводимый образец		Концентрация посевного материала, КОЕ/флакон (диапазон)	% выделения				Время до получения положительного сигнала (часы)	
Микроорганизм	Противомикробный препарат		Партия 1	Партия 2	Партия 3	Всего	Среднее	Диапазон
B. fragilis	Имипенем	136–406	100,0	100,0	100,0	100,0	36,9	30,2–55,2
C. perfringens	Ванкомицин	75–204	100,0	94,4	100,0	98,2	14,5	11,1–22,0
S. aureus	Оксациллин	94–158	100,0	100,0	100,0	100,0	17,7	15,1–24,3

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Воспроизводимость

Данные в таблице 14 представляют результаты исследований посевов, проведенных в трех центрах. В каждом центре было выполнено 144 повторения теста в течение 3 дней с участием не менее двух операторов на один центр. Воспроизводимость оценивалась для каждого из восьми микроорганизмов. Для одного микроорганизма (*S. pneumoniae*) культуры готовили путем последовательных разведений, для остальных семи — с использованием образцов BioBall®. *S. pneumoniae* были посеяны во флаконы BacT/ALERT FN Plus в концентрации 100 КОЕ/флакон с приемлемым диапазоном 30–300 КОЕ/флакон, а остальные семь микроорганизмов — в концентрации 1–17 КОЕ/флакон. Фактическая концентрация микроорганизмов составила 5–500 КОЕ/флакон для диапазона 30–300 КОЕ/флакон и 1–270 КОЕ/флакон для диапазона 1–17 КОЕ/флакон. Доля высеваемости соответствует флаконам с положительными результатами, определенными прибором, из которых при окрашивании по Граму/высеве получен результат, соответствующий посеянному организму.

Таблица 14. Воспроизводимость

Вводимый образец	**% выделения**				**Время до получения положительного сигнала (часы)**		**Диапазон уровней посевного материала (КОЕ/флакон)**
	Центр 1	**Центр 2**	**Центр 3**	**Всего**	**Среднее**	**Диапазон**	
S. aureus	96,3 % (26/27)	79,2 % (19/24)	100,0 % (33/33)	92,9 % (78/84)	20,2	18,5–35,7	2–12
E. coli	100,0 % (18/18)	79,2 % (19/24)	100,0 % (33/33)	93,3 % (70/75)	12,8	11,4–20,8	2–11
E. faecalis	100,0 % (30/30)	83,3 % (20/24)	97,0 % (32/33)	94,3 % (82/87)	24,6	17,9–30,4	2–15
C. perfringens	100,0 % (18/18)	96,8 % (61/63)	100,0 % (30/30)	98,2 % (109/111)	12,2	10,2–17,3	< 1–122
E. aerogenes	90,0 % (27/30)	75,0 % (18/24)	90,5 % (38/42)	86,5 % (83/96)	14,6	11,9–16,7	1–270*
L. monocytogenes	100,0 % (21/21)	100,0 % (24/24)	100,0 % (33/33)	100,0 % (78/78)	22,8	20,6–37,0	1–13
S. enterica	100,0 % (24/24)	79,2 % (19/24)	100,0 % (30/30)	93,6 % (73/78)	13,3	12,4–14,4	1–16
S. pneumoniae	100,0 % (30/30)	100,0 % (36/36)	100,0 % (18/18)	100,0 % (84/84)	17,5	13,3–23,1	5–500
Всего	98,0 % (194/198) 95 %-ный ДИ: 94,9 %, 99,5 %	88,9 % (216/243) 95 %-ный ДИ: 84,3 %, 92,6 %	98,0 % (247/252) 95 %-ный ДИ: 95,4 %, 99,4 %	94,8 % (657/693) 95 %-ный ДИ: 92,9 %, 96,3 %	–		

* Подсчет количества микроорганизмов на чашках Петри при концентрации посевного материала 270 КОЕ/флакон проводили с использованием последовательных разведений культуры.

Эти данные включают повторные тесты, выполнявшиеся вследствие технических ошибок в отдельно взятом центре (например, контаминация флаконов или реагентов, слишком малое или слишком большое количество колоний, не был изменен статус флакона после положительного сигнала от системы и положительного результата высева). Данные, из которых исключены лабораторные ошибки, демонстрируют 100-процентную высеваемость, за исключением *E. aerogenes* — частота выделения этого микроорганизма (суммарная для всех центров) составила 96,3 %.

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ССЫЛКИ

1. Thorpe TC, Wilson ML, Turner JE, DiGuiseppi JL, Willert M, Mirrett S, et al: BacT/ALERT: an Automated Colorimetric Microbial Detection System. *J Clin Micro* 1990;28(7), 1608-1612.
2. *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* 5th Edition. U.S. Department of Health and Human Services Centers for Disease Control and Prevention and National Institutes of Health. Fifth Edition. US Government Printing Office. Washington: Feb 2007.
3. Koneman EW, Allen SD, Janda WM, Schreckenberger PC, Winn WC. *Color Atlas and Textbook of Diagnostic Microbiology*, 6th ed. 2006, pp. 446,590.
4. Baron EJ, Weinstein MP, Dunne Jr. WM, Yagupsky P, Welch DF, Wilson DM. 2005. Cumitech 1C, Blood Cultures IV. Coordinating ed. Baron EJ. ASM Press, Washington, DC.
5. CLSI. *Principles and Procedures for Blood Cultures; Approved Guideline.* CLSI document M47-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2007.
6. CLSI. *Quality Control for Commercially Prepared Microbiological Culture Media*; Approved Standard—Third Edition. CLSI/NCCLS document M22-A3. Wayne, PA: NCCLS; 2004.
7. Kondratovich M. Comparing Two Medical Tests When Results of Reference Standard Are Unavailable for Those Negative via Both Tests. *J. Biopharm Stat* 2008;18:1,145-166.

ОГРАНИЧЕННАЯ ГАРАНТИЯ

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Символ	Обозначение
REF	Номер по каталогу
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	Дата изготовления
	Температурный диапазон
	Использовать до
LOT	Код партии
	Обратитесь к инструкции по применению
	Содержимого достаточно для <n>-количества тестов
EC REP	Уполномоченный представитель в Европейском сообществе
	Вверх
IVD	Медицинское изделие для диагностики in vitro
	Запрет на повторное использование
	Без латекса
Rx only	Только для США. Осторожно: Согласно федеральному закону США данное изделие допускается к продаже только лицензированным врачам или по их заказу.
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ИСТОРИЯ ПЕРЕСМОТРОВ

В этом разделе содержится обзор изменений, внесенных в инструкцию по применению флаконов BacT/ALERT FN Plus.

Дата пересмотра	Номер версии	Тип изменений	Обзор изменений
2017-11	043785-01 /9314506 H	Изменение содержания:	В раздел **«Сбор и подготовка образцов»** добавлено примечание относительно этикетки флакона с информацией о наполнении.
		Административные изменения:	Раздел **«Таблица символов и обозначений»** обновлен с целью внесения новых символов продукции.
2016-04	9309504 D	Изменение содержания:	**Реагенты** - Обновление информации о составе - Разъяснение по дате истечения срока годности
			В раздел **«Сбор и подготовка образцов»** добавлено предупреждение относительно давления во флаконе.
			В раздел **«Контроль качества»** добавлено предупреждение относительно ЛИС и сокращенных обозначений типов флаконов.
			Добавлено предупреждение «только по рецепту» и символ для клиентов в США
		Административные изменения:	В раздел **«Ограниченная гарантия»** добавлены методические рекомендации
			Раздел **«Таблица символов и обозначений»** обновлен с целью внесения новых символов продукции.
2013-04	9305049 C	Изменение содержания:	В разделах **«Сбор и подготовка образцов», «Ожидаемые результаты», «Нейтрализация противомикробных препаратов», «Рабочие характеристики теста»** пересмотренный текст включает дополнительную информацию по характеристикам продукта, основанную на данных клинических исследований.
			В раздел **«Ограничения метода»** после оценки FDA добавлены пункты 2, 8 и 9.
		Административные изменения:	Из раздела **«Реагенты»** текст о предупреждениях перенесен в раздел «Ограничения метода».

ПРИМЕЧАНИЕ: Незначительные типографские, грамматические изменения и изменения в форматировании в историю пересмотров не включены.

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НАЗНАЧЕНИЕ

BacT/ALERT PF Plus – Флаконы педиатрические BacT/ALERT PF Plus со средой и адсорбентом для выделения микроорганизмов из крови и стерильных биологических жидкостей (далее по тексту флаконы BacT/ALERT PF Plus) используются с анализаторами культур крови и микобактерий автоматическими бактериологическими семействами BacT/ALERT для качественного обнаружения и выделения аэробных и факультативно анаэробных микроорганизмов (бактерий и дрожжевых грибов) из крови.

КРАТКОЕ ОПИСАНИЕ

Анализаторы культур крови и микобактерий автоматические бактериологические семейства BacT/ALERT (по тексту анализаторы культур крови BacT/ALERT, система обнаружения микроорганизмов BacT/ALERT, анализатор BacT/ALERT, система BacT/ALERT, анализатор, система) используются для обнаружения микроорганизмов в крови, взятой у пациента с подозрением на бактериемию или фунгемию. Анализатор BacT/ALERT в сочетании с флаконами для культивирования представляет собой как систему обнаружения микроорганизмов, так и среду с питательными и атмосферными условиями, подходящими для микроорганизмов, которые часто встречаются в крови. С помощью флаконов BacT/ALERT PF Plus можно обнаружить микроорганизмы, если доступен небольшой объем крови. Флакон BacT/ALERT PF Plus, в который предварительно производится посев образца, помещается в анализатор, где осуществляется культивирование и непрерывный мониторинг наличия роста микроорганизмов во флаконе.

ПРИМЕЧАНИЕ: Если не указано иное, предоставленная информация относится ко всем конфигурациям системы обнаружения микроорганизмов BacT/ALERT.

ПРИНЦИП МЕТОДА

В основе работы анализатора культур крови BacT/ALERT лежит использование колориметрического датчика и светоотражения для регистрации наличия и накопления углекислого газа (CO2) в питательной среде. Если в анализируемом образце присутствуют микроорганизмы, то в процессе роста и утилизации субстратов питательной среды они вырабатывают углекислый газ. Под действием вырабатываемого микроорганизмами углекислого газа (CO2) цвет газопроницаемого датчика, встроенного в дно каждого флакона для культивирования, меняется с зелено-голубого на желтый.1 В результате осветления датчика коэффициент отражения повышается. Мониторинг и регистрация отражения флакона производится анализатором каждые 10 минут.

РЕАГЕНТЫ

Для диагностики *in vitro*.

ОСТОРОЖНО! С образцами и флаконами, в которые произведен посев, следует обращаться как с потенциально инфекционными материалами. Все флаконы, в которые был произведен посев, иглы для сбора образцов и системы для взятия крови следует обеззараживать в соответствии с процедурой, используемой в вашем учреждении.[2]

Флако **BacT/ALERT PF Plus** (цветовая кодировка: желтая) — флаконы BacT/ALERT PF Plus, предназначенные для однократного использования, содержат 30 мл комплексной питательной среды и ≥1,6 г адсорбирующих полимерных гранул. На момент изготовления питательная среда состоит из следующих компонентов: сочетание пептонов/биологических экстрактов (≥1,85 % масса/объем), антикоагулянтов (≥0,083 % масса/объем), витаминов и аминокислот (≥0,00145 % масса/объем), источников углерода (≥0,45 % вес/объем), следовых веществ (≥0,0005 % вес/объем). Флаконы содержат разреженную атмосферу, состоящую из N_2, O_2 и CO_2. Количественный/качественный состав среды может быть модифицирован для достижения необходимых функциональных характеристик.

ОСТОРОЖНО! Флаконы BacT/ALERT изготовлены из поликарбоната. Некоторые дезинфицирующие средства нельзя использовать на поликарбонатных поверхностях, так как они могут вызвать повреждение флаконов. Проверьте, совместимо ли дезинфицирующее средство с поликарбонатом, перед тем как использовать его для дезинфекции поверхностей флаконов BacT/ALERT.

ОСТОРОЖНО! При культивировании во флаконах BacT/ALERT PF Plus образцов крови очень малого объема (0,5 мл или менее) требуется добавление в питательную среду крови, например стерильной дефибринированной лошадиной крови (10,0 % объем/объем) для поддержания роста, особенно для выделения прихотливых микроорганизмов, таких как *Haemophilus influenzae, Streptococcus pneumoniae* и *Neisseria gonorrhoeae*.[3]

Необходимые дополнительные материалы

- Анализаторы культур крови BacT/ALERT
- Система взятия крови
- Стерильные иглы для вентилирования и высева из положительных флаконов
- Одноразовые перчатки
- Подходящий контейнер для биологически опасных отходов для сброса материалов, которые могут быть загрязнены инфекционными материалами.

Материалы, которые можно приобрести в компании bioMérieux

- BacT/ALERT Blood Collection Adapter Cap — Колпачок адаптера для взятия крови во флаконы BacT/ALERT (по тексту колпачок адаптера, колпачок адаптера для взятия крови во флаконы BacT/ALERT)
- Анализаторы культур крови BacT/ALERT
- Стерильные иглы для вентилирования и высева из положительных флаконов

Инструкции по хранению

Флаконы BacT/ALERT PF Plus готовы к использованию. Их следует хранить в вертикальном положении в месте, защищенном от прямого света, при комнатной температуре (15–30 °C). Срок годности флаконов указан на этикетке каждого флакона. Запрещается осуществлять посев во флаконы для культивирования по окончании срока годности. При хранении флаконов при температуре ниже 15 °C возможно образование осадка, который растворяется при нагревании флаконы до комнатной температуры. Перед использованием выдержите флакон до достижения комнатной температуры.

Химические или физические признаки нестабильности

Перед использованием флаконы BacT/ALERT PF Plus следует осмотреть на наличие признаков порчи или повреждения (обесцвечивание). Нельзя использовать флаконы с признаками порчи, повреждений или утечки. Среда в отстоявшемся флаконе должна быть прозрачной, хотя возможна небольшая опалесценция или следы осадка из-за наличия антикоагулянта полианетолсульфоната натрия (SPS) или адсорбирующих полимерных гранул. Не путайте эти изменения с помутнением, которое является признаком микробного роста. Не используйте флаконы при помутнении среды, пожелтении датчика или наличии признаков повышенного давления газа в флаконе, т. к. все перечисленное свидетельствует о контаминации.

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ПРИБОРЫ

Перед использованием прочтите руководство по эксплуатации анализаторов культур крови BacT/ALERT.

ВЗЯТИЕ И ПОДГОТОВКА ОБРАЗЦОВ

Общие сведения

1. Флаконы для посева BacT/ALERT PF Plus должны использоваться специально обученным медицинским персоналом. Правильный сбор образца имеет большое значение при работе с культурами крови. Рекомендованная процедура сбора образцов приведена в документе Cumitech 1C[4].
2. Во время подготовки флакона и внесения образца пациента необходимо принять меры для предотвращения контаминации. Обязательной мерой для снижения частоты контаминации является надлежащая дезинфекция кожи.
3. Кровь можно брать непосредственно в пробирки, содержащие полианетолсульфонат натрия (SPS), хотя это не рекомендуется компанией bioMérieux. Пробирки с другими антикоагулянтами для культур крови использовать нельзя.[5]
4. Компания bioMérieux рекомендует загружать флаконы для культур в анализаторы культур крови BacT/ALERT как можно скорее после взятия. Если флаконы невозможно загрузить в анализатор сразу после посева, то до загрузки в анализатор их следует хранить при комнатной температуре не более 24 часов.
5. Оптимальное выделение изолятов достигается при внесении во флакон максимального объема образца. Использование меньшего объема образца может исказить результаты выделения и/или увеличить время обнаружения некоторых микроорганизмов. Рекомендованный объем образца для внесения во флакон составляет до 4 мл. Следите за набранным объемом с помощью меток объема с шагом 4 мл, расположенных на этикетке флакона.
6. В целом, посев больших объемов крови, содержащей небольшое количество бактерий, повысит выделение бактерий.[5]
7. Минимальный объем образцов крови, использовавшихся в клинических исследованиях, составлял 0,1 мл. Однако, при посеве во флаконы BacT/ALERT PF Plus рекомендуется использовать до 4 мл крови. Чтобы избежать посева чрезмерного объема, отслеживайте объем крови, поступающей во флакон, с помощью меток с шагом 4 мл, расположенных на этикетке флакона.

ОСТОРОЖНО! Непосредственный (прямой) вакуумный способ взятия крови с помощью флаконов BacT/ALERT PF Plus может привести к тому, что объем образца крови превысит 4 мл. Поэтому рекомендуется с осторожностью проводить процедуру непосредственного (прямого) взятия крови у новорожденных, детей младшего и среднего возраста, для которых важен общий объем взятой крови.

Подготовка флакона

1. Запишите на флаконе информацию о пациенте. Условные обозначения на этикетке флакона (☺,#,🕑) могут быть определены пользователем.
2. Снимите пластиковую защитную пластину с верха пробки флакона для культивирования. Перед посевом продезинфицируйте верхнюю часть флакона тампоном, пропитанным спиртом, или аналогичным материалом. Дайте ей высохнуть естественным способом.
3. Обработайте выбранное для венепункции место в соответствии с утвержденной в вашем учреждении процедурой.

Процедура посева при непосредственном взятии крови

ПРИМЕЧАНИЕ: При одновременном посеве во флаконы BacT/ALERT нескольких типов с использованием системы взятия крови с иглой-бабочкой и адаптера для непосредственного взятия крови сначала нужно вносить образец во флакон для выделения аэробных микроорганизмов, а затем — для выделения анаэробных микроорганизмов, чтобы кислород, скопившийся в трубке, не попал во флакон для выделения анаэробных микроорганизмов.

ПРИМЕЧАНИЕ: В ходе всей процедуры тщательно контролируйте процесс непосредственного взятия, обеспечивая надлежащий поток и не допуская попадания содержимого флакона в трубку адаптера. Поскольку во флаконе для культивирования содержатся химические добавки, важно следовать указанной ниже пошаговой процедуре, чтобы не допустить возможный обратный поток и последующие нежелательные реакции.

а. Держите флакон для посева ниже руки пациента в вертикальном положении (пробкой кверху).
б. Возьмите кровь с помощью системы взятия крови с иглой-бабочкой и колпачка адаптера для взятия крови во флаконы, в соответствии с утвержденной в вашем учреждении процедурой, и выполните посев непосредственно во флакон для культур у кровати пациента. Можно использовать меньший объем образца, но высеваемость можно повысить, если объем образца составляет приблизительно 4 мл (рекомендованное значение).
в. Ослабьте жгут, как только кровь начнет поступать во флакон для посева или в течение 2 минут после его наложения.
d. Проследите за тем, чтобы содержимое флакона не касалось пробки или конца иглы во время взятия крови.

ОСТОРОЖНО! В контаминированном флаконе для культивирования может быть избыточное давление, и при его использовании для непосредственного взятия крови может произойти отток в вену пациента. Контаминация флакона для культивирования не всегда легко распознается. Во избежание оттока необходимо тщательно контролировать процесс непосредственного взятия крови. Не используйте флаконы при помутнении среды, пожелтении датчика или при наличии признаков повышенного давления газа во флаконе, т. к. все перечисленное свидетельствует о контаминации.

Процедура посева при взятии крови с помощью шприца

ПРИМЕЧАНИЕ: При одновременном посеве во флаконы BacT/ALERT нескольких типов с использованием шприца сначала следует вносить образец во флакон для выделения анаэробных микроорганизмов, а затем — для выделения аэробных микроорганизмов, чтобы кислород, скопившийся в шприце, не попал во флакон для выделения анаэробных микроорганизмов. Используйте метки объема на этикетке флакона для оценки объема внесенного образца.

а. Выполните венепункцию и перенос крови во флакон BacT/ALERT в соответствии с утвержденной в вашем учреждении процедурой.

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ОСТОРОЖНО! При выполнении посева запрещается вдавливать поршень шприца с усилием, так как может произойти разбрызгивание образца. . При достижении необходимого объема заполнения удалите шприц, так как из-за вакуума автоматически будет набрано количество, превышающее рекомендованный максимум. Во избежание нарушения вакуума прокалывайте пробку флакона вертикально. Не выполняйте посев во флакон с нарушенным вакуумом.

4. Незамедлительно доставьте флакон для культивирования, в который произведен посев, в лабораторию для исследований.

ПРОЦЕДУРА ПРОВЕДЕНИЯ ТЕСТА ДЛЯ ФЛАКОНА BacT/ALERT PF PLUS

Предварительные замечания и меры предосторожности

1. Необходимо использовать одноразовые перчатки и обращаться с флаконами, в которые был произведен посев, как с потенциально инфекционными материалами. При попадании контаминированных веществ внутрь или при их контакте с поврежденными участками кожи и слизистых оболочек — следует немедленно обратиться к врачу.
2 Все протечки и контаминированные материалы следует немедленно устранять, используя 5% раствор гипохлорита натрия, разведенный в соотношении 1:10 Использованные для очистки материалы следует утилизировать с соблюдением соответствующих процедур.
3. Все флаконы, в которые был произведен посев, иглы для сбора образцов и системы для взятия крови следует обеззараживать в соответствии с процедурой, используемой в вашем учреждении.[2]
4. Утилизацию этих флаконов должен осуществлять специально обученный медицинский персонал.
5. Только для США: Осторожно! Согласно федеральному закону США, данное изделие допускается к продаже только лицензированным врачам или по их заказу.

Замечания и меры предосторожности при выполнении процедуры

1. Необходимо принять все меры для предотвращения контаминации образца пациента во время венепункции и посева во флакон, поскольку контаминация может привести к получению положительного результата при отсутствии в образце клинически значимого изолята.
2. Взятие крови следует производить до начала антибиотикотерапии. Если это невозможно, взятие крови следует производить непосредственно перед введением очередной дозы препарата.
3. Если флаконы были доставлены в лабораторию не сразу после посева, а с задержкой или были предварительно инкубированы вне анализатора BacT/ALERT, осмотрите флаконы на предмет наличия признаков микробного роста. При наличии явных признаков микробного роста не помещайте флаконы в анализатор культур крови BacT/ALERT для проведения мониторинга, а продолжайте работу с ними как с положительными флаконами.

Процедура лабораторного исследования

ОСТОРОЖНО! При высеве материала из положительных флаконов следует соблюдать общие меры предосторожности. При внесении избыточного объема жидкости или наличии микроорганизмов, активно вырабатывающих газы, внутри флакона может быть создано повышенное давление. Положительные флаконы следует подвергать кратковременному вентилированию перед окрашиванием или утилизацией для удаления из них газов, вырабатываемых микроорганизмами.

1. Осмотрите флаконы перед началом работы. Не используйте флаконы при наличии повреждений и протечек. При помутнении среды, пожелтении датчика, наличии гемолиза, признаков избыточного давления газа или других признаков микробного роста флакон следует считать положительным. Возьмите материал для мазка и сделайте высев. Инкубируйте флакон только в том случае, если мазок положительный.
2. После загрузки флаконов в анализатор инкубируйте 5 суток или до получения положительного результата.
3. Мазок и высев следует выполнять для всех положительных флаконов. При отсутствии микроорганизмов в мазке (что может указывать на ложноположительный результат) флакон следует повторно загрузить в анализатор до получения роста на чашке, куда был произведен высев, или до повторной регистрации анализатором роста во флаконе. Из флаконов, результат которых первоначально был определен как ложноположительный и затем был классифицирован как положительный, следует повторно взять мазок и сделать высев.
4. Для проверки отрицательного результата также можно выполнять мазок и/или высев из флакона перед его утилизацией.
5. Процедура загрузки флаконов в анализатор и выгрузки из анализатора BacT/ALERT подробно описана в руководстве по эксплуатации.
6. **Не используйте флаконы BacT/ALERT повторно**. Утилизируйте флаконы BacT/ALERT, в которые произведен посев, в соответствии с правилами вашей лаборатории. Автоклавирование и/или сжигание являются приемлемыми процедурами утилизации таких флаконов BacT/ALERT.[2]
7. Использование средств сверления (например, тупых игл) для прокола пробки может привести к протечке флаконы.

КОНТРОЛЬ КАЧЕСТВА

Сертификат соответствия предоставляется с каждой партией флаконов для культур. При желании отдельные лаборатории могут выполнять дополнительный контроль качества флаконов BacT/ALERT PF Plus. См. соответствующее руководство пользователя анализатора BacT/ALERT и документ CLSI® M22-A3.[6]

Прибор

Комплект стандартов отражательной способности BacT/ALERT поставляется с каждым анализатором культур крови микобактерий автоматическим бактериологическим семейством BacT/ALERT 3D с принадлежностями (по тексту анализатор BacT/ALERT 3D, система обнаружения микроорганизмов BacT/ALERT 3D, система BacT/ALERT 3D). Любые процедуры контроля качества должны быть частью текущего профилактического обслуживания системы. Для получения дополнительной информации см. соответствующее руководство пользователя анализатора BacT/ALERT.

ОСТОРОЖНО! Если поставщик ЛИС вашего лечебного учреждения отправляет идентификационные номера флаконов и сокращенные обозначения типов флаконов в анализатор BacT/ALERT, используйте правильные сокращения типов флаконов во избежание возможного получения ложноположительных или ложноотрицательных результатов. Для получения более подробной информации свяжитесь с представителем компании bioMérieux.

РЕЗУЛЬТАТЫ

Положительный или отрицательный результат определяется программным обеспечением для принятия решений, которое является частью анализаторов культур крови BacT/ALERT. До получения положительного или отрицательного сигнала от анализатора BacT/ALERT никаких действий выполнять не требуется.

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ОГРАНИЧЕНИЯ МЕТОДА

На результат посева крови влияет множество факторов, которые практически не поддаются контролю, поэтому нельзя с уверенностью утверждать, что результат теста зависит только от правильного или неправильного использования питательной среды или работы системы обнаружения.

1. В образцах пациентов, определяемых анализатором BacT/ALERT как положительные, могут содержаться микроорганизмы, клетки которых видно в мазке, но которые не растут на обычно используемых для высева средах. При подозрении на наличие таких микроорганизмов высев следует выполнять на специальные среды. Кроме того, положительные флаконы BacT/ALERT могут содержать микроорганизмы, клеток которых не видно при обычной окраске мазка и для обнаружения и выделения которых могут требоваться специальные методы окрашивания мазков, а также специальные среды для высева.
2. Некоторые редко встречающиеся прихотливые микроорганизмы могут не расти или расти очень медленно в питательной среде флаконов BacT/ALERT PF Plus. Кроме этого, в редких случаях в образцах могут встречаться микроорганизмы, которые растут в питательной среде флаконов BacT/ALERT PF Plus, но не производят достаточного количества углекислого газа для определения роста. При подозрении на наличие редко встречающихся, прихотливых микроорганизмов, требующих специфических питательных сред и условий культивирования, следует рассмотреть возможность использования альтернативных методов выделения или увеличения времени инкубации.
3. Некоторые штаммы *Haemophilus influenzae, Neisseria meningitidis* и *Neisseria gonorrhoeae* могут быть чувствительны к антикоагулянту полианетолсульфонату натрия (SPS), что может привести к слабому росту или слабому выделению углекислого газа (CO_2) этими штаммами при посеве во флаконы недостаточного объема образца.
4. Иногда, при наличии в образце большого количества лейкоцитов, анализатор BacT/ALERT может определить результат как положительный. В этом случае результаты мазка и высева могут быть отрицательными.
5. Часто количество микроорганизмов незначительное, и они могут появляться в кровотоке периодически, поэтому необходимо последовательно выполнять взятие нескольких образцов крови каждого пациента.
6. При получении положительного сигнала от анализатора BacT/ALERT следует немедленно извлечь флакон из анализатора. Это позволит избежать ложноотрицательных результатов из-за аутолиза или по другим причинам. В частности, если флакон не извлекается из анализатора немедленно после получения положительного сигнала, для некоторых штаммов *Streptococcus pneumoniae* характерен аутолиз.
7. В окрашенном по Граму мазке из отрицательного флакона могут в небольших количествах встречаться нежизнеспособные клетки микроорганизмов, попавшие в мазок из компонентов питательной среды, реагентов для окраски, иммерсионного масла или с предметных стекол, что может привести к ложноположительному результату.
8. Компания bioMérieux рекомендует загружать флаконы для культивирования в анализаторы BacT/ALERT как можно скорее после взятия образца. Если неизбежна задержка доставки флаконов в лабораторию, следует принимать во внимание информацию по исследованиям образцов с отсроченной загрузкой, в разделе «Рабочие характеристики теста».
9. Нейтрализации цефтазидима и цефепима достичь не удалось.

ОЖИДАЕМЫЕ РЕЗУЛЬТАТЫ

1. Доля положительных посевов составляла 6,3 % (в диапазоне: 4,9 %–8,1 %) в целом, и 4,1 % (в диапазоне: 2,5 %–6,4 %) для значимых изолятов в трех центрах проведения клинических исследований флаконов BacT/ALERT PF Plus с 0,1–4 мл крови с использованием анализатора BacT/ALERT 3D.
2. Ожидаемая доля положительных результатов будет зависеть от таких факторов, как количество пациентов, распространенность значимых микроорганизмов, географическое расположение места проведения теста и уровень контаминации. Приведенные значения ожидаемых результатов основаны на данных, полученных в ходе нескольких клинических исследований.

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НЕЙТРАЛИЗАЦИЯ ПРОТИВОМИКРОБНЫХ ПРЕПАРАТОВ

Нейтрализация противомикробных препаратов с помощью адсорбирующих полимерных гранул различается в зависимости от уровня дозировки и времени взятия образца. Внутренние исследования, проведенные на системе обнаружения микроорганизмов BacT/ALERT 3D, показали, что противомикробные препараты эффективно нейтрализуются средой BacT/ALERT PF Plus на основании 100 % выделения тестируемых микроорганизмов. В этих исследованиях противомикробные препараты добавлялись в клинически значимых концентрациях непосредственно во флаконы для культур во время посева с чувствительными штаммами. Эффективность противомикробных препаратов была подтверждена параллельным тестированием с использованием среды без нейтрализующих свойств в качестве контрольного элемента. В среде были нейтрализованы противомикробные препараты, следующих групп: пенициллины, глицилциклины, полиены, макролиды, триазолы, эхинокандины, цефазолин, цефокситин, цефтаролин, аминогликозиды, фторхинолоны, линкозамиды, гликопептиды и оксазолидиноны.

Нейтрализации цефтазидима и цефепима достичь не удалось. Цефотаксим и цефтриаксон нейтрализовались не полностью. Цефотаксим нейтрализовался при концентрациях, составляющих от 2 до 50 % от его максимальной концентрации в сыворотке крови (PSL), в зависимости от микроорганизма. Цефтриаксон нейтрализовался при концентрациях, составляющих от 1 до 50 % от PSL, в зависимости от микроорганизма.

Свойства нейтрализации противомикробных препаратов зависят от состава материала флакона и не определяются алгоритмом анализа системы обнаружения микроорганизмов BacT/ALERT. Нейтрализация была продемонстрирована для амикацина (класс аминогликозидов), пиперациллина (класс пенициллинов), ванкомицина (класс гликопептидов) и вориконазола (класс триазолов). Испытания показали, что система анализатора не оказывала влияния на способность флакона к нейтрализации противомикробных препаратов.

За дополнительной информацией по противомикробным препаратам, которые нейтрализуются во флаконах BacT/ALERT PF Plus, обращайтесь к местному представителю компании bioMérieux.

РАБОЧИЕ ХАРАКТЕРИСТИКИ

Системы обнаружения микроорганизмов BacT/ALERT 3D

Вещества, которые могут помешать проведению теста

Были проведены внутренние исследования с использованием плазмы крови, цельной крови и кровяных сгустков. К аликвотам каждой из этих жидкостей были также добавлены лейкоциты в концентрациях, обычно наблюдаемых в крови при бактериемии. Тест проводился в присутствии микроорганизмов или в их отсутствие. Данные вещества не мешали выделению и обнаружению микроорганизмов и не давали ложноположительных результатов в отсутствие микроорганизмов.

Аналитическая чувствительность: Предел обнаружения (LoD)

В таблице 1 представлены результаты внутренних исследований посевов. Для каждого вида тестирование было выполнено не менее чем в 30 повторностях. На пределе обнаружения микроорганизмы были обнаружены не менее чем в 95 % случаев. Данные в таблице 1 получены при использовании флаконов в конце срока годности. Во флаконы, засеянные *H. influenzae*, добавляли по 4 мл смешанной крови человека.

Таблица 1. Аналитическая чувствительность: Предел обнаружения (LoD)

Микроорганизм	Идентификационный номер штамма	Предел обнаружения (LoD) (КОЕ/флакон)
Candida albicans	ATCC® 14053™	6
Enterobacter aerogenes	ATCC® 13048™	8
Enterococcus faecalis	NCTC 12697	5
Escherichia coli	NCTC 12923	4
Haemophilus influenzae	ATCC® 10211™	6
Klebsiella pneumoniae	STL 104016	4
Listeria monocytogenes	ATCC® 15313™	6
Pseudomonas aeruginosa	NCTC 12924	4
Salmonella enterica	ATCC® 14028™	5
Staphylococcus aureus	NCTC 10788	5
Streptococcus pneumoniae	ATCC® 6305™	6

ПРИМЕЧАНИЕ: В 96,7 % случаев высев материала из флаконов, признанных положительными, был произведен не позднее, чем через 30 минут.
Штамм STL 104016 был получен из внутренней коллекции культур микроорганизмов компании bioMérieux.

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Аналитическая чувствительность: Показатели роста

В таблице 2 представлены результаты внутренних исследований посевов с использованием крови здоровых людей-добровольцев. Было проверено несколько штаммов каждого вида при целевой концентрации посевного материала 125 КОЕ/флакон. Фактическая концентрация микроорганизмов составила 3–298 КОЕ/флакон. В данном исследовании высев материала из флаконов BacT/ALERT PF Plus проводился как минимум через 24 ч после того, как система зарегистрировала рост во флаконах. Перечисленные виды микроорганизмов являются представителями клинически распространенных микроорганизмов, обычно выделяемых при посевах крови.

Таблица 2. Аналитическая чувствительность: Показатели роста

Микроорганизм	Кровь			
	% выделения (кол-во)	Уровень посевного материала, КОЕ/флакон (диапазон)	Продолжительность культивирования до определения статуса флакона (часы)	
			Среднее	Диапазон
Staphylococcus aureus	100,0 (30/30)	54-150	13,3	12,2–15,2
Escherichia coli	100,0 (30/30)	71–254	11,2	10,3–11,7
Pseudomonas aeruginosa	100,0 (12/12)	74–148	15,7	13,7–17,8
Klebsiella pneumoniae	100,0 (12/12)	89–123	11,3	10,6–12,3
Candida albicans	100,0 (30/30)	88–298	29,0	19,2–52,8
Streptococcus pneumoniae	100,0 (30/30)	3–260	13,8	10,8–16,5
Staphylococcus epidermidis	100,0 (12/12)	44–135	17,6	14,3–18,8
Enterococcus faecalis	100,0 (12/12)	63–259	11,6	11,0–12,2
Enterococcus faecium	100,0 (12/12)	25–120	12,8	11,3–14,4
Enterobacter cloacae	100,0 (12/12)	111–200	11,6	10,8–12,5
Candida glabrata	100,0 (12/12)	118–281	43,5	27,3–64,8
Haemophilus influenzae	100,0 (12/12)	105–266	14,4	12,0–16,8
Proteus mirabilis	100,0 (12/12)	36–213	12,5	11,3–14,6

Для некоторых видов микроорганизмов, включая *Capnocytophaga ochracea*, *Cardiobacterium hominis*, *Eikenella corrodens, Haemophilus parainfluenzae, Granulicatella adiacens u Helicobacter cinaedi*, положительный сигнал был получен в менее, чем 100 % случаев.

Результаты клинических исследований (посевы крови)

Ниже приводятся результаты сравнения посевов крови с использованием флаконов BacT/ALERT PF Plus и BacT/ALERT PF (для всех соответствующих пар).

В трех разных центрах в США было проведено многоцентровое клиническое исследование, в котором сравнивали характеристики флаконов для посева крови BacT/ALERT PF Plus и BacT/ALERT PF при культивировании образцов крови детей объемом от 0,1 до 4 мл (соответствующие пары). Всего было получено 2188 пар флаконов от 1086 детей с подозрением на бактериальные или дрожжевые инфекции крови. Если хотя бы для одного флакона в паре анализатор BacT/ALERT регистрировал положительный результат, производился высев материала из обоих флаконов. Считалось, что пара флаконов дала положительный результат, если результаты высева материала либо из флакона BacT/ALERT PF Plus, либо из флакона BacT/ALERT PF были положительными. Результат считался истинно положительным, если анализатором BacT/ALERT был зарегистрирован рост во флаконе и при высеве материала из этого флакона был получен рост микроорганизма. Была определена доля истинно положительных результатов для флаконов BacT/ALERT PF Plus и для флаконов BacT/ALERT PF, для сравнения их характеристик было подсчитано соотношение количества истинно положительных результатов для обоих типов флаконов. Выделенные клинические изоляты относили к группе значимых, контаминантов или неизвестных по усмотрению центров, где проводилось исследование.

В общей сложности из всех соответствующих пар посевов крови детей, давших положительный результат, было выделено 172 изолята. При высеве материала из флаконов BacT/ALERT PF Plus или BacT/ALERT PF в 145 парах флаконов был выделен по крайней мере один изолят. Из 126 пар флаконов был выделен один изолят, из 12 пар — два изолята, из 6 пар — три изолята и из 1 пары — четыре изолята. Общая выборка результатов, приведенных в таблицах 3, 4 и 5, включает 172 изолята, выделенных из пар флаконов, давших положительный результат, и 2043 пар флаконов, давших отрицательный результат (всего 2215 результатов теста). При использовании флаконов BacT/ALERT PF Plus было выявлено в общей сложности 140 изолятов, а при использовании флаконов BacT/ALERT PF — 128 изолятов. Что касается значимых изолятов, при использовании флаконов BacT/ALERT PF Plus был выявлен всего 91 изолят, а при использовании флаконов BacT/ALERT PF — 77 изолятов. При высеве материала из флаконов BacT/ALERT PF Plus, давших положительный результат, был получен один ложноположительный результат, что составляет 0,05 % (1/2215) от всей исследованной популяции.

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В нижеследующих таблицах сравниваются результаты, полученные для всех соответствующих флаконов для культивирования крови BacT/ALERT PF Plus и BacT/ALERT PF, которые при высеве дали любое количество изолятов (Таблица 3), единственный изолят (Таблица 4) или несколько изолятов (Таблица 5).

Таблица 3. Все соответствующие пары, давшие один или несколько изолятов (посевы крови)

Определение клинических изолятов	Флаконы BacT/ALERT PF Plus, истинно положительные результаты	% истинно положительных результатов в популяции, флаконы BacT/ALERT PF Plus	Флаконы BacT/ALERT PF, истинно положительные результаты	% истинно положительных результатов в популяции, флаконы BacT/ALERT PF	Соотношение количества истинно положительных результатов*
Значимые	91	4,1 (91/2215)	77	3,5 (77/2215)	1,182
Контаминанты	24	1,1 (24/2215)	29	1,3 (29/2215)	0,828
Неизвестные	25	1,1 (25/2215)	22	1,0 (22/2215)	1,136
Всего	140	6,3 (140/2215)	128	5,8 (128/2215)	1,094

* 96 (девяносто шесть) изолятов было выявлено при использовании как флаконов BacT/ALERT PF Plus, так и флаконов BacT/ALERT PF; 44 изолята — только при использовании флаконов BacT/ALERT PF Plus и 32 изолята — только при использовании флаконов BacT/ALERT PF. Соотношение количества истинно положительных результатов по всем изолятам составило 1,094 (140/128) с 95 %-ным ДИ (0,954; 1,234).[7]

Таблица 4. Все соответствующие пары, давшие единственный изолят (посевы крови)

Клиническое определение	Флаконы BacT/ALERT PF Plus, истинно положительные результаты	Флаконы BacT/ALERT PF, истинно положительные результаты	Соотношение количества истинно положительных результатов*
Значимые	69	61	1,131
Контаминанты	17	17	1,000
Неизвестные	19	16	1,188
Всего	105	94	1,117

***** 73 (семьдесят три) изолята было выявлено при использовании как флаконов BacT/ALERT PF Plus, так и флаконов BacT/ALERT PF; 32 изолята — только при использовании флаконов BacT/ALERT PF Plus и 21 изолят — только при использовании флаконов BacT/ALERT PF. Соотношение количества истинно положительных результатов по единственным изолятам составило 1,117 (105/94) с 95 %-ным ДИ (0,957; 1,277).[7]

Таблица 5. Все соответствующие пары, давшие несколько изолятов (посевы крови)

Клиническое определение	Флаконы BacT/ALERT PF Plus, истинно положительные результаты	Флаконы BacT/ALERT PF, истинно положительные результаты	Соотношение количества истинно положительных результатов*
Значимые	22	16	1,375
Контаминанты	7	12	0,583
Неизвестные	6	6	1,000
Всего	35	34	1,029

* 23 (двадцать три) изолята было выявлено при использовании как флаконов BacT/ALERT PF Plus, так и флаконов BacT/ALERT PF; 12 изолятов — только при использовании флаконов BacT/ALERT PF Plus и 11 изолятов — только при использовании флаконов BacT/ALERT PF. Соотношение количества истинно положительных результатов по множественным изолятам составило 1,029 (35/34) с 95 % ДИ (0,748; 1,310).[7]

В данном клиническом исследовании для 2041 пары флаконов BacT/ALERT PF Plus и BacT/ALERT PF после 5 дней инкубации были получены отрицательные результаты теста для обоих типов флаконов. Для трех из этих пар был проведен высев материала из обоих флаконов, и не было получено ни одного ложноотрицательного результата для обоих типов флаконов; высев материала только из флаконов BacT/ALERT PF Plus был проведен для 2034 пар, и выявлен один ложноотрицательный результат; для четырех пар флаконов высевы не проводились. Результаты представлены в таблице 6.

Таблица 6. Количество ложноотрицательных результатов по соответствующим парам аэробных посевов крови, которые были отмечены системой в ходе теста как отрицательные для обоих посевов

Высев из флаконов BacT/ALERT PF Plus	Высев из флаконов BacT/ALERT PF	% ложноотрицательных результатов для Флакон BacT/ALERT PF Plus	% ложноотрицательных результатов для Флакон BacT/ALERT PF
Да	Да	0,00 (0/3)	0,00 (0/3)
Да	Нет	0,05 (1/2034)	-

Общая частота ложноотрицательных результатов для флаконов BacT/ALERT PF Plus на основании высевов материала составила 0,05 % (1/2037).

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Сравнение количества микроорганизмов (число изолятов), выделенных при высеве материала из флаконов BacT/ALERT PF Plus и BacT/ALERT PF, представлено в таблице 7.

Таблица 7. Сравнение количества микроорганизмов из флаконов BacT/ALERT PF Plus и BacT/ALERT PF

Группа микроорганизмов	Педиатрическая подгруппа	Флаконы BacT/ALERT PF Plus	Диапазон заполнения флаконов BacT/ALERT PF Plus (мл)	Флаконы BacT/ALERT PF	Диапазон заполнения BacT/ALERT PF (мл)
Enterobacteriaceae	Новорожденный (< 1 мес.)	6	0,1–1,4	7	0,1–1,6
	Ребенок младшего возраста (> 1 мес.–2 года)	19	0,1–3,7	13	0,1–3,1
	Ребенок (> 2–12 лет)	9	0,6–3,9	7	0,3–3,2
	Подросток (> 12 лет–21 год)	0	1,4	1	1,6
Прихотливые микроорганизмы (*Neisseria meningitidis, Neisseria sicca*)	Новорожденный (< 1 мес.)	0	-	0	-
	Ребенок младшего возраста (> 1 мес.–2 года)	1	0,2	1	0,5
	Ребенок (> 2–12 лет)	0	-	0	-
	Подросток (> 12 лет–21 год)	1	1,1	1	0,6
Дрожжевые грибы (*Candida albicans, C. guilliermondii, C. krusei, C. lusitaniae*)	Новорожденный (< 1 мес.)	0	-	0	-
	Ребенок младшего возраста (> 1 мес.–2 года)	0	0,5	1	0,9
	Ребенок (> 2–12 лет)	5	0,9–3,7	6	1,0–3,4
	Подросток (> 12 лет–21 год)	1	0,2–3,0	2	2,1–2,5
Неферментирующие грамотрицательные бациллы	Новорожденный (< 1 мес.)	0	-	0	-
	Ребенок младшего возраста (> 1 мес.–2 года)	5	1,7–3,5	6	1,5–2,5
	Ребенок (> 2–12 лет)	2	0,9–2,2	3	1,0–2,8
	Подросток (> 12 лет–21 год)	0	-	0	-
Коагулазоотрицательный *Staphylococcus*	Новорожденный (< 1 мес.)	5	0,1–0,5	5	0,1–0,9
	Ребенок младшего возраста (> 1 мес.–2 года)	12	0,1–3,0	10	0,1–3,4
	Ребенок (> 2–12 лет)	15	0,1–3,8	12	0,5–3,6
	Подросток (> 12 лет–21 год)	6	0,5–3,5	7	0,5–3,2
Staphylococcus aureus	Новорожденный (< 1 мес.)	0	0,3	1	0,1
	Ребенок младшего возраста (> 1 мес.–2 года)	5	0,5–1,5	5	0,6–1,6
	Ребенок (> 2–12 лет)	7	0,8–4,0	3	0,1–3,6
	Подросток (> 12 лет–21 год)	2	1,5–1,7	2	1,3–1,4
Enterococcus spp.	Новорожденный (< 1 мес.)	1	0,1	1	0,1
	Ребенок младшего возраста (> 1 мес.–2 года)	9	0,2–2,9	10	0,1–3,2
	Ребенок (> 2–12 лет)	2	0,2–1,0	1	0,8–1,8
	Подросток (> 12 лет–21 год)	8	1,5–3,1	7	1,9–2,9
Streptococcus pneumoniae	Новорожденный (< 1 мес.)	0	-	0	-
	Ребенок младшего возраста (> 1 мес.–2 года)	2	1,0–2,7	1	1,1–1,6
	Ребенок (> 2–12 лет)	0	-	0	-
	Подросток (> 12 лет–21 год)	0	-	0	-
Streptococcus spp., группы A, B	Новорожденный (< 1 мес.)	0	-	0	-
	Ребенок младшего возраста (> 1 мес.–2 года)	1	0,5	0	1,0
	Ребенок (> 2–12 лет)	0	-	0	-
	Подросток (> 12 лет–21 год)	0	-	0	-
Другие *Streptococcus* spp.	Новорожденный (< 1 мес.)	0	-	0	-

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	Ребенок младшего возраста (> 1 мес.–2 года)	4	0,1–1,6	5	0,1–1,5
	Ребенок (> 2–12 лет)	3	0,7–2,3	2	0,6–2,6
	Подросток (> 12 лет–21 год)	1	0,7–2,4	2	1,1–2,4
Другие грамотрицательные бактерии*	Новорожденный (< 1 мес.)	0	-	0	-
	Ребенок младшего возраста (> 1 мес.–2 года)	1	0,6	0	0,4
	Ребенок (> 2–12 лет)	0	-	0	-
	Подросток (> 12 лет–21 год)	0	-	0	-
Другие грамположительные бактерии†	Новорожденный (< 1 мес.)	1	0,1–0,7	2	0,1–0,4
	Ребенок младшего возраста (> 1 мес.–2 года)	3	0,5–3,0	2	0,9–2,3
	Ребенок (> 2–12 лет)	3	0,1–3,4	1	0,1–3,2
	Подросток (> 12 лет–21 год)	0	3,3	1	3,2

* Другие грамотрицательные бактерии, выделенные в этом клиническом исследовании: Неидентифицированные грамотрицательные палочки (1)

† Другие грамположительные микроорганизмы, выделенные в этом клиническом исследовании: *Bacillus* spp. (6), *Corynebacterium* spp. (2), Diphtheroids (1), *Micrococcus* spp. (2), *Stomatococcus* spp. (1).

В клинических исследованиях микроорганизмы были выделены из образцов крови объемом более 0,1 мл. Среди них:

- ≥ 1,0 мл для *Streptococcus pneumoniae*
- неферментирующие грамотрицательные палочки из образцов объемом ≥ 0,9 мл; неидентифицированные грамотрицательные палочки из образцов объемом ≥ 0,6 мл
- *Streptococcus* spp. групп A и B из образцов объемом ≥ 0,5 мл
- *S. aureus* из образцов объемом ≥ 0,3 мл
- прихотливые микроорганизмы (*N. meningitidis* и *N. sicca*) из образцов объемом ≥ 0,2 мл
- дрожжевые грибы (*Candida albicans, C. guilliermondii, C. krusei* и *C. lusitaniae*) из образцов объемом ≥ 0,2 мл

Контроль качества в ходе клинического исследования проводился по всем 13 микроорганизмам (*Candida albicans, Candida krusei, Enterococcus faecalis, Escherichia coli, Haemophilus influenzae, Neisseria meningitidis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Stenotrophomonas maltophilia, Streptococcus agalactiae, Streptococcus pneumoniae и Streptococcus pyogenes*), которые были приготовлены путем последовательных разведений и посеяны во флаконы BacT/ALERT FA Plus в концентрации 100 КОЕ/флакон с приемлемым диапазоном 30–300 КОЕ/флакон. Общие результаты контроля качества были расценены как удовлетворительные. Случаи, когда результаты контроля качества были неприемлемыми, связаны с техническими ошибками (например, слишком малое или слишком большое число колоний, не был изменен статус флакона после положительного сигнала от системы и положительного результата высева, не внесена добавка). Повторные тесты давали приемлемые результаты.

Отсроченная загрузка

В таблице 8 представлены результаты исследований посевов 11 видов микроорганизмов (*Staphylococcus aureus, Candida albicans, Candida krusei, Escherichia coli, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa, Streptococcus pneumoniae, Enterococcus faecium, Haemophilus influenzae* и *Neisseria meningitidis)* в концентрации 100 КОЕ/флакон (при допустимом диапазоне 30–300 КОЕ/флакон), выполненных в трех центрах. Фактическое количество микроорганизмов составило 35–290 КОЕ/флакон. Однако в одном случае концентрация посевного материала превысила >300 КОЕ/флакон (эти данные исключены из заключительного анализа данных). Флаконы были исследованы с кровью человека от здоровых добровольцев и хранились в заданных температурах и в течении заданного времени перед загрузкой в анализатор BacT/ALERT 3D. Доля выделения отражает флаконы, которые анализатор пометил как положительные, и из которых при высеве были получены колонии с морфологией, соответствующей посеянному микроорганизму.

Таблица 8. Отсроченная загрузка

Вводимый образец	**Температура инкубации (°C)**	**Время хранения (часы)**	**% выделения**	**Продолжительность культивирования до определения статуса флакона с момента посева (время хранения + продолжительность культивирования до определения статуса флаконаанализатором в часах)**		**Диапазон концентрацийпосевного материала (КОЕ/флакон)**
				Среднее	**Диапазон**	
Тестовые флаконы, в которые произведен посев	Контроль	Без задержки	100,0 (459/459)	14,3	8,5–84,0	35–288
	2–8	48	98,6 (292/296)	63,7	57,5–103,2	48–288
	20–25	24	98,0 (291/297)	31,8	26,2–74,4	50–288
	20–25	36	91,9 (272/296)	41,8	38,0–70,5	50–290
	35–37	8	98,9 (454/459)	16,1	10,2–53,8	35–288
	35–37	24	56,6 (259/458)*	28,3	26,0–74,4	35–288
Отрицательные контроли	Все условия		0,5 (1/221)†	-	-	-

* **ВНИМАНИЕ**: **Флаконы для культивирования, хранившиеся при 35–37 °C в течение 24 ч или дольше перед загрузкой в анализатор, могут не давать положительного сигнала и требуют высева.**

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† В этом исследовании был получен один ложноположительный результат. Отрицательный результат был подтвержден при окраске мазка по Граму и высеве.

Прецизионность в условиях одной лаборатории (повторяемость)

Данные в таблице 9 представляют результаты внутренних исследований посевов, которые проводились в течение 12 дней несколькими операторами с использованием нескольких анализаторов. Микроорганизмы выращивались при добавлении клинически значимых концентраций противомикробных препаратов, к которым они чувствительны. В данном исследовании высев материала из флаконов BacT/ALERT PF Plus проводился как минимум через 24 ч после того, как система зарегистрировала рост в флаконе. Для каждого сочетания микроорганизма и противомикробного препарата тестирование было выполнено не менее чем в 108 повторностях.

Таблица 9. Прецизионность в условиях одной лаборатории (повторяемость)

Вводимый образец		Диапазон (КОЕ/флакон)	% выделения				Продолжительность культивирования до определения статуса флакона (часы)	
Микроорганизм	Противомикробный препарат		Партия 1	Партия 2	Партия 3	Всего	Среднее	Диапазон
C. albicans	Флюконазол	140–364	100,0	100,0	100,0	100,0	26,0	22,8–31,3
E. coli	Амикацин	26–156	100,0	100,0	100,0	100,0	12,0	11,2–13,0
K. pneumoniae	Левофлоксацин	108–170	100,0	100,0	100,0	100,0	13,4	11,7–15,2
P. aeruginosa	Пиперациллин	80–148	100,0	97,2	100,0	99,1	19,2	17,4–24,1
S. pneumoniae	Пенициллин G	9–505	100,0	100,0	100,0	100,0	13,2	11,6–15,5
S. aureus	Ванкомицин	94–158	100,0	100,0	100,0	100,0	16,9	14,6–20,3

Воспроизводимость

В таблице 10 представлены результаты исследований посевов, проведенных в трех центрах. В каждом центре тестирование было выполнено в 162 повторностях в течение 3 дней с участием не менее двух операторов на один центр. Воспроизводимость оценивалась для каждого из девяти микроорганизмов. Для двух микроорганизмов (*C. albicans* и *S. pneumoniae*) культуры готовили путем последовательных разведений, для остальных семи — с использованием продукции BioBall®. *C. albicans* и *S. pneumoniae* были посеяны в флаконы BacT/ALERT PF Plus в количестве 100 КОЕ/флакон с приемлемым диапазоном 30–300 КОЕ/флакон, а остальные семь микроорганизмов — в количестве 1–17 КОЕ/флакон. Фактическое количество микроорганизмов составило 6–700 КОЕ/флакон для диапазона 30–300 КОЕ/флакон и 1–270 КОЕ/флакон для диапазона 1–17 КОЕ/флакон. Доля выделения отражает положительный результат теста, отмеченный системой, и результаты окрашивания по Граму/высева, подтверждающие наличие микроорганизма.

Таблица 10. Воспроизводимость

Вводимый образец	% выделения				Продолжительность культивирования до определения статуса флакона (часы)		Диапазон концентраций посевного материала (КОЕ/флакон)
	Центр 1	Центр 2	Центр 3	Всего	Среднее	Диапазон	
S. aureus	100,0 % (18/18)	87,5 % (21/24)	100,0 % (30/30)	95,8 % (69/72)	15,6	14,6–16,7	2-11
C. albicans	100,0 % (18/18)	83,3 % (30/36)	100,0 % (33/33)	93,1 % (81/87)	36,6	24,6–76,8	14–700
E. coli	100,0 % (27/27)	77,8 % (21/27)	100,0 % (30/30)	92,9 % (78/84)	12,8	11,8–14,1	1–38
P. aeruginosa	100,0 % (24/24)	75,0 % (18/24)	97,0 % (32/33)	91,4 % (74/81)	18,4	17,1–21,1	1–11
E. faecalis	100,0 % (18/18)	79,2 % (19/24)	96,7 % (29/30)	91,7 % (66/72)	13,9	12,6–15,3	1–15
E. aerogenes	74,4 % (29/39)	72,2 % (26/36)	85,4 % (41/48)	78,1 % (96/123)	14,9	11,7–20,8	<1–270*
L. monocytogenes	100,0 % (18/18)	100,0 % (24/24)	100,0 % (30/30)	100,0 % (72/72)	24,1	20,4–36,4	1–14
S. enterica	100,0 % (24/24)	75,0 % (18/24)	100,0 % (33/33)	92,6 % (75/81)	13,5	2,3–14,8	1-13
S. pneumoniae	100,0 % (30/30)	100,0 % (36/36)	100,0 % (21/21)	100,0 % (87/87)	14,2	11,6–18,9	6–500
Всего	95,4 % (206/216) 95% ДИ: 91,7 %; 97,8 %	83,5 % (213/255) 95% ДИ: 78,4 %; 87,9 %	96,9 % (279/288) 95% ДИ: 94,2 %; 98,6 %	92,0 % (698/759) 95% ДИ: 89,8 %; 93,8 %	-		

* Подсчет количества микроорганизмов на чашках при концентрации посевного материала 270 КОЕ/флакон проводили с использованием последовательных разведений.

Эти данные включают повторные тесты, выполнявшиеся вследствие технических ошибок в отдельно взятом центре (например, контаминация при высеве). Данные, из которых исключены лабораторные ошибки, демонстрируют 100-процентное выделение, за исключением *E. aerogenes* — частота выделения этого микроорганизма (суммарная для всех центров) составила 85 %.

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СПРАВОЧНАЯ ЛИТЕРАТУРА

1. Thorpe TC, Wilson ML, Turner JE, DiGuiseppi JL, Willert M, Mirrett S, et al: BacT/ALERT: an Automated Colorimetric Microbial Detection System. *J Clin Micro* 1990;28(7), 1608-1612.
2. *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* 5th Edition. U.S. Department of Health and Human Services Centers for Disease Control and Prevention and National Institutes of Health. Fifth Edition. US Government Printing Office. Washington: Feb 2007.
3. Koneman EW, Allen SD, Janda WM, Schreckenberger PC, Winn WC. *Color Atlas and Textbook of Diagnostic Microbiology*, 6th ed. 2006, pp. 446,590.
4. Baron EJ, Weinstein MP, Dunne Jr. WM, Yagupsky P, Welch DF, Wilson DM. 2005. Cumitech 1C, Blood Cultures IV. Coordinating ed. Baron EJ. ASM Press, Washington, DC.
5. CLSI. *Principles and Procedures for Blood Cultures; Approved Guideline*. CLSI document M47-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2007.
6. CLSI. *Quality Control for Commercially Prepared Microbiological Culture Media*; Approved Standard—Third Edition. CLSI/NCCLS document M22-A3. Wayne, PA: NCCLS; 2004.
7. Kondratovich M. Comparing Two Medical Tests When Results of Reference Standard Are Unavailable for Those Negative via Both Tests. *J. Biopharm Stat* 2008;18:1,145-166.

ОГРАНИЧЕННАЯ ГАРАНТИЯ

Компания bioMérieux гарантирует, что рабочие характеристики данного изделия соответствуют указанному предусмотренному назначению в течение всего срока эксплуатации при условии, что строго соблюдены все процедуры по использованию, хранению и обработке и меры безопасности, как подробно изложено в инструкциях по эксплуатации.

За исключением вышеуказанных случаев, компания bioMérieux не дает никаких гарантий, в том числе, подразумеваемых гарантий товарного качества и гарантий соответствия предполагаемому использованию, и не дает никаких обязательств, в том числе, явно выраженных, подразумеваемых или косвенных, в отношении использования какого-либо реагента, программного обеспечения, прибора и расходных материалов (далее — «Система»), отличного от указанного в инструкциях по эксплуатации.

ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ

bioMérieux

BacT/ALERT PF Plus – Флаконы педиатрические
BacT/ALERT PF Plus со средой и адсорбентом для выделения микроорганизмов из крови и стерильных биологических жидкостей

100 шт./уп. REF 410853

Для получения технической поддержки в США обращайтесь в Отдел по работе с клиентами компании bioMérieux по телефону 1-800-682-2666. За пределами США свяжитесь с местным представителем компании bioMérieux.

ТАБЛИЦА СИМВОЛОВ И ОБОЗНАЧЕНИЙ

Символ	Обозначение
REF	Номер по каталогу
	Изготовитель
	Дата изготовления
	Температурный диапазон
	Использовать до
LOT	Код партии
	Обратитесь к инструкции по применению
Σ	Содержимого достаточно для проведения n-количества тестов
EC REP	Уполномоченный представитель в Европейском сообществе
	Верх
IVD	Медицинское изделие для диагностики in vitro
	Запрет на повторное применение
LATEX	Без латекса
℞ only	Только для США: Внимание: Согласно федеральному закону США, данное изделие допускается к продаже только лицензированным врачам или по их заказу.

Инструкция прилагается к набору или ее можно загрузить с сайта www.biomerieux.com/techlib.

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ИСТОРИЯ ПЕРЕСМОТРОВ

В этом разделе содержится обзор изменений, внесенных в инструкцию по применению флаконов BacT/ALERT PF Plus.

Дата выпуска	Номер версии	Тип изменений	Обзор изменений
2016-04	056200-01/ 9309505 D	Изменение содержания:	**Реагенты** - Обновление информации о составе - Разъяснение по дате истечения срока годности
			В раздел **«Взятие и подготовка образцов»** добавлено предупреждение относительно высокого давления во флаконе
			В раздел **«Контроль качества»** добавлено предупреждение относительно ЛИС и сокращенных обозначений типов флаконов
			Добавлено предупреждение Rx-only для пользователей в США
		Административные изменения:	В раздел **«Ограниченная гарантия»** добавлено положение
			Раздел **«Таблица символов и обозначений»** обновлен с целью внесения новых символов для продукта
2013-04	9305130 C	Изменение содержания:	В разделах **«Назначение», «Взятие и подготовка образцов», «Ожидаемые результаты», «Нейтрализация противомикробных препаратов», «Рабочие характеристики»**, где пересмотренный текст включает дополнительную информацию по характеристикам продукта, основанную на данных клинических исследований
			В раздел **«Ограничения метода»** после оценки FDA добавлены пункты 2, 8 и 9
		Административные изменения:	Из раздела **«Реагенты»** текст о предупреждениях перенесен в раздел «Ограничения метода»

ПРИМЕЧАНИЕ: Незначительные типографские, грамматические изменения и изменения в форматировании в историю пересмотров не включены.

Категории типов изменений:

- **Корректура** = исправление ошибок в документации.
- **Изменение содержания** = внесение новых и измененных (обновленных) данных по назначению и рабочим характеристикам продукта.
- **Административные изменения** = введение изменений нетехнического характера, заслуживающих внимания пользователя.

Для получения технической консультации и поддержки просьба обращаться к уполномоченному
представителю производителя на территории Российской Федерации:
ООО «биоМерье Рус»
Адрес: Россия, 115230, Москва, 1-ый Нагатинский проезд, д. 10, стр. 1
Тел./факс: +7 (495) 221 10 79
Телефон горячей линии: 8 (800) 250 10 79
e-mail: info.russia@biomerieux.com
веб-сайт: www.biomerieux-russia.com

В случае выявления побочных действий, не указанных в инструкции по применению или руководстве по эксплуатации медицинского изделия, нежелательных реакций при его применении, особенностей взаимодействия медицинских изделий между собой, фактов и обстоятельств, создающих угрозу жизни и здоровью граждан и медицинских работников при применении и эксплуатации медицинских изделий, необходимо направить сообщение, содержащее указанные сведения, в Федеральную службу по надзору в сфере здравоохранения в соответствии с действующим законодательством.

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Этот продукт может быть защищен одним или несколькими патентами; см. http://www.biomerieux-usa.com/patents.

Товарный знак и товарное имя ATCC, а также любые номера по каталогу ATCC – товарные знаки компании American Type Culture Collection.

CLSI является зарегистрированным товарным знаком, принадлежащим Clinical and Laboratory Standards Institute.

Другие названия и товарные знаки принадлежат их законным владельцам.

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BacT/ALERT® SA

IVD

BacT/ALERT SA Aerobic — Флаконы BacT/ALERT SA со средой для выделения аэробных микроорганизмов из крови

НАЗНАЧЕНИЕ

BacT/ALERT SA Aerobic — Флаконы BacT/ALERT SA со средой для выделения аэробных микроорганизмов из крови (по тексту флаконы для культивирования BacT/ALERT SA, флаконы BacT/ALERT SA) используются с анализаторами культур крови и микобактерий автоматическими бактериологическими серии BacT/ALERT (по тексту анализаторы BacT/ALERT) для качественного обнаружения и выделения аэробных микроорганизмов (бактерий и грибов) в крови и других в норме стерильных биологических жидкостях.

КРАТКОЕ ОПИСАНИЕ

Анализаторы BacT/ALERT используются для определения наличия микроорганизмов в образцах крови и других в норме стерильных биологических жидкостей при подозрении на бактериемию или фунгемию. Анализатор BacT/ALERT в сочетании с флаконами для культивирования представляет собой как систему обнаружения микроорганизмов, так и среду с питательными и атмосферными условиями, подходящими для микроорганизмов, которые часто встречаются в крови и других в норме стерильных биологических жидкостях. Флакон BacT/ALERT SA, в который предварительно производится посев образца, помещается в прибор, где осуществляется культивирование и непрерывный мониторинг наличия роста микроорганизмов во флаконе.

ПРИНЦИП ТЕСТА

Анализаторы BacT/ALERT основаны на использовании колориметрического датчика и светоотражения для регистрации наличия и накопления углекислого газа (CO_2) в питательной среде. Если в анализируемом образце присутствуют микроорганизмы, то в процессе роста и утилизации субстратов питательной среды они вырабатывают CO_2. Под действием вырабатываемого микроорганизмами углекислого газа цвет газопроницаемого датчика, встроенного в дно каждого флакона для культивирования, меняется с зелено-голубого на желтый[1]. В результате осветления датчика коэффициент отражения повышается. Мониторинг и регистрация отражения флакона производится прибором каждые 10 минут.

РЕАГЕНТЫ

Для диагностики *in vitro*.

ОСТОРОЖНО! С образцами и флаконами, в которые произведен посев, следует обращаться как с потенциально инфекционными материалами. Все флаконы, в которые был произведен посев, иглы для забора образцов и системы для взятия крови следует обеззараживать в соответствии с процедурой, используемой в вашем учреждении[2].

BacT/ALERT SA (цветовая кодировка: синяя) — флаконы для культивирования BacT/ALERT SA, предназначенные для однократного использования, содержат 40 мл питательной среды и внутренний датчик углекислого газа, который является индикатором микробного роста. Препарат среды состоит из панкреатического гидролизата казеина (1,7 % масса/объем), папаинового гидролизата соевой муки (0,3 % масса/объем), полианетолсульфоната натрия (SPS) (0,035 % масса/объем), пиридоксина гидрохлорида (0,001 % масса/объем), а также других сложных аминокислот и углеводных субстратов в очищенной воде. Во флаконах создана атмосфера CO_2 в кислороде под вакуумом. Состав среды может быть модифицирован для достижения необходимых функциональных характеристик.

ОСТОРОЖНО! Флаконы для культивирования BacT/ALERT изготовлены из поликарбоната. Некоторые дезинфицирующие средства нельзя использовать на поликарбонатных поверхностях, так как они могут вызвать повреждение флаконов. Проверьте, совместимо ли дезинфицирующее средство с поликарбонатом, перед тем как использовать его для дезинфекции поверхностей флаконов для культивирования BacT/ALERT.

ОСТОРОЖНО! Некоторые редко встречающиеся прихотливые микроорганизмы могут не расти или расти очень медленно в питательной среде флаконов для культивирования BacT/ALERT SA. При подозрении на наличие редко встречающихся, прихотливых микроорганизмов, требующих специфических питательных сред и условий культивирования, следует рассмотреть возможность использования альтернативных методов выделения или увеличения времени инкубации.

ОСТОРОЖНО! При культивировании во флаконах BacT/ALERT SA образцов, не являющихся кровью, (в норме стерильных биологических жидкостей) может понадобиться добавление в питательную среду крови или других добавок, например стерильной дефибринированной лошадиной крови (5 % объем/объем), для поддержания роста, особенно для выделения прихотливых микроорганизмов, таких как *Haemophilus influenzae* и *Neisseria gonorrhoeae*[3].

ОСТОРОЖНО! В редких случаях в образцах могут встречаться микроорганизмы, которые растут во флаконах для культивирования BacT/ALERT SA, но не производят достаточного количества углекислого газа для определения роста. Фактором, способствующим возникновению такой ситуации, является наличие в образце активных антибиотиков.

Необходимые дополнительные материалы

- Анализаторы BacT/ALERT
- Система забора крови
- Стерильные иглы для вентилирования и пересева из положительных флаконов
- Одноразовые перчатки
- Подходящий контейнер для биологически опасных отходов для утилизации материалов, которые могут быть загрязнены инфекционными материалами

Материалы, которые можно приобрести в компании bioMérieux

- BacT/ALERT Blood Collection Adapter Cap - Колпачок адаптера для взятия крови во флаконы BacT/ALERT (по тексту колпачок адаптера, колпачок адаптера для взятия крови во флаконы BacT/ALERT)
- Анализаторы BacT/ALERT
- Стерильные иглы для вентилирования и пересева из положительных флаконов

Инструкции по хранению

Флаконы для культивирования BacT/ALERT SA готовы к использованию. Их следует хранить в вертикальном положении в месте, защищенном от прямого солнечного света, при комнатной температуре (15-30 °C). Срок годности флаконов указан на этикетке каждого флакона. Запрещается осуществлять посев во флаконы для культивирования по окончании срока годности. При хранении флаконов при температуре ниже 15 °C возможно образование осадка, который растворяется при нагревании флакона до комнатной температуры. Перед использованием выдержите флакон до достижения комнатной температуры.

Химические или физические признаки нестабильности

Перед использованием флаконы для культивирования BacT/ALERT SA следует осмотреть на наличие признаков порчи или повреждения (обесцвечивание). Флаконы с признаками порчи, повреждения или протекания использовать нельзя. Среда должна быть прозрачной, хотя возможна небольшая опалесценция или следы осадка из-за наличия антикоагулянта — полианетолсульфоната натрия (SPS). Не путайте опалесценцию с помутнением. Не используйте флаконы при помутнении среды, пожелтении датчика или при наличии признаков повышенного давления газа во флаконе, так как все перечисленное свидетельствует о контаминации.

ПРИБОРЫ

Перед использованием прочтите руководство по эксплуатации анализатора BacT/ALERT.

ЗАБОР И ПОДГОТОВКА ОБРАЗЦОВ

ПРИМЕЧАНИЕ. Флаконы для культивирования BacT/ALERT SA должны использоваться специально обученным медицинским персоналом. Правильный забор образца имеет большую важность при работе с культурами крови. Предпочтительным методом для получения образцов крови для посева является венепункция. Рекомендованная процедура забора образцов приведена в документе Cumitech 1C[4].

Регистрация МИ в Росздравнадзоре
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ПРИМЕЧАНИЕ. Во время подготовки флакона и внесения образца пациента необходимо принять меры для предотвращения контаминации. Обязательной мерой для снижения частоты контаминации является надлежащая дезинфекция кожи.

ПРИМЕЧАНИЕ. Кровь можно брать непосредственно в пробирки, содержащие полианетолсульфонат натрия (SPS), хотя это не рекомендуется компанией bioMérieux. Пробирки с другими антикоагулянтами для культур крови использовать нельзя[5].

ПРИМЕЧАНИЕ. Компания bioMérieux рекомендует загружать флаконы для культивирования в анализатор BacT/ALERT как можно скорее после забора образцов. Если флаконы для культивирования невозможно загрузить в анализатор сразу после посева, то до загрузки их следует держать при комнатной температуре.

Подготовка флакона

1. Запишите на флаконе информацию о пациенте. Значки на этикетке флакона (☺, #, ◴) может определять пользователь.
2. Снимите пластиковую защитную пластину с верха пробки флакона для культивирования. Перед посевом продезинфицируйте верхнюю часть флакона для культивирования тампоном, пропитанным спиртом, или аналогичным материалом. Дайте ей высохнуть естественным образом.
3. Очистите выбранное для венепункции место в соответствии с утвержденной в вашем учреждении процедурой.

   Процедура посева при непосредственном заборе крови посредством венепункции

   ПРИМЕЧАНИЕ. При использовании техники непосредственного забора крови из кровотока пациента запрещено делать это из внутрисосудистых устройств и портов для гемодиализа из-за вероятности деформации просвета катетера или заброса содержимого флакона в кровоток пациента.

   ПРИМЕЧАНИЕ. При одновременном посеве во флаконы для культивирования крови BacT/ALERT нескольких типов с использованием системы забора крови с иглой-бабочкой и колпачка-адаптера для непосредственного взятия крови сначала нужно вносить образец во флакон для выделения аэробных микроорганизмов, а затем во флакон для выделения анаэробных микроорганизмов, чтобы кислород, скопившийся в трубке, не попал во флакон для выделения анаэробных микроорганизмов.

   а. Можно использовать меньший объем образца, но выделение можно повысить, если объем образца составляет приблизительно 10 мл[5,6] (рекомендованное значение).
   б. Чтобы избежать посева чрезмерного объема, отслеживайте объем забираемой во флакон крови. Для наполнения флакона приблизительно на 10 мл ориентируйтесь по линии уровня заполнения на этикетке флакона. Или используйте метки объема с шагом 5 мл на этикетке флакона для оценки объема внесенного образца.

   ПРИМЕЧАНИЕ. В ходе всей процедуры тщательно контролируйте процесс непосредственного забора, обеспечивая надлежащий поток и не допуская попадания содержимого флакона в трубку адаптера. Поскольку во флаконе для культивирования содержатся химические добавки, важно следовать указанной ниже пошаговой процедуре, чтобы не допустить возможный обратный поток и последующие нежелательные реакции.

   а. Держите флакон для культивирования ниже руки пациента в вертикальном положении (пробкой кверху).
   б. Возьмите кровь с помощью системы забора крови с иглой-бабочкой и колпачка адаптера для взятия крови во флаконы BacT/ALERT в соответствии с утвержденной в вашем учреждении процедурой и выполните посев непосредственно во флакон для культивирования у кровати пациента. Можно использовать меньший объем образца, но выделение можно повысить, если объем образца составляет приблизительно 10 мл (рекомендованное значение). Чтобы избежать посева чрезмерного объема, отслеживайте объем забираемой во флакон крови с помощью меток с шагом 5 мл, расположенных на этикетке флакона.
   в. Ослабьте жгут, как только кровь начнет поступать во флакон для культивирования или в течение 2 минут после его наложения.
   г. Проследите за тем, чтобы содержимое флакона не касалось пробки или конца иглы во время забора крови.

   В контаминированном флаконе для культивирования может быть создано избыточное давление, и при его непосредственном использовании для забора крови может произойти отток среды в вену пациента. Контаминация флакона для культивирования не всегда легко распознается. Во избежание оттока необходимо тщательно контролировать процесс непосредственного забора крови. Не используйте флаконы при помутнении среды, пожелтении датчика или при наличии признаков повышенного давления газа во флаконе, так как все перечисленное свидетельствует о контаминации.

   Процедура посева при заборе крови с помощью шприца

   ПРИМЕЧАНИЕ. При одновременном посеве во флаконы для культивирования крови BacT/ALERT нескольких типов с использованием шприца сначала следует вносить образец во флакон для выделения анаэробных микроорганизмов, а затем во флакон для выделения аэробных микроорганизмов, чтобы кислород, скопившийся в шприце, не попал во флакон для выделения анаэробных микроорганизмов. Используйте метки объема на этикетке флакона для оценки объема внесенного образца.

   а. Выполните венепункцию и перенос крови во флакон для культивирования BacT/ALERT в соответствии с утвержденной в вашем учреждении процедурой.

   ОСТОРОЖНО! Запрещается вдавливать поршень шприца с усилием при выполнении посева, так как может произойти разбрызгивание образца. При достижении необходимого объема заполнения удалите шприц, так как из-за вакуума автоматически отберется количество, превышающее рекомендуемый максимум. Во избежание нарушения вакуума прокалывайте пробку флакона вертикально. Не выполняйте посев во флакон с нарушенным вакуумом.

4. Незамедлительно доставьте флакон для культивирования, в который произведен посев, в лабораторию для исследований.

ПРОЦЕДУРА ПРОВЕДЕНИЯ ТЕСТА ДЛЯ ФЛАКОНОВ ДЛЯ КУЛЬТИВИРОВАНИЯ BacT/ALERT SA

Предварительные замечания и предостережения

1. Необходимо использовать одноразовые перчатки и обращаться с флаконами, в которые был произведен посев, как с потенциально инфекционными материалами. При попадании контаминированных веществ внутрь организма или при их контакте с открытыми ранами или поврежденными участками кожи следует немедленно обратиться к врачу.
2. Все проливы и утечки контаминированных веществ следует немедленно устранять, используя 5-процентный раствор натрия гипохлорита, разведенный в соотношении 1:10. Использованные для очистки материалы следует утилизировать с соблюдением соответствующих процедур.
3. Все флаконы, в которые был произведен посев, иглы для забора образцов и системы для взятия крови следует обеззараживать в соответствии с процедурой, используемой в вашем учреждении[2].
4. Использовать эти флаконы должен специально обученный персонал лаборатории.
5. Только для США. Осторожно! Согласно федеральному закону США данное устройство допускается к продаже только лицензированным врачам или по их заказу.

Замечания и предостережения к процедуре проведения теста

1. Следует приложить все усилия к недопущению контаминации образцов крови пациента при венепункции и во время посева во флаконы для культивирования. Контаминация может привести к положительному результату анализа образца при отсутствии в образце клинически значимого изолята.
2. Забор крови следует производить до начала антибиотикотерапии. Если это невозможно, забор крови следует производить непосредственно перед введением очередной дозы антибиотика.
3. Если флаконы для культивирования были доставлены в лабораторию не сразу после посева, а с задержкой или были предварительно инкубированы вне анализатора BacT/ALERT, осмотрите флаконы на наличие признаков микробного роста. При наличии явных признаков микробного роста не помещайте флаконы в анализатор BacT/ALERT для проведения мониторинга, а продолжайте работу с ними как с положительными флаконами.

Лабораторная процедура

ОСТОРОЖНО! При пересеве материала из положительных флаконов для культивирования следует соблюдать общие меры предосторожности. Внутри флакона может быть создано повышенное давление при внесении излишка жидкости или при наличии микроорганизмов, активно вырабатывающих газы. Положительные флаконы следует подвергать кратковременному вентилированию перед окрашиванием или утилизацией для удаления из них газов, вырабатываемых микроорганизмами.

1. Осмотрите флаконы перед началом работы. Не используйте флаконы при наличии повреждений и протечек. При помутнении среды, пожелтении датчика, наличии гемолиза, признаков избыточного газового давления или других признаков микробного

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роста флакон следует считать положительным. Возьмите материал для мазка и сделайте пересев. Инкубируйте флакон, только если мазок отрицательный.

2. После загрузки флаконов для культивирования в прибор они должны оставаться там от пяти до семи суток или до получения положительного результата.
3. Из всех флаконов, результаты анализа которых положительны, следует взять мазок и сделать пересев. При отсутствии микроорганизмов в мазке (что может указывать на ложноположительный результат) флакон следует повторно загрузить в прибор до получения роста на чашке, куда был произведен пересев, или повторной регистрации прибором роста во флаконе. При повторном определении роста культуры во флаконе, который первоначально был определен как ложноположительный, из него следует повторно выполнить мазок и сделать пересев.
4. Для проверки отрицательного результата также можно выполнять мазок и/или пересев из флакона перед его утилизацией.
5. Процедура загрузки флаконов в анализатор и выгрузки из анализатора BacT/ALERT подробно описана в руководстве по эксплуатации.
6. **Не используйте флаконы для культивирования BacT/ALERT более одного раза.** Утилизируйте флаконы для культивирования BacT/ALERT, в которые был произведен посев, в соответствии с правилами вашей лаборатории. Автоклавирование и/или сжигание являются приемлемыми процедурами утилизации таких флаконов BacT/ALERT[2].
7. Использование средств сверления (например, тупых игл) для прокола пробки может привести к протечке флакона.

КОНТРОЛЬ КАЧЕСТВА

Сертификат соответствия предоставляется с каждой партией флаконов для культивирования. При желании лаборатории могут выполнять дополнительный контроль качества флаконов для культивирования BacT/ALERT SA. См. руководство по эксплуатации анализатора BacT/ALERT и документ CLSI® M22-A3[6].

Прибор

Набор стандартов для калибровки ячеек анализатора BacT/ALERT предоставляется с каждым прибором для проведения процедур QC и калибровки. Любые процедуры контроля качества должны быть частью текущего профилактического обслуживания системы. Дополнительные сведения см. в руководстве по эксплуатации анализатора BacT/ALERT.

РЕЗУЛЬТАТЫ

Положительный или отрицательный результат определяется программным обеспечением принятия решений, являющимся частью анализатора BacT/ALERT. До получения положительного или отрицательного сигнала от анализатора BacT/ALERT никаких действий выполнять не требуется.

ОГРАНИЧЕНИЯ ТЕСТА

На результат теста влияет множество практически неконтролируемых факторов, связанных с кровью и другими в норме стерильными биологическими жидкостями, поэтому нельзя с уверенностью утверждать, что результат теста зависит только от правильного или неправильного использования питательной среды или работы системы обнаружения.

1. В образцах пациентов, определяемых как положительные анализатором BacT/ALERT, могут содержаться микроорганизмы, клетки которых видны в мазке, но которые не растут на обычно используемых для пересева средах. При подозрении на наличие таких микроорганизмов пересев следует выполнять на специальные среды. Кроме того, положительные флаконы BacT/ALERT могут содержать микроорганизмы, клетки которых не видны при обычной окраске мазка и для обнаружения и выделения которых могут требоваться специальные методы окрашивания мазков, а также специальные среды для пересева.
2. Некоторые штаммы *Haemophilus influenzae*, *Neisseria meningitidis*, *Neisseria gonorrhoeae* и *Peptostreptococcus anaerobius* могут быть чувствительны к антикоагулянту — полианетолсульфонату натрия (SPS), что может привести к слабому росту или слабому выделению углекислого газа (CO_2) этими штаммами при посеве во флаконы недостаточного объема образца крови.
3. Иногда при наличии в образце крови большого количества лейкоцитов анализатор BacT/ALERT может определить результат как положительный. Это может привести к тому, что из фактически отрицательных флаконов будет повторно взят мазок и сделан пересев.
4. Часто количество микроорганизмов незначительно, и они могут появляться в кровотоке периодически, поэтому необходимо последовательно выполнять забор нескольких образцов крови каждого пациента.
5. При получении положительного сигнала от анализатора BacT/ALERT настоятельно рекомендуется немедленно извлечь флакон из прибора. Это позволит избежать нежизнеспособности культур из-за автолиза или по другим причинам. В частности, для некоторых штаммов *Streptococcus pneumoniae* характерен автолиз, если флакон не извлекается из прибора немедленно после получения положительного сигнала.
6. В окрашенном по Граму мазке из отрицательного флакона могут в небольших количествах встречаться нежизнеспособные клетки микроорганизмов, попавшие в мазок из компонентов питательной среды, реагентов для окраски мазка, иммерсионного масла или с предметных стекол, что может привести к ложноположительному результату.
7. Не рекомендуется применять отсроченную загрузку флаконов для культивирования крови. Любая отсрочка в загрузке может привести к увеличению времени до обнаружения или получению ложноотрицательных результатов. В случае если избежать отсрочки не удается, то согласно внутренним и опубликованным данным флаконы следует хранить при комнатной температуре не более 24 часов.

РАБОЧИЕ ХАРАКТЕРИСТИКИ ТЕСТА

Компанией были проведены внутренние исследования посевов следующих микроорганизмов в концентрациях ≤ 10 КОЕ/флакон и ≤ 100 КОЕ/флакон на образцах человеческой крови, отобранных в популяции здоровых взрослых.

Таблица 1.

Микроорганизм	Посевной материал (КОЕ/флакон)	Время культивирования до определения статуса флакона (часы)* BacT/ALERT SA (пластик)
Грамположительные (*M. luteus, S. aureus, S. epidermidis, S. agalactiae, E. faecalis, S. pneumoniae, S. pyogenes, Group C Streptococcus, L. monocytogenes, S. sanguis*)	≤ 100 ≤ 10	12,5—36,3 15,1—42,5
Грамотрицательные (*E. coli, H. influenzae, N. meningitidis, P. aeruginosa, S. maltophilia, S. marcescens, A. baumanii, E. cloacae, A. faecalis, K. pneumoniae*)	≤ 100 ≤ 10	10,6—24,1 11,7—26,5
Дрожжи (*C. albicans, T. glabrata, C. tropicalis*)	≤ 100 ≤ 10	18,3—33,6 20,5—48,6

* Каждый микроорганизм исследовался в трех повторностях, получены средние значения. Приведен диапазон этих средних значений.

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СПИСОК ЛИТЕРАТУРЫ

1. Thorpe TC, Wilson ML, Turner JE, DiGuiseppi JL, Willert M, Mirrett S, et al: BacT/ALERT: an Automated Colorimetric Microbial Detection System. *J Clin Micro* 1990;28(7), 1608-1612.
2. *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* 5th Edition. U.S. Department of Health and Human Services Centers for Disease Control and Prevention and National Institutes of Health. Fifth Edition. US Government Printing Office. Washington: Feb 2007.
3. Koneman EW, Allen SD, Janda WM, Schreckenberger PC, Winn WC. *Color Atlas and Textbook of Diagnostic Microbiology*, 6th ed. 2006, pp. 446,590.
4. Baron EJ, Weinstein MP, Dunne Jr. WM, Yagupsky P, Welch DF, Wilson DM. 2005. Cumitech 1C, Blood Cultures IV. Coordinating ed. Baron EJ. ASM Press, Washington, DC.
5. CLSI. *Principles and Procedures for Blood Cultures; Approved Guideline.* CLSI document M47-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2007.
6. CLSI/NCCLS. *Quality Control for Commercially Prepared Microbiological Culture Media*; Approved Standard—Third Edition. CLSI/NCCLS document M22-A3. Wayne, PA: NCCLS; 2004.

ОГРАНИЧЕННАЯ ГАРАНТИЯ

Компания bioMérieux гарантирует, что рабочие характеристики данного изделия соответствуют указанному предусмотренному назначению в течение всего срока эксплуатации при условии, что строго соблюдены все процедуры по использованию, хранению и обработке и меры безопасности, как подробно изложено в инструкциях по эксплуатации.

За исключением вышеуказанных случаев, компания bioMérieux не дает никаких гарантий, в том числе, подразумеваемых гарантий товарного качества и гарантий соответствия предполагаемому использованию, и не дает никаких обязательств, в том числе, явно выраженных, подразумеваемых или косвенных, в отношении использования какого-либо реагента, программного обеспечения, прибора и расходных материалов (далее — «Система»), отличного от указанного в инструкциях по эксплуатации.

ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ

bioMérieux

Флаконы BacT/ALERT SA

100 шт./уп. REF 259789

Для получения технической поддержки в США обращайтесь в службу технической поддержки компании bioMérieux по телефону 1-800-682-2666. За пределами США свяжитесь с местным представителем компании bioMérieux.

ТАБЛИЦА СИМВОЛОВ И ОБОЗНАЧЕНИЙ

Символ	Обозначение
REF	Номер по каталогу
	Официальный производитель
	Дата изготовления
	Температурный диапазон
	Использовать до
LOT	Номер партии
	Обратитесь к инструкции по применению
Σ	Содержимого достаточно для <n> тестов
EC REP	Уполномоченный представитель в Европейском сообществе
	Вверх
IVD	Изделие медицинское для диагностики in vitro
	Не использовать повторно
LATEX	Без латекса
Rx only	Только для США. Осторожно! Согласно федеральному закону США данное устройство допускается к продаже только лицензированным врачам или по их заказу.
FILL	Уровень заполнения

Инструкция по применению прилагается к набору. Кроме того, инструкцию можно загрузить с сайта www.biomerieux.com/techlib.

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ИСТОРИЯ ПЕРЕСМОТРОВ

В этом разделе содержится обзор изменений, внесенных в инструкцию по применению флаконов BacT/ALERT SA.

Дата выпуска	Номер версии	Тип изменений	Обзор изменений
2016-03	043259-01 /9313396 D	Изменение содержания	В раздел **«Ограничения теста»** добавлены сведения об отсроченной загрузке.
			Добавлено предупреждение Rx-only для пользователей в США.
		Административные изменения	В раздел **«Ограниченная гарантия»** добавлено указание.
			Раздел **«Таблица символов и обозначений»** обновлен с целью внесения обозначения символа Rx-only.
2015-05	9307042 B	Изменение содержания	В раздел **«Реагенты»** внесено разъяснение по дате истечения срока годности.
			Раздел «Забор и подготовка образцов»: - добавление предупреждения относительно вероятности высокого давления во флаконе; - добавление примечания касательно этикетки на флаконе с меткой уровня заполнения; - добавление примечаний с информацией о венепункции.
		Административные изменения	Раздел **«Таблица символов и обозначений»** обновлен с целью внесения новых символов для продукта.
			Добавление адреса технической библиотеки

ПРИМЕЧАНИЕ. Незначительные типографские, грамматические изменения и изменения в форматировании в историю пересмотров не включены.

Категории типов изменений:

- **Корректура** — исправление ошибок в документации.
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