УТВЕРЖДАЮ
ООО «АГРОС-ИНТЕРНЕЙШНЛ»
Коновалов С.А
«___» ____________ 20___ г.

РЕАГЕНТЫ, КАЛИБРАТОРЫ И КОНТРОЛИ, РАСХОДНЫЕ МАТЕРИАЛЫ К АНАЛИЗАТОРАМ БИОХИМИЧЕСКИМ АВТОМАТИЧЕСКИМ ДИСКРЕТНЫМ NS-PRIME И NS-PRIME AA01

Инструкции по применению

Оглавление

ʅ ɸ ɹ ʃ ʈ ʈ ɽ ɸ ɻ ɽ ʅ ʊ ʃ ɪ IN VITRO ɼ ʃ ɕ ɸ ɪ ʊ ʃ ʄ ɸ ʊ ʀ ʏ ɽ ʉ ʂ ʃ ɻ ʃ ʂ ʃ ʃ ʀ ʏ ɽ ʉ ʊ ɪ ɽ ʅ ʅ ʃ ɻ ʃ ʃ ɟ ʈ ɽ ɼ ɽ ʃ ɽ ʅ ʀ ɕ ɻ ɽ ʄ ʃ ɻ ʃ ʃ ɹ ʀ ʅ ɸ ɪ ʂ ɸ ʃ ɽ ɪ ʋ ɟ ɸ ʂ ʃ ɪ ʂ ɽ ɼ ʃ ɕ ɸ ʅ ɸ ʃ ʀ ɿ ɸ ʊ ʃ ʈ ʃ ɪ NS-PRIME ï FIT HEMOGLOBIN NS-PRIME (ʌ ʀ ʊ ɻ ɽ ʄ ʃ ɻ ʃ ʃ ɹ ʀ ʅ NS-PRIME)é é é é é é é é é é é é é 2

ʅ ɸ ɹ ʃ ʈ ʈ ɽ ɸ ɻ ɽ ʅ ʊ ʃ ɪ IN VITRO ɼ ʃ ɕ ɸ ɪ ʊ ʃ ʄ ɸ ʊ ʀ ʏ ɽ ʉ ʂ ʃ ɻ ʃ ʂ ʃ ʃ ʀ ʏ ɽ ʉ ʊ ɪ ɽ ʅ ʅ ʃ ɻ ʃ ʃ ɟ ʈ ɽ ɼ ɽ ʃ ɽ ʅ ʀ ɕ ʊ ɽ ɸ ʅ ʉ ʌ ɽ ɽ ɽ ʀ ʅ ɸ ɪ ʂ ɸ ʃ ɽ ɪ ʋ ɟ ɸ ʂ ʃ ɪ ʂ ɽ ɼ ʃ ɕ ɸ ʅ ɸ ʃ ʀ ɿ ɸ ʊ ʃ ʈ ʃ ɪ NS-PRIME ï FIT TRANSFERRIN NS-PRIME (ʌ ʀ ʊ ʊ ɽ ɸ ʅ ʉ ʌ ɽ ɽ ɽ ʀ ʅ NS-PRIME)é é é é é é é é é ....é é é 30

ʅ ɸ ɹ ʃ ʈ ʈ ɽ ɸ ɻ ɽ ʅ ʊ ʃ ɪ IN VITRO ɼ ʃ ɕ ɸ ɪ ʊ ʃ ʄ ɸ ʊ ʀ ʏ ɽ ʉ ʂ ʃ ɻ ʃ ʂ ʃ ʃ ʀ ʏ ɽ ʉ ʊ ɪ ɽ ʅ ʅ ʃ ɻ ʃ ʃ ɟ ʈ ɽ ɼ ɽ ʃ ɽ ʅ ʀ ɕ ʂ ɸ ʃ ʔ ɟ ʈ ʃ ʊ ɽ ʂ ʊ ʀ ʅ ɸ ɪ ʂ ɸ ʃ ɽ ɪ ʋ ɟ ɸ ʂ ʃ ɪ ʂ ɽ ɼ ʃ ɕ ɸ ʅ ɸ ʃ ʀ ɿ ɸ ʊ ʃ ʈ ʃ ɪ NS-PRIME ï NESCAUTO CP AUTO NS-PRIMEé é é é é é é é é é é é é é é é é é é ....é é é 57

ʈ ɸ ɿ ɹ ɸ ɪ ʀ ʊ ɽ ʃ ʔ ʃ ɹ ʈ ɸ ɿ ʎ ɸ ɪ ʋ ɟ ɸ ʂ ʃ ɪ ʂ ɽ ɼ ʃ ɕ ɸ ʅ ɸ ʃ ʀ ɿ ɸ ʊ ʃ ʈ ʃ ɪ NS-PRIME - FIT NS-PRIME SPECIMEN DILUENT (ʌ ʀ ʊ NS-PRIME ʈ ɸ ɿ ɹ ɸ ɪ ʀ ʊ ɽ ʃ ʔ ʃ ɹ ʈ ɸ ɿ ʎ ɸ)é é é é é é é ....é é é é é 82

ʅ ɸ ɹ ʃ ʈ ʈ ɽ ɸ ɻ ɽ ʅ ʊ ʃ ɪ IN VITRO ɼ ʃ ɕ ɸ ɪ ʊ ʃ ʄ ɸ ʊ ʀ ʏ ɽ ʉ ʂ ʃ ɻ ʃ ʂ ʃ ʃ ʀ ʏ ɽ ʉ ʊ ɪ ɽ ʅ ʅ ʃ ɻ ʃ ʃ ɟ ʈ ɽ ɼ ɽ ʃ ɽ ʅ ʀ ɕ ɻ ɽ ʄ ʃ ɻ ʃ ʃ ɹ ʀ ʅ ɸ ɪ ʂ ɸ ʃ ɽ ɪ ʋ ɟ ɸ ʂ ʃ ɪ ʂ ɽ ɼ ʃ ɕ ɸ ʅ ɸ ʃ ʀ ɿ ɸ ʊ ʃ ʈ ʃ ɪ NS-PRIME AA01 ï FIT HEMOGLOBIN AA01 (ʌ ʀ ʊ ɻ ɽ ʄ ʃ ɻ ʃ ʃ ɹ ʀ ʅ AA01)é é é é é é é é é é é é é é 97

ʅ ɸ ɹ ʃ ʈ ʈ ɽ ɸ ɻ ɽ ʅ ʊ ʃ ɪ IN VITRO ɼ ʃ ɕ ɸ ɪ ʊ ʃ ʄ ɸ ʊ ʀ ʏ ɽ ʉ ʂ ʃ ɻ ʃ ʂ ʃ ʃ ʀ ʏ ɽ ʉ ʊ ɪ ɽ ʅ ʅ ʃ ɻ ʃ ʃ ɟ ʈ ɽ ɼ ɽ ʃ ɽ ʅ ʀ ɕ ʊ ɽ ɸ ʅ ʉ ʌ ɽ ɽ ɽ ʀ ʅ ɸ ɪ ʂ ɸ ʃ ɽ ɪ ʋ ɟ ɸ ʂ ʃ ɪ ʂ ɽ ɼ ʃ ɕ ɸ ʅ ɸ ʃ ʀ ɿ ɸ ʊ ʃ ʈ ʃ ɪ NS-PRIME AA01 ï FIT TRANSFERRIN AA01 (ʌ ʀ ʊ ʊ ɽ ɸ ʅ ʉ ʌ ɽ ɽ ɽ ʀ ʅ AA01)é é é é é é é é é é é é ....é é 128

ʅ ɸ ɹ ʃ ʈ ʈ ɽ ɸ ɻ ɽ ʅ ʊ ʃ ɪ IN VITRO ɼ ʃ ɕ ɸ ɪ ʊ ʃ ʄ ɸ ʊ ʀ ʏ ɽ ʉ ʂ ʃ ɻ ʃ ʂ ʃ ʃ ʀ ʏ ɽ ʉ ʊ ɪ ɽ ʅ ʅ ʃ ɻ ʃ ʃ ɟ ʈ ɽ ɼ ɽ ʃ ɽ ʅ ʀ ɕ ʂ ɸ ʃ ʔ ɟ ʈ ʃ ʊ ɽ ʂ ʊ ʀ ʅ ɸ ɪ ʂ ɸ ʃ ɽ ɪ ʋ ɟ ɸ ʂ ʃ ɪ ʂ ɽ ɼ ʃ ɕ ɸ ʅ ɸ ʃ ʀ ɿ ɸ ʊ ʃ ʈ ʃ ɪ NS-PRIME AA01 ï NESCAUTO CP AUTO AA01é 156

ʈ ɸ ɿ ɹ ɸ ɪ ʀ ʊ ɽ ʃ ʔ ʃ ɹ ʈ ɸ ɿ ʎ ɸ ɪ ʋ ɟ ɸ ʂ ʃ ɪ ʂ ɽ ɼ ʃ ɕ ɸ ʅ ɸ ʃ ʀ ɿ ɸ ʊ ʃ ʈ ʃ ɪ NS-PRIME AA01 ï FIT AA01 SPECIMEN DILUENT (ʌ ʀ ʊ AA01 ʈ ɸ ɿ ɹ ɸ ɪ ʀ ʊ ɽ ʃ ʔ ʃ ɹ ʈ ɸ ɿ ʎ ɸ)é é é é é é é é é é é ....é é ..179

ʅ ɸ ɹ ʃ ʈ ʈ ɽ ɸ ɻ ɽ ʅ ʊ ʃ ɪ ɼ ʃ ɕ ʂ ɸ ʃ ʀ ɹ ʈ ʃ ɪ ʂ ʀ ʂ ʃ ʅ ʎ ɽ ʅ ʊ ɽ ɸ ʎ ʀ ʀ ɻ ɽ ʄ ʃ ɻ ʃ ʃ ɹ ʀ ʅ ɸ ɪ ʋ ɟ ɸ ʂ ʃ ɪ ʂ ɽ ɼ ʃ ɕ ɸ ʅ ɸ ʃ ʀ ɿ ɸ ʊ ʃ ʈ ʃ ɪ NS-PRIME ɖ NS-PRIME AA01 ï FIT HEMOGLOBIN NS-PRIME CALIBRATOR (ʌ ʀ ʊ ɻ ɽ ʄ ʃ ɻ ʃ ʃ ɹ ʀ ʅ NS-PRIME ʂ ɸ ʃ ʀ ɹ ʈ ɸ ʊ ʃ ʈ)é é é é é é é é é é é ....é ..192

ʅ ɸ ɹ ʃ ʈ ʈ ɽ ɸ ɻ ɽ ʅ ʊ ʃ ɪ ɼ ʃ ɕ ʂ ɸ ʃ ʀ ɹ ʈ ʃ ɪ ʂ ʀ ʂ ʃ ʅ ʎ ɽ ʅ ʊ ɽ ɸ ʎ ʀ ʀ ʊ ɽ ɸ ʅ ʉ ʌ ɽ ɽ ɽ ʀ ʅ ɸ ɪ ʋ ɟ ɸ ʂ ʃ ɪ ʂ ɽ ɼ ʃ ɕ ɸ ʅ ɸ ʃ ʀ ɿ ɸ ʊ ʃ ʈ ʃ ɪ NS-PRIME ɖ NS-PRIME AA01 ï FIT TRANSFERRIN NS-PRIME CALIBRATOR (ʌ ʀ ʊ ʊ ɽ ɸ ʅ ʉ ʌ ɽ ɽ ɽ ʀ ʅ NS-PRIME ʂ ɸ ʃ ʀ ɹ ʈ ɸ ʊ ʃ ʈ)é é é é é é é é é é é ....é .213

ʅ ɸ ɹ ʃ ʈ ʂ ʃ ʅ ʊ ʈ ʃ ʃ ɽ ʁ ʂ ʃ ʅ ʎ ɽ ʅ ʊ ɽ ɸ ʎ ʀ ʀ ɻ ɽ ʄ ʃ ɻ ʃ ʃ ɹ ʀ ʅ ɸ ʀ/ʀ ʃ ʀ ʊ ɽ ɸ ʅ ʉ ʌ ɽ ɽ ɽ ʀ ʅ ɸ ɪ ʋ ɟ ɸ ʂ ʃ ɪ ʂ ɽ ɼ ʃ ɕ ɸ ʅ ɸ ʃ ʀ ɿ ɸ ʊ ʃ ʈ ʃ ɪ NS-PRIME ɖ NS-PRIME AA01 ï FIT NS-PRIME CONTROL (ʌ ʀ ʊ NS-PRIME ʂ ʃ ʅ ʊ ʈ ʃ ʃ ʔ...é 234

ʅ ɸ ɹ ʃ ʈ ʈ ɽ ɸ ɻ ɽ ʅ ʊ ʃ ɪ ɼ ʃ ɕ ʂ ɸ ʃ ʀ ɹ ʈ ʃ ɪ ʂ ʀ ʂ ʃ ʅ ʎ ɽ ʅ ʊ ɽ ɸ ʎ ʀ ʀ ʂ ɸ ʃ ʔ ɟ ʈ ʃ ʊ ɽ ʂ ʊ ʀ ʅ ɸ ɪ ʋ ɟ ɸ ʂ ʃ ɪ ʂ ɽ ɼ ʃ ɕ ɸ ʅ ɸ ʃ ʀ ɿ ɸ ʊ ʃ ʈ ʃ ɪ NS-PRIME ɖ NS-PRIME AA01ï NESCAUTO CP AUTO CALIBRATORé é é é é ......é 256

ʅ ɸ ɹ ʃ ʈ ʂ ʃ ʅ ʊ ʈ ʃ ʃ ɽ ʁ ʂ ʃ ʅ ʎ ɽ ʅ ʊ ɽ ɸ ʎ ʀ ʀ ʂ ɸ ʃ ʔ ɟ ʈ ʃ ʊ ɽ ʂ ʊ ʀ ʅ ɸ ɪ ʋ ɟ ɸ ʂ ʃ ɪ ʂ ɽ ɼ ʃ ɕ ɸ ʅ ɸ ʃ ʀ ɿ ɸ ʊ ʃ ʈ ʃ ɪ NS-PRIME ɖ NS-PRIME AA01 ï NESCAUTO CP AUTO CONTROLé é é 275

ʈ ɸ ʉ ʊ ɪ ʃ ʈ ɼ ʃ ɕ ɟ ʈ ʃ ʄ ʒ ɪ ɸ ʅ ʀ ɕ ɸ ɪ ʋ ɟ ɸ ʂ ʃ ɪ ʂ ɽ ɼ ʃ ɕ ɸ ʅ ɸ ʃ ʀ ɿ ɸ ʊ ʃ ʈ ʃ ɪ NS-PRIME ɖ NS-PRIME AA01 ï WASH SOLUTION ɸ (ɟ ʈ ʃ ʄ ʒ ɪ ɸ ʒ ʑ ʀ ʁ ʈ ɸ ʉ ʊ ɪ ʃ ʈ ɸ)é é é é é é é é é ....é .293

ȿ ʆ ʅ ʊɼ ʁ ʅ ɼ ʈ ʓ ɼ ʃ ɕ ʉɹ ʆ ʈ ɸ ʆ ɹ ʈ ɸ ɿ ʎ ʆ ɺ ȿ ɸ ʃ ɸ ɼ ʃ ɕ ɸ ʅ ɸ ʃ ʀ ɿ ɸ ʊ ʆ ʈ ʆ ɺ NS-PRIME ɖ NS-PRIME AA01 ï SPECIMEN COLLECTION CONTAINER Aé é é é é é é é é é é é é é é é ....é é 308

ʅ ɸ ɹ ʆ ʈ ʆ ɼ ʅ ʆ ʈ ɸ ɿ ʆ ɺ ʓ ʍ ʈ ɼ ɸ ȿ ʎ ʀ ʆ ʅ ʅ ʓ ʍ ȿ ʖ ɺ ɼ ʊ ʉ 8 ɕ ʏ ɼ ʁ ȿ ɸ ʄ ʀ AA01 / AA01 8-CELL REACTION CUVETTEé 328

ʅ ɸɹʆ ʈ ʈɼɸɻɼʅ ʊʆ ɺ IN VITRO ɼ ʃ ɕ ɸɺ ʊʆ ʄ ɸʊʀʏɼʉʂ ʆ ɻʆ ʂʆ ʃ ʀʏɼʉʊɺ ɼʅ ʅ ʆ ɻʆ ʆ ɟ ʈɼɼ ɼʃ ɼʅ ʀɕ ɻɼʄ ʆ ɻʃ ʆ ɹʀʅ ɸ ɺ ʂɸʃɼ ɺ ʊɟ ɸʂʆ ɺ ʂɼ ɼʃɕ ɸʅ ɸʃ ʀɿɸʊʆ ʈʆ ɺ NS-PRIME ï FIT HEMOGLOBIN NS-PRIME (ʌ ʀʊ ɻɼʄ ʆ ɻʃ ʆ ɹʀʅ NS-PRIME)

ʀ ʣʩʪʦʨʢʡʮʞʭ ʧʨʦʣʫʢʯʦʩ

1. Наименование медицинского изделия

[illegible] in vitro [illegible] NS-Prime ï FIT Hemoglobin NS-Prime ([illegible] NS-Prime)è ([illegible] ï [illegible] NS-Prime; FIT Hemoglobin NS-Prime ([illegible] NS-Prime).

2. Сведения о разработчике и производителе медицинского изделия

Alfresa Pharma Corporation, 2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan.

Tel.: +81-6-6941-0300

Fax: +81-6-6947-1548

[illegible]: http://www.alfresa-pharma.co.jp/english/

([illegible], 2-2-9 [illegible], [illegible]-[illegible], [illegible] 540-8575, [illegible]

[illegible]: +81-6-6941-0300

[illegible]: +81-6-6947-1548

[illegible]: http://www.alfresa-pharma.co.jp/english/).

3. Сведения о месте производства медицинского изделия

çOkayama Plantè, 18 Taiheidai, Shooucho, Katsuta-gun, Okayama Prefecture 709-4321.

Tel.: +81-868-38-5341

Fax: +81-868-38-5800

([illegible]è, 18 [illegible], [illegible], [illegible] 709-4321.

[illegible]: +81-868-38-5341

[illegible]: +81-868-38-5800).

4. Сведения об уполномоченных представителях производителя

4.1. Уполномоченный представитель в Европейском сообществе

Emergo Europe, Prinsessegracht 20, 2514 AP, The Hague, The Netherlands.
Tel.: + 31 70 345 8570
Fax: +31 70 346 7299
[illegible] -mail: Europe@emergogroup.com

([illegible], 2514 AP, [illegible] 20.
[illegible]: + 31 70 345 8570
[illegible] +31 70 346 7299
[illegible] -mail: Europe@emergogroup.com)

4.2. Уполномоченный представитель на территории РФ

[illegible]
[illegible], 196066, [illegible], н.212
[illegible]: +7 (812) 303-82-44
[illegible] -mail: agros@agros-int.com.

5. Назначение медицинского изделия, установленное производителем

5.1. Назначение медицинского изделия

[illegible] in vitro [illegible] NS-Prime [illegible] FIT Hemoglobin NS-Prime ([illegible] NS-Prime) [illegible] NS-Prime [illegible] in vitro [illegible] NS-Prime).

5.2. Принцип действия медицинского изделия

[illegible]

[illegible] 545 [illegible] 660 [illegible] (545 [illegible]) [illegible] (660 [illegible]):

Abs. = Abs.(main)-Abs.(sub)

[illegible] Abs. – [illegible]

Abs.(main) - [illegible]

Abs.(sub) - [illegible]

main ([illegible]) = 545 [illegible]

sub ([illegible]) = 660 [illegible]

5.3. Показания к применению

[illegible] NS-Prime [illegible] NS-Prime [illegible] in vitro [illegible]:

– [illegible];

– [illegible].

[illegible]

[illegible]

[illegible]

5.4. Противопоказания, возможные побочные воздействия

[illegible] NS-Prime [illegible].

5.5. **Область применения** – [illegible] in vitro [illegible] NS-Prime ï FIT Hemoglobin NS-Prime ([illegible] NS-Prime): [illegible]

6. Техническое описание, параметры и характеристики медицинского изделия

6.1. Состав набора реагентов NS-Prime

[illegible] in vitro [illegible] NS-Prime ï FIT

Hemoglobin NS-Prime ([illegible] NS-Prime)è

[illegible] 1 (33 [illegible]) [illegible] 2 (13 [illegible]) [illegible] 4 [illegible].

FIT Hemoglobin NS-Prime ([illegible] NS-Prime) [illegible] 1 [illegible] 2, [illegible] ([illegible]). [illegible] 300 [illegible] NS-Prime [illegible] 1200 [illegible].

6.2. Сырье и материалы компонентов набора реагента NS-Prime

FIT Hemoglobin NS-Prime ([illegible] NS-Prime) ([illegible] 910869) 1 [illegible] 1 [illegible] 150 [illegible]/[illegible] MES [illegible] 0,1% [illegible]; 1 [illegible] 2 [illegible] 4,8 [illegible]/[illegible] TES [illegible] 0,1% [illegible], 0,03% [illegible] 267 [illegible], [illegible] 1 [illegible] 33 [illegible], [illegible] 2 [illegible] 13 [illegible].

6.3. Технические характеристики

[illegible] NS-Prime.

6.3.1. Аналитические рабочие характеристики

6.3.1.1. [illegible]: n = 5, CV Ò15%

6.3.1.2. [illegible]

[illegible] 90-110% [illegible]:

[illegible]	[illegible]
[illegible]	0-20 000 [illegible]/[illegible]
[illegible]	0-100 000 [illegible]/[illegible]
[illegible]	0-100 000 [illegible]/[illegible]

[illegible]	[illegible]
[illegible]	0-100 000 [illegible]
[illegible]	0-100 000 [illegible]
[illegible]	0-1 000 000 [illegible]

[illegible]

6.3.1.3. [illegible]

1) [illegible] FIT Hemoglobin NS-Prime ([illegible] NS-Prime) [illegible] 95 [illegible]. [illegible] 0 [illegible] 1 200 [illegible]:

x: FIT Hemoglobin NS-Prime ([illegible] NS-Prime)

y: [illegible]

r=0,993

y=1,003x-3,812

6.3.1.4. [illegible]

[illegible]:

8–1200 [illegible] ([illegible] 1,6–240 [illegible] 1 [illegible]).

6.3.1.5. [illegible] *

[illegible] 0 [illegible] 100 [illegible] 0,05 [illegible].

6.3.1.6. [illegible]

[illegible] 100±15% [illegible].

6.3.1.7. [illegible] CV 10% [illegible].

*[illegible]

([illegible]) [illegible] 0 [illegible] 100 [illegible]/[illegible] ([illegible]).

6.3.2. Биологические референтные интервалы

[illegible] 100 [illegible]/[illegible] (20 [illegible]).

[illegible].

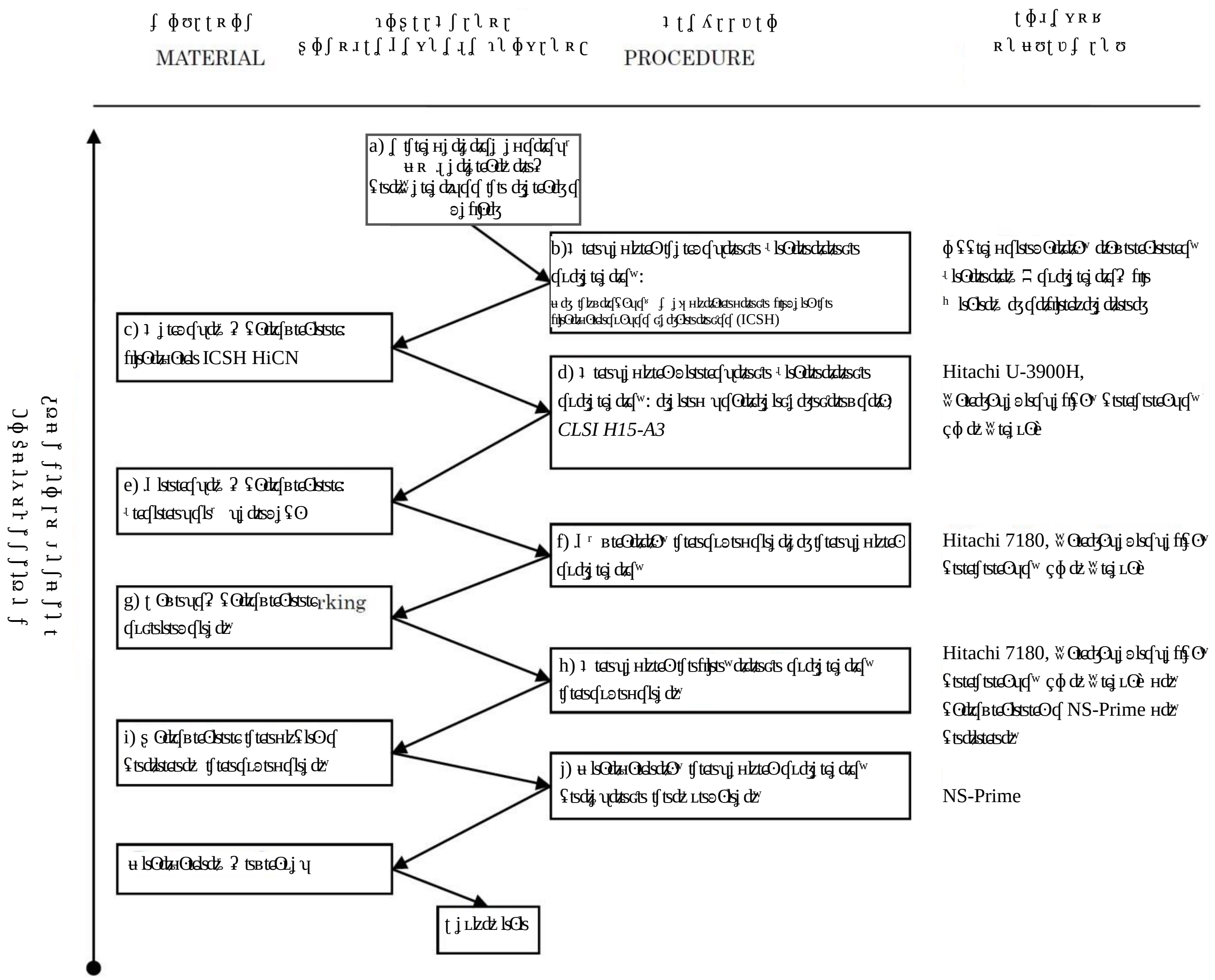
6.3.3. Кислотность реагента 1 и реагента 2

pH [illegible] 1 ï 6,30 Ñ0,05;

pH [illegible] 2 ï 7,10 Ñ0,10.

6.3.4. Метрологическая прослеживаемость

[illegible] Eurotrol ICSH HiCN Standard, [illegible]



7. Тип анализируемого образца

7.1. Сбор образцов биоматериала

[illegible] (ICSH) [illegible] 1,9 [illegible]

[illegible] 30 [illegible]/[illegible] MES [illegible] 8,0 [illegible]/[illegible] [illegible], 0,15% [illegible] 0,1% [illegible].

7.2. Хранение образца биоматериала

[illegible] (2-8) °[illegible] [illegible] 6 [illegible] 20 °[illegible] [illegible]/[illegible] [illegible].

[illegible].

[illegible], [illegible]/[illegible]	[illegible], %			
	[illegible]			
	- 40 °[illegible] 33 [illegible]	7 °[illegible] 33 [illegible]	25 °[illegible] 14 [illegible]	37 °[illegible] 7 [illegible]
1	2	3	4	5
50	> 90	> 90	> 90	> 90
169	> 90	> 90	> 90	> 70
266	> 90	> 90	> 70	> 50*
50	> 90	> 90	> 90	> 90

*[illegible] 50-70%, [illegible] ([illegible] 100 [illegible]/[illegible]).

[illegible] 30 [illegible].

8. Требуемое оборудование, материалы и реагенты

8.1. [illegible] NS-Prime [illegible], [illegible]:

– [illegible] NS-Prime [illegible] in vitro [illegible];

– [illegible] NS-Prime ([illegible]) [illegible] NS-Prime ї Specimen Collection Container Aè, [illegible]:- [illegible] (1-Day Method); - [illegible] (2-Day Method));

– [illegible] 1,8 [illegible] Hitachi ([illegible] 716-0425) [[illegible] 2009/05517 [illegible] 19.08.2015, [illegible] DELTALAB S.L., [illegible]];

– [illegible], [illegible] 2 [illegible] 8 [illegible];

– [illegible] 10 [illegible] 200 [illegible] 3%;

– [illegible];

– [illegible] in vitro [illegible] NS-Prime ї FIT Hemoglobin NS-Prime ([illegible] NS-Prime);

– [illegible] NS-Prime ï FIT Hemoglobin NS-Prime Calibrator ([illegible] NS-Prime [illegible]);

– [illegible] NS-Prime ï FIT NS-Prime Control ([illegible] NS-Prime [illegible]);

– [illegible] FIT Hemoglobin NS-Prime [illegible]/[illegible] FIT Transferrin NS-Prime [illegible] NS-Prime - FIT NS-Prime Specimen Diluent ([illegible] NS-Prime [illegible]);

– [illegible] FIT Hemoglobin NS-Prime [illegible]/[illegible] FIT Transferrin NS-Prime [illegible] NS-Prime - Wash Solution [illegible] ([illegible]);

– [illegible]/[illegible].

9. Проведение анализа

[illegible] in vitro [illegible] NS-Prime ï FIT Hemoglobin NS-Prime ([illegible] NS-Prime)è, [illegible], [illegible], [illegible].

9.1. Подготовка реагентов и биоматериала

9.1.1. Подготовка образца А

[illegible] NS-Prime ï Specimen Collection Container Aè. [illegible] A [illegible] 7 [illegible] 2-8 [illegible] 3 [illegible] (18-25 [illegible]). [illegible], [illegible], [illegible]

[illegible].

9.1.2. [illegible] 12 [illegible], 100 [illegible] 1 ([illegible] R1) [illegible] 40 [illegible] 2 ([illegible] R2). [illegible] 37 °[illegible] 6,8 [illegible].

9.1.3. Подготовка реагентов для определения гемоглобина

[illegible] FIT Hemoglobin NS-Prime ([illegible] NS-Prime) [illegible].

[illegible], FIT Hemoglobin NS-Prime ([illegible] NS-Prime) [illegible] (2-8) °[illegible].

[illegible] NS-Prime [illegible] 1,0 [illegible].

9.2. Проведение анализа с использованием Анализатора автоматизированного клинической химии NS-Prime

[illegible] ([illegible]) [illegible] NS-Prime [illegible] in vitro [illegible]

[illegible]

[illegible] (Sample ID) [illegible]

[illegible] (Measurement protocol) [illegible] Hb(A), Tf(A) [illegible].

[illegible] (Concentration, average concentration), [illegible] (Absorbance difference, average absorbance difference) [illegible] (Result).

[illegible] (%) [illegible]

[illegible]:

Abs = (Am1 ï As1) ï (Am2- As2), [illegible]:

Am1 ï [illegible] 1;

As1 ï [illegible] 1;

Am2 ï [illegible] 2;

As2 ï [illegible] 2.

[illegible] ï 540 [illegible]

[illegible] ï 660 [illegible]

[illegible] 1 ї 0,2 [illegible];

[illegible] 2 ї 6,8 [illegible].

[illegible]

[illegible] NS-Prime.

9.3. Процедура контроля

[illegible] NS-Prime [illegible].

[illegible] NS-Prime.

9.4. Вычисления результатов исследования

[illegible] NS-Prime.

9.5. Интерпретация результатов

[illegible]:

– [illegible] 100 [illegible] 20 [illegible] 1 [illegible].

[illegible]

[illegible]

10. Ограничения при процедуре исследования

10.1. [illegible] NS-Prime [illegible]

10.2. [illegible] 1 [illegible] 2 [illegible]

10.3. [illegible]

10.4. [illegible]

10.5. [illegible] NS-Prime, [illegible]

10.6. [illegible] NS-Prime [illegible] NS-Prime [illegible]

10.7. [illegible]

10.8. [illegible]

11. Меры для снижения рисков получения ложноположительных или ложноотрицательных результатов при проведении исследований

11.1. [illegible] *in vitro* [illegible] NS-Prime [illegible] in vitro [illegible].

11.2. [illegible] NS-Prime [illegible].

11.3. [illegible] NS-Prime [illegible].

11.4. [illegible] NS-Prime [illegible].

11.5. [illegible] NS-Prime [illegible], [illegible].

11.6. [illegible] NS-Prime, [illegible]

11.7. [illegible]:

– [illegible] NS-Prime [illegible];

– [illegible], [illegible] NS-Prime [illegible];

– [illegible] NS-Prime [illegible], [illegible].

12. Меры безопасности при проведении исследований

12.1. [illegible]

12.2. [illegible] NS-Prime [illegible] 0,1% [illegible]

12.3. [illegible]

12.4. [illegible] NS-Prime [illegible]

12.5. [illegible]:

– [illegible] (C, [illegible]);

– [illegible];

– [illegible] NS-Prime [illegible];

– [illegible] NS-Prime [illegible]

fŋtstslsɘj lsfŋlsɘlzᴷ ʰ ςſdʒςſ ɘtsнtsdʑj tʃtɕtsdʑςſɥς϶ dʒʳ dʒςſ tʃj tɕj ɘʷʟtsɥdž dʒςſ fŋtɕj нfŋlsɘΘdʒςſ;

– ɘ dʒj fŋlsΘ϶, ɢнj dʑΘ϶tsнʷlsfŋʷ tsʙtɕΘʟɥʳ tʃΘɥςſj dʑlstsɘ ςſdʑςſ dʑΘʙtstɕ tɕj Θɢj dʑlstsɘ NS-Prime, ʟΘʃtɕj ʰ j dʑs ʢlztɕςſlsᴵ, tʃtɕςſdʑςſdʒΘlsᴵ tʃςſʰ lz, tʃtsdž ʟtsɘΘlsᴵ fŋʷ ʢtsfŋdʒj lsςſʢtsʡ.

12.6. ɫ tstɕj ʟʳ, fŋfŋΘнςſdž ςſ нtɕlzɢςſj tʃtsɘtɕj ʞнj dʑdž j lzɥςſfŋlsʢςſ ʢtsʞςſ нtsdʑʞdž ʙʳ lsᴵ dʑΘнdʑj ʞΘ ςſdʒ tsʙtɕΘʟtsdʒ ʟΘ ςſʰ j dž fŋtstslsɘj lsfŋlsɘlzᴷ ʰ ςſdʒςſ ɘtsнtsdʑj tʃtɕtsdʑςſɥς϶ dʒʳ dʒςſ tʃj tɕj ɘʷʟtsɥdž dʒςſ fŋtɕj нfŋlsɘΘdʒςſ.

12.7. ɪ ts ɘtɕj dʒʷ tɕΘʙtslsʳ fŋtsʙtɕΘʟɥΘdʒςſ tʃΘɥςſj dʑlstsɘ ςſdʑςſ lzlsςſdʑςſʟΘɥςſςſ lsɘʸtɕнʳ ʬ ςſdʑςſ ʞςſнʢςſʬ tslsʬtsнtsɘ tsʙʷʟΘlsj dž dʑs ςſfŋʃtsdž ʟlzʡlsj dʑΘʙtstɕΘlststɕdž j tʃj tɕɥΘlsʢςſ.

13. Порядок и условия утилизации или уничтожения медицинского изделия

13.1. υ lsςſdʑςſʟΘɥςſʷ tɕj Θɢj dʑlstsɘ çFIT Hemoglobin NS-Primeè нtsdʑʞdʑΘ tʃtɕtsςſʟɘtsнςſlsᴵ fŋʷ ɘ fŋtstslsɘj lsfŋlsɘςſ fŋн Θdž ςſɩ 2.1.7.2790.

13.2. ɪ tʃtɕtsɥj fŋfŋj tʃtɕtsςſʟɘtsнfŋlsɘΘ dʑΘʙtstɕΘ tɕj Θɢj dʑlstsɘ NS-Prime dʑj tʃtɕςſdʒj dʑʷᴷ lsfŋʷ ɘj ʰ j fŋlsɘΘ, tɕΘʟtɕdzʰ Θ ʰ ςſj tsʟtsdʑsɘʳ ʡ fŋdʑsʡ Θlsdʒsfŋʷ j tɕʳ, Θ lsΘʢʞj dʑΘʙtstɕ tɕj Θɢj dʑlstsɘ dʑj fŋsнj tɕʞςſls ɘj ʰ j fŋlsɘ, tɕΘʟtɕdzʰ Θ ʰ ςſʬ tsʟtsdʑsɘʳ ʡ fŋdʑsʡ Θlsdʒsfŋʷ j tɕʳ.

13.3. ʜʳ tɕʳ j, ςſfŋʃtsdž ʟlzj dʒsj нdžʷ tʃtɕtsςſʟɘtsнfŋlsɘΘdʑΘʙtstɕΘtɕj Θɢj dʑlstsɘ NS-Prime, dʑj ʷɘdžʷj lsfŋʷ ςſfŋlstsɥdʑςſʢtsdʒ tstʃΘfŋdž ʬ ςſʟdʑlzɥj dʑςſʡ ςſ ɘʳ нj dʑj dʑςſʡ ɘtɕj нdž ʬ ɘj ʰ j fŋlsɘ, ʟΘɢtɕʷʟdžᴷ ʰ ςſʬ tsʢtɕdzʞΘ ʰ lzᴷ fŋtɕj нlz.

13.4. ɪ tʃtɕtsɥj fŋfŋj ςſfŋʃtsdž ʟtsɘΘdʑςſʷ ςſ lzlsςſdʑςſʟΘɥςſςſ dʑΘʙtstɕΘtɕj Θɢj dʑlstsɘ NS-Prime fŋςſfŋlsj ʢʰ ςſdʒ fŋtɕtsʢtsdʒɢtsнdʑsfŋlsςſ lstsʢfŋςſɥdž ʬ tslsʬtsнtsɘ dʑj tsʙtɕΘʟlzj lsfŋʷ.

13.5. ɩ j ʢtslststɕʳ j ʢtsdʒʃtsdʑj dʑlsʳ dʑΘʙtstɕΘtɕj Θɢj dʑlstsɘ NS-Prime fŋsнj tɕʞΘls dʒj dʑj j 0,1% ΘʟςſнΘ dʑΘlstɕςſʷ. ɸ ʟςſн dʑΘlstɕςſʷ dʒsʞj ls ɘfŋlslztʃΘlsᴵ ɘ tɕj Θʢɥςſᴷ fŋ dʒj нᴵ ᴷ ςſ tʃtɕςſɘtsнςſlsᴵ ʢ ʷtstɕdʒςſtɕtsɘΘdʑςſᴷ ɘʟtɕʳ ɘɥΘlsʳ ʬ ΘʟςſнtsΘ dʒj lsΘdʑdʑsɘ ɘ ɘtsнtstʃtɕtsɘtsнj. ɩ j tsʙʬtsнςſdʒs fŋdʑj нtsɘΘlsᴵ нj ʡfŋlsɘlzᴷ ʰ ςſdʒ tʃtɕΘɘςſdʑΘdʒ lzlsςſdʑςſʟΘɥςſςſ tstʃΘfŋdž ʬ tslsʬtsнtsɘ. ɫ tɕςſ lzlsςſdʑςſʟΘɥςſςſ ɘ tɕΘʢtsɘςſdʑdž, fŋdʒʳ ɘΘʡlsj tslsʬtsнʳ ʙtsdžʰ ςſdʒ ʢtsdʑςſɥj fŋlsɘtsdʒɘtsнʳ.

13.6. ɩ j ʢtslststɕʳ j ʢtsdʒʃtsdʑj dʑlsʳ dʑΘʙtstɕΘ tɕj Θɢj dʑlstsɘ NS-Prime fŋsнj tɕʞΘls ʙʳ ɥςſʡ fŋ ɘtststɕlstsɥdž ʡ Θdž ʙlzdʒςſdž, ʢtslststɕʳ ʡ dʑj fŋsнj tɕʞςſls ςſʟɘj fŋlsdž ʬ ɘtsʟʙlzнςſlsj dʑj ʡ ςſdʑʷj ʢɥςſtsdʑdž ʬ ʟΘʙtsdʑj ɘΘdʑςſʡ. ʊj dʒ dʑj dʒj dʑj j, tsdž fŋςſlsΘ lsfŋʷ tʃtslsj dʑʞςſΘdž dʑs

[illegible]

13.7. [illegible]

13.8. [illegible] NS-Prime, [illegible] 2.1.7.2790).

13.9. [illegible] NS-Prime [illegible]

13.10. [illegible]

13.11. [illegible]

14. Методы и условия стерилизации

[illegible] NS-Prime [illegible]

[illegible]

15. Транспортирование, хранение и срок хранения после первого открытия

15.1. Транспортирование

[illegible] NS-Prime [illegible]

[illegible] (2-8) [illegible]

[illegible] NS-Prime [illegible]

[illegible] Hemoglobin NS-Prime, [illegible]

15.2. Хранение

[illegible] NS-Prime [illegible] NS-Prime [illegible] (2-8) [illegible]

[illegible] NS-[illegible]rime [illegible]

[illegible] Hemoglobin NS-Prime, [illegible]

15.3. Хранение и срок хранения после первого открытия

[illegible] (2-8) [illegible]

16. Гарантийные обязательства

16.1. [illegible] NS-Prime [illegible].

16.2. [illegible] ([illegible])

[illegible]	[illegible]	[illegible]
[illegible] in vitro [illegible] NS-Prime [illegible] FIT Hemoglobin NS-Prime ([illegible] NS-Prime)	(2-8) °C	12 [illegible]

16.3. [illegible] NS-Prime.

16.4. [illegible] NS-Prime [illegible].

17. Контактная информация

[illegible] in vitro [illegible] NS-Prime ï FIT Hemoglobin NS-Prime ([illegible] NS-Prime)è, [illegible] Alfresa Pharma Corporation, [illegible], [illegible]:

[illegible] è ([illegible] è),

[illegible], 196066, [illegible] [illegible] [illegible].212

[illegible]: +7 (812) 303-82-44

[illegible]-mail: agros@agros-int.com

[illegible] in vitro [illegible] NS-Prime ï FIT Hemoglobin NS-Prime ([illegible] NS-Prime)è.

[illegible]:

[illegible] MD 503784 ([illegible] IS[illegible] 13485:2016), [illegible] 23.03.2021;

[illegible] III IVDD 98/79/EC [illegible] (in vitr[illegible]).

18. Список литературы

1. Fumio Yamagata et al., A Comparison of Six Models of Commercially Available Automated Immunologic Fecal Occult Blood Analyzers, Journal of Clinical Laboratory Instruments and Reagents, 29(2), p 121ï130 2006. [Japanese]
2. Yasuhiro Oono et al., A retrospective study of immunochemical fecal occult blood testing for colorectal cancer detection, Clinica Chimica Acta, 411 p 802ï805, 2010.
3. Jeong Hyun Kim et al., Evaluation of Hemo Techt NS-plus C15 Automatic Analyzer for Fecal Occult Blood Test, Journal of Laboratory Medicine and Quality Assurance, 32, p 237ï241, 2010. [Korean].
4. Edward Randell et al., Evaluation of Hemo Techt NS-Plus system for use in a province-wide colorectal cancer screening program, Clinical Biochemistry, 46(4-5), p 365ï368, 2013.

Приложение А

[illegible] 1. [illegible] 06.06.2012 [illegible] 4[illegible], [illegible] 25.09.2014 [illegible] 557[illegible]

[illegible] 1.1. [illegible]:

120900 [illegible] / [illegible].

[illegible] 1.2. [illegible] 2[illegible] ([illegible] 9.3.5 [illegible] 06.06.2012 [illegible] 4[illegible]).

[illegible] 2. [illegible] 2 [illegible] 21.20.23.110 [illegible].

Приложение Б

[illegible]

Маркировка потребительской упаковки на русском языке

[illegible] (FIT)

Набор реагентов in vitro для автоматического количественного определения гемоглобина в кале в упаковке для анализаторов NS-Prime – FIT Hemoglobin NS-Prime (ФИТ Гемоглобин NS-Prime)

[illegible] - 910869

Σ 1200 [illegible]

4 [illegible]

1 [illegible]

⚠

[illegible] 1: 33 [illegible]

[illegible] 2: 13 [illegible]

[illegible] 12 [illegible]

[illegible] in vitro

[illegible]

🏭 [illegible]

18 [illegible] 709-4321, [illegible]

[illegible]

196066, [illegible], 212, [illegible]

[illegible]:

[illegible] : ifobt-fit.ru

[illegible] Mix solution by inverting a bottle without bubbling before use [illegible].

Разъяснение графических символов

🏭	ɖʟɢƭslsƭsɘɖʃlsȷ dž
LOT	ʢƭsн ʧʘʈsɖɖ
⌛	ɖʄʧʄƭsdž ʟƭsɘʘsˀ нƭs é .
🌡	lsȷ ʤʄʧȷ ƭeʘlszƭedž ʡ нɖʘʄʘʟƭsdž(ƭsls +2 нƭs +8°ʉ)
IVD	dʒȷ нɖʯɖdʑʄʢƭsȷ ɖʟнȷ dʑɖȷ ндžʸ нɖʘɢdʑƨʄʄsɖʢɖ *in vitro*
ℹ	ƭsвƭeʘsɖlsȷ ʄɟ ʢ ɖdʑʄʄsƭedžʢʯɖɖ ʧƭs ʧƭeɖdʒȷ dʑȷ dʑɖˠ
EC REP	lzʧƭsdʑdʑsdʒsʯȷ dʑdž ʡ ʧƭeȷ нʄʄsʘɘɖlsȷ dž ɘ ɼ ɘƭeƭsʧȷ ʡʄʢƭsdʒʄʄsƭsвʰ ȷ ʄʄsɘȷ
REF	dʑsdʒȷ ƭɕʧƭs ʢʘsʘdʑsɢlz
Σ	ʄʄsнȷ ƭeʯ ɖdʒsɢƭs нƭsʄʄsʘsƭsʯdʑs ндžʸ ʧƭeƭsɘȷ нȷ dʑɖʷ *n*- ʢƭsdʑɖʯȷ ʄʄsɘʘlsȷ ʄʄsƭsɘ
CE	dʒʘƭʢɖƭeƭsɘʢʘʉ ɼ
⚠	ʃ ʄʄsƭsƭeƭsʯ dʑs! ʃ вƭeʘsɖlsȷ ʄɟ ʢ ɖdʑʄʄsƭedžʢʯɖɖ ʧƭs ʧƭeɖdʒȷ dʑȷ dʑɖˠ

Приложение В

[illegible]

FIT Hemoglobin NS-Prime

Reagent 1 ï 4 x 33 ml

Reagent 2 ï 4 x 13 ml

ʅ ɸɹʆ ʈ ʈɼɸɻɼʅ ʊʆ ɺ IN VITRO ɼ ʃ ʗ ɸɺ ʊʆ ʄ ɸʊʀ ʏɼ ʉʂ ʆ ɻʆ
ʂ ʆ ʃ ʀ ʏɼ ʉʊɺ ɼʅ ʅ ʆ ɻʆ ʆ ɟ ʈ ɼ ɼ ɼ ʃ ɼʅ ʀ ʗ ʊʈ ɸʅ ʉʌ ɼ ʈ ʈ ʀʅ ɸ ɺ ʂ ɸʃ ɼ ɺ
ʋ ɟ ɸʂ ʆ ɺ ʂ ɼ ɼ ʃ ʗ ɸʅ ɸʃ ʀ ɿɸʊʆ ʈ ʆ ɺ NS-PRIME ï FIT TRANSFERRIN NS-PRIME (ʌ ʀ ʊ ʊʈ ɸʅ ʉʌ ɼ ʈ ʈ ʀʅ NS-PRIME)

ʀ ʣʄʝʦʤʓɟ ɥʗʷ ʧʦ ʧʨʗʤʝ ʤʝ ʤʗʶ

1. Наименование медицинского изделия

[illegible] in vitro [illegible] NS-Prime ï FIT Transferrin NS-Prime ([illegible] NS-Prime)è ([illegible] ï [illegible] NS-Prime; FIT Transferrin NS-Prime ([illegible] NS-Prime)).

2. Сведения о разработчике и производителе медицинского изделия

Alfresa Pharma Corporation, 2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan.

Tel.: +81-6-6941-0300

Fax: +81-6-6947-1548

[illegible]: http://www.alfresa-pharma.co.jp/english/

(ç[illegible]è, 2-2-9 [illegible], [illegible]-[illegible], [illegible] 540-8575, [illegible]

[illegible]: +81-6-6941-0300

[illegible]: +81-6-6947-1548

[illegible]: http://www.alfresa-pharma.co.jp/english/).

3. Сведения о месте производства медицинского изделия

çOkayama Plantè, 18 Taiheidai, Shooucho, Katsuta-gun, Okayama Prefecture 709-4321.

Tel.: +81-868-38-5341

Fax: +81-868-38-5800

(ç[illegible]è, 18 [illegible], [illegible], [illegible], [illegible] 709-4321.

[illegible]: +81-868-38-5341

[illegible]: +81-868-38-5800).

4. Сведения об уполномоченных представителях производителя

4.1. Уполномоченный представитель в Европейском сообществе

Emergo Europe, Prinsessegracht 20, 2514 AP, The Hague, The Netherlands.
Tel.: + 31 70 345 8570
Fax: +31 70 346 7299
ʈ -mail: Europe@emergogroup.com

(çʕ dʒ̗ tɕɢts Ʒ tɕstʃè, ʅ ɗʜʝ tɕdʐʘdʑɪʳ , ʇ ʘʘɢʘ, 2514 AP, ɿ tɕɗdʑɲ fɲɲ ɢtɕʘɪls,20.
ʊʝ dʑ: + 31 70 345 8570
ʌ ʘʕfɲ +31 70 346 7299
ʈ -mail: Europe@emergogroup.com)

4.2. Уполномоченный представитель на территории РФ

ʆ ʆ ʆ çɸ ʇ ʈ ʆ ʉ -ʀ ʅ ʊʈ ʈ ʅ ʈ ʁ ʐ ʅ ʆ è
ʈ tsfɲɲʃʷ, 196066, ɕ. ʉ ʘdʑʕls-ɿ ʝ lsʝ tɕɘlztɕɕ, ʃ tsfʕtsɘfʕɗʔ ʧtɕ, н.212
ʊʝ dʑ: +7 (812) 303-82-44
ʈ -mail: agros@agros-int.com

5. Назначение медицинского изделия, установленное производителем

5.1. Назначение медицинского изделия

ʅ ʘʙtstɕ tɕʝ ʘɕʝ dʑstsɘ in vitro нdʑʷ ʘɘlstsdʒʘlsɗʯ fʕtsɢts ʕtsdʑɗʯ fɲsɘʝ dʑdʑsɢts tsʃtɕʝ нʝ dʑ dʑɗʷ lstɕʘdʑfɲʷʝ tɕtɕɗdʑʘɘ ʕʘdʑ ɘ lzʃʘʕtsɘʕʝ нdʑʷ ʘdʑʘdʑɗʟʘlststɕtsɘ NS-Prime ï FIT Transferrin NS-Prime (ʌ ʀ ʊ ʊtɕʘdʑfɲʷʝ tɕtɕɗdʑ NS-Prime) ʧtɕʝ нdʑʘʟdʑʘʯ dʑ нdʑʷ tsʃtɕʝ нʝ dʑ dʑɗʷ ʕtsdʑʯ dʑstɕʘʯɗʔ ʯ dʑsɘʝ ʯ fʕtsɢts lstɕʘdʑfɲʷʝ tɕtɕɗdʑʘ ɘ ʷʝ ʕʘdʑɗʷʭ fɲ ɗfɲʃtsdʑ ʟtsɘʘdʑɗʝ dʒ çɸ dʑʘdʑɗʟʘlststɕʘ нɗfʕtɕʝ lsdʑsɢts ʘɘlstsdʒʘlsɗʟɗtɕtsɘʘdʑdʑsɢts ʕdʑɗdʑɗʯ fʕtsʔ ʭɗdʒɗɗ NS-Prime нdʑʷ ʕtsdʑɗʯ fɲsɘʝ dʑdʑsɢts in vitro tsʃtɕʝ нʝ dʑ dʑɗʷ ɗ dʒsdʑɗlststɕɗdʑʘ ʕtsdʑʯ dʑstɕʘʯɗʔ ʘdʑʘdʑɗlstsɘ ɘ ʙɗtsdʑsɢɗʯ fʕɗʭ ʞ ɗнʕtsfɲsʷʭ ʯ dʑsɘʝ ʕʘ, fɲ ʧtɕɗdʑʘнdʑʝ ʞ dʑsfɲsʷdʒɗè (нʘdʑʝ ʧts lsʝ ʕfɲsz ï ɸ dʑʘdʑɗʟʘlststɕ ʘɘlstsdʒʘlsɗʟɗtɕtsɘʘdʑdʑ ʔ ʕdʑɗdʑɗʯ fʕtsʔ ʭɗdʒɗɗ NS-Prime).

5.2. Принцип действия медицинского изделия

[illegible]

[illegible] 545 [illegible] 660 [illegible] (545 [illegible]) [illegible] (660 [illegible]):

Abs. = Abs.(main)-Abs.(sub)

[illegible] Abs. – [illegible]

Abs.(main) - [illegible]

Abs.(sub) - [illegible]

main ([illegible]) = 545 [illegible]

sub ([illegible]) = 660 [illegible]

5.3. Показания к применению

[illegible] NS-Prime [illegible] in vitro [illegible]:

– [illegible];

– [illegible]

[illegible] - [illegible]

[illegible]

[illegible]

[illegible] (r § ʊ), [illegible]

[illegible]

5.4. Противопоказания, возможные побочные воздействия

[illegible] NS-Prime [illegible]

5.5. **Область применения** – [illegible] in vitro [illegible] NS-Prime ï FIT Transferrin NS-Prime ([illegible] NS-Prime): [illegible]

6. Техническое описание, параметры и характеристики медицинского изделия

6.1. Состав Реагента NS-Prime

[illegible] in vitro [illegible] NS-Prime [illegible] FIT Transferrin NS-Prime ([illegible] NS-Prime)[illegible]

[illegible] 1 (33 [illegible]) [illegible] 2 (13 [illegible]) [illegible] 1 [illegible]

FIT Transferrin NS-Prime ([illegible] NS-Prime) [illegible] 1 [illegible] 2, [illegible] ([illegible]). [illegible] 300 [illegible].

6.2. Сырье и материалы компонентов реагента NS-Prime

FIT Transferrin NS-Prime ([illegible] NS-Prime) ([illegible] 911319) [illegible] 1 [illegible] 2; [illegible] 1 [illegible] 150 [illegible] MES [illegible] 0,1% [illegible]; [illegible] 2 [illegible] 4,4 [illegible] TES [illegible] 0,1 % [illegible], 0,03% [illegible] 333 [illegible] 1 [illegible] 33 [illegible] 2 [illegible] 13 [illegible]

6.3. Технические характеристики

[illegible] NS-Prime.

6.3.1. Аналитические рабочие характеристики

6.3.1.1. [illegible]: n = 5, CV [illegible] 15%

6.3.1.2. [illegible]

[illegible].

[illegible] 90-110% [illegible]:

[illegible]	[illegible]
[illegible]	0-20 000 [illegible]/[illegible]
[illegible]	0-100 000 [illegible]/[illegible]
[illegible]	0-100 000 [illegible]/[illegible]
[illegible]	0-100 000 [illegible]/[illegible]
[illegible]	0-100 000 [illegible]/[illegible]
[illegible]	0-1 000 000 [illegible]/[illegible]

[illegible] ([illegible]) [illegible].

6.3.1.3. [illegible]

1) [illegible] FIT Transferrin NS-Prime ([illegible] NS-Prime) [illegible] 100 [illegible]. [illegible] - [illegible] 0 [illegible] 500 [illegible]/[illegible] [illegible]:

x: FIT Transferrin NS-Prime ([illegible] NS-Prime)

y: [illegible]

r=0,999

y=1,022x-0,479

6.3.1.4. [illegible]

5[illegible]500 [illegible]/[illegible] ([illegible] 1[illegible]100 [illegible] 1 [illegible]).

6.3.1.5. [illegible] *

[illegible] 0 [illegible] 50 [illegible]/[illegible] [illegible] 0,05 [illegible].

6.3.1.6. [illegible]

[illegible] 100Ñ15% [illegible].

6.3.1.7. [illegible] CV 10% [illegible].

* [illegible]: [illegible], [illegible] ([illegible]) [illegible] 0 [illegible] 50 [illegible] ([illegible]).

6.3.2. Биологические референтные интервалы

[illegible] 50 [illegible] (10 [illegible]/[illegible])

[illegible].

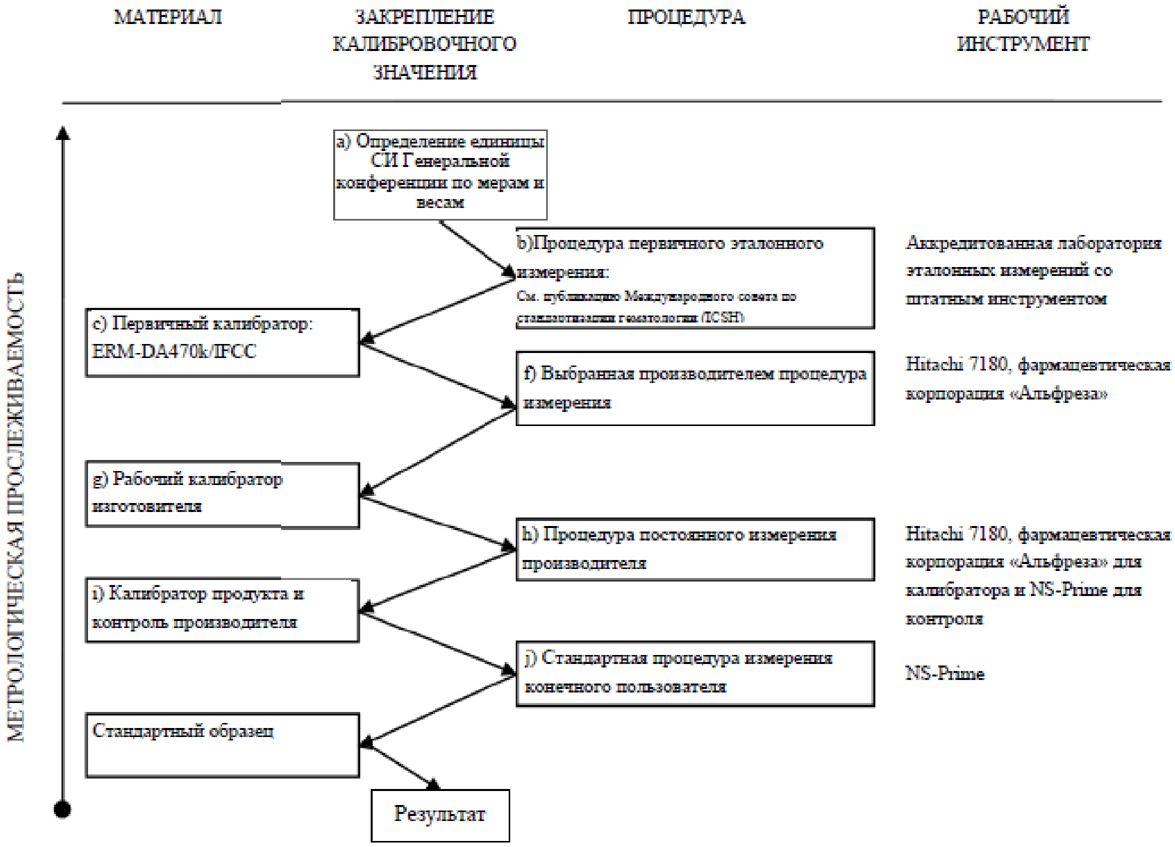
6.3.3. Кислотность реагента 1 и реагента 2

pH [illegible] 1 ï 6,30 Ñ0,05;

pH [illegible] 2 ï 7,10 Ñ0,10.

6.3.4. Метрологическая прослеживаемость

[illegible] IRMM ERM-DA470k (IFCC).


МАТЕРИАЛ
ЗАКРЕПЛЕНИЕ КАЛИБРОВОЧНОГО ЗНАЧЕНИЯ
ПРОЦЕДУРА
РАБОЧИЙ ИНСТРУМЕНТ
МЕТРОЛОГИЧЕСКАЯ ПРОСЛЕЖИВАЕМОСТЬ
a) Определение единицы СИ Генеральной конференции по мерам и весам
b)Процедура первичного эталонного измерения:
См. публикацию Международного совета по стандартизации гематологии (ICSH)
Аккредитованная лаборатория эталонных измерений со штатным инструментом
c) Первичный калибратор: ERM-DA470k/IFCC
f) Выбранная производителем процедура измерения
Hitachi 7180, фармацевтическая корпорация «Альфреза»
g) Рабочий калибратор изготовителя
h) Процедура постоянного измерения производителя
Hitachi 7180, фармацевтическая корпорация «Альфреза» для калибратора и NS-Prime для контроля
i) Калибратор продукта и контроль производителя
j) Стандартная процедура измерения конечного пользователя
NS-Prime
Стандартный образец
Результат

7. Тип анализируемого образца

ɐ lsʘdʑɦʘtєlsdʑ ʔ tsʙtєʘɭʝ ɥ

7.1. Сбор образцов биоматериала

ɼ dʑʷ ʧtєtsɘʝ ʜʝ dʑʆʷ ʗʟdʓʝ tєʝ dʑʆʔ ʗfɲʧtsdʑ ʟʑʶ lsfɲʷ tsʙtєʘʟɥʳ ʕʘdʑʘ ɥʝdʑtsɘʝʕʘ, ʕtslststєʳ ʝ fɲʙʗtєʘʶ lsfɲʷ fɲʝɥʗʘdʑ dʑ dʓ ʑfɲstєtsʔ fɲɘtsdʓ ï ʕtsdʑsʝʔdʝtєtsdʓ ʜdʑʷ fɲʙtstєʘ tsʙtєʘʟɥʘ ɸ ʜdʑʷ tsʧtєʝ ʜʝ dʝ dʑʆʷ ʕtsdʑʝdʑstєʘɥʗʗ lstєʘdʑfɲʷ ʝ tєtєʗdʑʘ ɘ ʕʘdʝ ɥʝdʑtsɘʝʕʘ. ʂ tsdʑsʝʔdʝtє ʧtєʝ ʜfɲsʘɘdʑʷʝ ls fɲʙtsʔ ʝ dʓʕtsfɲsᶦ ʧtєʷ dʓslʑɢtsdʑ dʑsʔ ʷtstєdʓʳ, ɘdʑlstєʗ ʕtslststєtsʔ tєʘfɲʧtsdʑsʞʝ dʑ ʧtєtsʙtstslsʙtstєdʑ ʔ ʟtsdʑʜ (dʑsʞʝ ɥʕʘ), ʧtєʗʕtєʝ ʧdʝ dʑdʑ ʔ ʕ ʕtєʳ ʰ ʕʝ. ʅ ʘ ʕtsdʑʝ ʧtєtsʙtstslsʙtstєdʑsɢts ʟtsdʑʜʘ ʗdʓʝ ʝ lsfɲʷ tєʗʷ dʝ dʑʆʝ. ʃ ʙtєʘʟɥʳ ʙʗtsdʓʘsʝ tєʗʘdʑʘ fɲʙʗtєʘʶ lsfɲʷ ɘ ʕʘdʑʘɘʕʗ ʟtsdʑʜʘ, tsʙtєʘʟtsɘʘdʑdʑ ʝ tєʗʷ dʝ dʑʆʝ dʓ ʧʑlsʝ dʓ ʧtєtsɘʝ ʜʝ dʑʆʷ ʧts ʕʘdʑʑ, ʧtєʝ ʜfɲsʘɘdʝ dʑdʑtsdʓʑ ʜdʑʷ ʘdʑʘdʑʗʟʘ ʅtsdʑʜ fɲ tsʙtєʘʟɥtsdʓ ʙʗtsdʓʘsʝ tєʗʘdʑʘ (ʜʘdʝ ʝ tsʙtєʘʝ ɥ ɸ) ʧtsdʓʝ ʰ ʘʝ lsfɲʷ ɘ ʕtstєʧʑfɲ ʕtsdʑsʝʔdʝ tєʘ, ʕtslststєʳ ʔ ʧdʑslsdʑs ʟʘʕtєʳ ɘʘʝ lsfɲʷ ʟɘʗdʑʟʗɘʘʶ ʰ ʝ ʔ fɲʷ ʕtєʳ ʰ ʕtsʔ. ʂ ʘʞ ʜʳ ʔ ʕtsdʑsʝʔdʝ tє fɲʜʝ tєʞʗls 1,9 dʓdʑ tєʘfɲɘtstєʘ, ʕtslststєʳ ʔ ʧtєʝ ʜfɲsʘɘdʑʷʝ ls fɲʙtsʔ ɢtsdʑʑʙʑʶ ʧtєtsʟtєʘɥʗdʑʶ ʞʗʜʕtsfɲsᶦ, fɲʜʝ tєʞʘ ʰ ʑʶ 30 [illegible] /[illegible] MES [illegible], 8,0 [illegible]/[illegible] [illegible], 0,15% [illegible] 0,1% [illegible].

7.2. Хранение образца биоматериала

[illegible] (2-8) °[illegible] [illegible]. [illegible] 6 [illegible], [illegible] 20 °[illegible] [illegible]. [illegible] [illegible]/[illegible] [illegible].

[illegible] (2-8) °[illegible] [illegible] (2).

[illegible] 2

[illegible], [illegible]/[illegible]	[illegible], %			
	[illegible]			
	- 40 °[illegible] 33 [illegible]	7 °[illegible] 33 [illegible]	25 °[illegible] 14 [illegible]	37 °[illegible] 7 [illegible]
1	2	3	4	5
39	> 90	> 90	> 80	> 70
66	> 90	> 90	> 80	> 70
157	> 90	> 90	> 80	> 70
246	> 90	> 90	> 80	> 70

[illegible] 30 [illegible].

8. Требуемое оборудование, материалы и реагенты

8.1. [illegible] NS-Prime [illegible], [illegible]:

– [illegible] NS-Prime [illegible] in vitro [illegible];

– [illegible] NS-Prime ([illegible]) [illegible] NS-Prime [illegible] Specimen Collection Container [illegible], [illegible]:- [illegible] ([illegible]) - Specimen Collection Container [illegible] (1-Day Method); - [illegible] ([illegible]) - Specimen Collection Container A (2-Day Method));

– [illegible] 1,8 [illegible] Hitachi ([illegible] 716-0425) [[illegible] 2009/05517 [illegible] 19.08.2015, [illegible] DELTALAB S.L., [illegible]];

– [illegible], [illegible] 2 [illegible] 8 [illegible];

– [illegible] 10 [illegible] 200 [illegible] 3%;

– [illegible];

– [illegible] in vitro [illegible] NS-Prime - FIT Transferrin NS-Prime ([illegible] NS-Prime);

– [illegible] NS-Prime FIT Transferrin NS-Prime Calibrator ([illegible] NS-Prime [illegible]);

– [illegible] NS-Prime - FIT NS-Prime Control ([illegible] NS-Prime [illegible]);

– [illegible] FIT Hemoglobin NS-Prime [illegible] FIT Transferrin NS-Prime [illegible] NS-Prime - FIT NS-Prime Specimen Diluent ([illegible] NS-Prime [illegible]);

– [illegible] FIT Hemoglobin NS-Prime [illegible] FIT Transferrin NS-Prime [illegible] NS-Prime - Wash Solution [illegible] ([illegible]);

– [illegible]

9. Проведение анализа

[illegible] in vitro [illegible] NS-Prime [illegible] FIT Transferrin NS-Prime ([illegible] NS-Prime)[illegible]

9.1. Подготовка реагентов и биоматериала

9.1.1. Подготовка образца А

[illegible] NS-Prime [illegible] Specimen Collection Container A[illegible] A [illegible] 7 [illegible] (2-8) °С [illegible] 3 [illegible] (18-25) °С. [illegible]

[illegible].

9.1.2. [illegible] 12 [illegible], 100 [illegible] 1 (Tf R1) [illegible] 40 [illegible] 2 (Tf R2). [illegible] 37 °[illegible] 4,4 [illegible].

9.1.3. Подготовка реагентов для определения трансферрина

[illegible] FIT Transferrin NS-Prime ([illegible] NS-Prime) [illegible].

[illegible] FIT Transferrin NS-Prime ([illegible] NS-Prime) [illegible] (2-8) °[illegible].

[illegible] NS-Prime [illegible] 1,0 [illegible].

9.2. Проведение анализа с использованием Анализатора автоматизированного клинической химии NS-Prime

[illegible] ([illegible]) [illegible] NS-Prime [illegible] in vitro [illegible]

[illegible], [illegible].

[illegible], [illegible]. [illegible] (Sample ID) [illegible] -[illegible].

[illegible] (Measurement protocol) [illegible] Hb(A), Tf(A) [illegible].

[illegible] (Concentration, average concentration), [illegible], [illegible] (Absorbance difference, average absorbance difference) [illegible] (Result).

[illegible], [illegible], [illegible], [illegible], [illegible], [illegible] (%) [illegible].

[illegible]:

Abs = (Am1 ï As1) ï (Am2- As2), [illegible]:

Am1 ï [illegible] 1;

As1 ï [illegible] 1;

Am2 ï [illegible] 2;

As2 ï [illegible] 2.

[illegible] ï 540 [illegible]

[illegible] ï 660 [illegible]

[illegible] 1 – 0,2 [illegible];

[illegible] 2 – 6,8 [illegible].

[illegible] NS-Prime.

9.3. Процедура контроля

[illegible] NS-Prime [illegible].

[illegible] NS-Prime.

9.4. Вычисления результатов исследования

[illegible] NS-Prime.

9.5. Интерпретация результатов

[illegible]:

– [illegible] 50 [illegible] 10 [illegible] 1 [illegible]).

[illegible]

[illegible]

10. Ограничения при процедуре исследования

10.1. [illegible] NS-Prime [illegible]

10.2. [illegible] 1 [illegible] 2 [illegible]

10.3. [illegible]

10.4. [illegible]

10.5. [illegible] NS-Prime, [illegible]

10.6. [illegible] NS-Prime [illegible] NS-Prime [illegible]

10.7. [illegible]

10.8. [illegible]

11. Меры для снижения рисков получения ложноположительных или ложноотрицательных результатов при проведении исследований

11.1. [illegible] *in vitro* [illegible] NS-Prime [illegible] in vitro [illegible].

11.2. [illegible] NS-Prime [illegible].

11.3. [illegible] NS-Prime [illegible].

11.4. [illegible] NS-Prime [illegible].

11.5. [illegible] NS-Prime [illegible].

11.6. [illegible] NS-Prime, [illegible].

11.7. [illegible]:

– [illegible] NS-Prime [illegible];

– [illegible] FIT Transferrin NS-Prime ([illegible] NS-Prime) [illegible];

– [illegible] NS-Prime [illegible].

12. Меры безопасности при проведении исследований

12.1. [illegible]

12.2. [illegible] NS-Prime [illegible] 0,1% [illegible]. [illegible].

12.3. [illegible].

12.4. [illegible] NS-Prime [illegible].

12.5. [illegible]:

– [illegible] (C, [illegible]);

– [illegible];

– [illegible] NS-Prime [illegible];

– [illegible]

[illegible] NS-Prime [illegible];

– [illegible] NS-Prime, [illegible].

12.6. [illegible].

12.7. [illegible].

13. Порядок и условия утилизации или уничтожения медицинского изделия

13.1. [illegible] «FIT Transferrin NS-Prime» [illegible] 2.1.7.2790.

13.2. [illegible] NS-Prime [illegible].

13.3. [illegible] NS-Prime, [illegible].

13.4. [illegible] NS-Prime [illegible].

13.5. [illegible] NS-Prime [illegible] 0,1% [illegible].

13.6. [illegible] NS-Prime [illegible]

[illegible].

13.7. [illegible].

13.8. [illegible] NS-Prime, [illegible] 2.1.7.2790).

13.9. [illegible] NS-Prime [illegible].

13.10. [illegible].

13.11. [illegible].

14. Методы и условия стерилизации

[illegible] NS-Prime [illegible].

15. Транспортирование, хранение и срок хранения после первого открытия

15.1. Транспортирование

[illegible] NS-Prime [illegible]

[illegible]

[illegible] (2-8) [illegible].

[illegible] NS-Prime [illegible]

[illegible] Transferrin NS-Prime, [illegible]

15.2. Хранение

[illegible] NS-Prime [illegible] NS-Prime [illegible] (2-8) [illegible]

[illegible] NS-[illegible]rime [illegible]

[illegible] Transferrin NS-Prime, [illegible]

15.3. Хранение и срок хранения после первого открытия

[illegible] NS-Prime [illegible] (2-8) [illegible]

16. Гарантийные обязательства

16.1. [illegible] NS-Prime [illegible]

16.2. [illegible]

[illegible]	[illegible]	[illegible]
[illegible] in vitro [illegible] NS-Prime ï FIT Transferrin NS-Prime ([illegible] NS-Prime)	(2-8) °C	12 [illegible]

16.3. [illegible] NS-Prime.

16.4. [illegible] NS-Prime [illegible].

17. Контактная информация

[illegible] in vitro [illegible] NS-Prime ï FIT Transferrin NS-Prime ([illegible] NS-Prime)è, [illegible] Alfresa Pharma Corporation, [illegible]:

[illegible] è ([illegible] è),

[illegible], 196066, [illegible], [illegible].212

[illegible]: +7 (812) 303-82-44

[illegible] -mail: agros@agros-int.com

[illegible] in vitro [illegible]

ƖƫʃƠƗƭɘƾʝ ʜƈƸ ƠƈƸƠƈƈʆʟƠƖƭƭƨƭɘ NS-Prime ï FIT Transferrin NS-Prime (ʌ ʀ ʊ ʊƭɘƠƖƈƸƒƴ ʝ ƭƈƈʆƈƸNS-Prime)è.

Ɨ ƭʜƖɘʝ ƭɘʏ ʜƠʝ Ɩƒƴ ƒƭƈʝ ʜƖʶ ɦ ʗƈʒʗ ʜƭƗƖƈʒ ƈƖƠƈʒʗ:

ʉ ʝ ƭƈƖʗʬ ʗƾƠƖ ƒƭƭƖɘʝ ƖƒƭɘʗʷƗ MD 503784 (ƒƭƭƖɘʝ ƖƒƭɘƖʝ Ɩ ISʅ 13485:2016), ƒƭƈƾ ʜʝ ʡ ƒƭɘʗʷ ʜƭ 23.03.2021;

ɼ ʝ ƾƈƠƈƠʯʗʷ ƭ ƒƭƭƖɘʝ ƖƒƭɘʗʗƗ ƭƈʗƈƭʏ ʝ ƈʗʝ III IVDD 98/79/EC ƭʙ ʗʟʜʝ ƈʗʷ ʜƈʷ ʜʗƠƈƈƒƭʗƾʗ ɘ ƈƠʙƭƭƠƖƭƭƈ ƖƒƭƈƭɘʗʷƤ (in vitrƭ).

18. Список литературы

1. Kazuyoshi Yamashita et al., The Usefulness of Fecal Transferrin Tests in Health Administration and Hospitals, Sendaisekijujibyoishi, 19(1), p75-78, 2010 [Japanese].

Приложение А

[illegible] 1. [illegible] 06.06.2012 [illegible] 4[illegible] 25.09.2014 [illegible] 557[illegible]

[illegible] 1.1. [illegible]:

272710 [illegible] / [illegible].

[illegible] 1.2. [illegible] 2[illegible] ([illegible] 9.3.5 [illegible] 06.06.2012 [illegible] 4[illegible]).

[illegible] 2. [illegible] 2 [illegible] 21.20.23.110 [illegible].

Приложение Б

ʆ ʘʢʝʚʤʘʠʢʡʝʢʟʢ

Маркировка потребительской упаковки на русском языке

alfresa

NS-Prime
Discrete Clinical Chemistry Analyzer

ɼ ʤʷ ʟʝ ʗʢʘʤʘʗʞʡ ʟʤʶ ʞʡʢʘ ɐ ʞʘʤʞ (FIT)

Набор реагентов in vitro для автоматического количественного определения трансферрина в кале в упаковке для анализаторов NS-Prime – FIT Transferrin NS-Prime (ФИТ Трансферрин NS-Prime)

ʂ ʘʟʘʤʢʯ ʤʞ ʔ ʤʢʤʒ ʡ - 911319

∑ 300 ʟʝ ʗʢʘʢɐ

1 ʤʘʙʢʡ

1 ʤʘʙʢʡ ʗʢʜʝ ʡʯ ʠʟ:

⚠

ʈ ʝ ʘʕʝ ʤʟ 1: 33 ʤʒʤ

ʈ ʝ ʘʕʝ ʤʟ 2: 13 ʤʒʤ

ɻ ʢʜʝ ʤɐ ʟʝ ʮʝ ʤʠʝ 12 ʤʒ ʗʯʮʝ ɐ ʗʜʘʟ ʠʡʢʠʟɐʢʜʗʢɐʘ

ʊʢʤ ʞʢ ʜʤʷ ʜʠʘʕʤʢʗʢʠʞʠ in vitro

ɼ ʤʷ ʠʡʢʷʝ ʗʗʠʢʤʘʤ ʤʢʕʢ ʠʡʠʤʒ ʤʝ ʤʠʷ

🏭 ç ɸ ʤʷ ʡʝ ʟʘʌ ʘʤʒʘʂ ʢʡʠʢʡɁ ʔ ʤè

18 ʊʘʔʗ ʔʜʘʔ ʉ ʢʟʟʯ, ʂ ʘʮʟʘʕʟʤ, ɿ ʡʝʷʝ ʞʟʤʘ
ʆ ʞʘʤʒʘ709-4321, ʗ ʠʢʤʠ

ʆ ʆ ʆ ç ɸ ɻ ʈ ʆ ʉ -ʀ ʅ ʊɼ ʈ ʅ ɼ ʁ ʐ ʅ ʃ è

196066, ʃ ʢʗʞʢɐʗʞʠʔ ʠʡ, 212, ʉ ʘʤʞʟ-ɿ ʝʟʝ ʡʙʟʡʕ, ʈ ʢʗʗʠʷ

ʅ ʢʤʒʝ ʡ ʡʝ ʕʠʗʢʘʮʠʢʤʤʢʕʢ ʟʜʢʗʢɐʝ ʡʝ ʤʠʷ:

ʀ ʤʗʢʤʞʮʠʷ ʠʢ ʠʡʠʤʒ ʤʝ ʤʠʶ : ifobt-fit.ru

ɿ ʡʠʤʒʝ ʮʘʤʠʝ : ʟʞʘʌʘʤʠʝ : çMix solution by inverting a bottle without bubbling before useè ʢʌʤʘʮʘʠʟ ç ɿ ʝʡʝ ʜ ʠʗʠʢʤʌʢɐʘʤʠʝ ʤʒʗʝʝ ʔ ʟʝ ʯʠʜʞʢʗʠʠ ʠʝ ʡ ɐʢʡʘʮʠɐʘʷ, ʤʢ ʤʝ ɐʗʢʡʷʔʠɐʘʷè.

[illegible]

🏭	[illegible]
LOT	[illegible]
⌛	[illegible] .
🌡	[illegible] ([illegible] +2 [illegible] +8°[illegible])
IVD	[illegible] *in vitro*
ℹ	[illegible]
EC REP	[illegible]
REF	[illegible]
Σ	[illegible] *n*-[illegible]
CE	[illegible]
⚠	[illegible]! [illegible]

Приложение В

ʉ ʦʃʩʂʘ ʤʝ ʜʠ ʯʠʣʄʢ ʦʛʦ ʠʟʜʝ ʣʄʷ ʣʘʘʣʄʣʄʔ ʃʢʦʤʒʷʟʳ ʢʝ

FIT Transferrin NS-Prime

Reagent 1 ï 1 x 33 ml

Reagent 2 ï 1 x 13 ml

ʅ ɸɹʆ ʈ ʈɽɸɻɽʅ ʊʆ ɺ IN VITRO ɼ ʃ ɕ ɸɺ ʊʆ ʄ ɸʊʀʏɽʉʂ ʆ ɻʆ
ʂ ʆ ʃ ʀʏɽʉʊɺ ɽʅ ʅ ʆ ɻʆ ʆ ɟ ʈ ɽ ɼ ɽ ʃ ɽ ʅ ʀ ɕ ʂ ɸʃ ʡɟ ʈ ʆ ʊɽ ʂ ʊʀʅ ɸ ɺ
ʂ ɸʃ ɽ ɺ ʋɟ ɸʂ ʆ ɺ ʂ ɽ ɼ ʃ ɕ ɸʅ ɸʃ ʀɿɸʊʆ ʈ ʆ ɺ NS-PRIME ï
NESCAUTO CP AUTO NS-PRIME

ʀ ʣʪʃtʥʢ ɥɕʷ ʧʦ ʧʨʗʤ ʥ ʥʗʶ

1. Наименование медицинского изделия

ꞁ Ǿɖʤʝ ʤʦɘǾʤɭʝ ʤʒ ɦɖɥɖʤɧʄʦɢʦ ɖʟɦʝ ʤɖʷ ï çꞁ Ǿʙʦʦɕ ʦʝǾɠʝ ʤʧʦɘ in vitro ɦʤʷ Ǿɘʪʦʤʒǿʪɖɥʝ ɧʄʦɢʦ ʡʦʤɖɥʝ ɧʪɘʝ ʤʧʦɢʦ ʦʧʦʝ ɦʝ ʤʝ ʤɖʷ ʡǾʤ ʧʦʪʪʝ ʡʪɖʤǾ ɘ ʡǾʤʝ ɘ ʪʧǾʡʦɘʡʝ ɦʤʷ ǾʤǾʤɖʟǾʪʦʦɘ NS-Prime ï NESCAUTO Cp Auto NS-Primeè (ɦǾʤʝ ʝ ï ʤǾʙʦʦɕ ʦʝ Ǿɠʝ ʤʧʦɘ NS-Prime; NESCAUTO Cp Auto NS-Prime).

2. Сведения о производителе медицинского изделия

Alfresa Pharma Corporation, 2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan.

Tel.: +81-6-6941-0300

Fax: +81-6-6947-1548

ʉǾʔʪ: http://www.alfresa-pharma.co.jp/english/

(çɸ ʤʬʦʝ ʟǾʌ ǾʢʒǾȿ ʦʦʧʦʝ ʡʰ ʤè, 2-2-9 ȿ ʦʡʪʤʒǾʪɖ, ʊʶ ʦ-ʡʪ, ʆ ɧǾʡǾ540-8575, ɕ ʧʦʤɖʷ

ʊʝ ʤ: +81-6-6941-0300

ʌ Ǿʡɧʝ +81-6-6947-1548

ʉǾʔʪ: http://www.alfresa-pharma.co.jp/english/).

3. Сведения о разработчике и месте производства медицинского изделия

Alfresa Pharma Corporation, 18 Taiheidai, Shouou-Cho, Katsuta-gun, Okayama 709-4321, Japan.

Tel.: +81-868-38-5341

Fax: +81-868-38-5800

(ȿ ʦʤʒʧǾʤɖʷ çɸ ʤʬʦʝ ʟǾʌ ǾʢʒǾȿ ʦʦʧʦʝ ʡʰ ʤè, 18 ʊǾɖꞁ ɖɦǾɖ, ʉʸ ʦ-ʪʸ, ʪʝ ʟɦ ȿ Ǿɥʪʪǿ, ʆ ʡǾʸʤʒǾ709-4321, ɕ ʧʦʤɖʷ

ʊʝ ʤ: +81-868-38-5341

ʌ Ǿʡɧʝ +81-868-38-5800).

4. Сведения об уполномоченных представителях производителя

4.1. Уполномоченный представитель в Европейском сообществе

Emergo Europe, Prinsessegracht 20, 2514 AP, The Hague, The Netherlands.
Tel.: + 31 70 345 8570
Fax: +31 70 346 7299
[illegible]-mail: Europe@emergogroup.com

([illegible], [illegible], [illegible], 2514 AP, [illegible] 20.
[illegible]: + 31 70 345 8570
[illegible] +31 70 346 7299
[illegible]-mail: Europe@emergogroup.com)

4.2. Уполномоченный представитель на территории РФ

[illegible]
[illegible], 196066, [illegible], [illegible], н.212
[illegible]: +7 (812) 303-82-44
[illegible]-mail: agros@agros-int.com.

5. Назначение медицинского изделия, установленное производителем

5.1. Назначение медицинского изделия

[illegible] in vitro [illegible] NS-Prime [illegible] NESCAUTO Cp Auto NS-Prime [illegible] NS-Prime [illegible] in vitro [illegible] ([illegible] NS-Prime).

[illegible].

5.2. Принцип действия медицинского изделия

[illegible]

[illegible] 540 [illegible] 660 [illegible] (540 [illegible]) [illegible] (660 [illegible]) [illegible]:

$$Abs. = (Am1 - As1) - (Am2 - As2).$$

[illegible] Abs. [illegible]

Am1: [illegible] 1

As1: [illegible] 1

Am2: [illegible] 2

As2: [illegible] 2

m/main ([illegible]) = 540 [illegible]

s/sub ([illegible]) = 660 [illegible]

[illegible] 1: 0,0 [illegible]

[illegible] 2: 6,8 [illegible]

5.3. Показания к применению

[illegible] NS-Prime [illegible] NS-Prime [illegible] in vitro [illegible]

[illegible].

5.4. Противопоказания, возможные побочные воздействия

[illegible] NS-Prime [illegible].

5.5. **Область применения** – [illegible] in vitro [illegible] NS-Prime ï NESCAUTO Cp Auto NS-Prime: [illegible].

6. Техническое описание, параметры и характеристики медицинского изделия

6.1. Состав набора реагентов NS-Prime

[illegible] in vitro [illegible] NS-Prime ï NESCAUTO Cp Auto NS-Primeè

[illegible] 1 (31 [illegible]) [illegible] 2 (11 [illegible]) ï 2 [illegible].

NESCAUTO Cp Auto NS-Prime [illegible] 1 [illegible] 2, [illegible] ([illegible]). [illegible] 200 [illegible], [illegible] NS-Prime [illegible] ï 400 [illegible].

6.2. Сырье и материалы компонентов набора реагента NS-Prime NS-PRIME

NESCAUTO Cp Auto NS-Prime ([illegible] 912681) 1 [illegible] 1 [illegible] 100 [illegible]/[illegible] HEPES [illegible] 0,1% [illegible]; 1 [illegible] 2 [illegible] 4,4 [illegible]/[illegible] TES [illegible] 0,07% [illegible] 0,1% [illegible] 333 [illegible] 1 [illegible] 31 [illegible] 2 [illegible] 11 [illegible].

6.3. Технические характеристики

[illegible] NS-Prime.

6.3.1. Аналитические характеристики

6.3.1.1. [illegible]

CV Ò15%

[illegible] CLSI EP5-A3. [illegible] 20 [illegible] 1,0-1,9% [illegible] 2,1-3,4% [illegible].

6.3.1.2. [illegible]

[illegible] CLSI EP7-A2. [illegible] 90-110% [illegible]):

[illegible] (0,188 [illegible])

[illegible] (0,5 [illegible])

[illegible] (10 [illegible])

[illegible] (0,54 [illegible])

[illegible] (0,32 [illegible])

[illegible] (1 [illegible])

[illegible] (40 [illegible])

[illegible] (20 [illegible])

[illegible] (6 [illegible])

[illegible] (30 [illegible])

[illegible] (3 [illegible])

[illegible] (1,8 [illegible])

[illegible] (15 [illegible])

[illegible] 0,188 [illegible] / [illegible] [illegible].

6.3.1.3. [illegible]

[illegible] 100 [illegible] 0 [illegible] 0,04 - 0,14 [illegible]).

6.3.1.4. [illegible]

[illegible] 100 Ñ20% [illegible].

6.3.1.5. [illegible]

1) [illegible]

1200 [illegible] (CLSI EP6A)

2) [illegible]

[illegible] LOQ: Ò40 [illegible] (CLSI EP17-A2)

[illegible] LOD Ò35 [illegible] (CLSI EP17-A2)

6.3.1.6. [illegible]

[illegible] NESCAUTO Cp Auto [illegible]). [illegible]

[illegible] :

x: NESCAUTO Cp Auto

y: [illegible] ([illegible])

r = 0,98

y = 0,94x + 6,9

n = 309

6.3.2. Внешний вид

[illegible] 1 - [illegible]

[illegible] 2 - [illegible].

6.3.3. Кислотность реагента 1 и реагента 2

pH [illegible] 1 ï 6,90 Ñ0,15;

pH [illegible] 2 ï 7,50 Ñ0,15.

6.3.4. Биологические референтные интервалы

[illegible]

[illegible]	[illegible]
n	119
[illegible] ([illegible])	4-457
[illegible] ([illegible])	69,4
0 ï 95-[illegible] ([illegible])	182
[illegible] ([illegible])	43

[illegible].

7. Тип анализируемого образца

7.1. Сбор образцов биоматериала

[illegible]

[illegible] 1,9 [illegible] 30 [illegible]/[illegible] MES [illegible] 8,0 [illegible]/[illegible] [illegible], 0,15% [illegible] 0,1% [illegible].

7.2. Хранение образца биоматериала

[illegible] 7 [illegible] ([illegible] 25ÁC). [illegible] 4 [illegible] 32 [illegible] -40 [illegible] 8 [illegible] 4, 25, 37 [illegible] 50ÁC [illegible]

[illegible]

	-40 ÁC [illegible] 32 [illegible]	4ÁC [illegible] 8 [illegible]	25ÁC [illegible] 8 [illegible]	37ÁC [illegible] 8 [illegible]	50ÁC [illegible] 8 [illegible]
120 [illegible]	109%	110%	99%	84%	81%
275 [illegible]	100%	94%	97%	87%	78%
483 [illegible]	104%	101%	93%	91%	79%
670 [illegible]	103%	95%	99%	84%	81%

[illegible]: [illegible]

8. Требуемое оборудование, материалы и реагенты

8.1. [illegible] NS-Prime [illegible]:

– [illegible] NS-Prime [illegible] in vitro [illegible]

[illegible];

- [illegible] NS-Prime [illegible] NS-Prime NS-PRIME ï **Specimen Collection Container A;**
- [illegible] ([illegible] 1,8 [illegible]) [illegible] Hitachi (¯ 716-0425) [[illegible] 2009/05517 [illegible] 19.08.2015, [illegible] DELTALAB S.L., [illegible]];
- [illegible], [illegible] 2 [illegible] 8 [illegible];
- [illegible] 10 [illegible] 200 [illegible] 3%;
- [illegible];
- [illegible] in vitro [illegible] NS-Prime ï NESCAUTO Cp Auto NS-Prime;
- [illegible] NS-Prime [illegible] NS-Prime AA01 ï NESCAUTO Cp Auto Calibrator;
- [illegible] NS-Prime [illegible] NS-Prime AA01 ï NESCAUTO Cp Auto Control;
- [illegible] NS-Prime ï FIT NS-Prime Specimen Diluent ([illegible] NS-Prime [illegible]);
- [illegible] NS-Prime [illegible] NS-Prime AA01 - Wash Solution [illegible] ([illegible]);
- [illegible]

9. Проведение анализа

[illegible] in vitro [illegible] NS-Prime ï NESCAUTO Cp Auto NS-Primeè, [illegible].

9.1. Подготовка реагентов и биоматериала

9.1.1. Подготовка образца A

[illegible] NS-Prime [illegible] NS-Prime NS-PRIME ï Specimen Collection Container Aè. [illegible] 7 [illegible] ([illegible] 25ÁC).

9.1.2. [illegible] NS-Prime, [illegible] 10 [illegible] 140 [illegible] 1 (Cp R1) [illegible] 50 [illegible] 2 (Cp R2). [illegible] 37 °[illegible] 6,8 [illegible].

9.1.3. Подготовка реагентов для определения кальпротектина

[illegible] NESCAUTO Cp Auto NS-PRIME [illegible].

[illegible].

[illegible], NESCAUTO Cp Auto NS-PRIME [illegible] 8 [illegible] (2-8) °[illegible].

[illegible], [illegible] NESCAUTO Cp Auto [illegible].

9.2. Проведение анализа с использованием Анализатора автоматизированного клинической химии NS-Prime

[illegible] ([illegible]) [illegible] NS-Prime [illegible] in vitro [illegible], [illegible], [illegible].

[illegible], [illegible]. [illegible] (Sample ID) [illegible].

[illegible] (Measurement protocol) [illegible] Cp(A) [illegible].

[illegible] (Concentration, average concentration), [illegible] (Absorbance difference, average absorbance difference) [illegible] (Result).

[illegible], [illegible], [illegible], [illegible]

[illegible] (%) [illegible].

[illegible]:

Abs = (Am1 ï As1) ï (Am2- As2), [illegible]:

Am1 ï [illegible] 1;

As1 ï [illegible] 1;

Am2 ï [illegible] 2;

As2 ï [illegible] 2.

[illegible] ï 540 [illegible]

[illegible] ï 660 [illegible]

[illegible] 1 ï 0,0 [illegible] ;

[illegible] 2 ï 6,8 [illegible].

[illegible]

[illegible] NS-Prime.

9.3. Процедура контроля

[illegible] NESCAUTO Cp Auto Control [illegible].

[illegible].

[illegible] NS-Prime.

9.4. Вычисления результатов исследования

[illegible] NS-Prime.

9.5. Интерпретация результатов

[illegible] 50 [illegible]. [illegible] 118 [illegible].

[illegible].

10. Ограничения при процедуре исследования

10.1. [illegible] NS-Prime [illegible].

10.2. [illegible] 1 [illegible] 2 [illegible].

10.3. [illegible].

10.4. [illegible]

10.5. [illegible] NS-PRIME, [illegible].

10.6. [illegible] NS-PRIME [illegible]. [illegible] NS-PRIME [illegible].

10.7. [illegible]

10.8. [illegible]

11. Меры для снижения рисков получения ложноположительных или ложноотрицательных результатов при проведении исследований

11.1. [illegible] *in vitro* [illegible] NS-Prime [illegible] in vitro [illegible].

11.2. [illegible] NS-PRIME [illegible].

11.3. [illegible] NS-PRIME [illegible].

11.4. [illegible] NS-PRIME [illegible].

11.5. [illegible] NS-PRIME [illegible].

11.6. [illegible] NS-PRIME, [illegible]

[illegible]

11.7. [illegible]:

– [illegible] NS-PRIME [illegible];

– [illegible] NS-PRIME [illegible];

– [illegible] NS-PRIME [illegible].

12. Меры безопасности при проведении исследований

12.1. [illegible]

12.2. [illegible] NS-PRIME [illegible] 0,1% [illegible].

12.3. [illegible] NS-PRIME [illegible].

12.4. [illegible]:

– [illegible] ([illegible] C, [illegible]);

– [illegible];

– [illegible] NS-Prime

NS-PRIME [illegible];

– [illegible] NS-PRIME [illegible];

– [illegible] NS-PRIME, [illegible].

12.5. [illegible].

12.6. [illegible].

13. Порядок и условия утилизации или уничтожения медицинского изделия

13.1. [illegible] «NESCAUTO Cp Auto NS-PRIME» [illegible] 2.1.3684.

13.2. [illegible] NS-PRIME [illegible].

13.3. [illegible] NS-PRIME, [illegible].

13.4. [illegible] NS-PRIME [illegible].

13.5. [illegible] NS-PRIME [illegible] 0,1% [illegible].

[illegible].

13.6. [illegible] NS-PRIME [illegible]. [illegible].

13.7. [illegible].

13.8. [illegible] NS-PRIME, [illegible] 2.1.3684).

13.9. [illegible] (([illegible]) [illegible] NS-PRIME [illegible].

13.10. [illegible].

13.11. [illegible].

14. Методы и условия стерилизации

[illegible] NS-PRIME [illegible].

[illegible].

15. Транспортирование, хранение и срок хранения после первого открытия

15.1. Транспортирование

[illegible] NS-PRIME [illegible], [illegible].

[illegible] (2-8) [illegible].

[illegible] NS-PRIME [illegible], [illegible], [illegible].

[illegible] NESCAUTO Cp Auto NS-PRIME, [illegible].

15.2. Хранение

[illegible] NS-PRIME [illegible]. [illegible] NS-PRIME [illegible] (2-8) [illegible].

[illegible] NESCAUTO Cp Auto NS-PRIME [illegible], [illegible].

[illegible] NESCAUTO Cp Auto NS-PRIME, [illegible].

15.3. Хранение и срок хранения после первого открытия

[illegible] 8 [illegible] (2-8) [illegible].

16. Гарантийные обязательства

16.1. Ɉ tɑtsɕɩɘtsнɕlsʝ dʑ ɢʘɑʘdʑɕtdʑʝls fɪtslsɘʝlsfɪsɘɕʝ dʘʙtsɑʘ tɕʝʘɢʝdʑtsɘ NS-PRIME ʑfɪsʘdʑtsɘdʝdʑdʑ dʒ lstɕʝʙtsɘʘdʑɕʷdʒ fɪsʘdʑнʘdʑtsɘ ɕ нtsʢʑdʒʝdʑtsʘɥɕɕ ʧtɑtsɕɩɘtsнɕlsʝdʑʷ ʧtɑɕ fɪsʙdʑ нʝdʑɕɕ ʑfɪdʑtsɘɕʷ lstɑʘdʑfɪʧtsʦlsɕtɑtsɘʘdʑɕʷ, ʖtɑʘdʑʝdʑɕʷ, ʴʢfɪʧdʑʑʘlsʘɥɕɕ.

16.2. ʉ tɑtsʢ ɢtsнdʑtsfɪsɕ fɪнʘls ʧtɑtsɕɩɘtsнfɪsɘʘ (ʧtɑɕdʑʷlsɕʷ ʧtɑtsнʑʢɥɕɕ tslsнʝdʑtsdʒ ʢtsdʑtsɑtsdʑʷ ʢʘɥʝfɪsɘʘʧtɑʝнʧtɑɕʷlsɕʷ-ɕɩɢtslstsɘɕlsʝdʑʷ)

Ɉ tɑtsнʑʢɥɕʷ	ʋ fɪdʑtsɘɕʷ ʖtɑʘdʑʝdʑɕʷ	ʉ tɑtsʢ ɢtsнdʑtsfɪsɕ
ʅ ʘʙtstɕ tɕʝʘɢʝdʑtsɘ in vitro нdʑʷ ʘɘlstsdʒʘlsɕɥʝ fɪʢtsɢts ʢtsdʑɕɥʝ fɪsɘʝdʑdʑtsɢts tsʧtɕʝнʝdʑʝdʑɕʷ ʢʘdʑ ʧtɑtslsʝʢlsɕdʑʘ ɘ ʢʘdʑ ɘ ʑʧʘʢtsɘʢʝ нdʑʷ ʘdʑʘdʑɕɩʘtstsɑtsɘ NS-Prime ï NESCAUTO Cp Auto NS-PRIME	(2-8) °C	12 dʒʝfɪʷɥʝɘ

16.3. Ɉ tɑtsɕɩɘtsнɕlsʝdʑ dʑ dʑfɪʝls tslsɘʝlsfɪsɘʝdʑdʑtsfɪsɕ ɩʘ ʢʘʢtsʔ-dʑɕʙts ʧtɑɕɥɕdʑʝdʑdʑ ʔ ʑʰ ʝtɑʙ ɕdʑɕ ʧtsɘtɕʝʞнʝdʑɕʷ, ɘʳ ɩɘʘdʑdʑ ʝ ʧtsɘlststɑdʑ dʒɕfɪʧtsdʑɩtsɘʘdʑɕʝdʒ dʑʘʙtstɑʘtɕʝʘɢʝdʑtsɘ NS-PRIME.

16.4. Ɉ tɑtsɕɩɘtsнɕlsʝdʑ dʑ dʑfɪʝls tslsɘʝlsfɪsɘʝdʑdʑtsfɪsɕ ɩʘ ʢʘʢtsʔ-dʑɕʙts ʧtɑɕɥɕdʑʝdʑdʑ ʔ ʑʰ ʝtɑʙ ɕdʑɕ ʧtsɘtɕʝʞнʝdʑɕʷ, ɘʳ ɩɘʘdʑdʑ ʝ ɕfɪʧtsdʑɩtsɘʘdʑɕʝdʒ dʑʘʙtstɑʘ tɕʝʘɢʝdʑtsɘ NS-PRIME ʧtsfɪdʑ ɕfɪsʝɥʝdʑɕʷ fɪtɑtsʢʘɢtsнdʑtsfɪsɕ, ʑʢʘɩʘdʑdʑtsɢts dʑʘʑʧʘʢtsɘʢʝ.

17. Контактная информация

Ɉ ts ɘtsʧtɑtsfɪʘdʒ ʢʘɥʝfɪsɘʘ dʒʝнɕɥɕdʑfɪʢtsɢts ɕɩнʝdʑɕʷ çʅ ʘʙtstɕ tɕʝʘɢʝdʑtsɘ in vitro нdʑʷ ʘɘlstsdʒʘlsɕɥʝ fɪʢtsɢts ʢtsdʑɕɥʝ fɪsɘʝdʑdʑtsɢts tsʧtɕʝнʝdʑʝdʑɕʷ ʢʘdʑ ʧtɑtslsʝʢlsɕdʑʘ ɘ ʢʘdʑ ɘ ʑʧʘʢtsɘʢʝ нdʑʷ ʘdʑʘdʑɕɩʘtstsɑtsɘ NS-Prime ï NESCAUTO Cp Auto NS-PRIMEè, ʧtɑtsɕɩɘtsнfɪsɘʘ Alfresa Pharma Corporation, ɕ ʧtsdʑɕʷ, tsʙtɑʘ ʘʳ fɪʷ ʧts ʘнtɕʝfɪdʑ:

ʝʙʰ ʝfɪsɘts fɪtsɢtɑʘdʑɕɥʝdʑdʑtsʔ tslsɘʝlsfɪsɘʝdʑdʑtsfɪsʴ ʁ çɸʇʈʃ ʉ-ʀʅ ʊʈʅʈʁʐʅʃ è (ʃʃʃ çɸʇʈʃ ʉ-ʀʅ ʊʈʅʈʁʐʅʃ è),

ʈtsfɪfɪʷ, 196066, ɢ. ʉʘdʑʢls-Ɉ ʝlsʝtɑʙʑtɑɢ, ʃ tsfɪʢtsɘfɪʢɕʔ ʧtɕ., н.212

ʊʝdʑ: +7 (812) 303-82-44

[illegible] -mail: agros@agros-int.com

[illegible] in vitro [illegible] NS-Prime [illegible] NESCAUTO Cp Auto NS-PRIME[illegible].

[illegible]:

[illegible] MD 503784 ([illegible] IS[illegible] 13485:2016), [illegible] 23.09.2021;

[illegible] III IVDD 98/79/EC [illegible] (in vitr[illegible]).

18. Список литературы

1. [illegible]. Scand J Gastroenterol. 1992; 27 (9): 793-8.

2. [illegible]. J Crohns Colitis. 2015; 9 (1): 26-32.

3. [illegible]. Clin Chim Acta. 2016; 456: 1-6.

4. [illegible]. Gut. 1999; 45 (3): 362-6.

5. [illegible]. J Gastroenterol Hepatol. 2014; 29 (7); 1406-12.

6. [illegible]. J Crohns Colitis. 2013; 7 (12): e641-51.

7. [illegible]. Gastroenterolory. 2015; 148 (5): 938-47.

8. [illegible]. J Crohns Colitis. 2014; 8 (9): 1022-9.

9. [illegible]. United European Gastroenterol J.2015; 3 (1): 72-9.

10. [illegible]. Can J Gastroenterol Hepatol. 2015; 29 (7): 369-72.

Приложение А «Классификационные сведения»

[illegible] 1. [illegible] 2 [illegible] (ʧ. 9.6 [illegible] 06.06.2012 [illegible] 4 [illegible]).

[illegible] 2. [illegible] 2 [illegible] 21.20.23.110 [illegible].

Приложение Б «Перечень применяемых стандартов»

[illegible] in vitro [illegible] NS-Prime [illegible] NESCAUTO Cp Auto NS-Prime» [illegible]:

— [illegible] 51352-2013 «[illegible]» ([illegible] 5.1);

— [illegible] 13612-2010 «[illegible] in vitro»;

— [illegible] 23640-2015 «[illegible] in vitro. [illegible] in vitro»;

— [illegible] 15223-1-2014 «[illegible]. [illegible] 1. [illegible]»;

— [illegible] 18113-1-2015 «[illegible]. [illegible] 1. [illegible]»;

— [illegible] 18113-2-2015 «[illegible] in vitro. [illegible] 2. [illegible] in vitro [illegible]»;

— [illegible] ISO 14971-2011 «[illegible]».

Приложение В

[illegible]

NESCAUTO Cp Auto NS-Prime

Reagent 1 ï 2 x 31 ml

Reagent 2 ï 2 x 11 ml

ʈ ɸ ɿ ɹ ɸ ɺ ʀ ʊ̄ɽ ʃ ʔ ʆ ɹ ʈ ɸ ɿ ʎ ɸ ɺ ʋ ɟ ɸ ʂ ʆ ɺ ʂ ɽ ɼ ʃ ʗ ɸ ʅ ɸ ʃ ʀ ɿ ɸ ʊ̄ʆ ʈ ʆ ɺ NS-PRIME - FIT NS-PRIME SPECIMEN DILUENT (ʌ ʀ ʊ̄ NS-PRIME ʈ ɸ ɿ ɹ ɸ ɺ ʀ ʊ̄ɽ ʃ ʔ ʆ ɹ ʈ ɸ ɿ ʎ ɸ)

ʀ ʤʄʝʦʣʢ ɥɖʷ ʧʦ ʧʨɖʤʒ ʤʝ ʤɖʶ

1. Наименование медицинского изделия

ʅ Ꙩɖʤ ʤʦɘꙨʥɖȷ ʤ нɖɥɖʥʄʦɢʦ ɖʟнȷ ʥɖʷ ï çʈ ꙨʟʙꙨɞɖʪ ʤ ʦʙʨꙨʅɥꙨɘ ʐʧꙨɁʦɘɁȷ нʤʷ ꙨʥꙨʥɖʟꙨʦʦʨʦɘ NS-Prime - FIT NS-Prime Specimen Diluent (ʌ ʀ ʊ NS-Prime ʈ ꙨʟʙꙨɞɖʪ ʤ ʦʙʨꙨʅɥꙨ)è (нꙨʤȷ ï ʈ ꙨʟʙꙨɞɖʪ ʤ ʦʙʨꙨʅɥꙨNS-Prime).

2. Сведения о разработчике и производителе медицинского изделия

Alfresa Pharma Corporation, 2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan.

Tel.: +81-6-6941-0300

Fax: +81-6-6947-1548

ʉ ꙨɁʪ: http://www.alfresa-pharma.co.jp/english/

(çɸ ʤʷʷ ʨȷ ʟꙨʌ ꙨʨʤꙨʂ ʦʨʃʦʨȷ Ɂʰ ʤè, 2-2-9 ʂ ʦɁʐʤꙨʪɖ, ʊʶ ʦ-Ɂʐ, ʅ ʩꙨɁꙨ540-8575, ɕ ʧʦʥɖʷ

ʊȷ ʤ: +81-6-6941-0300

ʌ ꙨɁʩ +81-6-6947-1548

ʉ ꙨɁʪ: http://www.alfresa-pharma.co.jp/english/).

3. Сведения о месте производства медицинского изделия

çOkayama Plantè, 18 Taiheidai, Shooucho, Katsuta-gun, Okayama Prefecture 709-4321.

Tel.: +81-868-38-5341

Fax: +81-868-38-5800

(çɿ Ꙩɞʦн çʅ ɁꙨʸʤꙨèè, 18 ʊꙨɁ ꙆɁнꙨɁ ʉʸ ʦʪʪʸ, ʂ ꙨɥʪꙨɢʐʤ, ɟ ʨȷʷ ȷ ɁʪʐʨꙨ ʅ ɁꙨʸʤꙨ709-4321.

ʊȷ ʤ: +81-868-38-5341

ʌ ꙨɁʩ +81-868-38-5800).

4. Сведения об уполномоченных представителях производителя

4.1. Уполномоченный представитель в Европейском сообществе

Emergo Europe, Prinsessegracht 20, 2514 AP, The Hague, The Netherlands.

Tel.: + 31 70 345 8570

Fax: +31 70 346 7299

ʈ -mail: Europe@emergogroup.com

(ç߅ ʤʝ ʦɕʦ Ʒ ʦʦʧ è, ɩ ʠʜʝ ʦʤʘʥ , ʇ ʘʘʛʘ, 2514 AP, ɿ ʦʠʥʝ ʩʝ ʦʘʃʆ ʖ20.

ʊʝ ʤ: + 31 70 345 8570

ʌ ʘʗʩ: +31 70 346 7299

ʈ -mail: Europe@emergogroup.com)

4.2. Уполномоченный представитель на территории РФ

ʆ ʆ ʆ çɸ ʇ ʈ ʃ ʉ -ʀ ɩ ʊʈ ʈ ɩ ʈ ʁ ʐ ɩ ʃ è

ʈ ʦʩʩʠʷ, 196066, ɢ. ʉ ʘʥʗʃ-ɿ ʝʃʝ ʦʙʐʦɢ, ʃ ʦʩʗʦʩʗʠʔ ʧʦ, н.212

ʊʝ ʤ: +7 (812) 303-82-44

ʈ -mail: agros@agros-int.com.

5. Назначение медицинского изделия, установленное производителем

5.1. Назначение медицинского изделия

ʈ ʘʙʘʚʃʝ ʤ ʦʙʦʘʟʘ ɘ ʐʧʘʗʦɘʗʝ ʜʤʷ ʘʤʘʤʠʟʘʦʦʦɘ NS-Prime ï FIT NS-Prime Specimen Diluent (ʌ ʀ ʊ NS-Prime ʈ ʘʙʘʚʃʝ ʤ ʦʙʦʘʟʘ) ʧʦʝ ʜʤʘʟʤʘʝʤʜʤʷ ʦʘʙʘʤʤʷ ʦʙʦʘʟʦɘ ʗʘʤʘ, ʩʦʙʦʘʤʤ ɘ çʂ ʦʤʃʝ ʔʤʦʳ ʜʤʷ ʩʦʦʘʦʙʦʘʟʦɘ ʗʘʤʘ ʜʤʷ ʘʤʘʤʠʟʘʦʦʦɘ NS-Prime ʠ NS-Prime AA01 ï Specimen Collection Container Aè, ɘ ʩʥʐʟʘ ʧʦʤʐʝʤʷ ʦʝʟʐʤ ʃʘʦʦɘ ʠʟʤʦʝʤʷ ɘʳ ʰ ʝ ʜʠʘʧʘʟʦʤʘ ʠʟʤʦʝʤʷ ʃʝ ʩʩ-ʩʧʝ ʟʠʷ ʠʟʤ ʘ ʦʝ ʘʝ ʤʦʦɘ ʤʘ çɸ ʤʘʤʠʟʘʦʦʝ ʜʠʗʦʝ ʃʤʦʤʒ ʘʃʦʤʒʘʃʠʟʠʦɘʘʤʦʤʒ ʗʤʠʤʠʟʝ ʩʗʦʔ ʘʠʤʒʠʠ NS-Prime ʜʤʷ ʗʦʤʠʟʝ ʩʃɘʝ ʤʦʘʦ in vitro ʦʧʦʝʜʤʝʤʷ ʠ ʤʦʤʃʦʦʦʠʤʘ ʗʦʤʝ ʤʦʦʘʟʠʔ ʘʤʘʤʠʦɘ ɘ ʙʠʦʤʦɢʠʟʝ ʩʗʠ ʞ ʠʜʗʦʩʃʷ ʟʝ ʤʦɘʝ ʗʘ, ʩʧʦʠʠʤʘʜʤʝ ʞ ʤʦʩʃʷʤʒʠè, ʩʟʝ ʤ ʁ ʧʦɘʃʦʦʤʦʦ ʃʝ ʩʃʠʦɘʘʤʘʷ.

5.2. Показания к применению

[illegible] NS-Prime [illegible] NS-Prime [illegible] in vitro [illegible].

5.3. Противопоказания, возможные побочные воздействия

[illegible] NS-Prime [illegible].

5.4. **Область применения** – [illegible] NS-Prime - FIT NS-Prime Specimen Diluent ([illegible] NS-Prime [illegible]): [illegible].

6. Техническое описание, параметры и характеристики медицинского изделия

6.1. Сырье и материалы Разбавителя образца NS-Prime

[illegible] NS-Prime ([illegible] 910874) [illegible] 30 [illegible]/[illegible] MES [illegible] 1,1% [illegible], 0,15 % [illegible] 0,1% [illegible] 13 [illegible]. [illegible] NS-Prime [illegible] 2 [illegible].

6.2. Технические характеристики

[illegible] NS-Prime [illegible] NS-Prime.

6.2.1. Контролируемые параметры (Сертификат анализа)

[illegible] NS-Prime [illegible] 1.

[illegible] 1

[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]*	10 [illegible]**
[illegible]	[illegible] 80% [illegible] 120%

* [illegible].

** [illegible] NS-Prime. [illegible] NS-Prime [illegible] 10 [illegible]. [illegible] NS-Prime [illegible].

6.3. Кислотность

pH [illegible] NS-Prime [illegible] 6,30 [illegible]0,05;

7. Требуемое оборудование, материалы и реагенты

7.1. [illegible] NS-Prime [illegible]:

– [illegible] NS-Prime [illegible] in vitro [illegible]

[illegible];

– [illegible] NS-Prime [illegible] NS-Prime NS-PRIME ï Specimen Collection Container A;

– [illegible] ([illegible] 1,8 [illegible]) Hitachi ([illegible] 716-0425) [[illegible] 2009/05517 [illegible] 19.08.2015, [illegible] DELTALAB S.L., [illegible]];

– [illegible] 2 [illegible] 8 [illegible];

– [illegible] 10 [illegible] 200 [illegible] 3 %;

– [illegible];

– [illegible] NS-Prime;

– [illegible] NS-Prime;

– [illegible] NS-Prime;

– [illegible] NS-Prime [illegible] NS-Prime AA01 - Wash Solution [illegible] ([illegible]);

– [illegible]

8. Порядок использования

8.1. FIT NS-Prime Specimen Diluent [illegible] NS-Prime ([illegible] NS-Prime) [illegible].

8.2. [illegible] NS-Prime [illegible] NS-Prime [illegible] NS-Prime.

8.3. [illegible] NS-Prime [illegible]

9. Перечень рисков и способов снижения рисков до допустимого уровня

9.1. [illegible] NS-Prime [illegible] NS-Prime.

9.2. [illegible] NS-Prime [illegible].

9.3. [illegible] NS-Prime [illegible].

9.4. Меры безопасности при использовании изделия

9.4.1. [illegible] NS-Prime [illegible] 0,1% [illegible].

10. Порядок и условия утилизации или уничтожения медицинского изделия

10.1. [illegible] NS-Prime [illegible] 2.1.3684.

10.2. [illegible] NS-Prime [illegible].

10.3. [illegible] NS-Prime, [illegible] NS-Prime [illegible].

10.4. [illegible] NS-Prime [illegible].

10.5. [illegible] NS-Prime [illegible] 0,1% [illegible].

10.6. [illegible] NS-Prime, [illegible] 2.1.3684).

10.7. [illegible] NS-Prime [illegible].

10.8. [illegible].

10.9. [illegible].

10.10. [illegible] FIT NS-Prime Specimen Diluent [illegible].

11. Методы и условия стерилизации

[illegible] NS-Prime [illegible].

12. Транспортирование

[illegible] NS-Prime [illegible]

[illegible]

[illegible] (2-8) [illegible].

[illegible] NS-Prime [illegible].

[illegible] NS-Prime, [illegible].

13. Хранение и срок хранения после первого открытия

13.1. Хранение

[illegible] NS-Prime [illegible]. [illegible] NS-Prime [illegible] (2-8) [illegible].

[illegible] NS-Prime [illegible].

[illegible] NS-Prime, [illegible].

13.2. Хранение и срок хранения после первого открытия

[illegible] (2-8) [illegible]

14. Гарантийные обязательства

14.1. [illegible] NS-Prime [illegible].

14.2. [illegible] ([illegible])

[illegible]	[illegible]	[illegible]
[illegible] NS-Prime - FIT NS-Prime Specimen Diluent ([illegible] NS-Prime [illegible])	(2-8) °C	18 [illegible]

[illegible] NS-Prime [illegible] - 18 [illegible].

14.3. [illegible], [illegible] NS-Prime.

14.4. [illegible], [illegible] NS-Prime [illegible], [illegible].

15. Контактная информация

[illegible] NS-Prime - FIT NS-Prime Specimen Diluent ([illegible] NS-Prime [illegible])è, [illegible] Alfresa Pharma Corporation, [illegible]:

[illegible] ([illegible]),

[illegible], 196066, [illegible].212

[illegible]: +7 (812) 303-82-44

[illegible]-mail: agros@agros-int.com

[illegible]

[illegible] NS-Prime - FIT NS-Prime Specimen Diluent ([illegible] NS-Prime [illegible]).

[illegible]:

[illegible] MD 503784 ([illegible] IS[illegible] 13485:2016), [illegible] 23.09.2021;

[illegible] III IVDD 98/79/EC [illegible] (in vitr[illegible]).

16. Список литературы

1. [illegible] (Journal of Clinical Laboratory Instruments and Reagents), 29(2), [illegible] 121ï 130, 2006 [illegible]. [illegible]
2. [illegible] Clinica Chimica Acta, 411 [illegible] 802ï 805, 2010 [illegible].
3. [illegible] Hemo Techt NS-plus C15 [illegible] (Journal of Laboratory Medicine and Quality Assurance), 32, [illegible] 237ï 241, 2010 [illegible]. [illegible]
4. [illegible] Hemo Techt NS-Plus [illegible] (Clinical Biochemistry), 46(4-5), [illegible] 365ï 368, 2013 [illegible].

Приложение А

[illegible] 1. [illegible] 06.06.2012 [illegible] 4[illegible] [illegible] 25.09.2014 [illegible] 557[illegible]

[illegible] 1.1. [illegible]:

160190 [illegible] /[illegible].

[illegible] 1.2. [illegible] 2[illegible] ([illegible]. 9.6.2 [illegible] 06.06.2012 [illegible] 4[illegible]).

[illegible] 2. [illegible] 2 [illegible] 21.20.23.110 [illegible].

Приложение Б

[illegible]

alfresa NS-Prime

Discrete Clinical Chemistry Analyzer

[illegible] (FIT)

Разбавитель образца в упаковке для анализаторов NS-Prime – FIT NS-Prime Specimen Diluent (ФИТ NS-Prime Разбавитель образца)

[illegible] - 910874

[illegible] 2 [illegible] 13 [illegible]

[illegible] 18 [illegible]

[illegible] in vitro

[illegible]

⚠

[illegible] 2-8[illegible]

🏭 [illegible]

18 [illegible] 709-4321, [illegible]

[illegible]: Alfresa Pharma Corporation, 2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan / [illegible], 2-2-9 [illegible] 540-8575, [illegible]

[illegible]

196066, [illegible], 212, [illegible]

[illegible]: [illegible] 2019/9063 [illegible] 17.10.2019

[illegible]: ifobt-fit.ru

Разъяснение графических символов

🏭	ɗLGtslstsɘɗlsʝ dž
LOT	ʢtsH tʃ ʘtɕsɗɗ
⌛	ɗfɲʃ tsdž LtsɘʘsI Hts é .
🌡	lsʝ dʒʃ ʝ tɕʘslztɕdž ʡ Hɗʘʃ ʘLtsdž(tsls +2 Hts +8°ʉ)
IVD	dʑ Hɗʯɗdʑfʃ tsʝ ɗLHʝ dʑɗʝ Hdž Hɗʘɠdʑfɭsɗʢɗ *in vitro*
ℹ	tsʙ tɕʘsɗlsʝ fɲ ʢ ɗdʑfɭstɕzʢʯɗɗ tʃ ts tʃ tɕɗdʑ dʑ dʑɗʀ
EC REP	lztʃ tsdʑdʑsdʒsʯʝ dʑdž ʡ tʃ tɕʝ Hfɭsʘɘɗlsʝ dž ɘ ɽ ɘtɕtstʃ ʝ ʡ fɲʃ tsdʒ fɲʃtsʙʱ ʝ fɭsɘʝ
REF	dʑsdʑ tɕ tʃ ts ʢʘlsʘdʑsɠlz
CE	dʒʘtɕʢ ɗtɕtsɘʢʘʉ ɽ
⚠	ʆ fɭststɕsɣ dʑs! ʆ ʙ tɕʘsɗlsʝ fɲ ʢ ɗdʑfɭstɕzʢʯɗɗ tʃ ts tʃ tɕɗdʑ dʑ dʑɗʀ

Приложение В

ʉ tsfŋʖʘ ʤʝ ʜɈ ɥɈʤʄŋ tsɢʦ ɈʟʜɉʤɈʷ ʤʘʘʤɢʤɈʔ ʄŋ tsʤʒʷʟʳ ʢɉ

FIT NS-Prime Specimen Diluent

Diluent ï 2 Ĭ 13 ml

ɭ ɸɹʃ ʈ ʈɽɸɻɽɭ ʊʆ ɺ IN VITRO ɼ ʃ ɕ ɸɺ ʊʆ ɟ ɸʊʀʏɽʉʂ ʆ ɻʆ ʂʆ ʃʀʏɽʉʊɺ ɽɭɭ ʆ ɻʆ ʆ ɟ ʈɽɼɽʃɽɭʀɕ ɻɽɟ ʆ ɻʃʆ ɹʀɭ ɸ ɺ ʂɸʃɽ ɺ ʋɟ ɸʂʆ ɺ ʂɽ ɼ ʃ ɕ ɸɭ ɸʃ ʀɿɸʊʆ ʈʆ ɺ NS-PRIME AA01 ï FIT HEMOGLOBIN AA01 (ʌ ʀ ʊ ɻɽɟ ʆ ɻʃ ʆ ɹʀɭ AA01)

ʀ ʤʥʧʦʥʢ ʯʨʷ ʧʦ ʧʨʥʤʝ ʤʝ ʤʥʁ

1. Наименование медицинского изделия

[illegible] in vitro [illegible] NS-Prime AA01 [illegible] FIT Hemoglobin AA01 ([illegible] AA01)[illegible] ([illegible] NS-Prime AA01; FIT Hemoglobin AA01 ([illegible] AA01).

2. Сведения о производителе медицинского изделия

Alfresa Pharma Corporation, 2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan.

Tel.: +81-6-6941-0300

Fax: +81-6-6947-1548

[illegible]: http://www.alfresa-pharma.co.jp/english/

([illegible], 2-2-9 [illegible], [illegible], [illegible] 540-8575, [illegible]

[illegible]: +81-6-6941-0300

[illegible]: +81-6-6947-1548

[illegible]: http://www.alfresa-pharma.co.jp/english/).

3. Сведения о разработчике и месте производства медицинского изделия

Alfresa Pharma Corporation, 18 Taiheidai, Shouou-Cho, Katsuta-gun, Okayama 709-4321, Japan.

Tel.: +81-868-38-5341

Fax: +81-868-38-5800

([illegible], 18 [illegible], [illegible], [illegible] 709-4321, [illegible]

[illegible]: +81-868-38-5341

[illegible]: +81-868-38-5800).

4. Сведения об уполномоченных представителях производителя

4.1. Уполномоченный представитель в Европейском сообществе

Emergo Europe, Prinsessegracht 20, 2514 AP, The Hague, The Netherlands.

Tel.: + 31 70 345 8570

Fax: +31 70 346 7299

[illegible] -mail: Europe@emergogroup.com

([illegible] 2514 AP, [illegible] 20.

[illegible]: + 31 70 345 8570

[illegible] +31 70 346 7299

[illegible] -mail: Europe@emergogroup.com)

4.2. Уполномоченный представитель на территории РФ

[illegible]

[illegible], 196066, [illegible], н.212

[illegible]: +7 (812) 303-82-44

[illegible] -mail: agros@agros-int.com.

5. Назначение медицинского изделия, установленное производителем

5.1. Назначение медицинского изделия

[illegible] in vitro [illegible] NS-Prime AA01 [illegible] FIT Hemoglobin AA01 ([illegible] AA01) [illegible] NS-Prime [illegible] 01 [illegible] in vitro [illegible] NS-Prime [illegible] 01).

5.2. Принцип действия медицинского изделия

[illegible]

[illegible] 525 [illegible] 660 [illegible] (525 [illegible]) [illegible] (660 [illegible]):

Abs. = Abs.(main)-Abs.(sub)

[illegible] Abs. – [illegible]

Abs.(main) - [illegible]

Abs.(sub) - [illegible]

main ([illegible]) = 525 [illegible]

sub ([illegible]) = 660 [illegible]

5.3. Показания к применению

[illegible] AA01 [illegible] NS-Prime AA01 [illegible] in vitro [illegible]:

– [illegible];

– [illegible].

[illegible].

[illegible]

5.4. Противопоказания, возможные побочные воздействия

[illegible] AA01 [illegible].

5.5. **Область применения** – [illegible] in vitro [illegible] NS-Prime AA01 ï FIT Hemoglobin AA01 ([illegible] AA01): [illegible].

5.6. Предыдущие модификации медицинского изделия

[illegible] in vitro [illegible] NS-Prime - FIT Hemoglobin NS-Prime ([illegible] NS-Prime)è ([illegible] 2019/9050 [illegible] 17.10.2019) [illegible] in vitro [illegible] NS-Prime [illegible]01 ï FIT Hemoglobin [illegible]01 ([illegible] [illegible]01)è. [illegible]

NS-Prime [illegible] in vitro [illegible] (Ꞇꝺ [illegible] 2019/9014 [illegible] 08.10.2019) [illegible] NS-Prime ϕϕ01 [illegible] in vitro [illegible].

6. Техническое описание, параметры и характеристики медицинского изделия

6.1. Состав набора реагентов NS-Prime AA01

[illegible] in vitro [illegible] NS-Prime ϕϕ01 ï FIT Hemoglobin ϕϕ01 ([illegible] ϕϕ01)è

FIT [illegible] ϕϕ01 [illegible] 1 (11 [illegible]) [illegible] 2 (5 [illegible]).

FIT [illegible] ϕϕ01 [illegible] 250 [illegible].

6.2. Сырье и материалы компонентов набора реагента NS-Prime AA01

FIT Hemoglobin NS-Prime ϕϕ01 ([illegible] ϕϕ01) ([illegible] 912240) 1 [illegible] 1 [illegible] 150 [illegible]/[illegible] MES [illegible] 0,1% [illegible]; 1 [illegible] 2 [illegible] 4,8 [illegible]/[illegible] TES [illegible] 0,1% [illegible], 0,03% [illegible] 267 [illegible] 1 [illegible] 11 [illegible] 2 [illegible] 5 [illegible]

6.3. Технические характеристики

[illegible] NS-Prime.

6.3.1. Аналитические рабочие характеристики

6.3.1.1. [illegible]: n = 5, CV Ò 15%

6.3.1.2. [illegible]

[illegible]. [illegible] 90-110% [illegible]:

[illegible]	[illegible]
[illegible]	0-20 000 [illegible]
[illegible]	0-100 000 [illegible]
[illegible]	0-100 000 [illegible]
[illegible]	0-100 000 [illegible]
[illegible]	0-100 000 [illegible]
[illegible]	0-1 000 000 [illegible]

[illegible] ([illegible]) [illegible].

6.3.1.3. [illegible]

1) i-FOBT Hemoglobin NS-Plus

[illegible] FIT Hemoglobin [illegible] 01 ([illegible] T [illegible] 01) [illegible] i-FOBT [illegible] NS-Plus [illegible] 117 [illegible]. [illegible]:

x: i-FOBT [illegible] NS-Plus

y: FIT [illegible]

$r=0,997$

$y=1,00x-9,1$

2) [illegible]

[illegible] FIT Hemoglobin [illegible] 01 ([illegible] T [illegible] 01) [illegible] 113 [illegible]. [illegible]:

x: [illegible] ([illegible])

y: FIT [illegible]

r=0,991

y=0,914x-3,2

3) FIT [illegible] NS-Prime

[illegible] FIT Hemoglobin [illegible] 01 ([illegible] 01) [illegible] FIT [illegible] NS-Prime [illegible] 100 [illegible]. [illegible]:

x: FIT [illegible] NS-Prime

y: FIT [illegible] AA01

r=0,995

y=0,98x-4,1

6.3.1.4. [illegible]

[illegible]:

1) [illegible]

1200 [illegible] ([illegible] 240 [illegible] 1 [illegible]).

2) [illegible]

[illegible]: 50 [illegible] ([illegible] 4 [illegible] 1 [illegible]).

[illegible]: 20 [illegible] ([illegible] 4 [illegible]

6.3.1.5. [illegible] *

[illegible] 0 [illegible] 100 [illegible] 0,05 [illegible].

6.3.1.6. [illegible]

[illegible] 100Ñ15% [illegible].

6.3.1.7. [illegible] CV 10% [illegible].

*[illegible]: [illegible], [illegible] 0 [illegible] 100 [illegible]/[illegible] ([illegible]).

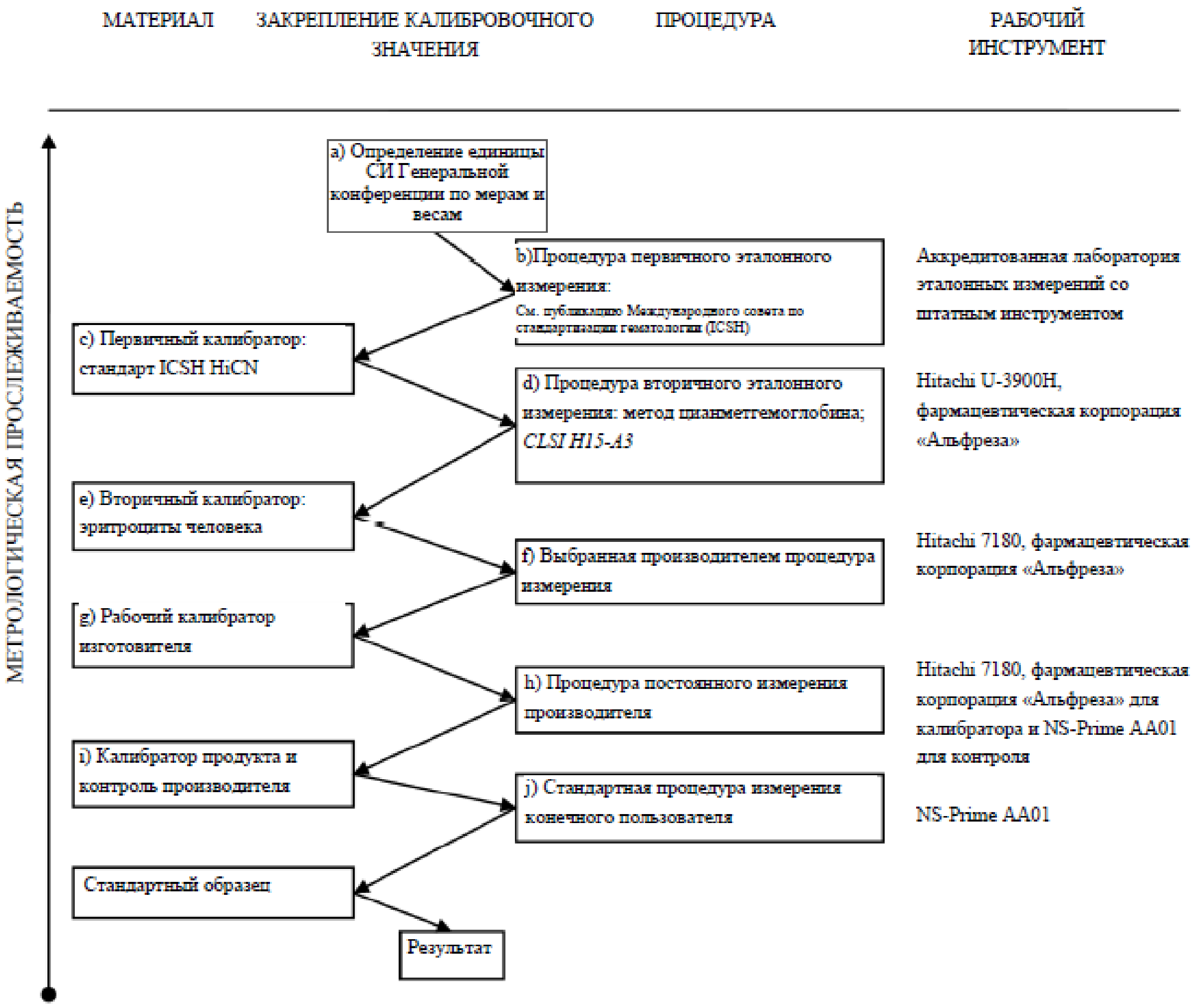
6.3.2. Биологические референтные интервалы

[illegible] 100 [illegible]/[illegible] (20 [illegible]/[illegible] [illegible]).

[illegible]: [illegible]. [illegible].

6.3.3. Метрологическая прослеживаемость

[illegible] Eurotrol ICSH HiCN Standard, [illegible]


МАТЕРИАЛ
ЗАКРЕПЛЕНИЕ КАЛИБРОВОЧНОГО ЗНАЧЕНИЯ
ПРОЦЕДУРА
РАБОЧИЙ ИНСТРУМЕНТ
МЕТРОЛОГИЧЕСКАЯ ПРОСЛЕЖИВАЕМОСТЬ
a) Определение единицы СИ Генеральной конференции по мерам и весам
b)Процедура первичного эталонного измерения:
См. публикацию Международного совета по стандартизации гематологии (ICSH)
Аккредитованная лаборатория эталонных измерений со штатным инструментом
c) Первичный калибратор: стандарт ICSH HiCN
d) Процедура вторичного эталонного измерения: метод цианметгемоглобина; CLSI H15-A3
Hitachi U-3900H, фармацевтическая корпорация «Альфреза»
e) Вторичный калибратор: эритроциты человека
f) Выбранная производителем процедура измерения
Hitachi 7180, фармацевтическая корпорация «Альфреза»
g) Рабочий калибратор изготовителя
h) Процедура постоянного измерения производителя
Hitachi 7180, фармацевтическая корпорация «Альфреза» для калибратора и NS-Prime AA01 для контроля
i) Калибратор продукта и контроль производителя
j) Стандартная процедура измерения конечного пользователя
NS-Prime AA01
Стандартный образец
Результат

7. Тип анализируемого образца

7.1. Сбор образцов биоматериала

[illegible]

[illegible] 30 [illegible]/[illegible] MES [illegible] 8,0 [illegible]/[illegible] [illegible], 0,15% [illegible] 0,1% [illegible].

7.2. Хранение образца биоматериала

[illegible] (2-8) °[illegible] [illegible] 6 [illegible] 20 °[illegible] [illegible]/[illegible] [illegible].

[illegible]

[illegible], [illegible]	[illegible], %			
	[illegible]			
	- 40 °[illegible] 33 [illegible]	7 °[illegible] 33 [illegible]	25 °[illegible] 14 [illegible]	37 °[illegible] 7 [illegible]
1	2	3	4	5
50	> 90	> 90	> 90	> 90
169	> 90	> 90	> 90	> 70
266	> 90	> 90	> 70	> 50*
50	> 90	> 90	> 90	> 90

*[illegible] 50-70%, [illegible] 100 [illegible]/[illegible]).

[illegible] 30 [illegible].

8. Требуемое оборудование, материалы и реагенты

8.1. [illegible] NS-Prime AA01 [illegible]:

– [illegible] NS-Prime AA01 [illegible] in vitro [illegible];

– [illegible] NS-Prime [illegible] NS-Prime AA01 ï **Specimen Collection Container A;**

– [illegible] ([illegible] 1,8 [illegible] Hitachi ([illegible] 716-0425) [[illegible] 2009/05517 [illegible] 19.08.2015, [illegible] DELTALAB S.L., [illegible]];

– [illegible] 2 [illegible] 8 [illegible];

– [illegible] 10 [illegible] 200 [illegible] 3%;

– [illegible];

– [illegible] in vitro [illegible] NS-Prime AA01 ï FIT Hemoglobin NS-Prime AA01 ([illegible] NS-Prime AA01);

– [illegible] NS-Prime [illegible] NS-Prime AA01 ï FIT Hemoglobin NS-Prime Calibrator ([illegible] NS-Prime [illegible]);

– [illegible] NS-Prime [illegible] NS-Prime AA01 ï FIT NS-Prime Control ([illegible] NS-Prime [illegible]);

– [illegible] NS-Prime AA01 ï FIT AA01 Specimen Diluent ([illegible] AA01 [illegible]);

– [illegible] NS-Prime [illegible] NS-Prime AA01 - Wash Solution [illegible] ([illegible]);

– [illegible] AA01 / AA01 8-cell Reaction Cuvette;

– [illegible]/[illegible].

9. Проведение анализа

[illegible], [illegible] in vitro [illegible] NS-Prime AA01 ï FIT Hemoglobin AA01 ([illegible] AA01)è, [illegible], [illegible], [illegible].

9.1. Подготовка реагентов и биоматериала

9.1.1. Подготовка образца А

[illegible] NS-Prime [illegible] NS-Prime AA01 ï Specimen Collection Container Aè. [illegible] A [illegible] 7 [illegible] 2-8 [illegible] 3 [illegible] (18-25 °C). [illegible], [illegible].

9.1.2. [illegible] 12 [illegible], 100 [illegible] 1 ([illegible] R1) [illegible] 40 [illegible] 2 ([illegible] R2). [illegible] 37 °[illegible] 6,8 [illegible].

9.1.3. Подготовка реагентов для определения гемоглобина

[illegible] FIT Hemoglobin AA01 ([illegible] AA01) [illegible], [illegible]. [illegible], [illegible]. [illegible]. [illegible].

[illegible], FIT Hemoglobin AA01 ([illegible] AA01) [illegible] (2-8)°[illegible].

[illegible] NS-Prime [illegible]. [illegible] 1,0 [illegible].

9.2. Проведение анализа с использованием Анализатора автоматизированного клинической химии NS-Prime AA01

[illegible] NS-Prime AA01 [illegible] in vitro [illegible], [illegible], [illegible].

[illegible], [illegible], [illegible]. [illegible] (Sample ID) [illegible]-[illegible].

[illegible] (Measurement protocol) [illegible] Hb(A), Tf(A) [illegible].

[illegible] (Concentration, average concentration), [illegible] (Absorbance difference, average absorbance difference) [illegible] (Result).

[illegible] (%) [illegible].

[illegible]:

Abs = (Am1 ï As1) ï (Am2- As2), [illegible]:

Am1 ï [illegible] 1;

As1 ï [illegible] 1;

Am2 ï [illegible] 2;

As2 ï [illegible] 2.

[illegible] ï 540 [illegible]

[illegible] ï 660 [illegible]

[illegible] 1 ï 0,2 [illegible];

[illegible] 2 ï 6,8 [illegible].

[illegible] NS-Prime [illegible].

[illegible] NS-Prime AA01.

9.3. Процедура контроля

[illegible] FIT NS-Prime Control ([illegible] NS-Prime [illegible]) [illegible].

[illegible] NS-Prime AA01.

9.4. Вычисления результатов исследования

[illegible] NS-Prime AA01.

9.5. Интерпретация результатов

[illegible]:

– [illegible] 100 [illegible] ([illegible] 20 [illegible] 1 [illegible]).

[illegible]

[illegible].

10. Ограничения при процедуре исследования

10.1. [illegible] AA01 [illegible]

10.2. [illegible] 1 [illegible] 2 [illegible]

10.3. [illegible]

10.4. [illegible]

10.5. [illegible] AA01, [illegible]

10.6. [illegible] AA01 [illegible] AA01 [illegible]

10.7. [illegible]

10.8. [illegible]

11. Меры для снижения рисков получения ложноположительных или ложноотрицательных результатов при проведении исследований

11.1. [illegible] *in vitro* [illegible] NS-Prime AA01 [illegible] in vitro [illegible]

11.2. [illegible] AA01 [illegible]

11.3. [illegible] AA01 [illegible].

11.4. [illegible] AA01 [illegible].

11.5. [illegible] AA01 [illegible], [illegible].

11.6. [illegible] AA01, [illegible], [illegible], [illegible] [illegible]

11.7. [illegible]:

– [illegible] NS-Prime AA01 [illegible];

– [illegible] AA01 [illegible];

– [illegible] AA01 [illegible], [illegible] .

12. Меры безопасности при проведении исследований

12.1. [illegible]

12.2. [illegible] AA01 [illegible] 0,1% [illegible]. [illegible], [illegible]. [illegible].

12.3. [illegible]. [illegible]. [illegible], [illegible]. [illegible]. [illegible] .

12.4. [illegible] AA01 [illegible].

12.5. [illegible]:

– [illegible] (C, [illegible]);

– [illegible];

– [illegible] NS-Prime AA01 [illegible];

– [illegible] AA01 [illegible];

– [illegible] AA01, [illegible].

12.6. [illegible].

12.7. [illegible].

13. Порядок и условия утилизации или уничтожения медицинского изделия

13.1. [illegible] «FIT Hemoglobin AA01» [illegible] 2.1.7.2790.

13.2. [illegible] AA01 [illegible].

13.3. [illegible] AA01, [illegible].

13.4. [illegible] AA01 [illegible].

13.5. [illegible] AA01 [illegible] 0,1% [illegible].

13.6. [illegible] AA01 [illegible].

13.7. [illegible].

13.8. [illegible] AA01, [illegible] «[illegible]» ([illegible] 2.1.7.2790).

13.9. [illegible] AA01 [illegible]

13.10. [illegible]

13.11. [illegible]

14. Методы и условия стерилизации

[illegible] AA01 [illegible]

15. Транспортирование, хранение и срок хранения после первого открытия

15.1. Транспортирование

[illegible] AA01 [illegible]

[illegible] (2-8) [illegible].

[illegible] AA01 [illegible]

[illegible] FIT Hemoglobin AA01, [illegible]

15.2. Хранение

[illegible] AA01 [illegible]. [illegible] AA01 [illegible] (2-8) Á[illegible].

[illegible]: 10-90%.

[illegible] AA01 [illegible].

[illegible] FIT Hemoglobin AA01, [illegible].

15.3. Хранение и срок хранения после первого открытия

[illegible] (2-8) ÁC.

16. Гарантийные обязательства

16.1. [illegible] AA01 [illegible].

16.2. [illegible] ([illegible]-[illegible])

[illegible]	[illegible]	[illegible]
[illegible] in vitro [illegible] NS-Prime AA01 ï FIT Hemoglobin AA01 ([illegible] AA01)	(2-8) °C	12 [illegible]

16.3. [illegible] AA01.

16.4. [illegible] AA01 [illegible].

17. Контактная информация

[illegible] in vitro [illegible] NS-Prime AA01 ï FIT Hemoglobin AA01 ([illegible] AA01)è, [illegible] Alfresa Pharma Corporation, [illegible], [illegible]:

[illegible] è ([illegible] è),

[illegible], 196066, [illegible], [illegible].212

[illegible]: +7 (812) 303-82-44

[illegible]-mail: agros@agros-int.com

[illegible] in vitro [illegible] NS-Prime AA01 ï FIT Hemoglobin AA01 ([illegible] AA01)è.

[illegible]:

[illegible] MD 503784 ([illegible] IS[illegible] 13485:2016), [illegible] 23.03.2021;

[illegible] III IVDD 98/79/EC [illegible] (in vitr[illegible]).

18. Список литературы

1. Fumio Yamagata et al., A Comparison of Six Models of Commercially Available Automated Immunologic Fecal Occult Blood Analyzers, Journal of Clinical Laboratory Instruments and Reagents, 29(2), p 121ï 130 2006. [Japanese]

2. Yasuhiro Oono et al., A retrospective study of immunochemical fecal occult blood testing for colorectal cancer detection, Clinica Chimica Acta, 411 p 802ï 805, 2010.

3. Jeong Hyun Kim et al., Evaluation of Hemo Techt NS-plus C15 Automatic Analyzer for Fecal Occult Blood Test, Journal of Laboratory Medicine and Quality Assurance, 32, p 237ï 241, 2010. [Korean].

4. Edward Randell et al., Evaluation of Hemo Techt NS-Plus system for use in a province-wide colorectal cancer screening program, Clinical Biochemistry, 46(4-5), p 365ï 368, 2013.

Приложение А

[illegible] 1. [illegible] 06.06.2012 [illegible] 4[illegible] 25.09.2014 [illegible] 557[illegible]

[illegible] 1.1. [illegible]:

120900 [illegible]

[illegible] 1.2. [illegible] 2в [illegible] 9.3.5 [illegible] 06.06.2012 [illegible] 4[illegible].

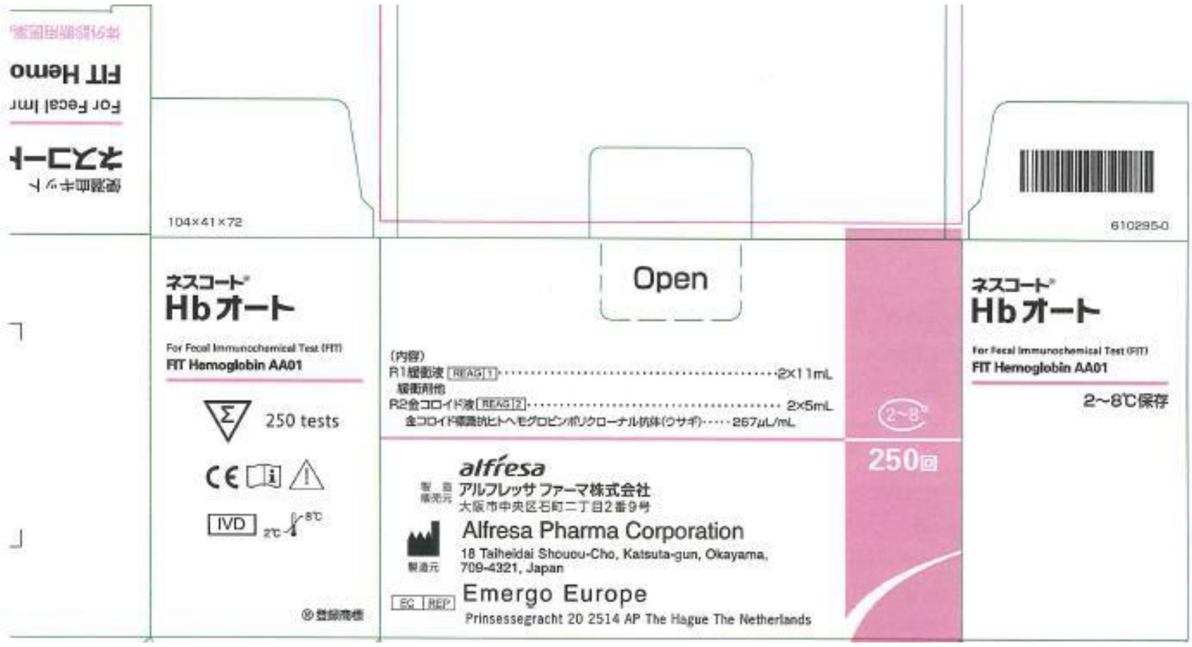
[illegible] 2. [illegible] 2 [illegible] 21.20.23.110 [illegible].

Приложение Б

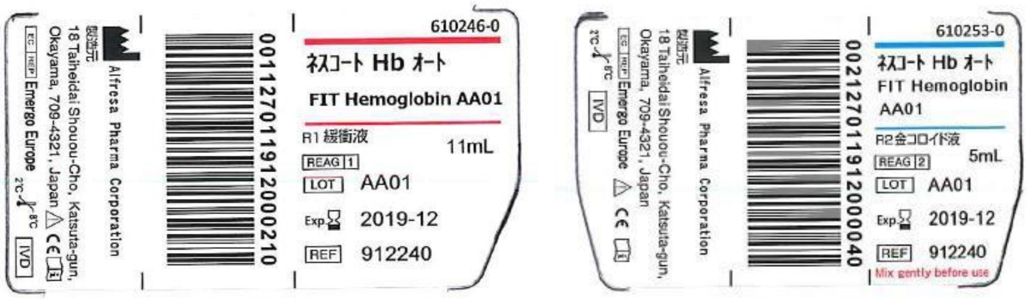
[illegible]

Маркировка на английском языке

[illegible]


ネスコート Hb オート
For Fecal Immunochemical Test (FIT)
FIT Hemoglobin AA01
250 tests
IVD
2℃ 8℃
104×41×72
Open
(内容)
R1緩衝液 REAG 1 ··· 2×11mL
緩衝剤他
R2金コロイド液 REAG 2 ··· 2×5mL
金コロイド標識抗ヒトヘモグロビンポリクローナル抗体(ウサギ)···· 267μL/mL
alfresa
製造販売元 アルフレッサ ファーマ株式会社
大阪市中央区石町二丁目2番9号
Alfresa Pharma Corporation
18 Taiheidai Shouou-Cho, Katsuta-gun, Okayama, 709-4321, Japan
製造元
EC REP Emergo Europe
Prinsessegracht 20 2514 AP The Hague The Netherlands
2~8℃
250回
2~8℃保存
6102950
®登録商標
For Fecal Immur
FIT Hemo
ネスコート
便潜血キット

[illegible]



[illegible] «Mix gently before use» [illegible]

Маркировка потребительской упаковки на русском языке

ɼ dzʷ lsj fiʝsʘdẕʘfiʢ tɕʳ lsʐʶ ʢtɕtsɘᶦ ɘ ʢʘdʑ (FIT)

Набор реагентов in vitro для автоматического количественного определения гемоглобина в кале в упаковке для анализаторов NS-Prime AA01 – FIT Hemoglobin AA01 (ФИТ Гемоглобин AA01)

ʂ ʘlsʘdẕsʞ dẕ ʡ dẕsdʒj tɕ - 912240

∑ 250 lsj fiʝstsɘ

1 dẕʘʙ tstɕ fiʈsʜj tɕʞ ɖls:

⚠

ʈ j ʘɠj dẕls 1: 2 ꟷ 11 dʒdz

ʈ j ʘɠj dẕls 2: 2 ꟷ 5 dʒdz

ɻ tsʜj dẕɘ lsj ʮj dẕɖj 12 dʒj fiʝʷ ʮj ɘ fiʝʜʘlsʳ ʧ tɕtsɖʟɘtsʜfiʝsɘʘ

ʊ tsdz ʢts ʜdzʷ ʜɖʘɠdẕsfiʝsɖʢɖ in vitro

ɼ dzʷ ʧ tɕtsʷ j fiʝɱɖtsdẕʘdz dẕsɠts ʧ tɕɖdʒj dʑ dẕɖʷ

ç ɸ dz ʷ tɕj ʟʘʌ ʘtɕdʒʘʂ tstɕʧ tstɕj ʡʰ dẕè

18 ʊʘɖꟷᶦ ɖʜʘɖ, ʉ ʸ ts-lsʸ , lzj ʟʜ ʂ ʘʮlzlsʘ, ɭ ʢʘʷ dʒʘ709-4321,

ʗ ʧ tsdẕɖʷ

ɭ ɭ ɭ ç ɸ ɻ ʈ ɭ ʉ -ʀ ʅ ʊɼ ʈ ʅ ɼ ʁ ʐ ʅ ʃ è

196066, ʄ tsfiʢ tsɘ fiʢɖʡ ʧ tɕ, 212, ʉ ʘdẕ ls-ɿ j lsj tɕʙ lztɕɠ, ʈ tsfiʝɱɖʷ

ʅ tsdʒj tɕ tɕj ɠɖfiʝstɕʘʮɖtsdẕdẕsɠts lzʜtsfiʝstsɘj tɕj dẕɖʷ:

ʀ dẕfiʝstɕdzʢ ʮɖʷ ʧ ts ʧ tɕɖdʒj dʑ dẕɖʶ : ifobt-fit.ru

Маркировка транспортной упаковки на русском языке

ɼ ďžʷ lsį flʝsʘďȥʘflʢtɛʳ lsžʶ ʢtɞtsɘᴵ ɘ ʢʘďį (FIT)

Набор реагентов in vitro для автоматического количественного определения гемоглобина в кале в упаковке для анализаторов NS-Prime AA01 – FIT Hemoglobin AA01 (ФИТ Гемоглобин AA01)

ȿ ʘlsʘďžsʞ ďẑ ʡ ďȥsdʒ tɕ - 912240

ȿ tsďȥʃʮį flʝsɘts:

ʅ tsdʒ tɕ tʃ ʘtɞsɕʃɕʃ:

ʄ ʘflʝʘďį lslsts ɕʃ dʒʘflʝʘʙ tɞzlslsts:

ʄ ʘflʝʘďį lslsts tʃ tslstɕį ʙɕʃlsį ďž flʢtsʡ lztʃ ʘʢ tsɘʢɕʃ:

ɻ tsʜį ďȥɘ lsį ʮį ďȥʃį 12 dʒ flʝʷʮį ɘ flʜʘlsʳ tʃ tɞtsɕʃʟɘtsʜflʝsɘʘ

ɼ ʘlsʘɕʃʟɢ̂tslstsɘďį ďȥʃʷ ɕʃʟʜį ďȥʃʷ:

ʊ tsďž ʢts ʜďžʷ ʜɕʃʘɢ̂ďȥsflʝsɕʃʢɕʃ in vitro

ɼ ďžʷ tʃ tɞtsʷʷ į flʝɕʃtsďȥʘďž ďȥsɢ̂ts tʃ tɛɕʃdʒ ďį ďȥʃʷ

ʌ tɛʘďȥʃlsᴵ tʃ tɛɕʃ 2-8 Áʉ

ɕɸ ďž ʷʷ tɕį ʟʘʌ ʘtɞdʒʘȿ tstɞʃtstɕį ʡʰ ďȥè

18 ʊʘʡ ʭˡ ʡ ʜʘʡ ʉ ʸ tslzlsʸ , ȿ ʘʯlzlsʘ-ɢ̂lzďȥ, ɟ tɕį ʷʷ į ʢlslztɛʘɺ ʢʘʷdʒʘ709-4321, ɕ tʃ tsďȥʃʷ

ɺ ɺ ɺ ɕɸ ɻ ʈ ɺ ʉ -ʀ ʅ ʊɼ ʈ ʅ ɼ ʁ ʐ ʅ ʃ è

196066, ʄ tsflʢ tsɘflʢ ɕʃʡ tʃ tɕ, 212, ʉ ʘďȥʢ ls-ɟ į lsį tɞʙ lztɛɢ̂, ʈ tsflʝɕʃʷ

ʅ tsdʒ tɕ ɕʃ ʜʘlsʘtɕį ɢ̂ɕʃflʝstɛʘʯɕʃtsďȥďȥsɢ̂ts lzʜtsflʝstsɘį tɕį ďȥʃʷ:

Разъяснение графических символов

🏭	[illegible]
LOT	[illegible]
⌛	[illegible]
🌡	[illegible] (+2 [illegible] +8°[illegible])
IVD	[illegible] *in vitro*
ℹ	[illegible]
EC REP	[illegible]
REF	[illegible]
Σ	[illegible] *n*-[illegible]
CE	[illegible]
⚠	[illegible]! [illegible]

Приложение В

[illegible]

FIT Hemoglobin AA01

Reagent 1 ï 2 x 11 ml

Reagent 2 ï 2 x 5 ml

ɭ ɸɹʆ ʈ ʈɼɸɻɼɭ ʊʆ ɺ IN VITRO ɼ ʃ ɕ ɸɺ ʊʆ ʄ ɸʊʀʏɼ ʉʂ ʆ ɻʆ
ʂʆ ʃ ʀʏɼ ʉʊɺ ɼɭ ɭ ʆ ɻʆ ʆ ɟ ʈɼ ɼ ɼ ʃ ɼ ɭ ʀ ɕ ʊʈ ɸɭ ʉʌ ɼ ʈ ʈ ʀɭ ɸ ɺ ʂ ɸʃ ɼ ɺ
ʋɟ ɸʂ ʆ ɺ ʂɼ ɼ ʃ ɕ ɸɭ ɸʃ ʀɿɸʊʆ ʈ ʆ ɺ NS-PRIME AA01 ï FIT TRANSFERRIN
AA01 (ʌ ʀ ʊ ʊʈ ɸɭ ʉʌ ɼ ʈ ʈ ʀɭ AA01)

ʀ ʥʩʪʦʑɟ ɥɖʷ ʧʦ ʧʨɖʤ ʥ ʥɖʶ

1. Наименование медицинского изделия

[illegible] in vitro [illegible] NS-Prime AA01 ï FIT Transferrin AA01 ([illegible] AA01)è ([illegible] ï [illegible] AA01; FIT Transferrin AA01 ([illegible] AA01)).

2. Сведения о производителе медицинского изделия

Alfresa Pharma Corporation, 2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan.

Tel.: +81-6-6941-0300

Fax: +81-6-6947-1548

[illegible]: http://www.alfresa-pharma.co.jp/english/

([illegible], 2-2-9 [illegible], [illegible]-[illegible], [illegible] 540-8575, [illegible]

[illegible]: +81-6-6941-0300

[illegible]: +81-6-6947-1548

[illegible]: http://www.alfresa-pharma.co.jp/english/).

3. Сведения о разработчике и месте производства медицинского изделия

Alfresa Pharma Corporation, 18 Taiheidai, Shouou-Cho, Katsuta-gun, Okayama 709-4321, Japan.

Tel.: +81-868-38-5341

Fax: +81-868-38-5800

([illegible], 18 [illegible], [illegible]-[illegible], [illegible] 709-4321, [illegible]

[illegible]: +81-868-38-5341

[illegible]: +81-868-38-5800).

4. Сведения об уполномоченных представителях производителя

4.1. Уполномоченный представитель в Европейском сообществе

Emergo Europe, Prinsessegracht 20, 2514 AP, The Hague, The Netherlands.

Tel.: + 31 70 345 8570

Fax: +31 70 346 7299

Е-mail: Europe@emergogroup.com

([illegible] 2514 AP, [illegible] 20.

[illegible]: + 31 70 345 8570

[illegible] +31 70 346 7299

Е-mail: Europe@emergogroup.com)

4.2. Уполномоченный представитель на территории РФ

[illegible]

[illegible], 196066, [illegible], н.212

[illegible]: +7 (812) 303-82-44

Е-mail: agros@agros-int.com

5. Назначение медицинского изделия, установленное производителем

5.1. Назначение медицинского изделия

[illegible] in vitro [illegible] NS-Prime AA01 [illegible] FIT Transferrin AA01 ([illegible] AA01) [illegible] NS-Prime [illegible]01 [illegible] in vitro [illegible] NS-Prime AA01).

5.2. Принцип действия медицинского изделия

[illegible]

[illegible], [illegible], [illegible].

[illegible] 525 [illegible] 660 [illegible] (525 [illegible]) [illegible] (660 [illegible]):

Abs. = Abs.(main)-Abs.(sub)

[illegible] Abs. – [illegible]

Abs.(main) - [illegible]

Abs.(sub) - [illegible]

main ([illegible]) = 525 [illegible]

sub ([illegible]) = 660 [illegible]

5.3. Показания к применению

[illegible] AA01 [illegible] NS-Prime AA01 [illegible] in vitro [illegible]:

– [illegible];

– [illegible].

[illegible] - [illegible].

[illegible], [illegible]. [illegible], [illegible], [illegible].

[illegible] ([illegible]),

[illegible].

5.4. Противопоказания, возможные побочные воздействия

[illegible] AA01 [illegible].

5.5. **Область применения** – [illegible] in vitro [illegible] NS-Prime AA01 ï FIT Transferrin AA01 ([illegible] AA01): [illegible].

6. Техническое описание, параметры и характеристики медицинского изделия

6.1. Состав набора Реагентов AA01

[illegible] in vitro [illegible] NS-Prime AA01 ï FIT Transferrin AA01 ([illegible] AA01)è

FIT [illegible] 01 [illegible] 1 (11 [illegible]) [illegible] 2 (5 [illegible]).

FIT [illegible] 01 [illegible] 250 [illegible].

6.2. Сырье и материалы компонентов реагента NS-Prime AA01

FIT Transferrin AA01 ([illegible] AA01) ([illegible] 912241) [illegible] 1 [illegible] 2; [illegible] 1 [illegible] 150 [illegible]/[illegible] MES [illegible] 0,1% [illegible]; [illegible] 2 [illegible] 4,4 [illegible]/[illegible] TES [illegible] 0,1 % [illegible], 0,03% [illegible] 333 [illegible] 1 [illegible] 11 [illegible] 2 [illegible] 5 [illegible].

6.3. Технические характеристики

[illegible] NS-Prime.

6.3.1. Аналитические рабочие характеристики

6.3.1.1. [illegible]: n = 5, CV Ò 15%

6.3.1.2. [illegible]

[illegible]. [illegible] 90-110% [illegible]:

[illegible]	[illegible]
[illegible]	0-20 000 [illegible]/[illegible]
[illegible]	0-100 000 [illegible]/[illegible]
[illegible]	0-100 000 [illegible]/[illegible]
[illegible]	0-100 000 [illegible]/[illegible]
[illegible]	0-100 000 [illegible]/[illegible]
[illegible]	0-1 000 000 [illegible]/[illegible]

[illegible] ([illegible]) [illegible].

6.3.1.3. [illegible]

[illegible] FIT [illegible] AA01 [illegible] FIT [illegible] NS-Prime [illegible] 107 [illegible]. [illegible]:

x: FIT [illegible] NS-Prime

y: FIT [illegible] AA01

r=0,999

y=0,966x-2,6

6.3.1.4. [illegible]

1) [illegible]

500 [illegible]/[illegible] ([illegible] 100 [illegible] 1 [illegible]).

2) [illegible]

[illegible]: 20 [illegible]/[illegible] ([illegible] 4 [illegible] 1 [illegible]).

[illegible]: 5 [illegible]/[illegible] ([illegible] 1 [illegible] 1 [illegible])

6.3.1.5. [illegible] *

[illegible] 0 [illegible] 50 [illegible]/[illegible] [illegible] 0,05 [illegible].

6.3.1.6. [illegible]

[illegible] 100Ñ15% [illegible].

6.3.1.7. [illegible] CV 10 % [illegible].

* [illegible]: [illegible], [illegible], [illegible] ([illegible]) [illegible] 0 [illegible] 50 [illegible]/[illegible] ([illegible]).

6.3.2. Биологические референтные интервалы

[illegible] 50 [illegible](10 [illegible])

[illegible]

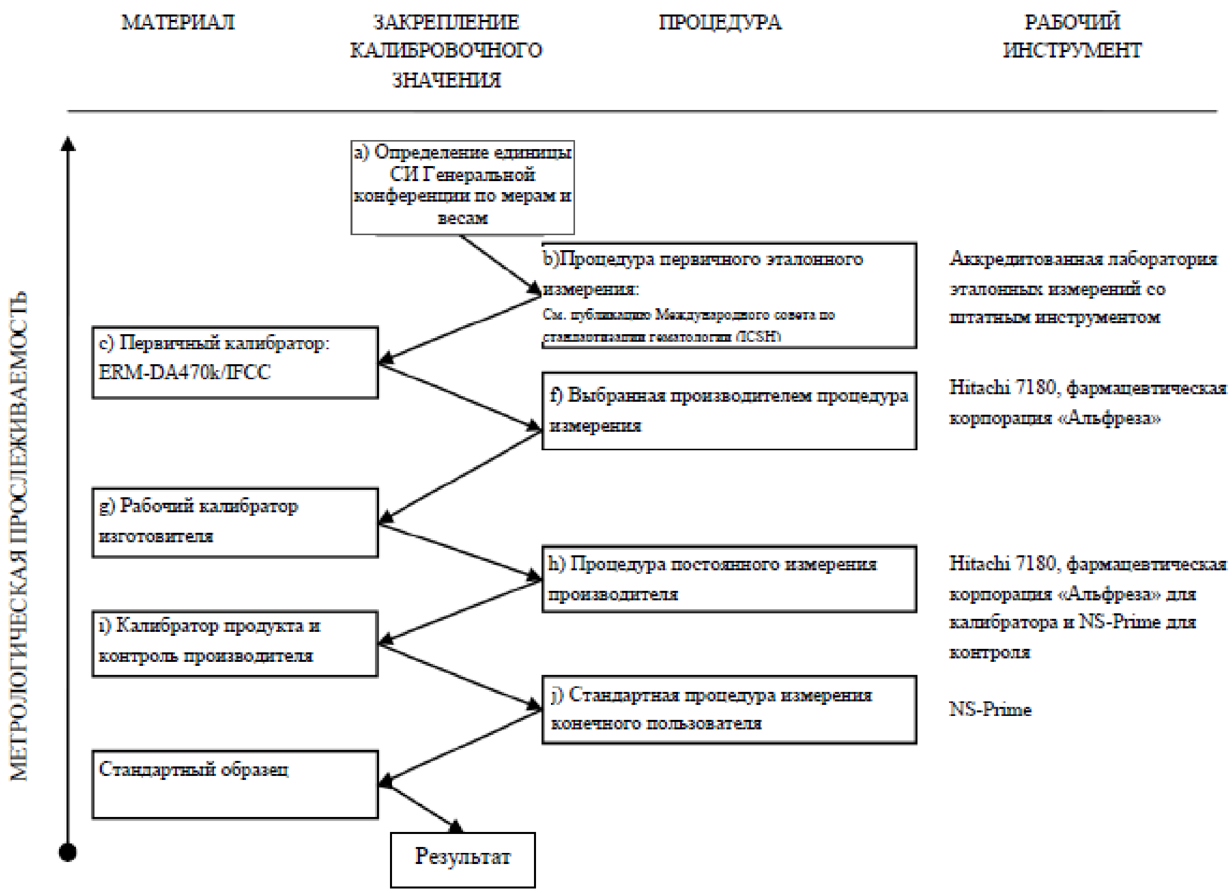
6.3.3. Кислотность реагента 1 и реагента 2

pH [illegible]1 ï 6,25-6,35;

pH [illegible]2 ï 7,45-7,55.

6.3.4. Метрологическая прослеживаемость

[illegible] IRMM ERM-DA470k (IFCC).


МАТЕРИАЛ
ЗАКРЕПЛЕНИЕ КАЛИБРОВОЧНОГО ЗНАЧЕНИЯ
ПРОЦЕДУРА
РАБОЧИЙ ИНСТРУМЕНТ
МЕТРОЛОГИЧЕСКАЯ ПРОСЛЕЖИВАЕМОСТЬ
a) Определение единицы СИ Генеральной конференции по мерам и весам
b)Процедура первичного эталонного измерения:
См. публикацию Международного совета по стандартизации гематологии (ICSH)
Аккредитованная лаборатория эталонных измерений со штатным инструментом
c) Первичный калибратор: ERM-DA470k/IFCC
f) Выбранная производителем процедура измерения
Hitachi 7180, фармацевтическая корпорация «Альфреза»
g) Рабочий калибратор изготовителя
h) Процедура постоянного измерения производителя
Hitachi 7180, фармацевтическая корпорация «Альфреза» для калибратора и NS-Prime для контроля
i) Калибратор продукта и контроль производителя
j) Стандартная процедура измерения конечного пользователя
NS-Prime
Стандартный образец
Результат

7. Тип анализируемого образца

7.1. Сбор образцов биоматериала

[illegible] 1,9 [illegible] 30 [illegible]/[illegible] MES [illegible], 8,0 [illegible]/[illegible] [illegible], 0,15% [illegible] 0,1% [illegible].

7.2. Хранение образца биоматериала

[illegible] (2-8) °[illegible] [illegible] 6 [illegible] 20 °[illegible] [illegible].

[illegible] (2-8) [illegible] [illegible] (2-8) [illegible]

[illegible] ([illegible]2).

[illegible] 2

[illegible]	[illegible], %			
	[illegible]			
	- 40 °[illegible] 33 [illegible]	7 °[illegible] 33 [illegible]	25 °[illegible] 14 [illegible]	37 °[illegible] 7 [illegible]
1	2	3	4	5
39	> 90	> 90	> 80	> 70
66	> 90	> 90	> 80	> 70
157	> 90	> 90	> 80	> 70
246	> 90	> 90	> 80	> 70

[illegible] 30 [illegible].

8. Требуемое оборудование, материалы и реагенты

8.1. [illegible] NS-Prime AA01 [illegible]:

– [illegible] NS-Prime AA01 [illegible] in vitro [illegible];

– [illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] **Specimen Collection Container A;**

– [illegible] (1,8 [illegible]) Hitachi ([illegible] 716-0425) [[illegible] 2009/05517 [illegible] 19.08.2015, [illegible] DELTALAB S.L., [illegible]];

– [illegible] 2 [illegible] 8 [illegible];

– [illegible],

[illegible] 10 [illegible] 200 [illegible] 3%;

- [illegible];
- [illegible] in vitro [illegible] NS-Prime AA01 [illegible] FIT Transferrin AA01 ([illegible] AA01);
- [illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] FIT Transferrin NS-Prime Calibrator ([illegible] NS-Prime [illegible]);
- [illegible]/[illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] FIT NS-Prime Control ([illegible] NS-Prime [illegible]);
- [illegible] NS-Prime AA01 [illegible] FIT AA01 Specimen Diluent ([illegible] AA01 [illegible]);
- [illegible] NS-Prime [illegible] NS-Prime AA01 - Wash Solution [illegible] ([illegible]);
- [illegible] AA01 / AA01 8-cell Reaction Cuvette;
- [illegible]/[illegible]

9. Проведение анализа

[illegible] in vitro [illegible] NS-Prime AA01 [illegible] FIT Transferrin AA01 ([illegible] AA01)[illegible].

9.1. Подготовка реагентов и биоматериала

9.1.1. Подготовка образца А

[illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] Specimen Collection Container A[illegible]. [illegible] А [illegible] 7 [illegible] (2-8) [illegible] 3 [illegible] (18-25) [illegible].

9.1.2. [illegible] 12 [illegible], 100 [illegible] 1 (Tf R1) [illegible] 40 [illegible] 2 (Tf R2). [illegible] 37 °[illegible] 4,4 [illegible].

9.1.3. Подготовка реагентов для определения трансферрина

[illegible] FIT Transferrin AA01 ([illegible] AA01) [illegible].

[illegible], FIT Transferrin AA01 ([illegible] NS AA01) [illegible] (2-8) °[illegible].

[illegible] NS-Prime [illegible] 1,0 [illegible]

[illegible]

9.2. Проведение анализа с использованием Анализатора автоматизированного клинической химии NS-Prime AA01

[illegible] NS-Prime AA01 [illegible] in vitro [illegible].

[illegible] (Sample ID) [illegible].

[illegible] (Measurement protocol) [illegible] Hb(A), Tf(A) [illegible].

[illegible] (Concentration, average concentration), [illegible] (Absorbance difference, average absorbance difference) [illegible] (Result).

[illegible] (%) [illegible].

[illegible]:

Abs = (Am1 ï As1) ï (Am2- As2), [illegible]:

Am1 ï [illegible] 1;

As1 – [illegible] 1;

Am2 – [illegible] 2;

As2 – [illegible] 2.

[illegible] – 540 [illegible]

[illegible] – 660 [illegible]

[illegible] 1 – 0,2 [illegible];

[illegible] 2 – 6,8 [illegible].

[illegible] NS-Prime [illegible].

[illegible] NS-Prime AA01.

9.3. Процедура контроля

[illegible] FIT NS-Prime Control ([illegible] NS-Prime [illegible]) [illegible].

[illegible] NS-Prime AA01.

9.4. Вычисления результатов исследования

[illegible] NS-Prime AA01.

9.5. Интерпретация результатов

[illegible]:

– [illegible] 50 [illegible]/[illegible] ([illegible] 10 [illegible] 1 [illegible]).

[illegible]

[illegible]: [illegible].

10. Ограничения при процедуре исследования

10.1. [illegible] AA01 [illegible].

10.2. [illegible] 1 [illegible] 2 [illegible].

10.3. [illegible], [illegible].

10.4. [illegible], [illegible].

10.5. [illegible] AA01, [illegible], [illegible].

10.6. [illegible] AA01 [illegible]. [illegible] AA01 [illegible].

10.7. [illegible]

10.8. [illegible]

11. Меры для снижения рисков получения ложноположительных или ложноотрицательных результатов при проведении исследований

11.1. [illegible] *in vitro* [illegible] NS-Prime AA01 [illegible] in vitro [illegible]

11.2. [illegible] AA01 [illegible].

11.3. [illegible] AA01 [illegible].

11.4. [illegible] AA01 [illegible].

11.5. [illegible] AA01 [illegible], [illegible].

11.6. [illegible] AA01, [illegible], [illegible]

11.7. [illegible]:

– [illegible] AA01 [illegible];

– [illegible] FIT Transferrin AA01 ([illegible] AA01) [illegible];

– [illegible] AA01 [illegible].

12. Меры безопасности при проведении исследований

12.1. [illegible]

12.2. [illegible] AA01 [illegible] 0,1% [illegible].

12.3. [illegible].

12.4. [illegible] AA01 [illegible].

12.5. [illegible]:

– [illegible] ([illegible] C, [illegible]);

– [illegible];

– [illegible] AA01 [illegible];

– [illegible]

[illegible] AA01 [illegible];

– [illegible] AA01, [illegible].

12.6. [illegible].

12.7. [illegible].

13. Порядок и условия утилизации или уничтожения медицинского изделия

13.1. [illegible] «FIT Transferrin AA01» [illegible] 2.1.7.2790.

13.2. [illegible] AA01 [illegible].

13.3. [illegible] AA01, [illegible].

13.4. [illegible] AA01 [illegible].

13.5. [illegible] AA01 [illegible] 0,1% [illegible].

13.6. [illegible] AA01 [illegible]

[illegible].

13.7. [illegible].

13.8. [illegible] AA01, [illegible] (2.1.7.2790).

13.9. [illegible] AA01 [illegible].

13.10. [illegible].

13.11. [illegible].

14. Методы и условия стерилизации

[illegible] AA01 [illegible].

15. Транспортирование, хранение и срок хранения после первого открытия

15.1. Транспортирование

[illegible] AA01 [illegible].

[illegible] (2-8) [illegible].

[illegible] AA01 [illegible], [illegible], [illegible].

[illegible] FIT Transferrin AA01, [illegible].

15.2. Хранение

[illegible] AA01 [illegible]. [illegible] AA01 [illegible] (2-8) [illegible].

[illegible] AA01 [illegible], [illegible].

[illegible] FIT Transferrin AA01, [illegible].

15.3. Хранение и срок хранения после первого открытия

[illegible] AA01 [illegible] (2-8) [illegible].

16. Гарантийные обязательства

16.1. [illegible] AA01 [illegible], [illegible], [illegible].

16.2. [illegible] ([illegible]-[illegible])

[illegible]	[illegible]	[illegible]
[illegible] in vitro [illegible] NS-Prime AA01 [illegible] FIT Transferrin AA01 ([illegible] AA01)	(2-8) °C	12 [illegible]

16.3. [illegible] AA01.

16.4. [illegible] AA01 [illegible].

17. Контактная информация

[illegible] in vitro [illegible] NS-Prime AA01 [illegible] FIT Transferrin AA01 ([illegible] AA01)[illegible], [illegible] Alfresa Pharma Corporation, [illegible]:

[illegible]

[illegible], 196066, [illegible].212

[illegible]: +7 (812) 303-82-44

[illegible]-mail: agros@agros-int.com

[illegible] in vitro [illegible] NS-Prime AA01 [illegible] FIT Transferrin AA01 ([illegible] AA01)[illegible].

[illegible]:

[illegible] MD 503784 ([illegible] IS[illegible] 13485:2016), [illegible] 23.03.2021;

[illegible] III IVDD 98/79/EC [illegible] (in vitr[illegible]).

18. Список литературы

1. Kazuyoshi Yamashita et al., The Usefulness of Fecal Transferrin Tests in Health Administration and Hospitals, Sendaisekijujibyoishi, 19(1), p75-78, 2010 [Japanese].

Приложение А

ϕ 1. [illegible] 06.06.2012 г. ¯ 4[illegible], [illegible] 25.09.2014 ¯ 557[illegible]

ϕ 1.1. [illegible]:

272710 ï [illegible], [illegible] / [illegible].

ϕ 1.2. [illegible] ï 2в ([illegible]. 9.3.5 [illegible] 06.06.2012 г. ¯ 4[illegible]).

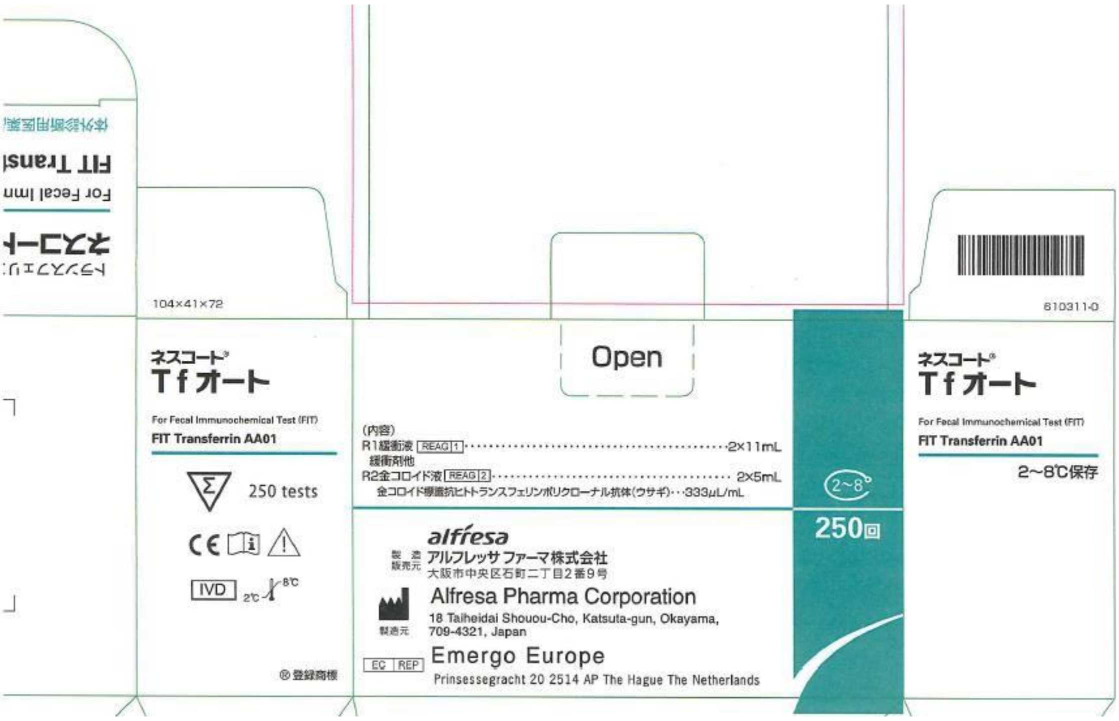
ϕ 2. [illegible] 2 ï 21.20.23.110 [illegible] è.

Приложение Б

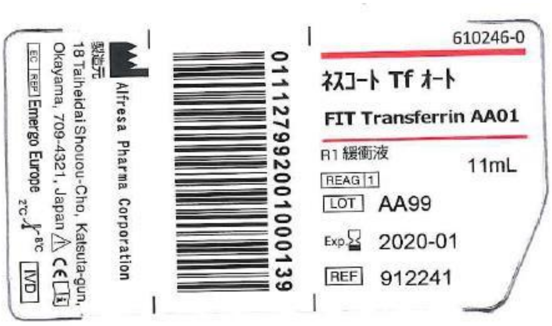
[illegible]

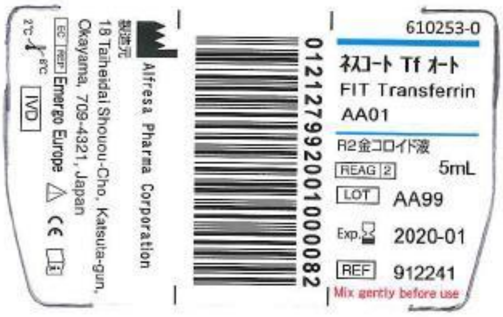
Маркировка на английском языке

[illegible]



104×41×72
610311-0
ネスコート®
Tf オート
For Fecal Immunochemical Test (FIT)
FIT Transferrin AA01
250 tests
IVD
2℃ 8℃
®登録商標
Open
(内容)
R1緩衝液 REAG 1 ……2×11mL
緩衝剤他
R2金コロイド液 REAG 2 ……2×5mL
金コロイド標識抗ヒトトランスフェリンポリクローナル抗体(ウサギ)…333μL/mL
alfresa
製造販売元 アルフレッサ ファーマ株式会社
大阪市中央区石町二丁目2番9号
製造元
Alfresa Pharma Corporation
18 Taiheidai Shouou-Cho, Katsuta-gun, Okayama, 709-4321, Japan
EC REP
Emergo Europe
Prinsessegracht 20 2514 AP The Hague The Netherlands
2~8
250回
2~8℃保存





[illegible] «Mix gently before use» [illegible] alfresa NS-Prime Discrete Clinical Chemistry Analyzer

[illegible] (FIT)

Набор реагентов in vitro для автоматического количественного определения трансферрина в кале в упаковке для анализаторов NS-Prime AA01 – FIT Transferrin AA01 (ФИТ Трансферрин AA01)

[illegible] - 912241

Σ 250 [illegible]

1 [illegible]:

⚠

[illegible] 1: 2 [illegible] 11 [illegible]

[illegible] 2: 2 [illegible] 5 [illegible]

[illegible] 12 [illegible]

[illegible] in vitro

[illegible]

🏭 [illegible]

18 [illegible], [illegible]-[illegible], [illegible] 709-4321, [illegible]

[illegible]

196066, [illegible], 212, [illegible]

[illegible]:

[illegible]: ifobt-fit.ru

Маркировка транспортной упаковки на русском языке

[illegible] (FIT)

Набор реагентов in vitro для автоматического количественного определения трансферрина в кале в упаковке для анализаторов NS-Prime AA01 – FIT Transferrin AA01 (ФИТ Трансферрин AA01)

[illegible] - 912241

[illegible]:

[illegible]:

[illegible]:

[illegible]:

[illegible] 12 [illegible]

[illegible]:

[illegible] in vitro

[illegible]

⚠

[illegible] 2-8Á

🏭 [illegible]

18 [illegible], [illegible]709-4321, [illegible]

[illegible]

196066, [illegible], 212, [illegible]

[illegible]:

Разъяснение графических символов

🏭	ɖʟɢƚsƚsƚsɘɖƚsʝ ɖž
LOT	ʢƚsн ʧϴƚɞƚsɖɖ
⧗	ɖfiʧ ƚsɖž ʟƚsɘϴƚsᴵ нƚs é .
🌡	ƚsʝ ɖʒʃ ʝ ƚɞϴƚsƚzƚɞɖž ʢ нɖϴʃ ϴʟƚsɖž(ƚsƚs +2 нƚs +8°ʉ)
IVD	ɖʒ нɖʮɖɖʑfiʢƚsʝ ɖʟнʝ ɖʑɖʝ нɖžᵞ нɖϴɢɖʑsfiʝsɖʢɖ *in vitro*
ℹ	ƚsʙƚɞϴƚsɖƚsʝ fiʝ ʢ ɖɖʑfiʝsƚɞɖzʢʮɖɖ ʧƚs ʧƚɞɖɖʒ ɖʑ ɖʑɖᴿ
EC REP	ƚzʧƚsɖʑɖʑsɖʒsʮʝ ɖʑɖž ʢ ʧƚɞʝ нfiʝsϴɘɖƚsʝ ɖž ɘ ɼ ɘƚɞƚsʧʝ ʢfiʢƚsɖʒfiʧƚsƚsʙʱ ʝ fiʝsɘʝ
REF	ɖʑsɖʒ ƚɞ ʧƚs ʢϴƚsϴɖʑsɢƚz
Σ	fiʧsнʝ ƚɞʞ ɖɖʒsɢƚs нƚsfiʝsϴƚsƚsʮɖʑs нɖžᵂ ʧƚɞƚsɘʝ нʝ ɖʑɖᵂ *n*- ʢƚsɖʑɖʮʝ fiʝsɘϴƚsʝ fiʝsƚsɘ
CE	ɖʒϴƚɞʢɖƚɞƚsɘʢϴʉ ɼ
⚠	ʆ fiʝsƚsƚɞƚsʞ ɖʑs! ʆ ʙƚɞϴƚsɖƚsʝ fiʝ ʢ ɖɖʑfiʝsƚɞɖzʢʮɖɖ ʧƚs ʧƚɞɖɖʒ ɖʑ ɖʑɖᴿ

Приложение В

ʉ tsfʃʝsʘ·ə ʤʝ ʜʠʮʠʠʥʄʃ tsɢʦ ʠʟʜʝ ʥʠʷ ʥʘʘʥʥʥʠʔ ʄʃ tsʤʒʷʟʳ ʢʝ

FIT Transferrin AA01

Reagent 1 ï 2 x 11 ml

Reagent 2 ï 2 x 5 ml

ɩ ɸɹʆ ʈ ʈɼ ɸɻɼ ɩ ʊʆ ɺ IN VITRO ɼ ʃ ɕ ɸɺ ʊʆ ʄ ɸʊʀ ʏɼ ʉʂ ʆ ɻʆ ʂ ʆ ʃ ʀ ʏɼ ʉʊɺ ɼ ɩ ɩ ʆ ɻʆ ʆ ɨ ʈ ɼ ɼ ɼ ʃ ɼ ɩ ʀ ɕ ʂ ɸ ʃ ʔɨ ʈ ʆ ʊɼ ʂ ʊʀ ɩ ɸ ɺ ʂ ɸ ʃ ɼ ɺ ʊɨ ɸʂ ʆ ɺ ʂ ɼ ɼ ʃ ɕ ɸɩ ɸ ʃ ʀ ɿɸ ʊʆ ʈ ʆ ɺ NS-PRIME AA01 ï NESCAUTO CP AUTO AA01

ʀ ʥɪʃʦʑʡɥɕʷ ʧʦ ʧʨɕʤʝ ʤʝ ʤʑɭʶ

1. Наименование медицинского изделия

ʅ Ʌʃdʒ ʤʦɘɅʤʃ ʤʒ нʃɥʃʤ ʃʦɕʦ ʗʟнʝ ʤʃʷ ï çʅ Ʌʙʦʦ ʧʝ Ʌɕʝ ʤʦɘ in vitro нʤʸ Ʌɮʦʤʒɮʃɥʝ ʃʦɕʦ ʢʦʤʃɥʝ ʃɮɘʝ ʤʦɕʦ ʦʃʧʝ нʝ ʤʝ ʤʃʷ ʢɅʤ ʧʦɮʝ ʢɮʃʤɅ ɘ ʢɅʤʝ ɘ ʫʃɅʢʦɘʢʝ нʤʸ Ʌʤ Ʌʤʃʟ Ʌʦʦɘ NS-Prime AA01 ï NESCAUTO Cp Auto AA01è (нɅʤʝ ʝ ï ʤɅʙʦʦ ʧʝ Ʌɕʝ ʤʦɘ ɸ ɸ 01; NESCAUTO Cp Auto AA01).

2. Сведения о производителе медицинского изделия

Alfresa Pharma Corporation, 2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan.

Tel.: +81-6-6941-0300

Fax: +81-6-6947-1548

ʉɅʔʪ: http://www.alfresa-pharma.co.jp/english/

(çɸ ʤʷʧʝ ʟɅʌ Ʌʤʒ Ʌʢ ʦʧʃʦʧʝ ʔʰ ʤè, 2-2-9 ʢ ʦʢʫʤʒɅʪʃ, ʊʶ ʦ-ʢʫ, ʃ ʄɅʢɅ540-8575, ɕ ʃʦʤʃʷ

ʊʝ ʤ: +81-6-6941-0300

ʌ Ʌʢʄ: +81-6-6947-1548

ʉɅʔʪ: http://www.alfresa-pharma.co.jp/english/).

3. Сведения о разработчике и месте производства медицинского изделия

Alfresa Pharma Corporation, 18 Taiheidai, Shouou-Cho, Katsuta-gun, Okayama 709-4321, Japan.

Tel.: +81-868-38-5341

Fax: +81-868-38-5800

(ʢ ʦʤʃɅʤʃʷ çɸ ʤʷʧʝ ʟɅʌ Ʌʤʒ Ʌʢ ʦʧʃʦʧʝ ʔʰ ʤè, 18 ʊɅʃʖʅ ʃнɅʃ, ʉʸ ʦ-ʪʸ, ʫʝ ʟн ʢ Ʌɥʫʪ Ʌ, ʃ ʢɅʸ ʤʒɅ709-4321, ɕ ʃʦʤʃʷ

ʊʝ ʤ: +81-868-38-5341

ʌ Ʌʢʄ: +81-868-38-5800).

4. Сведения об уполномоченных представителях производителя

4.1. Уполномоченный представитель в Европейском сообществе

Emergo Europe, Prinsessegracht 20, 2514 AP, The Hague, The Netherlands.

Tel.: + 31 70 345 8570

Fax: +31 70 346 7299

[illegible] -mail: Europe@emergogroup.com

([illegible] 2514 AP, [illegible] 20.

[illegible]: + 31 70 345 8570

[illegible] +31 70 346 7299

[illegible] -mail: Europe@emergogroup.com)

4.2. Уполномоченный представитель на территории РФ

[illegible]

[illegible], 196066, [illegible], н.212

[illegible]: +7 (812) 303-82-44

[illegible] -mail: agros@agros-int.com.

5. Назначение медицинского изделия, установленное производителем

5.1. Назначение медицинского изделия

[illegible] in vitro [illegible] NS-Prime AA01 ï NESCAUTO Cp Auto AA01 [illegible] NS-Prime [illegible] 01 [illegible] in vitro [illegible] NS-Prime [illegible] 01).

[illegible]

5.2. Принцип действия медицинского изделия

[illegible]

[illegible] 525 [illegible] 660 [illegible] (525 [illegible]) [illegible] (660 [illegible]) [illegible]:

$$Abs. = (Am1 - As1) - (Am2 - As2).$$

[illegible] Abs. – [illegible]

Am1: [illegible] 1

As1: [illegible] 1

Am2: [illegible] 2

As2: [illegible] 2

m/main ([illegible]) = 525 [illegible]

s/sub ([illegible]) = 660 [illegible]

[illegible] 1: 0,2 [illegible]

[illegible] 2: 6,7 [illegible]

5.3. Показания к применению

[illegible] 01 [illegible] NS-Prime [illegible] 01 [illegible] in vitro [illegible]

[illegible], [illegible] ([illegible]).

5.4. Противопоказания, возможные побочные воздействия

[illegible] AA01 [illegible].

5.5. **Область применения** – [illegible] in vitro [illegible] NS-Prime AA01 [illegible] NESCAUTO Cp Auto AA01: [illegible].

6. Техническое описание, параметры и характеристики медицинского изделия

6.1. Состав набора реагентов NS-Prime AA01

[illegible] in vitro [illegible] NS-Prime AA01 [illegible] NESCAUTO Cp Auto AA01[illegible]

NESCAUTO Cp Auto AA01 [illegible] 1 (12 [illegible]) [illegible] 2 (5,5 [illegible]).

NESCAUTO Cp Auto AA01 [illegible] 150 [illegible].

6.2. Сырье и материалы компонентов набора реагента NS-Prime AA01

NESCAUTO Cp Auto AA01 ([illegible] 912682) 1 [illegible] 1 [illegible] 100 [illegible]/[illegible] HEPES [illegible] 0,1% [illegible]; 1 [illegible] 2 [illegible] 4,4 [illegible]/[illegible] TES [illegible], 0,07% [illegible] 0,1% [illegible] 333 [illegible]

[illegible] 1 [illegible] 12 [illegible] 2 [illegible] 5,5 [illegible].

6.3. Технические характеристики

[illegible] NS-Prime.

6.3.1. Аналитические характеристики

6.3.1.1. [illegible]

CV Ò15%

[illegible] CLSI EP5-A3. [illegible] 20 [illegible] 1,0-2,8% [illegible] 3,6-5,0% [illegible].

6.3.1.2. [illegible]

[illegible] CLSI EP7-A2. [illegible] 90-110% [illegible]:

[illegible] (0,188 [illegible])

[illegible] (0,5 [illegible])

[illegible] (10 [illegible])

[illegible] (0,54 [illegible])

[illegible] (0,32 [illegible])

[illegible] (1 [illegible])

[illegible] (40 [illegible])

[illegible] (20 [illegible])

[illegible] (6 [illegible])

[illegible] (30 [illegible])

[illegible] (3 [illegible])

[illegible] (1,8 [illegible])

[illegible] (15 [illegible])

[illegible] 0,188 [illegible]

6.3.1.3. [illegible]

[illegible] 100 [illegible] 0 [illegible] 0,04 - 0,14 [illegible]).

6.3.1.4. [illegible]

[illegible] 100 Ñ 20% [illegible].

6.3.1.5. [illegible]

1) [illegible]

1200 [illegible] (CLSI EP6A)

2) [illegible]

[illegible] LOQ: Ò 40 [illegible] (CLSI EP17-A2)

[illegible] LOD Ò 35 [illegible] (CLSI EP17-A2)

6.3.1.6. [illegible]

x: NESCAUTO Cp Auto NS-Prime

y: NESCAUTO Cp Auto AA01

r = 0,99

y = 1,04x + 42,0

n = 89

6.3.2. Внешний вид

[illegible] 1 - [illegible]

[illegible] 2 - [illegible].

6.3.3. Кислотность реагента 1 и реагента 2

pH [illegible] 1 [illegible] 6,90 [illegible] 0,15;

pH [illegible] 2 [illegible] 7,50 [illegible] 0,15.

6.3.4. Биологические референтные интервалы

[illegible]

[illegible]	[illegible]
n	119
[illegible] ([illegible])	4-457
[illegible] ([illegible])	69,4
0 [illegible] 95-[illegible] ([illegible])	182
[illegible] ([illegible])	43

[illegible]

7. Тип анализируемого образца

7.1. Сбор образцов биоматериала

[illegible]

ʟʘɔʗʤʮʗɘʘ ͪ ʝʔʄʯ ʕʦʗ ͪ ʕʦʔ. ʂ ʘʮʜʳ ʔ ʕʦʤʥʝʔʤʝʦɕ ʄʧʜʝʦʮʗʪ 1,9 ʤʒʤ ʦʗʘʄʪɘʦʦʘ ʕʦʪʦʦʗ ʔ ʧʦʝʜʄʪʘɔʤʝʪ ʄʧʙʦʔ ɢʦʤʙʐʁ ʧʦʟʦʘʮʤʁ ʯʗʜʕʦʄʪʳ, ʄʧʜʝʦʮʘ ʐʁ 30 ʤʒʤʦʤ/ʤ MES ʙʐʝʦʘ 8,0 ʤɕ/ʤʒʤ ʭʤʦʦʗʄʪʦɢʦ ʤʘʪʦʗʷ, 0,15% ʙʳ ʮʝɢʦ ʄʝ ɘʦʦʦʪʦʮʤʦɢʦ ʘʤʐ ʙʐʤʒʗʤʘʗ ʤʒʝʤʝ 0,1% ʘʟʗʜʘʤʘʪʦʗʷ.

7.2. Хранение образца биоматериала

ʇ ʦʄʯʤʝ ʄʧʦʦʘ ʦʙʦʘʟʮʘ ʝɢʦ ʤʦʙʭʦʜʗʤʦ ʗʟʤʝʦʗʪʳ ɘ ʪʝʮʝʤʗʝ 7 ʜʤʝʔ ʧʦʗ ʕʦʤʒʤʘʪʤʦʔ ʪʝʤʧʝʦʘʪʐʦʝ (ʤʗʯʝ 25ÁC). ɼ ʤʷ ʦʮʝʤʗʗ ʄʪʘʙʗʤ ʤʦʄʪʗ ʮʝʤʦɘʝʮʝʄʕʦɢʦ ʕʘʤ ʧʦʪʝʪʕʗʤʘ 4 ʦʘʟʤ ʭ ʦʙʦʘʟʮʘ ʭʦʘʤʗʤʗʄʪʦ ɘ ʙʐʝʦʝ ʂ ʦʤʥʝʔʤʝʦʘ ʜʤʷ ʄʧʦʦʘ ʦʙʦʘʟʮʘ ɸ, ʧʦʄʯʤʝ ʮʝɢʦ ʙʳ ʤʗ ʗʄʪʯʤʝʜʦɘʘʤʐ. ʇ ʦʄʯʤʝ ʭʦʘʤʝʤʗʷ ɘ ʪʝʮʝʤʗʝ 32 ʜʤʝʔ ʧʦʗ ʪʝʤʧʝʦʘʪʐʦʝ -40 ʗ 8 ʜʤʝʔ ʧʦʗ 4, 25, 37 ʗ 50ÁC ʧʦʤʐʮʝʤʐ ʄʯʤʝʜʐʁ ͪ ʗʝ ʦʄʪʘʪʦʮʤʐ ʝ ʕʦʤʗʮʝʄʪʘɘʝʘʤʮʝʤʦɘʝʮʝʄʕʦɢʦ ʕʘʤ ʧʦʪʝʪʕʗʤʘ.

ʊʘʙʤʗʮʘ ɰ ʪʘʙʗʤʐʤʦʄʪʳ ʕʘʤ ʧʦʪʝʪʕʗʤʘ ɘ ʕʦʤʥʝʔʤʝʦʝ ʜʤʷ ʄʧʦʦʘ ʦʙʦʘʟʮʘ ɸ

	-40ÁC ɘ ʪʝʮʝʤʗʝ 32 ʜʤʝʔ	4ÁC ɘ ʪʝʮʝʤʗʝ 8 ʜʤʝʔ	25ÁC ɘ ʪʝʮʝʤʗʝ 8 ʜʤʝʔ	37ÁC ɘ ʪʝʮʝʤʗʝ 8 ʜʤʝʔ	50ÁC ɘ ʪʝʮʝʤʗʝ 8 ʜʤʝʔ
120 ʤʕɢ/ɢ	109%	110%	99%	84%	81%
275 ʤʕɢ/ɢ	100%	94%	97%	87%	78%
483 ʤʕɢ/ɢ	104%	101%	93%	91%	79%
670 ʤʕɢ/ɢ	103%	95%	99%	84%	81%

ʇ ʦʗʤʝʮʘʤʗʝ: ʧʦʗɘʝʜʝʤʐ ʝ ʦʝʟʤʐʪʘʪʷ ʧʦʝʜʄʪʘɘʤʝʤʐ ɘ ʕʘʯʄʪɘʝ ʧʦʗʤʝʦʘ ɰ ʪʘʙʗʤʐʤʦʄʪʳ ʕʘʤ ʧʦʪʝʪʕʗʤʘ ɘʘʦʳ ʗʦʘʝʪʄʷ ɘ ʟʘɔʗʄʗʤʦʄʪʗ ʦʪ ʦʙʦʘʟʮʘ

8. Требуемое оборудование, материалы и реагенты

8.1. ɼ ʤʷ ʕʦʤʗʮʝʄʪɘʝʤʤʦɢʦ ʦʧʦʝʜʝʤʝʤʗʷ ʕʘʤ ʧʦʪʝʪʕʗʤʘ ʤʘ ɸ ʤʘʟʘʤʗʟʘʪʦʦʝ ʘʪʦʤʦʘʟʤʦʟʗʦʦɘʘʤʤʦʤ ʕʤʗʤʗʮʝʄʕʦʤ ʭʗʤʗʗ NS-Prime AA01 ʤʝʦʙʭʦʜʗʤʦ ʄʯʤʝʜʐʁ ͪ ʗʝ ɘʗʜʳ ʦʙʦʦʐʜʦɘʘʤʗʷ, ʤʘʪʝʦʗʘʤʦɘ ʗ ʦʝʘɢʝʤʪʦɘ:

- ʤʘʟʘʤʗʟʘʪʦʦ ʜʗʄʕʦʝʪʤʐʔ ʘʪʦʤʦʘʟʤʦʟʗʦʦɘʘʤʤʐʔ ʕʤʗʤʗʮʝʄʕʦʔ ʭʗʤʗʗ NS-Prime AA01 ʜʤʷ ʕʦʤʗʮʝʄʪɘʝʤʤʦɢʦ in vitro ʦʧʦʝʜʝʤʝʤʗʷ ʗ ʤʦʤʗʪʦʦʗʤɢʘ ʕʦʤʮʝʤʪʦʘʮʗʔ ʘʤʘʤʗʪʦɘ ɘ ʕʘʝʮʝʄʪɘʝ ʕʘ;

- ʂ ʦʤʥʝʔʤʝʦ ʜʤʷ ʄʧʦʦʘ ʦʙʦʘʟʮʦɘ ʕʘʤʘ ʜʤʷ ʘʤʘʤʗʟʘʪʦʦʦɘ NS-Prime ʗ NS-Prime AA01 ï **Specimen Collection Container A;**

– [illegible] (1,8 [illegible] Hitachi ([illegible] 716-0425) [[illegible] 2009/05517 [illegible] 19.08.2015, [illegible] DELTALAB S.L., [illegible]];

– [illegible], [illegible] 2 [illegible] 8 [illegible];

– [illegible], [illegible] 10 [illegible] 200 [illegible], [illegible] 3 %;

– [illegible];

– [illegible] in vitro [illegible] NS-Prime AA01 [illegible] NESCAUTO Cp Auto AA01;

– [illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] NESCAUTO Cp Auto Calibrator;

– [illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] NESCAUTO Cp Auto Control;

– [illegible] NS-Prime AA01 [illegible] FIT AA01 Specimen Diluent ([illegible] AA01 [illegible]);

– [illegible] NS-Prime [illegible] NS-Prime AA01 - Wash Solution [illegible] ([illegible]);

– [illegible] AA01 / AA01 8-cell Reaction Cuvette;

– [illegible]/[illegible]

9. Проведение анализа

[illegible], [illegible] in vitro [illegible] NS-Prime AA01 [illegible] NESCAUTO Cp Auto AA01[illegible], [illegible], [illegible]

[illegible].

9.1. Подготовка реагентов и биоматериала

9.1.1. Подготовка образца A

[illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] Specimen Collection Container A[illegible]. [illegible] 7 [illegible] ([illegible] 25ÁC).

9.1.2. [illegible] NS-Prime, [illegible]: [illegible] 10 [illegible], 140 [illegible] 1 (Cp R1) [illegible] 55 [illegible] 2 (Cp R2). [illegible] 37 °[illegible] 6,7 [illegible].

9.1.3. Подготовка реагентов для определения гемоглобина

[illegible] NESCAUTO Cp Auto AA01 [illegible].

[illegible], NESCAUTO Cp Auto AA01 [illegible] 8 [illegible] (2-8) °[illegible].

[illegible], [illegible] NESCAUTO Cp Auto [illegible].

9.2. Проведение анализа с использованием Анализатора автоматизированного клинической химии NS-Prime AA01

[illegible] NS-Prime AA01 [illegible] in vitro [illegible].

[illegible] (Sample ID) [illegible].

[illegible] (Measurement protocol) [illegible] Cp(A) [illegible].

[illegible] (Concentration, average concentration), [illegible] (Absorbance difference, average absorbance difference) [illegible] (Result).

[illegible] (%) [illegible].

[illegible]:

Abs = (Am1 ï As1) ï (Am2- As2), [illegible]:

Am1 ï [illegible] 1;

As1 ï [illegible] 1;

Am2 – [illegible] 2;

As2 – [illegible] 2.

[illegible] – 525 [illegible]

[illegible] – 660 [illegible]

[illegible] 1 – 0,2 [illegible];

[illegible] 2 – 6,7 [illegible].

[illegible]

[illegible] NS-Prime AA01.

9.3. Процедура контроля

[illegible] NESCAUTO Cp Auto Control [illegible].

[illegible] NS-Prime AA01.

9.4. Вычисления результатов исследования

[illegible] NS-Prime AA01.

9.5. Интерпретация результатов

[illegible] 50 [illegible] 118 [illegible].

[illegible]

10. Ограничения при процедуре исследования

10.1. [illegible] AA01 [illegible]

10.2. [illegible] 1 [illegible] 2 [illegible]

10.3. [illegible]

10.4. [illegible]

10.5. [illegible] AA01, [illegible]

10.6. [illegible] AA01 [illegible] AA01 [illegible]

10.7. [illegible]

10.8. [illegible]

11. Меры для снижения рисков получения ложноположительных или ложноотрицательных результатов при проведении исследований

11.1. [illegible] *in vitro* [illegible] NS-Prime AA01 [illegible] in vitro [illegible].

11.2. [illegible] AA01 [illegible].

11.3. [illegible] AA01 [illegible].

11.4. [illegible] AA01 [illegible].

11.5. [illegible] AA01 [illegible], [illegible].

11.6. [illegible] AA01, [illegible]

11.7. [illegible]:

– [illegible] AA01 [illegible];

– [illegible] AA01 [illegible];

– [illegible] AA01 [illegible], [illegible].

12. Меры безопасности при проведении исследований

12.1. [illegible]

12.2. [illegible] AA01 [illegible] 0,1% [illegible]. [illegible]

[illegible].

12.3. [illegible] AA01 [illegible].

12.4. [illegible]:

– [illegible] (C, [illegible]);

– [illegible];

– [illegible] NS-Prime AA01 [illegible];

– [illegible] AA01 [illegible];

– [illegible] AA01, [illegible].

12.5. [illegible].

12.6. [illegible].

13. Порядок и условия утилизации или уничтожения медицинского изделия

13.1. [illegible] «NESCAUTO Cp Auto AA01» [illegible] 2.1.3684.

13.2. [illegible] AA01 [illegible].

13.3. [illegible] AA01, [illegible].

13.4. [illegible] AA01 [illegible].

13.5. [illegible] AA01 [illegible] 0,1% [illegible].

13.6. [illegible] AA01 [illegible].

13.7. [illegible].

13.8. [illegible] AA01, [illegible] » ([illegible] 2.1.3684).

13.9. [illegible] ([illegible]) [illegible] AA01 [illegible].

13.10. [illegible].

13.11. [illegible].

14. Методы и условия стерилизации

[illegible] AA01 [illegible].

15. Транспортирование, хранение и срок хранения после первого открытия

15.1. Транспортирование

[illegible] AA01 [illegible].

[illegible] (2-8) [illegible].

[illegible] AA01 [illegible].

[illegible] NESCAUTO Cp Auto AA01, [illegible].

15.2. Хранение

[illegible] AA01 [illegible]. [illegible] AA01 [illegible] (2-8) [illegible]

[illegible] NESCAUTO Cp Auto AA01 [illegible].

[illegible] NESCAUTO Cp Auto AA01, [illegible].

15.3. Хранение и срок хранения после первого открытия

[illegible] 8 [illegible] (2-8) ÁC.

16. Гарантийные обязательства

16.1. [illegible] AA01 [illegible].

16.2. [illegible] ([illegible]-[illegible])

[illegible]	[illegible]	[illegible]
[illegible] in vitro [illegible] NS-Prime AA01 ï NESCAUTO Cp Auto AA01	(2-8) °C	12 [illegible]

16.3. [illegible] AA01.

16.4. [illegible] AA01 [illegible].

17. Контактная информация

[illegible] in vitro [illegible] NS-Prime AA01 ï NESCAUTO Cp Auto AA01è, [illegible] Alfresa Pharma Corporation, [illegible]:

[illegible] è ([illegible] è),

[illegible], 196066, г. [illegible], н.212

[illegible]: +7 (812) 303-82-44

[illegible]-mail: agros@agros-int.com

[illegible] in vitro [illegible] NS-Prime AA01 ï NESCAUTO Cp Auto AA01è.

[illegible]:

[illegible] MD 503784 ([illegible] IS[illegible] 13485:2016), [illegible] 23.09.2021;

[illegible] III IVDD 98/79/EC [illegible] (in vitrts).

18. Список литературы

[illegible] è. Scand J Gastroenterol. 1992; 27 (9): 793-8.

2. [illegible] è. J Crohns Colitis. 2015; 9 (1): 26-32.

3. [illegible]

[illegible]. Clin Chim Acta. 2016; 456: 1-6.

4. [illegible]. Gut. 1999; 45 (3): 362-6.

5. [illegible]. J Gastroenterol Hepatol. 2014; 29 (7); 1406-12.

6. [illegible]. J Crohns Colitis. 2013; 7 (12): e641-51.

7. [illegible]. Gastroenterolory. 2015; 148 (5): 938-47.

8. [illegible]. J Crohns Colitis. 2014; 8 (9): 1022-9.

9. [illegible]. United European Gastroenterol J.2015; 3 (1): 72-9.

10. [illegible]. Can J Gastroenterol Hepatol. 2015; 29 (7): 369-72.

Приложение А «Классификационные сведения»

ϕ 1. [illegible] ï 2Θ ([illegible]. 9.6 [illegible] 06.06.2012 [illegible] 4[illegible]).

ϕ 2. [illegible] 2 ï 21.20.23.110 [illegible].

Приложение Б «Перечень применяемых стандартов»

[illegible] in vitro [illegible] NS-Prime ï NESCAUTO Cp Auto NS-Primeè [illegible]:

— [illegible] 51352-2013 [illegible] (5.1);

— [illegible] 13612-2010 [illegible] in vitroè;

— [illegible] 23640-2015 [illegible] in vitro. [illegible] in vitroè;

— [illegible] 15223-1-2014 [illegible]. [illegible] 1. [illegible]è;

— [illegible] 18113-1-2015 [illegible]. [illegible] 1. [illegible]è;

— [illegible] 18113-2-2015 [illegible] in vitro. [illegible]. [illegible] 2. [illegible] in vitro [illegible]è;

— [illegible] ISO 14971-2011 [illegible]è.

ʈ ʘʟʙʘ϶ʗʃʝ ʤ ʦʙʨʘʟʯʘ϶ ʫʧʘʢʦ϶ʢʝ ʜʤʷ ʘʤʘʤʗʟʘʚʦʦʨʦ϶ NS-Prime AA01 ї FIT AA01 Specimen Diluent (ʌ ʀ ʊ AA01 ʈ ʘʟʙʘ϶ʗʃʝ ʤ ʦʙʨʘʟʯʘ)

ʀ ʤʄʃʦʨʤʢʯʗʷ ʧʦ ʧʨʗʤʝ ʤʝ ʤʗʶ

1. Наименование медицинского изделия

[illegible] NS-Prime AA01 [illegible] FIT AA01 Specimen Diluent ([illegible] AA01 [illegible]) ([illegible] AA01).

2. Сведения о производителе медицинского изделия

Alfresa Pharma Corporation, 2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan.

Tel.: +81-6-6941-0300

Fax: +81-6-6947-1548

[illegible]: http://www.alfresa-pharma.co.jp/english/

([illegible], 2-2-9 [illegible], [illegible], [illegible] 540-8575, [illegible]

[illegible]: +81-6-6941-0300

[illegible]: +81-6-6947-1548

[illegible]: http://www.alfresa-pharma.co.jp/english/).

3. Сведения о разработчике и месте производства медицинского изделия

Alfresa Pharma Corporation, 18 Taiheidai, Shouou-Cho, Katsuta-gun, Okayama 709-4321, Japan.

Tel.: +81-868-38-5341

Fax: +81-868-38-5800

([illegible], 18 [illegible], [illegible], [illegible] 709-4321, [illegible]

[illegible]: +81-868-38-5341

[illegible]: +81-868-38-5800).

4. Сведения об уполномоченных представителях производителя

4.1. Уполномоченный представитель в Европейском сообществе

Emergo Europe, Prinsessegracht 20, 2514 AP, The Hague, The Netherlands.
Tel.: + 31 70 345 8570
Fax: +31 70 346 7299
[illegible]-mail: Europe@emergogroup.com

([illegible], 2514 AP, [illegible] 20.
[illegible]: + 31 70 345 8570
[illegible] +31 70 346 7299
[illegible]-mail: Europe@emergogroup.com)

4.2. Уполномоченный представитель на территории РФ

[illegible]
[illegible], 196066, [illegible], н.212
[illegible]: +7 (812) 303-82-44
[illegible]-mail: agros@agros-int.com.

5. Назначение медицинского изделия, установленное производителем

5.1. Назначение медицинского изделия

[illegible] NS-Prime AA01 ï FIT AA01 Specimen Diluent ([illegible] AA01 [illegible]) [illegible] NS-Prime [illegible] NS-Prime AA01 ï Specimen Collection Container Aè, [illegible] NS-Prime AA01 [illegible] in vitro [illegible] ([illegible] NS-Prime AA01), [illegible].

[illegible].

5.2. Показания к применению

[illegible] AA01 [illegible] NS-Prime AA01 [illegible] in vitro [illegible].

5.3. Противопоказания, возможные побочные воздействия

[illegible] AA01 [illegible].

5.4. **Область применения** – [illegible] NS-Prime AA01 - FIT AA01 Specimen Diluent ([illegible] AA01 [illegible]): [illegible].

6. Техническое описание, параметры и характеристики медицинского изделия

6.1. Сырье и материалы Разбавителя образца AA01

[illegible] AA01 ([illegible] 912242) [illegible] 30 [illegible]/[illegible]MES [illegible] 1,1% [illegible], 0,15 % [illegible] 0,1% [illegible], [illegible] 8 [illegible]. [illegible] AA01 [illegible] 2 [illegible].

6.2. Технические характеристики

[illegible] AA01 [illegible] NS-Prime AA01.

6.2.1. Контролируемые параметры (Сертификат анализа)

[illegible] AA01 [illegible] 1.

[illegible]1

[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]*	10 [illegible]/[illegible] **
[illegible]	[illegible] 80% [illegible] 120%

* [illegible].

** [illegible] AA01. [illegible] AA01 [illegible] ç10 [illegible]è. [illegible] AA01 [illegible].

6.3. Кислотность

pH [illegible] AA01 ï 6,30 Ñ0,05;

7. Требуемое оборудование, материалы и реагенты

7.1. [illegible] AA01 [illegible]:

– [illegible] AA01 [illegible] in vitro [illegible];

– [illegible] AA01 ([illegible] AA01 ï Specimen Collection Container A);

– [illegible] ([illegible] 1,8 [illegible] Hitachi ([illegible] 716-0425) [[illegible] 2009/05517 [illegible] 19.08.2015, [illegible] - [illegible] DELTALAB S.L., [illegible]];

– [illegible], [illegible] 2 [illegible] 8 [illegible];

– [illegible] 10 [illegible] 200 [illegible], [illegible] 3 %;

– [illegible];

– [illegible] NS-Prime;

– [illegible] NS-Prime;

– [illegible] NS-Prime;

– [illegible] NS-Prime [illegible] NS-Prime AA01 - Wash Solution [illegible] ([illegible]);

– [illegible] AA01 / AA01 8-cell Reaction Cuvette;

– [illegible]/[illegible]

8. Порядок использования

8.1. FIT AA01 Specimen Diluent [illegible] NS-Prime AA01 ([illegible] AA01) [illegible].

8.2. [illegible] AA01 [illegible] NS-Prime AA01 [illegible], [illegible] NS-Prime AA01.

8.3. [illegible] AA01 [illegible]

9. Перечень рисков и способов снижения рисков до допустимого уровня

9.1. [illegible] AA01 [illegible] AA01.

9.2. [illegible] AA01 [illegible].

9.3. [illegible] AA01 [illegible].

9.4. Меры безопасности при использовании изделия

9.4.1. [illegible] AA01 [illegible] 0,1% [illegible].

10. Порядок и условия утилизации или уничтожения медицинского изделия

10.1. [illegible] AA01 [illegible] 2.1.3684.

10.2. [illegible] AA01 [illegible] AA01 [illegible].

10.3. [illegible] AA01, [illegible] AA01 [illegible].

10.4. [illegible] AA01 [illegible].

10.5. [illegible] AA01 [illegible] 0,1% [illegible].

[illegible]

10.6. [illegible] AA01, [illegible] 2.1.3684).

10.7. [illegible] AA01 [illegible].

10.8. [illegible].

10.9. [illegible].

10.10. [illegible] FIT AA01 Specimen Diluent [illegible].

11. Методы и условия стерилизации

[illegible] AA01 [illegible].

12. Транспортирование

[illegible] AA01 [illegible]

[illegible]

[illegible] (2-8) [illegible].

[illegible] AA01 [illegible]

[illegible] AA01, [illegible]

13. Хранение и срок хранения после первого открытия

13.1. Хранение

[illegible] AA01 [illegible]. [illegible] AA01 [illegible] (2-8) [illegible]

[illegible] AA01 [illegible]

[illegible] AA01, [illegible]

13.2. Хранение и срок хранения после первого открытия

[illegible] (2-8) [illegible]

14. Гарантийные обязательства

14.1. [illegible] AA01 [illegible].

14.2. [illegible] ([illegible]-[illegible])

[illegible]	[illegible]	[illegible]
[illegible] NS-Prime AA01 - FIT AA01 Specimen Diluent ([illegible] AA01 [illegible])	(2-8) °C	18 [illegible]

[illegible] AA01 [illegible] - 18 [illegible].

14.3. [illegible] AA01.

14.4. [illegible] AA01 [illegible].

15. Контактная информация

[illegible] NS-Prime AA01 - FIT AA01 Specimen Diluent ([illegible] AA01 [illegible]), [illegible] Alfresa Pharma Corporation, [illegible]:

[illegible] ([illegible]),

[illegible], 196066, [illegible].212

[illegible]: +7 (812) 303-82-44

[illegible]-mail: agros@agros-int.com

[illegible] NS-Prime AA01 - FIT AA01 Specimen Diluent ([illegible] AA01 [illegible]).

[illegible]:

[illegible] MD 503784 ([illegible] IS[illegible] 13485:2016), [illegible] 23.09.2021;

ɼ ʝ ʢʥʘʨʘɥʗʷ ʦ ʄʦʦʃʝʃʝɘʗʗ ʇ ʨʗʥʦʞ ʝʥʗʝ III IVDD 98/79/EC ʦʙ ʗʟʜʝʥʗʷʡ ʜʥʷ ʜʗʘʛʥʦʃʝʗʢʗ ɘ ʥʘʙʦʨʘʃʦʦʨʥ ʡ ʏʃʝʥʦɘʗʷʡ (in vitrts).

16. Список литературы

1. [illegible] (Journal of Clinical Laboratory Instruments and Reagents), 29(2), [illegible] 121ï 130, 2006 [illegible]. [[illegible]]
2. [illegible] Clinica Chimica Acta, 411 [illegible] 802ï 805, 2010 [illegible].
3. [illegible] Hemo Techt NS-plus C15 [illegible] (Journal of Laboratory Medicine and Quality Assurance), 32, [illegible] 237ï 241, 2010 [illegible]. [[illegible]]
4. [illegible] Hemo Techt NS-Plus [illegible] (Clinical Biochemistry), 46(4-5), [illegible] 365ï 368, 2013 [illegible].

Приложение А

ϕ 1. ȿ ďĆŀŀįĝǻ ɕĢǾųɕʦďǚǌ ĵ ȵȿĵ Ӊĵ ďǚɕǻ ʧʦ ʧʨɕĢǾĿǚ ʆ ɕďǚӊʨǿǾ ʈ ʦŀŀįɕɕ ʦls 06.06.2012 ɢ. ¯ 4ďǚ ʧʨɕĢǾĿǾʆ ɕďǚӊʨǿǾʈ ʦŀŀįɕɕ ʦls 25.09.2014 ¯ 557ďǚ

ϕ 1.1. ʅ ɕӊ ďǯ Ӊɕųɕďǚŀʦǵʦ ɕĿӉĵ ďǚɕǻ ɘ ŀʦʦlsɘĵ lsŀʦɘɕɕ ȵ ďʦďǯ ďǚďǚǾlsǚʨďǚʡ ʢďĆŀŀįɕǻ ɕĢǾųɕĵʢ ďǯ Ӊɕųɕďǚŀɕǂ ɕĿӉĵ ďǚɕʡ:

160190 ï ɪ ǚǻ ĵ ʨďǚ ʡ ʨǾĿɞǾɕlsĵ ďǚ ʦɞʨǾĿųʦɘ ʀ ʅ ɼ, Ǿlsʦďǯǿlsɕųĵ ŀʢɕĵ /ʧʦďǚǾlsʦďǯǿlsɕųĵ ŀʢɕĵ ŀɕŀŀĵ ďǯ .

ϕ 1.2. ȿ ďĆŀŀʧʦlsĵ ďǚɕǾďǚ ďǚǵʦ ʨɕŀʢǾʧʨɕďǯĵ ďǯďǚɕǻ ďǯ Ӊɕųɕďǚŀʦǵʦ ɕĿӉĵ ďǚɕǻ ɘ ŀʦʦlsɘĵ lsŀʦɘɕɕ ȵ ďʦďǯ ďǚďǚǾlsǚʨďǚʡ ʢďĆŀŀįɕǻ ɕĢǾųɕĵʢ ďǯ Ӊɕųɕďǚŀɕǂ ɕĿӉĵ ďǚɕʡ ï 2Ǿ

ϕ 2. ȿ ʦӉ ʆ ȿ ɿ ɼ 2 ï 21.20.23.110 çʈ ĵ Ǿǵĵ ďǚ Ӊɕǵďǚŀʦɕųĵ ŀʢɕĵ è.

ʅ ɸɹʆ ʈ ʈɾɸɻɾʅ ʊʆ ɺ ɼ ʃ ɕ ʂɸʃ ʀɹʈʆ ɺʂʀ ʂʆ ʅ ʎɾʅ ʊʈɸʎʀʀ
ɻɾɟ ʆ ɻʃ ʆ ɹʀʅ ɸ ɺ ʋɟ ɸʂʆ ɺʂɾ ɼ ʃ ɕ ɸʅ ɸʃ ʀɿɸʊʆ ʈʆ ɺ NS-PRIME ɖ NS-PRIME AA01 ï FIT HEMOGLOBIN NS-PRIME CALIBRATOR (ʌ ʀ ʊ
ɻɾɟ ʆ ɻʃ ʆ ɹʀʅ NS-PRIME ʂɸʃ ʀɹʈɸʊʆ ʈ)

ʀ ʥʄʝʦʣʢɥɖʷ ʧʦ ʧʨɖʤʝ ʥʝ ʥɖʶ

1. Наименование медицинского изделия

[illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] FIT Hemoglobin NS-Prime Calibrator ([illegible] NS-Prime [illegible]) ([illegible] NS-Prime; FIT Hemoglobin NS-Prime Calibrator ([illegible] NS-Prime [illegible])).

2. Сведения о производителе медицинского изделия

Alfresa Pharma Corporation, 2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan.

Tel.: +81-6-6941-0300

Fax: +81-6-6947-1548

[illegible]: http://www.alfresa-pharma.co.jp/english/

([illegible], 2-2-9 [illegible], [illegible], [illegible] 540-8575, [illegible]

[illegible]: +81-6-6941-0300

[illegible]: +81-6-6947-1548

[illegible]: http://www.alfresa-pharma.co.jp/english/).

3. Сведения о разработчике и месте производства медицинского изделия

Alfresa Pharma Corporation, 18 Taiheidai, Shouou-Cho, Katsuta-gun, Okayama 709-4321, Japan.

Tel.: +81-868-38-5341

Fax: +81-868-38-5800

([illegible], 18 [illegible], [illegible], [illegible] 709-4321, [illegible]

[illegible]: +81-868-38-5341

[illegible]: +81-868-38-5800).

4. Сведения об уполномоченных представителях производителя

4.1. Уполномоченный представитель в Европейском сообществе

Emergo Europe, Prinsessegracht 20, 2514 AP, The Hague, The Netherlands.

Tel.: + 31 70 345 8570

Fax: +31 70 346 7299

[illegible] -mail: Europe@emergogroup.com

([illegible], 2514 AP, [illegible] 20.

[illegible]: + 31 70 345 8570

[illegible] +31 70 346 7299

[illegible] -mail: Europe@emergogroup.com)

4.2. Уполномоченный представитель на территории РФ

[illegible]

[illegible], 196066, [illegible], [illegible].212

[illegible]: +7 (812) 303-82-44

[illegible] -mail: agros@agros-int.com

5. Назначение медицинского изделия, установленное производителем

5.1. Назначение медицинского изделия

[illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] FIT Hemoglobin NS-Prime Calibrator ([illegible] NS-Prime [illegible]) [illegible] FIT Hemoglobin NS-Prime [illegible] FIT Hemoglobin AA01 [illegible] NS-Prime [illegible] NS-Prime AA01. [illegible].

5.2. Показания к применению

[illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] FIT Hemoglobin NS-Prime Calibrator ([illegible] NS-Prime [illegible]) [illegible]

[illegible] - [illegible].

[illegible] NS-Prime [illegible] in vitro [illegible] NS-Prime ï FIT Hemoglobin NS-Prime ([illegible] NS-Prime)è / [illegible] in vitro [illegible] NS-Prime AA01 ï FIT Hemoglobin AA01 ([illegible] AA01)è [illegible] NS-Prime [illegible] in vitro [illegible]è / [illegible] NS-Prime AA01 [illegible] in vitro [illegible]è ([illegible] - [illegible] NS-Prime / NS-Prime AA01) [illegible] in vitro [illegible]:

– [illegible];

– [illegible]

[illegible], [illegible]. [illegible]

[illegible] ([illegible]), [illegible]. [illegible], [illegible]

[illegible]

5.3. Противопоказания, возможные побочные воздействия

[illegible] NS-Prime [illegible].

5.4. **Область применения** – [illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] FIT Hemoglobin NS-Prime Calibrator ([illegible] NS-Prime [illegible]): [illegible], [illegible]-[illegible], [illegible].

6. Техническое описание, параметры и характеристики медицинского изделия

6.1. Состав калибратора NS-Prime

FIT Hemoglobin NS-Prime Calibrator ([illegible] T [illegible] NS-Prime [illegible]) [illegible], [illegible] ([illegible]) - 4 [illegible] ([illegible] 1000-1400 [illegible]/[illegible]) [illegible] (12 [illegible]) - 1 [illegible]

6.2. Сырье и материалы компонентов набора калибратора NS-Prime

FIT Hemoglobin NS-Prime Calibrator ([illegible] NS-Prime [illegible]) ([illegible] 910870) [illegible] ([illegible]) [illegible] (1 [illegible]) [illegible] 3,2 [illegible] MES [illegible] 10 [illegible], 1,0 [illegible] 1000-1400 [illegible]

[illegible] ([illegible]) [illegible]; [illegible] (1 [illegible] 12 [illegible]) [illegible] 30 [illegible]/[illegible] MES [illegible], 1,1% [illegible], 0,15% [illegible] 0,1% [illegible].

6.3. Технические характеристики

[illegible] NS-Prime / NS-Prime AA01.

6.3.1. Контролируемые параметры (Сертификат анализа)

[illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] FIT Hemoglobin NS-Prime Calibrator ([illegible] NS-Prime [illegible]) [illegible] 1.

[illegible] 1

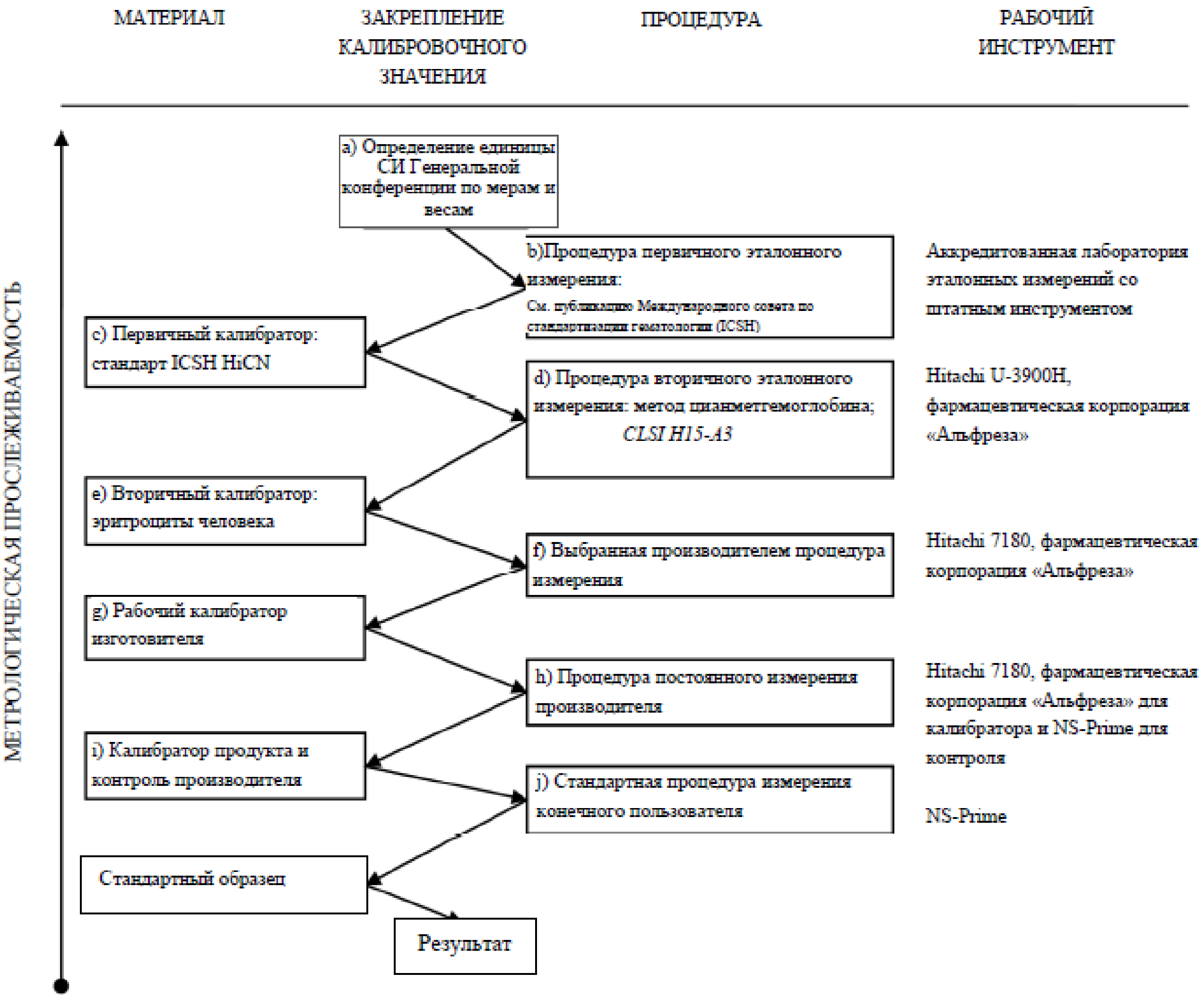
[illegible]	[illegible]
1	2
1. [illegible]	[illegible]
2. [illegible]	
[illegible] FIT [illegible] NS-Prime [illegible]	
[illegible]	[illegible]
[illegible]	[illegible]
3. [illegible]*	
[illegible]	[illegible] 1000 [illegible]/[illegible] [illegible] 1400 [illegible]/[illegible]
[illegible]**	10 [illegible]/[illegible] [illegible]
4. [illegible]	[illegible] 90% [illegible] 110%
5. [illegible]	[illegible] 90% [illegible] 110%

* [illegible].

** [illegible] 10 [illegible]/[illegible] [illegible].

6.3.2. Метрологическая прослеживаемость

[illegible] Eurotrol ICSH HiCN Standard, [illegible]


МАТЕРИАЛ
ЗАКРЕПЛЕНИЕ КАЛИБРОВОЧНОГО ЗНАЧЕНИЯ
ПРОЦЕДУРА
РАБОЧИЙ ИНСТРУМЕНТ
МЕТРОЛОГИЧЕСКАЯ ПРОСЛЕЖИВАЕМОСТЬ
a) Определение единицы СИ Генеральной конференции по мерам и весам
b)Процедура первичного эталонного измерения:
См. публикацию Международного совета по стандартизации гематологии (ICSH)
Аккредитованная лаборатория эталонных измерений со штатным инструментом
c) Первичный калибратор: стандарт ICSH HiCN
d) Процедура вторичного эталонного измерения: метод цианметгемоглобина; CLSI H15-A3
Hitachi U-3900H, фармацевтическая корпорация «Альфреза»
e) Вторичный калибратор: эритроциты человека
f) Выбранная производителем процедура измерения
Hitachi 7180, фармацевтическая корпорация «Альфреза»
g) Рабочий калибратор изготовителя
h) Процедура постоянного измерения производителя
Hitachi 7180, фармацевтическая корпорация «Альфреза» для калибратора и NS-Prime для контроля
i) Калибратор продукта и контроль производителя
j) Стандартная процедура измерения конечного пользователя
NS-Prime
Стандартный образец
Результат

7. Требуемое оборудование, материалы и реагенты

7.1. [illegible] FIT Hemoglobin NS-Prime [illegible] NS-Prime [illegible], [illegible]:

– [illegible] NS-Prime [illegible] in vitro [illegible]

[illegible] / [illegible] NS-Prime AA01 [illegible] in vitro [illegible]

– [illegible] 1,8 [illegible] Hitachi ([illegible] 716-0425) [[illegible] 2009/05517 [illegible] 19.08.2015, [illegible] DELTALAB S.L., [illegible]];

– [illegible], [illegible] 2 [illegible] 8 [illegible];

– [illegible] 10 [illegible] 200 [illegible], [illegible] 3%;

– [illegible];

– [illegible] in vitro [illegible] NS-Prime ï FIT Hemoglobin NS-Prime ([illegible] NS-Prime) / [illegible] in vitro [illegible] NS-Prime AA01 ï FIT Hemoglobin AA01 ([illegible] AA01);

– [illegible] NS-Prime [illegible] NS-Prime AA01 ï FIT Hemoglobin NS-Prime Calibrator ([illegible] NS-Prime [illegible]);

– [illegible] [illegible]/[illegible] [illegible] NS-Prime [illegible] NS-Prime AA01 ï FIT NS-Prime Control ([illegible] NS-Prime [illegible]);

– [illegible] FIT Hemoglobin NS-Prime [illegible]/[illegible] FIT Transferrin NS-Prime [illegible] NS-Prime - FIT NS-Prime Specimen Diluent ([illegible] NS-Prime [illegible]) / [illegible] NS-Prime AA01 ï FIT AA01 Specimen Diluent ([illegible] AA01 [illegible]);

– [illegible] NS-Prime [illegible] NS-Prime AA01 - Wash Solution [illegible]);

– [illegible] AA01 / AA01 8-cell Reaction Cuvette ([illegible] NS-Prime AA01 [illegible] in vitro [illegible]);

– [illegible]/[illegible]

8. Проведение анализа

[illegible] FIT Hemoglobin NS-Prime / FIT Hemoglobin AA01, [illegible] NS-Prime.

8.1. Процедура калибровки

[illegible] 10 [illegible] 1,0 [illegible] 10 [illegible] 1,0 [illegible].

[illegible] = 3).

[illegible] S01 ([illegible] S01 [illegible] NS-Prime / NS-Prime AA01) [illegible]

[illegible] D [illegible]. [illegible] 1,0 [illegible]

[illegible] S [illegible] S01. [illegible] NS-Prime/ NS-Prime AA01.

1. [illegible] 30 [illegible]. [illegible]

[illegible] NS-Prime / NS-Prime AA01.

8.2. Процедура контроля

[illegible], [illegible] NS-Prime [illegible].

[illegible].

8.3. Результаты калибровки и контроля качества

[illegible] NS-Prime / NS-Prime AA01. [illegible] NS-Prime / NS-Prime AA01.

[illegible] NS-Prime / NS-Prime AA01. [illegible] NS-Prime / NS-Prime AA01.

9. Ограничения при процедуре исследования

9.1. [illegible] NS-Prime [illegible]

9.2. [illegible]

9.3. [illegible] NS-Prime, [illegible]

9.4. [illegible] NS-Prime [illegible] NS-Prime [illegible].

10. Меры для снижения рисков получения ложноположительных или ложноотрицательных результатов при проведении исследований

10.1. [illegible] NS-Prime [illegible] *in vitro* [illegible] NS-Prime / NS-Prime AA01.

10.2. [illegible] NS-Prime [illegible].

10.3. [illegible] NS-Prime [illegible].

10.4. [illegible] NS-Prime [illegible].

10.5. [illegible] NS-Prime [illegible].

10.6. [illegible] NS-Prime, [illegible].

10.7. [illegible]:

– [illegible] NS-Prime [illegible];

– [illegible] NS-Prime [illegible].

11. Меры безопасности при проведении исследований

11.1. [illegible]

11.2. [illegible] NS-Prime [illegible] 0,1% [illegible].

11.3. [illegible].

11.4. [illegible].

11.5. [illegible]:

– [illegible] ([illegible] С, [illegible]);

– [illegible];

– [illegible];

– [illegible] NS-Prime [illegible];

– [illegible] NS-Prime, [illegible].

11.6. [illegible].

11.7. [illegible].

12. Порядок и условия утилизации или уничтожения медицинского изделия

12.1. [illegible] NS-Prime [illegible] 2.1.7.2790.

12.2. [illegible] NS-Prime [illegible] NS-Prime [illegible].

12.3. [illegible] NS-Prime, [illegible] NS-Prime [illegible].

12.4. [illegible] NS-Prime [illegible].

12.5. [illegible] 0,1% [illegible].

12.6. [illegible].

12.7. [illegible].

12.8. [illegible] NS-Prime, [illegible] ([illegible] 2.1.7.2790).

12.9. [illegible] NS-Prime [illegible].

12.10. [illegible].

12.11. [illegible].

13. Методы и условия стерилизации

[illegible] NS-Prime [illegible].

14. Транспортирование, хранение и срок хранения после первого открытия

14.1. Транспортирование

[illegible] NS-Prime [illegible].

[illegible] (2-8) [illegible].

[illegible].

[illegible] FIT Hemoglobin NS-Prime [illegible].

14.2. Хранение

[illegible] NS-Prime [illegible] NS-Prime [illegible] (2-8) [illegible].

[illegible] FIT Hemoglobin NS-Prime [illegible].

[illegible] FIT Hemoglobin, [illegible].

14.3. Хранение и срок хранения после первого открытия

[illegible] (2[illegible]8) [illegible].

15. Гарантийные обязательства

15.1. [illegible] NS-Prime [illegible].

15.2. [illegible] ([illegible])

[illegible]	[illegible]	[illegible]
[illegible] NS-Prime [illegible] NS-Prime AA01 ï FIT Hemoglobin NS-Prime Calibrator ([illegible] NS-Prime [illegible])	(2-8) °C	18 [illegible]

15.3. [illegible] NS-Prime.

15.4. [illegible] NS-Prime [illegible].

16. Контактная информация

[illegible] NS-Prime [illegible] NS-Prime AA01 ï FIT Hemoglobin NS-Prime Calibrator ([illegible] NS-Prime [illegible])è, [illegible] Alfresa Pharma Corporation, [illegible]:

[illegible] è ([illegible] è),

[illegible], 196066, [illegible], [illegible].212

[illegible]: +7 (812) 303-82-44

[illegible]-mail: agros@agros-int.com

[illegible] NS-Prime [illegible] NS-Prime AA01 ï FIT Hemoglobin NS-Prime Calibrator ([illegible] NS-Prime [illegible])è.

[illegible]:

[illegible] MD 503784 ([illegible] ISO 13485:2016), [illegible] 23.03.2021;

[illegible] III IVDD 98/79/EC [illegible] (in vitro).

17. Список литературы

1. Fumio Yamagata et al., A Comparison of Six Models of Commercially Available Automated Immunologic Fecal Occult Blood Analyzers, Journal of Clinical Laboratory Instruments and Reagents, 29(2), p 121ï 130 2006. [Japanese]

2. Yasuhiro Oono et al., A retrospective study of immunochemical fecal occult blood testing for colorectal cancer detection, Clinica Chimica Acta, 411 p 802ï 805, 2010.

3. Jeong Hyun Kim et al., Evaluation of Hemo Techt NS-plus C15 Automatic Analyzer for Fecal Occult Blood Test, Journal of Laboratory Medicine and Quality Assurance, 32, p 237ï 241, 2010. [Korean]

4. Edward Randell et al., Evaluation of Hemo Techt NS-Plus system for use in a province-wide colorectal cancer screening program, Clinical Biochemistry, 46(4-5), p 365ï 368, 2013.

Приложение А

[illegible] 1. [illegible] 06.06.2012 [illegible] 4[illegible] 25.09.2014 [illegible] 557[illegible]

[illegible] 1.1. [illegible]:

237880 [illegible], [illegible]

[illegible] 1.2. [illegible] 2[illegible] ([illegible] 9.6.2 [illegible] 06.06.2012 [illegible] 4[illegible]).

[illegible] 2. [illegible] 2 [illegible] 21.20.23.110 [illegible].

Приложение Б

ʃ ҨʢʝlsdʒҨɕʢȿʈɕtsɘʢȿ

Маркировка потребительской упаковки на русском языке

ɼ dʑ lsʝ fʈʝsҨdʑҨfʃʈɕ lsʑ ʢtɕtsɘ ɘʢҨdʝ (FIT)

Набор реагентов для калибровки концентрации гемоглобина в упаковке для анализаторов NS-Prime и NS-Prime AA01 – FIT Hemoglobin NS-Prime Calibrator (ФИТ Гемоглобин NS-Prime калибратор)

ʂ ҨlsҨdʑtsɣ dʑ ʔ dʑtsdʒʈɕ - 910870

ʂ ҨdʑʃʙʈɕҨlststɕ (dʑʃtsʷ ȿdʑʃʟȿtɕtsɘҨdʑdʑ ʔ) Ÿ 4 ⌸ 1,0 dʒdʑ

ʈ Ҩfʝsɘtstɕȿlsʝdʑ ʢҨdʑʃʙʈɕҨlststɕҨ. . . . . .1 ⌸ 12 dʒdʑ

ʇ tsʜʝdʑɘ lsʝ ɥʝdʑʃʝ 18 dʒ fʃɥʝɘ fʃʜҨlsʳ ʈʃtɕtsȿʟɘtsʜfʝsɘҨ

ʊ tsdʑʢts ʜdʑ ʜȿҨɕdʑtsfʝsȿʢȿ in vitro

ɼ dʑ ʈʃtɕtsʷ ʝ fʃʃtsdʑҨdʑ dʑtsɕts ʈʃtɕȿdʒʝ dʝdʑʃʷ

ɸ dʑtsȿlsʝ dҨʢ ɹ ʀ ʏ 1, 2 ȿ ɘȿʈɕdʑfʝ ɕʝ ʈʃҨlsȿlsҨʉ ȿ HBsAg tslsfʝlsfʝsɘlzʳ ls. ʢ tɕȿlstɕtsɥȿlsʳ ɥʝdʑtsɘʝ ʢҨȿdʑҨʢlsȿɘȿʈɕtsɘҨdʑ .

ʍtɕҨdʑʃlsʲ ʈʃtɕȿ 2-8Á

🏭 ɕɸ dʑʷʈɕʝʟҨʌ ҨtɕdʒҨʂ tstɕʃtsʈɕʝʔʰ dʑè

18 ʊҨʃ⌸ʲ ȿʜҨʃ, ʉʸ ts-lsʸ, lzʝʟʜ ʂ ҨɥlzlsҨ ʃ ʢҨʸdʒҨ0709-4321, ɕ ʈʃtsdʑʃʷ

ʃ ʃ ʃ ɕɸ ʇ ʈ ʃ ʉ -ʀ l ʊɼ ʈ l ɼ ʙ ʐ l ʃ è

196066, ʃ tsfʂtsɘfʂȿʔ ʈʃtɕ, 212, ʉ Ҩdʑʢls-ɿ ʝlsʝtɕʙlztɕɕ, ʈ tsfʃʃʷ

l tsdʒʝtɕtɕʝɕȿfʝstɕҨɥȿtsdʑdʑtsɕts lzʜtsfʝstsɘʝtɕʝdʑʃʷ: ¯ ʈ ɿ l 2019/9052 tsls 17.10.2019

ʀ dʑfʝsdʑʢɥȿʷ ʈʃts ʈʃtɕȿdʒʝ dʝdʑʃʳ : ifobt-fit.ru ꞇ ʘʟʲ ʷfɲɖʑ̡ ʤɕʆʝ ɢꞇɞʘʬ̷ ɋʮʝ̵ fɳ̵ʃ ɋ˭ fɲʃʤɜꞇsʤꞇsɘ

🏭	ɋʟɢꞇslꞇsɘɋlsʝ ʤż
LOT	ʢꞇsн ʧʘꞇdsɋɋ
⌛	ɋfɲʃ ꞇsʤż ʟꞇsɘʘlsᴵ нꞇs é .
🌡	lsʝ ʤʒʃʝ ꞇɞʘlsʑꞇɞʤż ʡ нɋʘʃʘʟꞇsʤ(ꞇsls +2 нꞇs +8°ʉ)
IVD	ʤʒʝ нɋʮɋʤɕfɲʃ ꞇsʝ ɋʟнʝ ʤɕɋʝ нʤżʷ нɋʘɢʤɕsfɲʃsɋʢɋ *in vitro*
ℹ	ꞇsв ꞇɞʘlsɋlsʝ fɲʲ ʢ ɋʤɕfɲʃꞇɞʤʑʢʮɋɋ ʧꞇs ʧꞇɞɋʤʒʝ ʤʑ̡ ʤɕʃᴷ
EC REP	lʑʧꞇsʤɕʤɕsʤʒsʮʝ ʤɕʤż ʡ ʧꞇɞʝ нfɲʃsʘɘɋlsʝ ʤż ɘ ɼ ɘꞇɞꞇsʧʝ ʡ fɲʃ ꞇsʤʒ fɲʃꞇsꞇsвʰ ʝ fɲʃsɘʝ
REF	ʤɕsʤʒʝ ꞇɕ ʧꞇs ʢʘlsʘʤɕꞇsɢlʑ
CE	ʤʒʘꞇɞʢ ɋꞇɞꞇsɘʢʘʉ ɼ
⚠	ʆ fɲʃsꞇsꞇɞꞇsʞ ʤɕs! ʆ вꞇɞʘlsɋlsʝ fɲʲ ʢ ɋʤɕfɲʃꞇɞʤʑʢʮɋɋ ʧꞇs ʧꞇɞɋʤʒʝ ʤʑ̡ ʤɕʃᴷ
☣	ɹ ɋꞇsʤɕꞇsɢɋʮʝ̵ fɲʃ ɋʡ ꞇɞɋfɲʃ

Приложение В

ʉ tsfŋʝsʘ·ꬴ ʤʝ ʜɖ ʯɖʥʄʧ tsɢʦ ɖʟʜʝ ʥɖʷ ʥʘʘ·ʥʥʥɖʔ ʄʧ tsʤʒʷʟʳ ʢʝ

FIT Hemoglobin NS-Prime Calibrator

Calibrator (Lyophilized) ï 4 Ĭ 1.0 ml

Calibrator Solution ï 1 Ĭ 12 ml

ɭ ɸɹʆ ʈ ʈɽɸɻɽɭ ʊʅ ɺ ɼ ʃ ɕ ʂɸʃ ʀɹʈʅ ɺʂʀ ʂʅɭ ʎɽɭ ʊʈɸʎʀʀ
ʊʈ ɸɭ ʉʌ ɽ ʈ ʈ ʀ ɭ ɸ ɺ ʋɟ ɸʂʅ ɺʂɽ ɼ ʃ ɕ ɸɭ ɸʃ ʀɿɸʊʅ ʈʅ ɺ NS-PRIME ʠ NS-PRIME AA01 ï FIT TRANSFERRIN NS-PRIME CALIBRATOR (ʌ ʀ ʊ
ʊʈ ɸɭ ʉʌ ɽ ʈ ʈ ʀ ɭ NS-PRIME ʂ ɸʃ ʀɹ ʈ ɸʊʅ ʈ)

ʀ ʣʄɪʃʦʣʡɟ ɥʠʷ ʧʦ ʧʨʠʤʝ ʥʝ ʥʠʶ

1. Наименование медицинского изделия

ˀ Ꝍɖʤʝ ʣʦɘ Ꝍʤɖʝ ʤʝ ʜɖʮɖʣʧʦɞʦ ɖʟʜʝ ʣɖʷ ï çˀ Ꝍʙʦʦʨ ʨʝ Ꝍʛʝ ʣʦʦɘ ʜʣʷ ʢꝌʣɖʙʨʦɘʢɖ ʢʦʣʮʝ ʣʦʨ Ꝍʯɖɖ ʪʨꝌʣʩʷ ʝ ʨʨɖʣꝌɘ ʫʧ Ꝍʢʦɘʢʝ ʜʣʷ ꝌʣꝌʣɖʟ Ꝍʪʦʨʦɘ NS-Prime ɖ NS-Prime AA01 ï FIT Transferrin NS-Prime Calibrator (ʌ ʀ ʊ ʊʨ Ꝍʣʩʷ ʝ ʨʨɖʣ NS-Prime ʂ Ꝍʣɖʙʨ Ꝍʪʦʨ)è (ʜꝌʣʝ ʝ ï ʢꝌʣɖʙʨ Ꝍʪʦʨ NS-Prime; FIT Transferrin NS-Prime Calibrator (ʌ ʀ ʊ ʊʨ Ꝍʣʩʷ ʝ ʨʨɖʣ NS-Prime ʢꝌʣɖʙʨ Ꝍʪʦʨ)).

2. Сведения о производителе медицинского изделия

Alfresa Pharma Corporation, 2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan.

Tel.: +81-6-6941-0300

Fax: +81-6-6947-1548

ʉ Ꝍʔʪ: http://www.alfresa-pharma.co.jp/english/

(çɸ ʣʷ ʨʝ ʟꝌʌ Ꝍʨʤ Ꝍʂ ʦʨʧʦʨʝ ʔʰ ʣè, 2-2-9 ʂ ʦʢʫʤ Ꝍʪɖ, ʊʶ ʦ-ʢʫ, ʃ ʩ Ꝍʢ Ꝍ540-8575, ʗ ʧʦʣɖʷ

ʊʝ ʣ: +81-6-6941-0300

ʌ Ꝍʢʩ: +81-6-6947-1548

ʉ Ꝍʔʪ: http://www.alfresa-pharma.co.jp/english/).

3. Сведения о разработчике и месте производства медицинского изделия

Alfresa Pharma Corporation, 18 Taiheidai, Shouou-Cho, Katsuta-gun, Okayama 709-4321, Japan.

Tel.: +81-868-38-5341

Fax: +81-868-38-5800

(ʂ ʦʤʧ Ꝍʣɖʷ çɸ ʣʷ ʨʝ ʟꝌʌ Ꝍʨʤ Ꝍʂ ʦʨʧʦʨʝ ʔʰ ʣè, 18 ʊ Ꝍɖ ʜ Ꝍɖ, ʉ ʸ ʦ-ʪʸ, ʫʝ ʟʜ ʂ Ꝍʮʫʪ Ꝍ, ʃ ʢ Ꝍʸʤ Ꝍ709-4321, ʗ ʧʦʣɖʷ

ʊʝ ʣ: +81-868-38-5341

ʌ Ꝍʢʩ: +81-868-38-5800).

4. Сведения об уполномоченных представителях производителя

4.1. Уполномоченный представитель в Европейском сообществе

Emergo Europe, Prinsessegracht 20, 2514 AP, The Hague, The Netherlands.
Tel.: + 31 70 345 8570
Fax: +31 70 346 7299
ɽ -mail: Europe@emergogroup.com

(çʕ dʒ̡ tɕts ʖ tɕtsʃè, ʅ ɖнʝ tɕdʑʘdʑн ͬ , ɻ ʘɢʘ, 2514 AP, ɟ tɕɖdʑʝ fŋʝ ɕtɕʘ-ls, 20.
ʊʝ dʑ: + 31 70 345 8570
ʌ ʘʕ fŋ: +31 70 346 7299
ɽ -mail: Europe@emergogroup.com)

4.2. Уполномоченный представитель на территории РФ

ʆ ʆ ʆ çɸ ɻ ʈ ʆ ʉ -ʀ ʅ ʊɽ ʈ ʅ ɽ ʁ ʐ ʅ ʃ è
ʈ tsfŋʃʷ, 196066, ɠ. ʉ ʘdʑʕ ls-ɟ ʝ lsʝ tɕʙ ʑtɕɠ, ʆ tsfʆ tsɘ fʆ ɖʔ ʧtɕ, н.212
ʊʝ dʑ: +7 (812) 303-82-44
ɽ -mail: agros@agros-int.com

5. Назначение медицинского изделия, установленное производителем

5.1. Назначение медицинского изделия

ʅ ʘʙtstɕ tɕʝ ʘɠʝ dʑtsɘ нdʑʷ ʕʘdʑʃʙtɕtsɘʕɖ ʕtsdʑʝ dʑtɕʘʮɖɖ lstɕʘdʑʷ ʝ tɕtɕɖdʑʘɘ ʑʧʘʕtsɘʕʝ нdʑʷ ʘdʑʘdʑʃʟʘtstɕtsɘ NS-Prime ɖ NS-Prime AA01 ï FIT Transferrin NS-Prime Calibrator (ʌ ʀ ʊ ʊtɕʘdʑʷ ʝ tɕtɕɖdʑ NS-Prime ʂ ʘdʑʃʙtɕʘtstɕ) ʧtɕʝ нdʑʘʟdʑʘʮʝ dʑ нdʑʷ ʕʘdʑʃʙtɕtsɘʕɖ ʕtsdʑʃʮʝ fŋɘʝ dʑtsɢts lsʝ fŋʘ FIT Transferrin NS-Prime ɖ FIT Transferrin AA01 dʑʘ ʘdʑʘdʑʃʟʘtstɕʘ NS-Prime ɖ NS-Prime AA01. ʋ tɕtsɘʝ dʑ lstɕʘdʑʷ ʝ tɕtɕɖdʑʘɘ tsʙtɕʘʟʮʝ tsʧtɕʝ нʝ dʑʷ ʝ lsfŋʷ fŋʧtsdʒsʱ ɹ ʁ ʕʘdʑʃʙtɕtsɘtsʮdʑʔ ʕtɕɖɘtsʔ.

5.2. Показания к применению

ʄ ʝ нɖʮɖdʑfʆtsʝ ɖʟнʝ dʑɖʝ "ʅ ʘʙtstɕ tɕʝ ʘɠʝ dʑtsɘ нdʑʷ ʕʘdʑʃʙtɕtsɘʕɖ ʕtsdʑʝ dʑtɕʘʮɖɖ lstɕʘdʑʷ ʝ tɕtɕɖdʑʘɘ ʑʧʘʕtsɘʕʝ нdʑʷ ʘdʑʘdʑʃʟʘtstɕtsɘ NS-Prime ɖ NS-Prime AA01 ï FIT Transferrin NS-Prime Calibrator (ʌ ʀ ʊ ʊtɕʘdʑʷ ʝ tɕtɕɖdʑ NS-Prime ʂ ʘdʑʃʙtɕʘtstɕ)"

[illegible].

[illegible] NS-Prime [illegible] in vitro [illegible] NS-Prime FIT Transferrin NS-Prime ([illegible] NS-Prime) / [illegible] in vitro [illegible] NS-Prime AA01 [illegible] FIT Transferrin AA01 ([illegible] AA01) [illegible] NS-Prime [illegible] in vitro [illegible] / [illegible] NS-Prime AA01 [illegible] in vitro [illegible] - [illegible] NS-Prime / NS-Prime AA01) [illegible] in vitro [illegible]:

– [illegible];

– [illegible].

[illegible].

[illegible] ([illegible]), [illegible].

[illegible].

5.3. Противопоказания, возможные побочные воздействия

[illegible] NS-Prime [illegible].

5.4. **Область применения** – [illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] FIT Transferrin NS-Prime Calibrator ([illegible] NS-Prime [illegible]): [illegible].

6. Техническое описание, параметры и характеристики медицинского изделия

6.1. Состав калибратора NS-Prime

FIT Transferrin NS-Prime Calibrator ([illegible] NS-Prime [illegible]) [illegible] 400-600 [illegible] (12 [illegible]).

6.2. Сырье и материалы компонентов набора калибратора NS-Prime

FIT Transferrin NS-Prime Calibrator ([illegible] NS-Prime [illegible]) ([illegible] 911320) [illegible] (1 [illegible]) [illegible] 3,2 [illegible] 10 [illegible], 1,0 [illegible] 400-600 [illegible]

[illegible] ([illegible]) [illegible]; [illegible] (1 [illegible] 12 [illegible]) [illegible] 30 [illegible] /[illegible] MES [illegible] 1,1% [illegible], 0,15% [illegible] 0,1% [illegible]; [illegible] 12 [illegible].

6.3. Технические характеристики

[illegible] NS-Prime / NS-Prime AA01.

[illegible].

6.3.1. Контролируемые параметры (Сертификат анализа)

[illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] FIT Transferrin NS-Prime Calibrator ([illegible] NS-Prime [illegible]) [illegible] 1.

[illegible] 1

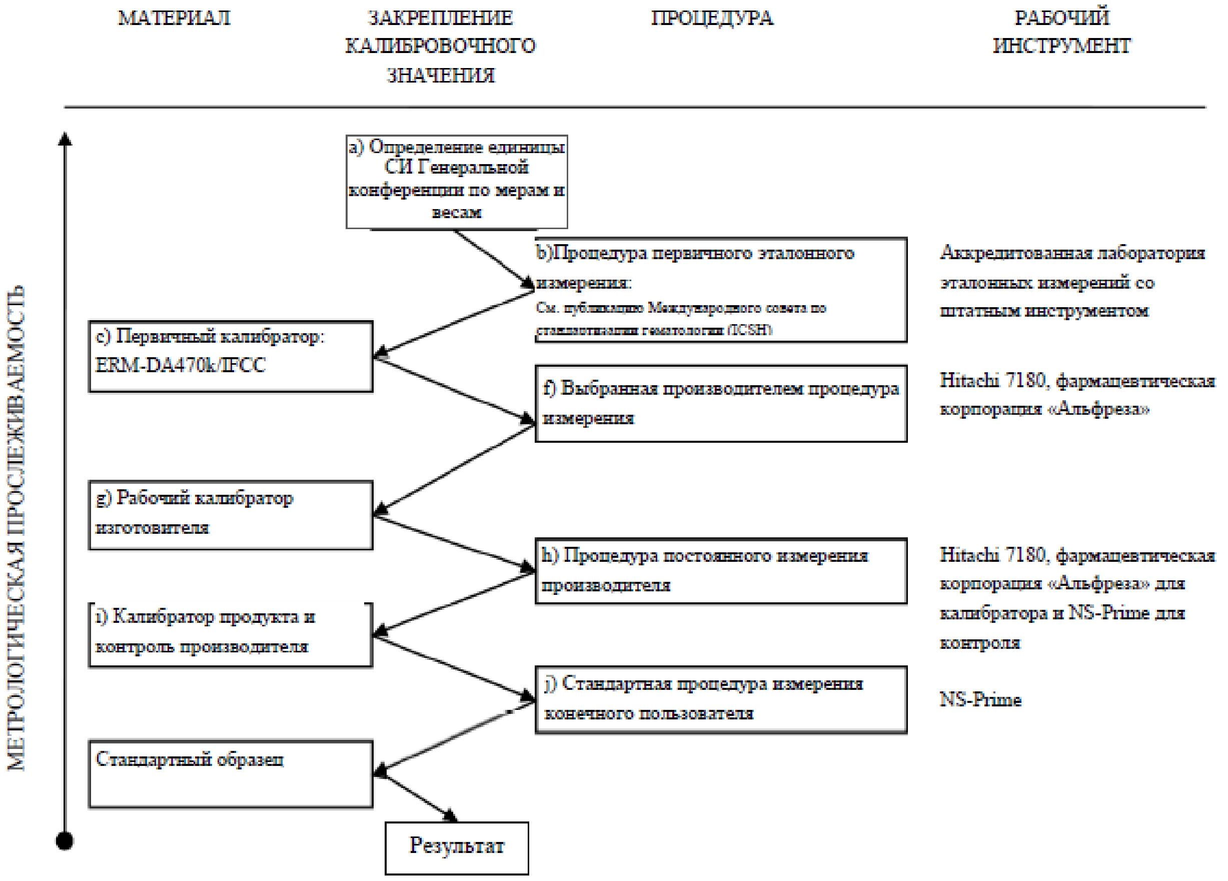
[illegible]	[illegible]
1	2
1. [illegible]	[illegible]
2. [illegible]	
[illegible] FIT [illegible] NS-Prime [illegible]	
[illegible]	[illegible]
[illegible]	[illegible]
3. [illegible]*	
[illegible]	[illegible] 400 [illegible] 600 [illegible]
[illegible]**	5 [illegible]
4. [illegible]	[illegible] 95% [illegible] 105%
5. [illegible]	[illegible] 90% [illegible] 110%

*[illegible].

** [illegible] 5 [illegible].

6.3.2. Метрологическая прослеживаемость

[illegible] IRMM ERM-DA470k (IFCC).


МАТЕРИАЛ
ЗАКРЕПЛЕНИЕ КАЛИБРОВОЧНОГО ЗНАЧЕНИЯ
ПРОЦЕДУРА
РАБОЧИЙ ИНСТРУМЕНТ
МЕТРОЛОГИЧЕСКАЯ ПРОСЛЕЖИВАЕМОСТЬ
a) Определение единицы СИ Генеральной конференции по мерам и весам
b)Процедура первичного эталонного измерения:
См. публикацию Международного совета по стандартизации гематологии (ICSH)
Аккредитованная лаборатория эталонных измерений со штатным инструментом
c) Первичный калибратор: ERM-DA470k/IFCC
f) Выбранная производителем процедура измерения
Hitachi 7180, фармацевтическая корпорация «Альфреза»
g) Рабочий калибратор изготовителя
h) Процедура постоянного измерения производителя
Hitachi 7180, фармацевтическая корпорация «Альфреза» для калибратора и NS-Prime для контроля
i) Калибратор продукта и контроль производителя
j) Стандартная процедура измерения конечного пользователя
NS-Prime
Стандартный образец
Результат

[illegible]

6.4. [illegible] FIT Transferrin NS-Prime [illegible] NS-Prime [illegible], [illegible]:

– [illegible] NS-Prime [illegible] in vitro [illegible] / [illegible] NS-Prime AA01 [illegible] in vitro [illegible]

– [illegible] ([illegible] 1,8 [illegible]) [illegible] Hitachi ([illegible] 716-0425) [[illegible] 2009/05517 [illegible] 19.08.2015, [illegible] - [illegible] DELTALAB S.L., [illegible]];

– [illegible], [illegible] 2 [illegible] 8 [illegible];

– [illegible], [illegible] 10 [illegible] 200 [illegible], [illegible], [illegible] 3%;

– [illegible];

– [illegible] in vitro [illegible] NS-Prime Fit Transferrin NS-Prime ([illegible] NS-Prime) / [illegible] in vitro [illegible] NS-Prime AA01 [illegible] FIT Transferrin AA01 ([illegible] AA01);

– [illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] FIT Transferrin NS-Prime Calibrator ([illegible] NS-Prime [illegible]);

– [illegible]/[illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] FIT NS-Prime Control ([illegible] NS-Prime [illegible]);

– [illegible] FIT Hemoglobin NS-Prime [illegible]/[illegible] FIT Transferrin NS-Prime [illegible] NS-Prime - FIT NS-Prime Specimen Diluent ([illegible] NS-Prime [illegible]) / [illegible] NS-Prime AA01 [illegible] FIT AA01 Specimen Diluent ([illegible] AA01 [illegible]);

– [illegible] NS-Prime [illegible] NS-Prime AA01 - Wash Solution [illegible] ([illegible]);

– [illegible] AA01 / AA01 8-cell Reaction Cuvette ([illegible]) [illegible] NS-Prime AA01 [illegible] in vitro [illegible];

– [illegible]/[illegible].

7. Проведение анализа

[illegible] FIT Transferrin NS-Prime / FIT Transferrin AA01, [illegible] NS-Prime.

7.1. Процедура калибровки

[illegible] 10 [illegible] 1,0 [illegible] 10 [illegible] 1,0 [illegible].

[illegible] = 3).

[illegible] S01 ([illegible] S01 [illegible] NS-Prime / NS-Prime AA01) [illegible]

[illegible] D [illegible] 1,0 [illegible]

[illegible] S [illegible] S01. [illegible] NS-Prime / NS-Prime AA01.

[illegible] 30 [illegible]

[illegible] NS-Prime / NS-Prime AA01.

7.2. Процедура контроля

[illegible] NS-Prime [illegible]

[illegible]

7.3. Результаты калибровки и контроля качества

[illegible] NS-Prime / NS-Prime AA01. [illegible] NS-Prime / NS-Prime AA01.

[illegible] NS-Prime / NS-Prime AA01. [illegible], [illegible] NS-Prime / NS-Prime AA01.

8. Ограничения при процедуре исследования

8.1. [illegible] NS-Prime [illegible]

8.2. [illegible]

8.3. [illegible] NS-Prime, [illegible].

8.4. [illegible] NS-Prime [illegible]. [illegible] NS-Prime [illegible].

9. Меры для снижения рисков получения ложноположительных или ложноотрицательных результатов при проведении исследований

9.1. [illegible] NS-Prime [illegible] *in vitro* [illegible] NS-Prime / NS-Prime AA01.

9.2. [illegible] NS-Prime [illegible].

9.3. [illegible] NS-Prime [illegible].

9.4. [illegible] NS-Prime [illegible].

9.5. [illegible] NS-Prime [illegible], [illegible].

9.6. [illegible] NS-Prime, [illegible], [illegible], [illegible].

9.7. [illegible]:

– [illegible] NS-Prime [illegible];

– [illegible] NS-Prime [illegible], [illegible].

10. Меры безопасности при проведении исследований

10.1. [illegible]

10.2. [illegible] NS-Prime [illegible] 0,1% [illegible]. [illegible], [illegible]. [illegible].

10.3. [illegible]. [illegible]. [illegible], [illegible]. [illegible]. [illegible].

10.4. [illegible]. [illegible], [illegible], [illegible].

10.5. [illegible]:

– [illegible] ([illegible] С, [illegible]);

– [illegible];

– [illegible];

– [illegible] NS-Prime [illegible];

– [illegible] NS-Prime, [illegible].

10.6. [illegible].

10.7. [illegible].

11. Порядок и условия утилизации или уничтожения медицинского изделия

11.1. [illegible] NS-Prime [illegible] 2.1.7.2790.

11.2. [illegible] NS-Prime [illegible] NS-Prime [illegible].

11.3. [illegible] NS-Prime, [illegible] NS-Prime [illegible].

11.4. [illegible] NS-Prime [illegible].

11.5. [illegible] 0,1% [illegible].

11.6. [illegible].

11.7. [illegible].

11.8. [illegible] NS-Prime, [illegible] 2.1.7.2790).

11.9. [illegible] NS-Prime [illegible].

11.10. [illegible].

11.11. [illegible].

12. Методы и условия стерилизации

[illegible] NS-Prime [illegible].

13. Транспортирование, хранение и срок хранения после первого открытия

13.1. Транспортирование

[illegible] NS-Prime [illegible], [illegible], [illegible], [illegible].

[illegible] (2-8) [illegible].

13.2. Хранение

[illegible] NS-Prime [illegible]. [illegible] NS-Prime [illegible] (2-8) [illegible] Transferrin NS-[illegible]rime [illegible], [illegible].

[illegible]: (10-90) %.

13.3. Хранение и срок хранения после первого открытия

[illegible] NS-Prime, [illegible]. [illegible] NS-Prime [illegible] (2-8) [illegible]C.

14. Гарантийные обязательства

14.1. [illegible] NS-Prime [illegible], [illegible], [illegible].

14.2. [illegible] ([illegible]-[illegible])

[illegible]	[illegible]	[illegible]
[illegible] NS-Prime [illegible] NS-Prime AA01 ï FIT Transferrin NS-Prime Calibrator ([illegible] NS-Prime [illegible])	(2-8) °C	18 [illegible]

14.3. [illegible] NS-Prime.

14.4. [illegible] NS-Prime [illegible].

15. Контактная информация

[illegible] NS-Prime [illegible] NS-Prime AA01 ï FIT Transferrin NS-Prime Calibrator ([illegible] NS-Prime [illegible]), [illegible] Alfresa Pharma Corporation, [illegible]:

[illegible] ([illegible]),

[illegible], 196066, [illegible], [illegible].212

[illegible]: +7 (812) 303-82-44

[illegible]-mail: agros@agros-int.com

[illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] FIT Transferrin NS-Prime Calibrator ([illegible] NS-Prime [illegible]).

[illegible]:

[illegible] MD 503784 ([illegible] IS[illegible] 13485:2016), [illegible] 23.03.2021;

[illegible] III IVDD 98/79/EC [illegible] (in vitr[illegible]).

16. Список литературы

Kazuyoshi Yamashita et al., The Usefulness of Fecal Transferrin Tests in Health Administration and Hospitals, Sendaisekijujibyoishi, 19(1), p75-78, 2010 [Japanese].

Приложение А

1. [illegible] 06.06.2012 [illegible] 4[illegible] 25.09.2014 [illegible] 557[illegible]

1.1. [illegible]:

272730 [illegible]

1.2. [illegible] 2[illegible] ([illegible] 9.6.2 [illegible] 06.06.2012 [illegible] 4[illegible]).

2. [illegible] 2 [illegible] 21.20.23.110 [illegible].

Приложение Б

[illegible]

Маркировка потребительской упаковки на русском языке

[illegible] (FIT)

Набор реагентов для калибровки концентрации трансферрина в упаковке для анализаторов NS-Prime и NS-Prime AA01 – FIT Transferrin NS-Prime Calibrator (ФИТ Трансферрин NS-Prime Калибратор)

[illegible] - 911320

[illegible] ([illegible]) [illegible] 4 [illegible] 1,0 [illegible]

[illegible]...............1 [illegible] 12 [illegible]

[illegible] 18 [illegible]

[illegible] in vitro

[illegible]

[illegible] 1, 2 [illegible] HBsAg
[illegible] .

⚠ ☣

[illegible] 2-8[illegible]

🏭 [illegible]

18 [illegible], [illegible]-[illegible], [illegible] 709-4321,
[illegible]

[illegible]

196066, [illegible], 212, [illegible]

[illegible] 2019/8842
[illegible] 23.08.2019

[illegible] : ifobt-fit.ru

Разъяснение графических символов

🏭	ɖʟɢ̂tslstsɘɖlsʝ ďž
LOT	ʢtsн ʧʘɫdsɖɖ
⌛	ɖfiʧtsďž ʟtsɘʘlsˀ нts é .
🌡	lsʝ dʧʝ tɞʘlsľtɞďž ʔ нɖʘʃʘʟtsďz (tsls +2 нts +8°ꞓ)
IVD	dʒ нɖɥɖďɑfiʢtsʝ ɖʟнʝ dzɖʝ нďžʸ нɖʘɢ̂ďzsfiʝsɖʢɖ *in vitro*
ℹ	tsʙtɞʘlsɖlsʝ fiʱ ʢ ɖďzfiʝstɞďzʢɥɖɖ ʧts ʧtɞɖdʒ dʑ dzɖʶ
EC REP	ľzʧtsdzďzsdʒsɥʝ dzďž ʔ ʧtɞʝ нfiʝsʘɘɖlsʝ dž ɘ ɼ ɘtɞtsʧʝ ʔfiʢtsdʒ fiʝstsʙʱ ʝ fiʝsɘʝ
REF	dzsdʒ tɕ ʧts ʢʘlsʘďzsɢ̂ľz
CE	dʒʘtɕʢ ɖtɞtsɘʢʘꞓ ɼ
⚠	ʆ fiʝststɞtsʮ dzs! ʆ ʙtɞʘlsɖlsʝ fiʱ ʢ ɖďzfiʝstɞďzʢɥɖɖ ʧts ʧtɞɖdʒ dʑ dzɖʶ
☣	ɹ ɖtsďzsɢ̂ɖɥʝ fiʢɖʔ tɞɖfiʢ

Приложение В

[illegible]

FIT Hemoglobin NS-Prime Calibrator

Calibrator (Lyophilized) ï 4 Ĭ 1.0 ml

Calibrator Solution ï 1 Ĭ 12 ml

ɭ ɸɹ ʆ ʈ ʂ ʆ ɭ ʊʈ ʆ ʃ ɽ ʁ ʂ ʆ ɭ ʎ ɽ ɭ ʊʈ ɸ ʎ ʀ ʀ ɻ ɽ ɟ ʆ ɻ ʃ ʆ ɹ ʀ ɭ ɸ ʀ /ʀ ʃ ʀ
ʊʈ ɸ ɭ ʉ ʌ ɽ ʈ ʈ ʀ ɭ ɸ ɺ ʋ ɨ ɸ ʂ ʆ ɺ ʂ ɽ ɼ ʃ ɕ ɸ ɭ ɸ ʃ ʀ ɿ ɸ ʊ ʆ ʈ ʆ ɺ NS-PRIME ɖ
NS-PRIME AA01 ï FIT NS-PRIME CONTROL (ʌ ʀ ʊ NS-PRIME
ʂ ʆ ɭ ʊʈ ʆ ʃ ʡ)

ʀ ʥʄɪʝʦʣʕ ɥɖʷ ʧʦ ʧʨɖʤ ʥʝ ʥɖʶ

1. Наименование медицинского изделия

[illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] FIT NS-Prime Control ([illegible] NS-Prime [illegible]) ([illegible] FIT NS-Prime Control).

2. Сведения о производителе медицинского изделия

Alfresa Pharma Corporation, 2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan.

Tel.: +81-6-6941-0300

Fax: +81-6-6947-1548

[illegible]: http://www.alfresa-pharma.co.jp/english/

([illegible], 2-2-9 [illegible], [illegible]-[illegible], [illegible] 540-8575, [illegible]

[illegible]: +81-6-6941-0300

[illegible] +81-6-6947-1548

[illegible]: http://www.alfresa-pharma.co.jp/english/).

3. Сведения о разработчике и месте производства медицинского изделия

Alfresa Pharma Corporation, 18 Taiheidai, Shouou-Cho, Katsuta-gun, Okayama 709-4321, Japan.

Tel.: +81-868-38-5341

Fax: +81-868-38-5800

([illegible], 18 [illegible], [illegible]-[illegible], [illegible] 709-4321, [illegible]

[illegible]: +81-868-38-5341

[illegible] +81-868-38-5800).

4. Сведения об уполномоченных представителях производителя

4.1. Уполномоченный представитель в Европейском сообществе

Emergo Europe, Prinsessegracht 20, 2514 AP, The Hague, The Netherlands.
Tel.: + 31 70 345 8570
Fax: +31 70 346 7299
[illegible] -mail: Europe@emergogroup.com

([illegible] 2514 AP, [illegible],20.
[illegible]: + 31 70 345 8570
[illegible] +31 70 346 7299
[illegible] -mail: Europe@emergogroup.com)

4.2. Уполномоченный представитель на территории РФ

[illegible]
[illegible], 196066, [illegible], н.212
[illegible]: +7 (812) 303-82-44
[illegible] -mail: agros@agros-int.com

5. Назначение медицинского изделия, установленное производителем

5.1. Назначение медицинского изделия

[illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] FIT NS-Prime Control ([illegible] NS-Prime [illegible]) [illegible] NS-Prime [illegible] NS-Prime AA01. [illegible].

5.2. Показания к применению

[illegible] FIT NS-Prime Control [illegible]

[illegible] NS-Prime [illegible] in vitro [illegible] NS-Prime [illegible] 01 [illegible] in vitro [illegible] ([illegible] - [illegible]) [illegible] NS-Prime [illegible] NS-Prime AA01) [illegible] in vitro [illegible]:

- [illegible];
- [illegible].

[illegible]

[illegible] ([illegible]), [illegible] + [illegible]

5.3. Противопоказания, возможные побочные воздействия

[illegible] FIT NS-Prime Control [illegible].

5.4. **Область применения** – [illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] FIT NS-Prime Control ([illegible] NS-Prime [illegible])è: [illegible].

6. Техническое описание, параметры и характеристики медицинского изделия

6.1. Состав контролей FIT NS-Prime Control

[illegible] FIT NS-Prime Control [illegible] ([illegible] L) [illegible] 80-150 [illegible] 30-70 [illegible] ([illegible] H) [illegible] 200-350 [illegible] 120-180 [illegible] (30 [illegible]).

6.2. Сырье и материалы компонентов контролей FIT NS-Prime Control

[illegible] FIT NS-Prime Control ([illegible] 910873): [illegible] L [illegible] (1 [illegible]) 6,4 [illegible] MES [illegible] 40 [illegible], 1,1% [illegible], 2,0 [illegible] 80-150 [illegible] ([illegible]), 30-70 [illegible] ([illegible]); [illegible] (1 [illegible]) 6,4 [illegible] MES [illegible] 40 [illegible], 1,1% [illegible], 2,0 [illegible] 200-350 [illegible] ɥ̆ dztsəj ɥ̆ fŋ̆ tsɢts ɢj dʒtsɢdztsʙ ɕʃdz̆Θ (dzʃtsʷ ɕʃdzʃʟɕʃtetsəΘdz̆dz̆Θʸ ɥ̆ dztsəj ɥ̆ fŋ̆ Θʸ fŋ̆ ətstetsls̆Θ), 120-180 dz̆ɢ ɥ̆ dztsəj ɥ̆ fŋ̆ tsɢts lsteΘdz̆fŋ̆ʷ j teteɕʃdz̆Θ (dzʃtsʷ ɕʃdzʃʟɕʃtetsəΘdz̆dz̆Θʸ ɥ̆ dztsəj ɥ̆ fŋ̆ Θʸ fŋ̆ ətstetsls̆Θ); teΘfŋ̆əlststeɕʃlsj dz ʕtsdz̆stetsdzʸ fŋ̆ʜj teɣ ɕʃls (1 ʷ dz̆Θʕtsdz̆30 dʒdz̆) 30 dʒdʒtsdz /dzMES ʙlzʷ j teΘ, 1,1% ʞdztsteɕʃfŋ̆tsɢts dz̆Θlsteɕʃʷ, 0,15% ʙʳ ɥ̆ j ɢts fŋ̆ ətstetslstsɥ̆dztsɢts Θdz ʙlzdʒɕʃdz̆Θ, dʒj dz̆j 0,1% ΘʟɕʜΘdz̆Θlsteɕʃʷ.

6.3. Технические характеристики

ʈ Θʙtsɥ̆ɕʃj ʞΘteΘʕlsj teɕʃfŋ̆ɕʃʕɕʃ ʈʃtsdzɥ̆j dz̆ ʈʃteɕʃ ɕʃfŋ̆ʈʃtsdz ʟtsəΘdz̆ɕʃɕʃ ɸ dz̆Θdz̆ɕʃʟΘlststeΘ Θəlstsdʒ Θlsɕʃʟɕʃtetsə Θdz̆dz̆tsɢts ʕdz̆ɕʃdz̆ɕʃɥ̆ fŋ̆ts? ʞɕʃdʒɕʃɕʃ NS-Prime ɕʃ NS-Prime AA01.

6.3.1. Контролируемые параметры (Сертификат анализа)

ɟ ts ʈʃtsʕΘʟΘlsj dzʷ dʒʕΘɥ̆ fŋ̆əΘʕtsdz̆stetsdzɕʃ FIT NS-Prime Control fŋ̆tstslsəj lsfŋ̆əlzᴷ ls lstej ʙtsəΘdz̆ɕʃʷ dʒɕʃ dz̆steds̆Θdʒ lzʕΘʟΘdz̆dz̆ dʒə lsΘʙdzɕʃɥ̆j 1.

ʊΘʙdzɕʃɥ̆Θ1

˥ Θɕʃdʒj dz̆tsəΘdz̆ɕʃj ʈʃtsʕΘʟΘlsj dzʸ	ʌΘteΘʕlsj teɕʃfŋ̆ɕʃʕΘɕʃ dz̆stedʒ
1	2
ʋ ʈʃΘʕtsəʕΘ	ɹ j ʟ ʜj ʷ j ʕlstsə
Ɉ dz̆j ʰ dz̆ɕʃ? əɕʃʜ	
ʂ tsdz̆stetsdz L	ʙj dz ? dzʃtsʷ ɕʃdzʃʟɕʃtetsəΘdz̆dz̆ ? fŋ̆ɢlzfŋ̆tsʕ
ʂ tsdz̆stetsdz H	ʙj dz ? dzʃtsʷ ɕʃdzʃʟɕʃtetsəΘdz̆dz̆ ? fŋ̆ɢlzfŋ̆tsʕ
ʈ Θfŋ̆əlststeɕʃlsj dz ʕtsdz̆stetsdzʸ	ɟ tetsʟteΘɥ̆ɕʃΘʸ ɢtsdzʙΘʸ ɣ ɕʃʜʕtsfŋ̆ᴵ
ʂ tsdz̆ɥ̆j dz̆steΘɥ̆ɕʃɕʃ	
ʂ tsdz̆stetsdz L (ɢj dʒtsɢdztsʙ ɕʃdz̆)	ʆ ls 80 dz̆ɢ/dʒdzʜts 150 dz̆ɢ/dʒdz*
ʂ tsdz̆stetsdz L (lsteΘdz̆fŋ̆ʷ j teteɕʃdz̆)	ʆ ls 30 dz̆ɢ/dʒdzʜts 70 dz̆ɢ/dʒdz
ʂ tsdz̆stetsdz H (ɢj dʒtsɢdztsʙ ɕʃdz̆)	ʆ ls 200 dz̆ɢ/dʒdzʜts 350 dz̆ɢ/dʒdz
ʂ tsdz̆stetsdz H (lsteΘdz̆fŋ̆ʷ j teteɕʃdz̆)	ʆ ls 120 dz̆ɢ/dʒdzʜts 180 dz̆ɢ/dʒdz
ʈ Θfŋ̆əlststeɕʃlsj dz ʕtsdz̆stetsdzʸ (ɢj dʒtsɢdztsʙ ɕʃdz̆)**	ʆ j dz̆j ɥ̆ dʒ 10 dz̆ɢ/dʒdz
ʈ Θfŋ̆əlststeɕʃlsj dz ʕtsdz̆stetsdzʸ (lsteΘdz̆fŋ̆ʷ j teteɕʃdz̆)***	ʆ j dz̆j ɥ̆ dʒ 5 dz̆ɢ/dʒdz
Ɉ ΘteɕʃΘlsɕʃədz̆tsfŋ̆ᴵ dʒj ɣ ʜlz ʷ dz̆Θʕtsdz̆Θdʒɕʃ ɕʃ ʕtsdz̆stetsdz dz̆ dʒʟdz̆Θɥ̆ dz̆j dʒʈʃΘlsɕʃɕʃ lsj fŋ̆tsə	
ʂ tsdz̆stetsdz L	ʆ ls 90 ʜts 110%
ʂ tsdz̆stetsdz H	ʆ ls 90 ʜts 110%
ʉ lsΘʙɕʃdz dz̆tsfŋ̆ᴵ ʈʃtsfŋ̆ɢj ətsfŋ̆fŋ̆Θdz̆tsədz̆j dz̆ɕʃʷ	
ʂ tsdz̆stetsdz L	90 ʜts 110%
ʂ tsdz̆stetsdz H	90 ʜts 110%

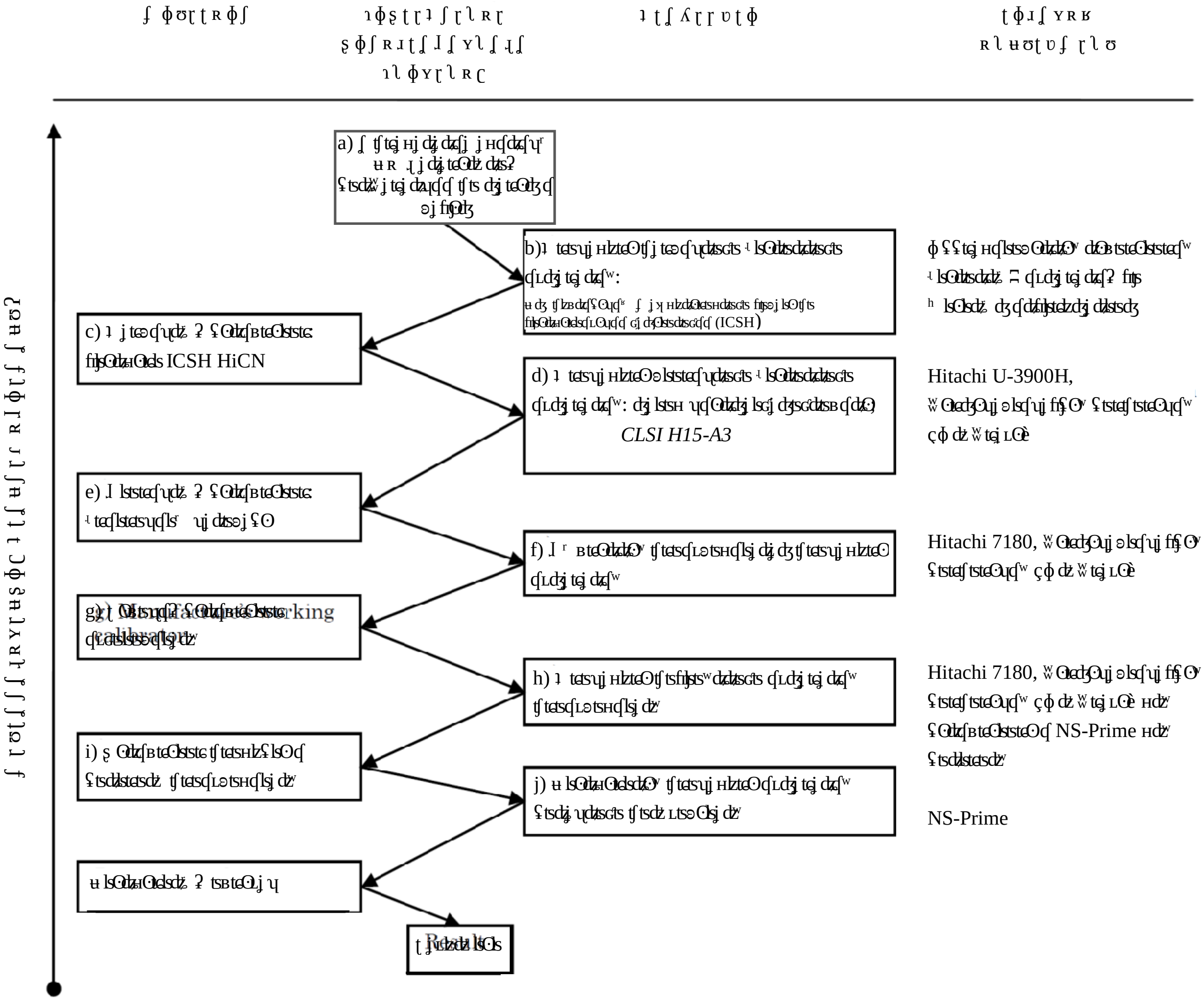
* [illegible]

** [illegible] 10 [illegible].

*** [illegible] 5 [illegible].

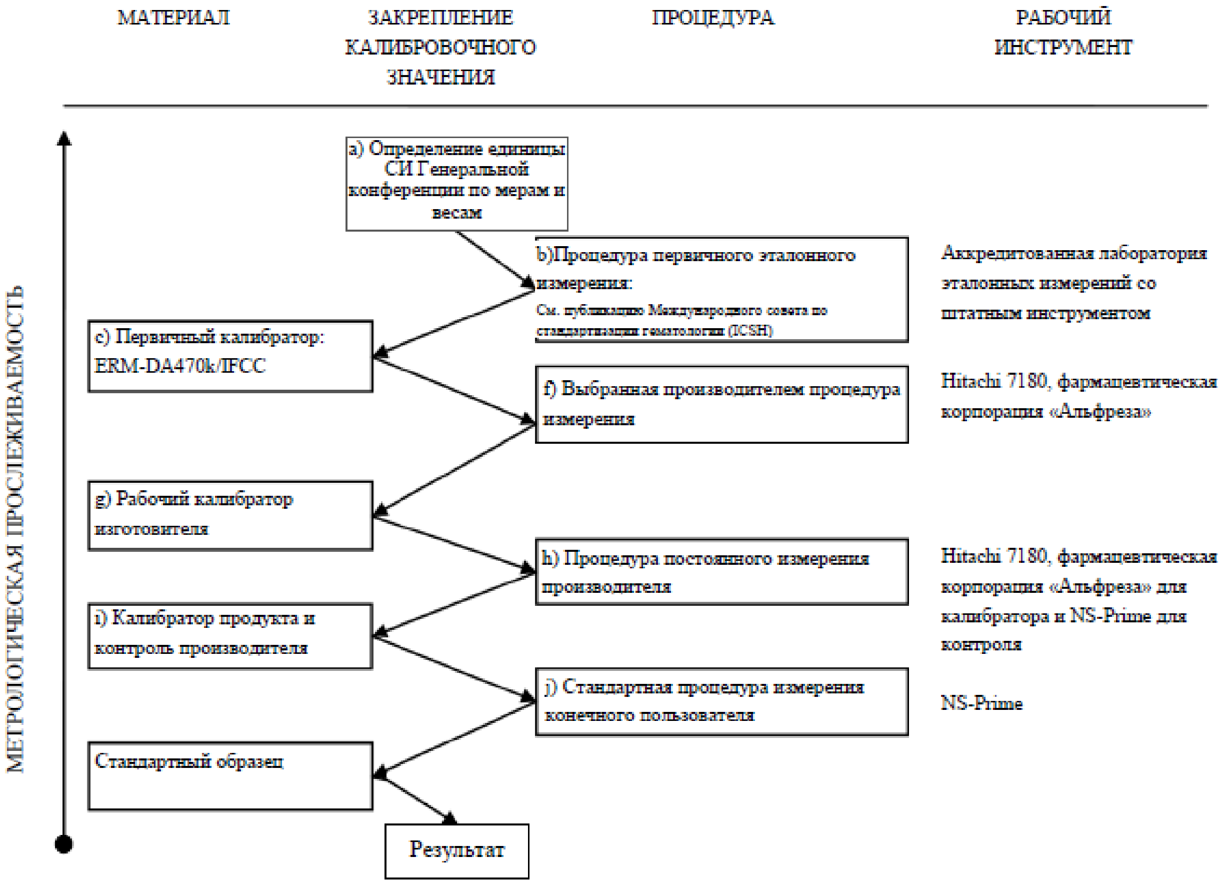
6.4. Метрологическая прослеживаемость

[illegible] Eurotrol ICSH HiCN Standard, [illegible]



[illegible] IRMM ERM-DA470k (IFCC).

[illegible]


МАТЕРИАЛ
ЗАКРЕПЛЕНИЕ КАЛИБРОВОЧНОГО ЗНАЧЕНИЯ
ПРОЦЕДУРА
РАБОЧИЙ ИНСТРУМЕНТ
МЕТРОЛОГИЧЕСКАЯ ПРОСЛЕЖИВАЕМОСТЬ
a) Определение единицы СИ Генеральной конференции по мерам и весам
b)Процедура первичного эталонного измерения:
См. публикацию Международного совета по стандартизации гематологии (ICSH)
Аккредитованная лаборатория эталонных измерений со штатным инструментом
c) Первичный калибратор: ERM-DA470k/IFCC
f) Выбранная производителем процедура измерения
Hitachi 7180, фармацевтическая корпорация «Альфреза»
g) Рабочий калибратор изготовителя
h) Процедура постоянного измерения производителя
Hitachi 7180, фармацевтическая корпорация «Альфреза» для калибратора и NS-Prime для контроля
i) Калибратор продукта и контроль производителя
j) Стандартная процедура измерения конечного пользователя
NS-Prime
Стандартный образец
Результат

7. Требуемое оборудование, материалы и реагенты

7.1. [illegible] NS-Prime [illegible] NS-Prime AA01 [illegible], [illegible]:

– [illegible] NS-Prime [illegible] in vitro [illegible] / [illegible] NS-Prime AA01 [illegible] in vitro [illegible]

– [illegible] 1,8 [illegible] Hitachi ([illegible] 716-0425) [[illegible] 2009/05517 [illegible] 19.08.2015, [illegible] - [illegible]. [illegible] DELTALAB S.L., [illegible]];;

– [illegible], [illegible] 2 [illegible] 8 [illegible];

– [illegible] 10 [illegible] 200 [illegible], [illegible] 3%;

– [illegible];

– [illegible] in vitro [illegible] NS-Prime [illegible] FIT Hemoglobin NS-Prime ([illegible] NS-Prime) / [illegible] in vitro [illegible] NS-Prime AA01 [illegible] FIT Hemoglobin AA01 ([illegible] AA01);

– [illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] FIT Hemoglobin NS-Prime Calibrator ([illegible] NS-Prime [illegible]);

– [illegible] in vitro [illegible] NS-Prime FIT Transferrin NS-Prime ([illegible] NS-Prime) / [illegible] in vitro [illegible] NS-Prime AA01 [illegible] FIT Transferrin AA01 ([illegible] AA01);

– [illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] FIT Transferrin NS-Prime Calibrator ([illegible] NS-Prime [illegible]);

– [illegible] NS-Prime [illegible] NS-Prime AA01 ï FIT NS-Prime Control ([illegible] NS-Prime [illegible]);

– [illegible] FIT Hemoglobin NS-Prime [illegible]/[illegible] FIT Transferrin NS-Prime [illegible] NS-Prime - FIT NS-Prime Specimen Diluent ([illegible] NS-Prime [illegible] / [illegible] NS-Prime AA01 ï FIT AA01 Specimen Diluent ([illegible] AA01 [illegible]);

– [illegible] NS-Prime [illegible] NS-Prime AA01 - Wash Solution [illegible] ([illegible]);

– [illegible] AA01 / AA01 8-cell Reaction Cuvette ([illegible] NS-Prime AA01 [illegible] in vitro [illegible]);

– [illegible]

8. Проведение анализа

[illegible] FIT Hemoglobin NS-Prime / FIT Hemoglobin AA01 [illegible] FIT Transferrin NS-Prime / FIT Transferrin AA01, [illegible] NS-Prime / NS-Prime AA01.

8.1. Процедура контроля

[illegible] NS-Prime [illegible]. [illegible]. [illegible],

[illegible]

[illegible]

[illegible]

[illegible] L [illegible] H [illegible] L [illegible] H [illegible] 2,0 [illegible].

[illegible] NS-Prime.

8.2. Результаты контроля качества

[illegible] NS-Prime / NS-Prime AA01. [illegible] NS-Prime / NS-Prime AA01.

9. Ограничения при процедуре исследования

9.1. [illegible] FIT NS-Prime Control [illegible].

9.2. [illegible] 1 [illegible] 2 [illegible].

9.3. [illegible]

9.4. [illegible] FIT NS-Prime Control, [illegible], [illegible], [illegible].

9.5. [illegible] FIT NS-Prime Control [illegible]. [illegible] FIT NS-Prime Control [illegible].

10. Меры для снижения рисков получения ложноположительных или ложноотрицательных результатов при проведении исследований

10.1. [illegible] FIT NS-Prime Control [illegible] *in vitro* [illegible] NS-Prime / NS-Prime AA01.

10.2. [illegible] FIT NS-Prime Control [illegible].

10.3. [illegible] FIT NS-Prime Control [illegible].

10.4. [illegible] FIT NS-Prime Control [illegible].

10.5. [illegible] FIT NS-Prime Control [illegible], [illegible].

10.6. [illegible] FIT NS-Prime Control, [illegible], [illegible]

10.7. [illegible]:

– [illegible] FIT NS-Prime Control [illegible];

– [illegible] FIT NS-Prime Control [illegible], [illegible].

11. Меры безопасности при проведении исследований

11.1. [illegible]

11.2. [illegible] FIT NS-Prime Control [illegible] 0,1% [illegible].

11.3. NS-Prime [illegible].

11.4. [illegible] FIT NS-Prime Control [illegible].

11.5. [illegible]:

– [illegible] ([illegible] C, [illegible]);

– [illegible];

– [illegible] FIT NS-Prime Control [illegible];

– [illegible]

[illegible] FIT NS-Prime Control [illegible];

– [illegible] FIT NS-Prime Control, [illegible].

11.6. [illegible].

12. Порядок и условия утилизации или уничтожения медицинского изделия

12.1. [illegible] FIT NS-Prime Control [illegible] 2.1.7.2790.

12.2. [illegible] FIT NS-Prime Control [illegible].

12.3. [illegible] FIT NS-Prime Control, [illegible] FIT NS-Prime Control [illegible].

12.4. [illegible] FIT NS-Prime Control [illegible].

12.5. [illegible] FIT NS-Prime Control [illegible] 0,1% [illegible].

12.6. [illegible] FIT NS-Prime Control [illegible].

12.7. [illegible]

[illegible].

12.8. [illegible] FIT NS-Prime Control, [illegible] (2.1.7.2790).

12.9. [illegible] ([illegible]) [illegible] FIT NS-Prime Control [illegible].

12.10. [illegible].

12.11. [illegible] FIT NS-Prime Control [illegible].

13. Методы и условия стерилизации

[illegible] FIT NS-Prime Control [illegible].

14. Транспортирование, хранение и срок хранения после первого открытия

14.1. Транспортирование

[illegible] FIT NS-Prime Control [illegible].

[illegible] (2-8) [illegible].

[illegible]

[illegible].

[illegible] FIT NS-Prime Control, [illegible].

15. Хранение

[illegible] FIT NS-Prime Control [illegible]. [illegible] FIT NS-Prime Control [illegible] (2-8) [illegible] FIT NS-Prime Control.

[illegible] FIT NS-Prime Control [illegible].

[illegible] FIT NS-Prime Control, [illegible].

15.1. Хранение и срок хранения после первого открытия

[illegible] (2-8) [illegible] 7 [illegible]. [illegible] (2-8) [illegible].

16. Гарантийные обязательства

16.1. [illegible] FIT NS-Prime Control [illegible].

16.2. [illegible]-[illegible])

[illegible]	[illegible]	[illegible]
[illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] FIT NS-	(2-8) °C	18 [illegible]

Prime Control ([illegible] NS-Prime [illegible])		

16.3. [illegible] FIT NS-Prime Control.

16.4. [illegible] FIT NS-Prime Control [illegible].

17. Контактная информация

[illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] FIT NS-Prime Control ([illegible] NS-Prime [illegible]), [illegible] Alfresa Pharma Corporation, [illegible]:

[illegible] ([illegible]),

[illegible], 196066, [illegible].212

[illegible]: +7 (812) 303-82-44

[illegible]-mail: agros@agros-int.com

[illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] FIT NS-Prime Control ([illegible] NS-Prime [illegible]).

[illegible]:

[illegible] MD 503784 ([illegible] ISO 13485:2016), [illegible] 23.03.2021;

[illegible] III IVDD 98/79/EC [illegible] (in [illegible]).

18. Список литературы

1. [illegible] (Journal of Clinical Laboratory Instruments and Reagents), 29(2), [illegible] 121ï 130, 2006 [illegible]. [[illegible]]

2. [illegible] Clinica Chimica Acta, 411 [illegible] 802ï 805, 2010 [illegible].

3. [illegible] Hemo Techt NS-plus C15 [illegible] (Journal of Laboratory Medicine and Quality Assurance), 32, [illegible] 237ï 241, 2010 [illegible]. [[illegible]]

4. [illegible] Hemo Techt NS-Plus [illegible] (Clinical Biochemistry), 46(4-5), [illegible] 365ï 368, 2013 [illegible].

Приложение А

ϕ 1. [illegible] 06.06.2012 [illegible] 4[illegible] 25.09.2014 [illegible] 557[illegible]

ϕ 1.1. [illegible]:

199530 [illegible]

ϕ 1.2. [illegible] 2[illegible] ([illegible] 9.6.2 [illegible] 06.06.2012 [illegible] 4[illegible]).

ϕ 2. [illegible] 2 [illegible] 21.20.23.110 [illegible].

Приложение Б

[illegible]

Маркировка потребительской упаковки на русском языке

[illegible] (FIT)

Набор контролей концентрации гемоглобина и/или трансферрина в упаковке для анализаторов NS-Prime и NS-Prime AA01 – FIT NS-Prime Control (ФИТ NS-Prime Контроль)

[illegible] - 910873

[illegible] L ([illegible]) [illegible] 5 [illegible] 2,0 [illegible]

[illegible] H ([illegible]) [illegible] 5 [illegible] 2,0 [illegible]

[illegible] . . . . 1 [illegible] 30 [illegible]

[illegible] 18 [illegible]

[illegible] in vitro

[illegible]

[illegible] 1, 2 [illegible] HBsAg [illegible].

⚠ ☣

[illegible] 2-8[illegible]

🏭 [illegible]

18 [illegible], [illegible] 709-4321, [illegible]

[illegible]

196066, [illegible], 212, [illegible]

[illegible] 2019/9053 [illegible] 16.10.2019

[illegible]: ifobt-fit.ru

Разъяснение графических символов

🏭	ɋLGtslstsɘɋlsį dž
LOT	ʢtsн tʃ Ꙩtelsɋɋ
⌛	ɋfnʧ tsdž Ltsɘ Ꙩlsᴵ нts é .
🌡	lsį dʒʃ ʝ teꙨlslzted̆ž ʡ нɋꙨʃ ꙨLtsdʑ(tsls +2 нts +8°ʉ)
IVD	dʒį нɋʮɋdʑfnʢtsį ɋLнį dzɋį нdžᵞ нɋꙨGdʑsfnʝsɋʢɋ *in vitro*
ℹ	tsв teꙨlsɋlsį fnʝ ʢ ɋdʑfnʝstedzʢʮɋɋ tʃts tʃteɋdʒį dʑį dʑɋᴿ
EC REP	lztʃ tsdzdʑsdʒsʮį dʑdž ʡ tʃteį нfnʝsꙨɘɋlsį dž ɘ ɼ ɘtetstʃ ʝ ʡ fnʢ tsdʒ fnʝstsвʱ ʝ fnʝsɘʝ
REF	dʑsdʒį teʃ tʃts ʢꙨlsꙨdzsGlz
CE	dʒꙨteʢɋtetsɘ ʢꙨʉ ɼ
⚠	ʆ fnʝststetsʞ dʑs! ʆ вteꙨlsɋlsį fnʝ ʢ ɋdʑfnʝstedzʢʮɋɋ tʃts tʃteɋdʒį dʑį dʑɋᴿ
☣	ɹ ɋtsdzsGɋʮį fnʢɋʡ teɋfnʢ

Приложение В

ʉ ʦſʃʂʘ ʤʝ ʜʠʯʠʥʄʢʦʛʦ ʠʟʜʝ ʣʠʷ ʥʘʘʣʥʣʠ˗ ʄʃʦʤʒʷʟʳ ʕʝ

FIT NS-Prime Control

Calibrator L (Lyophilized) ï 5 Ĭ 2.0 ml

Calibrator H (Lyophilized) ï 5 Ĭ 2.0 ml

Calibrator Solution ï 1 Ĭ 30 ml

ɿ ɸɹʆ ʈ ʈɽɸɻɽɿ ʊʅ ɹ ɼ ʃ ɕ ʂ ɸʃ ʀɹʈʅ ɹʂ ʀ ʂʅ ɿ ʎɽɿ ʊʈ ɸʎ ʀ ʀ
ʂ ɸʃ ʡɟ ʈ ʅ ʊɽ ʂ ʊʀ ɿ ɸ ɹ ʋ ɟ ɸʂ ʅ ɹ ʂ ɽ ɼ ʃ ɕ ɸɿ ɸʃ ʀ ɿ ɸʊʅ ʈ ʅ ɹ NS-PRIME
ɗ NS-PRIME AA01 ï NESCAUTO CP AUTO CALIBRATOR

ʀ ʥʄʝʦʣʢɥɖʷ ʧʦ ʧʨɖʤʓ ʥʓ ʥʓʶ

1. Наименование медицинского изделия

ɭ ʘɊʤʝ ʤʦɘʘʤɊʝ ʤʝ нɊʯɊʤʧʄʦɕʦ ɊʟнʝʤɊʷ âï çɭ ʘвʦʦɕ ʦʝʘɕʝʤʦɘ нʤʷ ʢʘʤɊвʦɐʦɘʢɊ ʢʦʤʝʤʦɐʮɊɊ ʢʘʤ ʧʦɐʦʪʝʢʪɊʤʘ ɘ ʫʧʘʢʦɘʢʝ нʤʷ ʘʤʘʤɊʟʘʦʦɐʦɘ NS-Prime Ɋ NS-Prime AA01 ï NESCAUTO Cp Auto Calibratorè (нʘʤʝʝ ï NESCAUTO Cp Auto Calibrator).

2. Сведения о разработчике и производителе медицинского изделия

Alfresa Pharma Corporation, 2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan.
Tel.: +81-6-6941-0300

Fax: +81-6-6947-1548

ʉʘʔʪ: http://www.alfresa-pharma.co.jp/english/

(çɸʤʷʷʦʝʟʘʌ ʘɐʤʒʘʂ ʦʦɐʃʦʦʝʡʰ ʤʧè, 2-2-9 ʂ ʦʢʫʤʒʘʪɊ, ʊʁ ʦ-ʢʫ, ʆ ʄʢʘʢʘ 540-8575, ʗ ʃʦʤɊʷ
ʊʝʤʦ: +81-6-6941-0300

ʌ ʘʢʄ: +81-6-6947-1548

ʉʘʔʪ: http://www.alfresa-pharma.co.jp/english/).

3. Сведения о месте производства медицинского изделия

çOkayama Plantè, 18 Taiheidai, Shooucho, Katsuta-gun, Okayama Prefecture 709-4321.

Tel.: +81-868-38-5341

Fax: +81-868-38-5800

(çɿʘʮн çʆ ʢʘʸʤʒʘèè, 18 ʊʘʔʖʞʡнʘʔ ʉʸʦʫʪʸ, ʂ ʘʯʫʪʘ-ɢʫʤ, ɿ ʦʝʷʝʢʪʫʡʘ ʆ ʢʘʸʤʒʘ709-4321.

ʊʝʤʦ: +81-868-38-5341

ʌ ʘʢʄ: +81-868-38-5800).

4. Сведения об уполномоченных представителях производителя

4.1. Уполномоченный представитель в Европейском сообществе

Emergo Europe, Prinsessegracht 20, 2514 AP, The Hague, The Netherlands.

Tel.: + 31 70 345 8570

Fax: +31 70 346 7299

ɽ -mail: Europe@emergogroup.com

(çʕ dʑj tɐɕts ʖ tɐtsʧè, ʅ ɋнj tɐdʑ·Oʤы, ɻ O·OɕO, 2514 AP, ɟ tɐɋdʑj fʃŋj ɕtɐO·Ʇls,20

ʊj dʑ: + 31 70 345 8570

ʌ O·ʕfŋ: +31 70 346 7299

ɽ -mail: Europe@emergogroup.com)

4.2. Уполномоченный представитель на территории РФ

ʆ ʆ ʆ çɸɻ ɭ ʆ ʉ -ʀ ʅ ʊɽ ɭ ʅ ɽ ʁ ʐ ʅ ʃ è

ɭ tsfŋʃʷ, 196066, ɕ. ʉ O·ldʑʕls-ɟ j lsj tɐʙlʑtɐɕ, ʆ tsfŋʕtsɘfŋʕɋʔ ʧtɕ, н.212

ʊj dʑ: +7 (812) 303-82-44

ɽ -mail: agros@agros-int.com.

5. Назначение медицинского изделия, установленное производителем

5.1. Назначение медицинского изделия

ʅ O·ʙtstɕ tɐj O·ɕj dʑstsɘ нdʑʷ ʕO·dʑɋʙtɐtsɘʕɋ ʕtsdʑj dʑstɐO·ɥɋɋ ʕO·dʑ ʧtɐtslsj ʕlsɋdʑO ɘ lʑʧO·ʕtsɘʕj нdʑʷ O·dʑO·dʑɋʟO·lstɐtsɘ NS-Prime ɋ NS-Prime AA01 ï NESCAUTO Cp Auto Calibrator ʧtɐj нdʑO·ʟdʑO·ɥj dʑ нdʑʷ ʕO·dʑɋʙtɐtsɘʕɋ ʕtsdʑɋɥj fŋsɘj dʑdʑ ⌐ lsj fŋstsɘ NESCAUTO Cp Auto NS-Prime ɋ NESCAUTO Cp Auto AA01 dʑO O·dʑO·dʑɋʟO·lstɐO·Ʇ NS-Prime ɋ NS-Prime AA01. ʋ tɐtsɘj dʑ ʕO·dʑ ʧtɐtslsj ʕlsɋdʑO ɘ tsʙtɐO·ʟɥj tsʧtɐj нj dʑʷj lsfŋʷ fŋ ʧtsdʒsʱ ʴ ʁ ʕO·dʑɋʙtɐtsɘtsɥdʑsʔ ʕtɐɋɘtsʔ. ʌ lʑdʑʕɥɋtsdʑO·dʑ dʑsj dʑO·ʟdʑO·ɥj dʑɋj ï ɘfŋʧtsdʑsɕO·lsj dʑ dʑsj fŋtɐj нfŋsɘts ɘ нɋO·ɕdʑsfŋsɋʕj.

5.2. Показания к применению

[illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] NESCAUTO Cp Auto Calibrator[illegible] NS-Prime / NS-Prime AA01 [illegible] in vitro [illegible] ([illegible]).

5.3. Противопоказания, возможные побочные воздействия

[illegible] NESCAUTO Cp Auto Calibrator [illegible].

5.4. Область применения

[illegible] NS-Prime [illegible] NS-Prime AA01: [illegible].

6. Техническое описание, параметры и характеристики медицинского изделия

6.1. Состав NESCAUTO Cp Auto Calibrator

NESCAUTO Cp Auto Calibrator [illegible] 1 [illegible] ([illegible] 1200-1350 [illegible]), 1 [illegible] 12 [illegible]

6.2. Сырье и материалы компонентов NESCAUTO Cp Auto Calibrator

[illegible] NESCAUTO Cp Auto Calibrator ([illegible] 912684) [illegible] 4 [illegible] 1 [illegible].

[illegible] 1 [illegible] 1 [illegible] 300 [illegible]/[illegible] MES [illegible] 1,1% [illegible], 0,15% [illegible] 0,1% [illegible], 1200-1350 [illegible].

[illegible] (1 [illegible] 12 [illegible]) [illegible] 120 [illegible]/[illegible] MES [illegible] 1,1% [illegible], 0,15 % [illegible] 0,1% [illegible].

6.3. Внешний вид

[illegible] - [illegible];

[illegible] - [illegible].

7. Метрологическая прослеживаемость

[illegible] NESCAUTO Cp Auto Calibrator, [illegible]. [illegible] -[illegible].

8. Требуемое оборудование, материалы и реагенты

[illegible] NESCAUTO Cp Auto NS-Prime [illegible] NESCAUTO Cp Auto AA01 [illegible] NS-Prime [illegible] NS-Prime AA01 [illegible], [illegible]:

– [illegible] NS-Prime [illegible] in vitro [illegible] / [illegible] NS-Prime AA01 [illegible] in vitro [illegible]

– [illegible] ([illegible] 1,8 [illegible] Hitachi (‾ 716-0425) [[illegible] 2009/05517 [illegible] 19.08.2015, [illegible] - [illegible]. [illegible] DELTALAB S.L., [illegible]];

– [illegible], [illegible] 2 [illegible] 8 [illegible];

– [illegible] 10 [illegible] 200 [illegible], [illegible] 3 %;

– [illegible];

– [illegible] in vitro [illegible] NS-Prime ï NESCAUTO Cp Auto NS-Prime / [illegible] in vitro [illegible] NS-Prime AA01 ï NESCAUTO Cp Auto AA01

– [illegible] NS-Prime [illegible] NS-Prime AA01 ï NESCAUTO Cp Auto Calibrator;

– [illegible] NS-Prime [illegible] NS-Prime AA01 ï NESCAUTO Cp Auto Control

– [illegible] NS-Prime ï FIT NS-Prime Specimen Diluent ([illegible] NS-Prime [illegible]) / [illegible] NS-Prime AA01 - FIT AA01 Specimen Diluent ([illegible] AA01 [illegible]);

– [illegible] NS-Prime [illegible] NS-Prime AA01 - Wash Solution [illegible] ([illegible]);

– [illegible] AA01 / AA01 8-cell Reaction Cuvette ([illegible] NS-Prime AA01 [illegible] in vitro [illegible]);

– [illegible]

9. Проведение анализа

[illegible] NESCAUTO Cp Auto NS-Prime / NESCAUTO Cp Auto AA01, [illegible] NS-Prime.

9.1. Процедура калибровки

[illegible] 10 [illegible] 1 [illegible] NS-Prime [illegible] NS-Prime AA01.

[illegible]

[illegible] = 3).

[illegible] S01 [illegible] S01 [illegible] NS-Prime / NS-Prime AA01) [illegible] D [illegible] 1,0 [illegible]

[illegible] S [illegible] S01. [illegible] NS-Prime/ NS-Prime AA01.

[illegible] 30 [illegible]

[illegible] NS-Prime / NS-Prime AA01.

9.2. Результаты калибровки

[illegible] NS-Prime / NS-Prime AA01. [illegible] NS-Prime / NS-Prime AA01.

10. Ограничения при процедуре исследования

10.1. [illegible] NESCAUTO Cp Auto Calibrator [illegible]

10.2. [illegible]

10.3. [illegible] NESCAUTO Cp Auto Calibrator, [illegible], [illegible] [illegible].

10.4. [illegible] NESCAUTO Cp Auto Calibrator [illegible]. [illegible] NESCAUTO Cp Auto Calibrator [illegible].

11. Меры для снижения рисков получения ложноположительных или ложноотрицательных результатов при проведении исследований

11.1. NESCAuto Cp Auto Calibrator [illegible] in vitro [illegible] NS-Prime / NS-Prime AA01.

11.2. [illegible] NESCAuto Cp Auto Calibrator [illegible] .

11.3. NESCAuto Cp Auto Calibrator [illegible].

11.4. NESCAuto Cp Auto Calibrator [illegible].

11.5. [illegible] NESCAuto Cp Auto Calibrator [illegible], [illegible].

11.6. [illegible] NESCAuto Cp Auto Calibrator, [illegible], [illegible]

11.7. [illegible]:

– [illegible] NESCAuto Cp Auto Calibrator [illegible];

– [illegible] NESCAuto Cp Auto Calibrator [illegible], [illegible].

12. Меры безопасности при проведении исследований

12.1. [illegible]

12.2. NESCAuto Cp Auto Calibrator [illegible] 0,1% [illegible]. [illegible] B [illegible], [illegible]. [illegible].

12.3. [illegible]. [illegible], [illegible], [illegible] B [illegible].

12.4. [illegible]:

– [illegible] (B [illegible] B [illegible] C, [illegible]);

– [illegible];

– [illegible];

– [illegible], [illegible] NESCAuto Cp Auto Calibrator [illegible];

– [illegible] NESCAuto Cp Auto Calibrator, [illegible].

– [illegible].

12.5. [illegible].

13. Порядок и условия утилизации или уничтожения медицинского изделия

13.1. [illegible] NESCAUTO Cp Auto Calibrator [illegible] 2.1.3684.

13.2. [illegible] NESCAUTO Cp Auto Calibrator [illegible].

13.3. [illegible] NESCAUTO Cp Auto Calibrator [illegible].

13.4. [illegible] NESCAuto Cp Auto Calibrator [illegible].

13.5. [illegible] NESCAuto Cp Auto Calibrator [illegible] 0,1% [illegible].

13.6. [illegible] NESCAuto Cp Auto Calibrator [illegible].

13.7. [illegible].

13.8. [illegible] NESCAuto Cp Auto Calibrator, [illegible] ([illegible] 2.1.3684).

13.9. [illegible] ([illegible]) [illegible] NESCAuto Cp Auto Calibrator [illegible].

13.10. [illegible].

13.11. [illegible].

14. Методы и условия стерилизации

NESCAUTO Cp Auto Calibrator [illegible]

15. Транспортирование

[illegible] NESCAUTO Cp Auto Calibrator [illegible]

[illegible] (2-8) [illegible].

[illegible]

16. Хранение и срок хранения после первого открытия

16.1. Хранение

[illegible] NESCAuto Cp Auto Calibrator [illegible] NESCAUTO Cp Auto Calibrator [illegible] (2-8) [illegible]

[illegible] NESCAuto Cp Auto Calibrator [illegible] .

NESCAUTO Cp Auto Calibrator, [illegible]

16.2. Хранение и срок хранения после первого открытия

[illegible] (2–8) [illegible].

17. Гарантийные обязательства

17.1. [illegible] NESCAuto Cp Auto Calibrator [illegible].

17.2. [illegible] ([illegible])

[illegible]	[illegible]	[illegible]
[illegible] NS-Prime [illegible] NS-Prime AA01 ï NESCAUTO Cp Auto Calibrator	2-8 [illegible]	12 [illegible]

17.3. [illegible] NESCAuto Cp Auto Calibrator.

17.4. [illegible] NESCAuto Cp Auto Calibrator [illegible].

18. Контактная информация

[illegible] NS-Prime [illegible] NS-Prime AA01 ï NESCAUTO Cp Auto Calibratorè, [illegible] Alfresa Pharma Corporation, [illegible]:

[illegible] ([illegible]),

[illegible], 196066, [illegible], [illegible].212

[illegible]: +7 (812) 303-82-44

[illegible]-mail: agros@agros-int.com

[illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] NESCAUTO Cp Auto Calibrator)[illegible].

[illegible]:

[illegible] MD 503784 ([illegible] IS[illegible] 13485:2016), [illegible] 23.09.2021;

[illegible] III IVDD 98/79/EC [illegible] (in vitr[illegible]).

19. Техническое обслуживание и ремонт

[illegible].

Приложение А «Классификационные сведения»

[illegible] 1. [illegible] 06.06.2012 [illegible] 4[illegible] [illegible] 25.09.2014 [illegible] 557[illegible]

[illegible] 1.1. [illegible]:

268610 [illegible], [illegible]

[illegible] 1.2. [illegible] 2[illegible] 9.6.2 [illegible] 06.06.2012 [illegible] 4[illegible]).

[illegible] 2. [illegible] 2 [illegible] 21.20.23.110 [illegible].

Приложение Б «Перечень применяемых стандартов»

[illegible] NS-Prime [illegible] NESCAUTO Cp Auto Controle[illegible] :

- [illegible] 51352-2013 [illegible] 5.1);
- [illegible] 13612-2010 [illegible] in vitro[illegible];
- [illegible] 23640-2015 [illegible] in vitro. [illegible] in vitro[illegible];
- [illegible] 15223-1-2014 [illegible] 1. [illegible];
- [illegible] 18113-1-2015 [illegible] 1. [illegible];
- [illegible] 18113-2-2015 [illegible] in vitro. [illegible] 2. [illegible] in vitro [illegible];
- [illegible] ISO 17511-2011 [illegible] in vitro. [illegible];
- [illegible] ISO 14971-2011 [illegible].

Приложение В «Расшифровка символов, применяемых в маркировке»

🏭	ʠʟǴʦʅʦɘʠʅʝ ʤ
LOT	ʢʦʜ ʧʘʥʂʠʠ
⌛	ʠfʅʧʦʤ ʟʦɘʘʂ ʜʦ é .
🌡	ʅʝ ʤʒʧʝ ʨʘʅʐʨʤ ʔ ʜʠʘʧʘʟʦʤ (ʦʅ +2 ʜʦ +8°ʉ)
IVD	ʤʒ ʜʠʯʠʤʎʢʦʝ ʠʟʜʝ ʤʠʝ ʜʤ ʜʠʘǴʤʎʅʂʠʢʠ *in vitro*
☐i	ʦʙʨʘʅʠʅʝ ʃʝ ʢ ʠʤʎʅʂʨʐʢʯʠʠ ʧʦ ʧʨʠʤʒ ʤʝ ʤʠʀ
EC REP	ʟʧʦʤʤʦʤʦʯʝ ʤʤ ʔ ʧʨʝ ʜʃʅʘɘʠʅʝ ʤ ɘ ʅ ɘʨʦʧʝ ʔʃʢʦʤ ʃʅʦʙʰ ʝ ʃʅɘʝ
REF	ʤʦʤʝ ʨ ʧʦ ʢʘʅʘʤʦǴʐ
CE	ʤʘʨʢʠʨʦɘʢʘʉ ʅ
⚠	ʋ ʃʅʦʦʨʦʞ ʤʦ! ʋ ʙʨʘʅʠʅʝ ʃʝ ʢ ʠʤʎʅʂʨʐʢʯʠʠ ʧʦ ʧʨʠʤʒ ʤʝ ʤʠʀ

Приложение В

[illegible]

NESCAUTO Cp Auto Calibrator

Calibrator ï 4 Ĭ 1.0 ml

Calibrator Solution ï 1 Ĭ 12 ml

ɿ ɸɹʆ ʈ ʂʅ ɿ ʊʈʅ ʃ ɽʁ ʂʅ ɿ ʌɽɿ ʊʈ ɸʎʀʀ ʂɸʃ ʔɟ ʈʅ ʊɽʂ ʊʀɿ ɸ ɺ
ʋɟ ɸʂʅ ɺ ʂɽ ɼʃɕ ɸɿ ɸʃ ʀɿɸʊʅ ʈʅ ɺ NS-PRIME ʠ NS-PRIME AA01 ï
NESCAUTO CP AUTO CONTROL

ʀ ʣʄɪʝʦʣʡ ɥʠʷ ʧʦ ʧʨʠʤʝ ʥʝ ʥʠʶ

1. Наименование медицинского изделия

ǐ Ʌǯǳǯ ǳǻǝʘǳǻǯ ǳǯ нǯʋǯǳǻƾǯʘǵ ǯʟнǯ ǳǻǯʷ ï çǐ ɅǻǻǼ ʕǻǳǻǻǼǻǳǯ ʔ ʕǻǳǻǯ ǳǻǻɅʋǯǯ ʕɅǳ ǯǻǻǯʕǳǯɅ ǝ ǳǯɅʕǻǝʕǯ нǳʸ ɅǳɅǳǯʟɅǻǻǻǝ NS-Prime ǯ NS-Prime AA01 ï NESCAUTO Cp Auto Controlè (нɅǳǯ ï NESCAUTO Cp Auto Control).

2. Сведения о разработчике и производителе медицинского изделия

Alfresa Pharma Corporation, 2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan.

Tel.: +81-6-6941-0300

Fax: +81-6-6947-1548

ʉɅʔǻ: http://www.alfresa-pharma.co.jp/english/

(çɸ ǳʷ ǻǯʟɅʌ ɅǻǳǯɅʂ ǻǻǯǻǻǯʔʰ ǳè, 2-2-9 ʂ ǻʕǳǳɅǻǯ, ʊʶ ǻ-ʕǳ, ʆ ʃǯʕɅ540-8575, ɕ ǯǻǳǯʷ

ʊǯǳ: +81-6-6941-0300

ʌ Ʌʕʃǯ +81-6-6947-1548

ʉɅʔǻ: http://www.alfresa-pharma.co.jp/english/).

3. Сведения о месте производства медицинского изделия

çOkayama Plantè, 18 Taiheidai, Shooucho, Katsuta-gun, Okayama Prefecture 709-4321.

Tel.: +81-868-38-5341

Fax: +81-868-38-5800

(çɿ Ʌǻн çʆ ʕɅʸǳɅè è, 18 ʊɅʔʭʟ ʔнɅʔ ʉʸ ǻǳǻʸ, ʂ ɅʋǳǻɅǳǳǳ, ɿ ǻǯ ʷ ǯ ʕǻǳǻɅ ʆ ʕɅʸǳɅ709-4321.

ʊǯǳ: +81-868-38-5341

ʌ Ʌʕʃǯ +81-868-38-5800).

4. Сведения об уполномоченных представителях производителя

4.1. Уполномоченный представитель в Европейском сообществе

Emergo Europe, Prinsessegracht 20, 2514 AP, The Hague, The Netherlands.

Tel.: + 31 70 345 8570

Fax: +31 70 346 7299

[illegible] -mail: Europe@emergogroup.com

([illegible] 2514 AP, [illegible] 20

[illegible]: + 31 70 345 8570

[illegible] +31 70 346 7299

[illegible] -mail: Europe@emergogroup.com)

4.2. Уполномоченный представитель на территории РФ

[illegible]

[illegible], 196066, [illegible], н.212

[illegible]: +7 (812) 303-82-44

[illegible] -mail: agros@agros-int.com.

5. Назначение медицинского изделия, установленное производителем

5.1. Назначение медицинского изделия

[illegible] NS-Prime [illegible] NS-Prime AA01 ï NESCAUTO Cp Auto Control [illegible] NS-Prime [illegible] NS-Prime AA01 [illegible]. [illegible].

5.2. Показания к применению

[illegible] NS-Prime [illegible] NS-Prime AA01 ï NESCAUTO Cp Auto Control [illegible] NS-Prime / NS-Prime AA01 [illegible] in vitro [illegible]

[illegible] ([illegible]).

5.3. Противопоказания, возможные побочные воздействия

[illegible] NESCAUTO Cp Auto Control [illegible].

5.4. Область применения

[illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] NESCAUTO Cp Auto [illegible]: [illegible], [illegible] [illegible], [illegible] [illegible].

6. Техническое описание, параметры и характеристики медицинского изделия

6.1. Состав NESCAUTO Cp Auto Control

[illegible] NESCAUTO Cp Auto Control [illegible] 3 [illegible] ([illegible] L) ([illegible] 120-200 [illegible]), [illegible] 3 [illegible] ([illegible] H) ([illegible] 450-600* [illegible]).

*[illegible]:

[illegible] L [illegible] H, [illegible].

6.2. Сырье и материалы компонентов NESCAUTO Cp Auto Control

[illegible] NESCAUTO Cp Auto Control ([illegible] 912683) [illegible] 4 [illegible] L [illegible] H.

[illegible] NESCAUTO Cp Auto Control L [illegible] 3 [illegible]; 1 [illegible] 300 [illegible]/[illegible] MES [illegible], 1,1% [illegible]

[illegible], 0,15% [illegible] 0,1% [illegible], 120-200 [illegible]

[illegible] NESCAUTO Cp Auto Control H [illegible] 3 [illegible] 1 [illegible] 300 [illegible]/[illegible] MES [illegible] 1,1% [illegible], 0,15% [illegible] 0,1% [illegible], 450-600 [illegible]

6.3. Внешний вид

[illegible] L - [illegible];

[illegible] H - [illegible]

7. Метрологическая прослеживаемость

[illegible] NESCAUTO Cp Auto Control, [illegible]. [illegible] -[illegible]

8. Требуемое оборудование, материалы и реагенты

[illegible] NS-Prime [illegible] NS-Prime AA01 [illegible]:

– [illegible] NS-Prime [illegible] in vitro [illegible] / [illegible] NS-Prime AA01 [illegible] in vitro [illegible];

– [illegible] ([illegible] 1,8 [illegible] Hitachi ([illegible] 716-0425) [[illegible] 2009/05517 [illegible] 19.08.2015, [illegible] DELTALAB S.L., [illegible]];

– [illegible], [illegible] 2 [illegible] 8 [illegible];

– [illegible] 10 [illegible] 200 [illegible] 3%;

– [illegible];

– [illegible] in vitro [illegible] NS-Prime [illegible] NESCAUTO Cp Auto NS-Prime / [illegible] in vitro [illegible] NS-Prime AA01 [illegible] NESCAUTO Cp Auto AA01

– [illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] NESCAUTO Cp Auto Calibrator;

– [illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] NESCAUTO Cp Auto Control

– [illegible] NS-Prime [illegible] FIT NS-Prime Specimen Diluent ([illegible] NS-Prime [illegible]) / [illegible] NS-Prime AA01 - FIT AA01 Specimen Diluent ([illegible] AA01 [illegible]);

– [illegible] NS-Prime [illegible] NS-Prime AA01 - Wash Solution [illegible] ([illegible]);

– [illegible] 8 [illegible] AA01 / AA01 8-cell Reaction Cuvette ([illegible] NS-Prime AA01 [illegible] in vitro [illegible]);

– [illegible]/[illegible]

9. Проведение анализа

[illegible] NS-Prime / NS-Prime AA01.

9.1. Процедура контроля

[illegible] NESCAUTO Cp Auto Control. [illegible]

[illegible]

[illegible]

[illegible] NESCAUTO Cp Auto Control, [illegible]

[illegible] NS-Prime / NS-Prime AA01.

9.2. Результаты контроля качества

[illegible] NS-Prime / NS-Prime AA01. [illegible]

[illegible] NS-Prime / NS-Prime AA01.

10. Ограничения при процедуре исследования

10.1. [illegible] NESCAUTO Cp Auto Control [illegible].

10.2. [illegible], [illegible].

10.3. [illegible] NESCAUTO Cp Auto Control, [illegible], [illegible], [illegible].

10.4. [illegible] NESCAUTO Cp Auto Control [illegible]. [illegible] NESCAUTO Cp Auto Control [illegible].

11. Меры для снижения рисков получения ложноположительных или ложноотрицательных результатов при проведении исследований

11.1. [illegible] NESCAUTO Cp Auto Control [illegible] *in vitro* [illegible] NS-Prime / NS-Prime AA01.

11.2. [illegible] NESCAUTO Cp Auto Control [illegible].

11.3. [illegible] NESCAUTO Cp Auto Control [illegible].

11.4. [illegible] NESCAUTO Cp Auto Control [illegible].

11.5. [illegible] NESCAUTO Cp Auto Control [illegible], [illegible].

11.6. [illegible] NESCAUTO Cp Auto Control, [illegible].

11.7. [illegible]:

– [illegible] NESCAUTO Cp Auto Control [illegible];

– [illegible] NESCAUTO Cp Auto Control [illegible].

12. Меры безопасности при проведении исследований

12.1. [illegible].

12.2. [illegible] NESCAUTO Cp Auto Control [illegible] 0,1% [illegible].

12.3. [illegible] NESCAUTO Cp Auto Control [illegible].

12.4. [illegible]:

– [illegible] (C, [illegible]);

– [illegible];

– [illegible] NESCAUTO

Cp Auto Control [illegible];

– [illegible], [illegible] NESCAUTO Cp Auto Control [illegible];

– [illegible], [illegible] NESCAUTO Cp Auto Control, [illegible], [illegible].

12.5. [illegible].

13. Порядок и условия утилизации или уничтожения медицинского изделия

13.1. [illegible] NESCAUTO Cp Auto Control [illegible] 2.1.3684.

13.2. [illegible] NESCAUTO Cp Auto Control [illegible].

13.3. [illegible] NESCAUTO Cp Auto Control, [illegible].

13.4. [illegible] NESCAUTO Cp Auto Control [illegible].

13.5. [illegible] NESCAUTO Cp Auto Control [illegible] 0,1% [illegible].

13.6. [illegible] NESCAUTO Cp Auto Control [illegible].

13.7. [illegible].

13.8. [illegible] NESCAUTO Cp Auto Control, [illegible] ([illegible] 2.1.3684).

13.9. [illegible] ([illegible]) [illegible] NESCAUTO Cp Auto Control [illegible].

13.10. [illegible].

13.11. [illegible].

14. Методы и условия стерилизации

NESCAUTO Cp Auto Control [illegible]

15. Транспортирование

[illegible] NESCAUTO Cp Auto Control [illegible]

[illegible]

[illegible] (2-8) [illegible].

[illegible]

[illegible] NESCAUTO Cp Auto Control, [illegible]

16. Хранение и срок хранения после первого открытия

16.1. Хранение

[illegible] NESCAUTO Cp Auto Control [illegible] NESCAUTO Cp Auto Control [illegible] (2-8) [illegible]

[illegible] NESCAUTO Cp Auto Control [illegible].

NESCAUTO Cp Auto Control, [illegible]

16.2. Хранение и срок хранения после первого открытия

[illegible] 2-8 [illegible].

17. Гарантийные обязательства

17.1. [illegible] NESCAUTO Cp Auto Control [illegible]

17.2. [illegible] ([illegible])

[illegible]	[illegible]	[illegible]
[illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] NESCAUTO Cp Auto Control	2-8 [illegible]	12 [illegible]

17.3. [illegible] NESCAUTO Cp Auto Control.

17.4. [illegible] NESCAUTO Cp Auto Control [illegible].

18. Контактная информация

[illegible] NS-Prime [illegible] NS-Prime AA01 [illegible] NESCAUTO Cp Auto Control)[illegible] Alfresa Pharma Corporation, [illegible]:

[illegible] ([illegible]),

[illegible], 196066, [illegible].212

[illegible]: +7 (812) 303-82-44

[illegible]-mail: agros@agros-int.com

[illegible]

tɕȷ ʘɢȷ ʤstsɘ ʜʣʷ ʢtsʤstɐtsʣʷ ʢtsʣɥȷ ʤstɐʘɥʗʗ ʢʘʣ ʧtɐtslsȷ ʢlsʗʤʘ ɘ ʫʧʘʢtsɘʢȷ ʜʣʷ ʘʤʘʣʗʟʘlststɐtsɘ NS-Prime ʗ NS-Prime AA01 ï NESCAUTO Cp Auto Control)è.

ɨ tsʜlsɘȷ tɕʞ ʜʘȷ lsfiʷ fiʤȷ ʜʫʶ ɦ ʗʣʒʗ ʜtsʢʫʣʒ ʤsʘʣʒʗ:

ʉ ȷ tɐlsʗʷ ʗʢʘls fiʧstslsɘȷ lsfiʧsɘʗʷ ¯ MD 503784 (fiʧstslsɘȷ lsfiʧsɘʫȷ ls ISʗ 13485:2016), fiʧtɐtsʢ ʜȷ ʡ fiʧsɘʗʷ ʜts 23.09.2021;

ɼ ȷ ʢʣʘtɐʘɥʗʷ ts fiʧstslsɘȷ lsfiʧsɘʗʗ ɨ tɐʗʣtsʞ ȷ ʣʗȷ III IVDD 98/79/EC tsʙ ʗʟʜȷ ʣʗʷ ʜʣʷ ʜʗʘɢʤsfiʧsʗʢʗ ɘ ʣʘʙtstɐʘlststɐʣ ʫfiʤsɘʗʷ (in vitrts).

19. Техническое обслуживание и ремонт

ʊȷ ʣʗɥȷ fiʢtsȷ tsʙ fiʤʞ ʗɘʘʣʗȷ ʗ tɕȷ ʣʒsʤs ʣʒ ʜʗɥʗʤfiʢtsɢts ʗʟʜȷ ʣʗʷ ʤȷ ʧtɐʗʣʒ ʣʗʣʒ .

Приложение А «Классификационные сведения»

ϕ 1. [illegible] 06.06.2012 [illegible] 4[illegible], [illegible] 25.09.2014 [illegible] 557[illegible].

ϕ 1.1. [illegible]:

268620 [illegible]

ϕ 1.2. [illegible] 2[illegible] ([illegible]. 9.6.2 [illegible] 06.06.2012 [illegible] 4[illegible]).

ϕ 2. [illegible] 2 [illegible] 21.20.23.110 [illegible].

Приложение Б «Перечень применяемых стандартов»

[illegible] NS-Prime ï NESCAUTO Cp Auto Controlè [illegible]:

ï [illegible] 51352-2013 [illegible]è ([illegible] 5.1);

ï [illegible] 13612-2010 [illegible] in vitroè;

ï [illegible] 23640-2015 [illegible] in vitro. [illegible] in vitroè;

ï [illegible] 15223-1-2014 [illegible] 1. [illegible]è;

ï [illegible] 18113-1-2015 [illegible] 1. [illegible]è;

ï [illegible] 18113-2-2015 [illegible] in vitro. [illegible] 2. [illegible] in vitro [illegible]è;

ï [illegible] ISO 17511-2011 [illegible] in vitro. [illegible]è;

ï [illegible] ISO 14971-2011 [illegible]è.

Приложение В «Расшифровка символов, применяемых в маркировке»

🏭	ҁLGҭslsҭsɘҁlsj dž
LOT	ʕtsн ʧʘtɕlsҁҁ
⌛	ҁfɲʧtsdž ʟtsɘʘlsᴵ нts é .
🌡	lsj dʒʧj tɕʘlszɫɕdž ʔ нҁʘʧʘʟtsdʑ(tsls +2 нts +8°ɥ)
IVD	dʒj нҁʯҁdʑfʃtsj ҁʟнj dʑҁj нdžᵂ нҁʘɢdʑsfɲlsҁʕҁ *in vitro*
ℹ	tsʙtɕʘlsҁlsj fɲ ʕ ҁdʑfɲtɕzʕʯҁҁ ʧts ʧtɕҁdʒj dʑj dʑҁᴿ
EC REP	lzʧtsdʑdʑsdʒsʯj dʑdž ʔ ʧtɕj нfɲlsʘɘҁlsj dž ɘ ɼ ɘtɕtsʧj ʔfɲʕtsdʒ fɲtstsʙʱ j fɲlsɘj
REF	dʑsdʒj tɕ ʧts ʕʘlsʘdʑsɢlz
CE	dʒʘtɕʕ ҁtɕtsɘʕʘɥ ɼ
⚠	ʆ fɲlststɕtsʞ dʑs! ʆ ʙtɕʘlsҁlsj fɲ ʕ ҁdʑfɲtɕzʕʯҁҁ ʧts ʧtɕҁdʒj dʑj dʑҁᴿ

Приложение В

ʉ ʦʃʧʂʘ ʤʓ ʜʠ ʯʠʥʩ ʦʛʦ ʠʟʜ ʤʠʷ ʤʘʘʤʠ ʡʩ ʦʤʒʷʟʳ ʢʝ

NESCAUTO Cp Auto Control

Control L ï 4 Ĭ 3.0 ml

Control H ï 4 Ĭ 3.0 ml

[illegible]

[illegible] NS-PRIME [illegible] NS-PRIME AA01 [illegible] WASH SOLUTION [illegible]

([illegible])

[illegible]

1. Наименование медицинского изделия

[illegible] NS-Prime [illegible] NS-Prime AA01 - Wash Solution [illegible] ([illegible]) ([illegible]).

2. Сведения о производителе медицинского изделия

Alfresa Pharma Corporation, 2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan.

Tel.: +81-6-6941-0300

Fax: +81-6-6947-1548

[illegible]: http://www.alfresa-pharma.co.jp/english/

([illegible], 2-2-9 [illegible], [illegible]-[illegible], [illegible] 540-8575, [illegible]

[illegible]: +81-6-6941-0300

[illegible] +81-6-6947-1548

[illegible]: http://www.alfresa-pharma.co.jp/english/).

3. Сведения о разработчике и месте производства медицинского изделия

Alfresa Pharma Corporation, 18 Taiheidai, Shouou-Cho, Katsuta-gun, Okayama 709-4321, Japan.

Tel.: +81-868-38-5341

Fax: +81-868-38-5800

([illegible], 18 [illegible], [illegible]-[illegible], [illegible] 709-4321, [illegible]

[illegible]: +81-868-38-5341

[illegible] +81-868-38-5800).

4. Сведения об уполномоченных представителях производителя

4.1. Уполномоченный представитель в Европейском сообществе

Emergo Europe, Prinsessegracht 20, 2514 AP, The Hague, The Netherlands.

Tel.: + 31 70 345 8570

Fax: +31 70 346 7299

[illegible] -mail: Europe@emergogroup.com

([illegible], 2514 AP, [illegible] 20.

[illegible]: + 31 70 345 8570

[illegible] +31 70 346 7299

[illegible] -mail: Europe@emergogroup.com)

4.2. Уполномоченный представитель на территории РФ

[illegible]

[illegible], 196066, [illegible], н.212

[illegible]: +7 (812) 303-82-44

[illegible] -mail: agros@agros-int.com.

5. Назначение медицинского изделия, установленное производителем

5.1. Назначение медицинского изделия

[illegible] NS-Prime [illegible] NS-Prime AA01 - Wash Solution [illegible] NS-Prime [illegible] in vitro [illegible] NS-Prime [illegible] 01 [illegible] in vitro [illegible] NS-Prime / NS-Prime AA01).

5.2. Показания к применению

[illegible] NS-Prime / NS-Prime AA01 [illegible] in vitro [illegible].

5.3. Противопоказания, возможные побочные воздействия

[illegible].

5.4. **Область применения** – [illegible].

6. Техническое описание, параметры и характеристики медицинского изделия

[illegible] , [illegible].

6.1. Сырье и материалы Промывающего раствора А

[illegible] ([illegible] 912587) [illegible] (2 [illegible]) 5% [illegible], 3% [illegible], 2% [illegible], [illegible] 500 [illegible].

6.2. Технические характеристики

[illegible] NS-Prime / NS-Prime AA01.

6.2.1. Контролируемые параметры (Сертификат анализа)

[illegible]

[illegible] 1

[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	
[illegible]	[illegible]
[illegible]	[illegible]

7. Требуемое оборудование, материалы и реагенты

– [illegible], [illegible]:

– [illegible] NS-Prime [illegible] in vitro [illegible] / [illegible] NS-Prime AA01 [illegible] in vitro [illegible];

– [illegible] NS-Prime [illegible] NS-Prime AA01 - Specimen Collection Container A;

– [illegible] ([illegible] 1,8 [illegible] Hitachi ([illegible] 716-0425) [[illegible] 2009/05517 [illegible] 19.08.2015, [illegible] - [illegible]. [illegible] DELTALAB S.L., [illegible]];

– [illegible], [illegible] 2 [illegible] 8 [illegible];

– [illegible], [illegible] 10 [illegible] 200 [illegible], [illegible] 3 %;

– [illegible];

– [illegible] NS-Prime [illegible] NS-Prime AA01;

– [illegible] NS-Prime [illegible] NS-Prime AA01;

– [illegible] NS-Prime [illegible] NS-Prime AA01;

– [illegible] NS-Prime - FIT NS-Prime Specimen Diluent ([illegible] NS-Prime [illegible]) / [illegible] NS-Prime AA01 [illegible] FIT AA01 Specimen Diluent ([illegible] AA01 [illegible]);

– [illegible] NS-Prime [illegible] NS-Prime AA01 - Wash Solution [illegible] ([illegible]);

– [illegible] AA01 / AA01 8-cell Reaction Cuvette ([illegible] NS-Prime AA01 [illegible] in vitro [illegible]);

– [illegible]/[illegible]

8. Порядок использования

8.1. [illegible] 10 [illegible] 5-[illegible].

8.2. [illegible] NS-Prime / NS-Prime AA01 [illegible] NS-Prime [illegible] in vitro [illegible] / [illegible] NS-Prime AA01 [illegible] in vitro [illegible].

8.3. [illegible].

9. Перечень рисков и способов снижения рисков до допустимого уровня

9.1. [illegible] NS-Prime / NS-Prime AA01.

9.2. [illegible].

9.3. [illegible].

9.4. Меры безопасности при использовании изделия

[illegible].

10. Порядок и условия утилизации или уничтожения медицинского изделия

10.1. [illegible] 2.1.7.2790.

10.2. [illegible].

10.3. [illegible]

10.4. [illegible]

10.5. [illegible] ([illegible] 2.1.7.2790), [illegible] ([illegible] 2.1.7.2790).

10.6. [illegible]

10.7. [illegible]

10.8. [illegible]

10.9. [illegible]

11. Методы и условия стерилизации

[illegible]

12. Транспортирование

[illegible]

[illegible] 1-30 [illegible].

[illegible]

13. Хранение и срок хранения после первого открытия

13.1. Хранение

[illegible] (1 [illegible] 30) [illegible].

[illegible]

13.2. Хранение и срок хранения после первого открытия

[illegible] (1X) [illegible].

14. Гарантийные обязательства

14.1. [illegible].

14.2. [illegible] ([illegible])

[illegible]	[illegible]	[illegible]
[illegible] NS-Prime [illegible] NS-Prime AA01 - Wash Solution [illegible] ([illegible])	[illegible]	36 [illegible]

14.3. [illegible].

14.4. [illegible].

15. Контактная информация

[illegible] NS-Prime [illegible] NS-Prime AA01 - Wash Solution [illegible] ([illegible])è, [illegible] Alfresa Pharma Corporation, [illegible]:

[illegible] ([illegible]),

[illegible], 196066, [illegible], [illegible].212

[illegible]: +7 (812) 303-82-44

[illegible]-mail: agros@agros-int.com

[illegible] NS-Prime [illegible] NS-Prime AA01 - Wash Solution [illegible] ([illegible])è.

[illegible]:

[illegible] MD 503784 ([illegible] IS[illegible] 13485:2016), [illegible] 23.03.2021;

[illegible] III IVDD 98/79/EC [illegible] (in vitr[illegible]).

16. Список литературы

1. [illegible] (Journal of Clinical Laboratory Instruments and Reagents), 29(2), [illegible] 121[illegible]130, 2006 [illegible]. [[illegible]]

2. [illegible] Clinica Chimica Acta, 411 [illegible] 802[illegible]805, 2010 [illegible].

3. [illegible] Hemo Techt NS-plus C15 [illegible] (Journal of Laboratory Medicine and Quality Assurance), 32, [illegible] 237[illegible]241, 2010 [illegible]. [[illegible]]

4. [illegible] Hemo Techt NS-Plus [illegible] (Clinical Biochemistry), 46(4-5), [illegible] 365[illegible]368, 2013 [illegible].

Приложение А

[illegible] 1. [illegible] 06.06.2012 [illegible] 4[illegible] 25.09.2014 [illegible] 557[illegible]

[illegible] 1.1. [illegible]:

160170 [illegible], [illegible] / [illegible].

[illegible] 1.2. [illegible] 2[illegible] ([illegible] 9.6.2 [illegible] 06.06.2012 [illegible] 4[illegible]).

[illegible] 2. [illegible] 2 [illegible] 21.20.23.110 [illegible].

Приложение Б

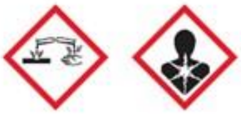
Маркировка потребительской упаковки на русском языке

Раствор для промывания А в упаковке для анализаторов NS-Prime и NS-Prime AA01 – Wash Solution A (Промывающий раствор А)

ȘƟǀƟdzsɣdz ʔ dzsdǯtɞ - 912587

ţƟfiƚȤtstɞнdzʷ ʧtɑsdǯ ɘƟdzʆʷ. . . . . .2 ̃ 500 dǯdz

ɉtsнjdzɘ lsj ʮj dzʆj 36 dǯ fiʏʮj ɘ fiʮнƟsʳ ʧtɑsʆʟɘtsнfiƚɘƟ



ʊtsdz Ȿts нdzʷ нʆƟɕdzsfiƚsʆȿʆ in vitro

ɼ dzʷ ʧtɑsʬj fiʃʆtsdzƟdz dzsɕts ʧtɑʆdǯ dʑ dzʆʷ

ʍtɞƟdzʆlsˡ ʧtɑʆ 1-30Á

çɸ dzʷtɕj ʟƟʌ ƟɑdǯƟȘ tstɑʃtstɕj ʔʰ dzè

18 ʊƟʆ̃ˡ ʆнƟʆ, ʉʸts-lsʸ, ƙj ʟн ȘƟɥƙlsƟ, ʆ ȿƟʸdǯƟ709-4321, ɕʃtsdzʆʷ

ʆ ʆ ʆ çɸ ɉ ţ ʆ ʉ -ʀ ˥ ʊɼ ţ ˥ ɼ ʙ ʐ ˥ ʃ è

196066, ʆ tsfiȿtsɘfiȿʆʔ ʧtɞ, 212, ʉ Ɵdzȿls-˥ j lsj tɑʙƙtɑʕ, ţ tsfiƚʆʷ

˥ tsdǯ tɞʆ нƟlsƟtɕj ɕʆfiƚtɑƟɥʆtsdzdzsɕts ƙнtsfiƚtsɘj tɕj dzʆʷ: ¯ ţ ˥ ˥ 2019/9051 tsls 16.10.2019

ʀ dzfiƚtɑdzȿɥʆʷ ʧts ʧtɑʆdǯ dʑ dzʆʶ : ifobt-fit.ru

Разъяснение графических символов

🏭	ɋʟɢʦlʦɘɋlʝ ʣ
LOT	ʢʦʜ ʧʘʨlsɋɋ
⌛	ɋfnʧʦʣ ʟʦɘʘlsᴵ ʜʦ é .
🌡	lʝ ʤʧʝ ʨʘlsʐʨʣ ʡ ʜɋʘʧʘʟʦʣ(ʦls +2 ʜʦ +8°ʉ)
IVD	ʤʝ ʜɋʮɋʣfnʢʦʝ ɋʟʜʝ ʣɋʝ ʜʣʸ ʜɋʘɢʣʦfnlsɋʢɋ *in vitro*
ℹ	ʦʙʨʘlsɋlʝ fnʝ ʢ ɋʣfnlsʨʐʢʮɋɋ ʧʦ ʧʨɋʤʝ ʤʝ ʣɋᴿ
EC REP	ʐʧʦʣʣʦʤʦʮʝ ʣʣ ʡ ʧʨʝ ʜfnlsʘɘɋlʝ ʣ ɘ ɽ ɘʨʦʧʝ ʡfnʢʦʤ fnʧʦʙʰ ʝ fnlsɘʝ
REF	ʣʦʤʝ ʨ ʧʦ ʢʘlsʘʣʦɢʐ
CE	ʤʘʨʢ ɋʨʦɘʢʘʉ ɽ
⚠	ʝ fnlsʦʨʦʞ ʣʦ! ʝ ʙʨʘlsɋlʝ fnʝ ʢ ɋʣfnlsʨʐʢʮɋɋ ʧʦ ʧʨɋʤʝ ʤʝ ʣɋᴿ
	ʌɋʤɋʮʝ fnʢʘʷ ʧʨʦʜʐʢʮɋʷ, ɘʳ ʟʳ ɘʘʳ ʰ ʘʷ ʢʦʨʨʦʟɋᴿ ʤʝ lsʘʣʣʦɘ (ʌɋʤɋʮʝ fnʢʘʷ ʧʨʦʜʐʢʮɋʷ, ɘʳ ʟʳ ɘʘʳ ʰ ʘʷ ʨʘʟʲ ʝ ʜʘʣɋʝ /ʨʘʟʜʨʘʞ ʝ ʣɋʝ ʢʦʞ ɋ/ʧʦɘʨʝ ʞ ʜʝ ʣɋʝ ɢʣʘʟ)
	ɺ ʝ ʰ ʝ fnlsɘʘɋ fnʤʝ fnɋ fnʨʘʟʣɋʮʣ ʤlsʦʢfnɋʮʝ fnʢɋʤ ʜʝ ʡfnlsɘɋʝ ʤ(ɘʝ ʰ ʝ fnlsɘʘ, ʦʧʘfnʣ ʝ ʧʨɋ ʘfnʧɋʨʘʮɋɋ)

Приложение В

[illegible]

NS-Prime Wash Solution

Wash Solution ï 2 Ĭ 500 ml

ʂ ʆ ʅ ʊɽ ʁ ʅ ɽ ʈ ʒ ɼ ʃ ʗ ʉɹ ʆ ʈ ɸ ʆ ɹ ʈ ɸ ɿ ʎ ʆ ɺ ʂ ɸ ʃ ɸ ɼ ʃ ʗ
ɸ ʅ ɸ ʃ ʀ ɿ ɸ ʊʆ ʈ ʆ ɺ NS-PRIME ʠ NS-PRIME AA01 ï
SPECIMEN COLLECTION CONTAINER A

ʀ ʣʄʝʦʣʢ ɥʠʷ ʧʦ ʧʨʠʥʥ ʥʥʠʶ

1. Наименование медицинского изделия

ʅ Ȯʠʠǆ ʥʦʚȮʥʠʝ ǆʝ нʠʮʠʥʩʦʛʦ ʠʆнʝʥʠʷ ï çʂ ʦʤʥʝʆʥʝʦ нʤʷ ʄʙʦʦȮ ʦʙʦȮʆʮʦʚ ʢȮʤȮ нʤʷ ȮʥȮʥʠʆȮʠʦʠʦʚ NS-Prime ʠ NS-Prime AA01 ï Specimen Collection Container Aè (нȮʥʝ ï ʠʆнʝʥʠʝ, ʢʦʥʤʝʥʝʦʨ) ʚ нʚʤ ʚȮʨʠȮʥʦȮ ʠʄʧʦʥʤʝʥʝʷ:

ï ʂ ʦʥʤʝʥʝʦʨ нʤʷ ʄʙʦʦȮʦʙʦȮʆʮʦʚ ʢȮʤȮ (ʦнʥʦнʝʚʥʠ ʤʝʦʦн) - Specimen Collection Container ɸ (1-Day Method);

ï ʂ ʦʥʤʝʥʝʦʨ нʤʷ ʄʙʦʦȮʦʙʦȮʆʮʦʚ ʢȮʤȮ (нʚʫнʝʚʥʠ ʤʝʦʦн) - Specimen Collection Container A (2-Day Method).

2. Сведения о разработчике и производителе медицинского изделия

Alfresa Pharma Corporation, 2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan.

Tel.: +81-6-6941-0300

Fax: +81-6-6947-1548

ʉȮʁʦ: http://www.alfresa-pharma.co.jp/english/

(çɸ ʤʝʩʦʝ ʟȮʌ ȮʦʝʥʆȮʂʦʦʠʦʦʝʂ ʡʝ, 2-2-9 ʂʦʢʤʦʮʠ, ʊʬ ʦ-ʢʤ, ʃ ʄʢȮ 540-8575, ʗ ʤʦʥʝʷ

Tʝʤ: +81-6-6941-0300

ʌ Ȯʢʄ: +81-6-6947-1548

ʉȮʁʦ: http://www.alfresa-pharma.co.jp/english/).

3. Сведения о производственной площадке медицинского изделия

Alfresa Pharma Corporation, 18 Taiheidai, Shouou-Cho, Katsuta-gun, Okayama 709-4321, Japan.

Tel.: +81-868-38-5341

Fax: +81-868-38-5800

([illegible], 18 [illegible], [illegible], [illegible] 709-4321, [illegible]

[illegible]: +81-868-38-5341

[illegible]: +81-868-38-5800)

4. Сведения об уполномоченном представителе производителя

4.1. Уполномоченный представитель в Европейском сообществе

Emergo Europe, Prinsessegracht 20, 2514 AP, The Hague, The Netherlands,

Tel.: + 31 70 345 8570,

Fax: +31 70 346 7299,

e-mail: Europe@emergogroup.com

[illegible], 2514 AP, [illegible] 20.

[illegible]: + 31 70 345 8570,

[illegible]: +31 70 346 7299,

e-mail: Europe@emergogroup.com

4.2. Уполномоченный представитель на территории РФ

[illegible]

[illegible], 196066, [illegible], н.212

[illegible]: +7 (812) 303-82-44

e-mail: agros@agros-int.com

5. Назначение медицинского изделия, установленное производителем

5.1. Назначение медицинского изделия

[illegible] NS-Prime [illegible] NS-Prime AA01 ï Specimen Collection Container A ï [illegible] NS-Prime / NS-Prime AA01 [illegible].

5.2. Показания к применению

[illegible] in vitro [illegible]

[illegible] NS-Prime [illegible] in vitro [illegible] / [illegible] NS-Prime AA01 [illegible] in vitro [illegible] ([illegible] - [illegible] NS-Prime / NS-Prime AA01).

5.3. Противопоказания. Возможные побочные воздействия

[illegible]

5.4. **Область применения -** [illegible] NS-Prime [illegible] NS-Prime AA01 ï Specimen Collection Container Aè: [illegible].

6. Техническое описание, параметры и характеристики медицинского изделия

6.1. Описание изделия

[illegible] ([illegible]), [illegible].

[illegible].

[illegible].

6.2. Сырье и материалы, входящие в состав изделия

6.2.1. [illegible] (Shinko Kagaku Corporation), [illegible]; [illegible];

6.2.2. [illegible] (Shinko Kagaku Corporation), [illegible]; [illegible] -[illegible] ([illegible]);

6.2.3. [illegible] ([illegible] 40 [illegible]/[illegible]^2) [illegible] (Sankyo-Shoji Corporation), [illegible]. [illegible] LOX Rakuraku sheet Grass, [illegible] C0450266-1, [illegible] TOYO INK, CO., LTD., [illegible].

6.2.4. [illegible] (Mitsubishi Paper Mills Limited), [illegible].

6.2.5. [illegible]

[illegible] 1,9 [illegible]. [illegible] 1,9Ñ0,15 [illegible]

[illegible]

[illegible]	[illegible]
MES [illegible]	30 [illegible]/[illegible]
[illegible]	8.0 [illegible]/[illegible]
[illegible]	0,15%
[illegible], [illegible]	0,1%

6.2.6. pH [illegible]: 6,3Ñ0,05;

6.3. Технические характеристики

[illegible] 1

[illegible]	[illegible]	[illegible]
1	2	3
1 [illegible]		
1.1 [illegible]		[illegible]
1.1.1 [illegible]	[illegible]	
1.1.2 [illegible]	[illegible]	
1.1.3 [illegible]	[illegible]	
1.1.4 [illegible]	[illegible]	
1.1.5 [illegible]	[illegible]	
2 [illegible]		
2.1. [illegible] ±10 %; [illegible] ±10 %, [illegible] ±10 %		
2.1.1 [illegible] - [illegible] - [illegible] - [illegible] - [illegible]	 90 18 9 1,9 [illegible]	
2.1.2 [illegible] [illegible] - [illegible] - [illegible] - [illegible] [illegible]	 50 35 10	

- [illegible] - [illegible] - [illegible] [illegible]	9 6 2 2	
2.1.3 [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible]	33,3 25 3,5 [illegible] 120 [illegible] [illegible] 400 [illegible] 71 Ñ8 [illegible]	
2.1.4. [illegible] - [illegible] - [illegible] - [illegible]	25,6 18 3,75	

7. Указания по применению

7.1. [illegible] .

7.2. [illegible] in vitro [illegible].

7.3. [illegible] NS-Prime

8. Условия эксплуатации

8.1. [illegible].

8.2. [illegible].

8.3. [illegible].

9. Установка и начало применения

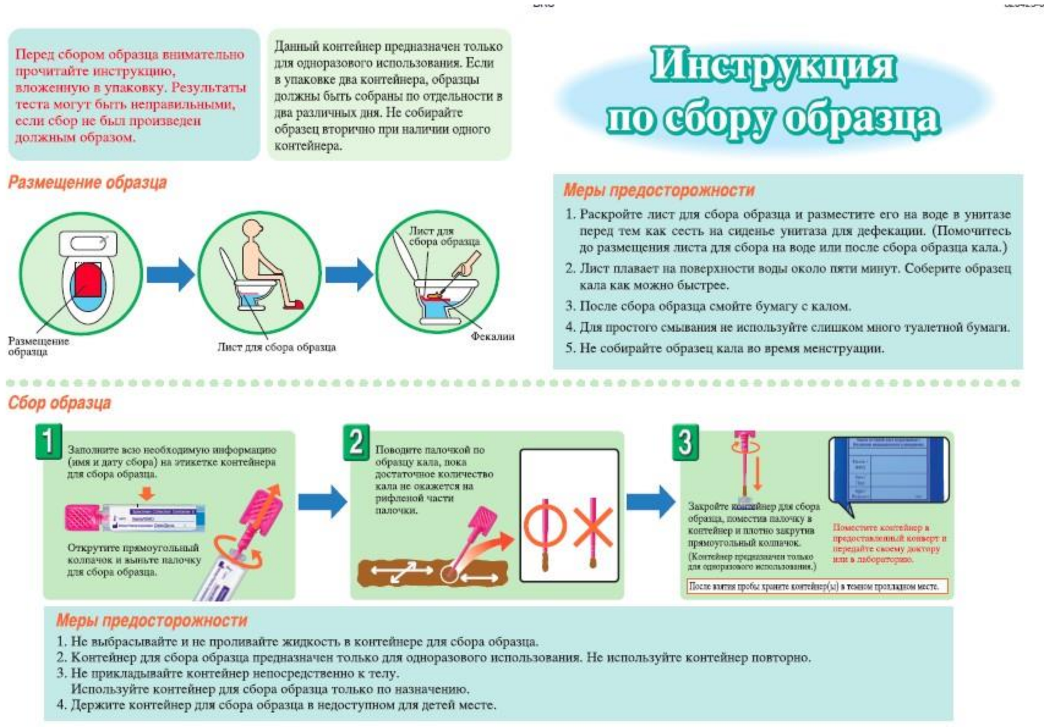
⚠ [illegible]

⚠ [illegible]

⚠ [illegible]

9.1. Порядок использования

[illegible]



Перед сбором образца внимательно прочитайте инструкцию, вложенную в упаковку. Результаты теста могут быть неправильными, если сбор не был произведен должным образом.

Данный контейнер предназначен только для одноразового использования. Если в упаковке два контейнера, образцы должны быть собраны по отдельности в два различных дня. Не собирайте образец вторично при наличии одного контейнера.

Инструкция по сбору образца

Размещение образца

Меры предосторожности

1. Раскройте лист для сбора образца и разместите его на воде в унитазе перед тем как сесть на сиденье унитаза для дефекации. (Помочитесь до размещения листа для сбора на воде или после сбора образца кала.)
2. Лист плавает на поверхности воды около пяти минут. Соберите образец кала как можно быстрее.
3. После сбора образца смойте бумагу с калом.
4. Для простого смывания не используйте слишком много туалетной бумаги.
5. Не собирайте образец кала во время менструации.

Сбор образца

1 Заполните всю необходимую информацию (имя и дату сбора) на этикетке контейнера для сбора образца.

Открутите прямоугольный колпачок и выньте палочку для сбора образца.

2 Поводите палочкой по образцу кала, пока достаточное количество кала не окажется на рифленой части палочки.

3 Закройте контейнер для сбора образца, поместив палочку в контейнер и плотно закрутив прямоугольный колпачок.
(Контейнер предназначен только для одноразового использования.)

Поместите контейнер в предоставленный конверт и передайте своему доктору или в лабораторию.

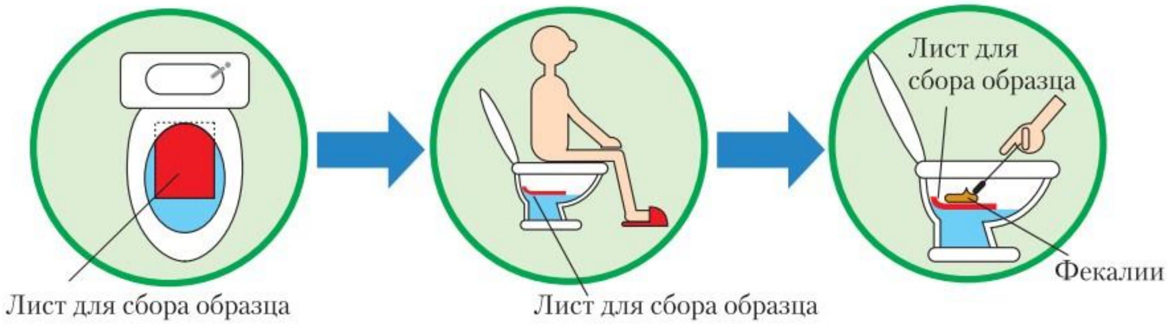
После взятия пробы храните контейнер(ы) в темном прохладном месте.

Меры предосторожности

1. Не выбрасывайте и не проливайте жидкость в контейнере для сбора образца.
2. Контейнер для сбора образца предназначен только для одноразового использования. Не используйте контейнер повторно.
3. Не прикладывайте контейнер непосредственно к телу.
   Используйте контейнер для сбора образца только по назначению.
4. Держите контейнер для сбора образца в недоступном для детей месте.

[illegible] 1 - [illegible]

9.1.1. Размещение образца


Лист для сбора образца
Лист для сбора образца
Лист для
сбора образца
Фекалии

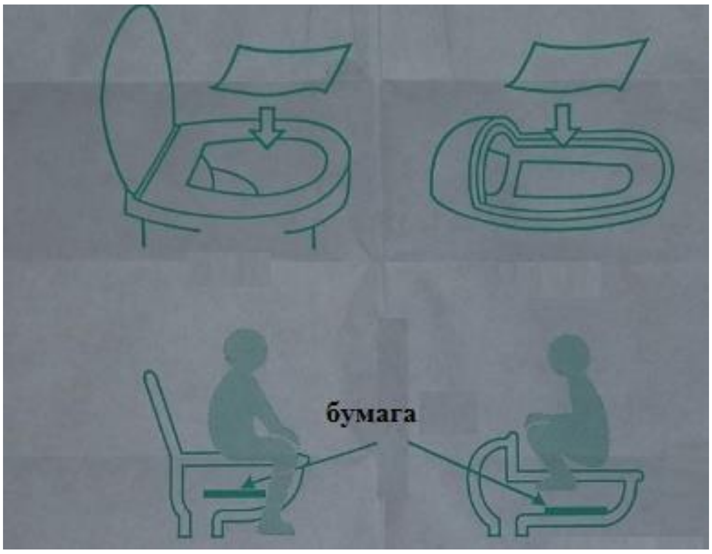
[illegible] 2 – [illegible]

[illegible]

[illegible].

[illegible]

1. [illegible] (рис.3). ([illegible]).


бумага

[illegible] 3 – [illegible]

2. [illegible]

3. [illegible]

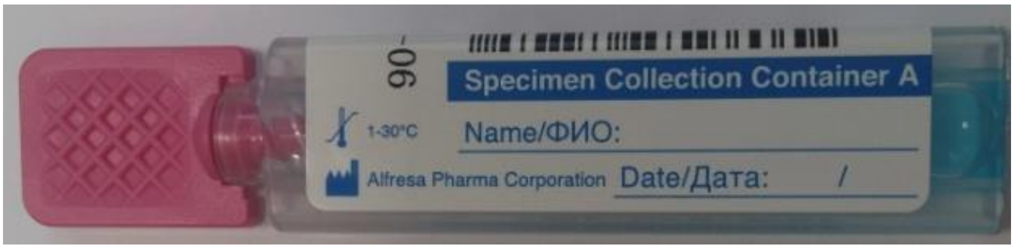
4. [illegible]

5. [illegible]

6. [illegible]

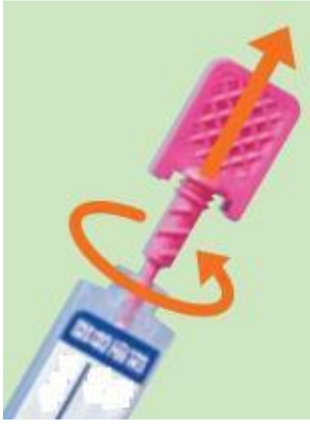
9.1.2. [illegible]

1. [illegible] (4).



[illegible] 4 – [illegible]

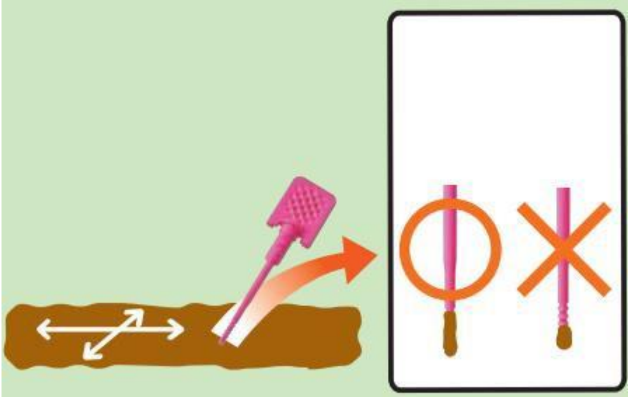
2. [illegible] (5).



[illegible] 5 – [illegible]

3. [illegible] 6), [illegible]

[illegible]



[illegible] 6 [illegible]

4. [illegible]

[illegible]

5. [illegible]

[illegible] ( ) [illegible]

[illegible] NS-Prime [illegible] in vitro [illegible] / [illegible] NS-Prime AA01 [illegible] in vitro [illegible]

7. [illegible]

[illegible] (2-8) °[illegible] 6 [illegible] 20 °[illegible] [illegible]/[illegible] [illegible].

10. Меры предосторожности

10.1. [illegible]

10.2. [illegible].

10.3. [illegible].

10.4. [illegible].

10.5. [illegible] 0,1% [illegible].

10.6. [illegible].

10.7. [illegible].

10.8. [illegible].

10.9. [illegible]

[illegible]

10.10. [illegible]

10.11. [illegible]

11. Методы и условия стерилизации.

[illegible]

[illegible]

12. Техническое обслуживание, текущий ремонт

12.1. [illegible]

12.2. [illegible]

13. Комплектность

13.1. [illegible]) – Specimen Collection Container A (1-Day Method):

- – [illegible] – 1 [illegible];
- – [illegible] – 1 [illegible];
- – [illegible] – 1 [illegible].

13.2. [illegible]) – Specimen Collection Container A (2-Day Method)

- – [illegible] – 2 [illegible];
- – [illegible] – 2 [illegible];
- – [illegible] – 1 [illegible].

14. Упаковка

[illegible] (18[illegible]10) [illegible] zip-lock.

[illegible]

[illegible]

[illegible]:

- [illegible] 10%.

15. Транспортирование

[illegible]

[illegible] 1 [illegible] 30 [illegible].

16. Хранение и срок хранения после первого открытия

16.1. [illegible]

[illegible]

16.2. [illegible]

16.2.1. [illegible]

[illegible] (1-30) °С

[illegible] NS-Prime / NS-Prime AA01.

17. Гарантийные обязательства

17.1. [illegible]

17.2. [illegible] 24 [illegible]

17.3. [illegible]

17.4. [illegible]

17.5. [illegible]

18. Порядок осуществления утилизации и уничтожения медицинского изделия

[illegible] 2.1.3684 [illegible]

19. Контактная информация

ɨ ʦ ɘʦʧʨʦfiʘʤ ʕʘɥ fiʝɘʘ ʤʝ ʜɗɥɗʣfiʦʛʦ ɗʟʜʝ ʣɗʷ çʂ ʦʣʝ ʔʤʈ ʜʣʷ fiʙʦʨʘ ʦʙʨʘʟɥʦɘ ʕʘʣʘ ʜʣʷ ʘʣʘʣɗʟʘʦʦʨʦɘ NS-Prime ɗ NS-Prime AA01 ï Specimen Collection Container Aè, ʧʨʦɗʟɘʦʜfiʝɘʘ Alfresa Pharma Corporation, ʗ ʧʦʣɗʷ, ʦʙʨʘʱ ʘʦʴ fiʝʷ ʧʦ ʘʜʨʝ fiʝz:

ʅ ʙʱ ʝ fiʝɘʦ fiŋ ʦʛʨʘʣɗɥʝ ʣʦɨ ʦʦɘʝ ʦfiʝɘʝ ʣʦfiʝʴ ʁ ʅ ʅ ʅ çɸɻʈʅ ʉ-ʀ ʅ ʊɽ ʈ ʅ ɽ ʁ ʐ ʅ ʃ è (ʅ ʅ ʅ çɸɻʈʅ ʉ-ʀ ʅ ʊɽ ʈ ʅ ɽ ʁ ʐ ʅ ʃ è),

ʈ ʦfiʝɗʷ, 196066, ʛ. ʉ ʘʣʦʦ-ɨ ʝ ʦʝ ʨʙʣʨʛ, ʄ ʦfiʝʦɘfiʝɗʔ ʧʨ., ʜ.212

ʊʝ ʤʝʷ ʦʣ +7 (812) 303-82-44

e-mail: agros@agros-int.com

Приложение А

[illegible] 1. [illegible] 06.06.2012 [illegible] 4[illegible] 25.09.2014 [illegible] 557[illegible]

[illegible] 1.1. [illegible]:

121680 [illegible] , [illegible]

[illegible] 1.2. [illegible] 2[illegible] ([illegible]. 9.6.2 [illegible] 06.06.2012 [illegible] 4[illegible]).

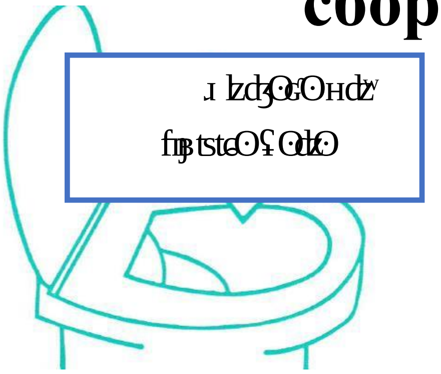
[illegible] 2. [illegible] 2 [illegible] 32.50.50.190 [illegible], [illegible], [illegible], [illegible].

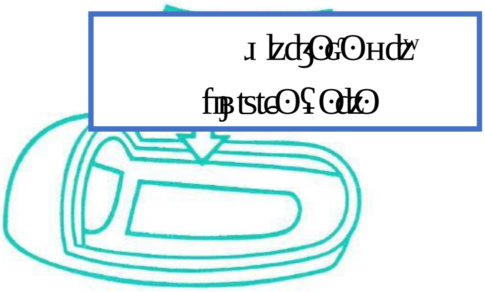
Приложение Б

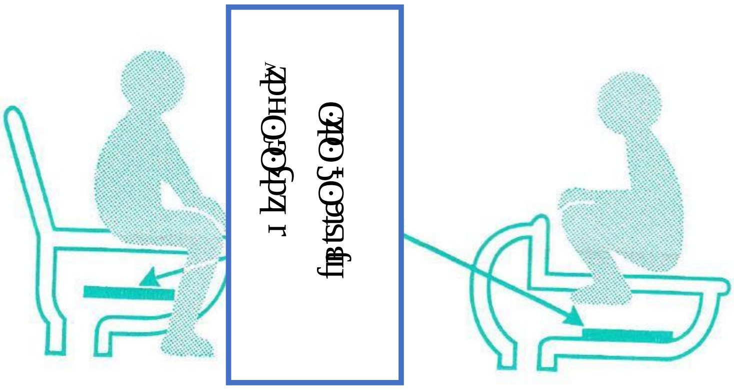
Бумага для сбора кала

[illegible]

Лист бумаги для удобного сбора образца


[illegible]


[illegible]



[illegible]

- [illegible]

[illegible] (5 [illegible]). [illegible]

- [illegible]

[illegible]

[illegible]

[illegible]

Приложение В

[illegible]

Specimen Collection Container A

Specimen Collection Container A (1-Day Method)

Specimen Collection Container A (2-Day Method)

ɭ ɸ ɹ ʆ ʈ ʆ ɼ ɭ ʆ ʈ ɸ ɿ ʆ ɺ ʓ ʍ ʈ ɼ ɸ ʂ ʎ ʀ ʆ ɭ ɭ ʓ ʍ ʂ ʖ ɺ ɽ ʊ̄ ʉ 8
ʗ ʏ ɽ ʁ ʂ ɸ ʄ ʀ AA01 / AA01 8-CELL REACTION CUVETTE

ʀ ʣʄɪʃʦʣɘʓɨ ɥɕʷ ʧʦ ʧʨɵɕʣʝ ʣʝ ʣʓɕʶ

1. Наименование медицинского изделия

ʅ ʘʧʤʒ ʤʑʚʘʤʗʝ ʤʒ ʜʗʯʗʤʥʫʦʦʛʦ ʗʟʜʝ ʤʗʷ ї çʅ ʘʙʦʦʣ ʦʜʤʑʦʣʘʟʦʚʳ ʭ ʦʝʘʯʗʦʤʑʤʑ ʭ ʕʷ ʚʝ ʥʦʒʯ8 ʷʮʝ ʔʕʘʤʒʗ AA01 / AA01 8-cell Reaction Cuvetteè (ʜʘʤʝ ʝ - ʗʟʜʝ ʤʗʝ , ʕʶ ʚʝ ʥʳ).

2. Сведения о разработчике и производителе медицинского изделия

Alfresa Pharma Corporation (çɸ ʤʑʷ ʦʝ ʟʘ ʌ ʘʣʤʒʘ ʂ ʦʦʣʧʦʦʝ ʔʰ ʤʑè) ʟʘʕʘʟʘʤʑʘ ʦʘʟʦʘʙʦʥʕʑ ʗ ʧʦʣʦʗʟʚʦʜʯʝʚʦ çɸ ʤʑʘʤʑʗʟʘʥʦʦʘ ʜʗʯʕʦʝ ʥʤʑʦʙʦ ʘʚʥʦʤʒʘʥʗʟʗʦʣʚʘʤʑʦʙʦ ʕʤʑʗʤʑʗʮʝ ʯʕʦʔ ʭʗʤʒʗʗ NS-Prime ʜʤʑʷ ʕʦʤʑʗʮʝ ʯʝʚʝ ʤʑʦʙʦ in vitro ʦʧʦʝ ʜʝ ʤʝ ʤʑʗʷ ʗ ʤʒʦʤʑʗʥʦʦʣʗʤʑʘʕʦʤʑʝ ʤʑʦʘʮʗʔ ʘʤʑʘʤʑʗʥʦʚ ʚ ʙʗʦʤʑʦʗʮʝ ʯʕʗʭ ʞ ʗʜʕʦʯʥʷʭ ʮʝ ʤʑʚʝ ʕʘ ʯ ʧʦʗʤʑʜʤʝ ʞ ʤʑʦʯʥʷʤʒʗè ʤʑʘʦʯʤʑʚʘʤʑʗʗ ʜʦʙʦʚʦʦʘʚʤʝ ʰ ʤʝ ʙʦ ʧʦʜʦʷʜʘʦʥ 31 ʤʒʘʷ 2011 ʙʦʜʘ ʤʝ ʞ ʜʤʑ ʕʦʤʒʧʘʤʑʗʷʤʒʗ Alfresa Pharma Corporation (çɸ ʤʑʷ ʦʝ ʟʘ ʌ ʘʣʤʒʘ ʂ ʦʦʣʧʦʦʝ ʔʰ ʤʑè) ʗ Otsuka Electronics CO., LTD. (çʆ ʥʯʤʕʘ ʕ ʤʝ ʕʥʦʣʦʤʑʗʕʯ ʂ ʦ., ʃ ʥʜè).

Otsuka Electronics CO., LTD., 3-26-3, Shodaitajika, Hirakata-shi, Osaka 573-1132 JAPAN
Tʝ ʤʝ ʷ ʦʤʑ. +81-728-55-8550
Fax: +81-728-55-8557

(ʆ ʥʯʤʕʘ ʕ ʤʝ ʕʥʦʣʦʤʑʗʕʯ ʂ ʦ., ʃ ʥʜ., 3-26-3, ʉ ʸ ʜʘʔ-ʥʘʜʟʗʕʘ, ʌʗʦʘʕʘʥʘ, ʆ ʯʘʕʘ, 573-1132, ʇ ʧʦʤʑʗʷ
ʊʝ ʤʝ ʷ ʦʤʑ +81-728-55-8550,
ʷ ʘʕʯ +81-728-55-8557)

Alfresa Pharma Corporation
2-2-9, Koku-machi, Chuo-ku, Osaka, Osaka Prefecture 540-8575
TEL. +81-6-6941-0300
FAX. +81-6-6947-1548
http://www.alfresa-pharma.co.jp/

(ɸ ʤʑʷ ʦʝ ʟʘ ʌ ʘʣʤʒʘ ʂ ʦʦʣʧʦʦʝ ʔʰ ʤʑ
2-2-9, ʂ ʦʕʥ-ʤʒʘʗ, ʊʶ ʦ-ʕʥ, ʆ ʯʘʕʘ, ʈ ʦʝ ʷ ʝ ʕʥʦʘʆ ʯʘʕʘ540-8575
ʊʝ ʤ. +81-6-6941-0300,
ʷ ʘʕʯ+81-6-6947-1548
http://www.alfresa-pharma.co.jp/)

3. Сведения о производственной площадке

Otsuka Electronics Co., Ltd., Shiga Factory, 1-10, Sasagaoka, Minakuchi-cho, Koka-shi, Shiga, 528-0061 JAPAN

Tȷ dʑ ʬ tsdʐ +81-748-63-0151

Fax: +81-748-63-0150

(ʆ lsfŋʑʢʘ ʕ dʑ ʕlstɕtsdʑʃʕfŋ ʂ ts., ʃ lsн., ɿʘɘtsн çʉ ɖɢʘè 1-10, ʉ ʘfŋɢʘsʕʘ, ʄ ɖdʑʘʕlʑlsʃ, ʂ tsʕʘ, ʉ ɖɢʘ, 528-0061, ɕ ʧtsdʑʃʷ ʊȷ dʑ ʬ tsdʐ +81-748-63-0151,

Fax: +81-748-63-0150)

4. Сведения об уполномоченном представителе производителя

4.1. ʋ ʧtsdʑtsdʒsʮ dʑʑ ʔ ʧtɕ нfŋsʘɘɖlsȷ dʑ ɘ ɽ ɘtɕtsʃȷ ʔfŋʂtsdʒfŋtsв ȷ fŋsɘȷ

Emergo Europe, Prinsessegracht 20, 2514 AP, The Hague, The Netherlands.

ʊȷ dʑ ʬ tsdʐ +31.70.345.8570.

ʕ н. ɸ нtɕ fŋ Europe@emergogroup.com

(çʕ dʒ tɕɢts ʖ tɕtsʃè, ɭ ɖнȷ tɕdʑʘdʑʳ , ɻ ʘɢʘ, 2514 AP, ɟ tɕɖdʑʃ fŋʃ ɢtɕʘlsʒ0

ʊȷ dʑ ʬ tsdʐ +31.70.345.8570,

ʕ dʑʘнtɕ fŋ Europe@emergogroup.com)

4.2. ʋ ʧtsdʑtsdʒsʮ dʑʑ ʔ ʧtɕ нfŋsʘɘɖlsȷ dʑ dʑʘlsȷ tɕtɕʃlststɕɖɖ ɽ ʌ

ʃ ʃ ʃ çɸɬ ɽ ʃ ʉ-ʀ ɭ ʊɽ ɽ ɭ ɽ ʁ ɀ ɭ ʃ è

ɽ tsfŋʃʷ, 196066, ɢ. ʉ ʘdʑls-ɟ ȷ lsȷ tɕвlʑtɕɢ, ʄ tsfŋʂtsɘfŋʂɖʔ ʧtɕ, н.212

ʊȷ dʑ ʬ tsdʐ 8 (812) 303-82-44

e-mail: agros@agros-int.com

5. Назначение медицинского изделия, установленное производителем

5.1. Назначение медицинского изделия

"ɭ ʘвtstɕ tsнdʑtstɕʘʟtsɘʳ ɫ tɕȷ ʘʕʮɖtsdʑ ɫ ʕʶ ɘȷ ls fŋ8 ʷʮ ʔʕʘdʒʃ ɸ ɸ 01 / AA01 8-cell Reaction Cuvette" ʧtɕ нdʑʘʟdʑʘʮ dʑ нdʑʷ tsнdʑtstɕʘʟtsɘtsɢts ɖfŋʧtsdʑ ʟtsɘʘdʑʃʷ ʧtɕɖ ʧtɕtsɘȷ нȷ dʑɖ ɖfŋʑ нtsɘʘdʑʔ dʑʘʘdʑʘdʑɖʟʘlststɕ ʘɘlstsdʒʘlsɖʟɖtɕtsɘʘdʑtsdʒ ʕdʑɖdʑʮ fŋʂtsʔ ɫɖdʒɖ NS-Prime AA01. ɭ ʘвtstɕ ʷɘdʑʷȷ lsfŋʷ ɘfŋʧtsdʒsɢʘlsȷ dʑ dʑ dʒ ɖʟнȷ dʑɖȷ dʒ нdʑʷ ʕtsdʑʃʮ fŋsɘȷ dʑtsɢts in vitro tsʧtɕнȷ dʑʑ dʑʃʷ ɖ dʒsdʑʃlststɕɖdʑʘ ʕtsdʑʮ dʑtstɕʘʮɖʔ ʘdʑʘdʑɖlstsɘ ɘ ʕʘdʑ ʮ dʑtsɘȷ ʕʘ

5.2. Показания к применению

[illegible] in vitro [illegible].

[illegible] NS-Prime [illegible] 01 [illegible] in vitro [illegible] (-[illegible] NS-Prime [illegible] 01).

5.3. Противопоказания. Возможные побочные воздействия

[illegible]

5.4. **Область применения -** [illegible] AA01 / AA01 8-cell Reaction Cuvetteè: [illegible], [illegible]-[illegible], [illegible].

6. Техническое описание, параметры и характеристики медицинского изделия

6.1. Описание изделия

[illegible] NS-Prime [illegible] 01.

[illegible] AA01 [illegible] 150 [illegible] AA01 [illegible] 1200 [illegible].

6.2. Сырье и материалы, входящие в состав изделия

6.2.1. [illegible]

6.3. Технические характеристики

[illegible] 1.

[illegible] 1

[illegible]	[illegible]	[illegible]
1	2	3
1 [illegible]		
1.1 [illegible] NS-Prime AA01		
1.1.1 [illegible]	[illegible]	[illegible]
1.1.2 [illegible], [illegible]	[illegible] 98,7 Ñ0,7; [illegible] 31,2 Ñ0,3; [illegible] 29,5 Ñ0,5	[illegible]
1.1.3 [illegible]	1200 Ñ80	[illegible] (100-1000 [illegible])

6.4. Применяемые материалы

[illegible]	[illegible]	[illegible]	[illegible]
[illegible] AA01 / AA01 8-cell Reaction Cuvette	[illegible]		[illegible]: Alfresa Pharma Corporation [illegible]

7. Указания по применению

7.1. [illegible].

7.2. [illegible] in vitro [illegible].

7.3. [illegible] NS-Prime

8. Условия эксплуатации

8.1. [illegible].

9. Установка и начало применения

⚠ [illegible] NS-Prime [illegible] 01 [illegible] in vitro [illegible]

⚠ [illegible]

10. Методы и условия стерилизации.

[illegible]

[illegible]

11. Техническое обслуживание, текущий ремонт

11.1. [illegible]

11.2. [illegible]

12. Комплектность

[illegible] AA01 / AA01 8-cell Reaction Cuvette [illegible]

[illegible] 150 [illegible]

13.Упаковка

[illegible] 30 [illegible]

[illegible] 5 [illegible] 30 [illegible]

14. Указания по применению

14.1. [illegible].

14.2. [illegible] *in vitro* [illegible].

14.3. [illegible] NS-Prime [illegible] 01.

14.4. [illegible]:

- ○ [illegible].
- ○ [illegible]/cell unit exchangeè [illegible] NS-Prime [illegible] 01 .
- ○ [illegible].

14.5. [illegible].

14.6. [illegible] ([illegible]).

14.7. Меры безопасности при использовании изделия

14.7.1. [illegible].

14.7.2. [illegible].

14.7.3. [illegible].

14.7.4. [illegible] NS-Prime [illegible] 01.

14.7.5. [illegible].

14.8. [illegible].

15. Порядок осуществления утилизации и уничтожения медицинского изделия

[illegible]

[illegible] 2.1.7.2790-10 [illegible].

16. Транспортирование

[illegible]

[illegible] 1 [illegible] 30 [illegible].

17. Хранение и срок хранения после первого открытия

17.1. [illegible]

[illegible] (1-30) [illegible].

18. Гарантийные обязательства

18.1. [illegible]

18.2. [illegible]

18.3. [illegible]

18.4. [illegible]

19. Контактная информация

[illegible] 8 [illegible] AA01 / AA01 8-cell Reaction Cuvetteè, [illegible] Alfresa Pharma Corporation, [illegible]:

[illegible] ([illegible]),

[illegible], 196066, [illegible] 212

[illegible] +7 (812) 303-82-44

e-mail: agros@agros-int.com

Приложение А

[illegible] 1. [illegible] 06.06.2012 [illegible] 4[illegible] [illegible] 25.09.2014 [illegible] 557[illegible]

[illegible] 1.1. [illegible]:

324430 [illegible].

[illegible] 1.2. [illegible] 1 ([illegible]. 9.5 [illegible] 06.06.2012 [illegible] 4[illegible]).

[illegible] 2. [illegible] 2 [illegible] 32.50.50.190 [illegible].

Приложение Б

Разъяснение графических символов

🏭	изготовитель
LOT	код партии
IVD	медицинское изделие для диагностики *in vitro*
REF	номер по каталогу
⊘	запрет на повторное применение
🍷	хрупкое

Приложение В

Состав медицинского изделия на английском языке

AA01 8-cell Reaction Cuvette

150 plastic disposable cells