

Фотографические изображения МИ:

«Набор калибраторов для количественного определения ревматоидного фактора (RF-II) в сыворотке и плазме крови на анализаторах и модулях биохимических Cobas Integra и cobas c (Preciset RF Roche/Hitachi)»

Набор калибраторов для количественного определения ревматоидного фактора (RF-II) в сыворотке и плазме крови на анализаторах и модулях биохимических Cobas Integra и cobas c (Preciset RF Roche/Hitachi), в составе:

1. Калибратор 1 (Preciset RF 1), флакон, объем 1,0 мл
2. Калибратор 2 (Preciset RF 2), флакон, объем 1,0 мл
3. Калибратор 3 (Preciset RF 3), флакон, объем 1,0 мл
4. Калибратор 4 (Preciset RF 4), флакон, объем 1,0 мл
5. Калибратор 5 (Preciset RF 5), флакон, объем 1,0 мл
6. Этикетка со штрих-кодом – 10 шт.
7. Паспорт присвоенных значений
8. Инструкция по применению.



Набор калибраторов для количественного определения ревматоидного фактора (RF-II) в сыворотке и плазме крови на анализаторах и модулях биохимических Cobas Integra и cobas c (Preciset RF

Preciset RF

Roche/Hitachi

REF 12172828322

CONTENT

CALIBRATOR 5 x 1 mL

COBAS and PRECISET are
trademarks of Roche.



 Roche Diagnostics GmbH
Sandhofer Str. 116
D-68305 Mannheim

06444857001 (1)

Distribution in USA by:
Roche Diagnostics,
Indianapolis, IN
Made in Germany

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IVD

CE

0123

 2-8 °C



 dialog.roche.com



cobas[®]

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Набор калибраторов для количественного определения ревматоидного фактора (RF-II) в сыворотке и плазме крови на анализаторах и модулях биохимических Cobas Integra и cobas c (Preciset RF Roche/Hitachi)



Набор калибраторов для количественного определения ревматоидного фактора (RF-II) в сыворотке и плазме крови на анализаторах и модулях биохимических Cobas Integra и cobas c (Preciset RF Roche/Hitachi), в составе:

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5. Калибратор 5 (Preciset RF 5), флакон, объем 1,0 мл
6. Этикетка со штрих-кодом – 10 шт.
7. Паспорт присвоенных значений
8. Инструкция по применению.

Регистрационное удостоверение № РЗН 2021/15453 от _____

Срок годности см. на упаковке

Температура хранения см. на упаковке

Номер лота см. на упаковке

Антитела к ВИЧ 1, 2 и вирусу гепатита С и HBsAg отсутствуют

Производитель: «Roche Diagnostics GmbH» ("Рош Диагностика ГмбХ"), Sandhofer Strasse 116, 68305 Mannheim, Germany, Германия

Изделие предназначено только для диагностики *in vitro*

Уполномоченный представитель производителя на территории РФ: Общество с ограниченной ответственностью «Рош Диагностика Рус» (ООО «Рош Диагностика Рус»), 107031, Москва, Трубная площадь, д.2 Тел: +7 495 229-69-99, факс: +7 495 229-62-64. E-mail: moscow.reception2_dia@roche.com

Кат. номер 12172828322

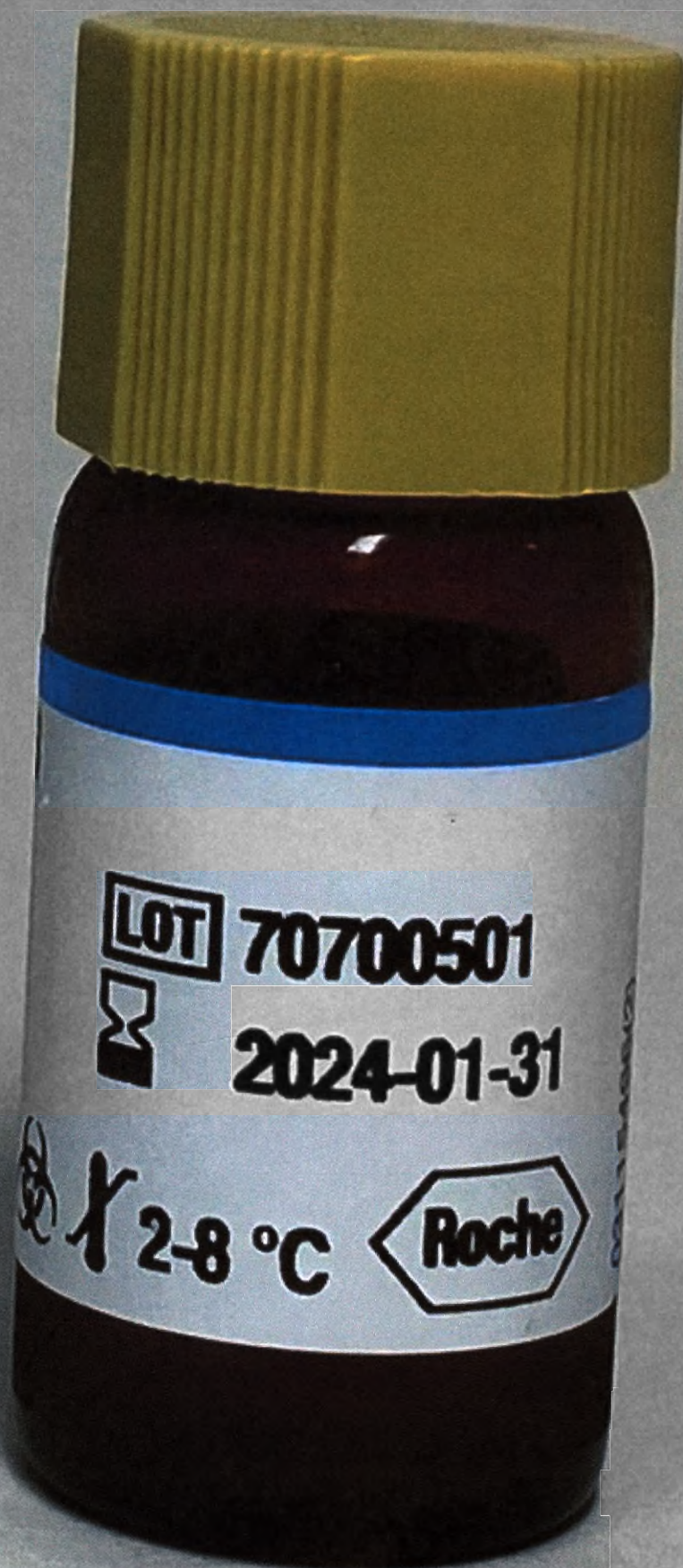
Калибратор 1 (Preciset RF 1), флакон, объем 1,0 мл



Калибратор 2 (Preciset RF 2), флакон, объем 1,0 мл



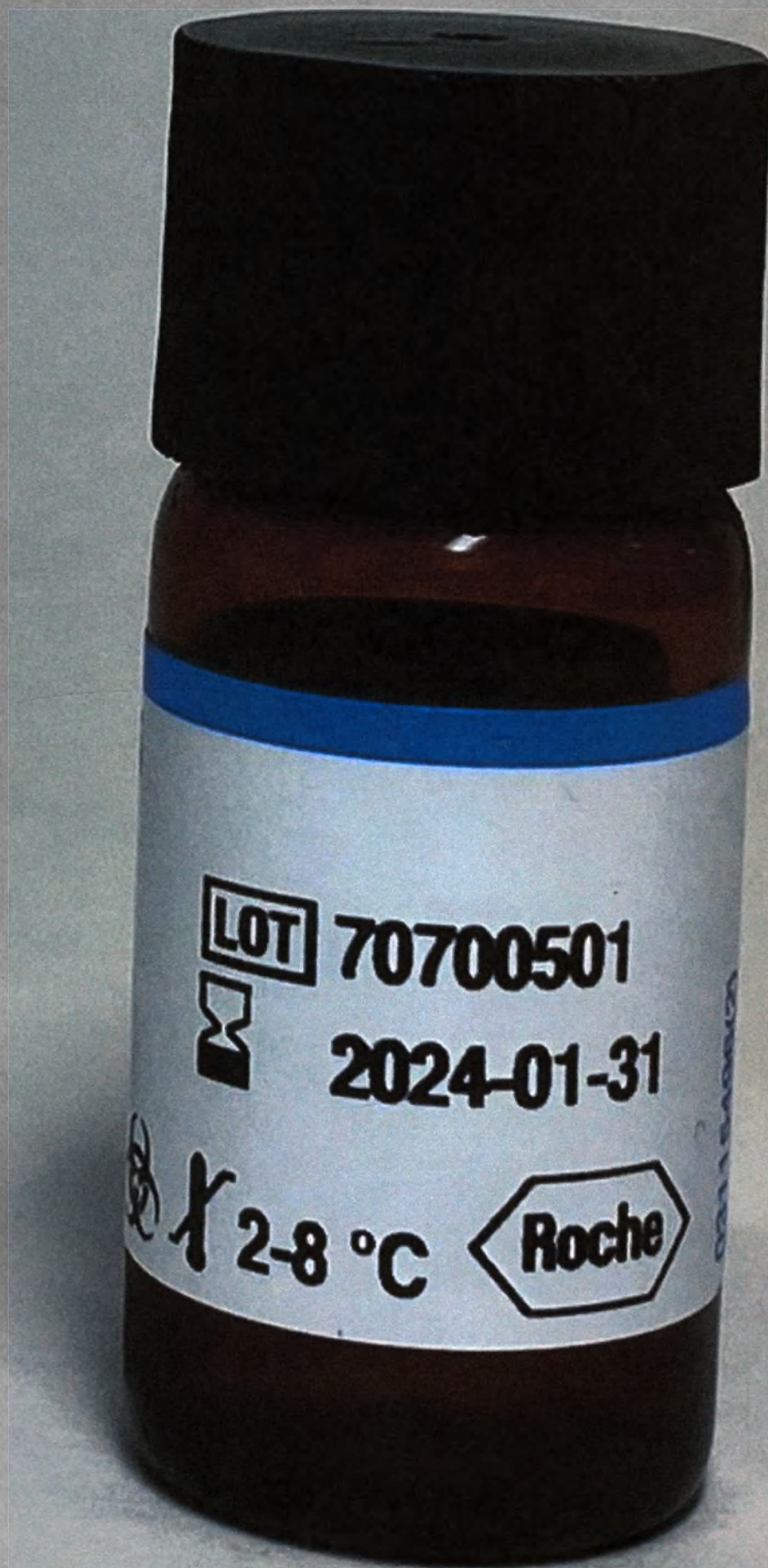
Калибратор 3 (Preciset RF 3), флакон, объем 1,0 мл



Калибратор 4 (Preciset RF 4), флакон, объем 1,0 мл



Калибратор 5 (Preciset RF 5), флакон, объем 1,0 мл



Этикетка со штрих-кодом – 10 шт.



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LOT 707005 Ver.1

2024-01

COBAS INTEGRA 400 plus

Short name / Component	Method	Test-ID	Std.	Calibration Value	Unit
RF-II	immunoturbidimetric serum, plasma	0-757	Bottle 5 = Std. 1	120	IU/mL
Rheumatoid factors			Bottle 4 = Std. 2	78.3	IU/mL
			Bottle 3 = Std. 3	40.0	IU/mL
			Bottle 2 = Std. 4	20.0	IU/mL
			Bottle 1 = Std. 5	10.5	IU/mL

COBAS INTEGRA 400 plus
Calibrator Barcode Ver. 1

[illegible]



12172828 322

Preciset RF

REF 12172828 322

5 x 1 mL Calibrator

English

System information

For use on Roche/Hitachi MODULAR analyzers and **cobas c** analyzers the calibrator codes are 725-729.

For use on COBAS INTEGRA analyzers the system ID is 07 7995 4.

Intended use

Preciset RF is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheets.

Summary

Preciset RF consists of 5 liquid ready-for-use calibrators based on a bovine serum albumin matrix.

The concentrations of the calibrator components have been adjusted to ensure optimal calibration of the appropriate Roche methods on clinical chemistry analyzers.

Some methods specified in the relevant value sheet may not be available in all countries.

Reagents – working solutions

Reactive components:

RF in human serum

Non-reactive components:

HEPES buffer, bovine serum albumin, sodium chloride, preservative

The concentrations of the components are lot-specific. The exact calibrator values are given in the electronically available or enclosed value sheets.

The values are also encoded in the enclosed calibrator barcode sheets for Roche/Hitachi MODULAR and COBAS INTEGRA analyzers.

For the **cobas c** analyzers (except for the **cobas c 111** analyzer) the values are encoded in electronic files sent via the **cobas** link to the analyzers.

Calibrator values

The calibrator values were determined using the method stated in the electronically available or enclosed value sheets. Determinations were performed under strictly standardized conditions on Roche analyzers using Roche system reagents and the Roche master calibrator.

The calibrator values were obtained via single determinations performed in different laboratories, in several separate runs. The calibrator value specified is the median of all values obtained.

Traceability information is given in the relevant Method Sheets for the system reagents.

Precautions and warnings

For in vitro diagnostic use for health care professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:

Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:

Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request.

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

All human material should be considered potentially infectious. All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV. The testing methods use assays that have been approved by the FDA or that are in compliance with the legal rules applicable to placing in vitro diagnostic medical devices for human use on the market in the European Union.

However, as no testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a patient specimen. In the event of exposure, the directives of the responsible health authorities should be followed.^{1,2}

Handling

The product is ready-for-use. Mix carefully before use. Avoid the formation of foam.

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The enclosed barcoded labels are intended exclusively for Roche/Hitachi MODULAR automated analyzers and **cobas c** systems to identify the calibrator. Attach the barcoded labels to the tubes carrying the sample cups containing the calibrator material.

Storage and stability

Store at 2-8 °C.

Criterion for the stability data stated by Roche:

Recovery within ± 10 % of initial value.

Stability:

Unopened:

Up to the stated expiration date at 2-8 °C.

After opening:

24 hours at 15-25 °C or 30 days at 2-8 °C, provided that dispensing of the calibrator occurs without microbial contamination, e.g. by pouring out.

Do not freeze.

Store calibrators tightly capped when not in use.

Materials provided

- See "Reagents – working solutions" section
- Barcoded labels

Materials required (but not provided)

- Roche system reagents and clinical chemistry analyzers
- General laboratory equipment

Assay

Use Preciset RF as specified in the relevant Method Sheet for the system reagents.

References

- 1 Occupational Safety and Health Standards: Bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.
- 2 Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see dialog.roche.com) for definition of symbols used).

CONTENT

Contents of kit

CALIBRATOR

Calibrator



Volume after reconstitution or mixing

GTIN

Global Trade Item Number

FOR US CUSTOMERS ONLY: LIMITED WARRANTY

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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2022-11, V 10.0 English



Всего пронумеровано,
прошнуровано и
скреплено печатью
13 листа (ов)



по доверенности
от 30.01.2023 г.