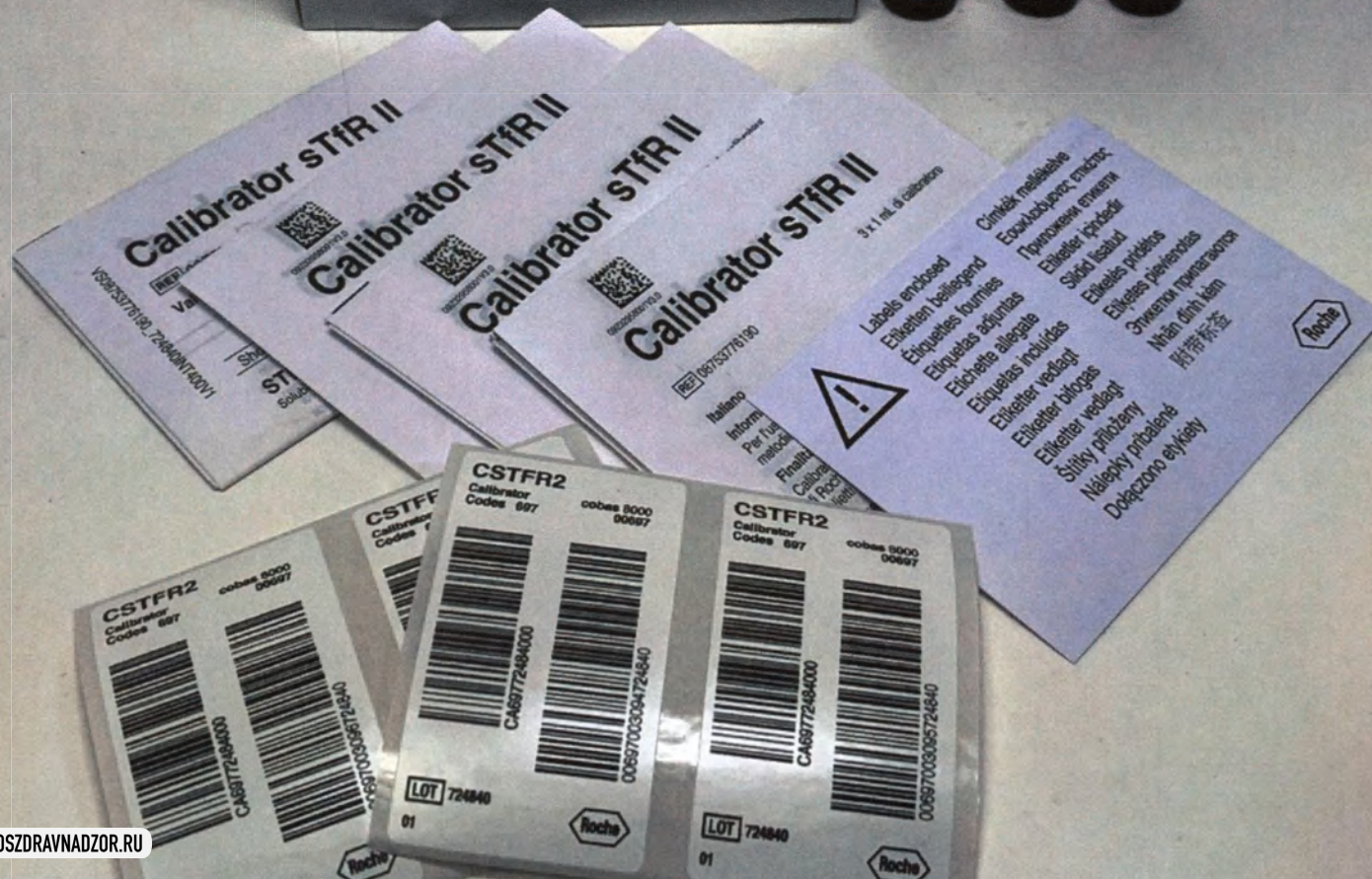
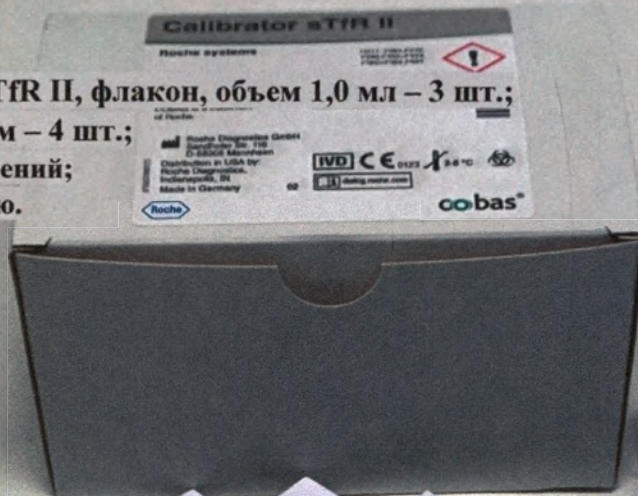


Фотографические изображения МИ:

«Набор калибраторов для количественного определения растворимого рецептора трансферрина (sTfR) в сыворотке и плазме крови на анализаторах и модулях биохимических cobas c, cobas Integra (Calibrator sTfR II Roche systems)»

Набор калибраторов для количественного определения растворимого рецептора трансферрина (sTfR) в сыворотке и плазме крови на анализаторах и модулях биохимических cobas c, cobas Integra (Calibrator sTfR II Roche systems), в составе:

1. Калибратор Calibrator sTfR II, флакон, объем 1,0 мл – 3 шт.;
2. Этикетка со штрих-кодом – 4 шт.;
3. Паспорт присвоенных значений;
4. Инструкция по применению.



Набор калибраторов для количественного определения растворимого рецептора трансферрина (sTfR) в сыворотке и плазме крови на анализаторах и модулях биохимических cobas c, cobas Integra (Calibrator sTfR II Roche systems)

Calibrator sTfR II

Roche systems

H317, P261, P272,
P280, P333+P313,
P362+P364, P501



REF 08753776190

CONTENT

CALIBRATOR 3 x 1 mL



COBAS is a trademark
of Roche.



Roche Diagnostics GmbH
Sandhofer Str. 116
D-68305 Mannheim

07020279001(1)

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

02

IVD

CE 0123

2-8 °C

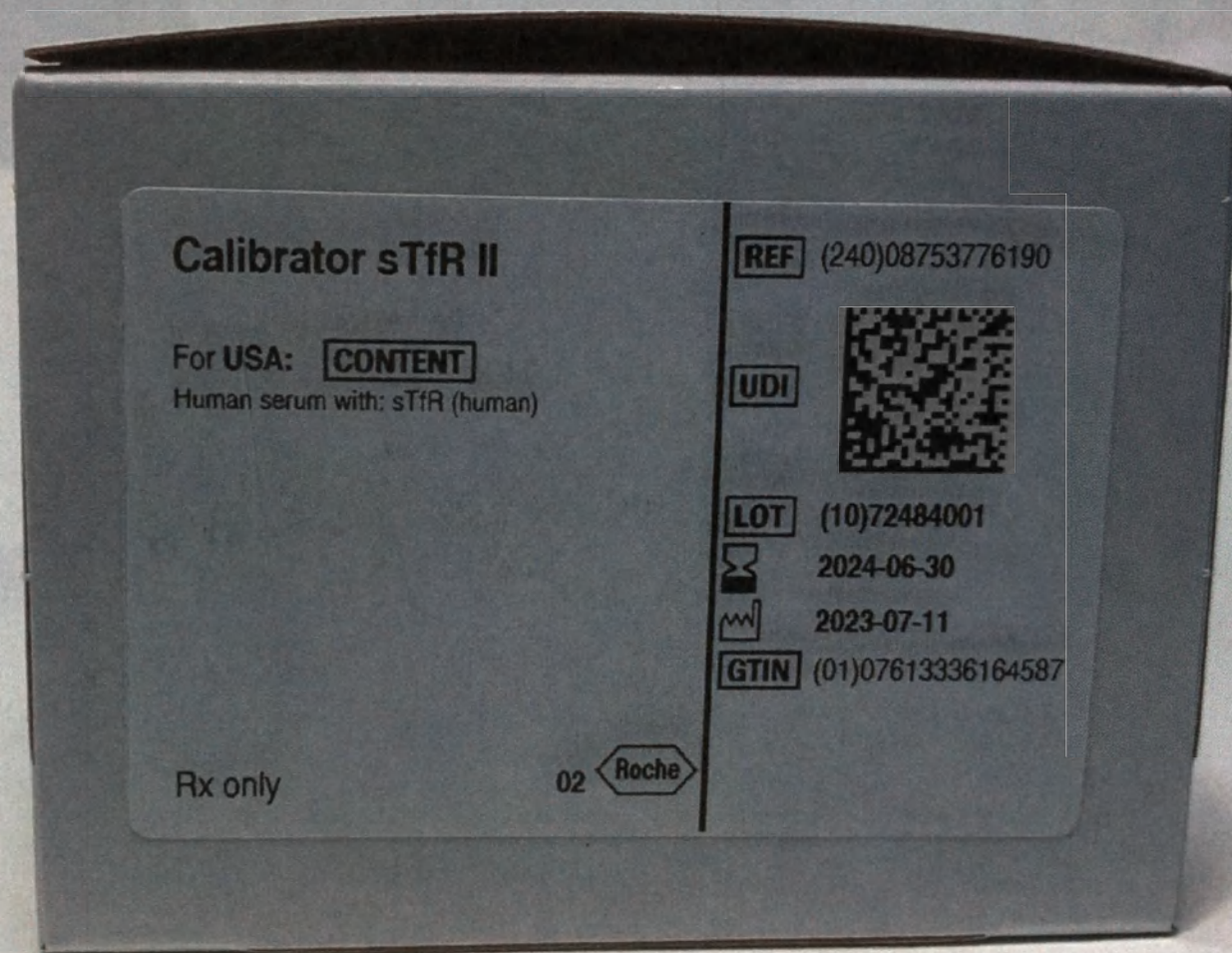


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cobas[®]

Набор калибраторов для количественного определения растворимого рецептора трансферрина (sTfR) в сыворотке и плазме крови на анализаторах и модулях биохимических cobas c, cobas Integra (Calibrator sTfR II Roche systems)



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Набор калибраторов для количественного определения растворимого рецептора трансферрина (sTfR) в сыворотке и плазме крови на анализаторах и модулях биохимических cobas c, cobas Integra (Calibrator sTfR II Roche systems), в составе:

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4. Инструкция по применению.

Регистрационное удостоверение № _____ 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 08753776190

Калибратор Calibrator sTfR II, флакон, объем 1,0 мл



CSTFR2
Calibrator
Codes 697

cobas 8000
00697

LOT 724840
01

CA69772484000

00697003094724840

Roche

CSTFR2
Calibrator
Codes 697

cobas 8000
00697

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Roche

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REF 08753776190

154840 Ver. 1

101

LOT 724840 Ver.1

2024-06

Value sheet

Short name / Component	Method	Test-ID	Std.	Calibration Value	Unit
STFR2 Soluble Transferrin Receptor	particle enhanced immunoturbidimetric	0-014	Level 1 Level 2 Level 3 Level 4 Level 5 Level 6	19.7 9.32 3.18 1.08 0.551 0.000	mg/L mg/L mg/L mg/L mg/L mg/L
			Level 1 Level 2 Level 3 Level 4 Level 5 Level 6	1.97 0.832 0.318 0.108 0.053 0.000	mg/dL mg/dL mg/dL mg/dL mg/dL mg/dL
			Level 1 Level 2 Level 3 Level 4 Level 5 Level 6	232 110 37.5 12.5 6.27 0.000	nmol/L nmol/L nmol/L nmol/L nmol/L nmol/L

COBAS INTEGRA 400 plus

Calibrator Barcode Ver. 1



—



9

[illegible]



09232958001V3.0

Calibrator sTfR II

REF 08753776190

3 x 1 mL Calibrator

English

System information

For use on **cobas c** and **COBAS INTEGRA** analyzer systems refer to the corresponding method sheet of the assay for the identification on the system.

Intended use

Calibrator sTfR II is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheets.

Summary

Calibrator sTfR II is a liquid ready-for-use calibrator based on human serum.

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:

Soluble transferrin receptor in human serum

Non-reactive components:

Preservatives and stabilizers

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 COBAS INTEGRA.

For the **cobas c** analyzers 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 mean 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.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:



Warning

H317

May cause an allergic skin reaction.

Prevention:

P261

Avoid breathing mist or vapours.

II sTfR II cobas®

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves.

Response:

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

P501 Dispose of contents/container to an approved waste disposal plant.

Product safety labeling follows EU GHS guidance.

Contact phone: all countries: +49-621-7590, USA: 1-800-428-2336

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. Allow the calibrators to reach room temperature before use and mix carefully to ensure homogeneity. Avoid the formation of foam.

The enclosed barcoded labels are intended exclusively for **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: 4 weeks 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 Calibrator sTfR II 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.



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

Максимов



по доверенности
от 30.01.2023 г.