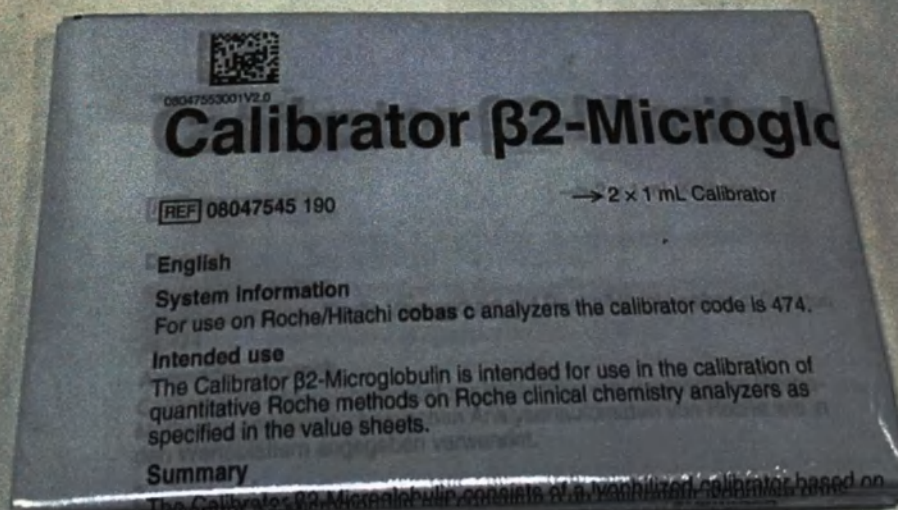
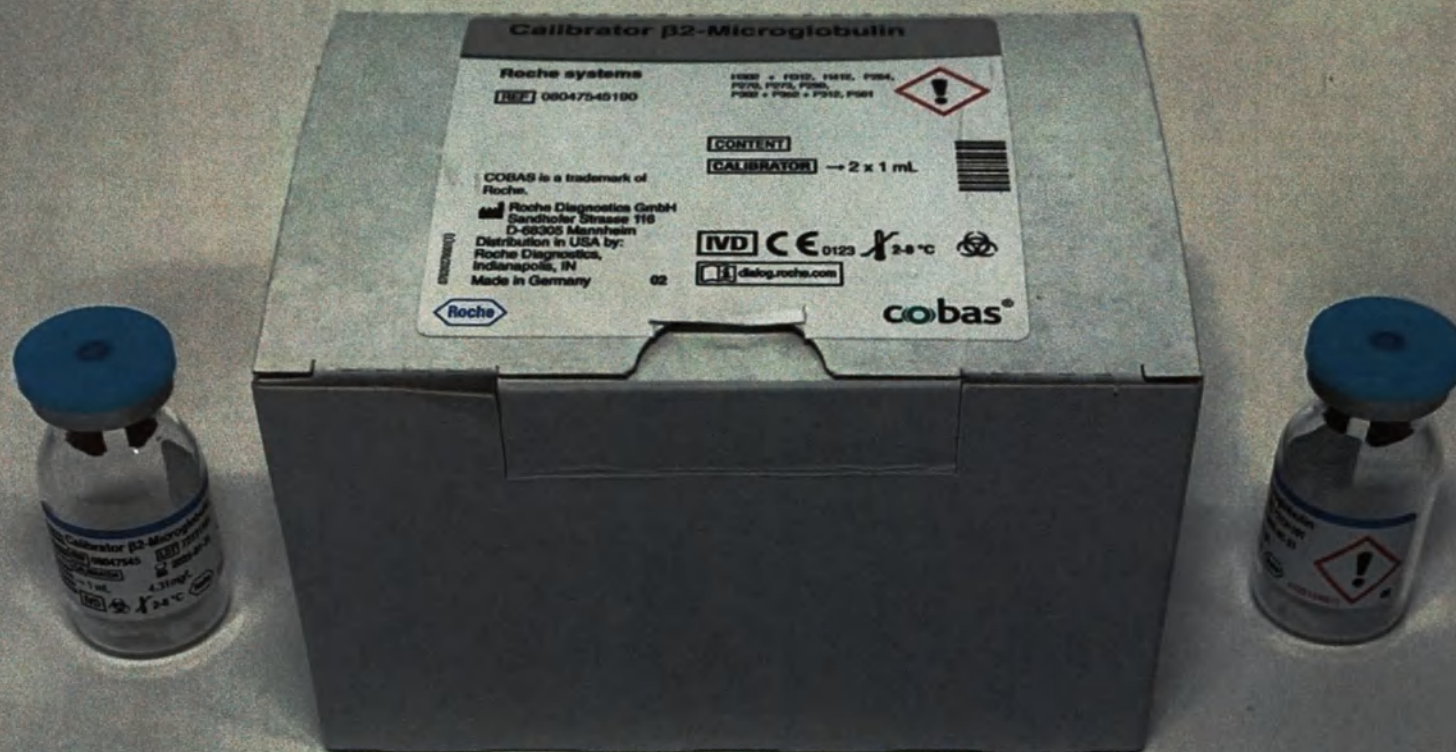


ФОТОГРАФИЧЕСКИЕ ИЗОБРАЖЕНИЯ

Набор калибраторов для количественного определения b2-микроглобулина (B2MG) в моче, сыворотке и плазме крови на модулях биохимических cobas c (Calibrator b2-Microglobulin)

производства Roche Diagnostics GmbH, Sandhofer Strasse 116, 68305 Mannheim, Germany

Набор калибраторов для количественного определения $\beta 2$ -микроглобулина ($\beta 2\text{MG}$) в моче, сыворотке и плазме крови на модулях биохимических cobas c (Calibrator $\beta 2$ -Microglobulin)



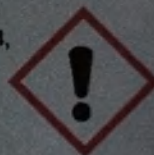
Набор калибраторов для количественного определения $\beta 2$ -микроглобулина ($\beta 2MG$) в моче, сыворотке и плазме крови на модулях биохимических cobas c (Calibrator $\beta 2$ -Microglobulin)

Calibrator $\beta 2$ -Microglobulin

Roche systems

REF 08047545190

H302 + H312, H412, P264,
P270, P273, P280,
P302 + P352 + P312, P501



CONTENT

CALIBRATOR → 2 x 1 mL



COBAS is a trademark of
Roche.

 Roche Diagnostics GmbH
Sandhofer Strasse 116
D-68305 Mannheim

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

07020279001(1)

02

IVD

CE

0123

2-8 °C

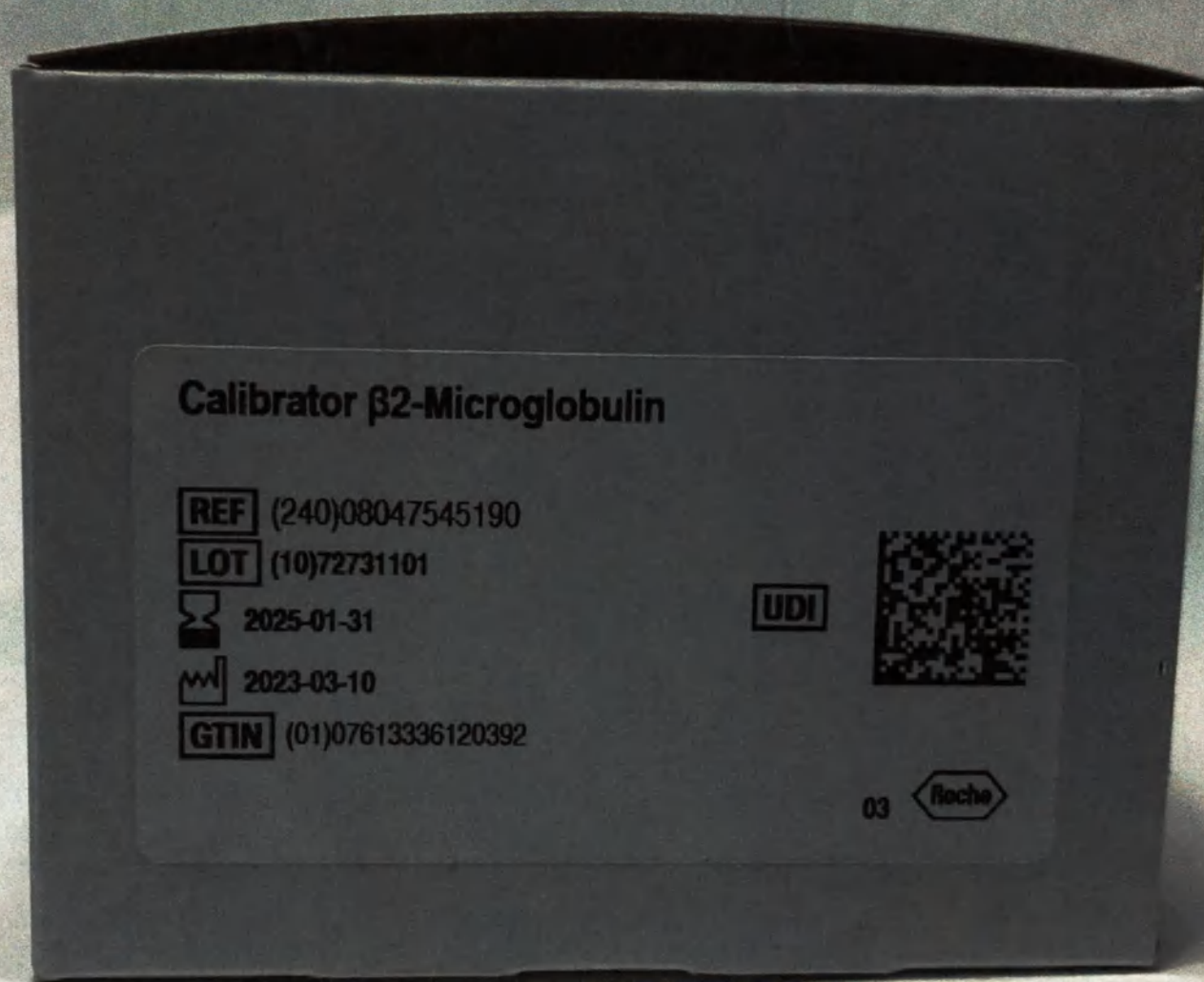


 dialog.roche.com



cobas®

Набор калибраторов для количественного определения β 2-микроглобулина (β 2MG) в моче, сыворотке и плазме крови на модулях биохимических cobas c (Calibrator β 2-Microglobulin)



Набор калибраторов для количественного определения β 2-микроглобулина (β 2MG) в моче, сыворотке и плазме крови на модулях биохимических cobas c (Calibrator β 2-Microglobulin)

For **USA:**

08047545 190

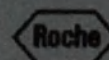
CONTENT

Bovine serum albumin matrix with β 2-Microglobulin
(human), contains 1.6 % NaN_3

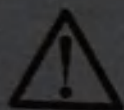


Rx only

001



Набор калибраторов для количественного определения b2-микроглобулина (B2MG) в моче, сыворотке и плазме крови на модулях биохимических cobas c (Calibrator b2-Microglobulin)



Набор калибраторов для количественного определения b2-микроглобулина (B2MG) в моче, сыворотке и плазме крови на модулях биохимических cobas c (Calibrator b2-Microglobulin), в составе:

1. Калибратор Calibrator b2-Microglobulin, флакон, объем 1 мл – 2 шт.;
2. Этикетка со штрих-кодом – 4 шт.;
3. 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

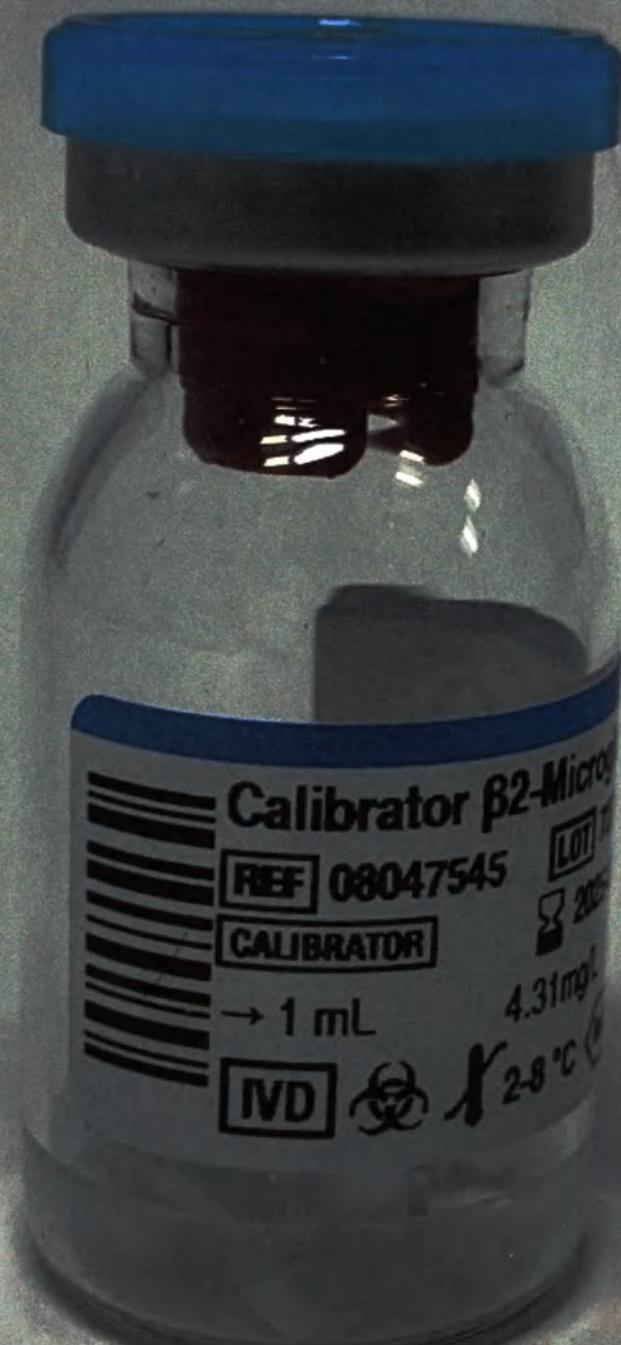
Производитель: «Roche Diagnostics GmbH» ("Рош Диагностика ГмбХ"), Sandhofer Strasse 116, 68305 Mannheim, Germany, Германия

Изделие предназначено только для диагностики in vitro

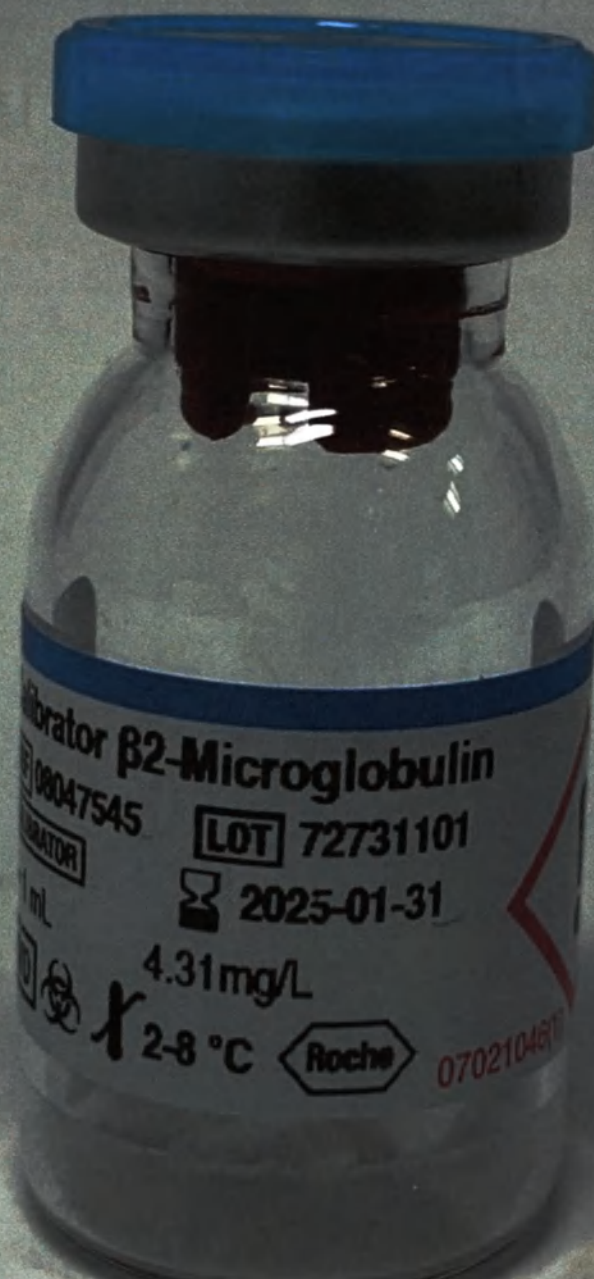
Уполномоченный представитель производителя на территории РФ: Общество с ограниченной ответственностью «Рош Диагностика Рус» (ООО «Рош Диагностика Рус»), 107031, Москва, Трубная площадь, д.2 Тел: +7 495 229-69-99, факс: +7 495 229-62-64. E-mail: moscow.reception2_dia@roche.com

Кат. номер 08047545190

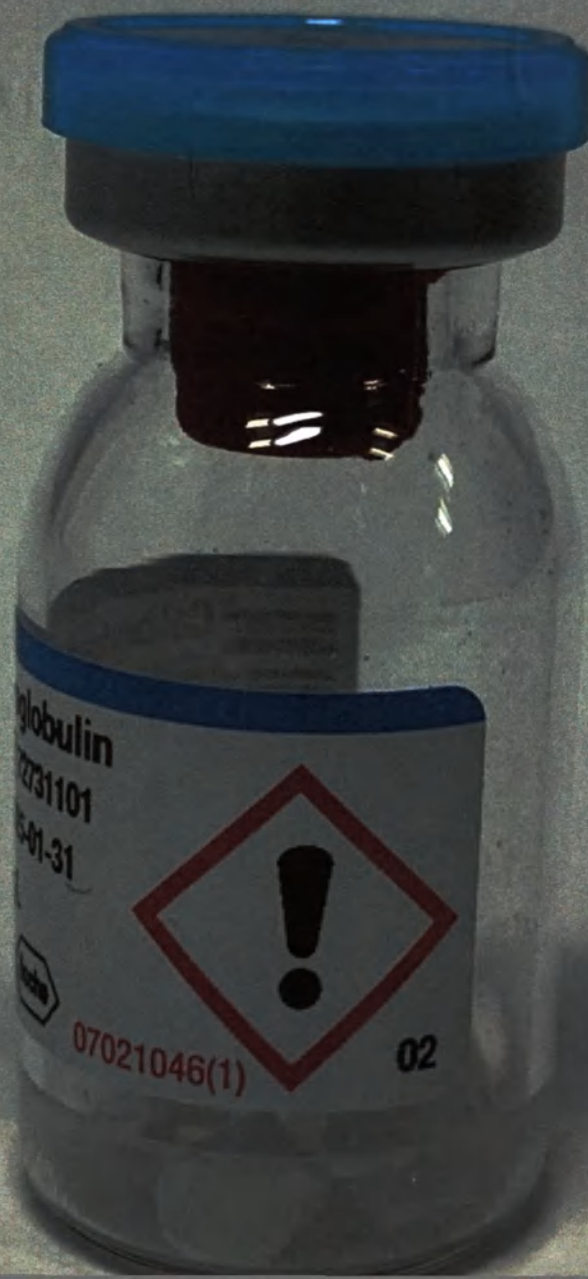
Калибратор Calibrator β 2-Microglobulin, флакон, объем 1 мл – 2 шт.;



Калибратор Calibrator β 2-Microglobulin, флакон, объем 1 мл – 2 шт.;



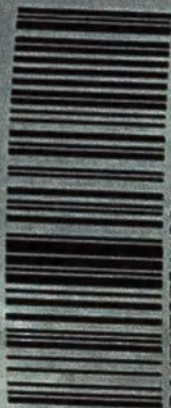
Калибратор Calibrator b2-Microglobulin, флакон, объем 1 мл – 2 шт.;



B2MIC

Calibrator
Codes 474

cobas 8000
00474



CA47472731100



00474006828727311

LOT 727311

001



B2MIC

Calibrator
Codes 474

cobas 8000
00474



CA47472731100



00474006829727311

LOT 727311

001



B2MIC

Calibrator
Codes 474

cobas 8000
00474



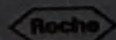
CA47472731100



00474006830727311

LOT 727311

001



B2MIC

Calibrator
Codes 474

cobas 8000
00474



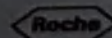
CA47472731100



00474006831727311

LOT 727311

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Этикетка со штрих-кодом – 4 шт.



08047553001V2.0

Calibrator β 2-Microglobulin IM-SQ to cobas®

REF 08047545 190

→ 2 x 1 mL Calibrator

English

System information

For use on Roche/Hitachi cobas c analyzers the calibrator code is 474.

Intended use

The Calibrator β 2-Microglobulin is intended for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheets.

Summary

The Calibrator β 2-Microglobulin consists of a lyophilized calibrator based on a bovine serum albumin matrix.

The concentration of the calibrator component has been adjusted to ensure optimal calibration of the appropriate Roche method on clinical chemistry analyzers.

Reagents – working solutions

Reactive components:

Bovine serum albumin matrix with chemical additives and material of biological origin as specified. The origin of the biological additive is as follows:

Analyte	Origin
β 2-Microglobulin	human

Non-reactive components:

1.0 % bovine serum albumin; 1.6 % Na₂S₂O₃

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

The values are also 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 value sheets. Determinations were performed under strictly standardized conditions on Roche analyzers using Roche system reagents and the Roche master calibrator.

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}

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



Warning

H302 + H312 Harmful if swallowed or in contact with skin.

H412 Harmful to aquatic life with long lasting effects.

Prevention:

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water. Call a POISON CENTER/doctor if you feel unwell.

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

Handling

Carefully open one bottle avoiding the loss of lyophilizate, and pipette in exactly 1.0 mL of distilled/deionized water. Carefully close the bottle and dissolve the contents completely by occasional gentle swirling within 30 minutes. Avoid the formation of foam.

The enclosed barcoded labels are intended exclusively for Roche/Hitachi 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 reconstitution:	at 15-25 °C 30 days
	at 2-8 °C 90 days
	at (-15)-(-25) °C 12 weeks (when frozen once)

Store calibrator 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

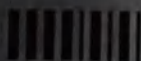
Use the Calibrator β 2-Microglobulin as specified in the relevant Method Sheet for the system reagents.

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.

Инструкция по применению.



по доверенности
от 30.01.2023 г.



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