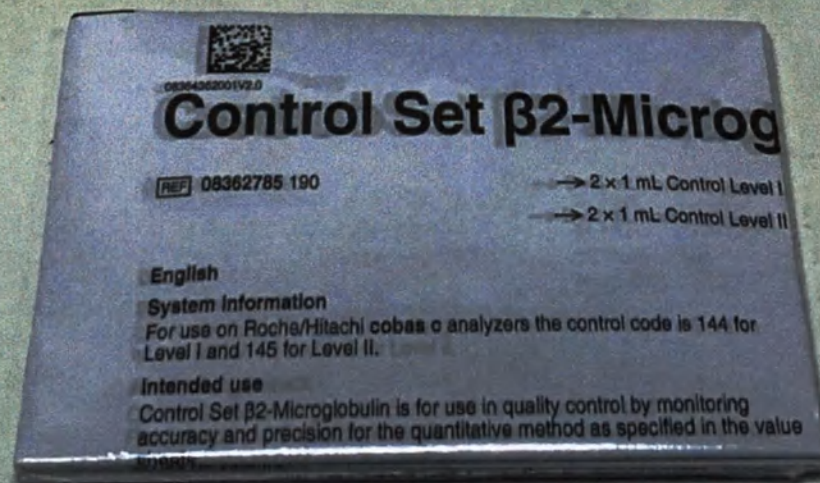


ФОТОГРАФИЧЕСКИЕ ИЗОБРАЖЕНИЯ

Набор контрольных материалов для контроля качества определения b2-микроглобулина (B2MG) в моче, сыворотке и плазме крови на модулях биохимических cobas c (Control Set b2-Microglobulin)

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

Набор контрольных материалов для контроля качества определения b2-микроглобулина (B2MG) в моче, сыворотке и плазме крови на модулях биохимических cobas c (Control Set b2-Microglobulin)



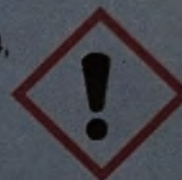
Набор контрольных материалов для контроля качества определения b2-микроглобулина (B2MG) в моче, сыворотке и плазме крови на модулях биохимических cobas c (Control Set b2-Microglobulin)

Control Set β 2-Microglobulin

Roche systems

REF 08362785190

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



CONTENT

I **CONTROL** → 2 x 1 mL
II **CONTROL** → 2 x 1 mL



COBAS is a trademark of
Roche.

 Roche Diagnostics GmbH
Sandhofer Strasse 116
D-68305 Mannheim

07020279001(1)
Distribution in USA by:
Roche Diagnostics,
Indianapolis, IN
Made in Germany

IVD

CE

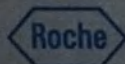
0123

 2-8 °C



dialog.roche.com

02



cobas[®]

Набор контрольных материалов для контроля качества определения β 2-микроглобулина (β 2MG) в моче, сыворотке и плазме крови на модулях биохимических cobas c (Control Set β 2-Microglobulin)

For USA:

08362785 190

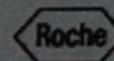
CONTENT

- I Bovine serum albumin matrix with β 2-Microglobulin (human), level I, contains 1.7 % NaN_3
- II Bovine serum albumin matrix with β 2-Microglobulin (human), level II, contains 1.6 % NaN_3



Rx only

001



Набор контрольных материалов для контроля качества определения β 2-микроглобулина (B2MG) в моче, сыворотке и плазме крови на модулях биохимических cobas c (Control Set β 2-Microglobulin)

Control Set β 2-Microglobulin

REF (240)08362785190

LOT (10)73959701

 2025-03-31

 2023-05-15

GTIN (01)07613336154243

UDI



03



Набор контрольных материалов для контроля качества определения b2-микроглобулина (B2MG) в моче, сыворотке и плазме крови на модулях биохимических cobas c (Control Set b2-Microglobulin)



Набор контрольных материалов для контроля качества определения b2-микроглобулина (B2MG) в моче, сыворотке и плазме крови на модулях биохимических cobas c (Control Set b2-Microglobulin), в составе:

1. Материал контрольный Control Set b2-Microglobulin I, флакон, объем 1 мл – 2 шт.;
2. Материал контрольный Control Set b2-Microglobulin II, флакон, объем 1 мл – 2 шт.;
3. Этикетка со штрих-кодом – 4 шт.;
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

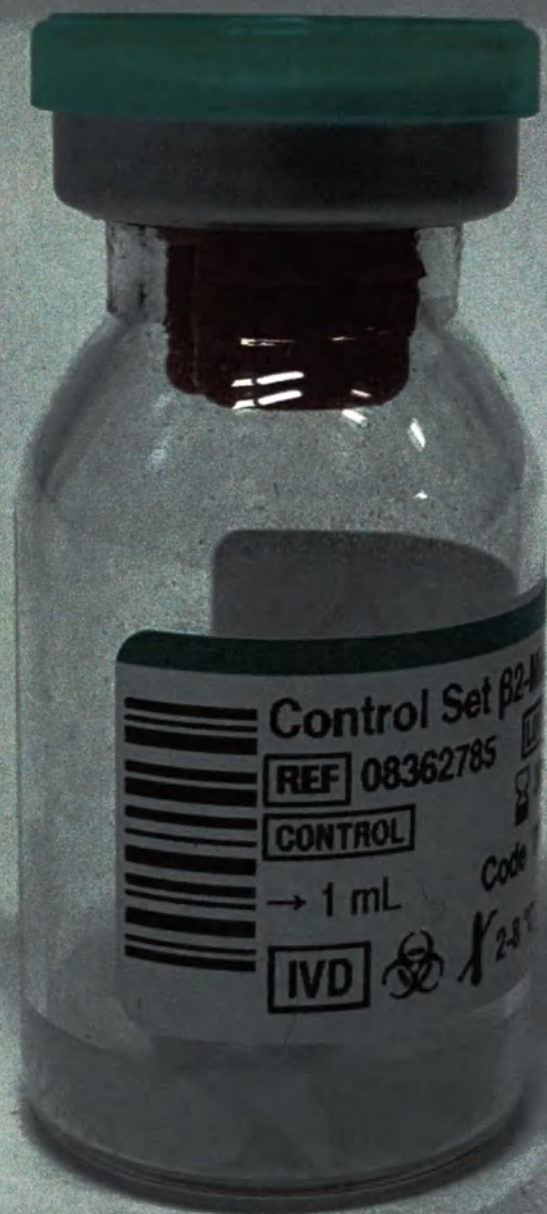
Производитель: «Roche Diagnostics GmbH» ("Рош Диагностика ГмбХ"), Sandhofer Strasse 116, 68305 Mannheim, Germany, Германия

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 08362785190

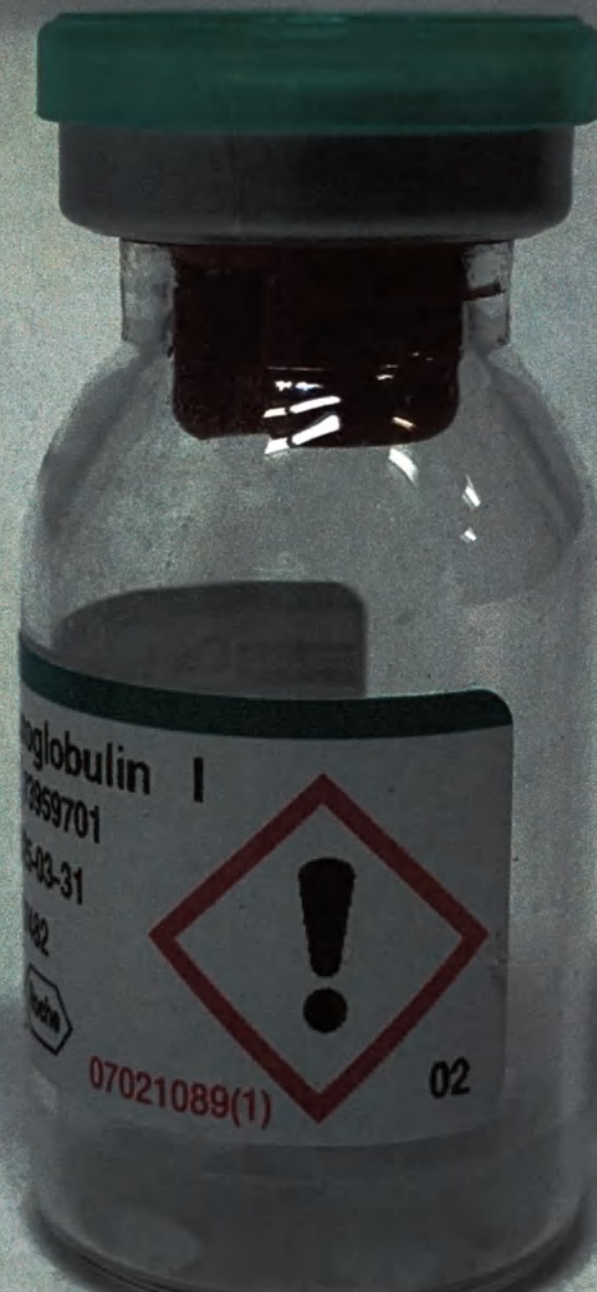
1. Материал контрольный Control Set b2-Microglobulin I, флакон, объем 1 мл – 2 шт.;



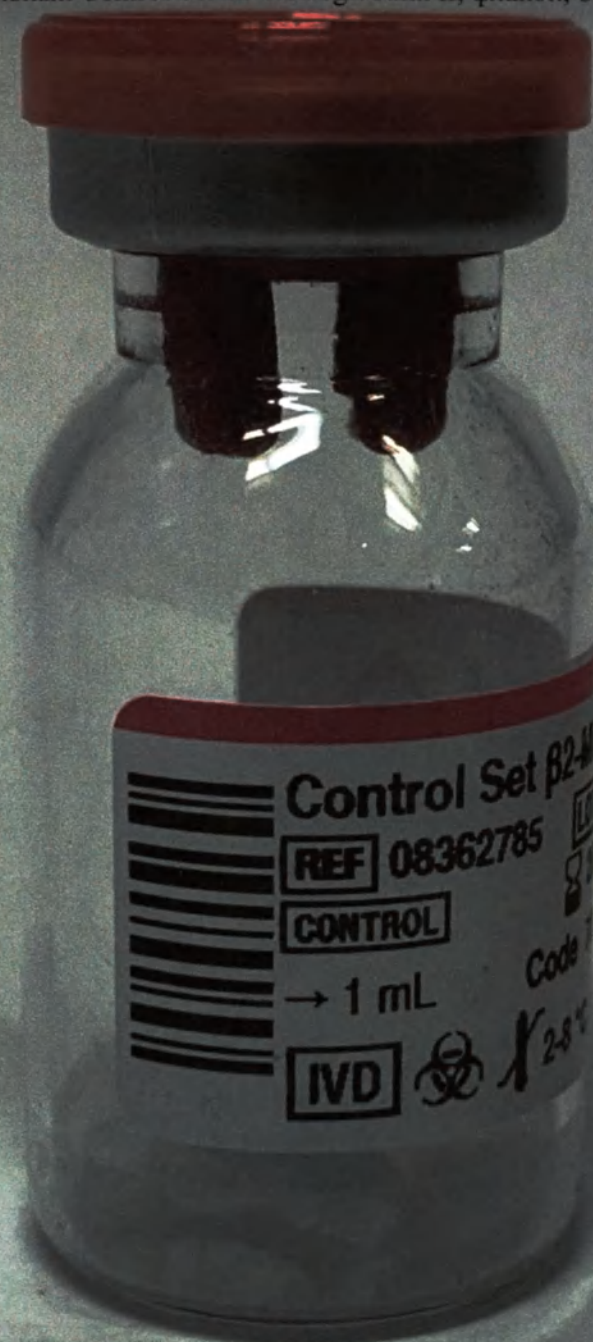
1. Материал контрольный Control Set β 2-Microglobulin I, флакон, объем 1 мл – 2 шт.;



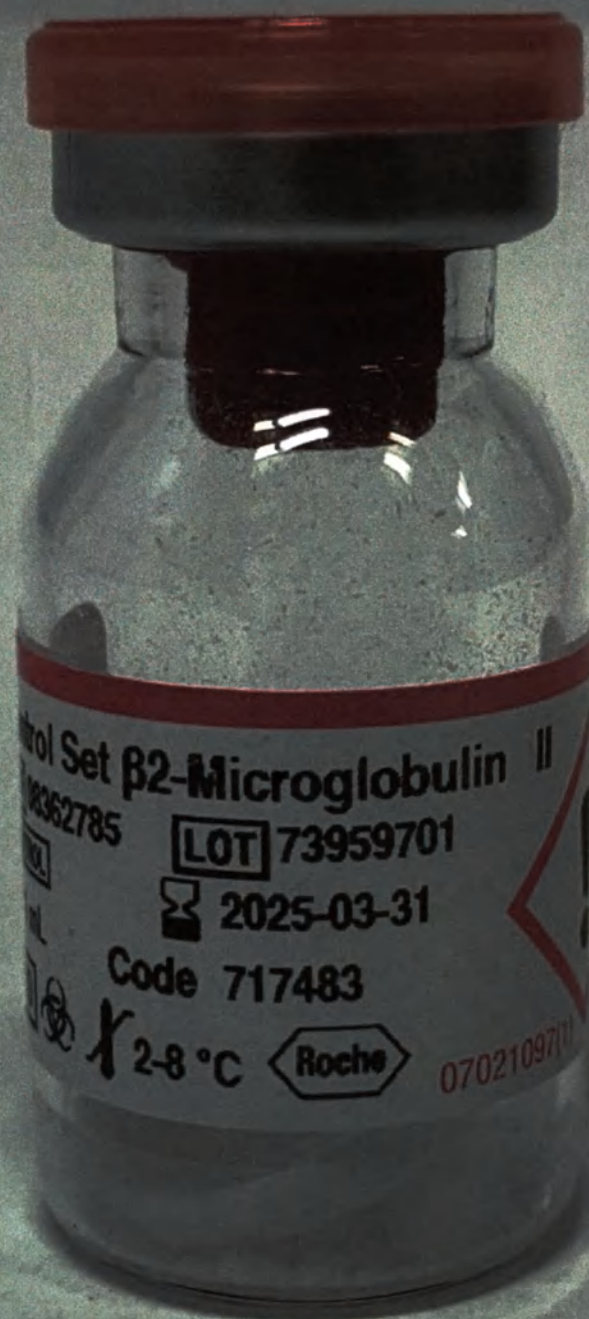
1. Материал контрольный Control Set b2-Microglobulin I, флакон, объем 1 мл – 2 шт.;



2.Материал контрольный Control Set b2-Microglobulin II, флакон, объем 1 мл – 2 шт.;



2.Материал контрольный Control Set b2-Microglobulin II, флакон, объем 1 мл – 2 шт.;



2. Материал контрольный Control Set b2-Microglobulin II, флакон, объем 1 мл – 2 шт.;



B2MG1
Control
Codes 144



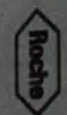
QC14471748200

cobas 8000
00144



00144002670717482

LOT 739597
001



B2MG1
Control
Codes 144



QC14471748200

cobas 8000
00144



00144002671717482

LOT 739597
001



B2MG2

Control
Codes 145



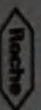
QC14571748300

cobas 8000
00145



00145002276717483

LOT 739597
001



B2MG2

Control
Codes 145



QC14571748300

cobas 8000
00145



00145002277717483

LOT 739597
001





08364362001V2.0

Control Set β 2-Microglobulin cobas®

REF 08362785 190

→ 2 x 1 mL Control Level I

→ 2 x 1 mL Control Level II

English

System Information

For use on Roche/Hitachi cobas c analyzers the control code is 144 for Level I and 145 for Level II.

Intended use

Control Set β 2-Microglobulin is for use in quality control by monitoring accuracy and precision for the quantitative method as specified in the value sheets.

Summary

Control Set β 2-Microglobulin consists of 2 lyophilized controls based on a bovine serum albumin matrix.

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

Level I 1.7 % Na₂S₂O₃

Level II 1.6 % Na₂S₂O₃

The concentrations of the reconstituted controls are lot-specific. The exact target 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.

Target values and ranges

The target values were determined using the method stated in the electronically available value sheets. Determinations for Roche methods were performed under strictly standardized conditions on Roche analyzers using Roche system reagents and the Roche master calibrator. The target value specified is the mean of all values obtained. The corresponding control range is calculated as the target value $\pm$ 3 standard deviations (the standard deviation being the value obtained from several target value determinations). Results should be within the defined ranges. Each laboratory should establish corrective measures to be taken if values fall outside the range.

A clinically insignificant difference may be seen between the value(s) listed on the value sheet and the value(s) obtained from the instrument readable data. This is caused by:

- the rounding of value(s) during conversion from the unit in the instrument readable data to the unit that is being used.
- the calculation of the ranges by the analyzer using the percentage values for the ranges encoded in the barcodes.

The traceability of the target value is given in the respective Method Sheets for the system reagents to be used in combination with the recommended calibrator.

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.

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 each 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 the Roche/Hitachi cobas c systems to identify the control. Attach the barcoded labels to the tubes carrying the sample cups containing the control material.

Storage and stability

Store at 2-8 °C.

Criterion for the stability data stated by Roche:
Recovery within $\pm$ 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 30 days

at (-15)-(-25) °C 12 weeks (when frozen once)

Store controls tightly capped when not in use.

Materials provided

- See "Reagents – working solutions" section

4. Инструкция по применению



по доверенности
от 30.01.2023 г.



Всего пронумеровано
прошнуровано и
скреплено печатью
14 листа (ов)