# ФОТОГРАФИЧЕСКИЕ ИЗОБРАЖЕНИЯ

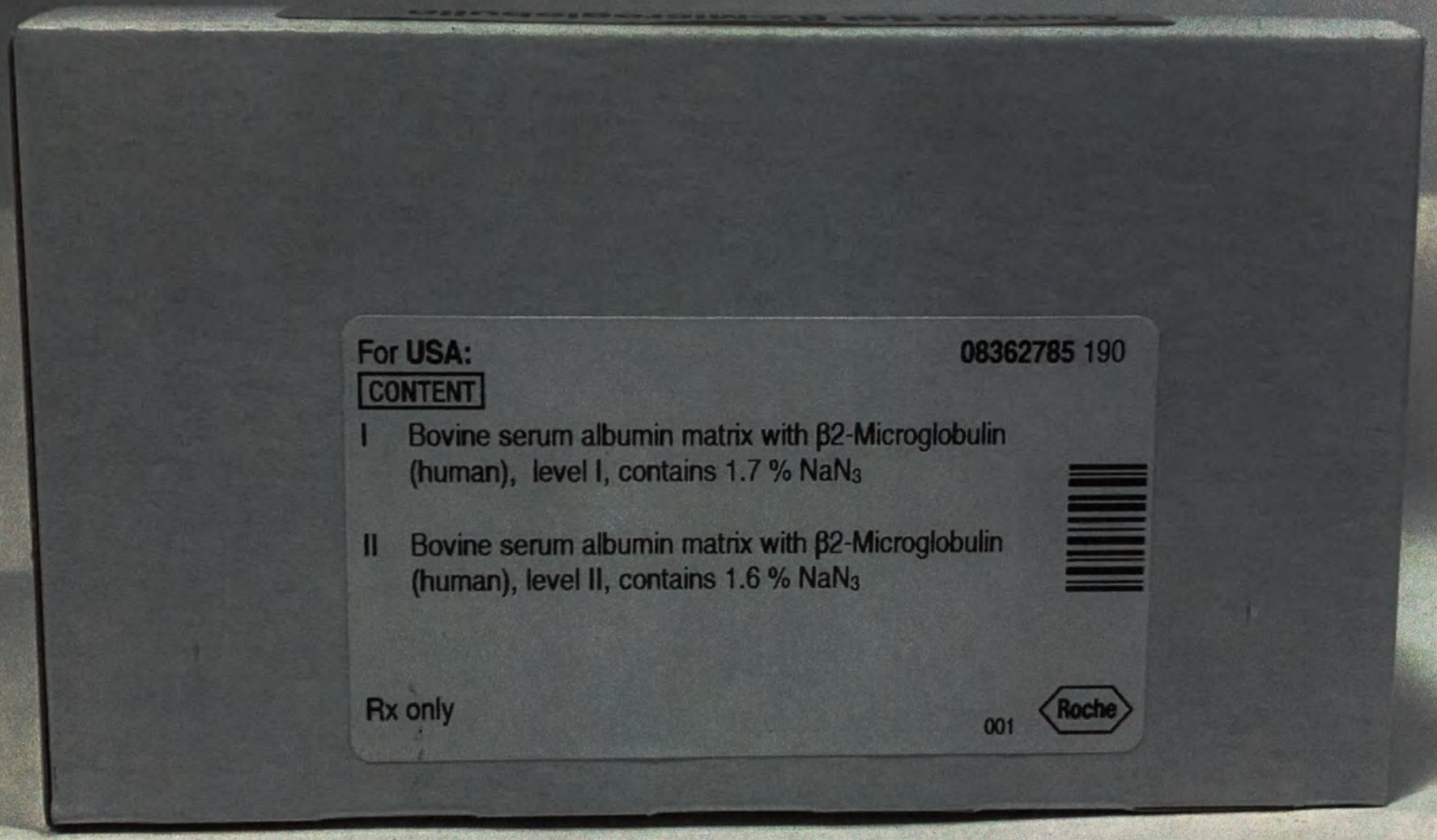
**Набор контрольных материалов для контроля качества определения b2-микроглобулина (B2MG) в моче, сыворотке и плазме крови на модулях биохимических cobas c (Control Set b2-Microglobulin)**

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

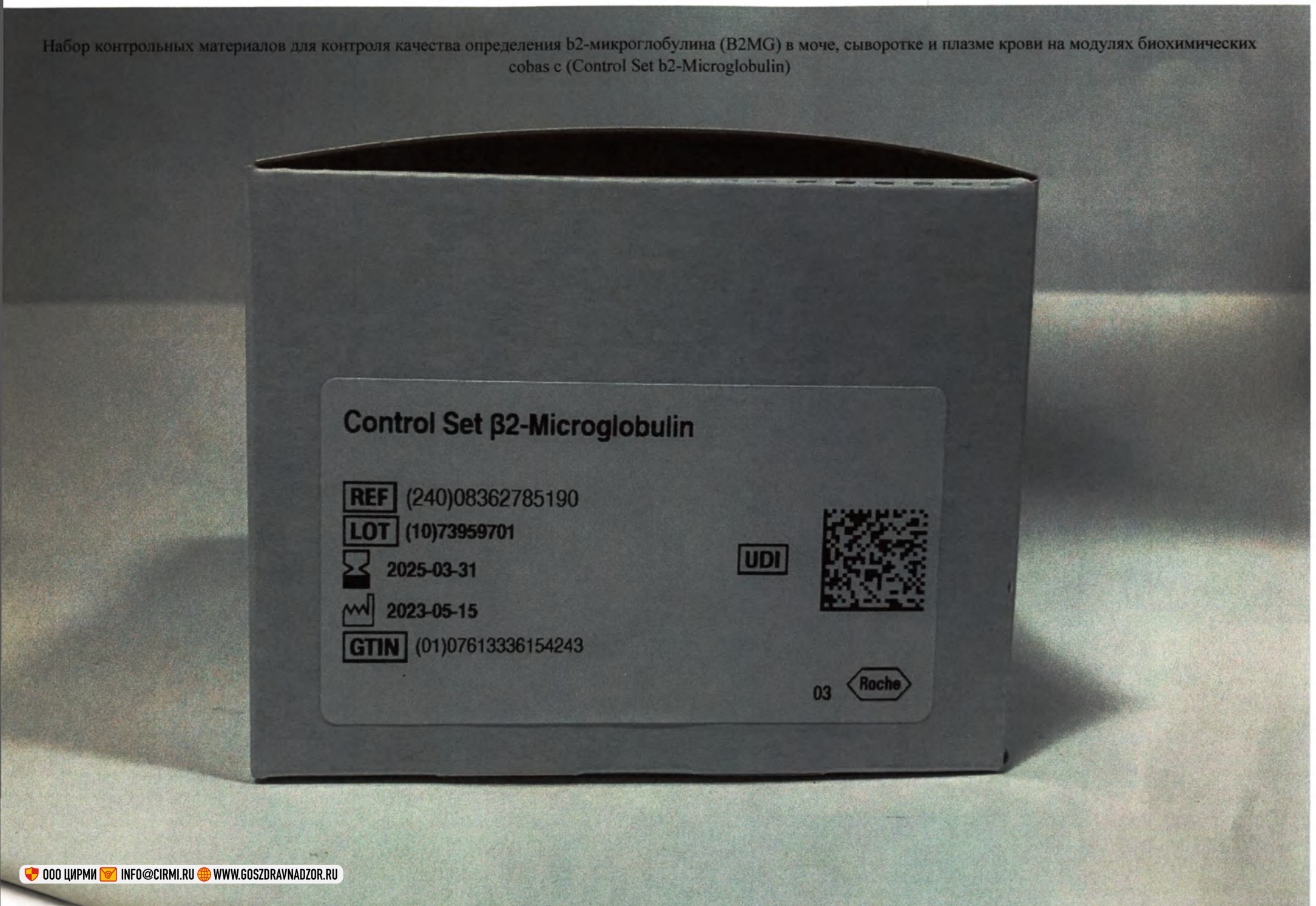
Набор контрольных материалов для контроля качества определения b2-микроглобулина (B2MG) в моче, сыворотке и плазме крови на модулях биохимических cobas c (Control Set b2-Microglobulin)

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)

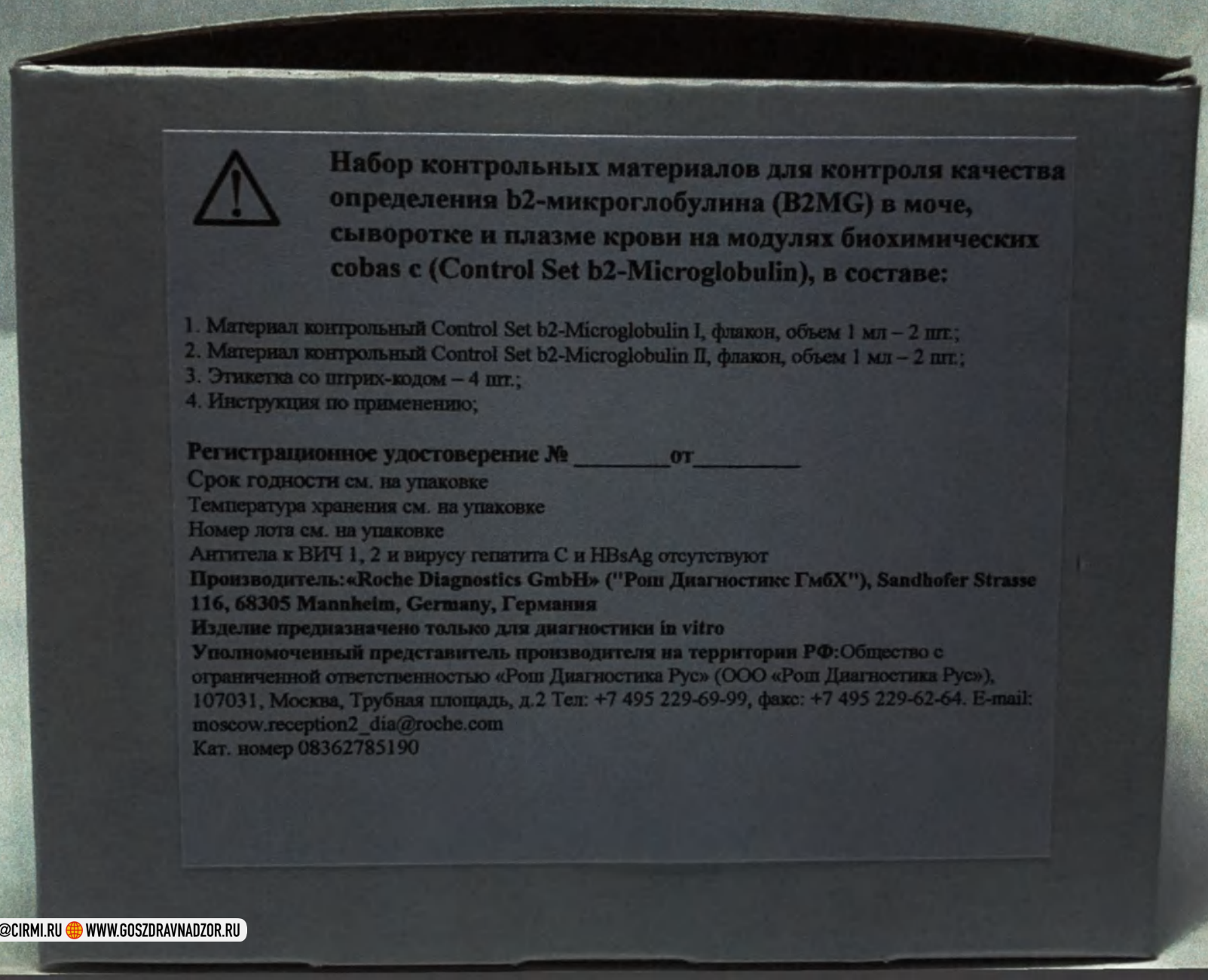
Набор контрольных материалов для контроля качества определения b2-микроглобулина (B2MG) в моче, сыворотке и плазме крови на модулях биохимических cobas c (Control Set b2-Microglobulin)



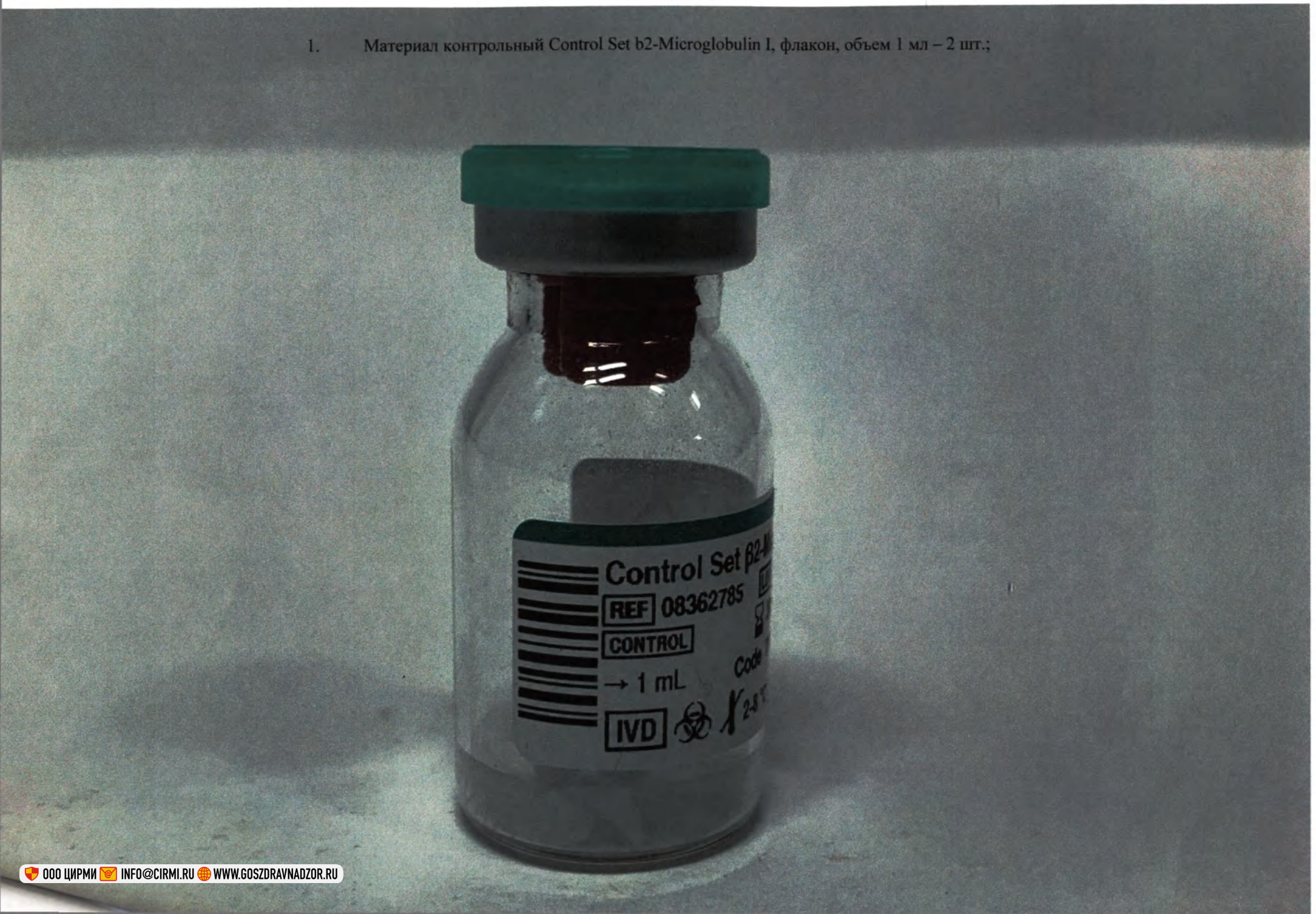
Набор контрольных материалов для контроля качества определения b2-микроглобулина (B2MG) в моче, сыворотке и плазме крови на модулях биохимических cobas c (Control Set b2-Microglobulin)



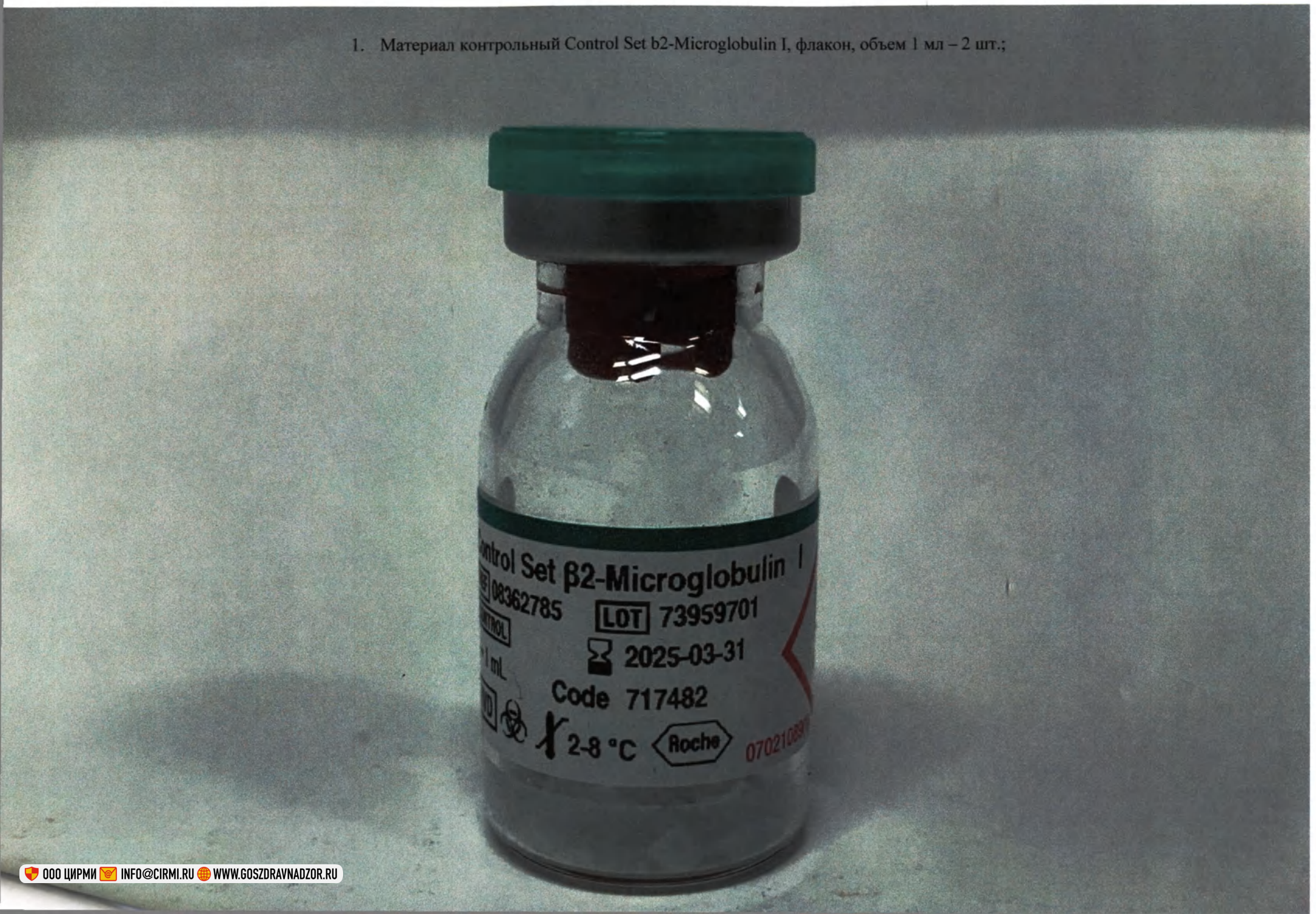
Набор контрольных материалов для контроля качества определения b2-микроглобулина (B2MG) в моче, сыворотке и плазме крови на модулях биохимических cobas c (Control Set b2-Microglobulin)



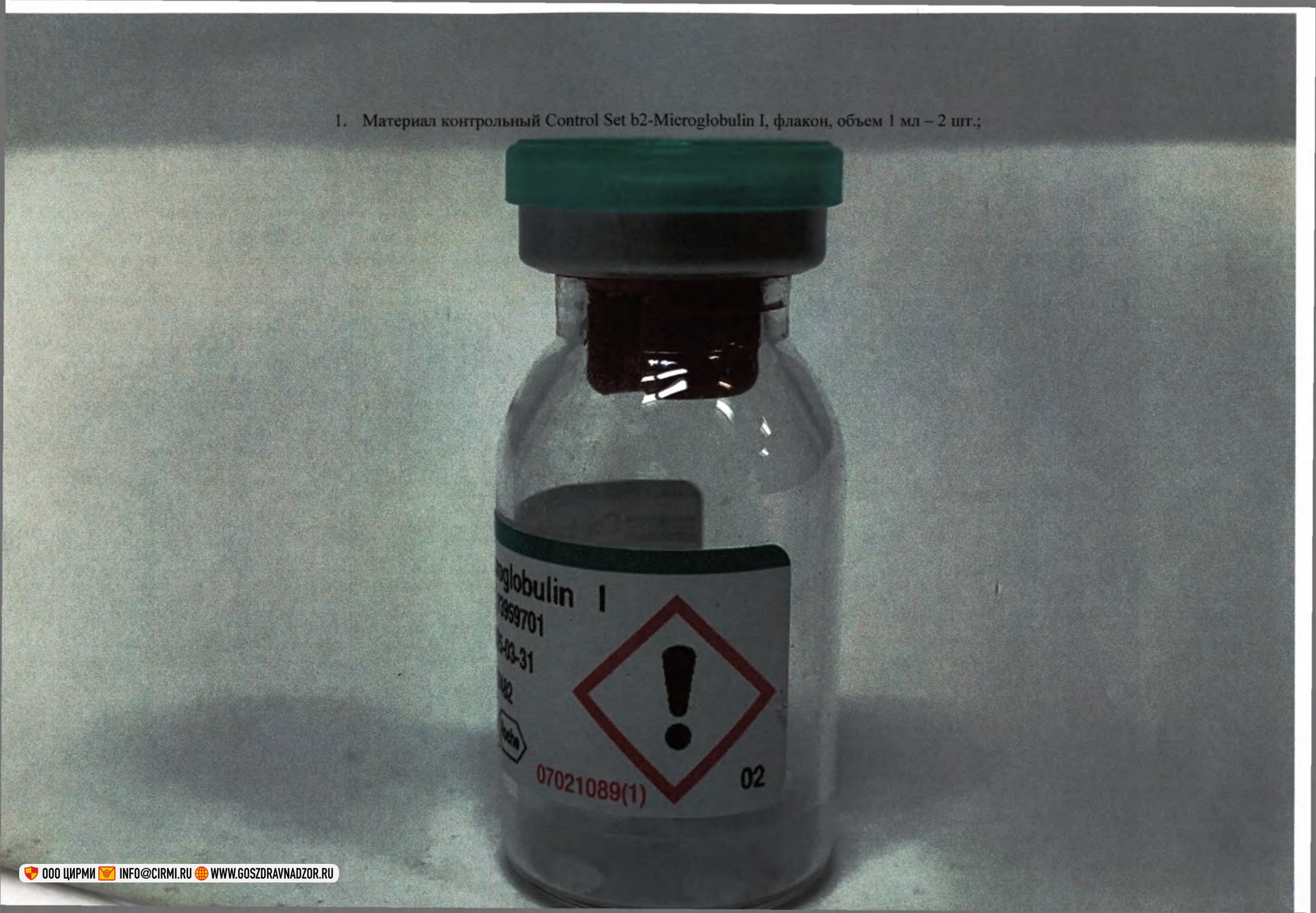
1. Материал контрольный Control Set b2-Microglobulin I, флакон, объем 1 мл – 2 шт.;



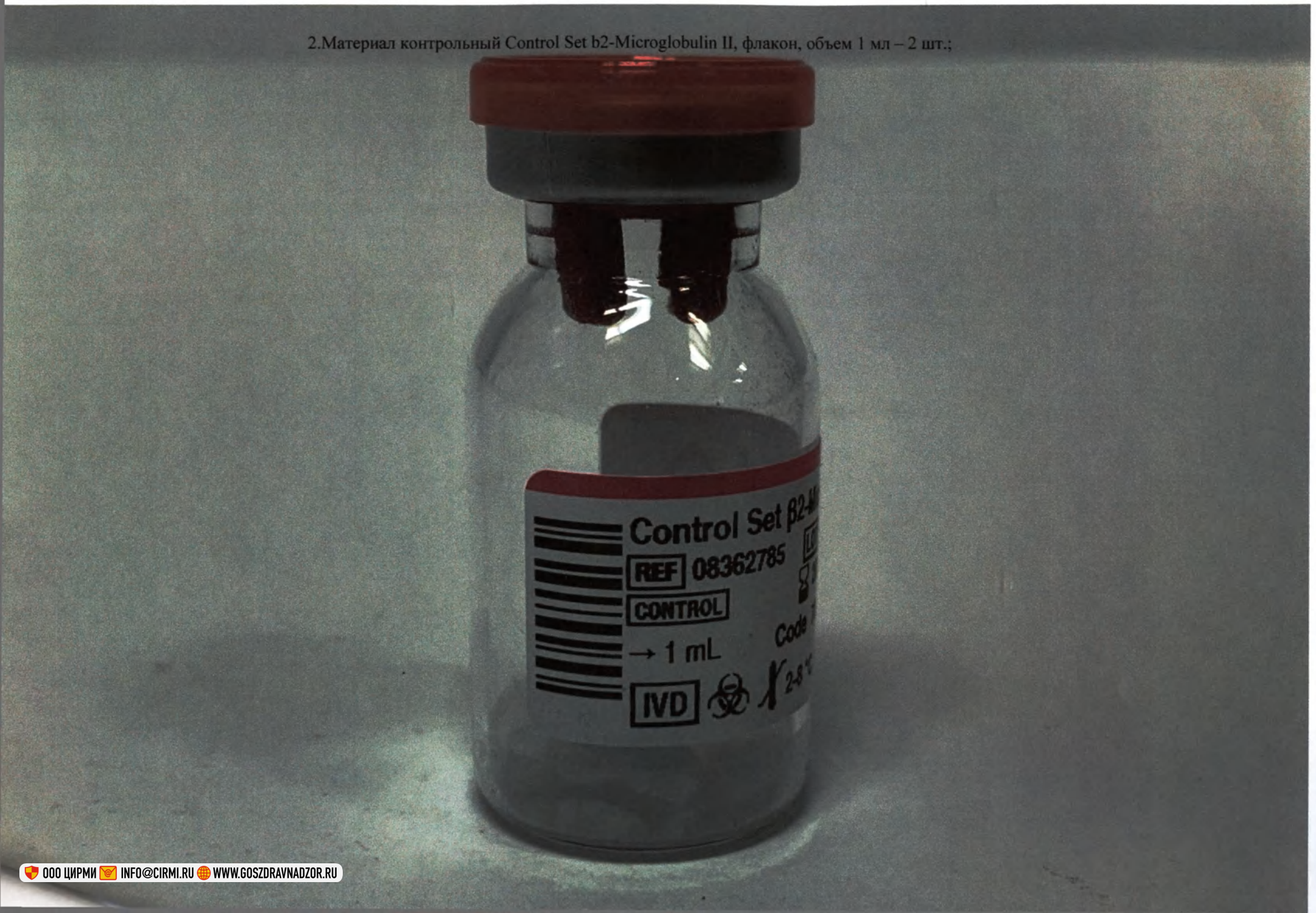
1. Материал контрольный Control Set b2-Microglobulin I, флакон, объем 1 мл – 2 шт.;



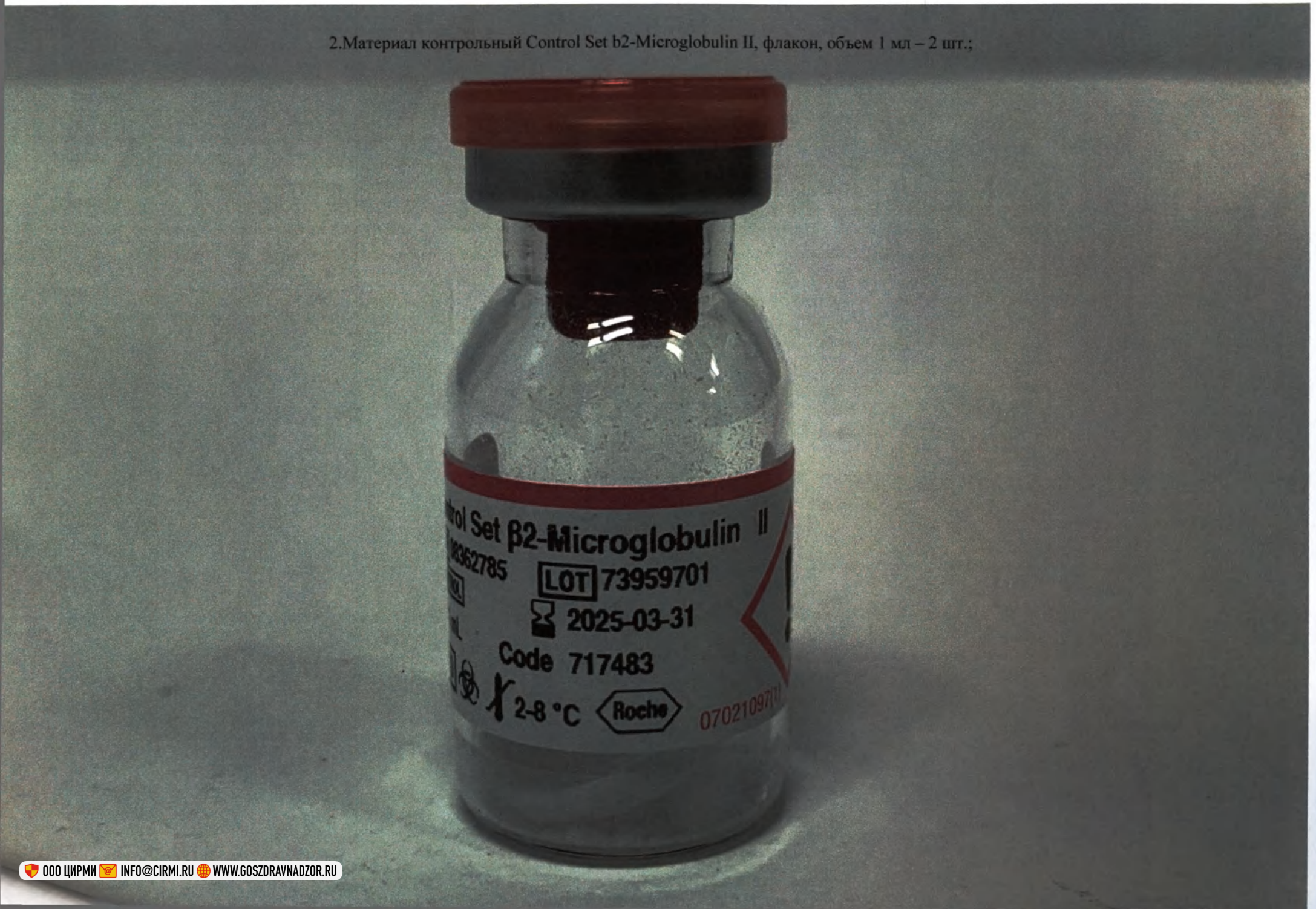
1. Материал контрольный Control Set b2-Microglobulin I, флакон, объем 1 мл – 2 шт.;



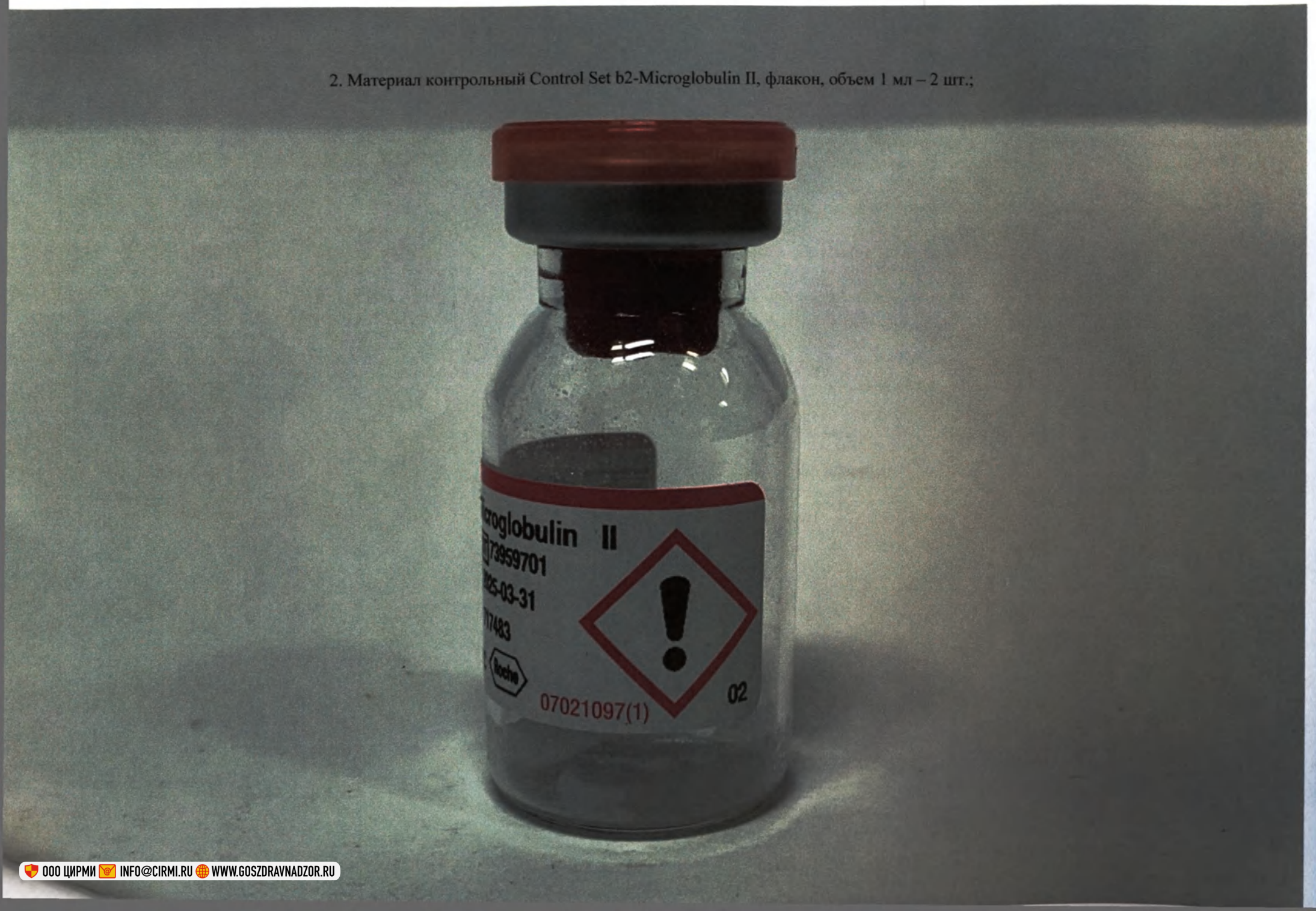
2.Материал контрольный Control Set b2-Microglobulin II, флакон, объем 1 мл – 2 шт.;



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.;



3.Этикетка со штрих-кодом – 4 шт.;

08364362001V2.0

# Control Set β2-Microglobulin cobas®

REF 08362785 190

→ 2 × 1 mL Control Level I

→ 2 × 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 β2-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 β2-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 |
|---|---|
| β2-Microglobulin | human |

*Non-reactive components:*

1.0 % bovine serum albumin

| | |
|---|---|
| Level I | 1.7 % $NaN_3$ |
| Level II | 1.6 % $NaN_3$ |

*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 ± 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 + P312 | 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 ± 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)