ФОТОГРАФИЧЕСКИЕ ИЗОБРАЖЕНИЯ

Набор калибраторов для количественного определения активности антитромбина в плазме крови человека на анализаторах и модулях биохимических cobas c, cobas Integra (Precimat Chromogen Roche Systems)

ЭЛЕКТРОННАЯ КОПИЯ ОФОРМЛЕНА ЦЕНТРОМ ИСПЫТАНИЙ И РЕГИСТРАЦИИ МЕДИЦИНСКИХ ИЗДЕЛИЙ

Набор калибраторов для количественного определения активности антитромбина в плазме крови человека на анализаторах и мо
биохимических cobas c, cobas Integra (Precimat Chromogen Roche Systems), в составе:

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

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р калибраторов для количественного определения активности антитромбина в плазме
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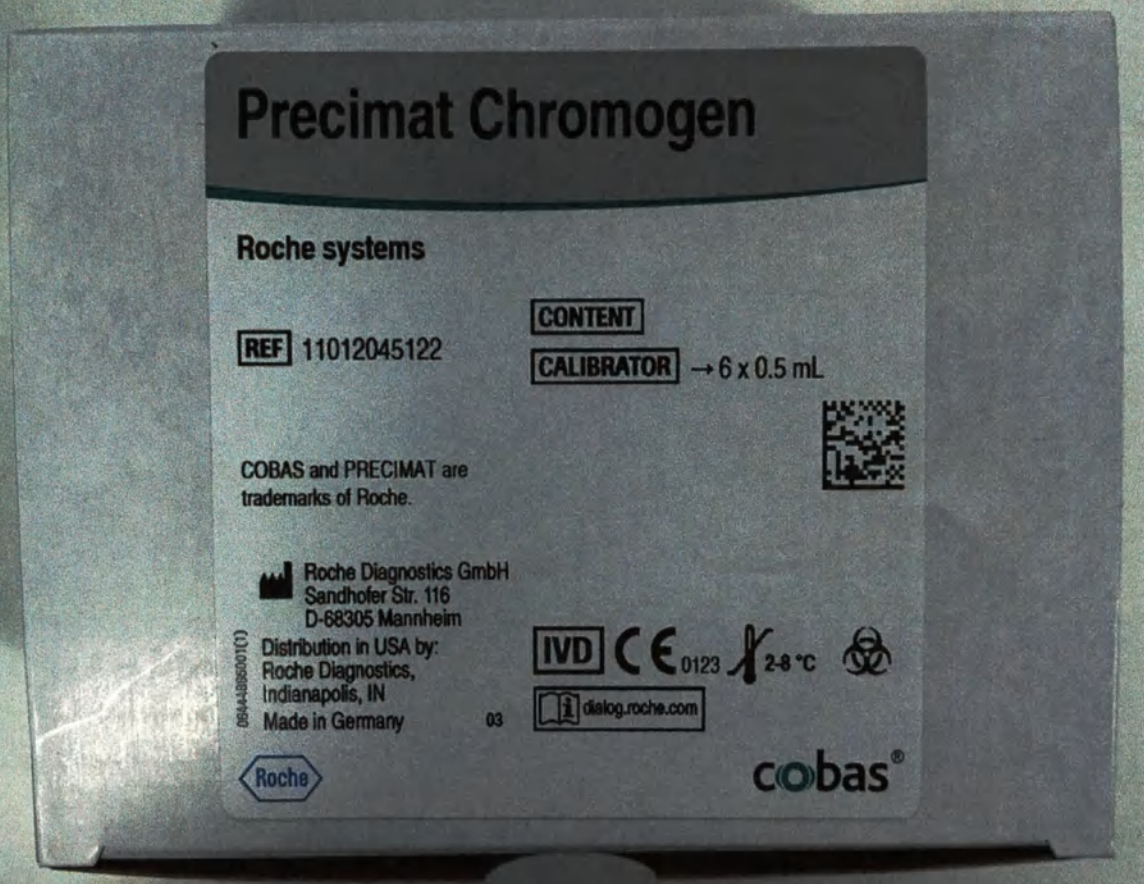
romogen Roche Systems)



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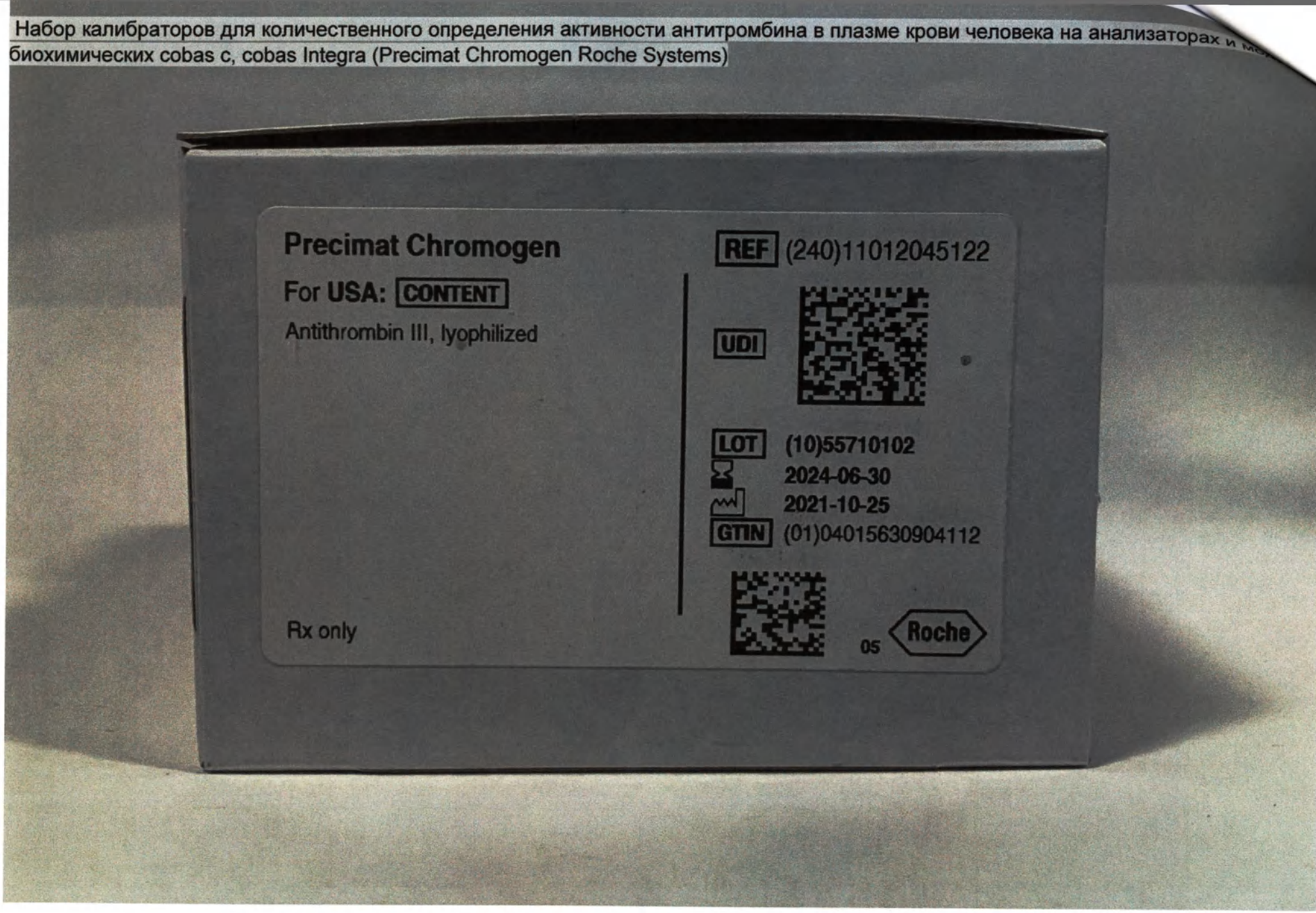

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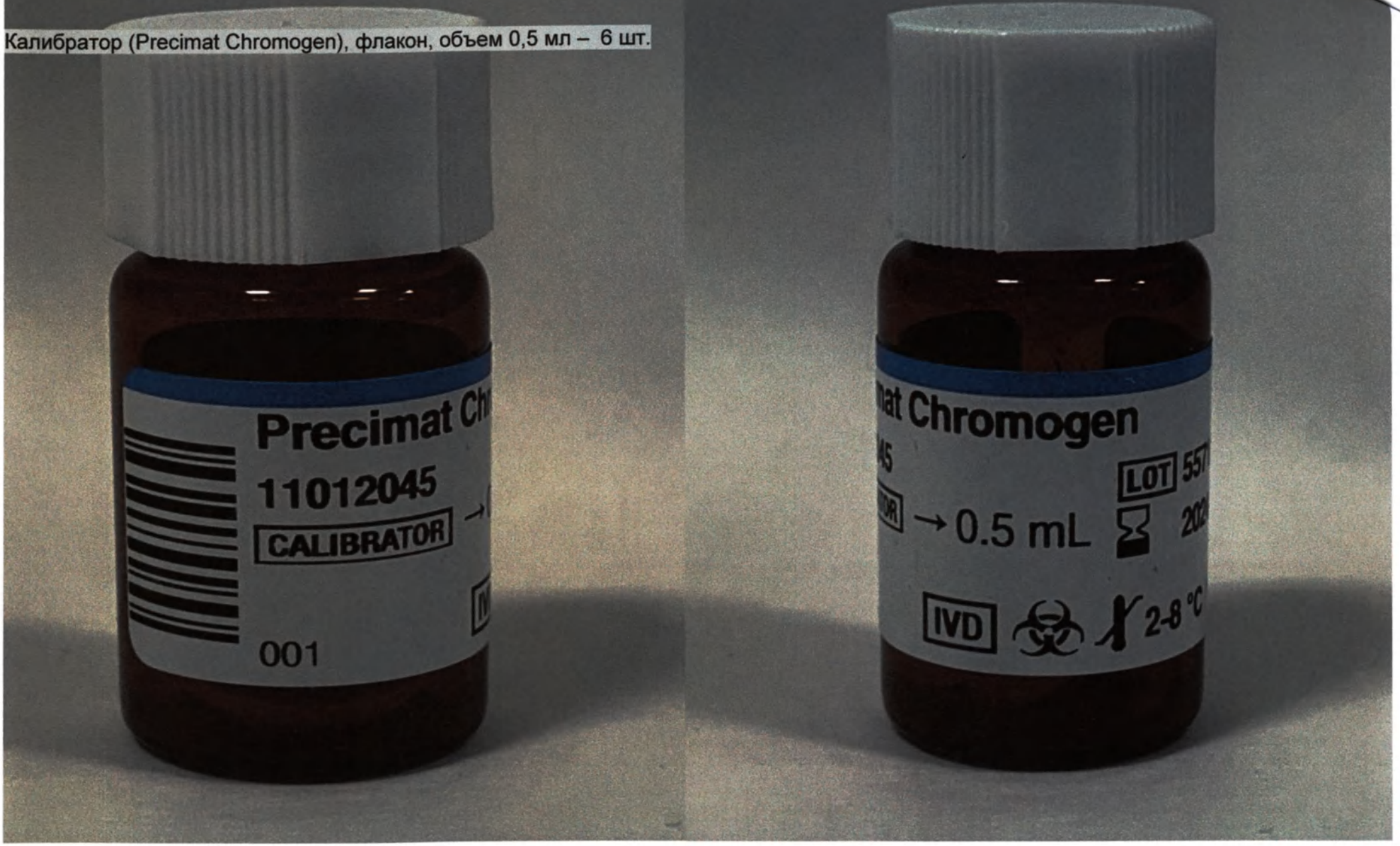
Калибратор (Precimat Chromogen), флакон, объем 0,5 мл – 6 шт.



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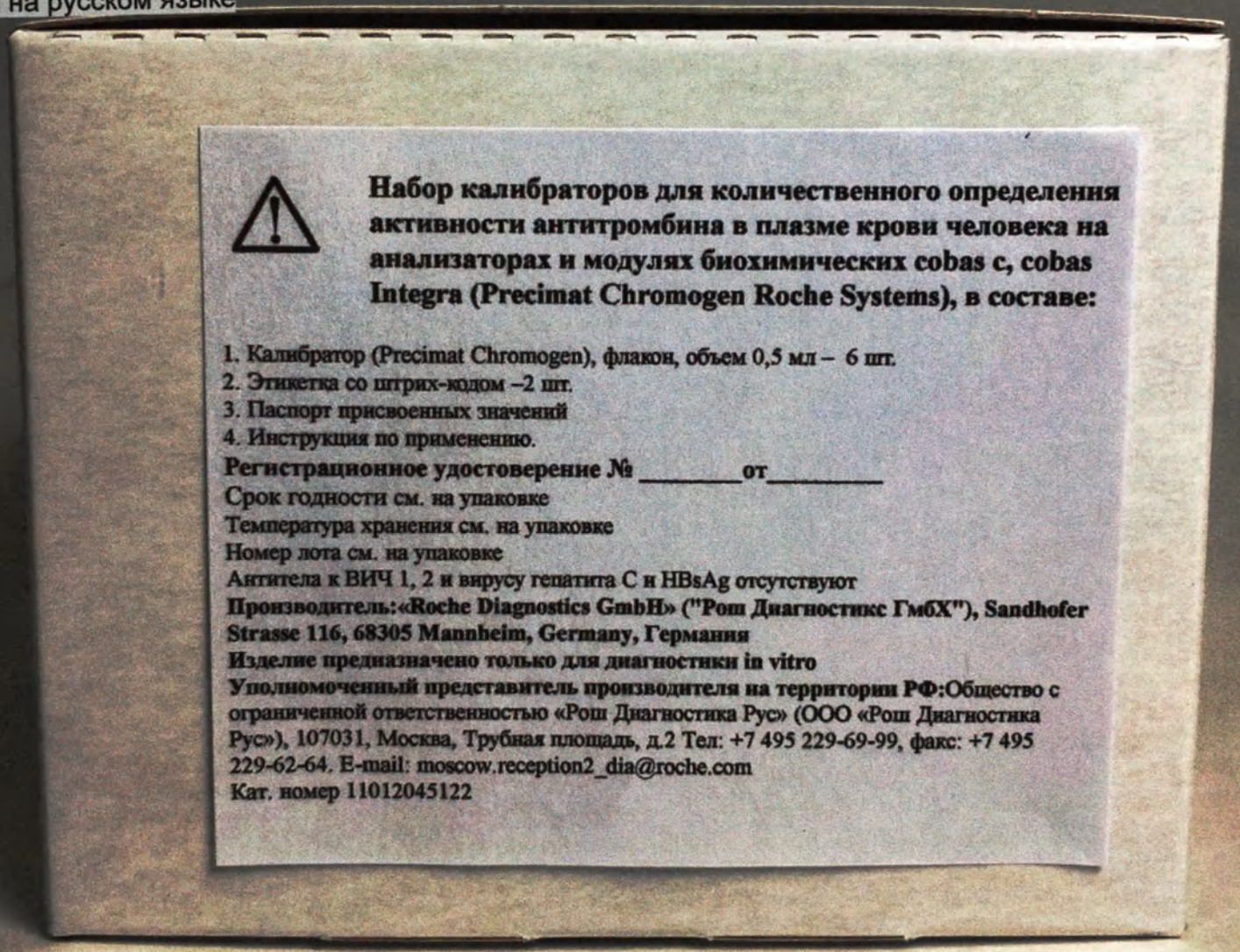
Макет маркировки на русском языке



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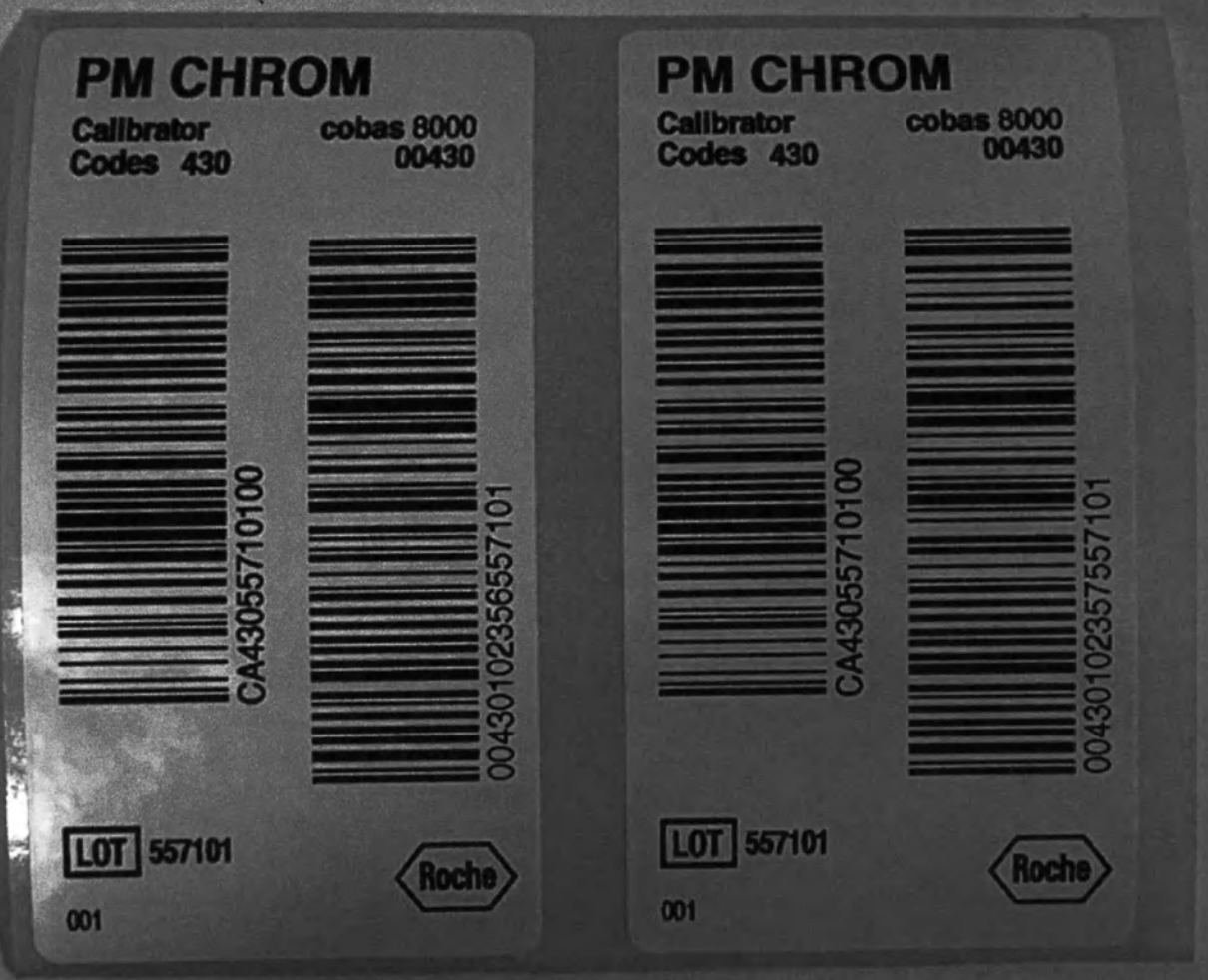
тикетка со штрих-кодом –2 шт.



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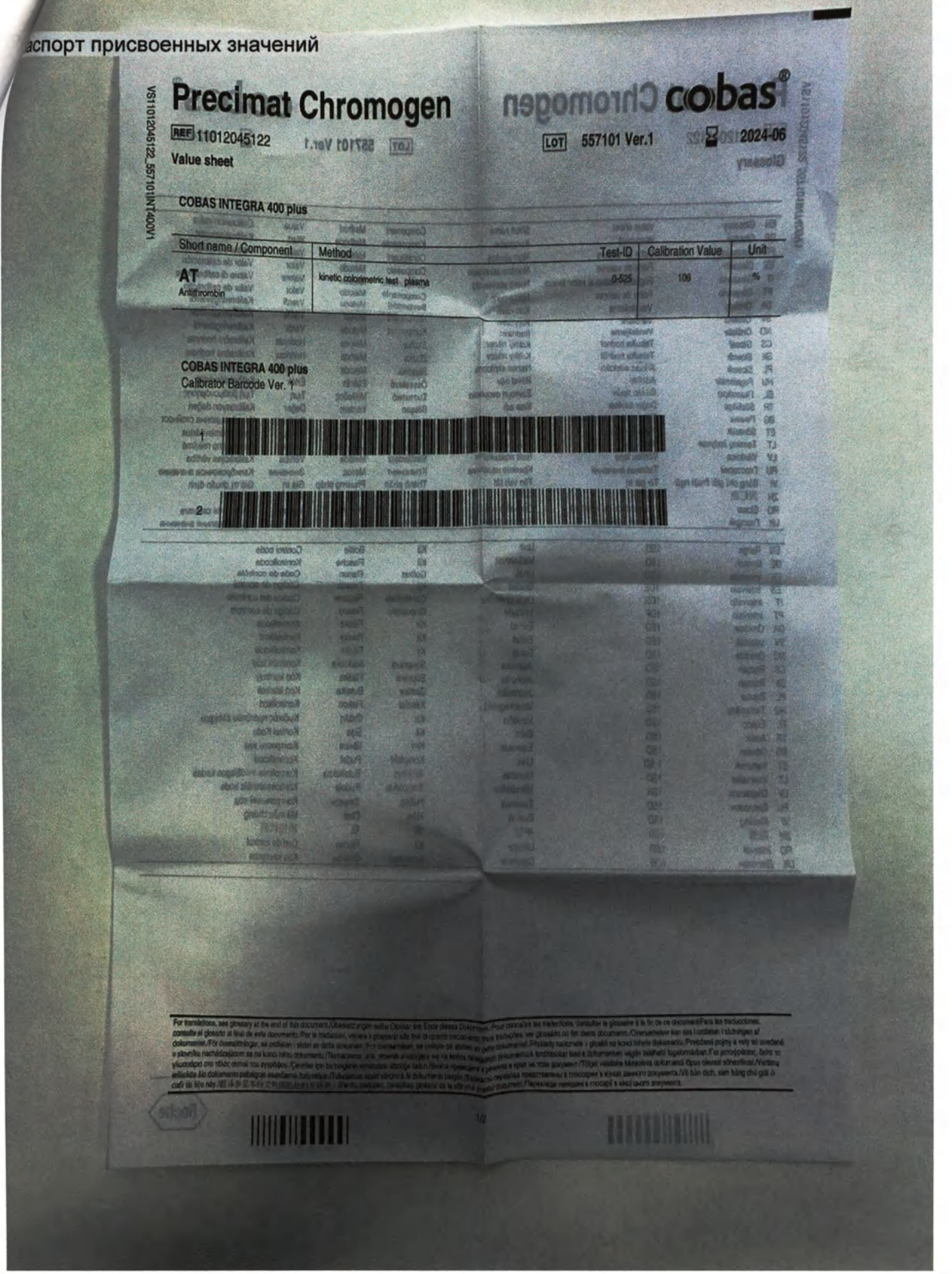
аспорт присвоенных значений



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струкция по применению

11887459001V9.0

Precimat Chromogen

cobas®

REF 11012045 122 → 6 x 0.5 mL Calibrator

English

System information

For use on Roche/Hitachi MODULAR and **cobas c** analyzers the calibrator code is 430.

For use on COBAS INTEGRA analyzers the system ID is 07 6585 6.

For use on Coasys Plus C analyzers.

Intended use

Precimat Chromogen is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the enclosed value sheet.

Summary

Precimat Chromogen is a lyophilized calibrator based on human citrated plasma. 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 in the lyophilizate:

Antithrombin III

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 *Roche/Hitachi MODULAR, COBAS INTEGRA and Coasys Plus C 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.

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:

H412 Harmful to aquatic life with long lasting effects.

Prevention:

P273 Avoid release to the environment.

Disposal:

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

Contact phone: all countries: +49-621-7590

Handling

Carefully open one bottle, avoiding the loss of lyophilizate, and pipette in exactly 0.5 mL of distilled/deionized water.

Carefully close the bottle and dissolve the contents completely by occasional gentle swirling within 30 minutes. Do not shake. Avoid the formation of foam. Leave the solution to stand for at least 30 minutes before use.

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 of the lyophilized calibrator at 2-8 °C: Up to the stated expiration date.

Stability of the components in the reconstituted calibrator:

at 15-25 °C:	8 hours
at 2-8 °C:	5 days
at (-15)-(-25) °C:	4 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 Precimat Chromogen 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

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

по доверенности
от 30.01.2023 г.

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