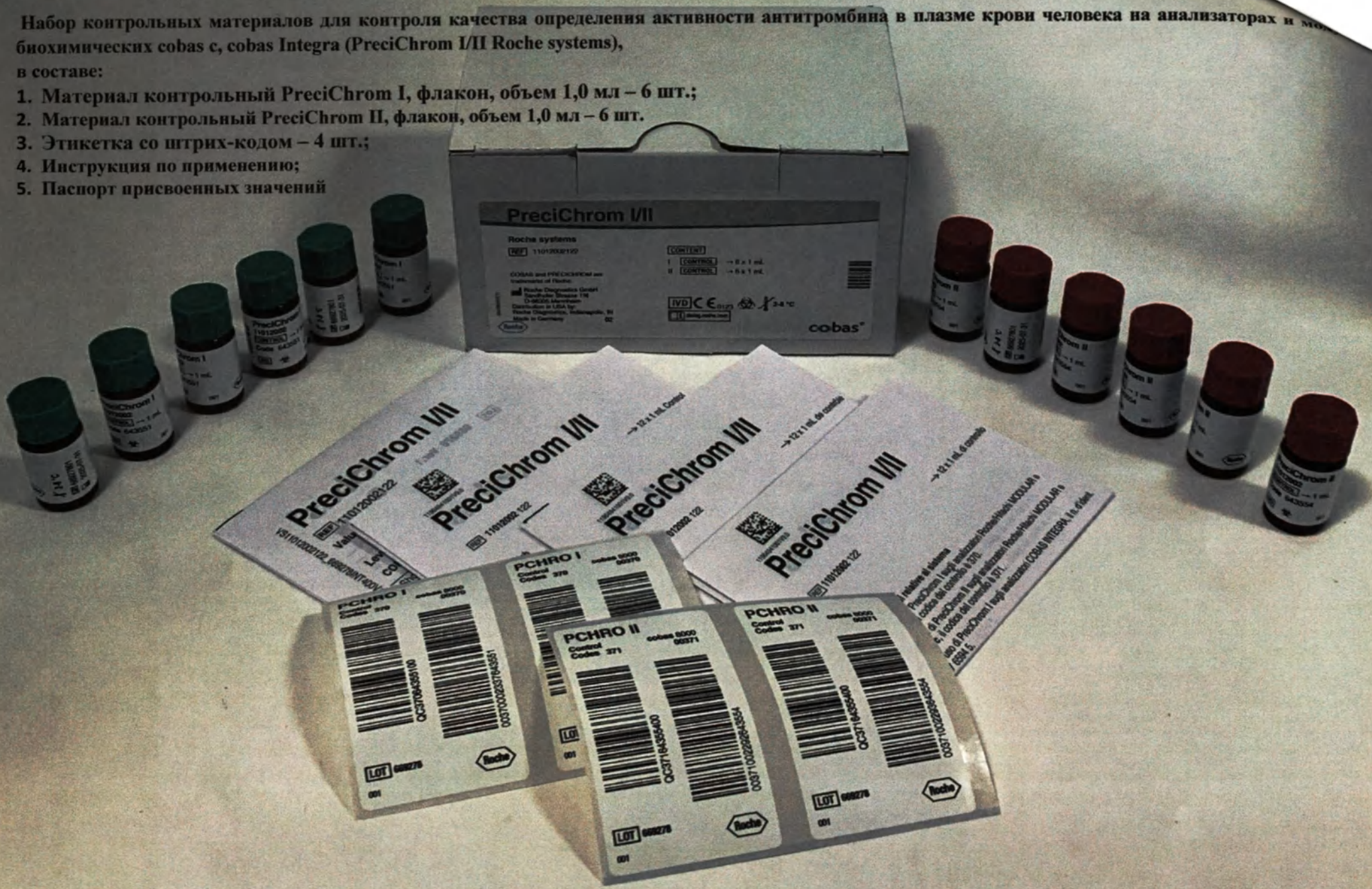
ФОТОГРАФИЧЕСКИЕ ИЗОБРАЖЕНИЯ

Набор контрольных материалов для контроля качества определения активности антитромбина в плазме крови человека на анализаторах и модулях биохимических cobas c, cobas Integra (PreciChrom I/II Roche systems)

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

Набор контрольных материалов для контроля качества определения активности антитромбина в плазме крови человека на анализаторах и м
биохимических cobas c, cobas Integra (PreciChrom I/II Roche systems),
в составе:

1. **Материал контрольный PreciChrom I, флакон, объем 1,0 мл – 6 шт.;**
2. **Материал контрольный PreciChrom II, флакон, объем 1,0 мл – 6 шт.**
3. **Этикетка со штрих-кодом – 4 шт.;**
4. **Инструкция по применению;**
5. **Паспорт присвоенных значений**



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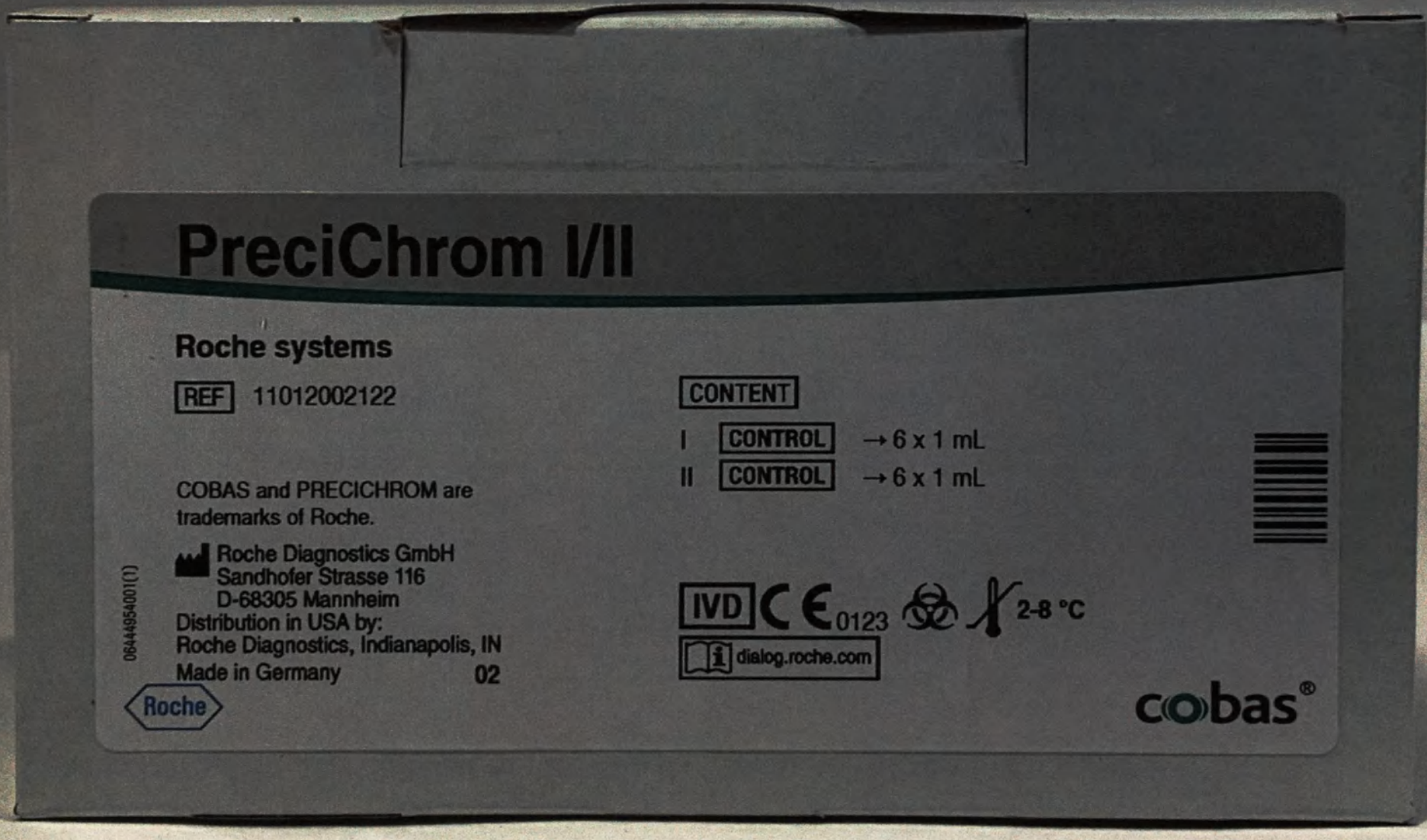

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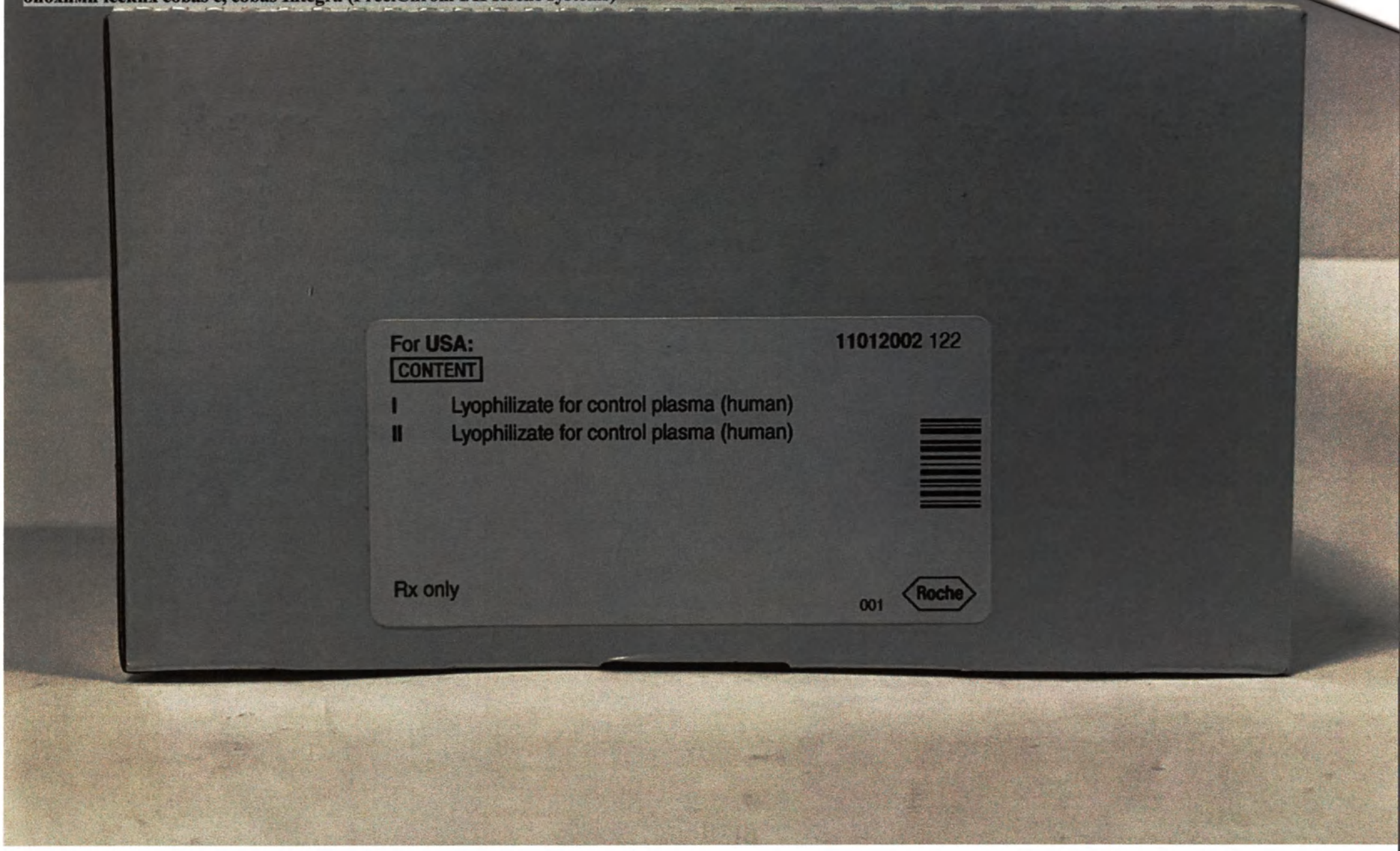

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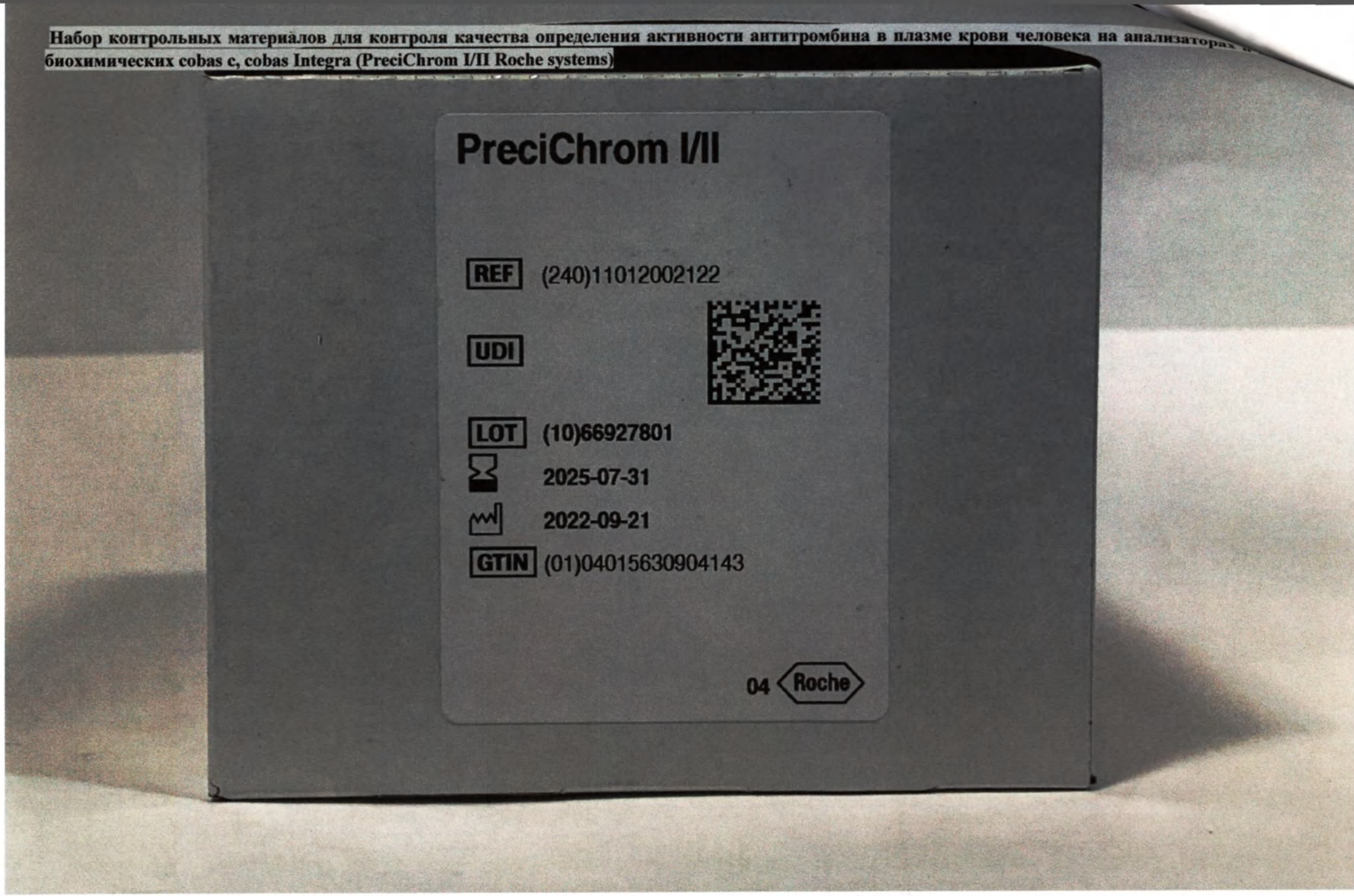

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5. Паспорт присвоенных значений

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 Диагностикс 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 11012002122

Набор контрольных материалов для контроля качества определения активности антитромбина в плазме крови человека на анализаторах и
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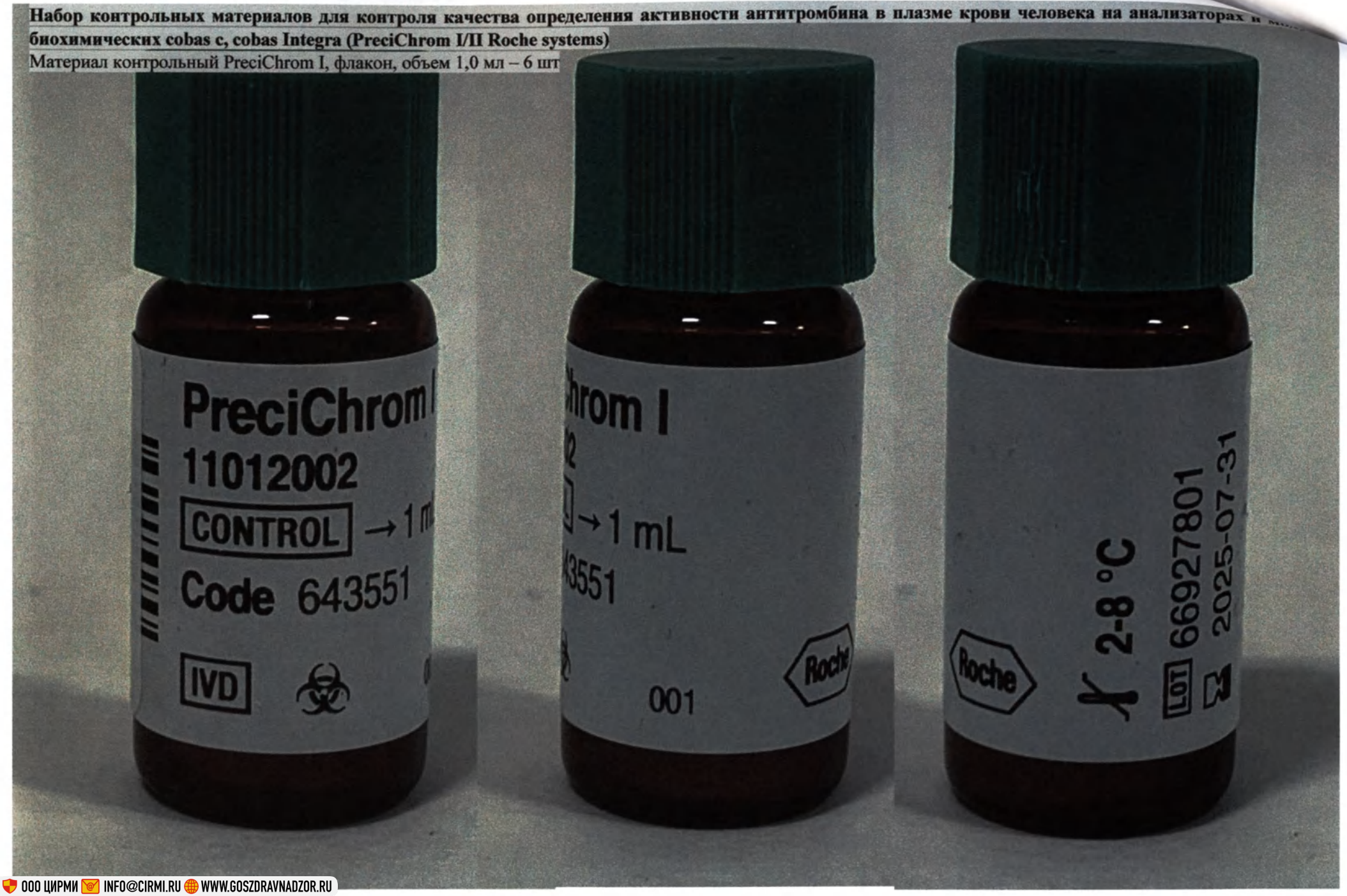
Материал контрольный PreciChrom I, флакон, объем 1,0 мл – 6 шт



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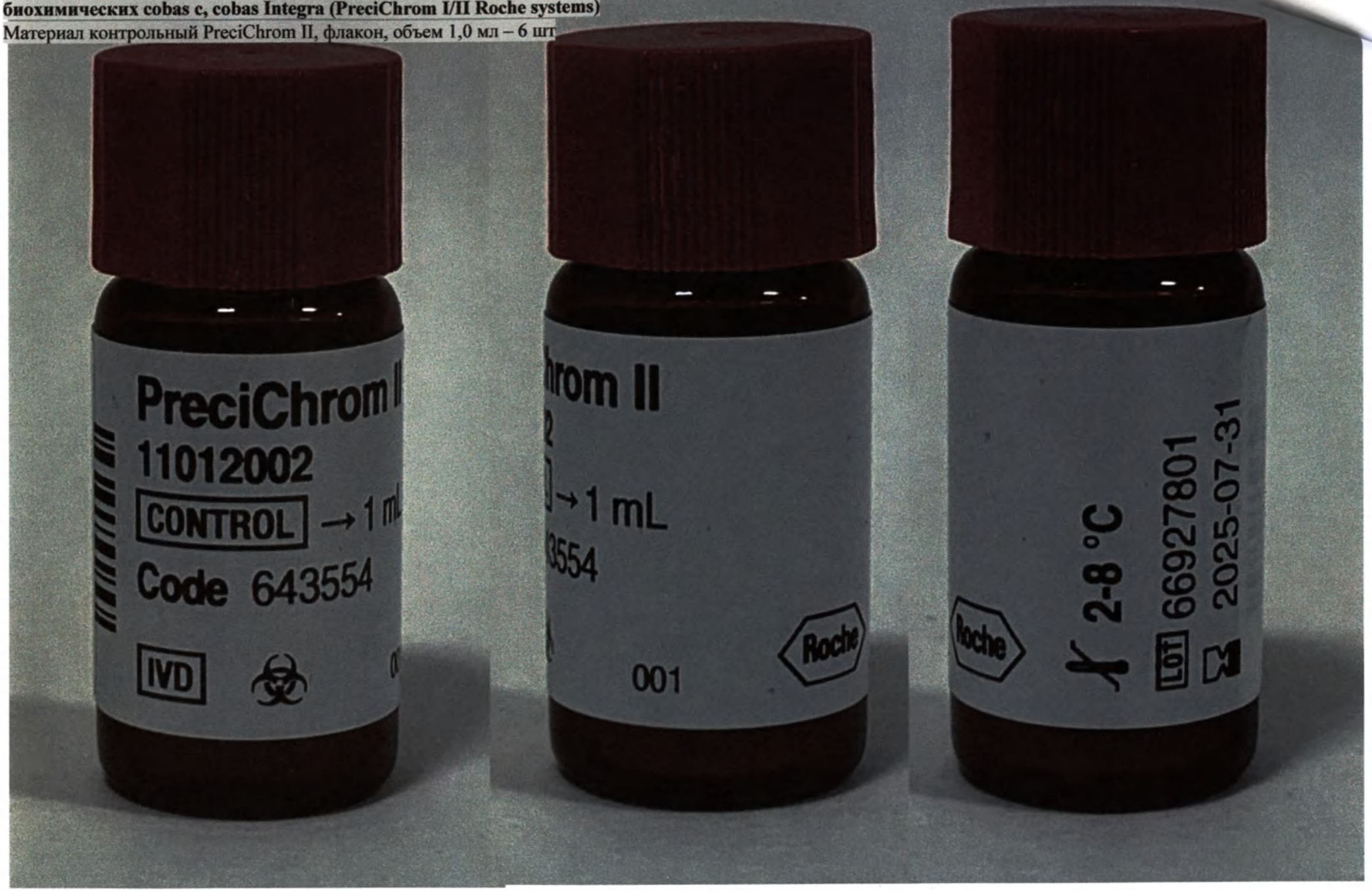

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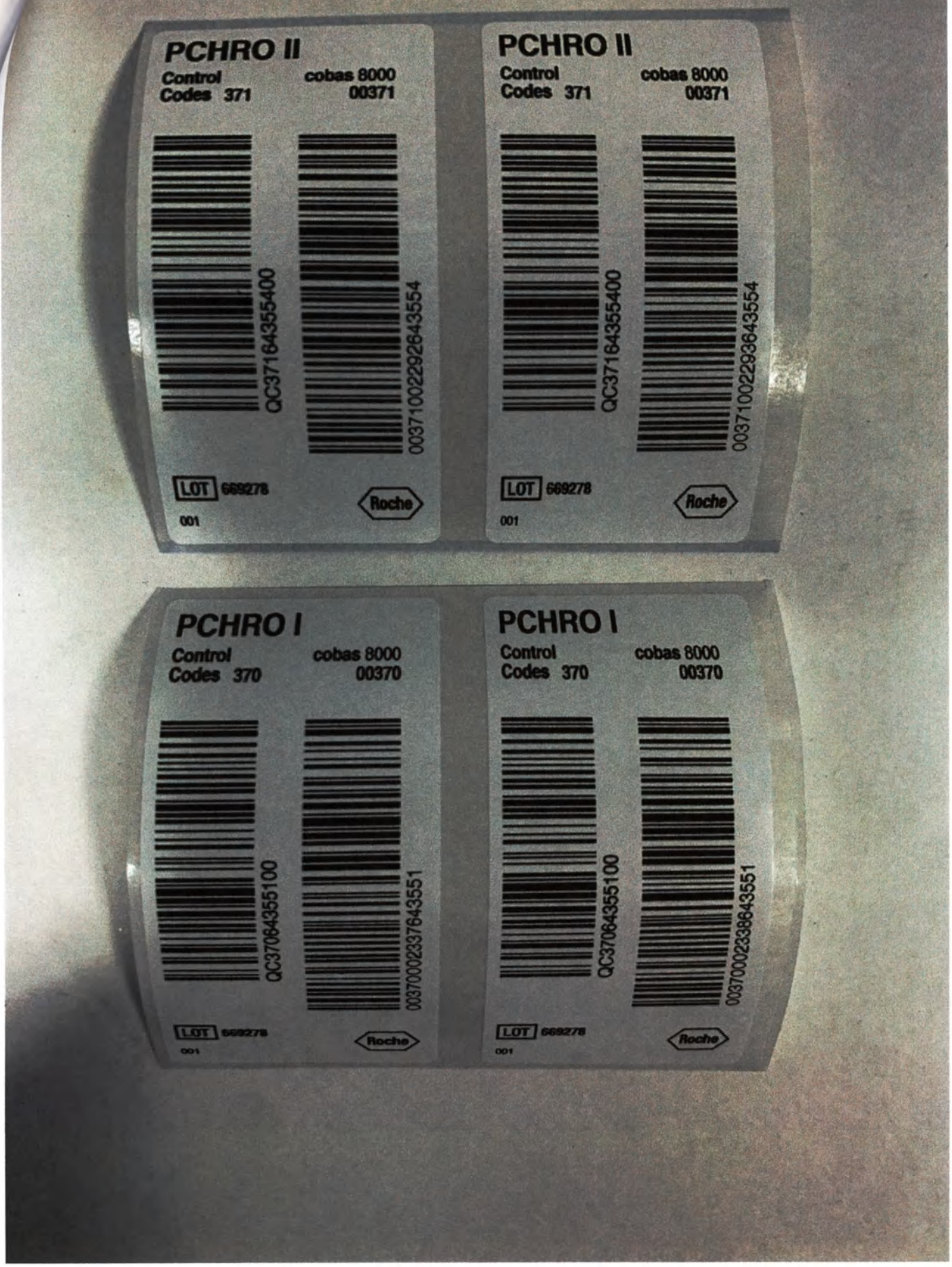
e systems)
кетка со штрих-кодом – 4 шт



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струкция по применению

11964941001V9.0

PreciChrom I/II

cobas®

REF 11012002 122 → 12 x 1 mL Control

English

System information

For use of PreciChrom I on Roche/Hitachi MODULAR and **cobas c** analyzers the control code is 370.

For use of PreciChrom II on Roche/Hitachi MODULAR and **cobas c** analyzers the control code is 371.

For use of PreciChrom I on COBAS INTEGRA analyzers the system ID is 07 6594 5.

For use of PreciChrom II on COBAS INTEGRA analyzers the system ID is 07 6595 3.

For use of PreciChrom I/II on Coasys Plus C analyzers.

Intended use

PreciChrom I/II is used for the quality control of photometric coagulation assays.

Summary

PreciChrom I/II is a lyophilized control based on human citrated plasma.

The adjusted concentrations of the control components are in the normal range for Control I and in the abnormal range for Control II.

Some methods specified in the relevant value sheet may not be available in all countries.

Reagents – working solutions

Reactive components in the lyophilizate:

Human serum with chemical additives and material of biological origin as specified.

The origin of the biological additives is as follows:

Analyte	*Origin*
Antithrombin III	human

Non-reactive components:

Preservative and stabilizers

The concentrations of the control components are lot-specific. The exact target values are given in the electronically available or enclosed value sheets.

The values are also encoded in the enclosed control 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.

Target values and ranges

The target values were determined using the method stated in electronically available or enclosed 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 median 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.

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 1 mL of distilled/deionized water. Carefully close the bottle. Before use let the reconstituted control stand for 30 minutes. Mix the content carefully avoiding the formation of foam.

The enclosed barcoded labels are intended exclusively for Roche/Hitachi MODULAR and **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.

Stability of the lyophilized control serum at 2-8 °C: up to the stated expiration date.

Stability of components in reconstituted control:

at 25 °C	8 hours
at 4 °C	5 days
at -20 °C	4 weeks (when frozen once)

Incubate the frozen control plasma for 10 minutes at 37 ± 0.5 °C until completely thawed and mix thoroughly. Let stand for 15 minutes at room temperature, then assay immediately.

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

Dispense the required volume into a sample cup and analyze in the same way as patient samples.

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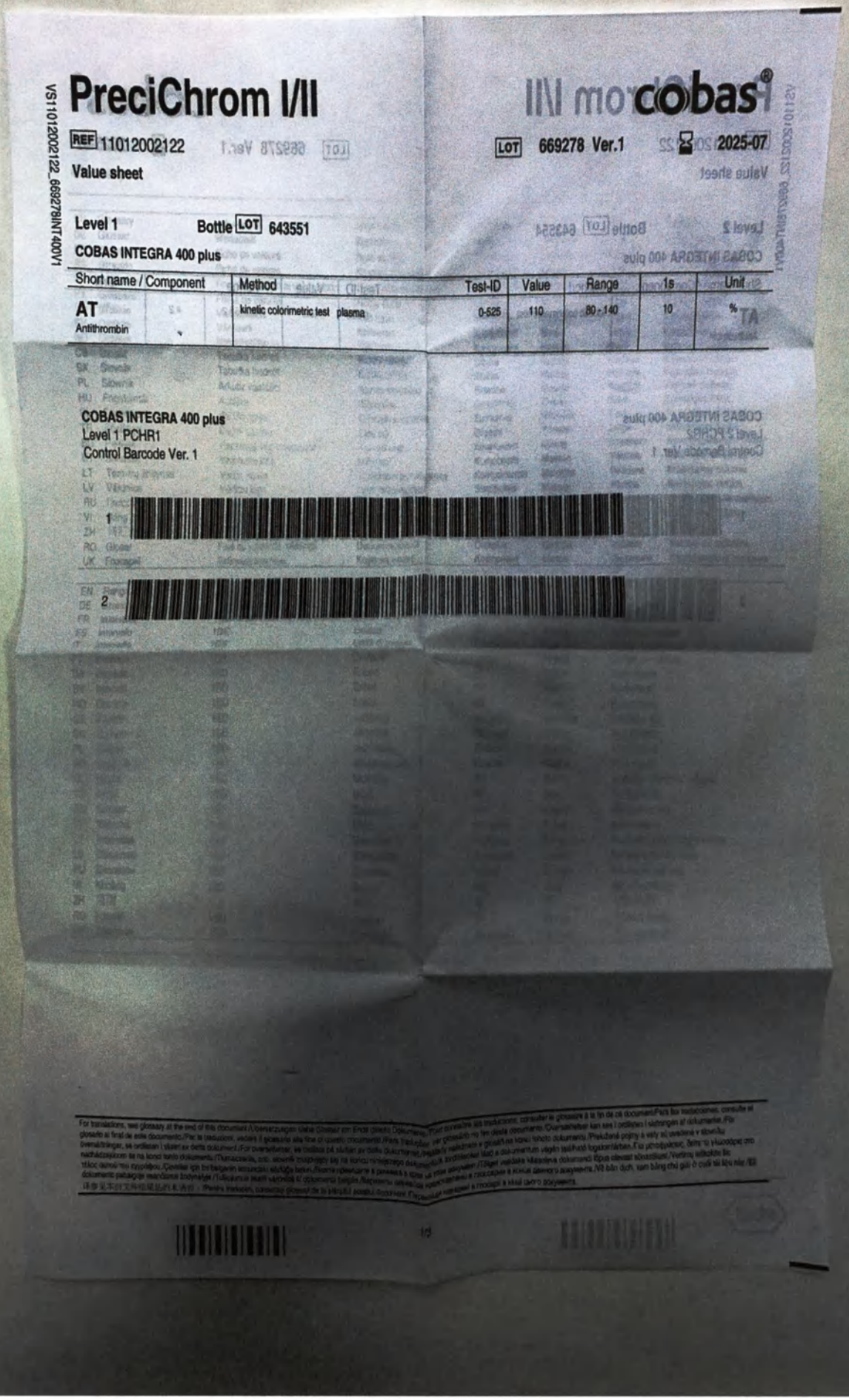

Всего пронумеровано,
прошнуровано и
скреплено печатью
11 листа (ов)

по доверенности
от 30.01.2023 г.