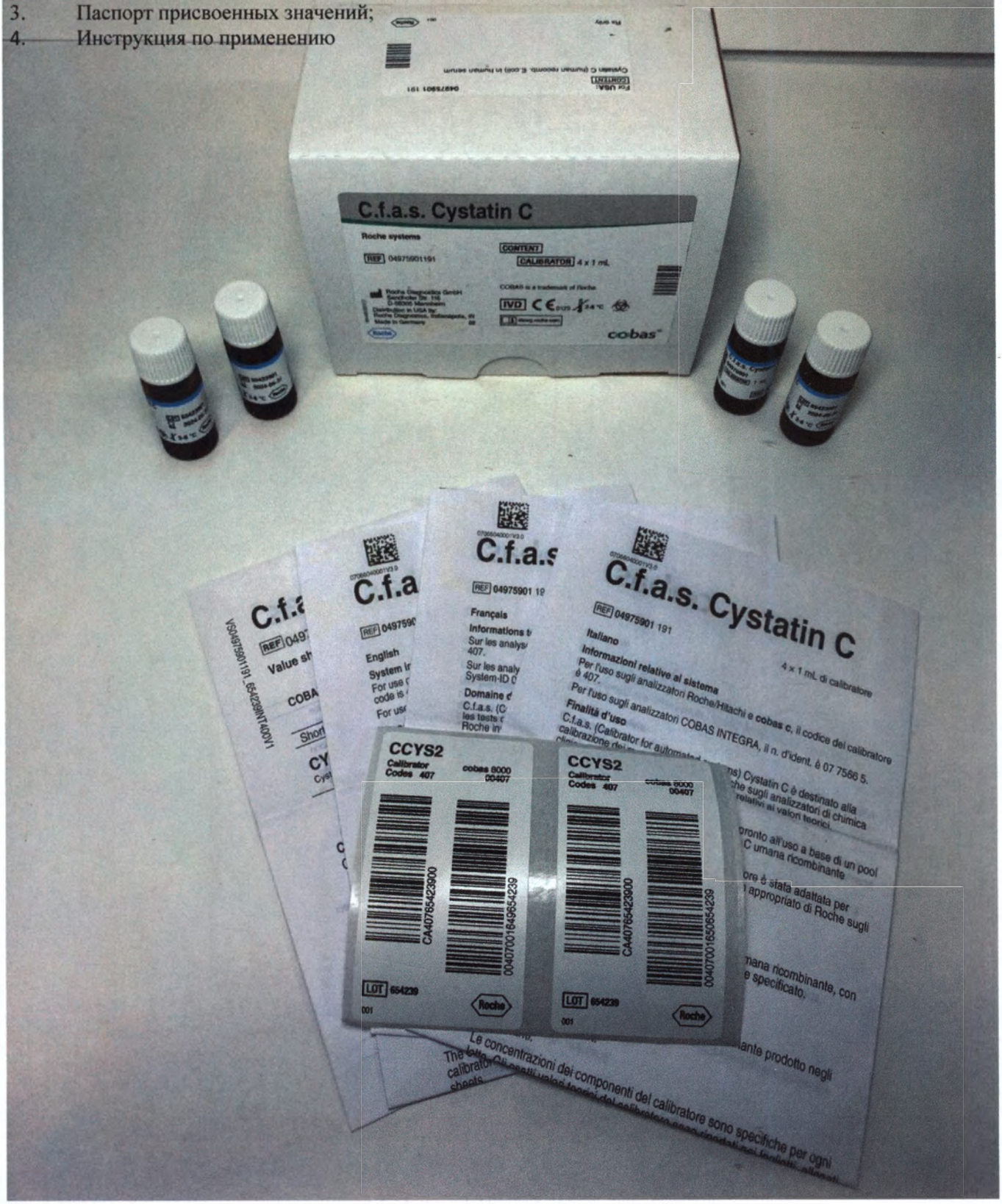
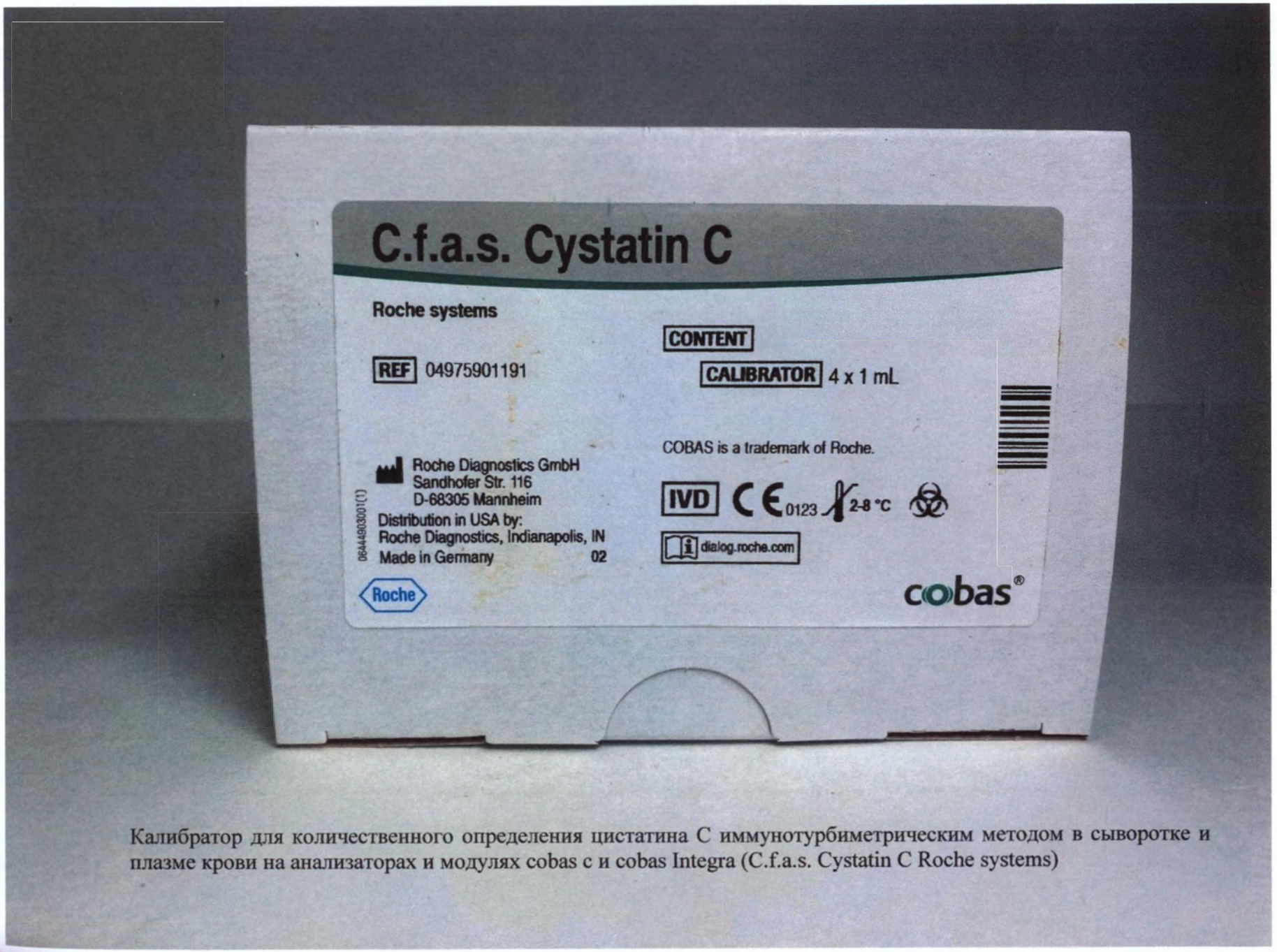
Фотографические изображения

Калибратор для количественного определения цистатина С иммунотурбиметрическим методом в сыворотке и плазме крови на анализаторах и модулях cobas c и cobas Integra (C.f.a.s. Cystatin C Roche systems)

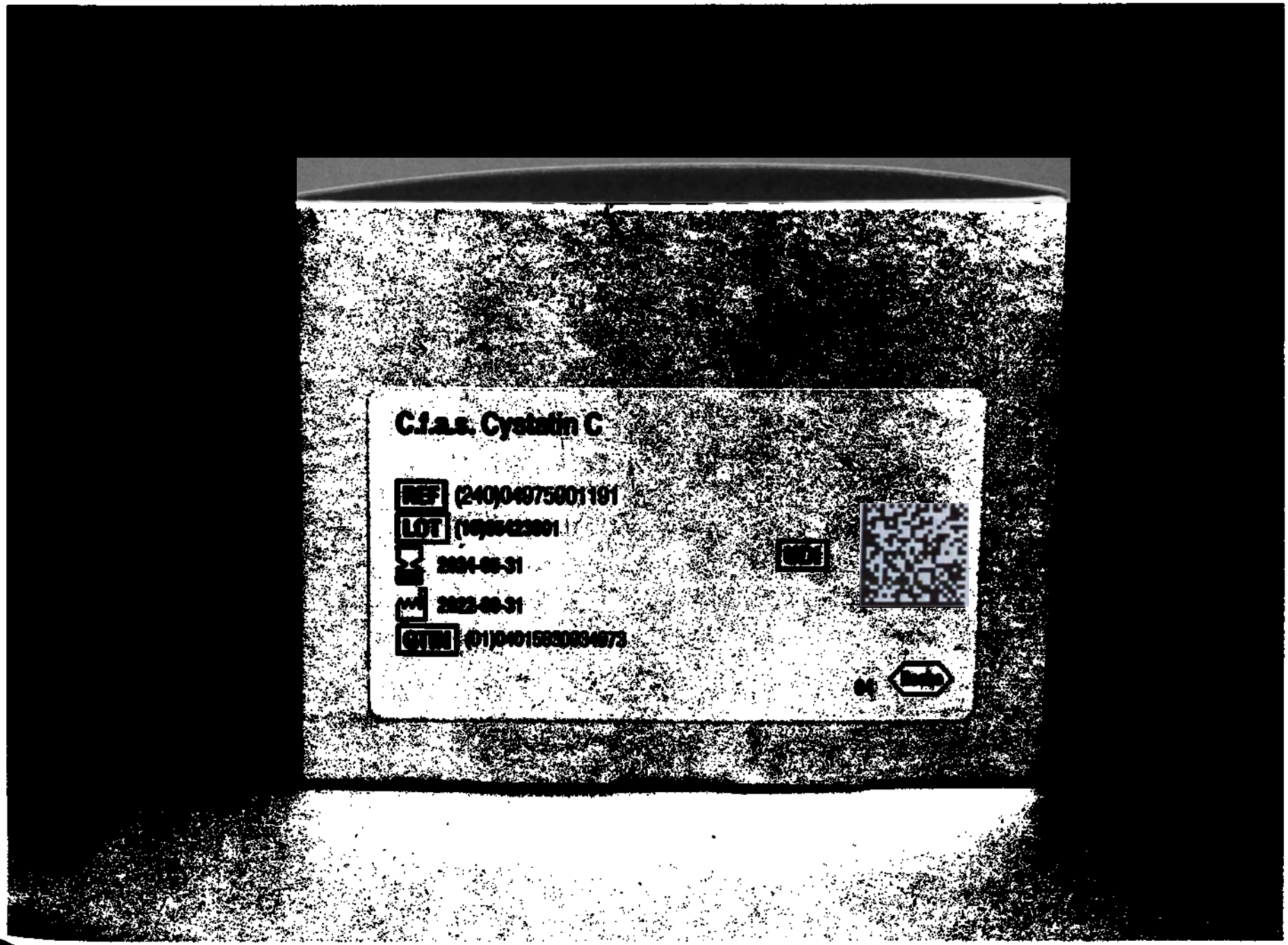
Калибратор для количественного определения цистатина С иммунотурбиметрическим методом в сыворотке и плазме крови на анализаторах и модулях cobas c и cobas Integra (C.f.a.s. Cystatin C Roche systems), в составе:

1. Калибратор C.f.a.s. Cystatin C, флакон, объем 1 мл – 4 шт.;
2. Этикетка со штрих-кодом – 2 шт.;
3. Паспорт присвоенных значений;
4. Инструкция по применению

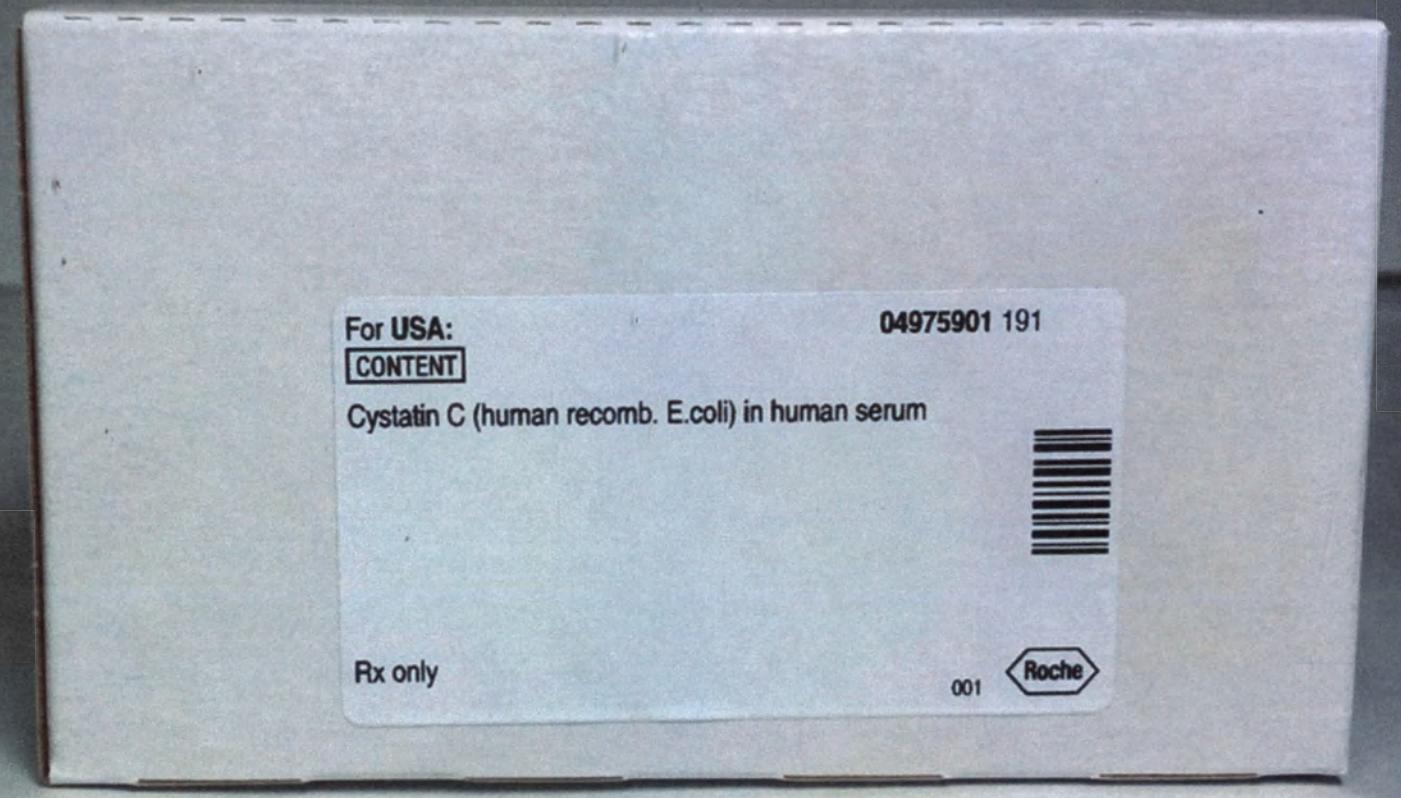




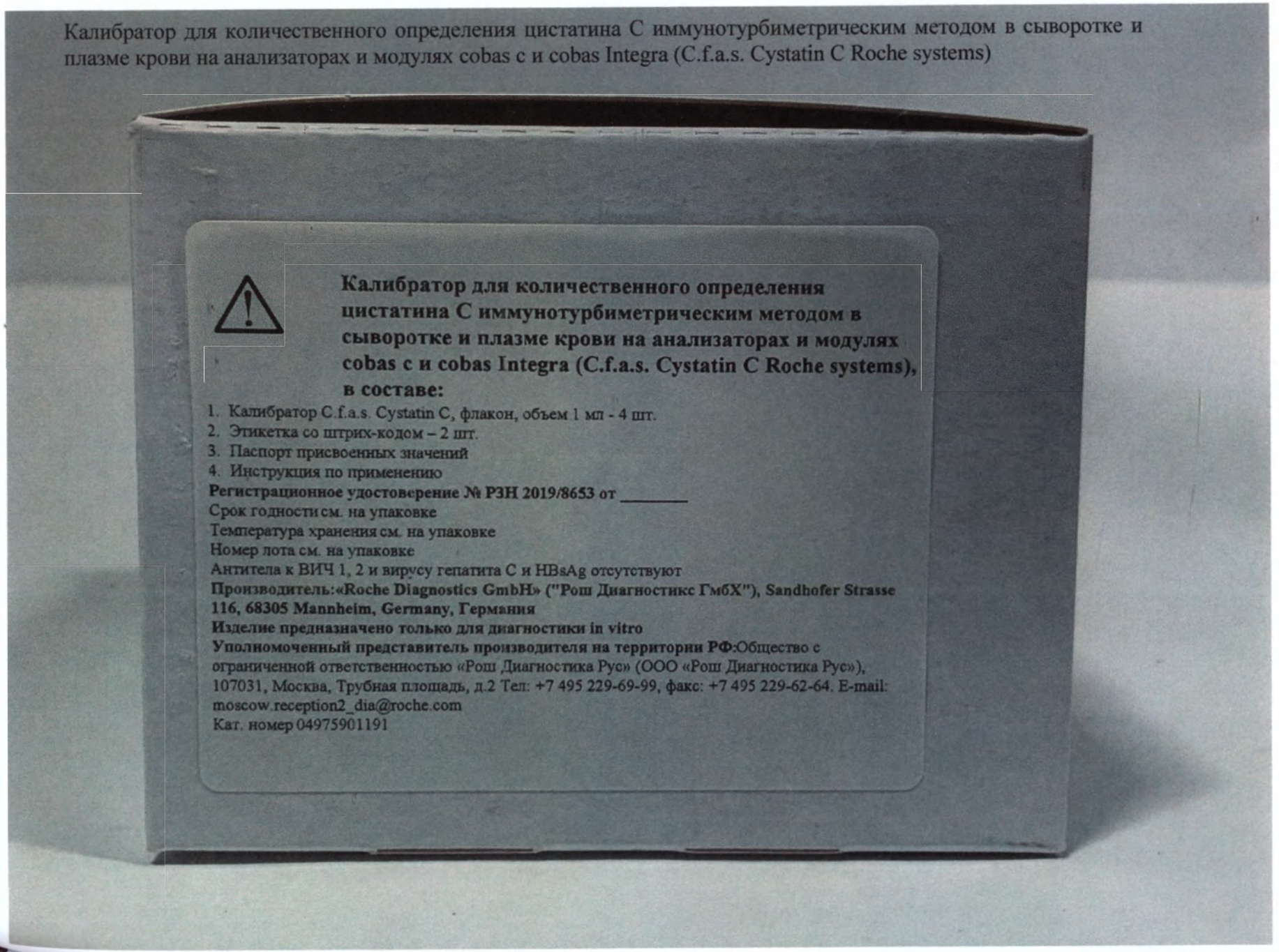
Калибратор для количественного определения цистатина С иммунотурбиметрическим методом в сыворотке и плазме крови на анализаторах и модулях cobas c и cobas Integra (C.f.a.s. Cystatin C Roche systems)

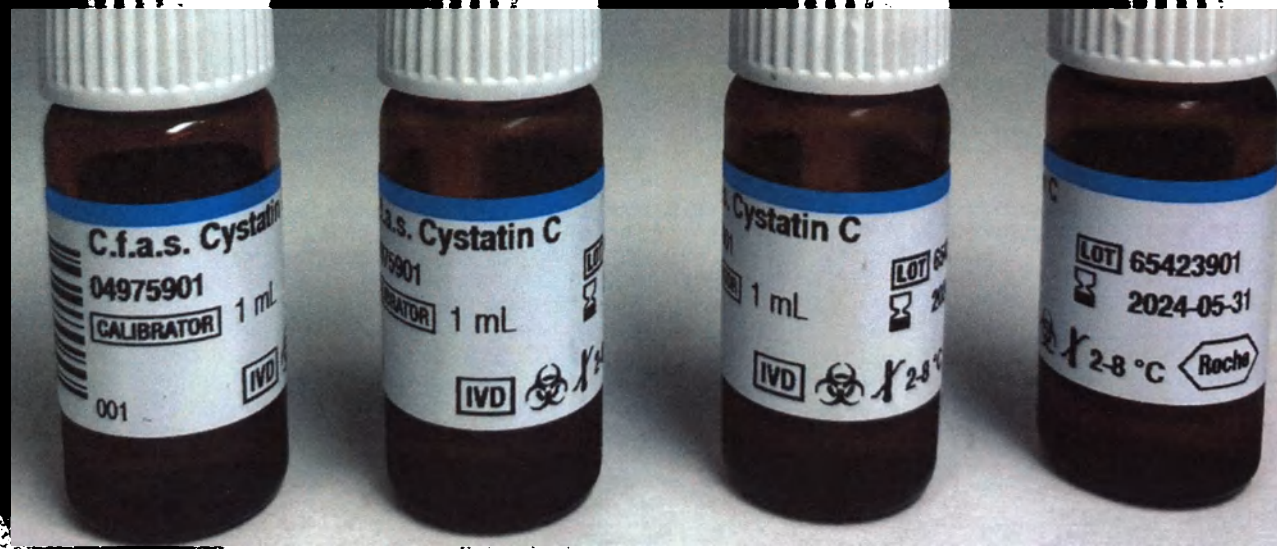


Калибратор для количественного определения цистатина С иммунотурбиметрическим методом в сыворотке и плазме крови на анализаторах и модулях cobas c и cobas Integra (C.f.a.s. Cystatin C Roche systems)



Калибратор для количественного определения цистатина С иммунотурбиметрическим методом в сыворотке и плазме крови на анализаторах и модулях cobas c и cobas Integra (C.f.a.s. Cystatin C Roche systems)



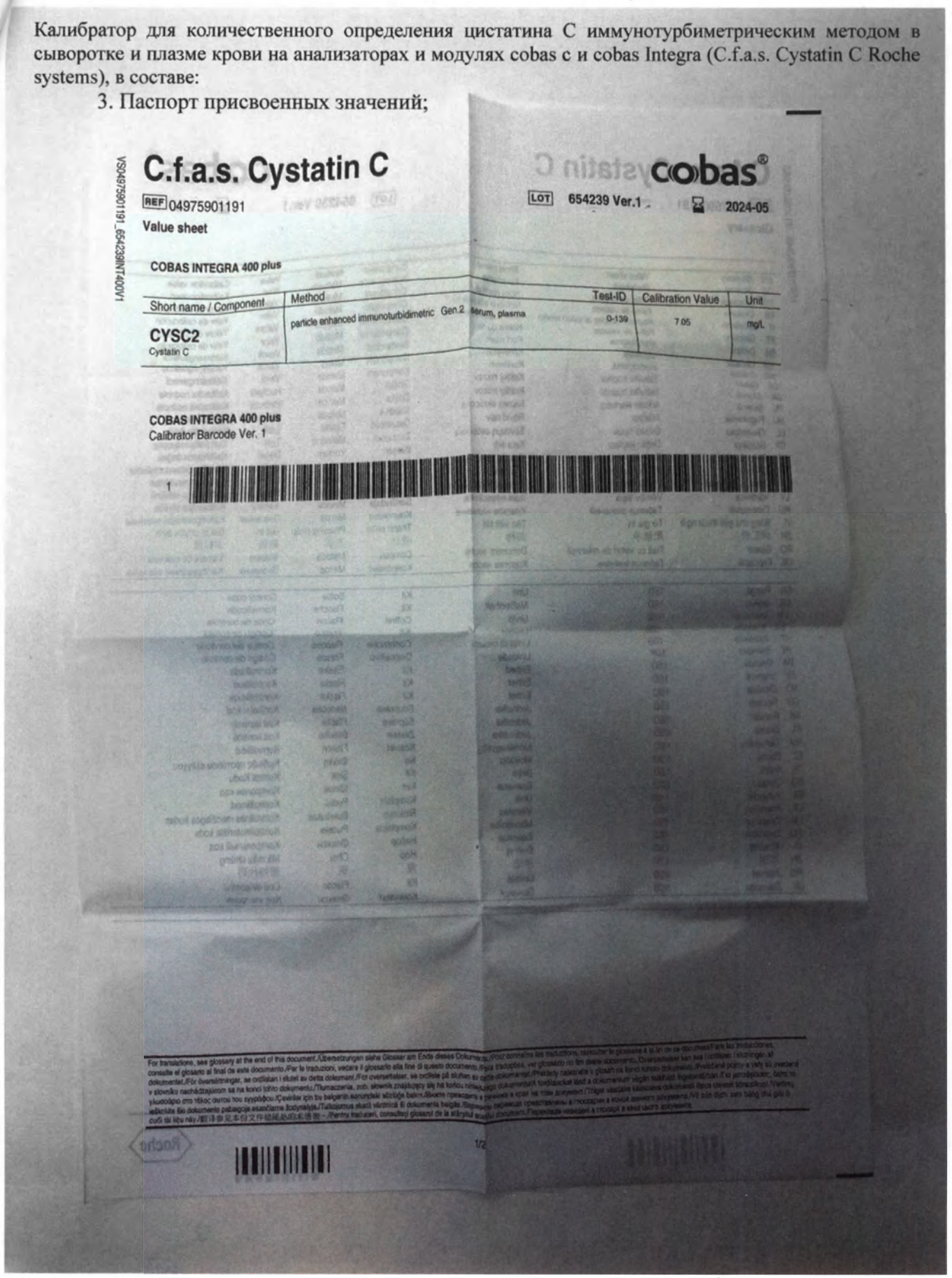


Калибратор для количественного определения цистатина С иммунотурбиметрическим методом в сыворотке и плазме крови на анализаторах и модулях cobas c и cobas Integra (C.f.a.s. Cystatin C Roche systems), в составе:

2. Этикетка со штрих-кодом – 2 шт.;

Калибратор для количественного определения цистатина С иммунотурбиметрическим методом в сыворотке и плазме крови на анализаторах и модулях cobas c и cobas Integra (C.f.a.s. Cystatin C Roche systems), в составе:

3. Паспорт присвоенных значений;



C.f.a.s. Cystatin C

cobas®

REF 04975901191

LOT 654239 Ver.1

2024-05

Value sheet

COBAS INTEGRA 400 plus

Short name / Component	Method		Test-ID	Calibration Value	Unit
CYSC2 Cystatin C	particle enhanced immunoturbidimetric	Gen.2	serum, plasma	0-139	7.05	mg/L

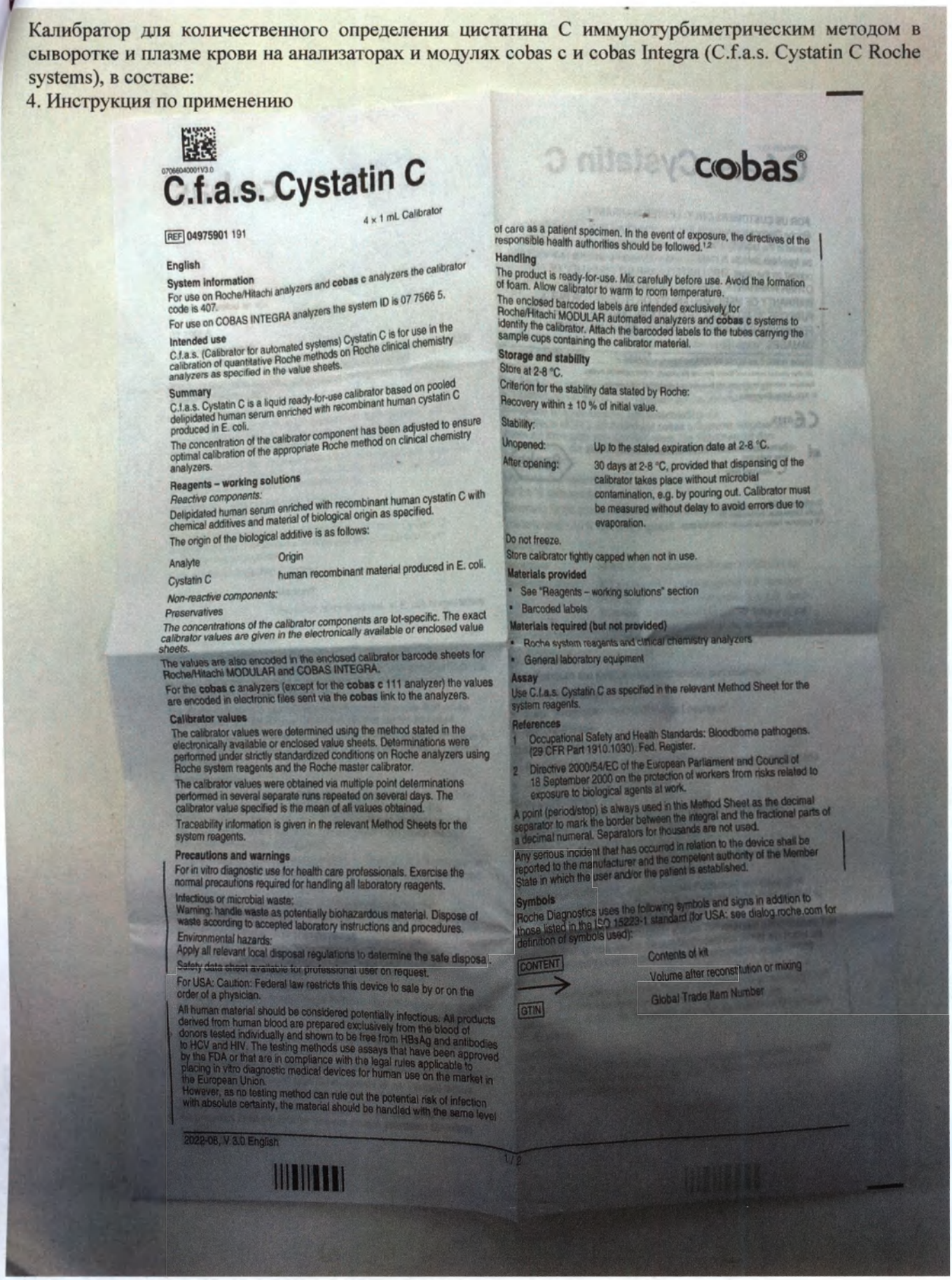
COBAS INTEGRA 400 plus

Calibrator Barcode Ver. 1

1

Калибратор для количественного определения цистатина С иммунотурбиметрическим методом в сыворотке и плазме крови на анализаторах и модулях cobas c и cobas Integra (C.f.a.s. Cystatin C Roche systems), в составе:

4. Инструкция по применению



07066040001V3.0

C.f.a.s. Cystatin C

4 x 1 mL Calibrator

REF 04975901 191

English

System information

For use on Roche/Hitachi analyzers and **cobas c** analyzers the calibrator code is 407.

For use on COBAS INTEGRA analyzers the system ID is 07 7566 5.

Intended use

C.f.a.s. (Calibrator for automated systems) Cystatin C is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheets.

Summary

C.f.a.s. Cystatin C is a liquid ready-for-use calibrator based on pooled delipidated human serum enriched with recombinant human cystatin C produced in E. coli.

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:

Delipidated human serum enriched with recombinant human cystatin C with chemical additives and material of biological origin as specified.

The origin of the biological additive is as follows:

Analyte	Origin
Cystatin C	human recombinant material produced in E. coli.

Non-reactive components:

Preservatives

The concentrations of the calibrator 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 and COBAS INTEGRA.

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 multiple point determinations performed in several separate runs repeated on several days. The calibrator value specified is the mean 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.

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]

Handling

The product is ready-for-use. Mix carefully before use. Avoid the formation of foam. Allow calibrator to warm to room temperature.

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:

Unopened:	Up to the stated expiration date at 2-8 °C.
After opening:	30 days at 2-8 °C, provided that dispensing of the calibrator takes place without microbial contamination, e.g. by pouring out. Calibrator must be measured without delay to avoid errors due to evaporation.

Do not freeze.

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 C.f.a.s. Cystatin C 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
→	Volume after reconstitution or mixing
GTIN	Global Trade Item Number

по доверенности
от 30.01.2023 г.

Ходова Ю.Г.

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