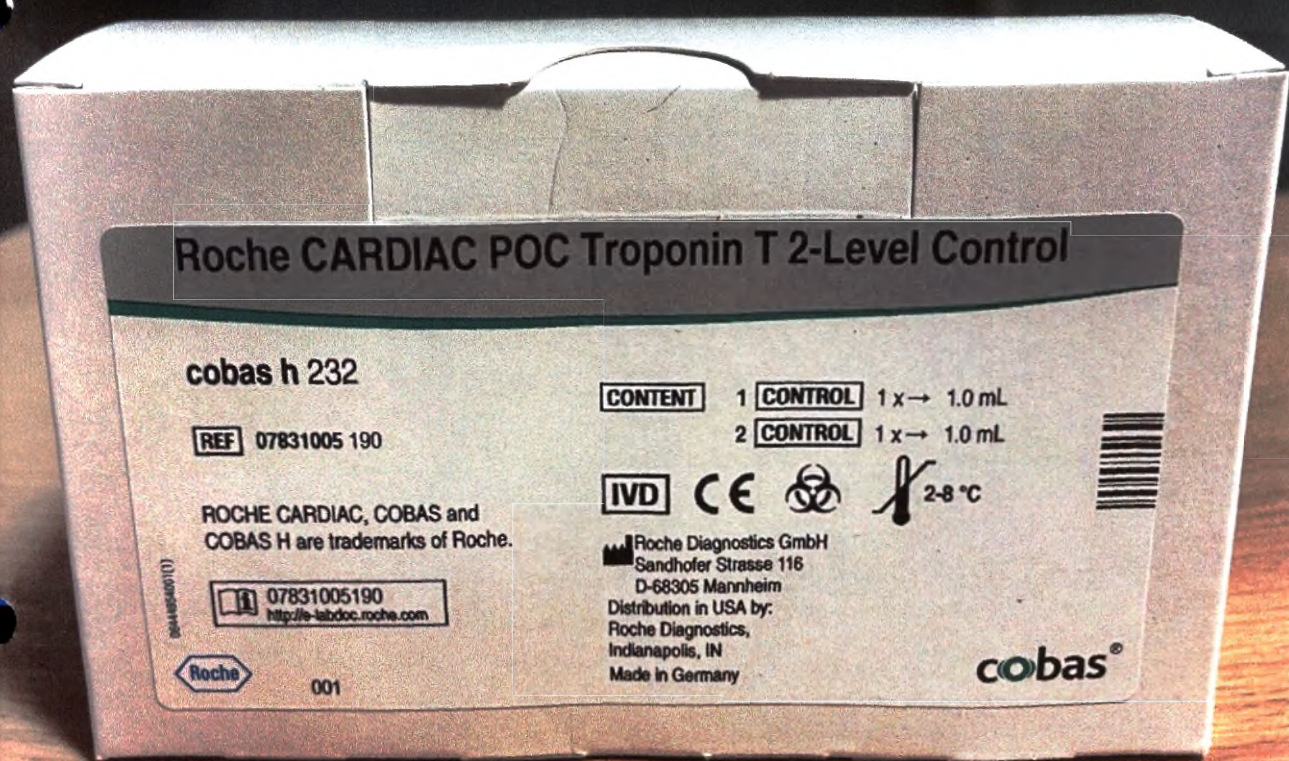


Фотографические изображения

**Набор контрольных материалов для контроля качества
количественного определения сердечного тропонина Т в крови на
экспресс-анализаторе иммунохимическом «Кобас h 232» (Cobas h 232)
(Roche CARDIAC POC Troponin T 2-Level Control cobas h 232)**

Набор контрольных материалов для контроля качества количественного определения сердечного тропонина Т в крови на экспресс-анализаторе иммунохимическом «Кобас h 232» (Cobas h 232) (Roche CARDIAC POC Troponin T 2-Level Control cobas h 232)



лабор контрольных материалов для контроля качества количественного
пределения сердечного тропонина Т в крови на экспресс-анализаторе
иммунохимическом «Кобас h 232» (Cobas h 232) (Roche CARDIAC POC Troponin T 2-
level Control cobas h 232)



Набор контрольных материалов для контроля качества количественного определения сердечного тропонина Т в крови на экспресс-анализаторе иммунохимическом «Кобас h 232» (Cobas h 232) (Roche CARDIAC POC Troponin T 2-Level Control cobas h 232)

Набор контрольных материалов для контроля качества количественного определения сердечного тропонина Т в крови на экспресс-анализаторе иммунохимическом «Кобас h 232» (Cobas h 232) (Roche CARDIAC POC Troponin T 2-Level Control cobas h 232), в составе:

1. Материал контрольный, уровень 1 (Roche CARDIAC POC Troponin T 2-Level Control Level 1), флакон, объем 1,0 мл, 1 шт.;
2. Материал контрольный, уровень 2 (Roche CARDIAC POC Troponin T 2-Level Control Level 2), флакон, объем 1,0 мл, 1 шт.;
3. Чип с кодом — 1 шт.;
4. Инструкция по применению.

Регистрационное удостоверение № _____ от _____



H317

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» ("Рох Диалогистикс ГмбХ"),

Bendhofer Strasse 116, 68305 Mannheim, Germany, Германия

Изделие предназначено только для диагностики in-vitro

Уполномоченный представитель производителя на территории РФ:

Общество с ограниченной ответственностью «Рох Диалогистикс Рус» (ООО

«Рох Диалогистикс Рус»), 107031, Москва, Трубная площадь, д. 2 Тел: +7 495

229-69-99, факс: +7 495 229-62-64. E-mail: moscow.reception_da@roche.com

Кат. номер 07831005190

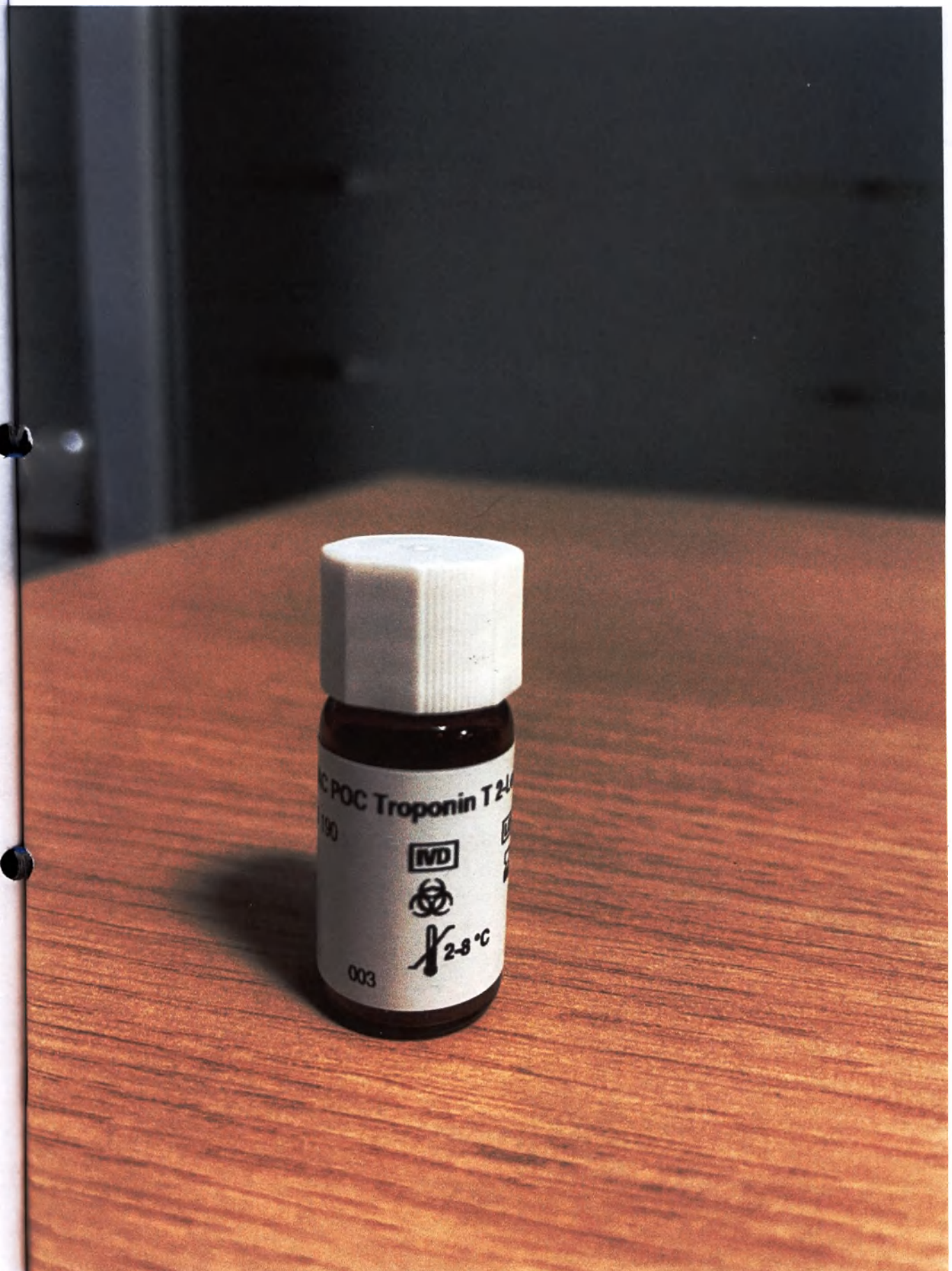
Набор контрольных материалов для контроля качества количественного определения сердечного тропонина Т в крови на экспресс-анализаторе иммунохимическом «Кобас h 232» (Cobas h 232) (Roche CARDIAC POC Troponin T 2-Level Control cobas h 232)



Материал контрольный, уровень 1 (Roche CARDIAC POC Troponin T 2-Level Control Level 1), флакон, объем 1,0 мл



Материал контрольный, уровень 1 (Roche CARDIAC POC Troponin T 2-Level Control Level 1), флакон, объем 1,0 мл



Материал контрольный, уровень 1 (Roche CARDIAC POC Troponin T 2-Level Control Level 1), флакон, объем 1,0 мл



Материал контрольный, уровень 2 (Roche CARDIAC POC Troponin T 2-Level Control Level 2), флакон, объем 1,0 мл



Материал контрольный, уровень 2 (Roche CARDIAC POC Troponin T 2-Level Control Level 2), флакон, объем 1,0 мл



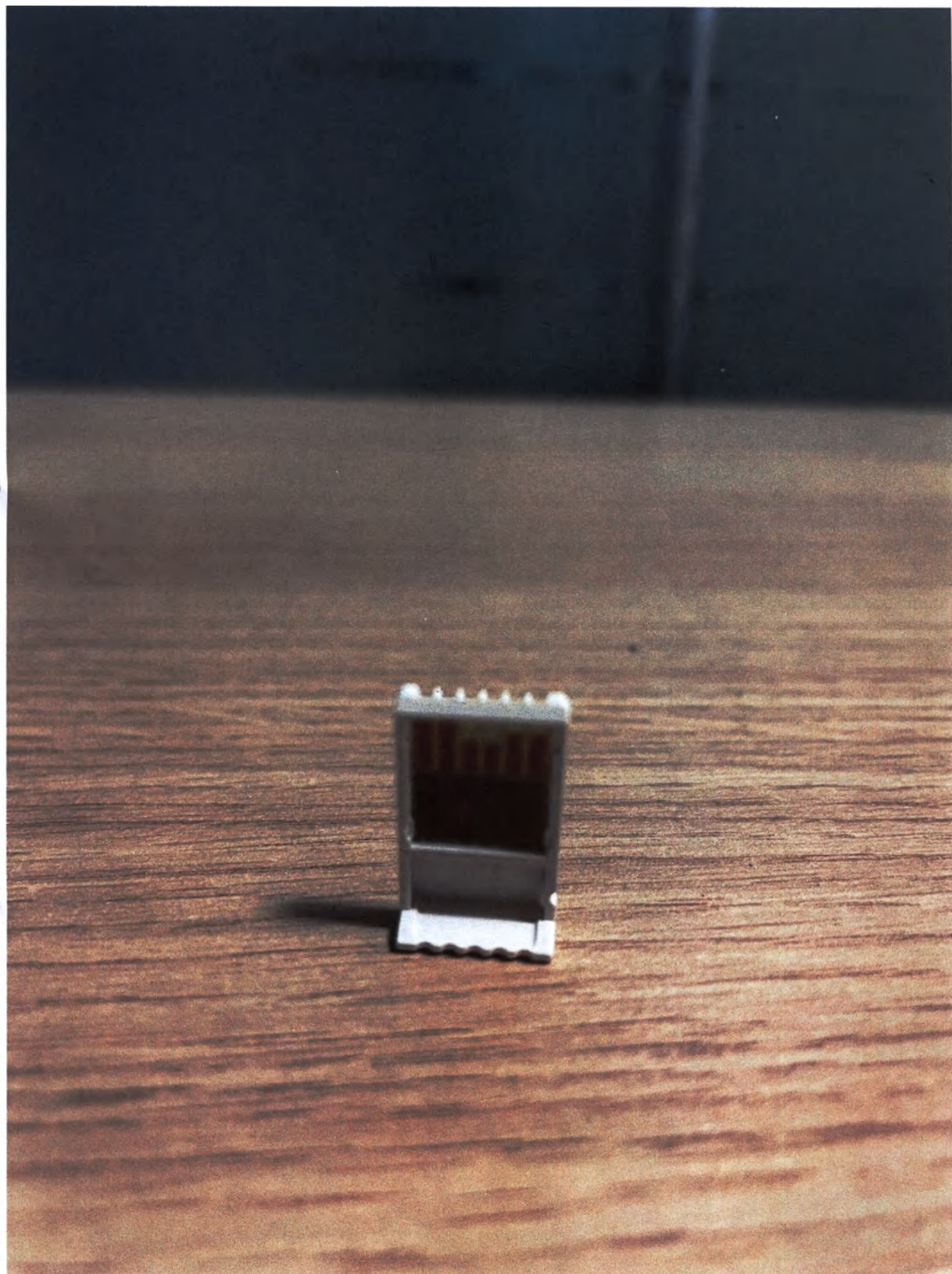
Материал контрольный, уровень 2 (Roche CARDIAC POC Troponin T 2-Level Control Level 2), флакон, объем 1,0 мл



Чип с кодом



Чип с кодом





078310001V2.0

CARDIAC POC Troponin T Control cobas®

Roche CARDIAC POC Troponin T 2-Level Control

REF 07831005 190

2 x → 1.0 mL

SYSTEM cobas h 232

English

Intended use

The Roche CARDIAC POC Troponin T 2-Level Control is used for quality control of the Roche CARDIAC POC Troponin T test on the cobas h 232 instrument.

Summary

The Roche CARDIAC POC Troponin T 2-Level Control is used for accuracy and precision control. Each Roche CARDIAC POC Troponin T 2-Level Control kit consists of two lyophilized controls based on human serum. Level I does not contain troponin T and serves as negative control. Level II contains a slightly elevated troponin T concentration.

Reagents - working solutions

- Level I: 1 bottle lyophilized control serum, for 1.0 mL
- Level II: 1 bottle lyophilized control serum, for 1.0 mL
- Human serum-based solution containing constituents of human origin
- Active ingredients: bovine troponin T

The concentrations of the components are lot-specific.

The exact target values and concentration ranges of the components are given in the code chip provided.

Precautions and warnings

For in vitro diagnostic use.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines. Safety data sheet available for professional user on request.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

2-methyl-2H-isothiazol-3-one hydrochloride.

EUH208 May produce an allergic reaction.

Product safety labeling follows EU GHS guidance.

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 used assays approved by the FDA or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.

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

Carefully dissolve the contents of one bottle by adding exactly 1.0 mL of distilled or deionized water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding foam formation.

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 serum:

- at 15-25 °C: up to 24 hours
 - at 2-8 °C: 3 days
 - at -20 °C: 8 weeks (can be frozen 4 times in the original vial)
- Store the controls tightly capped when not in use.

Materials provided

- Roche CARDIAC POC Troponin T 2-Level Control, Level I
- Roche CARDIAC POC Troponin T 2-Level Control, Level II
- 1 code chip

Materials required (but not provided)

- REF 07831002 190: Roche CARDIAC POC Troponin T

- REF 11622889 190, Roche CARDIAC Pipettes, 20 disposable syringes (150 µL)
- REF 04901126 190, cobas h 232 instrument, software version ≥ 09.00.02, serial number ≥ K00120000
- REF 04901142 190, cobas h 232 instrument with scanner, software version ≥ 09.00.02, serial number ≥ K50210000
- Distilled or deionized water
- General laboratory equipment

Assay

Dispense the required volume into the sample area of the Roche CARDIAC POC Troponin T test and analyze in the same way as a whole blood sample.

Sample volume: 150 µL.

Follow the test instructions in the Method Sheet of the Roche CARDIAC POC Troponin T test.

Frozen or refrigerated reconstituted control material must be brought to room temperature prior to use.

Target values and ranges

Target value determination procedure: Series with a significant number of determinations run on different cobas h 232 instruments.

The median is calculated as the target value.

The corresponding control range is based on 95 % confidence level.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Calibration

Each Roche CARDIAC POC Troponin T 2-Level Control kit contains a lot-specific code chip.

The code chip must be read into the instrument once for each new lot. The request to insert this code chip is made via the instrument's display. Correct assignment of code chip and control lot can be checked by comparing the lot number in the display with the imprint on the code chip. The code chip provides the cobas h 232 instrument with all lot-specific information and target value ranges necessary for evaluation. An error flag appears if the wrong code chip is inserted for the control lot in question.

Calibration interval may be extended based on acceptable verification of calibration by the laboratory.

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.

For further information, please refer to the appropriate operator's manual for the instrument concerned, and the Method Sheets of all necessary components.

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.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see <https://usdiagnostics.roche.com> for definition of symbols used):

CONTENT

Contents of kit

SYSTEM

Analyzers/instruments on which reagents can be used

→

Volume after reconstitution or mixing

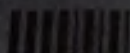
GTIN

Global Trade Item Number

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All other product names and trademarks are the property of their respective owners.

Additions, deletions or changes are indicated by a change bar in the margin.



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

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по доверенности
от 04.02.2021