04923570001V4.0

Roche CARDIAC Control D-Dimer

cobas®

REF 04890523190 | 2 x → 1.0 mL | SYSTEM **cobas h** 232

English

Intended use

The Roche CARDIAC Control D-Dimer is used with the Roche CARDIAC D-Dimer test for quality control testing on the **cobas h** 232 instrument.

The Roche CARDIAC Control D-Dimer is intended for near-patient testing.

Not for self-testing.

Summary

The Roche CARDIAC Control D-Dimer quality control is used for accuracy and precision control. Each Roche CARDIAC Control D-Dimer kit consists of two lyophilized controls based on human serum. The concentration of D-Dimer in level I is in the low concentration range. Level II contains an elevated D-Dimer 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
- Active ingredients: fragments containing human D-Dimer

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 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.

Product safety labeling follows EU GHS guidance.

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

Handling

Carefully and fully 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 at room temperature to reconstitute. Mix carefully by inverting the bottle minimum 5 times, 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: 24 hours
- at 2-8 °C: 3 days
- at -20 °C: 6 weeks (can be frozen up to 5 times in the original vial)

Store the controls tightly capped when not in use.

Materials provided

- Roche CARDIAC Control D-Dimer, level I
- Roche CARDIAC Control D-Dimer, level II
- 1 code chip

Materials required (but not provided)

- REF 04877802190, REF 04877802191 Roche CARDIAC D-Dimer
- REF 11622889190, Roche CARDIAC Pipettes, 20 disposable syringes, 150 µL (or other suitable pipettes with pipetting volume of 150 µL)
- REF 04901126xxx **cobas h** 232 instrument
- REF 04901142xxx **cobas h** 232 instrument with scanner
- General laboratory equipment
- Distilled or deionized water

Assay

Dispense the required volume into the sample area of the Roche CARDIAC D-Dimer 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 D-Dimer 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 mean of upper and lower target range 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.

Lot encoding

Each Roche CARDIAC Control D-Dimer 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.

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 Operators 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.

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.

The Summary of Safety & Performance Report can be found here:
https://ec.europa.eu/tools/eudamed

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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):



Device for near-patient testing



Device not for self-testing.

SYSTEM — Analyzers/Instruments on which reagents can be used

GTIN — Global Trade Item Number

UDI — Unique Device Identifier

PZN — Pharmazentralnummer (for Germany only)

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Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com
+800 5505 6606

Roche