



04923588001 V3.0

Roche CARDIAC Control proBNP

cobas[®]

REF 04890493 190

2 x → 1.0 mL

SYSTEM cobas h 232

English

Intended use

Roche CARDIAC Control proBNP is used for quality control of the Roche CARDIAC proBNP+ test on the **cobas h 232** instrument.

Summary

The Roche CARDIAC Control proBNP quality control is used for accuracy and precision control. Each Roche CARDIAC Control proBNP kit consists of two lyophilized controls based on equine serum. The concentration of proBNP in level I is in the slightly elevated range. Level II contains a highly elevated proBNP 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: synthetic NT-proBNP (1-76)

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.

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 2-25 °C: 24 hours
- at and below -20 °C: 12 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 proBNP, level I
- Roche CARDIAC Control proBNP, level II
- 1 code chip

Materials required (but not provided)

- REF 05533643190, Roche CARDIAC proBNP+ test
- REF 11622889190, Roche CARDIAC Pipettes, 20 disposable syringes (150 µL)
- **cobas h 232** instrument
- General laboratory equipment
- Distilled or deionized water

Assay

Dispense the required volume into the sample area of the Roche CARDIAC proBNP 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 proBNP 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 99.9 % 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 proBNP 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.

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.

SYSTEM

Analyzers/Instruments on which reagents can be used



Volume after reconstitution or mixing

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Significant additions or changes are indicated by a change bar in the margin.

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