04988566001V8.0

PreciControl Cardiac II

cobas®

REF **04917049** 190 → **4 x 2.0 mL**

REF **04917049** 922 (QCS)

English

Intended use

PreciControl Cardiac II is used for quality control of specified immunoassays on the Elecsys and **cobas e** immunoassay analyzers.

Summary

PreciControl Cardiac II is a lyophilized control serum based on human serum in two concentration ranges. The controls are used for monitoring the accuracy and precision of the Elecsys CK-MB, CK-MB STAT, Digitoxin, Digoxin, Myoglobin, Myoglobin STAT, proBNP II and proBNP II STAT immunoassays.

Reagents - working solutions

- PC CARD1: 2 bottles, each for 2.0 mL of control serum
- PC CARD2: 2 bottles, each for 2.0 mL of control serum

Substance in human serum matrix	PC CARD1 ng/mL	PC CARD2 ng/mL
CK-MB (human)	approx. 5	approx. 50
Digitoxin	approx. 17	approx. 38
Digoxin	approx. 1.2	approx. 3
Myoglobin (human)	approx. 80	approx. 1000
NT-proBNP 1-76 (synthetic)	approx. 0.15	approx. 5

The exact lot-specific target values and ranges are encoded in the barcodes as well as printed on the enclosed (or electronically available) value sheet.

Target values and ranges

The target values and ranges were determined and evaluated by Roche. They were obtained using the Elecsys assay reagents and analyzers available at the time of testing.

If the target values and control ranges are updated, this information is conveyed either via the reagent barcodes, or control barcodes (or provided electronically) and in an additional value sheet included in the reagent kit. This value sheet lists all control lots to which the new values apply. If some of the values remain unchanged, the original values conveyed via the CBC (Control Barcode), and in the value sheet included in the control kit (or provided electronically), remain valid.

Results must be within the specified ranges. In the event that increasing or decreasing trends, or any other suddenly occurring deviations beyond the range limits are observed, all test steps must be checked.

Traceability information is given in the Method Sheet of the relevant Elecsys assay.

Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

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.

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 applied were FDA-approved 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]

Avoid foam formation in all reagents and sample types (specimens, calibrators and controls).

Handling

Carefully dissolve the contents of one bottle by adding exactly 2.0 mL of distilled or deionized water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding foam formation.

Freeze aliquots immediately.

Transfer the reconstituted controls into the empty labeled snap-cap bottles supplied, or freeze aliquots immediately in additional snap-cap bottles (ControlSet Vials). Attach the supplied labels to these additional bottles.

Storage and stability

Store at 2-8 °C.

The lyophilized control serum is stable up to the stated expiration date.

Stability of the components in the reconstituted control serum:	
on the analyzers at 20-25 °C	up to 3 hours
at 2-8 °C	3 days
at -20 °C	3 months (freeze only once)
after thawing	use only once

Store controls **upright** in order to prevent the control solution from adhering to the snap-cap.

Materials provided

- PreciControl Cardiac II, 2 barcode cards, control barcode sheet, 2 x 2 empty labeled snap-cap bottles, 2 x 6 bottle labels

Materials required (but not provided)

- REF 03142949122, ControlSet Vials, 2 x 56 empty snap-cap bottles
- Elecsys 2010, MODULAR ANALYTICS E170 or **cobas e** immunoassay analyzers and assay reagents
- Distilled or deionized water

See the appropriate assay Method Sheet and the operator's manual for additionally required material.

Assay

Treat the reconstituted control serum in the system-compatible labeled bottles for analysis in the same way as patient samples.

Read the data into the analyzer.

Ensure the controls are at 20-25 °C prior to measurement.

Run controls daily in parallel with patient samples, once per reagent kit, and whenever a calibration is performed. The control intervals and limits should be adapted to each laboratory's individual requirements.

Follow the applicable government regulations and local guidelines for quality control.

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 analyzer concerned, the respective application sheets, the product information and the Method Sheets of all necessary components (if available in your country).

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.

CONTENT	Contents of kit
SYSTEM	Analyzers/Instruments on which reagents can be used
REAGENT	Reagent

PreciControl Cardiac II

cobas®

CALIBRATOR Calibrator

Volume after reconstitution or mixing

CE

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Roche