

PreciControl MultiAnalyte

REF 03609979 190

for 4 x 2.0 mL

REF 03609979 922 (QCS)

English

Intended use

Elecsys PreciControl MultiAnalyte is used for quality control of the Elecsys C-Peptide and Elecsys Insulin immunoassays on the Elecsys and **cobas e** immunoassay analyzers.

Summary

Elecsys PreciControl MultiAnalyte contains lyophilized control serum based on an equine serum matrix in two concentration ranges. The controls are used for monitoring the accuracy and precision of Elecsys C-Peptide and Elecsys Insulin immunoassays.

Reagents - working solutions

- PC MA1: 2 bottles, each for 2.0 mL of control serum
- PC MA2: 2 bottles, each for 2.0 mL of control serum

Substance in equine serum matrix	PC MA1	PC MA2
C-peptide (synthetic)	approx. 0.667 nmol/L (2 ng/mL)	approx. 3.33 nmol/L (10 ng/mL)
Insulin (human, recombinant from yeast)	approx. 139 pmol/L (20 µU/mL)	approx. 695 pmol/L (100 µU/mL)

The exact 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.

If the target values and control ranges are updated at a later time, this information is conveyed either via the reagent barcodes or control barcodes (or provided electronically) and on 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 on the value sheet included in the control kit (or provided electronically), continue to be valid.

Results must be within the corresponding specified ranges. All test steps must be checked when increasing or decreasing trends or suddenly occurring deviations beyond the range limits are seen.

Traceability information is given in the package inserts of the respective Elecsys assay.

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

Avoid the formation of foam with all reagents and sample types (specimens, calibrators, and controls).

Handling

Dissolve carefully 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 the formation of foam.

Transfer the reconstituted control 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 bottles.

Perform **only one** control procedure per aliquot.

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 -20 °C	1 month (freeze only once)
after thawing	use only once

Materials provided

- Elecsys PreciControl MultiAnalyte, 2 barcode cards, control barcode sheet, 2 x 2 labeled empty 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. See appropriate test package insert and operator's manual for additionally required materials.
- Distilled or deionized water

Assay

For use on the analyzers, treat the reconstituted control serum in the system-compatible labeled bottles for analysis in the same way as the patient samples. Read the data encoded in the barcoded bottle labels and barcodes into the analyzer.

Ensure the controls are at ambient temperature (20-25 °C) before measurement.

Run controls daily in parallel with patient samples, once per reagent kit, and whenever 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.

For further information, please refer to the appropriate operator's manual for the analyzer concerned, the respective application sheets, the product information, and the package inserts of all necessary components.

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