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PreciControl Everolimus

cobas®

REF **07294131** 190 → **3 x 3.0 mL**

English

Intended use

PreciControl Everolimus is used for quality control of the Elecsys Everolimus immunoassay on the Elecsys and **cobas e** immunoassay analyzers.

Summary

PreciControl Everolimus is a lyophilized control based on human blood in three concentration ranges. The controls are used for monitoring the accuracy and precision of the Elecsys Everolimus immunoassay.

Reagents - working solutions

- PC EVL 1: 1 bottle, for 3.0 mL of control blood
- PC EVL 2: 1 bottle, for 3.0 mL of control blood
- PC EVL 3: 1 bottle, for 3.0 mL of control blood

Substance in human blood; preservative	PC EVL 1	PC EVL 2	PC EVL 3
Everolimus	approximately 3.5 ng/mL	approximately 10 ng/mL	approximately 18 ng/mL

Note: The controls are not barcode-labeled and therefore have to be run like external controls. All values and ranges have to be entered manually. Please refer to the section "QC" in the operator's manual or to the online help of the instrument software.

Non-barcode labeled controls: Only one target value and range for each control level can be entered in the analyzer. The reagent lot-specific target values have to be re-entered each time a specific reagent lot with different control target values and ranges is used. Two reagent lots with different control target values and ranges cannot be used in parallel in the same run.

The exact lot-specific target values and ranges are printed on the enclosed (or electronically available) value sheet in the reagent kit or PreciControl kit.

Please make sure that the correct values are used.

Target values and ranges

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

If the target values and control ranges are updated, this information is conveyed 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 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]

The controls may not be used after the expiration date.

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

Handling

Carefully dissolve the contents of one bottle by adding exactly 3.0 mL of distilled or deionized water and allow to reconstitute closed for 30 minutes by permanent gentle agitation with a rotator until complete solution is obtained, avoiding foam formation.

Transfer aliquots (300 µL) of the reconstituted control into 2.0 mL microcentrifuge tubes. Aliquots intended for storage at -20 °C should be frozen immediately.

For each quality control procedure the aliquots must be pretreated following the pretreatment procedure given in the Elecsys Everolimus Method Sheet. Transfer the supernatant into an empty labeled snap-cap bottle (ControlSet Vial).

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

Storage and stability

Store at 2-8 °C.

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

Stability of the reconstituted controls:	
either at -20 °C	28 days (freeze only once)
or at 2-8 °C	7 days
or at 20-25 °C	5 days

Stability of the pretreated controls:	
Closed tube at 20-25 °C	4 hours
on the analyzers	up to 30 minutes (use only once)

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

Materials provided

- PreciControl Everolimus

Materials required (but not provided)

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

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

Assay

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

For pretreatment procedure refer to the respective section in the assay Method Sheet.

Treat the pretreated controls in the system-compatible labeled bottles for analysis in the same way as patient samples.

The control values and ranges must be entered manually. Please refer to the corresponding section in the operator's manual.

Ensure the pretreated controls are analyzed/measured within 30 minutes.

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

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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
CALIBRATOR	Calibrator
→	Volume after reconstitution or mixing
GTIN	Global Trade Item Number

CE

Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com