06323219001V3.0

PreciControl Toxo IgG Avidity

cobas®

REF **05802580** 190 **6 x 2.0 mL**

English

Intended use

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

Summary

PreciControl Toxo IgG Avidity is a ready-for-use control serum based on human serum. The controls are used for verification of correctly performed dilution and of functionality of the Diluent Toxo Avidity (DilToxoAv).

Reagents - working solutions

- PC TOXO-Av1: 3 bottles, each containing 2.0 mL of control serum

  Human serum, positive for Toxo IgG antibodies, low avidity (avidity < 70 %); preservative.

- PC TOXO-Av2: 3 bottles, each containing 2.0 mL of control serum

  Human serum, positive for Toxo IgG antibodies, high avidity (avidity ≥ 80 %); preservative.

Note: The controls are not barcode-labeled and must be treated as patient samples according to the "Assay" section of this document, or the Elecsys Toxo IgG Avidity assay Method Sheet.

Controls must not be defined as external controls.

Target values and ranges

- Verification of correctly performed 1:2 dilution:
  The target values and ranges (IU/mL) of the PreciControl Toxo IgG Avidity diluted 1:2 with Diluent Universal were determined and evaluated by Roche. They were obtained using the Elecsys Toxo IgG Avidity assay reagents and analyzers available at the time of testing. The control values obtained during testing must be within the control ranges (IU/mL) stated in the value sheet. The exact lot-specific target values and ranges are printed on the enclosed (or electronically available) value sheet.
- Verification of functionality of the Diluent Toxo Avidity (DilToxoAv):
  The avidity (Avi%) is calculated from the reference measurement and the DilToxoAv-treated measurement according to the "Assay" section of this document. The target range for the manually calculated avidity result (Avi%) of PreciControl Toxo IgG Avidity 1 is < 70 Avi%, while the respective range for PreciControl Toxo IgG Avidity 2 is ≥ 80 Avi%.

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

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.

When necessary, measurement of the patient sample tested should be repeated.

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 sera containing anti-Toxo IgG (PC TOXO-Av1, PC TOXO-Av2) were sterile filtrated.

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

The controls are supplied ready-for-use. Before measurement on the analyzer each control level needs to be prepared according to the "Assay" section of this document. Due to possible evaporation effects, the diluted control aliquots should be measured **only once**. When measuring a non-barcoded control, use only recommended sample tubes, cup on tube or cup on rack.

Storage and stability

Store at 2-8 °C.

Store controls **upright**.

Stability:	
unopened at 2-8 °C	up to the stated expiration date
after opening at 2-8 °C	8 weeks
on bench at 20-25 °C	5 weeks if stored alternately in the refrigerator and on bench (up to 5 hours)

Materials provided

- PreciControl Toxo IgG Avidity

Materials required (but not provided)

- REF 10394246001, 20 x 250 sample cups, needed for the manual dilution step
- REF 11732277122, Diluent Universal, 2 x 16 mL sample diluent or REF 03183971122, Diluent Universal, 2 x 36 mL sample diluent
- Elecsys 2010, MODULAR ANALYTICS E170 or **cobas e** immunoassay analyzers and assay reagents

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

Assay

Treat the control serum in the same way as patient samples.

Prepare two aliquots of each control level.

Dilute one aliquot of the control 1:2 with Diluent Universal (1 Vol. sample + 1 Vol. DilUni) and mix the diluted aliquot gently by pipetting the mixture up and down once. Dilute the second aliquot of the control 1:2 with Diluent Toxo Avidity (1 Vol. sample + 1 Vol. DilToxoAv) and mix as described above. Allow both aliquots to stand for at least 10 minutes at ambient temperature (20-25 °C) before placing into the analyzer. Measure both aliquots with the Elecsys Toxo IgG Avidity assay. Complete all determinations on the analyzer within 1 hour of preparing the dilutions. To calculate the avidity (Avi%) please use the formula given in the Method Sheet for the Elecsys Toxo IgG Avidity assay.

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.

PreciControl Toxo IgG Avidity

cobas®

CONTENT	Contents of kit
SYSTEM	Analyzers/Instruments on which reagents can be used
REAGENT	Reagent
CALIBRATOR	Calibrator
→	Volume after reconstitution or mixing

CE 0123

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