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PreciControl CMV IgG Avidity

cobas®

REF **05942322** 190 → **6 x 1.0 mL**

English

Intended use

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

Summary

PreciControl CMV IgG Avidity is a lyophilized control serum based on human serum. The controls are used for monitoring the accuracy and functionality of the Elecsys CMV IgG Avidity immunoassay.

Reagents - working solutions

- PC CMV-Av1: 3 bottles, each for 1.0 mL of control serum

  Human serum, positive for CMV IgG antibodies, low avidity (approximately 4.0 U/mL; avidity < 45.0 %); preservative.

- PC CMV-Av2: 3 bottles, each for 1.0 mL of control serum

  Human serum, positive for CMV IgG antibodies, high avidity (approximately 25.0 U/mL; avidity ≥ 55.0 %); preservative.

Note: The controls are not barcode-labeled and have to be treated as patient samples.

Controls must not be defined as external controls, as dilution of controls is not possible on the analyzers.

Target values and ranges

- Verification of calibration:

  The target values and ranges (U/mL) of the reference measurement were determined and evaluated by Roche. They were obtained using the Elecsys CMV IgG Avidity assay reagents and analyzers available at the time of testing. The reference measurements of the controls have to be recovered within the control ranges (U/mL) as stated in the value sheet. The control values have to be compared manually to the CMV IgG ranges (U/mL) given in the value sheet. The exact lot-specific target values and ranges are printed on the enclosed (or electronically available) value sheet.

- Verification of the functionality of the Diluent Avidity (DilCMVAv):

  The avidity (Avi%) is calculated from the reference measurement and the DilCMVAv treated measurement according to the “Calculation” section of the respective Elecsys assay. The target range for the manually calculated avidity result (Avi%) of PreciControl CMV IgG Avidity 1 is < 45.0 Avi%, while the respective range for PreciControl CMV IgG Avidity 2 is ≥ 55.0 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.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

2-methyl-2H-isothiazol-3-one hydrochloride

EUH 208 May produce an allergic reaction.

Product safety labeling primarily follows EU GHS guidance.

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-CMV IgG (PC CMV-Av1, PC CMV-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]

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 1.0 mL of distilled or deionized water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding foam formation.

Transfer the reconstituted controls into the empty labeled snap-cap bottles supplied. Aliquots intended for storage at -20 °C should be frozen immediately.

The controls should only be left on the analyzer during performance of quality control. After use, close the bottles as soon as possible and store upright at 2-8 °C.

When measuring non-barcoded controls, use only recommended sample tubes, “cup on tube” or “cup on rack”.

Due to possible evaporation effects, not more than 5 quality control procedures per bottle should be performed.

Storage and stability

Store at 2-8 °C.

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

Stability of the reconstituted control serum:	
either at -20 °C	12 weeks (3 freeze/thaw cycles possible)
or at 2-8 °C	4 weeks
on the analyzers at 20-25 °C	up to 5 hours

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

Materials provided

- PreciControl CMV IgG Avidity, 2 x 3 empty labeled snap-cap bottles, 2 x 6 bottle labels

Materials required (but not provided)

- 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 materials.

Assay

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

Prepare two aliquots of each control level for the reference measurement and the DilCMVAv treated measurement.

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.

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

CE 0123

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