



05199441001V2.0

# PreciControl CMV IgG

**cobas®**

REF 04784600 190

16 x 1.0 mL

## English

### Intended use

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

### Summary

PreciControl CMV IgG is a ready-for-use control serum based on human serum. The controls are used for monitoring the accuracy of the Elecsys CMV IgG immunoassay.

### Reagents - working solutions

- PC CMVIGG1: 8 bottles, each containing 1.0 mL of control serum  
Human serum, low positive for CMV IgG antibodies (approximately 1.5 U/mL); preservative.
- PC CMVIGG2: 8 bottles, each containing 1.0 mL of control serum  
Human serum, positive for CMV IgG antibodies (approximately 25 U/mL); preservative.

Note: The controls are not barcode-labeled and therefore the controls must run on all instruments as non-Roche controls. The control values and ranges have to be entered manually. Please refer to the corresponding section in the operator's manual.

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

Non-Roche controls: For 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 when 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. Always consider the value sheet included in the reagent kit or PreciControl kit (or electronically available) to 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 CMV IgG assay reagents and analyzers available at the time of testing.

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-CMV IgG (PC CMVIGG1, PC CMVIGG2) were sterile filtered.

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.<sup>1,2</sup>

The controls may not be used after the expiration date.

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

## Handling

The controls are supplied ready-for-use in bottles compatible with the system.

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

Elecsys 2010 and **cobas e** 411 analyzers: The original control vials may be used if the entire provided volume is used and no aliquots are prepared.

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.

Due to possible evaporation effects, not more than 7 quality control procedures per bottle should be performed.

## Storage and stability

Store at 2-8 °C.

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

Stability:	
unopened at 2-8 °C	up to the stated expiration date
after opening at 2-8 °C	8 weeks
on the analyzers	up to 5 hours

## Materials provided

- PreciControl CMV IgG

## 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 material.

## Assay

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

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

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

- Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.
- 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
CALIBRATOR	Calibrator



# PreciControl CMV IgG

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Volume after reconstitution or mixing

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