

PreciControl Anti-HBc IgM

cobas®

REF 11876333 122

16 x 1.0 mL

English

Intended use

PreciControl Anti-HBc IgM is used for quality control of the Elecsys Anti-HBc IgM immunoassay on the Elecsys and **cobas e** immunoassay analyzers.

Summary

PreciControl Anti-HBc IgM is a ready-for-use control serum based on human serum both in the negative and positive concentration range. The controls are used for monitoring the accuracy of the Elecsys Anti-HBc IgM immunoassay.

Reagents - working solutions

- PC A-HBCIGM1: 8 bottles, each containing 1.0 mL of control serum Human serum, negative for anti-HBc IgM; preservative.

Target range for the cutoff index:

0-0.3 for Elecsys 2010 and **cobas e** 411 analyzers

0-0.2 for MODULAR ANALYTICS E170 and **cobas e** 601 analyzers

- PC A-HBCIGM2: 8 bottles, each containing 1.0 mL of control serum Anti-HBc IgM antibodies (human) > 130 U/mL (Paul-Ehrlich-Institute units) in human serum; preservative.

Target range for the cutoff index: 1.1-2.5

The target ranges, given in the form of a cutoff index (COI), 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 Anti-HBc IgM 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.

Note:

For technical reasons re-assigned target values valid only for a specific reagent and control lot combination, must be entered manually on all analyzers (except for the **cobas e** 602 analyzer). Therefore always refer to the value sheet included in the reagent kit or PreciControl kit to make sure that the correct target values are used.

When a new reagent or control lot is used, the analyzer will use the original values encoded in the control barcodes.

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.

PC A-HBCIGM1 has been 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.

Materials of human origin used for the positive control (PC A-HBCIGM2) were tested for HIV and hepatitis C infections. The findings were negative. The serum containing anti-HBc IgM was inactivated using β -propiolactone and UV-radiation.

However, as no inactivation or 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

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

Please note: Both the vial labels, and the additional labels (if available) contain 2 different barcodes. The barcode between the yellow markers is for **cobas** 8000 systems only. If using a **cobas** 8000 system, please turn the vial cap 180° into the correct position so the barcode can be read by the system. Place the vial on the instrument as usual.

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 at 20-25 °C	up to 6 hours

Materials provided

- PreciControl Anti-HBc IgM, 2 barcode cards, control barcode sheet

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 control serum in the system-compatible labeled bottles for analysis in the same way as patient samples.

Read the data into the analyzer.

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

PreciControl Anti-HBc IgM

cobas®

CALIBRATOR

Calibrator



Volume after reconstitution or mixing

GTIN

Global Trade Item Number

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Significant additions or changes are indicated by a change bar in the margin.

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