ms_07143745190V2.0

PreciControl HBsAg II quant II

cobas®

REF **07143745** 190 **15 x 1.3 mL**

English

Intended use

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

Summary

PreciControl HBsAg II quant II 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 HBsAg II quant II immunoassay.

Reagents - working solutions

- PC HBSAGQN1: 5 bottles, each containing 1.3 mL of control serum HBsAg (human) in human serum; buffered, pH 6.5; preservative. Quantitative target value: approximately 3.75 IU/mL
- PC HBSAGQN2: 5 bottles, each containing 1.3 mL of control serum HBsAg (human) in human serum; buffered, pH 6.5; preservative. Quantitative target value: approximately 90 IU/mL
- PC HBSAGQN3 (dilution control)[a]: 5 bottles, each containing 1.3 mL of control serum HBsAg (human) in human serum; buffered, pH 6.5; preservative. Quantitative target value: approximately 90 IU/mL

Controls 1, 2 and 3 are not barcode-labeled. All values and ranges must be entered manually. Please refer to the "QC" section in the operator`s manual or to the online help for the instrument software.
PC HBSAGQN1 and PC HBSAGQN2 must be run like external controls.
PC HBSAGQN3 (dilution control) must be run as a patient sample in order to request an automatic dilution.
PC HBSAGQN2 must be run before PC HBSAGQN1 and PC HBSAGQN3 (dilution control).
PC HBSAGQN3 will be measured on only one measuring cell (MODULAR ANALYTICS E170, **cobas e** 601, **cobas e** 602) and printed in the same way as a sample result. Results for PC HBSAGQN3 will not be printed on the QC chart. The diluent used for PC HBSAGQN3 is HBSAGQN2 Dil Hep B.

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.

a) used to control the automated onboard dilution

Target values and ranges

The target values and ranges were determined and evaluated by Roche. They were obtained using the Elecsys HBsAg II quant II 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.

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

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 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.

The serum containing HBsAg used for the controls (PC HBSAGQN1, PC HBSAGQN2, PC HBSAGQN3) was inactivated using ß-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.

When measuring non-barcoded 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 analyzers 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 5 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 at 20-25 °C	up to 5 hours

Materials provided

- PreciControl HBsAg II quant II

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.

The control values and ranges must 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

1 Occupational Safety and Health Standards: Bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.

PreciControl HBsAg II quant II

cobas®

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:

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

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

Roche