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PreciControl HBsAg II

cobas®

REF **04687876** 190 **16 x 1.3 mL**

English

Intended use

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

Summary

PreciControl HBsAg 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 and Elecsys HBsAg II quant immunoassays.

Reagents - working solutions

- PC HBSAGII1: 8 bottles, each containing 1.3 mL of control serum

  Human serum, negative for HBsAg; preservative.

  Target range for the cutoff index: 0.0-0.80

  Quantitative target range: 0.0-0.05 IU/mL
- PC HBSAGII2: 8 bottles, each containing 1.3 mL of control serum

  HBsAg (human) approximately 0.2 IU/mL in human serum; preservative.

  Target range for the cutoff index: 2.6-5.0

  Quantitative target value: approximately 0.16 IU/mL

cobas e 801 analyzer: The exact lot-specific target values and ranges are available as an electronic barcode and value sheet provided via the **cobas** link.
All other analyzers: The exact lot-specific target values and ranges are encoded in the barcodes as well as printed on the enclosed (or electronically available) value sheet.
Please note: The value sheets for the **cobas e** 801 analyzer are only available electronically via the **cobas** link.

Target values and ranges

The target values and ranges were determined and evaluated by Roche. They were obtained using the Elecsys HBsAg II and
Elecsys HBsAg II quant assay reagents and analyzers available at the time of testing.

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

cobas e 801 analyzer: Updated target values and ranges are available both as an electronic barcode and as a value sheet provided via the **cobas** link.

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.

Elecsys HBsAg II assay:

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 and **cobas e** 801 analyzers). Therefore always refer to the respective value sheet 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.

Elecsys HBsAg II quant assay:

If the target values and control ranges are updated, this information is conveyed either via the reagent barcodes, or control barcodes (or provided electronically) and 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 via the CBC (Control Barcode), and in the value sheet included in the control kit (or provided electronically), remain valid.

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 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 (PC HBSAGII1 only) and antibodies to HCV and HIV.

The testing methods used assays approved by the FDA or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.

The serum containing HBsAg used for the positive control (PC HBSAGII2) 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 for **cobas e** 602 and **cobas e** 801 analyzers: Both the vial labels, and the additional labels (if available) contain 2 different barcodes. Please turn the vial cap 180° into the correct position so that the barcode between the yellow markers can be read by the system. Place the vial on the analyzer 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 5 hours

Materials provided

- PreciControl HBsAg II, 2 barcode cards, control barcode sheet

Materials required (but not provided)

- **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.

PreciControl HBsAg II

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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 (for USA: see dialog.roche.com for definition of symbols used):

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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