PreciControl HBsAg Auto Confirm

cobas®

REF 08741107190 08741107500 **8 x 1.3 mL**

English

Intended use

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

Summary

PreciControl HBsAg Auto Confirm is a ready-for-use control based on human serum positive for hepatitis B surface antigen (HBsAg). The control is used for monitoring the functionality of the Elecsys HBsAg II Auto Confirm immunoassay.

Reagents - working solutions

- PC HBSAGAC: 8 bottles, each containing 1.3 mL of control serum HBsAg (human) approximately 0.2 IU/mL in human serum; preservative.

Note: The control will be handled automatically by the analyzer.

The exact lot-specific ranges are available as an electronic barcode and value sheet provided via the **cobas** link.

Target values and ranges

Verification of the functionality of the pretreatment reagents of the Elecsys HBsAg II Auto Confirm assay (PT1 and PT2):
The target ranges were determined and evaluated by Roche. They were obtained using the Elecsys HBsAg II Auto Confirm assay reagents and analyzers available at the time of testing.

The confirmation result (%) is calculated from the control measurement and the confirmatory measurement according to the "Calculation" section of the Elecsys HBsAg II Auto Confirm assay method sheet. The target range for the confirmation result of PreciControl HBsAg Auto Confirm is ≤ 60 %.

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

Updated target 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.

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:

Warning

H317 May cause an allergic skin reaction.

Prevention:

P261 Avoid breathing mist or vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves.

Response:

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

P501 Dispose of contents/container to an approved waste disposal plant.

Product safety labeling follows EU GHS guidance.

Contact phone: all countries: +49-621-7590

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 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 PC HBSAGAC 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 4 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 8 hours

Materials provided

- PreciControl HBsAg Auto Confirm

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.

References

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

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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 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 for reconstitution
GTIN	Global Trade Item Number

CE 0123

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