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PreciControl HBsAg Auto Confirm cobas®

REF 08741107162 **8 x 1.3 mL**

English

For use in the USA only

Intended use

PreciControl HBsAg Auto Confirm is used for quality control of the Elecsys HBsAg II Auto Confirm immunoassay on **cobas pro** serology solution.

Summary

PreciControl HBsAg Auto Confirm is a ready-for-use control based on human serum reactive 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 HBSAGCB: 8 vials, each containing 1.3 mL of control serum

  Human serum, reactive for HBsAg; preservative.
  Target range for the cuttoff index (COI): 1.0-6.0 (for reaction with control pretreatment PT2)

The exact lot-specific ranges, given in the form of a cutoff index (COI), 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 **cobas e** 801 analytical units.

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.

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 donor sample tested should be repeated.

Precautions and warnings

For in vitro diagnostic use. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:
Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:
Apply all relevant local disposal regulations to determine the safe disposal.

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: 1-866-744-6397

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 use assays that have been approved or cleared by the FDA or that are in compliance with the legal rules of the European Union (IVDR 2017/746/EU, IVDD 98/79/EC, Annex II, List A).

The serum containing HBsAg used for PC HBSAGCB 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 donor 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 vials compatible with the **cobas pro** serology solution.

The controls should only be left on the analytical unit during performance of quality control. After use, close the vials as soon as possible and store upright at 2-8 °C. The lid of the control vials should only be open while on the analytical unit.

Due to possible evaporation effects, not more than 4 quality control procedures per vial should be performed.

A control procedure is the process from the placement of the control vial in the sample input buffer of the instrument until the control vial is transported to the sample output buffer.

Storage and stability

Store at 2-8 °C.

The lyophilized control serum is stable up to the stated expiration date.

Store controls **upright** in order to prevent the control solution from adhering to the lid of vial.

Stability:

after opening at 2-8 °C	7 days
on the analytical unit at 20-25 °C	up to 5 hours

Materials provided

- PreciControl HBsAg Auto Confirm

Materials required (but not provided)

- The **cobas pro** serology solution is a combination of the **cobas pro** serology controller, **cobas pro** integrated solutions (**cobas e** 801 analytical units only) and applicable licensed or cleared donor screening assays.

See the assay Method Sheet and the user guide for additionally required materials.

Assay

Treat the control serum in the **cobas pro** serology solution-compatible labeled vials for analysis in the same way as donor samples.

Read the data into the analytical unit.

The control must be run individually at least once every 24 hours when the test is in use, once per **cobas e** pack, and following each calibration.

PreciControl HBsAg Auto Confirm cobas®

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 user guide for the analytical unit concerned, the respective application sheets and the Method Sheets of all necessary components (if available in your country).

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see navifyportal.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
Rx only	For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

FOR US CUSTOMERS ONLY: LIMITED WARRANTY

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

Additions, deletions or changes are indicated by a change bar in the margin.

For USA: Rx only

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