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PreciControl Release HBsAg II

cobas®

REF 09366717190 **16 x 1.3 mL**

English

For use in the USA only

Intended use

PreciControl Release HBsAg II is used to validate the **cobas pro** serology solution and to release sample results for the Elecsys HBsAg II immunoassay. The recovery of the release control within Roche specified limits ensures the specified sensitivity of the assay under customer site conditions. The release control is tested at user-defined intervals with a maximum span of every 300 samples or 350 determinations and must be tested in order to release the test results. For release control values that fall outside the defined limits, samples measured before a failed release control are flagged as invalid by the **cobas pro** serology controller and need to be repeated. Reactive results will not be invalidated by a failed release control and must be retested in duplicate.

Summary

PreciControl Release HBsAg II is a ready-for-use control serum based on human serum.

PreciControl Release HBsAg II must be tested in order to release the donor sample results.

Reagents - working solutions

- PC HBSAGR: 16 vials, each containing 1.3 mL of control serum
  Human serum, reactive for HBsAg; preservative.
  Target range for the cutoff index (COI): 2.6-5.0

The exact lot-specific target values and 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

The target values and ranges were determined and evaluated by Roche. They were obtained using the Elecsys HBsAg II assay reagents and **cobas e** 801 analytical units.

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

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.

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 the control 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 control may not be used after the expiration date.

Avoid foam formation in all reagents and sample types (specimens, calibrators and controls).

Handling

The control is supplied ready-for-use in vials compatible with the **cobas pro** serology solution.

A single vial of the release control must only be used for 1 batch release. The lid of the control vial should only be open while on the analytical unit.

Storage and stability

Store at 2-8 °C.

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

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

Stability:

on the analytical unit at 20-25 °C	use only once, stable on-board for up to 5 hours

Materials provided

- PreciControl Release HBsAg II

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.

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).

PreciControl Release HBsAg II

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.

For USA: Rx only

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