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PreciControl HIV Gen II

cobas®

REF **06924107** 160 → **6 x 2.0 mL**

English

For use in the USA only

Intended use

PreciControl HIV Gen II is used for quality control of Elecsys HIV combi PT on the **cobas e** 602 analyzer.

Summary

PreciControl HIV Gen II is a lyophilized control serum based on human serum:

2X PC HIV1 Gen II:	negative for anti-HIV antibodies and negative for p24-Antigen.
2X PC HIV2 Gen II:	positive for anti-HIV-1 antibodies and negative for p24-Antigen.
2X PC HIV3 Gen II:	negative for anti-HIV antibodies and positive for p24-Antigen.

The controls are used for monitoring the accuracy of Elecsys HIV combi PT.

Reagents - working solutions

- PC HIV1 Gen II: 2 bottles, each for 2.0 mL of control serum
  Human serum, negative for anti-HIV (antigen and antibodies); preservative
  Target value for the cutoff index: approximately 0.250 COI
- PC HIV2 Gen II: 2 bottles, each for 2.0 mL of control serum
  Human serum, positive for anti-HIV antibodies; preservative
  Target value for the cutoff index: approximately 5.00 COI
- PC HIV3 Gen II: 2 bottles, each for 2.0 mL of control serum
  HIV p24-Ag (E. coli, rDNA) in human serum; preservative
  Target value for the cutoff index: approximately 4.00 COI

The exact lot-specific target values and ranges, given in the form of a cutoff index, 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 HIV combi PT reagents and analyzers available at the time of testing.

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 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.

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

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 and antibodies to HCV.
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 anti-HIV used for the positive controls 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

Carefully dissolve the contents of one bottle by adding exactly 2.0 mL of distilled or deionized water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding foam formation.

Transfer the reconstituted controls into the empty labeled snap-cap bottles supplied or into additional snap-cap bottles (ControlSet Vials). Attach the supplied labels to these additional bottles. Aliquots intended for storage at -20 °C should be frozen immediately.

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 5 quality control procedures per bottle set should be performed.

After use, close the bottles as soon as possible and store upright at 2-8 °C.

Please note: Both the vial labels and the additional labels (if available) contain a barcode for the **cobas** 8000 system only. Place the vial on the analyzer as usual.

Storage and stability

Store at 2-8 °C.

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

Stability of the reconstituted control serum:	
either at -20 °C (± 5 °C)	3 months (3 freeze/thaw cycles possible)
or at 2-8 °C	7 days
on the analyzer at 20-25 °C	up to 5 hours

Store controls **upright** in order to prevent the control solution from adhering to the snap-cap.

Materials provided

PreciControl HIV Gen II, 3 x 2 empty labeled snap-cap bottles, 3 x 6 bottle labels

Materials required (but not provided)

- REF 03142949122, ControlSet Vials, 2 x 56 empty snap-cap bottles
- **cobas e** 602 immunoassay analyzer and assay reagents
- Distilled or deionized water

See the assay Method Sheet and the operator's manual for additionally required materials.

Assay

Treat the reconstituted 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, the product information and the Method Sheets of all necessary components (if available in your country).

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see https://usdiagnostics.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

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.

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