PreciControl HIV Gen II

cobas®

REF 06924107162 → **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 Duo immunoassay on **cobas pro** serology solution.

Summary

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

2X PC HIV1 B:	non-reactive for anti-HIV antibodies and non-reactive for HIV-1 p24-Antigen.
2X PC HIV2 B:	reactive for anti-HIV-1 antibodies and non-reactive for HIV-1 p24-Antigen.
2X PC HIV3 B:	non-reactive for anti-HIV antibodies and reactive for HIV-1 p24-Antigen.

The controls are used for monitoring the accuracy of the Elecsys HIV Duo immunoassay.

Reagents - working solutions

- PC HIV1 B: 2 vials, each for 2.0 mL of control serum
  Human serum, non-reactive for anti-HIV (antigen and antibodies); preservative
  Target value for the cutoff index (COI):
  HIV Duo: approximately 0.250
- PC HIV2 B: 2 vials, each for 2.0 mL of control serum
  Human serum, reactive for anti-HIV-1 antibodies; preservative
  Target value for the cutoff index (COI):
  HIV Duo: approximately 5.00
- PC HIV3 B: 2 vials, each for 2.0 mL of control serum
  HIV p24-antigen (E. coli, rDNA) in human serum; preservative
  Target value for the cutoff index (COI):
  HIV Duo: approximately 10.0

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 Elecsys HIV Duo reagents and **cobas e** 801 analytical units.

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.

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.

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.
H412	Harmful to aquatic life with long lasting effects.

Prevention:

P261	Avoid breathing dust.
P273	Avoid release to the environment.
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: 1-800-428-2336

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 use assays that have been approved by the FDA or that are in compliance with the legal rules applicable to placing in vitro diagnostic medical devices for human use on the market in the European Union.

The serum containing anti-HIV used for the 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 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

Carefully dissolve the contents of 1 vial 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 vials supplied.

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 5 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 the vial.

PreciControl HIV Gen II

Stability of the reconstituted control serum:

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

Materials provided

- PreciControl HIV Gen II, 3 x 2 empty labeled snap-cap vials

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.
- Distilled or deionized water

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

Assay

Treat the reconstituted 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.

Controls for the various concentration ranges 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.

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.

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

The following symbols and signs are used 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
Rx Only	US only: 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.

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