ms_06924107190V1.0

PreciControl HIV Gen II

cobas®

REF **06924107** 190 → **6 x 2.0 mL**

English

Intended use

PreciControl HIV Gen II is used for quality control of the Elecsys HIV combi PT, Elecsys HIV Duo and Elecsys HIV Ag immunoassays on the Elecsys and **cobas e** immunoassay analyzers.

Summary

PreciControl HIV Gen II is a lyophilized control serum based on human serum. The control levels 1, 2 and 3 are used for monitoring the accuracy of the Elecsys HIV combi PT and Elecsys HIV Duo assays. The control levels 1 and 3 are used for monitoring the accuracy of the Elecsys HIV Ag assay.

Reagents - working solutions

- PC HIV1: 2 bottles, each for 2.0 mL of control serum

  Human serum, negative for HIV (antigen and antibodies); preservative.

  Target value for the cutoff index (COI):

  HIV combi PT: approximately 0.250

  HIV Duo: approximately 0.250

  HIV Ag: approximately 0.400
- PC HIV2: 2 bottles, each for 2.0 mL of control serum

  Human serum, positive for anti-HIV antibodies; preservative.

  Target value for the cutoff index:

  HIV combi PT: approximately 5.00

  HIV Duo: approximately 5.00

  HIV Ag: No target value. Do not use PC HIV2 for the Elecsys HIV Ag assay.
- PC HIV3: 2 bottles, each for 2.0 mL of control serum

  HIV p24 antigen (E. coli, rDNA) in human serum; preservative.

  Target value for the cutoff index:

  HIV combi PT: approximately 4.00

  HIV Duo: approximately 10.0

  HIV Ag: approximately 8.00

cobas e 801 analyzer: The exact ranges, given in the form of a cutoff index, are encoded in the electronic barcode and available via the **cobas** link.
All other analyzers: The exact ranges, given in the form of a cutoff index, are encoded in the barcode as well as printed on the enclosed (or electronically available) value sheet.

Target values and ranges

The target values and ranges were determined and evaluated by Roche. They were obtained using the Elecsys assay 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.

Note:
For technical reasons re-assigned target values valid only for a specific reagent and control lot combination must be entered manually on all analyzers (except for the **cobas e** 602 and **cobas e** 801 analyzers). Therefore always refer to the respective value sheet to make sure that the correct target values are used.
When a new reagent or control lot is used, the analyzer will use the original values encoded in the control barcodes.

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:

2-methyl-2H-isothiazol-3-one hydrochloride

EUH 208 May produce an allergic reaction.

Product safety labeling primarily 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 and HIV. The testing methods applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.

The serum containing anti-HIV antibodies used for the positive control (PC HIV2) 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 should be performed.

Please note: Both the vial labels, and the additional labels (if available) contain 2 different barcodes. The barcode between the yellow markers is for **cobas** 8000 systems only. If using a **cobas** 8000 system, please turn the vial cap 180° into the correct position so the barcode can be read by the system. Place the vial on the instrument 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	3 months (3 freeze/thaw cycles possible)
or at 2-8 °C	7 days
on the analyzers 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 barcode cards, control barcode sheet, 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
- MODULAR ANALYTICS E170 or **cobas e** immunoassay analyzers and assay reagents
- Distilled or deionized water

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

PreciControl HIV Gen II

cobas®

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.

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).

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:

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

CE 0123

Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com

Roche