

PreciControl HIV Gen II

REF 06924107190

06924107500

→ 6 x 2.0 mL

English

Intended use

PreciControl HIV Gen II is used for quality control of the Elecsys HIV combi PT and Elecsys HIV Duo immunoassays on **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.

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
- 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
- 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

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.

The control target values and ranges are encoded either in the barcode or in the electronic barcode (which is available via the **cobas** link).

cobas e 411, **cobas e 601** and **cobas e 602** analyzers: The value sheet is included in the control kit and is also provided electronically via the **cobas** link.

If the target values and control ranges are updated, this information is conveyed either via the reagent barcodes, or control barcodes (or provided electronically) and in an additional value sheet included in the reagent kit. This value sheet lists all control lots to which the new values apply. If some of the values remain unchanged, the original values and the original value sheet included in the control kit remain valid.

cobas e 402 and **cobas e 801** analyzers: The target values and ranges (original and updated) and the value sheet are only available electronically via the **cobas** link.

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.

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

Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Note:

For technical reasons re-assigned target values and ranges valid only for a specific reagent and control lot combination must be entered manually on all analyzers (except for the **cobas e 402**, **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 for laboratory professionals. 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.

Hazardous components:

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

Product safety labeling follows EU GHS guidance.

Contact phone: all countries: +49-621-7590

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 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 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 $-20\text{ }^{\circ}\text{C}$ ($\pm 5\text{ }^{\circ}\text{C}$) should be frozen immediately.

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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 for **cobas e 402**, **cobas e 602** and **cobas e 801** analyzers: Both the vial labels, and the additional labels (if available) contain 2 different barcodes. Please turn the vial cap 180° into the correct position so that the barcode between the yellow markers can be read by the system. 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 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, 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** immunoassay analyzers 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.
- 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 or operator's manual for the analyzer concerned, the respective application sheets 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.

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.

The Summary of Safety & Performance Report can be found here: <https://ec.europa.eu/tools/eudamed>

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

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