PreciControl HIV; HIV-2+GrpO

cobas®

REF 06924115190 → **4 x 2.0 mL**

English

Intended use

PreciControl HIV; HIV-2+GrpO is used for quality control of the Elecsys HIV combi PT and Elecsys HIV Duo immunoassays on **cobas e** immunoassay analyzers.

Summary

PreciControl HIV; HIV-2+GrpO is a lyophilized control serum based on human serum. The controls are used for monitoring the accuracy of the Elecsys HIV combi PT and Elecsys HIV Duo assays.

Reagents - working solutions

- PC HIV4: 2 bottles, each for 2.0 mL of control serum

  Human serum, positive for anti-HIV-2 antibodies; preservative.

  Target value for the cutoff index (COI):

  HIV combi PT: approximately 5.00

  HIV Duo: approximately 4.50
- PC HIV5: 2 bottles, each for 2.0 mL of control serum

  Human serum, positive for anti-HIV-1 GrpO antibodies; preservative.

  Target value for the cutoff index:

  HIV combi PT: approximately 5.00

  HIV Duo: approximately 4.50

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 controls will be handled automatically by the **cobas e** 402, **cobas e** 602 and **cobas e** 801 analyzers.

The target values and ranges (original and updated) and the value sheet are available electronically via the **cobas** link.

cobas e 411 and **cobas e** 601 analyzers: The lot-specific value sheet is included in the control or reagent kit and is also provided electronically via the **cobas** link. The controls are not barcode labeled and therefore have to be run like external controls. All values and ranges have to be entered manually. Please refer to the section “QC” in the operator's manual or to the online help of the instrument software.

Non-barcode labeled controls: Only one target value and range for each control level can be entered in the analyzer. The reagent lot-specific target values must be re-entered each time when a specific reagent lot with different control target values and ranges is used. Two reagent lots with different control target values and ranges cannot be used in parallel in the same run.

Please make sure that the correct values are used.

If the target values and control ranges are updated, this information is conveyed 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.

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.
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:

Warning

H317	May cause an allergic skin reaction.
H412	Harmful to aquatic life with long lasting effects.

Prevention:

P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
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: 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 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 antibodies used for the positive control (PC HIV4) 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 (± 5 °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

PreciControl HIV; HIV-2+GrpO

upright at 2-8 °C. Due to possible evaporation effects, not more than 5 quality control procedures per bottle should be performed.

When measuring non-barcoded controls, use only recommended sample tubes, “cup on tube” or “cup on rack”.

Please note: Both the vial labels and the additional labels (if available) contain a barcode for the **cobas e** 402, **cobas e** 602 and **cobas e** 801 analyzers 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 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; HIV-2+GrpO, 2 x 2 empty labeled snap-cap bottles, 2 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.

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 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 (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

CE 0123

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