PreciControl HIV; HIV-2 + GrpO

English

For use in the USA only

Intended use
PreciControl HIV; HIV-2 + GrpO is used for quality control of Elecsys HIV combi PT on the cobas e 602 analyzer.

Summary
PreciControl HIV; HIV-2 + GrpO is a lyophilized control serum based on human serum:

- 2X PC HIV4: positive for anti-HIV-2 antibodies and negative for p24-Antigen.
- 2X PC HIV5: positive for anti-HIV-1 group O antibodies and negative for p24-Antigen.

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

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: approximately 5.00 COI
- PC HIV5: 2 bottles, each for 2.0 mL of control serum
  - Human serum, positive for anti-HIV-1 group O antibodies; preservative
  - Target value for the cutoff index: approximately 5.00 COI

Note: cobas 8000 system: The controls will be handled automatically by the analyzer. The exact lot-specific target values and ranges 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 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 should be performed.

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.

<table>
<thead>
<tr>
<th>Stability of the reconstituted control serum:</th>
<th>3 months (3 freeze/thaw cycles possible)</th>
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<tr>
<td>either at -20 °C (± 5 °C)</td>
<td>7 days</td>
</tr>
<tr>
<td>or at 2-8 °C</td>
<td>up to 5 hours</td>
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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)

- 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


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).
PreciControl HIV; HIV-2 + GrpO

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):

<table>
<thead>
<tr>
<th>CONTENT</th>
<th>System</th>
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<tr>
<td></td>
<td>Analyzer/Instrument on which reagents can be used</td>
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<tr>
<td>REAGENT</td>
<td></td>
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<tr>
<td></td>
<td>Reagent</td>
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<td>CALIBRATOR</td>
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<td></td>
<td>Calibrator</td>
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<td>Volume</td>
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<td>after</td>
<td>reconstitution or mixing</td>
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<td>GTIN</td>
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<td></td>
<td>Global Trade Item Number</td>
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