PreciControl HIV Gen II

Intended use
PreciControl HIV Gen II is used for quality control of Elecsys HIV combi PT on the cobas 602 analyzer.

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

- PC HIV1 Gen II: negative for anti-HIV antibodies and negative for p24-Antigen.
- PC HIV2 Gen II: positive for anti-HIV-1 antibodies and negative for p24-Antigen.
- PC HIV3 Gen II: negative for anti-HIV antibodies and positive for p24-Antigen.

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

Reagents - working solutions

- PC HIV1 Gen II: 2 bottles, each for 2.0 mL of control serum
- PC HIV2 Gen II: 2 bottles, each for 2.0 mL of control serum
- PC HIV3 Gen II: 2 bottles, each for 2.0 mL of control serum

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 set should be performed. After use, close the bottles as soon as possible and store upright at 2-8 °C. 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.

Stability of the reconstituted control serum:

<table>
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<tr>
<th>Stability</th>
<th>Duration</th>
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<tr>
<td>either at -20 °C</td>
<td>3 months (3 freeze/thaw cycles possible)</td>
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<tr>
<td>or at 2-8 °C</td>
<td>7 days</td>
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<tr>
<td>on the analyzer at 20-25 °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 Gen II, 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 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
PreciControl HIV Gen II


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).

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>Symbol</th>
<th>Meaning</th>
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<tbody>
<tr>
<td>CONTENT</td>
<td>Contents of kit</td>
</tr>
<tr>
<td>SYSTEM</td>
<td>Analyzers/Instruments on which reagents can be used</td>
</tr>
<tr>
<td>REAGENT</td>
<td>Reagent</td>
</tr>
<tr>
<td>CALIBRATOR</td>
<td>Calibrator</td>
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<tr>
<td>STIN</td>
<td>Volume after reconstitution or mixing</td>
</tr>
<tr>
<td>GTIN</td>
<td>Global Trade Item Number</td>
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