PreciControl Release HIV Gen II

cobas®

REF 09367101190 → **6 x 2.0 mL**

English

For use in the USA only

Intended use

PreciControl Release HIV Gen II is used to validate the **cobas pro** serology solution and to release sample results for the Elecsys HIV Duo immunoassay.

The recovery of the release control within Roche specified limits ensures the specified sensitivity of the assay under customer site conditions. The release control is tested at user-defined intervals with a maximum span of every 300 samples or 350 determinations and must be tested in order to release the test results. For release control values that fall outside the defined limits, samples measured before a failed release control are flagged as invalid by the **cobas pro** serology controller and need to be repeated. Reactive results will not be invalidated by a failed release control and must be retested in duplicate. While the assay controls (PreciControl HIV Gen II and PreciControl HIV; HIV-2+GrpO) contain different HIV analytes, the selected HIV analyte for the release control is anti-HIV-1. The HIV release control is a lyophilized control serum based on human serum, reactive for anti-HIV-1 antibodies and non-reactive for p24 antigen.

Summary

PreciControl Release HIV Gen II is a lyophilized control serum based on human serum.

PreciControl Release HIV Gen II must be tested in order to release the donor sample results.

6X PC HIVR:	reactive for anti-HIV-1 antibodies and non-reactive for HIV-1 p24-Antigen

Reagents - working solutions

- PC HIVR: 6 vials, each for 2.0 mL of control serum
  Human serum, reactive for anti-HIV-1 antibodies; preservative
  Target value for the cutoff index (COI):
  HIV Duo: approximately 5.00
  HIVAGB (embedded application): 0.025-0.500
  AHIVB (embedded application): approximately 5.00

The exact lot-specific target values and ranges, given in the form of a cutoff index (COI), 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 Elecsys HIV Duo reagents and **cobas e** 801 analytical units.

Please note that the PreciControl Release HIV Gen II has two module specific target values and ranges. In order to release a batch of donor sample results the module specific subresults for HIVAGB and AHIVB must be within the specified ranges.

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

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.

Precautions and warnings

For in vitro diagnostic use. 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.

Product safety labeling follows EU GHS guidance.

Contact phone: 1-800-428-2336

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 use assays that have been approved by the FDA or that are in compliance with the legal rules applicable to placing in vitro diagnostic medical devices for human use on the market in the European Union.

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 donor 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 1 vial 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 vials supplied.

A single vial of the release control must only be used for 1 batch release, but can be used for both the HIVAGB and AHIVB modules. The lid of the control vial should only be open while on the analytical unit.

Storage and stability

Store at 2-8 °C.

The lyophilized control serum is stable up to the stated expiration date.

Store controls **upright** in order to prevent the control solution from adhering to the lid of the vial.

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Stability of the reconstituted control serum:

at 2-8 °C	7 days
on the analytical unit at 20-25 °C	use only once; stable onboard for up to 5 hours

Materials provided

- PreciControl Release HIV Gen II, 6 empty labeled snap-cap vials

Materials required (but not provided)

- The **cobas pro** serology solution is a combination of the **cobas pro** serology controller, **cobas pro** integrated solutions (**cobas e** 801 analytical units only) and applicable licensed or cleared donor screening assays.
- Distilled or deionized water.

See the assay Method Sheet and the user guide for additionally required materials.

Assay

Treat the reconstituted control serum in the **cobas pro** serology solution-compatible labeled vials for analysis in the same way as donor samples.

Read the data into the analytical unit.

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 for the analytical unit concerned, the respective application sheets and the Method Sheets of all necessary components (if available in your country).

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.

Symbols

The following symbols and signs are used 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
Rx Only	US only: Federal law restricts this device to sale by or on the order of a physician.

FOR US CUSTOMERS ONLY: LIMITED WARRANTY

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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