

REF 05162645 119

→ 6 x 2.0 mL

English

Intended use

PreciControl HIV is used for quality control of the Elecsys HIV combi PT and Elecsys HIV Ag immunoassays on the Elecsys and **cobas e** immunoassay analyzers.

Please note that some assays may not be licensed in all regulatory jurisdictions.

Note:

Please note that the catalogue number appearing on the package insert retains only the first 8 digits of the licensed 11-digit Catalogue Number: 05162645190 for the PreciControl HIV. The last 3 digits -190 have been replaced by -119 for logistic purposes.

Summary

PreciControl HIV is a lyophilized control serum based on human serum (PC HIV1 and PC HIV2) and on buffer (PC HIV3). The controls are used for monitoring the accuracy of the Elecsys HIV combi PT and Elecsys HIV Ag immunoassays.

Reagents - working solutions

- § PC HIV1: 2 bottles, each for 2 mL of control serum
Human serum, negative for HIV (antigen and antibodies); preservative.
Target value range for the cutoff index:
HIV combi PT: 0.00-0.67
HIV Ag: ≤ 0.80
- § PC HIV2: 2 bottles, each for 2 mL of control serum
Human serum, positive for anti-HIV antibodies; preservative.
Target value range for the cutoff index:
HIV combi PT: 10.0-32.0
HIV Ag: No target value. Do not use PC HIV2 for the Elecsys HIV Ag assay.
- § PC HIV3: 2 bottles, each for 2 mL of control serum
HIV p24-Ag (E. coli, rDNA) approx. 400 pg/mL in citrate buffer, pH 4.0; preservative.
Target value range for the cutoff index:
HIV combi PT: 30.0-100
HIV Ag: 95-250

The exact ranges, given in the form of a cutoff index, are encoded in the barcodes as well as printed on the enclosed (or electronically available) value sheet.

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.

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.

Note:

For technical reasons re-assigned target values valid only for a specific reagent and control lot combination, must be entered manually on all analyzers (except for the **cobas e 602** analyzer). Therefore always refer to the value sheet included in the reagent kit or PreciControl kit 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:

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

EUH 208 May produce an allergic reaction.

Product safety labeling primarily 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 and HIV (PC HIV1 only).

The testing methods applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.

The serum containing anti-HIV 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 °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 2 different barcodes. The barcode between the yellow markers is for **cobas 8000** systems only. If using a **cobas 8000** system, please turn the vial cap 180° into the correct position so the barcode can be read by the system. Place the vial on the instrument 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	3 months (3 freeze/thaw cycles possible)
or at 2-8 °C	8 weeks
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, 3 barcode cards, control barcode sheet, 3 x 2 empty labeled snap-cap bottles, 3 x 6 bottle labels

PreciControl HIV

Materials required (but not provided)

- § REF 03142949122, ControlSet Vials, 2 x 56 empty snap-cap bottles
- § Elecsys 2010, MODULAR ANALYTICS E170 or **cobas e** immunoassay analyzers and assay reagents
- § Distilled or deionized water

See the assay Method Sheet and the operator's manual for additionally required material.

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 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).

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.

CONTENT	Contents of kit
SYSTEM	Analyzers/Instruments on which reagents can be used
REAGENT	Reagent
CALIBRATOR	Calibrator
	Volume after reconstitution or mixing
GTIN	Global Trade Item Number

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