

English

Intended use

PreciControl HTLV is used for quality control of the Elecsys HTLV-I/II immunoassays on the **cobas e** immunoassay analyzers.

Summary

PreciControl HTLV is a lyophilized control serum based on human serum. The controls are used for monitoring the accuracy of the Elecsys HTLV-I/II immunoassays.

Reagents - working solutions

- PC HTLV 0: 2 bottles, each for 1.0 mL of control serum
Human serum, negative for anti-HTLV I or II antibodies; preservative.
Target value for the cutoff index: approximately 0.2
- PC HTLV 1: 2 bottles, each for 1.0 mL of control serum
Human serum, positive for anti-HTLV-I antibodies; preservative.
Target value for the cutoff index: approximately 5
- PC HTLV 2: 2 bottles, each for 1.0 mL of control serum
Human serum, positive for anti-HTLV-II antibodies; preservative.
Target value for the cutoff index: approximately 2.5

Note: 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 have to be re-entered each time 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.

The exact lot-specific target values and ranges are printed on the enclosed (or electronically available) value sheet in the reagent kit or PreciControl kit. Please make sure that the correct values are used.

Target values and ranges

The target values and ranges were determined and evaluated by Roche. They were obtained using the Elecsys HTLV-I/II assay reagents and analyzers available at the time of testing.

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.

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

However, as no 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 1.0 mL of distilled or deionized water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding foam formation.

When measuring non-barcode controls, use only recommended sample tubes, "cup on tube" or "cup on rack".

Transfer an aliquot of the reconstituted control into an appropriate tube and use the aliquot immediately.

Perform **only one** control procedure per aliquot.

Close the glass vial carefully and store the remainder of the reconstituted control at 2-8 °C or freeze immediately at -20 °C for later use.

Due to possible evaporation effects, not more than 5 quality control procedures per glass vial should be performed.

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	12 weeks (3 freeze/thaw cycles possible)
or at 2-8 °C	28 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 lid of the glass vial.

Materials provided

- PreciControl HTLV, 6 empty labeled snap-cap bottles

Materials required (but not provided)

- MODULAR ANALYTICS E170 or **cobas e** 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.

The control values and ranges must be entered manually. Please refer to the corresponding section in the operator's manual.

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).

PreciControl HTLV

cobas[®]

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.

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

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