

PreciControl Chagas



REF 07092571 190

16 x 1.0 mL

English

Intended use

PreciControl Chagas is used for quality control of the Elecsys Chagas immunoassay on the Elecsys and **cobas e** immunoassay analyzers.

Summary

PreciControl Chagas is a ready-for-use control serum based on human serum both in the negative and positive concentration range. The controls are used for monitoring the accuracy of the Elecsys Chagas immunoassay.

Reagents - working solutions

- PC Chagas 1: 8 bottles, each containing 1.0 mL of control serum Human serum, negative for antibodies to T. cruzi; preservative Target range for the cutoff index: 0-0.4
- PC Chagas 2: 8 bottles, each containing 1.0 mL of control serum Human serum, positive for antibodies to T. cruzi; preservative Target value for the cutoff index: approximately 4

Note: **cobas** 8000 system: The controls will be handled automatically by the analyzers.

All other analyzers: 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 must be re-entered each time when 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 included in the reagent kit or PreciControl kit.

Please make sure that the correct values are used.

cobas 8000 system: The exact lot-specific target values and ranges are available both as an electronic barcode and as a value sheet provided via the **cobas** link.

Please note: The value sheets for the **cobas e** 801 analyzer are only available electronically 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 Chagas assay reagents and analyzers available at the time of testing.

cobas 8000 system: Updated target values and ranges are available both as an electronic barcode and as a value sheet provided via the **cobas** link. All other analyzers: The control values and ranges must be entered manually. Please refer to the corresponding section in the operator's manual.

If the target values and control ranges are updated, this information is conveyed either via the reagent barcodes, or control barcodes (or provided electronically) and in an additional value sheet included in the reagent kit. This value sheet lists all control lots to which the new values apply. If some of the values remain unchanged, the original values conveyed via the CBC (Control Barcode), and in the value sheet included in the control kit (or provided electronically), remain valid.

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.

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 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-T. cruzi IgG (PC Chagas 2) was sterile filtrated.

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

The controls are supplied ready-for-use in bottles compatible with the system. 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.

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

Due to possible evaporation effects, not more than 5 quality control procedures per bottle set 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.

Store controls **upright** in order to prevent the control solution from adhering to the snap-cap.

Stability:	
unopened at 2-8 °C	up to the stated expiration date
after opening at 2-8 °C	28 days
on the analyzers at 20-25 °C	up to 5 hours

Materials provided

- PreciControl Chagas

Materials required (but not provided)

- MODULAR ANALYTICS E170 or **cobas e** immunoassay analyzers and assay reagents

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

Assay

Treat the 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 (except for the **cobas e** 602 and **cobas e** 801 analyzers). 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

- Occupational Safety and Health Standards: Bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.
- 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).

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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 (for USA: see <https://usdiagnostics.roche.com> for definition of symbols used):

	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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