

PreciControl Cortisol Saliva



REF 06687768 190

→ 4 x 1.0 mL

For USA: Elecsys PreciControl Cortisol Saliva

English

Intended use

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

Summary

PreciControl Cortisol Saliva is a lyophilized control based on buffer/protein matrix with added cortisol in two concentration ranges. The controls are used for monitoring the accuracy and precision of the Elecsys Cortisol II immunoassay.

Reagents - working solutions

- PC CS 1: 2 bottles, each for 1.0 mL of control buffer/protein matrix
 - PC CS 2: 2 bottles, each for 1.0 mL of control buffer/protein matrix
- Cortisol in two concentration ranges (approximately 10 nmol/L and approximately 30 nmol/L) in a buffer/protein matrix; preservative.

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 Cortisol II assay reagents and analyzers available at the time of testing.

If the target values and control ranges are updated, this information is conveyed 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 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.

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.

For USA: For prescription use only.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:



Danger

- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Prevention:

- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
- P280 Wear protective gloves.
- P284 Wear respiratory protection.

Response:

- P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
- P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

Product safety labeling primarily follows EU GHS guidance.
 Contact phone: all countries: +49-621-7590, USA: 1-800-428-2336
 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.

Transfer the reconstituted controls into appropriate tubes. Aliquots intended for storage at -20 °C should be frozen immediately.

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

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

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 matrix:	
either at -20 °C	28 days (freeze only once)
or at 2-8 °C	2 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 snap-cap.

Materials provided

- PreciControl Cortisol Saliva

Materials required (but not provided)

- 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 materials.

Assay

Treat the reconstituted control buffer/protein matrix 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.

PreciControl Cortisol Saliva



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.

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.

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

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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