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PreciControl TSH

cobas®

REF 11776479 122

4 x 2.0 mL

English

Intended use

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

Summary

PreciControl TSH is a ready-for-use control serum based on an equine serum matrix with human TSH concentrations at the euthyroid/hyperthyroid threshold. The control is used for monitoring the accuracy and precision of the Elecsys TSH immunoassay.

Reagents - working solutions

TSH Control: 4 bottles, each containing 2.0 mL of control serum

TSH (human, recombinant, from yeast) approx. 0.2 µIU/mL in equine serum matrix.

The exact lot-specific target value and range are encoded in the barcode 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 TSH assay reagents and analyzers available at the time of testing.

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.

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.

Avoid foam formation in all reagents and sample types (specimens, calibrators and controls).

Handling

The control is supplied ready-for-use in bottles compatible with the system.

The control should only be left on the analyzer during performance of quality control. After use, close the bottle as soon as possible and store at 2-8 °C.

Due to possible evaporation effects, not more than 20 quality control procedures per bottle should be performed.

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	12 weeks
on the analyzers at 20-25 °C	up to 5 hours

Materials provided

- PreciControl TSH, barcode card, control barcode sheet

Materials required (but not provided)

- Elecsys 2010, MODULAR ANALYTICS E170 or **cobas e** immunoassay analyzers and assay reagents

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

Assay

Treat the 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.

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

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