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PreciControl ThyroAB

cobas®

REF 05042666191 → **4 x 2.0 mL**

For USA: Elecsys PreciControl ThyroAB

English

Intended use

PreciControl ThyroAB is used for quality control of the Elecsys Anti-TSHR, Anti-TPO and Anti-Tg immunoassays on **cobas e** immunoassay analyzers.

Summary

PreciControl ThyroAB is a lyophilized control serum based on a human serum matrix in 2 concentration ranges. The controls are used for monitoring the accuracy and precision of the Elecsys Anti-TSHR, Anti-TPO and Anti-Tg immunoassays.

Reagents - working solutions

- PC THYRO1: 2 bottles, each for 2.0 mL of control serum
- PC THYRO2: 2 bottles, each for 2.0 mL of control serum

Substance in human serum matrix	PC THYRO1	PC THYRO2	Unit
Anti-TSHR antibodies (human)	approximately 4	approximately 16	IU/L
Anti-TPO antibodies (sheep)	approximately 35	approximately 100	IU/mL
Anti-Tg antibodies (sheep)	approximately 100	approximately 200	IU/mL

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.

The control target values and ranges are encoded either in the barcode or in the electronic barcode (which is available via the **cobas** link).

cobas e 411, **cobas e** 601 and **cobas e** 602 analyzers: The value sheet is included in the control kit and is also provided electronically via the **cobas** link.

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 and the original value sheet included in the control kit remain valid.

cobas e 402 and **cobas e** 801 analyzers: The target values and ranges (original and updated) and the value sheet are only available electronically via the **cobas** link.

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 for health care professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:
Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:
Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request.

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

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 use assays that have been approved by the FDA or that are in compliance with the legal rules applicable to placing in vitro diagnostic medical devices for human use on the market in the European Union.

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 2.0 mL of distilled or deionized water and allow to stand closed for 30 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 (± 5 °C) should be frozen immediately.

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

Please note for **cobas e** 402, **cobas e** 602 and **cobas e** 801 analyzers: Both the vial labels, and the additional labels (if available) contain 2 different barcodes. Please turn the vial cap 180° into the correct position so that the barcode between the yellow markers can be read by the system. Place the vial on the analyzer as usual.

Storage and stability

Store at 2-8 °C.

The lyophilized control serum is stable up to the stated expiration date.

Stability of all the components - except for anti-TSHR - in the reconstituted control serum:	
either at -20 °C (± 5 °C)	1 month (freeze only once)
or at 2-8 °C	3 days
on the analyzers at 20-25 °C	up to 5 hours

Stability of anti-TSHR in the reconstituted control serum:	
at -20 °C (± 5 °C)	1 month (freeze only once)
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 ThyroAB, 2 barcode cards, 2 x 2 empty labeled snap-cap bottles, 2 x 6 bottle labels

Materials required (but not provided)

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

See the appropriate 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.

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.

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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 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.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see dialog.roche.com for definition of symbols used):

CONTENT	Contents of kit
SYSTEM	Analyzers/Instruments on which reagents can be used
REAGENT	Reagent
CALIBRATOR	Calibrator
→	Volume for reconstitution
GTIN	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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