

# Anti-TPO CalSet

**cobas®**

REF 06472931 190

for 4 x 1.5 mL

## English

### Intended use

Elecsys Anti-TPO CalSet is used for calibrating the quantitative Elecsys Anti-TPO assay on the Elecsys and **cobas e** immunoassay analyzers.

### Summary

Elecsys Anti-TPO CalSet consists of lyophilized human serum matrix with added anti-TPO antibodies in two concentration ranges. The CalSet can be used with all reagent lots.

### Reagents - working solutions

- Anti-TPO Cal1: 2 bottles, each for 1.5 mL of calibrator 1
  - Anti-TPO Cal2: 2 bottles, each for 1.5 mL of calibrator 2
- Anti-TPO antibodies (sheep) in two concentration ranges (approx. 35 IU/mL and approx. 350 IU/mL) in a human serum matrix. The exact lot-specific calibrator values are encoded in the barcode as well as printed on the enclosed (or electronically available) calibrator barcode sheet.

### Calibrator values

Traceability: The Elecsys Anti-TPO assay has been standardized against the NIBSC (National Institute for Biological Standards and Control) 66/387 Standard.

### 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 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 treated just as carefully as a patient specimen. In the event of exposure the directives of the responsible health authorities should be followed.<sup>1,2</sup> Avoid the formation of foam with all reagents and sample types (specimens, calibrators, and controls).

### Handling

Dissolve carefully the contents of one bottle by adding exactly 1.5 mL of distilled or deionized water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the formation of foam. Transfer the reconstituted calibrator into the empty labeled snap-cap bottles supplied.

Elecsys 2010 and **cobas e** 411 analyzers: The calibrators should only be left on the analyzers during calibration at 20-25 °C. Perform **only one** calibration procedure per aliquot. If necessary, freeze in aliquots; see section on MODULAR ANALYTICS E170, **cobas e** 601 and **cobas e** 602 analyzers.

MODULAR ANALYTICS E170, **cobas e** 601 and **cobas e** 602 analyzers: Unless the entire volume is necessary for calibration on the analyzer, transfer aliquots of the reconstituted calibrator into empty snap-cap bottles (CalSet Vials). Attach the supplied labels to these additional bottles. Store the aliquots for later use at -20 °C. Perform **only one** calibration procedure per aliquot.

### Storage and stability

Store at 2-8 °C.

The lyophilized calibrators are stable up to the stated expiration date. Stability of the reconstituted/thawed calibrators:

at 2-8 °C	up to 8 hours
at -20 °C	8 weeks (freeze only once)
on the analyzers at 20-25 °C	use only once

### Materials provided

- Elecsys Anti-TPO CalSet, barcode card, calibrator barcode sheet, 4 empty labeled snap-cap bottles, 2 x 6 bottle labels

### Materials required (but not provided)

- REF 11776576322, CalSet Vials, 2 x 56 empty snap-cap bottles
- Elecsys 2010, MODULAR ANALYTICS E170 or **cobas e** immunoassay analyzers and Elecsys Anti-TPO assay reagents. See test package insert and operator's manual for additionally required materials.
- Distilled or deionized water

### Assay

For use on the analyzers, place the reconstituted calibrators (in the system-compatible bottles with barcoded labels) in the sample zone. Read in all the information necessary for calibrating the assay; these data are encoded in the supplied barcodes, the reagent barcode, and the barcode on the calibrator bottle label. Ensure the calibrators are at ambient temperature (20-25 °C) before measurement.

### References

- Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.
- Council Directive (2000/54/EC). Official Journal of the European Communities No. L262 from Oct. 17, 2000.

For further information, please refer to the appropriate operator's manual for the analyzer concerned, the respective application sheets, the product information, and the package inserts of all necessary components.

### 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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