ms_12017717122V14.0

T4 CalSet

cobas®

REF **12017717** 122 **4 x 1.0 mL**

For USA: Elecsys CalSet T4

English

Intended use

T4 CalSet is used for calibrating the quantitative Elecsys T4 assay on the Elecsys and **cobas e** immunoassay analyzers.

Summary

T4 CalSet is a buffer/protein matrix with added L-thyroxine in two concentration ranges.

The CalSet can be used with all reagent lots.

Reagents - working solutions

- T4 Cal1: 2 bottles, each containing 1.0 mL of calibrator 1
- T4 Cal2: 2 bottles, each containing 1.0 mL of calibrator 2

L-thyroxine in two concentration ranges (approximately 50 nmol/L or 3.9 µg/dL and approximately 230 nmol/L or 17.9 µg/dL) in a buffer/protein (bovine serum albumin) matrix.

cobas e 801 analyzer: The exact lot-specific calibrator values are encoded in the electronic barcode and available via the **cobas** link.
All other analyzers: 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 T4 assay has been checked via ID-GC/MS (isotope dilution-gas chromatography/mass spectrometry) on various control materials.[1]

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.

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

Handling

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

cobas e 411 analyzer: The calibrators should only be left on the analyzer during calibration at 20-25 °C. After use, close the bottles as soon as possible and store upright at 2-8 °C.

Due to possible evaporation effects, not more than 5 calibration procedures per bottle set should be performed.

MODULAR ANALYTICS E170, **cobas e** 601, **cobas e** 602 and **cobas e** 801 analyzers: Unless the entire volume is necessary for calibration on the analyzers, transfer aliquots of the ready-for-use calibrators into empty snap-cap bottles (CalSet Vials). Attach the supplied labels to these additional bottles. Store the aliquots at 2-8 °C for later use.

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

Please note: Both the vial labels, and the additional labels (if available) contain 2 different barcodes. The barcode between the yellow markers is for **cobas** 8000 systems only. If using a **cobas** 8000 system, please turn the vial cap 180° into the correct position so the barcode can be read by the system. Place the vial on the instrument as usual.

Storage and stability

Store at 2-8 °C.

Stability:	
unopened at 2-8 °C	up to the stated expiration date
after opening/in aliquots at 2-8 °C	12 weeks
on **cobas e** 411 analyzer at 20-25 °C	up to 5 hours
on MODULAR ANALYTICS E170, **cobas e** 601, **cobas e** 602 and **cobas e** 801 analyzers at 20-25 °C	use only once

Store calibrators **upright** in order to prevent the calibrator solution from adhering to the snap-cap.

Materials provided

- T4 CalSet, barcode card, calibrator barcode sheet, 2 x 6 bottle labels

Materials required (but not provided)

- REF 11776576322, CalSet Vials, 2 x 56 empty snap-cap bottles
- MODULAR ANALYTICS E170 or **cobas e** immunoassay analyzers and Elecsys T4 assay reagents

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

Assay

Place the bottles in the sample zone.

Read in all the information necessary for calibrating the assay.

Ensure the calibrators are at 20-25 °C prior to measurement.

References

1 Thienpont LM, De Brabandere VI, Stöckl D, et al. Development of a New Method for the Determination of Thyroxine in Serum Based on Isotope Dilution Gas Chromatography Mass Spectrometry. Biological Mass Spectrometry 1994;23:475-482.

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:

CONTENT	Contents of kit
SYSTEM	Analyzers/Instruments on which reagents can be used
REAGENT	Reagent
CALIBRATOR	Calibrator
→	Volume after reconstitution or mixing
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.

Additions, deletions or changes are indicated by a change bar in the margin.

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