

CalSet FT4 IV



REF 09043292190

4 x 1.0 mL

English

Intended use

CalSet FT4 IV is used for calibrating the quantitative Elecsys FT4 IV assay on **cobas e** immunoassay analyzers.

Summary

CalSet FT4 IV is a ready-for-use buffer/protein matrix with added L-thyroxine in two concentration ranges.

The CalSet can be used with all reagent lots.

Reagents - working solutions

- FT4 4 Cal1: 2 bottles, each containing 1.0 mL of calibrator 1
 - FT4 4 Cal2: 2 bottles, each containing 1.0 mL of calibrator 2
- L-thyroxine in two concentration ranges (approximately 10 pmol/L or 0.78 ng/dL and approximately 45 pmol/L or 3.5 ng/dL) in buffer/protein (bovine serum albumin) matrix.

cobas e 402 and **cobas e 801** analyzers: 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 FT4 IV assay was standardized against the Elecsys FT4 III method. The Elecsys FT4 III assay is traceable to the Elecsys FT4 II assay which in turn is traceable to the Enzymun-Test FT4 which has been standardized using equilibrium dialysis.^{1,2}

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.

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



Warning

H317 May cause an allergic skin reaction.

Prevention:

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves.

Response:

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

P501 Dispose of contents/container to an approved waste disposal plant.

Product safety labeling follows EU GHS guidance.

Contact phone: all countries: +49-621-7590

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.

cobas e 402, **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 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.

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 cobas e 402 , 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

- CalSet FT4 IV, barcode card, 2 x 6 bottle labels

Materials required (but not provided)

- REF 11776576322, CalSet Vials, 2 x 56 empty snap-cap bottles
 - cobas e** immunoassay analyzers and Elecsys FT4 IV 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

- Ekins RP. Measurement of free hormones in blood. *Endocr Rev* 1990;11:5.
- Ekins RP, Ellis SM. The radioimmunoassay of free thyroid hormones in serum. In: Robbins J, Braverman LE, eds. *Thyroid research, Proceedings of the Seventh International Thyroid Conference*, Boston. Amsterdam, Excerpta Medica 1975:597.

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.







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.

CalSet FT4 IV

cobas®

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):

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

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

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