FT3 III CalSet

cobas®

REF 09077871190 09077871500 → **4 x 1.0 mL**

English

Intended use

FT3 III CalSet is used for calibrating the quantitative Elecsys FT3 III assay on **cobas e** immunoassay analyzers.

Summary

FT3 III CalSet is a lyophilized human serum with added T3 in 2 concentration ranges.

The CalSet can be used with all reagent lots.

Reagents - working solutions

- FT3 III Cal1: 2 bottles, each for 1.0 mL of calibrator 1
- FT3 III Cal2: 2 bottles, each for 1.0 mL of calibrator 2

FT3 in 2 concentration ranges (approximately 2 pmol/L or 1.3 pg/mL and approximately 40 pmol/L or 26 pg/mL) in a human serum matrix.

Calibrator values

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

Traceability: The Elecsys FT3 III assay has been standardized against the Elecsys FT3 assay (REF 03051986190). The Elecsys FT3 assay (REF 03051986190) is traceable to the Elecsys FT3 assay (REF 11731386122) which was standardized using equilibrium dialysis.[1,2]

Precautions and warnings

For in vitro diagnostic use for laboratory 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.
H412	Harmful to aquatic life with long lasting effects.

Prevention:

P261	Avoid breathing dust.
P273	Avoid release to the environment.
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.

Hazardous components:

- 2-methyl-2H-isothiazol-3-one hydrochloride

Product safety labeling follows EU GHS guidance.

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

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 or cleared by the FDA or that are in compliance with the legal rules of the European Union (IVDR 2017/746/EU, IVDD 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 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.[3,4]

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

Handling

Carefully dissolve the contents of 1 bottle by adding exactly 1.0 mL of distilled or deionized water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding foam formation.

Transfer the reconstituted calibrators into the supplied empty labeled snap-cap bottles.

cobas e 411 analyzer: The reconstituted 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.

All other analyzers: Unless the entire volume is necessary for calibration on the analyzers, transfer aliquots of the reconstituted calibrators into empty snap-cap bottles (CalSet Vials). Attach the supplied labels to these additional bottles. See "Storage and stability" section for storage instructions.
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.

The lyophilized calibrators are stable up to the stated expiration date.

Stability of the reconstituted calibrators:	
at 2-8 °C	8 weeks
on **cobas e** 411 analyzer at 20-25 °C	up to 5 hours
on all other 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

- FT3 III CalSet, barcode card, 4 labeled empty snap-cap bottles, 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 FT3 III assay reagents
- Distilled or deionized water

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

Assay

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.

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

FT3 III CalSet

cobas®

References

1 Ekins RP. Measurement of free hormones in blood. Endocr Rev 1990;11(1):5-46.

2 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.

3 Occupational Safety and Health Standards: Bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.

4 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 user guide or 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:

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

CE 0123

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