

Tacrolimus CalSet

cobas®

REF 05889065 190

→ 6 x 1.0 mL

English

Intended use

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

Summary

Tacrolimus CalSet is a lyophilized calibrator based on human blood with added tacrolimus in two concentration ranges.

The CalSet can be used with all reagent lots.

Reagents - working solutions

- TCL Cal1: 3 bottles, each for 1.0 mL of calibrator 1
- TCL Cal2: 3 bottles, each for 1.0 mL of calibrator 2

Tacrolimus in two concentration ranges (approximately 1 ng/mL and approximately 30 ng/mL) in a human blood matrix; preservative.

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 Tacrolimus assay has been standardized against reference standards traceable to tacrolimus reference material (USP = United States Pharmacopeia) by weight.

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 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}

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

Handling

Carefully dissolve the contents of one bottle by adding exactly 1.0 mL of distilled or deionized water and allow to reconstitute closed for 30 minutes by permanent gentle agitation with a rotator until complete solution is obtained, avoiding foam formation.

Transfer aliquots (300 µL) of the reconstituted calibrator into 2.0 mL microcentrifuge tubes. Aliquots intended for storage at -20 °C should be frozen immediately.

For each calibration procedure the aliquots must be pretreated following the pretreatment procedure given in the Elecsys Tacrolimus Method Sheet. Transfer the supernatant into an empty labeled snap-cap bottle (CalSet Vial).

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

Storage and stability

Store at 2-8 °C.

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

Stability of the reconstituted calibrators:	
either at 20-25 °C	5 days
or at 2-8 °C	7 days
or at -20 °C	28 days (freeze only once)
Stability of the pretreated calibrators:	
Closed tube at 20-25 °C	4 hours

Stability of the pretreated calibrators:

on the analyzers	up to 30 minutes (use only once)
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Store calibrators **upright** in order to prevent the calibrator solution from adhering to the snap-cap.

Materials provided

- Tacrolimus CalSet, barcode card, calibrator barcode sheet, 2 x 10 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 Tacrolimus assay reagents
- Distilled or deionized water

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

Assay

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

For pretreatment procedure refer to the respective section in the Elecsys Tacrolimus Method Sheet.

Place the pretreated 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 pretreated calibrators are analyzed/measured within 30 minutes.

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, 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

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Significant additions or changes are indicated by a change bar in the margin.

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