ms_05109469190V4.0

IL-6 CalSet

cobas®

REF **05109469** 190 → **4 x 2.0 mL**

English

Intended use

IL-6 CalSet is used for calibrating the quantitative Elecsys IL-6 assay on the Elecsys and **cobas e** immunoassay analyzers.

Summary

IL-6 CalSet is a lyophilized equine serum matrix with added recombinant IL-6 in two concentration ranges.

The CalSet can be used with all reagent lots.

Reagents - working solutions

- IL-6 Cal1: 2 bottles, each for 2.0 mL of calibrator 1
- IL-6 Cal2: 2 bottles, each for 2.0 mL of calibrator 2

IL-6 (human, recombinant) in two concentration ranges (approximately 18 pg/mL and approximately 700 pg/mL) in an equine 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 IL-6 assay has been standardized against the 1st International Standard NIBSC Code No: 89/548.

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.

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

Handling

Carefully dissolve the contents of one bottle by adding exactly 2.0 mL of distilled or deionized water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding foam formation.

Transfer aliquots of the reconstituted calibrators into empty labeled snap-cap bottles (CalSet Vials). Attach the supplied labels to the additional bottles. Store the aliquots immediately at -20 °C.

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.

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

Stability of the reconstituted calibrators:	
either at -20 °C	3 months (freeze only once)
or at 2-8 °C	up to 5 hours
on the analyzers at 20-25 °C	up to 5 hours

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

Materials provided

- IL-6 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 IL-6 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.

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

CE

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