



12002396001V12.0

IgE CalSet

cobas[®]

REF 11930427 122

4 x 1.0 mL

English

Intended use

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

Summary

IgE CalSet is an equine serum with added human IgE in two concentration ranges.

The CalSet can be used with all reagent lots.

Reagents - working solutions

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

IgE (human) in two concentration ranges (approx. 1 IU/mL or 2.4 ng/mL and approx. 100 IU/mL or 240 ng/mL) in an equine serum 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 IgE II assay has been standardized against the 2nd IRP WHO Reference Standard 75/502.

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. Materials of human origin have been tested for HIV, hepatitis B, and hepatitis C infections. The findings were negative.

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

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

Elecsys 2010 and **cobas e** 411 analyzers: The calibrators should only be left on the analyzers during calibration at 20-25 °C. After use, close the bottles as soon as possible and store 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 and **cobas e** 602 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.

Storage and stability

Store at 2-8 °C.

Stability	
unopened at 2-8 °C	up to the stated expiration date
after opening at 2-8 °C	12 weeks
on Elecsys 2010 and cobas e 411 analyzers at 20-25 °C	up to 5 hours
on MODULAR ANALYTICS E170, cobas e 601 and cobas e 602 analyzers	use only once

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

Materials provided

- IgE 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
- Elecsys 2010, MODULAR ANALYTICS E170 or **cobas e** immunoassay analyzers and Elecsys IgE II assay reagents.

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

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 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

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