

REF 11731645322

11731645500

4 x 1.0 mL

For USA: Elecsys CEA CalSet

**English****Intended use**

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

**Summary**

CEA CalSet is a buffer/protein matrix with added CEA in 2 concentration ranges.

The CalSet can be used with all reagent lots.

**Reagents - working solutions**

- CEA Cal1: 2 bottles, each containing 1.0 mL of calibrator 1
  - CEA Cal2: 2 bottles, each containing 1.0 mL of calibrator 2
- CEA (human, from cell culture) in 2 concentration ranges (approximately 5 ng/mL and approximately 50 ng/mL) in a buffer/protein matrix.

1 ng/mL CEA corresponds to 16.9 mIU/mL.

**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 CEA assay has been standardized against the 1st IRP WHO Reference Standard 73/601.

**Precautions and warnings**

For in vitro diagnostic use for healthcare 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 mist or vapours.

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.

**Hazardous components:**

- 2-methyl-2H-isothiazol-3-one hydrochloride
- Product safety labeling follows EU GHS guidance.

Contact phone: all countries: +49-621-7590, USA: 1-800-428-2336

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.<sup>1,2</sup>

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.

All other 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
<b>cobas e 411 analyzer</b> 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**

- CEA CalSet, 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 CEA 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**

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

The Summary of Safety & Performance Report can be found here:  
<https://ec.europa.eu/tools/eudamed>

### Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see [navifyportal.roche.com](https://navifyportal.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

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

### FOR US CUSTOMERS ONLY: LIMITED WARRANTY

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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