

CalSet Anti-SARS-CoV-2 S

cobas®

REF 09289291190

→ 4 x 1.0 mL

English

Intended use

CalSet Anti-SARS-CoV-2 S is used for calibrating the Elecsys Anti-SARS-CoV-2 S assay on **cobas e** immunoassay analyzers.

Summary

CalSet Anti-SARS-CoV-2 S is a lyophilized human serum spiked with human serum from anti-SARS-CoV-2 S positive donors in two concentration ranges.

The CalSet can be used with all reagent lots.

Reagents - working solutions

- ACOVS Cal1: 2 bottles, each for 1.0 mL of calibrator 1
 - ACOVS Cal2: 2 bottles, each for 1.0 mL of calibrator 2
- Anti-SARS-CoV-2 positive serum in two concentration ranges.

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 Anti-SARS-CoV-2 S assay has been standardized against the internal Roche standard for anti-SARS-CoV-2-S.

Subsequently, it could be shown that the First WHO International Standard for anti-SARS-CoV-2 immunoglobulin (human), NIBSC code: 20/136, behaves identically to the internal Roche standard, with a Pearson correlation coefficient $r = 0.9996$ between LoQ and 1000 BAU/mL. Hence, the numeric results in U/mL of the Elecsys Anti-SARS-CoV-2 S assay and BAU/mL are equivalent (e.g. 1 U/mL of the Elecsys Anti-SARS-CoV-2 S assay corresponds to 1 BAU/mL).

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.

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 dust/fume/gas/mist/vapours/spray.

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.

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 used assays approved by the FDA or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.

The serum containing anti-SARS-CoV-2 used for calibrator material was heat-inactivated for 30 minutes at 56 °C.

However, as no inactivation or 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 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.

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. Store the aliquots at 2-8 °C or at -20 °C (± 5 °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.

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

Stability of the reconstituted calibrators:	
either at -20 °C (± 5 °C)	6 weeks
or at 2-8 °C	14 days
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

- CalSet Anti-SARS-CoV-2 S, barcode card, 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
- cobas e** immunoassay analyzers and Elecsys Anti-SARS-CoV-2 S 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.

CalSet Anti-SARS-CoV-2 S



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 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 (for USA: see dialog.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

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Additions, deletions or changes are indicated by a change bar in the margin.

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