

CalSet Vitamin D total III

cobas®

REF 09038116190

→ 4 x 1.0 mL

English

Intended use

CalSet Vitamin D total III is used for calibrating the quantitative Elecsys Vitamin D total III assay on **cobas e** immunoassay analyzers.

Summary

CalSet Vitamin D total III is a lyophilized human serum matrix with added 25-hydroxyvitamin D₃ in two concentration ranges.

The CalSet can be used with all reagent lots.

Reagents - working solutions

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

25-hydroxyvitamin D₃ in two concentration ranges (approximately 10 ng/mL or 25 nmol/L and approximately 70 ng/mL or 175 nmol/L) in a human serum matrix; preservative.

cobas e 402 and **cobas e 801** analyzers: The exact lot-specific calibrator values are encoded in the electronic barcode and available via the **cobas** link.

All other analyzers: 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 Vitamin D total III assay has been standardized against internal standards which are traceable to the ID-LC-MS/MS 25-hydroxyvitamin D RMP.^{1,2}

The ID-LC-MS/MS is traceable to the National Institute of Standards and Technology Standard Reference Material 2972.³

Precautions and warnings

For in vitro diagnostic use for health care 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.

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 by the FDA or that are in compliance with the legal rules applicable to placing in vitro diagnostic medical devices for human use on the market in the European Union.

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.^{4,5}

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 the reconstituted calibrators into the supplied empty labeled snap-cap 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.

If necessary, freeze in aliquots; see section on **cobas e 402**, **cobas e 601**, **cobas e 602** and **cobas e 801** analyzers.

cobas e 402, **cobas e 601**, **cobas e 602** and **cobas e 801** 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 -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)	12 weeks (freeze only once)
or at 2-8 °C	72 hours
on cobas e 411 analyzer at 20-25 °C	up to 6 hours
on cobas e 402 , cobas e 601 , cobas e 602 and cobas e 801 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 Vitamin D total III, barcode card, 4 empty labeled snap-cap bottles, 2 x 6 bottle labels

Materials required (but not provided)

- REF 11776576122, CalSet Vials, 2 x 56 empty snap-cap bottles
- cobas e** immunoassay analyzers and Elecsys Vitamin D total III 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.

References

- Sempos CT, Vesper HW, Phinney KW, et al. The Vitamin D Standardization Program (VDSP). Vitamin D Status as an International Issue: National Surveys and the Problem of Standardization. Scand J Clin Lab Invest 2012;72(Suppl 243):32-40.
- Thienpont LM, Stepman HCM, Vesper HW. Standardization of Measurements of 25-Hydroxyvitamin D3 and D2. Scandinavian Journal of Clinical & Laboratory Investigation, 2012;72(Suppl 243):41-49.
- Phinney KW. Development of a standard reference material for vitamin D in serum. Am J Clin Nutr 2008;88(2):511-512.
- 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 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.

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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.

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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