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Vitamin D3 (25-OH) CalSet

cobas®

03314855 190

for 4 x 1.0 mL

English

Intended use

Elecsys Vitamin D₃ (25-OH) CalSet is used for calibrating the quantitative Elecsys Vitamin D₃ (25-OH) assay on the Elecsys and **cobas e** immunoassay analyzers.

Summary

Elecsys Vitamin D₃ (25-OH) CalSet consists of a lyophilized human serum matrix with added 25-OH vitamin D₃ in two concentration ranges. The CalSet can be used with all reagent lots.

Reagents - working solutions

- VIT-D Cal1: 2 bottles, each for 1.0 mL of calibrator 1
 - VIT-D Cal2: 2 bottles, each for 1.0 mL of calibrator 2
- 25-OH vitamin D₃ in two concentration ranges (approx. 15 ng/mL or 37.5 nmol/L and approx. 70 ng/mL or 175 nmol/L) in a human 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 Vitamin D₃ (25-OH) assay has been standardized against LC-MS-MS.¹

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. 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 applied were FDA-approved or cleared in compliance with the European Directive 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 treated just as carefully as a patient specimen. In the event of exposure the directives of the responsible health authorities should be followed.^{2,3}

Avoid the formation of foam with all reagents and sample types (specimens, calibrators, and controls).

Handling

Dissolve carefully the contents of one bottle by adding exactly 1.0 mL of distilled water and allow to stand closed for 30 minutes to reconstitute. Mix carefully, avoiding the formation of foam.

Transfer aliquots of the reconstituted calibrator 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.

Storage and stability

Store at 2-8°C.

The lyophilized calibrators are stable up to the stated expiration date. Stability of the reconstituted calibrators:

at 2-8°C:	5 days
at -20°C:	3 months (freeze only once)
on the analyzers at 20-25°C:	up to 5 hours (use only once)

Materials provided

- Elecsys Vitamin D₃ (25-OH) CalSet, barcode card, calibrator barcode sheet, 4 empty labeled snap-cap bottles, 2 x 6 bottle labels

Materials required (but not provided)

- Cat. No. 11776576, CalSet Vials, 2 x 56 empty snap-cap bottles
- Elecsys 2010, MODULAR ANALYTICS E170 or **cobas e** immunoassay analyzers and Elecsys Vitamin D₃ (25-OH) assay reagents. See test package insert and operator's manual for additionally required materials.
- Distilled or deionized water

Assay

For use on the analyzers, 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; these data are encoded in the supplied barcodes, the reagent barcode, and the barcode on the calibrator bottle label.

Ensure the calibrators are at ambient temperature (20-25°C) before measurement.

References

- Vogeser M, et al. Candidate Reference Method for the Quantification of Circulating 25-Hydroxyvitamin D₃ by Liquid Chromatography-Tandem Mass Spectrometry. Clinical Chemistry 50, No. 8, 2004.
- Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register. July 1, 2001;17:260-273.
- Council Directive (2000/54/EC). Official Journal of the European Communities No. L262 from Oct. 17, 2000.

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For further information, please refer to the appropriate operator's manual for the analyzer concerned, the respective application sheets, the product information, and the package inserts of all necessary components.

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