

04896653001V1

# Vitamin D<sub>3</sub> (25-OH) CalSet



03314855 190

for 4 x 1.0 mL

## English

### Intended use

Elecsys Vitamin D<sub>3</sub> (25-OH) CalSet is used for calibrating the quantitative Elecsys Vitamin D<sub>3</sub> (25-OH) assay on the Elecsys and **cobas e** immunoassay analyzers.

### Summary

Elecsys Vitamin D<sub>3</sub> (25-OH) CalSet consists of a lyophilized human serum matrix with added 25-OH vitamin D<sub>3</sub> 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 D<sub>3</sub> 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 D<sub>3</sub> (25-OH) assay has been standardized against LC-MS-MS.<sup>1</sup>

### 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.<sup>2,3</sup>

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 D<sub>3</sub> (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 D<sub>3</sub> (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 D<sub>3</sub> 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.

### NOTICE TO PURCHASER: LIMITED LICENSE

The purchase of this product allows the purchaser to use it solely for detection by ECL Technology for human in vitro diagnostic uses. No general patent or other license of any kind other than this specific right of use from purchase is granted hereby. This product may not be used by purchaser to conduct life science research and/or development, patient self-testing, drug discovery and/or development or in any veterinary, food, water or environmental testing or use.

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.

### 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.

COBAS, COBAS E and ELECSYS are trademarks of Roche.  
Other brand or product names are trademarks of their respective holders.  
Significant additions or changes are indicated by a change bar in the margin.  
©2007 Roche Diagnostics.



Roche Diagnostics GmbH, D-68298 Mannheim  
for USA: US Distributor:  
Roche Diagnostics, Indianapolis, IN  
US Customer Technical Support 1-800-428-2336

