**Indication**

Vitamin D is a fat-soluble steroid hormone precursor that is mainly produced in the skin by exposure to sunlight. Vitamin D is biologically inert and must undergo hydroxylation steps to become active. Our body can only synthesize vitamin D3. Vitamin D2 is taken up with fortified food or given by supplements. Physiologically, vitamin D3 and D2 are bound to the vitamin D-binding protein (VDBP) in plasma and transported to the liver to become 25-hydroxyvitamin D (vitamin D (25-OH)). As vitamin D (25-OH) represents the major storage form, its blood concentration is used to assess the overall vitamin D status. More than 95% of vitamin D (25-OH), measurable in serum, is vitamin D3 (25-OH) whereas vitamin D2 (25-OH) reaches measurable levels only in patients taking vitamin D2 supplements. Vitamin D is essential for bone health. In children, severe deficiency leads to rickets. In elderly, the risk of falling has been attributed to vitamin D deficiency due to muscle weakness. Moreover, low vitamin D (25-OH) concentrations are associated with lower bone mineral density. Insufficiency has also been linked to diabetes, cancer, cardiovascular disease, and autoimmune diseases. The Elecsys Vitamin D assay employs VDBP to capture both 25-hydroxyvitamin D3 and D2. This assay is intended for the quantitative determination of total vitamin D (25-OH) in human serum and plasma, as an aid in the assessment of vitamin D sufficiency.

**Test principle: Competitive protein binding assay**

First, the sample is incubated with a pretreatment reagent for 9 minutes. Thereby, the natural VDBP in the sample is denatured to release the bound vitamin D (25-OH). Second, the sample is further incubated with a recombinant ruthenium-labeled VDBP to form a complex of vitamin D (25-OH) and the ruthenylated-VDBP. Third, with the addition of a biotinylated vitamin D (25-OH) a complex consisting of the ruthenium-labeled VDBP and the biotinylated vitamin D (25-OH) is formed. The entire complex becomes bound to the solid phase (by the interaction of biotin and streptavidin-coated microparticles which are captured on the surface of the electrode). Unbound substances are removed. Applying voltage to the electrode induces chemiluminescent emission which is measured by a photomultiplier. Results are determined via an instrument-specific calibration curve which is generated by 2-point calibration and a calibration master curve provided via the reagent barcode.
Elecsys® Vitamin D test characteristics

Testing time 27 minutes
Test principle Competitive protein binding assay
Calibration 2 points
Sample material Serum and plasma
Sample volume 1.5 μL
Limit of detection 3.00 ng/mL
Limit of quantitation (Functional sensitivity) 5.00 ng/mL (12.5 nmol/L) with CV ≤ 20%
Measuring range 5.00 - 60.0 ng/mL (12.5 - 150 nmol/L)
Dilution 1:2 (if concentration of diluted sample is > 25 ng/mL or 62.5 nmol/L)
Traceability Standardized against LC-MS/MS which in turn is traceable to NIST
Repeatability Within-run precision: LOQ - 15 ng/mL: SD ≤ 0.57 ng/mL
Reproducibility Intermediate precision: LOQ - 15 ng/mL: CV% ≤ 4.4%
Expected values Currently there is no standard definition of the optimal vitamin D status. Many specialists consider the commonly used population based reference values too low. Health based reference values are recommended to replace population based reference values. Most experts agree that vitamin D deficiency should be defined as vitamin D (25-OH) of ≤ 20 ng/mL (≤ 50 nmol/L). Vitamin D insufficiency is recognized as 21-29 ng/mL (52.5 nmol/L) and 63 ng/mL (158 nmol/L). Similarly, the US National Kidney Foundation considers levels < 30 ng/mL to be insufficient or deficient. The preferred level for vitamin D (25-OH) by many experts is now recommended to be ≥ 30 ng/mL (≥ 75 nmol/L).

Order information
Elecsys® Vitamin D 100 tests 06506780 160
Vitamin D CalSet 4 x 1 mL 06506798 160
PreciControl Varia 3 3 x 3 mL each 06364829 160

Method comparison

1. A comparison of the Elecsys Vitamin D assay (y) using samples measured with LC-MS/MS (x) gave the following correlation:

   \[ y = 1.03 x + 3.07 \]

2. A comparison of the Elecsys Vitamin D assay (y) using samples measured with a commercially available 25-hydroxyvitamin D immunoassay (x) gave the following correlation:

   \[ y = 0.992 x + 1.20 \]

References