

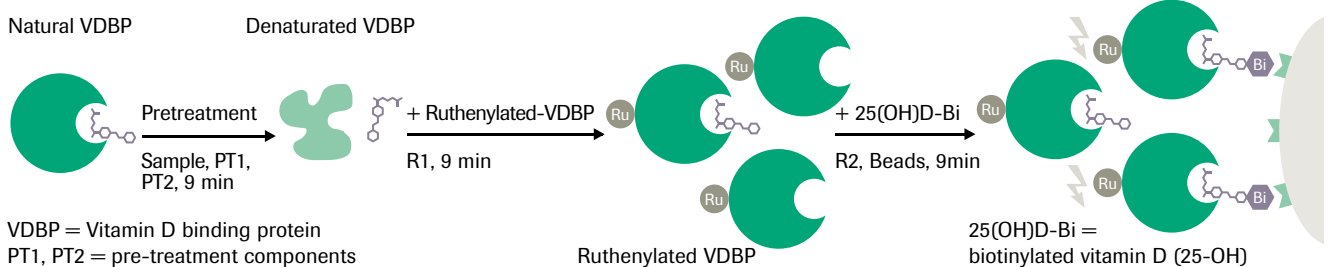
# Elecsys<sup>®</sup> Vitamin D total assay

## *Electro-chemiluminescence binding assay (ECLIA) for the in-vitro determination of total 25-hydroxyvitamin D*

### 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.<sup>1</sup> 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.<sup>1,2,3</sup> 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.<sup>1</sup> The Elecsys Vitamin D total 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



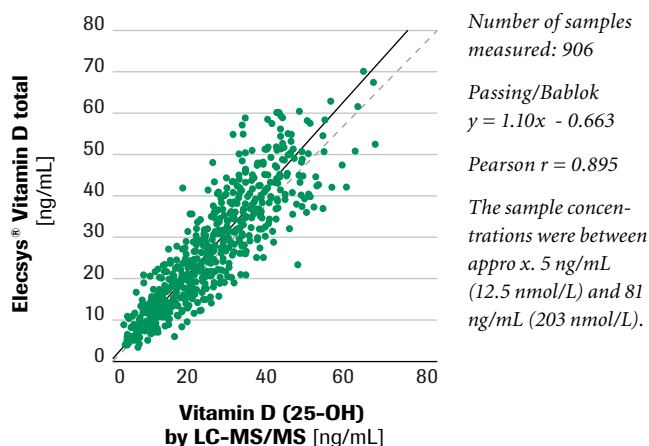
First, the sample is incubated with a pretreatment reagent for 9 minutes. Thereby, the natural VDBP in the sample is denatured to release the bound vitamin D (25-OH). Second, the sample is further incubated with a recombinant ruthenium-labeled VDBP to form a complex of vitamin D (25-OH) and the ruthenylated-VDBP. 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 total test characteristics

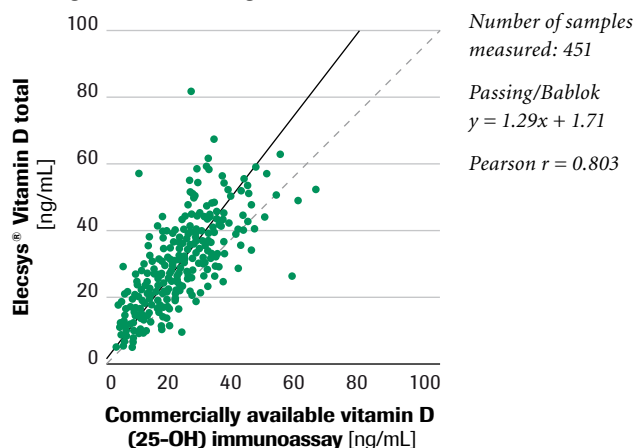
Testing time	27 min
Test principle	Competitive protein binding assay
Calibration	2 points
Sample material	Serum and plasma
Sample volume	15 µL
Detection limit	3.00 ng/mL (7.50 nmol/L)
Functional sensitivity	4.01 ng/mL (10.0 nmol/L) (CV 18.5 %)
Measuring range	3.00 – 70.0 ng/mL (7.50 – 175 nmol/L)
Dilution	1:2 (if concentration of diluted sample is > 30 ng/mL or 75 nmol/L)
Traceability	Standardized against LC-MS/MS which in turn is traceable to NIST
Repeatability	Within-run precision: < 15 ng/mL: SD ≤ 1 ng/mL > 15 ng/mL: ≤ 6.5 %
Reproducibility	Intermediate precision: < 15 ng/mL: SD ≤ 1.7 ng/mL > 15 ng/mL: ≤ 11.5 %
Expected values	Most experts agree that vitamin D deficiency should be defined as vitamin D (25-OH) of ≤ 20 ng/mL. <sup>4</sup> Vitamin D insufficiency is recognized as 21-29 ng/mL. <sup>4</sup> The preferred level for vitamin D (25-OH) is recommended to be ≥ 30 ng/mL. <sup>4,5</sup>

## Method comparison

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



**2. A comparison of the Elecsys Vitamin D total assay (y) using the same sample set as the left graph measured with a commercially available 25-hydroxyvitamin D immunoassay (x) gave the following correlations:**



## Order information

Elecsys® Vitamin D total	100 tests	05894913 190
Vitamin D total CalSet	4 x 1 mL	05894921 190
PreciControl Varia	2 x 3 mL each	05618860-190/-922

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