



DiaSino® 25OH Vitamin D total

One-step ELISA test for the in-vitro determination of 25-hydroxyvitamin D total



diasino®

Vitamin D testing

Indication

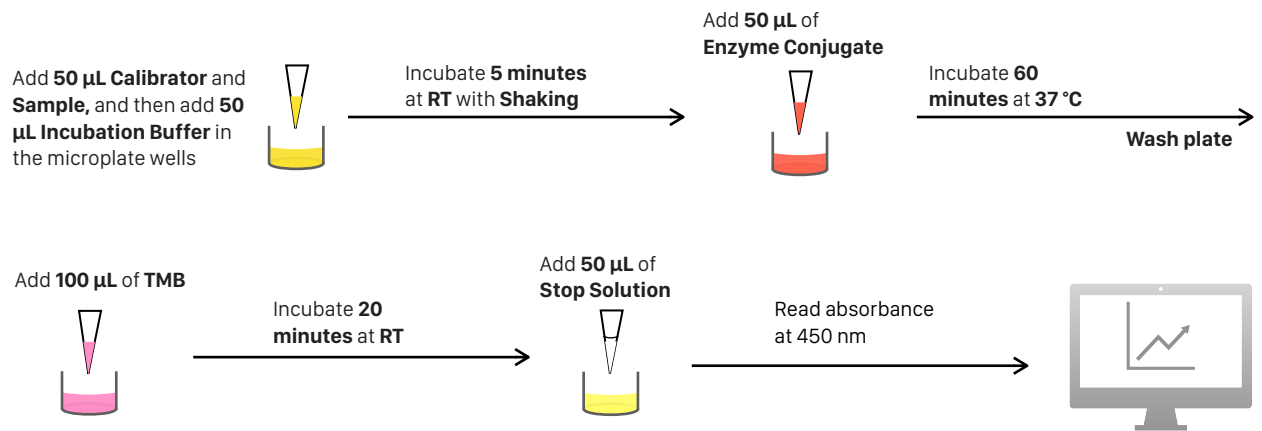
Vitamin D is a fat-soluble steroid hormone precursor that is mainly produced in the skin by exposure to sunlight. Vitamin D is biologically inert and must undergo hydroxylation steps to become active.¹ Our body can only synthesize vitamin D3. Vitamin D2 is taken up with fortified food or given by supplements. 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.^{1,2,3} 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.¹ The DiaSino 25-OH Vitamin D is intended for the quantitative determination of vitamin D (25-OH) in human serum, plasma, tissue homogenates and other biological fluids, as an aid in the assessment of vitamin D sufficiency.

Determining Vitamin D status

The measurement of the 25OH Vitamin D concentration in serum or plasma is so far the best indicator of Vitamin D nutritional status. It is generally accepted that serum 25OH Vitamin D levels reflect the body's storage levels of Vitamin D and correlate with the clinical symptoms of Vitamin D deficiency. There is no consensus about the optimal 25OH Vitamin D level, but many publications suggest a range ≥ 30 ng/mL (>80 nmol/L) as optimal. The most widely used intervals are indicated in table 1. Several population studies have identified widespread 25OH Vitamin D insufficiency ($> 40\%$ of the population) in apparent healthy populations. Paediatric reference intervals have not been established, but the American Association for Paediatrics (AAP) recommends a value of 20 ng/mL for healthy children.

Table 1: Suggested reference values for adults	
Vitamin D status	25OH Vitamin D total (ng/mL)
Deficient	<10
Insufficient	10-29
Sufficient	30-100
Potential Toxicity	>100

DiaSino® Assay protocol: Probably the most convenient 25OH Vitamin D total ELISA on the market



DiaSino® 25OH Vitamin D total test characteristics

Testing time	85 minutes
Test principle	One-step competition method
Calibrators	0, 7.5, 15, 30, 75, 150 ng/mL
Sample material	Serum
Sample volume	50 µL
Detection limit	2.0 ng/mL
Measuring range	2.0- 150 ng/mL
Traceability	Standardized against Roche Elecsys® 25OH Vitamin D total
Expected values	Most experts agree that vitamin D deficiency should be defined as vitamin D (25-OH) of ≤ 20 ng/mL. Vitamin D insufficiency is recognized as 21-29 ng/mL. The preferred level for vitamin D (25-OH) is recommended to be ≥ 30 ng/mL. ^{4,5}

Precision

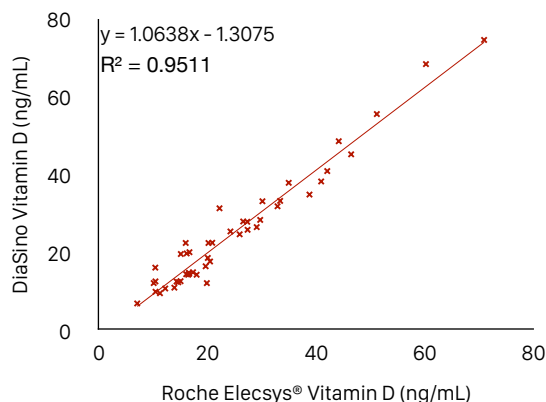
Precision was determined using DiaSino Vitamin D total reagents, pooled human sera, and controls in a modified protocol (EP5-A) of the CLSI (Clinical and Laboratory Standards Institute): 2 times daily for 20 days (n = 40). The following results were obtained below:

		Repeatability (Within-run precision)		Intermediate Precision	
Sample	Mean ng/mL	SD ng/mL	CV %	SD ng/mL	CV %
Human Serum 1	8.2	0.6096	7.4	0.6972	8.5
Human Serum 2	21.4	1.3268	6.2	1.5432	7.2
Human Serum 3	33.5	2.0544	6.1	1.9754	5.9
PC Universal 1	13.3	0.9773	7.3	0.9877	7.4
PC Universal 2	30.1	1.4050	4.7	1.8523	6.2

Method comparison

A comparison of the DiaSino® Vitamin D total assay (y) with the Roche Elecsys® Vitamin D (x) using clinical samples gave the following correlations:

Number of samples measured: 52



DiaSino® offers Vitamin D total, Intact PTH and Osteocalcin ELISA kits, which are used for diagnosis and monitoring of osteoporosis.

To learn more, visit <http://www.diasino.com/immunodiagnostics>

DiaSino bone marker panel and ordering information

Reference No.	Diagnostic assay	Testing time	Measuring range	Detection limit
DS167701	Vitamin D total	85 min	2.0-150 ng/mL	2.0 ng/mL
DS167702	Intact PTH	45 min	1.0-3500 pg/mL	1.0 pg/mL
DS167703	Osteocalcin	45 min	0.500-300 ng/mL	0.500 ng/mL

Thyroid

TSH
T3
T4
Free T3
Free T4
Anti-Tg
Anti-TPO

Fertility

AMH
Inhibin A
Inhibin B
β-hCG
LH
FSH
PRL
Progesterone
Testosterone
E2
DHEA-S*
SHBG*
17-OH Progesterone*

Anemia

Vitamin B12
Folate (FA)
Ferritin

Bone

25OH Vitamin D total
Intact PTH
Osteocalcin
β-CrossLaps*
P1NP*

Infection

HAV IgM
HBsAg
Anti-HCV
HIV1/2
HIV Ag/Ab
Syphilis TP
HEV IgM
H.Pylori IgA*
H.Pylori IgG*
H.Pylori IgM*

TORCH

TOXO IgG
CMV IgG
Rubella IgG
HSV-1 IgG
HSV-2 IgG
TOXO IgM
CMV IgM
Rubella IgM
HSV-1 IgM
HSV-2 IgM

Tumor

AFP
CEA
PSA
Free PSA

Autoimmune

ds-DNA
ANA
Anti-Tg
Anti-TPO

* In development

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1. Holick, M.F. (2007). Vitamin D deficiency. N Engl J Med, 357:266-281.
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3. Hart, G.R., Furniss, J.L., Laurie, D., et al. (2006). Measurement of vitamin D Status: background, clinical use and methodologies. Clin Lab, 52(7-8):335-343.
4. Holick, M.F. (2009). Vitamin D status: measurement, interpretation, and clinical application. Ann Epidemiol. 19(2):73-8.
5. Souberbielle, J.C., Body, J.J., Lappe, J.M., Plebani, M., et al. (2010). Vitamin D and musculoskeletal health, cardiovascular disease, autoimmunity and cancer: Recommendations for clinical practice. Autoimmun Rev. 9(11):709-15.

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