

MD

FOR OUTSIDE THE US AND CANADA ONLY

LIAISON[®] 25 OH VITAMIN D TOTAL Assay

METABOLIC DISORDERS

DiaSorin

The Diagnostic Specialist

MD

LIAISON® 25 OH Vitamin D Total Assay

What is Vitamin D?

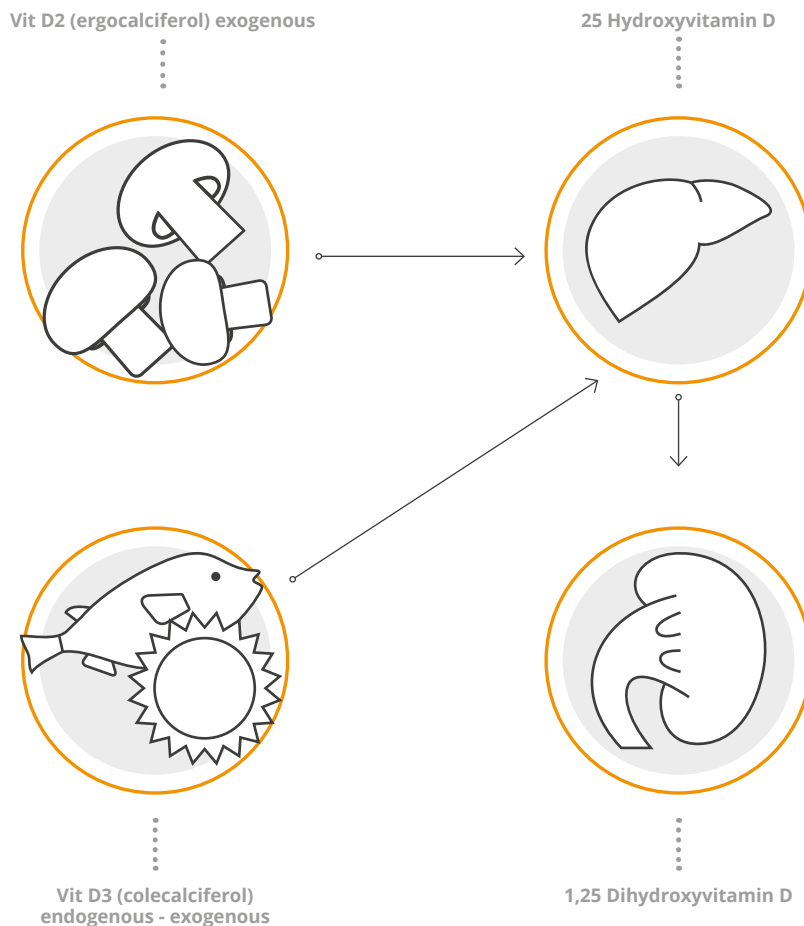
Vitamin D is a steroid hormone that is produced in the skin upon UV-B exposure or is ingested via the diet.

The 25-hydroxyvitamin D (25 OH Vitamin D) is the most common form of the hormone in the circulation and is the inactive precursor of the active form, 1,25-dihydroxyvitamin D (1,25 (OH)₂ Vitamin D). Because of its long half-life and high concentration, 25 OH Vitamin D is commonly measured for monitoring the Vitamin D status in the patient.

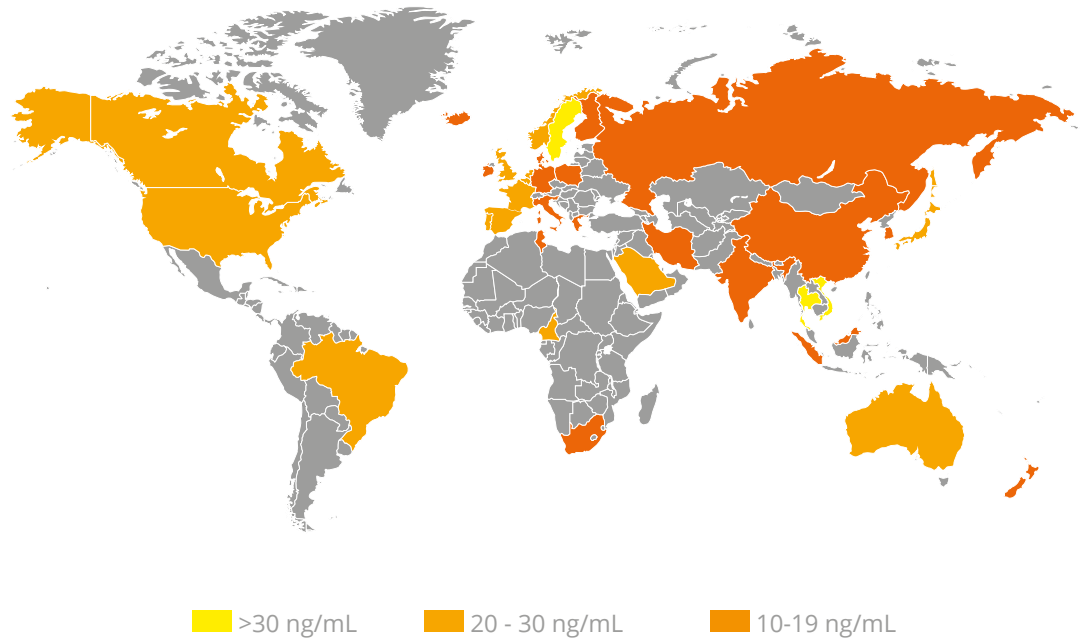
Vitamin D is maintained in the body thanks to two mechanisms, one endogenous, with the production of the hormone thanks to sun exposure and one exogenous, with the introduction of vitamin D with the food. The chemical structures of these types of Vitamin D are different and are called Vitamin D2 (ergocalciferol) and Vitamin D3 (cholecalciferol). D2 is present in some foods and food supplements. Vitamin D3, on the other hand, is produced by the body at the skin level under the influence of solar radiation. In Vitamin-based pharmaceutical preparations the two forms of Vitamin are indifferently present. The two forms of Vitamin D2 and D3 have the same effect and therefore it is important to know the sum of their quantities or the total concentration of 25 OH Vitamin D.

The concentration of 25 OH Vitamin D is used to estimate the reserve of Vitamin D.

Sources and forms of Vitamin:

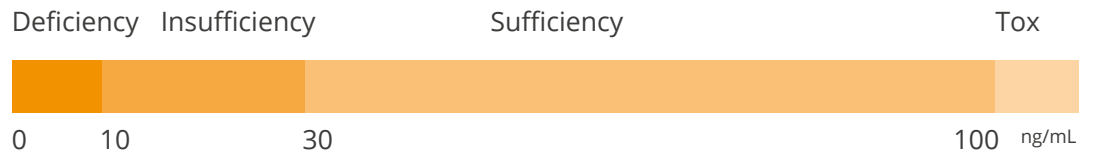


**Average Vitamin D
in adults (>18 years)
around the world**



Adapted from Wahl et al. Arch Osteoporos (2012) 7:155-172

**Health Based
Reference Values
as per LIAISON®
Vitamin D Total IFU**



**Why 25OH Vitamin D
level is relevant
for health status**

25OH Vitamin D status is an important indicator of health which is investigated in several diseases and conditions. Vitamin D is involved in the homeostasis of calcium and phosphorus and in bone metabolism. An inadequate level of 25OH Vitamin D can lead to a reduction of calcium and phosphorus in the blood circulation, which indirectly stimulate the release of calcium from the bone matrix and the increase of phosphate-wasting in the urine. This results in abnormalities of bone structure in children, muscle and bone weakness and increase falls in the elderly.

The monitoring of vitamin D is helpful in those diseases where calcium and phosphorus homeostasis or bone metabolism are altered, like rickets, osteomalacia, osteoporosis and patients with risk of falls and history of fractures, chronic kidney diseases patients, patients with malabsorption disorders, hepatic failure, patients under treatments with some medications and in granulomatosis diseases. Other individuals can suffer of Vitamin D deficiency and monitoring of the values are helpful, like pregnant and lactating women, obese people and afro-american and hispanic people*.

*Holick et al., Evaluation, Treatment and Prevention of Vitamin D Deficiency: an Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab, July 2011, 96(7):1911-1930

A Story of Quality

- A fully automated immunoassay for the direct measurement of 25 OH Vitamin D total levels in human serum, EDTA plasma and lithium heparin plasma.
- Allows quick and reliable determination of Vitamin D status and effective therapy monitoring.
- Uses advanced chemiluminescence technology with magnetic microparticle separation to achieve the best assay sensitivity and precision.



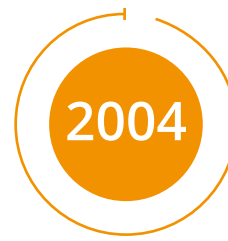
The history of DiaSorin Vitamin D test



DiaSorin (INCSTAR) introduced first 3H-based RIA.



DiaSorin's RIA Vitamin D was the first FDA-cleared.



LIAISON® 25 OH Vitamin D was the first fully automated CLIA assay FDA cleared.



LIAISON® 25 OH Vitamin D TOTAL Assay was FDA cleared.



The current version of LIAISON® 25OH Vitamin D is released and XL platform is added.



LIAISON® 25OH Vitamin D receives the VDSCP certification for the first time. The certification is confirmed in the following years.



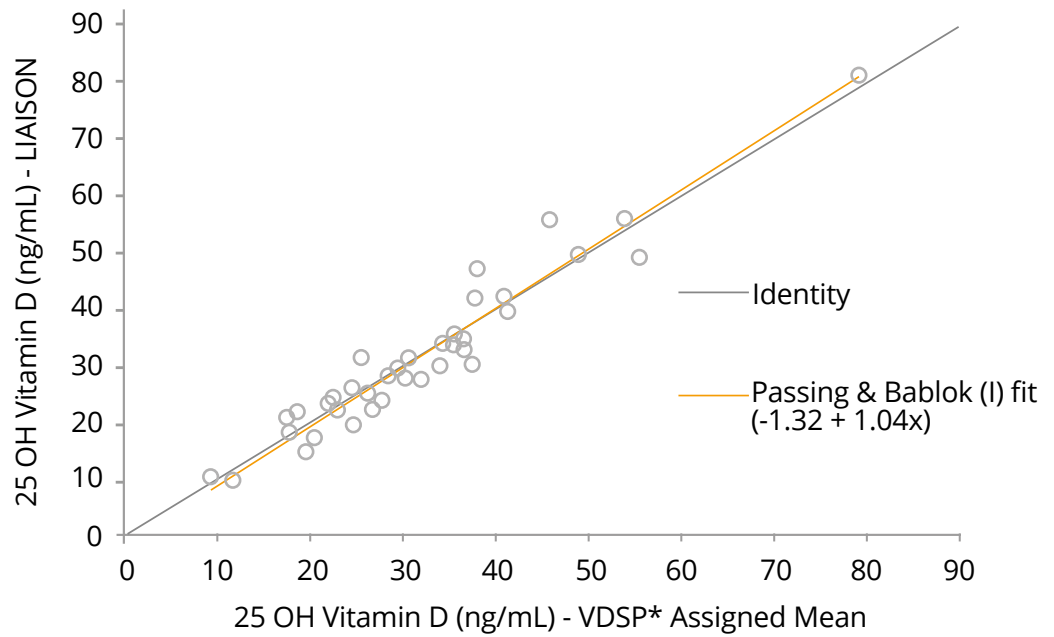
LIAISON® 25OH Vitamin D is available on LIAISON® XS



LIAISON® 25OH Vitamin D is available with the 200 test/integral format

CDC Vitamin D
Standardization
and Certification
Program

LIAISON® 25OH Vitamin D Total Assay is certified since 2014.



Scatter Plot with Passing & Bablok Fit (N = 40)

VDSCP: Vitamin D Standardization and Certification Program

The scatter plot generated with a Passing & Bablock regression obtained a fit of $y=1.04x -1.32$ vs the VDSP assigned mean, showing an excellent correlation to the DiaSorin 25 OH Vitamin D CLIA assay

✓
Dynamic range:
4.0 – 150 ng/mL

✓
Time to first result:
24 minutes

✓
Throughput:
170 tests/hour
(LIAISON® XL)

Functional Sensitivity

Guidelines	evaluated according to CLSI EP17-A
Definition	dose concentration at which the % CV exceeds 20%
Sample concentration	2-14 ng/mL
Assays	multiple runs performed
Result	Functional Sensitivity: ≤ 4.0 ng/mL

Assay precision

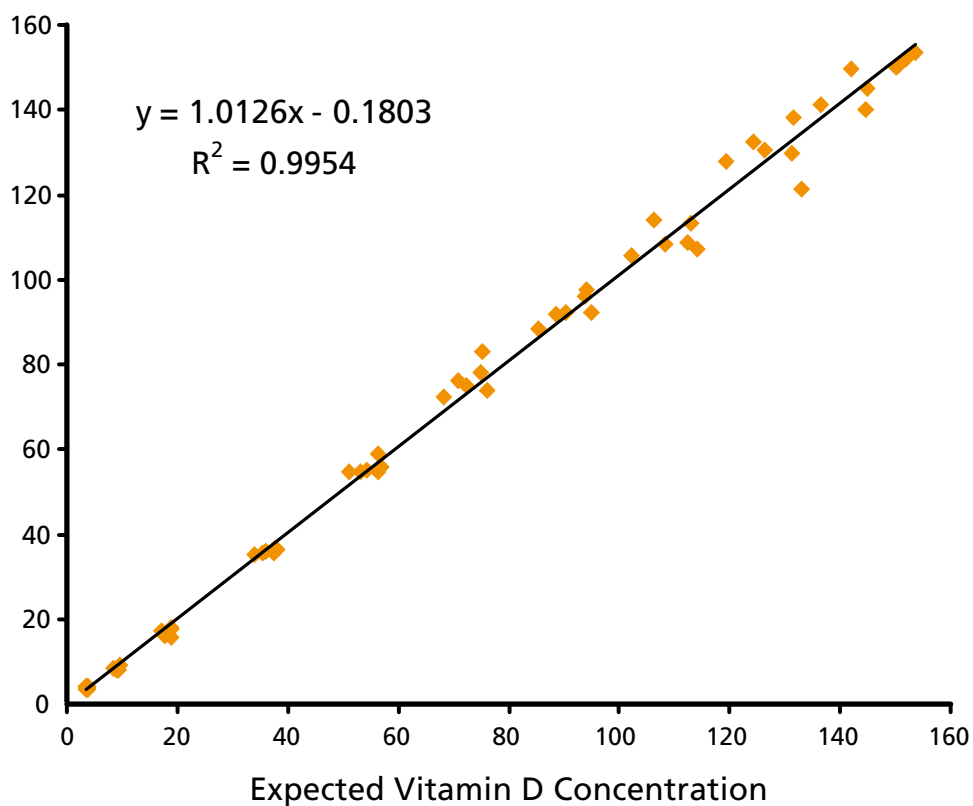
Guidelines	evaluated according to CLSI EP5-A2
# samples	6 samples + 2 controls

		Intra Run Across Lots and Sites		Total Across Lots and Sites		
		SD	% CV	SD	% CV	
LIAISON®		2.0	5.4	4.1	10.6	
			Intra Run Within One Lot and Site		Total Within One Lot and Site	
			SD	% CV	SD	% CV
			1.7	4.9	3.8	7.8
LIAISON® XL			Intra Run		Total	
			SD	% CV	SD	% CV
			0.8	2.3	3.8	7.80

Cross-reactivity

Guidelines	Evaluated according to CLSI EP7-A2
Sample concentration	spiking up to 100 ng/mL of the potential cross-reactant
Assays	cross-reactivity normalized to 25 OH Vitamin D3
Molecule	Cross-reactivity %
25 OH Vitamin D2	100.0
25 OH Vitamin D3	100.0
Vitamin D2	1.9
Vitamin D3	1.9
1,25 (OH) ₂ Vitamin D2	6.7
1,25 (OH) ₂ Vitamin D3	9.3
3-epi-25 OH Vitamin D3	1.3

LIAISON® 25 OH
Vitamin D TOTAL
Linearity
Serum and SST



DiaSorin: The Diagnostic Specialist in Vitamin D

25 OH Vitamin D TOTAL		
Part Number	310600	318360
Determinations per Reagent Integral	100	200
Instrument Assay ID	25OHD	25OHD2
Instrument Compatibility	LIAISON®, LIAISON® XL, LIAISON® XS	LIAISON® XL
Reagent Integral Open Stability	4 weeks	
Calibration Stability	7 days	
Assay Range	4.0 - 150 ng/mL	

Ordering information

LIAISON® 25 OH Vitamin D TOTAL Assay 100 test	code 310600
LIAISON® 25 OH Vitamin D TOTAL Assay 200 test	code 318360*
LIAISON® 25 OH Vitamin D TOTAL Control Set	code 310601
LIAISON® 25 OH Vitamin D TOTAL Specimen Diluent Set	code 310602

Please visit: www.diasorin.com
for more information and updates

LIAISON® is a registered trademark of DiaSorin

Available on LIAISON® Analyzer family

*Available on LIAISON® XL only

Product availability subject to required regulatory approval

DiaSorin S.p.A

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