LIAISON®
25 OH Vitamin D TOTAL Assay

25-hydroxyvitamin D: from bone and mineral to general health marker
25-hydroxyvitamin D: to general
The role of vitamin D in regulating circulating levels of calcium and phosphorus to ensure normal bone mineralization is well known.

Emerging evidence correlates insufficient levels of vitamin D to an increased risk of developing non-skeletal pathologies: cardiovascular diseases, hypertension, cancer, diabetes, multiple sclerosis, rheumatoid arthritis, infectious diseases.

The diverse effects of vitamin D are mediated by receptors that regulate more than 200 genes. Besides the receptors present in the intestine and the bone, vitamin D receptors have been identified in brain, prostate, breast, colon, immune cells, vascular smooth muscle and cardiomyocytes. (1,2)

Maintaining sufficient vitamin D levels is therefore key to maintain good general health.
Vitamin D status is assessed by measuring the serum concentration of 25-hydroxyvitamin D:

<table>
<thead>
<tr>
<th>Status</th>
<th>Range</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deficiency</td>
<td>&lt; 10 ng/mL</td>
<td>(0-25 nmol/L)</td>
</tr>
<tr>
<td>Insufficiency</td>
<td>10-30 ng/mL</td>
<td>(25-75 nmol/L)</td>
</tr>
<tr>
<td>Sufficiency</td>
<td>30-100 ng/mL</td>
<td>(75-250 nmol/L)</td>
</tr>
<tr>
<td>Toxicity</td>
<td>&gt; 100 ng/mL</td>
<td>(&gt;250 nmol/L)</td>
</tr>
</tbody>
</table>

It has been estimated that 1 billion people worldwide do not reach the minimum optimal concentration of 30 ng/mL. (1)

An increasing number of studies associate vitamin D insufficiency with a higher risk of developing several pathologies

A prospective study in which 1739 participants without prior cardiovascular disease were followed-up for 5 years showed that individuals with hypertension and 25(OH) vitamin D levels <15 ng/mL had a 2-fold risk of cardiovascular events compared to those with levels >15 ng/mL. (2)

An analysis of 454 men, who were free of diagnosed cardiovascular disease at baseline and developed myocardial infarction or coronary heart disease during 10 years of follow-up, and 900 controls indicated that the risk of myocardial infarction was double for individuals with insufficient levels of 25(OH) vitamin D (<15 ng/mL) compared to sufficient levels (>30 ng/mL). (3)

A 7-year follow-up study of 3258 patients referred for coronary angiography showed that decreasing 25(OH) vitamin D levels (Q1 = 7.6 ng/mL, Q2 = 13.3 ng/mL, Q3 = 18.9 ng/mL, Q4 = 28.4 ng/mL) were associated with increasing risk for all-cause and cardiovascular mortality. (4)

An increasing number of studies associate vitamin D insufficiency with a higher risk of developing several pathologies

A pooled analysis of two studies with 880 cases of breast cancer and 880 controls demonstrated that individuals with serum 25(OH) vitamin D of approximately 52 ng/mL had 50% lower risk of breast cancer than those with levels <13 ng/mL. (5)

An analysis of 1394 post-menopausal breast cancer cases and 1365 controls suggested that serum 25(OH) vitamin D concentration was significantly inversely associated with breast cancer risk, particularly at levels <20 ng/mL. (6)

A 4-year trial including 1085 healthy women supplemented with placebo, calcium or calcium + vitamin D showed that vitamin D supplementation reduced by 77% the relative risk of developing cancer. (7)

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The risk of multiple sclerosis in a white population of 148 patients and 296 controls was demonstrated to be 51% lower for individuals with 25(OH) vitamin D levels >40 ng/mL compared to levels <30 ng/mL. (8)

A study including 103 patients and 110 controls showed that for every 4 ng/mL increase of serum 25(OH) vitamin D the odds of multiple sclerosis were reduced by 19% in women. (9)

In a population of 206 patients with early inflammatory polyarthritis, an inverse relationship between 25(OH) vitamin D levels and the Disease Activity Score 28-joint assessment was found: each 10 ng/mL increase in 25(OH) vitamin D was associated with a decrease in the DAS28 score of 0.3. (10)

In a cohort of 10366 children, vitamin D supplementation with daily doses of 2000 IU was associated with a 78% reduced risk of developing type 1 diabetes compared to lower doses. (11)

A meta-analysis of 4 studies with a total of 1429 cases and 5026 controls indicated that children receiving vitamin D supplements had a 29% reduction in the risk of developing type 1 diabetes compared to non-supplemented children. (12)

A 10 years follow-up of 524 non-diabetic adults demonstrated and inverse association between baseline serum 25(OH) vitamin D levels and future hyperglycemia and insulin resistance. (13)

An analysis of studies demonstrating the role of vitamin D in the prevention of several pathologies suggests that reaching and maintaining 25-hydroxyvitamin D levels above 30 ng/mL, preferably around 36-40 ng/mL, is key to maintain good health. (14)

Such levels include the metabolites of both forms of vitamin D: D₂ and D₃. Whereas vitamin D₃ is produced by the skin upon exposure to sunlight, both D₂ and D₃ are contained in food sources.

In most countries, vitamin D supplements containing D₂ or D₃ are available, which can help compensate the insufficient dietary intake and sun exposure.

**Correct clinical decisions are based on the assessment of 25-hydroxyvitamin D TOTAL levels.**

Accurate assessment of vitamin D status relies on the measurement of 25-hydroxyvitamin D TOTAL levels (25-hydroxyvitamin D₂ + 25-hydroxyvitamin D₃), which can be compared with the optimal levels recommended by vitamin D experts.

Two separate values for 25(OH) vitamin D₂ and 25(OH) vitamin D₃ could lead to erroneously interpret low levels of one of the two metabolites as indicative of vitamin D insufficiency even when the sum is within the sufficiency range. (15)

Measuring 25-hydroxyvitamin D TOTAL levels is important to monitor treatment. Clinical cases of supplementation with vitamin D₂ have been reported in which an assay that was only able to detect 25-hydroxyvitamin D₃ was used for patient follow-up. The inability to measure the increase in 25-hydroxyvitamin D TOTAL levels upon supplementation can cause overtreatment and lead to further expensive and stressful studies. (16)

Since 1985, DiaSorin has provided laboratories with assays that accurately measure 25-hydroxyvitamin D total levels, thanks to antibodies that are co-specific for 25-hydroxyvitamin D$_2$ and 25-hydroxyvitamin D$_3$.

The $^{125}$I RIA 25-hydroxyvitamin D assay has set the standard for the clinical diagnosis of nutritional vitamin D deficiency and has been used in most studies correlating it to the risk of developing various diseases. (17)

The LIAISON 25 OH Vitamin D TOTAL Assay ensures the same specificity as the RIA assay, being based on the same antibody, with a much higher throughput (>100 results/hour).

The LIAISON 25 OH Vitamin D TOTAL Assay represents the only fully automated assay measuring 25-hydroxyvitamin D total levels and allows accurate and quick determination and monitoring of vitamin D status.

Summary

- The function of vitamin D is not limited to maintaining normal bone mineralization, but involves different organs and tissues containing specific receptors.
- Maintaining sufficient levels of 25-hydroxyvitamin D (>30 ng/mL) helps preventing several pathologies and maintaining good general health.
- Correct clinical decisions are based on the assessment of 25-hydroxyvitamin D TOTAL (D₂ + D₃) levels.
- The DiaSorin assays have been used to define the 25-hydroxyvitamin D reference levels.
- The LIAISON 25 OH Vitamin D TOTAL Assay, measuring 25-hydroxyvitamin D total levels on a fully automated platform, allows accurate and quick determination of vitamin D status and effective therapy monitoring.

LIAISON® 25 OH Vitamin D TOTAL Assay

- Recognizes 100% 25 (OH) vitamin D₂ and 25 (OH) vitamin D₃
- Excellent correlation with the DiaSorin 25-hydroxyvitamin D RIA assay, which has been used to define the reference levels.
- Advanced chemiluminescence technology with paramagnetic particles separation to achieve the best assay sensitivity and precision
- No solvent extraction
- Dynamic range: 4.0 – 150 ng/mL
- Functional sensitivity: ≤ 4.0 ng/mL
- First result in 35 minutes, throughput > 100 results/hour

LIAISON® 25 OH Vitamin D TOTAL Assay (code 310600)
LIAISON® 25 OH Vitamin D TOTAL Control Set (code 310601)
LIAISON® 25 OH Vitamin D TOTAL Specimen Diluent Set (code 310602)