Lumipulse® *G*

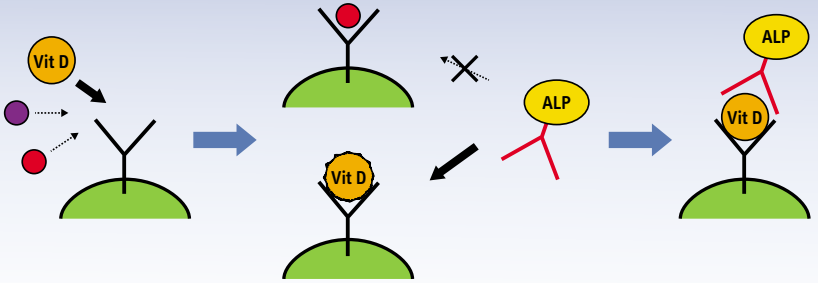
25-OH Vitamin D

New "ray of light" on Vitamin D testing

Offering a novel two-step sandwich assay showing improved performance

FUJIREBIO

Test Principle: Two-step Sandwich Assay



Specificity is predominated by Two Ab

Figure 1: Illustration of the Lumipulse® *G* 25-OH Vitamin D sandwich assay specificity

Performance Summary

Lumipulse® ***G*** 25-OH Vitamin D Assay uses chemiluminescent for the quantitative determination of 25-hydroxyvitamin D in human serum or plasma to be used in the assessment of Vitamin D sufficiency.

Sample type	Sample volume	Assay range	Functional Sensitivity	Limit of detection	Precision		Calibration frequency	Calibration level
					Within run	Total		
Serum or plasma	20 µl	4-150 ng/ml	3.491 ng/ml	0.907 ng/ml	0.7%-2.2%	1.6%-3.5%	every 30 days	6 points

- Improved assay performance, offering a novel new two-step sandwich assay
- Antibody that specifically recognizes immunocomplex consisting of 25-OH-D and anti-25-OH-D antibody
- Alignment with LC-MS/MS gold standard and high correlation with competitive assays
- 25 minute assay time
- No separate or additional pre-treatment steps or auxiliary solutions

Assay Characteristics

Method Comparison Data

Two method comparison studies consistent with the guidelines in the CLSI Protocol EP9-42, were performed where the Lumipulse® ***G*** 25-OH Vitamin D assay (y) was compared with a LC-MS/MS method (x) and with a commercially available immunoassay (DiaSorin LIAISON 25-OH Vitamin D TOTAL Assay (x), respectively. Regression analysis was performed using the Passing-Bablok method).

The sample concentrations were between approximately 4ng/ml and 140 ng/ml (LC-MS/MS) and between 10 ng/ml and 92 ng/ml (DiaSorin LIAISON). Data from these studies are summarized in the table below.

Comparison method	n	Slope	Intercept	Pearson correlation
LC-MS/MS	92	1.00	-2.0	0.99
DiaSorin LIAISON	104	0.99	1.2	0.90

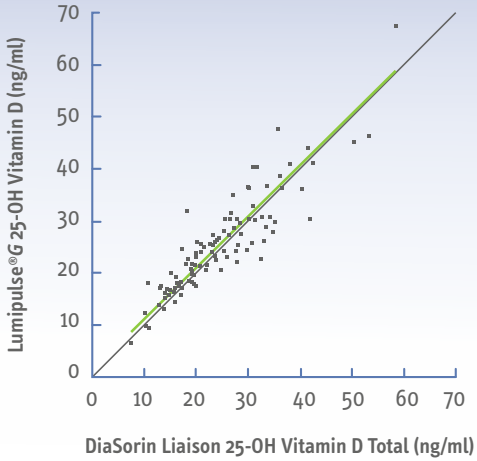
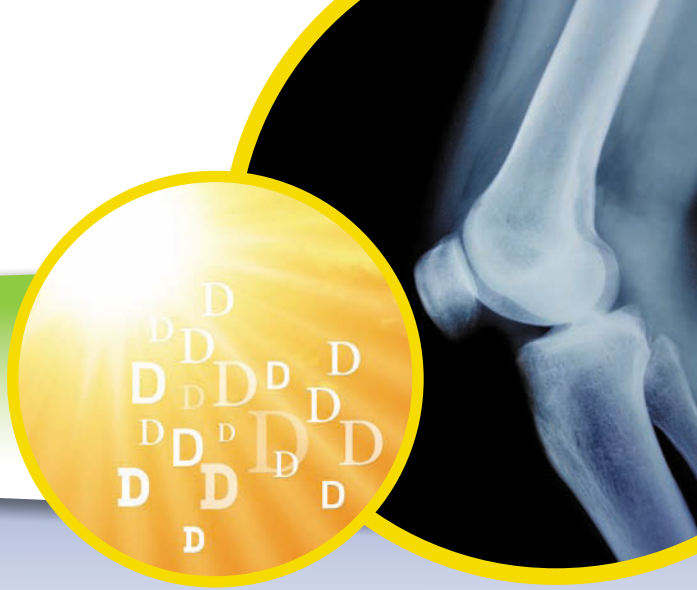


Figure 2: The Lumipulse® ***G*** 25-OH Vitamin D assay was compared with a commercially available immunoassay (DiaSorin LIAISON 25-OH Vitamin D TOTAL Assay) in a study comprising 104 serum samples. Regression analysis was performed using the Passing-Bablok method.*

* Lumipulse® ***G*** 25-OH Vitamin D (Passing-Bablok)=0.99 x Diasorin Liaison 25-OH Vitamin D + 1.2
r=0.90



Equimolarity

Sample 25-OH Vitamin D2* 25-OH Vitamin D3*	Expected values	Measured values	Equimolar response rate
	ng/ml	ng/ml	%
1:1	50.0	51.4	103
1:4	50.0	52.2	104
1:9	50.0	52.7	105
9:1	50.0	50.9	102
4:1	50.0	50.4	101

* The concentration of 25-OH Vit D2&3 solution were adjusted to 50 ng/ml each.

Cross-reactivity

Tested compound	Concentration	Cross reactivity
	ng/ml	%
Vitamin D2	1018	0.1
Vitamin D3	1012	0.0
24,25-$(OH)_2$ Vitamin D3	101	5.6
1,25-$(OH)_2$ Vitamin D2	104	46.3
1,25-$(OH)_2$ Vitamin D3	102	54.7
3-epi-25-OH Vitamin D3	100	19.9
Paricalcitol	25	33.6

Low 25-OH Vitamin D serum levels (lower than 10 ng/ml) have been found in 2-30% of adults within the European population [1]

Clinical Background

Vitamin D is a fat-soluble, secosteroid hormone precursor. In humans, the most abundant forms are Vitamin D3 (cholecalciferol), followed by Vitamin D2 (ergocalciferol), known together as calciferol. Calciferol primarily undergoes hydroxylation in the liver to 25-OH Vitamin D (calcidiol), the major circulating form of vitamin D. The serum or plasma level of 25-OH Vitamin D is recognized as the most reliable indicator of vitamin D sufficiency. A second hydroxylation in the kidneys of a small amount of 25-OH Vitamin D produces $1,25(OH)_2$ Vitamin D (calcitriol). Calcitriol regulates calcium and phosphate blood concentrations through amongst other intestinal absorption.

Although Vitamin D is commonly called a vitamin, it is not actually an essential dietary vitamin in the strict sense, as it can be synthesized in adequate amounts by most mammals exposed to sunlight. A substance is only classified as a vitamin when it cannot be synthesized in sufficient quantities by an organism, and must be obtained from a diet.

Vitamin D deficiency was first discovered in the childhood disease rickets. However due to recent trends to avoid prolonged sun exposure due to cancer and aging impacts, the world's population is even more at risk. Deficiency has been linked to various other medical conditions other than bone metabolism such as: adult osteomalacia, increased risk for fractures, secondary hyperparathyroidism, autoimmune diseases, diabetes, associated with increased risk for certain cancers, and cardiovascular problems.

<	DEFICIENCY	INSUFFICIENCY	SUFFICIENCY	POTENTIAL TOXICITY	>
	<10 ng/ml [2]	10-19 ng/ml [2]	20-100 ng/ml [2]	>100 ng/ml [2]	
	<20 ng/ml [3]	20-29 ng/ml [3]	30-100 ng/ml [3]	>100 ng/ml [3]	

[1] International Osteroporosis Foundation.

[2] WHO Scientific Group on the Prevention and Management of Osteoporosis 2003 Prevention and management of osteoporosis: report of a WHO scientific group. Geneva: World Health Organization.

[3] Holick MF et al. Evaluation, Treatment, and Prevention of Vitamin D Deficiency: an Endocrine Society Clinical Practice Guideline. J Clin Endocrin Metab. 2011; 96: 1911-1930.

Ordering Information

Cartridges

Vitamin D		
234013	Lumipulse® *G* 25-OH Vitamin D Immunoreaction Cartridges	3 x 14 Tests

Calibrators

Vitamin D		
234020	Lumipulse® *G* 25-OH Vitamin D Calibrators	6 point Calibrators - 1 x 6 concentrations (1.5 ml)

Controls

Vitamin D		
2130152	Fujirebio Diagnostics Vitamin D Control	3 control levels - 2 x 2 ml

Fujirebio Europe N.V.
Technologiepark 6- B-9052 Gent - Belgium
T +32 (0)9 329 13 29 - F +32 (0)9 329 17 75
www.fujirebio-europe.com

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