

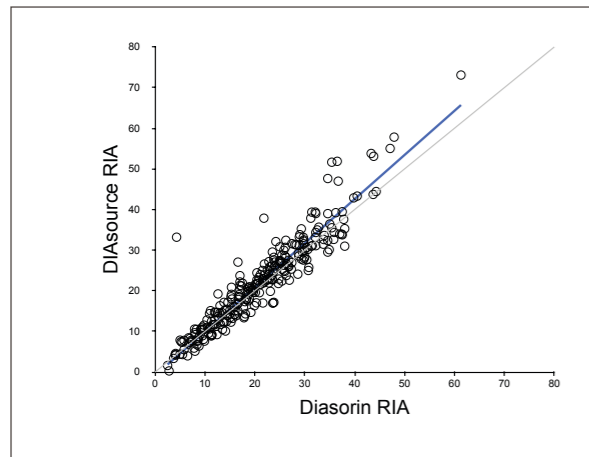
25OH VITAMIN D TOTAL RIA ASSAY

CORRELATION VS DIASORIN RIA

A correlation was performed comparing the DIAsource RIA assay with the DiaSorin RIA assay (n = 276 samples).

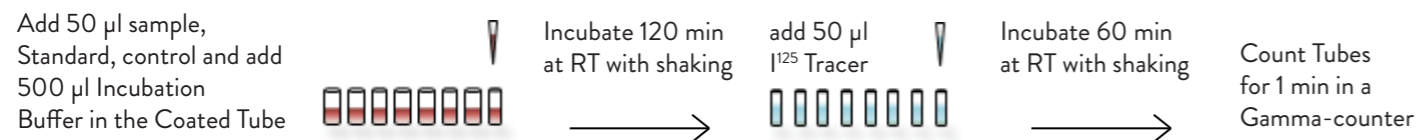
The Passing & Bablok regression analysis demonstrates a slope of 1.09 and an intercept of - 0.87 ng/ml.

$$\text{DIAsource} = 1,09 \text{ DiaSorin} - 0,87 \text{ ng/ml.}$$



ASSAY PROTOCOL: MOST CONVENIENT RIA ASSAY ON THE MARKET (ALL-IN-ONE)

The DIAsource 25OH Vitamin D Total RIA assay makes use of a novel pre-treatment step which eliminates the use of solvent precipitation and centrifugation. This sample pre-treatment step is performed inside the RIA coated tube which highly facilitates the automation on any brand of Pipetting instrument e.g. Tecan, BioTek and others.



PRACTICAL ADVANTAGES OF THE DIASOURCE 25OH VITAMIN D TOTAL RIA ASSAY

The DIAsource 25OH Vitamin D Total RIA (art. code KIP1971) assay shows very competitive sensitivity, precision and performance characteristics to all other immunoassays in the market but uses a novel and extremely easy pre-treatment step directly in the coated tubes.

The assay is calibrated in line with the Vitamin D Standardisation Program (VDSP). It shows a high correlation with other commercially available RIA assays but has interesting practical advantages: all steps are pipetting steps which can easily be programmed on any open pipetting instrument e.g. Tecan, BioTek and others.

The novel approach of the DIAsource RIA assay, based on proprietary Monoclonal Antibodies and antigen in combination with a unique releasing agent makes this assay unique.

	Description	Article code	Format	Size
Ordering information	25OH Vitamin D Total RIA	KIP1971	RIA	96 tubes
	25OH Vitamin D Total RIA Cubic	KIP1974	RIA	4 x 96 tubes
	1,25(OH) ₂ Vitamin D RIA	KIP1929	RIA	48 tubes
	1,25 (OH) ₂ Vitamin D Extraction Cartridges	1102491	For KIP1929	1 bag of 20 cartridges
	1,25(OH) ₂ Vitamin D Extraction kit (Solvents, Ready to use)	3019700	For KIP1929	5 x 48 Tests
	Intact PTH IRMA	KIP1491	IRMA	96 tubes
	Osteocalcin RIA	KIP1381	RIA	96 tubes

For more information: visit www.diasource-diagnostics.com

Manufactured by: DIAsource ImmunoAssays SA
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Distributed by:



Novel and automatable RIA assay.

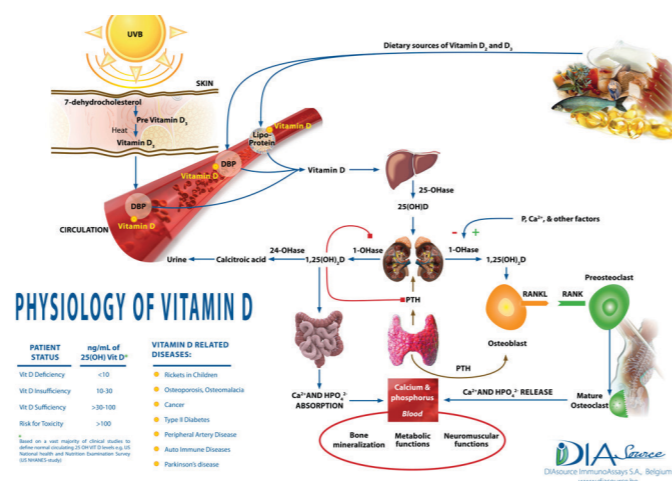
100% ALL-IN-ONE Simple automation.

The most user friendly 25OH Vitamin D Total RIA assay.

Since many years the importance of vitamin D is recognized in bone-related diseases. Clinical applications of 25OH Vitamin D measurements were merely related to the diagnosis and monitoring of therapy for rickets (children), osteomalacia, postmenopausal osteoporosis, and renal osteodystrophy. As a result of more recent studies a link between Vitamin D deficiency and many other diseases is suggested. These include cancer, cardiovascular disease, autoimmune diseases, diabetes, depression.

CLINICAL ASPECTS

There are two forms of Vitamin D in the human body namely Vitamin D3 (cholecalciferol) and Vitamin D2 (ergocalciferol), which are structurally very similar. Vitamin D3, the main form in humans, is produced in the skin from 7-dehydrocholesterol in response to direct sunlight and can also be obtained in small amounts from animal-based foods (oily fish, primarily salmon and mackerel). Vitamin D2 can be obtained in small amounts from plant-based foods (some vegetables, yeast and fungi). Vitamin D3 and D2 are metabolized in the liver to their respective 25OH Vitamin D3 and D2 forms which are converted in the kidneys to the active forms (1,25(OH)₂ Vitamin D3 and D2).



DETERMINING VITAMIN D STATUS

The measurement of the 25OH Vitamin D concentration in serum or plasma is 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.

Vitamin D Status	25OH Vitamin D Total (ng/mL)
Deficiency	< 10
Insufficiency	10 - 29
Sufficiency	30 - 100
Toxicity	> 100

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.

MEASUREMENT OF 25OH VITAMIN D LEVELS CAN BE USED IN:

- 1) Diagnosing Vitamin D insufficiency or deficiency, to help identifying individuals who may benefit from Vitamin D supplementation to reach optimal levels.
- 2) Monitoring response to Vitamin D supplements for bone-related diseases e.g. rickets (children), osteomalacia, postmenopausal osteoporosis, and renal osteodystrophy or non-bone related diseases.
- 3) Diagnosing Vitamin D toxicity, e.g. patients with suspected toxicity (hypercalcemia).

METHOD PRINCIPLE AND SPECIFICITY

The percentage of cross reaction was determined by testing sera with spiked and unspiked crossreactants. The results are summarized in the table on the right.

25OH Vitamin D Total RIA	
Art. Code	KIP1971
Format	RIA Coated Tube
Label	I125
Size	96 tests
Sample Type	Serum
Sample Volume	25 μ L
Controls	2 levels
Range	10-100 ng/mL
Sensitivity	1,5 ng/mL
Pretreatment	direct pretreatment in coated tube
Incubation	3 hours at room temperature
Shelf Life	8 weeks

Compound	Cross-Reactivity (in %)
25OH Vitamin D3	100
25OH Vitamin D2	86
1,25(OH) ₂ Vitamin D3	2,6
1,25(OH) ₂ Vitamin D2	2,1
Vitamin D3	0,8
Vitamin D2	0,1
24,25(OH) ₂ Vitamin D3	0,4
25,26(OH) ₂ Vitamin D3	≥ 100
3-epi-250 Vitamin D3	≥ 100

CALIBRATION

The DIAsource 25OH Vitamin D Total RIA is calibrated against the reference method ID-LC/MS-MS (Ghent University) according to the VDSP - Vitamin D Standardisation Program (<http://ods.od.nih.gov/Research/VitaminD.aspx#vdsp>).

VDSP is a collaboration between:

- a) NIH Office of Dietary Supplements (USA)
- b) National Institute of Standards and Technology (NIST) (USA)
- c) Center for Disease Control (USA)
- d) Ghent University (Belgium)

The aim is to standardize the measurement of serum total 25OH Vitamin D in national health surveys by linking them to the NIST reference measurement procedure. The NIST reference method procedure (RMP) 3-epi-25OH Vitamin D as the primary reference method for measuring total 25OH Vitamin D, including 25OH Vitamin D2, 25OH Vitamin D3, and 3-epi-25OH Vitamin D.

The method from the Ghent University is also traceable to the NIST RMP. Linda Thienpont, PhD, at Ghent University, has developed an ID-LC-MS/MS method for 25OH Vitamin D in human serum that is traceable to NIST SRM 972 (*) and that separates the 3-epi-25OH Vitamin D3 from 25OH Vitamin D3. This analysis ensures that 25OH Vitamin D3 is not overestimated in the result.

A correlation was performed with 20 serum samples (assigned values by ID-LC/MS-MS (Ref. method, Prof. L. Thienpont - Ghent University) comparing the DIAsource 25OH Vitamin D Total RIA to ID-LC/MS-MS. The regression analysis demonstrated a slope of 1.16, an intercept of - 5.21 ng/mL and a correlation coefficient of R= 0.97.

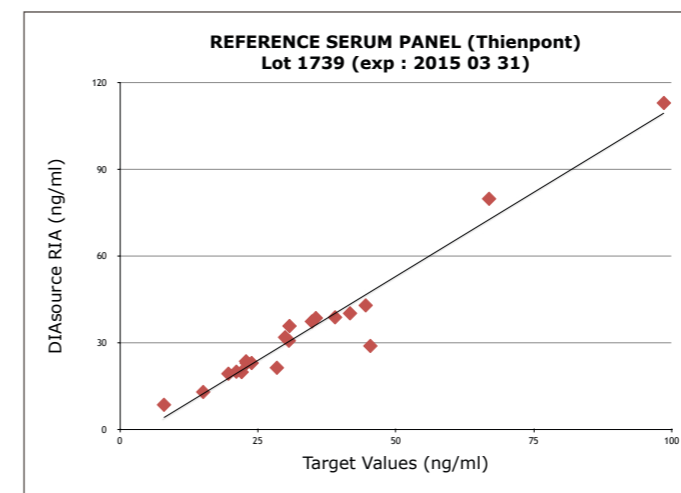


Figure 1: Correlation of DIAsource RIA with ID-LC/MS-MS

* Standardization of measurements of 25-hydroxyvitamin D3 and D2. Thienpont LM, Stepman HC, Vesper HW. Scand. J. Clin. Lab. Invest. Suppl. 2012, 243:41-9.

METHOD COMPARISON

	DIAsource (art. Code KIP1971)	IDS Ltd (RIA)	DiaSorin (RIA)
Pretreatment AIO *	In the coated tube	Sample dilution in tubes	Sample dilution in tubes
Pretreatment method	Novel approach, no organic solvents	Acetonitrile	Acetonitrile
Centrifugation	No	Vortex each sample 7 sec. 5' centrifugation	Vortex each sample 10 sec. 10' centrifugation
100 % Automatable	YES	NO	NO
Specificity	100 % D3 & 86 % D2	100 % D3 & 75 % D2	100 % D3 & 100 % D2
Analytical sensitivity	1,5 ng/ml	2,0 ng/ml	2,2 ng/ml
N° of steps	6	10	13
Total Incubation time	120' + 30' + 15'	120' + 30' + 30'	10' + 120' + 30' + 15'
Total Analysis time	< 240'	> 240'	> 240'

* ALL-IN-ONE: pretreatment directly in the coated tube