The background of the entire page is a warm, golden-orange color. It features a close-up, slightly blurred view of several glass test tubes or beakers. The glass reflects light, creating bright highlights and soft shadows. In the center of the page, there is a large, semi-transparent white circle with a thin orange border. Inside this circle, the text "VITAMIN D" and "PRODUCT OVERVIEW" is written in a clean, sans-serif font. Below the title, the text "by iDIA Source" is written in a smaller font, with "iDIA" in a stylized font and "Source" in a script font.

VITAMIN D  
PRODUCT OVERVIEW

by *iDIA* Source

The Vitamin D Expert

# TABLE OF CONTENTS

Our Company	p. 3
To contact us	p. 4
Clinical background	p. 5
Immunoassay overview	p. 8
RIA product	
• 25OH Vitamin D3	p. 10
• 25OH Vitamin D Total	p. 11
• 1,25(OH) <sub>2</sub> Vitamin D	p. 12
ELISA product	
• 25OH Vitamin D Total	p. 16
• 25OH Vitamin D Total 90'	p. 18
• Rat 25OH Vitamin D Total (RUO)	p. 21
• 1,25(OH) <sub>2</sub> Vitamin D	p. 23
• Free 25OH Vitamin D	p. 26
Raw materials for vitamin D assays	p. 29
Custom Diagnostic Laboratory Services & Sales Conditions	p. 33

# OUR COMPANY

## ➤ MORE THAN 30 YEARS OF EXPERIENCE IN IVD (KITS AND INSTRUMENTATION)

DIAsource ImmunoAssays (a BioVendor Group company), an international diagnostic company (Belgium), develops, manufactures and markets clinical diagnostic products in the field of endocrinology and infectious diseases. Core products are based on RIA and ELISA technology and also include reagents to be run on open ELISA automated analyzers as well as antibodies for use in in-vitro diagnostic assays. DIAsource has specific development and manufacturing programs for Vitamin D, Renin, Calcitonin and many others parameters. We also provide selected instrumentation: we offer ELISA reader, washer and shaker, along with open and closed fully automated ELISA platforms helping our customers to automate their tests. It is our ambition to use our 30 years of expertise in Antibody and Assay development to remain a well-known company of diagnostic immunoassays and instrumentation for the IVD market.

## ➤ MISSION

Our mission is to develop, manufacture and market a complete panel of quality immunoassays and instrumentation as accurate, reliable, diagnostic tools to detect and monitor endocrine disorders and infectious diseases. We are dedicated to provide highly reliable quality assays and instrumentation to deliver uncompromising support to our customers. We strive to meet for meeting our customers needs through a long-term professional relationship and by offering a real added value. Our company is driven by commitment to quality of products and services.

## ➤ PRODUCT RANGE

During the last 30 years, we have developed manual ELISA and RIA immunoassays for the diagnosis and monitoring of a wide variety of endocrine disorders. We constantly rework and develop specific antibodies for use in our diagnostic assays. In addition we offer these antibodies also to other diagnostic companies. Constantly looking for new technologies and applications, we put our expertise in the development of new antibodies (patent pending) and assays to measure 25OH Total Vitamin D (D2+D3). We strengthen our position in the diagnostic market by validating our ELISA assays on our open and closed automates. This innovation marks a turning point for our company, and makes of DIAsource, already renowned in the RIA market, a complete diagnostic provider. The interest in Vitamin D is rising rapidly. Since more than 10 years DIAsource manufactures immunoassays for 25OH Vitamin D3 and 1,25 (OH)<sub>2</sub> Vitamin D. In our assay development program, we are focusing specifically on new Vitamin D assays. We introduced a new Total Vitamin D (D2 + D3) RIA and ELISA assay, an innovative free 25OH Vitamin D ELISA kit, together with a Rat 25OH Vitamin D ELISA kit for clinical research studies. The ELISA versions can also be applied on our instruments.

## ➤ COMMITMENT TO QUALITY

We believe that the quality of products and services finds its origin in scientific expertise, good organization of all operational activities and in well-structured decision processes. These principles are laid out in our ISO 13485:2016 quality manual. Through the integration of product quality in our development and manufacturing processes and a specific customer-oriented approach, we have directed our quality system to comply with the harmonized standard for quality systems within the context of the European Directive for In Vitro Diagnostics. Our internal quality management system is designed to pursue a continuous improvement of our customer service, our product quality and the efficiency of our operations. All our kits and instruments for in-vitro diagnostics (IVD) carry the CE mark and comply with IVD Directive requirements.



**Eric Maes**  
Business Segment Manager ELISA, Instruments & Antibodies  
DIAsource ImmunoAssays S.A.



**Beatrice de Borman**  
CEO  
DIAsource ImmunoAssays S.A.

# TO CONTACT US

Our people, our professional and experienced Customer Service and Technical Support teams are dedicated to ensure complete customer satisfaction. We take pride in providing helpful and accurate information in a 24-hour turnaround time. Ordering: please see below and consult the 'How to order' section for your local contact.

## ⊗ CUSTOMER SERVICE - ORDERING

Tel.: +32 (0)10 84 99 00 - Fax: +32 (0)10 84 99 90-96 - customer.service@diasource.be  
Belgium Free Phone: 0800 159 59 - France Free Phone: 0800 908 443 - France Free Fax: 0800 902 588



**Planning, Logistics & Customer Service Manager**  
Manuelle Jadoul  
Tel.: +32 (0)10 84 99 12  
manuelle.jadoul@diasource.be



**Customers Service Representative**  
Muriel Hirsoux

**Customer Service Representative**



Sabrina Baio



Isabelle Rosman

## ⊗ SALES & MARKETING



**International Sales Director & Business Segment Manager RIA**  
Peter Kerckx  
Mobile: +32 (0)475 57 76 86  
peter.kerckx@diasource.be



**Sales Director Spain & Latino America**  
Pere Carbo  
Mobile SP: +34 618 566 458  
pere.carbo@diasource.be



M-F Sanchez



Tania Cabrera



**Business Segment Manager ELISA & Instrumentation and Antibodies**  
Eric Maes  
Mobile: +32 (0)479 70 00 71  
eric.maes@diasource.be



**Sales Manager Latinoamerica**  
Olga Lucia Guayacan  
Mobile: +57 32 358 759 50  
olga.guayacan@diasource.be



**Marketing Project Coordinator**  
Joëlle Bock  
Tel.: +32 (0)10 84 99 13  
joelle.bock@diasource.be



**Product Manager**  
Flore Laurent  
Mobile: +32 (0)472 02 36 47  
Tel.: +32 (10) 84 99 50  
products.support@diasource.be



**Sales Manager France & District Manager Wallonia**  
Laurent Augis  
Tel.: +32 (0)479 70 00 72  
Mobile: +33 6 85 60 17 85  
laurent.augis@diasource.be



**Product Manager**  
Valérie Preud'homme  
Mobile: +32 (0)494 71 35 21  
Tel.: +32 (10) 84 99 23  
products.support@diasource.be



**Service Engineer Instruments**  
Albert Rosell  
Mobile: +32 (0)471 32 60 35  
Tel.: +32 (10) 84 99 76  
Instrumentation@diasource.be

## ⊗ REGULATORY AFFAIRS



**Regulatory Affairs and Quality Assurance Supervisor**  
Simon Eechoudt  
Tel.: +32 (0)10 84 99 27  
Mobile: +32 (0)478 81 60 66  
regulatory.affairs@diasource.be

## ⊗ QUALITY & REGULATORY AFFAIRS MANAGER



David Degels  
Tel.: +32 (0)10 84 99 05  
david.degels@diasource.be

## ⊗ SHIPPING SUPERVISOR



Luciana Frasson  
Tel.: +32 (0)10 84 99 69  
Fax: +32 (0)10 84 99 95  
shipping@diasource.be



**CEO**  
Béatrice de Borman  
Tel.: +32 (0) 10 84 99 07  
beatrice.deborman@diasource.be

# CLINICAL BACKGROUND

25OH Vitamin D is so far the best biomarker to evaluate the Vitamin D status of individuals.

## ⊗ MEASUREMENT OF 25OH VITAMIN D

The measurement of 25OH Vitamin D is useful in:

- The diagnosis of Vitamin D Insufficiency or Deficiency
- To help identify individuals who may benefit from Vitamin D supplementation to reach optimal levels
- In monitoring response to Vitamin D supplements for the treatment of bone-related diseases, such as rickets (children), osteomalacia, postmenopausal osteoporosis, and renal osteodystrophy or non bone-related diseases
- In the diagnosis of Vitamin D toxicity, e.g., patients with suspected toxicity (hypercalcemia)

Total 25OH Vitamin D is today considered as the most appropriate measurement of 25OH Vitamin D in human. However increasing research on free 25OH Vitamin D seems to indicate that this parameter might be superior in a certain number of conditions. The terminology 'Total' refers here to the sum of the free fraction, and of the fractions bound to Vitamin D Binding Protein (VDBP) and Albumin.



## MEASUREMENT OF 1,25(OH)<sub>2</sub> VITAMIN D

1,25(OH)<sub>2</sub> Vitamin D is the active form of Vitamin D with regard to the known functions whereas 25OH Vitamin D and Vitamin D itself can be excluded as being physiologically functional. Furthermore since 1,25(OH)<sub>2</sub> Vitamin D is produced in the kidney and has some of its functions in the bone and intestine, it must be considered as a hormone. This hormone stimulates the intestinal absorption of both calcium and phosphorus. It also stimulates bone resorption and mineralization thereby preventing the development of rickets and osteomalacia. The levels of 1,25(OH)<sub>2</sub> Vitamin D in plasma or serum is 100 to 1000 less than that of 25OH Vitamin D. Due to its low concentrations and the presence of many similar metabolites, the measurement of 1,25(OH)<sub>2</sub> Vitamin D requires extraction and separation either by HPLC or by column chromatography preferable with the use of organic solvent. This extraction method is still recognized as the Golden Standard for 1,25(OH)<sub>2</sub> Vitamin D.

The measurement of 1,25(OH)<sub>2</sub> Vitamin D levels is indicated in:

- Assessment of Kidney functions: Chronic kidney failure and Haemodialysis (after kidney transplants)
- Hyper and hypo-parathyroidism
- Rickets disease
- Tumor-associated hypercalcemia
- Osteomalacia as a results of various types of Vitamine D metabolism disturbances



## VITAMIN D IMMUNOASSAY OVERVIEW

# IMMUNOASSAY OVERVIEW

Name	Cat#	Size	Sample type*	Sample size (µL)	Extraction	Automatable	Range	Incubation (hours)	Max shelf life (weeks)
------	------	------	--------------	------------------	------------	-------------	-------	--------------------	------------------------

## RIA

25OH Vitamin D3	KIP1961	96 T	S - HP	100	Yes	Partly	4-145 ng/mL	2	10
25OH Vitamin D Total	KIP1971 <sup>(1)</sup>	96 T	S	25	No	Fully	10-100 ng/mL	3	8
	KIP1974	4x96 T							
1,25(OH) <sub>2</sub> Vitamin D	KIP1929	48T	S-P	500	Yes	Partly	6-430 ng/mL	ON	10

## ELISA

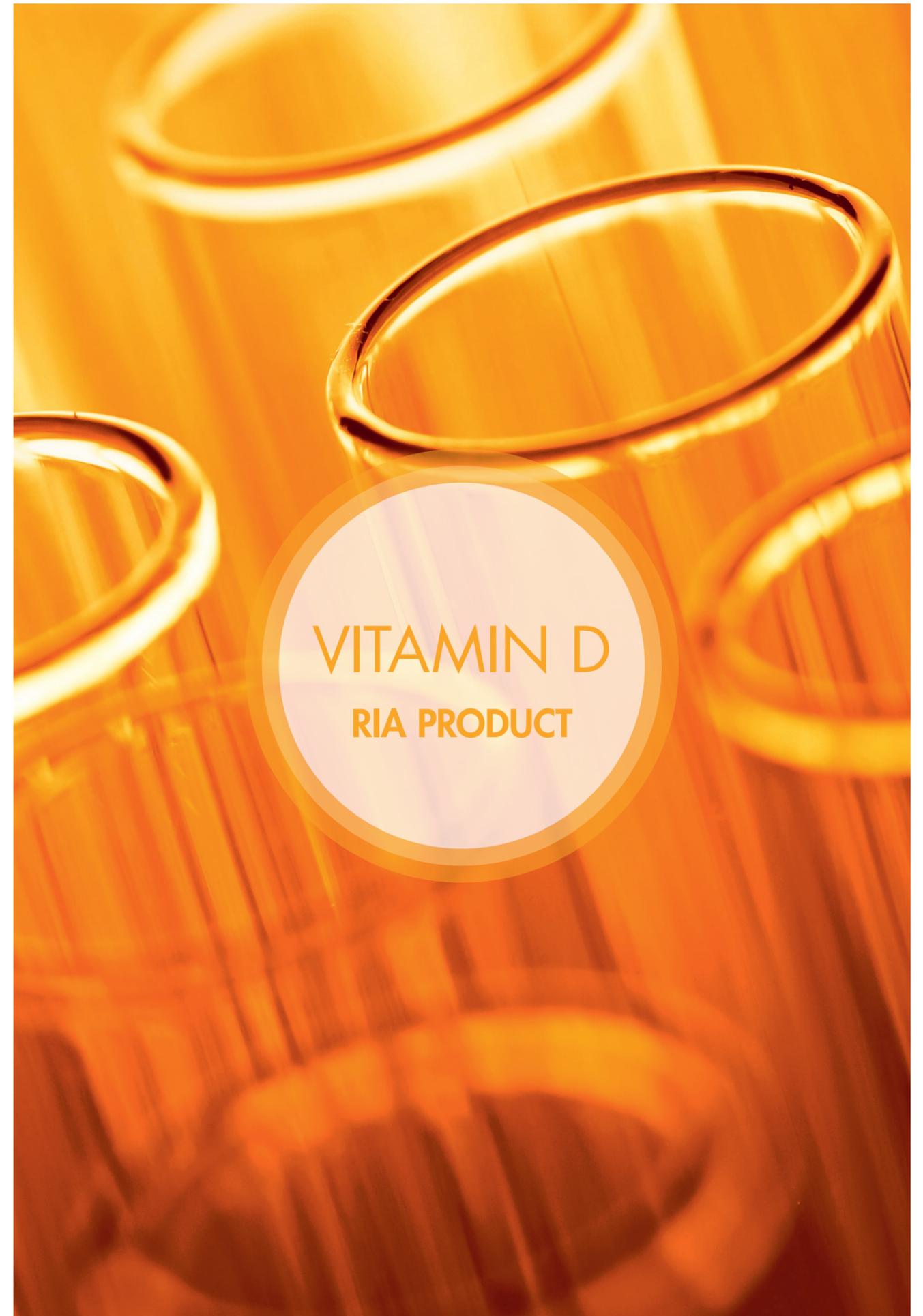
25OH Vitamin D Total	KAP1971	96 T	S	50	No	Fully	5,3-133 ng/mL	2,75	156
25OH Vitamin D Total 90'	KAP1971-F1	96 T	S - P	25	No	Fully	4,9-105 ng/mL	1,5	104
Rat 25OH Vitamin D Total (RUO)	KRR1971	96 T	S	50	No	Fully	5,3-133 ng/mL	2,75	130
1,25(OH) <sub>2</sub> Vitamin D	KAP1921	96 T	S	500	Yes	Partly	3-180 pg/mL	19	52
Free 25OH Vitamin D	KAPF1991	96 T	S	10	No	Fully	0,9-40,3 pg/mL	2,6	95

## Accessories/Consumables

Extraction kit	3019700	Set including solvents for 5 kits of 1,25(OH) <sub>2</sub> Vitamin D RIA or 2 kits of 1,25(OH) <sub>2</sub> Vitamin D ELISA							
Shaker	4300604	Shaker for extraction (IKA Vibrax 1200 RPM)							
Support rack	4300605	Support rack for tubes (to be used with shaker)							
Cartridges	1102491	Extra cartridges for extraction in single (1 bag of 20 cartridges) – FOR KIP1929							
Cartridges	1102496	Extra cartridges for extraction in single (1 bag of 42 cartridges) – FOR KAP1921							

(1) Due to local registration requirement, some products can not be sold in some countries without prior registration.  
The product with (1) have been already registered in USA.  
For Japan and Brazil specific registration requirements or for any further information on other products, please contact: RA@diasource.be

HP=Heparin Plasma - ON=Overnight - P=Plasma - S=Serum



# 25OH VITAMIN D3 RIA

Assay characteristics	25OH Vitamin D3 RIA
Article code	KIP1961
Format	Coated tubes
Size	96 Tests
Sample type	Serum, Heparin Plasma
Sample volume	100 µL
Controls	2 levels
Range	4 – 145 ng/mL
Total incubation time	120' (2h)
LoD	1.2 ng/mL
CV intra-assay	7.2 – 8.7 %
CV inter-assay	7.2 – 7.3 %

## COATED TUBE TECHNOLOGY

## CALIBRATED ACCORDING TO THE VDSP PROGRAM

## SPECIFIC FOR THE D3 FORM OF 25OH VITAMIN D



# 25OH VITAMIN D TOTAL RIA

Assay characteristics	25OH Vitamin D Total RIA
Article codes	KIP1971 – KIP1974
Format	Coated tubes
Size	KIP1971 : 96 Tests KIP1974 : 4 x 96 Tests
Sample type	Serum
Sample volume	25 µL
Controls	2 levels
Range	10 – 100 ng/mL
Total incubation time	180' (3h)
LoD	5.67 ng/mL
CV intra-assay	3.3 – 5.9 %
CV inter-assay	4.9 – 7.4 %

## COATED TUBE TECHNOLOGY

### All-In-One® technology:

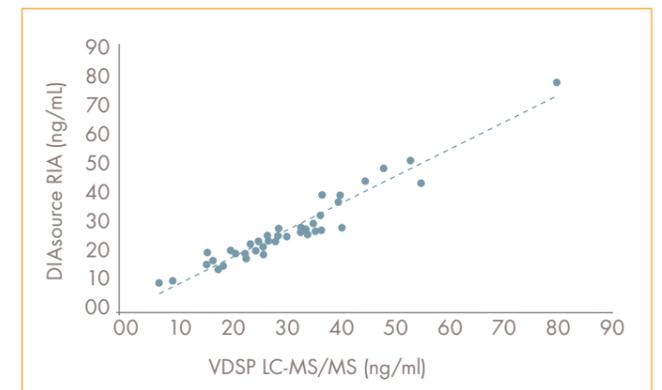
- no extraction step
- displacement solution directly into the tube
- automatable on a RIA platform or on a pipetting station

## CALIBRATED ACCORDING TO THE VDSP PROGRAM

The DIAsource 25OH Vitamin D Total RIA is calibrated against the reference method ID-LC-MS/MS.

A correlation was performed with 40 serum samples coming from Phase I of the Vitamin D Standardization Certification Program (VDSCP), comparing the DIAsource 25OH Vitamin D Total RIA to LC-MS/MS.

### DIAsource 25OH Vitamin D Total RIA vs VDSP LC-MS/MS:



$$y = 1,00x - 5,3 \quad R = 0,97$$

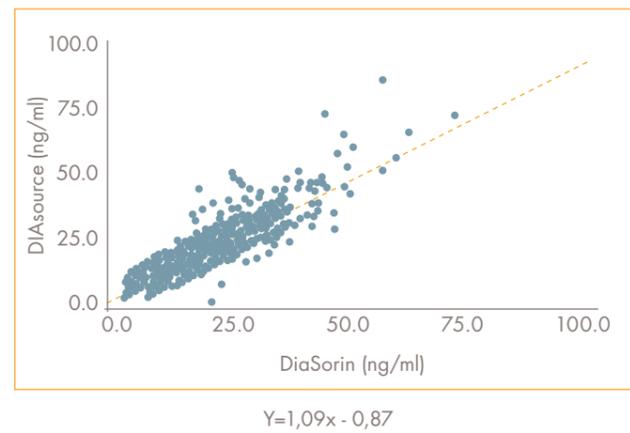
# 1,25(OH)<sub>2</sub> VITAMIN D RIA

## ☞ CORRELATIONS

A correlation was performed with 912 serum samples comparing the DAsource 25OH Vitamin D Total RIA to the DiaSorin 25OH Vitamin D RIA assay.

The DAsource 25OH Vitamin D Total RIA was run on a Tecan platform.

DAsource 25OH Vitamin D Total RIA vs DiaSorin 25OH Vitamin D RIA:



Assay characteristics	1,25(OH) <sub>2</sub> Vitamin D RIA
Article code	KIP1929
Format	Coated tubes
Size	48 Tests
Sample type	Serum, Plasma
Sample volume	500 µL
Controls	2 levels
Range	6 – 430 ng/ml
Total incubation time	19h (overnight)
LoD	2.88 pg/ml
CV intra-assay	6,8 – 7,4%
CV inter-assay	11.3 – 12.7 %

## ☞ GOLDEN STANDARD EXTRACTION METHODOLOGY

Samples and controls are extracted with a mixture of solvents and applied on cartridges to separate 1,25(OH)<sub>2</sub> Vitamin D from the other Vitamin D metabolites. Extraction with organic solvents is considered as the Golden Standard for steroids immunoassays.

**Extraction:** with organic solvent suppresses the potential interference from sample matrix, heterophilic antibodies and abnormal concentrations of Vitamin D binding proteins.

**Separation:** on solid phase cartridges suppresses the interference from other Vitamin D metabolites:  
25OH Vitamin D - 24,25(OH)<sub>2</sub> Vitamin D - 25,26(OH)<sub>2</sub> Vitamin D.

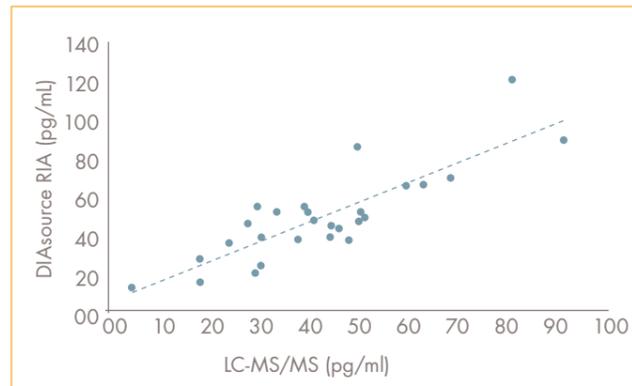
Compound	Cross-reactivity
1,25(OH) <sub>2</sub> Vitamin D3	100 %
1,25(OH) <sub>2</sub> Vitamin D2	92.3 %
25OH Vitamin D3	0.001 %
24,25(OH) <sub>2</sub> Vitamin D3	0.005 %
25,26(OH) <sub>2</sub> Vitamin D3	0.2 %

## ☞ COATED TUBE TECHNOLOGY

## ☞ CORRELATIONS

Correlation to the Gold Standard LC-MS/MS:

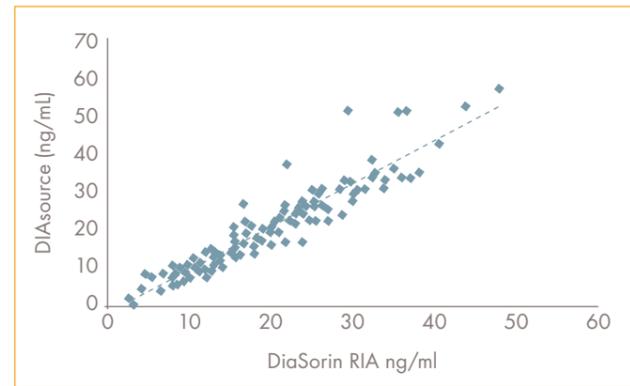
DIAsource 1,25(OH)<sub>2</sub> Vitamin D RIA vs LC-MS/MS



$$y = 1,12x - 1,0 \quad R = 0,84$$

Correlation to the DiaSorin 1,25(OH)<sub>2</sub> Vitamin D RIA:

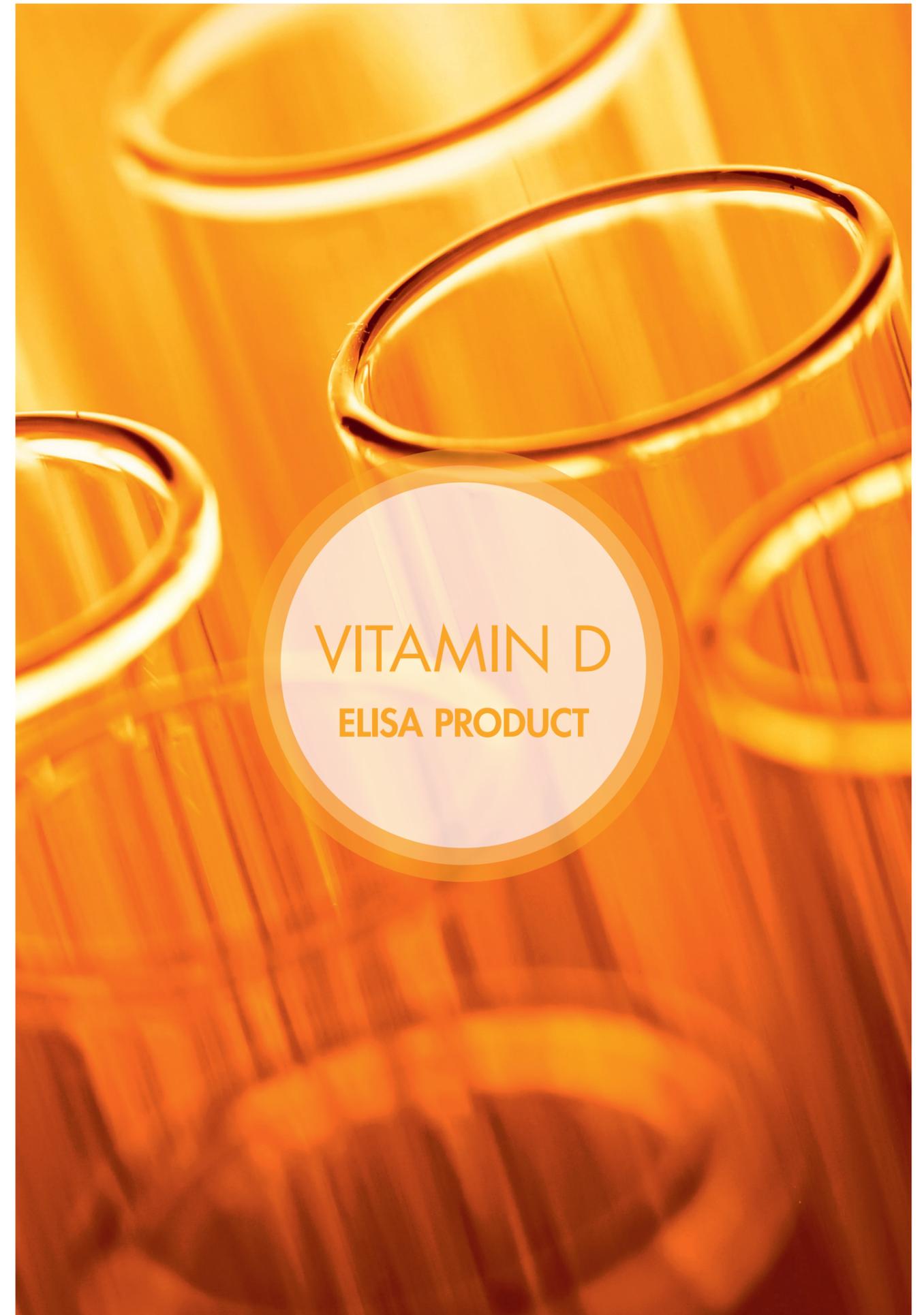
DIAsource 1,25(OH)<sub>2</sub> Vitamin D RIA versus DiaSorin RIA



$$y = 1,5x - 2,6 \quad R = 0,93$$

## ☞ ASSAY COMPARISON

	DIAsource RIA	IDS RIA	DiaSorin RIA
Hands-on-time	3.5 hrs	3.5 hrs	3.5 hrs
RIA coated tubes	Yes	No	No
Vacuum needed	No	Yes	Yes
N <sub>2</sub> needed	No	Yes	Yes
Sample volume needed	500 µL	500 µL	500 µL
Cartridges included in the kit	Yes	No	No
Nb of samples per kit	19 (38 with a second bag of cartridges)	2 versions: 20 and 28	24



# 25OH VITAMIN D TOTAL ELISA

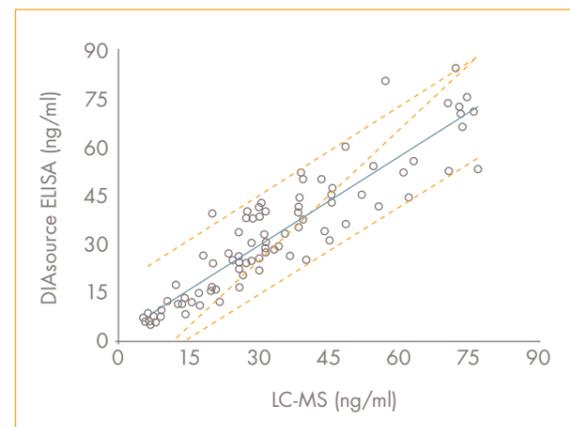
Assay characteristics	25OH Vitamin D Total ELISA
Article code	KAP1971
Format	Breakable wells
Size	96 Tests
Sample type	Serum
Sample volume	50 µL
Controls	2 levels
Range	5.3 – 133 ng/mL
Total analysis Time	210' (3h30)
Total incubation time	165' (2h45)
LoD	2.8 ng/mL
CV intra-assay	2.5 – 7.8 %
CV inter-assay	4.3 – 9.2 %

## ⤵ CALIBRATED ACCORDING TO THE VDSP PROGRAM

### Calibration

The DIAsource 25OH Vitamin D Total ELISA is calibrated against the reference method ID-LC-MS/MS. This LC-MS/MS methodology used for the correlation studies of the DIAsource 25OH Vitamin D Total ELISA assay shows a high level of traceability to the ID-LC/MS-MS reference methodology used in the Vitamin D Standardization Program VDSP (Correlation Coefficient  $R > 0.97$ ).

A correlation was performed with 94 serum samples comparing the DIAsource 25OH Vitamin D Total ELISA to LC-MS/MS. The regression analysis demonstrated a slope of 0.91, an intercept of 2.33 ng/mL and a correlation of  $R = 0.92$ .



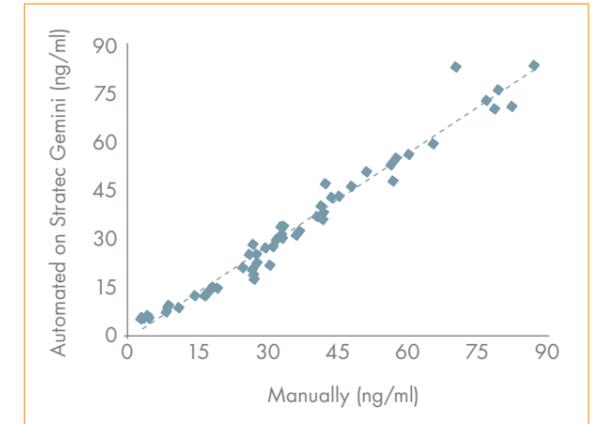
## ⤵ 100% AUTOMATABLE

The DIAsource 25OH Vitamin D Total ELISA assay makes use of a novel and extremely easy pre-treatment step. This sample pre-treatment step is performed inside the sample well of the ELISA microtiter plate and during the first incubation step. Validated applications are available on STRATEC GEMINI, GSD THUNDERBOLT®, DYNEX DSX® and DS2®.

- ⊗ 100% AUTOMATABLE
- ⊗ LESS RISKS OF ERRORS
- ⊗ LESS MANIPULATIONS
- ⊗ LESS CONSUMABLES REQUIRED

### Automation: validated application on Stratec Gemini open elisa platform:

The DIAsource 25OH Vitamin D Total ELISA has extensively been validated on the Stratec Gemini. A validated protocol is available and permits larger laboratories to easily automate their 25OH Vitamin D determinations. An in-house correlation was performed with 54 serum samples comparing the DIAsource 25OH Vitamin D Total ELISA assay manually performed and automated on the Stratec Gemini, an open ELISA automate. The regression analysis demonstrated a slope of 0.98, an intercept of - 2.29 ng/mL and a correlation of  $R = 0.98$ .



## ⤵ 36 MONTHS SHELF LIFE

## ⤵ CORRELATIONS

Multiple correlation studies were performed. A summary is listed below.

Assay	Place	Regression	R
LC-MS/MS	DIAsource – Manchester (UK)	$0.91 X + 2.33 \text{ ng/mL}$	0.92
IDS ELISA	DIAsource	$1.06 X + 0.83 \text{ ng/mL}$	0.93
IDS ELISA	US (3 sites)	$0.95 X + 3.05 \text{ ng/mL}$	0.96
DiaSorin Liaison	DIAsource – Nice (Fr)	$1.13 X - 1.34 \text{ ng/mL}$	Passing & Bablok*
DiaSorin Liaison	Nice (Fr)	$0.98 X + 1.94 \text{ ng/mL}$	0.94
Euroimmun	DIAsource – Nice (Fr)	$1.02 X - 2.14 \text{ ng/mL}$	Passing & Bablok*
DRG	DIAsource – Nice (Fr)	$1.19 X + 2.28 \text{ ng/mL}$	Passing & Bablok*
DRG	DRG – Nice (Fr)	$1.24 X + 1.12 \text{ ng/mL}$	Passing & Bablok*
Roche	China (2 sites)	$0.94 X + 0.98 \text{ ng/mL}$	0.94

\*Passing & Bablok regression procedure makes no special assumptions regarding the distribution of the samples and the measurement errors and does not provide a correlation coefficient R.

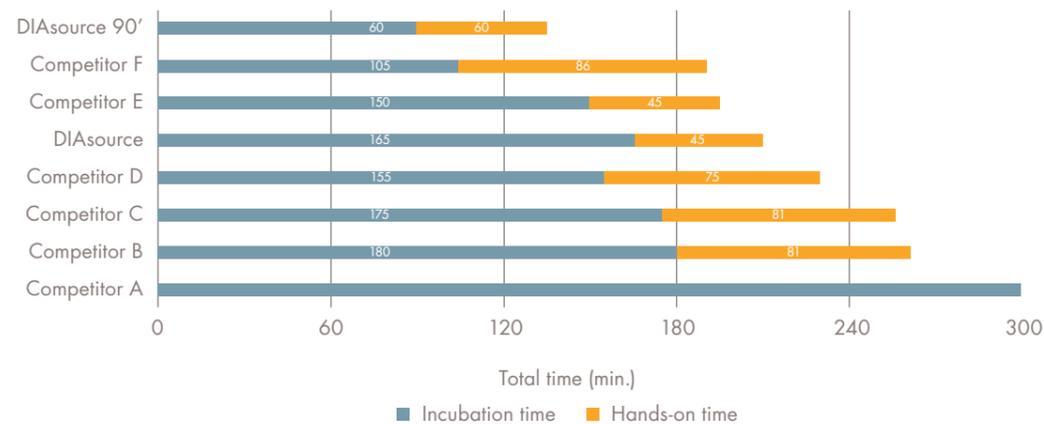
# 25OH VITAMIN D TOTAL 90' ELISA

Assay characteristics	25OH Vitamin D Total ELISA 90'
Article code	KAP1971-F1
Format	Breakable wells
Size	96
Sample type	Serum / Plasma
Sample volume	25 µL
Controls	2 levels
Range	4.9 – 105 ng/mL
Total analysis Time	125' (2h05)
Total incubation time	90' (1h30)
LoD	4.12 ng/mL
CV intra-assay	3.6 – 8.6 %
CV inter-assay	6.4 – 7.7 %

## ONE OF THE FASTEST 25OH VITAMIN D ELISA ASSAYS ON THE MARKET

Thanks to its short incubation time and to its pre-treatment step directly performed inside the ELISA microtiter plate, the DIAsource 25OH Vitamin D Total ELISA 90' is the fastest 25OH Vitamin D ELISA assay on the market.

25OH Vitamin D ELISA assay time:



## 100% AUTOMATABLE

The DIAsource 25OH Vitamin D Total ELISA assay makes use of a novel and extremely easy pre-treatment step. This sample pre-treatment step is performed inside the sample well of the ELISA microtiter plate and during the first incubation step. Validated application is available on STRATEC GEMINI.

100% AUTOMATABLE

LESS RISKS OF ERRORS

LESS MANIPULATIONS

LESS CONSUMABLES REQUIRED

## CALIBRATED ON VDSP REFERENCE LC-MS/MS

The DIAsource 25OH Vitamin D Total ELISA 90' is calibrated against the reference method ID-LC-MS/MS.

This LC-MS/MS methodology used for the correlation studies of the DIAsource 25OH Vitamin D Total ELISA assay shows a high level of traceability to the ID-LC/MS-MS reference methodology used in the Vitamin D Standardization Program VDSP ( $R > 0.97$ ).

A correlation was performed with 94 serum samples comparing the DIAsource 25OH Vitamin D Total ELISA to LC-MS/MS.

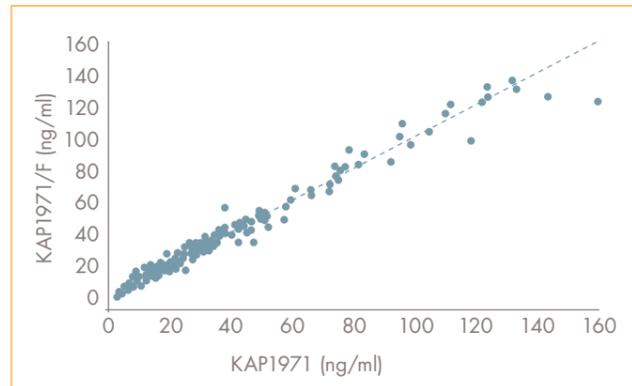
## 24 MONTHS SHELF LIFE



## ➤ CORRELATIONS

Correlation to the DAsource 25OH Vitamin D Total Elisa:

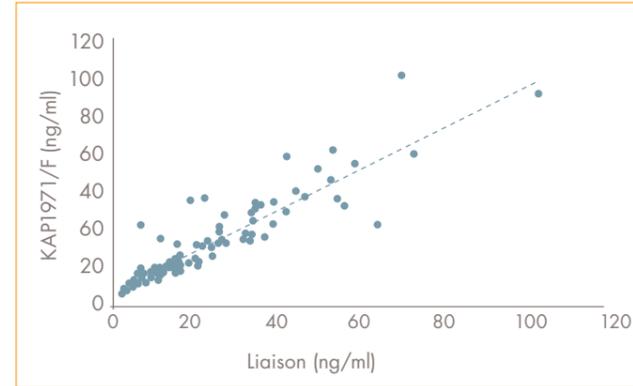
KAP1971-F1 vs KAP1971



$$Y = 0.99X + 2.31 \quad R^2 = 0.98 \quad n = 157$$

Correlation to the DiaSorin Liaison:

KAP1971-F1 vs Liaison



$$Y = 0.94X + 2.3 \quad R^2 = 0.85 \quad n = 84$$

# RAT 25OH VITAMIN D TOTAL ELISA (RUO)

Assay characteristics	Rat 25OH Vitamin D Total ELISA (RUO)
Article code	KRR1971
Format	Breakable wells
Size	96 Tests
Sample type	Rat serum
Sample volume	50 µL
Controls	On request
Range	5.3 – 133 ng/mL
Total analysis Time	210' (3h30)
Total incubation time	165' (2h45)
LoD	2.8 ng/mL
CV intra-assay	2.5 – 7.8 %
CV inter-assay	4.3 – 9.2 %

## ➤ VALIDATED ON RAT SAMPLES

30 adult rats have been divided in 3 groups of 10 rats. The first group has been fed with classical pellets for rodents containing 1200 UI 25OH Vitamin D<sub>3</sub>/kg and maintained in normal luminosity conditions (day and night).

The second group has been fed with pellets containing 3600 UI 25OH Vitamin D<sub>3</sub>/kg and maintained in normal luminosity conditions (day and night).

The third group has been fed with pellets without 25OH Vitamin D<sub>3</sub> and maintained in the dark day & night.

After 2 months, rats have been collected and tested: results in the table below.

	Group 1 N = 10	Group 2 N = 10	Group 3 N = 10
Mean value (ng/ml)	19.7	27.7	7.6
Range of values (ng/ml) (2/5 to 97.5 percentiles)	12.1 – 27.0	12.6 – 41.4	6.6 – 9.1

## 100% AUTOMATABLE

The DAsource Rat 25OH Vitamin D Total ELISA assay makes use of a novel and extremely easy pre-treatment step. This sample pre-treatment step is performed inside the sample well of the ELISA microtiter plate and during the first incubation step. Validated application is available on STRATEC GEMINI.

100% AUTOMATABLE

LESS RISKS OF ERRORS

LESS MANIPULATIONS

LESS CONSUMABLES REQUIRED

## 36 MONTHS SHELF LIFE



# 1,25(OH)<sub>2</sub> VITAMIN D ELISA

## RELIABLE TEST RESULTS

The only ELISA measuring D2 and D3 forms accurately

Assay characteristics	1,25(OH) <sub>2</sub> VITAMIN D ELISA
Article code	KAP1921
Format	Breakable wells
Size	96 Tests
Sample type	Serum
Sample volume	500 µL
Controls	2
Range	3 – 180 pg/mL
Total incubation time	19 h
LoD	0.8 pg/mL
CV intra-assay	5.0 – 13.9 %
CV inter-assay	13.2 – 17.5 %
Cross-reactivity with the D2 form	108 %

## GOLDEN STANDARD EXTRACTION METHODOLOGY

Samples and controls are extracted with a mixture of solvents and applied on cartridges to separate 1,25(OH)<sub>2</sub> Vitamin D from the other Vitamin D metabolites. Extraction with organic solvents is considered as the Golden Standard for steroids immunoassays.

**Extraction** with organic solvent suppresses the potential interference from sample matrix, heterophilic antibodies and abnormal concentrations of Vitamin D binding proteins.

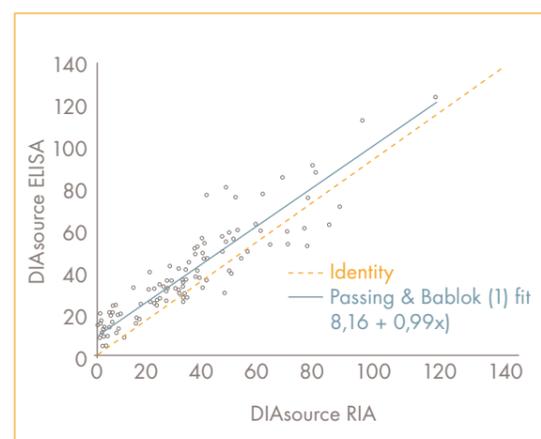
Substance	1,25(OH) <sub>2</sub> Vitamin D Mean % variation
Hemoglobin	5.0 %
Bilirubin conjugated	-12.3 %
Bilirubin unconjugated	-0.4 %
Triglyceride	-1.0 %
Vitamin C	4.9 %

**Separation** on solid phase cartridges suppresses the interference from other Vitamin D metabolites:  
 25OH Vitamin D - 24,25(OH)<sub>2</sub> Vitamin D - 25,26(OH)<sub>2</sub> Vitamin D.

Compound	Cross-reactivity
1,25(OH) <sub>2</sub> Vitamin D3	114 %
1,25(OH) <sub>2</sub> Vitamin D2	108 %
25OH Vitamin D3	0.004 %
25OH Vitamin D2	0.0003 %
24,25(OH) <sub>2</sub> Vitamin D3	0.03 %
25,26(OH) <sub>2</sub> Vitamin D3	0.02 %

## ⊙ CALIBRATED ON THE WELL ESTABLISHED DIASOURCE 1,25(OH)<sub>2</sub> VITAMIN D RIA

A correlation was performed with 110 serum samples comparing the DIAsource 1,25(OH)<sub>2</sub> Vitamin D ELISA to the DIAsource 1,25(OH)<sub>2</sub> Vitamin D RIA.

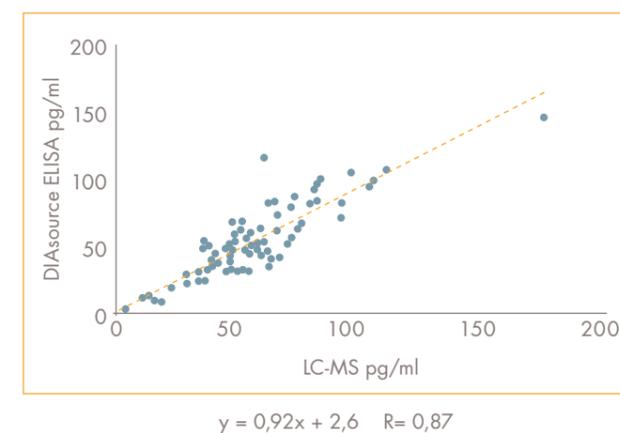


## ⊙ CORRELATIONS

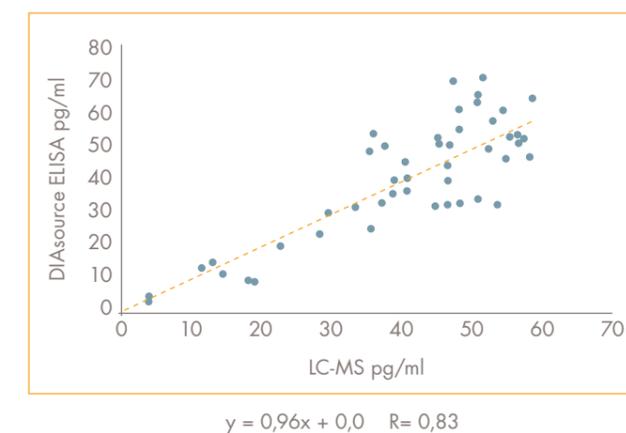
### Correlation to LC-MS/MS:

A correlation was performed by a reference clinical laboratory with 80 serum samples comparing the DIAsource 1,25(OH)<sub>2</sub> Vitamin D ELISA to a sensitive LC-MS/MS method.

### 1,25(OH)<sub>2</sub> Vitamin D DIAsource ELISA versus LC-MS:

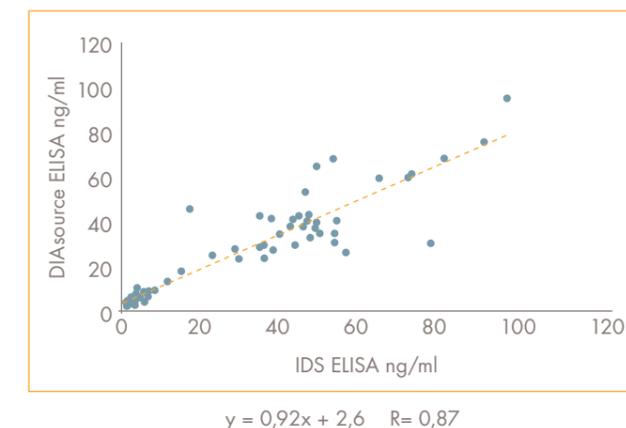


### 1,25(OH)<sub>2</sub> Vitamin D DIAsource ELISA versus LC-MS (<60pg/ml):



### Correlation to the IDS ELISA:

A correlation was performed with 75 serum samples comparing the DIAsource 1,25(OH)<sub>2</sub> Vitamin D ELISA to the IDS 1,25(OH)<sub>2</sub> Vitamin D ELISA.



## ⊙ ELISA METHOD COMPARISON

	DIAsource ELISA	ELISA A	ELISA B
Microplate	Breakable wells	Non-breakable wells	Non-breakable wells
Sample volume	500 µL	500 µL	1000 µL
Calibrators	6	7	7
Controls	2	2	2
Range	3-180 pg/mL	0-150 pg/mL	ND
Number of steps (separation+ELISA)	12 + 16	24 + 19	13 + 22
Sensitivity	0.8 pg/mL	2.5 pg/mL	4.8 pg/mL
Intra-assay CV	5.0 – 13.9 %	9.3 – 10.7 %	6.7 %
Inter-assay CV	13.2 – 17.5 %	17.1 – 19.7 %	9.0 %
CR 1,25(OH) <sub>2</sub> Vit D2	108 %	39 %	41 %
CR 1,25(OH) <sub>2</sub> Vit D2	0.03 %	0.006 %	< 0.1 %
CR 25OH Vit D3	0.004 %	0.009 %	< 0.01 %

# FREE 25OH VITAMIN D ELISA

Assay characteristics	Free 25OH Vitamin D ELISA
Article code	KAPF1991
Format	12 X 8
Size	96 Tests
Sample type	Serum
Sample volume	10 µL
Controls	2 levels
Range	0.9 – 40.3 pg/mL
Total analysis Time	190' (3h10)
Total incubation time	155' (2h35)
LoD	2.4 pg/mL
CV intra-assay	1.9 – 5.5 %
CV inter-assay	4.0 – 6.3 %

## ⊙ SIMPLE ACCURATE AND DIRECT

- Direct Measurement of Free 25OH Vitamin D
- No sample Pre-treatment
- Low volume: 10µL volume
- Calibrated against Rate Dialysis

## ⊙ CLINICAL APPLICATIONS

Free 25OH Vitamin D is a novel laboratory biomarker for Vitamin D Status monitoring in Woman Health:

- Human Pregnancy
- In-Vitro Fertilization
- The use of Oral Contraceptives

Free 25OH Vitamin D seems to be a better marker of Vitamin D status than total 25OH Vitamin D for:

- Obesity/Insulin
- Liver disease
- Pregnancy
- Renal disease
- Cancer
- Respiratory disease
- Intensive care
- Osteoporosis/Bone mineral density

The measurement of Free 25OH Vitamin D helps to reduce the inter-racial Vitamin D status variation, by mitigating the differences in the affinity of the different forms of the Vitamin D Binding Protein. More particularly in studies in which the following populations are represented:

- Black
- Hispanic
- Asian

## ⊙ SCIENTIFIC CONCEPT

According to the free hormone hypothesis the biological activity of the hormone is directly linked to the concentration of its free form:

- 25OH Vitamin D is for >99,9% bound to binding proteins: 90% to DBP, 10% to Albumin
- About 0,04% circulates as the free form = "Free 25OH Vitamin D"
- All current 25OH Vitamin D assays measure the sum of the bound and free forms, and do not reflect the concentration of the free hormone

## ⊙ OUR OFFERING

If you need support for internal validation and/or for a study design with our free Vitamin D ELISA test in your laboratory please contact Diasource: [info@diasource.be](mailto:info@diasource.be) and/or visit our new dedicated website: [www.freevitamind.org..](http://www.freevitamind.org..)

## ⊙ 12 MONTHS SHELF-LIFE



### References:

Hoche B., J Steroid Biochem Mol Biol. 2018, p.30375-8, Reference intervals for measured and calculated free 25-hydroxyvitamin D in normal pregnancy.  
 Pilz S., J Clin Endocrinol Metab. 2018, doi: 10.1210/je.2018-00336, Hormonal Contraceptive Use is Associated with Higher Total but Unaltered Free 25-Hydroxyvitamin D Serum Concentrations.  
 Hoche B., J Steroid Biochem Mol Biol. 2018 (80), 87-104, Why should we measure free 25(OH) Vitamin D.  
 Aloia J., J. Clin. Endocrinol. Metab. 2015 (100), 3356-63, Free 25(OH)D and the Vitamin D Paradox in African Americans.

# RAW MATERIALS FOR VITAMIN D ASSAYS

Over the years DIAsource has built extensive experience in Vitamin D immunoassays development and Vitamin D chemistry. DIAsource offers all components to develop your own Vitamin D assay.

The DIAsource Vitamin D raw materials portfolio is the most complete offering on the market. It includes Monoclonal and Polyclonal Antibodies against both forms of Vitamin D (D2 and D3), a large variety of high purity Antigens/Conjugates, and a collection of Release Solutions, to cover all the needs for the development of your Vitamin D assay.

DIAsource raw materials have been successfully used in RIA, ELISA, CLIA and POCT assays, by DIAsource and by partners.

## ➤ ANTIBODIES

Based on proprietary Vitamin D haptens, we developed a line of mouse monoclonal and rabbit polyclonal antibodies directed towards 25OH Vitamin D2 and D3 and 1,25(OH)<sub>2</sub> Vitamin D2 and D3.

## ➤ ANTIGENS

We developed a specific collection of Vitamin D analogues that pair with our antibodies and from other antibodies from the market. Depending on your specific application, you may want to use our carboxylic acid, amine, biotin or BSA functionalized antigens. Furthermore, we offer services tailored to your specific requirements.

## ➤ RELEASE SOLUTIONS

Displacing 25OH Vitamin D from its binding proteins (VDBP) is still a big challenge in Vitamin assay development.

DIAsource offers a wide panel of unique displacement solutions that are compatible with most of the 25OH Vitamin D antibodies.



VITAMIN D  
RAW MATERIALS

## RAW MATERIALS

Cat#	Name	Size	Type	Subtype	Clone/Host	Format
------	------	------	------	---------	------------	--------

### 25OH Vitamin D

#### Antibodies:

Cat#	Name	Size	Type	Subtype	Clone/Host	Format	
5319706	Monoclonal Antibody against 25OH Vitamin D2/D3*	1mg	Monoclonal Antibody <sup>1</sup>	Tail	LMBP 7013CB	Purified, Unconjugated	
5319716							LMBP 7012CB
5319726							LMBP 7011CB
5319835	Polyclonal Antibody against 25OH Vitamin D2/D3	100µl	Polyclonal Antibody <sup>1</sup>	Tail	Rabbit	Crude	

#### Antigens & others:

Cat#	Name	Size	Type	Subtype	Clone/Host	Format
5019700	Vitamin D derivative - Carboxylic acid	1mg	Antigen/Conjugate <sup>1</sup>	Tail	NA	Purified, Carboxylic acid (COOH)
5019700-100		100µg				
5019701	Vitamin D derivative - BSA conjugate	1mg				Purified, BSA conjugate
5019701-100		100µg				
5019703	Vitamin D derivative - amino	1mg				Purified, Amino (NH <sub>2</sub> )
5019703-100		100µg				
5019708	Vitamin D derivative - biotin conjugate	1mg				Purified, Biotin conjugate
5019708-100		100µg				
5019502	Vitamin D antigen - 3-carboxylic acid	1mg	Antigen/Conjugate <sup>2</sup>	Position-3	NA	Purified, Carboxylic acid (COOH)
5019503	Vitamin D antigen - 3-amino					Purified, Amino (NH <sub>2</sub> )
5019504	Vitamin D antigen - 3-biotin					Purified, Biotin conjugate
3019702	Vitamin D Release Solution - 10 solutions screening kit	1 kit	Release Solution	NA	NA	Liquid, ready to use

\*In 2009, DIAsource Immunoassays has patented Mouse Monoclonal Antibodies, based on a proprietary Vitamin D hapten, recognizing both 25OH Vitamin D3 and 25OH Vitamin D2.  
1. Matching 25OH Vitamin D pairs – Tail. 2. Matching with 25OH Vitamin D antibodies - position-3, from the market.

## RAW MATERIALS

Cat#	Name	Size	Type	Subtype	Clone/Host	Format
------	------	------	------	---------	------------	--------

### 1,25(OH)<sub>2</sub> Vitamin D

#### Antibodies:

Cat#	Name	Size	Type	Subtype	Clone/Host	Format	
5319306	Monoclonal Antibody against 1,25(OH) <sub>2</sub> Vitamin D2/D3	1mg	Monoclonal Antibody <sup>1</sup>	Tail	BA2	Purified, Unconjugated	
5319316							283/C4 GF3 Mouse
5319256							EG4

#### Antigens & Conjugates:

Cat#	Name	Size	Type	Subtype	Clone/Host	Format
5019220	1,25(OH) <sub>2</sub> Vitamin D antigen - carboxylic acid	1mg	Antigen/Conjugate <sup>1</sup>	Tail	NA	Purified, Carboxylic acid (COOH)
5019221	1,25(OH) <sub>2</sub> Vitamin D antigen - BSA					Purified, BSA conjugate
Please contact us	1,25(OH) <sub>2</sub> Vitamin D antigen - amino					Purified, Amino (NH <sub>2</sub> )
Please contact us	1,25(OH) <sub>2</sub> Vitamin D antigen - biotin					Purified, Biotin conjugate

\*In 2009, DIAsource Immunoassays has patented Mouse Monoclonal Antibodies, based on a proprietary Vitamin D hapten, recognizing both 25OH Vitamin D3 and 25OH Vitamin D2.  
1. Matching 1,25(OH)<sub>2</sub> Vitamin D pairs.

Cat#	Name	Size	Type	Subtype	Clone/Host	Format
------	------	------	------	---------	------------	--------

FREE 25OH Vitamin D ELISA

Antibodies:

5319706	Monoclonal Antibody against 25OH Vitamin D2/D3*	1mg	Monoclonal Antibody <sup>1</sup>	Tail	LMBP 7013CB	Purified, Unconjugated
5319716					LMBP 7012CB	
5319726					LMBP 7011CB	
5319835	Polyclonal Antibody against 25OH Vitamin D2/D3	100µl	Polyclonal Antibody <sup>1</sup>	Tail	Rabbit	Crude

Antigens & Conjugates:

5019700	Vitamin D derivative - Carboxylic acid	1mg	Antigen/Conjugate <sup>1</sup>	Tail	NA	Purified, Carboxylic acid (COOH)	
5019700-100		100µg					
5019701	Vitamin D derivative - BSA conjugate	1mg				Purified, BSA conjugate	
5019701-100		100µg					
5019703	Vitamin D derivative - amino	1mg					Purified, Amino (NH <sub>2</sub> )
5019703-100		100µg					
5019708	Vitamin D derivative - biotin conjugate	1mg				Purified, Biotin conjugate	
5019708-100		100µg					

# CUSTOM DIAGNOSTIC LABORATORY SERVICES & SALES CONDITIONS

➤ SERVICES AVAILABLE

Coating services

- Coating of polystyrene tubes individually capped: batch size from 30,000 up to 100,000 tubes with your antibodies according to your coating procedure.
- Coating of microtiter plates in sealed aluminum bags with your antibodies according to your coating procedure: batch size from 150 up to 900 microtiter plates.
- Primary coated tubes with anti-rabbit, anti-sheep or avidin-streptavidin for RIA-IRMA applications.
- Primary microtiter plates with anti-rabbit, anti-sheep, or avidin-streptavidin for ELISA applications.

➤ ISO 9001 AND ISO 13485 APPROVED

The scientists at DIAsource have extensive experience in the development of antibodies and related enzymatic or radioactive assays. They can help guide you through each step in the process of purifying, fragmenting, coating and labeling antibodies. High level technicians can be consulted at any time to discuss other services like filling and freeze-drying. We can offer specific and flexible suggestions to enhance the performance of your final product. All services are manufactured under strict ISO 9001 and 13485 guidelines.

Filling services

- From solution preparation to filling, capping and labeling.

Freeze-drying services

- Freeze-dry from 0.25ml up to 15ml in glass vials: batch size up to 27,000 vials for 5ml vials.

Tailored <sup>125</sup>I labeling

- Iodization and purification of your antigen (hapten, peptide, protein) either by gel filtration or HPLC.

Mabs fragmentation

- From the antibodies you send us we can produce F(ab')<sub>2</sub> fragments on a large scale.

Labeling Services

- Labeling of your antibody or antigen (hapten, peptide) with several markers such as peroxidase, biotin, fluorescent tag or other labels.

Antibody Purification

- Whatever antibody you send us we can purify it by protein-A, protein-G or caprylic acid precipitation and even by affinity chromatography.



\*In 2009, DIAsource Immunoassays has patented Mouse Monoclonal Antibodies, based on a proprietary Vitamin D hapten, recognizing both 25OH Vitamin D3 and 25OH Vitamin D2.  
1. Matching 25OH Vitamin D pairs – Tail.



# OUR OTHER AVAILABLE PRODUCT CATALOGS



## ➤ INSTRUMENTS

- Automated System for ELISA & RIA
- Automated Processor for DOT Technology "Auto-Immunity"
- ELISA Instruments



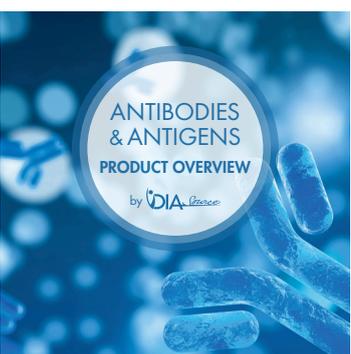
## ➤ IMMUNOASSAYS

- Biogenic Amines
- Bone Metabolism
- Cancer Markers
- Cardiovascular & Salt
- Balance
- Diabetes & Metabolism
- Fertility
- Gastrointestinal
- Metabolism
- Growth Factors
- Thyroid Function



## ➤ MULTI-SPECIES

- Allergy
- Endocrinology & Metabolism
- Infectious Disease



## ➤ ANTIBODIES

- Bone Metabolism
- Cancer Markers
- Cardiovascular & Salt Balance
- Diabetes & Metabolism
- Fertility
- Growth Factors
- Thyroid Function

### ⊕ MANUFACTURED BY:

**DIAsource ImmunoAssays® S.A.**

rue du Bosquet 2 - BE 1348 Louvain-la-Neuve - Belgium  
Tel.: +32 (0)10 84 99 11 - Fax: +32 (0)10 84 99 90  
info@diasource.be - customer.service@diasource.be

### ⊕ FOR MORE INFORMATION:

[www.diasource-diagnostics.com](http://www.diasource-diagnostics.com) - [www.freevitamind.org](http://www.freevitamind.org)

### ⊕ DISTRIBUTED BY:



Tel: +44 (0)1235 431390  
[sales@oxfordbiosystems.com](mailto:sales@oxfordbiosystems.com)  
[www.oxfordbiosystems.com](http://www.oxfordbiosystems.com)