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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.

O 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)₂ 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.

O 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.

O 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.



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

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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

Sales Director Spain

& Latino America

Pere Carbó

Customer Service Representative





M-F Sanchez Tania Cabrera

SALES & MARKETING



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

International Sales Director





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

Mobile SP: +34 618 566 458

pere.carbo@diasource.be



Sales Manager France

Laurent Augis

David Degels

Tel.: +32 (0)10 84 99 05

david.degels@diasource.be

& District Manager Wallonia

Tel.: +32 (0)479 70 00 72

laurent.augis@diasource.be

Mobile: +33 6 85 60 17 85



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

(X) REGULATORY AFFAIRS



MANAGER

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



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

CLINICAL BACKGROUND

250H Vitamin D is so far the best biomarker to evaluate the Vitamin D status of individuals.

MEASUREMENT OF 250H 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 250H Vitamin D is today considered as the most appropriate measurement of 250H Vitamin D in human. However increasing research on free 250H 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.

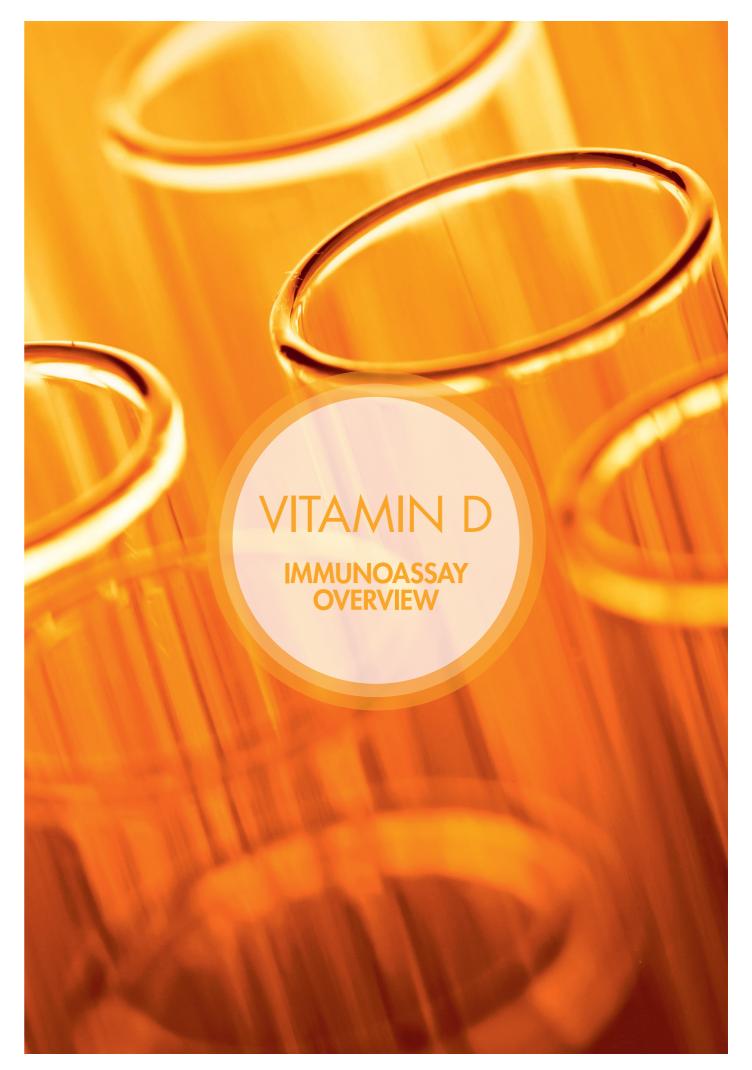


1,25(OH)₂ Vitamin D is the active form of Vitamin D with regard to the known functions whereas 25OH Vitamin D and Vitamin D itself can be excluded as being physiologically functional. Furthermore since 1,25(OH)₂ Vitamin D is produced in the kidney and has some of its functions in the bone and intestine, 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)₂ 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)₂ 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)₂ Vitamin D.

The measurement of 1,25(OH), 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





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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
05011/2:	KIP1971(1)	96 T		0.5		F. II	10.100 / 1		
25OH Vitamin D Total	KIP1974	4x96 T	S	25	No	Fully	10-100 ng/mL	3	8
1,25(OH) ₂ 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
250H Vitamin D Total 90'	KAP1971-F1	96 T	S - P	25	No	Fully	4,9-105 ng/mL	1,5	104
Rat 250H Vitamin D Total (RUO)	KRR1971	96 T	S	50	No	Fully	5,3-133 ng/mL	2,75	130
1,25(OH) ₂ 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) ₂ Vitamin D RIA or 2 kits of 1,25(OH) ₂ 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



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

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⁽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

250H 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 %	

O COATED TUBE TECHNOLOGY

O CALIBRATED ACCORDING TO THE VDSP PROGRAM



250H VITAMIN D TOTAL RIA

Assay characteristics	250H 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 %	

O COATED TUBE TECHNOLOGY

All-In-One® technology:

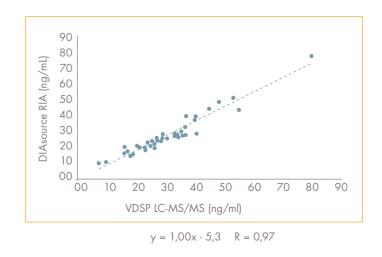
- no extraction step
- displacement solution directly into the tube
- automatable on a RIA platform or on a pipetting station

© 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:



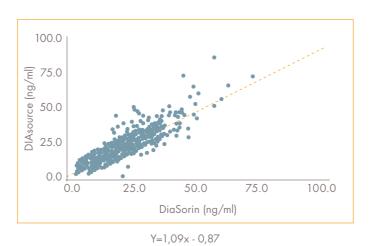
$1,25(OH)_2$ VITAMIN D RIA

O CORRELATIONS

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

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

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



250H-Vitamin D total-RIA-CT KIP1971 / KIP1974 250H Vitamin D Total RIA-CT REE KIP1971 TOT 172404/D 2017-08-11

Assay characteristics	1,25(OH) ₂ 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 %	

O GOLDEN STANDARD EXTRACTION METHODOLOGY

Samples and controls are extracted with a mixture of solvents and applied on cartridges to separate 1,25(OH)₂ 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)₂ Vitamin D - 25,26(OH)₂ Vitamin D.

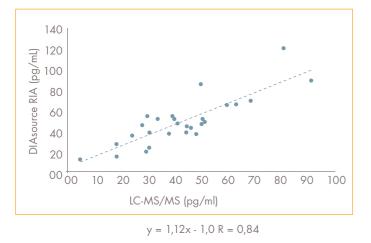
Compound	Cross-reactivity
1,25(OH) ₂ Vitamin D3	100 %
1,25(OH) ₂ Vitamin D2	92.3 %
250H Vitamin D3	0.001 %
24,25(OH) ₂ Vitamin D3	0.005 %
25,26(OH) ₂ Vitamin D3	0.2 %

O COATED TUBE TECHNOLOGY

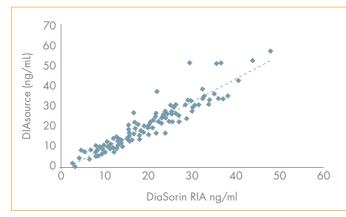
O CORRELATIONS

Correlation to the Gold Standard LC-MS/MS:

DIAsource $1,25 \text{(OH)}_2$ Vitamin D RIA vs LC-MS/MS



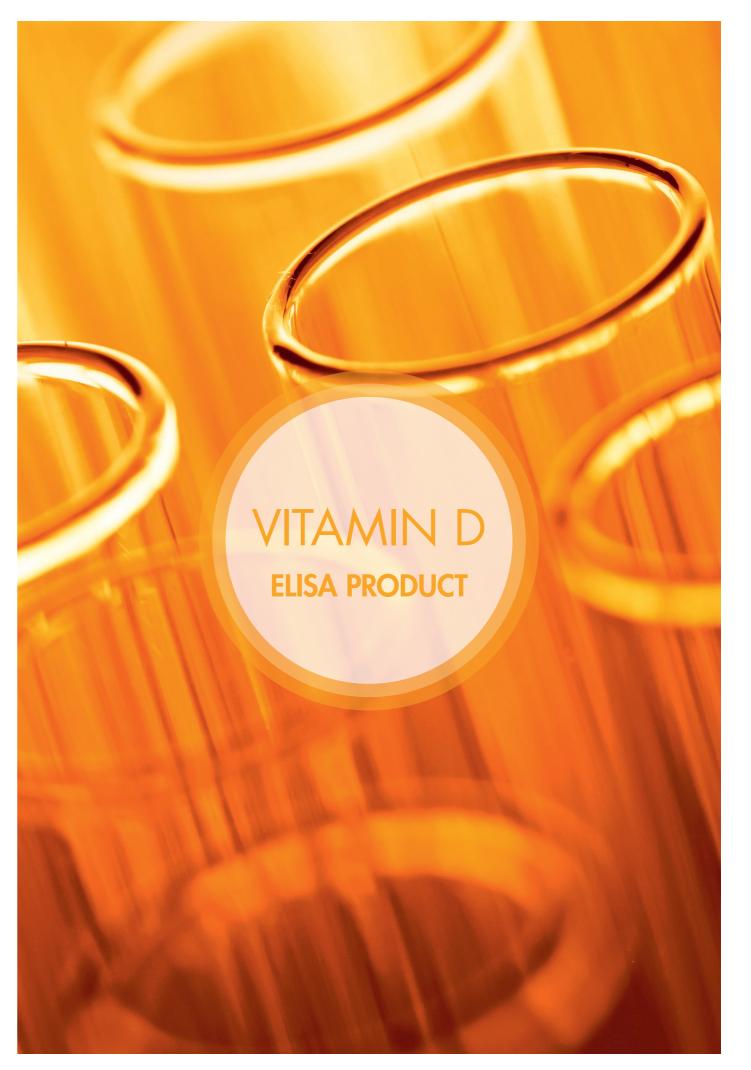
Correlation to the DiaSorin 1,25(OH)₂ Vitamin D RIA: DIAsource 1,25(OH)₂ Vitamin D RIA versus DiaSorin RIA



y = 1.5x - 2.6 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 ₂ 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



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250H VITAMIN D TOTAL ELISA

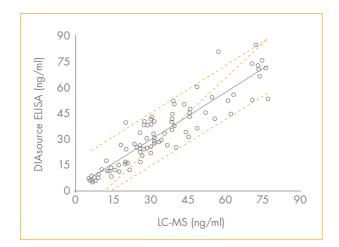
Assay characteristics	250H Vitamin D Total ELISA	
Article code	KAP1971	
Format	Breakable wells	
Size	96 Tests	
Sample type	Serum	
Sample volume	50 μL	
Controls	2 levels	
Range	5.3 - 133 ng/mL	
Total analysis Time	210' (3h30)	
Total incubation time	165' (2h45)	
LoD	2.8 ng/mL	
CV intra-assay	2.5 – 7.8 %	
CV inter-assay	4.3 – 9.2 %	

O 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

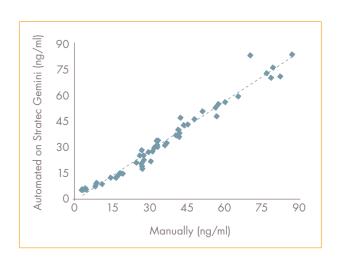
⊗ LESS RISKS OF ERRORS

ESS MANIPULATIONS

SELESS 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

O 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 ng/mL	0.92
IDS ELISA	DIAsource	1.06 X + 0.83 ng/mL	0.93
IDS ELISA	US (3 sites)	0.95 X + 3.05 ng/mL	0.96
DiaSorin Liaison	DIAsource – Nice (Fr)	1.13 X - 1.34 ng/mL	Passing & Bablok*
DiaSorin Liaison	Nice (Fr)	0.98 X + 1.94 ng/mL	0.94
Euroimmun	DIAsource – Nice (Fr)	1.02 X - 2.14 ng/mL	Passing & Bablok*
DRG	DIAsource – Nice (Fr)	1.19 X + 2.28 ng/mL	Passing & Bablok*
DRG	DRG – Nice (Fr)	1.24 X + 1.12 ng/mL	Passing & Bablok*
Roche	China (2 sites)	0.94 X + 0.98 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.

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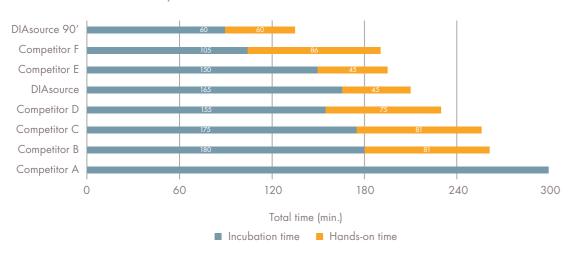
250H VITAMIN D TOTAL 90' ELISA

Assay characteristics	25OH Vitamin D Total ELISA 90'	
Article code	KAP1971-F1	
Format	Breakable wells	
Size	96	
Sample type	Serum / Plasma	
Sample volume	25 μΙ	
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 250H 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

ESS MANIPULATIONS

S LESS CONSUMABLES REQUIRED

O 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



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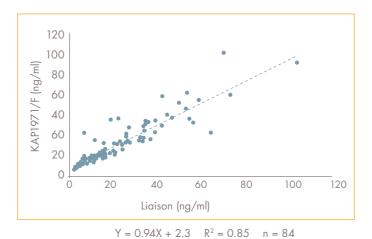
O CORRELATIONS

Correlation to the DIAsource 25OH Vitamin D Total Elisa:

KAP1971-F1 vs KAP1971

Correlation to the DiaSorin Liaison:

KAP1971-F1 vs Liaison



RAT 250H 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 %	

OVALIDATED 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 D3/kg and maintained in normal luminosity conditions (day and night).

The second group has been fed with pellets containing 3600 UI 250H Vitamin D3/kg and maintained in normal luminosity conditions (day and night).

The third group has been fed with pellets without 25OH Vitamin D3 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) Range of values (ng/ml) (2/5 to 97.5 percentiles)	19. <i>7</i> 12.1 – 27.0	27.7 12.6 - 41.4	<i>7.</i> 6 6.6 – 9.1

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○ 100% AUTOMATABLE

The DIAsource 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.

⊗ LESS RISKS OF ERRORS

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36 MONTHS SHELF LIFE



$1,25(OH)_2$ VITAMIN D ELISA

O RELIABLE TEST RESULTS

The only ELISA measuring D2 and D3 forms accurately

Assay characteristics	1,25(OH) ₂ 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 %

O GOLDEN STANDARD EXTRACTION METHODOLOGY

Samples and controls are extracted with a mixture of solvents and applied on cartridges to separate 1,25(OH)₂ 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) ₂ Vitamin D Mean % variation
Hemoglobin	5.0 %
Bilirubin conjugated	-12.3 %
Bilirubin unconjugated	-0.4 %
Triglyceride	-1.0 %
Vitamin C	4.9 %

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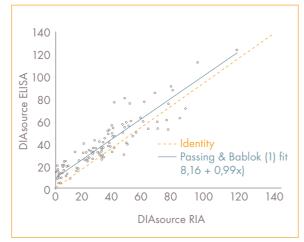
Separation on solid phase cartridges suppresses the interference from other Vitamin D metabolites:

250H Vitamin D - 24,25(OH)₂
Vitamin D - 25,26(OH)₂ Vitamin D.

Compound	Cross-reactivity
1,25(OH) ₂ Vitamin D3	114 %
1,25(OH) ₂ Vitamin D2	108 %
250H Vitamin D3	0.004 %
250H Vitamin D2	0.0003 %
24,25(OH) ₂ Vitamin D3	0.03 %
25,26(OH) ₂ Vitamin D3	0.02 %

\odot Calibrated on the Well established diasource 1,25(OH) $_2$ VITAMIN D RIA

A correlation was performed with 110 serum samples comparing the DIAsource $1,25(OH)_2$ Vitamin D ELISA to the DIAsource $1,25(OH)_2$ Vitamin D RIA.

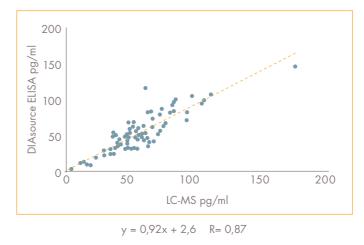


O CORRELATIONS

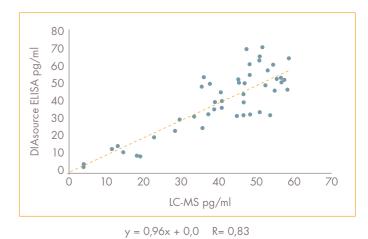
Correlation to LC-MS/MS:

A correlation was performed by a reference clinical laboratory with 80 serum samples comparing the DIAsource $1,25(OH)_2$ Vitamin D ELISA to a sensitive LC-MS/MS method.

1,25(OH)₂ Vitamin D DIAsource ELISA versus LC-MS:

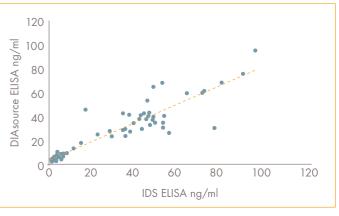


1,25(OH)₂ Vitamin D DIAsource ELISA versus LC-MS (<60pg/mL):



Correlation to the IDS ELISA:

A correlation was performed with 75 serum samples comparing the DIAsource $1,25(OH)_2$ Vitamin D ELISA to the IDS $1,25(OH)_2$ Vitamin D ELISA.



y = 0.92x + 2.6 R= 0.87

O ELISA METHOD COMPARISON

	DIAsource ELISA	ELISA A	ELISA B
Microplate	Breakable wells	Non-breakable wells	Non-breakable wells
Sample volume	500 µL	500 pL	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) ₂ Vit D2	108 %	39 %	41 %
CR 1,25(OH) ₂ Vit D2	0.03 %	0.006 %	< 0.1 %
CR 250H Vit D3	0.004 %	0.009 %	< 0.01 %

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FREE 250H 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 %

O SIMPLE ACCURATE AND DIRECT

• Direct Measurement of Free 250H Vitamin D

No sample Pre-treatment

• Low volume: 10µL volume

• Calibrated against Rate Dialysis

O 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

O SCIENTIFIC CONCEPT

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

- 250H 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 250H 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

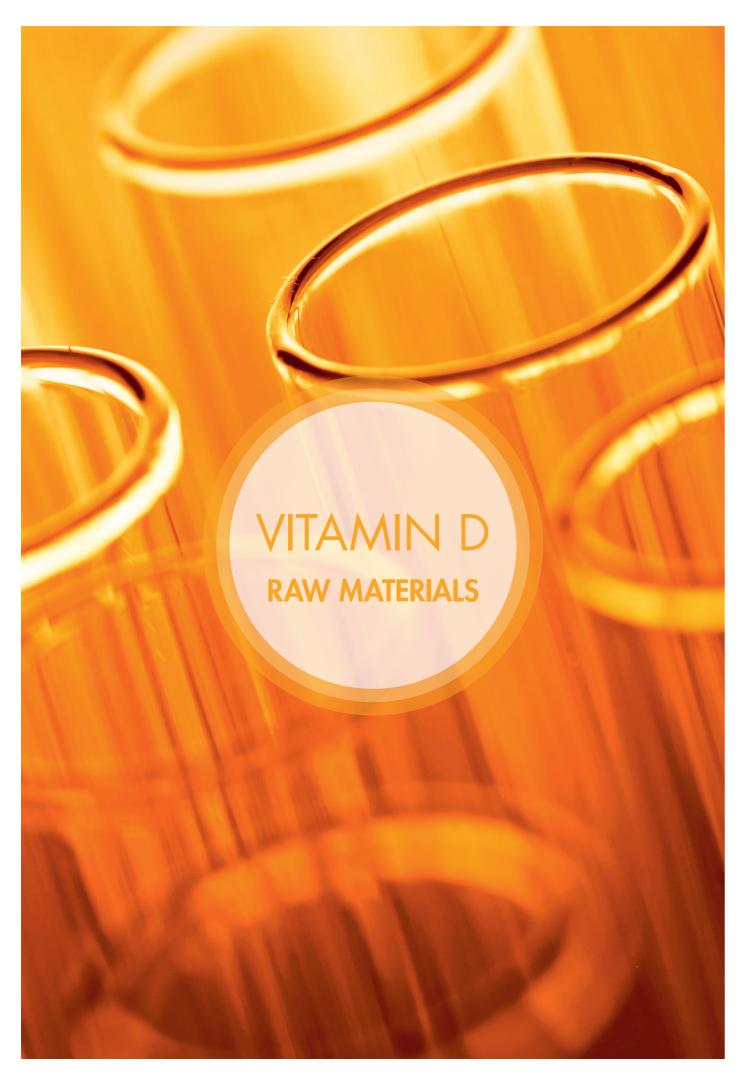
If you need support for internal validation and/or for a study design with our free Vitamin D ELISA test in your laboratory please contact Diasource: info@diasource.be and/or visit our new dedicated website: www.freevitamind.org...



References:

Hocher 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/jc.2018-00336, Hormonal Contraceptive Use is Associated with Higher Total but Unaltered Free 25-Hydroxyvitamin D Serum Concentrations.
Hocher 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.

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RAVV 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.

O 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)₂ Vitamin D2 and D3.

O 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.

O 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.

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○ RAW MATERIALS

Cat#	Name	Size	Туре	Subtype	Clone/Host	Format
		25OH \	Vitamin D			

Antibodies:

5319706					LMBP 7013CB	
5319716	Monoclonal Antibody against 250H Vitamin D2/D3*	1mg	Monoclonal Antibody ¹	Tail	LMBP 7012CB	Purified, Unconjugated
5319726					LMBP 7011CB	
5319835	Polyclonal Antibody against 250H Vitamin D2/D3	100µl	Polyclonal Antibody ¹	Tail	Rabbit	Crude

Antigens & others:

5019700	Vitamin D derivative -	1mg			NA	Purified, Carboxylic acid
5019700-100	Carboxylic acid	100µg				(COOH)
5019701	Vitamin D derivative -	1mg				Purified, BSA
5019701-100	BSA conjugate Vitamin D derivative - amino Vitamin D derivative -	100µg	Antinon (Conjuncto)	Tail		conjugate
5019703		1mg	Antigen/Conjugate ¹	Idii		Purified, Amino (NH2)
5019703-100		100µg				
5019708		1mg				Purified, Biotin
5019708-100	biotin conjugate	100µg				conjugate
5019502	Vitamin D antigen - 3-carboxylic acid					Purified, Carboxylic acid (COOH)
5019503	Vitamin D antigen - 3-amino	1mg	Antigen/Conjugate ²	Position-3	NA	Purified, Amino (NH2)
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

O RAW MATERIALS

Cat#	Name	Size	Туре	Subtype	Clone/Host	Format
1,25(OH) ₂ Vitamin D						

Antibodies:

5319306					BA2	
5319316	Monoclonal Antibody against 1,25(OH)2 Vitamin D2/D3	1mg	Monoclonal Antibody ¹	Tail	283/C4 GF3 Mouse	Purified, Unconjugated
5319256					EG4	

Antigens & Conjugates:

5019220	1,25(OH)2 Vitamin D antigen - carboxylic acid	Ü		Tail	NA	Purified, Carboxylic acid (COOH)
5019221	1,25(OH)2 Vitamin D antigen - BSA		A - ti / (C i t - 1			Purified, BSA conjugate
Please contact us	1,25(OH)2 Vitamin D antigen - amino		Antigen/Conjugate ¹			Purified, Amino (NH2)
Please contact us	1,25(OH)2 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 25OH Vitamin D pairs – Tail. 2. Matching with 25OH Vitamin D antibodies - position-3, from the market.

^{*}In 2009, DIAsource Immunoassays has patented Mouse Monoclonal Antibodies, based on a proprietary Vitamin D hapten, recognizing both 250H Vitamin D3 and 250H Vitamin D2.

1. Matching 1,25(OH)2 Vitamin D pairs.

RAW MATERIALS



FREE 25OH Vitamin D ELISA

Antibodies:

5319706					LMBP 7013CB	
5319716	Monoclonal Antibody against 25OH Vitamin D2/D3*	1mg	Monoclonal Antibody ¹	Tail	LMBP 7012CB	Purified, Unconjugated
5319726					LMBP 7011CB	
5319835	Polyclonal Antibody against 250H Vitamin D2/D3	100µl	Polyclonal Antibody ¹	Tail	Rabbit	Crude

Antigens & Conjugates:

5019700	Vitamin D derivative - Carboxylic acid	1mg	- Antigen/Conjugate ¹	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 (NH2)
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.

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 1251 labeling

• lodization 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')2 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 caprilic 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 250H Vitamin D3 and 250H Vitamin D2.

1. Matching 250H Vitamin D pairs – Tail.

O GENERAL CONDITIONS OF SALES

Article 1 – Application

Unless there is an explicit deviation agreed upon in writing, the present general terms and conditions

Article 7 - Hardship apply to every DIAsource offer as well as every contract that is formed on the basis of such an offer or an order confirmed by DIAsource. The client waives explicitly and fully the application of its own general terms and conditions by virtue of its relationship with DIAsource. Contracts that have been concluded through the staff or representatives of DIAsource and that do not observe these general terms and conditions do not bind DIAsource.

Article 2 – Conclusion of the contract

An offer from DIAsource is only binding if it is accompanied by a period of acceptance and only if this period has not yet expired. A client's order can only be considered accepted by DIAsource after DIAsource's express written confirmation of that acceptance. As any order has its own specific characteristics and, therefore, the products ordered by one client cannot be redirected to another client, the client cannot cancel an accepted order whether in full or in part. If the client would cancel an accepted order, it will still have to pay the full price of the relevant order. DIAsource reserves the right to (i) refuse requests for customized orders, or requests for modifications of accepted orders; and/ or to (ii) charge such modifications or customizations to the client at the then-prevailing actual cost, with a minimum of 25 EUR (excl. VAT). Without prejudice to the third paragraph of this article 2, an administrative fee of 25 EUR (excl. VAT) will be charged by DIAsource for any order with a value of less than 500 EUR (excl. VAT).

Article 3 – Price and related costs

Unless agreed otherwise in writing, all of DIAsource's set prices apply to packaged products that are delivered Ex Works (in the sense of Incoterms 2010) to the registered seat of DIAsource. The following, on top of the stipulated price, are to be paid by the client, unless there is any explicit written deviation from this rule:

(i) All costs of insurance, security, loading, transport, and unpacking of the products. (ii) All taxes and levies (including VAT and customs duties) related to the delivered products or the items mentioned under (i), including the taxes and levies that are applied or adapted only after the conclusion of the contract

(iii) All additional costs for DIAsource that have been incurred as a result of differences in the currency exchange rates that are detrimental to DIAsource. Every cost that is charged for execution of payments must always be borne by the client ultimately.

Article 4 – Payment

Unless agreed on otherwise, (i) if DIAsource sends a pro forma invoice to the client, such pro forma invoice must be paid before the confirmed shipment date and (ii) if DIAsource does not send a pro forma invoice to the client, all invoices should be paid upon receipt. The payment of a (pro forma) invoice may not be refused or postponed for any reason whatsoever. Any late payment will make all debts of the client to DIAsource immediately due upon notification to that effect by DIAsource. An interest on late payment will be charged—ex officio and without notice—on the unpaid balance of all debts of the client to DIAsource which are due and payable, and the rate of it will be equal to the interest rate calculated according to Article 5, paragraph 2 of the Act of 2 August 2002 on combating late payments in commercial transactions, increased by 3.5% per year. On top of this, a compensation of 15% of the unpaid balance will be charged to cover the administrative costs associated with late payments, and this at a minimum of EUR 100 per invoice that is paid late. All of this is without prejudice to (i) the possibility for DIAsource to prove the actual damage it suffered and to demand compensation for it, or (ii) the possibility for DIAsource to suspend the further performance of its obligations under this or any other contract with the client, or apply any other common law sanction. Article 5 – Reservation of ownership – transfer of risk

The ownership of every sold product only passes to the client after the client has fully paid the price and related costs for this product, as well as the late interest and compensation that would be due by virtue of late payment of this price. Before full payment is made, and unless explicitly agreed otherwise in writing, the client may not alienate the product, encumber it with securities, or transform it or attach it to an immovable property in any way; in that time span, the client will conserve the product safely and have it insured; it will also conserve it in a way it can be identified individually, with a legible and visible mark on it, explicitly confirming that it is property of DIAsource. The risk of loss, destruction, or damage to the product (also if caused by force majeure) will nevertheless pass to the client as soon as the product is delivered to the client.

Article 6 – Delivery Period

Every agreed upon delivery term is only (and is to be considered) indicative. Not observing this term does not entitle the client to any remedy, unless the parties agree explicitly in writing that the delivery term is binding (in that event, not observing the delivery term can only give way to both parties are able to submit observations, or to the termination of the sale, any of which GDPR@diasource.be

can only be sought at the earliest 1 month from the date of a notice demanding delivery).

If, beyond the will of DIAsource, unforeseen circumstances (e.g., strike, accidents, weather conditions, material defects, etc.) materialize in the procurement-, production-, distribution- or any other necessary type of process that make the delivery or timely delivery or the performance of any other obligation impossible (or strongly impede this), then DIAsource, depending on the nature of the circumstances, has the right to terminate the contract or suspend the performance of its obligations. DIAsource will not incur any liability if this occurs.

Article 8 – Complaints

Complaints regarding visible defects or non-conformity are only admissible if (i) the product has not been used yet, and (ii) the complaint is in writing and is sent to the commercial services department of DIAsource in Louvain-La-Neuve no later than 3 working days from the date of delivery. After that, the products will irrefutably be considered accepted. Following complaints are also non-receivable: anonymous complaints, claims related to results dating more than a year before the introduction of the same complaint, complaints linked to a "mistake" of the customer "(ex: mishandling, error in following the protocol, etc.), claims related to facts that are not within the competence of DIAsource, claims relating to a failure to provide information by the client, claims related to a subjective nature of the said claim. Article 9 - Liability/Security

DIAsource will only be liable for hidden defects if the client notifies DIAsource thereof by registered letter within 7 business days after such hidden defects are discovered by the client. This term is to be considered a term unable to be suspended or reset ("délai de déchéance" / "vervaltermijn"). In that event, the client will not be entitled to claim the dissolution of the sale of the relevant product, and DIAsource will only be liable for (i) the decrease in value of the product, and, to the extent DIAsource can be held liable for it, and (ii) the additional damage suffered by the client, it being understood that the client bears the burden of proof. This indemnity (i & ii) will in any event be limited to the price paid by the client for the relevant product. The client must conform strictly with the directives regarding the good distribution practices (GDP) applicable to medical devices marked 'CE'. The client must use the products in a professional way and in accordance with the instructions of DIAsource. The client must inform DIAsource immediately of any dysfunction or any alteration of the properties and/or performances of the product he has bought from DIAsource. If the products are resold by the client to a third party outside of Belgium, the client must provide all documents and necessary instructions to that third party in the language(s) of the country of destination. DIAsource must only accept returned goods to the extent that they are the subject of a complaint which DIAsource has declared admissible and well-founded. Article 10 – Netting in case of insolvency of the client

In case the client is declared bankrupt, or in case any other insolvency or insolvency-like procedure is initiated in respect of the client, any amounts reciprocally due by and between DIAsource and the client shall be netted automatically and by force of law on the date of the opening of the insolvency procedure, regardless of whether such amounts are already due or determined ("vaststaand"/"liquide") on the date of the opening of the insolvency procedure, and even if they are not entirely certain.

Article 11 – No assignment

The client may not assign its rights and obligations against DIAsource to any third party (through a sale, a capital contribution, a donation or any other transaction, including the sale or contribution of a division ("bedrijfstak"/"branche d'activité") or of a business as a whole ("algemeenheid/ "universalité"), or a merger, spin-off, split-up or other corporate restructuring) without the prior written consent of DIAsource.

Article 12 – Applicable law and competent court

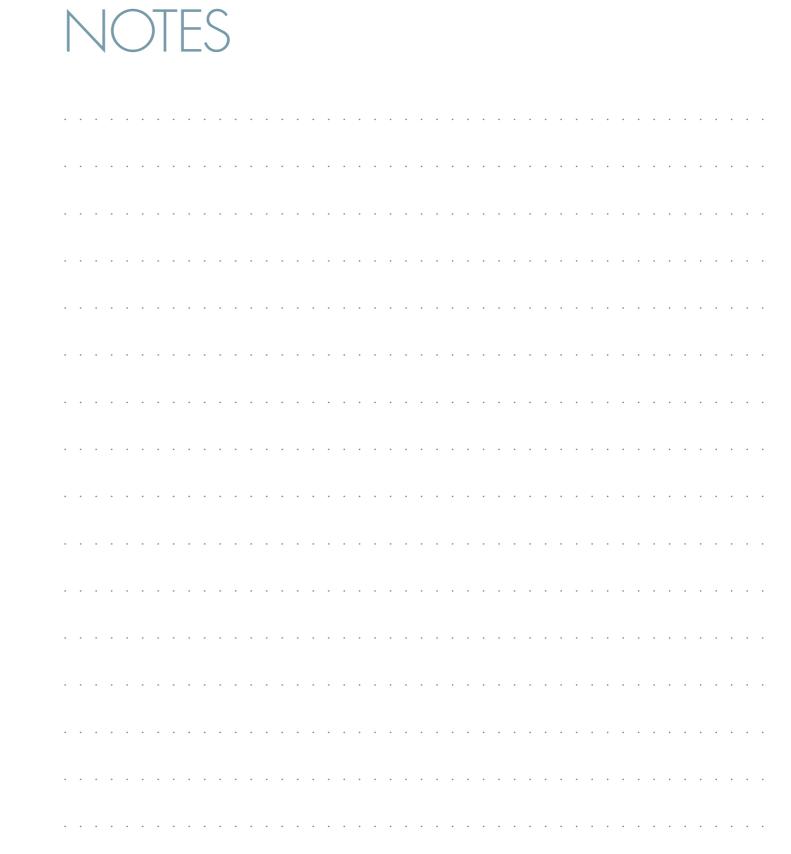
Belgian law applies to all agreements to which the present general terms and conditions apply, but with the exclusion of the application of Belgian private international law and the Convention on the International Sale of Goods of Vienna dated 11 April 1980 (except for the Convention on the Limitation Period in the International Sale of Goods of 14 June 1974, whose application remains). The courts of Walloon Brabant, Belgium are exclusively competent to hear all disputes arising out of or in connection with contracts concluded by DIAsource (including the pre-contractual disputes) to which the present general terms and conditions apply.

Article 13 – Discrepancies between language versions

The present general terms and conditions have been drafted in Dutch, English, French and Spanish. In case of discrepancies between the different language versions, the French version will prevail.

Article 14 – GDPR & Privacy policy

DIAsource is compliant to the General Data Protection Regulation. Our policy for privacy and data indemnification for the damage that is actual, proven, and established in such a way that protection is available on our website www.diasource-diagnostics.com. Any questions can be sent to:





OUR OTHER AVAILABLE PRODUCT CATALOGS



O INSTRUMENTS

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



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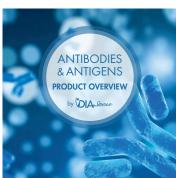
- Biogenic Amines
- Bone Metabolism
- Cancer Markers
- Cardiovascular & Salt
- Balance
- Diabetes & Metabolism

- 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 - www.freevitamind.org

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Tel: +44 (0)1235 431390 sales@oxfordbiosystems.com www.oxfordbiosystems.com