Free 250H Vitami	n D ELISA - RUO (KARF1991)
Art. Code	KARF1991
Format	ELISA
Label	HRP
Size	96 tests
Sample Type	Serum
Sample Volume	10 μL
Controls	2 levels
Range	0-40 pg/mL
Sensitivity	1,9 ng/mL
Incubation	90' + 30' + 20' + 15' (at 37°C)
Shelf Life	9 months

According to the Free Hormone Hypothesis, the biological
activity of 25OH Vitamin D is better reflected by its free
concentration than by the total concentration in the plasma. $ \\$

Particularly in situations with an elevated or decreased level of the Vitamin D binding protein, or with different phenotypes of this protein, Free 25OH Vitamin D may provide better diagnostic information than total 25OH Vitamin D.

Directly measured free 25OH Vitamin D concentrations were related to iPTH and calcium, but calculated estimates were not. J Schwartz et al_Comparison of Direct and Calculated Free 25(OH) D_JCEM June 2014_Published online.

RUO = Research Use Only

Intact PTH ELISA (KAP1481)											
Art. Code	KAP1481										
Format	ELISA										
Label	HRP										
Size	96 tests										
Sample Type	Serum, plasma										
Sample Volume	200 μL										
Controls	2 levels										
Range	15-1040 pg/mL										
Sensitivity	2 pg/mL										
Incubation	3 hours at RT with shaking										
Shelf Life	60 weeks										

Osteocal	cin ELISA (KAP1381)
Art. Code	KAP1381
Format	ELISA
Label	HRP
Size	96 tests
Sample Type	Serum, plasma
Sample Volume	25 μL
Controls	2 levels
Range	2-50 ng/mL
Sensitivity	0,4 ng/mL
Incubation	2.5 hours at RT with shaking
Shelf Life	60 weeks

The DIAsource Intact PTH assay is a true INTACT PTH assay, which is CE-labelled and calibrated against the International Reference Material NIBSC Reference 95/646.

The DIAsource Osteocalcin assay is a true INTACT OSTEOCALCIN assay, which makes use of native human osteocalcin standards. The assay has a proven absence of cross reaction with osteocalcin fragments.

	Description	Article code	Format	Size				
	25OH Vitamin D Total ELISA	KAP1971	ELISA	96 tests				
uc	1,25(OH) ₂ Vitamin D ELISA	KAP1921	ELISA	96 tests				
rmation	1,25(OH) ₂ Vitamin D Extraction Cartridges	1102496	For KAP1971	1 bag of 42 cartridges				
info	1,25 (OH) ₂ Vitamin D Extraction kit (Solvents), ready to use	3019700	For KAP1971	2 x 42 extractions				
Ordering	Free 250H Vitamin D ELISA - RUO	KARF1991	ELISA	96 tests				
Ō	Intact PTH ELISA	KAP1481	ELISA	96 tests				
	Osteocalcin ELISA	KAP1381	ELISA	96 tests				
	Aggrecan (PG – Proteoglycan) ELISA	KAP1461	ELISA	96 tests				

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

Manufactured by: DIAsource ImmunoAssays SA Rue du Bosquet 2 BE 1348 Louvain-La-Neuve Tel. 32 10 84 99 00 Fax 32 10 84 99 96

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

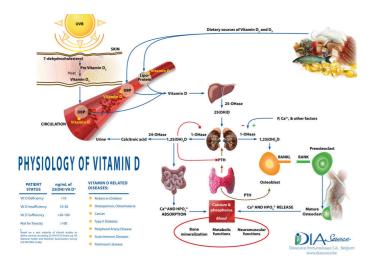


BONE METABOLISM ELISA ASSAYS



Assessment of Bone & Mineral clinical status with novel ELISA based assays.

25OH Vitamin D Total 1,25(OH)₂ Vitamin D Free 25OH Vitamin D Osteocalcin Intact PTH



Bone is a supportive connective tissue. It has multiple functions such as supporting the body weight, protection of the internal organs, and storage of the minerals. The cartilage-covered ends of the bone form articulate joints to allow multiplication of the force of the muscles attached to them. Assessment of bone metabolism diseases requires a portfolio of tests that measure both calcium regulation and bone turnover.

CALCIUM REGULATION

Calcium, along with phosphorous, is one of most abundant minerals found in the human bone. Calcium regulation is required for many basic body functions, because a decrease (hypocalcaemia) or increase (hypercalcaemia) seriously impacts normal body activities. The body regulates calcium through parathyroid glands and thyroid gland by releasing the parathyroid hormone (PTH) and Vitamin D, and to a lesser extent calcitonin.

Maintains strong and healthy bones by increasing the amount of dietary calcium absorbed by the intestines.

Regulates the function of the parathyroid gland to secrete parathyroid hormone, and to maintain adequate l

Regulates the function of the parathyroid gland to secrete parathyroid hormone, and to maintain adequate levels of calcium in the blood.

New developments suggest not only protecting against osteoporosis (increase bone density), but plays a role in the prevention of cancer, cardiovascular disease, autoimmune diseases, diabetes, depression and others.

Maintains calcium absorption in the intestines by stimulating the renal synthesis of 1,25(OH)₂ Vitamin D.

Regulates the level of calcium in the blood and the removal of calcium from the bone, as a results of Vitamin D action on the parathyroid gland.

Vitamin D Deficiency releases high levels of PTH, with bone weakening as a result. This is called secondary hyperparathyroidism.

VITAMIN D DEFICIENCY

Lack of sun exposure, mostly not compensated by adapted diet, is the most essential cause of Vitamin D deficiency, which results in decreased efficiency of intestinal Ca-absorption. 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.

Paediatric reference intervals have not been established, but the American Association for Paediatrics (AAP) recommends a value of 20 ng/mL for healthy children. Several population studies have identified widespread 25OH Vitamin D insufficiency (> 40% of the population) in apparent healthy populations.

FREE 25OH VITAMIN D

Only small fractions of circulating 1,25(OH)₂ Vitamin D and 25OH Vitamin D are circulating in the unbound form or "free" from (< 0.01 %). Nonetheless, the 'free hormone hypothesis' attributes biologic activity to the unbound or free fractions. The potential benefit of measuring "free or unbound" concentrations of 25OH Vitamin D has been suggested in literature. A unique ELISA assay that directly measures serum free 25OH Vitamin D levels has been developed based on the DIAsource proprietary and patented 25OH Vitamin D Monoclonal Antibody.

Table 1: Suggested	Reference Values for Adults
Vitamin D Status	25OH Vitamin D Total (ng/mL)
Deficiency	<10
Insufficiency	10 - 29
Sufficiency	30 - 100
Toxicity	>100

BONE TURNOVER: OSTEOCALCIN

Bone metabolism or bone turnover is the constant process of the body by replacing old bone with newly developed bone: process of bone absorption and bone resorption. Bone markers provide a real-time evaluation of bone turnover and can be helpful to evaluate progress of therapeutic interventions within a reasonable time compared to bone mineral density (BMD), one of the most often used bone turnover markers is Osteocalcin. The determination of the blood levels of Osteocalcin is valuable for:

- The identification of women at risk of developing osteoporosis
- Monitoring bone metabolism during the peri-and post menopause
- Monitoring bone metabolism during hormone replacement therapy and treatment of premenopausal women with LH-RH agonists

250H Vit	amin D Total (KAP 1971)						
Art. Code	KAP1971						
Format	ELISA breakable wells						
Label	HRP						
Size	96 tests						
Sample Type	Serum						
Sample Volume	50 μL						
Controls	2 levels						
Range	0-180 ng/mL						
Sensitivity	1,4 ng/mL						
Pretreatment	direct pretreatment						
Incubation	120min./30 min./15 min						
Shelf life	24 months						

•	Unique sample pre-treatment INSIDE MT-plate: no transfer
	of pre-treated samples from tube to MT-plate

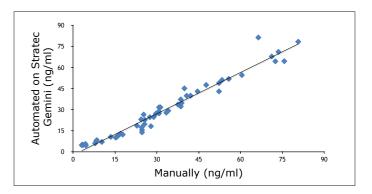
- Very robust assay: good precision
- Specificity: co-specific for 25OH Vitamin D3 (100%) and 25OH Vitamin D2 (83%)
- Calibrated against ID-LC/MS-MS (traceable to NIST VDSP)
- Easily Automable on Open ELISA platforms: only pipetting steps
- Superior sensitivity
- User friendly: easy, fast and reliable

1,25(OH), Vitamin D ELISA (KAP1921) Art. Code KAP1921 Format ELISA breakable wells HRP Label Size 96 tests Sample Type Serum Sample Volume 500 µL Controls 2 levels Range 0-320 pg/mL Sensitivity 1,7 pg/mL Extraction 60 min Incubation 1h, Over night, 1,5 h Shelf life 12 months

- The only ELISA with breakable wells
- Coated tube technology: no hassle with PEG
- Very robust assay: good precision
- Specificity: co-specific for 1,25 (OH), Vitamin D3 and D2
- Extraction kit: ready-to-use
- Excellent analytical sensitivity
- 2 Kit controls included
- Extraction of 1,25 (OH)₂ Vitamin D based on superior extraction procedure (Gold Standard method)
- Fastest turnaround time (see Table 1 Timetable)

AUTOMATISATION ON OPEN ELISA AUTOMATE STRATEC GEMINI

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. The regression analysis demonstrated a slope of 0.98, an intercept of – 2.29 ng/ml and a correlation of R= 0.98.

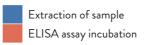


PRACTICAL ADVANTAGES OF THE DIASOURCE 1,25(OH), VITAMIN D ELISA ASSAY - TIMELINE

The timetable represent a graphic overview of the protocol handling time. The DIAsource $1,25(OH)_2$ Vitamin D ELISA assay has the fastest TAT (Turn Around Time) compared with 2 other commercially available ELISA assays.

Hour of the day	9)	1(О	1	1	12		1	13		14		15		6	17		9		10		11		12	
ELISA kit DIAsource																										
ELISA Kit Competitor A																										
ELISA Kit Competitor B																										
DIAsource Automated																										

16:00h - 10:00h overnight incubation □



Isolation of 1,25 (OH)₂ Vitamin D by specific separation technique ELISA assay separation and absorbance reading