

## BONE METABOLISM RIA ASSAYS

Intact PTH RIA (KIP1491)	
Art. Code	KIP1491
Format	IRMA
Label	I125
Size	96 tests
Sample Type	Serum, plasma
Sample Volume	300 µL
Controls	2 levels
Range	0 - 973 pg/mL
Sensitivity	4,1 pg/mL
Incubation	2 hours at RT with shaking
Shelf Life	7 weeks

Osteocalcin RIA (KIP1381)	
Art. Code	KIP1381
Format	IRMA
Label	I125
Size	96 tests
Sample Type	Serum, plasma
Sample Volume	50 µL
Controls	2 levels
Range	0 -69 ng/mL
Sensitivity	0,22 ng/mL
Incubation	2 hours at RT with shaking
Shelf Life	7 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.

Less than 1% cross-reactivity with 7-84 fragment (Fournier, M. E. Cohen Solal, R. Oprisiu, H. Mazouz, P. Morinire, G. Choukroun and R. Bouillon Optimal Range of Plasma Concentration of True 1-84 Parathyroid Hormone in Patients on Maintenance Dialysis. The Journal of Clinical Endocrinology & Metabolism Vol. 86, No. 4 1840- 1841).

The DIAsource Osteocalcin assay measures full length osteocalcin, and has a proven absence of cross reaction with N-terminal and C-terminal fragments. The assay makes use of native human osteocalcin standards. It combines superior sensitivity (0.22 ng/ml) with a broad measuring range.

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



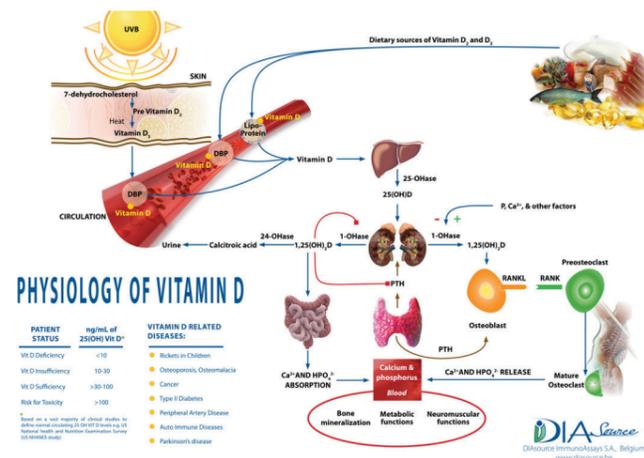
For more information: visit [www.diasource-diagnostics.com](http://www.diasource-diagnostics.com)

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Assessment of Bone & Mineral clinical status with RIA based assays.

25OH Vitamin D Total  
1,25(OH)<sub>2</sub> 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 requires a portfolio of tests that measure both calcium regulation and bone turnover.

### CALCIUM REGULATION

Calcium, along with phosphorus, is one of the 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 the thyroid gland by releasing the parathyroid hormone (PTH) and by vitamin D, and to a lesser extent calcitonin.

Vitamin D	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 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.
PTH	Maintains calcium absorption in the intestines by stimulating the renal synthesis of 1,25(OH) <sub>2</sub> Vitamin D.
	Regulates the level of calcium in the blood and the removal of calcium from the bone, as a result 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.

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

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

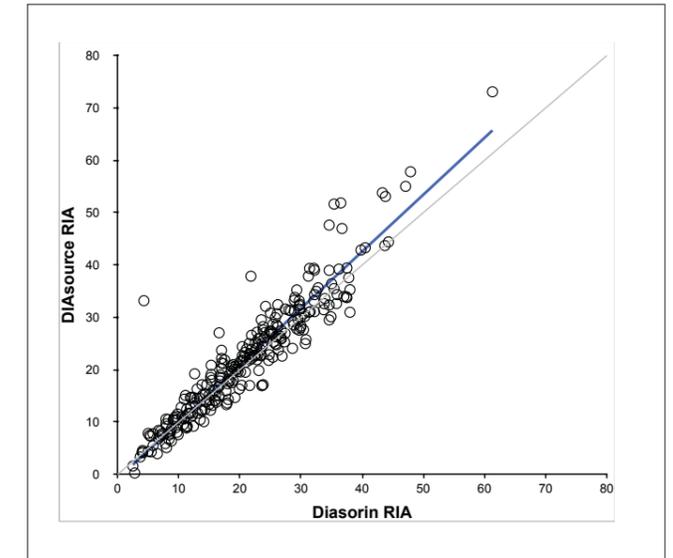
### BONE TURNOVER: OSTEOCALCIN

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
- Monitoring bone metabolism in patients with growth hormone deficiency, hypothyroidism, hyperthyroidism, chronic renal failure

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



- The only coated tube assay on the market
- Very robust assay: good precision
- Co-Specificity: 100% 25OH Vitamin D3 + 86% D2
- Calibrated against ID-LC/MS-MS (traceable to NIST – VDSP)
- Easily Automatable: only pipetting steps, no centrifugal steps
- Superior sensitivity
- User friendly: easy, fast and reliable

### METHOD COMPARISON

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

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

1,25(OH) <sub>2</sub> Vitamin D RIA (KIP1929)	
Format	RIA Coated Tube
Label	I125
Size	48 tests
Sample Type	Serum, plasma
Sample Volume	500 µL
Controls	2 levels
Range	4,7-411 pg/mL
Sensitivity	1,6 pg/mL
Incubation	Overnight
Shelf Life	10 weeks
Art. Code	KIP1929

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

### PROTOCOL HANDLING TIME FOR 1,25(OH)<sub>2</sub> VITAMIN D TOTAL RIA ASSAY:

Hour of the day	9	10	11	12	13	14	15	16	17	18	9	10	11	12
RIA kit DIAsource						Extraction of sample	Isolation of 1,25(OH) <sub>2</sub> Vitamin D by specific separation technique	RIA assay incubation	RIA assay separation and absorbance reading					
RIA Kit Competitor A		Extraction of sample	Isolation of 1,25(OH) <sub>2</sub> Vitamin D by specific separation technique	RIA assay incubation	RIA assay separation and absorbance reading									
RIA Kit Competitor B		Extraction of sample	Isolation of 1,25(OH) <sub>2</sub> Vitamin D by specific separation technique	RIA assay incubation	RIA assay separation and absorbance reading									

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

Extraction of sample  
RIA assay incubation

Isolation of 1,25(OH)<sub>2</sub> Vitamin D by specific separation technique  
RIA assay separation and absorbance reading