

25-OH Vitamin D ELISA

DRG



DRG

DRG ELISA

25-OH Vitamin D Total

A reliable and fast way to discover 25-OH Vitamin D Total

Intended use:

The DRG 25-OH Vitamin D Total ELISA (Order No. EIA-5396) is an enzyme immunoassay for the quantitative *in vitro diagnostic* measurement of 25-OH Vitamin_{D_{3/2}} in serum and plasma.

Summary and explanation of the test

Vitamin D is a steroid hormone involved in the intestinal absorption of calcium and the regulation of calcium homeostasis. The two major forms of Vitamin D, named Vitamin D₃ (cholecalciferol) and Vitamin D₂ (ergocalciferol), have isomeric structures, but D₂ is supposed to be less active than D₃. Physiological Vitamin D₃ levels result not only from dietary uptake but can also be produced in the skin during sun exposure. In consequence, the concentration of 25-OH Vitamin D decreases during winter time (reduced sun exposure), with dark skin colour and with age.

In the liver, the Vitamin D is hydroxylated to 25-hydroxyvitamin D (25-OH D), the major circulating metabolite of Vitamin D. Vitamin D and 25-OH D enter the circulation bound to Vitamin D binding protein (VDBP). Upon request, a small portion of 25-OH D is further hydroxylated in the kidney to form the biologically active hormone 1,25-dihydroxyvitamin D. Although 1,25-dihydroxyvitamin D portrays the biological active form of Vitamin D, it is widely accepted that the measurement of circulating 25-OH Vitamin D provides better information with respect to patients Vitamin D status.

Consequences of Vitamin D deficiency

Bone Metabolism

- Osteoporosis
- Osteomalacia
- Rickets

Cancer

- Possibly associated with different cancer types (breast, colon, prostate, ovarian)

Cardiovascular Diseases

- Stroke
- High blood pressure
- increasing risk for all-cause and cardiovascular mortality

Autoimmune Diseases

- Diabetes Mellitus Type I
- Multiple Sclerosis
- Rheumatoid Arthritis

Clinical Relevance

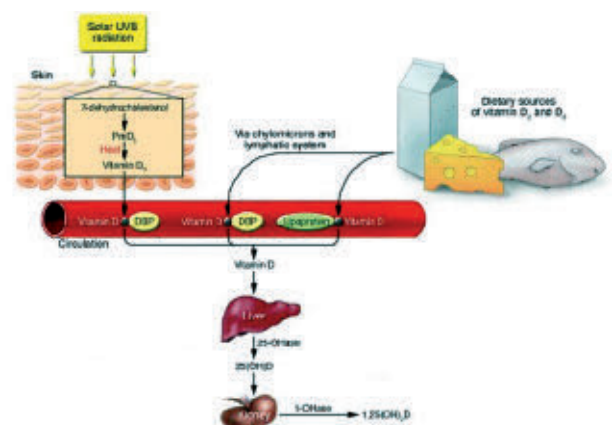
Determination of 25-OH D in serum or plasma will support the diagnosis and therapy control of postmenopausal osteoporosis, rickets in children, osteomalacia, renal osteodystrophy, neonatal hypocalcemia and hyperparathyroidism. In recent years, Vitamin D has become an indicator of general health status, linking Vitamin D deficiency to several disease states such as cancer, cardiovascular disease, diabetes and autoimmune diseases.

Assay characteristics

Assay Principle:	Competitive ELISA
Dynamic range:	2.9 - 130 ng/mL
Total assay time:	approx. 2h (30 min pre-treatment; 60 + 15 min ELISA)
Sample volume:	25 µL Serum or Plasma (EDTA, Citrate, Heparin)
Intra Assay precision:	4.7 %
Inter Assay precision:	10.2 %
Specificity:	100 % 25-OH-Vitamin D ₃ ; 74.7 % 25-OH-Vitamin D ₂
Analytical sensitivity:	2.89 ng/mL

Advantages of DRG ELISAS

- Straight forward sample preparation
- Measurement of 25-OH-Vitamin D₂ and D₃
- First results in less than 2 hours
- Standards are calibrated against international NIST Standard Reference Material (SRM) 2972
- Two controls included in the kit
- Good correlation to Diasorin LIAISON and re-developed Roche Cobas



Principle of the test

The DRG 25-OH Vitamin D total ELISA Kit is a solid phase enzyme-linked immunosorbent assay (ELISA), based on the principle of competitive binding.

Sensitivity

The analytical sensitivity of the DRG Vitamin D Total ELISA is 2.9 ng/mL.

Dynamic Range

The dynamic range of the DRG Vitamin D Total ELISA is between 2.9 - 130 ng/mL.

Linearity

	Sample 1	Sample 2	Sample 3
Concentration (ng/mL)	69.4	88.7	104.8
Average Recovery	104.6	98.4	114.8
Range of Recovery (%)	from 85.8 to 97.8	94.7 103.3	105.7 109.2

Recovery

	Sample 1	Sample 2	Sample 3
Concentration (ng/mL)	36.4	60.5	82.6
Average Recovery	104.1	105.2	92.5
Range of Recovery (%)	from 92.9 to 112.4	96.9 111.3	88.2 94.1

Specificity

25-OH Vitamin D₃: 100.0 %
 25-OH Vitamin D₂: 74.7 %
 1.25 (OH)₂ Vitamin D₃: < 0.1 %
 Vitamin D₃: 3.6 %

Expected Normal Values

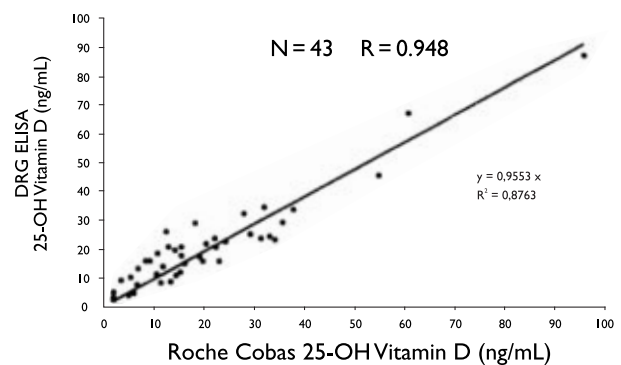
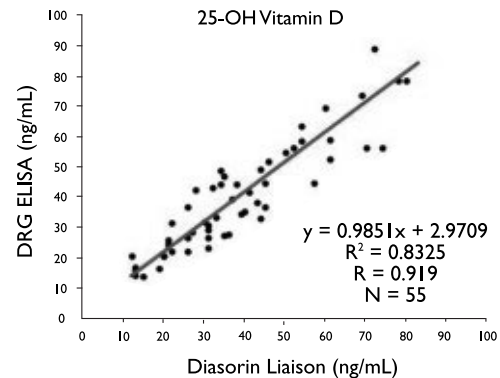
In a study conducted with apparently normal healthy Caucasian adolescents and adults, using the DRG 25-OH Vitamin D ELISA the following values were observed:

Population	Valid N	Age years	Mean Age	Mean Conc. (ng/mL)	5 th Percentile (ng/mL)	95 th Percentile (ng/mL)
Males	77	14 - 79	58	26.1	11.7	46.8
Females	82	17 - 79	55	30.2	14.3	56.9

Samples were collected in the month of September.

Method Comparison

The DRG 25-OH Vitamin D ELISA EIA-5396 showed good correlation to the Diasorin LIAISON ($r=0.919$; $n=55$) and to re-developed Roche Cobas ($r=0.948$; $n=43$)



Reproducibility

Intra Assay

Sample	n	Mean (pg/mL)	CV (%)
1	20	25.1	4.4
2	20	43.2	3.0
3	20	93.7	6.6

Inter Assay

Sample	n	Mean (pg/mL)	CV (%)
1	40	23.7	9.9
2	40	47.8	10.7
3	40	64.2	8.6

A review of the literature suggests the following ranges for the classification of 25-OH Vitamin D status (Pilz et al. 2011; J. Laboratory Medicine, 35, 211):

Vitamin D status	25-OH Vitamin D (ng/mL)	25-OH Vitamin D (nmol/L)
Deficiency	< 10	< 25
Insufficiency	10 - 29	25 - 72.5
Sufficiency	30 - 100	75 - 250
Toxicity	> 100	> 250

Conversion Factor: 1 ng/mL corresponds to 2.5 nmol/L

DRG ELISAS

Tumormarker

CYFRA 21-I
CA 72-4
CA 15-3
CA 125
CA 19-9
CEA
TPS
TPA
PSA
free PSA
NSE
Chromogranin

Gyn. Endocrinology

Estradiol
Progesterone
17a-OH Progesterone
DHEA-S
Testosterone
DHEA
Estrone
Androstendione
DHT
SHBG
DHEA
LH, FSH, PRL

Prenatal Supervision

PAPP-A
Free β HCG
AFP
Free Estriol
HCG
HPL
PLGF

Saliva Diagnostics

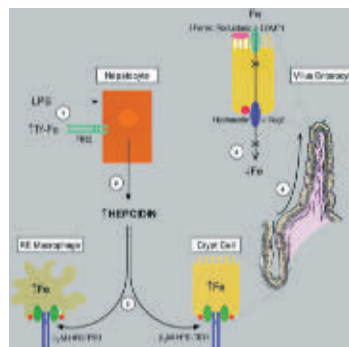
Cortisol
Estradiol
Testosterone
DHEA
Progesterone
17a-OH Progesterone
Estrone

Diabetes/Obesity

Insulin
C-Peptid
Proinsulin
Leptin

Iron Metabolism

Hepcidin 25 (bioactive)



Bone Metabolism

25-OH Vitamin D Total

Hypertension

Renin
Aldosterone

ELISAS that perform

DRG develops and manufactures ELISAS for use in clinical and research laboratories.

The experience of our production and management team guarantees to provide high quality products, competitive prices and excellent customer service.

DRG works to DIN EN ISO 9001:2008, ISO 13485:2012/AC:2012 and ISO 13485:2003 under CMDCAS standard, certified by TÜV Rheinland Product Safety GmbH, an indication of our commitment to customer service, quality control and improved health care.

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