

Immunoassays

EIA & RIA Product Portfolio

Please check availability and regulatory status in your country.





Calcium Metabolism

Vitamin D deficiency results in abnormalities in calcium, phosphorus and bone metabolism and affects one billion people worldwide across all ethnicities and age groups¹. Our comprehensive calcium metabolism panel enables laboratories to measure Vitamin D deficiencies in line with the Clinical Practice Guidelines set by the Endocrine Society².



Bone Turnover Markers

Throughout life, old bone is constantly removed (resorption) and replaced by new bone (formation). This continual process is essential for the maintenance of healthy bone mass and micro-architecture. Changes in bone turnover can be effectively assessed by using the comprehensive IDS bone turnover marker panel.



Animal Research

IDS offers a complete panel of bone and cartilage turnover markers reflecting the processes in formation and degradation³ of cartilage. These markers are suitable for cell culture e.g. ex vivo cultures of bone and/or cartilage, *in vitro* osteoclast or osteoblasts; in different animal species, from rodents to mammals, and in blood or urine test samples.



Growth

Accurate determinations of circulating GH, IGF-I and IGFBP-3 concentrations are crucial in the diagnosis and monitoring of growth disorders such as acromegaly and growth hormone deficiency. The IDS Growth panel can be used to identify these diseases and conditions, evaluate pituitary function and monitor the effectiveness of growth hormone (GH) treatment.



Cartilage

Cartilage is a connective tissue found in many areas of the body, including joints between bones (articular cartilage). Individuals whose cartilage is affected suffer from joint disease (arthritis) is mainly degenerative and causes arthritis/osteoarthritis (OA), but also inflammatory arthritis including rheumatoid arthritis (RA) and ankylosing spondylitis (AS). IDS is committed to providing highly accurate and reproducible assays and offers the most promising markers according to BIPED criteria to analyse cartilage related events in body fluids or tissues⁴.



Autoimmune Disease

An illness that occurs when the body tissues are attacked by its own immune system. The immune system is a complex organization within the body that is designed normally to "seek and destroy" invaders of the body, including infectious agents. Patients with autoimmune diseases frequently have unusual antibodies circulating in their blood that target their own body tissues. Examples of autoimmune diseases include systemic lupus erythematosus, Sjogren syndrome, Hashimoto thyroiditis, rheumatoid arthritis, juvenile (type 1) diabetes, celiac disease, vasculitis and Addison disease.



Steroids

Steroid hormones can be grouped into two classes: corticosteroids (typically made in the adrenal cortex, hence cortico-) and sex steroids (typically made in the gonads or placenta). Steroid hormones help control metabolism, inflammation, immune functions, salt and water balance, development of sexual characteristics, and the ability to withstand illness and injury.



Tumour Markers

Tumour markers are biomarkers found in blood, urine or body tissue which can be produced by cancer cells or other cells in response to cancer. Most tumour markers are made by normal cells as well as cancerous cells and as a result, an elevated level of these biomarkers may only be indicative of the presence of cancer. There are many different tumour markers each suggestive of a specific type of cancer; although, not everyone with a certain cancer will have elevated levels of the marker associated with that type of cancer. Unfortunately, there is no single tumour marker that has been identified, to date, that is able to detect any type of cancer.

- 1. Holick MF., "Vitamin D deficiency". N. Engl. J. Med. (2007) 357 (3): 266–81
- 2. The Journal of Clinical Endocrinology & Metabolism 96.7 (2011): 1911-1930
- 3. Schaller S et al., In vitro, ex vivo, and in vivo methodological approaches for studying therapeutic targets of osteoporosis and degenerative joint diseases:
- how biomarkers can assist? Assay Drug Dev Technol. 2005 Oct;3(5):553-80
- 4. Rousseau JC, Delmas PD.Biological markers in osteoarthritis. Nat Clin Pract Rheumatol. 2007 Jun; 3(6):346-56

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Expertise in

ELISA & RIA

Diagnostics

Immunodiagnostic Systems Limited is a leading *in vitro* diagnostic solutions provider to the clinical and research laboratory markets.

Since 1977, we have developed, manufactured and marketed innovative

immunoassays to provide improved diagnostic outcomes for patients.

We offer a wide variety of specialised high quality products, delivering

innovative solutions for diagnostics, therapy monitoring and research.

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Hypertension

30% of the adult population suffer from hypertension and out of these, 15-20% of hypertensive patients may have Primary Aldosteronism (PA) or Renovascular Hypertension (RVH)¹⁻³. In PA excess, aldosterone levels may be produced due to an adenoma (Conn's syndrome) or hyperplasia, causing blood pressure elevation⁴. Patients with this condition are at a stronger risk of heart disease and stroke than those with essential hypertension⁴. PA patients also have higher cardiovascular morbidity and mortality than age and sex-matched patients with essential hypertension. RVH is due to the narrowing of one or both renal arteries due to an atherosclerotic plaque or fibro muscular dysplasia.

According to the Endocrine Society guidelines, both Renin and Aldosterone need to be measured as the Aldosterone to Renin ratio (ARR) is the screening test for PA⁵. An elevated ARR is indicative of the presence of PA. The measurement of Renin can also be used to stratify risk of essential hypertension patients.



Thyroid Monitoring

The thyroid is a small, butterfly-shaped gland located at the base of the neck just below the Adam's apple. It's part of an intricate network of glands called the endocrine system. The endocrine system is responsible for coordinating many of the body's activities. The thyroid gland manufactures hormones that regulate the body's metabolism (the process of creating and using energy). There are several different disorders that can arise when the thyroid produces too much hormone (hyperthyroidism) or not enough (hypothyroidism). Four common thyroid disorders include Hashimoto's disease, Graves' disease, goiter, and thyroid nodules.



Diabetes

Diabetes, often referred to by doctors as diabetes mellitus, describes a group of metabolic diseases in which the person has high blood glucose (blood sugar), either because insulin production is inadequate, or because the body's cells do not respond properly to insulin, or both. Diabetes is a long-term condition that causes high blood sugar levels. In 2013 it was estimated that over 382 million people throughout the world had diabetes (Williams textbook of endocrinology). Type I or insulin-dependent diabetes mellitus is the result of a frank deficiency of insulin. The onset of this disease typically is in childhood. It is due to destruction pancreatic beta cells. Type II or non-insulin-dependent diabetes mellitus begins as a syndrome of insulin resistance. Approximately 90% of all cases of diabetes worldwide are of this type.



Fertility

Most people will have the strong desire to conceive a child at some point during their lifetime. Understanding what defines normal fertility is crucial to helping a person, or couple, know when it is time to seek help. Most couples (approximately 85%) will achieve pregnancy within one year of trying, with the greatest likelihood of conception occurring during the earlier months. Only an additional 7% of couples will conceive in the second year. Depending on the results of the evaluation discussed above, your physician may request specific blood tests. The most common of these tests include measurements of blood levels of certain hormones such as estradiol and FSH, which are related to ovarian function and overall egg numbers.



Circulating Immunocomplex

An immune complex is a molecule formed from the binding of antibody to antigen⁶ which then essentially functions as a separate antigen, with its own unique epitope. Immune complexes are normally removed from tissues by phagocytic cells of the immune system. In patients with elevated levels of immune complexes, these can be deposited in tissues where they can initiate several responses such as complement activation, localised inflammation resulting in tissue lesions (in several autoimmune disease) which in turn exacerbate the disease⁷. Circulating immune complexes are detectable in a variety of disorders such as rheumatoid arthritis, autoimmune and allergic diseases, viral and bacterial infections.



Miscellaneous

A limited number of test kits that covers different area of pathologies like allergia, anemia or cardiac dysfunctions are also available in our portfolio.

- 1. Kearney, PM et al., Global burden of Hypertension: analysis of worldwide data. Lancet, 2005.
- 2. Rossi, GP et al., Clinical use of laboratory test for the identification of secondary hypertension, Crit Rev Clin Lab Sci, 2007.
- 3. Mulatero, Pet al., Increased diagnosis of Primary aldosteronism in centers from five continents. JCEM, 2004.
- 4. Milliez, P. et al., Evidence for an increased rate of cardiovascular events in patients with primary Aldosteronism. J Am Coll Cardiol 2005 Apr 19; 45 [8]: 1243-8.
- 5. Funder, J.W. et al., Case detection, diagnosis, and treatment of patients with primary aldosteronism: an endocrine society clinical practice guideline. J Clin Endocrinol Metab 93 [9] 3266-81.
- 6. Cush, John; Kavanaugh, Arthur; Stein, Charles (2005). Rheumatology: Diagnosis and Therapeutics. Lippincott Williams & Wilkins. p. 78.
- 7. Eggleton, Paul, Javed, Moazzam, Pulavar, David, and Sheldon, Gemma(Apr 2015) Immune Complexes. In: eLS. John Wiley & Sons Ltd, Chichester. http://www.els.net/doi:10.1002/9780470015902.a0001118.pub2]



25-Hydroxy Vitamin D^s EIA

Enzyme immunoassay for the quantitative determination of total 25-hydroxyvitamin D – Traceable to ID-LCMS/MS 25(OH)D reference method procedure

Sample Type	Human serum, plasma (EDTA, heparin, citrate)	IVD	AC-57SF1		CE/FDA
Sample Volume	• 25 µL			96	
Sensitivity	 Limit of Detection (LoD): 6.8 nmol/L (2.7 ng/mL) Limit of Quantitation (LoQ): 12 nmol/L (4.8 ng/mL) 	.,,	7.0 0.0.	Wells	02,1271

25-Hydroxy Vitamin D RIA

Radioimmunoassay for the quantitative determination of total 25-hydroxyvitamin D

Sample Type	Human serum, plasma (EDTA, heparin)				
Sample Volume	• 50 µL	IVD	AA-35F1	100 Tubes	CE/FDA
Sensitivity	• 3 nmol/L (1.2 ng/mL)				

1,25-Dihydroxy Vitamin D EIA

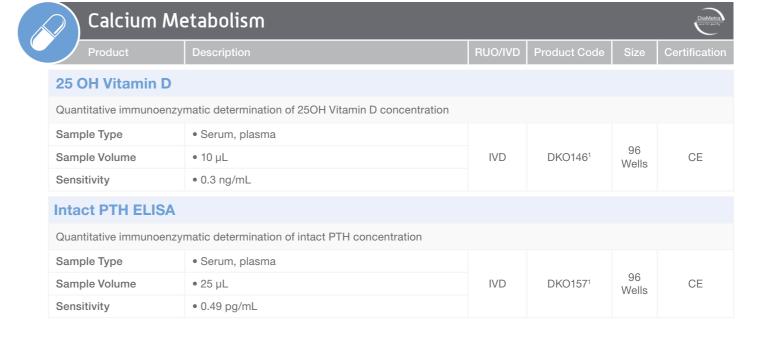
Complete assay system for the purification of total 1,25-dihydroxyvitamin D by immunoextraction with quantitation by enzyme immunoassay – Proprietary immunoextraction system, no organic or radioactive waste

Sample Type	• Human serum, plasma (EDTA, heparin)		AC-62F1	96 Wells	CE/FDA
Sample Volume	• 500 µL	IVD			
Sensitivity	• 6 pmol/L (2.5 pg/mL)				

1,25-Dihydroxy Vitamin D RIA

Complete assay system for the purification of total 1,25-dihydroxyvitamin D by immunoextraction with quantitation by radioimmunoassay – Proprietary immunoextraction system, no organic waste

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Sample Type	• Human serum, plasma (EDTA, heparin)		AA-54F1	40	
Sample Volume	• 500 µL	IVD		Cols 56	CE/FDA
Sensitivity	• 5 pmol/L (2.1 pg/mL)		AA-54F2	Cols	



- * Not yet listed with FDA as IVD | ** Not yet CE Marked as IVD
- RUO Research Use Only | IVD In Vitro Diagnostic Use | FDA FDA Cleared | CE CE Marked | ¹Manufactured by DiaMetra S.r.I

Alpha CrossLaps® (CTX-I) ELISA

Quantification of degradation of non-isomerised fragments of C-terminal telopeptides of type I collagen (CTX-I)

Sample Type	Human urine		AC-04F1	96 Wells	CE/FDA
Sample Volume	• 25 μL	IVD			
Sensitivity	• 0.8 ng/mL				

BoneTRAP® (TRAcP 5b) ELISA

Quantitative determination of the active isoform 5b of tartrate-resistant acid phosphatase (TRAcP 5b)

Sample Type	Human serum, EDTA plasma		SB-TR201A	96 wells	
Sample Volume	• 100 µL	IVD			CE
Sensitivity	• < 0.5 U/L				

N-MID® Osteocalcin ELISA

Quantitative determination of osteocalcin as an indicator of osteoblastic activity; both intact and N-MID® Osteocalcin fragments are detected with equal affinity

Sample Type	Human serum, plasma (EDTA, heparin)				
Sample Volume	• 20 µL	IVD	AC-11F1	96 Wells	CE/FDA
Sensitivity	• 0.5 ng/mL				

Ostase® BAP EIA

Quantitative determination of bone specific alkaline phosphatase as an indicator of osteoblastic activity

Sample Type	Human serum				
Sample Volume	• 50 µL	IVD	AC-20F1	96 Wells	CE/FDA
Sensitivity	• 0.7 µg/L				

Serum CrossLaps® (CTX-I) ELISA

Quantitative determination of degradation products of C-terminal telopeptides of type I collagen (CTX-I)

Sample Type	Human serum, plasma (EDTA, heparin)				
Sample Volume	• 50 µL	IVD	AC-02F1	96 Wells	CE/FDA
Sensitivity	• 0.02 ng/mL				

Bone Turno	ver				
Product	Description	RUO/IVD	Product Code	Size	Certification
Urine BETA Crossl	Laps® (CTX-I) ELISA				
Quantitative determination	of degradation products of C-terminal telopeptides of ty	pe-I collage	en (βCTX-I)		
Sample Type	• Human urine			96 Wells	CE/FDA
Sample Volume	• 20 µL	IVD	AC-05F1 ,		
Sensitivity	• 0.8 µg/L				
Urine CrossLaps®	(CTX-I) EIA				
Quantitative determination	of degradation products of C-terminal telopeptides of ty	pe I collage	n (CTX-I)		
Sample Type	Human urine				
Sample Volume	• 15 µL	IVD	AC-03F1	96 Wells	CE/FDA
Sensitivity	• 50 µg/L				

Growth					
Product	Description	RUO/IVD	Product Code	Size	Certification
Insulin-like Growt	h Factor-I (IGF-I) IRMA				
Immunoradiometric assay	for the determination of IGF-I				
Sample Type	Human serum			100 Tubes	CE
Sample Volume	• 25 µL	IVD	CL-BC1110		
Sensitivity	• 1.25 ng/mL				
Insulin-like Growth	n Factor Binding Protein-3 (IGFBP-3) IRM	IA			
Immunoradiometric assay	for the determination of IGFBP-3				
Sample Type	Human serum				
Sample Volume	• 10 µL	IVD	CL-BC1014	100 Tubes	CE
Sensitivity	• 50 ng/mL				



IGF-I

Quantitative immunoenzymatic determination of human Insulin-like Growth Factor 1 (IGF-1)

Sample Type	Human serum				
Sample Volume	• 50 µL	IVD	DKO1861	96 Wells	CE
Sensitivity	• 7.8 ng/mL				

hGH ELISA

Quantitative immunoenzymatic determination of human Growth Hormone

Sample Type	Serum, plasma				
Sample Volume	• 50 µL	IVD	DKO0501	96 Wells	CE
Sensitivity	• 0.105 µIU/mL				

Cartilage

Product	Description	RUO/IVD	Product Code	Size	Certification

Urine CartiLaps® (CTX-II) EIA

Quantitative determination of degradation products of C-terminal telopeptides of type II collagen (CTX-II)

Sample Type	Human urine				
Sample Volume	• 40 µL	IVD	AC-10F1	96 Wells	CE/FDA
Sensitivity	• 0.2 µa/L				

Human COMP® ELISA

Quantitative determination of Cartilage Oligomeric Matrix Protein (COMP)

Sample Type	Human serum, plasma (heparin)				
Sample Volume	• 25 µL	IVD	AN-14- 1006-71	96 Wells	CE
Sensitivity	• < 0.1 U/L				

Animal Research

Product	Description	RUO/IVD	Product Code	Size	Certification

CrossLaps® for Culture (CTX-I) ELISA

Quantitative determination of bone related degradation products from C-terminal telopeptides of type I collagen

Sample Type	Cell culture supernatant				N/A
Sample Volume	• 30 µL	RUO	AC-07F1	96 Wells	
Sensitivity	• 0.75 nM				



RatLaps™ (CTX-I) EIA

Quantitative determination of bone related degradation products from C-terminal telopeptides of type I collagen

Sample Type	Rat/mouse serum (Rat urine supernatants can also be utilised)				
Sample Volume	• 20 µL	RUO	AC-06F1	96 Wells N/A	N/A
Sensitivity	• Limit of Detection (LoD): 4.5 ng/mL				

Rat-MID™ Osteocalcin EIA

Quantitative determination of Osteocalcin in rats

Sample Type	Rat serum, plasma		AC-12F1		
Sample Volume	• 20 µL	RUO		96 Wells N/A	N/A
Sensitivity	• 50 ng/mL				

Rat/Mouse PINP EIA

Quantitative determination of N-terminal propeptide of type I procollagen (PINP) in rats/mice

Sample Type	Rat/mouse serum, plasma (EDTA, heparin)				
Sample Volume	• 5 µL	RUO	AC-33F1	96 Wells	N/A
Sensitivity	• 0.33 ng/mL				

RatTRAP™ (TRAcP 5b) ELISA

Quantitative determination of osteoclast-derived tartrate-resistant acid phosphatase form 5b (TRAcP 5b) in rats

Sample Type	Rat serum				
Sample Volume	• 25 µL	RUO	SB-TR102	96 Wells	N/A
Sensitivity	• 0.1 U/L				

MouseTRAP™ (TRAcP 5b) ELISA

Quantitative determination of osteoclast-derived tartrate-resistant acid phosphatase form 5b (TRACP 5b) in mice

Sample Type	Mouse serum				
Sample Volume	• 25 µL	RUO	SB-TR103	96 Wells	N/A
Sensitivity	• 0.1 U/L				

RUO – Research Use Only | IVD – In Vitro Diagnostic Use | FDA – FDA Cleared | CE – CE Marked

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(a)	Animal Res	earch				
	Product	Description	RUO/IVD	Product Code	Size	Certification

Animal COMP® ELISA

Quantitative determination of Cartilage Oligomeric Matrix Protein (COMP) in animal serum

Sample Type	Serum (rat, mouse, sheep, bovine, pig or goat)		AN-14- 2004-86	96 Wells	N/A
Sample Volume	• 50 µL (pre-diluted 1/10)	RUO			
Sensitivity	• < 0.02 U/L				

Serum Pre-Clinical CartiLaps® (CTX-II) ELISA

Quantitative determination of degradation products of C-terminal telopeptides of type II collagen (CTX-II)

Sample Type	Animal serum (EDTA plasma or synovial fluid can also be utilised		AC-08F1	96 Wells	
Sample Volume	• 25 µL	RUO			N/A
Sensitivity	• 3.7 pg/mL				

Urine Pre-Clinical CartiLaps® (CTX-II) EIA

Quantitative determination of degradation products of C-terminal telopeptides of type II collagen (CTX-II)

Sample Type	Non-human urine or cell culture supernatant		AC-09F1		
Sample Volume	• 10 µL	RUO		96 Wells	N/A
Sensitivity	• 0.75 µg/L				

Corticosterone EIA

Assay for the quantitative determination of corticosterone without the need for extraction

Sample Type	Rat/mouse serum, plasma (EDTA, heparin, citrate)				
Sample Volume	• 30 µL	RUO	AC-14F1	96 Wells	N/A
Sensitivity	• 0.55 ng/mL				

Corticosterone HS (High Sensitivity) EIA

Assay for the quantitative determination of corticosterone

Sample Type	Serum, plasma (EDTA and heparin)				
Sample Volume	• 100 µL	RUO	AC-15F1	96 Wells	N/A
Sensitivity	• 0.17 ng/mL				

	Research C	onsumables			
	Product	Description	RUO/IVD	Product Code	:

Bone Slices

Cortical bone slices from bovine femur for the in vitro assessment of osteoblastic bone resorption	RUO	DT-1BON 1000-96	50 Pieces	N/A

Dentine Discs

5 mm diameter wafers of devitalised dentine for use as a bone resorption substrate

Unique Feetures	• 5mm diameter wafers of devitalised dentine	RUO	AE-8050	50 Discs	N/A
Unique Features		RUO	AE-80100	100 Discs	N/A

Sac-Cel®

Double antibody separation has been commonly used since the earliest days of radioimmunoassay (RIA)^{1,2} and is very reliable. Less demanding procedures have been sought, in particular solid phase antibody techniques^{3,4}. Sac-Cel[®], which is antibody covalently coupled to microfine cellulose particles, successfully combines the specificity of liquid antibody with the speed, simplicity and precision of solid phase separation.

RUO	AA-SAC1 AA-SAC2	N/A	N/A

⁴ Sluiter, W.J. et al. (1972). Clin. Chim. Acta., 42, 255.



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¹ Hales, C.N. and Randle, P.J. (1963). Biochem. J., 88, 137.

² Koninckx, Ph., Bouillon, R. and De Moor, P. (1976). Acta Endocr. (Kbh)., 81, 45-53.

³ Morgan, C.R. and Lazarow, A. (1963). Diabetes, 12, 115.



17-OH Progesterone ELISA

Quantitative immunoenzymatic	determination of	f 17-OH Progesterone
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Sample Type	Serum, plasma			96 Wells	CE
Sample Volume	• 25 µL	IVD	DKO004		
Sensitivity	• 0.05 ng/mL				

Cortisol ELISA

Quantitative immunoenzymatic determination of Cortisol

Sample Type	Serum, plasma		DKO001	96 Wells	CE
Sample Volume	• 20 µL	IVD			
Sensitivity	• 2.42 ng/mL				

Urinary Cortisol ELISA

Quantitative immunoenzymatic determination of free Cortisol in urine

Sample Type	• Urine			96 Wells	
Sample Volume	• 10 µL	IVD	D DKO018		CE
Sensitivity	• 2.95 ng/mL				

Testosterone ELISA

Quantitative immunoenzymatic determination of Total Testosterone

Sample Type	Serum, plasma				
Sample Volume	• 25 µL	IVD	DKO002	96 Wells	CE
Sensitivity	• 0.10 ng/mL				

Free Testosterone ELISA

Quantitative immunoenzymatic determination of Free Testosterone

Sample Type	Serum, plasma				
Sample Volume	• 20 µL	IVD	DKO015	96 Wells	CE
Sensitivity	• 0.04 pg/mL				

Androstenedione ELISA

Quantitative immunoenzymatic determination of $\Delta 4$ -Androstenedione

Sample Type	Serum, plasma				
Sample Volume	• 25 µL	IVD	DKO008	96 Wells	CE
Sensitivity	• 0.01 ng/mL				

Steroid Hormones

Progesterone ELISA

Quantitative immunoenzymatic determination of Progesterone

Sample Type	Serum, plasma					
Sample Volume	• 20 µL	IVD	DKO006	96 Wells	CE	
Sensitivity	• 0.05 ng/mL					

Estradiol ELISA

Quantitative immunoenzymatic determination of 17β-Estradiol

Sample Type	Serum, plasma						
Sample Volume	• 25 µL	IVD	DKO003	96 Wells	CE		
Sensitivity	• 8.68 pg/mL						

DHEA-S ELISA

Quantitative immunoenzymatic determination of Dehydroepiandrosterone sulfate

Sample Type	Serum, plasma				
Sample Volume	• 30 µL	IVD	DKO005 96 Wells	CE	
Sensitivity	• 0.04 µg/mL				

Free Estriol ELISA

Direct immunoenzymatic determination of Free Estriol

Sample Type	Serum, plasma				
Sample Volume	• 25 µL	IVD	DKO007	96 Wells	CE
Sensitivity	• 0.03 ng/mL				

Total Estriol ELISA

Quantitative immunoenzymatic determination of Total Estriol

Sample Type	Serum, plasma					
Sample Volume	• 20 µL	IVD	LIKCINTU	96 Wells	CE	
Sensitivity	• 1.05 ng/mL					

DHEA

Quantitative immunoenzymatic determination of Dehydroepiandrosterone

Sample Type	Serum, plasma				
Sample Volume	• 25 µL	IVD	DKO124	96 Wells	CE
Sensitivity	• 0.10 ng/mL				

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Cortisol Saliva ELISA

Quantitative direct immunoenzymatic determination of Cortisol in saliva

Sample Type	Saliva				
Sample Volume	• 25 µL	IVD	IVD DKO020	96 Wells	CE
Sensitivity	• 0.12 ng/mL				

Testosterone Saliva ELISA

Quantitative direct immunoenzymatic determination of Testosterone in saliva

Sample Type	• Saliva				
Sample Volume	• 100 µL	IVD	DKO021	96 Wells	CE
Sensitivity	• 3.3 pg/mL				

Estradiol Saliva ELISA

Quantitative direct immunoenzymatic determination of Estradiol in saliva

Sample Type	• Saliva				
Sample Volume	• 100 µL	IVD	DKO022	96 Wells	CE
Sensitivity	• 0.5 pg/mL				

DHEA-S Saliva ELISA

Quantitative direct immunoenzymatic determination of DHEA-S in saliva

Sample Type	• Saliva				
Sample Volume	• 50 µL	IVD	DKO024	96 Wells	CE
Sensitivity	• 0.05 ng/mL				

Progesterone Saliva ELISA

Quantitative direct immunoenzymatic determination of Progesterone in saliva

Sample Type	• Saliva				
Sample Volume	• 100 µL	IVD	DKO025	96 Wells	CE
Sensitivity	• 3.8 pg/mL				



Estriol Saliva ELISA

Quantitative direct immunoenzymatic determination of Estriol in saliva

Sample Type	• Saliva				
Sample Volume	• 50 μL	IVD	DKO026	96 Wells	CE
Sensitivity	• 1.0 pg/mL				

Androstenedione Saliva ELISA

Quantitative direct immunoenzymatic determination of Androstenedione in saliva

Sample Type	Saliva				
Sample Volume	• 50 µL	IVD	DKO027	96 Wells	CE
Sensitivity	• 5.0 pg/mL				

Estriol Saliva HS

Quantitative direct immunoenzymatic determination of Estriol in saliva

Sample Type	• Saliva				
Sample Volume	• 200 µL	IVD	DKO178	96 Wells	CE
Sensitivity	• 1.48 pg/mL				

IgA Saliva ELISA

Quantitative direct immunoenzymatic determination of IgA in saliva

Sample Type	Saliva				
Sample Volume	• 25 µL	IVD	DKO078	96 Wells	CE
Sensitivity	• 0.5 μg/mL				

Saliva Collector Device

Method for collection of saliva samples using the glass collection device

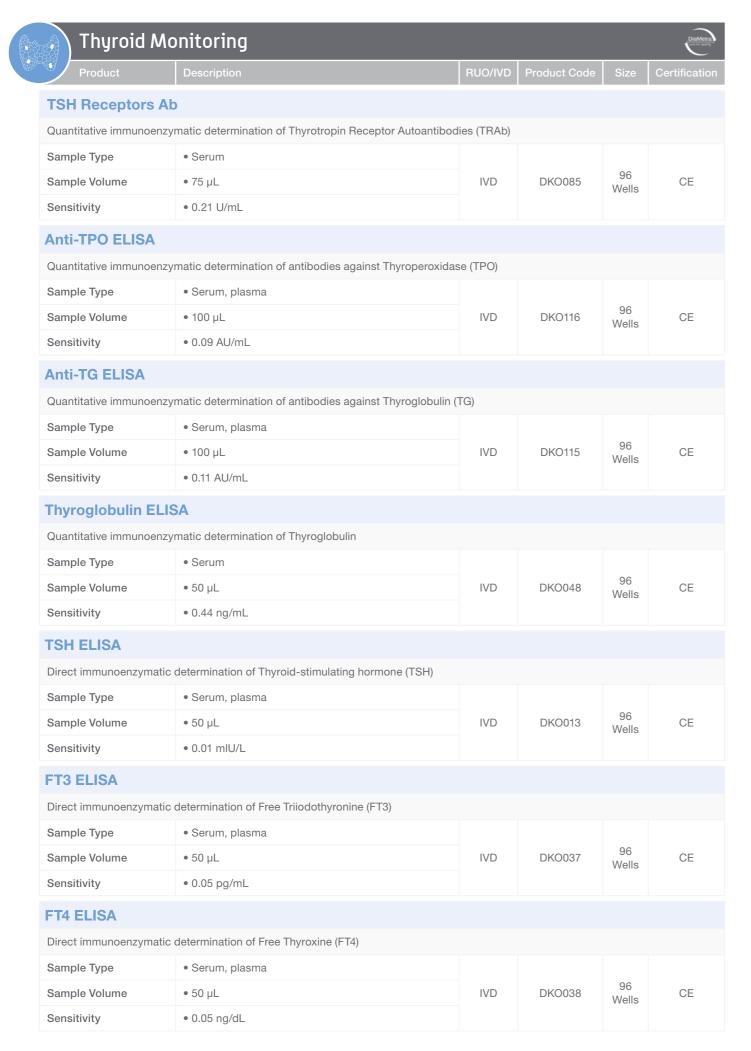
Sample Type	• Saliva				
Sample Volume	• N/A	IVD	DKO063	100 Pieces	CE
Sensitivity	• N/A				

Salivette (Sarsted – External Supplier)

Method for collection of saliva samples using the plastic collection device

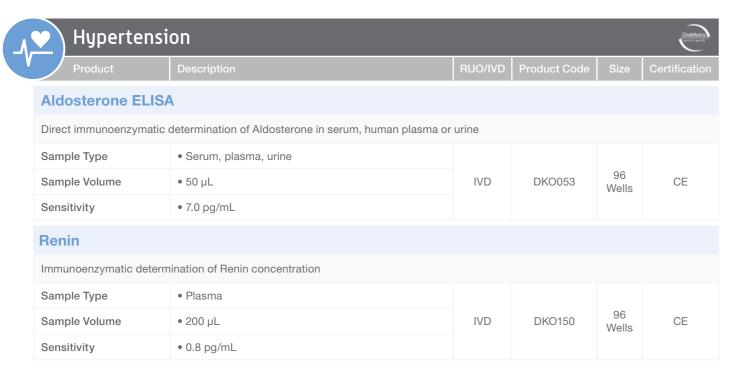
Sample Type	• Saliva				
Sample Volume	• N/A	IVD	51.1534.500	100 Pieces	CE
Sensitivity	• N/A				

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Thyroid Monitoring								
Product	Description	RUO/IVD	Product Code	Size	Certification			
T3 ELISA								
Direct immunoenzymatic determination of Triiodothyronine (T3)								
Sample Type	Serum, plasma							
Sample Volume	• 50 µL	IVD	DKO044	96 Wells	CE			
Sensitivity	• 5.0 ng/dL							
T4 ELISA								
Direct immunoenzymatic	determination of Thyroxine (T4)							
Sample Type	Serum, plasma							
Sample Volume	• 25 µL	IVD	DKO045	96 Wells	CE			
Sensitivity	• 0.4 µg/dL							
T3 ELISA 192T								
Direct immunoenzymatic	determination of Triiodothyronine (T3)							
Sample Type	Serum, plasma		DKO201	192 Wells				
Sample Volume	• 50 µL	IVD			CE			
Sensitivity	• 5.0 ng/dL							
T4 ELISA 192T								
Direct immunoenzymatic	determination of Thyroxine (T4)							
Sample Type	Serum, plasma							
Sample Volume	• 25 µL	IVD	DKO202	192 Wells	CE			
Sensitivity	• 0.4 µg/dL							
TSH ELISA 192T								
Direct immunoenzymatic	determination of Thyroid-stimulating hormone (TSH)							
Sample Type	Serum, plasma							
Sample Volume	• 50 µL	IVD	DKO200	192 Wells	CE			
Sensitivity	• 0.01 mIU/L							

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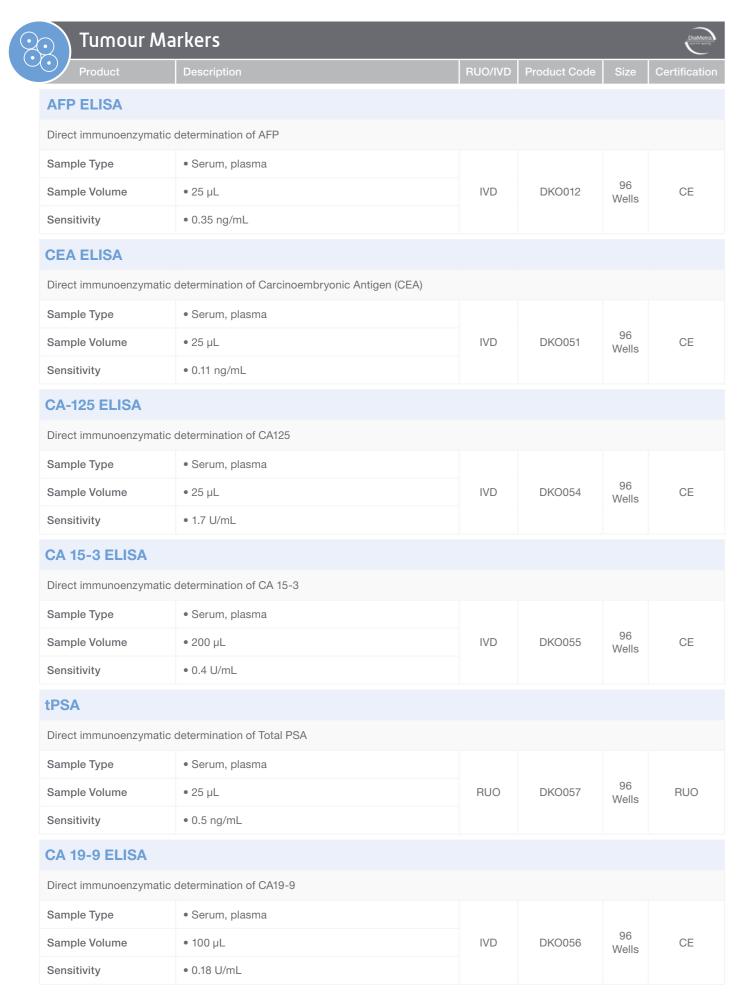


Diabetes Monitoring								
Product	Description	RUO/IVD	Product Code	Size	Certification			
Insulin ELISA								
Quantitative immunoenzy	matic determination of Insulin							
Sample Type	Serum, plasma							
Sample Volume	• 100 µL	IVD	DKO076	96 Wells	CE			
Sensitivity	• 0.25 μIU/mL							
C-Peptide ELISA								
Quantitative immunoenzy	matic determination of C-Peptide							
Sample Type	Serum, plasma		DKO077	96 Wells				
Sample Volume	• 50 µL	IVD			CE			
Sensitivity	• 0.01 ng/mL							
Anti-GAD								
Quantitative immunoenzy	matic determination of autoantibodies to Glutamic Acid D	ecarboxylas	se (GAD)					
Sample Type	• Serum							
Sample Volume	• 25 µL	IVD	DKO082	96 Wells	CE			
Sensitivity	• 0.24 IU/mL							
IAA								
Quantitative immunoenzy	matic determination of autoantibodies to human native In-	sulin						
Sample Type	• Serum							
Sample Volume	• 100 µL	IVD	DKO083	96 Wells	CE			
Sensitivity	• 0.1 U/mL							

Diabetes	Monitoring				DiaMetra
Product	Description	RUO/IVD	Product Code	Size	Certification
IA2					
Quantitative immunoe	nzymatic determination of autoantibodies to Protein Tyrosine	Phosphata	se (IA2)		
Sample Type	Serum				
Sample Volume	• 50 µL	IVD	DKO084	96 Wells	CE
Sensitivity	• 0.37 IU/mL				

Sample Volume	• 50 µL	IVD	DKO084	96 Wells	CE
Sensitivity	• 0.37 IU/mL				
Fertility F	Proteic Hormones				DiaMetra Diametra
Product	Description	RUO/IVD	Product Code	Size	Certification
LH ELISA					
Direct immunoenzyma	tic determination of the Luteinizing Hormone (LH)				
Sample Type	Serum, plasma				
Sample Volume	• 20 µL	IVD	DKO009	96 Wells	CE
Sensitivity	• 0.22 mlU/mL				
FSH ELISA					
Direct immunoenzyma	tic determination of the Follicle-Stimulating Hormone (FSH)			
Sample Type	Serum, plasma		DKO010	96 Wells	
Sample Volume	• 50 µL	IVD			CE
Sensitivity	• 0.17 mIU/mL				
Prolactin ELISA					
Direct immunoenzyma	tic determination of Prolactin				
Sample Type	Serum				
Sample Volume	• 50 µL	IVD	DKO011	96 Wells	CE
Sensitivity	• 0.12 ng/mL				
o-HCG ELISA					
Direct immunoenzyma	tic determination of β-HCG				
Sample Type	Serum, plasma				
Sample Volume	• 25 µL	IVD	DKO014	96 Wells	CE
Sensitivity	• 0.09 mIU/mL				
SHBG					
Quantitative immunoer	nzymatic determination of SHBG (Sex Hormone Binding Gl	obulin)			
Sample Type	Serum, plasma				
Sample Volume	• 25 µL	IVD	DKO087	96 Wells	CE
Sensitivity	• 0.2 nmol/L			AAGIIO	

^{*} Not yet listed with FDA as IVD \mid ** Not yet CE Marked as IVD RUO – Research Use Only \mid IVD – *In Vitro* Diagnostic Use \mid FDA – FDA Cleared \mid CE – CE Marked All products shown on this page are manufactured by DiaMetra S.r.I



Tumour Ma	rkers				DiaMetra Control of State Control of Sta
Product	Description	RUO/IVD	Product Code	Size	Certification
fPSA					
Direct immunoenzymatic	determination of fPSA				
Sample Type	Serum, plasma				
Sample Volume	• 50 μL	RUO	DKO064	96 Wells	RUO
Sensitivity	• 0.052 ng/mL				
hNSE ELISA					
Direct immunoenzymatic	determination of hNSE				
Sample Type	• Serum				
Sample Volume	• 25 μL	IVD	DKO073	96 Wells	CE
Sensitivity	• 0.19 ng/mL				
S100B ELISA					
Direct immunoenzymatic	determination of S100B				
Sample Type	• Serum, plasma		DKO074	96 Wells	
Sample Volume	• 50 μL	IVD			CE
Sensitivity	• 35 pg/mL				
Total PSA					
Enzyme immunoassay for	the quantitative determination of Total PSA (Prostate Spe	ecific Antige	n)		
Sample Type	Serum, plasma				
Sample Volume	• 25 μL	IVD	DKO137	96 Wells	CE
Sensitivity	• 0.2 ng/mL				
Free PSA					
Enzyme immunoassay for	the quantitative determination of Free PSA (Prostate Spe	ecific Antiger	٦)		
Sample Type	Serum, plasma				
Sample Volume	• 25 μL	IVD	DKO138	96 Wells	CE
Sensitivity	• 0.1 ng/mL				

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CIC C1q ELISA

Direct immunoenzymatic determination of Circulating Immune Complexes C1q (CIC-C1q) in human serum or plasma

Sample Type	• Serum, plasma				
Sample Volume	• 100 µL	IVD	DKO016	96 Wells	CE
Sensitivity	• 1.0 µg Equiv/mL				

CIC C3d ELISA

Direct immunoenzymatic determination of Circulating Immune Complex C3d (CIC C3d) in human serum or plasma

Sample Type	Serum, plasma				
Sample Volume	• 100 µL	IVD	DKO017	96 Wells	CE
Sensitivity	• 0.60 µg/mL				

CH50

Functionality test of complement (CH 50)

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Sample Type	• Serum				
Sample Volume	• 50 µL	IVD	DKO040	96 Wells	CE
Sensitivity	• N/A				

Autoimmunity: Thrombosis					
Product	Description	RUO/IVD	Product Code	Size	Certification
Anti Beta 2 Glyco	protein 1 IgG				
Quantitative determination	on of IgG auto-antibodies against β2-Glycoprotein 1				
Sample Type	Serum, plasma		DKO110	96 Wells	
Sample Volume	• 100 µL	IVD			CE
Sensitivity	• 0.47 AU/mL				
Anti Beta 2 Glycop	protein 1 lgM				
Quantitative determination	on of IgM auto-antibodies against β2-Glycoprotein 1				
Sample Type	Serum, plasma				
Sample Volume	• 100 µL	IVD	DKO111	96 Wells	CE
Sensitivity	• 0.11 AU/mL				

Autoimmur	nity: Thrombosis				DiaMetra
Product	Description	RUO/IVD	Product Code	Size	Certification
Anti Cardiolipin Ig	М				
Quantitative determination	n of IgM auto-antibodies against Cardiolipin				
Sample Type	Serum, plasma				
Sample Volume	• 100 µL	IVD	DKO112	96 Wells	CE
Sensitivity	• 0.12 AU/mL				
Anti Cardiolipin Igo	G				
Quantitative determination	n of IgG auto-antibodies against Cardiolipin				
Sample Type	• Serum, plasma		DKO113	96 Wells	
Sample Volume	• 100 µL	IVD			CE
Sensitivity	• 0.08 AU/mL				
Anti Phospholipid	Screen				
Quantitative determination	n of auto-antibodies against Phospholipids				
Sample Type	• Serum, plasma				
Sample Volume	• 100 µL	IVD	DKO114	96 Wells	CE
Sensitivity	• IgG = 0.3 AU/mL; IgM = 0.16 AU/mL				
Anti Cardiolipin Sc	reen				
Quantitative determination	n of IgG or IgM auto-antibodies against Cardiolipin				
Sample Type	Serum, plasma				
Sample Volume	• 100 µL	IVD	DKO144	96 Wells	CE
Sensitivity	• IgG = 0.08 AU/mL; IgM = 0.12 AU/mL				
Anti Beta 2 Glycop	rotein 1 Screen				
Quantitative determination	n of IgG or IgM auto-antibodies against β2-Glycoprotein 1				

IVD

DKO145

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• IgG = 0.47 AU/mL; IgM = 0.11 AU/mL

• Serum, plasma

• 100 µL

Sample Type

Sensitivity

Sample Volume

CE

Autoimm	nunity: Gastroenterology				DiaMetra Diametra
Product	Description	RUO/IVD	Product Code	Size	Certification

Anti Deamidated Gliadin Peptides (DGP) IgG

Quantitative determination of IgG auto-antibodies against Deamidated Gliadin Peptide (DGP)

Sample Type	Serum, plasma				
Sample Volume	• 100 µL	IVD	DKO106	96 Wells	CE
Sensitivity	• 0.13 AU/mL				

Anti Deamidated Gliadin Peptides (DGP) IgA

Quantitative determination of IgA auto-antibodies against Deamidated Gliadin Peptides (DGP)

Sample Type	Serum, plasma		DKO107	96 Wells	CE
Sample Volume	• 100 µL	IVD			
Sensitivity	• 0.74 AU/mL				

Anti Transglutaminase IgA

Enzyme Immunoassay for the quantitative determination of IgA auto-antibodies against Tissue Transglutaminase

Sample Type	Serum, plasma		DKO108	96 Wells	
Sample Volume	• 100 µL	IVD			CE
Sensitivity	• 0.11 AU/mL				

Anti Transglutaminase IgG

Enzyme Immunoassay for the quantitative determination of IgG auto-antibodies against Tissue Transglutaminase

,		0		o .		
Sample Type	Serum, plasma					
Sample Volume	• 100 µL		IVD	DKO109	96 Wells	CE
Sensitivity	• 0.12 AU/mL					

Autoimmunity: Anca Vasculitis

Anti PR-3 (c-ANCA)

Quantitative determination of IgG auto-antibodies against Proteinase 3 (PR-3)

Sample Type	Serum, plasma				
Sample Volume	• 100 µL	IVD	DKO091	96 Wells	CE
Sensitivity	• 0.13 AU/mL				

Anti MPO (p-ANCA)

Quantitative determination of IgG auto-antibodies against Myeloperoxidase (MPO)

Sample Type	Serum, plasma				
Sample Volume	• 100 µL	IVD	DKO092	96 Wells	CE
Sensitivity	• 0.73 AU/mL				

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Autoimm	unity: Rheumatology				DiaMetra Diametra
Product	Description	RUO/IVD	Product Code	Size	Certification
ANA Screen					
Semi-quantitative dete	rmination of IgG auto-antibodies against Nuclear Antigens				
Sample Type	Serum, plasma				
Sample Volume	• 100 µL	IVD	DKO099	96 Wells	CE
Sensitivity	• 0.69 AU/mL				
Anti CCP					
Quantitative determina	tion of IgG auto-antibodies against cyclical citrullinated per	otides (CCP)			
Sample Type	Serum, plasma				
Sample Volume	• 100 µL	IVD	DKO117	96 Wells	CE
Sensitivity	• 1.12 U/mL				

ENA Profile

Indirect immunoenzymatic determination of IgG auto-antibodies against ENA (Extractable Nuclear Antigens)

Sample Type	Serum, plasma				
Sample Volume	• 100 µL	IVD	DKO119	96 Wells	CE
Sensitivity	Determined for each antigen separately				

Anti CP IgG

Quantitative determination of IgG auto-antibodies against Citrullinated Peptides (CP)

Sample Type	Serum, plasma				
Sample Volume	• 100 µL	IVD	DKO149	96 Wells	CE
Sensitivity	• 0.16 AU/mL				

Anti ds-DNA IgG

Quantitative determination of IgG auto-antibodies against ds-DNA

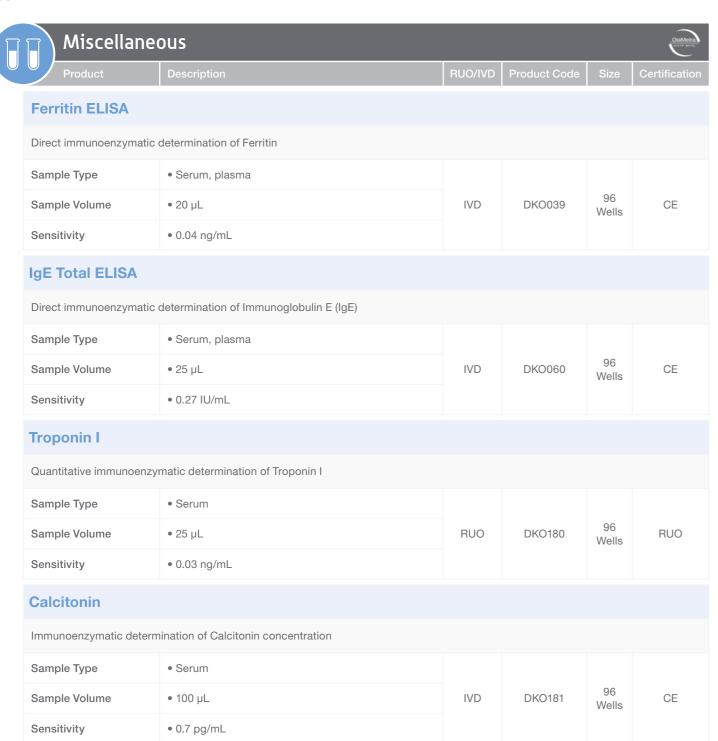
Sample Type	Serum, plasma				
Sample Volume	• 100 µL	IVD	DKO095	96 Wells	CE
Sensitivity	• 0.135 IU/mL				

ENA Screen

Quantitative determination of IgG auto-antibodies against Extractable Nuclear Antigens (ENA)

Sample Type	Serum, plasma				
Sample Volume	• 100 µL	IVD	DKO098	96 Wells	CE
Sensitivity	• 3.68 AU/mL				

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