



ROW
Version



Immunoassays

EIA & RIA Product Portfolio

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.

Introduction



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.



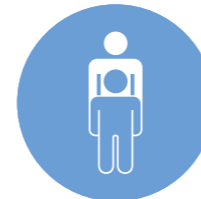
Bone Turnover Markers

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.



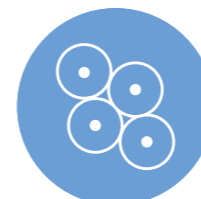
Autoimmune Disease

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

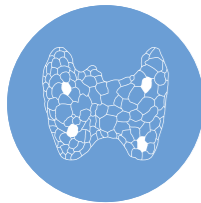
4. Rousseau JC, Delmas PD. Biological markers in osteoarthritis. Nat Clin Pract Rheumatol. 2007 Jun; 3(6):346-56



Endocrine 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 allergy, 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, P et 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 \[doi:10.1002/9780470015902.a0001118.pub2\]](http://www.els.net [doi:10.1002/9780470015902.a0001118.pub2])



Calcium Metabolism

Product	Description	RUO/IVD	Product Code	Size	Certification
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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	96 Wells	CE/FDA
Sample Volume	• 25 µL				
Sensitivity	• Limit of Detection (LoD): 6.8 nmol/L (2.7 ng/mL) • Limit of Quantitation (LoQ): 12 nmol/L (4.8 ng/mL)				

25-Hydroxy Vitamin D RIA

Radioimmunoassay for the quantitative determination of total 25-hydroxyvitamin D

Sample Type	• Human serum, plasma (EDTA, heparin)	IVD	AA-35F1	100 Tubes	CE/FDA
Sample Volume	• 50 µL				
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)	IVD	AC-62F1	96 Wells	CE/FDA
Sample Volume	• 500 µL				
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

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



Calcium Metabolism

Product	Description	RUO/IVD	Product Code	Size	Certification
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25 OH Vitamin D

Quantitative immunoenzymatic determination of 25OH Vitamin D concentration

Sample Type	• Serum, plasma	IVD	DKO146 ¹	96 Wells	CE
Sample Volume	• 10 µL				
Sensitivity	• 0.3 ng/mL				

Intact PTH ELISA

Quantitative immunoenzymatic determination of intact PTH concentration

Sample Type	• Serum, plasma	IVD	DKO157 ¹	96 Wells	CE
Sample Volume	• 25 µL				
Sensitivity	• 0.49 pg/mL				

* Not yet listed with FDA as IVD | ** Not yet CE Marked as IVD

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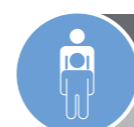
Bone Turnover

Product	Description	RUO/IVD	Product Code	Size	Certification
Alpha CrossLaps® (CTX-I) EIA					
Quantification of degradation of non-isomerised fragments of C-terminal telopeptides of type I collagen (CTX-I)					
Sample Type	• Human urine	IVD	AC-04F1	96 Wells	CE/FDA
Sample Volume	• 25 µL				
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	IVD	SB-TR201A	96 wells	CE
Sample Volume	• 100 µL				
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)	IVD	AC-11F1	96 Wells	CE/FDA
Sample Volume	• 20 µL				
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	IVD	AC-20F1	96 Wells	CE/FDA
Sample Volume	• 50 µL				
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)	IVD	AC-02F1	96 Wells	CE/FDA
Sample Volume	• 50 µL				
Sensitivity	• 0.02 ng/mL				



Bone Turnover

Product	Description	RUO/IVD	Product Code	Size	Certification
Urine BETA CrossLaps® (CTX-I) ELISA					
Quantitative determination of degradation products of C-terminal telopeptides of type-I collagen (βCTX-I)					
Sample Type	• Human urine	IVD	AC-05F1	96 Wells	CE/FDA
Sample Volume	• 20 µL				
Sensitivity	• 0.8 µg/L				
Urine CrossLaps® (CTX-I) EIA					
Quantitative determination of degradation products of C-terminal telopeptides of type I collagen (CTX-I)					
Sample Type	• Human urine	IVD	AC-03F1	96 Wells	CE/FDA
Sample Volume	• 15 µL				
Sensitivity	• 50 µg/L				



Growth

Product	Description	RUO/IVD	Product Code	Size	Certification
Insulin-like Growth Factor Binding Protein-3 (IGFBP-3) IRMA					
Immunoradiometric assay for the determination of IGFBP-3					
Sample Type	• Human serum	IVD	CL-BC1014	96 Tubes	CE
Sample Volume	• 10 µL				
Sensitivity	• 50 ng/mL				

Growth					
Product	Description	RUO/IVD	Product Code	Size	Certification

IGF-1

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

Sample Type	• Human serum	IVD	DKO186 ¹	96 Wells	CE
Sample Volume	• 50 µL				
Sensitivity	• 7.8 ng/mL				

hGH ELISA

Quantitative immunoenzymatic determination of human Growth Hormone

Sample Type	• Serum, plasma	IVD	DKO050 ¹	96 Wells	CE
Sample Volume	• 50 µL				
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	IVD	AC-10F1	96 Wells	CE/FDA
Sample Volume	• 40 µL				
Sensitivity	• 0.2 µg/L				

Human COMP® ELISA

Quantitative determination of Cartilage Oligomeric Matrix Protein (COMP)

Sample Type	• Human serum, plasma (heparin)	IVD	AN-14-1006-71	96 Wells	CE
Sample Volume	• 25 µL				
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	RUO	AC-07F1	96 Wells	N/A
Sample Volume	• 30 µL				
Sensitivity	• 0.75 nM				

Animal Research					
Product	Description	RUO/IVD	Product Code	Size	Certification

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)	RUO	AC-06F1	96 Wells	N/A
Sample Volume	• 20 µL				
Sensitivity	• Limit of Detection (LoD): 4.5 ng/mL				

Rat-MID™ Osteocalcin EIA

Quantitative determination of Osteocalcin in rats

Sample Type	• Rat serum, plasma	RUO	AC-12F1	96 Wells	N/A
Sample Volume	• 20 µL				
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)	RUO	AC-33F1	96 Wells	N/A
Sample Volume	• 5 µL				
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	RUO	SB-TR102	96 Wells	N/A
Sample Volume	• 25 µL				
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	RUO	SB-TR103	96 Wells	N/A
Sample Volume	• 25 µL				
Sensitivity	• 0.1 U/L				

* Not yet listed with FDA as IVD | ** Not yet CE Marked as IVD

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Animal Research

Product	Description	RUO/IVD	Product Code	Size	Certification
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)	RUO	AC-08F1	96 Wells	N/A
Sample Volume	• 25 µL				
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	RUO	AC-09F1	96 Wells	N/A
Sample Volume	• 10 µL				
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)	RUO	AC-14F1	96 Wells	N/A
Sample Volume	• 30 µL				
Sensitivity	• 0.55 ng/mL				
Corticosterone HS (High Sensitivity) EIA					
Assay for the quantitative determination of corticosterone					
Sample Type	• Serum, plasma (EDTA and heparin)	RUO	AC-15F1	96 Wells	N/A
Sample Volume	• 100 µL				
Sensitivity	• 0.17 ng/mL				



Research Consumables

Product	Description	RUO/IVD	Product Code	Size	Certification
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 Features	• 5mm diameter wafers of devitalised dentine	RUO	AE-8050	50 Discs	N/A
		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

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.

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



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Steroid Hormones



Product	Description	RUO/IVD	Product Code	Size	Certification
17OH Progesterone ELISA					
Quantitative immunoenzymatic determination of 17-OH Progesterone					
Sample Type	• Serum, plasma	IVD	DKO004	96 Wells	CE
Sample Volume	• 25 µL				
Sensitivity	• 0.05 ng/mL				
Cortisol ELISA					
Quantitative immunoenzymatic determination of Cortisol					
Sample Type	• Serum, plasma	IVD	DKO001	96 Wells	CE
Sample Volume	• 20 µL				
Sensitivity	• 2.42 ng/mL				
Urinary Cortisol ELISA					
Quantitative immunoenzymatic determination of free Cortisol in urine					
Sample Type	• Urine	IVD	DKO018	96 Wells	CE
Sample Volume	• 10 µL				
Sensitivity	• 0.22 ng/mL				
Testosterone ELISA					
Quantitative immunoenzymatic determination of Total Testosterone					
Sample Type	• Serum, plasma	IVD	DKO002	96 Wells	CE
Sample Volume	• 25 µL				
Sensitivity	• 0.10 ng/mL				
Free Testosterone ELISA					
Quantitative immunoenzymatic determination of Free Testosterone					
Sample Type	• Serum, plasma	IVD	DKO015	96 Wells	CE
Sample Volume	• 20 µL				
Sensitivity	• 0.04 pg/mL				
Androstenedione ELISA					
Quantitative immunoenzymatic determination of Δ 4-Androstenedione					
Sample Type	• Serum, plasma	IVD	DKO008	96 Wells	CE
Sample Volume	• 25 µL				
Sensitivity	• 0.01 ng/mL				



Steroid Hormones



Product	Description	RUO/IVD	Product Code	Size	Certification
Progesterone ELISA					
Quantitative immunoenzymatic determination of Progesterone					
Sample Type	• Serum, plasma	IVD	DKO006	96 Wells	CE
Sample Volume	• 20 µL				
Sensitivity	• 0.05 ng/mL				
Estradiol ELISA					
Quantitative immunoenzymatic determination of 17 β -Estradiol					
Sample Type	• Serum, plasma	IVD	DKO003	96 Wells	CE
Sample Volume	• 25 µL				
Sensitivity	• 8.68 pg/mL				
DHEA-S ELISA					
Quantitative immunoenzymatic determination of Dehydroepiandrosterone sulfate					
Sample Type	• Serum, plasma	IVD	DKO005	96 Wells	CE
Sample Volume	• 30 µL				
Sensitivity	• 0.04 µg/mL				
Total Estriol ELISA					
Quantitative immunoenzymatic determination of Total Estriol					
Sample Type	• Serum, plasma	IVD	DKO019	96 Wells	CE
Sample Volume	• 20 µL				
Sensitivity	• 1.05 ng/mL				
DHEA					
Quantitative immunoenzymatic determination of Dehydroepiandrosterone					
Sample Type	• Serum, plasma	IVD	DKO124	96 Wells	CE
Sample Volume	• 25 µL				
Sensitivity	• 0.10 ng/mL				

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Saliva		Product	Description	RUO/IVD	Product Code	Size	Certification
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Cortisol Saliva ELISA

Quantitative direct immunoenzymatic determination of Cortisol in saliva

Sample Type	• Saliva	RUO/IVD	Product Code	Size	Certification
Sample Volume	• 25 µL				
Sensitivity	• 0.12 ng/mL				

Testosterone Saliva ELISA

Quantitative direct immunoenzymatic determination of Testosterone in saliva

Sample Type	• Saliva	RUO	Product Code	Size	Certification
Sample Volume	• 100 µL				
Sensitivity	• 3.3 pg/mL				

DHEA-S Saliva ELISA

Quantitative direct immunoenzymatic determination of DHEA-S in saliva

Sample Type	• Saliva	RUO	Product Code	Size	Certification
Sample Volume	• 50 µL				
Sensitivity	• 0.05 ng/mL				

Androstenedione Saliva ELISA

Quantitative direct immunoenzymatic determination of Androstenedione in saliva

Sample Type	• Saliva	RUO	Product Code	Size	Certification
Sample Volume	• 50 µL				
Sensitivity	• 5.0 pg/mL				

Saliva		Product	Description	RUO/IVD	Product Code	Size	Certification
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IgA Saliva ELISA

Quantitative direct immunoenzymatic determination of IgA in saliva

Sample Type	• Saliva	RUO	Product Code	Size	Certification
Sample Volume	• 25 µL				
Sensitivity	• 0.5 µg/mL				

Saliva Collector Device

Method for collection of saliva samples using the glass collection device

Sample Type	• Saliva	IVD	Product Code	Size	Certification
Sample Volume	• N/A				
Sensitivity	• N/A				

Thyroid Monitoring		Product	Description	RUO/IVD	Product Code	Size	Certification
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TSH Receptors Ab

Quantitative immunoenzymatic determination of Thyrotropin Receptor Autoantibodies (TRAb)

Sample Type	• Serum	IVD	Product Code	Size	Certification
Sample Volume	• 75 µL				
Sensitivity	• 0.21 U/mL				

Anti-TPO ELISA

Quantitative immunoenzymatic determination of antibodies against Thyroperoxidase (TPO)

Sample Type	• Serum, plasma	IVD	Product Code	Size	Certification
Sample Volume	• 100 µL				
Sensitivity	• 0.09 AU/mL				

Anti-TG ELISA

Quantitative immunoenzymatic determination of antibodies against Thyroglobulin (TG)

Sample Type	• Serum, plasma	IVD	Product Code	Size	Certification
Sample Volume	• 100 µL				
Sensitivity	• 0.11 AU/mL				

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Thyroid Monitoring



Product	Description	RUO/IVD	Product Code	Size	Certification
Thyroglobulin ELISA					
Quantitative immunoenzymatic determination of Thyroglobulin					
Sample Type	• Serum	IVD	DKO048	96 Wells	CE
Sample Volume	• 50 µL				
Sensitivity	• 0.44 ng/mL				
TSH ELISA					
Direct immunoenzymatic determination of Thyroid-stimulating hormone (TSH)					
Sample Type	• Serum, plasma	IVD	DKO013	96 Wells	CE
Sample Volume	• 50 µL				
Sensitivity	• 0.01 mIU/L				
FT3 ELISA					
Direct immunoenzymatic determination of Free Triiodothyronine (FT3)					
Sample Type	• Serum, plasma	IVD	DKO037	96 Wells	CE
Sample Volume	• 50 µL				
Sensitivity	• 0.05 pg/mL				
FT4 ELISA					
Direct immunoenzymatic determination of Free Thyroxine (FT4)					
Sample Type	• Serum, plasma	IVD	DKO038	96 Wells	CE
Sample Volume	• 50 µL				
Sensitivity	• 0.05 ng/dL				
T3 ELISA					
Direct immunoenzymatic determination of Triiodothyronine (T3)					
Sample Type	• Serum, plasma	IVD	DKO044	96 Wells	CE
Sample Volume	• 50 µL				
Sensitivity	• 5.0 ng/dL				
T4 ELISA					
Direct immunoenzymatic determination of Thyroxine (T4)					
Sample Type	• Serum, plasma	IVD	DKO045	96 Wells	CE
Sample Volume	• 25 µL				
Sensitivity	• 0.4 µg/dL				



Endocrine Hypertension



Product	Description	RUO/IVD	Product Code	Size	Certification
Aldosterone ELISA					
Direct immunoenzymatic determination of Aldosterone in serum, human plasma or urine					
Sample Type	• Serum, plasma, urine	IVD	DKO053	96 Wells	CE
Sample Volume	• 50 µL				
Sensitivity	• Limit of Blank (LoB): 15.3 pg/mL				



Diabetes Monitoring



Product	Description	RUO/IVD	Product Code	Size	Certification
Insulin ELISA					
Quantitative immunoenzymatic determination of Insulin					
Sample Type	• Serum, plasma	IVD	DKO076	96 Wells	CE
Sample Volume	• 100 µL				
Sensitivity	• 0.25 µIU/mL				
C-Peptide ELISA					
Quantitative immunoenzymatic determination of C-Peptide					
Sample Type	• Serum, plasma	IVD	DKO077	96 Wells	CE
Sample Volume	• 50 µL				
Sensitivity	• 0.01 ng/mL				
Anti-GAD					
Quantitative immunoenzymatic determination of autoantibodies to Glutamic Acid Decarboxylase (GAD)					
Sample Type	• Serum	IVD	DKO082	96 Wells	CE
Sample Volume	• 25 µL				
Sensitivity	• 0.24 IU/mL				
IA2					
Quantitative immunoenzymatic determination of autoantibodies to Protein Tyrosine Phosphatase (IA2)					
Sample Type	• Serum and plasma	IVD	DKO084	96 Wells	CE
Sample Volume	• 50 µL				
Sensitivity	• 0.37 IU/mL				

* Not yet listed with FDA as IVD | ** Not yet CE Marked as IVD

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Fertility Proteic Hormones



Product	Description	RUO/IVD	Product Code	Size	Certification
LH ELISA					
Direct immunoenzymatic determination of the Luteinizing Hormone (LH)					
Sample Type	• Serum, plasma	IVD	DKO009	96 Wells	CE
Sample Volume	• 20 µL				
Sensitivity	• 0.22 mIU/mL				
FSH ELISA					
Direct immunoenzymatic determination of the Follicle-Stimulating Hormone (FSH)					
Sample Type	• Serum, plasma	IVD	DKO010	96 Wells	CE
Sample Volume	• 50 µL				
Sensitivity	• 0.17 mIU/mL				
Prolactin ELISA					
Direct immunoenzymatic determination of Prolactin					
Sample Type	• Serum	IVD	DKO011	96 Wells	CE
Sample Volume	• 50 µL				
Sensitivity	• 0.12 ng/mL				
b-HCG ELISA					
Direct immunoenzymatic determination of β-HCG					
Sample Type	• Serum, plasma	IVD	DKO014	96 Wells	CE
Sample Volume	• 25 µL				
Sensitivity	• 0.09 mIU/mL				
SHBG					
Quantitative immunoenzymatic determination of SHBG (Sex Hormone Binding Globulin)					
Sample Type	• Serum, plasma	IVD	DKO087	96 Wells	CE
Sample Volume	• 25 µL				
Sensitivity	• 0.2 nmol/L				



Tumour Markers



Product	Description	RUO/IVD	Product Code	Size	Certification
AFP ELISA					
Direct immunoenzymatic determination of AFP					
Sample Type	• Serum, plasma	IVD	DKO012	96 Wells	CE
Sample Volume	• 25 µL				
Sensitivity	• 0.35 ng/mL				
CEA ELISA					
Direct immunoenzymatic determination of Carcinoembryonic Antigen (CEA)					
Sample Type	• Serum, plasma	IVD	DKO051	96 Wells	CE
Sample Volume	• 25 µL				
Sensitivity	• 0.11 ng/mL				
CA-125 ELISA					
Direct immunoenzymatic determination of CA125					
Sample Type	• Serum, plasma	IVD	DKO054	96 Wells	CE
Sample Volume	• 25 µL				
Sensitivity	• 1.7 U/mL				
CA 15-3 ELISA					
Direct immunoenzymatic determination of CA 15-3					
Sample Type	• Serum, plasma	IVD	DKO055	96 Wells	CE
Sample Volume	• 200 µL				
Sensitivity	• 0.4 U/mL				
tPSA					
Direct immunoenzymatic determination of Total PSA					
Sample Type	• Serum, plasma	RUO	DKO057	96 Wells	RUO
Sample Volume	• 25 µL				
Sensitivity	• 0.5 ng/mL				
CA 19-9 ELISA					
Direct immunoenzymatic determination of CA19-9					
Sample Type	• Serum, plasma	IVD	DKO056	96 Wells	CE
Sample Volume	• 100 µL				
Sensitivity	• 0.18 U/mL				

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Tumour Markers



Product	Description	RUO/IVD	Product Code	Size	Certification
hNSE ELISA					
Direct immunoenzymatic determination of hNSE					
Sample Type	• Serum	IVD	DKO073	96 Wells	CE
Sample Volume	• 25 µL				
Sensitivity	• 0.19 ng/mL				

Total PSA

Enzyme immunoassay for the quantitative determination of Total PSA (Prostate Specific Antigen)

Sample Type	• Serum, plasma	IVD	DKO137	96 Wells	CE
Sample Volume	• 25 µL				
Sensitivity	• 0.2 ng/mL				

Free PSA

Enzyme immunoassay for the quantitative determination of Free PSA (Prostate Specific Antigen)

Sample Type	• Serum, plasma	IVD	DKO138	96 Wells	CE
Sample Volume	• 25 µL				
Sensitivity	• 0.1 ng/mL				



Circulating Immunocomplex



Product	Description	RUO/IVD	Product Code	Size	Certification
CIC C1q ELISA					
Direct immunoenzymatic determination of Circulating Immune Complexes C1q (CIC-C1q) in human serum or plasma					
Sample Type	• Serum, plasma	IVD	DKO016	96 Wells	CE
Sample Volume	• 100 µL				
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	IVD	DKO017	96 Wells	CE
Sample Volume	• 100 µL				
Sensitivity	• 0.60 µgEq/mL				

CH50

Functionality test of complement (CH 50)

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

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Autoimmunity: Thrombosis



Product	Description	RUO/IVD	Product Code	Size	Certification
Anti Beta 2 Glycoprotein 1 IgG					
Quantitative determination of IgG auto-antibodies against β 2-Glycoprotein 1					
Sample Type	• Serum, plasma	IVD	DKO110	96 Wells	CE
Sample Volume	• 100 μ L				
Sensitivity	• 0.47 AU/mL				
Anti Beta 2 Glycoprotein 1 IgM					
Quantitative determination of IgM auto-antibodies against β 2-Glycoprotein 1					
Sample Type	• Serum, plasma	IVD	DKO111	96 Wells	CE
Sample Volume	• 100 μ L				
Sensitivity	• 0.11 AU/mL				
Anti Cardiolipin IgM					
Quantitative determination of IgM auto-antibodies against Cardiolipin					
Sample Type	• Serum, plasma	IVD	DKO112	96 Wells	CE
Sample Volume	• 100 μ L				
Sensitivity	• 0.12 AU/mL				
Anti Cardiolipin IgG					
Quantitative determination of IgG auto-antibodies against Cardiolipin					
Sample Type	• Serum, plasma	IVD	DKO113	96 Wells	CE
Sample Volume	• 100 μ L				
Sensitivity	• 0.08 AU/mL				
Anti Phospholipid Screen					
Quantitative determination of auto-antibodies against Phospholipids					
Sample Type	• Serum, plasma	IVD	DKO114	96 Wells	CE
Sample Volume	• 100 μ L				
Sensitivity	• IgG = 0.03 AU/mL; IgM = 0.16 AU/mL				



Autoimmunity: Thrombosis



Product	Description	RUO/IVD	Product Code	Size	Certification
Anti Cardiolipin Screen					
Quantitative determination of IgG or IgM auto-antibodies against Cardiolipin					
Sample Type	• Serum, plasma	IVD	DKO144	96 Wells	CE
Sample Volume	• 100 μ L				
Sensitivity	• IgG = 0.08 AU/mL; IgM = 0.12 AU/mL				
Anti Beta 2 Glycoprotein 1 Screen					
Quantitative determination of IgG or IgM auto-antibodies against β 2-Glycoprotein 1					
Sample Type	• Serum, plasma	IVD	DKO145	96 Wells	CE
Sample Volume	• 100 μ L				
Sensitivity	• IgG = 0.47 AU/mL; IgM = 0.11 AU/mL				

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Autoimmunity: Gastroenterology



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	IVD	DKO106	96 Wells	CE
Sample Volume	• 100 µL				
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	IVD	DKO107	96 Wells	CE
Sample Volume	• 100 µL				
Sensitivity	• 0.74 AU/mL				

Anti Tissue Transglutaminase IgA

Enzyme Immunoassay for the quantitative determination of IgA auto-antibodies against Tissue Transglutaminase					
Sample Type	• Serum, plasma	IVD	DKO108	96 Wells	CE
Sample Volume	• 100 µL				
Sensitivity	• 0.11 AU/mL				

Anti Tissue Transglutaminase IgG

Enzyme Immunoassay for the quantitative determination of IgG auto-antibodies against Tissue Transglutaminase					
Sample Type	• Serum, plasma	IVD	DKO109	96 Wells	CE
Sample Volume	• 100 µL				
Sensitivity	• 0.12 AU/mL				



Autoimmunity: Anca Vasculitis



Product	Description	RUO/IVD	Product Code	Size	Certification
Anti PR-3 (c-ANCA)					
Quantitative determination of IgG auto-antibodies against Proteinase 3 (PR-3)					
Sample Type	• Serum, plasma	IVD	DKO091	96 Wells	CE
Sample Volume	• 100 µL				
Sensitivity	• 0.13 AU/mL				

Anti MPO (p-ANCA)

Quantitative determination of IgG auto-antibodies against Myeloperoxidase (MPO)					
Sample Type	• Serum, plasma	IVD	DKO092	96 Wells	CE
Sample Volume	• 100 µL				
Sensitivity	• 0.73 AU/mL				



Autoimmunity: Rheumatology



Product	Description	RUO/IVD	Product Code	Size	Certification
ANA Screen					
Semi-quantitative determination of IgG auto-antibodies against Nuclear Antigens					
Sample Type	• Serum, plasma	IVD	DKO099	96 Wells	CE
Sample Volume	• 100 µL				
Sensitivity	• 0.69 AU/mL				

Anti CCP

Quantitative determination of IgG auto-antibodies against Cyclical Citrullinated Peptides (CCP)					
Sample Type	• Serum, plasma	IVD	DKO117	96 Wells	CE
Sample Volume	• 100 µL				
Sensitivity	• 1.12 U/mL				

Anti CP IgG

Quantitative determination of IgG auto-antibodies against Citrullinated Peptides (CP)					
Sample Type	• Serum, plasma	IVD	DKO149	96 Wells	CE
Sample Volume	• 100 µL				
Sensitivity	• 0.16 AU/mL				

Anti ds-DNA IgG

Quantitative determination of IgG auto-antibodies against ds-DNA					
Sample Type	• Serum, plasma	IVD	DKO095	96 Wells	CE
Sample Volume	• 100 µL				
Sensitivity	• 0.135 IU/mL				



Miscellaneous

Product	Description	RUO/IVD	Product Code	Size	Certification
Ferritin ELISA					
Direct immunoenzymatic determination of Ferritin					
Sample Type	• Serum, plasma	IVD	DKO039	96 Wells	CE
Sample Volume	• 20 µL				
Sensitivity	• 0.04 ng/mL				
IgE Total ELISA					
Direct immunoenzymatic determination of Immunoglobulin E (IgE)					
Sample Type	• Serum, plasma	IVD	DKO060	96 Wells	CE
Sample Volume	• 25 µL				
Sensitivity	• 0.27 IU/mL				



COVID-19

Product	Description	RUO/IVD	Product Code	Size	Certification
Spike Protein Inhibition Assay (SPIA)					
Detection of neutralising antibodies to SARS-CoV-2					
Sample Type	• Serum	RUO	DKO205/RUO	96 Wells	N/A
Sample Volume	• 50 µL				
Sensitivity	• 96%				

Index

1,25-Dihydroxy Vitamin D EIA	AC-62F1	5	hGH ELISA	DKO050	8
	AA-54F1		hNSE ELISA	DKO073	20
1,25-Dihydroxy Vitamin D RIA	AA-54F2	5	Human COMP® ELISA	AN-14-1006-71	8
17OH Progesterone ELISA	DKO004	12	IA2	DKO084	17
25 OH Vitamin D	DKO146	5	IgA Saliva ELISA	DKO078	15
25-Hydroxy Vitamin D RIA	AA-35F1	5	IgE Total ELISA	DKO060	26
25-Hydroxy Vitamin D ⁵ EIA	AC-57SF1	5	IGF-1	DKO186	8
AFP ELISA	DKO012	19	Insulin ELISA	DKO076	17
Aldosterone ELISA	DKO053	17	Insulin-like Growth Factor Binding Protein-3 (IGFBP-3) IRMA	CL-BC1014	7
Alpha CrossLaps® (CTX-I) EIA	AC-04F1	6	Intact PTH ELISA	DKO157	5
ANA Screen	DKO099	25	LH ELISA	DKO009	18
Androstenedione ELISA	DKO008	12	MouseTRAP™ (TRAcP 5b) ELISA	SB-TR103	9
Androstenedione Saliva ELISA	DKO027	14	N-MID® Osteocalcin ELISA	AC-11F1	6
Anti Beta 2 Glycoprotein 1 IgG	DKO110	22	Ostase® BAP EIA	AC-20F1	6
Anti Beta 2 Glycoprotein 1 IgM	DKO111	22	Progesterone ELISA	DKO006	13
Anti Beta 2 Glycoprotein 1 Screen	DKO145	23	Prolactin ELISA	DKO011	18
Anti Cardiolipin IgG	DKO113	22	Rat/Mouse PINP EIA	AC-33F1	9
Anti Cardiolipin IgM	DKO112	22	RatLaps™ (CTX-I) EIA	AC-06F1	9
Anti Cardiolipin Screen	DKO144	23	Rat-MID™ Osteocalcin EIA	AC-12F1	9
Anti CCP	DKO117	25	RatTRAP™ (TRAcP 5b) ELISA	SB-TR102	9
Anti CP IgG	DKO149	25		AA-SAC1	
Anti Deamidated Gliadin Peptides (DGP) IgA	DKO107	24	Sac-Cel®	AA-SAC2	11
Anti Deamidated Gliadin Peptides (DGP) IgG	DKO106	24	Saliva Collector Device	DKO063	15
Anti ds-DNA IgG	DKO095	25	Serum CrossLaps® (CTX-I) ELISA	AC-02F1	6
Anti MPO (p-ANCA)	DKO092	25	Serum Pre-Clinical CartiLaps® (CTX-II) ELISA	AC-08F1	10
Anti Phospholipid Screen	DKO114	22	SHBG	DKO087	18
Anti PR-3 (c-ANCA)	DKO091	25	Spike Protein Inhibition Assay (SPIA)	DKO205/RUO	26
Anti Tissue Transglutaminase IgA	DKO108	24	T3 ELISA	DKO044	16
Anti Tissue Transglutaminase IgG	DKO109	24	T4 ELISA	DKO045	16
Anti-GAD	DKO082	17	Testosterone ELISA	DKO002	12
Anti-TG ELISA	DKO115	15	Testosterone Saliva ELISA	DKO021	14
Anti-TPO ELISA	DKO116	15	Thyroglobulin ELISA	DKO048	16
b-HCG ELISA	DKO014	18	Total Estriol ELISA	DKO019	13
Bone Slices	DT-1BON-1000-96	11	Total PSA	DKO137	20
BoneTRAP® (TRAcP 5b) ELISA	SB-TR201A	6	tPSA	DKO057	19
CA 15-3 ELISA	DKO055	19	TSH ELISA	DKO013	16
CA 19-9 ELISA	DKO056	19	TSH Receptors Ab	DKO085	15
CA-125 ELISA	DKO054	19	Urinary Cortisol ELISA	DKO018	12
CEA ELISA	DKO051	19	Urine BETA CrossLaps® (CTX-I) ELISA	AC-05F1	7
CH50	DKO040	21	Urine CartiLaps® (CTX-II) EIA	AC-10F1	8
CIC C1q ELISA	DKO016	21	Urine CrossLaps® (CTX-I) EIA	AC-03F1	7
CIC C3d ELISA	DKO017	21	Urine Pre-Clinical CartiLaps® (CTX-II) EIA	AC-09F1	10
Corticosterone EIA	AC-14F1	10			
Corticosterone HS (High Sensitivity) EIA	AC-15F1	10			
Cortisol ELISA	DKO001	12			
Cortisol Saliva ELISA	DKO020	14			
C-Peptide ELISA	DKO077	17			
CrossLaps® for Culture (CTX-I) ELISA	AC-07F1	8			
	AE-8050				
Dentine Discs	AE-80100	11			
DHEA	DKO124	13			
DHEA-S ELISA	DKO005	13			
DHEA-S Saliva ELISA	DKO024	14			
Estradiol ELISA	DKO003	13			
Ferritin ELISA	DKO039	26			
Free PSA	DKO138	20			
Free Testosterone ELISA	DKO015	12			
FSH ELISA	DKO010	18			
FT3 ELISA	DKO037	16			
FT4 ELISA	DKO038	16			

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