



**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 groups<sup>1</sup>. Our comprehensive calcium metabolism panel enables laboratories to measure Vitamin D deficiencies in line with the Clinical Practice Guidelines set by the Endocrine Society<sup>2</sup>.



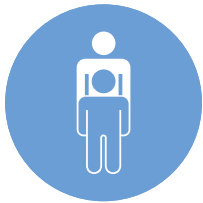
## Bone Turnover Markers

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 degradation<sup>3</sup> 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.



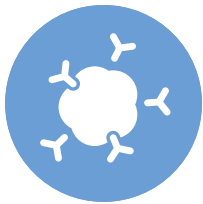
## Growth

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 tissues<sup>4</sup>.



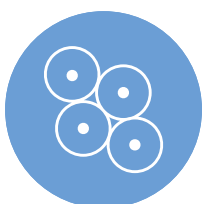
## Autoimmune Disease

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

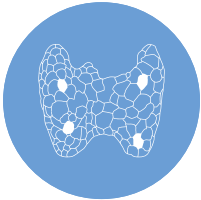
4. Rousseau JC, Delmas PD. Biological markers in osteoarthritis. Nat Clin Pract Rheumatol. 2007 Jun; 3(6):346-56



## 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)<sup>1-3</sup>. In PA excess, aldosterone levels may be produced due to an adenoma (Conn's syndrome) or hyperplasia, causing blood pressure elevation<sup>4</sup>. Patients with this condition are at a stronger risk of heart disease and stroke than those with essential hypertension<sup>4</sup>. 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 PA<sup>5</sup>. 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 antigen<sup>6</sup> 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 disease<sup>7</sup>. 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, 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]





## Calcium Metabolism

Product	Description	RUO/IVD	Product Code	Size	Certification
<b>25-Hydroxy Vitamin D<sup>s</sup> EIA</b>					
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)				
<b>25-Hydroxy Vitamin D RIA</b>					
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)				
<b>1,25-Dihydroxy Vitamin D EIA</b>					
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)				
<b>1,25-Dihydroxy Vitamin D RIA</b>					
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		AA-54F2	56 Cols	
Sensitivity	• 5 pmol/L (2.1 pg/mL)				



## Calcium Metabolism



Product	Description	RUO/IVD	Product Code	Size	Certification
<b>25 OH Vitamin D</b>					
Quantitative immunoenzymatic determination of 25OH Vitamin D concentration					
Sample Type	• Serum, plasma	IVD	DKO146 <sup>1</sup>	96 Wells	CE
Sample Volume	• 10 µL				
Sensitivity	• 0.3 ng/mL				
<b>Intact PTH ELISA</b>					
Quantitative immunoenzymatic determination of intact PTH concentration					
Sample Type	• Serum, plasma	IVD	DKO157 <sup>1</sup>	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

RUO – Research Use Only | IVD – *In Vitro* Diagnostic Use | FDA – FDA Cleared | CE – CE Marked | <sup>1</sup>Manufactured by DiaMetra S.r.l



## Bone Turnover

Product	Description	RUO/IVD	Product Code	Size	Certification
<b>Alpha CrossLaps® (CTX-I) ELISA</b>					
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				
<b>BoneTRAP® (TRAcP 5b) ELISA</b>					
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				
<b>N-MID® Osteocalcin ELISA</b>					
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				
<b>Ostase® BAP EIA</b>					
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				
<b>Serum CrossLaps® (CTX-I) ELISA</b>					
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
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### Urine BETA CrossLaps® (CTX-I) ELISA

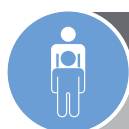
Quantitative determination of degradation products of C-terminal telopeptides of type-I collagen (βCTX-I)

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
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### Insulin-like Growth Factor-I (IGF-I) IRMA

Immunoradiometric assay for the determination of IGF-I

Sample Type	• Human serum	IVD	CL-BC1110	100 Tubes	CE
Sample Volume	• 25 µL				
Sensitivity	• 1.25 ng/mL				

### 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	100 Tubes	CE
Sample Volume	• 10 µL				
Sensitivity	• 50 ng/mL				

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



## Growth



Product	Description	RUO/IVD	Product Code	Size	Certification
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### IGF-1

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

Sample Type	• Human serum	IVD	DKO186 <sup>1</sup>	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 <sup>1</sup>	96 Wells	CE
Sample Volume	• 50 µL				
Sensitivity	• 0.105 µIU/mL				



## Cartilage

Product	Description	RUO/IVD	Product Code	Size	Certification
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### 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
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### 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
<b>RatLaps™ (CTX-I) EIA</b>					
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				
<b>Rat-MID™ Osteocalcin EIA</b>					
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				
<b>Rat/Mouse PINP EIA</b>					
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				
<b>RatTRAP™ (TRAcP 5b) ELISA</b>					
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				
<b>MouseTRAP™ (TRAcP 5b) ELISA</b>					
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

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



## Animal Research

Product	Description	RUO/IVD	Product Code	Size	Certification
<b>Serum Pre-Clinical CartiLaps® (CTX-II) ELISA</b>					
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				
<b>Urine Pre-Clinical CartiLaps® (CTX-II) EIA</b>					
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				
<b>Corticosterone EIA</b>					
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				
<b>Corticosterone HS (High Sensitivity) EIA</b>					
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
<b>Bone Slices</b>					
	Cortical bone slices from bovine femur for the in vitro assessment of osteoblastic bone resorption	RUO	DT-1BON 1000-96	50 Pieces	N/A
<b>Dentine Discs</b>					
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
<b>Sac-Cel®</b>					
	Double antibody separation has been commonly used since the earliest days of radioimmunoassay (RIA) <sup>1,2</sup> and is very reliable. Less demanding procedures have been sought, in particular solid phase antibody techniques <sup>3,4</sup> . 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

<sup>1</sup> Hales, C.N. and Randle, P.J. (1963). *Biochem. J.*, 88, 137.

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

<sup>3</sup> Morgan, C.R. and Lazarow, A. (1963). *Diabetes*, 12, 115.

<sup>4</sup> Sluiter, W.J. et al. (1972). *Clin. Chim. Acta.*, 42, 255.



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

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