



Immunoassays

EIA & RIA Product Portfolio

Commitment to innovation

info@idsplc.com www.idsplc.com

Expertise

in Endocrinology 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.

EIA AND RIA Immunoassay Product Portfolio



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 test panel.



Animal Research

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



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.



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. 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

Our Current Immunoassay Kits



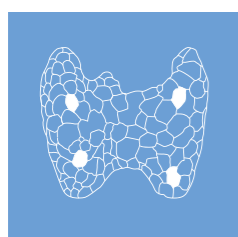
Autoimmune disease

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) diabete, celiac disease, vasculitys and Addison disease.



Steroids

One of the most complete steroid panels including exoteric tests is offered by IDS for androgen assessment and IVD monitoring. The high quality of this panel is well recognised worldwide.



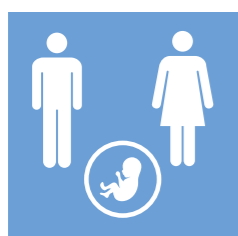
Thyroid Monitoring

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.

Calcium Metabolism

Product	Description	RUO/IVD	Product Code	Size	Certification
25-Hydroxy Vitamin D^e EIA					
Enzyme immunoassay for the quantitative determination of 25-hydroxyvitamin D					
Sample Type	• Human serum, plasma (EDTA, heparin, citrate)	IVD	AC-57SF1	96 Wells	CE/FDA
Sample Volume	• 25 µL				
Sensitivity	• Limit of Detection (LoD): 6.9 nmol/L (2.7 ng/mL) • Limit of Quantitation (LoQ): 12 nmol/L (4.8 ng/mL)				
Unique Features	• VDSP Certified • Traceable to ID-LCMS/MS 25(OH)D Reference Method Procedure • 4 hours total assay time; 45 minutes hands-on time				

Product	Description	RUO/IVD	Product Code	Size	Certification
25-Hydroxy Vitamin D RIA					
Radioimmunoassay for the quantitative determination of 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)				
Unique Features	• 3 hours total assay time; 60 minutes hands-on time				

Product	Description	RUO/IVD	Product Code	Size	Certification
1,25-Dihydroxy Vitamin D EIA					
Complete assay system for the purification of 1,25-dihydroxyvitamin D by immunoextraction with quantitation by enzyme immunoassay					
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)				
Unique Features	• Detects both 1,25(OH) ₂ D ₂ and D ₃ • Proprietary immunoextraction system • No organic and radioactive waste				

Product	Description	RUO/IVD	Product Code	Size	Certification
1,25-Dihydroxy Vitamin D RIA					
Complete assay system for the purification of 1,25-dihydroxyvitamin D by immunoextraction with quantitation by radioimmunoassay					
Sample Type	• Human serum, plasma (EDTA, heparin)	IVD	AA-54F1	40 Cols	CE/FDA
Sample Volume	• 500 µL				
Sensitivity	• 2.1 pg/mL (5 pmol/L)				
Unique Features	• Detects both 1,25(OH) ₂ D ₂ and D ₃ • Proprietary immunoextraction system • No organic waste		AA-54F2	56 Cols	

Calcium Metabolism

Product	Description	RUO/IVD	Product Code	Size	Certification
25 OH Vitamin D					
Quantitative immunoenzymatic determination of 25OH Vitamin D concentration in human serum and plasma					
Sample Type	• Serum, Plasma	IVD	DKO 146 ¹	96 Test	CE
Sample Volume	• 10 µL				
Sensitivity	• 0.67 ng/mL				

Product	Description	RUO/IVD	Product Code	Size	Certification
Intact PTH ELISA					
Quantitative immunoenzymatic determination of intact PTH concentration in human serum and plasma					
Sample Type	• Serum, Plasma	IVD	DKO 157 ¹	96 Test	CE
Sample Volume	• 25 µL				
Sensitivity	• 0.49 pg/mL				

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Bone Turnover

Product	Description	RUO/IVD	Product Code	Size	Certification
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Alpha CrossLaps® (CTX-I) ELISA

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

Sample Type	• Urine	IVD	AC-04F1	96 Wells	CE/FDA
Sample Volume	• 25 µL				
Sensitivity	• 0.80 ng/mL				
Unique Features	• 1.5 hours total assay time; 30 minutes hands-on time				

BoneTRAP® (TRAcP 5b) ELISA

Enzymeimmunoassay for the quantitative determination of Tartrate Resistant Acid Phosphatase 5b

Sample Type	• Human serum, EDTA plasma	IVD	SB-TR201A	96 Wells	CE
Sample Volume	• 100 µL				
Sensitivity	• <0.5 U/L				
Unique Features	<ul style="list-style-type: none"> • TRAcP 5b is derived exclusively from bone-resorbing osteoclasts • No accumulation of TRAcP 5b activity into the circulation in renal or hepatic failure 				

N-MID® Osteocalcin ELISA

Quantitative measurement of osteocalcin as an indicator of osteoblastic activity

Sample Type	• Human serum, plasma (EDTA, heparin)	IVD	AC-11F1	100 Tubes	CE/FDA
Sample Volume	• 20 µL				
Sensitivity	• 0.5 ng/mL				
Unique Features	• Recognises both intact and large N-MID® Osteocalcin fragments with equal affinity				

Ostase® BAP EIA

Ostase® BAP - Quantitative measurement 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				
Unique Features	• 1 hour 15 minutes total assay time; <30 minutes hands-on time				

Serum CrossLaps® (CTX-I) ELISA

Quantification 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	• 0.020 ng/mL				
Unique Features	• 3 hours total assay time; 30 minutes hands-on time				

Bone Turnover

Product	Description	RUO/IVD	Product Code	Size	Certification
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Urine BETA CrossLaps® (CTX-I) ELISA

Quantification of degradation products of C-terminal telopeptides of Type-I collagen (CTX-I)

Sample Type	• Human urine	IVD	AC-05F1	96 Wells	CE/FDA
Sample Volume	• 10 µL				
Sensitivity	• 0.80 µg/L				
Unique Features	• 3 hours total assay time; 30 minutes hands-on time				

Urine CrossLaps® (CTX-I) EIA

Quantification of degradation products of C-terminal telopeptides of Type I collagen (CTX-I)

Sample Type	• Human urine	IVD	AC-03F1	96 Wells	CE
Sample Volume	• 15 µL				
Sensitivity	• 50 µg/L				
Unique Features	• 3 hours total assay time; 45 minutes hands-on time				

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	Serum	IVD	CL-BC1110	100 Tubes	CE
Sample Volume	25 µL				
Sensitivity	1.25 ng/mL				
Unique Features	• 2 monoclonal antibodies with high affinity and specificity are used which recognise two different epitopes of IGF-I				

Insulin-like Growth Factor Binding Protein-3 (IGFBP-3) IRMA

Immunoradiometric assay for the determination of IGFBP-3

Sample Type	Serum	IVD	CL-BC1014	100 Tubes	CE
Sample Volume	10 µL				
Sensitivity	50 ng/mL				
Unique Features	<ul style="list-style-type: none"> • One step solid phase immunoradiometric assay • A single IGFBP-3 determination is an excellent screening parameter for growth hormone deficiency 				

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NB: Ostase® is a registered trademark of Hybritech Incorporated, a subsidiary of Beckman Coulter, Inc.

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	• Serum	IVD	DKO 186 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 or Plasma	IVD	DKO 050 ¹	96 Wells	CE
Sample Volume	• 50 µL				
Sensitivity	• 0.105 IU/mL				

Cartilage

Product Description RUO/IVD Product Code Size Certification

Urine CartiLaps® (CTX-II) EIA

Assay for the quantification of degradation products of C-terminal telopeptides of type II collagen (CTX-II)

Sample Type	• Urine	IVD	AC-10F1	96 Wells	CE/FDA
Sample Volume	• 40 µL				
Sensitivity	• 0.20 µg/L				
Unique Features	• May be used as an aid for assessment of structural damage of articular cartilage in patients with RA and OA				

Human COMP® ELISA

The COMP ELISA is a quantitative enzyme-linked immunosorbent assay for the determination of Cartilage Oligomeric Matrix Protein (COMP) in human serum.

Sample Type	• Serum, Heparin plasma	IVD	AN-14-1006-71	96 Wells	CE
Sample Volume	• 25 µL (pre-diluted 1/10)				
Sensitivity	• <0.1 U/L				

Animal Research

Product Description RUO/IVD Product Code Size Certification

CrossLaps® for Culture (CTX-I) ELISA

Quantitative determination of fragments of type I collagen released into bone cell culture supernatants (CTX-I)

Sample Type	Cell culture supernatant	RUO	AC-07F1	96 Wells	Research Use Only**
Sample Volume	50 µL				
Sensitivity	0.44 nM				
Unique Features	• 3 hours total assay time; 45 minutes hands-on time • Allows the use of bone slices in multi-well screening formats				

Animal Research

Product Description RUO/IVD Product Code Size Certification

RatLaps™ (CTX-I) EIA

Quantitative determination of fragments of type I collagen in rats/mice and from bone released into cell culture supernatants by osteoclasts (CTX-I)

Sample Type	• Rat/mouse serum, urine, cell culture supernatant	RUO	AC-06F1	96 Wells	Research Use Only**
Sample Volume	• 20 µL				
Sensitivity	• 2 ng/mL				
Unique Features	• Possibility of measuring both urine and serum samples • Low sample volume • 60 minutes hands-on time				

Rat-MID™ Osteocalcin EIA

Quantitative determination of Osteocalcin in rats

Sample Type	• Serum, plasma (EDTA, heparin)	RUO	AC-12F1	96 Wells	Research Use Only**
Sample Volume	• 20 µL				
Sensitivity	• 50 ng/mL				
Unique Features	• Low sample volume				

Rat/Mouse PINP EIA

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

Sample Type	• Serum, plasma (EDTA, heparin)	RUO	AC-33F1	96 Wells	Research Use Only**
Sample Volume	• 5 µL				
Sensitivity	• 0.7 ng/mL				
Unique Features	• Use in conjunction with IDS RatTRAP™ • Low sample volume				

RatTRAP™ (TRAcP 5b) ELISA

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

Sample Type	• Serum	RUO	SB-TR102	96 Wells	Research Use Only**
Sample Volume	• 25 µL				
Sensitivity	• 0.1 U/L				
Unique Features	• TRAcP 5b is derived exclusively from bone-resorbing osteoclasts • No accumulation of TRAcP 5b activity into the circulation in renal or hepatic failure				

MouseTRAP™ (TRAcP 5b) ELISA

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

Sample Type	• Serum	RUO	SB-TR103	96 Wells	Research Use Only**
Sample Volume	• 25 µL				
Sensitivity	• 0.1 U/L				
Unique Features	• TRAcP 5b is derived exclusively from bone-resorbing osteoclasts • No accumulation of TRAcP 5b activity into the circulation in renal or hepatic failure				

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Animal Research

Product	Description	RUO/IVD	Product Code	Size	Certification
Animal COMP® ELISA					
Animal COMP ELISA provides a method for the determination of Cartilage Oligomeric Matrix Protein (COMP) in rat, mouse, sheep, bovine, pig and goat serum					
Sample Type	• Serum	RUO	AN-14-2004-86	96 Wells	Research Use Only**
Sample Volume	• 50 µL (pre-diluted 1/10)				
Sensitivity	• <0.2 U/L				
Unique Features	• Multi-species application				
Serum Pre-Clinical CartiLaps® (CTX-II) ELISA					
Assay for the quantitative determination of degradation products of C-terminal telopeptides of type II collagen (CTX-II)					
Sample Type	• Serum	RUO	AC-08F1	96 Wells	Research Use Only**
Sample Volume	• 100 µL				
Sensitivity	• 3.7 pg/mL				
Unique Features	• Reflects cartilage degradation activity				
Urine Pre-Clinical CartiLaps® (CTX-II) EIA					
Assay for the quantitative determination of degradation products of C-terminal telopeptides of type II collagen (CTX-II)					
Sample Type	• Non-human urine or cartilage explant culture supernatant	RUO	AC-09F1	96 Wells	Research Use Only**
Sample Volume	• 10 µL				
Sensitivity	• 0.75 µg/L				
Unique Features	• Reflects cartilage degradation activity • Multi-species application				
Corticosterone EIA					
Assay for the quantitative determination of corticosterone					
Sample Type	Rat and mouse serum or plasma	RUO	AC-14F1	96 Wells	Research Use Only**
Sample Volume	30 µL				
Sensitivity	0.55 ng/mL				
Unique Features	• Non-extraction • A simple dilution step replaces tedious solvent extraction/evaporation				
Corticosterone HS (High Sensitivity) EIA					
Assay for the quantitative determination of corticosterone					
Sample Type	Serum or plasma	RUO	AC-15F1	96 Wells	Research Use Only**
Sample Volume	100 µL for duplicate determination				
Sensitivity	0.17 ng/mL				
Unique Features	• Multiple species application • Ideal tool for researchers investigating metabolic status and stress levels in various animal species				

Research Consumables

Product	Description	RUO	Product Code	Size	Certification
Bone Slices					
For the <i>in vitro</i> assessment of osteoclastic bone resorption					
Unique Features	• Cortical bone slices from the femur of bovine bones	RUO	DT-1BON 1000-96	50 Pieces	Research Use Only**
Dentine Discs					
For use as bone resorption substrates					
Unique Features	• 5mm diameter wafers of devitalised dentine	RUO	AE-8050	50 Discs	Research Use Only**



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Steroid Hormones		DiaMetra care for quality			
Product	Description	RUO/IVD	Product Code	Size	Certification
17-OH Progesterone ELISA					
Quantitative immunoenzymatic determination of 17-OH Progesterone					
Sample Type	• Serum, plasma	IVD	DKO 004	96 Wells	CE
Sample Volume	• 25 µL				
Sensitivity	• 0.05 ng/mL				
Cortisol ELISA					
Quantitative immunoenzymatic determination of Cortisol					
Sample Type	• Serum, plasma	IVD	DKO 001	96 Wells	CE
Sample Volume	• 20 µL				
Sensitivity	• 2.44 ng/mL				
Urinary Cortisol ELISA					
Quantitative immunoenzymatic determination of free Cortisol in urine					
Sample Type	• Urine	IVD	DKO 018	96 Wells	CE
Sample Volume	• 10 µL				
Sensitivity	• 2.95 ng/mL				
Testosterone ELISA					
Quantitative immunoenzymatic determination of Total Testosterone					
Sample Type	• Serum, plasma	IVD	DKO 002	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	DKO 015	96 Wells	CE
Sample Volume	• 20 µL				
Sensitivity	• 0.04 pg/ml				
Androstenedione ELISA					
Quantitative immunoenzymatic determination of Δ4-Androstenedione					
Sample Type	• Serum, plasma	IVD	DKO 008	96 Wells	CE
Sample Volume	• 25 µL				
Sensitivity	• 0.01 ng/mL				

Steroid Hormones		DiaMetra care for quality			
Product	Description	RUO/IVD	Product Code	Size	Certification
Progesterone ELISA					
Quantitative immunoenzymatic determination of Progesterone					
Sample Type	• Serum, plasma	IVD	DKO 006	96 Wells	CE
Sample Volume	• 20 µL				
Sensitivity	• 0.05 ng/mL				
Estradiol ELISA					
Quantitative immunoenzymatic determination of 17β-Estradiol					
Sample Type	• Serum, plasma	IVD	DKO 003	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	DKO 005	96 Wells	CE
Sample Volume	• 30 µL				
Sensitivity	• 0.03 µg/mL				
Free Estriol ELISA					
Direct immunoenzymatic determination of Free Estriol					
Sample Type	• Serum, plasma	IVD	DKO 007	96 Wells	CE
Sample Volume	• 25 µL				
Sensitivity	• 0.03 ng/mL				
Total Estriol ELISA					
Quantitative immunoenzymatic determination of Total Estriol					
Sample Type	• Serum, plasma	IVD	DKO 019	96 Wells	CE
Sample Volume	• 20 µL				
Sensitivity	• 0.22 ng/mL				
DHEA					
Quantitative immunoenzymatic determination of Dehydroepiandrosterone					
Sample Type	• Serum, plasma	IVD	DKO 124	96 Wells	CE
Sample Volume	• 25 µL				
Sensitivity	• 0.10 ng/mL				

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All products shown on this page are manufactured by DiaMetra S.r.l

Steroid in 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	IVD	DKO 020	96 Test	CE
Sample Volume	• 25 µL				
Sensitivity	• 0.12 ng/mL				

Testosterone saliva ELISA

Quantitative direct immunoenzymatic determination of Testosterone in saliva

Sample Type	• Saliva	IVD	DKO 021	96 Test	CE
Sample Volume	• 100 µL				
Sensitivity	• 3.0 pg/mL				

Estradiol saliva ELISA

Quantitative direct immunoenzymatic determination of Estradiol in saliva

Sample Type	• Saliva	IVD	DKO 022	96 Test	CE
Sample Volume	• 100 µL				
Sensitivity	• 0.5 pg/mL				

DHEA-S saliva ELISA

Quantitative direct immunoenzymatic determination of DHEA-S in saliva

Sample Type	• Saliva	IVD	DKO 024	96 Test	CE
Sample Volume	• 50 µL				
Sensitivity	• 0.05 ng/mL				

Progesterone saliva ELISA

Quantitative direct immunoenzymatic determination of Progesterone in saliva

Sample Type	• Saliva	IVD	DKO 025	96 Test	CE
Sample Volume	• 100 µL				
Sensitivity	• 3.8 pg/mL				

Steroid in saliva

Product	Description	RUO/IVD	Product Code	Size	Certification
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Estriol saliva ELISA

Quantitative direct immunoenzymatic determination of Estriol in saliva

Sample Type	• Saliva	IVD	DKO 026	96 Test	CE
Sample Volume	• 50 µL				
Sensitivity	• < 2.0 pg/m				

Androstenedione saliva ELISA

Quantitative direct immunoenzymatic determination of Androstenedione in saliva

Sample Type	• Saliva	IVD	DKO 027	96 Test	CE
Sample Volume	• 50 µL				
Sensitivity	• 5.0 pg/mL				

Estriol saliva HS

Quantitative direct immunoenzymatic determination of Estriol in saliva

Sample Type	• Saliva	IVD	DKO 178	96 Test	CE
Sample Volume	• 200 µL				
Sensitivity	• 1.48 pg/mL				

Saliva Miscellaneous

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	IVD	DKO 078	96 Test	CE
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	DKO 063	100 Pieces	CE
Sample Volume	• N/A				
Sensitivity	• N/A				

Salivette (Sarsted)

Method for collection of saliva samples using the plastic collection device

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

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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	DKO 085	96 Wells	CE
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	DKO 116	96 Wells	CE
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	DKO 115	96 Wells	CE
Sample Volume	• 100 µL				
Sensitivity	• 0.11 AU/mL				

Thyroglobulin ELISA

Quantitative immunoenzymatic determination of Thyroglobulin

Sample Type	• Serum	IVD	DKO 048	96 Wells	CE
Sample Volume	• 50 µL				
Sensitivity	• 0.44 ng/mL				

TSH ELISA

Direct immunoenzymatic determination of TSH in human serum or plasma

Sample Type	• Serum, Plasma	IVD	DKO 013	96 Test	CE
Sample Volume	• 50 µL				
Sensitivity	• 0.01 mIU/mL				

FT3 ELISA

Direct immunoenzymatic determination of Free Triiodothyronine (FT3) in human serum or plasma.

Sample Type	• Serum, Plasma	IVD	DKO 037	96 Test	CE
Sample Volume	• 50 µL				
Sensitivity	• 0.05 pg/mL				

Thyroid Monitoring

Product	Description	RUO/IVD	Product Code	Size	Certification
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FT4 ELISA

Direct immunoenzymatic determination of Free Thyroxine (FT4) in human serum or plasma.

Sample Type	• Serum, Plasma	IVD	DKO 038	96 Test	CE
Sample Volume	• 50 µL				
Sensitivity	• 0.05 ng/dL				

T3 ELISA

Direct immunoenzymatic determination of Triiodothyronine (T3) in human serum or plasma.

Sample Type	• Serum, Plasma	IVD	DKO 044	96 Test	CE
Sample Volume	• 50 µL				
Sensitivity	• 5.0 ng/dL				

T4 ELISA

Direct immunoenzymatic determination of Thyroxine (T4) in human serum or plasma.

Sample Type	• Serum, Plasma	IVD	DKO 045	96 Test	CE
Sample Volume	• 25 µL				
Sensitivity	• 0.4 µg/dL				

Hypertension

Product	Description	RUO/IVD	Product Code	Size	Certification
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Aldosterone ELISA

Direct immunoenzymatic determination of Aldosterone in serum, human plasma or urine.

Sample Type	• Serum, Plasma, Urine	IVD	DKO 053	96 Test	CE
Sample Volume	• 50 µL				
Sensitivity	• 7.0 pg/mL				

Renin

Immunoenzymatic determination of Renin concentration in human plasma

Sample Type	• Plasma	IVD	DKO 150	96 Test	CE
Sample Volume	• 200 µL				
Sensitivity	• 0.8 pg/mL				

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Diabetes Monitoring		DiaMetra care for quality		Product Code	Size	Certification
Product	Description	RUO/IVD	Product Code	Size	Certification	
Insulin ELISA						
Quantitative immunoenzymatic determination of Insulin						
Sample Type	• Serum	IVD	DKO 076	96 Wells	CE	
Sample Volume	• 100 µL					
Sensitivity	• 0.25 µIU/mL					
C-Peptide ELISA						
Quantitative immunoenzymatic determination of C-Peptide						
Sample Type	• Serum	IVD	DKO 077	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	DKO 082	96 Wells	CE	
Sample Volume	• 25 µL					
Sensitivity	• 0.24 IU/mL					
IAA						
Quantitative immunoenzymatic determination of autoantibodies to human native Insulin						
Sample Type	• Serum	IVD	DKO 083	96 Wells	CE	
Sample Volume	• 100 µL					
Sensitivity	• 0.1 U/ml					
IA2						
Quantitative immunoenzymatic determination of autoantibodies to Protein Tyrosine Phosphatase (IA2)						
Sample Type	• Serum, Plasma	IVD	DKO 084	96 Wells	CE	
Sample Volume	• 50 µL					
Sensitivity	• 0.37 IU/mL					
Fetuin A						
Direct immunoenzymatic determination of Fetuin A in human serum or plasma						
Sample Type	• Serum, Plasma	IVD	DKO 128	96 Test	CE	
Sample Volume	• 100 µL					
Sensitivity	• 0.04 ng/mL					

Fertility Proteic Hormones		DiaMetra care for quality		Product Code	Size	Certification
Product	Description	RUO/IVD	Product Code	Size	Certification	
LH ELISA						
Direct immunoenzymatic determination of the Luteinizing Hormone (LH) in human serum or plasma.						
Sample Type	• Serum, Plasma	IVD	DKO 009	96 Test	CE	
Sample Volume	• 20 µL					
Sensitivity	• 0.22 IU/mL					
FSH ELISA						
Direct immunoenzymatic determination of the Follicle-Stimulating Hormon (FSH) in human serum or plasma.						
Sample Type	• Serum, Plasma	IVD	DKO 010	96 Test	CE	
Sample Volume	• 50 µL					
Sensitivity	• 0.17 IU/mL					
Prolactin ELISA						
Direct immunoenzymatic determination of Prolactin in human serum						
Sample Type	• Serum	IVD	DKO 011	96 Test	CE	
Sample Volume	• 50 µL					
Sensitivity	• 0.12 ng/mL					
b-HCG ELISA						
Direct immunoenzymatic determination of β-HCG in human serum or plasma						
Sample Type	• Serum, Plasma	IVD	DKO 014	96 Test	CE	
Sample Volume	• 25 µL					
Sensitivity	• 0.09 mIU/mL					
SHBG						
Quantitative immunoenzymatic determinati on of SHBG (Sex Hormone Binding Globulin)						
Sample Type	• Serum, plasma	IVD	DKO 087	96 Wells	CE	
Sample Volume	• 25 µL					
Sensitivity	• 0.2 nmol/l					

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Tumour Markers		DiaMetra care for quality		Product Code	Size	Certification
Product	Description	RUO/IVD				
AFP ELISA						
Direct immunoenzymatic determination of AFP in human serum or plasma						
Sample Type	• Serum, Plasma	IVD	DKO 012	96 Test	CE	
Sample Volume	• 25 µL					
Sensitivity	• 0.35 ng/mL					
CEA ELISA						
Direct immunoenzymatic determination of Carcinoembryonic Antigen (CEA) in human serum or plasma.						
Sample Type	• Serum, Plasma	IVD	DKO 051	96 Test	CE	
Sample Volume	• 25 µL					
Sensitivity	• 0.11 ng/mL					
CA-125 ELISA						
Direct immunoenzymatic determination of CA125 in human serum or plasma.						
Sample Type	• Serum, Plasma	IVD	DKO 054	96 Test	CE	
Sample Volume	• 25 µL					
Sensitivity	• 1.7 U/mL					
CA 15-3 ELISA						
Direct immunoenzymatic determination of CA 15-3 in human serum or plasma						
Sample Type	• Serum, Plasma	IVD	DKO 055	96 Test	CE	
Sample Volume	• 200 µL					
Sensitivity	• 0.5 U/mL					
PSA						
Direct immunoenzymatic determination of PSA in human serum or plasma.						
Sample Type	• Serum, Plasma	RUO	DKO 057	96 Test	RUO	
Sample Volume	• 25 µL					
Sensitivity	• 0.5 ng/mL					
CA 19-9 ELISA						
Direct immunoenzymatic determination of CA19-9 in human serum or plasma.						
Sample Type	• Serum, Plasma	IVD	DKO 056	96 Test	CE	
Sample Volume	• 100 µL					
Sensitivity	• 0.18 U/mL					
PAPP-A						
Quantitative immunoenzymatic determination of PAPP-A (Pregnancy Associated Plasma Protein A) concentration in human serum.						
Sample Type	• Serum	IVD	DKO 184	96 Test	CE	
Sample Volume	• 10 µL					
Sensitivity	• 34 mIU/mL					

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Tumour Markers		DiaMetra care for quality		Product Code	Size	Certification
Product	Description	RUO/IVD				
Free PSA						
Direct immunoenzymatic determination of Free PSA in human serum or plasma.						
Sample Type	• Serum, Plasma	RUO	DKO 064	96 Test	RUO	
Sample Volume	• 50 µL					
Sensitivity	• 0.052 ng/mL					
hNSE ELISA						
Direct immunoenzymatic determination of hNSE in human serum						
Sample Type	• Serum	IVD	DKO 073	96 Test	CE	
Sample Volume	• 25 µL					
Sensitivity	• 0.19 ng/mL					
S100B ELISA						
Direct immunoenzymatic determination of S100B in human serum or plasma						
Sample Type	• Serum, Plasma	IVD	DKO 074	96 Test	CE	
Sample Volume	• 50 µL					
Sensitivity	• 35 pg/mL					
Total PSA						
Enzyme immunoassay for the quantitative determination of Total PSA (Prostata Specific Antigen) in human serum and plasma						
Sample Type	• Serum, Plasma	IVD	DKO 137	96 Test	CE	
Sample Volume	• 25 µL					
Sensitivity	• 0.2 ng/mL					
Free PSA						
Enzyme immunoassay for the quantitative determination of Free PSA (Prostata Specific Antigen) in human serum and plasma						
Sample Type	• Serum, Plasma	IVD	DKO 138	96 Test	CE	
Sample Volume	• 25 µL					
Sensitivity	• 0.1 ng/mL					
Free B-HCG						
Quantitative Immunoenzymatic determination of Free b-HCG (free b-subunit Human Chorionic Gonadotropin) in human serum						
Sample Type	• Serum	IVD	DKO 183	96 Test	CE	
Sample Volume	• 25 µL					
Sensitivity	• 0.019 mIU/mL					

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Circulating Immunocomplex

Product	Description	RUO/IVD	Product Code	Size	Certification
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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	IVD	DKO 016	96 Test	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	DKO 017	96 Test	CE
Sample Volume	• 100 µL				
Sensitivity	• 1.0 µg Equiv/mL				

CH50					
Functionality test of complement (CH 50)					
Sample Type	• Serum	IVD	DKO 040	96 Test	CE
Sample Volume	• 50 µL				
Sensitivity	• N/A				

Autoimmunity Thrombosis

Product	Description	RUO/IVD	Product Code	Size	Certification
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Anti Beta 2 Glycoprotein 1 IgG					
Quantitative determination of IgG class antibodies against β2-Glycoprotein 1 in human serum or plasma					
Sample Type	• Serum, Plasma	IVD	DKO 110	96 Test	CE
Sample Volume	• 100 µL				
Analytical sensitivity	• 0.47 AU/mL				

Anti Beta 2 Glycoprotein 1 IgM					
Quantitative determination of IgM class antibodies against ββ-Glycoprotein 1 in human serum or plasma					
Sample Type	• Serum, Plasma	IVD	DKO 111	96 Test	CE
Sample Volume	• 100 µL				
Analytical sensitivity	• 0.11 AU/mL				

Autoimmunity Thrombosis

Product	Description	RUO/IVD	Product Code	Size	Certification
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Anti Cardiolipin IgM					
Quantitative determination of IgM autoantibodies against Cardiolipin in human serum or plasma					
Sample Type	• Serum, Plasma	IVD	DKO 112	96 Test	CE
Sample Volume	• 100 µL				
Analytical sensitivity	• 0.12 AU/mL				

Anti Cardiolipin IgG					
Quantitative determination of IgG autoantibodies against Cardiolipin in human serum or plasma					
Sample Type	• Serum, Plasma	IVD	DKO 113	96 Test	CE
Sample Volume	• 100 µL				
Analytical sensitivity	• 0.08 AU/mL				

Anti Phospholipid Screen					
Quantitative determination of auto-antibodies against Phospholipids in human serum or plasma					
Sample Type	• Serum, Plasma	IVD	DKO 114	96 Test	CE
Sample Volume	• 100 µL				
Analytical sensitivity	• IgG= 0.3 AU/mL; IgM= 0.16 AU/mL				

Anti Cardiolipin Screen					
Quantitative determination of IgG or IgM autoantibodies against Cardiolipin in human serum or plasma					
Sample Type	• Serum, Plasma	IVD	DKO 144	96 Test	CE
Sample Volume	• 100 µL				
Analytical sensitivity	• IgG =0.08 AU/mL IgM =0.12 AU/mL				

Anti Beta 2 Glycoprotein 1 Screen					
Quantitative determination of IgG or IgM class antibodies against ββ-Glycoprotein 1 in human serum or plasma.					
Sample Type	• Serum, Plasma	IVD	DKO 145	96 Test	CE
Sample Volume	• 100 µL				
Analytical 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
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Anti Deamidated Gliadin Peptides (DGP) IgG

Quantitative determination of IgG class antibodies against Deamidated Gliadin Peptide (DGP) in human serum or plasma

Sample Type	• Serum, Plasma	IVD	DKO 106	96 Test	CE
Sample Volume	• 100 µL				
Analytical sensitivity	• 0.13 AU/mL				

Anti Deamidated Gliadin Peptides (DGP) IgA

Quantitative determination of IgA class antibodies against Deamidated Gliadin Peptides (DGP) in human serum or plasma

Sample Type	• Serum, Plasma	IVD	DKO 107	96 Test	CE
Sample Volume	• 100 µL				
Analytical sensitivity	• 0.74 AU/mL				

Anti Transglutaminase IgA

Enzyme Immunoassay for the quantitative determination of IgA autoantibodies against Tissue Transglutaminase

Sample Type	• Serum, Plasma	IVD	DKO 140	96 Test	CE
Sample Volume	• 100 µL				
Analytical sensitivity	• 1.0 AU/mL				

Anti Transglutaminase IgG

Enzyme Immunoassay for the quantitative determination of IgG autoantibodies against Tissue Transglutaminase

Sample Type	• Serum, Plasma	IVD	DKO 141	96 Test	CE
Sample Volume	• 100 µL				
Analytical sensitivity	• 1.0 AU/mL				

Autoimmunity: Anca Vasculitis

Product	Description	RUO/IVD	Product Code	Size	Certification
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Anti PR-3 (c-ANCA)

Quantitative determination of IgG class antibodies against Proteinase 3 (PR-3) in human serum or plasma.

Sample Type	• Serum, Plasma	IVD	DKO 091	96 Test	CE
Sample Volume	• 100 µL				
Analytical sensitivity	• 0.13 AU/mL				

Anti MPO (p-ANCA)

Quantitative determination of IgG class antibodies against Myeloperoxidase (MPO) in human serum or plasma

Sample Type	• Serum, Plasma	IVD	DKO 092	96 Test	CE
Sample Volume	• 100 µL				
Analytical sensitivity	• 0.73 AU/mL				

Autoimmunity: Rheumatology

Product	Description	RUO/IVD	Product Code	Size	Certification
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ANA Screen

Semi-quantitative determination of IgG class against Nuclear Antigens in human serum or plasma

Sample Type	• Serum, plasma	IVD	DKO 099	96 Test	CE
Sample Volume	• 100 µL				
Analytical sensitivity	• 0.69 AU/mL				

Anti CCP

Quantitative determination of IgG antibodies against cyclical citrullinated peptides (CCP) in human serum or plasma

Sample Type	• Serum, Plasma	IVD	DKO 117	96 Test	CE
Sample Volume	• 100 µL				
Analytical sensitivity	• 1.12 U/mL				

ENA Profile

Indirect immunoenzymatic determination of IgG class autoantibodies against ENA (Extractable Nuclear Antigens) in human serum or plasma

Sample Type	• Serum, Plasma	IVD	DKO 119	96 Test	CE
Sample Volume	• 100 µL				
Analytical sensitivity	• determined for each antigen separately				

Anti CP IgG

Quantitative determination of IgG class antibodies against Citrullinated Peptides (CP) in human serum or plasma

Sample Type	• Serum, Plasma	IVD	DKO 149	96 Test	CE
Sample Volume	• 100 µL				
Analytical sensitivity	• 0.16 AU/mL				

Anti ds-DNA IgG

Quantitative determination of IgG class antibodies against ds-DNA in human serum or plasma

Sample Type	• Serum, Plasma	IVD	DKO 095	96 Test	CE
Sample Volume	• 100 µL				
Analytical sensitivity	• 0.135 IU/mL				

ENA Screen

Quantitative determination of IgG class antibodies against Extractable Nuclear Antigens (ENA) in human serum or plasma

Sample Type	• Serum, Plasma	IVD	DKO 098	96 Test	CE
Sample Volume	• 100 µL				
Analytical sensitivity	• 3.68 AU/mL				

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Miscellaneous		DiaMetra care for quality		Product Code	Size	Certification
Product	Description	RUO/IVD				
Ferritin ELISA						
Direct immunoenzymatic determination of Ferritin in human serum or plasma						
Sample Type	• Serum, Plasma	IVD	DKO 039	96 Test	CE	
Sample Volume	• 20 µL					
Sensitivity	• 0.53 ng/mL					
IgE Total ELISA						
Direct immunoenzymatic determination of Immunoglobulin E (IgE) in human serum or plasma						
Sample Type	• Serum, Plasma	IVD	DKO 060	96 Test	CE	
Sample Volume	• 25 µL					
Sensitivity	• 0.27 IU/mL					
Troponin I						
Quantitative Immunoenzymatic determination of Troponin I in human serum						
Sample Type	• Serum	RUO	DKO 180	96 Test	RUO	
Sample Volume	• 25 µL					
Sensitivity	• 0.03 ng/mL					
Calcitonin						
Immunoenzymatic determination of Calcitonin concentration in human serum						
Sample Type	• Serum	IVD	DKO 181	96 Test	CE	
Sample Volume	• 100 µL					
Sensitivity	• 0.7 pg/mL					

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Connect with us



+44 (0) 191 519 6155



info@idsplc.com



www.idsplc.com

Global Headquarters

Immunodiagnostic Systems Holdings PLC
10 Didcot Way, Boldon Business Park
Boldon, Tyne & Wear, NE35 9PD,
United Kingdom

Tel: +44 (0) 191 519 0660
Fax: +44 (0) 191 519 0760

UK

10 Didcot Way
Boldon Business Park
Boldon
Tyne & Wear
NE35 9PD

Tel: +44 (0) 191 519 0660
Fax: +44 (0) 191 519 0760

Germany

IDS Immunodiagnostic Systems GmbH
Rahmhofstraße 2-4
60313 Frankfurt am Main
Germany

Tel: +49 (0) 69 26019 0940
Fax: +49 (0) 69 26019 0949

France

153 avenue d'Italie
75013 Paris
France

Tel: +33 (0) 1 40 77 04 50
Fax: +33 (0) 1 40 77 04 55

USA

948 Clopper Road
Gaithersburg, MD 20878
USA

Tel: +1 (877) 852 6210
Fax: +1 (301) 990 4236

Belgium

101, rue Ernest Solvay
B 4000 Liège
Belgium

Tel: +32 (0) 4 252 26 36
Fax: +32 (0) 4 252 51 96

Nordic

International House
Center Boulevard 5
2300 København S
Denmark

Tel: +45 44 84 00 91

Brazil

Rua dos Pinheiros, 610 conj 41
Edifício Win Work
Pinheiros São Paulo SP
Brazil CEP: 05422-001

Tel: +55 11 37406100
Fax: +55 11 37406105

Italy

Diametra S.r.l
Via Calabria 15
20090 Segrate (MI)
Italy

Tel: +39 (0) 221 39184
Fax: +39 (0) 022 133354

