

Selected

Immunoassays.





# Selected Products.

## Expertise in immunodiagnostics

**IBL International – part of the Tecan Group – is an expert diagnostics provider focusing on special and rare indications. The company has over 30 years of experience in the development, manufacture and supply of immunoassays – including enzyme, radiolabeled, and luminescence-based assays – for research and routine diagnostics.**

We are a pioneer and market leader in saliva diagnostics, offering a broad portfolio of luminescence- and ELISA-based tests for analytes such as cortisol, testosterone, estriol and various interleukins also melatonin. The company also offers a number of specialist diagnostic assays for Endocrinology, neurotransmitters and Infectious disease in clinical diagnostics, along with key assays for the research segment, including HMGB1 and NF Light . By combining IBL International's immunodiagnostics expertise with Tecan's long tradition in serving the clinical diagnostic market, many of these assays have been specifically optimized for fully automated processing on the Freedom EVOLyzer® or Freedom EVO® platforms, offering complete solutions for the biochemical diagnosis.

IBL International products are available worldwide, through dedicated Tecan sales teams in the US, Europe and China, as well as an extensive distributor network and worldwide support from Tecan's regional offices. An experienced team of product managers and customer service staff ensure the rapid support necessary in a clinical environment, and the company's active research and development program has close ties with academic centers and commercial partners around the world.

All the company's assays have been designed with uniform pipetting procedures and shared reagents – offering easy adaptation for automated Tecan liquid handling platforms – and are manufactured to meet the highest global regulatory requirements and quality standards. IBL International is certified under ISO 9001, ISO 13485 and CMDCAS, meets GMP regulations and is audited by notified body according to Medical Device Single Audit Program (MDSAP). Combining these high quality assays with Tecan's flexible automated solutions offers exceptional productivity, throughput and reproducibility for clinical diagnostics and research.

For more information about the products, please visit our website [www.IBL-International.com](http://www.IBL-International.com)  
For publications, please contact us via [IBL@Tecan.com](mailto:IBL@Tecan.com)

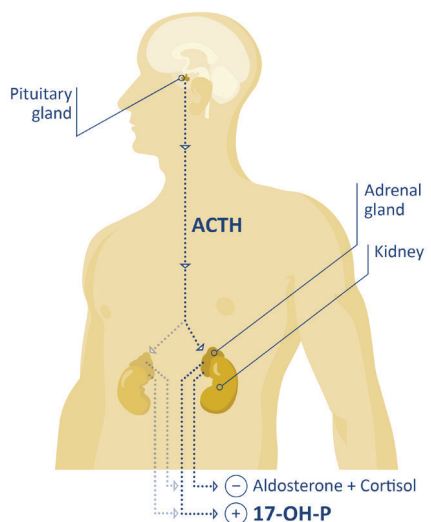


<b>ENDOCRINE FUNCTION .....</b>	<b>4 - 7</b>
Gynecology, Andrology, ivF, Hypertension	
Tumor markers	
Bone and mineral metabolism	
Metabolic Syndrome	
Growth hormones	
Thyroid Function	
<b>COMPLEMENTARY MEDICINE .....</b>	<b>8 - 9</b>
Salivary testing	
Urinary neurotransmitters testing	
Food Intolerance testing	
<b>NEURODEGENERATION .....</b>	<b>10 - 11</b>
<b>INFECTIOUS DISEASE .....</b>	<b>12 - 13</b>
Bacterial Disease	
Viral Disease	
Parasite Disease	
<b>AUTOIMMUNITY .....</b>	<b>14 - 15</b>
Myasthenia Gravis	
Rheumatoid Diseases	
Coeliac Disease	
Systemic Lupus Erythematosus	
<b>IMMUNOLOGY .....</b>	<b>16 - 17</b>
Neopterin	
HMGB1	
Biologics Drug Monitoring	
<b>AUTOMATION .....</b>	<b>18 - 19</b>
ThunderBolt®	
Freedom EVolyzer®	



# Endocrine Function.

**Endocrinology is the medical specialty that addresses hormones and the endocrine glands and tissues that secrete them.**



Influence of Congenital Adrenal Hyperplasia (CAH) on the hormones in the body system. Due to enzyme deficiency the production of Cortisol and Aldosterone is decreased and elevated values of 17-OH-P are measured in serum or plasma. 17-OH-P represents one of the most suitable biochemical marker for the diagnosis of CAH.

IBL International provides a comprehensive portfolio of highly sensitive, reliable immunoassays for measuring steroids, peptides, proteins and amino hormones. They can overcome the disadvantages of working with radioactivity without the need for huge investments. This is especially interesting to departments that have no access to MS equipment. Numerous studies have shown that IBL's assays correlate strongly to LC-MS/MS and RIA. The relevant publications are available on request. In addition, ELISAs are far easier to perform than mass spectrometry measurements.



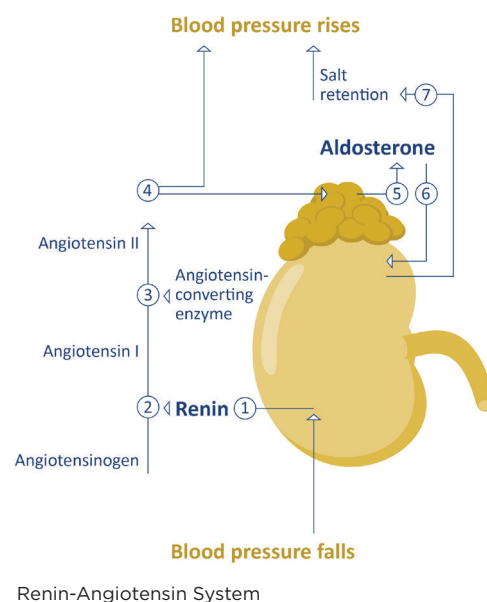
## GYNECOLOGY, ANDROLOGY, IVF

### Complementary assays to random access systems:

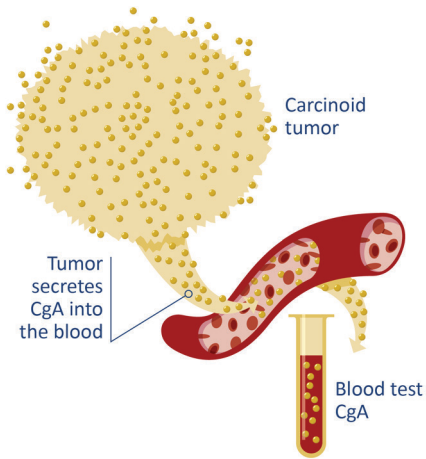
Parameter	Catalog No.	Method	Features	CE
17-OH-Progesterone (17-OHP)	RE52071 MG12181	ELISA RIA	Excellent analytical characteristics Easy procedure Also reference values for children available on request Widely used and cited in multiple publications in numerous medical fields: endocrinology, gynaecology (late onset), paediatrics	Yes Yes
Free Testosterone	DB52181	ELISA RIA	Measures the biologically active form Direct procedure without extraction Total assay time <1.5 hours Detailed reference ranges	Yes Yes
5 $\alpha$ -Dihydrotestosterone (DHT)	DB52021	ELISA	Direct procedure without extraction and oxidation Total assay time <1.5 hours Low cross reactivity to testosterone Not available on closed systems	Yes
DHEA	RE52221	ELISA	Direct procedure without extraction and oxidation Excellent correlation to reference method LC-MS/MS	Yes
Pregnenolone	DB52031	ELISA	The only ELISA available in the market Total assay time <1 hour Not available on closed systems	Yes
Androstenedione	DB52161 MG11091	ELISA RIA	Good correlation to reference method LC-MS/MS and external quality control samples Total assay time <1.5 hours	Yes Yes
Androstane-diol-Glucuronide (3 $\alpha$ -Diol-G)	DB52171 MG11081	ELISA RIA	The only ELISA available in the market Total assay time <1 hour Not available on closed systems	Yes Yes

## HYPERTENSION

Hypertension is a cardiac chronic medical condition in which systemic arterial blood pressure is elevated. Persistent hypertension is a significant risk factor for strokes, heart attacks, heart failure, and arterial aneurysm, and is leading cause of chronic renal failure. IBL International offers assays for routine diagnostics and research purposes in the area of Hypertension and its initial reasons.



Parameter	Catalog No.	Method	Features	CE
Aldosterone	RE52301 MG13051	ELISA RIA	Direct procedure without extraction Good correlation to reference method LCMS/MS	Yes Yes
Renin (active)	RE53321 MG11101	ELISA RIA	Renin levels are indicative for the activity of the Renin-Angiotensin-Aldosterone System (RAAS) Aldosterone-Renin ratio ranges available	Yes Yes



TUMOR MARKERS

IBL International offers a broad portfolio of tumor markers for routine diagnostics, clinical research and therapy follow up. Some tumor markers are specific for a single type of cancer, while others can be found in many types of cancer.

Parameter	Catalog No.	Method	Features	CE
Chromogranin A	30126469	ELISA	High clinical utility for patients with neuroendocrine tumors Reliable and consistent results: standards based on human recombinant CgA High precision < 10% CV% Excellent correlation to gold standard RIA	Yes
TriCat (Adrenalin/Noradrenalin/ Dopamine)	RE59395	ELISA	Manual and automated ELISA IVD quantitative determination of adrenalin (epinephrine), noradrenalin (norepinephrine) and dopamine in human plasma and urine Excellent correlation to HPLC method No drugs interferences	Yes
MetCombi Plasma (Metanephrine/ Normetanephrine)	RE59202	ELISA	IBL International's MetCombi ELISA has: Shorter assay time: ca. 4.5 h Calibrated to LC-MS/MS Automated test procedure Smaller sample volume: 200 µL Higher sensitivity	Yes

BONE AND MINERAL METABOLISM

Dysfunction of the Vitamin D and parathyroid hormone (PTH) pathways are usually indicators of diseases involving acalcosinosis (too little calcium) or calcium excess. Typically, these are Hypo- and Hyperparathyreodism and kidney calcification.

Especially, patients already having kidney problems are at high risk. As such the determination of a patient's vitamin D and PTH levels are essential to the correct therapeutic intervention.

Parameter	Catalog No.	Method	Features	CE
25-Hydroxy-Vitamin D	MG11021 MG11051	ELISA RIA	ELISA detection limit: 1.5 ng/mL RIA detection limit: 1.2 ng/mL	Yes Yes
Parathyroid hormone intact (PTH intact)	RE11061 NM59041	IRMA ELISA	PTH acts to regulate the concentration of calcium and phosphate in the blood; PTH levels are related to Vitamin D levels	Yes Yes
1,25-Dihydroxy-Vitamin D	MG59051 MG11015	ELISA RIA	Detection limit for both assays: 1.6 pg/mL Not available in all countries	Yes Yes

## METABOLIC SYNDROME

Metabolic syndrome is associated with several medical conditions typically associated with “western lifestyle” such as obesity or a disturbed lipoprotein (fat) metabolism. All these conditions can lead to developing cardiovascular diseases, gastrointestinal

diseases or even diabetes type II. Again a deficiency in Vitamin B12 will lead to effects on our central nervous system and is associate i.e. with fatigue, anemia and even depression.

Parameter	Catalog No.	Method	Features	CE
Active-B12 (Holotranscobalamin/Holo TC)	AX53101	ELISA	HoloTC is the biologically active form of Vitamin B12. HoloTC measurement is more sensitive and more specific than Total-B12 measurement. Changes in HoloTC levels occur earlier than Total-B12 depletion No pre-analytical steps required	Yes
Adiponectin	30126762	ELISA	Detects total Adiponectin (so all low, medium and high molecular variants) Gender and age group specific reference values Automated test procedure	Yes
Leptin	MD53001	ELISA	Calibrated against WHO NIBSC 97/594 international standard Reference ranges correlated with BMI and Tanner stages of children and adolescents Automated test procedure	Yes

## GROWTH HORMONES

The measurement of insulin-like growth factor-I (IGF-I) and Insulin-like Growth Factor Binding Protein 3 (IGFBP-3) in serum or plasma is of especially

high utility in the diagnostic work-up of growth disturbances, particularly with regard to human growth hormone (hGH) deficiency or acromegaly.

Parameter	Catalog No.	Method	Features	CE
IGF-I (Insulin-like Growth Factor-I)	MD58011	ELISA	Non-extraction assay with high specificity for IGF-I No interference from IGF-binding proteins Calibrated against the international standard of WHO NIBSC 02/254 High sensitivity (0.09 ng/mL) and outstanding accuracy - 98.7% recovery	Yes
IGFBP-3	MD58031	ELISA	Best indicator of the GH deficiency due to better stability in serum Only 10µl sample volume, ideal for use in pediatrics Very good precision No cross-reactivity to homologous proteins (IGFBP-1, -2, 4, and -6)	Yes

## THYROID FUNCTION

Thyroid function tests (TFTs) are amongst the most commonly requested laboratory investigations in the world.

Most TFTs are effective at interpretation and confirmation of the clinical picture of euthyroidism, hypothyroidism or hyperthyroidism. However, thyroid

function testing becomes problematic when the tests are performed in patients who have any significant co-existing illness.

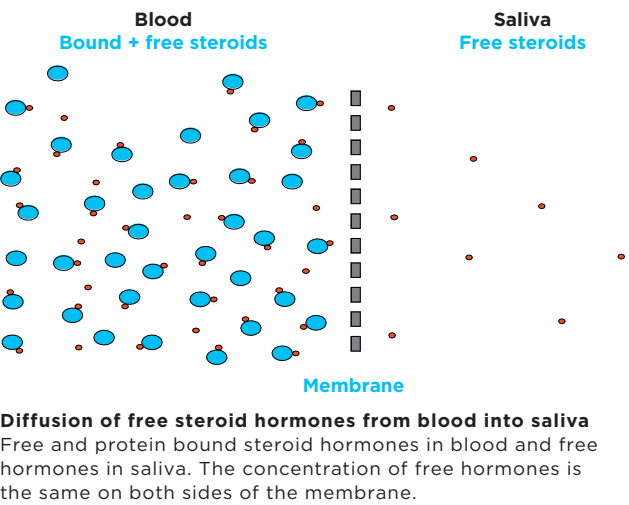
IBL International offers a complete range of tests for correct diagnostics of thyroid status.

Parameter	Catalog No.	Method	Features	CE
rT3	30123153	ELISA	The only existing ELISA assay for clinical use. The only CE-marked assay available No sample preparation Total assay time: less than 2 hours Correlates with LC-MS/MS results Automatable Outstanding assay sensitivity: 0.005 ng/mL Minimal cross-reactivity: T3 < 0.001%, T4 < 0.005%, T2 < 0.004%	Yes
FT3 (Free Triiodothyronine)	RE55231	ELISA	Detection of thyroid hormone deficiency (hypothyroidism) Very good correlation to RIA High specificity and sensitivity	Yes
FT4 (Free Thyroxine)	RE55241	ELISA	Detection of thyroid hormone deficiency (hypothyroidism) Very good correlation to RIA High specificity and sensitivity	Yes





Changes in sex hormones and adrenal hormones can lead to neurotransmitter imbalances. And vice versa. Testing both neurotransmitters and hormones provides a comprehensive view of the body’s functional neuroendocrine status, and brings light to additional factors that may be contributing to symptoms. Furthermore it may be useful to screen patients who suffer from unclear and chronic disorders for specific food intolerances.



**SALIVARY TESTING**

Importantly, the hormone concentrations measured in saliva, unlike in blood, represent the levels of free, biologically active hormones, which have greater clinical relevance than do measures of total hormone. The easiness and stress free collection makes it very attractive for patients and practitioners.

All IBL International Immunoassays are calibrated to LC-MS/MS and the most common parameters use interchangeable components to enable an easier automation. Meaningful reference ranges are stated in the instructions for use of the single parameters.

**Stress measurement, sleep disorders**

Parameter	Catalog No.	Method	Features	CE
Cortisol Saliva	RE62111 RE52611	LUM ELISA	LUM sensitivity: 0.12 ng/mL Total precision: <5% Wide measuring range: 0.12 - 30 ng/mL Easier method than LC-MS/MS	Yes Yes
DHEA Saliva	RE62151 RE52651	LUM ELISA	Wide measuring range: 12.3 - 3,000 pg/mL Not available on closed systems ELISA: Clearly defined reference values by gender, age and day time	Yes Yes
Melatonin Saliva	RE54041 RE29301	ELISA RIA	Clinically validation data available on request Because of homology, the assay can be used for various species	Yes Yes

## Hormonal sexual disorders, androgenism, evaluation of ovarian function

Beside assays for measuring estrogens, IBL International also offers following steroids kits:

Parameter	Catalog No.	Method	Features	CE
Progesterone Saliva	RE62021 RE52281	LUM ELISA	High sensitivity: 3 pg/mL Wide measuring range: 3 - 5,000 pg/mL Direct procedure without extraction Not available on closed systems	Yes Yes
Testosterone Saliva	RE62031 RE52631	LUM ELISA	Correlates to reference methods (GC-MS/MS; RIA) LUM analytical sensitivity: 1.8 pg/mL High precision: 6.9 - 4.0% at 20.7 - 557 pg/mL Easier method than LC-MS/MS Not available on closed systems	Yes Yes

### Furthermore, IBL International proposes following benefits

- Collection tubes Salicaps available
- Expertise for saliva diagnostics, high technical support
- Free of charge EQAS for salivary steroids

## URINARY NEUROTRANSMITTERS TESTING

Measurement of neurotransmitters in urine samples helps to identify neurostress in a non-invasive way. Depression, mood disorders, anxiety, fatigue,

insomnia, addiction and dependency are examples of consequences from neurotransmitter imbalances.

Parameter	Catalog No.	Method	Features	CE
TriCat™ (Adrenalin/Noradrenalin/ Dopamine)	RE59395	ELISA	Calibrated to HPLC No drug interference Validated for urine testing Easier to run than HPLC with higher throughput	Yes
Serotonin	RE59121	ELISA	Calibrated to HPLC User friendly (calibrators acylated) Overnight incubation possible Used and cited in numerous publications	Yes

## FOOD INTOLERANCE TESTING

IBL International has a large product line for assessing individual sensitization to food allergens. The assays are intended for quantitative determination of specific IgG and/or IgG<sub>4</sub> in serum or plasma from venous or

capillary blood.

We are flexible regarding the configuration of the tests; please contact us for your specific needs.

### Examples

Parameter	Catalog No.	Method	Features	CE
IgG Food Screen 24 IgG <sub>4</sub> Food Screen 24	30113481 30113482	ELISA ELISA	Screening of IgG / IgG <sub>4</sub> Antibodies against 24 allergens 3 patients can be screened with one microtiterplate	Yes
IgG Food Screen 7 IgG <sub>4</sub> Food Screen 7	30131629 30131628	ELISA	Screening of IgG / IgG <sub>4</sub> Antibodies against 7 allergens 12 patients can be screened with one microtiterplate	Yes

The raw data from Tecan Magellan™ software can be exported in Excel. The laboratory can print out a patient specific report with graphical overview of the food sensitivities.

The best approach to assessing these food intolerances is to measure specific IgG or IgG<sub>4</sub> antibodies.

Laboratory:  
Test performance



Nutritionist:  
Patient information  
Sampling  
Diet advice

If you would like to use this assay for an indication not validated by IBL International, your laboratory should perform a validation study for this specific indication as indicated by national regulation.



**Neurodegeneration or neurodegenerative diseases are a group of disorders that are characterized by progressive loss of structure respective function of neurons, including their death.**

Most known neurodegenerative diseases are Alzheimer's disease, Parkinson's disease, Multiple sclerosis and Amyotrophic Lateral Sclerosis. Yet,

research in the field of neurodegeneration elucidates many more often overlapping diseases that have similar cellular and sub-cellular pathogenic mechanisms.

#### **Alzheimers Diagnostics**

Alzheimer's disease (AD), a neurodegenerative disease leading to dementia, can be characterized by 3 hallmarks, which are formation of Amyloid-beta plaques, TAU fibrils and loss of neurons and synapses, leading to a significant brain volume reduction. The first 2 hallmarks lead to the fact that measuring these proteins in CSF is a valuable tool to support the diagnosis of Alzheimer's disease.

To assess Amyloid-beta pathology in AD more recent clinical research has shown that the determination of the Amyloid-beta ratio of Amyloid-beta (1-42)/ Amyloid-beta (1-40) significantly improves the diagnostic value towards AD (Figure 1). Furthermore as fibril formation of TAU proteins is characterized by hyperphosphorylation, the determination of either phosphoTAU or the non-phosphorylated TAU fraction (pTAUrel) confirms the TAU pathology in AD.

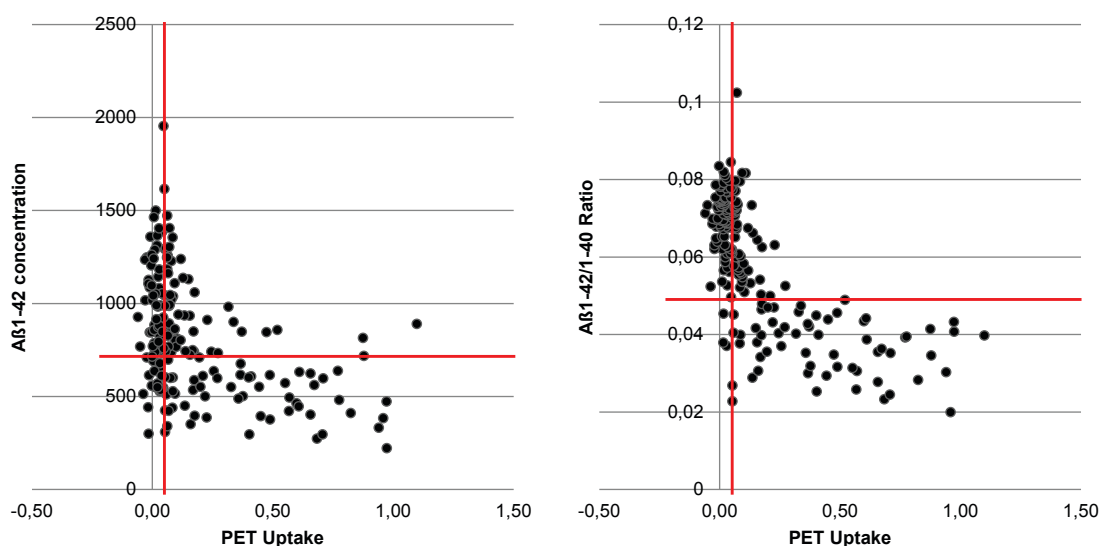


Figure 1 The Amyloid-beta ratio of Amyloid-beta (1-42) to Amyloid-beta (1-40) significantly improves the accuracy of concordant samples in comparison to PiB from 74.9% to 89.4% (Lewczuk et al. J Alzheimers Dis. 2017;55(2):813-822.):



Parameter	Catalog No.	Method	Features	CE
Amyloid- $\beta$ (1-40)	RE59651	ELISA	Ready to use 6 point standard curve No serial dilution necessary Low inter- and intra assay CVs 2 Kit controls included	Yes
Amyloid- $\beta$ (1-42)	RE59661	ELISA	As part of the Amyloid-beta ratio excellent sensitivity and specificity	Yes
phosphoTAU	30121609*	ELISA	Ready to use 6 point standard curve No serial dilution necessary Low inter- and intra-assay CVs 2 kit controls included	Yes
hTAU total	RE59631*	ELISA	Ready to use 6 point standard curve No serial dilution necessary Low inter- and intra-assay CVs 2 kit controls included	Yes
pTAUrel	RE59641*	ELISA	Ready to use 6 point standard curve No serial dilution necessary Low inter- and intra-assay CVs 2 kit controls included	Yes

### Research of axonal destruction

Neurofilaments are the backbone of the neuronal cytoskeleton. Neurofilament light is found to be elevated in neurodegenerative disorders that are associated with the destruction of white matter (substantia alba). Typically these are:

- Parkinson's disease (PD)
- Multiple Sclerosis (MS)
- Amyotrophic Lateral Sclerosis (ALS)

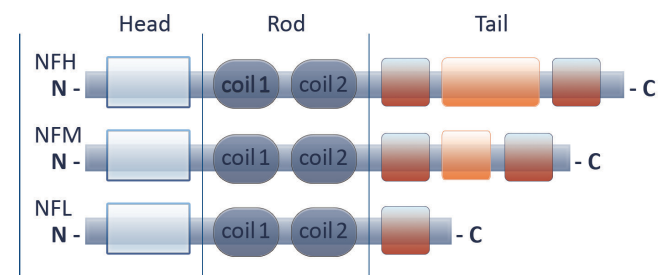


Figure 2: Schematic illustration of neurofilament subunits

Parameter	Catalog No.	Method	Features	CE
Neurofilament light (NF-light*)	UD51001*	ELISA	Wide standard range Age-dependent normal values available	Yes

### Further research in neurodegeneration

Yet, as the field of neurodegeneration still has much more to be discovered and understanding of disease mechanisms has still to be completely understood, IBL International offers a large range of assays to enable research in this field.

Parameter	Catalog No.	Method	Features	CE
Amyloid- $\beta$ (1-38)	RE59771	ELISA	Discrimination of frontotemporal lobar degeneration (FTLD) and Alzheimer's disease Highly sensitive: <1 pg/mL The only ELISA available in the market	
sAPP- $\alpha$	JP27734*	ELISA	No cross-reactivity to sAPP- $\beta$ Can be used for serum, plasma, CSF and cell culture supernatants	
sAPP- $\beta$	JP27732*	ELISA	No cross-reactivity to sAPP- $\alpha$ Can be used for serum, plasma, CSF and cell culture supernatants	

\*Distributed by IBL International

If you would like to use this assay for an indication not validated by IBL International, your laboratory should perform a validation study for this specific indication as indicated by national regulation.



Infectious disease are caused by pathogenic microorganisms, such as bacteria, viruses, parasites or fungi. Some infectious diseases can be passed from person to person; some are transmitted via bites from insects or animals.

IBL International offers a wide range of ELISAs for detecting infectious diseases caused by pathogenic microorganisms, including bacteria, viruses, parasites or fungi. Our assays are based on detecting specific

antibody classes (IgA, IgG, IgM) in serum, plasma or cerebrospinal fluid (CSF) or detection of antigens from stool samples.

**BACTERIAL DISEASE**

The high-quality ELISAs from IBL International are suitable for diagnosis and therapy monitoring for Heliobacter plyori, Lyme borreliosis, Chlamydia and Syphillis.

Furthermore, the vaccine status of Tetanus, Diphtheria, Pertussis and Haemophilus influenza B can be determined by antibody concentration measuring with IBL International immunoassays.

Parameter	Catalog No.	Method	Features	CE
Borrelia + VlsE IgG Borrelia 14 kDa + OspC IgM	RE57201 RE57211	ELISA ELISA	Superior antigen mixture Diagnostic sensitivity IgG: 98% and IgM: 99% Diagnostic specificity IgG: 94% and IgM: 95% Quantitative (titer) or qualitative (cut-off) results can be obtained Low- and high level kit controls included Ready to use reagents Evaluated for serum, plasma and CSF	Yes Yes
Bordetella pertussis IgA Bordetella pertussis IgG Bordetella pertussis IgM Bordetella FHA IgG Bordetella FHA IgA Bordetella PT IgG Bordetella PT IgA	RE56131 RE56141 RE56151 RE56091 RE56081 RE56061 RE56051	ELISA ELISA ELISA ELISA ELISA ELISA ELISA	Complete range of mixed and single antigen ELISAs Single antigen ELISA are calibrated against 1st Int. Standard WHO 06/140 Qualitative or quantitative results (IU/mL for single antigen ELISAs) Wide linear measurement range Diagnostic sensitivity and specificity: 95%	Yes Yes Yes Yes Yes Yes Yes
Haemophilus influenzae B IgG	RE56351	ELISA	Antigen: polyribosylribitolphosphate (PRP), which correlates to common vaccines Calibrated to NIBSC code 09/222 Shelf life: >18 months Low- and high level kit controls included	Yes
Helicobacter pylori IgA Helicobacter pylori IgG Helicobacter pylori IgM Fecal Helicobacter-Antigen	RE56371 RE56381 RE56391 RE58891	ELISA ELISA ELISA ELISA	Antibody as well as antigen (stool) ELISA available Antigens (antibody assays): CagA (cytotoxin associated proteine) and VacA (vasculised cytotoxin) High diagnostic sensitivity (98%) and specificity (100%) of IgG ELISA proven in external method comparison study (AFSSAPS, France)	Yes Yes Yes Yes

## VIRAL DISEASE

The IBL International ELISAs for identification of viral infectious diseases are appropriate for routine and special diagnostic markers, like Measles, Epstein-Barr,

Hantavirus and Zika virus. In addition, ELISA assays for the detection of antibodies from the TORCH panel are part for the product portfolio.

Parameter	Catalog No.	Method	Features	CE
Zika virus IgM $\mu$ -capture	30113441	ELISA	$\mu$ -capture technology No significant cross reactivity to other Flaviviridae Qualitative result evaluation Sensitivity: > 99% and specificity: 98.5%	Yes
Dengue IgG Dengue IgM $\mu$ -capture	RE58671 RE58581	ELISA ELISA	Detection of all 4 Dengue types $\mu$ -capture technology for IgM Diagnostic sensitivity and specificity: 99% Dengue NS1 ELISA will be available soon	Yes Yes
Chikungunya IgG capture Chikungunya IgM $\mu$ -capture	RE58831 RE58841	ELISA ELISA	High diagnostic sensitivity (98%) and specificity (99%) due to antibody capture technology	Yes Yes
Epstein-Barr virus EA IgA Epstein-Barr virus EA IgG Epstein-Barr virus EA IgM Epstein-Barr virus EBNA-1 IgA Epstein-Barr virus EBNA-1 IgG Epstein-Barr virus EBNA-1 IgM Epstein-Barr virus VCA IgA Epstein-Barr virus VCA IgG Epstein-Barr virus VCA IgM $\mu$ -capture	RE56211 RE57311 RE56231 RE56241 RE56251 RE56261 RE56271 RE57351 RE57361	ELISA ELISA ELISA ELISA ELISA ELISA ELISA ELISA ELISA	Complete product portfolio of EBV diagnostics Highly specific antigens: gp125 (VCA), p54 (EA), p72 (EBNA) $\mu$ -capture configuration for VCA IgM ELISA High diagnostic sensitivity and specificity in primary, past infections and reactivation Quantitative (titer) or qualitative (cut-off) results	Yes Yes Yes Yes Yes Yes Yes Yes Yes

## PARASITE DISEASE

The choice of products in parasites diagnosis includes species-selective ELISAs for most common parasites, e.g. Echinococcus, Malaria and Toxocara.

Parameter	Catalog No.	Method	Features	CE
Toxocara canis IgG	RE58721	ELISA	High diagnostic sensitivity (97%) and specificity (99%) Antigens: synthetic oligopeptides with glycosylation	Yes

“Due to the interchangeable reagents and same workflow of each assay the automation on open systems, like the Freedom EVOlyzer is very easy realizable. For more information on this topic please see page 18.”





Autoimmune disease are chronic inflammatory processes. They can be either organ-specific or systemic in nature. Autoimmune diseases predominantly affect women and correlate with the production of disease-associated autoantibodies. The impact of autoimmune diseases on the cost of healthcare and effective treatment underline the importance of accurate and reliable methods for diagnosis, prognosis and monitoring autoimmune diseases.

**MYASTHENIA GRAVIS**

Myasthenia gravis (MG) is caused by the failure of neuromuscular signal transmission. To confirm the diagnosis of MG the determination of acetylcholine receptors (ARAb) and muscle-specific receptor tyrosine kinase (MuSK) autoantibodies is needed. The ARAb Radioimmunoassay is the state of the art diagnosis method for autoantibodies in serum of 80-90 % of patients with generalized myasthenia gravis and in 55-70 % of patients with ocular myasthenia.

In 10-20 % of the patients with generalized MG, and in up to 50 % of the patients with ocular MG these autoantibodies cannot be detected. In these cases the disease is commonly referred to as seronegative MG (SNMG). The antibodies to the muscle-specific receptor tyrosine kinase can be detected and measured via MuSK-Ab ELISA.

Parameter	Catalog No.	Method	Features	CE
Acetylcholine Receptor Autoantibodies (ARAb)*	RE21023 / RE21021	RIA	Antigen: human muscle acetylcholine receptor Sensitivity: 93% and specificity: 98% Total assay time is only 3 hours Easy to perform assay Cut-off and positive control Very robust assay with excellent between-lot reproducibility Free Quality Assessment Scheme (QAS)	Yes
MuSK-Ab (Muscle-specific Receptor Tyrosine Kinase-Ab)	RE51021	ELISA	The only available ELISA in the market Sensitivity: 95% and specificity: 99% Wide measurement range Quantitative results from standard curve	Yes

\*Twice a year, IBL International provides a free of charge QAS for ARAb binding and blocking.

## RHEUMATOID DISEASE

Rheumatoid factors are autoantibodies they are increasingly detachable in patients suffering under rheumatoid arthritis. Simultaneously, the RF can occur in other autoimmune diseases such as Sjögren's

syndrome and systemic lupus erythematosus. At the beginning of the RA the RF are rarely positive and after a duration of more than one year the frequency reaches of 70-80 %.

Parameter	Catalog No.	Method	Features	CE
Cyclic Citrullinated Peptide-Ab (CCP-Ab)	RE75791	ELISA	Antigen: 2 <sup>nd</sup> generation highly purified synthetic cyclic citrullinated peptides (CCP2) containing modified arginine residues Sensitivity: 79% and specificity: 97% Ready to use reagents 2 Kit controls included Quantitative results from standard curve can be obtained	Yes
Rheumatoid factor (RF) IgA/ IgG/IgM	RE70341	ELISA	Qualitative and quantitative result interpretation.	Yes

## COELIAC DISEASE

The immune-mediated inflammatory process following ingestion of wheat, rye, or barley proteins occurs in genetically susceptible individuals. Coeliac disease is associated with a variety of autoantibodies, including tissue transglutaminase (tTG) and gliadin antibodies.

Although the IgA isotype of these antibodies usually predominates in coeliac disease, individuals may also produce IgG isotypes. The most sensitive and specific serologic test is the tTG-IgA test.

Parameter	Catalog No.	Method	Features	CE
tissue Transglutaminase IgA (tTG IgA)	30132293	ELISA	Antigen: recombinant, eukaryotic expressed transglutaminase. Excellent high sensitivity and specificity.	Yes
tissue Transglutaminase IgG (tTG IgG)	30132295	ELISA		Yes
Modified Gliadin Peptide IgA (MGP IgA)	RE75741	ELISA	Antigen: synthetic instead of native gliadin Higher sensitivity and significantly more specific than conventional gliadin antibodies (especially IgG subclass) Children (MGP IgG)	Yes
Modified Gliadin Peptide IgG (MGP IgG)	RE75751	ELISA		Yes

## SYSTEMIC LUPUS ERYTHEMATOSUS

The Systemic lupus erythematosus (SLE) is an episodes/in stages occurring, chronic inflammatory autoimmune disease with numerous organ systems pressure such as skin, joints, kidneys, blood cells and

central nervous system. Antibodies against dsDNA have a high pathogenetic and diagnostic significance for SLE. More than 60 % of patients with SLE contain Auto-Ab to dsDNA.

Parameter	Catalog No.	Method	Features	CE
dsDNA-Ab	RE19011	RIA	Recommended as most reliable assay ("Gold standard"). dsDNA antibody titer is highly correlated with disease activity. Therapy monitoring and development of disease. High specificity, sensitivity and diagnosis efficiency. Checked against WHO standard preparation Wo/80. Total assay time only 1.5 hours	Yes
dsDNA-Ab	RE75201	ELISA	High diagnostic sensitivity and specificity for SLE Total assay time is only 1.5 hours	Yes



**Immunology is the medical field that addresses the study of physiological functioning of the immune system in health and disease.**

Dysfunctions of the immune system are generally termed “immune disorders”. These types of disorders can be characterized in different ways. First by the component(s) of the immune system affected, second whether the immune system is either overactive or underactive, third whether the condition is congenital

or acquired. The immune system can be divided into the ancient, primitive innate immune system and (in vertebrates) the adaptive immune system. This can be further divided into humoral (antibody response) and cell-mediated components.

**NEOPTERIN**

Neopterin is a low molecular weight molecule belonging to the chemical group known as pteridines. It plays a major role in the adaptive, cell mediated immune response. It is synthesised by cellular immune reaction of macrophages and dendritic cells upon stimulation with the cytokine interferon- $\gamma$  and as a consequence released. Neopterin has a higher stability in body fluids which makes the sample handling and

measurement easier compared to other cytokines. The low molecular weight, let neopterin molecules rapidly pass the intravascular area, where it is released into urine after glomerular filtration. The half-life period in human bodies is only affected by renal excretion. So neopterin values reflect the totality of immunological processes for monocytes/macrophages and dendritic cells and can be seen as a general marker of immune activity.

Parameter	Catalog No.	Method	Features	CE
Neopterin	RE59321	ELISA	Suitable for all vertebrates (validated for human) Validated for serum, plasma, urine Can be used from pre-clinical to clinical phase of development High throughput screening in combination with TECAN automation	Yes

**HMGB1**

**The multi-tasker of the innate immune system!**  
Over years, HMGB1 has increasingly attracted the attention of all kinds of researchers. It is one of the most intriguing molecules within the complete arsenal of proteins of the innate immune system as HMGB1 is either actively secreted by immune cells, or passively by injured cells as the cell’s immediate cry for help.

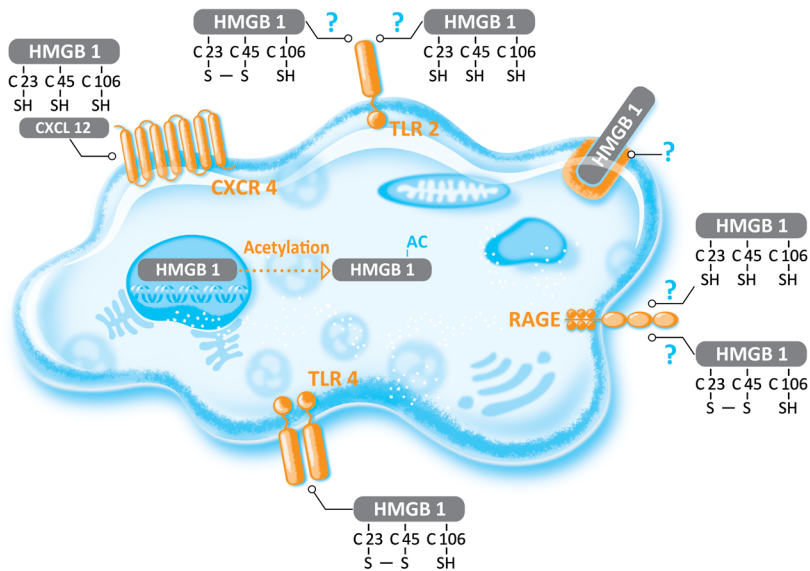
IBL International’s HMGB1 ELISA, which has been developed by Shino-Test Corporation, Japan, in cooperation with Prof. Dr. Ikuro Maruyama, Kagoshima University, is the worldwide renown assay to quantify HMGB1 in any experimental setting.



Parameter	Catalog No.	Method	Features	CE
HMGB1	ST51011	ELISA	Widely used and cited in multiple publications, including sepsis, cancer, diabetes and others Can be used for all mammals and all types of body fluids	Yes

HMGB1 is a nuclear protein that can bind and bend DNA, but it can also be released to the extracellular environment where it exerts additional functions. The unraveling of the post-translational modifications has led to a better understanding of the mechanism of its translocation and its function within the immune system. It will now also allow more in-depth studies into the role of HMGB1 in numerous pathologies, including

- Autoimmune diseases
- Sepsis
- Cancer
- Diabetes
- Cardial infarction
- Stroke
- ... any inflammatory process



HMGB1 biology by the current state of scientific knowledge

BIOLOGICS DRUG MONITORING

With the development of the first therapeutic monoclonal antibodies during the last decade of the 20th century, the use of these types of drug has grown significantly. As biologics, or also termed biopharmaceuticals, are always produced in living organisms such as *E.coli*, yeast (*Saccharomyces cerevisiae*) or cell lines, the drug quality and its functioning are dependent on the production process

itself and as such have to be tightly controlled in its function. IBL International therefore offers now a large range of assays to detect biopharmaceuticals and possible corresponding autoantibodies against the drug produced by the patient's immune system. Testing biologics is a further step towards personalized medicine.

Parameter	Catalog No.	Method	Features	CE
Infliximab (Remicade®)	QS51001*	ELISA	Optimized for Cmin-Cmax levels Low sample volume Short assay time	Yes
	QS51101*	ELISA	Quantitative (only one on market) Low sample volume	Yes
Adalimumab (Humira®)	QS51011*	ELISA	Optimized for Cmin-Cmax levels Low sample volume Short assay time	Yes
	QS51111*	ELISA	Quantitative (only one on market) Low sample volume	Yes

The above shown products for Infliximab and Adalimumab though are only a small excerpt of assays. We can also provide other assays for biological drugs as Bevacizumab, Cetuximab, Etanercept, Golimumab, Nivolumab, Trastuzumab and many more.

\*Distributed by IBL International

If you would like to use this assay for an indication not validated by IBL International, your laboratory should perform a validation study for this specific indication as indicated by national regulation.

# Smart, small and precise.

## ThunderBolt® 1 small footprint, big opportunities

A cost-efficient solution optimized for lower throughput demands – ideally suited to the Tecan IBL specialty assay portfolio.

### ECONOMICAL

**Small footprint** saves space.

**Single probe, dual needle system with liquid level sensing** enables clot detection and minimizes dead volume.

**Advanced diagnostics** through start-up instrument check, and logging and archiving of files for every operation.

**Probe-mounted camera** for remote troubleshooting, to maximize uptime.

### EFFICIENT

**High sample and reagent loading capacity** for parallel processing of up to eight assays.

**Orbital microplate shaker**, with no-spill design, improves adherence to assay protocols.

**Sliding tray** provides easy access for sample and reagent loading reducing hands-on time.

### PRECISE

**High precision microsyringe** enables direct 1:100 dilution in reaction wells.

**Individual well tracking and timing** of all process steps eliminates OD drifts over plates.

**Forced air convection incubator** evenly heats each well and avoids the edge effects.

### SAFE

**Intelligent racks** automatically detect and record sample positions during loading to reduce errors.

**Built-in barcode reader** streamlines loading and decreases sample tracking errors.

**Intuitive workflow**, with adjustable lot-specific information, flexible data reduction, multi-language support and more.

*ThunderBolt™*



<sup>1</sup> Manufactured by Gold Standard Diagnostics and distributed by Tecan. The instrument is available in Europe in conjunction with Tecan / IBL immunoassays. The combined use of assays, process script and instrument has to be validated individually on site by each laboratory.

# Automated multi-parameter analysis.

## Freedom EVolyzer<sup>® 2</sup> high throughput with process security

A high throughput solution for processing entire diagnostic panels – offering improved result comparability.

### ECONOMICAL

**Continuous sample loading** enables fast response to changing demands, offering higher throughput and time savings.

**Liquid level sensors** pre-check sample, reagent and wash buffer volumes, reducing manual interactions and preempting pipetting errors.

**Integrated maintenance reports** support laboratory quality management and reduce administrative efforts.

### EFFICIENT

**Dual parallel arm processing** with up to eight pipetting tips offers rapid sample and reagent distribution.

Choose between **washable tips, conductive disposable tips or use a combination of both** to optimize productivity and minimize sample carryover.

**Dynamic scheduler** optimizes machine usage and turnaround time with interleaved processing of up to 12 plates in parallel.

### PRECISE

**Optimized pipetting parameters** for consistent processing of precious and difficult to pipette samples.

**Parallel processing of up to 15 assays** for better result comparability.

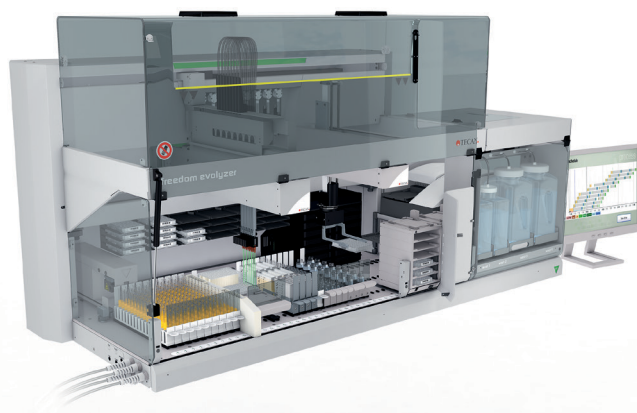
**Established protocols** for high reproducibility.

### SAFE

**Automatic barcode scanning** tracks samples, plates and reagents throughout the process, ensuring traceability and complete process security.

**Customizable result reports** indicate run status for straightforward result validation.

**Simple and supported operation**, with reagent shopping list and loading guide, cherry-picking of assays and multi-language software.



<sup>2</sup> Manufactured by Tecan. Not available in the USA. The combined use of assays, process scripts and instrument has to be validated individually on site by each laboratory.

**Manufactured by**

IBL International GmbH  
Flughafenstrasse 52a  
D-22335 Hamburg  
Germany

Phone: +49 (0)40-53 28 91-0  
Fax: +49 (0)40-53 28 91-11  
Email: IBL@Tecan.com  
www.tecan.com/immunoassays

.....  
**Australia** +61 3 9647 4100 **Austria** +43 62 46 89 330 **Belgium** +32 15 42 13 19 **China** +86 21 220 63 206 **France** +33 4 72 76 04 80 **Germany** +49 79 51 94 170  
**Italy** +39 02 92 44 790 **Japan** +81 44 556 73 11 **Netherlands** +31 18 34 48 17 4 **Nordic** +46 8 750 39 40 **Singapore** +65 644 41 886 **Spain** +34 93 93 595 25 31  
**Switzerland** +41 44 922 89 22 **UK** +44 118 9300 300 **USA** +1 919 361 5200 **Other countries** +41 44 922 81 11  
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