40 YEARS SPECIALTY DIAGNOSTICS.

Selected Immunoassays and LC-MS

TECAN.

40 YEARS OF SPECIALTY DIAGNOSTICS TO IMPROVE HEALTH.

Tecan is celebrating 40 years of innovation of in vitro diagnostic testing for endocrinology, immunology and autoimmunity at IBL International. The company specializes in the development, manufacture and supply of enzyme-, radiolabel- and luminescence-based immunoassays, as well as LC-MS solutions. These products are designed and manufactured to the highest standards, providing diagnostics labs with reliable data and improved workflow efficiency to assess various health conditions from blood, urine, saliva and cerebrospinal fluid samples.

The company offers a number of specialty diagnostic assays for endocrinology, neurotransmitters and autoimmunity in clinical diagnostics, along with key assays for the research segment, including HMGB1 and NF Light®*. By combining Tecan's immunodiagnostics expertise and long tradition in serving the clinical diagnostic market, many of these assays have been specifically adapted on ELISA platforms such as the Freedom EVOlyzer® or Thunderbolt®.

Rising to the top.

It is often said that necessity is the mother of invention, a concept that certainly rings true here, as Dagmar Kasper, Managing Director at IBL International, explained: "Our rise to a global market leader in immunoassay diagnostics all began with a German endocrinologist's need for specific radiolabel-based assays that were only available in the US at the time. Realizing that many other diagnostic labs across Germany had similar needs to support their patients, the decision was made to service this market niche by importing and developing specialty immunoassays for clinical research and diagnostics."

The perfect match.

"As the company reach, team size and product range has grown, we are proud to say that we have not abandoned our heritage, values, team spirit and close working partnerships," Dagmar continued. "We continue to rely heavily on the core principles that drove our early success – high quality solutions, technical expertise and dynamic customer service – and it was these shared principles that led to the company joining the Tecan group. The combination of Tecan's automation expertise and leading position within the instrumentation market with IBL International's comprehensive range of immunoassays for specialty diagnostics has paved the way for the supply of complete, automated solutions that improve lab processes by offering increased productivity and operation efficiency, and the highest levels of regulatory compliance."

Staying agile.

The introduction of the European Union's In Vitro Diagnostic Regulation (IVDR) presented a major compliance hurdle for all IVD manufacturers, but Tecan has met the challenge head-on to become one of the very first companies to achieve product certification under the new regulations. Dagmar added: "We have successfully navigated this rapidly evolving regulatory landscape with our change-agile mentality, relying on our extensive market experience to respond quickly and effectively to challenges that come our way. This empowers our customers with access to an uninterrupted supply of high quality and certified tests, helping to ensure reliable care for their patients. After all, that's why we do what we do."

*Distributed by Tecan, IBL International

Focused on the future.

This agility extends to product development too, and Tecan is always looking to stay ahead of the curve by combining legacy technologies with new and innovative solutions. This is exemplified by its new 'gold standard' for automated workflow for LC-MS based diagnostics, combining the Steroid Panel LC-MS Kit* and Resolvex® A200 Positive Pressure Workstation to automate the entire sample preparation process for easy identification of multiple clinically relevant steroids from human plasma and serum samples. "As we continue to expand our MS portfolio to better serve this rapidly evolving market, we are also looking forwards towards the next 40 years of innovation, with the goal of improving patient outcomes via the acceleration of discovery in medicine and life sciences," Dagmar concluded.

For more information about the products, please visit our website.

For publications, please contact us via IBL@tecan.com

*Product availability and regulatory status may vary across regions outside the EU depending on local country-specific registration. Consult with your Tecan associate for further information.

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LC-MS SOLUTIONS.

JOHN ROHLOFF, PRODUCT MANAGER, TECAN

Tecan has always sought to take a leading role in the development and manufacture of clinical assays for endocrinology applications, offering a product portfolio that keeps up to speed with the latest scientific developments and customer needs. Putting the spotlight on specialty diagnostics has seen our range of innovative in vitro diagnostic tests grow from radioactive immunoassays for clinical endocrinology applications to ELISAs and LIAs to measure steroids, peptides, proteins, and other hormones. Immunoassay approaches lie very much at the heart of our portfolio but, as LC-MS has emerged as the state-of-the-art method in many laboratories, we are constantly broaden our product range

Similar but different.

Laboratories are increasingly relying on MS for the measurement of small molecules – typically steroids – but also other products, such as biogenic amines. The challenge for laboratories is how best to distinguish between small molecules that are very similar in structure, yet act on the body in quite distinct ways. For example, the steroid pathway starts with cholesterol, which is converted by specific enzymes into pregnenolone and then progesterone. The biological impact of these two steroids is quite different but, because the structures are so similar, they can be quite challenging to measure with immunoassays. Although immunoassays are highly accurate and widely used for many analytes across clinical research and diagnostics, they can lack specificity to distinguish subtle molecular differences between some surface antigens.

Overcoming the identification challenge.

Clinical laboratories are turning to MS to improve the specificity of hormone diagnostics, with LC-MS now being recognized as the reference method for endocrinology. MS offers deeper insights into a sample, breaking down the molecules and analyzing them by mass and retention time to clearly identify the different steroid hormones present. This state-of-the-art technology enables a range of steroids to be determined and quantified in a single assay, providing all the information necessary to enhance the quality of diagnostics. Simultaneous measurement of all the different analytes involved in the particular steroid cascade adds value for clinicians by allowing them to, for example, pinpoint and treat issues with a specific metabolic enzyme. For instance, an elevated 17-OH progesterone value, combined with a very low cortisol concentration, suggests the patient's 21-hydroxylase enzyme is not performing as it should. While the sample could be screened by immunoassay, additional work would be required to fully understand the patient's condition.

To find out more or to see our full portfolio, visit
www.ibl-international.com/lc-ms-solutions

THE NOVELTY IN TECAN'S REAGENTS: STEROID PANEL LC-MS.

NEW

Complete solution for steroid determination in human serum and EDTA plasma by LC-MS.

Tecan has extensive experience in LC-MS workflows from across its life sciences and diagnostics businesses, and is using this know-how to offer labs all over the world the best and latest technologies in endocrinology. Recognizing the growing demand for MS approaches in hormone diagnostics, we developed the Steroid Panel LC-MS kit. This CE-IVDD assay enables easy measurement of 18 analytes across clinically relevant ranges — which vary for different steroids — from a single sample. In addition, sample preparation for this assay can be automated using the Resolvex® A200 Positive Pressure Workstation, providing a complete solution that eases the sample preparation bottleneck to save time and precious resources.

LC-MS/MS is considered the gold standard in the determination of steroid hormones due to its high selectivity!

Steroids	Catalog No.	Method	Features	CE
11-deoxycorticosterone 11-deoxycortisol 17-hydroxypregnenolone 17-hydroxyprogesterone 21-deoxycortisol aldosterone androstenedione corticosterone cortisol cortisone dehydroepiandrosterone dehydroepiandrosterone sulfate dihydrotestosterone estradiol estrone progesterone testosterone dexamethasone	30191875	LC-MS	Steroid kit 18 steroids 2 chromatographic runs (guarantees the best possible performance of all analytes) Only one sample preparation with 96-well SPE-plate Manual or automated sample preparation possible (e.g. Tecan Resolvex® A200) All standards in one mix Individual isotopic standard for each analyte Total runtime (LC-MS): 10 min for 15 steroids, second injection for another 3 analytes in 6 min runtime	Yes

www.ibl-international.com/steroid-panel-lc-ms

Are you looking for a fast and automated solution for sample preparation? We can help!

Automation saves time and resources. With our reagents and devices this can be done easily and reliably! By adapting the workflow, an implementation on devices such as Resolvex® A200 can be easily accomplished.

The combined use of the Steroid Panel LC-MS, process script and instrument has to be validated individually on site by each laboratory.

Complete solution includes XBridge BEH C8 Column, 130Å, 3.5 µm, 2.1 mm X 100 mm, manufactured by Waters®, distributed by Tecan.

All pictures of the products are for illustration purpose only. Actual products may vary due to product enhancement.

STEROID PANEL TEC-TRACE™.

The Steroid Panel Tec-Trace (30220283) includes one set of calibrators, quality controls and internal standard.

The calibrators are human serum based with steroid concentration values assigned to certified reference materials and traceable to SI units through an unbroken chain of calibration according to ISO 17511:2021. This allows the laboratories to establish trueness of measurement results and be traceable to SI units. They are provided in six concentrations plus the zero standard.

The quality control samples are human serum based with steroids of target concentrations and acceptable ranges assigned. This allows the laboratory to check the validity of analytical measurements. Two levels are provided.

The internal standards are stable isotope labelled counterparts of the 17 natural steroid hormones and dexamethasone. These can be added to all samples prior to processing and allow measurement results to be normalized at the end.

For Research Use Only. Not for use in diagnostic procedures.

Analyte	Calibrator ranges ng/mL
11-Deoxycorticosterone	0.040-5.13
11-Deoxycortisol	0.10-12.8
17-Hydroxyprogesterone	0.10-12.8
21-Deoxycortisol	0.10-12.8
Aldosterone	0.10-4.59
Androstenedione	0.10-12.2
Corticosterone	0.30-38.5
Cortisol	2.00-256
Cortisone	0.50-64.1
Dexamethasone	0.50-64.1
Dehydroepiandrosterone	1.00-45.9
Dehydroepiandrosterone sulfate	50.0-6412
Dihydrotestosterone	0.15-1.57
Progesterone	0.10-12.8
Testosterone	0.040-13.4
17-Hydroxypregnenolone	0.30-38.47
Estradiol	0.030-3.85
Estrone	0.010-1.28

BENEFIT FROM TECAN TEC-TRACE™ CALIBRATORS AND CONTROLS TO ALLOW RELIABLE QUANTIFICATION WITH LC-MS METHODS.

Our products ensure consistent and standardized calibration across different laboratories and LC-MS systems; at relevant concentration ranges.

Trusted data generation by high reproducibility.

- Achieve reliable and reproducible results.
- New lots are verified with internal and external QC to guarantee comparability.

Limit waste and save resources by using robust material.

- Lyophilized material in proper size to maximize lifetime.
- Covering matrix effects to ensure robust quantification.

Enlarge your team. Tecan at your side.

We assist with implementing and automating your workflow using our products.

- Allowing reliable quantification with LC-MS
- Replaces time-consuming and complicated self-production

Tec-Trace™ Calibrator Sets feature.

- **CE IVDD**
- Relevant concentration ranges
- Including blank Calibrator (no analytes)
- In **dedicated matrix** to cover matrix effects
- Lyophilizates (stable and robust)
- **Two aliquots**
  - › to minor aliquoting time
  - › to maximize lifetime
  - › to minimize cross contamination

Tec-Trace™ Control Sets feature.

- **CE IVDD**
- Covering whole concentration range
- In **dedicated matrix** to cover matrix effects
- Lyophilizates (stable and robust)
- **Three aliquots**
  - › to minor aliquoting time
  - › to maximize lifetime
  - › to minimize cross contamination

Analytes	Calibrators Order nr.*	Matrix	Approx. Range	Volume
Tec-Trace™ Cortisol & Cortisone	30232626	Urine	Cortisol: 1.5 – 603 nmol/L Cortisone: 0 - 720 nmol/L	6x2x1 mL
Tec-Trace™ Metanephrines	30232628	Serum	Metanephrine: 0 – 5.31 nmol/L Normetanephrine: 0 – 5.98 nmol/L 3-methoxytyramine (3-MT): 0 – 5.96 nmol/L	6x2x2 mL
Tec-Trace™ Methylmalonic Acid	30232630	Serum	<40 – 1577 nmol/L	6x2x500 µL
Tec-Trace™ Vitamin A & E	30232632	Serum	Vitamin A: 0 – 4.51 µmol/L Vitamin E: < 0.50 – 49.50 µmol/L	6x2x500 µL
Tec-Trace™ Vitamin B1 & B6	30232634	Whole blood	Vitamin B1: 49 - 662 nmol/L Vitamin B6: 26 - 384 nmol/L	6x2x250 µL
Analytes	**Controls Order nr.***	**Matrix**	**Approx. Range**	**Volume**
Tec-Trace™ Cortisol & Cortisone	30232627	Urine	Low, mid, high concentration	3x3x1 mL
Tec-Trace™ Metanephrines	30232629	Serum	Low, mid, high concentration	3x3x2 mL
Tec-Trace™ Methylmalonic Acid	30232631	Serum	Low, mid, high concentration	3x3x500 µL
Tec-Trace™ Vitamin A & E	30232633	Serum	Low, mid, high concentration	3x3x500 µL
Tec-Trace™ Vitamin B1 & B6	30232635	Whole blood	Low, mid, high concentration	3x3x250 µL

*Distributed by Tecan, IBL International

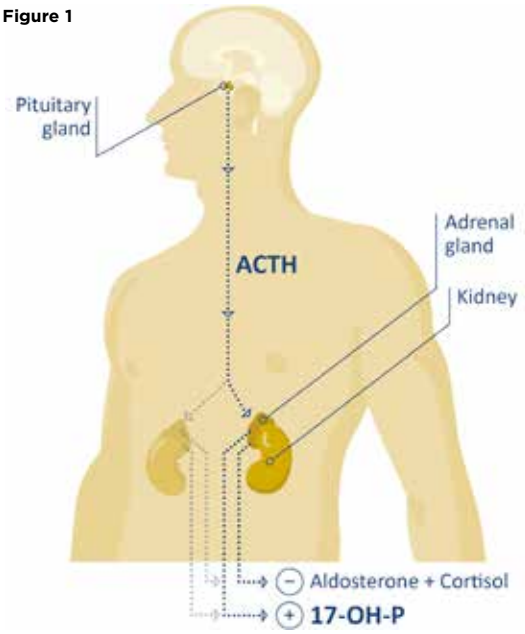
ENDOCRINE FUNCTION.

OLIVER SCHMIDT, JOHN ROHLOFF AND DR DAJANA DOMIK, PRODUCT MANAGERS AT TECAN

Tecan provides a comprehensive portfolio of highly sensitive, reliable immunoassays and LC-MS solution 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.

For steroid measurement with LC-MS please see section 1.

Figure 1



Steadfast support for endocrinology.

Endocrinology is a diverse and complex field, dealing with all aspects of the endocrine glands and hormones, and covering numerous diseases and hormone imbalances, including fertility assessment, bone metabolism, hypertension and other metabolic disorders.

Figure 1: 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.

Gynecology, Andrology, ivF

Complementary assays to random access systems:

Parameter	Catalog No.	Method	Features	CE
17-OH-Progesterone (17-OHP)	RE52071	ELISA	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
DHEA	RE52221	ELISA	Direct procedure without extraction and oxidation Excellent correlation to reference method LC-MS/MS	Yes
Free Testosterone	DB52181	ELISA	Measures the biologically active form Direct procedure without extraction Total assay time <2 hours Detailed reference ranges	Yes
5α-Dihydrotestosterone (DHT)	DB52021	ELISA	Direct procedure without extraction and oxidation Total assay time <2.5 hours Low cross reactivity to testosterone Not available on closed systems	Yes
Pregnenolone	DB52031	ELISA	Total assay time >1.5 hour Not available on closed systems	Yes
Androstenedione	DB52161	ELISA	Total assay time <1.5 hours	Yes
Androstane-diol-Glucuronide (3α-Diol-G)	DB52171	ELISA	Total assay time <1 hour Not available on closed systems	Yes

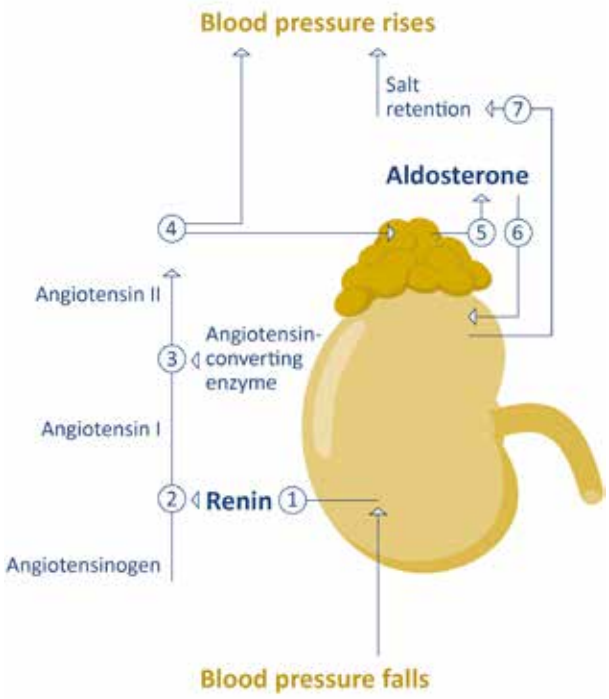
Bone and mineral metabolism.

Dysfunction of the Vitamin D and parathyroid hormone (PTH) pathways are usually indicators of diseases involving acalcinosis (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	RE53041	ELISA	Ready-to-use standards and controls Limit of Quantitation: 8.2 ng/mL	Yes
Free 25-Hydroxy-Vitamin D	30113750*	ELISA	Worldwide only available ELISA. Useful for screening and monitoring purposes	Yes

*Distributed by Tecan, IBL International



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.

Tecan offers assays for routine diagnostics and research purposes in the area of Hypertension and its initial reasons.

Figure 2: Renin-Angiotensin-Aldosterone System

Parameter	Catalog No.	Method	Features	CE
Aldosterone	RE52301	ELISA	Direct procedure without extraction	Yes
Renin (active)	RE53321	ELISA	Renin levels are indicative for the activity of the Renin-Angiotensin-Aldosterone System (RAAS) Ranges for Renin-Aldosterone ratio are available	Yes
Plasma Renin activity / Angiotensin	DB52011	ELISA	Measures Plasma Renin Activity	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.

Parameter	Catalog No.	Method	Features	CE
Active-B12 (Holotranscobalamin/Holo TC)	30221798*	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	Yes
Adiponectin	30126762	ELISA	Detects total Adiponectin (low, medium and high molecular variants) Gender and age group specific reference values	Yes
Leptin	MD53001	ELISA	Calibrated against WHO NIBSC 97/594 international standard Reference ranges correlated with BMI and Tanner stages of children and adolescents	Yes

*Distributed by Tecan, IBL International

Tumor markers.

Tecan 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.

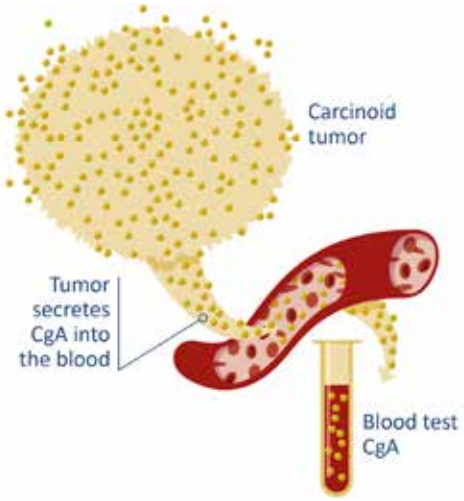


Figure 3: Release of Chromogranin A into the blood

Parameter	Catalog No.	Method	Features	CE
Chromogranin A	30208352*	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)	30143814	ELISA	Measurement of adrenalin (epinephrine), noradrenalin (norepinephrine) and dopamine in urine samples. Excellent correlation to HPLC method Automated protocol for open ELISA systems like Freedom EVOlyzer® available	Yes
MetCombi Plasma (Metanephrine/ Normetanephrine)	RE59202	ELISA	Short assay time: ca. 4.5 h Calibrated to LC–MS/MS Automated test procedure Small sample volume: 200 µL High sensitivity	Yes
Metanephrine Normetanephrine	RE59181 RE59171	ELISA ELISA	Measurement in urine samples. Catecholamine-secreting pheochromocytomas and paragangliomas diagnostic Monitoring tool for therapy follow-up	Yes

To find out more or to see our full portfolio, visit
www.ibl-international.com/endocrinology

*Distributed by Tecan, IBL International

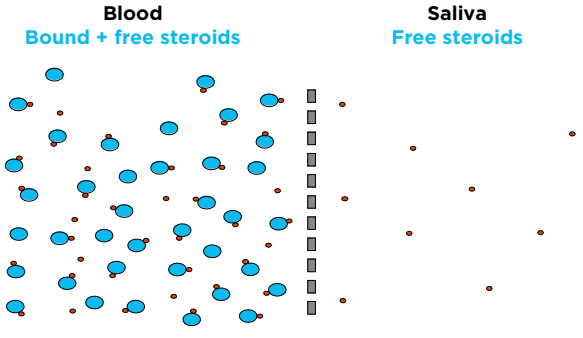
COMPLEMENTARY MEDICINE.

DR DAJANA DOMIK, PRODUCT MANAGER AT TECAN

Blood has been the preferred medium for a wide range of diagnostic tests for decades, overshadowing saliva testing due to concerns regarding sensitivity, specificity and reproducibility. However, significant progress has been made in saliva diagnostics over the years, and the increasing availability of sensitive and robust saliva-based assays is now allowing clinicians to put away their syringes. Tecan offers an extensive range of immunoassays based on luminescence and enzyme-linked immunosorbent assay (ELISA) technologies – including steroid assays for cortisol and sex hormones, as well as tests for melatonin and alpha amylase – that have been specially developed and validated for saliva.

A matter of bioavailability.

Saliva contains various hormones and other biomolecules that can serve as direct or indirect indicators of human health, biochemical imbalances and even certain disease states.[1] These analytes are also present in blood, but a key advantage of saliva testing lies in its ability to measure the biological active free fraction.[2] Most steroid hormones in the bloodstream are bound to carrier proteins, and are therefore metabolically inactive, with just a small unbound proportion available to exert an effect. In contrast, only free, unbound hormones leave the bloodstream and make their way into saliva via passive diffusion, so saliva testing provides a measure of biologically active hormones.[3,4]



The ability to measure bioactive hormones is crucial in identifying hormonal imbalances and managing conditions effectively. However, saliva-based assays need to be very sensitive, as saliva contains only low concentrations – between one and five percent – of hormones compared to blood.[2] Fortunately, saliva testing has come a long way since the topic was first discussed in scientific literature over 40 years ago,[5] with a growing range of ever-more sensitive saliva-based immunoassays on the market today.

The benefits of saliva sampling.

While 24-hour urine collection is a valid method for monitoring hormones, it can be inconvenient for patients, and only measures the total amount of a hormone produced, without offering insights into its hourly profile throughout the day. Similarly, studying diurnal variations in cortisol requires multiple blood samples to be taken throughout the day. Unfortunately, blood sampling is invasive and impractical for repeated sampling, and can be a stressful process for patients that are fearful of

Figure 1: Diffusion of free steroid hormones from blood into saliva Free and protein bound steroid hormones in blood (left side) and free hormones in saliva (right side). The concentration of free hormones is the same on both sides of the membrane.

needles. Any unnecessary anxiety during sample collection can potentially also affect their cortisol levels, skewing results. Saliva testing overcomes these challenges, as it is non-invasive, easily repeatable and can be performed in any setting. Samples can be collected by patients in the comfort of their own homes, allowing for frequent measurements without the necessity of medical supervision.

Efficient sample handling is another area where saliva testing shines. After sample collection, it is crucial to transport the specimen to the laboratory without any deterioration, as this can compromise results. While blood collection tubes are only suitable for short-term storage and transport, saliva samples are easy to handle and transport in collection tubes.

Beyond traditional medicine.

Saliva testing is both efficient and convenient, with standard operating procedures (SOPs) now in place for sample collection methods as well as analytical processes. Saliva diagnostics is growing consistently globally based on market trends and experience. Being particularly popular in emerging areas of medicine, such as the 'wellness' space, which includes occupational medicine, sports medicine, mental health and sleep disorders.[3,4]

Saliva testing offers a simple way to establish baseline hormone levels, serving as a starting point for further investigations. Commonly requested tests include cortisol, estradiol, progesterone, testosterone, and its precursor dehydroepiandrosterone (DHEA). By identifying hormonal imbalances, these tests pave the way to effective solutions for a range of health concerns. Salivary biomarkers have also been found to be helpful in detecting and monitoring mental health conditions – such as depression[6] – evaluating circadian rhythms and diagnosing sleep disorders,[7] monitoring the outcomes of hormone replacement therapy (HRT) in perimenopausal women,[8] and as a benchmark for optimizing recovery and performance in athletes.[9,10]

Choosing the right assay.

FLUIDS iQ in Canada relies on saliva-based immunoassays from Tecan to offer its patients a personalized approach to health and wellness. **President and CEO Dr Aron Gonshor explained why Tecan was the company's provider of choice: "We chose Tecan for its high-quality assays, but the company does more than just supply saliva testing kits. It also offers an independent proficiency testing program to help laboratories safeguard the accuracy and reliability of analytical results."**

Another diagnostic laboratory based in Slovenia, Medicare PLUS, relies on ELISA kits from Tecan to measure more than six separate biological mediators in patient saliva samples. **Aleš Koščak, CEO of Medicare PLUS, commented: "The kits are very reliable, consistently performing to the high standards we require, and generating very low CVs (coefficients of variation) of under eight percent. Tecan also runs an independent quality control scheme as an additional service, which allows us to compare the performance of our testing results against other labs, and this is vital to meet our external quality control regulations set by the Ministry of Health."**

Transforming healthcare testing.

Laboratories worldwide rely on Tecan's luminescence- and ELISA-based saliva immunoassays due to their high analytical sensitivity. Tecan offers a wide range of IVDR certified saliva diagnostic kits*, as well as a fast, reliable and professional service – backed by capable scientific and technical support – to laboratories across the world. These reliable, convenient and effective diagnostic tools are revolutionizing many areas of healthcare testing for patients and medical professionals alike and, ultimately, saliva-based assays from Tecan have the potential to replace invasive diagnostic testing and significantly improve patient outcomes.

Mostly all 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.

Please find the references on page 15

* Product availability and regulatory status may vary across regions outside the EU depending on local country-specific registration. Consult with your Tecan associate for further information.

Stress measurement.

Parameter	Catalog No.	Method	Features	CE
DHEA Saliva	RE52651	ELISA	Not available on closed systems ELISA: Clearly defined reference values by gender, age and day time	Yes
Cortisol Saliva	30221150 RE52611	LUM ELISA	LUM sensitivity: 0.12 ng/mL Intra-assay precision CV 4.3% Easier method than LC-MS/MS	Yes Yes
Melatonin Saliva	RE54041	ELISA	No extraction needed	Yes

Hormonal sexual disorders, androgenism, evaluation of ovarian function.

Parameter	Catalog No.	Method	Features	CE
Progesterone Saliva	RE52281	ELISA	Standard range: 25 - 5,000 pg/mL Direct procedure without extraction	Yes
Testosterone Saliva	RE52631 30191568/30191569	ELISA LUM	Functional sensitivity LoQ 8.6 pg/mL Functional sensitivity LoQ 3.9 pg/mL Easier method than LC-MS/MS	Yes Yes
17ß-Estradiol Saliva	30121045	ELISA	Only 50 µL sample volume needed Defined reference values for females and males	Yes
Estriol High Sensitive Saliva	30121046	ELISA	Only 100 µL sample volume needed	Yes

Furthermore, Tecan proposes following benefits.

- Collection tubes SaliCap Set (RE69981/ RE69985) available
- Free of charge EQAS for salivary steroids twice per year
- Experience in automation of Salivary assays on EVOlyzer® and ThunderBolt® ELISA systems.**

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
Serotonin	RE59121	ELISA	Calibrated to HPLC (platelets, serum) List of publications available upon request	Yes
TriCat Urine (Adrenaline/Noradrenaline/Dopamine)	30143814	ELISA	Calibrated to HPLC Validated for urine testing	Yes
Melatonin Sulfate	RE54031	ELISA	Concentration of 6-hydroxymelatonin sulfate in urine correlates well with the total level of melatonin in the blood during the collection period	Yes

**The combined use of assays, process script and open system instrument (e.g. EVOlyzer®, ThunderBolt®) has to be validated individually on site by each laboratory. Interchangeability is only valid within same lot numbers for the single components.

Food Intolerance testing.

Tecan's Food intolerance product line includes a variety of assays for assessing individual sensitivity to food allergens. The assays are intended for quantitative determination of specific IgG and/or IgG4 antibodies in serum or plasma from venous or capillary blood. The assays are all distributed by Tecan.

Parameter	Catalog No.	Method	Features	CE
IgG Food Screen 24 IgG4 Food Screen 24	30113481* 30113482*	ELISA	Screening of IgG / IgG4 Antibodies against 24 allergens 3 patients can be screened with one microtiterplate	Yes
IgG Food Screen 7 IgG4 Food Screen 7	30131629* 30131628*	ELISA	Screening of IgG / IgG4 Antibodies against 7 allergens 12 patients can be screened with one microtiterplate	Yes
IgG4 Food Screen 280	30115845*	ELISA	Screening of IgG4 Antibodies against 280 allergens – complete screening, 1 patient can be screened with 3 microtiterplates	Yes
IgG Food Screen Mediterranean 20 / 40 /80	30155431* 30155432* 30155433*	ELISA	Screening of IgG Antibodies against 20 / 40 / 80 allergens from region specific foods	Yes

To find out more or to see our full portfolio, visit
www.ibl-international.com/complementary-medicine

References for page 13

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AUTOMATION SOLUTIONS.

SAMPLE-TO-RESULT ELISA SOLUTION

The processing of entire diagnostic panels increases speed, enhances throughput, ensures assay reproducibility and result comparability while providing an efficient use of resources.

Measurement of salivary steroids, urinary neurotransmitters and blood samples for Food Intolerance testing can be done on open systems like the ThunderBolt® or the Freedom EVOlyzer®. The ThunderBolt® represents an ideal solution for laboratories with lower throughput demands, starting in the field of complementary medicine. The EVOlyzer® is a high throughput solution for processing entire diagnostic panels, and as such perfectly suits to laboratories established in the functional medicine field.

Both automation platforms can be offered with reagent rental agreement on our immunoassay portfolio. Such equipment rental plans are a great option for small as well as large volume labs that face budgetary constraints for the purchase of new instruments for in-lab testing.

- Analyzed protocols*

Our Service for you.

- Complete integration of the system in your lab
- Feasibility analysis
- Workflow analysis
- Application support after installation

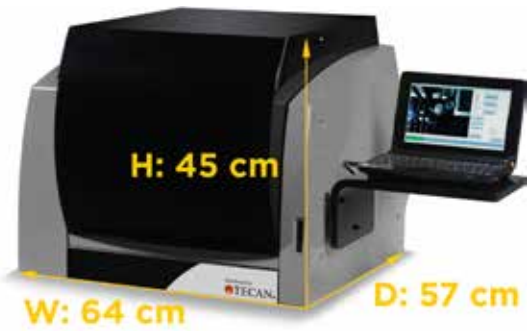
THUNDERBOLT®.

Small footprint, big opportunities.

The ThunderBolt® is a robust and compact system for the automation of ELISA applications, ideal for customers who process 2 microplates per day. A cost-efficient solution, ideally suited for the IBL specialty assay portfolio.

- loading capacity of 192 samples; up to 8 protocols per run
- high precision pipetting for direct 1:100 dilutions
- fast loading and increased process safety with intelligent racks

ThunderBolt™



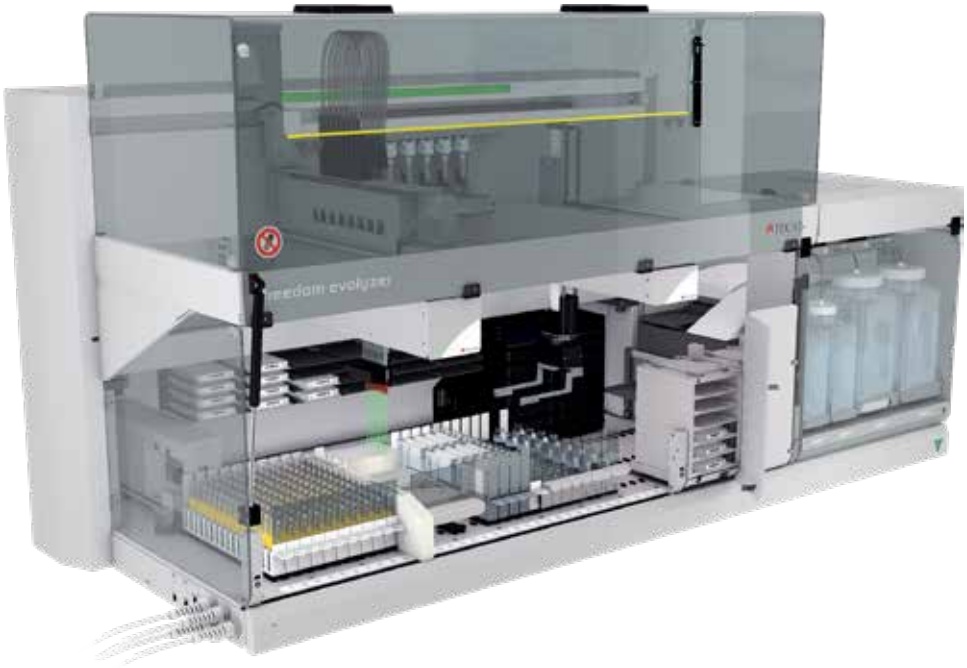
*The combined use of assays, process script and instrument has to be validated individually on site by each laboratory.

EVOLYZER®.

Fully automated ELISA processing.

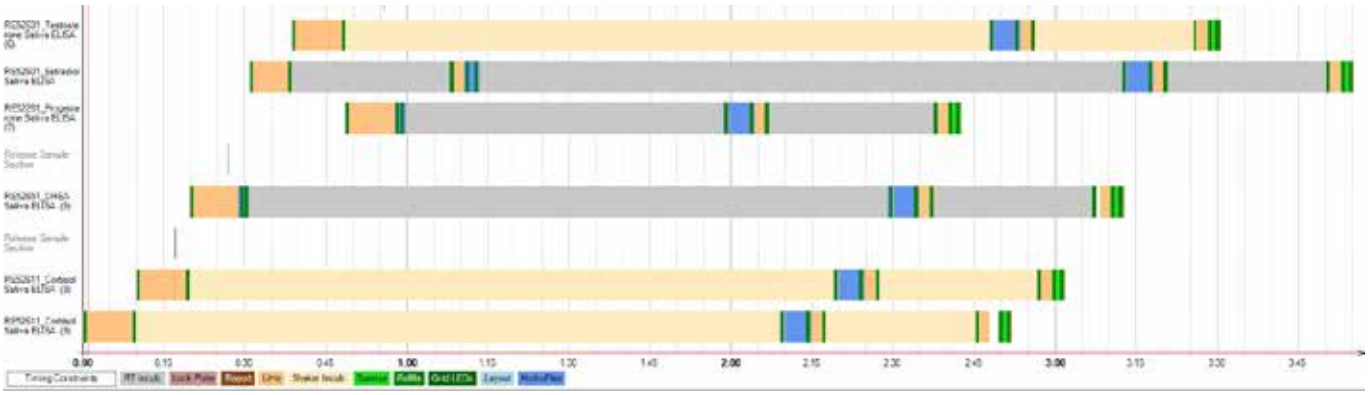
The Freedom EVOlyzer meets the demands of laboratories which process between 4 and 12 plates per run. Combine up to 15 assays per

- Continuous sample and reagent loading
- Support of disposable tips, fixed tips or a mix of both for increased productivity and safety
- Dynamic scheduling for optimized run times
- Unattended overnight runs
- Reliable pipetting of complex & delicate sample types
- And many more...



Processing schedule example.

Processing schedule example with 5 different assays on a Freedom EVOlyzer® 150. 40 patients are tested in less than 4 hours for a Cortisol and DHEA diurnal profile, Progesterone, Estradiol and Testosterone.



Simulation of laboratory workflow. This will be adapted to customer requirements upon implementation.

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NEURODEGENERATIVE DISEASES.

OLIVER SCHMIDT, PRODUCT MANAGER AT TECAN

Neurodegenerative diseases (NDs) affect millions of people worldwide, with age, genetics and environmental factors contributing to increasing risk. All NDs are characterized by the loss of neurons, resulting in cognitive or functional impairment, or sometimes both. For example, Alzheimer's disease (AD), Creutzfeldt-Jakob disease and frontotemporal dementia (FTD) are conditions that predominantly cause cognitive decline, while Parkinson's disease (PD), multiple sclerosis (MS) and amyotrophic lateral sclerosis (ALS) – the condition that affected Stephen Hawking – all inflict motor function impairment. One of the key challenges in diagnosing these conditions is the high overlap of symptoms, especially those causing cognitive impairment. However, more recent research has identified a number of proteins that can aid in the characterization of NDs, leading to the development of assays – such as those supplied by Tecan – that could help to guide both clinicians and further research in the field.

Protein power.

Many NDs have been classified as neurodegenerative proteinopathies over recent decades, as they result in the accumulation of misfolded proteins in the brain. These atypical protein conformations – or amyloids – are thought to be the cause of almost 50 conditions, and are likely shaped by primary amyloid-forming proteins that contribute differentially towards disease prognosis.[1] In the meantime, assays are available to measure many of the proteins thought to be involved in CSF and serum, potentially aiding the diagnosis and management of various conditions.

Alzheimer's disease (AD).

AD is one of the most common neurodegenerative proteinopathies, and has been the subject of much research since the early nineties, leading to the discovery of specific proteins involved in its pathology. Current theory suggests that patients with AD have lowered amyloid-beta 1-42 (Aβ1-42) and elevated tubulin-associated unit (TAU) levels compared to healthy controls. However, these proteins also play a role in the pathogenesis of other NDs, and additional proteins must be measured in conjunction to improve diagnostic accuracy. For example, increased TAU levels in the brain are also representative of FTD, but elevated phosphorylated TAU (pTAU) is a hallmark of AD alone, and so measuring both markers can aid differential diagnosis. Furthermore, measuring Aβ1-42 by itself can produce false positive or negative results, but the ratio of Aβ1-42 to amyloid-beta 1-40 (Aβ1-40) has been shown to be a superior diagnostic marker for AD (see figure 1).[2] This can help to distinguish between AD and other dementias, such as vascular dementia, dementia with Lewy bodies and FTD.[3] These proteins feature heavily in the latest paper by the International Working Group for AD, which recognizes the diagnosis of AD should be based on both clinical and biological characteristics, recommending Aβ1-42, Aβ1-40:Aβ1-42 ratio and pTAU as favorable biomarkers.[4]

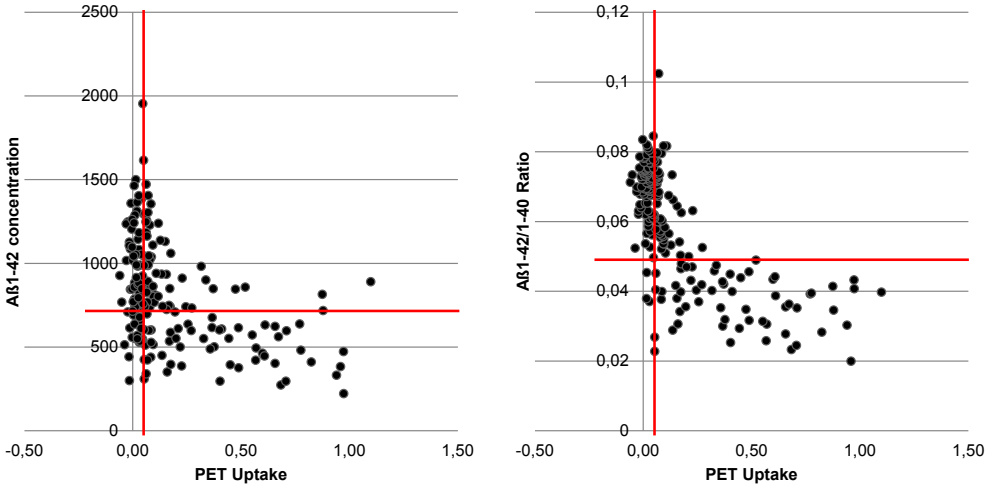

Figure 1: The Amyloid-beta ratio of Amyloid-beta (1-42) to Amyloid-beta (1-40) significantly improves the accuracy of concordant samples in comparison to PiB from 74.9% to 89.4% [5]

Parameter	Catalog No.	Method	Features	CE
Amyloid-ß (1-40)	RE59651	ELISA	Ready to use 6 point standard curve Only 5µL CSF needed	Yes
Amyloid-ß (1-42)	RE59661	ELISA	Low inter- and intra assay CVs As part of the Amyloid-beta ratio Excellent analytical sensitivity and specificity Amyloid-ß (1-42) calibrated against IFCC standard preparation	Yes
phosphoTAU	30121609*	ELISA	Ready to use 6 point standard curve Only 25µL CSF needed	Yes
hTAU total	RE59631*	ELISA	Ready to use 6 point standard curve	Yes
non-phospho TAU	RE59641*	ELISA	Ready to use 6 point standard curve excellent discriminatory marker between AD and CJD	Yes

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Research of axonal destruction.

Another set of biomarkers garnering interest for the management of NDs is neurofilament proteins. These are structural components of myelinated axons on neurons, which define the shape and diameter of the axon, as well as playing a crucial role in signal propagation. The neurofilament light chain (NF-L) is a subunit that is especially of interest to the management of many NDs, as its level increases in the CSF and blood in proportion to the degree of axonal damage.[5] Being able to identify and quantify axonal damage could help to improve diagnostic and prognostic accuracy for many diseases, including MS and ALS.[6]

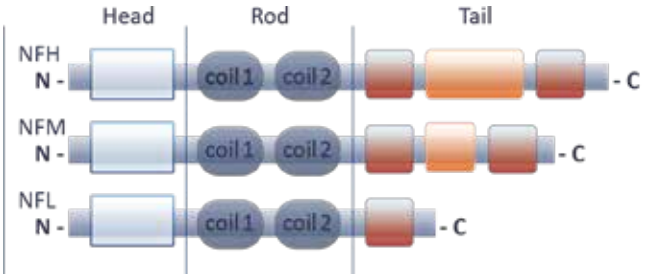

Figure 2: Schematic illustration of neurofilament subunits

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

References

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Further research in neurodegeneration.

Parameter	Catalog No.	Method	Features	
NF-light Serum	30210101*	ELISA	Limit of Detection (LoD): 0.4 pg/mL Recovery of endogenous NF-Light >90%	RUO**
Amyloid-ß (1-38)	JP27717*	ELISA	widely used in research of different neurodegenerative diseases Highly sensitive: >2pg/mL	RUO**
sAPP-α	JP27734*	ELISA	Cross-reactivity to sAPP-ß <0.1% Can be used for serum, plasma, CSF and cell culture supernatants	RUO**
sAPP-ß	JP27732*	ELISA	Cross-reactivity to sAPP-α = 1.41% Can be used for EDTA plasma, CSF and cell culture supernatants	RUO**
α-Synuclein PATHO	30227870*	ELISA	Detects specifically the pathological form of α-synuclein	RUO**
BetaPrion®	30227871*	ELISA	Detects specifically the total prion protein in human cerebrospinal fluid (CSF)	RUO**
AGGREGATE TAU	30227874*	ELISA	Detects specifically aggregated forms of the TAU protein	RUO**

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SCALING HEALTHCARE INNOVATION GLOBALLY.

INFECTIOUS DISEASES.

DR. CONSTANZE DRECHSEL, PRODUCT MANAGER AT TECAN

Tecan 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.

Due to interchangeable reagents and same workflow of most of the assays the automation on open ELISA systems, like the Freedom EVOlyzer® is easy to perform. **

Viral Diseases.

The Tecan ELISAs for identification of viral infectious diseases are appropriate for routine and special diagnostic markers.

Parameter	Catalog No.	Method	Features	CE
Zika virus IgM µ-capture	30113441*	ELISA	µ-capture technology No significant cross reactivity to other Flaviviridae Qualitative result evaluation Diagnostic sensitivity: > 99% and diagnostic specificity: 98.5%	Yes
Dengue IgG	RE58671*	ELISA	Detection of all 4 Dengue types	Yes
Dengue IgM µ-capture	RE58581*	ELISA	µ-capture technology for IgM Diagnostic sensitivity and specificity: > 98%	Yes
Chikungunya IgG capture	RE58831*	ELISA	High diagnostic sensitivity (100% for IgM, 98.68% for IgG) and specificity (100% for IgM and IgG) due to antibody capture technology	Yes
Chikungunya IgM µ-capture	RE58841*	ELISA		Yes
Epstein-Barr virus EA-D IgG	30219300*	ELISA	Highly specific antigens	Yes
Epstein-Barr virus EBNA IgG	RE58741*	ELISA	High diagnostic sensitivity and specificity in primary, past infections and reactivation	Yes
Epstein-Barr virus VCA IgA	30113624*	ELISA		Yes
Epstein-Barr virus VCA IgG	RE58751*	ELISA		Yes
Epstein-Barr virus VCA IgM	RE58761*	ELISA		Yes

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**The combined use of assays, process script and open system instrument (e.g. EVOlyzer®, ThunderBolt®) has to be validated individually on site by each laboratory. Interchangeability is only valid within same lot numbers for the single components.

Bacterial diseases.

Parameter	Catalog No.	Method	Features	CE
Borrelia + VlsE IgG Borrelia 14 kDa + OspC IgM	RE57201 RE57211	ELISA ELISA	Diagnostic sensitivity IgG: 94% and IgM: 99% Diagnostic specificity IgG: 98% and IgM: 95% Quantitative (titer) or qualitative (cut-off) results can be obtained Positive and negative 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 PT IgG Bordetella PT IgA	30113472* 30113473* 30113474* 30113476* 30113475*	ELISA ELISA ELISA ELISA ELISA	Complete range of mixed and single antigen ELISAs Qualitative or quantitative results (IU/mL for single antigen ELISAs) Wide linear measurement range	Yes Yes Yes Yes Yes
Haemophilus influenzae B IgG	RE56351	ELISA	Antigen: polyribosylribitolphosphate (PRP), which correlates to common vaccines Shelf life: >18 months Low- and high level kit controls included	Yes
Helicobacter IgG Helicobacter IgM Fecal Helicobacter-Antigen	30114048* 30219302* RE58891	ELISA ELISA ELISA	Antibody as well as antigen tests available.	Yes Yes Yes

Parasite Diseases.

Parameter	Catalog No.	Method	Features	CE
Toxocara canis IgG	RE58721*	ELISA	High diagnostic sensitivity (97%) and specificity (99%)	Yes
Malaria Ab	RE58901*	ELISA	Highly specific antigen as well as high diagnostic sensitivity and specificity	Yes
Echinococcus IgG	30113623*	ELISA	Highly specific antigen as well as high diagnostic sensitivity and specificity	Yes

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AUTOIMMUNE DISEASES.

DR CONSTANZE DRECHSEL, PRODUCT MANAGER AT TECAN

Autoimmune diseases 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 is an autoimmune disease, in which the body's own immune system produces antibodies that attack important proteins at neuromuscular junctions, affecting the skeletal muscles responsible for breathing and various other movements. Early and accurate diagnosis is important because, despite the absence of a cure, timely treatment can help to control symptoms and improve patients' quality of life.

A complex condition.

The hallmark of MG is muscle weakness – particularly in the muscles controlling the eyes and eyelids, facial expressions, chewing, swallowing and speaking – which worsens after periods of activity and improves with rest.[2]

In most cases of MG, autoantibodies target the acetylcholine receptors, transmembrane proteins that carry electrical signals between nerve endings and muscles to stimulate muscle contractions.[3] Acetylcholine receptor autoantibodies (ARAbs) prevent acetylcholine from binding to its receptor, blocking normal muscle contractions. However, about 15 percent of patients with clinical symptoms will have no detectable ARAbs and, in these cases, the disease will be classed as seronegative.[3] Approximately 40 percent of seronegative MG cases can be diagnosed based on the detection of autoantibodies to muscle-specific kinase (MuSK), a protein involved in cross-linking the acetylcholine receptor to the cytoskeleton.[4] Seronegative patients tend to have a more severe form of the condition that demands more intensive therapy –making early and definitive diagnosis crucial.

Leading the way in MG diagnostics.

Tecan's expertise in MG diagnostics began in 1995, when the company pioneered a radioreceptor assay (RRA) to detect ARAbs. This assay uses receptors from human muscle in combination with a radio-labeled alpha-bungarotoxin snake venom marker that binds very specifically to acetylcholine receptors without interfering with ARAb binding. Due to that fact, the RRA assay is highly sensitive – making it the gold standard for serological diagnosis of MG.

In 2012, Tecan progressed its range of diagnostic tools of MG with the launch of an ELISA to identify autoantibodies against muscle-specific tyrosine kinase (MuSK). This test is the world's first commercially available, non-radioactive assay for detecting anti-MuSK autoantibodies, and is designed to help improve both diagnostic certainty and the clinical management and monitoring of seronegative MG patients.

Parameter	Catalog No.	Method	Features	CE
Acetylcholine Receptor Autoantibodies (ARAb)	30221148 / 30221149	RIA	Antigen: human muscle acetylcholine receptor Sensitivity: 100% and specificity: 93% Total assay time is only 3 hours Easy to perform assay Cut-off and positive control Free Quality Assessment Scheme (EQAS)	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

To find out more or to see our full portfolio, visit
www.ibl-international.com/autoimmunity/myasthenia-gravis

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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. 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

Rheumatoid disease.

Rheumatoid factors (RF) are autoantibodies they are increasingly detachable in patients suffering under rheumatoid arthritis (RA). 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)	30218671*	ELISA	Sensitivity = 93.2 %; Specificity > 99% Quantitative results from standard curve can be obtained Measuring range 2.8-400 U/mL with cut-off 10 U/mL	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 serological test is the tTG-IgA test.

Parameter	Catalog No.	Method	Features	CE
tissue Transglutaminase IgA (tTG IgA)	30132293	ELISA	Antigen: recombinant, eukaryotic expressed transglutaminase	Yes
tissue Transglutaminase IgG (tTG IgG)	30132295	ELISA		Yes
Modified Gliadin Peptide IgA (MGP IgA)	RE75741	ELISA	Antigen: synthetic instead of native gliadin	Yes
Modified Gliadin Peptide IgG (MGP IgG)	RE75751	ELISA	Antibodies directed against modified (deamidated) gliadin peptides (MGP) exhibit a better diagnostic accuracy for Coeliac Disease, as compared to antibodies directed at crude gliadin (especially IgG subclass)	Yes

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PORTFOLIO.

IMMUNE INSIGHTS.

OLIVER SCHMIDT AND DR DAJANA DOMIK, BOTH PRODUCT MANAGERS AT TECAN

The immune system.

The complexity of the immune system is difficult to summarize succinctly, but it can be broadly categorized into two main branches: the innate and adaptive immune responses. The former is the body's first line of defense, providing a range of mechanisms for rapid, non-specific protection. This includes both physical barriers – such as the skin and mucous membranes – and cellular and inflammatory responses. The adaptive immune system is even more expansive, comprising highly specialized and specific defense mechanisms that develop over time. This is further divided into two classes: antibody- and cell-mediated immune responses, which involve B cells and T cells, respectively. However, these pathways do not function independently, but work in harmony to ensure our health and survival.

Biomarkers – a critical element of modern medicine.

Immune biomarkers have become commonplace in clinical practice, providing accurate, reproducible and quantifiable assessment of various biological processes. This can help to potentially catch a disease before symptoms appear, as well as aid in the diagnosis and treatment of many disorders. Tecan offers a range of assays to quantify some of the key biomarkers involved in the immune response.

Neopterin.

Neopterin is a molecule synthesized by macrophages when stimulated by the cytokine interferon-γ, which is released by T cells upon activation. It is considered a universal biomarker, with elevated levels in the blood or urine of a patient associated with a cellular immune response before the onset of an antibody response. As such, it could help clinicians narrow down the potential cause of symptoms earlier, as increasing levels correlate with severity of disease. Its vital role in immune responses makes it an incredibly important biomarker, and it is associated with a range of conditions, including viral and bacterial infections, allograft rejections, autoimmune disorders and sarcoidosis.[3]

Parameter	Catalog No.	Method	Features	CE
Neopterin	RE59321	ELISA	Validated for serum, plasma, urine High throughput screening possible in combination with TECAN automation*	Yes

*The combined use of assays, process script and open system instrument (e.g. EVOlyzer®, ThunderBolt®) has to be validated individually on site by each laboratory. Interchangeability is only valid within same lot numbers for the single components.

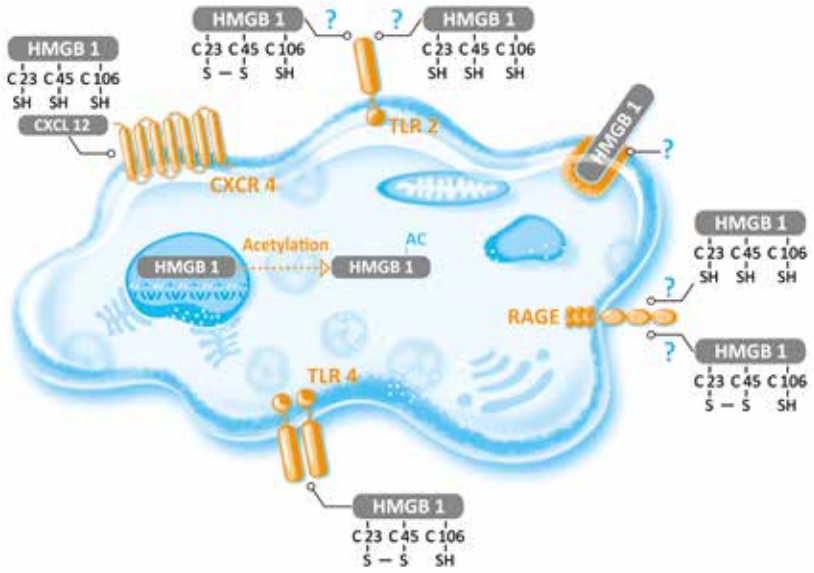
HMGB1.

High mobility group box 1 (HMGB1) is a fundamental mediator of the immune response, and increased levels can be an important indicator of several conditions, from sepsis and cancer to arthritis and stroke.[1] It is one of the most common nuclear proteins found in most cells – where it stabilizes chromosome structure and plays a central role in controlling gene expression – but it is its extracellular activity that has fascinated researchers for decades. During cell stress, HMGB1 can be modified and translocated to the cytosol, then secreted into the extracellular space, where it functions as an alarm – known as a damage-associated molecular pattern (DAMP) – to trigger critical processes of the innate immune system. This makes it a valuable biomarker, and an attractive target for many therapies.

Tecan's HMGB1 Express ELISA is CE-marked in Europe for the quantitative determination of HMGB1 in human serum and plasma. Key opinion leaders widely consider it the gold standard in the field,[2] and its predecessor has been cited in more than 1,400 publications.

Parameter	Catalog No.	Method	Features	CE
HMGB1*	30164033	ELISA	Results in 4 hours Large dynamic range Validated for human serum and plasma	Yes

*Can be used for research purposes only for all mammals and various types of body fluids



HMGB1 biology by the current state of scientific knowledge

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*The combined use of assays, process script and open system instrument (e.g. EVOlyzer®, ThunderBolt®) has to be validated individually on site by each laboratory. Interchangeability is only valid within same lot numbers for the single components.

sIL-2R.

Interleukin-2 (IL-2) is a cytokine and key signaling molecule in the human immune system, regulating the activities of white blood cells responsible for immunity. It is primarily produced by antigen-stimulated CD4+ T cells, which secrete the soluble form of the interleukin-2 receptor (sIL-2R) upon activation. This results in elevated concentrations of sIL-2R in serum or plasma in patients suffering from a range of conditions, making it an extremely useful tool for clinicians to assess immune function.

Parameter	Catalog No.	Method	Features	CE
sIL-2R	30201813	ELISA	automatable* all reagents ready-to-use easy-to-use protocol	Yes

Histamine.

Histamine is the most important mediator substance in human. Studies demonstrate that histamine elicits immunomodulatory and proinflammatory effects through the differential expression of histamine receptors. It is present in an inactive bound form and is only released as required.

Tecan offers the Histamine ELISA for the quantitative determination of histamine in human EDTA plasma and urine. Relevant reference intervals are covered for easy clinical implementation.

Parameter	Catalog No.	Method	Features	CE
Histamine	RE59221	ELISA	Suitable for plasma and urinary samples	Yes

Product availability and regulatory status may vary across regions outside the EU depending on local country specific registration. Consult with your Tecan associate for further information.

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

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*The combined use of assays, process script and open system instrument (e.g. EVOlyzer®, ThunderBolt®) has to be validated individually on site by each laboratory. Interchangeability is only valid within same lot numbers for the single components. Automation protocol for validation available upon request.

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