

LC-MS PRODUCT LINE.

LC-MS KITS, CALIBRATORS AND CONTROLS.

SPOTLIGHT ON TECAN'S LC-MS INNOVATIONS.

LC-MS plays a crucial role in clinical laboratory medicine due to its ability to provide highly sensitive and specific analysis of a wide range of compounds.

Advancing Precision in Clinical Diagnostics

LC-MS offers capabilities in detecting and quantifying low concentrations of various analytes in complex biological samples and is therefore advantageous against traditional techniques. The versatility makes it applicable to various areas of clinical laboratory medicine, such as toxicology, pharmacology, and endocrinology. Monitoring drug levels, hormones, metabolites, and other biomarkers precisely is vital for making informed clinical decisions. It provides accurate and precise quantification of analytes over a wide dynamic range, making it suitable for both routine clinical assays and research applications. This accuracy is essential for making informed clinical decisions and ensuring patient safety. Furthermore, Analyte-Multiplexing offers the simultaneous analysis of multiple compounds in a single run. This provides efficiency and comprehensive profiling of biological samples are essential the understanding a patient's problems holistically. It is widely used in clinical diagnostics to measure specific biomarkers associated with diseases.

TECAN OFFERS A WIDE SELECTION OF LC-MS PRODUCTS COVERING A VARIETY OF APPLICATIONS AND USE CASES.

LC-MS Kits

Tecan LC-MS Kits offer the complete package. Each kit contains Calibrators, internal Standards and Controls, as well as all necessary buffers and eluents to run the LC-MS instrument. All consumables can be re-ordered separately as needed.

MS Enhances Hormone Diagnostics in Clinical Laboratories

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. 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. It can be quite challenging to measure similar-structured hormones like pregnenolone and progesterone using an immunoassay. MS offers deeper insights into a sample, breaking down the molecules and analyzing them by mass. 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.

Tec-Trace™

Tec-Trace products offer consistent and standardized calibration and controls across different laboratories and LC-MS systems.



ADVANCING PRECISION IN CLINICAL DIAGNOSTICS.

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TECAN LC-MS KITS IN THE FIELD.

A review conducted at the children's hospital in Erlangen (Kinder- und Jugendklinik, Universitätsklinikum Erlangen, Germany) focused on evaluating the clinical performance of the in-house method compared to a commercially available CE-IVDD kit solution, the Steroid Panel LC-MS from Tecan.

LC-MS also allows for simultaneous detection of various steroid classes with improved precision compared to traditional methods.

The Steroid Panel LC-MS offers such a comprehensive Kit for the measurement of 17 steroids hormones and dexamethasone in a routine clinical laboratory that will use the full capacity of Mass Spectrometer.

For both methods, clinical samples were measured for the determination of the concentration of testosterone, 17-OH-progesterone, progesterone, 11-deoxycortisol, 21-deoxycortisol, androstenedione, corticosterone, cortisone, cortisol, and 11-deoxycorticosterone.

Given the strong association between steroid hormones and endocrine disorders like adrenal insufficiency, Cushing's syndrome, and congenital adrenal hyperplasia e.g., steroid testing has become an integral part of diagnostic procedures and is recommended by many clinical practice guidelines. The advantage of the current Tecan Steroid Panel LC-MS is the comprehensive analysis of 17 circulating steroids and dexamethasone. This allows the measurement of a complete steroid profile for the patient and as such is an aid to diagnosis and

monitoring patients with suspected or confirmed endocrine disorders.

The results obtained with the commercial Steroid Panel LC-MS kit were in concordance with the established in-house method. Additionally, this assay allows the clinicians to gain a broader clinical picture of the patients, as it includes 17 steroids and dexamethasone which is helpful for the diagnosis and the understanding of the endocrine disorders.

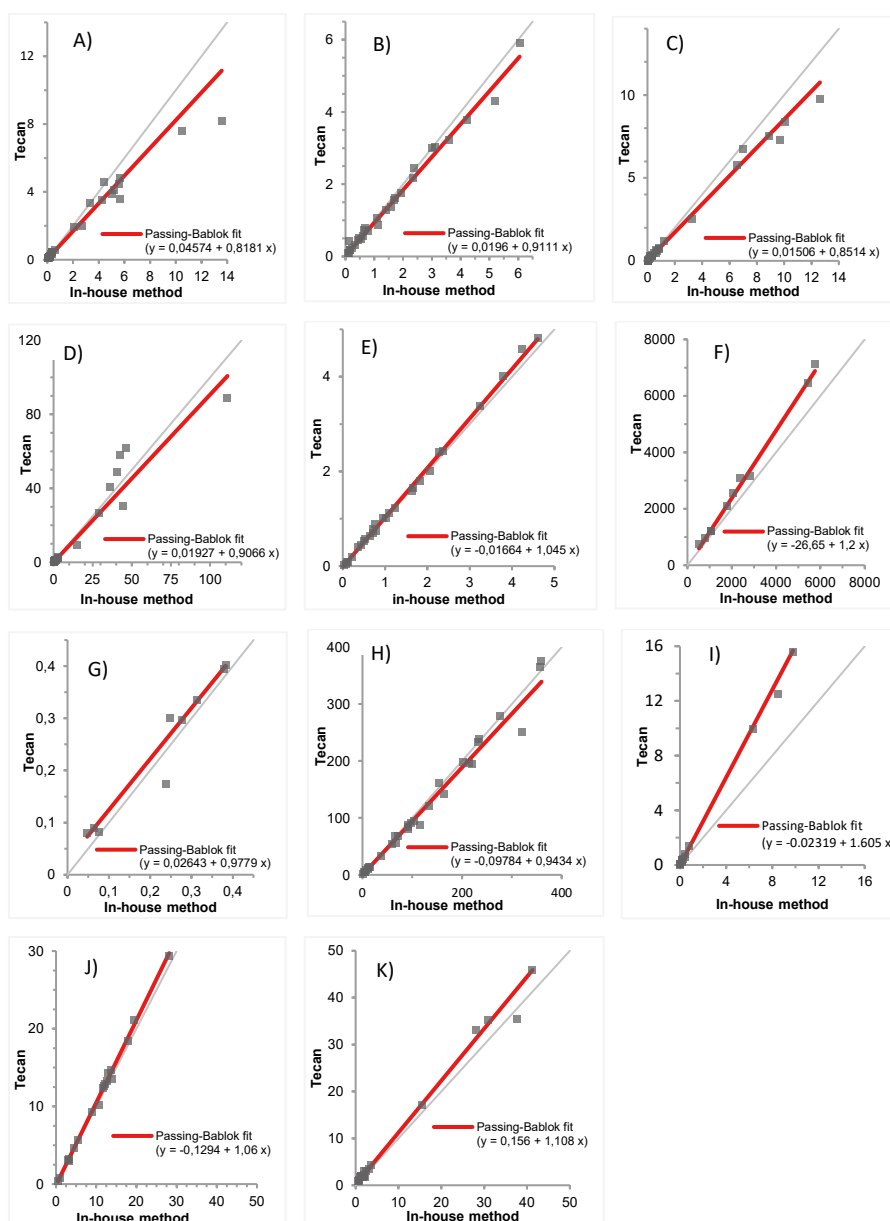


Figure: Method comparison of the in-house method to Steroid Panel LC-MS by Tecan. Passing-Bablok fit based on at least 9 samples is shown for each analyte separately; all values are in ng/mL: (A) Testosterone, (B) 17-Hydroxyprogesterone, (C) Progesterone, (D) 11-Deoxycortisol, (E) Androstenedione, (F) DHEAS, (G) Aldosterone, (H) Cortisol, (I) 11-Deoxycorticosterone, (J) Cortisone and (K) Corticosterone.



SKU 30191875

STERIOD PANEL LC-MS.

- **CE-IVDD**
- 18 steroids (17 Steroid hormones and Dexamethasone)
- 2 chromatographic runs guarantee the best possible performance of all analytes
- Only one sample preparation with 96-well SPE-plates
- Manual or automated sample preparation possible (e.g. Tecan Resolvex® A200)
- Total runtime (LC-MS): 10 min for 15 steroids, second injection for another 3 analytes with 6 min runtime
- One set of calibrators, quality controls and internal standards included and additional separately available
- Solid Phase Extraction (SPE) cartridges included, featuring the patented narrow bore extraction (NBE™) process
- Only a 250 µL sample is necessary
- All standards in one mix
- Individual isotopic standard for each analyte

Included in Kit

- Calibrators
- Internal Standard
- Controls
- Mobile Phase
- SPE Plates

For 96 Assays



Matrix

- Human Serum
- EDTA Plasma

Measured Components

- 11-Deoxycorticosterone
- 17-hydroxyprogesterone
- 21-Deoxycortisol
- Aldosterone
- Androstenedione
- Corticosterone
- Dexamethasone
- DHEA
- DHEA-S
- Dihydrotestosterone
- Cortisone
- Cortisol
- Progesterone
- 11-Deoxycortisol
- Testosterone
- 17-Hydroxypregnenolone
- Estrone
- Estradiol

Runtime

- 10 min for 15 steroids
- 6 min for the second injection for another 3 analytes



500 µL Plasma
250 µL Serum



Spike with Internal
Standard



SPE



Evaporate and
Reconstitute



Inject into LC-MS





SKU 30246150

CORTISOL & CORTISONE URINE DILUTE & SHOOT LC-MS.

- **CE-IVDD**
- Easy to use and fast method
- No SPE needed

Also available

Cortisol & Cortisone LC-MS

- **CE-IVDD**
- Using SPE to clean to inject a clean sample into the MS
- High throughput method



SKU 30225388

Included in Kit

- 6 Points calibrator set
- Internal Standard
- Mobile Phases
- Autosampler Wash Solution

For 300 Assays



Matrix

- Urine



Runtime

- Combined results in 5 min per assay



Measured Components

- Cortisone
- Cortisol



Centrifuge Sample



Collect 100 µL
Supernatant



Spike with Internal
Standard



Mix



Inject into LC-MS



SKU 30225389

METHYLMALONIC ACID LC-MS.

• CE-IVDD

- Methylmalonic Acid (as well as Homocysteine levels) can indicate Vitamine B12 deficiency
- Monitoring MMA helps to observe the effectiveness of Vitamin B12 supplementation or dietary interventions

- Robust, straight-forward LC Method

- Full chromatographic separation between Methylmalonic acid and Succinyl acid

Included in Kit

- 6 Points calibrator set
- Internal Standard
- Deproteinization Solution
- Mobile Phases
- Solvent
- Autosampler Wash Solution

For 300 Assays



Matrix

- Serum
- EDTA- and Heparin-plasma

Runtime

- 6 min per assay



Measured Components

- Methylmalonic Acid (MMA)



100 µL Sample



Spike with Internal Standard



Deproteinize & Vortex



Centrifuge and Evaporate



Inject into LC-MS



SKU 30225393

VITAMIN B1 & B6 LC-MS.

- **CE-IVDD**
- Optimal measure both as the ratio is important (holistic approach)
- Diagnosing conditions related to their deficiencies, such as Wernicke-Korsakoff syndrome or peripheral neuropathy
- Helps guiding supplement strategies to address deficiencies
- Especially helpful for patients with alcohol use disorder
- Easy workflow (compared to HPLC), no derivatization needed
- Cost- and time-effective
- One simple measurement in whole blood to quantify both analytes

Included in Kit

- 6 Points calibrator set
- Internal Standard
- Deproteinization Solution
- Mobile Phases
- Autosampler Wash Solution

For 300 Assays



Matrix

- Whole Blood

Runtime

- Combined results in 2 min per assay



Measured Components

- Vitamin B1 (Thiaminediphosphate - TDP)
- Vitamin B6 (Pyridoxal-5'-phosphate - PLP)



50 µL Sample



Spike with Internal Standard



Deproteinize & Mix



Centrifuge



Inject into LC-MS



SKU 30225389

METANEPHRINES LC-MS.

• CE-IVDD

- Best biomarkers for Pheochromocytoma, a rare endocrine tumor found in the adrenal glands
- Symptoms: Elevated blood pressure and heart rate, Headache, Sweating

- Robust HILIC method allows good separation of all three Metanephrine
- SPE extraction with only 10 mg bedding

Included in Kit

- 6 Points calibrator set
- Internal Standard
- Elution Solution
- Washing Solution
- Buffer
- Mobile Phases
- Autosampler Wash Solution

For 200 Assays



Matrix

- EDTA-Plasma



Runtime

- Combined results in 4 min per ass



Measured Components

- Metanephrine
- Normetanephrine
- 3-Methoxytyramine (3-MT)

500 μ L Sample

Spike with Internal Standard



SPE



Collect Eluat



Inject into LC-MS



SKU 30225392
(150 Assays)



SKU 30225391
(300 Assays)

VITAMIN A & E LC-MS.

• CE-IVDD

- Fat-soluble vitamins that perform different important functions
- Vitamin A: Crucial for vision, bone metabolism, and synthesis of steroid hormones. Deficiency can lead to night blindness, hair loss
- Vitamin E protects unsaturated fatty acids in the cell membranes and the LDL cholesterol from attacks by

reactive radicals Deficiency can lead to permanent joint pain

- Easy to use and easily automatable
- Only 25 μ L Sample
- Internal Standard is already included in Deproteinization solution
- 6 Level Calibrator

Included in Kit

- 6 Points calibrator set
- Deproteinization Solution with Internal Standard
- Mobile Phases
- Autosampler Wash Solution

For 300 Assays



Matrix

- Serum, Plasma



Runtime

- Combined results in 4 min per assay



Measured Components

- Vitamin A - Retinol
- Vitamin E - α -Tocopherol



25 μ L Sample



Add deproteinization
solution with Internal
Standard



Vortex



Centrifuge



Inject into LC-MS



SKU 30246638

PSYCHOTROPIC MEDICATION 1 LC-MS.

Tricyclic Antidepressants

- **CE-IVDD**
- Very easy sample preparation
- Tricyclic antidepressant (TCA) related and antipsychotics
- Internal Standard included in the Deproteinization Reagent

Included in Kit

- 6 Points calibrator set
- Deproteinization Solution with Internal Standard
- Mobile Phases
- Autosampler Wash Solution

For 300 Assays



Matrix

- Serum

Runtime

- Combined results in 7 min per assay



Measured Components

- Amitriptyline
- Nortriptyline
- Z-10-OH-nortriptyline
- E-10-OH-nortriptyline
- Clozapine
- Norclozapine
- Clomipramine
- Norclomipramine
- Imipramine
- Desipramine
- Zuclophenthixol



25 µL Sample



Add deproteinization
solution with Internal
Standard



Mix



Centrifuge



Inject into LC-MS



SKU 30246801

PSYCHOTROPIC MEDICATION 2 LC-MS.

Neuroleptics

• CE-IVDD

- Very easy sample preparation
- Internal Standard included in the Deproteinization Reagent
- Neuroleptic related: used for treatment of schizophrenia & schizoaffective disorder, bipolar disorder, aggression and psychotic symptoms in patients with moderate to severe Alzheimer's dementia, Parkinson's disease, etc.

Included in Kit

- 6 Points calibrator set
- Internal Standard
- Deproteinization Solution
- Mobile Phases
- Autosampler Wash Solution

For 300 Assays



Matrix

- Serum



Runtime

- Combined results in 7 min per assay



Measured Components

- Aripiprazole
- Clozapine
- Haloperidol
- Olanzapine
- Quetiapine
- Risperidone
- 9-OH-risperidone

25 μ L Sample

Add deproteinization solution with Internal Standard



Mix



Centrifuge



Inject into LC-MS



SKU 30246639

IMMUNOSUPPRESSANTS LC-MS.

• CE-IVDD

- Immunosuppressants need to be controlled for example at solid organ transplantations or stem cell transplantations
- Four widely used Immunosuppressant agents
- No need for (online) SPE or HPLC Guard columns

Included in Kit

- 6 Points calibrator set
- Deproteinization Solution with Internal Standard
- Mobile Phases
- Autosampler Wash Solution

For 300 Assays



Matrix

- Whole Blood



Runtime

- Combined results in 4 min per assay



Measured Components

- Tacrolimus
- Everolimus
- Sirolimus
- Cyclosporin-A



50 µL Sample



Add zinc sulphate



Add deproteinization
solution with Internal
Standard



Centrifuge



Inject into LC-MS

TEC-TRACE™ CALIBRATORS AND CONTROLS.

Tec-Trace™ from Tecan addresses this challenge by providing certified Controls and Calibrators specifically designed for Mass Spectrometry labs.

Whether it's steroids, vitamins, immunosuppressants, or drug monitoring, Tec-Trace offers a comprehensive range of products tailored to meet the requirements of well-established LC-MS tests. Calibrators and Controls are available separately, allowing labs to utilize only the necessary products for their specific applications.

With up to six calibrator levels and three different controls covering a broad spectrum of analytes, all presented in a dedicated matrix and lyophilized format, Tec-Trace streamlines workflow processes in the lab. By encompassing relevant concentration ranges, it instils the confidence necessary for accurate and reliable results.

Tec-Trace offers

- Trusted data generation and high reproducibility.
- Reliable and reproducible results.
- Verified lots with internal and external QC to guarantee comparability.
- 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

Steroid Panel Tec-Trace (30220283)

Just for this set, Calibrators, Controls as well as Internal Standards were combined into one single set.

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. They are provided in six concentrations plus the zero standard.

- Lyophilizates
- **Two aliquots**
 - › Minimizing aliquoting time
 - › Maximize lifetime
 - › Minimize cross-contamination

Tec-Trace™ Control Sets feature.

- CE IVDD
- In a dedicated matrix to cover matrix effects
- Lyophilizates
- **Three aliquots**
 - › Minimizing aliquoting time
 - › Maximize lifetime
 - › Minimize cross-contamination

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 before processing and allow measurement results to be normalized at the end.

PRODUCT ORDERING INFORMATION.

LC-MS Kits IVDD

Steroid Panel	30191875
Cortisol & Cortisone Urine Dilute&Shoot LC-MS	30246150
Cortisol & Cortisone LC-MS Kit 200 Assays	30225388
Immunosuppressants LC-MS Kit 300 Assays	30246639
Metanephrines LC-MS Kit 200 Assays	30225389
Methylmalonic Acid LC-MS Kit 300 Assays	30225390
Psychotropic Medication 2 LC-MS Kit 300 Assays	30246801
Psychotropic Medication 1 LC-MS Kit 300 Assays	30246638
Vitamin A & E LC-MS Kit 150 Assays	30225392
Vitamin A & E LC-MS Kit 300 Assays	30225391
Vitamin B1 & B6 LC-MS Kit 300 Assays	30225393

Tec-Trace Calibrators

Tec-Trace Cortisol Cortisone Calibrator Set LC-MS	30225360
Tec-Trace Cortisol Cortisone DiluteShoot Calibrator Set LC-MS	30246454
Tec-Trace Metanephrines Calibrator Set LC-MS	30225362
Tec-Trace Methylmalonic Acid Calibrator Set LC-MS	30225364
Tec-Trace Vitamin A and E Calibrator Set LC-MS	30225371
Tec-Trace Vitamin B1 and B6 Calibrator Set LC-MS	30225376
Tec-Trace Psychotropic Medication 1 Calibrator Set LC-MS	30246584
Tec-Trace Psychotropic Medication 2 Calibrator Set LC-MS	30246585
Tec-Trace Immunosuppressants Calibrator Set LC-MS	30246586

Tec-Trace Controls

Tec-Trace Cortisol Cortisone Control Set LC-MS	30225361
Tec-Trace Cortisol Cortisone DiluteShoot Control Set LC-MS	30246455
Tec-Trace Metanephrines Control Set LC-MS	30225363
Tec-Trace Methylmalonic Acid Control Set LC-MS	30225370
Tec-Trace Vitamin A and E Control Set LC-MS	30225375
Tec-Trace Vitamin B1 and B6 Control Set LC-MS	30225377
Tec-Trace Psychotropic Medication 1 Control Set LC-MS	30246589
Tec-Trace Psychotropic Medication 2 Control Set LC-MS	30246590
Tec-Trace Immunosuppressants Control Set LC-MS	30246591

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