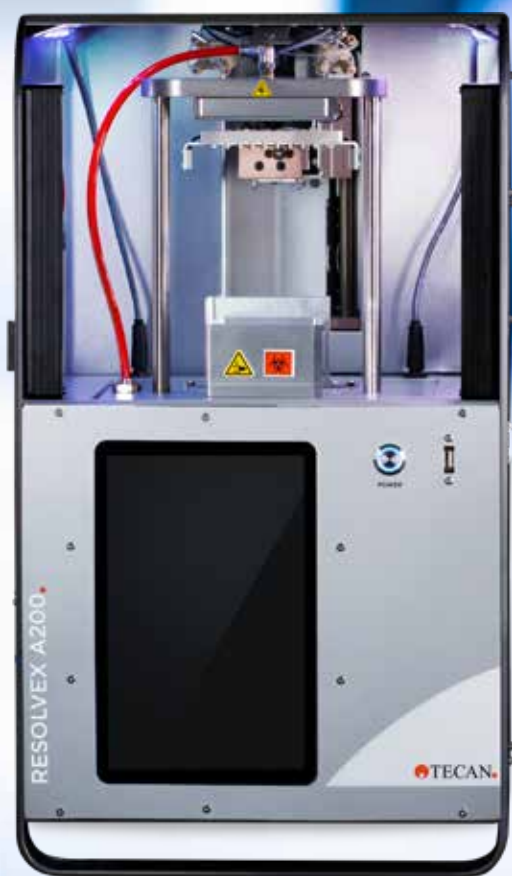


Technical Info Sheet

Steroid Panel LC-MS.



Steroid Panel LC-MS

A CE-IVD liquid chromatography-mass spectrometry (LC-MS) assay kit for the quantitative determination of steroid hormones (11-deoxycorticosterone, 11-deoxycortisol, 17-hydroxypregnenolone, 17-hydroxyprogesterone, 21-deoxycortisol, aldosterone, androstenedione, corticosterone, cortisol, cortisone, dehydroepiandrosterone, dehydroepiandrosterone sulfate, dihydrotestosterone, estradiol, estrone, progesterone, testosterone) and dexamethasone, or a subset thereof, in human serum and EDTA plasma.

The kit contains two boxes of the following approximate dimensions: 21 cm x 18 cm x 13 cm, and 15 cm x 13 cm x 7 cm, with a total weight of about 1.1 kg. All essential components,

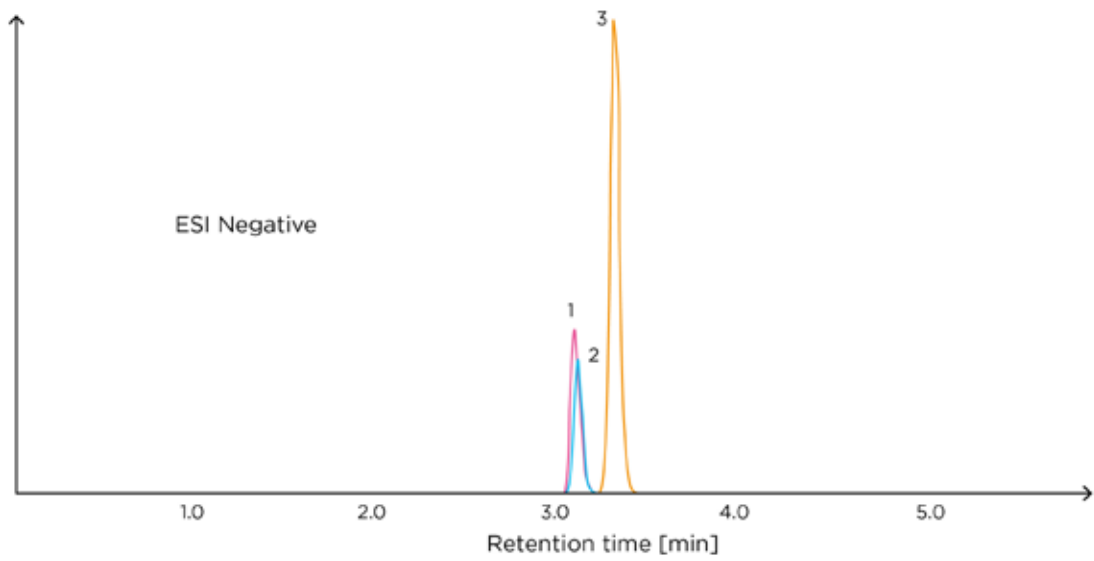
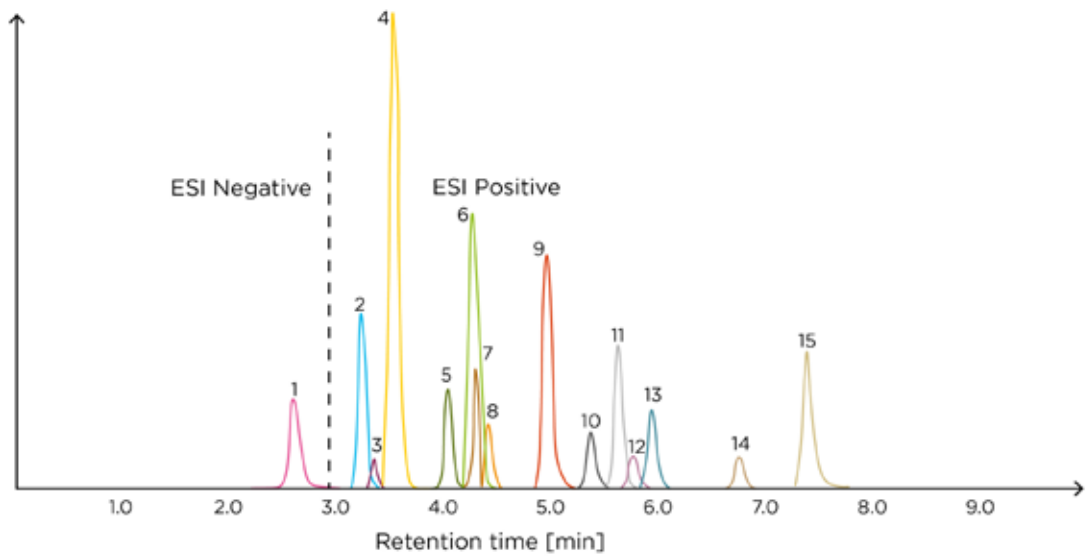
including solvent concentrates, SPE plate, injection plate, calibrators, controls, and internal standards are provided in it.

The kit is designed to be used both manually and semi-automatically. Automation protocols and scripts for use with Tecan Resolvex® A200 are available upon request.

Sample chromatogram

Two LC-MS runs are used to analyze all 18 steroids to balance throughput and sensitivity.



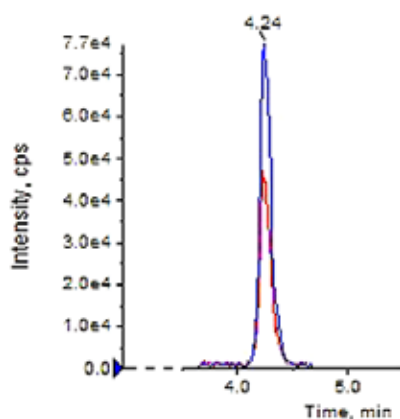
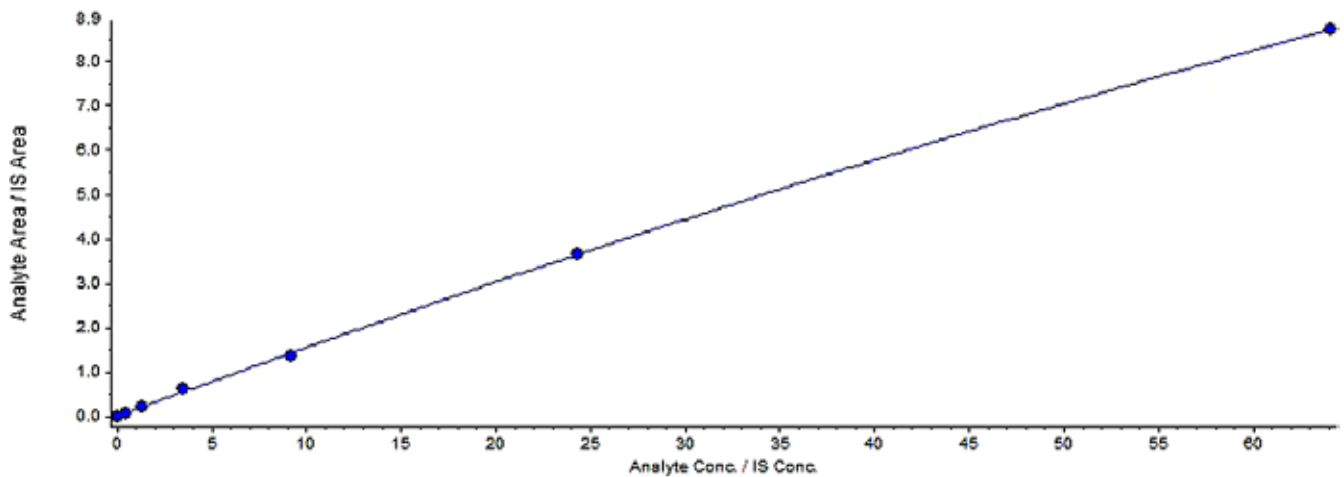


Run 1:

1. aldosterone
2. cortisone
3. dehydroepiandrosterone sulfate
4. cortisol
5. 21-deoxycortisol
6. corticosterone
7. dexamethasone
8. 11-deoxycortisol
9. androstenedione
10. 11-deoxycorticosterone
11. testosterone
12. dehydroepiandrosterone
13. 17-hydroxyprogesterone
14. dihydrotestosterone
15. progesterone

Run 2:

16. estrone
17. estradiol
18. 17-hydroxypregnenolon



Sample calibration curve of dexamethasone and trace showing the analyte and its internal standard.

Selected indications

Female health and fertility: androgen excess in females often causes symptoms of hyperandrogenism such as polycystic ovary syndrome (PCOS), hirsutism and amenorrhea, which could affect fertility [1]. Genetic disorders like congenital adrenal hyperplasia can also be a contributing factor. Sex hormone profiles including estrogens, androgens, and progestogens are essential to aid the diagnosis.

Pediatric endocrinology: premature adrenarche causes \geq 90% premature pubarche and is associated with increased risk for obesity, insulin resistance, and PCOS [2]. Severe forms often require androgen or estrogen testing to aid the diagnosis.

Primary aldosteronism: it is the most common form of secondary hypertension, and is currently drastically underdiagnosed and undertreated despite the readily available screening tools and therapies [3]. Accurate measurement of aldosterone plays a key role.

Cushing's syndrome: a disorder resulting from too much cortisol over a prolonged period of time, which is associated with diabetes and high blood pressure [4]. Dexamethasone suppression test is often prescribed for its diagnosis. A 2021 clinical guideline update has recommended measuring dexamethasone along with cortisol to improve test interpretability [4].

Literature

1. Yildiz, B. O. Diagnosis of hyperandrogenism: clinical criteria. *Best Practice & Research Clinical Endocrinology & Metabolism* 20, 167-176 (2006).
2. Rosenfield, R. L. Normal and Premature Adrenarche. *Endocrine Reviews* 42, 783-814 (2021).

3. Byrd, J. B., Turcu, A. F. & Auchus, R. J. Primary aldosteronism: Practical approach to diagnosis and management. *Circulation* 138, 823-835 (2018).
4. Fleseriu, M. et al. Consensus on diagnosis and management of Cushing's disease: a guideline update. *The Lancet Diabetes & Endocrinology* 9, 847-875 (2021).

Calibrator ranges

The kit covers relevant reference intervals and clinical decision limits. Calibrators are metrologically traceable to

SI units according to ISO 17511:2021. Concentrations are given in ng/mL in the table below.

Analyte	0	A	B	C	D	E	F
11-deoxycorticosterone	0.00	0.04	0.11	0.28	0.74	1.94	5.13
11-deoxycortisol	0.00	0.10	0.26	0.70	1.84	4.86	12.8
17-hydroxyprogesterone	0.00	0.10	0.26	0.70	1.84	4.86	12.8
21-deoxycortisol	0.00	0.10	0.26	0.70	1.84	4.86	12.8
aldosterone	0.00	0.10	0.22	0.46	0.99	2.14	4.59
androstenedione	0.00	0.10	0.26	0.70	1.84	4.86	12.2
corticosterone	0.00	0.30	0.79	2.09	5.52	14.6	38.5
cortisol	0.00	2.00	5.28	13.9	36.8	97.2	256
cortisone	0.00	0.50	1.32	3.48	9.20	24.3	64.1
dexamethasone	0.00	0.50	1.32	3.48	9.20	24.3	64.1
dehydroepiandrosterone	0.00	1.00	2.15	4.62	9.94	21.4	45.9
dehydroepiandrosterone sulfate	0.00	50.0	132	348	920	2429	6412
dihydrotestosterone	0.00	0.15	0.24	0.38	0.61	0.98	1.57
progesterone	0.00	0.10	0.26	0.70	1.84	4.86	12.8
testosterone	0.00	0.04	0.13	0.41	1.31	4.19	13.4
17-hydroxypregnenolone	0.00	0.30	0.79	2.09	5.52	14.57	38.47
estradiol	0.00	0.03	0.08	0.21	0.55	1.46	3.85
estrone	0.00	0.01	0.03	0.07	0.18	0.49	1.28

Analytical performance

Analyte	LoQ [ng/mL]	ULMI [ng/mL]
11-deoxycorticosterone	0.022	5.13
11-deoxycortisol	0.168	12.8
17-hydroxyprogesterone	0.092	12.8
21-deoxycortisol	0.098	12.8
aldosterone	0.070	4.59
androstenedione	0.057	12.8
corticosterone	0.265	38.5
cortisol	1.516	256
cortisone	0.748	64.1

Limit of quantitation (LoQ) and upper limit of measuring interval (ULMI) are determined according to CLSI guidelines. LoQ is established on a SCIEX™ 5500 Triple Quad™ by injecting 20 µL out of 100 µL reconstituted volume. In-house performance verification by each laboratory is recommended.

Different brands and models of mass spectrometry systems exhibit different intrinsic characteristics and sensitivities. For

Analyte	LoQ [ng/mL]	ULMI [ng/mL]
dexamethasone	0.620	64.1
dehydroepiandrosterone	0.621	45.9
dehydroepiandrosterone sulfate	61.2	3600
dihydrotestosterone	0.084	1.57
progesterone	0.080	12.8
testosterone	0.040	13.4
17-hydroxypregnenolone	0.166	38.5
estradiol	0.017	3.85
estrone	0.006	1.28

example, the SCIEX Triple Quad 3500, 4500, 5500+, 6500+, and 7500 systems all belong to the SCIEX triple quadrupole lineup but have different performance characteristics.

Consequently, analytical performance of the kit will vary depending on the exact instruments and configurations used.

Consultation with Tecan prior to deployment is recommended.

Quality controls

Each kit has lot specific controls that allow the user to evaluate the validity of LC-MS measurements. One example QC certificate is shown below.



Quality Control Certificate

Steroid-Panel LC-MS

REF 30191875

LOT MST113



2023-05-31

YYYY-MM-DD

Final Release Results:

	CONTROL L			
	Concentration	Acceptable range		
	found ng/mL	lower limit ng/mL	target value ng/mL	upper limit ng/mL
11-Deoxycorticosterone	0,184	0,134	0,192	0,250
11-Deoxycortisol	0,473	0,310	0,477	0,644
21-Deoxycortisol	0,469	0,337	0,482	0,627
Androstenedione	0,484	0,331	0,473	0,615
Cortisol	9,74	6,69	9,56	12,43
Cortisone	2,37	1,68	2,40	3,13
Progesterone	0,458	0,326	0,466	0,606
Testosterone	0,232	0,167	0,238	0,309
17 α -Hydroxyprogesterone	0,462	0,331	0,473	0,615
Dihydrotestosterone	0,316	0,223	0,319	0,415
Corticosterone	1,46	1,02	1,46	1,89
Dexamethasone	2,38	1,63	2,33	3,03
Dehydroepiandrosterone	3,40	2,13	3,27	4,42
Dehydroepiandrosterone-3-sulfate	256	165	253	342
Aldosterone	0,348	0,242	0,346	0,449
17 β -Estradiol	0,144	0,101	0,145	0,188
Estrone	0,049	0,034	0,049	0,063
17 α -Hydroxypregnenolone	1,45	1,02	1,46	1,89

	CONTROL H			
	Concentration	Acceptable range		
	found ng/mL	lower limit ng/mL	target value ng/mL	upper limit ng/mL
	3,49	2,46	3,51	4,57
	8,98	5,67	8,73	11,78
	8,71	6,16	8,79	11,43
	8,72	6,07	8,67	11,28
	176	119	170	221
	42,7	29,3	41,8	54,4
	8,54	6,05	8,65	11,24
	9,16	6,27	8,96	11,65
	8,55	6,08	8,69	11,30
	1,298	0,911	1,301	1,692
	25,9	18,2	26,1	33,9
	42,5	30,0	42,9	55,8
	38,2	23,6	36,3	49,0
	4420	2802	4310	5819
	3,28	2,30	3,28	4,26
	2,61	1,85	2,64	3,44
	0,884	0,613	0,875	1,138
	27,8	18,9	27,0	35,1

Comparison to certified reference materials

Certified reference materials with concentration values assigned by reference measurement procedures (RMPs) were measured with the Steroid Panel LC-MS kit. The measured results closely match certified target values and are within 95 percentiles for all analytes.

Analyte	Sample	Mass Concentration ng/mL		
		Target	Lower 95%	Upper 95%
Testosterone	NIST Fe-male	0.323	0.318	0.328
	Tecan	0.320		
	NIST Male	5.808	5.718	5.898
	Tecan	5.815		
Progesterone	NIST Fe-male	2.63	2.31	2.96
	Tecan	2.37		
	NIST Male	0.0421	0.0361	0.048
	Tecan	0.0402		

NIST: United States National Institute of Standards and Technologies

JRC: European Commission Joint Research Centre

Analyte	Sample	Mass Concentration ng/mL		
		Target	Lower 95%	Upper 95%
Estradiol	JRC Low	0.114	0.109	0.119
	Tecan	0.113		
	JRC Medium	0.69	0.65	0.73
	Tecan	0.70		
Cortisol	JRC High	1.34	1.27	1.41
	Tecan	1.34		
	JRC Low	98.8	96.8	100.8
	Tecan	99.2		
Progesterone	JRC High	277	272	282
	Tecan	274		
	JRC	8.5	8.1	8.9
	Tecan	8.7		

Disclaimers

- 1) Product and solution may not be available in all territories. Please contact your local Tecan partner for more information.
- 2) The combined use of the Steroid Panel LC-MS kit, process script and instrument has to be validated individually on site by each laboratory.
- 3) Complete solution includes XBridge BEH C8 Column, 130 Å, 3.5 µm, 2.1 mm x 100 mm, manufactured by Waters™, distributed by

Tecan.

- 4) All pictures of the products are for illustration purpose only. Actual products may vary due to product enhancement.
- 5) In the USA, the product is for research use only and not for use in diagnostic procedures.
- 6) The referenced SCIEX and Triple Quad are trademarks of AB Sciex Pte. Ltd. Waters is a trademark of Waters Corporation.

Contact your local Tecan representative for more information and a dedicated offer!

All products are only available for sale to laboratory professionals and may not be available in all countries.

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