

Instructions for Use



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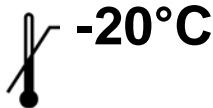
Steroid Panel Tec-Trace

The Steroid Panel Tec-Trace includes one set of calibrators, quality controls and internal standard and is intended to be used as an aid in the analysis of 17 steroid hormones and dexamethasone.

REF **30220283**



1 Set



For research use only.
Not for use in diagnostic procedures.



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Always there for you



REVISION HISTORY OF INSTRUCTIONS FOR USE**Changes from the previous version 2022-12 to actual version 2024-10**

Chapter 7 Update

Chapter 9 Update and additional data

1. INTENDED USE

The Steroid Panel Tec-Trace includes one set of calibrators, quality controls and internal standard. It is intended to be used as an aid in the analysis of 17 steroid hormones and dexamethasone, especially using LC-MS methods. The 17 steroid hormones are:

11-deoxycorticosterone, 11-deoxycortisol, 17-hydroxyprogesterone, 21-deoxycortisol, aldosterone, androstenedione, corticosterone, cortisol, cortisone, dehydroepiandrosterone, dehydroepiandrosterone sulfate, dihydrotestosterone, progesterone, testosterone, 17-hydroxypregnenolone, estradiol and estrone.

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2. SUMMARY AND EXPLANATION

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.

Steroid Panel Tec-Trace can be used for a subset of the 17 steroid hormones and dexamethasone.

3. WARNINGS AND PRECAUTIONS

1. For research use only. Not for use in diagnostic procedures. For professional use only.
2. Read the instructions completely and carefully. Use the valid version of the package insert provided with the kit. Be sure that everything is understood.
3. In case of severe damage of the kit package please contact IBL or your supplier in written form, latest one week after receiving the kit. Do not use damaged components in test runs, but keep safe for complaint related issues.
4. Broken glass may cause injury. Handle glass vessels with caution.
5. Obey lot number and expiry date. Do not mix reagents of different lots. Do not use expired reagents.
6. Follow good laboratory practice and safety guidelines. Wear lab coats, disposable gloves and protective glasses where necessary.
7. Reagents of this kit containing hazardous material may cause eye and skin irritations. See MATERIALS SUPPLIED and labels for details. Safety Data Sheets for this product are available on the IBL-Homepage or upon request directly from IBL.
8. Chemicals and prepared, used, unused or expired reagents have to be treated as hazardous waste according to national biohazard and safety guidelines or regulations.
9. The cleaning staff should be guided by the professionals regarding potential hazards and handling.
10. Avoid contact with solutions provided. They may cause skin irritations and burns.
11. All reagents of this kit containing human serum or plasma have been tested and were found negative for anti-HIV I/II, HBsAg and anti-HCV. However, a presence of these or other infectious agents cannot be excluded absolutely. For this reason reagents should be treated as potential biohazards in use and for disposal.

4. STORAGE AND STABILITY




The kit is shipped at ambient temperature and should be stored at $\leq -20^{\circ}\text{C}$

For components included see MATERIALS SUPPLIED

Keep away from heat or direct sun light. The storage and stability of prepared reagents is stated in the corresponding chapters.

The Internal Standard is stable up to 6 months after the first opening (not exceeding the expiry date) when stored at indicated storage temperature. The unopened reagents are stable until the expiry date indicated.

5. MATERIALS SUPPLIED

Storage	Quantity	Symbol	Origin	Component
$\leq -20^{\circ}\text{C}$	1x 6x 1.3 mL	CAL A-F LYO		Standard A-F , lyophilized Concentrations see CONCENTRATIONS OF STANDARDS.
	1x 1.3 mL	CAL ZERO LYO		Standard Zero , lyophilized Concentrations see CONCENTRATIONS OF STANDARDS.
	1x 5.4 mL	INT STD		Internal Standard , Ready to use. Contains: Methanol Concentrations see CONCENTRATIONS OF STANDARDS.
	1x 2x 1.3 mL	CONTROL H LYO CONTROL L LYO		Control High and Control Low , lyophilized Concentrations / acceptable ranges see QC certificate.

6. MATERIALS REQUIRED BUT NOT SUPPLIED

1. Water (LC-MS grade)
2. Pipettes
3. Timer
4. Roller mixer

7. PROCEDURE NOTES

Avoid contamination of reagents.

Use new disposable plastic pipette tips for each component and specimen.

Do not interchange caps.

Always cap not used vials.

7.1. Preparation of lyophilized components

Dissolve component	with	Diluent	Remarks	Storage	Stability
CAL A-F LYO	1.3 mL	Water (LC-MS grade)	Mix 15 minutes on a roller mixer.	≤ - 20°C Aliquots*	6 months
CAL ZERO LYO	1.3 mL	Water (LC-MS grade)	Mix 15 minutes on a roller mixer.	≤ - 20°C Aliquots*	6 months
CONTROL H LYO	1.3 mL	Water (LC-MS grade)	Mix 15 minutes on a roller mixer.	≤ - 20°C Aliquots*	6 months
CONTROL L LYO	1.3 mL	Water (LC-MS grade)	Mix 15 minutes on a roller mixer.	≤ - 20°C Aliquots*	6 months

* It is recommended to limit the number of freeze /thaw cycles to a maximum of 3

8. QUALITY CONTROL

The user must strictly adhere to the rules of GLP (Good Laboratory Practice) or comparable standards/laws. All kit controls must be found within the acceptable ranges as stated in the QC certificate. Each laboratory should use known samples as further controls.

9. CONCENTRATIONS OF STANDARDS

In the following the concentrations of standards and internal standards are listed in [ng/mL] and [nmol/L]. To check for correct conditions during the quantification experiment and calculation method please run the two controls (high and low) in the beginning of the batch.

Concentration Standards [ng/mL]

Analyte	0	A	B	C	D	E	F	Internal Standard
11-Deoxycorticosterone	0.00	0.04	0.11	0.28	0.74	1.94	5.13	1.00
11-Deoxycortisol	0.00	0.10	0.26	0.70	1.84	4.86	12.8	2.00
17-Hydroxyprogesterone	0.00	0.10	0.26	0.70	1.84	4.86	12.8	2.00
21-Deoxycortisol	0.00	0.10	0.26	0.70	1.84	4.86	12.8	3.00
Aldosterone	0.00	0.10	0.22	0.46	0.99	2.14	4.59	3.00
Androstenedione	0.00	0.10	0.26	0.70	1.84	4.86	12.2	2.00
Corticosterone	0.00	0.30	0.79	2.09	5.52	14.6	38.5	5.00
Cortisol	0.00	2.00	5.28	13.9	36.8	97.2	256	25.0
Cortisone	0.00	0.50	1.32	3.48	9.20	24.3	64.1	5.00
Dexamethasone	0.00	0.50	1.32	3.48	9.20	24.3	64.1	20.0
Dehydroepiandrosterone	0.00	1.00	2.15	4.62	9.94	21.4	45.9	50.0
Dehydroepiandrosterone sulfate	0.00	50.0	132	348	920	2429	6412	500
Dihydrotestosterone	0.00	0.15	0.24	0.38	0.61	0.98	1.57	4.00
Progesterone	0.00	0.10	0.26	0.70	1.84	4.86	12.8	2.00
Testosterone	0.00	0.04	0.13	0.41	1.31	4.19	13.4	1.00
17-Hydroxypregnenolone	0.00	0.30	0.79	2.09	5.52	14.57	38.47	4.00
Estradiol	0.00	0.03	0.08	0.21	0.55	1.46	3.85	1.00
Estrone	0.00	0.01	0.03	0.07	0.18	0.49	1.28	1.00

Concentration Standards [nmol/L]

Analyte	0	A	B	C	D	E	F	Internal Standard
11-Deoxycorticosterone	0.00	0.121	0.333	0.848	2.24	5.88	15.5	3.03
11-Deoxycortisol	0.00	0.289	0.751	2.02	5.32	14.0	37.0	5.78
17-Hydroxyprogesterone	0.00	0.303	0.788	2.12	5.58	14.7	38.8	6.06
21-Deoxycortisol	0.00	0.289	0.751	2.02	5.32	14.0	37.0	8.67
Aldosterone	0.00	0.277	0.609	1.27	2.74	5.93	12.7	8.31
Androstenedione	0.00	0.349	0.907	2.44	6.42	17.0	42.6	6.98
Corticosterone	0.00	0.867	2.28	6.04	16.0	42.2	111	14.4
Cortisol	0.00	5.52	14.6	38.4	102	268	707	69.0
Cortisone	0.00	1.39	3.66	9.64	25.5	67.3	178	13.9
Dexamethasone	0.00	1.28	3.37	8.87	23.5	62.0	163	51.0
Dehydroepiandrosterone	0.00	3.47	7.46	16.0	34.5	74.3	159	174
Dehydroepiandrosterone sulfate	0.00	136	358	943	2493	6583	17377	1355
Dihydrotestosterone	0.00	0.516	0.826	1.31	2.10	3.37	5.40	13.8
Progesterone	0.00	0.318	0.827	2.23	5.85	15.5	40.7	6.36
Testosterone	0.00	0.139	0.451	1.42	4.55	14.5	46.5	3.47
17-Hydroxypregnenolone	0.00	0.903	2.38	6.29	16.6	43.9	116	12.0
Estradiol	0.00	0.110	0.294	0.771	2.02	5.36	14.1	3.67
Estrone	0.00	0.037	0.111	0.259	0.666	1.81	4.74	3.70

The concentrations and acceptable ranges for Control High and Control Low are to be found in the provided lot-specific QC certificate.

10. METROLOGICAL TRACEABILITY

The concentrations assigned to kit calibrators and controls are metrologically traceable to SI unit ng/mL through an unbroken chain of calibration from Certified Reference Material to the kit calibrators and controls according to ISO 17511:2021.

The combined uncertainty of concentration for each analyte assigned to kit calibrators and controls is assessed as the result of all single uncertainties of measurement procedures used in the calibration hierarchy.

Analyte	Combined uncertainty of concentration assigned to kit calibrators and controls
11-Deoxycorticosterone	4.3 %
11-Deoxycortisol	4.3 %
17-Hydroxyprogesterone	4.3 %
21-Deoxycortisol	4.3 %
Aldosterone	3.0 %
Androstenedione	4.3 %
Corticosterone	4.3 %
Cortisol	4.3 %
Cortisone	4.3 %
Dexamethasone	4.3 %
Dehydroepiandrosterone	3.1 %
Dehydroepiandrosterone sulfate	4.3 %
Dihydrotestosterone	3.1 %
Progesterone	4.3 %
Testosterone	3.1 %
17-Hydroxypregnenolone	4.3 %
Estradiol	4.3 %
Estrone	4.3 %

Symbols / Symbole / Symboles / Símbolos / Simboli / Símbolos / Σύμβολα

	Cat.-No.: / Kat.-Nr.: / No.- Cat.: / Cat.-No.: / N.-Cat.: / N.º Cat.: / Αριθμός-Κατ.:
	Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lotto n.: / Lote N.º: / Αριθμός -Παραγωγή:
	Use by: / Verwendbar bis: / Utiliser à: / Usado por: / Da utilizzare entro:/ Usar até: / Χρησιμοποιείται από:
	No. of Tests: / Kitgröße: / Nb. de Tests: / No. de Determ.: / Quantità dei tests: / N.º de Testes: / Αριθμός εξετάσεων:
	Concentrate / Konzentrat / Concentré / Concentrar / Concentrato / Concentrado / Συμπύκνωμα
	Lyophilized / Lyophilisat / Lyophilisé / Liofilizado / Liofilizzato / Liofilizado / Λυοφιλοσμένο
	In Vitro Diagnostic Medical Device / In-vitro-Diagnostikum / Appareil Médical pour Diagnostics In Vitro / Dispositivo Médico para Diagnóstico In Vitro / Dispositivo Medico Diagnostico In vitro / Equipamento Médico de Diagnóstico In Vitro / Ιατρική συσκευή για In-Vitro Διάγνωση
	Contains biological material of human origin / Enthält biologisches Material menschlichen Ursprungs / Contient une substance biologique d'origine humaine / Contiene material biológico de origen humano / Contiene materiale biologico di origine umana / Contém material biológico de origem humana / Περιέχει βιολογικό υλικό ανθρώπινης προέλευσης
	Contains biological material of animal origin / Enthält biologisches Material tierischen Ursprungs / Contient une substance biologique d'origine animale / Contiene material biológico de origen animal / Contiene materiale biologico di origine animale / Contém material biológico de origem animal / Περιέχει βιολογικό υλικό ζωικής προέλευσης
	Unique Device Identification / Eindeutige Geräteerkennung / Identifiant de dispositif unique / Identificación única de producto / Identificatore univoco del dispositivo / Identificador de dispositivo único / Μοναδικός αναγνωριστικός κωδικός προϊόντος
	Read instructions before use / Arbeitsanleitung lesen / Lire la fiche technique avant emploi / Lea las instrucciones antes de usar / Leggere le istruzioni prima dell'uso / Ler as instruções antes de usar / Διαβάστε τις οδηγίες πριν την χρήση
	Keep away from heat or direct sun light / Vor Hitze und direkter Sonneneinstrahlung schützen / Garder à l'abri de la chaleur et de toute exposition lumineuse / Manténgase alejado del calor o la luz solar directa / Non esporre ai raggi solari / Manter longe do calor ou luz solar directa / Να φυλάσσεται μακριά από θερμότητα και άμεση επαφή με το φως του ηλίου
	Upper limit of temperature / Oberer Temperaturgrenzwert / Limite supérieure de température / Limite superiore di temperatura / Límite superior de temperatura / Limite superior de temperatura / Ανώτατο όριο θερμοκρασίας
	Store at: / Lagern bei: / Stocker à: / Almacene a: / Armazemar a: / Conservare a: / Armazemar em: / Αποθήκευση στους:
	Store at: 2 - 8°C / Lagern bei: 2 - 8°C / Stocker à: 2 - 8°C / Almacene a: 2 - 8°C / Armazemar a: 2 - 8°C / Conservare a: 2-8°C / Armazemar em: 2-8°C / Αποθήκευση στους: 2-8°C
	Manufacturer: / Hersteller: / Fabricant: / Productor: / Fabricante: / Fabbricante: / Παραγωγός:
	Distributor: / Distributor: / Distributeur: / Distributor: / Distributore: / Distribuidor: / Διανομέας:
	Caution! / Vorsicht! / Attention! / ¡Precaución! / Attenzione! / Cuidado! / Προσοχή!
	Symbols of the kit components see MATERIALS SUPPLIED. Die Symbole der Komponenten sind im Kapitel KOMPONENTEN DES KITS beschrieben. Voir MATERIEL FOURNI pour les symboles des composants du kit. Símbolos de los componentes del juego de reactivos, vea MATERIALES SUMINISTRADOS. Per i simboli dei componenti del kit si veda COMPONENTI DEL KIT. Para símbolos dos componentes do kit ver MATERIAIS FORNECIDOS. Για τα σύμβολα των συστατικών του kit συμβουλευτείτε το ΠΑΡΕΧΟΜΕΝΑ ΥΛΙΚΑ.

Generic table, not all symbols are present in the product

COMPLAINTS: Complaints may be submitted initially written or vocal. Subsequently they need to be filed including the test performance and results in writing in case of analytical reasons.

WARRANTY: The product is warranted to be free from material defects within the specific shelf life and to comply with product specifications delivered with the product. The product must be used according to the Intended use, all instructions given in the instructions for use and within the product specific shelf life. Any modification of the test procedure or exchange or mixing of components of different lots could negatively affect the results. These cases invalidate any claim for replacement.

LIMITATION OF LIABILITY: IN ALL CIRCUMSTANCES THE EXTENT OF MANUFACTURER'S LIABILITY IS LIMITED TO THE PURCHASE PRICE OF THE KIT(S) IN QUESTION. IN NO EVENT SHALL MANUFACTURER BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING DAMAGES FOR LOST PROFITS, LOST SALES, INJURY TO PERSON OR PROPERTY OR ANY OTHER INCIDENTAL OR CONSEQUENTIAL LOSS.

The labelling of hazardous substances is according to European directive.

For further country-specific classifications, please refer to the corresponding safety data sheet.



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