

## MassTrak Endocrine Steroid Calibrator Set

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### I. INTRODUCTION

Thank you for purchasing Waters MassTrak™ Endocrine Steroid Calibrator Set.

A list of applicable symbols used in this Instructions for Use (IFU) document can be found in Section II. The MassTrak Endocrine Steroid Calibrator Set intended use can be found in Section III. The product description can be found in Section IV. Expanded Uncertainty in section V. Warnings and precautions are provided in Section VI. Instructions for using the MassTrak Endocrine Steroid Calibrator Set can be found in Section VII. Entering Calibration COA calibrator concentrations in Section VIII. Limitations of the procedure is in section IX. Ordering information is provided in Section X.

For additional product information, visit:  
[waters.com/MassTrak](http://waters.com/MassTrak)



## II. APPLICABLE SYMBOLS

Table 1 provides a list of symbols used in the labelling along with the definition for each symbol.















Symbol	Definition
	Confirms that a manufactured product complies with all applicable European community directives
	For <i>in vitro</i> diagnostic use
	Biological risk
	Contents
	Damaged packaged instructions
	Caution, risk of danger
	Store below -10 °C
	Store between 2 °C to 8 °C
	Authorized representative in the European community
	Consult instructions for use
	Legal manufacturer
	Expiration date
	Lot number
	Part number

Table 1. Applicable symbols.

## III. INTENDED USE/INTENDED PURPOSE

The MassTrak Endocrine Steroid Calibrator Set is intended to be used in a clinical biochemistry laboratory by trained professionals for the quantitative determination of steroids (mineralocorticoids, androgens, glucocorticoids, and progestogens) in human serum to aid diagnosis of steroid related disorders. The MassTrak Endocrine Steroid Calibrator Set are used to establish a calibration curve which is used to interpolate the steroid concentrations using liquid chromatography – tandem mass spectrometry (LC-MS/MS) systems.


MassTrak



## IV. PRODUCT DESCRIPTION

Part A is a detailed description of the contents of the MassTrak Endocrine Steroid Calibrator Set. Part B provides a description of the metrological traceability associated with the calibrator set, manufactured to enable labs to achieve ISO 15189 certification.

### A) CONTENTS

 The Waters MassTrak Endocrine Steroid Calibrator Set [one box] contains 7 matrix-matched calibrators in human serum and labeling. Contents include:

- Calibrator 0 (Cal. 0)
- Calibrator 1 (Cal. 1)
- Calibrator 2 (Cal. 2)
- Calibrator 3 (Cal. 3)
- Calibrator 4 (Cal. 4)
- Calibrator 5 (Cal. 5)
- Calibrator 6 (Cal. 6)
- Insert Card referencing the IFU (Instructions for Use) SDS (Safety Data Sheets) and COA (Certification of Analysis)

Calibrators 1–6 contain the following analytes:

- Progesterone
- Testosterone
- Androstenedione
- Cortisol
- Corticosterone
- 11-deoxycortisol
- 21-deoxycortisol
- 11-deoxycorticosterone

- 17-OHP (17-hydroxyprogesterone)
- DHT (Dihydrotestosterone)
- DHEAS (dehydroepiandrosterone sulfate)
- DHEA (dehydroepiandrosterone)

The concentration for each analyte across calibrators 1–6 spans the clinically relevant analytical range. The target analyte concentrations in each calibrator are provided in Table 2. Table 3 provides the target specification range for each calibrator. Cal. 0 is blank human serum. The calibrators are supplied lyophilized in glass vials and must be reconstituted with 2 mL water prior to use (see Section VI).

Analyte	Concentration (ng/mL)					
	Cal. 1	Cal. 2	Cal. 3	Cal. 4	Cal. 5	Cal. 6
Progesterone	0.025	0.075	0.5	5	30	50
Testosterone	0.01	0.03	0.2	2	12	20
Androstenedione	0.05	0.15	0.5	5	30	50
Cortisol	1	3	10	50	300	500
Corticosterone	0.05	0.15	0.5	5	30	50
11-deoxycortisol	0.05	0.15	0.5	5	30	50
21-deoxycortisol	0.05	0.15	0.5	5	30	50
11-deoxycorticosterone	0.01	0.03	0.2	2	12	20
17-OHP (17-hydroxyprogesterone)	0.05	0.15	1	10	60	100
DHT (dihydrotestosterone)	0.03	0.09	0.3	0.75	1.5	2.5
DHEAS (dehydroepiandrosterone sulfate)	25	75	250	1250	7500	12500
DHEA (dehydroepiandrosterone)	0.2	0.6	1	5	30	50

Table 2. Target analyte concentrations.

Notes: Cal. 0 is not listed in the table above. Cal. 0 is blank human serum. See the certificate of analysis (COA) for lot-specific calibrator concentration levels.

To request a paper copy of COA or Instructions for Use contact [Certofanalysis@waters.com](mailto:Certofanalysis@waters.com), providing the product part number and lot/batch number.

Analyte	Cal. 1	Cal. 2	Cal. 3	Cal. 4	Cal. 5	Cal. 6
<b>Target specification range</b>	±30%	±30%	±30%	±30%	±30%	±20%

Table 3. Target specification range.

## B) TRACEABILITY

The MassTrak Endocrine Steroid Calibrators were assessed for metrological traceability and certified reference materials to identify the highest order metrological traceability that is available.

Reference Method Procedures are available for the following 4 analytes:

1. Cortisol (ID/GC/MS, NRMeth 8)
2. Testosterone (ID/GC/MS, NRMeth 7)
3. 17-hydroxyprogesterone (ID/GC/MS, NRMeth 39)
4. Progesterone (ID/GC/MS, NRMeth 58)

Cortisol and Testosterone are value assigned by University of Ghent measurement procedures.

Progesterone and 17-hydroxyprogesterone are value assigned by RfB (Germany) measurement procedures.

The remaining 8 steroids (Androstenedione, DHEAS, DHEA, DHT, 21-deoxycortisol, 11-deoxycortisol, Corticosterone, and 11-Deoxycorticosterone) are gravimetrically manufactured from certified reference material in stripped Serum, the highest order material available. These are value assigned.

The values assigned are value confirmed with Independent QCs and Proficiency Testing Schemes. NEQAS: DHEAS, Cortisol, Testosterone, Androstenedione, Progesterone, and 17-OH progesterone.

## V. EXPANDED UNCERTAINTY

The measurement uncertainty for the MassTrak Endocrine Steroid Calibrator Set were calculated using the following measurement data: accuracy, precision, the expanded uncertainty of material and laboratory equipment used.

Steroid	Progesterone		Testosterone		11-deoxycorticosterone		Cortisol		DHEA		DHEAS	
	Conc.	Expanded uncertainty	Conc.	Expanded uncertainty	Conc.	Expanded uncertainty	Conc.	Expanded uncertainty	Conc.	Expanded uncertainty	Conc.	Expanded uncertainty
ng/mL												
Cal. 1	0.025	0.0011	0.01	0.0002	0.01	0.0004	1.00	0.0173	0.20	0.0101	25.00	1.1688
Cal. 2	0.075	0.0015	0.03	0.0006	0.03	0.0007	3.00	0.0493	0.60	0.0172	75.00	1.5012
Cal. 3	0.50	0.0034	0.20	0.0053	0.20	0.0025	10.00	1.0327	1.00	0.0320	250.00	3.0546
Cal. 4	5.00	0.1837	2.00	0.0372	2.0	0.0124	50.00	6.1919	5.00	0.1182	1250.00	8.5104
Cal. 5	30.00	0.3419	12.00	0.5925	12.0	0.1304	300.00	11.8258	30.00	0.3239	7500.00	15.8771
Cal. 6	50.00	0.5808	20.00	0.5993	20.0	0.2652	500.00	12.5135	50.00	1.2027	12500.00	51.1944

Steroid	Androstenedione		Corticosterone		11-deoxycortisol		21-deoxycortisol		17-OHP		DHT	
	Conc.	Expanded uncertainty	Conc.	Expanded uncertainty	Conc.	Expanded uncertainty	Conc.	Expanded uncertainty	Conc.	Expanded uncertainty	Conc.	Expanded uncertainty
ng/mL												
Cal. 1	0.05	0.0009	0.05	0.0008	0.05	0.0008	0.05	0.0021	0.05	0.0011	0.03	0.0015
Cal. 2	0.15	0.0016	0.15	0.0032	0.15	0.0018	0.15	0.0044	0.15	0.0014	0.09	0.0027
Cal. 3	0.50	0.0004	0.50	0.0090	0.50	0.0051	0.50	0.0183	1.00	0.0056	0.30	0.0041
Cal. 4	5.0	0.0379	5.0	0.0486	5.0	0.0366	5.0	0.1006	10.00	0.8525	0.75	0.0085
Cal. 5	30.0	0.2694	30.0	0.4185	30.0	0.2463	30.0	0.6285	60.00	1.2335	1.50	0.0245
Cal. 6	50.0	0.2515	50.0	0.8125	50.0	0.2649	50.0	1.5332	100.00	1.6866	2.50	0.0410

Table 4. Expanded uncertainty measurement table.

## VI. WARNINGS AND PRECAUTIONS



Warning: The MassTrak Endocrine Steroid Calibrator Set contains components derived from human-sourced blood. It is recommended that all human-sourced materials be considered potentially infectious. Although the MassTrak Endocrine Steroid Calibrator Set contains components manufactured from human serum, the components all test negative for anti-HIV-1/anti-HIV-2 antibodies, HCV antibodies, and HBsAg.

Handle all human-sourced materials according to procedures prescribed by OSHA Standard on Bloodborne Pathogens, Biosafety Level 2, or other appropriate biosafety practices.

Unused components and wastes may be classified and regulated as Hazardous Wastes. To determine proper disposal, consult all applicable regulations.

Do not use remnant calibrators from different lots.

## VII. INSTRUCTIONS FOR USE

### A) INSPECTION



Perform content inventory and inspection upon arrival. Do not use this product if its packaging is opened, damaged, items are missing, or items are beyond expiry date.

Replacement product can be ordered by contacting your local: Waters sales representative: [waters.com/office](http://waters.com/office)

For additional support: [waters.com/support](http://waters.com/support)

For additional product information, visit: [waters.com/MassTrak](http://waters.com/MassTrak)

## B) STORAGE

Storage temperatures, shelf-life, and in-use stability are provided in Table 5.

**Warning: Improper calibrator storage may adversely affect the contents of the calibrators, resulting in erroneous calibration results.**


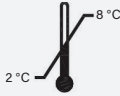
Condition	Storage temp.	Time	Comment
Unopened vials (shelf-life)	 -10 °C	24 months	Upper temperature limit is -10 °C
Opened, reconstituted vials (in-use stability)	 2 °C - 8 °C	4 weeks	Store between 2 °C and 8 °C

Table 5. Storage temperatures, shelf-life, and in-use stability.

## C) RECONSTITUTION

Calibrators require reconstitution with LC-MS-grade water prior to use. Below, find a list of the additional equipment and reagents needs to prepare the calibrators as well as the reconstitution instructions.

**Warning: Improper preparation of calibrators may adversely affect the contents of the calibrators, causing inaccurate results.**

### i. Additional Equipment

1. Pipettes
2. Pipette tips
3. Vortex-mixer
4. Roller mixer

### ii. Reconstitution Instructions

1. Remove the calibrator vials from storage and allow them to equilibrate to room temperature for at least 10 minutes.
2. Unscrew the blue caps from the vial.
3. Open the vials by removing the rubber stoppers.

**Be careful not to lose any powder that may be on the vial stopper. This may cause inaccurate results.**

4. Using an appropriately calibrated pipette, slowly add 2 mL of LC-MS-grade water directly into the vials.
5. Securely refit the rubber stoppers and caps to the vials.
6. Vortex-mix the vials for 30 seconds.
7. Roll the vials on a roller mixer for at least 60 minutes prior to further analysis.
8. Examine the contents of the calibrator to ensure that all the powder is fully dissolved.

The calibrator is now reconstituted and ready for use.

After reconstitution, the calibrators can be stored at 2–8 °C for up to 4 weeks.

## VIII. ENTERING CALIBRATOR COA CONCENTRATION VALUES

Enter the calibrator concentration values from the lot specific Certificate of Analysis for each analyte into the standard concentration column in the sample list.

## IX. LIMITATIONS OF THE EXAMINATION PROCEDURE

The calibrator concentration values were assigned on the Waters ACQUITY™ UPLC™ I-Class/Xevo™ TQ-S micro System. A system of equivalent sensitivity is required for accurate determination of low level calibrators.

## X. ORDERING INFORMATION

Product description	Part Number
MassTrak Endocrine Steroid Calibrator Set	186009311IVD
Related products	
MassTrak Endocrine Steroid Quality Control Set	186009312IVD

### Contact Information

To locate your local sales representative: [waters.com/offices](https://www.waters.com/offices)

For additional support: [waters.com/support](https://www.waters.com/support)

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