

MassTrak Endocrine Steroid Quality Control Set

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I. INTRODUCTION

Thank you for purchasing Waters MassTrak™ Endocrine Steroid Quality Control Set.

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

For additional product information, visit:
[waters.com/MassTrak](https://www.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 Quality Control 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 Quality Control 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 Quality Control Set. Part B provides a description of the metrological traceability associated with the control set, manufactured to enable labs to achieve ISO 15189 certification.

A) CONTENTS

The Waters MassTrak Endocrine Steroid Quality Control Set [one box] contains 3 matrix-matched controls in human serum and labeling. Contents include:

- Quality Control Low (QC Low)
- Quality Control Medium (QC Medium)
- Quality Control High (QC High)
- Insert Card referencing the IFU (Instructions for Use) SDS (Safety Data Sheets) and COA (Certification of Analysis)

Quality Controls 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 target analyte concentrations in each control is provided in Table 2. Table 3 provides the target specification range for each control. The controls are supplied lyophilized in glass vials and must be reconstituted with water prior to use (see Section VI).

Analyte	Concentration (ng/mL)		
	Low	Medium	High
Progesterone	0.1	1.0	35.0
Testosterone	0.05	0.5	14.0
Androstenedione	0.2	2.0	35.0
Cortisol	10.0	100.0	350.0
Corticosterone	0.2	2.0	35.0
11-deoxycortisol	0.2	2.0	35.0
21-deoxycortisol	0.2	2.0	35.0
11-deoxycorticosterone	0.035	0.35	15.0
17-OHP (17-hydroxyprogesterone)	0.2	2.0	70.0
DHT (dihydrotestosterone)	0.1	1.0	1.75
DHEAS (dehydroepiandrosterone sulfate)	200	2000	8750
DHEA (dehydroepiandrosterone)	0.8	8.0	35.0

Table 2. Target analyte concentrations.

Analyte	QC Low	QC Medium	QC High
Target specification range	±30 %	±30 %	±30 %

Table 3. Target specification range.

Notes: See the certificate of analysis (COA) for lot-specific control concentration levels.

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

B) TRACEABILITY

The MassTrak Endocrine Steroid Quality Controls 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 key 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. WARNINGS AND PRECAUTIONS



Warning: The MassTrak Endocrine Steroid Quality Control 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 Quality Control 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 controls from different lots.

VI. 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

For additional support: waters.com/support

For additional product information, visit: waters.com/MassTrak

B) STORAGE

Storage temperatures, shelf-life, and in-use stability are provided in Table 4.

Warning: Improper control storage may adversely affect the contents of the controls, 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 4. Storage temperatures, shelf-life, and in-use stability.

C) RECONSTITUTION

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

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

i. Additional Equipment

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

ii. Reconstitution Instructions

1. Remove the control vials from storage and allow them to equilibrate to room temperature for at least 10 minutes.
2. Unscrew the green 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 control to ensure that all the powder is fully dissolved.

The control is now reconstituted and ready for use.

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

VII. ENTERING CONTROL COA CONCENTRATION VALUES

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

VIII. LIMITATIONS OF THE EXAMINATION PROCEDURE

The values assigned to the quality controls were assigned on the Waters ACQUITY™ UPLC™ I-Class/Xevo™ TQ-S micro System. A system of equivalent sensitivity is required for measurement determination of the lower concentration quality control.

IX. ORDERING INFORMATION

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

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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