

Illustration of the Analytical Performance of the Waters MassTrak Endocrine Steroid Calibrators and QC Set Using the ACQUITY UPLC I-Class and Xevo TQ-S micro Mass Spectrometer

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This is an Application Brief and does not contain a detailed Experimental section.

For *in vitro* diagnostic use. Not available in all countries.

MassTrak Endocrine Steroid Hormones Calibrator and QC Sets are currently under development and not available for sale

Abstract

This document describes a test of the analytical performance of the MassTrak Endocrine Steroid Calibrator and QC Set (IVD) using the Waters ACQUITY UPLC I-Class/Xevo TQ-S micro IVD System.

Introduction

The Waters MassTrak Endocrine Steroid Calibrator and QC Set (IVD) contains metrological traceable steroid

hormones in lyophilized human serum, which can be used for quantification of DHEA-S, cortisol, 21-deoxycortisol, corticosterone, 11-deoxycortisol, androstenedione, 11-deoxycorticosterone, testosterone, DHEA, 17-OHP, DHT, and progesterone. The Waters ACQUITY UPLC I-Class/Xevo TQ-S micro IVD System enables the quantification of compounds in biological matrices.

Experimental

The ACQUITY UPLC I-Class/Xevo TQ-S micro IVD System was controlled by MassLynx IVD Software (v4.2) and the data processed using the TargetLynx XS Application Manager. Calibrators and Quality Controls were prepared by reconstituting the MassTrak Endocrine Steroid Calibrator and QC Set (IVD) following the Instructions for Use (IFU) and the samples were processed using the following conditions:

Sample Preparation Conditions

125 μ L sample was processed with internal standard, methanol, diluted with water and centrifuged. An aliquot of each sample was transferred to the collection plate and the remaining sample was loaded onto Oasis MAX μ Elution Plates, washed and eluted into the collection plate prior to analysis.

Liquid Chromatography Conditions

Column:	CORTECS C ₈ , 2.1 mm x 100 mm, 2.6 μ m with VanGuard Pre-Column
Mobile phase A:	0.1 mM Ammonium fluoride in water
Mobile phase B:	0.1 mM Ammonium fluoride in methanol
Flow rate:	0.3 mL/min
Gradient:	40% B over 1.25 minutes, 40–52.5% B over 1.75 minutes, 52.5% B for 1 minutes, 52.5%–65% B over 1 minutes, 65% B for 1.25 minutes, 95% B for 0.75 minutes

Mass Spectrometry Conditions

Resolution:	MS1 (0.75 FWHM), MS2 (0.5 FWHM)
Acquisition mode:	MRM
Polarity:	ESI (+/-)

Results and Discussion

Performance characteristics of the steroid hormones on the Waters ACQUITY UPLC I-Class/Xevo TQ-S micro IVD System are shown in Table 1. Analytical sensitivity of the system for analysing extracted steroid hormone samples is illustrated in Figure 1.

Compound	Range (nmol/L)	Mean r^2	Mean S/N (PtP) at Cal 1	Total precision	Repeatability	Mean bias
DHEA-S	61–29392	0.994	186	≤4.0%	≤4.0%	7.8%
Cortisol	3–1388	0.997	277	≤2.8%	≤2.8%	2.5%
21-Deoxycortisol	0.14–141	0.996	26	≤7.7%	≤5.8%	–
Corticosterone	0.14–141	0.995	52	≤7.7%	≤7.7%	–
11-Deoxycortisol	0.14–141	0.999	86	≤3.6%	≤3.4%	–
Androstenedione	0.17–169	0.999	79	≤3.9%	≤3.9%	3.4%
11-Deoxycorticosterone	0.03–59	0.996	20	≤3.6%	≤3.6%	–
Testosterone	0.05–74	0.995	59	≤7.3%	≤5.2%	2.1%
DHEA	0.90–224	0.994	27	≤7.7%	≤6.1%	–
17-OHP	0.15–293	0.995	55	≤3.7%	≤3.7%	-6.9%
DHT	0.10–8.2	0.998	16	≤5.2%	≤4.9%	6.6%
Progesterone	0.08–164	0.998	42	≤3.5%	≤3.2%	-1.2%

Table 1. Performance characteristics of the steroid hormones. The calibration ranges are based on assigned values for the steroid hormones. The mean linear fit (r^2) and S/N (PtP) were calculated over five runs. Total precision and repeatability of QCs performed over five runs (n=25). Mean bias was determined through Altman-Bland comparison of calculated concentrations to EQA mass spectrometry mean values for cortisol, DHEA-S 17-OHP, testosterone, and androstenedione; all method mean (ALTM) value for progesterone; and to RCPA QAP MS mean value for DHT.

Note: To convert SI units to conventional mass units divide by 2.76 for cortisol (nmol/L to ng/mL), 2.71 for DHEA-S (nmol/L to ng/mL), 2.89 for 21-deoxycortisol, corticosterone, and 11-deoxycortisol (nmol/L to ng/mL), 3.49 for

androstenedione (nmol/L to ng/mL), 3.03 for 11-deoxycorticosterone and 17-OHP (nmol/L to ng/mL), 3.47 for testosterone (nmol/L to ng/mL), 3.47 for DHEA (nmol/L to ng/mL), 3.45 for DHT (nmol/L to ng/mL), and 3.18 for progesterone (nmol/L to ng/mL).

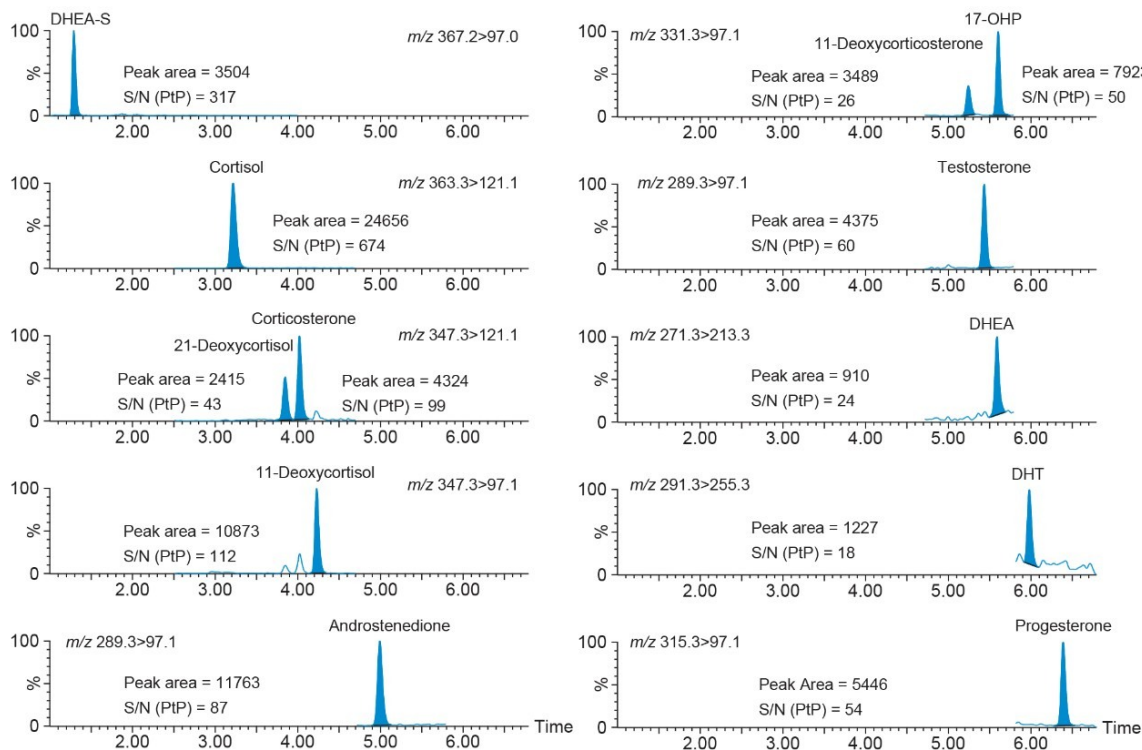


Figure 1. Performance characteristics of the extracted C1 calibrator from the MassTrak Endocrine Steroid Calibrator set analyzed using the ACQUITY UPLC I-Class/Xevo TQ-S micro IVD System.

Conclusion

The Waters MassTrak Endocrine Steroid Calibrators and QC Set (IVD) in combination with the Waters ACQUITY UPLC I-Class/Xevo TQ-S micro IVD System has demonstrated the capability to deliver analytically sensitive and selective performance with excellent precision and accuracy for DHEA-S, cortisol, 21-deoxycortisol, corticosterone, 11-deoxycortisol, androstenedione, 11-deoxycorticosterone, testosterone, DHEA, 17-OHP, DHT, and progesterone in serum.

Disclaimer

The analytical performance data presented here is for illustrative purposes only. Waters does not recommend or suggest analysis of the analytes described herein. These data are intended solely to demonstrate the

performance capabilities of the system for analytes representative of those commonly analyzed using liquid chromatography and tandem mass spectrometry. Performance in an individual laboratory may differ due to a number of factors, including laboratory methods, materials used, intra-operator technique, and system conditions. This document does not constitute a warranty of merchantability or fitness for any particular purpose, express or implied, including for the testing of the analytes in this analysis.

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- [Xevo TQ-S micro Triple Quadrupole Mass Spectrometry <https://www.waters.com/134798856>](https://www.waters.com/134798856)
- [MassLynx MS Software <https://www.waters.com/513662>](https://www.waters.com/513662)
- [TargetLynx <https://www.waters.com/513791>](https://www.waters.com/513791)

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