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应用纪要

ACQUITY UPLC I-Class/Xevo TQ-S micro IVD System: Analytical Performance for Progestogens and Androgens

Waters Corporation

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

Introduction

The Waters ACQUITY UPLC I-Class/Xevo TQ-S micro IVD System enables the quantification of organic compounds in human biological liquid matrices.

This document describes a test of the analytical performance of the ACQUITY I-Class/Xevo TQ-S micro IVD System for the analysis of dihydrotestosterone (DHT), dehydroepiandrosterone (DHEA), testosterone, androstenedione, 17-hydroxyprogesterone, and progesterone in serum.

ACQUITY UPLC I-Class/Xevo TQ-S micro IVD System.

Experimental

The ACQUITY UPLC I-Class/Xevo TQ-S micro IVD System was controlled by MassLynx IVD Software (v4.1) and the data processed using the TargetLynx Application Manager. Calibrators and Quality Controls were prepared by spiking commercially available reference material in stripped serum and the samples

were processed using the following conditions:

Sample Description

Sample preparation conditions 100 µL sample was processed with methanol, diluted with water, and centrifuged. Samples were loaded on Oasis MAX µElution plates, washed, and eluted prior to analysis.

LC Conditions

Column:	CORTECS UPLC C_{18} 1.6 µm, 2.1 mm × 50 mm
Mobile phase A:	0.05 mM Ammonium fluoride in water
Mobile phase B:	Methanol
Flow Rate:	0.25 mL/min
Gradient:	40% B over 0.5 minutes, 40–70% B over 3.5 minutes, 95% B for 0.5 minutes

MS 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 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)	LLOQ (nmol/L)	%RSD at LLOQ	Total precision	Repeatability	Mean bias
DHT	0.086–34	0.086	13%	≤6.5%	≤6.4%	4.9%
DHEA	1.0–69	0.35	11%	≤4.7%	≤4.4%	–
Testosterone	0.017–69	0.017	11%	≤5.3%	≤2.9%	-1.4%
Androstenedione	0.087–349	0.035	18%	≤5.4%	≤3.7%	0.2%
17-OHP	0.076–303	0.030	17%	≤4.4%	≤4.0%	-5.6%
Progesterone	0.064–64	0.016	15%	≤4.5%	≤4.1%	–

Table 1. Performance characteristics of the analytes evaluated. Range defined by linear fit where r^2 >0.99. LLOQ defined by S/N (PtP) >10 and %RSD ≤20%. %RSD at LLOQ determined through analytical sensitivity experiments performed over five occasions (n=40). Total precision and repeatability of QCs performed over five occasions (n=25). Mean bias determined through Bland-Altman comparison of calculated concentrations to RCPA QAP target values for DHT and EQA mass spectrometry mean values for testosterone, androstenedione, and 17-OHP.

Note: To convert SI units to conventional mass units divide by 3.45 for DHT (nmol/L to ng/mL), 3.47 for DHEA (nmol/L to ng/mL), 3.47 for testosterone (nmol/L to ng/mL), 3.49 for androstenedione (nmol/L to ng/mL), 3.03 for 17-OHP (nmol/L to ng/mL), and 3.18 for progesterone (nmol/L to ng/mL).

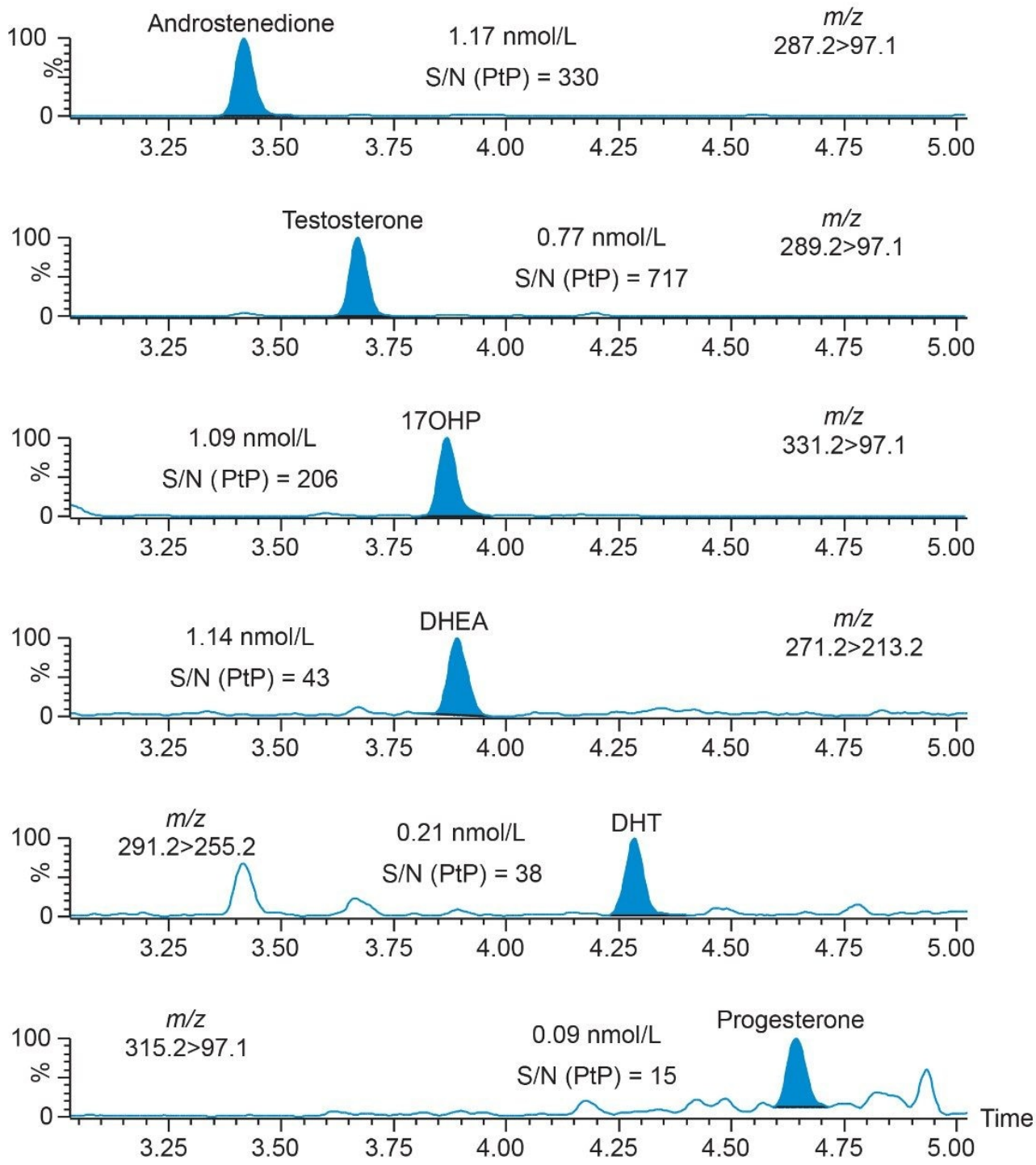

Figure 1. Performance characteristics of low concentration serum steroid hormone samples using the ACQUITY

UPLC I-Class/Xevo TQ-S micro IVD System.

Conclusion

The 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 DHT, DHEA, testosterone, androstenedione, 17-hydroxyprogesterone, 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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