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ACQUITY UPLC I-Class/Xevo TQD 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 TQD 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 UPLC I-Class/Xevo TQD IVD System for the analysis of testosterone, androstenedione, 17-hydroxyprogesterone (17-OHP), and dehydroepiandrosterone sulfate (DHEAS) in serum.

ACQUITY UPLC I-Class/Xevo TQD IVD System.

Experimental

The ACQUITY UPLC I-Class/Xevo TQD 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 Preparation Conditions

100 µL sample was precipitated with methanol, diluted with water, and centrifuged. Samples were loaded onto Oasis PRiME HLB µElution plates, washed, and eluted prior to analysis.

LC Conditions

Column:	ACQUITY UPLC HSS T3 (IVD) 1.8 µm, 2.1 mm × 50 mm
Pre-column:	VanGuard HSS T3 1.8 µm, 2.1 mm × 5 mm
Mobile phase A:	2 mM ammonium acetate + 0.1% formic acid in water
Mobile phase B:	2 mM ammonium acetate + 0.1% formic acid in methanol
Flow rate:	0.6 mL/min
Gradient:	45% B over one minute, 45–65% B over 2.5 minutes, 98% B for 0.5 minutes

MS Conditions

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

Results and Discussion

Performance characteristics of the steroid hormones on the Waters ACQUITY UPLC I-Class/Xevo TQD IVD System are shown in Table 1. Analytical sensitivity of the system for analyzing the steroid hormones in plasma is illustrated in Figure 1.

Compound	Range (nmol/L)	LLOQ (nmol)	%RSD at LLOQ	Total precision	Repeatability	EQA mean bias
Testosterone	0.17–69	0.17	12.0%	≤4.7%	≤3.6%	-0.5%
Androstenedione	0.17–69	0.17	9.1%	≤6.3%	≤5.2%	0.4%
17-OHP	0.76–303	0.76	9.2%	≤8.2%	≤8.2%	-5.0%
DHEAS	140–54000	140	7.0%	≤3.9%	≤2.7%	5.8%

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 three occasions (n=30). Total Precision and Repeatability of QCs performed over five occasions in stripped serum (n=30). EQA Mean Bias determined through Altman-Bland comparison of calculated concentrations to EQA mass spectrometry mean values.

Note: To convert SI units to conventional mass units divide by 3.470 for testosterone (nmol/L to ng/mL), 3.494 for androstenedione (nmol/L to ng/mL), 3.028 for 17-OHP (nmol/L to ng/mL) and 2.716 for DHEAS (nmol/L to ng/mL).

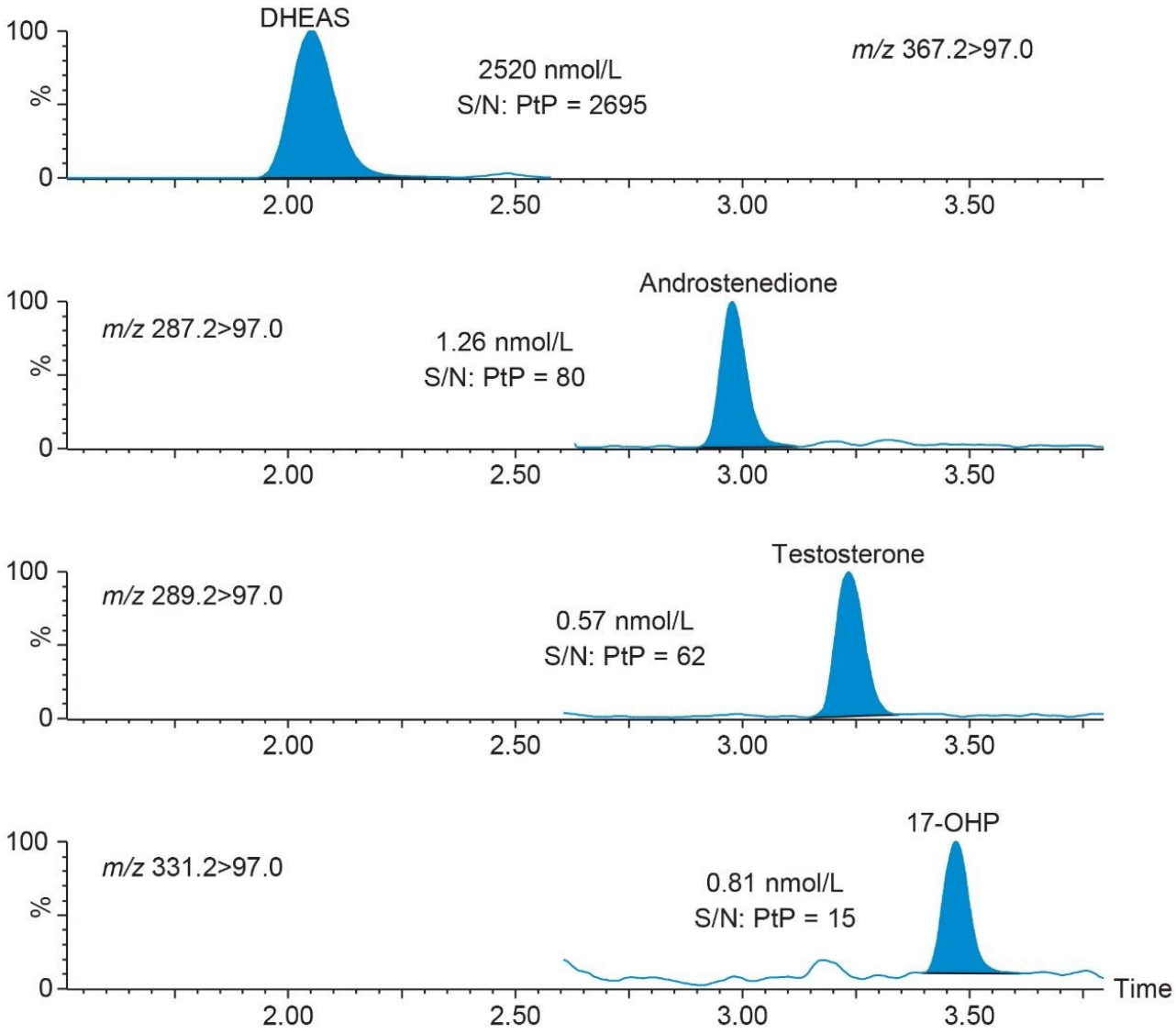

Figure 1. Low steroid hormone concentrations in serum containing DHEAS, androstenedione, testosterone, and 17-OHP.

Conclusion

The Waters ACQUITY UPLC I-Class/Xevo TQD IVD System has demonstrated the capability to deliver analytically

sensitive, selective performance with excellent precision and accuracy for testosterone, androstenedione, 17-OHP, and DHEAS 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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