

ACQUITY UPLC I-Class/Xevo TQ-XS IVD System: Analytical Performance for a Mineralocorticoid

Waters Corporation

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

Introduction

The Waters ACQUITY UPLC I-Class/Xevo TQ-XS 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 TQ-XS IVD System for the analysis of aldosterone in plasma.



Figure 1. The Waters ACQUITY UPLC I-Class System and Xevo TQ-XS Mass Spectrometer.

Experimental

The ACQUITY UPLC I-Class/Xevo TQ-XS IVD System was controlled by MassLynx IVD (v4.2) 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

200 μ L sample was precipitated with ZnSO_4 /methanol, diluted, and centrifuged. Samples were loaded onto Oasis MAX μ Elution Plates, washed, and eluted prior to analysis.

LC Conditions

Column:	CORTECS C ₁₈ , 2.7 µm, 2.1 × 100 mm with VanGuard Pre-column
Mobile phase A:	Water with 0.05 mM ammonium fluoride
Mobile phase B:	Methanol
Flow rate:	0.5 mL/min
Gradient:	35% B over 1 min, 35–60% B over 0.7 min, 60% for 0.5 min, 95% B for 0.8 min

MS Conditions

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

Results and Discussion

Performance characteristics of aldosterone using the ACQUITY UPLC I-Class/Xevo TQ-XS IVD System is shown in Table 1. Analytical sensitivity of the system for analyzing extracted aldosterone plasma samples is illustrated in Figure 2.

Compound	Range (pmol/L)	LLOQ (pmol/L)	%RSD at LLOQ	Total precision	Repeatability	Mean Bias
Aldosterone	8–4161	8	6.1%	≤6.3%	≤6.0%	-3.2%

Table 1. Performance characteristics of aldosterone. Range defined by linear fit where $r^2 > 0.99$. LLOQ defined by S/N (PtP) > 10 and $\%RSD \leq 20\%$. $\% RSD$ 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 Altman-Bland comparison of calculated concentrations to EQA mass spectrometry mean values for aldosterone.

Note: To convert SI units to conventional mass units, divide by 2.774 for aldosterone (pmol/L to pg/mL).

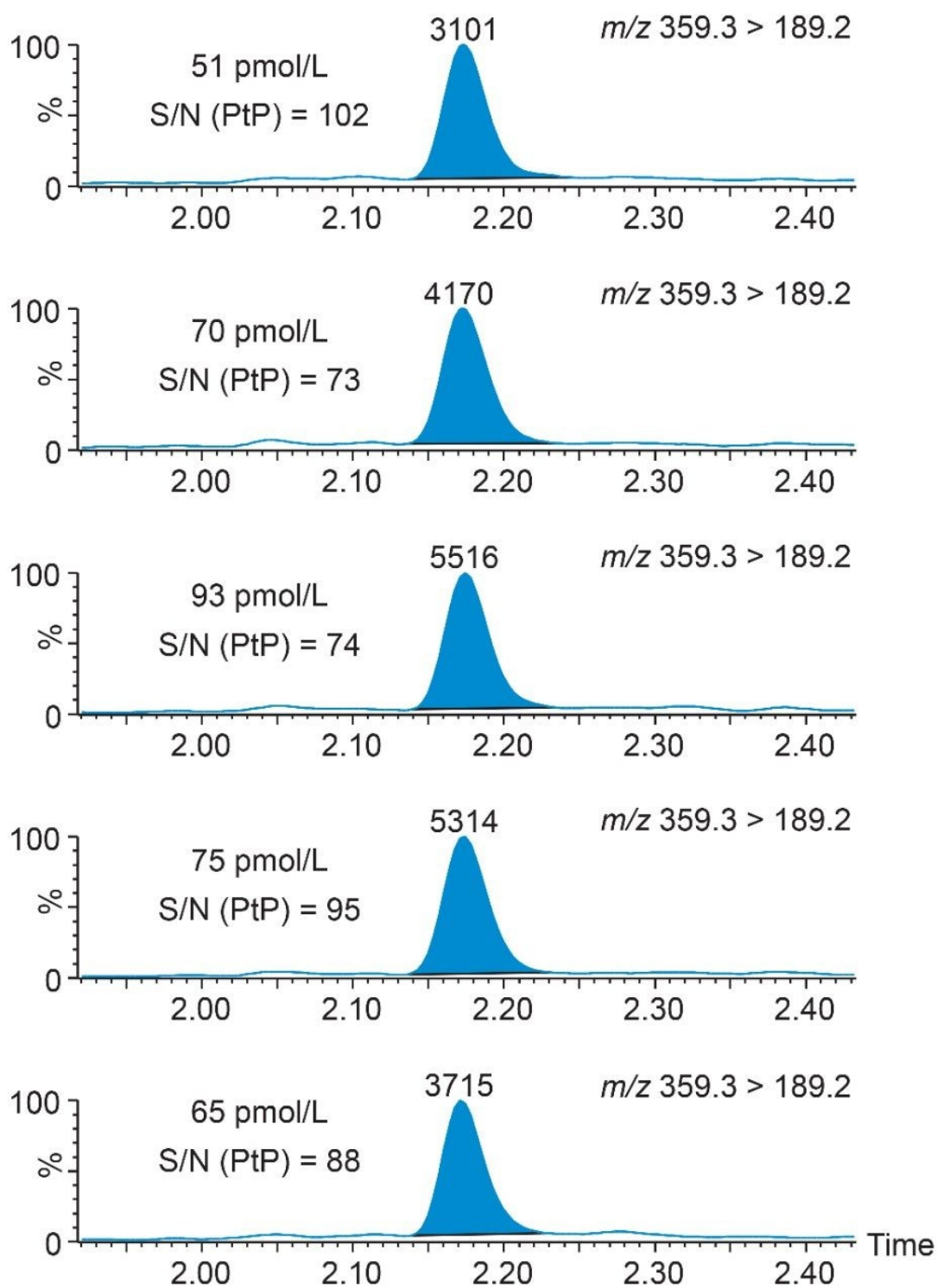


Figure 2. Chromatograms to show S/N (PtP) of extracted plasma aldosterone samples using the ACQUITY UPLC

Conclusion

The Waters ACQUITY UPLC I-Class/Xevo TQ-XS IVD System has demonstrated the capability to deliver analytically sensitive and selective performance with excellent precision and accuracy for the analysis of aldosterone in plasma.

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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720006678, September 2019

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