

Exemplary performance data for steroids

Analytical performance of clinically relevant compounds

TSQ Quantis MD Triple-Stage Quadrupole
Mass Spectrometer

Vanquish MD HPLC | HESI | APCI

Preface

Liquid chromatography systems

Intended use: The Thermo Scientific™ Vanquish™ MD HPLC (high performance liquid chromatograph) is a general purpose laboratory instrument intended to separate drugs or compounds in human specimens. For *in vitro* diagnostic use only by trained, qualified laboratory personnel.

Indications for use: The Vanquish MD HPLC will be used by clinical diagnostic laboratories as a component of a laboratory developed test (LDT) method or workflow.

Contraindications of use: For *in vitro* diagnostic applications only. The Vanquish MD HPLC is to be operated only with hardware or software approved for *in vitro* diagnostic application.

Limitations of use: The Vanquish MD HPLC is compatible with the following Thermo Fisher Scientific instruments: Thermo Scientific™ TSQ Altis™ MD Series and Thermo Scientific™ TSQ Quantis™ MD Series mass spectrometers.



Mass spectrometers

Intended use: The TSQ Quantis MD Series mass spectrometer is intended to identify and quantify inorganic and organic compounds in human specimens. For *in vitro* diagnostic use only by trained, qualified laboratory personnel.

Indications for use: The TSQ Quantis MD Series mass spectrometer will be used by clinical diagnostic laboratories as a component of a laboratory developed test (LDT) method or workflow.

Contraindications of use: For *in vitro* diagnostic applications only. The TSQ Quantis MD Series mass spectrometer is to be operated only with hardware or software labeled for *in vitro* diagnostic use.

Limitations of use: The TSQ Quantis MD Series mass spectrometer is compatible with the Vanquish MD HPLC.

Exemplary performance data

Liquid chromatography tandem mass spectrometry systems enable *in vitro* quantification of a variety of compounds in biological matrices. The performance data presented in this paper is for illustrative purposes only and may not represent the performance that laboratories will obtain. Thermo Fisher Scientific does not recommend or suggest analysis of the analytes described herein using its systems. Performance in an individual laboratory may differ from what is presented in this document due to factors, including but not limited to laboratory methods, materials used, operator technique, and system conditions. It is the laboratory's responsibility to validate performance of any assay it intends to utilize in its facility and to comply with all applicable laws and policies.

Materials and methods

Samples

Sample preparation

Methyl tert-butyl ether extraction followed by transfer to HPLC vial.

Calibrators and controls		
UTAK Custom Calibrator	TESTO+ BLK SMX-S F TF	Custom Calibrator prepared by UTAK
UTAK Custom Calibrator	TESTO+ CAL1 SMX-S F TF	Custom Calibrator prepared by UTAK
UTAK Custom Calibrator	TESTO+ CAL2 SMX-S F TF	Custom Calibrator prepared by UTAK
UTAK Custom Calibrator	TESTO+ CAL3 SMX-S F TF	Custom Calibrator prepared by UTAK
UTAK Custom Calibrator	TESTO+ CAL4 SMX-S F TF	Custom Calibrator prepared by UTAK
UTAK Custom Calibrator	TESTO+ CAL5 SMX-S F TF	Custom Calibrator prepared by UTAK
UTAK Custom Calibrator	TESTO+ CAL6 SMX-S F TF	Custom Calibrator prepared by UTAK
UTAK Custom Calibrator	TESTO+ CAL7 SMX-S F TF	Custom Calibrator prepared by UTAK
UTAK Custom QC	TESTO+QC 1SMX-S F TF	Custom QC prepared by UTAK, level 1, 0.14 ng/mL Estrone and 0.27 ng/mL Testosterone
UTAK Custom QC	TESTO+QC 2SMX-S F TF	Custom QC prepared by UTAK, level 2, 1.1 ng/mL Estrone and 1.0 ng/mL Testosterone
UTAK Custom QC	TESTO+QC 3SMX-S F TF	Custom QC prepared by UTAK level 3, 7.6 ng/mL Estrone and 6.2 ng/mL Testosterone

Liquid chromatography

- Mobile phase A: 0.5 mM Ammonium fluoride (NH₄F) in water
- Mobile phase B: methanol

Mass spectrometry

- Duration: 6 minutes
- Negative polarity: HESI and APCI
- Positive polarity: HESI and APCI
- Transitions: SRM
- Source conditions: Optimized

Instruments

The TSQ Quantis MD Series MS configured for HESI or APCI was tested with the Vanquish MD HPLC.

Test configurations		
TSQ Quantis MD Series MS (HESI)	Vanquish MD HPLC	TSQ Series II Thermo Scientific TSQ Quantis MD software for system calibration, diagnostics, compound optimization and method development.
TSQ Quantis MD Series MS (APCI)		TraceFinder LDT Software for quantitation.

Acceptance criteria

Acceptance criteria, based on five injections of each commercial control sample, are shown in the table below:

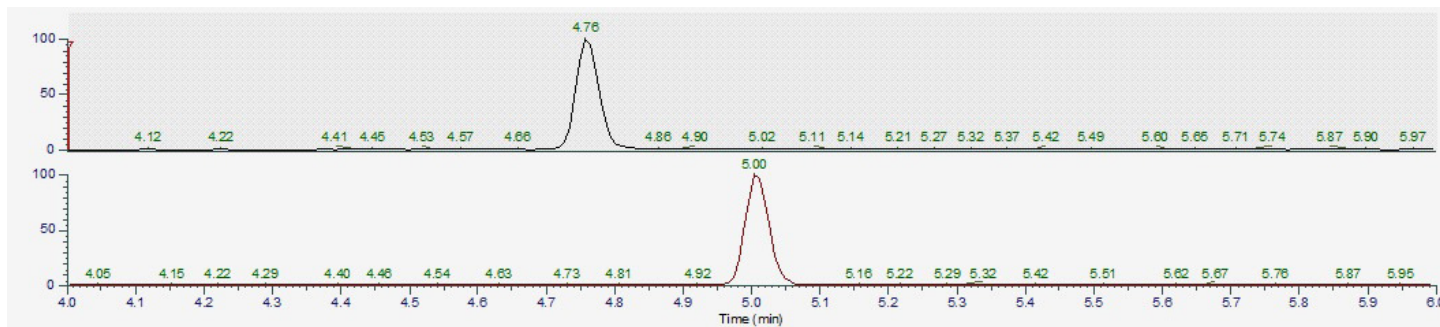
Acceptance criteria	
Accuracy	Difference between the assigned and measured value of control samples at low, medium and high levels < ±15%
Imprecision	CV at low, medium and high levels of control samples <15%
CLSI	Liquid Chromatography-Mass Spectrometry Methods; Approved Guideline. CLSI document C62-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2014.

Results

TSQ Quantis MD Series MS (HESI) Vanquish MD HPLC n = 5	Calibrator %Diff	R ²	QC% Diff	QC1 %RSD	QC2 %RSD	QC3 %RSD
Estrone (negative polarity)	pass	0.9986 (pass)	pass	3.36 (pass)	2.42 (pass)	1.74 (pass)
Testosterone (positive polarity)	pass	0.9992 (pass)	pass	1.07 (pass)	0.24 (pass)	0.25 (pass)

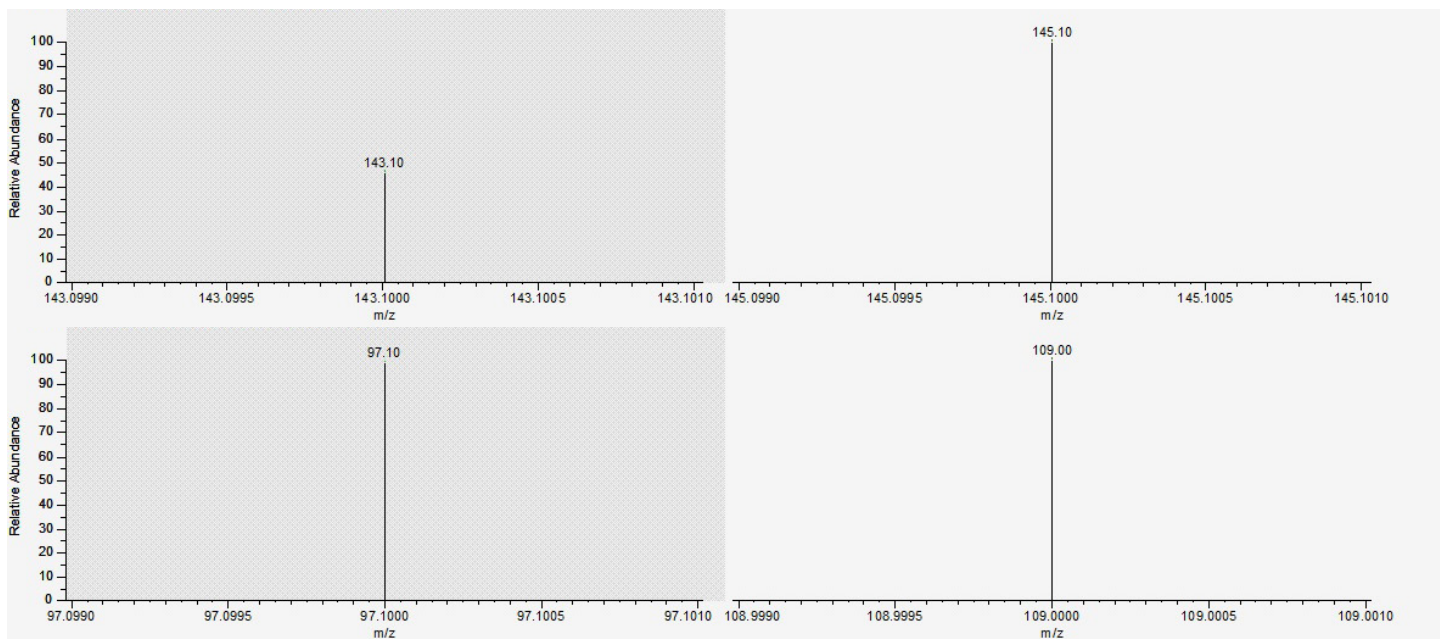
TSQ Quantis MD Series MS (APCI) Vanquish MD HPLC n = 5	Calibrator %Diff	R ²	QC% Diff	QC1 %RSD	QC2 %RSD	QC3 %RSD
Estrone (negative polarity)	pass	0.9978 (pass)	pass	5.88 (pass)	1.18 (pass)	1.76 (pass)
Testosterone (positive polarity)	pass	0.9986 (pass)	pass	1.60 (pass)	7.00 (pass)	4.61 (pass)

Chromatogram for QC2 run on TSQ Quantis MD Series MS (HESI) and Vanquish MD HPLC



From top to bottom: Estrone and Testosterone.

MS² Spectra for QC2 run on TSQ Quantis MD Series MS (HESI) and Vanquish MD HPLC



From top to bottom: Estrone, greater relative abundance quantifier ion and lesser relative abundance confirming ion. Testosterone, 97.1 m/z quantifier ion and 109.0 m/z confirming ion.

Find out more at thermofisher.com/BeSure

IVD In Vitro Diagnostic Medical Device

© 2020 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. UTAK is the registered trademark of UTAK Laboratories, Inc. This information is presented as an example of the capabilities of Thermo Fisher Scientific Inc. products. It is not intended to encourage use of these products in any manners that might infringe the intellectual property rights of others. Specifications, terms and pricing are subject to change. Not all products are available in all locations. Please consult your local sales representative for details. **DS73382-EN 0920M**

ThermoFisher
SCIENTIFIC