

Exemplary performance data for immunosuppressants

Analytical performance of clinically relevant compounds

TSQ Quantis MD Triple-Stage Quadrupole
Mass Spectrometer | Vanquish MD HPLC

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 robust and reliable *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

Protein precipitation with ZnSO₄ followed by transfer to HPLC vial.

Calibrators and controls		
Calibrators	Art. No. 9933	RECIPE® ClinCal® Whole Blood Calibrators for Immunosuppressants Levels 0–6 (RECIPE Chemicals + Instruments GmbH), LOT#1428
Calibrator	Art. No. 9028	RECIPE® ClinCal® Whole Blood Calibrators for Immunosuppressants Level 7 (Iris Technologies International GmbH)
Controls	Art. No. 8833	RECIPE® ClinCheck® Whole Blood Controls for Immunosuppressants Levels I–III (Iris Technologies International GmbH)
Controls	Art. No. 8903	RECIPE® ClinCheck® Whole Blood Controls for Immunosuppressants Levels IV–V (Iris Technologies International GmbH)

Liquid chromatography

- Mobile phase A: 0.1% formic acid and 10 mM of ammonium formate in water.
- Mobile phase B: 0.1% formic acid and 10 mM of ammonium formate in methanol.

Mass spectrometry

- Duration: 3 minutes
- Positive polarity: HESI
- Transitions: SRM
- Source conditions: Default

Instruments

For intra-system and inter-system precision, TSQ Quantis MD Series MS #1 was tested with Vanquish MD HPLC #1, #2 and #3. Vanquish MD HPLC #1 was also tested with TSQ Quantis MD Series MS #2 and #3. For between-day precision, testing was continued for TSQ Quantis MD Series MS #3 and Vanquish MD HPLC #1.

Test configurations			
TSQ Quantis MD #1	Vanquish MD HPLC #1	Vanquish MD HPLC #2	Vanquish MD HPLC #3
TSQ Quantis MD #2	Vanquish MD HPLC #1	TSQ Series II Thermo Scientific™ TSQ Altis™ MD and Quantis MD software for system calibration, diagnostics, compound optimization and method development.	
TSQ Quantis MD #3	Vanquish MD HPLC #1	Thermo Scientific™ 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

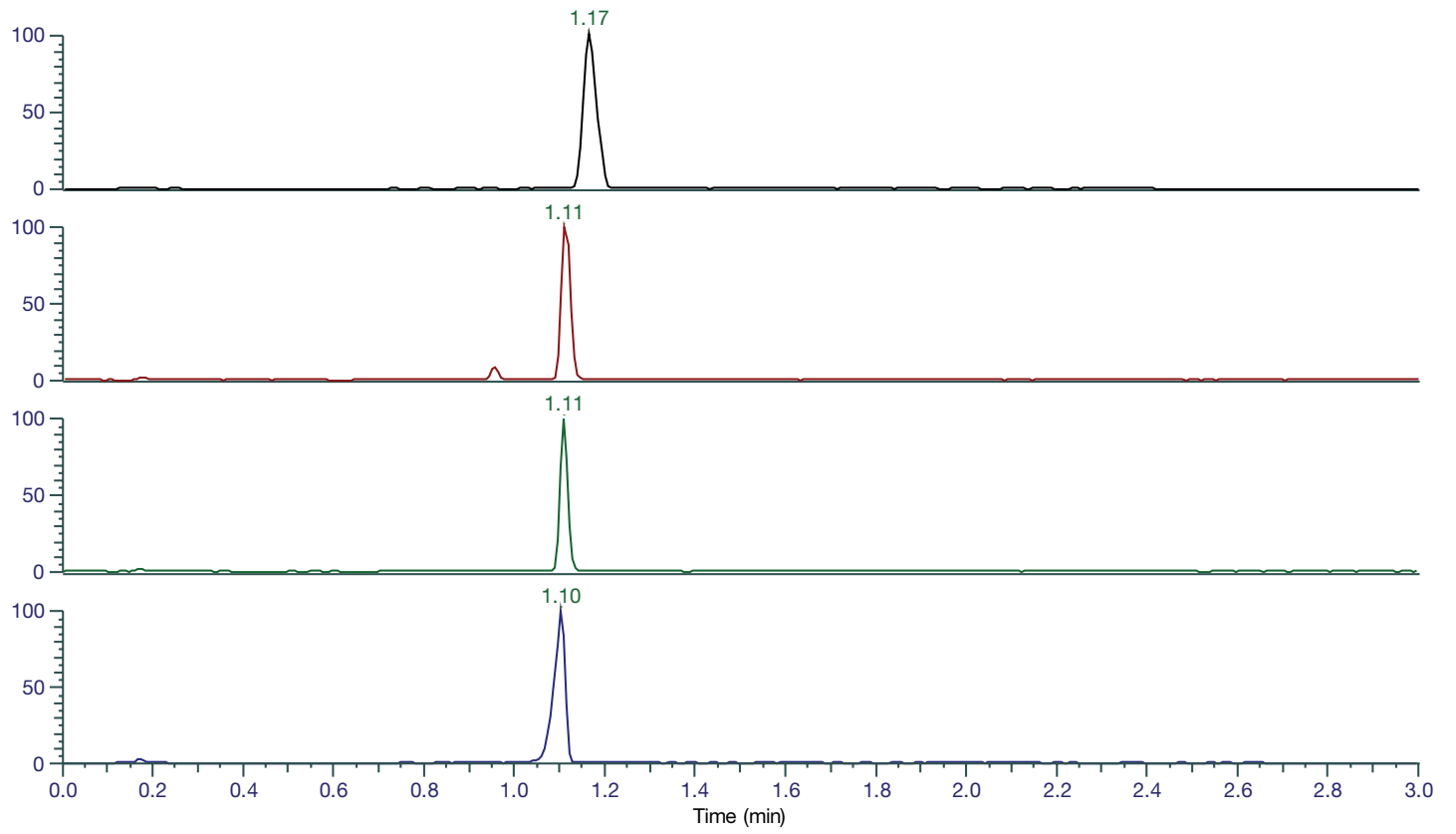
Vanquish MD HPLC

TSQ Quantis MD #1 Vanquish MD HPLC #1 n=5	Calibrator %Diff	R²	QC% Diff	QC1 %RSD	QCIII %RSD	QCV %RSD
Cyclosporin A	Pass	0.998 (pass)	pass	6.08 (pass)	6.17 (pass)	5.03 (pass)
Everolimus	Pass	0.9974 (pass)	pass	7.70 (pass)	4.78 (pass)	3.93 (pass)
Sirolimus	Pass	0.9972 (pass)	pass	6.67 (pass)	5.51 (pass)	3.64 (pass)
Tacrolimus	Pass	0.9977 (pass)	pass	4.77 (pass)	2.95 (pass)	1.92 (pass)
TSQ Quantis MD #1 Vanquish MD HPLC #2 n=5	Calibrator %Diff	R²	QC% Diff	QC1 %RSD	QCIII %RSD	QCV %RSD
Cyclosporin A	Pass	0.9998 (pass)	pass	0.64 (pass)	0.70 (pass)	1.26 (pass)
Everolimus	Pass	0.9991 (pass)	pass	3.03 (pass)	1.72 (pass)	0.41 (pass)
Sirolimus	Pass	0.9981 (pass)	pass	3.77 (pass)	1.58 (pass)	1.37 (pass)
Tacrolimus	Pass	0.9978 (pass)	pass	1.73 (pass)	1.66 (pass)	0.73 (pass)
TSQ Quantis MD #1 Vanquish MD HPLC #3 n=5	Calibrator %Diff	R²	QC% Diff	QC1 %RSD	QCIII %RSD	QCV %RSD
Cyclosporin A	Pass	0.9996 (pass)	pass	0.27 (pass)	0.51 (pass)	1.01 (pass)
Everolimus	Pass	0.9989 (pass)	pass	3.70 (pass)	0.57 (pass)	1.30 (pass)
Sirolimus	Pass	0.9983 (pass)	pass	2.37 (pass)	1.10 (pass)	0.83 (pass)
Tacrolimus	Pass	0.9976 (pass)	pass	1.79 (pass)	1.43 (pass)	0.49 (pass)
TSQ Quantis MD #2 Vanquish MD HPLC #1 n=5	Calibrator %Diff	R²	QC% Diff	QC1 %RSD	QCIII %RSD	QCV %RSD
Cyclosporin A	Pass	0.9973 (pass)	pass	0.88 (pass)	1.87 (pass)	2.26 (pass)
Everolimus	Pass	0.9995 (pass)	pass	5.33 (pass)	2.64 (pass)	2.35 (pass)
Sirolimus	Pass	0.9985 (pass)	pass	3.59 (pass)	1.98 (pass)	5.07 (pass)
Tacrolimus	Pass	0.9986 (pass)	pass	1.95 (pass)	2.65 (pass)	2.49 (pass)
TSQ Quantis MD #3 Vanquish MD HPLC #1 n=5 (Day One)	Calibrator %Diff	R²	QC% Diff	QC1 %RSD	QCIII %RSD	QCV %RSD
Cyclosporin A	Pass	0.9998 (pass)	pass	0.34 (pass)	0.30 (pass)	0.32 (pass)
Everolimus	Pass	0.9989 (pass)	pass	2.29 (pass)	0.94 (pass)	2.22 (pass)
Sirolimus	Pass	0.9984 (pass)	pass	2.95 (pass)	0.55 (pass)	1.75 (pass)
Tacrolimus	Pass	0.9981 (pass)	pass	1.87 (pass)	0.60 (pass)	1.09 (pass)
TSQ Quantis MD #3 Vanquish MD HPLC #1 n=5 (Day Two)	Calibrator %Diff	R²	QC% Diff	QC1 %RSD	QCIII %RSD	QCV %RSD
Cyclosporin A	Pass	0.9996 (pass)	pass	0.50 (pass)	0.46 (pass)	0.21 (pass)
Everolimus	Pass	0.9994 (pass)	pass	3.03 (pass)	1.49 (pass)	0.91 (pass)
Sirolimus	Pass	0.9986 (pass)	pass	2.85 (pass)	0.85 (pass)	0.84 (pass)
Tacrolimus	Pass	0.9988 (pass)	pass	1.47 (pass)	1.04 (pass)	0.46 (pass)
TSQ Quantis MD #3 Vanquish MD HPLC #1 n=5 (Day Three)	Calibrator %Diff	R²	QC% Diff	QC1 %RSD	QCIII %RSD	QCV %RSD
Cyclosporin A	Pass	0.9997 (pass)	pass	0.58 (pass)	0.42 (pass)	0.40 (pass)
Everolimus	Pass	0.999 (pass)	pass	4.13 (pass)	1.33 (pass)	0.83 (pass)
Sirolimus	Pass	0.998 (pass)	pass	3.45 (pass)	0.56 (pass)	0.76 (pass)
Tacrolimus	Pass	0.9983 (pass)	pass	2.22 (pass)	1.06 (pass)	0.77 (pass)

Vanquish MD HPLC (Continued)

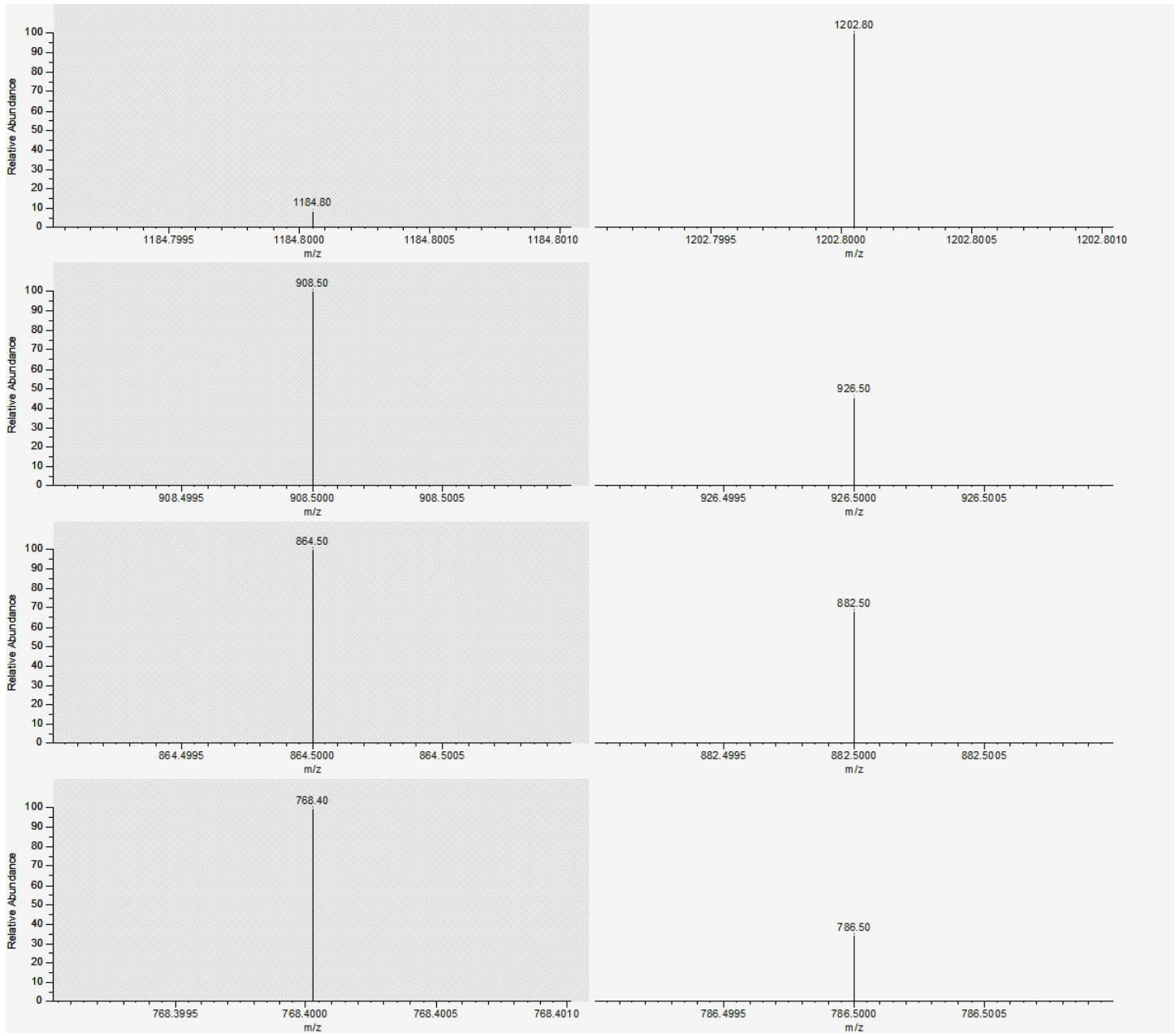
TSQ Quantis MD #1 Vanquish MD HPLC #1 Vanquish MD HPLC #2 Vanquish MD HPLC #3 n=15	QC1 %RSD	QCIII %RSD	QCV %RSD
Cyclosporin A	3.32 (pass)	3.35 (pass)	2.84 (pass)
Everolimus	4.91 (pass)	3.31 (pass)	3.00 (pass)
Sirolimus	4.71 (pass)	3.81 (pass)	2.62 (pass)
Tacrolimus	3.36 (pass)	3.01 (pass)	1.25 (pass)
TSQ Quantis MD #1 TSQ Quantis MD #2 TSQ Quantis MD #3 (Day One) Vanquish MD HPLC #1 n=15	QC1 %RSD	QCIII %RSD	QCV %RSD
Cyclosporin A	3.34 (pass)	3.47 (pass)	3.65 (pass)
Everolimus	5.38 (pass)	4.01 (pass)	3.70 (pass)
Sirolimus	4.55 (pass)	3.91 (pass)	4.01 (pass)
Tacrolimus	3.10 (pass)	3.11 (pass)	1.88 (pass)
TSQ Quantis MD #3 (Day One) TSQ Quantis MD #3 (Day Two) TSQ Quantis MD #3 (Day Three) Vanquish MD HPLC #1 n=15	QC1 %RSD	QCIII %RSD	QCV %RSD
Cyclosporin A	0.83 (pass)	0.55 (pass)	0.75 (pass)
Everolimus	4.00 (pass)	2.18 (pass)	1.85 (pass)
Sirolimus	4.15 (pass)	1.53 (pass)	2.31 (pass)
Tacrolimus	1.74 (pass)	0.96 (pass)	1.04 (pass)
TSQ Quantis MD #1 Vanquish MD HPLC #1 Vanquish MD HPLC #2 Vanquish MD HPLC #3 TSQ Quantis MD #2 Vanquish MD HPLC #1 TSQ Quantis MD #3 (Day One) TSQ Quantis MD #3 (Day Two) TSQ Quantis MD #3 (Day Three) Vanquish MD HPLC #1 n=35	QC1 %RSD	QCIII %RSD	QCV %RSD
Cyclosporin A	2.23 (pass)	2.31 (pass)	2.55 (pass)
Everolimus	4.56 (pass)	2.79 (pass)	2.60 (pass)
Sirolimus	4.23 (pass)	2.81 (pass)	2.97 (pass)
Tacrolimus	2.62 (pass)	2.35 (pass)	1.39 (pass)

Chromatogram for QC III run on TSQ Quantis MD #2 and Vanquish MD HPLC



From top to bottom: Cyclosporin A, Everolimus, Sirolimus and Tacrolimus

MS² Spectra for QC III run on TSQ Quantis MD #2 and Vanquish MD HPLC



From top to bottom: Cyclosporin A, Everolimus, Sirolimus and Tacrolimus. Greater relative abundance quantifier ion. Lesser relative abundance confirming ion.

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IVD In Vitro Diagnostic Medical Device

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