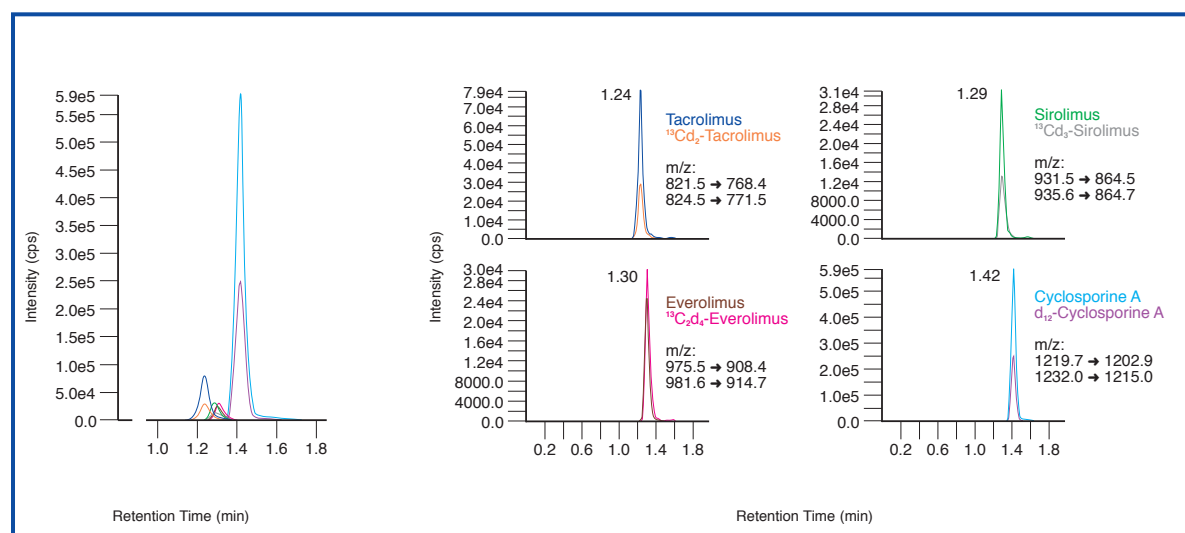


Therapeutic Drug Monitoring by LC-MS/MS

ClinMass® Immunosuppressants in Whole Blood, *advanced* – On-Line Analysis

Chromatogram (left) and mass traces (right) of the ClinCal® Whole Blood Calibrator (order no. 9933), level 4



This ClinMass® Complete Kit is an advancement of our reliable complete kit (order no. MS1000) for the therapeutic drug monitoring of cyclosporine A, tacrolimus, sirolimus and everolimus. The sample analysis is performed on-line within a 2 min injection interval. For analysis a new internal standard containing the isotope labelled analytes (d₁₂-cyclosporine A, ¹³Cd₂-tacrolimus, ¹³Cd₅-sirolimus and ¹³C₂d₄-everolimus) is available. A 4-Level and a 7-Level ClinCal® Whole Blood Calibrator Set are provided for precise calibration and measurement. The calibration range may be optionally extended by use of an additional high calibration point. Quality control is performed with ClinChek® Whole Blood Controls in five different levels.

- Fully automated on-line method
- Internal standard with isotope labelled analytes
- Two multi level calibrator sets available
- Calibration range optionally extensible
- Whole blood controls available in five levels

LC-MS/MS Parameters

LC-Parameters

Pump 1:	SPE-Buffer (0.1 - 2.5 ml/min)
Pump 2:	Mobile Phase (0.5 - 1.0 ml/min)
Injection volume:	50 µl
Injection interval:	2 min
Switching valve:	Automatic switching valve, 6-port/3-channel
Column heater:	60 °C

MS-Parameters

Ion-Source:	ESI positive
MS/MS-Mode:	MRM

Sample pretreatment

Precipitation:

200 µl Precipitant P	20 µl Internal Standard IS	100 µl whole blood (calibrator, control, patient)
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1. mix and incubate
(ambient temperature)
 2. mix and centrifuge

On-Line Analysis:

Inject 50 µl of the supernatant

Ordering Information

Order No.	Description	Quantity
MS1100	ClinMass® Complete Kit, <i>advanced</i> , for Immunosuppressants in Whole Blood for 400 assays	1 pce.
Contents (order no. MS1100):		
MS1005	Autosampler Washing Solution	1000 ml
MS1009	SPE-Buffer	1000 ml; within the kit: 2 x order no. MS1009
MS1010	Mobile Phase	800 ml
MS1412	IS Internal Standard, lyophil.	3 ml; within the kit: 3 x order no. MS1412
MS1020	Sample Pretreatment Vials	100 pcs.; within the kit: 4 x order no. MS1020
MS1021	P Precipitant Manual	80 ml
Additional Components:		
MS1006	Reagent MP	8 ml
MS1014	Optimisation Mix 1, lyophil.	2 ml
MS1115	Optimisation Mix 2, lyophil.	2 ml
5013	Whole Blood Calibrator, lyophil. (single point)	5 x 2 ml
9028	Whole Blood Calibrator, lyophil. (additional level for order nos. 9033 and 9933)	2 x 2 ml
9033	Whole Blood Calibrator Set, lyophil. (Level 0 - 3)	4 x 1 x 2 ml
9933	Whole Blood Calibrator Set, lyophil. (Level 0 - 6)	7 x 1 x 2 ml
Start Accessories:		
MS1030	Analytical Column with test chromatogram	1 pce.
MS1031	SPE-Column	1 pce.
MS1032	Guard Column Holder incl. 1 Guard Column	1 pce.
MS1033	Guard Column	5 pcs.
FK7400	Inline-Filter (stainless steel sieve, free of dead volume)	1 pce.
Accessories:		
FK1102	Switching valve Sykam (6-port/3-channel incl. electr. drive, PEEK)	1 pce.
FK7330	Endfittings	2 pcs.
FK7340	Sealings and sieves	4 pcs. each
FK7350	Endstoppers	2 pcs.
ClinChek® Controls:		
8830	Whole Blood Control, lyophil., Level I	5 x 2 ml
8831	Whole Blood Control, lyophil., Level II	5 x 2 ml
8832	Whole Blood Control, lyophil., Level III	5 x 2 ml
8833	Whole Blood Control, lyophil., Level I, II, III	3 x 2 x 2 ml
8903	Whole Blood Control, lyophil., Level IV, V	2 x 2 x 2 ml

RECIPE

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ISO 13485