



## DOSIMMUNE™

Ready-to-use LC-MS/MS reagent kit for immunosuppressants  
in whole blood

### **For Cyclosporin A, Tacrolimus, Sirolimus and Everolimus**

DOSIMMUNE™ is a turnkey solution:

- 3 sets consisting of: calibrators with 6 levels and blank, internal standards and quality controls with 4 levels
- ready-to-use consumables: Mobile Phase A, Mobile Phase B, System Cleaning Phase, extraction & reconstitution buffer, LC vials, microtubes, Analytical & Trap columns

**With Carbon 13 and Deuterium internal standards developed in-house**

# All-in-one support for you

The ALSACHIM ready-to-use DOSIMMUNE™ reagent kit supports your daily diagnostic work.

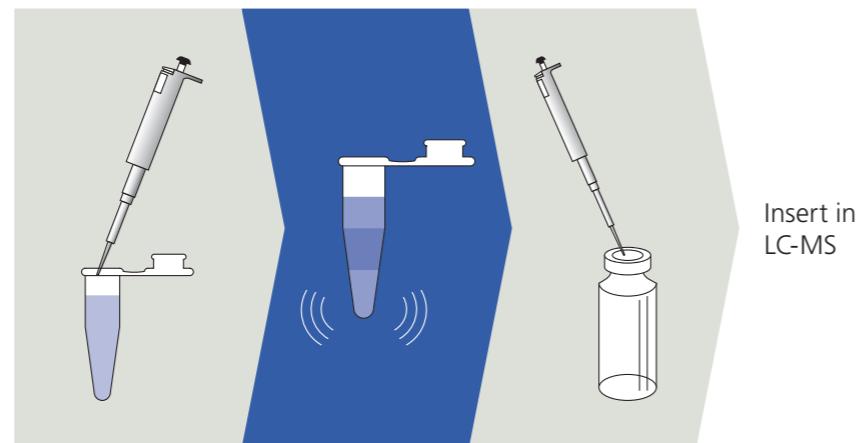
Accurate monitoring of immunosuppressant drugs is necessary for two reasons:

- to reduce transplant rejection or side-effects for patients
- their narrow therapeutic index.

Due to its specificity and sensitivity, mass spectrometry is the method of choice for the quantification of these molecules in such complex matrices.

## Sample preparation:

- Transfer calibrator or control or human blood sample
- Add Internal Standard
- Add Extraction buffer
- Shake and centrifuge
- Extract the supernatant
- Analyze



## LC-MS/MS parameter:

Injection volume: 1 – 50 µL

Ionization: ESI positive

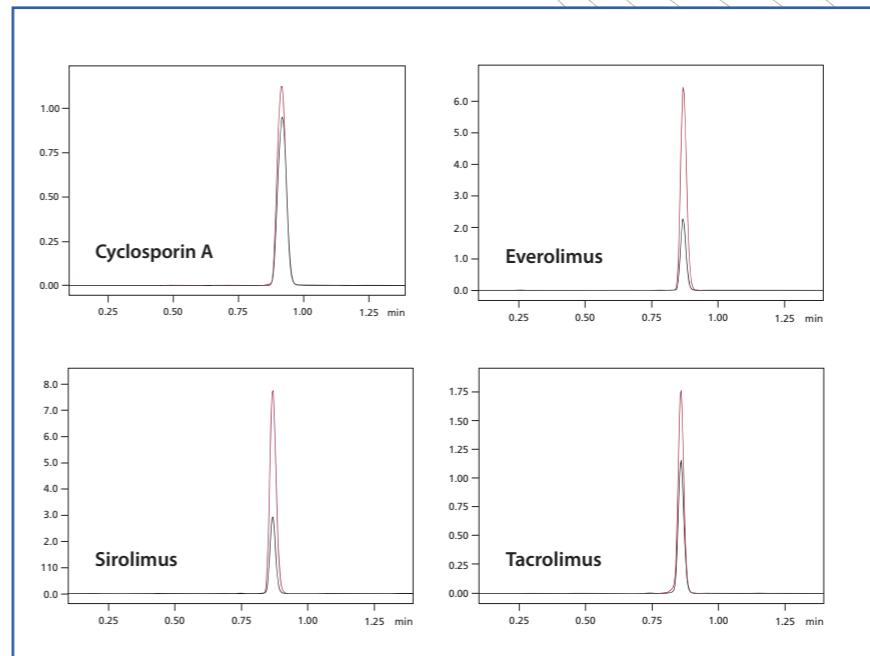
MS/MS-Mode: MRM

Molecules	MRM transitions
Everolimus	975.6 > 908.6
[ <sup>13</sup> C <sub>2</sub> , <sup>2</sup> H <sub>4</sub> ]-Everolimus	981.6 > 914.6
Sirolimus	931.5 > 864.5
[ <sup>13</sup> C, <sup>2</sup> H <sub>3</sub> ]-Sirolimus	935.5 > 864.5
Tacrolimus	821.5 > 768.5
[ <sup>13</sup> C, <sup>2</sup> H <sub>4</sub> ]-Tacrolimus	826.5 > 773.5
Cyclosporin A	1,219.8 > 1,202.8
[ <sup>2</sup> H <sub>12</sub> ]-Cyclosporin A	1,231.8 > 1,214.8

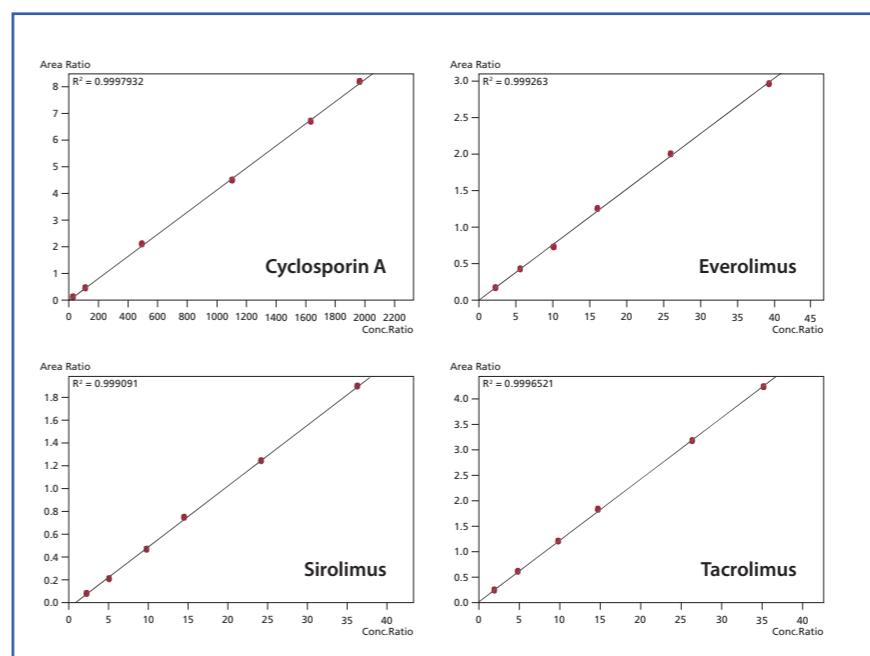


# LC-MS/MS analysis method

## Chromatograms:



## Calibration curves:



Analysis time: 1.4 min

## Specifications

### (Limit of quantification):

Cyclosporin A:	≤ 5.0 µg/L
Everolimus:	≤ 0.5 µg/L
Sirolimus:	≤ 0.5 µg/L
Tacrolimus:	≤ 0.5 µg/L

## Linearity:

Cyclosporin A:	up to 3,000 µg/L
Everolimus:	up to 100 µg/L
Sirolimus:	up to 100 µg/L
Tacrolimus:	up to 100 µg/L

## Calibrators concentration:

Cyclosporin A:	25 – 1,800 µg/L
Everolimus, Sirolimus, Tacrolimus:	2 – 35 µg/L

The validation method was developed following the ICH and COFRAC bioanalytical guidelines. DOSIMMUNE™ has been tested on Shimadzu, Agilent, ABSciex and Waters equipment.

# Key benefits of ready-to-use DOSIMMUNE™ kit



- **Standardized:**

Routine operation making interlaboratory comparison easier

- **Time saving:**

Ready-to-use and optimized method (resolution, sensitivity, speed of analysis), validated method incl. sample preparation and data acquisition methods

- Supported by the equipment manufacturer
- Consistent QC material available

Ref.	CE/IVD	RUO	Description
227-40100	-55	-58	DOSIMMUNE™ Kit for 1,000 analysis
227-40101	-55	-58	DOSIMMUNE™ Kit for 500 analysis
227-40102	-55	-58	Mobile Phase A
227-40103	-55	-58	Mobile Phase B
227-40104	-55	-58	System Cleaning Phase
227-40105	-55	-58	Extraction Buffer
227-40106	-55	-58	Internal Standard Set (lyoph.)
227-40110	-55	-58	Calibrator Set (lyoph.)
227-40120	-55	-58	Control Set (lyoph.)
227-40142	-55	-58	Columns Set
227-40135	-55	-58	Microtubes
227-40143	-55	-58	LC Vials Set (vials with low volume glass insert & caps)

## Methods and documentation

Complete Manual including analytical and sample preparation methods, safety data sheets, quality and analysis certificates, expiry dates, etc.

**ALSA CHIM**

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