



## 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.

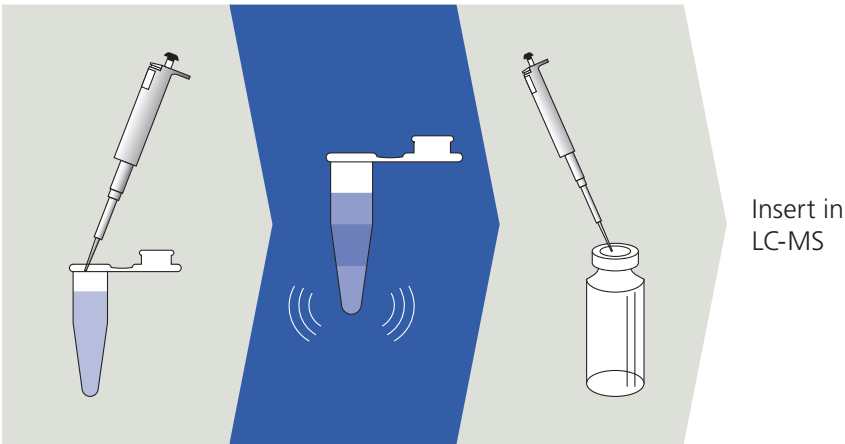
Due to its specificity and sensitivity, mass spectrometry is the method of choice for the quantification of these molecules in such complex matrices.

Consequently, ALSACHIM offers an LC-MS/MS method kit for the quantification of immunosuppressant drugs in whole blood.

Based on MRM technology and the use of stable labeled internal standards, the DOSIMMUNE™ kit enables simultaneous quantification of 4 immunosuppressant drugs in blood: **Cyclosporin A, Sirolimus, Tacrolimus and Everolimus.**

### 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:

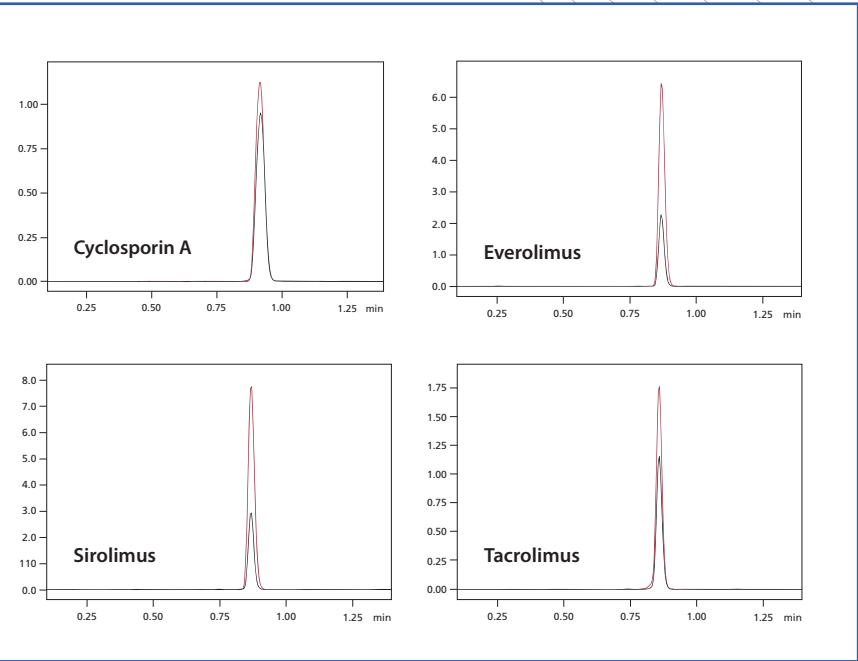
Injection volume: 1 – 50 µL  
Ionization: ESI positive  
MS/MS-Mode: MRM

| 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:



**Analysis time: 1.4 min**

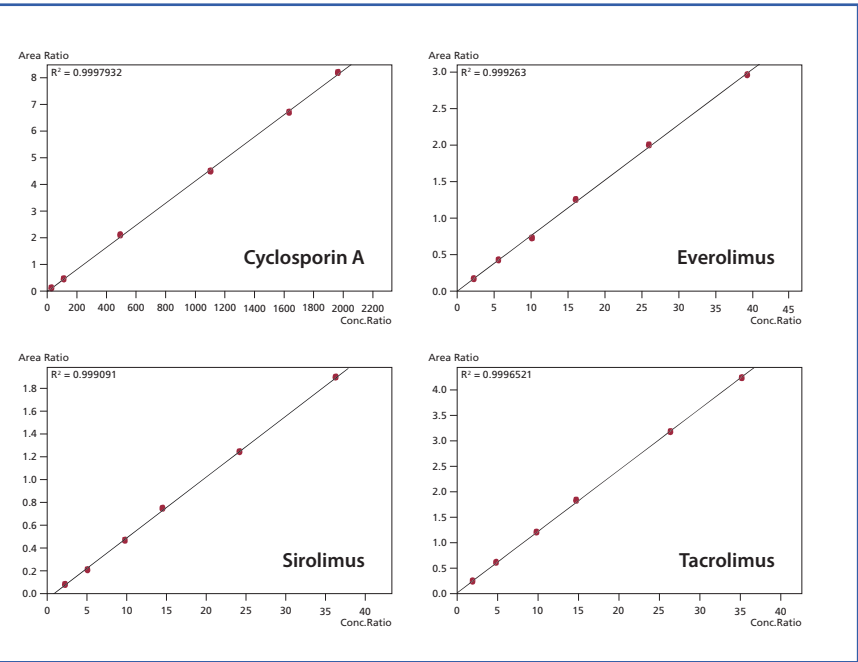
### Specifications (Limit of quantification):

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

### Calibration curves:

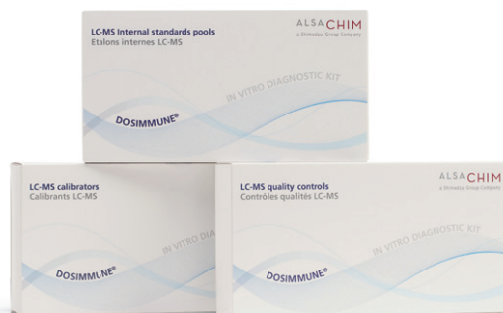


### Calibrators concentration:

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.

**ALSACHIM**

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