

# Can you run Sirolimus with other ISD Assays on one platform?



## Enduring Expertise

The proven Viva® Drug Testing Systems and Syva® EMIT® reagents offer the flexibility and capacity to meet all your immunosuppressant drug monitoring needs. Tailor your instrument and reagent combination to ideally suit your lab's needs.

Siemens Healthcare Diagnostics has more than 30 years of experience in drug testing. Our support provides your laboratory with a high level of service, education and training materials that enable you to keep up-to-date with the latest advancements in immunosuppressive drug monitoring.

## Expand your immunosuppressive drug testing offering

Monitoring Sirolimus levels in transplant patients ensures the delicate balance between appropriate immunosuppression and adverse effects. The new EMIT® 2000 Sirolimus Assay is a flexible and convenient solution to help clinicians effectively manage sirolimus therapy in their kidney transplant patients.

## Maximize your profitability – minimize your equipment

Concentrate your immunosuppressive drug (ISD) testing on just one platform to enhance productivity. You can run up to 5 ISD methods on a single Viva-E® or V-Twin® Drug Testing System:

- Cyclosporine A (CSA)
- Cyclosporine Extended Range (CSA-E)
- Mycophenolic Acid (MPA)\*
- Tacrolimus
- Sirolimus

## Incorporate Sirolimus Testing into your workflow

The EMIT 2000 Sirolimus Assay provides

- Simple sample pretreatment
- Reliable results in 14 minutes
- No reagent preparation
- Good correlation to LC/MS/MS

\* not available for sale in the US

**EMIT 2000 Sirolimus Assay**

Answers for life.

**SIEMENS**

# EMIT 2000 Sirolimus Assay Specifications

## Assay Analytical Performance

EMIT 2000 Sirolimus Assay	
Assay Principle	Homogeneous enzyme multiplied (EMIT)
Sample Type	EDTA Whole Blood
Sample Volume	400 µL (200 µL with own validation)
Assay Range	3.5 – 30 ng/mL
Reagent Stability	Unopened until expiry date, Opened reagent stability 4 weeks
Pretreatment	manual pretreatment
Calibration Frequency	Based on control results
Dilution	Manual dilution – 1:2
Limit of Detection	3.5 ng/mL
Functional Sensitivity	3.5 ng/mL

## Assay Precision/Reproducibility

Level	Mean ng/mL	Repeatability %CV	Within lab %CV
<b>Whole Blood Pools</b>			
Pool 1	5.0	8.0	13.4
Pool 2	4.9	5.4	10.1
Pool 3	10.7	3.6	8.3
Pool 4	10.3	4.9	7.4
Pool 5	25.3	4.2	8.3
Pool 6	23.6	4.2	8.2

## Ordering Information

Catalog No.	Contents	Volume
8S019UL	EMIT 2000 Sirolimus Assay	22 mL R1, 11 mL R2, 11 mL R3
8S109UL	EMIT 2000 Sirolimus Calibrators	6 x 2.5 mL (six levels)
8S079UL	EMIT 2000 Siro/Tacro Sample Pretreatment reagent	4 x 29 mL

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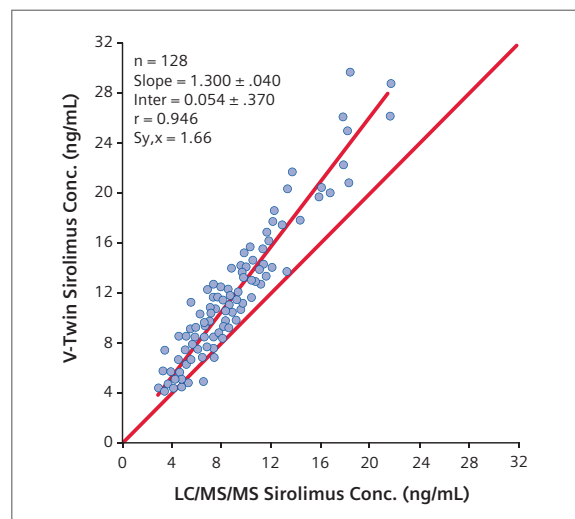
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## Analytical Agreement

Method	Slope	Intercept ng/mL	Correlation Coefficient	n
LC-MS/MS	1.30	0.054	0.95	128

CLSI/NCCLS EP9-A2 was used. The method used to fit the linear regression line was ordinary least squares. The model equation for regression statistics is: Result of V-Twin system = (Slope x comparative method result) + intercept.

## Method Comparison – SIROLIMUS V-Twin vs. LC/MS/MS



## Global Division

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