The Most Parent Drug Specific Cyclosporine A (CsA) Assay

Turn to the proven drug testing expert

The proven Viva® drug testing systems and Emit® reagents and the Dimension® integrated chemistry systems – for monitoring Cyclosporine C_0 and C_2, Mycophenolic Acid[1] and Tacrolimus – have 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.

Your solution is accompanied by the strong support network of Siemens Healthcare Diagnostics with 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 your field of expertise.

Enhance your productivity: Streamline your ISD monitoring workflow

The Emit 2000 Cyclosporine assay is designed for the quantitative analysis of Cyclosporine in human whole blood.[2] The challenge in CsA monitoring is differentiating CsA from its metabolites to reduce risk of under-dosing. The preferred method is highly specific for the parent drug.

In addition to the trough (C_0) level samples, the measurement of C_2 values (blood levels 2 hours after medication) can also be performed with the Emit 2000 Cyclosporine Assay.
With C_2 plus C_0 capability, the assay satisfies your patient and laboratory needs.[3,4,5,6]

Assay characteristics:

- Parent drug specific antibody
- Excellent correlation with HPLC, the reference method
- Simple pre-treatment procedure
- Liquid, ready to use reagent
- Able to measure C_0 and C_2
- Rapid results – 10 minutes to first results, up to 130 tests per hour on Viva-E® and 260 tests per hour on V-Twin®
- 3 ISD assays on one analyzer

Cyclosporine, the drug

Cyclosporine is a cyclic undecapeptide immunosuppressant of fungal origin. It is a calcineurin inhibitor with selective action on T lymphocytes. CsA undergoes hepatic metabolism before biliary excretion, which is the major route of elimination. CsA metabolites can be reabsorbed into systemic circulation.

Administrated Drugs: Sandimune®, Novartis Neoral®, Novartis/ SangCya®, SangStat.

Emit® 2000 Cyclosporine A (CsA) Assay

Answers for life.

SIEMENS

Meeting the need – the Emit 2000 Cyclosporine A (CsA) Assay

Assay performance data

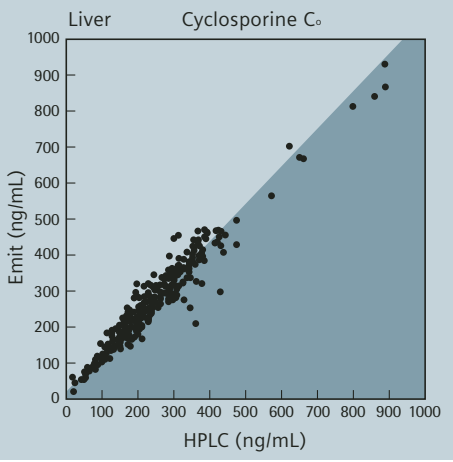
No significant cross-reactivity with CsA metabolites

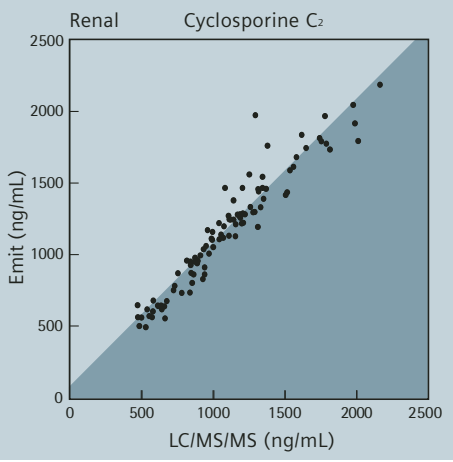
Cross-reactivity of Emit 2000 Cyclosporine Specific Assay to Major Metabolites of Cyclosporine

Cyclosporine Metabolite	Level (ng/mL)	Cross-reactivity (%)
AM1 (M17)	500	<0.3
AM19 (M8)	500	3.0
AM4N (M21)	500	<0.3
AM9 (M1)	670	7.3

Assay Range: C_0 40-500 ng/mL, C_2 500-2000 ng/mL

Patient correlation[7]





Quality Control	BioRad or MORE
Stability	Eighteen (18) months
Assay Principle	Homogenous enzyme immunoassay technique
Type of Measurement	Photometric
Sample Type	EDTA Whole Blood (200 µl)
Reportable Range	CSA: 40-500 ng/mL CSAE: 350-2000 ng/mL
Sensitivity Limit	Analytical: 40 ng/ml Functional (CSAE): < 350 ng/mL

Ordering Information:

Product code: 6R019UL
6R079UL

Packaging: 100 assays

[1] Emit MPA assay is available outside the US; Dimension MPA assay is in development.
* automated

[2] Johnston A, Holt D W: Cyclosporine C_2 Monitoring: The Story so far. Dade Behring Journal; July 2005; p. 7-13.
[3] Levy G et al: Improved Clinical Outcomes for Liver Transplant Recipients Using Cyclosporine Monitoring Based on 2-hr-Post-Dose Levels (C_2). Transpl 2002; 73(6): 953-959.
[4] Holt D W, Johnston A: The Impact of Cyclosporine Formulation in Clinical Outcomes. Transpl Proc 2000; 32(7): 1552-1555.
[5] Jorga A, Holt D W, Johnston A: Therapeutic Drug Monitoring of Cyclosporine. Transpl Proc 2004; 36(2S): 396S-496S.
[6] Einecke G et al: The Value of C_2 Monitoring in Stable Renal Allograft Recipients on Maintenance Immunosuppression. Nephrol Dial Transpl 2004; 19(1): 215-222.
[7] Evaluation Report for Emit® 2000 Cyclosporine Assay

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