

The First Automated Assay for Monitoring Mycophenolic Acid

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 C₀ and C₂, Mycophenolic Acid¹ 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 Mycophenolic Acid Assay is designed for the quantitative analysis of Mycophenolic Acid (MPA) in human plasma as an aid in the management of MPA therapy in transplant patients. MPA concentration in patients is highly variable and hence needs to be individualized depending on transplant type, co-administrated drugs, time post transplant, etc.

Assay characteristics:

- Unique automated immunoassay
- Excellent correlation with HPLC, the reference method²
- No sample pre-treatment (plasma)
- 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

Cellcept®, Myfortic®, the drug

Cellcept® and Myfortic® deliver the active moiety of Mycophenolic Acid (MPA), an immunosuppressive agent. MPA is a potent and specific inhibitor of the de novo purine synthesis, and blocks the proliferation of both T and B lymphocytes. Administrated drugs: Cellcept®/Roche, Myfortic®/Novartis. MPA is further metabolized to Mycophenolic Acid Glucuronide (MPAG). MPAG is considered pharmacologically inactive but may be reconverted to MPA by enterohepatic recirculation. MPA concentrations vary between CsA or Tacrolimus co-administration. Children metabolize the drug faster than adults.



Emit® 2000 Mycophenolic Acid (MPA) Assay

Answers for life.

SIEMENS

Meeting the need – the Emit 2000 Mycophenolic Acid (MPA) Assay

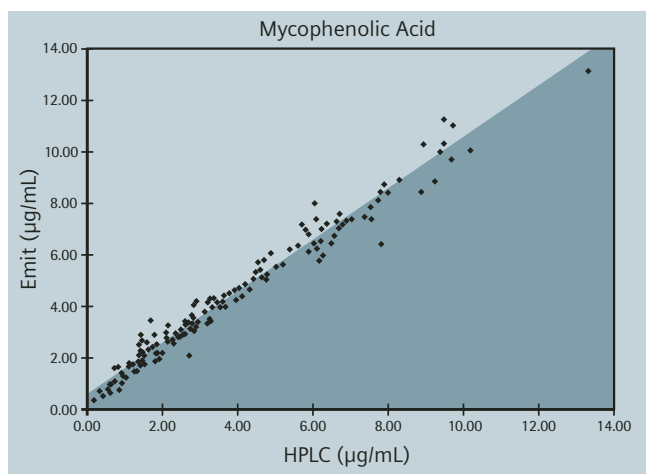
Assay performance data

- No cross-reactivity with MPAG (Mycophenolic Acid Glucuronide)³
- No cross-reactivity with Cyclosporine, Tacrolimus or 55 commonly co-administrated drugs
- No interference from triglycerides, bilirubin, uric acid, cholesterol or hemoglobin

Precision and recovery

Test Level	Mean (µg/ml)	Within run Precision (%)	Total Precision (%)	Recovery (%)
Low	1.0	3.4	6.1	99
Medium	7.5	3.6	4.5	103
High	12.0	4.9	6.5	102

Patient correlation⁴



Trough level: 1-3.5 µg/mL (predose concentration)³
30-60 mg*h/L total MPA AUC 0-12 level for the early post transplant period when prescribed together with cyclosporine.^{5,6}
Trough: between 3-8 µg/mL

Ordering Information:

Product code: 6R919UL

Packaging: 100 assays

- ¹ Emit MPA assay is available outside the US; Dimension MPA assay is in development.
- ² Weber L T et al: Comparison of the Emit Immunoassay with HPLC for Therapeutic Drug Monitoring of Mycophenolic Acid in Pediatric Renal-Transplant Recipients on Mycophenolic Mofetil Therapy. *ClinChem* 2002; 48(3): 517-525.
- ³ Vogl M et al: Evaluation of the Emit Mycophenolic Acid Assay from Dade Behring. *Ther Drug Monit* 1999; 21(6): 638.
- ⁴ Scientific Poster, 5th ICTDMCT, Vancouver, Nov 1997.
- ⁵ Shaw L M et al: Using Established Immunosuppressant Therapy Effectively – Lessons from the Measurement of Mycophenolic Acid Plasma Concentrations. *Ther Drug Monit* 2004; 26(4): 347-351.
- ⁶ CellCept® Package Insert; Roche Laboratories Inc., Dec 2000.

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