

Overview

Useful For

Monitoring therapy to ensure adequate blood levels and avoid over-immunosuppression

Method Name

Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS)

NY State Available

Yes

Specimen

Specimen Type

Serum Red

Specimen Required

Collection Container/Tube: Red top (serum gel/SST are **not acceptable**)

Submission Container/Tube: Plastic vial

Specimen Volume: 1 mL

Collection Instructions:

- 1. Draw blood immediately before the next scheduled dose (trough).
- 2. Centrifuge and aliquot serum into a plastic vial.

Forms

If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:

- [Renal Diagnostics Test Request](#) (T830)
- [Therapeutics Test Request](#) (T831)
- [Kidney Transplant Test Request](#)

Specimen Minimum Volume

0.25 mL

Reject Due To

Gross hemolysis	OK
Gross lipemia	OK
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum Red	Refrigerated (preferred)	28 days	
	Ambient	21 days	
	Frozen	28 days	

## Clinical & Interpretive

### Clinical Information

Mycophenolate mofetil (CellCept) is an immunosuppressive agent useful in organ transplantation. It is approved for use in renal, hepatic, and cardiac transplants. When mycophenolate mofetil enters the blood, it is immediately metabolized to the active drug, mycophenolic acid (MPA), which inhibits inosine monophosphate dehydrogenase and interferes with the *de novo* pathway of guanosine nucleotide synthesis selectively in lymphocytes. MPA inhibits proliferative responses of T and B lymphocytes to both mitogenic and allo-specific stimulation. MPA acts in the same fashion as azathioprine, and MPA is suggested as replacement therapy for azathioprine. The drug is deactivated by the hepatic enzyme, uridine diphosphate glucuronosyltransferase to form MPA glucuronide (MPA-G).

The principle clinical problem encountered in MPA therapy is excessive immunosuppression, which predisposes the patient to systemic infection. Measurement of the blood level of MPA and MPA-G can be useful to guide therapy.

Monitoring is recommended before and after making any changes to immunosuppressive therapy or when initiating or discontinuing concomitant medications. Additional monitoring is indicated if the MPA level is not in the therapeutic range or if a major change in health status occurs.

### Reference Values

MYCOPHENOLIC ACID (MPA)

1.0-3.5 mcg/mL

MPA GLUCURONIDE

35-100 mcg/mL

### Interpretation

Trough steady-state serum levels of mycophenolic acid (MPA) (>2 weeks at the same dose) in the range of 1.0 to 3.5 mcg/mL indicate adequate therapy. MPA glucuronide (MPA-G) levels in the range of 35 to 100 mcg/mL indicate that the patient has normal uridine diphosphate glucuronosyltransferase (UGT) metabolic capacity. MPA-G levels are typically in the range of 100 to 250 mcg/mL during the 2 weeks following transplantation. MPA-G typically decreases after this initial post-transplant phase.

Trough steady-state serum MPA levels over 4.0 mcg/mL indicate that the patient is over-immunosuppressed and susceptible to systemic infections. Decreased dosages may be indicated in these cases.

Low MPA levels and high MPA-G levels suggest that the patient has an active UGT metabolic capability; higher doses may be required to maintain therapeutic levels of MPA. Some patients have a high UGT metabolic capacity. These patients may require 1 or more grams 3 times a day to maintain trough serum MPA levels in the range of 1.0 mcg/mL to

3.5 mcg/mL. They are likely to have MPA-G levels over 100 mcg/mL. MPA-G is inactive; MPA-G levels only describe the patient's metabolic status.

Patients who have low UGT conjugating capability may become over-immunosuppressed, indicated by a trough steady-state serum MPA level over 4.0 mcg/mL and an MPA-G level below 40 mcg/mL. Dose reduction or interval prolongation is indicated in this case.

### Cautions

Correct interpretation requires a trough serum specimen (just before the next regular dose). Specimens collected at other times in the dosing cycle are likely to have higher mycophenolic acid levels. In these cases, the reference range does not apply.

### Clinical Reference

1. Moyer TP, Shaw LM. Therapeutic drug monitoring. In: Burtis CA, Ashwood ER, Bruns DE, eds. Tietz Textbook of Clinical Chemistry. 4th ed. WB Saunders Company; 2005:1237-1285
2. Milone M, Shaw LM. Therapeutic drugs and their management. In: Rifai N, Rossa WKC, Young I, Carey-Ann DB, Wittwer CT, eds. Tietz Textbook of Laboratory Medicine. 7th ed. Elsevier; 2023:chap 42
3. Shaw LM, Sollinger HW, Halloran P, et al. Mycophenolate mofetil: a report of the consensus panel. Ther Drug Monit. 1995;17:690-699

## Performance

### Method Description

Liquid chromatography tandem mass spectrometry is used to quantify the serum concentration of mycophenolic acid (MPA) and MPA glucuronide.(Unpublished Mayo method)

### PDF Report

No

### Day(s) Performed

Monday through Sunday

### Report Available

Same day/1 to 3 days

### Specimen Retention Time

2 weeks

### Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Superior Drive

## Fees & Codes

Fees

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact [Customer Service](#).

Test Classification

This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

80180

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
MPA	Mycophenolic Acid, S	87432-1

Result ID	Test Result Name	Result LOINC® Value
15226	Mycophenolic Acid	23905-3
15227	MPA Glucuronide	23906-1