

**Overview**
**Useful For**

Monitoring therapy with CellCept to ensure adequate blood levels and avoid overimmunosuppression

**Method Name**

TandemMassSpectrometry(MS/MS)

**NY State Available**

Yes

**Specimen**
**Specimen Type**

Serum Red

**Specimen Required**

**Container/Tube:**Red top

**Specimen Volume:**1 mL

**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)

**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	
	Frozen	28 days	
	Ambient	21 days	

**Clinical and Interpretive**

## Clinical Information

Mycophenolate mofetil (CellCept) is a new 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 allospecific 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 mycophenolic acid 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 immediately after transplant up to 3 weeks after therapy is initiated to evaluate dosing adequacy. 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 serum levels of mycophenolic acid (MPA) at steady-state (>2 weeks at the same dose) in the range of 1.0 to 3.5 mcg/mL indicate adequate therapy. Mycophenolic acid 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 >4.0 mcg/mL indicate that the patient is overimmunosuppressed 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 gram or more 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 >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 overimmunosuppressed, indicated by a trough steady-state serum MPA level >4.0 mcg/mL and a MPA-G level <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 drawn 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 Tietz Textbook of Clinical Chemistry. Fourth edition. Edited by CA Burtis, ER Ashwood, DE Bruns. Philadelphia, WB Saunders Company, 2005, pp 1237-1285
2. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics Sixth edition. Edited by Nader Rifai, Andrea Rita Horvath, Carl T. Wittwer. Elsevier, St. Louis, MO, 2018

## Performance

### Method Description

Tandem mass spectrometry is used to quantify the serum concentration of mycophenolic acid (MPA) and mycophenolic acid glucuronide (MPA-G). The test involves direct measurement of serum for MPA and MPA-G. (Moyer TP, Shaw LM: Therapeutic drug monitoring. In Tietz Textbook of Clinical Chemistry. Fourth edition. Edited by CA Burtis, ER Ashwood, DE Bruns. Philadelphia, WB Saunders Company, 2005, pp 1237-1285)

### PDF Report

No

### Day(s) and Time(s) Test Performed

Monday through Sunday; Varies

### Analytic Time

Same day/1 day

### Maximum Laboratory Time

3 days

### Specimen Retention Time

2 weeks

### Performing Laboratory Location

Rochester

## Fees and 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 Regional Manager. 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. This test has not been cleared or approved by the U.S. Food and Drug Administration.

### CPT Code Information

80180

### LOINC® Information



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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