

Mycophenolic Acid Drug Monitoring

Indications for Ordering

Optimize drug therapy and monitor patient adherence

Test Description

Quantitative liquid chromatography-tandem mass spectrometry

- Includes testing for mycophenolic acid and mycophenolic acid glucuronide

Tests to Consider

[Mycophenolic Acid and Metabolites 2010359](#)

- Predose (trough) concentration at steady state should be assessed
- Trade names include CellCept, Myfortic

Disease Overview

Clinical issues

- Mycophenolate is an immunosuppressant
- Extensively utilized in organ transplantation regimens
 - Most commonly renal, cardiac, or hepatic transplants
- Also used in treatment of some autoimmune disorders (eg, systemic lupus erythematosus, Crohn disease)

Physiology

- Inhibits inosine monophosphate dehydrogenase
 - Enzyme is crucial for the formation of DNA in cells
 - Blocking of enzyme impairs function of immune system cells
- Major metabolites are mycophenolic acid glucuronide and mycophenolic acid acyl-glucuronide
 - Mycophenolic acid glucuronide – inactive metabolite
 - Concentrations typically 100-250 µg/mL during first two weeks post transplantation
 - Mycophenolic acid acyl-glucuronide – active metabolite

Drug profile

- Long list of drugs that interfere with metabolism of mycophenolate
- Dose adjustments do not appear necessary in severe renal or hepatic disease

Test Interpretation

Analytical sensitivity – limit of detection is 0.5 µg/mL

Results

- Concentration is reported
- Suggested therapeutic range
 - Mycophenolic acid
 - 2 g/day dose – 1.0-3.5 µg/mL
 - 3g/day dose – may have up to 5.0 µg/mL concentration
 - 2.0-4.0 µg/mL range is suggested for maximal efficacy with minimal toxicity
 - Mycophenolic acid glucuronide – 35.0-100.0 µg/mL
- Toxic range
 - Mycophenolic acid – >25.0 µg/mL

Limitations

Toxic and therapeutic ranges are not well established for metabolites