

Overview

Useful For

Monitoring whole blood cyclosporine concentration during therapy, particularly in individuals coadministered CYP3A4 substrates, inhibitors, or inducers

Adjusting dose to optimize immunosuppression while minimizing toxicity

Evaluating patient compliance

Method Name

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

NY State Available

Yes

Specimen

Specimen Type

Whole Blood EDTA

Necessary Information

Date of last dose, time of last dose, and dosage information are required.

Specimen Required

Container/Tube: Lavender top (EDTA)

Specimen Volume: 3 mL

Collection Instructions:

1. Do not centrifuge.
2. Send specimen in original tube.

Additional Information: No definitive therapeutic or toxic ranges have been established for this Peak testing.

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

1 mL

Reject Due To

Gross hemolysis	OK
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Gross lipemia	OK
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Whole Blood EDTA	Refrigerated (preferred)	14 days	
	Ambient	14 days	
	Frozen	14 days	

Clinical and Interpretive

Clinical Information

Cyclosporine is a lipophilic polypeptide used to prevent rejection after solid organ transplantation; it suppresses T-cell activation by inhibiting calcineurin to decrease interleukin-2 (IL-2) production. There is substantial interpatient variability in absorption, half-life, and other pharmacokinetic parameters. Cyclosporine is extensively metabolized by CYP3A4 to at least 30 less-active metabolites, many of which are detected by immunoassays. Cyclosporine is known for many drug interactions, including increased neuro- and nephrotoxicity when coadministered with antibiotics, antifungals, or other immunosuppressants. Cyclosporine has a narrow therapeutic range with frequent adverse effects making therapeutic drug monitoring essential. With 80% of cyclosporine sequestered in erythrocytes, whole blood is the preferred specimen for analysis.

Reference Values

No definitive therapeutic or toxic ranges have been established.

Optimal blood drug levels are influenced by type of transplant, patient response, time posttransplant, coadministration of other drugs, and drug formulation.

The following 2-hour postdose cyclosporine ranges are only suggested guidelines:

Renal transplant: 800-1700 ng/mL

Liver transplant: 600-1000 ng/mL

Target steady-state peak concentrations vary depending on the type of transplant, concomitant immunosuppression, clinical/institutional protocols, and time posttransplant. Results should be interpreted in conjunction with this clinical information and any physical signs/symptoms of rejection/toxicity.

Interpretation

No definitive therapeutic or toxic ranges have been established for postdose peak monitoring. Preferred therapeutic ranges may vary by transplant type, protocol, and comedication. The 2-hour postdose cyclosporine ranges listed for this test are only suggested guidelines.

This assay is specific for cyclosporine; it does not cross-react with cyclosporine metabolites, sirolimus, sirolimus metabolites, tacrolimus, or tacrolimus metabolites. Results by liquid chromatography with detection by tandem mass spectrometry are approximately 30% less than by immunoassay.

Cautions

No definitive therapeutic or toxic ranges have been established for postdose peak monitoring. Preferred therapeutic ranges may vary by transplant type, protocol, and comedications.

Clinical Reference

1. Moyer TP, Post GR, Sterioff S, et al: Cyclosporine nephrotoxicity is minimized by adjusting dosage on the basis of drug concentration in blood. Mayo Clin Proc 1988 March;63(3):241-247
2. Kahan BD, Keown P, Levy GA, et al: Therapeutic drug monitoring of immunosuppressant drugs in clinical practice. Clin Ther 2002 March; 24(3):330-350
3. Dunn CJ, Wagstaff AJ, Perry CM, et al: Cyclosporin: an updated review of the pharmacokinetic properties, clinical efficacy, and tolerability of a microemulsion-based formulation (Neoral) 1 in organ transplantation. Drugs 2001;61(13):1957-2016

Performance**Method Description**

Blood specimens are subjected to protein precipitation. The resulting supernatant is analyzed by liquid chromatography-tandem mass spectrometry.(Charlson JC, Moyer TP. In Tietz Textbook of Clinical Chemistry. Fourth edition. Edited by CA Burtis, ER Ashwood, DE Bruns. New York, WB Saunders Company, 2004)

PDF Report

No

Day(s) Performed

Monday through Sunday

Report Available

Same day/1 day

Specimen Retention Time

14 days

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 US Food and Drug Administration.

CPT Code Information

80158

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
CYCPK	Cyclosporine, Peak, B	53834-8

Result ID	Test Result Name	Result LOINC Value
42398	Cyclosporine, Peak, B	53834-8
DATEC	Date of last dose	29742-4
TIMEC	Time of last dose	29637-6
DOSEC	Dose, mg	4207-7