

## Overview

### Useful For

Monitoring whole blood peak cyclosporine concentration during therapy, particularly in individuals coadministered cytochrome P450 (CYP) 3A4 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 whole blood specimen in original tube. **Do not aliquot.**

**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
Gross lipemia	OK
Gross icterus	OK
Clotted specimen	Reject

Specimen Stability Information

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

Clinical & 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 cytochrome P450 (CYP) 3A4 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:

Kidney 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 comedications. 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**

Established (trough) cyclosporine reference ranges do not apply to specimens collected after administration of a dose. For trough specimens, order CYCSP / Cyclosporine, Blood.

**Clinical Reference**

1. Milone MC, Shaw LM: Therapeutic drugs and their management. In: Rifai N, Chiu RWK, Young I, Burnham CAD, eds. Tietz Textbook of Laboratory Medicine. 7th ed. Elsevier; 2023:420-453
2. Moyer TP, Post GR, Sterioff S, Anderson CF: Cyclosporine nephrotoxicity is minimized by adjusting dosage on the basis of drug concentration in blood. Mayo Clin Proc. 1988 March;63(3):241-247
3. Kahan BD, Keown P, Levy GA, Johnston A: Therapeutic drug monitoring of immunosuppressant drugs in clinical practice. Clin Ther. 2002 March;24(3):330-350
4. Dunn CJ, Wagstaff AJ, Perry CM, Plosker GL, Goa KL: 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.(Bjergum MW, Jannetto PJ, Langman LJ. Simultaneous determination of tacrolimus and cyclosporine A in whole blood by ultrafast LC-MS/MS. Methods Mol Biol. 2019;1872:111-118. doi: 10.1007/978-1-4939-8823-5\_11)

**PDF Report**

No

**Day(s) Performed**

Monday through Sunday

**Report Available**

2 to 4 days

**Specimen Retention Time**

14 days

**Performing Laboratory Location**

Rochester

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

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