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**Overview****Useful For**

Monitoring whole blood tacrolimus 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**

High-Performance Liquid Chromatography/Tandem Mass Spectrometry (HPLC-MS/MS)

**NY State Available**

Yes

**Specimen****Specimen Type**

Whole Blood EDTA

**Specimen Required**

**Container/Tube:** Lavender top (EDTA)

**Specimen Volume:** 3 mL

**Collection Instructions:**

1. Draw blood immediately before a schedule dose.
2. Do not centrifuge.
3. Send specimen in original tube.

**Additional Information:** Therapeutic range applies to trough specimens drawn immediately prior to a.m. dose.

**Forms**

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

-[General Request](#) (T239)

-[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

### 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

Tacrolimus is a macrolide antibiotic derived from the fungus *Streptomyces tsukubaensis*. Like cyclosporine, tacrolimus inhibits calcineurin to suppress T cells. Tacrolimus is metabolized by CYP3A4, thus its concentrations are affected by drugs that inhibit (calcium channel blockers, antifungal agents, some antibiotics, grapefruit juice) or induce (anticonvulsants, rifampin) this enzyme. Tacrolimus has a narrow therapeutic range, and adverse effects are common, particularly at high dose and concentrations, making therapeutic drug monitoring essential.

Since 90% of tacrolimus is in the cellular components of blood, especially erythrocytes, whole blood is the preferred specimen for analysis of trough concentrations. Target steady-state concentrations vary depending on clinical protocol, the presence or risk of rejection, time from transplant, type of allograft, concomitant immunosuppression, and side effects (mainly nephrotoxicity). Optimal trough blood concentrations are generally between 5.0 and 15.0 ng/mL. Higher levels are often sought immediately after transplant, but as organ function stabilizes at about 4 weeks from transplant, doses are generally reduced in stable patients for most solid organ transplants. Trough concentrations should be maintained below 20 ng/mL.

#### Reference Values

5.0-15.0 ng/mL (Trough)

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

#### Interpretation

[Most individuals display optimal response to tacrolimus with trough whole blood levels of 5.0 to 15.0 ng/mL. Preferred therapeutic ranges may vary by transplant type, protocol, and comedications.](#)

Therapeutic ranges are based on samples drawn at trough (ie, immediately before a scheduled dose). Blood drawn at other times will yield higher results.

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

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**Cautions**

The recommended therapeutic range applies to trough specimens drawn immediately before a dose. Blood drawn at other times will yield higher results.

**Clinical Reference**

1. 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

2. Scott LJ, McKeage K, Keam SJ, et al: Tacrolimus: a further update of its use in the management of organ transplantation. Drugs 2003;63(12):1247-1297

**Performance****Method Description**

Blood samples are subjected to protein precipitation. The resulting supernatant is analyzed by liquid chromatography-tandem mass spectrometry. (Charlson JC, Moyer TP: Therapeutic drug monitoring. 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) and Time(s) Test Performed**

Monday through Friday; Continuous until 3 p.m.

Saturday, Sunday; Continuous until 1 p.m.

**Analytic Time**

Same day/1 day

**Maximum Laboratory Time**

2 days

**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 U.S. Food and Drug Administration.

**CPT Code Information**

80197

**LOINC® Information**

Test ID	Test Order Name	Order LOINC Value
TAKRO	Tacrolimus, B	77348-1

Result ID	Test Result Name	Result LOINC Value
35145	Tacrolimus, B	77348-1