Test Definition: TAKRO

Tacrolimus, B

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.

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) Performed

Monday through Sunday

Report Available

Same day/1 to 3 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 US Food and Drug Administration.

CPT Code Information

80197

LOINC® Information

Test Definition: TAKRO

Tacrolimus, B

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