Test Definition: TACPK

Tacrolimus, Peak, B

Overview

Useful For

Assessment of postdosing (peak) blood tacrolimus concentrations

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.

Forms

If not ordering electronically, complete, print, and send a Therapeutics Test Request (T831) with the specimen.

Specimen Minimum Volume

1 mL

Reject Due To

Gross hemolysis	OK
Gros lipemia	OK
Gross icterus	OK

Specimen Stability Information

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

Specimen Type	Temperature	Time	Special Container
	Frozen	14 days	

Clinical and Interpretive

Clinical Information

Tacrolimus (Prograf) is a macrolide antibiotic derived from the fungus *Streptomyces tsukubaenesis*. Like cyclosporine, tacrolimus inhibits calcineurin to suppress T cells. Tacrolimus is metabolized by CYP3A4; thus, its concentration is 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 solid organ transplant patients who are stable. Trough concentrations should be maintained below 20 ng/mL.

Optimal postdose sampling strategies and blood concentrations have not been well established for tacrolimus. A study of 54 liver transplant patients suggested that most individuals have tacrolimus blood concentrations ranging between 5.0 and 30.0 ng/mL in samples drawn 1 to 4 hours after dosing, although some patients showed slightly higher blood concentrations at 1-hour postdose.

Reference Values

5.0-30.0 ng/mL

Target steady-state trough 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 or symptoms of rejection or toxicity.

Interpretation

This test measures postdose levels of tacrolimus. Established reference ranges reflect trough measurement, and are not applicable to samples drawn after dosing. No reference ranges or standard sampling protocols have been established for postdosing tacrolimus levels, but a limited study of liver transplant recipients suggests most patients will show postdose tacrolimus levels ranging from 5.0 to 30.0 ng/mL when drawn 1 to 4 hours after dosing. The narrow therapeutic window and high individual pharmacokinetic variability of tacrolimus make regulation of dose by blood concentrations essential. Since 90% of the drug is in the cellular components of blood, especially erythrocytes, whole blood, rather than plasma, concentrations are measured and correlate better with efficacy and toxicity.

This 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 (LC-MS/MS) are approximately 30% less than by immunoassay.

Cautions

Established (trough) tacrolimus reference ranges do not apply to samples drawn after administration of a dose. Order TACRO / Tacrolimus, Blood, for trough samples.

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 (LC-MS/MS).(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

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 Definition: TACPK

Tacrolimus, Peak, B

Test ID	Test Order Name	Order LOINC Value
TACPK	Tacrolimus, Peak, B	59822-7

Result ID	Test Result Name	Result LOINC Value
88157	Tacrolimus, Peak, B	59822-7
DAT7	Date of last dose	29742-4
TM01	Time of last dose	29637-6
DOSE1	Dose, mg	32594-4