Test Definition: TACPK

Tacrolimus, Peak, Blood

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

Ordering Guidance

This test is for specimens collected during a peak period. For specimens collected at trough, order TAKRO / Tacrolimus, Blood.

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.**

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

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

Tacrolimus (Prograf) is a macrolide antibiotic derived from the fungus *Streptomyces tsukubaensis*. Like cyclosporine, tacrolimus inhibits calcineurin to suppress T cells. Tacrolimus is metabolized by cytochrome P450 (CYP) 3A4; 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 doses 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.

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 specimens collected 1 to 4 hours after dosing, although some patients showed slightly higher blood concentrations 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 specimens collected 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 collected 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 are approximately 30% less than by immunoassay.

Cautions

Results by liquid chromatography with detection by tandem mass spectrometry are approximately 30% less than by immunoassay.

Established (trough) tacrolimus reference ranges do not apply to specimens collected after administration of a dose. For trough specimens, order TACRO / Tacrolimus, 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. Kahan BD, Keown P, Levy GA, Johnston A. Therapeutic drug monitoring of immunosuppressant drugs in clinical practice. Clin Ther. 2002;24(3):330-350
3. Scott LJ, McKeage K, Keam SJ, Plosker GL. Tacrolimus: a further update of its use in the management of organ transplantation. Drugs. 2003;63(12):1247-1297

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

Same day/1 to 2 days

Specimen Retention Time

14 days

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Superior Drive

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

80197

LOINC® Information

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