MAYO CLINIC LABORATORIES

Test Definition: TAKRO

Tacrolimus, Blood

Overview

Useful For

Monitoring whole blood tacrolimus 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

Specimen Required

Container/Tube: Lavender top (EDTA)

Specimen Volume: 3 mL

Collection Instructions:

1. Draw blood immediately before a scheduled dose.

2. Do not centrifuge.

3. Send whole blood specimen in original tube. **Do not aliquot.**

Additional Information: Therapeutic range applies to trough specimens collected 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)

-Therapeutics Test Request (T831)

-Kidney Transplant Test Request

Specimen Minimum Volume

1 mL

Reject Due To

Gross	OK

hemolysis	
Gross lipemia	OK
Gross icterus	OK
Clotted specimens	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 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 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 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.

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 specimen collected at trough (ie, immediately before a scheduled dose). Higher results will be obtained when the blood is drawn at other times.

The assay is specific for tacrolimus; it does not cross-react with cyclosporine, cyclosporine metabolites, sirolimus, sirolimus metabolites, or tacrolimus metabolites.

Cautions

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

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

Clinical Reference

1. Kahan BD, Keown P, Levy GA, Johnston A. Therapeutic drug monitoring of immunosuppressant drugs in clinical practice. Clin Ther. 2002;24(3):330-350
2. 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
3. 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

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 3 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
TAKRO	Tacrolimus, B	77348-1

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