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MAYO CLINIC LABORATORIES

Test Definition: POSA

Posaconazole, Serum

Overview

Useful For
Monitoring posaconazole therapy

Method Name
Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS)

NY State Available
Yes

Specimen

Specimen Type
Serum Red

Specimen Required
Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube: Red top (serum gel/SST are **not acceptable**)
Submission Container/Tube: Plastic vial
Specimen Volume: 2 mL serum
Collection Instructions: Within 2 hours of collection, centrifuge, and aliquot serum into plastic vial.

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

Specimen Minimum Volume
Serum: 0.6 mL

Reject Due To

Gross hemolysis	OK
Gross lipemia	OK
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum Red	Refrigerated (preferred)	28 days	
	Ambient	28 days	

	Frozen	28 days	

Clinical & Interpretive

Clinical Information

Posaconazole interferes with fungal cytochrome P450 (CYP) lanosterol-14 alpha demethylase activity, thereby decreasing synthesis of ergosterol, the principal sterol in fungal cell membrane, and inhibiting fungal cell membrane formation.(1,2)

Posaconazole has been approved for prophylaxis of invasive *Aspergillus* and *Candida* infections in severely immunocompromised patients (eg, hematopoietic stem cell transplant recipients with graft-versus-host disease [GVHD] or those with prolonged neutropenia secondary to chemotherapy for hematologic malignancies) and treatment of oropharyngeal candidiasis (including patients refractory to itraconazole or fluconazole).(1,3) It also is approved for ocular administration (drug monitoring not required for this use).

Posaconazole has a variable absorption. Food and liquid nutritional supplements increase absorption, and fasting states do not provide sufficient absorption to ensure adequate plasma concentrations.(4,5) The drug has a high volume of distribution (Vd=465-1774 L) and is highly protein bound (> or =97%), predominantly to albumin.(1,3) The drug does not undergo significant metabolism; approximately 15% to 17% undergoes non-CYP-mediated metabolism, primarily via hepatic glucuronidation into metabolites.(1) The half-life elimination is approximately 35 hours (range: 20-66 hours); steady state is achieved after about 5 to 7 days. Time to maximum concentration is approximately 3 to 5 hours, but due to the highly variable absorption, trough level monitoring is recommended.

Therapeutic drug monitoring should be considered in the following situations:
-To document optimal absorption when used for prophylaxis or active treatment of a fungal infection
Consider rechecking a level even if initial level was in the goal range if the patient:
-Is unable to meet optimal nutritional intake
-Is receiving continuous tube feeding
-Is receiving a proton pump inhibitor (decreased posaconazole levels in some studies)
-Has mucositis, diarrhea, vomiting, GVHD, or other reason that the drug may not be absorbed well

Reference Values

>700 ng/mL (trough)

Interpretation

Levels greater than 700 ng/mL (0.7 mcg/mL) have been suggested for prophylaxis.

Levels greater than or equal to 1250 ng/mL (1.25 mcg/mL) were shown to be optimal in a salvage trial for treatment of invasive *Aspergillus* infections.

A toxic range has not been established.

Cautions

No significant cautionary statements

Clinical Reference

1. Walsh TJ, Raad I, Patterson TF, et al. Treatment of invasive aspergillosis with posaconazole in patients who are refractory to or intolerant of conventional therapy: an externally controlled trial. Clin Infect Dis. 2007;44(1):2-12
2. Milone MC, Shaw LM. Therapeutic drugs and their management. In: Rifai N, Chiu RWK, Young I, Burnham CAD, Wittwer CT, eds. Tietz Textbook of Laboratory Medicine. 7th ed. Elsevier; 2023:420-453
3. Package insert: Noxafil (posaconazole). Schering Corporation, Kenilworth, NJ, 2006
4. Physician's Desk Reference. 61st edition. Montvale NJ, Thomson PDR, 2007
5. Goodman and Gilman's: The Pharmacological Basis of Therapeutics. 10th edition. New York, NY: McGraw-Hill Professional, 2001.
6. Courtney R, Wexler D, Radwanski E, Lim J, Laughlin M. Effect of food on the relative bioavailability of two oral formulations of 12liquoting12e in healthy adults. Br J Clin Pharmacol. 2004;57(2):218-222
7. Courtney R, Radwanski E, Lim J, Laughlin M. Pharmacokinetics of posaconazole coadministered with antacid in fasting or nonfasting healthy men. Antimicrob Agents Chemother. 2004;48(3):804-808

Performance

Method Description

Posaconazole is extracted by mixing serum samples with acetonitrile to precipitate proteins. The supernatant is removed and analyzed by a liquid chromatography tandem mass spectrometry method.(Unpublished Mayo method)

PDF Report

No

Day(s) Performed

Monday through Saturday

Report Available

2 to 5 days

Specimen Retention Time

2 weeks

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.

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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

80187

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
POSA	Posaconazole, S	53731-6

Result ID	Test Result Name	Result LOINC® Value
89591	Posaconazole, S	53731-6