Test Definition: POSA

Posaconazole, S

Overview

Useful For

Monitoring of posaconazole therapy

Method Name

LiquidChromatography-TandemMassSpectrometry(LC-MS/MS)

NY State Available

Yes

Specimen

Specimen Type

Serum Red

Specimen Required

Collection Container/Tube: Red top (serum gel/SST are **not** acceptable)

Submission Container/Tube: Plastic vial

Specimen Volume: 2 mL

Forms

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

Specimen Minimum Volume

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 and Interpretive

Clinical Information

Posaconazole interferes with fungal cytochrome P450 (CYP) lanosterol-14 alpha demethylase activity, 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=465-1,774 L) and is highly protein bound (> or =97%), predominantly bound 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.

Toxic range has not been established.

Cautions

No significant cautionary statements

Clinical Reference

1. Noxafil (posaconazole). Package insert. Schering Corporation; 2006

2. Goodman and Gilman's: The Pharmacological Basis of Therapeutics. 10th ed. McGraw-Hill Professional; 2001

3. Physicians' Desk Reference (PDR). 61st ed. Thomson PDR; 2007

4. Courtney R, Wexler D, Radwanski E, et al: Effect of food on the relative bioavailability of two oral formulations of posaconazole in healthy adults. Br J Clin Pharmacol. 2004;57:218-222

5. 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

6. Rifai N, Horvath AR, Wittwer CT eds: Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. 6th ed.Â Elsevier; 2018

Performance

Method Description

Posaconazole is extracted into diethyl ether from alkaline serum. The diethyl ether layer is removed and the specimen dried down and reconstituted. The reconstituted sample is then injected into a liquid chromatography system and detected by tandem mass spectrometry.(Unpublished Mayo method)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

2 to 5 days

Specimen Retention Time

2 weeks

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

80187

LOINC® Information

Test Definition: POSA

Posaconazole, S

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