Overview

Useful For
Monitoring of posaconazole therapy

Method Name
Liquid Chromatography-Tandem Mass Spectrometry (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

<table>
<thead>
<tr>
<th>Gross hemolysis</th>
<th>OK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross lipemia</td>
<td>OK</td>
</tr>
<tr>
<td>Gross icterus</td>
<td>OK</td>
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</tbody>
</table>

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Serum Red</td>
<td>Refrigerated (preferred)</td>
<td>28 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ambient</td>
<td>28 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>28 days</td>
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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 (e.g., 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**

\(>700\text{ ng/mL (trough)}\)

**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**


Test Definition: POSA
Posaconazole, S


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) and Time(s) Test Performed
Monday through Friday; 10 a.m.

Analytic Time
2 days

Maximum Laboratory Time
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**

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<td>Posaconazole, S</td>
<td>53731-6</td>
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<table>
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<td>Posaconazole, S</td>
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