Isavuconazole (CRESEMBA®) LC-MS/MS
Test Code: 4900

Clinical and Procedure

Clinical Utility
Isavuconazole is for the treatment of life threatening fungal infections, specifically invasive aspergillosis and invasive mucormycosis.¹ There is a significant need for alternative antifungal therapies that address some of the limitations of voriconazole, such as reduced potential for nephrotoxicity for the intravenous formulation², in addition to other dose-related toxicities.³ Given the difficulty in diagnosis and similarity with which infections may present, having an antifungal that is effective for both indications would be particularly useful to physicians treating immunocompromised patients.

About Immunosuppressive Drug Level Monitoring
The successful management of invasive fungal infections (IFI) continues to pose a difficult challenge for physicians treating immunocompromised patients, and despite recent advances in therapy, the morbidity and mortality due to IFI remains unacceptably high.⁴ Triazole antifungal drugs are commonly used to either prevent or treat IFI in at-risk patients. However, extensive intra- and inter-patient variability is observed in the pharmacokinetics of triazole antifungal drugs. This variability supports quantitative monitoring, i.e., therapeutic drug monitoring of triazole blood drug levels.⁴,⁵

By using drug level monitoring with timely results, the physician is able to individualize drug dosage to improve efficacy and reduce toxicity. Drug monitoring of triazoles is included in the Infectious Diseases Society of America guidelines for treating aspergillosis and candidiasis.⁶,⁷ Recommendations indicate that blood samples should be obtained one to two weeks after the start of therapy, immediately before the next dose (“trough time”) and repeated following a change in dosage, formulation, initiation or discontinuation of an interacting medication, potential treatment failure or non-adherence to dosing schedule. Patients with altered hepatic and/or renal clearance will also benefit from drug level monitoring of triazoles.

Several triazole drugs are commonly used to treat IFI in immunocompromised patients. Voriconazole is used in treatment for a broad range of fungal infections, including invasive aspergillosis, candidiasis and other emerging IFI. Posaconazole is a broad spectrum triazole antifungal agent for treatment and prophylaxis of fungal and mold infections, including candidiasis, aspergillosis and zygomycosis. Itraconazole is used as therapy for a variety of invasive and non-invasive fungal infections, and is approved for the treatment of histoplasmosis, aspergillosis, esophageal candidiasis, and oropharyngeal candidiasis. Isavuconazole (CRESEMBA) is used to treat invasive aspergillosis and mucormycosis.¹

Procedure
Isavuconazole is extracted from serum or plasma by protein precipitation with methanol followed by centrifugation. Chromatographic separation and quantitative analysis of the supernatant are performed using reversed-phase UPLC-MS/MS. This test has not been cleared or approved for diagnostic use by the U.S. Food and Drug Administration.

Turnaround Time
Same day (within 8 - 12 hours from receipt of specimen), Monday through Saturday.

Specimen Information

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<th>Specimen Type</th>
<th>Order Code</th>
<th>CPT Code</th>
<th>NY Approved</th>
<th>Volume</th>
<th>Assay Range</th>
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<tbody>
<tr>
<td>plasma</td>
<td>4901</td>
<td>80299</td>
<td>Yes</td>
<td>1 mL (min. 0.5 mL)</td>
<td>0.1-10 mcg/mL</td>
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<td>serum</td>
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<td>80299</td>
<td>Yes</td>
<td>1 mL (min. 0.5 mL)</td>
<td>0.1-10 mcg/mL</td>
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**Special Instructions**
- Collect 4-5 mL whole blood in EDTA tube (ACD and Sodium Heparin tubes are not acceptable).
- Separate plasma by centrifugation within 30 minutes of draw time.
- Transfer 1 mL to a sterile, screw top tube, DO NOT draw in a gel tube.
- Ship frozen on dry ice Monday through Friday.

**Shipping**
Ship Monday through Friday. Label Friday shipments for Saturday delivery. All specimens must be labeled with patient's name and collection date. A Viracor Eurofins test requisition form must accompany each specimen. Multiple tests can be run on one specimen. Ship specimens FedEx Priority Overnight® to: Viracor Eurofins, 1001 NW Technology Dr, Lee's Summit, MO 64086.

**Causes for Rejection**
Specimens received not frozen, whole blood collected in serum or plasma gel, serum gel tubes, or specimen types other than those listed are not accepted.

**Disclaimer**
Specimens are approved for testing in New York only when indicated in the Specimen Information field above.

The CPT codes provided are based on Viracor Eurofins’ interpretation of the American Medical Association's Current Procedural Terminology (CPT) codes and are provided for general informational purposes only. CPT coding is the sole responsibility of the billing party. Questions regarding coding should be addressed to your local Medicare carrier. Viracor Eurofins assumes no responsibility for billing errors due to reliance on the CPT codes illustrated in this material.

**References**