

# 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.<sup>1</sup> 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 formulation<sup>2</sup>, in addition to other dose-related toxicities.<sup>3</sup> 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.

### 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

Specimen Type	Order Code	CPT Code	NY Approved	Volume	Assay Range
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plasma	4901	80299	Yes	1 mL (min. 0.5 mL)	0.1-10 mcg/mL
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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.

serum	4910	80299	Yes	1 mL (min. 0.5 mL)	0.1-10 mcg/mL
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#### Special Instructions

- Collect 4-5 mL whole blood in red top tube.
- Allow to clot for 30 to 60 minutes and centrifuge to isolate the serum.
- Transfer 1 mL to a sterile, screw top tube. DO NOT draw in a gel tube.
- Ship frozen on dry ice Monday through Friday.

0.1 to 10 mcg/mL

## 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

1. Astellas Pharma US, Inc., CRESEMBA® Package Insert.
2. von Mach MA1, Burhenne J, Weilemann LS. 2006. Accumulation of the solvent vehicle sulphobutylether beta cyclodextrin sodium in critically ill patients treated with intravenous voriconazole under renal replacement therapy. *BMC Clin Pharmacol* . 2006 6:6.
3. Pascual A1, Calandra T, Bolay S, Buclin T, Bille J, Marchetti O. 2008. Voriconazole therapeutic drug monitoring in patients with invasive mycoses improves efficacy and safety outcomes. *Clin Infect Dis*. 46(2):201-11.