Mucorales Real-time PCR  
Test Code: 3200

Clinical and Procedure

Clinical Utility
Real-time PCR detection of Mucorales (also referred to as Zygomycetes) DNA in BAL and tissue samples may aid in diagnosis of invasive fungal infection (IFI) in high risk populations. High risk patients include those with neutropenia, solid organ transplant, hematopoietic stem cell transplant, cancer, diabetes and skin trauma. Difficult to differentiate from other filamentous fungi, mucormycosis has been found to have mortality rates in excess of 50%, depending on patient population and presentation. Further, Mucorales demonstrates limited susceptibility to a variety of antifungal therapies including Voriconazole. Early diagnosis of Mucorales has been associated with improved patient outcomes.

The use of Mucorales PCR in BAL and tissue has shown superior sensitivity over culture samples from animal models of infection and various publications indicate performance in human specimens (e.g. 100% sensitivity in biopsy tissue, 100% sensitivity established in fresh tissue samples that were culture negative, and 100% specificity in control tissue samples). The number of published studies utilizing BAL (15 studies) and biopsy (>1300) are significantly higher than any other specimen type, the next most often cited being upper respiratory specimens (n=3).

Procedure
Extraction of Mucorales DNA from specimen followed by amplification and detection using qualitative real-time PCR. A full-process internal control is added to each clinical specimen in order to ensure the extraction was performed correctly and the PCR reaction was not inhibited. This test has not been cleared or approved for diagnostic use by the U.S. Food and Drug Administration.

Specificity
The Mucorales PCR detects the most common causative agents of mucormycosis including 32 strains encompassing eight Mucorales genera. Additionally, no cross reactivity was detected from the most common non-Mucorales fungal pathogens with the exception of high levels of Trichosporon spp.

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

Specimen Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Order Code</th>
<th>CPT Code</th>
<th>NY Approved</th>
<th>Volume</th>
<th>Assay Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tissue</td>
<td>3205</td>
<td>87798</td>
<td>No</td>
<td>5 mg fresh tissue (approximately ½ of a pencil eraser size)</td>
<td>Detected/Not Detected</td>
</tr>
</tbody>
</table>

Special Instructions
- Place fresh tissue in a sterile, screw top container.
- The preferred handling is to not add water, saline or other fluid media to the tissue container; however, fluid media filled containers will be accepted for qualitative results.
- Store frozen and ship on dry ice for overnight delivery.
- Formalin fixed, paraffin embedded tissue will not be accepted.

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</tr>
</thead>
<tbody>
<tr>
<td>BAL</td>
<td>3209</td>
<td>87798</td>
<td>No</td>
<td>2 mL (min. 0.5 mL)</td>
<td>Detected/Not Detected</td>
</tr>
</tbody>
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Special Instructions
- Collect in a sterile, screw top tube.
- Specimen should be stored at 2 to 8°C or frozen in a non-self-defrosting freezer.
- Ship with frozen gel packs or dry ice for overnight delivery.
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If storage longer than 2 days is needed, specimens should be frozen at -70°C prior to shipment.

### Shipping

Ship Monday through Friday. Friday shipments must be labeled 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 that have been stored at ambient temperature, specimens received in trap containers, specimens other than those listed or specimens that have been stored at 2 to 8°C for >2 days. If storage longer than 2 days is needed, specimens should be frozen at -70°C. Unless indicated as stored frozen, the specimen will be rejected if the draw date is >2 days upon receipt to Viracor Eurofins.

### 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 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.

PCR tests are performed pursuant to a license agreement with Roche Molecular Systems, Inc.

### References


Data on file at Viracor Eurofins.