Aspergillus Real-time PCR Panel  
Test Code: 8900

Clinical and Procedure

Clinical Utility
Inhaled dormant Aspergillus spores (conidia) can germinate and cause invasive pulmonary aspergillosis, a disease with a mortality rate often exceeding 50%. Invasive pulmonary aspergillosis is seen primarily in the immunocompromised host. Standard laboratory techniques for the diagnosis of invasive pulmonary aspergillosis include direct examination, lung tissue histology and culture of respiratory secretions. Under the best of circumstances, bronchoalveolar lavage (BAL) fluid analysis yields a diagnosis by culture and direct exam in only approximately 50% of cases. However, some centers have shown that the rate of diagnosis is substantially lower using these techniques.

The Aspergillus PCR panel is comprised of 3 real-time PCR assays: a Pan-Aspergillus assay that detects all Aspergillus species, an A. fumigatus assay that detects the most common Aspergillus species, and an A. terreus assay that detects a clinically important Aspergillus species that is resistant to Amphotericin B. When used in conjunction with other diagnostic procedures, such as microbiological culture, Aspergillus Galactomannan EIA, Fungitell® β-D Glucan, histological examination of biopsy specimens, and radiographic evidence, the Aspergillus PCR panel can be useful in the diagnosis of invasive pulmonary aspergillosis.

About Aspergillus
Invasive aspergillosis is a common opportunistic fungal infection in patients who are profoundly neutropenic, either as a result of chemotherapy or after having received hematopoietic stem cell or solid organ transplantation. Prevalence of invasive aspergillosis is 1–15% and mortality can exceed 90%. Early diagnosis of invasive aspergillosis remains a challenge, but screening of patients in the early stage of infection may be useful in establishing an early diagnosis and may result in improved outcomes.

Procedure
Extraction of Aspergillus DNA from specimen followed by amplification and detection using real-time, qualitative 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.

Turnaround Time
Same day (within 12 - 24 hours from receipt of specimen), Monday through Friday.

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>BAL</td>
<td>8909</td>
<td>87798 x3</td>
<td>Yes</td>
<td>2 mL (min. 0.5 mL)</td>
<td>Qualitative results are independently resulted for Pan-Aspergillus, A. fumigatus and A. terreus and are reported as “Detected/Not Detected”. The lowest order of detection for the Aspergillus PCR Panel is 13 germinated conidia per mL BAL.</td>
</tr>
</tbody>
</table>

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.
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</tr>
</thead>
<tbody>
<tr>
<td>bronch wash</td>
<td>8926</td>
<td>87798 x3</td>
<td>Yes</td>
<td>2 mL (min. 0.5 mL)</td>
<td>Qualitative results are independently resulted for Pan-Aspergillus, A. fumigatus and A. terreus and are reported as “Detected/Not Detected”. The lowest order of detection for the Aspergillus PCR Panel is 13 germinated conidia per mL BAL.</td>
</tr>
</tbody>
</table>

**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.
- If storage longer than 2 days is needed, specimens should be frozen at -70° C prior to shipment.

**Assay Limitations**

A negative test result cannot rule out the diagnosis of invasive pulmonary aspergillosis.

The performance of the Aspergillus PCR Panel has not been evaluated outside of lung transplant patient populations (e.g. HSCT).

**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 from receipt at 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.

**References**

