Aspergillus Galactomannan EIA
Test Code: 1600

Clinical and Procedure

Clinical Utility
The Platelia™ Aspergillus Galactomannan EIA is a test, when used in conjunction with other diagnostic procedures, such as microbiological culture, histological examination of biopsy specimens, and radiographic evidence that can be used to aid in the diagnosis of Invasive Aspergillosis. Twice weekly monitoring of neutropenic patients is often recommended in the peer-reviewed literature to obtain maximum diagnostic utility of the assay.

About Aspergillus Galactomannan

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

This test is an immunoenzymatic sandwich microplate assay for the detection of Aspergillus galactomannan antigen in adult and pediatric CSF, bronch wash, BAL and serum samples. The assay uses EBA-2 monoclonal antibodies which detect Aspergillus galactomannan. This test has been cleared or approved for diagnostic use by the U.S. Food and Drug Administration for bronch wash, BAL and serum specimens only.

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>BAL</td>
<td>1609</td>
<td>87305</td>
<td>Yes</td>
<td>2 mL (min. 0.5 mL)</td>
<td>- The reference range is an index of &lt;0.5 numerical index values will be reported.</td>
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<tr>
<td></td>
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<td></td>
<td>- Patients with an index of ≥0.5 are considered to be positive for galactomannan antigen.</td>
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<td></td>
<td>- Patients with an index of &lt;0.5 are considered to be negative for galactomannan antigen.</td>
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<td>- Specimens testing positive will be retested to confirm the positive result.</td>
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<td>- A reference Index Value of &lt;0.5 has been shown to be appropriate for both serum</td>
</tr>
<tr>
<td>Specimen Type</td>
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<td>CPT Code</td>
<td>NY Approved</td>
<td>Volume</td>
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<tr>
<td>Serum</td>
<td>1610</td>
<td>87305</td>
<td>Yes</td>
<td>2 mL (min. 0.5 mL)</td>
<td>and bronchial lavage specimen types.</td>
</tr>
<tr>
<td>Special Instructions</td>
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</tbody>
</table>
- Collect in a sterile, screw top tube.
- Specimen should be stored at 2 to 8°C up to 24 hours or frozen in a non-self-defrosting freezer.
- Ship on dry ice for overnight delivery.

<table>
<thead>
<tr>
<th>CSF</th>
<th>1603</th>
<th>87305</th>
<th>Yes</th>
<th>2 mL (min. 0.5 mL)</th>
<th>- The reference range is an index of &lt;0.5. Numerical index values will be reported.</th>
</tr>
</thead>
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<tr>
<td>Special Instructions</td>
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</tbody>
</table>
- Collect 3-5 mL blood specimen in a gel separator tube (SST) without anti-coagulants.
- Allow specimen to clot, then centrifuge specimen within 2 hours of draw to pellet cells below the gel. Minimum volume is 1.0 mL serum following centrifugation.
- Specimen may be stored 30 days ambient, refrigerated (2-8°C), or frozen (-20°C).
- Can be shipped ambient, refrigerated or frozen temperature Monday through Friday.

- Patients with an index of ≥0.5 are considered to be positive for galactomannan antigen.
- Patients with an index of <0.5 are considered to be negative for galactomannan antigen.
- Specimens testing positive will be retested to confirm the positive result.
- A reference Index Value of <0.5 has been shown to be appropriate for both serum and bronchial lavage specimen types.

- The reference range is an index of <0.5. Numerical index values will be reported.
- Patients with an index of ≥0.5 are considered to be positive for galactomannan antigen.
- Patients with an index of <0.5 are considered to be negative for galactomannan antigen.
- Specimens testing positive will be retested to confirm the positive result.
- A reference Index Value of <0.5 has been shown to be appropriate for both serum and bronchial lavage specimen types.

| Special Instructions |
- Collect in a sterile, screw top tube.
- Freeze and ship on dry ice for overnight delivery.
<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Order Code</th>
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<th>Volume</th>
<th>Assay Range</th>
</tr>
</thead>
</table>
| bronch wash   | 1626       | 87305    | Yes         | 2 mL (min. 0.5 mL) | - The reference range is an index of <0.5. Numerical index values will be reported.  
- Patients with an index of ≥0.5 are considered to be positive for galactomannan antigen.  
- Patients with an index of <0.5 are considered to be negative for galactomannan antigen.  
- Specimens testing positive will be retested to confirm the positive result.  
- A reference Index Value of <0.5 has been shown to be appropriate for both serum and bronchial lavage specimen types. |

Special Instructions
- Collect in a sterile, screw top tube.
- Specimen should be stored at 2 to 8°C up to 24 hours or frozen in a non-self-defrosting freezer.
- Ship on dry ice for overnight delivery.

Diagnosis and Monitoring

For maximum sensitivity, the test should be performed at least twice weekly during neutropenia. The exact frequency of testing in non-hospitalized patients with chronic graft-versus-host-disease (CGVHD) would depend upon the degree of immunosuppression. The test should be used in conjunction with other diagnostic procedures.

Two consecutive positive results are required for classification as true positive, thus it is recommended that a follow-up specimen be submitted from the patient upon receipt of the initial positive result; ideally prior to initiation of anti-fungal therapy to achieve maximum specificity.

Assay Limitations

A negative test result cannot rule out the diagnosis of Invasive Aspergillosis. Patients at risk for Invasive Aspergillosis should be tested twice per week.

If a positive result is obtained, a second specimen should be collected and sent for testing immediately.

The performance of the test has not been evaluated with neonatal specimens.

This test may exhibit reduced detection in patients with chronic granulomatous disease and Job's Syndrome.

The concomitant use of mold-active, anti-fungal therapy in some patients with Invasive Aspergillosis may result in reduced sensitivity of the test.

There are reports in the literature of positive galactomannan test results in patients receiving piperacillin/tazobactam, therefore, results in these patients should be interpreted with caution and confirmed with other diagnostic methods.

There are reports in the literature of positive galactomannan test results in patients with intestinal mucositis caused by chemotherapy and irradiation, which allows for extra absorption of dietary galactomannan.
False-positive Galactomannan results have been shown in patients receiving Plasmalyte for intravenous hydration or if Plasmalyte is used for BAL collection.

Shipping
Shipment 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
Lipemic, icteric, or hemolyzed specimens, specimens that have been stored at ambient temperature, specimens received in trap containers, specimens beyond their acceptable length of time from collection as listed in the specimen handling.

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.

Information derived from the Platelia™ Aspergillus EIA package insert (Bio-Rad Laboratories). Aspergillus Galactomannan EIA is a product of Bio-Rad Laboratories.

References
