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L. Joseph Wheat, M.D., Director

Clinical Consults: x452
Result Inquires: x450

Current licensure available on our website

Platelia® *Aspergillus* Antigen EIA

Test Code 309

MiraVista Diagnostics offers the Platelia® *Aspergillus* EIA for the detection of *Aspergillus* galactomannan antigen in adult and pediatric specimens by enzyme immunoassay. The Platelia® *Aspergillus* EIA is an aid in the early diagnosis of invasive aspergillosis, and, along with other diagnostic tests and clinical signs of disease, allows for the effective early treatment of disease. Testing at MiraVista is performed daily Monday through Friday. All specimens are double extracted on Fridays or before a Holiday so results are released the same day.

The Platelia® *Aspergillus* EIA kit was evaluated for sensitivity (52.9% and 79.3%) and specificity (87.0% and 88.8%) in the multicenter US study that led to its FDA clearance of serum for pediatric and adult patients, respectively.

The MVista® Process was validated in-house for BAL (bronchial alveolar lavage) and CSF (cerebral spinal fluid) specimens. BAL specimens showed sensitivity of 88% and specificity of 84%. Serum, BAL and CSF specimens show nearly identical limits of detection (~0.5 ng/ml) and no matrix effect has been identified. Performance characteristics, including reproducibility, are very similar in serum and BAL.

REPORTING AND EXPRESSION OF RESULTS

- All results are faxed to the referring lab.
- Results are reported as numeric values (Index) which are interpreted as positive or negative.
- The reference range is <0.5.

SPECIMEN REQUIREMENTS - Test Code 309

- **The test is performed on serum, BAL and CSF from adult and pediatric patients.**
 - Serum should be separated from the clot.
 - Minimum volume needed to test is 1.5mL, though 2.0mL is the preferred volume.
- Unopened specimens may be stored at 2-8°C for up to 5 days prior to testing, or for only 48 hours after they have been opened. Longer storage requires freezing at -70°C. Unless indicated as stored frozen, samples that are older than 5 days when received at MiraVista Diagnostics' Laboratory will be considered unacceptable for testing.
- Shipment requirements: Leak-proof containers sent according to Federal Regulations. Samples should be packaged with cold packs for shipping and shipped using an overnight delivery courier.
- Specimen Labeling: Patient's name or ID# must be visible on the specimen.
- Shipping Address: 4444 Decatur Blvd., Suite 300, Indianapolis, IN 46241

LIMITATIONS OF THE METHOD

- False positive results can be caused by:
 - Piperacillin-tazobactam and a few other antibiotics
 - Plasmalyte and other fluids containing sodium gluconate
 - Infection with *Penicillium*, *Alternaria*, and *Paecilomyces*
 - Airway colonization with *Aspergillus* spp, *Penicillium*, *Alternaria*, and *Paecilomyces* in BAL specimens
 - Histoplasmosis, and possibly other endemic mycoses
- This assay has not been evaluated for urine.
- The performance of this assay has not been evaluated with neonate samples.
- Antifungal therapy may reduce the assay's sensitivity.

BILLING

- Referring facility will be billed. CPT code is 87305.

CAP 7182293
CLIA 15D0996282
Medicare Part B 190460
NPI 1588600456

CA COS800133
FL L800017215
MD 1077
NY 8036

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