GM Antigen Kinetics
Several investigators have described declining GM serum levels in patients who responded to antifungal therapy and a gradual increase or no change in those who were refractory. 1-4, 11-13, 25, 26

The following graphs represent GM antigen kinetics that have been reported in two patients: 11 12

• Probable IA in a patient with acute myeloid leukemia treated with liposomal amphotericin B. Rapid rise of the GM antigen, followed by a decrease under antifungal therapy until remission.

• Probable IA in a child with septiceptic encephalitis. The GM antigen remained positive during clinical failure to treatment with liposomal amphotericin B. This patient improved significantly after treatment with voriconazole which corresponded with clinical improvement: 11 12

Benefits of Platelia™ Aspergillus Ag Assay
Compared to conventional diagnostic methods, the assay developed by Bio-Rad Laboratories provides a safe, rapid and reliable tool for the early diagnosis of Invasive Aspergillosis:

• Early detection of Aspergillus galactomannan antigen, preceding diagnosis based on clinical and laboratory methods.

• Non-invasive procedure: performed on serum, the test allows a twice-weekly screening of high-risk patients. 1-4, 11-13

• Results can be obtained within 3 hours instead of several days with traditional mycological tests.

• The EIA microplate assay, a standardized format, is easy to perform and interpret. Results are reported as index values.

• Platelia™ Aspergillus QMI assay demonstrates excellent performance characteristics for the diagnosis of invasive aspergillosis in neutropenic hematological patients (twice-weekly GM antigenemia screening). 5, 8

• Automated testing in a BAL fluid sample is a valuable adjunctive tool for the diagnosis of invasive pulmonary aspergillosis in patients with hematological diseases. 9

• Testing BAL fluid for GM antigen improves the sensitivity of invasive aspergillosis diagnosis in at-risk patient populations: Solid-Organ Transplant Recipients 2, 3, 14-16, 17, 18, 19 and Hematologic Diseases. 20

• The QMI antigen detection is among the mycological criteria defined by the EORTC/MSG Consensus Group for Invasive Aspergillosis. 21

Platelia™ Aspergillus Ag Testing Improves Early Diagnosis of Invasive Aspergillosis.

Platelia™ Aspergillus Ag Testing Helps Physicians to Initiate Appropriate Antifungal Treatment Faster.

Early Diagnosis of Invasive Aspergillosis
Platelia™ Aspergillus Ag Assay

Platelia™ Aspergillus Ag

Physicians to Initiate Appropriate Antifungal Treatment Faster.

Improves Early Diagnosis of Invasive Aspergillosis

Optimizes Treatment in At-Risk Populations

Platelia™ Aspergillus Ag Testing Helps Physicians to Initiate Appropriate Antifungal Treatment Faster.

Clinical benefit of early and accurate diagnosis

A prospective study of 150 patients with hemato-oncologic diseases and solid organ transplant recipients with suspected fungal infection. 1-4, 5, 8, 9, 11-13, 14-16

transplantation (SOT), followed by neutropenic patients are the immunosuppressed patients. The incidence of invasive fungal infections in adults and 75% in children.

Aspergillus

Aspergillus is a fungus that causes invasive fungal infections. The spores are present in the environment and inhaled into the lungs. The spores are naturally destroyed by the immune system.

Aspergillosis

Aspergillosis is an infection due to a filamentous fungus Aspergillus. The infection can affect the lungs (pulmonary aspergillosis), eyes, skin, kidneys, bones and the central nervous system (CNS aspergillosis), via blood vessels.

Invasive Aspergillosis

Invasive Aspergillosis (IA) is an invasive fungal infection that results in disease. The diagnosis can be challenging due to difficulties in diagnosing the disease reliably and in a timely manner, before fungal growth becomes established. Early diagnosis is critical for effective treatment and for avoiding inappropriate administration of costly antifungal therapy.

Diagnosis

The chart demonstrates mortality rates reported in the literature. The chart shows that the risk of mortality, as well as data on WHT (Bone Marrow Transplant), is highest in patients with leukemias, lung transplantation, and lung fibrosis.

Testing Algorithm

<table>
<thead>
<tr>
<th>Patient without clinical symptoms of IA</th>
<th>Patient with Proven IA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>0.5 92.1% 97.5% 87.5% 98.5%</td>
</tr>
<tr>
<td>Negative</td>
<td>97.5% 87.5% 98.5%</td>
</tr>
</tbody>
</table>

The Platelia™ Aspergillus Ag Assay is a non-invasive diagnostic device that tests for the presence of Aspergillus species in patient samples. The Platelia™ Aspergillus Ag Assay is a non-invasive diagnostic device that uses a sandwich ELISA method to detect Aspergillus species in patient samples. The test is performed on patient serum throughout the entire period of increased risk for IA, and the results are interpreted based on the presence or absence of a positive result.

The guidelines for testing GM antigenemia are as follows:

- **Screening and Diagnosing IA in high-risk patients**

  - GM antigenemia is used to screen high-risk patients for IA.
  - GM antigenemia is positive in 60% of patients who develop IA, and it is positive in 90% of patients who die of IA.
  - GM antigenemia is positive in 80% of patients who die of IA, and it is positive in 90% of patients who die of IA.

- **Guidelines and Indications for Testing GM Antigenemia**

  - Testing is recommended in high-risk patients who have neutropenia or other immunosuppressive conditions.
  - Testing is recommended in patients who have a history of IA or who have a high-risk condition for IA.
  - Testing is recommended in patients who have a history of IA or who have a high-risk condition for IA.

- **Testing algorithm using Platelia™ Aspergillus Ag assay**

  - The testing algorithm is performed as follows:
    - **Step 1:** Collect a serum sample and test for GM antigenemia.
    - **Step 2:** If the GM antigenemia is positive, perform a follow-up sample and test for GM antigenemia.
    - **Step 3:** If the GM antigenemia is positive in the follow-up sample, the test result is positive.

- **Sensitivity, Specificity, Positive Predictive Value, and Negative Predictive Value**

  - Sensitivity: 92.1%
  - Specificity: 97.5%
  - Positive Predictive Value: 87.5%
  - Negative Predictive Value: 98.5%

A recent clinical study performed in hematological patients reported that using a cut-off index value of 0.5 and requiring two consecutive positive samples for IA diagnosis resulted in the highest test accuracy, with an improved positive predictive value of 92.1%.