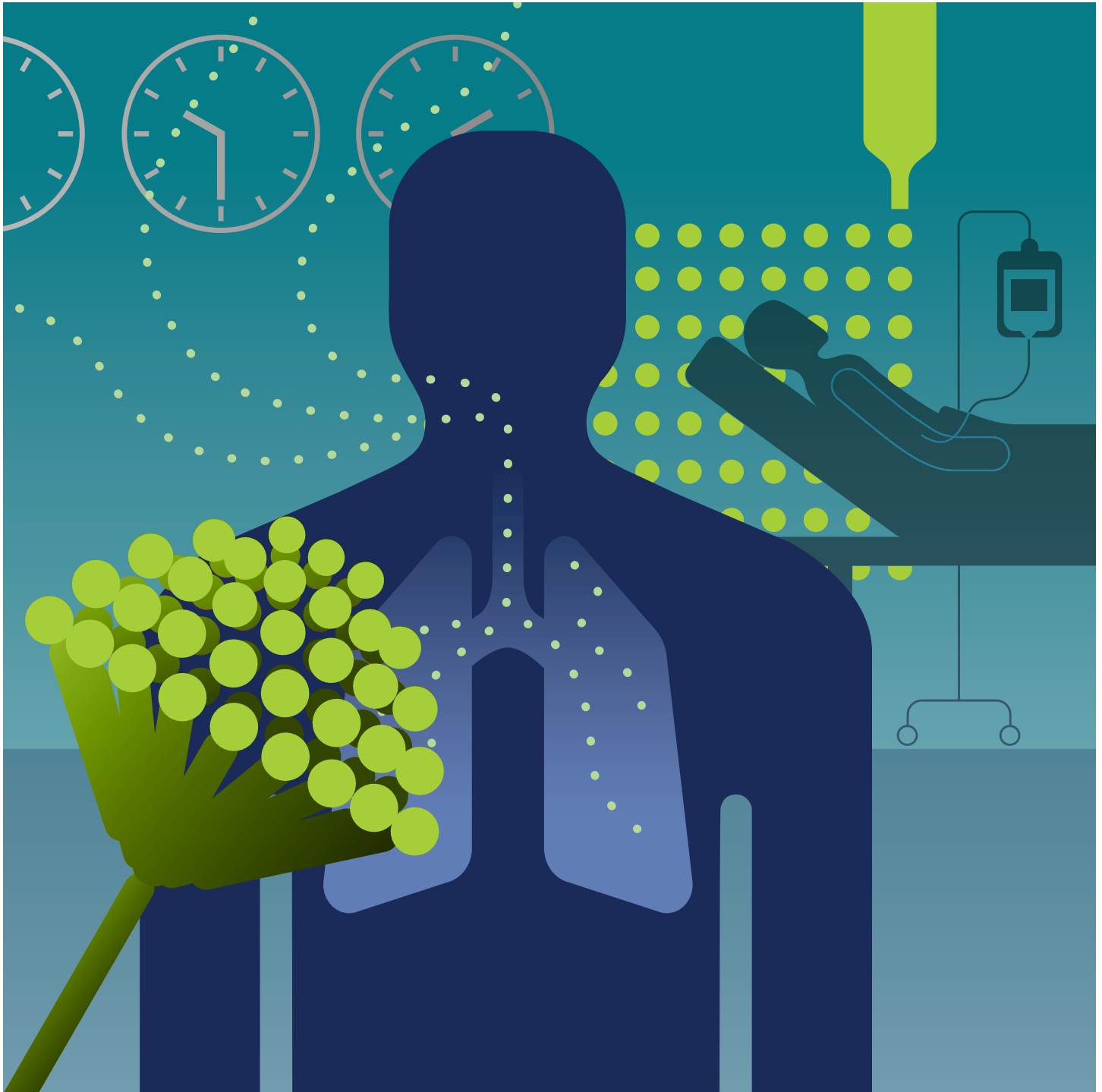


## Platelia™ *Aspergillus* Ag Assays

Aids in diagnosing invasive aspergillosis in adult and pediatric patients. The Verification Panel Kit helps ensure reliable results.



# High-Performance Platelia *Aspergillus* Ag Assay

Immunosuppressed patients are an at-risk population for invasive aspergillosis (IA). IA mortality rates are high in part because diagnosing IA in a timely manner can be challenging. To initiate efficient treatment and avoid costly antifungal therapy, early and reliable IA diagnosis is essential.

The Platelia *Aspergillus* Ag Assay aids in diagnosis by detecting circulating galactomannan (GM) Ag — the most relevant biomarker for invasive aspergillosis.

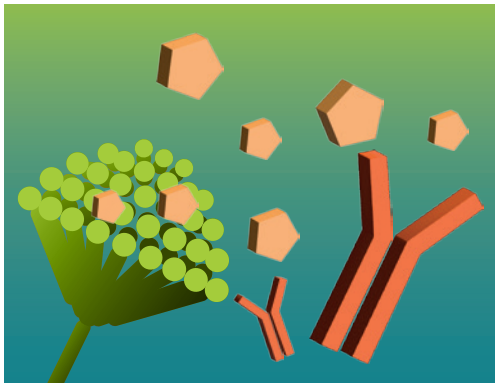
The highly sensitive assay improves the rapid and specific diagnosis of IA when used with other diagnostic procedures such as clinical, microbiological, histopathological, and radiographical examinations.

It is the only *Aspergillus* Ag assay that is U.S. FDA 510(k) cleared and EU-IVDR certified for both adult and pediatric patient samples.



## Aids in Diagnosing High-Risk Patients

- ICU patients
- Neutropenic and non-neutropenic patients with hematologic malignancies
- Solid organ and hematopoietic stem cell transplant recipients
- Pediatric patients with the pathologies listed here



## Detects Circulating Galactomannan Ag

Galactomannan is found in the *Aspergillus* cell wall. GM is considered the most relevant biomarker for IA because, during active IA, GM antigen is released from the cell wall. As a result, low levels of circulating GM Ag can be detected in biological fluids.

The Platelia *Aspergillus* Ag Assay provides rapid and reliable detection of circulating GM in adult and pediatric serum samples and bronchoalveolar lavage (BAL) fluid samples, aiding in IA diagnosis.

## Gold Standard Galactomannan-Based Assay

### Distributed in More than 80 Countries. Certifications Include:

- U.S. & Canada: U.S. FDA 510(k); Health Canada MDEL
- Latin America: ANVISA (Brazil); COFEPRIS (Mexico)
- Europe: EU-IVDR
- Asia Pacific: NMPA (China); HAS (Singapore); MHLW (Japan); TGA (Australia)

### Guidelines and Recommendations

- Since 2008, GM antigen detection using the Platelia *Aspergillus* Ag Assay has been among the mycological criteria defined by the **EORTC/MSG Consensus Group**.<sup>1</sup>
- In 2014, the **U.S. FDA** drafted guidance (approved in 2020) designating the GM antigen, detected by the Platelia *Aspergillus* Ag Assay, as the sole microbiological criterion to classify patients as having probable IA.<sup>2</sup>



## Enables Screening of High-Risk Patients

The *Platelia Aspergillus* Ag Assay is a non-invasive procedure performed on human serum and BAL fluid. The high-performance assay allows for twice-weekly screening of high-risk patients. Results are reported as GM index values.



### Performance

- Only *Aspergillus* Ag EIA that is U.S. FDA 510(k) cleared and EU-IVDR certified for both adult and pediatric patient samples
- Available in more than 80 countries



### Confidence

- Gold standard assay for GM Ag detection
- Delivers reliable results with well-known test limitations: validated 0.5 cut-off index for serum and BAL fluid testing and no gray zone for result interpretation



### Expertise

- Extensively studied by the global scientific community across various patient cohorts
- More than 270 references describing the *Platelia Aspergillus* Ag Assay have been published

## Packaging and Use

The assay is available in a packaging of 1 plate – 96 tests. Breakable strips enable flexibility in testing. It is a conventional one-step sandwich EIA; no specialized technical skills or materials are required for use.

## Systems to Fit Your Lab

The assay can be used manually or with semi-automated microplate systems.



### PW 41 Microplate Washer

Enables consistent wash and aspiration processes for 96-well plates

### IPS Microplate Incubator

Maintains a controlled, homogeneous temperature inside microplate wells

### PR 4100 Absorbance Microplate Reader

Provides fast, accurate, and reproducible measurements in a compact design

## Verification Panel Assay

Ensure proper performance with the Platelia *Aspergillus* Ag Verification Panel Kit that can be used periodically with the Platelia *Aspergillus* Ag Assay. It allows laboratories to verify operator proficiency in running the assay during training — before testing patient specimens and before participating in external quality assurance (EQA). Labs can also ensure proper performance of equipment and troubleshoot issues.

This product is not a substitute for the controls provided in the Platelia *Aspergillus* Ag Assay kit.



For more information on the Platelia *Aspergillus* Ag Assays, visit [bio-rad.com/aspergillus-ag](https://bio-rad.com/aspergillus-ag)

Contact your Bio-Rad representative to learn more about the Platelia *Aspergillus* Ag Assays, testing instruments, and world-class technical support.

## Ordering Information

Catalog No.	Description	
12014064	Platelia <i>Aspergillus</i> Ag Assay.....	96 tests
62792	Platelia <i>Aspergillus</i> Ag Verification Panel .....	6-member panel, 3 tests
<b>Instruments</b>		
87530	IPS Microplate Incubator .....	1 unit
85508	PW 41 Microplate Washer .....	1 unit
91587	PR 4100 Absorbance Microplate Reader.....	1 unit
12020451	PR4100 US Magellan V5.1 Dell 3540 PC).....	1 unit

## REFERENCES

- De Pauw et al. (2008). Revised definitions of invasive fungal disease from the European Organization for Research and Treatment of Cancer/Invasive Fungal Infections Cooperative Group and the National Institute of Allergy and Infectious Diseases Mycoses Study Group (EORTC/MSG) Consensus Group. Clin Infect Dis 46, 1813–1821.
- U.S. FDA (2020). Guidance on qualification of biomarker — galactomannan in studies of treatments of invasive aspergillosis. <https://www.fda.gov/media/94480/download>, accessed 10/18/2024.

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