Platelia *Aspergillus* Ag Assay

Galactomannan Antigen, First Clinical Biomarker Qualified

BIO-RAD

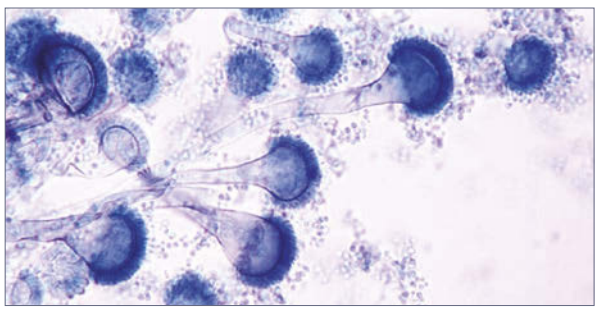
Platelia *Aspergillus* Ag
A Unique Tool

- **For the Screening and Diagnosis of Invasive Aspergillosis (IA) in High-Risk Patients** [4, 5, 6, 7, 8, 9, 10]
- **For the Follow-up of the Antifungal Treatment for IA** [3, 11, 12, 13, 14]

International Standards

"In 2002, a consensus group of the European Organization for Research and Treatment of Cancer/Invasive Fungal Infections Cooperative Group (EORTC) and the National Institute of Allergy and Infectious Diseases Mycoses Study Group (MSG) published standard definitions for invasive fungal infections (IFI) for clinical and epidemiological research.

The definitions assigned three levels of probability to the diagnosis of IFI that develops in immunocompromised patients with cancer and in hematopoietic stem cell transplant recipients-namely, proven, probable and possible IFI". [1]



Aspergillus fumigatus heads

In 2008, the EORTC/MSG Consensus Group published revised definitions "retaining the original classifications of *proven*, *probable*, and *possible* IFI".

The revised criteria for the classification of Invasive Aspergillosis Disease (IA) are:

- Proven IA requires that an *Aspergillus* species be detected by histological analysis or culture in diseased tissue.
- "Probable IA requires the presence of a host factor, a clinical criterion, and a mycological criterion".
- Possible IA requires the presence of a host factor and a clinical criterion.

In the revised definitions, "the category of proven IA can apply to any patient, regardless of whether the patient is immunocompromised, whereas the probable and possible categories are proposed for immunocompromised patients only."

Galactomannan antigen (GM) detection (Platelia *Aspergillus* Ag assay) is among the mycological criteria defined by the EORTC/MSG Consensus Group for IA. [2]

Galactomannan Ag Draft Guidance

In 2014, the U.S. FDA published the GM Draft Guidance [3] on October 24 with the following use statement:

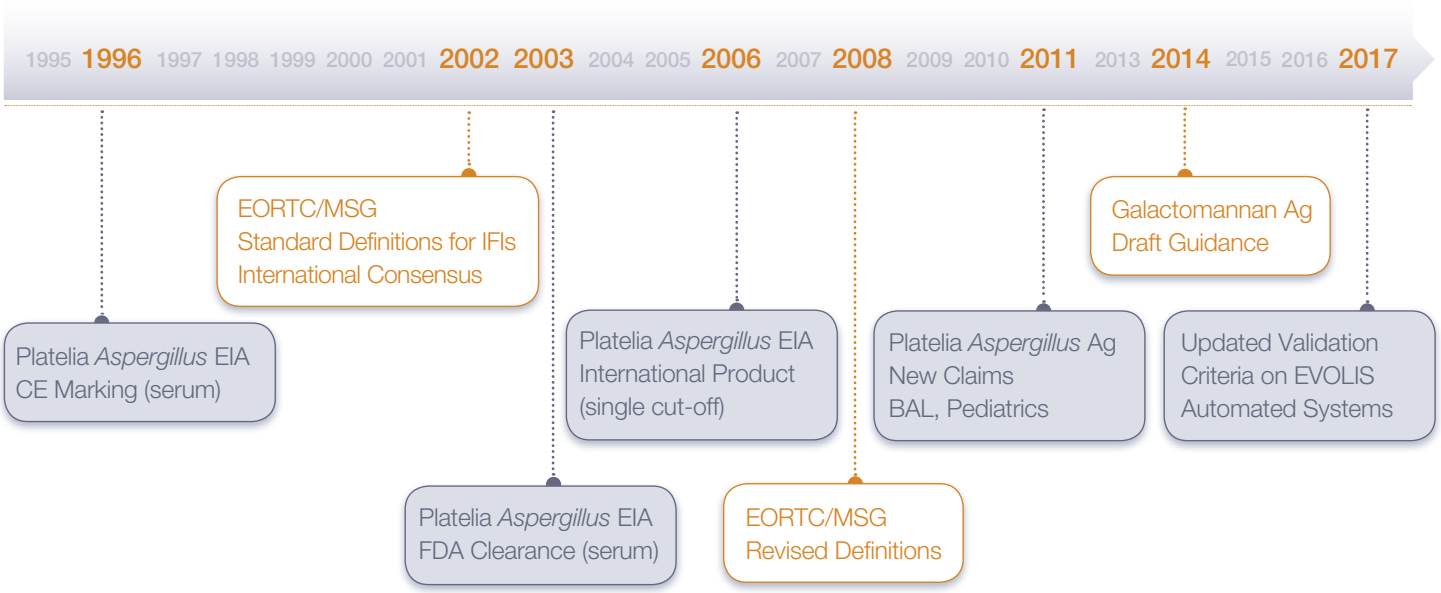
"Galactomannan in serum and/or BAL fluid is qualified as a sole microbiological criterion to classify patients as having probable Invasive Aspergillosis (IA) as defined by the European Organization for Research and Treatment of Cancer/Invasive Fungal Infections Cooperative Group and Infectious Diseases Mycoses Study Group (EORTC/MSG) in 2008, **for enrollment in, and analysis of, clinical trials conducted to evaluate the efficacy and safety of drugs for the treatment of IA."**

The FDA Center for Drug Evaluation and Research (CDER) has approved **GM testing by Platelia *Aspergillus* Ag** as the First Clinical Biomarker Qualified through the Biomarker Qualification Program.

This Biomarker approval allows for patients to be enrolled in clinical trials for antifungal therapy of IA, using the GM result.

This guidance applies to research use only in investigational-studies of treatments for invasive aspergillosis.

Platelia *Aspergillus* Ag Major Milestones



Thanks to the Experts for your Support over the Years!
This is the Fruit of your Efforts!

For more information, please visit the site http://www.fda.gov/Medical Devices/galactomannan draft guidance

Click here for the guidance:

Click here for the statistical review:

Click here for the performance in BAL fluids:

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Ordering Information

Catalog #	Description
62794	**Platelia *Aspergillus* Ag**, 96 tests
62792	**Platelia *Aspergillus* Proficiency Panel**, 3 x 6 tests

Visit **www.bio-rad.com/serology-reagents** for more information.

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