sōna

ASPERGILLUS GM
LATERAL FLOW ASSAY

IMMY

REF: AF2003
CE: Serum, BAL

BENEFITS

- Results in ***45 minutes***
- Reduce time to proper treatment for at-risk patients
- Simplified procedure that can be ***run on all shifts***
- Eliminate delays in diagnosis caused by batch testing
- Highly sensitive and specific

It's About **TIME**

99% NPV in Proven IPA[1]

- **15 minute hands-on**
- **30 minute test run**

The IMMY sōna Aspergillus galactomannan LFA has high sensitivity and specificity

In a multicentric, retrospective study on bronchoalveolar lavage (BAL) fluid from hematology patients, samples were obtained and tested using IMMY's *Aspergillus* Galactomannan LFA. The study found a good overall performance in proven IPA (Invasive Pulmonary Aspergillosis). In cases of proven and probable IPA vs controls, the LFA appeared to perform better with a significantly higher sensitivity and negative predictive value (NPV) when compared to another lateral flow device.[1]

IMMY LFA	Sensitivity	Specificty	Negative Predictive Value
Proven IPA (n=11) vs Controls (n=117)	91%	87%	99%
Proven/Probable IPA (n=75) vs Controls (n=117)	83%	87%	89%

Table 1. Diagnostic Performance of Both Lateral Flow Tests

Current direct tests (microscopy, culture) are insensitive. Indirect tests (PCR, galactomannan [GM], β-D-glucan) have good sensitivity but require significant hands-on time, often have long turnaround times, or are batched for cost-efficiency.[1] Galactomannan ELISA tests have also shown significantly high rates of false positivity in BAL fluid, especially at lower cut-off values.[2]

Number (%) of Patients with False Positive BAL-GM ELISA Results at Various Cut-Offs

Cut-Off Values	BAL-GM ELISA > 0.5	BAL-GM ELISA > 0.8	BAL-GM ELISA > 1.0
All Patient Populations	56/134 (42%)	31/94 (33%)	24/75 (32%)
Hematology Patients	20/74 (27%)	11/56 (20%)	6/44 (14%)

The *Aspergillus* Galactomannan LFA is shown to have high sensitivity, reduces hands-on-time, provides faster results, and eliminates the need for batch testing. With the LFA's high specificity the occurrence of false positivity could be reduced compared to GM ELISA testing, eliminating the need for further confirmatory GM testing.

SAVING LIVES
ONE DIAGNOSTIC AT A TIME

1. Mercier T, Dunbar A, de Kort E, et al. Comparison of the IMMY sōna Aspergillus galactomannan LFA and the OLM Diagnostics AspLFD. Poster presented at: Fungal Update 2019; March, 2019; London, England.

2. Farmakiotis D, Le A, Weiss Z, Ismail N, Kubiak DW, Koo S. False positive bronchoalveolar lavage galactomannan: Effect of host and cut-off value. Mycoses. 2019 Mar;62(3):204-213.