
# A Rapid, High-Throughput Chemiluminescence Immunoassay for the Detection of *Aspergillus* Galactomannan

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## • Background •

Invasive aspergillosis (IA), a life-threatening fungal infection, continues to be associated with significant mortality despite diagnostic and therapeutic advances. Rapid diagnosis of IA is critical due to its high mortality rate. The galactomannan (GM) antigen test is a valuable non-invasive alternative that significantly improves IA detection. This study aims to evaluate the diagnostic performance of a novel GM chemiluminescence immunoassay (CLIA) for the early detection and management of IA (Figure 1).

## • Methods •

A total of 265 patients with suspected IA were prospectively enrolled between March and May 2023, and stratified into IA (n=48) and non-IA (n=217) groups. A total of 265 specimens (208 serum, 57 BALF) were tested using the GM-CLIA. Specificity, sensitivity, negative predictive value (NPV), and positive predictive value (PPV) were calculated. Diagnostic performance was evaluated using receiver operating characteristic (ROC) curves.

## • Results •

The GM-CLIA assay achieved a sensitivity and specificity of 88.00% and 93.44% for serum samples, versus 91.30% and 76.47% for BALF specimens. The sensitivity for all samples was 89.58% with a specificity of 90.78%, while PPV and NPV were 69.25% and 97.52%, respectively (Table 1). The area under the ROC curve (AUC) was 0.93 (95% CI, 0.89-0.97, $p$<0.001), with an optimal cutoff value of 0.70 ng/mL.

## • Conclusions •

Dynamiker GM demonstrates high sensitivity and specificity, making it a reliable biomarker for IA. The CLIA platform provides rapid results suitable for clinical practice. When combined with a fully automated chemiluminescence immunoassay analyzer, the GM-CLIA enables on-demand automated testing with short turnaround time (<30 minutes) and high throughput (120–300 samples per hour), reducing contamination risk and manual workload. Early diagnosis of IA allows timely initiation of appropriate therapy, which helps reduce mortality.

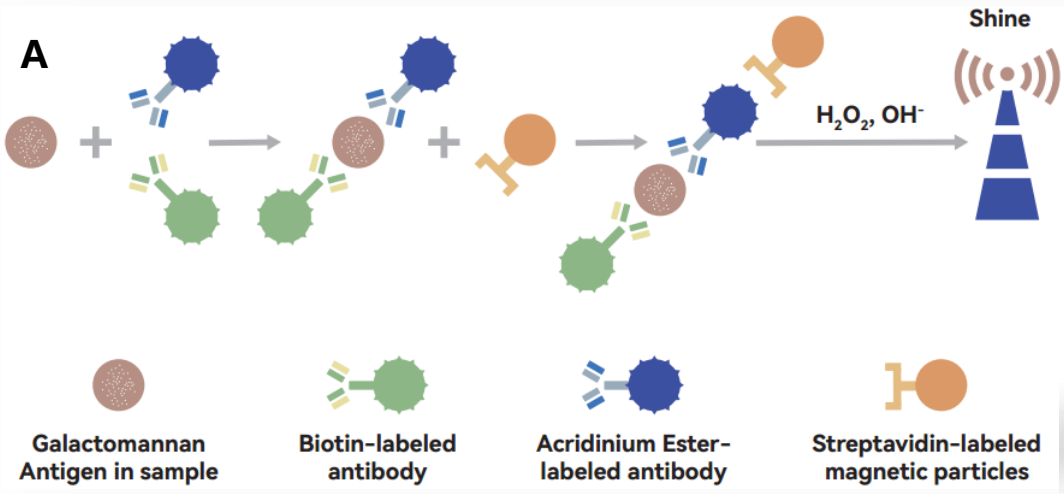



Figure 1 Detection Principle of the Dynamiker *Aspergillus* galactomannan Assay (Chemiluminescence, A); Fully Automated Chemiluminescence Analyzer (B)

| Performance parameters | Sensitivity, % (95% CI) | Specificity, % (95% CI) | PPV, % (95% CI) | NPV, % (95% CI) |
|---|---|---|---|---|
| Serum (n=208) | 88.00 (22/25) (67.66-96.85) | 93.44 (171/183) (88.56-96.41) | 64.71 (22/34) (46.47-79.70) | 98.28 (171/174) (94.64-99.55) |
| BALF (n=57) | 91.30 (21/23) (70.49-98.48) | 76.47 (26/34) (58.43-88.62) | 72.41 (21/29) (52.51-86.55) | 92.86 (26/28) (75.04-98.75) |
| Serum + BALF (n=265) | 89.58 (43/48) (76.56-96.10) | 90.78 (197/217) (85.93-94.14) | 69.25 (43/63) (55.18-79.09) | 97.52 (197/202) (94.00-99.09) |

Table 1 Diagnostic performance of GM-CLIA in serum and BALF compared with the 2019 EORTC/MSG guidelines (BALF, bronchoalveolar lavage fluid; CI, confidence interval)