

Evaluation of a Novel *Aspergillus* Galactomannan Chemiluminescence Immunoassay for the Diagnosis of Invasive Pulmonary Aspergillosis: A Multicenter Controlled Study

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Background

- Invasive pulmonary aspergillosis (IPA) is the most prevalent fungal infection in patients with hematological malignancy (HM), lung cancer, intensive care, or chronic obstructive pulmonary disease (COPD), with a crude annual incidence of 2.113 million cases and a crude annual mortality of 1.801 million cases in these four population groups.
- The Dynamiker *Aspergillus* galactomannan chemiluminescence Immunoassay (GM-CLIA) is a newer non-culture-based diagnostic test that detects *Aspergillus* GM in serum and bronchoalveolar lavage fluid (BALF) for the diagnosis of IPA.**
- The aim of this study was to explore its value in IPA by a multicenter, retrospective, and controlled study.

Methods

We enrolled 465 patients with suspected IPA between March 2023 and July 2024 and divided them into two groups: IPA (n=229) and non-IPA (n=236). A total of 246 serum specimens and 228 BALF specimens were collected and tested for GM-CLIA detection, and the results were quantitatively compared with Bio-Rad Galactomannan ELISA (GM-EIA) by Spearman rank correlation analysis. Sensitivity, specificity, and positive predictive (PPV) and negative predictive values (NPV) in diagnosing IPA were calculated. Study assessments included reproducibility, limit of detection (LOD), linear range, and cross reactivity experiments.

Conclusions

- The Dynamiker *Aspergillus* GM-CLIA kit test is an alternative novel streptavidin-magnetic particle-based chemiluminescence immunoassay, which has shorter time (30 min) and easier protocol than the ones of conventional ELISA for the early diagnosis of patients with IPA.

Advantages

- High sensitivity
- POCT
- High throughput
- Rapid turnaround times
- Simple operation procedures



Results

- The sensitivity, specificity, PPV and NPV of serum GM-CLIA for diagnosing IPA were 91.41%, 97.46%, 97.50% and 91.27%, and those of BALF GM-CLIA were 92.73%, 95.76%, 95.33% and 93.39%, respectively (Table 1).
- The GM concentrations measured by the two assays showed a strong degree of correlation (Spearman r_s [95% CI] = 0.838, $P < 0.0001$) (Fig 1).
- The percent coefficient variations (CVs%) of the reproducibility were lower than 10.0%, and the LOD for detection of GM-CLIA was 0.09 ng/mL.
- The linear range was 0.133~45.547 ng/mL ($r > 0.990$) and there was no cross-reaction with non-*Aspergillus* pathogens.

Table 1 Diagnostic performance of the GM-CLIA in patients with IA compared with Non-IA patients.

Sample type	Sensitivity [% (95% CI)]	Specificity [% (95% CI)]	PPV [% (95% CI)]	NPV [% (95% CI)]
Serum	91.41 (84.80-95.42)	97.46 (92.19-99.34)	97.50 (92.32-99.35)	91.27 (84.56-95.35)
BALF	92.73 (85.74-96.58)	95.76 (89.90-98.43)	95.33 (88.91-98.27)	93.39 (86.98-96.89)

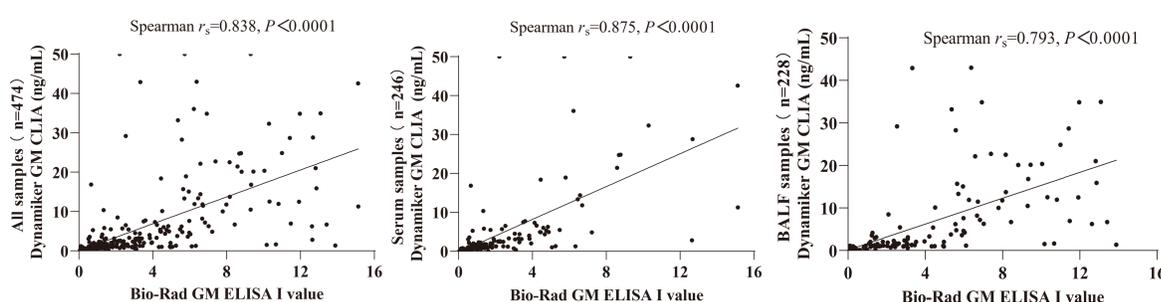


Fig. 1 Linear correlation between galactomannan (GM) values generated by the DNK GM-CLIA and the Bio-Rad GM-EIA when testing serum samples and BALF samples.