

Aspergillus Galactomannan Lateral Flow Assay with Digital Reader for the Diagnosis of Invasive Aspergillosis

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BACKGROUND

- The Novel QuicGM™ *Aspergillus* Galactomannan Ag Lateral Flow Assay from Dynamiker Biotechnology (Tianjin) Co., Ltd is a fluorescent immunochromatographic cassette test using a monoclonal antibody against GM with Digital Reader (Fig. 1).
- We conduct a comparative study between the Dynamiker QuicGM™ and the Platelia™ GM (Bio-Rad, USA) to validate the performance of the novel assay for the diagnosis of Invasive Aspergillosis (IA).

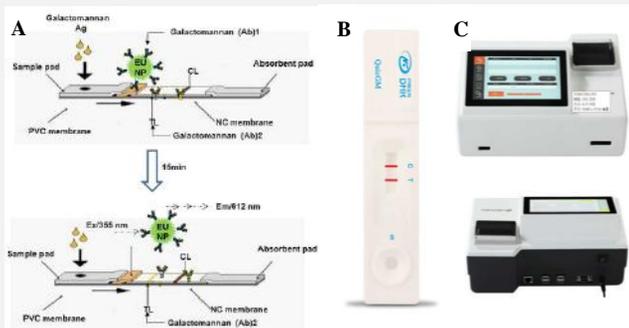


Fig. 1 Diagram of the Dynamiker Quic GM (Fig. 1A), Dynamiker Quic CiM test (Fig. 1B) and its reader (Fig. 1C).

METHODS

A total of 573 serum samples and 97 BALF samples with proven IA (Serum n = 9, BALF n = 2), probable IA (Serum n = 174, BALF n = 25), possible IA (Serum n = 98, BALF n = 16) and patients not fulfilling 2019 EORTC/MSG guideline IA criteria (control, Serum n = 292, BALF n = 54) were included. All the samples were tested in parallel using the Quic GM and Platelia GM.

RESULTS

- The total coincidence rate of QuicGM™ compared with Platelia™ GM was 91.10%, 91.75% and 91.79% in different samples, respectively (Table 1).
- The concentrations generated by QuicGM™ and Platelia™ GM were linearly correlated.

Table 1 The coincidence rate of QuicGM™ compared with Platelia™ GM

	Positive coincidence rate % (95% CI)	Negative coincidence rate % (95% CI)	Total coincidence rate % (95% CI)	Kappa value
Serum	92.17 (88.43-94.77)	90.07 (86.10-93.00)	91.10 (88.49-93.17)	0.82
BALF	90.70 (78.40-96.32)	92.59 (82.45-97.08)	91.75 (84.56-95.76)	0.83
Serum+BALF	91.98 (88.50-94.47)	90.46 (86.91-93.13)	91.19 (88.81-93.11)	0.82

CONCLUSION

In conclusion, the Dynamiker QuicGM™ yielded significant consistency with Bio-Rad Platelia™ GM ELISA, and showed good performances for IA diagnosis, with the benefit of a relatively short handling time (around 20 min).