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

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BACKGROUND

The study evaluated the *Aspergillus* Galactomannan Lateral Flow Assay with automated reader for the diagnosis of Invasive Aspergillosis (IA). The Novel *Aspergillus* Galactomannan Lateral Flow Assay（Quic GM）from Dynamiker Biotechnology (Tianjin) Co., Ltd is a fluorescent immunochromatographic cassette test using a monoclonal antibody against GM with Digital Reader (Figure 1), which was rapid and easy to operate compared with the traditional GM ELISA assay. Here we conducte a comparative study between the Dynamiker Quic GM and the Platelia GM (Bio-Rad, USA) to validate the performance of the novel assay.

METHOD

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.

RESULT

The total coincidence rate of Quic GM compared with Platelia GM was 97.91% (Kappa value was 0.95>0.75), 97.94% (Kappa value was 0.95>0.75) and 97.91% (Kappa value was 0.95>0.75) in serum samples, BALF samples and serum+BALF samples, respectively (Table 1). The concentrations generated by Quic GM and Platelia GM were linearly correlated (Serum: slope=0.97, r^2 = 0.96, $p<0.0001$; BALF: slope=0.95, r^2 = 0.94, $p<0.0001$) (Figure 2).

CONCLUSION

In conclusion, the Dynamiker Quic GM 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).

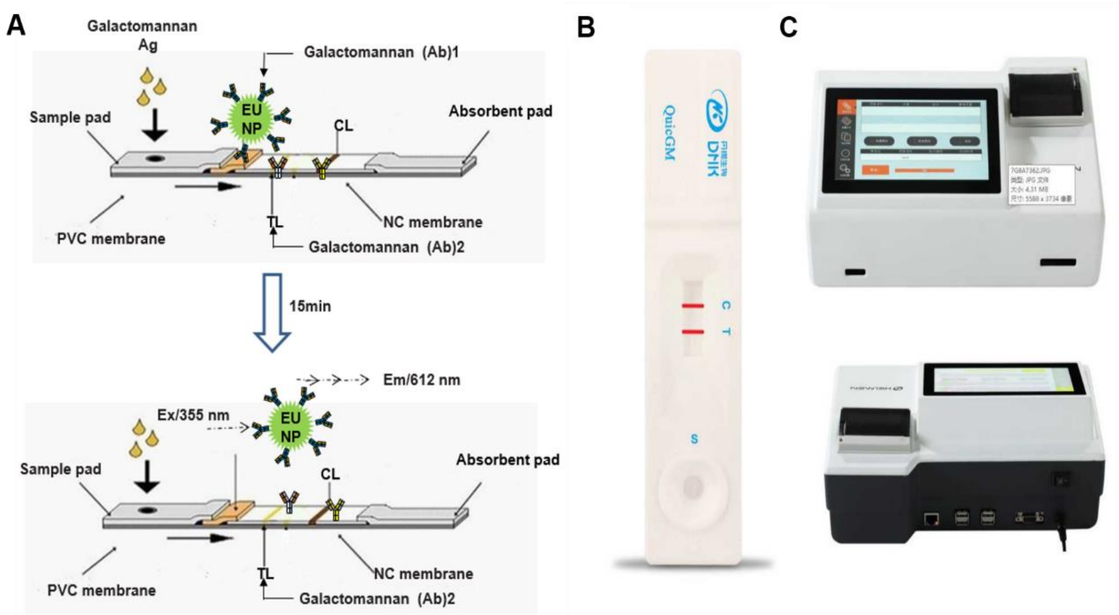

Figure 1 Diagram of the Dynamiker Quic GM (Fig. 1A), Dynamiker Quic GM test (Fig. 1B) and its reader (Fig. 1C).

Table 1 The coincidence rate of Quic GM compared with Platelia GM

	Positive coincidence rate % (95% CI)	Negative coincidence rate % (95% CI)	Total coincidence rate % (95% CI)	Kappa value (95% CI)
Serum	96.17 (92.32-98.13)	98.72 (97.03-99.45)	97.91 (96.38-98.80)	0.95 (0.91-0.99)
BALF	96.67 (83.33-99.41)	98.51 (92.02-99.74)	97.94 (92.79-99.43)	0.95 (0.85-1.05)
Serum+BALF	96.24 (92.76-98.08)	98.69 (97.17-99.40)	97.91 (96.52-98.75)	0.95 (0.91-0.99)

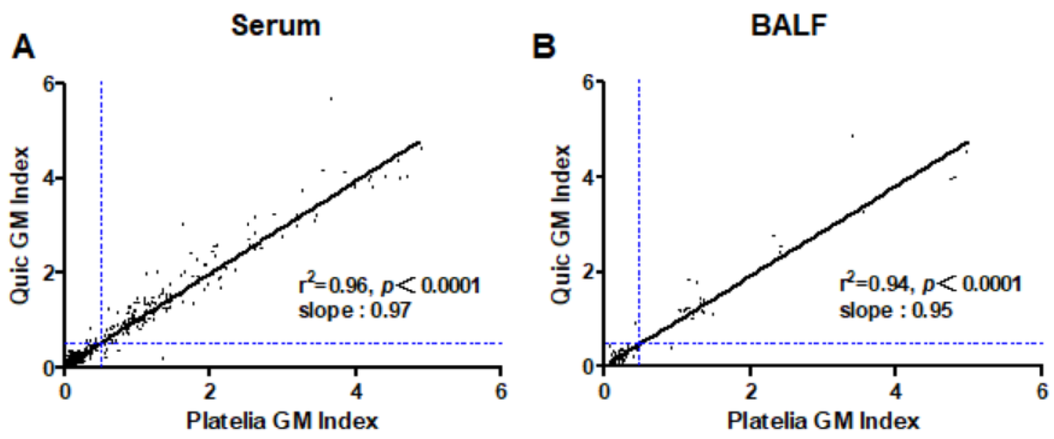

Figure 2 Scatter plot. Data distribution and probability density for all serum samples (Fig. 2A), and all BALF samples (Fig. 2B) individually tested by Quic GM and Platelia GM. The blue dotted lines indicate the manufacturer's cut-off value of each test (I Value=0.5).

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