

A Novel MycoMDx *Aspergillus* PCR Assay for Detection of Invasive Aspergillosis

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Background

Invasive aspergillosis (IA) is a well-known infectious complication in patients with severe immunosuppression, associated with high morbidity and mortality, and diagnosis is not straightforward. The traditional way to diagnose IA is cultures, direct microscopy, and histopathology, these methodologies fall short in terms of turn-around time and sensitivity, and they still require a trained mycologist to differentiate between fungal species. The novel MycoMDx *Aspergillus* PCR Assay with melting curve analysis produced by Dynamiker Biotechnology (Tianjin) Co., Ltd was a rapid, reliable and sensitive clinical diagnostic technique. This methodology can specifically identify and distinguish between *Aspergillus spp.* (*A. fumigatus*, *A. niger*, *A. flavus*, and *A. terreus*). The study evaluated the MycoMDx *Aspergillus* PCR Assay for the diagnosis of IA.

Methods

A total of 611 patients were included in the study. All patients were classified as proven IA (n=114), probable IA (n=177) and non-IA (n=320) patients according to the 2019 EORTC/MSG guideline. All the patients were tested using the MycoMDx *Aspergillus* PCR Assay.

Results

The sensitivity and specificity of MycoMDx *Aspergillus* PCR Assay were 90.03%(262/291) and 95.63%(306/320, Table 1). The concordance of detection results between Dynamiker MycoMDx *Aspergillus* PCR Assay and Sanger sequencing assays was high (Table 2).

Conclusion

The Dynamiker MycoMDx *Aspergillus* PCR Assay is a useful tool for the rapid identification of *Aspergillus* species and might be useful as an early diagnostic tool to detect invasive aspergillosis.

Table 1 Results of detection performance of Dynamiker MycoMDx *Aspergillus* PCR Assay

Sensitivity [%(95% CI)]	Specificity [%(95% CI)]	Positive predictive value [%(95% CI)]	Negative predictive value [%(95% CI)]	Kappa Value (95% CI)
90.03 (85.86-93.11)	95.63 (92.60-97.49)	94.93 (91.45-97.09)	91.34 (87.67-94.03)	0.86 (0.82-0.90)

Table 2 Comparison results of Dynamiker MycoMDx *Aspergillus* PCR Assay and Sanger sequencing assays in differentiate various *Aspergillus* species

	Positive percent agreement [%(95% CI)]	Negative percent agreement [%(95% CI)]	Total percent agreement [%(95% CI)]
<i>A. fumigatus</i>	99.03 (96.53-99.73)	99.53 (98.30-99.87)	99.37 (98.38-99.75)
<i>A. flavus</i>	100.00 (94.50-100.00)	100.00 (99.33-100.00)	100.00 (99.40-100.00)
<i>A. niger</i>	100.00 (89.28-100.00)	99.83 (99.06-99.97)	99.84 (99.11-99.97)
<i>A. terreus</i>	100.00 (74.12-100.00)	100.00 (99.39-100.00)	100.00 (99.40-100.00)