

A Novel Multiplex Aspergillus PCR Assay for Detection of Invasive Aspergillosis

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INTRODUCTION

- 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.

AIM

- The novel MycoMDx *Aspergillus* PCR Assay can specifically identify and distinguish between *Aspergillus* spp (*A. fumigatus*, *A. niger*, *A. flavus*, and *A. terreus*) (Figure 1).
- The study evaluated the MycoMDx *Aspergillus* PCR Assay for the diagnosis of IA

METHOD

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.

CONCLUSIONS

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.

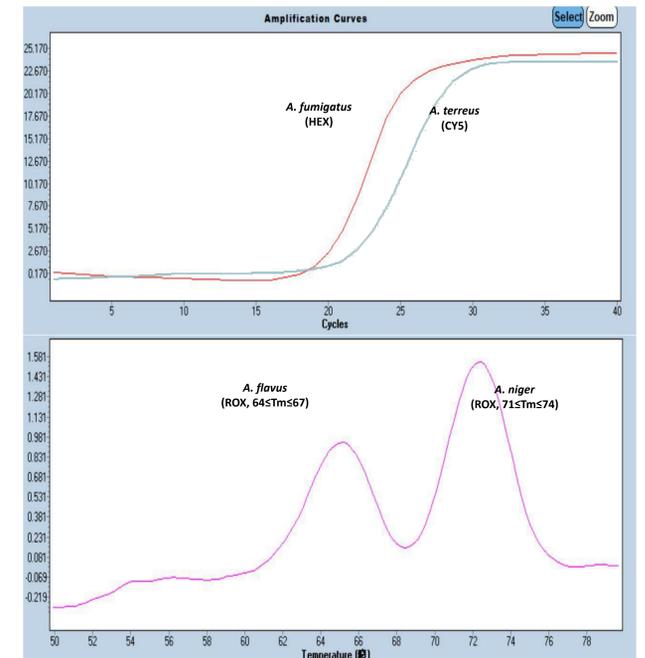
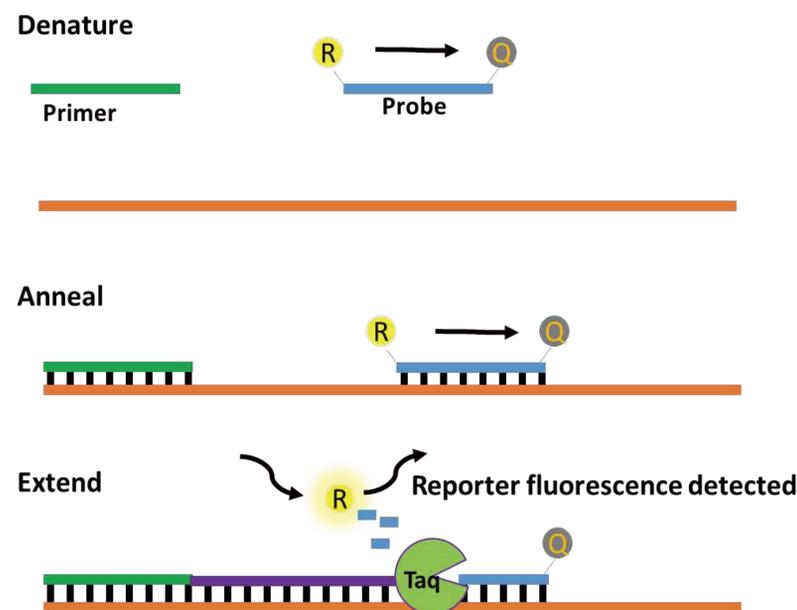


Figure 1 Detection Principle of the MycoMDx *Aspergillus* PCR Assay .

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).

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 (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. niger</i>	100.00 (94.50-100.00)	100.00 (99.33-100.00)	100.00 (99.40-100.00)
<i>A. flavus</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)