A Novel Rapid test for MycoMDX *Mucor* PCR Assay

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BACKGROUND

Mucormycosis is a rare and often fatal conditional fungal infection whose course can be acute, subacute, or chronic. Due to the characteristics of rapid progression, easy misdiagnosis and missed diagnosis, and high mortality, the early diagnosis and treatment of the disease has always been a major problem that plagues the clinic. Diagnosis of invasive fungal disease by PCR is superior to existing methods in terms of speed, sensitivity and specificity. The real-time fluorescence quantitative PCR method based on fluorescent probes can simultaneously detect five common pathogenic *Mucorales* clinically, including *Mucor spp.*, *Rhizopus spp.*, *Rhizomucor spp.*, *Lichtheimia spp.* and *Cunninghamella spp.*, which has the advantages of rapid detection, high sensitivity and specificity. Based on this principle, we developed the MycoMDX *Mucor* PCR Assay for the early diagnosis and treatment of invasive *Mucorales* infections.

METHOD

This kit is used to detect *Mucor* DNA extracted from Biopsy samples, serum samples and bronchoalveolar lavage fluid (BALF) obtained from human patients considered at risk of IFD. The two dye channels of FAM and ROX are set as the detection targets of the internal control and the detection gene, respectively, and the five common pathogenic *Mucorales* clinically can be detected at the same time (Fig. 1), and when the amplification curve appears in the detection sample, the results can be interpreted according to Table 1. In the present study, we evaluated the clinical performance of the MycoMDx *Mucor* PCR Assay, which includes 53 BALF samples (Positive samples 12; Negative samples 41). The above PCR detection reagents were developed and produced by Dynamiker Biotechnology (Tianjin) Co., Ltd..

RESULT

The sensitivity and specificity of BALF samples detected by the MycoMDX *Mucor* PCR Assay were 91.7% and 100.0%.

CONCLUSION

This kit established a method that can simultaneously detect five common pathogenic *Mucorales* clinically. This method has high sensitivity and specificity, which is of great significance for the early diagnosis and treatment of invasive *Mucorales* infections.

KEY WORDS

Mucorales; PCR; rapid test

Table 1 Analysis of detection results for the MycoMDx *Mucor* PCR Assay

Channel	ROX	FAM	
Target MycoMDx Mucor	Mucor	Internal Control	Result interpretation
Ct value	< 38	Anything	Positive sample
	N/A or > 38	$10 \leq Ct < 35$	Negative sample
		N/A or < 10 or ≥ 35	Retest
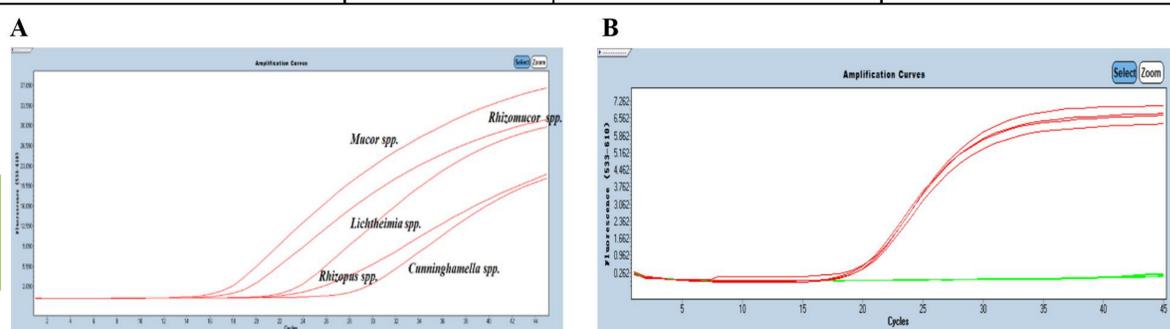
MycoMDx *Mucor* PCR Assay

Fig. 1 A: Results of detecting 5 standard Mucorales strains with MycoMDx *Mucor* PCR Assay; B: Results of detecting clinical sample with MycoMDx *Mucor* PCR Assay.