Poster number: 01048

CCMID Copenhagen, Denmark 15–18 April 2023 33rd E

Application of PCR-fluorescence probe method in molecular diagnosis of *Talaromyces marneffei* infection

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BACKGROUND

Talaromyces marneffei (T. marneffei) is a dimorphic pathogenic fungus, which is a life-threatening invasive mycosis in the immunocompromised host. The clinical manifestations of *T. marneffei* patients are diverse and atypical, and there is a lack of means for early and rapid diagnosis of the disease, which can easily lead to underdiagnosis and misdiagnosis in the early stages of the disease, resulting in delayed treatment, and therefore a high proportion of patients progressing to systemic disseminated infection and severe disease. Without early diagnosis and timely treatment, the mortality rate is high (over 80%). Prompt diagnosis of *T. marneffei* infection remains difficult although there has been progress in attempts to expedite the diagnosis of this infection. Based on the above principles, MycoMDx *Talaromyces marneffei* PCR Assay were developed by Dynamiker Biotechnology (Tianjin) Co., Ltd using fluorescent PCR (Fig. 1).

METHOD

In this study, we did a performance evaluation of the MycoMDx *Talaromyces marneffei* PCR Assay (CE-approved), including diagnostic sensitivity and specificity, the limit of detection (LoD), precision and stability.

RESULT

The sensitivity and specificity of the PCR assay reagents in different clinical samples were above 90% (Table 1). The LoD was 2000 copies/mL, and the precision and the stability were in accordance with the requirements (CV≤5%). (Table 2)

CONCLUSION

The MycoMDx *Talaromyces marneffei* PCR assay provides an attractive alternative for identification of *T. marneffei* DNA in different clinical samples to improve the management of patients with *Talaromycosis marneffei*.

Figure1. The product photo of MycoMDx *Talaromyces marneffei* PCR Assay

Table 2 Diagnostic performance of the kit in four sample types

	Sample Type	Positive samples (n) Proven/probable	Negative samples (n)	Sensitivity%	Specificity%
1	Serum	47	48	95.7(45/47)	95.8(46/48)
2	Plasma	46	50	91.3(42/46)	90.0 (45/50)
3	Whole blood	44	54	93.2(41/44)	94.4(51/54)
4	BALF	52	51	90.2(47/52)	96.1(49/51)