

A Novel MycoMDx PCR Assay for the Detection of *Candida auris*

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Background

Candida auris is a multidrug-resistant opportunistic fungal pathogen capable of causing serious infections and healthcare-associated outbreaks. Screening for colonization with *C. auris* has become routine and is recommended in many hospitals and healthcare facilities as an infection control and prevention strategy. The MycoMDx *C. auris* PCR Assay is a multiplex real-time qualitative PCR detection of *C. auris* DNA extracted from whole blood, plasma, serum samples and swabs. In this work, we validated the performance of MycoMDx PCR Assay from the Dynamiker Biotechnology (Tianjin) Co., Ltd (Figure 1).

Methods

The detection performance was evaluated by testing with swabs(armspits, groin, etc.). Clinical sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were determined by assessing 209 clinical specimens by the fungal culture as the gold standard.

Results

For the validation of the method, a total of 209 specimens were tested, a total of 88 specimens were clinically diagnosed as *C. auris* positive, of which 85 were PCR positive. The remaining 121 specimens were PCR negative for *C. auris*, consistent with the fungal culture results. The sensitivity, specificity, PPV and NPV of MycoMDx *C. auris* PCR Assay were 96.59%, 100.00%, 100.00% and 97.58%, respectively (Table 1). The results indicated that the limit of detection was 1000 Copies/mL. Furthermore, no significant differences were observed across the triplicates, indicating a high level of test reproducibility and calibration curve reliability ($R^2=0.992$).

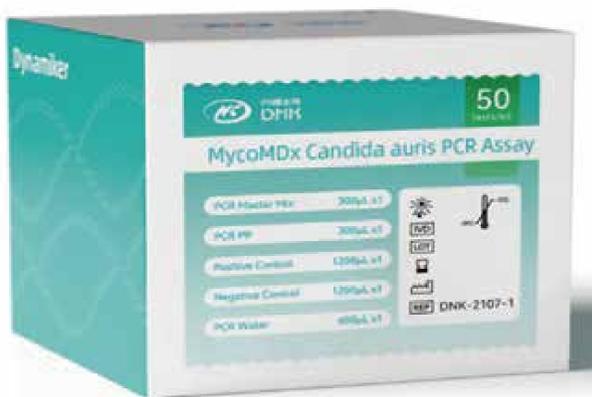
Conclusion

MycoMDx PCR Assay demonstrates both high sensitivity and specificity and has significant health-system cost-savings associated with significantly reduced turn-around-time compared to traditional standard-of-care culture-based work up. This method is of interest to support clinical microbiology diagnostics and to help aid in hospital inpatient, and infection prevention control screening.

Table 1. Performance of the MycoMDx *C. auris* PCR Assay compared to clinical diagnostic outcomes

		Clinical Diagnosis Results	
		Positive	Negative
MycoMDx PCR	Positive	85	0
	Negative	3	121
Clinical performance		Value[%(95% CI)]	
Sensitivity		96.59(89.66-99.12)	
Specificity		100.00(96.17-100.00)	
Positive predictive value		100.00(94.61-100.00)	
Negative predictive value		97.58(92.56-99.37)	

Figure 1. Dynamiker MycoMDx *C. auris* PCR Assay



Specimens types: whole blood, serum, plasma, urine and environmental samples (swabs)

TAT : 2.5 hours