

# PRIME AurisDetect™ RAPID ASSAY



## SCIENTIFIC APPLICATION NOTE

### Prime AurisDetect™ qPCR kit for the detection of *Candida auris*

*Candida auris* is an emerging fungus that presents a serious global health threat. It is often multidrug-resistant, meaning that it is resistant to multiple antifungal drugs commonly used to treat *Candida* infections. Some strains are resistant to all three available classes of antifungals. It is difficult to identify with standard laboratory methods, and can be misidentified in labs without specific technology. Misidentification may lead to inappropriate management. It has caused outbreaks in healthcare settings. For this reason, it is important to quickly identify *C. auris* so that healthcare facilities can take special precautions to stop its spread.

## SCIENTIFIC APPLICATION NOTE

Prime AurisDetect™, an extraction-less, rapid, culture-free detection of *Candida auris*

### 1. INTRODUCTION

*Candida auris* is an emerging fungus that presents a serious global health threat. Since its first isolation in 2009 cases have been reported globally. It is often multidrug-resistant, meaning that it is resistant to multiple antifungal drugs commonly used to treat *Candida* infections including Fluconazole. Some strains are resistant to all three available classes of antifungals. It is difficult to identify with standard laboratory methods, and it can be misidentified in labs without specific technology. Misidentification may lead to inappropriate management. It has caused outbreaks in healthcare settings. For this reason, it is important to quickly identify *C.auris* in a hospitalized patient so that healthcare facilities can take special precautions to stop its spread.

Rapid detection of *C.auris* will help promote active surveillance and prevent outbreaks in healthcare settings. This requires highly sensitive assays that reduce time from sample to results and are specific to *C.auris* and not cross reactive to other closely related organisms. These tests should provide results directly from samples without need for culture, preventing delays and reducing steps required for sample processing.

Prime Discoveries has developed AurisDetect™, an extraction-less, rapid, culture-free assay which can detect *C.auris* directly from a sample within 45 minutes.

### 2. RESULTS

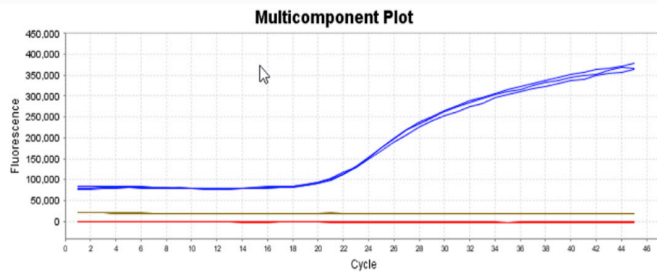
#### Extraction vs Extraction-less

Prime AurisDetect™ was designed and developed for extraction-less processing of samples. We compared our results for a positive control *Candida auris* sample (ATCC cat# MYA-5001) with and without DNA extraction. Samples were placed in MawiDNA iSwab-EL extractionless sample collection buffer which was previously validated for SARS-CoV-2 using Prime CovidDetect™ assay and has been shown to release nucleic acid into medium at room temperature without heating or addition of lysates.

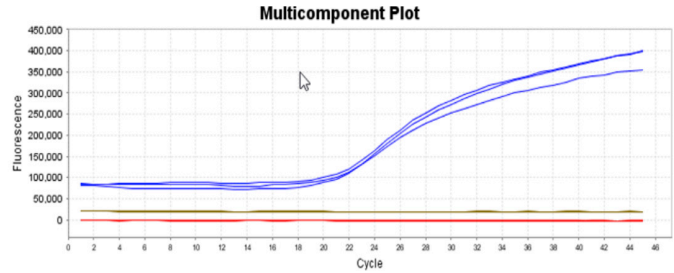
Our results show similar performance between the extracted and extraction-less sample in detecting *C.auris* using Prime AurisDetect™ primers/probes.

**2. RESULTS (CONTINUED)**

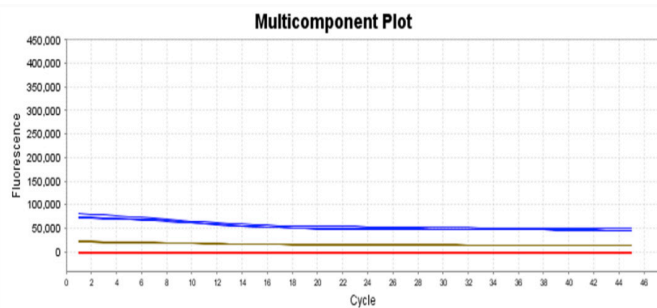
*Candida Auris* (gDNA Extraction using the Monarch gDNA extraction kit from NEB)



*Candida Auris* (MawiDNA iSwab-EL Extraction-less Buffer)



Negative Control (Non-Fungal DNA)  
Drosophila Melanogaster: Embryo Schneider's Drosophila Line 2 [D. Mel. (2), SL2]  
ATCC cat# CRL-1963



No Template Control (Ultra-Pure Water)



**3. INCLUSIVITY**

- Prime AurisDetect™ primers/probes were optimized for inclusivity to detect all known strains of *C.auris*.
- We tested 98 available strains and our primers/probes were able to detect all 98 genomes with 100% match.

**4. CROSS-REACTIVITY**

- Prime AurisDetect™ primers were optimized to be specific for *C.auris* and not detect any other closely related organisms.
- We tested multiple Candida and other closely related organisms and saw that none of the primers had a match of >80% for any of the other non-specific organisms.

#### 4. CROSS-REACTIVITY TABLE

Taxonomy	Assembly / Strain	AurisDetect™ Primers
<i>Candida haemulonii</i>	GCF_002926055.2	72.3%
<i>Candida duobushaemulonii</i>	GCF_002926085.2	73.8%
<i>Candida dubliniensis</i>	GCF_000026945.1	69.2%
<i>Candida lipolytica</i>	GCF_000002525.2	66.2%
<i>Candida lusitanae</i>	GCF_000003835.1	75.4%
<i>Candida albicans</i>	GCF_000182965.3	64.6%
<i>Candida glabrata</i>	GCF_000002545.3	64.6%
<i>Candida krusei</i>	GCF_003054445.1	63.1%
<i>Candida sake</i>	CBA6005	66.2%
<i>Candida parapsilosis</i>	GCF_000182765.1	67.7%
<i>Candida tropicalis</i>	GCF_000006335.3	63.1%
<i>Kodamaea ohmeri</i>	148	65.1%
<i>Rhodotorula glutinis</i>	ATCC 204091	67.7%
<i>Saccharomyces cerevisiae</i>	GCF_000146045.2	66.2%
<i>Aspergillus fumigatus</i>	GCF_000002655.1	67.7%

#### 5. CONCLUSION

- *Candida auris* has been recently categorized into a global threat since it is multi-drug resistant, has the ability to cause widespread outbreaks and can spread in healthcare settings.
- Standard laboratory techniques can misidentify the samples and time delays due to culturing the organism may result in poor clinical management.
- Hence a rapid, novel assay with high analytical sensitivity is required.
- Prime AurisDetect™ is a highly sensitive, qPCR-based™ assay that reduces the sample to result time to under 45 minutes. Prime AurisDetect™ is highly inclusive of all strains of *C.auris* and does not cross react with other closely related organisms.
- Adapting to Prime AurisDetect™ has the potential to empower healthcare professionals to make rapid decisions in threat reduction, spread management and allow management of infections in real time.