



Department of Health

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TO: Clinical Laboratories, Hospitals, Local Health Departments

FROM: New York State Department of Health (NYSDOH)
Wadsworth Center and Division of Epidemiology

**HEALTH ADVISORY:
CANDIDA AURIS AUTOMATED SAMPLE-TO-RESULT
REAL-TIME PCR TEST USING BD MAX™ OPEN SYSTEM**

Please distribute immediately to:

Laboratory Directors, Infection Preventionists, Medical Directors, Administrators, Hospital Epidemiologists, Directors of Environmental Services, Infectious Disease Physicians, Critical Care Medicine Physicians, and Risk Managers

Purpose:

The purpose of this advisory is to provide guidance to clinical and public health laboratory partners regarding development of a *Candida auris* (*C. auris*) automated sample-to-result real-time polymerase chain reaction (PCR) test using BD MAX™ Open System. The new test is based upon a successful improvement of the manual *C. auris* real-time polymerase chain reaction test developed by the NYSDOH Wadsworth Center. The new high throughput test provides capacity for an automated and timely method for *C. auris* identification. The rapid *C. auris* laboratory identification method could assist healthcare facilities in endemic regions by enabling timely implementation of *C. auris* infection prevention and control measures. In addition, the test could be used to improve the feasibility for implementing other prevention strategies such as admission screening protocols, point prevalence surveys, and assessment for *C. auris* environmental surface contamination. NYSDOH recommends clinical and commercial laboratories that serve healthcare facilities in areas most highly affected by *C. auris* consider adopting the automated sample-to-result *C. auris* real-time PCR as an added measure for the ongoing response to this emerging pathogen affecting hospitals and other healthcare facilities in NYS.

Background:

Candida auris, an emerging multi-drug resistant yeast, causes bloodstream infections and even death, particularly in hospital patients and nursing home residents with chronic medical problems. Antifungal medications commonly used to treat *Candida* infections often do not work for *C. auris*, and some *C. auris* strains are resistant to all three classes of antifungal medications. *C. auris* has caused outbreaks in healthcare facilities (hospitals and nursing homes) and can spread through contact with affected patients and contaminated surfaces or equipment. Since 2016, the NYSDOH has confirmed 365 clinical and 507 surveillance cases of *C. auris* affecting 151 hospitals and nursing homes located almost entirely in New York City metropolitan area, with a focus in Brooklyn and Queens. NYSDOH staff have been working to ensure that epidemiologic surveillance and laboratory testing are conducted expeditiously and that on-site facility infection control measures are enhanced to control this emerging public health threat.

To prevent *C. auris* transmission within the healthcare setting, rapid laboratory detection is critical. Most importantly, admission screening of patients in highly sensitive healthcare settings such as ventilator units and intensive care units can inform healthcare facilities on how to most effectively implement contact precautions to prevent the spread of *C. auris* among patients, residents, and/or within units. Traditional laboratory culture methods for the detection of *C. auris* may take from 1-7 days for growth and species identification. To this end, the Wadsworth Center, New York State's public health laboratory, previously developed a manual real-time PCR test for surveillance swab samples (nares, axilla, groin, axilla/groin, nares/axilla/groin, and wound) to assess if patients are potentially colonized with *C. auris*. The real-time PCR test was also useful for the assessment of environmental surfaces and patient care equipment for *C. auris* contamination that can inform additional measures needed within a facility to contain spread and ensure effective cleaning and disinfection. To improve the utility of the *C. auris* PCR assay, the NYSDOH Wadsworth Center developed and validated a real-time PCR for *C. auris* using BD MAX™ System, a fully integrated and automated platform.

Process for Implementation of the Wadsworth Center real-time PCR for *C. auris*:

To implement the Wadsworth Center *C. auris* automated sample-to-answer real-time PCR test using BD MAX™ Open System, laboratories will need the following:

- Approved Laboratory Director with a Mycology Certificate of Qualification from the NYSDOH's Clinical Laboratory Evaluation Program (CLEP)
- CLEP permit in Mycology
- Have BD MAX™ Open System testing capabilities for infectious diseases
- Utilize the automated real-time PCR protocol developed by Wadsworth Center without technical modification. This Standard Operating Procedure can be obtained by emailing mycology@health.ny.gov.
- Validate the automated real-time PCR method via an expedited pathway.
- Laboratories seeking expedited approval will be required to:
 - Submit their Standard Operating Procedure Manual reflecting this testing

- method based on your own institutional guidelines
- Submit sample reports for all potential test results that may be reported (e.g., positive, negative, inhibited)
- Submit streamlined validation data (details below)

To help facilities' efforts to develop this testing capability in an expedited manner given the emerging concern, a streamlined validation process has been developed that includes performance of a limit of detection for a skin swab matrix and an accuracy study that includes a minimum of 20 positive and 10 negative swab samples. Laboratories do not need to perform specificity or reproducibility studies. If needed, Wadsworth Center can provide mock surveillance samples and control strains to assist in facilitating these validation studies. All required validation materials must be submitted as described at:

<https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval>.

Labs that wish to modify the Wadsworth Center assay procedure, including adding other specimen types, are not eligible for an expedited validation submission and would instead need to submit through the standard process.

Wadsworth Center staff are available to assist laboratories and healthcare facilities seeking to obtain NYS CLEP approval of the automated real-time PCR method for *C. auris*. Please contact mycology@health.ny.gov with any questions.