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Evaluation of the NG-TEST® *Candida auris* Immunoassay for the Detection of *Candida auris* Across Geographical Clades I-VI

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Revised Abstract

Background: *Candida auris* is an emerging fungal pathogen of public health concern, associated with high rates of antifungal resistance, healthcare transmission, and high mortality. Since its emergence in Japan in 2009, six distinct clades of *C. auris* have been identified globally, with variable antifungal susceptibility patterns across clades. As a result, there is increasing emphasis on the comprehensive identification of isolates from all six clades. Current identification methods for *C. auris* include traditional phenotypic, molecular, or matrix-assisted laser desorption/ionization time-of-flight (MALDI-TOF) techniques. The high upfront cost, complex instrumentation, specialized training, laboratory space, and electrical requirements associated with these methods are barriers to adoption into diagnostic labs. Additionally, many of these methods have not been thoroughly evaluated against all *C. auris* clades. Given the urgent public health need for improved surveillance of *C. auris*, the high mortality rate associated with invasive infection, and the diagnostic barriers present in many healthcare facilities, there is a clear and compelling rationale for improving early detection with an accessible, easy-to-use test. NG-TEST® *Candida auris* is an *in vitro*, rapid, visual immunochromatographic assay for the detection of *C. auris* from isolated colonies and does not require any specialized equipment or extensive training, thus filling a gap within the current *C. auris* diagnostic market. The purpose of this study was to evaluate the performance of the NG-TEST® *Candida auris* with target and non-target isolates.

Methods: Well-characterized *C. auris* strains representing clades I-VI were tested with the NG-TEST® *Candida auris* from colonies grown on Sabouraud Dextrose (SabDex) agar (*n* = 33) and HardyCHROM™ Candida + auris (HCCA) agar (*n* = 29). Non-target yeast species were also tested on the NG-TEST® *Candida auris* from SabDex agar (*n* = 35) and HCCA agar (*n* = 30). SabDex agar plates were incubated at 35°C for 48 hours and HCCA agar plates at 35°C for 24-72 hours. HCCA plates were examined for colony color and presence/absence of fluorescence. Once color development was observed, colonies were tested.

Results: NG-TEST® *Candida auris* demonstrated 100% agreement with *C. auris* strains representing clades I-VI tested from SabDex agar (33/33) and HCCA agar (29/29). 100% of non-target species tested from SabDex agar (35/35) and HCCA agar (30/30) yielded negative results with the NG-TEST® *Candida auris*.

Conclusions: This evaluation demonstrated that the NG-TEST® *Candida auris* is a reliable, low cost, and rapid method for accurate detection of all *C. auris* clades.

Introduction

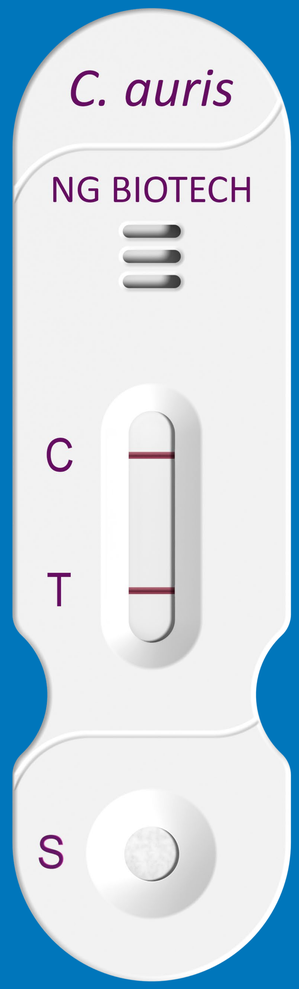
C. auris is an emerging yeast pathogen associated with invasive infections, multidrug resistance, and environmental persistence driving transmission and outbreaks in healthcare settings. The U.S. Centers for Disease Control and Prevention (CDC) has classified *C. auris* as an urgent antimicrobial resistance threat due to its multidrug resistant profile.[1] Similarly, the World Health Organization (WHO) has designated *C. auris* as a fungal priority pathogen of critical urgency.[2]

Reported mortality rates for invasive *C. auris* infections range from 29% to 53%, with the highest risk observed among immunocompromised or critically ill patients, particularly those who require invasive medical devices such as endotracheal tubes or catheters.[2,3] Beyond infection, *C. auris* can colonize patients, contributing to transmission in healthcare settings and complicating infection control efforts.

Since it was first described in 2009, six geographical clades of *C. auris* have been identified: clade I (South Asia), clade II (East Asia), clade III (South Africa), clade IV (South America), clade V (Iran), and clade VI (first reported in Singapore and Bangladesh). Clades I, III, and IV are most frequently associated with outbreaks worldwide, with clade I being the predominant driver of global transmission. Antifungal resistance trends vary by clade, with higher azole resistance in clades I and III, and higher amphotericin B resistance in clades I, III, and IV. Echinocandin resistance remains relatively uncommon across all clades, although increasing resistance rates have been reported.[4]

Rapid and reliable detection of infection and colonization is critical to guide therapy and prevent further spread, respectively. Current *C. auris* detection methods include traditional phenotypic, molecular, or MALDI-TOF techniques.[5] However, high upfront costs, complex instrumentation, and the need for specialized training are barriers to adoption into many diagnostic labs. Additionally, many of these devices have not been thoroughly evaluated against all *C. auris* clades.

Given the urgent public health need for improved surveillance of *C. auris*, high mortality associated with invasive infection, and diagnostic barriers present in healthcare settings, there is a clear need for an accessible detection method. NG-TEST® *Candida auris* is an *in vitro* rapid and visual immunochromatographic assay for the detection of *C. auris*. Results are available within 15 minutes of sample application, offering a simple and lower cost option for in-house testing for *C. auris*.



Methods

Characterized strains sourced from various culture collections (ATCC, the CDC and FDA AR isolate bank, BEI Resources, and NRRL) as well as clinical isolates were evaluated covering clades I-VI. Isolates were inoculated to SabDex agar from frozen (-80°C) stock vials and incubated at 35°C. After overnight incubation, isolates were subcultured to SabDex (*n* = 68) and HCCA (*n* = 59) and incubated at 35°C for 48 hours and 24-72 hours, respectively. After incubation, colonies from SabDex and HCCA cultures were tested on the NG-TEST® *Candida auris*. HCCA colonies were tested once color was observed. Fluorescence was also examined on HCCA agar.

Results

All target organisms tested from SabDex and HCCA agar showed expected positive results with NG-TEST® *Candida auris*, resulting in 100% agreement. Additionally, all non-target organisms tested from SabDex and HCCA agar showed expected negative results with NG-TEST® *Candida auris*, resulting in 100% agreement with expected results.

Table 1. NG-TEST® *Candida auris* Target Results (*n* = 33)

Organism	Clade	Number of Strains Tested	NG-TEST® *Candida auris* Result	
			SabDex	HCCA
Candida auris	I	10	Positive	Positive
Candida auris	II	4	Positive	Positive
Candida auris	III	4	Positive	Positive
Candida auris	IV	6	Positive	Positive
Candida auris	V	5	Positive	Positive
Candida auris	VI	4[1]	Positive	-------

[1] Strains were evaluated from SabDex alone.

Table 2. NG-TEST® *Candida auris* Non-Target Species Evaluated (*n* = 35)

Organism	
Candida albicans	*Candida utilis*
Candida dubliniensis	*Cryptococcus liquefaciens*
Candida duobushaemulonii	*Cryptococcus neoformans*
Candida glabrata	*Cutaneotrichosporan dermatis*
Candida guilliermondii	*Galactomyces candidus*
Candida haemulonii	*Kluyveromyces marxianus*
Candida intermedia	*Kodameae ohmeri*
Candida jadinii	*Magnusiomyces capitatus*
Candida kefyr	*Rhodotorula mucilaginosa*
Candida krusei	*Saccharomyces cerevisiae*
Candida lambica	*Trichosporon asahii*
Clavispora lusitaniae	*Wickerhamomyces anomalus*
Candida metapsilosis	*Candida boidinii*[1]
Candida norvegensis	*Candida inconspicua*[1]
Candida orthopsilosis	*Candida zeylanoides*[1]
Candida parapsilosis	*Debaromyces hansenii* (*Candida famata*)[1]
Candida pararugosa	*Pichia membranifaciens* (*Candida valida*)[1]
Candida tropicalis	

[1] Strains were evaluated from SabDex alone.

Conclusions

- Rapid and accurate detection of all *C. auris* clades is essential for patient treatment, infection control, and containment efforts.
- NG-TEST® *Candida auris* reliably detects all *C. auris* clades (clades I-VI).
- NG-TEST® *Candida auris* demonstrated 100% agreement with expected results across 68 strains of target and non-target organisms.
- NG-TEST® *Candida auris* offers a rapid, user-friendly, and cost-effective *C. auris* detection method.
- NG-TEST® *Candida auris* received FDA Breakthrough Device Designation due to its ability to accurately detect *C. auris* across all major clades, meeting WHO ASSURED criteria, and will allow all labs (even low-resource) to easily implement on-site testing for this critical pathogen.

Acknowledgments:
Thank you to Mr. Tahsin Khan and colleagues, at icddr,b, for performing the clade VI testing and for providing the resulting data.

References:

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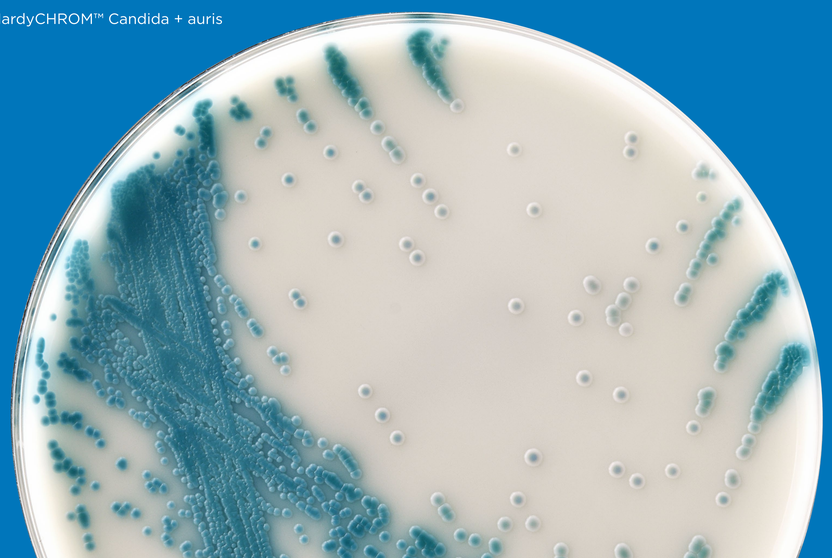
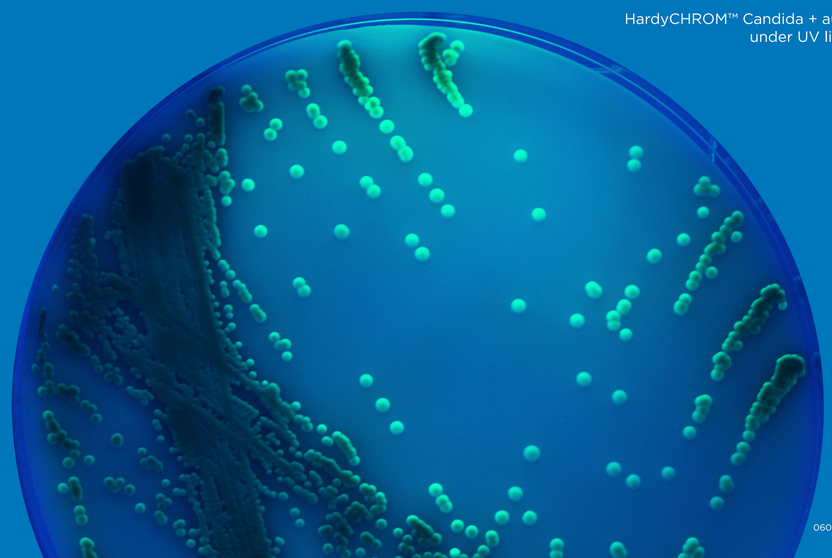
HardyCHROM™ Candida + auris



HardyCHROM™ Candida + auris under UV light



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