## Title

A simple and sensitive test for Candida auris colonization, surveillance, and infection control suitable for near patient use.



## Journal

Journal of Clinical Microbiology, 62(7)

## Authors

Banik, Sukalyani
Ozay, Burcu
Trejo, Marisol
et al.

## Publication Date

2024-07-16

## DOI

10.1128/jcm.00525-24

Peer reviewed

AMERICAN SOCIETY FOR MICROBIOLOGY | Journal of Clinical Microbiology

Clinical Microbiology | Full-Length Text

# A simple and sensitive test for *Candida auris* colonization, surveillance, and infection control suitable for near patient use

**Sukalyani Banik,[1] Burcu Ozay,[2] Marisol Trejo,[3] YanChun Zhu,[4] Charan Kanna,[1] Cynthia Santellan,[3] Bennett Shaw,[3] Sukantha Chandrasekaran,[3] Sudha Chaturvedi,[4] Lindy Vejar,[2] Soumitesh Chakravorty,[1,2] David Alland,[1] Padmapriya Banada[1]**

**AUTHOR AFFILIATIONS** See affiliation list on p. 10.

**ABSTRACT** *Candida auris* is a multidrug-resistant fungal pathogen with a propensity to colonize humans and persist on environmental surfaces. *C. auris* invasive fungal disease is being increasingly identified in acute and long-term care settings. We have developed a prototype cartridge-based *C. auris* surveillance assay (CaurisSurV cartridge; "research use only") that includes integrated sample processing and nucleic acid amplification to detect *C. auris* from surveillance skin swabs in the GeneXpert instrument and is designed for point-of-care use. The assay limit of detection (LoD) in the skin swab matrix was 10.5 and 14.8 CFU/mL for non-aggregative (AR0388) and aggregative (AR0382) strains of *C. auris*, respectively. All five known clades of *C. auris* were detected at 2-3-5× (31.5–52.5 CFU/mL) the LoD. The assay was validated using a total of 85 clinical swab samples banked at two different institutions (University of California Los Angeles, CA and Wadsworth Center, NY). Compared to culture, sensitivity was 96.8% (30/31) and 100% (10/10) in the UCLA and Wadsworth cohorts, respectively, providing a combined sensitivity of 97.5% (40/41), and compared to PCR, the combined sensitivity was 92% (46/50). Specificity was 100% with both clinical (*C. auris* negative matrix, $N = 31$) and analytical (non-*C. auris* strains, $N = 32$) samples. An additional blinded study with $N = 60$ samples from Wadsworth Center, NY yielded 97% (29/30) sensitivity and 100% (28/28) specificity. We have developed a completely integrated, sensitive, specific, and 58-min prototype test, which can be used for routine surveillance of *C. auris* and might help prevent colonization and outbreaks in acute and chronic healthcare settings.

**IMPORTANCE** This study has the potential to offer a better solution to healthcare providers at hospitals and long-term care facilities in their ongoing efforts for effective and timely control of *Candida auris* infection and hence quicker response for any potential future outbreaks.

**KEYWORDS** *Candida auris*, surveillance, skin swabs, GeneXpert, point of care, colonization, test, assay, specific test, simple test

The United States Centers for Disease Control and Prevention (CDC) has reported increasing incidences of invasive *Candida auris* infections in healthcare facilities in recent years (1, 2). Although *C. auris* is primarily a skin colonizer, this often multi-drug-resistant (MDR) fungal pathogen can cause bloodstream infections (3, 4) that lead to a crude mortality rate of 30%–40% (5, 6). Consequently, *C. auris* is the first fungal pathogen that the CDC has classified as an "urgent threat" (6–8). The World Health Organization declared antibiotic-resistant (AR) fungal pathogens as a major public health threat and has designated it in the "critical priority group" for public health and research (7–9). The COVID-19 pandemic has also been associated with a further surge in the number of *C. auris* cases in the United States (10) and worldwide (11–14), with clinical cases increasing from 478 (2019) to 2,377 cases in 2022 in the United States alone (1, 13, 15).

**Editor** Elitza S. Theel, Mayo Clinic Minnesota, Rochester, Minnesota, USA

Address correspondence to David Alland, allandda@njms.rutgers.edu, or Padmapriya Banada, banadapp@njms.rutgers.edu.

David Alland and Padmapriya Banada contributed equally to this article.

D.A. receives research support and royalty payments from Cepheid. B.O. and S.C. are employees of Cepheid. The other authors do not declare any competing interests.

See the funding table on p. 10.

**Received** 4 April 2024
**Accepted** 22 May 2024
**Published** 18 June 2024

There are five different clades of *C. auris*, which were originally classified based on their geographical distribution (4, 16–19): the South Asian clade (clade I), the East Asian clade (clade II), the South African clade (clade III), the South American clade (clade IV), and Iranian clade (clade V) (6, 16). However, *C. auris* clades are now reported on all continents except Antarctica (18, 20, 21). Clade I isolates have the highest reported rate of multi-drug resistance including isolates resistant to both azoles and amphotericin B (22) and pan-resistant isolates (23); Clade II isolates are often drug susceptible (24, 25), whereas Clade III isolates are most often resistant to azoles (24); Clade IV isolates carry the highest percentage of echinocandin resistance (24). Clades I, III, and IV isolates include the MDR strains most often associated with hospital infections and outbreaks (24, 26) and are the clades responsible for most cases of candidemia and associated mortality (19, 27). Strains belonging to Clades II (25) and V commonly cause ear infections and rarely cause bloodborne infections and outbreaks (22, 28). The majority of these clades include both aggregating and non-aggregating phenotypes (29, 30), which differ from each other in terms of resistance to disinfectants and antifungals, biofilm formation, host immune response evasion, and colonizing ability on biotic and abiotic surfaces (29–32).

Given the high potential of *C. auris* for colonization and nosocomial spread, a simple and rapid test to detect this pathogen on human and environmental surfaces could provide critical protection against *C. auris* outbreaks especially in Intensive Care Unit settings (33) and in long-term care facilities (34). Routine testing for *C. auris* could help guide proper treatment as well as the implementation of effective infection control practices (1, 2, 35). Indeed, PCR-based tests have become the preferred choice for identifying *C. auris* from clinical and surveillance samples by many laboratories (1, 36–43). Here, we present a highly specific, sensitive, and a <1 h test to enable the detection of *C. auris*.

## MATERIALS AND METHODS

### Sample matrix, media, and pathogens

All bacterial and fungal strains used in this study are listed in Table 1. Assay optimization and limit of detection (LoD) studies were performed with clade I *C. auris* strains AR0388 (non-aggregative) and AR0382 (aggregative). All strains were obtained from the CDC and Food and Drug Administration (FDA) Antimicrobial Resistance Isolate Bank, Atlanta, GA (CAU, 2022) and used for all analytical studies. Initial inoculum was prepared by culture in Sabouraud dextrose (SD) broth for 16–18 hours at 37°C in a shaker incubator. Tenfold serial dilutions were made in SD broth and plated on SD agar to enumerate CFU/mL.

PCR (BD Max System) confirmed *C. auris*-negative skin swab matrix (skin swabs collected in liquid Amies transport media) collected at the Department of Pathology and Laboratory Medicine, the University of California Los Angeles (UCLA), Los Angeles, CA, were used as a negative matrix in the analytical dynamic range and LoD experiments. The negative samples were banked at −20°C or −80°C and were aliquoted and shipped to our lab at Public Health Research Institute (PHRI), Rutgers New Jersey Medical School, Newark, NJ where they were stored at −20°C until further use.

### Cartridge-based real-time PCR assay

The assay was optimized in a GeneXpert filter-based cartridge system (44–46) controlled by a GeneXpert instrument. It is a real-time molecular beacon-based PCR assay targeting the *ITS2* gene of *C. auris* (proprietary). An internal control (IC) assay (proprietary) was also included in the cartridge, serving as a positive control for both sample processing and PCR amplification. After optimization of the reagents and the sample preparation, robotically built, reagent -filled, ready-to-use filter-based cartridges for *C. auris* surveillance assay (CaurisSurV cartridge) were made by Cepheid for this study. All the experiments presented in this manuscript were performed using CaurisSurV cartridges.

**TABLE 1** Microbial strains[a]

| | | Microorganism | Strain no. | Source | Clade | CaurisSurV test result |
|---|---|---|---|---|---|---|
| Inclusivity panel | | *C. auris* | AR 0381 | CDC-FDA AR | II | + |
| | | | AR 0383 | CDC-FDA AR | III | + |
| | | | AR 0384 | CDC-FDA AR | III | + |
| | | | AR 0385 | CDC-FDA AR | IV | + |
| | | | AR 0386 | CDC-FDA AR | IV | + |
| | | | AR 0387 | CDC-FDA AR | I | + |
| | | | AR 0389 | CDC-FDA AR | I | + |
| | | | AR 0390 | CDC-FDA AR | I | + |
| | | | AR 0931 | CDC-FDA AR | IV | + |
| | | | AR 1097 | CDC-FDA AR | V | + |
| | | | AR 1099 | CDC-FDA AR | NK | + |
| | | | AR 1100 | CDC-FDA AR | NK | + |
| | | | AR 1101 | CDC-FDA AR | II | + |
| | | | AR 1102 | CDC-FDA AR | III | + |
| | | | AR 1103 | CDC-FDA AR | III | + |
| | | | AR 1104 | CDC-FDA AR | IV | + |
| | | | AR 1105 | CDC-FDA AR | NK | + |
| Exclusivity panel | Non-auris Yeast and other fungi | *Candida duobushaemulonii* | AR 0391 | CDC-FDA AR | | – |
| | | | AR 0392 | CDC-FDA AR | | – |
| | | | AR 0394 | CDC-FDA AR | | – |
| | | *Candida haemulonii* | AR 0393 | CDC-FDA AR | | – |
| | | | AR 0395 | CDC-FDA AR | | – |
| | | | AR 0932 | CDC-FDA AR | | – |
| | | *Candida lusitaniae* | AR 0398 | CDC-FDA AR | | – |
| | | *Candida albicans* | 470547 | ATCC | | – |
| | | *Candida tropicalis* | 66029 | ATCC | | – |
| | | | CAB54-6763-3, HM-1124 | BEI | | – |
| | | *Candida parapsilosis* | 22019 | ATCC | | – |
| | | *Candida glabrata* | 15126 | ATCC | | – |
| | | *Candida krusei* | 6258 | ATCC | | – |
| | | | AR 0397 | CDC-FDA AR | | – |
| | | *Kodameae ohmeri* | AR 0396 | CDC-FDA AR | | – |
| | | *Cryptococcus neoformans* | China Isolate 5, NR-41295 | BEI | | – |
| | | | NIH398, NR-50333 | BEI | | – |
| | | *Cryptococcus gattii* | CBS1930, NR-50185 | BEI | | – |
| | | | MIC64-C1, NR-50421 | BEI | | – |
| | | *Saccharomyces cerevisiae* | AR 0399 | CDC-FDA AR | | – |
| | | | AR 0400 | CDC-FDA AR | | – |
| | | *Aspergillus fumigatus* | B6081, NR-50386 | BEI | | – |
| | Gram-positive bacteria | *Staphylococcus aureus* | Clinical isolate | UH | | – |
| | | *Staphylococcus epidermidis* | SK135, HM-118 | BEI | | – |
| | | *Streptococcus pyogenes* | ABC020063118, NR-48702 | BEI | | – |
| | | *Corynebacterium amycolatum* | SK46, HM-109 | BEI | | – |
| | | *Enterococcus faecium* | TX1330, HM-204 | BEI | | – |
| | | *Propionibacterium acnes* | HL030PA2, HM-505 | BEI | | – |
| | | | HL005PA1, | BEI | | – |

(*Continued on next page*)

**TABLE 1** Microbial strains[a] (*Continued*)

| | Microorganism | Strain no. | Source | Clade | CaurisSurV test result |
|---|---|---|---|---|---|
| | | HM-519 | | | |
| | *Proteus mirabilis* | WGLW4, HM-752 | BEI | | – |
| Gram-negative bacteria | *Klebsiella oxytoca* | MIT 10–5244, HM-625 | BEI | | – |
| | *Pseudomonas aeruginosa* | Shr42, NR-48982 | BEI | | – |

[a]NK, not known; UH, University Hospital; CDC-FDA-AR, The United States Center for Disease Control and FDA Antimicrobial Resistance Bank; ATCC, American Type Culture Collection; BEI, BEI resources.

## Sample processing

We developed a simple point-of-care applicable method that involves a single manual step of adding the sample to the CaurisSurV cartridge, producing results within an hour (Fig. 1). The cartridge-based system in the GeneXpert instruments offers the advantage of completely automating the assay after the sample is added as described earlier (44–48). We tested the performance of CaurisSurV cartridge by spiking *C. auris* at various concentrations into Amies transport medium (Thomas Scientific, Swedesboro, NJ) and/or *C. auris* negative skin swab matrix. Five hundred microliters of this spiked sample was then added to the CaurisSurV cartridges and loaded into the GeneXpert system (Fig. 1). During automated processing in the CaurisSurV cartridge, the programmed microfluidic movements resuspended the internal control assay target with 200 µL of 50 mM Tris–0.1 mM EDTA (0.1 mM)–0.1% Tween (TET) buffer (pH 8) which was then added to the sample matrix. The sample was then mixed with 1.5 mL of TET buffer and passed through the internal cartridge filter. The filter-captured fungal cells were extensively washed with both TET and guanidine hydrochloride buffers. Glass beads present in the filter were then agitated by an ultrasonic horn to lyse the captured fungal cells. Finally, approximately 80% of the total eluted DNA was moved into the PCR tube that is integrated into the assay cartridge for PCR amplification and detection. The test was considered positive when real-time cycles vs fluorescence units for the *C. auris*-specific molecular beacon reached a value above 20. The cycle threshold (Ct) was calculated by the GeneXpert software. A negative test required a positive internal control (IC) reaction. All negative tests with negative IC reactions were considered invalid.

## Analytical dynamic range and LoD

The dynamic range of the assay was evaluated in *C. auris*-negative skin swab matrix by spiking *C. auris* AR0388 (non-aggregative strain) at $10^7$ CFU/mL through 1 CFU/mL concentrations ($N$ = 4). Five hundred microliters of the spiked matrix was then added to the sample chamber of the CaurisSurV cartridge. The analytical sensitivity of the CaurisSurV cartridge was assessed using a representative strain of both the aggregative (AR0382) and non-aggregative (AR0388) phenotype of *C. auris*. The analytical LoD was

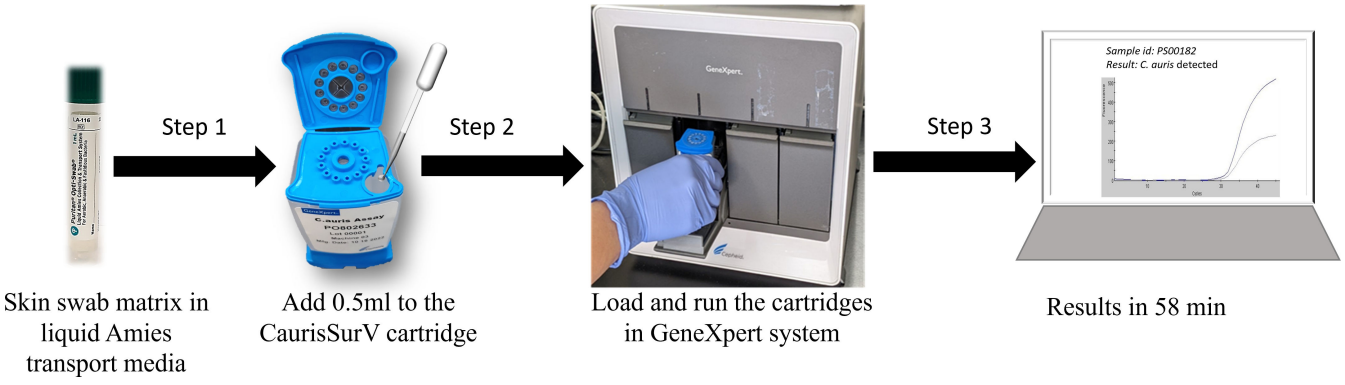


**FIG 1** A simple three-step sample to result in testing protocol.

determined by testing 10-fold serial dilutions of respective *C. auris* CFU spiked into PCR-negative skin swab matrix (Fig. 2). A total of 20 technical replicates were tested at each concentration including negatives. For this study, the LoD was defined as the lowest concentration of CFU at which 19/20 or 95% of the replicates tested were positive.

## Assay inclusivity and exclusivity

Assay inclusivity was carried out in Amies transport media at 3× (31.5 CFU/mL) or 5× (52.5 CFU/mL) the LOD (of AR0388) for 17 different strains of *C. auris* belonging to all five clades (Table 1 inclusivity). All these isolates were obtained from the CDC and FDA Antimicrobial Resistance (AR) Isolate Bank, Atlanta, GA (CAU 2022). The specificity of the CaurisSurV cartridge was determined by spiking $10^6$ to $10^8$ CFU/mL of different bacteria or non-*C. auris* yeast/fungal species or genomic DNA where quantified cells were not possible, into Amies transport media (Table 1 exclusivity). Test isolates included non-*C. auris* yeast species (*N* = 21), other related fungi (*N* = 1), representative gram-positive (*N* = 7), and gram-negative bacteria (*N* = 3).

## Clinical evaluation

A clinical evaluation was performed in two phases: (i) an initial validation phase and (ii) a blinded study where the tester was blinded to the sample PCR or culture results. For the initial validation study, a total of 85 PCR-confirmed *C. auris* positive and negative skin swab samples (Table S1) were collected from the sample banks of Dr. Garner, UCLA, Los Angeles, CA (*N* = 72) and Dr. Chaturvedi at Public Health Laboratory, Wadsworth Center, NY (*N* = 13). UCLA *C. auris* PCR-positive skin swab samples (*N* = 41) were initially identified using BD Max PCR using BioGx *C. auris* reagents (Cat. No.450–043), and 31 were further confirmed for *C. auris* and clade identity by culture (HardyCHROM Candida) and whole-genome sequencing (Illumina). *C. auris* positive samples (*N* = 10) from the Wadsworth Center, NY were identified both by BD Max using PCR established at Dr. Chaturvedi's lab (42) and culture using CHROMagar Candida plus agar media (49). At both sites, PCR-negative samples were not further confirmed by culture. Our primary analysis used culture positivity and culture negativity as reference for positive and negative standards, respectively. We also performed a secondary analysis against PCR positivity regardless of culture result as the reference positive standard and both culture and PCR positivity as the reference negative standard.

For the blinded study, 60 skin swab samples were coded and shipped to our lab at PHRI, Rutgers New Jersey Medical School, Newark, NJ from Wadsworth Center, NY (Table S2). The tester at the PHRI laboratory was blinded to the sample identification at the time

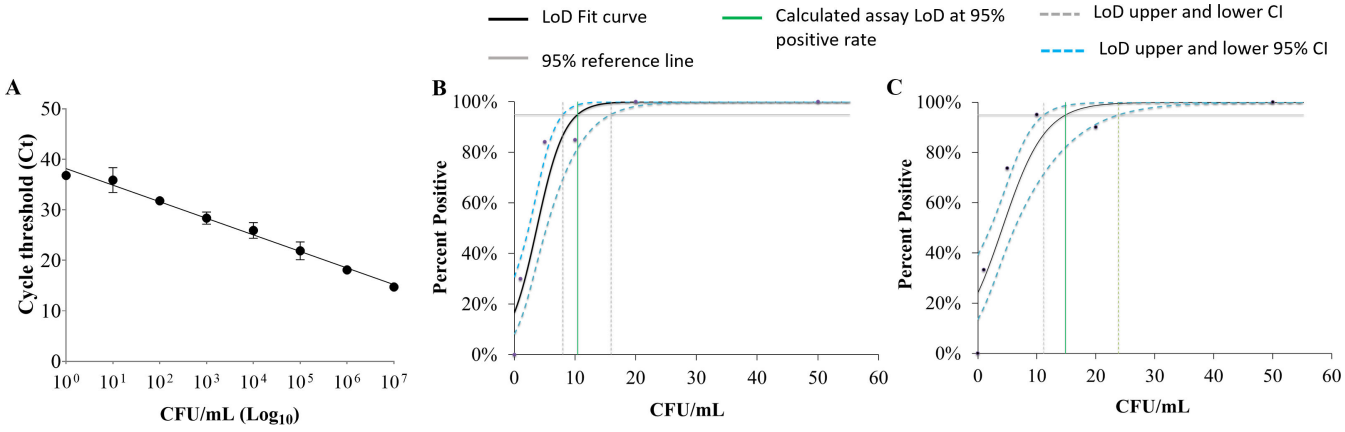


**FIG 2** *C. auris* surveillance assay cartridge (CaurisSurV cartridge) performance is demonstrated analytically showing wide dynamic range of *C. auris* spiked from 1 to $10^7$ CFU/mL in skin swab matrix (A, $R^2$ = 0.9911); LoD with non-aggregative strain (AR0388, B) and an aggregative strain (AR0382, C) of *C. auris* spiked in clinical skin swab matrix.

of testing. Once the testing was completed for all 60 samples, the resulting output from the CaurisSurV cartridge was matched with the answer key.

For the UCLA samples, a final volume of 0.5 mL of the skin swab matrix was added to the sample chamber of the CaurisSurV cartridge and then loaded into the GeneXpert instrument. Only 0.25 mL of the matrix was available for the Wadsworth samples which were supplemented with liquid Amies transport media to make the final test volume up to 0.5 mL and then tested in CaurisSurV cartridges. All samples used for the clinical evaluation study were aliquoted and kept frozen (−80°C/−20°C) or refrigerated (4°C) for different lengths of time (Tables S1 and S2), before shipping to Rutgers and were tested at the PHRI laboratory within a week of receiving the samples.

### Statistical analysis

Standard statistical analyses (average, SD, and correlation) and graphing were performed using Microsoft Excel (ver 2102) and GraphPad Prism 8.4.3 for Windows. Pearson's and Spearman's correlation coefficient $r$ and $R^2$ (coefficient of determination and square of the regression line) values were interpreted based on the literature (50), where $r$ value of >0.7 indicates a strong to very strong correlation.

## RESULTS

### Dynamic range and analytical LoD

*C. auris* surveillance assay dynamic range was tested to determine its logarithmic range of detection and linearity as measured by Ct vs target concentration. *C. auris* AR0388 was spiked at 1 to $10^7$ CFU/mL in the skin swab matrix and tested in the CaurisSurV cartridge. As shown in Fig. 2A, the assay demonstrated an excellent dynamic range in the skin swab matrix as well as linearity across this range ($R^2$ = 0.9911). The CaurisSurV cartridge LoD was then evaluated by spiking *C. auris* AR0388 (non-aggregative strain) or AR0382 (aggregative strain) in skin swab matrix at 1, 5, 10, 20, and 50 CFU/mL (e.g., 0.5, 2.5, 5, 10, and 25 CFU/test) and then tested in replicates of 20. In this study, the LoD was defined as the CFU/mL concentration that was positive at a 95% rate. Microsoft Excel-based probit analysis determined the assay LoD to be 10.5 CFU/mL (Ct = 34.8) for the non-aggregative strain AR0388 (Fig. 2B) and 14.8 CFU/mL (Ct ~ 34) for the aggregative strain AR0382 (Fig. 2C) of *C. auris*.

### Inclusivity and exclusivity

The assay inclusivity was tested on 17 different strains of *C. auris* belonging to all five clades reported until now (Table 1). All tests were performed in Amies transport medium at 3× (31.5 CFU/mL) or 5× (52.5 CFU/mL) the LOD of *C. auris* AR0388. The assay detected *C. auris* in all samples tested regardless of their clades yielding an analytic assay inclusivity of 100%. The assay exclusivity (specificity) was evaluated by testing $10^6$ to $10^8$ CFU/mL of different bacteria and non-*C. auris* yeast/fungal species spiked into Amies transport medium (Table 1). The assay did not detect any of the non-target pathogens tested, indicating an analytic specificity of 100%.

### Clinical evaluation

The initial clinical sample validation was performed using banked skin swab specimens stored at the UCLA ($N$ = 72) and Wadsworth ($N$ = 13) laboratories. As summarized in Fig. 3, out of 41 BDMAX PCR-positive samples identified at the UCLA lab, 31 were both PCR and culture positive, and 10 were positive by PCR but negative by culture. The remaining 31 out of 72 samples were PCR negative (which were not culture confirmed). The Wadsworth Center provided 10 PCR and culture-positive samples and 3 PCR-negative samples (which were not culture confirmed) for validation (Fig. 3). All samples were tested with the CaurisSurV cartridge. Considering culture as the positive reference standard (Table 2), we detected 30/31 (96.8%) of the positive samples from the UCLA site and 10/10 (100%) of the Wadsworth samples, for a combined sensitivity of 97.5%.

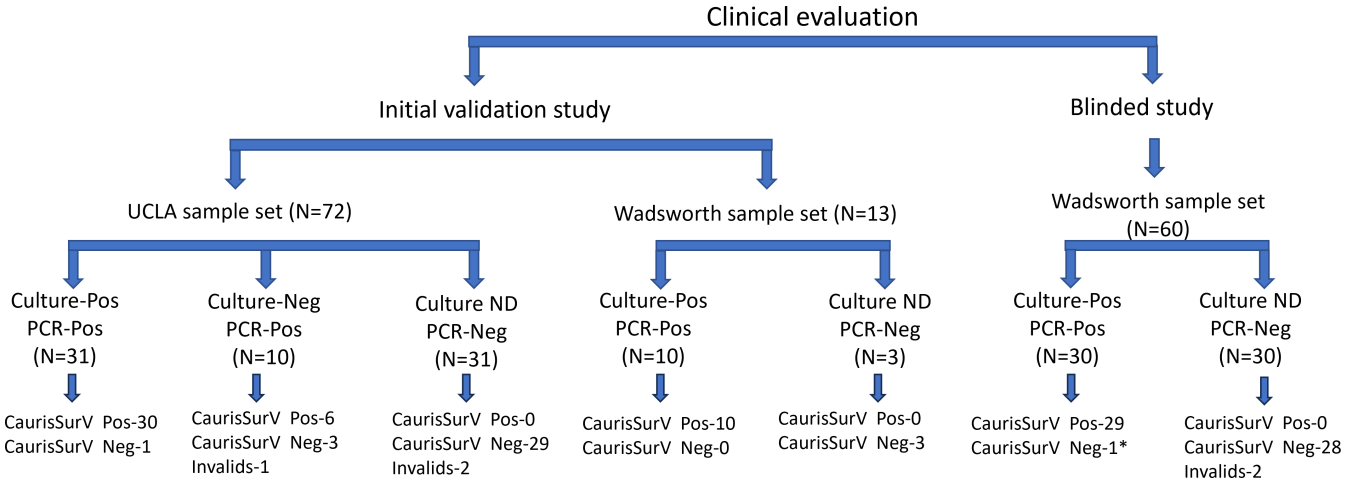


**FIG 3** Flow chart of the clinical evaluation study performed with *C. auris* surveillance assay cartridge (CaurisSurV cartridge).

Considering PCR-negative samples as the negative reference standard, we confirmed 32/32 samples as negative for a combined specificity of 100% and two invalids. In a secondary analysis, we considered PCR positivity as the secondary positive reference standard regardless of the culture results. Using this analysis, we determined a combined sensitivity of 92% (46/50) from both sites. Of the 10 culture-negative PCR-positive samples from UCLA, we detected six as *C. auris*, three as *C. auris* negative, with one invalid sample. A total of three invalid results due to failure of the internal control were seen out of 85 samples (3.5%), which could not be repeated due to lack of sample volume. Although PCR testing at the sites and CaurisSurV testing were not concurrently done, a correlation plot of the Ct values from our CaurisSurV cartridge to the respective PCR Ct values from both sites showed a correlation of $r = 0.86/R^2 = 0.74$ for UCLA (Fig. S1A) and $R^2 = 0.98$ (Fig. S1B) $r = 0.99$/for Wadsworth validation sample sets.

In the blinded study, out of 60 samples, 29 tested positive, 29 negative, and 2 were invalid. Referencing against the PCR and culture positivity key from Wadsworth Center, CaurisSurV cartridge had correctly identified 29/30 (96.6%) positives and 28/28 (100%) negatives (Table 3). Although the tests were not concurrently done at both sites, we evaluated the Ct correlation between the BDMax PCR performed at Wadsworth Center vs CaurisSurV cartridge (Fig. S1C) and found a Pearson's correlation coefficient $r = 0.94/R^2 = 0.89$, indicating strong correlation (50). The sample WW19, the CaurisSurV cartridge missed detecting, was further investigated and found to have BDMax PCR Ct value of 31.4. This pauci fungal nature of the sample might have resulted in aliquot-to-aliquot variation resulting in CFU quantities below the LoD in the aliquot tested in the

**TABLE 2** *C. auris* surveillance assay cartridge (CaurisSurV cartridge) performance against the sample sets from two different sites[e]

| | | Culture positives PCR[a] positives | | Culture negatives PCR positives | | Combined PCR Positives[b] | PCR negatives[c] | |
|---|---|---|---|---|---|---|---|---|
| | | UCLA (*N* = 31) | WW (*N* = 10) | UCLA (*N* = 10) | WW | UCLA + WW (*N* = 51) | UCLA (*N* = 31) | WW (*N* = 3) |
| CaurisSurV Cartridge | Positives | 30 | 10 | 6 | 0 | 46 | 0 | 0 |
| | Negatives | 1 | 0 | 3 | 0 | 4 | 29 | 3 |
| | Invalids[d] | 0 | 0 | 1 | 0 | 1 | 2 | 0 |
| | Sensitivity (%) | 96.8 | 100.0 | 66.7 | NA | | NA | |
| | Combined sensitivity (%) | 97.5 | | | | 92 | | |
| | Specificity (%) | | | | | | 100.0 | 100.0 |

[a]BDMax PCR assay.
[b]Irrespective of culture positivity.
[c]Culture not done.
[d]Invalids were excluded from sensitivity/specificity calculations.
[e]WW, Wadsworth Center, NY; NA, not applicable.

**TABLE 3** *C. auris* surveillance assay cartridge (CaurisSurV cartridge) performance against the skin swab sample set (*N* = 60) from Wadsworth Center, NY in a blinded study

| | | Culture positives PCR[a] positives | PCR negatives[b] |
|---|---|---|---|
| CaurisSurV Cartridge | Positives | 29 | 0 |
| | Negatives | 1 | 28 |
| | Invalids[c] | 0 | 2 |
| | Sensitivity (%) | 96.6 | |
| | Specificity (%) | 100.0 | |

[a]BDMax PCR assay.
[b]Culture not done.
[c]Invalids were excluded from sensitivity and specificity calculations.

CaurisSurV cartridge. Therefore, we obtained the culture isolate from this sample (WW19) and tested in the CaurisSurV cartridge, which correctly identified the isolate further asserting our reasoning of Poisson distribution.

As shown in Table S1, the UCLA *C. auris* positive sample set (*N* = 41) had been in storage at −20°C or −80°C from 6 to 66 weeks (Av 147.5 ± 121.4 days). The Wadsworth validation sample set (*N* = 10) was stored in refrigerated condition (2°C–8°C) for <8 weeks.

## DISCUSSION

The CaurisSurV prototype cartridge is a completely integrated sample processing-DNA extraction-PCR approach that detects *C. auris* from skin swabs within 1 h (Fig. 1). Users are only required to add 0.5 mL of the sample to the cartridge and load the cartridge into the GeneXpert instrument for *C. auris* testing. Results are produced in less than an hour. The test is recommended to be used for composite skin swab samples (bilateral axilla, groin) collected in Amies transport media as per CDC recommendations (https://www.cdc.gov/candida-auris/hcp/screening-hcp/?CDC_AAref_Val=https://www.cdc.gov/fungal/candida-auris/c-auris-screening.html). To the best of our knowledge, there are no commercially available point of care capable PCR-based tests for *C. auris* surveillance testing similar to CaurisSurV test. However, the CDC and other public health laboratories use fully automated PCR-based tests such as the T2Cauris test that runs on the T2Dx instrument (51) and the partially automated BDMax PCR-based test, for detection of *C. auris* from patient skin samples (41, 52). The CDC also recommends a lab-designed traditional PCR test for use in ABI 7500 platform (https://www.cdc.gov/candida-auris/hcp/laboratories/real-time-pcr-identification.html). However, these assays are not rapid, include many manual steps and are not suitable for point of care or near patient testing which this assay is expected to offer.

The CaurisSurV cartridge demonstrated an analytical LoD of 10.5–14.8 CFU/mL for both non-aggregative and aggregative strains of clade 1 *C. auris* and confirmatory tests of the four other *C. auris* clades at 3×–5× this LOD were positive, confirming a high sensitivity for all *C. auris* clades. Although this test can detect all five clades of *C. auris*, it does not cross-react with other closely related *Candida* species or any other fungal or bacterial pathogens, demonstrating high specificity for *C. auris*. Further validation of the CaurisSurV cartridge assay performed using banked specimens showed the test to be highly sensitive (97%) and 100% specific compared to the culture as primary reference standard. Our test missed detecting four PCR-positive samples from the UCLA laboratory. Three of these four samples were culture negative indicating a low pathogen load (BDMax PCR Ct values of 33.7, 34.8, 33.8, and 27.8). This low load could have resulted in CFU levels below the assay LoD in the aliquots we received. We analyzed these four samples on their length, temperature of storage, and comparison to Ct values from the BD max PCR assay (Table S1), noting that these samples had all been stored frozen for long periods (70–461 days) without any cryo-preservatives before testing in CaurisSurV cartridges. It should also be noted that the samples were not concurrently tested in both systems and were freeze thawed at least two times before testing in CaurisSurV cartridge. Other than aliquot variation and long-term storage effect on sample stability, we could

not conclusively establish a reason for the CaurisSurV-negative PCR, for these culture negatives samples. The blinded study further confirmed the assay sensitivity of 96.6% (29/30) and specificity of 100% (28/28). The single sample that was missed had a Ct value of 31.4 by BDMax PCR, but a culture isolate from this sample tested in CaurisSurV cartridge was positive. Due to similar reasons as explained above, this could be likely due to aliquot-to-aliquot variation or reduced sample stability in this stored (4°C–8°C for 4–8 weeks) sample containing a very low CFU titer (Table S2). Overall, our assay had a low invalid rate at 3.4% (5/145) as indicated by the failed internal control, which was likely caused either by the presence of PCR inhibitors, the absence of PCR reagents in the cartridge, or other in-cartridge assay errors. We could not repeat these samples due to low available sample volume. Future work will focus on improving the assay to be more sensitive and resilient to the inhibitors and other assay errors thereby reducing the invalid rate.

In summary, we have developed a completely integrated, rapid, low-complexity *C. auris* surveillance assay that is highly sensitive and specific. This assay offers a better solution to healthcare providers at hospitals and long-term care facilities in their ongoing efforts for effective and timely control of *C. auris* infection and hence quicker response for any potential future outbreaks.

## ACKNOWLEDGMENTS

This study was funded by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health (NIH) under award number R01 AI148437.

We thank Dr. Milena Kordalewska and Dr. David Perlin, Center for Discovery and Innovation at Hackensack Meridian Health, NJ, for donating *C. auris* strains for our initial assay optimization. We thank Raquel Green for her help at the initial phases of this project and Darshini Shah from Pathology and Laboratory Medicine, University Hospital, for donating the Candida ATCC quality control (QC) strains (ATCC 470547, ATCC 66029, ATCC 22019, ATCC 15126, and ATCC 6258). We thank Dr. Omai Garner and Dr. Shangxin Yang, Department of Pathology and Laboratory Medicine, the University of California Los Angeles, Los Angeles, CA (UCLA), for their support in obtaining the clinical samples.

The following reagents were obtained through BEI Resources, NIAID, NIH: *Cryptococcus neoformans*, Isolate 5, NR-41295; *Cryptococcus neoformans*, Strain NIH398, NR-50333; Genomic DNA from *Aspergillus fumigatus*, Strain B6081, NR 50386; *Streptococcus pyogenes*, Strain ABC020063118, NR-4870; *Pseudomonas aeruginosa*, Strain Shr42, NR-48982. The following reagent was obtained through BEI Resources, NIAID, NIH as part of the Human Microbiome Project: *Candida tropicalis*, Strain CAB54-6763-3, HM-1124; *Cryptococcus gattii*, Strain CBS1930, NR-50185; *Cryptococcus gattii*, Strain MIC64-C1, NR-50421; *Staphylococcus epidermidis*, Strain SK135, HM-118; *Corynebacterium amycolatum*, Strain SK46, HM-109; *Enterococcus faecium*, Strain TX1330, HM-204; *Propionibacterium acnes*, Strain HL030PA2, HM-505; *Propionibacterium acnes*, Strain HL050PA1, HM-519; *Proteus mirabilis*, Strain WGLW4, HM-752; *Klebsiella oxytoca*, Strain MIT 10-5244, HM-625.

S.B.: Optimized the assay, designed and executed the experiments, and wrote the manuscript. B.O.: executed the ROBAL cartridge build. M.T.: UCLA samples and data collection. C.K.: executed LoD experiments. C.S.: UCLA samples and data collection. SuCh: UCLA team lead, executed sample, and data collection. Y.Z.: Wadsworth samples and data collection. SuC: Wadsworth team lead, sample, and data collection. L.V.: managed the Cepheid project program and finances, contributed as a Cepheid liaison between the collaborating groups. S.C.: Co-Investigator, Cepheid lead, contributed to experimental design and data interpretation, helped in optimizing assay definition file, and executed the ROBAL cartridge build. D.A.: PI, Rutgers lead, conceived and directed the study, and wrote and edited the manuscript. P.B.: conceived the study, designed the primers and probes, designed the experiments, and wrote the manuscript

## AUTHOR AFFILIATIONS

[1]Center for Emerging Pathogens, Department of Medicine, Public Health Research Institute, Rutgers New Jersey Medical School, Newark, New Jersey, USA
[2]Research and Development, Cepheid, Sunnyvale, California, USA
[3]UCLA DGSOM Pathology & Lab Medicine, UCLA, Los Angeles, California, USA
[4]Mycology laboratory, Wadsworth Center, Albany, New York, USA

## AUTHOR ORCIDs

Sukantha Chandrasekaran https://orcid.org/0000-0002-6232-5535
Sudha Chaturvedi https://orcid.org/0000-0003-0906-8426
David Alland http://orcid.org/0000-0001-5196-1571
Padmapriya Banada http://orcid.org/0000-0002-5217-6142

## FUNDING


| Funder | Grant(s) | Author(s) |
|---|---|---|
| HHS \| NIH \| National Institute of Allergy and Infectious Diseases (NIAID) | R01 AI148437 | Sukalyani Banik<br>David Alland<br>Padmapriya Banada |


## ETHICS APPROVAL

The study was approved by the Rutgers-Newark Institutional Review Board (IRB) under protocol number Pro20170000818.

## ADDITIONAL FILES

The following material is available online.

### Supplemental Material

**Supplemental material (JCM00525-24-s0001.docx).** Fig. S1; Tables S1 and S2.

## REFERENCES

1. LymanM, ForsbergK, SextonDJ, ChowNA, LockhartSR, JacksonBR, Chiller T. 2023. Worsening spread of *Candida auris* in the United States. Ann Intern Med 176:489–495. https://doi.org/10.7326/M22-3469
2. CDC. 2023. Increasing threat of spread of antimicrobial-resistant fungus in healthcare facilities
3. Lee WG, Shin JH, Uh Y, Kang MG, Kim SH, Park KH, Jang HC. 2011. First three reported cases of nosocomial fungemia caused by *Candida auris*. J Clin Microbiol 49:3139–3142. https://doi.org/10.1128/JCM.00319-11
4. Chow NA, Muñoz JF, Gade L, Berkow EL, Li X, Welsh RM, Forsberg K, Lockhart SR, Adam R, Alanio A, Alastruey-Izquierdo A, Althawadi S, Araúz AB, Ben-Ami R, Bharat A, Calvo B, Desnos-Ollivier M, Escandón P, Gardam D, Gunturu R, Heath CH, Kurzai O, Martin R, Litvintseva AP, Cuomo CA. 2020. Tracing the evolutionary history and global expansion of *Candida auris* using population genomic analyses. mBio 11:03364–19. https://doi.org/10.1128/mBio.03364-19
5. Benedict K, Forsberg K, Gold JAW, Baggs J, Lyman M. 2023. *Candida auris*–associated hospitalizations, United States, 2017-2022. Emerg Infect Dis 29:1485–1487. https://doi.org/10.3201/eid2907.230540
6. Egger NB, Kainz K, Schulze A, Bauer MA, Madeo F, Carmona-Gutierrez D. 2022. The rise of *Candida auris*: from unique traits to co-infection potential. Microb Cell 9:141–144. https://doi.org/10.15698/mic2022.08.782
7. Sharma C, Kadosh D. 2023. Perspective on the origin, resistance, and spread of the emerging human fungal pathogen *Candida auris*. PLoS Pathog 19:e1011190. https://doi.org/10.1371/journal.ppat.1011190
8. Mishra SK, Yasir M, Willcox M. 2023. *Candida auris*: an emerging antimicrobial-resistant organism with the highest level of concern. Lancet Microbe 4:e482–e483. https://doi.org/10.1016/S2666-5247(23)00114-3
9. TEAM W. 2022. WHO fungal priority pathogens list to guide research, development and public health action.
10. Biran R, Cohen R, Finn T, Brosh-Nissimov T, Rahav G, Yahav D, Amit S, Shachor-Meyouhas Y, Atamna A, Bishara J, Ashkenazi-Hoffnung L, Ben Zvi H, Hershman-Sarafov M, Maayan S, Maor Y, Schwartz O, Zimhony O, Lellouche J, Elbaz M, Burdelova E, Mizrahi N, Novikov A, Henig O, Ben-Ami R. 2023. Nationwide outbreak of *Candida auris* infections driven by COVID-19 hospitalizations, Israel, 2021-2022. Emerg Infect Dis 29:1297–1301. https://doi.org/10.3201/eid2907.221888
11. Najeeb H, Siddiqui SA, Anas Z, Ali SH, Usmani SUR, Jawed F, Jatoi HN. 2022. The menace of *Candida auris* epidemic amidst the COVID-19 pandemic: a systematic review. Diseases 10:58. https://doi.org/10.3390/diseases10030058
12. Kohlenberg A, Monnet DL, Plachouras D, Candida auris survey collaborative group, Candida auris survey collaborative group includes the following national experts. 2022. Increasing number of cases and outbreaks caused by *Candida auris* in the EU/EEA, 2020 to 2021. Euro Surveill 27:2200846. https://doi.org/10.2807/1560-7917.ES.2022.27.46.2200846
13. Nelson R. 2023. Emergence of resistant *Candida auris*. Lancet Microbe 4:e396. https://doi.org/10.1016/S2666-5247(23)00143-X

14. Bing J, Du H, Guo P, Hu T, Xiao M, Lu S, Nobile CJ, Chu H, Huang G. 2024. *Candida auris*-associated hospitalizations and outbreaks, China, 2018-2023. Emerg Microbes Infect 13:2302843. https://doi.org/10.1080/22221751.2024.2302843
15. CDC. 2023. Tracking *Candida auris*. Available from: https://www.cdc.gov/fungal/candida-auris/tracking-c-auris.html
16. Chow NA, de Groot T, Badali H, Abastabar M, Chiller TM, Meis JF. 2019. Potential fifth clade of *Candida auris*, Iran, 2018. Emerg Infect Dis 25:1780–1781. https://doi.org/10.3201/eid2509.190686
17. Lockhart SR, Etienne KA, Vallabhaneni S, Farooqi J, Chowdhary A, Govender NP, Colombo AL, Calvo B, Cuomo CA, Desjardins CA, Berkow EL, Castanheira M, Magobo RE, Jabeen K, Asghar RJ, Meis JF, Jackson B, Chiller T, Litvintseva AP. 2017. Simultaneous emergence of multidrug-resistant *Candida auris* on 3 continents confirmed by whole-genome sequencing and epidemiological analyses. Clin Infect Dis 64:134–140. https://doi.org/10.1093/cid/ciw691
18. Chow NA, Gade L, Tsay SV, Forsberg K, Greenko JA, Southwick KL, Barrett PM, Kerins JL, Lockhart SR, Chiller TM, Litvintseva AP, US Candida auris Investigation Team. 2018. Multiple introductions and subsequent transmission of multidrug-resistant *Candida auris* in the USA: a molecular epidemiological survey. Lancet Infect Dis 18:1377–1384. https://doi.org/10.1016/S1473-3099(18)30597-8
19. Narayanan A, Selvakumar P, Siddharthan R, Sanyal K. 2022. ClaID: a rapid method of clade-level identification of the multidrug resistant human fungal pathogen *Candida auris*. Microbiol Spectr 10:e0063422. https://doi.org/10.1128/spectrum.00634-22
20. Massic L, Gorzalski A, Siao DD, Dykema P, Hua C, Schneider E, Van Hooser S, Pandori M, Hess D. 2023. Detection of five instances of dual-clade infections of *Candida auris* with opposite mating types in southern Nevada, USA. Lancet Infect Dis 23:e328–e329. https://doi.org/10.1016/S1473-3099(23)00434-6
21. Borman AM, Szekely A, Johnson EM. 2017. Isolates of the emerging pathogen *Candida auris* present in the UK have several geographic origins. Med Mycol 55:563–567. https://doi.org/10.1093/mmy/myw147
22. Rybak JM, Cuomo CA, Rogers PD. 2022. The molecular and genetic basis of antifungal resistance in the emerging fungal pathogen *Candida auris*. Curr Opin Microbiol 70:102208. https://doi.org/10.1016/j.mib.2022.102208
23. Jacobs SE, Jacobs JL, Dennis EK, Taimur S, Rana M, Patel D, Gitman M, Patel G, Schaefer S, Iyer K, Moon J, Adams V, Lerner P, Walsh TJ, Zhu Y, Anower MR, Vaidya MM, Chaturvedi S, Chaturvedi V. 2022. *Candida auris* pan-drug-resistant to four classes of antifungal agents. Antimicrob Agents Chemother 66:e0005322. https://doi.org/10.1128/aac.00053-22
24. Muñoz JF, Welsh RM, Shea T, Batra D, Gade L, Howard D, Rowe LA, Meis JF, Litvintseva AP, Cuomo CA. 2021. Clade-specific chromosomal rearrangements and loss of subtelomeric adhesins in *Candida auris*. Genetics 218:iyab029. https://doi.org/10.1093/genetics/iyab029
25. Welsh RM, Sexton DJ, Forsberg K, Vallabhaneni S, Litvintseva A. 2019. Insights into the unique nature of the East Asian clade of the emerging pathogenic yeast *Candida auris*. J Clin Microbiol 57:00007–00019. https://doi.org/10.1128/JCM.00007-19
26. Govender NP, Magobo RE, Mpembe R, Mhlanga M, Matlapeng P, Corcoran C, Govind C, Lowman W, Senekal M, Thomas J. 2018. *Candida auris* in South Africa, 2012-2016. Emerg Infect Dis 24:2036–2040. https://doi.org/10.3201/eid2411.180368
27. Forgács L, Borman AM, Prépost E, Tóth Z, Kardos G, Kovács R, Szekely A, Nagy F, Kovacs I, Majoros L. 2020. Comparison of *in vivo* pathogenicity of four *Candida auris* clades in a neutropenic bloodstream infection murine model. Emerg Microbes Infect 9:1160–1169. https://doi.org/10.1080/22221751.2020.1771218
28. Safari F, Madani M, Badali H, Kargoshaie A-A, Fakhim H, Kheirollahi M, Meis JF, Mirhendi H. 2022. A chronic autochthonous fifth clade case of *Candida auris* otomycosis in Iran. Mycopathologia 187:121–127. https://doi.org/10.1007/s11046-021-00605-6
29. Ramos LS, Parra-Giraldo CM, Branquinha MH, Santos ALS. 2023. Cell aggregation capability of clinical isolates from *Candida auris* and *Candida haemulonii* species complex. TropicalMed 8:382. https://doi.org/10.3390/tropicalmed8080382
30. Santana DJ, Zhao G, O'Meara TR. 2024. The many faces of *Candida auris*: phenotypic and strain variation in an emerging pathogen. PLoS Pathog 20:e1012011. https://doi.org/10.1371/journal.ppat.1012011
31. Bing J, Guan Z, Zheng T, Zhang Z, Fan S, Ennis CL, Nobile CJ, Huang G. 2023. Clinical isolates of *Candida auris* with enhanced adherence and biofilm formation due to genomic amplification of ALS4. PLoS Pathog 19:e1011239. https://doi.org/10.1371/journal.ppat.1011239
32. Malavia-Jones D, Farrer RA, Stappers MHT, Edmondson MB, Borman AM, Johnson EM, Lipke PN, Gow NAR. 2023. Strain and temperature dependent aggregation of *Candida auris* is attenuated by inhibition of surface amyloid proteins. Cell Surf 10:100110. https://doi.org/10.1016/j.tcsw.2023.100110
33. Sokou R, Palioura AE, Kopanou Taliaka P, Konstantinidi A, Tsantes AG, Piovani D, Tsante KA, Gounari EA, Iliodromiti Z, Boutsikou T, Tsantes AE, Bonovas S, Iacovidou N. 2024. *Candida auris* infection, a rapidly emerging threat in the neonatal intensive care units: a systematic review. J Clin Med 13:1586. https://doi.org/10.3390/jcm13061586
34. Yune PS, Coe J, Rao M, Lin MY. 2023. *Candida auris* in skilled nursing facilities. Ther Adv Infect Dis 10:20499361231189958. https://doi.org/10.1177/20499361231189958
35. Wasylyshyn A, Stoneman EK. 2024. Management of *Candida auris*. JAMA 331:611–612. https://doi.org/10.1001/jama.2023.24921
36. Freitas BL, Leach L, Chaturvedi V, Chaturvedi S. 2022. Reverse transcription-quantitative real-time PCR (RT-qPCR) assay for the rapid enumeration of live *Candida auris* cells from the health care environment. J Clin Microbiol 60:e0077921. https://doi.org/10.1128/JCM.00779-21
37. Zhu Y, Hager KM, Manjari SR, Banavali NK, Chaturvedi V, Chaturvedi S. 2023. Development and validation of TaqMan chemistry probe-based rapid assay for the detection of Echinocandin-resistance in Candida Auris. J Clin Microbiol 61:e0176722. https://doi.org/10.1128/jcm.01767-22
38. Contreras DA, Morgan MA. 2022. Surveillance diagnostic algorithm using real-time PCR assay and strain typing method development to assist with the control of *C. auris* amid COVID-19 pandemic. Front Cell Infect Microbiol 12:887754. https://doi.org/10.3389/fcimb.2022.887754
39. Dennis EK, Chaturvedi S, Chaturvedi V. 2021. So many diagnostic tests, so little time: review and preview of *Candida auris* testing in clinical and public health laboratories. Front Microbiol 12:757835. https://doi.org/10.3389/fmicb.2021.757835
40. Keighley C, Garnham K, Harch SAJ, Robertson M, Chaw K, Teng JC, Chen S-A. 2021. *Candida auris*: diagnostic challenges and emerging opportunities for the clinical microbiology laboratory. Curr Fungal Infect Rep 15:116–126. https://doi.org/10.1007/s12281-021-00420-y
41. Leach L, Russell A, Zhu Y, Chaturvedi S, Chaturvedi V. 2019. A rapid and automated sample-to-result *Candida auris* real-time PCR assay for high-throughput testing of surveillance samples with the BD. J Clin Microbiol 57:e00630-19. https://doi.org/10.1128/JCM.00630-19
42. Leach L, Zhu Y, Chaturvedi S. 2018. Development and validation of a real-time PCR assay for rapid detection of *Candida auris* from surveillance samples. J Clin Microbiol 56:e01223-17. https://doi.org/10.1128/JCM.01223-17
43. Sexton DJ, Kordalewska M, Bentz ML, Welsh RM, Perlin DS, Litvintseva AP. 2018. Direct detection of emergent fungal pathogen *Candida auris* in clinical skin swabs by SYBR green-based quantitative PCR assay. J Clin Microbiol 56:e01337-18. https://doi.org/10.1128/JCM.01337-18
44. Banada PP, Deshpande S, Banik S, Shah D, Koshy R, Patel B, Kwiatkowski R, Persing D, Alland D. 2019. Multiplex detection of three select agents directly from blood by use of the GeneXpert system. J Clin Microbiol 57:e00036-19. https://doi.org/10.1128/JCM.00036-19
45. Banada PP, Deshpande S, Chakravorty S, Russo R, Occi J, Meister G, Jones KJ, Gelhaus CH, Valderas MW, Jones M, Connell N, Alland D. 2017. Sensitive detection of *Francisella tularensis* directly from whole blood by use of the GeneXpert system. J Clin Microbiol 55:291–301. https://doi.org/10.1128/JCM.01126-16
46. Banada PP, Deshpande S, Russo R, Singleton E, Shah D, Patel B, Burday M, Koshy R, Wang Q, Jones M, Gall A, Lokhov S, Kwiatkowski R, Persing D, Connell N, Alland D. 2017. Rapid detection of *Bacillus anthracis* bloodstream infections by use of a novel assay in the GeneXpert system. J Clin Microbiol 55:2964–2971. https://doi.org/10.1128/JCM.00466-17
47. Helb D, Jones M, Story E, Boehme C, Wallace E, Ho K, Kop J, Owens MR, Rodgers R, Banada P, Safi H, Blakemore R, Lan NTN, Jones-López EC, Levi M, Burday M, Ayakaka I, Mugerwa RD, McMillan B, Winn-Deen E, Christel L, Dailey P, Perkins MD, Persing DH, Alland D. 2010. Rapid detection of *Mycobacterium tuberculosis* and rifampin resistance by use of

on-demand, near-patient technology. J Clin Microbiol 48:229–237. https://doi.org/10.1128/JCM.01463-09
48. Chakravorty S, Simmons AM, Rowneki M, Parmar H, Cao Y, Ryan J, Banada PP, Deshpande S, Shenai S, Gall A, Glass J, Krieswirth B, Schumacher SG, Nabeta P, Tukvadze N, Rodrigues C, Skrahina A, Tagliani E, Cirillo DM, Davidow A, Denkinger CM, Persing D, Kwiatkowski R, Jones M, Alland D. 2017. The new Xpert MTB/RIF ultra: improving detection of *Mycobacterium tuberculosis* and resistance to rifampin in an assay suitable for point-of-care testing. mBio 8:e00812-17. https://doi.org/10.1128/mBio.00812-17
49. Marathe A, Zhu Y, Chaturvedi V, Chaturvedi S. 2022. Utility of CHROMagar Candida Plus for presumptive identification of *Candida auris* from surveillance samples. Mycopathologia 187:527–534. https://doi.org/10.1007/s11046-022-00656-3
50. Akoglu H. 2018. User's guide to correlation coefficients. Turk J Emerg Med 18:91–93. https://doi.org/10.1016/j.tjem.2018.08.001
51. Sexton DJ, Bentz ML, Welsh RM, Litvintseva AP. 2018. Evaluation of a new T2 magnetic resonance assay for rapid detection of emergent fungal pathogen *Candida auris* on clinical skin SWAB samples. Mycoses 61:786–790. https://doi.org/10.1111/myc.12817
52. Lima A, Widen R, Vestal G, Uy D, Silbert S. 2019. A TaqMan probe-based real-time PCR assay for the rapid identification of the emerging multidrug-resistant pathogen *Candida auris* on the BD max system. J Clin Microbiol 57:e01604-18. https://doi.org/10.1128/JCM.01604-18