

Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

**SPECIFICATIONS:** 

Product Name: Candida albicans

Catalog Number: 0443

Lot Number: 443-1613\*\*

Reference Number: ATCC® 10231™\*

Passage from Reference: 3

(7) Mean Assay Value (MAV): 48 CFU per 0.1 ml

Expiration Date: 2026/04/30

**RELEASE INFORMATION:** 

Quality Control Technologist: Tiffany A Lewandowski

Release Date: 2024/04/26

Method:

Performance

Macroscopic Features: Medium:

Small to medium, white, circular, convex, dull colonies. Nutrient

N/A

ID System: MALDI-TOF (1)

Microscopic Features:

See attached ID System results document.

Amanda Kuperus

Director of Quality Control AUTHORIZED SIGNATURE

\*\*Disclaimer: The last digit(s) of the lot number appearing on the product label and packing slip are merely a packaging event number. The lot number displayed on this certificate is the actual base lot number.

#### Refer to the enclosed product insert for instructions, intended use and hazard/safety information.

Individual products are traceable to a recognized culture collection.

(1) These tests are accredited to ISO/IEC 17025.



TESTING CERT #2655.01



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(7) The Mean Assay Value (MAV) stated above may deviate from the end-user's MAV based on variables inherent to each laboratory environment, such as methods, media type, equipment, pipettes, and individual technician technique.

## **Bruker Daltonik MALDI Biotyper Classification Results**



### **Meaning of Score Values**

Range	Interpretation	Symbols	Color
2.00 - 3.00	High-confidence identification	(+++)	Green
1.70 – 1.99	Low-confidence identification	(+)	Yellow
0.00 - 1.69	No Organism Identification Possible	(-)	Red

## **Meaning of Consistency Categories (A - C)**

Category	Interpretation
(A)	<b>High consistency:</b> The best match is a high-confidence identification. The second-best match is (1) a highconfidence identification in which the species is identical to the best match, (2) a low-confidence identification in which the species or genus is identical to the best match, or (3) a non-identification.
(B)	<b>Low consistency:</b> The requirements for high consistency are not met. The best match is a highor low-confidence identification. The second-best match is (1) a high- or low-confidence identification in which genus is identical to the best match or (2) a non-identification.
(C)	No consistency: The requirements for high or low consistency are not met.

Run Creation Date/Time: 2024-04-25T09:05:22.956 tal

Applied MSP Library(ies): BDAL, Mycobacteria Library (bead method), Filamentous Fungi Library

Sample Name	Sample ID	Organism (best match)	Score Value
D9 (+++) (A)	443-1613	Candida albicans	2.18

#### Comments:

n/a	
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# Statistical Analysis Certificate

Microorganism Name: Candida albicans

Reference #: ATCC® 10231™\*

Catalog #: 0443 Lot #: 443-1613\*\*

Expiration Date: 2026/04/30

(7) Mean Assay Value (MAV): 48 CFU per 0.1 ml

Standard Deviation: 5.2E+00 Coefficient of Variation: 11 %

99% Confidence Interval of 4.6E+01 to 5.0E+01 CFU 95% Confidence Interval of 4.6E+01 to 5.0E+01 CFU

Method used to determine Mean Assay Value: Spiral Plate Method

Medium Employed: TSA

Incubation Time and Temp: 48-72 hrs at 28-32 degrees C

Amanda Kuperus

Director of Quality Control
AUTHORIZED SIGNATURE

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