

Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

Specifications Microorganism Name: Candida albicans

Catalog Number: 0443 Lot Number: 443-1502**

Reference Number: ATCC® 10231™*

Passage from Reference: 3

(7) Mean Assay Value (MAV): 53 CFU per 0.1 ml

Expiration Date: 2025/2/28

Release Information:

Quality Control Technologist: Mariah H Smith

Release Date: 2023/3/27

Performance

Macroscopic Features: Medium:

Small to medium, white, circular, convex, dull colonies. Nutrient Method: Microscopic Features: Gram positive, ovoidal, budding yeast cells. Gram Stain (1)

ID System: MALDI-TOF (1)

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.

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

Individual products are traceable to a recognized culture collection.





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



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)	High consistency: The best match is a high-confidence identification. The second-best match is (1) a high-confidence 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)	Low consistency: The requirements for high consistency are not met. The best match is a high- or 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: 2023-03-27T11:37:43.796 MHS

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

Sample Name	Sample ID	Organism (best match)	Score Value
A3 (+++) (A)	443-1502	Candida albicans	2.32

Comments:

N/A		



Statistical Analysis Certificate

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Standard Deviation: 4.3E+00 Coefficient of Variation: 8 %

99% Confidence Interval of 5.2E+01 to 5.4E+01 CFU 95% Confidence Interval of 5.2E+01 to 5.4E+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

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