

Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

Specifications

Microorganism Name: Candida albicans

Catalog Number: 0443

Lot Number: 443-630 Reference Number: ATCC® 10231™*

Purity: > 99.9% of Total Pellet CFU Mean Assay Value: 5.3E+07 CFU per pellet

Passage from Reference: 3

Expiration Date: 2018/7/31

Release Information:

Quality Control Technologist: Tanner E Rothstein

Release Date: 2016/10/3

Performance

Macroscopic Features:

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

Microscopic Features:

Gram positive, ovoidal, budding yeast cells.

Medium:

Nutrient Method:

Gram Stain (1)

ID System: MALDI-TOF

See attached ID System results document.

Other Features/ Challenges: Results

- (1) Germ Tube Test: positive
- (1) Chlamydospore production: positive

Brad Goskowicz, President **AUTHORIZED SIGNATURE**

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

Note for Vitek®: Although the Vitek® panel uses many conventional tests, the unique environment of the card, combined with the short incubation period, may produce results that differ from published results obtained by other methods.

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 17025:2005.



TESTING CERT #2655.01

Bruker Daltonik MALDI Biotyper Classification Results



Meaning of Score Values

Range	Description	Symbols	Color
2.300 3.000	highly probable species identification		green
2.000 2.299	secure genus identification, probable species identification	(++)	green
1.700 1.999	probable genus identification	(+)	yellow
0.000 1.699	not reliable identification	(-)	red

Meaning of Consistency Categories (A - C)

Category	Description
Α	Species Consistency: The best match was classified as 'green' (see above). Further 'green' matches are of the
	same species as the first one. Further 'yellow' matches are at least of the same genus as the first one.
В	Genus Consistency: The best match was classified as 'green' or 'yellow' (see above). Further 'green' or 'yellow'
	matches have at least the same genus as the first one. The conditions of species consistency are not fulfilled.
С	No Consistency: Neither species nor genus consistency (Please check for synonyms of names or microbial
	mixture).

Analyte Name: Candida albicans

Analyte Description: 0443 Analyte ID: 443-630

Analyte Creation Date/Time: 2016-09-28T08:46:04.565 TR

Applied MSP Library(ies): BDAL, Mycobacteria Library (bead method), Filamentous Fungi Library 1.0, IVD, Listeria

Applied Taxonomy Tree:

Analyte Name	Analyte ID	Organism (best match)	Score Value
(++)(B)	443-630	Candida albicans	2.112

Comments:

N/A		
		1