



Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

Specifications

Microorganism Name: Clostridium difficile

Catalog Number: 0527

Lot Number: 527-29

Reference Number: ATCC® 700057™*

Purity: Pure

Passage from Reference: 3

Expiration Date: 2019/5/31

Release Information:

Quality Control Technologist: Mary L Bowman

Release Date: 2017/6/29

Performance

Macroscopic Features:

Small to large, irregular, raised, erose edge with occasional rhizoid protrusions, gray, rough.

Microscopic Features:

Long gram positive straight rods with rounded ends.

Medium:

A/R SBAP

Method:

Gram Stain (1)

ID System: MALDI-TOF

See attached ID System results document.

Amanda Kuperus

Quality Control Manager

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.

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.

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

Individual products are traceable to a recognized culture collection.



(*) The ATCC Licensed Derivative Emblem, the ATCC Licensed Derivative word mark and the ATCC catalog marks are trademarks of ATCC. Microbiologics, Inc. is licensed to use these trademarks and to sell products derived from ATCC® cultures.



(1) These tests are accredited to ISO/IEC 17025:2005.

TESTING CERT #2655.01



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 the 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.

Sample Name: Clostridium difficile
 Sample Description: 0527
 Sample ID: 527-29
 Sample Creation Date/Time: 2017-06-21T12:36:51.833 MB
 Applied MSP Library(ies): BDAL, Mycobacteria Library (bead method), Filamentous Fungi Library 1.0, Listeria

Sample Name	Sample ID	Organism (best match)	Score Value
H9 (+++)(A)	527-29	Clostridium difficile	2.32

Comments:

N/A