

Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

Specifications

Microorganism Name: Clostridium sporogenes

Catalog Number: 0487 Lot Number: 487-338**

Reference Number: ATCC® 11437TM*

Purity: Pure

Passage from Reference: 3

(7) Mean Assay Value (MAV): 41 CFU per 0.1 ml

Expiration Date: 2019/9/30

Release Information:

Quality Control Technologist: Megan B Stein

Release Date: 2017/10/16

Performance

Macroscopic Features:

Medium:

Large, irregularly circular, with coarse rhizoid edge, have a raised yellowish- A/R SBAP gray center and flattened periphery, beta hemolytic, adheres to agar.

Microscopic Features:

Method:

Gram positive straight rods. Spores, when seen, are oval, central or Gram Stain (1) subterminal and distend the cell slightly.

ID System: MALDI-TOF

See attached ID System results document.

Other Features/ Challenges: Results

Egg yolk agar: lecithinase - negative Egg yolk agar: lipase - positive

> Amanda Kuperus Quality Control Manager **AUTHORIZED SIGNATURE**

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.



ATCC Licensed

Derivative

- 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.

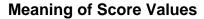


TESTING CERT #2655.01

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.

^{**}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.

Bruker Daltonik MALDI Biotyper Classification Results





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 sporogenes

Sample Description: 0487 Sample ID: 487-338

Sample Creation Date/Time: 2017-10-12T13:49:15.833 cs

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

Sample Name	Sample ID	Organism (best match)	Score Value	
C12 (+++) (A)	487-338	Clostridium sporogenes	2.27	

Comments:

Clostridium sporogenes is closely related and shows very similar spectra to the strains of the highly pathogenic Clostridium botulinum groups A, B and F. Clostridium botulinum is not included in the MALDI Biotyper database. For differentiation an adequate identification method has to be selected by an experienced professional.