Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

Specifications
Microorganism Name: Bacillus subtilis subsp. spizizenii
Catalog Number: 0486
Lot Number: 486-576
Reference Number: ATCC® 6633™*
Purity: Pure
Passage from Reference: 3
Mean Assay Value (MAV): 7.2E+06 CFU per pellet

Expiration Date: 2019/4/30
Release Information:
Quality Control Technologist: Caitlyn J Laudenbach
Release Date: 2017/5/18

Performance

Macroscopic Features:
Large, irregular, flat, undulate edge, gray and wrinkled with ground glass appearance; beta hemolysis and slight yellow coloring may appear in wrinkles by 48 hours.

Medium:
SBAP

Microscopic Features:
Straight, gram positive rod, with an ellipsoidal, central or terminal endospore.

Method:
Gram Stain (1)

ID System: MALDI-TOF
See attached ID System results document.

Other Features/ Challenges: Results
(1) Purple Broth w/Rhamnose: negative
(1) Purple broth w/Lactose: negative
MYP Agar: Growth of yellow, dry colonies without precipitate

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.

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.

ACCREDITED
TESTING CERT #2655.01

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

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 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: Bacillus subtilis subsp. spizizenii
Sample Description: 0486
Sample ID: 486-576
Sample Creation Date/Time: 2017-05-17T17:25:58.743 CL
Applied MSP Library(ies): BDAL, Mycobacteria Library (bead method), Filamentous Fungi Library 1.0, Listeria

Sample Name	Sample ID	Organism (best match)	Score Value
F12 (+++) (A)	486-576	Bacillus subtilis	2.03

Comments:

Is a member of Bacillus subtilis group. The quality of spectra (score) depends on the degree of sporulation: Use fresh material.

Statistical Analysis Certificate

Microorganism Name: Bacillus subtilis subsp. spizizenii
Reference #: ATCC® 6633™*
Catalog #: 0486
Lot #: 486-576
Expiration Date: 2019/4/30
Mean Assay Value (MAV): 7.2E+06 CFU per pellet
Standard Deviation: 1.2E+06
Coefficient of Variation: 17%
99% Confidence Interval of 6.6E+06 to 7.8E+06 CFU
95% Confidence Interval of 6.7E+06 to 7.7E+06 CFU

Method used to determine Mean Assay Value: Spiral Biotech Test Method
Medium Employed: TSA
Incubation Time and Temp: 24 hrs at 34-38 degrees C

Amanda Kuperus
Quality Control Manager
AUTHORIZED SIGNATURE

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. The information included in this Statistical Analysis Certificate is strictly based on the product's lot number. A product lot number may be assigned to multiple packaging configurations. As a result, this certificate only lists the lot number and does not include a product description.