



Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

Specifications Microorganism Name: Staphylococcus aureus subsp. aureus Catalog Number: 0485 Lot Number: 485-722** Reference Number: ATCC® 6538™* Purity: Pure Passage from Reference: 3 (7) Mean Assay Value (MAV): 70 CFU per 0.1 ml	Expiration Date: 2020/1/31 Release Information: Quality Control Technologist: Alexandra D Stensvad Release Date: 2018/8/2
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Performance	
Macroscopic Features: Medium to large, convex, circular, glistening, smooth, creamy, opaque, beta hemolytic - both light gold and darker gold colonies may be present. A second colony type maybe present a white, circular, entire, low convex, and beta hemolytic.	Medium: SBAP
Microscopic Features: Gram positive cocci occurring singly, in pairs and in irregular clusters.	Method: Gram Stain (1)
ID System: MALDI-TOF (1) See attached ID System results document.	Other Features/ Challenges: Results (1) Catalase (3% Hydrogen Peroxide): positive (1) Coagulase (rabbit plasma - tube): positive (1) Beta Lactamase (Cefinase Disk): negative  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.



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



(7) 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 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: Staphylococcus aureus subsp. aureus
 Sample Description: 0485
 Sample ID: 485-722
 Sample Creation Date/Time: 2018-07-31T13:16:36.028 JS
 Applied MSP Library(ies): BDAL, Mycobacteria Library (bead method), Filamentous Fungi Library 1.0, Listeria

Sample Name	Sample ID	Organism (best match)	Score Value
G4 (+++)(A)	485-722	Staphylococcus aureus	2.49

Comments:

n/a



Statistical Analysis Certificate

Microorganism Name: Staphylococcus aureus subsp. aureus

Reference #: ATCC® 6538™*

Catalog #: 0485

Lot #: 485-722**

Expiration Date: 2020/1/31

(7) Mean Assay Value (MAV): 70 CFU per 0.1 ml

Standard Deviation: 8.4E+00

Coefficient of Variation: 12%

99% Confidence Interval of 6.6E+01 to 7.3E+01 CFU

95% Confidence Interval of 6.7E+01 to 7.2E+01 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

A handwritten signature in black ink that reads "Amanda Kuperus".

Amanda Kuperus

Quality Control Manager

AUTHORIZED SIGNATURE

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