



Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

Specifications Microorganism Name: Staphylococcus aureus subsp. aureus Catalog Number: 0485 Lot Number: 485-1116** Reference Number: ATCC® 6538™** Passage from Reference: 3 (7) Mean Assay Value (MAV): 36 CFU per 0.1 ml	Expiration Date: 2024/5/31 Release Information: Quality Control Technologist: Kalina E Larsen Release Date: 2022/6/28
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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.


 Amanda Kuperus
 Director of Quality Control
 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.

⚠ 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.



(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 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.

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

Sample Name	Sample ID	Organism (best match)	Score Value
E12 (+++) (A)	485-1116	Staphylococcus aureus	2.37

Comments:

N/A



Statistical Analysis Certificate

Microorganism Name: *Staphylococcus aureus* subsp. *aureus*

Reference #: ATCC® 6538™*

Catalog #: 0485

Lot #: 485-1116**

Expiration Date: 2024/5/31

(7) Mean Assay Value (MAV): 36 CFU per 0.1 ml

Standard Deviation: 4.4E+00

Coefficient of Variation: 12%

99% Confidence Interval of 3.4E+01 to 3.8E+01 CFU

95% Confidence Interval of 3.5E+01 to 3.8E+01 CFU

Method used to determine Mean Assay Value: Spiral Plate 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

Director of Quality Control

AUTHORIZED SIGNATURE

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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.

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