

Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

**Specifications** 

Microorganism Name: Staphylococcus aureus subsp. aureus

Catalog Number: 0485 Lot Number: 485-1162\*\*

Reference Number: ATCC® 6538™\*

Passage from Reference: 3

(7) Mean Assay Value (MAV): 6.7E+03 CFU per pellet

Expiration Date: 2024/12/31

Release Information:

Quality Control Technologist: Ubah A Jama

Release Date: 2023/1/30

#### Performance

### **Macroscopic Features:**

Medium:

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. SBAP

Microscopic Features:

Method:

Gram Stain (1)

Gram positive cocci occurring singly, in pairs and in irregular clusters.

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.

A 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.



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.

## **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)	<b>High consistency:</b> 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)	<b>Low consistency:</b> 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.

Run Creation Date/Time: 2023-01-24T09:54:56.288 UAJ

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

Sample Name	Sample ID	Organism (best match)	Score Value
E11 (+++) (A)	485-1162	Staphylococcus aureus	2.23

### Comments:

N/A		



# Statistical Analysis Certificate

Microorganism Name: Staphylococcus aureus subsp. aureus

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(7) Mean Assay Value (MAV): 6.7E+03 CFU per pellet

Standard Deviation: 1.2E+03 Coefficient of Variation: 18%

99% Confidence Interval of 6.3E+03 to 7.0E+03 CFU 95% Confidence Interval of 6.4E+03 to 6.9E+03 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

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Director of Quality Control AUTHORIZED SIGNATURE

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