


Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

<p>SPECIFICATIONS:</p> <p>Product Name: Enterococcus faecalis</p> <p>Catalog Number: 0366</p> <p>Lot Number: 366-471**</p> <p>Reference Number: ATCC® 29212™*</p> <p>Passage from Reference: 3</p> <p>(7) Mean Assay Value (MAV): 53 CFU per 0.1 ml</p> <p>Expiration Date: 2026/01/31</p>	<p>RELEASE INFORMATION:</p> <p>Quality Control Technologist: Glenna L Jaede</p> <p>Release Date: 2024/02/01</p>
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Performance	
<p>Macroscopic Features:</p> <p>Small to medium, gray/white, translucent, smooth, circular with entire edge</p> <p>Microscopic Features:</p> <p>N/A</p>	<p>Medium:</p> <p>SBAP</p> <p>Method:</p> <p>N/A</p>
<p>ID System: MALDI-TOF (1)</p> <p>See attached ID System results document.</p>	



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.

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



TESTING CERT #2655.01



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REFERENCE MATERIAL PRODUCER
 CERT #2655.02

(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 highconfidence 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.

Run Creation Date/Time: 2024-01-30T10:16:13.810 MEW

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

Sample Name	Sample ID	Organism (best match)	Score Value
D8 (+++) (A)	366-471	Enterococcus faecalis	2.44

Comments:

N/A



Statistical Analysis Certificate

Microorganism Name: Enterococcus faecalis

Reference #: ATCC® 29212™*

Catalog #: 0366

Lot #: 366-471**

Expiration Date: 2026/01/31

(7) Mean Assay Value (MAV): 53 CFU per 0.1 ml

Standard Deviation: 7.0E+00

Coefficient of Variation: 13%

99% Confidence Interval of 4.7E+01 to 5.8E+01 CFU

95% Confidence Interval of 4.9E+01 to 5.6E+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, appearing to read "Amanda Kuperus". The signature is fluid and cursive.

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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