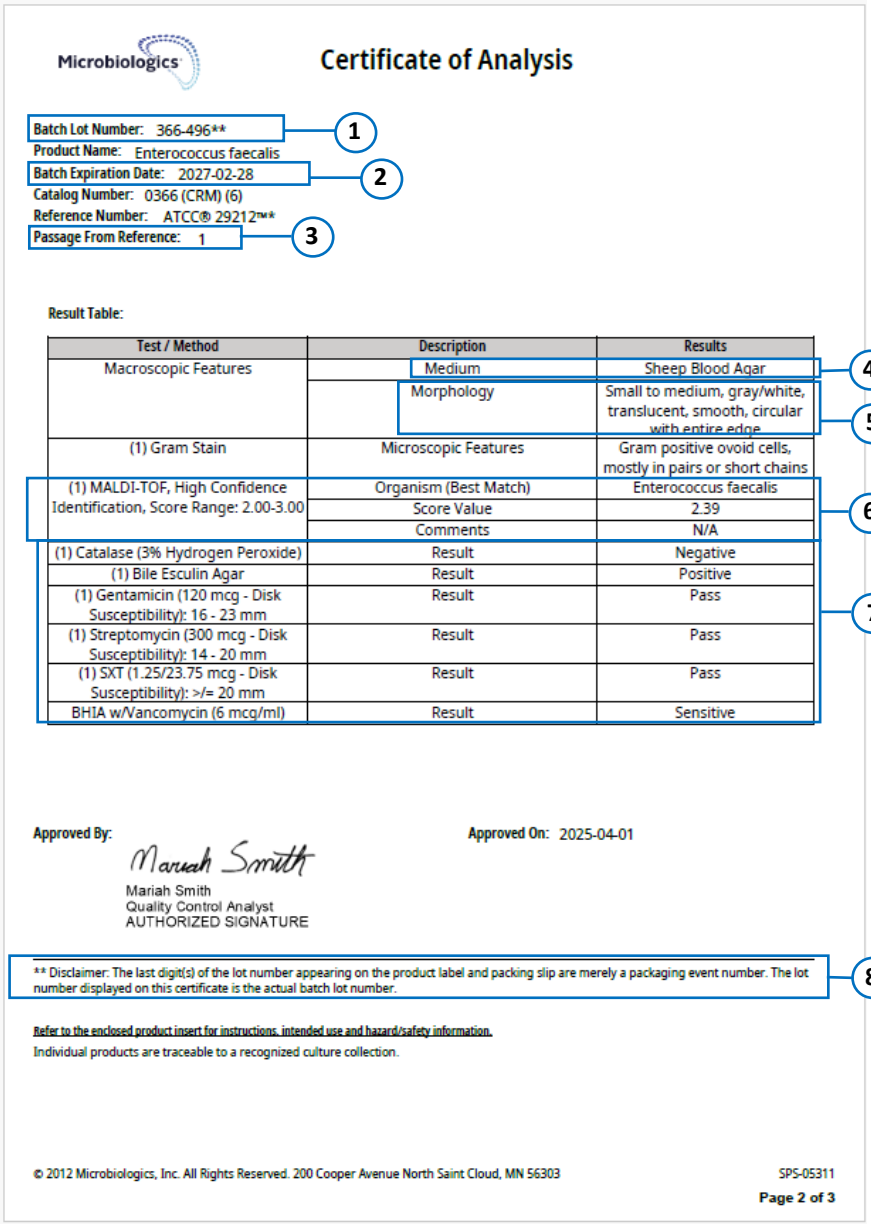
Microbiologics Live Culture Certificate of Analysis Interpretation Guide

This guide describes the information provided on the Certificate of Analysis for Microbiologics' live culture controls (for example, KWIK-STIK™, KWIK-STIK™ Plus and EZ-Accu Shot™). The Certificate of Analysis is a record of the results obtained at Microbiologics during release testing.

Non-Enumerated Certificate of Analysis Interpretation

1. Batch lot number
2. Expiration date of the lot
3. Number of passages the lot is from the reference culture
4. Primary media used to assess morphology and growth
5. Colony morphology observed on medium listed under Macroscopic Features
6. Name of the ID System or Technology used to identify the strain. The ID system used has been validated to provide the most robust ID of the strain.
7. Additional confirmatory tests performed and their results
8. Packaging Event Disclaimer



Microbiologics

Certificate of Analysis

Batch Lot Number: 366-496** (1)
Product Name: Enterococcus faecalis
Batch Expiration Date: 2027-02-28 (2)
Catalog Number: 0366 (CRM) (6)
Reference Number: ATCC® 29212™*
Passage From Reference: 1 (3)

Result Table:

Test / Method	Description	Results	
Macroscopic Features	Medium	Sheep Blood Agar	4
	Morphology	Small to medium, gray/white, translucent, smooth, circular with entire edge	5
(1) Gram Stain	Microscopic Features	Gram positive ovoid cells, mostly in pairs or short chains	
(1) MALDI-TOF, High Confidence Identification, Score Range: 2.00-3.00	Organism (Best Match)	Enterococcus faecalis	6
	Score Value	2.39	
	Comments	N/A	
(1) Catalase (3% Hydrogen Peroxide)	Result	Negative	7
(1) Bile Esculin Agar	Result	Positive	
(1) Gentamicin (120 mcg - Disk Susceptibility): 16 - 23 mm	Result	Pass	
(1) Streptomycin (300 mcg - Disk Susceptibility): 14 - 20 mm	Result	Pass	
(1) SXT (1.25/23.75 mcg - Disk Susceptibility): >/= 20 mm	Result	Pass	
BHIA w/Vancomycin (6 mcg/ml)	Result	Sensitive	

Approved By: Mariah Smith
Mariah Smith
Quality Control Analyst
AUTHORIZED SIGNATURE

Approved On: 2025-04-01

** 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 batch lot number. (8)

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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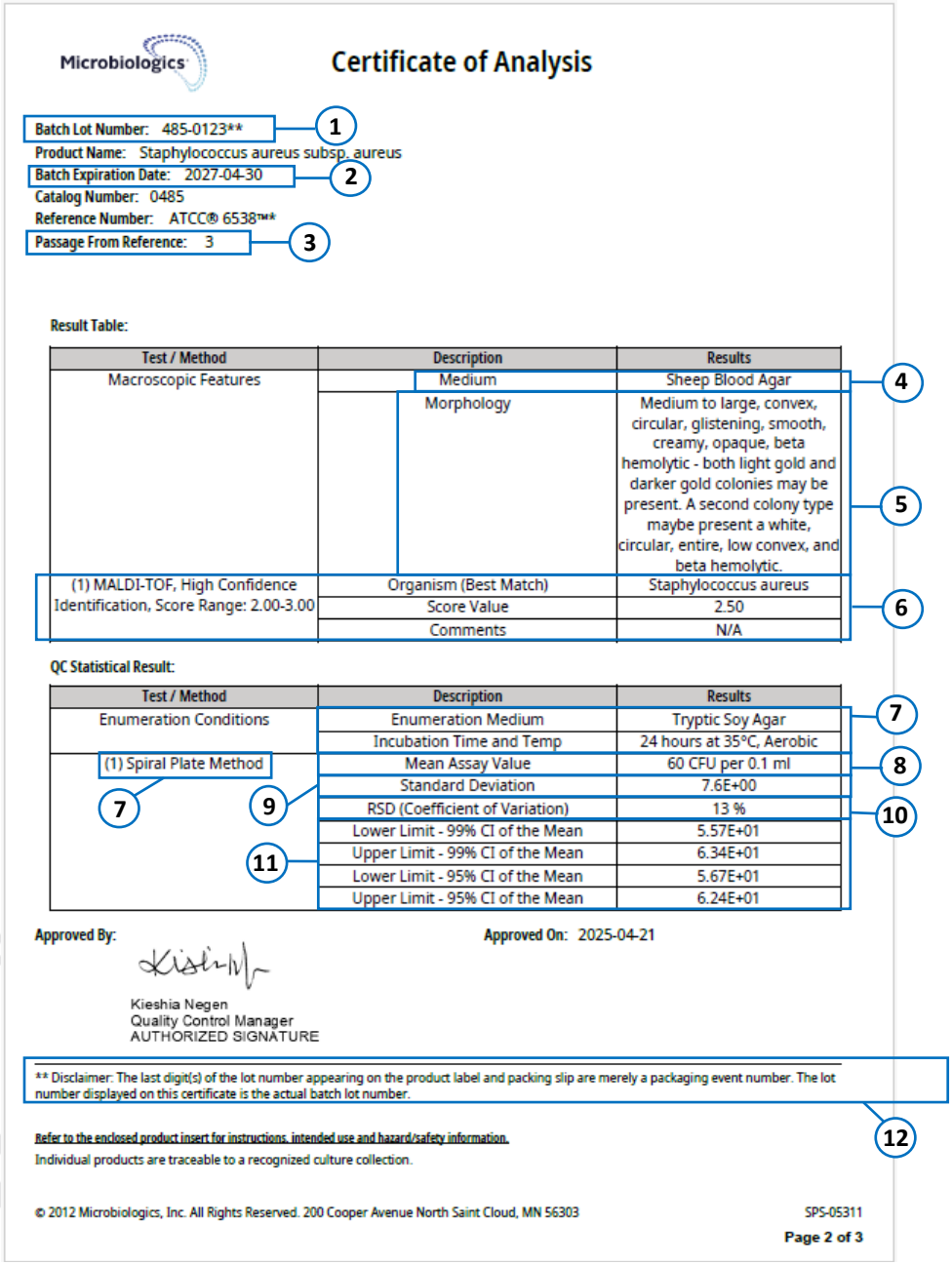
Enumerated Certificate of Analysis Interpretation

1. Batch lot number
2. Expiration date of the lot
3. Number of passages the lot is from the reference culture
4. Primary media used to assess morphology and growth
5. Colony morphology observed on medium listed under Macroscopic Features
6. Name of the ID System or Technology used to identify the strain. The ID system used has been validated to provide the most robust ID of the strain.
7. Methods utilized by Microbiologics during enumeration of the product.
8. Mean Assay Value (MAV) is the average counts obtained at Microbiologics to ensure the lot is recovering within the correct range. This is not a warranted value.
9. The Standard Deviation (SD) is computed using a standard statistical formula. This value is a measure of how close a set of data points are to the mean.
10. The Coefficient of Variation (CV) is computed using a standard statistical formula. This result is a measure of the variability of a data set around its mean.
11. The Confidence Interval (CI) is computed using astandard statistical formula. It is a measure of where the true mean of the population lies.
12. Packaging Event Disclaimer



Microbiologics

Certificate of Analysis

Batch Lot Number: 485-0123** (1)
Product Name: Staphylococcus aureus subsp. aureus
Batch Expiration Date: 2027-04-30 (2)
Catalog Number: 0485
Reference Number: ATCC® 6538™*
Passage From Reference: 3 (3)

Result Table:

Test / Method	Description	Results	
Macroscopic Features	Medium	Sheep Blood Agar	4
	Morphology	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.	5
(1) MALDI-TOF, High Confidence Identification, Score Range: 2.00-3.00	Organism (Best Match)	Staphylococcus aureus	6
	Score Value	2.50	
	Comments	N/A	

QC Statistical Result:

Test / Method	Description	Results	
Enumeration Conditions	Enumeration Medium	Tryptic Soy Agar	7
	Incubation Time and Temp	24 hours at 35°C, Aerobic	
(1) Spiral Plate Method (7)	Mean Assay Value	60 CFU per 0.1 ml	8
	Standard Deviation (9)	7.6E+00	
	RSD (Coefficient of Variation)	13 %	10
	Lower Limit - 99% CI of the Mean	5.57E+01	
	Upper Limit - 99% CI of the Mean (11)	6.34E+01	
	Lower Limit - 95% CI of the Mean	5.67E+01	
	Upper Limit - 95% CI of the Mean	6.24E+01	

Approved By: Kieshia Negen, Quality Control Manager, AUTHORIZED SIGNATURE
Approved On: 2025-04-21

** 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 batch lot number. (12)

Refer to the enclosed product insert for instructions, intended use and hazard/safety information.
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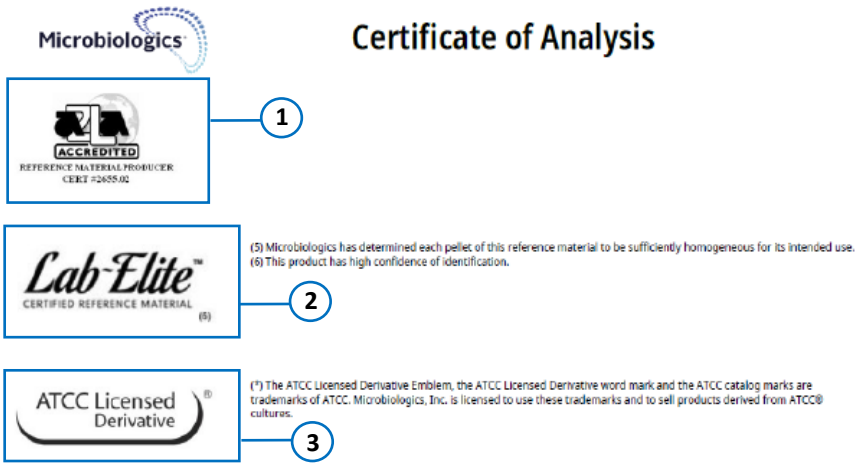
Accreditation Stamp Interpretation

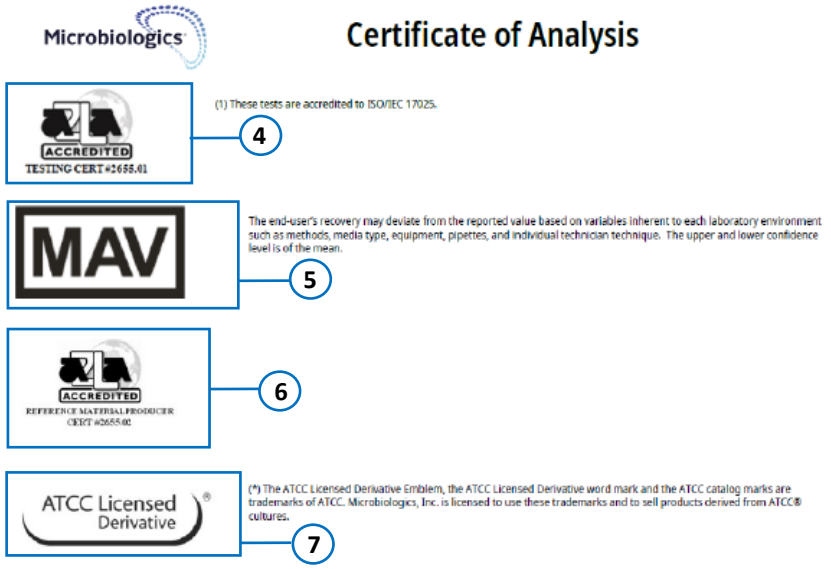
Non-Enumerated Certificate

1. ISO 17034 accreditation stamp
2. Certified Reference Material (CRM) stamp. This will only be displayed on products that are Certified Reference Materials.
3. ATCC Licensed Derivative emblem

Non-Enumerated Certificate of Analysis



Enumerated Certificate

4. ISO 17025 accreditation stamp
5. Mean Assay Value (MAV) disclaimer
6. ISO 17034 accreditation stamp
7. ATCC Licensed Derivative emblem

Enumerated Certificate of Analysis