

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™ 2 Pack, KWIK-STIK™ Plus and LYFO DISK™). The Certificate of Analysis is a record of the results obtained at Microbiologics during release testing. Test conditions and results listed on the Certificate of Analysis are not required by the end user, please use methods and conditions appropriate for your assay and applicable regulatory requirements.

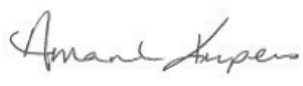
Non-Enumerated Certificate of Analysis Interpretation

1. Base lot number
2. Number of passages the lot is from the reference culture
3. Expiration date of the lot
4. Primary media used to assess morphology and growth
5. Colony morphology on medium listed on Certificate of Analysis
6. Additional confirmatory tests performed and their results
7. Name of the ID system used (report will be attached). The ID system used has been validated to provide the most robust ID of the strain.
8. Packaging Event Disclaimer
9. ISO 17034 accreditation stamp
10. ATCC Licensed Derivative emblem
11. ISO 17025 accreditation stamp



Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

Specifications Microorganism Name: Escherichia coli Catalog Number: 0483 Lot Number: 483-1259** (1) Reference Number: ATCC® 8739™ (2) Passage from Reference: 3	Expiration Date: 2024/4/30 (3) Release Information: Quality Control Technologist: Madison C Vogt Release Date: 2022/6/27
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Macroscopic Features: (5) Medium to large, gray, mucoid, convex. Microscopic Features: Gram negative straight rod.	Performance Medium: (4) SBAP Method: Gram Stain (1)
ID System: MALDI-TOF (1) (7) See attached ID System results document.	Other Features/ Challenges: Results (6) (1) Oxidase (Kovacs): negative Beta-glucuronidase (E. coli Broth w/MUG): positive  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. (8)

Individual products are traceable to a recognized culture collection.




(*) The ATCC Licensed Derivative Emblem, the ATCC Licensed Derivative word mark and the ATCC catalog marks are trademarks of ATCC. Microbiologics, Inc. is licensed to use these trademarks and to sell products derived from ATCC® cultures.



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

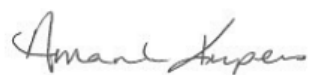
Enumerated Certificate of Analysis Interpretation

1. Base lot number
2. Number of passages the lot is from the reference culture
3. Expiration date of the lot
4. 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.
5. Primary media used to assess morphology and growth
6. Colony morphology on medium listed on Certificate of Analysis
7. Additional confirmatory tests performed and their results will be listed here. If the same strain is available in both a non-enumerated and enumerated format, the same tests may or may not be present
8. Name of the ID system used (report will be attached). The ID system used has been validated to provide the most robust ID of the strain.
9. Packaging Event Disclaimer
10. ISO 17034 accreditation stamp
11. ISO 17025 accreditation stamp
12. ATCC Licensed Derivative emblem



Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release


Specifications Microorganism Name: Pseudomonas aeruginosa Catalog Number: 0484 Lot Number: 484-1468** 1 Reference Number: ATCC® 9027™* Passage from Reference: 3 2 (7) Mean Assay Value (MAV): 40 CFU per 0.1 ml 4	Expiration Date: 2024/2/29 3 Release Information: Quality Control Technologist: Madison C Vogt Release Date: 2022/3/8
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Macroscopic Features: 6 Large, flat, circular to irregular shaped, gray with silver sheen. A second colony type may also be present as small, round, shiny colonies.	Performance Medium: 5 SBAP
Microscopic Features: Straight or slightly curved gram negative rod.	Method: Gram Stain (1)
ID System: MALDI-TOF (1) 8 See attached ID System results document.	Other Features/ Challenges: Results 7 Growth at 42 C: positive <div style="text-align: center;">  Amanda Kuperus Director of Quality Control AUTHORIZED SIGNATURE </div>


**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. 9

Individual products are traceable to a recognized culture collection.

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 ACCREDITED
 REFERENCE MATERIAL PRODUCER
 CERT #2655.02

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 TESTING CERT #2655.01

(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.

Microbiologics Statistical Analysis Certificate Interpretation Guide

This guide describes the information provided on the Statistical Analysis Certificate for Microbiologics' enumerated product lines (for example, Epower™, EZ-Accu Shot™, and EZ-CFU™ One Step). The Statistical Analysis Certificate is a record of the results obtained at Microbiologics during release testing. These results are not warranted. Test conditions and results listed on the Statistical Analysis Certificate are not required by the end user. Please use methods and conditions appropriate for your assay and applicable regulatory requirements.

Statistical Analysis Certificate Interpretation

1. Base lot number
2. The 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. See Disclaimer (7).
3. The Standard deviation (SD) is calculated using an established statistical formula. This data point indicates how far, on average, each score lies from the mean of the data set.
4. The Coefficient of Variation (CV) is calculated using an established statistical formula. This result is measure of precision of the data points from the mean.
5. The Confidence Interval (CI) is calculated using an established statistical formula. The 95% CI is a range of values with a 95% probability of containing the true meaning of the population. The 99% CI is a range of values with a 99% probability of containing the true meaning of the population.
6. Methods Utilized my Microbiologics during enumeration of the product. Optimum growth time, temperature and atmosphere are selected for the strain.



Statistical Analysis Certificate

Microorganism Name: Staphylococcus aureus subsp. aureus

Reference #: ATCC® 6538™*

Catalog #: 0485

Lot #: 485-1106 1

Expiration Date: 2024/4/30

(7) Mean Assay Value (MAV): 40 CFU per 0.1 ml 2

Standard Deviation: 5.7E+00 3

Coefficient of Variation: 14% 4

99% Confidence Interval of 3.8E+01 to 4.1E+01 CFU 5

95% Confidence Interval of 3.9E+01 to 4.1E+01 CFU

Method used to determine Mean Assay Value: Spiral Plate Method 6

Medium Employed: TSA

Incubation Time and Temp: 24 hrs at 34-38 degrees C



Amanda Kuperus
Director of Quality Control
AUTHORIZED SIGNATURE

(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.