Microbiologics

Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

Specifications	
Microorganism Name: Escherichia coli	**Expiration Date:** 2025/1/31
Catalog Number: 0483	**Release Information:**
Lot Number: 483-1317**	**Quality Control Technologist:** Kalina E George
Reference Number: ATCC® 8739™*	**Release Date:** 2023/2/13
Passage from Reference: 3	
(7) Mean Assay Value (MAV): 6.2E+03 CFU per pellet	

Performance

Macroscopic Features:	**Medium:**
Medium to large, gray, mucoid, convex.	SBAP
Microscopic Features:	**Method:**
Gram negative straight rod.	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.

A2LA ACCREDITED
REFERENCE MATERIAL PRODUCER
CERT #2655.02

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TESTING CERT #2655.01

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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.

Run Creation Date/Time: 2023-02-10T11:05:34.998 kel

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

Sample Name	Sample ID	Organism (best match)	Score Value
G12 (+++) (A)	483-1317	Escherichia coli	2.46

Comments:

closely related to Shigella / Escherichia fergusonii and not definitely distinguishable at the moment

Microbiologics

Statistical Analysis Certificate

Microorganism Name: Escherichia coli

Reference #: ATCC® 8739™*

Catalog #: 0483

Lot #: 483-1317**

Expiration Date: 2025/1/31

(7) Mean Assay Value (MAV): 6.2E+03 CFU per pellet

Standard Deviation: 1.2E+03

Coefficient of Variation: 20%

99% Confidence Interval of 5.7E+03 to 6.6E+03 CFU

95% Confidence Interval of 5.9E+03 to 6.5E+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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