Microbiologics®

Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

Specifications
Microorganism Name: Escherichia coli
Catalog Number: 0483
Lot Number: 483-886**
Reference Number: ATCC® 8739™*
Purity: Pure
Passage from Reference: 3
(7) Mean Assay Value (MAV): 45 CFU per 0.1 ml

Expiration Date: 2020/11/30
Release Information:
Quality Control Technologist: Alexandra D Stensvad
Release Date: 2018/12/17

Performance

Macroscopic Features:
Medium to large, gray, mucoid, convex.

Microscopic Features:
Gram negative straight rod.

Medium:
SBAP

Method:
Gram Stain (1)

ID System: MALDI-TOF (1)
See attached ID System results document.

Other Features/ Challenges: Results
(1) Oxidase (Kovacs): negative
Beta-glucuronidase (E. coli Broth w/MUG): positive

Amanda Kuperus
Quality Control Manager
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.

Note for Vitek®: Although the Vitek® panel uses many conventional tests, the unique environment of the card, combined with the short incubation period, may produce results that differ from published results obtained by other methods.

⚠ **Refer to the enclosed product insert for instructions, intended use and hazard/safety information.**

Individual products are traceable to a recognized culture collection.

ACCREDITED
REFERENCE MATERIAL PRODUCER
CERT #2655.02

ATCC Licensed Derivative®

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(1) These tests are accredited to ISO/IEC 17025:2005.

ACCREDITED
TESTING CERT #2655.01

(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 the 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.

Sample Name: Escherichia coli
Sample Description: 0483
Sample ID: 483-886
Sample Creation Date/Time: 2018-12-11T12:37:48.139 ADS
Applied MSP Library(ies): BDAL, Mycobacteria Library (bead method), Filamentous Fungi Library 1.0, Listeria

Sample Name	Sample ID	Organism (best match)	Score Value
C11 (+++) (A)	483-886	Escherichia coli	2.37

Comments:

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

Statistical Analysis Certificate

Microorganism Name: Escherichia coli
Reference #: ATCC® 8739™*
Catalog #: 0483
Lot #: 483-886**
Expiration Date: 2020/11/30
(7) Mean Assay Value (MAV): 45 CFU per 0.1 ml
Standard Deviation: 4.8E+00
Coefficient of Variation: 11%
99% Confidence Interval of 4.3E+01 to 4.7E+01 CFU
95% Confidence Interval of 4.3E+01 to 4.6E+01 CFU

Method used to determine Mean Assay Value: Spiral Biotech Test Method
Medium Employed: TSA
Incubation Time and Temp: 24 hrs at 34-38 degrees C

Amanda Kuperus
Quality Control Manager
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