



Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

Specifications

Microorganism Name: Escherichia coli
Catalog Number: 0335
Lot Number: 335-245
Reference Number: ATCC® 25922™*
Purity: Pure
Passage from Reference: 2

Expiration Date: 2019/4/30

Release Information:

Quality Control Technologist: Christine Condon

Release Date: 2017/8/21

Performance

Macroscopic Features:

2 colony types, both are gray & beta hemolytic; one is circular to irregular, convex, slightly erose edge & smooth; other is larger, irregular, low convex, erose edge & rough

Microscopic Features:

Gram negative straight rod

Medium:

SBAP

Method:

Gram Stain (1)

ID System: MALDI-TOF

See attached ID System results document.

Other Features/ Challenges: Results

(1) Oxidase (Kovacs): negative

Beta-glucuronidase (E. coli Broth w/MUG): positive

(1) Ampicillin (10 mcg - Disk Susceptibility): 16 - 22 mm

(1) Gentamicin (10 mcg - Disk Susceptibility): 19 - 26 mm

(1) SXT (1.25/23.75 mcg - Disk Susceptibility): 23 - 29 mm

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.



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

TESTING CERT #2655.01

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: 0335
 Sample ID: 335-245
 Sample Creation Date/Time: 2017-05-18T13:15:36.549 CC
 Applied MSP Library(ies): BDAL, Mycobacteria Library (bead method), Filamentous Fungi Library 1.0, Listeria

Sample Name	Sample ID	Organism (best match)	Score Value
A3 (+++)(A)	335-245	Escherichia coli	2.42

Comments:

closely related to Shigella and not definitely distinguishable at the moment