



Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

Specifications Microorganism Name: Escherichia coli (serotype O145:NM) Catalog Number: 01097 Lot Number: 1097-17 Reference Number: CDC 99-3311 Purity: Pure Passage from Reference: 2	Expiration Date: 2018/12/31 Release Information: Quality Control Technologist: Christine Condon Release Date: 2017/2/16
--	--

Performance	
Macroscopic Features: Medium to large, circular, convex, entire edge, gray, glistening. Microscopic Features: Short gram negative rods	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 E. coli OK O antiserum O145: positive Immunocard STAT! EHEC Kit: Shiga toxin 1 (+) / Shiga toxin 2 (-)  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.

(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 (serotype O145:NM)
 Sample Description: 01097
 Sample ID: 1097-17
 Sample Creation Date/Time: 2017-02-10T10:48:31.196 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
G5 (+++)(A)	1097-17	Escherichia coli	2.53

Comments:

closely related to Shigella and not definitely distinguishable at the moment



Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

Specifications Microorganism Name: Escherichia coli (serotype O45:H2) Catalog Number: 01098 Lot Number: 1098-16 Reference Number: CDC 00-3039 Purity: Pure Passage from Reference: 2	Expiration Date: 2018/12/31 Release Information: Quality Control Technologist: Christine Condon Release Date: 2017/2/16
---	--

Performance	
Macroscopic Features: Medium to large, circular, convex, entire edge, gray, glistening. Microscopic Features: Short gram negative rods	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 E. coli OK O antiserum O45: positive Immunocard STAT! EHEC Kit: Shiga toxin 1 (+) / Shiga toxin 2 (-)  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.

(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 (serotype O45:H2)
 Sample Description: 01098
 Sample ID: 1098-16
 Sample Creation Date/Time: 2017-02-10T10:48:31.195 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
G4 (+++)(A)	1098-16	Escherichia coli	2.51

Comments:

closely related to Shigella and not definitely distinguishable at the moment



Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

Specifications Microorganism Name: Escherichia coli (serotype O121:H19) Catalog Number: 01099 Lot Number: 1099-20 Reference Number: CDC 02-3211 Purity: Pure Passage from Reference: 2	Expiration Date: 2018/12/31 Release Information: Quality Control Technologist: Christine Condon Release Date: 2017/2/16
---	--

Performance	
Macroscopic Features: Medium, grey, glossy, circular, convex, entire edge Microscopic Features: Short gram negative rods	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 E. coli OK O antiserum O121: positive Immunocard STAT! EHEC Kit: Shiga toxin 1 (-) / Shiga toxin 2 (+)  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.

(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 (serotype O121:H19)
 Sample Description: 01099
 Sample ID: 1099-20
 Sample Creation Date/Time: 2017-02-10T10:48:31.194 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
G3 (+++)(A)	1099-20	Escherichia coli	2.42

Comments:

closely related to Shigella and not definitely distinguishable at the moment



Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

Specifications Microorganism Name: Escherichia coli (serotype O26:H11) Catalog Number: 01100 Lot Number: 1100-16 Reference Number: CDC 03-3014 Purity: Pure Passage from Reference: 2	Expiration Date: 2018/12/31 Release Information: Quality Control Technologist: Christine Condon Release Date: 2017/2/16
--	--

Performance	
Macroscopic Features: Medium to large, circular, convex, entire edge, gray, glistening. Microscopic Features: Short gram negative rods	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 E. coli OK O antiserum O26: positive Immunocard STAT! EHEC Kit: Shiga toxin 1 (+) / Shiga toxin 2 (+)  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.

(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 (serotype O26:H11)
 Sample Description: 01100
 Sample ID: 1100-16
 Sample Creation Date/Time: 2017-02-10T10:48:31.193 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
G2 (+++)(A)	1100-16	Escherichia coli	2.39

Comments:

closely related to Shigella and not definitely distinguishable at the moment



Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

Specifications Microorganism Name: Escherichia coli (serotype O103:H11) Catalog Number: 01101 Lot Number: 1101-21 Reference Number: CDC 06-3008 Purity: Pure Passage from Reference: 2	Expiration Date: 2019/3/31 Release Information: Quality Control Technologist: Kieshia L Negen Release Date: 2017/5/3
---	---

Performance	
Macroscopic Features: Medium to large, circular, convex, entire edge, gray, glistening. Microscopic Features: Short gram negative rods	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 E. coli OK O antiserum O103: positive Immunocard STAT! EHEC Kit: Shiga toxin 1 (+) / Shiga toxin 2 (-)  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.

(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 (serotype O103:H11)
 Sample Description: 01101
 Sample ID: 1101-21
 Sample Creation Date/Time: 2017-04-26T16:24:44.041KN
 Applied MSP Library(ies): BDAL, Mycobacteria Library (bead method), Filamentous Fungi Library 1.0, Listeria

Sample Name	Sample ID	Organism (best match)	Score Value
E1 (+++)(A)	1101-21	Escherichia coli	2.35

Comments:

closely related to Shigella and not definitely distinguishable at the moment



Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

Specifications Microorganism Name: Escherichia coli (serotype O111:H8) Catalog Number: 01102 Lot Number: 1102-15 Reference Number: CDC 2010C-3114 Purity: Pure Passage from Reference: 2	Expiration Date: 2018/12/31 Release Information: Quality Control Technologist: Christine Condon Release Date: 2017/2/16
---	--

Performance	
Macroscopic Features: Medium to large, circular, convex, entire edge, gray, glistening. Microscopic Features: Short gram negative rods	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 E. coli OK O antiserum O111: positive Immunocard STAT! EHEC Kit: Shiga toxin 1 (+) / Shiga toxin 2 (+)  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.

(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 (serotype O111:H8)
 Sample Description: 01102
 Sample ID: 1102-15
 Sample Creation Date/Time: 2017-02-10T10:48:31.191 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
F12 (+++)(A)	1102-15	Escherichia coli	2.34

Comments:

N/A



Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

Specifications Microorganism Name: Escherichia coli (serotype O157:H7) Catalog Number: 0617 Lot Number: 617-98 Reference Number: ATCC® 35150™* Purity: Pure Passage from Reference: 3	Expiration Date: 2019/3/31 Release Information: Quality Control Technologist: Christine Condon Release Date: 2017/4/25
--	---

Performance	
Macroscopic Features: Medium to large, gray, entire, glistening, smooth, convex. 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 MacConkey w/sorbitol: negative (good growth of colorless colonies/sorbitol negative) Beta-glucuronidase (E. coli Broth w/MUG): negative (1) E. coli O157 Test (RIM Latex Test): positive (1) E. coli H7 Test (RIM Latex Test): 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.



(*) 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 17025:2005.

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 (serotype O157:H7)
 Sample Description: 0617
 Sample ID: 617-98
 Sample Creation Date/Time: 2017-04-19T12:41:55.541 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
E6 (+++)(A)	617-98	Escherichia coli	2.25

Comments:

closely related to Shigella and not definitely distinguishable at the moment