

Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

<p>SPECIFICATIONS:</p> <p>Product Name: Escherichia coli</p> <p>Catalog Number: 0335 (CRM) (6)</p> <p>Lot Number: 335-576**</p> <p>Reference Number: ATCC® 25922™*</p> <p>Passage from Reference: 1</p> <p>Expiration Date: 2025/10/31</p>	<p>RELEASE INFORMATION:</p> <p>Quality Control Technologist: Kalina E George</p> <p>Release Date: 2023/12/28</p>
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Performance	
<p>Macroscopic Features:</p> <p>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</p> <p>Microscopic Features:</p> <p>Gram negative straight rod</p> <p>ID System: MALDI-TOF (1)</p> <p>See attached ID System results document.</p> <p>Other Features/ Challenges: Results</p> <p>(1) Oxidase (Kovacs): negative Beta-glucuronidase (E. coli Broth w/MUG): positive (1) Ampicillin (10 mcg - Disk Susceptibility): 15 - 22 mm (1) Gentamicin (10 mcg - Disk Susceptibility): 19 - 26 mm (1) SXT (1.25/23.75 mcg - Disk Susceptibility): 23 - 29 mm</p>	<p>Medium:</p> <p>SBAP</p> <p>Method:</p> <p>Gram Stain (1)</p> <div style="text-align: right;">  Amanda Kuperus Director of Quality Control AUTHORIZED SIGNATURE </div>

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REFERENCE MATERIAL PRODUCER
CERT #2655.02

(5) Microbiologics has determined each pellet of this reference material to be sufficiently homogeneous for its intended use.

(6) This product has high confidence of identification.

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 highconfidence 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: 2023-12-08T10:59:01.702 KEG

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

Sample Name	Sample ID	Organism (best match)	Score Value
F1 (+++) (A)	335-576	Escherichia coli	2.61

Comments:

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

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<p>SPECIFICATIONS:</p> <p>Product Name: Salmonella enterica subsp. enterica serovar Enteritidis (group D) Catalog Number: 0345 (CRM) (6) Lot Number: 345-131** Reference Number: ATCC® 13076™* Passage from Reference: 1 Expiration Date: 2025/03/31</p>	<p>RELEASE INFORMATION:</p> <p>Quality Control Technologist: Christine Condon Release Date: 2023/08/16</p>
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Performance	
<p>Macroscopic Features: Medium, gray/white, circular, convex colonies</p> <p>Microscopic Features: Gram negative straight rod</p>	<p>Medium: SBAP</p> <p>Method: Gram Stain (1)</p>
<p>ID System: MALDI-TOF (1)</p>	
<p>See attached ID System results document.</p>	
<p>Other Features/ Challenges: Results</p> <p>(1) Oxidase (Kovacs): negative Hektoen Enteric agar: good growth, blue-green colonies with black centers (1) Salmonella O antiserum Factor O:9 (Included in group D1): positive (1) Salmonella O antiserum Factor O:12 (Included in group D1): positive</p> <div style="text-align: right;">  Amanda Kuperus Director of Quality Control AUTHORIZED SIGNATURE </div>	

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Bruker Daltonik MALDI Biotyper Classification Results



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0.00 – 1.69	No Organism Identification Possible	(-)	Red

Meaning of Consistency Categories (A - C)

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(A)	High consistency: The best match is a high-confidence identification. The second-best match is (1) a highconfidence 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: 2023-04-04T09:18:31.762 uaj

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

Sample Name	Sample ID	Organism (best match)	Score Value
D6 (+++) (A)	345-131	Salmonella sp	2.21

Comments:

Salmonella can only be identified on genus level.

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<p>SPECIFICATIONS:</p> <p>Product Name: Pseudomonas aeruginosa</p> <p>Catalog Number: 0353 (CRM) (6)</p> <p>Lot Number: 353-526**</p> <p>Reference Number: ATCC® 27853™*</p> <p>Passage from Reference: 1</p> <p>Expiration Date: 2025/04/30</p>	<p>RELEASE INFORMATION:</p> <p>Quality Control Technologist: Margaret E Wagener</p> <p>Release Date: 2023/08/07</p>
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Performance	
<p>Macroscopic Features:</p> <p>Two colony types: Large, flat, circular to irregular shaped, gray with silver sheen(98%); And small and compact</p>	<p>Medium:</p> <p>SBAP</p>
<p>Microscopic Features:</p> <p>Straight or slightly curved gram negative rod</p>	<p>Method:</p> <p>Gram Stain (1)</p>
<p>ID System: MALDI-TOF (1)</p>	
<p>See attached ID System results document.</p>	
<p>Other Features/ Challenges: Results</p> <p>(1) Oxidase (Kovacs): positive Motility (Wet Mount): positive (1) Gentamicin (10 mcg - Disk Susceptibility): 17 - 23 mm</p> <div style="text-align: right;">  Amanda Kuperus Director of Quality Control AUTHORIZED SIGNATURE </div>	

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Bruker Daltonik MALDI Biotyper Classification Results



Meaning of Score Values

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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 highconfidence 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: 2023-05-02T09:55:51.407 mew

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

Sample Name	Sample ID	Organism (best match)	Score Value
G6 (+++) (A)	353-526	Pseudomonas aeruginosa	2.58

Comments:

N/A

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<p>SPECIFICATIONS:</p> <p>Product Name: Salmonella enterica subsp. enterica serovar Typhimurium</p> <p>Catalog Number: 0363 (CRM) (6)</p> <p>Lot Number: 363-682**</p> <p>Reference Number: ATCC® 14028™*</p> <p>Passage from Reference: 1</p> <p>Expiration Date: 2025/11/30</p>	<p>RELEASE INFORMATION:</p> <p>Quality Control Technologist: Jacob A Lohman</p> <p>Release Date: 2024/01/02</p>
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Performance	
<p>Macroscopic Features:</p> <p>Two colony types observed: CT1: glistening, convex, circular, entire, and beige CT2: flat, glossy, slightly irregular and rough edges</p> <p>Microscopic Features:</p> <p>Gram negative straight rods</p> <p>ID System: MALDI-TOF (1)</p> <p>See attached ID System results document.</p> <p>Other Features/ Challenges: Results</p> <p>(1) Oxidase (Kovacs): negative Hektoen Enteric agar: good growth, blue-green colonies with black centers (1) Salmonella O antiserum Factor O:4 (Included in group B): positive (1) Salmonella O antiserum Factor O:5 (Included in group B): positive (1) Salmonella O antiserum Factor O:12 (Included in group B): positive</p>	<p>Medium:</p> <p>SBAP</p> <p>Method:</p> <p>Gram Stain (1)</p> <div style="text-align: right; margin-top: 20px;">  Amanda Kuperus Director of Quality Control AUTHORIZED SIGNATURE </div>

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0.00 – 1.69	No Organism Identification Possible	(-)	Red

Meaning of Consistency Categories (A - C)

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(A)	High consistency: The best match is a high-confidence identification. The second-best match is (1) a highconfidence 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: 2023-12-19T09:19:37.837 JAL

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

Sample Name	Sample ID	Organism (best match)	Score Value
C4 (+++) (A)	363-682	Salmonella sp	2.35

Comments:

Salmonella can only be identified on genus level.

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<p>SPECIFICATIONS:</p> <p>Product Name: Enterococcus faecalis</p> <p>Catalog Number: 0367 (CRM) (6)</p> <p>Lot Number: 367-161**</p> <p>Reference Number: ATCC® 19433™*</p> <p>Passage from Reference: 1</p> <p>Expiration Date: 2025/08/31</p>	<p>RELEASE INFORMATION:</p> <p>Quality Control Technologist: Margaret E Wagener</p> <p>Release Date: 2023/10/10</p>
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Performance	
<p>Macroscopic Features:</p> <p>Small to medium, gray/white, translucent, smooth, circular with entire edge</p>	<p>Medium:</p> <p>SBAP</p>
<p>Microscopic Features:</p> <p>Gram positive ovoid cells, mostly in pairs or short chains</p>	<p>Method:</p> <p>Gram Stain (1)</p>
<p>ID System: MALDI-TOF (1)</p>	
<p>See attached ID System results document.</p>	
<p>Other Features/ Challenges: Results</p> <p>(1) Catalase (3% Hydrogen Peroxide): negative</p> <p>(1) Bile Esculin Agar: positive</p> <div style="text-align: right;">  Amanda Kuperus Director of Quality Control AUTHORIZED SIGNATURE </div>	

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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 highconfidence 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: 2023-10-03T13:25:07.771 mew

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

Sample Name	Sample ID	Organism (best match)	Score Value
H7 (+++) (A)	367-161	Enterococcus faecalis	2.31

Comments:

N/A