



CERTIFICATION

AOAC[®] Performance TestedSM

Certificate No.

011805

The AOAC Research Institute hereby certifies that method as:

RapidChek[®] *Listeria monocytogenes*

manufactured by

Romer Labs, Inc.

130 Sandy Drive

Newark, Delaware 19713

USA

This method has been evaluated in the AOAC[®] Performance Tested MethodsSM Program and found to perform as stated by the manufacturer contingent to the comments contained in the manuscript. This certificate means that an AOAC[®] Certification Mark License Agreement has been executed which authorizes the manufacturer to display the AOAC Performance TestedSM certification mark along with the statement - "THIS METHOD'S PERFORMANCE WAS REVIEWED BY AOAC RESEARCH INSTITUTE AND WAS FOUND TO PERFORM TO THE MANUFACTURER'S SPECIFICATIONS" - on the above-mentioned method for a period of one calendar year from the date of this certificate (November 20, 2021 – December 31, 2022). Renewal may be granted at the end of one year under the rules stated in the licensing agreement.

Scott Coates

Scott Coates, Senior Director
Signature for AOAC Research Institute

November 30, 2021

Date

METHOD AUTHORS Gregory Juck, Verapaz Gonzalez, Ann-Christine Olsson Allen, Meredith Sutzko, Kody Seward, and Mark T. Muldoon	SUBMITTING COMPANY Romer Labs, Inc. 130 Sandy Drive Newark, Delaware 19713
---	--

METHOD NAME(S) RapidChek® <i>Listeria monocytogenes</i>	CATALOG NUMBERS 7000297, 3000038, 7000297,7000297S, 7000298, 7000243,7000244, 7000173, 7000178 10001180, 10001435, 10001734, 10001436, 10001409, 10001410, 10001363, 10001368
---	--

INDEPENDENT LABORATORY Q Laboratories, inc. 1400 Harrison Ave. Cincinnati, OH 45214 USA	AOAC EXPERTS AND PEER REVIEWERS Yvonne Salfinger ¹ , Michael Brodsky ² , Patrice Arbault ³ ¹ Consultant, Denver, CO, USA ² Brodsky Consulting, Thornhill, Canada ³ Nexidia/BioAdvantage Consulting, France
--	---

APPLICABILITY OF METHOD Target organism – <i>Listeria monocytogenes</i> Matrixes – (FSIS MLG 8.10) (25 g) - hot dogs, cured ham, frozen cooked breaded chicken (AOAC OMA 993.12) (25 mL) - ice cream (FDA BAM Ch. 10) - frozen cooked shrimp (25 g), stainless steel (4x4 in sponge), and plastic (1x1 in swab) Performance claims - The method was found to be equivalent in performance to the reference methods.	REFERENCE METHODS USDA FSIS. Microbiological Laboratory Guidelines. Chapter 8.10. <i>Isolation and Identification of Listeria monocytogenes from Red Meat, Poultry, Ready-To-Eat Siluriformes (Fish) and Egg Products, and Environmental Samples</i> (11) FDA BAM Chapter 10. <i>Detection and Enumeration of Listeria monocytogenes in Foods.</i> (12) AOAC Official Method 993.12. <i>Listeria monocytogenes</i> in Milk and Dairy Products. (13)
---	---

ORIGINAL CERTIFICATION DATE January 30, 2018	CERTIFICATION RENEWAL RECORD Renewed annually through December 2022.
--	--

METHOD MODIFICATION RECORD 1. November 2018 Level 1 2. May 2019 Level 1 3. November 2021 Level 1	SUMMARY OF MODIFICATIONS 1. Editorial changes for clarity and to fix omitted information. 2. Update of catalog numbers. 3. Updated USDA/FDA information.
--	--

Under this AOAC® <i>Performance Tested</i> SM License Number, 011805 this method is distributed by: NONE	Under this AOAC® <i>Performance Tested</i> SM License Number, 011805 this method is distributed as: NONE
--	--

PRINCIPLE OF THE METHOD (1)

The Romer Labs RapidChek® *Listeria monocytogenes* method utilizes a proprietary enrichment system. After enrichment (44 to 48 h), an aliquot of the sample broth is dispensed into a test tube and a test strip is added directly to the tube. The sample flows up the strip through a zone containing antibody-coated colloidal gold reagents specific to *L. monocytogenes*. If antigens are present in the sample, they will bind to the antibody-conjugates to form an antigen/antibody complex. As this complex migrates through the nitrocellulose matrix, it passes a zone of anti-*L. monocytogenes* antibody. If antigen is present, the complex is captured in this zone forming an antibody-antigen “sandwich” and is visualized by the formation of a red line. A second zone on the membrane is designed to capture any antibody-gold complex not bound in the first zone. As a result, when *L. monocytogenes* antigen is present, the formation of 2 red lines is observed, whereas when no *L. monocytogenes* is present, only 1 line forms in the second zone.

DISCUSSION OF THE VALIDATION STUDY (1)

The Romer Labs, Inc. RapidChek® *Listeria monocytogenes* test system was validated against the USDA-FSIS-MLG, FDA-BAM, and AOAC-OMA cultural reference method for the detection of *Listeria monocytogenes* on selected foods and environmental surfaces in an unpaired study design. In the method developer matrix studies the number of presumptive positive results obtained with the RapidChek® method at 44 h to 48 h was 88, whereas the number of positive samples identified by the respective cultural reference methods was 63. One of the presumptive positives was not confirmed culturally; this was most likely due to the high background flora found in shrimp. Additionally, one of the culturally confirmed samples did not exhibit a presumptive positive; this was most likely due to a cross-reactor on the stainless steel surface. The independent lab matrix study results were very similar to the method developer matrix study results, with 23 presumptive positives for the RapidChek® method and 16 positive samples identified by the respective cultural reference methods. All of the independent lab RapidChek® presumptive results were culturally confirmed. For all sample types, Probability of Detection (POD) analysis showed that the number of positive test results obtained by the RapidChek® test method were not significantly different than the number of positive test results obtained by the respective cultural reference method (dPOD_C) at the 95% confidence interval for both dPOD_C and dPOD_{CP}. Additionally, POD analysis showed no significant difference between the RapidChek® presumptive results and alternate/reference confirmed results (dPOD_{CP}) at the 95% confidence interval.

The RapidChek® *Listeria monocytogenes* test system was able to detect all 50 *L. monocytogenes* strains. *L. marthii* was the only non-*L. monocytogenes* strain to exhibit a positive result in the exclusivity panel with the full RapidChek® *Listeria monocytogenes* test system (test strip and media). The reaction of *L. marthii* with the RapidChek® *Listeria monocytogenes* test strip is not surprising, since *L. marthii* is closely related to *L. monocytogenes*. DNA relatedness between *L. marthii* and *L. monocytogenes* has been reported as 60-75% (15).

Additionally, in the exclusivity studies, the number of positives with the RapidChek® *Listeria monocytogenes* test strip in BHI/MRS broth differs. In the initial study, six strains were positive in BHI/MRS with the RapidChek® *Listeria monocytogenes* test strip. In the follow-up study (Table 14), only two of the exclusivity strains were positive in BHI/MRS with the RapidChek® *Listeria monocytogenes* test strip. The 4 exclusivity strains that were positive in the first study and not the second study are *B. cereus* ATCC 6464, *L. acidophilus* ATCC 314, *L. lactis* ATCC 4797, and *S. aureus* ATCC 29213. This inconsistency is probably due to pH effects. Since the discrepancies are seen in the non-selective media, which has a lower buffering capacity than the RapidChek® media, it is possible that bacteria decreased the media pH and thus caused non-specific binding with the test strip.

Table 2. POD Results from the Analysis of *Listeria monocytogenes* ATCC 51774 in 25 g hot dogs after 44 h enrichment time. (1)

Independent Laboratory Matrix Study																			
Statistic	Concentration MPN/sample	Candidate Presumptive (CP)			Alternative Candidate Confirmed (CC)			Reference Candidate Confirmed (CC)			Candidate Method (C)			Reference Method (R)			dPOD ¹		
		N ²	x ³	POD (CP)	N	x	POD (CC)	N	x	POD (CC)	N	x	POD (C)	N	x	POD (R)	CP VS CC Alternative	CP VS CC Traditional	C vs R
Estimate	0 (negative)	5	0	0.00	5	0	0.00	5	0	0.00	5	0	0.00	5	0	0.00	0.00	0.00	0.00
LCL ⁴	-			0.00			0.00			0.00			0.00			0.00	-0.43	-0.43	-0.43
UCL ⁵	-			0.43			0.43			0.43			0.43			0.43	0.43	0.43	0.43
Estimate	0.78	20	12	0.60	20	12	0.60	20	12	0.60	20	12	0.60	20	8	0.40	0.00	0.00	0.20
LCL	0.47			0.39			0.39			0.39			0.39			0.22	-0.28	-0.28	-0.10
UCL	1.23			0.78			0.78			0.78			0.78			0.61	0.28	0.28	0.46
Estimate	1.13	5	5	1.00	5	5	1.00	5	5	1.00	5	5	1.00	5	5	1.00	0.00	0.00	0.00
LCL	0.52			0.57			0.57			0.57			0.57			0.57	-0.43	-0.43	-0.43
UCL	2.45			1.00			1.00			1.00			1.00			1.00	0.43	0.43	0.43

Method Developer Matrix Study																			
Statistic	Concentration MPN/sample	Candidate Presumptive (CP)			Alternative Candidate Confirmed (CC)			Reference Candidate Confirmed (CC)			Candidate Method (C)			Reference Method (R)			dPOD ¹		
		N ²	x ³	POD (CP)	N	x	POD (CC)	N	x	POD (CC)	N	x	POD (C)	N	x	POD (R)	CP VS CC Alternative	CP VS CC Reference	C vs R
Estimate	0 (negative)	5	0	0.00	5	0	0.00	5	0	0.00	5	0	0.00	5	0	0.00	0.00	0.00	0.00
LCL ⁴	-			0.00			0.00			0.00			0.00			0.00	-0.43	-0.43	-0.43
UCL ⁵	-			0.43			0.43			0.43			0.43			0.43	0.43	0.43	0.43
Estimate	0.79	20	12	0.60	20	12	0.60	20	12	0.60	20	12	0.60	20	9	0.45	0.00	0.00	0.15
LCL	0.47			0.39			0.39			0.39			0.39			0.26	-0.28	-0.28	-0.15
UCL	1.27			0.78			0.78			0.78			0.78			0.66	0.28	0.28	0.41
Estimate	10.30	5	5	1.00	5	5	1.00	5	5	1.00	5	5	1.00	5	5	1.00	0.00	0.00	0.00
LCL	3.95			0.57			0.57			0.57			0.57			0.57	-0.43	-0.43	-0.43
UCL	26.80			1.00			1.00			1.00			1.00			1.00	0.43	0.43	0.43

¹dPOD, difference in Probability of Detection. If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level. ²N, number of replicates. ³x, number of positive test results. ⁴LCL, lower 95% confidence limit. ⁵UCL, upper 95% confidence limit.

Table 3. POD Results from the Analysis of *Listeria monocytogenes* ATCC 19118 in 25 g cured ham after 44 h enrichment time. (1)

Statistic	Concentration MPN/sample	Candidate Presumptive (CP)			Alternative Candidate Confirmed (CC)			Reference Candidate Confirmed (CC)			Candidate Method (C)			Reference Method (R)			dPOD ¹		
		N ²	x ³	POD (CP)	N	x	POD (CC)	N	x	POD (CC)	N	x	POD (C)	N	x	POD (R)	CP VS CC Alternative	CP VS CC Reference	C vs R
Estimate	0 (negative)	5	0	0.00	5	0	0.00	5	0	0.00	5	0	0.00	5	0	0.00	0.00	0.00	0.00
LCL ⁴	-			0.00			0.00			0.00			0.00			0.00	-0.43	-0.43	-0.43
UCL ⁵	-			0.43			0.43			0.43			0.43			0.43	0.43	0.43	0.43
Estimate	1.01	20	14	0.70	20	14	0.70	20	14	0.70	20	14	0.70	20	13	0.65	0.00	0.00	0.05
LCL	0.67			0.48			0.48			0.48			0.48			0.43	-0.27	-0.27	-0.23
UCL	1.56			0.85			0.85			0.85			0.85			0.82	0.27	0.27	0.32
Estimate	5.54	5	5	1.00	5	5	1.00	5	5	1.00	5	5	1.00	5	5	1.00	0.00	0.00	0.00
LCL	2.30			0.57			0.57			0.57			0.57			0.57	-0.43	-0.43	-0.43
UCL	13.36			1.00			1.00			1.00			1.00			1.00	0.43	0.43	0.43

¹dPOD, difference in Probability of Detection. If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level. ²N, number of replicates. ³x, number of positive test results. ⁴LCL, lower 95% confidence limit. ⁵UCL, upper 95% confidence limit.

Table 4. POD Results from the Analysis of *Listeria monocytogenes* SDI 15 (M15) in 25 g frozen breaded cooked chicken after 44 h enrichment time. (1)

Statistic	Concentration MPN/sample	Candidate Presumptive (CP)			Alternative Candidate Confirmed (CC)			Reference Candidate Confirmed (CC)			Candidate Method (C)			Reference Method (R)			dPOD ¹		
		N ²	x ³	POD (CP)	N	x	POD (CC)	N	x	POD (CC)	N	x	POD (C)	N	x	POD (R)	CP VS CC Alternative	CP VS CC Reference	C vs R
Estimate	0 (negative)	5	0	0.00	5	0	0.00	5	0	0.00	5	0	0.00	5	0	0.00	0.00	0.00	0.00
LCL ⁴	-			0.00			0.00			0.00			0.00			0.00	-0.43	-0.43	-0.43
UCL ⁵	-			0.43			0.43			0.43			0.43			0.43	0.43	0.43	0.43
Estimate	0.31	20	7	0.35	20	7	0.35	20	7	0.35	20	7	0.35	20	5	0.25	0.00	0.00	0.10
LCL	0.14			0.18			0.18			0.18			0.18			0.11	-0.28	-0.28	-0.18
UCL	0.54			0.57			0.57			0.57			0.57			0.47	0.28	0.28	0.36
Estimate	2.37	5	4	0.80	5	4	0.80	5	4	0.80	5	4	0.80	5	4	0.80	0.00	0.00	0.00
LCL	1.15			0.38			0.38			0.38			0.38			0.38	-0.47	-0.47	-0.47
UCL	4.90			1.00			1.00			1.00			1.00			1.00	0.47	0.47	0.47

¹dPOD, difference in Probability of Detection. If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level. ²N, number of replicates. ³x, number of positive test results. ⁴LCL, lower 95% confidence limit. ⁵UCL, upper 95% confidence limit.

Table 5. POD Results from the Analysis of *Listeria monocytogenes* ATCC 43256 in 25 g frozen cooked shrimp after 44 h enrichment time. (1)

Statistic	Concentration MPN/sample	Candidate Presumptive (CP)			Candidate Confirmed (CC)			Candidate (C)			Reference Method (R)			dPOD ¹	
		N ²	x ³	POD (CP)	N	x	POD (CC)	N	x	POD (C)	N	x	POD (R)	CP VS CC	C vs R
Estimate	0 (negative)	5	0	0.00	5	0	0.00	5	0	0.00	5	0	0.00	0.00	0.00
LCL ⁴	-			0.00			0.00			0.00			0.00	-0.43	-0.43
UCL ⁵	-			0.43			0.43			0.43			0.43	0.43	0.43
Estimate	1.63	20	15	0.75	20	16	0.80	20	15	0.75	20	11	0.55	-0.05	0.20
LCL	1.06			0.53			0.58			0.53			0.34	-0.30	-0.09
UCL	2.83			0.89			0.92			0.89			0.74	0.21	0.45
Estimate	10.30	5	5	1.00	5	5	1.00	5	5	1.00	5	5	1.00	0.00	0.00
LCL	3.95			0.57			0.57			0.57			0.57	-0.43	-0.43
UCL	26.80			1.00			1.00			1.00			1.00	0.43	0.43

¹dPOD, difference in Probability of Detection. If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level. ²N, number of replicates. ³x, number of positive test results. ⁴LCL, lower 95% confidence limit. ⁵UCL, upper 95% confidence limit.

Table 6. POD Results from the Analysis of *Listeria monocytogenes* SDI 16 in 25 mL ice cream after 44 h enrichment time. (1)

Statistic	Concentration MPN/sample	Candidate Presumptive (CP)			Alternative Candidate Confirmed (CC)			Reference Candidate Confirmed (CC)			Candidate Method (C)			Reference Method (R)			dPOD ¹		
		N ²	x ³	POD (CP)	N	x	POD (CC)	N	x	POD (CC)	N	x	POD (C)	N	x	POD (R)	CP VS CC Alternative	CP VS CC Reference	C vs I
Estimate	0 (negative)	5	0	0.00	5	0	0.00	5	0	0.00	5	0	0.00	5	0	0.00	0.00	0.00	0.00
LCL ⁴	-			0.00			0.00			0.00			0.00			0.00	-0.43	-0.43	-0.43
UCL ⁵	-			0.43			0.43			0.43			0.43			0.43	0.43	0.43	0.43
Estimate	0.50	20	14	0.70	20	14	0.70	20	14	0.70	20	14	0.70	20	8	0.40	0.00	0.00	0.30
LCL	0.25			0.48			0.48			0.48			0.48			0.22	-0.27	-0.27	-0.01
UCL	0.86			0.85			0.85			0.85			0.85			0.61	0.27	0.27	0.54
Estimate	16.33	5	5	1.00	5	5	1.00	5	5	1.00	5	5	1.00	5	5	1.00	0.00	0.00	0.00
LCL	5.75			0.57			0.57			0.57			0.57			0.57	-0.43	-0.43	-0.43
UCL	46.35			1.00			1.00			1.00			1.00			1.00	0.43	0.43	0.43

¹dPOD, difference in Probability of Detection. If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level. ²N, number of replicates. ³x, number of positive test results. ⁴LCL, lower 95% confidence limit. ⁵UCL, upper 95% confidence limit.

Table 7. POD Results from the Analysis of *Listeria monocytogenes* ATCC 51780 on stainless steel (containing 10-fold excess *Enterococcus faecalis* ATCC 19433) after 44 h enrichment time. (1)

Independent Laboratory Matrix Study															
Statistic	Concentration Target Spike/sample	Candidate Presumptive (CP)			Candidate Confirmed (CC)			Candidate Method (C)			Reference Method (R)			dPOD ¹	
		N ²	x ³	POD (CP)	N	x	POD (CC)	N	x	POD (C)	N	x	POD (R)	CP VS CC	C vs R
Estimate	0 (negative)	5	0	0.00	5	0	0.00	5	0	0.00	5	0	0.00	0.00	0.00
LCL ⁴	-			0.00			0.00			0.00			0.00	-0.43	-0.43
UCL ⁵	-			0.43			0.43			0.43			0.43	0.43	0.43
Estimate	60.00	20	11	0.55	20	11	0.55	20	11	0.55	20	8	0.40	0.00	0.15
LCL	-			0.34			0.34			0.34			0.22	-0.28	-0.15
UCL	-			0.74			0.74			0.74			0.61	0.28	0.41
Estimate	375.00	5	5	1.00	5	5	1.00	5	5	1.00	5	5	1.00	0.00	0.00
LCL	-			0.57			0.57			0.57			0.57	-0.43	-0.43
UCL	-			1.00			1.00			1.00			1.00	0.43	0.43
Method Developer Matrix Study															
Statistic	Concentration Target Spike/sample	Candidate Presumptive (CP)			Candidate Confirmed (CC)			Candidate Method (C)			Reference Method (R)			dPOD ¹	
		N ²	x ³	POD (CP)	N	x	POD (CC)	N	x	POD (C)	N	x	POD (R)	CP VS CC	C vs R
0	0 (negative)	5	0	0.00	5	0	0.00	5	0	0.00	5	0	0.00	0.00	0.00
LCL ⁴	-			0.00			0.00			0.00			0.00	-0.43	-0.43
UCL ⁵	-			0.43			0.43			0.43			0.43	0.43	0.43
0	6.00	20	12	0.60	20	11	0.55	20	11	0.55	20	9	0.45	0.05	0.10
LCL	-			0.39			0.34			0.34			0.26	-0.24	-0.19
UCL	-			0.78			0.74			0.74			0.66	0.33	0.37
0	60.00	5	5	1.00	5	5	1.00	5	5	1.00	5	4	0.80	0.00	0.20
LCL	-			0.57			0.57			0.57			0.38	-0.43	-0.28
UCL	-			1.00			1.00			1.00			1.00	0.43	0.62

¹dPOD, difference in Probability of Detection. If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level. ²N, number of replicates. ³x, number of positive test results. ⁴LCL, lower 95% confidence limit. ⁵UCL, upper 95% confidence limit.

Table 8. POD Results from the Analysis of *Listeria monocytogenes* (SDI 21) on plastic after 44 h enrichment time. (1)

Statistic	Concentration Target Spike/sample	Candidate Presumptive (CP)			Candidate Confirmed (CC)			Candidate (C)			Reference Method (R)			dPOD ¹	
		N ²	x ³	POD (CP)	N	x	POD (CC)	N	x	POD (C)	N	x	POD (R)	CP VS CC	C vs R
Estimate	0 (negative)	5	0	0.00	5	0	0.00	5	0	0.00	5	0	0.00	0.00	0.00
LCL ⁴	-			0.00			0.00			0.00			0.00	-0.43	-0.43
UCL ⁵	-			0.43			0.43			0.43			0.43	0.43	0.43
Estimate	33	20	14	0.70	20	14	0.70	20	14	0.70	20	8	0.40	0.00	0.30
LCL	-			0.48			0.48			0.48			0.22	-0.27	-0.01
UCL	-			0.85			0.85			0.85			0.61	0.27	0.54
Estimate	333	5	5	1.00	5	5	1.00	5	5	1.00	5	5	1.00	0.00	0.00
LCL	-			0.57			0.57			0.57			0.57	-0.43	-0.43
UCL	-			1.00			1.00			1.00			1.00	0.43	0.43

¹dPOD, difference in Probability of Detection. If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level. ²N, number of replicates. ³x, number of positive test results. ⁴LCL, lower 95% confidence limit. ⁵UCL, upper 95% confidence limit.

Table 12. Results from the Inclusivity Evaluation. (1)

Sample Number	Bacteria	Source	Strain Number	Serotype	RapidChek® <i>Listeria monocytogenes</i> Result in NextDay™ Broth	RapidChek® <i>Listeria monocytogenes</i> Result in NextDay™ Broth With Supplement
1	<i>Listeria monocytogenes</i>	ATCC ¹	19111	1/2C	+	+
2	<i>Listeria monocytogenes</i>	UVM ⁵	CWD1554	1/2A	+	+
3	<i>Listeria monocytogenes</i>	UVM ⁵	CWD1609	1/2A	+	+
4	<i>Listeria monocytogenes</i>	UVM ⁵	CWD1620	1/2A	+	+
5	<i>Listeria monocytogenes</i>	ATCC ¹	51772	1/2A	+	+
6	<i>Listeria monocytogenes</i>	ATCC ¹	15313	1/2A	+	+
7	<i>Listeria monocytogenes</i>	ATCC ¹	49594	1/2A	+	+
8	<i>Listeria monocytogenes</i>	UVM ⁵	CWD1601	1/2A	+	+
9	<i>Listeria monocytogenes</i>	UVM ⁵	CWD1612	1/2A	+	+
10	<i>Listeria monocytogenes</i>	UVM ⁵	CWD1613	1/2A	+	+
11	<i>Listeria monocytogenes</i>	UVM ⁵	CWD1614	1/2A	+	+
12	<i>Listeria monocytogenes</i>	UVM ⁵	CWD1618	1/2A	+	+
13	<i>Listeria monocytogenes</i>	UVM ⁵	CWD1629	1/2A	+	+
14	<i>Listeria monocytogenes</i>	UVM ⁵	CWD1630	1/2A	+	+
15	<i>Listeria monocytogenes</i>	UVM ⁵	CWD1611	1/2A	+	+
16	<i>Listeria monocytogenes</i>	UVM ⁵	CWD1626	1/2B	+	+
17	<i>Listeria monocytogenes</i>	UVM ⁵	CWD1627	1/2B	+	+
18	<i>Listeria monocytogenes</i>	ATCC ¹	51780	1/2B	+	+
19	<i>Listeria monocytogenes</i>	ATCC ¹	BAA-751	1/2B	+	+
20	<i>Listeria monocytogenes</i>	UVM ⁵	CWD1561	1/2B	+	+
21	<i>Listeria monocytogenes</i>	UVM ⁵	CWD1584	1/2B	+	+
22	<i>Listeria monocytogenes</i>	UVM ⁵	CWD1588	1/2B	+	+
23	<i>Listeria monocytogenes</i>	UVM ⁵	CWD1597	1/2B	+	+
24	<i>Listeria monocytogenes</i>	UVM ⁵	CWD1553	1/2C	+	+
25	<i>Listeria monocytogenes</i>	ATCC ¹	7644	1/2C	+	+
26	<i>Listeria monocytogenes</i>	ATCC ¹	19112	2	+	+
27	<i>Listeria monocytogenes</i>	ATCC ¹	19113	3	+	+
28	<i>Listeria monocytogenes</i>	ATCC ¹	51782	3A	+	+
29	<i>Listeria monocytogenes</i>	UVM ⁵	CWD1600	3B	+	+
30	<i>Listeria monocytogenes</i>	UVM ⁵	CWD1586	3B	+	+
31	<i>Listeria monocytogenes</i>	Cornell ²	FSL J1-049	3C	+	+
32	<i>Listeria monocytogenes</i>	ATCC ¹	19114	4A	+	+
33	<i>Listeria monocytogenes</i>	Cornell ²	FSL J1-129	4AB	+	+
34	<i>Listeria monocytogenes</i>	UVM ⁵	CWD1563	4B	+	+
35	<i>Listeria monocytogenes</i>	UVM ⁵	CWD1567	4B	+	+
36	<i>Listeria monocytogenes</i>	UVM ⁵	CWD1571	4B	+	+
37	<i>Listeria monocytogenes</i>	UVM ⁵	CWD1590	4B	+	+
38	<i>Listeria monocytogenes</i>	ATCC ¹	51778	4B	+	+
39	<i>Listeria monocytogenes</i>	Cornell ²	FSL F6-366	4B	+	+
40	<i>Listeria monocytogenes</i>	ATCC ¹	13932	4B	+	+
41	<i>Listeria monocytogenes</i>	ATCC ¹	19115	4B	+	+
42	<i>Listeria monocytogenes</i>	ATCC ¹	43256	4B	+	+
43	<i>Listeria monocytogenes</i>	QL ⁴	030911-10	4B	+	+
44	<i>Listeria monocytogenes</i>	UVM ⁵	CWD1574	4B	+	+
45	<i>Listeria monocytogenes</i>	UVM ⁵	CWD1596	4B	+	+
46	<i>Listeria monocytogenes</i>	ATCC ¹	19116	4C	+	+
47	<i>Listeria monocytogenes</i>	ATCC ¹	19117	4D	+	+
48	<i>Listeria monocytogenes</i>	ATCC ¹	19118	4E	+	+
49	<i>Listeria monocytogenes</i>	NCTC ³	10890	7	+	+
50	<i>Listeria monocytogenes</i>	ATCC ¹	BAA-2658	N/A	+	+

¹ATCC - American Type Culture Collection

²Cornell - Cornell University

³NCTC - National Culture Type Collection

⁴QL –Q Laboratories Culture Collection

⁵UVM - University of Vermont

Table 13. Results from the RapidChek® *Listeria* NextDay™ Broth Exclusivity Evaluation. (1)

Sample Number	Bacteria	Source	Strain Number	Serotype	RapidChek® <i>Listeria monocytogenes</i> Test Strip in Non-Selective Broth Result	RapidChek® <i>Listeria monocytogenes</i> Test Strip in RapidChek® <i>Listeria</i> ™ NextDay Broth Re-analysis Result ³
1	<i>L. grayi</i>	ATCC ¹	19120		-	
2	<i>L. innocua</i>	ATCC ¹	33090	6a	-	
3	<i>L. ivanovii</i>	ATCC ¹	19119	5	-	
4	<i>L. marthii</i>	ATCC ¹	BAA-1595		+	+
5	<i>L. rocourtiae</i>	Cornell ²	FSL F6-0920		-	
6	<i>L. welshimeri</i>	ATCC ¹	35897	6b	-	
7	<i>L. seeligeri</i>	ATCC ¹	35967	1/2b	-	
8	<i>Acinetobacter baumannii</i>	ATCC ¹	19606		-	
9	<i>Aeromonas hydrophila</i>	ATCC ¹	49140		-	
10	<i>Bacillus cereus</i>	ATCC ¹	6464		+	-
11	<i>Bacillus mycoides</i>	ATCC ¹	6462		-	
12	<i>Bacillus subtilis</i>	ATCC ¹	27370		-	
13	<i>Bacillus licheniformis</i>	ATCC ¹	12759		-	
14	<i>Brochothrix thermosphacta</i>	ATCC ¹	11509		-	
15	<i>Enterobacter cloacae</i>	ATCC ¹	23355		-	
16	<i>Enterococcus durans</i>	ATCC ¹	19432		-	
17	<i>Enterococcus faecalis</i>	ATCC ¹	19433		-	
18	<i>Escherichia coli</i>	ATCC ¹	35150	O157:H7	-	
19	<i>Lactobacillus acidophilus</i>	ATCC ¹	314		+	-
20	<i>Lactobacillus plantarum</i>	ATCC ¹	8014		+	-
21	<i>Lactococcus lactis</i>	ATCC ¹	4797		+	-
22	<i>Pseudomonas aeruginosa</i>	ATCC ¹	27853		-	
23	<i>Rhodococcus equi</i>	ATCC ¹	6939		-	
24	<i>Salmonella</i> Typhimurium	ATCC ¹	14028	B	-	
25	<i>Staphylococcus aureus</i>	ATCC ¹	29213		+	-
26	<i>Staphylococcus saprophyticus</i>	ATCC ¹	15305		-	
27	<i>Staphylococcus epidermidis</i>	ATCC ¹	12228		-	
28	<i>Staphylococcus haemolyticus</i>	ATCC ¹	29970		-	
29	<i>Staphylococcus hominis</i>	ATCC ¹	27844		-	
30	<i>Staphylococcus warneri</i>	ATCC ¹	29885		-	
31	<i>Streptococcus mutans</i>	ATCC ¹	25175		-	
32	<i>Streptococcus pyogenes</i>	ATCC ¹	19615		-	

¹ATCC - American Type Culture Collection

²Cornell - Cornell University

³Exclusivity organisms that produced a positive result were reanalyzed after being cultured in *Listeria* NextDay Broth

Table 14. Results from the RapidChek® *Listeria* NextDay™ Broth with RapidChek® *Listeria* Supplement Exclusivity Evaluation. (1)

Sample Number	Bacteria	Source	Strain Number	Serotype	RapidChek® <i>Listeria monocytogenes</i> Test Strip in Non-Selective Broth Result	RapidChek® <i>Listeria monocytogenes</i> Test Strip in RapidChek® <i>Listeria</i> ™ NextDay Broth with Supplement Result
1	<i>L. grayi</i>	ATCC ¹	19120		-	-
2	<i>L. innocua</i>	ATCC ¹	33090	6a	-	-
3	<i>L. ivanovii</i>	ATCC ¹	19119	5	-	-
4	<i>L. marthii</i>	ATCC ¹	BAA-1595		+	+
5	<i>L. rocourtiae</i>	Cornell ²	FSL F6-0920		-	-
6	<i>L. welshimeri</i>	ATCC ¹	35897	6b	-	-
7	<i>L. seeligeri</i>	ATCC ¹	35967	1/2b	-	-
10	<i>Bacillus cereus</i>	ATCC ¹	6464		-	-
17	<i>Enterococcus faecalis</i>	ATCC ¹	19433		-	-
19	<i>Lactobacillus acidophilus</i>	ATCC ¹	314		-	-
20	<i>Lactobacillus plantarum</i>	ATCC ¹	8014		+	-
21	<i>Lactococcus lactis</i>	ATCC ¹	4797		-	-
23	<i>Rhodococcus equi</i>	ATCC ¹	6939		-	-
25	<i>Staphylococcus aureus</i>	ATCC ¹	29213		-	-
32	<i>Streptococcus pyogenes</i>	ATCC ¹	19615		-	-

¹ATCC - American Type Culture Collection²Cornell - Cornell University

REFERENCES CITED

- Juck, G., Gonzalez, V., Allen, A.C.O., Sutzko, M., Seward, K., and Muldoon, M.T., Romer Labs RapidChek® *Listeria monocytogenes* Test System for Detection of *L. monocytogenes* on Selected Foods and Environmental Surfaces, AOAC® Performance TestedSM certification number 011805.
- Peccio, A., Autio, T., Kokeala, H., Rosminir, R., and Trevisnai, M. (2003) *L. monocytogenes* occurrence and characterization in meat processing plants. *Letter Appl. Microbiol.* **37**, 234-238.
- Miethinen, M.K., Palma, L., Bjorkroth, K.J., and Korkeala, H. (2001) Prevalence of *L. monocytogenes* in broilers at the abattoir, processing plant, and retail level. *J. Food Protect.* **64**, 994-999.
- Cox, L.J., Kleiss, T., Cordier, L., Cordellana, C., Knokel, P., Pedrazzini, C., Beumer, R., and Siebenga, A. (1989) *Listeria* species in the food processing, non food and domestic environments. *Food Microbiol.* **6**, 49-61.
- Schuchat, A., Swaminathan, B., and Broome, C.V. (1991) Epidemiology of human listeriosis. *Clin. Microbiol. Rev.* **4**, 169-183.
- Orsi, R.H. and Wiedmann, M. (2016) Characteristics and distribution of *Listeria* spp., including *Listeria* species newly described since 2009. *Appl. Microbiol. Biotechnol.* **100**, 5273-5287.
- Scallan E., Hoekstra R.M., Angulo, F.J., Tauxe, R.V., Widdowson, M.A., Roy, S.L., Jones, J.L., Griffin, P.M. (2011) Foodborne Illness Acquired in the United States – Major Pathogens. *Emerging Infectious Diseases.* **17** (1), 7-15.
- Doganay, M. (2003) Listeriosis: clinical presentation. *FEMS Immunol. Med. Microbiol.* **35**, 173-175.
- U.S. Department of Agriculture. Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products; Final Rule. (2003) *Federal Register* **68**, 34207-34254.
- U.S. Department of Agriculture. Not Applying the Mark of Inspection Pending Certain Test Results. (2011) *Federal Register* **76**, 19952-19970.
- US Department of Agriculture, Food Safety and Inspection Service. Microbiological Laboratory Guidelines. Chapter 8.10. *Isolation and Identification of Listeria monocytogenes from Red Meat, Poultry, Ready-To-Eat Siluriformes (Fish) and Egg Products, and Environmental Samples.* January 2nd, 2017. <http://www.fsis.usda.gov/wps/wcm/connect/1710bee8-76b9-4e6c-92fc-fdc290dbfa92/MLG-8.pdf?MOD=AJPERES>
- Food and Drug Administration Bacteriological Analytical Manual Chapter 10. *Detection and Enumeration of Listeria monocytogenes in Foods.* March, 2017. <http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm071400.htm>
- AOAC Official Method 993.12. *Listeria monocytogenes* in Milk and Dairy Products. 1996. <http://www.eoma.aoac.org/methods/info.asp?ID=48309>
- Anderson, G. and Scott, M. (1991) Determination of Product Shelf Life and Activation Energy for Five Drugs of Abuse. *Clin. Chem.* **37/3**, 398-402.
- Graves, L.M., Helsel, L.O., Steigerwalt, A.G., Morey, R.E., Daneshvar, M.I., Roof, S.E., Orsi, R.H., Fortes, E.D., Milillo, S.R., den Bakker, H. C., Wiedmann, M., Swaminathan, B., and Sauders, B. D. (2010) *Listeria marthii* sp. nov., isolated from the natural environment, Finger Lakes National Forest. *Intl. J. Syst. Evol. Microbiol.* **60**, 1280-1288.