



# CERTIFICATION

## AOAC® *Performance Tested*<sup>SM</sup>

Certificate No.

**091901**

The AOAC Research Institute hereby certifies that the performance of the test kit known as:

### **Clear Safety *Listeria***

manufactured by

**Clear Labs, Inc.**

**3565 Haven Ave, Suite 2**

**Menlo Park, CA 94025**

**USA**

This method has been evaluated in the AOAC® *Performance Tested Methods*<sup>SM</sup> 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 Tested*<sup>SM</sup> 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 (September 04, 2019 – December 31, 2020). Renewal may be granted at the end of one year under the rules stated in the licensing agreement.

*Scott Coates*

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Scott Coates, Senior Director  
Signature for AOAC Research Institute

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September 04, 2019

Date

<b>METHOD AUTHORS</b> Stephanie Pollard, Atul Singh, Andrew Lin, James Maloney, Anay Campos, Ramin Khaksar, Benjamin Bastin, Wesley Thompson, M. Joseph Benzinger, Jr., and James Agin	<b>SUBMITTING COMPANY</b> Clear Labs, Inc. 3565 Haven Ave, Suite 2 Menlo Park, CA 94025
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<b>KIT NAME(S)</b> Clear Safety <i>Listeria</i>	<b>CATALOG NUMBERS</b> CL-LIS-096
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<b>INDEPENDENT LABORATORY</b> Q Laboratories, Inc. 1930 Radcliff Dr. Cincinnati, OH 45204	<b>AOAC EXPERTS AND PEER REVIEWERS</b> Yi Chen <sup>1</sup> , Yvonne Salfinger <sup>2</sup> , Elliot Ryser <sup>3</sup> <sup>1</sup> FDA CFSAN, College Park, MD, USA <sup>2</sup> Independent Consultant, Tallahassee, FL, USA <sup>3</sup> Michigan State University, East Lansing, MI, USA
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<b>APPLICABILITY OF METHOD</b> <b>Analyte – <i>Listeria monocytogenes</i> and <i>Listeria</i> spp. (<i>Listeria monocytogenes</i>, <i>Listeria innocua</i>, <i>Listeria ivanovii</i>, <i>Listeria marthii</i>, <i>Listeria grayi</i>, <i>Listeria welshimeri</i>, and <i>Listeria seeligen</i>)</b>  <b>Matrices – (MLG 8.11) hot dogs (125 g) (FDA BAM Ch 10) -stainless steel (4x4 in sponge), plastic (4x4 in sponge), ceramic (4x4 in sponge), sealed concrete (4x4 in sponge)</b>  <b>Performance claims - The Clear Safety <i>Listeria</i> method is statistically equivalent to the U. S. Department of Agriculture-Food Safety and Inspection Service (FSIS) <i>Microbiology Laboratory Guidebook</i> (MLG), 8.11, <i>Isolation and Identification of Listeria monocytogenes from Red Meat, Poultry, Ready-To-Eat Siluriformes (Fish) and Egg Products, and Environmental Samples</i> (2) for hot dog matrix and the U. S. Food &amp; Drug Administration Bacteriological Analytical Manual (FDA/BAM) Chapter 10: <i>Detection of Listeria monocytogenes in Foods and Environmental Samples, and Enumeration of Listeria monocytogenes in Foods</i> (3) reference culture methods for the environmental surfaces (stainless steel, plastic, ceramic, and sealed concrete).</b>	<b>REFERENCE METHODS</b> U. S. Department of Agriculture-Food Safety and Inspection Service (FSIS) <i>Microbiology Laboratory Guidebook</i> (MLG), 8.11, <i>Isolation and Identification of Listeria monocytogenes from Red Meat, Poultry, Ready-To-Eat Siluriformes (Fish) and Egg Products, and Environmental Samples</i> . Effective Date: 1/02/19 <a href="https://www.fsis.usda.gov/wps/wcm/connect/1710bee8-76b9-4e6c-92fc-fdc290dbfa92/MLG-8.pdf?MOD=AJPERES">https://www.fsis.usda.gov/wps/wcm/connect/1710bee8-76b9-4e6c-92fc-fdc290dbfa92/MLG-8.pdf?MOD=AJPERES</a> . (Accessed June 2019) (2) U. S. Food & Drug Administration Bacteriological Analytical Manual (FDA/BAM) Chapter 10: <i>Detection of Listeria monocytogenes in Foods and Environmental Samples, and Enumeration of Listeria monocytogenes in Foods</i> . Revised: March 2017. <a href="https://www.fda.gov/food/laboratory-methods-food/bam-detection-and-enumeration-listeria-monocytogenes">https://www.fda.gov/food/laboratory-methods-food/bam-detection-and-enumeration-listeria-monocytogenes</a> (Accessed June 2019) (3)
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<b>ORIGINAL CERTIFICATION DATE</b> September 04, 2019	<b>CERTIFICATION RENEWAL RECORD</b> New Approval 2019
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<b>METHOD MODIFICATION RECORD</b> NONE	<b>SUMMARY OF MODIFICATION</b> NONE
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<b>Under this AOAC® Performance Tested<sup>SM</sup> License Number, 091901 this method is distributed by:</b> NONE	<b>Under this AOAC® Performance Tested<sup>SM</sup> License Number, 091901 this method is distributed as:</b> NONE
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**PRINCIPLE OF THE METHOD (1)**  
The Clear Safety *Listeria* assay is a molecular method that combines nucleic acid amplification and Next Generation Sequencing (NGS) on an automated platform, enabling targeted identification of foodborne pathogens in an enrichment medium via sequence analysis and alignment of genomic regions with a proprietary reference database.  
Clear Safety *Listeria* is designed for detection of *Listeria* spp. including *Listeria monocytogenes*, *Listeria grayi*, *Listeria innocua*, *Listeria ivanovii*, *Listeria marthii*, *Listeria seeligeri*, and *Listeria welshimeri* in select food and environmental surface samples. After enriching environmental sponge samples for 22-48 h and hot dog samples for 26-30 h, sub-samples are added to transfer tubes and loaded onto the automated platform for analysis or analyzed manually.

#### DISCUSSION OF THE VALIDATION STUDY (1)

The Clear Safety *Listeria* Method successfully detected *Listeria* spp. and *Listeria monocytogenes* in 125 g test portions of hot dogs after 26 h of enrichment using the manual and automated methods with equivalent results for both methods. Additionally, the Clear Safety *Listeria* Method successfully detected *Listeria* spp. and *Listeria monocytogenes* in stainless steel, plastic, sealed concrete, and ceramic environmental sponge samples after both 22 and 48 h of enrichment using the manual and automated methods with equivalent results for both methods. Using POD analysis, no statistically significant differences were observed between the number of positive samples detected by the candidate methods and the reference method for all samples tested. The Independent Laboratory matrix study data corroborated the method developer data for hot dogs and stainless steel surfaces for both the manual and automated methods using different *Listeria* strains. Both the *L. monocytogenes* and *L. innocua* strains used in the method developer studies had a higher degree of injury following the same heat stress protocol without impacting Clear Safety *Listeria* detection resulting in 100% match with culture confirmation results with each sample. The matrix study results also confirm that the Clear Safety *Listeria* Method can accurately detect *L. monocytogenes* in the presence of other *Listeria* spp. In addition, the Clear Safety *Listeria* Method accurately detected the target analyte(s) and correctly excluded all non-target organisms in the inclusivity and exclusivity evaluation.

The product consistency and stability study revealed no differences in results across three different retention lots of reagent kits spanning the entirety of the claimed shelf-life for each kit. The robustness studies showed equivalent results across variations of sample treatment volume and aliquot volume for PCR treatment combinations, indicating that the assay is robust to sample treatment volume changes of  $\pm 1 \mu\text{L}$  and PCR aliquot volume changes of  $\pm 1 \mu\text{L}$ . However, enrichment temperature variations did result in greater *L. monocytogenes* recovery with an incubation at  $37 \pm 1^\circ\text{C}$  as compared to incubation at  $30 \pm 1^\circ\text{C}$  or  $35 \pm 1^\circ\text{C}$ . This result is surprising given that *L. monocytogenes* can grow between temperatures of 1-45°C with an optimal temperature of 30-37°C (12), indicating that the difference in 30, 35, and 37°C incubation temperatures is not expected to impact recovery rate. Given the widely-accepted knowledge of the growth and recovery of *Listeria* across a wide temperature range and the fact that recovery of *Listeria* spp. was not significantly impacted by the incubation temperature variations, the method developers have elected to keep the recommended incubation temperature of  $35 \pm 1^\circ\text{C}$ .

Clear Safety *Listeria* Method provides accurate and reliable results. The data generated from the validation showed the sensitivity and specificity of the method by producing zero false positive results and zero false negative results during the validation. However, because of the numerous steps, the manual method does require a skilled laboratory technician for proper method execution.

## Original Validation Data

Table 1. Clear Safety detection presumptive result vs. confirmed result: POD analysis (1)

Matrix (test portion)	Strains	MPN per test portion <sup>b</sup>	N <sup>c</sup>	Analysis	Clear Safety Presumptive <sup>a</sup>				Confirmed				
					Time, h	x <sup>d</sup>	POD <sub>CP</sub> <sup>e</sup>	95% CI <sup>f</sup>	x	POD <sub>CC</sub> <sup>g</sup>	95% CI	dPOD <sub>CP</sub> <sup>h</sup>	95% CI <sup>i</sup>
Hot dogs (125 g) <sup>j</sup>	<i>L. monocytogenes</i> 4b (CWD 1563)	-	5	<i>L. monocytogenes</i>	26	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>L. innocua</i> (CWD 663)	0.50 (0.25, 0.86)	20			7	0.35	0.18, 0.57	7	0.35	0.18, 0.57	0.00	-0.13, 0.13
		3.70 (1.52, 9.02)	5			5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Hot dogs (125 g) <sup>j</sup>	<i>L. monocytogenes</i> 4b (CWD 1563)	-	5	<i>Listeria. spp.</i>	26	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>L. innocua</i> (CWD 663)	0.50 (0.25, 0.86)	20			12	0.60	0.39, 0.78	12	0.60	0.39, 0.78	0.00	-0.13, 0.13
		3.70 (1.52, 9.02)	5			5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Hot dogs (125 g)	<i>L. monocytogenes</i> 4b (Cornell/ILSI FSL J1-110)	0	5	<i>L. monocytogenes</i>	26	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>L. innocua</i> (Cornell/ILSI FSL C2-008)	0.62 (0.34, 1.04)	20			5	0.25	0.11, 0.47	5	0.25	0.11, 0.47	0.00	-0.28, 0.28
		9.25 (3.8, 22.55)	5			5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Hot dogs (125 g)	<i>L. monocytogenes</i> 4b (Cornell/ILSI FSL J1-110)	0	5	<i>Listeria. spp.</i>	26	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>L. innocua</i> (Cornell/ILSI FSL C2-008)	0.62 (0.34, 1.04)	20			10	0.50	0.30, 0.70	10	0.50	0.30, 0.70	0.00	-0.28, 0.28
		9.25 (3.8, 22.55)	5			5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43

<sup>a</sup>Both manual and automated results were equivalent so they are not distinguished in this table.

<sup>b</sup>MPN is calculated using the LCF MPN calculator version 1.6 provided by AOAC Research Institute, with 95% confidence intervals indicated in parentheses.

<sup>c</sup>n = Number of test portions.

<sup>d</sup>x = Number of positive test portions.

<sup>e</sup>POD<sub>CP</sub> = Candidate method presumptive outcomes divided by total number of trials.

<sup>f</sup>CI = Confidence interval.

<sup>g</sup>POD<sub>CC</sub> = Candidate method confirmed positive outcomes divided by the total number of trials.

<sup>h</sup>dPOD<sub>CP</sub> = Difference between the candidate method presumptive result and candidate method confirmed result POD values

<sup>i</sup>If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

<sup>j</sup>Matrix study was performed by Independent Laboratory

Table 2. Clear Safety *Listeria* detection result vs reference method: POD analysis (1)

Matrix (test portion)	Strains	MPN per test portion <sup>b</sup>	N <sup>c</sup>	Analysis	Clear Safety <sup>g</sup>				Reference				
					Time, h	x <sup>d</sup>	POD <sub>c</sub> <sup>e</sup>	95% CI <sup>f</sup>	x	POD <sub>r</sub> <sup>g</sup>	95% CI	dPOD <sub>c</sub> <sup>h</sup>	95% CI <sup>i</sup>
Hot dogs (125 g) <sup>j</sup>	<i>L. monocytogenes</i> 4b (CWD 1563) <i>L. innocua</i> (CWD 663)	-	5	<i>L. monocytogenes</i>	26	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.50 (0.25, 0.86)	20			7	0.35	0.18, 0.57	6	0.30	0.11, 0.47	0.05	-0.18, 0.47
		3.70 (1.52, 9.02)	5			5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Hot dogs (125 g) <sup>j</sup>	<i>L. monocytogenes</i> 4b (CWD 1563) <i>L. innocua</i> (CWD 663)	-	5	<i>Listeria. spp.</i>	26	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.50 (0.25, 0.86)	20			12	0.60	0.39, 0.78	10	0.50	0.30, 0.70	0.10	-0.19, 0.37
		3.70 (1.52, 9.02)	5			5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Hot dogs (125 g) <sup>j</sup>	<i>L. monocytogenes</i> 4b (Cornell/ILSI FSL J1-110) <i>L. innocua</i> (Cornell/ILSI FSL C2-008)	0	5	<i>L. monocytogenes</i>	26	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.62 (0.34, 1.04)	20			5	0.25	0.11, 0.47	4	0.20	0.08, 0.42	0.05	-0.21, 0.30
		9.25 (3.8, 22.55)	5			5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Hot dogs (125 g) <sup>j</sup>	<i>L. monocytogenes</i> 4b (Cornell/ILSI FSL J1-110) <i>L. innocua</i> (Cornell/ILSI FSL C2-008)	0	5	<i>Listeria. spp.</i>	26	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.62 (0.34, 1.04)	20			10	0.50	0.30, 0.70	9	0.45	0.26, 0.66	0.05	-0.24, 0.33
		9.25 (3.8, 22.55)	5			5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43

<sup>a</sup>Both manual and automated results were equivalent so they are not distinguished in this table.

<sup>b</sup>MPN is calculated using the LCF MPN calculator version 1.6 provided by AOAC Research Institute, with 95% confidence intervals indicated in parentheses.

<sup>c</sup>n = Number of test portions.

<sup>d</sup>x = Number of positive test portions.

<sup>e</sup>POD<sub>c</sub> = Confirmed candidate method positive outcomes divided by total number of trials.

<sup>f</sup>CI = Confidence interval.

<sup>g</sup>POD<sub>r</sub> = Reference method confirmed positive outcomes divided by the total number of trials.

<sup>h</sup>dPOD<sub>c</sub> = Difference between the candidate method and the reference method POD values.

<sup>i</sup>If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

<sup>j</sup>Matrix study was performed by Independent Laboratory

Table 3. Clear Safety detection presumptive result vs. confirmed result: POD analysis (1)

Surface type	Strains	CFU / Test		Analysis	Clear Safety Presumptive <sup>a</sup>				Confirmed		dPOD <sub>CP</sub> <sup>h</sup>	95% CI <sup>i</sup>	
		area <sup>b</sup>	N <sup>c</sup>		Time, h	x <sup>d</sup>	POD <sub>CP</sub> <sup>e</sup>	95% CI <sup>f</sup>	x	POD <sub>CC</sub> <sup>g</sup>			95% CI
Stainless steel <sup>l</sup>	<i>L. monocytogenes</i> 1/2a (ATCC 51772)	-	5	<i>L. monocytogenes</i>	22	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>L. ivanovii</i> (ATCC BAA-139)	32	20			7	0.35	0.18, 0.57	7	0.35	0.18, 0.57	0.00	-0.13, 0.13
	<i>E. faecalis</i> (ATCC 33186)	160	5			5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Stainless steel <sup>l</sup>	<i>L. monocytogenes</i> 1/2a (ATCC 51772)	-	5	<i>Listeria</i> spp.	22	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>L. ivanovii</i> (ATCC BAA-139)	32	20			12	0.60	0.39, 0.78	12	0.60	0.39, 0.78	0.00	-0.13, 0.13
	<i>E. faecalis</i> (ATCC 33186)	160	5			5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Stainless steel <sup>l</sup>	<i>L. monocytogenes</i> 1/2a (ATCC 51772)	-	5	<i>L. monocytogenes</i>	48	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>L. ivanovii</i> (ATCC BAA-139)	32	20			7	0.35	0.18, 0.57	7	0.35	0.18, 0.57	0.00	-0.13, 0.13
	<i>E. faecalis</i> (ATCC 33186)	160	5			5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Stainless steel <sup>l</sup>	<i>L. monocytogenes</i> 1/2a (ATCC 51772)	-	5	<i>Listeria</i> spp.	48	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>L. ivanovii</i> (ATCC BAA-139)	32	20			12	0.60	0.39, 0.78	12	0.60	0.39, 0.78	0.00	-0.13, 0.13
	<i>E. faecalis</i> (ATCC 33186)	160	5			5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Stainless steel	<i>L. monocytogenes</i> 1/2a (ATCC 15313)	0	5	<i>L. monocytogenes</i>	22	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>L. ivanovii</i> (ATCC 19119)	Approx. 20	20			8	0.40	0.22, 0.61	8	0.40	0.22, 0.61	0.00	-0.28, 0.28
	<i>E. faecalis</i> (ATCC 33186)	Approx. 40	5			5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Stainless steel	<i>L. monocytogenes</i> 1/2a (ATCC 15313)	0	5	<i>Listeria</i> spp.	22	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>L. ivanovii</i> (ATCC 19119)	Approx. 20	20			12	0.60	0.39, 0.78	12	0.60	0.39, 0.78	0.00	-0.28, 0.28
	<i>E. faecalis</i> (ATCC 33186)	Approx. 40	5			5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Stainless steel	<i>L. monocytogenes</i> 1/2a (ATCC 15313)	0	5	<i>L. monocytogenes</i>	48	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>L. ivanovii</i> (ATCC 19119)	Approx. 20	20			8	0.40	0.22, 0.61	8	0.40	0.22, 0.61	0.00	-0.28, 0.28
	<i>E. faecalis</i> (ATCC 33186)	Approx. 40	5			5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Stainless steel	<i>L. monocytogenes</i> 1/2a (ATCC 15313)	0	5	<i>Listeria</i> spp.	48	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>L. ivanovii</i> (ATCC 19119)	Approx. 20	20			12	0.60	0.39, 0.78	12	0.60	0.39, 0.78	0.00	-0.28, 0.28
	<i>E. faecalis</i> (ATCC 33186)	Approx. 40	5			5	1.00	0.57, 1.0	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Plastic	<i>L. monocytogenes</i> 3b (Cornell/ILSI FSL J1-169)	0	5	<i>L. monocytogenes</i>	22	0	0.00	0.0, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43

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	<i>L. marthii</i> (Cornell/ILSI FSL S4-965L)	Approx. 20	20			6	0.30	0.15, 0.52	6	0.30	0.15, 0.52	0.00	-0.28, 0.28
		Approx. 40	5			5	1.00	0.57, 1.0	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Plastic	<i>L. monocytogenes</i> 3b (Cornell/ILSI FSL J1-169)	0	5			0	0.00	0.0, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>L. marthii</i> (Cornell/ILSI FSL S4-965L)	Approx. 20	20	<i>Listeria</i> spp.	22	10	0.50	0.30, 0.70	10	0.50	0.30, 0.70	0.00	-0.28, 0.28
		Approx. 40	5			5	1.00	0.57, 1.0	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Plastic	<i>L. monocytogenes</i> 3b (Cornell/ILSI FSL J1-169)	0	5			0	0.00	0.0, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>L. marthii</i> (Cornell/ILSI FSL S4-965L)	Approx. 20	20	<i>L. monocytogenes</i>	48	6	0.30	0.15, 0.52	6	0.30	0.15, 0.52	0.00	-0.28, 0.28
		Approx. 40	5			5	1.00	0.57, 1.0	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Plastic	<i>L. monocytogenes</i> 3b (Cornell/ILSI FSL J1-169)	0	5			0	0.00	0.0, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>L. marthii</i> (Cornell/ILSI FSL S4-965L)	Approx. 20	20	<i>Listeria</i> spp.	48	10	0.50	0.30, 0.70	10	0.50	0.30, 0.70	0.00	-0.28, 0.28
		Approx. 40	5			5	1.00	0.57, 1.0	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Sealed concrete	<i>L. monocytogenes</i> 1/2b (Cornell/ILSI FSL J2-064)	0	5			0	0.00	0.0, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>L. welshimeri</i> (Cornell/ILSI FSL H6-105)	Approx. 20	20	<i>L. monocytogenes</i>	22	6	0.30	0.15, 0.52	6	0.30	0.15, 0.52	0.00	-0.28, 0.28
		Approx. 40	5			5	1.00	0.57, 1.0	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Sealed concrete	<i>L. monocytogenes</i> 1/2b (Cornell/ILSI FSL J2-064)	0	5			0	0.00	0.0, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>L. welshimeri</i> (Cornell/ILSI FSL H6-105)	Approx. 20	20	<i>Listeria</i> spp.	22	14	0.70	0.48, 0.85	14	0.70	0.48, 0.85	0.00	-0.28, 0.28
		Approx. 40	5			5	1.00	0.57, 1.0	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Sealed concrete	<i>L. monocytogenes</i> 1/2b (Cornell/ILSI FSL J2-064)	0	5			0	0.00	0.0, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>L. welshimeri</i> (Cornell/ILSI FSL H6-105)	Approx. 20	20	<i>L. monocytogenes</i>	48	6	0.30	0.15, 0.52	6	0.30	0.15, 0.52	0.00	-0.28, 0.28
		Approx. 40	5			5	1.00	0.57, 1.0	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Sealed concrete	<i>L. monocytogenes</i> 1/2b (Cornell/ILSI FSL J2-064)	0	5			0	0.00	0.0, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>L. welshimeri</i> (Cornell/ILSI FSL H6-105)	Approx. 20	20	<i>Listeria</i> spp.	48	14	0.70	0.48, 0.85	14	0.70	0.48, 0.85	0.00	-0.28, 0.28
		Approx. 40	5			5	1.00	0.57, 1.0	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Ceramic	<i>L. monocytogenes</i> 4c (Cornell/ILSI W1-110)	0	5			0	0.00	0.0, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>L. seeligeri</i> (Cornell/ILSI FSL H6-169)	Approx. 20	20	<i>L. monocytogenes</i>	22	8	0.40	0.22, 0.61	8	0.40	0.22, 0.61	0.00	-0.28, 0.28
		Approx. 40	5			5	1.00	0.57, 1.0	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Ceramic	<i>L. monocytogenes</i> 4c (Cornell/ILSI W1-110)	0	5			0	0.00	0.0, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>L. seeligeri</i> (Cornell/ILSI FSL H6-169)	Approx. 20	20	<i>Listeria</i> spp.	22	11	0.55	0.34, 0.74	11	0.55	0.34, 0.74	0.00	-0.28, 0.28
		Approx. 40	5			5	1.00	0.57, 1.0	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Ceramic	<i>L. monocytogenes</i> 4c (Cornell/ILSI W1-110)	0	5			0	0.00	0.0, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>L. seeligeri</i> (Cornell/ILSI FSL H6-169)	Approx. 20	20	<i>L. monocytogenes</i>	48	8	0.40	0.22, 0.61	8	0.40	0.22, 0.61	0.00	-0.28, 0.28
		Approx. 40	5			5	1.00	0.57, 1.0	5	1.00	0.57, 1.00	0.00	-0.43, 0.43

Ceramic	<i>L. monocytogenes</i> 4c (Cornell/ILSI W1-110)	0	5			0	0.00	0.0, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>L. seeligeri</i> (Cornell/ILSI FSL H6-169)	Approx. 20	20	<i>Listeria</i> spp.	48	11	0.55	0.34, 0.74	11	0.55	0.34, 0.74	0.00	-0.28, 0.28
		Approx. 40	5			5	1.00	0.57, 1.0	5	1.00	0.57, 1.00	0.00	-0.43, 0.43

<sup>a</sup>Both manual and automated results were equivalent so they are not distinguished in this table.

<sup>b</sup>Test area = Results of the CFU/Test area were determined by plating the inoculum for each matrix in triplicate.

<sup>c</sup>n = Number of test portions.

<sup>d</sup>x = Number of positive test portions.

<sup>e</sup>POD<sub>CP</sub> = Candidate method presumptive outcomes divided by total number of trials.

<sup>f</sup>CI = Confidence interval.

<sup>g</sup>POD<sub>CC</sub> = Candidate method confirmed positive outcomes divided by the total number of trials.

<sup>h</sup>dPOD<sub>CP</sub> = Difference between the candidate method presumptive result and candidate method confirmed result POD values.

<sup>i</sup>If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

<sup>j</sup>Matrix study was performed by Independent Laboratory

**Table 4. Clear Safety *Listeria* detection result vs reference method: POD analysis (1)**

Surface type	Strain	CFU / Test area <sup>b</sup>		Analysis	Time, h	Clear Safety <sup>a</sup>			Reference				
		N <sup>c</sup>				x <sup>d</sup>	POD <sub>C</sub> <sup>e</sup>	95% CI <sup>f</sup>	x	POD <sub>R</sub> <sup>g</sup>	95% CI	dPOD <sub>C</sub> <sup>h</sup>	95% CI <sup>i</sup>
Stainless steel <sup>j</sup>	<i>L. monocytogenes</i> 1/2a (ATCC 51772)	-	5			0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>L. ivanovii</i> (ATCC BAA-139) <i>E. faecalis</i> (ATCC 33186)	32	20	<i>L. monocytogenes</i>	22	7	0.35	0.18, 0.57	5	0.25	0.01, 0.47	0.10	-0.18, 0.36
		160	5			5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Stainless steel <sup>j</sup>	<i>L. monocytogenes</i> 1/2a (ATCC 51772)	-	5			0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>L. ivanovii</i> (ATCC BAA-139) <i>E. faecalis</i> (ATCC 33186)	32	20	<i>Listeria</i> spp.	22	12	0.60	0.39, 0.78	9	0.45	0.26, 0.66	0.15	-0.15, 0.41
		160	5			5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Stainless steel <sup>j</sup>	<i>L. monocytogenes</i> 1/2a (ATCC 51772)	-	5			0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>L. ivanovii</i> (ATCC BAA-139) <i>E. faecalis</i> (ATCC 33186)	32	20	<i>L. monocytogenes</i>	48	7	0.35	0.18, 0.57	5	0.25	0.01, 0.47	0.10	-0.18, 0.36
		160	5			5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Stainless steel <sup>j</sup>	<i>L. monocytogenes</i> 1/2a (ATCC 51772)	-	5			0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>L. ivanovii</i> (ATCC BAA-139) <i>E. faecalis</i> (ATCC 33186)	32	20	<i>Listeria</i> spp.	48	12	0.60	0.39, 0.78	9	0.45	0.26, 0.66	0.15	-0.15, 0.41
		160	5			5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43



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		160	5		5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43	
Stainless steel	<i>L. monocytogenes</i> 1/2a (ATCC 15313)	0	5		0	0.00	0.00, 0.43	0	0.00	-0.43, 0.43	0.00	-0.43, 0.43	
	<i>L. ivanovii</i> (ATCC 19119)	Approx. 20	20	<i>L. monocytogenes</i>	22	8	0.40	0.22, 0.61	4	0.20	0.08, 0.42	0.20	-0.08, 0.44
	<i>E. faecalis</i> (ATCC 33186)	Approx. 40	5			5	1.00	0.57, 1.00	5	1.00	-0.43, 0.43	0.00	-0.43, 0.43
Stainless steel	<i>L. monocytogenes</i> 1/2a (ATCC 15313)	0	5		0	0.00	0.00, 0.43	0	0.00	-0.43, 0.43	0.00	-0.43, 0.43	
	<i>L. ivanovii</i> (ATCC 19119)	Approx. 20	20	<i>Listeria</i> spp.	22	12	0.60	0.39, 0.78	8	0.40	0.22, 0.61	0.20	-0.10, 0.46
	<i>E. faecalis</i> (ATCC 33186)	Approx. 40	5			5	1.00	0.57, 1.0	5	1.00	-0.43, 0.43	0.00	-0.43, 0.43
Stainless steel	<i>L. monocytogenes</i> 1/2a (ATCC 15313)	0	5		0	0.00	0.0, 0.43	0	0.00	-0.43, 0.43	0.00	-0.43, 0.43	
	<i>L. ivanovii</i> (ATCC 19119)	Approx. 20	20	<i>L. monocytogenes</i>	48	8	0.40	0.22, 0.61	4	0.20	0.08, 0.42	0.20	-0.08, 0.44
	<i>E. faecalis</i> (ATCC 33186)	Approx. 40	5			5	1.00	0.57, 1.0	5	1.00	-0.43, 0.43	0.00	-0.43, 0.43
Stainless steel	<i>L. monocytogenes</i> 1/2a (ATCC 15313)	0	5		0	0.00	0.0, 0.43	0	0.00	-0.43, 0.43	0.00	-0.43, 0.43	
	<i>L. ivanovii</i> (ATCC 19119)	Approx. 20	20	<i>Listeria</i> spp.	48	12	0.60	0.39, 0.78	8	0.40	0.22, 0.61	0.20	-0.10, 0.46
	<i>E. faecalis</i> (ATCC 33186)	Approx. 40	5			5	1.00	0.57, 1.0	5	1.00	-0.43, 0.43	0.00	-0.43, 0.43
Plastic	<i>L. monocytogenes</i> 3b (Cornell/ILSI FSL J1-169)	0	5		0	0.00	0.0, 0.43	0	0.00	-0.43, 0.43	0.00	-0.43, 0.43	
	<i>L. marthii</i> (Cornell/ILSI FSL S4-965L)	Approx. 20	20	<i>L. monocytogenes</i>	22	6	0.30	0.15, 0.52	8	0.40	0.22, 0.61	-0.10	-0.36, 0.18
		Approx. 40	5			5	1.00	0.57, 1.0	5	1.00	-0.43, 0.43	0.00	-0.43, 0.43
Plastic	<i>L. monocytogenes</i> 3b (Cornell/ILSI FSL J1-169)	0	5		0	0.00	0.0, 0.43	0	0.00	-0.43, 0.43	0.00	-0.43, 0.43	
	<i>L. marthii</i> (Cornell/ILSI FSL S4-965L)	Approx. 20	20	<i>Listeria</i> spp.	22	10	0.50	0.30, 0.70	9	0.45	0.26, 0.66	0.05	-0.24, 0.33
		Approx. 40	5			5	1.00	0.57, 1.00	5	1.00	-0.43, 0.43	0.00	-0.43, 0.43
Plastic	<i>L. monocytogenes</i> 3b (Cornell/ILSI FSL J1-169)	0	5		0	0.00	0.00, 0.43	0	0.00	-0.43, 0.43	0.00	-0.43, 0.43	
	<i>L. marthii</i> (Cornell/ILSI FSL S4-965L)	Approx. 20	20	<i>L. monocytogenes</i>	48	6	0.30	0.15, 0.52	8	0.40	0.22, 0.61	-0.10	-0.36, 0.18
		Approx. 40	5			5	1.00	0.57, 1.00	5	1.00	-0.43, 0.43	0.00	-0.43, 0.43
Plastic	<i>L. monocytogenes</i> 3b (Cornell/ILSI FSL J1-169)	0	5		0	0.00	0.00, 0.43	0	0.00	-0.43, 0.43	0.00	-0.43, 0.43	
	<i>L. marthii</i> (Cornell/ILSI FSL S4-965L)	Approx. 20	20	<i>Listeria</i> spp.	48	10	0.50	0.30, 0.70	9	0.45	0.26, 0.66	0.05	-0.24, 0.33
		Approx. 40	5			5	1.00	0.57, 1.00	5	1.00	-0.43, 0.43	0.00	-0.43, 0.43
Sealed concrete	<i>L. monocytogenes</i> 1/2b (Cornell/ILSI FSL J2-064)	0	5		0	0.00	0.00, 0.43	0	0.00	-0.43, 0.43	0.00	-0.43, 0.43	
	<i>L. welshimeri</i> (Cornell/ILSI FSL H6-105)	Approx. 20	20	<i>L. monocytogenes</i>	22	6	0.30	0.15, 0.52	5	0.25	0.11, 0.47	0.05	-0.22, 0.31
		Approx. 40	5			5	1.00	0.57, 1.00	5	1.00	-0.43, 0.43	0.00	-0.43, 0.43
Sealed concrete	<i>L. monocytogenes</i> 1/2b (Cornell/ILSI FSL J2-064)	0	5		0	0.00	0.00, 0.43	0	0.00	-0.43, 0.43	0.00	-0.43, 0.43	
	<i>L. welshimeri</i> (Cornell/ILSI FSL H6-105)	Approx. 20	20	<i>Listeria</i> spp.	22	14	0.70	0.48, 0.85	9	0.45	0.26, 0.66	0.25	-0.05, 0.5
		Approx. 40	5			5	1.00	0.57, 1.00	5	1.00	-0.43, 0.43	0.00	-0.43, 0.43
Sealed concrete	<i>L. monocytogenes</i> 1/2b	0	5	<i>L.</i>	48	0	0.00	0.00, 0.43	0	0.00	-0.43, 0.43	0.00	-0.43, 0.43

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	(Cornell/ILSI FSL J2-064)	Approx. 20	20	<i>monocytogenes</i>		6	0.30	0.15, 0.52	5	0.25	0.11, 0.47	0.05	-0.22, 0.31
	<i>L. welshimeri</i> (Cornell/ILSI FSL H6-105)	Approx. 40	5			5	1.00	0.57, 1.00	5	1.00	-0.43, 0.43	0.00	-0.43, 0.43
Sealed concrete	<i>L. monocytogenes</i> 1/2b (Cornell/ILSI FSL J2-064)	0	5			0	0.00	0.00, 0.43	0	0.00	-0.43, 0.43	0.00	-0.43, 0.43
	<i>L. welshimeri</i> (Cornell/ILSI FSL H6-105)	Approx. 20	20	<i>Listeria spp.</i>	48	14	0.70	0.48, 0.85	9	0.45	0.26, 0.66	0.25	-0.05, 0.50
		Approx. 40	5			5	1.00	0.57, 1.00	5	1.00	-0.43, 0.43	0.00	-0.43, 0.43
Ceramic	<i>L. monocytogenes</i> 4c (Cornell/ILSI W1-110)	0	5			0	0.00	0.00, 0.43	0	0.00	-0.43, 0.43	0.00	-0.43, 0.43
	<i>L. seeligeri</i> (Cornell/ILSI FSL H6-169)	Approx. 20	20	<i>L. monocytogenes</i>	22	8	0.40	0.22, 0.61	9	0.45	0.26, 0.66	-0.05	-0.33, 0.24
		Approx. 40	5			5	1.00	0.57, 1.00	5	1.00	-0.43, 0.43	0.00	-0.43, 0.43
Ceramic	<i>L. monocytogenes</i> 4c (Cornell/ILSI W1-110)	0	5			0	0.00	0.00, 0.43	0	0.00	-0.43, 0.43	0.00	-0.43, 0.43
	<i>L. seeligeri</i> (Cornell/ILSI FSL H6-169)	Approx. 20	20	<i>Listeria spp.</i>	22	11	0.55	0.34, 0.74	10	0.50	0.3, 0.7	0.05	-0.24, 0.33
		Approx. 40	5			5	1.00	0.57, 1.00	5	1.00	-0.43, 0.43	0.00	-0.43, 0.43
Ceramic	<i>L. monocytogenes</i> 4c (Cornell/ILSI W1-110)	0	5			0	0.00	0.00, 0.43	0	0.00	-0.43, 0.43	0.00	-0.43, 0.43
	<i>L. seeligeri</i> (Cornell/ILSI FSL H6-169)	Approx. 20	20	<i>L. monocytogenes</i>	48	8	0.40	0.22, 0.61	9	0.45	0.26, 0.66	-0.05	-0.33, 0.24
		Approx. 40	5			5	1.00	0.57, 1.00	5	1.00	-0.43, 0.43	0.00	-0.43, 0.43
Ceramic	<i>L. monocytogenes</i> 4c (Cornell/ILSI W1-110)	0	5			0	0.00	0.00, 0.43	0	0.00	-0.43, 0.43	0.00	-0.43, 0.43
	<i>L. seeligeri</i> (Cornell/ILSI FSL H6-169)	Approx. 20	20	<i>Listeria spp.</i>	48	11	0.55	0.34, 0.74	10	0.50	0.3, 0.7	0.05	-0.24, 0.33
		Approx. 40	5			5	1.00	0.57, 1.00	5	1.00	-0.43, 0.43	0.00	-0.43, 0.43

<sup>a</sup>Both manual and automated results were equivalent so they are not distinguished in this table.

<sup>b</sup>Test area = Results of the CFU/Test area were determined by plating the inoculum for each matrix in triplicate.

<sup>c</sup>n = Number of test portions.

<sup>d</sup>x = Number of positive test portions.

<sup>e</sup>POD<sub>c</sub> = Confirmed candidate method positive outcomes divided by total number of trials.

<sup>f</sup>CI = Confidence interval.

<sup>g</sup>POD<sub>r</sub> = Reference method confirmed positive outcomes divided by the total number of trials.

<sup>h</sup>dPOD<sub>c</sub> = Difference between the candidate method and the reference method POD values.

<sup>i</sup>If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

<sup>j</sup>Matrix study was performed by Independent Laboratory.

Table 10. Clear Safety *Listeria* Method, *Listeria monocytogenes* Inclusivity Results – Propagated in CLM Broth (1)

No.	Organism <sup>a</sup>	Source	Origin	Result	No.	Organism <sup>a</sup>	Source	Origin	Result
1	<i>L. monocytogenes</i> (1/2C)	CWD <sup>b</sup> 1553	Human, Denmark	+	26	<i>L. monocytogenes</i> (N/A)	ATCC 19113	Not Available	+
2	<i>L. monocytogenes</i> (1/2A)	CWD 1554	Carlisle, 1981	+	27	<i>L. monocytogenes</i> (4A)	ATCC 19114	Animal Tissue	+
3	<i>L. monocytogenes</i> (4B)	CWD 1563	Lausanne, 1987	+	28	<i>L. monocytogenes</i> (4B)	ATCC 19115	Human	+
4	<i>L. monocytogenes</i> (4B)	CWD 1567	Los Angeles, 1985	+	29	<i>L. monocytogenes</i> (4C)	ATCC 19116	Chicken	+
5	<i>L. monocytogenes</i> (4B)	CWD 1571	Not Available	+	30	<i>L. monocytogenes</i> (4E)	ATCC 19118	Chicken	+
6	<i>L. monocytogenes</i> (4B)	CWD 1590	San Francisco	+	31	<i>L. monocytogenes</i> (N/A)	ATCC 49953	Goat, Belgium	+
7	<i>L. monocytogenes</i> (3B)	CWD 1600	Not Available	+	32	<i>L. monocytogenes</i> (1/2A)	ATCC 49594	Food, France	+
8	<i>L. monocytogenes</i> (1/2A)	CWD 1609	Turkey Factory	+	33	<i>L. monocytogenes</i> (3A)	ATCC 51782	Cheese	+
9	<i>L. monocytogenes</i> (1/2A)	CWD 1620	Turkey Factory	+	34	<i>L. monocytogenes</i> (N/A)	ATCC BAA- 2658	Not Available	+
10	<i>L. monocytogenes</i> (1/2B)	CWD 1626	Turkey Franks	+	35	<i>L. monocytogenes</i> (N/A)	QL <sup>f</sup> 030911-10	Clinical	+
11	<i>L. monocytogenes</i> (1/2B)	CWD 1627	Mother/Baby	+	36	<i>L. monocytogenes</i> (4B)	CWD 1561	Placenta	+
12	<i>L. monocytogenes</i> (4D)	ATCC <sup>c</sup> 19117	Sheep	+	37	<i>L. monocytogenes</i> (1/2B)	CWD 1601	Los Angeles	+
13	<i>L. monocytogenes</i> (1/2A)	ATCC 51772	Dairy Product, Belgium	+	38	<i>L. monocytogenes</i> (1/2A)	CWD 1612	Turkey Factory	+
14	<i>L. monocytogenes</i> (4B)	ATCC 51778	Dairy Products, Belgium	+	39	<i>L. monocytogenes</i> (1/A)	CWD 1613	Turkey Factory	+
15	<i>L. monocytogenes</i> (1/2B)	ATCC 51780	Cheese	+	40	<i>L. monocytogenes</i> (1/2A)	CWD 1614	Oklahoma	+
16	<i>L. monocytogenes</i> (1/2B)	ATCC BAA-751	Not Available	+	41	<i>L. monocytogenes</i> (1/2A)	CWD 1618	Turkey Factory	+
17	<i>L. monocytogenes</i> (7)	NCTC <sup>d</sup> 10890	Human Feces	+	42	<i>L. monocytogenes</i> (1/2A)	CWD 1629	Turkey Franks	+
18	<i>L. monocytogenes</i> (4B)	FSL <sup>e</sup> -F6-367	Not Available	+	43	<i>L. monocytogenes</i> (1/2A)	CWD 1630	Turkey Factory	+
19	<i>L. monocytogenes</i> (4AB)	FSL J1-129	Not Available	+	44	<i>L. monocytogenes</i> (4B)	CWD 1574	Halifax, 1983	+
20	<i>L. monocytogenes</i> (3C)	FSL J1-049	Not Available	+	45	<i>L. monocytogenes</i> (1/2B)	CWD 1584	Not Available	+
21	<i>L. monocytogenes</i> (1/2C)	ATCC 7644	Human	+	46	<i>L. monocytogenes</i> (3B)	CWD 1586	Not Available	+
22	<i>L. monocytogenes</i> (4B)	ATCC 13932	Child with Meningitis	+	47	<i>L. monocytogenes</i> (1/2B)	CWD 1588	Not Available	+
23	<i>L. monocytogenes</i> (1/2A)	ATCC 15313	Rabbit	+	48	<i>L. monocytogenes</i> (4B)	CWD 1596	Not Available	+
24	<i>L. monocytogenes</i> (1)	ATCC 19111	Poultry	+	49	<i>L. monocytogenes</i> (1/2B)	CWD 1597	Not Available	+
25	<i>L. monocytogenes</i> (2)	ATCC 19112	Spinal Fluid	+	50	<i>L. monocytogenes</i> (1/2A)	CWD 1611	Turkey Factory	+

<sup>a</sup>*Listeria* serotype is denoted in parentheses<sup>b</sup>CWD – University of Vermont Culture Collection<sup>c</sup>ATCC – American Type Culture Collection<sup>d</sup>NCTC – National Culture Type Collection<sup>e</sup>FSL – Cornell University Culture Collection<sup>f</sup>QL – Q Laboratories Culture Collection

Table 11. Clear Safety *Listeria* Method, *Listeria* spp. Inclusivity Results – Propagated in CLM Broth (1)

No.	Organism	Reference Number	Origin	Result
1	<i>Listeria grayi</i>	ATCC <sup>a</sup> 19120	Animal Feces	+
2	<i>Listeria grayi</i>	ATCC 25401	Corn Stalks and Leaves	+
3	<i>Listeria grayi</i>	ATCC 25402	Corn Stalks and Leaves	+
4	<i>Listeria grayi</i>	ATCC 25403	Corn Stalks and Leaves	+
5	<i>Listeria grayi</i>	ATCC 700545	Not Available	+
6	<i>Listeria innocua</i>	UVM <sup>b</sup> 167	Not Available	+
7	<i>Listeria innocua</i>	UVM 217	Not Available	+
8	<i>Listeria innocua</i>	UVM 658	Not Available	+
9	<i>Listeria innocua</i>	UVM 661	Not Available	+
10	<i>Listeria innocua</i>	UVM 662	Not Available	+
11	<i>Listeria ivanovii</i>	ATCC 19119	Sheep	+
12	<i>Listeria ivanovii</i>	ATCC 49953	Goat	+
13	<i>Listeria ivanovii</i>	ATCC 49954	Food, France	+
14	<i>Listeria ivanovii</i>	ATCC BAA-139	Washing Water	+
15	<i>Listeria ivanovii</i>	ATCC BAA-678	Sheep Fetus	+
16	<i>Listeria marthii</i>	FSL <sup>c</sup> R9-8561	Animal Feces	+
17	<i>Listeria marthii</i>	FSL W9-0242	Farm Stream Water	+
18	<i>Listeria marthii</i>	QL <sup>d</sup> 15013.1	Environmental	+
19	<i>Listeria marthii</i>	QL 12231.5	Environmental	+
20	<i>Listeria marthii</i>	ATCC BAA-1595	Soil	+
21	<i>Listeria seeligeri</i>	ATCC 11289	Human Feces	+
22	<i>Listeria seeligeri</i>	NCTC <sup>e</sup> 11856	Not Available	+
23	<i>Listeria seeligeri</i>	NCTC 11889	Not Available	+
24	<i>Listeria seeligeri</i>	ATCC 35967	Soil, Germany	+
25	<i>Listeria seeligeri</i>	ATCC 51334	Intestinal Content	+
26	<i>Listeria welshimeri</i>	ATCC 35897	Decaying plant material	+
27	<i>Listeria welshimeri</i>	ATCC 43548	Not Available	+
28	<i>Listeria welshimeri</i>	ATCC 43549	Soil	+
29	<i>Listeria welshimeri</i>	ATCC 43550	Human Feces	+
30	<i>Listeria welshimeri</i>	UVM LW003	Not Available	+

<sup>a</sup>ATCC – American Type Culture Collection<sup>b</sup>UVM – University of Vermont Culture Collection<sup>c</sup>FSL – Cornell University Culture Collection<sup>d</sup>QL – Q Laboratories Culture Collection<sup>e</sup>NCTC – National Culture Type Collection

Table 12. Clear Safety *Listeria* Method, Exclusivity Results for *Listeria monocytogenes* - Propagated in TSB (1)

No.	Organism	Reference Number	Origin	Result
1	<i>L. grayi</i>	ATCC <sup>a</sup> 19120	Animal Feces	-
2	<i>L. innocua</i>	ATCC 33090	Cow Brain	-
3	<i>L. ivanovii</i>	ATCC 19119	Sheep	-
4	<i>L. marthii</i>	ATCC BAA-1595	Soil	-
5	<i>L. rocourtia</i>	FSL <sup>b</sup> F6-0920	Not Available	-
6	<i>L. welshimeri</i>	ATCC 35897	Decaying plant material	-
7	<i>L. seeligeri</i>	ATCC 35967	Soil	-

<sup>a</sup>ATCC – American Type Culture Collection<sup>b</sup>FSL – Cornell University Culture CollectionTable 13. Clear Safety *Listeria* Method, Exclusivity Results for *Listeria* spp. - Propagated in TSB (1)

No.	Organism	Reference Number	Origin	Result
1	<i>Bacillus mycoides</i>	ATCC <sup>a</sup> 6462	Soil	-
2	<i>Brochothrix thermosphacta</i>	ATCC 11509	Fresh pork sausage	-
3	<i>Rhodococcus fascians</i>	ATCC 12974	Not Available	-
4	<i>Enterococcus hirae</i>	ATCC 8043	Not Available	-
5	<i>Enterococcus faecium</i>	ATCC 19434	Not Available	-
6	<i>Enterococcus durans</i>	ATCC 19432	Not Available	-
7	<i>Enterococcus faecalis</i>	ATCC 29212	Urine	-
8	<i>Kurthia gibsonii</i>	ATCC 43195	Meat	-
9	<i>Escherichia coli</i>	ATCC 8739	Feces	-
10	<i>Klebsiella oxytoca</i>	ATCC 43165	Clinical Isolate	-
11	<i>Klebsiella pneumoniae</i>	ATCC 13883	Not Available	-
12	<i>Kurthia zopfii</i>	ATCC 10538	Not Available	-
13	<i>Listeria fleischmannii</i>	FSL <sup>b</sup> S10-1203	Not Available	-
14	<i>Listeria weihenstephanensis</i>	FSL R9-0317	Not Available	-
15	<i>Listeria coloradensis</i>	ATCC BAA-2414	Soil sample from grazing pasture	-
16	<i>Listeria floridensis</i>	FSL S10-1187	Running Water	-
17	<i>Listeria cornellensis</i>	FSL F6-0969	Water	-
18	<i>Listeria grandensis</i>	FSL F6-0971	Water	-
19	<i>Listeria riparia</i>	FSL S10-1204	Running Water	-
20	<i>Bacillus subtilis subsp. subtilis</i>	ATCC 6051	Not Available	-
21	<i>Staphylococcus aureus</i>	ATCC 29247	Not Available	-
22	<i>Staphylococcus epidermidis</i>	ATCC 12228	Not Available	-
23	<i>Staphylococcus haemolyticus</i>	ATCC 29970	Human Skin	-
24	<i>Staphylococcus warneri</i>	ATCC 29885	Not Available	-
25	<i>Streptococcus pneumoniae</i>	ATCC 6302	Not Available	-
26	<i>Streptococcus pyogenes</i>	ATCC 19615	Pharynx of Child	-
27	<i>Bacillus cereus</i>	QL <sup>c</sup> 15166-1	Psyllium	-
28	<i>Bacillus coagulans</i>	ATCC 7050	Evaporated Milk	-
29	<i>Bacillus licheniformis</i>	ATCC 12759	Plant	-
30	<i>Serratia liquefacians</i>	ATCC 27592	Milk	-

<sup>a</sup>ATCC – American Type Culture Collection<sup>b</sup>FSL – Cornell University Culture Collection<sup>c</sup>QL – Q Laboratories Culture Collection

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