

# CERTIFICATION

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

Certificate No. **052003** 

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

### Molecular Environmental Monitoring Program (MEMP) Listeria Assay

manufactured by

Applied Food Diagnostics, Inc. 387 Hazle Street Nuremberg, PA USA

This method has been evaluated in the AOAC<sup>®</sup> *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<sup>®</sup> 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 (May 15, 2020 – December 31, 2020). 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 May 18, 2020 Date

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METHOD AUTHORS Thomas Lonczynski and Laura Cowin	SUBMITTING COMPANY Applied Food Diagnostics, Inc. 387 Hazle Street Nuremberg, PA USA					
<b>KIT NAME(S)</b> Molecular Environmental Monitoring Program (MEMP) <i>Listeria</i> Assay	CATALOG NUMBERS MEMP-LIS-032- MEMP <i>Listeria</i> Assay Kit MEMP-SWB-032 – AFD MEMP Swab Kit					
INDEPENDENT LABORATORY Q Laboratories 1930 Radcliff Drive Cincinnati, OH 45204 USA	AOAC EXPERTS AND PEER REVIEWERS Yi Chen <sup>1</sup> , Michael Brodsky <sup>2</sup> , Wayne Ziemer <sup>3</sup> <sup>1</sup> US FDA CFSAN, College Park, MD, USA <sup>2</sup> Brodsky Consultants, Ontario, CANADA <sup>3</sup> Independent Consultant, Loganville, MD, USA					
APPLICABILITY OF METHOD Analyte – <i>Listeria</i> species Matrices – Stainless steel (1"x 1"), plastic (1"x 1"), rubber (1"x 1"), ceramic tile (1"x 1") and sealed concrete (1"x 1")	REFERENCE METHOD Food and Drug Administration Bacteriological Analytical Manual, Detection and Enumeration of Listeria monocytogenes in Foods, Chapter 10 (2017) (2)					
Performance claims - Performance equivalent to that of the U.S. Food and Drug Administration (FDA) <i>Bacteriological</i> <i>Analytical Manual</i> (BAM) Chapter 10 (2) for environmental surface swabs.						
ORIGINAL CERTIFICATION DATE May 15, 2020	CERTIFICATION RENEWAL RECORD New Approval					
METHOD MODIFICATION RECORD NONE	SUMMARY OF MODIFICATION NONE					
Under this AOAC <sup>®</sup> <i>Performance Tested<sup>SM</sup></i> License Number, 052003 this method is distributed by: NONE	Under this AOAC <sup>®</sup> <i>Performance Tested<sup>sm</sup></i> License Number, 052003 this meth is distributed as: NONE					

#### PRINCIPLE OF THE METHOD (1)

For qPCR amplification and detection, forward and reverse primers hybridize to a unique sequence *Listeria* genomic DNA. A fluorogenic probe consisting of a DNA probe labeled with a 5<sup>-</sup>-dye and a 3<sup>-</sup>-quencher is included in the same reaction mixture. During PCR amplification, the probe is cleaved, and the reporter dye and quencher are separated. The resulting increase in fluorescence can be detected on the real-time PCR instrument. Unique primer and probe mixtures specific for *Listeria* are present in this assay.

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

Inclusivity and Exclusivity

Of the 75 inclusivity strains analyzed by the MEMP *Listeria* Assay, all 75 inclusivity strains were correctly detected by the *Listeria* assay kit. Of the 30 exclusivity strains, none were detected by the *Listeria* MEMP method. See Tables 1 and 2.

Matrix Study

Results from both the method developer and independent studies of the MEMP *Listeria* Assay for the environmental samples are outlined in Tables 3 and 4. Throughout the study, the method developer had difficulty achieving fractional results, and repeat attempts had to be made to spike at the correct inoculation levels. Environmental surfaces proved challenging to recover cells off the surface at low levels due to the humidity in the environment. Multiple trials were run for some of the surfaces to achieve fractional levels.

For stainless steel, a 1" x 1" area was tested using a swab. For the low contamination level, the swab detected 17 presumptive positive results, 15 of which confirmed positive. The MEMP swabs are able to collect all cell types, including live and dead cells. For the presumptive positive test portions that did not confirm, it is likely that dead cells were present, leading to a positive PCR reaction, but these cells were not enriched. For the high contamination level, the swab detected all five portions, which all confirmed positive. The FDA BAM Chapter 10 method had 5 positive results at the high contamination level and 13 positive results at the low contamination level, which showed no statistically significant difference with the candidate method when analyzed using POD analysis. For plastic, a 1" x 1" area was tested using a swab. Twelve portions were presumptive positive, and nine confirmed positive. Again, it is likely that dead cells were present, leading to a positive PCR reaction, but these cells were not enriched. The FDA BAM Chapter 10 method had seven positive portions. Both methods had 5 positive portions in the high contamination level, with all candidate method portions confirming positive. There were no statistically significant differences between the two methods.

The rubber was also swabbed in a 1" x 1" area. For the low contamination level, 16 portions were presumptive on the PCR, 14 of which confirmed positive. Again, it is likely that MEMP assay is detecting dead cells from the surface. For the FDA BAM Chapter 10 method, 14 portions were positive. Both methods had 5 positive portions in the high contamination level, with all candidate method portions confirming positive. When performing the POD analysis on the two methods, no statistically significant differences were observed.

For ceramic, a 1" x 1" area was swabbed. For the low contamination level, the candidate method had nine presumptive positive results, and all nine confirmed positive. The FDA BAM Chapter 10 method also had nine positive results. Both methods had 5 positive portions in the high contamination level, with all candidate method portions confirming positive. There were no statistically significant differences between the two methods.

For concrete, a 1" x 1" surface was also swabbed. For the low contamination level, the candidate method had twelve presumptive positive results, all of which confirmed positive. The FDA BAM Chapter 10 reference method had ten positive results. Both methods had 5 positive portions in the high contamination level, with all candidate method portions confirming positive. There were no statistically significant differences between the two methods. *Independent Laboratory Study* 

In the independent study, there were 8 presumptive positive results at the low contamination level, and 8 confirmed results. For the reference method, there were 7 positive results at the low level. Both methods had 5 positive portions in the high contamination level, with all candidate method portions confirming positive. The POD analysis between the MEMP Assay and the reference method indicated that there was no significant difference, with 95% confidence. A summary of POD analyses is presented in Tables 3 and 4.

No.	Genus	Species	Serotype <sup>a</sup>	Source	Origin	MEMP Result
L	Listeria	grayi	N/A <sup>b</sup>	ATCC <sup>c</sup> 25401	Standing corn stalks and leaves	+
2	Listeria	welshimeri	N/A	USDA <sup>d</sup> ERRC B-33266	Florida, USA	+
3	Listeria	grayi	N/A	ATCC 19120	Animal feces	+
1	Listeria	grayi	N/A	USDA ERRC B-33214	Wheat processing plant	+
5	Listeria	seeligeri	N/A	USDA ERRC B-57212	Unknown	+
5	Listeria	innocua	N/A	USDA ERRC B-33314	Unknown	+
7	Listeria	ivanovii subsp. Ivanovii	N/A	USDA ERRC B-33165	Bovine	+
3	Listeria	marthii	N/A	BEI <sup>e</sup> NR-9581	Run-off water	+
Ð	Listeria	marthii	N/A	BEI NR-9582	Stream water	+
LO	Listeria	marthii	N/A	BEI NR-9579	Soil	+
11	Listeria	marthii	N/A	BEI NR-9580	Standing water puddle	+
12	Listeria	seeligeri	N/A	USDA ERRC B-33019	Soil	+
13	Listeria	ivanovii	N/A	USDA ERRC B-33017	Sheep	+
L4	Listeria	welshimeri	N/A	USDA ERRC B-33020	Decaying vegetation	+
15	Listeria	innocua	N/A	USDA ERRC B-33003	California, USA	+
L6	Listeria	innocua	N/A	ATCC 33091	Human feces	+
L7	Listeria	ivanovii subsp. londoniensis	N/A	ATCC BAA-139	Washing water	+
18	Listeria	welshimeri	N/A	ATCC 35897	Decaying plant material	+
19	Listeria	Innocua	6a	ATCC 33090	Cow brain	+
20	Listeria	grayi	N/A	USDA ERRC B-33023	Chinchilla feces	+
21	Listeria	seeligeri	N/A	ATCC 35967	Soil	+
22	Listeria	aquatica	N/A	USDA ERRC B-57629	Running water	+
23	Listeria	riparia	N/A	USDA ERRC B-57632	Running water	+
24	Listeria	welshimeri	N/A	USDA ERRC B-33194	Wheat processing plant	+
25	Listeria	grayi	N/A	ATCC 700545	Unknown	+

26	Listeria	monocytogenes	4b	USDA ERRC B-33000	Cheese	+
27	Listeria	monocytogenes	1/2b complex	USDA ERRC B-33045	Turkey, Pork, Beef hot dogs	+
28	Listeria	monocytogenes	1/2b	USDA ERRC B-33258	Smoked boneless ham	+
29	Listeria	monocytogenes	1/2b	USDA ERRC B-33272	<b>Environmental isolates</b>	+
30	Listeria	monocytogenes	1/2b	USDA ERRC B-33273	<b>Environmental isolates</b>	+
31	Listeria	monocytogenes	1/2b	USDA ERRC B-33254	Roast beef	+
32	Listeria	monocytogenes	1/2b	USDA ERRC B-33046	Chicken	+
33	Listeria	monocytogenes	1/2b	USDA ERRC B-33073	Bovine	+
34	Listeria	monocytogenes	1/2a	USDA ERRC B-33106	Raw milk	+
35	Listeria	monocytogenes	4d	USDA ERRC B-33116	Sheep	+
36	Listeria	monocytogenes	4e	USDA ERRC B-33120	Chicken	+
37	Listeria	monocytogenes	1/2b	USDA ERRC B-33130	Bovine milk	+
38	Listeria	monocytogenes	1/2b	USDA ERRC B-33162	Bovine	+
39	Listeria	monocytogenes	1/2b complex	BEI NR-108	Human	+
40	Listeria	monocytogenes	За	BEI NR-110	Human cerebrospinal fluid	+
41	Listeria	monocytogenes	4b	BEI NR-111	Chicken	+
42	Listeria	monocytogenes	4c	BEI NR-112	Sheep	+
43	Listeria	monocytogenes	4d	BEI NR-113	Chicken	+
44	Listeria	monocytogenes	1/2a	BEI NR-13233	Soil	+
45	Listeria	monocytogenes	1/2a	BEI NR-13229	Human	+
46	Listeria	monocytogenes	1/2b	BEI NR-13237	Bovine abortion	+
47	Listeria	monocytogenes	4c	BEI NR-13232	Bovine	+
48	Listeria	monocytogenes	4b	BEI NR-13231	Trout	+
49	Listeria	monocytogenes	1/2b	BEI NR-13230	Human	+
50	Listeria	monocytogenes	N/A	BEI NR-4098	Human meningitis	+
51	Listeria	monocytogenes	4a	BEI NR-109	Ruminant tissue	+
52	Listeria	monocytogenes	N/A	USDA ERRC B-33259	Chicken	+
53	Listeria	monocytogenes	N/A	USDA ERRC B-33260	Beef sausage links	+

54	Listeria	monocytogenes	N/A	USDA ERRC B-33261	Beef jerky	+
55	Listeria	monocytogenes	N/A	USDA ERRC B-33264	Sliced cooked beef	+
56	Listeria	monocytogenes	N/A	USDA ERRC B-33274	Florida, USA	+
57	Listeria	monocytogenes	N/A	USDA ERRC B-33276	Chicken	+
58	Listeria	monocytogenes	1/2a	USDA ERRC B-33814	Clinical Isolate	+
59	Listeria	monocytogenes	За	USDA ERRC B-33225	Unknown	+
60	Listeria	monocytogenes	N/A	USDA ERRC B-33282	Duck Breast	+
61	Listeria	monocytogenes	Зc	USDA ERRC B-33226	Unknown	+
62	Listeria	monocytogenes	N/A	USDA ERRC B-33238	Beef jerky	+
63	Listeria	monocytogenes	1/2b complex	USDA ERRC B-33239	Beef/pork franks	+
64	Listeria	monocytogenes	1/2b complex	USDA ERRC B-33240	Beef/pork franks	+
65	Listeria	monocytogenes	N/A	USDA ERRC B-33241	Cooked apple sausage	+
66	Listeria	monocytogenes	1/2b complex	USDA ERRC B-33242	Roast beef	+
67	Listeria	monocytogenes	N/A	USDA ERRC B-33243	Cooked beef	+
68	Listeria	monocytogenes	1/2b complex	USDA ERRC B-33245	<b>Environmental isolates</b>	+
69	Listeria	monocytogenes	N/A	USDA ERRC B-33246	White chicken salad	+
70	Listeria	monocytogenes	N/A	USDA ERRC B-33247	Roast beef	+
71	Listeria	monocytogenes	1/2b complex	USDA ERRC B-33248	BBQ Chicken	+
72	Listeria	monocytogenes	1/2b complex	USDA ERRC B-33250	Boneless smoked ham steak	+
73	Listeria	monocytogenes	N/A	USDA ERRC B-33253	Cooked ham	+
74	Listeria	monocytogenes	N/A	BEI HM-1048	Human	+
75	Listeria	monocytogenes	4c	USDA ERRC B-33115	Arabian oryx	+

<sup>*a*</sup>Serotype listed if applicable.

<sup>b</sup>Not applicable.

<sup>c</sup>American Type Culture Collection, Manassas, VA.

<sup>d</sup>United States Department of Agriculture Eastern Regional Research Center, Wyndmoor, PA. <sup>e</sup>BEI Resources, Manassas, VA.

No.	Genus	Species	Origin	MEMP Resul			
10.	Alcaligenes	faecalis subsp. faecalis	Source USDA <sup>a</sup> ERRC B-170	USDA, Beltsville, MD	WEIWI Resul		
	-		SGSC <sup>b</sup> 5610 Unknown				
2	Citrobacter	koseri			-		
3	Bacillus	subtilus	BEI <sup>c</sup> NR-607	Unknown	-		
1	Bacillus	cereus	BEI NR-608	Laboratory isolate	-		
5	Citrobacter	freundii	ATCC <sup>d</sup> 43864	Unknown	-		
5	Cronobacter	sakazakii	ATCC BAA-894	Human clinical specimen	-		
7	Klebsiella	ozaenae	SGSC 2810	Unknown	-		
3	Escherichia	fergusonii	SGSC 5718	Human feces	-		
Ð	Escherichia	<i>coli</i> 075:K95:H5	BEI NR-17715	Human	-		
LO	Enterobacter	taylorae	SGSC 5283	Unknown	-		
11	Providencia	stuartii	SGSC 5639	Unknown	-		
12	Ewingella	americana	SGSC 5640	-			
13	Hafnia	alvei	SGSC 5583	Unknown	-		
L4	Klebsiella	oxytoca	SGSC 5366	Unknown	-		
15	Klebsiella	pneumoniae subsp. pneumoniae	SGSC 5926	Unknown	-		
16	Lactobacillus	lactis	ATCC 19257	Unknown	-		
17	Serratia	marcescens	SGSC 5354	Unknown	-		
18	Serratia	odorifera	SGSC 5576	Unknown	-		
.9	Shigella	sonnei	SGSC 5576	Unknown	-		
20	Shigella	flexneri	SGSC 5577	Unknown	-		
21	Staphylococcus	aureus	ATCC 29213	Wound	-		
22	Pseudomonas	aeruginosa	BEI NR-48982	Human	-		
23	Yersinia	enterocolitica	USDA ERRC B-41479	Ground Beef	-		
24	Morganella	morganii	SGSC 5435	Unknown	-		
25	Proteus	mirabilis	SGSC 5445	Unknown	-		
26	Escherichia	<i>coli</i> O157:H7	ATCC 43888	Human feces	-		
27	Escherichia	coli 0121	MSU <sup>e</sup> TW08004	Human	-		
28	Escherichia	coli O111	MSU TW05150	Cow	-		
29	Salmonella	<i>enterica</i> subsp. e <i>nterica</i> Enteritidis	SGSC 2475	Unknown, Connecticut	-		
30	Salmonella	<i>enterica</i> subsp. <i>enterica</i> Typhimurium	SGSC 2522	Human, Mexico			

<sup>a</sup>United States Department of Agriculture Eastern Regional Research Center, Windsor, PA. <sup>b</sup>Salmonella Genetic Stock Centre, University of Calgary, Canada

<sup>c</sup>BEI Resources, Manassas, VA.

<sup>d</sup>American Type Culture Collection, Manassas, VA. <sup>e</sup>Michigan State University STEC Center, East Lansing, MI.

				Ν	/IEMP <i>Listeria</i> p	resumptive results	MEMP Listeria confirmed results				
Matrix	Strain	CFU <sup>a</sup> /test area	N <sup>b</sup>	xc	$POD_{CP}^d$	95% CI	x	POD <sub>CC</sub> <sup>e</sup>	95% Cl	dPOD <sub>CP</sub> <sup>f</sup>	95% Cl <sup>g</sup>
Stainless	Listeria monocytogenes	N/A <sup>k</sup>	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
teel	4a (BEI <sup>h</sup> NR-109)/10X E.	80 & 1000	20	17	0.85	0.64, 0.95	15	0.75	0.53, 0.89	0.10	-0.15, 0.34
(1"x 1")	faecalis (BEI NR-31884)	150 & 3500	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Stainless steel <sup>/</sup> (1"x 1")	Listeria monocytogenes	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	4a (ATCC <sup>i</sup> 19114)/10X E.	77 & 800	20	8	0.40	0.22, 0.61	8	0.40	0.22, 0.61	0.00	-0.13, 0.13
	faecalis (ATCC 29212)	190 & 2600	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Plastic (1"x 1")	Listeria innocua (USDA ERRC <sup>i</sup> B-33003)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		200	20	12	0.60	0.39, 0.78	9	0.45	0.26, 0.66	0.15	-0.15, 0.41
		1000	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
		N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
Rubber (1"x 1")	Listeria grayi (USDA ERRC B-33214)	200	20	16	0.80	0.58, 0.92	14	0.70	0.48, 0.85	0.10	-0.17, 0.35
. ,	,	600	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
		N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
Ceramic tile (1"x 1")	Listeria ivanovii (USDA ERRC B-33165)	170	20	9	0.45	0.26, 0.66	9	0.45	0.26, 0.66	0.00	-0.28, 0.28
. ,		500	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
aalad		N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
ealed oncrete	Listeria marthii (BEI NR-9580)	110	20	12	0.60	0.39, 0.78	12	0.60	0.39, 0.78	0.00	-0.28, 0.28
1"x 1")		500	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43

<sup>a</sup>CFU = Colony forming units per test 1"x 1" test area

<sup>b</sup>N = Number of test potions.

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

 ${}^{d}POD_{CP}$  = Candidate method presumptive positive outcomes divided by the total number of trials.

ePOD<sub>cc</sub> = Candidate method confirmed positive outcomes (using the FDA BAM Chapter 10 reference method) divided by the total number of trials.

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

<sup>9</sup>95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

<sup>h</sup>BEI Resources, Manassas, VA.

<sup>j</sup>United States Department of Agriculture Eastern Regional Research Center, Windsor, PA.

 $^{k}N/A = Not applicable.$ 

<sup>1</sup>Matrix tested in the independent laboratory.

			-	MEMP Listeria results			Reference n	nethod results			
Matrix	Strain	CFU <sup>o</sup> /test area	N <sup>b</sup>	xc	$POD_{C}^d$	95% CI	x	POD <sub>R</sub> <sup>e</sup>	95% CI	dPOD <sub>C</sub> <sup>f</sup>	95% Cl <sup>g</sup>
Stainless steel (1"x 1")	Listeria	N/A/	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	monocytogenes 4a (BEI <sup>h</sup> NR-109)/10X <i>E.</i> faecalis (BEI NR-	80 & 1000	20	15	0.75	0.53, 0.89	13	0.65	0.43, 0.82	0.10	-0.18, 0.36
	31884)	150 & 3500	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	Listeria	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
Stainless steel <sup>k</sup> (1"x 1")	<i>monocytogenes</i> 4a (ATCC <sup>/</sup> 19114)/10X E.	77 & 800	20	8	0.40	0.22, 0.61	7	0.35	0.18, 0.57	0.05	-0.23, 0.32
	faecalis (ATCC 29212)	190 & 2600	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Plastic (1"x 1")	<i>Listeria innocua</i> (USDA ERRC <sup>I</sup> B-33003)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		200	20	9	0.45	0.26, 0.66	7	0.35	0.18, 0.57	0.10	-0.19, 0.37
		800	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
		N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
Rubber (1"x 1")	Listeria grayi (USDA ERRC B-33214)	200	20	14	0.70	0.48, 0.85	14	0.70	0.48, 0.85	0.00	-0.27, 0.27
		600	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
		N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
Ceramic tile (1″x 1″)	<i>Listeria ivanovii</i> (USDA ERRC B-33165)	170	20	9	0.45	0.26, 0.66	9	0.45	0.26, 0.66	0.00	-0.28, 0.28
	(	500	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Sealed concrete		N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>Listeria marthii</i> (BEI NR-9580)	110	20	12	0.60	0.39, 0.78	10	0.50	0.30. 0.70	0.10	-0.19, 0.37
1"x 1")	•	500	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43

<sup>*a*</sup>CFU = Colony forming units per test 1''x 1'' test area.

<sup>b</sup>N = Number of test potions.

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

<sup>d</sup>POD<sub>c</sub> = Candidate method presumptive positive outcomes that confirmed positive divided by the total number of trials.

<sup>e</sup>POD<sub>R</sub> = Reference method positive outcomes divided by the total number of trials.

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

<sup>9</sup>95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

<sup>h</sup>BEI Resources, Manassas, VA.

<sup>j</sup>United States Department of Agriculture Eastern Regional Research Center, Windsor, PA.

 $^{k}N/A = Not applicable.$ 

<sup>1</sup>Matrix tested in the independent laboratory.

#### **REFERENCES CITED**

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