



CERTIFICATION

AOAC[®] Performance TestedSM

Certificate No.

020401

The AOAC Research Institute hereby certifies that the method known as:

RapidChek[®] Listeria

manufactured by

Romer Labs

130 Sandy Drive

Newark, DE 19713

This method has been evaluated in the AOAC[®] *Performance Tested Methods*SM 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*SM 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.

A handwritten signature in black ink that reads "Scott Coates".

Scott Coates, Senior Director
Signature for AOAC Research Institute

November 20, 2021

Date

METHOD AUTHORS ORIGINAL VALIDATION: Jingkun Li, Carolyn Figard, Meredith Sutzko, Ly Tran, and George Teaney MODIFICATION MAY 2008: Meredith Sutzko, Mark Muldoon, Michael Brown, and Jim Stave	SUBMITTING COMPANY Strategic Diagnostics Inc. 111 Pencaer Drive Newark, Delaware 19702	CURRENT SPONSOR Romer Labs Technology, Inc. 130 Sandy Drive Newark, Delaware 19713
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KIT NAME(S) RapidChek® <i>Listeria</i>	CATALOG NUMBERS Original catalog numbers: 3000019, 7000171, 7000174, 7000174P, 7000175, 7000175P, 7000175S, 7000176, 7000179, 7000180, 7000182, 7000246 Updated catalog numbers: 10001173, 10001361, 10001364, 10001697, 10001365, 10001699, 10001700, 10001366, 10001369, 10001370, 10001372, 10001412
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INDEPENDENT LABORATORY Silliker Corporate Research Center 160 Amory Drive South Holland, IL 60473 USA	AOAC EXPERTS AND PEER REVIEWERS Wallace Andrews ¹ , Catherine Donnelly ² , Edward Richter ³ ¹ Retired USDA FDA CFSAN, College Park, MD, USA ² University of Vermont, VT, USA ³ Richter International, Columbus, OH, USA
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APPLICABILITY OF METHOD Target analyte – <i>Listeria</i> spp. Matrixes – (25 g samples) - Ice cream, soft cheese, pasteurized whole milk, deli turkey, pepperoni, hot dogs, roast beef, cooked shrimp, smoked fish, potato salad, rubber (sponge, 4 x 4 in), painted concrete (swab, 1 x 1 in), stainless steel (swab, 1 x 1 in) Performance claims - The Lateral Flow Device (LFD) test Method for <i>Listeria</i> species was evaluated and was shown be equivalent to the reference methods.	REFERENCE METHODS Hitchens, A.D. (1998) FDA, Bacteriological Analytical Manual; 8 th Edition; Chapter 10: <i>Listeria monocytogenes</i> . (2) USDA/FSIS, (2006) Microbiology Laboratory Guidelines, Chapter 8; revision 5; <i>Isolation and Identification of Listeria monocytogenes from Red Meat, Poultry, Egg, and Environmental Samples</i> . (4)
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ORIGINAL CERTIFICATION DATE June 15, 2004	CERTIFICATION RENEWAL RECORD Renewed annually through December 2022.
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METHOD MODIFICATION RECORD	SUMMARY OF MODIFICATION
1. May 2008	1. Filter pad component change
2. December 2012 Level 1	2. Name change from Strategic Diagnostics to Romer Labs
3. May 2019 Level 1	3. Updated catalog numbers.
4. November 2021 Level 1	4. Updated USDA/FDA information.

Under this AOAC® <i>Performance Tested</i> SM License Number, 020401 this method is distributed by: NONE	Under this AOAC® <i>Performance Tested</i> SM License Number, 020401 this method is distributed as: NONE
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PRINCIPLE OF THE METHOD (1)

The LFD Test for *Listeria* species can be used in combination with the proprietary RapidChek *Listeria* enrichment system for a rapid 40 hour test. After enrichment, an aliquot of sample broth is dispensed into a 12mm x 75mm test tube and boiled for 5 minutes. Once the sample has cooled, 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 *Listeria* species. 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-*Listeria* antibody. If antigen is present, the complex is captured in this zone 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 *Listeria* antigen is present, the formation of 2 red lines is observed, whereas when no *Listeria* is present, only 1 line forms.

DISCUSSION OF THE VALIDATION STUDY (1)

The RapidChek LFD and cultural methods have demonstrated excellent accuracy, sensitivity and specificity throughout these studies. Overall method agreement averaged 91% for the LFD and the cultural methods in food samples, though when method agreement data were adjusted to reflect the cases where the RapidChek methods recovered a greater number of positive samples than the reference methods, 100% and 102% method agreement were reported, respectively. In all 3 surface studies, the RapidChek methods reported greater numbers of positives than the reference method with the corresponding method agreement averaging 69% (131% when adjusted to reflect greater recovery). Overall, there were no false positive results and 2 false negative results observed using the LFD detection system (1% false negative rate, 0% false positive rate). There were 2 reported false positives and no false negative results using the RapidChek cultural method as the detection system with the food and surfaces tested (0% false negative rate, 3% false positive rate). In total, the RapidChek LFD and cultural methods reported 189 and 191 confirmed positive results, while the reference methods reported 169 confirmed results. The 2 methods have been shown to be capable of detecting very low levels (1cfu/25g) of *Listeria* spp. in a variety of food and has performed as well or better than the reference method with select environmental matrices. Sample matrix effects on the LFD within the food and environmental samples examined in these studies were not apparent. Assay robustness studies indicate that the assay will perform under a wide range of environmental conditions. The assay is stable for at least a year at room temperature and results are highly reproducible from lot to lot.

Table 1 *Listeria* Isolates Source List – Inclusivity Study (1)

#	Species	Serotype	Strain	Source	LFD Activity
1	<i>L. monocytogenes</i>	1/2a	ATCC 51774 ^a	Human Blood	+
2	<i>L. monocytogenes</i>	1/2a	SDI 10-3b/c1 ^b		+
3	<i>L. monocytogenes</i>	1/2a	SDI 10a-3b/c2 ^b		+
4	<i>L. monocytogenes</i>	1/2a	SDI 11-3b/c3 ^b		+
5	<i>L. monocytogenes</i>	1/2a	USDA 472 ^c		+
6	<i>L. monocytogenes</i>	1/2b	SDI 12-3b/c5 ^b		+
7	<i>L. monocytogenes</i>	1/2c	SDI 13-3b/c7 ^b		+
8	<i>L. monocytogenes</i>	1	ATCC 7644 ^a	Human	+
9	<i>L. monocytogenes</i>	2	ATCC 19112 ^a	Human Spinal Fluid	+
10	<i>L. monocytogenes</i>	3	ATCC 19113 ^a	Human	+
11	<i>L. monocytogenes</i>	3a	SDI 14-3b/c9 ^b		+
12	<i>L. monocytogenes</i>	3b	SDI 15-3b/d2 ^b		+
13	<i>L. monocytogenes</i>	3c	SDI 16-3b/d4 ^b		+
14	<i>L. monocytogenes</i>	4a	SDI 17-3b/d6 ^b		+
15	<i>L. monocytogenes</i>	4ab	SDI 18-3b/d8 ^b		+
16	<i>L. monocytogenes</i>	4b	ATCC 13932 ^a	Human Spinal Fluid	+
17	<i>L. monocytogenes</i>	4b	ATCC 19115 ^a	Human	+
18	<i>L. monocytogenes</i>	4b	ATCC 43256 ^a	Mexican Cheese	+
19	<i>L. monocytogenes</i>	4b	ATCC 51414 ^a	Raw Milk	+
20	<i>L. monocytogenes</i>	4b	SDI 19-3b/e1 ^b		+
21	<i>L. monocytogenes</i>	4b	U of G H7650 ^d		+
22	<i>L. monocytogenes</i>	4c	SDI 20-3b/e3 ^b		+
23	<i>L. monocytogenes</i>	4d	SDI 21-3b/e5 ^b		+
24	<i>L. monocytogenes</i>	4e	SDI 22-3b/e7 ^b		+
25	<i>L. monocytogenes</i>	7	SDI 23-3b/e9 ^b		+
26	<i>L. monocytogenes</i>		SDI-51 ^b	Chicken Isolate	+
27	<i>L. monocytogenes</i>		U of G H7649 ^d		+
28	<i>L. monocytogenes</i>		SDI 201 ^b		+
29	<i>L. monocytogenes</i>		SDI-52 ^b	Raw Beef	+
30	<i>L. grayi</i>		ATCC 19120 ^a	Chinchilla Feces	+
31	<i>L. grayi</i>		ATCC 25401 ^a	Corn Stalks	+
32	<i>L. innocua</i>		USDA 15-666 ^c		+
33	<i>L. innocua</i>	6a	ATCC 33090 ^a	Cow Brain	+
34	<i>L. innocua</i>	6b	ATCC 33091 ^a	Human Feces	+
35	<i>L. innocua</i>		SDI-3 ^b	Beef Isolate	+
36	<i>L. innocua</i>		SDI-198 ^b	Drain Sponge	+
37	<i>L. innocua</i>		SDI-53 ^b	Raw Turkey	+
38	<i>L. seeligeri</i>		ATCC 51334 ^a	<i>Clethrionomys glareolus</i> Intestine	+
39	<i>L. seeligeri</i>	4a	ATCC 51335 ^a		+
40	<i>L. seeligeri</i>		ATCC 35967 ^a	Soil	+
41	<i>L. seeligeri</i>		SDI 3BF1 ^b		+
42	<i>L. seeligeri</i>		SDI 3BF2 ^b		+
43	<i>L. welshimeri</i>	6b	ATCC 35897 ^a	Plant Material	+
44	<i>L. welshimeri</i>	6a	ATCC 43548 ^a		+
45	<i>L. welshimeri</i>		SDI-199 ^b		+
46	<i>L. welshimeri</i>		SDI-50 ^b	Chicken Isolate	+
47	<i>L. welshimeri</i>		SDI-54 ^b	Smoked Salmon	+
48	<i>L. ivanovii</i>		SDI 200 ^b		+
49	<i>L. ivanovii</i>		ATCC 700402 ^a		+
50	<i>L. ivanovii</i>		ATCC 19119 ^a	Sheep	+

^aAmerican Type Culture Collection, Manassas, VA; ^bStrategic Diagnostics Inc. Culture Collection, Newark, DE; ^c*Listeria* Reference Laboratory, Donald S. Munro Collection;c; ^dUnited States Department of Agriculture, Wyndmoor, PA; ^eUniversity of Georgia Culture Collection, Athens, GA.

Table 2: Non-*Listeria* isolates (1)

	Strain	BHI	RapidChek <i>Listeria</i>
1	<i>Brochothrix thermosphacta</i> 11509	-	-
2	<i>Citrobacter freundii</i> 7A12	-	-
3	<i>Enterobacter cloacae</i> #2	-	-
4	<i>Lactobacillus plantarum</i> 8014	-	-
5	<i>Micrococcus luteus</i> 533	-	-
6	<i>Rhodococcus equi</i> ATCC 7698	-	-
7	<i>Salmonella typhimurium</i> 14028	-	-
8	<i>Streptococcus mitis</i>	-	-
9	<i>Proteus vulgaris</i> ATCC 6380	-	-
10	<i>Bacillus cereus</i> 11778	-	-
11	<i>Enterococcus faecalis</i> 19433	-	-
12	<i>Staphylococcus aureus</i>	+	-
13	<i>Acinetobacter baumannii</i> 19606	-	-
14	<i>Aeromonas hydrophila</i> #10	-	-
15	<i>Chryseobacterium meningosepticum</i> 13253	-	-
16	<i>Klebsiella pneumoniae</i> #9	-	-
17	<i>Pseudomonas aeruginosa</i> 10145	-	-
18	<i>Myroides odoratus</i> 4651	-	-
19	<i>Vibrio spp.</i> 62A1	-	-
20	<i>Yersinia enterocolitica</i> 23715	-	-
21	<i>Lactobacillus/coccus lacti</i> 11454	-	-
22	<i>Lactobacillus acidophilus</i> 314	-	-
23	<i>Pseudomonas spp.</i>	-	-
24	<i>E. coli</i> 0157 35150	-	-
25	<i>Hafnia alvei</i> ATCC 25927	-	-
26	<i>Enterococcus durans</i> biotype 6	-	-
27	<i>Enterococcus faecalis</i> Biotype 43497	-	-
28	<i>Corynebacterium diphtheriae</i> biotype 13	-	-
29	<i>Enterococcus faecium</i> biotype 11	-	-
30	<i>Corynebacterium pseudogenitalium</i> biotype	-	-
31	<i>Enterococcus raffinosus</i> biotype 5	-	-
32	<i>Leuconostoc citreum</i> biotype 109929	-	-
33	<i>Streptococcus pyogenes</i> 19615	-	-
34	<i>Staphylococcus vitulinus</i> biotype 265308	-	-
35	<i>Bacillus subtilis</i> biotype 987649	-	-
36	<i>Corynebacterium spp.</i> Biotype 5	-	-

Table 4: Extramural Comparison of the 40-h RapidChek *Listeria* Methods with the USDA/FSIS and FDA/BAM Reference Methods: Roast Beef, Ricotta Cheese. (1)

Sample Matrix	Method type	Strain	MPN /25g	# of Sample	Presumptive Positives	Confirmed Positives	Sensitivity (%)	Specificity (%)	Method Agreement (%)	Chi-Square
Roast Beef	RapidChek LFD 40 h	<i>Listeria innocua</i>	0	5	0	0	n/a	100	100	n/a
			0.225 (0.05-0.93)*	20	14	14	100	100	75	1.45
	RapidChek Cultural 40 h		0	5	0	0	n/a	100	100	n/a
			0.225 (0.05-0.93)*	20	14	14	100	100	75	1.45
	USDA/FSIS 48 h		0	5	0	0	n/a	n/a	n/a	n/a
			0.225 (0.05-0.93)*	20	9	9	n/a	n/a	n/a	n/a
Ricotta Cheese	RapidChek LFD 40 h	<i>Listeria monocytogenes</i> 4ab	0	5	0	0	n/a	100	100	n/a
			0.575 (0.17-2.0)*	20	12	12	100	100	95	0
	RapidChek Cultural 40 h		0	5	0	0	n/a	100	100	n/a
			0.575 (0.17-2.0)*	20	12	12	100	100	95	0
	FDA/BAM 48 h		0	5	0	0	n/a	n/a	n/a	n/a
			0.575 (0.17-2.0)*	20	13	13	n/a	n/a	n/a	n/a

n/a = not applicable

Note: Roast Beef Aerobic Plate Count = 1.0×10^4 cfu/g

Ricotta Cheese Aerobic Plate Count = <10 cfu/g

* = 95% confidence Interval

Table 5: Extramural Comparison of the 40-h RapidChek *Listeria* Methods with the USDA/FSIS Reference Method: Rubber environmental samples. (1)

Sample Matrix	Method type	Strain	Nominal cfu /4 inch ²	# of Sample	Presumptive Positives	Confirmed Positives	Sensitivity (%)	Specificity (%)	Method Agreement	Chi-Square
Rubber Surfaces	RapidChek LFD 40 h	<i>Listeria monocytogenes</i> 4ab	0	5	0	0	n/a	100	100	n/a
			1100	20	9	9	100	100	65	4.0
	RapidChek Cultural		0	5	0	0	n/a	100	100	n/a
			1100	20	9	9	100	100	65	4.0
	USDA/FSIS 48 h		0	5	0	0	n/a	n/a	n/a	n/a
			1100	20	3	2	n/a	n/a	n/a	n/a

n/a = not applicable

Table 6: Intramural Comparison of the 40-h RapidChek *Listeria* Methods with the USDA/FSIS Reference Method: Deli Turkey, Hotdogs. (1)

Sample Matrix	Method type	Strain	MPN /25g	# of Sample	Presumptive Positives	Confirmed Positives	Sensitivity (%)	Specificity (%)	Method Agreement (%)	Chi-Square
Deli Turkey	RapidChek LFD 40 h	<i>Listeria monocytogenes</i> 1/2a	0	5	0	0	n/a	100	100	n/a
			0.4 (0.1-1.3)*	20	14	15	93	100	95	0
	RapidChek Cultural 40 h		0	5	0	0	n/a	100	100	n/a
			0.4 (0.1-1.3)*	20	15	15	100	100	90	0.1
	USDA/FSIS 48 h		0	5	0	0	n/a	n/a	n/a	n/a
			0.4 (0.1-1.3)*	20	13	13	n/a	n/a	n/a	n/a
Hotdogs	RapidChek LFD 40 h	<i>Listeria welshimeri</i>	0	5	0	0	n/a	100	100	n/a
			2.3 (0.6-9.5)*	20	16	16	100	100	100	0.13
	RapidChek Cultural 40 h		0	5	0	0	n/a	100	100	n/a
			2.3 (0.6-9.5)*	20	16	16	100	100	100	0.13
	USDA/FSIS 48 h		0	5	0	0	n/a	n/a	n/a	n/a
			2.3 (0.6-9.5)*	20	16	16	n/a	n/a	n/a	n/a

n/a = not applicable

Note: Deli Turkey Aerobic Plate Count = <9 X 10³ cfu/g

Hotdogs Aerobic Plate Count = < 8 10³ cfu/g

* = 95% confidence Interval

Table 7: Intramural Comparison of the 40-h RapidChek *Listeria* Methods with the USDA/FSIS and FDA/BAM Reference Methods: Pepperoni and Smoked Fish. (1)

Sample Matrix	Method type	Strain	MPN /25g	# of Sample	Presumptive Positives	Confirmed Positives	Sensitivity (%)	Specificity (%)	Method Agreement (%)	Chi-Square
Pepperoni	RapidChek LFD 40 h	<i>Listeria monocytogenes</i> 3b	0	5	0	0	n/a	100	100	n/a
			1.1 (0.3-4.3)*	20	10	10	100	100	90	0.07
	RapidChek Cultural 40 h		0	5	0	0	n/a	100	100	n/a
			1.1 (0.3-4.3)*	20	10	10	100	100	90	0.07
	USDA/FSIS 48 h		0	5	0	0	n/a	n/a	n/a	n/a
			1.1 (0.3-4.3)*	20	12	12	n/a	n/a	n/a	n/a
Smoked Fish	RapidChek LFD 40 h	<i>Listeria monocytogenes</i> 7	0	5	0	0	n/a	100	100	n/a
			5.0 (1.5-17.8)*	20	14	14	100	100	90	0.1
	RapidChek Cultural 40 h		0	5	0	0	n/a	100	100	n/a
			5.0 (1.5-17.8)*	20	14	14	100	100	90	0.1
	FDA/BAM 48 h		0	5	0	0	n/a	n/a	n/a	n/a
			5.0 (1.5-17.8)*	20	16	16	n/a	n/a	n/a	n/a

n/a = not applicable

Note: Pepperoni Aerobic Plate Count = 1.8×10^5 cfu/g

Smoked Fish Aerobic Plate Count = 1.89×10^5 cfu/g

* = 95% confidence Interval

Table 8: Intramural Comparison of the 40-h RapidChek *Listeria* Methods with the FDA/BAM Reference Method: Cooked Shrimp, and Potato Salad. (1)

Sample Matrix	Method type	Strain	MPN /25g	# of Sample	Presumptive Positives	Confirmed Positives	Sensitivity (%)	Specificity (%)	Method Agreement (%)	Chi-Square
Cooked Shrimp	RapidChek LFD 40 h	<i>Listeria monocytogenes</i> 3c	0	5	0	0	n/a	100	100	n/a
			0.2 (0.1-0.9)*	20	11	11	100	100	100	0.1
	RapidChek Cultural 40 h		0	5	0	0	n/a	100	100	n/a
			0.2 (0.1-0.9)*	20	11	11	100	100	100	0.1
	FDA/BAM 48 h		0	5	0	0	n/a	n/a	n/a	n/a
			0.2 (0.1-0.9)*	20	11	11	n/a	n/a	n/a	n/a
Potato Salad	RapidChek LFD 40 h	<i>Listeria monocytogenes</i> 1/2b	0	5	0	0	n/a	100	100	n/a
			1.1 (0.2-4.3)*	20	16	17	94	100	90	0.17
	RapidChek Cultural 40 h		0	5	0	0	n/a	100	100	n/a
			1.1 (0.2-4.3)*	20	18	17	100	87	95	0
	FDA/BAM 48 h		0	5	0	0	n/a	n/a	n/a	n/a
			1.1 (0.2-4.3)*	20	18	18	n/a	n/a	n/a	n/a

n/a = not applicable

Note: Cooked Shrimp Aerobic Plate Count = 1.8×10^4 cfu/g

Potato Salad Aerobic Plate Count = 1.8×10^4 cfu/g

* = 95% confidence interval

Table 9: Intramural Comparison of the 40-h RapidChek *Listeria* Method with the FDA/BAM Reference Method: Whole Milk, and Ice cream. (1)

Sample Matrix	Method type	Strain	MPN /25g	# of Sample	Presumptive Positives	Confirmed Positives	Sensitivity (%)	Specificity (%)	Method Agreement (%)	Chi-Square
Whole Milk	RapidChek LFD 40 h	<i>Listeria monocytogenes</i> 4b	0	5	0	0	n/a	100	100	n/a
			5.3 (1.5-18.3)*	20	17	17	100	100	95	0
	RapidChek Cultural 40 h		0	5	0	0	n/a	100	100	n/a
			5.3 (1.5-18.3)*	20	17	17	100	100	95	0
	FDA/BAM 48 h		0	5	0	0	n/a	n/a	n/a	n/a
			5.3 (1.5-18.3)*	20	18	18	n/a	n/a	n/a	n/a
Ice Cream	RapidChek LFD 40 h	<i>Listeria monocytogenes</i> 3a	0	5	0	0	n/a	100	100	n/a
			5.8 (1.7-20.3)*	20	20	20	100	100	80	2.25
	RapidChek Cultural 40 h		0	5	0	0	n/a	100	100	n/a
			5.8 (1.7-20.3)*	20	20	20	100	100	80	2.25
	FDA/BAM 48 h		0	5	0	0	n/a	n/a	n/a	n/a
			5.8 (1.7-20.3)*	20	16	16	n/a	n/a	n/a	n/a

n/a = not applicable

Note: Whole Milk Aerobic Plate Count = 9×10^3 cfu/g

Ice Cream Aerobic Plate Count = $< 9 \times 10^3$ cfu/g

* = 95% confidence Interval

Table 10: Intramural Comparison of the 40-h RapidChek *Listeria* Methods with the USDA/FSIS Reference Method: Painted Concrete, and Stainless Steel. (1)

Sample Matrix	Method type	Strain	Nominal MPN /inch ²	# of Sample	Presumptive Positives	Confirmed Positives	Sensitivity (%)	Specificity (%)	Method Agreement (%)	Chi-Square
Painted Concrete	RapidChek LFD 40 h	<i>Listeria monocytogenes</i> 4b	0	5	0	0	n/a	100	100	n/a
			1X10 ⁴	20	18	18	100	100	60	6.13
	RapidChek Cultural 40 h		0	5	0	0	n/a	100	100	n/a
			1X10 ⁴	20	19	18	100	86	60	6.13
	USDA/FSIS 48 h		0	5	0	0	n/a	n/a	n/a	n/a
			1X10 ⁴	20	10	10	n/a	n/a	n/a	n/a
Stainless Steel	RapidChek LFD 40 h	<i>Listeria innocua</i>	0	5	0	0	n/a	100	100	n/a
			5.5X10 ²	20	18	18	100	100	82	0.57
	RapidChek Cultural 40 h		0	5	0	0	n/a	100	100	n/a
			5.5X10 ²	20	18	18	100	100	82	0.57
	USDA/FSIS 48 h		0	5	0	0	n/a	n/a	n/a	n/a
			5.5X10 ²	20	15	15	n/a	n/a	n/a	n/a

n/a = not applicable

DISCUSSION OF MODIFICATION APPROVED MAY 2008 (3)

The RapidChek method has demonstrated excellent sensitivity, specificity, and accuracy in the detection of *Listeria* species in food and environmental surfaces throughout these studies. The RapidChek method reported greater numbers of positive results than the reference method in all three matrixes. Overall, there were no false positives results and two false negative results observed using the lateral flow device. In total, the RapidChek method reported 35 confirmed positive results, while the reference method reported 26 confirmed positive results. Both methods have been shown to be capable of detecting very low levels (0.575 cfu/25g) of *Listeria* spp. in food and the RapidChek method has performed as well or better than the reference method with the selected environmental surfaces.

Table 1. Results from the Hot Dog Method Comparison (3)

Matrix	Analyte	Method	Number of Samples	Inoculation Level, MPN/25g	Presumptive Positives	Confirmed Positives	Reference Method	Chi-Square	Sensitivity Rate	False Negative Rate	Specificity Rate	False Positive Rate
Hot Dogs	L. mono 4d M21	RapidChek	5	0	0	0	0	-	-	-	100	0
			20	0.575	11	12	11	0	92	8	-	-

Table 2. Results from Plastic Surface Method Comparison (3)

Matrix	Analyte	Method	Number of Samples	Nominal cfu/4inch ²	Presumptive Positives	Confirmed Positives	Reference Method	Chi-Square	Sensitivity Rate	False Negative Rate	Specificity Rate	False Positive Rate
Plastic	L. innocua ATCC 33090	RapidChek	5	0	0	0	0	-	-	-	100	0
			20	1.00E+03	13	14	9	1.58	93	7	-	-

Table 3. Results from Stainless Steel Method Comparison (3)

Matrix	Analyte	Method	Number of Samples	Nominal cfu/4inch ²	Presumptive Positives	Confirmed Positives	Reference Method	Chi-Square	Sensitivity Rate	False Negative Rate	Specificity Rate	False Positive Rate
Steel	L. mono 4b ATCC 13932	RapidChek	5	0	0	0	0	-	-	-	100	0
			20	3.00E+02	9	9	6	0.94	100	0	-	-

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