



CERTIFICATION

AOAC[®] Performance TestedSM

Certificate No.

040501

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

PDX-LIB

manufactured by

**Paradigm Diagnostics, Inc.
1360 University Avenue, West
Saint Paul, MN 55104
USA**

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 (January 19, 2016 – December 31, 2016). Renewal may be granted at the end of one year under the rules stated in the licensing agreement.

Deborah McKenzie

Deborah McKenzie, Senior Director
Signature for AOAC Research Institute

January 19, 2016

Date

METHOD AUTHORS

H. Cem Yurttas, Jessica Maher, William Dantzer, Leena Bagroo, Mary Brown, Alan Olstein, and Joellen Feirtag

SUBMITTING COMPANY

Paradigm Diagnostics, Inc.
1334 Eckles Ave
St. Paul, MN 55108

KIT NAME(S)

PDX-LIB

CATALOG NUMBERS

25009-50, 25005-100, 25004-100, 25003-25

INDEPENDENT LABORATORY

R-Tech Labs
P.O. Box 64101
St. Paul, MN 55164-0101
USA

AOAC EXPERTS AND PEER REVIEWERS

Thomas Hammack¹, Catherine Donnelly², Edward Richter³
¹USDA FDA CFSAN, College Park, MD, USA
²University of Vermont, Burlington, VT, USA
³Richter International, Columbus, OH, USA

APPLICABILITY OF METHOD

Target organism – *Listeria* species including *L. monocytogenes*, *L. innocua*, *L. ivanovii*, & *L. welshimeri*

Matrices – Ceramic tile, stainless steel, plastic, and sealed concrete

Performance claims - Performance of PDX-LIB has been tested rigorously in both AOAC-guided studies and real environmental samples studies. The results are suggesting that PDX-LIB was associated with acceptable levels of sensitivity, specificity and accuracy values when it was compared to USDA methods while providing presumptive results about 18 hour earlier than the reference method.

REFERENCE METHOD

<http://www.fsis.usda.gov/OA/pubs/lmtips.htm> (8)

PRINCIPLE OF THE METHOD

The principle of the PDX-LIB is based on colorimetric detection of *Listeria spp* in a unique blend of antibiotics, growth enhancers and *Listeria* specific color indicator working all synergistically. A light brown to black color formation within 30 hours indicates presence of *Listeria spp*. in an environmental sample. PDX-LIB has a limit of detection for most *Listeria spp*. between (>1-100 CFU/mL) within 30 hours.

DISCUSSION OF THE VALIDATION STUDY

PDX-LIB is an easy to use and interpret screening test for *Listeria spp* in environmental samples. Presumptive results are available within 30 hours compared to minimum after 48 hours with the typical cultural methods. Results of inclusivity – exclusivity studies suggested that PDX-LIB was associated with 100% sensitivity, and 96.7% selectivity when tested for *Listeria* and non-*Listeria* species. The minimum limit of detection is the critical piece of information that needs to be highlighted herein. It has been found out that most of the *Listeria spp* that were used in inclusivity – exclusivity studies gave minimum detection range at 1 – 100 CFU/ mL. However, there were a few in our culture collection required >1000 CFU/mL for detection within 30 hours. Regarding percent selectivity rate, again the cell concentration is the critical piece. It has been found that some non-*Listeria spp* if they were at higher than 1.0E+6 CFU/mL concentration level, then they might give false (+) results. It has been found a rare species of *Enterococci*, *Enterococcus hire* is capable of giving false (+) readings at the end of 30th hour if the initial inoculation is as low as 100 CFU/mL at time zero.

Internal method comparison studies produced χ^2 values that suggested there were no significant differences between the test method, PDX-LIB, and the reference method, USDA. External method comparison studies resulted in same conclusion for Lm on sealed concrete; however, Li on tile study resulted in slightly different than what has been obtained in internal validation studies. The main difference between two studies was the fact that tiles used by independent lab were over-saturated with concentrated bleach. According to the independent lab data, on average cell load onto surface before drying was 1.4E+5 CFU/area for high level of inoculated and it resulted in 12 presumptive out of 20 replicates. According to internal validation studies, on average cell load onto surface before drying was 2.93E+4 CFU/area for high and it resulted in 20 presumptive positives were obtained out of 20 replicates. It was also observed that oversaturated tiles, when used for evaluating another rapid detection kit, were causing more severe reductions in cell populations drying on the surface for overnight (data not shown). This type of an injury is rare and displays an extreme example of how *Listeria* would be found in the environment.

DISCUSSION OF THE VALIDATION STUDY Continued

Recovery of *Listeria* cells off of surfaces after overnight drying was monitored by plating 100 µL out from the test bag onto TSAIE plates. This plating information has revealed that drying on surfaces was causing an average 2 to 3 decimal reductions in cell population in addition to sub-lethal drying injuries in the remaining population (Appendix IV). In order to assess the effect of drying injury on the detection limits of PDX-LIB, logarithmic dilutions of healthy cells were tested before they were placed onto test surfaces (Appendix V). Data in appendix IV and V suggested that drying injury might have reduced detectability within 30 hours. Samples taken from very dry surfaces might require extended incubation times in order to minimize false interpretations. It is important to note that method comparison studies weighed more towards dry injured cells and therefore did represent just a fraction of how *Listeria* would be found in real world samples. Another very important fact needs to be highlighted here is the fact that PDX-LIB was getting 1/3 of what has been dislodged into the peptone after samples were taken off of surfaces. This fact is indeed very important and explains why always reference method was coming out with higher confirmed positives in each method comparison study conducted.

Regarding the ruggedness studies, recommended parameters have been studied for PDX-LIB. Results of ruggedness studies suggested selected deviations from test parameters did not interfere with the true detection of microorganisms selected. Although not seen in ruggedness studies, results in method comparison studies suggested extension of incubation times up to 4-6 hours would provide more reliability in detection for drying + bleach injured cells.

Shelf life and lot-to-lot variability has been monitored by internally developed quality control protocol. PDX-LIB has been shown to be reliably reproducible and stable at refrigerated storage conditions more than 6 months. Targeted shelf life for PDX-Lib is 1 year under refrigeration. More real time data will be submitted to AOAC as they become available.

Performance of PDX-IMC-List in real environmental samples were encouraging considering the fact that those presumptive results were available in about 30 hours in a self contained environment as opposed to minimum 48 hours with USDA-like method. As seen in Table 10 c, false positive and false negative rates are ~ 2 % in 508 real environmental samples containing 98 double-blinded control samples. Most of false negatives (5 / 9) in the whole study came from double blinded control samples (three different *Listeria*, two of which came out false negative both in binary competition and in pure culture formats, Appendix III B). Presumptive positives, although associated with ~2 % false (+) rate, are still valuable for the end user as they could be used as a measure for overall

DISCUSSION OF THE VALIDATION STUDY Continued

microbial cleanliness of the environment. As mentioned above, false positive results are very likely due to high (>1.0E+6 CFU/mL) concentrations of *Enterococcus spp*. In case an end user gets a presumptive positive in a sample, recommended first action is spot cleaning and sanitizing the location where the sample was taken. This simple action could save millions of dollars and non-measurable “reputation” asset of a food company. Based on PDX-LIB results, end user could obtain warnings regarding the presence of *Listeria* via a very simple low cost test and reduce the number of samples that necessitates confirmation.

As mentioned earlier, real environmental samples and double blinded control studies were included into this report as they provided a complementary perspective on how PDX-LIB would perform in the real world. Based on the data in Table 9 and Table 10, performance characteristics of PDX-LIB in AOAC- guideline studies and those in real environmental samples studies were different. As seen in Table 9, all false negatives in AOAC guideline studies originated from method comparison studies where drying injured cells were tested. Conclusively, although AOAC guideline studies were quite valuable (as by design characteristics, they leaned more towards inspecting the false (-) issue than false (+) issue), they should be supported with real environmental samples data. PDX-LIB is a unique easy to perform screening test available for food safety professionals in the industry. PDX-LIB being a self-contained test minimizes cross contamination. It is expected that PDX-LIB will reliably reduce the number of tests that require costly confirmation step.

REFERENCES CITED

1. Yurttas, H.C., Maher, J., Danter, W., Bagroo, L., Brown, M., Olstein, A., and Feirtag, J., Evaluation of the PDX-LIB, AOAC® Performance TestedSM certification number 040501.
2. AOAC Research Institute Validation Outline for PDX-LIB, Approved – April 2005.
3. Siragusa, Gregory R. and Johnson, Michael. 1990. Monoclonal Antibodies Specific for *Listeria monocytogenes*, *Listeria innocua*, and *Listeria welshimeri*. Applied and Environmental Microbiology. 56:1897-1904.
4. Johnson, J., Jinneman, K., Stelma, G., Smith, B. G., Lye, D., Messer, J., Ulaszek, J., Evsen, L., Gendel, S., Bennett, R. W., Swaminathan, B., Pruckler, J., Steigerwalt, A., Kathariou, S., Yildirim, S., Volokhov, D., Rasooly, a., Chizhikov, V., Wiedmann, M., Fortes, E., Duvall, R. E., Hitchins, A. D. 2004. Natural Atypical *Listeria innocua* Strains with *Listeria monocytogenes* Pathogenicity Island 1 Gene. Applied and Environmental Microbiology. 70:4256-4266.
5. FDA/CFSAN Bad Bug Book, online version at <http://vm.cfsan.fda.gov/~mow/chap6.html>
6. Donnelly, Catherine W. and Busch, Susan. 1992. Development of a Repair-Enrichment Broth for Resuscitation of Heat-Injured *Listeria monocytogenes* and *Listeria innocua*. Applied and Environmental Microbiology. 58:14-20.
7. CDC Division of Bacterial and Mycotic Diseases on line publication http://www.cdc.gov/ncidod/dbmd/diseaseinfo/listeriosis_g.htm
8. <http://www.fsis.usda.gov/OA/pubs/lmtips.htm>
9. Donnelly, CW. 2001. *Listeria monocytogenes*: a Continuing Challenge. Nutr. Rev. 59:183-194.
10. Nogca, Hege Kari, Rudi, Knut, Naterstad, Kristine, Holck, Askild, Lillehaug, Dag. 2000. Application of 5'-Nuclease PCR for Quantitative Detection of *Listeria monocytogenes* in Pure Cultures, Water, Skim Milk, and Unpasteurized Whole Milk. Applied and Environmental Microbiology. 66:4266-4271
11. Chen, Y., Ross, W.H., Scott, V.N. and Gombas, D.E. 2003. *Listeria monocytogenes*. Low levels equal low risk. J. Food Prot. 66:570-57.
12. FSIS- Recall Information Center, online publication http://www.fsis.gov/OA/recalls/rec_pr.htm

Appendix I: Inclusivity-Exclusivity Data

INCLUSIVITY				EXCLUSIVITY			
Description and Code	Color	Presumptive Result	Confirmation	Description and Code	Color	Presumptive Result	Confirmation
<i>Listeria monocytogenes</i> 19114	Black	+	Lm	<i>Pseudomonas fluorescens</i> 49838	Yellow	-	Not Listeria
<i>Listeria welshmeri</i> 35897	Black	+	Lw	<i>Staphylococcus aureus</i> 35548	Yellow	-	Not Listeria
<i>Listeria monocytogenes</i> 49594	Black	+	Lm	<i>Klebsiella pneumoniae</i> 13883	Yellow	-	Not Listeria
<i>Listeria monocytogenes</i> 2399	Black	+	Lm	<i>Proteus mirabilis</i> 25933	Yellow	-	Not Listeria
<i>Listeria monocytogenes</i> 19117	Black	+	Lm	<i>Kurtzia zopfii</i> 6900	Yellow	-	Not Listeria
<i>Listeria monocytogenes</i> 1914	Black	+	Lm	<i>Micrococcus luteus</i> 4698	Yellow	-	Not Listeria
<i>Listeria monocytogenes</i> 2417	Black	+	Lm	<i>Pseudomonas aeruginosa</i> 27853	Yellow	-	Not Listeria
<i>Listeria monocytogenes</i> 4b rt 652 (B)	Black	+	Lm	<i>Enterobacter aerogenes</i> 13048	Yellow	-	Not Listeria
<i>Listeria welshmeri</i> 43551 (B)	Brown	+	Lw	<i>Bacillus subtilis</i> 6051	Yellow	-	Not Listeria
<i>Listeria monocytogenes</i> 2392	Black	+	Lm	<i>Staphylococcus epidermidis</i> 1228	Yellow	-	Not Listeria
<i>Listeria monocytogenes</i> 2421	Black	+	Lm	<i>Proteus vulgaris</i> 8427	Yellow	-	Not Listeria
<i>Listeria ivanovi</i> 19119	Black	+	Liv	<i>Klebsiella pneumoniae</i> 27799	Yellow	-	Not Listeria
<i>Listeria monocytogenes</i> 3522	Black	+	Lm	<i>Streptococcus pyogenes</i> 19615	Yellow	-	Not Listeria
<i>Listeria monocytogenes</i> 2426	Black	+	Lm	<i>Enterococcus faecalis</i> 29212	Yellow	-	Not Listeria
<i>Listeria monocytogenes</i> 19118 (B)	Brown	+	Lm	<i>Enterobacter cloacae</i> 13047	Yellow	-	Not Listeria
<i>Listeria monocytogenes</i> 2415	Black	+	Lm	<i>Salmonella heidelberg</i> FSIS 109	Yellow	-	Not Listeria
<i>Listeria monocytogenes</i> 19112 (B)	Brown	+	Lm	<i>Salmonella choleraesuis typhimurium</i> 14028	Yellow	-	Not Listeria
<i>Listeria innocua</i> 3757	Black	+	Li	<i>Staphylococcus aureus</i> 8095	Yellow	-	Not Listeria
<i>Listeria innocua</i> 2249	Black	+	Li	<i>E. coli</i> O157:H7 43895	Yellow	-	Not Listeria
<i>Listeria monocytogenes</i> 2396	Black	+	Lm	<i>Staphylococcus aureus</i> 25923	Yellow	-	Not Listeria
<i>Listeria monocytogenes</i> 3550	Black	+	Lm	<i>E. coli</i> 25922	Yellow	-	Not Listeria
<i>Listeria innocua</i> 3181	Black	+	Li	<i>Rhodococcus equi</i> 6939	Yellow	-	Not Listeria
<i>Listeria monocytogenes</i> 2349	Black	+	Lm	<i>E. coli</i> 10798	Yellow	-	Not Listeria
<i>Listeria monocytogenes</i> 2410	Black	+	Lm	<i>E. coli</i> 51739	Yellow	-	Not Listeria
<i>Listeria seeligeri</i> 2232	Brown	+	Ls	<i>Enterococcus hire</i> 8043	Black	+	Not Listeria
<i>Listeria monocytogenes</i> 3528	Black	+	Lm	<i>Staphylococcus aureus</i> 51740	Yellow	-	Not Listeria
<i>Listeria monocytogenes</i> 1/2 a rt 651 (B)	Black	+	Lm	<i>Bacillus licheniformis</i> 12759	Yellow	-	Not Listeria
<i>Listeria monocytogenes</i> 2388	Black	+	Lm	<i>E. coli</i> 026	Yellow	-	Not Listeria
<i>Listeria monocytogenes</i> 2397	Black	+	Lm	<i>E. coli</i> 0111	Yellow	-	Not Listeria
<i>Listeria ivanovi</i> 700402	Black	+	Liv	<i>E. coli</i> 3051	Yellow	-	Not Listeria
<i>Listeria monocytogenes</i> 2404	Black	+	Lm				
<i>Listeria monocytogenes</i> 2424	Black	+	Lm				
<i>Listeria monocytogenes</i> 2578	Black	+	Lm				
<i>Listeria monocytogenes</i> 2427	Black	+	Lm				
<i>Listeria monocytogenes</i> 15313	Black	+	Lm				
<i>Listeria monocytogenes</i> 3742	Black	+	Lm				
<i>Listeria innocua</i> 2241	Black	+	Li				
<i>Listeria monocytogenes</i> 1/2 b rt 541 (B)	Black	+	Lm				
<i>Listeria monocytogenes</i> 2422	Black	+	Lm				
<i>Listeria innocua</i> 51742	Black	+	Li				
<i>Listeria monocytogenes</i> 2395	Black	+	Lm				
<i>Listeria welshmeri</i> 43550	Black	+	Lw				
<i>Listeria monocytogenes</i> 4b 19115	Black	+	Lm				
<i>Listeria monocytogenes</i> 2413	Black	+	Lm				
<i>Listeria welshmeri</i> 2231	Black	+	Lw				
<i>Listeria innocua</i> 2242	Black	+	Li				
<i>Listeria monocytogenes</i>	Black	+	Lm				
<i>Listeria monocytogenes</i>	Black	+	Lm				
<i>Listeria monocytogenes</i>	Black	+	Lm				

Appendix II. Method Comparison Data A) Internal Evaluation of Li on Tile

PDX- LIB - Li on tile					USDA - Li on tile				
Level	Code	Color	Presumptive	Confirmed	Level	Code	Presumptive	Confirmed	
High	a	Black	+	<i>Listeria innocua</i>	High	a	+	<i>Listeria innocua</i>	
	b	Black	+	<i>Listeria innocua</i>		b	+	<i>Listeria innocua</i>	
	c	Black	+	<i>Listeria innocua</i>		c	+	<i>Listeria innocua</i>	
	d	Black	+	<i>Listeria innocua</i>		d	+	<i>Listeria innocua</i>	
	e	Black	+	<i>Listeria innocua</i>		e	+	<i>Listeria innocua</i>	
	f	Black	+	<i>Listeria innocua</i>		f	+	<i>Listeria innocua</i>	
	g	Black	+	<i>Listeria innocua</i>		g	+	<i>Listeria innocua</i>	
	h	Black	+	<i>Listeria innocua</i>		h	+	<i>Listeria innocua</i>	
	i	Black	+	<i>Listeria innocua</i>		i	+	<i>Listeria innocua</i>	
	j	Black	+	<i>Listeria innocua</i>		j	+	<i>Listeria innocua</i>	
	k	Black	+	<i>Listeria innocua</i>		k	+	<i>Listeria innocua</i>	
	l	Black	+	<i>Listeria innocua</i>		l	+	<i>Listeria innocua</i>	
	m	Black	+	<i>Listeria innocua</i>		m	+	<i>Listeria innocua</i>	
	n	Black	+	<i>Listeria innocua</i>		n	+	<i>Listeria innocua</i>	
	o	Black	+	<i>Listeria innocua</i>		o	+	<i>Listeria innocua</i>	
	p	Black	+	<i>Listeria innocua</i>		p	+	<i>Listeria innocua</i>	
	q	Black	+	<i>Listeria innocua</i>		q	+	<i>Listeria innocua</i>	
	r	Black	+	<i>Listeria innocua</i>		r	+	<i>Listeria innocua</i>	
	s	Black	+	<i>Listeria innocua</i>		s	+	<i>Listeria innocua</i>	
	t	Black	+	<i>Listeria innocua</i>		t	+	<i>Listeria innocua</i>	
Low	a	Black	+	<i>Listeria innocua</i>	Low	a	+	<i>Listeria innocua</i>	
	b	Black	+	<i>Listeria innocua</i>		b	+	<i>Listeria innocua</i>	
	c	Black	+	<i>Listeria innocua</i>		c	+	<i>Listeria innocua</i>	
	d	Black	+	<i>Listeria innocua</i>		d	+	<i>Listeria innocua</i>	
	e	Black	+	<i>Listeria innocua</i>		e	+	<i>Listeria innocua</i>	
	f	Black	+	<i>Listeria innocua</i>		f	+	<i>Listeria innocua</i>	
	g	Black	+	<i>Listeria innocua</i>		g	+	<i>Listeria innocua</i>	
	h	Black	+	<i>Listeria innocua</i>		h	+	<i>Listeria innocua</i>	
	i	Black	+	<i>Listeria innocua</i>		i	+	<i>Listeria innocua</i>	
	j	Black	+	<i>Listeria innocua</i>		j	+	<i>Listeria innocua</i>	
	k	Black	+	<i>Listeria innocua</i>		k	+	<i>Listeria innocua</i>	
	l	Black	+	<i>Listeria innocua</i>		l	+	<i>Listeria innocua</i>	
	m	Black	+	<i>Listeria innocua</i>		m	+	<i>Listeria innocua</i>	
	n	Black	+	<i>Listeria innocua</i>		n	+	<i>Listeria innocua</i>	
	o	Black	+	<i>Listeria innocua</i>		o	+	<i>Listeria innocua</i>	
	p	Black	+	<i>Listeria innocua</i>		p	+	<i>Listeria innocua</i>	
	q	Yellow	-	<i>Listeria innocua</i>		q	+	<i>Listeria innocua</i>	
	r	Yellow	-	<i>Listeria innocua</i>		r	+	<i>Listeria innocua</i>	
	s	Yellow	-	<i>Listeria innocua</i>		s	+	<i>Listeria innocua</i>	
	t	Yellow	-	<i>Listeria innocua</i>		t	+	<i>Listeria innocua</i>	
Uninoculated	a	Yellow	-	Not Listeria	Uninoculated	a	-	Not Listeria	
	b	Yellow	-	Not Listeria		b	-	Not Listeria	
	c	Yellow	-	Not Listeria		c	-	Not Listeria	
	d	Yellow	-	Not Listeria		d	-	Not Listeria	
	e	Yellow	-	Not Listeria		e	-	Not Listeria	

Appendix II. Method Comparison Data B) Internal Evaluation of Liv on Stainless Steel

PDX- LIB - Liv on stainless steel				USDA-Liv on Stainless Steel				
Level	Code	Color	Presumptive	Confirmed	Level	Code	Presumptive	Confirmed
High	a	Black	+	<i>Listeria ivanovii</i>	High	a	+	<i>Listeria ivanovii</i>
	b	Black	+	<i>Listeria ivanovii</i>		b	+	<i>Listeria ivanovii</i>
	c	Black	+	<i>Listeria ivanovii</i>		c	+	<i>Listeria ivanovii</i>
	d	Black	+	<i>Listeria ivanovii</i>		d	+	<i>Listeria ivanovii</i>
	e	Black	+	<i>Listeria ivanovii</i>		e	+	<i>Listeria ivanovii</i>
	f	Black	+	<i>Listeria ivanovii</i>		f	+	<i>Listeria ivanovii</i>
	g	Black	+	<i>Listeria ivanovii</i>		g	+	<i>Listeria ivanovii</i>
	h	Black	+	<i>Listeria ivanovii</i>		h	+	<i>Listeria ivanovii</i>
	i	Black	+	<i>Listeria ivanovii</i>		i	+	<i>Listeria ivanovii</i>
	j	Black	+	<i>Listeria ivanovii</i>		j	+	<i>Listeria ivanovii</i>
	k	Black	+	<i>Listeria ivanovii</i>		k	+	<i>Listeria ivanovii</i>
	l	Black	+	<i>Listeria ivanovii</i>		l	+	<i>Listeria ivanovii</i>
	m	Black	+	<i>Listeria ivanovii</i>		m	+	<i>Listeria ivanovii</i>
	n	Black	+	<i>Listeria ivanovii</i>		n	+	<i>Listeria ivanovii</i>
	o	Black	+	<i>Listeria ivanovii</i>		o	+	<i>Listeria ivanovii</i>
	p	Black	+	<i>Listeria ivanovii</i>		p	+	<i>Listeria ivanovii</i>
	q	Black	+	<i>Listeria ivanovii</i>		q	+	<i>Listeria ivanovii</i>
	r	Black	+	<i>Listeria ivanovii</i>		r	+	<i>Listeria ivanovii</i>
	s	Black	+	<i>Listeria ivanovii</i>		s	+	<i>Listeria ivanovii</i>
	t	Black	+	<i>Listeria ivanovii</i>		t	+	<i>Listeria ivanovii</i>
Low	a	Black	+	<i>Listeria ivanovii</i>	Low	a	+	<i>Listeria ivanovii</i>
	b	Black	+	<i>Listeria ivanovii</i>		b	+	<i>Listeria ivanovii</i>
	c	Black	+	<i>Listeria ivanovii</i>		c	+	<i>Listeria ivanovii</i>
	d	Black	+	<i>Listeria ivanovii</i>		d	+	<i>Listeria ivanovii</i>
	e	Black	+	<i>Listeria ivanovii</i>		e	+	<i>Listeria ivanovii</i>
	f	Black	+	<i>Listeria ivanovii</i>		f	+	<i>Listeria ivanovii</i>
	g	Black	+	<i>Listeria ivanovii</i>		g	+	<i>Listeria ivanovii</i>
	h	Black	+	<i>Listeria ivanovii</i>		h	+	<i>Listeria ivanovii</i>
	i	Black	+	<i>Listeria ivanovii</i>		i	+	<i>Listeria ivanovii</i>
	j	Black	+	<i>Listeria ivanovii</i>		j	+	<i>Listeria ivanovii</i>
	k	Black	+	<i>Listeria ivanovii</i>		k	+	<i>Listeria ivanovii</i>
	l	Black	+	<i>Listeria ivanovii</i>		l	+	<i>Listeria ivanovii</i>
	m	Black	+	<i>Listeria ivanovii</i>		m	+	<i>Listeria ivanovii</i>
	n	Black	+	<i>Listeria ivanovii</i>		n	+	<i>Listeria ivanovii</i>
	o	Black	+	<i>Listeria ivanovii</i>		o	+	<i>Listeria ivanovii</i>
	p	Black	+	<i>Listeria ivanovii</i>		p	+	<i>Listeria ivanovii</i>
	q	Yellow	-	<i>Listeria ivanovii</i>		q	+	<i>Listeria ivanovii</i>
	r	Yellow	-	<i>Listeria ivanovii</i>		r	+	<i>Listeria ivanovii</i>
	s	Yellow	-	<i>Listeria ivanovii</i>		s	+	<i>Listeria ivanovii</i>
	t	Yellow	-	<i>Listeria ivanovii</i>		t	+	<i>Listeria ivanovii</i>
Uninoculated	a	Yellow	-	Not Listeria	Uninoculated	a	-	Not Listeria
	b	Yellow	-	Not Listeria		b	-	Not Listeria
	c	Yellow	-	Not Listeria		c	-	Not Listeria
	d	Yellow	-	Not Listeria		d	-	Not Listeria
	e	Yellow	-	Not Listeria		e	-	Not Listeria

Appendix II. Method Comparison Data C) Internal Evaluation of Lw in 10xSa on Plastic

PDX- LIB Lw in 10xSa on Plastic					USDA-Lw in 10xSa on Plastic				
Level	Code	Color	Presumptive	Confirmed	Level	Code	Presumptive	Confirmed	
High	a	Black	+	<i>Listeria welshmeri</i>	High	a	+	<i>Listeria welshmeri</i>	
	b	Black	+	<i>Listeria welshmeri</i>		b	+	<i>Listeria welshmeri</i>	
	c	Black	+	<i>Listeria welshmeri</i>		c	+	<i>Listeria welshmeri</i>	
	d	Black	+	<i>Listeria welshmeri</i>		d	+	<i>Listeria welshmeri</i>	
	e	Black	+	<i>Listeria welshmeri</i>		e	+	<i>Listeria welshmeri</i>	
	f	Black	+	<i>Listeria welshmeri</i>		f	+	<i>Listeria welshmeri</i>	
	g	Black	+	<i>Listeria welshmeri</i>		g	+	<i>Listeria welshmeri</i>	
	h	Black	+	<i>Listeria welshmeri</i>		h	+	<i>Listeria welshmeri</i>	
	i	Black	+	<i>Listeria welshmeri</i>		i	+	<i>Listeria welshmeri</i>	
	j	Black	+	<i>Listeria welshmeri</i>		j	+	<i>Listeria welshmeri</i>	
	k	Black	+	<i>Listeria welshmeri</i>		k	+	<i>Listeria welshmeri</i>	
	l	Black	+	<i>Listeria welshmeri</i>		l	+	<i>Listeria welshmeri</i>	
	m	Black	+	<i>Listeria welshmeri</i>		m	+	<i>Listeria welshmeri</i>	
	n	Black	+	<i>Listeria welshmeri</i>		n	+	<i>Listeria welshmeri</i>	
	o	Black	+	<i>Listeria welshmeri</i>		o	+	<i>Listeria welshmeri</i>	
	p	Black	+	<i>Listeria welshmeri</i>		p	+	<i>Listeria welshmeri</i>	
	q	Black	+	<i>Listeria welshmeri</i>		q	+	<i>Listeria welshmeri</i>	
	r	Black	+	<i>Listeria welshmeri</i>		r	+	<i>Listeria welshmeri</i>	
	s	Black	+	<i>Listeria welshmeri</i>		s	+	<i>Listeria welshmeri</i>	
	t	Black	+	<i>Listeria welshmeri</i>		t	+	<i>Listeria welshmeri</i>	
Low	a	Black	+	<i>Listeria welshmeri</i>	Low	a	+	<i>Listeria welshmeri</i>	
	b	Black	+	<i>Listeria welshmeri</i>		b	+	<i>Listeria welshmeri</i>	
	c	Black	+	<i>Listeria welshmeri</i>		c	+	<i>Listeria welshmeri</i>	
	d	Black	+	<i>Listeria welshmeri</i>		d	+	<i>Listeria welshmeri</i>	
	e	Black	+	<i>Listeria welshmeri</i>		e	+	<i>Listeria welshmeri</i>	
	f	Black	+	<i>Listeria welshmeri</i>		f	+	<i>Listeria welshmeri</i>	
	g	Black	+	<i>Listeria welshmeri</i>		g	+	<i>Listeria welshmeri</i>	
	h	Black	+	<i>Listeria welshmeri</i>		h	+	<i>Listeria welshmeri</i>	
	i	Black	+	<i>Listeria welshmeri</i>		i	+	<i>Listeria welshmeri</i>	
	j	Black	+	<i>Listeria welshmeri</i>		j	+	<i>Listeria welshmeri</i>	
	k	Black	+	<i>Listeria welshmeri</i>		k	+	<i>Listeria welshmeri</i>	
	l	Black	+	<i>Listeria welshmeri</i>		l	+	<i>Listeria welshmeri</i>	
	m	Black	+	<i>Listeria welshmeri</i>		m	+	<i>Listeria welshmeri</i>	
	n	Black	+	<i>Listeria welshmeri</i>		n	+	<i>Listeria welshmeri</i>	
	o	Black	+	<i>Listeria welshmeri</i>		o	+	<i>Listeria welshmeri</i>	
	p	Black	+	<i>Listeria welshmeri</i>		p	+	<i>Listeria welshmeri</i>	
	q	Black	+	<i>Listeria welshmeri</i>		q	+	<i>Listeria welshmeri</i>	
	r	Black	+	<i>Listeria welshmeri</i>		r	+	<i>Listeria welshmeri</i>	
	s	Yellow	-	<i>Listeria welshmeri</i>		s	+	<i>Listeria welshmeri</i>	
	t	Yellow	-	<i>Listeria welshmeri</i>		t	+	<i>Listeria welshmeri</i>	
Uninoculated	a	Yellow	-	Not Listeria	Uninoculated	a	-	Not Listeria	
	b	Yellow	-	Not Listeria		b	-	Not Listeria	
	c	Yellow	-	Not Listeria		c	-	Not Listeria	
	d	Yellow	-	Not Listeria		d	-	Not Listeria	
	e	Yellow	-	Not Listeria		e	-	Not Listeria	

Appendix II. Method Comparison Data D) Independent Lab Evaluation of Li on tile

PDX-LIB Li on Tile-Independent Lab				USDA Li on Tile-Independent Lab			
Treatment	Color	Presumptive	Confirmed	Treatment	Presumptive	Confirmed	
HIGH	Black	+	L. innocua	HIGH	+	L. innocua	
HIGH	Black	+	L. innocua	HIGH	+	L. innocua	
HIGH	Black	+	L. innocua	HIGH	+	L. innocua	
HIGH	Yellow	-		HIGH	+	L. innocua	
HIGH	Black	+	L. innocua	HIGH	+	L. innocua	
HIGH	Black	+	L. innocua	HIGH	+	L. innocua	
HIGH	Black	+	L. innocua	HIGH	+	L. innocua	
HIGH	Black	+	L. innocua	HIGH	+	L. innocua	
HIGH	Black	+	L. innocua	HIGH	+	L. innocua	
HIGH	Yellow	-	L. innocua	HIGH	+	L. innocua	
HIGH	Black	+	L. innocua	HIGH	+	L. innocua	
HIGH	Yellow	-	L. innocua	HIGH	+	L. innocua	
HIGH	Yellow	-		HIGH	-		
HIGH	Yellow	-	L. innocua	HIGH	+	L. innocua	
HIGH	Yellow	-		HIGH	+	L. innocua	
HIGH	Black	+	L. innocua	HIGH	+	L. innocua	
HIGH	Black	+	L. innocua	HIGH	+	L. innocua	
HIGH	Black	+	L. innocua	HIGH	+	L. innocua	
HIGH	Black	+	L. innocua	HIGH	+	L. innocua	
HIGH	Yellow	-		HIGH	+	L. innocua	
HIGH	Yellow	-		HIGH	+	L. innocua	
LOW	Yellow	-		LOW	+	L. innocua	
LOW	Yellow	-		LOW	+	L. innocua	
LOW	Yellow	-		LOW	-		
LOW	Yellow	-		LOW	+	L. innocua	
LOW	Yellow	-		LOW	+	L. innocua	
LOW	Yellow	-		LOW	-		
LOW	Yellow	-		LOW	-		
LOW	Yellow	-		LOW	-		
LOW	Yellow	-		LOW	-		
LOW	Yellow	-		LOW	+	L. innocua	
LOW	Yellow	-		LOW	+	L. innocua	
LOW	Yellow	-		LOW	+	L. innocua	
LOW	Black	+	L. innocua	LOW	+	L. innocua	
LOW	Yellow	-		LOW	-		
LOW	Yellow	-	L. innocua	LOW	-		
LOW	Yellow	-		LOW	+	L. innocua	
LOW	Yellow	-		LOW	+	L. innocua	
LOW	Black	+	L. innocua	LOW	+	L. innocua	
LOW	Yellow	-		LOW	-		
LOW	Black	+	L. innocua	LOW	+	L. innocua	
UNINOCULATED	Yellow	-	Not Listeria	UNINOCULATED	-		
UNINOCULATED	Yellow	-	Not Listeria	UNINOCULATED	-		
UNINOCULATED	Yellow	-	Not Listeria	UNINOCULATED	-		
UNINOCULATED	Yellow	-	Not Listeria	UNINOCULATED	-		
UNINOCULATED	Yellow	-	Not Listeria	UNINOCULATED	-		

Appendix II. Method Comparison Data E) Independent Lab Evaluation of Lm on Sealed Concrete

PDX- LIB Lm on Sealed Concrete-Independent Lab				USDA Lm on sealed concrete - Independent Lab		
Treatment	Color	Presumptive	Confirmed	Treatment	Presumptive	Confirmed
HIGH	Black	++	L. mono	HIGH	-	
HIGH	Black	+	L. mono	HIGH	+	L. mono
HIGH	Yellow	-	L. mono	HIGH	-	
HIGH	Yellow	-		HIGH	-	
HIGH	Black	++	L. mono	HIGH	+	L. mono
HIGH	Yellow	-	L. mono	HIGH	+	L. mono
HIGH	Yellow	-		HIGH	-	
HIGH	Black	++	L. mono	HIGH	+	L. mono
HIGH	Black	+	L. mono	HIGH	+	L. mono
HIGH	Brown	+very light	L. mono	HIGH	-	
HIGH	Black	+	L. mono	HIGH	+	L. mono
HIGH	Black	+	L. mono	HIGH	-	
HIGH	Yellow	-		HIGH	+	L. mono
HIGH	Black	+	L. mono	HIGH	+	L. mono
HIGH	Yellow	-		HIGH	+	L. mono
HIGH	Black	++	L. mono	HIGH	+	L. mono
HIGH	Black	+	L. mono	HIGH	+	L. mono
HIGH	Black	+	L. mono	HIGH	+	L. mono
HIGH	Yellow	-	L. mono	HIGH	+	L. mono
HIGH	Black	++	L. mono	HIGH	+	L. mono
LOW	Yellow	-		LOW	-	
LOW	Yellow	-		LOW	-	
LOW	Yellow	-		LOW	-	
LOW	Yellow	-		LOW	-	
LOW	Yellow	-		LOW	-	
LOW	Yellow	-		LOW	-	
LOW	Yellow	-		LOW	+	L. mono
LOW	Yellow	-		LOW	-	
LOW	Black	++	L. mono	LOW	+	L. mono
LOW	Black	+	L. mono	LOW	+	L. mono
LOW	Yellow	-		LOW	+	L. mono
LOW	Yellow	-		LOW	+	L. mono
LOW	Yellow	-		LOW	-	
LOW	Black	++	L. mono	LOW	-	
LOW	Yellow	-		LOW	-	
LOW	Black	++	L. mono	LOW	+	L. mono
LOW	Yellow	-		LOW	-	
LOW	Yellow	-		LOW	-	
LOW	Yellow	-		LOW	-	
LOW	Yellow	-		LOW	-	
LOW	Yellow	-		LOW	+	L. mono
LOW	Brown	+very light	L. mono	LOW	-	
UNINOCULATED	Yellow	-		UNINOCULATED	-	
UNINOCULATED	Yellow	-		UNINOCULATED	-	
UNINOCULATED	Yellow	-		UNINOCULATED	-	
UNINOCULATED	Yellow	-		UNINOCULATED	-	
UNINOCULATED	Yellow	-		UNINOCULATED	-	

ORIGINAL CERTIFICATION DATE April 12, 2005	CERTIFICATION RENEWAL RECORD Renewed Annually through December 2016
--	---

METHOD MODIFICATION RECORD None	SUMMARY OF MODIFICATION
---	--------------------------------

Under this AOAC® <i>Performance TestedSM</i> License Number, 040501 this method is distributed by:	Under this AOAC® <i>Performance TestedSM</i> License Number, 040501 this method is distributed as:
---	---