



# CERTIFICATION

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

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.  
800 Transfer Road, Ste 12  
Saint Paul, MN 55114  
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 (July 03, 2019 – December 31, 2019). 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

\_\_\_\_\_  
July 03, 2019

Date

**METHOD AUTHORS**

**ORIGINAL VALIDATION:** H. Cem Yurttas, Jessica Maher, William Dantzer, Leena Bagroo, Mary Brown, Alan Olstein, and Joellen Feirtag  
**MODIFICATION JULY 2019:** Nicole Klass, Benjamin Bastin, Erin Crowley, James Agin

**SUBMITTING COMPANY**

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

**CURRENT ADDRESS**

Paradigm Diagnostics, Inc.  
 800 Transfer Road, Ste 12  
 Saint Paul, MN 55114

**KIT NAME(S)**

PDX-LIB

**CATALOG NUMBERS**

25009-50, 25005-100, 25003-25

**INDEPENDENT LABORATORY****Original Validation**

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

**July 2019 Modification**

Q Laboratories  
 1930 Radcliff Drive  
 Cincinnati, Ohio 45204

**AOAC EXPERTS AND PEER REVIEWERS**

Thomas Hammack<sup>1</sup>, Yi Chen<sup>1,6</sup>, Catherine Donnelly<sup>2</sup>, Edward Richter<sup>3</sup>, Joseph Odumeru<sup>4,6</sup>, Wayne Ziemer<sup>5,6</sup>

<sup>1</sup> US FDA CFSAN, College Park, MD, USA

<sup>2</sup> University of Vermont, Burlington, VT, USA

<sup>3</sup> Richter International, Columbus, OH, USA

<sup>4</sup> University of Guelph, Guelph, Ontario, CANADA

<sup>5</sup> Consultant, Loganville, GA, USA

<sup>6</sup> Modifications: July 2019

**APPLICABILITY OF METHOD**

Target organism – *Listeria* species including *L. monocytogenes*, *L. innocua*, *L. ivanovii*, *L. seeligeri*, *L. welshimeri*, *L. grayi*, and *L. marthii*

Matrices – (4 x 4 in) - Ceramic tile, stainless steel (18 gauge, 304 food grade with a brushed finish), plastic (polypropylene), and sealed concrete

Performance claims – Performance equivalent to the reference methods.

**REFERENCE METHOD**

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

FDA Bacteriological Analytical Manual Chapter 10: *Detection and Enumeration of Listeria monocytogenes*. March 2017.

<https://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm071400> (Accessed April 2019) (14)

**ORIGINAL CERTIFICATION DATE**

April 12, 2005

**CERTIFICATION RENEWAL RECORD**

Renewed annually through December 2019

**METHOD MODIFICATION RECORD**

1. July 2019 Level 3

**SUMMARY OF MODIFICATION**

1. Modification of *Listeria* Indicator Broth (PDX-LIB) to increase the specificity without sacrificing the sensitivity of the method.

Under this AOAC® *Performance Tested*<sup>SM</sup> License Number, 040501 this method is distributed by:

NONE

Under this AOAC® *Performance Tested*<sup>SM</sup> License Number, 040501 this method is distributed as:

NONE

**PRINCIPLE OF THE METHOD (1)**

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 (1)

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 30<sup>th</sup> hour if the initial inoculation is as low as 100 CFU/mL at time zero.

Internal method comparison studies produced  $\chi^2$  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.

Recovery of *Listeria* cells off of surfaces after overnight drying was monitored by plating 100  $\mu$ L 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 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.

**Appendix I: Inclusivity-Exclusivity Data (1)**

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 seeligeni</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 (1)**

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 (1)**

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 (1)**

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 (1)**

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	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 (1)**

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	Yellow	-		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	+	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	-	

**DISCUSSION OF MODIFICATION APPROVED JULY 2019 (13)**

The composition of the PDX-LIB Broth was modified to increase the specificity without sacrificing the sensitivity of the method. For the inclusivity/exclusivity study, the PDX-LIB Broth successfully detected all 50 inclusivity isolates. Although it did not detect 26 exclusivity isolates, all four *Enterococcus* isolates evaluated produced a positive result. For the method comparison study, the PDX-LIB Broth successfully detected *Listeria* spp. from various environmental surfaces sponges after 30–48 h of enrichment. Using POD analysis, no statistically significant differences were observed between the number of positive samples detected by the candidate method and the reference methods for the matrix evaluated. The PDX-LIB Broth allows for a visual detection of *Listeria* spp. in as few as 30 h. Because the method reduces the enrichment time, it allows the user to obtain results quicker than the reference method for a presumptive positive result. In addition, the reduction in the required volume of enrichment media allows for incubator space to be reduced with enriched samples.

**JULY 2019 MODIFICATION DATA**

**Table 1: Inclusivity Results for PDX-LIB (13)**

No.	Organism	Source	Origin	Result	No.	Organism	Source	Origin	Result
1	<i>Listeria grayi</i>	NCTC <sup>a</sup> 19120	Animal Feces	+	26	<i>Listeria monocytogenes</i> 1/2c	CWD <sup>b</sup> 1552	Not Available	+
2	<i>Listeria grayi</i>	ATCC <sup>c</sup> 25401	Corn Stalks	+	27	<i>Listeria monocytogenes</i> 1/2c	CWD 1553	Not Available	+
3	<i>Listeria grayi</i>	ATCC 700545	Not Available	+	28	<i>Listeria monocytogenes</i> 1/2a	CWD 1554	Carlisle 1981e	+
4	<i>Listeria innocua</i>	QL <sup>d</sup> 030911-12	Environmental	+	29	<i>Listeria monocytogenes</i> 1/2a	CWD1555	Carlisle 1981	+
5	<i>Listeria innocua</i>	QL 051111-1	Environmental	+	30	<i>Listeria monocytogenes</i> 4b	CWD 1561	Human Placenta	+
6	<i>Listeria innocua</i>	QL 32811.2	Seasoning Powder	+	31	<i>Listeria monocytogenes</i> 4b	CWD 1563	Lausanne	+
7	<i>Listeria innocua</i>	ATCC 33091	Human Feces	+	32	<i>Listeria monocytogenes</i> 4b	CWD 1590	San Francisco	+
8	<i>Listeria innocua</i>	QL 32911.1	Environmental	+	33	<i>Listeria monocytogenes</i> 1/2a	CWD 1611	Turkey	+
9	<i>Listeria innocua</i>	CSU <sup>e</sup> W1-301	Not Available	+	34	<i>Listeria monocytogenes</i> 1/2a	CWD 1613	Turkey	+
10	<i>Listeria marthii</i>	ATCC BAA 1595	Soil	+	35	<i>Listeria monocytogenes</i> 1/2a	CWD 1614	Oklahoma	+
11	<i>Listeria ivanovii</i>	ATCC 49954	Food, France	+	36	<i>Listeria monocytogenes</i> 1/2b	CWD 1626	Oklahoma	+
12	<i>Listeria ivanovii</i>	ATCC BAA-678	Sheep Fetus	+	37	<i>Listeria monocytogenes</i> 1/2b	CWD 1627	Mother/Baby	+
13	<i>Listeria ivanovii</i>	ATCC Liv004	Not Available	+	38	<i>Listeria monocytogenes</i> 1/2a	CWD 1629	Oklahoma	+
14	<i>Listeria ivanovii</i>	ATCC Liv005	Not Available	+	39	<i>Listeria monocytogenes</i> 1/2a	CWD 1630	Turkey	+
15	<i>Listeria ivanovii</i>	QL 030911-9	Clinical Isolate	+	40	<i>Listeria monocytogenes</i>	QL 030911-10	Shellfish	+
16	<i>Listeria monocytogenes</i> 1/2c	ATCC 7644	Human Isolate	+	41	<i>Listeria seeligeri</i> 6b	ATCC 11289	Human Feces	+
17	<i>Listeria monocytogenes</i> 4b	ATCC 13932	Spinal Fluid	+	42	<i>Listeria seeligeri</i>	ATCC 11856	Not Available	+
18	<i>Listeria monocytogenes</i> 1/2a	ATCC 15313	Rabbit	+	43	<i>Listeria seeligeri</i> 1/2b	ATCC 35967	Soil	+
19	<i>Listeria monocytogenes</i> 4a	ATCC 19114	Animal Tissue	+	44	<i>Listeria seeligeri</i>	FSL <sup>f</sup> -S4-035	Not Available	+
20	<i>Listeria monocytogenes</i> 4b	ATCC 19115	Human Isolate	+	45	<i>Listeria seeligeri</i>	QL 030911-2	Creamer	+
21	<i>Listeria monocytogenes</i> 4d	ATCC 19117	Sheep	+	46	<i>Listeria welshimeri</i>	ATCC 35897	Not Available	+
22	<i>Listeria monocytogenes</i> 1/2a	ATCC 49594	Not Available	+	47	<i>Listeria welshimeri</i> 6a	ATCC 43548	Not Available	+
23	<i>Listeria monocytogenes</i> 4b	ATCC 51778	Dairy Products	+	48	<i>Listeria welshimeri</i> 6b	ATCC 43549	Soil	+
24	<i>Listeria monocytogenes</i> 1/2b	ATCC 51780	Dairy Products	+	49	<i>Listeria welshimeri</i> 1/2b	ATCC 43550	Human Feces	+
25	<i>Listeria monocytogenes</i> 4b	ATCC Li2	Human Isolate	+	50	<i>Listeria welshimeri</i>	LW <sup>g</sup> 003	Not Available	+

<sup>a</sup>National Collection of Type Cultures, Public Health England, Salisbury, UK.    <sup>e</sup>Colorado State Culture Collection, Fort Collins, CO.

<sup>b</sup>University of Vermont Culture Collection, Burlington, VT.

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

<sup>d</sup>Q Laboratories Inc. Culture Collection, Cincinnati, OH.

<sup>f</sup>University of Vermont Culture Collection, Burlington, VT.

<sup>g</sup>Cornell University Culture Collection, Ithaca, NY.

**Table 2: Exclusivity Results for PD-LIB (13)**

No	Organism	Source	Origin	Result	No	Organism	Source	Origin	Result
1	<i>Bacillus mycoides</i>	ATCC <sup>a</sup> 6462	Soil	-	16	<i>Lactobacillus fermentum</i>	ATCC 9338	Not Available	-
2	<i>Brochothrix thermosphacta</i>	ATCC 11509	Pork Sausage	-	17	<i>Lactobacillus lactis</i>	ATCC 4797	Not Available	-
3	<i>Bacillus cereus</i>	ATCC 14579	Not Available	-	18	<i>Lactobacillus plantarum</i>	ATCC 8014	Not Available	-
4	<i>Geobacillus stearothermophilus</i>	ATCC 12980	Not Available	-	19	<i>Micrococcus luteus</i>	ATCC 7468	Not Available	-
5	<i>Rhodococcus fascians</i>	ATCC 12974	Not Available	-	20	<i>Proteus mirabilis</i>	ATCC 7002	Urine	-
6	<i>Enterococcus hirae</i>	ATCC 8043	Not Available	+	21	<i>Streptococcus mutans</i>	ATCC 25715	Not Available	-
7	<i>Enterococcus faecium</i>	ATCC 19434	Not Available	+	22	<i>Rhodococcus equi</i>	ATCC 6939	Lung Abscess	-
8	<i>Enterococcus durans</i>	ATCC 19432	Not Available	+	23	<i>Salmonella Typhimurium</i>	ATCC 14028	Chicken Hearts and Livers	-
9	<i>Enterococcus faecalis</i>	ATCC 29212	Urine	+	24	<i>Bacillus subtilis</i>	ATCC 6051	Not Available	-
10	<i>Kurthia gibsonii</i>	ATCC 43195	Not Available	-	25	<i>Staphylococcus aureus</i>	ATCC 29247	Not Available	-
11	<i>Escherichia coli</i>	ATCC 8739	Feces	-	26	<i>Staphylococcus epidermidis</i>	ATCC 12228	Not Available	-
12	<i>Klebsiella oxytoca</i>	ATCC 43165	Clinical Isolate	-	27	<i>Staphylococcus haemolyticus</i>	ATCC 29970	Human Skin	-
13	<i>Klebsiella pneumoniae</i>	ATCC 13883	Not Available	-	28	<i>Staphylococcus warneri</i>	ATCC 29885	Not Available	-
14	<i>Kurthia zopfii</i>	ATCC 10538	Not Available	-	29	<i>Streptococcus pneumoniae</i>	ATCC 6302	Not Available	-
15	<i>Lactobacillus casei</i>	ATCC 11578	Oral Cavity	-	30	<i>Streptococcus pyogenes</i>	ATCC 19615	Pharynx of Child	-

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

**Table 3: PDX - LIB Candidate vs. Reference – POD Results (13)**

Surface	Strain	CFUa/Test Area	Nb	Candidate			Reference			dPODCf	95% Clg
				Xc	PODCd	95% CI	X	PODRe	95% CI		
Stainless Steel	<i>L. monocytogenes</i> ATCC <sup>h</sup> 7644/ <i>E. faecalis</i> ATCC 29212	-	5	0	0.00	0.00,0.43	0	0.00	0.00,0.43	0.00	-0.43,0.43
		80 & 960	20	7	0.35	0.18,0.57	8	0.40	0.22,0.61	-0.05	-0.32,0.23
		320 & 4200	5	5	1.00	0.57,1.00	5	1.00	0.57,1.00	0.00	-0.43,0.43
Ceramic Tile	<i>L. welshimeri</i> ATCC 43550	-	5	0	0.00	0.00,0.43	0	0.00	0.00,0.43	0.00	-0.43,0.43
		60	20	9	0.45	0.26,0.66	8	0.40	0.22,0.61	0.05	-0.24,0.33
		240	5	5	1.00	0.57,1.00	5	1.00	0.57,1.00	0.00	-0.43,0.43
Plastic (Polypropylene)	<i>L. innocua</i> ATCC 33090	-	5	0	0.00	0.00,0.43	0	0.00	0.00,0.43	0.00	-0.43,0.43
		72	20	9	0.45	0.26,0.66	7	0.35	0.18,0.57	0.10	-0.19,0.37
		210	5	5	1.00	0.57,1.00	5	1.00	0.57,1.00	0.00	-0.43,0.43
Sealed Concrete	<i>L. ivanovii</i> ATCC BAA-678	-	5	0	0.00	0.00,0.43	0	0.00	0.00,0.43	0.00	-0.43,0.43
		73	20	8	0.40	0.22,0.61	5	0.25	0.11,0.47	0.15	-0.13,0.40
		330	5	5	1.00	0.57,1.00	5	1.00	0.57,1.00	0.00	-0.43,0.43

aCFU/Test Area = Results of the CFU/Test area were determined by plating the inoculum for all surfaces.

bN = Number of test portions.

cX = Number of positive test portions.

dPODC = Candidate method confirmed positive outcomes divided by the total number of trials.

ePODR = Reference method confirmed positive outcomes divided by the total number of trials.

f dPODCf = Difference between the confirmed candidate method result and reference method confirmed result POD values.

g95% CI = If the confidence interval of a dPODC does not contain zero, then the difference is statistically significant at the 5% level.

hATCC = American Type Culture Collection, Manassas, VA.

Table 4: PDX - LIB Presumptive vs. Confirmed – POD Results (13)

Surface	Strain	CFU <sup>a</sup> /Test Area	N <sup>b</sup>	Presumptive			Confirmed			dPOD <sub>CP</sub> <sup>f</sup>	95% CI <sup>g</sup>
				X <sup>c</sup>	POD <sub>CP</sub> <sup>d</sup>	95% CI	X	POD <sub>CC</sub> <sup>e</sup>	95% CI		
Stainless Steel	<i>L. monocytogenes</i> ATCC <sup>h</sup> 7644/ <i>E. faecalis</i> ATCC 29212	-	5	0	0.00	0.00,0.43	0	0.00	0.00,0.43	0.00	-0.47,0.47
		80 & 960	20	7	0.35	0.18,0.57	7	0.35	0.18,0.57	0.00	-0.13,0.13
		320 & 4200	5	5	1.00	0.57,1.00	5	1.00	0.57,1.00	0.00	-0.47,0.47
Ceramic Tile	<i>L. welshimeri</i> ATCC 43550	-	5	0	0.00	0.00,0.43	0	0.00	0.00,0.43	0.00	-0.47,0.47
		60	20	9	0.45	0.26,0.66	9	0.45	0.26,0.66	0.00	-0.13,0.13
		240	5	5	1.00	0.57,1.00	5	1.00	0.57,1.00	0.00	-0.47,0.47
Plastic (Polypropylene)	<i>L. innocua</i> ATCC 33090	-	5	0	0.00	0.00,0.43	0	0.00	0.00,0.43	0.00	-0.47,0.47
		72	20	9	0.45	0.26,0.66	9	0.45	0.26,0.66	0.00	-0.13,0.13
		210	5	5	1.00	0.57,1.00	5	1.00	0.57,1.00	0.00	-0.47,0.47
Sealed Concrete	<i>L. ivanovii</i> ATCC BAA-678	-	5	0	0.00	0.00,0.43	0	0.00	0.00,0.43	0.00	-0.47,0.47
		73	20	8	0.40	0.22,0.61	8	0.40	0.22,0.61	0.00	-0.13,0.13
		330	5	5	1.00	0.57,1.00	5	1.00	0.57,1.00	0.00	-0.47,0.47

<sup>a</sup>CFU/Test Area = Results of the CFU/Test area were determined by plating the inoculum for all surfaces.

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

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

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

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

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

<sup>g</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>ATCC = American Type Culture Collection, Manassas, VA.

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