



CERTIFICATION

AOAC Research Institute *Performance Tested Methods*SM

Certificate No.
040501

The AOAC Research Institute hereby certifies the method 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 Research Institute *Performance Tested Methods*SM Program and found to perform as stated in the applicability of the method. This certificate indicates an AOAC Research Institute Certification Mark License Agreement has been executed which authorizes the manufacturer to display the AOAC Research Institute *Performance Tested Methods*SM certification mark on the above-mentioned method for the period below. Renewal may be granted by the Expiration Date under the rules stated in the licensing agreement.

A handwritten signature in black ink, appearing to read "Bradley A. Stawick".

Bradley A. Stawick, Senior Director
Signature for AOAC Research Institute

Issue Date
Expiration Date

January 22, 2024
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| METHOD NAME PDX-LIB | CATALOG NUMBERS 25009-50, 25005-100, 25003-25 |
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| 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 USA |

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| APPLICABILITY OF METHOD Target organism – <i>Listeria</i> species including <i>L. monocytogenes</i> , <i>L. innocua</i> , <i>L. ivanovii</i> , <i>L. seeligeri</i> , <i>L. welshimeri</i> , <i>L. grayi</i> , and <i>L. marthii</i> . Matrixes – (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 METHODS USDA FSIS http://www.fsis.usda.gov/OA/pubs/lmtips.htm (8) FDA Bacteriological Analytical Manual Chapter 10: <i>Detection and Enumeration of Listeria monocytogenes</i> . March 2017. (14) |
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| ORIGINAL CERTIFICATION DATE April 12, 2005 | CERTIFICATION RENEWAL RECORD Renewed annually through December 2024. |
| METHOD MODIFICATION RECORD 1. July 2019 Level 3 | SUMMARY OF MODIFICATION 1. Modification of <i>Listeria</i> Indicator Broth (PDX-LIB) to increase the specificity without sacrificing the sensitivity of the method. |
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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 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.
Recovery of *Listeria* cells off of surfaces after overnight drying was monitored by plating 100 μ 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). 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.

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>Proteius 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 typhimurum</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 seeligen</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 ^a 19120 | Animal Feces | + | 26 | <i>Listeria monocytogenes</i> 1/2c | CWD ^b 1552 | Not Available | + |
| 2 | <i>Listeria grayi</i> | ATCC ^c 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 ^d 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 ^e 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 ^f -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 ^g 003 | Not Available | + |

^aNational Collection of Type Cultures, Public Health England, Salisbury, UK.^bColorado State Culture Collection, Fort Collins, CO.^cUniversity of Vermont Culture Collection, Burlington, VT.^fUniversity of Vermont Culture Collection, Burlington, VT.^eAmerican Type Culture Collection, Manassas, VA.^gCornell University Culture Collection, Ithaca, NY.^dQ Laboratories Inc. Culture Collection, Cincinnati, OH.

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

| No | Organism | Source | Origin | Result | No | Organism | Source | Origin | Result |
|----|---------------------------------------|------------------------|------------------|--------|----|------------------------------------|------------|---------------------------|--------|
| 1 | <i>Bacillus mycoides</i> | ATCC ^a 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 | - |

^aAmerican 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% CIg |
|----------------------------|--|----------------|----|-----------|-------|-----------|-----------|-------------------|-----------|--------|------------|
| | | | | Xc | PODCd | 95% CI | X | PODR _e | 95% CI | | |
| Stainless Steel | <i>L. monocytogenes</i> ATCC ^a 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 ^a /Test Area | N ^b | Presumptive | | | Confirmed | | | dPOD _{CP} ^f | 95% CI ^g |
|----------------------------|--|-----------------------------|----------------|----------------|--------------------------------|-----------|-----------|--------------------------------|-----------|---------------------------------|---------------------|
| | | | | X ^c | POD _{CP} ^d | 95% CI | X | POD _{CC} ^e | 95% CI | | |
| Stainless Steel | <i>L. monocytogenes</i> ATCC ^h 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 |

^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.

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

^ePOD_{CC} = Candidate method confirmed positive outcomes divided by the total number of trials.

^fdPOD_{CP} = Difference between the candidate method presumptive result and candidate method confirmed result POD values.

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

^hATCC = American Type Culture Collection, Manassas, VA.

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