



## Paradigm Diagnostics Listeria Indicator Broth (PDX-LIB)

### User Guide

#### Listeria species Test Kit

#### Catalog Number:

25004-100

25005-100

25009-50

#### INTENDED USE

Paradigm Diagnostics Listeria indicator broth (PDX-LIB) is intended to be used in the food processing environment and on food contact surfaces to detect the presence of Listeria species. A color change from yellow to light brown/black is considered presumptive positive. Applicability of PDX-LIB is limited for selected common Listeria spp (Listeria monocytogenes, L. innocua, L. ivanovii, and L.welshmeri) on selected common surface types (Sealed concrete, ceramic tile, stainless steel, and plastic). AOAC-RI PTM validation studies were conducted at 4 inch x 4-inch surface areas.

#### SCIENTIFIC PRINCIPLE OF THE TEST

PDX-LIB contains a patented formula of antibiotics, growth enhancers and color changing compounds. The antibiotics function synergistically to inhibit most non-Listeria microorganisms. Growth enhancers provide recovery nutrients to support the growth of sub-lethally injured Listeria. Indicator compounds will turn the broth from yellow to black by utilizing the  $\beta$ -glucosidase enzyme produced by Listeria species. A brown to black color 30-48 hours at 37°C indicates a presumptive positive test for Listeria spp. Positive results can be read as early as 30 hours. Results cannot be considered negative until samples have been incubated for 48 hours.

## ADDITIONAL NOTES

Paradigm Diagnostics recommends the use of TECRA EnviroSwab (BioTrace International Bioproducts, Bothell, Washington, 425-398-7993) or equivalent products\* as sampling device for increased reliability of PDX-LIB.

## MATERIALS AND EQUIPMENT REQUIRED

Tecra Enviroswabs for sampling and an incubator capable of maintaining 37°C ± 1°C (e.g. heat block, water bath, air incubator).

## CONFIRMATION STEPS

Presumptive positive samples from food contact surfaces must be confirmed by confirmatory methods including PCR, DNA fingerprinting or biochemical panel analysis with commercial products such as the API test (Biomérieux) or Micro-ID ( Microgen ) conducted on well isolated colonies obtained from selective agars. Selective agars commonly used selective Listeria agar plates such as Modified Oxford Agar or Palcam agars. Typical Listeria colonies (dark gray colonies with black zones, generally with dimples) on MOX are used in confirmation protocols given in FDA/BAM(<http://www.cfsan.fda.gov/~ebam/bam-10.html>) or USDA ([http://www.fsis.usda.gov/Ophs/Microlab/Mlg\\_8\\_04.pdf](http://www.fsis.usda.gov/Ophs/Microlab/Mlg_8_04.pdf)) methods. Presumptive positive samples from non-food contact surfaces may be confirmed at the discretion of the operator; in all cases corrective action must be consistent with HACCP plan guidance documents.

## DISPOSAL

Decontaminate the PDX-LIB after use by autoclave, bleach or other disinfectants in accordance with local, state and federal regulations.

## PRODUCT SHELF LIFE

PDX-LIB is stable for 12 months at refrigeration temperatures. The expiration date appears on the label along with the lot number. Keep PDX-LIB away from light during storage. Validation data available upon request.

## PRECAUTIONS

1. PDX-LIB amplifies the concentration of Listeria cells in the enrichment media. Listeria monocytogenes is a human pathogen, a bio-hazardous material. When handling samples that possibly contain L.monocytogenes, extreme care should be taken to contain the samples and the enriched samples (presumptive positive tubes). Immuno-compromised individuals and pregnant women are particularly endangered by exposure to L.monocytogenes and should not be allowed to handle enriched samples.

2. **WARNING:** When sampling non-food contact surfaces from poorly maintained areas, some Enterococcus species, particularly E.hirea , E. avium, E.feacalis, and E. gallinarum could result in presumptive false positive results. To rapidly screen for the presence of these interferents add a few drops of 3% hydrogen peroxide available at any drug store. **Samples exhibiting bubbling are positive for Listeria spp.** Samples which do not bubble are likely to contain cell populations of Enterococcus spp. Please refer to addendum 1 for a more detailed explanation.

3. Do not use PDX-LIB past the expiration date that appears on the label.

4. Follow standard Good Microbiological Practices where appropriate.

## WARRANTIES AND LIABILITIES

Paradigm Diagnostics Inc warrants the Products manufactured by it will be free from defects in materials and workmanship when used in accordance with the applicable instructions until the expiration date noted on the product packaging. Application protocols suggested by Paradigm are intended to be guidelines to the Buyers of the Products. Each Buyer is expected to validate the applicability of each application protocol to their individual applications. PARADIGM DIAGNOSTICS MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED. THERE IS NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

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## Instructions for Use: PDX-LIB Labor Saver for Environmental Samples

1. **SAMPLING STEP:** Take an environmental sample following USDA guidelines.

- Remove recommended sponge or swab out of its sterile wrapping.
- Sponge the 4"x 4", 9"x9" or 12"x12" area to be tested.
- Return the sponge into the original sampling container.
- Aseptically add one unit (20 mL) of PDX-LIB on top of sponge in sampling container, and snap close the sampling container.
- Incubate upright (sponge fully submerged in PDX-LIB) at 37°C for 30 to 48 hours.

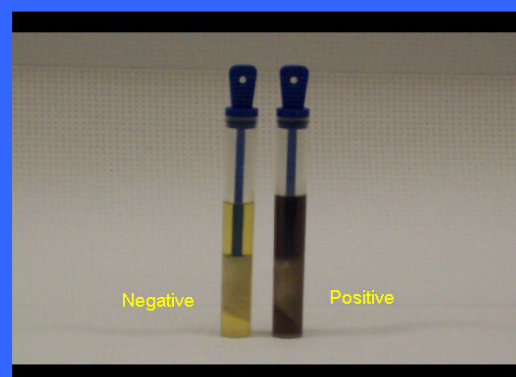
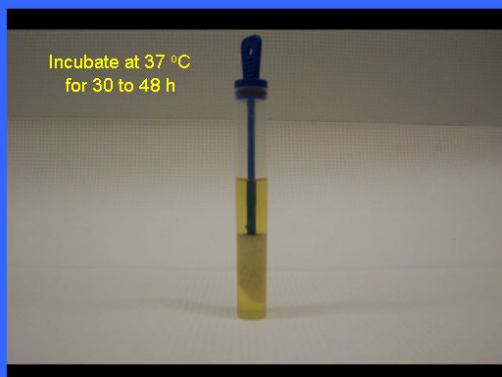
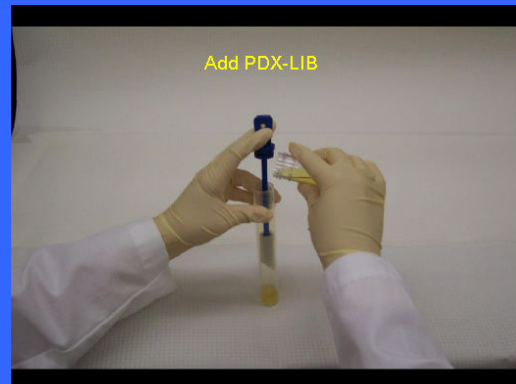
**2. INTERPRETATION STEP:** If color of the media changes from yellow/amber to brown/black, after 30 to 48 hours of incubation at 37°C, the sample is considered a presumptive positive for *Listeria* spp. Positive results can be read as early as 30 hours. Results cannot be considered negative until samples have been incubated for 48 hours. (Note: Although PDX-LIB has been designed to provide results within 30 hours, 48 hours of incubation at 37 °C has been shown to significantly improve the sensitivity of the test, and therefore highly recommended for maximum sensitivity). As with all experimental protocols, use of negative control (an unused sampling device containing one unit of PDX-LIB, incubated along side with the environmental samples) in each set of samples is recommended.

\* Equivalent product collection devices:

1. *Flexi-swabs* available from Biolabs, Australia (<http://www.thermofisher.com.au>).
2. Whirl-Pak *Speci-sponge* bags (18oz.) available from NASCO, Fort Dodge, WI (<http://www.enasco.com/whirlpak>).
3. 3M *Sponge on a stick* available through 3M microbiology ([http://solutions.3m.com/wps/portal/3M/en\\_US/Microbiology/FoodSafety](http://solutions.3m.com/wps/portal/3M/en_US/Microbiology/FoodSafety)).



THE EASIEST SOLUTION TO ENVIRONMENTAL *Listeria* MONITORING  
PDX-LIB LABOR SAVER



For more Information: Phone (651) 226-0381 E-mail: [TechSupport@pdx-inc.com](mailto:TechSupport@pdx-inc.com)

## **Addendum 1**

### **A Helpful Tip for LIB Based Tests:**

All *Listeria* species are catalase positive. This means that when hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) is added *Listeria* decomposes it to water (H<sub>2</sub>O) and oxygen gas (O<sub>2</sub>). Production of oxygen gas is visible by the formation of bubbles. It is known that some *Enterococcus* species are capable of giving false positive reactions with LIB based tests. Because *Enterococcus* species are catalase negative, a simple catalase test would distinguish *Listeria* from *Enterococcus* species in the LIB platform. Before forwarding presumptive positive samples to genetic or immunological tests, conducting a simple catalase test could offer further cost savings to you.

Hydrogen peroxide is available in tablet forms (urea adducts) from various suppliers or can be used as a 3% solution. To test presumptive positive LIB put 3 ml of presumptive positive LIB into a sterile container and add a tablet of urea adduct of hydrogen peroxide, wait for 3-5 minutes. A thick layer of bubbles on the surface and bubbles sticking to the inside of the tube indicates a catalase positive reaction (See photographs on the next page). It is advised to run a negative control (add a tablet into 3 ml of unused LIB).