



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 β -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 Securswabs or Enviromax Swabs, available through Paradigm Diagnostics, Inc., or Puritan Medical. as sampling device for increased reliability of PDX-LIB.

MATERIALS AND EQUIPMENT REQUIRED

Securswabs or equivalent 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 (Biomerieux) 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) 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. The best methods for distinguishing *Enterococci* sp.from Listeria sp. involve streaking blackened media onto selective differential agars such as MOX, Palcam or other commercial medias. Suspect colonies must be further analyzed by immunoassay and biochemical panels as described in the confirmation steps outlined previously.

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.

Paradigm Diagnostics' sole obligation with respect to the foregoing warranties shall be, at its option, to either replace or to refund the purchase price of the Product(s) or part thereof that proves defective in materials or workmanship within the warranty period, provided the customer notified Paradigm Diagnostics promptly of any such defect. PARADIGM DIAGNOSTICS SHALL NOT BE LIABLE FOR ANY DIRECT, INDIRECT OR CONSEQUENTIAL DAMAGES RESULTING FROM ECONOMIC LOSS OR PROPERTY DAMAGES SUSTAINED BY BUYER OR ANY CUSTOMER FROM THE USE OF THE PRODUCT(S).

For Technical Support, contact Paradigm Diagnostics LLC.

Paradigm Diagnostics, LLC

800 Transfer Road Suite 12

St. Paul, MN 55114

Fax: (651) 405-9490

Technical Support:

Ms. Leena Griffith

(651) 226-0381

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.



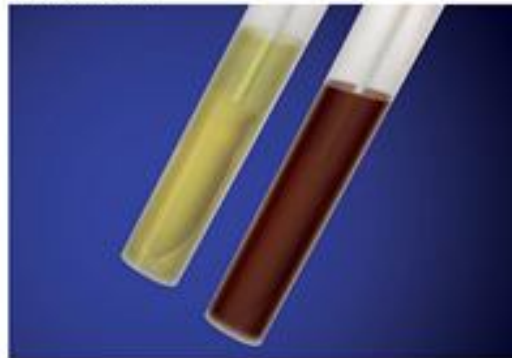
1. Remove sampling device from container and swab the surface.



2. Return sampling device to container. Add media.



3. Incubate at 37 °C for 30 hours.*



4. Read results.