InTray™ Colorex™ Listeria and

For the detection and enumeration of *Listeria monocytogenes*

InTray™ Colorex™ Identification Listeria

For the confirmation of *Listeria monocytogenes*

VALUE

High Throughput – Once the device is inoculated no other culture preparation is required saving time

Cost Savings – Reduces laboratory materials and medical waste

High specificity – Selective for the growth of selected *Listeria* species

BENEFITS

Convenient - Combines collection, culture, and observation into one device

Easy to use - Minimal lab procedures and equipment needed

Easy observation - No fogging or condensation on the InTray™ viewing window

Safe - Fully enclosed InTray™ system prevents contamination and reduces exposure to collected samples

PRODUCT SPECIFICS

Storage - Refrigeration recommended (2-8 °C)

Incubation - 18 - 24 hours at 37 °C

InTray™ Colorex™ Listeria

Quantity Sold

5 Pack (10-7507)
20 Pack (10-7501)

InTray™ Colorex™ Identification Listeria

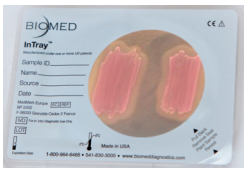
Quantity Sold

5 Pack (10-7517)
20 Pack (10-7511)

PRODUCT BIO

BioMed Diagnostics' InTray™ Colorex™ Listeria and InTray™ Colorex™ Identification Listeria tests serve as microbiology sample collection, transport, and culture devices that allow for growth, detection, chromogenic differentiation, and identification of *Listeria monocytogenes*. The InTray™ Colorex™ Listeria test is for the differentiation of *Listeria* species from other bacteria, while the InTray™ Colorex™ Identification Listeria test is for confirmation of *Listeria monocytogenes* from suspect colonies taken from the InTray™ Colorex™ Listeria. **BioMed's patented InTray™ system saves time and money, while reducing exposure to collected samples by combining several procedures into a single device.**

InTray™ Colorex™ Listeria



InTray™ Colorex™ Identification Listeria

The patented InTray™ system consists of a re-closable outer seal containing an optically clear, anti-fog viewing window. The seal creates an airtight 2" diameter chamber providing a large enough area to streak for isolation. The innovative design of the InTray™ high-performance viewing window makes it possible to place the device directly under a microscope. This removes the need to prepare slides and prevents unnecessary exposure of the sample after inoculation. **By combining both growth and observation into one fully enclosed device, BioMed's InTray™ system negates the need for multiple procedures increasing throughput and decreasing the cost of laboratory materials and medical waste.**

Additionally, the InTray™ design lends itself to high performance not only in laboratory settings and controlled point-of-care, but also off-site locations or austere environments. The InTray™ Colorex™ Listeria and InTray™ Colorex™ Identification Listeria tests are fully enclosed systems and do not require any reagents or complicated procedures to inoculate or obtain results. These systems are also equipped with small air filters creating a controlled air exchange, which maintains the integrity of the growth environment inside the devices.

Both devices make preliminary detection easy by producing distinct chromogenic differences between growing organisms with as little as 18-24 hours. The InTray™ Colorex™ Listeria quickly identifies suspect colonies of *Listeria*, while the InTray™ Colorex™ Identification Listeria quickly confirms *Listeria monocytogenes* from suspect colonies. **The specially formulated chromogenic media makes preliminary visual identification easy while inhibiting potential interference in obtaining accurate results.**

Visual Results of the InTray™ Colorex™ Listeria Test:

- *Listeria monocytogenes* - Blue with white halo
- *Listeria innocua* – Blue without halo
- *E. faecalis* – Inhibited
- *E. coli* – Inhibited

Visual Results of suspect colonies taken from the InTray™ Colorex™ Listeria plated on the InTray™ Colorex™ Identification Listeria Test:

- *Listeria monocytogenes* - Rose with white halo
- *Listeria innocua* – Rose without halo
- *Listeria ivanovii* – Colorless with halo
- *Bacillus cereus* – Colorless with halo

QUALITY CONTROL

The InTray™ Colorex™ Listeria and Identification Listeria devices are tested with ATCC™ strains of the indicated species. At the time of manufacture, quality control tests are preformed on each lot to ensure viability and sterility. These tests are repeated throughout the product shelf life by BioMed Diagnostics confirming the products ability to support growth of selected species while maintaining specificity.

InTray™ Colorex™ Listeria and InTray™ Colorex™ Identification Listeria

BACKGROUND

Listeria monocytogenes is a bacterium that is commonly present in soil, sewage, or fecal matter. *Listeria* has the ability to form biofilms on contact surfaces, which makes it difficult to eliminate. This pathogen can cause serious food borne illness and is frequently the target for food-processing facilities' quality control procedures. Contamination can occur at all steps of the food manufacturing chain from raw materials to place of consumption.

Listeriosis usually consists of fever and muscle aches, often preceded by diarrhea or other gastrointestinal symptoms. Most who are diagnosed with listeriosis have "invasive" infection, in which the bacteria spread beyond the gastrointestinal tract. It is important to rapidly distinguish harmful *Listeria monocytogenes* from other harmless *Listeria* species such as *L.ivanovii* and *L. innocua*.

The general diseases associated with *Listeria* infection are Meningitis and Septicaemia. For pregnant women fever syndrome, which can cause fetal death, abortion, or neonatal infection, can also occur.

These devices result in rapid identification when compared to traditional methods for identification of *L. monocytogenes*.

DIRECTIONS

The sample should be enriched in Half Fraser Broth for 24 hours, and then transferred into a "room temperature" InTray™ Colorex™ Listeria test. Incubate tray for 24 hours at 37°C for the isolation of *L. monoctyogenes* from other organisms. For further confirmation of *Listeria* species take a sample colony from the InTray™ and place it on a "room temperature" InTray™ Colorex™ Identification Listeria and incubate at 37°C for an additional 24 hours.

To inoculate devices, pull back the lower right corner of the label adjacent to the clear window until the silver protective seal is completely visible. Remove the seal by pulling the tab, discard the seal but do not remove the white filter strip over the vent hole. Obtain a small amount of specimen and place on top of the agar. The 2" diameter well allows for a large enough surface area to streak for isolation.

The agars used have been validated by AFNOR for both presence/absence and enumeration methods.

Method	AFNOR Certification No.
Presence/absence	(CHR-21/1-12/1)
Enumeration	(CHR-21/2-12/06)

DETECTION

InTray™ Colorex™ Listeria and InTray™ Colorex™ Identification Listeria tests are formulated to produce distinctive colony growth with typical identifying characteristics both macro and microscopically. For examination using a microscope, simply place the InTray™ on the microscope stage and observe.

NOTATION

Colorex™ is a trademark of Dr. A. Rambach.

REFERENCES

1. *Risk Assessment of Listeria monocytogenes in Ready-to-eat Foods: Technical Report, Microbiological Risk Assessment Series, No. 5* Nonserial Publication World Health Organization. 2004

CORPORATE OVERVIEW

BioMed Diagnostics, Inc., a boutique biotech firm and an industry leader since 1989, develops and manufactures *in vitro* diagnostic devices. BioMed's point-of-care ready tests provide accurate diagnostic tools for scientists worldwide to aid in the identification of bacteria, parasites and fungi. The company formed as the result of a mercy mission conducted by a group of physicians to Central America; there they discovered the need for robust diagnostic tools for use in austere environments. Their experience unleashed the inspiration for BioMed's innovative products that support medical professionals, veterinarians, research teams, and environmental and industry scientists.

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