

InTray™ Colorex™ ESBL (Extended Spectrum Beta-Lactamase)

For overnight detection Extended Spectrum Beta-Lactamase (ESBL) producing gram-negative bacteria; often used in identification of Hospital Acquired Infections (HAIs) using stool or urine samples

PRODUCT BIO

BioMed Diagnostics' InTray™ Colorex™
ESBL test serves as a microbiology sample collection, transport, and culture device that allows for simultaneous growth, observation, and chromogenic differentiation of Extended Spectrum Beta-Lactamase producing gramnegative bacteria. BioMed's patented InTray™ system saves time and money, while reducing exposure to collected samples By combining several procedures into a single device.



The patented InTrayTM system consists of a re-closable outer seal containing an optically clear, anti-fog window. The seal creates an airtight 2" diameter chamber with a large enough area to streak for isolation. The innovative design of the InTrayTM 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 InTrayTM 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 and controlled point-of-care settings, but also off-site locations or austere environments. The InTray™ Colorex™ ESBL test is a fully enclosed system and does not require any reagents or complicated procedures to inoculate or obtain results. The InTray™ system is also equipped with a small air filter creating a controlled air exchange. The InTray™ system is ideal for use in the field and in austere environments due to its low reliance on laboratory equipment.

The InTray™ Colorex™ ESBL makes preliminary detection easy by producing distinctive color and morphology differences between the growth of Extended Spectrum Beta-Lactamase producing gram-negative bacteria species. The InTray™ Colorex™ ESBL inhibits the growth of yeasts, mold, fungi, and all non-ESBL bacterial strains increasing specificity. The specially formulated chromogenic media makes detection and preliminary visual identification easy, while inhibiting potential interference in obtaining accurate results.

Visual Results: ESBL Producing Strains

- E. coli Red
- Klebsiella, Enterobacter and Citrobacter Metallic blue
- Proteus Brown halo
- Non-ESBL Producing Strains Inhibited

QUALITY CONTROL

The InTray™ Colorex™ ESBL is tested with ATCC™ strains of the indicated species. At the time of manufacture, quality control tests are preformed on each lot of InTray™ Colorex™ ESBL to ensure viability, doubling time, and sterility. These tests are repeated throughout the product

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 – Sensitivity of 99.2% and 89% selective

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 (2-8 °C)

Shelf Life - 6 months

Incubation - 18 - 24 hours at 37 °C

Quantity Sold -

5 Pack (10-7307) 20 Pack (10-7301)



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 globally.

BIOMED DIAGNOSTICS

PO Box 2366 1388 Antelope Road White City, Oregon 97503

P 800.964.6466 F 541.830.3001

www.biomeddiagnostics.com

InTray[™] Colorex[™] ESBL (Extended Spectrum Beta-Lactamase)

shelf life by BioMed Diagnostics confirming the products ability to support growth of selected species while maintaining specificity.

BACKGROUND

Extended Spectrum Beta-Lactamase (ESBL) are enzymes that mediate resistance to penicillins, cephalosporins, and monobactams. ESBL producing *Enterobacteriaceae* started to appear in the 1980s and have since emerged as some of the most significant HAIs with *Escherichia coli* and *Klebsiella* species being the main culprits. In many parts of the world 10–40% of strains of *Escherichia coli* and *Klebsiella pneumoniae* express ESBL.

The emergence of ESBL-producing isolates has important clinical and therapeutic implications. Resistance determinants for ESBL production are carried on plasmids that can be easily spread from one organism to another. In addition, the spread of resistance toward third-generation cephalosporins may require the increased prescription of more broad-spectrum and expensive drugs. These resistant isolates may escape detection with routine susceptibility testing performed by a clinical microbiology laboratory, which can result in adverse therapeutic outcomes. Therefore, the early detection of ESBL-producing bacteria carriers is important to minimize their impact and the spread of infections and customize therapeutic patient treatment.

DIRECTIONS

Prior to inoculation, the InTray™ Colorex™ ESBL should be brought to room temperature.

To inoculate the InTray™ Colorex™ ESBL, pull back the lower right corner of the label adjacent to the clear window until the 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

2" medium well. The 2" diameter well offers a large enough surface area to streak for isolation.

To culture the sample, reseal the InTray™ by returning the label to its original position so the optically clear anti-fog window covers the medium. Press the edges of the label against the plastic tray to ensure an airtight seal. Once inoculated, the InTray™ Colorex™ ESBL should be incubated at 37 °C and visual results can occur within as little as 18 - 24 hours.

REFERENCES

- Extended Spectrum Beta Lactamase (ESBL)-Producing Enterobacteriaceae: Considerations for Diagnosis, Prevention and Drug Treatment. Mark E. Rupp and Paul D. Fey, Drugs 2003; 63 (4): 353-36.
- "Evaluation of a chromogenic medium for extended-spectrum beta-lactamase (ESBL) producing Enterobacteriaceae" Philippe Lagacé Wiens et al. University of Manitoba, Canada. ECCMID Poster 2010

NOTATION

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