

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 *E. coli* O157 with chromogenic differentiation from other organisms

BENEFITS

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

Easy to use - Minimal lab procedures and equipment needed

Easy to store - 12 month shelf life under refrigeration (2-8 °C)

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 - 12 months

Incubation - 18 - 24 hours at 37 °C

Quantity Sold

20 Pack (10-7601)

5 Pack (10-7607)

InTray™ Colorex™ O157 (*E. coli* O157)

For the selective isolation and differentiation of *E. coli* O157 from clinical and food samples

PRODUCT BIO

BioMed Diagnostics' InTray™ Colorex™ O157 (*E. coli* O157) test serves as a microbiology sample collection, transport, and culture device that allows for simultaneous growth, observation, and chromogenic differentiation of *E. coli* O157 from food or clinical samples. **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 InTray™ system consists of a re-closable outer seal containing an optically clear, anti-fog 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 and controlled point-of-care settings, but also off-site locations or austere environments. The InTray™ Colorex™ O157 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.

This device makes preliminary detection easy by producing distinctive color differences between the growth of *E. coli* O157, *E. coli* as well as other organisms within as little as 18-24 hours. The InTray™ Colorex™ O157 inhibits the growth of mold, fungi, and other bacteria increasing specificity. The specially formulated chromogenic media makes detection and preliminary visual identification easy, while inhibiting potential interference in obtaining accurate results.

Visual Results:

- *E. coli* O157 – Mauve
- *E. coli* - Metallic blue
- *Klebsiella pneumoniae* - Metallic blue

QUALITY CONTROL

The InTray™ Colorex™ O157 is tested with ATCC™ strains of the indicated species. At the time of manufacture, quality control tests are performed on each lot to ensure viability and sterility. These tests are repeated throughout the product shelf life by BioMed Diagnostics confirming the ability to support growth of selected species while maintaining specificity.

BACKGROUND

Escherichia coli are bacteria commonly found in the intestinal flora of humans and warm-blooded animals. Most strains of *E. coli* are harmless. Some strains, however, such as Verocytotoxigenic *E. coli* (VTEC), also known as Shigatoxigenic *E. coli* (STEC) can cause severe foodborne diseases. Enterohaemorrhagic *E. coli* (EHEC), a subset of VTEC, can cause disease in humans such as Haemolytic Uraemic Syndrome (HUS) and can be fatal.

VTEC have been isolated from the intestinal flora of many animals, including cattle and sheep. Transmitted to humans occurs primarily through consumption of contaminated foods, but can be transmitted through handling animals carrying this bacteria.



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

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The *E. coli* serotype O157:H7 or its non-motile variant O157:H- is the most common VTEC serotype with public health implications. Its significance was recognized in 1982, following two outbreaks in the USA. Since then, more than 180 outbreaks have been reported worldwide, with an estimated WHO figure of 70,000 infections per year.

E. coli O157 is naturally found in the intestinal contents of livestock. Their presence in livestock feces makes them a significant source of food and water contamination.

Symptoms appearing between a few hours to ten days of infection include: stomach cramps, bloody diarrhea, vomiting, urinary tract infections, and fever. These symptoms can lead to fatal complications such as HUS; the young and the elderly are especially susceptible.

DIRECTIONS

Prior to inoculation, the InTray™ Colorex™ O157 should be brought to room temperature.

To inoculate the InTray™ Colorex™ O157, 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. This device can be plated with samples from food, meat trimmings and animal or human fecal samples.

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™ O157 should be incubated at 37°C and visual results can occur within as little as 18 - 24 hours.

DETECTION

InTray™ Colorex™ O157 medium is formulated to produce distinctive colony growth with typical identifying characteristics both macro and microscopically. For examination using a microscope, simply place the InTray™ Colorex™ O157 on the microscope deck and observe.

NOTATION

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

REFERENCES

1. Outbreak investigation: STEC O157. Medical Laboratory Observer. P.42. Durso, Lisa, et al. March 1, 2010.