

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 vancomycin resistant enterococci

BENEFITS

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

Easy to use - Minimal lab procedures and equipment needed

Easy to store - 6 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 - 6 months

Incubation - 18 - 24 hours at 37 °C

Quantity Sold

5 Pack (10-6207) 20 Pack (10-6201)

InTray[™] Colorex[™] VRE (Vancomycin Resistant Enterococci)

For the clinical identification of acquired, VanA and VanB type Vancomycin resistance in *E. faecalis* and *E. faecium*

PRODUCT BIO

BioMed Diagnostics' InTray™ Colorex™ VRE serves as a microbiology sample collection, transport, and culture device for simultaneous growth, observation, and chromogenic differentiation of vancomycin resistant enterococci. BioMed's patented InTray™ system saves time and money while reducing exposure to collected samples by combining several procedures into a single device.



The 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 reducing the risk of contamination. 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 in the laboratory controlled point-of-care settings as well as off-site locations or austere environments. The InTray™ Colorex™ VRE 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 identification easy by producing distinctive color differences between the growth of VRE strains of enterococci in as little as 18-24 hours. Further, the InTray™ Colorex™ VRE inhibits the growth of mold, fungi, and non-vancomycin resistant 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:

- VRE.faecalis/VRE.faecium Pink to mauve
- E.gallinarum/E.casseliflavus Blue or inhibited
- Other bacteria Inhibited

QUALITY CONTROL

The InTray™ Colorex™ VRE 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™ VRE 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.

BACKGROUND

There are two types of vancomycin resistance in enterococci. The first type is intrinsic, non-transmissible resistance, commonly referred to as VanC, VanD, VanE or VanF resistance. This type is commonly found in *E. gallinarum*, *E. casseliflavus* or *E. flavescens* and demonstrates a low-level resistance to vancomycin. The second type of vancomycin resistance in enterococci is acquired or transmissible resistance, e.g., VanA and VanB, mostly seen in *E. faecium* and *E. faecalis*.

To avoid the spread of this resistance to more virulent pathogens, it is crucial to promptly detect the presence of any VanA or VanB resistance and accurately differentiate them from other enterococci.

There are significant epidemiologic issues related to acquired vancomycin resistance in enterococci. Vancomycin-resistant *Enterococcus* infections are



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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especially aggressive and have been associated with mortality rates approaching 60% to 70%. Furthermore, According to the CDC: "Knowledge of the type of resistance is critical for infection control purposes. VanA and VanB genes are transferable and can spread from organism to organism. In contrast, VanC and other genes are not transferable, and have not been associated with outbreaks."

The InTray[™] VRE provides results within as little as 18-24 hours facilitating rapid response to the presence of these organisms.

DIRECTIONS

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

To inoculate, 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 agar. 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™ VRE should be incubated at 37°C and visual results can occur within as little as 18-24 hours.

DETECTION

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

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

REFERENCES

1. Vancomycin-resistant Enterococci (VRE) and the Clinical Laboratory. Healthcare-associated Infections (HAIs). Center for Disease Control. December 8, 2010.