InTray™ Colorex™ KPC (*Klebsiella pneumoniae* carbapenemase)

For the detection of carbapenem class resistance in gram-negative bacteria; often used in identification of Hospital Acquired Infections using stool or urine samples. This device can also be used to detect pathogenic bacteria on surfaces.

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 – 100% sensitivity and 98.4% Selective for the growth of Gram-negative bacteria expressing reduced susceptibility to antibiotics of the carbapenem family

BENEFITS

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

Easy to use - Direct plating methods can be used, no need for pre-enrichment broth, and minimal lab procedures and equipment are 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 (10-7207)
20 Pack (10-7201)

PRODUCT BIO

BioMed Diagnostics' InTray™ Colorex™ KPC serves as a microbiology sample collection, transport, and culture device. This device is designed for simultaneous growth, observation, and chromogenic differentiation of microbes resistant to carbepenem class antimicrobials including *Klebsiella pneumonia, Escherichia coli,* and *Pseudomonas* species. **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, which creates an airtight 2" diameter chamber with 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 removing the need to prepare slides and prevents unnecessary exposure of the sample after inoculation. **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™ KPC test is fully enclosed and does not require any reagents or special procedure 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™ KPC makes preliminary detection easy by producing distinctive color differences between the growth of the selected species within as little as 18-24 hours. In addition, the InTray™ Colorex™ KPC inhibits the growth of yeasts, mold, and fungi increasing specificity. **The specially formulated chromogenic media makes detection and preliminary visual identification easy, while inhibiting potential interference in obtaining accurate results.**

Visual Results:

Carbapenem Resistant Strains

- *E. coli* - Red
- *Klebsiella Enterobacter, Citrobacter* – Metallic blue
- *Psuedomononas* – Cream to translucent
- Non-Carbapenem resistant strains– Inhibited

QUALITY CONTROL

The InTray™ Colorex™ KPC is tested with ATCC™ strains of selected species. At the time of manufacture, quality control tests are performed on each lot of InTray™ Colorex™ KPC 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.

InTray™ Colorex™ KPC (*Klebsiella pneumoniae* carbapenemase)

BACKGROUND

KPC carbapenemase is an enzyme class first found in *Klebsiella pneumonia* isolates. However, it can also be found in other organisms including *E. coli, Citrobacter freundii, Salmonella enterica,* as well as *Serratia* and *Enterobacter* species. Carbapenemase enzymes are able to hydrolyze beta-lactam agents, reducing the effectiveness of the widely used carbapenems, a group of antibiotics used as the last resort in treating many serious gram-negative infections. Production of these enzymes also results in resistance to penicillins, cephalosporins, and aztreonam, thereby producing truly multidrug-resistant pathogens and making treatment very challenging. Therefore, in order to limit the spread of these serious pathogens, rapid detection, followed by implementation of adequate infection control methods is essential.

This product results in fast and accurate identification of carbapenem class resistance in specimens facilitating timely reaction to their presence.

DIRECTIONS

Prior to inoculation, the InTray™ Colorex™ KPC should be brought to room temperature and samples can be stool, urine, blood, or sputum samples.

To inoculate the InTray™ Colorex™ KPC, 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 allows for a large enough surface area to streak for isolation.

To culture the sample, reseal the InTray™ by returning the clear 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, recommended incubation is 37°C and visual results can occur within as little as 18 - 24 hours.

REFERENCES

1. Cuzon G, Naas T, Truong HV, Villegas M-V, Wisell KT, Carmeli Y, et al. *Worldwide diversity of Klebsiella pneumoniae that produce β-lactamase blaKPC-2 gene.* Emerging Infectious Disease.
2. Evans, et al. 2009. *Evaluation of CHROMagar KPC and Other Sleective Media for Surveillance of Carbapanemase-producing Enterobacteriaceae and Multi-drug Resistant Acinetobacter species.* At: Poster presentation, 2009 ASM Meeting. Philadelphia, Pa
3. Lippincott Williams & Wilkins. Southern Medical Journal. 2011;104(1):40-45.
4. Samra et al. 2008. *Evaluation of CHROMagar KPC for Rapid Detection of Carbapanem-Resistant Enterobacteriaceae.* Journal of Clinical Microbiology. 46-9, p. 3110-11

NOTATION

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.

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