BIOMED

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 specified pathogenic species

BENEFITS

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

Easy to use - Minimal lab procedures and equipment needed

Easy to store - 12 months shelf life under temperature

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)

Shelf Life - 12 months

Incubation - 18-24 hours at 37 °C

Quantity Sold -5 Pack (10-7107) 20 Pack (10-7101)

InTray[™] Colorex[™] Screen

Primarily for use in isolation and differentiation of urinary tract pathogens, as well as differentiation of microorganisms from other infected areas.

PRODUCT BIO

BioMed Diagnostics' InTray[™] Colorex[™] Screen serves as a microbiology sample collection, transport, and culture device. The InTray[™] Colorex[™] Screen allows for simultaneous growth, observation, and chromogenic differentiation of selected pathogenic species frequently found in the urinary tract, including gram-positive and 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 InTray[™] 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 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. **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, but

also off-site locations or austere environments. The InTray[™] Colorex[™] Screen can be stored for twelve months under refrigeration (2-8 °C). The InTray[™] system is equipped with a small air filter, in addition to its airtight seal, creating a controlled air exchange. The airtight seal and controlled air exchange system maintain the integrity of the growth environment inside the device.

The InTray[™] Colorex[™] Screen makes preliminary detection easy by producing distinctive color and morphology differences between selected pathogenic species, sometimes within as little as 24 hours. The InTray Colorex[™] Screen inhibits the growth of yeasts, mold, and fungi. InTray[™] Colorex[™] Screen's specially formulated media makes detection and preliminary identification easy.

Visual Results:

- Escherichia coli Dark pink to reddish
- Enterococcus species Turquoise blue
- Klebsiella, Enterobacter, Citrobacter -Metallic blue
- Proteus mirabilis Brown with halo
- Staphylococcus aureus Golden, opaque, small
- Staphylococcus saprophyticus Pink, opaque, small

QUALITY CONTROL

The InTray[™] Colorex[™] Screen is tested with either clinical isolates or ATCC strains of the indicated species. At the time of manufacture, quality control tests are preformed on each lot of InTray[™] Colorex[™] Screen to ensure viability, doubling time, and sterility. These tests are repeated throughout the product shelf life by BioMed Diagnostics confirming the ability of the InTray[™] Colorex[™] Screen to support growth of selected pathogenic species while maintaining specificity.

BIOMED

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 forBioMed's innovative products that support medical professionals, veterinarians, research teams, and environmental and industry scientists globally.

BIOMED DIAGNOSTICS

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InTray[™] Colorex[™] Screen

BACKGROUND

Urinary tract infections (UTI) have been estimated to cause over 7 million clinician visits every year. Up to 40% of women will develop UTI at least once in their lives, with a significant number having recurrent urinary tract infections. Infections in men primarily occur in infancy and after the age of 50. During reproductive years, women have a 50-fold increased infection rate when compared to males.

The predominant pathogen in uncomplicated UTI in women is *Escherichia coli*, which accounts for more than 80% of cases. Members of the *Enterobacteriaceae* family, such as *Klebsiella, Proteus*, or *Enterobacter* species, can also associated with UTI. *Staphylococcus saprophyticus* is found in 15% of cases.

Urine cultures add a great amount of specificity towards diagnosing a UTI and are considered the Gold Standard for diagnostic surveillance. The InTray[™] Colorex[™] Screen makes in-house UTI screening and organism identification easy by creating chromogenic differentiation between growing species saving time and reducing laboratory expenses. InTray[™] Colorex[™] Screen positively identifies *E. coli* on the primary plate resolving 80% of UTI without the need for confirmatory tests.

DIRECTIONS

Prior to inoculation, the InTray[™] Colorex[™] Screen should be brought to room temperature. Samples introduced to the media can be oral, vaginal, urine, skin, ear, eye, urethral, throat or fecal samples where pathogenic infections are suspected. It may also be used for sanitation testing of objects or surfaces.

To inoculate the InTray[™] Colorex[™] Screen, 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. When introducing urine samples, use a calibrated loop (0.01 ml) for inoculation by dipping the loop into the urine and dragging the loop through the middle of the agar. The 2" diameter well allows for a large enough surface area to streak for isolation.

To culture the device, reseal the InTray[™] by returning the clear window 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[™] Screen can be incubated for up to 72 hours at 37°C and visual results can occur within as little as 24 hours.

DETECTION

InTray[™] Colorex[™] Screen 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[™] Screen on the microscope stage and observe. Samples should be checked every 24 hours.

REFERENCES

- Evaluation of use of a new chromogenic agar in detection of urinary tract pathogens. Samra Z. et al. 1998. Journal of Clinical Microbiology, 36: 990-994.
- Clinical microbiology procedures handbook, vol. 1. Isenberg, H.D. (ed.). 1992. American Society for Microbiology. Washington, D.C

NOTATION

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