InPouch™ TV (*Trichomonas vaginalis)*

VALUE

High Throughput – Once the device is inoculated no other culture preparation is required saving time

Cost Savings – The InPouch™ TV reduces laboratory materials and medical waste

High specificity – Designed for the growth of *Trichomonas* by inhibiting the growth of yeasts, mold, bacteria, and other commensal micro flora

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 at room temperature

Mobile - Compact and non-breakable package is ideal for off-site sampling or for point-of-care testing

Safe - Fully enclosed InPouch™ system prevents contamination and reduces exposure to collected samples

Functional - PCR compatible transport and incubation device

PRODUCT SPECIFICS

Storage - Room Temperature (18-25 °C)

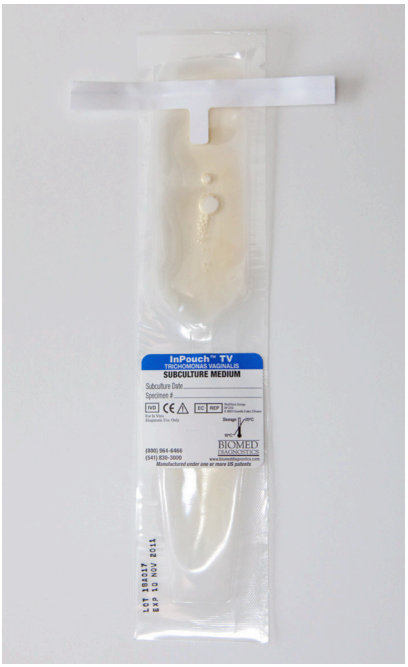
Shelf Life - 12 months

Incubation - 37°C

Quantity Sold
10 Pack (10-2010)
100 Pack (10-2003)

PRODUCT BIO

BioMed's InPouch™ TV test is a microbiology sample collection, transport, and culture device that allows for simultaneous growth and observation of *Trichomonas vaginalis*, the parasite responsible for the sexually transmitted infection trichomoniasis. **By combining several procedures into a single device, BioMed's patented InPouch™ TV test saves time and money while reducing exposure to collected samples.**



The patented InPouch™ system consists of a high barrier, oxygen resistant, plastic pouch with two V-shaped chambers connected by a narrow passage. The innovative two-compartment system allows for direct preliminary "wet-mount" observation of a newly collected specimen in the upper chamber before expressing the contents into the lower chamber for culture and further observation when necessary**. Combining both growth and observation into one fully enclosed system removes the need to prepare wet mount slides increasing efficiency and throughput while decreasing the cost of laboratory materials and medical waste.**

Additionally, the InPouch™ design lends itself to high performance in off-site or austere environments with limited reliance on laboratory equipment making the InPouch™ TV ideal for point-of-care testing or off-site sampling. This is possible because the InPouch™ TV can be stored for up to a year at room temperature (18-25 °C) and organisms can be kept viable at this temperature for up to 48 hours prior to incubation. **Transport from off-site locations and point-of-care testing can be performed easily due to the flexible packaging and robust, integral design of the InPouch™ system.**

As the first, most robust and economical IVD for clinical trichomoniasis, the InPouch™ TV is known as "The Gold Standard" diagnostic for this STI. The proprietary medium of the InPouch™ TV is selective for the transport and growth of *T. vaginalis* and increases specificity by inhibiting the growth of yeasts, mold, bacteria, and other commensal microflora. **The specially formulated media inhibits the potential for interference in obtaining accurate results.**

QUALITY CONTROL

Quality control testing is performed on each lot of InPouch™ TV tests prior to shipment in order to ensure viability, doubling time and sterility. Quality control tests are repeated throughout the product shelf life by BioMed Diagnostics confirming the ability of the InPouch™ TV to support the growth of *T. vaginalis* while maintaining suppression of commensal micro-flora.

BACKGROUND

Trichomonas vaginalis is a flagellated, parasitic protozoan, and the cause of the STI trichomoniasis in humans. *T. vaginalis* is the most common non-viral STI globally. Infection rates are relatively the same between men and women and there are an estimated 7.4 million new cases each year.

Trichomoniasis can cause many complications in women, such as: preterm delivery, low birth rate, infant mortality, and cervical cancer, but can also cause: pneumonia, bronchitis, and oral lesions in immunocompromised individuals.

InPouch™ TV (*Trichomonas vaginalis)*

Symptoms in women usually appear 5-28 days after exposure while men are commonly asymptomatic. Whether symptomatic or asymptomatic, an infection in either males or females leads to dramatically increased susceptibility to HIV transmission.

Signs of infection in women usually consist of a frothy, yellow-green discharge, strong odor, inflammation, itching, and discomfort during intercourse or urination. Although trichomoniasis in men is often asymptomatic, when symptoms do occur, they usually consist of irritation inside the genitalia and are often accompanied by mild discharge, and slight burning after urination or ejaculation.

In the developing world, STIs and their complications rank among the top five disease categories for which adults seek treatment. According to WHO the presence of untreated *Trichomonas* infection increases the probability of acquisition and transmission of HIV by a factor of ten, even more for people in high-risk areas.

DIRECTIONS

Specimen collection for culture should be taken from the posterior fornix of the vagina or from the male urethra. Male seminal fluid or urine can also be used as specimens.

To inoculate the upper chamber, tear along the notched area and pull the tabs to open, squeeze the top to close and fold the top edge down, roll twice and fold the wire tabs to prevent the InPouch™ from opening. Immediate specimen concentration can be observed under the microscope using the accompanying viewing clip. **Only a few viable organisms are needed for detection; an inoculum containing 1 to 10 organisms is sufficient to result in a presumptive positive test.**

To culture, express all liquid from the upper chamber into the lower chamber; **use the edge of a straight hard surface, such as a workstation or table, for best** results. Roll down the pouch until it reaches the top of the lower chamber then fold the wire tabs to lock the InPouch™ into position.

Inoculated InPouch™ TV medium can be held up to 48 hours at room temperature (18°-25°C), before incubation at 37°C is required. Best practice suggests specimens should be examined every 24 hours for three days for urine, amniotic fluid, or prostatic fluid; five days using seminal fluid samples. If no trichomonads are observed during this period and incubation at 37°C, the test is presumptive negative for *T. vaginalis*.

DETECTION

As the parasites multiply, white sediment along the sides and bottom of the chamber will become visible. *T. vaginalis* are oval shaped, flagellated, and measure slightly larger than a white blood cell. Five flagella arise from the organism, four immediately extend out, while the fifth wraps backwards along the surface of the organism. A barb-like axostyle projection can be seen across from the four-flagella bundle. If *T. vaginalis* organisms are present, they will be identifiable by their distinct features; characteristically the rolling, jerky motions exhibited by the protozoan and can be observed using a 10X objective lens.

ALSO AVAILABLE FROM BIOMED

Other products available from BioMed Diagnostics for education, research and laboratory maintenance of live organisms include:

InPouch™ TV Lab Kit (10-2016)
Provides all the items needed for growth and study of *T. vaginalis* from the point of inoculation and to begin using the InPouch™ TV diagnostic system.

InPouch™ TVC Subculture (10 Pack) (10-2108)
Culture medium with slower growth rate than the InPouch™ TV; for maintenance of live *T. vaginalis* cultures in the laboratory.

REFERENCES

1. Soper, D. 2004. Trichomoniasis: under control or undercontrolled, American Journal of Obstetrics and Gynecology 190 (1): 281–90
2. Schwebke, J. R., D. Burgess. 2004. Trichomoniasis. Clinical Microbiology Reviews 17: 794–803
3. Center for Disease Control (CDC). Trichomoniasis CDC Fact Sheet
4. Ryan K. J., C. G. Ray, ed. 2004. Sherris Medical Microbiology (4th ed.) McGraw Hill
5. World Health Organization (WHO). Fact Sheet N°110.

CORPORATE OVERVIEW

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InTray™ Brilliant Green Agar

For the selective isolation of *Salmonella* species other than *S. typhi* from fecal samples, water and foodstuffs. This medium is included in procedures in *Standard Methods for the Examination of Water and Wastewater*.

VALUE

High Throughput – Once the device is inoculated, no other preparation is required saving time

Cost Savings – Reduces laboratory materials and medical waste

High specificity – Selective against the growth of *S. typhy* and *S. paratyphi*

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

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 – 24–48 hours at 35 ± 2°C

Quantity Sold
20 Pack (39-1001)
5 Pack (39-1000)

PRODUCT BIO

BioMed's InTray™ Brilliant Green is a microbiology sample collection, transport, culture device for the growth and observation of *Salmonella* species other than *S. typhi*. **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 an outer, re-sealable label with an optically clear, anti-fog window covering the media, which creates an airtight seal over the 2" diameter agar surface. The innovative design of the InTray™, with its unique, high-performance viewing window, can be placed directly under a microscope while remaining sealed removing the need to prepare slides or expose the sample once the device has been inoculated**. By combining both growth and observation into one fully enclosed system, the InTray™ system increases throughput while decreasing the cost of laboratory materials and medical waste.**

Additionally, the InTray™ design lends itself to high performance in laboratory or controlled point-of-care settings as well as off-site locations or austere environments. The InTray™ Brilliant Green is a fully enclosed system and does not require any reagents or complicated procedures to inoculate or obtain presumptive 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.

Visual Results:

- *Salmonella* sp. (other than *S. typhi* and *S. paratyphi*) – White to red, opaque colonies surrounded by red zones in the medium
- *S. typhi* and *S. paratyphi* – No growth to trace growth
- *Shigella* – No growth to trace growth
- *Escherichia coli*, *Enterobacter, Klebsiella* – Yellow to green-yellow colonies surrounded by intense yellow-green zones in medium
- *Pseudomonas* – Pink to red colonies
- *Proteus* – No growth to trace growth
- Gram-positive bacteria – No growth to trace growth

QUALITY CONTROL

At the time of manufacture, quality control testing is performed on each lot of the InTray™ Brilliant Green using ATCC strains to ensure viability and sterility. These tests are repeated through the end of the product shelf life by BioMed Diagnostics confirming the ability of the InTray™ Brilliant Green to support growth while maintaining specificity.

BACKGROUND

Brilliant Green Agar was first described in 1925 and later modified in 1935. The medium is included in *Standard Methods for the Examination of Water and Wastewater*. The brilliant green dye included in the medium inhibits gram-positive bacteria while phenol red acts as a pH indicator for certain organisms. Phenol red changes to a yellow color due to the acid produced during fermentation of the lactose included in the medium.

DIRECTION

To inoculate the InTray™ Brilliant Green, 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 sample and place sample on top of the agar. The 2" diameter well allows for a large enough surface area to streak for isolation.

To incubate the device, return 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. Best practice suggests incubation at 35 ± 2°C for 24-48 hours. **Consult appropriate reference for ultimate sample collection, incubation and confirmation procedure.**

DETECTION

Observe for colony growth and appearance through the clear window. For examination using a microscope, simply place the InTray™ Brilliant Green on the microscope and observe through the clear viewing window.

REFERENCES

1. Eaton, Rice and Baird (ed.). 2005. *Standard methods for the examination of water and wastewater, 21st ed*. American Public Health Association, Washington, D.C.

2. Kristensen, M., V. Lester, and A. Jurgens. 1925. *On the use of trypsinized casein, bromthymol blue, bromcresol purple, phenol red and brilliant green for bacteriological nutrient media*. Br. J. Exp. Pathol. 6:291

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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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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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InTray™ Colorex™ Salmonella

For the detection of *Salmonella* species primarily used with clinical stool or blood samples

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% sensitive and 89% specific for the growth *Salmonella* species

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 (10-7707)
20 Pack (10-7701)

PRODUCT BIO

BioMed Diagnostics' InTray™ Colorex™ *Salmonella* test serves as a microbiology sample collection, transport, and culture device. This device allows for simultaneous growth, observation, and chromogenic differentiation of the *Salmonella* genus of bacteria, *S. typhi, S. paratyphi.* This test is 89% specific allowing the rare, real positives, often overlooked in routine testing, to be targeted and reduces excess testing on false positives. **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™ *Salmonella* 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, which maintains the integrity of the growth environment inside the device. **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™ *Salmonella* makes preliminary detection easy by producing distinctive color and morphology differences between the growth of *Salmonella* species and other organisms within as little as 18-24 hours. In addition, the InTray™ Colorex™ *Salmonella* inhibits the growth of yeasts, mold, fungi, and other bacteria increasing specificity resulting in 100% sensitivity and 89% specificity for *Salmonella* compared to 78% specificity with Hektoen Agar. **The specially formulated chromogenic media makes detection and preliminary visual identification easy, while inhibiting potential interference in obtaining accurate results.**

Visual Results:

- *Salmonella* species -Mauve
- Other bacteria or coliforms – Blue, colorless, or inhibited

QUALITY CONTROL

The InTray™ Colorex™ *Salmonella* 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™ *Salmonella* to ensure viability, doubling time, 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™ Salmonella

BACKGROUND

Salmonella is a foodborne pathogen and infections caused by this species, including *S. typhi*, remain a major worldwide health problem. According to the CDC, in 2008 *Salmonella* had an incidence rate of 40,000 new cases a year within the US. In Europe, it is reported as the primary cause of collective "toxi-infections" and in a 2007 European Food Safety Authority report it was found that in developing countries *S. typhi* and *S. paratyphi* have an estimated annual incidence of about 17 million cases. According to the recent WHO report, *Salmonella* infections are responsible for 2 million deaths per year from diarrhea.

Most commonly present in meat, eggs, and dairy products, *Salmonella* species are also found in water, with the serotypes *S. typhi* and *S. paratyphi* being responsible for typhoid and paratyphoid fever. *Salmonella* surveillance represents the most common analysis in food chain processes. Consequently, improving the efficiency of testing will lead not only to a reduction in the number of contaminated foodstuffs needing to be recalled on the market, but also to substantial economic savings in costs related to microbial quality control.

DIRECTIONS

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

To inoculate the InTray™ Colorex™ *Salmonella*, 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 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, the InTray™ Colorex™ *Salmonella* can be incubated at 37°C and visual results can occur within as little as 18 - 24 hours.

DETECTION

InTray™ Colorex™ *Salmonella* 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™ *Salmonella* on the microscope stage and observe.

REFERENCES

1. *Food related illness and death in the United States.* Mead PS, Slutsker L, Dietz V, McCraig LF, Bresee JS, Shapiro C, Griffin PM, Tauxe RV (1999) Emerging Infectious Diseases, 5:607-625
2. *Drug Resistant Salmonella Fact Sheet N°139.* World Health Organization.
3. *Comparison of CHROMagar Salmonella medium and Hektoen Enteric Agar for isolation of Salmonellae from stool samples.* Gaillot O. et al. 1999. Journal of Clinical Microbiology, 37 : 762-765

CORPORATE OVERVIEW

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InTray™ Colorex™ Screen

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

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 - One year 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)

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 gram-negative 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 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. **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 up to twelve months if kept 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 while inhibiting potential interference in obtaining accurate results.**

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.

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

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2. Clinical microbiology procedures handbook, vol. 1. Isenberg, H.D. (ed.). 1992. American Society for Microbiology. Washington, D.C

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.

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InTray™ Colorex™ VRE
(Vancomycin Resistant Enterococci)

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

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)

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:

- VR*E.faecalis*/VR*E.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

InTray™ Colorex™ VRE
(Vancomycin Resistant Enterococci)

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.

REFERENCES

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

CORPORATE OVERVIEW

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InTray™ Colorex™ Yeast

For isolation and differentiation of major clinical-significant *Candida* species; commonly used in the detection of yeast infections

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 – 99% specificity and sensitivity for *C. albicans, C. tropicalis* and *C. krusei*

BENEFITS

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

Easy to use - Minimal lab procedures and equipment needed

Easy to store - One year 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 recommended (2-8 °C)

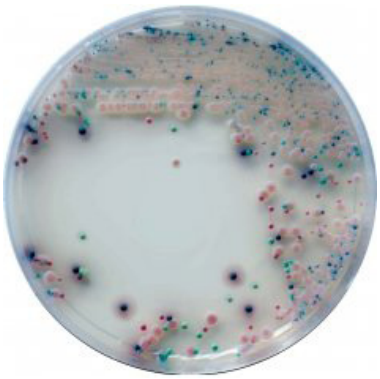
Shelf Life - 12 months

Incubation - 48 hours at 37 °C

Quantity Sold -
5 Pack (10-6107)
20 Pack (10-6101)

PRODUCT BIO

BioMed Diagnostics' InTray™ Colorex™ Yeast test serves as a microbiology sample collection, transport, and culture device. This device allows for simultaneous growth, observation, and chromogenic differentiation of selected *Candida* species as well as *Malassezia pachydermatis*, which has been added for veterinary applications. **By combining several procedures into a single device, BioMed's patented InTray™ system saves time and money, while reducing exposure to collected samples.**



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 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 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 settings, but also off-site locations or austere environments. The InTray™ Colorex™ Yeast can be stored for up to a year if kept 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 regardless of the local environment by allowing only clean, filtered air to reach the media.**

The InTray™ Colorex™ Yeast makes preliminary detection easy by producing distinctive color and morphology differences between the growth of selected *Candida* species within as little as 24 hours. The InTray™ Colorex™ Yeast discriminates against the growth of bacteria, mold, and other fungi. **The specially formulated media makes detection and preliminary identification easy while inhibiting potential interference in obtaining accurate results.**

Visual Results:

- *Candida glabrata* - Mauve
- *Candida albicans* - Green
- *Candida tropicalis* - Metallic Blue
- *Candida krusei* - Pink and fuzzy
- *E. coli* - Inhibited
- *Malassezia pachydermis* - Brick Red with dark center
- Other species - Mauve to White

QUALITY CONTROL

The InTray™ Colorex™ Yeast 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™ Yeast to ensure viability and sterility. These tests are repeated throughout the product shelf life by BioMed Diagnostics confirming the ability of the InTray™ Colorex™ Yeast to support growth of selected Candida species while maintaining specificity.

BIOMED

InTray™ Colorex™ Yeast

BACKGROUND

Candidiasis is a fungal infection caused by any of the *Candida* species (all yeasts), of which *Candida albicans* is the most common. These infections are commonly referred to as yeast infections and range from superficial, such as oral thrush and vaginitis, to systemic and potentially life-threatening diseases. Common in many human populations are the superficial infections caused by *Candida*, effecting the skin and mucosal membranes.

Of the many infections caused by *Candida*, most are treatable. Severe complications can arise, even leading to fatality, if infections in certain populations, such as those who are immune-compromised are left untreated.

DIRECTIONS

Prior to inoculation, the InTray™ Colorex™ Yeast should be brought to room temperature. Samples introduced to the media can be skin swabs, oral or vaginal samples, urine or sputem.

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

To culture the sample, 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. For best results, incubate the InTray™ Colorex™ Yeast for 48 hours at 30 to 37 °C. Visual results can occur within as little as 24 hours.

REFERENCES

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CORPORATE OVERVIEW

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InTray™ DM (Dermatophyte)

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 dermatophytes by inhibiting the growth of both gram-positive and gram-negative bacteria

BENEFITS

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

Easy to use - Minimal lab procedures and equipment needed

Easy to store - 27 month shelf life at room 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 - Room Temperature (18-25 °C)

Shelf Life - 27 months

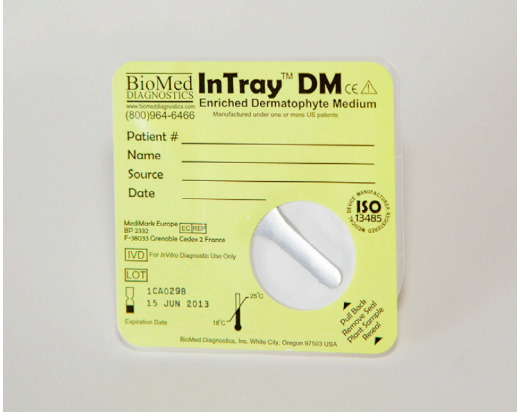
Incubation - 1 to 14 days at room temperature (18-25 °C)

Quantity Sold

5 Pack (10-4007)

PRODUCT BIO

BioMed's InTray™ DM culture serves as a microbiology sample collection, transport, and culture device allowing for simultaneous detection and observation of the dermatophyte fungal group. **By combining several procedures into a single device, BioMed's patented InTray™ DM saves time and money, while reducing exposure to collected samples.**



The InTray™ system consists of an outer, re-sealable label with an optically clear, anti-fog window covering the media creating an airtight seal over the 1" diameter surface. The innovative design of the InTray™, with its unique, high-performance viewing window, can be placed directly under a microscope, while remaining sealed. The InTray™ removes the need to prepare slides or expose the sample once the device has been inoculated. **By combining both growth and observation into one fully enclosed system, BioMed's InTray™ DM removes the need for multiple procedures, increases throughput and decreases the cost of laboratory materials and medical waste.**

Additionally, the InTray™ design lends itself to high performance in off-site locations or in austere environments. InTray™ DM has a shelf life of 27 months at room temperature (18-25 °C).

The InTray™ DM produces distinctive morphology between dermatophyte species and increases specificity by inhibiting the growth of both gram-positive and gram-negative bacteria.

The specially formulated media makes detection and preliminary identification easy while inhibiting potential interference in obtaining accurate results.

QUALITY CONTROL

At the time of manufacture, quality control tests are preformed on each lot of InTray™ DM. Testing repeats through the end of the shelf life assuring the highest quality product.

BACKGROUND

Dermatophytes are a specific group of fungi that cause common skin, nail and hair infections in both humans and animals. Dermatophytes are zoonotic, meaning they can be transmitted from human to animal, vice-versa, and can even contaminate areas of the environment. Infections caused by these fungi are commonly referred to as "tinea," "ringworm," and "athlete's foot" depending on the location of infection and genera of the fungus. Areas infected are usually itchy and are prone to redness, scaling or fissuring. Abscesses can occur and in some cases infected areas may also develop secondary bacterial infections. More aggressive infections can lead to cellulitis resulting in fever, chills or shaking, as well as soreness in the infected area.

The types of fungus that receive the dermatophyte label are generally made up of the three genera: *Microsporum*, *Epidermophyton* and *Trichophyton*. Dermatophytes thrive in moist, protected areas of the skin. Dermatophytes prefer these areas due to the reliance on obtaining nutrients from keratinized material. Once the organisms colonize they cause inflammation due to the host's reaction to their invasion. Dermatophytes are usually restricted to the nonliving cornified layer of the epidermis since they are generally unable to penetrate into the sub-dermal layer.

DIRECTIONS

To inoculate the InTray™ DM, 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.

Obtain a small amount of specimen and place on top of the 1" agar medium. With hair samples, several (3-6) small pieces, about 2cm long, should be cut from the infected portion for inoculation onto the surface of the medium. Skin scrapings should be taken with a sharp blade from the outer ridge of an active lesion. Both nail pieces and scrapings from beneath the nail may be cultured. For best results, cut nails into small pieces. Be sure to prevent samples from extending beyond the well area.

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, incubate the InTray™ DM at room temperature in the dark.

DETECTION

InTray™ agar is formulated to produce a red color and give white to cream colored, dusty or powdery colony morphology, which will appear within 1-14 days of inoculation. The 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™ DM on the microscope stage and observe.

REFERENCES

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2. Parsonson, I.M., B.L. Clark and J.h. Duffy. 1976. Early pathogensis and pathology of Tritrichomonas\ foetus infection in virgin heifers. Journal of Comparative Pathology 86: 59-66

CORPORATE OVERVIEW

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InTray™ GC (*Neisseria gonorrhoeae*)

VALUE

High Throughput – Once the device is inoculated no other culture preparation is required saving time

Cost Savings – Reduces laboratory materials and medical waste and removes the need for a CO_2 incubator

High specificity – Selective for the growth of Neisseria species by inhibiting the growth of other bacteria including: *E. coli*, *S. epidermis*, *P. mirabilis*, and C. *albicans*

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 refrigeration

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 at under refrigeration

Incubation – 24 - 48 hours at 37 °C

Quantity Sold
5 Pack (10-8007)
20 Pack (10-8001)

PRODUCT BIO

BioMed's InTray™ GC is a microbiology sample collection, transport, and culture IVD allowing for simultaneous detection, and observation of *Neisseria gonorrhoeae*, the bacterium responsible for the sexually transmitted infection Gonorrhea. By combining several procedures into a single device, BioMed's patented InTray™ GC saves time and money, while reducing exposure to collected samples.

The patented InTray™ system consists of an outer, re-sealable label with an optically clear, anti-fog window covering the media, which creates an airtight seal over the 2" diameter surface. The innovative design of the InTray™, with its unique, high-performance viewing window, can be placed directly under a microscope while remaining sealed removing the need to prepare slides or expose the sample post inoculation. **By combining both growth and observation into one fully enclosed system, BioMed's InTray™ GC increases throughput while decreasing the cost of laboratory materials and medical waste.**

The InTray™ GC system is equipped with a CO_2 tablet, which is contained in a sealed inner chamber to prevent degradation during storage. Once the CO_2 chamber is punctured and the InTray™ sealed, the tablet generates the required atmosphere of CO_2 gas, approximately 7%, to create the anaerobic environment needed for the growth of *N. gonorrhoeae.*

InTray™ GC's internal CO_2 system supports the integrity of the growth environment while safely containing the organism within the InTray™ and removes the need for costly CO_2 incubators.

Additionally, it is also designed to perform in austere environments, making the InTray™ GC ideal for point-of-care testing. This is possible because the InTray™ GC stores for up to a year under refrigeration (2-8 °C). In addition, the unique, internal CO_2 generation system provides the necessary anaerobic atmosphere for culture giving it a reduced reliance on laboratory equipment. Point-of-care sampling can be performed easily due to the InTray™ GC's robust design and integral CO_2 generation system.

The specially formulated enriched medium in the InTray™ GC is selective in the growth *of Neisseria* species and inhibits the growth of fungi and other bacteria. The list of inhibited fungi and bacteria include: *C. albicans*, *E. coli*, *S. epidermis*, and *P. mirabilis*. InTray™ GC's specially formulated media makes detection easy, while inhibiting potential interference in obtaining accurate results.

QUALITY CONTROL

At the time of manufacture, quality control testing is performed on each lot of the InTray™ GC prior to shipment in order to ensure viability and sterility. These tests are repeated through the end of the product shelf life by BioMed Diagnostics confirming the ability of the InTray™ GC to support the growth of *N. gonorrhoeae,* while maintaining specificity against other organisms.

DETECTION

At 24 hours and at 48 hours, observe for colony growth and appearance through the clear window. For examination using a microscope, simply place the InTray™ GC on the microscope stage and observe. Colonies of *N. gonorrhoeae* on this medium appear smooth and gray in color. However, typical colony morphology is insufficiently specific to confirm the identification of the gonococcal organism.

InTray™ GC (*Neisseria gonorrhoeae*)

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Presumptive gonococcal colonies should be confirmed according to the CDC recommended criteria. Presumptive negative cultures have no growth at 48 hours.

BACKGROUND

Neisseria gonorrhoeae is the bacteria responsible for the sexually transmitted infection Gonorrhea. *Neisseria* are gram-negative cocci that require nutrient supplementation to grow in laboratory settings. They usually appear in pairs and are similar in shape to coffee beans.

Symptoms usually appear 2-5 days after infection, however, in men, symptoms may take up to a month to appear. Although the disease may be asymptomatic, patients typically experience burning and pain during urination, increased urination, sore throat, and discharge. In women, Gonorrhea can be found in the reproductive tract including the fallopian tubes, uterus, cervix, and can even grow in the eyes. Bleeding between periods is found in some women, as is painful sexual intercourse, severe lower abdomen pain and fever if infection has spread to stomach or fallopian tubes. Symptoms that appear in men are red or swollen opening of the penis and tender, swollen testicles. If infection spreads to the bloodstream, fever, rash, and arthritis like symptoms can appear. Left untreated, Gonorrhea can cause serious complications including pelvic inflammatory disease, increased risk of infertility, and an increased risk of HIV transmission.

According to the CDC, more than 700,000 new cases appear each year in the United States, but only 300,000-400,000 of those are reported. Infection is more common in large cities and inner city areas. A person is more likely to develop infection if they have multiple sexual partners and do not use a condom during sex.

DIRECTIONS

To inoculate the InTray™ GC, 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 sample using a cotton swab or microbiology loop and place the sample on top of the agar. The 2" diameter well allows for a large enough surface area to streak for isolation. Specimens may include oral, vaginal, urethral and rectal swabs.

To initiate the internal CO_2 system, poke a small hole in the cover of the CO_2 tablet chamber then 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 sealed, incubate the InTray™ GC for 24-48 hours at 37ºC.

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InTray™ PDA (Potato Dextrose Agar)

Potato Dextrose Agar is a recommended by the American Public Health Association for plate counts of yeasts and molds in the examination of foods and dairy products.

VALUE

High Throughput – Once the device is inoculated no other preparation is required saving time

Cost Savings – Reduces laboratory materials and medical waste

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

Quantity Sold

20 Pack (19-1001)
5Pack (19-1007)

PRODUCT BIO

BioMed Diagnostics' InTray™ PDA (Potato Dextrose Agar) is a general-purpose microbiology sample collection, transport, and culture device. The InTray™ PDA allows for simultaneous growth and observation of many species of organisms including yeasts, molds, and fungus and is also used for the cultivation and sporulation of various dermatophytes. **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.

The InTray™ design lends itself to high performance in laboratory settings as well as off-site locations or austere environments. It is fully enclosed and does not require any reagents or complicated procedures to inoculate or obtain presumptive 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 procedures and controlled air exchange system, which maintains the integrity of the growth environment inside the device.

QUALITY CONTROL

At the time of manufacture, quality control tests are preformed on each lot of InTray™ PDA using ATCC organism strains to ensure viability and sterility. These tests are repeated throughout the product shelf life by BioMed

BACKGROUND

Potato Dextrose Agar is recommended by the American Public Health Association for plate counts of yeasts and molds in the examination of foods and dairy products. It is also used for maintenance, cultivation and sporulation of stock cultures of various dermatophytes.

DIRECTIONS

Prior to inoculation the InTray™ PDA should be brought to room temperature.

To inoculate the InTray™ PDA, 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 allows for 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 and press the edges of the label against the plastic tray to ensure an airtight seal before being stored for incubation.

For isolation of fungi from potentially contaminated specimens, best practice suggests a selective medium be inoculated along with the non-selective InTray™ PDA.

InTray™ PDA (Potato Dextrose Agar)

For isolation of fungi causing systemic mycoses, two sets of media should be inoculated, with one set incubated at 25-30°C and a duplicate set at 35±2°C. All cultures should be examined weekly for fungal growth and should be held for 4-6 weeks before being reported as negative. Consult appropriate references for ultimate specimen collection, incubation, and confirmation procedure.

REFERENCES

1.Downes and Eto. 2001 *Compendium of methods for the microbiological examination of foods. 4th ed*. APHA.

2.MacFadden. 1985 *Media for isolation-cultivation-identification-maintenance of medical bacteria, vol.1*. Williams & Wilkins, Baltimore,

3.Marshall. 1993. *Standard methods for the examination of dairy products, 16th ed*. American Public Health Association.

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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InTray™ Pseudomonas Isolation Agar

For the isolation of Pseudomonas species and differentiation of *Pseudomonas aeruginosa* in clinical and environmental specimens. This device integrates with direct plating and membrane filtration procedures.

VALUE

High Throughput - Once the device is inoculated no other preparation is required saving time

Cost Savings - Reduces laboratory materials, medical waste

BENEFITS

Safe – Fully enclosed InTray™ system prevents contamination and reduces exposure to collected samples

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

Easy to use – 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

PRODUCT SPECIFICS

Storage - Refrigeration recommended (2-8 °C)
Shelf Life - 6 months
Incubation - 18 - 48 hours at 35 ±2°C

Quantity Sold
20 Pack (20-2201)
5 Pack (20-2207)

PRODUCT BIO

BioMed Diagnostics' InTray™ Pseudomonas Isolation serves as a microbiology sample collection, transport, and culture device for simultaneous growth, observation, and chromogenic differentiation of *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 InTray™ system consists of a re-closable outer seal containing an optically clear, anti-fog window, which 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 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 in laboratory and controlled point-of-care settings as well as off-site locations or austere environments. The InTray™ Pseudomonas Isolation 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™ Pseudomonas Isolation makes preliminary detection easy by producing distinctive color and morphology differences between the growth of *P. aeruginosa* and other organisms within as little as 18 hours. In addition, InTray™ Pseudomonas inhibits the growth of yeasts, mold, and fungi increasing specificity.

Visual Results:
P. aeruginosa--Appears green during first 18 hours of incubation, and as incubation continues *P. aeroginosa* emerges blue to blue-green with pigment diffusion into the medium.

QUALITY CONTROL

The InTray™ Pseudomonas Isolation is tested with ATCC™ strains of selected species. At the time of manufacture, quality control tests are performed on each lot of InTray™ Pseudomonas Isolation to ensure viability and sterility using. 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

P. aeruginosa is an opportunistic, gram-negative bacterium that can infect the eyes and ears as well as burns and wound sites. The bacteria can also cause urinary tract, respiratory system, bone, skin and soft tissue infections. In healthy individuals infections are rare, but in hospitalized individuals with injuries, on certain antibiotics or in patients who are immunosuppressed due to cancer or AIDS infections are more common with an increased morbidity and mortality rate. The young and elderly are also at an increased risk of infection.

P. aeruginosa is one of the most common gram-negative bacterial causes of Hospital Acquired Infections with incident rates of up to 4 per 1000 discharges according to the CDC.

This bacterium is commonly found in water and soil and can easily be brought into a healthcare setting from fruits and vegetables as well visitors and hospital personnel.

InTray™ Pseudomonas Isolation Agar

Once introduced, this bacterium resides in a number of reservoirs including sinks, mops and even disinfectants.

It is important to identify *P. aeruginosa* contamination and infection early to provide quick and proper treatment due to its high mortality rate in already immunosuppressed individuals and its resistance to a wide range of antibiotics. **The InTray™ Pseudomonas Isolation device provides fast results while safely containing the organism preventing further contamination and exposure for laboratory staff.**

Directions

Prior to inoculation, the InTray™ Pseudomonas Isolation should be brought to room temperature. This device is especially useful in isolating *P. aeruginosa* from stool, urine or specimens from wound sites and also integrates with the membrane filtration procedure for non-clinical samples.

To inoculate the InTray™, 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 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.

Best practice suggests incubation at 35 ± 2°C. Visual results can occur within as little as 18 - 24 hours. Consult appropriate references for ultimate sample collection, incubation and confirmation procedure.

References

1. Akhabue E, Synnestvedt M, Weiner MG, Bilker WB, Lautenbach E. Cefepime-*resistant Pseudomonas aeruginosa*. Emerg Infect Dis. Vol 17, Number 6, 2011 June

2. *Prevention of Hospital Acquired Infections, A Practical Guide. 2nd edition*. World Health Organization. 2002.

CORPORATE OVERVIEW

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InTray™ SDA (Sabouraud Dextrose Agar) and InTray™ SDA+PVG Antibiotics (Polymyxin B, Vancomycin & Gentamicin)

The *Unites States Pharmacopoeia* (USP) recommends SAB agar for use in performing total combined mold and yeast counts (Microbial Limits Tests)

VALUE

High Throughput – Once the device is inoculated no other preparation is required saving time

Cost Savings –Reduces laboratory materials and medical waste

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 – 18-48 hours (1 to 14 days for *Trichophyton*)

Quantity Sold

InTray™ SDA
20 Pack (15-1001)
5 Pack (15-1000)

InTray™ SDA + PVG
20 Pack (18-1001)
5 Pack (18-1000)

PRODUCT BIO

BioMed Diagnostics' InTray™ SDA and InTray™ SDA+ PVG are general purpose microbiology sample collection, transport, culture and observation devices that allow for simultaneous growth and observation of pathogenic and non-pathogenic fungi including yeasts and dermatophytes. **By combining several procedures into a single device, BioMed's patented InTray™ system saves time and money, while reducing exposure to collected samples.**

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. **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 settings, but also off-site locations or austere environments. The InTray™ SDA and InTray™ SDA+ PVG are fully enclosed and don't 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 airtight seal and controlled air exchange system maintain the integrity of the growth environment inside the device allowing only clean, filtered air to reach the media.

For Isolation of fungi from potentially contaminated specimens, best practice suggests the selective InTray™ SDA+ PVG test should be run in parallel with the non-selective InTray™ SDA.

QUALITY CONTROL

At the time of manufacture, quality control tests are preformed on each lot of InTray™ SDA and InTray™ SDA+ PVG using ATCC™ strains to ensure viability and sterility. These tests are repeated throughout the product shelf life by BioMed Diagnostics confirming the ability of these devices to support growth.

BACKGROUND

The InTray™ SDA is a slightly selective, general-purpose medium devised by Sabouraud and is used in qualitative procedures for the cultivation of pathogenic and non-pathogenic fungi. Sabouraud dextrose media are peptone media supplemented with dextrose to support growth of fungi. Peptones are sources of nitrogenous growth factors, the carbohydrate that provides the energy source for the growth of microorganisms. SDA is recommended in the *United States Pharmacopoeia* (USP) for the use in performing total combined mold and yeasts counts (Microbial Limits Tests).

The InTray SDA + PVG, with the addition of polymyxin B, vancomycin, and gentamicin is a modification designed to increase fungal specificity by bacterial inhibition.

For Isolation of fungi from potentially contaminated specimens, best practice suggests the selective InTray™ SDA+ PVG test should be run in parallel with the non-selective InTray™ SDA.

InTray™ SDA (Sabouraud Dextrose Agar) and InTray™ SDA+PVG Antibiotics (Polymyxin B, Vancomycin & Gentamicin)

DIRECTIONS

Prior to inoculation the InTray™ SDA or InTray™ SDA+ PVG should be brought to room temperature.

To inoculate the InTray™ SDA or InTray™ SDA+ PVG, 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. The 2" diameter well allows for a large enough surface area to streak for isolation. Obtain a small amount of specimen and place on top of the agar.

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. Best practice suggests incubation at 30 ± 2°C (20-25°C for *A. niger, 30-35*°C for *Candida* species) and results can be obtained within as little as 18-48 hours (7-14 days for *Trichophyton*). Consult appropriate references for ultimate sample collection, incubation and confirmation procedure.

DETECTION

Cultures should be examined once a week at minimum. For examination using a microscope, simply place the InTray™ SDA and SDA+ PVG on the microscope stage and observe through the clear viewing window.

REFERENCES

1. Sabouraud. 1892. Ann Dermatol. Syphil. 3:1061.

2. Ajello et al. 1963. *CDC laboratory manual for medical mycology.* PHS Publication No. 994, U.S. Government Printing Office, Washington, D.C.

3. Reisner et al. 1999, In Murray et al (ed.*). Manual of Clinical Microbiology, 7th ed.* American Society for Microbiology, Washington, D.C.

4. Kwon-Chung and Bennett. 1992. *Medical Mycology.* Lea & Febiger, Philadelphia, Pa.

5. United States Pharmacopeial Convention, Inc. 2001. *The United States Pharmacopeia 25/The National Formulary 20-*2002. United States Pharmacopeial Convention, Inc., Rockville, Md.

CORPORATE OVERVIEW

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InTray™ SMA (Sorbitol McConkey's Agar)

For the detection and differentiation of non-sorbitol fermenting *Escherichia coli* serotype O157:H7; primarily used with clinical stool and food specimens

VALUE

High Throughput – Once the device is inoculated, no other preparation is required saving time

Cost Savings – Reduces laboratory materials and medical waste

High specificity – Selective for the growth of coagulase-positive Staphylococci

BENEFITS

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

Easy to use - Minimal lab procedures and equipment needed

Easy to store – Three month shelf life under refrigeration

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)
Incubation - 35 ± 2ºC

Quantity Sold
20 Pack (20-2501)
5 Pack (20-2507)

PRODUCT BIO

BioMed's InTray™ SMA is a microbiology sample collection, transport, and culture device for the growth and detection of *E. coli* serotype O157:H7 primarily from clinical and food specimens. **BioMed's patented InTray™ SMA saves time and money while reducing exposure to collected samples by combining several procedures into a single device.**

The InTray™ system consists of an outer, re-sealable label with an optically clear, anti-fog window covering the media, which creates an airtight seal over the 2" diameter agar surface. The innovative design of the InTray™, with its unique, high-performance viewing window, can be placed directly under a microscope while remaining sealed removing the need to prepare slides or expose the sample once the device has been inoculated**. By combining both growth and observation into one fully enclosed system, BioMed's InTray™ SMA increases throughput while decreasing the cost of laboratory materials and medical waste.**

Additionally, the InTray™ design lends itself to high performance in laboratory or controlled point-of-care settings as well as off-site locations or austere environments. The InTray™ SMA is a fully enclosed system and does not require any reagents or complicated procedures to inoculate or obtain presumptive results. The InTray™ system is also equipped with a small air filter creating a controlled air exchange.

Visual Results

- *E. coli* O157 (sorbitol negative) – Colorless to beige
- *E. coli* (sorbitol positive) – Rose to pink

QUALITY CONTROL

At the time of manufacture, quality control testing is performed on each lot of the InTray™ SMA to ensure viability and sterility. These tests are repeated through the end of the product shelf life by BioMed Diagnostics confirming the ability of the InTray™ SMA to support growth 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. Transmission to humans occurs primarily through consumption of contaminated foods, but can also be spread through handling animals carrying the bacteria.

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 are naturally found in the intestinal contents of livestock. Their presence in livestock feces makes them a significant source of food and water contamination leading to human infection.

DIRECTIONS

Prior to inoculation the InTray™ SMA should be brought to room temperature.

To inoculate the InTray™ SMA, 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 sample and place on top of the agar. The 2" diameter well allows for a large enough surface area to streak for isolation.

To incubate the device, return 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 sealed, incubate the InTray™ SMA for 24-48 hours at 35 ± 2ºC.

DETECTION

At 18-24 hours, observe for colony growth and appearance through the clear window. For examination using a microscope, simply place the InTray™ SMA on the microscope and observe. Consult appropriate references for ultimate sample collection, incubation, and confirmation procedure.

References

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

CORPORATE OVERVIEW

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InTray™ XLT4

For the isolation of non-typhi *Salmonella* species from samples contaminated with fecal matter; commonly used with environmental drag swabs or clinical stool samples

VALUE

High Throughput – Once the device is inoculated no other preparation is required saving time

Cost Savings – Reduces laboratory materials and medical waste

High specificity – Most organisms other than

BENEFITS

Safe – Fully enclosed InTray™ system prevents contamination and reduces exposure to collected samples

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

PRODUCT SPECIFICS

Storage – Refrigeration recommended (2-8 °C)

Shelf Life – 12 months

Incubation – 18–24 hours at 35°C

Quantity Sold

20 Pack (55-1001)
5 Pack (55-1000)

PRODUCT BIO

BioMed Diagnostics' InTray™ XLT4 is a microbiology sample collection, transport, and culture device for the simultaneous growth and observation of non-Typhi *Salmonella*. **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, which 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 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 in laboratory and controlled point-of-care settings as well as off-site locations or austere environments. The InTray™ XLT4 is a fully enclosed system and does not require any reagents or complicated procedures to inoculate or obtain presumptive results. The InTray™ system is also equipped with a small air filter creating a controlled air exchange, which maintains the integrity of the growth environment inside the device.

The InTray™ XLT4 makes preliminary detection easy by producing distinctive color differences between the growth of non-Typhi *Salmonella* species and other organisms within as little as 18-24 hours. In addition, the growth of yeasts, mold, fungi, and other bacteria are inhibited increasing specificity.

Visual Results:

- Non-Typhi (H_2S-Positive) *Salmonella* species – Black or black centered with yellow periphery
- H_2S-Negative *Salmonella* species – Pinkish yellow
- *Citrobacter* species– Yellow with no evidence of blackening
- Other organisms – Marked to complete inhibition

QUALITY CONTROL

The InTray™ XLT4 is tested with ATCC™ strains of the indicated species. At the time of manufacture, quality control tests are preformed on each lot of InTray™ XLT4 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

Clinical

Salmonella is a foodborne pathogen and infections caused by this species remain a major worldwide health problem. According to the CDC, in 2008 *Salmonella* infections had an incidence rate of 40,000 new cases a year within the US. In Europe, it is reported as the primary cause of collective "toxi-infections." According to a recent WHO report, *Salmonella* infections are responsible for 2 million deaths per year from diarrhea.

It is especially important to identify non-Typhi *Salmonella* species in clinical specimens, as treatment is generally separate from other *Salmonella* species. Furthermore, traditional antibiotic treatments can increase the risk of relapse in cases of non-Typhi *Salmonella*, according to the Ontario Agency for Health Protection and

InTray™ XLT4

Promotion. **XLT4 agar has shown sensitivity comparable to Hektoen enteric ager and nearly 100% specificity when used to isolate non-Typhi *Salmonella* from stool samples.**

Food Quality Management

Most frequently present in meat, eggs, and dairy products, *Salmonella* species are also found in water. *Salmonella* surveillance represents the most common analysis in the food production processes. The InTray™ XLT4 improves the efficiency of testing by inhibiting other contaminating fecal bacteria such as *Proteus*, *Providencia* and *Pseudomonas,* which can lead to overgrowth on other media. **XLT4 agar has shown improved growth of non-Typhi *Salmonella* species from specimens collected using environmental drag swabs.**

DIRECTIONS

Prior to inoculation, the InTray™ XLT4 should be brought to room temperature.

To inoculate the InTray™ XLT4, 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 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.

Best practice suggests pre-enrichment using a *Salmonella* enrichment broth with incubation at 35°C for 18-24 hours followed by incubation at 35°C for 18-24 hours on XLT4 agar. **Consult appropriate references for ultimate sample collection, incubation and confirmation procedure.**

DETECTION

InTray™ XLT4 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™ XLT4 on the microscope stage and observe through the clear-view window.

REFERENCES

1. *Food related illness and death in the United States*. Mead PS, Slutsker L, Dietz V, McCraig LF, Bresee JS, Shapiro C, Griffin PM, Tauxe RV (1999) Emerging Infectious Diseases, 5:607-625

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4.. *Evaluation of five new plating media for the isolation of Salmonella species*. Dusch, H., and M. Altwegg . J. Clinical Microbiology. 33: 802-804.1995

CORPORATE OVERVIEW

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