

#### 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<sub>2</sub> 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)

## InTray™ GC (*Neisseria gonorrhoeae*)

#### 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<sub>2</sub> tablet, which is contained in a sealed inner chamber to prevent degradation during storage. Once the CO<sub>2</sub> chamber is punctured and the InTray™ sealed, the tablet generates the required atmosphere of CO<sub>2</sub> gas, approximately 7%, to create the anaerobic environment needed for the growth of *N. gonorrhoeae*.

InTray™ GC's internal CO<sub>2</sub> system supports the integrity of the growth environment while safely containing the organism within the InTray™ and removes the need for costly CO<sub>2</sub> 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<sub>2</sub> 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<sub>2</sub> 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.

#### 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™ GC (*Neisseria gonorrhoeae*)

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<sub>2</sub> system, poke a small hole in the cover of the CO<sub>2</sub> 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 37°C.

#### REFERENCES

- Centers for Disease Control and Prevention (CDC). *Update to CDC's Sexually Transmitted Diseases Treatment Guidelines, 2006: Fluoroquinolones No Longer Recommended for Treatment of Gonococcal Infections*. MMWR. 2007; 56(14); 332-336.
- U.S. Preventive Services Task Force. *Screening for Gonorrhea: Recommendation Statement*. American Family Physician, Nov. 1, 2005; 72(9); 1783-1786.
- Centers for Disease Control and Prevention. *Sexually Transmitted Disease Surveillance, 2007*. Atlanta, GA: U.S. Department of Health and Human Service, December 2008.
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- Bamberger DM. *Gonorrhea*. In: *Rakel P, Bope ET, eds. Conn's Current Therapy* 2008. 60th ed. Philadelphia, Pa: Saunders Elsevier; 2008:chap 184.
- Bauer HM, Wohlfeiler D, Klausner JD, Guerry S, Gunn RA, Bolan G., *California Guidelines for Expedited Partner Therapy for Chlamydia trachomatis and Neisseria gonorrhoeae*. *Sexually Transmitted Disease*.