

## INTRODUCTION

### INTENDED USE

The InTray™ GC is intended for use in the qualitative detection of oral, rectal and genitourthral *Neisseria gonorrhoeae* colonization.

### PRINCIPALS OF THE PRODUCT

*N. gonorrhoeae* is a common sexually transmitted disease organism broadly disseminated throughout the world. The InTray™ device is a fully enclosed microbiology cassette, which enables sample collection, transport, culture and identification in a single device. The InTray™ GC simplifies diagnostic procedures and provides extended shelf life without requirement for refrigeration. The proprietary modified Thayer-Martin agar is selective for gonococcal bacteria. Results can be interpreted after 24-48 hours incubation.

The InTray™ GC is a single exposure culture system with dynamic built-in components and features that are designed for user compatibility and ease of detection. The following are key highlights that come with this product:

- Single exposure system
- A “ready to start” 5% CO<sub>2</sub> environment
- Modified Thayer Martin medium, selective for GC
- Direct microscopic observation of the culture with anti-fog viewing
- Incubatory and transport capabilities
- Extended shelf-life without required refrigeration

### REAGENTS

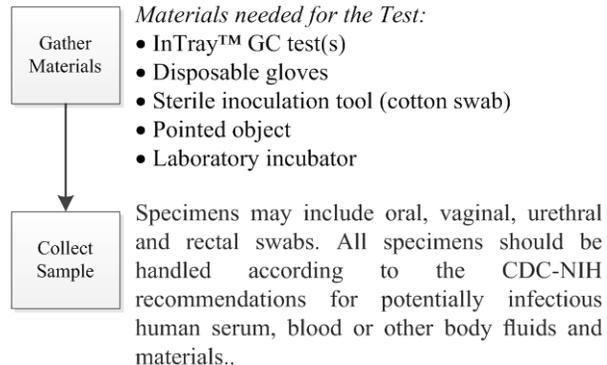
This product contains a GC medium base, defibrinated sheep blood, organic supplements, salts and antibiotics.

### STORAGE AND SHELF LIFE

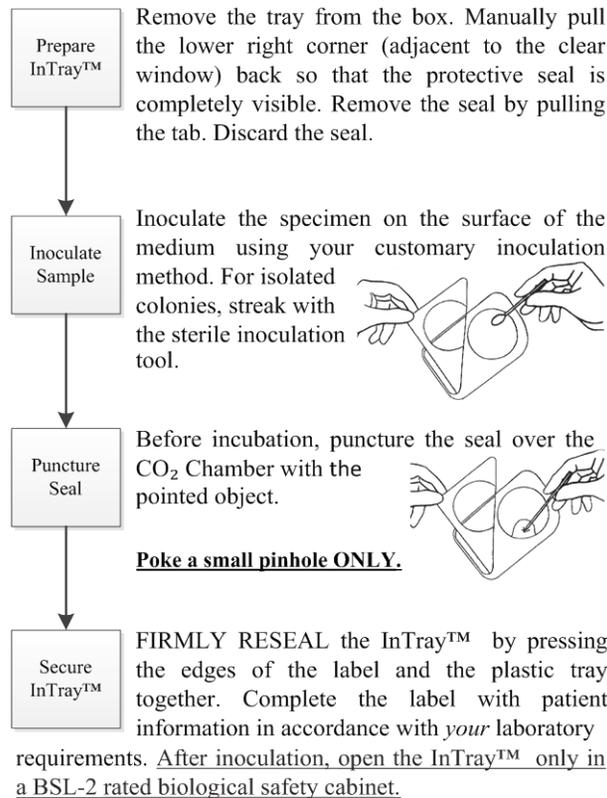
The InTray™ GC has a shelf life of up to 12 months from the date of manufacture when stored at 2°C – 25°C. Refrigerated storage is recommended for temperature stability. However, the InTray™ GC can tolerate extended periods at controlled room temp ( $\leq 25^{\circ}\text{C}$ ), i.e. for transport, storage, etc.

## INSTRUCTIONS

### SAMPLE COLLECTION



### INOCULATION



### INCUBATION

Incubate the InTray™ GC *flat* to avoid moisture leaking into the CO<sub>2</sub> pill chamber. *Incubate the tray right side up for 24 – 48 hours at 37°C under ambient atmosphere.*

## READING THE RESULTS

### EVALUATION

At 24 and 48 hours observe the InTray™ GC for colony growth through the clear window. Colony growth may be observed in the InTray™ GC by *microscopic examination* as well. To accomplish this, place the InTray™ GC (window side up) on the microscope and observe using top illumination.

Colonies of *N. gonorrhoeae* on this medium appear smooth and gray in color. However, typical colony morphology is insufficient to confirm the identification of gonococcal organisms, as other *Neisseria* and related ssp., e.g. *N. cinerea*, *B. catarrhalis*, and some strains of *N. meningitides* may demonstrate similar morphology.

Presumptive gonococcal colonies should be confirmed according to the U.S. CDC Recommended Criteria:

- isolation of *N. gonorrhoeae* from sites of exposure (e.g., urethra, endocervix, throat, rectum) by culture (usually a selective medium) and demonstrating typical gram-negative morphology and
- confirmation of isolates by biochemical, enzymatic, serologic, or nucleic acid testing, e.g. carbohydrate utilization, rapid enzyme substrate tests, serologic methods such as co-agglutination or fluorescent antibody tests supplemented with additional tests that will ensure accurate identification of isolated, or DNA probe culture conformation technique.<sup>3</sup>

Presumptive *negative* cultures have **no growth** after 48 hours of incubation.

### SAFETY & DISPOSAL

The InTray™ GC is for anaerobic eukaryotic identification and test results only. After inoculation the InTray™ GC must be handled in accordance with BSL-2 organism requirements.

Since InTray™ GC may contain live, infectious materials, the InTray™ GC must be destroyed by autoclaving at 121°C for 20 minutes or other suitable means for sterilization and disposal of BSL-2 organisms.

## QUALITY CONTROL

This product has been tested and meets the CLSI Approved Standard, M22-A3, for commercially prepared media. At the time of manufacture, quality control testing is performed on each lot of the InTray™ GC. The ability of the media to support growth and demonstrate expected morphology is verified.

Testing of control organisms should be performed in accordance with established laboratory quality control procedures. The following QC strains are recommended for customers who choose to complete independent QC testing of the InTray™ GC:

Table 1: Recommended Strains for QC Testing the InTray™ GC

Test Strain	Strain Number	Expected Results
<i>Neisseria gonorrhoeae</i>	ATCC 43069	Growth
<i>Candida albicans</i>	ATCC 60193	Inhibition
<i>E. coli</i>	ATCC 25922	Inhibition
<i>Proteus mirabilis</i>	ATCC 43071	Inhibition
<i>Staphylococcus epidermatis</i>	ATCC 12228	Inhibition

\**Neisseria* Reference Laboratory (NRL), Center for AIDS and STD Department

## LIMITATIONS

The InTray™ GC is not intended to diagnose *Gonorrhoea* infection or to guide or monitor treatment for infections. Confirmation of isolates by additional testing may be required. Other *Neisseria* and related ssp., e.g. *N. cinerea*, *B. catarrhalis*, and some strains of *N. meningitides* may grow on the InTray™ GC medium.

## PERFORMANCE CHARACTERISTICS

Two studies were performed comparing InTray™ GC that had been stored for one year at room temperature against fresh chocolate and MTM agars. Pure laboratory cultures were used including and CLSI standard strain of *N. gonorrhoeae*, three other strains, and five potential contaminants. For two of the *N. gonorrhoeae* strains, recovered colony counts were comparable to fresh commercially prepared media. For the other two, colony counts were approximately half compared to freshly prepared media. In no case was there failure to recover the organism. Potential contaminants that were tested include *E. coli*, *S. epidermidis*, *P. mirabilis*, *N. sicca* and *C. albicans*.

After one year at room temperature, InTray™ GC was superior to fresh commercial media in suppressing these organisms. A clinical study was performed with 228 female patients using cervical swabs. Results for *N. gonorrhoeae* were identical to commercially prepared media, 18 positive and 210 negative. The principal contaminant was *C. albicans*, with 17 positive for the InTray™ GC and 30 positive on comparison MTM media. There were no adverse indications in any of these tests.

## REFERENCES

1. Beverly, et al., InTray GC Medium Versus Modified Thayer-Martin Agar Plates for Diagnosis of Gonorrhea from Endocervical Specimens, JCM, Oct 2000; p. 3825-3826.
2. Whittingham, W.L., et al., Abstr., 13th Meeting International Soc. Sex. Transm. Dis. Res., abstr. 526, Denver, 1999.
3. Internet site: [www.cdc.gov/std/Gonorrhea/](http://www.cdc.gov/std/Gonorrhea/)

# InTray™ GC

*Neisseria gonorrhoeae*

Catalog No. 10-8007      5 Test Kit  
Catalog No. 10-8001      20 Test Kit

A SELECTIVE CULTURE SYSTEM  
FOR THE DIAGNOSIS OF HUMAN  
*Neisseria gonorrhoeae*

For *In Vitro* Diagnostic Use Only



BIOMED

Manufactured by:

Biomed Diagnostics, Inc.

PO Box 2366 • White City, OR 97503  
tel. (800)-964-6466 • fax. (541) 830-3001  
[info@biomeddiagnostics.com](mailto:info@biomeddiagnostics.com)  
[www.biomeddiagnostics.com](http://www.biomeddiagnostics.com)