

InTray™ GC

Chocolate Blood medium for *Neisseria gonorrhoeae*

REF Catalog# 10-8007 5 Test Box

REF Catalog# 10-8001 20 Test Box

For In Vitro Diagnostic Use Only



BIOMED
DIAGNOSTICS

1-800-964-6466

White City, OR 97503

INDICATIONS

Neisseria gonorrhoeae is a common sexually transmitted disease organism broadly disseminated throughout the world. The InTray GC is intended to contribute to the ease of diagnosis of GC by providing extended shelf life without refrigeration and simplifying diagnostic procedures. It is intended for use in qualitative procedures for the isolation of *Neisseria gonorrhoeae* from clinical specimens. The InTray GC is a novel device containing a plated medium for use in qualitative procedures for the isolation of *Neisseria gonorrhoeae* from clinical specimens. It provides a long shelf life and the ability to examine the growth of organisms through a window without opening the InTray.

DESCRIPTION OF THE SYSTEM AND ITS PRINCIPLES

The InTray GC is a combined Petri dish with its own 5% CO₂ environment and a microscope slide. It consists of a 3" x 4" rectangular plastic tray with an inner well (2" in diameter) for the modified Thayer Martin medium (selective medium) and a sealed inner chamber containing a tablet that generates a 5% CO₂ atmosphere. A bonded seal over the well prevents evaporation and oxidation during storage. The outer seal of the InTray is a label attached with a resealable medical grade adhesive. The label has a transparent window over the agar medium and the window is made of a material that does not fog up in the high humidity of the InTray.

INTENDED METHOD OF USE

The InTray is easy to use for specimen collection, transport, incubation, examination and disposal. After inoculation, the InTray GC is resealed and transported to the laboratory for evaluation. The InTray GC does NOT require a CO₂ incubator, or a CO₂ jar system, or a CO₂ Bio Bag system.

PATIENT SPECIMENS

Specimens may include oral, vaginal, urethral and rectal swabs. All specimens should be handled according to the CDC-NIH recommendations for potentially infectious human serum, blood or other body fluids and materials. After inoculation, open the InTray only in a biological safety cabinet. (Bio-hazard Level 2).

STORAGE

InTray GC may be kept at the location where the patient is examined. Store the InTrays FLAT to avoid any moisture from the media leaking into the CO₂ pill chamber. Decreased results may occur.

This product has demonstrated a shelf life of 12 months at room temperature (18°C - 25°C and 24 months under refrigeration (2°C - 8°C) from the date of manufacture.

INOCULATION PROCEDURE

Pull back the lower right corner adjacent to the clear window of the InTray lid until the protective seal over the medium is completely visible. Remove the seal by pulling the tab and discard the seal. (Figure 1)

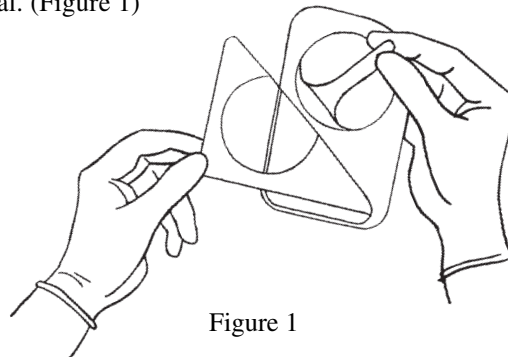


Figure 1

Inoculate the specimen on the surface of the medium using your customary inoculation method. (Figure 2) Streak for isolated colonies.

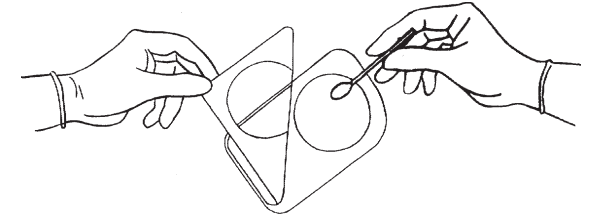


Figure 2

Puncture the seal over the chamber containing the carbon dioxide generator tablet, with a pointed object. (Figure 3)

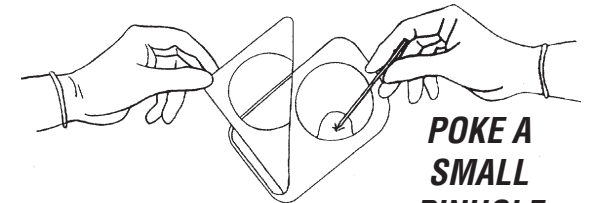


Figure 3

**POKE A
SMALL
PINHOLE
ONLY!**

FIRMLY RESEAL the InTray by pressing together the edges of the lid against the plastic tray. (Figure 4) Do not press the window against the agar.

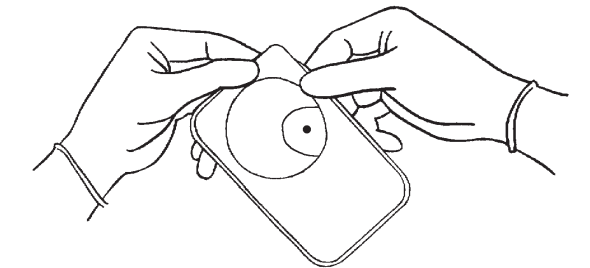


Figure 4

Incubate for 24 to 48 hours at 37°C in a normal incubator.

READING RESULTS

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 (window side up) on the microscope and observe using top illumination. Colonies of *Neisseria gonorrhoeae* on this medium appear smooth and gray in color. However, typical colony morphology is insufficiently specific to confirm the identification of gonococcal organisms, as other *Neisseria* and related ssp., e.g. *N. cinerea*, *B. catarrhalis*, and some strains of *N. meningitidis* may demonstrate similar morphology.

Presumptive gonococcal colonies should be confirmed according to the following CDC Recommended Criteria:

A definitive diagnosis of gonorrhea must be obtained for medico legal purposes. A Definitive diagnosis of gonorrhea requires:

(i) isolation of *Neisseria gonorrhoeae* from sites of exposure (e.g., urethra, endocervix, throat, rectum) by culture (usually a selective medium) and demonstrating typical gram-negative morphology and

(ii) confirmation of isolates by biochemical, enzymatic, serologic, or nucleic acid testing e.g., carbohydrate utilization, rapid enzyme substrate tests, serologic methods such as coagglutination or fluorescent antibody tests supplemented with additional tests that will ensure accurate identification of isolated, or DNA probe culture conformation technique.³

Presumptive Negative cultures have No Growth at 48 hours.

LIMITATIONS

Other *Neisseria* and related ssp., e.g. *N. cinerea*, *B. catarrhalis*, and some strains of *N. meningitidis* 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 about 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 organism. 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.

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.

Test Strain	Strain Number	Expected Results
AHU auxotype	NRL* 93-617	Growth
<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

PRECAUTIONS











For *in vitro* diagnostic use only. Once the InTray has been inoculated and resealed, open only in a biological safety cabinet. Because of the infectious materials involved, the InTray must be destroyed by autoclave or equivalent means of disposal.

REAGENTS

This product contains a GC medium base, fresh sheep blood, supplements and antibiotics.

References:

- 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.
- Whittingham, W.L., et al., Abstr., 13th Meeting International Soc. Sex. Transm. Dis. Res., abstr. 526, Denver, 1999.
- Internet site: www.cdc.gov/ncidod

SYMBOL KEY			
Symbol	Used For	Symbol	Used For
	Batch code		Temperature limitation
	Date of manufacture		Catalog number
	Use by YYYY-MM-DD or YYYY-MM		Caution, consult accompanying documents
	Manufacturer		Authorized representative in the European Community
	In vitro diagnostic medical device		in European community

The label on the InTray GC test includes a section where the patient information can be written. The information is: patient #, sample, source, name and date. It is up to the discretion of the practitioner to complete this section or not.

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