

Introduction

Intended Use

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

Description and Principle

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. InTray GC simplifies diagnostic procedures and provides extended shelf life. The proprietary modified Thayer-Martin agar is selective for gonococcal bacteria. Results can be interpreted after 24-48 hours incubation.

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% CO₂ environment
- Modified Thayer Martin medium, selective for GC
- Direct microscopic observation of the culture with anti-fog viewing
- Incubatory and transport capabilities
- Extended 12 month shelf-life from date of manufacture

Reagents and Appearance

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

Precautions, Safety and Disposal

For In Vitro Diagnostic Use
Rx only

Read the Safety Data Sheets (SDSs) and follow the handling instructions. Wear appropriate protective eyewear, clothing and gloves.

InTray GC is for presumptive culture identification only. After inoculation InTray GC must be handled in accordance with BSL-2 organism requirements.

Once the tray has been inoculated and resealed, re-open only in a biological safety cabinet. Because of the potential for containing infectious materials, the tray must be destroyed by autoclaving at 121°C for 20 minutes.

Storage

DO NOT FREEZE. Refrigerated 2–8°C storage is recommended for agar stability. However, InTray GC can tolerate extended periods at 2-25°C (36-72°F), with no loss in performance, i.e. for transport, storage, etc.

Shelf Life

InTray GC has a shelf life of 12 months from the date of manufacture.

Procedure

Key Notes Regarding Specimen Collection

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.

1 - Prepare InTray



Allow the InTray to warm to 18-25°C (64-77°F)! Manually pull the lower right corner (adjacent to the clear window) back so that the protective seal is completely visible.

Remove the seal by pulling the tab and discard.

3 - Puncture Seal



Before incubation, puncture the seal over the CO₂ Chamber with the pointed object.

Incubation

Incubate InTray GC flat to avoid moisture leaking into the CO₂ pill chamber. Incubate the tray right side up for 24–48 hours at 37°C (98.6°F) under ambient atmosphere.

Quality Control

This product has been tested and meets the CLSI (formerly NCCLS) Approved Standard for commercially prepared media (M22-A3). 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 to demonstrate expected selectivity and morphology is verified by lot.

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:

Materials Provided

- InTray GC test(s)

Materials Required but Not Provided

- Sterile inoculation tool, i.e. Dacron[®], rayon or cotton swab with charcoal transport medium.⁵
- Laboratory incubator capable of incubation at 37°C (98.6°F)

2 - Inoculate Sample



Inoculate the specimen by rolling the sample swab on the surface of the medium in a large "C" pattern for maximum transfer. For isolated colonies, cross-streak with the sterile inoculation tool.

4 - Secure InTray



FIRMLY RESEAL InTray by pressing the edges of the label and the plastic tray together. Complete the label with patient information in accordance with your laboratory requirements.

After inoculation, open InTray only in a BSL-2 rated biological safety cabinet.

Recommended Strains for QC Testing InTray GC

Organism	ATCC [®]	Expected Result
<i>N. Gonorrhoeae</i>	43069	Growth
<i>N. meningitides</i>	13090	Growth
<i>N. sicca</i>	9913	Inhibition
<i>C. albicans</i>	60193	Inhibition
<i>E. coli</i>	25922	Inhibition
<i>P. mirabilis</i>	13071	Inhibition
<i>S. epidermidis</i>	12228	Inhibition

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

Reading the Results

Evaluation

At 24 and 48 hours observe InTray GC for colony growth through the clear window.

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. meningitidis* may demonstrate similar morphology.

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

- (i) 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
- (ii) 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.³

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

Limitations

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. meningitidis* may grow on InTray GC medium.

InTray GC is an agar medium that is susceptible to condensation collection within the inner seal, especially when stored at low temperatures and/or having been exposed to extreme temperature fluctuations. If moisture is visible on the surface of the InTrays, dry them (with the seal removed and InTray label in a position allowing for air flow) under a BSL-2 cabinet just prior to inoculation. There should be no visible droplets of moisture on the surface of the agar when they are inoculated. The surface of the dried medium should be smooth and should not show signs (webbed ribbing pattern on the agar surface) of desiccation.⁴

Performance Characteristics

Two studies were performed comparing InTray GC that had been stored for one year at 18-25°C 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

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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 18-25°C, 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 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: cdc.gov/std/Gonorrhoea/
4. CDC, Neisseria Gonorrhoeae Reference Strains For Antimicrobial Susceptibility Testing, Brochure B88, Feb 2005: pg.4.
5. Tille, et al., Bailey & Scott's Diagnostic Microbiology, Elsevier, 2014: p. 450.

Symbol glossary: biomeddiagnostics.com/1/symbol-glossary

Document Revision History

Rev. G, August 2019

New format; added new catalog numbers, "R only" indication, °F, reference to online symbol glossary, document revision history; reorganized and retitled some sections.



Manufactured by:
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InTray[®] GC

Neisseria gonorrhoeae

REF	11-080-001		5
REF	11-080-002		20

Not available in all countries; please inquire.

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

For In Vitro Diagnostic Use



Download



Certificate of Analysis