Reading the Results

Evaluation

At 24 and 72 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. meningitides* 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 Gonorrhoeal 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 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]
- InTray GC devices intended for transport must be pre-incubated for 24 hours at 35°C.
- Transport of pre-incubated InTray GC devices should not exceed 72 hours at ambient temperature (18-25°C).

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 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 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.

Transportation claim was supported using a transport simulation study and a comparative assessment study. The transport simulation study showed that inoculated samples pre-incubated at 35°C for 24 hours followed by transport at 18-25°C for 72 hours, demonstrated recovery via increased colony size when compared to samples that were not pre-incubated. The comparative assessment study assessed six *N. gonorrhoeae* strains on multiple variously aged lots of InTray GC devices, that were either pre-incubated at 35°C for 24 hours followed by transport simulation at 18-25°C for 72 hours or were incubated without the transport simulation (time zero). Growth on the InTray GC device and from a legally marketed transport device with subsequent subculture on chocolate agar, were used as the end point analysis. The results of the comparative assessment study showed acceptable results as there were ≤2 log10 CFU/mL difference in *N. gonorrhoeae* recovery, for each strain, when the time zero InTray GC device was compared to InTray GC that had been transported. The results for the legally marketed transport device were also acceptable as they too showed ≤2 log10 CFU/mL difference in *N. gonorrhoeae* recovery when using traditional transport and culture techniques. Overall, the results substantiate that the InTray GC device may be used for transport when following the new procedure.

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.
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3. Internet site: **cdc.gov/std/Gonorrhea/**
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/l/symbol-glossary

Document Revision History

Rev. A, May 2025

Removed QR codes, updated manufactured by and company address.

Rev. B, May 2025

Clarified Rx under disposal, looked like Px.

Rev. C-I, September 2025

C-I- Keeping revision consistent. **I-** Replaced ® with ™.

Manufactured by:
Biomed Diagnostics, a DCN Dx brand
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biomeddiagnostics.com

BIOMED™
DIAGNOSTICS
A DCN DX BRAND

InTray™ GC

Neisseria gonorrhoeae

REF 11-080-001 Σ 5

REF 11-080-002 Σ 20

Not available in all countries; please inquire.

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

For In Vitro Diagnostic Use

CE IVD 2°C–8°C

Introduction

Intended Use

InTray GC is a microbiological device intended to differentiate and support the growth of pathogenic *Neisseria gonorrhoeae* when incubated at 35°C for 24-72 hours. Inoculated samples can optionally be pre-incubated prior to transport when pre-incubated at 35°C for 24 hours. Subsequent transport, of the pre-incubated specimen under controlled room temperature (18 to 25°C), is supported out to 72 hours.

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 without requirement for refrigeration. The proprietary modified Thayer Martin agar is selective for gonococcal bacteria. Results can be interpreted after 24-72 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% CO_2 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

For transportation from the point of collection to the laboratory, the inoculated, InTray GC plate should be pre-incubated at 35°C for 24 hours before transportation. Incubation after transportation should follow at 35°C for 72 hours.

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.

Procedure

Key Notes Regarding Specimen Collection

All specimens should be handled according to the CDC-NIH recommendations for potentially infectious human serum, blood or other body fluids and materials.

Materials Provided

- InTray GC test(s)

Materials Required but Not Provided

- Sterile inoculation tool, i.e. Dacron® or rayon swab with charcoal transport medium.[5]
- Standard Laboratory incubator.

1- Prepare InTray

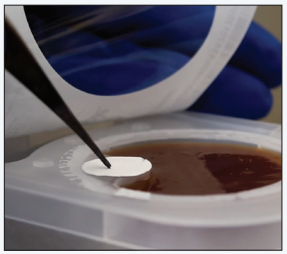
Allow the InTray to warm to 18-25°C (64-77°F)! Manually pull the lower right corner (adjacent to the clear window) back so that the protective seal is completely visible.

Remove the seal by pulling the tab and discard.

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.

3- Puncture Seal



Before incubation, puncture the seal over the CO_2 Chamber with the pointed objected.

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 and incubate at 35°C for 24 -72 hours. The inoculated sealed InTray can be transported to the Laboratory at room temperature (18 – 25°C) in a sealed biohazard container after an initial incubation at 35°C for 24 hours. After inoculation, InTray can only be opened in a BSL-2 rated biological safety cabinet.

Shelf Life

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

Incubation

Incubate InTray GC flat to avoid moisture leaking into the CO_2 pill chamber. Incubate the tray right side up for 24–72 hours at 35°C (95°F) under ambient atmosphere.

If the InTray GC device is being used for transport, to any laboratory located outside of the facility where collection was performed, then pre-incubation at 35°C for 24 hours is required. After the pre-incubation step, the InTray GC device can be transported up to 72 hours at ambient temperature (18-25°C) to the testing laboratory for analysis.

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:

Recommended Strains for QC Testing InTray GC

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