510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K210511

B Applicant

Biomed Diagnostics Incorporated

C Proprietary and Established Names

InTray GC

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JTY	Class II	21 CFR 866.2410 - Culture Media for Pathogenic Neisseria Spp.	MI- Microbiology

II Submission/Device Overview:

A Purpose for Submission:

The purpose of the submission is to add a transport function for the previously cleared device, K993033.

B Measurand:

Not Applicable

C Type of Test:

Culture medium for pathogenic *Neisseria spp.*

III Intended Use/Indications for Use:

A Intended Use(s):

The 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.

B Indication(s) for Use:

Same as Intended Use above.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

Not Applicable

IV Device/System Characteristics:

A Device Description:

The InTray GC is a Modified Thayer-Martin medium within a sealed inner well. The inner seal covers the inner well containing agar and an additional sealed cavity containing a CO_2 generating tablet. There is also an outer adhesive label seal with a window that does not fog up under 100% relative humidity. The user opens and inoculates the surface of the medium with the patient sample followed by resealing the outer adhesive label. High humidity within the InTray GC causes the tablet to generate CO_2 thus providing adequate bacterial growth condition for the target pathogen. After incubation of the inoculated InTray GC, the bacterial growth can be observed through the window without opening the InTray GC and therefore not disturbing the established CO_2 concentration. Observation of culture growth can be by eye, hand lens or microscope.

B Principle of Operation:

InTray GC is a culture system that has built-in features, components and atmospheric conditions that under certain incubation conditions allow for transport of inoculated specimens to facilitate growth and detection of *Neisseria gonorrhoeae*. For transportation from the point of collection to the laboratory, the inoculated InTray GC plate is pre-incubated at 35°C for 24 hours before transportation. After appropriate inoculation, preincubation and other procedural steps, the InTray GC is then transported in a sealed biohazard container to the laboratory for subsequent incubation and microbiological examination using appropriate biosafety procedures.

V Substantial Equivalence Information:

A Predicate Device Name(s):

InTray Gc

B Predicate 510(k) Number(s):

K993033

C Comparison with Predicate(s):

Device & Predicate Device(s):	Device: K210511	Predicate: K993033
Device Trade Name	InTray GC	InTray Gc
General Device Characteristic Similarities		
Intended Use/Indications for Use	The 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.	InTray Gc is used, like conventional Thayer-Martin media plates, to grow *Neisseria gonorrhoeae* and similar organisms
Device Product Code	JTY	Same
Prescription/OTC use	Rx only	Same
Collection apparatus	Does not include a specimen collection swab	Same
Reagents	Modified Thayer Martin medium (agar)	Same
Specimen type	Only sample intended for growth of *Neisseria* species	Same
Shelf-life	12 months	Same
General Device Characteristic Differences		
Transport claim	Transport at 18-25ºC for up to 72 hours	No transport

VI Standards/Guidance Documents Referenced:

1. CLSI. 2014. Quality Control of Microbiological Transport Systems; Approved Standard—Second Edition, vol CLSI document M40-A2.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Not Applicable

2. Linearity:

   Not Applicable

3. Analytical Specificity/Interference:

   Not Applicable

4. Assay Reportable Range:

   Not Applicable

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Shelf life: The shelf life for the InTray GC was determined to be 12 months from the date of manufacture. The shelf life of the InTray GC was established using a real time stability study for the cleared InTray GC device that was cleared in 1999 (510k #: K993033).

   Sterilization: The sponsor does not intend to claim that the InTray GC is provided sterile. However, the manufacturing process for the InTray GC is based on ISO 13485:2016 standard (Biomed holds certificate no. FM 545530) and ensures that InTray GC is aseptic. The manufacturing steps include a filtration process using biopharmaceutical grade 0.2µM filter. The aseptic status of the manufactured InTray GC is then validated by Quality Control process which evaluates the absence of bacteria and fungi growth on the uninoculated agar plate incubated at 37ºC.

   Performance analysis:

   a. Transport Simulation: To determine the optimal specimen transport condition that ensures recovery of viable *N. gonorrhoeae* in the InTray GC, various transport conditions that simulated potential conditions in the healthcare operations were evaluated to determine the clinical utility of the InTray GC as a specimen transport device from site of collection to the laboratory. Four InTray GC replicates were inoculated with approximately 20 colony forming units (CFU) for each experimental group outlined in Table 1 below and the process was repeated with the five different AR isolate bank strains (*N. gonorrhoeae* strains 0165, 0202, 0175, 0181 & 0197) and *N. gonorrhoeae* strain ATCC 43069. One lot of InTray GC transport device was used in the study.

Table 1: Experimental groups

Experimental Group	Experimental Treatment Post Inoculation with 20 CFU *N. gonorrhoeae*		
	Pre-incubate:	Store:	Incubate*:
Group A	At 35°C for 24 hours	At 18-25°C for 72 hours	At 35°C for at least 72 hours
Group B	At 35°C for 24 hours	None	At 35°C for at least 72 hours
Group C1	No pre-incubation	At 18-25°C for 24 hours	At 35°C for at least 72 hours
Group C2	No pre-incubation	At 18-25°C for 48 hours	At 35°C for at least 72 hours
Group C3	No pre-incubation	At 18-25°C for 72 hours	At 35°C for at least 72 hours

*Also, continuous observation for up to 144 hours.

b. Viability Assessment: Semi-quantitative assessment was performed by examining both total CFU count and changes in the estimated average colony size. Inoculum was verified on standard chocolate agar plates for all 5 *N. gonorrhoeae* strains and yielded 1.5 x 10^7 CFU/mL for all strains except AR0181 (4.88 x 10^5 CFU/mL). Experimental groups C2 and C3 that were inoculated and then immediately exposed (no pre-incubation) to 48 and 72 hours, respectively, of 18-25°C simulated transport temperatures before incubation at 35°C for 72 hours showed no recovery of *N. gonorrhoeae* at any time. Group C1, which was inoculated and immediately exposed to 24 hours of 18-25°C transport temperatures before incubation at 35°C for 72 hours showed very poor recovery. Group B, which served as a positive incubation control, showed consistent increase in colony size over 144 hours (6 days) of incubation at 35°C. Group A, which was preincubated at 35°C for 24 hours after inoculation followed by 72 hours of 18-25°C transport temperatures, demonstrated recovery via increased colony sizes. This study demonstrated that pre-incubation at 35°C for 24 hours is required after plating the specimen in the InTray GC and this will be reflected in labeling and instructions for use.

c. Comparative Assessment:

The InTray GC claims to support transport and recovery of *N. gonorrhoeae* were evaluated using recovery studies described in CLSI M40-A2. Recovery and enumeration of six *N. gonorrhoeae* strains with the subject InTray GC transport device were compared to recovery of the same six strains inoculated with a swab into a legally marketed transport device containing Amies media. The latter was cultured on chocolate agar to enumerate organism recovery.

Multiple lots (12 different lots) that originated from lots of variously aged InTray GC devices were used to test six strains of *N. gonorrhoeae*. Three lots of the InTray GC devices were used for testing five of the six *N. gonorrhoeae* strains (N=15 replicates) and two separate lots were used for one of the six *N. gonorrhoeae* strains tested (N=2 replicates). The InTray GC devices were inoculated using 20 µL of a 1.5x10^3

CFU/mL of *N. gonorrhoeae* sample in 0.85% saline. Group B experimental design was used to establish time zero of incubation and Group A experimental design was used to evaluate the 72-hour transport claim - schematic in Table 1 above.

Three replicates of the legally marketed transport device were used. The swab included in the device was used to spike each of the six *N. gonorrhoeae* strains (N=18). Chocolate agar culture media was used for the determination of the organism recovery and for enumeration of the colony forming units recovered. The legally marketed transport device was spiked with $1.5x10^7$ CFU/mL of *N. gonorrhoeae* sample in 0.85% saline. The differences in inoculum concentration between the InTray GC device and the comparator was to account for the 24-hour pre-incubation step and the size of the InTray GC device.

Acceptable recovery was achieved for each *N. gonorrhoeae* strain tested with a 72-hour transport using the InTray GC. An average of Log_{10} difference of 0.08 (± SD 0.77), between time zero (no transport) and 72 hours (transport) followed by a 72hour incubation at 35ºC, across the six strains tested was observed. The change in CFU/mL from time zero to the experiment endpoint of 72 hours at 35ºC was ≤2 log_{10}, which supports the shelf-life stability claims for the InTray GC, across multiple aged lots, shows that InTray GC can maintain the viability of *N. gonorrhoeae* when the device is transported.

Acceptable recovery performance was achieved for the legally marketed transport device and culture. Culture recovery demonstrated that each of the *N. gonorrhoeae* strains tested, with an average Log_{10} difference, between time zero and an incubation time of 24 hours at room temperature (20-25ºC), had an average -1.73 Log reduction (± SD 0.52) across the six strains tested. A decline in the CFU/mL of ≤2 Log_{10} between time zero and the end of the experimental incubation was considered acceptable. These studies demonstrated that sufficient viability of *N. gonorrhoeae* was achieved using traditional transport and culture techniques and supported the conclusions regarding the InTray GC ability to maintain viability of *N. gonorrhoeae*.

The viability of the recovered *N. gonorrhoeae* strains at the end of the experiment was confirmed by subculture on chocolate agar plates for all experimental groups. The results substantiate that the InTray GC device may be used for transport when following the new procedure.

6. Detection Limit:

   Not Applicable

7. Assay Cut-Off:

   Not Applicable

B Comparison Studies:

1. Method Comparison with Predicate Device:

Not Applicable

2. Matrix Comparison:

Not Applicable

C Clinical Studies:

1. Clinical Sensitivity:

Not Applicable

2. Clinical Specificity:

Not Applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not Applicable

D Clinical Cut-Off:

Not Applicable

E Expected Values/Reference Range:

Not Applicable

VIII Proposed Labeling:

The labeling support the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.