Instructions For Use

Indications for Use

GTM (General Transport Medium) is intended for the collection, transportation, and preservation of clinical specimens containing viruses, chlamydia, mycoplasma and ureaplasma from the collection site to the testing laboratory.

Directions for Use

Procedure:

1. Prepare an FDA cleared swab compatible with tube
2. Collect Specimen using the appropriate technique (professional use RX ONLY)
3. Transfer swab into tube, label according to local regulations, and transport according to local regulations.

Precautions for Use

Specimens may be dispatched at ambient (2-25°C) or refrigerated temperature to arrive at the laboratory for processing within 48 hours.

If a delay in testing or shipping is expected, specimens should be frozen at -70°C or below (repeated freezing and thawing should be avoided as may reduce the recovery of viable organisms).

- This product is an in vitro use diagnostic only device.
- This product is disposable and cannot be repackaged or reused.
- Users must be familiar with how to use (RX ONLY)
- Use product immediately after opening.
- Not to be taken internally, and if reagent contacts skin or eyes, wash thoroughly with water
- There is risk of potentially phosphorus infection when dealing with biologically hazardous reagents and clinical samples, and so should be handled in the same way as infectious agents.
- Transport according to national and local regulations.
- Dispose of the used products according to national and local regulations.
- As an EUA device, the transport medium has not been reviewed by FDA

List of materials provided

- Sterilized SAL 10^{-6} self-standing plastic (PP) 12mL tubes with conical bottom and screw cap.
- (Infused with) Non-propagating transport medium of either 1mL, 2mL, or 3mL

Sterility statement

The sterility of GTM as a final product is validated by the ISO 11737-2 (membrane filtration) test procedure. During manufacturing, the medium mixture undergoes a 2-step filtration process. Once the formulation is complete, the medium mixture is first filtered at 0.45 microns, followed by 0.20-micron filtration. The sterile tubes are then aseptically infused with the medium.

Storage and Shelf Life

Do not freeze the GTM device. Upon receipt, store at 2-30°C, and keep away from direct light exposure. Do not use expired tubes. Do not use a tube if it appears to be damaged, leaking or the media appears to be cloudy. The GTM device has a shelf-life of 18 months when stored at 2-30°C.

Device description/ summary

GTM is a Non-Propagating, Transport Medium Device. The device is manufactured in an ISO 13485 compliant facility, and meets the EU's essential requirements of the council directive 98/79/EEC in vitro diagnostics.

GTM is stable at room temperature, and can be stored between 2 - 30°C. The medium consists of Hank's balanced salt solution, bovine serum albumin, gelatin, L-cysteine, sucrose, L-glutamic acid, colistin, phenol red, sodium bicarbonate, amphotericin B, vancomycin, and HEPES buffer. The medium is isotonic and non-toxic to mammalian host cells. After the collection, the specimen should be stored at 2 - 25°C and processed within 48 hours.

If delivery and processing exceed 48 hours, specimens should be transported in dry ice and once in laboratory frozen at -70°C or colder.

GTM is provided in plastic tubes sterilized via E-beam. The tubes are then infused with the medium in an aseptic environment compliant with ISO 13485. The final product is pressured tested at -95 kPa. GTM is routinely inspected to ensure quality control.

QC

The GTM is manufactured in an ISO 13485 compliant facility. At the time of manufacturing, quality control testing is performed on each lot of GTM for the verification of sterility and pH. Sterility and pH stability have also been validated beyond the suggested shelf life. Monitoring of sterility and pH are conducted on a lot by lot basis.

Sample set of the final product was subjected to -95 kPa vacuum pressure testing. Three medium tubes filled with medium were randomly selected by the tester. The tubes were placed cap side down in the vacuum chamber where -95 kPa was applied for 30 minutes. Devices were visually inspected during depressurizing, and inspected once again when the chamber was depressurized (0 kPa). No evidence of leakage was observed.

The pH of the test has been determined as an indicator of product stability, and was tested 1 month, at 6 months, 12 months and 18 months after manufacturing date, on 3 representative lots of GTM stored under recommended temperature conditions. At specific time intervals, 10 tubes from each of the 3 lots were randomly selected from storage and medium inside the tube tested using pH meter. For all products, pH was tested within the target pH value 7.3 ±0.2.

Limitations

- The performance of GTM may be impacted by extreme temperatures and repeated freeze and thaw cycles.
- The use of GTM for uses other than described here shall be evaluated by the end-user.
- The use of swabs with wooden or calcium alginate components has not been tested with the GTM and should not be used.
- The use of this product with any diagnostic test should be evaluated and tested by the end-user.

Biocompatibility

According to OSHA & TSCA, the medium is not a hazardous substance of mixture.This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulate(vPvB) at levels of 0.1%, or Higher No special risks known. Using method OECD Test Guideline 404, no skin irritation was concluded. Slight irritation in assessment of eye tolerance was observed. According to the classification criteria of the EC, the product is not considered as an eye irritant.

Performance criteria

Summary Performance of Relevant Specimens

Organism	**ATCC number**	**% reduction of fluorescing infected cells after 48 hours (2-6°C)**	**% reduction of fluorescing infected cells after 48 hours (20-25°C)**
Herpes simplex virus type I	ATCC VR-539	≤ 50%	≤ 50%
Herpes simplex virus type II	ATCC VR-734	≤ 50%	≤ 50%
Respiratory syncytial virus	ATCC VR-1580	≤ 50%	≤ 50%
Coxsackie B1 virus	ATCC VR-28	≤ 50%	≤ 50%
Influenza A	ATCC VR-1679	≤ 50%	≤ 50%
Cytomegalovirus	ATCC VR-977	≤ 50%	≤ 50%
Chlamydia trachomatis	ATCC VR-880	≤ 50%	≤ 50%
Mycoplasma hominis	ATCC 23114	33%	23%
Ureaplasma urealyticum	ATCC 15531	0%	8%

Swabs were inoculated in triplicate with 100 µl of suspended organism in respect to the above panel of representative organisms. Subsequently, the swabs were inserted into the representative test tubes containing the medium and held at both 4°C and room temperature (20-25°C) for the required amount of time. At key time points following inoculation (0 and 48 hours), each sample was vortexed after which an aliquot of the suspension was inoculated into cellular lines (200 µl) or into appropriate culture medium. All cultures were processed using the standard laboratory culture technique. Organism viability was determined by fluorescent foci cell counting. The results demonstrate the ability of GTM to sustain the viability and recovery of test organisms for at least 48 hrs at 4°C and room temperature (20-25°C).

Manufacturer name, address, and contact information

MANUFACTURER: HAN CHANG MEDIC

ADDRESS: 79-35, Jangsan 2-Gil, Susin-Myeon, Dongnam-Gu, Cheonan,Chungcheongnamdo, SOUTH KOREA (31252)

EMAIL: hcstep@hcok8898.com

AUTHORIZED DISTRIBUTOR:

GANG DONG GROUP via GANG DONG NETWORKS (gdnetworks@gd-group.co.kr)

List of ingredients/reagents

Chemical Nature: Aqueous Solution
[components (1L per)]

Chemical Name	CAS-No. / Index.No / Registration No.
Hank's Balanced Salt Solution BSA (Bovine Serum Albumin)	
BSA	9048-46-8
L-cysteine	616-91-1
Gelatin	9000-70-8
Sucrose	57-50-1
L-glutamic acid	56-86-0
HEPES	7365-45-9
Sodium bicarbonate	144-55-8
Vancomycin	1404-93-9
Amphotericin B	1397-89-3
Colistin	1264-72-8
Phenol Red	143-74-8

Glossary of symbols

LOT	Batch / Lot Identification Code
2	Do not reuse
IVD	For In vitro Diagnostic Use Only