

- Use of HiMedias Liquid Collection & Transport System in conjunction with other commercial rapid diagnostic kits and instruments must be validated prior to use by the user.

Performance and evaluation

The performance characteristics of HiMedia Liquid Collection & Transport System swabs are determined using the procedures outlined in the Clinical Laboratory Standards Institute (CLSI) M40-A2 document (9). A variety of aerobic, anaerobic, and fastidious organisms are tested in this study. Roll Plate methods and swab elution methods are conducted to perform bacterial viability studies. Acceptance criteria for recovery of bacteria as recommended in the CLSI document M40-A2 are followed. For Roll-Plate Method, the viability to be considered acceptable, there shall be >5 CFU following the specified holding time from the specific dilution that yields zero-time plate counts closest to 300 CFU. For viability in the Swab Elution Method to be considered acceptable there shall be no more than a $3 \log_{10}$ ($1 \times 10^3 \pm 10\%$) decline in CFU between the zero-time CFU count and the CFU of the swabs that were stored. Performance of the product is expected when used as per the directions and organisms grown under recommended incubation conditions.

Quality Control

Appearance

Sterile Liquid Amies medium in tubes. Sterile flocked swab for collection of specimen.

Colour

Clear to slightly opalescent colourless liquid in tubes.

Quantity of Medium

1ml of medium in tubes

Reaction

7.10-7.50

Cultural response

Viability of following organisms was established for a period of 48 hours. Organisms grew luxuriantly when recovered on Soyabean Casein Digest Agar (Tryptone Soya Agar) (M290) and incubated at 35 - 37°C for 18-24 hours.

Sterility test

Passes release criteria

Cultural Response

Organism

Neisseria meningitidis ATCC 13090

Staphylococcus aureus ATCC 25923

Staphylococcus epidermidis ATCC 12228

Streptococcus pyogenes ATCC 19615

Recovery

Good –Luxuriant

Good –Luxuriant

Good –Luxuriant

Good –Luxuriant

Specimen cultures in the laboratory:

Vortex or mix well by shaking the Swab in tube inside to release cells and create even suspension in the liquid medium. Being in suspended form, the specimen culture can be used for either of the following:

1. Bacteriological culturing method using standard laboratory techniques for isolation and identification of bacteria.

Remove the cap with swab applicator. Using the swab applicator, streak the first quadrant of the agar plate while rolling the swab tip to create a primary inoculum. If additional plates are required replace swab back into the tube for a few seconds to recharge the swab and repeat streaking. For recommended culture media and techniques for the isolation and identification of bacteria from clinical swab specimens refer to published microbiology manuals and guidelines.

2. Direct microscopic examination of patient clinical samples.

3. Processing specimens for molecular screening.

4. Automated processing techniques

Storage and Shelf Life

Store between 5 – 25°C with caps firmly screwed. DO NOT FREEZE. Avoid exposure to excessive heat. Use before expiry date on label

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (7, 8).

Reference

1. Moffett, Young and Stuart, 1948, Brit. Med. J., 2:241.
2. Stuart R. D., Toshach S. R. and Patsula T. M., 1954, Can. J. Pub. Hlth., 45:75.
3. Cary and Blair, 1964, J. Bacteriol., 88:96.
4. Amies C. R., 1967, Can. J. Public Health, 58:296
5. Stuart R. D., 1946, J. Path. Bact., 58:343.
6. Stuart R. D., 1959, Pub. Hlth. Rep., 74: 431.
7. Leber, A. 2016 Clinical Microbiology Procedures Handbook 4th edition 2016, ASM, Washington DC.
8. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock, D.W., 2015 11th Edition. Vol. 1. Manual of Clinical Microbiology, ASM, Washington, D.C.
9. Clinical and Laboratory Standards Institute. 2014. Quality control of microbiological transport systems; approved standard— 2nd ed. CLSI document M40-A2. Clinical and Laboratory Standards Institute, Wayne, PA.

IVD For In Vitro Diagnostics

Do Not Use
If pack is Damaged



CE

IEC REP

CEpartner4U,
ESDOORNLAAN 13,
3951DB MAARN, NL

On receipt store
between



HIMEDIA

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HIMEDIA

REF MS684D

HiCulture™ Transport swabs w/Amies Medium (D)

Intended Use

HiMedia's Liquid Transport Medium is specially designed transport system to collect and transport specimen samples in suspension form. With 1.0 ml Amies Medium MS684D is recommended for collection & transport of aerobic, anaerobic and fastidious organisms from nasopharyngeal and urogenital sites and for paediatric use.

Contents

HiMedias HiCulture™ Transport swabs w/ Amies Medium (D) consists of

Sterile Amies Medium, in tube	1.0 ml
Sterile Flocked swab, PW1320	1 No.

Details

Medium is provided in a polypropylene screw-capped tube with inbuilt swab capture mechanism.

PW1320 swab is provided in Sterile peel-open pouch. It is natural coloured mini flocked tip swab w/narrow shaft having red scored break point. This molded breakpoint allows the swab to be broken in tube and gets captured* in vial containing transport medium.

*If required, sterile forceps should be used to remove the swab from the vial or from the cap in case the swab is attached loosely to the screw cap.

Composition**

Ingredients	Gms / Litre
Sodium chloride	3.000
Potassium chloride	0.200
Calcium chloride	0.100
Magnesium chloride	0.100
Potassium dihydrogen phosphate	0.200
Disodium hydrogen phosphate	1.150
Sodium thioglycollate	1.000

Final pH (at 25°C) 7.3±0.2

** Formula adjusted, standardized to suit performance parameters.

Directions for Use

Follow directions as given overleaf for collection of clinical specimens from nasopharyngeal and urogenital sites and for paediatric use. using flocked swab PW1320. Specimens should be collected and processed as per the recommendations given in published protocols. Once a specimen is collected with a swab, it should be placed into the screw capped polypropylene tube containing the transport medium immediately and processed as soon as possible to achieve optimum recovery. In cases where immediate processing (i.e., within 2 hours) is not possible, specimens can be stored at 2-25 °C and processed within 48 hours.

Principle and Interpretation

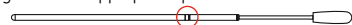
Transport Medium is generally a non-nutrient, reductive medium which hampers the self-destructive enzymatic reactions within the cells and also inhibits toxic oxidation effects. Transport Medium was primarily developed in a semisolid form by Moffett et al (1) and Stuart et al (2) for carrying gonococcal specimens. However Cary and Blair (3) observed the problem of overgrowth of contaminating organisms while carrying faecal specimens containing Shigellae. It was seen that the contaminants derive their energy from the glycerophosphate and therefore a buffer having inorganic salts was a better replacement for glycerophosphate. Amies (4) modified Stuart's Transport Medium (2,5,6) by replacing glycerophosphate with an inorganic phosphate buffer, provides a reduced environment due to the presence of sodium thioglycollate and small amount of agar. Amies Medium is devoid of methylene blue. Calcium, magnesium, potassium and sodium salts help the survival of gonococcal cells by restricting their permeability. Phosphates buffer the medium.

Type of Specimen

Nasopharyngeal and urogenital specimen

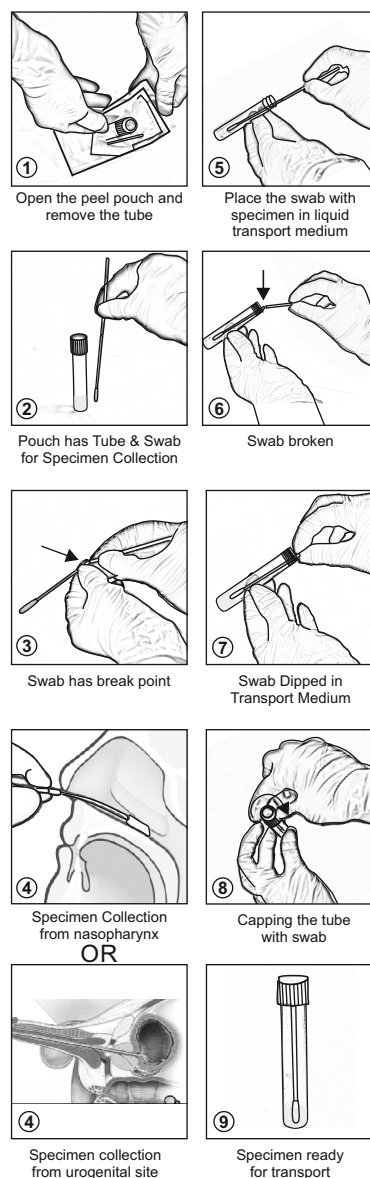
Guideline For Specimen Collection

- 1] Open the pouch from the side marked with the arrow 'Cut to open'.
 - 2] Remove self-standing polypropylene screw capped tube from the pouch and the sterile swab.
 - 3] Observe aseptic techniques wherever applicable. Always perform hand hygiene and wear clean gloves when collecting clinical specimens.
 - 4] Collect the specimen from the patient using sterile swab as below (i,ii,iii).
- i] Procedure for collection from nasopharynx.
Insert flocked swab into nostril and back to the nasopharynx. Leave in place for a few seconds. Slowly withdraw the swab with rotating motion (Refer Figure 1).
- ii] Procedure for collection from urogenital sites.
For endocervical specimen collection, first remove the cervical mucus using appropriate device. Insert the flocked swab into the cervical canal and rotate around the walls for few seconds. Withdraw the swab gently (Refer Figure 1).
- For urethral specimens, insert the flocked swab into the urethral lumen at a distance of 2-4 cm and leave for few seconds. Withdraw the swab gently. Please note that the urethral specimens should be collected atleast an hour after the patient has urinated.
- iii] For Paediatric applications
Mini flocked swab, PW1320 is recommended for paediatric use.
- 5] After collection of specimen remove the cap and insert the swab into the tube.
 - 6] Carefully break the swab by bending at the printed breakpoint line. Discard the broken handle part of the swab into biohazard labelled bag or follow appropriate precautions.



- 7] Tighten the screw cap so as to secure the swab into the cap. Ensure to secure tightly.
- 8] Record patient information in the space provided on the tube label. Transport the specimen to the laboratory for testing.

Figure 1: Illustration for use of MS684D



Specimen Collection Instructions for Use

Clinical specimens are considered as biohazard. Wear appropriate protective clothing while collecting and handling potential infectious specimens. Care should be taken to avoid splashes and aerosols when breaking the swab handle into the tube containing medium. When collecting specimen with swab applicator, the area below the red colored printed breakpoint must not be touched.

Warning

- In Vitro diagnostic use only.
- Read the instructions before opening the container.
- Product should be handled by trained personnel and qualified person only or who has knowledge of microbiological lab practices.
- Safety guidelines may be referred in individual safety data sheets.
- Please read and follow the instructions in this package insert carefully and use appropriate aseptic techniques.

Precautions

- All clinical specimens should be considered biohazards and handled with care.
 - Wear appropriate personal protective equipment.
 - Follow good microbiological lab practices while handling specimens and culture.
 - Standard precautions as per established guidelines should be followed while handling clinical specimens (7,8).
 - It is suggested to also refer to the recommendations of the Centers for Disease Control and Prevention's Biosafety in Microbiological and Biomedical Laboratories for in vitro diagnostic use.
 - Do not use the transport system beyond the expiration date printed on the label.
 - Do not use if the sterile pouch seal is damaged.
 - The flocked tipped swab provided in the pouch is scored at a specific point to allow for easy breakage after transferring the swab tip to the vial containing the transport medium. If by chance these are not held within grip feature of cap, sterile forceps may be necessary.
 - Use caution when removing swab from tube.
 - Sterilize the unit after use, and dispose of it according to biohazard waste disposal regulations.
 - Do not ingest Liquid Amies Medium.
- ## Limitations
- HiMedias Liquid Amies Collection & Transport System is recommended for aerobic, anaerobic, and fastidious organisms.
 - Extreme temperatures should be avoided during transportation of the collection system.
 - The performance of the MS684D, Liquid Amies Collection & Transport System for storage time over 48 h has not been evaluated.