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 (7). 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 x 10^3 +/- 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 Selenite medium in tubes. Sterile foam tipped swab for collection of specimen.

Colour

Colourless to pale coloured liquid medium in tubes.

Quantity of Medium

2ml of medium in tubes

Reaction

6.80- 7.20

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	Recovery
Escherichia coli ATCC 25922	None –Poor
Salmonella Choleraesuis ATCC 12011	Good –Luxuriant
Salmonella Typhi ATCC 6539	Good –Luxuriant
Salmonella Typhimurium ATCC 14028	Good –Luxuriant
Escherichia coli ATCC 8739	None –Poor
Escherichia coli NCTC 9002	None –Poor

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 (5,6).

Reference

1. Klett A., 1900, Zeitsch Für Hyg. Und. Infekt., 33: 137.
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4. Kelly, Brenner and Farmer, 2003, Manual of Clinical Microbiology, 8th ed., Lennett and others (Eds.), ASM, Washington, D.C.
5. Leber, A.2016 Clinical Microbiology Procedures Handbook 4th edition 2016, ASM, Washington DC.
6. 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.
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HIMEDIA®

HiMedia Laboratories Pvt. Limited

A-516, Swastik Disha Business Park, Via Vadhani Indl. Est. Mumbai - 400 086, India Phone : 00-91-22-4095 1919 Fax : 4095 1920 Email : info@himedialabs.com

www.himedialabs.com

HIMEDIA®

REF MS052A

HiCulture™ Transport swabs w/Selenite Medium (A)

Intended Use

HiMedia's Liquid Transport Medium is specially designed transport system to collect and transport specimen samples in suspension form. With 2.0 ml Selenite medium it is recommended for enrichment of enteric organisms from faecal specimens. Feacal matter from any stool specimens can be inoculated directly into the medium or the rectal swab can be used for collection of aerobic, anaerobic and fastidious organisms from rectal area.

Contents

HiMedias HiCulture™ Transport swabs w/ Selenite Medium (A) consists of

Sterile Selenite Medium, in tube	2.0 ml
Sterile Rectal swab, PW1323	1 No.

Details

Medium is provided in a polypropylene screw-capped tube with inbuild swab capture mechanism. PW1323 swab is provided in Sterile peel-open pouch. It is foam tipped, with 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
Tryptone	5.00
Lactose	4.00
Sodium hydrogen phosphate	10.00
Sodium hydrogen selenite	4.00
Final pH (at 25°C) 7.0±0.2	

**Formula adjusted, standardized to suit performance parameters.

Directions for Use

Follow directions as given overleaf for collection of faecal specimens or clinical specimen using rectal swab. 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-nutritive, chemically defined,

buffered medium. The sole purpose of this medium is to maintain the viability of organisms during the time from collection to examination of the specimen. Transport Medium should be essentially non-nutritive so that the test organisms do not increase in numbers during transport. Klett (1) first demonstrated the selective inhibitory effects of selenite and Guth (2) used it to isolate *Salmonella* Typhi .

Leifson fully investigated selenite and formulated the media (3). Enrichment media are routinely employed for detection of pathogens in faecal specimens as the pathogens are present in a very small number in the intestinal flora. Selenite Broth is useful for enriching Salmonella in the nonacute stages of illness when organisms occur in the faeces in low numbers and for epidemiological studies to enhance the detection of low number of organisms from asymptomatic or convalescent patients (4).

Components of the medium as tryptone and lactose helps to maintain viability of the cells while being nitrogen and carbon sources. Selenite is reduced by bacterial growth and alkali is produced. An increase in pH lessens the toxicity of the selenite and results in overgrowth of other bacteria. The acid produced by bacteria due to lactose fermentation serves to maintain a neutral pH. Sodium hydrogen phosphate maintains a stable pH and also lessens the toxicity of selenite. Enriched Selenie medium can be subcultured on differential plating media such as Bismuth Sulphite Agar (M027), Brilliant Green Agar (M016), XLD Agar (M031) etc .

Type of Specimen

Faeces specimen, Rectal swabs for enteric organisms

Guideline For Specimen Collection

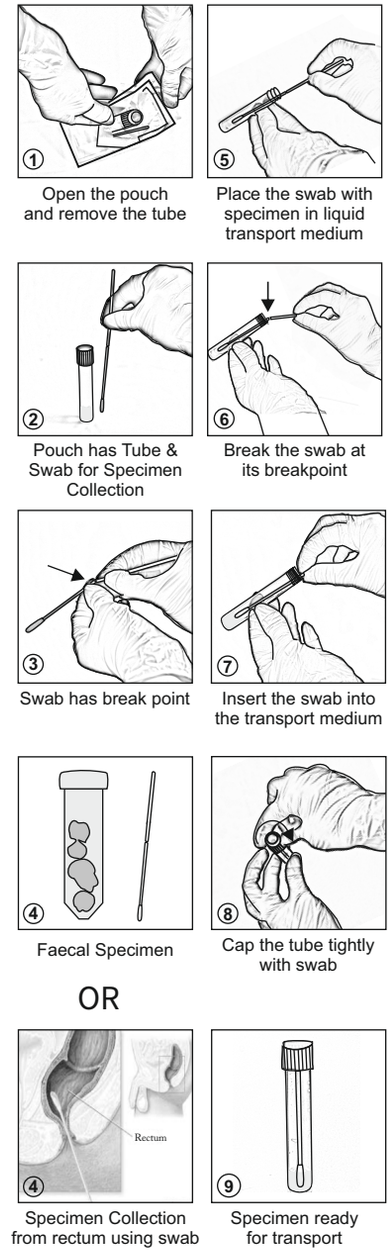
1. Open the pouch from the side marked with the arrow 'Cut to open'.
2. Remove self-standing polypropylene screw capped tube and the sterile swab from the pouch .
3. Observe aseptic techniques wherever applicable.
4. Collect the specimen from the patient using sterile swab or insert swab into the faecal specimen sample which has been already collected.
5. Remove the cap and insert the swab into the tube.
6. If rectal swab (PW1323) is used, 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.

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.

Figure 1: Illustration for use of MS052A



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 (5,6).
- 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 foam tipped rectal 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 Selenie medium.

Limitations

- HiMedias Liquid Selenite Medium Collection & Transport System is recommended for enteric organisms from faecal specimens.
- Extreme temperatures should be avoided during transportation of the collection system.
- The performance of the MS052A for storage time over 48 hr has not been evaluated.
- 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.