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(6). 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 SCDM w/ 6.5% NaCL medium in tubes. Sterile flocked swab for collection of specimen.

Colour

Light yellow coloured medium in tubes.

Quantity of Medium

2ml 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 Tryptone Soya Agar (M290) and incubated at 35 - 37°C for 18-24 hours.

Sterility test

Passes release criteria

Cultural Response

Organism	Recovery
Staphylococcus aureus subsp. *aureus* ATCC 6538	luxuriant
Staphylococcus epidermidis ATCC 12228	luxuriant
Staphylococcus aureus, MRSA ATCC 43300	luxuriant
Staphylococcus aureus ATCC 25923	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 (4, 5).

Reference

1. Clinical and Laboratory Standards Institute (CLSI). 2006. Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically; Approved Standard, 7th ed. M7-A7. CLSI, Wayne, PA.
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4. Leber,A.2016 Clinical Microbiology Procedures Handbook 4th edition 2016 , ASM, Washington DC.
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6. 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**

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HIMEDIA®

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REF **MS2016A**

HiCulture™ Transport Swab w/ Soyabean Casein Digest Medium w/6.5% NaCl

Intended Use

HiMedia's Liquid Transport Medium is specially designed transport system to collect and transport specimen samples in suspension form. MS2016A has 2.0 ml Soyabean Casein Digest Medium (SCDM) w/6.5% NaCL and one swab recommended for collection & transport of aerobic, anaerobic and fastidious organisms from nose, throat, axilla, perineum, groin for MRSA Screening.

Contents

HiMedias HiCulture™ Transport swabs w/ Soyabean Casein Digest Medium w/6.5% NaCl consists of

Sterile SCDM w/6.5% NaCL, in tube	2.0 ml
Sterile Flocked Swab, PW1320	1 No.

Details

Medium is provided in a polypropylene screw-capped tube with inbuild swab capture mechanism. Swab is provided in sterile peel-open pouch. It is sterile mini flocked tip swab w/narrow shaft, 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	17.00
Soyapeptone	3.00
Sodium chloride	6.50
Dextrose	2.50
Dipotassium hydrogen phosphate	2.50
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 the collection of clinical specimens for MRSA screening from nose, throat, axilla , perineum or groin region using flocked tip 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

The sole purpose of this medium is to maintain viability of organisms during the time from collection to examination of specimen. Soyabean

Casein Digest Medium, a general purpose medium is known to support growth of bacterial species. Mueller Hinton Agar with 2% and 4% sodium chloride has been studied for isolating MRSA that are resistant to oxacillin (1, 2).

Conventional methods for screening MRSA detects by inhibiting contaminants and selection based on antibiotic resistance. Direct plating methods are often followed but broth enrichment step prior to plating helps in good recovery of MRSA.

Staphylococci have the unique ability of growing on a high salt containing media (3).Therefore growth medium supplemented with high concentration of sodium chloride inhibits normal organisms other than Staphylococci. Enriched specimen can be then plated directly onto selective media or chromogenic media for direct identification of MRSA. MRSA strains are referred to as hetero-resistant because two subpopulations coexist within a culture. The resistant population usually grows much more slowly than the susceptible subpopulation leading to detection problems with traditional in vitro susceptibility test methods. Successful detection depends largely on promoting the growth of the resistant subpopulation, which favors lower temperatures, longer incubation and the presence of salt in the media.

Type of Specimen

Nasal swab, throat swab, swab of axilla, perineum, groin region for MRSA screening

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.
4. Collect the specimen from the patient using sterile swab as below (i, ii, iii).

i) Procedure for collection from nose.

Insert flocked swab and roll into the nostril up and back. Leave in place for a few seconds .Slowly withdraw the swab with rotating motion (Refer Figure 1).

ii) Procedure for collection from throat: Insert swab into throat for specimen collection. Ask patient to open his/her mouth. Swab the back of the throat near the tonsils thoroughly (Refer Figure 1).

iii) Similarly collect specimen by swabbing over axillary region (arm pits or underarms), perineum and groin region.

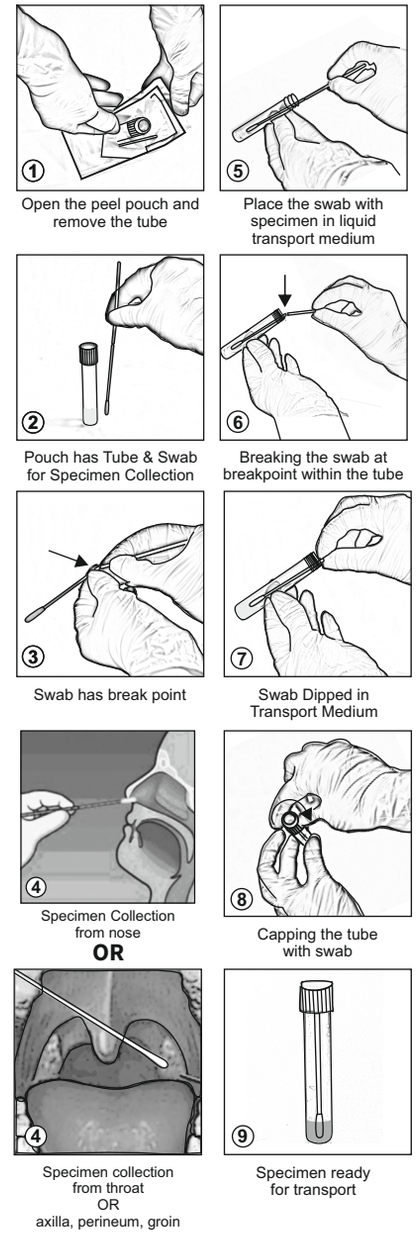
5. Remove the cap and insert the swab into the in to the tube.
6. Carefully break the swab by bending at the printed breakpoint line. Discard the broken handle part of the swab into biohazard labelled bag or follow appropriate precautions.

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.

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 MS2016A



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 (4,5).
- 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 tip 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 Soyabean Casein Digest Medium w/ 6.5% NaCL.

Limitations

- HiMedias Liquid SCDM w/6.5% NaCL Collection & Transport System isrecommended for MRSA screening from different sites .
- Extreme temperatures should be avoided during transportation of the collection system.
- The performance of the MS2016A for storage time over 48 h 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.