

HiCulture™ Transport Swab w/Middlebrook 7H9 Broth w/ MS198S metal stick

Intended Use:

Recommended for transportation of *Mycobacterium tuberculosis*.

Composition**

| Ingredients | Gms / Litre |
|--------------------------------|-------------|
| Ammonium sulphate | 0.500 |
| Disodium hydrogen phosphate | 2.500 |
| Potassium dihydrogen phosphate | 1.000 |
| Sodium citrate | 0.100 |
| Magnesium sulphate | 0.050 |
| Calcium chloride | 0.0005 |
| Zinc sulphate | 0.001 |
| Copper sulphate | 0.001 |
| Ferric ammonium citrate | 0.040 |
| L-Glutamic acid | 0.500 |
| Pyridoxine | 0.001 |
| Biotin | 0.0005 |
| Bovine albumin fraction V | 5.000 |
| Dextrose (Glucose) | 2.000 |
| Catalase | 0.030 |
| Glycerol | 2 ml |
| Final pH (at 25°C) | 6.6±0.2 |

**Formula adjusted, standardized to suit performance parameters

Directions

Using the capped swab provided along with the medium containing tube, collect the sample or specimen from surface. Discard the cap of the tube and insert the capped swab with the sample till the bottom of the medium. Tighten the cap firmly. The specimen will be preserved during transportation and also the viability of the organisms will be maintained but it will diminish over the time. Some growth of contaminants may occur during longer period of transport. After the transportation, the specimen should be inoculated in proper medium as soon as possible. The cultures on transport swabs must not be kept at room temperature for more than 24 hours.

Principle And Interpretation

Effective recovery of microorganisms and its identification is dependent on a number of factors such as collection and transportation to the laboratory under conditions which allow maintenance of viability. Middlebrook 7H9 Broth Base was formulated by Middlebrook (3) and Middlebrook et al and Schaeffer (3,4). Middlebrook media consists of many inorganic salts, which help, in growth of *Mycobacteria*. Citric acid formed from sodium citrate helps in retaining inorganic cations in solution. Glycerol supplies carbon and energy. Oleic acid and other long chain fatty acids are essential for metabolism of *Mycobacteria*. Middlebrook ADC Growth Supplement (FD019) contains bovine albumin, dextrose, catalase and sodium chloride. Some free fatty acids are toxic to *Mycobacteria* but albumin binds to those fatty acids and prevents toxic action on *Mycobacteria*. Dextrose(Glucose) serves as an energy source. Catalase neutralizes toxic peroxides. Proper collection and transportation of clinical specimens is vital for detection of tuberculosis bacilli. Sterile cotton swabs allow absorption of specimen material. Middlebrook medium serves as medium for maintaining viability of *Mycobacteria* during transport.

Type of specimen

Clinical samples

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (1,2). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

In Vitro diagnostic use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. Further recovery from this enriched medium onto selective media is required.
2. *Mycobacteria* are strict aerobes and therefore increased CO₂ tension and aerobic conditions must be provided during incubation.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Sterile Middlebrook 7H9 Broth Base medium in tubes with sterile cotton swab with metal stick.

Colour

Cream to beige coloured, clear to slight opalescent medium.

Quantity of Medium

8ml of medium in tubes

Sterility test

Passes release criteria

Reaction

6.40- 6.80

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.

| Organism | Recovery |
|--|-----------|
| <i>Mycobacterium fortuitum</i> ATCC 6841 | Luxuriant |
| <i>Mycobacterium smegmatis</i> ATCC 14468 | Luxuriant |
| <i>Mycobacterium tuberculosis</i> H37RV 25618 | Luxuriant |

Storage and Shelf Life

Store between 5-25°C. Use before expiry date on the label. Product performance is best if used within stated expiry period.

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 (1,2).

Reference

1. Isenberg, (Ed.), Clinical Microbiology Procedures Handbook 2nd Edition.
2. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
3. Middlebrook G. and Cohn M. L., 1958, Am. J. Public Health, 48:844.
4. Middlebrook G., Fitzsimmons Army Hospital, Denver, Co, Report 1, 1955

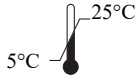
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In vitro diagnostic medical device



CE Marking



Storage temperature



Do not use if package is damaged



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