QUALITY CONTROL PROCEDURES (Optional)

I INTRODUCTION
Mycosel™ Agar is a selective medium for the isolation of pathogenic fungi from materials having a mixed flora of other fungi and bacteria.

II PERFORMANCE TEST PROCEDURE
1. Inoculate representative samples with the cultures listed below.
   a. Inoculate the containers with a 0.01 mL calibrated loop using fungal broth cultures (up to 7 days in age) of the fungi and 10⁻¹ dilutions of 18- to 24-h cultures of the Escherichia strain.
   b. Incubate containers with loosened caps at 25 ± 2 °C in an aerobic atmosphere.
   c. Include Sabouraud Dextrose Agar slants as nonselective controls for all fungal strains and Trypticase™ Soy Agar slants as growth controls for the Escherichia strains.
2. Examine containers for up to 7 days for growth and selectivity.
3. Expected Results

<table>
<thead>
<tr>
<th>CLSI Organisms</th>
<th>ATCC®</th>
<th>Recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Candida albicans</td>
<td>10231</td>
<td>Growth</td>
</tr>
<tr>
<td>*Trichophyton mentagrophytes</td>
<td>9533</td>
<td>Growth</td>
</tr>
<tr>
<td>*Escherichia coli</td>
<td>25922</td>
<td>Inhibition (partial to complete)</td>
</tr>
<tr>
<td>*Aspergillus brasiliensis</td>
<td>16404</td>
<td>Inhibition (partial to complete)</td>
</tr>
</tbody>
</table>

Additional Organism
Penicillium roquefortii 9295 Inhibition (partial)

*Recommended organism strain for User Quality Control.

III ADDITIONAL QUALITY CONTROL
1. Examine tubes, bottles, flasks or Mycoflask™ bottles as described under “Product Deterioration.”
2. Visually examine representative tubes, bottles, flasks or Mycoflask™ bottles to assure that any existing physical defects will not interfere with use.
3. Incubate uninoculated representative tubes, bottles, flasks or Mycoflask™ bottles at 20–25 °C and 30–35 °C and examine after 7 days for microbial contamination.

PRODUCT INFORMATION

IV INTENDED USE
Mycosel™ Agar is a highly selective medium containing cycloheximide and chloramphenicol. It is recommended for the isolation of pathogenic fungi from materials having a large amount of flora of other fungi and bacteria.¹,²

V SUMMARY AND EXPLANATION
Mycosel™ Agar was developed by using the ingredients of Mycofhill™ Agar as a nutritive base to which cycloheximide and chloramphenicol were added as selective agents. It is widely used for the isolation of fungi from a variety of sources, and is recommended for the recovery of dermatophytes.³

VI PRINCIPLES OF THE PROCEDURE
The nutritive properties of Mycosel™ Agar are supplied by the peptone prepared from soybean meal. Dextrose is an energy source for the metabolism of fungi. Cycloheximide inhibits most saprophytic molds. Chloramphenicol is a broad-spectrum antibiotic which inhibits a wide range of gram-positive and gram-negative bacteria.

VII REAGENTS
Mycosel™ Agar

<table>
<thead>
<tr>
<th>Approximate Formula* Per Liter Purified Water</th>
</tr>
</thead>
<tbody>
<tr>
<td>Papaic Digest of Soybean Meal.................................10.0 g</td>
</tr>
<tr>
<td>Dextrose................................................................10.0 g</td>
</tr>
<tr>
<td>Agar ......................................................................15.5 g</td>
</tr>
<tr>
<td>Cycloheximide ......................................................0.4 g</td>
</tr>
<tr>
<td>Chloramphenicol ....................................................0.05 g</td>
</tr>
</tbody>
</table>

*Adjusted and/or supplemented as required to meet performance criteria.

Warnings and Precautions: For in vitro Diagnostic Use.
Tubes, bottles and flasks with tight caps should be opened carefully to avoid injury due to breakage of glass.

Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. “Standard Precautions”⁴-⁷ and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids. After use, prepared media, specimen containers and other contaminated materials must be sterilized by autoclaving before discarding.

Storage Instructions: On receipt, store tubes, bottles and flasks in the dark at 2–8 °C. Avoid freezing and overheating. Do not open until ready to use. Minimize exposure to light. Media stored as labeled until just prior to use may be inoculated up to the expiration date and incubated for the recommended incubation times. Allow the medium to warm to room temperature before inoculation.
Product Deterioration: Do not use media if they show evidence of microbial contamination, discoloration, drying or other signs of deterioration.

VIII SPECIMEN COLLECTION AND HANDLING
Specimens suitable for culture may be handled using various techniques. For detailed information, consult appropriate texts. Specimens should be obtained before antimicrobial agents have been administered. Provisions must be made for prompt delivery to the laboratory.

IX PROCEDURE
Material Provided: Mycosel Agar
Materials Required But Not Provided: Ancillary culture media, reagents, quality control organisms and laboratory equipment as required.
Test Procedure: Observe aseptic techniques.
Streak the specimen as soon as possible after it is received in the laboratory. Streak the specimen onto the medium with a sterile inoculating loop to obtain isolated colonies. Consult appropriate references for information about the processing and inoculation of specimens.
For isolation of fungi from potentially contaminated specimens, a nonselective medium should be inoculated along with the selective medium. Incubate the containers at 25–30 °C with increased humidity.
For isolation of fungi causing systemic mycoses, two sets of media should be inoculated, with one set incubated at 25–30 °C and a duplicate set at 35 ± 2 °C. All cultures should be examined at least weekly for fungal growth and should be held for 4–6 weeks before being reported as negative.
User Quality Control: See “Quality Control Procedures.”
Each lot of media has been tested using appropriate quality control organisms and this testing meets product specifications and CLSI standards, where relevant. As always, QC testing should be performed in accordance with applicable local, state, federal or country regulations, accreditation requirements, and/or your laboratory’s standard quality control procedures.

X RESULTS
After sufficient incubation, the medium should show isolated colonies in streaked areas and confluent growth in areas of heavy inoculation. Examine containers for fungal colonies exhibiting typical color and morphology. Biochemical tests and serological procedures should be performed to confirm findings.

XI LIMITATIONS OF THE PROCEDURE
Some fungi may be inhibited by the antibiotics in this medium.
For identification, organisms must be in pure culture. Morphological, biochemical, and/or serological tests should be performed for final identification. Consult appropriate texts for detailed information and recommended procedures.

XII PERFORMANCE CHARACTERISTICS
Prior to release, all lots of Mycosel Agar slants, flasks and bottles are tested for performance characteristics. Using a 0.01 mL calibrated loop, representative samples of the lot are streak-inoculated with fungal broth cultures of Candida albicans (ATCC 10231), Penicillium roquefortii (ATCC 9295), Trichophyton mentagrophytes (ATCC 9533), a spore suspension of Aspergillus brasiliensis (ATCC 16404) diluted to a final concentration of 50–300 colony-forming units (CFU) per loopful and a Trypticase Soy Broth culture diluted 10⁻¹ of Escherichia coli (ATCC 25922). After inoculation, the containers are incubated at 25 ± 2 °C and read for growth and colony pigmentation after 2, 5 and 7 days incubation. C. albicans demonstrates fair to heavy growth with white to cream colonies. T. mentagrophytes demonstrates fair to heavy growth with white colonies. Growth of P. roquefortii, A. brasiliensis and E. coli is either light or completely inhibited.

XIII AVAILABILITY

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>220966</td>
<td>BD BBL™ Mycosel™ Agar Slants, Pkg. of 10 size A tubes</td>
</tr>
<tr>
<td>220967</td>
<td>BD BBL™ Mycosel™ Agar Slants, Ctn. of 100 size A tubes</td>
</tr>
<tr>
<td>221130</td>
<td>BD BBL™ Mycosel™ Agar, Mycoflask™ Bottles, Pkg. of 10</td>
</tr>
</tbody>
</table>
XIV REFERENCES


Technical Information: In the United States contact BD Technical Service and Support at 800-638-8663 or www.bd.com/ds.