QUALITY CONTROL PROCEDURES

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

CLSI Organisms	ATCC™	Recovery
******Candida albicans*	10231	Growth
******Trichophyton mentagrophytes*	9533	Growth
******Escherichia coli*	25922	Inhibition (partial to complete)
******Aspergillus niger*	16404	Inhibition (partial to complete)
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 **Mycophil™** 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

Approximate Formula* Per Liter Purified Water

Papaic Digest of Soybean Meal	10.0 g
Dextrose	10.0 g
Agar	15.5 g
Cycloheximide	0.4 g
Chloramphenicol	0.05 g

*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.[1-3] 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.[1-3]

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."

Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to pertinent CLSI (formerly NCCLS) guidance and CLIA regulations for appropriate Quality Control practices.

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.[8] 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.[9]

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.[1-3,8,9]

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 niger* (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. niger* and *E. coli* is either light or completely inhibited.

XIII AVAILABILITY

Cat. No.	Description
220966	**BBL™ Mycosel™** Agar Slants, Pkg. of 10 size A tubes
220967	**BBL™ Mycosel™** Agar Slants, Ctn. of 100 size A tubes
297456	**BBL™ Mycosel™** Agar Slants, Ctn. of 100 size C tubes
296233	**BBL™ Mycosel™** Agar, 1 oz. Bottles, Pkg. of 10
295698	**BBL™ Mycosel™** Agar, 1 oz. Bottles, Ctn. of 100
221130	**BBL™ Mycosel™** Agar, **Mycoflask™** Bottles, Pkg. of 10
221131	**BBL™ Mycosel™** Agar, **Mycoflask™** Bottles, Ctn. of 100
297411	**BBL™ Mycosel™** Agar, Plastic Flasks, Pkg. of 10
297718	**BBL™ Mycosel™** Agar, Transgrow-style Bottles, Ctn. of 100

XIV REFERENCES

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2. Kwon-Chung, K.J., and J.E. Bennett. 1992. Medical mycology. Lea & Febiger, Philadelphia.
3. Forbes, B.A., D.F. Sahm, and A.S. Weissfeld. 2002. Bailey & Scott's diagnostic microbiology, 11th ed. Mosby, Inc., St. Louis.
4. National Committee for Clinical Laboratory Standards. 2001. Approved Guideline M29-A2. Protection of laboratory workers from occupationally acquired infections, 2nd ed. NCCLS, Wayne, Pa.
5. Garner, J.S. 1996. Hospital Infection Control Practices Advisory Committee, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Guideline for isolation precautions in hospitals. Infect. Control Hospital Epidemiol. *17*:53-80.
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7. Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC). Official Journal L262, 17/10/2000, p. 0021-0045.
8. Ajello, L., L.K. Georg, W. Kaplan, and L. Kaufman. 1963. CDC laboratory manual for medical mycology. PHS Publication No. 994, U.S. Government Printing Office, Washington, D.C.
9. Larone. 1995. Medically important fungi: a guide to identification, 3rd ed. American Society for Microbiology, Washington, D.C.

Becton, Dickinson and Company
7 Loveton Circle
Sparks, Maryland 21152 USA
800-638-8663

EC REP BENEX Limited
Bay K 1a/d, Shannon Industrial Estate
Shannon, County Clare, Ireland
Tel: 353-61-47-29-20
Fax: 353-61-47-25-46