PRODUCT INFORMATION AND QUALITY CONTROL SHEET
MYCOBIOTIC AGAR PLATE

I. INTENDED USE
Mycobiotic Agar is a selective and differential medium for use in the isolation of pathogenic fungi.

II. 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.

III. PRINCIPLES OF THE PROCEDURE
The nutritive properties of Mycosel Agar are supplied by the peptone prepared from soybean meat. 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.

IV. TYPICAL FORMULA AND APPEARANCE
(Approximate formula* per liter of processed water)

MYCOSEL AGAR
Appearance = light to medium amber, slightly opalescent

Papaic Digest of Soy bean meal	10.0g
Dextrose	10.0
Agar	15.5
Cycloheximide	0.4
Chloramphenicol	0.05

*adjusted and/or supplemented to meet performance criteria.

V. PRECAUTIONS
This product is for IN VITRO diagnostic use only. Culture specimens may contain microorganisms which can be potentially infectious to the user. Strict adherence to aseptic techniques and established precautions against microbiological hazards should be followed throughout the procedure. Carefully dispose of all items which contact patient specimens or isolated bacteria. (See Material Safety Data Sheet for further information.)

VI. STORAGE/SHELF LIFE
Plated media should be stored at 2-8^{0}C (36-46^{0}F), media side up, in the unopened or resealed package protected from light. DO NOT FREEZE OR EXPOSE TO HIGH TEMPERATURES. Allow unopened plates to warm to room temperature prior to inoculation. Prior to and during inoculation procedures, plates should be handled in a manner that minimizes product exposure to the environment. Product which has exceeded the assigned expiration date noted on the label should not be used.

Do not use plates that exhibit evidence of drying, cracking, discoloration, microbial contamination or any other signs of deterioration. The presence of excessive condensate may indicate plates which have been damaged by exposure to temperature extremes.

VII. SPECIMEN COLLECTION
The quality of culture results depends primarily on the adequacy and condition of the specimen submitted for examination. Proper specimen collection techniques must be followed to ensure the most accurate culture results. Consult appropriate references for information about the processing and inoculation of specimens for fungal culture.[1,2,3] Sterile swabs and collection containers should be used. Plates should be inoculated promptly after specimen collection. Specimens should be collected prior to the initiation of antifungal therapy.

VIII. MATERIALS PROVIDED
Mycosel Agar Plates and lot specific Quality Control Certificate.

IX. MATERIALS REQUIRED BUT NOT PROVIDED
Incubator maintaining 33-37^{0}C and/or 25±2^{0}C.
Ancillary culture media, reagents and laboratory equipment as required.

X. PROCEDURE
Inoculate the specimen as soon as possible after it is received in the laboratory. Streak the specimen with a sterile inoculating loop to obtain isolated colonies. Reference texts should be consulted for detailed information on processing and inoculating specimens for fungal culture.[1,2,3] When isolating fungus from specimens containing contaminating microbial flora, a selective fungal isolation medium in addition to Sabouraud Dextrose Agar should be inoculated.

Incubate the inoculated plates at 25±2^{0}C , agar side up, in an atmosphere containing increased humidity. For isolation of fungus associated with systemic mycoses, two sets of culture plates should be inoculated. Incubate one set of plates at 25-30^{0}C and the duplicate set at 33-37^{0}C.

Examine cultures at least weekly for fungal growth. Plates should be held for 4-6 weeks before being reported as negative for growth.

XI. EXPECTED RESULTS

NCCLS Control Organisms (ATCC Strains)

MYCOSEL AGAR

Candida albicans (ATCC 10231)	Growth
Tricophyton mentagrophytes (ATCC 9533)	Growth
Escherichia coli (ATCC 25922)	Inhibition (partial to complete)
Aspergillus niger (ATCC 16404)	Inhibition (partial to complete)

XII. LABORATORY RESULTS
This medium is intended to be used as a primary isolation medium. Identification of fungal organisms may be made on the basis of typical gross colony morphology, microscopic characteristics, and physiologic and pathologic characteristics. Additional test procedures should be used to confirm findings.

XIII. LIMITATIONS
The ability to detect microorganisms by culture techniques can be affected by the following factors: improper specimen collection, storage and inoculation , initiation of antiinfective therapy prior to specimen collection, improper culture incubation temperatures and atmospheres, improper length of culture incubation, and improper storage and handling of culture media.

Some fungi may be inhibited by the antibiotics contained in Mycosel Agar. Cultures for fungi other than *Candida albicans* need to be inoculated onto a non selective fungal medium such as Sabaroud Dextrose (BCS Cat. No. 1137). Dual incubation temperatures may be required. Cultures for dermatophytes and agents of superficial mycoses should be inoculated onto Dermatophyte Test Medium (DTM - BCS Cat. No. 1034) and incubated according to the product information sheet. Appropriate reference materials should be consulted for appropriate processing and inoculation of specific specimens.[1]

XIV. REFERENCES

1. 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.
2. McGinnis, M.R. 1980. Laboratory Handbook of Medical Mycology. Academic Press Inc., N.Y., N.Y.
3. Lennette, E.H., ed. 1985. Manual of Clinical Microbiology, 4th ed. American Society for Microbiology, Washington, D.C.

USER QUALITY ASSURANCE/ QUALITY CONTROL PROCEDURES AND INFORMATION

HealthLInk recommends that the following quality assurance and quality control procedures be performed on each batch of product.

I. QUALITY ASSURANCE

The following quality assurance procedures must be performed to assure the product will perform according to its intended use within the assigned expiry date:

1. Daily, document that product storage refrigerator maintains temperature within the recommended range: 2-8^{0}C.
2. Daily, document that laboratory incubator maintains temperature within the recommended range: 22-35^{0}C.

II. QUALITY CONTROL

The following incoming inspection procedures must be performed for each batch (batch = same lot, same shipment) of culture media received in the laboratory :

1. Inspect plates according to instructions contained on the "Quality Control Log Sheet." (See also Section VI "STORAGE/SHELF LIFE")
2. Peel off the lower portion of a product bag label (Quality Control Certificate) for the lot being accepted into the laboratory and affix it to the Quality Control Log Sheet.
3. Initial and date the Quality Control Log Sheet.

Note: Notify Technical Service immediately if media does not meet the inspection criteria.

TECHNICAL SERVICE

HealthLink provides a toll free technical service line (1-800-638-2625) to assist with product usage. To receive additional product information, procedural instructions, QA/QC log sheets, Material Safety Data Sheets, or to have technical questions answered; please call between the hours of 9:00 am to 5:00 pm EST.

HealthLink
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