PRODUCT INFORMATION AND QUALITY CONTROL SHEET
DERMATOPHYTE TEST MEDIUM

I. INTENDED USE
Dermatophyte Test Medium is a selective medium used for the isolation of pathogenic fungi from cutaneous specimens.

II. SUMMARY AND EXPLANATION
Dermatomycoses are common clinical fungal infections. The dermatophytes are mycelial fungi which possess keratolytic properties that allow them to invade skin, nails and hair.[1,2] Dermatophyte Test Medium incorporates antibiotics that suppress the growth of saprophytic fungi and contaminating bacteria while allowing the growth of dermatophytic fungi.

Dermatophytes are presumptively identified by gross colonial morphology and the production of alkaline metabolites which cause a color change in the medium from yellow to red.

III. PRINCIPLES OF THE PROCEDURE
Dermatophyte Test Medium contains papaic digest of soybean meal as an amino acid source and other nitrogenous substances necessary for fungal growth. Dextrose provides an energy source and phenol red, a colorimetric indicator, is used to visualize the pH shift in the medium.

IV. TYPICAL FORMULA AND APPEARANCE
Appearance = orange/yellow, slightly opalescent
(Approximate formula* per liter of processed water)

Papaic Digest of Soybean Meal	10.0g
Dextrose	10.0
Phenol Red	0.2
Cycloheximide	0.4
Chloramphenicol	0.05
Agar	15.5
Tartaric Acid	0.55

*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.

VI. STORAGE/SHELF LIFE
Culture media should be stored at 2-25^{0}C (36-77^{0}F), in the unopened vials protected from light. DO NOT FREEZE OR EXPOSE TO HIGH TEMPERATURES. Allow vials to warm to room temperature prior to inoculation. Prior to and during inoculation procedures, vials should be handled in a manner that minimizes product exposure to the environment. Product that has exceeded the assigned expiration date noted on the label should not be used.

Do not use vials that exhibit evidence of drying, cracking, discoloration, microbial contamination or any other signs of deterioration. The presence of excessive condensate may indicate vials 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.[2,3,4] Specimens should be collected prior to the initiation of antifungal therapy.

VIII. MATERIALS PROVIDED
Dermatophyte Test Medium vials

IX. MATERIALS REQUIRED BUT NOT PROVIDED
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. Place the specimen onto the center of the agar with sterile forceps. Press carefully to ensure firm contact with the agar surface. Replace the cap but do not tighten completely. Incubate the inoculated media at 22 - 30^{0}C for up to 14 days. (Do not incubate cultures at 35-37^{0}C.) Examine the culture daily for a change in the color of the medium and evidence of fungal growth.

XI. EXPECTED RESULTS
NCCLS CONTROL ORGANISMS (ATCC STRAINS)
Expected cultural response on Dermatophyte Test Medium at 30^{0}C after 2-7 days.

Trichophyton mentagrophytes (ATCC 9533)	White cotton-like growth, pink to red medium
Aspergillus niger (ATCC 16404)	Inhibition, partial to complete
*Candida albicans** (ATCC 10231)	White/off-white growth.
Escherichia coli (ATCC 25922)	Inhibition, partial to complete

*Certain strains of *C. albicans* are capable of converting the indicator to red, but yeasts can be recognized by their white bacteria-like appearance

XII. LABORATORY RESULTS
This medium is intended to be used as a primary isolation medium. Dermatophytes produce typical morphology and a pink to red color in the medium surrounding the colony within 10 - 14 days of incubation. Occasionally, a bacterial contaminant may produce a color change in the medium within this period but can be distinguished by colonial morphology. Disregard any color changes in the medium after 14 days of incubation. This may be caused by contaminating fungi.

Identification of dermatophytes requires a pure culture. Morphological, biochemical and/or serological tests should be performed. References should be consulted for additional information.[1,2,3,4]

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.

A single selective medium is rarely adequate for detecting all organisms of clinical importance in a specimen. Selective agents may inhibit some strains of a desired species. It is recommended that a non-selective media also be inoculated to obtain additional culture information.

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. Haley, L.D., J. Trandel, and M.B. Coyle. 1980. Cumitech 11, Practical methods for culture and identification of fungi in the clinical mycology laboratory. Coordinating ed., J. C. Sherris. American Society for Microbiology, Washington, D.C.
3. McGinnis, M.R. 1980. Laboratory Handbook of Medical Mycology. Academic Press Inc., N.Y., N.Y.
4. 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 area maintains temperature within the recommended range: 2-25^{0}C.
2. Daily, document that laboratory incubator maintains temperature within the recommended range: 22-30^{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 in Section VI "STORAGE/SHELF LIFE"
2. Write in the lot number and expiration date of the product being accepted into the laboratory on a log sheet.
3. Initial and date the 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 have technical questions answered; please call between the hours of 9:00 am to 5:00 pm EST.

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