

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

Plated media should be stored at 2-8°C (36-46°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.^{2,3,4} Specimens should be collected prior to the initiation of antifungal therapy.

VIII. MATERIALS PROVIDED

Dermatophyte Test Medium Plates – 10 each / sleeve

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. Incubate the inoculated plate at 22 - 25°C for up to 14 days. (Do not incubate cultures at 33-37°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°C after 2-7 days.

<i>Trichophyton mentagrophytes</i> (ATCC 9533)	White, cotton-like growth, pink to red medium
<i>Aspergillus niger</i> (ATCC 16404)	Inhibition, partial to complete
<i>Candida albicans</i> * (ATCC 10231)	White/off-white growth
<i>Escherichia coli</i> (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 anti-infective 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 should 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:

Daily, document that product storage refrigerator maintains temperature within the recommended range: 2-8^oC.

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:

Inspect plates according to instructions contained in the Section VI "STORAGE/SHELF LIFE"

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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