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HARDY DIAGNOSTICS
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Instructions for Use

DERMATOPHYTE TEST MEDIUM (DTM)

Cat. no. J107	Sabouraud Dextrose (SabDex) Agar with Chloramphenicol and Gentamicin / DTM, 15x100mm Biplate, 15ml/15ml	10 plates/bag
Cat. no. L27	Dermatophyte Test Medium, 10ml Vial, 7.5ml Slant	20 vials/box
Cat. no. X15	Dermatophyte Test Medium, 50ml Hardy Flask™, 12ml	20 flasks/box

INTENDED USE

Hardy Diagnostics Dermatophyte Test Medium (DTM) is a selective and differential medium recommended for the cultivation and isolation of pathogenic dermatophytic fungi.

SUMMARY

Dermatophyte Test Medium is a modification of a commercial formulation made by Taplin in 1969.[6-8] Nitrogenous and carbonaceous compounds essential for microbial growth are provided by soy peptone. Dextrose serves as the energy source for metabolism. Chloramphenicol acts as a broad spectrum antimicrobic which inhibits a wide range of gram-positive and gram-negative bacteria. Cycloheximide is added to inhibit saprophytic fungi. Phenol red, the pH indicator, is affected by the presence of dermatophytes (*Epidermophyton*, *Microsporum*, and *Trichophyton* spp.), which all produce alkaline metabolites. Production of alkali results in the medium changing from yellow-orange to red in color.

Other organisms that may grow on the medium can be recognized as non-dermatophytes by their color and colony morphology. Bacteria and certain yeast can grow on this medium showing characteristic white or creamy bacteria like colonies. Contaminating saprophytes can turn Dermatophyte Test Medium from its yellow-orange color to red, but can be ruled out due to the green to black hyphae produced. Dermatophytes typically produce white aerial hyphae.

FORMULA

Ingredients per liter of deionized water:*

Papaic Digest of Soybean Meal	10.0gm
Dextrose	10.0gm
Cycloheximide	0.5gm
Phenol Red	0.2gm
Chloramphenicol	0.05gm
Agar	20.0gm

Final pH 5.6 +/- 0.2 at 25ºC.

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

STORAGE AND SHELF LIFE

Storage: Upon receipt store Cat. no. J107 and X15 at 2-8ºC. and Cat. no. L27 at 2-30ºC. away from direct light. Media should not be used if there are any signs of deterioration (shrinking, cracking, or discoloration), contamination, or if the expiration date has passed. Product is light and temperature sensitive; protect from light, excessive heat, moisture, and freezing.

The expiration date on the product label applies to the product in its intact packaging when stored as directed. The product may be used and tested up to the expiration date on the product label and incubated for the recommended incubation times as stated below.

Refer to the document "Storage" for more information.

PRECAUTIONS

This product may contain components of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not guarantee the absence of transmissible pathogenic agents. Therefore, it is recommended that these products be treated as potentially infectious, and handle observing the usual Universal Precautions for blood. Do not ingest, inhale, or allow to come into contact with skin.

This product is for *in vitro* diagnostic use only. It is to be used only by adequately trained and qualified laboratory personnel. Observe approved biohazard precautions and aseptic techniques. All laboratory specimens should be considered infectious and handled according to "standard precautions." Refer to the document "Guidelines for Isolation Precautions" from the Centers for Disease Control and Prevention.

For additional information regarding specific precautions for the prevention of the transmission of all infectious agents from laboratory instruments and materials, and for recommendations for the management of exposure to infectious disease, refer to CLSI document M29: *Protection of Laboratory Workers from Occupationally Acquired Infections.*

Sterilize all biohazard waste before disposal.

Refer to the document "Precautions When Using Media" for more information.

PROCEDURE

Specimen Collection: Infectious material should be submitted directly to the laboratory without delay and protected from excessive heat and cold. If there is to be a delay in processing, the specimen should be inoculated onto an appropriate transport medium and refrigerated until inoculation. Consult listed references for information on specimen collection.[1-5]

Method of Use: The medium should be brought to room temperature, and the agar surface should be dry prior to inoculation. Once received by the lab, the specimen should be inoculated directly onto the medium by pressing the specimen lightly into the surface of the agar. Alternatively, a small amount of fungus may be placed on the agar surface if subculturing from another culture medium. A control medium, Sabouraud Dextrose Agar (Cat. no. L40), may be inoculated in parallel.[9] Incubate media at room temperature (15-30ºC.), aerobically, for up to fourteen days. Examine media daily and observe for development of a red color change in the medium. Most pathogenic dermatophytes will produce a color change in three to six days.

INTERPRETATION OF RESULTS

Media should be examined daily for up to fourteen (14) days.

Positive: Appearance of white aerial hyphae and red color around the fungal growth is positive for the presence of dermatophytic fungi.

Negative: Growth, without a color change to red, indicates that the organism is probably not a dermatophyte. Further biochemical and/or serological testing is recommended for complete identification.

If growth appears on the control medium (Sabouraud Dextrose Agar) and no growth appears on DTM, the organism is not a dermatophyte. Colonies with green or black hyphae is not typical of dermatophytes even though the media may turn red.

LIMITATIONS

It is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on colonies from pure culture for complete identification of bacteria and/or fungi.

This medium is more useful as a general screening test, as opposed to an identification medium.

False-positive reactions may result, if interpretations are made beyond 14 days of incubation. An alkaline reaction will eventually be produced by most non-dermatophytic fungi that are capable of growing on this medium.

If the dormant area of an infection is cultured, false-negative reactions may arise.

The caps of inoculated media must be kept loose to assure optimal recovery of dermatophytes.

A color change in the medium may be produced by certain strains of yeast. A characteristic white, creamy, bacteria-like colony will be produced by these organisms and thus allow differentiation from dermatophytic fungi.

If the specimen is heavily contaminated, saprophytic fungi may result in a color change on the medium.[9] Some of these organisms may be recognized by their dark green to black hyphae; white aerial hyphae is exhibited by dermatophytes.

Refer to the document "Limitations of Procedures and Warranty" for more information.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as loops, other culture media, swabs, applicator sticks, incinerators, and incubators, etc., as well as serological and biochemical reagents, are not provided.

QUALITY CONTROL

Hardy Diagnostics tests each lot of commercially manufactured media using appropriate quality control microorganisms and quality specifications as outlined on the Certificate of Analysis (CofA) and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media*. The following microorganisms are routinely used for testing at Hardy Diagnostics:

Test Organisms	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	
Trichophyton mentagrophytes ATCC® 9533	G	4-7 days	15-30°C	Aerobic	Growth; white colonies and a red color change develops in the medium surrounding the colonies
Candida albicans ATCC® 10231	A	24hr	15-30°C	Aerobic	Growth; small white colonies and no color change in the medium

Escherichia coli ATCC® 25922	B	24hr	35°C	Aerobic	Inhibited
Aspergillus brasiliensis ATCC® 16404	G	up to 7 days	15-30°C	Aerobic	Inhibited
Staphylococcus aureus ATCC® 25923	B	24hr	35°C	Aerobic	Inhibited
Pseudomonas aeruginosa ATCC® 27853	B	24hr	35°C	Aerobic	Inhibited

* Refer to the document "Inoculation Procedures for Media QC" for more information.

USER QUALITY CONTROL

End users of commercially prepared culture media should perform QC testing in accordance with applicable government regulatory agencies, and in compliance with accreditation requirements. Hardy Diagnostics recommends end users check for signs of contamination and deterioration and, if dictated by laboratory quality control procedures or regulation, perform quality control testing to demonstrate growth or a positive reaction and to demonstrate inhibition or a negative reaction, if applicable. Hardy Diagnostics quality control testing is documented on the certificate of analysis (CofA) available from Hardy Diagnostics Certificate of Analysis website. Also refer to the document "Finished Product Quality Control Procedures," and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media* for more information on the appropriate QC procedures. See the references below.

PHYSICAL APPEARANCE

Dermatophyte Test Medium (DTM) should appear clear to slightly opaque, and yellow-orange in color.

REFERENCES

1. Anderson, N.L., et al. *Cumitech 3B; Quality Systems in the Clinical Microbiology Laboratory*, Coordinating ed., A.S. Weissfeld. American Society for Microbiology, Washington, D.C.

2. Jorgensen., et al. *Manual of Clinical Microbiology*, American Society for Microbiology, Washington, D.C.

3. Tille, P., et al. *Bailey and Scott's Diagnostic Microbiology*, C.V. Mosby Company, St. Louis, MO.

4. Isenberg, H.D. *Clinical Microbiology Procedures Handbook*, Vol. I, II & III. American Society for Microbiology, Washington, D.C.

5. Koneman, E.W., et al. *Color Atlas and Textbook of Diagnostic Microbiology*, J.B. Lippincott Company, Philadelphia, PA.

6. Rebell, E., and Taplin. 1970. *Dermatophytes*, 2nd ed. University of Miami Press, Miami.

7. Taplin, D. 1965. *J. Invest. Der.*; 45:545.

8. Taplin, D., et al. 1969. *Arch. Derm.*; 99:203.

9. Campbell, M.C., and J.L. Stewart. 1980. *The Medical Mycology Handbook*, John Wiley & Sons, New York.

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The Hardy Diagnostics manufacturing facility and quality management system is certified to ISO 13485.

HDQA 2207F [D]