IFU

Instructions for Use

CRITERION™ DERMATOPHYTE TEST MEDIUM (DTM)

Cat. no. C5570	CRITERION™ Dermatophyte Test Medium	83.6gm
Cat. no. C5571	CRITERION™ Dermatophyte Test Medium	500gm
Cat. no. C5572	CRITERION™ Dermatophyte Test Medium	2kg
Cat. no. C5573	CRITERION™ Dermatophyte Test Medium	10kg

INTENDED USE

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

This dehydrated culture medium is a raw material intended to be used in the making of prepared media products, which will require further processing, additional ingredients, or supplements.

SUMMARY

CRITERION™ 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. Gentamicin and Chlortetracycline act as a broad spectrum antimicrobics that inhibit 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*

Gram weight per liter:	41.8gm/L
Soy Peptone	10.0gm
Dextrose	10.0gm
Cycloheximide	0.5gm
Phenol Red	0.2gm
Gentamicin	0.1gm

Chlortetracycline	0.1gm
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

Store the sealed bottle(s) containing dehydrated culture medium at 2-30ºC. Dehydrated culture medium is very hygroscopic. Keep lid tightly sealed. Protect dehydrated culture media from moisture and light. The dehydrated culture media should be discarded if it is not free-flowing or if the color has changed from its original beige.

Store the prepared culture media at 2-8ºC.

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 blood precautions. Do not ingest, inhale, or allow to come into contact with skin.

This product is for laboratory 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.

METHOD OF PREPARATION FOR DEHYDRATED CULTURE MEDIA

1. Suspend 41.8gm of the dehydrated culture media in 1 liter of distilled or deionized water. Stir to mix thoroughly.

2. Heat to boiling to dissolve completely.

3. Sterilize in the autoclave at 121ºC. for 15 minutes.

4. Cool to 45-50ºC.

PROCEDURE AND INTERPRETATION OF RESULTS

For information on procedures and interpretation of results, consult listed references or refer to the prepared media Instructions for Use (IFU) for Cat. No. X15.

LIMITATIONS

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

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

Some formulations may require a settling period before pH testing of the prepared medium. If the pH is tested immediately after preparation and is out of specification, retest the medium after 24 hours to obtain final pH results. Always take pH reading at room temperature.

False-positive reactions may result, if interpretations are made beyond 14 days of incubation. An alkaline reaction will eventually be produced by most non-dermatophyte 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 autoclaves, incinerators, and incubators, etc., 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 interdigitale ATCC® 9533**	G	4-7 days	15-30°C	Aerobic	Growth; white colony with red color change in media on reverse
Candida albicans ATCC® 10231	A	24hr	15-30°C	Aerobic	Growth; small white colonies
Aspergillus brasiliensis ATCC® 16404**	G	7 days	15-30°C	Aerobic	Partial to complete inhibition; no color change
Escherichia coli ATCC® 25922	B	24hr	35°C	Aerobic	Partial to complete inhibition
Staphylococcus aureus ATCC® 25923	B	24hr	35°C	Aerobic	Partial to complete inhibition

Pseudomonas aeruginosa ATCC® 27853	B	24hr	35°C	Aerobic	Partial to complete inhibition

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

** Recommended QC strains for User Quality Control according to the CLSI document M22 when applicable.

USER QUALITY CONTROL

Users of dehydrated 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. In addition, refer to the following document "Finished Product Quality Control Procedures," for more information on QC or see the reference(s) for more specific information.

PHYSICAL APPEARANCE

CRITERION™ Dermatophyte Test Medium powder should appear homogeneous, free-flowing, and beige in color. The prepared media should appear 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 2207B [D]