IFU

HARDY DIAGNOSTICS
A Culture of Service™

Instructions for Use

CRITERION™ MYCOBIOTIC AGAR

Cat. no. C6430	CRITERION™ Mycobiotic Agar	65.2gm
Cat. no. C6431	CRITERION™ Mycobiotic Agar	500gm
Cat. no. C6432	CRITERION™ Mycobiotic Agar	2kg
Cat. no. C6433	CRITERION™ Mycobiotic Agar	10kg
Cat. no. C6434	CRITERION™ Mycobiotic Agar	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ Mycobiotic Agar is recommended for use in the selective isolation and recovery of pathogenic fungi and dermatophytes.

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

Leach, Ford and Whiffen described the use of cycloheximide for the inhibition of saprophytic fungi.[1,2] Cooke et al., employed the use of chloramphenicol to various media to inhibit bacterial growth.[3,4] Researchers later found that the addition of both cycloheximide and chloramphenicol achieved more complete selectivity against the growth of saprophytic fungi and bacteria.[5,6] Therefore, the incorporation of both of these antimicrobics into the soybean basal medium of Mycobiotic Agar promotes its selectivity. Consequently, Georg recommends the exclusive use of Mycobiotic Agar for isolating dermatophytes, which are not sensitive to cycloheximide or chloramphenicol, and in parallel to media without antibiotics for isolating fungi which may cause systemic disease.[7]

CRITERION™ Mycobiotic Agar is a selective medium consisting of peptones, dextrose, cycloheximide and chloramphenicol. The basal medium is soybean meal. Peptones from soybean meal provide the nutritive properties necessary for growth. Dextrose serves as the energy source. Cycloheximide inhibits most saprophytic fungi while chloramphenicol acts as a broad-spectrum antimicrobic. Chloramphenicol inhibits a wide variety of gram-positive and gram-negative bacteria

FORMULA*

Gram weight per liter:	35.6gm/L
Pancreatic Digest of Soybean Meal	10.0gm
Dextrose	10.0gm
Cycloheximide	0.5gm

Chloramphenicol	0.05gm
Agar	15.0gm

Final pH 6.5 +/- 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 tan to light 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 32.6gm 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. and aseptically dispense into sterile containers. Product may be autoclaved in tubes if desired.

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. W50.

LIMITATIONS

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.

The antimicrobics in this medium may result in the inhibition of some pathogenic fungi that cause systemic disease. It is recommended that a non-selective media be set-up in parallel for optimum recovery.

It is recommended that media containing cycloheximide be incubated at room temperature (25-30ºC.) for best results.

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	7 days	15-30°C	Aerobic	Growth
Candida albicans ATCC® 10231	A	7 days	15-30°C	Aerobic	Growth
Escherichia coli ATCC® 25922	B	7 days	15-30°C	Aerobic	Partial to complete inhibition
Aspergillus brasiliensis formerly *A. niger* ATCC® 16404	G	7 days	15-30°C	Aerobic	Partial to complete inhibition

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

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™ Mycobiotic Agar powder should appear homogeneous, free-flowing, and tan to light beige in color. The prepared media should appear slightly opalescent, and light amber in color.

REFERENCES

1. *J. Am. Chem. Soc*.; 69:474, 1947.

2. *J. Bacteriology*; 56:283, 1948.

3. *Antibiotics and Chemotherapy*; 4:657, 1954.

4. *J. Am. Med. Assoc*.; 160:537, 1956.

5. *J. Chron. Dis*.; 5:545, 1957.

6. *J. Lab. and Clin. Med.*; 55:116, 1960.

7. Georg, L.K., E.S. McDonough, L. Ajello, and S. Brinkman. 1960. In vitro effects of antibiotics on yeast phase of *Blastomyces dermatitidis* and other fungi. *J. Lab. & Clin. Med.*; 55:116-19.

8. Kwon-Chung, K.J., and J.E. Bennett. 1992. *Medical Mycology*. Lea and Febiger, Malvern, PA.

9. Larone, D.H. *Medically Important Fungi: A Guide to Identification,* American Society for Microbiology. Washington, D.C.

10. St. Germain, Guy, et al. 1996. *Identifying Filamentous Fungi*. Star Publishing Company, Belmont, CA.

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

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

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

14. *Quality Assurance for Commercially Prepared Microbiological Culture Media*, M22. Clinical and Laboratory Standards Institute (CLSI - formerly NCCLS), Wayne, PA.

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

HDQA 2207B [D]