IFU

HARDY DIAGNOSTICS
A Culture of Service™

Instructions for Use

MYCOBIOTIC AGAR

Cat. no. W50	Mycobiotic Agar, 15x100mm Plate, 26ml	10 plates/bag
Cat. no. L45	Mycobiotic Agar, 20x125mm Tube, 10ml Slant	20 tubes/box
Cat. no. X30	Mycobiotic Agar, 50ml HardyFlask™, 12ml Slant	20 flasks/box
Cat. no. J79	All Purpose Quad Plate (Eosin Methylene Blue Agar (EMB) / Mannitol Salt Agar (MSA) / Mycobiotic Agar / Blood Agar, 5%), 15x100mm Quadplate, 5ml/section	10 plates/bag

INTENDED USE

Hardy Diagnostics Mycobiotic Agar is recommended for use in the isolation of pathogenic fungi from clinical specimens.

SUMMARY

Leach, Ford and Whiffen described the use of cycloheximide for the inhibition of saprophytic fungi.[5,7] Cooke, et al., employed the use of chloramphenicol to various media to inhibit bacterial growth.[1,6] Researchers later found that the addition of both cycloheximide and chloramphenicol achieved more complete selectivity against growth of saprophytic fungi and bacteria.[8,9] The incorporation of both these antimicrobics in the soybean basal medium of Mycobiotic Agar provides selectivity to the medium.

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

Ingredients per liter of deionized water:*

Pancreatic Digest of Soybean Meal	10.0gm
Dextrose	10.0gm
Cycloheximide	0.4gm
Chloramphenicol	0.05gm
Agar	15.5gm

Final pH 6.5 +/- 0.3 at 25ºC.

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

STORAGE AND SHELF LIFE

Storage: Upon receipt store Mycobiotic Agar plates (Cat. no. W50) at 2-8ºC. Products L45 and X30 should be stored at 2-30ºC Products should not be used if there are any signs of contamination, deterioration (shrinking, cracking, or discoloration) 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: Specimen should be inoculated onto medium as soon as possible after receipt. Streak so as to obtain isolated colonies. Consult listed references for information on specimen collection.

Method of Use: A non-selective medium should be inoculated along with the selective medium for isolation of fungi from potentially contaminated specimens. Incubate medium at 25-30ºC. Two sets of media should be inoculated for isolation of fungi causing systemic mycoses. One set should be incubated at 25-30ºC. and the second set at 35ºC. Examine weekly and observe for growth and typical colonial morphology. Cultures should be held for 4 to 6 weeks before being reported as negative.

INTERPRETATION OF RESULTS

Consult listed references for the interpretation of growth and other identification tests to identify growth of organism in this medium.[13-15]

LIMITATIONS

It is recommended that macroscopic and microscopic morphology of isolates in pure culture be examined. Further biochemical tests may be necessary for complete identification. For more information, see appropriate references.

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

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 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.

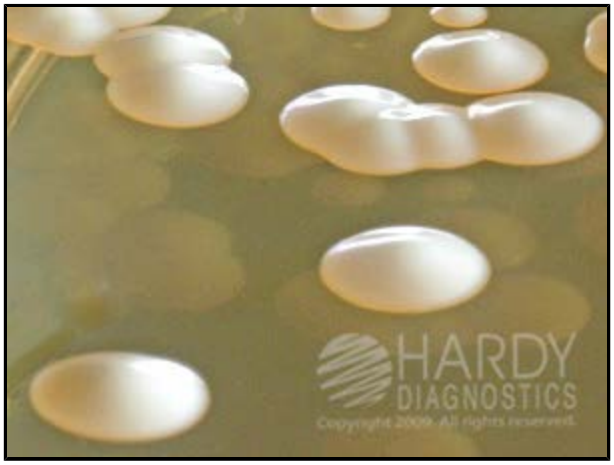
USER QUALITY CONTROL

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

Mycobiotic Agar should appear slightly opalescent, and light amber in color.

Trichophyton mentagrophytes (ATCC® 9533) growing on Mycobiotic Agar (Cat. no. W50). Incubated aerobically for 5 days at 30ºC.



Candida albicans (ATCC® 10231) growing on Mycobiotic Agar (Cat. no. W50). Incubated aerobically for 2 days at 30ºC.

Uninoculated plate of Mycobiotic Agar (Cat. no. W50).

REFERENCES

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

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

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11. Versalovic, J., et al. *Manual of Clinical Microbiology.* American Society for Microbiology, Washington, D.C.

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

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

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

HDQA 2207F [D]