IFU

HARDY DIAGNOSTICS
A Culture of Service™

Instructions for Use

INHIBITORY MOLD AGAR

Cat. no. W25	Inhibitory Mold Agar, 15x100mm Plate, 26ml	10 plates/bag
Cat. no. W58	Inhibitory Mold Agar, 25x100mm Plate, 60ml	5 plates/bag
Cat. no. X20	Inhibitory Mold Agar, 50ml HardyFlask™, 12ml	20 flasks/box
Cat. no. L47	Inhibitory Mold Agar, 20x125mm Tube, 10ml	20 tubes/box
Cat. no. W27	Inhibitory Mold Agar with Gentamicin, 15x100mm Plate, 26ml	10 plates/bag

INTENDED USE

Hardy Diagnostics Inhibitory Mold Agar and Inhibitory Mold Agar with Gentamicin are recommended for the selective isolation of fungi.

This product is not intended to be used for the diagnosis of human disease.

SUMMARY

Inhibitory Mold Agar was formulated by Ulrich for use as a general cultivation medium for various strains of pathogenic fungi.[8]

The medium is composed of nutritional factors and inorganic salts which support the growth of most pathogenic fungi. Casein and animal tissue provide growth nutrients. Yeast extract provides a rich source of vitamins. Dextrose, starch and dextrin serve as energy sources. Essential minerals and ions are supplied by sodium chloride and metallic salts. Gram-positive and gram-negative bacteria are inhibited by chloramphenicol, a broad spectrum antimicrobic. Gram-negative microorganisms are inhibited by gentamicin.

FORMULA

Ingredients per liter of deionized water:*

Yeast Extract	5.0gm
Dextrose	5.0gm
Pancreatic Digest of Casein	3.0gm
Peptic Digest of Animal Tissue	2.0gm
Starch	2.0gm
Sodium Phosphate	2.0gm
Dextrin	1.0gm

Magnesium Sulfate	0.8gm
Manganese Sulfate	0.16gm
Chloramphenicol	0.125gm
Iron Sulfate	0.04gm
Sodium Chloride	0.04gm
Agar	15.0gm

Additionally, Inhibitory Mold Agar with Gentamicin contains:

Gentamicin Sulfate	50.0mg

Final pH 6.7 +/- 0.3 at 25ºC.

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

STORAGE AND SHELF LIFE

Storage: Upon receipt store plates at 2-8ºC. Store tubed and bottled media at 2-30 degrees C. Store products 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.

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 media and refrigerated until inoculation. Consult listed references for information regarding the

processing and inoculation of specimens.

Method of Use: A non-selective medium should be inoculated in addition to the selective medium in order to ensure recovery of pathogenic fungi from potentially contaminated specimens. Inoculated media should be incubated in increased humidity at 25-30ºC. Inoculate two sets of media for isolation of fungi that cause systemic mycoses; incubate one set at 25-30ºC. and the other set at 35 +/- 2.0ºC. Examine cultures weekly for a period of four to six weeks.

INTERPRETATION OF RESULTS

Media should be examined for charateristic colonial growth and morphology. Consult listed references for the interpretation of fungal growth on this medium.[2-6,9]

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.

For proper identification of fungi, microscopic examination and evaluation of morphological structures is required. Further biochemical, physiological, serological tests and microscopic morphology of pure cultures are recommended for complete identification. For more information see appropriate references.

Specific strains of fungi for which the medium is designed to isolate often may be inhibited. Fungi for which the medium is designed to inhibit may grow.

A non-selective and selective medium should be inoculated for isolation of fungi from potentially contaminated specimens.

Due to the incorporation of chloramphenicol, the medium is not recommended for use in culturing sterile body fluids.

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	15-35°C	Aerobic	Growth
Candida albicans ATCC® 10231**	A	48hr	35°C	Aerobic	Growth
Escherichia coli ATCC® 25922**	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

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

Inhibitory Mold Agar should appear opalescent, and light amber in color; small number of fine black flecks may be present.

Trichophyton mentagrophytes (ATCC® 9533) growing on Inhibitory Mold Agar (Cat. no. W25). Incubated aerobically for 7 days at 30ºC.

Candida albicans (ATCC® 10231) growing on Inhibitory Mold Agar (Cat. no. W25). Incubated aerobically for 48 hours at 35ºC.

Escherichia coli(ATCC® 25922) growth inhibited on Inhibitory Mold Agar (Cat. no. W25). Incubated aerobically for 24 hours at 35ºC.

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

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

4.*Cumitech 11: Practical Methods for Culture and Identification of Fungi in the Clinical Microbiology Laboratory*. 1980. American Society for Microbiology, Washington, D.C.

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

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

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

8. Ulrich. 1956. Bacteriol. Proc., S.A.B.; M75, p. 87.

9. 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]