IFU

Instructions for Use

CELLULOSE AGAR, MODIFIED

Cat. no. W83	Cellulose Agar, Modified, 15x100mm Plate, 28ml	10 plates/bag

INTENDED USE

Hardy Diagnostics Cellulose Agar, Modified is recommended for use as a general all-purpose growth media for the cultivation of cellulose-utilizing fungi from environmental sources.

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

SUMMARY

The genus *Chaetomium* contains a wide variety of fungal species found worldwide on substrates containing cellulose, including paper and plant compost materials. *Chaetomium* spp. often thrive in the presence of other fungal species that digest cellulose and require a high water content (e.g. *Stachybotrys, Trichoderma, Acremonium,* among others). These fungi dissolve cellulose fibers found in cotton and paper, causing the materials to disintegrate. This process is accelerated under moist or damp conditions. Consequently, *Chaetomium* have been recovered from indoor environmental surfaces: bathrooms, kitchens, wood, wallboard, dry wall, carpet and window frames. They are commonly found in dwellings and buildings with chronic water intrusion and are considered to be an indication of indoor environmental mold infestation.

Recent medical evidence suggests that individuals exposed to *Chaetomium* may be predisposed to neurological damage of the myelin sheath, autoimmune disorders like multiple sclerosis and lupus, as well as certain types of cancer. Moreover, *Chaetomium* is the only mold known to cause permanent DNA damage and inhibit cellular replication. Some species of *Chaetomium* (e.g. *C. globosum* and *C. atrobrenneum)* have been implicated in fatal infectious mycoses. *C. globosum* has also been known to cause onychomycosis, peritonitis, and cutaneous lesions. Therefore, the genus *Chaetomium* may be considered a potential pathogen when present in indoor environmental samples.

Hardy Diagnostics Cellulose Agar, Modified is an enrichment medium designed for the cultivation of cellulose-utilizing fungi from environmental samples. Cellulose is added as a carbon source. L-aspargine is added as a nitrogen source. Yeast extract not only provides vitamins and co-factors required for growth, but also serves as an additional source of nitrogen and carbon.

FORMULA

Ingredients per liter of deionized water:*

Cellulose	20.0gm
Potassium Phosphate	1.0gm
Ammonium Sulfate	0.5gm
L-Asparagine	0.5gm

Potassium Chloride	0.5gm
Yeast Extract	0.5gm
Magnesium Sulfate	0.2gm
Calcium Chloride	0.1gm
Agar	15.0gm

Final pH 7.0 +/- 0.3 at 25ºC.

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

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-8ºC. 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 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.

PROCEDURE

Inoculate Hardy Diagnostics Cellulose Agar, Modified as per the techniques and procedures established by laboratory policy. Incubate media for up to 14 days at 15-30ºC.

INTERPRETATION OF RESULTS

Chaetomium colonies are rapidly growing, cottony and white in color initially. Mature colonies become gray to olive in color. From the reverse, the color is tan to red or brown to black.

Stachybotrys produces cottony, rapidly growing colonies which mature in about 4 days. From both front and reverse,

the color of the colony is white initially and turns to black by aging. Refer to standard mycology textbooks and other resources for complete inhibition.

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.

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, microscopes. stains, swabs, applicator sticks, other culture media, 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	
Stachybotrys chartarum ATCC® 9182	G	up to 14 days	15-30°C	Aerobic	Growth; white sporulating colonies
Pseudomonas aeruginosa ATCC® 27853	A	up to 3 days	15-30°C	Aerobic	Partial to complete inhibition
Escherichia coli ATCC® 25922	A	up to 3 days	15-30°C	Aerobic	Partial to complete inhibition
Staphylococcus aureus ATCC® 25923	A	up to 3 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.

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

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California · Washington · Utah · Arizona · Texas · Ohio · New York · Florida · North Carolina

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

HDQA 2207D [D]