

Instructions for Use

CRITERION™ MALT EXTRACT AGAR

Cat. no. C6200	CRITERION [™] Malt Extract Agar	110.5gm
Cat. no. C6201	CRITERION [™] Malt Extract Agar	500gm
Cat. no. C6202	CRITERION [™] Malt Extract Agar	2kg
Cat. no. C6203	CRITERION™ Malt Extract Agar	10kg
Cat. no. C6204	CRITERION™ Malt Extract Agar	50kg

INTENDED USE

Hardy Diagnostics CRITERIONTM Malt Extract Agar is recommended for the isolation, cultivation and maintenance of yeasts and molds.

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

Fungal testing is conducted to identify the fungal impact on manufacturing processes, avoid structural damage that can accompany mold growth, as well as recognize fungal isolates that may compromise human health. In addition to being the etiologic agents for disease, fungi have the potential to produce allergens, irritants, and in some cases potentially toxic substances (mycotoxins), which can induce an allergic response, cause asthma attacks, and irritate the eyes, skin, throat, and lungs of susceptible individuals.⁽⁸⁾ CRITERIONTM Malt Extract Agar is used as a general purpose growth media to isolate and cultivate yeasts and molds from clinical samples as well as a wide range of environmental sources.

CRITERIONTM Malt Extract Agar, based on the formula recommended by Thom and Church, is designed to contain the proper formulation of carbon, protein and nutrient sources essential for yeast and mold growth.⁽⁷⁾ Dextrose is added to the medium to provide a carbon and energy source for fungi. Additionally, CRITERIONTM Malt Extract Agar contains digests of animal tissues (peptones) which provide a nutritious source of amino acids and nitrogenous compounds for the growth of mold and yeasts. The pH is adjusted to approximately 5.5 in order to enhance the growth of fungi and to slightly inhibit bacterial growth commonly found as environmental contaminants.⁽⁶⁾

FORMULA

Gram weight per liter:	55.25gm/L				
Malt Extract	20.0gm				
Dextrose	20.0gm				
Peptone	2.25gm				

Final pH 5.5 +/- 0.2 at 25°C.

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

STORAGE AND SHELF LIFE

Store the sealed bottle(s) containing dehydrated culture medium at 2-30°C. 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 color.

Store the prepared culture media at 2-8°C.

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 "<u>Guidelines for Isolation</u> <u>Precautions</u>" 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 55.25gm of the dehydrated culture media in 1 liter of distilled or deionized water. Stir to mix thoroughly.
- 2. Heat to boiling to dissolve completely. Do not overheat.
- 3. Sterilize in the autoclave at 121°C. for 15 minutes.
- 4. Cool to 45-50°C. and pour into sterile petri dishes or tubes.

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. W28.

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.

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			Desulta
		Time	Temperature	Atmosphere	Results
Aspergillus brasiliensis formerly A. niger ATCC [®] 16404	G	1-7 days	15-20°C	Aerobic	Growth
Candida albicans ATCC [®] 10231	А	1-7 days	35°C	Aerobic	Growth
Saccharomyces cerevisiae ATCC [®] 9763	А	1-7 days	35°C	Aerobic	Growth
Escherichia coli ATCC [®] 25922	А	1-7 days	35°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 <u>Certificate of Analysis</u> website. In addition, refer to the following document "<u>Finished Product</u> <u>Quality Control Procedures</u>," for more information on QC or see the reference(s) for more specific information.

PHYSICAL APPEARANCE

CRITERIONTM Malt Extract Agar powder should appear homogeneous, free-flowing, and beige in color. The prepared media should appear clear, and light to medium amber in color.

REFERENCES

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

2. Atlas, R.M. 1995. Handbook of Microbiological Media for the Examination of Food. CRC Press, Boca Raton, LA.

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

4. APHA Technical Committee on Microbiological Methods for Foods. *Compendium of Methods for the Microbiological Examination of Foods*, APHA, Washington, D.C.

5. U.S. Food and Drug Administration. *Bacteriological Analytical Manual*. AOAC, Arlington, VA. http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm.

6. Ajello, et al. 1963. *CDC Laboratory Manual for Medical Mycology*, PHS Publication No. 994. U.S. Gov't Printing Office, Washington, D.C.

7. Thom, C. and M.B. Church. 1926. The aspergilli. Williams & Wilkins Co., Baltimore, MD.

8. U.S. Environmental Protection Agency. 2002. "A brief guide to mold, moisture, and your home." Internet: www.epa.gov/iaq/molds/moldguide.html.

ATCC is a registered trademark of the American Type Culture Collection.

IFU-10200[A]



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Distribution Centers: 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.

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