IFU

Instructions for Use

CRITERION™ POTATO DEXTROSE AGAR (PDA)

Cat. no. C6620	CRITERION™ Potato Dextrose Agar	72.4gm
Cat. no. C6621	CRITERION™ Potato Dextrose Agar	500gm
Cat. no. C6622	CRITERION™ Potato Dextrose Agar	2kg
Cat. no. C6623	CRITERION™ Potato Dextrose Agar	10kg
Cat. no. C6624	CRITERION™ Potato Dextrose Agar	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ Potato Dextrose Agar is used for the cultivation and identification of fungi.

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

Potato Dextrose Agar contains dextrose as a carbohydrate source, and potato infusion to supply other necessary growth requirements. Potato infusion provides a nutrient base for luxuriant growth of most fungi. Dextrose serves as a growth stimulant. The incorporation of tartaric acid (TA) in the medium lowers the pH to 3.5 thereby inhibiting bacterial growth.

Potato Dextrose Agar is formulated according to procedures in *Standard Methods for the Examination of Dairy Products* and *Compendium of Methods for the Microbiological Examination of Foods.*[1,2]

The American Public Health Association and the Association of Analytical Chemists recommend Potato Dextrose Agar for use in plate counts of yeasts and molds in the examination of dairy products and foods.[15,16,18,20] This product is recommended by the U.S. Pharmacopeia for Microbial Limit Tests.[17] Potato Dextrose Agar is used in slide preparations of fungi for the stimulation of sporulation and in the maintenance of dermatophyte stock cultures. Additionally, the medium is useful for differentiation of atypical dermatophytes based on pigment production.[19]

FORMULA

Gram weight per liter:	36.0gm/L
Dextrose	20.0gm
Potato Infusion	4.0gm
Agar	12.0gm

Final pH 5.6 +/- 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 light beige.

Store the prepared media, except plated, at 2-30ºC. Prepared plated media should be stored 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 36.2gm of the dehydrated culture media in 1 liter of distilled or deionized water.

2. Heat to boiling and mix to dissolve completely.

3. Sterilize in the autoclave at 121ºC. for 15 minutes.

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. W60.

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.

Potato Dextrose Agar (without TA) is not for use as a primary isolation medium. Direct inoculation of specimens will result in erroneous results.

For proper identification of mold 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.[8-13]

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			Results
		Time	Temperature	Atmosphere	
Trichophyton interdigitale ATCC® 9533	G	7 days	15-30°C	Aerobic	Growth; may take up to 7 days
Trichophyton rubrum ATCC® 28188	G	3-4 weeks	15-30°C	Aerobic	Growth visible in 7 days, may take 3-4 weeks for color to develop on reverse side of colony
Aspergillus brasiliensis ATCC® 16404	J	1-5 days	15-30°C	Aerobic	Growth; may take up to 5 days
Candida albicans ATCC® 10231	J	1-3 days	15-30°C	Aerobic	Growth

* 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™ Potato Dextrose Agar powder should appear homogeneous, free-flowing, and light beige in color. The prepared media should appear slightly opalescent, and light amber in color.

REFERENCES

1. Marshall, R.T., ed. 1992. *Standard Methods for the Examination of Dairy Products*, 16th ed. APHA, Washington, D.C.

2. Vanderzant, C. and D.F. Splittstoesser, (ed.). 1992. *Compendium of Methods for the Microbiological Examination of Foods*, 3rd ed. APHA, Washington, D.C.

3. *Standard Methods for the Examination of Water and Waste Water*, 19th ed. 1995. APHA, Washington, D.C.

4. Association of Official Agricultural Chemists, 10th ed. 1965. p. 737.

5. *U.S. Pharmacopeia*, 22nd rev. 1990. U.S. Pharmacopeial Convention, Rockville, MD.

6. MacFaddin, J.F. 1985. *Media for Isolation, Cultivation, Identification, Maintenance of Bacteria*, Vol. I. Williams & Wilkins, Baltimore, MD.

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

8. 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.

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

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

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

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

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

14. Campbell, M.C. and J.L. Stewart. 1980. *The Medical Mycology Handbook*, John Wiley and Sons, New York, NY.

15. Richardson, (ed.). 1985. *Standard Methods for the Examination of Dairy Products*, 15th ed. American Public Health Association, Washington, D.C.

16. Speck, (ed.). 1984. *Compendium of Methods for the Microbiological Examination of Foods*, 2nd ed. American Public Health Association, Washington, D.C.

17. Association of Official Analytical Chemists (AOAC), 15th ed. 1990. Arlington, VA.

18. Robell and Taplin. 1970. Dermatophytes, University of Miami Press.

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

20. The Official Compendia of Standards. USP General Chapter <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests. *USP-NF*. United States Pharmacopeial Convention Inc., Rockville, MD.

21. The Official Compendia of Standards. USP General Chapter <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms. *USP-NF*. United States Pharmacopeial Convention Inc., Rockville, MD.

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

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

HDQA 2207B [D]