



Instructions for Use

POTATO DEXTROSE AGAR (PDA), USP

| <u>Cat. no. H51</u> | Potato Dextrose Agar, USP, 15x150mm Plate, 68ml | 10 plates/bag |
|---------------------|--|----------------|
| Cat. no. L90 | Potato Dextrose Agar, USP, 20x125mm Tube, 10ml | 20 tubes/box |
| <u>Cat. no. Q29</u> | Potato Dextrose Agar, USP, 20x125mm Tube, 18ml Deep | 20 tubes/box |
| Cat. no. U294 | Potato Dextrose Agar, USP, 8 oz. Bottle, 200ml | 12 bottles/box |
| Cat. no. U376 | Potato Dextrose Agar, USP, 500ml Polycarbonate Bottle, 500ml | 10 bottles/box |
| Cat. no. U379 | Potato Dextrose Agar, USP, 1L Polycarbonate Bottle, 1000ml | 10 bottles/box |
| Cat. no. W60 | Potato Dextrose Agar, USP, 15x100mm Plate, 26ml | 10 plates/bag |

INTENDED USE

Hardy Diagnostics Potato Dextrose Agar (PDA), USP is recommended for the cultivation of yeast and mold, and for the inducement of sporulation in non-clinical samples. Potato Dextrose Agar (PDA), USP is formulated as outlined by the U.S. Pharmacopoeia for the preparation of test strains used in microbial enumeration tests.⁽³⁾

SUMMARY

The Food and Drug Administration (FDA), the American Public Health Association (APHA), and the Association of Analytical Chemists (AOAC) recommend Potato Dextrose Agar for use in plate counts of yeast and mold cultures for the examination of dairy products and foods.^(1,2,4,5) Potato Dextrose Agar is also recommended by the U.S. Pharmacopeia for the preparation and maintenance of test strains used for microbial enumeration tests as outlined in USP <61> and <62>.⁽³⁾

Potato Dextrose Agar, USP consists of potato infusion and dextrose. Potato infusion provides a nutrient base for luxuriant growth and sporulation of most fungi. Dextrose is an energy source. Agar is the solidifying agent.

FORMULA

Ingredients per liter of deionized water:*

| Infusion from Potatoes | 200.0gm |
|------------------------|---------|
| Dextrose | 20.0gm |
| Agar | 15.0gm |

Final pH 5.6 +/- 0.2 at 25°C.

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

STORAGE AND SHELF LIFE

Storage: Upon receipt, store plated media (Cat. no. H51 and W60) at 2-8°C away from direct light. Upon receipt, store tube (Cat. no. L90 and Q29) and bottle (Cat. no. U294, U376, and U379) media at 2-30°C 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

For Cat. nos. L90, Q29, and W60.

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 "<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.

For Cat. nos. H51, U294, U376, and U379.

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.

PROCEDURE

Before Use: The medium should be warmed to room temperature and the surface should be dry prior to inoculating.

For re-melting solid tube and bottle media: Autoclave containers with slightly loose caps at 121°C for 1-3 minutes or until melted. Do not heat media longer than 3 hours at 45-50°C. Alternatively, solid agar in capped containers can be racked and placed in a covered, boiling waterbath (100°C) before use. There should be enough water in the waterbath to reach the top of the media line. A covered waterbath will maintain consistent temperature of the media until melted. Cool media to 45-50°C and aseptically dispense into sterile containers. **Note:** Sterile solidified media can be remelted only once. In addition, the use of microwaves to melt media is not advised.

Preparation of Test Strains: Use stable standardized suspensions of test strains per reference method. Use appropriate diluent for making test suspensions and use suspensions within the specified time period or maintain under appropriate storage practices.⁽³⁾

Inoculate the surface of the medium and incubate aerobically at 20-25°C for 5-7 days or until good sporulation is achieved. During incubation, caps should remain loose on tube or flask cultures to ensure adequate air circulation.

INTERPRETATION OF RESULTS

Consult listed references for information regarding the interpretation of growth of fungal species and for performing microscopic examinations.⁽¹⁻⁵⁾

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.

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, 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:

| Toot Organisms | Inoculation Method* | Incubation | | | Results |
|---|------------------------|------------|-------------|------------|--|
| Test Organisms | | Time | Temperature | Atmosphere | Kesuits |
| Trichophyton mentagrophytes ATCC [®] 9533** | G | 5-7 days | 20-25°C | Aerobic | Growth; may take up to 7 days |
| Trichophyton rubrum ATCC [®] 28188** | G | 3-4 weeks | 20-25°C | Aerobic | Growth seen in 7 days; may take 3-4 weeks for red color on reverse side of colony to be visible |
| | | | | | |

| Aspergillus brasilliensis ATCC [®] 16404 | J | 1-5 days | 20-25°C | Aerobic | Growth; may take up to 5 days |
|--|---|----------|---------|---------|-------------------------------|
| Candida albicans ATCC [®] 10231 | J | 1-3 days | 20-25°C | Aerobic | Growth; may take up to 3 days |

* Refer to the document "Inoculation Procedures for Media QC" for more information.

**Not tested with U376 and U379. Tested in accordance with USP <61>.⁽³⁾

USER QUALITY CONTROL

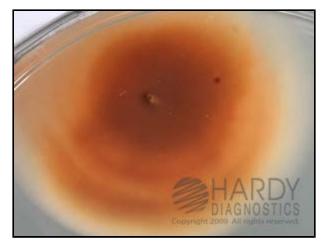
End users of commercially prepared culture media should perform QC testing in accordance with applicable government regulatory agencies, and in compliance with accreditation requirements. Hardy Diagnostics recommends end users check for signs of contamination and deterioration and, if dictated by laboratory 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 <u>Certificate of Analysis</u> website. Also refer to the document "<u>Finished Product</u> <u>Quality Control Procedures</u>," 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

Potato Dextrose Agar, USP should appear slightly opalescent and light amber in color.



Trichophyton mentagrophytes (ATCC[®] 9533) growing on Potato Dextrose Agar, USP (Cat. no. W60). Incubated aerobically for 7 days at 20°C.



Showing red color on reverse side of *Trichophyton rubrum* (ATCC[®] 28188) growing on Potato Dextrose Agar, USP (Cat. no. W60). Incubated aerobically for four weeks at 20°C.

REFERENCES

1. American Public Health Association. 2012. *Standard Methods for the Examination of Dairy Products*, 22nd ed. APHA, Washington, D.C.

2. APHA Technical Committee on Microbiological Methods for Foods. 2001. *Compendium of Methods for the Microbiological Examination of Foods*, 4th ed. APHA, Washington, D.C.

3. The U.S. Pharmacopeial Convention. *USP-NF: U.S. Pharmacopoeia National Formulary*. Rockville, MD.



4. Association of Official Analytical Chemists. 2012. *Official Methods of Analysis*, 19th ed. AOAC, Washington, D.C.

Uninoculated plate of Potato Dextrose Agar, USP (Cat. no. W60).

5. U.S. Food and Drug Administration. Bacteriological

Analytical Manual. AOAC, Arlington, VA. http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm

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

IFU-10676[C]



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