IFU

Instructions for Use

POTATO FLAKE MEDIA

Cat. no. W59	Potato Flake Agar, 15x100mm Plate, 26ml	10 plates/bag
Cat. no. X32	Potato Flake Agar, 50ml HardyFlask™, 12ml Slant	20 flasks/box
Cat. no. W159	Potato Flake Selective Agar, 15x100mm Plate, 26ml	10 plates/bag
Cat. no. X59	Potato Flake Selective Agar, 50ml HardyFlask™, 12ml Slant	20 flasks/box

INTENDED USE

Hardy Diagnostics Potato Flake Media is used in the cultivation, isolation, and induction of sporulation of fungi from clinical specimens.

SUMMARY

As a result of therapeutic technology advances and the continuing AIDS epidemic, rates of fungal infections have increased significantly in recent years. Proper diagnosis and treatment of fungal disease is dependent upon the accurate identification of these emerging pathogens.[1] Although yeasts can be identified in clinical microbiology laboratories by biochemical tests, molds require microscopic evaluation of morphological structures for their proper identification. Identification of fungi in clinical laboratories is further complicated by the failure to observe characteristic morphological structures on standard mycological media. Hardy Diagnostics Potato Flake Media is specifically designed to enhance the production of characteristic morphological features in molds.[7]

Potato Flake Agar, based on the formula recommended by M.G. Rinaldi, is designed to contain the proper formulation of carbon, protein and nutrient sources recommended for the identification of mold fungi encountered in the clinical mycology laboratory.[6] Glucose is added to the medium to provide a carbon and energy source. The media also contains potato flakes which promote conidiation by molds. The pH is adjusted to approximately 5.6 in order to enhance the growth of fungi and to slightly inhibit bacterial growth commonly found as contaminants.[1-4,6] In addition, selective agents are added to increase the inhibitory properties of Potato Flake Selective Agar to inhibit growth of gram-positive and gram-negative bacteria.

FORMULA

Ingredients per liter of deionized water:*

Potato Flakes	20.0gm
Glucose	10.0gm
Agar	15.0gm

In addition to the above ingredients,
Potato Flake Selective Agar contains 11.0mg of selective agents per liter.

Final pH 5.6 +/- 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. (except Cat. no. X32 and L64 should be stored at 2-30ºC) 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 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: Consult listed references for information on specimen collection.[1-4] 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.

Method of Use:

1. Allow media to warm to room temperature, and the agar surface to dry before inoculating. A non-selective medium should be inoculated along with the selective medium for isolation of fungi from potentially contaminated specimens. Consult listed references for appropriate incubation temperature.[1-4]

2. Inoculate and streak the specimen as soon as possible after collection. If the specimen to be cultured is on a swab, roll the swab over a small area of the agar surface. Streak for isolation with a sterile loop. If the specimen is collected on a loop or needle, inoculate the plate with fungi in two or three distinct places by pressing the inoculum onto the agar surface.

3. Incubate plates in an inverted position. Once inoculated, media should be protected from light and incubated

aerobically at 25-35ºC. with increased humidity for four weeks or longer. Our MycoSeal™ product (Cat. no. SS9225) may be used to seal the plates to keep moisture from evaporating from the Potato Flake plated media, while still allowing atmospheric circulation.

4. Examine plates for typical colonial and hyphal morphology and color. Cultures should be held from 4 to 6 weeks before being reported as negative.

INTERPRETATION OF RESULTS

Identification of fungi is performed by observing various aspects of colony morphology, characteristic microscopic structures, rate of growth, media which supports the organisms growth, and source of the specimen. Consult the listed references for information regarding the identification and further testing of fungi and yeast cultures.[1-4,7,8]

LIMITATIONS

A non-selective and selective medium should be inoculated for isolation of fungi from potentially contaminated specimens.[1]

Potato Flake Selective Agar is not recommended for *Nocardia* spp. that are sensitive to quinolones. Other media, such as Sabouraud Dextrose, would be recommended to select for these organisms.

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.

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	
Potato Flake Agar:					
Candida albicans ATCC® 10231	A	24-48hr	15-30°C	Aerobic	Growth
Trichophyton mentagrophytes ATCC® 9533	G	up to 7 days	15-30°C	Aerobic	Growth
Aspergillus brasiliensis ATCC® 16404	G	up to 7 days	15-30°C	Aerobic	Growth
Potato Flake Selective Agar:					
Candida albicans ATCC® 10231	A	24-48hr	15-30°C	Aerobic	Growth
Aspergillus brasiliensis					

ATCC® 16404	G	up to 7 days	15-30°C	Aerobic	Growth
Trichophyton mentagrophytes ATCC® 9533	G	up to 7 days	15-30°C	Aerobic	Growth
Staphylococcus aureus ATCC® 25923	B	18-24hr	35°C	Aerobic	Partial to complete inhibition
Escherichia coli ATCC® 25922	B	18-24hr	35°C	Aerobic	Partial to complete inhibition

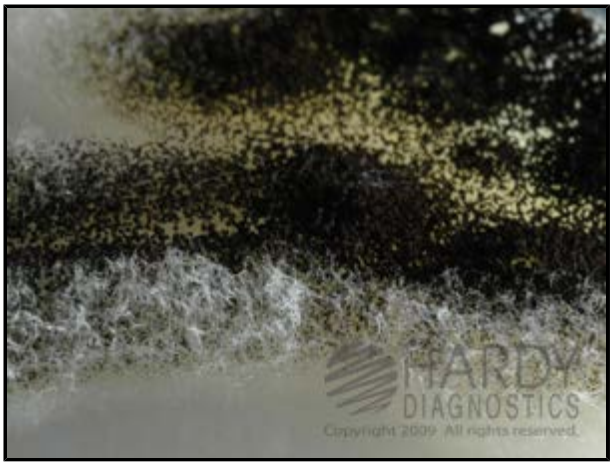
* Refer to the document "Inoculation Procedures for Media QC" for more information.

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.

PHYSICAL APPEARANCE

Potato Flake Media should appear slightly opaque, may have a slight precipitate, and white in color.



Aspergillus brasiliensis formerly *A. niger* (ATCC® 16404) colonies growing on Potato Flake Agar (Cat no. W59). Incubated aerobically for 72 hours at 30ºC.

Trichophyton mentagrophytes (ATCC® 19533) colonies growing on Potato Flake Agar (Cat no. W59). Incubated aerobically for 72 hours at 30ºC.

Uninoculated plate of Potato Flake Agar (Cat. no. W59)

REFERENCES

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

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

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

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

5. Thom, C. and M.B. Church. 1926. *The Aspergilli*. Williams & Wilkins Co., Baltimore, MD.

6. Rinaldi, M.G. 1982. Use Of Potato Flakes In Clinical Mycology. *J. Clin. Microbiol.*; 15:1159-1160.

7. Larone, D.H. *Medically Important Fungi: A Guide to Identification*, American Society for Microbiology. Washington, D.C.

8. 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]