

BLUEMOUNTTM

INTENDED USE

Hardy Diagnostics BlueMount[™] is recommended for the permanent mounting and staining of yeasts and molds.

SUMMARY

Hardy Diagnostics BlueMountTM is a formulation of lactophenol cotton blue with polyvinyl alcohol and is recommended for preparing permanent, long-lasting mounts of fungal wet preparations or slide cultures. BlueMountTM may be used as a replacement for lactophenol cotton blue. BlueMountTM consists of lactic acid, phenol, cotton blue, and polyvinyl alcohol (PVA). Lactic acid serves as a clearing agent and also helps preserve fungal structures. Phenol acts as a killing agent. Cotton blue is an acid dye that stains the chitin present in the cell walls of fungi. Polyvinyl alcohol (PVA) acts as a fixative, thus allowing the mount to be saved for years.⁽⁷⁾ Once completely dry, the permanent mounts will not dissolve in ether, xylene, or alcohols.⁽⁷⁾

REAGENT FORMULA*

Phenol	440.0gm
Lactic Acid	440.0gm
Polyvinyl Alcohol	150.0gm
Cotton Blue	1.0gm
Deionized Water	1000.0ml

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

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-30°C. Products should not be used if there are any signs of contamination, deterioration, or if the expiration date has passed. Product is light sensitive; protect from light.

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 "<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.

This product is not recommended for use with MycoMountTM (Cat. no. MM40). Application of MycoMountTM to a BlueMountTM fungal preparation will deteriorate the MycoMountTM adhesive backing and result in obstruction of fungal structures upon microscopic observation.

Warning: This product causes irritation, may cause eye burns and is harmful if inhaled. Avoid contact with skin. Use with adequate ventilation. Wash thoroughly after handling.

Refer to the SDS Search instructions on the Hardy Diagnostics website for more information.

PROCEDURE

Specimen Collection: This product is intended to be used primarily with pure cultures, although certain specimens may be examined directly using this stain. Consult appropriate references for further information concerning the use of this product with specimens.⁽⁷⁾

Method of Use: Place one drop of BlueMountTM in the center of a clean slide. Remove a fragment of the fungus colony 2-3 mm from the colony edge using an inoculating or teasing needle. Place the fragment in the drop of stain and tease gently. Apply a cover slip. Do not push down or tap the cover slip as this may dislodge the conidia from the conidiophores. Take care to prevent coverslip runover or from dropping the stain on the bench top (once the solution dries, it is difficult to remove). Spills may be cleaned with water before it dries. The preparation can be examined immediately under low and high-dry magnification for the presence of characteristic mycelia and fruiting structures. Once the slide has dried on a flat surface for a period of two to four days, it can be examined under oil immersion, cleansed in xylene, or decontaminated by dipping in disinfectant.⁽⁷⁾

INTERPRETATION OF RESULTS

Consult appropriate references for diagnostic features of fungi isolated in clinical and non-clinical specimens.⁽¹⁻⁸⁾

LIMITATIONS

BlueMountTM is useful in the recognition and presumptive identification of fungi. Additional characteristics including colony morphology and biochemical tests should be used where appropriate for definitive identification. For further information, consult the appropriate references.⁽¹⁻⁸⁾

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as loops, culture media, incinerators, incubators, pasteur pipets, slides, coverslips, microscopes, 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	Reaction
Aspergillus brasiliensis ATCC [®] 16404	Delicate blue hyphae and fruiting structures with a clear background
Trichophyton mentagrophytes ATCC [®] 9533	Delicate blue hyphae and fruiting structures with a clear background

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 <u>Quality Assurance for Commercially Prepared</u> <u>Microbiological Culture Media</u> for more information on the appropriate QC procedures. See the references below.

PHYSICAL APPEARANCE

BlueMountTM should appear slightly viscous, and deep blue in color.



BlueMountTM

REFERENCES

1. Versalovic, J., 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. 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.

4. "*Cumitech 11; Practical Methods for Culture and Identification of Fungi in the Clinical Microbiology Laboratory*". 1980. American Society for Microbiology, Washington D.C.

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

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

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

8. Kwon-Chung, K.J. and J.E. Bennett. 1992. Medical Mycology. Lea and Febiger, Malvern, PA.

ATCCis a registered trademark of the American Type Culture Collection.

IFU-10076[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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