IFU

Instructions for Use

INDIA INK

Cat. no. Z64	India Ink, 0.5oz. Polyethylene Dropper Bottle, 15ml	1 bottle

INTENDED USE

Hardy Diagnostics India Ink is recommended for use in the identification of *Cryptococcus neoformans*.

SUMMARY

Cryptococcus neoformans, because of its large polysaccharide capsule, can be visualized by the India Ink stain. Organisms that possess a polysaccharide capsule exhibit a halo around the cell against the black background created by the India Ink.

REAGENT FORMULA

- Black Pelican Drawing Ink No. 17
- Deionized Water
- Thimerosol

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-30ºC away from direct light. Product should not be used if there are any signs of deterioration, 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: Specimens should be collected in sterile containers or with sterile swabs and transported immediately to the laboratory. This product is used in conjunction with other biochemical and serological tests to identify cultures of isolated organisms.

Method of Use: Mix the specimen with a small drop of India Ink on a clean glass slide. Place a cover slip over the smear and press gently. The preparation should be brownish, not black. Using reduced examine the smear microscopically (100X) for the presence of encapsulated cells as indicated by clear zones surrounding the cells.

Note: The India Ink is ready to use. Further dilution with water is not recommended.

Note: Production of capsular material may be increased by cultivation in a 1% peptone solution (Peptone Broth, Cat. no. K151).[7]

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.

The India Ink test may be used in the presumptive identification of *C. neoformans*. Culture, biochemical and serological testing is recommended for complete identification.

The diagnosis of *C. neoformans* by negative staining should be considered a presumptive result. Leukocytes, fat droplets, and tissue cells are sometimes confused with *C. neoformans* cells. Leukocytes and tissue cells may be dissolved by adding a drop of 10% KOH.

Some strains of *C. neoformans*, as well as other cryptococci may not produce discernible capsules *in vitro*.[7]

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, glass slides, coverglass, microscopes, 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	**Results**
Cryptococcus neoformans ATCC® 32045	Encapsulated
Candida albicans	

ATCC® 10231	Non-encapsulated

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

India Ink should appear opaque, and black in color.

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. Haley, L.D. and C.S. Callaway. 1978. *Laboratory Methods in Medical Mycology*, U.S. Department of Health, Education and Welfare, Atlanta, Georgia.

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. *Commission on Laboratory Accreditation, Laboratory Accreditation Program Microbiology Checklist*. College of American Pathologists. Rev. 9/30/2004.

9. Centers for Medicare and Medicaid, *Appendix C, Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services*. Subpart K - Quality System for Non-Waived Testing. 493;1200-1265. www.cms.hhs.gov/clia.

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

HDQA 2207F [D]