IFU

Instructions for Use

BIGGY AGAR

Cat. no. G17	BiGGY Agar, 15x100mm Plate, 18ml	10 plates/bag
Cat. no. R21	BiGGY Agar, 13x100mm Tube, 3ml Slant	20 or 100 tubes/box

INTENDED USE

Hardy Diagnostics BiGGY Agar (Bismuth Sulfite Glucose Glycine Yeast Agar) is a selective and differential medium used for the isolation and presumptive identification of *Candida* spp.

SUMMARY

BiGGY Agar was developed by Nickerson in 1953 following a study of sulfite reduction by *Candida* species. Nickerson found many yeast capable of reducing bismuth sulfite to bismuth sulfide when grown on an acidic or neutral medium containing the reducing substrate. Substrate reduction was noted by the production of brown to black pigmented colonies, a result of sulfide combining with bismuth.[1-7]

Bismuth sulfite inhibits bacterial growth, thereby enabling the recovery of isolated colonies of *Candida*. *Candida* spp. reduce the bismuth sulfite resulting in pasty brown to black colonies. Some *Candida* species present as brown to black colonies surrounded by zones of dark precipitate in the medium. Dextrose and yeast extract provide the nutrients in the formulation.

FORMULA

Ingredients per liter of deionized water:*

Dextrose	10.0gm
Glycine	10.0gm
Bismuth Ammonium Citrate	5.0gm
Sodium Sulfite	3.0gm
Yeast Extract	1.0gm
Agar	20.0gm

Final pH 6.8 +/- 0.2 at 25ºC.

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

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-8ºC. 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: 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. Consult listed references for information on specimen collection.[1-5]

BiGGY Agar should be inoculated, incubated, and results recorded according to accepted procedures described in the listed reference texts.[1-5]

The streak plate technique is used primarily to obtain isolated colonies from specimens containing mixed flora. When inoculating slants, streak the surface with a sterile inoculating loop using two to three isolated colonies.

BiGGY Agar may be used directly from the specimen for isolation and growth as well as for the presumptive recognition of various *Candida* spp.

When used as a direct medium, BiGGY Agar should be inoculated similar to routine bacterial isolation and incubated at 25-30ºC. The medium should be examined daily for a period of up to 5 days.

When used as a secondary test medium, an isolate of the unknown yeast should be streaked to the agar surface and incubated at 25-30ºC. The medium should be examined daily for a period of up to 5 days.

INTERPRETATION OF RESULTS

C. albicans appears as smooth, circular tan-brown to rust colonies with slight mycelial fringe. There is no pigment diffusion into surrounding media and no sheen is apparent.

C. tropicalis appears as smooth, dark brown to black colonies. Slight mycelial fringe.

C. krusei appears as large, flat, shiny, wrinkled reddish-brown colonies with silver metallic sheen and yellow pigment diffusion in surrounding media.

C. kefyr appears as medium sized, flat, wrinkled, dark reddish-brown, glistening colonies with slight mycelial fringe. No pigment diffusion is present.

C. parakrusei appears as medium sized, flat, wrinkled, glistening, dark reddish-brown, colonies with extensive yellow mycelial fringe.

C. stellatoidea appear as medium sized, flat, dark brown colonies with very light mycelial fringe.

Consult listed references for further information regarding characteristic growth patterns and morphology of *Candida* spp. on this medium.[6,7]

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.

Bacteria and non-Candida yeast like fungi are mostly inhibited on this media, however, if break-through occurs they can be easily differentiated by microscopic examination.

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, 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	
Candida albicans ATCC® 60193	A	24-72hr	15-30°C	Aerobic	Growth; smooth tan or brown to rust colonies, no diffusion of color
Candida krusei ATCC® 14243	A	24-72hr	15-30°C	Aerobic	Growth; flat wrinkled reddish-brown colonies, yellow diffusion of color in medium, silver sheen
Candida tropicalis ATCC® 750	A	24-72hr	15-30°C	Aerobic	Growth; smooth brown to black colonies, no diffusion of color
Escherichia coli ATCC® 25922	B	24hr	15-30°C	Aerobic	Partial to complete inhibition

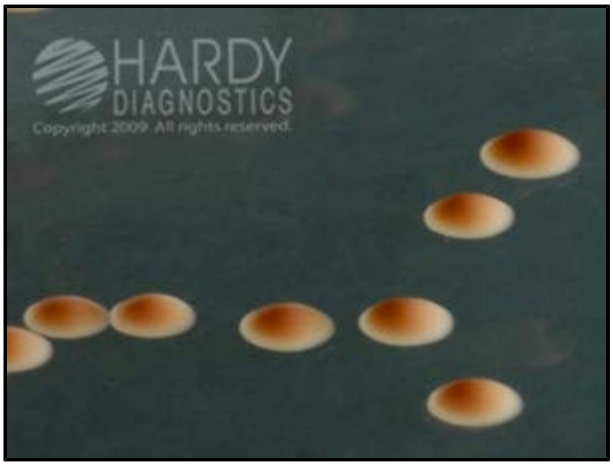
* Refer to the document "Inoculation Procedures for Media QC" for more information.

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

BiGGY Agar should appear opalescent with moderate precipitate evenly suspended throughout the medium, and slightly white in color.



Candida albicans (ATCC® 60193) colonies growing on BiGGY Agar (Cat. no. G17). Incubated aerobically for 48 hours at 35ºC.

Candida tropicalis (ATCC® 750) colonies growing on BiGGY Agar (Cat. no. G17). Incubated aerobically for 48 hours at 35ºC.

Candida krusei (ATCC® 14243) colonies growing on BiGGY Agar (Cat. no. G17). Incubated aerobically for 48 hours at 35ºC.

Escherichia coli (ATCC® 25922) growth inhibited on BiGGY Agar (Cat. no. G17). Incubated aerobically for 24 hours at 35ºC.

REFERENCES

1. 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.

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

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

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

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

6. Nickerson. 1953. *Journal of Infectious Diseases*; 93:43.

7. Atlas, Ronald M. 1993. *Handbook of Microbiological Media,* CRC Press, Inc.

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HDQA 2207F [D]