IFU

Instructions for Use

CRITERION™ BIGGY AGAR

Cat. no. C5160	CRITERION™ BiGGY Agar	114.2gm
Cat. no. C5161	CRITERION™ BiGGY Agar	500gm
Cat. no. C5162	CRITERION™ BiGGY Agar	2kg
Cat. no. C5163	CRITERION™ BiGGY Agar	10kg
Cat. no. C5164	CRITERION™ BiGGY Agar	50kg

INTENDED USE

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

This dehydrated culture medium is a raw material intended to be used in the making of prepared media products, which will require further processing, additional ingredients, or supplements.

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

Gram weight per liter:	49.0gm/L
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

Store the sealed bottle(s) containing dehydrated culture medium at 2-30 degrees C. Dehydrated culture medium is very hygroscopic. Keep lid tightly sealed. Protect dehydrated culture media from moisture and light. The dehydrated culture media should be discarded if it is not free-flowing or if the color has changed from its original light beige.

Store the prepared media in plates at 2-8ºC.

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 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 "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 AND INTERPRETATION OF RESULTS

For information on procedures and interpretation of results, consult listed references or refer to the prepared media Instructions for Use (IFU) for Cat. No. G17.

LIMITATIONS

It is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on colonies from pure culture for complete identification.

Some formulations may require a settling period before pH testing of the prepared medium. If the pH is tested immediately after preparation and is out of specification, retest the medium after 24 hours to obtain final pH results. Always take pH reading at room temperature.

Bacteria and 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 autoclaves, incinerators, and incubators, etc., 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/td>	Growth; smooth brown to black colonies
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

Users of dehydrated 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. In addition, refer to the following document "Finished Product Quality Control Procedures," for more information on QC or see the reference(s) for more specific information.

PHYSICAL APPEARANCE

CRITERION™ BiGGY Agar powder should appear homogeneous, free-flowing, and light beige in color. The prepared media should appear opalescent with moderate precipitate evenly suspended throughout the medium, and slightly white in color.

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

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.

IFU-10120[B]

1430 West McCoy Lane, Santa Maria, CA 93455, USA
Phone: (805) 346-2766 ext. 5658
Fax: (805) 346-2760
Website: HardyDiagnostics.com
Email: TechnicalServices@HardyDiagnostics.com
Ordering Information

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.

HDQA 2207B [D]