IFU

Instructions for Use

CRITERION™ SABHI AGAR BASE

Cat. no. C6790	CRITERION™ SabHI Agar Base	118gm
Cat. no. C6791	CRITERION™ SabHI Agar Base	500gm
Cat. no. C6792	CRITERION™ SabHI Agar Base	2kg
Cat. no. C6793	CRITERION™ SabHI Agar Base	10kg

INTENDED USE

Hardy Diagnostics CRITERION™ SabHI Agar Base is recommended for use as a general purpose growth medium in qualitative procedures for the isolation and cultivation of dermatophytes and other pathogenic and nonpathogenic fungi from clinical and nonclinical samples.This medium may be enriched with blood to promote the growth of more fastidious microorganisms or it may be made selective by incorporating the use of antimicrobial agents.

Dehydrated culture media is a raw material not intended for use in the diagnosis of human disease. For implementation, this product requires additional processing and supplementation of ingredients before use.

SUMMARY

Sabouraud designed Sabouraud Dextrose Agar for the cultivation of dermatophytes.[9]It is a general purpose medium used in qualitative procedures for the cultivation of dermatophytes and other pathogenic and non-pathogenic fungi from clinical and non-clinical specimens. Brain Heart Infusion Agar is used for the primary isolation and cultivation of fungi from clinical specimens.[2] In 1967, Gorman combined the two media to produce SabHI Agar, and the combined formulation is superior for the recovery of pathogenic fungi than either medium on its own.[8]

The peptones and brain heart digest in CRITERION™ SabHI Agar Base provide essential amino acids, nitrogen, sulfur, carbon and trace minerals. Dextrose provides an energy source for metabolism. Sodium chloride is an essential electrolyte, whereas disodium phosphate acts as a pH buffer. Defibrinated sheep blood can be added to the medium to provide essential growth factors for more fastidious, dimorphic fungil. Gorman demonstrated increased recovery of *H. capsulatum* when the medium was supplemented with blood.[8] Blood also aids in the conversion of *H. capsulatum* and *B. dermatitidis* to the yeast phase.

CRITERION™ SabHI Agar Base can be made selective by the incorporation of chloramphenicol, cycloheximide and gentamicin. Chloramphenicol inhibits a range of gram-positive and gram-negative bacteria; cycloheximide inhibits saprophytic molds but may also inhibit the growth of some significant pathogens (e.g., *Cryptococcus neoformans*, some *Candida* species, some *Aspergillus* spp. and mucormycetes (formally zygomycetes)); gentamicin inhibits the growth of most gram-negative bacteria.

FORMULA*

Gram weight per liter:	59.0gm/L

Dextrose	21.0gm
Brain Heart Infusion	10.0gm
Meat Peptone	7.25gm
Casein Peptone	2.25gm
Sodium Chloride	2.5gm
Disodium Phosphate	1.25gm
Agar	15.0gm

Final pH 7.0 +/- 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 2-30ºC. Dehydrated culture medium is very hygroscopic and will clump when exposed to moisture and air. Keep lid tightly sealed. Protect dehydrated culture media from moisture and light. Dehydrated culture media should be discarded if clumped, if the media is not free-flowing or if the color has changed from its original light beige.

Store the prepared culture media at 2-8ºC and do not remove the container desiccant, if applicable.

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.

METHOD OF PREPARATION FOR DEHYDRATED CULTURE MEDIA

1. Suspend 59.0gm of the dehydrated culture media in one liter of distilled or deionized water. Stir to mix thoroughly.

2. Heat to boiling for one minute to dissolve completely. Do not overheat.

3. Sterilize in the autoclave at 121ºC for 15 minutes.

4. Cool to 45-50ºC and dispense as desired.*

5. Aseptically pour desired volume into sterile containers.

* Note: Additional selective ingredients and/or blood may be aseptically added prior to dispensing media into desired sterile containers.

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. W75.

LIMITATIONS

For the proper identification of fungi, microscopic examination and evaluation of morphological structures is required. Further biochemical, physiological, serological tests and microscopic morphology of pure cultures are recommended for complete identification. For more information see appropriate references.

For selective media, specific strains of fungi for which the medium is designed to isolate often may be inhibited. Fungi for which the medium is designed to inhibit may grow.

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

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.

Accurate counting may be difficult with molds or spreading colonies.

Rare, fastidious microorganisms may not grow on selective media formulations

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, incubators, tubes, bottles, petri dishes, 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	24-48hr	35°C	Aerobic	Growth

Trichophyton mentagrophytes ATCC® 9533	G	7 days	15-30°C	Aerobic	Growth

* 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™ SabHI Agar Base powder should appear homogeneous, free-flowing, and light beige in color. The prepared media should appear slightly opalescent, and amber 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. Versalovic, J., 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. *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. *Quality Assurance for Commercially Prepared Microbiological Culture Media*, M22. Clinical and Laboratory Standards Institute (CLSI - formerly NCCLS), Wayne, PA.

8. Gorman, J.W. 1967. *Am. J. Med. Technol.*; 33:151.

9. Sabouraud. 1892. *Ann. Dermatol. Syphil.*; 3:1061.

IFU-10249[A]

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

HDQA 2207B [D]