CRITERION™ SABOURAUD DEXTROSE (SABDEX) AGAR

Cat. no. C6810	CRITERION™ Sabouraud Dextrose Agar	127gm
Cat. no. C6811	CRITERION™ Sabouraud Dextrose Agar	500gm
Cat. no. C6812	CRITERION™ Sabouraud Dextrose Agar	2kgm
Cat. no. C6813	CRITERION™ Sabouraud Dextrose Agar	10kg
Cat. no. C6814	CRITERION™ Sabouraud Dextrose Agar	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ Sabouraud Dextrose Agar is recommended for the isolation, cultivation, and maintenance of non-pathogenic and pathogenic species of fungi and yeasts.

SUMMARY

Sabouraud Dextrose Agar was formulated by Sabouraud in 1892, for culturing dermatophytes.[13] The pH is adjusted to approximately 5.6 in order to enhance the growth of fungi, especially dermatophytes, and to slightly inhibit bacterial growth in clinical specimens.[2] This medium is recommended for mold and yeast counts by the *U.S. Pharmacopeia*, *Standard Methods for the Examination of Water and Wastewater*, the Association of Official Analytical Chemists, and the *Compendium of Methods for the Microbiological Examination of Foods*.[3,6,14,15]

CRITERION™ Sabouraud Dextrose Agar contains peptones which provide a nutritious source of amino acids and nitrogenous compounds for the growth of fungi and yeasts. Dextrose is added as the energy and carbon source. Chloramphenicol may be added as a broad spectrum antimicrobial, to inhibit growth of a wide range of gram-positive and gram-negative bacteria.

FORMULA

Gram weight per liter:	65.0gm/L
Dextrose	40.0gm
Pancreatic Digest of Casein	5.0gm
Peptic Digest of Animal Tissue	5.0gm
Agar	15.0gm

Final pH 5.6 +/- 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. 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 plated media at 2-8ºC. Store the prepared tubed and/or bottled media at 2-30ºC.

The expiration dating 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 quality control incubation times.

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." The "Guidelines for Isolation Precautions" is available from the Centers for Disease Control and Prevention at www.cdc.gov/ncidod/dhqp/gl_isolation.html.

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 M-29: *Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline.*

Sterilize all biohazard waste before disposal.

Refer to the document "Precautions When Using Media" for more information.

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

METHOD OF PREPARATION FOR DEHYDRATED CULTURE MEDIA

1. Suspend 63.5gm of the dehydrated culture media in 1 liter of distilled or deionized water.

2. Heat to boiling and mix to dissolve completely.

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

PROCEDURE

Specimen Collection: Consult listed references for information on specimen collection.[1,2,4,5,7-10] 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 the listed references for information regarding the processing and inoculation of specimens.[1,2,4,5,7-10]

Method of Use: Allow media to warm to room temperature, and the agar surface to dry before inoculating. Inoculate

and streak the specimen as soon as possible after collection. If the specimen to be cultured is on a swab, roll the swab over a small area of the agar surface. Streak for isolation with a sterile loop. Incubate plates in an inverted position. The caps of tubed media should be slightly loosened. Once inoculated, media should be protected from light and incubated aerobically at 25-35ºC. with increased humidity for four weeks or longer. Our MycoSeal™ product (Cat. no. SS9225) may be used to seal the plates to keep moisture from evaporating from SabDex plated media, while still allowing atmospheric circulation. Examine plates for typical colonial and hyphal morphology and color.

Spread Plate Method:

1. Prepare decimal dilutions in sterile diluent to obtain 30-300 CFU per plate.

2. Aseptically inoculate agar surface with 0.1ml of well mixed diluted sample.

3. Spread the dilution evenly over the surface of the medium.

4. Using a sterile spreader device, distribute the inoculum evenly over the agar surface.

5. Incubate plates aerobically at 15-30ºC. for up to 7 days.

Pour Plate Method:

1. Melt agar by placing in a boiling waterbath until liquified.

2. Cool media to 45-50ºC. Maintain in a 45-50º waterbath until ready to pour.

3. Prepare decimal dilutions in sterile diluent to obtain 30-300 CFU per plate.

4. Place a 1ml inoculation into a sterile petri plate.

5. Aseptically pour approximately 18ml of the cooled media (45-50ºC.) over the inoculum. Carefully swirl the plate to mix the inoculum evenly.

Note: After autoclaving, do not heat media longer than 3 hours at 45-50ºC. Sterile solidified medium can only be remelted once.

6. Allow to solidify.

7. Incubate plates aerobically at 15-30ºC. for up to seven days.

INTERPRETATION OF RESULTS

Identification of fungi is performed by observing various aspects of colony morphology, characteristic microscopic structures, rate of growth, media which supports the organisms growth, and source of the specimen. Yeasts are identified by various biochemical tests. Consult the listed references for information regarding the identification and further testing of fungi and yeast cultures.[1,2,4,5,7-10]

Spread and Pour plate Methods

Following incubation, examine the plates for growth. Count the number of colonies and express in number of colony forming units (CFU) per gram or milliliter of sample; take into account the dilution factor. If duplicate plates were set-up, express the average for the two plates in terms of the number of microorganisms per gram or milliliter of sample. Consult listed references for additional information on interpretation and enumeration of microbial growth on this medium.[1-8]

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.

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

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 Certificates of Analysis (CofA). The following organisms are routinely used for testing at Hardy Diagnostics:

Test Organisms	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	
Candida albicans ATCC ® 10231	J	1-3 days	15-30°C	Aerobic	Growth
Trichophyton mentagrophytes ATCC ® 9533	G	1-3 days	15-30°C	Aerobic	Growth, may take up to one week
Aspergillus brasiliensis ATCC ® 16404	J	1-5 days	15-30°C	Aerobic	Growth, may take up to one week

* 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 certificates of analysis (CofA) available from Hardy Diagnostics Certificates of Analysis website. In addition, refer to the following document "Finished Product Quality Control Procedures," for more information on QC or see reference(s) for more specific information.

PHYSICAL APPEARANCE

CRITERION™ Sabouraud Dextrose Agar powder should appear homogeneous, free-flowing, and light beige in color. The prepared media should appear translucent, and light 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. Ajello, et al. 1963. *CDC Laboratory Manual for Medical Mycology*, PHS Publication No. 994. U.S. Gov't Printing Office, Washington, D.C.

3. Association of Official Analytical Chemists (AOAC). 1992. U.S. Food and Drug Administration, *Bacteriological Analytical Manual*, 7th ed. Arlington, VA.

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

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

6. Greenberg, A.E., et al. (ed.). 1992. *Standard Methods for the Examination of Water and Wastewater*, 18th ed. APHA, Washington, D.C.

7. Haley, L.D., et al. 1980. *Cumitech 11: Practical Methods for Culture and Identification of Fungi in the Clinical Microbiology Laboratory*, Coordinating ed., J.C. Sherris. American Society for Microbiology, Washington, D.C.

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

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

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

11. MacFaddin, J.F. 1985. *Media for Isolation, Cultivation, Identification, Maintenance of Bacteria*, Vol. I. Williams & Wilkins, Baltimore, MD.

12. *Quality Assurance for Commercially Prepared Microbiological Culture Media*, M22. Clinical and Laboratory Standards Institute (CLSI - formerly NCCLS), Wayne, PA.

13. Sabouraud, R. 1892. *Ann. Dermatol. Syphil.*; 3:1061.

14. *U.S. Pharmacopeia*, 22nd rev. 1990. U.S. Pharmacopeial Convention, Rockville, MD.

15. Vanderzant, C. and D.F. Splittstoesser, (ed.). 1992. *Compendium of Methods for the Microbiological Examination of Foods*, 3rd ed. APHA, Washington, D.C.

16. The Official Compendia of Standards. USP General Chapter <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests. *USP-NF*. United States Pharmacopeial Convention Inc., Rockville, MD.

17. The Official Compendia of Standards. USP General Chapter <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms. *USP-NF*. United States Pharmacopeial Convention Inc., Rockville, MD.

IFU-10250[A]

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

Email: TechService@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 [C]