IFU

HARDY DIAGNOSTICS
A Culture of Service™

Instructions for Use

CRITERION™ SABOURAUD DEXTROSE (SABDEX) AGAR WITH CHLORAMPHENICOL

Cat. no. C6780	CRITERION™ SabDex Agar with Chloramphenicol	127gm
Cat. no. C6781	CRITERION™ SabDex Agar with Chloramphenicol	500gm
Cat. no. C6782	CRITERION™ SabDex Agar with Chloramphenicol	2kg
Cat. no. C6783	CRITERION™ SabDex Agar with Chloramphenicol	10kg
Cat. no. C6784	CRITERION™ SabDex Agar with Chloramphenicol	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ Sabouraud Dextrose (SabDex) Agar with Chloramphenicol is recommended as a selective agar medium for the isolation, identification and cultivation of fungi.

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

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] Sabouraud Dextrose Agar 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] Chloramphenicol in Sabouraud Dextrose with Chloramphenicol is added to inhibit bacterial overgrowth while permitting successful selective isolation of fungi and yeasts.

Sabouraud Dextrose Medium 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:	63.4gm/L
Dextrose	40.0gm
Pancreatic Digest of Casein	5.0gm
Peptic Digest of Animal Tissue	5.0gm

Chloramphenicol	50.0mg
Agar	13.0gm

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 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 culture media 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.

METHOD OF PREPARATION FOR DEHYDRATED CULTURE MEDIA

1. Suspend 63.4gm 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.

4. Dispense into sterile containers as desired.

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. W72.

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.

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® 10231	A	48hr	35°C	Aerobic	Growth
Trichophyton mentagrophytes ATCC® 9533	G	7 days	15-30°C	Aerobic	Growth
Aspergillus brasiliensis ATCC® 16404	G	7 days	15-30°C	Aerobic	Growth
Escherichia coli ATCC® 25922	B	24hr	35°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™ SabDex Agar with Chloramphenicol powder should appear homogeneous, free-flowing, and light beige in color. The prepared media should appear clear to trace hazy, 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. 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.

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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* , 23nd rev. 1995. 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.

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Ordering Information

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

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