IFU

Instructions for Use

CRITERION™ SABOURAUD DEXTROSE (SABDEX) AGAR WITH LECITHIN AND TWEEN® 80

Cat. no. C6800	CRITERION™ SabDex Agar with Lecithin and Tween® 80	138gm
Cat. no. C6801	CRITERION™ SabDex Agar with Lecithin and Tween® 80	500gm
Cat. no. C6802	CRITERION™ SabDex Agar with Lecithin and Tween® 80	2kg
Cat. no. C6803	CRITERION™ SabDex Agar with Lecithin and Tween® 80	10kg
Cat. no. C6804	CRITERION™ SabDex Agar with Lecithin and Tween® 80	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ Sabouraud Dextrose Agar with Lecithin and Tween® 80 is recommended for the cultivation of fungi from environmental surfaces.

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 (Sabdex) Agar was formulated by Sabouraud in 1892, for culturing dermatophytes.[5] 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*.[1,2,6,7]

Germicidal or disinfectant residue from environmental surfaces is neutralized by the addition of lecithin and Tween® 80. Neutralization of these residues reduces their inhibitory effect which would ultimately result in the lowering of the microbial count. Quaternary ammonia compounds are neutralized by lecithin while phenolic disinfectants and hexachlorophene are neutralized by Tween® 80. Together, lecithin and Tween® 80 neutralize ethanol.

Sabouraud Dextrose Medium contains digests of animal tissues (peptones) which provide a 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:	71.0gm/L
Dextrose	40.0gm

Pancreatic Digest of Casein	10.0gm
Tween® 80	5.0gm
Lecithin	0.7gm
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 2-8ºC. 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 homogeneous, moist, and lumpy 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 69.0gm 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. **Do not overheat.**

4. Cool to 45-50ºC.

To prepare contact plates, aseptically pour approximately 17ml into 15x60mm plates to give a meniscus of agar which

extends above the top of the poured plate.

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. W71.

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	
Aspergillus brasiliensis formerly *A. niger* ATCC® 16404	J	up to 7 days	15-30°C	Aerobic	Growth
Candida albicans ATCC® 10231	J	up to 7 days	15-30°C	Aerobic	Growth
Trichophyton mentagrophytes ATCC® 9533	J	up to 7 days	15-30°C	Aerobic	Growth, may take up to one week

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USER QUALITY CONTROL

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

PHYSICAL APPEARANCE

CRITERION™ Sabouraud Dextrose Agar with Lecithin and Tween® 80 powder should appear homogeneous, moist,

and lumpy, and light beige in color. The prepared media should appear slightly opalescent, and light amber in color.

REFERENCES

1. Association of Official Analytical Chemists. *Official Methods of Analysis*[sm], AOAC, Washington, D.C.

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

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

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

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

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

7. 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

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]