IFU

Instructions for Use

SABOURAUD DEXTROSE (SABDEX) WITH LECITHIN AND TWEEN® 80 MEDIA

Cat. no. Q75	SabDex Agar with Lecithin and Tween® 80, 20x125mm Tube, 18ml Deep	20 tubes/box
Cat. no. U175	SabDex Agar with Lecithin and Tween® 80, 500ml Polycarbonate Bottle, 400ml	10 bottles/box
Cat. no. U431	SabDex Agar with Lecithin and Tween® 80, 16oz Glass Bottle, 400ml	12 bottles/box
Cat. no. P46	SabDex Agar with Lecithin and Tween® 80, 15x60mm Contact Plate, 15ml	10 plates/bag
Cat. no. W71	SabDex Agar with Lecithin and Tween® 80, 15x100mm Plate, 26ml	10 plates/bag

INTENDED USE

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

Dabouraud Dextrose Agar with Lecithin and Tween® 80 is not intended to be used for diagnosis of human disease.

SUMMARY

Sabouraud Dextrose Agar was formulated by Sabouraud in 1892 for culturing dermatophytes.[4] Sabouraud Dextrose Medium contains digests of animal tissues (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. Lecithin and Tween® 80 are added to neutralize the antimicrobial effects of disinfectants or cleaning solutions used on environmental surfaces.The pH is adjusted to approximately 5.6 in order to enhance the growth of fungi, especially dermatophytes.

FORMULA

Ingredients per liter of deionized water:*

Sabouraud Dextrose Agar:	
Dextrose	40.0gm
Pancreatic Digest of Casein	5.0gm
Peptic Digest of Animal Tissue	5.0gm
Agar	15.0gm
Lecithin	0.7gm
®	

Tween 80	5.0ml

Final pH 5.6 +/- 0.2 at 25ºC.

* Adjusted and/or supplemented as required to meet performance criteria.

STORAGE AND SHELF LIFE

Upon receipt store SabDex Agar with Lecithin and Tween® 80 at 2-8ºC. away from direct light. Media should not be used if there are any signs of deterioration (shrinking, cracking, or discoloration), contamination, or if the expiration date has passed. Product is light and temperature sensitive; protect from light, excessive heat, moisture, and freezing.

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

Specimen Collection: Consult listed references for information on specimen collection.[1-3, 5-7] 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.[1-3, 5-7]

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. MycoSeal™ (Cat. no. SS9225) may be used to seal plate lids to keep moisture from evaporating from plated media, while still allowing for atmospheric circulation. Examine plates for typical colonial and hyphal morphology and color.

For melting bottled media and agar deeps: Liquefy the medium by autoclaving at 121ºC. for 1-3 minutes Cool the medium to 45-50ºC. and pour into sterile petri dishes. Allow the agar to solidify for at least 30 minutes prior to use. Alternatively, a covered, boiling waterbath (100ºC.) can be used. There should be enough water in the waterbath to

reach the top of the media line. Heat in a waterbath until melted through. A covered waterbath will help to reach and maintain the media temperature prior to dispensing.

Note: After autoclaving, do not heat media using a hot plate, heat block or waterbath for longer than 3 hours at 45-50 degrees C. Melt only enough media that can be poured within a 3 hour time period. For optimal performance, sterile solidified medium should be remelted only once prior to use.

For tubed media: Inoculate the deep and replace the cap loosely to allow for air circulation. Media should be protected from light and incubated aerobically; solid media should be incubated under conditions of increased humidity during prolonged incubation. Examine SabDex Broth for growth by comparing turbidity to an uninoculated control. Subculture onto an appropriate agar medium when growth is observed.

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 organism's growth, and source of 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.[1-3, 5-7]

LIMITATIONS

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

Refer to the document "Limitations of Procedures and Warranty" for more information.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as loops, slides, colony counters, microscopes, MycoSeals™ (Cat. no. SS9225), incinerators, and incubators, etc., as well as serological and biochemical reagents, 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 ATCC® 16404	G	1-5 days	20-25°C	Aerobic	Growth
Candida albicans ATCC® 10231	A	24-48 hrs	30-35°C	Aerobic	Growth
Trichophyton mentagrophytes ATCC® 9533	G	1-5 days	20-25°C	Aerobic	Growth may take up to one week

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

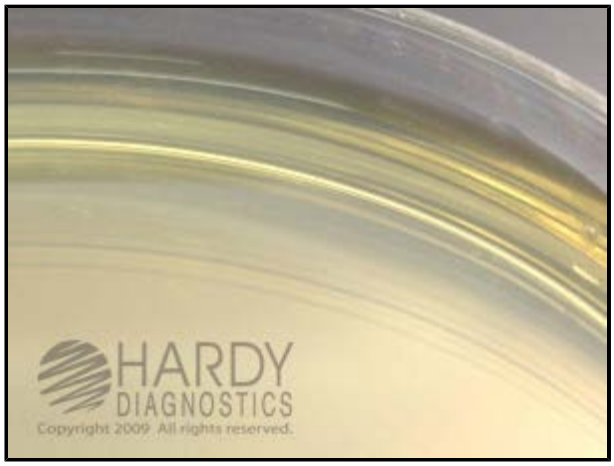
** Consult appropriate regulatory agency for user QC requirements.

USER QUALITY CONTROL

End users of commercially prepared 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. Also refer to the document "Finished Product Quality Control Procedures," and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media* for more information on the appropriate QC procedures. See the references below.

PHYSICAL APPEARANCE

Sabouraud Dextrose Media should appear translucent, and light amber in color.



Uninoculated plate of Sabouraud Dextrose Agar, with Lecithin and Tween® 80.

REFERENCES

1. U.S. Food and Drug Administration. *Bacteriological Analytical Manual.* AOAC, Arlington, VA. www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm

2. American Public Health Association. *Standard Methods for the Examination of Water and Wastewater,* APHA, Washington, D.C.

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

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

5. APHA Technical Committee on Microbiological Methods for Foods. *Compendium of Methods for the Microbiological Examination of Foods*, APHA, Washington, D.C.

6. 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.

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

ATCC is a registered trademark of the American Type Culture Collection.

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