IFU

Instructions for Use

SABOURAUD DEXTROSE (SABDEX) MEDIA, USP

Cat. no. W70	SabDex Agar, USP, 15x100mm Plate, 26ml	10 plates/bag
Cat. no. H39	SabDex Agar, USP, 15x150mm Plate, 70ml	10 plates/bag
Cat. no. Q31	SabDex Agar, USP, 20x125mm Tube, 18ml Deep	20 tubes/box
Cat. no. Q83	SabDex Agar, USP, 20x150mm Tube, 20ml Deep	100 tubes/box
Cat. no. U227	SabDex Agar, USP, 16oz Glass Bottle, 200ml	12 bottles/box
Cat. no. U270	SabDex Agar, USP, 500ml Polypropylene Bottle, 200ml	10 bottles/box
Cat. no. U352	SabDex Agar, USP, 16oz Glass Bottle, 400ml	12 bottles/box
Cat. no. U353	SabDex Agar, USP, 500ml Polycarbonate Bottle, 500ml	10 bottles/box
Cat. no. W70R	SabDex Agar, USP, Red Tinted 15x100mm Plate, 26ml	10 plates/bag
Cat. no. W82	SabDex Agar Blue, USP, 15x100mm Plate, 26ml	10 plates/bag
Cat. no. U73	SabDex Broth, USP, 125ml Polycarbonate Bottle with Septum Cap, 100ml	16 bottles/box

INTENDED USE

Hardy Diagnostics Sabouraud Dextrose Agar, USP and Sabouraud Dextrose Broth, USP are recommended for the isolation, cultivation, and maintenance of non-pathogenic and pathogenic species of fungi (yeast and mold), and meet the harmonized USP/EP/JP standards for the microbial examination of non-sterile products.[5,6]

Cat. nos. H39, Q31, Q83, U227, U270, U352, U353, W70R, W82, and U73 are not intended to be used for the diagnosis of human disease.

SUMMARY

Sabouraud Dextrose Agar was formulated by Sabouraud in 1892 for culturing dermatophytes.[3] The pH is adjusted to approximately 5.6 in order to enhance the growth of fungi, especially dermatophytes, and to slightly inhibit bacterial growth.[1] 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 (AOAC), and the *Compendium of Methods for the Microbiological Examination of Foods*.[2,4-6] Sabouraud Dextrose Broth is a modification of the original formulation made with only half the amount of dextrose and no agar. It is recommended by the *U.S. Pharmacopeia* for sterility testing of pharmaceutical products.[5,6]

Sabouraud Dextrose Medium contains digests of animal tissues (peptones) and casein 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. Agar, when used, is added as a solidifying agent.

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

Final pH 5.6 +/- 0.2 at 25°C.

In addition,

Sabouraud Dextrose Broth contains only 20.0gm of Dextrose and does not contain any Agar.

Final pH 5.6 +/- 0.2 at 25°C.

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

STORAGE AND SHELF LIFE

Storage: Upon receipt store plated products (Cat. no. W70, W70R, H39, and W82) at 2-8°C away from direct light. SabDex media tubed and bottled products (Cat no. Q83, Q31, U73, U227, U270, U352, and U353) should be stored at 2-30°C 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

Cat. no. W70

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 Precautions for blood. Do not ingest, inhale, or allow to come into contact with skin.

This product is for *in vitro* diagnostic 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.

Cat. nos. H39, Q31, Q83, U227, U270, U352, U353, W70R, W82, U73

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, processing and inoculation. [2,4-6]

Before Use: The medium should be warmed to room temperature and the surface dry - *for solid media* prior to inoculating. To reduce the potential for cross-contamination, it is strongly suggested that appropriate gowning and glove procedures, designated aseptic processing areas, appropriate use of sporicidal disinfectants, and environmental monitoring procedures be strictly enforced to reduce the likelihood of accidental contamination.[1] Use of stringent aseptic techniques, appropriate sporicidal agents, and a laminar clean bench are recommended in accordance with *USP Microbiological Best Laboratory Practices <1117>* and *Sterility Testing - Validation of Isolator Systems <1208>*.

For re-melting solid tube and bottle media: Autoclave containers with slightly loose caps at 121ºC for 1-3 minutes or until melted. Do not heat media longer than 3 hours at 45-50ºC. Alternatively, solid agar in capped containers can be racked and placed in a covered, boiling water bath (100ºC) before use. There should be enough water in the water bath to reach the top of the media line. A covered water bath will maintain consistent temperature of the media until melted. Cool media to 45-50ºC and aseptically dispense into sterile containers. **Note:** Sterile solidified media can be re-melted only once. In addition, the use of microwaves to melt media is not advised.

Examine SabDex Broth for growth by comparing turbidity to an uninoculated control. Subculture onto an appropriate agar medium when growth is observed.

Sedimentation (Settling) Plate Method: Place the plate on a clean piece of paper and expose the agar by removing the lid. Do not invert the lid while removed to avoid exposure to falling sediment. Expose the agar for 15 minutes or

longer, depending upon established procedures, and replace the lid. Incubate according to laboratory protocol.

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.[2,4-6]

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	
Candida albicans ATCC® 10231	J	24-48hr	20-25°C	Aerobic	Growth
Candida albicans ATCC® 10231 ****	J	24-48hr	30-35°C	Aerobic	Growth
Aspergillus brasiliensis ATCC® 16404	J	1-5 days	20-25°C	Aerobic	Growth
Trichophyton mentagrophytes ATCC® 9533 ***	G	1-5 days	20-25°C	Aerobic	Growth

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

** Tested in accordance with USP <61> and <62>.[1]

*** Organism tested only on Cat. no. W70.

**** Organism not tested in this format on Cat. no. U73.

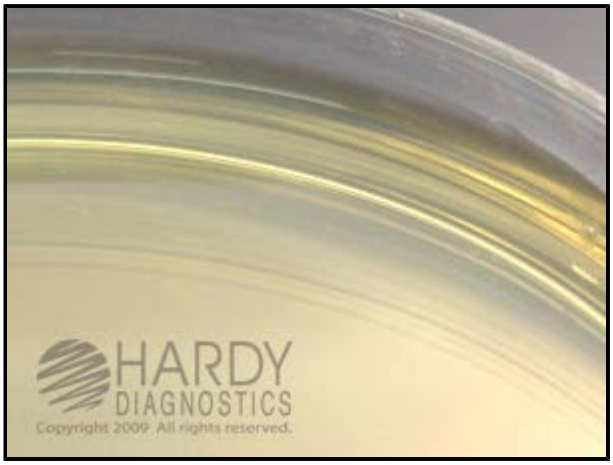
USER QUALITY CONTROL

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.

REFERENCES

1. Ajello, et al. 1963. *CDC Laboratory Manual for Medical Mycology*, PHS Publication No. 994. U.S. Gov't Printing Office, Washington, D.C.

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

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

4. APHA Technical Committee on Microbiological Methods for Foods. 2001. *Compendium of Methods for the Microbiological Examination of Foods,* 4th ed. APHA, Washington, D.C.

5. 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.

6. 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.

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

HDQA 2207H [D]