IFU

Instructions for Use

SABOURAUD DEXTROSE (SABDEX) MEDIA, USP, IRRADIATED

Cat. no. P595	SabDex (Sabouraud Dextrose) Agar with Lecithin and Tween® 80, USP, Irradiated, Triple Bagged, Contact Plate, Lok-Tight™, 15ml*	10 plates/bag
Cat. no. W565	SabDex (Sabouraud Dextrose) Agar, USP, SterEM™, Irradiated, Triple Bagged, 15x100mm Plate, 26ml*	10 plates/bag
Cat. no. W595	SabDex Agar with Lecithin and Tween® 80, USP, SterEM™, Irradiated, Triple Bagged, 15x100mm Plate, 34ml*	10 plates/bag
* A fourth sterile sample bag is included for packaging after the sample is collected.		

INTENDED USE

Hardy Diagnostics Sabouraud Dextrose (SabDex) Agar, USP, Irradiated is recommended for the detection, isolation, cultivation, and maintenance of non-pathogenic and pathogenic species of fungi (yeast and mold). Sabouraud Dextrose (SabDex) Agar with Lecithin and Tween® 80, USP, Irradiated is recommended for the detection and enumeration of fungi (yeast and mold) from environmental sources.

The media are formulated according to the United States Pharmacopoeia (USP) and meet the harmonized USP/EP/JP standards for the microbial examination of non-sterile products.[7]

This product is not intended to be used for the diagnosis of human disease.

SUMMARY

Sabouraud Dextrose Agar was formulated by Sabouraud in 1892, for culturing dermatophytes.[6] The pH is adjusted to approximately 5.6 in order to enhance the growth of fungi, especially dermatophytes, and to slightly inhibit bacterial growth. This medium is recommended for mold and yeast counts by the *United States 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*.[1-3,7,8]

Sabouraud Dextrose (SabDex) Agar contains digests of animal tissues (peptones), which provide a nutritious source of amino acids and nitrogenous compounds for the growth of fungi. Dextrose is added as the energy and carbon source. Lecithin and Tween® 80 in the formulation serve to neutralize quarternary ammonium compounds and phenolic disinfectants, respectively.

Sabouraud Dextrose (SabDex) Agar with Lecithin and Tween® 80 Contact Plates are used to sample environmental surfaces for the presence of fungi (yeast and mold) using the Contact Method for sampling floors, counters, etc.

The plates are triple bagged and sterilized by irradiation to promote a higher sterility assurance level.

FORMULA

Ingredients per liter of deionized water:*

SabDex Agar contains:	
Dextrose	40.0gm
Pancreatic Digest of Casein	5.0gm
Peptic Digest of Animal Tissue	5.0gm
Agar	15.0gm
SabDex Agar with Lecithin and Tween® 80 also contain:	
Lecithin	0.7gm
Tween® (polysorbate) 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

Storage: Upon receipt store media at 15-30ºC. away from direct light. Media should not be used if there are any signs of contamination, deterioration, discoloration, or if the expiration date has passed. Product is light and temperature sensitive. Protect from freezing.

Do not use irradiated media if there is any damage to the packaging prior to use.

For irradiated media: Inspect each bag prior to opening and using the product.

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

Before Use of Plates: For irradiated media, it is possible that variation in temperature and pressure during shipping and storage may cause condensation on the innermost bag surrounding the plates. If condensation of the packaging or plates is observed, remove the plates from the innermost packaging in a sterile environment and allow them to dry for 10-15 minutes before use.

SabDex Sedimentation Plate Method of Use: Place a new paper towel or parchment paper at the location where the sample is to be taken. Place the petri dish on the paper and expose the agar by removing the lid. In order to prevent sediment from falling into the lid, place the lid, without inversion on the paper. Expose the agar for 15 minutes, replace the lid and incubate according to laboratory procedures. Consult listed references for information on these methods.[1-4,7,8]

SabDex Contact Plate Method of Use: Select a surface to test. Sample the surface by firmly pressing the agar against the test area, using the thumb and second finger to hold the plate, and the first finger to press firmly and evenly on the base. The same amount of pressure should be used for each sample. Do not move the plate laterally, as this spreads contaminants across the agar surface. A rolling motion may be used when slightly curved surfaces are sampled. Areas to be assayed may by divided into grids or sections, and samples taken from specific areas within the divisions. Incubate exposed plates at 25 to 35ºC. for 1-7 days, as required. Consult listed references for information on these methods.[1-4,7,8]

INTERPRETATION OF RESULTS

Consult the appropriate reference for information regarding further testing and identification of microbial cultures.[1-8]

Because of the inherent variability of environmental sampling methods, it is more useful to trend contamination recovery results rather than focus on the number of colonies recovered from a single sample. Action should be required when the contamination recovery rate trends above the recommended action levels for a significant time.

If action levels have been identified, a thorough investigation into the adequacy of personnel work practices, operational procedures, cleaning procedures and solutions, and air filtration efficiency within the processing area must be made. Once changes have been made, monitoring procedures must be repeated to determine if the changes made were effective. Documentation of all monitoring results, remedial action and follow-up monitoring must be maintained. Consult listed reference for more detailed information concerning plate count methods.[7]

Sedimentation Method: After incubation, colonies are counted, and results expressed as the number of colonies per square foot per minute. For contact plates, the media area is approximately 60cm^2, the number counted colonies can be divided by 60 to provide the estimated number of colonies per square centimeter.[1-3,8] Similarly, for 15x100mm plates, the number of counted colonies can be divided by 100 to provide the estimated number of colonies per square centimeter.

Contact Plate Method: After incubation, colonies are counted, and results recorded as the number of colonies per centimeter squared or as colonies per plate.[1-3,8]

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.

Avoid repeated and/or extreme variations in temperatures during storage, as this can cause the release of excessive moisture from the media in the bags and plates.

Accurate counting may be difficult with molds or spreading colonies.

Sampling challenges may occur with irregular, porous, rough or textured media surfaces.

Contact plate media are not recommended for sampling crevices or irregular surfaces.

If removing the Mylar bag and storing plates long-term in a controlled environment, 2-8°C storage conditions are recommended to prevent dehydration of the medium prior to use.

Storage at 2-8°C in the Mylar bags may result in moisture build-up inside sealed packs.

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, other culture media, swabs, applicator sticks, microscope slides and coverslips, 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
Aspergillus brasiliensis ATCC® 16404	J	1-5 days	20-25°C	Aerobic	Growth

Representative samples from each lot of irradiated media are held for seven days to confirm the media meet the validated sterilization process sterility assurance level (SAL) of 10^{-6} following ANSI/AAMI/ISO 11137.

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

** Tested in accordance with USP <61> and <62>.[7]

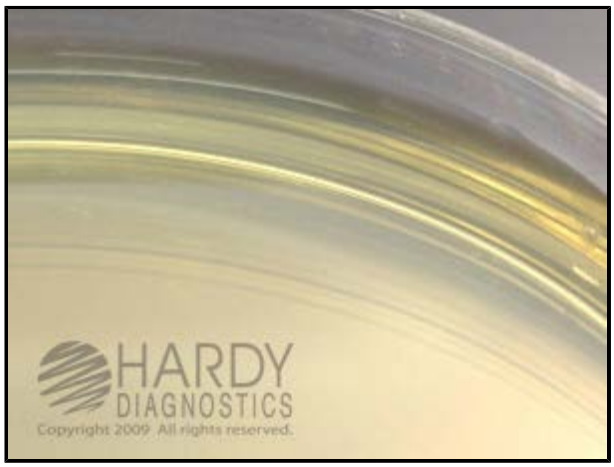
USER QUALITY CONTROL

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 (SabDex) Agar, USP, Irradiated should appear clear, slightly opalescent, and light amber in color.

Sabouraud Dextrose (SabDex) with Lecithin and Tween® 80, USP, Irradiated should appear translucent, and light amber in color.



Uninoculated plate of Sabouraud Dextrose Agar, USP, Irradiated.

REFERENCES

1. American Public Health Association. *Standard Methods for the Examination of Dairy Products,* APHA, Washington, D.C.

2. Vanderzant, C. and D.F. Splittstoesser, (ed.). 2001 *Compendium of Methods for the Microbiological Examination of Foods*, 4th ed. APHA, Washington, D.C.

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

4. MacFaddin, J.F. *Biochemical Tests for Identification of Medical Bacteria,* Lipincott Williams & Wilkins, Philadelphia, PA.

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

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

7. The Official Compendia of Standards. *USP-NF*. United States Pharmacopeial Convention, Rockville, MD.

8. Association of Official Analytical Chemists. *Official Methods of Analysis*, AOAC, Washington, D.C.

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

HDQA 2207D [D]