

PRODUCT INFORMATION AND QUALITY CONTROL SHEET

SABOURAUD DEXTROSE AGAR SLANT

I. INTENDED USE

Sabouraud Dextrose Agar is a general purpose medium used for the cultivation of yeasts and molds, especially dermatophytes.

II. SUMMARY AND EXPLANATION

Sabouraud Dextrose Agar was designed by Sabouraud for the cultivation of fungi, especially those associated with skin infections. The media is favorable for the isolation of fungi over bacteria due to the low pH (approximately 5.6).

III. PRINCIPLES OF THE PROCEDURE

Sabouraud Dextrose Agar contains peptones which are sources of nitrogenous growth factors. Dextrose provides an energy source for the growth of microorganisms.

IV. TYPICAL FORMULA AND APPEARANCE

Appearance = light amber, slightly opalescent

(Approximate formula* per liter of processed water)

Pancreatic Digest of Casein	5.0g
Peptic Digest of Animal Tissue	5.0
Dextrose	40.0
Agar	15.0
Cycloheximide	0.4
Chloramphenicol	0.05

*Adjusted and/or supplemented to meet performance criteria.

Final pH: 5.6 ± 0.2 @ 25°C

V. PRECAUTIONS

This product is for IN VITRO diagnostic use only. Culture specimens may contain microorganisms which can be potentially infectious to the user. Strict adherence to aseptic techniques and established precautions against microbiological hazards should be followed throughout the procedure. Carefully dispose of all items which contact patient specimens or isolated bacteria.

VI. STORAGE / SHELF LIFE

Media should be stored at 2-25°C (36-77°F). DO NOT FREEZE OR EXPOSE TO HIGH TEMPERATURES. Allow unopened tubes to warm to room temperature prior to inoculation. Prior to, and during inoculation procedures, tubes should be handled in a manner that minimizes product exposure to the environment. Product which has exceeded the assigned expiration date noted on the label should not be used. Do not use tubes that exhibit evidence of drying, cracking, discoloration, microbial contamination or any other signs of deterioration.

VII. SPECIMEN COLLECTION

The quality of culture results depends primarily on the adequacy and condition of the specimen submitted for examination. Proper specimen collection techniques must be followed to ensure the most accurate culture results. Consult appropriate references for information about the processing and inoculation of specimens for fungal culture.^{2,3,4} Sterile swabs and collection containers should be used. Specimens should be collected prior to the initiation of antifungal therapy.

VIII. MATERIALS PROVIDED

Sabouraud Dextrose Agar Slants (10/pkg)

IX. MATERIALS REQUIRED BUT NOT PROVIDED

Incubator maintaining 33-37°C and/or 25-30°C.

Ancillary culture media, reagents and laboratory equipment as required.

X. PROCEDURE

Inoculate the specimen as soon as possible after it is received in the laboratory. Streak the specimen with a sterile inoculating loop to obtain isolated colonies. Reference texts should be consulted for detailed information on processing and inoculating specimens for fungal culture.^{2,3,4} When isolating fungus from specimens containing contaminating microbial flora, a selective fungal isolation medium in addition to Sabouraud Dextrose Agar should be inoculated.

Incubate the inoculated plates at 25-30°C, agar side up, in an atmosphere containing increased humidity. For isolation of fungus associated with systemic mycoses, two sets of culture plates should be inoculated. Incubate one set of plates at 25-30°C, and the duplicate set at 33-37°C.

Examine cultures at least weekly for fungal growth. Plates should be held for 4-6 weeks before being reported as negative for growth.

XI. EXPECTED RESULTS

CLSI CONTROL ORGANISMS (ATCC STRAINS)

Candida albicans Growth (smooth, white-grey glistening colonies)
(ATCC 60193)

Trichophyton mentagrophytes Growth (white cotton-like colonies)
(ATCC 9533)

XII. LABORATORY RESULTS

This medium is intended to be used as a primary isolation medium. Identification of fungal organisms may be made on the basis of typical gross colony morphology, microscopic characteristics, and physiological and pathological characteristics. Additional test procedures should be used to confirm findings.

XIII. LIMITATIONS

The ability to detect microorganisms by culture techniques can be affected by the following factors: improper specimen collection, storage and inoculation, initiation of anti-infective therapy prior to specimen collection, improper culture incubation temperatures and atmospheres, improper length of culture incubation, and improper storage and handling of culture media.

XIV. REFERENCES

- Difco Manual. 1984. Difco Laboratories, Inc. Detroit, MI.
Ajello, L.K. Georg, W. Kaplan and L. Kaufman. 1963. CDC Laboratory Manual for Medical Mycology, PHS Publication No. 994, U.S. Government Printing Office, Washington D.C.
McGinnis, M.R. 1980. Laboratory Handbook of Medical Mycology. Academic Press Inc., N.Y., N.Y.
Lennette, E.H., ed. 1985. Manual of Clinical Microbiology, 4th ed. American Society for Microbiology, Washington, D.C.

QUALITY CONTROL PROCEDURES AND INFORMATION

It is recommended that the following quality assurance and quality control procedures be performed on the batch of product.

I. QUALITY ASSURANCE

The following quality assurance procedures must be performed to assure the product will perform according to its intended use within the assigned expiry date:

- Daily, document that product storage area maintains temperature within the recommended range.
- Daily, document that laboratory incubator maintains temperature within the recommended range: 25-30°C, or 33-37°C.

II. QUALITY CONTROL

The following incoming inspection procedures must be performed for each batch (batch = same lot, same shipment) of culture media received in the laboratory:

- Inspect vials according to instructions in Section VI "STORAGE/SHELF LIFE".
- Write in the lot number and expiration date of the product being accepted into the laboratory on a log sheet.
- Initial and date the log sheet.

Note: Notify Technical Service Immediately if media does not meet the inspection criteria.

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