BBL™ Sabouraud Brain Heart Infusion Agar Slants with Chloramphenicol and Gentamicin

IVD CE

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QUALITY CONTROL PROCEDURES

R_X Only

I INTRODUCTION

This medium is used in qualitative procedures for the selective isolation and cultivation of pathogenic fungi from clinical and nonclinical specimens.

II PERFORMANCE TEST PROCEDURE

1. Inoculate representative samples with the cultures listed below.
   a. For *B. dermatitidis* and *T. mentagrophytes* inoculate directly using a 0.01 mL loopful of fungal broth culture.
   b. For *C. albicans* and *E. coli* inoculate using 0.01 mL of saline suspensions diluted to yield 10^3–10^4 CFUs.
2. Incubate tubes with loosened caps at 25 ± 2 °C for up to 7 days in an aerobic atmosphere.
3. Expected Results

Organisms	ATCC®	Recovery
**Blastomyces dermatitidis*	56216	Fair to heavy growth
**Candida albicans*	10231	Fair to heavy growth
**Trichophyton mentagrophytes*	9533	Fair to heavy growth
**Escherichia coli*	25922	Inhibition (partial to complete)

*Recommended organism strain for User Quality Control.

III ADDITIONAL QUALITY CONTROL

1. Examine the tubes for signs of deterioration as described under "Product Deterioration."
2. Visually examine representative tubes to assure that any existing physical defects will not interfere with use.
3. Determine the pH potentiometrically at room temperature for adherence to the specification of 6.8 ± 0.2.
4. Incubate uninoculated representative samples at 20–25 °C and 30–35 °C and examine after 7 days for microbial contamination.

PRODUCT INFORMATION

IV INTENDED USE

This medium is used in qualitative procedures for the selective isolation and cultivation of pathogenic fungi from clinical and nonclinical specimens.

V SUMMARY AND EXPLANATION

Sabouraud Brain Heart Infusion Agar is based on the formulation of Gorman.[1] The combination of Brain Heart Infusion Agar and Sabouraud Dextrose Agar in this medium improves the recovery of fungi compared with the recovery on either medium individually.

The antimicrobial agents chloramphenicol and gentamicin are incorporated to improve the recovery of pathogenic fungi from specimens heavily contaminated with bacteria and saprophytic fungi.[2]

VI PRINCIPLES OF THE PROCEDURE

Sabouraud Brain Heart Infusion Agar consists of a combination of peptones and infusions of brain and heart tissue to supply amino acids and other complex nitrogenous substances. Dextrose is an energy source. Sodium chloride provides essential electrolytes. Disodium phosphate buffers the medium to maintain the pH.

Chloramphenicol is a broad-spectrum antibiotic that inhibits a wide range of gram-negative and gram-positive bacteria. Gentamicin is an aminoglycoside antibiotic that inhibits the growth of gram-negative bacteria.

VII REAGENTS

BD BBL Sabouraud Brain Heart Infusion Agar with Chloramphenicol and Gentamicin

Approximate Formula* Per Liter Purified Water

Brain Heart, Infusion from (Solids)	4.0 g	Disodium Phosphate	1.25 g
Peptic Digest of Animal Tissue	5.0 g	Agar	15.0 g
Pancreatic Digest of Casein	10.5 g	Chloramphenicol	0.05 g
Dextrose	21.0 g	Gentamicin	0.05 g
Sodium Chloride	2.5 g		

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

Warnings and Precautions: For *in vitro* Diagnostic Use.

Tubes with tight caps should be opened carefully to avoid injury due to breakage of glass.

Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. "Standard Precautions"[2-5] and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids. Prior to discarding, sterilize prepared tubes, specimen containers and other contaminated materials by autoclaving.

Storage Instructions: On receipt, store tubes in the dark at 2–8 °C. Avoid freezing and overheating. Do not open until ready to use. Minimize exposure to light. Tubed media stored as labeled until just prior to use may be inoculated up to the expiration date and incubated for up to 6 weeks. Allow the medium to warm to room temperature before inoculation.

Product Deterioration: Do not use medium if it shows evidence of microbial contamination, discoloration, drying, or other signs of deterioration.

VIII SPECIMEN COLLECTION AND HANDLING

Refer to appropriate texts for details of specimen collection and handling procedures.[6-8]

IX PROCEDURE

Material Provided: BD BBL Sabouraud Brain Heart Infusion Agar with Chloramphenicol and Gentamicin

Materials Required But Not Provided: Ancillary culture media, reagents, quality control organisms and laboratory equipment as required.

Test Procedure: Observe aseptic techniques.

Inoculate the medium as soon as possible after the specimen arrives at the laboratory. Streak the specimen over the surface of the medium with a sterile inoculating loop or needle. Consult appropriate references for information about the processing and inoculation of specimens such as tissues, skin scrapings, hair, nail clippings, etc.[6-12]

For isolation of fungi causing cutaneous mycoses, a general-purpose, nonselective medium should be inoculated along with selective medium. Incubate at 25–30 °C with increased humidity.

For isolation of fungi causing systemic mycoses, two sets of media should be inoculated, with one set incubated at 25–30 °C and the other set at 35 ± 2 °C.

All cultures should be examined at least weekly for fungal growth and should be held for 4–6 weeks before being reported as negative.

User Quality Control:

Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to pertinent CLSI guidance and CLIA regulations for appropriate Quality Control practices.

X RESULTS

Examine the medium for growth. Microscopic examination of the colony aids in identification.

XI LIMITATIONS OF THE PROCEDURE

This prepared medium is intended for primary isolation. Some diagnostic tests may be performed with the primary medium. However, a pure culture is recommended for biochemical tests and other identification procedures. Consult appropriate texts for further information.[7-12]

A single medium is rarely adequate for detecting all organisms of potential significance in a specimen. The agents in selective media may inhibit some strains of the desired species or permit growth of a species they were designed to inhibit, especially if the species is present in large numbers in the specimen. Specimens cultured on selective media should, therefore, also be cultured on nonselective media to obtain additional information and help ensure recovery of potential pathogens.

XII PERFORMANCE CHARACTERISTICS

Prior to release, all lots of **BD BBL** Sabouraud Brain Heart Infusion Agar with Chloramphenicol and Gentamicin are tested for performance characteristics. Representative samples of the lot are inoculated directly by streaking the agar slant with fresh broth cultures of *Trichophyton mentagrophytes* ATCC 9533 and *Blastomyces dermatitidis* ATCC 56216. Additional samples are inoculated with saline suspensions of *Candida albicans* ATCC 10231 and *Escherichia coli* ATCC 25922 diluted to yield 10^3–10^4 CFUs. Tubes are incubated with loose caps at 25 ± 2 °C for up to 7 days in an aerobic atmosphere. Fair to heavy growth is observed with *T. mentagrophytes*, *B. dermatitidis* and *C. albicans*. No growth is observed with *E. coli*.

XIII AVAILABILITY

Cat. No.	Description
297252	**BD BBL™** Sabouraud Brain Heart Infusion Agar Slants with Chloramphenicol and Gentamicin, Pkg. of 10 tubes

XIV REFERENCES

1. Gorman, J.W. 1967. SABHI, a new culture medium for pathogenic fungi. Am. J. Med. Technol. *33*:151–157.
2. Clinical and Laboratory Standards Institute. 2005. Approved Guideline M29-A3. Protection of laboratory workers from occupationally acquired infections, 3rd ed. CLSI, Wayne, Pa.
3. Garner, J.S. 1996. Hospital Infection Control Practices Advisory Committee, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Guideline for isolation precautions in hospitals. Infect. Control Hospital Epidemiol. *17*:53–80.
4. U.S. Department of Health and Human Services. 2007. Biosafety in microbiological and biomedical laboratories, HHS Publication (CDC), 5th ed. U.S. Government Printing Office, Washington, D.C.
5. Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC). Official Journal L262, 17/10/2000, p. 0021–0045.
6. Merz, W.G., and G.D. Roberts. 1991. Detection and recovery of fungi from clinical specimens, p. 588–600. *In* A. Balows, W.J. Hausler, Jr., K.L. Herrmann, H.D. Isenberg, and H.J. Shadomy (ed.), Manual of clinical microbiology, 5th ed. American Society for Microbiology, Washington, D.C.
7. Haley, L.D., H. Trandel, and M.B. Coyle. 1980. Cumitech 11, Practical method for culture and identification of fungi in the clinical mycology laboratory. Coordinating ed., J.C. Sherris. American Society for Microbiology, Washington, D.C.
8. Kwon-Chung, K.J., and J.E. Bennett. 1992. Medical mycology. Lea & Febiger, Philadelphia.
9. Forbes, B.A., D.F. Sahm, and A.S. Weissfeld. 1998. Bailey & Scott's diagnostic microbiology, 10th ed. Mosby, Inc., St. Louis.
10. Murray, P.R., E.J. Baron, M.A. Pfaller, F.C. Tenover, and R.H. Yolken (ed.). 1999. Manual of clinical microbiology, 7th ed. American Society for Microbiology, Washington, D.C.
11. Konenman, E.W., S.D. Allen, W.M. Janda, P.C. Schreckenberger, and W.C. Winn, Jr. 1992. Mycology, p. 791–877. Color atlas and textbook of diagnostic microbiology, 4th ed., J.P. Lippincott Co., Philadelphia.
12. Larone, D.H. 1993. Medically important fungi: a guide to identification, 2nd ed. American Society for Microbiology, Washington, D.C.

Technical Information: In the United States contact BD Technical Service and Support at 1.800.638.8663 or www.bd.com.

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