



## QUALITY CONTROL PROCEDURES

### I INTRODUCTION

This medium is used for the cultivation of dermatophytes and other pathogenic and nonpathogenic fungi from clinical and non-clinical specimens.

### II PERFORMANCE TEST PROCEDURE

- Inoculate representative samples with the cultures listed below.
  - For *Trichophyton mentagrophytes* ATCC® 9533 and *Aspergillus brasiliensis* ATCC 16404 inoculate directly using a 0.01 mL loopful of culture grown on **BBL™ Sabouraud Dextrose Agar**.
  - For *Candida albicans* ATCC 10231 and *Escherichia coli* ATCC 25922 inoculate using 0.01 mL of saline suspensions diluted to yield  $10^3 - 10^4$  CFUs.
- Incubate tubes with loosened caps at 25 – 30 °C for up to 7 days in an aerobic atmosphere.
- Expected Results

Organisms	ATCC	Recovery
* <i>Candida albicans</i>	10231	Fair to heavy growth
* <i>Trichophyton mentagrophytes</i>	9533	Fair to heavy growth
* <i>Aspergillus brasiliensis</i>	16404	Inhibition (partial to complete)
* <i>Escherichia coli</i>	25922	Inhibition (partial to complete)

\*Recommended organism strain for User Quality Control.

### III ADDITIONAL QUALITY CONTROL

- Examine tubes as described under "Product Deterioration."
- Visually examine representative tubes to assure that any existing physical defects will not interfere with use.
- Determine the pH potentiometrically at room temperature for adherence to the specification of  $5.6 \pm 0.2$ .
- 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 cultivation of dermatophytes and other pathogenic and nonpathogenic fungi from clinical and non-clinical specimens.

### V SUMMARY AND EXPLANATION

Sabouraud Dextrose Agar is a general-purpose medium developed by Sabouraud for the cultivation of dermatophytes.<sup>1</sup> The low pH of approximately 5.6 is favorable for the growth of fungi, especially dermatophytes, and inhibitory to contaminating bacteria in clinical specimens.<sup>2</sup>

The acidic pH of the medium may, however, also inhibit some species of fungi.<sup>2</sup> The addition of antimicrobial agents improves the recovery of pathogenic fungi from specimens heavily contaminated with bacteria and saprophytic fungi.<sup>3</sup>

### VI PRINCIPLES OF THE PROCEDURE

Sabouraud Dextrose Agar is a peptone medium supplemented with dextrose to support the growth of fungi. The addition of antibiotics and antifungal agents reduces the growth of bacteria and saprophytic fungi, which interfere with the recovery of dermatophytes and the fungi that cause systemic mycoses.<sup>3</sup> Chloramphenicol is a broad-spectrum antibiotic inhibitory to a wide range of gram-negative and gram-positive bacteria. Cycloheximide is an antifungal agent that is primarily active against saprophytic fungi and does not inhibit yeasts or dermatophytes.

### VII REAGENTS

#### Sabouraud Dextrose CC Agar

Approximate Formula\* Per Liter Purified Water

Pancreatic Digest of Casein .....	5.0 g	Agar .....	15.0 g
Peptic Digest of Animal Tissue .....	5.0 g	Chloramphenicol .....	0.05 g
Dextrose .....	40.0 g	Cyclohexamide .....	0.5 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"<sup>4-7</sup> 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.<sup>8-11</sup>

## IX PROCEDURE

**Material Provided:** Sabouraud Dextrose CC Agar

**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 onto the medium with a sterile inoculating loop. Consult appropriate texts for information about the processing and inoculation of specimens such as tissues, skin scrapings, hair, nail clippings, etc.<sup>3,8-11</sup>

For isolation of fungi causing cutaneous mycoses, a nonselective medium should be inoculated along with a selective medium. Incubate the tubes at 25 – 30 °C.

**User Quality Control:** See “Quality Control Procedures.”

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 tubes at least once a week for fungal growth. Cultures should be held for 4 – 6 weeks before reporting as negative.

## XI LIMITATIONS OF THE PROCEDURE

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.

For identification of microorganisms, the organism must be in pure culture. Morphological, biochemical and/or serological tests should be performed for final identification. Consult appropriate texts for detailed information and recommended procedures.<sup>3,8,9,11-13</sup>

## XII PERFORMANCE CHARACTERISTICS

Prior to release, all lots of Sabouraud Dextrose CC Agar are tested to verify expected performance characteristics. Representative samples of the lot are inoculated directly with *Trichophyton mentagrophytes* ATCC 9533 and *Aspergillus brasiliensis* ATCC 16404 grown on BBL Sabouraud Dextrose Agar. Samples are also tested with normal saline suspensions of *Escherichia coli* ATCC 25922 and *Candida albicans* ATCC 10231 diluted to yield 10<sup>3</sup> – 10<sup>4</sup> CFUs. Tubes are incubated with loose caps at 25 – 30 °C for up to 7 days in an aerobic atmosphere. Fair to heavy growth is observed with *T. mentagrophytes* and *C. albicans*. *A. brasiliensis* and *E. coli* are partially to completely inhibited.

## XIII AVAILABILITY

Cat. No.	Description
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297649	BD BBL™ Sabouraud Dextrose CC Agar, Pkg. of 10 Slants, size A tubes
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## XIV REFERENCES

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