



BBL™ Sabouraud Liquid Broth, Modified (Antibiotic Medium 13)

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QUALITY CONTROL PROCEDURES

I INTRODUCTION

Sabouraud Liquid Broth, Modified is a medium for the cultivation of fungi.

II PERFORMANCE TEST PROCEDURE

- Inoculate representative samples with the cultures listed below.
 - For *Candida albicans* and *Saccharomyces cerevisiae*, inoculate with 10^3 - 10^4 CFU using dilutions of **Trypticase™** Soy Broth cultures. For other organisms, inoculate tubes with a 0.01 mL calibrated loop using fresh fungal cultures (up to 7 days in age).
 - Incubate tubes with loosened caps at 25 ± 2 °C in an aerobic atmosphere.
- Examine tubes for up to 7 days for growth.
- Expected Results

Organisms	ATCC™	Recovery
* <i>Candida albicans</i>	60193	Growth
* <i>Trichophyton mentagrophytes</i>	9533	Growth
<i>Saccharomyces cerevisiae</i>	9763	Growth
<i>Microsporum audouinii</i>	9079	Growth

*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.
- Incubate uninoculated representative tubes at 20–25 °C and 30–35 °C and examine after 7 days for microbial contamination.

PRODUCT INFORMATION

IV INTENDED USE

Sabouraud Liquid Broth, Modified is used for the cultivation of yeast and molds.

V SUMMARY AND EXPLANATION

Sabouraud Liquid Broth, Modified is made according to the formula stated in *The United States Pharmacopeia (USP)*, 17th rev.¹ It was the recommended medium for the detection of mold and yeast contaminants in the sterility testing of pharmaceutical products. This formulation is no longer included with the media recommended for use in sterility testing of pharmaceutical products in the *USP*. This formulation is also that designated as Medium 13 in *The United States Pharmacopeia* and the *Official Methods of Analysis* of AOAC International.^{2,3}

VI PRINCIPLES OF THE PROCEDURE

The casein and meat peptones supply nitrogenous and carbon compounds which are growth requirements for bacteria and fungi. Dextrose is a source of energy for those organism strains capable of fermenting it.

VII REAGENTS

Sabouraud Liquid Broth, Modified

Approximate Formula* Per Liter Purified Water

Pancreatic Digest of Casein	5.0 g
Peptic Digest of Animal Tissue	5.0 g
Dextrose.....	20.0 g

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

Warnings and Precautions: For Laboratory Use.

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

Observe aseptic techniques and established precautions against microbiological hazards throughout all procedures. After use, prepared tubes, specimen containers and other contaminated materials must be sterilized by autoclaving before discarding.

Storage Instructions: On receipt, store tubes in the dark at 2–25 °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 the recommended incubation times. Allow the medium to warm to room temperature before inoculation.

Product Deterioration: Do not use tubes if they show evidence of microbial contamination, discoloration, drying or other signs of deterioration.

VIII SPECIMEN COLLECTION AND HANDLING

This product is not intended for use directly with specimens or mixed cultures. The organism to be tested must first be in pure culture.

IX PROCEDURE

Material Provided: Sabouraud Liquid Broth, Modified

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

Test Procedure: Observe aseptic techniques.

Media may be inoculated up to the expiration date and incubated for up to 28 days.

After inoculation, incubate tubes with loosened caps, preferably at 25 ± 2 °C (but duplicates may be incubated at 35 ± 2 °C, if desired) for up to 28 days in an aerobic atmosphere.

For use in antibiotic assays, follow instructions provided in the Code of Federal Regulations.²

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 (formerly NCCLS) guidance and CLIA regulations for appropriate Quality Control practices.

X RESULTS

Growth in broth media is evidenced by the appearance of turbidity. Subcultures should be made in order to obtain pure cultures of isolates. If the medium is used for assessing the sterility of a product, any growth is considered a positive result and identification of the organisms may not be required.

XI LIMITATIONS OF THE PROCEDURE

Culture media sometimes contain dead organisms derived from medium constituents, which may be visible in smears of culture media. Other sources of dead organisms visible upon Gram staining include staining reagents, immersion oil, glass slides and the specimens used for inoculation. If there is uncertainty about the validity of the Gram stain, the culture should be reincubated for another hour or two and the test repeated before a report is given.

XII AVAILABILITY

Cat. No.	Description
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221014	BBL™ Sabouraud Liquid Broth, Modified (Antibiotic Medium 13), Pkg. of 10 size K tubes
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XIII REFERENCES

1. The United States Pharmacopeia, 17th rev. 1965. United States Pharmacopeial Convention, New York.
2. United States Pharmacopeial Convention, Inc. 2005. The United States pharmacopeia 28/The national formulary 23—2005. United States Pharmacopeial Convention, Inc., Rockville, Md.
3. Horwitz (ed.). 2000. Official methods of analysis of AOAC International, 17th ed., vol.1. AOAC International, Gaithersburg, Md.

Technical Information: In the United States contact BD Technical Services and Support at 800-638-8663 or www.bd.com/ds.

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