

Reading the Results

Evaluation

S. agalactiae Mauve
Other bacteria Blue, colorless or Inhibited.

Limitations

For in vitro diagnostic use.

Incubation under CO₂ atmosphere may result in false positive cultures. Some rare strains of *Streptococcus B* may require additional 24 hours incubation for a satisfactory colony size. Some strains of A, C and G Group streptococci may appear as mauve colonies. Final identification may require additional testing.

The InTray COLOREX GBS is an agar medium that is susceptible to condensation collection within the inner seal, especially when stored at low temperatures and/or having been exposed to extreme temperature fluctuations. If moisture is visible on the surface of the InTrays, dry them (with the seal removed and InTray label in a position allowing for air flow) under a BSL-2 cabinet just prior to inoculation. There should be no visible droplets of moisture on the surface of the agar when they are inoculated. The surface of the dried medium should be smooth and should not show signs (webbed ribbing pattern on the agar surface) of desiccation.

Symbol glossary: biomeddiagnostics.com/1/symbol-glossary

IFU Translations: biomeddiagnostics.com

Document Revision History

Rev. B, October 2019

New format; added new catalog numbers, limitation about condensation, reference to online symbol glossary and IFU translations, document revision history; specified 18-25°C instead of room temperature; specified 35-37°C for incubation instead of 37 ± 2°C; reorganized and retitled some sections



Manufactured by:
Biomed Diagnostics, Inc.
1388 Antelope Road
White City, OR 97503 USA
biomeddiagnostics.com

BIOMED

InTray[®]
COLOREX[™] GBS

REF 11-563-001 Σ 5

REF 11-563-002 Σ 20

Not available in all countries; please inquire.

For In Vitro Diagnostic Use



Download



Certificate
of Analysis

Introduction

Intended Use

InTray® COLOREX™ GBS agar is a chromogenic medium for differentiation and isolation of pure cultures of *Streptococcus agalactiae* (GBS). The test can be performed with samples composed of mixed populations of bacteria, e.g., vaginal or rectal swabs, urine, feces, etc. COLOREX GBS is not intended for use in the identification of colonization with GBS to aid in the prevention and control of GBS in healthcare settings. COLOREX GBS is not intended to diagnose GBS infections, guide or monitor treatment for infections, or provide susceptibility results. Sub-culture is necessary for bacterial identification and susceptibility testing.

Description and Principle

With COLOREX GBS medium, *S. agalactiae*, including non-haemolytic strains are distinguishable by colony color. High sensitivity and specificity of the medium lead to a higher detection rate of *S. agalactiae* spp. Selective agents inhibit the growth of Gram-positive organisms. Artificial substrates are metabolized by specific microbial enzymes liberating insoluble chromogenic compounds. *S. agalactiae* species produce deep pink to mauve colored colonies. Bacteria other than *S. agalactiae* spp. produce blue colonies or are colorless or inhibited. Enrichment of original samples in Todd Hewitt or LIM broth is possible and may give best results.

Reagents and Appearance

COLOREX GBS contains agar appears transparent with a light amber hue and contains peptone nutrients, salts, antimicrobial and selective compounds and chromogenic additives. The media final pH is 7.3 ± 0.2 at 25°C.

Precautions, Safety and Disposal

For In Vitro Diagnostic Use

Read the Safety Data Sheets (SDSs) and follow the handling instructions. Wear appropriate protective eyewear, clothing and gloves.

Once the tray has been inoculated and resealed, re-open only in a biological safety cabinet. Because of the potential for containing infectious materials, the tray must be destroyed by autoclaving at 121°C for 20 minutes.

Storage

Upon receipt, store InTray COLOREX GBS under refrigeration (2-8°C). Medium can be kept for one day at ambient temperature. Protect media from exposure to light, excessive heat, moisture and freezing. Do not open until ready to use. Do not use if the medium shows signs of deterioration, shrinking, cracking, discoloration or contamination.

Shelf Life

InTray COLOREX GBS has a 6-month expiration date from the date of manufacturing.

Procedure

Materials Provided

- InTray COLOREX GBS test(s)

1 Prepare InTray



Allow the InTray to warm to 18-25°C.

Lift the lower right corner of the flexible InTray label until the protective seal is completely visible

3 Inoculate Sample



Streak sample onto the agar surface for isolation.

Materials Required but Not Provided

- Sterile inoculating tool (e.g., cotton swab/forceps/scalpel blade)
- Laboratory incubator capable of incubation at 35-37°C

2 Open Seals



Remove the paper-foil seal by pulling the tab.

Discard the seal.

Do not remove or alter the white filter strip over the vent hole!

4 Secure InTray



Reseal InTray label to the plastic tray body.

Press all around the perimeter of the InTray to ensure a complete seal.

Immediately label the InTray with sample information and date.

Do not cover the viewing window.

Incubation

Incubate at 35-37°C for 18-24 hours under ambient atmosphere. Colonies of *S. agalactiae* spp. appear deep pink to mauve. Non *S. agalactiae* bacteria are blue, colorless or are inhibited. Latex agglutination testing can be performed directly from the colony.

Quality Control

This product has been tested and meets the CLSI (formerly NCCLS) Approved Standard for commercially prepared media (M22-A3). At the time of manufacture, quality control testing is performed on each lot of the InTray COLOREX GBS. The ability of the media to support growth and demonstrate expected biochemical reactions and morphology is verified by lot.

All COLOREX GBS agar products are performance verified with the following ATCC® microbe strains. Product performance is also verified periodically throughout the marked shelf life of each lot.

Organism	ATCC	Expected Result
<i>S. agalactiae</i>	12386	Mauve
<i>S. agalactiae</i>	13813	Mauve
<i>E. faecalis</i>	29212	Metallic Blue
<i>E. coli</i>	25922	Inhibited
<i>C. albicans</i>	60193	Inhibited