

Reading the Results

Evaluation

ESBL strains:

<i>E. coli</i>	Dark pink to red
<i>Klebsiella</i>	Metallic blue
<i>Enterobacter</i>	Metallic blue
<i>Citrobacter</i>	Metallic blue
<i>Proteus</i>	Brown halo
Non-resistant Gram (-) and Gram (+) strains.....	Inhibited
Yeasts.....	Inhibited

Limitations

For *in vitro* diagnostic use. Sub-culturing is required for identification as ESBL-resistant Enterobacteriaceae, e.g., by biochemical profiling or extended-spectrum beta-lactam susceptibility testing. If extended-spectrum beta-lactam susceptibility testing is necessary, one of the Clinical and Laboratory Standards Institute (CLSI) reference methods should be used; alternatively, a commercial antibiotic susceptibility test can be substituted. Some *Pseudomonas* spp. and *Acinetobacter* spp., widely known to be frequently Multi Drug Resistant, could grow on the COLOREX ESBL medium with typical colony aspects as expected on InTray COLOREX Screen (Cat. Nos. 11-103-001, 11-103-002).

The InTray COLOREX ESBL 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. D, 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


Scan for additional product information




Manufactured by:
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InTray[®]
COLOREX[™] ESBL

REF 11-173-001  5

REF 11-173-002  20

Not available in all countries; please inquire.
For *In Vitro* Diagnostic Use



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Certificate
of Analysis

Introduction

Intended Use

COLOREX™ ESBL Agar is a selective and differential chromogenic medium, containing an extended-spectrum beta-lactam selective agent, intended for use as a plating technique to obtain a pure culture of *Enterobacteriaceae* that produce extended-spectrum beta-lactamase (ESBL). The test can be performed with samples composed of mixed populations of bacteria, e.g., stool, biological fluids, surface streaks, etc. COLOREX ESBL is not intended for use in the identification of colonization with extended-spectrum beta-lactam-resistant bacteria to aid in the prevention and control of ESBL-resistance in healthcare settings. COLOREX ESBL is not intended to diagnose infections by extended-spectrum beta-lactam-resistant bacteria, guide or monitor treatment for infections, or provide susceptibility results to extended-spectrum beta-lactam. Sub-culture is necessary for bacterial identification and susceptibility testing.

Description and Principle

Extended-spectrum beta-lactamases are enzymes that mediate resistance to penicillins, extended-spectrum third generation cephalosporins (C3G) and monobactams. ESBL-producing *Enterobacteriaceae* started to appear in the 1980s, and have since emerged as some of the most significant hospital-acquired infections with *E. coli* and *Klebsiella* species being the main agents, but other Gram-negative species are also observed.

Reagents and Appearance

COLOREX ESBL contains agar, peptone nutrients, salts, antimicrobial selective compounds and chromogenic additives. The media has a final pH 7.0 ± 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 ESBL under refrigeration at 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 ESBL has an expiration of 6 months from date of manufacture.

Procedure

Materials Provided

- InTray COLOREX ESBL

Materials Required but Not Provided

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

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

2 Open Seals



Remove the paper-foil seal by pulling the tab.

Discard the seal.

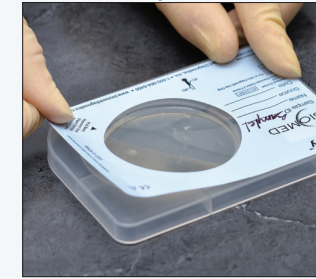
Do not remove or alter the white filter strip over the vent hole!

3 Inoculate Sample



Streak sample onto the agar surface for isolation.

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 patient or 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 ESBL-resistant *Enterobacteriaceae* appear red, blue, or halloed. Non resistant bacteria or yeasts are inhibited.

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 ESBL. The ability of the media to support growth and demonstrate expected biochemical reactions and morphology is verified by lot.

All COLOREX ESBL 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.

ATCC Control Strains

Organism	ATCC	Colony Appearance
ESBL strains:		
<i>K. pneumoniae</i>	700603	Metallic blue
<i>E. coli</i>	BAA-196	Reddish, small
Non-ESBL strains:		
<i>E. coli</i>	25922	Inhibited
<i>E. faecalis</i>	24212	Inhibited
<i>P. aeruginosa</i>	10145	Inhibited
<i>S. aureus</i>	25923	Inhibited
<i>C. albicans</i>	60193	Inhibited