



Colorex™ ESBL Agar

Instructions for Use

10-7301 InTray™ Colorex™ ESBL, 2"tray, 20 trays/box

10-7307 InTray™ Colorex™ ESBL, 2"tray, 5 trays/box

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 OF USE

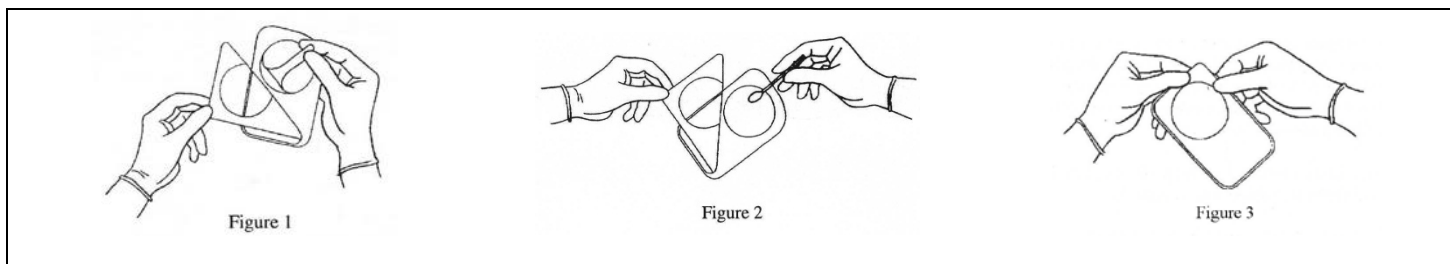
Extended-spectrum beta-lactamases are enzymes that mediate resistance to penicillins, extended-spectrum third generation cephalosporins (C3G) and monobactams. ESBL-producing *Enterobacteriaceae* started to appear in the 1980s, and have since emerged as some of the most significant hospital-acquired infections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

STORAGE

Upon receipt, store InTray™ Colorex™ ESBL 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.

INOCULATION PROCEDURE

Allow the InTray™ to warm to room temperature. Lift the lower right corner of the flexible InTray™ label until the protective seal is completely visible. Remove the paper-foil seal by pulling the tab (Fig. 1). **Discard** the seal. **DO NOT REMOVE OR ALTER THE WHITE FILTER STRIP OVER THE VENT HOLE!**



Streak laboratory sample onto the agar surface for isolation (Fig. 2). Reseal the InTray™ label to the plastic tray body. **Press all around the perimeter of the InTray™ to ensure a complete seal** (Fig. 3). Immediately label the InTray™ with sample information and date. **DO NOT COVER THE VIEWING WINDOW.**

CULTURE AND RESULTS



Incubate at 37°±2°C for 18-24 hours under ambient atmosphere. Colonies of ESBL-resistant *Enterobacteriaceae* appear red, blue, or haloed. Non resistant bacteria or yeasts are inhibited.

LIMITATIONS/PRECAUTIONS

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 cleared for use by the Food and Drug Administration (FDA) 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 Colorex™ Screen (Cat # 10-7101, 10-7107). Once the InTray™ has been inoculated and resealed, re-open only in a biological safety cabinet. Because of the potential for containing infectious materials, the InTray™ must be destroyed by autoclaving at 121°C for 20 minutes.



INTERPRETATION

| Organism | Colony Appearance | | |
|-------------------------------------------|-------------------|------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ESBL strains: | | | |
| <i>E. coli</i> | Dark pink to red |  <p>E.coli ESBL</p> <p>Dark pink to reddish</p> |  <p>Klebsiella, Enterobacter, Citrobacter group -ESBL</p> <p>Metallic Blue</p> |
| <i>Klebsiella</i> | metallic blue | | |
| <i>Enterobacter</i> | " | | |
| <i>Citrobacter</i> | " | | |
| <i>Proteus</i> | brown halo | | |
| Non-resistant Gram(-) and Gram(+) strains | inhibited | | |
| Yeasts | inhibited | | |

REAGENTS

Colorex™ ESBL contains agar, peptone nutrients, salts, antimicrobial selective compounds and chromogenic additives.

QUALITY CONTROL

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.

| 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 | " |
| <i>P. aeruginosa</i> | 10145 | " |
| <i>S. aureus</i> | 25923 | " |
| <i>C. albicans</i> | 60193 | " |

| SYMBOL KEY | | | |
|------------|------------------------------------|--------|-----------------------------------------------------|
| Symbol | Used For | Symbol | Used For |
| | Batch code | | Temperature limitation |
| | Date of manufacture | | Catalog number |
| | Use by YYYY-MM-DD or YYYY-MM | | Caution, consult accompanying documents |
| | Manufacturer | | Authorized representative in the European Community |
| | In vitro diagnostic medical device | | in European community |

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