

Introduction

Intended Use

COLOREX™ KPC is a selective and differential chromogenic medium containing a carbapenem selective agent intended for use in obtaining a pure culture of Gram-negative bacteria expressing reduced susceptibility to carbapenem-class antibiotics. The test can be performed with samples composed of mixed populations of bacteria, e.g., stool, biological fluids, surface streaks, etc. COLOREX KPC is not intended for use in the identification of colonization with carbapenem-resistant bacteria to aid in the prevention and control of carbapenem-resistant bacteria in healthcare settings. COLOREX KPC is not intended to diagnose infections with carbapenem-resistant bacteria, guide or monitor treatment for infections, or provide susceptibility results to carbapenem. Sub-culture is necessary for bacterial identification and susceptibility testing.

Description and Principle

The selective components in COLOREX KPC Agar inhibit the growth of yeast, Gram-positive bacteria and Gram-negative carbapenem-sensitive bacteria. The presence of chromogens allows the differentiation of Gram-negative bacteria that produce carbapenemase (or that inactivate carbapenems by mechanisms other than production of carbapenemase). The colonies of carbapenemase-resistant bacteria appear colored.

Reagents and Appearance

COLOREX KPC appears clear with an amber hue and contains agar, peptone nutrients, salts, antimicrobial selective compounds and chromogenic additives. The media has a final pH of 7.0 ± 0.2 at 25°C.

Precautions, Safety and Disposal

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 KPC 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 KPC has a shelf life of 6 months from the date of manufacture.

Procedure

Materials Provided

- InTray COLOREX KPC

1 Prepare InTray



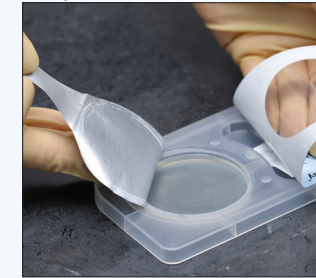
Allow the InTray to warm to 18-25°C.

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

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.

3 Inoculate Sample



Streak sample onto the agar surface for isolation.

4 Secure InTray



Reseal the 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.

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

All COLOREX KPC 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
Carbapenem^R		
<i>K. pneumoniae</i>	BAA-1705	Metallic blue
Carbapenem^S		
<i>K. pneumoniae</i>	13883	Inhibited
Other Bacteria/Yeast:		
<i>E. faecalis</i>	29212	Inhibited
<i>S. aureus</i>	29523	Inhibited
<i>C. albicans</i>	60193	Inhibited

Reading the Results

Evaluation

Colonies of carbapenem-resistant strains appear red, blue or cream colored. Yeast and non-resistant bacteria are inhibited..

Carbapenem^R strains:

<i>E. coli</i>	Red
<i>Klebsiella</i>	Metallic blue
<i>Enterobacter</i>	Metallic blue
<i>Citrobacter</i>	Metallic blue
<i>Pseudomonas</i>	Cream/green translucent
<i>Acinetobacter</i>	Cream

Carbapenem^S strains Inhibited

Gram (+) strains Inhibited

Limitations

For in vitro diagnostic use. Sub-culturing is required for identification of carbapenem-resistance, e.g., by biochemical profiling or carbapenem susceptibility testing. If carbapenem 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.

InTray COLOREX KPC 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.

Scan for additional product information



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

IFU translations: biomeddiagnostics.com

Document Revision History

Rev. E, December 2019

New format; added new catalog numbers, shelf life, additional organisms to Quality Control, 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:
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InTray[®]
COLOREX™ KPC

REF	11-163-001	5
REF	11-163-002	20

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



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Certificate of Analysis