



Colorex™ KPC Agar

Instructions for Use

10-7201 InTray™ Colorex™ KPC, 2"tray, 20 trays/box

10-7207 InTray™ Colorex™ KPC, 2"tray, 5 trays/box

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 OF USE

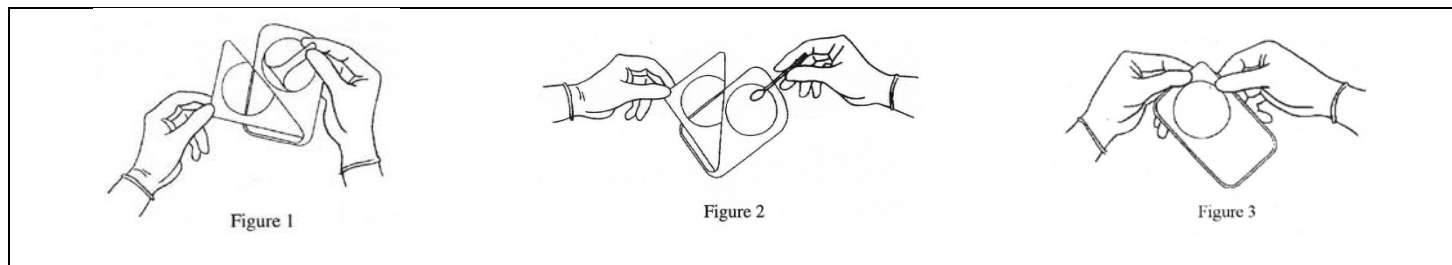
The selective components in Colorex™ KPC Agar inhibit the growth of yeast, gram-positive bacteria and gram-negative carbapenem-sensitive bacteria. The presence of chromogens allows the differentiation of gram-negative bacteria that produce carbapenemase (or that inactivate carbapenems by mechanisms other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

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.

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

LIMITATIONS/PRECAUTIONS

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. 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		
Carbapenem ^R strains:			
<i>E. coli</i>	red	 <p><i>E.coli</i> CarbapenemR</p> <p>Red</p>	 <p><i>Klebsiella, Enterobacter, Citrobacter</i> CarbapenemR</p> <p>Metallic blue</p>
<i>Klebsiella</i>	metallic blue		
<i>Enterobacter</i>	"		
<i>Citrobacter</i>	"		
<i>Pseudomonas</i>	cream, translucent		
Carbapenem ^S strains	inhibited		
Gram (+) strains	inhibited		

REAGENTS

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

QUALITY CONTROL

All Colorex™ KPC 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
Carbapenem ^R <i>K. pneumoniae</i>	BAA-1705	Metallic blue
Carbapenem ^S <i>K. pneumoniae</i>	700603	Inhibited

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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