HiCrome® KPC Agar Base

M1831

Intended Use:

Recommended for detection of Gram-negative bacteria with a reduced susceptibility to carbapenem agents.

Composition**

Ingredients	g / L
Peptone special	15.000
Chromogenic mixture	3.000
Agar	15.000
Final pH (at 25°C)	7.0±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 16.5 gram in 500 ml purified / distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool to 45-50°C. Aseptically add rehydrated contents of 1 vial of Selective Mix Supplement (FD279). Mix well and pour into sterile Petri plates.

Principle And Interpretation

HiCrome® KPC Agar Base is a chromogenic medium designed for the detection and differentiation of KPC producing gram negative bacterial species without selective pre-enrichment. Carbapenems are the last line of defense against invasive or serious infections and are used to treat these life threatening infections that are caused by gram negative, drug resistant pathogens (1). Production of carbapenemase enzyme results in resistance to penicillins, cephalosporins (i.e. cefepime, ceftriaxone), carbapenems (i.e. meropenem, ertapenem) and aztreonam there by making these pathogens multi drug resistant.

Most carbapenemase producing bacteria are included in the family *Enterobacteriaceae*, and are thus termed as carbapenem resistant *Enterobacteriaceae* (CRE). Besides the *Enterobacteriaceae* family, rare strains of *Pseudomonas aeruginosa* and *Acinetobacte baumannii* have also be found to produce catrbapenemase (1,2,3). Peptone special provides nitrogenous compounds and other essential growth nutrients. This medium can be made selective by supplementation with antibiotics for detecting microorganisms associated with hospital borne infections. Selective supplements have been added to inhibit the growth of yeast, gram positive organisms and gram negative organisms that do not produce carbapenemase. This medium is intended to be used as a screening medium. Isolates should be tested further for carbapenem susceptibility following CLSI guidelines. Indole test may be performed for the confirmation of carbapenem resistant *E. coli* because some rare strains of *C. freundii* may produce small pink to magenta coloured colonies similar to *E. coli*. Carbapenem resistant strains of *Klebsiella, Enterobacter* and *Serratia* species produce bluish green colonies. *Acinetobacter* and *Salmonella* species produce smooth, colourless colonies. *Pseudomonas* species produce colourless to light yellowish green, translucent colonies with wrinkled edges. Further biochemical tests may be needed for complete identification.

Type of specimen

Clinical samples- urine, throat swabs, lung abscess, etc.

Specimen Collection and Handling:

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (4,5).
After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions :

In Vitro diagnostic Use only. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations :

1. Some species may show poor growth due to nutritional variations and resistance to antibiotics.
2. Slight colour variation may be observed depending upon strains.
3. Final confirmation of suspected colonies must be carried out by serological and biochemical tests.
4. Indole test may be perform for the confirmation of carbapenem resistant *E. coli* because some rare strains of *C. freundii* may produce small pink to magenta coloured colonies similar to *E. coli.*

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within expiry period when stored at the recommended temperature.

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder

Gelling

Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium

Light amber coloured, clear to slightly opalescent gel forms in Petri plates

Reaction

Reaction of 3.3% w/v aqueous solution at 25°C. pH : 7.0±0.2

Cultural Response

Cultural characteristics observed with added Selective Mix Supplement (FD279) after an incubation at 35-37°C for 18-24 hours

Organism	Inoculum (CFU)	Growth	Recovery	Colour of Colony
Enterococcus faecalis ATCC 29212 (00087*)	>=10^4	Inhibited	0%	-
Klebsiella pneumoniae ATCC BAA 1705	50-100	luxuriant	>=50%	bluish green
Klebsiella pneumoniae ATCC 13883(00097*)	>=10^4	Inhibited	0%	-
Candida albicans ATCC 60193	>=10^4	Inhibited	0%	-
Staphylococcus aureus subsp. *aureus* ATCC 25923 (00034*)	>=10^4	Inhibited	0%	-

Key : (*) Corresponding WDCM numbers

Storage and Shelf Life

Store between 15-25°C in a tightly closed container and the prepared medium at 2-8°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (4,5).

Reference

1. Pillai D.R. et.al. 2009. Emerg. Infect. Dis; Vol. 15, P.827-829
2. Hindiyeth, M., et. al. 2008, J. Clin. Microbiol.; Vol. 46, p.2879 -2883.
3. Samra, Z., 2008, J. Clin. Microbiol; Vol. 146, P.3110-3111.
4. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
5. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

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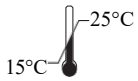
IVD ***In vitro*** **diagnostic medical device**



Storage temperature

EC REP CEpartner4U, Esdoornlaan 13,
3951DB Maarn, NL
www.cepartner4u.eu

CE Marking

Do not use if package is damaged

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