HiCrome™ KPC Agar Plate

MP1831

Intended Use

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

Composition**

Ingredients	g / L
Peptone special	15.000
Chromogenic mixture	3.000
Agar	15.000
Selective Mix Supplement (FD279)	**2.0 vials**
Selective Mix	50mg
Final pH (at 25°C)	7.0±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Either streak, inoculate or surface spread the test inoculum (50-100 CFU) aseptically on the plate.

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 *Acinetobacter 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 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.* 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 Rectal swab

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. 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. Individual organisms differ in their growth requirement and may show variable growth patterns on the medium
2. Each lot of the medium has been tested for the organisms specified on the COA. It is recommended to users to validate the medium for any specific microorganism other than mentioned in the COA based on the user's unique requirement.
3. Further biochemical and serological tests needs to be carried out for confirmation.

Performance and Evaluation

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

Quality Control

Appearance

Sterile HiCrome™ KPC Agar in 90mm disposable plates with smooth surface and absence of black particles/ cracks/ bubbles

Colour of medium

Light amber coloured medium

Quantity of medium

25 ml of medium in 90 mm disposable plates.

pH

6.80-7.20

Sterility check

Passes release criteria

Cultural Response

Cultural characteristics observed after an incubation at 35-37°C for 18-24 hours

Organism	Inoculum (CFU)	Growth	Recovery	Colour of Colony
Enterococcus faecalis ATCC 29212 (00087*)	>=10^3	inhibited	0%	-
Klebsiella pneumoniae ATCC BAA 1705	50-100	luxuriant	>=50%	bluish green
Klebsiella pneumoniae ATCC 13883 (00097*)	>=10^3	inhibited	0%	-
Candida albicans ATCC 60193	>=10^3	inhibited	0%	-
Staphylococcus aureus ATCC 25923 (00034*)	>=10^3	inhibited	0%	-

Key : (*) Corresponding WDCM numbers

Storage and Shelf Life

On receipt store between 2-8°C. Use before expiry date on the label. 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.

Revision : 02 / 2024

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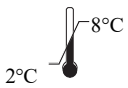
IVD ***In vitro*** **diagnostic medical device**



Storage temperature

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

CE **CE Marking**

Do not use if package is damaged

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