Chromogenic medium for detection of carbapenem-resistant Enterobacteria (CRE). REFERENCES

∑ Pack Size		Ordering References		Base (RT)		Supplement (KP)	
5000 mL	250 Tests of 20 mL	KPRT2	=	RT412 Weight: 165 g	+	KP102 Weight: 2 g	
25 L	1250 Tests of 20 mL	KPRT3-25	=	RT413-25 Weight: 825 g	+	KP103-25 Weight: 10 g	

INTENDED USE

CHROMagar™ KPC is a selective and differential chromogenic culture medium, intended for use in the qualitative direct detection of gastrointestinal colonization with carbapenem-resistant Enterobacteria (CRE) to aid in the prevention and control of CRE in healthcare settings. The test is performed with rectal swab and stools from patients to screen for CRE colonization. Results can be interpreted after 18-24 h of aerobic incubation at 35-37 °C. The medium can also be used as an early warning indicator for diagnostic tests of infections to signal the possible presence of multi drug-resistant bacteria. This use does not replace the institution's protocols.

CHROMagar™ KPC is not intended to diagnose CRE infection nor to guide nor monitor treatment for infections. A lack of growth or the absence of colonies on CHROMagar™ KPC does not preclude the presence of CRE. Further identification, susceptibility testing, and epidemiological typing is needed on suspect colonies.

COMPOSITION

The product is composed of a powder base (CHROMagar™ Orientation) and 1 supplement (CHROMagar™ KPC supplement).

Product =	Base (RT)	+	Supplement (KP)
Total g/L	33.0 g/L		0.4 g/L
Composition g/L	Agar 15.0 Peptone and yeast extract 17.0 Chromogenic mix 1.0		Selective mix 0.4
Aspect	Powder Form	• •	Powder Form
STORAGE	15-30 °C		2-8 °C

Need some Technical Documents?

Available
for download on
www.CHROMagar.com

• Certificate of Analysis
(CoA) --> One per Lot

• Material Safety Data
Sheet (MSDS)

FINAL MEDIA pH

7.0 +/- 0.2

PREPARATION (Calculation for 1 L)

Step 1 Preparation of the base CHROMagarTM Orientation

- Disperse slowly 33 g of powder base in 1 L of purified water.
- Stir until the agar is well thickened.
- Heat and bring to boil (100 °C) while swirling or stirring regularly.

Advice 1: For enhanced growth, add 0.5 g/L of Tween 80 to the previous preparation mix. Advice 2: For the 100 °C heating step, mixture may also be brought to a boil in a microwave oven: after initial boiling, remove from oven, stir gently, then return to oven for short repeated bursts of heating until complete fusion of the agar grains has taken place (large bubbles replacing foam).

Step 2 Autoclave

- AUTOCLAVE at 121 °C during 15 min.
- Cool in a water bath to 45-50 °C, swirling or stirring gently.

Step 3 Preparation of CHROMagar™ KPC supplement

- Weigh 400 mg of the required supplement powder.
- Add 10 mL of purified sterile water to this powder to make a supplement solution.

Warning 1: This step may require several minutes of stirring to obtain a good and homogenous suspension: opaque yellowish appearance.

Warning 2: Reconstituted supplement solution must be used the same day.

Warning 3: Do not store and re-use a supplement solution.

Step 4 Integrate the supplement to the melted base

- Vortex this supplement to homogenize and add the supplement solution to melted CHROMagar™ Orientation cooled at 45/50 °C.
- Stir to make CHROMagar™ KPC.

Step 5 Pouring

- Pour into sterile Petri dishes.
 - Let it solidify and dry.

Storage

- Store in the dark before use.
- Prepared media plates can be kept for one day at room temperature.
- Plates can be stored for up to 1 month under refrigeration (2/8 °C) if properly prepared and protected from light and dehydration.

Media 1 Rehydrate 400 mg into 10 mL of purified water 5 Rehydrate 2 g into 50 mL of purified water 25 Rehydrate 10 g into 250 mL of purified water

SPECIMEN COLLECTION AND HANDLING

CHROMagar™ KPC

CHROMagar™ KPC can be used with the following specimens: Rectal swab and stools.

Sampling and transport equipment must be used in accordance with the recommendations of their suppliers for the conservation of Carbapenem^R strains.

MATERIAL REQUIRED BUT NOT PROVIDED

Standard microbiological laboratory material for culture media preparation, control, streaking, incubation and waste disposal.

INOCULATION

Related samples are inoculated by direct streaking on the plate.

- If the agar plate has been refrigerated, allow to warm to room temperature before inoculation.
- Streak sample onto plate.
- Incubate in aerobic conditions at 35-37 °C for 18-24 hours.

INTERPRETATION

Qualitative reading and interpretation of the petri dishes

Microorganism	Typical colony appearance
Carbapenem ^R E. coli	→ dark pink to reddish
Carbapenem ^R KEC (Klebsiella, Enterobacter, Citrobacter)	→ metallic blue (+/- reddish halo)
Carbapenem ^R Pseudomonas	→ translucent, (+/- natural pigmentation cream to green)
Carbapenem ^R Acinetobacter	→ cream
Stenotrophomonas	→ colourless
Gram (+) strains	→ inhibited
Carbapenem ^s strains	→ inhibited
Yeasts	→ mostly inhibited

Typical colony appearance









The pictures shown are not contractual.

PERFORMANCE

	Analytical data *	Clinical data **			
		CHROMagar™ KPC	Reference medium (MacConkey Agar)		
Sensitivity	97.8 %	100 %	92.7 %		
Specificity	100 %	98.4 %	95.9 %		

- * Data obtained after a 16-24 h incubation at 37 °C in aerobic conditions in the study "Rapid identification of OXA-48-like, KPC, NDM, and VIM carbapenemase-producing Enterobacteriaceae from culture: Evaluation of the RESIST-4 O.K.N.V. multiplex lateral flow assay. Song et al., 2020. Ann. Lab. Med.
- ** Data obtained by testing 122 rectal swabs, being positive 41, on plates incubated at 37 °C for 24 h in aerobic conditions. "Evaluation of CHROMagar™ KPC for rapid detection of carbapenem-resistant Enterobacteriaceae". Samra et al., 2008. J. Clin. Microbiol.

LIMITATIONS AND COMPLEMENTARY TESTS

- Widely-known to be frequently Multi Drug Resistant bacteria, some *Pseudomonas* spp and *Acinetobacter* spp, , could grow on the medium with typical colony aspects as typical on CHROMagar $^{\text{TM}}$ Orientation.
- Final identification may require additional testing such as biochemical or immunological test: Latex agglutination confirmation test can be performed directly from the plates on suspected colonies.
- Some low carbapenemase-resistant may have difficult growth.

QUALITY CONTROL

Please perform Quality Control according to the use of the medium and the local QC regulations and norms.

Good preparation of the medium can be tested, isolating the following ATCC strains:

Microorganism	Typical colony appearance
E. coli IMP NCTC 13476	→ dark rose
K. pneumoniae ATCC® BAA 1705	→ steel blue
K. pneumoniae NCTC 13438	→ steel blue
E. faecalis ATCC® 29212	→ inhibited
K. pneumoniae ATCC® 13883	→ inhibited
S. aureus ATCC® 25293	→ inhibited
C. albicans ATCC® 60193	→ inhibited

WARNINGS AND PRECAUTIONS

- For Research Use Only (RUO). Not for use in diagnostic procedures.
- This laboratory product should be used only by trained personnel (healthcare professional, etc). Wear appropriate protective clothing, gloves and eye/face protection and handle appropriately with procedures and good laboratory practices.
- Use of the medium may be difficult for people who have problems recognising colours.
- Culture media should not be used as manufacturing material or components.
- Do not ingest or inhale the product.
- Do not use the product after the expiry date.
- Do not use the product if it shows any evidence of contamination or any sign of deterioration (compacted powder, color change, ...).
- Do not use the product if the packaging is damaged.
- Any change or modification in the production procedure may affect the results.
- Any change or modification of the required storage temperature may affect the performance of the product.
- Unappropriate storage may affect the shelf life of the product.
- Recap the bottles/vials tightly after each preparation and keep them in a low humidity environment, protected from moisture and light.
- Do not use the culture medium poured into a petri dish after a first use.
- After opening the bottles and with an appropriate conversation, open bottles can be used under the same conditions until each product's expiry date.
- Reading and interpretation should be performed using isolated colonies.
- Some precipitate may be observed in the agar but these do not affect the performance of the product.

Instructions For Use For Research Use Only (RUO). Not for use in diagnostic procedures.

- Interpretation of the test results should be made taking into consideration colonial and microscopic morphology and if necessary, the results of any other tests performed.
- Laboratory, chemical or biohazardous wastes must be handled and discarded in accordance with all local and national regulations.
- For hazard and precaution recommendations related to some chemical components in this medium, please refer to the pictogram(s) mentioned on the labels. The Material Safety Data Sheet (MSDS) is available on www.chromagar.com
- Any incident or complaint related to the environment must be declared to the manufacturer at the following email address: chromagar@chromagar.com
- Any serious incident occurring in connection with the environment must be declared to the competent authorities and to the manufacturer at the following email address:

chromagar@chromagar.com

DISPOSAL OF WASTE

After use, all plates and any other contaminated materials must be sterilized or disposed of by appropriate internal procedures and in accordance with local legislations. Plates can be destroyed by autoclaving at 121 °C for at least 20 minutes.

LITERATURE REFERENCES

Please refer to our website page «Publications» for scientific publications about this particular product.

Web link: http://www.chromagar.com/publication.php

IFU/LABEL INDEX

REF Catalogue reference

Consult instructions for use

Quantity of powder sufficient for X liters of media

Expiry date

Required storage temperature

Store away from humidity

Store away monimum

Protect from light

Manufacturer

NT-EXT-049 USA V9.1 / 06-May-24

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