CHROMagar™ mSuperCARBA™

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

Chromogenic medium for detection and isolation of Carbapenemase-Resistant Enterobacteriaceae (CRE)

REFERENCES

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$\overline{\Sigma}$ Pack Size	Ordering References		Base (B)		Supplement (S1)		Supplement (S2)
5000 mL = 250 Tests of 20 mL	SC172	=	SC172(B) Weight: 212.5 g	+	SC172(S1) Volume: 10 mL	+	SC172(S2) Weight: 1.25 g
25 L = 1250 Tests of 20 mL	SC173-25	=	SC173-25(B) Weight: 1062.5 g	+	SC173-25(S1) Volume: 50 mL	+	SC173-25(S2) Weight: 6.25 g

INTENDED USE

CHROMagar^M mSuperCARBA^M is a selective and differential chromogenic culture medium, intended for use in the qualitative direct detection of gastrointestinal colonization with carbapenem-resistant Enterobacteria (CRE), including OXA-48 producers, 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.

CHROMagar[™] mSuperCARBA[™] 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[™] mSuperCARBA[™] 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 (B) and 2 supplements (S1 + S2).

Product =	Base (B)	+	Supplement (S1)	+	Supplement (S2)	Need some Technical Documents?
Total	42.5 g/L		2 mL/L		0.25 g/L	Available for download on
Composition	Agar 15.0 Peptones 20.0 Salt 5.0 Chromogenic and selective mix 0.8 Growth factors 1.7		Growth factors mix		Selective mix 0.25	 Certificate of Analysis (CoA)> One per Lot Material Safety Data Sheet (MSDS)
Aspect	Powder Form	• • •	Liquid Form	•••	Powder Form	
STORAGE	15-30 °C		15-30 °C		2-8 °C	
FINAL MEDIA pH			7.2 +/- 0.2			

PREPARATION (Calculation for 1 L)

Step 1 Preparation of Base + S1	 Disperse slowly 42.5 g of powder base in 1 L of purified water. Add 2 mL of CHROMagar[™] mSuperCARBA[™] supplement S1 into slurry. Stir until the agar is well thickened. Heat and bring to boiling (100 °C) while swirling or stirring regularly. DO NOT HEAT TO MORE THAN 100 °C. DO NOT AUTOCLAVE AT 121 °C. Warning 1: If using an autoclave, do so without pressure. Advice 1: 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). Cool in a water bath to 45-50 °C, swirling or stirring gently to homogenize. 					
Step 2 Preparation of S2	 In a transparent vessel, add 250 mg of CHROMagar[™] mSuperCARBA[™] supplement S2 in 2 mL of purified water. Swirl well until complete dissolution. Filter to sterilize at 0.45 μm. 	Final Media 1 L 5 L 25 L	HELPING CALCULATION 250 mg in 2 mL 1.25 g in 10 mL 6.25 g in 50 mL			
Step 3 Base + S1 + S2	 Add the 2 mL of the supplement solution (S2) to the melted base (Step1) Swirl or stir gently to homogenize.) at 45-	50 °C.			
Step 4 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 proprotected from light and dehydration. 	perly p	repared and			

CHROMagar™ mSuperCARBA™

SPECIMEN COLLECTION AND HANDLING

CHROMagar[™] mSuperCARBA[™] can be used with the following specimens: Rectal swabs and stools.

This medium can be also used in food industry with samples from the following specimens: livestock and poultry.

Use of transport devices approved for collection of such specimens is recommended.

MATERIAL REQUIRED BUT NOT PROVIDED

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

INOCULATION

Related samples can be processed 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.

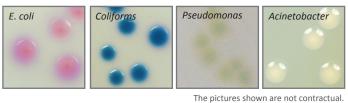
INTERPRETATION

Typical colony appearance
→ dark pink to reddish
→ metallic blue
→ translucent, +/- natural pigmentation cream to green
\rightarrow cream
→ colourless, natural pigmentation
\rightarrow inhibited
\rightarrow inhibited
\rightarrow inhibited

* CPE : Carbapenemase producing-Enterobacteriaceae

* CPO : Carbapenemase producer organism

Typical colony appearance



PERFORMANCE

	Analytical data *	Clinical Data **
		CHROMagar [™] mSuperCARBA [™]
Sensitivity	100 %	100 %
Specificity	71 %	100 %

* Data obtained after 24 h incubation at 37 °C in aerobic conditions in the study «Amélioration de la détection des Entérobactéries Productrices de Carbapénémase (EPC)». Dos Santos *et al.* RICAI 2017.

** Data obtained after 24 h incubation at 35 °C with 211 rectal swabs from the study «CHROMagar™ mSuperCARBA: performance in carbapenem-resistant Enterobacteriaceae isolates characterized at molecular level and routine surveillance rectal swabs specimens». García-Fernández *et al.* 2017. *Diagn. Microbiol. Infect. Dis.*

LIMITATIONS AND COMPLEMENTARY TESTS

• Species final identification may require additional testing such as biochemical tests or MALDI-TOF.

• CPE characterization can be done using methods based on the detection of the acidification resulting from imipenem hydrolysis or by susceptibility testing methods, directly from CHROMagar[™] mSuperCARBA[™].

• Some strains with multidrug resistance or with a decrease in membrane permeability may grow.

• Some strains showing a low level of carbapenem resistance may have an irregular to poor growth.

• Rarely, some VRE may grow in small blue colonies.

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	ightarrow dark pink to reddish
K. pneumoniae ATCC® BAA 1705	\rightarrow metallic blue
K. pneumoniae KPC NCTC 13438	\rightarrow metallic blue
E. faecalis ATCC [®] 29212	\rightarrow inhibited
<i>K. pneumoniae</i> ESBL ATCC [®] 700603	ightarrow mostly 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.

• For a good microbial detection, collection and transport of specimen should be well handled and adapted to the particular specimen according to good laboratory practices.

• 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 show any evidence of contamination or any sign of deterioration.

• Do not use the product if the packaging is damaged.

• Any change or modification in the 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.

• Reading and interpretation should be performed using isolated colonies.

ENGLISH

CHROMagar[™] mSuperCARBA[™]

 Some precipitate may be observed in the agar but these do not affect the performance of the product.

• 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 Safety Data Sheet (SDS) is available on www.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 «Scientific Publications» for scientific publications about this particular product. link: www.chromagar.com/product/chromagar-Web

msupercarba/

IFU/LABEL INDEX

REF Catalogue reference

- Ĩ Consult instructions for use
 - Quantity of powder sufficient for X liters of media
 - Expiry date

Required storage temperature

Store away from humidity

- Protect from light
- Manufacturer

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