CHROMagar™ C.difficile

Fluorogenic medium for detection of *Clostridioides difficile*.

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

ENGLISH

Instructions For Use

REFERENCES

Pack Size		Ordering References	Base		Supplement
5000 mL	250 Tests of 20 mL	CD122	CD122(B) Weight: 273.5 g	+	CD122(S) Weight: 1.63 g

INTENDED USE

CHROMagar™ C.difficile is a selective and differential fluorogenic culture medium, intended for use in the qualitative direct detection of gastrointestinal colonization with *Clostridioides difficile* to aid in the prevention and control in healthcare settings. The test is performed with stools. Results can be interpreted under UV light after 24 h of anaerobic incubation at 35-37 °C.

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

COMPOSITION

The product is composed of a powder base (B) and 1 supplement (S).

Product =	Base (B)	+ Supplement (S)
Total g/L	54.7 g/L	325 mg/L
Composition g/L	Agar 15.0 Peptones and yeast extract 25.0 Salts 9.0 Growth factors 4.0 Chromogenic mix 1.7	Selective mix
Aspect	Powder Form	Powder form
STORAGE	**15/30 °C**	**2/8 °C**
FINAL MEDIA pH	7.8 +/- 0.2	

Need some Technical Documents?

Available for download on www.CHROMagar.com

- Certificate of Analysis (CoA) --> One per Lot
- Material Safety Data Sheet (MSDS)

PREPARATION **(Calculation for 1 L)**

Step 1
Preparation of the base CHROMagar™ C.difficile base (B)

- Disperse slowly 54.7 g of powder base in 1 L of purified water.
- Stir until agar is well thickened.
- Heat and bring to boil (100 °C) while swirling or stirring regularly.

DO NOT HEAT TO MORE THAN 100°C. DO NOT AUTOCLAVE AT 121 °C.
Warning: 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. Swirl or stir gently to homogenize.

Step 2
Preparation of the Supplement (S) and addition to the prepared base (B)

- Aseptically rehydrate 325 mg of CHROMagar™ C.difficile supplement with 3 mL of sterile water.
- Swirl well until complete dissolution.
- Filter to sterilise at 0.45 µ.
- Aseptically add the 3 mL of the reconstituted CHROMagar™ C.difficile supplement to the CHROMagar™ C.difficile base cooled at 45-50 °C.
- Swirl gently to homogenize.

Final Media	HELPING CALCULATION
1 L	use 325 mg
5 L	use 1.63 g

Step 3
Pour plates

- 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.

Advice 2: Plates can be stored for up to one month under refrigeration (2/8 °C) if properly prepared and protected from light and dehydration.

CHROMagar™ C.difficile

SPECIMEN COLLECTION AND HANDLING

CHROMagar™ C.difficile can be used with the following specimens: stools.

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

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

INTERPRETATION

Microorganism	Typical colony appearance
C. difficile	→ colourless and fluorescent
Most of other bacteria	→ inhibited

Note: fluorescence under UV lamp (365 nm.)

Typical colony appearance

The pictures shown are not contractual.

PERFORMANCE

	Analytical data *	Clinical data**	
		CHROMagar™ C. difficile	Reference medium (Taurocholate-CCFA)
Sensitivity	-	95.4 %	70 %
Specificity	100 %	88.8 %	97 %

* Data obtained after a 24 h incubation at 35 °C under anaerobic atmosphere in the study «Comparison of CHROMagar C.difficile and taurocholate-CCFA media for isolation of toxigenic *Clostridium difficile* from stools». CCFA = Cefoxitin-Cycloserine-Fructose Agar. Roux *et al.* Poster ASM 2014.

** Data obtained after a 24 h incubation at 35 °C under anaerobic atmosphere with 594 stool samples, being positive 174, in the study «Comparison of CHROMagar C.difficile and taurocholate-CCFA media for isolation of toxigenic *Clostridium difficile* from stools». Roux *et al.* Poster ASM 2014.

LIMITATIONS AND COMPLEMENTARY TESTS

- A confirmation test is required for a final identification as *C. difficile*.
- Research of toxins A and/or B can be directly performed by a classical immunochromatography test.

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
C. difficile ATCC® 43255	→ colourless and fluorescent
C. perfringens ATCC® 13124	→ inhibited
E. faecalis ATCC® 29212	→ inhibited
E. coli ATCC® 25922	→ 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.
- 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 «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

Protect from light

Manufacturer

REVISION HISTORY

This is version V8.0 of this document.
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CHROMagar™
The Chromogenic Media Pioneer

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