Chromogenic medium for detection of Shiga-Toxin producing E. coli (STEC).

| Pack Size | | Ordering References | | Base | | Supplement | | |
|----------------------------|---|---------------------|---|----------------------------------|---|--------------------------------------|--|--|
| 5000 mL 250 Tests of 20 mL | = | ST162 | = | ST162(B) Weight: 154 g | + | ST162(S) 5 x 1000 mL vials | | |
| 10 kg | = | ST163-10 kg | = | ST163-10kg(B) Weight: 10 kg | + | ST163-325(S) Weight: 16.25 g | | |

INTENDED USE

DEEEDENICES

CHROMagar™ STEC is a selective chromogenic culture medium intended for use in the qualitative direct detection, differentiation and presumptive identification of Shiga-like-toxin producing *Escherichia coli* (STEC), to aid in the diagnosis of STEC infections. The test is performed with rectal swab and stools. Results can be interpreted after 18-24 h of aerobic incubation at 35-37 °C.

Concomitant cultures are necessary to recover organisms for further microbiological testing or epidemiological typing. A lack of growth or the absence of mauve colonies on CHROMagar™ STEC does not preclude the presence of STEC. CHROMagar™ STEC is not intended to diagnose infection nor to guide nor monitor treatment for infections.

CHROMagar™ STEC can also be used in the detection of STEC in the analyses of food products for human consumption, animal feed and in environmental samples.

COMPOSITION

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

| Product = | Base (B) | + | Supplement (S) |
|-----------------|--|-------|--------------------|
| Total g/L | 30.8 g/L | | 10 mL/L |
| Composition g/L | Agar 15.0 Peptones and yeast extract 8.0 Salts 5.2 Chromogenic mix 2.6 | | Selective mix |
| Aspect | Powder Form | • • • | freeze-dried vials |
| STORAGE | 15/30 °C | | 15/30 °C |
| FINAL MEDIA pH | 6.9 +/- 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™ STEC base (B)

- Disperse slowly 30.8 g of powder base in 1 L of purified water.
- Stir until agar is well thickened.
- \bullet 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 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. Swirl or stir gently to homogenize.

Step 2

Preparation of the Supplement (S) and Mix of the prepared mix (B)

- Aseptically rehydrate ONE vial with 10 mL of sterile water.
- Swirl well until complete dissolution.
- \bullet Add this rehydrated solution to the CHROMagar $^{\text{TM}}$ STEC base cooled at 45-50 °C.
- Swirl gently to homogenize.

Final Media

1 L use one vial

5 L use 5 vials

1 vial --> qsf 1 liter

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.

Advice 3: If not fully used, rehydrated CHROMagar™ STEC supplement can be stored up to 2 months at 2/8 °C.

CHROMagar™ **STEC**

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

SPECIMEN COLLECTION AND HANDLING

CHROMagar[™] STEC can be used with the following specimens:

- In clinical field: rectal swabs and stools
- In food industry : products for human consumption, animal feed, environmental samples.

Sampling and transport equipment must be used in accordance with the recommendations of their suppliers for the conservation of STEC.

MATERIAL REQUIRED BUT NOT PROVIDED

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

INOCULATION

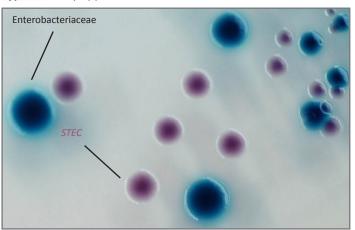
Related samples can be processed by direct streaking on the plate.

- 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.
- Possible use of enrichment broth (ex. TSB)

INTERPRETATION

| Microorganism | Typical colony appearance | | |
|--|---------------------------------|--|--|
| STEC | → mauve | | |
| Other Enterobacteriaceae | → colourless, blue or inhibited | | |
| Gram (+) bacteria | → inhibited | | |
| Note: fluorescence under UV lamp (365nm.): | | | |
| STEC O157 | → non fluorescent | | |
| STEC non O157 | → +/- fluorescent | | |

Typical colony appearance



The pictures shown are not contractual.

LIMITATIONS AND COMPLEMENTARY TESTS

- Some STEC could have a poor or no growth on the media.
- Some strains of non-STEC could appear as mauve colonies w/o fluorescence.
- Rare O157 are fluorescent positive.
- Final confirmation as STEC must be done by appropriate methods.
- Serotypes with agglutination tests can be performed directly from the colony.

PERFORMANCE

| Analytical data * | Clinical data** | | |
|-------------------|--|--|--|
| | CHROMagar™ STEC | | |
| | | | |
| 96 % | | | |
| 100 % | | | |
| 86 % | 91.4 % | | |
| 50 % | 91.4 % | | |
| 92 % | | | |
| 80 % | | | |
| 100 % | | | |
| 81 % | 86.7 % | | |
| | 96 % 100 % 86 % 50 % 92 % 80 % 100 % | | |

^{*} Data obtained after 18-24 h incubation at 37 °C in aerobic conditions in the study «Performance comparison of CHROMagar™ STEC and the SHIGA TOXIN QUIK CHEK™ assay using a panel of Shiga toxin *Escherichia coli* isolates». Lubeskie *et al.* Poster ECCMID 2016.

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:

| Typical colony appearance | | |
|---------------------------|--|--|
| → mauve | | |
| → mauve | | |
| → inhibited | | |
| → 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.
- \bullet 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.

^{**} Data obtained after 24 h incubation at 37 °C in aerobic conditions with 329 stool samples in the study «Evaluation of CHROMagar STEC and STEC O104 Chromogenic Agar Media for Detection of Shiga Toxin-Producing *Escherichia coli* in Stool Specimens». Gouali *et al.*, 2013. *Eur. J. Clin. Microbiol.*

CHROMagar™ **STEC**

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

- 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.
- 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
- 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 «Scientific Publications» for scientific publications about this particular product.

Web link: www.chromagar.com/product/chromagar-stec/

IFU/LABEL INDEX

REF Catalogue reference

i 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

NT-EXT-060 USA V11.0 / 10-Jun-22

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