CHROMagar™ StrepB

Chromogenic medium for the isolation and differentiation of Group B Streptococcus (S. agalactiae).

REFERENCES

| Σ Pack Size | Ordering References | | Base (B) | | Supplement S1 | | Supplement S2 |
|---------------------------------|---------------------|---|--|---|--------------------------------|---|------------------------------------|
| 5000 mL = 250 Tests of 20 mL | SB282 | = | SB282(B) Weight: 223.5 g | + | SB282(S1) Volume: 40 mL | + | SB282(S2) Weight: 1.25 g |
| 25 L = 1250 Tests of 20 mL | SB283-25 | = | SB283-25(B) Weight: 1117.5 g | + | SB283-25(S1) Volume: 200 mL | + | SB283-25(S2) Weight: 6.25 g |

INTENDED USE

CHROMagar[™] StrepB is a selective chromogenic culture medium that is intended to aid in the qualitative determination of Group B *Streptococcus* (GBS) colonization in pregnant women. This medium supports the growth of hemolytic and non-hemolytic GBS strains. The test is performed by direct, or after enrichment, plating of urine, vaginal and/or vagino/rectal swabs obtained from pregnant women. CHROMagar[™] StrepB results can be interpreted after 18-24 h aerobic incubation at 35-37 °C.

CHROMagar[™] StrepB is not intended to diagnose infection nor to guide nor monitor treatment for infections. 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 | |
|-----------------|---|--------------------|--------------------|--|
| Total g/L | 44.7 g/L | 8 mL/L | 0.25 g/L | Need some Technical Documents? |
| Composition g/L | Agar 15.0 Salts 7.5 Peptones and yeast extract 20.0 Chromogenic mix 2.2 | Growth factors mix | Selective mix 0.25 | Available for download on www.CHROMagar.com • Certificate of Analysis |
| Aspect | Powder Form | Liquid Form | Powder Form | (CoA)> One per Lot |
| STORAGE | 15/30 °C | 15/30 °C | 2/8 °C | Material Safety Data Sheet (MSDS) |
| FINAL MEDIA pH | | 7.3 +/- 0.2 | | i |

PREPARATION (Calculation for 1 L)

| Step 1 Base + S1 | Disperse slowly 44.7 g of powder base in 1 L of purified water. Add 8 mL of supplement S1 into slurry. Stir until agar is well thickened. Autoclave at 121 °C during 15 min. Cool at 45/50 °C keeping on stirring. |
|---------------------------------|--|
| Step 2 | In a transparent vessel, add 250 mg of <u>supplement S2</u> in 10 mL of purified water. Place under agitation with a magnetic stirring until S2 is solubilized. |
| Step 3 Base + S1 + S2 | Filter at 0.45 μm and aseptically add 10 mL of S2 preparation into (base + S1) slurry cooled at 45/50 °C while mixing. Swirl or stir gently to homogenize. |
| Step 4 Pouring | Pour into sterile Petri dishes. Let it solidify and dry. Once dried, the appearance of the plates is translucent grey. |
| 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, dehydration and microbial contamination. |

CHROMagar™ StrepB

SPECIMEN COLLECTION AND HANDLING

CHROMagar[™] StrepB can be used with the following specimens: urine, rectal and vaginal specimens.

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

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, as well as prior appropriate enrichment step in Todd Hewitt/LIM broth (CDC recommendations).

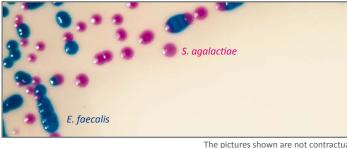
- If the agar plate has been refrigerated, allow to warm to room temperature before inoculation.
- Streak sample onto plate.
- Incubate in aerobic conditions at 35-37 °C for 18-24 hours.

INTERPRETATION

Qualitative reading and interpretation of the Petri dishes.

| Microorganism | Typical colony appearance |
|--|--|
| Streptococcus agalactiae (group B) | \rightarrow mauve |
| Enterococcus species | ightarrow steel blue |
| Lactobacilli, Leuconostoc, Lactococci | → light pink Scanty growth to inhibited |
| Other microorganism | ightarrow blue, colourless or inhibited |

Typical colony appearance



The pictures shown are not contractual

PERFORMANCE

| | Analytical data * | Clini | Clinical data** | | |
|-------------|-------------------|----------------------|---------------------------|--|--|
| | | CHROMagar™ StrepB | Reference medium (CNA) | | |
| Sensitivity | 100 % | 94 % | 92 % | | |
| Specificity | 80 % | 100 % | 100 % | | |

* In-house data obtained after 24 h incubation at 37 °C in aerobic conditions.

** Data obtained after 24 h incubation at 35 °C in aerobic conditions with 242 vaginal and rectal swabs in the study «Evaluation of four chromogenic media for the isolation of Group B Streptococcus from vaginal specimens in pregnant women». Salem & Anderson, 2015. Pathology.

LIMITATIONS AND COMPLEMENTARY TESTS

• Incubation in CO, may result in false positive cultures.

• The final identification must be confirmed by biochemical tests (ex: hydrolysis of Hippurate, CAMP test), immunological tests (ex: latex agglutination) or by mass spectrophotometry (ex: Maldi-Tof) • They can be done directly from the suspicious colonies observed on the medium.

• Rare strains of Group B Streptoccocus may require an additional 24 h incubation for a satisfactory colony size.

• Some strains of C, F & G Group Streptococci may appear as mauve colonies.

• Some organisms may appear as pale mauve-violet colonies, like Aerococcus, Lactobacillus, Lactococcus and Leuconostoc.

• Most of Group A Streptoccocus grow mauve as false positive. However, they can be differentiated with PYR test :

PYR(+) --> StrepA ; PYR(-) --> StrepB

• Few strains of Staphylococcus may appear as mauve colonies. However, they can be differentiated by a Catalase test:

Catalase (-) --> StrepB ; Catalase (+) --> Staphylococcus.

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 |
|---------------------------------------|---------------------------|
| S. agalactiae ATCC [®] 12386 | → mauve |
| S. agalactiae ATCC [®] 13813 | → mauve |
| E. faecalis ATCC [®] 29212 | \rightarrow steel blue |
| E. coli ATCC [®] 25922 | \rightarrow 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.

ENGLISH

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

CHROMagar™ **StrepB**

• After opening the bottles and with an appropriate conservation, 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 precipitates 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 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: www.chromagar.com/product/chromagar-strep-b/

IFU/LABEL INDEX

REF Catalogue reference

Consult instructions for use

- \overline{E} 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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