CHROMagar™ **StrepB**

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

REFERENCES

∑ 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

MEDIUM PURPOSE

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

Group B Streptococci (GBS), also known as *Streptococcus agalactiae*, are the cause of many infections in adults but above all a major cause of severe neonatal infections occurring within the first 3 weeks of life. Studies indicate that approximately 12-27 % of pregnant women (WHO, Infectious diseases, Group B *Streptococcus*) are colonized by Group B Streptococci (GBS). According to recommendations of HAS ANAES 2001 (France) or the CDC 2010 (USA), it is necessary to search qualitatively for Streptococcus of group B in pregnant women 34 to 38 weeks of gestation. CHROMagar™ StrepB is particularly suitable for this prepartum screening of women.

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
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
Aspect	Powder Form	Liquid Form	Powder Form
STORAGE	15/30 °C	15/30 °C	2/8 °C
FINAL MFDIA pH		7.3 +/- 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 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 supplement S2 in 10 mL of purified water.
- Place under agitation with a magnetic stirring until S2 is solubilized.

Step 3Base + S1 + S2

- Filter to sterilise 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.

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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).

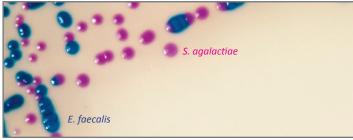
- If the agar plate has been refrigerated, allow to warm to room temperature before inoculation.
- Streak sample onto plate.
- Incubate in aerobic conditions at 35-37 °C for 18-24 hours.

INTERPRETATION

Qualitative reading and interpretation of the Petri dishes.

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

Typical colony appearance



The pictures shown are not contractual.

PERFORMANCE

In the following study, 242 vaginal and rectal swabs were tested and read after 24 h incubation at 35 °C in aerobic atmosphere.

	CHROMagar™ StrepB	Reference Method (CNA)	
Sensitivity	94 % *	92 %	
Specificity	100 % *	100 %	

^{*} Data obtained from the study «Evaluation of four chromogenic media for the isolation of Group B *Streptococcus* from vaginal specimens in pregnant women» N. Salem and J. J. Anderson. Austin Pathology, Microbiology Department 2015.

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	→ steel blue		
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.
- 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.

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- 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: 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

NT-EXT-051 V10.0 / 30-Mar-21

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