

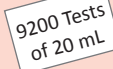


CHROMagar™ StrepA

Chromogenic medium for the screening of Group A Streptococci in throat samples.

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

REFERENCES

Σ Pack Size	Ordering References	Base (B)	Supplement (S1)	Supplement (S2)
5000 mL = 	SP372	SP372(B) Weight: 271.5 g	SP372(S1) Volume: 10 mL	SP372(S2) Weight: 0.5 g
25 L = 	SP373-25	SP373-25(B) Weight: 1357.5 g	SP373-25(S1) Volume: 50 mL	SP373-25(S2) Weight: 2.5 g
10 kg = 	SP373-10kg	SP373-10kg(B) Weight: 10 kg	2 x SP373-100(S1) Volume: 2 x 200 mL	SP373-184(S2) Weight: 18.4 g

INTENDED USE

CHROMagar™ StrepA is a selective chromogenic culture medium intended for use in the qualitative direct detection, differentiation and presumptive identification of *Streptococcus pyogenes* -group A *Streptococcus* (GAS) to aid in the diagnosis of GAS throat infections. The test is performed with throat swabs. Results can be interpreted after 18-24 h of incubation at 35-37 °C under CO₂ atmosphere. Concomitant cultures are necessary to recover organisms for further microbiological testing or epidemiological typing. A lack of growth or the absence of colonies on CHROMagar™ StrepA does not preclude the presence of GAS. CHROMagar™ StrepA is not intended to diagnose infection nor to guide nor monitor treatment for infections.

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	=	54.3 g/L	+	2 mL/L	+	0.1 g/L
Composition g/L	=	Agar 15.0 Peptones and yeast extract 27.0 Salts 9.0 Growth factors 3.0 Chromogenic and selective mix 0.3	+	Growth factors 2.0	+	Selective mix 0.1
Aspect	=	Powder Form	+	Liquid Form	+	Powder Form
STORAGE	=	15/30 °C	+	15/30 °C	+	2/8 °C
FINAL MEDIA pH	=	7.2 +/- 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 54.3 g of powder base in 1 L of purified water.
- Add 2 mL of supplement S1 into slurry.
- Stir until agar is well thickened.
- Autoclave at 121 °C during 15 min.

Warning: Some green particles may be observed in the agar but these do not affect the performance of the product.

- Cool at 45/50 °C keeping on stirring.

Step 2

S2

- In a transparent vessel, add 100 mg of supplement S2 in 1 mL of purified water.
- Filter to sterilize at 0.45 µm.

Step 3

Base + S1 + S2

- Aseptically add 1 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 plate 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 and dehydration.

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SPECIMEN COLLECTION AND HANDLING

CHROMagar™ StrepA can be used with the following specimens: throat swabs.

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

MATERIAL REQUIRED BUT NOT PROVIDED

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

INOCULATION

Related samples are inoculated by direct streaking on the plate.

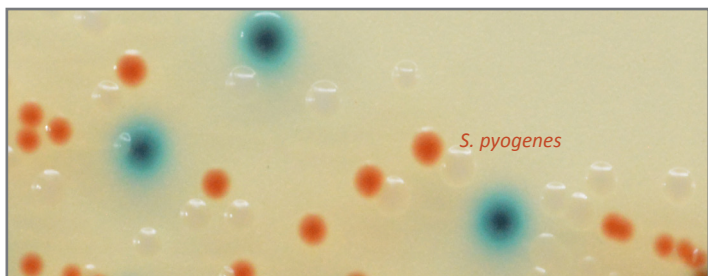
- If the agar plate has been refrigerated, allow to warm to room temperature before inoculation.
- Streak sample onto plate.
- Incubate at 35-37 °C for 18-24 hours in a CO₂ atmosphere.

INTERPRETATION

Qualitative reading and interpretation of the petri dishes.

Microorganism	Typical colony appearance
<i>Streptococcus pyogenes</i> (group A)	→ orange to red
Other <i>Streptococcus</i>	→ steel blue or colourless
Other Gram (+) bacteria	→ inhibited
Yeasts	→ inhibited
Gram (-) bacteria	→ inhibited

Typical colony appearance



The pictures shown are not contractual.

PERFORMANCE

	Analytical data *	Clinical data**
Sensitivity	100 %	96.7 %
Specificity	97.5 %	100 %

* Data obtained after a 24 h incubation at 35-37 °C in aerobic conditions in the study "Digital detection and the use of artificial intelligence to detect Group A *Streptococcus* using a chromogenic agar". Keyak *et al.*, Poster ASM 2019.

** Data obtained after a 20 h incubation at 35 °C in a CO₂ atmosphere with 159 throat samples being positive 120, in the study "Validation and implementation of Colorex™ CHROMagar™ Strep A agar on WASP™/WASPLab™ for screening for *Streptococcus pyogenes* using the ESwab™". Gaskin *et al.*, Poster ASM 2019.

LIMITATIONS AND COMPLEMENTARY TESTS

- Rare strains of Group A *Streptococcus* may require an additional 24 h of incubation for a satisfactory colony size.
- The final identification must be confirmed by biochemical tests or by mass spectrophotometry (eg MALDI-TOF). They can be done directly from the suspicious colonies observed on the medium.

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
<i>S. pyogenes</i> ATCC® 19615	→ orange to red
<i>E. faecalis</i> ATCC® 29212	→ steel blue
<i>E. coli</i> ATCC® 25922	→ inhibited
<i>S. aureus</i> ATCC® 25923	→ 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.
- 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 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.

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ENGLISH

Instructions For Use

- 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 contact DRG for further information.


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

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CHROMagar™ and Rambach™ are trademarks created by Dr A. Rambach
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CHROMagar™
The Chromogenic Media Pioneer

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