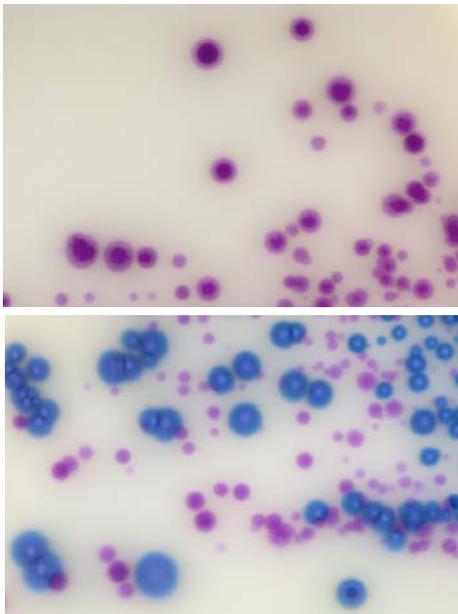




Biolife

ChromArt
STREPTO B
STREPTO B BASE
STREPTO B SUPPLEMENT

Cultural response



Pure culture of Group B *Streptococcus*
Mixed culture of Group B *Streptococcus* (magenta red-colonies) and *Enterococcus* sp. (blue colonies)

Intended use

Dehydrated and ready to use culture medium, selective/chromogenic supplement for the isolation and presumptive identification of Group B Streptococci (*Streptococcus agalactiae*) from clinical specimens.

Principle of the method and explanation

ChromArt Strepto B is a selective and chromogenic medium useful for the isolation of Group B Streptococci (*S.agalactiae*) from clinical specimens and for the differentiation of the colonies based on a typical colour.

The selectivity is based on the presence into the medium of an antibiotic mix. The differential characteristics are based on specific enzymatic reactions, which allow the differentiation of *S.agalactiae* colonies (pink-magenta) from other bacteria not inhibited by selective agents (e.g. Enterococci) which grow with green-blue, blue, without or with a pink halo or colourless colonies.

Directions for preparation from dehydrated medium

Suspend 35,14 g in 500 ml of cold purified water. Heat to boiling with frequent agitation and sterilise by autoclaving at 121 °C for 15 minutes. Cool to approximately 45-50 °C and, under aseptic conditions, add the contents of one vial of ChromArt Strepto B Supplement (cat. N° 4240053) reconstituted with 5ml of sterile distilled water. Mix well and distribute into sterile petri dishes.

Physical characteristics

Dehydrated medium appearance: beige, fine, homogeneous, free-flowing powder.

Prepared medium appearance: amber opaque

Final pH: 7,3 ± 0,2

Specimens

Specimens consist of ano-vaginal and urine samples from pregnant women or ingested gastric fluid from newborns.



Typical formulas

Dehydrated medium (g/L)

ChromArt STREPTO B BASE	
Peptones	28,000
Buffer salts	5,250
Growth factors	6,700
Inorganic salts	8,500
Antimicrobial mix	0,027
Chromogenic mix	0,300
Opacifier compounds	6,500
Agar	15,000

Ready to use plates (g/L)

ChromArt STREPTO B	
Peptones	28,000
Buffer salts	5,250
Growth factors	6,700
Inorganic salts	8,500
Antimicrobial mix	0,067
Chromogenic mix	0,800
Opacifier compounds	6,500
Agar	15,000

Supplement (g/vial)

ChromArt STREPTO B SUPPLEMENT	
Antimicrobial mix	0,04
Chromogenic mix	0,05

Technique

- 1- Chromart Strepto B Agar can be used according to two protocols:
 - Inoculation of the plate after pre-enrichment in Todd Hewitt Broth+antibiotics (recommended because enrichment significantly increase the sensitivity of the test)
 - Direct inoculation of the specimen onto the agar surface
- 2- Incubate the inoculated plates at 37° C in aerobic conditions.
- 3- Observe for the presence of typical colonies after 24 h of incubation. If no typical colonies are observed or if no growth will occur or if the colonies reading is difficult due to the presence of mixed colours or if the developed colonies colours are of unsure interpretation, prolong incubation up to 48 hours. Anyway the final reading and colonies interpretation shall be done after a complete 48 hours incubation time.

Interpretation of the results

- Typical *Streptococcus agalactiae* colonies are pale pink to pink after 24 hours of incubation. The colour will intensify to pink-magenta or magenta after 48 hours of incubation.
- If colourless or blue or blue-green colonies without or with a magenta halo will be observed, the results should be interpreted as microorganisms belonging to other species resistant to the antibiotic mix present in the medium (e.g. Enterococci).
- Confirm the typical colonies using a biochemical or immunological test (e.g. Strep Grouping Rapid Latex Test REF 271070) or other appropriate identification test.

Limitations of the method

- The identification obtained with the medium should be considered as a presumptive identification. It must be confirmed with biochemical, immunological or other appropriate identification test.
- It is possible that few strains of *S.agalactiae* with specific growth requirements, may not grow. It is recommended to use a non-selective blood agar in conjunction with Chromart Strepto B.
- Some species (e.g. Enterococcus spp.) which are resistant to antibiotics may develop and produce colonies with a non-typical colour. However, during the validation tests, 5 strains of Enterococci produced small pink colonies.
- The final reading and colonies interpretation shall be done after a complete 48 hours incubation time.
- Interpretation of the test results should be do considering the patient's history, the source of the specimen, colonial and microscopic reading and the results of other tests performed.



Quality control: microbiological characteristics

Test Strains		Incubation T° / t / At.	Growth characteristics
<i>S.agalactiae</i>	ATCC 12386	37°C / 48H / A	Good growth, magenta colonies
<i>S.agalactiae</i>	ATCC 13813	37°C / 48H / A	Good growth, magenta colonies
<i>E.gallinarum</i>	ATCC 49573	37°C / 48H / A	Good growth, blue colonies
<i>E.faecium</i>	ATCC 700221	37°C / 48H / A	Good growth, blue colonies
<i>E.faecalis</i>	ATCC 19433	37°C / 48H / A	Good growth, blue colonies
<i>S.xylosum</i>	ATCC 35033	37°C / 48H / A	Scanty growth, light blue colonies
<i>P.aeruginosa</i>	ATCC 27853	37°C / 48H / A	Growth totally inhibited
<i>C.albicans</i>	ATCC 10231	37°C / 48H / A	Growth totally inhibited

Notes

A: aerobic incubation

Performances

ChromArt Strepto B was evaluated by an independent Clinical Microbiological Laboratory in Italy on 225 ano-vaginal specimens. The medium was inoculated after enrichment of the specimen in Todd Hewitt Broth + antibiotics. Reading was performed after 24 and 48 hours of incubation at 37°C. ChromArt Strepto B Agar has been compared to a chromogenic medium of the market.

The table below shows a comparison of ChromArt Strep B Agar with the Chromogenic Medium used as reference medium.

		ChromArt Strepto B			
		True negatives	False negatives	True positives	False positives
Chromogenic Medium used as reference	True negatives	168			4**
	False negatives			3*	
	True positive			44	
	False positive	5**			1**

* Strains identified as Group B Streptococci by latex agglutination

** Strains identified as Non-Group B Streptococci by latex agglutination

168 samples have been found "negative" with both chromogenic media; 44 samples have been found "positive" with both chromogenic media. 3 strains have been found "positive" with Chromart Strepto B, "negative" with the reference medium and confirmed as Group B Streptococci by latex agglutination.

4 samples on Chromart Strepto B and 5 samples on reference medium originated small pink colonies identified as Enterococci (false positive in the above table).

1 sample originated doubtful colonies on both media confirmed as non-Group B *Streptococcus* and considered in the above table as a "false positive".

Chromart Strepto B didn't give any false negative result: sensitivity 100%

Chromart Strepto B gave 5 false positive results: specificity: 97,2%

After 24 hours of incubation, 5 samples have been found "negative" on the Chromogenic Medium used as reference and originated typical colonies on Chromart Strepto B; after 48 hours of incubation typical colonies were observed on reference medium too.

The performance characteristics have been evaluated with 20 clinical collection *S.agalctiae* strains: all strains developed typical colonies on both media after 24 hours of incubation.



Biolife

Technical Sheet-Instructions for use

N°408010-2 EN 09-2014 page 4/ 4

Warnings and precautions

- Bring the plates to room temperature before the use
- Do not use plates that are pink in colour or contaminated or with a lot of water condensation.
- For in vitro diagnostic use only; for professional use only.
- Dispose of used plates as well as any other contaminated materials following procedures for infectious or potentially infectious products, in accordance with any applicable regulations.

Storage

Dehydrated medium: keep tightly closed, away from bright light, at 2°C to 8 °C.

Ready to use plates: store the ready to use plates in their original box at 2°C to 8 °C.

Supplement: store at 2 °C to 8 °C

When stored as directed the products remain stable until the expiry date shown on the label. Do not use beyond stated expiry date.

References

- Craven R.R., Weber C.J., Jennemann R.A., Dunne M.D. Jr. Evaluation of a chromogenic agar for detection of group B Streptococcus in pregnant women. J. Clin. Microbiol. 48, 3370-3371, 2010.
- Dunne W.M. Jr, Holland-Staley C.A. Comparison of NNA culture and selective broth culture for the detection of Group B Streptococci colonization in women. J. Clin. Microbiol. 36, 2298-2300, 1998.
- Gray B.A.; Pass M.N.; Dillon H.C Jr. Laboratory and field evaluation of selective media for isolation of Group B Streptococci. J. Clin. Microbiol. 9, 466-470, 1979.
- Verani J.R., McGee L., Schrag S.J. Prevention of Perinatal Group B Streptococcal Disease. MMWR Recomm Rep. 2010 Nov 19; 59(RR-10):1-36

Ordering information

Product	Type	Cat. N°	Pack size
ChromArt STREPTO B BASE	DCM	4080102	500 g (7,1 L)
ChromArt STREPTO B SUPPLEMENT	Supplement	4240053	10 X 500 mL
ChromArt STREPTO B	Ready to use plates (Ø90mm)	548010	20 plates



Biolife Italiana S.r.l. Viale Monza 272, 20128 Milan, Italy.