

# G. PAPANIKOLAOU & SIA E.E.

Production laboratories of Culture Media Potamou 5 VIOPA Kerateas PC 19001 – Greece.

Tel: +30 2299 0 66113 Fax: +30 2299 0 66112 E-mail: bioprep1@otenet.gr www.bioprepare.gr

# **QUALITY CONTROL CERTIFICATE**

## **FINAL PRODUCT DATA**

Description	CHROMagar™ Strep B	
Code	010362	
Lot number	2750c129	
Production date	29/01/24	
Expiration date	29/03/24	

# PHYSICAL AND CHEMICAL CONTROL OF FINAL PRODUCT

Control	Expected results	Observed results
Final pH at 25°C	7,3 +/- 0,2	7,3 (Confirmed)
Quantity of material	20ml (010362)	Confirmed
Color & cleanliness of the material	Agar gray clear	Confirmed

# STERILITY TEST OF FINAL PRODUCTS

Number of controlled products Incubation		Number of suitable products	Number of inappropriate products
(3‰)			
2/010362	36 ± 1 °C for 48 hours	2/010362	0

FINAL PRODUCT PERFORMANCE TEST. Incubate:  $(37 \pm 1)$  °C for  $(24 \pm 2)$  h

Microorganism	Expected results	Observed results
Streptococcus agalactiae (≥500 cfu/10µl)	PR ≥ 0 ,5	Pink – mauve Colony Color
ATCC: 13813. Lot: 01603402,b (productivity)	Pink – mauve Colony Color	291 cfu
Escherichia coli (≥500 cfu/10μl)	Inhibited (0)	Confirmed
ATCC: 25922. Lot: 00207501 (Selectivity)		0 cfu

- Production and quality control tests were carried out at the premises of Bioprepare G. Papanikolaou & Co. According to EN ISO 9001:2015 / EAOT EN ISO 13485:2016. In addition, the company's audit department implements to ISO 11133: 2014.
- The products of this batch will have the results reported once the user receives them cool (8-25 °C) then keep them at the temperature indicated on the packaging until the expiration date and follow the using instructions of the brochure.
- 0: Growth zero. 1: Weak growth. 2: Good growth. PR: Productivity Rate.

Release of the	batch	DATE	Iniotaki Fofi
YES V NO		03/02/2024	Afrilas
			Quality Control Manager