

# G. PAPANIKOLAOU & SIA E.E.

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# **QUALITY CONTROL CERTIFICATE**

## **FINAL PRODUCT DATA**

Description	CHROMagar™ Strep B
Code	010362
Lot number	2765k119
Production date	19/02/24
Expiration date	19/04/24

# 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 (3‰)	Incubation	Number of suitable products	Number of inappropriate products
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	327 cfu
Escherichia coli (≥500 cfu/10μl)	Inhibited (0)	0 cfu
ATCC: 25922. Lot: 00207501 (Selectivity)		

- 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	22/02/2024	Africa
		Quality Control Manager