

G. PAPANIKOLAOU & SIA E.E.

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QUALITY CONTROL CERTIFICATE

FINAL PRODUCT DATA

Description	CHROMagar™ ORIENTATION
Code	010030
Lot number	2768k122
Production date	22/02/24
Expiration date	22/05/24

PHYSICAL AND CHEMICAL CONTROL OF FINAL PRODUCT

Control	Expected results	Observed results
Final pH at 25°C	7,0 +/- 0,2	7,0 (Confirmed)
Quantity of material	20ml (010030)	Confirmed
Color & cleanliness of the material	Beige agar light clear.	Confirmed

STERILITY TEST OF FINAL PRODUCTS

Number of controlled products		Incubation	Number of suitable products	Number of inappropriate products
	(3‰)			
	2/010030	36 ± 1 °C for 48 hours	2/010030	0

FINAL PRODUCT PERFORMANCE TEST Incubate: (36 ± 1) °C for (24 ± 2) h

Microorganism	Expected results	Observed results
Escherichia coli (≥500 cfu/10µl) e10.24	PR ≥ 0,7	Dark pink to reddish
ATCC 25922. Lot: 00207501. (Productivity)	Dark pink to reddish	398 cfu
Enterococcus faecalis (≥500 cfu/10µl) e10.24	PR ≥ 0,7	Turquoise blue with blue halo.
ATCC 29212. Lot: 01805401 (productivity)	Turquoise blue with blue halo.	381 cfu

- Production and quality control tests were carried out at the premises of Bioprepare G. Papanikolaou & Co. According to EN ISO 9001:2015 / ΕΛΟΤ 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.

DATE	Iniotaki Fofi
26/02/2024	Quality Control Manager