

G. PAPANIKOLAOU & SIA E.E.

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QUALITY CONTROL CERTIFICATE

FINAL PRODUCT DATA

Description	CHROMagar™ ORIENTATION	
Code	010030	
Lot number	2753k101	
Production date	01/02/24	
Expiration date	01/05/24	

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 (3‰)	Incubation	Number of suitable products	Number of inappropriate products
5/010030	36 ± 1 °C for 48 hours	5/010030	0

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

Microorganism	Expected results	Observed results
Escherichia coli (≥500 cfu/10μl)	<i>PR</i> ≥ 0,7	Dark pink to reddish
ATCC: 25922.Lot: 00207501 (productivity)	Dark pink to reddish	380 cfu
Enterococcus faecalis (≥500 cfu/10µl)	<i>PR</i> ≥ 0,7	Turquoise blue with blue halo.
ATCC: 29212. Lot: 01805401 (productivity)	Turquoise blue with blue halo.	362 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

Release of the batch

YES V NO

DATE

06/02/2024

Iniotaki Fofi

Quality Control Manager