

# 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™ CANDIDA
Code	010028
Lot number	2747c124
Production date	24/01/24
Expiration date	24/04/24

# PHYSICAL AND CHEMICAL CONTROL OF FINAL PRODUCT

Control	Expected results	Observed results
Final pH at 25°C	6.1 +/- 0,2	6.2 (Confirmed)
Quantity of material	20ml (010028)	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
3/010028	36 ± 1 °C for 48 hours	3/010028	0

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

Microorganism	Expected results	Observed results
Candida albicans (≥500 cfu/10μl)	PR ≥ 0,7	Green colonies
ATCC: 2091 Lot: 04205401 (productivity)	Green colonies	383 cfu
Incubate: (36 ± 1) °C for (24 ± 2) h		
Candida krusei (≥500 cfu/10μl)	PR ≥ 0,7	Pink colonies
NCPF 3100. Lot: 00300101 (productivity)	Pink colonies	357 cfu
Incubate: (36 ± 1) °C for (24 -48) h		
Escherichia coli (≥500 cfu/10μl)	Inhibited (0)	0 cfu
ATCC 25922 Lot: 00207501 (selectivity)		
Incubate: (36 ± 1) °C for (24 ± 2) h		

- 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.

Release of the b	atch	DATE	Iniotaki Fofi
YES V NO		29/01/2024	Africa
			<b>Ouality Control Manager</b>