

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: <u>bioprep1@otenet.gr</u> <u>www.bioprepare.gr</u>

QUALITY CONTROL CERTIFICATE

FINAL PRODUCT DATA

Description	PSEUDOMONAS F AGAR (KING B) (USP)		
Code	010538		
Lot number	2760r212		
Production date	12/02/24		
Expiration date	12/05/24		

PHYSICAL AND CHEMICAL CONTROL OF FINAL PRODUCT

Control	Expected results	Observed results
Final pH at 25°C	7,0 +/- 0,2	7,1 (Confirmed)
Quantity of material	20ml (010538)	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
2/010538	36 ± 1 °C for 48 hours	2/010538	0

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

Microorganism	Expected results	Observed results
Pseudomonas aeruginosa (≥500 cfu/10µl)	Growing (2)	Blue-green colonies
ATCC: 27853. Lot: 01007301 (productivity)	Blue-green colonies	278 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

16/02/24

Iniotaki Fofi

Quality Control Manager