

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	TRYPTONE SOY AGAR (USP/EP)	
Code	010119	
Lot number	2759m109	
Production date	09/02/24	
Expiration date	09/06/24	

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 (010119)	Confirmed
Color & cleanliness of the material	Beige clear	Confirmed

STERILITY TEST OF FINAL PRODUCTS

Number of controlled products (3‰)	Incubation	Number of suitable products	Number of inappropriate products
5/010119	36 ± 1 °C for 48 hours	5/010119	0

FINAL PRODUCT PERFORMANCE TEST Incubate: (30-35) °C for (18-24) hours

Microorganism	Expected results	Observed results
Escherichia coli (≥500 cfu/10μl)	PR ≥ 0,7	390 cfu
ATCC: 25922. Lot: 00207501 (productivity)		
Staphylococcus aureus (≥500 cfu/10μl)	PR ≥ 0,7	387 cfu
ATCC: 29213. Lot: 01403703 (productivity)		

- 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.
- PR: Productivity Rate. IV: Inoculum Value

Release of the batch

YES V NO

DATE

13/02/2024

Iniotaki Fofi

Quality Control Manager