

# G. PAPANIKOLAOU & SIA E.E.

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# **QUALITY CONTROL CERTIFICATE**

## **FINAL PRODUCT DATA**

Description	TRYPTONE SOY AGAR (USP/EP)
Code	010119
Lot number	2793k101
Production date	01/04/24
Expiration date	01/08/24

# PHYSICAL AND CHEMICAL CONTROL OF FINAL PRODUCT

Control	Expected results	Observed results
Final pH at 25°C	7.3 +/- 0,2	7.2 (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
3/010119	36 ± 1 °C for 48 hours	3/010119	0

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

Microorganism	Expected results	Observed results
Escherichia coli (≥500 cfu/10μl) e10.24	PR ≥ 0,7	413 cfu
ATCC: 25922. Lot: 00207501 (productivity)		
Staphylococcus aureus (≥500 cfu/10µl) e10.24	PR ≥ 0,7	397 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		DATE	Iniotaki Fofi
YES V	NO	05/03/2024	Afula

**Quality Control Manager**