

# G. PAPANIKOLAOU & SIA E.E.

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# **QUALITY CONTROL CERTIFICATE**

## **FINAL PRODUCT DATA**

Description	LISTERIA AGAR (PALCAM) (ISO 11290-2)
Code	010445
Lot number	2761r213
Production date	13/02/24
Expiration date	13/04/24

## PHYSICAL AND CHEMICAL CONTROL OF FINAL PRODUCT

Control	Expected results	Observed results
Final pH at 25°C	7,2 +/- 0,2	7.2 (Confirmed)
Quantity of material	20ml (010445)	Confirmed
Color & cleanliness of the material	Agar red clear.	Confirmed

## STERILITY TEST OF FINAL PRODUCTS

Number of controlled products (3%)	Incubation	Number of suitable products	Number of inappropriate products
1/010445	36 ± 1 °C for 48 hours	1/010445	0

FINAL PRODUCT PERFORMANCE TEST (According to 11290-2) Incubation: (37 ± 1) °C for (44 ± 4) h

Microorganism	Expected results	Observed results
Listeria monocytogenes (≥500 cfu/10µl)	PR ≥ 0,5	Gray-green to black colonies
NCTC 11994. Lot: 08700306 (productivity)	Gray-green to black colonies	with black halo
	with black halo	278 cfu
Escherichia coli (≥500 cfu/10μl)		
ATCC 25922. Lot: 00207501 (selectivity)	Inhibited	0 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.
- PR: Productivity Rate. IV: Inoculum Value

Release of the batch	DATE	Iniotaki Fofi
YES V NO	16/02/2024	Afrilas
		Quality Control Manager