

## G. PAPANIKOLAOU & SIA E.E.

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## **QUALITY CONTROL CERTIFICATE**

### **FINAL PRODUCT DATA**

Description	HALF FRASER BROTH PLUS (ISO 11290-1)	
Code	150374	
Lot number	2722d108	
Production date	08/12/23	
Expiration date	08/06/24	

### PHYSICAL AND CHEMICAL CONTROL OF FINAL PRODUCT

Control	Expected results	Observed results
Final pH at 25°C	7,2 +/- 0,2	7,20 (Confirmed)
Quantity of material	225ml (150374)	Confirmed
Color & cleanliness of the material	Broth green - yellow clear.	Confirmed

# STERILITY TEST OF FINAL PRODUCTS

Number of controlled products (3%)	Incubation	Number of suitable products	Number of inappropriate products
1/150374	36 ± 1 °C for 48 hours	1/150374	0

FINAL PRODUCT PERFORMANCE TEST (According to 11290-1)

Microorganism	Expected results	Observed results
Listeria monocytogenes (1000 cfu/10ml)	(Growth in ALOA > 100)	Confirmed
WDCM 00021 / ATCC 13932 (productivity)	Blue - green colonies with	IV = 611
Incubation: (30 ± 1) °C for (24 ± 2) h	opaque halo	
Escherichia coli (1000 cfu/10ml)		
WDCM 00013 / ATCC 25922 (selectivity)	Inhibited in TSA	Confirmed
Incubation: (30 ± 1) °C for (24 ± 2) h		
Enterococcus faecalis (1000 cfu/10ml)	(Partial inhibition)	Confirmed
WDCM 00087 / ATCC 29212 (selectivity)	Growth in TSA < 100 colonies	IV = 27
Incubation: (30 ± 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 / 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	11/12/2023	Afrika
		Quality Control Manager