

QUALITY CONTROL CERTIFICATE**FINAL PRODUCT DATA**

Description	FRASER BROTH (ISO 11290-1)
Code	070368
Lot number	2721r207
Production date	07/12/23
Expiration date	07/06/24

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	10ml (070368)	Confirmed
Color & cleanliness of the material	Broth straw-colored - greenish-yellow fluorescent clear.	Confirmed

STERILITY TEST OF FINAL PRODUCTS

Number of controlled products (3‰)	Incubation	Number of suitable products	Number of inappropriate products
1/070368	36 ± 1 °C for 48 hours	1/070368	0

FINAL PRODUCT PERFORMANCE TEST Incubation: According to ISO 11290-1. Incubation: (37 ± 1) °C for (48 ± 2) h

Microorganism	Expected results	Observed results
<i>Listeria monocytogenes</i> (300 cfu) ATCC: 13932. Lot: 04700402 (productivity)	(Growth) Growth at ALOA (36 ± 1 °C / 24h) of 10 blue-green colonies with opaque halo	Confirmed IV = 46
<i>Escherichia coli</i> (≤1000 cfu/ml) ATCC: 25922. Lot: 00206103 (selectivity)	Complete suspension in TSA (36 ± 1 °C / 24h)	Confirmed
<i>Enterococcus faecalis</i> (≤1000 cfu) ATCC: 29212. Lot: 01804803 (selectivity)	(Partial suspension) Growth in TSA (36 ± 1 °C / 24h) < 100 colonies	Confirmed IV = 53

- Production and quality control tests were carried out at the premises of Bioprep 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. IV: Inoculum Value

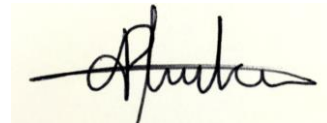
Release of the batch

YES NO

DATE

10/12/2023

Iniotaki Fofi



Quality Control Manager