

QUALITY CONTROL CERTIFICATE**FINAL PRODUCT DATA**

| | |
|-----------------|----------------------------|
| Description | FRASER BROTH (ISO 11290-1) |
| Code | 070368 |
| Lot number | 2748r225 |
| Production date | 25/01/24 |
| Expiration date | 25/07/24 |

PHYSICAL AND CHEMICAL CONTROL OF FINAL PRODUCT

| Control | Expected results | Observed results |
|-------------------------------------|--|------------------|
| Final pH at 25°C | 7,2 +/- 0,2 | 7,3 (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 |
|------------------------------------|------------------------|-----------------------------|----------------------------------|
| 2/070368 | 36 ± 1 °C for 48 hours | 2/070368 | 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> (≥500 cfu/10μl) NCTC: 11994. Lot: 08700306 (productivity) | (Growth) Growth at ALOA (36 ± 1 °C / 24h) of 10 blue-green colonies with opaque halo | Confirmed IV = 112 |
| <i>Escherichia coli</i> (≥500 cfu/10μl) ATCC: 25922. Lot: 00207501 (selectivity) | Complete suspension in TSA (36 ± 1 °C / 24h) | Confirmed IV = 0 |
| <i>Enterococcus faecalis</i> (≥500 cfu/10μl) ATCC: 29212. Lot: 01805401 (selectivity) | (Partial suspension) Growth in TSA (36 ± 1 °C / 24h) < 100 colonies | Confirmed IV = 14 |

- 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

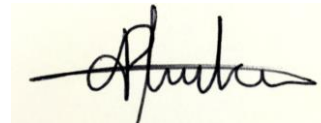
Release of the batch

YES NO

DATE

30/01/2024

Iniotaki Fofi



Quality Control Manager