

QUALITY CONTROL CERTIFICATE**FINAL PRODUCT DATA**

Description	LOWENSTEIN – JENSEN MEDIUM
Code	070060
Lot number	2773r329
Production date	29/02/24
Expiration date	29/10/24

PHYSICAL AND CHEMICAL CONTROL OF FINAL PRODUCT

Control	Expected results	Observed results
Final pH at 25°C	7,0 +/- 0,2	6,9 (Confirmed)
Quantity of material	8 ml (070060)	Confirmed
Color & cleanliness of the material	Greenish-green non-clear.	Confirmed

STERILITY TEST OF FINAL PRODUCTS

Number of controlled products (3‰)	Incubation	Number of suitable products	Number of inappropriate products
4/070060	36 ± 1 °C for 48 hours	4/070060	0

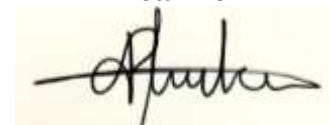
FINAL PRODUCT PERFORMANCE TEST (Incubate at 35 ± 2 °C in 5 - 10% CO₂ for 5 – 7 days.

Microorganism	Expected results	Observed results
<i>Mycobacterium smegmatis</i> (≥200 cfu/10μl) e10.24 ATCC 19420. Lot: 06700201.2 (productivity) Incubate: 35 ± 2 °C in 5 - 10% CO ₂ for 5 – 7 days	PR ≥ 0,7 Irregular dry yellowish colonies	151 cfu Irregular dry yellowish colonies
<i>Escherichia coli</i> (≥500 cfu/10μl) e10.24 ATCC 25922. Lot: 00207501 (selectivity) Incubate: 35 ± 2 °C for 18-24 h	Inhibited (0)	0 cfu

- 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. PR: Productivity Rate.

Release of the batchYES NO **DATE**

12/02/24

Iniotaki Fofi**Quality Control Manager**