

QUALITY CONTROL CERTIFICATE**FINAL PRODUCT DATA**

Description	BILE ESCULINE AZIDE AGAR (ISO 7899-2)
Code	010263
Lot number	2761r213
Production date	13/02/24
Expiration date	13/06/24

PHYSICAL AND CHEMICAL CONTROL OF FINAL PRODUCT

Control	Expected results	Observed results
Final pH at 25°C	7,1 +/- 0,2	7.0 (Confirmed)
Quantity of material	20ml (010263)	Confirmed
Color & cleanliness of the material	Gray - Brown clear.	Confirmed

STERILITY TEST OF FINAL PRODUCTS

Number of controlled products (3‰)	Incubation	Number of suitable products	Number of inappropriate products
2/010263	36 ± 1 °C for 48 hours	2/010263	0

FINAL PRODUCT PERFORMANCE TEST (Incubate at 36 ± 1 °C for 18 - 24 h).

Microorganism	Expected results	Observed results
<i>Enterococcus faecalis</i> (≥500 cfu/10μl) ATCC: 29212. Lot: 01805401 (Productivity) (Incubate: 44 ± 0,5 °C for 24 h).	PR ≥ 0,5 (Esculin hydrolysis +) Brown – Black agar colour	(Esculin hydrolysis +) Brown – Black agar colour 264 cfu
<i>Escherichia coli</i> (≥500 cfu/10μl) ATCC: 25922. Lot: 00207501 (Selectivity) (Incubate: 36 ± 1 °C for 18 - 24 h).	Not growing (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 batch

YES NO

DATE

16/02/24

Aspasia Papanikolaou



Quality Control Responsible