

G. PAPANIKOLAOU & SIA E.E.

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QUALITY CONTROL CERTIFICATE

FINAL PRODUCT DATA

Description	BILE ESCULINE AZIDE AGAR (ISO 7899-2)
Code	010263
Lot number	2742n117
Production date	17/01/24
Expiration date	17/05/24

PHYSICAL AND CHEMICAL CONTROL OF FINAL PRODUCT

Control	Expected results	Observed results
Final pH at 25°C	7,1 +/- 0,2	7.1 (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
Enterococcus faecalis (≥300 cfu)	PR ≥ 0,5 (Esculin hydrolysis +)	(Esculin hydrolysis +) Brown – Black agar colour
ATCC: 29212. Lot: 01805401 (Productivity)	Brown – Black agar colour	181 cfu
Escherichia coli (≥500 cfu/ml)	Not growing (0)	0 cfu
ATCC: 25922. Lot: 00207501 (Selectivity)		

- 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.
- 0: Growth zero. 1: Weak growth. 2: Good growth. PR: Productivity Rate.

Release of the batch	DATE	Aspasia Papanikolaou
YES V NO	22/01/24	- June

Quality Control Responsible