

G. PAPANIKOLAOU & SIA E.E.

Production laboratories of Culture Media Potamou 5 VIOPA Kerateas PC 19001 – Greece.

Tel: +30 2299 0 66113 Fax: +30 2299 0 66112 E-mail: bioprep1@otenet.gr www.bioprepare.gr

QUALITY CONTROL CERTIFICATE

FINAL PRODUCT DATA

Description	THAYER MARTIN AGAR
Code	010111
Lot number	2762f114
Production date	14/02/24
Expiration date	14/05/24

PHYSICAL AND CHEMICAL CONTROL OF FINAL PRODUCT

Control	Expected results	Observed results
Final pH at 25°C	7,3 +/- 0,2	7.3 (Confirmed)
Quantity of material	20ml (010111)	Confirmed
Color & cleanliness of the material	Coffee agar - unclear chocolate.	Confirmed

STERILITY TEST OF FINAL PRODUCTS

Number of controlled products Incubation		Number of suitable products	Number of inappropriate products
(3‰)			
2/010111	36 ± 1 °C for 48 hours	2/010111	0

FINAL PRODUCT PERFORMANCE TEST (Incubate at 37 ± 1 °C for 24 - 48 h with 10% CO2.)

Microorganism	Expected results	Observed results
Neisseria gonorrhoeae (≥500 cfu/10μl)	PR ≥ 0,5	Colonies small, gray, white
ATCC: 19424. Lot: 00502402 (productivity)	Colonies small, gray, white	274 cfu
Escherichia coli (≥500 cfu/10μl)	Inhibited (0)	Confirmed
ATCC 25922. Lot: 00207501 (selectivity)		0 cfu

- Production and quality control tests were carried out at the premises of Bioprepare G. Papanikolaou & Co. According to EN ISO 9001:2015 / ΕΛΟΤ 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	Iniotaki Fofi
YES V	NO	18/02/2024	Auto
			Quality Control Manager