

G. PAPANIKOLAOU & SIA E.E.

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QUALITY CONTROL CERTIFICATE

FINAL PRODUCT DATA

Description	E. COLI COLIFORMS CHROMOGENIC MEDIUM (CCA) (ISO 9308)	
Code	050572	
Lot number	2753n101	
Production date	01/02/24	
Expiration date	01/05/24	

PHYSICAL AND CHEMICAL CONTROL OF FINAL PRODUCT

Control	Expected results	Observed results
Final pH at 25°C	6.8 +/- 0,2	6.8 (Confirmed)
Quantity of material	9ml (050572)	Confirmed
Color & cleanliness of the material	Like beige clear.	Confirmed

STERILITY TEST OF FINAL PRODUCTS

Number of controlled products (3‰)	Incubation	Number of suitable products	Number of inappropriate products
3/050572	36 ± 1 °C for 48 hours	3/050572	0

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

Microorganism	Expected results	Observed results
Escherichia coli (≥500 cfu/10μl)	PR ≥ 0,5	Blue-green colonies
ATCC: 25922.Lot: 00207501 (productivity)	Blue-green colonies	290 cfu
Citrobacter freundii (≥500 cfu/10μl)	PR ≥ 0,5	Pink-red colonies
ATCC: 9634. Lot: 02700501 (specificity)	Pink-red colonies	285 cfu
Enterococcus faecalis (≥500 cfu/10µl)	Growth zero (0)	0 cfu
ATCC 29212. Lot: 01805401 (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

06/02/24

Aspasia Papanikolaou

Quality Control Responsible