

QUALITY CONTROL CERTIFICATE**FINAL PRODUCT DATA**

Description	COLUMBIA W/ 5% SHEEP BLOOD AGAR
Code	010250
Lot number	2756m106
Production date	06/02/24
Expiration date	06/04/24

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 (010250)	Confirmed
Color & cleanliness of the material	Agar red not clear	Confirmed

STERILITY TEST OF FINAL PRODUCTS

Number of controlled products (3‰)	Incubation	Number of suitable products	Number of inappropriate products
2/010250	36 ± 1 °C for 48 hours	2/010250	0

FINAL PRODUCT PERFORMANCE TEST (Incubate: 35-37 °C for 18-24 hours)

Microorganism	Expected results	Observed results
<i>Streptococcus pyogenes</i> (≥500 cfu/10μl) ATCC 19615. Lot:02004702. (Productivity)	PR ≥ 0,7 β - haemolysis	Growing, β - haemolysis 412 cfu
<i>Escherichia coli</i> (≥500 cfu/10μl) ATCC 25922. Lot: 00207501. (Productivity)	PR ≥ 0,7 Without haemolysis	Growing, Without haemolysis 385 cfu

- Production and quality control tests were carried out at the premises of Bioprep 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.
- PR: Productivity Rate. IV: Inoculum Value
- 0: Growth zero. 1: Weak growth. 2: Good growth

Release of the batch

YES NO

DATE

08/02/24

Aspasia Papanikolaou



Quality Control Responsible