

QUALITY CONTROL CERTIFICATE**FINAL PRODUCT DATA**

| | |
|-----------------|---------------------------------|
| Description | COLUMBIA W/ 5% SHEEP BLOOD AGAR |
| Code | 010250 |
| Lot number | 2768m122 |
| Production date | 22/02/24 |
| Expiration date | 22/04/24 |

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) e11.24 ATCC 19615. Lot: 02004702.1. (Productivity) | PR ≥ 0,7 β - haemolysis | Growing, β - haemolysis 415 cfu |
| <i>Escherichia coli</i> (≥500 cfu/10μl) e10.24 ATCC 25922. Lot: 00207501. (Productivity) | PR ≥ 0,7 Without haemolysis | Growing, Without haemolysis 403 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

26/02/24

Aspasia Papanikolaou



Quality Control Responsible