

QUALITY CONTROL CERTIFICATE**FINAL PRODUCT DATA**

Description	TBX CHROMOGENIC AGAR (TRYPTONE BILE X-GLUCURONIDE) ISO 16649-2,3
Code	010534
Lot number	2761r213
Production date	13/02/24
Expiration date	13/05/24

PHYSICAL AND CHEMICAL CONTROL OF FINAL PRODUCT

Control	Expected results	Observed results
Final pH at 25°C	7,2 +/- 0,2	7.2 (Confirmed)
Quantity of material	20ml (010534)	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
1/010534	36 ± 1 °C for 48 hours	1/010534	0

FINAL PRODUCT PERFORMANCE TEST According ISO 16649-1,2) Incubate: (44 ± 1) °C for (21 ± 3) h.

Microorganism	Expected results	Observed results
<i>Escherichia coli</i> (≥500 cfu/10μl) ATCC: 25922. Lot: 00207501 (productivity)	PR ≥ 0,5 Blue – Green colonies	Blue – Green colonies 286 cfu
<i>Citrobacter freundii</i> (≥500 cfu/10μl) ATCC: 9634. Lot: 02700501 (specificity)	PR ≥ 0,5 White colonies	White colonies 275 cfu
<i>Enterococcus faecalis</i> (≥500 cfu/10μl) ATCC 29212. Lot: 01805401 (Selectivity)	Growth zero (0)	0 cfu

- Production and quality control tests were carried out at the premises of Bioprep 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

Release of the batch

YES NO

DATE

16/02/2024

Aspasia Papanikolaou



Quality Control Responsible