

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	BLOOD AGAR (SHEEP BLOOD)	
Code	010011	
Lot number	2749t126	
Production date	26/01/24	
Expiration date	26/03/24	

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 (010011)	Confirmed
Color & cleanliness of the material	Agar red not clear	Confirmed

STERILITY TEST OF FINAL PRODUCTS

Number of controlled products Incubation		Number of suitable products	Number of inappropriate products
(3‰)			
5/010011	36 ± 1 °C for 48 hours	5/010011	0

FINAL PRODUCT PERFORMANCE TEST (According to the European Pharmacopoeia)

Microorganism	Expected results	Observed results
Streptococcus pyogenes (≥500 cfu)	PR ≥ 0,7	Growing, β – haemolysis
ATCC 19615. Lot:02004702. (Productivity)	β - haemolysis	361 cfu
Escherichia coli (≥500 cfu)	PR ≥ 0,7	Growing, Without haemolysis
ATCC 25922. Lot: 00207501. (Productivity)	Without haemolysis	385 cfu

- 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.
- PR: Productivity Rate. IV: Inoculum Value
- 0: Growth zero. 1: Weak growth. 2: Good growth. PR: Productivity Rate.

Release of	the batch	DATE	Iniotaki Fofi
YES V	NO	29/01/24	Africa
			Quality Control Manager