

G. PAPANIKOLAOU & SIA E.E.

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QUALITY CONTROL CERTIFICATE

FINAL PRODUCT DATA

Description	RPMI GLUCOSE AGAR
Code	010293
Lot number	2762c114
Production date	14/02/24
Expiration date	14/05/24

PHYSICAL AND CHEMICAL CONTROL OF FINAL PRODUCT

Control	Expected results	Observed results
Final pH at 25°C	7,0 +/- 0,2	7.1 (Confirmed)
Quantity of material	20ml (010293)	Confirmed
Color & cleanliness of the material	Light pink clear	Confirmed

STERILITY TEST OF FINAL PRODUCTS

Number of controlled products	Incubation	Number of suitable products	Number of inappropriate products
(3‰)			
3/010293	36 ± 1 °C for 48 hours	3/010293	0

FINAL PRODUCT PERFORMANCE TEST Incubate at 35 - 37 °C for 48 h

ETest for 48h. MIC limits to (μg/ml).

Μικροοργανισμός	Flucytosine	Ketoconazole	Amphotericin B	Fluconazole
	0,002 - 32 μg/ml	0.002 - 32 μg/mL	0.002 - 32 μg/mL	0.016 - 256 μg/mL
Candida albicans ATCC: 2091. Lot: 02802705 (Cloudiness RPMI 0,5 McFarlant)	0.5 <cmi -="" mic<1<br="">(Acceptance)</cmi>	0,008 <cmi -="" mic<0,0032<br="">(Acceptance)</cmi>	0.129 <cmi -="" mic<0,5<br="">(Acceptance)</cmi>	0.125 <cmi- mic<0.5<br="">(Acceptance)</cmi->

- Production and quality control tests were carried out at the premises of Bioprepare G. Papanikolaou & Co. According to EN ISO 9001: 2008. 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.
- * Expected results. ** Observed results.

Release of the batch	DATE	Iniotaki Fofi
YES V NO	15/02/2024	Afrika
		Quality Control Manager