

# Certificate of Analysis



Lot status: **APPROVED**

<b>MODEL</b> RODAC ø55mm Triple Wrapped Sterile Irradiated	<b>PRODUCT CODE</b>	<b>449PEN4000/21</b>
<b>MEDIA</b> TSA+Lec+T80+PEN4000	<b>MEDIA COMPOSITION</b>	Tryptone Soy Agar + 0.07% Lecithin + 0.5% Tween80 + 4000U.I./Lt Penicillinase
<b>BATCH</b> 39402	<b>STORAGE CONDITIONS</b>	at 2-25°C until expiry date
<b>DATE OF MANUFACTURING</b> 16 Feb 2024	<b>EXPIRY DATE</b>	<b>16 Oct 2024</b>

Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	light amber coloured, clear to slightly opalescent gel forms in plates	Conforms
pH specification	7.3±0.2	Conforms
Filling media volume	17ml±1ml	Conforms
Packaging	Triple Wrapped Sterile Irradiated (T.W.S.I.)	Conforms
Dose of irradiation	10-25 KGy	Conforms Irradiation certificate Nr:3506931

## MICROBIOLOGICAL TEST CONTROLS

- Sterility control**

TESTS	SPECIFICATION	RESULT
32.5±2.5°C aerobic for 120 hours	No growth	Conforms
22.5±2.5°C aerobic for 120 hours		

- Fertility – Growth Promotion Test** according to USP/EP

Control strain	Medium inoculation level	Incubation Conditions	Recovery Specifications	Recovery Results	Cultural Response
<i>E. coli</i> ATCC 8739	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	104,8%	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	100,0%	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	115,5%	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	79,5%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	94,7%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	94,7%	Conforms

- Enzimatic Activity Test**

Control strain	Incubation Conditions	Antibiotics	Response
<i>S. aureus</i> ATCC 6538	24 h at 32.5 ± 2.5°C	Penicillin 10IU	Conforms
		Meropenem 10µg	Conforms
		Cefuroxime 30µg	Conforms
		Ceftazidime 30µg	Conforms
		Cefoxitin 30µg	Conforms

<b>Start analysis</b>	16 Feb 2024	<b>End analysis</b>	11 Mar 2024
<b>Quality Control</b>	Elisabetta Peri	<i>Elisabetta Peri</i>	
<b>Quality Assurance</b>	Celeste Annovazzi	<i>Celeste Annovazzi</i>	

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<b>Customer Name:</b>	<b>CPC Biotech S.r.L.</b>	<b>Processing Facility:</b>	<b>Minerbio</b>	<b>Work Order #</b>	<b>3506931</b>
<b>P.O.#</b>	<b>84043</b>			<b>Sales Order #</b>	<b>3498384</b>
	<b>10-25 kGy</b>	<b>CPCB gamma treatment</b>	<b>Irradiation Date/Time:</b>	<b>23-Feb-24 11:38:09 GMT</b>	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	1	PL	2684/20_870/20	Microbiological culture media	WWW0539900749	DDT 84043
		Dose Map	270_CPCB_870/20	Std cycle 15kGy		
102.000	1	PL	2684/20_870/20	Microbiological culture media	WWW0539900750	DDT 84043
		Dose Map	270_CPCB_870/20	Std cycle 15kGy		
103.000	1	PL	2684/20_870/20	Microbiological culture media	WWW0539900751	DDT 84043
		Dose Map	270_CPCB_870/20	Std cycle 15kGy		
104.000	1	PL	2684/20_870/20	Microbiological culture media	WWW0539900752	DDT 84043
		Dose Map	270_CPCB_870/20	Std cycle 15kGy		
	<b>4</b>	<b>PL</b>	<b>Total</b>			

**Quality Test Summary**

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail
450.00	Minimum Dose	10.0 kGy	25.0 kGy	15.6 KGY	Pass
450.00	Maximum Dose	10.0 kGy	25.0 kGy	19.3 KGY	Pass

Sterigenics certifies that the materials listed above (as described by the Manufacturer) received the indicated doses within the precision and accuracy of the dosimetry system employed.

Electronically Signed By: CLAUDIA SQUARZANTI  
Reason: Work Order Completions

Date: 26-Feb-24 08:28:14 GMT