

Certificate of Analysis



Lot status: APPROVED

MODEL Petri ø90mm Triple Wrapped Sterile Irradiated	PRODUCT CODE	449LAC1000/22
MEDIA TSA+Lec+T80+LCT1000	MEDIA COMPOSITION	Tryptone Soy Agar + 0.07% Lecithin + 0.5% Tween80 + 1000U.I./Lt Lactamator TM
BATCH 96311	STORAGE CONDITIONS	at 2-25°C until expiry date
DATE OF MANUFACTURING 28 Nov 2023	EXPIRY DATE	28 Jul 2024

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	30ml±1ml	Conforms
Packaging	Triple Wrapped Sterile Irradiated (T.W.S.I.)	Conforms
Dose of irradiation	10-25 KGy	Conforms 3461449 Irradiation certificate Nr: 3464858 3469858

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%	90,0%	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	76,4%	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	83,1%	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	90,3%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	89,0%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	70,4%	Conforms

• Enzymatic 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

Start analysis	28 Nov 2023	End analysis	08 Jan 2024
Quality Control	Elisabetta Peri	<i>Elisabetta Peri</i>	
Quality Assurance	Celeste Annovazzi	<i>Celeste Annovazzi</i>	

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Customer Name:	CPC Biotech S.r.L.	Processing Facility:	Minerbio	Work Order #	3461449
P.O.#	80211			Sales Order #	3445745
	10-25 kGy	CPCB gamma treatment	Irradiation Date/Time:	1-Dec-23 11:58:23 GMT	

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	WWW0539900705	DDT 80211
		Dose Map	270_CPCB_870/20	Std cycle 15kGy		
102.000	1	PL	2684/20_870/20	Microbiological culture media	WWW0539900706	DDT 80211
		Dose Map	270_CPCB_870/20	Std cycle 15kGy		
103.000	1	PL	2684/20_870/20	Microbiological culture media	WWW0539900707	DDT 80211
		Dose Map	270_CPCB_870/20	Std cycle 15kGy		
104.000	1	PL	2684/20_870/20	Microbiological culture media	WWW0539900708	DDT 80211
		Dose Map	270_CPCB_870/20	Std cycle 15kGy		
	4	PL	Total			

Quality Test Summary

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail
450.00	Minimum Dose	10.0 kGy	25.0 kGy	16.0 KGY	Pass
450.00	Maximum Dose	10.0 kGy	25.0 kGy	19.6 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: MILENA TAMPELLINI
Reason: Work Order Completions

Date: 4-Dec-23 08:33:45 GMT

Certificate of Processing

STERIGENICS Via Marzabotto, 4 Minerbio BO 40061 Italy
 TEL 39 051-6605998 FAX 39 051-6605574 www.sterigenics.com

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Customer Name:	CPC Biotech S.r.L.	Processing Facility:	Minerbio	Work Order #	3464858
P.O.#	80213			Sales Order #	3449539
	10-25 kGy	CPCB gamma treatment	Irradiation Date/Time:	7-Dec-23 11:00:40 GMT	

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	WWW0539900709	DDT 80213
			270_CPCB_870/20	Std cycle 15kGy		
102.000	1	PL	2684/20_870/20	Microbiological culture media	WWW0539900710	DDT 80213
			270_CPCB_870/20	Std cycle 15kGy		
	2	PL	Total			

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	19.7 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: VALERIA LOSITO
 Reason: Work Order Completions

Date: 11-Dec-23 07:44:38 GMT

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Customer Name:	CPC Biotech S.r.L.	Processing Facility:	Minerbio	Work Order #	3469858
P.O.#	80220			Sales Order #	3455234
	10-25 kGy	CPCB gamma treatment	Irradiation Date/Time:		15-Dec-23 13:25:07 GMT

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	WWW0539900711	DDT 80220
		Dose Map	270_CPCB_870/20	Std cycle 15kGy		
102.000	1	PL	2684/20_870/20	Microbiological culture media	WWW0539900712	DDT 80220
		Dose Map	270_CPCB_870/20	Std cycle 15kGy		
103.000	1	PL	2684/20_870/20	Microbiological culture media	WWW0539900713	DDT 80220
		Dose Map	270_CPCB_870/20	Std cycle 15kGy		
104.000	1	PL	2684/20_870/20	Microbiological culture media	WWW0539900714	DDT 80220
		Dose Map	270_CPCB_870/20	Std cycle 15kGy		
105.000	1	PL	2684/20_870/20	Microbiological culture media	WWW0539900715	DDT 80220
		Dose Map	270_CPCB_870/20	Std cycle 15kGy		
106.000	1	PL	2684/20_870/20	Microbiological culture media	WWW0539900716	DDT 80220
		Dose Map	270_CPCB_870/20	Std cycle 15kGy		
	6	PL	Total			

Quality Test Summary

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail
450.00	Minimum Dose	10.0 kGy	25.0 kGy	15.7 KGY	Pass
450.00	Maximum Dose	10.0 kGy	25.0 kGy	19.6 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: **18-Dec-23 08:46:30 GMT**