

# Certificate of Analysis



Lot status: APPROVED

MODEL: Petri ø90mm Triple Wrapped Sterile Irradiated  
 MEDIA: TSA+Lec+T80+LCT1000

PRODUCT CODE: 449LAC1000/22

BATCH: 96307

STORAGE CONDITIONS: at 2-25°C until expiry date

DATE OF MANUFACTURING: 10 Jul 2023

EXPIRY DATE: 10 Mar 2024

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
Media composition	Tryptone Soy Agar + 0.07% Lecithin + 0.5% Tween80 + 1000U.I./Lt Lactamator TM	Conforms
	Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer	
Packaging	Triple Wrapped Sterile Irradiated (T.W.S.I.)	Conforms
Dose of irradiation	10-25 KGy	Conforms 3381833 Irradiation certificate Nr: 3379681 3384351

## MICROBIOLOGICAL TEST CONTROLS

- Sterility control**

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

- 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%	78,8%	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	74,4%	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	80,0%	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	73,9%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	77,6%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	87,2%	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	10 Jul 2023	End analysis	07 Aug 2023
Quality Control	Giulia Brusati	<i>Giulia Brusati</i> <i>Celeste Annovazzi</i>	
Quality Assurance	Celeste Annovazzi		