

# Certificate of Analysis



Lot status: APPROVED

MODEL	Petri ø90mm Single Wrapped	PRODUCT CODE	962E/10
MEDIA	R2A	MEDIA COMPOSITION	R-2A Agar
BATCH	83305	STORAGE CONDITIONS	at 2-25°C until expiry date
DATE OF MANUFACTURING	22 Nov 2023	EXPIRY DATE	22 Jul 2024

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

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	Light yellow coloured, clear to slightly opalescent gel forms in plates	Conforms
pH specification	7.2±0.2	Conforms
Filling media volume	30ml±2ml	Conforms
Packaging	Single Wrapped (S.W.)	Conforms

## 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%	91,8%	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	91,1%	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	93,5%	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	123,5%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	94,7%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	96,6%	Conforms

Start analysis	22 Nov 2023	End analysis	27 Nov 2023
Quality Control	Elisabetta Peri	<i>Elisabetta Peri</i>	
Quality Assurance	Alessia Diego	<i>Alessia Diego</i>	