

# Certificate of Analysis



Lot status: **APPROVED**

<b>MODEL</b>	<b>Petri ø90mm Single Wrapped</b>	<b>PRODUCT CODE</b>	<b>962E/10</b>
<b>MEDIA</b>	<b>R2A</b>	<b>MEDIA COMPOSITION</b>	<b>R-2A Agar</b>
<b>BATCH</b>	<b>83402</b>	<b>STORAGE CONDITIONS</b>	at 2-25°C until expiry date
<b>DATE OF MANUFACTURING</b>	<b>29 Feb 2024</b>	<b>EXPIRY DATE</b>	<b>29 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 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%	90,6%	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	92,2%	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	74,5%	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	102,5%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	97,0%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 22.5 ± 2.5°C	70%≤R%≤200%	103,6%	Conforms

Start analysis	29 Feb 2024	End analysis	05 Mar 2024
Quality Control	Elisabetta Peri	<i>Elisabetta Peri</i>	
Quality Assurance	Celeste Annovazzi	<i>Celeste Annovazzi</i>	