

Certificate of Analysis



Lot status: **APPROVED**

| | | | |
|------------------------------|-----------------------------------|---------------------------|-----------------------------|
| MODEL | Petri ø90mm Single Wrapped | PRODUCT CODE | 962E/10 |
| MEDIA | R2A | MEDIA COMPOSITION | R-2A Agar |
| BATCH | 83403 | STORAGE CONDITIONS | at 2-25°C until expiry date |
| DATE OF MANUFACTURING | 22 Mar 2024 | EXPIRY DATE | 22 Nov 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% | 108,8% | Conforms |
| <i>P. aeruginosa</i> ATCC 9027 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 70,5% | Conforms |
| <i>S. aureus</i> ATCC 6538 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 100,0% | Conforms |
| <i>B. subtilis</i> ATCC 6633 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 95,1% | Conforms |
| <i>C. albicans</i> ATCC 10231 | 10-100 viable microorganisms | 72-120 h at 22.5 ± 2.5°C | 70%≤R%≤200% | 101,1% | Conforms |
| <i>A. brasiliensis</i> ATCC 16404 | 10-100 viable microorganisms | 72-120 h at 22.5 ± 2.5°C | 70%≤R%≤200% | 104,7% | Conforms |

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|-------------------|-----------------|------------------------|-------------|
| Start analysis | 22 Mar 2024 | End analysis | 02 Apr 2024 |
| Quality Control | Elisabetta Peri | <i>Elisabetta Peri</i> | |
| Quality Assurance | Alessia Diego | <i>Alessia Diego</i> | |