# Rapid Micro Biosystems

## Certificate of Analysis

**Product Name:** **Environmental Monitoring Cassette: Tryptic Soy Agar with Lecithin, Polysorbate 80, Histidine and Sodium Thiosulfate**

**Catalogue number:** ET80HT-100 **Manufacture Date:** 11Apr2022

**Lot Number:** 10122L1 **Expiration Date:** 09Jan2023

The above lot has been produced in an ISO9001 certified facility and irradiated in accordance with Rapid Micro Biosystems Quality System. Representative samples were tested per Rapid Micro Biosystems protocols and were found to meet the performance and physical characteristics release criteria for this product.

**Storage:** 2-8°C

**Physical Characteristics:**

| Test | Specification | Result |
|---|---|---|
| Media appearance | Light amber brown color, no surface blemishes | Satisfactory |
| pH# | 7.3 +/- 0.2 at 25°C | Satisfactory |

#Media pH will vary within the stated range depending on the age of the product and the type of pH meter and probe used.

**Growth Promotion*:**

| Microorganism | ATCC®** | Result |
|---|---|---|
| *Aspergillus brasiliensis* | 16404® | Satisfactory |
| *Bacillus subtilis* | 6633® | Satisfactory |
| *Candida albicans* | 10231® | Satisfactory |
| *Pseudomonas aeruginosa* | 9027® | Satisfactory |
| *Staphylococcus aureus* | 6538® | Satisfactory |

*A standardized inoculum of the test organisms listed above was inoculated on selected cassettes. Growth was measured after 24-72 hours incubation on the Growth Direct system at 30-35°C. Satisfactory results indicate recovery within 50-200% compared to the control media and/or comparable to a previously released batch.
** Test organisms from alternative equivalent reference organizations may be substituted as required.

**Irradiation:**

| | |
|---|---|
| Irradiation Dose | Certified to be between 8-12.5 kGy |
| Sterility Evaluation | No growth detected at 5-7 days' incubation 32.5°C +/- 2.5°C |

Country of origin is USA. Media components of animal origin used in the manufacture of this product are certified, by Rapid Micro Biosystems suppliers, as sourced from BSE-TSE free countries, as identified by the United States Department of Agriculture (USDA). Certificates are held on file at Rapid Micro Biosystems.

Certificate results reported here were obtained at time of release. Product is for exclusive use with Rapid Micro Biosystems Growth Direct system. Not for In Vitro Diagnostic use.

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Released by: _____ Release Date 29 APR 2022

Quality Representative

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