# 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:** | 02Mar2021 |
| **Lot Number:** | 06121L4 | **Expiration Date:** | 30Nov2021 |

The above lot has been produced in a microbiologically controlled environment and irradiated in accordance with Rapid Micro Biosystems' Quality Systems. Representative samples were tested per Rapid Micro Biosystems' protocols and were found to meet the performance and physical characteristics release criteria for this product.

**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 a previously released batch.
** Test organisms from alternative equivalent reference organisations 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 MicroBiosystems' 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 MicroBiosystems.

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

** ATCC retains all right, title and interest in the ATCC trademark and trade-name, ATCC®, and any and all ATCC Catalog Marks (example ATCC® CRL-1740™) or ATCC specific designations of ATCC Materials sold by ATCC, or other trademarks registered or owned by the ATCC. **The ATCC trademark, the ATCC trade-name, or the ATCC Catalog numbers cannot be used in any way in connection with any offering, marketing, promotion, or sale without ATCC's prior written agreement.**

Released by:

Jim Lafferty
QA Vice President

Release Date 12 MAR 2021

Rapid Micro Biosystems, Inc.
1001 Pawtucket Blvd West, Suite 280, Lowell, MA 01854
Phone: +1 978-349-3200 Fax: +1 978-349-2065
www.rapidmicrobio.com
Email: technical@rapidmicrobio.com