Rapid Micro Biosystems

Certificate of Analysis

Product Name: **Bioburden Cassette: Tryptic Soy Agar with Lecithin and added Polysorbate 80**

Catalogue number: BTST-048 **Manufacture Date:** 22Mar2022

Lot Number: 08122L4 **Expiration Date:** 20Sep2022

The above lot has been produced in an ISO9001-certified facility and sterilized 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
Escherichia coli	8739®	Satisfactory
Pseudomonas aeruginosa	9027®	Satisfactory
Staphylococcus aureus	6538®	Satisfactory
Streptococcus pyogenes	19615®	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 30-35°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 05 APR 2022

Quality Representative

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