Rapid Micro Biosystems

Certificate of Analysis

Product Name:	**Bioburden Cassette: R2A Agar**		
Catalogue number:	BR2A-048	**Manufacture Date:**	22Mar2021
Lot Number:	08121L2	**Expiration Date:**	20Dec2021

The above lot has been produced in a microbiologically controlled environment 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	Pale to light tan, no surface blemishes	Satisfactory
pH#	7.2 +/- 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
Bacillus subtilis	6633®	Satisfactory
Escherichia coli	8739®	Satisfactory
Methylobacterium extorquens	BAA-2500	Satisfactory
Pseudomonas aeruginosa	9027®	Satisfactory
Sphingomonas japonica	N/A	Satisfactory
Staphylococcus aureus	6538®	Satisfactory

*A standardized inoculum of the test organisms listed above was inoculated on selected cassettes. Growth was measured after 24-168 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.

Contamination Evaluation:

Contamination Evaluation	No growth detected at 5-7 days' incubation at 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.

Released by:

Release Date 31 MAR 2021

Jim Lafferty,
QA Vice President

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