

#### SCOPE OF ACCREDITATION TO ISO 17034:2016

### MICROBIOLOGICS, INC. 200 Cooper Avenue North St. Cloud, Minnesota 56303 Tina Sobania Phone: 320 229 7050

#### **REFERENCE MATERIAL PRODUCER**

Valid To: February 29, 2024

Certificate Number: 2655.02

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this Reference Material Producer for the production of Certified Reference Materials and Reference Materials of the following types:

Certified Reference Material/ Artifact or Matrix	Concentration Ranges and Associated Uncertainty	Test Analysis Measurement	Method/ Characterization Technique
Microbial Reference Cultures			
Epower <sup>™</sup> CRM Quantitative Certified Reference Materials for	Range: $(10^2 \text{ to } 10^8)$ Uncertainty: within $\pm 0.6$ of a log of the assigned value	Viability	CFU enumeration using automated plating and counting
the Identity and Quantitation of Bacteria, Fungi and Yeast. (Lyophilized Format)	N/A	Identity	Phenotyping: Manual and automated biochemical, serological; staining, microscopy, selective media
Lab-Elite <sup>™</sup> CRM Qualitative Certified Reference Materials for Bacteria, Fungi and Yeast. (Lyophilized Format)	N/A	Identity	Phenotyping: Manual and automated biochemical, serological; staining, microscopy, selective media.

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Reference Material/ Artifact or Matrix	Concentration Ranges	Test Analysis Measurement	Method/ Characterization Technique
Microbial Reference Cultures			
Epower <sup>™</sup> , EZ-Accu Shot <sup>™</sup> , EZ-Accu Shot Select, EZ-CFU <sup>™</sup> , EZ- CFU <sup>™</sup> One Step.	(10 to 100) CFU per 0.1 ml on non- selective media	Viability	CFU enumeration using automated plating and counting
Quantitative Reference Materials for the Identity and Quantitation of Bacteria, Fungi and Yeast. (Lyophilized Format)	N/A	Identity	Phenotyping: Manual and automated biochemical, serological; staining, microscopy, selective media
KWIK-STIK <sup>™</sup> , KWIK-STIK <sup>™</sup> Plus, LYFO DISK <sup>™</sup> , UVBioTAG <sup>™</sup> Qualitative Reference Materials for Bacteria, Fungi and Yeast. (Lyophilized Format)	N/A	Identity	Phenotyping: Manual and automated biochemical, serological; staining, microscopy, selective media
EZ-Accu Shot <sup>TM</sup> Starved Cells Quantitative Reference Materials for the	(500 to 2000) CFU per pellet	Viability	CFU enumeration using automated plating and counting
Identity and Quantitation of Bacteria, Fungi and Yeast. (Lyophilized Format)	N/A	Identity	Phenotyping: Manual and automated biochemical, serological; staining, microscopy, selective media
EZ-PEC <sup>™</sup> Quantitative Reference Materials for the Identity and	$2.0 \times 10^{7}$ to 9.9 x $10^{7}$ CFU per pellet	Viability	CFU enumeration using automated plating and counting
Quantitation of Bacteria, Fungi and Yeast. (Lyophilized Format)	N/A	Identity	Phenotyping: Manual and automated biochemical, serological; staining, microscopy, selective media

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Reference Material/ Artifact or Matrix	Concentration Ranges	Test Analysis Measurement	Method/ Characterization Technique
Microbial Reference Cultures			
EZ-Spore <sup>™</sup> Quantitative Reference Materials for the Identity and	10 <sup>4</sup> CFU per pellet	Viability	CFU enumeration using automated plating and counting
Quantitation of Bacteria, Fungi and Yeast. (lyophilized format)	N/A	Identity	Phenotyping: Manual and automated biochemical, serological; staining, microscopy, selective media
Enumerated Mycoplasma Quantitative Reference	10 <sup>4</sup> CFU/ml	Viability	Plating, visual assessment
Materials for the Identity and Quantitation of Bacteria. (liquid format)	N/A	Identity	Phenotyping: Manual and automated biochemical, serological; staining, microscopy, selective media

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# **Accredited Reference Material Producer**

A2LA has accredited

## MICROBIOLOGICS, INC. St. Cloud, MN

This accreditation covers the specific materials listed on the agreed upon Scope of Accreditation. This producer meets the requirements of ISO 17034:2016 General Requirements for the Competence of Reference Material Producers. This accreditation demonstrates technical competence for a defined scope and the operation of a quality management system.



Presented this 18<sup>th</sup> day of February 2022.

Vice President, Accreditation Services For the Accreditation Council Certificate Number 2655.02 Valid to February 29, 2024

For reference materials to which this accreditation applies, please refer to the reference material producer's Scope of Accreditation.