



SCOPE OF ACCREDITATION TO ISO 17034:2016

MICROBIOLOGICS, INC.  
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REFERENCE MATERIAL PRODUCER

Valid To: February 28, 2022

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 in the following categories:

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

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



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





## 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 7<sup>th</sup> day of May 2020.

Vice President, Accreditation Services  
For the Accreditation Council  
Certificate Number 2655.02  
Valid to February 28, 2022



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