



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

U.S. MICRO-SOLUTIONS, INC.  
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ENVIRONMENTAL

Valid To: March 31, 2027

Certificate Number: 7000.01

In recognition of the successful completion of the A2LA evaluation process, including an assessment of the laboratory's compliance with the 2016 TNI Environmental Testing Laboratory Standard, as well as an assessment of the laboratory's conformance with U.S. FDA Good Laboratory Practice (GLP) Regulations per 21 CFR Part 58<sup>1</sup>), accreditation is granted to this laboratory to perform the following tests on air, surface, bulk, and liquid using the below methodologies:

<u>Test(s)</u>	<u>Analyte(s)</u>	<u>Method(s)</u>
USP <797> <sup>1</sup> <ul style="list-style-type: none"><li>Enumeration</li><li>Microbial Identification via MALDI-TOF</li><li>Media Fill</li></ul>	Aerobic Bacteria & Fungi	USP-NF <797> USP-NF <1117> MIC 05, MIC 16
<i>Legionella</i> <ul style="list-style-type: none"><li>Enumeration</li><li>Microbial Identification via MALDI-TOF</li></ul>	<i>Legionella</i> spp.	ISO 11731:2017 MIC 06, MIC 07
Total Coliforms & <i>Escherichia coli</i> <ul style="list-style-type: none"><li>Presence/Absence</li></ul>	Total Coliforms & <i>E. coli</i>	SM 9223B MIC 55
Enterolert (Sewage Screen) <ul style="list-style-type: none"><li>Presence/Absence</li></ul>	<i>Enterococcus</i> spp.	SM 9230D MIC 11
Heterotrophic Plate Count <ul style="list-style-type: none"><li>Enumeration</li></ul>	Heterotrophic Bacteria	ASTM D8516-23 ANSI/AAMI/ISO 23500-3:2019 MIC 08
Indoor & Outdoor Environment <ul style="list-style-type: none"><li>Enumeration</li><li>Microbial Identification</li></ul>	Aerobic Bacteria & Fungi	MIC 03, MIC 04
Spore Trap	Microscopic Examination of Fungal Spores, Fungal Structures, Hyphae, Pollen, Insect Fragments, and Fibrous Material from Air Samples	ASTM D7391-20 MIC 01
Direct Microscope Examination (DME)	Microscopic Examination of Fungal Spores, Fungal Structures, Hyphae, Pollen, Insect Fragments, and Fibrous Material from Surface Samples	ASTM D7658-17 MIC 02
Mycobacteria	Non-tuberculous Mycobacteria	MIC 15

<u>Test(s)</u>	<u>Analyte(s)</u>	<u>Method(s)</u>
Medical Device Cleaning Surveillance Testing <ul style="list-style-type: none"> <li>• Duodenoscope</li> <li>• Heater Cooler Units</li> </ul>	Aerobic Bacteria & Fungi, Non-Tuberculous Mycobacteria	CDC/FDA/ASM MIC 12, MIC 13
Ultrapure Water Testing <ul style="list-style-type: none"> <li>• Endotoxin</li> <li>• Bioburden</li> </ul>	Endotoxin Bioburden	USP<85> ANSI/AAMI/ISO 23500-3:2019 MIC 61, MIC 62 USP<1231> ANSI/AAMI ST108:2023 MIC 59
Ultrapure Water Testing <ul style="list-style-type: none"> <li>• Total Organic Carbon (TOC) &amp; Conductivity</li> </ul>	Total Organic Carbon & Conductivity	USP<643> USP<645> ANSI/AAMI ST108: 2023 MIC 60

<sup>1</sup>Assessment to the U.S. FDA GLP (21CFR58) Regulations does not imply acceptance by the FDA.

## BIOLOGICAL

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests on media and water:

<u>Test(s)</u>	<u>Analyte(s)</u>	<u>Method(s)</u>
Opportunistic Pathogens <ul style="list-style-type: none"> <li>• Enumeration</li> <li>• Microbial Identification</li> </ul>	<i>Burkholderia cepacia</i> complex <i>Acinetobacter</i> spp. <i>Pseudomonas aeruginosa</i>	MIC 48
Growth Promotion	Bacteria & Fungi	USP<61> MIC 14



# Accredited Laboratory

A2LA has accredited

**U.S. MICRO-SOLUTIONS, INC.**

Latrobe, PA

for technical competence in the field of

**Environmental Testing**

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*. This laboratory also meets the requirements of the A2LA R206 – *Specific Requirements – Environmental Testing Laboratory Accreditation Program*. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communiqué dated April 2017).



Presented this 27<sup>th</sup> day of March 2025.

A blue ink signature of Mr. Trace McInturff, written over a horizontal line.

Mr. Trace McInturff, Vice President, Accreditation Services  
For the Accreditation Council  
Certificate Number 7000.01  
Valid to March 31, 2027

*For the tests to which this accreditation applies, please refer to the laboratory's Environmental Scope of Accreditation.*