



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

ELEMENT CINCINNATI  
3701 Port Union Road  
Fairfield, Ohio 45014  
Meghan Smith Phone: 513 984 4112

BIOLOGICAL

Valid To: April 30, 2024

Certificate Number: 2422.02

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

<u>Test Description:</u>	<u>Method(s):</u>
Limulus Amebocyte Lysate (LAL)	USP 85; ANSI/AAMI ST72
Bioburden	ISO 11737-1
Total Aerobic Microbial Count, Total Yeast and Mold Count-Microbial Limits	USP 61
Total Microbial Count in Water	USP 1231 Section 8
<i>Escherichia coli, Salmonella, Staphylococcus aureus, Pseudomonas aeruginosa, Candida albicans, Clostridia speices</i>	USP 62
Cytotoxicity	ISO 10993-5; USP 87
Heterotrophic Plate Count	SM 9215

CHEMICAL

<u>Test Description:</u>	<u>Method(s):</u>
TOC	SM 5310C; USP 643
Conductivity	USP 645
Gravimetric	ASTM F2459-18 11.5 and 11.8



# Accredited Laboratory

A2LA has accredited

## ELEMENT CINCINNATI

Fairfield, OH

for technical competence in the field of

## Biological 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 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 23<sup>rd</sup> day of May 2022.

A blue ink signature of the Vice President of Accreditation Services.

Vice President, Accreditation Services  
For the Accreditation Council  
Certificate Number 2422.02  
Valid to April 30, 2024

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