



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

WUXI APTEC, INC.¹
1265 Kennestone Circle
Marietta, GA 30066
Heather Laird Phone: 888-847-6633

BIOLOGICAL

Valid To: January 31, 2027

Certificate Number: 2784.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory at the location listed above as well as the one satellite laboratory location listed below to perform the following microbiological and biological tests for biopharmaceutical/biotechnology, medical device/medical products, and textile industries:

<u>Test</u>	<u>Internal Procedures</u>	<u>Test Method(s)</u>
Bacterial Endotoxin Testing and Validation by Kinetic Chromogenic and Kinetic Turbidimetric Methods	SOP-00364	USP<85>, USP<161>; ANSI/AAMI/ISO ST 72
Evaluation of Environmental Monitoring Samples	SOP-00643 SOP-00656	USP <1116>
Microbial Analysis of Water	SOP-00646	USP<1231>; “Standard Methods for the Examination of Water and Wastewater”, American Public Health Association, Current Edition
<u>Organism Identification:</u> Gram Stain, Colony Morphology, MALDI-TOF DNA Sequencing	SOP-00657 SOP-00656 Appendix 12.1 SOP-00586 SOP-00584 SOP-02708	Bergey’s Manual of Determinative Bacteriology
Sterility Testing – Validation of Sterility Tests Direct Immersion, Membrane Filtration Fluid Path, In Situ	SOP-00376 SOP-00378 SOP-00379 SOP-00647	USP<71>, USP<1227>; British Pharmacopoeia (BP), Appendix XVI; European Pharmacopoeia (EP), Section 2.6.1; Japanese Pharmacopoeia (JP), 4.05; ANSI/AAMI/ISO 11737-2
Sterilization of Health Care Products- Microbiological Methods- Part 1:	SOP-00352 SOP-00354	ANSI/AAMI/ISO 11737-1;

<u>Test</u>	<u>Internal Procedures</u>	<u>Test Method(s)</u>
Determination of a Population of Microorganisms on Products		
Validation of Sterilization of Health Care Products – Radiation	SOP-00352 SOP-00354 SOP-00376 SOP-00378 SOP-00379	ANSI/AAMI/ISO 11137

¹ This accreditation covers testing performed at the main laboratory listed above, and the following satellite laboratory listed below:

WUXI APPTEC, INC.
1279 Kennestone Circle
Marietta, GA 30066

<u>Test</u>	<u>Internal Procedures</u>	<u>Test Method(s)</u>
Antimicrobial Effectiveness	SOP-00602	USP<51>, USP<1227>
Biological Indicators – Total Viable Spore Count	SOP-00623	USP<55>
Microbiological Examination of Non-Sterile Products	SOP-00631 SOP-00632	USP<61>, USP<62> (Harmonized) USP<1227>
Qualitative Assessment of Antimicrobial Activity of Textile Material, Carpets, Polymeric Materials and Plastics	SOP-00613 SOP-00619 SOP-00615 SOP-00617	AATCC Test Methods 147, 30 Part III; 174 Part 1, 174 Part III; ASTM Test Methods G21
Quantitative Assessment of Antimicrobial Activity of Textile Material, Carpets, Polymeric Materials and Plastics	SOP-00611 SOP-00616 SOP-00636 SOP-00608 SOP-00622 SOP-00606 SOP-00604	AATCC Test Methods 100, 174 Part II; ASTM Test Methods E2180, E2149, E2471; ISO 22196
Validation of Cleaning Efficacy of Reusable Medical Devices	-----	AAMI TIR 30 (Modified: – soiling, cleaning, exhaustive extraction. and visual inspection only)
Validation of the Sterilization/Reprocessing of Reusable Medical Devices	-----	AAMI TIR 12; ISO 17665



Accredited Laboratory

A2LA has accredited

WUXI APTEC, INC.

Marietta, GA

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 25th day of April 2025.

A blue ink signature of Trace McInturff, written in a cursive style.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 2784.01
Valid to January 31, 2027

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