



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

WUXI APPTEC
2540 Executive Dr
St. Paul, MN 55120
Deborah Erickson Phone: 888-794-0077

BIOLOGICAL

Valid To: January 31, 2021

Certificate Number: 2785.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following biological tests on medical devices including, but not limited to: polymers, metals & alloys, ceramics, drug compounds, and natural macromolecules:

Table with 2 columns: Test Title and Test Method(s). Rows include In Vitro Tests (Bacterial Mutagenicity, Chromosome Aberration, Mouse Lymphoma, etc.), In Life Studies (28 Day Osteoinduction, Subcutaneous Implant, etc.), and various cytotoxicity assays.

Test Title	Test Method(s)	
ISO Intracutaneous Reactivity Test		
Japanese Intracutaneous Reactivity Test		
Primary Skin Irritation		
USP Intracutaneous Injection Test		
Vaginal Mucosal Irritation Study		
Acute Systemic Toxicity Test	ISO 10993-11: Current Edition, Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	
Rabbit Pyrogen Test		
Subacute/Subchronic Toxicity Test		
In Vivo Assay for Viral Contaminants	Guidance for Industry – Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications (FDA, 2010)	
	Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals (1993) - FDA	
	European Pharmacopeia Current Edition; 2.6.16 Tests for extraneous agents in viral vaccines	
Sample Preparation Procedures		
Japanese Extraction Procedures and Alternate Preparation Methods	ISO 10993-12: Current Edition, Biological evaluation of medical devices – Part 12: Sample preparation and reference materials	
Preparation of Biomaterials for Agarose Overlay, Primary Skin Irritation, and Repeated Patch Dermal Sensitization		
Preparation of Biomaterial for Extraction		
Preparation of Biomaterials for Hemocompatibility Tests		
Preparation of Biomaterials for Implant Tests		
Sample Preparation for USP Rabbit Pyrogen Test and the Material Mediated Rabbit Pyrogen		
Mycoplasma		
Mycoplasma Detection	European Pharmacopeia Current Edition; 2.6.7 Mycoplasma Testing (EP)	
Mycoplasma Detection including <i>Mycoplasma putrefaciens</i>		
Mycoplasma Detection with Mycoplasmastasis		
Mycoplasma Detection with Mycoplasmastasis including <i>Spiroplasma melliferum</i>	21 CFR 610.30 Subpart D; Mycoplasma Testing U.S. Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (CBER) 1993. “Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals”	
Mycoplasma Detection		
Mycoplasma Detection		
Mycoplasma Detection including <i>M. putrefaciens</i>		
Mycoplasma Detection with Mycoplasmastasis		
Mycoplasma Detection including <i>S. melliferum</i>		
Research Products Test for the Presence of Mycoplasma		
Mycoplasma Detection		United States Pharmacopeia Current Edition: USP <63>
Mycoplasma Detection with Mycoplasmastasis		
Mycoplasma Detection with Mycoplasmastasis including <i>S. melliferum</i>		



Accredited Laboratory

A2LA has accredited

WUXI APTEC, INC.

St. Paul, MN

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 21st day of March 2019.

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

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 2785.01
Valid to January 31, 2021
Revised on April 24, 2019

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



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

WUXI APPTEC, INC.¹
2520 Pilot Knob Rd.
St. Paul MN, 55120
Deborah Erickson Phone: 1-888-794-0077

CHEMICAL

Valid To: January 31, 2021

Certificate Number: 2785.02

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests on medical devices including, but not limited to: polymers, metals & alloys, ceramics, drug compounds, and natural macromolecules:

<u>Test Technology</u>	<u>Test Method</u>
Extraction	ISO 10993-18
Gas Chromatography / Mass Spectrometry (GC/MS)	ISO 10993-18
Inductively Coupled Plasma / Mass Spectrometry (ICP/MS)	ISO 10993-18
Residual Solvent Headspace Gas Chromatography / Mass Spectrometry (HSGC/MS)	ISO 10993-18
Ultra Performance Liquid Chromatography / Mass Spectrometry (UPLC/MS)	ISO 10993-18

¹ This scope meets the A2LA *P112 Flexible Scope Policy*



Accredited Laboratory

A2LA has accredited

WUXI APTEC, INC.

St. Paul, MN

for technical competence in the field of

Chemical 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 21st day of March 2019.

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

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 2785.02
Valid to January 31, 2021
Revised on April 25, 2019

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