SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

WUXI APPTEC
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BIOLOGICAL

Valid To: January 31, 2025 Certificate Number: 2785.01

In recognition of the successful completion of the A2LA evaluation process (including an assessment of the organization's compliance with A2LA's FDA ASCA Accreditation Program[1] requirements and with applicable requirements of the *U.S. FDA Good Laboratory Practice (GLP) Regulations* per 21 CFR 58), 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:

Test Title	Test Method(s)
In Vitro Tests	
Bacterial Mutagenicity Test (Ames Assay)	ISO 10993-3: Current Edition, Biological evaluation of medical devices – Part 3: Tests for genotoxicity carcinogenicity and reproductive toxicity
In Vitro Mouse Lymphoma Assay	
The In Vivo Mouse Micronucleus Assay	
ASTM Hemolysis Assay	ISO 10993-4: Current Edition, Biological evaluation of medical devices – Part 4: Selection of test for interactions with blood
Complement Activation C3a Assay	
Complement Activation SC5b-9 (TCC) Assay	
In Vitro Hemocompatibility Assay	
Partial Thromboplastin Time (PTT) Assay	
Platelet and Leukocyte Count Assay	
Agarose Overlay Cytotoxicity Test	ISO 10993-5: Current Edition, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
Direct Cell Contact Cytotoxicity Test	
Minimum Essential Medium (MEM) Elution Assay	
MTT Assay	
Neutral Red Uptake Assay	
In-Vitro Skin Irritation Test	ISO 10993-23 Current Edition, Biological evaluation of medical devices – Part 23: Tests for irritation
In Life Studies	
28 Day Osteoinduction Assay in Mice or Rats	ISO 10993-6: Current Edition, Biological Intramuscular evaluation of medical devices – Part 6: Tests for local effects after implantation
Intramuscular Implant	
Subcutaneous Implant Test	

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Test Title	**Test Method(s)**
Buehler Sensitization Test	ISO 10993-10: Current Edition, Biological evaluation of medical devices – Part 10: Tests for irritation and delayed type hypersensitivity
ISO Guinea Pig Maximization Sensitization 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	
ISO Intracutaneous Reactivity Test	ISO 10993-23 Current Edition, Biological evaluation of medical devices – Part 23: Tests for irritation
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	
Preparation of Biomaterials for Agarose Overlay, Primary Skin Irritation, and Repeated Patch Dermal Sensitization	ISO 10993-12: Current Edition, Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
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 with Mycoplasmastasis	European Pharmacopeia Current Edition; 2.6.7 Mycoplasma Testing (EP)
Mycoplasma Detection with Mycoplasmastasis	United States Pharmacopeia Current Edition: USP <63>

ASCA Biocompatibility

[1]Testing Activities performed under the scope of the U.S FDA ASCA Pilot Program Specifications: Biocompatibility Testing of Medical Devices – Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program published on September 25th, 2020, and in accordance with all requirements of A2LA *R256 Specific Requirements - FDA ASCA Program*

Test	**Standard(s) or Test Method(s)**
Direct and Indirect Hemolysis Complement Activation C3a Assay Complement Activation SC5b-9 (TCC) Assay	ISO 10993-4: Third Edition 2017-04, Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions With Blood; ASTM F756-17: Standard Practice for Assessment of Hemolytic Properties of Materials
MEM Elution Cytotoxicity[1]	ISO 10993-5: Third Edition 2009-06-01, Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
Intracutaneous Reactivity Irritation Buehler Sensitization Test Primary Skin Irritation	ISO 10993-10: Third Edition 2010-08-01, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization
Guinea Pig Maximization Sensitization	ISO 10993-10: Third Edition 2010-08-01, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization; ASTM F720-17: Standard Practice for Testing Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test
Acute Systemic Toxicity	ISO 10993-11: Third Edition 2017-09, Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity
Material-Mediated Pyrogenicity	ISO 10993-11: Third Edition 2017-09, Biological Evaluation of Medical Devices -Part 11: Tests for Systemic Toxicity; USP 43-NF38:2020 <151>: Pyrogen Test (USP Rabbit Test)
Sample Preparation Procedures	ISO 10993-12: Fourth Edition 2012-07-01, Biological Evaluation of Medical Devices -Part 12: Sample Preparation and Reference Materials

[2]These methods have been assessed by A2LA according to A2LA's FDA ASCA Program requirements. Accreditation by A2LA does not imply FDA ASCA-Accreditation. All ASCA-accreditation decisions for testing laboratory applications are made solely by the FDA, a list of approved laboratories can be found at https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/asca-accredited-testing-laboratories.

Accredited Laboratory

A2LA has accredited

WUXI APPTEC, 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 laboratory also meets the A2LA *R256 – Specific Requirements – FDA ASCA 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 11th day of April 2023.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 2785.01
Valid to January 31, 2025

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