



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

WUXI APPTEC, INC.¹
2520 Pilot Knob Rd.
Mendota Heights, MN 55120
Natasha Overbo Phone: (651) 675-2000

CHEMICAL

Valid to: May 31, 2024

Certificate Number: 6597.01

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, including but not limited to: polymers, metals & alloys, ceramics, drug compounds, and natural macromolecules:

<u>Test/Technology</u>	<u>Test Method</u>
Elemental Scan by Inductively Coupled Plasma / Mass Spectrometry (ICP/MS)	ISO 10993-18
Extraction	ISO 10993-18
Screening of Residual Solvent Headspace by Gas Chromatography / Mass Spectrometry (HSGC/MS)	ISO 10993-18
Screening of Semi-Volatile and Non-Volatile Compounds by Ultra Performance Liquid Chromatography / Mass Spectrometry (UPLC/MS) and Ultra-High Performance Liquid Chromatography-Quadrupole Time-of-Flight Mass Spectrometry (UHPLC/Q-TOF-MS)	ISO 10993-18
Screening of Semi-Volatile and Volatile Compounds by Direction Injection Gas Chromatography / Mass Spectrometry (GC/MS)	ISO 10993-18

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



Accredited Laboratory

A2LA has accredited

WUXI APPTec, INC.

Mendota Heights, 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 25th day of April 2022.

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

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 6597.01
Valid to May 31, 2024

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