



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

WUXI ADVANCED THERAPIES, INC.¹
4751 League Island Blvd.
Philadelphia, PA 19112
Andi Nerozzi Phone: 215-218-7100 ext. 5593

BIOLOGICAL

Valid To: May 31, 2023

Certificate Number: 3141.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests on bio-pharmaceutical raw materials, intermediates, and finished products:

<u>Test/Technology</u>	<u>Test Method(s)</u>
Co-Cultivation of Test Article for Detection of Retrovirus	Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals, US FDA (1993) (E.g. WuXi AppTec Method 30201)
Replication Competent Viral Assay	(E.g. WuXi AppTec Method 30698)
Titration Assay to Determine Potency of Virus	WuXi AppTec Custom Developed and Validated Methodology (E.g. WuXi AppTec Method 30099)

Molecular Biology²

Detection of Mycoplasma by PCR

Determination of Residual Host Cell DNA by qPCR

Reverse Transcriptase Assay

Virus Detection by qPCR

CHEMICAL

Analytical²

Determination of Process Residuals by ELISA

Determination of Protein Concentration by Absorbance using BCA

Determination of Protein Concentration by UV Spectrophotometry

Osmolality

pH and Appearance

Size Exclusion Chromatography (SEC) of Monoclonal Antibodies for Monomer

¹In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this satellite laboratory to perform the following tests on bio-pharmaceutical raw materials, intermediates, and finished products:

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BIOLOGICAL

<u>Test/Technology</u>	<u>Test Method(s)</u>
Detection Assay for Bovine/Equine/Porcine Adventitious Virus	E.g. WuXi AppTec Method 33281 (Bovine and Porcine); WuXi AppTec Method 30217 (Equine)
In Vitro Assay for Adventitious Virus	Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals, US FDA (1993); Characterization and Qualification of Cell Substrates and Other Biological Material Used in the Production of Viral Vaccines for Infectious Disease Indications, US FDA (2010) (E.g. WuXi AppTec Method 33864)

²These portions of this scope meet the A2LA P112 *Flexible Scope Policy*





Accredited Laboratory

A2LA has accredited

WUXI ADVANCED THERAPIES, INC.

Philadelphia, PA

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 1st day of March 2021.

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

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3141.01
Valid to May 31, 2023

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