



## SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

WUXI ADVANCED THERAPIES, INC.  
400 Rouse Blvd.  
Philadelphia, PA 19112  
Andi Nerozzi Phone: 215-218-7100 ext. 5593

### BIOLOGICAL

Valid To: May 31, 2025

Certificate Number: 3141.01

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 satellite location listed below, to perform the following tests on bio-pharmaceutical raw materials, intermediates, and finished products:

<b><u>Test</u></b>	<b><u>Test Method(s)</u></b>
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)
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)
Replication Competent Viral Assay	(E.g. WuXi AppTec Method 30698)

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BIOLOGICAL

<b><u>Test/Technology</u></b>	<b><u>Test Method</u></b>
Titration Assay to Determine Potency of Virus	WuXi AppTec Custom Developed and Validated Methodology (E.g. WuXi AppTec Method 30099)

CHEMICAL

<b><u>Test/Technology</u></b>	<b><u>Test Method</u></b>
<sup>2</sup> Size Exclusion Chromatography (SEC) of Monoclonal Antibodies for Monomer	

**Molecular Biology<sup>1</sup>**

Detection of Mycoplasma by PCR  
Determination of Residual Host Cell DNA by qPCR  
Reverse Transcriptase Assay  
Virus Detection by qPCR

**Analytical<sup>1</sup>**

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

<sup>1</sup>These 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 29<sup>th</sup> day of August 2023.

A handwritten signature in blue ink, appearing to read "Trace McInturff".

Mr. Trace McInturff, Vice President, Accreditation Services  
For the Accreditation Council  
Certificate Number 3141.01  
Valid to May 31, 2025

