



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

WUXI APPTEC, INC.  
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Philadelphia, PA 19112  
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BIOLOGICAL

Valid To: May 31, 2019

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:

**Test(s)**

**Test Method(s)**

Analytical

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) (30201)
Detection Assay for Bovine/Equine/Porcine Adventitious Virus	WuXi AppTec Method 33281 (Bovine and Porcine) 30217 (Equine)
Detection of Mycoplasma by PCR	WuXi AppTec Methods 33231, 33156, 33159
Determination of Process Residuals by ELISA	WuXi AppTec Method 38045
Determination of Protein Concentration by Absorbance using BCA	WuXi AppTec Method 38001
Determination of Protein Concentration by UV Spectrophotometry	WuXi AppTec Method 38004
Determination of Residual Host Cell DNA by qPCR	WuXi AppTec Methods 33369, 33699
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). (Eg 33864)

**Test(s) (continued)**

Osmolality

pH and Appearance

Replication Competent Viral Assay

Reverse Transcriptase Assay

Size Exclusion Chromatography (SEC) of Monoclonal Antibodies for Monomer

Titration Assay to Determine Potency of Virus

**Virology**

Virus Detection by qPCR

**Test Method(s) (continued)**

WuXi AppTec Method 30923

WuXi AppTec Method 38026

WuXi AppTec Method 30698

WuXi AppTec Methods 33611, 33241, 21390

WuXi AppTec Method 30882

WuXi AppTec Custom Developed and Validated Methodology (Eg 30099)

WuXi AppTec Methods 21395, 33248, 33198, 33394, 314452, 314454, 21181

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## Accredited Laboratory

A2LA has accredited

**WUXI APPTec, 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 17025:2005 *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 8 January 2009).



Presented this 25<sup>th</sup> day of May 2017.

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President & CEO  
For the Accreditation Council  
Certificate Number 3141.01  
Valid to May 31, 2019

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