



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, 2017

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</u>	<u>Test Method(s)</u>
<u>Virology</u>	
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)
In Vivo Assay for Adventitious Virus	WuXi AppTec Methods 30027, 30193, 30194
Detection Assay for Bovine/Equine/Porcine Adventitious Virus	WuXi AppTec Method 31822
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)
Replication Competent Viral Assay	WuXi AppTec Method 30698
Titration Assay to Determine Potency of Virus	WuXi AppTec Custom Developed and Validated Methodology
<u>Molecular Biology</u>	
Virus Detection by qPCR	WuXi AppTec Methods 33665, 33671, 33198, 32827, 33703, 33705, 33713, 33734, 33761
Determination of Residual Host Cell DNA by qPCR	WuXi AppTec Methods 33369, 33699

Peter Blayze

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Test

Test Method(s)

Molecular Biology (Continued)

Detection of Mycoplasma by PCR

WuXi AppTec Methods 33231, 33156, 33159

Reverse Transcriptase Assay

WuXi AppTec Methods 33730, 33733

Analytical

Cell Line Authentication and Identification by Isoenzyme Electrophoresis

WuXi AppTec Method 30330

Determination of Protein Concentration by UV Spectrophotometry

WuXi AppTec Method 38004

Determination of Protein Concentration by Absorbance using BCA

WuXi AppTec Method 38001

Determination of Process Residuals by ELISA

WuXi AppTec Method 38045

Size Exclusion Chromatography (SEC) of Monoclonal Antibodies for Monomer

WuXi AppTec Method 30882

pH and Appearance

WuXi AppTec Method 38026

Osmolality

WuXi AppTec Method 30923





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 laboratory also meets the requirements of any additional program requirements in the field of Biological. 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 6th day of July 2015.

A handwritten signature in black ink, reading "Peter Abney".

President & CEO
For the Accreditation Council
Certificate Number 3141.01
Valid to May 31, 2017

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