



World Class Accreditation

The American Association for Laboratory Accreditation

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 8th day of July 2011.





Peter Abney

President & CEO
For the Accreditation Council
Certificate Number 3141.01
Valid to May 31, 2013

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



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

WUXI APPTEC, INC.
4751 League Island Blvd.
Philadelphia, PA 19112
Michael Kenville Phone: 215 218 5544

BIOLOGICAL

Valid To: May 31, 2013

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

Test Method(s)

Virology

In Vitro Assay for Adventitious Virus

1993 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 February 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

1993 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

Molecular Biology

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

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 33330

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 38067

HPLC for Assessment of Concentration or Purity

WuXi AppTec Method 32255

pH and Appearance

WuXi AppTec Method 38026

Osmolality

WuXi AppTec Method 30923