



The American Association for Laboratory Accreditation

World Class Accreditation

Accredited Laboratory

A2LA has accredited

WUXI APPTec, INC.

St. Paul, MN

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 25th day March 2011.





Peter Abney

President & CEO
For the Accreditation Council
Certificate Number 2785.01
Valid to January 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.
2540 Executive Drive
St. Paul, MN 55120
Sylvester Williams III Phone: (651) 675-2055

BIOLOGICAL

Valid To: January 31, 2013

Certificate Number: 2785.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following biological tests:

Test Title

Test Method(s)

In-Vitro Tests

Bacterial Mutagenicity Test (Ames Assay)
In Vitro Mouse Lymphoma Assay
The In Vivo Mouse Micronucleus Assay
In Vitro Chromosome Aberration Analysis - Using
Chinese Hamster Ovary (CHO) Cells

ISO 10993-3: Current Edition, Biological
evaluation of medical devices - Part 3: Tests
for genotoxicity carcinogenicity and
reproductive toxicity

Complement Activation SC5b-9 (TCC) Assay
Complement Activation C3a Assay
Platelet and Leukocyte Count Assay
In Vitro Hemocompatibility Assay
Partial Thromboplastin Time (PTT) Assay
ASTM Hemolysis Assay
Prothrombin Time Assay
NIH Hemolysis Testing: Extract Method and Direct
Contact Methods

ISO 10993-4: Current Edition, Biological
evaluation of medical devices - Part 4:
Selection of test for interactions with blood

Agarose Overlay Cytotoxicity Test
Extract Colony Assay Cytotoxicity Test
Direct Cell Contact Cytotoxicity Test
Minimum Essential Medium (MEM) Elution Assay
Growth Inhibition Assay

ISO 10993-5: Current Edition, Biological
evaluation of medical devices - Part 5: Tests
for in vitro cytotoxicity

Test Title

Test Method(s)

In-Life Studies

Subcutaneous Implant Test
Intramuscular Implant
28 Day Osteoinduction Assay in Mice or Rats

ISO 10993-6: Current Edition, Biological evaluation of medical devices - Part 6: Tests for local effects after implantation

Japanese Primary Skin Irritation
Japanese Intracutaneous Reactivity Test
USP Intracutaneous Injection Test
ISO Intracutaneous Reactivity Test
ISO Guinea Pig Maximization Sensitization Test
Buehler Sensitization Test
Primary Skin Irritation
Guinea Pig Maximization Sensitization Test - Method for
Japanese Ministry of Health, Labor and Welfare
Murine Local Lymph Node Assay
Vaginal Mucosal Irritation Study

ISO 10993-10: Current Edition, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

Acute Systemic Toxicity Test
Systemic Injection Test
Subacute (14 Day) Toxicity Test
Rabbit Pyrogen Test

ISO 10993-11: Current Edition, Biological evaluation of medical devices – Part 11: Tests for systemic toxicity

Sample Preparation Procedures

Japanese Extraction Procedures and Alternate Preparation Methods
Preparation of Biomaterials for Extraction
Preparation of Biomaterials for Implant Tests
Preparation of Biomaterials for Agarose Overlay, Primary Skin Irritation, and Repeated Patch Dermal Sensitization
Preparation of Biomaterials for Hemocompatibility Tests
Sample Preparation for USP Rabbit Pyrogen Test and the Material Mediated Rabbit Pyrogen Test

ISO 10993-12: Current Edition, Biological Evaluation of medical devices - Part 12: Sample preparation and reference materials

Mycoplasma

Mycoplasma Detection
Mycoplasma Detection with MycoplasmaStatis

European Pharmacopeia Current Edition; 2.6.7 Mycoplasma Testing (EP)

Test Title

Test Method(s)

Mycoplasma (Continued)

Mycoplasma Detection including *S. melliferum*
Mycoplasma Detection with Mycoplasma mastitis including
S. melliferum
Mycoplasma Detection including *M. putrefaciens*
Mycoplasma Detection with Mycoplasma mastitis including
M. putrefaciens

European Pharmacopeia Current Edition; 2.6.7
Mycoplasma Testing (EP)

Mycoplasma Detection
Mycoplasma Detection and DNA Fluorochrome Staining

21 CFR 610.30 Subpart D; Mycoplasma
Testing

Mycoplasma Detection
Mycoplasma Detection with Mycoplasma mastitis
Mycoplasma Screening of Cell Cultures by DNA
Fluorochrome Staining
Mycoplasma Detection including *S. melliferum*
Mycoplasma Detection with Mycoplasma mastitis including
S. melliferum
Mycoplasma Detection including *M. putrefaciens*
Mycoplasma Detection with Mycoplasma mastitis including
M. putrefaciens
Research Products Test for the Presence of Mycoplasma

U.S. Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research
(CBER). 1993. "Points to Consider in the
Characterization of Cell Lines Used to
Produce Biologicals"

Mycoplasma Detection
Mycoplasma Detection with Mycoplasma mastitis
Mycoplasma Detection including *S. melliferum*
Mycoplasma Detection with Mycoplasma mastitis including
S. melliferum

United States Pharmacopeia Current Edition:
USP <63>