



SERVICES FOR

Devices and Combination Products



How to Contact Us

U.S. FACILITIES / CLIENT SERVICES



St. Paul

2540 Executive Drive
St. Paul, MN 55120
FAX 651.675.2005

888-794-0077

651-675-2000

Atlanta

1265 Kennestone Circle
Marietta, GA 30066
FAX 770.514.0294

888-847-6633

770-514-0262

Philadelphia

4751 League Island Blvd.
Philadelphia, PA 19112
FAX 215.218.5990

800-622-8820

215-218-5500

ACCOUNT MANAGERS



Your Account Manager serves as your primary contact for all inquiries regarding testing programs and pricing.

888-794-0077

OR

651-675-2000

Enter your Account Manager's extension or press "0" to reach the WuXi AppTec operator.

EMAIL



WuXi AppTec personnel can be emailed at: firstname.lastname@wuxiapptec.com
Or use our general mailbox: info@wuxiapptec.com

INTERNET



Visit our website at: www.wuxiapptec.com.

[This catalog is also available on the website.]

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BIOBURDEN / MICROBIAL ASSAYS

A

Bioburden Testing
Microbial Identification
USP Microbiological Examination
Antimicrobial Efficacy (AME) Testing – *In Vitro* Assays
Antimicrobial Efficacy (AME) Testing – *In Vivo* Studies
Antimicrobial Assays for Industrial Products

BIOCOMPATIBILITY

B

Cytotoxicity
Genotoxicology / Mutagenicity
Hemocompatibility
Implantation
Irritation / Intracutaneous
Pyrogenicity
Sensitization
Subacute/Subchronic Toxicity
Systemic (Acute) Toxicity
Finished Product Release

JMHLW Testing

Reference Materials

Guide to Assessing Biocompatibility Testing Needs [Chart]
Testing Requirements Under GLP Regulations
Required Biocompatibility Tests for Classifications of Plastics (USP)
Device Categories
Initial Evaluation Tests for Consideration
[Chart based on ISO 10993-1 and FDA G95-1 Guidelines]
“Quick Guide” to Sample Requirements and Turnaround Times

CHEMISTRY

C

Analytical Chemistry
Chemical / Physical Tests
EO Residual Testing

ENDOTOXIN (LAL)

D

Kinetic Chromogenic LAL Tests
Kinetic Turbidimetric LAL Tests
Gel Clot LAL Tests

ENVIRONMENTAL

E

Environmental Monitoring Programs
Microbial Sampling Tests
Microbial Identification
Environmental Sampling Products

PACKAGE TESTING

F

Seal Integrity Testing
Package Integrity Testing
Transportation/Distribution Simulation Testing
Accelerated Aging / Shelf-Life Studies

STERILITY TESTING

G

Biological Indicators
Sterility Method Suitability Test (B/F)
Product Sterility Tests
Liquid Sterility Tests
Inoculated Product Tests

STERILIZATION VALIDATION

H

EO Sterilization Validation
Radiation Sterilization Validation
Reusable Medical Device Validation

Introduction to WuXi AppTec

INTEGRATED TESTING AND MANUFACTURING SERVICES

Medical Devices

GLP- and GMP-compliant testing services for safety and lot release include *in vivo* and *in vitro* biocompatibility/toxicology, hemocompatibility, chemistry, microbiology, sterilization validation, viral and bacterial clearance, environmental testing, quality assurance support/monitoring of manufacturing processes, reusable device validation, package testing, and custom studies.

Combination Products (Device + Drug)

To meet specific needs for combination products, WuXi AppTec's GLP- and GMP-compliant testing services for efficacy, safety and lot release for medical device services are integrated with our services designed for the cell therapy, tissue, biotechnology and pharmaceutical industries.

Tissue-Based Products

GLP- and GMP-compliant testing services for processed tissue and tissue-based products include viral and bacterial inactivation studies, safety and lot release testing such as osteoinductivity (*in vitro* and *in vivo*), and custom studies. cGMP manufacturing services include tissue processing, R&D pilot projects, product assembly and final packaging.

Biologics / Biopharmaceuticals

GLP/GMP-compliant contract testing services include viral and bacterial clearance/inactivation validation studies, cell and viral bank characterization, lot release testing and stability studies with supporting virology, cell biology, microbiology, molecular biology, toxicology/*in vivo* and analytical laboratories.

Cellular Therapeutics

GLP- and GMP-compliant testing services for cellular therapeutics include viral and bacterial inactivation studies, safety and lot release testing (*in vitro* and *in vivo*) and custom studies. cGMP manufacturing services include cell line development, GMP cell banking and cell therapy technology transfer, process development and manufacturing.

Pharmaceutical Industry

WuXi AppTec provides integrated services for pharmaceuticals across the discovery-to-IND spectrum. Discovery services include: synthetic and medicinal chemistry, analytical chemistry, discovery biology, safety pharmacology, DMPK and ADMET, and bioanalytics. Development services include: process research and development, research and commercial manufacturing, analytical development, and pre-formulation/formulation development. WuXi AppTec also offers a full-range of *in vivo* and *in vitro* non-clinical safety evaluation (toxicology) programs.

FACILITIES

All WuXi AppTec U.S. facilities are FDA registered. Additional qualifications include ISO certification, AAALAC accreditation, FDA registration for HCT/Ps and medical devices, and accreditation by AATB.

St. Paul, Minnesota

This 82,000-square-foot facility houses laboratories for *in vivo* and *in vitro* biocompatibility/toxicology testing, as well as laboratories for cGMP contract manufacturing and pilot projects for processed tissue and cell/tissue-based products.

Atlanta, Georgia

Located in facility space of 51,000 square feet, this laboratory performs routine and custom microbiology, chemistry and package testing, with additional specialized expertise in sterilization validation studies and dose audits.

Philadelphia, Pennsylvania

This 75,000-square-foot building houses testing laboratories for biopharmaceuticals, as well as cell therapy manufacturing services, including cell banking and cell expansion. Testing laboratories include virology, cell biology, molecular biology, analytical and viral clearance.

Global/Corporate Sites

WuXi AppTec's global headquarters is located in Shanghai. Primary China-based facilities include a 782,000-square-foot R&D center, and a 22,000-square-foot cGMP-quality formulation pilot plant in Shanghai Waigaoqiao Free Trade Zone; a 293,000-square-foot cGMP-quality process development and manufacturing plant in the Jinshan area of Shanghai; a 253,000-square-foot R&D center in Tianjin; and a 314,000-square-foot toxicology center in Suzhou.

QUALITY ASSURANCE

Every aspect of WuXi AppTec's operations is governed by a focus on quality assurance and quality control. A highly trained, internal quality assurance unit monitors all testing to assure accuracy, precision, reliability and timeliness. A continuous quality improvement process is in place to review any discrepancies and make improvements that will consistently enhance the quality of our service.

STAFFING

Our staff prides itself on being the vital, dedicated human resource for expertise that enhances every service we offer. All personnel are qualified and experienced professionals. Senior technical staffing includes experts who are nationally recognized in their fields. All division directors and laboratory supervisors are highly trained with many years of experience. A well-organized and experienced reporting unit is staffed by personnel skilled in data transfer, and proficient in handling both high-volume reporting and the demands of rapid turnaround times.

Information for Clients

The following is intended to be a quick guide for answers to Frequently Asked Questions. Please contact your WuXi AppTec Account Manager for more information/details regarding these subjects or any other questions you may have about our services.

CONFIDENTIALITY

WuXi AppTec's entire staff is sensitive to our clients' need for confidentiality regarding products, testing, and laboratory reports and data. All such information is held in strictest confidence and will be released only to persons or agencies authorized in writing by the client. [Confidentiality agreements, to be signed by the client and WuXi AppTec management, can be provided. Contact your Account Manager for more information.]

Likewise, this catalog is provided with the understanding that its contents remain the property of WuXi AppTec, and that it will be kept confidential and used only by the company or person to whom it is addressed/provided, for no other purpose than accessing information regarding the service offerings of WuXi AppTec.

AUDITS

We welcome the opportunity for clients to see first hand our scientific expertise and laboratory capabilities. Audits of any of our facilities may be arranged by contacting your Account Manager or the Quality Assurance Manager at the appropriate facility.

SAMPLE SUBMISSION / SAMPLE HANDLING

- **Sample Submission**

Samples sent to WuXi AppTec for testing should be accompanied by the appropriate paperwork for testing to be initiated. (See note below on Test Request Forms.) Where you will be submitting your sample depends on the test. As a general rule, samples for biocompatibility/in life and related testing should be sent directly to the St. Paul facility. Samples for most other services described in this catalog should be sent directly to the Atlanta facility. WuXi AppTec can accommodate sample-specific handling requirements, including centralized sample coordination, < -60°C or cryogenic handling requirements, and BSL/cleanroom accommodations. For more information regarding sample submissions, contact your Account Manager or Client Services.

- **Test Request Forms**

WuXi AppTec will supply test request forms to accompany your samples in pre-printed format (for you to make copies of and fill in as necessary) or in electronic format (a PDF form you can complete and print out). To receive personalized test request form(s), contact your Account Manager or email: info@wuxiapptec.com. PDF test request forms can also be found online at www.wuxiapptec.com/trf. Online sample submission is also available via our secure client portal. For more information, please contact your Account Manager or Client Services.

- **Sample Transportation**

How a sample is shipped (e.g., overnight air) is dependent on the nature of the sample and the type of testing. Some tests require that samples receive special shipping and handling (e.g., environmental water and some chemistry tests). See individual test listings or contact Client Services.

- **Sample Retention and Return**

Samples are discarded following completion of testing unless their return is requested by the client on the test request form. Return shipments entail additional fees that may vary depending on size/weight and quantity of samples and whether they are hazardous. The Sponsor can provide a courier account number in place of incurring a return shipment fee.

NOTE: Clients should be mindful of FDA and EPA GLP regulations regarding retention of samples. Retention of samples to meet these regulations is the responsibility of the Sponsor.

TESTING

- **GLP**

All WuXi AppTec operations are performed according to applicable good laboratory and good manufacturing practices. Certain studies for submission to regulatory bodies must be performed according to GLP (Good Laboratory Practices) regulations. GLP services are available at the client's request and entail additional fees. NOTE: For GLP tests, a protocol signed by the client must be in place at WuXi AppTec prior to test initiation. Contact your Account Manager for more information.

- **Turnaround Time**

Most test listings in this catalog provide an estimated turnaround time, which is calculated as the time from test initiation at the testing facility to the time your final report is issued. Except where noted, these turnaround times are for testing that does not include GLP. GLP testing requires additional time and clients will be notified as to the date they can expect to receive their final reports.

- **STAT Requests**

Arrangements can be made with the testing facility to accommodate stat testing whenever possible. Additional fees will be charged for this service. For more information, contact Client Services at the testing facility.

- **Customized Testing**

WuXi AppTec is uniquely qualified to assist clients with special testing needs. Our global organization draws on scientists with many years of industry and academic experiences who provide exceptional expertise in building customized programs and performing assays in accordance with FDA, ISO, GMP, GLP, JMHLW and other guidelines.

- **Consultation Services**

WuXi AppTec's expert scientific staff is available for client consultations in such areas as efficacy, safety, sterilization validations, biocompatibility, viral clearance, environmental monitoring, quality systems, and regulatory testing requirements. Contact your Account Manager for more information regarding rates and availability.

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REPORTS

- **Test Results Reporting**

Test reports include sample description, reference to a protocol or procedure, calculation methods when applicable, data summaries and a conclusion as applicable. Unexpected test results are reported promptly to the client. In the interest of accuracy, and to avoid possible miscommunication, we advise clients to rely on written reports for routine testing rather than requesting results by phone.

- **Amended or Re-Issued Reports**

If, at the client's request, a test report is amended and a new report is issued, or if the client requests that WuXi AppTec re-issue a report, additional fees will apply.

- **Record Retention**

Copies of test reports are retained in a secure archive managed by WuXi AppTec's Quality Assurance department.

PAYMENT

- **Pricing**

Clients should contact their Account Manager regarding all pricing information.

- **Purchase Orders / Billing**

Submitted samples should be accompanied by a purchase order (P.O.) number. Testing projects of unusual length or complexity may require initial, partial and/or interim payment. Credit applications may be required of new clients and WuXi AppTec may require new clients to make a payment in advance of test initiation. Invoices are billed and payable in U.S. dollars only. Payment for all invoices is net 30 days.