

Viral Bank Characterization

**Comprehensive testing programs for
regulatory acceptance worldwide**

ILLUSTRATION:
Example of influenza virus

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WuXi AppTec – Trusted Leader in Viral Bank Characterization

Characterization of viral banks used for either vaccines or gene therapy requires technical expertise across a wide range of biological disciplines. In addition, understanding the requirements and subsequent development of the testing regimens to ensure acceptance by the worldwide regulatory agencies takes experience only gained through the performance of hundreds of these studies. WuXi AppTec has this experience in both the technical and regulatory aspects, and has established all the necessary laboratories, assays and quality oversight to conduct these critical testing programs.

As viral bank characterization is a case-by-case program, WuXi AppTec’s team of experts can consult with you to determine the testing regimen that will stand-up to regulatory scrutiny while providing you a program that is also cost effective.

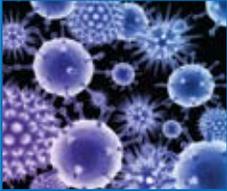
	MASTER VIRAL BANK	MANUFACTURERS WORKING VIRAL BANK
Authenticity & Characteristics		
Identity	Yes	Yes
Titer	Yes	Yes
Genetic Characterization (e.g., Vector and/or Gene DNA Sequencing)	Yes	Yes
Adventitious Agents		
Sterility	Yes	Yes
Mycoplasma	Yes	Yes
General Virus Screens	Yes	No
Species-Specific Virus Tests (<i>in-vivo</i> / <i>in-vitro</i>)	Yes	No
Replication-Competent Virus Tests	Program Dependent	Program Dependent
Adventitious Agents from Raw Materials	Yes	Program Dependent

The table above provides an overview of the tests typically required to characterize viral banks as outlined in the worldwide regulatory guidance documents. Which tests to conduct and at which stage – and the quality oversight required – is where WuXi AppTec’s extensive, 20-year experience can make the critical difference.

The following WuXi AppTec laboratories support viral bank characterizations, with each lab offering world-class expertise.

VIROLOGY

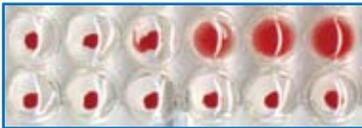
Identity, Potency and Titer Assays



WuXi AppTec's professional staff has a broad and detailed understanding of human and animal virology, and the detection methods required for a wide variety of viruses used for either vaccines or as delivery vehicles in gene therapy programs.

Staff knowledgeable in the technical transfer or development of virus identity (IFA), cell-based potency or titer assays (e.g., plaque/foci/syncytia-forming or TCID₅₀ assays) can assist your team of scientists. Determination of replication competent virus is often a requirement and WuXi AppTec has several assays available or can develop a custom assay if required. With our many years of experience, we can assist you in the complex development of neutralization assays or the determination of neutralization methodologies to conduct the biosafety tests.

Adventitious Virus Assays



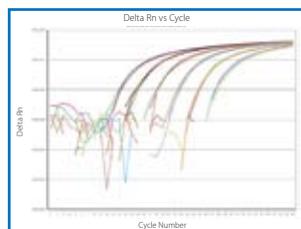
For adventitious virus testing, we employ over 50 well-characterized cell lines for use as indicator cells to propagate and detect adventitious virus, and over 60 different virus positive controls. A variety of *in-vitro* and cell-based virology tests, including the general virus screens to detect adventitious virus, are available. These assays enable our highly trained personnel (including many Ph.D.-level virologists) to detect contaminating viruses by various forms of cytopathic effect (CPE), hemadsorption, and hemagglutination. Routinely conducted as well are the 9CFR protocols for the detection of adventitious virus from the use of animal-derived raw materials or cell culture components.

MOLECULAR BIOLOGY

Understanding the genetic characteristics of your virus is paramount for regulatory submissions, and WuXi AppTec's extensive molecular biology program offers state-of-the-art nucleic acid-based molecular detection technologies (e.g., qPCR methodologies and DNA sequencing) for identity assays and genetic characterization of specific viral vectors. A variety of molecular biology techniques may be utilized in these programs including:

- Southern Blotting (Restriction Digest of Vector)
- DNA Sequencing of Gene Insert
- Whole Vector Sequencing

WuXi AppTec's experienced staff and state-of-the-art molecular biology labs employ the latest instrumentation and techniques to efficiently assess your viral bank.



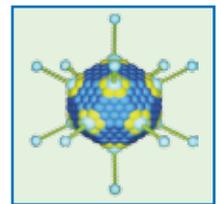
MICROBIOLOGY



Individual sterility and mycoplasma laboratories perform the necessary detection of adventitious micro-organism testing required for all viral bank characterization programs, conducting with exacting standards the bacteriostasis/fungistasis, sterility, mycoplasma and mycoplasma detection assays. All microbial assays used in viral bank characterization programs follow the harmonized USP/EP/JP protocols. If required, specific assays that follow CFR or Points-to-Consider protocols and guidelines are available. In addition, our staff is experienced with viral vectors that are difficult to test in these assays (e.g., vectors that are inherently toxic or that infect and kill the indicator cell lines used in mycoplasma assays) and thus have solutions for adjusting these protocols to still meet the regulatory requirements. Highly trained and skilled personnel process over 30,000 samples per month in these laboratories while maintaining industry-leading turnaround times.

CELL BIOLOGY & ANALYTICAL

In some instances, cell-based assays (e.g., for potency) combined with ELISA end-point analysis or HPLC procedures are required for virus bank characterization. WuXi AppTec's team of scientists and virologists work with our fully-staffed cell biology and analytical laboratories to develop the customized testing program to meet your regulatory filing needs.



IN-LIFE / IN-VIVO

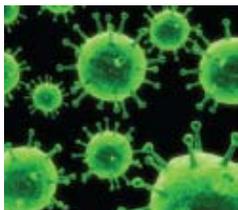


WuXi AppTec provides fully accredited AAALAC facilities for GLP animal assays, including testing in a wide variety of rodents, guinea pigs and eggs. Staff veterinarians and experienced in-life study directors test viral banks using the required routes of administration as dictated in guidance document protocols.

Methods for detecting adventitious virus that follow both U.S. and EU requirements are available. General Safety assays are also available for use in novel virus-based programs.

Additional related services offered by WuXi AppTec:

- Stability Studies
- GMP Cell Banking & Characterization
- Lot Release Testing



Viral Bank Characterization

A successful characterization program has many essential elements, including identity and detection of microorganisms and mycoplasma. The most highly customized element is the detection of adventitious virus.

EXPERIENCE

WuXi AppTec is the clear leader in this field with exceptional expertise and over 20 years of experience.

- Complete assay panels performed for hundreds of viral banks.
- Strong track record for supporting IND, BLA, and market approvals by regulatory agencies worldwide.
- Senior staff members serve on industry task forces to remain current on regulatory policies.

PROGRAM FEATURES

- Over 50 cell lines of human and animal origin for use as indicator cells and over 60 human and animal viruses available as positive controls.
- Over 100 PCR assays developed for detection of specific adventitious or contaminating viruses.
- Expert advice/consulting on worldwide regulatory requirements.
- Custom assays developed for unique viruses as needed.
- Dedicated virology, molecular biology, cell biology, and analytical labs of over 21,000 square feet.

**Contact WuXi AppTec for your viral bank characterization studies:
(1) 651-675-2000 / 888-794-0077 • www.wuxiapptec.com • www.virologyexperts.com**