



Viral Clearance Studies

**Expertise that can make the critical difference
for regulatory acceptance worldwide**

*ILLUSTRATION:
Variety of potential virus contaminants*

 **WuXi AppTec**

**THE
VIROLOGY
EXPERTS**



Viral Clearance Studies

WuXi AppTec's expertise and years of experience have made us the industry leader

WuXi AppTec offers custom studies to validate removal, inactivation, or cleaning processes for viruses. Our scientific and quality teams have comprehensive expertise in infectivity and quantitative PCR assays, process development, and international regulatory considerations for early- and late-stage products.

PROCESSES EXPERIENCE

Our experience spans a broad number of different processes including:

INACTIVATION

- Heat / Pasteurization
- Low and High pH
- Solvent / Detergent
- Irradiation
- Sterilization
- High-Energy Light
- Ethanol

REMOVAL

- Column Chromatography
- Filtration

CLEANING

- Kinetics of Inactivation
- Coupon Studies

CAPACITY

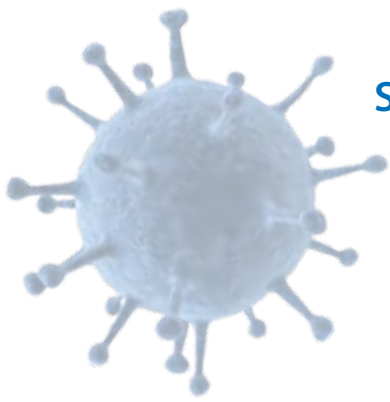
To help ensure clients meet critical timelines, we offer the highest capacity in the industry as demonstrated by:

- 8 BSL-2 and 2 BSL-3 client labs/suites
- Over 10 AKTA and AVANT systems
- Molecular biology suites for Real Time qPCR analyses
- Analytical labs for routine analysis of other process parameters
- Project managers dedicated to viral clearance/inactivation studies
- Multiple study directors, each with experience on over 100 viral clearance studies
- Over 100 lots of virus made and purified specifically for viral clearance studies by dedicated staff

STUDY EXPERIENCE

Studies conducted for R&D, Phase 1-3, BLA, Marketing-Approval and 510K submissions include:

- Monoclonal antibodies
- Recombinant proteins
- Blood-derived products
- Gene therapy vectors
- Viral vaccines
- Tissues (bone, skin, collagen, heart valves)
- Virus removal/inactivation instruments, technologies, resins, matrices & devices



SPECIALIZED SERVICES

Process Development Support through Database Mining

With over 20 years experience and 2000 studies conducted at WuXi AppTec, we have assembled a powerful database mining tool to help our clients in their process development efforts. WuXi AppTec can consult on which process steps or process parameters may be ideal or problematic in achieving the desired clearance levels before performing the actual clearance studies. This information could be critical to avoid costly delays, or the inclusion or evaluation of unnecessary process steps.

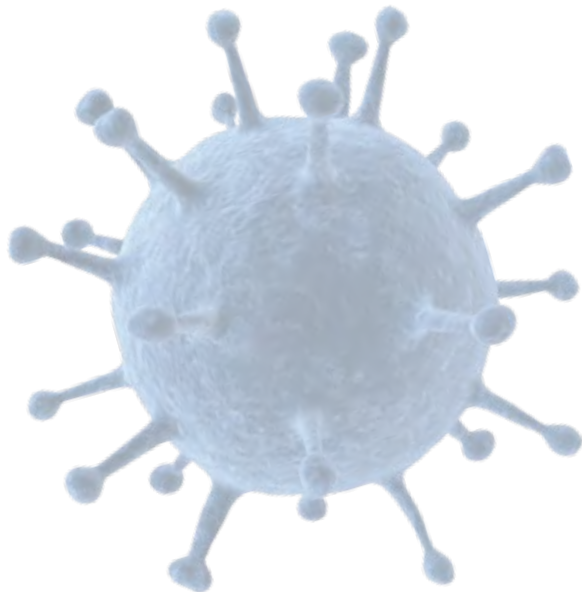
Preparation of High Titer Virus Stocks

As preparation, purification and use of high titer viral stocks is one of the most critical aspects in the performance of a viral clearance study, WuXi AppTec has set the standard for how these stocks should be made.

We believe our “5-tiered” system of stock generation and comprehensive testing, in conjunction with three different purification levels is the best available in the industry for production of highly qualified virus stocks. These ultra-purified stocks help ensure the data generated is the most accurate assessment of your processes’ ability to clear or inactivate virus.

Purification Methodology	Ultra 1 Purification Grade	Ultra 2 Purification Grade	Sucrose-purified Purification Grade
Serum Free or Reduced Serum	✓	✓	
Low & Mid Speed Centrifuged	✓	✓	✓
Ultra-centrifuged (Glycerol Shelf)	✓	✓	✓
Membrane Purification		✓	
Additional Purification Technologies (proprietary)			✓

Other Features	Ultra 1 Purification Grade	Ultra 2 Purification Grade	Sucrose-purified Purification Grade
Stock Generation (triple-plaque purification, MVB, WVB, Production Lot)	✓	✓	✓
Certificate of Analysis	✓	✓	✓
Release Criteria	Identity, purity, titer	Identity, purity, titer, residual DNA	Identity, purity, titer, residual DNA
Recommended Steps for Evaluation	Removal and inactivation steps	Nanofiltration	Nanofiltration
Viruses Available	30 Virus Types	MVM, PPV	A-MuLV, X-MuLV



Real-Time Quantitative PCR

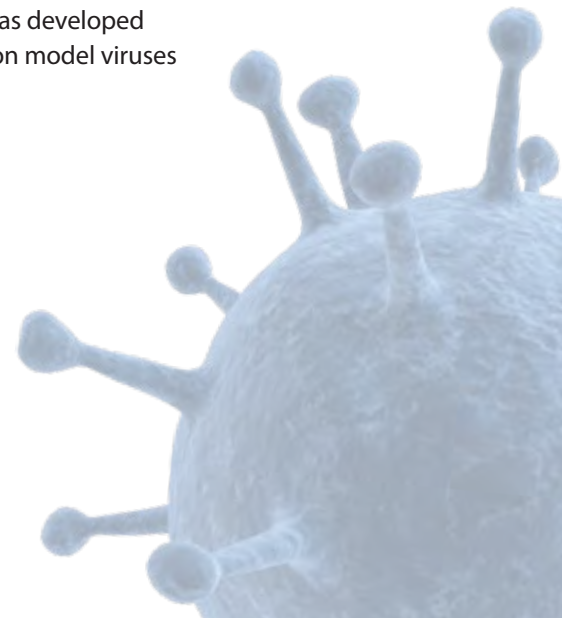
For processes in which both clearance/removal and inactivation occur, qPCR has become a leading technology in determining clearance and removal, or to complement standard viral titration assays. WuXi AppTec has developed over 15 qPCRs assays to common model viruses used in viral clearance studies.

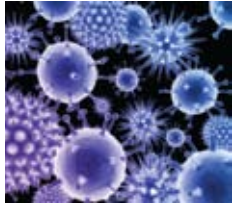
ADDITIONAL SERVICES

Cleaning Validations

Resin Cycling Studies

Performance of Process Scale-Down Validations





Viral Clearance Studies

WuXi AppTec is the clear leader in this field with exceptional expertise and more than two decades of experience.

EXPERIENCE

- Over 2000 custom viral clearance studies performed for IND, BLA, 501K, Marketing-Approval, and other.
- Over 30 human and animal viruses available as high-titer stocks.
- Experience with recombinant proteins, monoclonal antibodies, tissue and plasma products, vaccines, gene therapy vectors, and other product types.
- Many years of performing testing services based on global regulatory requirements – including FDA, ICH, ISO, CEN, AAMI, HIMA, USP, JMHLW, ANSI, WHO and ASTM – and applicable GLP and GMP guidelines.

PROGRAM FEATURES

- Large-volume testing to improve log reduction claims.
- Experienced staff can perform entire study for Sponsor, including scale-down and resin cycling, or can work with client to execute the study.
- Regulatory advice and consulting – from executing risk analysis to mining WuXi AppTec's database of previous study results.
- Ten fully-equipped suites and over 10 AKTA and AVANT systems available for custom studies, enabling easy scheduling of customer on-site validations.
- Senior staff study directors and dedicated project managers with experience on hundreds of custom studies.



Contact WuXi AppTec for your viral clearance studies:

(1) 651-675-2000 / 888-794-0077 • www.wuxiapptec.com • www.virologyexperts.com