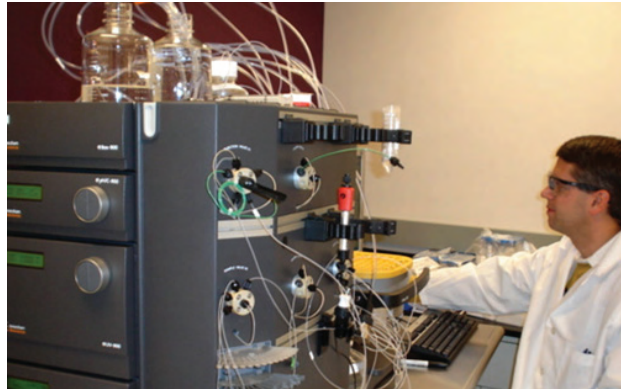




Inactivation / Clearance Validation Studies

**Inactivation or
Removal Studies
for Virus, Bacteria,
Mycoplasma, DNA
and Endotoxin**



WuXi AppTec is a global leader in providing discovery, testing and manufacturing services for the pharmaceutical, biotechnology and medical device industries. Research-driven and customer-focused, with operations in China and the U.S., WuXi AppTec offers a broad and integrated portfolio of services designed to assist our customers with cost-effective and efficient outsourcing solutions.

**WX
LISTED
NYSE**

WuXi AppTec offers custom studies to validate removal, inactivation, or cleaning processes for viruses, bacteria, and mycoplasma agents, with studies performed for R&D, GLP or GMP as needed. Our scientific and quality teams have comprehensive expertise in virology, microbiology, infectivity and quantitative PCR assays, process development, and international regulatory considerations for early- and late-stage products.

Clearance studies have broad application for Phase 1-3, BLA and 510K submissions for:

- Monoclonal antibodies • Tissues (bone, skin, collagen, heart valves) • Blood
- Gene therapy vectors • Viral vaccines • Other expressed proteins

Multi-Step Validations & Cleaning Analyses

INACTIVATION

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

REMOVAL

- ▶ Column Chromatography
- ▶ Cohn Fractionation
- ▶ Filtration
- ▶ Specialized viral / microbial devices

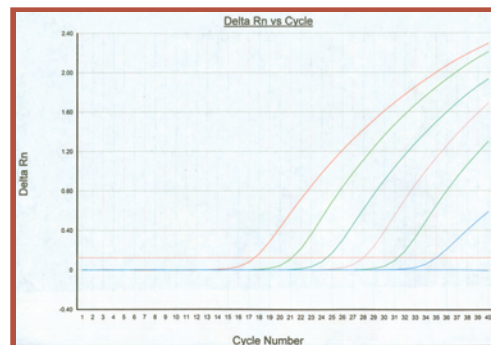
For a list of available microorganisms and information regarding characterization and purification of virus stocks, contact a WuXi AppTec Account Manager.

Dedicated Laboratories

- ▶ 6 BSL-2 and 2 BSL-3 client labs for process performance
- ▶ Viral, microbial & mycoplasma culture rooms
- ▶ Molecular biology suites for Real Time PCR analyses
- ▶ Analytical labs for routine analysis

Real Time Quantitative PCR

qPCRs are available for a wide range of viruses to complement standard viral titration assays.



The PCR (Polymerase Chain Reaction) tests are performed pursuant to an agreement with Roche Molecular Systems, Inc.

**For more information on
WuXi AppTec's services
please contact:**

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www.virologyexperts.com