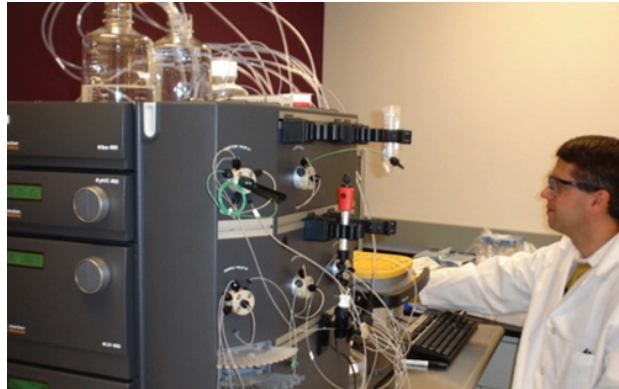


Inactivation / Clearance Validation Studies

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, biologics 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

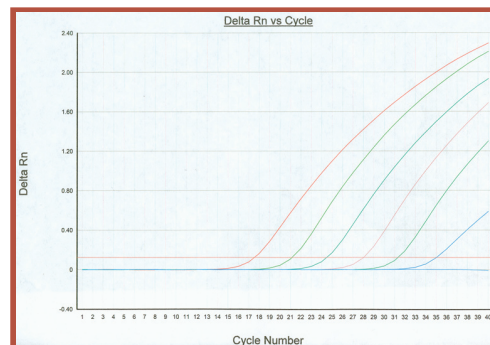
For a list of available microorganisms and information regarding characterization and purification of virus stocks, contact a WuXi AppTec Account Manager.

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:

U.S.
+1 (651) 675-2000 • +1 (888) 794-0077
info@wuxiapptec.com

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www.wuxiapptec.com

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