

# Residual DNA Testing

**S**tate-of-the-art, fully validated assays – quantitative PCR (qPCR) testing as well as slot blot hybridization – are provided by WuXi AppTec to ensure the quality, safety, and consistency of biologically derived products in support of process development and lot release programs.

Our molecular biology department has many years of experience in testing biological materials for the presence of residual DNA, including DNA from diverse eukaryotic and prokaryotic species. Products tested are commonly from genetically modified materials (e.g., recombinant proteins expressed in mammalian cells, insect cells, yeast, and *E. coli*), monoclonal antibodies, and products derived from natural materials (e.g., blood products, bone and cartilage). The testing methods are also applicable to vaccines and gene therapy products.

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.

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## PROGRAM FEATURES

### ► Regulatory Compliance

Testing can be performed from research level to testing regulated according to Good Laboratory Practices (21 CFR, Part 58) or Good Manufacturing Practices for Finished Pharmaceuticals (21 CFR, Part 211). Raw materials are obtained from approved vendors whose products meet required specifications. Certificates of Analysis (C of A) are maintained for specific lots of reagents used in testing.

### ► Species of DNA Detected

WuXi AppTec's technology is able to detect residual DNA from multiple species, including human (several cell lines), monkey, pig, mouse, hamster, chicken, insect, mollusk, yeast and *E. coli* (plasmid and chromosomal).

### ► Assays

- **qPCR** assays for detection of the same species range of DNAs are available. The assays are performed as quantitative GLP/GMP assays (using ABI Fast 7500 Taqman® technology) and generate exact values for mass of DNA in a sample. The assays routinely have a detection limit in the sub-pg range, well below the mandated detection limit for residual DNA assays.
- **Slot blot hybridization** assays meet or exceed current U.S. and foreign regulatory requirements to detect residual DNA in biological specimens. The assays routinely have a detection limit in the 5 pg range, well below the mandated detection limit for residual DNA assays.

*NOTE: qPCR and slot blot hybridization assays are fully validated to fulfill ICH guidelines to evaluate precision (repeatability and intermediate precision), accuracy, specificity, limit of detection, range and linearity. Critical assay parameters are optimized for use with specific sample matrices by qualification.*

- **Sizing** assays generate a size profile for contaminating DNA along with values for extraction and recovery efficiency for the different size DNA components. DNAs are extracted from a sample spiked and unspiked with standards of known size and mass. Extracted samples are separated by size and detected by southern blotting. Sizing by qPCR is also available, using qPCR amplicons of different known size.
- **Cleaning and process validations for DNA removal.**

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

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