



DNA Sequencing Services

Essential data analysis for product development and regulatory submission

*ILLUSTRATION:
DNA double helix*



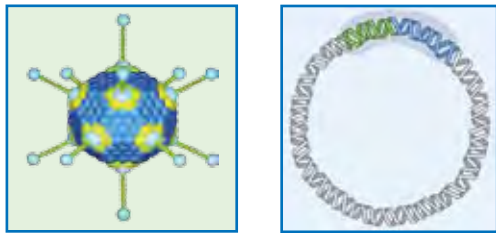
DNA Sequencing in Support of Biopharmaceutical Product Development

WuXi AppTec offers R&D, GLP and GMP DNA sequencing services — from early-stage development to GMP lot release of clinical and commercial products.

Applications

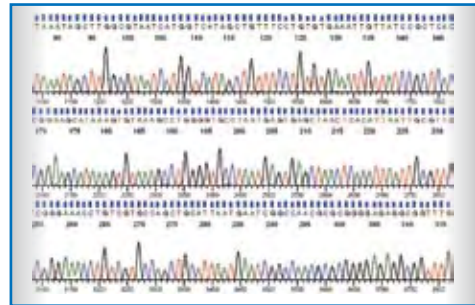
Construct Development and Cloning

DNA sequencing is commonly used to confirm the integrity of a gene cloned into a plasmid or viral vector prior to transfection into a producer cell line or infection in the case of viral vaccines. In addition, sequencing of the entire plasmid or viral construct is also required for many therapeutic or vaccine product regulatory submissions.



Whole Virus / Vector Sequencing

Mapping and confirming the sequence of large viral vectors or virus (over 10,000 bp) is a requirement of current EMA and FDA regulations. Whether you are developing a viral vaccine or a gene therapy product, our next-generation sequencing technologies can provide rapid, extensive, and cost-effective means of sequencing large vectors. In addition, the sequencing platforms allow for multiple samples to be sequenced simultaneously – ideal for discovery/development programs when the need to sequence several plasmid or virus vectors is required.



Genetic Stability of Producer Cell Lines

For protein therapeutics, determining genetic stability of the producer cell line is also a regulatory filing necessity. WuXi AppTec's DNA sequencing and molecular biology laboratories in Philadelphia offer support with the following studies on the Master Cell Bank and the End of Production Cells:

- Genomic DNA sequencing (gene and flanking regions)
- RT-PCR cDNA sequencing (mRNA/message integrity)
- Construct DNA sequencing

In addition to DNA sequencing, the molecular biology lab can support other genetic stability studies, including Southern and Northern Blotting and qPCR for copy number determination.

Next-Generation Sequencing Services

WuXi AppTec utilizes Life Technologies™ and Illumina® sequencing systems for the following applications:

- Adventitious agent detection via its AgentSCREEN™ and AgentID™ services
- Biomarker development for R&D, preclinical and clinical studies
- Whole genome and transcriptome sequencing
- Exome sequencing

WuXi AppTec is a Life Technologies Certified Service Provider



Product Types Supported

Recombinant Protein Therapeutic • Monoclonal Antibody • Plasmid or Viral Gene Therapy • Vaccine

Industry-Leading Technologies

Next Generation Technology

Advanced sequencing platforms are utilized by WuXi AppTec to meet your specific project needs. Our expert teams are fully trained on a wide range of technologies including: Life Technologies™ (Ion Proton™, Ion PGM™) and Illumina® (HiSeq 2000/2500, MiSeq, Genome Analyzer IIX).



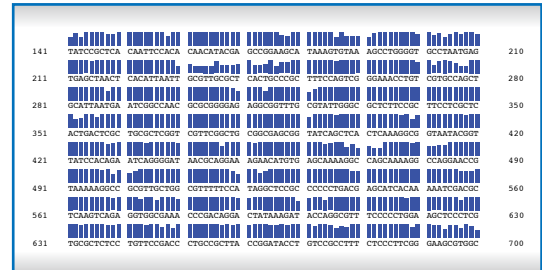
ion torrent
by life technologies™

certified
service
provider



Capillary Electrophoresis [Sanger Method]

For R&D, GLP or GMP genetic stability and gene integrity and vector construct sequencing, WuXi AppTec utilizes the Applied Biosystems (ABI) 3500 system (24 capillary). Along with ABI PCR instrumentation, we can provide a wide variety of sequencing applications that meet your exacting quality standards.



Next-Generation Data Analysis and Bioinformatics

- Raw data analysis to meet stringent quality criteria.
- Accurate sequencing data assembly using validated commercial software.
- Structural variant identification.
- Sanger sequencing available for gap closure (if required).



Experience & Program Features

- 25-year history with an expert support team, including six Ph.D.s with 80 years' combined molecular biology and virology experience.
- Experience from analyzing a wide range of vectors from different virus families, including: adenovirus, herpesvirus, etc.
- Ability to sequence viruses with high GC content and complexity.
- Industry-standard platforms (next generation and capillary electrophoresis) for speed and optimized data management.

Additional Related Services Offered by WuXi AppTec

- Cell Line Development & Engineering
- Cell Line Identification
- GMP Cell Banking & Characterization
- Lot Release Testing
- Stability Studies



DNA Sequencing Services

Using over 25 years of industry experience and state-of-the-art DNA sequencing technology, WuXi AppTec will provide you a high quality, regulatory compliant and cost-effective solution that meets your highest expectations.

PROGRAM FEATURES

- Wide range of applications, including gene insert confirmation, whole virus/vector sequencing, adventitious agent detection, biomarker development, whole genome, transcriptome, and exome sequencing.
- Utilization of high-throughput and cost-effective, next-generation DNA sequencing technologies.
- Services conducted using industry-leading technologies from Life Technologies™ and Illumina®.
- R&D, GLP and GMP services available.
- Quick turnaround time.
- Project Manager to oversee your project from initiation to final report delivery.
- Ph.D.-level Study Directors to answer technical questions regarding your study.
- Experience in DNA isolation/library preparation, sequencing template preparation/sequencing, and bioinformatic analysis & gap closure.
- Detailed report of study and sequencing data analysis.

BENEFITS

- As part of our integrated services, WuXi AppTec offers the most time-sensitive and cost-effective solutions to meet your DNA sequencing needs, as well as your budget requirements.
- High-quality services help ensure regulatory compliance.
- 20 years of cell line characterization experience enable us to provide consultation for appropriate genetic stability test regimens.

**Contact WuXi AppTec for your DNA sequencing needs:
(1) 651-675-2000 / 888-794-0077 • www.wuxiapptec.com**