



DNA Sequencing Services

**High-Quality GLP and GMP Solutions
for Regulatory Submissions**

*ILLUSTRATION:
DNA double helix*

 **WuXi AppTec**

DNA Sequencing in Support of Biopharmaceutical Product Development

DNA sequencing is essential for biopharmaceutical or vaccine 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.

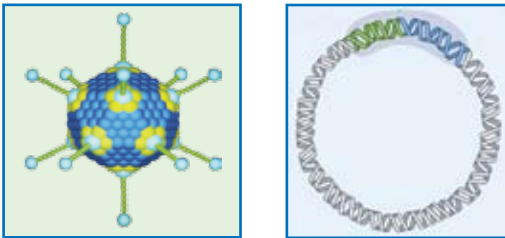
Product Types

Recombinant protein therapeutic • Monoclonal antibody • Plasmid or viral gene therapy • Vaccine

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.

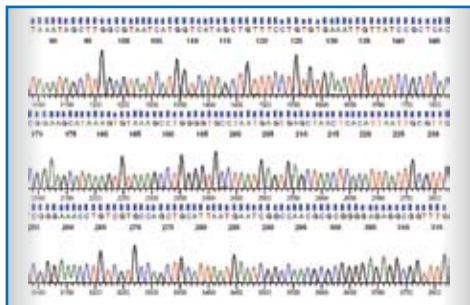


Genetic Stability of Producer Cell Lines

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

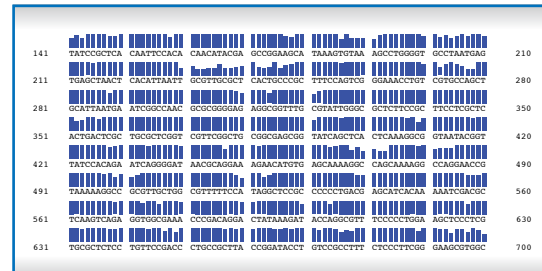


Industry-Leading Technologies



Image provided courtesy of Life Technologies / Ion Torrent

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, WuXi AppTec can provide a wide variety of sequencing applications that meet your exacting quality standards.



Additional Related Services Offered by WuXi AppTec

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

Contact WuXi AppTec for your DNA sequencing needs:

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