



NGS Applied to Biologic Production and Safety

By Colette Côté, Ph.D.
Principal Scientist, Genomics, Head of Next Generation Sequencing and Bioinformatics

Next Generation Sequencing (NGS) affords a radically different approach to the challenge of identifying and characterizing known and unknown agents with pinpoint precision and accuracy. NGS delivers significantly more data than traditional sequencing methods, opening up a range of possibilities for the analysis of biologic therapeutics such as monoclonal antibodies or viruses.

NGS vs. Traditional Sequencing

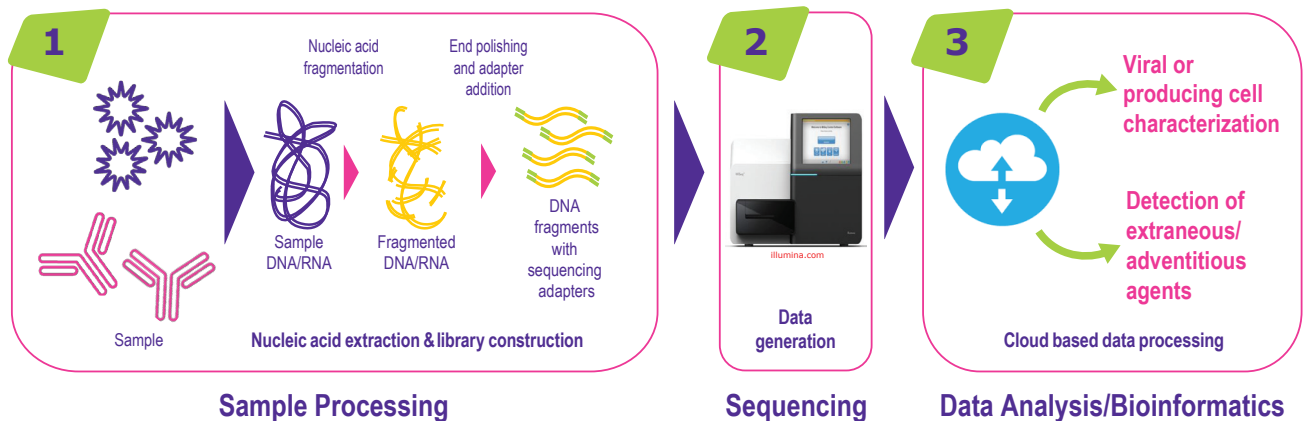
NGS is similar to Sanger sequencing, only it is massively parallel in nature. This allows millions to billions of nucleic acid fragments to be sequenced in a single run, versus Sanger Sequencing, which only produces one forward or reverse read per target. Traditional sequencing may detect a contaminant,

but you only see what you are looking for. NGS is sequence-agnostic: nothing needs to be known about the sequence in order to gain information about it.

NGS: A Validated Process

NGS analysis may be undertaken on any material in the biologic production process, including viral vaccines, gene therapy vectors, cell lines and any other raw material products. All samples are initially processed by performing a total nucleic acid extraction. The purified nucleic acid is converted to double stranded DNA (dsDNA), quantified and then sequenced. Once sequenced, the data is securely analyzed using a fully validated process that is in compliance with regulatory expectations and guidance.

NGS: Three Basic Steps



BioReliance® Next Generation Sequencing Services

- Confirm genomic identity
- Detect sequence variants & sub-populations

Virus Characterization

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Virus Adventitious Agent Detection

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- Provide analysis of samples where a neutralizing antibody is difficult to obtain - e.g. Dengue
- Assure stock purity

Genetic Integration & Stability

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- Integration site assessment
- Genetic stability of Master and End of Production cell banks
- Rich data set

- Rapidly identify contaminants
- Troubleshoot sources of contamination

Cell Line Adventitious Agent Detection

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- On and off-target analysis of gene editing
- Application to cellular therapies

Gene Editing Assessment

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Custom NGS Service

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North America
Toll Free: 800 553 5372
Ph: 301 738 1000

Europe & International
Ph: +44 (0)141 946 9999
Japan Ph: +81 3 6758 3610

Email info@bioreliance.com

bioreliance.com

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