



Accurate, Robust, Efficient

NGS applied to production and safety

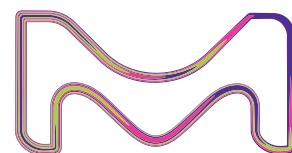
Next Generation Sequencing (NGS), sometimes referred to as high throughput sequencing, affords a radically different approach to the challenge of identifying and characterizing known and unknown agents with pin-point precision and accuracy. NGS delivers significantly more data than traditional sequencing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

NGS vs. Traditional Sequencing

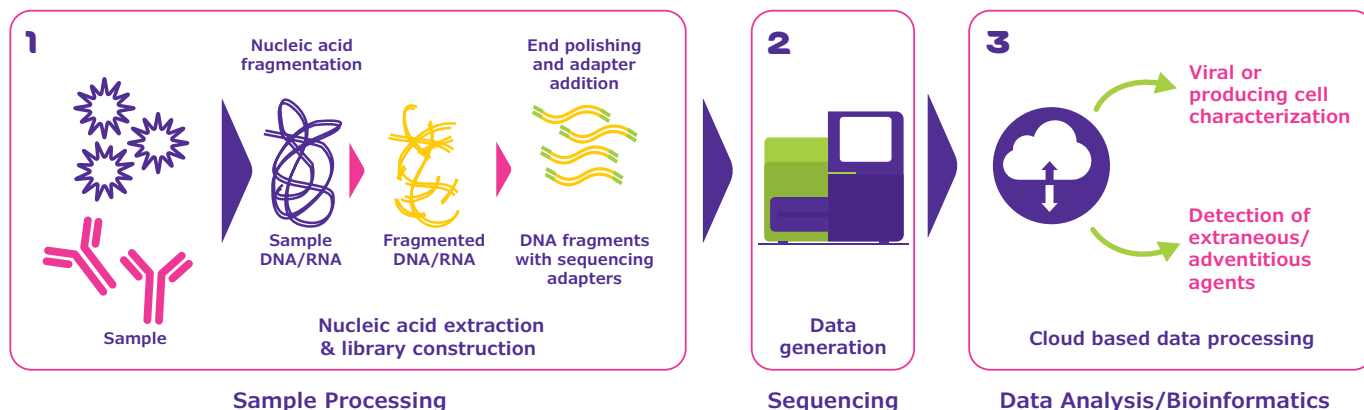
NGS is massively parallel in nature, allowing millions to billions of nucleic acid fragments to be sequenced in a single run, versus the more traditional Sanger sequencing, which only produces one forward or reverse read per target. While traditional sequencing may detect a contaminant, it will only provide confirmation of what you are looking for. However, 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.



NGS: Three Basic Steps



NGS Applied to Biologic Production and Safety

BioReliance® Next Generation Sequencing Services

Virus & vector characterization

- Confirm genomic identity
- Detect sequence variants & subpopulations

Genetic Integration & Stability

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

Gene Editing Assessment

- On and off-target analysis
- Application to cellular therapies

Cell Line Adventitious Agent Detection

- Rapidly identify contaminants
- Troubleshoot sources of contamination

Adventitious Virus Detection

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

Custom NGS Service

- Speak with our experts about your specific needs, our services include:
 - Bioinformatic programming
 - Dedicated bioinformaticians
 - Secure data management & delivery



[SigmaAldrich.com/NGS](https://sigmaaldrich.com/NGS)

Europe:

Todd Campus
West of Scotland Science
Park Glasgow,
G20 0XA, Scotland
Tel: +44 (0)141 946 9999
info@bioreliance.com

North America:

14920 Broschart Road
Rockville, MD 20850-3349 USA
Tel: 301 738 1000
info@bioreliance.com

Singapore:

#2 Science Park Drive
#04-01/12 Ascent Building,
Tower A Singapore 118222
BiosafetyAP@merckgroup.com

China:

15-18F, No.3, Building C,
The New Bund World Trade
Center(Phase II) Lane 227
Dongyu Road, Pudong New
District, Shanghai, China
BiosafetyCN@merckgroup.com

