BioReliance®
Contract Testing Services

MilliporeSigma

Next Generation Sequencing

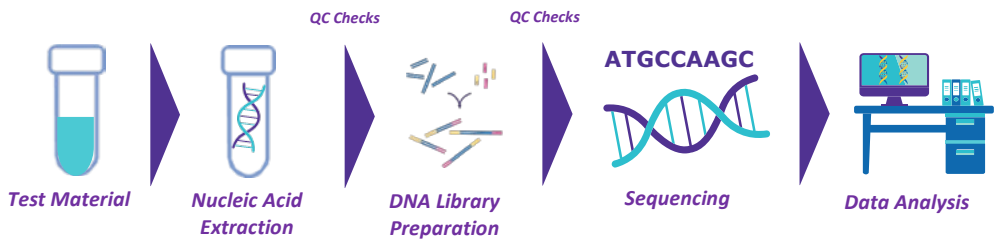
In biosafety testing & product characterization

Next Generation Sequencing (NGS), or high-throughput sequencing, is a transformative method for precisely identifying and characterizing known and unknown sequences. It provides significantly more data than traditional sequencing, enabling advanced analysis of biologic therapeutics, including monoclonal antibodies, cell and gene therapy applications, and vaccines.

NGS Workflow: A validated process

NGS is a versatile method that can be applied across various sample types, requiring no prior knowledge of their genomic sequences. The NGS workflow begins with total nucleic acid extraction from test samples. The purified nucleic acid is then converted into double-stranded DNA (dsDNA), quantified and sequenced to generate sequencing data, which is analyzed using bioinformatics. Our NGS methods are rigorously validated throughout the entire workflow to ensure compliance with most up-to-date regulatory standards.

NGS Workflow Process



Regulatory support for the use of NGS methods

Our NGS assays are validated following global regulatory guidance. Regulatory authorities support the use of state-of-the-art techniques for safety and characterization testing, and recognizes NGS for its enhanced sensitivity and broad detection capabilities. ICH Q5A(R2) recommends NGS as a substitute for *in vivo* virus detection assays to reduce the use of animals in biosafety testing. NGS methods also provide a sensitive approach to confirm sequence identity and identify potential variants that can impact product safety and quality for vaccines and gene therapy vectors. Furthermore, NGS is a powerful tool to characterize genetically modified cells through virus vector transductions and gene editing techniques.

NGS Testing Services

Broad Virus Safety Screening

- Identify viral contaminants in cell banks, raw materials, virus seed stocks or virus-based products, including vaccines
- Replacement of *in vivo* virus testing in alignment with ICH Q5A(R2)
- Contaminating virus detection in virus samples without the need for neutralizing antibodies

Genetic Stability & Integration analysis

- Aptegra™ CHO Genetic Stability Assay
- Whole-genome-sequencing method to replace 5 traditional assays – Gene of Interest analysis, flanking region sequence analysis, variant analysis, copy number determination, vector integration site determination

Genomic Sequence Identity Testing

- Identity confirmation of viruses, vectors, plasmids, bacteria, RNA, and more
- Detects sequence variance & heterogeneity

Gene editing assessment

- On/Off target assessment
- Guide RNA sequence identity

AAV Characterization

- Long-read sequencing for characterization of encapsidated nucleic acids

Contact us to learn more about our NGS Testing services and custom NGS applications.

SigmaAldrich.com/NGS

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