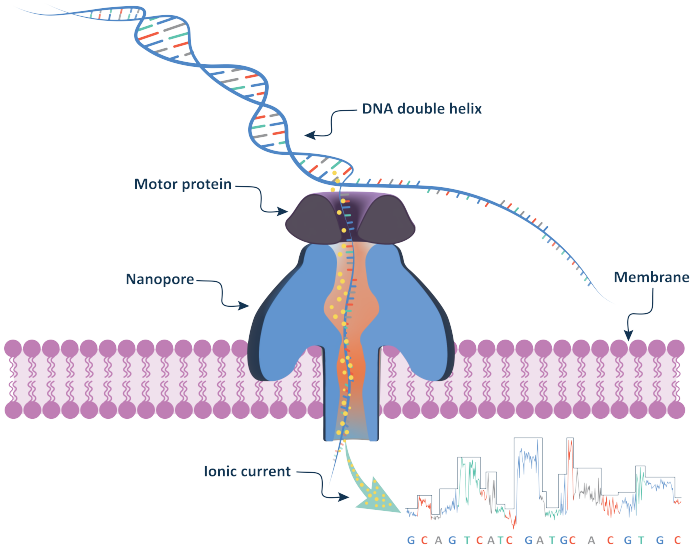
VIRUSURE
Quality is no coincidence

NGS for Quality Control Testing of Biologics

NGS is a revolutionary technology in the field of biosafety testing. It can be used to determine the complete nucleic sequence information from a variety of biological samples (e.g., cell banks, bulk harvests, and cell and gene therapy products). A major advantage of NGS is that it allows the performance of multiple analyses of one biological product by using just one data set.

ViruSure focuses on ***Oxford Nanopore's long-read sequencing approach***. Long reads allow the recovery of more of a contaminant's genome within smaller data sets and reduce signal to noise ratios, therefore reducing the risk of false positive signals.

Further, they allow sequencing through genome stretches that pose problems to short-read sequencing methods (e.g., repetitive regions) leading to improved resolutions in sequence confirmation approaches.

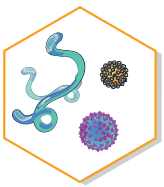


Oxford Nanopore's Long Read Next Generation Sequencing Technology

Adventitious Agent Testing

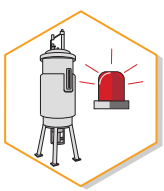
Sterility and Mycoplasma

Sterility testing is performed to detect the presence of microbiological contaminations. NGS can deliver faster turnaround times than the current 14 days of culture-based assays. Additionally, it is not as prone to interfering effects, and delivers immediately the identity of the potential contaminant.



Adventitious Viruses

By being able to detect viral contaminations without any prior sequence knowledge, NGS combines the advantages of the current testing panel in a single approach. It provides a broad range of detection, like *in-vivo* and *in-vitro* adventitious agent tests, and comparable sensitivities to qPCR assays. Different testing strategies can be applied for the detection of adventitious viruses: *Genomics* (detection of viral sequences present in cellular DNA), *Transcriptomics* (detection of replicating virus in total RNA extractions), and *Viromics* (detection of viral genomes present in viral particles).



Contamination Events

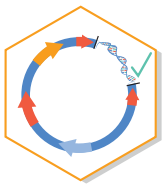
NGS is an ideal tool for the rapid identification of a potential contamination event over the entire development and production process of a biopharmaceutical product. Results can be obtained in just a few days, which is especially critical in the event of a bulk harvest contamination in manufacturing, where a quick and reliable identification of the contaminant is required.

virus_safety@virusure.com

Genetic Characterization

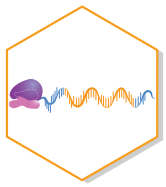
Sequencing

Sanger Sequencing can be used for resequencing of genetic inserts in the context of genetic stability testing. However, if the region of interest that needs to be sequenced gets very large, NGS provides faster turnaround times, as the entire sample can be sequenced with just a single sample preparation.



Resequencing of Genetic Inserts

The stability of genetic inserts within cell banks or virus stocks has to be demonstrated over the entire production cycle. NGS can be used to compare the sequence and location of the insert to a reference sequence, and possible mutations can be detected.



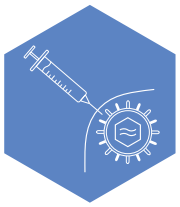
mRNA Sequencing

Nanopore sequencing is the only technology offering the capability to sequence RNA directly in its native form, making it an ideal tool to confirm the correct transcription of a genetic insert into mRNA (e.g., mRNA vaccines). This way, additional RNA processing steps can be removed, reducing the accompanying risk of introducing transcription biases and providing the possibility of analysing full length transcripts in a single read.

Sequence Identity Confirmation for Viral Vectors

To confirm the identity of a viral vector, NGS data can be used to compare sequencing data to a reference sequence. Simultaneously, mutation screening can be performed on the same data set can be used to identify any mutations that have occurred within the genome of the viral vector.

Biological Products Tested by NGS



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