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Whole Genome Sequencing (WGS) for Therapeutic Cell Characterization

Whole genome sequencing, WGS, is a powerful approach for evaluating genomic integrity and supporting tumorigenicity risk assessment for therapeutic cells advancing toward clinical development. Avance Biosciences provides WGS services under CGMP/GLP-aligned workflows to support genome integrity assessment as a primary objective. Our WGS services are designed to identify both sequence-level variants and large-scale genomic abnormalities that may impact product safety, stability, and regulatory readiness.

Our Expertise

Our approach integrates complementary short-read and long-read sequencing to evaluate a broad range of genomic risk factors, from single-nucleotide variants to chromosomal-scale events. This combined strategy helps sponsors characterize therapeutic cells more comprehensively than short-read sequencing alone, particularly when structural rearrangements, copy number alterations, or complex integrations are a concern.

Genomic Integrity Assessment Across Cell Platforms

Platform	Descriptions
iPSC-derived Cell Therapies	Pluripotent stem cell–based products requiring careful genomic stability monitoring due to extended culture and differentiation processes.
Engineered T Cell Products	Genetically modified immune cell therapies, such as CAR-T or TCR-T, where insertional events and structural integrity must be assessed.
Gene-edited Cell Lines	CRISPR- or nuclease-edited cells requiring comprehensive on-target, off-target, and chromosomal integrity evaluation.

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Genomic Integrity Assessment Across Cell Platforms (Continued)

Platform	Descriptions
Stem cell–derived Products	Differentiated or expanded stem cell populations where prolonged culture may introduce genomic alterations.
Immortalized Production Cell Lines	Manufacturing cell substrates that require genomic characterization to ensure stability and safety.

Whole Genome Sequencing Services

Primary Capability	Platform/ Coverage	Deliverables
Genome-wide Variant Detection	• Short-read • Element AVITI • ≥ 50 x coverage	• Small nucleotide variants and small indels • Annotation against clinically relevant databases (e.g., ClinVar and COSMIC) to assess pathogenicity and cancer relevance of variants identified in tumor suppressor, oncogene, DNA repair, and cell cycle regulatory genes. • Variant classification where applicable
Detection of Large Insertions and Deletions	• Long-read • PacBio Vega • ≥ 15 x coverage	• Large insertions/deletions: inversions, translocations, complex rearrangements • Copy number alteration and aneuploidy assessment • Chromosomal integrity and genome architecture summary
Unbiased Integration Site Analysis	• Short-read and long-read with Element AVITI and PacBio Vega	• Detection of integration events • Characterization of integration structure and events (e.g., intact vs partial) • Annotation of off-target integration sites against clinically relevant gene databases as part of tumorigenicity and genomic stability safety assessment. • Detection of concatemers and tandem integration events.

Scan to learn more.

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