



Single Cell Sequencing Services

In the field of gene-edited cell therapy, regulatory agencies require the study of gene-edited cells to determine gene transfer efficiency and gene editing profiles. With traditional bulk analysis, only the average profile of gene transfer and gene editing across an entire cell population can be determined. By collaborating with Mission Bio and several cell therapy developers, Avance Biosciences has validated an innovative method based on the Tapestri single cell sequencing platform. This method allows researchers to evaluate gene transfer efficiency and gene editing profiles at the single-cell level, providing unparalleled insights into gene-edited therapeutic cells.

Our Expertise

We incorporated the Tapestri® Platform into our GMP analytical lab in 2021. By working closely with Mission Bio and a gene therapy developer, we collectively validated a single-cell sequencing-based assay to characterize gene-edited therapeutic cells. This innovative method complements traditional analyses based on qPCR, ddPCR, and NGS, providing detailed insights into gene copy number per cell, the percentage of cells with gene transfer, and mutation and indel profiles.

Selected Applications:

| Product Type | Assay Description |
|----------------------------------|---|
| CAR-T, TIL, TCR, DC Cell Therapy | Cell and gene therapies employ viral and nonviral vectors to introduce transgenes into target cells. Accurately assessing transduction/transfection efficiency and vector copy number is essential for characterizing these therapies. The Tapestri Platform facilitates the simultaneous measurement of multiple genotypic and phenotypic attributes across thousands of individual cells. |
| CAR-T, TIL, TCR, DC Cell Therapy | Gene-editing technologies, such as CRISPR, are advancing the development of advanced cell and gene therapies. Genome engineering, however, generates heterogeneous cell populations with diverse edits. Some cells may also contain unwanted or deleterious alterations, including off-target edits and chromosomal aberrations like translocations. The Tapestri Platform enables high-resolution single-cell DNA sequencing to analyze gene-edited cells, covering on/off-target editing, multiplex edits, zygosity, and chromosomal aberrations. |

Key Services (Cont.)

| Product Type | Assay Description |
|--------------------------------|---|
| Gene-Edited Human Cells | <ul style="list-style-type: none"> • On/Off Target Sites Screening and Verification • On/Off Target Sites Characterization and Quantification • Gene Editing Translocations • Clonality by single-cell sequencing |
| Stem Cells (HSCs, iPSCs, MSCs) | <ul style="list-style-type: none"> • Flow cytometric analysis of select markers. • Differentiation-specific protein analysis by Western • Hematopoietic colony-forming unit (CFU) analysis by STEMvision™ • reprogramming, differentiation, and maturation analysis • RNA-Seq and Whole-Exome Sequencing (WES) |
| All Cell Therapy products | <ul style="list-style-type: none"> • Viability/Proliferation testing • Sterility Testing • Endotoxin Testing • Mycoplasma Testing • Adventitious Agent Testing |

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