



## Cell Therapy Support

Cell therapy is a rapidly evolving field in medicine that involves the use of living cells to treat various diseases and medical conditions. Cell Therapy technologies encompass a variety of product classifications, from Chimeric Antigen Receptor T Cell (CAR-T) to various stem cell-based drug products (HSC, MSC, iPSCs) to human cells modified via gene editing technologies such as CRISPR.

### Our Expertise

At Avance Biosciences, we excel in supporting the CMC of cell therapy products across all stages of development, in addition to our extensive offering of CAR-T release tests. Our dedicated team designs and validates custom assays using state-of-art analytical technologies tailored to client specifications, leveraging our expertise in regulatory requirements. From early development through clinical trials and release testing, we are committed to being your trusted partner in advancing cell-based therapeutics.

1. Early-stage Research and Development supports pre-IND assay qualification and drug substance/drug-product characterization.
2. Method Development and Assay Validation expertise in the design and validation of robust and efficient analytical techniques tailored to the unique requirements of your cell-based therapeutic.
3. Sample Testing support through clinical trials and drug product release.
4. Quality Control and GMP Compliance we place a stringent emphasis on quality and regulatory compliance to ensure the accuracy and reliability of the services we provide.

### Key Services

Product Type	Assay Description
CAR-T, TIL, TCR, DC Cell Therapy	<ul style="list-style-type: none"> <li>• Plasmid and Viral Vector Identity by Sequencing</li> <li>• Vector Copy Number (VCN) Analysis</li> <li>• Replication Competent Lentivirus (RCL) Testing</li> <li>• Replication Competent Retrovirus (RCR) Testing</li> <li>• Transgene Expression Analysis</li> <li>• Residual Plasmid in viral stocks; drug substance</li> <li>• Immunophenotyping by flow cytometry</li> </ul>

## Key Services (Cont.)

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