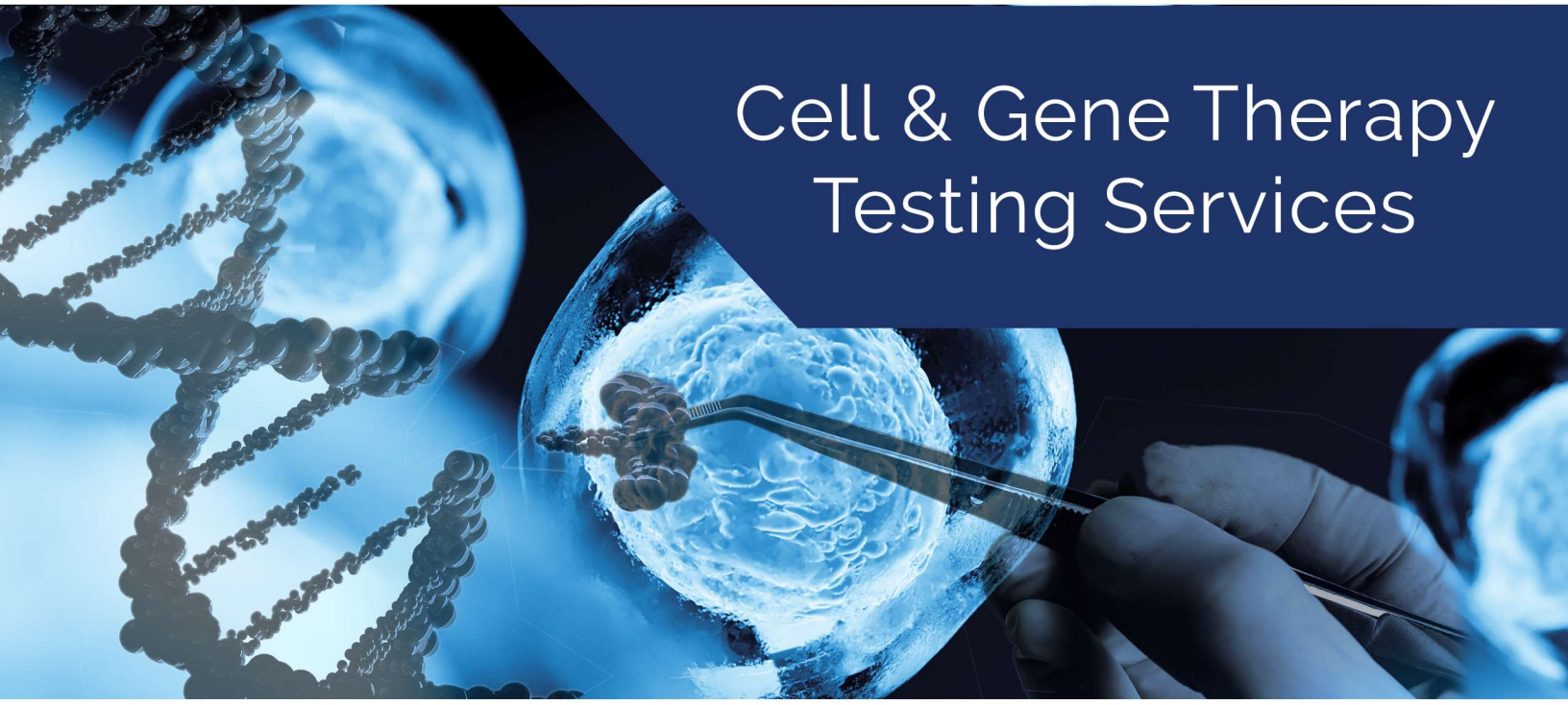
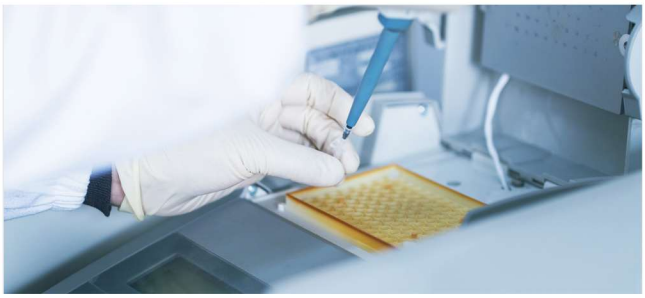
AVANCE BIOSCIENCES

Assays To Support Your Biopharmaceutical Drug Development & Manufacturing



# Cell & Gene Therapy Testing Services

Fast turnaround QPCR, ddPCR, and NGS assays to ensure the safety of your cell or gene therapy products.



Avance Biosciences is a leading CRO providing CGMP/GLP compliant assay development, assay validation, and sample testing services to support biological drug development and manufacturing activities world-wide.

## CGMP/GLP Compliance

The Avance Biosciences team is committed to strict adherence to CGMP and GLP regulations and guidelines enacted by the US, European, Japanese, and other international regulatory agencies.

## Extensive Experience

Our team has extensive knowledge and experience working with scientists, QA/QC professionals, and project managers from over 100 pharmaceutical and biotechnology companies and organizations throughout the world.

## Cutting Edge Science

Avance Biosciences' CGMP/GLP compliant genomic assays make use of the very latest techniques and technologies including droplet digital PCR and next generation sequencing.

**CONTACT US**

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# Cell & Gene Therapy Testing Services

## Supporting Drug Development and Manufacturing


## Supporting Clinical Trials

To ensure the safety of CAR / TCR therapies, the FDA and other regulatory agencies require thorough characterization and qualification of the manufactured therapeutic cells using validated assays before releasing the drug product for clinical trials. In addition, during the clinical trials, patients' blood must be tested frequently to monitor the level of modified cells over time, and to ensure the absence of replication competent lentivirus (RCL). For early-phase gene therpy clinical trials, FDA requires developers to evaluate the identity, purity, quality, dose, and safety of their products with validated assays. To understand and mitigate the risk of a delayed adverse event, FDA recommends that subjects in gene therapy trials be monitored for an extended period of time.

## Biological Testing Expertise

Avance Biosciences is a leader in genomic assay development, validation, and sample testing focused on supporting the development and manufacturing of biological drugs. We provide advanced and customized testing solutions designed to facilitate the research and development of your therapeutic products. Avance Biosciences offers customized QPCR, ddPCR and NGS solutions to help determine copy numbers of inserted or edited genes, potential presence of replication competent lentivirus (RCL), and any other target of interest in therapeutic products or clinical trial patient blood samples, to support our clients' efforts in cell and gene therapy.

## Trust Avance Biosciences for your Biological Testing Needs

- ✓ Study directors and managers who are highly experienced in leading CGMP / GLP compliant biological testing projects.
- ✓ Independent quality units for assuring regulatory compliance.
- ✓ Professional testing reports which can be readily used in your regulatory submissions.
- ✓ Transparent and routine updates on project progress.
- ✓ Controlled laboratory environments during sample processing to prevent cross-contamination.
- ✓ Rigorous sample management and tracking to ensure chain of custody.
- ✓ Fast turnaround time for product release testing to ensure no delays to the clinic.
- ✓ Over 20 years experience supporting our clients.

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# Cell & Gene Therapy Testing Services

## Potency Assays

Potency testing is an essential part of developing cellular and gene therapy (CGT) products. We use case-by-case approach to develop, qualify, or validate custom potency assays in accordance with current Good Manufacturing Practice (cGMP) regulations, ensuring that they comply with the necessary standards for GMP product release.

## CRISPR Edited Gene Assays

Since its discovery, CRISPR technology has been rapidly applied to biological drug development and gene and/or cell therapies. Avance Biosciences™ has adopted accurate and sensitive methods, such as using NGS amplicon sequencing, real-time PCR (qPCR), and ddPCR, to support our clients for evaluating indel profiles introduced by CRISPR or other gene editing tools, and for evaluating the percentage of cells with edited genes.

## Biodistribution DNA Assays

Studies on gene vector and transgene biodistribution, gene expression, protein expression, viral shedding, vector integration, and other areas are crucial for cell and gene therapy preclinical and clinical research. Avance Biosciences™ offers GLP compliant quantitative real-time PCR (qPCR) services to accurately assess the quantity of gene therapy vectors (DNA) in animal blood, CFS, and tissues for biodistribution studies.

## Single-cell Multi-omics Analysis

Avance Biosciences™' single-cell services for cell and gene therapies leverage the cutting-edge Mission Bio Tapestri® Platform to provide unparalleled insights into single-cell genomics. Avance is the "First-in-World" to GMP qualify an % transduction assay to characterize a lentiviral vector transduced drug product using the Mission Bio Tapestri® platform for single-cell characterization.

## CAR-T & Other Cell Therapy Assays

To ensure the safety of the CAR-T treatment, regulatory agencies require thorough characterization of the manufactured CAR T-Cells. Avance Biosciences™ offers customized qPCR and ddPCR solutions to help to determine the copy numbers of inserted or edited genes, replication competent lentivirus (RCL), and any other target of interest. In addition, we are experienced in supporting our clients in their preclinical biodistribution studies and preclinical/clinical pharmacokinetics studies.

## ABOUT US

Our leading scientists have designed and completed hundreds of studies under CGMP/GLP regulations for the FDA, EPA, as well as European and Japanese regulatory agencies. This team has extensive knowledge and experience working with scientists, QA/QC professionals and project managers from over 100 pharmaceutical and biotechnology companies and organizations throughout the world.

# Your Trusted CGMP/GLP Compliant Biological Testing Partner

### Biologic Drug Development Support

Avance Biosciences provides custom CGMP/GLP compliant testing solutions to evaluate the identity, purity and genetic stability of biologics in support of drug research, preclinical safety studies, clinical trials and CGMP manufacturing.

### Assay Development & Validation

With its breadth of service platforms and experienced scientific team, Avance Biosciences offers a broad range of custom assay development services to support all phases of drug development.

### Molecular Biology & Microbiology Testing

Avance Biosciences offers clients worldwide, a variety of molecular biology and microbiology services based on state-of-the-art technology platforms and techniques.

## Science, Compliance, Service


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