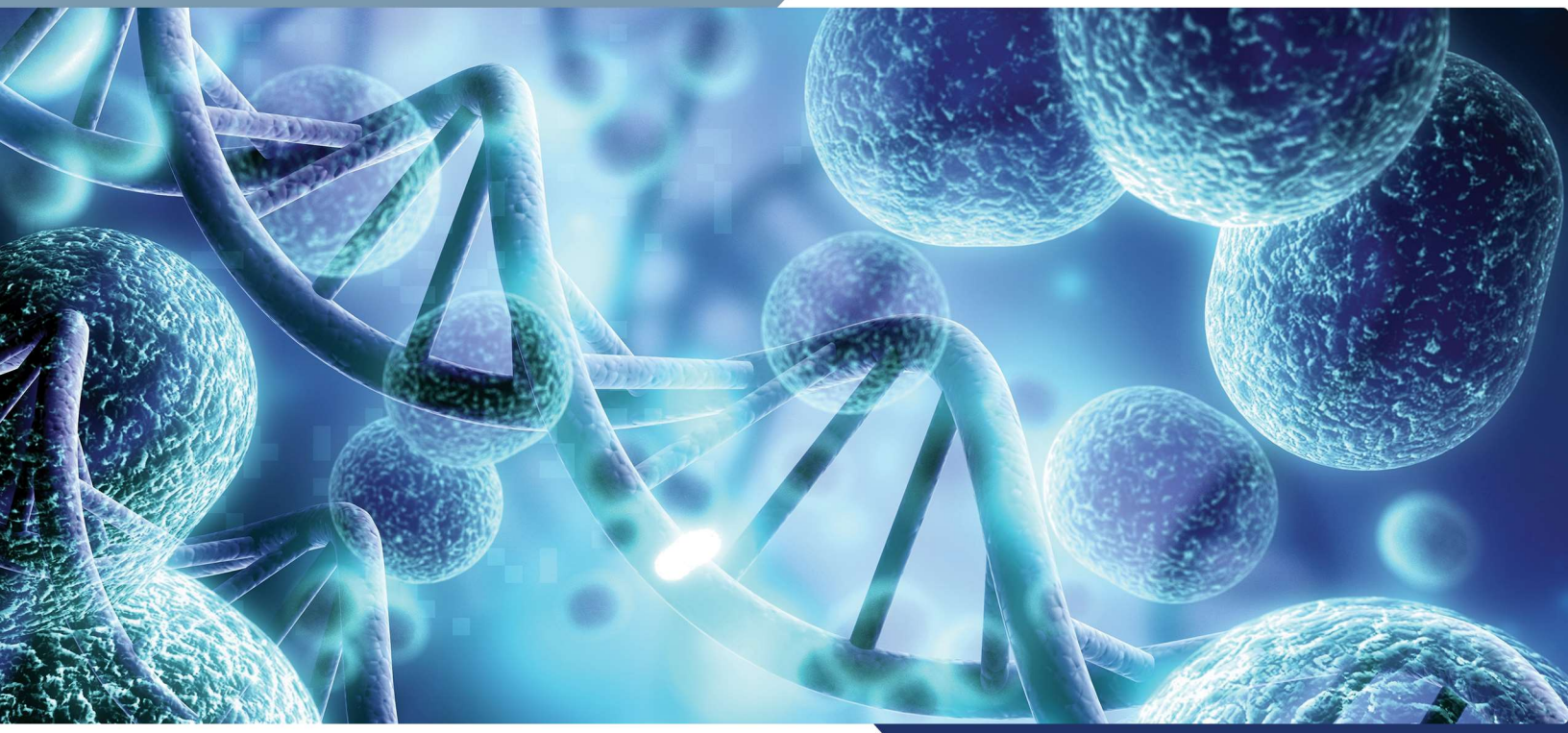
Biological Testing Services Supporting CGT Non-clinical and Clinical Studies

AVANCE BIOSCIENCES



Non-clinical and clinical studies that evaluate pharmacokinetic (ADME) and toxicology characteristics are essential to determine cellular and gene therapy (CGT) product safety and efficacy.

Studies on gene vector and transgene biodistribution (BD), gene expression, protein expression, viral shedding, vector integration, and other areas are crucial for CGT preclinical and clinical research.

Avance Biosciences has more than three decades of experience providing biological testing services to support CGT development and manufacturing.

Our unsurpassed expertise in real-time PCR, digital droplet PCR (ddPCR), next-generation sequencing (NGS), and many other molecular biology, cell biology, and microbiology tools, enables us to provide testing solutions that bolster our clients' CGT programs.

We specialize in assay development, assay qualification or validation, and sample testing that complies with GLP and CGMP regulations.

CONTACT US

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Assay Services Supporting Non-Clinical & Clinical Studies

Finding a reliable testing partner is obviously essential to ensuring that a CGT program successfully launches.

The Avance Biosciences team is adept at providing a wide range of testing services to aid in non-clinical studies and clinical trials during CGT development.

Testing Services	Descriptions
Non-Clinical Studies	
BD of DNA viral vectors or transgenes	We offer GLP and non-GLP qPCR, ddPCR, and NGS testing services to support gene therapy biodistribution studies.
BD of RNA transgenes	Our RT-qPCR method utilizes RNA standard curves to evaluate the distribution of inserted genes that do not occur naturally in the tested animal.
BD of therapeutic cells	We provide GLP and non-GLP qPCR, ddPCR, and NGS testing services to support cellular therapy biodistribution studies.
Gene expression of gene of interest	Both ΔΔCt and RNA standard curve methods are offered to quantify gene expression.
Protein expression of transgenes	We assist our clients with developing specific and sensitive ELISA and Western blot assays for measuring protein expression levels.
Shedding/excretion analysis	Our effective extraction methods enable us to design sensitive assays to ensure the success of viral or bacterial shedding studies of animal urine, feces, and bodily fluids.
Vector integration study	When required, we can aid our clients in developing and validating NGS-targeted sequencing methods that detect less than 50 copies of integrated events in 1 µg of host genomic DNA.
Gene editing site profiling	We offer quantitative NGS amplicon sequencing and rhAmpSeq assay panels to support studies on the distribution and stability of therapeutic cells with edited genes.
Viral vector titer determination for dosing	To accurately determine viral vector titers at various doses, we have developed accurate and robust assays that utilize a proprietary viral-handling process that improves viral recovery.
Clinical Studies	
Transgene RNA expression study	We are experienced with handling patient blood samples to determine the RNA expression of transgenes using GLP-compliant qPCR and ddPCR methods.
Gene editing site profiling	We offer quantitative NGS amplicon sequencing that evaluates the persistence and stability of gene editing sites during human trials.
Shedding/excretion analysis	We provide qPCR, ddPCR, and NGS amplicon assays with a sufficient LOQ to ensure the success of viral or bacterial shedding studies in human urine, stool, nasal swab, throat swab, etc.
Immunogenicity study	Our comprehensive assay development and validation services support our clients in determining the immunogenicity of CGT products.

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qPCR Biodistribution Studies

The team at Avance Biosciences has nearly three decades of experience providing services to support CGT BD studies, including qPCR, ddPCR, and NGS. Throughout the years, we have designed and validated numerous TaqMan assays and analyzed massive quantities of animal tissue samples.

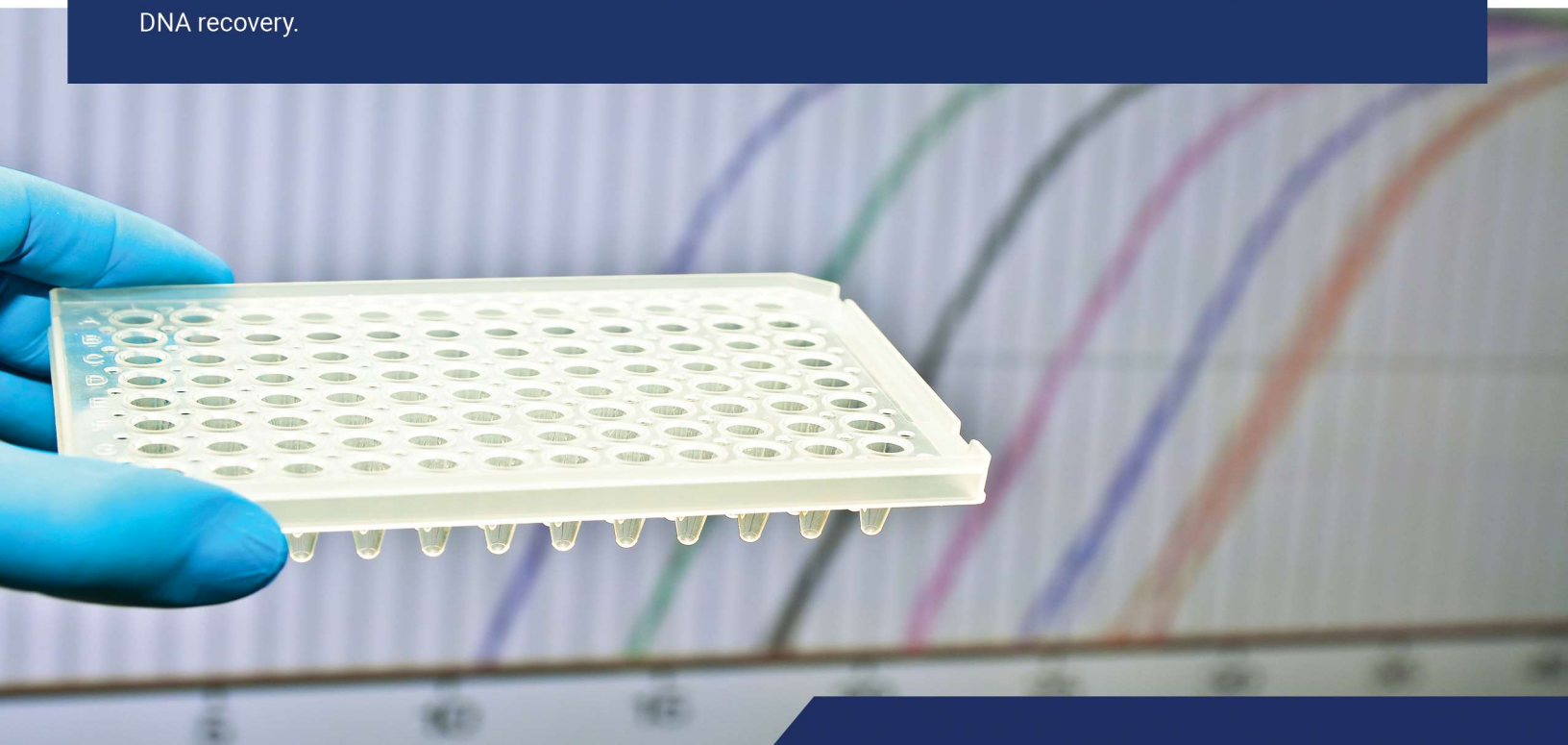
Whether you are working on plasmid-based or AAV gene therapies, CAR-T cell therapeutics, or iPSC-based therapies, Avance Biosciences' experienced team of scientists has seen it all. We can assist you in developing specific and sensitive assays for your BD studies.

Our team is experienced with all common animal models used in BD studies, including mouse, rat, monkey, rabbit, pig, and canine. In addition to the standard BD study tissue panels, we have experience working with almost every major organ as well as different sections of target and non-targeted organs and tissues.

We follow FDA guidance and industry standards for PCR-based assays to measure the BD of gene therapy. Our PCR-based assays satisfy FDA requirements.

- The limit of quantification (LOQ) is ≥ 50 copies/µg of host genomic DNA, with 95% confidence.
- Samples are tested in triplicate with a third well spike.
- PCR efficiency is between 90 and 100%, with an $R^2 > 0.99$.
- Assays are qualified and/or validated following FDA guidance.
- Stringent process controls are used to prevent cross-contamination.

DNA and RNA extraction from animal tissues and blood is an underappreciated yet crucial process in biodistribution research. To ensure our processes are free of any potential contaminants, Avance Biosciences takes the utmost precautions to prevent sample cross-contamination in various lab processes, including tissue cutting, homogenization, and extraction, DNA/RNA quantitation and normalization, and PCR plate setup. Our extraction methods are tailored to the animal species and vector type, ensuring high-yield and high-quality vector DNA recovery.



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Our customers say...

"Avance Biosciences (AB) has delivered the sequencing data in a record time. Very impressive! We have benefited from AB's hard work and are very grateful for that. AB team should feel proud of themselves. We thank AB team for their support and contributions, much appreciated."

Head of Quality Control, Microbial Manufacturing Services

"Your team met the timelines we needed and did exceptional technical work. I will definitely make my management aware that Avance is a very capable partner for our bioanalytical needs. "

Bioanalytical Senior Project Manager

"Avance has been the ideal partner in helping Mission Bio and our client,... be the first in the world to GMP qualify our single cell % transduction assay for a lentiviral gene therapy product. Excellent execution on the part of the Avance team. We look forward to more collaborations in the future."

Senior Director, Cell & Gene Therapy Business

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 30 years experience supporting our clients.

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