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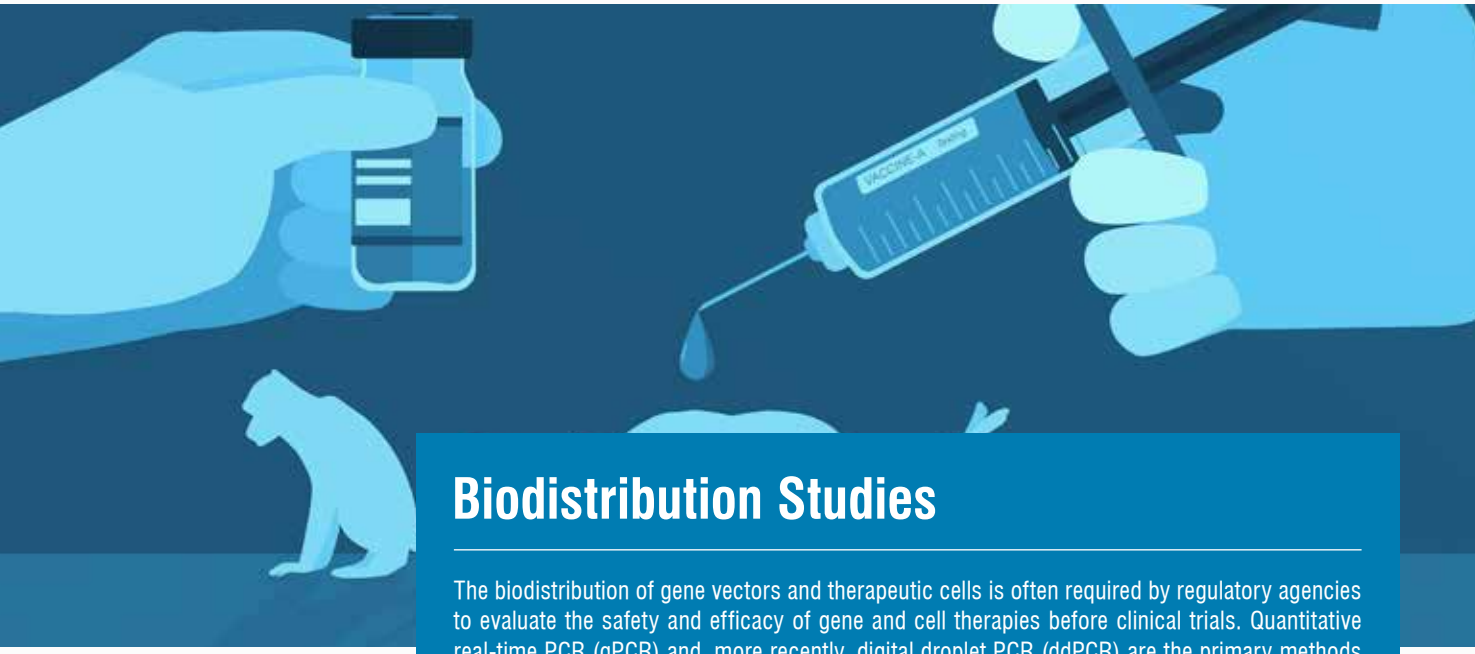

Biodistribution Studies

The biodistribution of gene vectors and therapeutic cells is often required by regulatory agencies to evaluate the safety and efficacy of gene and cell therapies before clinical trials. Quantitative real-time PCR (qPCR) and, more recently, digital droplet PCR (ddPCR) are the primary methods used to assess the distribution and persistence of these vectors and cells. In a typical biodistribution study, thousands of tissue and blood samples from animals in various dosing groups and at multiple time points are analyzed. The scale and complexity of such studies demand robust assay design and validation, as well as meticulous execution, to ensure data quality and adherence to study timelines.

Our Expertise

Avance Biosciences has been providing qPCR biodistribution studies to support gene and cell therapy since the early 2000s, making us one of the most experienced labs in the world in assay design, validation (GLP or non-GLP), and study execution. Our extensive experience encompasses handling all types of tissues and blood samples from various animal models. We pride ourselves on having one of the best-designed workflows in the industry, meticulously structured to prevent potential contamination and ensure high-quality study results.

Our Testing Services

Testing Service	Description
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.
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 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.

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Our Experience

Our team has extensive experience with a wide variety of gene therapy vectors, including various viruses, therapeutic cells, microbial vectors, and plasmids. We are well-versed in working with tissues from numerous animal species. We excel at handling large numbers of samples while maintaining strict contamination control, consistently delivering high-quality study results within demanding timelines.

Gene Vectors	Animal Species	Sample Types
Adeno-Associated Virus (AAV)	Mouse	Tissue/Organs
Adenovirus (AdV)	Rat	Urine
Vaccina Virus	Rabbit	Feces
Newcastle Disease Virus	Non-Human Primate	Blood (plasma, serum, PBMC)
Poxvirus	Pig	Saliva
Myxoma Virus	Canine	Semen
Epstein-Barr Virus		Tumor
Plasmid		Cerebral fluid
Human Cell		
Salmonella S. Typhi ZH9		
sgRNA/mRNA/LNP		

Key Features

Extraction Method Development

At Avance Biosciences, significant emphasis is placed on the development of nucleic acid extraction methods to ensure the efficient recovery of targets from tissues and biofluids. We often achieve an extraction recovery rate exceeding 50% for a wide range of samples. Custom extraction methods are designed and validated as needed, especially for difficult-to-extract vectors such as vaccinia and poxvirus.

DNA Biodistribution Assay

At Avance Biosciences, we design and validate highly sensitive assays capable of quantifying as few as 50 copies of a vector gene in 1 microgram of animal DNA. To ensure accuracy and reliability, samples are tested in triplicate wells, with the third well spiked with a known positive sample to evaluate the PCR inhibition effect.

RNA Biodistribution Assay

RNA samples are tested with three reactions, along with a fourth reaction without the RT enzyme, to evaluate potential DNA contamination. For quantitation, a standard curve is prepared using an in vitro synthesized RNA reference sample.

Human Cell Biodistribution Assay

Our lab at Avance Biosciences has developed a sensitive Alu assay designed to detect low amounts of therapeutic human cells in animal tissues and bodily fluids. We pride ourselves on having the most robust Alu assay available, carefully balancing the need for sensitivity with stringent measures to minimize environmental contamination from human debris in the air, water, and reagents used.