



Gene Therapy Analysis Services

Welcome to our Gene Therapy Analysis Services! With over two decades of experience supporting gene therapy development, we offer comprehensive analytical services tailored to facilitate the development and regulatory approval of various gene therapy modalities. Below, you'll find an overview of each type of gene therapy we support, along with the analytical and bioanalytical services we offer to support preclinical and clinical studies, as well as CMC.

Our Expertise

We specialize in quality control, product release, and bioanalytical testing, to support all phases of gene therapy products from development through manufacture. Our contributions to preclinical and clinical studies have been instrumental in securing numerous successful gene therapy approvals.

Preclinical/Clinical Testing (GLP or non-GLP)

Vectors	Experience
Viral Vector	Since the early 1990s, we have been actively supporting gene therapy utilizing viral vectors such as AAV, adenovirus, lentivirus, and vaccinia virus.
Plasmid	Our team excels in providing comprehensive analytical support of plasmid gene therapy, from vector design and construction through preclinical testing and clinical study support.
Microbial Vector	We have experience supporting clients utilizing microbial vectors, such as Salmonella, to deliver therapeutic genes to target cells or tissues.
In Situ sgRNA/mRNA in LNPs	We leverage advanced qPCR, ddPCR, and NGS tools to deliver innovative analytical and bioanalytical methods supporting in situ sgRNA and mRNA therapies.
mRNA in LNPs	Since 2015, we have been a pivotal partner to one of the leading mRNA vaccine developers, offering extensive expertise in supporting mRNA vaccine and therapeutics.

Analytical Support through ALL Stages of Product Lifecycle

Critical Quality Attributes	Assay	Description
Development	qPCR, ddPCR, PCR, Sanger Sequencing, NGS, HPLC, Flow Cytometry, cloning, CRISPR/cas9	<ul style="list-style-type: none"> • Gene editing profiling • Cytokine release assays • Surface marker analysis • Integration site analysis
Preclinical	qPCR, ddPCR, NGS, ELISA, MSD, Western blot	<ul style="list-style-type: none"> • PK/PD studies • Dose quantitation • Biodistribution studies • Gene expression analysis • Protein expression analysis • Gene editing profiling • Immunogenicity study
Clinical	qPCR, ddPCR, NGS, ELISA, Western blot	<ul style="list-style-type: none"> • Patient stratification • PK/PD studies • Gene expression analysis • Protein expression analysis • Gene editing profiling • Immunogenicity testing • Genotyping
CMC Support	qPCR, ddPCR, PCR, Sanger Sequencing, NGS, Flow Cytometry, compendial assays	<ul style="list-style-type: none"> • Identity assays • Potency assays • Vector genome integrity testing • Stability testing • Replication competent virus testing • Copy number variation (CNV) testing • Adventitious agents testing • Sterility testing • Mycoplasma testing • Endotoxin testing • Bioburden testing • Residual DNA assays • Residual host cell protein assays • Other release assays

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