AVANCE BIOSCIENCES

Testing Service for Cell Therapy

Cell therapy, which encompasses various treatment modalities such as CAR-T, TCR, TIL, NK, DC, Treg, B cells, and stem cells, represents a class of cutting-edge biotherapeutics aimed at treating and potentially curing a range of diseases, including cancers and genetic disorders. Ensuring the safety, efficacy, and quality of these therapies requires reliable testing services. For autologous therapies, timely delivery of quality control tests is crucial for product release.

Our Expertise

Avance Biosciences is a leading CRO and CTO dedicated to providing analytical and bioanalytical solutions for cell therapy developers. Our comprehensive suite of testing services supports every stage of cell therapy development, from initial research through clinical trials to commercialization. We strive to deliver quality services based on solid science, strict compliance, and exceptional customer care, setting us apart from our competitors.

Analytical Support through ALL Stages of Product Lifecycle

Phase	Assay	Description
Development	qPCR, ddPCR, PCR, Sanger, NGS, Single Cell NGS, Nanopore, Flow Cytometry, Southern/ Northern analysis, Capillary electrophoresis	• E coli cell bank testing • Plasmid identification • Viral identification • Target identification and validation • Integration site analysis • Surface marker analysis • Stem Cell Reprogramming factor analysis • Gene editing profiling • Cytokine release assays
Preclinical Studies	qPCR, ddPCR, NGS, ELISA, MSD, Western blot	• PK/PD studies • Biodistribution studies • Gene editing profiling • Vector Integration study • Immunogenicity study
Clinical Studies	qPCR, ddPCR, NGS, ELISA, Western blot	• Patient stratification • PK/PD studies • Gene editing profiling • Vector Integration study • Immunogenicity testing • Genotyping

Phase	Assay	Description
CMC Support	qPCR, ddPCR, PCR, Sanger, NGS, Single Cell NGS, Nanopore, Flow Cytometry, Southern/ Northern analysis, Capillary electrophoresis, StemVision, NC-200	• Cell count and viability assays • Transduction efficiency analysis • Gene editing profiling • Activation marker analysis • Surface marker analysis • Pluripotency marker analysis • Immunophenotyping • Potency assays • Stability testing • Replication competent virus testing • Vector Copy Number (VCN) testing • Adventitious agents testing • Sterility testing • Mycoplasma testing • Endotoxin testing • Other release assays • Custom release assay development and validation

Regulatory Compliance

All testing services are conducted in compliance with Good Laboratory Practice (GLP) and current Good Manufacturing Practice (CGMP) standards, adhering to regulatory guidelines set by agencies such as the FDA and other regulatory bodies worldwide. Our prioritization to not only meet, but to exceed regulatory standards ensures that all data generated is reliable, reproducible, and acceptable for regulatory submissions.