

Cell & Gene Therapy from KCAS

Our team has hands-on experience and scientific knowledge of the intricacies of drug development processes for quantification of the gene, vector and target cells. Our scientists know the regulatory guidances and can collaborate in developing bioanalytical methods for support of cell and gene therapies and molecular services.

Potential Applications

- Viral vector vaccine and oncolytic viral therapies
- Biodistribution and persistence of cell and gene therapies
- Transgene expression of gene therapies
- Detection of copy number variation
- Transgene copy numbers
- Detection of quantification of gene edits in modified cells (VCN)
- Rare sequence/mutation detection
- Gene expression alterations
- Nucleic acid biomarker analysis including rare mRNAs, mRNA, and cell-free DNA
- Cell-based biomarker assays
- Pathogen detection
- Contaminant testing of cell and gene therapy products
- Targeted microbiome analysis

Our Expertise

Our dedicated Cell & Gene Therapy staff is made up of three teams: Flow Cytometry, Cell, and Molecular. We work with a variety of instrumentation and combined 50+ years of experience to develop the most robust assays for the most challenging and complex targets.



Our Facilities

We operate in a 70,000 square foot purpose-built facility with a variety of instruments to help develop, perform and support clinical research studies. In addition to state-of-the-art facilities, we utilize Coulter CytoFLEX LX Flow Cytometers, qPCR, ddPCR, SpectraMax i3x with SoftMax Pro 7.1.2 GXP, and CTL S6 Ultimate M2 Analyzer with Immunosoft Software, to name a few.

Our Workflow

Our road map to success is simple. We operate a world-class, purpose-built, and regulated unidirectional workflow for PCR-based methods that includes two dedicated preamplification areas and a dedicated postamplification area to support molecular services. This method allows for no backward reaction movement.

Molecular Services

- PK with flow cytometry, qPCR, ddPCR
- Biodistribution with flow cytometry, qPCR, ddPCR
- Immunogenicity with flow cytometry, LBA cell-based (NAB) assays
- Pharmacodynamic markers with Luminex, qPCR, ddPCR, flow cytometry (high parameter flow cytometry) ELISPOT