PRECISION
for medicine ®

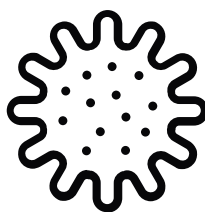# qPCR and ddPCR Services for Cell Therapy and Gene Therapy Development

Precision has demonstrated expertise in the use of PCR technologies – including quantitative PCR (qPCR) and droplet digital PCR (ddPCR) in cell and gene therapy applications, both at the preclinical stage and for clinical sample analysis. Precision performs assay development/transfer as well as validation for custom targets, with rapid turnaround time available for real-time data reporting.

Cell Therapy

Assay	Assay Matrices and Features
Pharmacokinetics (PK) / Persistence of cell therapy product such as CAR-T	• Common matrices: blood, bone marrow, tissue • Custom duplex assays targeting cell therapy vector and a reference gene • Often performed with flow cytometry for CAR-T quantification
Replication-Competent Lentivirus (RCL) Assay	• Precision has developed and validated several RCL assays; off-the-shelf assays available

Gene Therapy

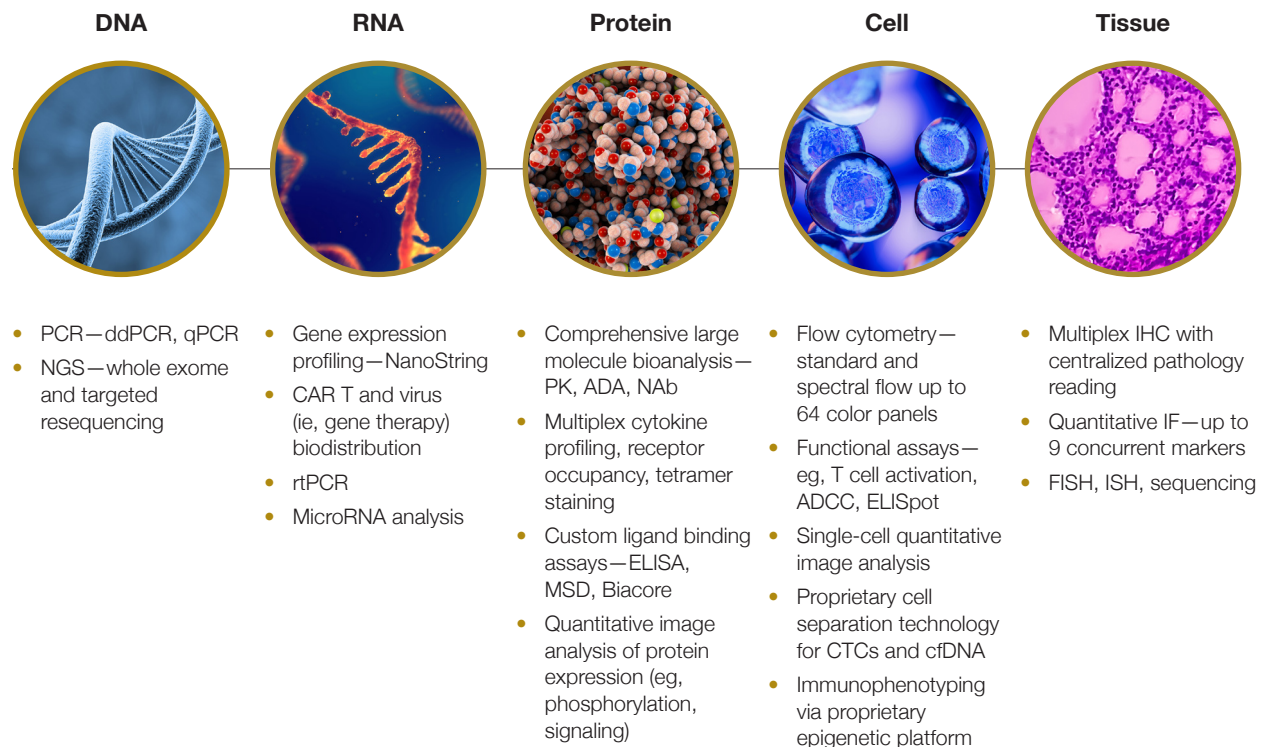| Assay	Assay Matrices and Features
Biodistribution	• Species: NHP, murine, canine, feline, porcine • in vivo distribution, persistence, and clearance of gene therapy product
Shedding	• Common matrices: saliva, urine, feces • Precision recommends ddPCR for shedding assays due to ultrasensitive and absolute nucleic acid quantification.
Transgene Expression	• Assess expression of transgene via RNA analysis • Routinely performed in tissues with positive biodistribution results.

Sample Processing & DNA/RNA Extraction

Precision has a global network of sample logistics and sample processing facilities, and the ability to extract nucleic acids from a range of matrices utilizing automated DNA/RNA extraction platforms.

Solving the most complex challenges in biomarker-driven and precision therapeutic development

Precision for Medicine is the first clinical research services organization engineered to support life sciences companies in the use of biomarkers essential to targeting patient treatments more precisely and effectively. Combining deep scientific expertise, clinical trial excellence, and advanced approaches for data science, Precision accelerates therapeutic development from the late preclinical phase through commercialization.

- 7 specialty labs throughout North America and Europe
- Sample processing labs on 5 continents
- Central lab services, including custom kitting, logistics, processing, and storage
- Assays available under GxP, CLIA, CLSI, CAP, ISO 9001/13485

Comprehensive suite of technologies, capabilities, and proprietary approaches to interrogate any sample type

DNA	RNA	Protein	Cell	Tissue

DNA
- PCR—ddPCR, qPCR
- NGS—whole exome and targeted resequencing

RNA
- Gene expression profiling—NanoString
- CAR T and virus (ie, gene therapy) biodistribution
- rtPCR
- MicroRNA analysis

Protein
- Comprehensive large molecule bioanalysis—PK, ADA, NAb
- Multiplex cytokine profiling, receptor occupancy, tetramer staining
- Custom ligand binding assays—ELISA, MSD, Biacore
- Quantitative image analysis of protein expression (eg, phosphorylation, signaling)

Cell
- Flow cytometry—standard and spectral flow up to 64 color panels
- Functional assays—eg, T cell activation, ADCC, ELISpot
- Single-cell quantitative image analysis
- Proprietary cell separation technology for CTCs and cfDNA
- Immunophenotyping via proprietary epigenetic platform

Tissue
- Multiplex IHC with centralized pathology reading
- Quantitative IF—up to 9 concurrent markers
- FISH, ISH, sequencing

For more information about Precision for Medicine visit precisionformedicine.com

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