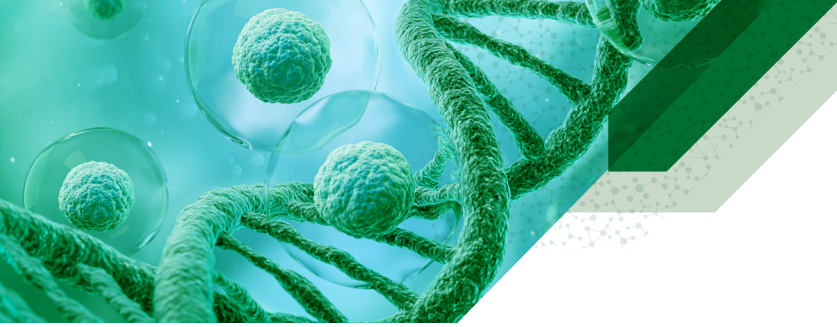

Q² Solutions®

Cell and Gene Therapy (CAGT)

Providing industry-leading science and innovative laboratory solutions across the cell and gene therapy spectrum.

Expert services to stay ahead of advancing science

The use of alternative treatments such as Cell and Gene Therapies (CAGT) holds great potential for bridging the gaps left by traditional treatments. These innovative CAGT clinical development programs require a suite of complex laboratory assessments to satisfy regulatory submissions and support Proof of Mechanism, Pharmacodynamic, Safety and Efficacy investigations. Q² Solutions, with its global laboratory network and industry leading subject matter experts, is ideally positioned to shape, validate, and deliver those biomarker assessments. In partnership with **IQVIA** and **IQVIA Biotech**, Q² Solutions can provide flexible, integrated Cell and Gene Therapy development solutions throughout the drug development journey, beginning with the pre-clinical phase and continuing through post-approval.

Industry-leading technology and expertise with a global footprint

Genomics technology

We quickly design and validate potential therapeutics and can accommodate early safety testing with specialized assays, including ddPCR, Next Generation Sequencing and single-cell portfolio.

Thought leadership

We offer not only laboratory testing but also expertise in the design, validation, and choosing the correct assay for your specific need.

Global assays

We develop customized assays in our North Carolina laboratory and transfer them seamlessly to Beijing and other laboratories around the world.

Turning Hope Into Help™

Q² Solutions offers an extensive array of CAGT laboratory solutions to meet the unique demands of CAGT clinical development.

		Gene-modified Cell Therapy *(e.g., CAR-T, CAR-NK, TCR-T)*	Gene Therapy
Diagnostics, IP characterization and identification of therapy targets	Patient Selection		• Presence of anti-AAV total and nAbs (titers) • High resolution HLA
	Immuno-phenotypification	• Flow cytometry	
	Therapy target ID	• Target assessment in tissues: qPCR / IHC • Immune cell profiling (surface markers)	
Safety	Biodistribution	• CAR transgene: qPCR / ddPCR	• Transgene: qPCR / ddPCR
	Presence and Persistence	• Chimeric Receptor detection: qPCR / ddPCR • CAR-T tracking (enumeration): Flow Cytometry • Replication-comp virus detection: qPCR/ddPCR • Integration site analysis: PCR / NGS	• Vector genome: qPCR / ddPCR • TG mRNA: qPCR • TG Protein: WB / IHC / ELISA / LBA / LC-MS • Integration site analysis: PCR / NGS • Replication-comp virus detection: qPCR/ddPCR
	Clearance		• Viral shedding: qPCR / ddPCR
	Immunogenicity	• Anti-Chimeric receptor Abs & ELISpot	• Anti-vector / TG nAbs or total Abs (ADA) • Anti-vector / TG T cell responses (ELISpot)
Efficacy	Pharmacodynamics	• Cytokine Profiling: single and multiplex ELISA, NGS • Genomics: Tumor Mutation Load (Bespoke), T Cell Expansion and Persistence (TCR sequencing), Immune Landscape Signature	
	Exploratory	• High resolution HLA, Tumor Profiling NGS, RNA sequencing, Whole Exome Sequencing • Single-Cell RNA sequencing, Immune Cell Profiling, Spatial Genomics • CAR-T tumor infiltration • Cell depletion (B cell): Flow cytometry • Soluble targets (e.g., sBCMA)	

See Cell Therapy Testing Location Guidance on page three

See Gene Therapy Testing Location Guidance on page four

CELL THERAPY

Cell Therapy Testing Location Guidance

CAP/CLIA/GCP vs GLP/BioA

	Indication	Validation Level Required	Testing Location	Off the Shelf Solutions
Total Antibodies	Inclusion/Exclusion	CAP, CLIA	Central Lab	
Neutralizing Antibodies	Inclusion/Exclusion	CAP, CLIA	Central Lab	
Total Antibodies	Immunogenicity (testing after screening)	FDA/EMA ADA	BioA Lab	
Neutralizing Antibodies	Immunogenicity (testing after screening)	FDA/EMA ADA	BioA Lab	
Vector Testing (Molecular)	Biodistribution or Vector Shedding	EX, FFP	Central Lab, Genomics, Nexelis Laval	Lentiviral VCN Assay using PSI (HIV-1) by ddPCR (blood) – targets vector backbone
Vector Testing (Molecular)	Replication Competency	EX, FFP	Central Lab, Genomics, Nexelis Laval	Replication Competent Lentivirus (VSV-G) Quantiation by ddPCR (blood) Replication Competent Retrovirus (GALV) quantitation by ddPCR (blood)
Vector Testing (Molecular)	Integration Testing	EX, FFP	Central Lab/Genomics	
Transgene (Soluble Protein)	Pharmacokinetics, Pharmacodynamics, or Immunogenicity	ICH M10, FDA BMV, FDA/EMA ADA	BioA Lab	
Transgene (Molecular)	RNA Expression	EX, FFP	Central Lab/Genomics	
Transgene (Tissue Expression)	IHC/Western Blot	EX, FFP	Central Lab AP/TSAIL	
Cytokines	Safety/ Pharmacodynamics	EX, FFP	Central Lab/RBM/BioA	RBM, BioA and the CL have hundreds of assays available
ELISPOT	T-Cell Immune Response	EX, FFP	Nexelis or CTL	
Flow Cytometry	PD Immunophenotyping	EX	Central Lab	Numerous off the shelf and bespoke

CAP — College of American Pathologists

CLIA — Clinical Laboratory Improvement Act (US clinical lab regulations)

FFP — Fit for Purpose Validation

EX — Exploratory

ICH M10 — M10 Bioanalytical Method Validation Guidance

FDA BMV — FDA Bioanalytical Method Validation

FDA/EMA ADA — FDA/EMA Anti-Drug Antibodies

GENE THERAPY

Gene Therapy Testing Location Guidance

CAP/CLIA/GCP vs GLP/BioA

	Indication	Validation Level Required	Testing Location	Off the Shelf Solutions
Total Antibodies	Inclusion/Exclusion	CAP CLIA	Central Lab	Total AAV9 is available at Athena
Neutralizing Antibodies	Inclusion/Exclusion	CAP CLIA	Central Lab	
Total Antibodies	Immunogenicity (testing after screening)	FDA/EMA ADA	BioA Lab	
Neutralizing Antibodies	Immunogenicity (testing after screening)	FDA/EMA ADA	BioA Lab	
Vector Testing (Molecular)	Biodistribution or Vector Shedding	EX FFP	Central Lab, Genomics, Nexelis Laval	Lentiviral VCN Assay using PSI (HIV-1) by ddPCR (blood) – targets vector backbone
Vector Testing (Molecular)	Replication Competency	EX FFP	Central Lab, Genomics, Nexelis Laval	Replication Competent Lentivirus (VSV-G) Quantiation by ddPCR (blood) Replication Competent Retrovirus (GALV) quantitation by ddPCR (blood)
Vector Testing (Molecular)	Integration Testing	EX FFP	Central Lab/Genomics	
Transgene (Soluble Protein)	Pharmacokinetics, Pharmacodynamics, or Immunogenicity	ICH M10 FDA BMV FDA/EMA ADA	BioA Lab	
Transgene (Molecular)	RNA Expression	EX FFP	Central Lab/Genomics	
Transgene (Tissue Expression)	IHC/Western Blot	EX FFP	Central Lab AP/TSAIL	
Cytokines	Safety/ Pharmacodynamics	EX FFP	Central Lab/RBM/BioA	RBM, BioA and the CL have hundreds of assays available
ELISPOT	T-Cell Immune Response	EX FFP	Nexelis or CTL	CTL has several AAV assays

CAP **College of American Pathologists**

CLIA **Clinical Laboratory Improvement Act (US clinical lab regulations)**

FFP **Fit for Purpose Validation**

EX **Exploratory**

ICH M10 **M10 Bioanalytical Method Validation Guidance**

FDA BMV **FDA Bioanalytical Method Validation**

FDA/EMA ADA **FDA/EMA Anti-Drug Antibodies**

Contact us

Toll free: +1 855.277.9929
Direct: +1 919.998.7000
International: +44 (0) 1506 814000
Website: www.Q2LabSolutions.com

Q² Solutions®