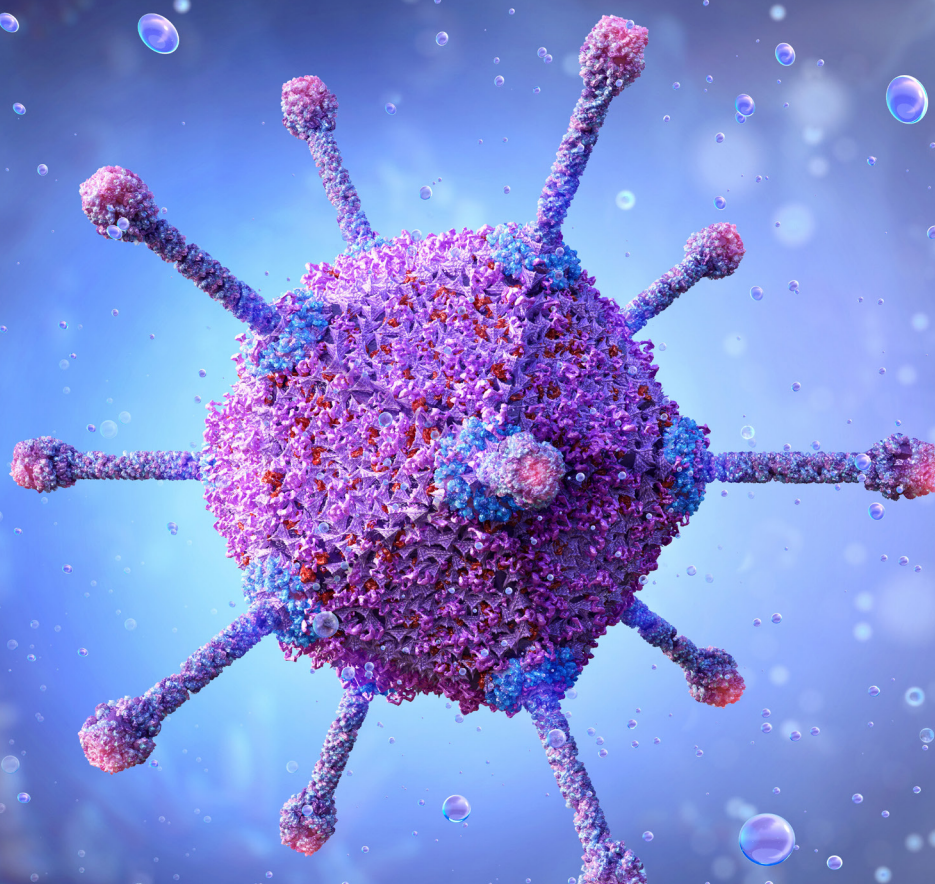




Cerba Research

Advancing Cell & Gene Therapy in clinical trials with specialty laboratory solutions

Bringing together scientific insights
and operational agility



The cell & gene therapy landscape brings the potential for health improvements for patients waiting for appropriate personalized treatments. Biotech and pharma communities face the challenge of bringing novel therapeutics to the market within tight deadlines. Meeting the demands of cell & gene therapy development at the clinical translational stage of the drug development process requires a strategic partner capable of dealing with highly complex clinical trial research challenges. As a specialty laboratory services provider, Cerba Research provides an extensive offering of cell & gene therapy capabilities.

Experience you can trust

 **~50**
CGT trials since 2018

 **~95%**
Trials include specialty testing

 **~50%**
CAR T-driven

 **~65%**
In hematological malignancies

 **4**
Approved CGTs

 **AAV**
Adeno-associated virus assay development

 **~6,000**
Patients screened

 **~4,800**
Randomized patients

Committed to providing the highest quality



Specialized Solutions – Essential Assays

Assay Category	Adoptive Cell Therapy e.g. CAR-T, CAR-NK, TCR-T	Gene Therapy (Viral Vector Mediated) e.g., rAAV, lentiviral, retroviral vectors	Viral Therapy And Others e.g. Oncolytics (including adenoviruses), RNA-based therapeutics, genome-/base- editing
Product development & preclinical studies	VIS (ISA)	ISA	
	Immunophenotyping	Immunophenotyping	Immunophenotyping
	ADA/histopathology	TAb/ADA/Histopathology	ADA/Histopathology
		NAb	
Biodistribution [Pharmacokinetics]	CAR-expression/VCN	Viral vector load	Viral vector/Virus load
	CAR-detection/tracking		
	CAR-detection	Viral vector detection	Viral vector/Virus detection
Safety	Repl. comp. (RCL/RCR)	Repl. comp. (rcAAV)	Repl. comp. (RCA)
	VIS (ISA)	Infectivity assay	Infectivity assay
Persistence [Pharmacokinetics]	CAR-enumeration		
	VCN	Viral vector load	Viral vector/Virus load
Efficacy [Pharmacodynamics]	CAR-detection/tracking		
	CAR-expression/VCN		
		Tx protein expression	Tx protein expression
Shedding [Pharmacokinetics]		Viral vector load	Viral vector/Virus load
			Infectivity assay
Biomarkers [Pharmacodynamics]	Immunophenotyping	Immunophenotyping	Immunophenotyping
	Cytokines/Histopathology	Cytokines/Histopathology	Cytokines/Histopathology
Immunogenicity	ADA	TAb/ADA	ADA
	ELISPOT	NAb/ELISPOT	ELISPOT
Immune Characterization	HLA/IRS		HLA/IRS

AAV: Adeno associated virus, **rAAV:** recombinant AAV, **rcAAV:** replication competent AAV, **Repl. comp.:** Replication competent, **ADA:** Anti drug antibody (antibody targeting vector or transgene), **CAR:** Chimeric antigen receptor, **VCN:** Vector copy numbers, **VIS:** Vector integration sites, **ISA:** Integration site analysis, **TAb:** Total/binding antibody, **NAb:** Neutralizing antibody, **RCL:** Replication competent lentivirus, **RCR:** Replication competent retrovirus, **RCA:** Replication competent adenovirus, **TCR-T:** T-cell receptor T-cells, **CAR-NK:** CAR-natural killer cells, **CAR-T:** CAR T-cells, **Tx:** Transgene/therapeutic target, **ELISPOT:** Enzyme linked immunosorbent spots, **HLA:** Human leukocyte antigen, **IRS:** Immune repertoire sequencing.

Molecular assays

Flow cytometry

Cell-based assays

Immunoassays/Histopathology

Customized solutions for your study

Genomics

- NGS (broad panel, custom panels, etc)
- HLA typing
- Genome mapping
- Single-gene
- TCR/BCR sequencing
- ...

Molecular Biology

- RCR/RCL (custom & generic assay; qPCR)
- Vector copy number (ddPCR)
- CAR copy number (PK; ddPCR)
- Vector integration site analysis (Sequencing)
- ...

Histopathology

- Full histopathology service
- Board certified pathologists
- Multiplex/simplex IHC (275+ biomarkers/protocols)
- Spatial analysis (tumor microenvironment)
- ...

Liquid biopsy (ctDNA), FISH, ISH, Nanostring

Flow Cytometry

- CAR-T enumeration & phenotyping
- Immunophenotyping cell subsets (including characterization of memory subset, activation & exhaustion status)
- Intracellular cytokine staining (ICS) assay
- MRD for multiple myeloma (Euroflow)
- ...

Immunoassays

- Cytokine profiling (Cytokine release syndrome)
- Soluble proteins (ie., BCMA)
- Immunogenicity (Cellular and humoral)
- Anti-AAV human IgG (IVDR)
- ...

Diagnostics

- Assay development
- Analytical & clinical performance for CE-marking
- PBMC processing network
- BMMC processing
- ...

Patient Screening And Selection (IVDR)

AAV: Adeno associated virus, **NGS:** Next generation sequencing, **HLA:** Human leukocyte antigen, **TCR:** T cell receptor, **BCR:** B cell receptor, **ddPCR:** droplet digital PCR, **qPCR:** quantitative PCR, **PK:** Pharmacokinetics, **ISH:** *In situ* hybridisation, **FISH:** Fluorescence ISH, **ctDNA:** circulating tumor DNA, **CAR-T:** Chimeric antigen receptor T-cells, **VCN:** Vector copy numbers, **VIS:** Vector integration sites, **ISA:** Integration site analysis, **RCL:** Replication competent lentivirus, **RCR:** Replication competent retrovirus, **IHC:** Immunohistochemistry, **MRD:** Minimum residual disease, **IVDR:** *In vitro* diagnostics regulation, **PBMC:** Peripheral blood mononuclear cells, **BMMC:** Bone marrow mononuclear cells.



Central Laboratory and Global Logistics Services

Comprehensive laboratory and logistics services tailored specifically for cell & gene therapy development:

- A global network of labs for complex testing
- A worldwide PBMC/BMMC isolation network
- 24/7 monitored and temperature-controlled sample transport
- Customized kit manufacturing and distribution

AAV Immunogenicity Screening

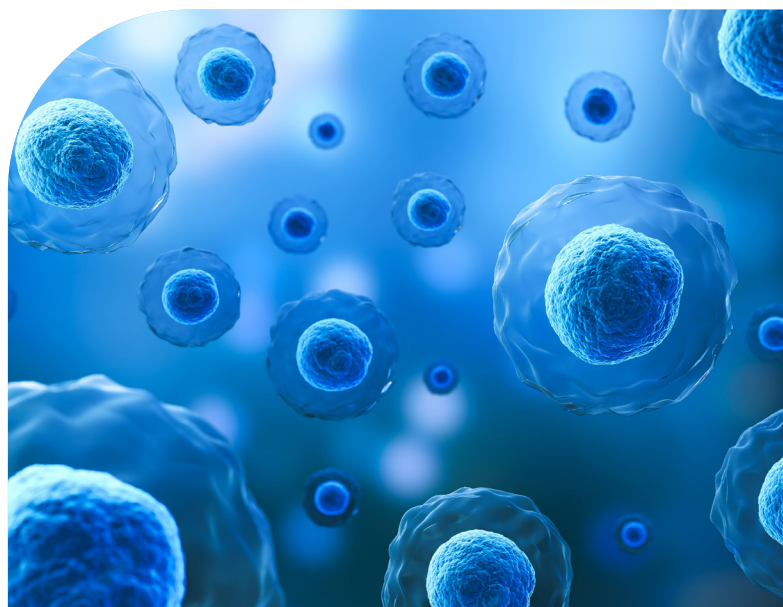
With an established track record in support of market authorized AAV therapies, Cerba Research is the go-to partner for highly customizable logistics and specialty testing.

- Various assays and platforms available, including, ELISA, MSD platform, NAb and more
- In-house produced and quality controlled IVD and IVDR compliant sample and assay kits
- 24/7 logistics support and diagnostic services
- Rapid turn-around times (average 1-5 days) from sample pick up to reporting
- A network of satellite analytical labs for AAV screening in remote regions

Bioanalysis and Biomarker Services

We support sponsors from pre-clinical to post-market authorization with our in-depth biologics and biosimilar experience. Cerba Research offers deep scientific expertise in pharmacokinetics and immunogenicity testing, including anti-drug antibodies and neutralizing antibodies.

Cerba Research provides access to a network of specialized testing laboratories for cell and gene therapy trials. Our dedicated project teams, supported by a global footprint and customizable logistics capabilities, ensure responsiveness and agility. Additionally, our in-house scientific expertise includes flow cytometry, genomics, molecular diagnostics, and histopathology.





About Cerba Research

Cerba Research is a leading specialty laboratory services provider with the capacity and breadth of a global central laboratory network. Our highly qualified scientists provide insight on the latest biomarkers, assays and testing approaches and develop innovative solutions for unique challenges across all research phases, to pharmaceutical, biotechnology, medical device, government, public health, and CRO organizations.

Cerba Research's extensive capability in laboratory testing and global logistics including Cell & Gene Therapy, Bioanalysis, Flow Cytometry, HistoCytopathology, and Next-Generation Sequencing, enables us to drive operational agility at scale in a wide range of therapeutic areas, with recognized expertise in Virology, Immunology, Oncology and Cell & Gene Therapy. Cerba Research is part of the Cerba HealthCare Group with 15,000 employees on five continents, driven to advance diagnosis and health.

Connect with our experts

Request a meeting [here](#) to learn more about our cell & gene therapy capabilities.

www.cerbaresearch.com