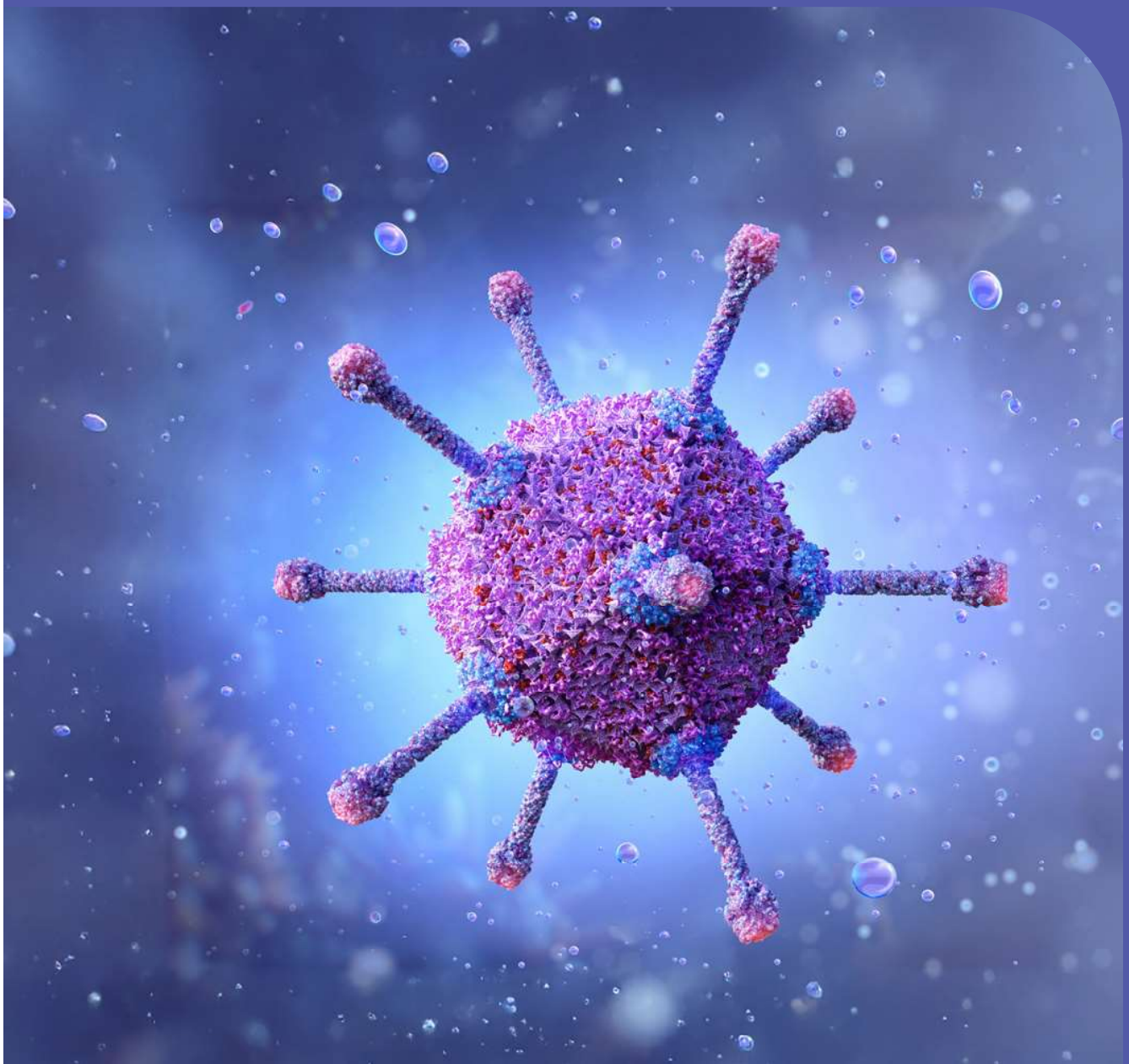
Cerba Research

Cell & Gene Therapy Laboratory Solutions

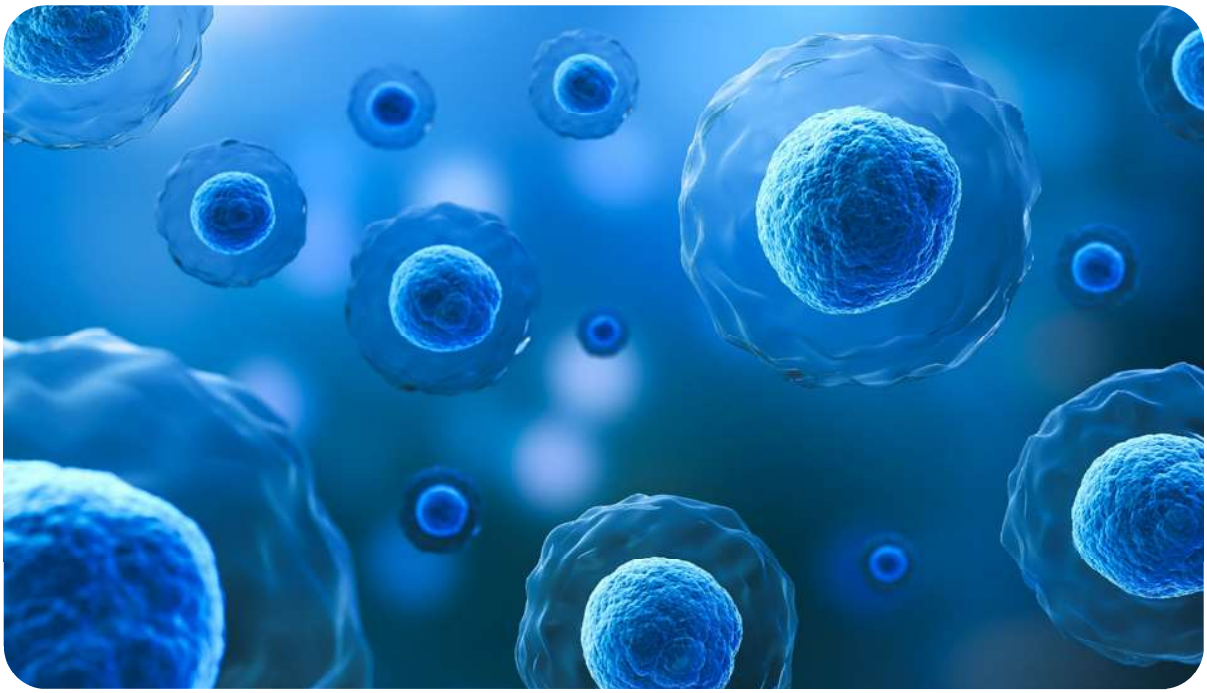
Agility and customization
with global reach

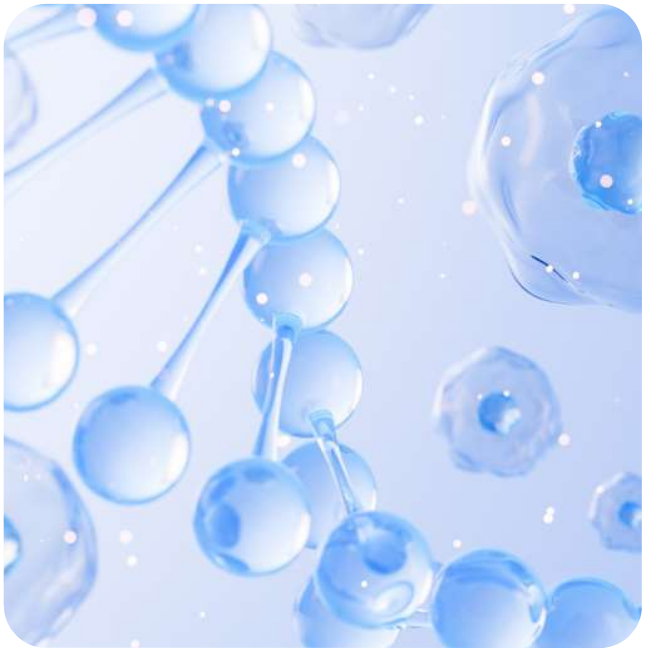


Cerba Research provides the solutions to challenges in laboratory testing for Cell & Gene Therapy

As a specialty laboratory solutions provider, we are at the forefront of addressing the complexity in Cell & Gene Therapy clinical trials, and offer a comprehensive suite of solutions:

- Project management expertise with Cell & Gene Therapy specific experience
- Access to a scientific and specialist network
- Extensive assay offering and testing customization, in line with regulatory guidance including IVDR compliant assay kits
- Global specialty laboratory with central laboratory network
- Tailor-made logistics solutions for sample and kit management





Project management expertise with Cell & Gene Therapy specific experience

Cerba Research provides end-to-end project management, ensuring a seamless process from sample receipt to data reporting. Each project plan is tailored to meet specific needs, with special attention to assay development, sample handling, and logistics management. Our scalable solutions guarantee consistent output, while proactive risk management and mitigation strategies help to navigate any challenges that may arise throughout your clinical trial.

Access to a scientific and specialist network

Cerba Research offers a comprehensive scientific and specialist network, ensuring early engagement with experts to develop tailored laboratory solutions. We specialize in genomics, molecular biology, histopathology, flow cytometry, immunology, and diagnostics. In addition, we provide dedicated account management to support the logistics of sample management, and kit distribution, streamlining the entire process for our clients to ensure that they reach their clinical trial endpoints efficiently.

Extensive assay offering and testing customization

Our extensive assay offering aligned to relevant regulatory guidance, such as In Vitro Diagnostic Regulation (IVDR), includes a wide range of research areas, such as rare diseases, oncology, autoimmune diseases, neurodegenerative disorders, and metabolic conditions.

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 & Others e.g. Oncolytics (including adenoviruses), RNA-based therapeutics, genome-/base- editing
Product Development & Preclinical Studies	VIS (ISA) Immunophenotyping ADA/histopathology	ISA Immunophenotyping TAb/ADA/Histopathology NAb	Immunophenotyping ADA/Histopathology
Biodistribution [Pharmacokinetics]	CAR-expression/VCN CAR-detection/tracking CAR-detection	Viral vector load Viral vector detection	Viral vector/Virus load Viral vector/Virus detection
Safety	Repl. comp. (RCL/RCR) VIS (ISA)	Repl. comp. (rcAAV) Infectivity assay	Repl. comp. (RCA) 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 Cytokines/Histopathology	Immunophenotyping Cytokines/Histopathology	Immunophenotyping Cytokines/Histopathology
Immunogenicity	ADA ELISPOT	TAb/ADA NAb/ELISPOT	ADA ELISPOT
Immune Characterization	HLA/IRS		HLA/IRS

Key: Molecular assays | Flow cytometry | Cell-based assays | Immunoassays/Histopathology

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.

Customized solutions for your study

Genomics

- TCR/BCR sequencing
- NGS
- HLA typing
- Optical Genome mapping
- RNA sequencing
- Single-cell sequencing

Molecular Biology

- RCR/RCL (custom & generic assay)
- Vector copy number
- CAR copy number (PK)
- Vector integration site analysis (VIS/ ISA)

Histopathology

- Full histopathology service
- Board certified pathologists
- Multiplex/singleplex IHC (250+ biomarkers/ protocol)
- Spatial analysis (tumor microenvironment)

Liquid biopsy (ctDNA)

Flow Cytometry

- CAR T enumeration & phenotyping
- Immuno-phenotyping for various trials (including characterization of memory subset, activation exhaustion status)
- Intracellular cytokine staining (ICS) assay
- MRD for multiple myeloma (Euroflow)

Immunoassays

- Cytokine Profiling (Cytokine Release Storm)
- Soluble proteins (ie. BCMA)
- Immunogenicity (T and B cell)
- Anti-AAV Human IgG (IVDR)
- ELISA, ELLA, MSD, ELISpot

Diagnostics

- Assay development and validation
- Analytical & clinical performance for CE marking
- Extensive medical diagnostic laboratory network

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.

Global specialty laboratory with central laboratory network

Cerba Research provides access to specialized testing for Cell & Gene Therapy trials, supported by global central laboratory services. Our in-house molecular, genetics, biomarkers, histopathology, and flow cytometry capabilities are available in North America, Europe, Asia-Pacific, and Africa. In addition, we offer a global network comprising:

Pre-processing labs

PBMC/ BMMC isolation network

Research, and partner laboratories

By identifying laboratory partners early on, we can support and project manage your study across downstream processing, verify laboratory qualification, manage auditing, and the contracting process.

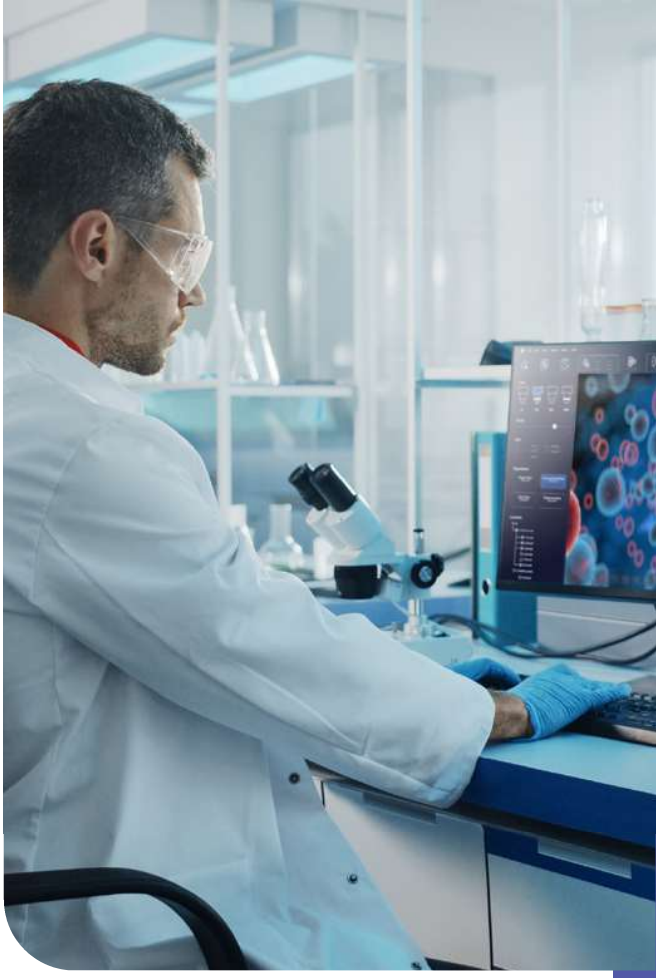
Customized logistics solutions for sample and kit management

Our tailor-made logistics solutions for sample and kit management are designed to meet the diverse specifications of Cell & Gene Therapy trials. Cerba Research offers multiple levels of services, including standard and premium, that are fully customizable, to ensure seamless and sensitive handling of international sample shipments. Understanding the complexities of Cell & Gene Therapy trial logistics, we have the agility to adapt to both regional and global regulations (IATA/ ADR compliant). Additionally, our comprehensive contingency planning and 24/7 helpdesk ensure that support is always available, providing peace of mind for our customers.

AAV Immunogenicity Screening

Cerba Research has an established track record in support of market authorized AAV therapies.

- Various assays and platforms are available, including, ELISA, MSD platform, NAb and more
- In-house produced and quality controlled IVD and IVDR compliant sample and assay kits
- Dedicated account management team for 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



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

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

FDA

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ISO 15189 ACCREDITATION
MEDICAL LABORATORY

CLIA
Clinical Laboratory Improvement Amendments

*** CGT:** Cell & Gene Therapy

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 Laboratory Solutions.

www.cerbaresearch.com