

Cerba Research Specialized Solutions: Table Of 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	<ul style="list-style-type: none"> VIS (ISA) Immunophenotyping ADA / histopathology 	<ul style="list-style-type: none"> ISA Immunophenotyping TAb / ADA / Histopathology NAb 	<ul style="list-style-type: none"> Immunophenotyping ADA / Histopathology
Biodistribution [Pharmacokinetics]	<ul style="list-style-type: none"> CAR-expression / VCN CAR-detection / tracking CAR-detection 	<ul style="list-style-type: none"> Viral vector load Viral vector detection 	<ul style="list-style-type: none"> Viral vector/ Virus load Viral vector / Virus detection
Safety	<ul style="list-style-type: none"> Repl. comp. (RCL / RCR) VIS (ISA) 	<ul style="list-style-type: none"> Repl. comp. (rcAAV) Infectivity assay 	<ul style="list-style-type: none"> Repl. comp. (RCA) Infectivity assay
Persistence [Pharmacokinetics]	<ul style="list-style-type: none"> CAR-enumeration VCN 	<ul style="list-style-type: none"> Viral vector load 	<ul style="list-style-type: none"> Viral vector/ Virus load
Efficacy [Pharmacodynamics]	<ul style="list-style-type: none"> CAR-detection / tracking CAR-expression / VCN 	<ul style="list-style-type: none"> Tx protein expression 	<ul style="list-style-type: none"> Tx protein expression
Shedding [Pharmacokinetics]		<ul style="list-style-type: none"> Viral vector load 	<ul style="list-style-type: none"> Viral vector/ Virus load Infectivity assay
Biomarkers [Pharmacodynamics]	<ul style="list-style-type: none"> Immunophenotyping Cytokines / Histopathology 	<ul style="list-style-type: none"> Immunophenotyping Cytokines / Histopathology 	<ul style="list-style-type: none"> Immunophenotyping Cytokines / Histopathology
Immunogenicity	<ul style="list-style-type: none"> ADA ELISPOT 	<ul style="list-style-type: none"> TAb / ADA NAb / ELISPOT 	<ul style="list-style-type: none"> ADA ELISPOT
Immune Characterization	<ul style="list-style-type: none"> HLA / IRS 		<ul style="list-style-type: none"> 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.

Our Customized Solutions Include:

Genomics

- NGS (broad panel, custom panels, etc)
- HLA typing
- Genome mapping
- RNA seq
- 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 (VIS/ISA; 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
- BMDC 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:** Immuno histo chemistry, **MRD:** Minimum residual disease, **IVDR:** In vitro diagnostics regulation, **PBMC:** Peripheral blood mononuclear cells, **BMDC:** Bone marrow mononuclear cells.

Central Laboratory

Routine / Safety

- Coagulation
- Hematology
- Biochemistry
- Urinalysis
- β -2 macroglobulin
- ...

Global Logistics & Kit Management

- Kits distributed world-wide & complex logistics scheme
- Specialized pick up and transport on dry ice
- Rapid turn around times
- 24/7 logistics, support and diagnostic services
- Report anti-AAV9: on average 2 business days

Contact Us [Here](#) To Discuss Your Project

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