

In-Vivo Lentiviral CAR-T Lot Release

Flyer

A Comprehensive Testing Panel for Confident Release

Minaris Advanced Testing provides fully integrated, GMP-compliant lot release testing solutions to support the development and commercialization of in-vivo lentiviral CAR-T products. Our scientific experts understand the unique complexity of lentiviral vector-based gene delivery systems and the critical quality attributes required to ensure safety, purity, potency, and regulatory compliance. We offer comprehensive testing panels for both Drug Substance (DS) and Drug Product (DP), tailored to your product design and global regulatory expectations.



Drug Substance (DS)

Our DS testing portfolio supports lentiviral vector intermediates and bulk drug substance with validated and phase-appropriate assays, including:

Identity – Genome confirmation, transgene verification

Strength – Infectious titer, p24, vector genome titer (qPCR/ddPCR)

Potency – Functional assay

Safety – Sterility, mycoplasma, endotoxin, RCL

Purity – Residual host cell DNA/protein, plasmid DNA, Benzonase

Quality Attributes – Osmolality, pH and appearance, particle concentration



Drug Product (DP)

For final formulated in-vivo CAR-T drug products, we provide comprehensive release support, including:

Identity – Genome confirmation, transgene verification

Strength – Infectious titer, p24, vector genome titer (qPCR/ddPCR)

Potency – Functional assay

Safety – Sterility, endotoxin

Quality Attributes – Appearance, pH, osmolality, fill volume, particulates

Stability Support – ICH-aligned stability programs



Product Specific Customization

In-vivo lentiviral CAR-T therapies present unique analytical challenges given that the vector is administered directly to the patient and must selectively and safely transduce immune cells within the body. As a result, Replication-Competent Lentivirus (RCL) testing and Infectious Titer (TU/mL) assays often require product-specific customization. Customization of these two assays ensures patient safety, accurate dose assignment, supports regulatory expectations and provides defensible data across phases.

For in-vivo CAR-T products, potency assays must also be customized as clinical activity depends not only on transduction efficiency, but on selective in-vivo targeting and functional CAR signaling driven by engineered vector design. Customization typically includes the use of biologically relevant primary or receptor-expressing target cells, along with measurement of CAR expression, downstream signaling, and functional activity (e.g., cytotoxicity or activation) in a matrix appropriate for the final drug product.



Why Minaris?

Minaris Advanced Testing combines specialized expertise in cell and gene therapy analytics with extensive experience supporting lentiviral vector programs across all stages of development.

Our GMP-compliant laboratories provide comprehensive method development, qualification, and validation services, backed by global regulatory support for FDA, EMA, and PMDA submissions—delivering the scientific rigor and reliability needed to advance your therapy with confidence.

Attribute	Full Assay Name	DS	DP	Test Code	Minimum Sample Requirements	TAT (days)
Safety	Isolator Sterility Testing by Direct Inoculation USP<71> (GMP) - (Up to 100mL TA or 20 Vials)	✓	✓	3000004994	Per USP guidelines	21
Safety	Bacteriostasis and Fungistasis (Direct Method) (GMP) ¹	✓	✓	3000004996	Varies depending on fill/volume	21
Safety	Analysis of Bacterial Endotoxin Contamination Using Endosafe® nexgen-PTS™ (GMP)	✓	✓	3000005222	1 mL	7
Safety	Analysis of Bacterial Endotoxin Contamination Using the Endosafe® nexgen-PTS™ - Test for Interfering Factors (GMP)	✓	✓	3000005260	1 mL	14
Safety	EP, JP, and USP Mycoplasma Detection (GMP) ²	✓		3000005147	1x15 mL & 1e6 cells/mL	35
Safety	EP, JP, and USP Mycoplasma Detection with MycoplasmaStasis (GMP) ²	✓		3000007121	1x45 mL & 1e6 cells/mL	35
Safety	Mycobacterium Tuberculosis DNA Detection by qPCR (GMP) ²	✓		3000005638	1e7 cells frozen	9
Safety	In Vitro Assay for Adventitious Viral Contaminants: MRC-5, VERO, and HEK Cells (Extended Duration) with Hemadsorption and Hemagglutination Endpoints (GMP) ²	✓		3000005475	2x6 mL at 1e7 cells/mL	35
Safety	RCL Assay: Co-cultivation of Test Article Cells with C8166 Cells (GMP) ^{2,3}	✓		3000007915	1% or 1e8 cells (whichever is less)	56
Safety	RCL Assay: Amplification of Test Article Supernatant with C8166 Cells - Large Scale (5% of total supernatant, 200 mL to 300 mL) (GMP) ^{2,3}	✓		3000007492	5% or 300 mL of supernatant (whichever is less)	56
Safety	Microbial Safety Enumeration Test According to USP<61> (GMP)	✓		3000005066	2x specification	14
Safety	Microbial Enumeration Test Suitability <61> (GMP)	✓		3000005068	8x routine	21
Strength	Lentiviral Infectious Titer Assay with a qPCR Endpoint (GMP) ⁴	✓	✓	3000005157	3x0.5 mL	35
Strength	Lentivirus Titer Determination by p24 ELISA (GMP) ⁴	✓	✓	3000005164	1 mL	21
Strength	p30 ELISA (GMP) ⁴	✓	✓	Custom	Varies	TBD
Strength	Genomic Titer by ddPCR for Customer Gene of Interest (GMP)	✓	✓	Custom	Varies	TBD
Potency	Product Specific Assessment Indicative of MOA (GMP)	✓	✓	Custom	Varies	TBD
Quality	Dynamic Light Scattering Analysis for Determination of Particle Size of Virus Lots (GMP)		✓	3000007812	0.1 mL	8
Quality	Determination of Appearance According to the USP (GMP)		✓	3000005469	2 mL	8
Quality	USP<697> and EP 2.9.17 Determination of Extractable Volume in Containers (GMP)		✓	3000005712	Varies ⁵	14
Quality	USP<785> Determination of Osmolality (GMP)		✓	3000007458	0.1 mL	8
Quality	USP <791> Determination of the pH and Appearance (GMP)		✓	3000004853	1 mL	8
Identity	High Throughput Sequencing Using Ion Torrent Genexus (GMP)	✓		3000004999	Reference sequence, >= 2e10 GC	18
Purity	Immunoenzymetric Assay for the Determination of HEK 293 Host Cell Proteins (GMP)	✓		3000004873	0.5 mL	21
Purity	Immunological Detection of Benzonase Endonuclease (GMP)	✓		3000004866	1 mL	8
Purity	Quantitation of Residual DNA Using PrepSEQ™ and TaqMan® Technology by qPCR (GMP)-7 Targets 18S (102bp 200bp 254bp 401bp-amplicons) +EIA+SV40+E1B	✓	✓	Varies	1e7 cells frozen	TBD

¹ Ingress Study may need to be conducted if the container has not been previously validated.

² Testing performed on bulk harvest materials.

³ RCL assays can be customized to leverage a generic Jurkat cell line that has been developed to accommodate other vector targets or create a testing method for a different cell line to align with product specific vectors.

⁴ Infectious titer assay method can be customized as needed for product specific attributes and endpoints.

⁵ 1 container if contents are 10 mL or more; 3 containers if volume is between 3 mL and <10 mL; 5 containers if volume is <3 mL.



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