LVV Lot Release Testing

Minaris Advanced Testing

Flyer

A Comprehensive Testing Panel for Confident Release

Lentiviral vectors (LVVs) have become a cornerstone of modern gene and cell therapies, enabling stable gene transfer for transformative treatments. As these advanced therapeutics move from development to commercialization, robust and reliable lot release testing is critical to ensure patient safety, product consistency, and regulatory compliance.This flyer includes many of the assays needed for lot release and characterization with specific drugs and production processes dictating which are chosen to support a final testing strategy.

Unique Challenges for LVV

Testing LVVs presents a unique set of scientific and operational challenges that are more pronounced than for AAV and many other viral vectors, largely due to LVV's retroviral biology and reliance on functional infectivity. Unlike AAV, LVVs integrate into the host genome and carry a theoretical risk of generating replication-competent lentivirus (RCL), requiring extended, highly scrutinized cell-based amplification assays.

Lot release decisions also depend heavily on infectious titer— a variable, cell-based assay that is sensitive to envelope incorporation, handling, and stability—rather than genome titer alone. In addition, the multi-plasmid production system introduces recombination and residual DNA complexities that demand careful monitoring. Together, these factors make LVV lot release more biologically driven, safety-focused, and operationally time-sensitive than many other viral vector platforms.

Why Minaris?

With decades of experience in viral safety, retrovirus detection, and cell-based assay systems, Minaris is uniquely positioned to manage the biological variability and extended timelines associated with LVV testing. Our expertise in designing, validating, and executing amplification-based RCL assays ensures rigorous safety evaluation aligned with global regulatory standards. At the same time, our proficiency in cell-based potency and infectivity assays supports consistent, reproducible results for one of the most critical release attributes.

Minaris Advanced Testing combines technical depth with operational discipline, offering coordinated testing programs that integrate safety, potency, identity, and impurity testing into a streamlined release strategy. Our established quality systems, experienced scientific teams, and robust assay platforms enable comprehensive, predictable, and reliable lot release testing services tailored specifically to the demands of lentiviral vector products. A structured testing panel — built around LVV-specific challenges — enables reliable lot disposition, regulatory confidence, and ultimately, safe delivery of life-changing therapies to patients.

Attribute	Full Assay Name	BH	DS	DP	Stability	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)	✓				3000005147	1x15 mL & 1e6 cells/mL	35
Safety	EP, JP, and USP Mycoplasma Detection with Mycoplasmastasis (GMP)	✓				3000007121	1x45 mL & 1e6 cells/mL	35
Safety	Mycoplasma DNA Detection by MycoSEQ Plus using TaqMan Technology - Cell + Suspension (GMP)	✓				3000004752	30 mL cell suspension	10
Safety	Microbiological Examination: Microbial Enumeration Test according to USP<61> (GMP)	✓				3000005066	2x specification	14
Safety	Microbiological Examination of Non-sterile products: Microbial Enumeration Test Suitability <61> (GMP)	✓				3000005068	8x routine	21
Safety	9 CFR Bovine Viruses Detection in Bovine Serum or Other Products - 21 day (GMP)	✓				3000007314	1x500 mL serum or 2x8 mL cell lysate	31
Safety	9 CFR Porcine Viruses Detection - 21 day (GMP)	✓				3000007387	1x500 mL serum or 2x8 mL cell lysate	31
Safety	In Vitro Assay for Adventitious Viral Contaminants: MRC-5, VERO, and HEK Cells (Extended Duration) with Hemadsorption and Hemagglutination Endpoints (GMP)	✓				3000005475	2x6 mL at 1e7 cells/mL	35
Safety	Mycobacterium Tuberculosis DNA Detection by qPCR (GMP)	✓				3000005638	1e7 cells frozen	9
Safety	RCL Assay: Co-cultivation of Test Article Cells with C8166 Cells (GMP)	✓				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)	✓				3000007492	5% or 300 mL of supernatant (whichever is less)	56
Strength	Lentiviral Infectious Titer Assay with a qPCR Endpoint (GMP)	✓	✓	✓	✓	3000005157	3x0.5 mL	35
Strength	Lentivirus Titer Determination by p24 ELISA (GMP)	✓	✓	✓		3000005164	1 mL	21
Strength	Lentivirus Titer Determination by p30 ELISA (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[2]	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

Attribute	Full Assay Name	BH	DS	DP	Stability	Test Code	Minimum Sample Requirements	TAT (days)
Quality	EU Appearance of Liquids (GMP)			✓	✓	3000005395	10 mL	14
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	Determination of Residual Bovine Serum Albumin (BSA) by ELISA using Bethyl ELISA Kit E11-113 (GMP)		✓			3000004586	0.3 mL	21
Purity	Quantitation of Residual DNA Using PrepSEQ™ and TaqMan® Technology by qPCR (GMP)-7 Targets 18S (102bp 200bp 254bp 401bp-amplicons)+E1A+SV40+E1B		✓			Varies	1e7 cells frozen	TBD

[1]Ingress Study may need to be conducted if the container has not been previously validated.
[2]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.

Minaris Advanced Testing

FL-T-261085-2

CONTACT US

Get in Touch With Our Team Today

minaris.com/contact