

gibco

ONE

lentiviral vector production system

Suspension lentiviral vector
production for cell and gene therapy

ThermoFisher
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ONE lentiviral vector production system from research to commercialization

Scaling to meet demand

Cost-effective lentiviral (LV) vector production is critical to meet commercial demand, and a smooth ramp-up to clinical production is essential. To address these needs, we have created a complete LV vector production system to help reduce costs and streamline your transition from research to clinical scale. The Gibco™ LV-MAX™ Lentiviral Production System is the first complete suspension production system. It can produce up to ten times more lentivirus, cutting costs by more than half compared to using polyethyleneimine (PEI)-based lentiviral production methods.

The first optimized GMP LV vector production system for suspension culture

The LV-MAX Lentiviral Production System:

- **Cost-effective**—Reduce cost by more than 50%*
- **High titers**—greater than 1×10^8 TU/mL (unconcentrated)
- **Research-grade and GMP options**—seamlessly transition from discovery to commercial production



GMP quality and regulatory support

Our products are backed by our global scale, regulatory and technical support teams, an unrelenting focus on quality, and decades of experience with Good Manufacturing Practices (GMP). The LV-MAX Lentiviral Production System is available in research grade and also as a Gibco™ Cell Therapy Systems™ (CTS™) product (Gibco™ CTS™ LV-MAX™ Lentiviral Production System), which is manufactured in conformity with GMP for medical devices (21 CFR Part 820) and follows USP <1043>** and European Pharmacopoeia (Ph. Eur.) 5.2.12 recommendations. All CTS products come with a Drug Master File or a Regulatory Support File.

Accelerate your path to the clinic

The LV-MAX Lentiviral Production System provides a smooth transition from discovery through clinical and commercial manufacturing, offering one optimized, scalable platform with research-grade and GMP reagent options.

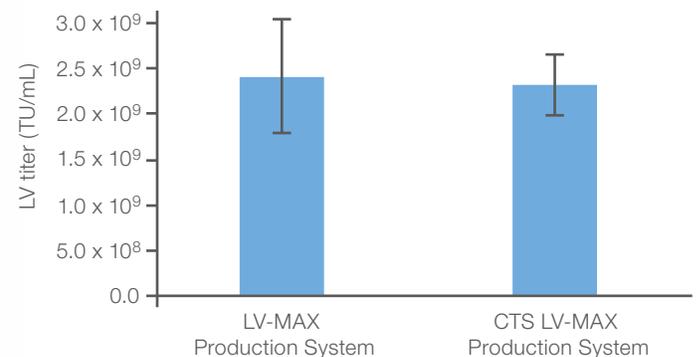


Figure 1. Comparison of LV titers between research-grade and CTS (clinical) reagents. LV vectors were produced in a 30 mL format in 125 mL shaker flask system. Performance of the LV-MAX Lentiviral Production System was shown to be equivalent to the CTS LV-MAX production system as measured by viral titers determined by transduction of HT1080 cells and flow cytometry analysis of GFP-positive cells.

ONE optimized and fully integrated system



A cost-effective LV vector production solution

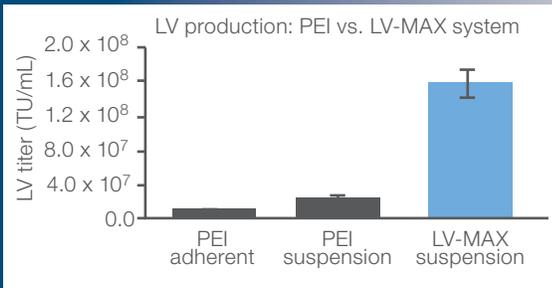
Challenges associated with existing LV vector production systems include high labor cost, extensive infrastructure for manufacturing, and using research-grade raw materials that don't meet regulatory requirements. The CTS LV-MAX system can help overcome these challenges by allowing viral vector manufacturers to produce high-titer GMP LV vectors using a scalable suspension platform.

Dedicated to your commercial success

Our commitment to maintaining a robust quality management system, material qualification, redundant manufacturing, and continuity of supply is upheld through our supply agreements, risk assessment, and mitigation strategies. Through these mechanisms, we enable our customers' success by helping to clear the path to commercialization.

Efficient and cost-effective LV vector production

The LV-MAX system produces **15x** more virus than the PEI-mediated system in adherent cells and **10x** more virus than in suspension cells ...



... resulting in **over 50% cost reduction** compared to PEI-based LV vector production methods.

Switch to the LV-MAX system and save†

- **58%** on adherent PEI
- **52%** on suspension PEI

† Cost comparison based on the list price in USD and LV yield of 1×10^8 TU/mL using the LV-MAX system and 1×10^7 TU/mL using PEI-based adherent and suspension methods. Cost consideration includes media, transfection reagents, and culture vessels.

Figure 2. Increased viral titer obtained using the LV-MAX system compared to other production methods. Unfiltered LV vectors produced using the LV-MAX Lentiviral Production System were compared to PEI-mediated LV vector production in adherent HEK293T/FT cells and suspension HEK293 cells. The LV titer was determined by transducing HT1080 cells and analyzing GFP-positive cells.

ONE complete optimized system

In an effort to accelerate your development timelines, our scientific team has tested hundreds of different reagent combinations to develop a complete optimized system that delivers maximum titers.

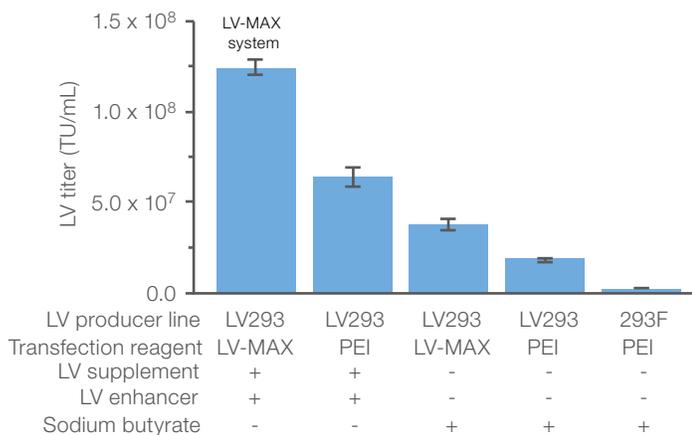


Figure 3. System components work synergistically for maximum performance. LV vector was produced in a 30 mL format using the LV-MAX Lentiviral Production System. These data highlight the high titers when using the complete system compared to reduction of titer when using an incomplete or non-optimized system. LV293 = Gibco™ Viral Production Cells (HEK293-derived suspension cells), 293F = Gibco™ FreeStyle™ 293-F cell line, PEI = polyethylenimine.

High titer at any scale

The innovative LV-MAX Lentiviral Production System is the first complete optimized suspension system that allows you to seamlessly and efficiently scale your LV vector production with high titers in a xeno-free system.

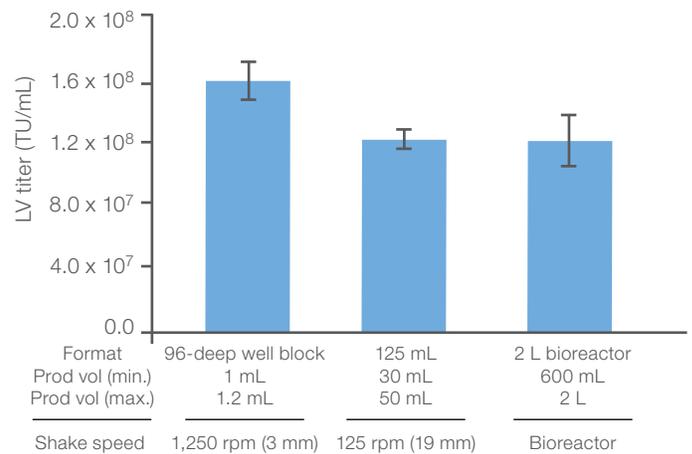


Figure 4. LV vector was produced in different culture formats using the LV-MAX Lentiviral Production System. The lentiviral titer was determined by transducing HT1080 cells and analyzing GFP-positive cells. Analysis of data showed no statistical significance between titers among the different production formats.

GMP viral production cells

Gibco™ CTS™ Viral Production Cells:

- GMP-banked HEK293 cell line
- Extensive documentation of cell line lineage
- Absence of SV40 large T antigen
- Supports >10 million cells/mL in chemically defined medium
- Flexible licensing structure tailored to your business needs

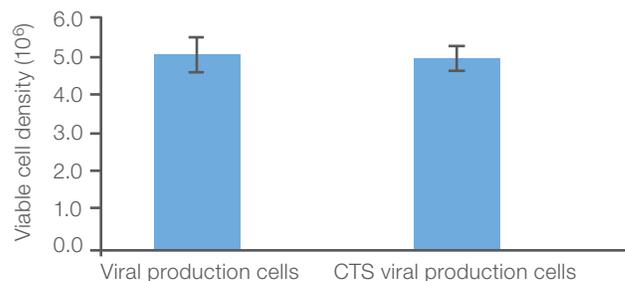


Figure 5. Comparable viable cell density for research-grade vs. GMP-banked viral production cell lines. Research-grade cells were thawed and passaged in Gibco™ LV-MAX™ Production Medium. GMP-banked cells were thawed and passaged in Gibco™ CTS™ LV-MAX™ Production Media. At passage 5, cells were seeded at a density of 0.55 x 10⁶ cells/mL and cultured for 72 hours. Viable cell density measurements using trypan blue exclusion analysis were performed. These data demonstrate equivalent growth kinetics between the two cell lines.

Ordering Information

Product	Quantity	Cat. No.
Research-grade kit		
LV-MAX Lentiviral Production System Starter Kit	For 0.3 L of LV vector production	A35684
Research-grade cells		
Gibco Viral Production Cells	1 mL (1 x 10 ⁷ cells/mL)	A35347
	6 x 1 mL (1 x 10 ⁷ cells/mL)	A35827
Research-grade medium		
LV-MAX Production Medium	1 L	A3583401
	6 x 1 L	A3583402
Research-grade transfection reagents		
LV-MAX Transfection Kit	For 1 L of LV vector production	A35348
Opti-MEM I Reduced Serum Medium	100 mL	31985062
	500 mL	31985070
	10 x 500 mL	31985088
Research-grade plasmid		
LV-MAX Lentiviral Packaging Mix	1.5 mL	A43237
CTS cells		
CTS Viral Production Cells	Contact outlicensing@thermofisher.com for details	
CTS medium		
CTS LV-MAX Production Medium	1,000 mL	A4124001
	6 x 1 L	A4124004
	10 L	A4124002
	20 L	A4124003
CTS transfection reagents		
CTS Opti-MEM I Reduced Serum Medium	100 mL	A4124801
	500 mL	A4124802
CTS LV-MAX Transfection Kit	1 L	A4132601
	10 L	A4132602

* Compared with PEI-based lentiviral production methods.

** CTS products are manufactured to meet the ancillary material supplier responsibilities for cell-, gene-, and tissue-engineered products. Other aspects of USP <1043> are the responsibility of the end user to assess.

Get more information on our lentiviral solutions at thermofisher.com/lvmax

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