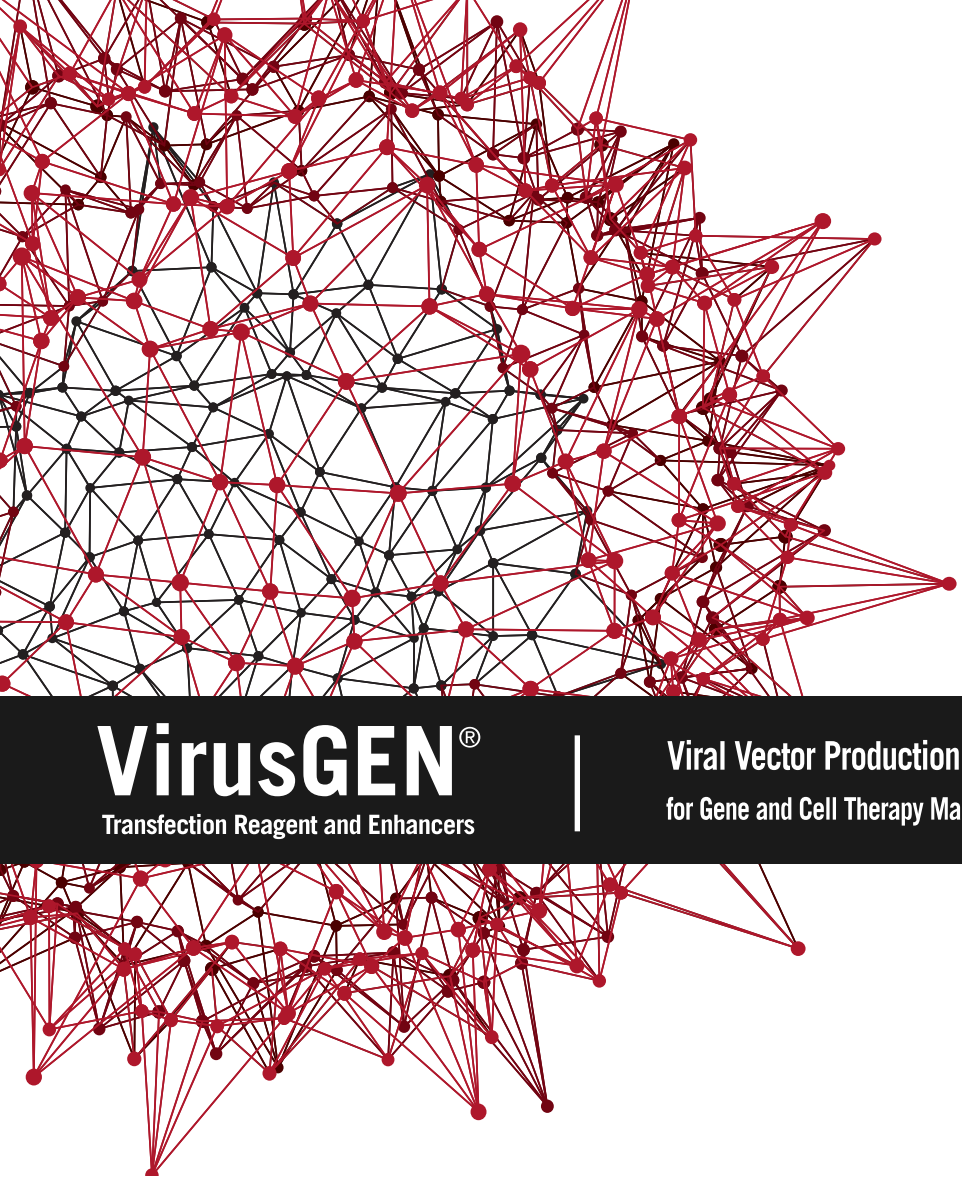


VirusGEN®

Transfection Reagent and Enhancers

Viral Vector Production Platform

for Gene and Cell Therapy Manufacturing

Research Grade | SELECT™ | GMP

Mirus®

OUR MISSION

Deliver Innovation.

Empower Discovery.

Improve Life.

Mirus

THE TRANSFECTION EXPERTS

In 1995, Mirus began its journey with the goal of providing the best tools for gene delivery. With over 25 years of experience and multiple breakthroughs in the field of transfection, Mirus is a global leader and trusted brand in nucleic acid delivery.

Driven by our passion for science, we take pride in the fact that our team of chemists and biologists push the boundaries of transfection technology to enable groundbreaking discoveries and the development of life-changing biotherapeutics throughout the world.

We care about **transfection** as much as you care about your research.

GMPTRANSFECTION.COM

Contents

VirusGEN® VIRAL VECTOR PRODUCTION PLATFORM

OVERVIEW

Background: Anatoly P, PhD, Chemist
Foreground: Nick R, PhD, Chemist
Keith P, PhD, Chemist

The Mirus Difference

VirusGEN® Biomimetic Transfection Technology

Many traditional non-viral methods for nucleic acid delivery were characterized by single-component, synthetic formulations, and the majority of first-generation transfection reagents relied on simple, linear polymers such as polyethyleneimine (PEI) or liposomes that transported DNA to cells via non-specific, electrostatic interactions.

In contrast, the technology underlying *Trans*IT-VirusGEN® and other Mirus reagents utilizes fully synthetic components to more closely mimic the natural mechanisms that viruses developed over billions of years to deliver nucleic acid cargo to cells and subsequently release them to their nuclear or cytoplasmic destinations. These biomimetic transfection formulations rely on lipid-polymer nanocomplexes (LNPCs) and other components that enable researchers to achieve higher titers than what can be accomplished with PEI-derived polymers or liposomes alone.

FROM R&D TO GMP

The Transfection Experts

With a history spanning more than 25 years of innovation in gene delivery technology, Mirus Bio is a long-standing leader in the field of transfection. Our VirusGEN® product line is a breakthrough in the generation of high-titer viral vectors for gene and cell therapy and enables biopharmaceutical manufacturers to produce viral vectors at scales that were not previously possible in order to bring more doses to patients in need.

VirusGEN® Transfection Reagents and Enhancers for Production of AAV and Lentivirus

*Trans*IT-VirusGEN® GMP Transfection Reagent is designed to enhance delivery of packaging and transfer vector DNA to suspension and adherent HEK 293 cell types in order to increase production of recombinant lentivirus and adeno-associated virus (AAV). Key benefits of *Trans*IT-VirusGEN® GMP Transfection Reagent include:

- ✓ **Performance**—Efficient DNA delivery for large-scale production of high-titer viral vectors
- ✓ **Quality**—Available from research-grade to GMP
- ✓ **Flexibility**—Compatible with different virus production platforms and repeat filtration
- ✓ **Animal Origin Free**—Fully synthetic transfection reagent formulation

With industry-leading performance in high-titer virus manufacturing, *Trans*IT-VirusGEN® GMP offers a simplified, cost-effective workflow, making it the superior choice for large-scale therapeutic virus production. Titers can be further increased with optimized enhancers included in the VirusGEN® GMP AAV Transfection Kit and VirusGEN® GMP LV Transfection Kit.

VirusGEN® GMP AAV Transfection Kit

VirusGEN® GMP LV Transfection Kit

*Trans*IT-VirusGEN® Transfection Reagents

***Trans*IT-VirusGEN®**

- Research-grade reagent
- For R&D and Discovery

***Trans*IT-VirusGEN® SELECT**

- Research-grade reagent
- Additional quality testing
- For preclinical applications

***Trans*IT-VirusGEN® GMP**

- GMP-grade reagent
- For clinical trials and commercial manufacturing

VirusGEN® Complex Formation Solution and Enhancers

***Trans*IT-VirusGEN® AAV Complex Formation Solution & Enhancer**

- Available as a research-grade or GMP solution
- Optimized for complex formation with *Trans*IT-VirusGEN® transfection reagents
- Enhances AAV titers when used with *Trans*IT-VirusGEN® transfection reagents

***Trans*IT-VirusGEN® LV Enhancer**

- Available as a research-grade or GMP solution
- Enhances lentiviral titers when used with *Trans*IT-VirusGEN® transfection reagents

***Trans*IT-VirusGEN® LV Complex Formation Solution**

- Available as a research-grade or GMP solution
- Optimized for complex formation with *Trans*IT-VirusGEN® transfection reagents

From Research to Commercialization

*Trans*IT-VirusGEN® Transfection Reagent provides industry-leading virus titers for AAV and lentivirus production and is available as research-grade, SELECT and GMP formats to support seamless transitions from discovery through clinical trials and commercialization.

VirusGEN® AAV and LV complex formation solutions and enhancers are available as research-grade or GMP-grade products.

VirusGEN® VIRAL VECTOR PRODUCTION PLATFORM

PERFORMANCE

Background: Tony L, Biologist
Foreground: Myla G, Production Scientist

VirusGEN® GMP for AAV Production

Adeno-associated virus (AAV) vectors are the most rapidly growing gene therapy delivery platform for the treatment of a vast array of human diseases. The unique properties of AAV (non-pathogenic, non-integrating genome, low immunogenicity and broad tropism) combined with recent advances in capsid optimization have catalyzed rapid growth in the gene therapy field.

The VirusGEN® GMP AAV Transfection Kit was specifically developed for high-titer, industrial scale AAV manufacturing in suspension HEK 293 cells and includes *Trans*IT-VirusGEN® GMP Transfection Reagent (150 ml) and VirusGEN® GMP AAV Complex Formation Solution and Enhancer (5 × 1 L).

VirusGEN® GMP AAV Transfection Kit

Kit includes: *Trans*IT-VirusGEN® GMP Transfection Reagent (150 ml), VirusGEN® GMP AAV Complex Formation Solution and Enhancer (5 × 1 L)

AAV Performance

*Trans*IT-VirusGEN® Transfection Reagent outperforms commonly used competitor reagents when measured by functional AAV titers or AAV genome copies in suspension 293 cells (**FIGURE 1**). This is also reflected in the higher GC/capsid ratio obtained with *Trans*IT-VirusGEN®. The amount of AAV obtained is further increased in suspension HEK 293 cells with the use of VirusGEN® AAV Complex Formation Solution and Enhancer, included in the VirusGEN® AAV Transfection Kit.

The VirusGEN® AAV Transfection Kit demonstrates superior performance across multiple suspension HEK 293 cell lines and media formulations (**FIGURE 2**), and AAV titers obtained with *Trans*IT-VirusGEN® Transfection Reagent are significantly higher than what can be obtained with competitor reagents in adherent HEK 293 cells (**FIGURE 3**). Note that VirusGEN® AAV Complex Formation Solution and Enhancer is only recommended for suspension HEK 293 cells.

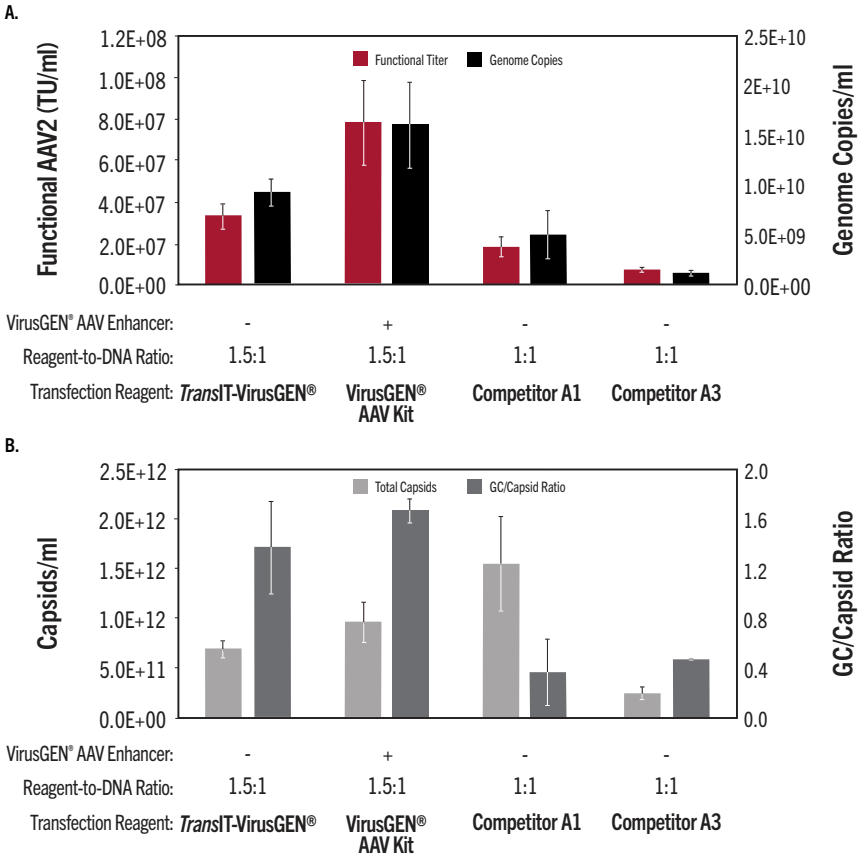


FIGURE 1. *Trans*IT-VirusGEN® and the VirusGEN® AAV Transfection Kit Produce High AAV Titers. (A) Expi293F™ cells (Thermo Fisher Scientific) grown in Expi293™ Expression Medium (Thermo Fisher Scientific) were used to generate recombinant AAV2 via transient transfection using *Trans*IT-VirusGEN® Transfection Reagent (1.5:1 reagent-to-DNA ratio (vol:wt), Mirus Bio LLC), VirusGEN® AAV Transfection Kit (Mirus Bio LLC), Competitor A1 (1:1) or Competitor A3 (1:1) using the manufacturer's recommended protocol. AAV2 was produced by transfecting pAAV-hrGFP, pAAV-RC and pAAV-Helper plasmids (1:1:1 DNA ratio, 2 µg/ml-2 mg per flask, Agilent Technologies). Cells were transfected at a cell density of 2 x 10^6 cells/ml, 1 L in a 2.8 L Thomson shake flask. AAV2 was harvested at 72 hours post-transfection using chemical lysis. (A) Functional titers were determined via transduction of HT-1080 cells and GFP expression was measured 48 hours post-transduction using Guava® easyCyte™ 5HT Flow Cytometer. AAV functional titers were measured from virus dilutions with less than 20% GFP positive cells. Genome copies were determined by ddPCR using primers and a probe targeting the CMV promoter. (B) Total assembled capsids were determined using the AAV2 Titration ELISA Kit (Progen) and the GC/capsid ratio was determined by dividing the number of genome copies by total assembled capsids for each condition. The error bars represent the range of duplicate flasks.

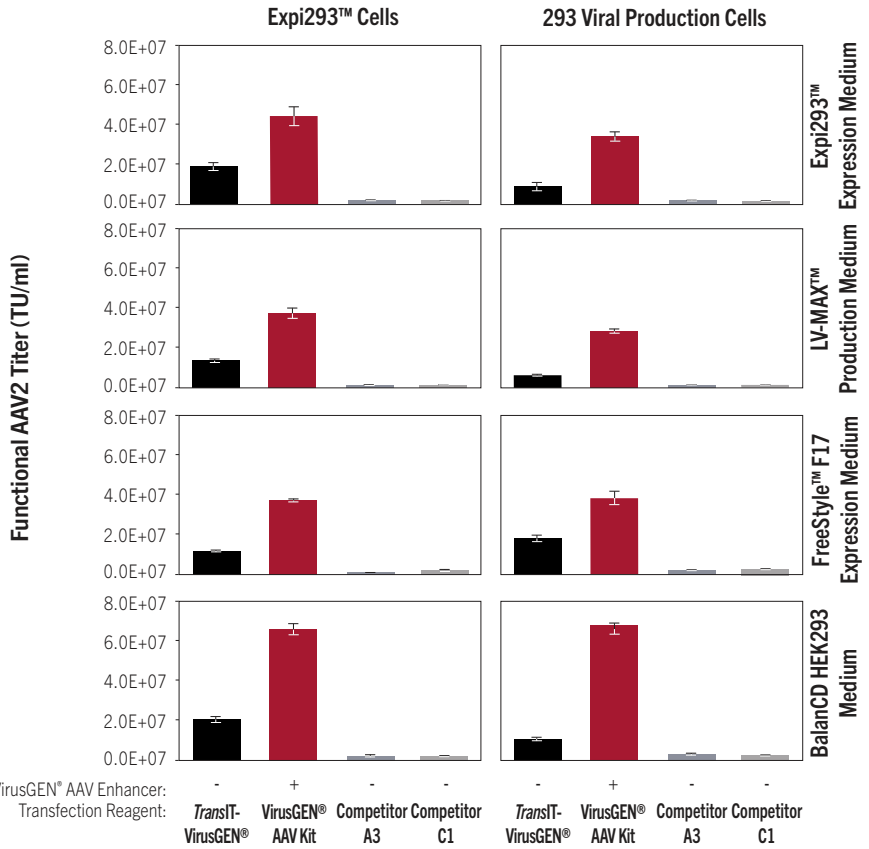


FIGURE 2. *Trans*IT-VirusGEN® and the VirusGEN® AAV Transfection Kit are Compatible with Different Cell Types and Media Formulations. (A) Expi293F™ cells (Thermo Fisher Scientific) or (B) Viral Production cells (Thermo Fisher Scientific) were grown or adapted to Expi293™ Expression Medium (Thermo Fisher Scientific), LV-MAX™ Production (Thermo Fisher Scientific), FreeStyle™ F17 (Thermo Fisher Scientific) or BalanCD HEK293 (Irvine Scientific) media prior to transfection. AAV production using *Trans*IT-VirusGEN® Transfection reagent (2:1 reagent-to-DNA ratio (vol:wt), Mirus Bio LLC), VirusGEN® AAV Transfection Kit (Mirus Bio LLC) was compared to Competitor A3 (1:1 reagent-to-DNA ratio (vol:wt)) and Competitor C1 (2:1 reagent-to-DNA ratio (vol:wt)) using the manufacturer's recommended protocol. AAV2 was produced by transfecting pAAV-hrGFP, pAAV-RC and pAAV-Helper plasmids (1:1:1 DNA ratio, 1.5 µg/ml = 3 µg/well, Agilent Technologies). Cells were transfected at a cell density of 2 million cells/ml. Harvested virus was used to transduce HT-1080 cells and GFP expression was measured 48 hours post-transduction using Guava® easyCyte™ 5HT Flow Cytometer. AAV functional titers were measured from virus dilutions with less than 20% GFP positive cells. The error bars represent the range of duplicate wells.

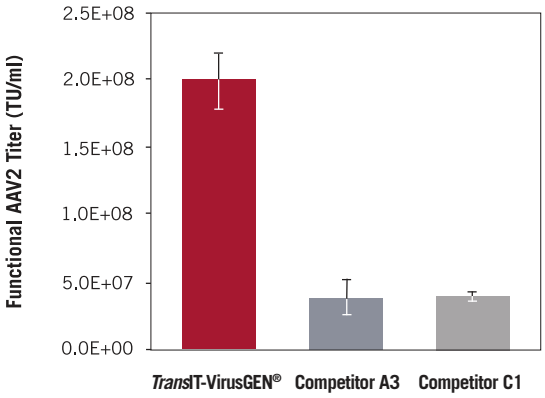


FIGURE 3. *Trans*IT-VirusGEN® Outperforms PEI-based Reagents for AAV Production in Adherent 293 Cells. AAV2 was produced using adherent 293-AAV cells (Agilent Technologies) grown in DMEM + 10% FBS and transfected using pAAV-hrGFP, pAAV-RC and pAAV-Helper plasmids (1:1:1 DNA ratio, 1.5 µg/ml plasmid DNA, 3 µg/well, Agilent Technologies) using *Trans*IT-VirusGEN® Transfection Reagent (2:1, vol:wt, Mirus Bio LLC), Competitor A3 (2:1) or Competitor C1 (2:1) or in 6-well plates. Harvested virus was used to transduce HT-1080 cells and GFP expression was measured 48 hours post-transduction using a Guava® easyCyte™ 5HT Flow Cytometer. Functional AAV titers were measured from virus dilutions with less than 20% GFP positive cells. The error bars represent the standard deviation of triplicate wells.

VirusGEN® GMP for Lentivirus Production

Lentiviral (LV) vectors provide a highly efficient means for modifying mammalian cells and have been extensively utilized for clinical gene and cell therapy applications. In particular, the success of chimeric antigen receptor (CAR) T-cell therapy has been made possible through lentiviral gene transfer.

The VirusGEN® GMP LV Transfection Kit was specifically developed for high-titer, industrial-scale LV manufacturing in suspension or adherent HEK 293 cells and includes *Trans*IT-VirusGEN® GMP Transfection Reagent (150 ml), VirusGEN® GMP LV Complex Formation Solution (5 x 1 L) and VirusGEN® GMP LV Enhancer (5 × 1 L).

The VirusGEN® GMP LV Transfection Kit

Kit includes: *Trans*IT-VirusGEN® SELECT Transfection Reagent (150 ml), VirusGEN® GMP LV Complex Formation Solution (5 × 1 L), VirusGEN® GMP LV Enhancer (5 × 1 L)

LV Performance

*Trans*IT-VirusGEN® Transfection Reagent outperforms commonly used competitor reagents when measured by functional LV titers obtained from suspension HEK 293 cells (**FIGURE 4**). Lentivirus titers are further increased with the use of VirusGEN® LV Complex Formation Solution and VirusGEN® LV Enhancer, included in the VirusGEN® LV Transfection Kit (red bar).

The VirusGEN® LV Transfection Kit demonstrates high and consistent performance across multiple suspension HEK 293 cell lines and media formulations (**FIGURE 5**) and is compatible with a variety of commercially available packaging and transfer plasmid systems (**FIGURE 6**). The VirusGEN® LV Transfection Kit also achieves high functional LV titers in adherent HEK 293 cells, and the amount of total DNA can be titrated for optimal results, depending on experimental conditions (**FIGURE 7**).

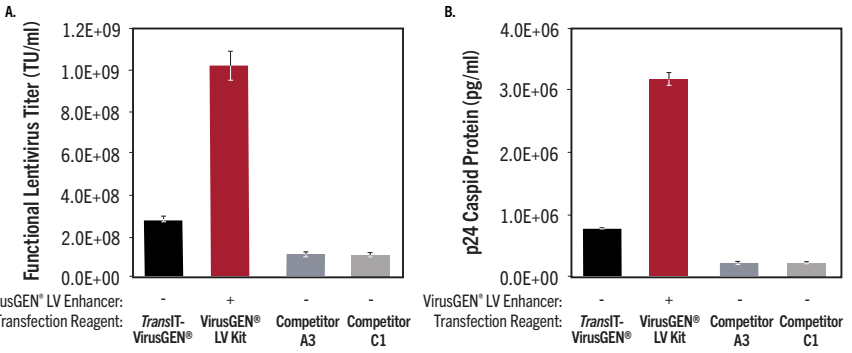


FIGURE 4. *Trans*IT-VirusGEN® Transfection Reagent and VirusGEN® LV Enhancer Outperform PEI-based Transfection Reagents. Viral Production cells (Thermo Fisher Scientific) were grown in LV-MAX™ Production Medium (Thermo Fisher Scientific) and seeded at 4×10^6 cells/ml prior to transfection (25 ml/125 ml shake flask). Lentivirus was produced using the *Trans*IT-VirusGEN® Transfection Reagent +/- VirusGEN® LV Enhancer (Mirus Bio, 3:1 reagent-to-DNA ratio (wt:vol)), Competitor A3 (2:1 reagent-to-DNA ratio (wt:vol)) or Competitor C1 (4:1 reagent-to-DNA ratio (wt:vol)) using the manufacturer's recommended protocol. Lentivirus was produced by transfecting 3rd generation vectors pALD-LentiEGFP-A transfer vector and pALD-VSV-G-A, pALD-Rev-A, pALD-GagPol-A packaging vectors at a 3:0.5:0.5:2 DNA ratio (Aldevron, 25 µg/flask (1 µg/ml final concentration)). The VirusGEN® LV Enhancer was added 21 hours post-transfection. (A) Functional titers from virus containing supernatant was measured following transduction of 293T/17 cells and GFP expression was measured at 72 hours post-transduction using Guava® easyCyte™ 5HT Flow Cytometer. Lentivirus functional titers were measured from virus dilutions with less than 20% GFP positive cells. (B) p24 cCapsid protein was measured from virus containing supernatants using a HIV-1 p24 Antigen ELISA kit according to the manufacturer's protocol (Zeptometrix). The error bars represent the standard deviation of triplicate wells.

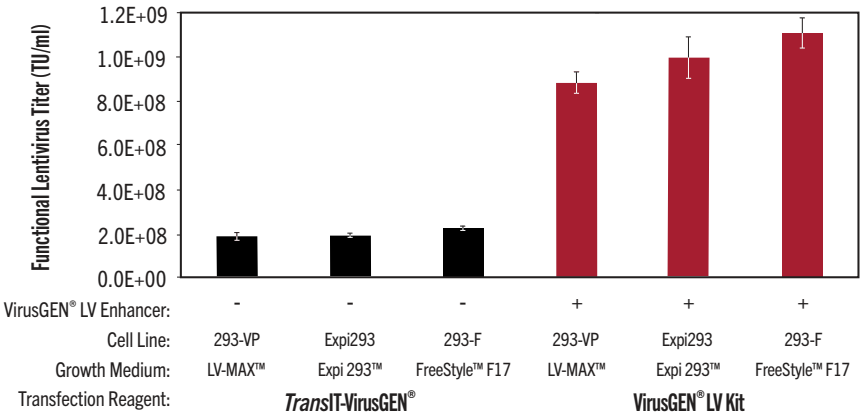


FIGURE 5. *Trans*IT-VirusGEN® Transfection Reagent and VirusGEN® LV Enhancer Allow for Cell Line and Media Formulation Flexibility. Viral Production cells (293-VP) grown in LV-MAX™ Production Medium (Thermo Fisher Scientific), Expi293™ cells grown in Expi293™ Expression Medium (Thermo Fisher Scientific) or FreeStyle™ 293-F cells grown in FreeStyle™ F17 (Thermo Fisher Scientific) were seeded at 4×10^6 cells/ml prior to transfection (2 ml/non-treated 6-well plate). Lentivirus was produced using the *Trans*IT-VirusGEN® Transfection Reagent ± VirusGEN® LV Enhancer (Mirus Bio, 3:1 reagent-to-DNA ratio (wt:vol)) according to the recommended protocol. Lentivirus was produced by transfecting 3rd generation vectors pALD-LentiEGFP-A transfer vector and pALD-VSV-G-A, pALD-Rev-A, pALD-GagPol-A packaging vectors at a 3:0.5:0.5:2 DNA ratio (Aldevron, 25 µg/flask (1 µg/ml final concentration)). The VirusGEN® LV Enhancer was added 18 hours post-transfection. Functional titers from virus containing supernatant was measured following transduction of 293T/17 cells and GFP expression was measured at 72 hours post-transduction using Guava® easyCyte™ 5HT Flow Cytometer. Lentivirus functional titers were measured from virus dilutions with less than 20% GFP positive cells. The error bars represent the standard deviation of triplicate wells.

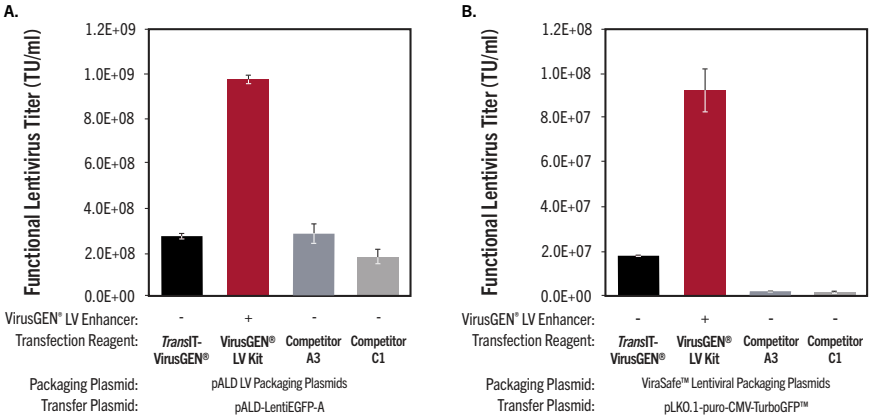


FIGURE 6. Lentivirus Commercially Available Vector Competitor Comparison. Lentivirus production using *Trans*IT-VirusGEN® Transfection Reagent ± the VirusGEN® LV Enhancer was compared to Competitor A3 (2:1 reagent-to-DNA ratio) and Competitor C1 (4:1 reagent-to-DNA ratio) using the manufacturer's recommended protocol. Lentivirus was produced by transfecting Expi293™ cells grown in Expi293™ Expression Medium (Thermo Fisher Scientific) at 4×10^6 cells/ml with two different LV vector mixtures (1 µg/ml, 2 µg/well) including: (A) 3rd generation vectors pALD-LentiEGFP-A transfer vector and pALD-VSV-G-A, pALD-Rev-A, pALD-GagPol-A packaging vectors (3:0.5:0.5:2 DNA ratio, Aldevron) or (B) 3rd generation vectors pLKO.1-puro-CMV-TurboGFP™ transfer vector (Sigma) and ViraSafe™ Pantropic Packaging mix (pRSV-Rev, pCMV-VSV-G, pCgpV, CellBio Labs) at a 3:0.5:0.5:2 DNA ratio. The VirusGEN® LV Enhancer was added at 18 hours post-transfection. Virus containing supernatant was used to transduce 293T/17 cells and GFP expression was measured at 72 hours post-transduction using Guava® easyCyte™ 5HT Flow Cytometer. Lentivirus functional titers were measured from virus dilutions with less than 20% GFP positive cells. The error bars represent the range of duplicate wells.

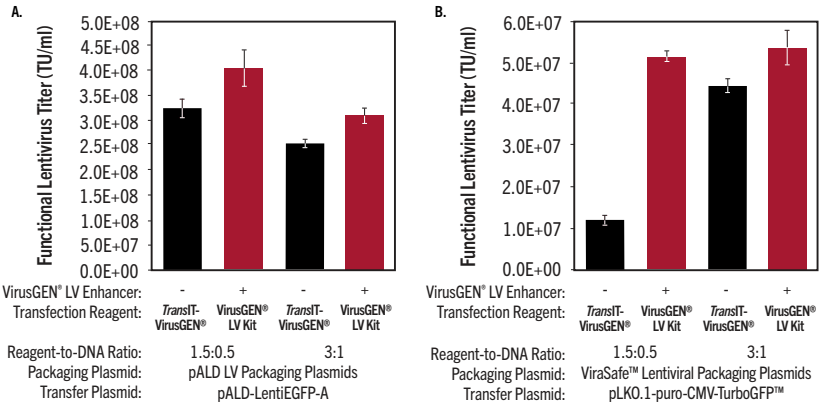


FIGURE 7. Adherent Lentivirus Production With Commercially Available Vector at Different Reagent-to-DNA Ratios. Lentivirus production using *Trans*IT-VirusGEN® Transfection Reagent ± the VirusGEN® LV Enhancer using the recommended protocol. Lentivirus was produced by transfecting adherent 293T/17 cells grown in serum containing medium with two different LV vector mixtures (1 µg/ml, 0.5 µg/well of 24-well plate) including: (A) 3rd generation vectors pALD-LentiEGFP-A transfer vector and pALD-VSV-G-A, pALD-Rev-A, pALD-GagPol-A packaging vectors (3:0.5:0.5:2 DNA ratio, Aldevron) or (B) 3rd generation vectors pLKO.1-puro-CMV-TurboGFP™ transfer vector (Sigma) and ViraSafe™ Pantropic Packaging mix (pRSV-Rev, pCMV-VSV-G, pCgpV, CellBio Labs) at a 3:0.5:0.5:2 DNA ratio. The VirusGEN® LV Enhancer was added at 20 hours post-transfection. Virus containing supernatant was used to transduce 293T/17 cells and GFP expression was measured at 72 hours post post-transduction using Guava® easyCyte™ 5HT Flow Cytometer. Lentivirus functional titers were measured from virus dilutions with less than 20% GFP positive cells. The error bars represent the standard deviation of triplicate wells.

VirusGEN® VIRAL VECTOR PRODUCTION PLATFORM

QUALITY

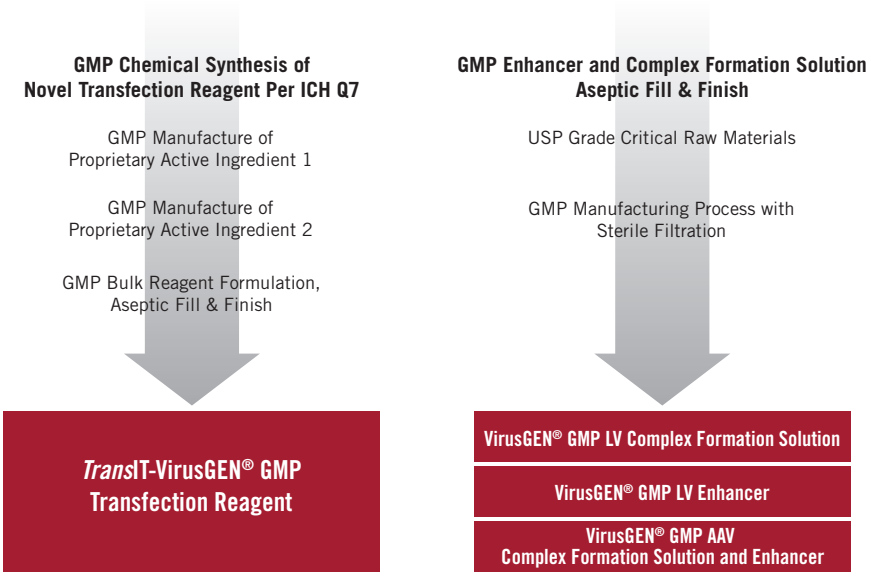
Susan E, Quality Supervisor

Peace of Mind: Mirus GMP Transfection

With the increasing regulatory obligations facing AAV and LV manufacturers, there is a need to utilize more stringent quality processes at earlier stages in the development of gene and cell therapies.

Our commitment to quality is integral to our brand and your success. With our VirusGEN® GMP family of products for recombinant AAV and lentivirus production, Mirus is dedicated to ensuring that customers can rely on Mirus for transfection reagents of exceptional quality from early stages of research and development through clinical trials and commercial manufacturing.

*Trans*IT-VirusGEN® GMP: Highest Quality Grade *Trans*IT-VirusGEN® Available



VirusGEN® GMP products are manufactured in compliance with 21 CFR 820 and are held to the highest standards of traceability. All products are produced according to a GMP manufacturing process and tested in accordance with documented procedures.

QUALITY

Available Analytical Assays

_Trans_IT-VirusGEN® Transfection Reagents

- ✓ Residual Reagent Assay
- ✓ Identity Assay

VirusGEN® AAV Complex Formation Solution and Enhancer

- ✓ Residual Reagent Assay
- ✓ Identity Assay

VirusGEN® LV Enhancer

- ✓ Identity Assay

Quality Control Documentation

Below is an example of the Certificate of Analysis for *Trans*IT-VirusGEN® GMP Transfection Reagent that includes testing for: appearance, endotoxin, identity, mycoplasma and sterility.

CERTIFICATE OF ANALYSIS

Product Name: *Trans*IT-VirusGEN® GMP Transfection Reagent, 150 mL
Product Number: MIR 6845-GMP
Lot Number: XXXX
Date of Manufacture: DD/MMM/YYYY
Retest Date: DD/MMM/YYYY
Storage Condition: -10 to -30 °C
Certificate Issue Date: DD/MMM/YYYY

Quality Control Testing and Results:

Test Method	Specification	Result	Pass/Fail
Appearance	Clear, Colorless Solution, Free of Particulates		
Endotoxin; USP <85>	≤ 1 EU/mL		
Identity (NMR) – Proprietary Active Ingredient 1	Conforms		
Identity (NMR) – Proprietary Active Ingredient 2	Conforms		
Identity – Water by GC	Detected		
Identity – Ethanol by GC	Detected		
Mycoplasma; USP <63>	None Detected		
Sterility; USP <71>	No Growth Observed		

The product was GMP manufactured in compliance with 21 CFR 820. This certificate confirms that the product meets the specifications above. The product was tested in accordance with documented procedures and approved as a result of meeting the required specification.

Amanda Rice, Quality Manager

Mirus Bio LLC | 5602 Research Park Blvd, Ste 210 | Madison, WI 53719 USA | 608.441.2852 | FAX 608.441.2849 | www.mirusbio.com

CoO and Animal Origin Free Documentation

Below is an example of the Certificate of Origin and BSE/TSE Statement for *Trans*IT-VirusGEN® GMP Transfection Reagent documenting that it is chemically synthesized and is not manufactured with any animal-derived components.

CERTIFICATE OF ORIGIN & BSE/TSE STATEMENT

Product Name:	*Trans*IT-VirusGEN® GMP Transfection Reagent, 150 mL
Product Number:	MIR 6845-GMP
Lot Number:	XXXX
Animal Derived Components:	None
Type of Manufacture:	Chemical Synthesis
Country of Manufacture:	USA
Certificate Issue Date:	DD/MMM/YYYY

Quality Control Testing and Results:

This product is manufactured via chemical synthesis in the USA entirely from material of non-animal origin. The manufacture, packaging, storage, and transportation of these materials do not involve the use of material of animal origin. This information is to be used for the purpose of determining animal origin only and not to be confused with "country of origin" for import/export purposes.

This product has minimal risk of contamination with Bovine Spongiform Encephalopathy (BSE) or Transmissible Bovine Encephalopathy (TSE). Mirus Bio LLC does not have plans to change the production of this material in any way that would increase the risk of BSE/TSE contamination.

Amanda Rice, Quality Manager

Mirus Bio LLC | 5602 Research Park Blvd, Ste 210 | Madison, WI 53719 USA | 608.441.2852 | FAX 608.441.2849 | www.mirusbio.com

Compare *Trans*IT-VirusGEN® Reagents

Therapeutic Development Pipeline	Research & Development	Preclinical & Early Phase Clinical Trial	Late Phase Clinical Trial & Commercial Manufacturing
***Trans*IT-VirusGEN® Reagents**	 *Trans*IT-VirusGEN®	 *Trans*IT-VirusGEN® SELECT	 *Trans*IT-VirusGEN® GMP
Composition	**Identical *Trans*IT-VirusGEN® Reagent Formulation** (ready to use, chemically defined, animal origin free in 77.5% ethanol)		
AAV and LV Enhancer Kits Available	Available	Coming Soon	Available
Quality	R&D	Preclinical	GMP
Quality Control	Functional AAV titer assay	• Functional AAV titer assay • Formulation identity • Appearance • Sterility: per USP <71> • Bacterial endotoxin: per USP <85> • Mycoplasma: per USP <63>	• Validated formulation identity assay • Appearance • Sterility: per USP <71> • Bacterial endotoxin: per USP <85> • Mycoplasma: per USP <63>
Configuration	0.3 ml; 0.75 ml; 1.5 ml; 5 and 10 pack, 1.5 ml vials	• 30 ml bottle • 150 ml bottle	150 ml bottle
Manufacturing	Research grade manufacturing with aseptic filtration	Research grade manufacturing with aseptic filtration	GMP validated manufacturing process with sterile filtration
Raw Materials	Research grade		GMP grade critical raw materials
Available Documentation	• Certificate of Analysis • Certificate of Origin	• Certificate of Analysis • Certificate of Origin Includes: TSE/BSE Statement	• Certificate of Analysis • Certificate of Origin Includes: TSE/BSE Statement • DMF Available in 2022 with Quality Agreement
Available Analytical Assays	—		• Validated identity assay • Residual reagent assay

Compare VirusGEN® R&D Complex Formation Solution and Enhancers

Therapeutic Development Pipeline	Research & Development	Preclinical through Clinical Trials and Commercialization
VirusGEN® Enhancers	 **VirusGEN® Research Grade Complex Formation Solution and Enhancers** • VirusGEN® AAV Complex Formation Solution and Enhancer • VirusGEN® LV Complex Formation Solution • VirusGEN® LV Enhancer	 **VirusGEN® GMP Complex Formation Solution and Enhancers** • VirusGEN® GMP AAV Complex Formation Solution and Enhancer • VirusGEN® GMP LV Complex Formation Solution • VirusGEN® GMP LV Enhancer
Composition	Proprietary aqueous solutions	
Quality Control	• Identity • Appearance • Sterility: per USP <71> • Bacterial endotoxin: per USP <85> • Osmolality • pH	• Identity • Appearance • Sterility: per USP <71> • Bacterial endotoxin: per USP <85> • Osmolality • pH • Mycoplasma: per USP <63>
Configuration	100 ml	1 L
Manufacturing	Research grade with sterile filtration	GMP manufacturing process with sterile filtration
Raw Materials	USP-Grade Critical Raw Materials	
Available Documentation	Certificate of Analysis with Material Origin and TSE/BSE Statement	• Certificate of Analysis • Certificate of Origin Includes: TSE/BSE Statement • DMF Available in 2022 with Quality Agreement
Available Analytical Assays	—	• Residual Reagent Assay Available for VirusGEN® AAV Enhancer • Identity Assay

VirusGEN® VIRAL VECTOR PRODUCTION PLATFORM

WORKFLOW SAVINGS

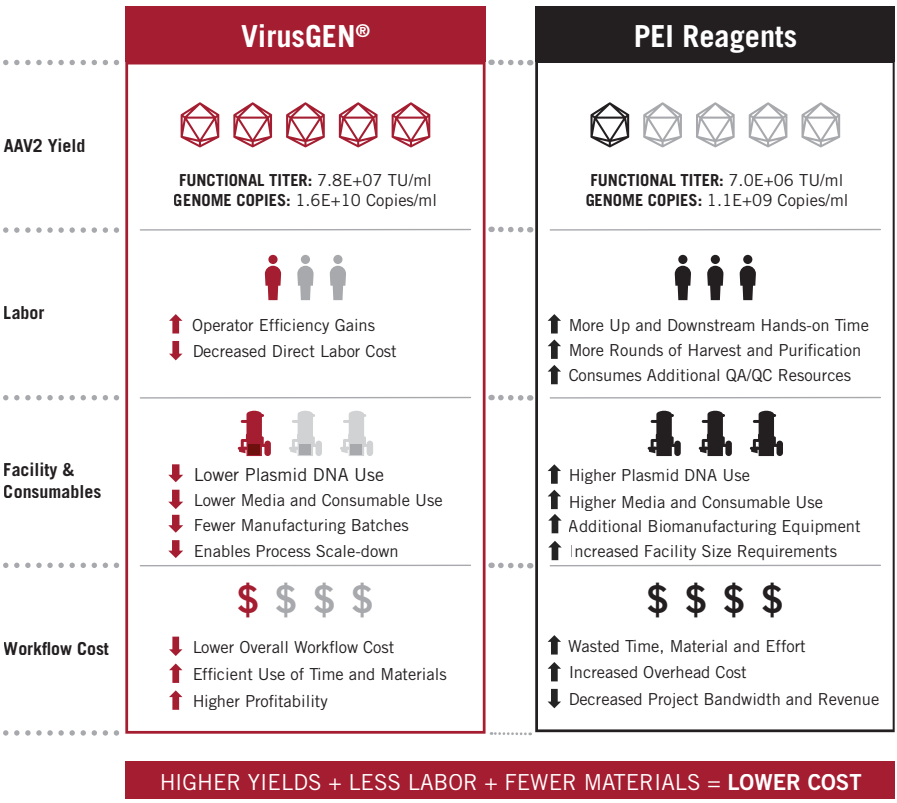
Background: Austin S, Associate Scientist III
Foreground: Laura J, PhD, Vice President, Scientific Operations

Produce More Doses Per Batch

Gene and cell therapy manufacturers are facing increasing demands in two critical areas:

1. Identifying a cost-effective means to produce lentivirus and AAV vectors in sufficient quantities to address the rapidly expanding gene and cell therapy market.

2. Minimizing safety and regulatory risks by using GMP raw materials in upstream manufacturing processes.



*Trans*IT-VirusGEN® GMP offers a solution to both of these challenges by providing industry-leading virus titers and compliance with GMP viral vector manufacturing. Higher titers directly translate into cost-savings opportunities by either scaling down biomanufacturing or producing more therapeutic doses per batch.

FROM R&D TO GMP Product Information

Research-Grade Reagents & Kits

	Product	Product No.	Description
	***Trans*IT-VirusGEN® Transfection Reagent**	MIR 6703	0.3 ml
		MIR 6704	0.75 ml
		MIR 6700	1.5 ml
		MIR 6705	5 x 1.5 ml
		MIR 6706	10 x 1.5 ml
	**VirusGEN® AAV Transfection Kit**	MIR 6750	**Kit includes:** *Trans*IT-VirusGEN® Transfection Reagent (2 × 1.5 ml), VirusGEN® AAV Complex Formation Solution and Enhancer (100 ml)
	**VirusGEN® LV Transfection Kit**	MIR 6760	**Kit includes:** *Trans*IT-VirusGEN® Transfection Reagent (2 × 1.5 ml), VirusGEN® LV Complex Formation Solution (100 ml), VirusGEN LV Enhancer (100 ml)

SELECT-Grade Reagents & Kits

	Product	Product No.	Description
	***Trans*IT-VirusGEN® SELECT Transfection Reagent**	MIR 6730	30 ml
		MIR 6735	150 ml
	***Trans*IT-VirusGEN® SELECT AAV Transfection Kit**	MIR 6770	**Kit includes:** *Trans*IT-VirusGEN® SELECT Transfection Reagent (30 ml), VirusGEN® SELECT AAV Complex Formation Solution and Enhancer (1 L)
		MIR 6775	**Kit includes:** *Trans*IT-VirusGEN® SELECT Transfection Reagent (150 ml), VirusGEN® SELECT AAV Complex Formation Solution and Enhancer (1 L)
	***Trans*IT-VirusGEN® SELECT LV Transfection Kit**	MIR 6780	**Kit includes:** *Trans*IT-VirusGEN® SELECT Transfection Reagent (30 ml), VirusGEN® SELECT LV Complex Formation Solution (1 L), VirusGEN® SELECT LV Enhancer (1 L)
		MIR 6785	**Kit includes:** *Trans*IT-VirusGEN® SELECT Transfection Reagent (150 ml), VirusGEN® SELECT LV Complex Formation Solution (1 L), VirusGEN® SELECT LV Enhancer (1 L)

GMP-Grade Reagents & Kits

	Product	Product No.	Description
	***Trans*IT-VirusGEN® GMP Transfection Reagent**	MIR 6845-GMP	150 ml
	**VirusGEN® GMP AAV Transfection Kit**	MIR 6815-GMP	**Kit includes:** *Trans*IT-VirusGEN® GMP Transfection Reagent (150 ml), VirusGEN® GMP AAV Complex Formation Solution, VirusGEN® GMP AAV Enhancer (5 × 1 L)
	**VirusGEN® GMP LV Transfection Kit**	MIR 6825-GMP	**Kit includes:** *Trans*IT-VirusGEN® GMP Transfection Reagent (150 ml), VirusGEN® GMP LV Complex Formation Solution (5 × 1 L), VirusGEN® GMP LV Enhancer (5 × 1 L)

SAVINGS

Will H, Production Scientist

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Mirus Bio LLC
5602 Research Park Blvd, Ste 210
Madison, WI 53719 USA
Attention: Accounts Payable
Fax: 608.441.2849

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