

Helper and Packaging Plasmids for Viral Vectors Product Guide

**Innovative Science.
Consistent Biologics.
Experienced Partner.**

**Aldevron makes high quality
plasmid DNA to support your work:**

Adeno-Associated Virus (AAV)

Lentivirus



Aldevron makes the highest quality biologics

Aldevron specializes in inventory plasmid DNA products for viral vector applications, as well as custom plasmid development and manufacturing services supporting research, clinical and commercial use. Our inventory of clinical-grade plasmids provides a fast, cost-effective sourcing option for your cell or gene therapy projects.



Research Grade, GMP-Source® and cGMP products

Aldevron's GMP-Source® (GMP-S) plasmids retain the key hallmarks of cGMP manufacturing while reducing costs and shortening development timelines. You can then transition seamlessly to a full cGMP process as you progress toward commercialization. As your manufacturing partner, Aldevron can help you save money and time without putting your programs at risk.

pALD-X80 (AAV Helper)

Available Pack Sizes	Research Grade		GMP-Source®	cGMP
pALD-X80	5 mg	10 mg	10 mg	10 mg

pALD-Lenti

Available Pack Sizes	Research Grade		GMP-Source™	cGMP
pALD-Lenti	5 mg	10 mg	10 mg	Custom Request
pALD-VSV-G	5 mg	10 mg	10 mg	Custom Request
pALD-GagPol	5 mg	10 mg	10 mg	Custom Request
pALD-Rev	5 mg	10 mg	10 mg	Custom Request

Aldevron Inventory Plasmids for Viral Vector Manufacturing

Success in gene and cell therapy has increased demand for plasmid DNA used to produce viral vectors, both in quantities for commercial products as well as the breadth of different vectors for the expanding number of programs in development. Our data and analysis indicate that standardization and large-scale production of helper and packaging plasmids, those that are the same regardless of the specific viral vector produced, represents an opportunity to significantly reduce timeline, cost, and risk. We have developed processes to quickly produce a set of helper plasmids that consistently generate functional viral vectors, are immediately available for research and clinical production and are free of any royalties or future payments.

Our data show the performance of lentiviral vectors produced with optimized plasmids, indicating improved performance over other plasmid systems. The availability, cost, freedom to operate, and consistency of these plasmids will help address the growing demands of cell and gene therapy.

Quality Specifications

Assay	Method	Specification
ABS 260/280 Ratio Purity	UV Spectrophotometry	1.80 – 2.00
Appearance	Visual Inspection	Clear and Colorless
Buffer Formulation	N/A	Multi-compendial 10mM Tris, 1mM EDTA, pH 8.0
Concentration	UV Spectrophotometry	1.0 mg/mL +/- 10%
DNA Homogeneity	Densitometry Analysis of EtBr Stained AGE	> 80% supercoiled
Endotoxin	Kinetic Chromogenic LAL	<100 EU/mg
Identity	EtBr Stained AGE, Sequencing, Restriction Digest	Co-migrates with Reference DNA
Residual Host Genomic DNA	Quantitative PCR	< 5%
Residual Host RNA	SYBR Gold Stained AGE	< 5% by Semi-Quantitative Densitometry
Residual Host Protein	Micro BCA	< 2%
USP Sterility <71>	USP <71> Direct Inoculation	No Growth
Mycoplasma Contamination	Quantitative PCR	Negative for the Presence of Mycoplasma

Aldevron pALD-X80 Technical Data

Gene Therapy With AAV

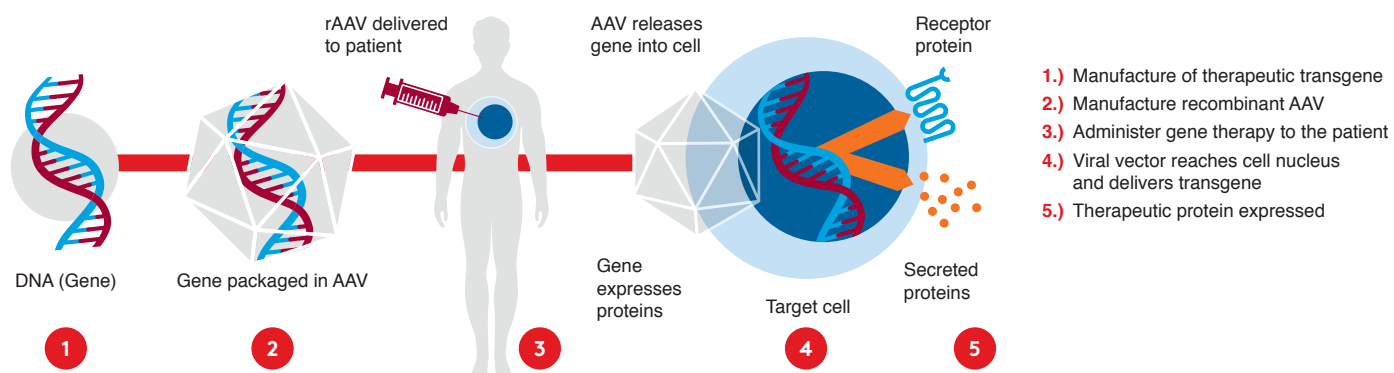


FIGURE 1. *In vivo* gene therapy process using adeno associated virus (AAV) as the vector to deliver the therapeutic transgene.

Standardized Helper Plasmid for rAAV

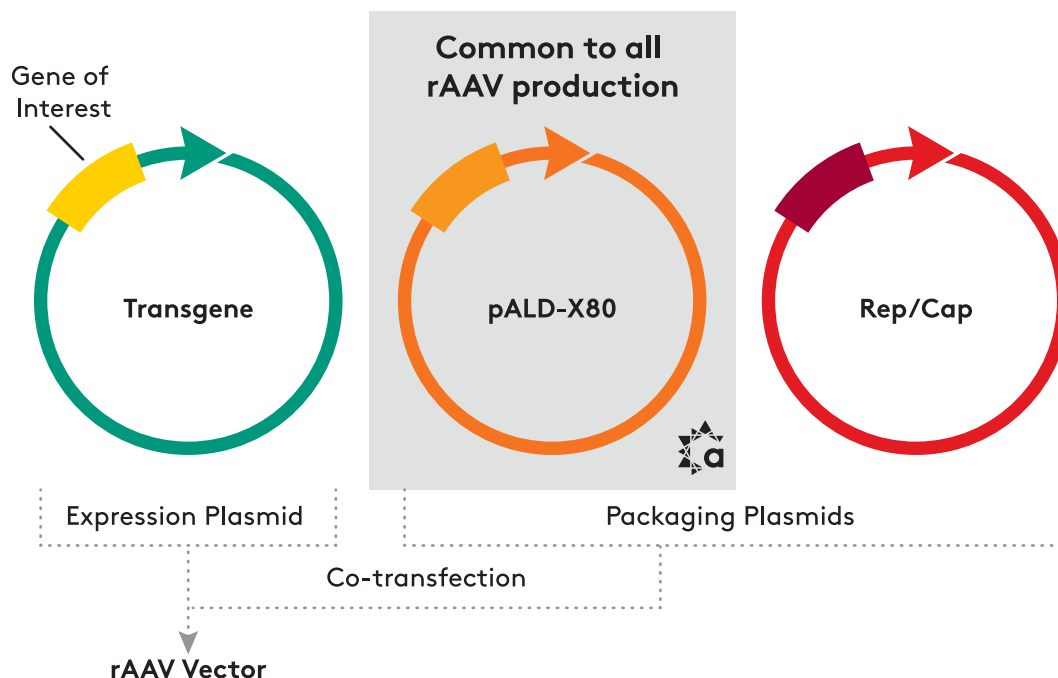


FIGURE 2. Plasmids used in AAV viral vector production illustrating the helper plasmid, common to all rAAV vectors.

pALD-X80 Successfully Produces rAAV

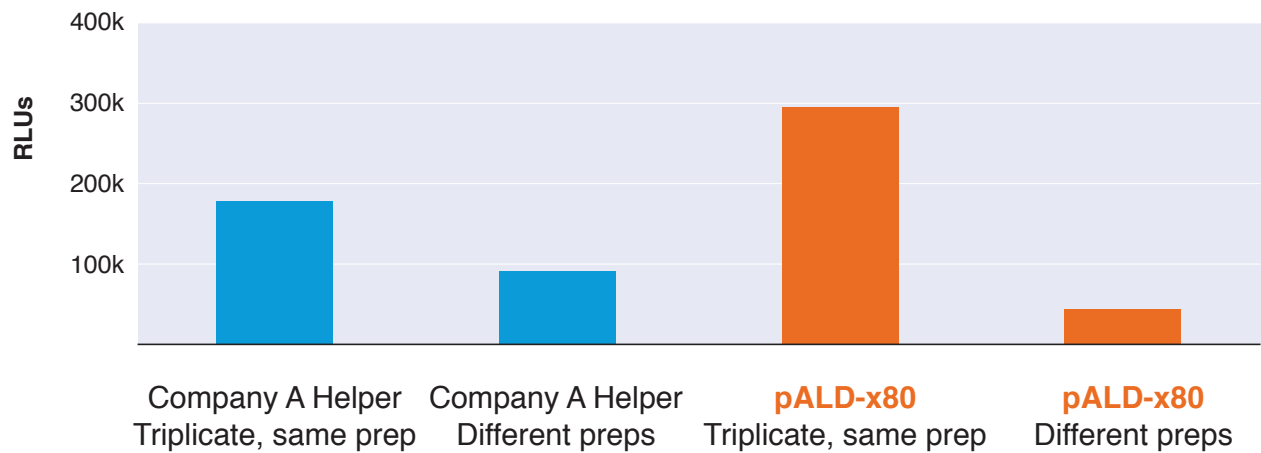


FIGURE 3. Transduction data from AAV2 viral vector with luciferase transgene indicating performance of pALD-X80 relative to commercially available helper plasmid.

Plasmid Production Scales Efficiently

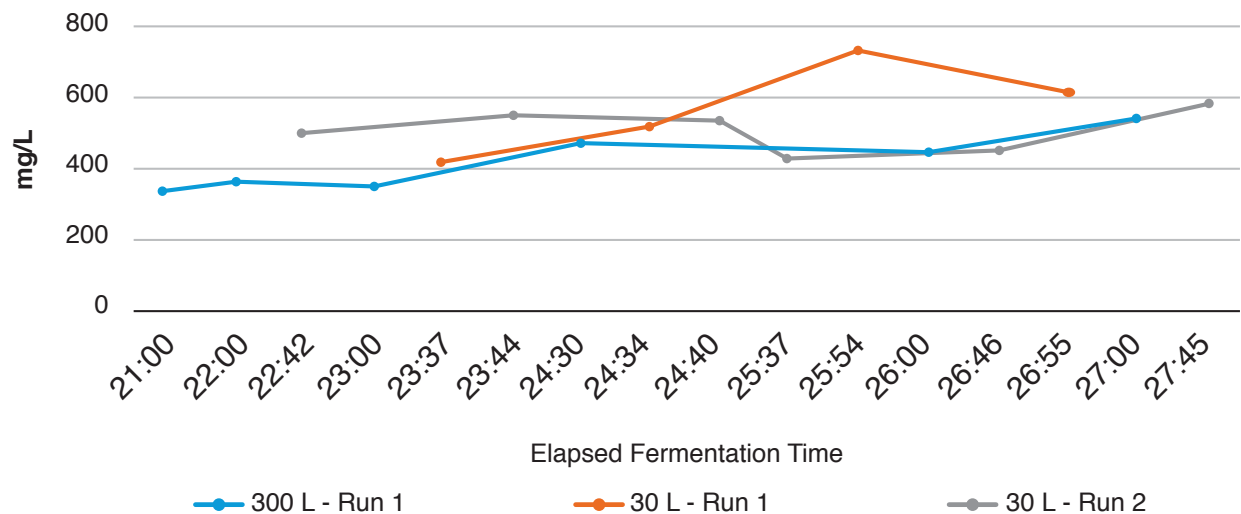


FIGURE 4. Fermentation data showing scalability of plasmid DNA production at 30 L and 300 L scales.

Aldevron pALD-Lenti Technical Data

Cell Therapy With Lentivirus

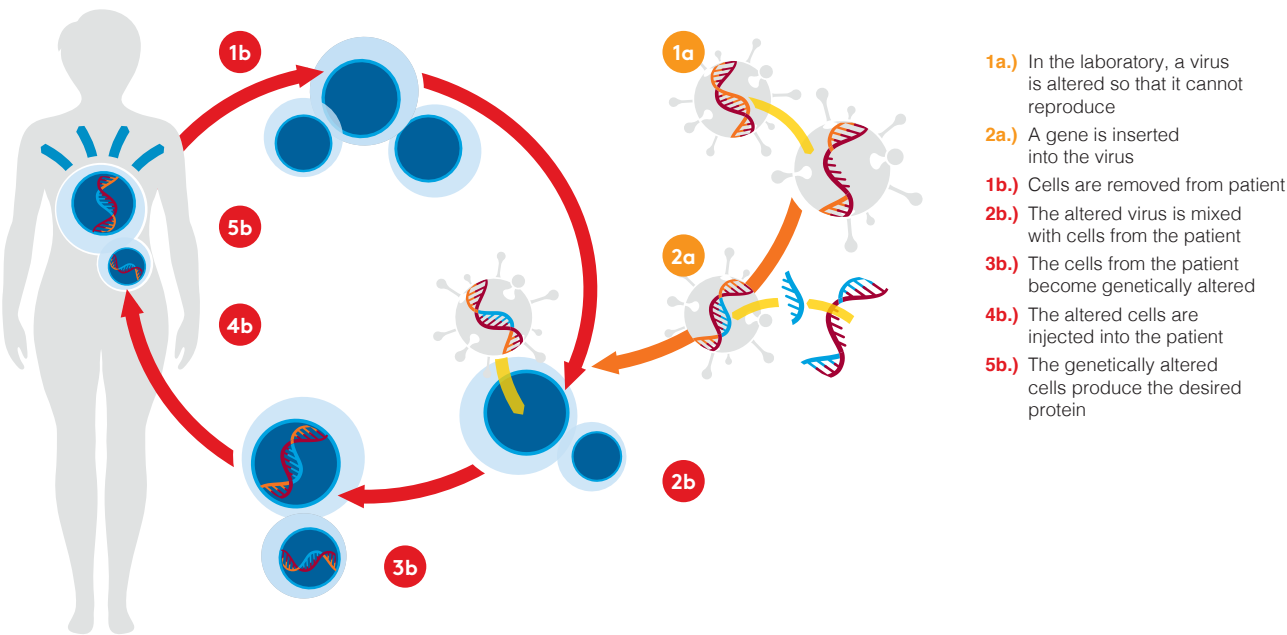


FIGURE 5. *Ex vivo* cell therapy process using lentivirus as the vector to deliver the therapeutic transgene.

Standardized Plasmids for Lentivirus

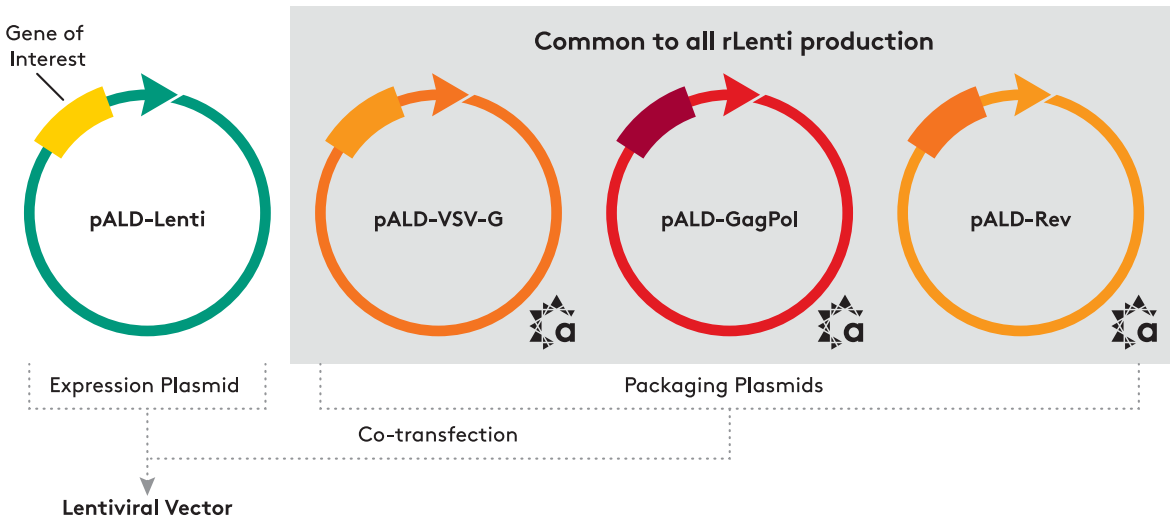


FIGURE 6. Plasmids used in lentiviral vector production, illustrating the plasmids common to all lentiviral vectors.

pALD-Lenti Successfully Produces Lentivirus

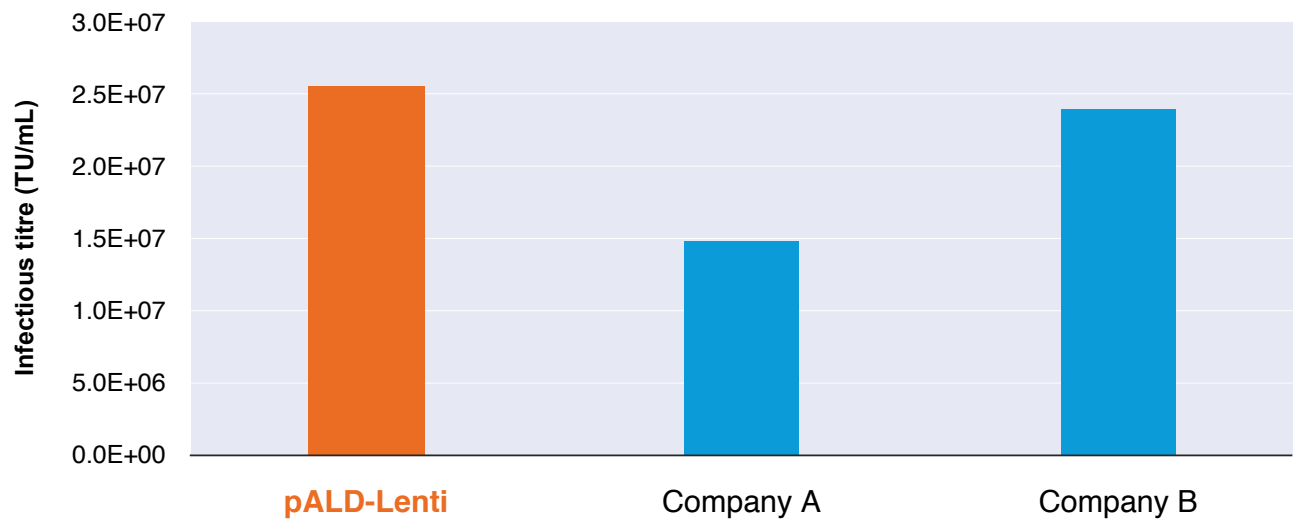


FIGURE 7. Infectious titer data for lentiviral vector production in suspension HEK293 cells relative to commercially available packaging plasmids.

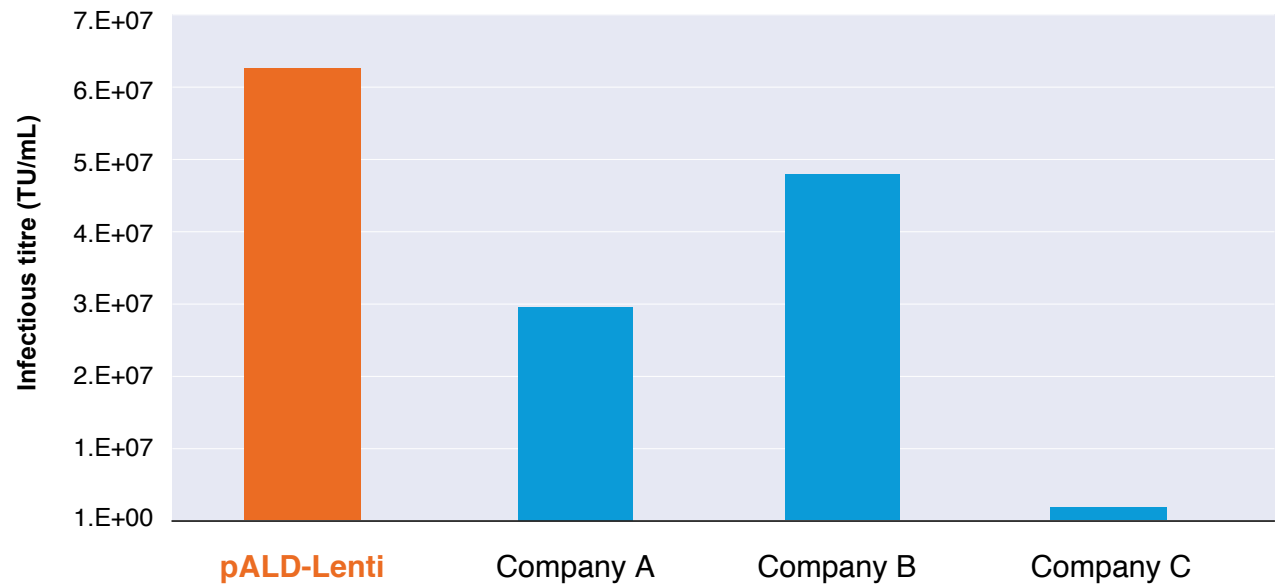


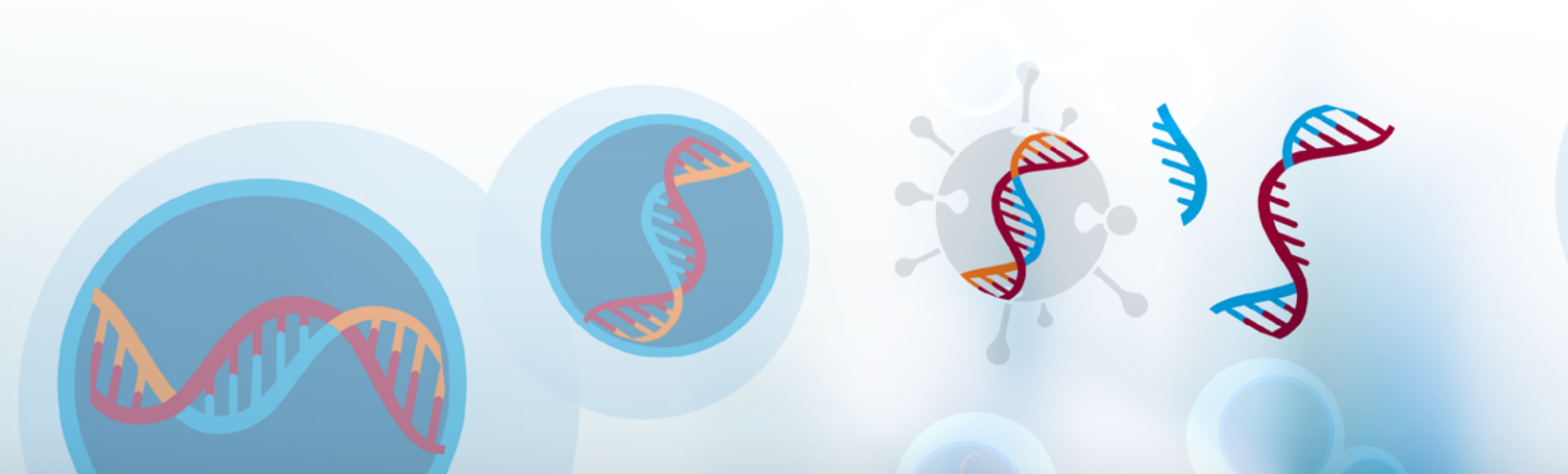
FIGURE 8. Infectious titer data for lentiviral vector production in adherent HEK293 cells relative to commercially available packaging plasmids.



Since 1989, Aldevron has been a proud partner of the biotechnology industry through the production of:

- Plasmid DNA at any scale, with fast turnaround times
- Proteins in bacterial, insect and mammalian expression systems
- mRNA to your specifications using a robust and scalable process

Aldevron supports research-use production through commercialization.



Contact Aldevron today for more information or to order a free sample.

4055 41st Avenue South, Fargo, ND 58104 USA

+1 (701) 297-9256 Toll-free (U.S. and Canada): +1 (877) 787-3362

Additional facility in Madison, WI

Visit: aldevron.com/contact