AAV-MAX Helper-Free AAV Production System

Cost-effective, scalable adeno-associated virus (AAV) vector production is critical to meet commercial demand, and smooth scale-up to clinical production is essential. We created the Gibco™ AAV-MAX Helper-Free AAV Production System to help reduce production costs and streamline your transition from research to the clinical scale.

The AAV-MAX system features:

- High AAV titers—more viral particles per volume to reduce production costs
- Scalability—suspension system with scalable protocols from shake flask to bioreactor scale
- Simplified workflow—streamlined helper virus–free triple transfection protocol
- Animal origin–free (AOF)—no animal- or human-derived components to reduce raw material safety risk
- Clonal 293F-derived producer cells—high-production clonal cell line; documented, cGMP bank*

Components of the Gibco AAV-MAX Helper-Free AAV Production System:

- Gibco™ Viral Production Medium
- Gibco™ Viral Production Cells 2.0
- Gibco™ AAV-MAX Transfection Kit
  - Gibco™ AAV-MAX Transfection Reagent
  - Gibco™ AAV-MAX Transfection Booster
  - Gibco™ AAV-MAX Enhancer
- Gibco™ Viral-Plex™ Complexation Buffer
- Gibco™ AAV-MAX Lysis Buffer

* cGMP will be available with the Gibco™ Cell Therapy Systems (CTS™) AAV-MAX Production System.

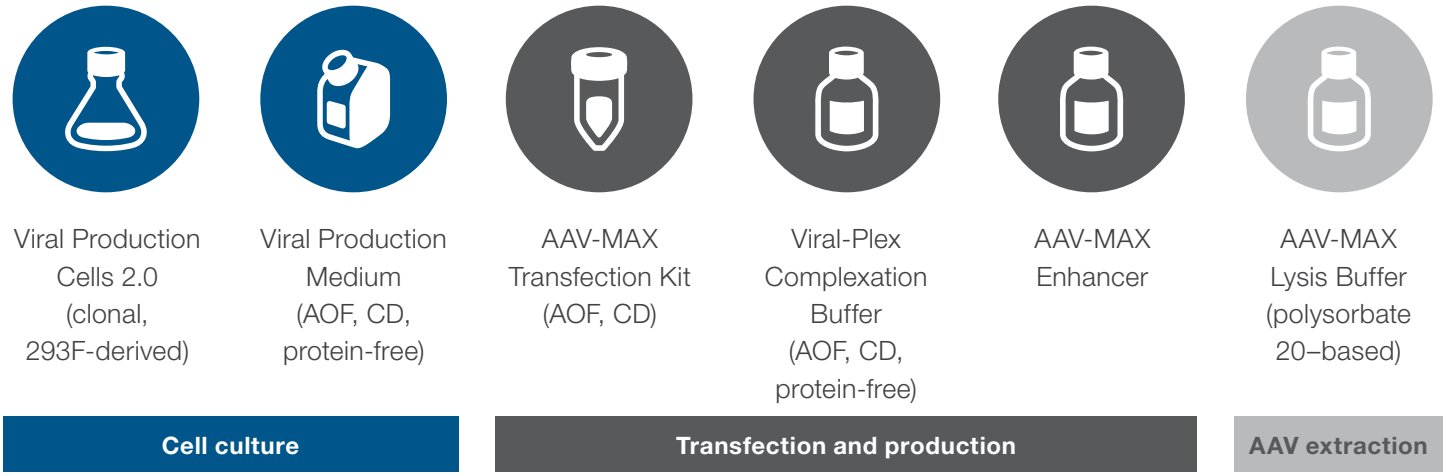
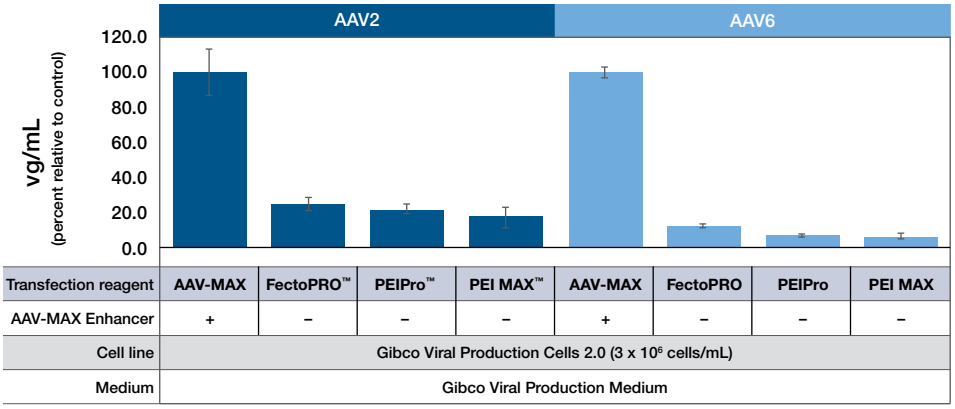


Figure 1. The components comprising the AAV-MAX Helper-Free AAV Production System.

To accelerate your development timelines, our scientific team has developed a complete, optimized system with integrated components to help deliver higher AAV titers than alternative platforms (Figure 1).

Optimized and fully integrated system

The components of the AAV-MAX system are designed to work synergistically, resulting in maximal titers and eliminating the need to optimize reagents and protocols. Using the complete system is more effective for producing high titers than replacing individual components or using conventional polyethyleneimine (PEI)-based transfection reagents (Figure 2).



Transfection reagent	AAV-MAX	FectoPRO™	PEIPro™	PEI MAX™	AAV-MAX	FectoPRO	PEIPro	PEI MAX
AAV-MAX Enhancer	+	–	–	–	+	–	–	–
Cell line	Gibco Viral Production Cells 2.0 (3 x 10^6 cells/mL)							
Medium	Gibco Viral Production Medium							

Figure 2. A complete system for maximal performance. AAV2 and AAV6 were produced at 30 mL scale in 125 mL shake flasks using the AAV-MAX system. The performance of the complete AAV-MAX system was evaluated and compared to performance when alternative transfection reagents were used. Titers were measured by qPCR, and the data were normalized to the titer (vg/mL) of the complete AAV-MAX system.

High titers across multiple serotypes

The innovative AAV-MAX Helper-Free AAV Production System is a complete and optimized suspension system that allows you to seamlessly and efficiently produce your AAV vector in high titers across multiple AAV serotypes (Figure 3).

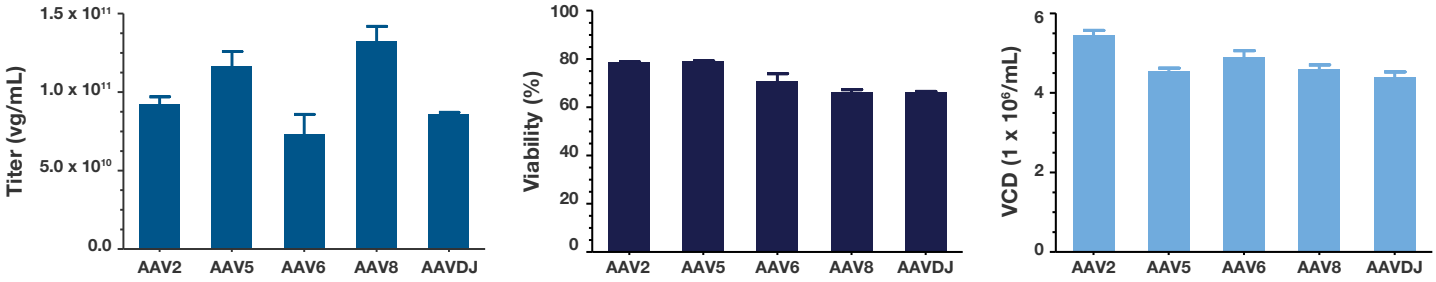


Figure 3. The AAV-MAX system yields high titers across multiple AAV serotypes. The system was used to produce 5 AAV serotypes at 30 mL scale in 125 mL shake flasks. These data show that high titers, high cell viabilities, and high viable cell densities (VCDs) were achieved for each of the 5 serotypes. Titers were measured by qPCR.

A cost-effective AAV production solution

Get more viral particles per dollar. With the AAV-MAX system, you can obtain the same viral titer in less volume than you can with PEI-based production systems, which translates to savings in media, downstream purification, lab space, and labor. Working with smaller batches can also mitigate contamination risk. In addition, the AAV-MAX system requires less plasmid DNA per 1 x 10^6 cells than alternative transfection reagents, which drives production costs down further.

Switch to the AAV-MAX system and save

- Save 50% on average compared to alternative PEI-based suspension systems
- Cut plasmid DNA costs by 25%

Scaling to meet demand

Challenges associated with existing AAV production systems include low titers, the high cost of cGMP plasmid DNA, poor scalability, and a lack of fit-for-purpose cGMP reagents. The AAV-MAX system can help you overcome these challenges by allowing you to produce high AAV titers using preoptimized and regulatory-compliant* reagents developed for AAV production in a scalable suspension platform that maintains volumetric viral titers as you scale up (Figures 4 and 5).

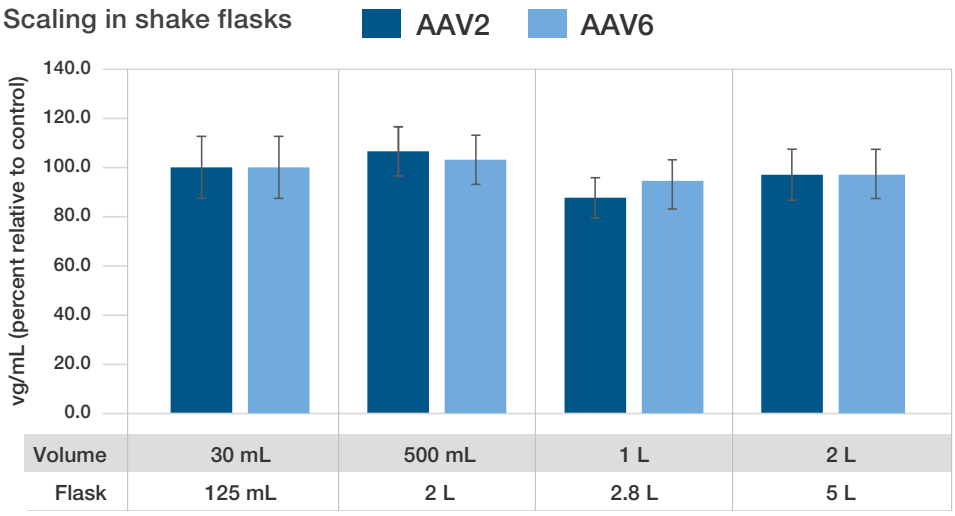


Figure 4. The system yields high titers across multiple production scales. The AAV-MAX system was used to produce AAV2 and AAV6 at four different scales in shake flasks. Titers were measured by qPCR, and the data were normalized to the titer (vg/mL) at 30 mL production scale in a 125 mL shake flask.

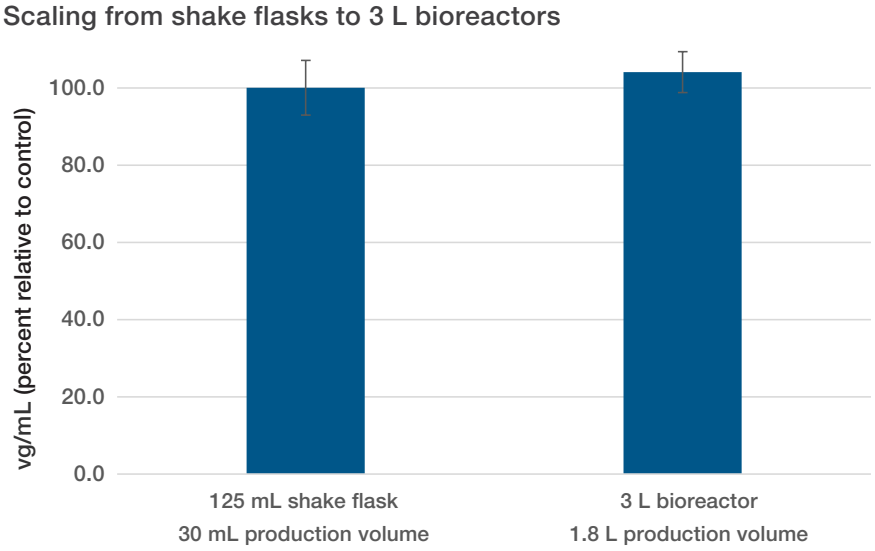


Figure 5. High titers are achieved at both shake flask and bioreactor scales. AAV2 was produced using the AAV-MAX system in 125 mL shake flasks (30 mL production volume) and 3 L bioreactors (1.8 L production volume). Titers were measured by qPCR, and the data were normalized to the titer (vg/mL) at 30 mL production scale in a 125 mL shake flask.

Clonal producer cell line

Viral Production Cells 2.0:

- Clonal, 293F-derived, high-producing cell line
- Optimized for high-density suspension culture (>12 million cells/mL) in a chemically defined medium
- No SV40 large T antigen or genetic engineering
- Robust scalability and passage stability (Figures 6–8)
- Documented, cGMP-bank manufacturing will be available as CTS*

AAV cell line growth curve

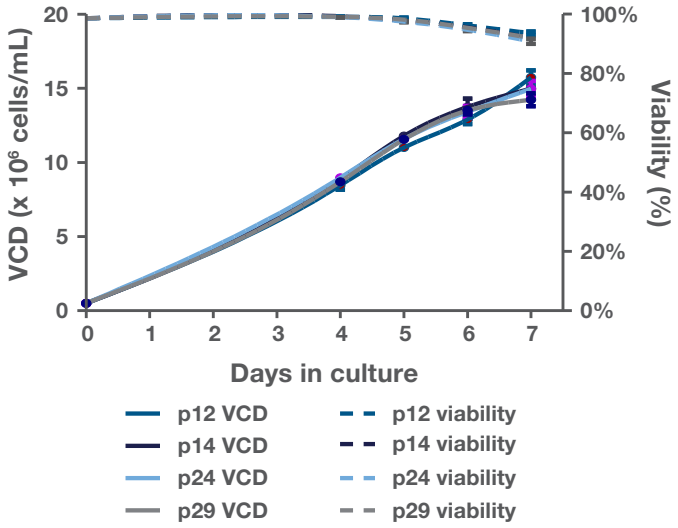


Figure 6. Viral Production Cells 2.0 maintain similar growth profiles over multiple passages. Cells were cultured in Viral Production Medium, and cell viability and VCD were measured from day 4 to day 7 post-seeding.

Post-thaw recovery

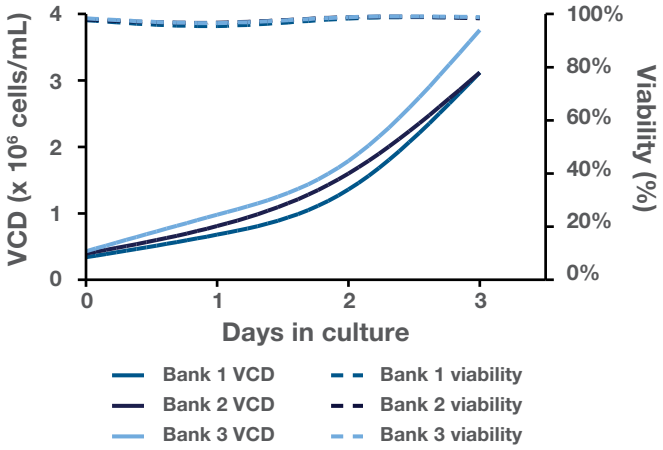


Figure 8. Viral Production Cells 2.0 maintain good viability and viable cell density following a thaw cycle. Cells were thawed, and cell viability and VCD were monitored for 3 days post-thaw.

Doubling time

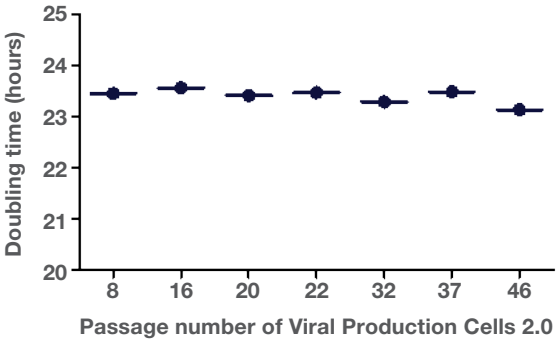


Figure 7. Viral Production Cells 2.0 maintain a doubling time of approximately 23.5 hours over many passages. The doubling times were calculated based on growth between days 3 and 4 post-seeding.

* cGMP will be available with the Cell Therapy Systems (CTS) AAV-MAX Production System.

Simplified workflow

To accelerate your development timelines, our scientific team has tested hundreds of different reagent combinations to develop a complete system with preoptimized reagents that work in concert to deliver maximum titers.

Ordering information:

Product	Size	Cat. No.
Gibco AAV-MAX Helper-Free AAV Production System	1 kit	A51217
Gibco Viral Production Medium	1 L	A4817901
	6 x 1 L	A4817902
	10 L (bag)	A4817903
Gibco Viral Production Cells 2.0	1.0 mL (1 x 10^7 cells)	A49784
	6 x 1.0 mL (6 x 1 x 10^7 cells)	A51218
Gibco AAV-MAX Transfection Kit • Gibco AAV-MAX Transfection Reagent • Gibco AAV-MAX Transfection Booster • Gibco AAV-MAX Enhancer	For 1 L culture	A50515
	For 10 L culture	A50516
Gibco Viral-Plex Complexation Buffer	100 mL	A4983901
Gibco AAV-MAX Lysis Buffer	100 mL	A50520

Find out more at **thermofisher.com/aavmax**

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