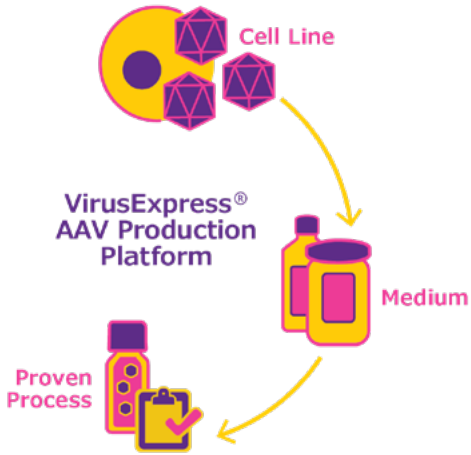
SAFC®
Pharma & Biopharma Raw Material Solutions

Data Sheet

VirusExpress® 293 AAV Production Platform

Draw on our experience to get on the fast track through production

The VirusExpress® Platform offers a transfection-based solution to Adeno-Associated Viral (AAV) production challenges, featuring a suspension adapted cell line, chemically defined medium, and a clinically relevant process dramatically reducing time to commercial production. VirusExpress® offers the flexibility to use either our contract manufacturing capabilities or your own facilities to speed your therapy to patients.



Our VirusExpress® Platform offers:

- A transfection-based solution to adeno-associated viral (AAV) upstream production challenges
- A suspension adapted cell line of 293 AAV Production Cells optimized for production of AAV vectors for gene therapy applications
- Chemically defined medium to alleviate animal origin and supply chain concerns
- Proven process performance at 3 L scale with genome titer exceeding 8 x 10^9 gc/mL
- Comprehensive user protocols to guide from seed train through at-scale transfection and virus production, allowing for seamless scale-up

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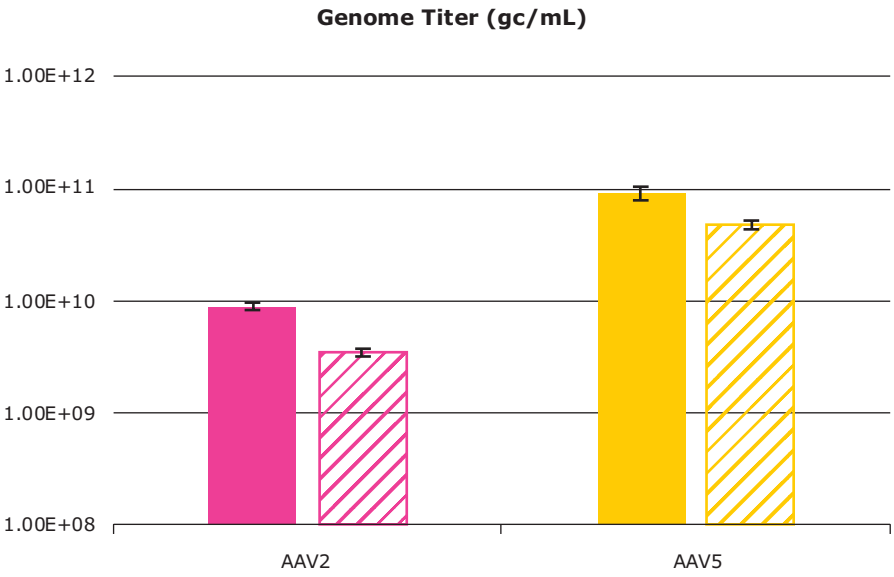

Figure 1. VirusExpress® 293 AAV Production Cells – AAV2 and AAV5 crude harvest genome titers (gc/mL) titers of GFP model virus in 3L Bioreactors (solid color bars) and in shake flasks (striped color bars) using PEI based transfection. For AAV2 3 L BR, n=6; for AAV2 SF, n=9; for AAV5 3 L BR, n=3; for AAV5 SF, n=6.

During optimization of the transfection conditions, consistently higher titers were obtained in 3L bioreactors than shake flasks for both AAV2 and AAV5 production.

Benefits

- Cell banks manufactured according to GMP (21CFR210, 211, 600, 610) and fully characterized.
- Proven performance for cell growth, plasmid transfection, and AAV production in large-scale bioreactors at clinically and commercially relevant scale which yielded genome titers in excess of 8 x 10^9 gc/mL.
- Licenses available for research, clinical and commercial use dependent on which phase of gene therapy development is needed.
- Reduced time in process development and scale-up by approximately 40%.
- Flexibility to use in your own facilities or by using our contract manufacturing capabilities.
- Ability to speed your therapy to patients.
- Robust quality documentation to support regulatory filings and commercialization of your gene modified cell therapy or gene therapy.

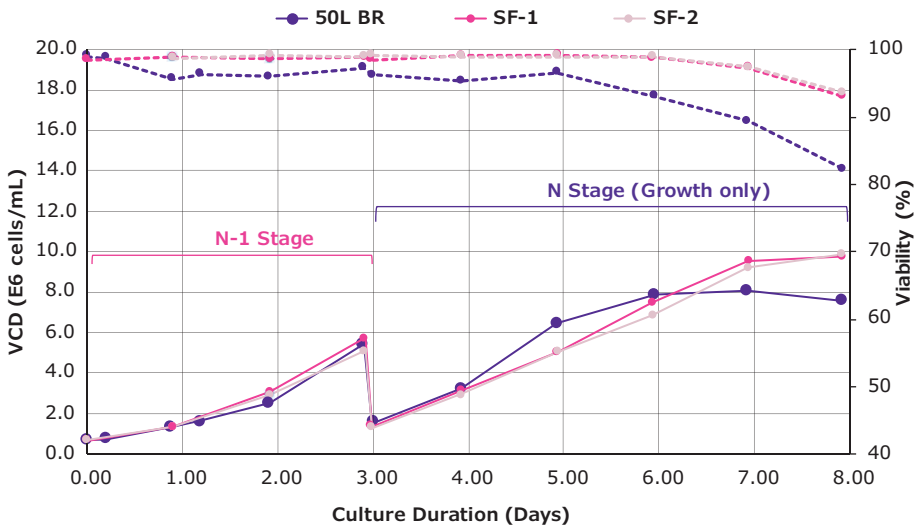

Figure 2. VirusExpress® 293 AAV Production Cells were cultured for batch growth in Mobius® 50 L Single-Use Bioreactors. Cells were seeded at 6 x 10^5 cells/mL and diluted with fresh media on Day 3. Peak viable cell density (VCD) of 8 x 10^6 cells/mL was obtained in Mobius® 50L bioreactor with viability >90%.

Comparable growth of cells was achieved with both bench-scale and large-scale bioreactors.

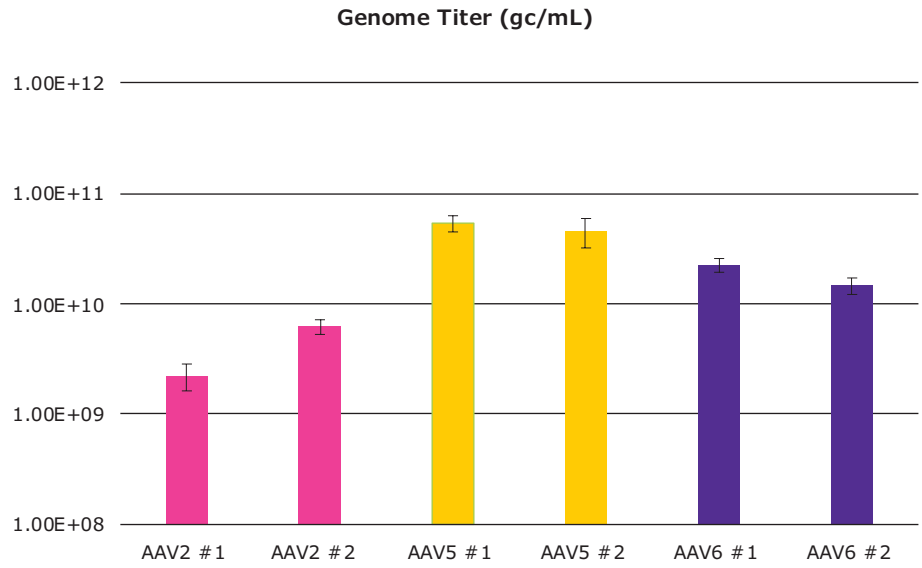

Figure 3. VirusExpress® 293 AAV Production Cells – productivity shown as crude harvest genome titers (gc/mL) of GFP model virus in shake flasks using multiple serotypes, AAV2, AAV5 and AAV6.

VirusExpress® 293 AAV production cells, media, and processes are amendable to multiple serotypes.

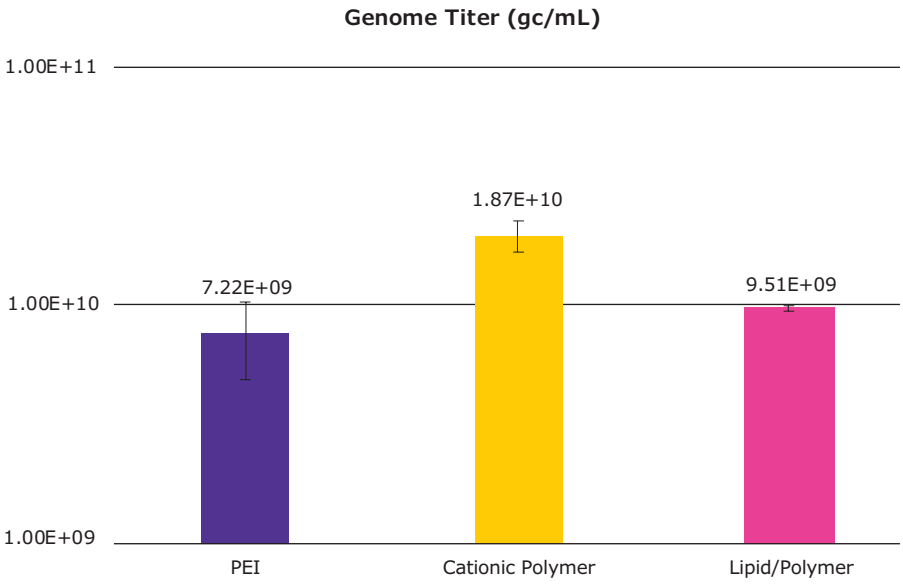

Figure 4. VirusExpress® 293 AAV Production Cells – AAV2 crude harvest genome titers (gc/mL) of GFP model virus in shake flasks using PEI based transfection versus alternative transfection reagents.

Even though the cell culture media was designed for PEI mediated transfection, the platform is compatible with alternative transfection reagents in our proven process.

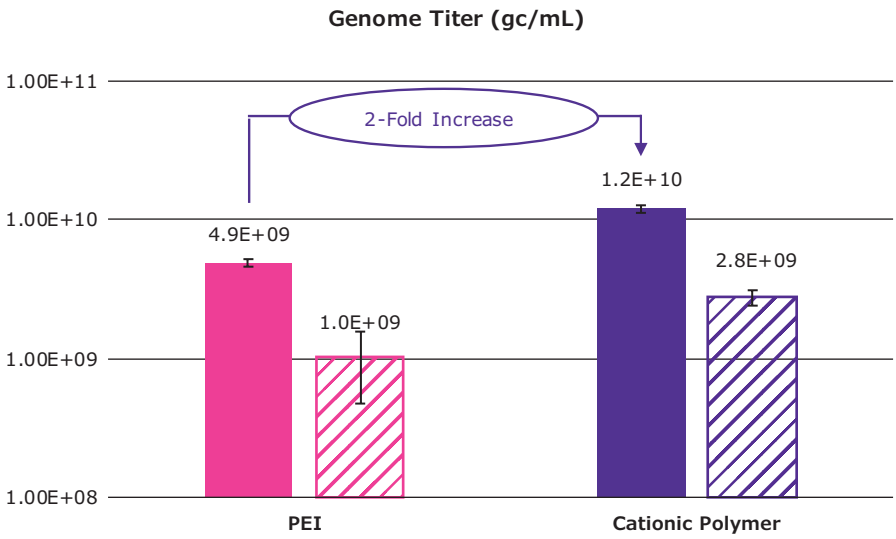

Figure 5. VirusExpress® 293 AAV Production Cells – AAV2 production with a cationic polymer transfection reagent consistently delivers a 2-fold increase in genome titers (gc/mL) of GFP model virus when compared to PEI mediated transfection at the 3 L bioreactor scale (solid color bars) versus shake flask controls (striped color bars).

We continue to optimize the platform to improve performance such as identifying alternative transfection reagents suitable for AAV vector production.

Product Description	Storage Temperature	Package Size	Cat. No.
VirusExpress® 293 AAV Production Cells*	-196 °C (Liquid N2 vapor phase)	—	**VP002-1VL**
EX-CELL® CD HEK293 Viral Vector Medium – Chemically defined, animal component-free, without L-glutamine, liquid, sterile-filtered, suitable for cell culture	2–8 °C	1000 mL in bottle (10 L in bag)	**14385C-1000ML** **14385C-10B**

* Research and commercial licensing are required to use this cell line. Please contact us before placing your order.

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To place an order or receive technical assistance

Connect with us at: **MerckMillipore.com**

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