

Xcell™ Eng-HEK293

**A next-generation cell line
engineered for scalable, high-
quality rAAV production**

Delivering higher yields, superior genome stability, and
consistent performance from R&D to GMP.



**NEW
BIOLOGIX**



State of The Industry: Gene Therapy Manufacturing

Gene therapy pipelines are growing rapidly, yet manufacturing remains the limiting factor. Low yields, poor reproducibility, and high costs continue to delay clinical and commercial progress.

INDUSTRY SNAPSHOT

7,000+ genetic diseases

30 approved gene therapies
(as of Dec 2024)

1,400+ preclinical programs

INTRODUCING



Designed for Scalable, High-Quality rAAV Production

Engineered for Performance

Delivers consistently high titers and full, infectious viral particles across production scales.

Built for Stability

Genetically stable clonal cell line with no translocations or mutations observed over extended passaging.

Manufacturing-Ready

Seamless transition from R&D to GMP with low COGS (Cost of Goods Sold) and reproducible product quality.

Data-Driven by Design

Supported by comprehensive analytics, identified hotspot regions, and AI-enabled genomic optimization.

Xcell™ Eng-HEK293 is a fully characterized, GMP-aligned platform cell line built to reduce development risk and accelerate timelines.

The Bottleneck Isn't Biology - It's Manufacturing

Despite rapid clinical progress, current AAV manufacturing approaches struggle to meet the demands of scale, consistency, and cost required for widespread therapeutic use.

- **1,400+** gene therapy programs in preclinical development
- **AAV** is the dominant vector for in vivo gene therapy
- Manufacturing limitations **constrain** scalability and commercialization

(Source: GlobalData, 2025)

PTRS at IND filing is high (~62%), yet manufacturing failures remain a leading cause of delay post-IND.

LIMITATIONS



Scalability -
Transient transfection is difficult to scale efficiently.

Cost - High reagent and process costs limit commercial viability.

Reproducibility -
Batch-to-batch variability impacts yield and quality.

A Stable Cell Line Is the Foundation of Reliable Manufacturing

Xcell™ Eng-HEK293 was engineered as a clonal, genomically stable platform to ensure consistent performance across extended passaging and scale.

Clonal by Design

Derived from a single clonal origin to eliminate population heterogeneity and reduce variability observed in parental HEK293 systems.

Genomically Stable

Demonstrates stable genomic architecture across extended population doublings, supporting reproducibility throughout development and manufacturing.

Built for Consistency

Provides a reliable upstream foundation that minimizes batch-to-batch variability and supports long-term process control.

Conceptual schematic illustrating clonal lineage control and stability



Built for Consistent, Scalable Manufacturing

From Master Cell Bank to commercial production, Xcell™ Eng-HEK293 enables controlled, reproducible rAAV manufacturing.

Single-cell-derived parental cell → **MCB** → **WCB** → **Production Runs**

MCB Integrity Master Cell Bank Control

- Fully characterized clonal MCB
- Genetic stability verified
- Qualified for reproducible manufacturing

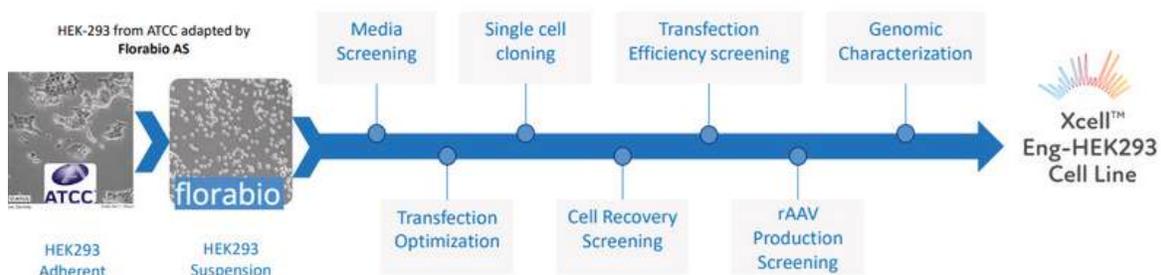
Process Consistency Run-to-Run Reproducibility

- Consistent yields across batches
- Reduced process variability
- Supports scale-up and tech transfer

GMP & Commercial Readiness Manufacturing-Ready Platform

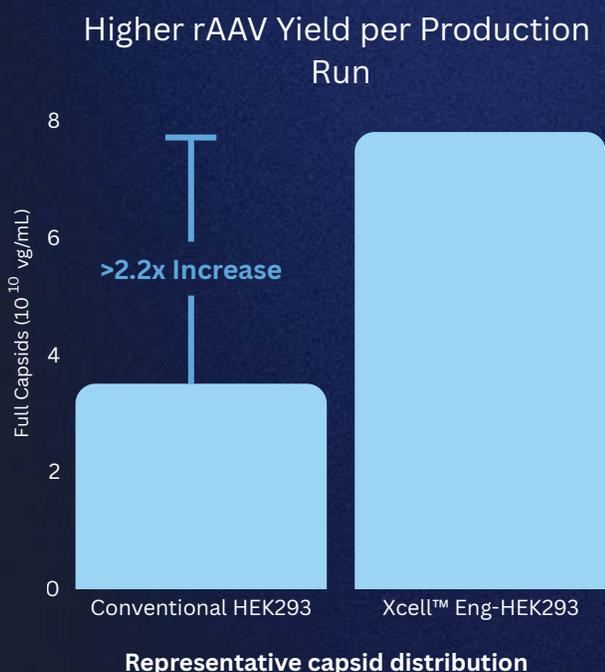
- GMP-aligned cell banking strategy
- Designed for clinical → commercial progression
- Supports long-term supply continuity

Cell Line Development & Qualification Workflow



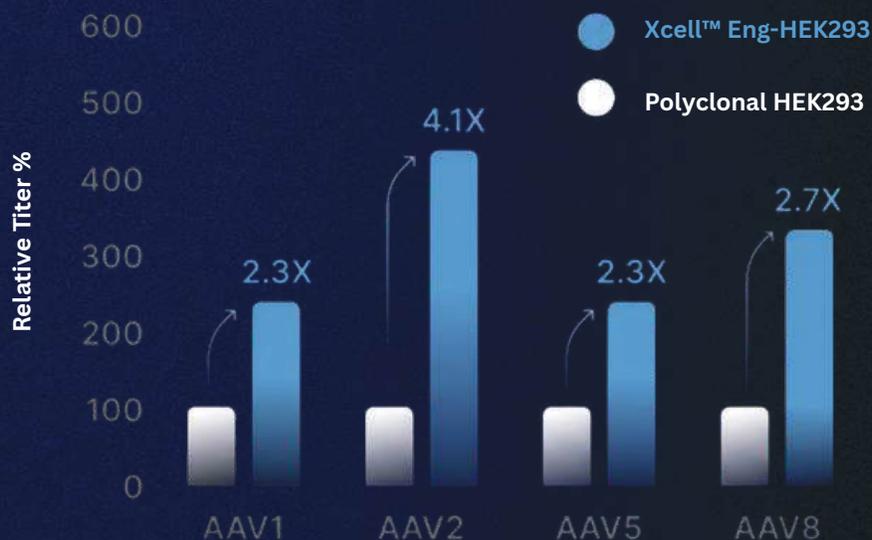
Demonstrated Performance Across Key Metrics

Performance data generated using Xcell™ Eng-HEK293 in standard rAAV production workflows.



NBX cell line produces **4–6x more full capsids** than the leading commercial cell line.

Superior rAAV Titers for Multiple Serotypes



Maximizing Functional rAAV Output

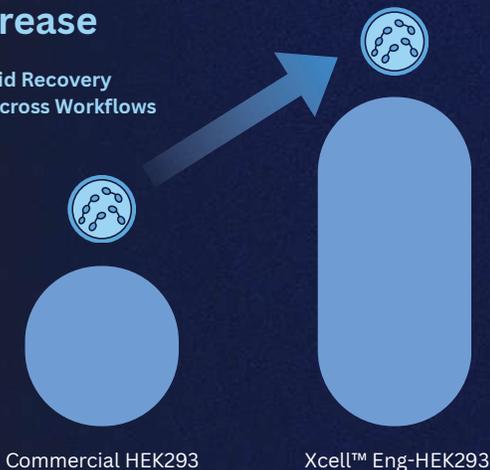
Improvements in yield, capsid integrity, and purification efficiency combine to deliver significantly greater functional rAAV output per production run.

Across production workflows, Xcell™ Eng-HEK293 consistently produces a higher proportion of full, genome-intact capsids relative to conventional commercial HEK293 platforms. When combined with increased upstream yield and improved downstream recovery, this results in meaningfully higher functional rAAV output per batch.

Significantly higher full/empty ratios (~2× improvement), supporting better dose efficiency and reduced downstream purification burden: = **Higher Potency + Lower COGS**

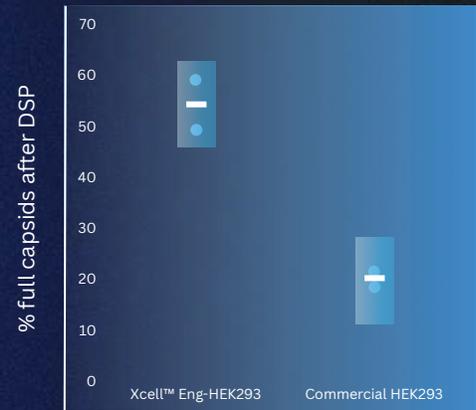
2X Increase

in Full Capsid Recovery Observed Across Workflows

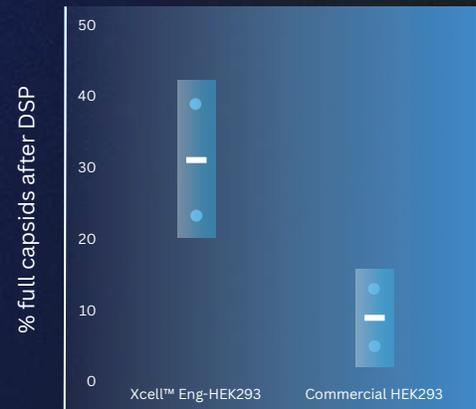


Functional rAAV Output

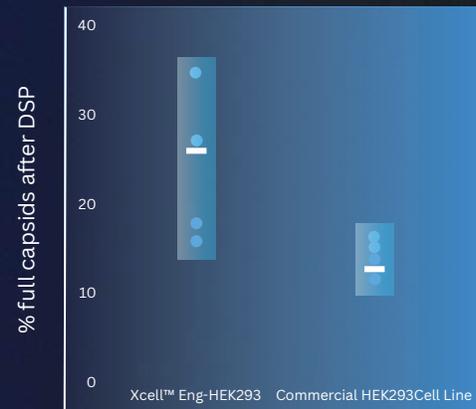
AAV1



AAV5



AAV8

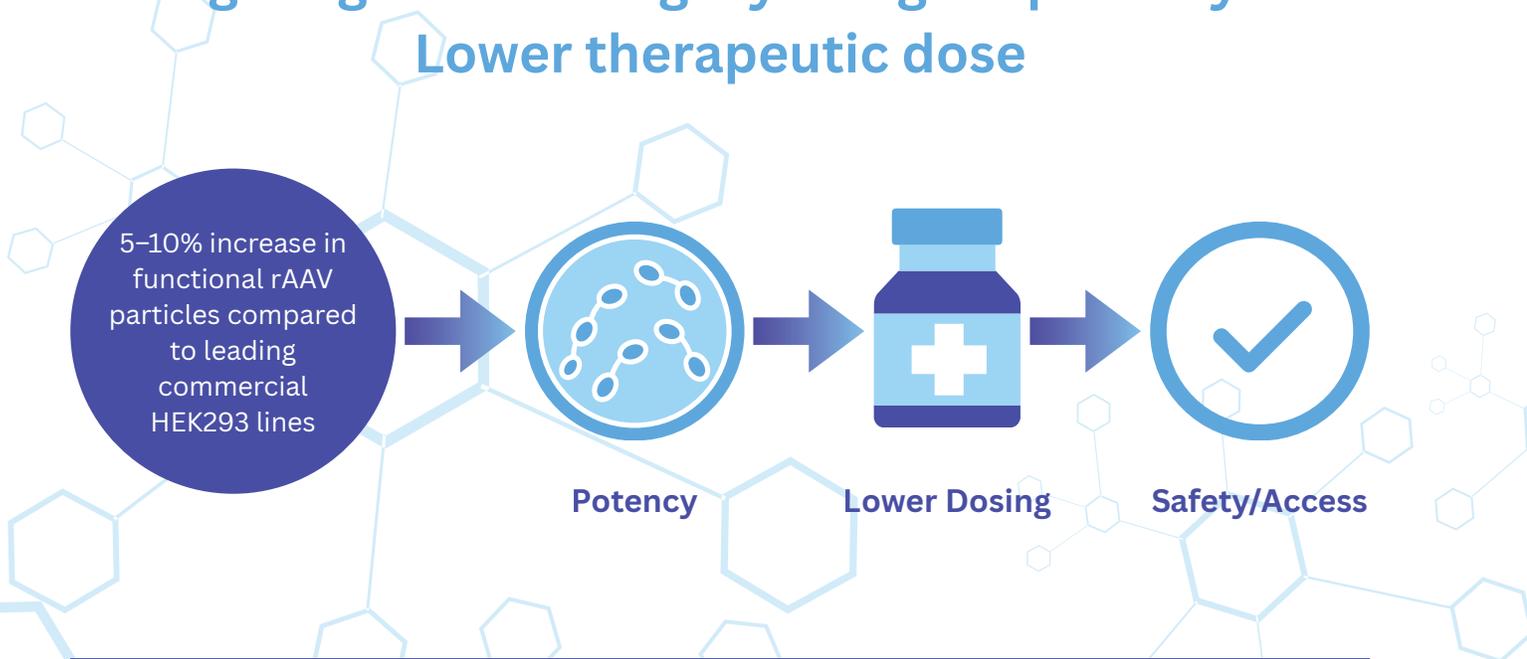


*DSP: Downstream process

Why Vector Quality Matters Clinically

Improvements in vector quality and consistency have downstream implications for potency, dosing strategy, and overall therapeutic performance.

Higher genome integrity → Higher potency → Lower therapeutic dose



✓ Higher functional particle content supports improved potency

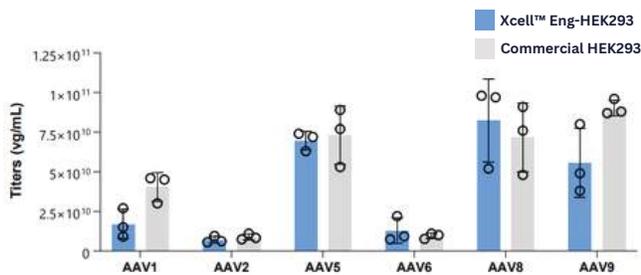
✓ Increased potency may enable lower effective dosing

✓ Lower dosing can reduce manufacturing burden and clinical risk

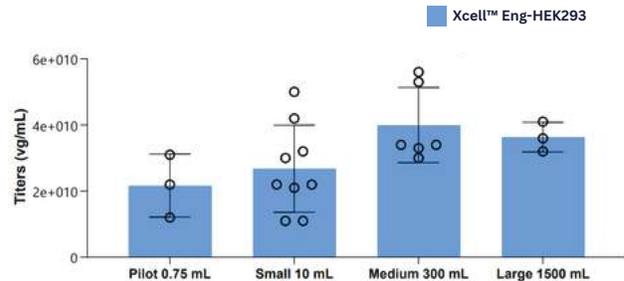
Proven Performance Across AAV Serotypes

The Xcell™ Eng-HEK293 platform eliminates the need for serotype-specific optimization. Our engineered host cell factors favor high-efficiency viral assembly regardless of the capsid, providing a robust foundation for your entire pipeline.

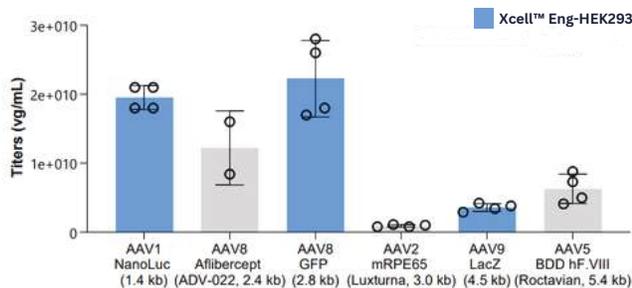
rAAV Serotypes



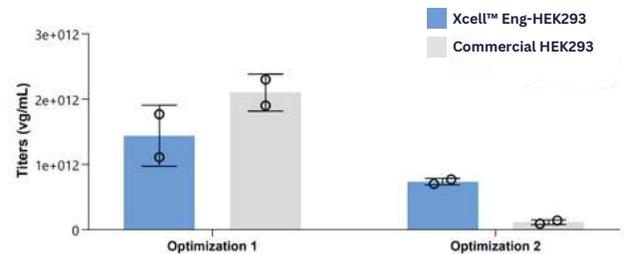
Scalability



Size of Gene of Interest



Titers After Manufacturing



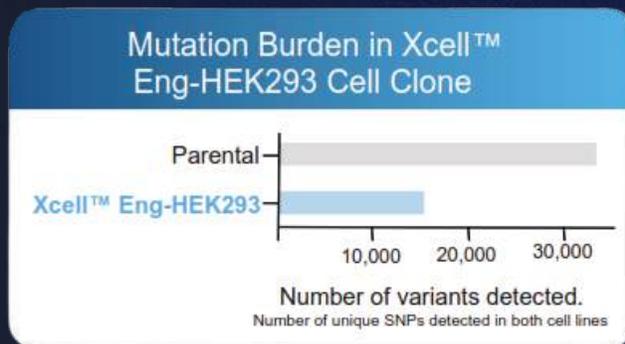
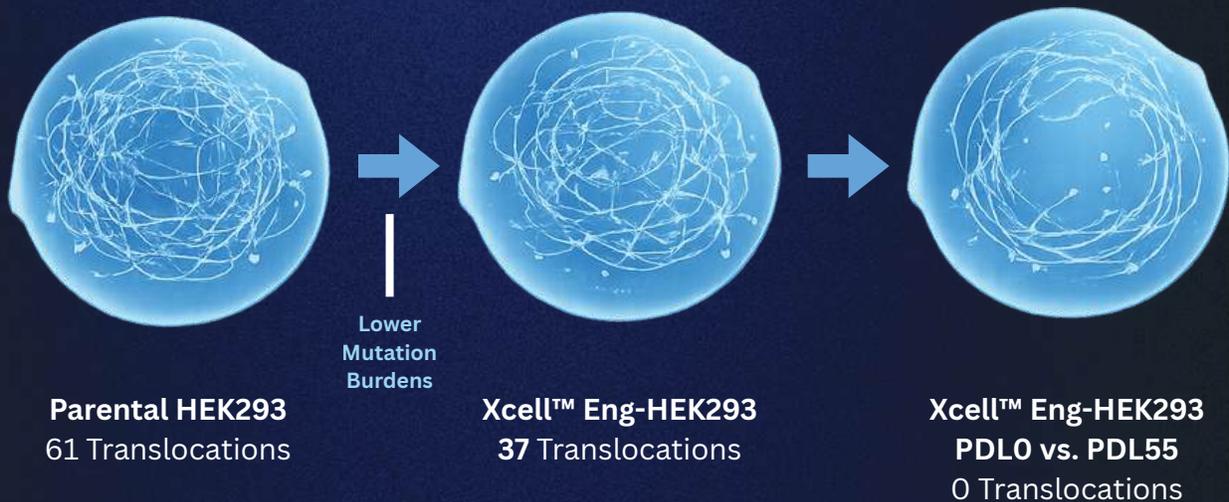
Key Data Highlight:

Validated results across AAV1, 2, 5, 6, 8, and 9 demonstrate a consistent productivity advantage. Xcell Eng-HEK293 achieves up to a 4.1x increase in functional viral recovery (vg/mL) compared to industry-standard HEK293 lines, ensuring high-titer production regardless of your program's serotype.

Genomic Stability Built for Long-Term Manufacturing Reliability

Unlike conventional HEK293 pools, Xcell™ Eng-HEK293 is a fully characterized, clonal platform with preserved genomic integrity across extended passaging.

Solid Genomic Integrity is the CORE of Xcell™ Eng-HEK293



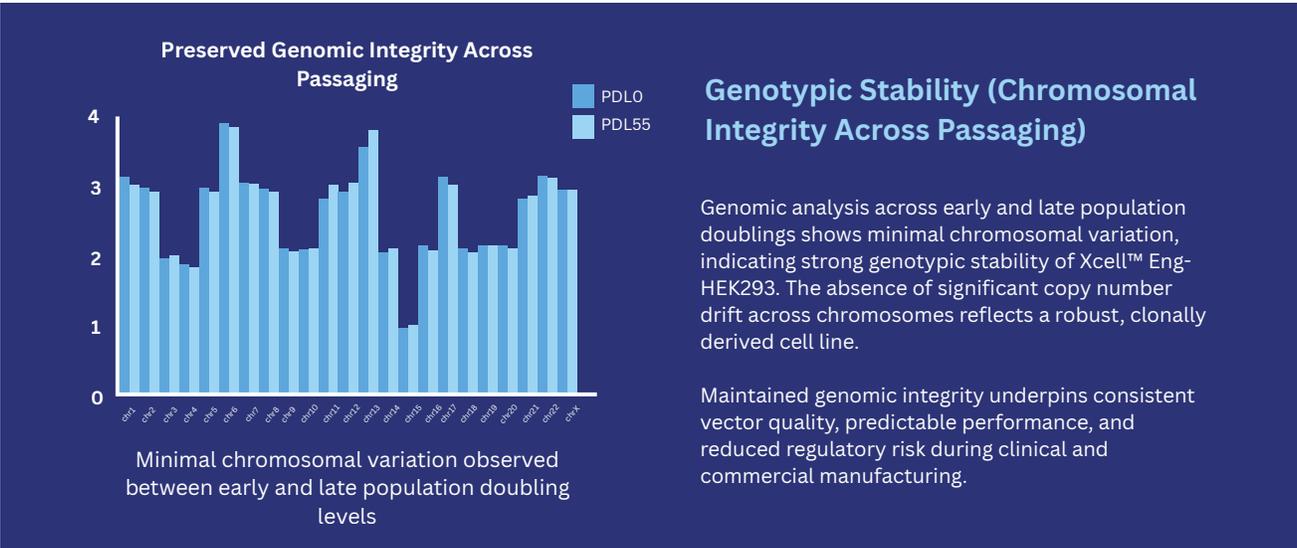
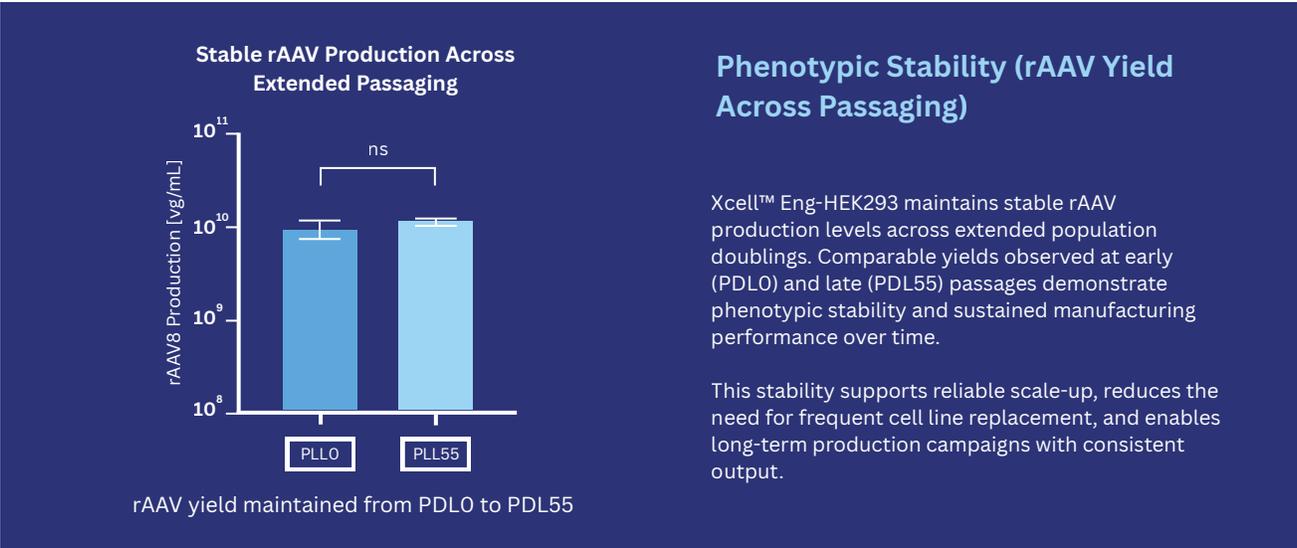
- Reduced translocation burden minimizes genetic drift
- Stable host genome supports consistent vector quality over time
- Low-risk foundation for late-stage and commercial programs

Technical Validation

Stability Across Extended Passaging

Representative data demonstrating phenotypic and genotypic stability of Xcell™ Eng-HEK293.

For teams evaluating long-term manufacturing consistency, representative phenotypic and genotypic stability data are shown below.



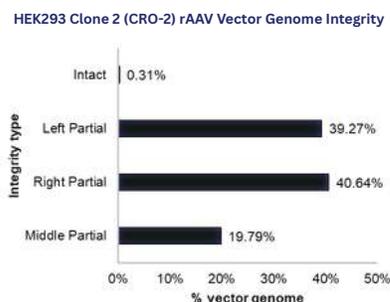
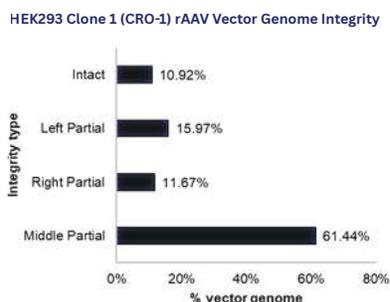
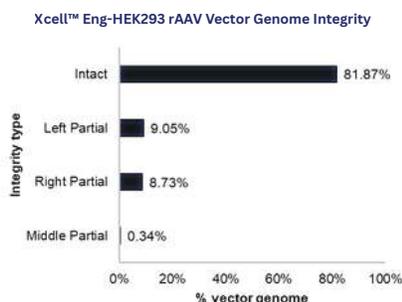
Together, phenotypic and genotypic stability ensure consistent vector yield, quality, and reproducibility across the full manufacturing lifecycle.

rAAV Quality by NGS: Encapsidated DNA Species

Our comparative analysis demonstrates that rAAV vectors produced with NewBiologix’s Xcell™ Eng-HEK293 cell line and chromatography-based purification deliver superior quality compared to vectors generated by leading CROs using commercial HEK293 cells and (ultra-)centrifugation-based methods.

	rAAV produced at NBX using Xcell™ Eng-HEK293 cells and NBX downstream chromatography process
CRO 1	rAAV produced at a CRO using commercial HEK293 cells and an ultra-centrifugation downstream process.
CRO 2	rAAV produced at a CRO using commercial HEK293 cells and an ultra-centrifugation downstream process.

	% Sequencing Reads	% Sequencing Reads	% Sequencing Reads
Plasmid Backbone	0.9	2.0	1.1
Host Cell DNA	0.9	17.1	13.8
Rep/Cap Genes	0.1	0.9	1.1
AdV Helper Genes	0.1	1.7	0.9
Other	12.1	11.7	30.2
ITR - GOI - ITR	85.9	66.6	52.9



The Xcell™ Advantage: From Challenge to Opportunity

THE FUTURE OF GENE THERAPY MANUFACTURING IS NOW

The Xcell™ Advantage Traditional HEK293 lines are the industry standard, but they weren't designed for the rigors of modern gene therapy. We've re-engineered the foundation to provide higher productivity, improved genomic stability, and consistent performance across scale and passaging.

THE CHALLENGE

rAAV manufacturing today is constrained by **low yields, high costs, and limited scalability.**

OUR SOLUTION

Xcell™ Eng-HEK293: A high-performance, genomically stable cell line engineered for consistent, scalable rAAV production.

THE IMPACT

2x more full capsids vs. commercial lines, seamless scale-up from R&D to GMP.

YOUR OPPORTUNITY

Partner with NewBiologix to accelerate your gene therapy pipeline with a next-generation manufacturing platform.

Why Partners Choose



Xcell™ Eng-HEK293 Master Cell Bank

A proprietary, single-cell-derived host cell platform engineered for scalable, high-quality rAAV manufacturing.

- Xcell™ Eng-HEK293 Master Cell Bank
- Patent pending genomic landing pads
- Fully sequenced genome with identified safe harbors
- Genomically stable for high quality production

Strategic Access Options

- Made available under Research and Commercial License
- Same cell line for research and commercial to ensure consistency
- Designed to accelerate development timelines while reducing CMC risk

In-House Expertise & Support

- Optional analytics, characterization, and research cell banking services
- Deep in-house know-how supporting downstream development
- May reduce time-consuming technology transfer and operational hand-offs

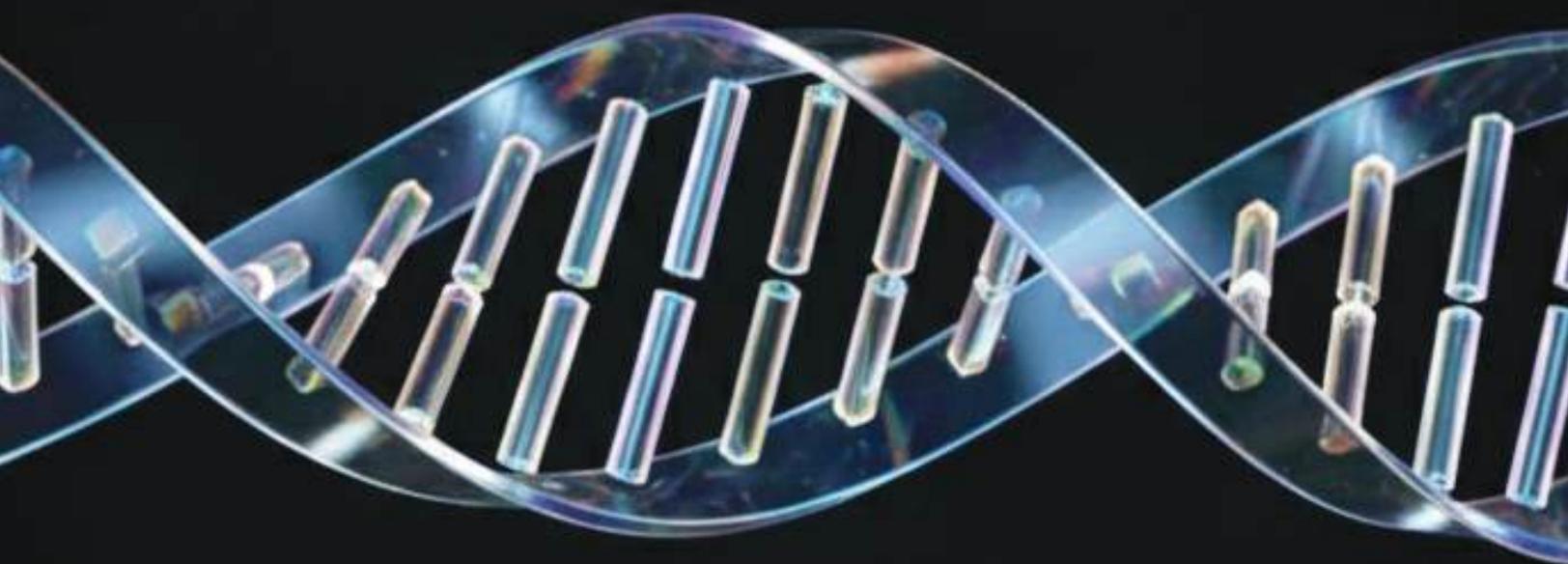
Next Steps

Additional data available under Confidential Disclosure Agreement (CDA)

NewBiologix welcomes discussions with partners seeking reliable, scalable rAAV manufacturing platforms.

The Future of Gene Therapy Manufacturing Is Here

Partner with New Biologix to accelerate your gene therapy pipeline.



FOR MORE INFORMATION, CONTACT:

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