

AAV Analytics Solutions



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Powered by Gator®
Next-gen Biolayer
Interferometry



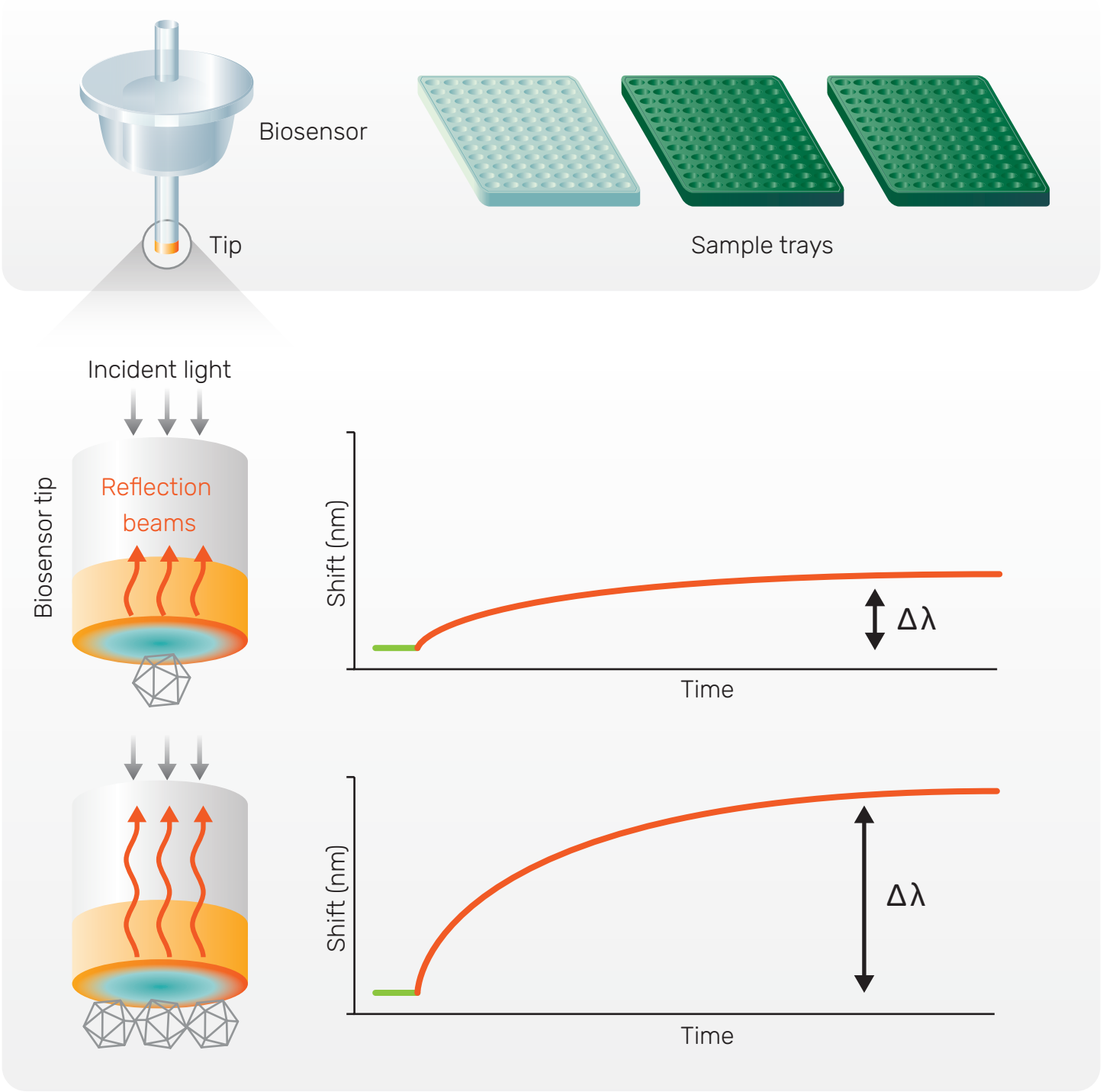
What is BLI?



BLI is a label free detection method based on reflection of white light from the surface of a biosensor tip.

It analyzes the changes in interference pattern of white light reflected from the tip when biomolecules bind to it. This change is recorded in real time and is expressed as nanometer shift. It is proportional to the number and size of biomolecules bound to the tip.

Gator Bio's AAV Analytics solution includes the BLI Instrument, biosensors coated with a nanobody that binds specifically to AAV capsids, reagents, and GatorOne software.



BLI principle

Next-gen BLI for AAV Analytics



Gator® Bio presents Next-gen Biolayer Interferometry (BLI)-based AAV Analytics suite of solutions that include capsid titer, empty/full ratio determination, and TAb and NAb assays of adeno-associated viral vector.

AAV analytics during manufacturing process is challenging due to lack of standardized methods and crude matrix incompatible empty/full ratio determination techniques.

Gator Bio's AAV Analytics solutions offer crude sample compatibility, high sensitivity, accuracy, robustness, automation, reduced hands-on time, and fluidic-free instrumentation, making them suitable for integration into manufacturing processes.

Our AAV solutions include



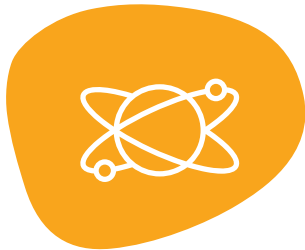
Automated and robust titer of AAV serotypes 1-10 and chimerics in the range 10^7 - 10^{13} vp/mL



Automated empty/full determination with dynamic range of 0% - 100% full capsids with resolution of 5%

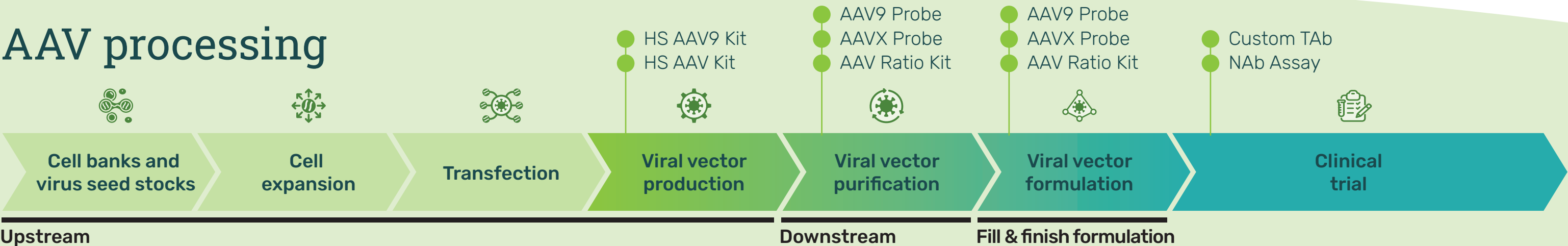


Custom TAb and NAb assays for clinical trials



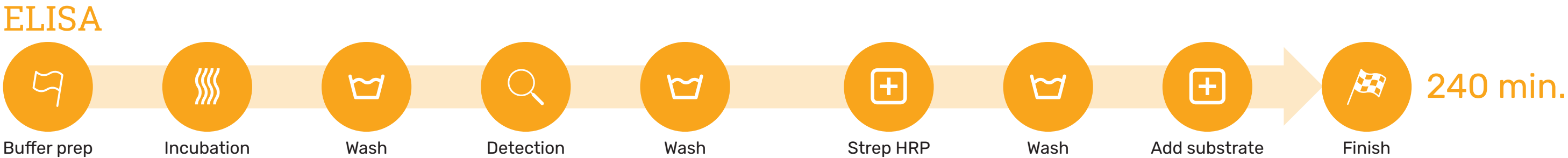
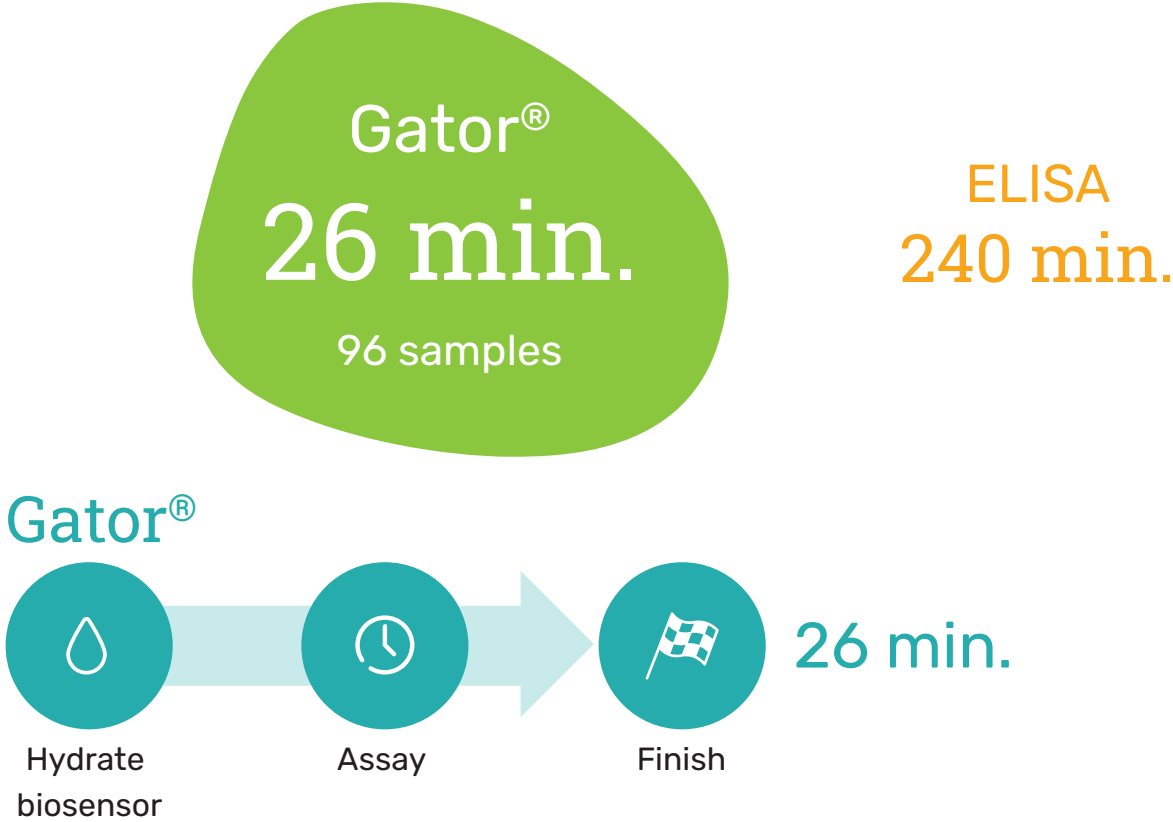
Kinetic characterization of AAV neutralizing antibodies

AAV processing



Comparison of Gator® workflow

Gator® AAV solutions are based on simple single technology obviating the need for different types of instrumentation and expertise. The "dilute and dip" method for complex matrices simplifies the workflow that can be deployed in any laboratory supporting AAV processing. These methods have much shorter turnaround time compared to other methods.



Gator® BLI benefits

	Fully automated	Crude sample tolerant	Dynamic range vp/mL	CQA
Gator® Titer	●	●	10 ⁷ - 10 ¹³	Capsid titer
Gator® E/F	●	●	0% - 100% full and resolution of 5%	E/F ratio
DLS/UV	●	○		E/F ratio
Mass photometry	●	○		E/F ratio
ELISA	○	●	10 ⁷ - 10 ⁹	Capsid titer
q PCR	●	●	10 ⁵ - 10 ¹⁰	Genome titer
dd PCR	●	●	10 ² - 10 ⁷	Genome titer
AUC	○	○		E/F ratio
TEM	○	○		E/F ratio

Our kits



Upstream			Downstream	
High Sensitivity AAV Kit	High Sensitivity AAV 9 Kit	AAV Ratio Kit	AAVX Probe	AAV9 Probe
High sensitivity titer of AAV 1 - 8, 10 and chimerics	High sensitivity titer of AAV9	E/F ratio	Binds serotypes AAV1 - 10	Binds specifically to AAV9
Titer	Titer	Ratio determination	Titer	Titer
Dynamic range: 10 ⁷ - 5 x 10 ¹⁰ vp/mL	Dynamic range: 10 ⁷ - 10 ⁹ vp/mL	Dynamic range: 0% - 100% full and resolution of 5%	Dynamic range: 10 ⁹ - 10 ¹³ vp/mL	Dynamic range: 3 x 10 ⁹ - 10 ¹³ vp/mL

What makes us different?

One platform for titer and empty/full ratio determination in pure and crude matrices.

Crude sample tolerant

LoQ 10⁷ vp/mL

Single platform for titer and ratio

Automated assay

High precision



Wide dynamic range - 10⁷ vp/mL to 10¹³ vp/mL



Single platform for titer and empty/full ratio determination



Automated with minimal time



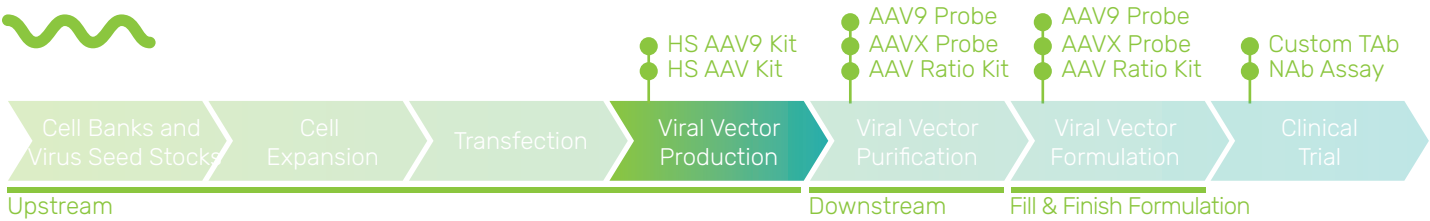
Crude matrix compatibility



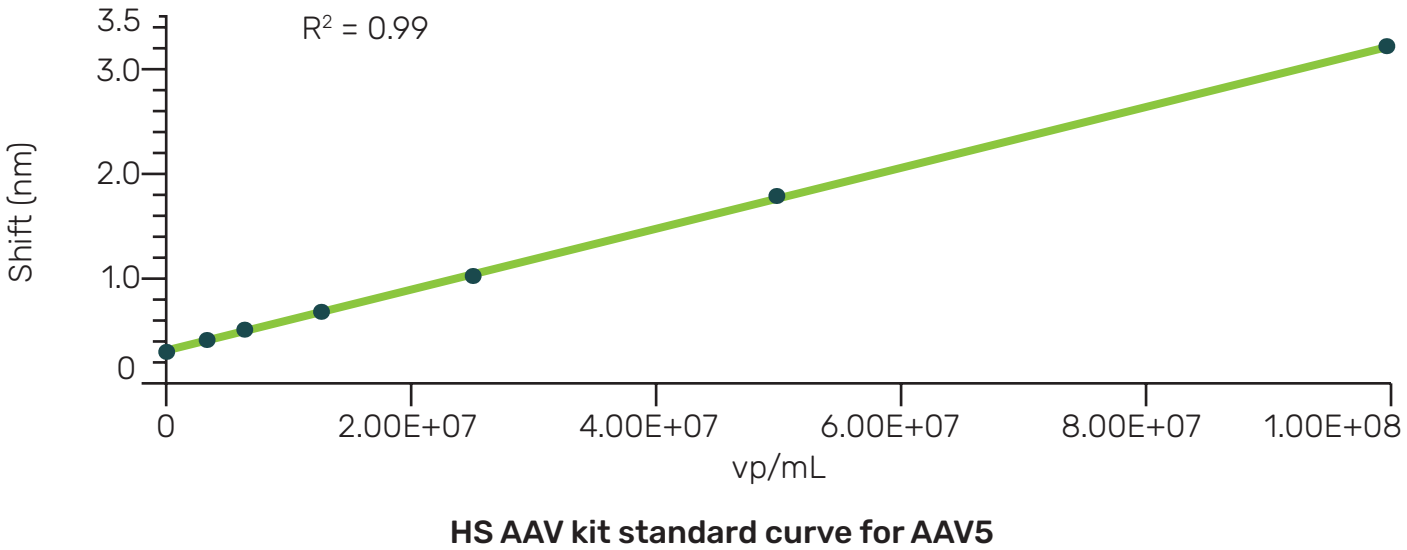
Easy integration into manufacturing process



Titer solutions for upstream application



The Gator® HS AAV and HS AAV9 Kits enable high sensitivity titer of AAV serotypes 1 – 8, 10, chimeric serotypes, and AAV9 respectively in purified and crude samples.

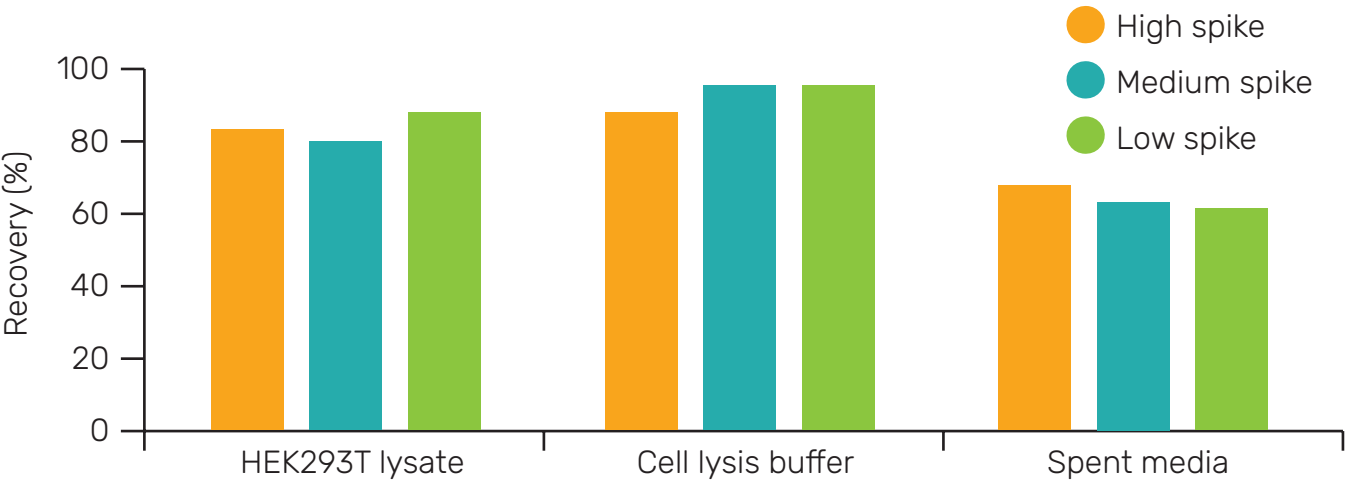


Performance

	HS AAV	HS AAV9
LoQ	10 ⁷ vp/mL	10 ⁷ vp/mL
Dynamic range	10 ⁷ – 5 x 10 ¹⁰ vp/mL	10 ⁷ – 10 ⁹ vp/mL
Assay runtime for 96 samples	100 min.	100 min.
Precision	<10%	<10%

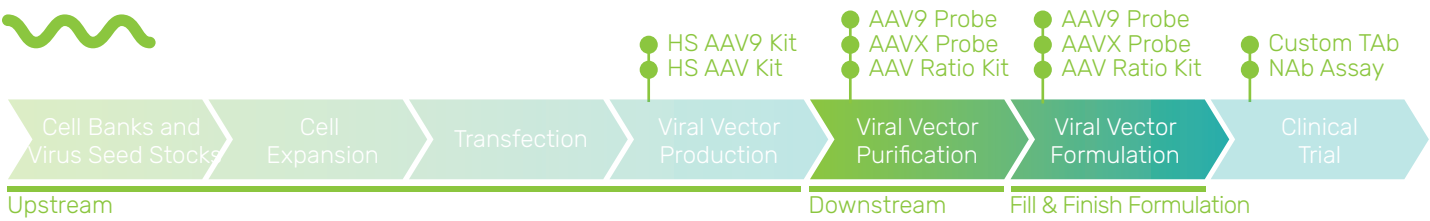
Advantages

- Powered by a patented signal amplification technology
- Dilute and dip: minimal hands on time compared to ELISA
- Samples such as cell culture media, clarified cell lysate, and cell lysis buffer
- LoQ of 10⁷ vp/mL
- Automated assay steps including washes compatible with crude samples

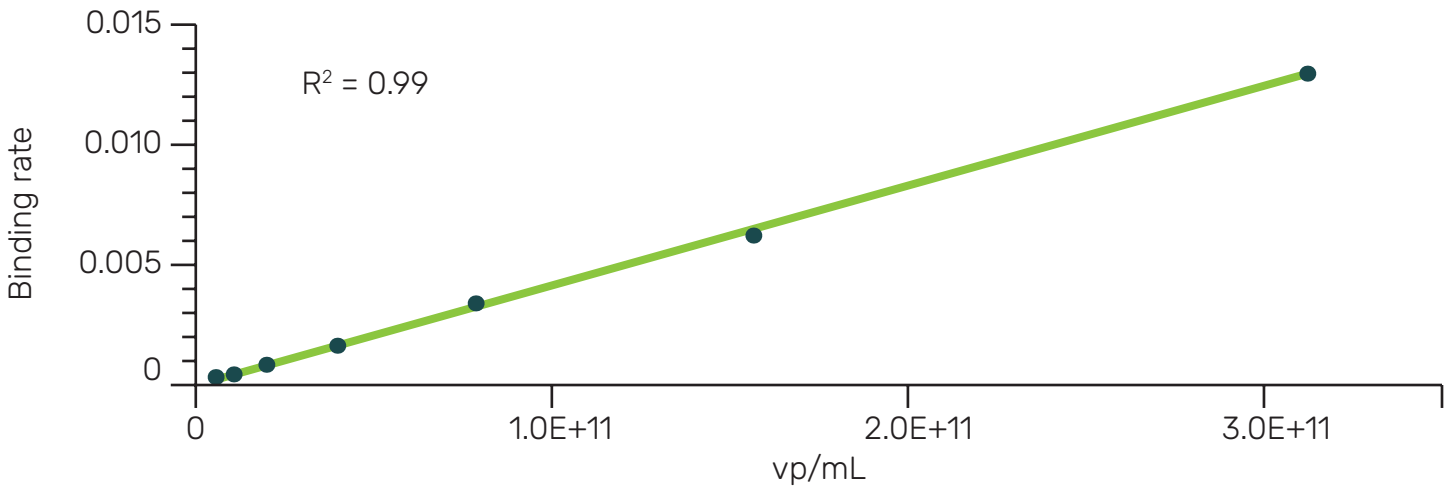


Recovery of AAV spiked at high (10⁸ vp/mL), medium (5.33 x 10⁷ vp/mL) and low (10⁷ vp/mL) concentration in various matrices

Titer solutions for downstream application



The Gator® AAVX and AAV9 probes enable direct capture and titer of AAV1-10, and AAV9 respectively in crude lysates, column eluates, cell lysates, and cell culture supernatants. These probes use proven CaptureSelect™ (Thermo Fisher Scientific) high affinity nanobodies.



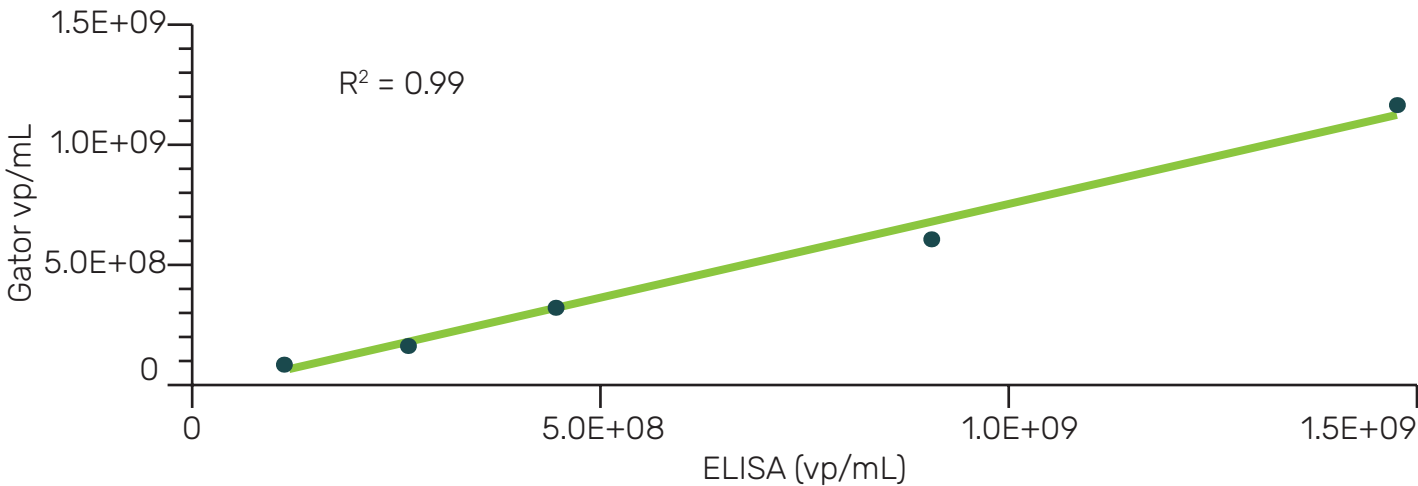
Standard curve showing the dynamic range of AAVX probes using AAV2

Performance

	AAVX	AAV9
Serotype compatibility	AAV1-10 and chimerics	AAV9
Dynamic range	10 ⁹ – 10 ¹³ vp/mL	3 x 10 ⁹ – 10 ¹³ vp/mL
Assay runtime for 384 samples	32 min.	32 min.
Regenerable	Yes	Yes
Precision	<10%	< 10%

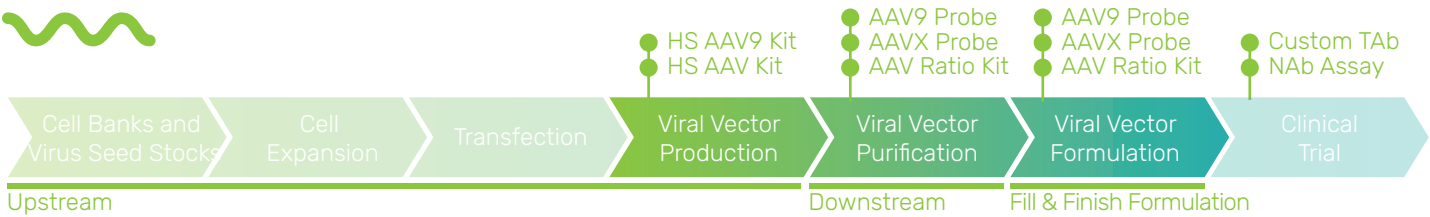
Advantages

- Faster than ELISA with minimal hands-on time
- Compatible with crude samples such as cells lysates and media
- Significantly cost effective because of reusable probes
- Excellent correlation with ELISA



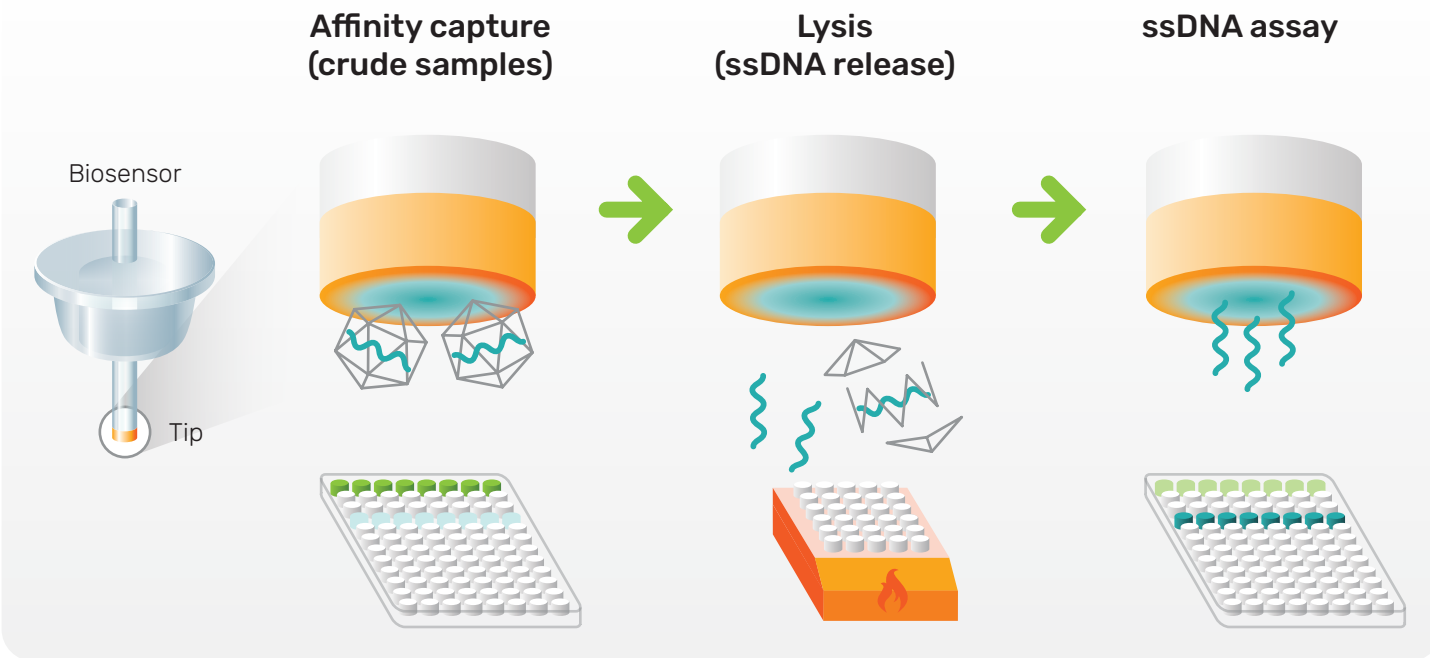
Gator AAVX and ELISA titer correlation for AAV9

AAV empty/full ratio determination



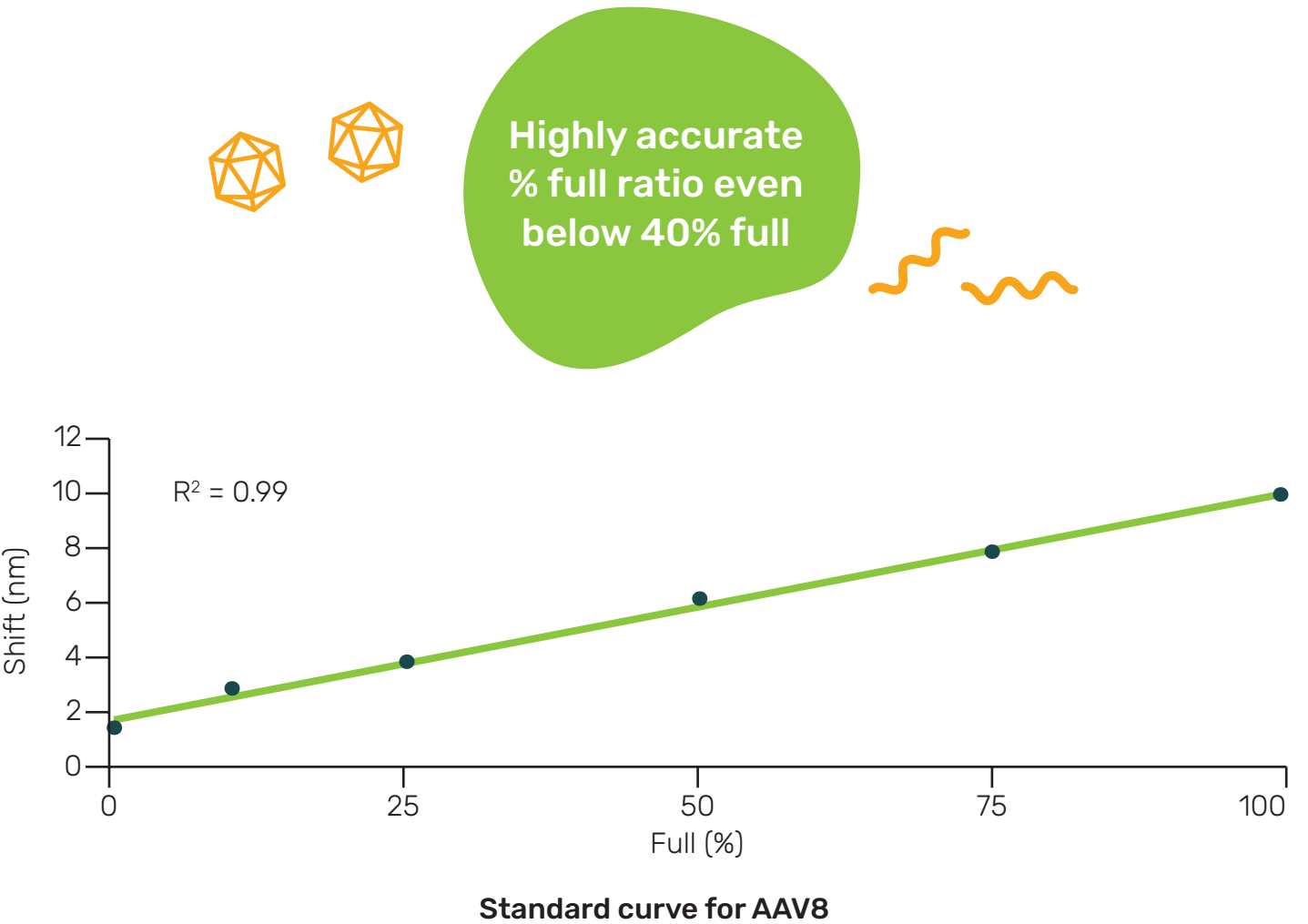
Gator® AAV Ratio Kit detects single stranded DNA content in crude and purified AAV capsids. Unlike techniques like AUC that are only accurate above 40% full, the Gator method is accurate from 0-100% full.

3-step workflow

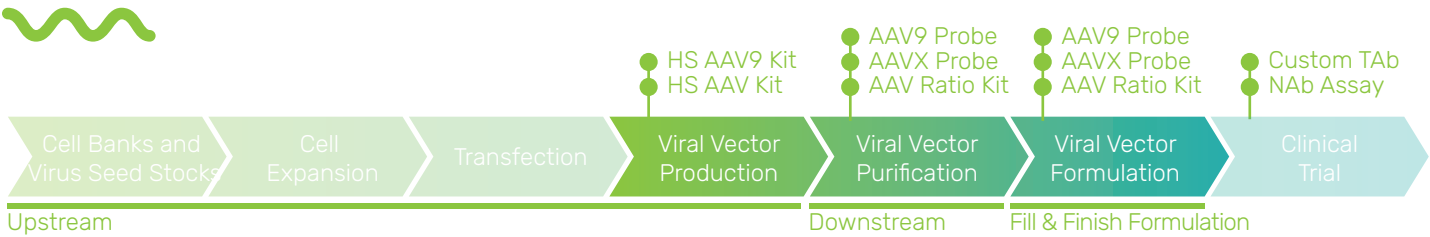


Advantages

- Automated and fast workflow
- Easy integration into upstream process due to no sample preprocessing
- Single platform for empty/full determination
- Fast turnaround time
- Low sample requirement



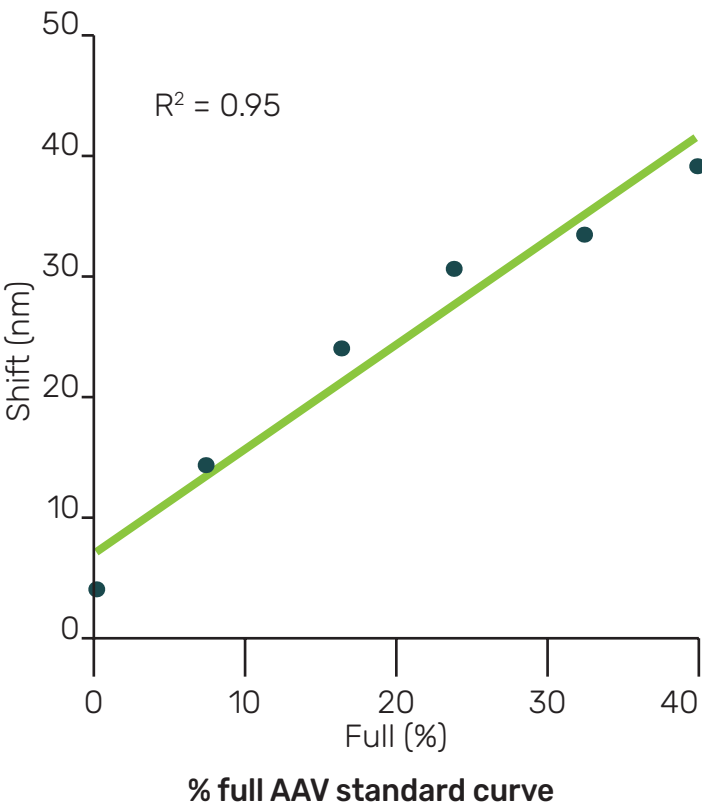
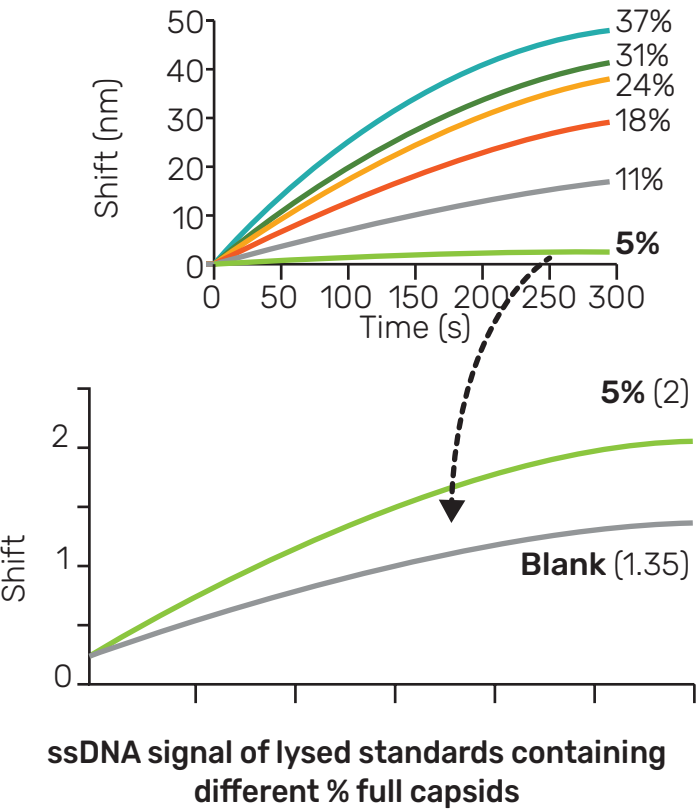
AAV empty/full ratio determination



AAV Ratio kit MDL determination in crude customer samples

The AAV Ratio Kit has an estimated Method Detection Limit (MDL) of 1.8% percent full with customer provided samples that range from 5% to 37% full.

MDL = 1.8% full

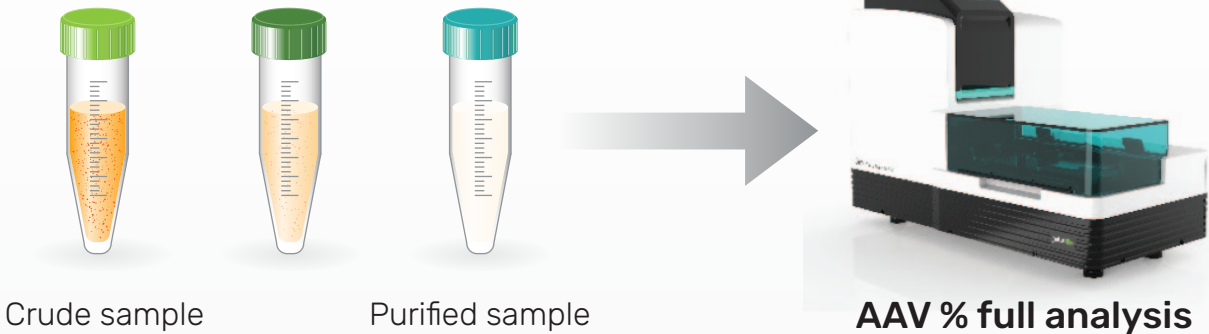


% full ratio determination in crude customer samples

The AAV Ratio Kit crude sample compatibility is demonstrated by data using customer samples from different stages of AAV manufacturing process.

Measured values and rank ordering is in line with gold standard method measurement

Stage of manufacturing



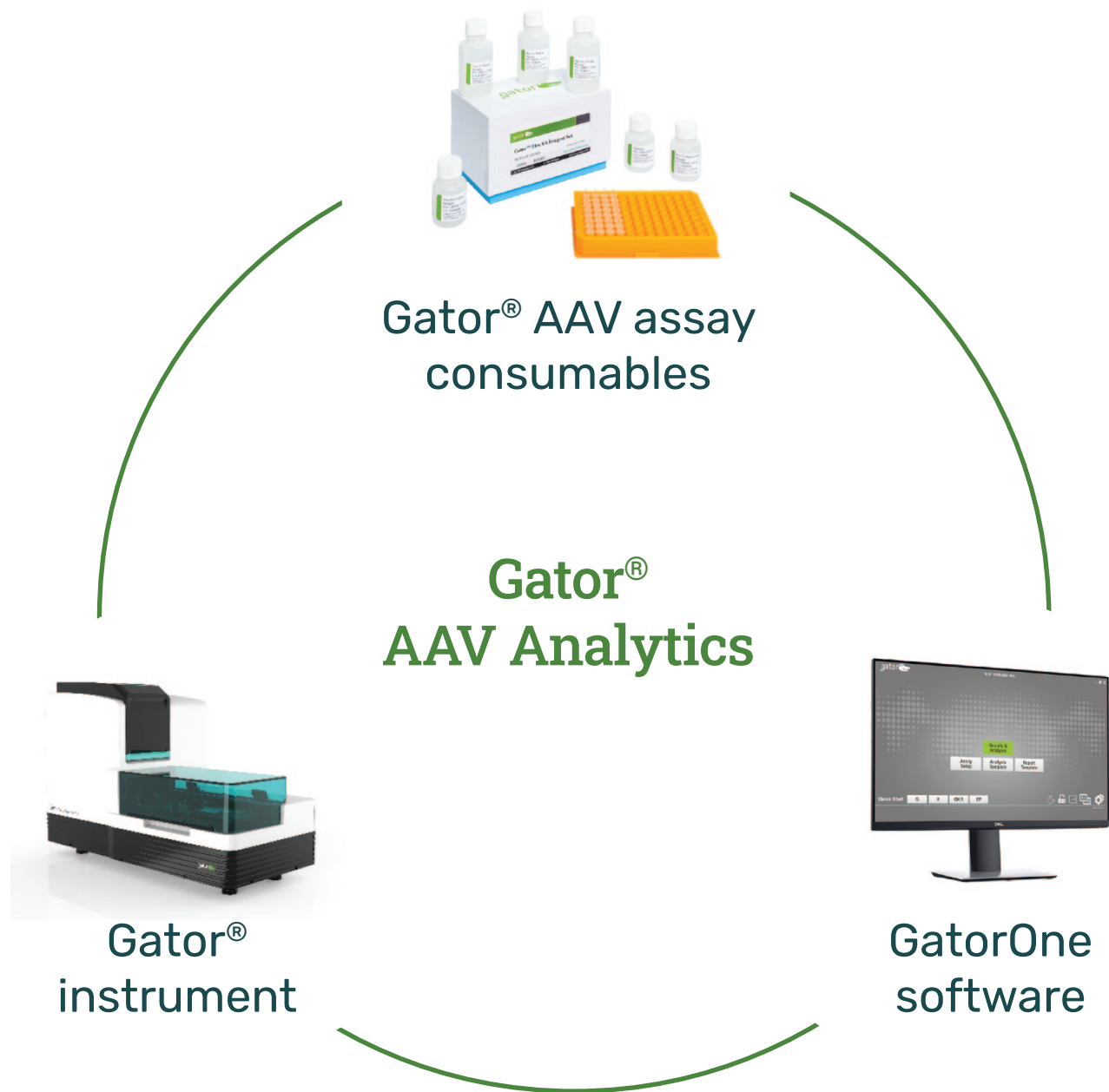
% Full	Buffer							
	1	2	3	4	5	6	7	8
90%	9	4	2	14	13	18	6	10
75%	12	13	3	24	18	17	8	19
60%	2	1	15	28	4	3	13	17
45%	5	12	6	19	10	0	19	19
30%	2	22	9	12	8	8	11	12
10%	27	33	40	5	9	11	38	3

Difference from expected values: <15% 15-25% >25%

Difference between measured and expected % full values for eight different buffers utilized in chimeric AAV2 manufacturing



The patented Gator[®] solution includes BLI instruments, biosensors, chemistry, and software for titer and E/F ratio determination.



Get in touch with us

We're always here to help



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