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AAV Analytics Solutions



Powered by Gator[®] Next-gen Biolayer Interferometry





What is BLI?

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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 10⁷ - 10¹³ vp/mL



Custom TAb and NAb assays for clinical trials





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



Kinetic characterization of AAV neutralizing antibodies

Comparison of Gator® workflow \sim

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.



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Gator® Titer

Gator[®] BLI benefits

Fully

automated

| Crude sample tolerant | Dynamic range vp/mL | CQA | |
|--------------------------|--|--------------|--|
| • | 10 ⁷ - 10 ¹³ | Capsid titer | |
| ٠ | 0% - 100% full and resolution of 5% | E/F ratio | |
| 0 | | E/F ratio | |
| 0 | | E/F ratio | |
| ٠ | 10 ⁷ - 10 ⁹ | Capsid titer | |
| • | 10 ⁵ - 10 ¹⁰ | Genome titer | |
| • | 10 ² - 10 ⁷ | Genome titer | |
| 0 | | E/F ratio | |
| 0 | | E/F ratio | |



Our kits



What makes us different? \sim

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

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Crude matrix compatibility



Single platform for titer and empty/full ratio determination

Automated with minimal time

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.





HS AAV kit standard curve for AAV5

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





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

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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.





Performance

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

Advantages



Significantly cost effective because of reusable probes



Standard curve showing the dynamic range of AAVX probes using AAV2

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Excellent correlation with ELISA

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

Performance

| | AAV Ratio Kit |
|-----------------------------|----------------|
| Range | 0% - 100% full |
| Assay runtime for 8 samples | 40 min. |
| Resolution | 5% |



Advantages



 $R^2 = 0.99$

25



12—

10

8

6

2

0

0

Shift (nm)



888 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**

20

Full (%)

30

40

% 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.





Crude sample

Purified sample

| Upstream samples | | D | ownstream samples | | | | | | |
|---------------------|----|----|----------------------|-------------|--------------|---------|----------|---------|--|
| 000 | | | | | | | | - | |
| Buffer | | | | | | | | | |
| % Full | 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 | |
| | | | Diff | erence fron | n expected v | values: | 15% 15-2 | 5% >25% | |

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

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AAV % full analysis

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.



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We're always here to help

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