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Gator® Next-Gen Biolayer Interferometry

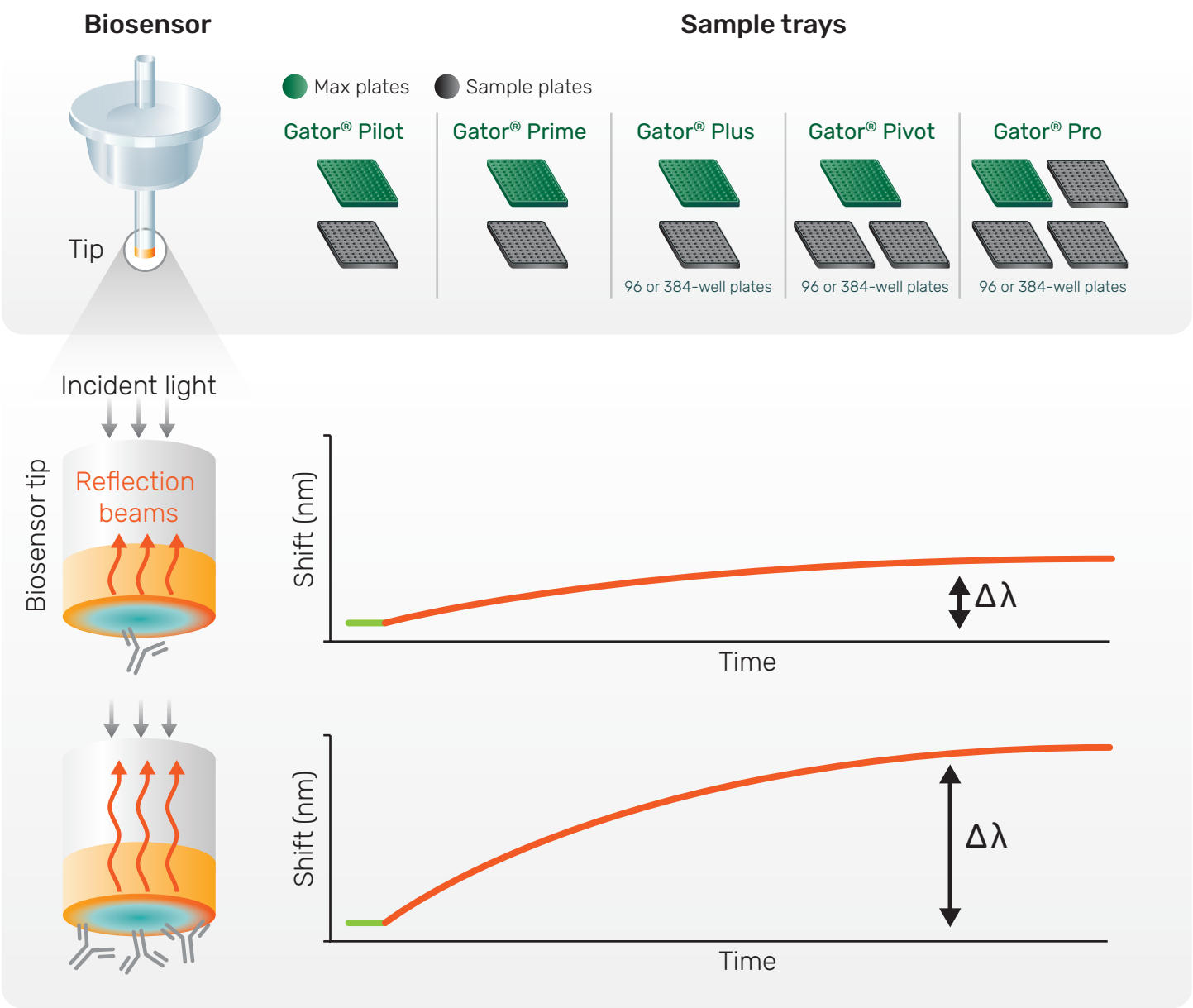


What is BLI?



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.



One tool. Many answers



Gator® systems are label-free analysis instruments based on next-gen biolayer interferometry (BLI) technology.

BLI detects biomolecular interactions by immersing biosensing probes in samples. The next-gen BLI demonstrates higher sensitivity and more robust performance than the other commercial BLI products. It also supports wider range of applications, from drug discovery to therapeutics manufacturing.

Range of Gator instruments also support viral vector analytics with crude sample compatibility, including capsid and genome titer of AAVs and determination of empty versus full (E/F) content, making them suitable for integration into manufacturing processes.

Early discovery	Early development	Lead antibody
Antibody titer determination	Lead optimization	Binding kinetics
Yes/no binding to target antigen	Lead characterization	Activity assay
Isotyping	Detailed kinetic characterization	Stability study
Epitope binning	Epitope binning	
Cross-reactivity testing	Affinity maturation	
Assay development		
Off-rate ranking		
Binding constant determination		

Gator[®] BLI system

The Gator BLI system offers a range of advantages for researchers.

-  Simple and fast assay setup
-  Crude sample analysis
-  Scalable throughput
-  Reusable biosensor
-  Fast to result
-  Robust and low maintenance
-  Real-time binding curves

These features collectively make the Gator BLI system a valuable tool for a wide spectrum of applications, from biotherapeutics development to drug discovery and life science research, enhancing efficiency and accelerating drug discoveries.



Full Suite of Biosensors for Diverse Applications

Probes	Function	Applications	Dynamic Range	Regeneration
ProA	IgG titer	Q	0.02-2000 µg/mL	Yes
ProG	IgG titer	Q	0.02-2000 µg/mL	Yes
ProL	Kappa light chain titer	Q	0.02-2000 µg/mL	Yes
SA	Biotinylated and Avi-tagged molecules	K/EP	Protein dependent	No
SA XT	Biotinylated proteins and large molecules	K	Protein dependent	No
Flex SA	Reusable SA kit	K	Protein dependent	Yes
SMAP	Measurement of small molecules, peptides (<150 Da)	K	Protein dependent	No
HFC	Human IgG characterization	Q/K/QKR/EP	0.05-300 µg/mL	Yes
HFCII	Advanced human IgG characterization	Q/K/QKR/EP	0.3-6000 µg/mL	Yes
MFC	Mouse IgG characterization	Q/K/QKR/EP	0.02-6000 µg/mL	Yes
Anti-FAB	F(ab), F(ab)2	Q/K/QKR/EP	0.3-3000 µg/mL	Yes
APS	Direct adsorption	K	Protein dependent	No
AR	Amine coupling immobilization	K/EP	Protein dependent	No
His	His-tagged proteins	Q/K/QKR/EP	Protein dependent	Yes
Ni-NTA	His-tagged proteins through Ni-NTA	Q/K/QKR/EP	0.25-1000 µg/mL	Yes
Strep-Tactin XT	Proteins with Twin-Strep-tag [®]	Q/K	Protein dependent	Yes
Anti-PEG	PEGylated lipid-based molecules	Q/K	Analyte dependent	No
Anti-GST	GST-tagged proteins	Q/K	0-100% full	No for Q
AAVX	Direct binding titer (AAV1-10)	Q/K	Protein dependent	Yes
AAV9	Direct binding titer (AAV9)	Q/K	1x10 ⁹ - 1x10 ¹³ vp/mL	No
HS AAV	High sensitivity titer (AAV1-8, 10)	Q	3x10 ⁹ - 1x10 ¹³ vp/mL	No
HS AAV9	High sensitivity titer (AAV9)	Q	1x10 ⁷ -5x10 ¹⁰ vp/mL	No
AAV Ratio	Empty vs Full Ratio Determination	Ratio	1x10 ⁷ -1x10 ⁹ vp/mL	No



Epitope binning

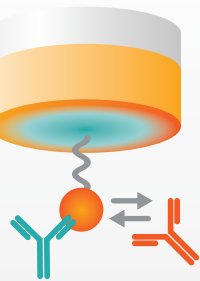


The Gator system is a powerful tool for epitope binning to understand antibody-antigen interactions. Epitope binning plays a pivotal role in selecting and developing antibodies for diverse applications such as diagnostics, therapeutics, and vaccine design. Gator system’s label-free operation, streamlined assay development and high throughput capabilities make it an indispensable asset in antibody engineering and development pipelines.

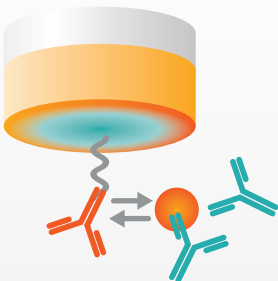
-  Quick and simple assay development
-  Comprehensive suite of biosensors for both sandwich and tandem format
-  Up to 32 x 32 EP assay in less than 8 hours
-  Up to 96 x 96 in 5 days

The workflow is powered by Gator® NaviGator software. Easy data visualization and presentation make interpretation straightforward. Multiple assays can be combined into a larger binning matrix. By combining eight 32 x 32 binning assays, the report for one 96 x 96 competition profile can be achieved in less than 5 days

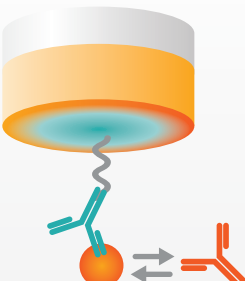
In-tandem



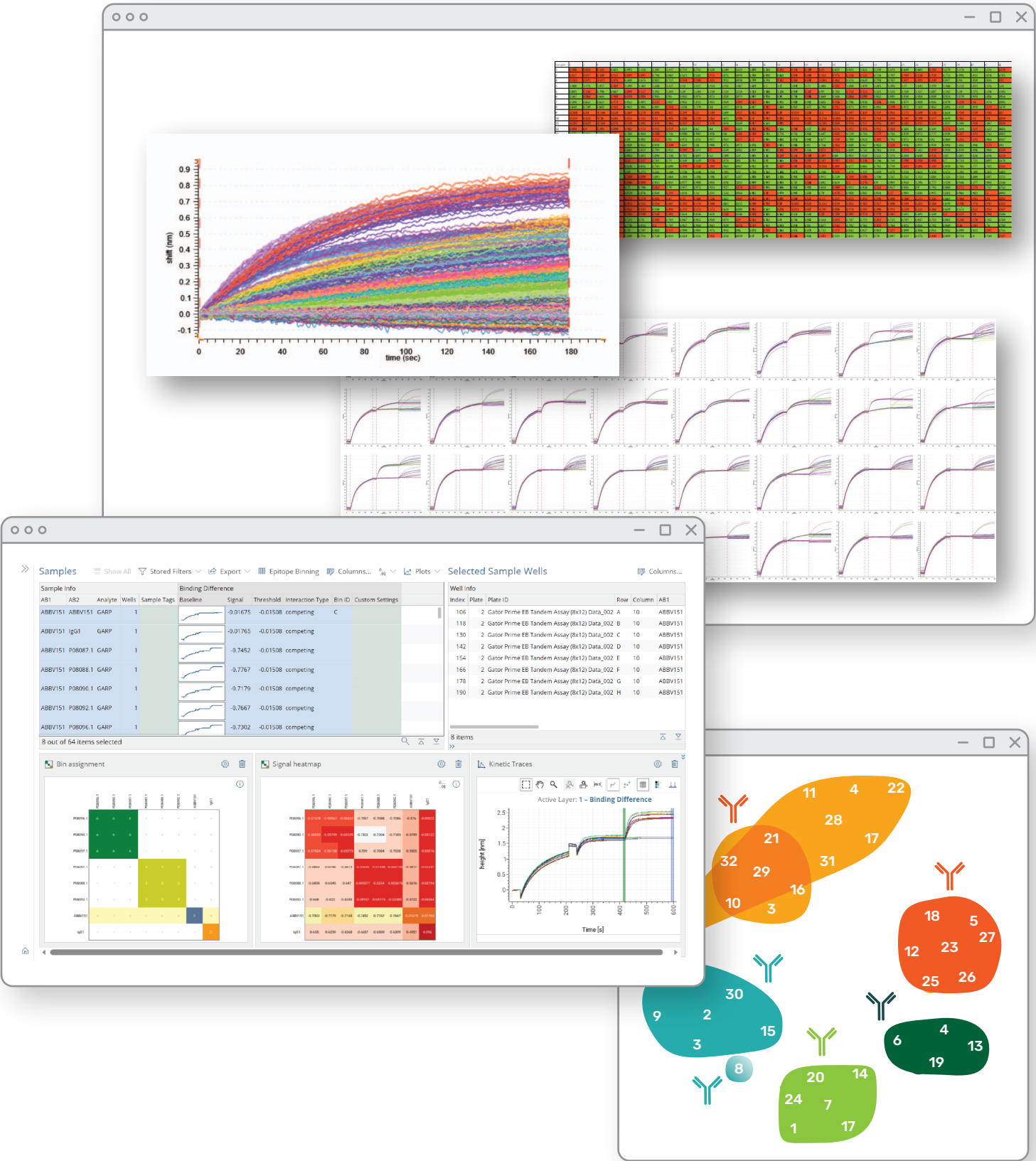
Premix



Classic sandwich



Three epitope binning formats with Gator BLI



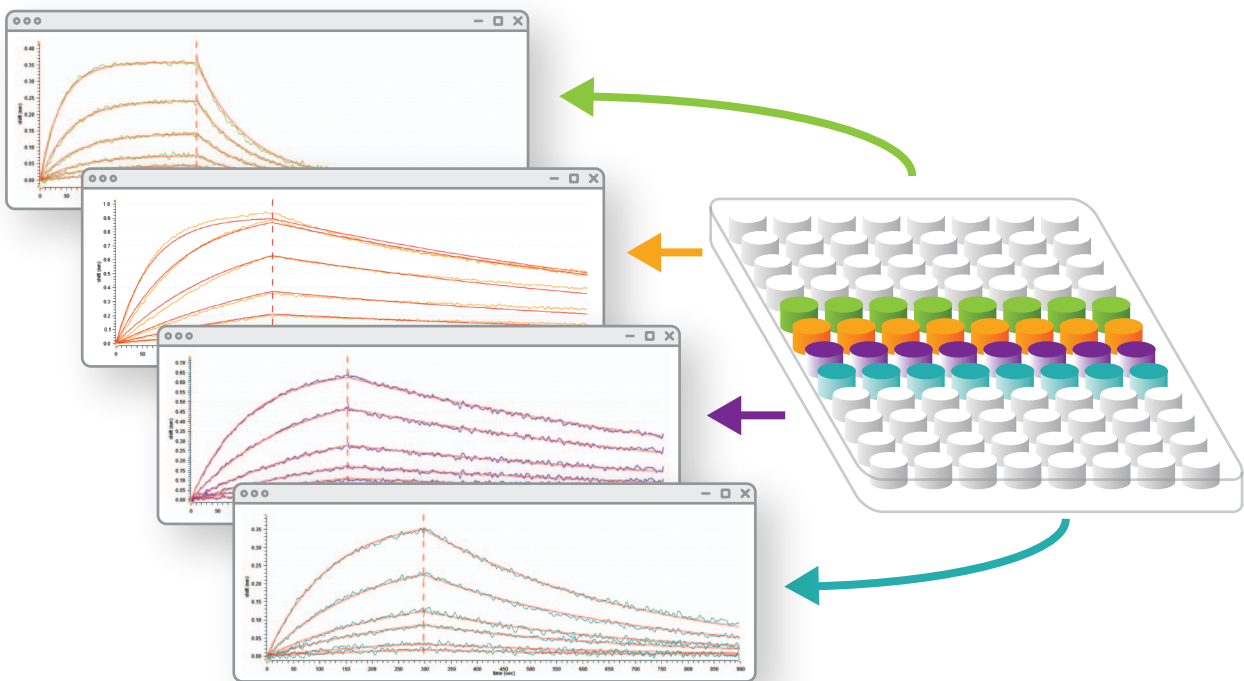
32 x 32 mAb competition matrix performed in less than 8 hours

Kinetic Analysis

The Gator system can be utilized to determine the kinetics of a drug molecule binding to its target.

Association rates (k_{on}), dissociation rates (k_{off}), and equilibrium dissociation constants (K_D) can be determined for antigen-antibody interactions with or without the use of labeled reagents. The Gator system's stable baseline further enhances the quality of high affinity kinetic data.

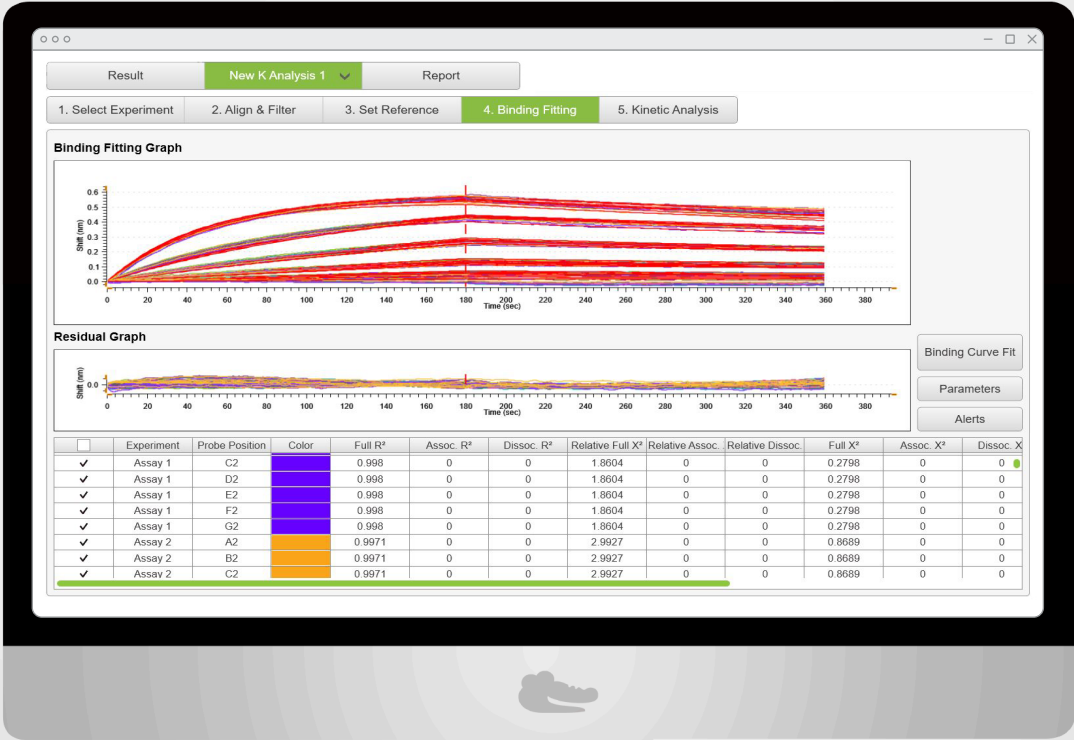
With high-throughput capabilities, Gator system enables the simultaneous analysis of multiple samples and interactions, increasing experimental efficiency. Off-rate ranking in crude media as well as complete binding characterization of a purified antigen-antibody binding pair can be accurately determined using a variety of different biosensors and assay configurations.



Kinetic sensorgrams of 4 different biosimilars in a single run

Highlights

- Simultaneous throughput kinetic analysis
- Customizable analyte concentration ranges for accurate results
- Rapid binding constant determination within 10 minutes
- Wide range of biosensors to support multiple kinetic assay configurations



Gator system is capable of high throughput kinetics screening

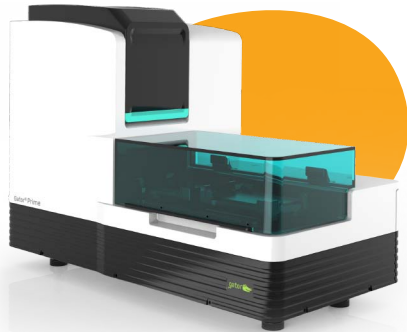
The Gator[®] Family Portfolio

Gator’s comprehensive BLI instrument portfolio, a suite of cutting-edge systems designed to empower researchers to get deeper insights into biomolecular interactions, each meticulously engineered to deliver high performance.



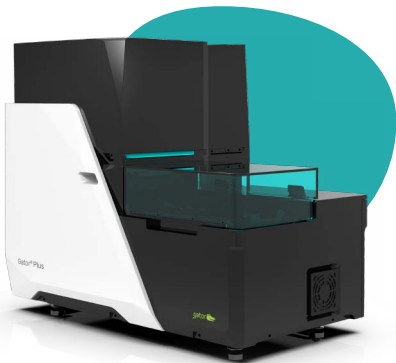
Gator[®] Pilot

- 4-channel simultaneous read
- 96 well format
- 40 samples/batch



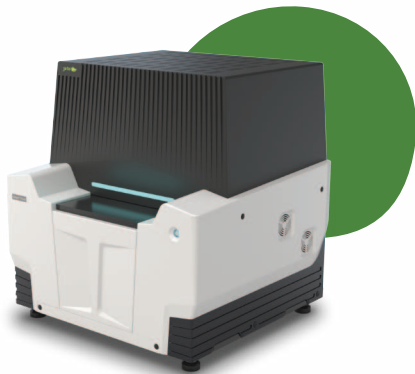
Gator[®] Prime

- 8-channel simultaneous read
- 96 well format
- 168 samples/batch



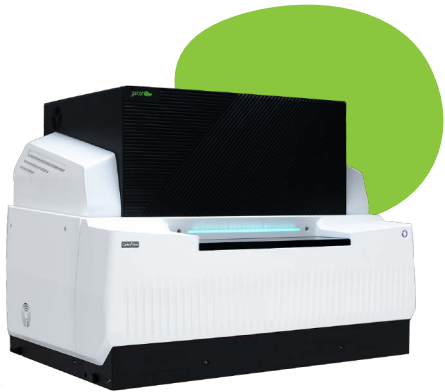
Gator[®] Plus

- 8-channels simultaneous read
- 96 or 384 well format
- 468 samples/batch



Gator[®] Pivot

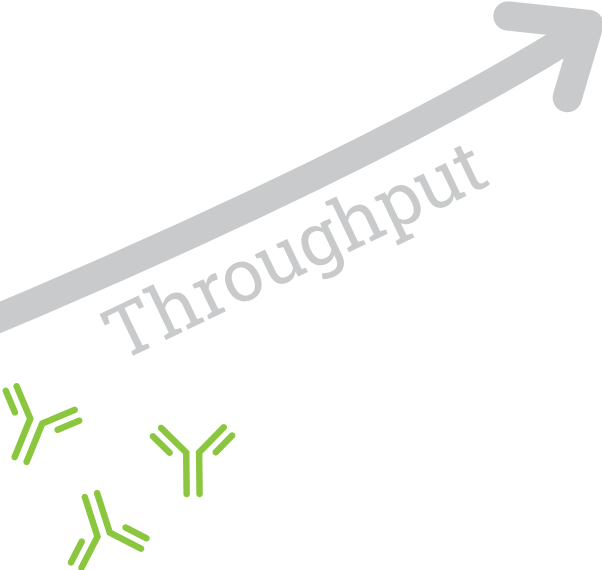
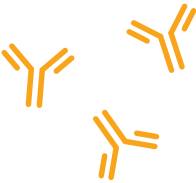
- 16-channel simultaneous read
- Flexible 2 plate format (96 or 384-well plates)
- 816 samples/batch
- Evaporation control & sample cooling



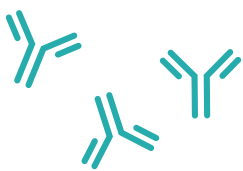
Gator[®] Pro

- 32-channel simultaneous read
- Flexible 3 plate format (96 or 384- well plates)
- 1152 samples/batch

Up to
1,152
samples per batch



Antibody quantitation



Rapid automated direct binding format ensures analytical throughput and accuracy

The Gator system directly determines the concentration of proteins in solution with minimal disruption from intricate matrices in as little as 30 seconds per read, employing a simple one-step assay

Enhanced sensitivity, reaching sub-ng/ml levels, is attainable through 2-step and 3-step assay formats. Additionally, the system allows for better process economics by facilitating the regeneration and reuse of biosensors.

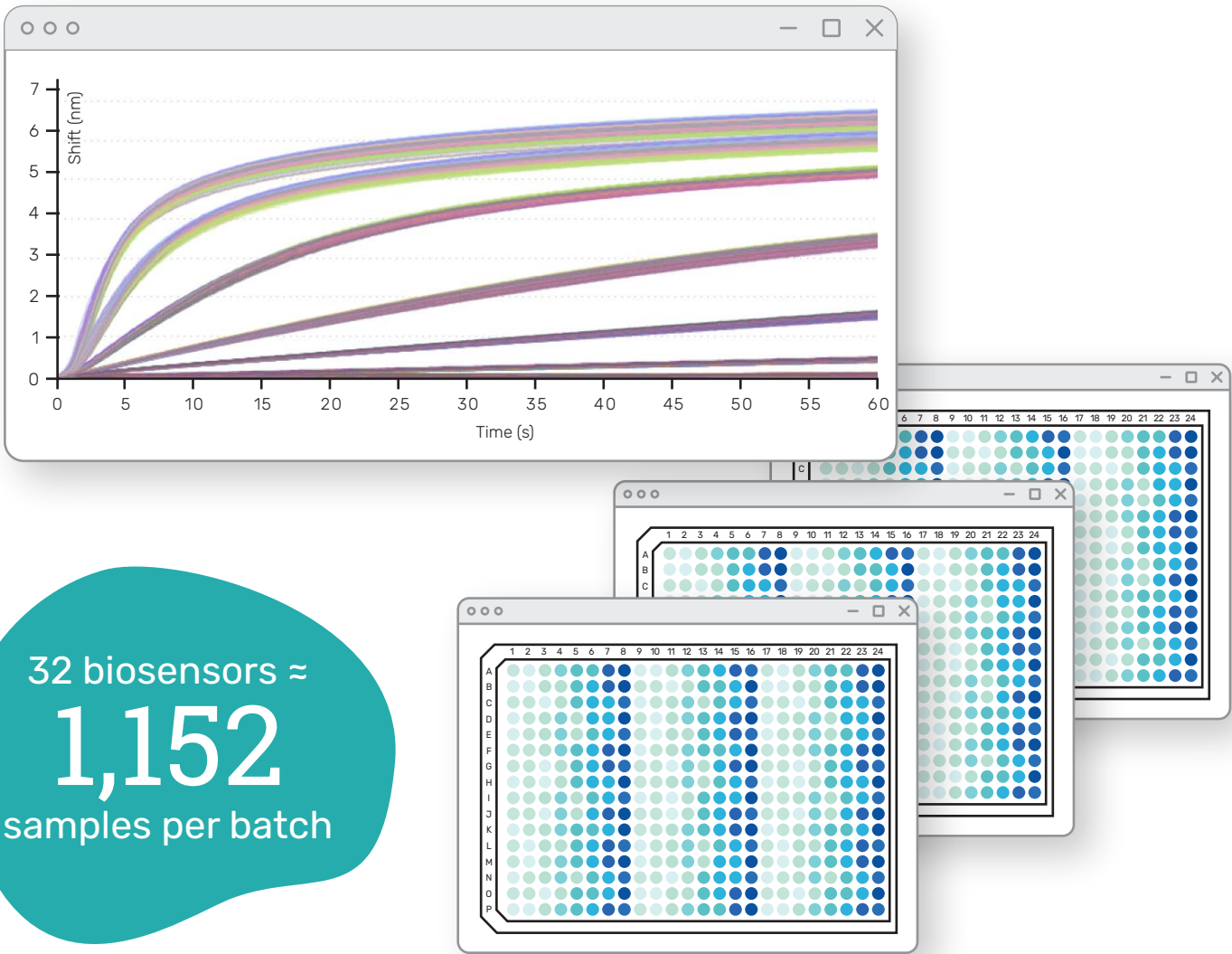
Performance

Known conc. (µg/mL)	Calculated conc. (µg/mL)	Binding rate	Standard deviation	% CV (n = 144)
700	704.00	1.2888	0.0541	4%
300	297.79	0.7435	0.0344	5%
100	103.74	0.2970	0.0159	5%
30	28.35	0.0807	0.0045	6%
10	10.14	0.0260	0.0012	5%
3	3.19	0.0069	0.0004	6%
1	0.98	0.0016	0.0001	9%

Accurate and precise data for 1152 human IgG sample analysis using Gator Bio Protein A biosensors

Highlights

- 5-log dynamic range for titer determination
- Up to 1152 samples per batch from 3 sample plates
- Fully automated quantitation as ELISA replacement
- Reusable biosensors through regeneration for both purified and crude samples



Heat map generated by software for human IgG concentration analysis using Gator Bio Protein A biosensors

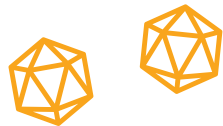
Viral vector analytics



The Gator system provides fast and accurate determination of AAV capsid titer, genome titer, and empty/full ratios.

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.

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



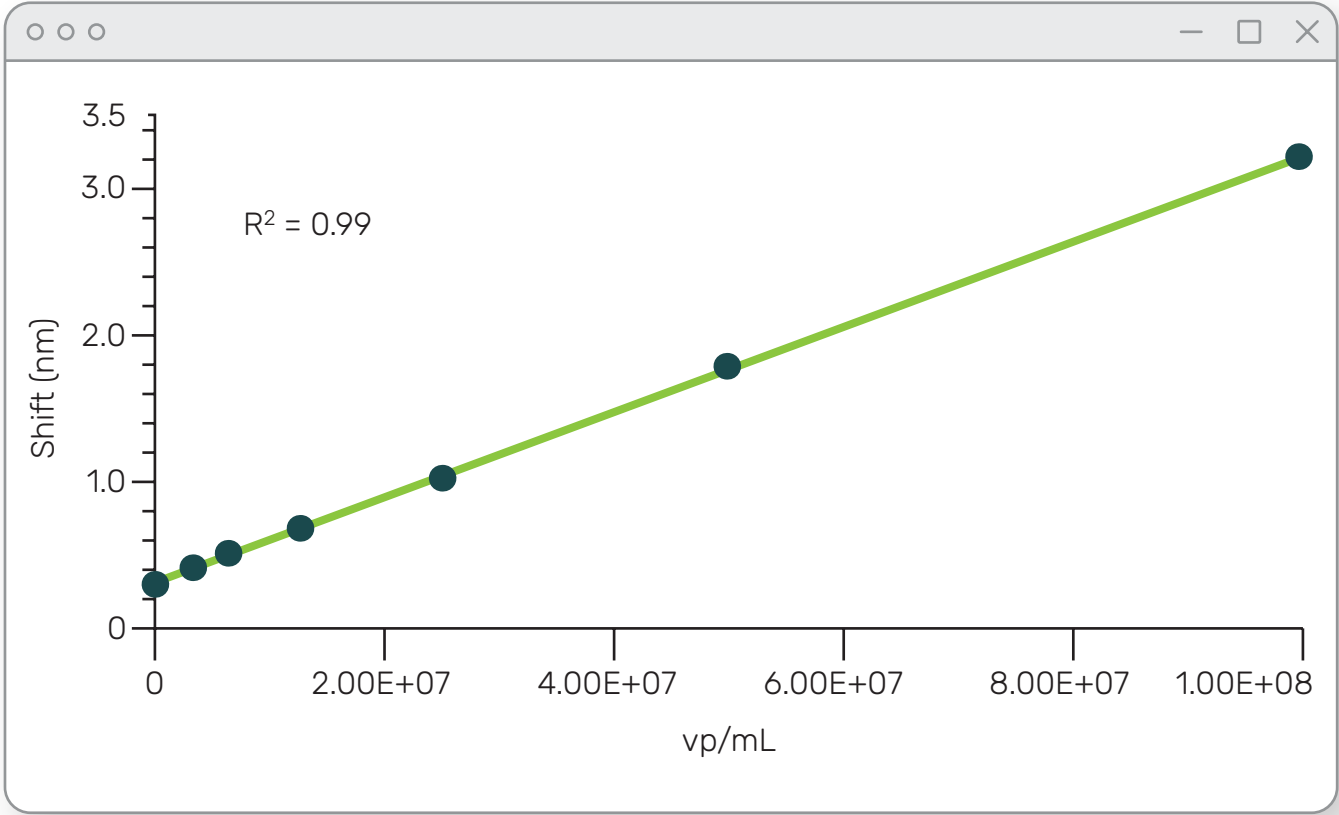
High throughput crude sample analysis



Performance

Known conc. (vp/mL)	Calculated conc.	Standard deviation % CV	(n=6)
1.00E+09	8.70E+08	3.50E+07	4%
5.00E+08	5.31E+08	4.87E+07	9%
2.50E+08	2.78E+08	1.91E+07	7%
1.25E+08	1.31E+08	6.06E+08	5%
6.25E+07	6.60E+07	2.90E+06	4%
3.13E+07	3.06E+07	2.69E+06	3%
1.56E+07	1.58E+07	5.37E+05	9%
7.80E+06	7.60E+06	3.95E+05	5%

Dynamic range and reproducibility of AAV9 titer with high sensitivity AAV9 kit



HS AAV kit standard curve for AAV5

Highlights

- High throughput crude sample analytics
- Up to 32 genome titer assays one run
- "Dilute and dip" workflow for upstream titer determination from complex matrices
- Up to 32 E/F ratio determinations
- Easily customizable assays
- 96 upstream titer samples completed in 100 minutes
- Compatible with all serotypes including chimerics

Gator® Product Specifications



Gator® Pilot



Gator® Prime



Gator® Plus



Gator® Pivot



Gator® Pro

Performance					
Type of analysis	Proteins, antibodies, peptides, nucleic		acids, liposomes, viruses, small molecules		
Simultaneous reads	4	8	8	8 and 16	8, 16, 24, and 32
Maximum sample capacity	40	168	456	816	1152
Molecular weight	> 150 Da	> 150 Da	> 150 Da	> 150 Da	> 150 Da
Association rate (k _{on})	10 ¹ to 10 ⁷ M ⁻¹ s ⁻¹	10 ¹ to 10 ⁷ M ⁻¹ s ⁻¹	10 ¹ to 10 ⁷ M ⁻¹ s ⁻¹	10 ¹ to 10 ⁷ M ⁻¹ s ⁻¹	10 ¹ to 10 ⁷ M ⁻¹ s ⁻¹
Dissociation rate (k _{off})	10 ⁻⁶ to 10 ⁻¹ s ⁻¹	10 ⁻⁶ to 10 ⁻¹ s ⁻¹	10 ⁻⁶ to 10 ⁻¹ s ⁻¹	10 ⁻⁶ to 10 ⁻¹ s ⁻¹	10 ⁻⁶ to 10 ⁻¹ s ⁻¹
Affinity constant (K _D)	10 pM – 1 mM	10 pM – 1 mM	10 pM – 1 mM	10 pM – 1 mM	10 pM – 1 mM
Quantitation range (Protein A biosensor)	0.02 – 2000 µg/mL	0.02 – 2000 µg/mL	0.02 – 2000 µg/mL	0.02 – 2000 µg/mL	0.02 – 2000 µg/mL
Binning capacity	6x6	12x12	16x16	20x20	32x32
Baseline noise (RMS)	≤ 4 pm	≤ 4 pm	≤ 4 pm	≤ 4 pm	≤ 4 pm
Baseline drift	≤ 0.12 nm/hour	≤ 0.12 nm/hour	≤ 0.1 nm/hour	≤ 0.1 nm/hour	≤ 0.1 nm/hour
Acquisition rate	2, 5, and 10 Hz	2, 5, and 10 Hz	2, 5, and 10 Hz	2, 5, and 10 Hz	2, 5, and 10 Hz
Specifications					
Spectrometers	4	8	8	16	32
Sample microplate*	96-well format ¹	96-well format ^{1,2}	96 or 384-well format ^{1,2,3,4}	2 x 96 or 384-well format ^{1,2,3,4}	3 x 96 or 384-well format ^{1,2,3,4}
Evaporation control	No	No	No	Yes	No
Sample temperature control	Ambient plus 4°C to 40°C	Ambient plus 4°C to 40°C	Ambient plus 4°C to 40°C	15°C to 40°C	Ambient plus 4°C to 40°C
Automation compatible	No	No	No	Yes	Yes
Minimum sample volume	180 µL ¹	130 µL ²	40 µL ⁴	40 µL ⁴	40 µL ⁴
Smart monitoring	No	No	No	Yes	Yes
Self-cleaning	No	No	No	Yes	Yes
Dimension - HxWxD (cm)	49 x 68 x 33	47 x 67 x 31	68 x 73 x 44	92 x 87 x 79	84 x 114 x 77
Weight (kg)	31 kg	35 kg	55 kg	130 kg	220 kg

*Gator Bio offers ¹ 96-well flat-bottom, ² 96-well tilt-bottom, ³ 384-well flat-bottom and ⁴ 384-well tilt-bottom microplates for range of BLI applications

Compliance

Biopharma GxP Compliant Total Solution

Gator® IQOQ Service Bundle

Gator Bio offers Installation Qualification (IQ) and Operational Qualification (OQ) for systems to ensure critical components are tested and validated.

Certified Gator Bio personnel provide installation of supplied computer workstations and systems, and systematically document the instrument qualifications in alignment with Gator Bio's verified specifications.

Gator Software for GMP and GLP

Gator® Part11 Software enables users in GMP or GLP environments to comply with FDA 21 CFR Part 11 regulations. All data acquired with the Part11 Software is time-stamped and traceable. Features such as account management, enhanced audit trails, and recorded user sessions are in compliance with FDA guidance.



The patented Gator® solution includes BLI instruments, biosensors, chemistry and software for biotherapeutics discovery.

