



Gator Next-Gen Biolayer Interferometry

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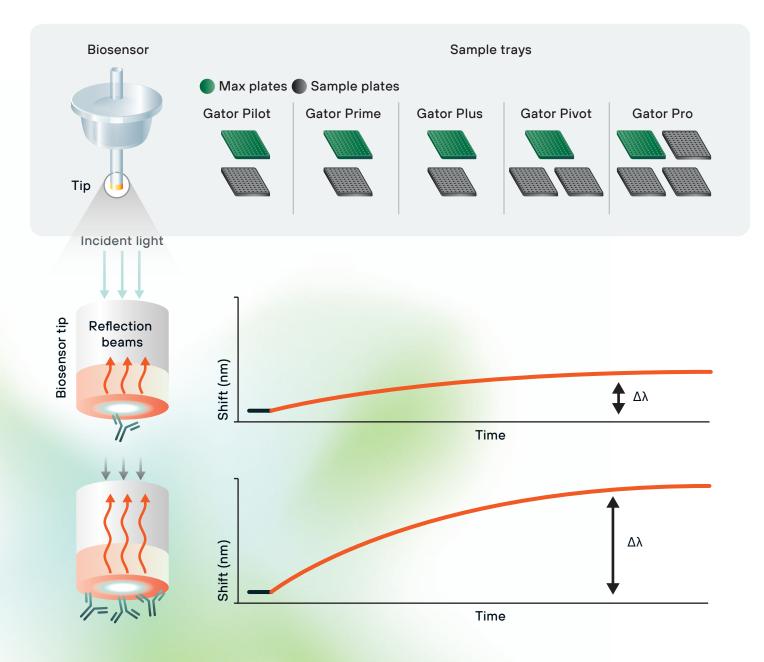




What is BLI?

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

Antibody titer determination

Yes/no binding to target antigen

Isotyping

Epitope binning

Cross-reactivity testing

Assay development

Off-rate ranking

Binding constant determination

Early development

Lead optimization

Lead characterization

Detailed kinetic characterization

Epitope binning

Affinity maturation

Lead antibody

Binding kinetics

Activity assay

Stability study

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Gator Bio BLI System

The Gator Bio BLI System offers a range of advantages for researchers.

Simple and fast assay setup

Scalable throughput

Fast to result

Real-time binding curves

These features collectively make the Gator Bio 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.



Crude sample analysis

Robust and low maintenance

Reusable biosensor



Full Suite of Biosensors for Diverse Applications

Gator Probes	Applications	~	Jantita	inor Lines	Dynamic ran (μg/mL)	ge /sè
ANTIBODY BIOSENSO		G	/ 4	s/ v	х/ (ру/піс)	/ Ұ
Pro A	lgG titer	•		•	0.02 - 2000	•
Pro G	IgG titer	•		•	0.02 - 2000	•
Pro L	lgG Titer using kappa-light chain	•		•	0.02 - 2000	•
HFC	Human IgG characterization by human IgG Fc capture		•	•		•
► HFC Gen II	Second-generation HFC probes with higher affinity capture and better regenerability	•	•	•	0.3 - 6000	•
MFC	Mouse IgG characterization by mouse IgG Fc capture	•	•	•	0.02 - 6000	•
Anti-Rabbit Fc	Rabbit IgG characterization by rabbit IgG Fc capture	•	•	•	0.05 - 4000	
Anti-FAB	F(ab), F(ab)2 characterization by CH1 capture	•	•	•	0.3 - 3000	•
∍ IgM	Human IgM titer/characterization	•	•		0.4 - 300	•
► Anti-VHH	Camelid anti-VHH characterization	•	•		0.05 - 10	•
PURIFICATION TAGS						
Anti-His	Captures C- and N-terminal 6-His and 8-His tagged proteins	•	•	•	~1 - 100	•
Ni-NTA kit	Ni-NTA capture surface for purified His-tagged proteins	•	•	•	~1 - 100	•
Strep-Tactin XT	Captures win-strep-tagged proteins (seq: SAWSHPQFEKGGGSGGSGGSAWSHPQFEK)	•	•	•	~0.02 - 20	•
Anti-GST	Captures GST-tagged proteins	•	•	•	0.5 - 300	•
Anti-FLAG	Captures FLAG-tagged proteins		•			
STREPTAVIDIN SUITE						
SA	Streptavidin surface. Captures biotinylated molecules		•	•		
♥ SA XT	High sensitivity SA probe for low Mw (>1 kDa) and high Mw (<2MDa) analytes		•	•		
SMAP	High sensitivity SA for small molecule and small peptide analytes.		•			
FlexSA kit	Re-activatable SA biosensor kit		•			•
CELL & GENE THERAF	γ					
AAVX/AAV9	Measures intact AAV viral particle titer	•	•		7E ⁹ - 1E ¹⁴ vp/ml	
HSAAVX/AAV9 kit	Measures low concentration intact AAV viral particle titer	•			1E ⁷ - 1E ⁹ vp/ml	
AAV Ratio kit	Determine AAV empty/full capsid ratio	•			5 - 100% full	
Anti-PEG	Captures PEGylated proteins/LNPs		•			
JSER-CUSTOMIZED (CHEMISTRIES					
AR	Amine coupling surface ready for EDC-NHS coupling		•			
APS	APS surface for hydrophobic ligand capture		•			
· Custom	Customized to your specifications	•	•	•	Varies	Varie

Conly available with Gator® Bio.

Epitope Binning

The Gator Bio BLI 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



Up to 32 x 32 EP assay in less than 8 hours

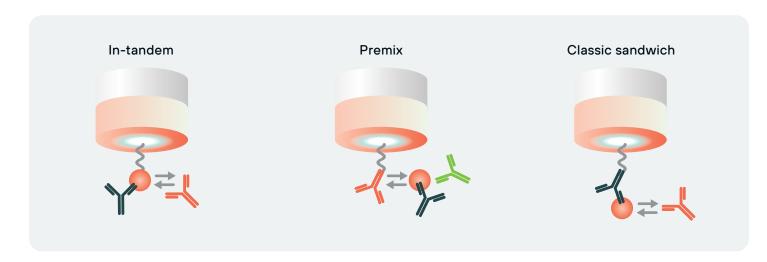


Comprehensive suite of biosensors for both sandwich and tandem format



Up to 96 x 96 in 5 days

The workflow enables streamlined data visualization and presentation, making interpretation straightforward. Multiple assays can be combined into a larger binning matrix, allowing rapid and efficient generation of comprehensive competition profiles. By combining eight 32 × 32 binning assays, the report for one 96 × 96 competition profile can be achieved less than 5 days. This workflow is designed to integrate seamlessly with downstream high-throughput data analysis and visualization solutions.



Three epitope binning formats on Gator Pro



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

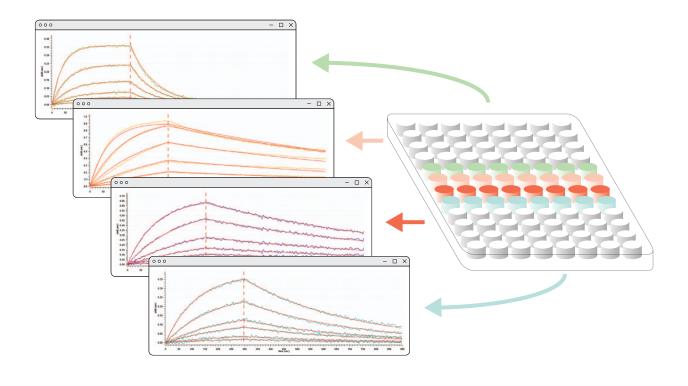
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Kinetic Analysis

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 Bio BLI 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

X Simultaneous throughput kinetic analysis

Rapid binding constant
determination within 10 minutes

Customizable analyte concentration ranges for accurate results

Wide range of biosensors to support multiple kinetic assay configurations



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Gator Bio BLI Instruments

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



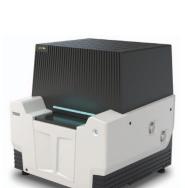
Gator Prime

- 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



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

Throughput

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Antibody Quantitation

Rapid automated direct binding format ensures analytical throughput and accuracy

The Gator Bio BLI System directly determines the concentration of proteins in solution with minimal disruptions 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

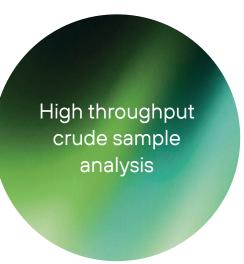
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Viral Vector Analytics

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.

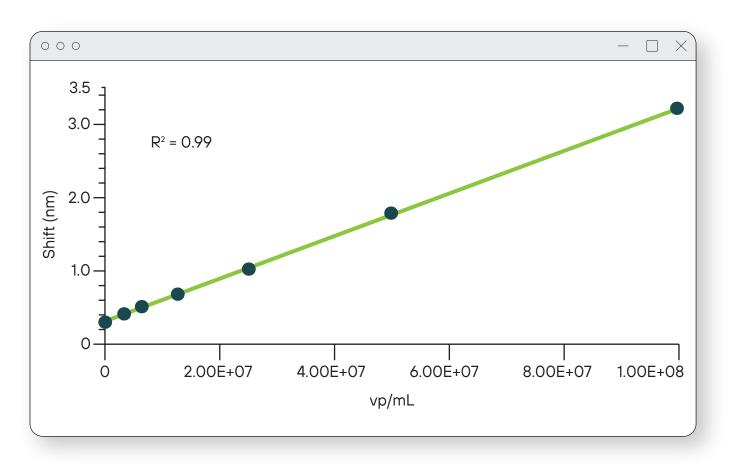
The "dilute and dip" method for complex matrices simplifies the workflow that can be deployed in any laboratory supporting AAV processing. These methods have much shorter turnaround time compared to other methods



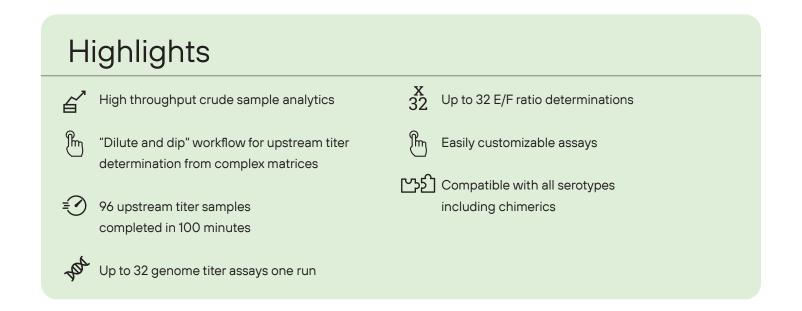
Performance

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



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Gator Bio Product Specifications







Gator Pivot



Gator Pilot

Gator Prime

Gator Plus

Gator Pro

PERFORMANCE							
Type of analysis		Proteins, antibodies,	peptides, nucleic acids, liposomes, v	iruses, small molecules			
Maximum simultaneous read	4	8	8	Up to 16	Up to 32		
Maximum sample capacity	40	168	456	816	1152		
Molecular weight	> 150 Da						
Association rate (k _{on})	10¹ to 10 ⁷ M ⁻¹ s ⁻¹						
Dissociation rate (k _{off})	10 ⁻⁶ to 10 ⁻¹ s ⁻¹						
Affinity constant (K _D)	10 pM – 1 mM						
Quantitation range (Protein A biosensor)			0.02 – 2000 μg/mL				
Binning capacity	6x6	12x12	16x16	20x20	32x32		
Baseline noise (RMS)	≤ 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						
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} .		
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 μL¹	130 µL²	40 µL⁴	40 µL⁴	40 µL⁴		
Smart monitoring	No	No	No	Yes	Yes		
Self-cleaning	No	No	No	Yes	Yes		
Dimension - H x W x D (cm)	50 x 68 x 33	48 x 67 x 31	69 x 73 x 44	95 x 87 x 79	84 x 114 x 78		
Weight (kg)	31 kg	35 kg	55 kg	130 kg	220 kg		

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Compliancy

Biopharma GxP Compliant Total Solution

Gator Bio IQOQ Service Bundle

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

Certified Gator Bio personnels 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 Bio BLI System 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 Bio solution includes BLI instruments, biosensors, chemistry and software for biotherapeutics discovery.



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