

Octet® Systems

Superior Performance, Unrivaled Flexibility Simplifying Progress

SARTURIUS

# Answer Your Toughest Research Questions

Your research should be guided by your imagination, not by the limitations of your label-free system. The Octet® platform's flexible, open-format design and comprehensive menu of biosensors lets you attack research challenges in unique new ways. Perform truly comprehensive structure/function studies with large panels of structural variants.

### Antibody and antibody fragment characterization

- Determination of  $k_a$ ,  $k_d$  and  $K_D$  for antibody-antigen binding
- Affinity and off-rate ranking in crude supernatants
- Antibody engineering and affinity maturation

#### Protein-protein and proteinpeptide interactions

- Structure/function and mechanism-of-action studies
- Kinetic analysis of panels of structural variants
- Wild-type versus mutant analysis

#### Protein DNA/RNA interactions

- Transcription factor interaction studies
- RNA regulation by RNA binding proteins
- Translational control mechanisms

#### Protein-lipid interactions

- Protein-liposome interactions
- Kinetic analysis of membrane proteins

#### Virus and vaccine research

- HIV envelope protein research
- Evolution of virus binding selectivity
- Antiviral antibody development

#### Protein-small molecule interactions

- Label-free detection down to 150 Da
- Binding constants including
   k<sub>a</sub>, k<sub>a</sub> and K<sub>D</sub>
- Rapid label-free library screening



# Robust and Versatile Platform for Label-Free Interaction Analysis

The Octet® platform's unique Dip and Read assay format handles crude, unpurified samples with ease. Study molecular interactions and binding kinetics in real-world samples that just can't be run on microfluidics-based platforms.

#### Analyze your toughest samples

The Octet® platform's design and configuration enables the analysis of complex samples.

- Analyze unfiltered cell culture supernatants and lysates
- Study molecular interactions in biologically-relevant environments
- Straightforward avidity analysis of viruses and virus-like particles

#### Perfect for multiuser environments

Octet® systems are known for their reliable, trouble-free operation and have quickly become the go-to systems at both academic and industrial labs because of their ease of use and application flexibility.

- Low maintenance, no need for dedicated operators
- Learn to use in two hours or less
- Full menu of biosensors enables unconstrained exploration

#### Label-free simplicity

Our Dip and Read biosensor technology enables direct determination of active protein concentrations with tight CVs and a broad dynamic range, without the need for expensive detection reagents.

- Quantitate 96 samples in as little as 2 minutes
- Excellent data correlation with HPLC and ELISA
- No pre-analysis purification steps needed

#### Boost your productivity

All Octet® systems offer intuitive workflows and walk-away automation to accelerate your research programs. Octet® 96- and 384-well format instruments use identical biosensors, letting you transfer methods worldwide with confidence.

- Develop assays in hours, not weeks
- Powerful screening applications for mAb selection and optimization
- Run 384-well plates in as little as 15 minutes

#### Need based upgradeability

The Octet® R series comes in a modular format of 2-, 4- and 8-channel instruments.

- Along with the high sensitivity and performance offered by the Octet® platform, this new series offers field upgradeability for maximum flexibility and future proofing of your investment. Increase your system's throughput when you need it.
- Field based upgradeability saves time, since no packaging of the old system and shipping to the depot site or trade-in are required.
- Modular platform allows you to enter the automated BLI market at a low cost and upgrade according to your budget and throughput requirements.



### **Analytical Workhorse**

#### Target identification and validation

Real-time binding data provide unique insights into the specific molecular interactions that regulate cellular processes, and can help pinpoint the aberrant molecular interactions that lead to pathway dysregulation and ultimately to disease.

- Probe cell signaling control mechanisms
- Dissect ligand/receptor interactions
- Discover novel therapeutic targets

#### **Lead optimization**

Label-free kinetic characterization data provide key insights that help drive your drug optimization process and guide the evolution of secondary screening hits into true lead candidates.

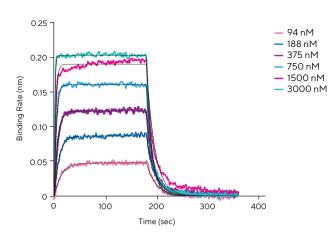
Octet® systems dramatically accelerate protein engineering studies by providing detailed kinetic profiles, expert data analysis tools, and walk-away automation.

- Affinity engineering and maturation
- Engineering of Fc receptor binding profiles
- Tools for epitope binning and mapping

#### Lead identification

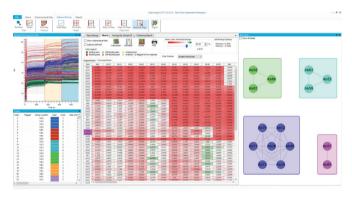
Octet® systems let you perform screening-based lead identification, whether the samples are derived from primary hybridoma hits or from phage display libraries. Early identification and selection of candidates with promising affinities, dissociation rates and epitopic diversity helps avoid later-phase failures caused by non-ideal binding characteristics.

- Unmatched throughput for screening campaigns
- Kinetic screening and off-rate ranking
- Direct kinetic profiles from crude samples
- Advanced tools for epitope binning in unpurified samples



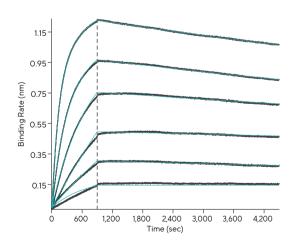
#### Small molecule kinetics.

Octet® R2, R4, R8, RH16 and RH96 systems combine rapid data acquisition and high sensitivity detection to enable label-free kinetic analysis of small molecule-protein binding interactions.



#### Epitope binning.

Powerful epitope binning data analysis tools enable easy visualization of large data sets. Automatically find the binning cycle pattern, assign Antibody 1 and Antibody 2, to create a gradient matrix and BinChart.



#### Large molecule kinetics.

Affinity and binding rate constants can be determined by running an analyte concentration series. Octet® software provides a selection of data fitting models to accommodate both simple and complex binding interactions.

### Accelerating Biotherapeutic Development

#### Cell line development

Traditional titer determination techniques create bottlenecks during process optimization due to long analysis times, lack of specificity, and labor-intensive protocols. Octet® systems accelerate upstream process optimization by offering rapid assay development, exquisite specificity, and full-plate quantitation in record time.

- Full-plate titer determination in as little as 5 minutes
- Optimize media and growth conditions
- Excellent data correlation with HPLC and ELISA
- Glycosylation screening of cell culture supernatants

#### Pharmacokinetics and pharmacodynamics

High detection sensitivity, a wide dynamic range, and streamlined workflows that shave hours or even days from standard processes make the Octet® system a compelling alternative to ELISA for pharmacokinetic and pharmacodynamic studies.

Anti-drug immune responses can be precisely characterized in serum samples, providing a detailed profile of antibody isotype, specificity, and affinity.

- Detection of immune response
- Antibody isotype, specificity and affinity
- Perfect for low-affinity ADAs

#### Process development

Octet® assays significantly speed downstream process development and optimization studies, enabling rapid quantitation of protein products and process-related impurities at multiple in-process points.

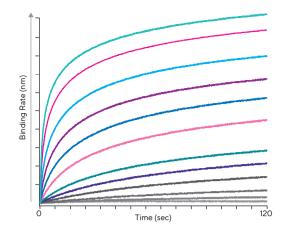
- Monitor column flow-through for dynamic binding capacity studies
- Optimize binding and elution conditions
- Ultrasensitive detection of contaminant testing including host cell proteins and residual Protein A

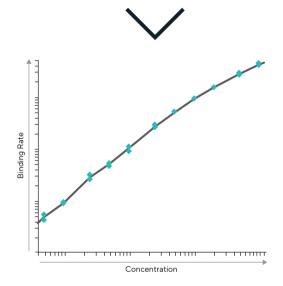
#### Manufacturing and quality control

Monitor protein activity, stability, and impurity profiles throughout your downstream processing – right down to the final product.

Octet® software and systems tools enable seamless transfers to GxP environments.

- Characterize biotherapeutic activity and binding kinetics
- Monitor potency and stability
- Ideal orthogonal technique for cell-based studies



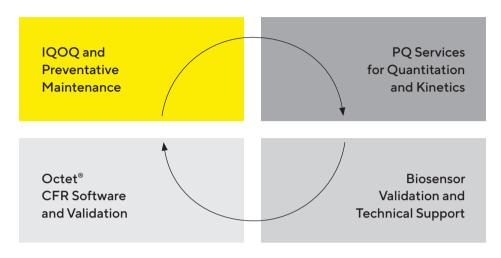


#### Protein quantitation.

The Octet® system's Dip and Read format allows direct quantitation of mAbs and other proteins. A standard curve is generated using known analyte concentrations, and unknown sample concentrations are interpolated from the standard curve.

### Confident Compliance

Octet® systems accelerate every stage of biotherapeutic drug discovery and development by delivering results rapidly for a large number of assay types. Comprehensive tools for GxP compliance combined with extreme simplicity of operation enable application of Octet® systems in analytical development and regulated quality control (QC) labs.

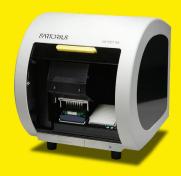


Octet® assays for concentration and impurity analysis have been implemented in both upstream and downstream process development workflows, and for in-process testing to monitor the quality of the product during manufacturing.

Octet® systems are ideal for use in regulated environments, with available installation and operational qualification services, maintenance support and 21 CFR Part 11-compliant software tools.







### Comprehensive Qualification and Validation

An optional GxP package is available to easily integrate Octet® systems into your GxP workflow.

### The GxP package includes the following:

- Installation and Operational Qualification (Biosensor) Services
- Performance Qualification (PQ) Kits
- Octet® CFR Software
- Software Validation Package Support
- Biosensor Validation Service

#### Service Plans

The GxP packages also include IQOQ and PQ service service plans for qualified engineers to perform the various qualifications on-site and generate reports for audit trails of the instrument qualification and performance to fulfill regulatory requirements.

### Installation and operational qualification kit and services

The IQOQ Kit provides comprehensive documentation to verify the Octet® instrument, accessories and computer system are supplied and installed per Sartorius' guidelines by certified personnel. It also provides documented verification that the Octet® instrument operates as intended at the user site by inspecting the critical components.

#### Performance qualification kits

Sartorius PQ Kits provide rapid and convenient methods to verify performance of your Octet® R8 and RH16 instruments. PQ can be performed using one or both of two tightly controlled kinetics and quantitation assays, depending on the intended use of the instrument.

### Octet® CFR Software and software validation package

Using software that complies with 21 CFR Part 11 guidelines and validating the software are regulatory requirements prior to using any analytical instruments in a GxP environment. Octet® CFR Software includes features such as controlled user access, comprehensive audit trails, customized locked reports and electronic signatures.

For researchers working in GLP or GMP laboratories, the Octet® Software Validation Package provides the most comprehensive documentation and tools available to validate the Octet® CFR Software features. It trims validation time to just three days using documentation that mirrors the validation process in a regulated laboratory.

#### Biosensor validation service

This service enables Octet® system users to sample multiple lots of a biosensor during assay qualification and validation, and reserve a well-characterized lot for purchase.



### Choosing Your System

The Octet® family of instruments meet a broad range of application and workflow requirements. Your local Sartorius representative can provide detailed information on system capabilities and our extensive library of Octet® application solutions to help you choose the system that's right for your lab.



Octet® R2 System 2-channel researchfriendly small and large molecule characterization



Octet® R4 System 4-channel automated small and large molecule characterization



Octet® R8 System 8-channel automated small and large molecule characterization



Octet® RH16 System 16-channel high throughput small and large molecule characterization



Octet® RH96 System 96-channel highest throughput small and large molecule characterization

	Octet® R2 System	Octet® R4 System	Octet® R8 System	Octet® RH16 System	Octet® RH96 System
Applications					
Small molecule applications					+
Large molecules - e.g., virus, VPL, nanoparticles, cells				+	+
DNA, RNA, Peptides, Protein analytes		-		+	+
Measuring weak binding affinities					
Measuring tight binding affinities					-
Screening applications - e.g., epitope binning, off-rate ranking				-	+
Antibody characterization					+
Quantitation assays (ELISA replacement)				-	+
Antibody titer measurements					+
Assay capability and workflow effici	ency -	<b>→</b>			
Throughput	<b>—</b>	<b>→</b>			
Rating	Low	High			



	Octet® R2 System	Octet® R4 System	Octet® R8 System	Octet® RH16 System	Octet® RH96 System
 Performance					
Maximum simultaneous reads	2	4	8	16	96
Molecular weight	>150 Da	> 150 Da	>150 Da	>150 Da	>150 Da
On-rate $(k_a)$ range $(M^{-1}s^{-1})$	10¹ - 10²	10 <sup>1</sup> – 10 <sup>7</sup>	10 <sup>1</sup> – 10 <sup>7</sup>	10¹ - 10²	10¹ - 10²
Off-rate (k <sub>d</sub> ) range (s <sup>-1</sup> )	10 <sup>-6</sup> – 10 <sup>-1</sup>	10 <sup>-6</sup> - 10 <sup>-1</sup>	10 <sup>-6</sup> - 10 <sup>-1</sup>	10 <sup>-6</sup> – 10 <sup>-1</sup>	10 <sup>-6</sup> - 10 <sup>-1</sup>
Affinity $(K_{\scriptscriptstyle D})$ range	1 mM - 10 pM				
Evaporation control	No	No	Yes	No	No
Minimum sample volume	200 μL	200 μL	200 μL	40 μL*	40 μL*
Acquisition rate (Hz)	2, 5, 10	2, 5, 10	2, 5, 10	2, 5, 10	0.3, 0.6, 2, 5, 10
Specifications					
Number of spectrometers	2	4	8	16	16
Temperature Control	15 - 40°C	15 - 40°C	15 - 40°C	Ambient +4 - 40°C	Ambient +4 - 40°C
Microplate positions	1 (96-well)	1 (96-well)	1 (96-well)	2 (96- or 384-well)	2 (96- or 384-well)
Integration with automation	No	No	No	Yes	Yes
Dimensions					
Size H × W × D (cm)	49 x 56 x 46	49 x 56 x 46	49 x 56 x 46	77 × 80 × 80	77 × 80 × 80
Weight (kg)	32.7	32.7	32.7	68.2	90.7

<sup>\*</sup> In a 384-well tilted-bottom microplate (Sartorius, part no. 18-5080)

### Biosensors for Flexible Assay Design

Biosensors are coated with a uniform, non-denaturing biocompatible matrix that provides minimal nonspecific binding, even in crude, unfiltered samples. A broad range of surface chemistries lets you design experiments with maximum flexibility.

Biosensor	Intended	Best Use	Quantitation dynamic range <sup>2</sup>		
	Application <sup>1</sup>		Octet® R2 System	Octet® R4, R8, RH16 Systems	Octet® RH96 System
Octet® APS - Aminopropylsilane	K	Binding measurement of lipids, liposomes, hydrophobic proteins that don't have other methods of surface attachment	N/A	N/A	N/A
Octet® AR2G - Amine Reactive 2G	K	Covalently immobilizing any molecule with a terminal amine group for all kinetic analyses	N/A	N/A	N/A
Octet® SSA – Super Streptavidin	K	Small molecule and fragment analysis	N/A	N/A	N/A
Octet® AHC - Anti-Human Fc-Capture	K	Capturing human IgGs or human Fc-fusion proteins for kinetic analysis	N/A	N/A	N/A
Octet® APS — AMC - Anti-Mouse Fc-Capture	K	Capturing mouse IgGs or mouse Fc-fusion proteins for kinetic analysis	N/A	N/A	N/A
Octet® SA – Streptavidin	K	Immobilizing biotinylated molecules for all kinetic analyses	N/A	N/A	N/A
Octet® SAX - High Precision Streptavidin	Q and K	Immobilizing biotinylated molecules for quantitation and kinetics analyses	Protein dependent	Protein dependent	Protein dependent
Octet® SAX2 – High Precision Streptavidin 2.0	Q and K	Immobilizing biotinylated molecules for high precision and reproducible kinetic characterization and custom quantitation	Protein dependent	Protein dependent	Protein dependent
Octet® AHQ – Anti-Human IgG Fc	Q	Quantitation measurements of human IgGs or human Fc-fusion proteins	0.5 - 100 μg/mL	0.025-200 μg/mL	0.025-200 μg/mL
Octet® AMQ - Anti-Murine IgG Fv	Q	Quantitation measurements of mouse IgGs or mouse F(ab')2	0.5-100 μg/mL	0.1-200 μg/mL	0.1-200 μg/mL
Octet® HIS1K – Anti-Penta HIS	Q and K	Quantitation of HIS-tagged proteins, direct capturing of HIS-tagged proteins for kineticanalysis	Protein and protocol dependent, 0.1-500 µg/mL	Protein and protocol dependent, 0.1-500 µg/mL	Protein and protocol dependent, 0.1–500 µg/mL
Octet® HIS2 - Anti-Penta-HIS 2G	Q	Quantitation of HIS-tagged proteins in crude matrices or buffer or column eluent	Protein and protocol dependent, 0.1-200 µg/mL	Protein and protocol dependent, 0.1-200 µg/mL	Protein and protocol dependent, 0.1-200 µg/mL
Octet® ProA - Protein A	Q	Quantitation of IgGs of various species including human	0.1-700 μg/mL	0.025-2000 μg/mL	0.025-2000 µg/mL
Octet® ProG - Protein G	Q	Quantitation of IgGs of various species including human	0.1-700 µg/mL	0.025-2000 µg/mL	0.025-2000 µg/mL
Octet® ProL - Protein L	Q	Quantitation of IgGs of various species via the kappa light chain	0.1-700 µg/mL	0.05-2000 μg/mL	0.05-2000 μg/mL
Octet® FAB2G - Anti-Human Fab-CH1 2nd Generation	Q and K	Quantitation of human Fab and IgG. Kinetic analysis of Fab fragments and IgG with target antigen, Fc receptors, or other analytes	Analyte dependent, typically 0.5–1000 µg/mL	Analyte dependent, typically 0.5–1000 µg/mL	Analyte dependent, typically 0.5 – 1000 µg/mL
Octet® GST - Anti-GST	Q and K	Quantitation of GST-tagged proteins, direct capturing of GST-tagged proteins for kinetic analyses	Protein dependent, typically 0.1-2000 µg/mL	Protein dependent, typically 0.1-2000 µg/mL	Protein dependent, typically 0.1-2000 µg/mL
Octet® NTA - Ni-NTA	Q and K	Quantitation of HIS-tagged proteins in buffer or diluted matrix, capturing of HIS tagged proteins for kinetic analyses	Protein dependent, typically 0.5-1000 µg/mL	Protein dependent, typically 0.5–1000 µg/mL	Protein dependent, typically 0.5-1000 µg/mL

<sup>&</sup>lt;sup>1</sup> Biosensors are developed, manufactured and tested specifically for kinetic assays (K), quantitation assays (Q), or both. Use of biosensors outside their intended purpose requires user validation.

<sup>&</sup>lt;sup>2</sup> Dynamic range may vary. Listed values are provided as guidelines only and are based on testing of specified analyte molecules. Users should validate the dynamic range for their specific analyte/sample.

## Ready BLI Detection Kits

Item	Use
Octet® RPA Kit	Protein A and biosimilars such as MabSelect SuRe
Octet® Anti-CHO HCP Kit	Rapid, high-throughput detection of CHO host cell proteins
Octet® Sialic Acid (GlyS) Kit	High-throughput sialic acid screening of cell culture samples



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