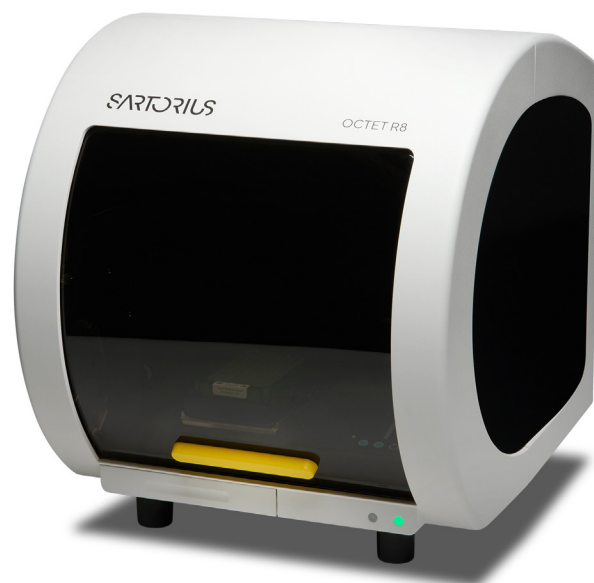


Octet® R8 System

Unmatched Flexibility
and Versatility for Biologics
Discovery, Development
and Quality Control



Key Features and Benefits

- High-quality kinetic screening and affinity characterization
- Microfluidics-free Dip and Read format reduces assay time and maintenance cost
- Eight parallel, independent channels provide high speed, sensitivity and flexibility
- Versatility to detect and analyze a diverse range of biomolecules from small molecules to viruses
- Non-destructive sampling to conserve precious samples for other assays
- Crude sample compatibility saves valuable time by eliminating the need for sample pre-treatment
- Evaporation cover facilitates up to 12 hours of unattended run time
- Equipped with sample plate cooling for temperature-sensitive proteins and assays
- Flexibility to upgrade from a non-GMP to GMP system for regulatory compliance
- Octet® R8 GMP package fully equipped to operate in regulated environments
- Easy to learn and use
- Integrated acquisition and analysis software eliminates dependency on external software.

Product Information

The 8-channel Octet® R8 system offers an advanced, fluidics-free approach to biomolecule analysis, with a wide variety of off-the-shelf Dip and Read biosensors for rapid binding kinetics and quantitation analysis. This system utilizes Sartorius' label-free Bio-Layer Interferometry (BLI) technology, enabling direct detection of specific proteins and other biomolecules — even in complex mixtures like crude cell culture supernatants and lysates. The Octet® R8 system performs quantitation and kinetic analysis of up to 96 samples in 0.5-2.5 hours, depending on the specific assay. An optional microplate evaporation cover minimizes losses in sample volume, allowing post-analysis sample recovery even after an experiment.

The Octet® R8 system can be used for a wide range of analyses including kinetic analysis, quantitation of IgGs and other proteins, reagent qualification, immunoassay development, bioprocess development, quality analysis, crude antibody screening, epitope binning/mapping, ligand binding assays, small molecule analysis, cell signaling mechanism studies and infectious disease monitoring. Analysis can be done using a single channel or up to eight channels, enabling flexibility in sample throughput.

Making Quality Analysis Affordable

In contrast to microfluidics-based systems such as SPR, the Octet® R8 system offers ease of use and flexibility in Design of Experiment (DoE) during assay method development. Sample reuse capability and minimal preparation time combined with robust instrumentation, reduces significant equipment and reagent costs. Optional biosensor regeneration further lowers assay cost per sample. All Octet® platforms come with integrated Octet® BLI Discovery Software for data acquisition and the BLI Analysis Studio Software for high throughput data analysis.

Quantitation Assays

The Octet® R8 system directly measures the presence of specific proteins and other molecules in solution with minimal interference from complex matrices. Accurate and reproducible concentrations can be determined in as little as 2 minutes per sample or 32 minutes for a whole 96-well plate using a simple, one-step assay (Figure 1A). High sensitivity in quantitation can be easily achieved by increasing read time and shake speed as shown in Figure 1B. Even higher sensitivity can be achieved to sub-ng/mL levels with 2-step or 3-step assay formats as shown in Figure 1C, allowing automated measurement of contaminants such as host cell proteins and residual protein A, faster and more precisely than ELISA. Process economics can be improved further by regenerating and reusing the biosensors.

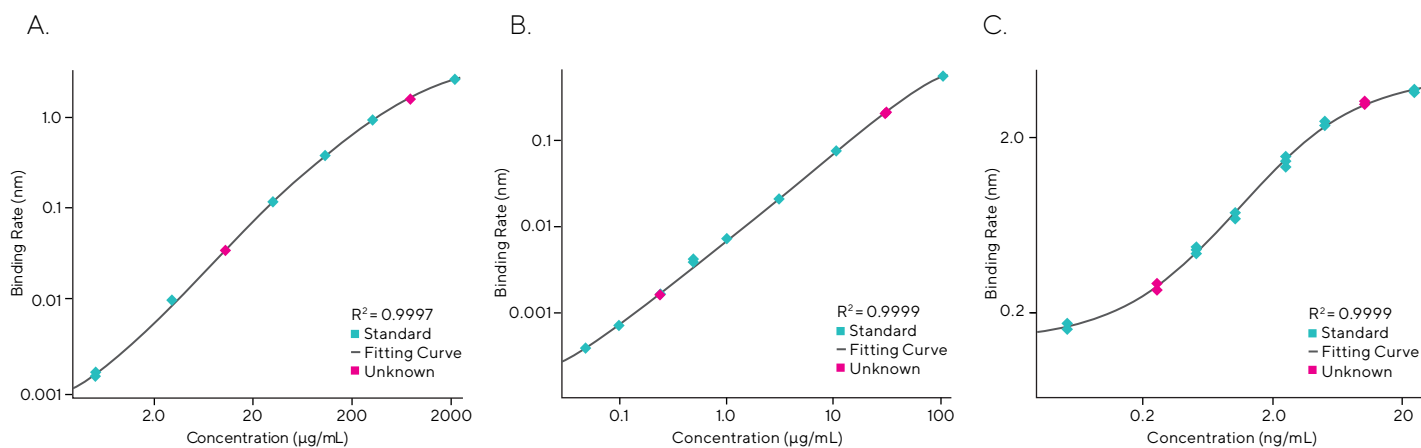


Figure 1: **Quantitation Assays.**

A) Protein A Standard Curve Assay, detection of Human IgG and unknown samples using Protein A Biosensors on the Octet® R8 system with assay parameters of 400 rpm speed, 2 minutes per sample, at 30°C. The standard curve (0.5–2000 µg/mL) is shown on a log-log scale fitted with the unweighted 5-parameter logistic (5PL) regression model.

B) High Sensitivity Protein A Assay, detection of Human IgG and unknown samples using Protein A Biosensors on the Octet® R8 system with assay parameters of 1000 rpm speed, 5 minutes per sample, at 30°C. The standard curve (0.05–100 µg/mL) is shown on a log-log scale fitted with the unweighted 5-parameter logistic (5PL) regression model.

C) Residue Protein A Assay, detection of MabSelectSure analyte and unknown samples using Protein A Biosensors on the Octet® R8 system. The standard curve (0.05–25 ng/mL) is shown on a log-log scale fitted with the weighted 4-parameter logistic (4PL) regression model.

Kinetic Assays

The Octet® R8 system monitors binding events in real time to calculate on rates (k_{on}), off rates (k_{off}) and affinity constants (K_D). The superior sensitivity of the system enables measurement of small (Figure 2) and large (Figure 3) molecules and kinetic constants over a broad range. The sample plate temperature can be controlled from 15–40°C, which enables reliable kinetic determinations at different temperatures for temperature-sensitive proteins. Additional advantages of sample cooling include the ability to rapidly determine binding rate constants at multiple temperatures to extrapolate thermodynamic measurements. The Octet® R8 system's eight channels can be used independently to measure samples for screening purposes or in tandem, pairing the sample read with a dedicated reference for high-quality kinetic characterization.

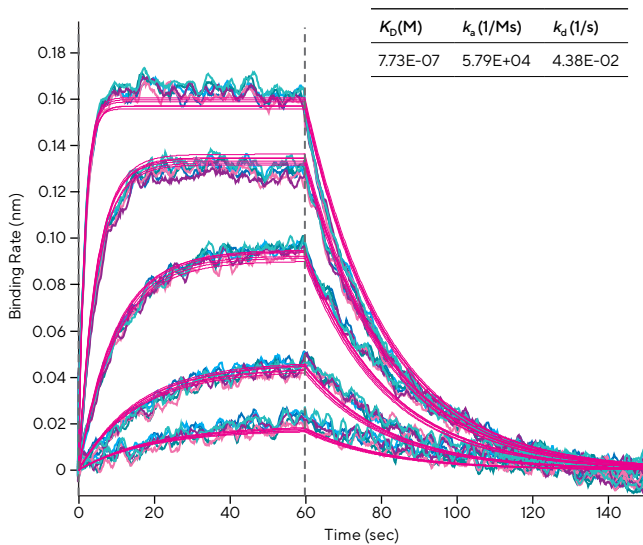


Figure 2: **Small Molecule Characterization.**

Kinetic analysis of the interaction between a ligand, biotinylated-carbonic-anhydrase and the small molecule analyte Furosemide (330.7 Da) with Super Streptavidin (SSA) Biosensors at 1000 rpm and 25°C on an Octet® R8 system. Furosemide working solutions were prepared in serial dilutions of 0.1, 0.3, 1.0, 3.0, 10.0 μ M (n=4), respectively. Data was processed and curve fitted using a 1:1 binding model.

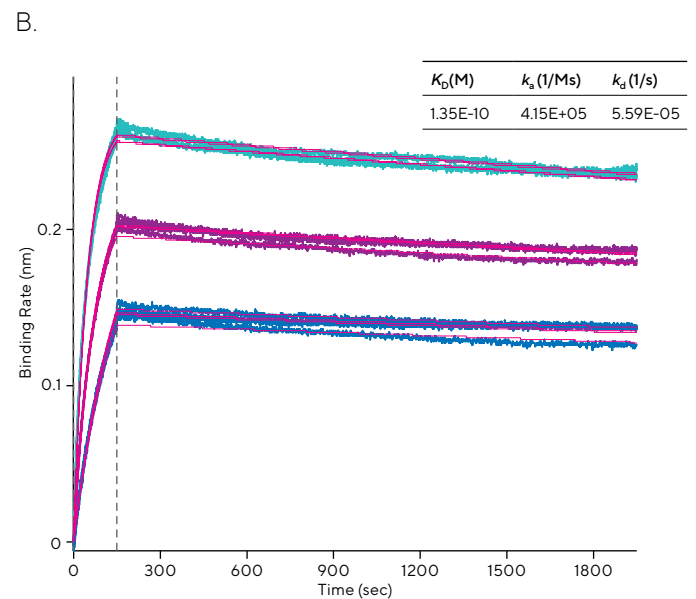
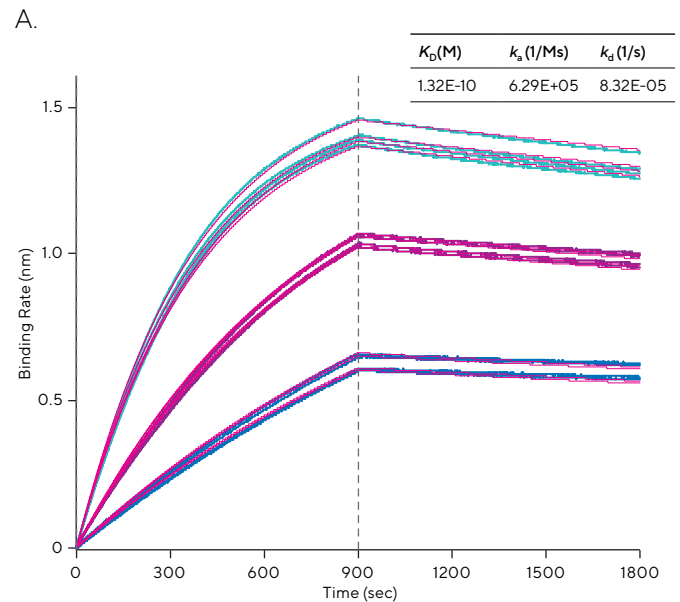


Figure 3: **Large Molecule Characterization.**

A) Kinetic analysis of the interaction between biotinylated human CD64 and humanized IgG1K monoclonal antibody with High Precision Streptavidin 2.0 (SAX 2.0) Biosensors at 1000 rpm and 25°C on an Octet® R8 system. Humanized IgG1K mAb working solutions were prepared in serial dilutions of 1, 2 and 4 nM (n=4) respectively. Data was processed and curve fitted using a 1:1 binding model.

B) Kinetic analysis of the interaction between biotinylated anti Her2 and Her2 protein with High Precision Streptavidin 2.0 (SAX 2.0) Biosensors at 1000 rpm and 25°C on an Octet® R8 system. Her2 working solutions were prepared in serial dilutions of 14.3, 28.5 and 57.0 nM (n=2) respectively. Data was processed and curve fitted using a 1:1 binding model.

Octet® BLI Discovery and Analysis Studio Software

Pre-defined templates in Octet® BLI Discovery Software streamlines setup prior to running an assay and minimizes training needs. Octet® Analysis Studio Software can overlay data from multiple plates over an extensive range of parameters and metrics to analyze acquired data from an

Octet® BLI Discovery and Analysis Studio Software

Pre-defined templates in Octet® BLI Discovery Software streamlines setup prior to running an assay and minimizes training needs. Octet® Analysis Studio Software can overlay data from multiple plates over an extensive range of parameters and metrics to analyze acquired data from an entire project, thereby reducing analysis time from hours to minutes. All settings in Octet® Analysis Studio Software can be saved and re-loaded for new similar datasets to speed up routine assays. The software can also generate

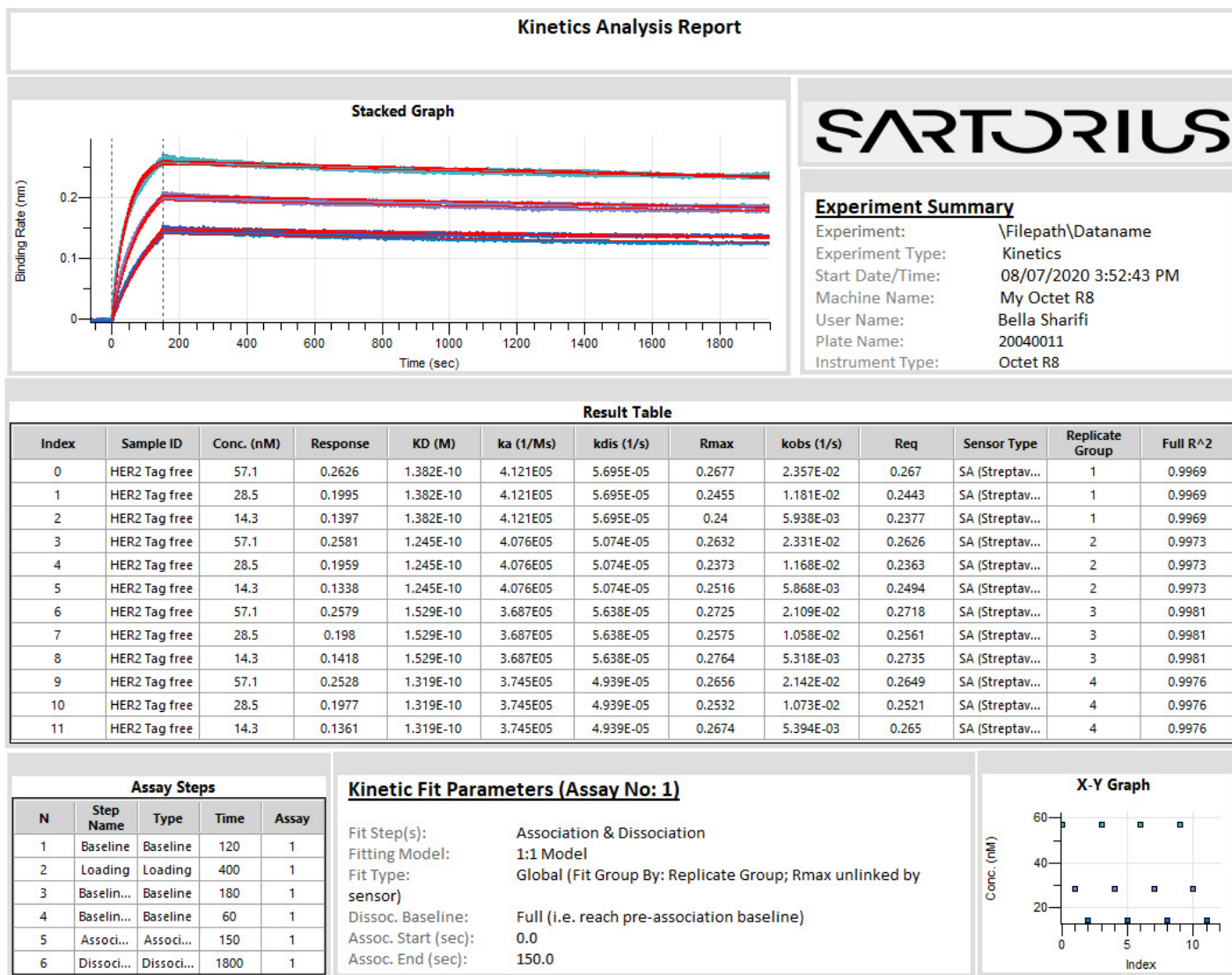


Figure 4: Octet® Analysis Studio Software version 12.2 and above enables creation of customized reports that can be uploaded into electronic notebooks and added to the database. In addition to the customized reports, Octet® Analysis Studio Software enables analysis of multiple plates and experiments together to maximize workflow efficiency.

customized reports of the experiments, combining various data elements such as graphs, text boxes, data tables, images and experimental details (Figure 4). These reports are ready to be uploaded to an electronic notebook or stored in the company database.

Operate in GxP Regulated Environments

The Octet® R8 system has been developed to operate reliably in a regulated environment. Sartorius offers Octet® 21 CFR Part 11 Software and a full line of GxP products and services as part of the Octet® R8 GxP Package.

These include:

- Octet® 21 CFR Part 11 Software and Octet® GxP Server features such as:
 - Controlled access with multiple user privileges – administrator, developer, supervisor and lab user
 - Primary data integrity – digitally signed acquired data that is rendered invalid after data tampering
 - Electronic signatures – enable data to be locked after analysis is complete
 - Enhanced audit trail – all actions are recorded and time stamped with details of old vs. new values
 - Full control of routine assays that speed up analysis – method files and analysis settings can be saved for routine assays
 - Customized reports – created by combining various data elements such as graphs, text, data tables and images ready to be uploaded to your ELN
- Installation and Operational Qualification (IQOQ) and Performance Qualification (PQ) packages ensure your system is qualified and operate as intended and that performance meets specifications
- Performance Certification (PMOQ) services maintain

- your system in a calibrated state and in peak condition
- Customer-run Software Validation Package to reduce the validation time down to just three days
- Biosensor Validation Support Services for multiple biosensor lot sampling and selection
- Excellent Global Technical Support assistance

Octet® R8 System Technical Specifications¹

Technical information and specifications

Detection technology	Bio-Layer Interferometry (BLI)
Biosensor type	Disposable, single-use fiber optic biosensors with optional reuse by regeneration and re-racking in the sensor tray
Information provided	<ul style="list-style-type: none"> ▪ Yes/No binding ▪ Kinetic and affinity analysis (k_{obs}, k_a, k_d, K_D) ▪ Specific and selective detection of molecules, even in crude samples ▪ Relative and absolute quantitation of specific proteins in crude matrices or purified samples
Data presentation	<ul style="list-style-type: none"> ▪ Graphs displaying real-time kinetic binding traces, fitted result plots and residuals of fits ▪ Concentration data analysis including calibration curves and output of tabulated concentration data ▪ Tabulated kinetic data ▪ Epitope binning and cross-blocking matrices and trace overlays
Sample types	Proteins, antibodies, peptides, DNA, RNA, liposomes, viruses and VLPs in various media including serum, buffers containing DMSO, periplasmic fractions, bacterial cells, nanoparticles, untreated cell culture supernatants and crude cell lysates
Number of spectrometers	8
Maximum simultaneous reads	8
Data collection rate	2, 5 or 10 Hz

¹ All specifications are subject to change without notice.

Sample position and format	1 standard 96-well, black, flat bottom microplate
Sample volume	180-220 μ L/well, non-destructive testing
Orbital flow capacity	Static or 100-1500 rpm
Analysis temperature range	15-40°C, 1°C increments

*All specifications are subject to change without notice.

Kinetics

Workflow	Up to 8 assays in parallel
Molecular weight detection	> 150 Da
Analysis time per sample	Real-time kinetic binding experiments from 5 minutes to 4 hours, or up to 12 hours at 25°C with the evaporation cover
Association rate constant (k_a)	10^1 - 10^7 $M^{-1}s^{-1}$
Dissociation rate constant (k_d)	10^{-6} - 0.1 s^{-1}
Affinity (K_D) constant	1 mM-10 pM
Baseline noise ²	\leq 4.0 pm (RMS)
Baseline drift ²	\leq 0.12 nm/hour

² Baseline noise and drift are tested at 25 °C.

Quantitation

Workflow	Up to 8 assays in parallel
Analysis time per sample	Human IgG quantitation in 2 minutes for 8 samples, \leq 32 minutes for 96 samples
Direct quantitation range for human IgG with Protein A Biosensor	0.05-2000 μ g/mL

Instrument

Dimensions (H x W x D)	19.5 in x 22 in x 18.2 in (49 cm x 56 cm x 46 cm)
Weight	72 lb (32.7 Kg)
Electrical requirements	Mains: 100-120/200-240 VAC, 50/60 Hz, 4 A max
Power consumption	200 W (300 W peak)

Data handling and storage

PC operating systems	Windows® 10 Professional, 64-bit Windows 7 Professional, 64-bit Windows 7 Professional, 32-bit
Compliance	
Safety standards	CE, Nemko

Ordering Information and Related Products

Part No	UOM	Description
Octet® R8 / 30-0518	System	Includes Octet® R8 instrument, Octet® Software, desktop computer, LCD monitor, accessory kit and one-year warranty
Octet® R8-GxP Package / 30-0518-GxP	System	Includes Octet® R8 instrument, Octet® 21 CFR Part 11 Software, desktop computer, LCD monitor, accessory kit, IQOQ/PQ kits and services and one-year warranty
18-5132	Pack	Single-use evaporation covers to extend the experiment up to 12 hours. 3 covers per pack
18-1176	Kit	Octet® R8 Performance Qualification – Quantitation Kit
18-1177	Kit	Octet® R8 Performance Qualification – Kinetics Kit
18-1178	Kits Bundle	Octet® R8 Performance Qualification Kits Bundle
41-0325	Kit	Octet® R8 Installation and Operational Qualification Kit
50-0296	Pack	Octet® Software Validation Package

Upgrade and Maintenance Services

Contact your regional sales representative for all the upgrade and maintenance services offered with the Modular Octet® R series configurations.

More Information

For more information about Sartorius' Octet® platform for label-free, real-time detection of biomolecular interactions, applications and services, visit www.sartorius.com/octet or contact us directly at +1 888 OCTET 75.

Technical Support

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