SARTORIUS

Octet® RH16 System

Label-Free Quantitation and Kinetics with Enhanced Throughput and Extended Dynamic Range

Key Features and Benefits

- 384- and 96-well assay formats for flexibility of experimental design
- 16-well simultaneous detection for high throughput analysis
- Two plate positions on deck to maximize process economy
- Automation compatibility for a simplified workflow
- Re-rack and reuse regenerated biosensors for cost efficiency
- Microfluidics-free Dip and Read format to reduce assay time and maintenance cost
- Non-destructive sampling to conserve precious samples for other assays
- Fully equipped to operate in GxP-regulated environments

Product Information

Sartorius' Octet® RH16 system is designed for increased throughput of label-free protein quantitation and kinetic characterization. Get accurate concentration, kinetic constants, and affinity data for protein-protein, small molecule-protein and other molecular interactions – all with Dip and Read simplicity. The system utilizes Sartorius' Bio-Layer Interferometry (BLI) technology, enabling direct detection of specific proteins and other biomolecules — even in complex mixtures like cell culture supernatants and lysates.

The Octet® RH16 system can be used for a wide range of analyses including IgG and other protein titer, bioprocess development, quality analysis, crude antibody screening, epitope binning/mapping, ligand binding assays, small molecule analysis, elucidating cell signaling mechanisms, and infectious disease monitoring. Analysis can be done using a single channel or up to sixteen channels, enabling more flexibility in sample throughput when needs change.

The Octet® RH16 system is easy to set up and offers a large dynamic range for titer determination and efficient signal resolution for reliable affinity data. This system analyzes 8 or 16 wells simultaneously and take advantage of our large menu of biosensor chemistries.

Increasing Throughput

The two plate positions support either 96- or 384-well microplates for samples and reagents, and the biosensor regeneration/reuse capabilities keeps your workflow speeding along. Compatibility with crude samples and high tolerance to DMSO facilitates analysis without laborious sample preparation.

Making Quality Analysis Affordable

The Octet® RH16 system costs a fraction of an SPR system while providing comparable data. In contrast to SPR systems, the Octet® RH16 offers Design of Experiments (DOE) capability and ease of use. Reduced sample consumption (40–130 µL/well in 384-well tilted microplates) and preparation time combined with robust instrumentation reduces significant equipment and reagent costs. Optional biosensor regeneration further lowers assay cost per well.

Simplifying Your Workflow

The Octet® RH16 system provides increased throughput for rapid optimization of assay conditions. Automation compatibility for plate loading enables walkaway freedom for longer experiments and high number of samples. Advanced software offers rapid processing of kinetic data, protein quantitation determinations, and epitope binning experiments.

Quantitation Assays

The Octet® RH16 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 two minutes for 16 samples, ≤ 20 minutes for 96 samples and ≤ 75 minutes for 384 samples, in a simple one-step assay (Figure 1). High sensitivity in quantitation can be achieved to sub-ng/mL levels with 2-step and 3-step assay formats, allowing automated measurement of contaminants such as host cell proteins and residual protein A faster and more accurately than ELISA. Process economics can be improved further by regenerating and re-using the biosensors.
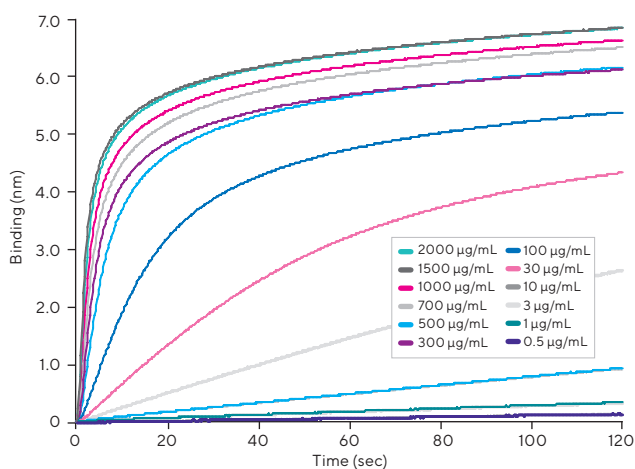

Figure 1: Concentration curves obtained on the Octet® RH16 system for human IgG at 0.5 µg/mL to 2000 µg/mL using ProA (Protein A) Biosensors and two-minute incubation per well.

Kinetic Assays

The Octet® RH16 system monitors binding events in real time to calculate on rates (k_a), off rates (k_d), and affinity constants (K_D). The superior sensitivity of the system enables measurement of biomolecules (Figure 2) and kinetic constants over a broad range of molecular weights and kinetic rates. The Octet® RH16 system's ability to collect data from sixteen independent biosensor channels simultaneously provides throughput levels for screening purposes or pairing the sample readouts with a dedicated reference biosensor experiment for high-quality kinetic characterization.

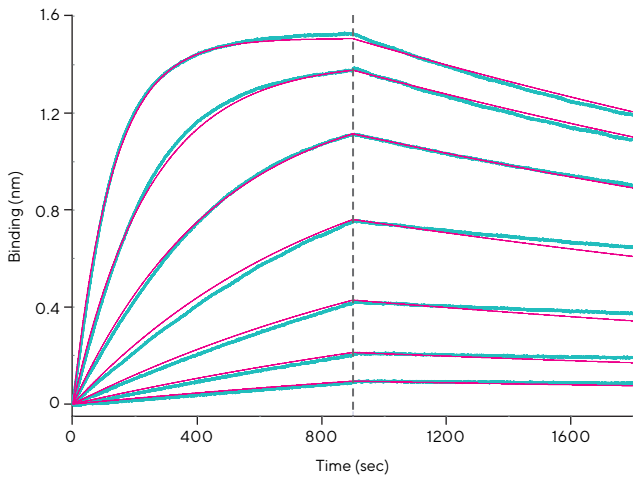| K_D (M)	k_a (1/Ms)	k_d (1/s)
5.22E-10	4.75E+05	2.48E-04

Figure 2: Large molecule characterization. An example data from a human IgG1 monoclonal antibody binding to Cluster of Differentiation 64 (CD64) immobilized on SAX (High Precision Streptavidin) Biosensors using the Octet® RH16 system. Binding was performed at 30°C, with a shake speed of 1000 rpm. Two-fold dilution seriesof antibody from 16-0.25 nM to obtain a seven concentration binding series.

Easy and Powerful Experimental Setup and Analysis Software

Pre-defined templates in Octet® BLI Discovery Software streamline the setup prior to running an assay and minimize training needs. The Octet® Analysis Studio Software is designed for fast analysis of large datasets from quantitation, kinetic, and epitope binning assays. Additionally, the 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. The analysis settings in Octet® Analysis Studio Software can be saved and re-loaded for new datasets to speed up routine assays. The software can also generate customized reports of the experiments, combining various data elements such as graphs, text boxes, data tables, images and experimental details (Figure 3). These reports are ready to be uploaded to an electronic notebook or stored in the company database.

Kinetics Analysis Report

Stacked Graph

Experiment Summary

Experiment:	\filepath\dataname
Method File:	\project\methodfile.fmf
Experiment Type:	Kinetic
Start Date/Time:	11/18/2019 10:12:47 AM
Machine Name:	MyOctet
User Name:	Labuser
Plate Name:	200305
Instrument Type:	OctetRH16

Result Table

Index	Color	Assoc. (Sample) Loc.	Sample ID	Dissoc. Loc.	Conc. (nM)	Response	KD (M)	ka (1/Ms)	kdis (1/s)	Rmax	kobs (1/s)	Req
0		p1A17	HIgG	p1A9	4	1.2514	2.366E-…	6.726E…	1.591E-…	1.4345	2.849E-…	1.3544
1		p1C17	HIgG	p1C9	2	0.9752	2.366E-…	6.726E…	1.591E-…	1.4828	1.504E-…	1.3259
2		p1E17	HIgG	p1E9	1	0.5785	2.366E-…	6.726E…	1.591E-…	1.396	8.317E-…	1.1289
3		p1I17	HIgG	p1I9	4	1.2567	2.287E-…	6.947E…	1.589E-…	1.4284	2.938E-…	1.3511
4		p1K17	HIgG	p1K9	2	0.9706	2.287E-	6.947E	1.589E-	1.4444	1.548E-	1.2962

Assay Steps

N	Step Name	Type	Time	Assay	Sample Location
1	Baseline	Baseline	180	1	p1A1
2	Loading	Loading	240	1	p1A13
3	Baseli…	Baseline	1200	1	p1A5
4	Baseli…	Baseline	60	1	p1A9
5	Associ…	Associ…	900	1	p1A17
6	Dissoc…	Dissoci…	900	1	p1A9

Kinetic Fit Parameters (Assay No: 1)

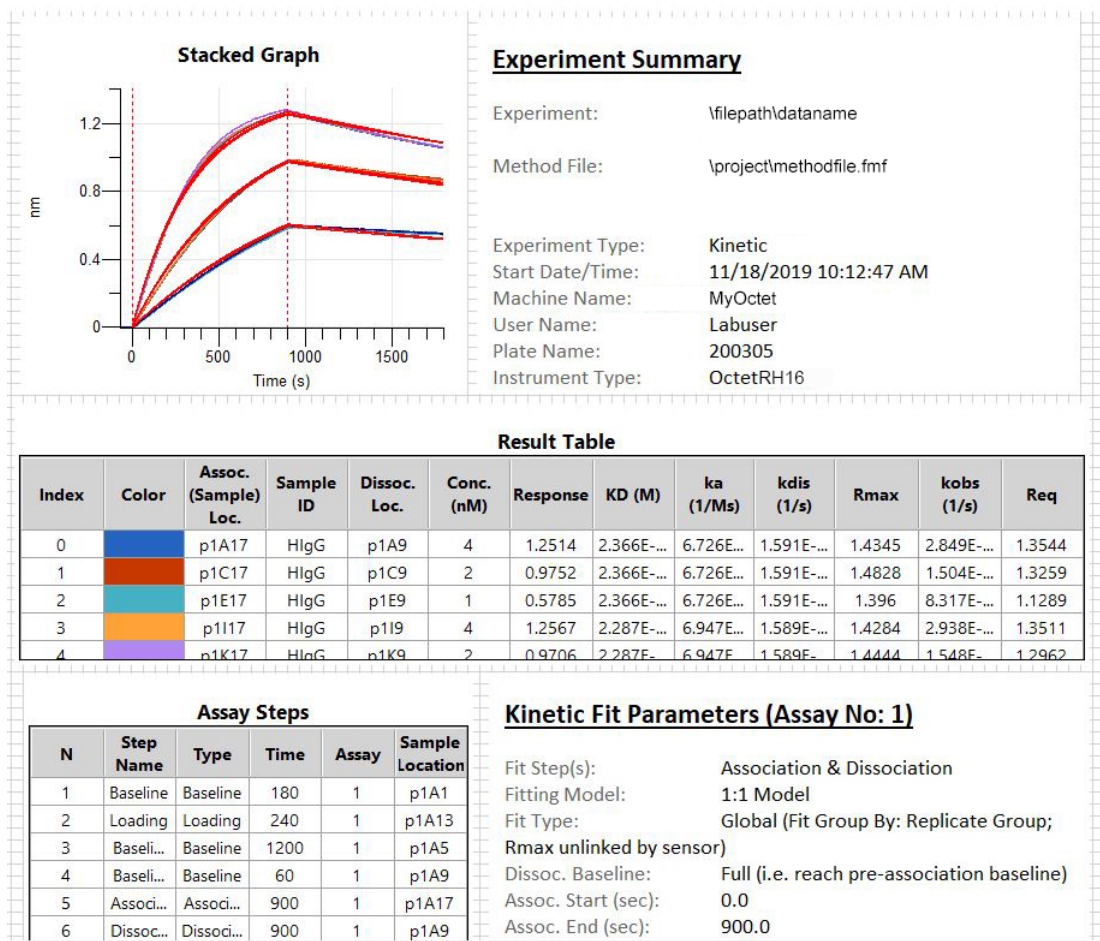| Fit Step(s): | Association & Dissociation |
Fitting Model:	1:1 Model
Fit Type:	Global (Fit Group By: Replicate Group; Rmax unlinked by sensor)
Dissoc. Baseline:	Full (i.e. reach pre-association baseline)
Assoc. Start (sec):	0.0
Assoc. End (sec):	900.0

Figure 3: Octet® Analysis Studio Software enables making customized reports that can be uploaded into electronic notebooks and added to the database. In addition to customized report, Octet® Analysis Studio Software enables analysis of multiple plates and experiments together to maximize workflow efficiency.

Operate in GxP Regulated Environments

The Octet® RH16 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® RH16 GxP Package. These include:

- Octet® CFR Software and Sartorius FB Server features such as:
  - Controlled access with multiple user privileges – administrator, developer, supervisor, lab user
  - Primary data integrity – acquired data is digitally signed and it is rendered invalid after data tampering
  - Electronic signatures – which enable the data to be locked after analysis is complete
  - Enhanced audit trail – all actions are recorded and timestamped 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 electronic notebook
- Installation and Operational Qualification (IQOQ) and Performance Qualification (PQ) packages to ensure that your system is qualified and operates as intended and that performance meets specifications
- Performance Certification (PC) services to maintain your system in a calibrated state and in peak condition
- Customer-run software validation package. Decreasing validation times to just three days
- Biosensor Validation Support Services for multiple biosensor lot sampling and selection
- Excellent Global Technical Support assistance

Specifications*

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	- Yes/No binding - Kinetic and affinity analysis (k_a, k_d, K_D) - Specific and selective detection of molecules, even in crude samples - Relative and absolute quantitation (using a standard curve) of specific proteins in crude matrices or purified samples
Data presentation	- In the form of real time kinetic binding and fitted results plots/graphs - Concentration data analysis including calibration curves and output of tabulated concentration data - Tabulated kinetic data - Epitope binning and cross-blocking matrices and trace overlays - Customized reports in PDF format
Sample types	Proteins, antibodies, peptides, DNA, RNA, liposomes, bacterial cells, viruses, mammalian cells, small molecules in various media including serum, buffers containing DMSO, periplasmic fractions, untreated cell culture supernatants, and crude cell lysates
Number of spectrometers	16
Maximum simultaneous reads	Up to 16
Data collection rate	2, 5 or 10 Hz
Sample position and format	2 positions; standard, 96-well and 384-well black, flat bottom microplates and 384 tilted-well microplate
Sample volume	40–100 uL/well (384TW microplate); 80–130 µL/well (384-well microplate); 180–220 µL/well (96-well microplate) Nondestructive testing, easily recoverable
Orbital flow capacity	Static or 100–1500 rpm
Analysis temperature range	(Ambient + 4°C)–40°C, 1° C increments

Kinetics

Workflow	Up to 16 assays in parallel; up to 96 assays per 96-well microplate and 384 assays per 384-well microplate
Molecular weight detection	≥ 150 Da
Analysis time per sample	Real-time kinetic binding experiments from 5 minutes to 4 hours
Association rate constant (k_a)	10^1–10^7 M^{-1}s^{-1}
Dissociation rate constant (k_d)	10^{-6}–10^{-1}
Affinity (K_D) constant	1 mM–10 pM
Baseline noise**	≤ 4 pm (RMS)
Baseline drift**	≤ 0.1 nm/hour

Quantitation

Workflow	Up to 16 assays in parallel; up to 96 assays per 96-well microplate and 384 assays per 384-well microplate
Analysis time per sample	Human IgG quantitation in 2 minutes for 16 samples, ≤ 20 minutes for 96 samples and ≤ 75 minutes for 384 samples
Direct quantitation range for human IgG with ProA Biosensor	0.05–2000 µg/mL

Instrument

Dimensions (H x W x D)	30.1 in x 31.5 in x 31.5 in (H x W x D) (77 cm x 80 cm x 80 cm)
Weight	150 lb (68.2 kg)
Electrical requirements	Mains: AC 100–240 V AC, 5.0–2.0 A, 50/60 Hz, single phase
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

*All specifications are subject to change without notice.

**Baseline drift and noise is measured at 30 °C in 384 TW microplates .

Ordering Information

Part No.	UOM	Description
OCTET-RH16	System	Includes Octet® RH16 instrument, Octet® Software, desktop computer, LCD monitor, accessory kit and one-year warranty
OCTET-RH16-GXP	System	Includes Octet® RH16 instrument, Octet® CFR Software, Software Vaildation Package, desktop computer, LCD monitor, accessory kit, IQOQ Kit, IQOQ service, PQ Kits, PQ service, 2 PMOQ services and and one-year warranty