



Octet RED384 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

FortéBio's Octet® RED384 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 FortéBio's 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 RED384 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 RED384 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 RED384 system costs a fraction of an SPR system while providing comparable data. In contrast to SPR systems, the Octet RED384 offers 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 RED384 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 RED384 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.

Kinetic assays

The Octet RED384 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. The Octet RED384 system's sixteen channels can be used independently to measure samples for screening purposes or simultaneously, pairing the sample read with a dedicated reference for high-quality kinetic characterization.

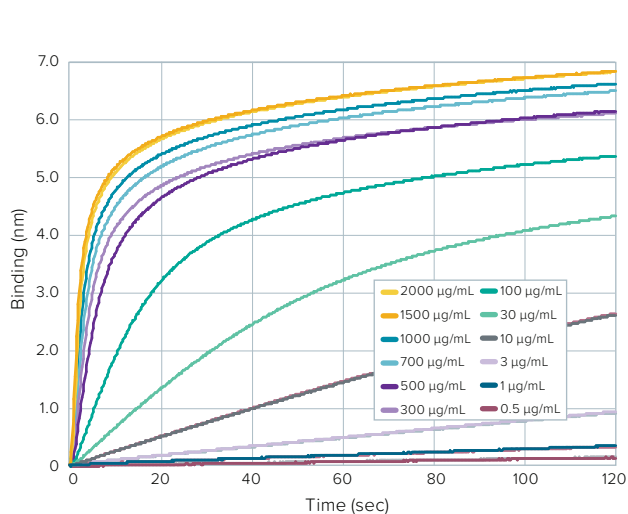


Figure 1: Concentration curves obtained on the Octet RED384 system for human IgG at 0.5 µg/mL to 2000 µg/mL using Protein A biosensors and two-minute incubation per well.

Octet Data Analysis HT software

Pre-defined templates in Octet Data Acquisition software streamline the setup prior to running an assay and minimize training needs. Additionally, the Octet Data Analysis High Throughput (HT) 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 Data Analysis HT 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.

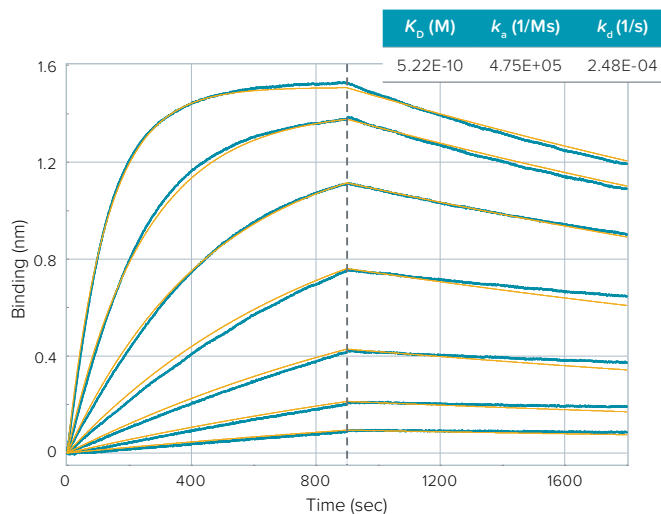


Figure 2: Large molecule characterization. An example data from a human IgG1 monoclonal antibody binding to Cluster of Differentiation 64 (CD64) immobilized on High Precision Streptavidin (SAX) biosensors using the Octet RED384 system. Binding was performed at 30° C, with a shake speed of 1000 RPM. Two-fold dilution series starting at 16 nM of the antibody was prepared to obtain the 7 concentrations run.

Kinetics Analysis Report

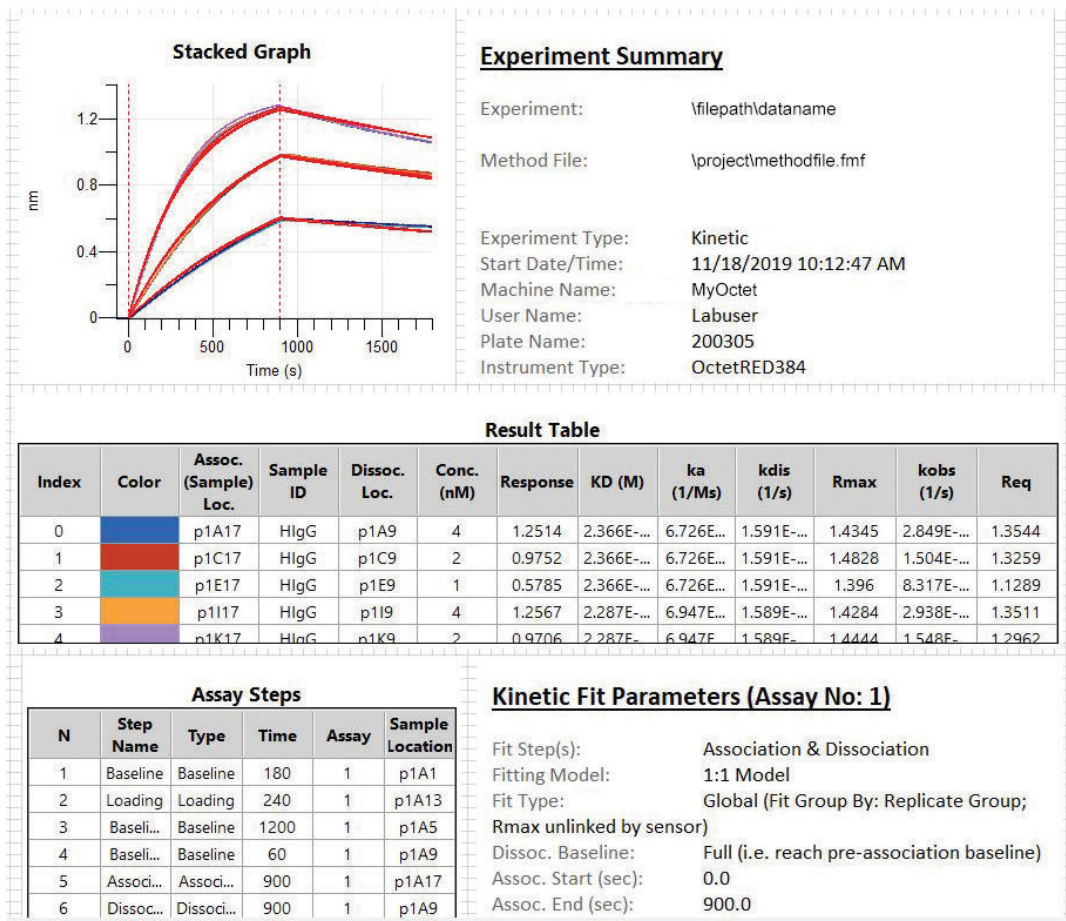


Figure 3: Octet Data Analysis HT software enables making customized reports that can be uploaded into electronic notebooks and added to the database. In addition to customized report, Data Analysis HT enables analysis of multiple plates and experiments together to maximize workflow efficiency.

Operate in GxP regulated environments

The Octet RED384 system has been developed to operate reliably in a regulated environment. ForteBio offers 21 CFR Part 11 software and a full line of GxP products and services as part of the Octet RED384 GxP Package. These include:

- Octet CFR software and ForteBio 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 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 electronic notebook
- Installation and Operational Qualification (IQ/OQ) 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
- Support on customer-run software validation packages to decrease validation times to just three days
- Biosensor Validation Support Services for multiple biosensor lot sampling and selection
- Excellent Global Technical Support assistance

Octet RED384 system 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 | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • 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 μ L/well (384TW microplate); 80–130 μ L/well (384-well microplate); 180–220 μ L/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 |

| Kinetics (continued) | |
|--------------------------------------|---|
| Analysis time per sample | Real-time kinetic binding experiments from 5 minutes to 6 hours |
| 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 | ≤ 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 Protein A Biosensor | 0.05–2000 μ g/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 | <ul style="list-style-type: none"> • 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.

Ordering information

| Part No. | UOM | Description |
|------------------|--------|--|
| OCTET RED384 | System | Includes Octet RED384 instrument, Octet software, desktop computer, LCD monitor, accessory kit and one-year warranty |
| OCTET RED384-GXP | System | Includes Octet RED384 instrument, Octet CFR software, desktop computer, LCD monitor, accessory kit, IQ/OQ kit, PQ Kits and one-year warranty |

Distributore per l'Italia:

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