SARTORIUS

Product Datasheet

Octet® BLI Discovery and Octet® Analysis Studio Software

Faster, More Powerful Data Analysis with Version 11.0+

Key Features

- Analyze multiple plates and experiments together
- Customize PDF data reports using text, graphs, data tables and images
- More flexible and advanced reference subtraction options and preprocessing tools for kinetic data prior to analysis
- Additional data correction options to choose from
- New graphical display options to thicken sensor traces and customize axis scale and title options
- Automated analysis for quantitation, kinetic, dose-response analysis, and epitope binning data
- Compatible with 32- and 64-bit versions of Windows® 10 and 11

Upgrade Information

Octet® Software provides an intuitive and easy to use interface for data acquisition and analysis on all Octet® instruments, enabling label-free kinetic, affinity, epitope binning, activity, concentration, potency, and screening applications. To upgrade your software to the latest version, please complete the software download form or contact your local sales representative.

Beginning with Octet® Software version 12.1, the applications have been renamed. The Data Acquisition Software has been renamed Octet® BLI Discovery. The Data Analysis HT Software has been renamed Octet® Analysis Studio Software.

Octet® BLI Discovery Software

An Experiment Wizard and built-in protocols guide users through a step-by-step data acquisition process, facilitating both assay setup and efficient experimental design. Interactive sample plate maps allow rapid plate definition using simple click and drag mouse movements, and sample wells, standard wells, biosensors and regeneration steps are descriptively color-coded. During acquisition, data are displayed in real time with a detailed graphical interface that shows experimental progress. Interactive zoom tools and advanced viewing options, such as real-time reference subtraction and alignment of traces to a step or a certain time, are available while the experiment is running.

Octet® Analysis Studio Software

The Octet® Analysis Studio Sortware user interface is now more interactive and updates automatically when settings are changed. The latest software version contains all analyses, including quantitation, data processing and corrections, kinetics and epitope binning. All setting parameters are saved locally in a new .efrd file to ensure user-customized settings are stored.

Data Preprocessing

The software allows overlay of multiple experiments and plates for simplified viewing. Datasets can also be appended and analyzed simultaneously, reducing analysis time from hours to minutes. Hundreds to thousands of samples can be visualized, processed, analyzed and presented in the final report, so an entire campaign or project to select leads from the global dataset (Figure 1).

Octet® Analysis Studio Software with an interactive interface offers more flexible tools for customizing data analysis that caters to users at all experience levels. There are no restrictions on reference sample(s) placement, and advanced options for reference subtraction are available that remove any non-specific binding and/or baseline drift (Figure 2). For rapid analysis of multiple plates that were run using similar experiment setups, the same reference subtraction and data corrections applied to one plate can also be applied automatically to other plates in the dataset.

Advanced inter-step correction options remove bulk shifts or artifacts to ensure data has been appropriately processed prior to fitting (Figure 3).

Figure 1: 10 large molecule kinetics datasets overlaid and combined to significantly speed up analysis and viewing.

Report point values can be added to any step in the sensor trace, providing flexibility of comparing loading, baseline, association or dissociation levels between traces. This feature is especially useful in assessing loading levels, analyte association levels, as well as early and late dissociation levels in screening applications such as ranking several clones based of off-rates.

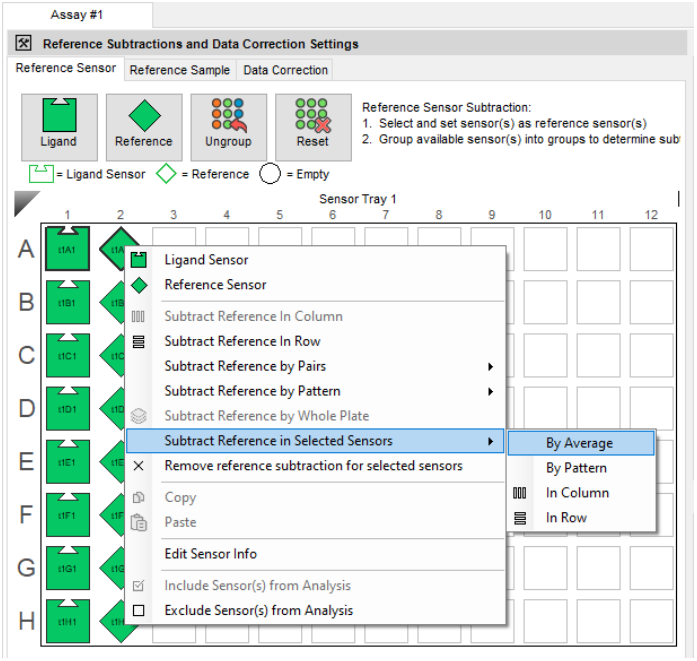

Figure 2: More flexible reference subtraction options.

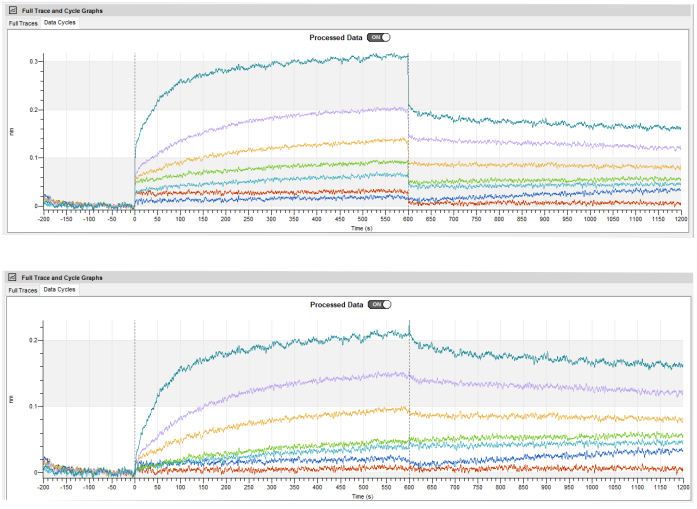

Figure 3: Advanced data processing option to remove bulk shifts or assay artifacts.

Kinetics Analysis

Multiple interactions from several plates or experiments can now be fitted and evaluated in parallel (Figure 4). Faster and more optimized 1:1 and 2:1 algorithms enable better fitting with lower residuals and rapid analysis for large datasets.

Once analysis is complete, customized reports can be created by combining various data elements such as graphs, text, data tables, company logo, images and experimental details (Figure 5). Reports are then ready to be uploaded to an electronic notebook or stored in the database. Report templates can be saved and re-loaded to make similar reports for additional datasets.

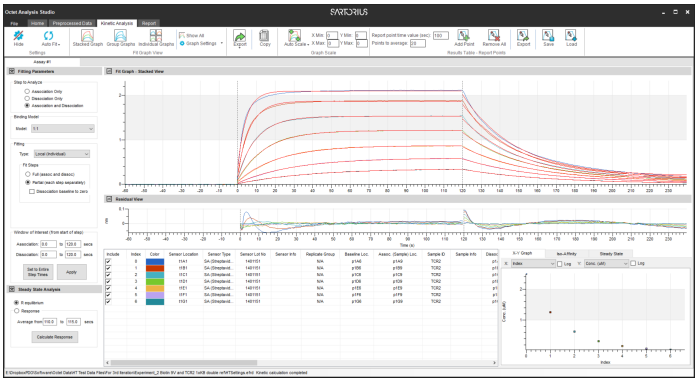

Figure 4: Kinetic analysis on a combined dataset.

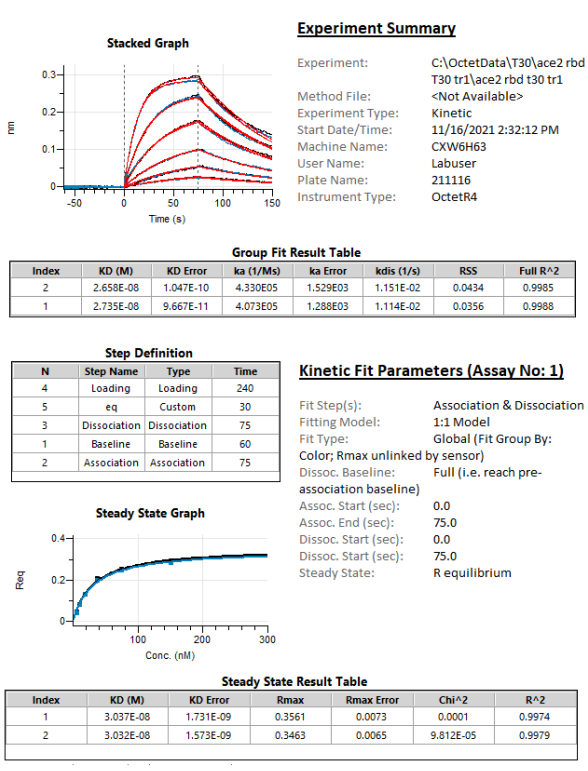

Figure 5: Customized experimental report.

Quantitation Analysis

Octet® Analysis Studio Software also enables multi-experiment analysis of quantitation datasets that significantly speeds up analysis of multiple plates (Figure 6).

Simple 1-step and multi-step quantitation assays can be easily analyzed with a few clicks. Extended data preprocessing options are available to perform one or multiple reference subtractions depending on the assay setup. Once the data has been processed, binding rate is calculated based on initial slope or rate at equilibrium. The data can then be fitted using unweighted or weighted 4 parametric (4-PL) 5-PL or linear fits (Figure 7).

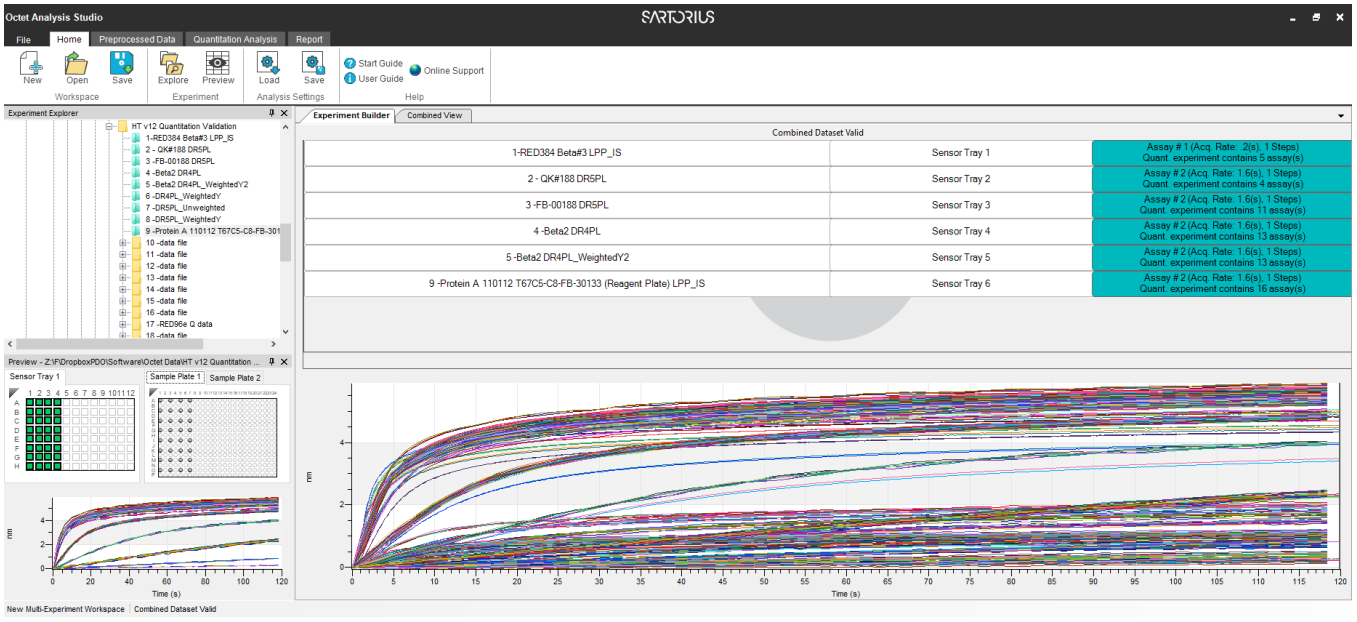

Figure 6: Multi-experiment quantitation analysis.

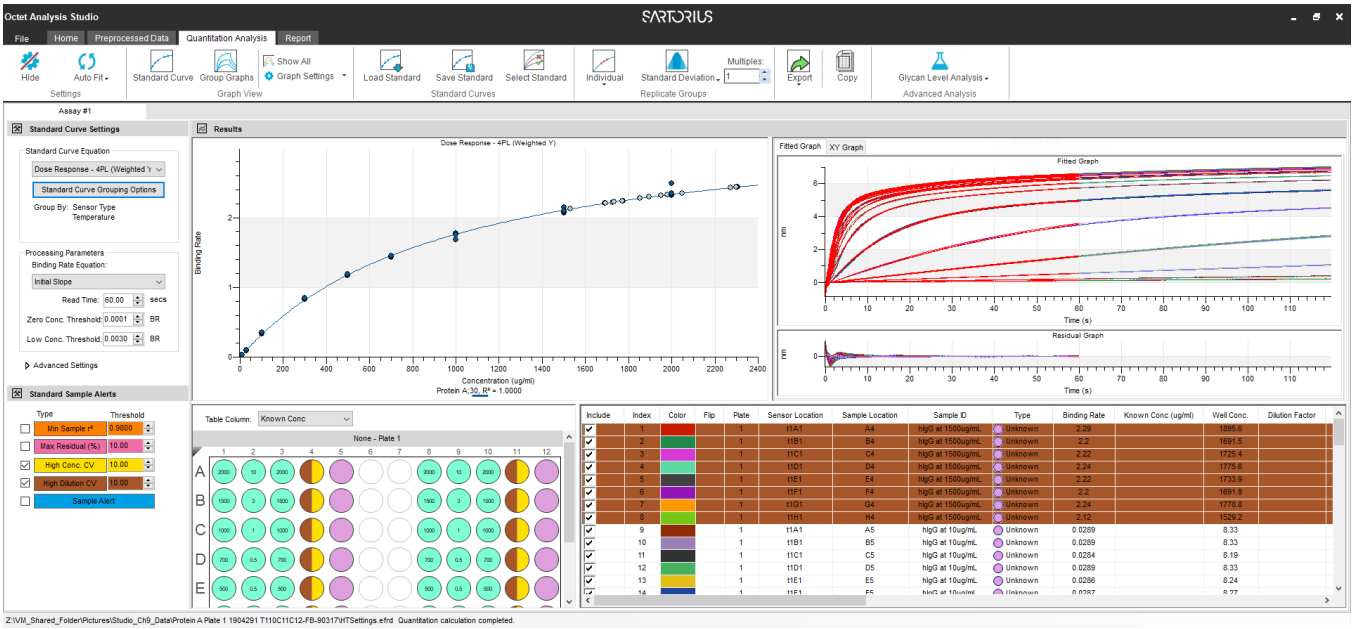

Figure 7: Quantitation binding rate calculation and curve fitting.

Automated sample alert tools are now available that analyze data quality for the magnitude of precision between replicates, accuracy, dilution linearity and residuals, enabling interpretation of results with confidence (Figure 8). Customized reports, similar to Figure 5, can also be generated.

Once quantitation analysis is complete, customized reports can be created by combining various data elements such as graphs, text, data tables, company logo, images and experimental details as described earlier. Reports are then ready to be uploaded to an electronic notebook or stored in the database.

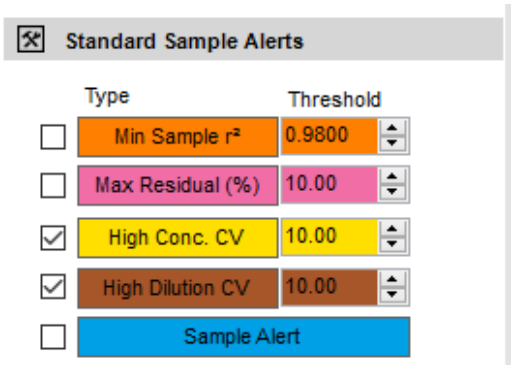

Figure 8: Sample alert tools.

Dose-Response Analysis Capabilities

Determination of product activity is vital during drug development and manufacturing to ascertain the intended biological activity of the therapeutic. A potency or potency-indicating assay is a requirement by regulatory bodies before the release of every manufactured drug lot. Typically, potency measurements are obtained using bioassays in animal models or cell-based assays to capture biological activities directly. However, alternative assay formats such as ELISA or BLI are used for potency measurements when drug binding activities to target molecules correlate with the biological activity of the drug. These assays are coined as potency-indicating or surrogate assays for their ability to reveal drug activity based on target binding. Octet® dose-response assays provide fast time to results with automated workflows, minimal hands-on times, and reduced assay variabilities. Unlike ELISA, all assay steps can be monitored and evaluated in real time.

- Conveniently setup EC_{50} and IC_{50} experiments with in-built experimental method templates in Octet® Discovery Software.
- 3-PL, 4-PL, 5-PL, linear, and semi-log fitting algorithms
- Monitor biosensor loading responses and flag data points based on user-defined biosensor loading criteria
- Independent and global dose-response fitting options and similarity assessments to effectively compare against standard and test sample groups

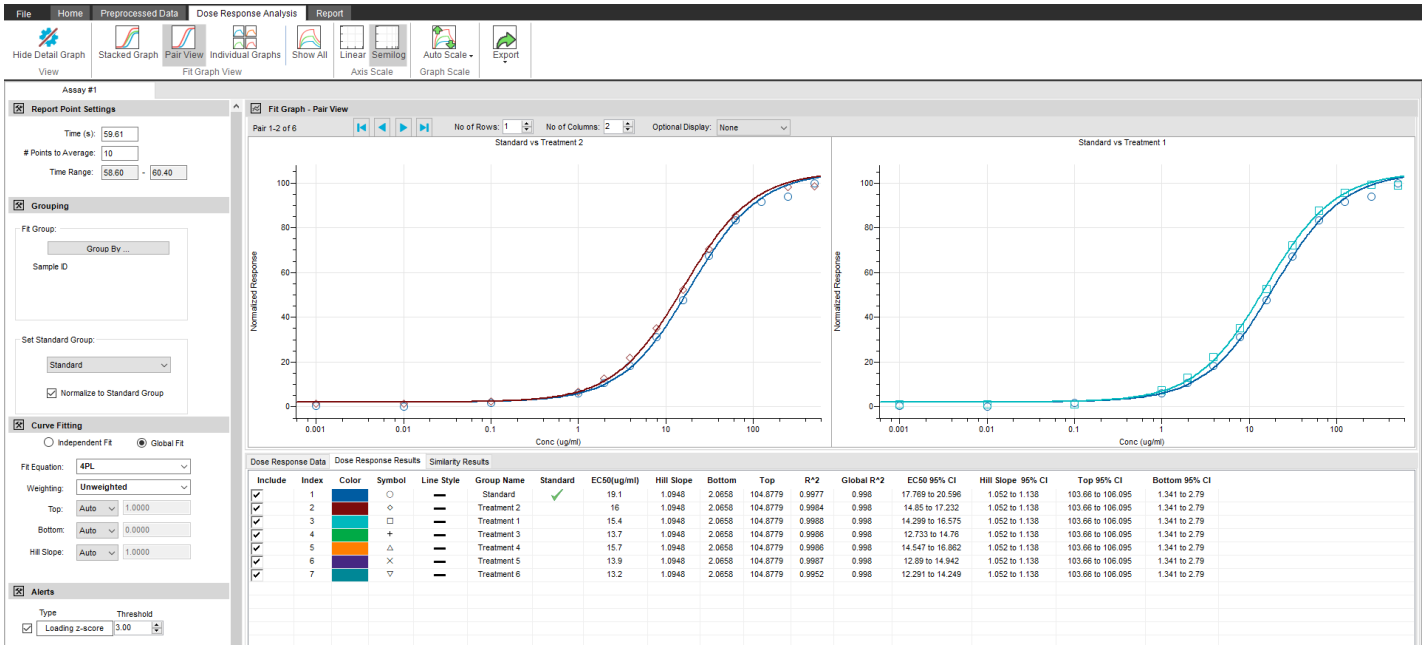

Figure 9: Anti-Her2 lot-to-lot potency evaluation using an Octet® potency assay. Relative potency evaluation between two anti-Her2 antibody lots using the binding activity to Her2. Dose-repose binding data from multiple lots were fitted globally to a 4-PL fitting algorithm in Octet® Analysis Studio Software.

Epitope Binning

Epitope binning groups a panel of monoclonal antibodies (mAbs) into bins based upon similarities in antigen recognition sites or epitopes. This grouping is performed using cross competition assays, in which the competitive binding of antibody pairs to a specific antigen is characterized. If the binding of antigen to one mAb prevents the binding of another mAb, then these mAbs are considered to bind to similar or overlapping epitopes. If binding of a mAb to the antigen does not interfere with the binding of the other mAb, then they are considered to bind to distinct, non-overlapping epitopes. Two criteria must be fulfilled in order to assign mAbs into the same bin. First, all mAbs in the same bin should block each other's ability to bind the antigen. Second, all mAbs in the same bin should have similar blocking profiles when paired with other mAbs in the panel.

The BinChart feature assigns screened antibodies to bins based on the binding threshold set during analysis. This binding threshold can be adjusted to analyze varying binning of antibodies as a result of the changing threshold (Figure 10).

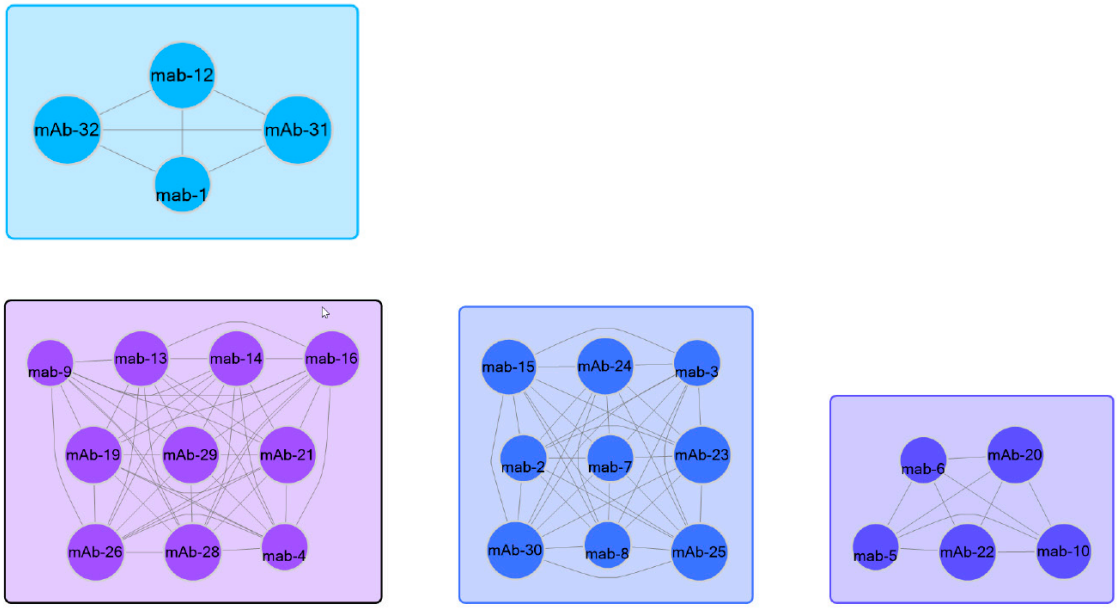

Figure 10: Example BinChart from a 32x64 screen. Each bin represents antibodies that block each other's ability to bind the antigen, and have similar blocking profiles when paired with other antibodies in the panel. In this example, a higher binding nm threshold setting was used.

21 CFR Part 11 Compliance Features

Recent enhancements to our Octet® CFR Software enable all Octet® instruments to be integrated seamlessly into GxP regulated environments (Figure 11).

21 CFR Part 11 Compliance features include:

- Primary data integrity
- Control access with multiple user levels
- Enhanced Audit Trails
- Electronic Signatures
- Full control for routine assays and speed up analysis
- Customized reports

Automated Acquisition and Analysis for All Types of Octet® Data

Octet® BLI Discovery and Octet® Analysis Studio Software provide support for an automation interface through a Serial Port (RS-232) or a Transmission Control Protocol/ Internet Protocol (TCP/IP) socket for Octet® RH16 and RH96 instruments. Octet® Analysis Studio Software also enables automated analysis of all types of datasets, including quantitation, kinetic, dose-response and epitope binning data which was not previously possible. The automation interface was designed to be as universal as possible, making no assumptions about the communication medium or the language of the client application connecting to Octet® Software.

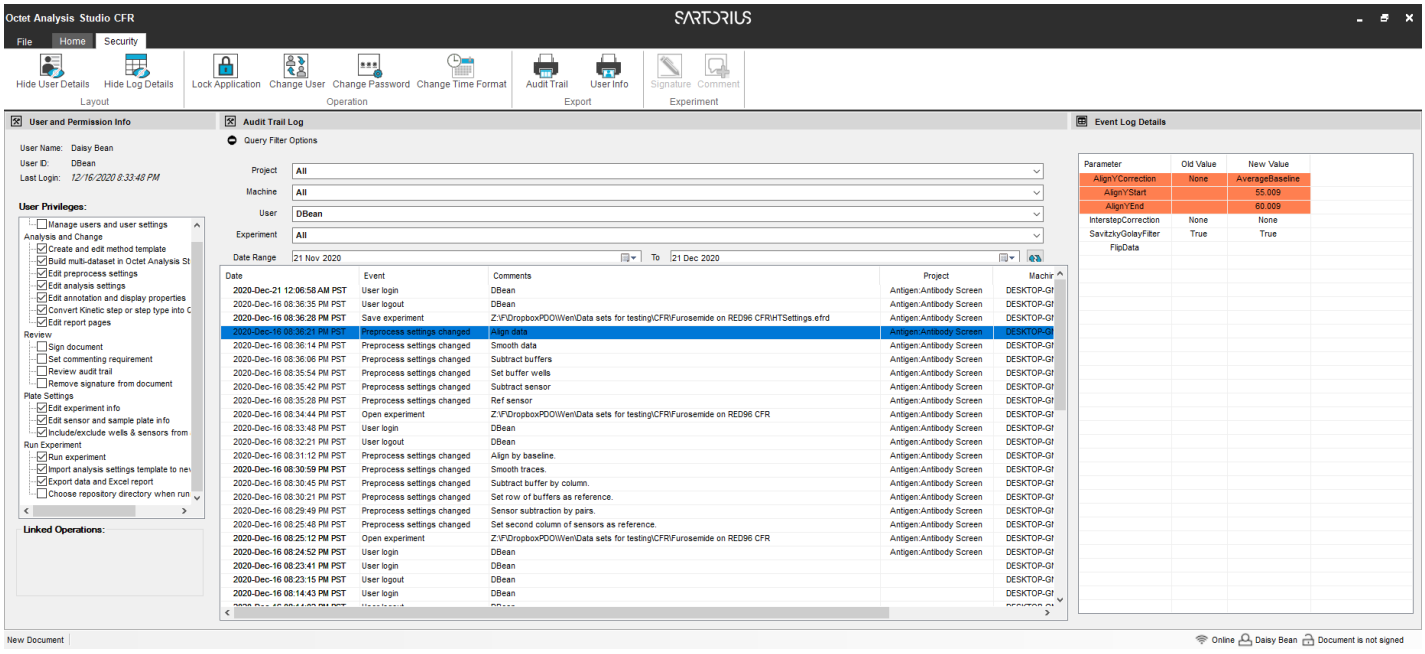

Figure 11: Octet® Data Analysis Studio CFR Software's new Security tab. User info, including username and privileges, are on the left panel. Audit Trail details are in the middle and the old vs. new values are on the right panel on the Security tab.

Octet® BLI Discovery Software Version Feature Comparison

Feature	V11.x	V12.x	V13.x
Increased flexibility in Kinetic method generation when entering dilution factors and designating controls		✓	✓
Increased flexibility in Advanced Quantitation method generation – more step types and reuse step types	✓	✓	✓
Customize default settings – plate type, plate definition (row, columns, or quadrants) and data input	✓	✓	✓
Support for glycoanalysis biosensors (GlyS/GlyM)	✓	✓	✓
Shortcuts to minimize number of clicks	✓	✓	✓
Support for the Biosensor Mount Cleaning Tool for Octet® RH16 and RH96 systems	✓	✓	✓
Support for Octet® R8 system and its microplate evaporation cover consumable	✓	✓	✓
Experiment Wizard includes built-in protocol templates for kinetics, quantitation, and epitope binning	✓	✓	✓
Additional concentration units for virus analysis VP/mL, VG/mL, GC/mL, and CP/mL			✓
Data bridge interface to import Ambr®15 data, and optimize Octet® sample layout assignments			✓
Ability to assign a file locations for routine data transfers between Ambr®15 Software and Octet® Discovery Software			✓
Displaying both sample and reagent plate temperatures in Octet® RH16 and RH96 systems			✓
Built-in method templates for dose-response experiment setup			✓
Ability to continue using Octet® RH96 systems with up to two malfunctioning lamps until service is performed to reduce instrument downtimes			✓

Octet® Analysis Studio Software Version Feature Comparison

Feature	V11.x	V12.x	V13.x
Automated analysis of datasets			
Available as a 64-bit application		✓	✓
Ability to sort multiple fields in data tables		✓	✓
Pre-defined analysis settings import to maximize speed	✓	✓	✓
Automated kinetic analysis of multiple plates	✓	✓	✓
Automated epitope binning analysis of multiple plates	✓	✓	✓
Automated quantitation analysis of multiple plates	✓	✓	✓
Dose-response analysis automation for data analysis and report creation			✓
Automated quantitation data export to Ambr®15 file formats			✓
Data preprocessing			
Cross-plate referencing		✓	✓
Epitope Binning: ability to exclude full sensor trace		✓	✓
Epitope Binning: ability to export data to a csv file		✓	✓
New buttons for reference assignment for better usability	✓	✓	✓
More editable columns for flexibility - loading sample ID, loading concentration, dilution factor	✓	✓	✓
Perform data processing for a combined data from multiple experiments, plates and/or biosensor trays	✓	✓	✓
More flexible referencing options – by column, row, selected wells, pairs, pattern and between biosensor trays	✓	✓	✓

Octet® Analysis Studio Software Version Feature Comparison (continued)

Feature	V11.x	V12.x	V13.x
Advanced inter-step correction to remove bulk shifts or assay artifacts	✓	✓	✓
Report point feature for whole sensor traces – can be added in any step in the trace	✓	✓	✓
More graphical options – thicken line, change trace colors, customize x- and y-axis scales	✓	✓	✓
NEW Dose-response analysis			
3-PL, 4-PL, 5-PL, and linear fitting algorithms for EC_{50}/IC_{50} analysis			✓
Independent and global data fitting of dose-response data			✓
Ability to manually constrain upper and lower asymptote, and hill slope			✓
Automatic assignment of loading, sample, and detection steps in data cycles			✓
Availability of stacked, individual, and pairwise plot views			✓
Calculate and report biosensor immobilization statistics and flag data cycles based on a user defined loading variability threshold			✓
Ability to assign standard groups for relative EC_{50}/IC_{50} analysis between sample groups			✓
Ability to normalize response values to a user specified standard sample group			✓
Export dose-response data and results to CSV. and Excel file formats			✓
Epitope binning analysis			
BinChart for automated binning of antibodies		✓	✓
Color schemes for Matrix display		✓	✓
Ability to export BinChart, original and corrected matrix, table with clustering info		✓	✓
Enable sample ID and information correction, if necessary	✓	✓	✓
Copy epitope binning matrix image	✓	✓	✓
Subtract self-binding in the matrix	✓	✓	✓
Subtract the matrix against a select row or column	✓	✓	✓
Append or overlay data from multiple experiments, plates and biosensor trays	✓	✓	✓
Automatically create 2D traffic light matrix	✓	✓	✓
Kinetic analysis			
Ability to use multiple parameters in global fitting groups		✓	✓
Analyze kinetic cycles with different association/disassociation times in the same experiment file		✓	✓
Batch export of group graphs to image files		✓	✓
Pause auto-fitting of kinetic datasets option	✓	✓	✓
Flip data option	✓	✓	✓
Enable kinetic analysis of multiple experiments that can be visualized together in All Assays tab	✓	✓	✓
More graphical options – thicken line, tooltip, legends, custom y-scaling	✓	✓	✓
Additional data table with individual fitting groups for a concise data view			✓
Additional data table with for reporting steady-state analysis by fit group			✓
Quantitation analysis			
Overlay fitted traces on top of raw binding traces		✓	✓
Exportable Fitted Graph that shows binding signal and curve fit for each sample well		✓	✓
Advanced option to choose the model classifier for binding rate determination		✓	✓
Pause auto-fitting of quantitation datasets option	✓	✓	✓

Octet® Analysis Studio Software Version Feature Comparison (continued)

Feature	V11.x	V12.x	V13.x
One step or one step type (when regeneration is performed) can be quantitated from a kinetic assay	✓	✓	✓
Enables quantitation analysis of multiple experiments and plates by forming a single, combined mega dataset	✓	✓	✓
Standard curve sorted automatically by sensor type if multiple types of sensors are used in an experiment	✓	✓	✓
More advanced sample alerts for data quality	✓	✓	✓
Custom report generation			
Multi-page table support for large experiments		✓	✓
Formatting and sorting capability for data tables		✓	✓
Add residual, steady-state, iso-affinity, XY scatter and grouped graphs to report	✓	✓	✓
Add experiment summary, sensor tray layout, sample plate layout, graphs and tables from any analysis module – quantitation, kinetics, preprocessing or epitope binning	✓	✓	✓
Add text boxes and any image(s)	✓	✓	✓
Export the report in PDF format or print a hard copy	✓	✓	✓
Save report template and load to generate similar reports for other datasets	✓	✓	✓
Create custom reports for presenting dose-response data			✓

Octet® 21 CFR Part 11 Support

Feature	V11.x	V12.x	V13.x
Ability to authorize users to remove signatures from an analysis file		✓	✓
Ability to inactivate the default Administrator account		✓	✓
More detailed audit log of changes made within ForteBio Server Monitor		✓	✓
Ability to choose time zone and date/time format		✓	✓
New Security tab in Octet® Analysis Studio Software	✓	✓	✓
Controlled access with multiple user levels and expanded privileges	✓	✓	✓
Electronic signatures to lock dataset and prevent changes after analysis is complete	✓	✓	✓
Digitally signed data files that are invalidated if any modification is made outside the software	✓	✓	✓
Log all critical user actions in Octet® BLI Discovery and Analysis Studio Software Audit Trail with old versus new values	✓	✓	✓ (New dose response)
Audit Trail can be filtered by project, machine, user, experiment and date interval	✓	✓	✓
Exporting Audit Trail and user information to PDF reports	✓	✓	✓
Option to add customized comments to each analysis event in Audit Trail	✓	✓	✓
Full control over running and analyzing routine assays in regulated labs	✓	✓	✓
Lock all Microsoft® Excel® export reports	✓	✓	✓
Software Validation Package product support	✓	✓	✓
Ability for users with administrative privileges to force users to change a password at next log-in			✓

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