

Octet[®] Software Version 13

Added Features to Improve EC_{50} , IC_{50}
and Potency Analysis

New Key Features

- New EC_{50} and IC_{50} analysis capabilities to determine drug product activities using surrogate potency assays, reducing assay variability, timelines, and costs
- Data bridge to support data transfer between Sartorius Octet[®] and Sartorius Ambr[®] bioreactor systems to accelerate cell line development workflows

Overview

Sartorius Octet[®] BLI Discovery and Analysis Studio Software are evolving to address growing applications, and user needs with every release version.

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 EC₅₀ and IC₅₀ experiments with built-in 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
- Create customized data reports for presenting and reporting dose-response data and conclusions

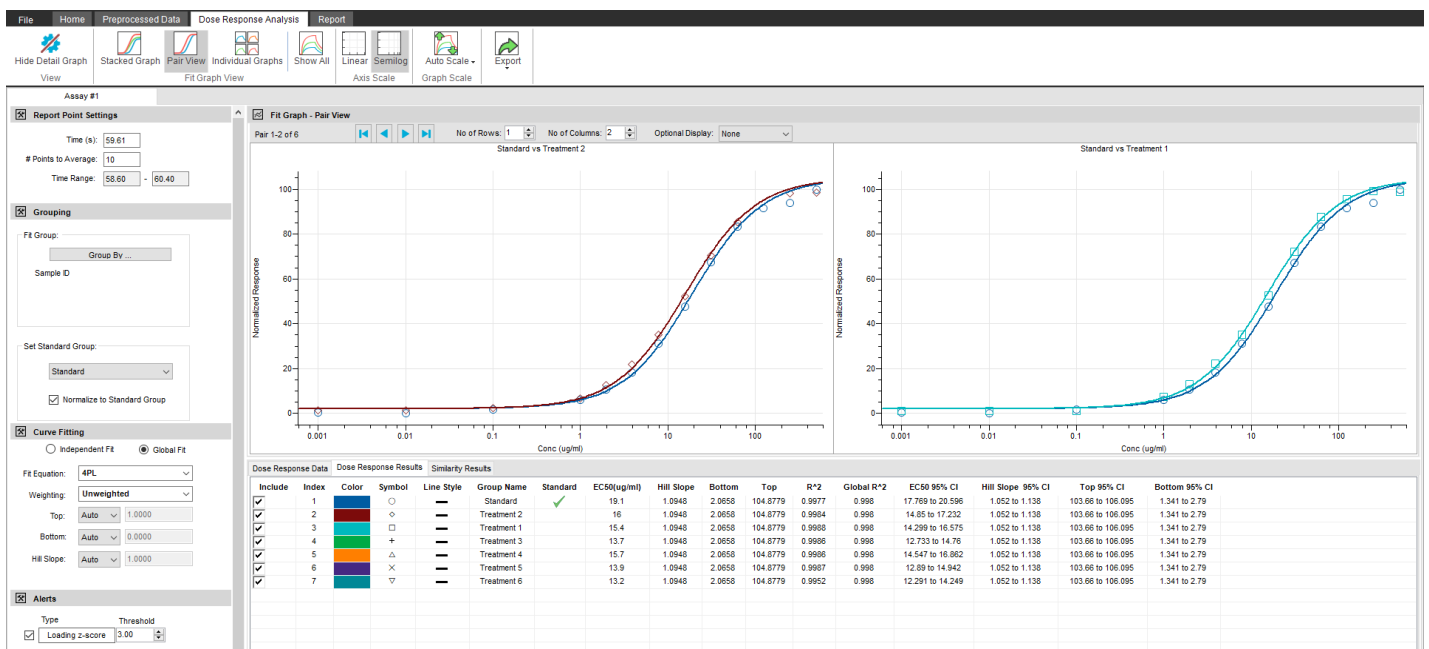


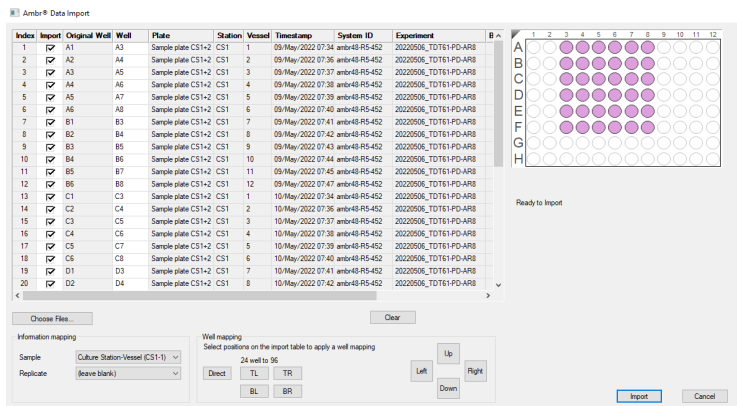
Figure 1: Anti-Her2 lot-to-lot potency evaluation using an Octet® potency assay. Relative potency evaluation between two anti-Her2 antibody lots using the binding activity to Her2. Dose-reponse binding data from multiple lots were fitted globally to a 4-PL fitting algorithm in Octet® Analysis Studio Software.

Octet®- Ambr® 15 Data Bridge

Octet® BLI platforms are routinely implemented in upstream and downstream cell line development workflows measuring critical quality attributes (CQAs) such as product titer, binding activity, or glycosylation ranking. The Ambr® 15 is an automated high-throughput single-use bioreactor system that provides parallel operation of up to 48 single-use microbioreactors at a time where multiple cell culture experiments can be used to evaluate different cell lines, clones, or to identify desirable cell culture process parameters. Ambr® cell culture workflows are often combined with label-free binding assays due to fast time to results and minimal hands-on time.

- Built-in Octet®-Ambr® data bridge in Octet® BLI Discovery Software for importing Ambr® sample and condition information, saving analyst time and eliminating data transfer errors.*
- Directly import Ambr® 15 sample plate map configurations with experimental information, rearrange sample well positions for Octet® assays, and modify sample information or replicate groups using the Octet®-Ambr® 15 data bridge.
- Preconfigure data import and export file locations to streamline data import and export to and from the Octet® to Ambr® 15 data bridge.
- Seamless transfer of Octet® data analytics from Octet® Analysis Studio Software to Ambr® Software for integrating cell culture analytics for faster data feedback.*

A.



B.

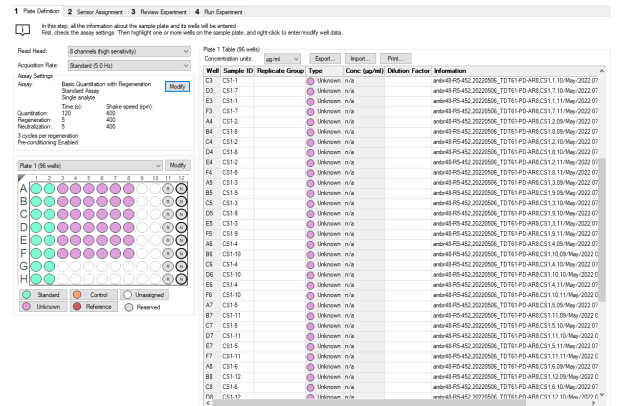


Figure 2: Ambr® 15 process data import to Octet® BLI Discovery Software for product concentration measurement in the Octet® system. (A) The new data interface allows for importing critical sample information from Ambr® 15 process runs. Users can track sample information and reconfigure sample plate maps suitable for the Octet® assay without manually entering information in the Octet® Software. (B) Ambr® 15 sample information is automatically populated for an Octet® experiment and method set up in Octet® BLI Discovery Software.

New Virus Concentration Units

Setup, calculate, and report virus concentration data in VP/mL, VG/mL, CP/mL and GC/mL units in Octet® BLI Discovery and Analysis Studio Software.

Reduce Experiment Downtimes Even Further on Octet® RH96 Instruments

Octet® RH96 instruments are powered by multiple lamps supporting the 96-channel read heads. In the event of a malfunctioning lamp, the Octet® BLI Discovery Software will guide users to continue using the instrument with the remaining lamps and reduced throughput until service on the Octet® instrument is completed to reduce instrument downtimes.

Specifications

Component	Requirement
Processor	3.0 GHz Quad Core processor or greater
Operating system	Windows 10 or Windows 11 Professional, 64-bit
Memory	4 GB RAM or greater
Graphic display	Monitor with 1920x1080 resolution or better
Hard disk	250 GB hard drive or greater. 200 MB available hard disk space required for application files more to acquire data – a single experiment can range from 1 MB to over 100 MB.
Additional software	Microsoft Office

*Use of Octet®-Ambr® 15 Data Bridge will require purchase of Ambr® 15 data interface license and require Ambr® Software version R10.0 or above.

Ordering Information

Part No.	Description
50-5029	Upgrade of Octet® instrument software to the latest version of software. Includes 4 seat licenses. Includes Octet® Software Version 13. Requires previous version of Octet® Software.
50-5098	4-seat licenses of Octet® Software version 13.X. Includes FREE upgrades within 13.X. Requires previous purchase (50-5029) or installation of version 13.X software.
50-5099	1-seat license of Octet® Software version 13.X. Includes FREE upgrades within 13.X. Requires previous purchase (50-5029) or installation of version 13.X software.
50-5100	2-seat license of Octet® Software version 13.X. Includes FREE upgrades within 13.X. Requires previous purchase (50-5029) or installation of version 13.X software.
50-5101	Site license for Octet® Software version 13.X for offline data analysis. Installation and use of the Octet® Software version 13.X at a physical site (single city or ZIP code) as defined in the purchase order. Includes FREE upgrades within 13.X. Requires previous purchase (50-5029) or installation of version 13.X software.
50-5034	Upgrade of Octet® CFR instrument software to the latest version of software. Includes 4 seat licenses. Requires previous version of Octet® CFR Part 11 Software.
50-5102	4-seat licenses of Octet® BLI CFR part 11 software version 13.x at a physical site (single city or ZIP code) as defined in the purchase order. Includes FREE upgrades within 13.X. Requires previous purchase of Octet® BLI CFR part 11 Software version 13.x.
50-5103	1-seat licenses of Octet® BLI CFR part 11 Software version 13.x at a physical site (single city or ZIP code) as defined in the purchase order. Includes FREE upgrades within 13.X. Requires previous purchase of Octet® BLI CFR part 11 Software version 13.x.
50-5104	2-seat licenses of Octet® BLI CFR part 11 Software version 13.x at a physical site (single city or ZIP code) as defined in the purchase order. Includes FREE upgrades within 13.X. Requires previous purchase of Octet® BLI CFR part 11 Software version 13.x. Includes 2-additional licenses.
50-5105	Site license for Octet® BLI CFR part 11 Software version 13.x at a physical site (single city or ZIP code) as defined in the purchase order. Includes FREE upgrades within 13.X. Requires previous purchase of Octet® BLI CFR part 11 Software version 13.x.
50-0300	13.X SOFTWARE VALIDATION PACKAGE. For researchers working in GLP or GMP laboratories, the Octet® Software Validation Package provides comprehensive documentation and tools available to validate GxP administrator features, and quantitation and kinetics functions for data generated on Octet® instrumentation.
001-8B39	Ambr® 15 Octet® data interface.

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