# SVISCISVS

## Product Datasheet

## Octet<sup>®</sup> Software Version 13

## Added Features to Improve EC<sub>50</sub>, IC<sub>50</sub> and Potency Analysis

### New Key Features

- New EC<sub>50</sub> and IC<sub>50</sub> 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<sup>®</sup> and Sartorius Ambr<sup>®</sup> bioreactor systems to accelerate cell line development workflows

#### Overview

Sartorius Octet<sup>®</sup> 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 potencyindicating 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® doseresponse 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<sub>50</sub> and IC<sub>50</sub> experiments with built-in experimental method templates in Octet<sup>®</sup> 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

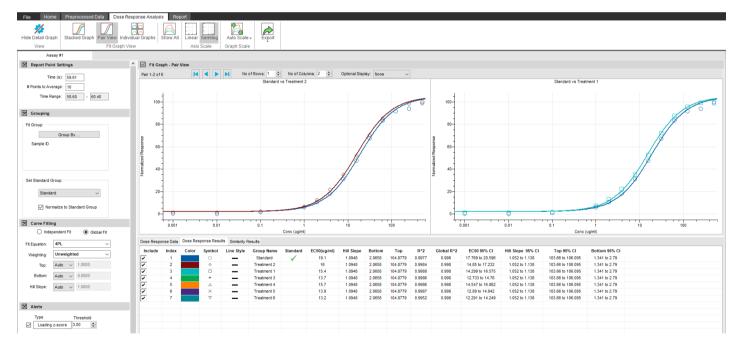


Figure 1: Anti-Her2 lot-to-lot potency evaluation using an Octet<sup>®</sup> potency assay. Relative potency evaluation between two anti-Her2 antibody lots using the binding activity to Her2. Dose-repose binding data from multiple lots were fitted globally to a 4-PL fitting algorithm in Octet<sup>®</sup>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

## Octet<sup>®</sup>- Ambr<sup>®</sup> 15 Data Bridge

Octet<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>-Ambr<sup>®</sup> data bridge in Octet<sup>®</sup> BLI Discovery Software for importing Ambr<sup>®</sup> 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<sup>®</sup> to Ambr<sup>®</sup> 15 data bridge.
- Seamless transfer of Octet<sup>®</sup> data analytics from Octet<sup>®</sup> Analysis Studio Software to Ambr<sup>®</sup> Software for integrating cell culture analytics for faster data feedback.\*

Ambr® Data import										1 Pase Definition 2 Sensor Assorment 3 Review Emersent 4 Run Eccentrent			
	_	ginal Well Well	Plate		sel Timestamp Syste				D In this Rest. of	tep, all the information about the sample plate and its we teck the assay settings. Then highlight one or more wells	Is will be entered. on the sample plate, and right click to enter	nodły wel data.	
1 5	7 A1	A3	Sample plate CS1+2		09/May/2022 07:34 ambr4		06_TDT61-PD-AR8		Read Head:	8 channels (high sensitivity)	Plate 1 Table (96 wells)		
2	7 A2	A4	Sample plate CS1+2	CS1 2	09/May/2022 07:35 ambr4	8-R5-452 20220508	06_TDT61-PD-AR8	BOOOOOOO	Acquistion Rate	Standard (5.0 Hz)	Concentration units: µg/el ~	Export Import Print.	
3 5	Z A3	AS	Sample plate CS1+2	CS1 3	09/May/2022 07:37 ambr4	8-R5-452 20220500	06 TDT61-PD-AR8			Standard (D.U.P.z)	Well Sample ID Replicate Group	Type Conc (µg/ml) Diluti	ion Factor Information
4 5	2 44	AG	Sample plate CS1+2	151 4	09/May/2022 07:38 ambr4	8.85452 2022050F	06_TDT61-PD-AR8		Assay Seconds	Standard Assay	C3 CS1-1	<ul> <li>Unknown n/a</li> </ul>	anbr48-R5-452.20220506_TDT61-PD-AR8.CS1.1.10/May/202
5 5		AZ	Sample plate CS1+2		09/May/2022 07:39 ambr4		06 TDT61-PD-AR8				D3 CS1-7	Unknown n/a	anbr48 R5 452,20220506_TD T61 PD AR8,CS 1,7,10/May/202
										Single analyte Time (s): Shake speed (rpm):	E3 CS1-1	🕘 Unknown n/a	ambr48-R5-452,20220506_TDT61-PD-AR8,CS1,1,11/May/202
6 1		AS	Sample plate CS1+2		09/May/2022 07:40 ambr4		06_TDT61-PD-AR8		Quantitation: 120 400 Receneration: 5 400	120 400	F3 CS1-7	<ul> <li>Unknown n/a</li> </ul>	anbr48-R5-452,20220506_TDT61-PD-AR8.CS1.7.11/May/202
7 🕟	7 B1	B3	Sample plate CS1+2	CS1 7	09/May/2022 07:41 ambr4	8-R5-452 20220508	06_TDT61-PD-AR8			5 400	A4 CS1-2	<ul> <li>Unknown n/a</li> </ul>	anbr48-R5-452.20220506_TDT61-PD-AR8.CS1.2.09/May/202
8 15	7 82	B4	Sample plate CS1+2	S1 8	09/May/2022 07:42 ambr4	8-R5-452 20220508	06_TDT61-PD-AR8		3 cycles per rece	neration	B4 CS1-8	<ul> <li>Unknown n/a</li> </ul>	anbr48-R5-452.20220506_TDT61-PD-AR8.CS1.8.09/May/202
9 15	2 83	85	Sample plate CS1+2	-51 9	09/May/2022 07:43 ambr4	8.R5452 20220506	06 TDT61-PD-AR8	<b>G</b> 000000000000000000000000000000000000	Pre-conditioning	ng Enabled efa) v Modify	C4 C51-2	<ul> <li>Unknown n/a</li> </ul>	anbr48-R5-452,20220506_TDT61-PD-AR8,CS1,2,10/May/202
		86	Sample plate CS1+2		09/May/2022 07:44 ambr4		06 TDT61-PD-AR8	HAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAA			D4 CS1-8	Unknown n/a	ambr48-R5-452,20220506_TDT61-PD-AR8,CS1,8,10/May/20
											E4 CS1-2	<ul> <li>Unknown n/a</li> </ul>	anbr48-R5-452.20220506_TDT61-PD-AR8.CS1.2.11/May/20
1 5		87	Sample plate CS1+2		09/May/2022 07:45 ambr4		06_TDT61-PD-AR8				F4 CS1-8	<ul> <li>Unknown n/a</li> </ul>	anbr48-R5-452.20220506_TDT61-PD-AR8.CS1.8.11/May/20
2 🕟	7 B6	B8	Sample plate CS1+2	CS1 12	09/May/2022 07:47 ambr4	8-R5-452 20220506	06_TDT61-PD-AR8				A5 CS1-3	<ul> <li>Unknown n/a</li> </ul>	anbr48 R5 452,20220506_TDT61 PD -AR8,CS 1,3.09 / May / 202
3 1	7 C1	C3	Sample plate CS1+2	S1 1	10/May/2022 07:34 ambr4	8-R5-452 20220508	06_TDT61-PD-AR8	Ready to Import		85 CS1-9	🕘 Unknown n/a	ambr48-R5-452,20220506_TDT61-PD-AR8,CS1,9,09/May/202	
4 15	7 C2	C4	Sample plate CS1+2	51 2	10/May/2022 07:35 ambr4	8.85452 20220506	06 TDT61-PD-AR8			C5 C51-3	<ul> <li>Unknown n/a</li> </ul>	anbr48-R5-452,20220506_TDT61-PD-AR8,CS1.3.10/May/20	
5 15		C5	Sample plate CS1+2		10/May/2022 07:37 ambr4		06 TDT61-PD-AR8				06 CS1-9	Unknown n/a	anbr48-R5-452.20220506_TDT61-PD-AR8.CS1.9.10/May/20
											E5 CS1-3	Unknown n/a	anbr48-R5-452.20220506_TDT61-PD-AR8.CS1.3.11/May/20
6 1		C6	Sample plate CS1+2		10/May/2022 07:38 ambr4		06_TDT61-PD-AR8			F5 CS1-9	Unknown n/a	anbr48 R5 452,20220506_TDT61 PD AR8,CS1,9,11/May/20	
7 5	7 C5	C7	Sample plate CS1+2	CS1 5	10/May/2022 07:39 ambr4	8-R5-452 20220500	06_TDT61-PD-AR8			A6 CS1-4 86 CS1-10	Unknown n/a	ambr48-RS-452,20220506_TDT61-PD-AR8,CS1,4,09/May/20	
8 5	7 C6	C8	Sample plate CS1+2	CS1 6	10/May/2022 07:40 ambr4	8-R5-452 20220508	06_TDT61-PD-AR8				Unknown n/a	anbr48-R5-452.20220506_TDT61-PD-AR8.CS1.10.09/May/2	
9 15	7 01	D3	Sample plate CS1+2	S1 7	10/May/2022 07:41 ambr4	8-R5-452 20220508	06 TDT61-PD-AR8			C6 C51-4 D6 C51-10	O Unknown n/a	anbr43-R5-452.20220506_TDT61-PD-AR8.CS1.4.10/May/20	
		D4	Sample plate CS1+2		10/May/2022 07:42 ambr4		06 TDT61-PD-AR8		HOO	0000000000	E5 C514	O Unknown n/a	anbr43 R5-452,20220506_TDT61 PD-AR8.CS1,10.10/May/2
	/ 02	04	Sample plate CS142	- o	10/May/2022 07/42 anot4	0110402 20220001	00_10101+0-MMo 0		Standard	Control Ubassioned	F6 C51-10	Unknown n/a	anbr48.R5.452,20220506_TDT61.PD AR8,CS1.4,11/May/202
							>				A7 CS1-5	O Unknown n/a	ambr48-RS-452,20220506_TDT61-PD-AR8,CS1,10,11/May/20
									O Unknown	Reference Reserved	87 CS1-11	<ul> <li>Unknown n/a</li> <li>Unknown n/a</li> </ul>	anbr48-R5-452.20220506_TDT61-PD-AR8.C51.5.05/May/20 anbr48-R5-452.20220506_TDT61-PD-AR8.C51.11.05/May/20
Choose	e Files					Clear					67 CS1-5	Unknown n/a	antir49+6-452,20220506_10161+PD-AR8.CS1.510.9/May/20 antir48-R5452,20220506_TD161-PD-AR8.CS1.5.10./May/20
											D7 C51-11	Unknown n/a	anbr48-H5-452,20220506_10161-PD-AR8.C51.5.10/May/20 anbr48-R5-452,20220506_TD161-PD-AR8.C51.11.10/May/20
ormation	mapping			napping							E7 CS1-5	Unknown n/a	anti-48-PS-452,20220506_10161-PD-4PB,CS151110448/202 anti-48-PS-452,20220506_TD161-PD-4PB,CS15111/Max/202
		Culture Station-Vessel			the import table to apply a well m	apping	Up				E7 CS1-11	Unknown n/a	antor45-P5-452,20220506_10161-PD-4R8,C51,511/Map/202 antor45-P5-452,20220506_TD161-PD-4R8,C51,31,11/Map/202
nple		Culture station-Vessel	(CS1-1) V	24 we	to 96						A8 C51-6	Unknown n/a	antin40+65-452,20220506_10161+PD-4460C51.11.11/May/20 antin40-85-452,20220506_TD161-PD-488.C51.6.09/May/20
licate		(leave blank)	~ D	set TL	TR	Le	.eft Right				88 C51-12	Unknown n/a	antor4945452,20220506_10161PD-4483.CS136.05/May/2 antor4945452,20220506_10161PD-4483.CS132,05/May/2
											C8 CS1-6	Unknown n/a	anti-48-R5-452,22220506_101611PD-4R8.C51,12.05/Hay/20 anti-48-R5-452,20220506_TDT61-PD-4R8.C51,6.10/May/20
				BL	BR		Down				08 05142		ampro-PD-452,2220506_10161PD-4R6,CS15,10/May/2 ambro48,85,452 20220506_10161PD-4R6,CS112 10/May/2

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<sup>®</sup> RH96 instruments are powered by multiple lamps supporting the 96-channel read heads. In the event of a malfunctioning lamp, the Octet<sup>®</sup> BLI Discovery Software will guide users to continue using the instrument with the remaining lamps and reduced throughput until service on the Octet<sup>®</sup> 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<sup>®</sup>-Ambr<sup>®</sup> 15 Data Bridge will require purchase of Ambr<sup>®</sup> 15 data interface license and require Ambr<sup>®</sup> 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 <sup>®</sup> 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 <sup>®</sup> 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 <sup>®</sup> 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.

#### Germany

USA

Sartorius Lab Instruments GmbH & Co. KG Otto-Brenner-Strasse 20 37079 Goettingen Phone +49 551 308 0 Sartorius Corporation 565 Johnson Avenue Bohemia, NY 11716 Phone +1 888 OCTET 75 Or +1 650 322 1360

For further contacts, visit www.sartorius.com/octet-support