

Agilent xCELLigence RTCA Software Pro

GMP compliant support for your manufacturing QC needs



Continuous Cell Analysis for Rapid Cell Therapy and Vaccine Discovery, Development, and Manufacturing



The Agilent xCELLigence Real-Time Cell Analysis (RTCA) Software Pro is an integrated software package to generate and analyze data obtained from xCELLigence RTCA DP, SP, MP, S16, and HT instruments. Using proprietary impedance-based biosensors attached to electronic microtiter plates (E-Plates), RTCA technology enables label-free, real-time, automated monitoring of cell number, size, and shape, with minimal hands-on time. In addition to basic data analysis functions, the software offers modules for immunotherapy analysis and GMP compliance support.

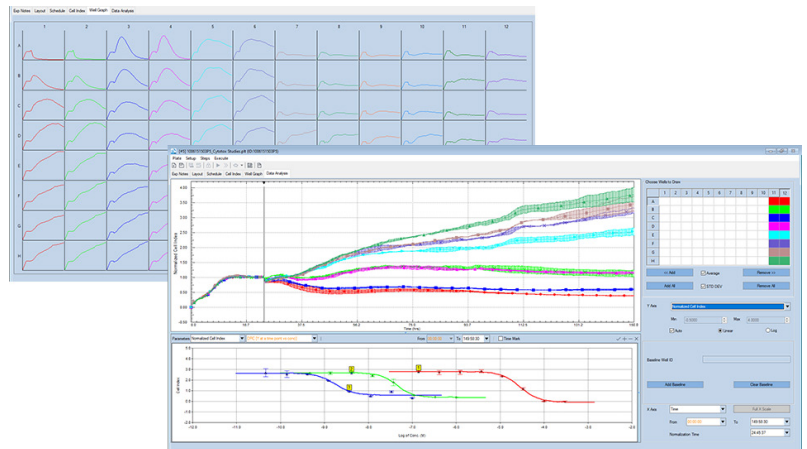
[F1] (ID:210802****P1)											
Plate: Setup Steps Execute											
Exp Notes Layout Schedule Cell Index Well Graph Data Analysis											
Cell	Treatment										
	1	2	3	4	5	6	7	8	9	10	11
A	Taxol 100.0nM	Taxol 100.0nM	Taxol 100.0nM	SFU 100.0nM	SFU 100.0nM	SFU 100.0nM	Vincristine 100.0nM	Vincristine 100.0nM	Vincristine 100.0nM	CpdX 1.0uM	CpdX 1.0uM
B	Taxol 33.3nM	Taxol 33.3nM	Taxol 33.3nM	SFU 33.3nM	SFU 33.3nM	SFU 33.3nM	Vincristine 33.3nM	Vincristine 33.3nM	Vincristine 33.3nM	CpdX 0.33uM	CpdX 0.33uM
C	Taxol 11.1nM	Taxol 11.1nM	Taxol 11.1nM	SFU 11.1nM	SFU 11.1nM	SFU 11.1nM	Vincristine 11.1nM	Vincristine 11.1nM	Vincristine 11.1nM	CpdX 0.11uM	CpdX 0.11uM
D	Taxol 3.70nM	Taxol 3.70nM	Taxol 3.70nM	SFU 3.70nM	SFU 3.70nM	SFU 3.70nM	Vincristine 3.70nM	Vincristine 3.70nM	Vincristine 3.70nM	CpdX 37.0nM	CpdX 37.0nM
E	Taxol 1.23nM	Taxol 1.23nM	Taxol 1.23nM	SFU 1.23nM	SFU 1.23nM	SFU 1.23nM	Vincristine 1.23nM	Vincristine 1.23nM	Vincristine 1.23nM	CpdX 12.3nM	CpdX 12.3nM
F	Taxol 0.41nM	Taxol 0.41nM	Taxol 0.41nM	SFU 0.41nM	SFU 0.41nM	SFU 0.41nM	Vincristine 0.41nM	Vincristine 0.41nM	Vincristine 0.41nM	CpdX 4.1nM	CpdX 4.1nM
G	Taxol 0.14nM	Taxol 0.14nM	Taxol 0.14nM	SFU 0.14nM	SFU 0.14nM	SFU 0.14nM	Vincristine 0.14nM	Vincristine 0.14nM	Vincristine 0.14nM	CpdX 1.37nM	CpdX 1.37nM
H	Taxol 45.72pM	Taxol 45.72pM	Taxol 45.72pM	SFU 45.72nM	SFU 45.72nM	SFU 45.72nM	Vincristine 45.72pM	Vincristine 45.72pM	Vincristine 45.72pM	CpdX 0.46nM	CpdX 0.46nM

Simple assay setup

- Enter cell and treatment conditions for each well using an intuitive software interface.
- View conditions undergoing analysis with a color-coded plate map.
- Load a template to create a new experiment and export details as Excel, text, or PDF files.
- Convenient assay scheduling for both single and multiple users.

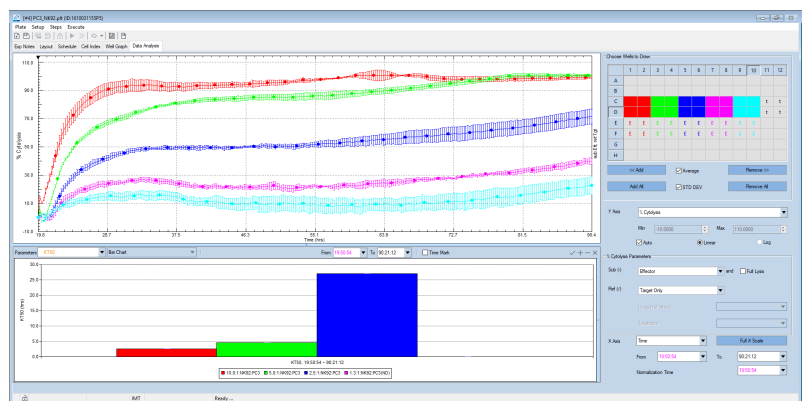
Streamlined real-time data acquisition and analysis

- Obtain early insights by viewing and analyzing acquired data during ongoing experiments.
- Select and simultaneously display relevant data from specific wells.
- Automatically generate dose response curves and IC_{50}/EC_{50} values to create customized reports and publication-quality figures.



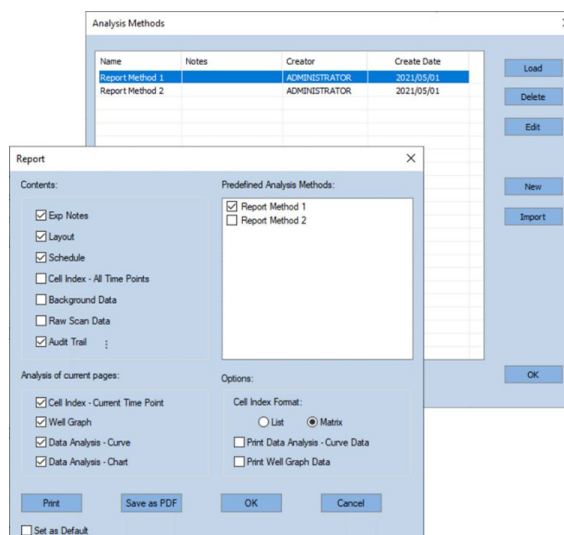
Powerful immunotherapy analysis tools

- Streamline immunotherapy experimental design and analysis of cytolytic activity.
- Consistently calculate real-time effector cytotoxicity at low, physiologically relevant E:T ratios.
- Calculate killing time (KT_{50}) and measure treatment efficacy against various controls.



Experimental template for automated data output and analysis

- Conveniently save and load user-defined templates to standardize experimental design and workflow.
- Templates for Analysis Method & Report enable users to easily manage the data analysis process and results.



RTCA Software Pro supports for FDA 21 CFR Part 11 compliance

- Achieves requirements of each section of 21 CFR Part 11 and related sections of EU Annex 11.
- Ensures authenticity and integrity of electronic data acquisition and analysis.
- Includes three specific elements of regulated laboratory operations:
 - Security of electronic records
 - Attribution of work
 - Electronic signatures

What is FDA 21 CFR Part 11 compliance?

CFR stands for Code of Federal Regulation. 21 CFR Part 11 is a U.S. Food and Drug Administration (FDA) regulatory requirement for companies in a regulated environment detailing specific criteria to ensure electronic records, audit trails, and signatures are trustworthy and equivalent to paper records.

Why is FDA 21 CFR Part 11 compliance important?

Most biopharma customers require products incorporated into their workflows to enable FDA 21 CFR Part 11 compliance, particularly if they will be directly or eventually used in a manufacturing environment. Requirements of FDA 21 CFR Part 11 compliance not only ensure authenticity, integrity, and confidentiality of raw electronic data, but also confirm electronic signatures.



RTCA Software Pro highlighted features for GxP and FDA 21 CFR Part 11

Data security

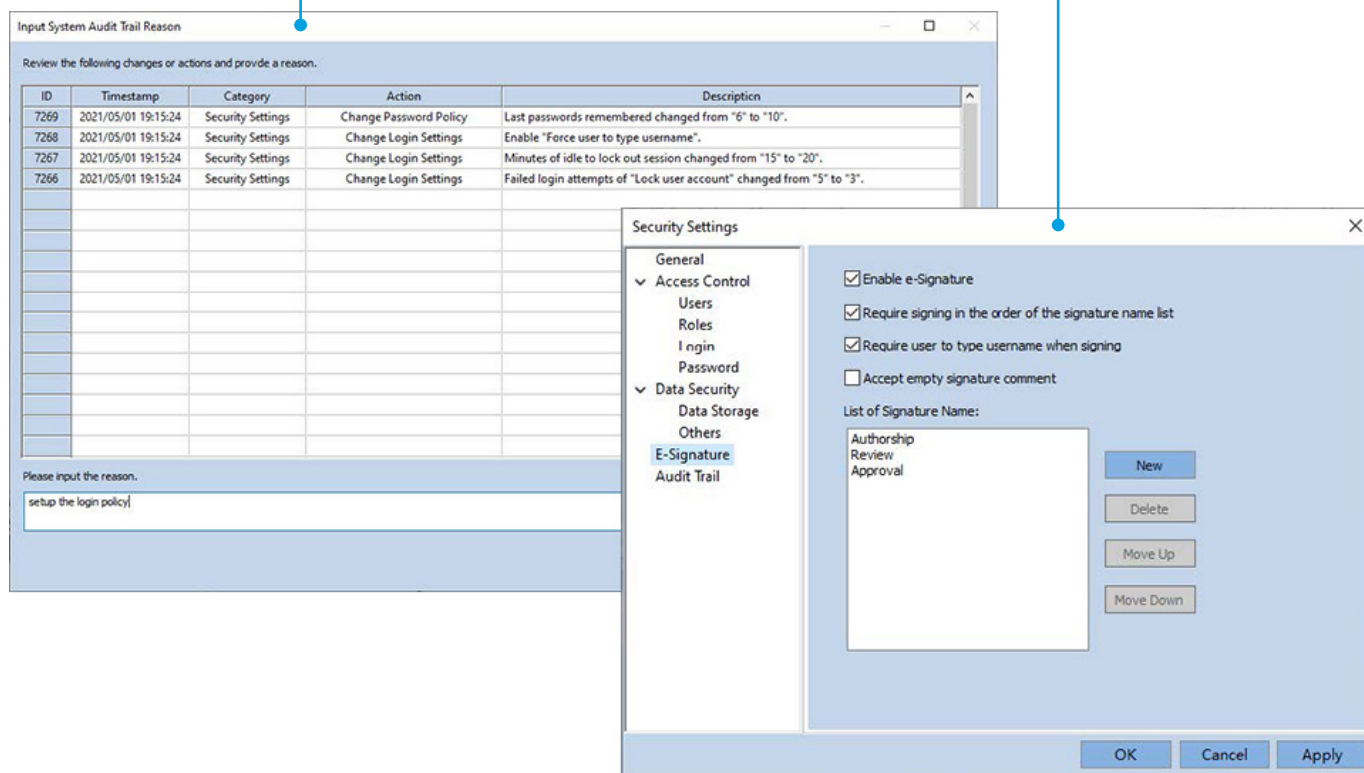
- A Windows account is required to allow the software to write and read data in the secure data folder.
- The Experiment File (*.plt) is in a database format, which is password-protected and can only be opened by RTCA Software Pro.

System audit trail

- Saved in a single database file (SystemLog.sys) located in the software installation folder.
- Records software configuration changes, instrument operation activities, software run logs, etc.

File audit trail

Records activities at the file level: creating new experiments, modifying experiment settings, operating the instrument, creating or modifying data analysis, creating reports, etc.



eSignatures

- Ensure record authenticity, integrity, and confidentiality.
- Are permanently linked to their respective records.
- Include the date and time the signature was executed.

Supported instruments



SP



DP



MP



HT



S16

Assays	RTCA SP	RTCA DP	RTCA MP	RTCA HT	RTCA S16
Cell characterization/QC	✓	✓	✓	✓	✓
Immunotherapy/cell killing	✓	✓	✓	✓	✓
Adhesion	✓	✓	✓	✓	✓
Receptor signaling	✓	✓	✓	✓	✓
Cell invasion/migration		✓			
Specifications					
Format	1 × 96 wells	3 × 16 wells	6 × 96 wells	1 × 384 wells	1 × 16 wells
Maximum throughput	96 wells	48 wells	576 wells	384 wells	16 wells

RTCA software license selection guide

RTCA Software Pro Features	Basic License	Immunotherapy License	Compliance License (Additional Module)
Doubling time calculation	✓	✓	
Slope calculation	✓	✓	
Time-dependent IC ₅₀ calculation	✓	✓	
Automated bar chart generation	✓	✓	
Dose response curve	✓	✓	
Percentage of control curve	✓	✓	
Immunotherapy experiment template (target, effector, mock effector cells)		✓	
Killing time KT ₅₀ calculation		✓	
% Cytolysis calculation from target, target/effectors, target/mock effectors		✓	
Normalized Cell Index curve with effector subtraction		✓	
Supports users in achieving requirements of FDA 21 CFR Part 11			✓
Security of electronic records			✓
Attribution of work with system and file audit trail			✓
Electronic signatures			✓

Customer testimonial

"It is bewildering to me why anyone would maintain generating end-point assay data when you can use xCELLigence. There is no labeling required. Simply plate the cells, and 24 hours later add compound or CAR-T, and walk away for the next 80 hours. When the experiment is over, analyze with the built-in software and you have report/publication-grade data in about 15 minutes! The xCELLigence platform is phenomenal – as a CRO, the MP (multiplate) version is the workhorse of the more than 80 to 90 CAR-T and CAR-NK projects already completed."

- John Wu, ProMab Biotechnologies

Learn more:

www.agilent.com/en/product/cell-analysis/real-time-cell-analysis/rtca-software/rtca-software-pro-741236

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