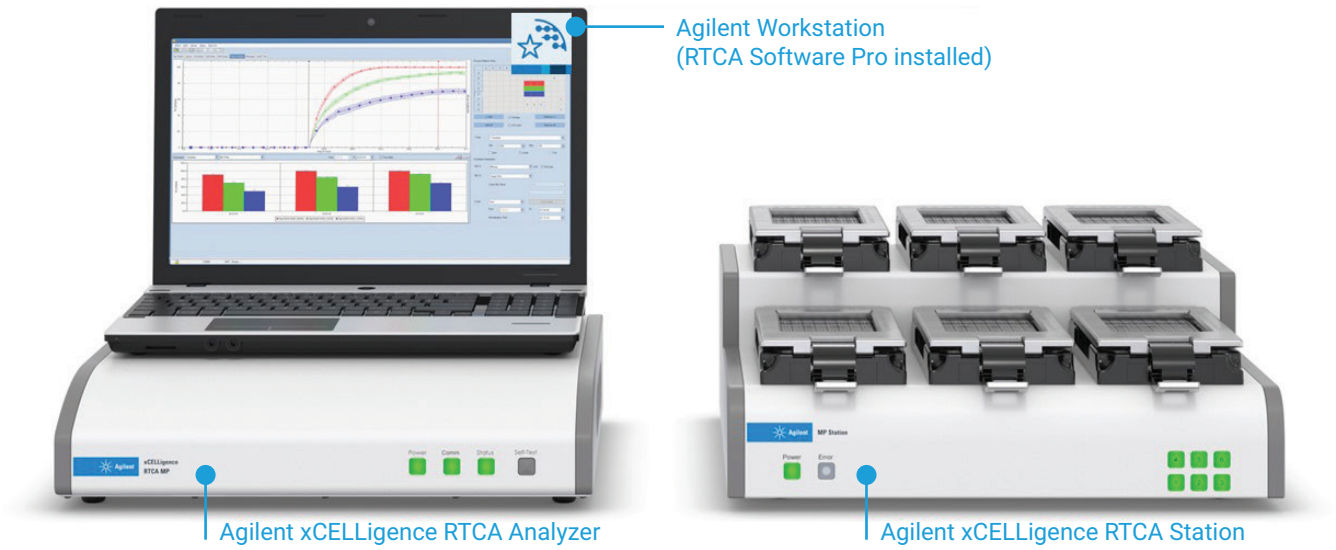
Agilent

Trusted Answers

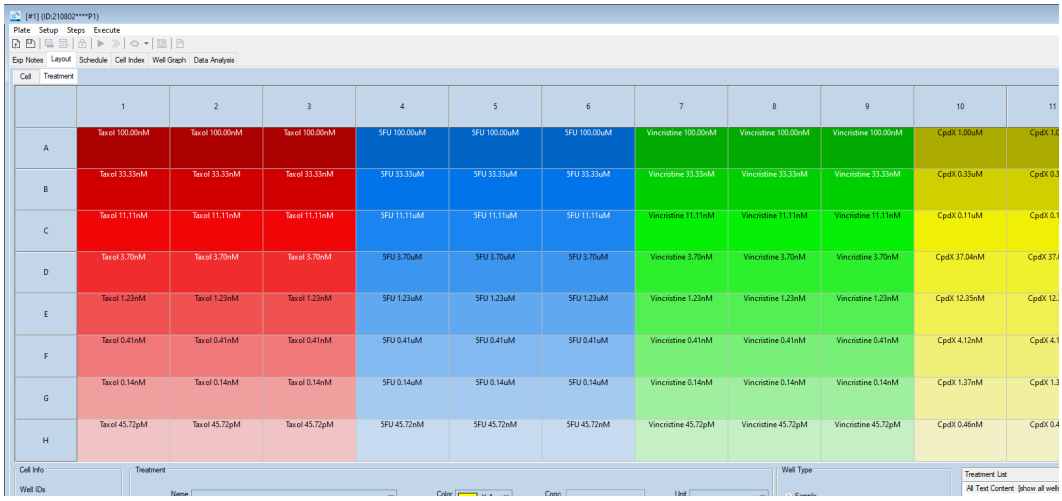
Agilent xCELLigence RTCA Software Pro

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 microplates (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.

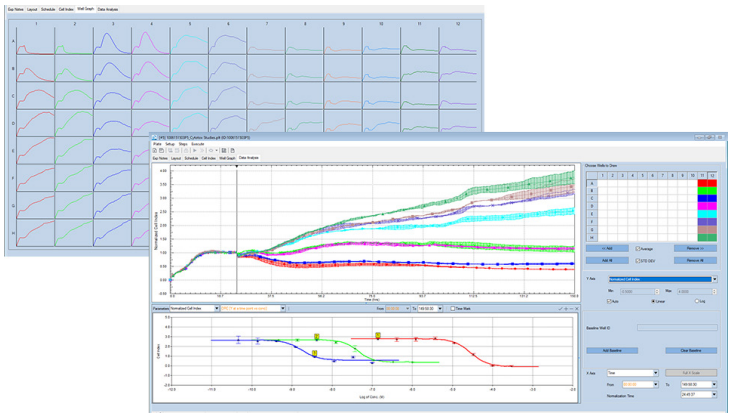


Simple assay setup

- 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.

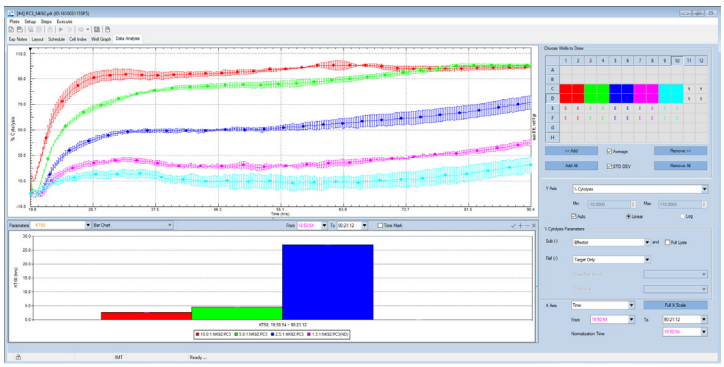
Streamlined real-time data acquisition and analysis

- 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.



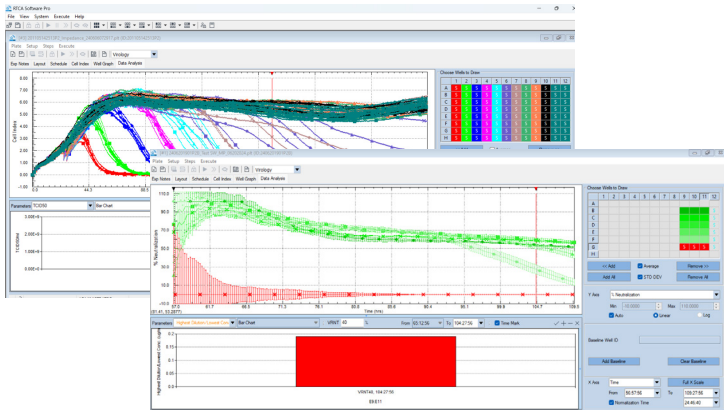
Powerful immunotherapy analysis tools

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



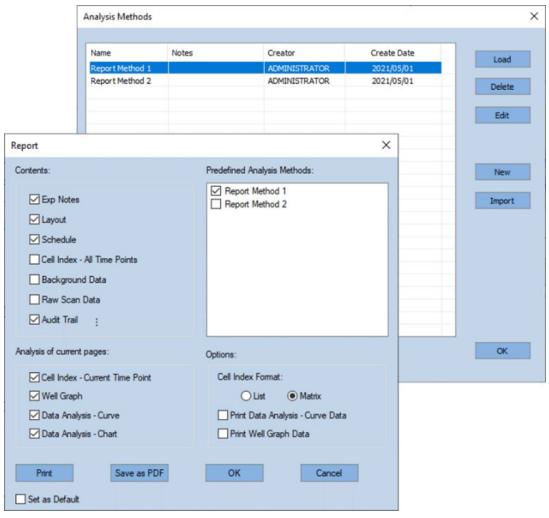
Deeper insights into advanced virological research

- Breadth of customizable features for TCID50 calculation, user-defined threshold for CPE-postive wells.
- Support a wide array of cell lines and viruses with simplified assay process.
- Highly increased sensitivity, objectivity, and ease-of-use with reduced exposure to harmful viruses.



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

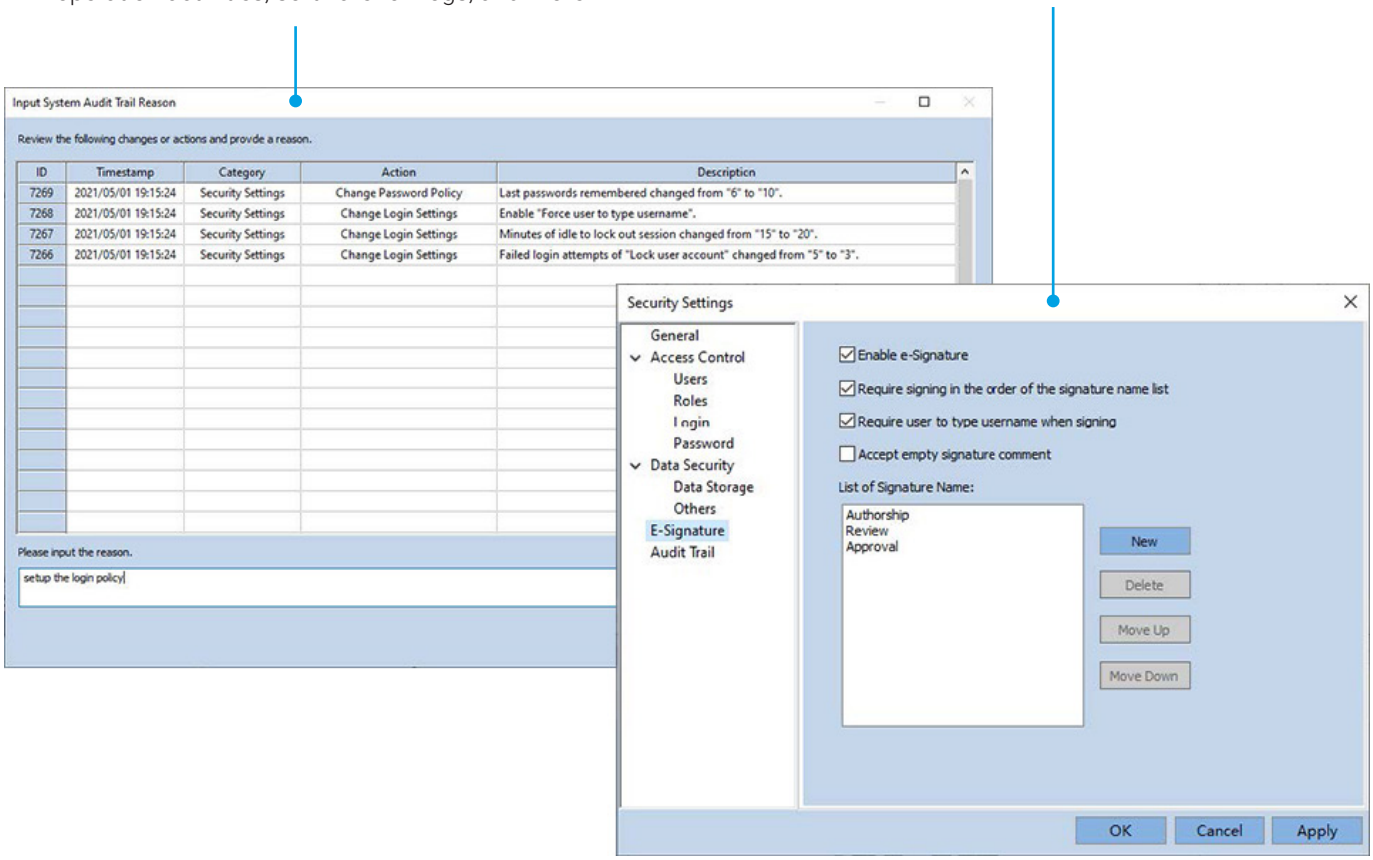
- A Windows account is required to allow the software to write and read data in the secure data folder.
- The Experiment File (*.plt) is in a database format, which is password-protected and can only be opened by RTCA Software Pro.

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, and more.

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, and more.



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	√	√	√	√	√
Chemotactic cell invasion/migration		√			
Wound healing	√		√		
Viral titer/TCID50 calculation	√	√	√	√	√
Virus Reduction Neutralization Test (VRNT)	√	√	√	√	√
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	Virology License (Add-on Module)	Compliance License (Add-on 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		√		
Percent 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				√
Viral titer/TCID50 calculation			√	
Virus Reduction Neutralization test (VRNT)			√	
Percentage of CPE			√	
Percentage of neutralization			√	
Input for virus inoculation volume			√	
Input for virus dilution			√	

Customer testimonial

"The advantage of the xCELLigence RTCA is that the data are easily analyzed with the software since killing curves are automatically generated. The xCELLigence RTCA also saves time—it does not require additional reagents, and the ability to perform statistical analysis at any time point provides a more comprehensive data set in a single run. Most importantly, the in vitro xCELLigence RTCA killing data correlate well with in vivo efficacy data, which helps us accelerate timelines."

- Vita Golubovskaya, ProMab Biotechnologies

Learn more:
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