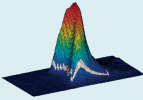

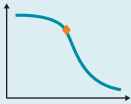




Gyrolab® software modules

Product Information Sheet

D0016374/G

	Gyrolab Viewer	Review binding profiles for individual data points at your desktop
	Gyrolab ADA Software	Monitor anti-drug antibodies – use together with Gyrolab CDs
	Gyrolab Affinity Software	Facilitates the design and evaluation of in-solution affinity experiments
	Gyrolab LIMS interface	Integrate with LIMS
	Gyrolab Control Report	Automatically generate non-editable raw data reports

Enhance functionality and retain 21 CFR Part 11 compliance

Gyrolab® instruments enable immunoassays to be performed at nanoliter-scale within Gyrolab CDs. Each instrument is delivered with Gyrolab Manager to set up immunoassays for assay development or routine analysis, Gyrolab Control to control automated workflows, and Gyrolab Evaluator, to analyze data and generate reports. All Gyrolab software are designed for 21 CFR Part 11 compliance.

Gyrolab software modules provide additional functions that can be added to any workstation. All modules are designed for 21 CFR Part 11 compliance to ensure suitability for use from research through to regulated GxP environments, and to facilitate transfer of assays between laboratories.



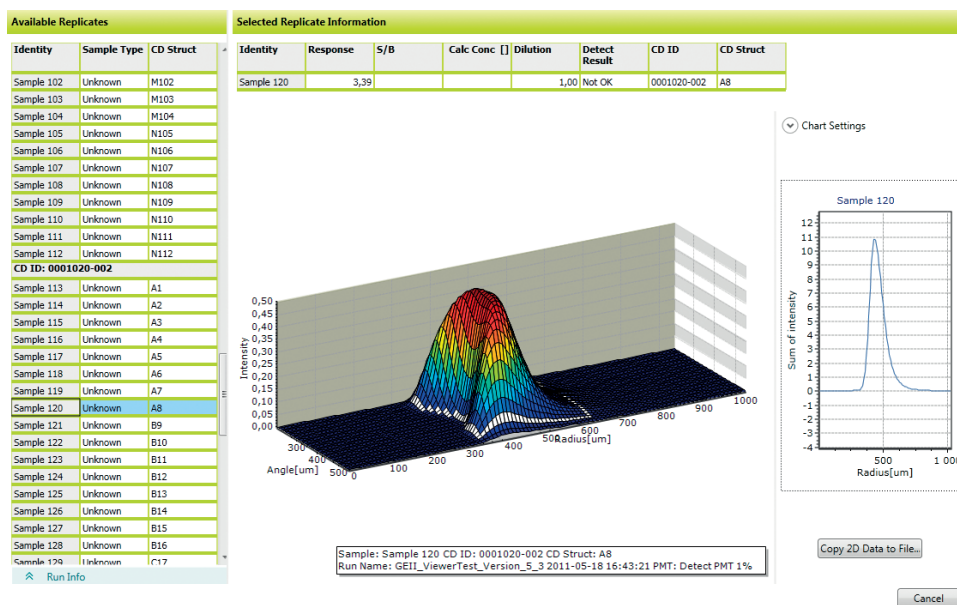
Gyrolab Viewer

- **Review each data point at your desktop**
 - See binding profile, sample and run details
 - Compare samples run under the same conditions on different CDs
- **Facilitate assay development**
 - Compare binding profiles
 - Identify optimal binding pairs
- **Quality control data**
 - Investigate outliers
 - Troubleshoot during development or routine analysis

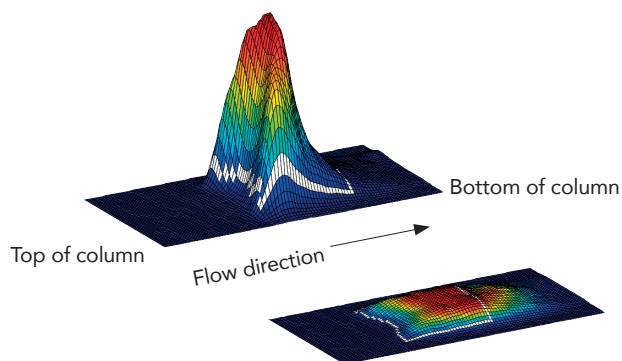
The unique Gyrolab Viewer module converts on-column fluorescence signals into binding profiles, revealing the interaction of each data point. Gyrolab Viewer is accessed directly through Gyrolab Evaluator to facilitate assay development and troubleshooting from research through to regulated environments.

Gyrolab Viewer visualizes the binding response for each data point. You can compare binding profiles and samples run under the same conditions on different CDs, quality-control data by investigating outliers, and troubleshoot during development or routine analysis.

Gyrolab Viewer is compatible with Gyrolab Control v 5.3 or higher and Gyrolab Evaluator v 3.2 or higher. The module is supplied under license. No additional installation is required.



Display binding profile, sample and run details at your desktop.



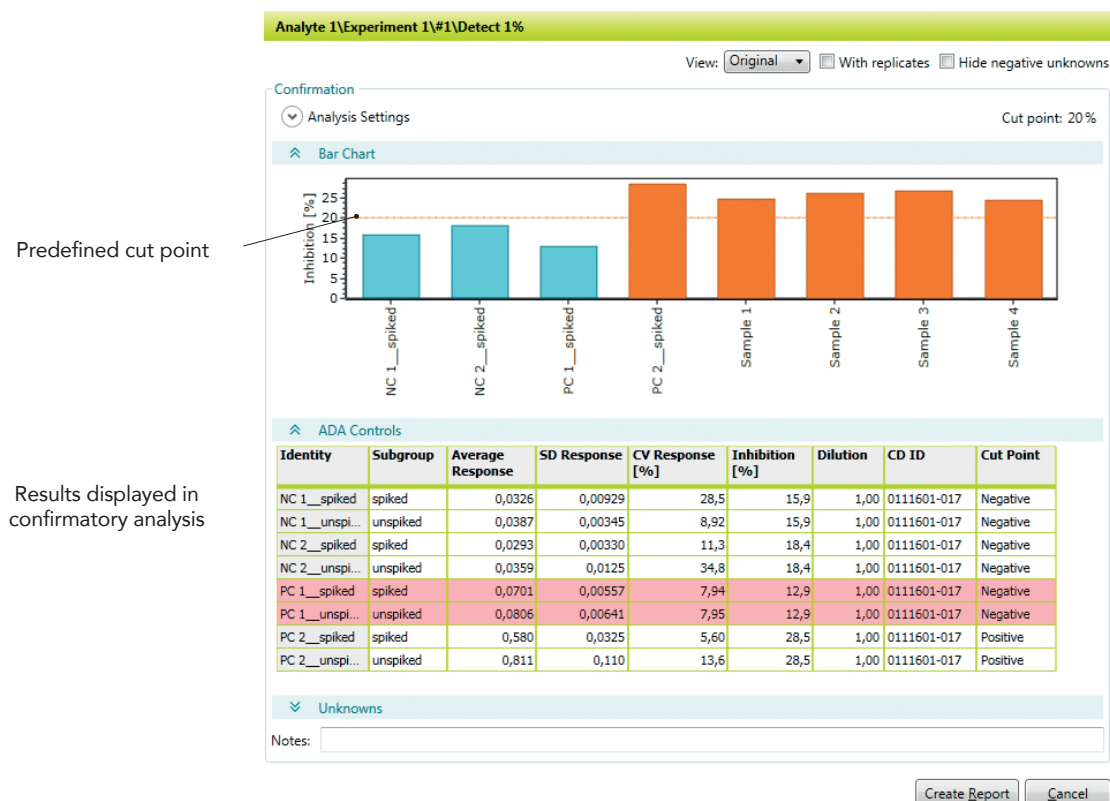
Binding profiles from Gyrolab Viewer assist in selection of optimal binding pairs and during troubleshooting. Data can be exported to enable comparison of 2D profiles.

Gyrolab ADA Software

- Streamlines workflows from assay development through screening to confirmation
- Follow guidelines and recommendations in the Gyrolab ADA assay protocol
- Define preferred cut point formula
- Visualize results according to predefined acceptance criteria and cut point

Gyrolab ADA Software, used together with Gyrolab CDs, follows a standard assay workflow to provide time-efficient, drug-tolerant analysis of anti-drug antibodies (ADA). You can define the preferred cut point formula and view results according to predefined acceptance criteria and cut point. The software will help your confirmatory analysis by displaying results according to your acceptance criteria and confirmatory cut point, and highlight any samples that fall outside.

Gyrolab ADA Software is compatible with Gyrolab Control v 5.4 or higher and Gyrolab Evaluator v 3.3 or higher. The module is supplied under license and no additional installation is required.



Gyrolab ADA Software takes the user smoothly through an ADA assay workflow.

Gyrolab LIMS interface

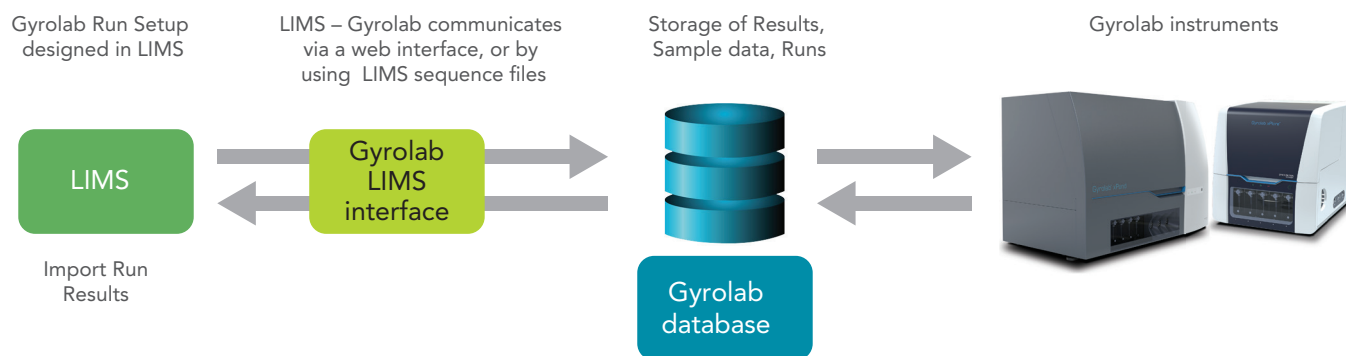
- **Optimized interface for validation and analysis of clinical and pre-clinical samples**
- **Ensures data integrity**
 - Communication via Gyrolab web interface enables full control from LIMS
 - Multiple options for transfer of data using LIMS sequence files
- **Designed for 21 CFR part 11 compliance**

Gyrolab LIMS Interface module enables full integration of Gyrolab systems into a Laboratory Information Management System (LIMS) in compliance with GxP requirements. The module enables a fully automated process where the entire setup is controlled by LIMS, which communicates with Gyrolab via a web interface. Alternatively, Gyrolab LIMS interface provides options to transfer sample information from LIMS to Gyrolab using LIMS sequence files, including a direct transfer from LIMS into the Gyrolab database.

After the run execution, the Gyrolab LIMS interface can export result files to any location, or LIMS can import run results directly from the Gyrolab database.

Although the Gyrolab LIMS sequence file format is based on the generic raw data file format for Watson LIMS 6.4, it can be supported by other LIMS as well.

Gyrolab LIMS Interface is compatible with Gyrolab Control v 5.2 or higher. The module is supplied under license and no additional installation is required.



Schematic of data workflow.

- Extend the utility of Gyrolab systems to include affinity determinations
- Set up in-solution affinity experiments guided by intuitive software
- Generate accurate KD values down to low picomolar levels
- Compare interaction pairs with ease
- Multi curve analysis for globally fitted parameters

Gyrolab Affinity Software module facilitates the design and evaluation of in-solution affinity experiments. The Affinity Design Type module guides you in setting up the affinity experiment. The affinity experiment involves:

1. Defining the Affinity Series consisting of two interactants; one interactant which is diluted to form a concentration series and the second interactant which is added to each sample at a fixed concentration.
2. At equilibrium, the response of unbound 'fixed' interactant is measured with an automated Gyrolab Affinity analysis method, needing as little as 4 µl sample volumes for duplicates.

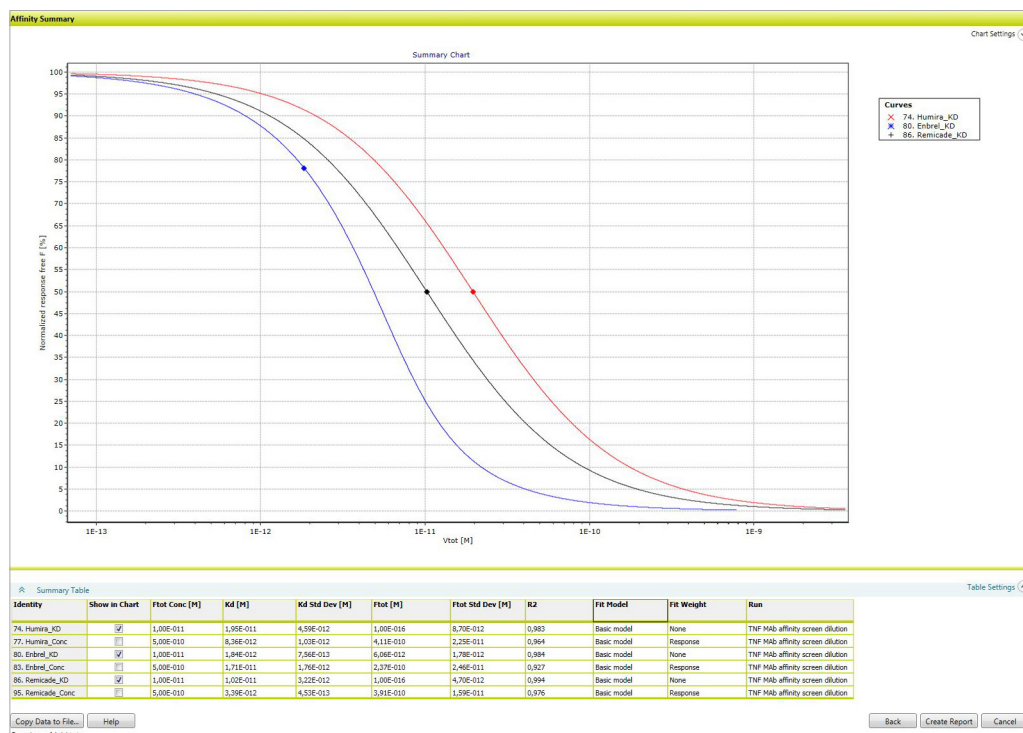
The Gyrolab method defines the method protocol and reagents required, and the subsequent run results are compatible with the Affinity module in Gyrolab Evaluator.

Depending on the goal of the affinity determination, K_D 's of up to 14 interacting pairs can be generated per CD in one hour.

Once the run has been completed, the Affinity Evaluator Software generates affinity curves by plotting the response against the concentration of the variable interactant. The affinity curves are then fitted according to the selected interaction model. The affinity summary page presents fitted curves, K_D values, calculated (active) concentrations of fixed or variable interactants, and their confidence intervals. You can use the affinity curves to compare the affinity series originating from different interaction pairs or assay variants.

Gyrolab Affinity Software module is supplied under license and is compatible with Gyrolab Control v7.1 and Gyrolab Evaluator v3.4.

With Gyrolab Evaluator v.3.6 and higher you can also analyze multiple curves from one interaction pair obtaining globally fitted parameters.



Gyrolab Affinity Software module guides the user in the design and evaluation of in-solution affinity experiments.

- Automatically generate non-editable, raw data reports after each run
- Support GLP/GMP and quality assurance requirements – 21 CFR Part 11 compliant
- Minimize environmental impact – store results in database and pdf format

[illegible]

1. Experiment D (Copy4, Data)

Ordering information

Product	Contents/Description	Product number
Gyrolab Viewer	<p>Provides access to binding profiles of each data point directly from within Gyrolab Evaluator.</p> <p>Software module compatible with Gyrolab Control v 5.3 or higher and Gyrolab Evaluator v 3.2 or higher.</p> <p>Includes Instruction For Use and software licence for one instrument.</p>	P0020028
Gyrolab ADA Software	<p>Enables analysis of anti-drug antibodies using Gyrolab CDs. Supports ADA assay workflow through development and validation to screening and confirmatory analysis.</p> <p>Software module is compatible with Gyrolab Control v 5.4 or higher and Gyrolab Evaluator v 3.3 or higher.</p> <p>Includes Instruction For Use, software licence for one instrument, Gyrolab ADA assay protocol, instrument re-validation by Gyrolab-certified service engineer and one day training by Gyrolab-certified application specialist.</p>	P0020025
Gyrolab Affinity Software	<p>Gyrolab Affinity Software module facilitates the design and evaluation of in-solution affinity experiments. The Affinity Software module is compatible with Gyrolab Control v 7.1 or higher and Gyrolab Evaluator v 3.4 or higher. Includes software license and one hour remote training by Gyrolab-certified application specialist.</p>	P0020413
Gyrolab LIMS Interface	<p>Integrates Gyrolab systems into a LIMS workflow.</p> <p>Software module compatible with Gyrolab Control v 5.2 or higher.</p> <p>Includes Instruction For Use, software licence for one instrument and support to cover the LIMS connection.</p>	P0005028
Gyrolab Control Report	<p>Enables automatic generation of 21 CFR Part 11 compliant, non-editable, raw data report after each run.</p> <p>Software module compatible with Gyrolab Control v 5.3 or higher.</p> <p>Includes Instruction For Use and software licence for one instrument.</p>	P0020006

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