

GYROLAB USER GUIDE

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A1 Important user information

A1.1 User manuals

Gyrolab Instrument Guide is the main manual for the Gyrolab® system. It contains basic operational instructions, maintenance procedures and safety information. It also holds guidance on how to decontaminate the instrument which is mandatory before a service visit if the system has been exposed to biohazards. Gyrolab Instrument Guide is found in the instrument binder. There is one version of Gyrolab Instrument Guide specific to each Gyrolab system.

Gyrolab User Guide contains detailed information on system usage. This Gyrolab User Guide is valid for Gyrolab xPand product no. P0020520, Gyrolab xPlore P0020300, and Gyrolab xP P0004943 with software Gyrolab Control version 8.1, Gyrolab Manager 1.1 and Gyrolab Evaluator 3.6 or higher.

Gyrolab Quick Guide is a short instruction that describes the most common tasks performed with the Gyrolab system.

A1.2 Intended use

The Gyrolab Instrument is a flexible instrument platform used for running Gyrolab CD microlaboratories. The CDs are designed for development and processing of miniaturized immunoassays. Products are for research use only. Not for use in diagnostic procedures.

A1.3 Disclaimer

Do not use the Gyrolab instrument, or other products from Gyros Protein Technologies AB in any way other than described in Gyrolab Instrument Guide or other documentation provided by Gyros Protein Technologies. The built-in safety functions of the system may be reduced if operations not described in Gyrolab Instrument Guide are performed.

Gyros Protein Technologies AB will use reasonable efforts to include accurate and up-to-date information in this document, but Gyros Protein Technologies AB makes no warranties or representations of any kind as to its accuracy, currency or completeness. Gyros Protein Technologies AB disclaims all warranties, expressed or implied, including warranties of satisfactory quality or fitness for a particular purpose. Neither Gyros Protein Technologies AB nor any party involved in creating, producing or delivering this document shall be liable for any damages arising out of use of this document, or any errors or omissions in the content thereof.

A1.4 Symbols

The following symbols are used throughout Gyrolab User Guide to draw attention to important usage and safety issues when working with the Gyrolab instrument.



WARNING: Indicates a situation that could result in potential injury to operators of the equipment or those nearby. Situations highlighted with these precautionary symbols may also cause mechanical or electrical damage to the Gyrolab instrument.

CAUTION: Indicates an action or condition that could potentially damage equipment, data or materials. To disregard this caution may cause mechanical damage.

NOTE: *Provides and highlights information for the user that will help ensure proper execution of an action or procedure.*

TIP: *Provides suggestions.*

A1.5 User training

Gyros Protein Technologies provides Gyrolab user training. The system should not be used by personnel which has not been given this training.

A1.6 Trademarks

Gyrolab and REXXIP are registered trademarks and Gyros, Gyrolab xPlore, Bioaffy and Gyros logo are trademarks of Gyros Protein Technologies Group. All other trademarks are the property of their respective owners. Products and technologies from Gyros Protein Technologies are covered by one or more patents and/or proprietary intellectual property rights. All infringements are prohibited and will be prosecuted. Please contact Gyros Protein Technologies AB for further details. Products are for research use only. Not for use in diagnostic procedures. © Gyros Protein Technologies AB 2021.

A1.7 Patents

Products and technologies from Gyros Protein Technologies are covered by one or more patents and/or proprietary intellectual property rights. All infringements are prohibited and will be prosecuted. Please contact Gyros Protein Technologies AB for further details.

A1.8 Designation

The Product model name and commercial name for the Gyrolab xP system is Gyrolab xP.

The Gyrolab xPlore system has the commercial name Gyrolab xPlore, and Product model name Gyrolab xPS.

The Product model and commercial name for the Gyrolab xPand system is Gyrolab xPand.

A2 Gyrolab immunoassay workflow

This section provides an introduction to immunoassay workflow, run recommendations and assay development on the Gyrolab platform. For further information and support on assay development, please contact Gyros Protein Technologies.

A2.1 Gyrolab software

A2.1.1 Standard software

- **Gyrolab Control:** Gyrolab Control is the software used to control the Gyrolab instrument, process runs. Refer to Chapter G1 for details.
- **Gyrolab Manager:** Gyrolab Manager is a companion to Gyrolab Control, to set up experiments and perform other operations at an office computer where direct instrument access is not required. Refer to Chapter B for details.
- **Gyrolab Evaluator:** Gyrolab Evaluator is used for evaluation of experiment raw data created by Gyrolab Control. Refer to Chapter D for details.
- **Gyrolab Result Database Explorer:** Gyrolab Result Database Explorer is used to generate status reports and instrument log file reports. Refer to Chapter G3 for details.
- **Gyrolab Database Backup Manager:** Gyrolab Database Backup Manager is used for backing up of the database at a desired location either regularly or at specified time points. Refer to Chapter G3 for details.
- **Gyrolab Set System Time:** Gyrolab Set System Time is used for changing system time. All changes of system time will be recorded in the audit trail. Refer to Chapter G4 for details.
- **Gyrolab Service Application:** Gyrolab Service Application is intended only for Gyros Protein Technologies service personnel.

A2.1.2 Additional software

A number of software add-on modules are available:

- **Gyrolab Viewer:** The Gyrolab Viewer module for Gyrolab Control version 5.3 and Gyrolab Evaluator version 3.2 or higher converts on-column fluorescence data into a binding profile, revealing the interaction taking place on the column within each CD microstructure. The binding profiles are accessed through Gyrolab Evaluator. Gyrolab Viewer is used during assay development for relative ranking of binding affinity and to aid in the selection of optimal reagent pair. It is also used during quality control and assay troubleshooting to investigate outliers. Refer to Chapter E1 for details.
- **Gyrolab ADA Software:** The Gyrolab ADA Software module for Gyrolab Control version 5.4 and Gyrolab Evaluator version 3.3 or higher is designed to analyze anti-drug antibodies (ADA) assays run on the Gyrolab Mixing CD. During ADA analysis, clinical samples are screened for ADA positives in a screening assay. Confirmation assays are then performed to investigate whether positive samples from screening are true positives. Evaluation functionalities are available in Gyrolab ADA Software to support these analyses. Refer to Chapter E2 for details.
- **Gyrolab LIMS Interface:** The Gyrolab LIMS Interface module for Gyrolab Control version 5.2 or higher is compatible with the generic raw data file for Watson LIMS 6.4. The software module is designed to support users that carry out experiment set-up and data analysis within a LIMS system. Refer to Chapter E3 for details.
- **Gyrolab Control Report:** The Gyrolab Control Report module for Gyrolab Control version 5.2 or higher enables automatic generation of a condensed, printable, raw data report in pdf format after each run on the Gyrolab instrument. The generated report is compliant with 21 CFR Part 11 regulations and cannot be edited. The report includes raw data and general information about the run and experimental details. Refer to Chapter E4 for details.
- **Gyrolab Affinity Software:** Gyrolab Affinity Software consist of an add-on module for Gyrolab Evaluator version 3.4 or higher and a design type, to facilitate affinity runs, for Gyrolab Control version 7.1.1 or Gyrolab Manager version 1.1 or higher.

A2.1.3 Gyrolab software user roles

The users of Gyrolab software are given certain user roles, each user role given certain user rights (privileges) depending on their role in the laboratory flow and result generation. There are six user roles available: System Administrator, Project Manager, Method Developer, Operator, Auditor, and Executor. In addition to this, one can create custom made user roles. One additional user role is also available for Gyros Protein Technologies service personnel only. For information about User roles see Chapter I8.

A2.1.4 Gyrolab software terminology list

Terminology used in the Gyrolab software and throughout this manual is explained in the list below.

Term	Description
Design Type	There are a number of workflows (or Design Types) available for setting up experiments and running assays on the Gyrolab system called Wizard Run, Custom Run, Affinity and LIMS run (LIMS is an optional add-on module).
Loading List	A list generated from a Run Setup in Gyrolab Manager, or during the Execute Run:Run procedure (Wizard Run from Gyrolab Client), containing information of microplate location and volumes of samples and reagents.
Method	The method describes how the instrument handles samples, reagents and CDs.
Preparation	When creating a Run Design for the Wizard Design Type, rules for how to dilute and/or spike an Unknown sample can be defined. For example, a Preparation can be created specifying a dilution series, defining the number of dilutions and their dilution factors. That Preparation can later be selected for an Unknown sample as a way to specify all the dilutions to process for that Unknown sample.
Reagent list	Used only for runs of design type Custom. The list holds information about samples and solutions in the transfer list, e.g. sample type and concentration.
Run	A Run is a collection of information required to perform a set of experiments on the instrument. A Run is always based on a Run Design or Run Setup, but includes additional information like unknown samples to process. A Run can be prepared in advance, using Gyrolab Manager, by creating a Run Setup.
Run Design	A Run Design adds information to a Method, specifying additional information for the experiments to perform on the instrument, such as reagents to use, standard series and quality controls.
Run Setup	A Run Setup provides information on unknown samples to process in a Run, and is a way to prepare a Run in advance when using Gyrolab Manager. A Run Setup can be based on a Run Design or created from scratch.
Run result	The result after executing a Run on a Gyrolab instrument.
Sample List	The Sample List holds information about the samples in a run, primarily unknown samples. If using Gyrolab Manager to prepare a run (by creating a Run Setup), unknown samples can be defined directly in Gyrolab Manager eliminating the need for a separate Sample List.

Term	Description
Sample	Sample is the common name for: - Unknown samples (samples to be analyzed) - Standard series (samples with known concentration used for standard curves) - Blanks (samples without protein added) - Calibration Controls (selected Standard samples used in CDs as controls in multi-CD runs) - Quality Controls (spiked samples with known concentration used for quality evaluation but not used for standard curve)
Target	Targets define the output format and location for result files generated by the control software that are stored in the data-base and accessed by evaluation software.
Transfer list	Used only for Custom design type. This list defines order and location in which samples and solutions are transferred to the CD.
Terminology used specifically in Gyrolab Evaluator:	
Structure folder	Structure folders are used to organize Projects in Gyrolab Evaluator, for example collect Projects within an experimental series or all assay development Projects in a specific Structure folder.
Project	Projects are entities in which analyses of one or more Runs is kept in Gyrolab Evaluator. Analysis setting may be locked for a Project. All analysis made in a Project are tracked in the Audit trail.
Run	Same as Run Result, but often abbreviated to just Run in Gyrolab Evaluator. Results from Gyrolab Runs are selected by Run (Result) name for analysis in a Project.
Analyte	The Analyte subset of the Run results comprises all results using a certain assay for a certain substance. There can be one or more Analyte subsets in a Run.
Experiment	The Experiment subset of the Analyte results comprises all results using a certain combination of reagents at specific concentrations. There can be one or more Experiment subsets in a Analyte subset of a Run.
Data set	The Data set subset of the Experiment results comprises all results using a common standard curve. In some Runs a common standard curve is used for all CDs generating a single Data set subset per Experiment subset. In other Runs one standard curve per CD is used, generating a number of Data set subsets per Experiment subset.
PMT setting	Each Data set subset of samples is detected in Gyrolab using one or more PMT settings. Normally each sample is detected using three different PMT settings. In Quantification module analysis one or more PMT setting subsets are selected for inclusion in analysis reports.
Quantification analysis	Run results analyzed using Quantification module in Gyrolab Evaluator.

Term	Description
Data Comparison analysis	Results of comparison of Quantification Analyses using the Data Comparison module in Gyrolab Evaluator.

A2.2 Gyrolab workflow options

There are four main workflow options, called Design types, available to Gyrolab users when performing immunoassays:

- Wizard
- LIMS (available as a software add-on module)
- Custom
- Affinity

A fifth Design type, External, is used when an external system, like a LIMS, creates Runs by communicating directly with the Gyrolab database.

The Design types differ mainly in the way that runs are set up and what output is generated.

Preparing a run with Gyrolab Manager provides additional features compared to preparing a run with Gyrolab Control. Preparing a run using Gyrolab Control is mainly intended for backward compatibility with older versions of Gyrolab software.

Both Gyrolab Manager and Gyrolab Control provide support for preparing runs for most Design types, but runs based on the Custom Design type are prepared using Gyrolab Control.

A2.2.1 Wizard Run

The **Wizard Run** workflow is designed for a flexible but also easy entering of various experimental parameters. One or more analytes and sets of reagents can be used.

Gyrolab software generates a Loading List with volume requirements for all types of samples, assay reagents and wash buffer. The Loading List is used when preparing microplates, either manually, or with a dispensing robot.

When using Gyrolab Manager, unknown samples are defined directly in the software, or defined by a Sample List. Quantification of Unknown samples against experiments, e.g. specific standard curves, can be controlled with Experiment Mapping. The Dilution/Spike set up functionality can be used to generate samples when having a serial sample dilution and/or when performing spike recovery experiments.

When using Gyrolab Control to prepare a Wizard Run, unknown samples are always defined with a Sample List. All Unknown samples are quantified against all combination of reagents (all experiments).

A Sample List can be created by generating a template from Gyrolab software or it can be created directly in Microsoft Excel.

Refer to Chapter B for more information on Wizard workflow using Gyrolab Manager, or Chapter C for more information on Wizard workflow using Gyrolab Client.

Recommended for:

- Assay development and assay optimization
- Routine analysis
- Validation experiments

A2.2.2 LIMS Run

The **LIMS Run** workflow allows integration of Gyrolab quantification analyses with LIMS. Contact Gyros Protein Technologies for compatibility questions.

The **LIMS Run** workflow is designed for immunoassay work in combination with a LIMS. The **LIMS Run** workflow ensures traceability and efficient communication with LIMS by import of LIMS worklists and generation of output files for LIMS. The **LIMS Run** workflow is GxP compliant.

One assay and one set of reagents is used per Run. The **LIMS Run** workflow is not designed for assay optimization studies. Assay optimization is performed using the Wizard Run workflow.

Gyrolab Control generates a Loading List with volume requirements for all types of samples, assay reagents and wash buffer. Alternatively, the Loading List can be created in LIMS. The loading list describes the placement of all standards and reagents within the microplates.

Refer to Chapter Chapter E3 for more detailed information on LIMS workflow.

NOTE: *To use the LIMS Run workflow a license from Gyros Protein Technologies is required to activate the add-on. A temporary license can be provided for a limited trial period. Please contact Gyros Protein Technologies.*

Recommended for:

- Routine analysis for users with a LIMS

A2.2.3 Custom Run

The **Custom Run** workflow is designed for maximal flexibility.

The **Custom Run** workflow allows the user to customize what samples are quantified towards what reagent set. Custom Run can be used when non-standard transfer from microplates to CD microlaboratories is required or when a variation of replicates for different samples and standard points for example during assay development is required.

Note that the sample mapping functionality of the Gyrolab Manager allows this in a Wizard Run as well.

No Loading List is generated. Transfer and Reagent List necessary.

Refer to Chapter I3 for more detailed information on Custom workflow.

Recommended for:

- Assay development and assay optimization experiments with special demands

A2.2.4 Affinity Run

See Chapter E5 for more info about the Affinity design type.

A2.3 Gyrolab methods

Gyrolab methods are comparable to assay protocols. The assay run is automated within the Gyrolab workflow but is still as flexible as manual assay protocols.

Gyrolab methods are designed for one specific CD-type and Run Design Type. The method name describes what it is used for.

For example: **1000-3W-001-A**

- **1000** is the code for which CD type is used in the method
 - 20 = Gyrolab Bioaffy 20HC
 - 200 = Gyrolab Bioaffy 200
 - 1000 = Gyrolab Bioaffy 1000
 - Mixing 96 = Gyrolab Mixing CD 96
- **3** defines the number of steps the method has.
 - 3 = The standard method (3-step method): In this method 3 liquid transfers occur sequentially (washes not included). There is one capture addition, one analyte addition and one detection addition.
 - 1 = The 1-step method: In this method only one analyte addition occurs. This can for example be applicable when running a homogeneous assay where capture, analyte and detection reagent have been pre-mixed in a microplate prior to the run.
 - 2 = The 2-step method: This method contains one capture addition and one analyte addition.

- **4** = The 4-step method: This method contains two capture additions, one analyte addition and one detection addition.
- **W** defines design type
 - W = wizard design type
 - C = custom design type
- **001** is a unique identity number for a specific combination on CD type, number of steps in the method and design type
- **A** stands for approved and official method released by Gyros Protein Technologies and **B** for beta method released by Gyros Protein Technologies

Methods can be downloaded from Gyrolab User Zone. Contact Gyros Protein Technologies for more information.

A2.4 Run setup and recommendations

A Run is a collection of information required to perform a set of experiments using the Gyrolab platform. The run is designed in Gyrolab Manager or Gyrolab Control and is executed by Gyrolab Control software.

After each Run, results and statistics are analyzed with Gyrolab Evaluator software. Resulting column profiles can be examined using Gyrolab Viewer to facilitate assay optimization and evaluation of possible outliers.

The concentration of analyte in each unknown sample is quantified against a standard curve. It is also possible to include quality control samples in a run. Refer to Chapter A2.4.1 for recommendations on how to set up a run that contribute to good data quality and facilitates data analysis.

A2.4.1 Standard samples and Blanks

In general, using Standard samples with many different concentrations in a Standard series facilitates generation of a high quality standard curve. However, this requires a larger number of microstructures on the CDs, leaving fewer microstructures available for analysis of unknown samples.

Set the highest and lowest concentration in a Standard series to be higher and lower, respectively, than the expected concentration range of the Unknown samples. This ensures the standard curve to be in a range where unknown concentrations can be determined. Use serial dilution steps of five or lower.

In addition to the Standard concentrations at least one blank sample must be included.

A2.4.2 Calibration Controls

The purpose of Calibration Control samples is to save CD structures for analysis of unknown samples in multi-CD runs. For each experiment, a standard series must be present on at least one CD. With the use of Calibration Controls on the remaining CDs instead of an entire Standard series structures are saved. It is recommended to use at least two Calibration Controls with concentrations corresponding to two different Standard sample concentrations.

When analyzing results, check that Calibration Control data do not differ from Standard series data for corresponding concentration values. If there is a significant difference discard the sample results from that particular CD. It is very important that the Standard sample and Calibration Control of the same concentration are from the identical aliquot.

A2.4.3 Unknown samples

When preparing a Run with Gyrolab Control, Unknown samples are placed in designated sample microplates and information about each Unknown sample is entered into a Sample List to allow traceability of the generated results.

When preparing a Wizard Run with Gyrolab Manager, the Run Setup is saved for later reference if desired, which includes information on all Unknown samples. Placement of Unknown samples in microplates can be controlled by selecting a microplate layout.

A2.4.4 Quality Controls

Quality Controls are samples that have been spiked with known analyte concentrations into identical sample matrix as present in your unknown samples. Quality Controls are used to ensure that the assay is working properly within a CD run and between runs over extended periods of time. A set of Quality Controls should be acquitted and stored under the same conditions as your unknown samples. Selected Quality Controls should be prepared independently from each other and from Standard series samples.

A2.4.5 ADA controls

ADA controls are used in the ADA module (see chapter E2). ADA controls can be either Negative Control (NC) e.g. pre-dose serum, or Positive Controls (PC), spiked with anti-drug antibody.

A2.4.6 Affinity samples

Affinity samples are used in the affinity application (see chapter E5). Affinity series consists of a number of Affinity samples containing mixtures with one Fixed interactant concentration and a concentration series of the Variable interactant. The measured responses from Affinity series are plotted to form an affinity curve. From this curve the equilibrium dissociation constant K_D and/or an active concentration can be determined.

A2.5 Assay optimization

To ensure the best possible data quality each assay must be optimized.

A2.5.1 Capture reagent concentration

A concentration of 700 nM biotinylated capture reagent is sufficient to saturate the column. For each new batch of capture reagent, perform a test run analyzing samples with known concentration. Study resulting column profiles using Gyrolab Viewer, refer to Chapter E1, to ensure that the target protein is sufficiently enriched at the top of the column.

A2.5.2 Detection reagent concentration

The degree of detection reagent fluorophor labeling may affect immunoassay performance. When developing a new assay, perform a titration to determine the optimal detection reagent for the specific assay. When labelling a fresh batch of detection reagent for an assay that has already been optimized, a titration is not needed provided that the fluorophor to protein ratio is within recommended values (Chapter C1.2).

A lower detection reagent concentration gives lower background noise which allows for increased assay sensitivity. If the desired measurement is higher then the concentration of the detection reagent concentration must also be higher to still be in sufficient excess at the high concentration end of the measuring range. Always optimize detection reagent concentration towards expected sample concentration.

The data in Figure 1 displays results from a titration run in which detection reagent concentration was varied whilst capture reagent concentration was held fixed. For this assay a detection reagent concentration of 10 nM is recommended since this option gives the lowest limit of detection while still sufficiently concentrated to allow measurements in high end of the calibration curve.

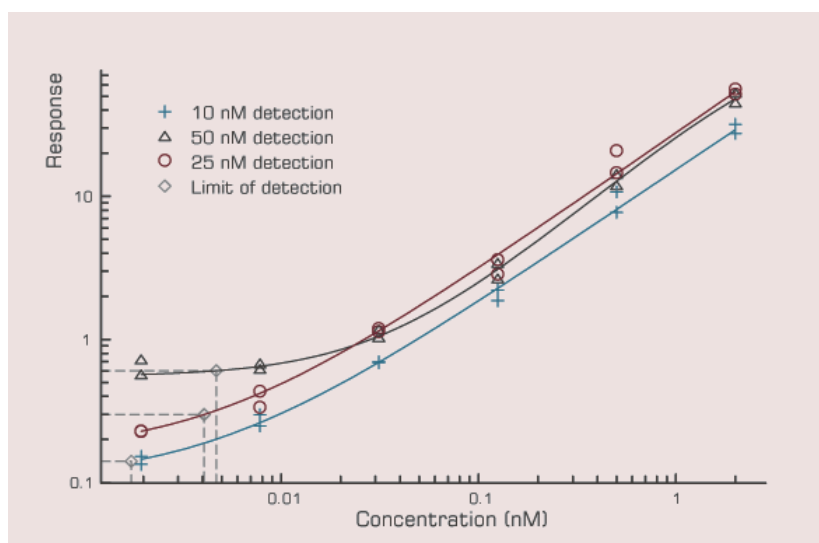


Figure 1: Standard curves for human IL-8 sandwich assay. The concentration of the detection antibody was varied to determine the optimal working concentration. Diamonds mark the limit of detection for the different concentrations.

A2.5.3 Evaluation of PMT: Fluorescence detector settings

The fluorescent signal from the microstructure column is amplified by a photo multiplier tube (PMT) when the signal reaches the detector. The degree of amplification needed to obtain a sufficient response value depends on the signal intensity of the measured sample. The signal amplification is controlled by the PMT setting in a Gyrolab method. If the degree of amplification is too high, the detector will be saturated. If the PMT setting is too low weak signals may be lost in the background scatter.

To investigate proper amplification level (expressed in percentage of incoming signal amplification, % PMT), different PMT-levels can be tested in the same run. Normally three PMT-levels are included in the methods used during assay development phase to illustrate assay performance. When the assay is fully optimized it is sufficient to use one selected PMT setting. Refer to Chapter E1 for guidance on how to optimize PMT setting using the Gyrolab Viewer software module.

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B1 Introduction to Gyrolab Manager

Gyrolab Manager is an application primarily used to prepare runs for execution on Gyrolab instruments. Gyrolab Manager also provides functions for administrative tasks.

The current version of Gyrolab Manager provides tools to create and handle Run Designs and Run Setups of the Wizard, LIMS, and Affinity design types.

To work with runs of design type Custom (Chapter I3) use Gyrolab Client.

In addition to normal Wizard Run Designs, Gyrolab Manager also allows creation of Wizard Run Designs for use with Gyrolab ADA Software (Chapter E2). But to evaluate the result of an ADA Run, the Gyrolab instrument where the run is executed must have the ADA Software module.

Gyrolab Manager is installed by default on the external computer used to control a Gyrolab instrument. But Gyrolab manager can also be installed on office computers. In fact, an important feature of Gyrolab Manager is that a run can be prepared at the desktop, without needing access to a Gyrolab instrument until starting execution on the instrument.

The following chapters describe how to use Gyrolab Manager, where the focus is on creating Run Designs (Chapter B4) and Run Setups (Chapter B5) for the Wizard Design type.

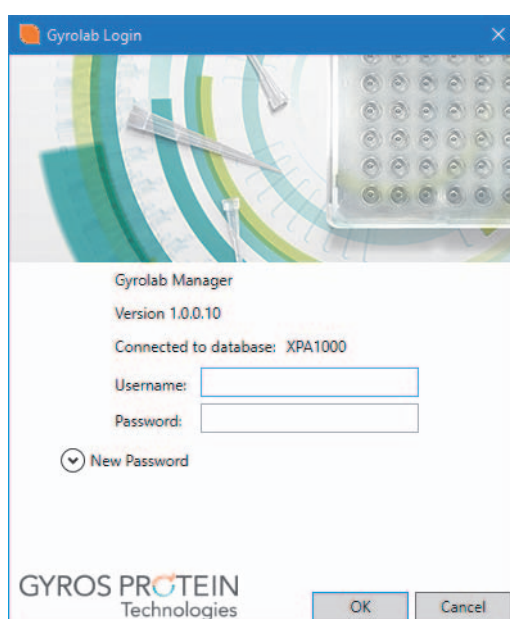
To install Gyrolab Manager on an office computer, see Chapter B10.

B2 Log in and main functions

This chapter describes log in procedure and available functions in the main window of Gyrolab Manager.

B2.1 Start and log in

Step	Action
1.	Start Gyrolab Manager Select Start:Gyros:Gyrolab Manager
2.	Enter Username and Password in the Login dialog box and click OK .



Note that the database you are connected to is displayed in the **Login** dialog.

The Username and Password is the same for all Gyrolab software. For further information on user and password administration, refer to Chapter B9.

Password must be changed if requested by the software. Password may also be changed when desired by the user. To change password:

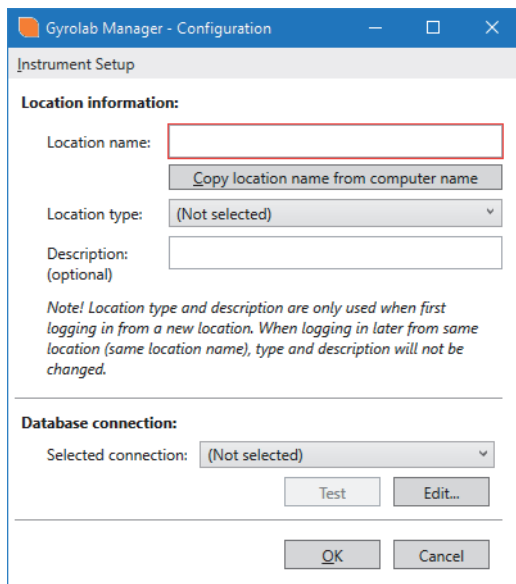
- Mark the dropdown **New Password**.
- Enter current password in **Password** field, new password in **New Password** field and confirm new password in **Confirm Password** field.
- Click **OK**.

NOTE: *Username and Password are case sensitive.*

NOTE: *The software will request the user to log in anew when the system has been inactive for a specified time. This time is controlled by system setting "Maximum inactivity time". For more information, see Chapter B10.*

Step Action

3. The following dialog is displayed the first time Gyrolab Manager is started, as it is necessary to configure the database connection to use. For details, see Chapter B7.



The image shows a Windows-style dialog box titled "Gyrolab Manager - Configuration". It has a tab labeled "Instrument Setup". The dialog is divided into two main sections: "Location information:" and "Database connection:". Under "Location information:", there is a text field for "Location name:" with a red border, a button labeled "Copy location name from computer name", a dropdown menu for "Location type:" currently showing "(Not selected)", and a text field for "Description: (optional)". A note below these fields states: "Note! Location type and description are only used when first logging in from a new location. When logging in later from same location (same location name), type and description will not be changed." Under "Database connection:", there is a dropdown menu for "Selected connection:" currently showing "(Not selected)", and buttons for "Test" and "Edit...". At the bottom of the dialog are "OK" and "Cancel" buttons.

4. Gyrolab Manager main window opens.

B2.2 Gyrolab Manager main window

The Gyrolab Manager window consists of three main areas:

- A. In this area, a folder tree is displayed. Gyrolab Methods (see Chapter A2.3), Run Designs (see Chapter B4), Run Setups (see Chapter B5), Run Results, and Gyrolab Evaluator Projects (see Chapter D3) are all organized in folders.

A new installation includes some predefined folders for standard Gyrolab Methods and Run Designs. You can create new and organize folders as required. See Chapter B3.1.
- B. Run Setups, that is, setups intended for execution on a Gyrolab instrument, are listed here. See Chapter B5 for more information on Run Setups in general.

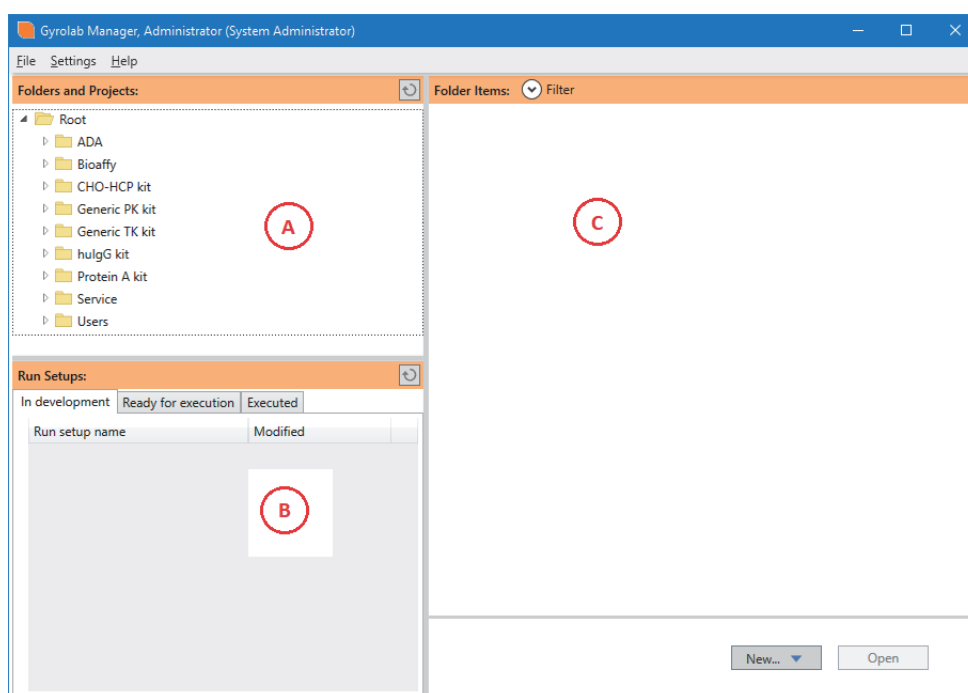
Run Setups still under work are listed in the **In development** section, while those ready to be executed on Gyrolab are listed in the **Ready for execution** section.

Run Setups that have been executed on a Gyrolab instrument are listed in the **Executed** section.

See Chapter B3.2 for information on the Run Setup lists.
- C. On the right side of the main window, details are presented on the item selected on the left side.

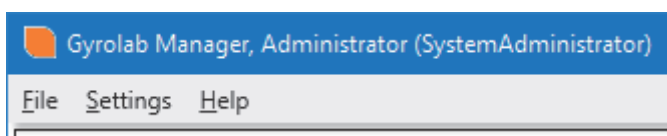
If a folder from area A is selected, objects located in that folder are presented. For more information on folder presentation, see Chapter B3.1.

If a Run Setup from area B is selected, details on the Run Setup are presented. See Chapter B3.2.

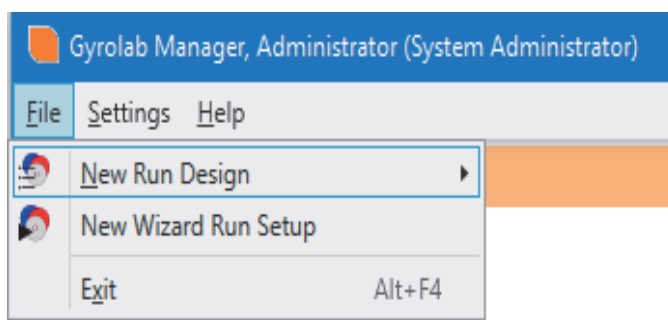


In the main window title, the current user and its user role is shown. Some actions are restricted to certain user roles. For information about User roles see Chapter I8.

At the top of the main window there is a menu bar.

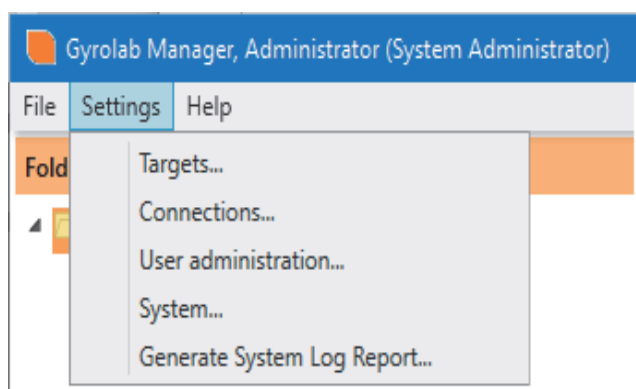


The menu provides the following submenus



File:New Run Design and **File:New Wizard Run Setup** work in the same way as the New... button in area C, with the exception that when saving the created Run Design or Run Setup, no folder is preselected and you have to specify the target folder when saving. For more information, see Chapter B3.1.

File:Exit will exit Gyrolab Manager application. If any secondary windows have been opened, these will have to be closed first.



Settings:Target... will allow configuration of Targets and Reports. See Chapter B6.

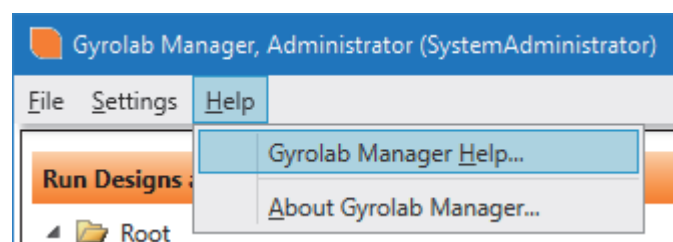
Settings:Connections... will allow configuration of the connection to the database to work with. See Chapter B7.

Settings:User administration... will allow administration of Users and User Roles. See Chapter B9.

Settings:System... will allow configuration of system wide settings. See Chapter B9.

Settings:Generate System Log Report... will allow a readable audit trail to be exported to an external disk file. The output format is .XML which is a readable format suitable to archive or study at user site. Since this report does not contain any run data it can be used when data cannot be shared for some reason.

After selecting to generate a report, an option is provided to limit the report to a specified date interval, to limit its size.



Help:Gyrolab Manager Help... will display this User Guide.

Help:About Gyrolab Manager... will display information on the current version of Gyrolab Manager.

B2.3 Gyrolab Manager Audit trail

Many of the Gyrolab Manager functions correspond to similar functions in Gyrolab Control. To allow all related audit trail to be found in one place, Gyrolab Manager is designed to produce Audit trail records in the same format as Gyrolab Control.

To retrieve Audit trail for Gyrolab Manager, see Chapter B8.1.2.

NOTE: *Audit trail for Gyrolab Control is organized according to the instrument on which operations are performed. When configuring Gyrolab Manager after installation, the Location information you provide will correspond to the instrument names used by Gyrolab Control. Take care when configuring the Location information for Gyrolab Manager to make it easy to find the corresponding Audit trail information.*

B2.4 Close Gyrolab Manager

Select **File:Exit**. If any secondary windows have been opened, these will have to be closed first.

B3 Folder handling and Run Setup lists

Many objects in Gyrolab are organized in folders. This includes Methods, Run Designs, Run Setups, Run Results and Projects in Gyrolab Evaluator. These folders are common for Gyrolab Control, Gyrolab Manager, and Gyrolab Evaluator, although there are some differences regarding the operations that can be performed depending on the Gyrolab application.

Folders can be administered from Gyrolab Manager (described in Chapter B3.1) or Gyrolab Evaluator (described in Chapter D2.2.3).

A note on folders when updating from an older version of Gyrolab Control.

In Gyrolab Control version 8.1 and older, Run Setups and Run Results were not stored in folders. Also, Gyrolab Evaluator had a separate folder structure for storing Projects. In Gyrolab Control 8.2, the use of folders and objects in folders has been harmonized.

- Gyrolab Evaluator now uses the same folder tree as Gyrolab Control and Gyrolab Manager. As part of the update to Gyrolab Control 8.2, the previous Gyrolab Evaluator folder tree is migrated and stored inside a new top-level folder named "Migrated Gyrolab Evaluator Folder Tree".
- Run Setups created before Gyrolab Control 8.2 are all placed in a new folder "Run Setups/Migrated Run Setups".
- Run Results created before Gyrolab Control 8.2 are all placed in a new folder "Run Results/Migrated Run Results".
- If directly executing a Run from a Run Design in Gyrolab Client, without first creating a Run Setup in Gyrolab Manager, the Run Result will be placed in the folder "Run Results/Run Results from Run Designs".

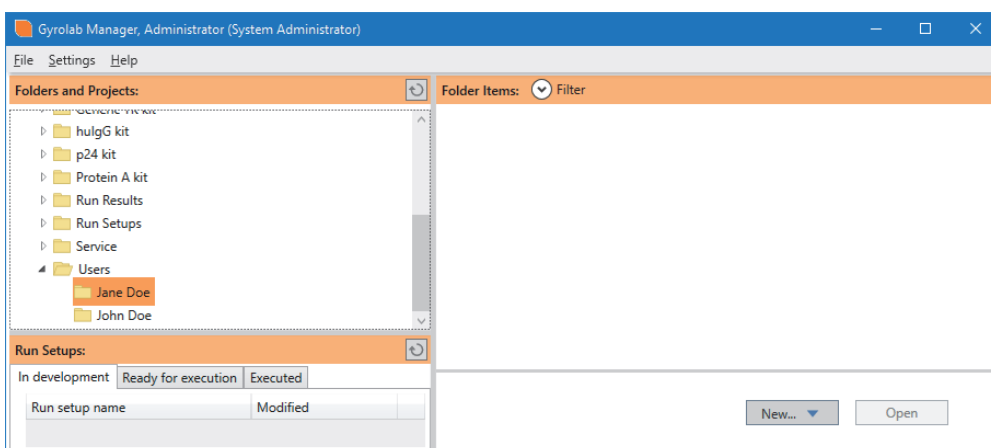
After finishing the update to Gyrolab Control version 8.2, the migrated objects can be moved to other folders.

B3.1 Folder handling

Methods, Run Designs, Run Setups, Run Results and Gyrolab Evaluator Projects are organized in folders.

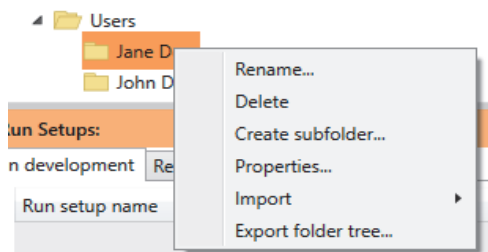
NOTE: *To create or manage folders, certain user privileges are required, especially to create folders on a high level in the folder tree. For details, see Chapter I8.*

The folder structure is displayed in the upper left corner of the Gyrolab Manager main window.



When selecting a folder, in this example “Jane Doe”, the content of that folder is displayed on the right side of the main window. In this example, the folder is a new folder, and is initially empty.

By right-clicking a folder in the folder structure, the folder can be modified.



Select **Rename...** to rename the folder. A new dialog is displayed where you can enter the new name. The name can also be changed by editing the folder properties. See below.

Select **Delete** to delete the folder. A folder must be empty to be deleted.

Select **Create subfolder...** to create a new folder located inside the selected folder. A new dialog is opened where properties of the new folder can be specified. See below.

Select **Properties...** to display properties of the selected folder. A new dialog is opened where properties of the selected folder can be changed. See below.

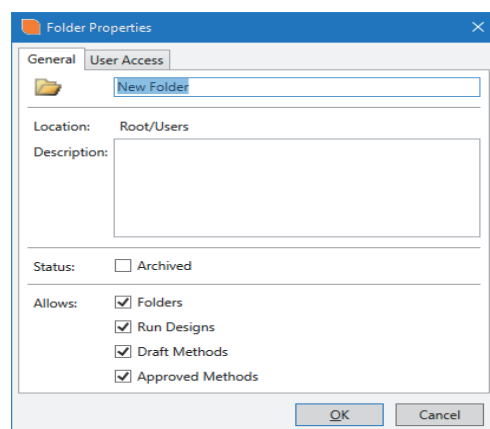
Select **Import** to import an object from a disk file to this folder. See Chapter B3.3 for more information.

Select **Export folder tree...** to export all relevant data from all folders in a folder tree. See Chapter B3.3.3 for more information.

The Root folder also provides an additional menu option **Show/Hide archived folders**. For more information, see the **Archived** folder option below.

A folder can be moved by dragging the source folder with the left mouse button and dropping it onto the desired target folder.

When creating a new folder, or editing properties of an existing folder, a new dialog is displayed.



At the top, the name of a new folder can be entered, or the name of an existing folder can be changed.

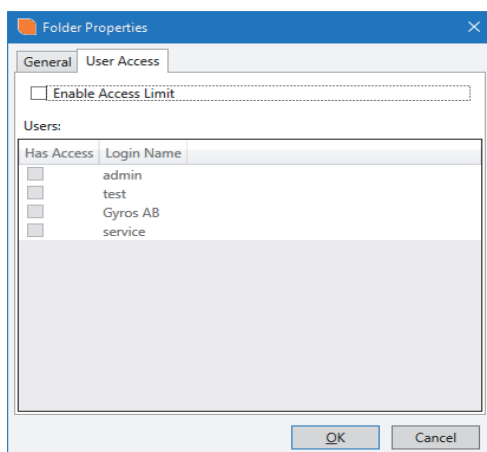
A description can also be entered to further describe the intended use for the folder.

By selecting **Archived** the folder will be marked as archived. An archived folder is hidden in normal use. By selecting **Show archived folders** in the context menu on the Root folder, archived folders are displayed. Select **Hide archived folders** in the context menu on the Root folder to hide archived folders again. Only top-level folders, that is, folders directly below the

Root folder, can be marked as archived. Archiving a folder can be used to hide information on old projects that are no longer active, and unclutter the folder tree.

By default, a folder can contain any permitted item. By deselecting **Folders allowed**, **Run Designs allowed**, **Draft Methods allowed**, and/or **Approved Methods allowed**, the folder will not accept the corresponding item(s) to be stored in the folder.

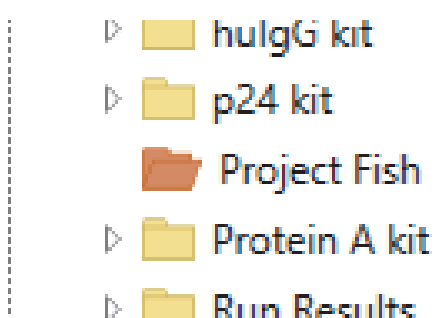
Any existing item currently in a folder will remain even though the folder properties do not allow new items of that type.



The folder properties dialog has a second tab **User Access**. This tab is only enabled on top-level folders (folders located in Root folder). Access to the folder, and its subfolders, can be enabled by selecting **Enable Access Limit**. When a folder (folder tree) has enabled limited access, only the users marked in the user list will have access to the folder tree and the objects stored in folders in the limited folder tree. (Users with privilege "Edit all folders" will always have access, even if their names are not selected.)

It may be best to store all objects to which access should be limited in a consistent way. For example, if a Gyrolab Evaluator Project includes a Run (Run Result) and the Project is located in a non-limited folder, but the Run Result is later moved to a limited folder, users working on the Project will still be able to see the Run Result even if they do not have access to the folder to which the Run Result has been moved.

A folder with limited access is displayed in another color than normal folders.



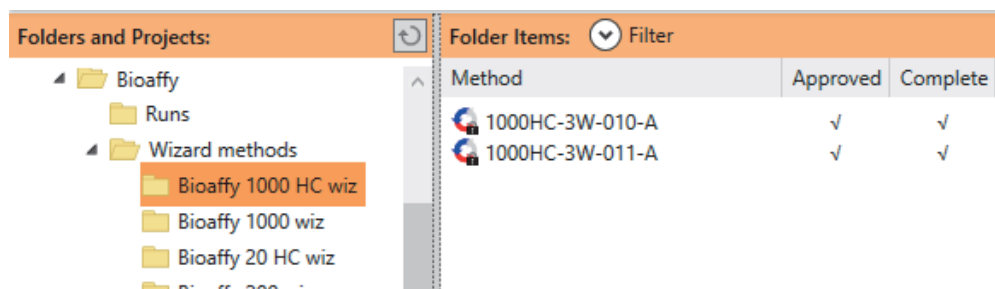
Select **OK** to save the folder.

B3.1.1 Objects inside folders

On the right side of the main window, objects located in the folder are listed.

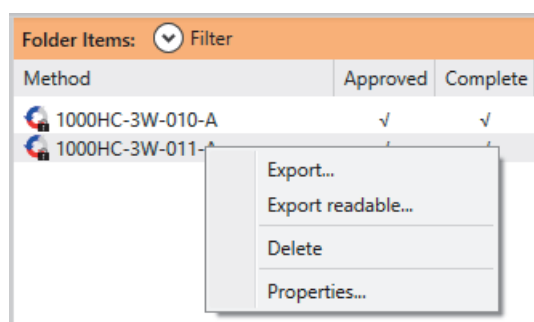
An exception is that Gyrolab Evaluator Projects, which can be seen as folders containing Analyses and Runs (Run Results), are instead presented as a type of folder. In this case, the right side of the main window will present the contents of the Project.

B3.1.1.1 Method



Methods can be listed, inspected and moved from the folder tree in Gyrolab Manager and Gyrolab Evaluator but creating or editing a Method is done from Gyrolab Control software. See Chapter G1.3.1.

By right clicking a Method, a set of operations can be performed on the Method.



Select **Export...** to export the Method to a file on disk. See Chapter B3.3 for more information.

Select **Export readable...** to export the Method to a file on disk in a readable format. See Chapter B3.3 for more information.

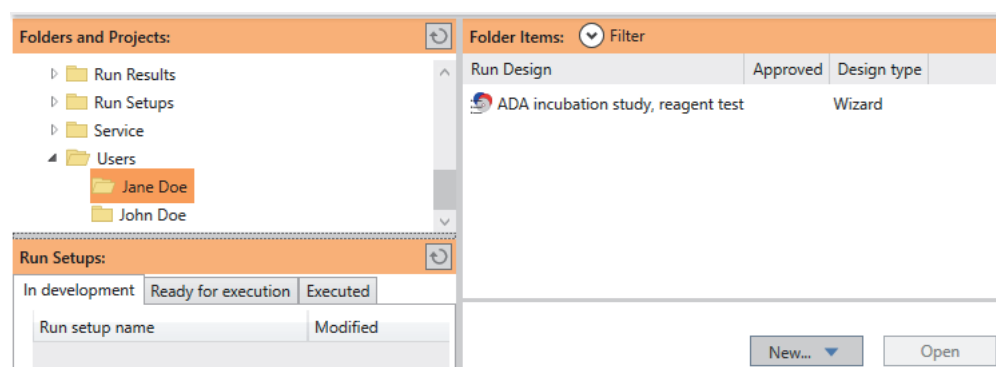
Select **Delete** to delete the Method.

Select **Properties...** to display properties for the Method.

In the Method Properties dialog, there is an option to set a Method **Visible to LIMS**. For some types of external systems, typically LIMS, this option must be selected to allow the external system to access information about the Method. This option can be used to select which Methods to make externally visible.

A Method can be moved by dragging and then dropping the Method into a target folder.

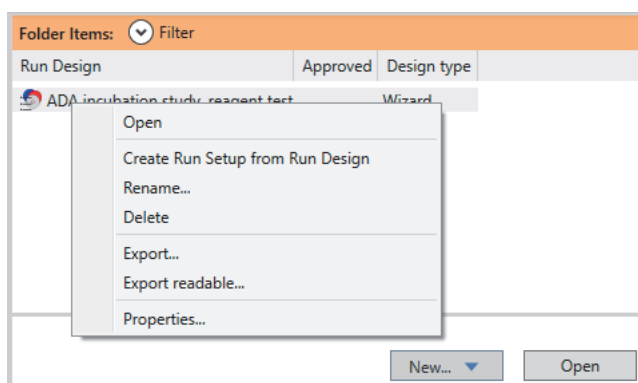
B3.1.1.2 Run Design



Run Designs can be created or handled in both Gyrolab Control and Gyrolab Manager. But note that Run Designs created in Gyrolab Manager cannot be opened in Gyrolab Control, while the opposite is true. A Run Design created in Gyrolab Control can be opened in Gyrolab Manager. If

saving the Run Design from Gyrolab Manager, it can no longer be opened in Gyrolab Control, as it includes new features not supported by Gyrolab Control.

By right clicking a Run Design, a set of operations can be performed on the Run Design.



To open the Run Design, select the Run Design and then click the button **Open**. Alternatively, the Run Design can be opened by right clicking and selecting **Open** in the context menu, or by double clicking the Run Design.

Select **Create Run Setup from Run Design** to create a new Run Setup based on the selected Run Design. A Run Setup can also be created by selecting the Run Design and then clicking **New...:Run Setup from Design**.

Select **Rename...** to rename the Run Design.

Select **Delete** to delete the Run Design.

Select **Export...** to export the Run Design to a file on disk. See Chapter B3.3 for more information.

Select **Export readable...** to export the Run Design to a file on disk in a readable format. See Chapter B3.3 for more information.

Select **Properties...** to display properties for the Run Design

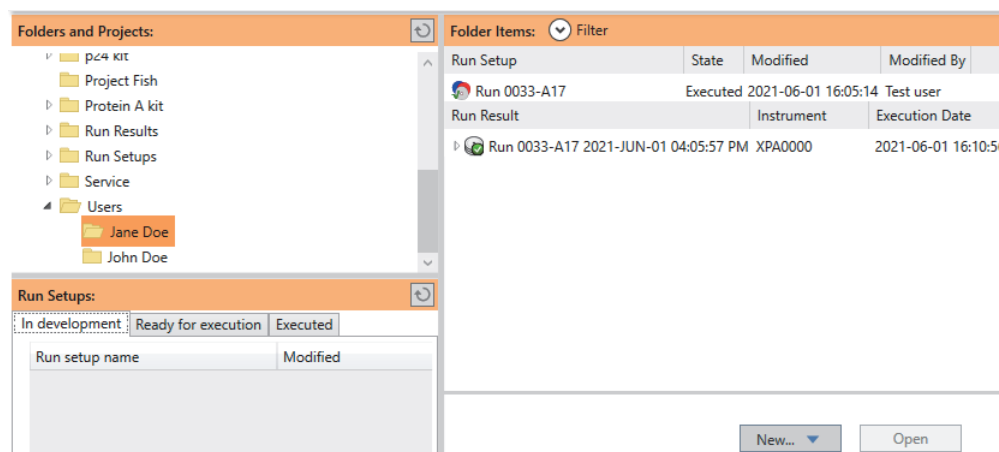
A new Wizard Run Design can be created by selecting the **New...:Run Design::Wizard** button. To create Run Designs of other Design types, select **New...:Run Design** and the desired Design type.

A Run Design can be moved by dragging and then dropping the Run Design into a target folder.

NOTE: *At this time, Gyrolab Manager does not provide functionality for Run Designs of Custom Design Type. To open or create a Run Setup from a Run Design, the Run Design must be one of the supported Design types.*

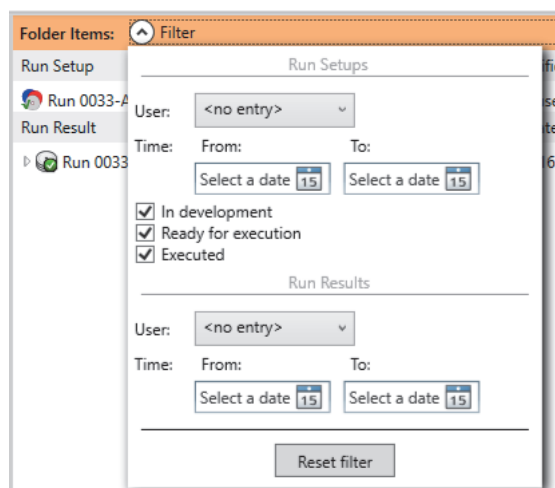
NOTE: *An approved Run Design cannot be renamed. If opening an approved Run Design for editing, a read-only copy is opened.*

B3.1.1.3 Run Setup



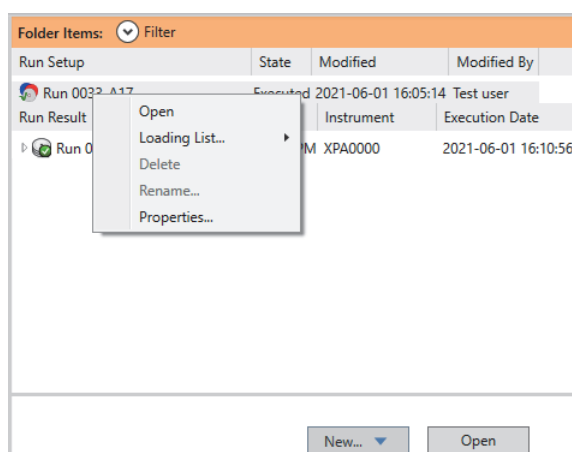
Run Setups can only be created and handled in Gyrolab Manager.

When there are many Run Setups in a folder, the list of Run Setups can become long. If the folder contains more than 20 Run Setups, only the first 20 are displayed. A button **Next 20** is displayed at the end of the list if the number of Run Setups is larger than 20. By clicking the button, an additional 20 Run Setups are displayed. This can be repeated to ultimately display all Run Setups in the folder.



The list of Run Setups can also be limited by filtering the list. Run Setups can be filtered on created/modified/queued/executed by a specific user, and/or those being created/modified/queued/executed during a specified period of time.

By right clicking a Run Setup, a set of operations can be performed on the Run Setup.



Select **Open** to open the Run Setup for editing. The Run Setup can also be opened by selecting it and then clicking the **Open** button. A Run Setup that has been executed cannot be modified. If opening an executed Run Setup, it will be locked for editing. But a new copy can be made with **File::Save As....**

Select **Loading List...** to get access to the Loading List saved for the Run Setup, if applicable. In the submenu for **Loading List...**, select **Save to File...** to save the loading list to a file, **Open** to open the Loading List in an external PDF viewer, and **Print** to print the Loading List to the default printer. For more information on the Loading List, see Chapter B5.4.3.

Select **Create Run Setup from Run Design** to create a new Run Setup based on the selected Run Design. A Run Setup can also be created by selecting the Run Design and then clicking **New...::Run Setup from Design**.

Select **Delete** to delete the Run Setup. A Run Setup that has been executed cannot be deleted.

Select **Rename...** to rename the Run Setup. A Run Setup that has been executed cannot be renamed.

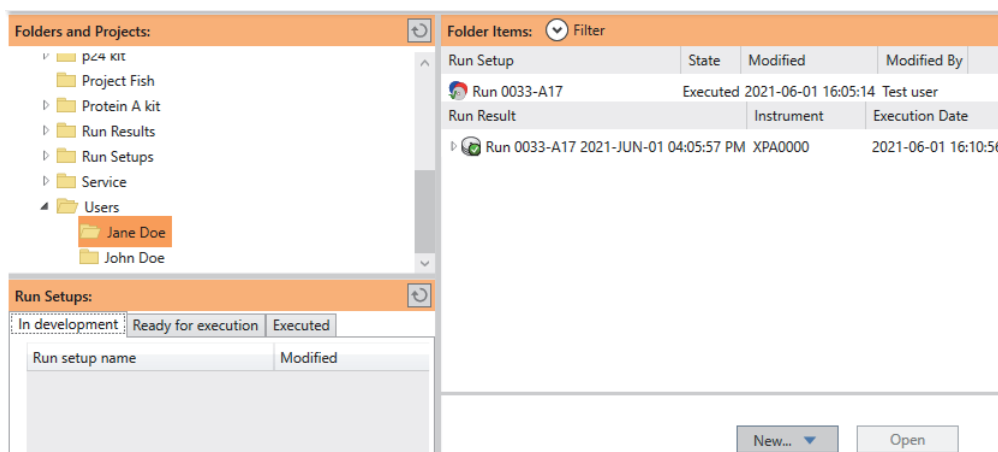
Select **Properties...** to display properties for the Run Setup.

A new Wizard Run Setup can be created by clicking the **New...:Wizard Run Setup button**. In this case, the Run Setup is not based on a Run Design. In contrast to when a Run Setup is based on a Run Design, all parameters of the Run Setup must be specified.

A Run Setup can be moved by dragging and then dropping the Run Setup into a target folder.

NOTE: *At this time, Gyrolab Manager does not provide functionality for Run Setups of Custom Design Type. Also, creating a Run Setup without basing it on a Run Design is currently only supported for Run Setups of Design type Wizard.*

B3.1.1.4 Run Result



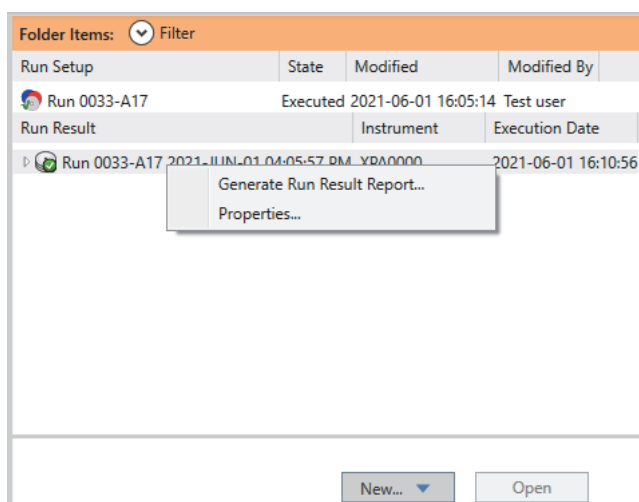
Run Results are created when executing a Run on a Gyrolab instrument.

If the Run is based on a Run Setup, the Run Result will be placed in the same folder as the Run Setup.

If directly executing a Run from a Run Design created in Gyrolab Client, without first creating a Run Setup in Gyrolab Manager, the Run Result will be placed in the folder "Run Results/Run Results from Run Designs".

The list of Run Results can, just as for Run Setups, become long, and only the first 50 Run Results in a folder are listed by default. The procedure to see more Run Results, or filter the list of Run Results, is the same as for Run Setups. See Chapter B3.1.1.3. Run Result filtering is based on the user executing the Run, and the time of execution.

By right clicking a Run Result, a set of operations can be performed on the Run Result.

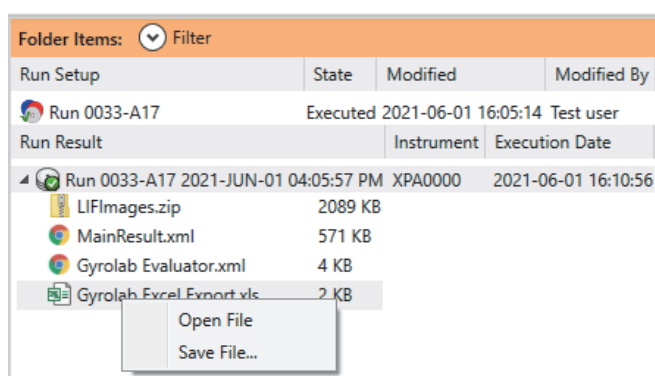


Select **Generate Run Result Report...** to generate a Run Result Report. A Run Result Report contains a Run Result and the corresponding system logs. A new dialog is opened where the output file name and location can be selected. The file is generated in the file format ".gyr" which is a compressed format suitable to e-mail to the support at Gyros Protein Technologies.

Select **Properties...** to display properties for the Run Result.

A Run Result can be moved by dragging and then dropping the Run Result into a target folder.

A Run Result can be expanded to see its Result Items (components). By right clicking a Result Item, a set of operations can be performed on the Result Item.

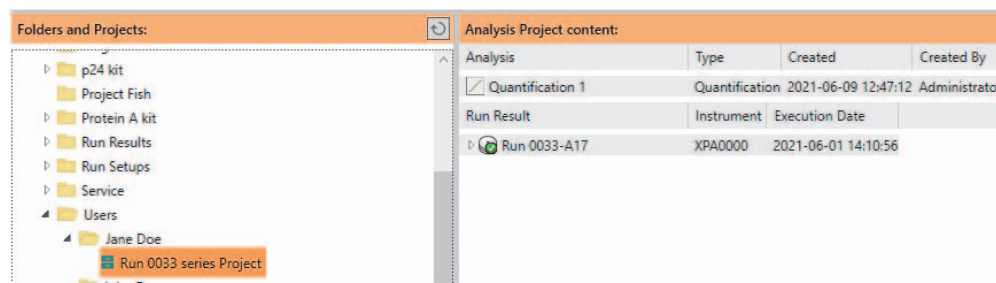


Select **Open File** or double click the item to open it. The item will be opened in the default application for the corresponding item type. For example, a file of type .xls may be opened in Microsoft Excel.

Select **Save File...** to save a copy of the item to disk.

Note that Run Results, including Result Items, are stored in the Gyrolab database, and cannot be modified.

B3.1.1.5 Gyrolab Evaluator Project



Gyrolab Evaluator Projects are also stored in the folder tree. As they are similar to a normal folder, being containers for other objects, typically Analyses, they are displayed on the left side, in the same way as for normal folders.

When selecting a Gyrolab Evaluator Project, the right side shows the objects included in the project, Analyses and Run Results. In Gyrolab Manager, a Project can only be displayed, not opened. See Chapter D2.2 for more information on working with Projects.

Right click a Project and select **Rename...** to rename the Project.

A Gyrolab Evaluator Project can be moved by dragging and then dropping the Project into a target folder.

B3.1.2 Moving multiple objects

Multiple objects of the same type can be moved together.

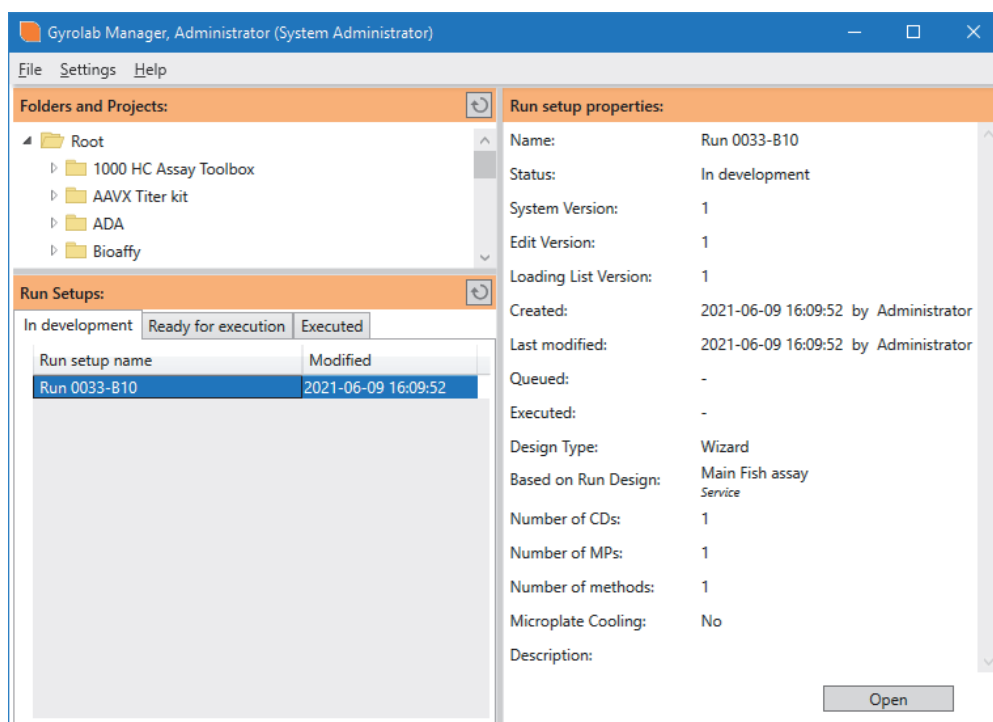
Select the first object to include in the move. After selecting the first object, additional objects can be added to the selection by holding down the Ctrl key on the keyboard and then selecting additional objects by clicking on them. Alternatively, after selecting the first object, holding down the Shift key and selecting a new object will also select all objects between the first object and the new object in the selection.

After selecting multiple objects, drag them to, and drop them into, the target folder in the same way as when moving single objects.

Note that moving many objects may take considerable time.

B3.2 Run Setup lists

In addition to being listed in the folder in which they are located, Run Setups are also presented in the lower left part of the Gyrolab Manager main window. In this area, Run Setups are organized in lists, depending on their state. For information on Run Setup states, see Chapter B5.1.



Run Setups are listed in three tabs based on their state. If selecting a Run Setup from either list, properties of the Run Setup are displayed at the right side of the main window.

The information displayed depends on the list where the Run Setups is found. For example, the date and time when the Run Setup was **Queued** is not displayed while on the **In development** list.

Once a Run Setup is ready for execution, the properties **Number of CDs**, **Number of MPs** and **Number of methods** shows the extent of the Run Setup.

B3.2.1 Run Setup list In development

In the list **In development**, the Run Setups are listed that are still in development. These Run Setups cannot be selected at a Gyrolab instrument for execution.

To continue working on a Run Setup from this list, select the Run Setup and then select **Open** on the right side of the main window.

It is also possible to right-click the Run Setup in the list to get access to additional functions.

In development

Run setup name		Modified
Project XXX, Test	Open	04-13 09:13:25
Project XXX, Test	Delete	04-13 09:30:08
	Rename...	

Select **Open** to open the Run Setup for editing. This is the same function as selecting the Open button on the right side of the main window.

Select **Delete** to delete the Run Setup.

Select **Rename...** to rename the Run Setup. A new dialog is displayed where the name can be changed.

B3.2.2 Run Setup list Ready for execution

In the list **Ready for execution**, the Run Setups are listed that are ready for execution on a Gyrolab instrument. These Run Setups can be selected at a Gyrolab instrument for execution.

If it is necessary to change a Run Setup from this list, select the Run Setup and then select **Open** on the right side of the main window. The Run Setup will then be automatically removed from the **Ready for execution** list to avoid that someone selects the Run Setup at an instrument and starts execution. To place the Run Setup on the **Ready for execution** list again, select **Queue for Execution** and **Close** when closing the Run Setup. See Chapter B5.5

It is also possible to right-click the Run Setup in the list to get access to additional functions.

Ready for execution

Run setup name	
Reagent R2, C	Open
BA4399-003	Loading List...
	Delete

Select **Open** to open the Run Setup for editing. This is the same function as selecting the Open button on the right side of the main window.

Select **Loading List...** to get access to the Loading List saved for the Run Setup. In the submenu for **Loading List...**, select **Save to File...** to save the loading list to a file, **Open** to open the Loading List in an external PDF viewer, and **Print** to print the Loading List to the default printer. For more information on the Loading List, see Chapter B5.4.3.

Select **Delete** to delete the Run Setup.

B3.2.3 Run Setup list Executed

In addition to the two lists for Run Setups that are not yet executed, there is a third list where all executed Run Setups can be found. These are listed by selecting the Expand button  to the left of the **Executed** header.

Executed

 Filter

Run setup name	Executed
BA4399-002	2018-04-14 12:20:00
BA4399-001	2018-04-14 11:13:40

Next 50

Executed Run Setups are listed, with the last executed Run Setup at the top.

The list does not show all Run Setups by default, as the list will become long with time. To see additional Run Setups, click **Next 50**.

A Run Setup on the Executed list can be opened by selecting the **Open** button on the right side of the main window. By opening the Run Setup, it is possible to inspect the settings for the Run Setup.

It is also possible to create a copy of the Run Setup by saving the Run Setup with **Save As...**. See Chapter B5.5 for more information.

To find a Run Setup, it is possible to filter the list to include only Run Setups with certain properties. To enable the filter function, select the expand button  to the left of the Filter header.

⬆ Filter

Name:

Design type:

Created: From: To:

Modified: From: To:

Queued: From: To:

Executed: From: To:

Created by:

Modified by:

Queued by:

Executed by:

No of methods:

No of MPs:

No of CDs:

Clear

By setting values on the different filter criteria, only Run Setups matching the criteria will be displayed in the list.

Select **Clear** to clear the filter to the initial setting.

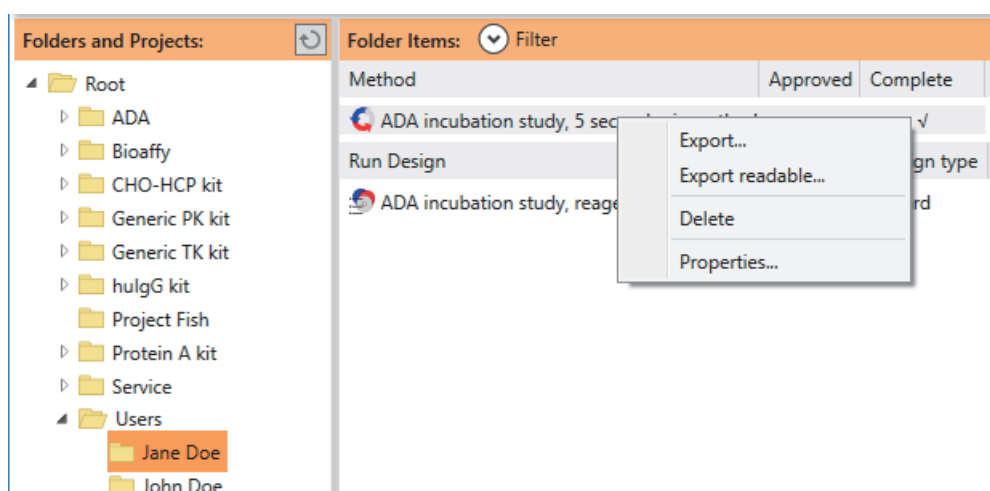
B3.3 Export and import

Some objects can be exported from one Gyrolab system (Gyrolab database) and imported into another Gyrolab system (Gyrolab database). In this way, assay development performed on one system can be shared with systems installed at another site.

In the current version, the objects that can be exported and imported using this procedure are Methods and Run Designs.

B3.3.1 Export

To export an object, select the folder in which the object is located, right click the object, and select **Export...**



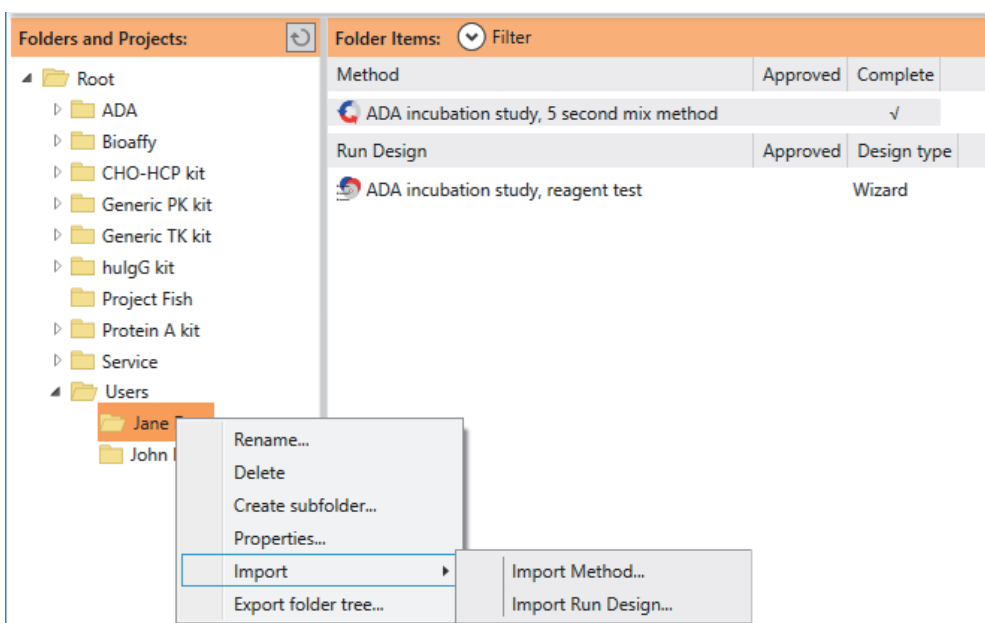
A file dialog is opened and the user may select the target location on disk for the object. The exported object is written to a file in the Gyros ".zml" format to avoid unintentional change outside the Gyrolab database.

When exporting a Run Design, the Method(s) used by the Run Design is/are included in the export.

Objects can also be exported in a readable format by selecting **Export readable...** instead of **Export...**. The file in readable format cannot be further used in Gyrolab but it can be useful for example when contacting Gyros Protein Technologies for support. To import an object to another system, **Export...** must be used.

B3.3.2 Import

To import an object, right click the target folder, select Import, and then select the object type to import.



When the file dialog opens, select which file to import.

If a Method is imported, the import will fail if the folder already contains a Method with the same name.

If a Run Design is imported, any Methods that were exported as part of the Run Design are also imported. All the imported objects are placed in the selected folder. The import will fail if the folder already contains an object of the same type and name.

Note that Gyrolab Users are local to a Gyrolab database. The creator/modifier of the imported object typically does not exist in the database into which the object is imported. To solve this conflict, the full name of the creator/modifier of an imported object is preserved and can be viewed by right clicking the imported object and selecting **Properties....** But no further information on the creator/modifier is available after import to a new system.

B3.3.3 Folder tree export

In Gyrolab Evaluator, it is possible to export Project and Run Result files in bulk by **Export folder tree....** These files will be in a readable format. The complete folder structure will be exported into a.zip-file, with the selected folder as the root folder. Refer to Chapter B3.1 on how to do a folder tree export.

For every Project in the folder tree, the following files will be exported:

- Run Reports of every Run in Project (.pdf)
- Analysis Reports of every Analysis in Project (.pdf)
- Analysis Data for every Analysis in Project (.xls)
- Project Audit Trail (.xls)

For every Run Result in the folder tree, the following files will be exported:

- The raw data of the Run Result (MainResult.xml)
- Run Result Report (.gyr). Refer to Chapter B3.1.1.4 for more details about this file.

When exporting a large folder tree with many files to be exported, it can be a time-consuming operation, therefore it is recommended to perform this operation when not intending to use Gyrolab Evaluator for a while. It is also recommended to not work with projects to be exported at the same time as a folder tree export.

NOTE: *To export a full folder tree it is required to have the privileges for viewing a project, export analysis data and exporting reports. See chapter User privileges.*

NOTE: *When exporting a folder tree, it will only export Projects and Run Results that were in the folder tree upon start of export. This means that when moving a Run Result or Project from or to the folder tree during export, it will not affect the export.*

B4 Wizard Run Design

The processing of samples in Gyrolab instruments is mainly controlled by the Method, see Chapter A2.3.

In most cases, it is not very practical to process unknown samples only, as evaluation of the result typically requires additional samples with known concentrations, like a standard curve.

Also, the reagents to use together with the method must be specified.

It is the task of the Run Design to define this additional information, setting up the environment for processing unknown samples.

As this information is often used multiple times, processing different unknown samples, it is also practical to perform the definition once only, reusing it every time unknown samples are processed.

Furthermore, when an assay is validated with a given combination of method and Run Design, the Run Design can be approved, locking it from future changes.

It is possible to create a Wizard Run Setup directly, without creating a Run Design first. You may want to do this in cases where you are not interested in separating the setup done in a Run Design from the remaining work for a Run Setup (typically adding information on unknown samples). For more information, (see Chapter B5.2.1).

How to set up a Run Design differs between the Design Types supported by Gyrolab software. Gyrolab Manager supports creation of Run Designs for all Design Types except the Custom Design Type, which currently must be created using Gyrolab Client (see chapter I3).

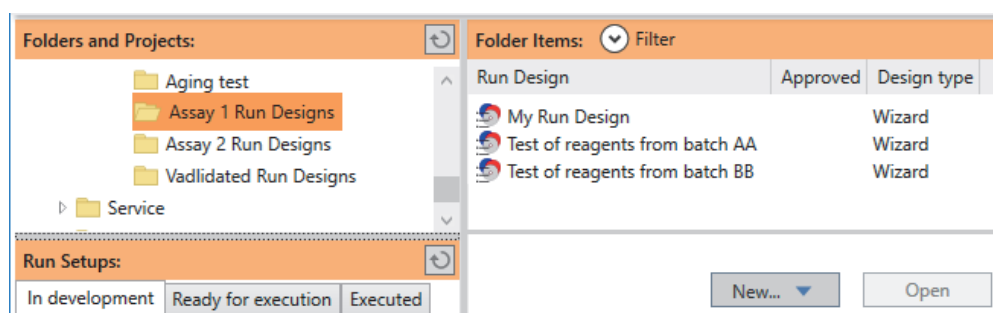
The most common Design Type is the Wizard Design Type, described in this chapter. For other Design Types, see chapter E, Software add-on modules.

B4.1 Overview of workflow

A Wizard Run Design can be created in either Gyrolab Client or Gyrolab Manager, where Gyrolab Manager provides additional features, and the option to perform the task from an office computer.

If a Run Design has been created in Gyrolab Client, using Design Run, the same Run Design can be opened in Gyrolab Manager. However, if the Run Design has been created or modified in Gyrolab Manager, it can no longer be opened in Gyrolab Client.

Run Designs are stored in folders, allowing them to be organized according to user needs.



Even if a Run Design has been used as the base for a Run Setup, see Chapter B5, or has been executed in a Gyrolab instrument, it is possible to later delete the Run Design. Run Setups or results from execution are not affected.

The following list shows the steps to create a basic Run Design, with references to applicable chapters for more information. The following chapters explain the parts of a Run Design in more detail.

This list does not include the optional setups for Dilution/Spike (Chapter B4.5) and Experiment Mapping (Chapter B4.6). See the corresponding chapters for more details.

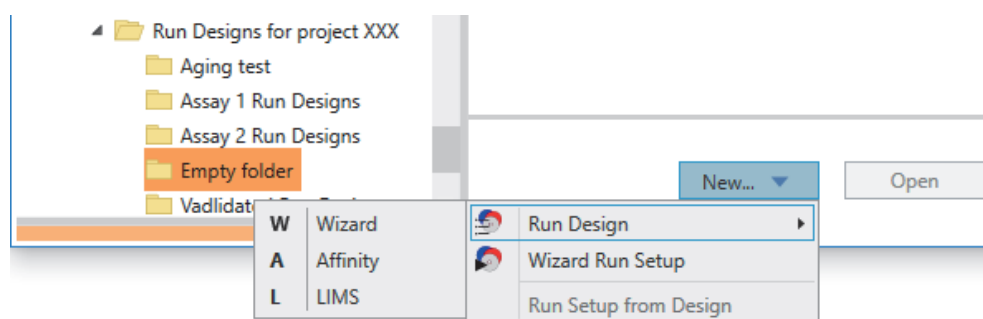
Step Action

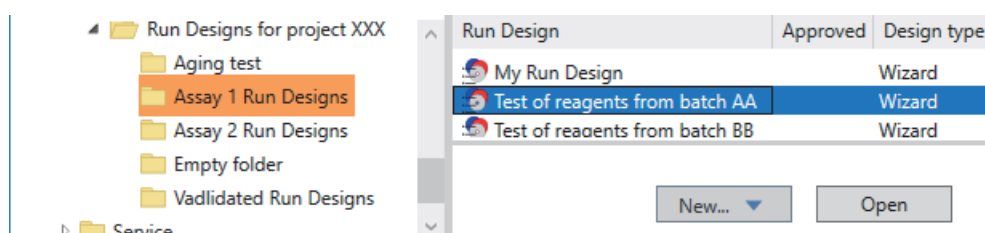
1. Select a suitable folder in the main window folder tree or create a new folder (Chapter B3.1).
2. On the right side of the main window, select **New...:Run Design::Wizard** to create a new Run Design of design type Wizard in the selected folder.
3. A Run Design edit window is opened.
4. Enter a **Name** for the Run Design.
5. In **Method Setup**, select **Add** to select and add a method (Chapter B4.3.1).
6. In **Reagents**, rename the reagents to match the assay (Chapter B4.3.2).
7. In **Standard Series**, select **Add** to create a Standard Series.
In the section for definition for standard Points, adjust the number of points and replicates. Also enter the desired **Concentration** for each Standard Point (Chapter B4.3.3).
8. Optionally, in **Quality controls**, select **Add** to add a Quality Controls. Repeat for the desired number of Quality Controls. Name the Quality Controls and specify their **Concentration** and **Dilution** (Chapter B4.3.4).
9. Create an Experiment based on the Setup by selecting **Add Analyte** followed by **Add Experiment** (Chapter B4.3.6).
10. Select the reagents to use for the reagent transfer operations in the Method.
11. Save the Run Design from the **File** menu by selecting **Save** (Chapter B4.4).
12. Close the Design Wizard Run window from the **File** menu by selecting **Exit**.

B4.2 Creating or opening a Run Design

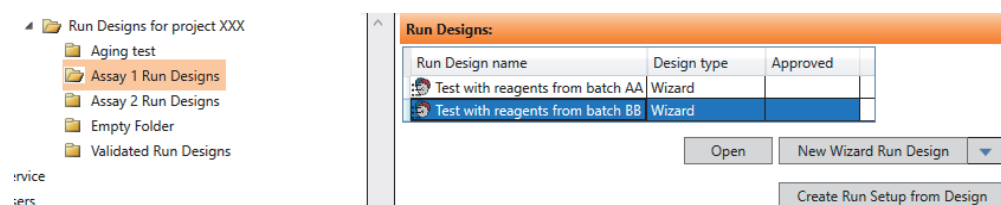
To create a new Run Design, select a folder.

Select **New...:Run Design::Wizard** to create a new Run Design of Design type Wizard. Select **New...:Run Design::Affinity** or **New...:Run Design::LIMS** for creating a Run Design of type Affinity or LIMS respectively. For information on Run Designs for other Design types, see Chapter E.

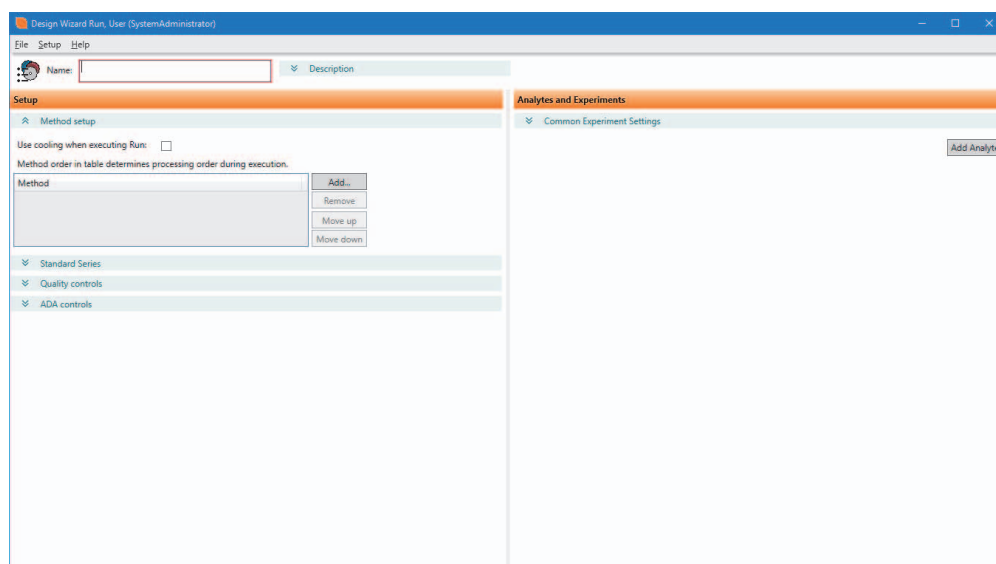




To open an existing Run Design, select the folder where the Run Design is located. To open the Run Design, select the Run Design and then **Open** from the Run Design section, right click and select **Open**, or double click the Run Design.



After creating or opening a Run Design, a new window is displayed.



When creating a new Run Design, a name must be entered in the **Name** field.

A description (comment) on the Run Design can optionally be made in the **Description** section, for example for what type of assays the Run Design is intended.



B4.3 Experiment Setup

The primary, and mandatory part, of a Run Design, is to set up the Experiments.

A Run Design must include at least one Experiment.

An Experiment is a set of information describing how to process samples. The most important information is the Method to use, which must be specified, but the Experiment also defines other important aspects on how to process the samples.

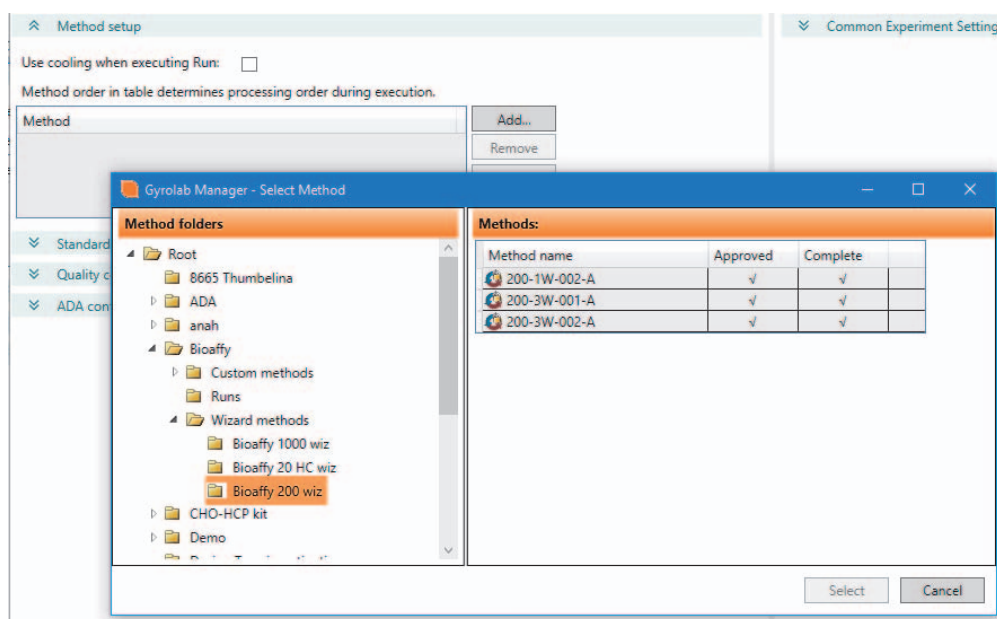
Experiments are organized into Analyte sections. This does not affect processing in any way, and Experiments can be freely placed in the same or different Analyte section.

B4.3.1 Selecting methods

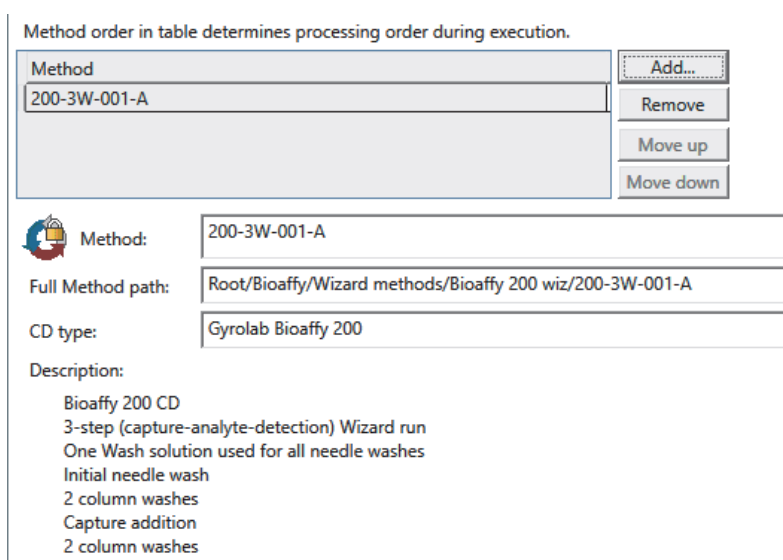
Any Run Design must include at least one Method. This is done in the **Method Setup** section.

To add a method, select **Add...**. A method selection dialog is opened. Browse and select the desired Method. The selected Method must contain W in the name which indicates that it is designed for use with a Wizard run, refer to Chapter A2.3 for more information.

When selecting a Method, it is possible to right click the Method and select **Properties...** to get more information on the Method.



When a method has been selected in a folder, click **Select**. The selected Method is added to the Run Design and Method information is displayed.



A Run Design must specify at least one Method, but it is possible to select additional methods. Each Experiment will specify the Method to use, and different Experiments may specify different Methods.

If defining multiple Experiments with different Methods, all samples will by default be processed with all Experiments when executing the run. (See also Chapter B4.6.) The different

Methods will be processed one at a time, including all Experiments specifying that Method, starting with the first Method in the list of Methods.

The processing order can be modified by moving Methods up and down in the list of Methods by selecting a Method and using the **Move up** and **Move down** buttons.

Method order in table determines processing order during execution.

Method	
200-3W-001-A	Add... Remove Move up Move down
1000-3W-001-A	

An added Method can also be removed by selecting the Method and using the **Remove** button.

For single-method runs, an unknown sample will normally be placed in one microplate well only. (Exception when using the "Keep on same CD" for an Experiment. See Chapter B4.3.6.) When using multiple methods, the methods will be processed in sequence, and it may be a long time between the processing of a sample by the first method, and the processing by the next method. To avoid evaporation, an unknown sample processed with multiple Methods will require a separate microplate well for each Method.

For more information on using multiple methods, see Chapter B5.6.

It is also possible to specify whether sample cooling shall be turned on when executing the run (given that the Gyrolab instrument provides cooling functionality) by selecting **Use cooling when executing Run**.

Use cooling when executing Run: ☐

B4.3.2 Reagents

For Methods requiring Reagents, the name of the Reagents must be specified.

When initially adding a Method requiring Reagents, a default list of Reagents will be created automatically.

Reagents		
Reagent name	Condition	
▶ Reagent 1		Add Delete
▶ Reagent 2		

Specify the **Reagent name** for the Reagents to use in the run. The **Condition** field is optional and can be used for additional information such as concentration value or matrix.

Click **Add** to add additional Reagents.

To delete a Reagent, select the entire row by clicking the black triangle and then selecting **Delete**. Multiple Reagents can be deleted at the same time by marking multiple lines and selecting **Delete**.

Reagent names and conditions can be copied and pasted. Use Ctrl+C to copy and Ctrl+V to paste, or right click and select **Copy** or **Paste**.

The Reagents can be sorted on name or condition by clicking the table header. Note that this is only a temporary sorting and will not affect the underlying order defined when adding the Reagents.

B4.3.3 Standard Series

To get a reference for calculating the concentration of unknown samples, a Standard Series (Standard Curve) can be used.

Multiple Standard Series can be created. Each Experiment may use zero or one Standard Series. One Standard Series can be used in multiple Experiments.

Click **Add** to add a Standard Series. Specify the **Standard Series name**, and optionally a **Condition**.

Standard Series		
Standard Series name	Condition	
▶ Standard A		Add Copy Delete

To delete a Standard Series, select the entire row by clicking the black triangle and then selecting **Delete**. Multiple Standard Series can be deleted at the same time by marking multiple lines and selecting **Delete**.

As considerable time may have been spent on creating a Standard Series, you will have to confirm when attempting to delete a Standard Series.

A Standard Series can be copied by selecting the Standard Series and selecting **Copy**. It is possible to copy multiple Standard Series by selecting many Standard Series before selecting **Copy**.

Standard Series names and conditions can be copied and pasted. Use Ctrl+C to copy and Ctrl+V to paste, or right click and select **Copy** or **Paste**.

The Standard Series can be sorted on name or condition by clicking the table header. Note that this is only a temporary sorting and will not affect the underlying order defined when adding the Standard Series.

When selecting a Standard Series, details about the Standard Series become visible.

Standard Series name	Condition	
▶ Standard A		Add Copy Delete

Standard A	Number	Replicates
Blank:	1	2
Standard Points:	7	2
Calibration Controls (CC):	0	2

(CC only used in multi-CD runs)

Dilution factor: 2.0 High ▶ Low Low ▶ High

Standard Point name	Concentrati	CC
▶ Standard A_Blank	0.0	☐
▶ Standard A_1	0.0	☐
▶ Standard A_2	0.0	☐
▶ Standard A_3	0.0	☐
▶ Standard A_4	0.0	☐
▶ Standard A_5	0.0	☐
▶ Standard A_6	0.0	☐
▶ Standard A_7	0.0	☐

Concentration unit: Not defined

A Standard Series always includes one **Blank**. The number of **Standard Points** can be selected, with a minimum of three Standard Points.

The number of **Replicates** for the blank and the standard points can be selected independently with a maximum of 20 replicates for the blank and 8 for the standard points.

The **Concentration** value should be entered for every Standard Point.

The concentration value can be entered manually.

The concentration values can also be copied and pasted. Use Ctrl+C to copy and Ctrl+V to paste, or right click and select **Copy** or **Paste**.

Additionally, concentration values can be automatically generated as a series. The values are all based on the concentration value entered for the first standard point.

If selecting **High > Low**, the concentration value of each standard points will be set to the value of the previous standard point divided by the value entered as **Dilution Factor**, using the value of the first standard point as reference value.

If selecting **Low > High**, the concentration value of each standard points will be set to the value of the previous standard point multiplied by the value entered as **Dilution Factor**, using the value of the first standard point as reference value.

Dilution factor: High ▶ Low Low ▶ High

Standard Point name	Concentration	CC
▶ Standard A_Blank	0.0	☐
▶ Standard A_1	1.0	☐
▶ Standard A_2	2.0	☐
▶ Standard A_3	4.0	☐
▶ Standard A_4	8.0	☐
▶ Standard A_5	16.0	☐
▶ Standard A_6	32.0	☐
▶ Standard A_7	64.0	☐

If multiple standard points are assigned the same concentration value, Gyrolab Evaluator will calculate statistics based on all points having the same concentration.

For multi-CD runs, where the Standard Series is placed on one CD only (can be selected in the Experiment), **Calibration Controls** will be placed on all other CDs where samples are processed for the Experiment in question.

The number of calibration controls and the number of replicates for calibration controls can be specified. To select which standard points to use as calibration controls, mark the corresponding checkboxes in the CC column.

The unit in which concentration values are given can be defined in the **Concentration Unit** section. It is recommended to select one of the predefined units, if possible.

Concentration unit:

≡ Quality control
≡ ADA controls

M
mM
uM
nM
pM
g/mL
mg/mL
g/L
ug/mL
ng/mL
pg/mL
User defined
Not defined

If the desired unit is not available, a user defined unit can be specified, where the unit can be entered in the associated textbox.

Concentration unit: User defined ▼ My unit

B4.3.4 Quality Controls

Quality Controls are samples with known concentration. Quality Controls may be used for quality control or when comparing results from different runs and Experiments.

Multiple Quality Controls can be created. Each Experiment may use zero or more of the defined Quality Controls, and the Quality Controls used may be different for different Experiments.

Click **Add** to add a Quality Control.

Quality controls

Replicates: 2 ▼ ☐ Group controls with same concentration and dilution

Quality control name	Concentration	Dilution	
▶ QC 1	0.0	1.0	Add Delete

To delete a Quality Control, select the entire row by clicking the black triangle and then selecting **Delete**. Multiple Quality Controls can be deleted at the same time by marking multiple lines and selecting **Delete**.

The **Concentration** and **Dilution** value should be entered for every Quality Control. The concentration value corresponds to Quality Control sample concentration before dilution. The dilution value corresponds to the dilution of the Quality Control sample. A value of 1 corresponds to an undiluted sample. Dilution values must be 1 or larger.

Quality Control names, concentrations and dilutions can be copied and pasted. Use Ctrl+C to copy and Ctrl+V to paste, or right click and select **Copy** or **Paste**.

The Quality Controls can be sorted by name, concentration, or dilution by clicking the table header. Note that this is only a temporary sorting and will not affect the underlying order defined when adding the Quality Controls.

The number of replicates for Quality Controls can be specified in the **Replicates** section. The same number of replicates is used for all Quality Controls.

By selecting **Group controls with same concentration and dilution**, Gyrolab Evaluator will calculate statistics based on all Quality Controls having the same combination of concentration, concentration unit, and dilution.

A common unit in which concentration values are given can be defined in the **Concentration Unit** section in the same way as for the Standard Series. It is recommended to select one of the predefined units, if possible.

Quality control name	Concentration	Dilution	
▶ QC 1	0.0	1.0	Add Delete
▶ QC 2	0.0	1.0	

☐ Specify concentration Unit per sample

Common concentration Unit: Not defined ▼

If creating multiple experiments where it is desirable to have different concentration units in different experiments, the concentration unit can be defined individually for each Quality Control. Click **Specify concentration Unit per sample**. The Quality Control table will be changed to offer a concentration unit to be specified for each Quality Control.

Quality control name	Concentration	Predef Unit	User def Unit	Dilution	Add
▶ QC 1	0.0	Not defined		1.0	Delete
▶ QC 2	0.0	Not defined		1.0	

☒ Specify concentration Unit per sample :

Common concentration Unit: Not defined

B4.3.4.1 Quality Control Sample Sets (QC Sets)

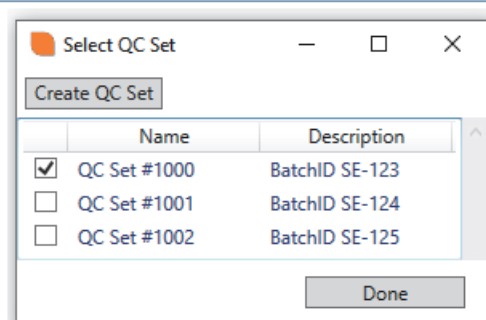
QC Sets are used together with the Gyrolab QC Trending module to analyze QC concentration measurements between runs and evaluate any visible trends. For details on this software module, see Chapter D4.4, where the use of QC Sets is explained further.

A QC Set represents a set of defined Quality Controls that is consistently used in routine experiments and their performance is monitored over time. Unlike regular Quality controls, QC Sets are version controlled and can be added to multiple Run Designs/Setups.

Multiple QC Sets can be created and then added to an experiment. Each Experiment may use zero or more of the defined QC Sets, but the concentration unit of the QC Set must be the same as the Standard Series in the experiment.

Click **Add...** to include a QC Set to the Run Design. A list of available QC Sets will be presented. Check the ones to include in Run Design.

QC Set Name	Description	Add...
▶ QC Set #1000	BatchID SE-123	Remove



To create a new QC Set, click **Create QC Set** and fill in the QC Set properties.

To edit or view the content of an existing QC Set, double click on a QC Set.

Click **Save** to save the created or updated QC set.

The properties of a QC set consist of a name of the QC set, an optional description, and the Quality Control Sample definitions.

Edit Quality Control Sample Set

Quality Control Sample Set

Name: QC Set #1000

Description: BatchID SE-123

Quality Controls

Replicates: 2

Quality control name	Concentration	Dilution
QC 1	1.0	1.0
QC 2	2.0	1.0
QC 3	3.0	1.0

☒ Common concentration Unit: g/mL

Add Delete

It is possible to optionally specify the acceptance criteria for one or more Quality Controls. These limits will later be visible in the Gyrolab QC Trending module. Specify the upper acceptance criteria limit for a QC in the **Upper limit** column and/or the lower acceptance criteria limit for a QC in the **Lower limit** column. The values entered can be a percentage value, absolute value, or relative value from the expected concentration of the QC.

Optionally specify the accepted tolerance for the defined quality controls:

Quality control name	Upper limit	Lower limit	
QC 1	5.0	5.0	☒ Percent (%) ☐ Absolute ☐ Relative from concentration
QC 2	2.0	2.0	☐ Percent (%) ☐ Absolute ☒ Relative from concentration
QC 3			☒ Percent (%) ☐ Absolute ☐ Relative from concentration

Click **Done** when having included the necessary QC sets to the Run Design.

B4.3.5 ADA controls

ADA Controls are used together with the Gyrolab ADA Software add-on module. For details on this software module, see Chapter E2, where the use of ADA controls is explained further.

Multiple ADA Controls can be created. Each Experiment may use zero or more of the defined ADA Controls, and the ADA Controls used may be different for different Experiments.

Click **Add** to add an ADA Control.

ADA controls

Use spiked/unspiked: ☐

ADA control name	Dilution	Replicates	Type
ADA 1	1.0	2	NC

Add Delete

To delete an ADA Control, select the entire row by clicking the black triangle and then selecting **Delete**. Multiple ADA Controls can be deleted at the same time by marking multiple lines and selecting **Delete**.

The **Dilution** value is optional, but may be entered for every ADA Control. The dilution value corresponds to the dilution of the ADA Control sample. A value of 1 corresponds to an undiluted sample. Dilution values must be 1 or larger. The dilution value is used for concentration calculations in the Gyrolab Evaluator. The value can be changed during data analysis.

The number of **Replicates** for ADA Controls can be specified individually for each ADA Control. The **Type** for each ADA control must be selected as PC (positive control) or NC (negative control). ADA Control names and dilutions can be copied and pasted. Use Ctrl+C to copy and Ctrl+V to paste, or right click and select **Copy** or **Paste**.

The ADA Controls can be sorted by name, dilution, or number of replicates by clicking the table header. Note that this is only a temporary sorting and will not affect the underlying order defined when adding the ADA Controls.

Mark **Use spiked/unspiked** check box when performing confirmation runs. This automatically doubles the number of ADA Controls and the sample subgroup for ADA Controls is set to "Spiked" and "Unspiked" respectively within each pair. (See also Chapter B4.5.5.)

As for Quality Controls, the concentration unit can be specified for ADA Controls, either collectively, or individually for each ADA control. See Chapter B4.3.4 for details.

B4.3.6 Analytes and Experiments

The setup made when selecting or defining Methods, Standard Series, Quality Controls, Quality Control Sample Sets and ADA Controls will just create the building blocks for use in Experiments.

Each Experiment then defines which of these building blocks to use when executing the run, and processing samples with the Experiment in question.

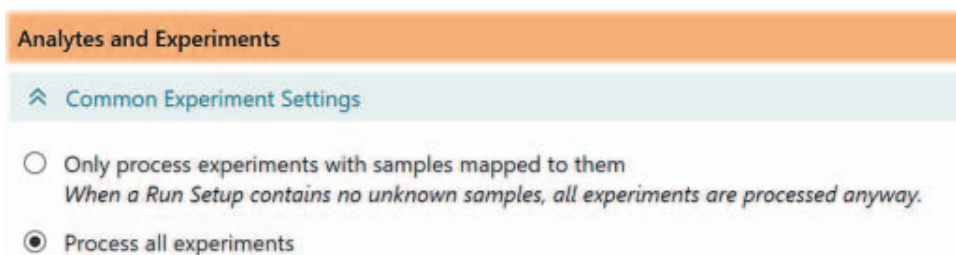
Experiments are organized in Analytes sections. This does not have any effect on how the Experiments are processed, but may be used to organize Experiments.

In the **Common Experiment Settings** section, settings that are common to all Experiments are found.

Normally, all samples are processed with all Experiments, but by using Experiment Mapping (see Chapter B4.6), it is possible to select what unknown samples to process with each Experiment.

By default, all experiments will be processed even when not all experiments have unknown samples mapped to them in the Run Setup. The experiments that have other samples associated with them (Standard Series, Quality Controls, Quality Control Sample Sets and ADA Controls) will be processed as well.

It is possible to override this setting by selecting **Only process experiments with samples mapped to them**. Then experiments with no mapped unknown samples will simply be ignored. However, when executing a run with no unknown samples at all, then all Experiments will be processed anyway. (The effect would otherwise be to have no samples at all in the run, of any kind, making the run meaningless.)



To add an Analyte, select **Add Analyte**. This will create a new Analyte section with no Experiments. The Analyte will be given a default name. You can change the name as desired.

Analytes and Experiments

Common Experiment Settings

Add Analyte

Then add an Experiment by selecting **Add Experiment**. As for Analytes, the Experiment will be given a default name, which can be changed.

Analytes and Experiments

Common Experiment Settings

Analyte 1

Add Experiment

Add Analyte

In most simple cases, it is desirable that the Experiment includes all the Reagents, Standard Series, Quality Controls, Quality Control Sample Sets and ADA controls that are defined. To make the process easy in this case, a new Experiment will by default be configured to match the design in the setup section.

- If exactly one Method has been selected, the Experiment will be configured to use that Method.
- If there is exactly one Standard Series, the Experiment will be configured to use that Standard Series.
- The Experiment will be configured to use all Quality Controls that have been defined.
- The Experiment will be configured to use all Quality Control Sample Sets that have been defined.
- The Experiment will be configured to use all ADA Controls that have been defined.

For Reagents, the Experiment is prepared for entry of reagents for all reagent transfer operations defined by the Method, but as the Reagent to use for each reagent transfer operation is important to specify correctly, the actual selection of Reagents must be done manually to avoid mistakes.

Experiment 1

Method to process: 1000HC-3W-010-A

Capture reagent addition

Detection reagent addition

Number of Standard Series: 1 ☐ Use on all CDs (*)

Standard Series name: Standard A

Quality Controls: QC 1 QC 2

Quality Controls Sets: QC Set #1000

☐ Use on all CDs (*)

Number of ADA Controls: 0 ☐ Use on all CDs (*)

Unknown sample replicates: 2

Keep experiment within one CD: ☐ (May require additional wells for unknown samples)

(*) Only used in multi-CD runs

Add Experiment

Once an Experiment has been created, it is possible to modify what to include in the experiment.

- To change Method, select **Method to process**. In case the reagent transfer operations match those from the previously selected Method, the software will offer to keep the reagent selection. Otherwise, the list of selected Reagents will be cleared.
- To change Standard Series, select **0** or **1** for **Number of Standard series**. Select the Standard Series to use in the **Standard Series name** drop-down list.
- To add Quality Controls or QC Sets to use in experiment, select one or multiple Quality Controls from the set up (left side of window) and then click **Add from Setup**. To remove all Quality Controls and QC Sets from experiment, select **Clear**, or **Remove** to only remove selected ones.
- To change the number of ADA Controls, select a new number for **Number of ADA Controls**. To select the actual ADA Controls, select the ADA Control to use from the **ADA Control name** drop-down list.

The Standard Series, Quality Controls, QC Sets and ADA Controls included in the experiment must all have the same setting for concentration unit. If not, a warning will be presented when trying to save the Run Design.

For Standard Series, Quality Controls, and ADA Controls, there is a selection whether to **Use on all CDs**. This setting only applies to a multi-CD run.

If unchecked, the Standard Series/Quality Controls/ADA Controls will be placed once only on the set of CDs included in a multi-CD run. If checked, the Standard Series/Quality Controls/ADA Controls will be placed in multiple copies, with one copy on every applicable CD. (If an Experiment is not represented at all on a CD, there is no need to place Standard Series/Quality Controls/ADA Controls on that CD.)

If **Use on all CDs** has been checked for the Standard Series, unknown samples placed on a CD will be quantified against the Standard Series located on the same CD. One analysis per CD will be created in Gyrolab Evaluator. The Quality Controls and/or ADA Controls located on the same CD will be included in the analysis.

If **Use on all CDs** has not been checked for the Standard Series, all unknown samples (and Quality Controls/ADA Controls) will be quantified against the same Standard Series. Calibration Controls, if specified for the Standard Series, will be placed on all CDs except the one where the Standard Series is placed.

Quality Controls and ADA Controls, when both are present, must have the same setting for **Use on all CDs**.

If Quality Controls/ADA Controls are not placed on all CDs, they will be processed in a way that as much as possible resembles how unknown samples are processed. This means that selected Quality Controls/ADA Controls will be evenly spread amongst the unknown samples, both over the entire set of CDs, and within each CD.

The Experiment also specifies how unknown samples processed with this experiment will be handled.

The number of replicates to use is specified in **Unknown sample replicates**. The highest number of replicates is eight.

Unknown sample replicates:

In some cases, it may also be important to keep all samples (unknown samples, and samples defined by the Experiment, like the Standard Series) together on one single CD. This can be achieved by checking the checkbox **Keep Experiment within one CD**. This has the following effects on the run:

- All samples related to the Experiment are kept together on the same CD.
- As the samples for the Experiment are kept together, it may be more difficult to use the CD segments efficiently. CD use may increase.
- In normal cases, the software will place unknown samples on CDs in such a way that the sample needs one microplate well only. (All uses of the unknown sample will be placed on the same CD.) But if you
 - select **Keep Experiment within one CD**, and
 - the same sample is used in multiple Experiments, and
 - the Experiments end up on different CDs

the sample will need to be placed in multiple microplate wells. This may require a larger amount of the unknown sample to be available.

- If two Experiments using the same set of reagents are placed on the same CD, CD structures will not be shared as is normally the case when not setting **Keep Experiment within one CD**. The sample will be placed in one copy per Experiment.

Keep experiment within one CD: ☐ (May require additional wells for unknown samples)

To delete an Analyte or Experiment, click the corresponding  button.

An Experiment can be copied. Click the  button. This will create a new Experiment with the same setup as the original Experiment.

Analytes and Experiments can be reorganized within the Run Design. To move an existing Analyte or Experiment, grab the title bar for the Analyte or Experiment, to the right of the Analyte/Experiment name, with the default (normally the left) mouse button, and drag it up and down to the desired destination. When grabbing the Analyte/Experiment, an icon will

initially be displayed showing that the Analyte/Experiment cannot be dropped. When moving the mouse up and down, a legal destination will be highlighted with a black stripe. Release the mouse button at the desired destination to complete the move.

B4.3.7 Using the Experiment Setup to Execute a Run

After defining Analytes and Experiments, all required steps have been performed for a Run Design.

You may now save the Run Design (see Chapter B4.4), and then prepare for executing a run by first creating a Run Setup based on this Run Design, adding unknown samples as required, and then execute the run at a Gyrolab instrument. For more information, see Chapter B5.

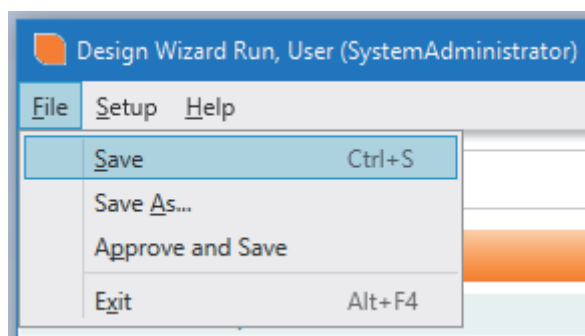
Optionally, you can also add more features to the Run Design by setting up Dilution/Spike preparations and/or use Experiment Mapping to define Sample Sets allowing you to map unknown samples to specific Experiments.

Defining Dilution/Spike preparations is described in Chapter B4.5.

Defining Experiment Mapping is described in chapter Chapter B4.6 and Chapter B4.7.

B4.4 Saving a Run Design

There are three different ways to save a Run Design, all found at the Run Design menu bar **File** entry.



Save will save the work in progress. The Run Design window will remain open, allowing additional changes to be performed.

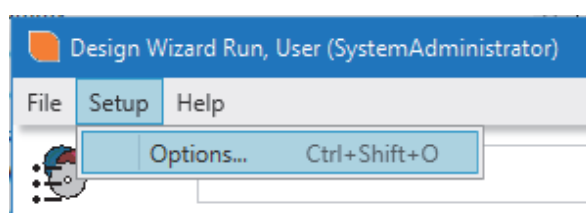
Save As... will open a new dialog where you can specify a new Run Design name, and a target folder. Clicking **Save** in that dialog will save the Run Design as a copy with a new name. The Run Design window will remain open. Note that the Run Design being edited is now the new copy. To continue editing the original Run Design, you will have to go the Gyrolab Manager main window and open the original Run Design.

Approve and Save will first show a confirmation dialog, as an approved Run Design can no longer be changed. If you decide to approve the Run Design, it will remain open for further editing, but you can no longer Save it. (But it is still possible to **Save As...** to make a copy.)

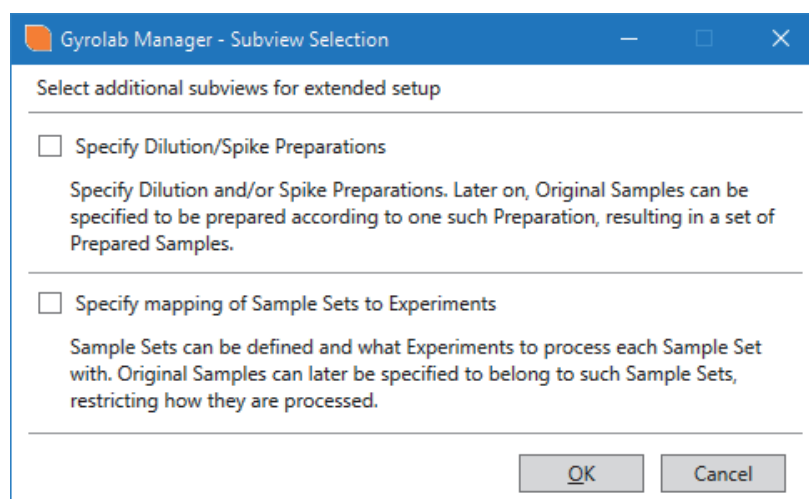
B4.5 Dilution/Spike Setup

Dilution/Spike Setup is an extended experiment setup used to specify dilution and/or spike Preparations for unknown samples. A Preparation created in Dilution/Spike Setup can later be used to specify how unknown samples shall be prepared. Specifying a Preparation for an unknown sample is done in the in the **Run Setup**. See Chapter B5.3.4 for more details.

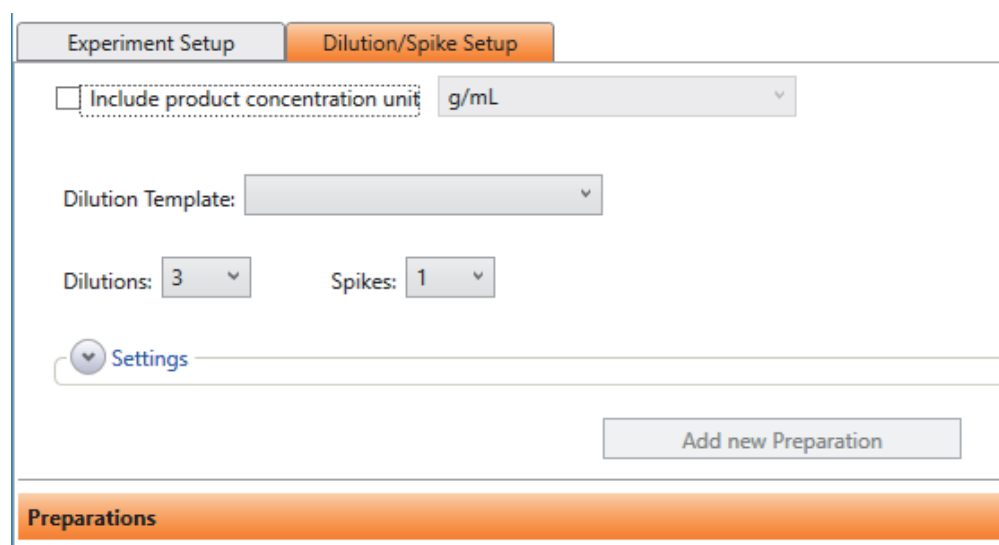
Select **Setup** and then **Options...** on the **Run Design** menu bar to display the options dialog.



To enable Dilution/Spike Setup, click **Specify Dilution/Spike Preparations**. Select **OK**.



A new tab named **Dilution/Spike Setup** appears next to the **Experiment Setup** tab.

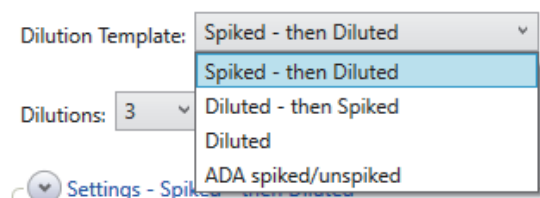


A product concentration unit can be specified by checking **Include product concentration unit** and selecting the desired unit. The actual product concentration for an unknown sample is given later, when creating a Run Setup where unknown samples are added. If not selected here, the product concentration unit can also be specified later, in the Run Setup. But if the unit is selected here, it will be locked for changes in the Run Setup and will automatically be set for all Run Setups based on this Run Design.

To create a Preparation, follow these steps.

Step Action

1. Select a **Dilution Template** to select the type of Preparation to define. The different Dilution Templates are described in more detail below.



2. For Dilution Templates where samples are diluted or spiked, select the number of dilutions and/or spikes in the **Dilutions** and **Spikes** drop-down lists.
3. If desired, open the **Settings** panel to specify properties for the Dilution Template. The properties for each Dilution Template are described in more detail below. Changes to the settings for a Dilution Template will apply to Preparations created from that template. The settings for a created Preparation can also be changed later, individually for each created Preparation.
4. Create a Preparation based on the Dilution Template with its setting by selecting **Add new Preparation**.

A new Preparation is now created with a default name. The new Preparations are found in the lower part of the window, under **Preparations**. Continue by adding additional Preparations, or adding required information to the created Preparations.



Any changes to the settings for Dilution Templates are not saved when the Run Design is saved. Settings for the created Preparations are saved when the Run Design is saved.

B4.5.1 General operations on Preparations

Preparations that have been created can be named by directly editing the name in the corresponding Preparation header.

To delete a Preparation, click the corresponding  button.

A Preparation can be copied. Click the  button. This will create a new Preparation with the same setup as the original Preparation.

Properties for a specific Preparation can be displayed by expanding the Preparation using the  button in the Preparation header.

Preparation: (Spiked - then Diluted)

3 dilutions and 1 spikes are used

Settings

Final dilution	Dilution factor	Spike 1 conc
1	1	1
1	1	1
1	1	1

Comments:

A comment can be entered in the **Comments** field for a Preparation. The comment can later be consulted in the Run Setup, when selecting the Preparation to use for an unknown sample.

B4.5.2 Spiked – then Diluted Preparation

The **Spiked – then Diluted Preparation** allows for an unknown sample to be spiked with the specified number of known analyte concentrations. Spiked dilutions are then diluted according to the specified number of dilutions.

The following settings are available for the **Spiked – then Diluted Preparation**:

- ☐ Use equal dilution step factor
- ☒ Include unspiked ☐ Use separate well replicates (May require additional wells for samples)
- ☒ Process samples on same CD

Check **Use equal dilution step factor** to specify a common dilution step factor used for all dilutions. If unchecked, the final dilution for each dilution will have to be specified. See below.

Check **Include unspiked** to include an unspiked samples in addition to the spiked samples when preparing an unknown sample.

Check **Use separate well replicates** to include analysis of sample replicates from separate microplate wells. If unchecked, all sample replicates placed on a CD will originate from the same well.

Check **Process samples on same CD** to force all preparations of an unknown sample to be placed on the same CD. If unchecked, different preparations of an unknown sample may be placed on different CDs. Placing all preparations on the same CD may increase the CD use.

Dilutions and spikes to use when preparing an unknown sample is entered in the dilution/spike table. The example table below illustrates a preparation with three dilutions and three spikes.

Final dilution	Dilution factor	Spike 1 conc	Spike 2 conc	Spike 3 conc
1	1	1	1	1
1	1	1	1	1
1	1	1	1	1

For each dilution, enter the **Final dilution**. The **Dilution Factor** is automatically calculated from the final dilutions.

If **Use equal dilution step factor** has been checked, only enter the **Final dilution** for the first dilution. The remaining dilutions will be calculated automatically from the specified dilution step factor.

Enter the spike concentration for each spike in the topmost cell in each spike column.

B4.5.3 Diluted – then Spiked Preparation

The **Diluted – then Spiked Preparation** allows for an unknown sample to be diluted the specified number of times. Each dilution is then spiked with the specified number of known analyte concentrations.

The following settings are available for the **Diluted – then Spiked Preparation**:

- ☐ Use individual sample start dilution factor
- ☐ Use equal dilution step factor
- ☒ Include unspiked ☐ Use separate well replicates (May require additional wells for samples)
- ☒ Process samples on same CD

Check **Use individual sample start dilution factor** to specify an individual start dilution factor for every unknown sample prepared according to this Preparation. See Chapter B5.3.4. If unchecked, the final dilutions are specified in the dilution/spike table. See below.

Check **Use equal dilution step factor** to specify a common dilution step factor used for all dilutions. If unchecked, the final dilution for each dilution will have to be specified. See below.

Check **Include unspiked** to include an unspiked samples in addition to the spiked samples when preparing an unknown sample.

Check **Use separate well replicates** to include analysis of sample replicates from separate microplate wells. If unchecked, all sample replicates placed on a CD will originate from the same well.

Check **Process samples on same CD** to force all preparations of an unknown sample to be placed on the same CD. If unchecked, different preparations of an unknown sample may be placed on different CDs. Placing all preparations on the same CD may increase the CD use.

Dilutions and spikes to use when preparing an unknown sample is entered in the dilution/spike table. The example table below illustrates a preparation with three dilutions and three spikes.

Final dilution	Dilution factor	Spike 1 conc	Spike 2 conc	Spike 3 conc
1	1	1	1	1
1	1	1	1	1
1	1	1	1	1

For each dilution, enter the **Final dilution**. The **Dilution Factor** is automatically calculated from the final dilutions.

If **Use equal dilution step factor** has been checked, only enter the **Final dilution** for the first dilution. The remaining dilutions will be calculated automatically from the specified dilution step factor.

Enter the spike concentration for each dilution and spike in the spike columns.

If **Use individual sample start dilution factor** has been checked, final dilution factors cannot be entered as they depend on the start dilution factor entered for the unknown sample in the Run Setup. In this case, instead enter the **Dilution factor** for each succeeding dilution.

If **Use equal dilution step factor** has been checked, the **Dilution factor** is given there and need not be entered in the table.

Also in this case, enter the spike concentration for each dilution and spike in the spike columns.

Final dilution	Dilution factor	Spike 1 conc	Spike 2 conc	Spike 3 conc
<from sample>	<from sample>	1	1	1
<calculated later>	1	1	1	1
<calculated later>	1	1	1	1

B4.5.4 Diluted Preparation

The **Diluted Preparation** allows for an unknown sample to be diluted the specified number of times.

The following settings are available for the **Diluted Preparation**:

- ☐ Use individual sample start dilution factor
- ☐ Use equal dilution step factor
- ☐ Use separate well replicates (May require additional wells for samples)
- ☒ Process samples on same CD

Check **Use individual sample start dilution factor** to specify an individual start dilution factor for every unknown sample prepared according to this Preparation. See Chapter B5.3.4. If unchecked, the final dilutions are specified in the dilution table. See below.

Check **Use equal dilution step factor** to specify a common dilution step factor used for all dilutions. If unchecked, the final dilution for each dilution will have to be specified. See below.

Check **Use separate well replicates** to include analysis of sample replicates from separate microplate wells. If unchecked, all sample replicates placed on a CD will originate from the same well.

Check **Process samples on same CD** to force all preparations of an unknown sample to be placed on the same CD. If unchecked, different preparations of an unknown sample may be placed on different CDs. Placing all preparations on the same CD may increase the CD use.

Dilutions to use when preparing an unknown sample is entered in the dilution table. The example table below illustrates a preparation with three dilutions.

Final dilution	Dilution factor
1	1
1	1
1	1

For each dilution, enter the **Final dilution**. The **Dilution Factor** is automatically calculated from the final dilutions.

If **Use equal dilution step factor** has been checked, only enter the **Final dilution** for the first dilution. The remaining dilutions will be calculated automatically from the specified dilution step factor.

If **Use individual sample start dilution factor** has been checked, final dilution factors cannot be entered as they depend on the start dilution factor entered for the unknown sample in the Run Setup. In this case, instead enter the **Dilution factor** for each succeeding dilution.

If **Use equal dilution step factor** has been checked, the **Dilution factor** is given there and need not be entered in the table.

Final dilution	Dilution factor
<from sample>	<from sample>
<calculated later>	1
<calculated later>	1

B4.5.5 ADA spiked/unspiked Preparation

The **ADA spiked/unspiked Preparation** is used when performing confirmation runs together with the Gyrolab ADA Software add-on module. For details on this software module, see Chapter E2.

If selecting the **ADA spiked/unspiked Preparation** for an unknown sample, the unknown sample will be prepared as one ADA Spiked and one ADA Unspiked sample.

The sample subgroup value for the two prepared samples will be used to qualify them as the spiked and the unspiked sample respectively.

By default, the two labels used are "Spiked" and "Unspiked". In the settings for the **ADA spiked/unspiked Preparation**, these labels can be changed if desired.

Spiked:	Spiked
Unspiked:	Unspiked

Besides using these labels for unknown samples prepared with the **ADA spiked/unspiked Preparation**, these labels are also used for ADA controls generated in spiked/unspiked pairs. See Chapter B4.3.5.

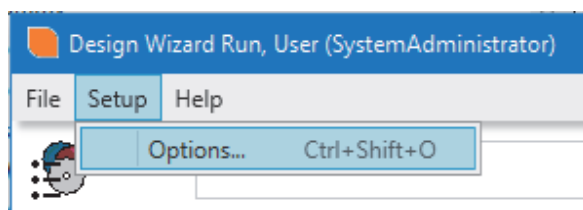
See Chapter B4.4 for information on how to save the Run Design before continuing with creating a Run Setup (Chapter B5).

B4.6 Experiment Mapping

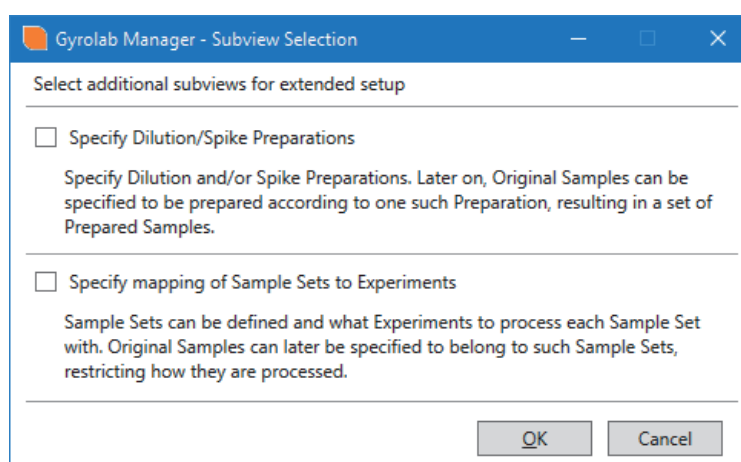
By default, all unknown samples will be processed with all defined Experiments. This also implies that all unknown samples will be processed with all selected Methods, in case the Experiments specify different Methods.

In some cases, it may be desirable to process some samples with a subset of Experiments only. This can be specified with the optional Experiment Mapping setup.

Select **Setup** and then **Options...** on the Run Design menu bar to display the options dialog.



To enable Experiment Mapping, click **Specify mapping of Sample Sets to Experiments**. Select **OK**.



A tab named **Experiment Mapping** appears.

In the examples below, it is assumed that you have created three Experiments in the **Experiment Setup**.

Experiment Setup		Experiment Mapping		
		Add	Delete	
Sample Set	Analyte 1 Experiment 1	Analyte 1 Experiment 2	Analyte 1 Experiment 3	
▶ Sample Set 01	☐	☐	☐	

A list of **Sample Sets** is displayed. A Sample Set represents a collection of unknown samples for which you want to specify the Experiments to process.

To the right of the Sample Set name, all Experiments created in the **Experiment Setup** are presented. For each Experiment, there is a checkbox. If the checkbox is checked, it means that samples belonging to the Sample Set in question will be processed with the corresponding Experiment.

Note that it is not part of the Run Design to specify the exact unknown samples to include in each Sample Set. This is done later, when creating a Run Setup, see Chapter B5.3.5, where samples are assigned to Sample Sets. The setup in the **Experiment Mapping** defines the different categories of unknown samples, and how to process such samples.

Initially, one **Sample Set** has been created. Additional Sample Sets can be created by clicking **Add**. A new Sample Set will get a default name. Change the Sample Set name so that it describes the set of samples in a meaningful way.

To delete a Sample Set, select the entire row by clicking the black triangle and then selecting **Delete**. Multiple Sample Sets can be deleted at the same time by marking multiple lines and selecting **Delete**.

In the example below, it has been decided that mouse samples shall be processed with experiments 1 and 2, while rat samples shall be processed with experiment 3 only.

Sample Set	Analyte 1 Experiment 1	Analyte 1 Experiment 2	Analyte 1 Experiment 3
▶ Mouse samples	☒	☒	☐
▶ Rat samples	☐	☐	☒

When later creating a Run Setup based on this Run Design, the unknown samples can be categorized as being "Mouse samples" or "Rat samples" by assigning them to the corresponding Sample Set, implying with which Experiments to process the samples.

Note that if an unknown sample later is not assigned to any Sample Set, it will be processed with all Experiments, which is the default behavior.

See Chapter B4.4 for information on how to save the Run Design before continuing with creating a Run Setup (Chapter B5).

B4.7 Experiment Mapping with Dilution/Spike Setup

Besides specifying the Experiments to process for samples assigned to a Sample Set, the Sample Set can also specify how to prepare samples assigned to a Sample Set. This only applies if you have enabled Dilution/Spike Setup, see Chapter B4.5.

In the examples below, it is assumed that you have created two separate Preparations, one where samples are prepared into three different dilutions, here named "3 dilutions", and one Preparation where samples are prepared into five different dilutions, here named "5 dilutions".

If enabling Dilution/Spike Setup, the Experiment Mapping tab will change to allow selection of a Preparation by adding a new column **Dilution/Spike**.

Add
Delete

Sample Set	Dilution/ Spike	Analyte 1 Experiment 1	Analyte 1 Experiment 2	Analyte 1 Experiment 3
▶ Mouse samples	3 dilutions	☒	☒	☐
▶ Rat samples	5 dilutions	☐	☐	☒

☒ Allow selection of a preparation in Run Setup for samples assigned to a sample set that is not associated with a preparation

When later creating a Run Setup and adding unknown samples, a Preparation can be assigned to each unknown sample specifying that the sample will be used in multiple dilutions and/or spikes. Chapter B5.3.4.

By selecting one of the Preparations created in Dilution/Spike Setup, In the **Dilution/Spike** column, you can associate one of the defined Preparations with the Sample Set. By doing this, an unknown sample assigned to a Sample Set will be processed with the Experiments specified by the Sample Set, but will also be prepared according to the Preparation associated with the Sample Set.

If not associating a Preparation with the Sample Set, a Preparation can be selected independently when later adding the unknown sample in the Run Setup.

If unchecking the checkbox **Allow selection of preparation in Run Setup for samples assigned to a sample set that is not associated with a preparation**, a Sample Set with no associated Preparation implies that unknown samples assigned to that Sample Set may not be assigned an individual Preparation. In other words, the Preparation to apply to the unknown sample is completely controlled by the Sample Set, also when no Preparation has been associated with the Sample Set.

See Chapter B4.4 for information on how to save the Run Design before continuing with creating a Run Setup (Chapter B5).

B5 Wizard Run Setup

While the processing of samples in Gyrolab instruments is controlled by the Method, see Chapter A2.3, and the additional information required for analyzing/quantifying the run result is provided by the Run Design, see Chapter B4, the main purpose for the Run Setup is to add information on the unknown samples to process.

The Run Setup collects the information required for one single run in Gyrolab, and is then "consumed" once the run has been executed. To set up the next run, a new Run Setup is created. Each Run Setup typically creates one run result to be analyzed in Gyrolab Evaluator. (Exception: If the run includes multiple Methods, each processed Method will generate one result.)

The Run Setup concept is introduced with Gyrolab Manager, and is not used to execute runs in the traditional way in Gyrolab Client. Before the introduction of the Run Setup, a Run Design was selected in Gyrolab Client, sample information was added by importing a sample list, a loading list was created and execution of the run was started, all in one sequence. (For more information, see Chapter I2.4)

The Run Setup concept splits the workflow into two different parts; definition of the Run, performed at the desktop, and execution, performed at the Gyrolab instrument.

The Run Setup can be created at the desktop. Information on unknown samples is added, a loading list can be created and printed, and the finished Run Setup is put on a queue for later execution. None of this work requires access to a Gyrolab instrument.

After preparing the microplates for the run, the Run Setup can be selected at the instrument, CDs and microplates loaded, and execution is started.

By splitting the work in two parts, the time at the instrument is minimized, allows the setup to be conveniently done at a desktop computer, and allows the two parts to be performed by different categories of personnel.

How to create a Run Setup differs between the different Design Types supported by Gyrolab software. How to create a Wizard Run Setup is described in this chapter. For other Design Types, see Chapter E

B5.1 Overview of workflow

Run Setups are stored in folders as most other objects but can also be found in the Run Setup lists displayed in the Gyrolab Manager main window. For more information on Run Setup lists, see Chapter B3.2.

Run Setups are characterized by their state. A Run Setup can be in the following states.

In development After creating the Run Setup, but before being ready for execution, it can be **In development**. In many cases, the Run Setup is immediately made ready for execution, but in case the setup is not finished immediately, it can be saved as being in development.

Ready for execution When the Run Setup is ready to be executed on an instrument, it has the state **Ready for execution**. A Run Setup in this state can be opened on Gyrolab Instruments for execution by selecting **Execute Run...**, **Run Setup...**, and selecting the queued Run Setup. To place a Run Setup in the **Ready for Execution** state, the Run Setup is queued instead of saved. See Chapter B5.5 for more information.

Executed Once a run has been executed, the corresponding Run Setup is given the state **Executed**. In this state, the Run Setup can no longer be modified. But it can be opened for viewing, and a copy can be created with **Save As...** in case it is desirable to execute it again (potentially with some changes).

The following list shows the steps to create a Run Setup based on a Run Design, with references to applicable chapters for more information. The following chapters explain the process of creating a Run Setup in more detail.

A Run Setup can also be created without being based on a Run Design. For more information, see Chapter B5.2.1.

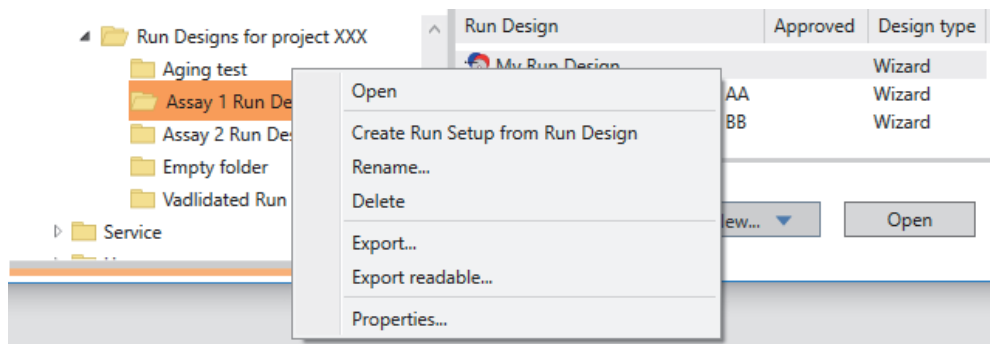
This list assumes a basic Run Design without the optional Dilution/Spike (Chapter B4.5) and Experiment Mapping (Chapter B4.6). If the Run Design includes these optional parts, see Chapter B5.3.4 and Chapter B5.3.5 for more information on prepared samples.

Step Action

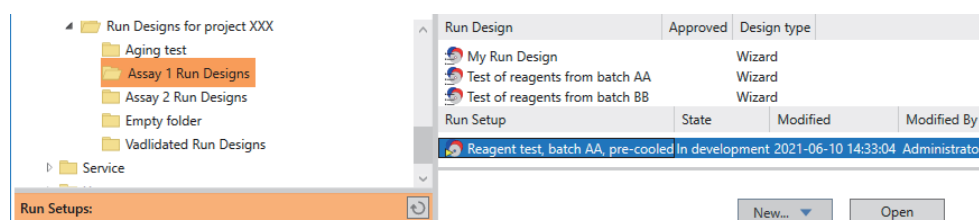
1. Select the Run Design to base the Run Setup on from the main window folder tree
2. On the right side of the main window, select **New...::Run Setup from Design** to create a new Run Setup based on the selected Run Design.
3. A Run Setup edit window is opened.
4. Enter a **Name** for the Run Setup.
5. In the **Samples** tab, select **Add** and specify the number of unknown samples to process in the run. Select **OK** (Chapter B5.3.1). Samples can also be loaded from a Sample list, Chapter B5.3.3
6. Enter information on the unknown samples, primarily sample **Identity**.
7. If desired, select **Recalculate** in the lower part of the window to show the CD consumption for the Run Setup (Chapter B5.3.2).
8. Go to tab **MP Layout**.
9. Produce a Loading List to guide the microplate preparation from the Loading List section, using either **Save...**, **Open...** or **Print** as desired (Chapter B5.4.3).
10. Queue the Run Setup from the **File** menu, by selecting **Queue for Execution and Close** (Chapter B5.5). If **Target and Report Settings** dialog is displayed, close it with **OK** (Chapter B6).
11. Prepare microplates according to Loading List. The Run Setup is now ready for execution at a Gyrolab instrument.

B5.2 Creating or opening a Run Setup

To create a Run Setup from a Run Design, navigate to the desired folder, select the Run Design to use and either click the button **New...:Run Setup from Design**, or right click the Run Design and select **Create Run Setup from Run Design**.



To open an existing Run Setup, first select a Run Setup from a folder, or from one of the Run Setup lists.



To open the Run Setup, select the Run Setup and then click the button **Open**. Alternatively, the Run Setup can be opened by right clicking and selecting **Open** in the context menu, or by double clicking the Run Setup.

If the Run Setup is in state **Ready for execution**, it will be changed to state **In development** to avoid that someone starts execution while the Run Setup is open for editing. You will also get the option to open the Run Setup in Read Only mode in case you just want to view it or create a copy.

If the Run Setup is in state **Executed**, it is always opened in Read Only mode. To create a copy from an open Run Setup, select **Save As...** after opening the executed Run Setup.

B5.2.1 Creating a Run Setup not based on a Run Design

The previous chapters described how to create a Run Setup based on a Run Design. In those cases, the parts that were defined in the Run Design (the Experiment Setup, Chapter B4.3, and optionally a Dilution/Spike Setup, Chapter B4.5 and/or an Experiment Mapping, Chapter B4.6, were locked for editing. Those parts could be viewed but not modified.

In some cases, especially in an experimental phase like in assay development, the two-step process of working both with a Run Design and then creating Run Setups based on the Run Design may be less convenient. In this case, the workflow may be improved if a Run Setup is created directly, without basing it on a Run Design.

All components and settings of a Run Setup, from Method selection, through Experiment Setup, to definition of unknown samples can be specified and modified. For details, see corresponding Chapter B4.3, Chapter B4.5, and Chapter B4.6.

This workflow may be especially convenient in cases where unknown samples are not used in the Runs, for example when different combinations of standard curves and reagents are explored.

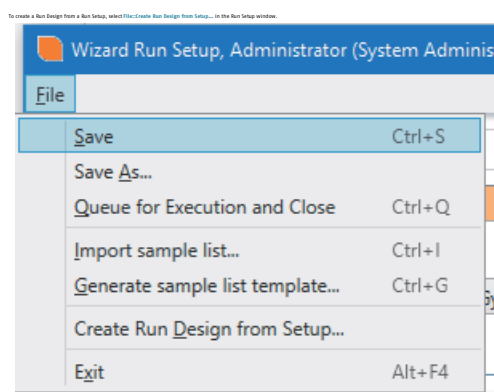
To create a new Run Setup without basing it on a Run Design, select **New...:Wizard Run Setup** from the Gyrolab Manager main window.

B5.2.2 Creating a Run Design from a Run Setup

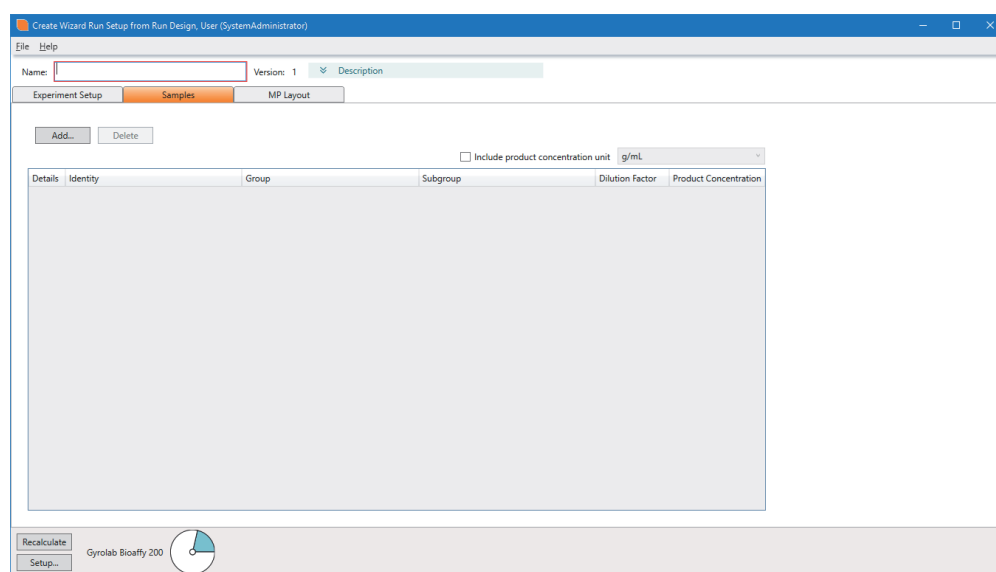
If a Run Setup has been created without being based on a Run Design, see Chapter B5.2.1, it may be of interest to save common parts of the Run Setup as a new Run Design.

For example, assume that assay development has been performed by testing several variants of a Run Setup without basing it on a Run Design. After some iterations, the optimal combination of Methods, standard curves, and reagents may have been found. It is now of interest to perform a larger number of Runs based on this design, processing different unknown samples each time, without risking changing the design. A Run Design can now be created from the Run Setup and then used to create new Run Setups and new Runs where the set of unknown samples can be varied.

This also has the advantage that the subsequent Run Setups, based on the Run Design, can be created by users with less privileges, typically users with role Operator.



After creating or opening a Run Setup, a new window is displayed.



When creating a new Run Setup, a name must be entered in the **Name** field.

B5.3 Adding samples

The main purpose for a Run Setup is to add information on the unknown samples to process when executing a run. When creating or opening a Run Setup, the initial view shows the **Samples** tab, where unknowns samples are specified.

The setup from the underlying Run Design is also available as reference. This includes the **Experiment Setup** tab, and optionally the **Dilution/Spike Setup** and/or **Experiment Mapping**

tabs, if present in the Run Design. The information defined by the Run Design can be viewed, but not modified.

How unknown samples are placed on microplates can be viewed and controlled from the **MP Layout** tab. For more information, see Chapter B5.4.

B5.3.1 Defining samples in a Run Setup

To add samples interactively, start by clicking **Add....** A new dialog is opened where you can specify the number of unknown samples to process in the run.

Enter the desired number of unknown samples to add. As a hint, the maximal number of normal (not prepared) unknown samples that will fit, given a five-CD Gyrolab instrument, is presented.

The samples will be named from the specified **Series name prefix**, followed by a sequence number.

Click **OK** to add the specified number of samples.

The process of adding samples can be repeated later to add more samples. The list of generated samples is now presented.

	Detail	Identity	Group	Subgroup	Dilution Factor	Product Concentration
1		Sample1				
2		Sample2				
3		Sample3				
4		Sample4				
5		Sample5				
6		Sample6				
7		Sample7				
8		Sample8				
9		Sample9				
10		Sample10				

You can modify the **Identity** of each sample, assign values for **Group** and **Subgroup**, and specify the **Dilution Factor** and **Product Concentration** for each sample.

The dilution factor corresponds to the dilution of the sample. A value of 1 corresponds to an undiluted sample. Dilution values must be 1 or larger. If not entering a dilution factor, the sample is assumed to be undiluted.

When evaluating results in Gyrolab Evaluator, see Chapter D, samples are sorted based on sample identity, group and subgroup. See table I2-2 for details. Statistics such as average, standard deviation and CV are available for these groups.

To delete a sample, select the entire row by clicking the line number in the leftmost column and then selecting **Delete**. Multiple samples can be deleted at the same time by marking multiple lines and selecting **Delete**.

Information on samples can be copied and pasted. Use Ctrl+C to copy and Ctrl+V to paste, or right click and select **Copy** or **Paste**.

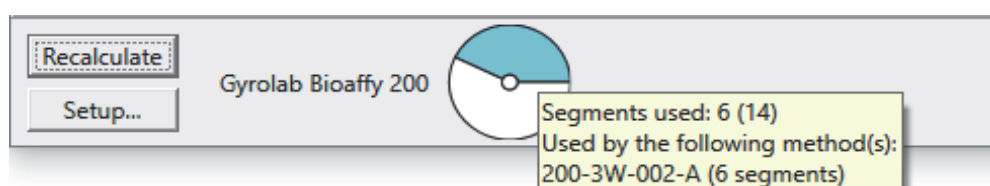
Samples can be sorted by clicking the table headers. Note that this is only a temporary sorting and will not affect the underlying order defined when adding the samples. To remove all sorting, right click somewhere in the table and select **Clear list sorting**.

The product concentration unit can be specified by checking the **Include product concentration unit** checkbox, and selecting a suitable unit. Note that if the Run Design includes a Dilution/Spike Setup, and the product concentration unit was defined there, it cannot be changed here.

☐ Include product concentration unit g/mL

B5.3.2 Displaying the required number of CDs

The required number of CDs is presented in the lower section of the window. At any time, the software can be asked to recalculate the CD and CD segment consumption based on the number of samples and replicates. This includes the unknown samples, but also any samples required by the Experiment Setup, such as Standard Series samples and Quality Controls.



To trigger a new calculation of the CD requirement, click Recalculate, or press F5 on the keyboard.

The presentation includes the CD type required from the Experiment Setup, and illustrates the amount of CD segments required. By holding the mouse pointer over a CD, details about the use for that CD is presented.

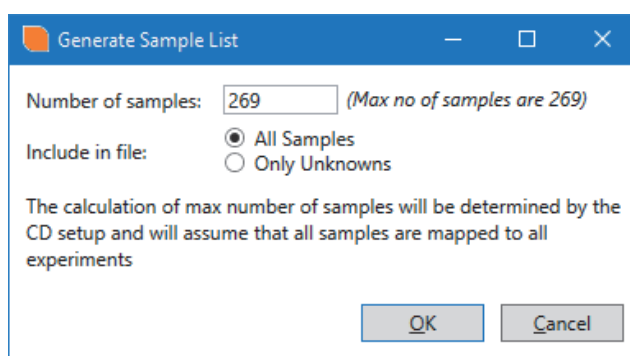
For more details on CD use, see Chapter B5.7.

B5.3.3 Using a Sample List

As an alternative to defining samples interactively, it is possible to import samples from a Sample List file.

Normally, a template for the Sample List is first generated. This has the advantage that samples defined by the Experiments (such as Standard Series samples) may be included correctly. This procedure is the most convenient way to generate a Sample List and is described below. Sample Lists can also be created manually and automatically generated lists can be edited prior to run start, refer to Chapter I2.3 for details. Gyros Protein Technologies recommends using a generated Sample Lists template as base as this will reduce the risk for errors.

To generate a list automatically, select **File** and then **Generate sample list template...** in the Run Setup window main menu. The following dialog will be displayed.



Specify the desired number of unknown samples in the template.

If selecting **All Samples** in the **Include in file** section, the template will also include all other samples required by the Experiment Setup, such as Standard Series samples. If selecting **Only**

Unknowns, other samples required by the Experiment Setup will not be included in the generated Sample List.

All samples in the Sample List will get a default microplate location (microplate name and well).

After selecting **OK**, you will be offered to enter the file name for the generated Sample List file.

The generated file can now be edited to specify the desired sample properties. The location of the samples can also be modified as desired as long as the maximum number of microplates is not exceeded. See Chapter 12.3 for details.

NOTE: *The Sample List file does not include other reagents and wash liquids. When reimporting the sample list, these liquids will be placed on a separate microplate. Make sure that the number of microplates used in the Sample List is one less than the maximum number of microplates supported by the Gyrolab instrument to execute the run on.*

After being edited, the Sample List can be reimported, replacing any samples currently defined with the samples defined in the imported Sample List file.

To import a Sample List, select **File** and then **Import sample list...** in the Run Setup window main menu and select the Sample List to import.

If the imported Sample List contains unknown samples only, Gyrolab Manager will automatically add any additional samples required by the Experiment Setup, such as Standard Series samples. If the Sample List includes samples defined by the Experiment Setup, it must contain all such samples.

NOTE: *The imported file will replace any existing unknown samples. It is not possible to combine already defined unknown samples with unknown samples imported from a Sample List.*

By default, imported sample lists are assumed to be in a format defined by Gyros, named "Sample3.0". This is the format generated by **Generate sample list template**. How to interpret the contents of an imported sample list is defined by a List Loader. Gyrolab is distributed with a List Loader for this format named **Gyrolab default Sample List Loader**. Contact Gyros Protein Technologies in case support for an alternate sample list format is required. In this case, the List Loader to use when importing a sample list can be selected.

List Loader: Gyrolab default Sample List Loader

B5.3.4 Sample setup for Dilution/Spike prepared samples

If the Run Design on which the Run Setup is based includes **Dilution/Spike Setup** (see Chapter B4.5), it is possible to specify that any sample (defined interactively, or imported from a Sample List) shall be prepared according to one of the Preparations defined in the Dilution/Spike Setup.

The **Samples** tab will in this case include an extra column **Dilution/Spike**.

Detail	Identity	Group	Subgroup	Dilution Factor	Product Concentratio	Dilution/Spike
1	Sample1					
2	Sample2					
3	Sample3					
4	Sample4					

It is possible to, individually for each sample, associate a Preparation with the sample by selecting one of the Preparations in the drop-down list. For samples that will not be prepared, do not select a Preparation.

Detail	Identity	Group	Subgroup	Dilution Factor	Product Concentration	Dilution/Spike
1	Sample1					
2	Sample2					
3	Sample3					3 dilutions
4	Sample4					3 dilutions
5	Sample5					5 dilutions
6	Sample6					5 dilutions
7	Sample7					
8	Sample8					<no entry>
9	Sample9					3 dilutions
10	Sample10					5 dilutions

To speed up the process when many samples shall be prepared in the same way, it is possible to select all the desired samples by marking the corresponding lines in the leftmost line number column, right clicking and selecting **Set Dilution/Spike Preparation....** A dialog is displayed where the Preparation to associate with the samples can be selected.

For samples to prepare, by clicking the arrow in the **Details** column, information on the prepared samples can be displayed. The information is generated from the selected Preparation and cannot be modified. This means that when selecting a Dilution/Spike Preparation, it is no longer possible to specify **Group**, **Subgroup**, or **Dilution Factor** for the sample.

3	Sample3								3 dilutions
4	Sample4								3 dilutions
	Use	Identity	Group	SubGroup	Final Dilution	Spike Concentration	Neat Concentration		
	☒	Sample4		d1	1				
	☒	Sample4		d2	10				
	☒	Sample4		d3	100				
	Sample5								5 dilutions
	Use	Identity	Group	SubGroup	Final Dilution	Spike Concentration	Neat Concentration		
	☒	Sample5		d1	1				
	☒	Sample5		d2	5				
	☒	Sample5		d3	25				
	☒	Sample5		d4	125				
	☒	Sample5		d5	625				

An exception is when the Preparation has specified **Use individual sample start dilution factor**, where the start dilution (first dilution) must be entered for unknown samples where the Preparation has been selected. See Chapter B4.5.3 and Chapter B4.5.4 for how to select this option.

By default, all prepared samples will be included in the run. To exclude some of the preparations, uncheck the corresponding check box in the **Use** column.

Prepared samples cannot be loaded directly from a sample list file. The original, unprepared, sample names can be imported and later associated with a preparation, see Chapter B5.3.3.

B5.3.5 Sample setup with Experiment Mapping

If the Run Design on which the Run Setup is based includes **Experiment Mapping** (see Chapter B4.6), it is possible to specify that any sample (defined interactively, or imported from a Sample List) shall be assigned to one of the defined Sample Sets.

The **Samples** tab will now include an extra column **Sample Set**.

Detail	Identity	Group	Subgroup	Dilution Factor	Product Concentration	Sample Set
1	Sample1					
2	Sample2					
3	Sample3					
4	Sample4					

It is possible to, individually for each sample, assign the sample to a Sample Set by selecting one of the Sample Sets in the drop-down list. In this case, the run will process the sample with the Experiments specified by the Sample Set only. Samples that are not assigned to a Sample Set will be processed by all Experiments.

Detail	Identity	Group	Subgroup	Dilution Factor	Product Concentration	Sample Set
1	Sample1					Mouse samples
2	Sample2					Mouse samples
3	Sample3					Mouse samples
4	Sample4					Rat samples
5	Sample5					Rat samples
6	Sample6					Rat samples
7	Sample7					Rat samples
8	Sample8					
9	Sample9					<no entry>
10	Sample10					Mouse samples Rat samples

To speed up the process when many samples shall be assigned to the same Sample Set, it is possible to assign multiple samples at one time by marking the corresponding lines in the leftmost line number column, right clicking and selecting **Set Sample Set ...**. A dialog is displayed where the Sample Set can be selected.

If the Run Design on which the Run Setup is based includes both **Dilution/Spike Setup** and **Experiment Mapping**, and a Dilution/Spike preparation has been associated with the Sample Sets, samples assigned to a Sample Set will also be automatically associated with the corresponding preparation.

In this way, by assigning a sample to a Sample Set, all information on how to process the sample is provided without additional setup.

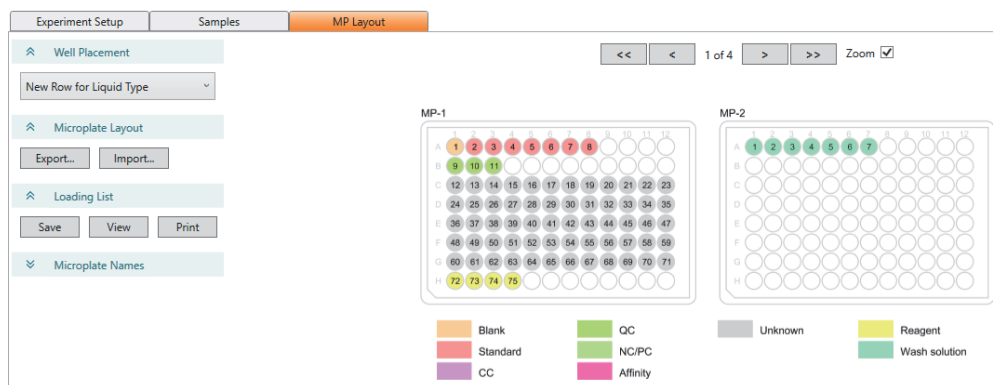
In the example below, the Run Design has specified that samples belonging to the Sample Set "Mouse samples" shall be prepared in three dilutions, while "Rat samples" shall be prepared in five dilutions. Samples 8 to 10 are not assigned to a Sample Set, and how to prepare these samples (if at all) can be selected freely.

Detail	Identity	Group	Subgroup	Dilution Factor	Product Concentration	Dilution/Spike	Sample Set
1	Sample1					3 dilutions	Mouse samples
2	Sample2					3 dilutions	Mouse samples
3	Sample3					3 dilutions	Mouse samples
4	Sample4					5 dilutions	Rat samples
5	Sample5					5 dilutions	Rat samples
6	Sample6					5 dilutions	Rat samples
7	Sample7					5 dilutions	Rat samples
8	Sample8						
9	Sample9						
10	Sample10						

B5.4 MP Layout

The **MP Layout** tab provides information on how samples, and other liquids included in a run, are placed on microplates.

The main components of the **MP Layout** tab are given here, and are explained in more detail later.



By default, all liquids are automatically placed on microplates according to one of a set of predefined strategies, or methods. The placement method can be selected in the **Well Placement** section.

If the suggested layout cannot be used, the layout can be exported, modified, and then reimported with tools in the **Microplate Layout** section.

As a help when preparing the microplates, a **Loading List** can be created, saved on file, opened in an external viewer, or printed. The Loading List is also displayed on the right side of the tab in a format suited for the screen (leaving out page headers and footers, and similar information). To get a quick overview of the assignment of liquids to microplates, the first page of the Loading List is a graphical summary of all microplates. Details about the microplates can be found on the remaining pages. By default, the display shows an entire page of the Loading List, but can be zoomed with the **Zoom** button.

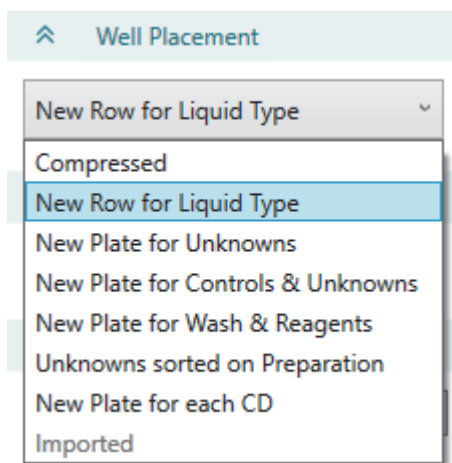


The names of the microplates can be specified in the **Microplate Names** section.

B5.4.1 Well Placement

Normally, the placement of samples and other liquids on microplates is performed automatically by the software.

It is possible to select one of several layout methods to control the placement.



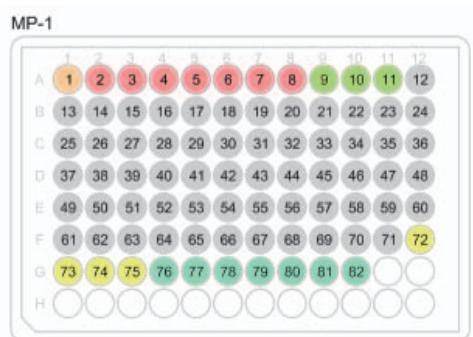
To illustrate the layouts, a Run Setup with one Standard Series, three Quality Controls, and 60 unknown samples will be used. In addition, the Run Setup will require reagents and wash solutions.

For this example only, where some sample types are not present, the following color code applies.

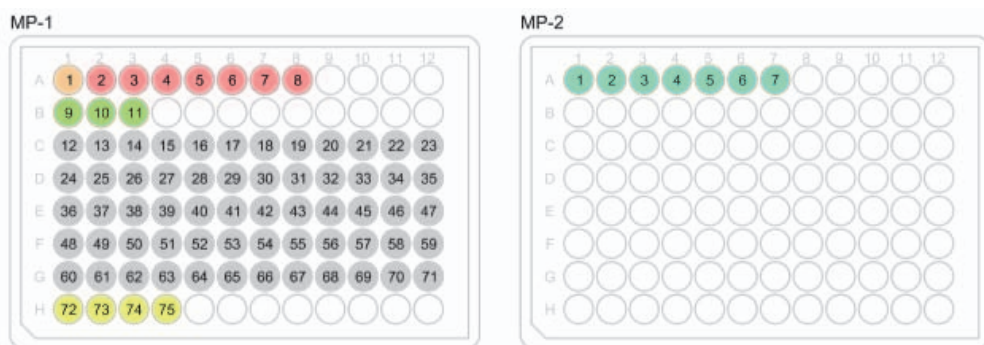


The layout types are as follows.

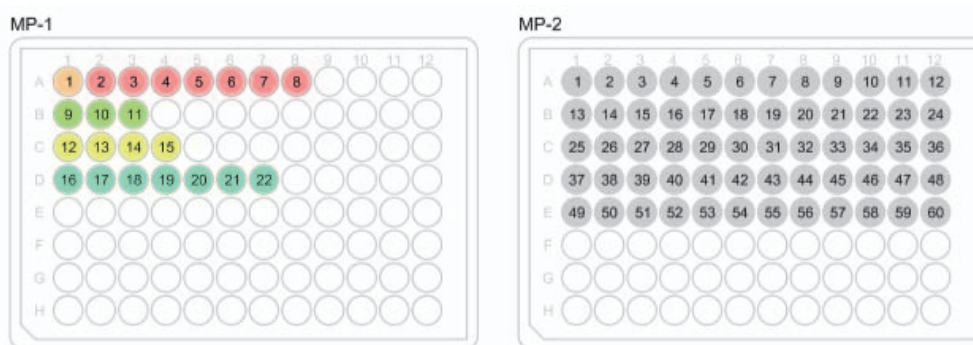
Compressed will place liquids as close together as possible, minimizing the number of microplates.



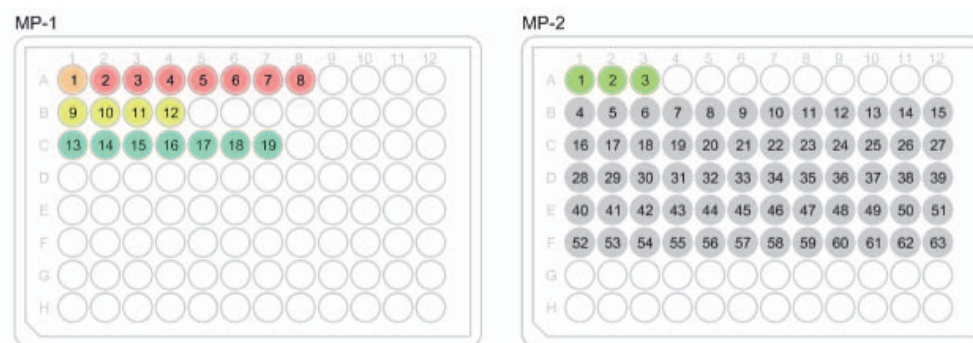
New Row for Liquid Type will place each new type of sample or other liquid on a new microplate row. In this example, the Standard Series (including the blank) is placed on the first row, Quality Controls on the second, then unknown samples, reagents, and finally wash liquids, causing the wash liquids to wrap over to a second microplate.



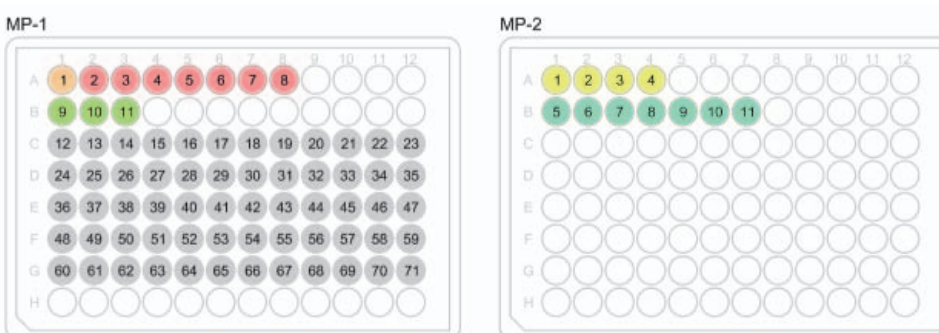
New Plate for Unknowns will place unknown samples on separate plates, while other liquids are kept together. This placement may be particularly interesting if preparation of unknown samples is made separate from preparation of other samples.



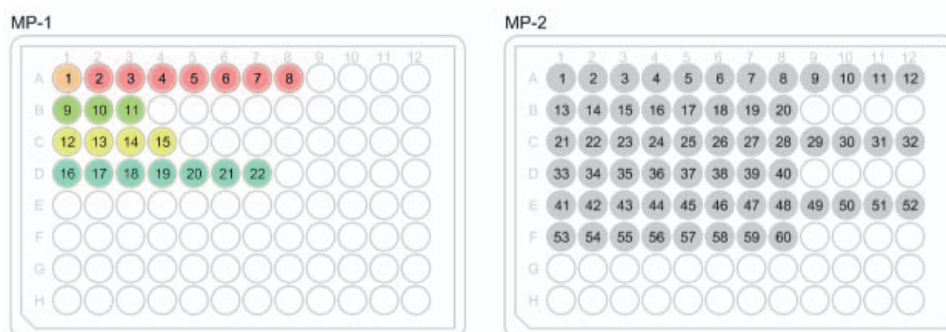
New Plate for Controls & Unknowns is similar to **New Plate for Unknowns**, but in this case Quality Controls and ADA Controls are placed together with unknown samples.



New Plate for Wash & Reagents places all samples compressed, while reagents and wash solutions are placed on a separate plate.



Unknowns sorted on Preparation can be of use when having Dilution/Spike prepared samples, see Chapter E5.4.4. Samples are placed in the same way as for **New Plate for Samples**, but unknowns are further organized according to how they are prepared. In this example, where we have 20 samples diluted in three dilutions, all samples are placed on MP-2. The samples in their first dilution will be placed first (well numbers 1–20), followed on a new row by all samples in their second dilution (well numbers 21–40), and finally all samples in their third dilution (well numbers 41–60).



New Plate for each CD is mainly intended for use when creating Run Setups of Design type LIMS. See Chapter E3.4 for details. But this layout can be used for any Design type. It will place all samples to be processed on a specific CD on a separate microplate, and reagents and wash liquids on a separate microplate. In this case, two standard samples and three unknown samples are found on CD 1 and CD 2, placed on separate microplates.



If samples are imported from a Sample List, see Chapter B5.3.3, the placement for samples found in the file is picked from the Sample List, while other liquids are placed on separate microplates.

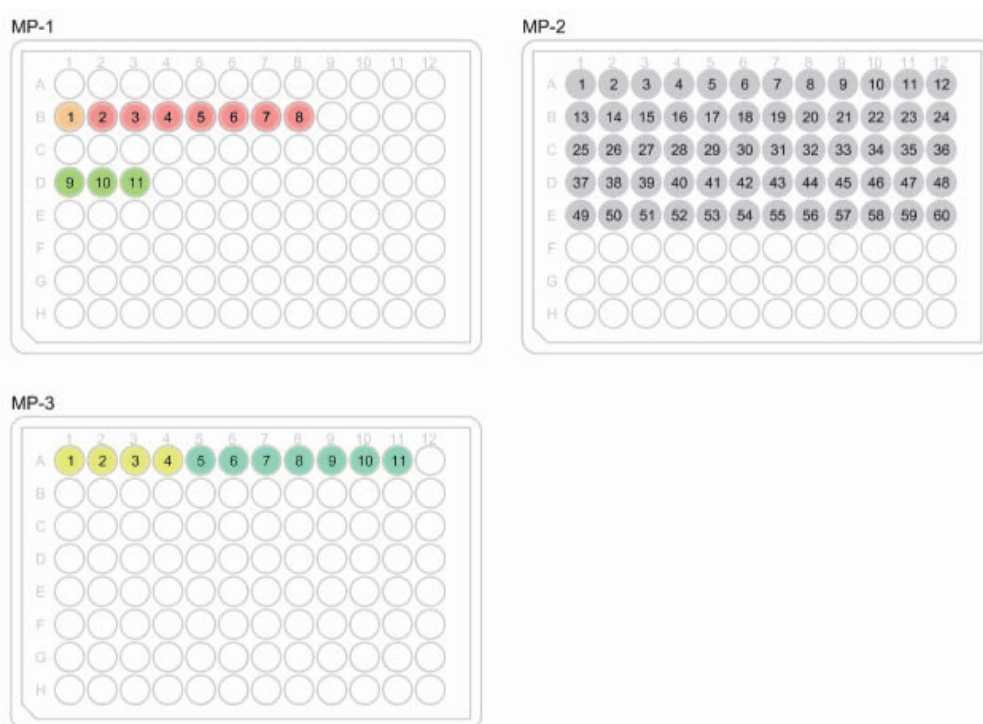
If the Sample List includes both unknown samples and other samples, like Standard Series samples, only reagents and wash liquids are placed on separate microplates (normally one). If the Sample List includes unknown samples only, all other samples are placed on separate microplates.

Well Placement will in this case automatically be set to **Imported** to reflect that the placement is defined by the imported Sample List. Another **Well Placement** can be selected after the import to let the software rearrange the placement of samples and other liquids.

In this example, the user has imported a Sample List, causing the **Well Placement** to change to **Imported**.



The imported Sample List had placed the Standard Series on row B on the first microplate, and Quality Controls on row D. Unknown samples are placed on a separate microplate. The remaining liquids, reagents and wash solutions, are placed by Gyrolab Manager on a third microplate.



It is not possible to select **Imported** manually. The **Imported** placement is always a consequence of importing a Sample List.

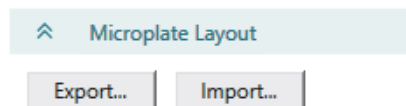
Well Placement will also be set to **Imported** also used after importing a Microplate Layout. See Chapter B5.4.2.

When a Sample List has been imported (or a Microplate Layout, see Chapter B5.4.2), the list of samples on the **Samples** tab is locked for editing. To enable changes to be performed, another **Well Placement** layout must be selected.

If a Sample List is used just to enter sample names or related information like dilution factors, it may be easier to simply copy the information from the source file and paste it into the unknown sample table on the **Samples** tab rather than importing a Sample List file. The Sample List import is mainly designed for cases when the list of samples is completely defined by the Sample List and no further editing is required inside Gyrolab Manager.

B5.4.2 Microplate Layout

If the layout of the samples and other liquids needs to be modified, it is possible to export the current layout in the **Microplate Layout** section.



With the **Export...** button, the current layout can be exported to a “well placement file”. The file can then be edited to assign new microplate names and wells to the liquids.

The modified file can then be reimported with the **Import...** button to update the layout with the information from the file.

Note that in contrast to importing a Sample List, the imported file must contain the exact same list of liquids as are already present in the Run Setup. The only information that can be modified is the placement (microplate name and well).

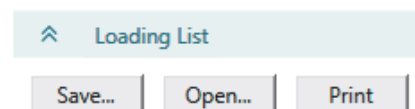
The **Microplate Layout** export and import is primarily designed for a situation where a Run Setup has been finalized, and the microplates have been prepared, but the microplates were prepared incorrectly by mistake.

To correct the Run Setup to match a set of already-prepared microplates

Step	Action
1.	Reopen the Run Setup from the Gyrolab Manager main window.
2.	Go to Microplate Layout , and select Export... to generate a file with the layout suggested by Gyrolab Manager.
3.	Adjust the microplate and well positions in the generated file to match the actual preparation of the microplates.
4.	Import the adjusted positions from the modified file with Microplate Layout , selecting Import...
5.	Queue the Run Setup again.
6.	If desired, print a new loading list. This can be done before queueing the Run Setup, or by right clicking the Run Setup from the main window.

B5.4.3 Loading List

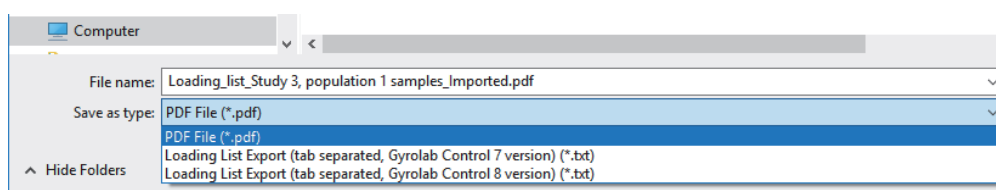
In the **Loading List** section, it is possible to generate a Loading List file for use when preparing the microplates.



The information in the file is the same as can be viewed on the right side of the screen, but suited for printing or other use outside Gyrolab Manager. The file version of the Loading List includes information such as an overview of the CD use, and administrative information like Run Setup name and date and time when the file was generated.

Use **Save...** to save the file on disk. By default, the file will be saved in the Adobe Systems Incorporated Portable Document Format, commonly called PDF (also ISO 32000-1).

It is also possible to save the information in a tab separated text format, for use in other systems, like dispenser robots.



There are two versions of the Loading List Export format. The first format is compatible with Gyrolab Control version 7, but will, due to this, lack some information that may be of interest.

The second format is new for Gyrolab Control version 8, and includes additional information

- A header has been added identifying the format version, Run Setup name, and Run Setup version.
- A new data column, placed as the last column to make migration from the older format easier, which includes the sample spike concentration, where applicable.

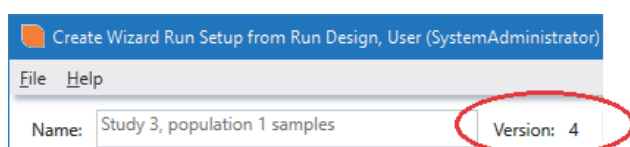
Open... will open the Loading List in an external PDF viewer. The viewer opened depends on the software installation on the computer, but is commonly Adobe Reader™.

Print will send the Loading List to the default printer configured on the computer. If additional printing control is required, for example to send the print job to another printer, open the Loading List with the **Open...** command and print the file from the external viewer.

NOTE: *When saving the Loading List to an external file, or printing it, it is no longer under control from Gyrolab Manager. Make sure to discard the external copy if any changes are made to the Run Setup which may cause the Loading List to become invalid.*

In case the Run Setup has been changed since it was opened, it must be saved before it is possible to generate a Loading List file. The reason is to guarantee that the Loading List can be uniquely associated with a version of the Run Setup.

NOTE: *While editing a Run Setup, the version displayed at the top of the Run Setup edit window indicates the version number that will be set when saving the Run Setup next time. The generated Sample List file will be based on the previously saved version, which is one less than the version displayed in the Run Setup edit window.*



Gyrolab Loading List

Run Setup name	Study 3, population 1 samples
Created from version	3

B5.4.4 Microplate Names

The microplates required to place all liquids are given default names "MP-1", "MP-2" etc. If other names are required, it is possible to change the names to other values in the **Microplate Names** section.

Edit microplate names as desired, and click **Apply** to set the new names.

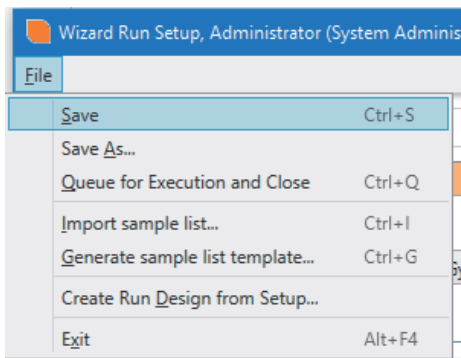
Microplate Names

1	MP-1
2	MP-2
3	MP-3
4	MP-4
5	MP-5
6	MP-6

Apply

B5.5 Saving a Run Setup

There are three different ways to save a Run Setup, all found at the Run Setup menu bar **File** entry.



A Run Setup can be saved to continue working on the Run Setup later. This will set the saved Run Setup in the **In Development** state. The Run Setup edit window is not closed, and the saved Run Setup is not available for execution on Gyrolab instruments.

To save a Run Setup, select **Save**.

To save the Run Setup to a new name, making a copy, select **Save As...** and specify the name of the new Run Setup. After saving, the window will be open, allowing continued work on the copy.

When a Run Setup is considered ready for execution on a Gyrolab instrument, instead select **Queue for Execution and Close**. The Run Setup is now set in the **Ready for Execution** state, and is now possible to select on a Gyrolab instrument to start execution. The Run Setup edit window will automatically be closed after queueing the Run Setup.

When queueing a Run Setup, you may also need to specify whether any secondary results from the run shall be placed on disk. For more information, see Chapter B6.

A Run Setup that has been queued can be opened again from the main window. When doing so, it will automatically be unqueued again unless it is opened in Read Only mode.

The **File** menu also includes entries for generating a sample list template, and importing a sample list, see Chapter B5.3.3, and for creating a Run Design from the Run Setup, see Chapter B5.2.2.

B5.6 Understanding multi-method Runs

In many cases, a run includes one Method only. All Experiments specify the same Method, and the unknown samples to process can be packed as closely as possible on the CDs (subject to limitations like keeping samples for a Standard Series together on the same CD).

If a Run Design adds multiple Methods (see Chapter B4.3.1), and the Methods are used in different Experiments, this will affect how the run is executed.

The run execution must process all the used Methods, one by one, in the order specified when adding the Methods to the Run Design. This means that a two-Method run will typically take twice as long to execute as a one-Method run.

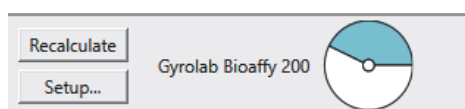
Also, if a sample is processed with multiple Methods (processed with multiple Experiments, specifying different Methods), the sample must be placed in one microplate well per Method. If the same well was used for multiple Methods, there would be a risk that the sample could evaporate or dry from the time when the microplate foil was penetrated for use in the first Method, until processing the second Method.

Calculation of the number of wells is done automatically by the software.

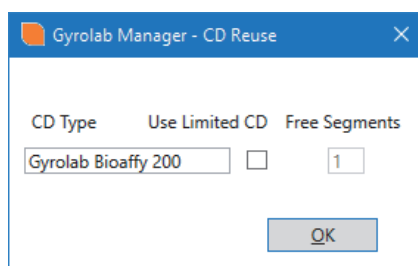
B5.7 Use of partial CDs and compression

When defining a Run Setup, it is possible to specify that one of the CDs to use in the run has already been partially used in a previous run.

To specify this, select **Setup...** in the CD use section, at the bottom part of the window.



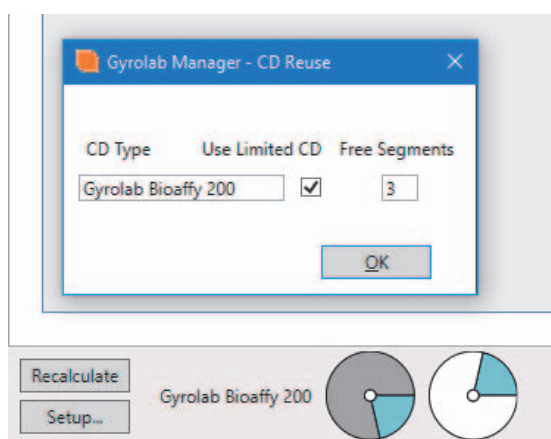
A new dialog is opened, showing the CD type used by the Method.



To specify that a limited CD should be used, check the **Use Limited CD** checkbox, and specify the number of free segments in the **Free Segments** text box. The number can range from 1 (for a CD with one free segment) to as many segments as the CD type has, minus 1 (for a CD where only one segment has been used).

To change to not use a limited CD, uncheck the **Use Limited CD** checkbox again.

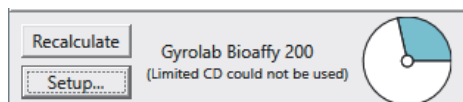
When changing the settings, the display showing the CD use is updated, where a grey color indicates the already used CD segments.



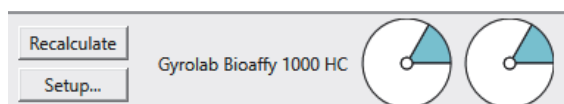
In this example, the limited CD has three free segments, and the CD use has been updated to place parts of the samples on these three segments, and the remaining samples on a new CD.

NOTE: *Using a limited CD may result in an increased processing time. In the example above, the use of a limited CD causes the run to use two CDs instead of one, thereby nearly doubling the processing time as CDs must be processed one at a time.*

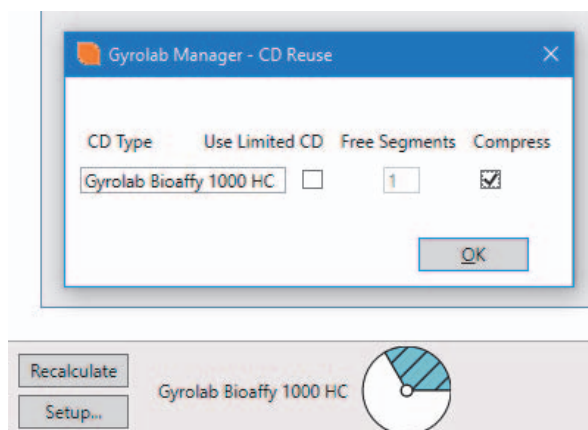
In some cases, a limited CD cannot be used. For example, if an Experiment specifies that the Standard Series must be placed on all CDs, and the Standard Series itself occupies one CD segment, a limited CD with one segment only cannot be used, as it will not be able to hold an unknown sample, plus the required Standard Series. In this case, the display shows the text **(Limited CD could not be used)** and the setup is done ignoring the request to use a limited CD.



If the Run Design specifies multiple Methods, where the Methods use the same CD type, the default setting will be to start each Method on a new CD, as this has a potential to minimize the processing time.



In the **Setup...** dialog, it is possible to select **Compress**. This will modify the CD placement to place samples from all Methods using this CD type to (if possible) share the same CD. Shared CDs are indicated with a striped pattern.



NOTE: *When compression results in a Method requiring more CDs than otherwise, then the processing time for that method will increase.*

If the Run Design specifies multiple Methods, where the Methods use different CD types, the display will show the CD use for each CD type.



In the **Setup...** dialog, each used CD type now has a separate setting for **Use Limited CD**.

CD Type	Use Limited CD	Free Segments
Gyrolab Bioaffy 200	☐	1
Gyrolab Bioaffy 1000 HC	☐	1

If having multiple Methods where some Methods used the same CD type, and some use different CD types, the **Setup...** dialog will allow **Compress** to be specified for all CD types used by multiple Methods.

B6 Targets and Reports

When executing a run on a Gyrolab instrument, the result(s) are automatically saved in the Gyrolab database. Much of the data produced is for use in other applications, primarily Gyrolab Evaluator, for data analysis of the run.

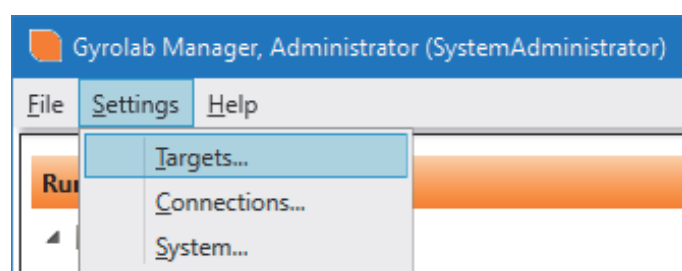
However, it is also possible to produce results intended for manual viewing, or for export to other systems, e.g. LIMS.

While it is perfectly possible to extract the results from the run from the database using Gyrolab Manager, it is sometimes convenient to let the software automatically save the results as external disk files as part of run execution. Specifying creation of external disk files is the task for the Targets and Reports setting.

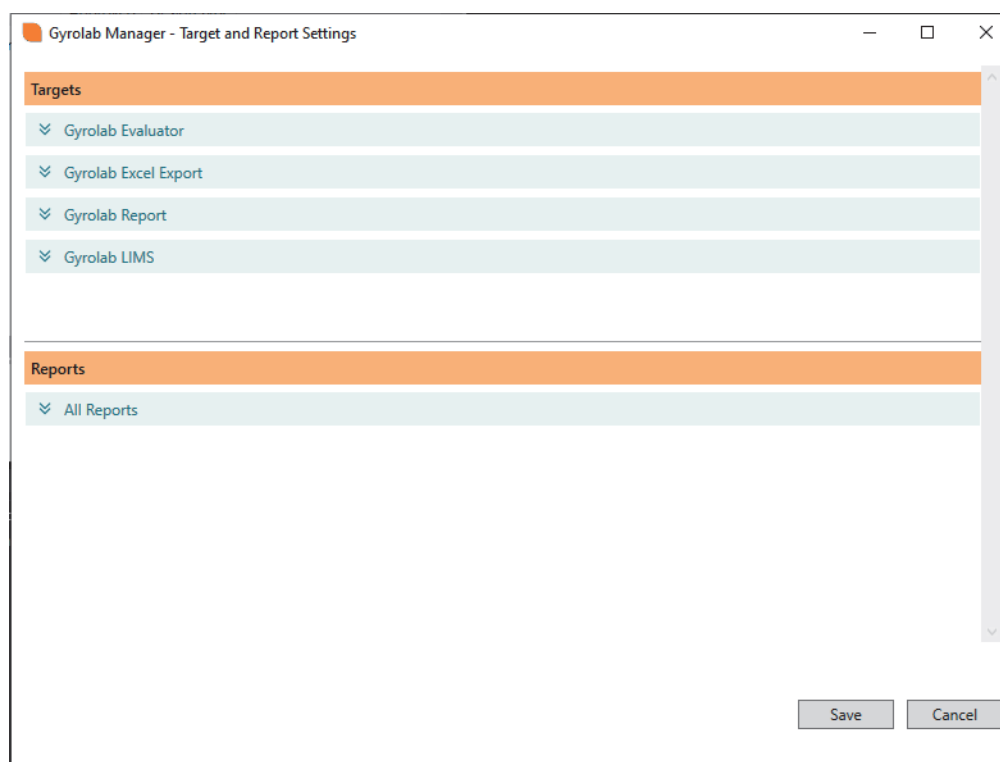
A Target is one of the predefined Gyrolab run results. These are always stored in the Gyrolab database, but can optionally also be saved to disk files.

A Report is a secondary output of the run result that is never stored in the Gyrolab database, and is only available as a disk file. A Report cannot be retrieved from the Gyrolab database after run execution, as it is not saved there.

Settings for Targets and Reports can be opened from the Gyrolab Manager main menu. Select **Settings**, and then **Targets...**.



An overview of Targets and Reports is presented.



The Target and Reports Settings dialog is displayed when opening it from the Gyrolab Manager main menu, as described in this chapter.

B6.1 Targets

Target settings are quite similar for the different targets. In this chapter, target settings for Gyrolab Evaluator is described.

Additional targets are available as software add-on modules. See Chapter E.

To setup up the Gyrolab Evaluator Target, expand the setting by clicking **Gyrolab Evaluator** in the **Targets** section.

Targets

^ Gyrolab Evaluator

☒ Copy file(s) to disk

Gyrolab Evaluator result folder

\$(gyrolabresultfolder)\\\$(user)\\\$(date)\\\$(run)_\$(time)

Gyrolab Evaluator result file name

Info:

This target generates a result file from a Gyrolab run for further analysis in Gyrolab Evaluator.
 The result file is copied to the selected file destination.
 The user sets the name and destination for the result folder and file name.
 The settings from the last run of the current user will be pre-selected.
 Note that result files are always saved in Gyrolab Result Database.

If checking the checkbox **Copy file(s) to disk**, files written to the database will also be written to disk when executing the run.

If not checked, remember that files for targets are always written to the Gyrolab database and can be retrieved later. Checking the **Copy file(s) to disk** checkbox for a target is only necessary to get additional copies written to disk.

The folder in which to store the file from the target is specified in the **Gyrolab Evaluator result folder** text box. Either enter a disk folder path directly, or use the **Browse...** button to locate the folder.

Enter the desired result file name in the text box **Gyrolab Evaluator result file name**.

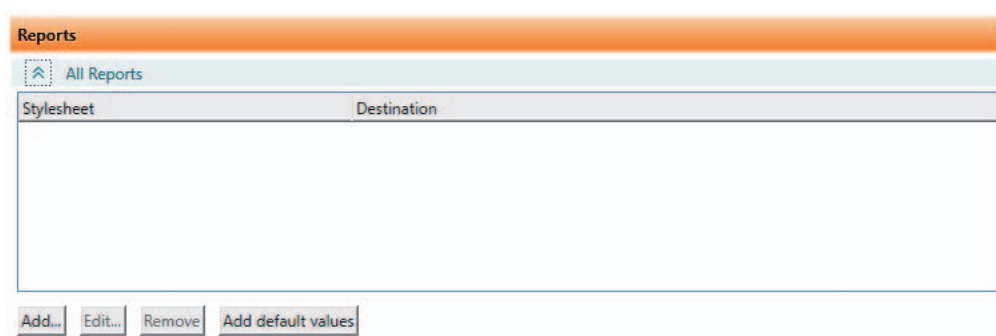
To reset to default values, click **Use defaults**.

Both disk folder and file name can include macros. See Chapter B6.3 for details.

B6.2 Reports

Reports are only written to disk, when executing a run, and will never end up in the Gyrolab database.

To edit settings, make the report settings visible by clicking [All Reports](#).



By default, Gyrolab Manager includes a standard report in HTML format. To add this report, click [Add default values](#).

In addition, other custom reports can be added. A report requires two parts

- An XSLT stylesheet able to transform the primary run result to the desired format.
- A destination must be specified where to write the resulting output from the XSLT.

For more information on adding custom reports, please contact Gyros Protein Technologies.

B6.3 Target and Report macros

The output from a Target or Report will be written to a specific folder, and a specific file name. If an exact folder and/or file name is specified, the file will be overwritten each time a run is executed. To avoid that, the folder and/or file name would need to be changed for each run.

To avoid this, the folder and file names can include "macros".

A macro is a part of the folder or file name that will be replaced with another value when the run is executed. For example, by including a date and time macro in the file name, the final file name will include the date and time when run execution was started, thereby avoiding that a run overwrites previous files.

To add a macro, manually edit the folder and/or file name, replacing desired parts with macros.

The available macros are

Macro	Description
\$(user)	Expands to the full Username.
\$(run)	Expands to the Run name.
\$(cdid)	Expands to the CD id, for example 1234567-123.
\$(date)	Expands to the executed Run start date.
\$(time)	Expands to the executed Run start time.

Dates are in ISO 8601 format "YYYY-MM-DD". Times are in format "HH_MM_SS".

Examples:

If a folder name is entered as "C:\RunData\\$(user)\\$(date)", and the user executing the run has the name "John", and the run is executed on 1st of April 2018, the result file would be written to a folder named "C:\RunData\John\2018-04-01".

If a disk copy of the Gyrolab Report target is specified with the file name "GyrolabReport_\$(run)_\$(date)_\$(time).pdf", and the executed run is named "My test run", executed on 1st of April, at 10:14 in the morning, the resulting file name would be "GyrolabReport_My test run_2018-04-01_10_14_00.pdf".

B7 Database configuration

Gyrolab Manager works with data located in a Gyrolab database. By default, each Gyrolab instrument comes with a database holding data for that instrument.

Optionally, multiple Gyrolab instruments may be connected to a common database. Contact Gyrolab Protein Technologies for details on this option.

For Gyrolab Manager to work with a database, two sets of information are required:

- Gyrolab Manager must identify itself so that Audit trail from operations performed in Gyrolab Manager is properly identified.
- Gyrolab Manager must know how to locate the database.

Configuring this information is performed in the Gyrolab Manager database configuration tool.

The first time Gyrolab Manager is started on a new computer, the configuration dialog is displayed.

Perform the following steps to make the initial configuration of the location in which Gyrolab Manager is installed:

Step Action

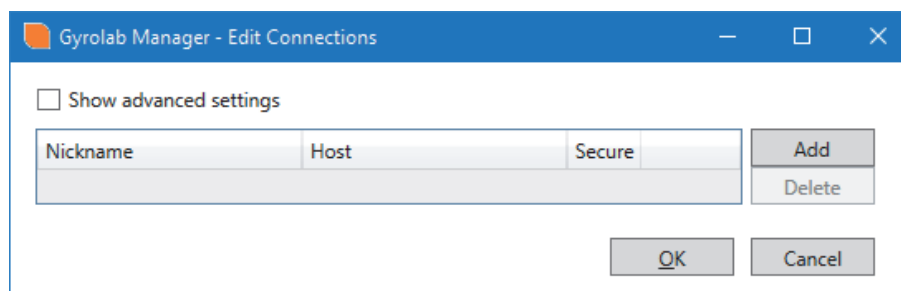
1. Enter a suitable **Location name** describing the location where Gyrolab Manager is installed. This name will be used to identify all Audit trail entries created when using Gyrolab Manager from this computer. Select the name carefully.

It is also possible to use the name assigned to the computer by Microsoft Windows as **Location name** by selecting **Copy location name from computer name**.
2. As **Location type**, select **Office computer**.
3. Optionally, it is possible to enter an additional **Description** of the location where Gyrolab Manager is installed.

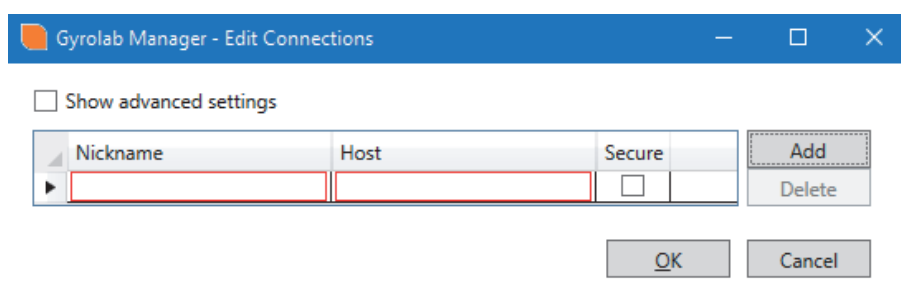
To configure the initial database connection, perform the following steps:

Step Action

1. In the **Database connection** section, select **Edit...** to display the **Edit Connections** dialog.



2. Select **Add** to add a new database connection.



To configure the new database connection, enter the name of the **Host** (computer) where the Gyrolab database is located. To get this information, you may have to contact your system administrator.

Your system administrator may have updated the system to use a communication with extended security. In this case, you will have to check the **Secure** check box. If you connect to a database where your security setting does not match the one for the database, you will be informed when starting Gyrolab Manager

In rare cases, the database setup must be done in a non-standard way. In this case, you may have to check **Show advanced settings**. This will add a new column to the table where a **Port** number may be entered. Unless instructed by your system administrator, do not change the **Port** settings.

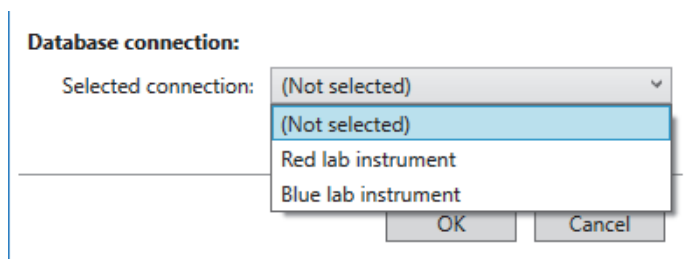
Also assign a **Nickname** to the connection. The **Nickname** is there to name the connection. If the **Host** name is not intuitive, it may be easier to associate the database connection with a friendly name. For example, if the **Host** was something like "Net43_78AA", naming the connection to "New Gyrolab downstairs" would make it easier to remember.

The **Nickname** is only used to identify a specific database at this installation of Gyrolab Manager. The **Nickname** can be freely modified later if desired.

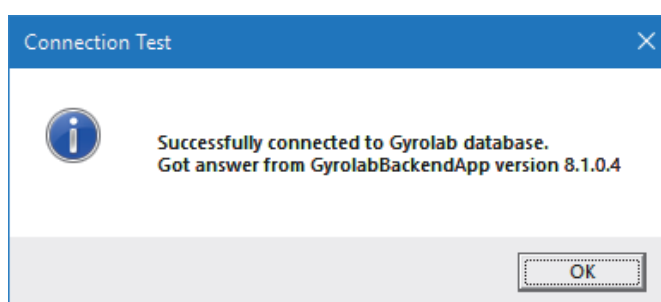
3. If there are several Gyrolab databases, for example several separately installed Gyrolab instruments without using a common database, add one database connection for each Gyrolab database.
4. To delete a database connection, select the entire row by clicking the black triangle and then selecting **Delete**. Multiple database connections can be deleted at the same time by marking multiple lines and selecting **Delete**.
5. When all database connections have been entered, confirm with **OK**.

Step Action

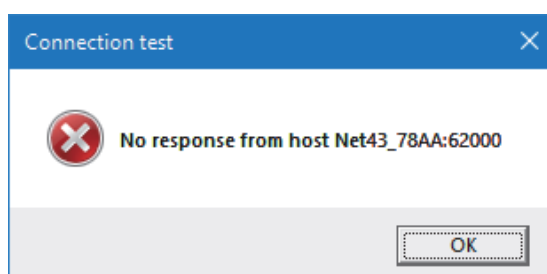
6. In the main configuration dialog, the database connection to use is selected from the **Selected connection** drop-down list.



After selecting a connection, select **Test** to test the connection to the database. If the connection is working, a message like the one below is displayed.



If the connection test failed, an error message is displayed, where the displayed message depends on the type of failure. This is an example where the database cannot be reached over the network.



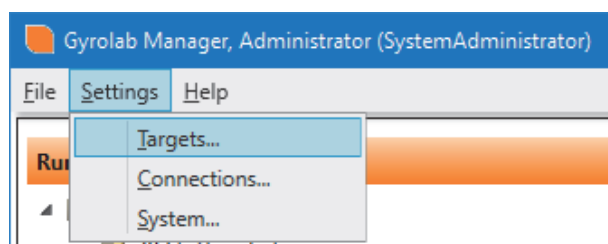
On failures, ask your system administrator for assistance.

7. When the Gyrolab Manager configuration is completed, select **OK** in the main configuration dialog to exit to save the configuration. When the initial configuration has been completed, Gyrolab Manager will show the login dialog. See Chapter B2.1.

When Gyrolab Manager is installed on the external computer connected to a Gyrolab instrument, the initial configuration will be performed as part of the Gyrolab Control installation.

After configuring the initial database connection, it is possible to edit the configuration to change settings for existing connections, or to add additional database connections.

In Gyrolab Manager main window, select **Settings:Connections...** to change the configuration.



If changing the database configuration, Gyrolab Manager must be restarted for the new settings to take effect.

When working with multiple databases, the recommended procedure is to add one connection for each database in the **Edit Connections** dialog. To change database, follow these steps

Step	Action

1.	In Gyrolab Manager main menu, select Settings:Connections... to open the configuration dialog.
2.	Select database from the Selected connection drop-down list.
3.	Verify that the connection is working by selecting Test .
4.	Close the configuration dialog with OK .
5.	Restart Gyrolab Manager.

Note that every time Gyrolab Manager is started, the currently selected database connection is displayed in the login dialog.

NOTE: *The Username and Password is stored in the database and is thus specific to the selected database. This implies that every database can have a different set of users and passwords. It is recommended to, if possible, connect all Gyrolab instruments to a common database to avoid confusion.*

If Gyrolab Manager fails to connect to the configured database when started, Gyrolab Manager will automatically display the configuration dialog to allow the database configuration to be tested, and if required, corrected.

NOTE: *To System Administrators: In order for Gyrolab Manager to be able to communicate with the Gyrolab database from a remote computer, port 62000 must be configured to be open for access in the firewall. In case port 62000 cannot be used, Gyrolab Control currently has some limited support for change to another port. Please contact Gyrolab Protein Technologies in case port 62000 cannot be used.*

B8 User administration

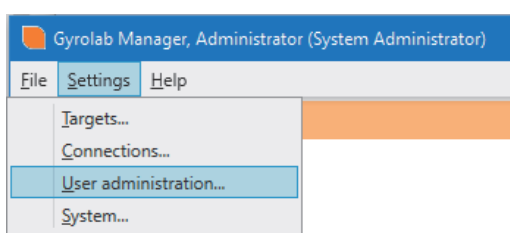
For an individual to get access to Gyrolab software, a user account with a username must be created for them.

Information on a Gyrolab User is stored within the Gyrolab database and applies to all Gyrolab software applications connected to that database. If multiple Gyrolab instruments are configured to use individual databases, users must be created individually in each database.

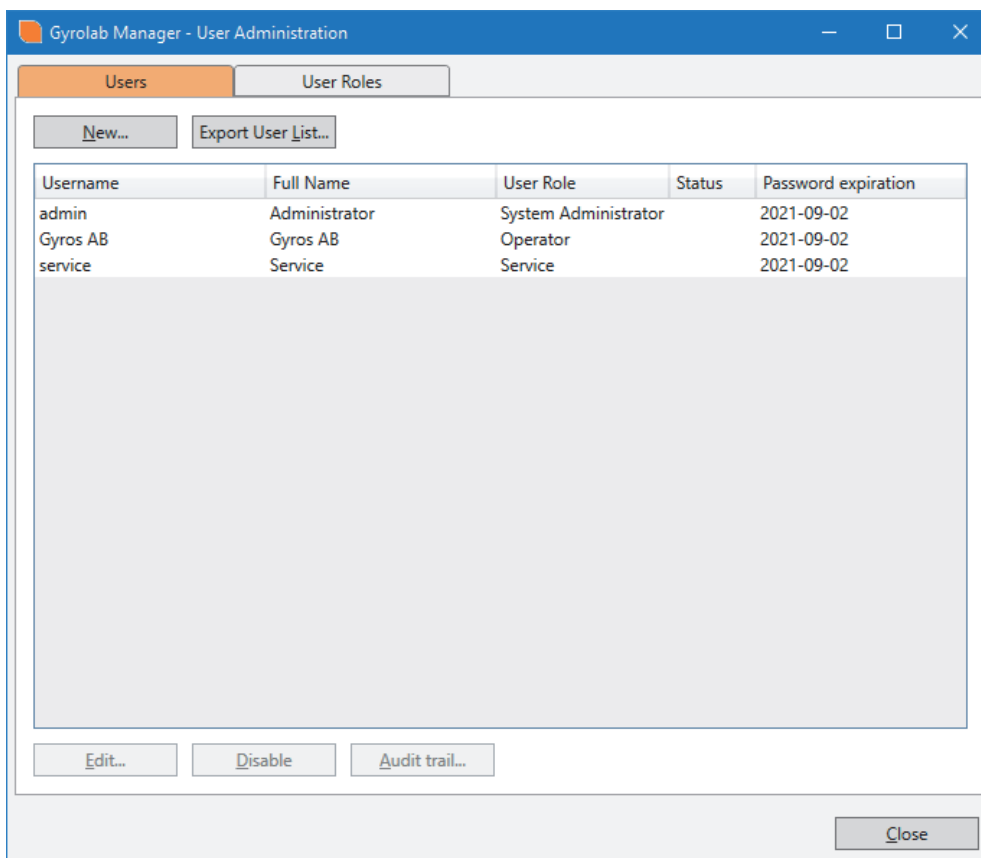
A Gyrolab User is always assigned a User Role, where the role specifies a set of privileges. The user will gain the privileges associated with his/her role.

Users can be administrated by a Gyrolab user with sufficiently high privileges, by default a user with user role System Administrator.

To administer users and user roles, in Gyrolab Manager main window, select **Settings:User administration....**



A newly installed system will contain three default users.



Given that you have the required privileges, two tabs are displayed, one for User administration and one for User Role administration. These are described separately below.

B8.1 User administration

For User administration, the dialog shows a list of all Gyrolab Users in the database.

Users		User Roles		
New...		Export User List...		
Username	Full Name	User Role	Status	Password expiration
admin	Administrator	System Administrator		2021-09-02
Gyros AB	Gyros AB	Operator		2021-09-02
service	Service	Service		2021-09-02

The list includes the **Username** which is used to log in to the various Gyrolab software applications. The username must be different from any other username in the same database.

For each user, the following is also presented

- The **Full Name**, presenting a longer name given the user.
- The **User Role** for the user.
- **Status**, which shows **Disabled** for a user which has been disabled (see below) or **Locked** for a user who cannot log in any longer because too many attempts were made to log in with an incorrect password. If Status is empty, the user is enabled and can log in with the specified username.
- **Password expiration**, showing when the user's password will expire.

Select **Export User List...** to generate a PDF report of all users.

Select **New...** to create a new user. For more information, see Chapter B8.1.1.

By selecting a user in the list, operations can be performed on that user.

Username	Full Name	User Role	Status	Password expiration
admin	Administrator	System Administrator		2021-09-02
Gyros AB	Gyros AB	Operator		2021-09-02
service	Service	Service		2021-09-02

Edit...	Disable	Audit trail...

- Select **Edit...** to change the properties of the selected user. For more information, see Chapter B8.1.1.
- Select **Disable** to disable the selected user. The user will no longer be able to log in once the user has been disabled. A user can be re-enabled if a new password is assigned to the user. See Chapter B8.1.1.
- Select **Audit trail...** to present an audit trail for the selected user, see Chapter B8.1.2.

During introductory customer training Gyros Protein Technologies provides information on a user and user password for a system administrator. From this user, the customer may create additional users and user roles.

NOTE: *Service personnel from Gyros Protein Technologies must be given access as a System Administrator if requested.*

NOTE: *Do not change the properties (except assigning a new password if required) of the default users present in a new Gyrolab database. These are admin, Gyros AB, and service.*

B8.1.1 Create or Edit User

When selecting to create a new user, or edit an existing user, the following dialog is displayed.

For a new user, the fields are empty. Add the desired information.

- **Username** is the name to specify when the user logs in. The username must be unique. The username is case sensitive.
- **Full Name** is used to provide a longer name describing the user. Make sure to use unique names also for the full name to avoid confusion in cases where the full name is displayed. It is the responsibility of the administrator to link a username to a physical person.
- In the **Role** drop-down, select the User Role for this user. For more information on user roles, see Chapter B8.2.
- Assign an initial **Password** for the new user. Repeat the password in the **Confirm password** field. Information on the current rules for a legal password is displayed below the password fields. Password rules is a system setting and can be changed. See Chapter B9.

By changing to the tab **User Privileges**, a detailed list of privileges for the selected user role can be viewed. The role assigned to the user can be changed here as well. To change privileges assigned to a role, see Chapter B8.2.

If editing an existing user, the fields in the dialog are already filled in, but can be modified.

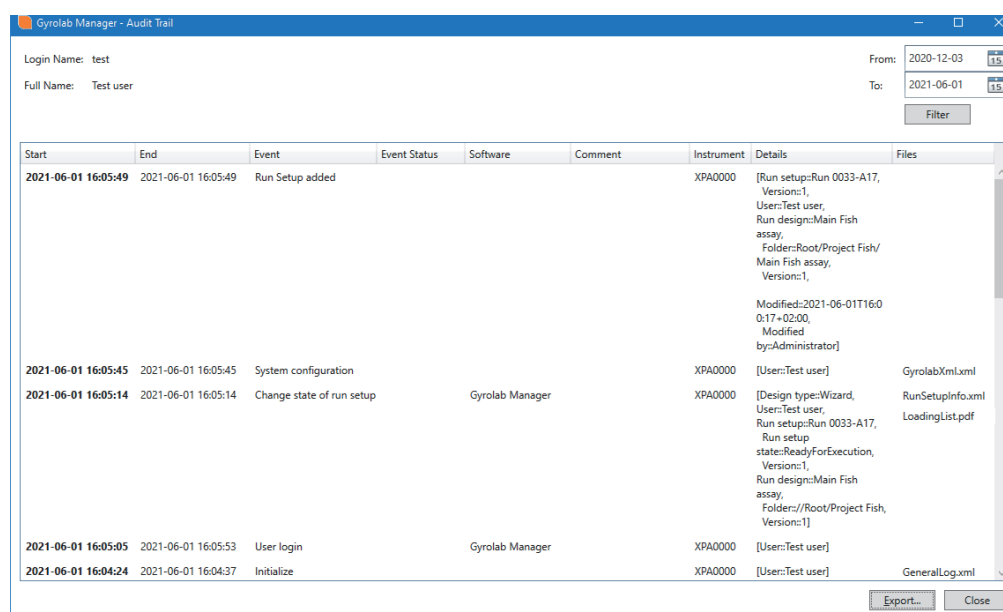
After creating a new user, or updating the password for an existing user, the list of users will show "n/a" in the column **Password expiration** for the user in question. This indicates that the password is pre-expired. The user will need to select a new password next time the user logs in.

B8.1.2 User audit trail

The audit trail for a user includes the actions performed by a user. It includes actions from Gyrolab Manager, Gyrolab Control, and Gyrolab Evaluator¹.

After selecting **Audit trail...** for a user, the following dialog is displayed.

1. Gyrolab Evaluator version 3.6 and older used another system for storing non-project audit trail. This information has been migrated to be part of the user audit trail when updating to Gyrolab Evaluator version 3.7. Project-specific audit trail in Gyrolab Evaluator has not been changed.



The screenshot shows the 'Gyrolab Manager - Audit Trail' window. It has a search bar at the top with 'Login Name: test' and 'Full Name: Test user'. Date filters are set for 'From: 2020-12-03' and 'To: 2021-06-01'. A 'Filter' button is present. Below is a table of audit events.

Start	End	Event	Event Status	Software	Comment	Instrument	Details	Files
2021-06-01 16:05:49	2021-06-01 16:05:49	Run Setup added				XPA0000	[Run setup:Run 0033-A17, Version:1, User:Test user, Run design:Main Fish assay, Folder:Root/Project Fish/Main Fish assay, Version:1, Modified:2021-06-01T16:00:17+02:00, Modified by:Administrator]	
2021-06-01 16:05:45	2021-06-01 16:05:45	System configuration				XPA0000	[User:Test user]	GyrolabXml.xml
2021-06-01 16:05:14	2021-06-01 16:05:14	Change state of run setup		Gyrolab Manager		XPA0000	[Design type:Wizard, User:Test user, Run setup:Run 0033-A17, Run setup state:ReadyForExecution, Version:1, Run design:Main Fish assay, Folder:Root/Project Fish, Version:1]	RunSetupInfo.xml LoadingList.pdf
2021-06-01 16:05:05	2021-06-01 16:05:53	User login		Gyrolab Manager		XPA0000	[User:Test user]	
2021-06-01 16:04:24	2021-06-01 16:04:37	Initialize				XPA0000	[User:Test user]	GeneralLog.xml

Buttons at the bottom: Export..., Close

A list of actions taken by the user is displayed.

The list also includes actions taken on the user account by another user, e.g. when the account was created or when any attribute of the user was changed.

Files listed in the **Files** column can be opened by clicking them.

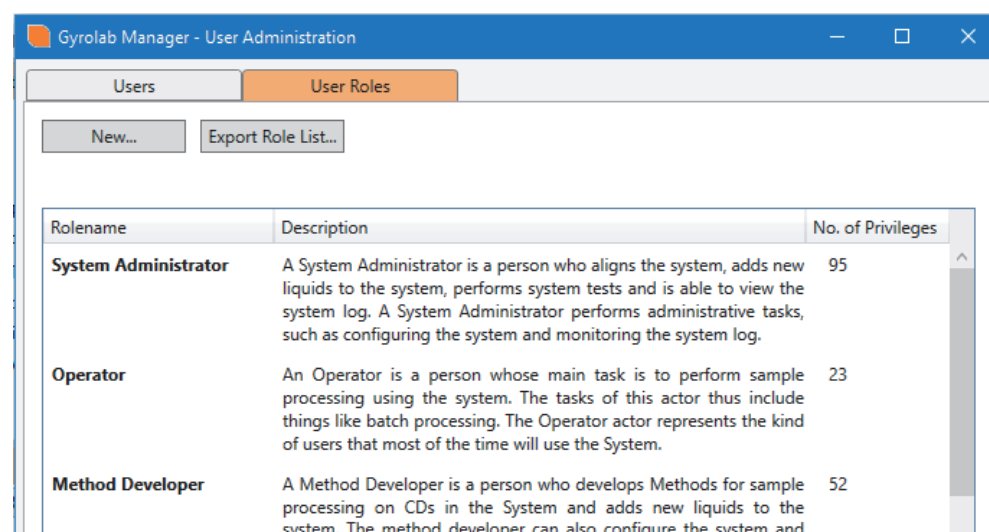
The list can become very long. To limit the size of the list, a date interval can be specified. Set desired dates for **From** and **To** and select **Filter** to update the list.

By default, the **To** date is current day, and **From** date is 180 days back.

Select **Export...** to generate a PDF report of the user audit trail. The PDF report is limited to the date range specified in the dialog.

B8.2 User Role administration

For User Role administration, the dialog shows a list of all Gyrolab User Roles in the database.



The screenshot shows the 'Gyrolab Manager - User Administration' window. It has two tabs: 'Users' and 'User Roles' (selected). Below the tabs are buttons for 'New...' and 'Export Role List...'. The main area contains a table of user roles.

Role name	Description	No. of Privileges
System Administrator	A System Administrator is a person who aligns the system, adds new liquids to the system, performs system tests and is able to view the system log. A System Administrator performs administrative tasks, such as configuring the system and monitoring the system log.	95
Operator	An Operator is a person whose main task is to perform sample processing using the system. The tasks of this actor thus include things like batch processing. The Operator actor represents the kind of users that most of the time will use the System.	23
Method Developer	A Method Developer is a person who develops Methods for sample processing on CDs in the System and adds new liquids to the system. The method developer can also configure the system and	52

For each User Role, the following is also presented

- The **Role name**, the name of the user role.
- A **Description** of the user role.

- **No. Of Privileges**, indicating the number of privileges assigned to the user role.

Select **Export Role List...** to generate a PDF report of all user roles.

Select **New...** to create a new User Role. For more information, see Chapter B8.2.1.

By selecting a User Role in the list, operations can be performed on that role.

Method Developer	A Method Developer is a person who develops Methods for sample processing on CDs in the System and adds new liquids to the system. The method developer can also configure the system and import/export methods.	52
Project Manager	A Project Manager is a person who mainly administers the software system, adds new users, adds new method folders.	65
Service	A Service is a person whose main task is to perform instrument tests and needs to configure the system	95

- Select **Edit...** to change the properties of the selected User Role. For more information, see Chapter B8.2.1.
- Select **Audit trail...** to present an audit trail for the selected User Role, see Chapter B8.2.2.

Default User Roles which are present in a new Gyrolab database are described further in Chapter I8.

NOTE: *The properties of the default User Roles present in a new Gyrolab database cannot be modified, but it is possible to select Edit... to view the privileges assigned to these User Roles.*

B8.2.1 Create or Edit User Role

When selecting to create a new User Role, or edit an existing role, the following dialog is displayed.

Gyrolab Manager - Edit User Role

Rolename:

Description:

User

- ☐ Create new user
- ☐ Edit user
- ☐ Disable user
- ☐ Export user list
- ☐ View user audit trail

User Role

- ☐ Create new user role
- ☐ Edit user role
- ☐ Export user role list
- ☐ View user role audit trail

Folder management

- ☐ Edit all folders
- ☐ Edit level 1 folders
- ☐ Edit level 2 folders
- ☐ Move method
- ☐ Move run design
- ☐ Move run result
- ☐ Move maintenance

Miscellaneous

- ☐ Configure system

Instrument handling

- ☐ Instrument startup
- ☐ Instrument shutdown
- ☐ Configure instrument
- ☐ System alignment
- ☐ Start run
- ☐ Manage CD
- ☐ Prime system
- ☐ Perform maintenance
- ☐ Resolve warnings

Run Related

	View	Create	Edit	Delete	Delete Approved	Export	Export Readable	Import	Archive
Method	☐	☐	☐	☐	☐	☐	☐	☐	
Run Design	☐	☐	☐	☐		☐	☐	☐	
Run Setup	☐	☐							
QC Set		☐	☐						☐

Evaluator projects

- ☐ View project
- ☐ Manage project
- ☐ Edit project
- ☐ Approve project
- ☐ Unapprove project
- ☐ Administrate Gyrolab project
- ☐ Export project

Evaluator configuration

- ☐ Configure analysis
- ☐ Configure presentation
- ☐ Configure report
- ☐ Edit settings
- ☐ Lock settings
- ☐ Unlock settings

Evaluator analyses

- ☐ Analyze
- ☐ Manage analysis
- ☐ Edit analysis samples
- ☐ Export analysis result
- ☐ Export analysis data
- ☐ Export report

OK Cancel

For a new User Role, the **Rolename** and **Description** fields are empty. Enter the name of the new role, and optionally, a description of the role.

The checkboxes indicate all available user privileges, grouped according to their use in the system. A new User Role will have all checkboxes unchecked, corresponding to not having any privileges.

To assign desired privileges to the User Role, check the corresponding checkboxes.

The checkbox for some privileges depend on other privileges and may be grayed out until the superseding privilege is selected.

Hover the mouse pointer over a grayed out privilege for a tooltip describing the privilege and if applicable, any dependencies. When a selected privilege is grayed out it cannot be unselected. This means that another privilege depends on it. Hover the mouse pointer over the selected grayed out privilege for a tooltip describing the privilege and if applicable, which other privileges depend on it.

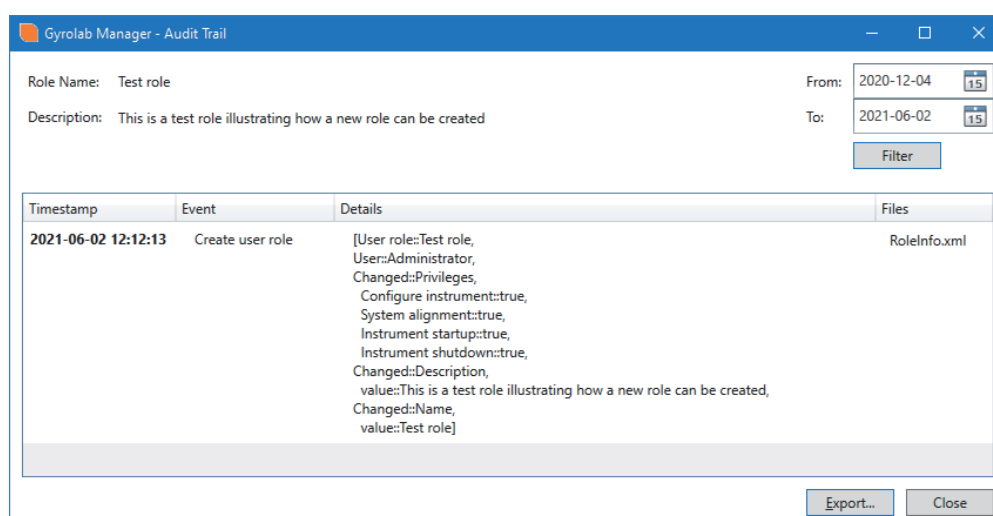
User privileges are described further in Chapter I8.

If editing an existing User Role, the fields and checkboxes in the dialog are already filled in, but can be modified.

B8.2.2 User Role audit trail

The audit trail for a User Role includes the actions performed on it.

After selecting **Audit trail...** for a User Role, the following dialog is displayed.



A list of the operations performed on the user role is displayed.

Files listed in the **Files** column can be opened by clicking them.

The list can become long. To limit the size of the list, a date interval can be specified. Set desired dates for **From** and **To** and select **Filter** to update the list.

By default, the **To** date is current day, and **From** date is 180 days back.

Select **Export...** to generate a PDF report of the User Role audit trail. The PDF report is limited to the date range specified in the dialog.

Pre-defined User Roles do not have a audit trail.

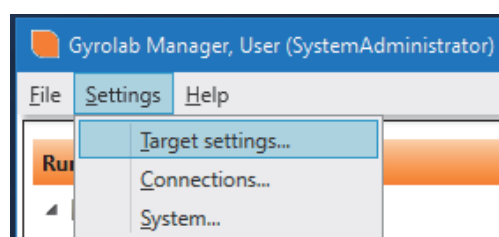
B9 System settings

Some properties of a Gyrolab system are controlled by global settings. These settings are associated with one Gyrolab database and apply to all Gyrolab software applications and all users working on that database.

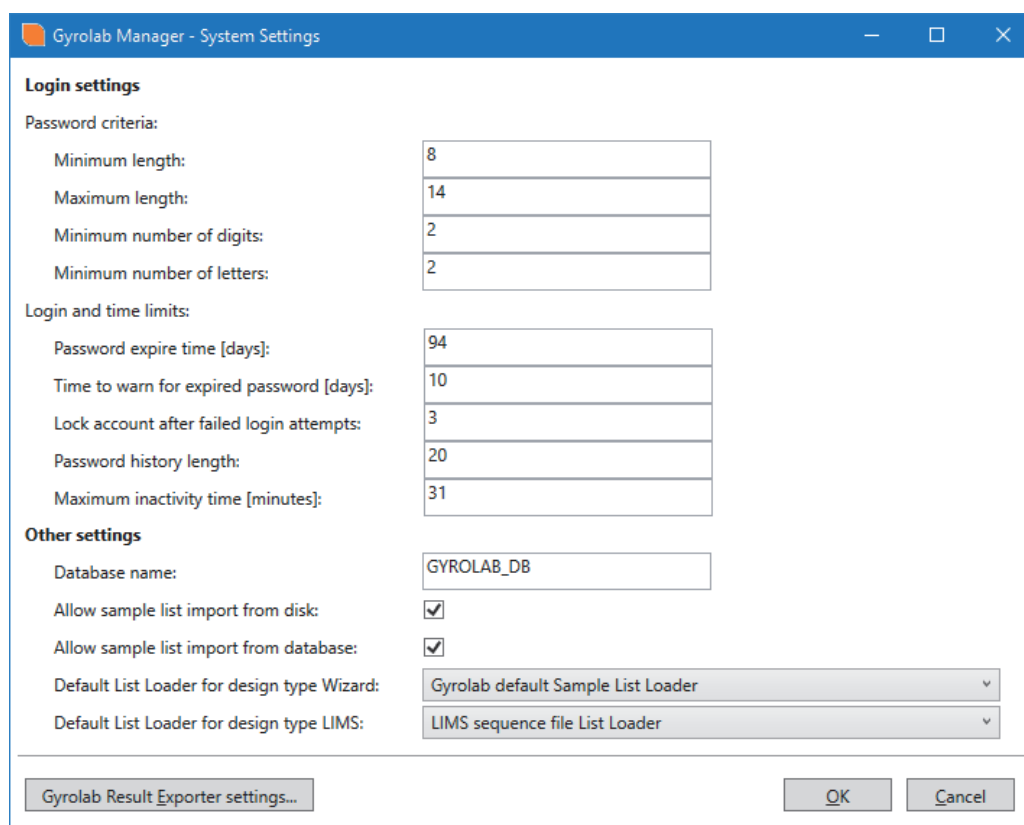
These settings can be changed by a Gyrolab user with sufficiently high privileges.

Any user can view the settings, but to change settings, the **Configure System** privilege is required¹.

In Gyrolab Manager main window, select **Settings:System...** to change the system settings.



The following dialog is displayed.



The system settings are grouped according to their use in Gyrolab.

- **Login settings** are related to login and session handling for Gyrolab users and is further divided in criteria for user passwords and other settings.

1. The privilege **Configure System** in Gyrolab Control 8.0 and earlier provided the privilege to configure a Gyrolab instrument. It has now been renamed **Configure Instrument**. A new privilege **Configure System** has been added in Gyrolab Control 8.1/Gyrolab Manager 1.1. See Chapter 18

- Most remaining system settings are found under **Other settings**.
- Settings for the Gyrolab Result Exporter utility added in Gyrolab Control 8.1 can be opened with the button **Gyrolab Result Exporter settings**....See Chapter B9.1.

Under **Login settings, password criteria**, it is possible to specify the requirements on user passwords. Settings include minimum number of digits and letters in the password and the minimum and maximum length of the password.

Under **Login settings, Login and time limits**, other settings related to user login are listed.

- **Password expire time** specifies the number of days a new password is valid until a user must change to a new password.
- **Time to warn for expired password** specifies the number of days, before a password expires, that the user will be reminded.
- **Lock account after failed login attempts** controls how many times a user may try to login with an incorrect password before being locked out. After a user has been locked out, a system administrator must reset the password for the locked user using Gyrolab Manager, see Chapter B9.
- **Password history length** controls the number of unique passwords a user must set before being allowed to reuse a previously used password.
- **Maximum inactivity time** specifies the number of minutes a user can be inactive before being required to log in again. This works somewhat different in Gyrolab Client compared to Gyrolab Manager and Gyrolab Evaluator. In Gyrolab Client, a user is not required to log in again until an attempt is made to issue a new command for the instrument. This is helpful when a user has started a Run. A new login is not required until a user (the same or another user) tries to use the instrument again, typically to unload CDs and microplates from a previous run.

Settings not related to users and login are found under **Other settings**.

- **Database name** allows the database to be assigned a name. This may be useful in environments where multiple databases are used. Gyrolab Evaluator presents the database name in the Run Report.
- **Allow sample list import from disk/database**. In Gyrolab Manager 1.1, when creating a Run Setup for the LIMS design type, LIMS sequence files can be fetched from the Gyrolab database in addition to fetching the files from disk. With these settings a system administrator can limit how such files are fetched. Typically, file import from disk is disallowed to improve data integrity.
- **Default List Loader for design type Wizard/LIMS** is used for installations where additional List Loaders are added to the system, to select which of the List Loaders to use by default. These settings are of no use in a standard installation, where there is only one List Loader per Design Type.

Settings for Gyrolab Result Exporter are described in Chapter B9.1.

To save any changed settings, select **OK**. To exit without saving any changed settings, select **Cancel**.

If changing the system settings, Gyrolab software will in general need to be restarted for the new settings to take effect. This applies to Gyrolab Manager, Gyrolab Evaluator, and Gyrolab Control.

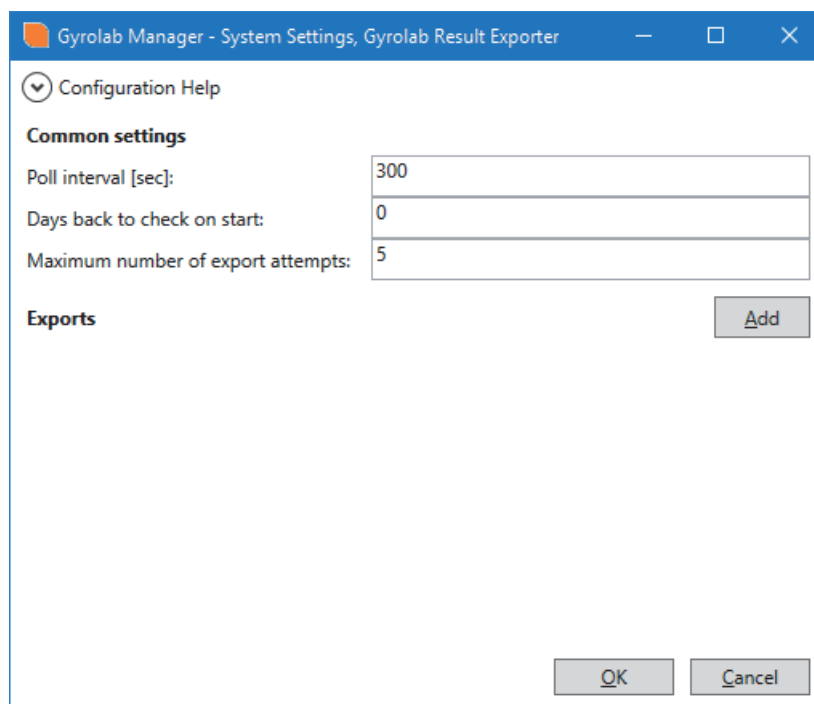
B9.1 Gyrolab Result Exporter settings

Gyrolab Result Exporter is a utility added in Gyrolab Control 8.1. Configuration of Gyrolab Result Exporter is done from Gyrolab Manager System Settings.

To use Gyrolab Result Exporter, additional steps must be taken to activate the utility. See Chapter G7.

When activated, Gyrolab Result Exporter will periodically check the Gyrolab database for new Run Results. If a new result is found, it is exported to disk controlled by the rules defined in the System settings.

When opening Gyrolab Result Exporter Settings, the following dialog is displayed. The first time opened, the **Exports** section is empty. When exports have been configured, those will be presented in the **Exports** section.



Common settings include the following settings.

- **Poll interval** specifies the number of seconds between checks for new results in the database. A low value will result in more frequent checks but will also have a slightly higher impact on system performance. The default value is 300, corresponding to a poll interval of five minutes.
- **Days back to check on start** can be used to ask Gyrolab Result Exporter to attempt export of results added to the database at a number of days before Gyrolab Result Exporter was started. The default value of 0 will make Gyrolab Result Exporter to attempt export of new results only.
- **Maximum number of export attempts** controls the number of times Gyrolab Result Exporter shall retry a specific export before giving up. Failed export attempts are logged. For more information on logging of failed export attempts, see Chapter G7.4. The default value is 5.

Besides common settings, Gyrolab Result Exporter is controlled by adding one or more **Exports**. On every new Run Result in the Gyrolab database, Gyrolab Result Exporter will investigate the Run Result and apply all exports that apply. Exports that do not apply because the selected Run Result Item is not present in the Run Result are ignored for that particular Run Result.

Select **Add** to add a new export. A new export is added.

Select the **Run Result Item to export**. Run Result Items are also called Files in some cases.

- **MainResult.xml** is the main item produced when executing a Run on a Gyrolab instrument. It contains raw information produced by the Run, except for binding profile images.
- **LIF Images** contain the binding profile images from a Run. This export will produce a large folder tree on disk with many files for each Run Result and is not recommended for routine export.
- **Gyrolab Evaluator.xml** is a processed version of MainResult.xml where sample responses have been extracted. The main purpose is for use in Gyrolab Evaluator.
- **Gyrolab Excel Export.xls** is a tab separated text file with responses from all processed samples. This is the recommended format for exporting sample responses for further processing by other tools.
- **Gyrolab Report.pdf** is the report file produced by the Gyrolab Control Report software add-on module. See Chapter E4 for more information.
- **LIMS Sequence Files** will export all files generated when executing a Run based on the LIMS Design type. See Chapter E3 for more information.
- **Gyrolab Functionality Check.pdf** is the report file produced when performing a Gyrolab Functionality Check. See Gyrolab Instrument Guide for more information on Gyrolab Functionality Check.

Also configure the other settings for the export.

- **Top folder for this Export Request** specifies the top folder where to export the **Run Result Item**. It is possible to enter a folder path directly or browse for a folder. All exported items will be saved to this folder, or subfolders to this folder.

NOTE: *Gyrolab Result Exporter is running as a Windows service, and the entered folder path must be relevant and accessible for the Windows account running the Windows service. Network folders mapped as drive letters cannot be used in a Windows service. If the export is made to a network folder, use an UNC path. For more information on UNC, see [https://en.wikipedia.org/wiki/Path_\(computing\)#Uniform_Naming_Convention](https://en.wikipedia.org/wiki/Path_(computing)#Uniform_Naming_Convention).*

- **Create subfolder per instrument** will, when checked, organize the exported items in folders based on the name of the Gyrolab instrument where the Run was executed.
- **Create subfolder per Run Result** will, when checked, create a new subfolder for each exported Run Result. The subfolder is named after the Run Result. As Run Results may have identical names, it is strongly recommended to also check **Add time stamp to Run Result subfolder name** to make folder names unique.
- **Add time stamp to Run Result subfolder name** will, when checked, add a time stamp to the name of the subfolder created for a Run Result. Not applicable if **Create subfolder per Run Result** is unchecked.
- **Add time stamp to Run Result item name** will, when checked, add a time stamp to each exported Run Result Item. If not creating a subfolder per Run Result, adding a time stamp to the Item name may be necessary to make the names of the exported items unique.

An export can be removed by selecting **Remove** for the export to remove.

Select **OK** to exit the Gyrolab Result Exporter dialog with the new settings or **Cancel** to ignore any changes. Note that the Gyrolab Result Exporter settings will not be saved in the Gyrolab database until the main System Settings dialog is exited with **OK**.

NOTE: *When changing settings for Gyrolab Result Exporter, the corresponding Windows service must be restarted for the new settings to be activated. For more information, see Chapter G7.*

B10 Gyrolab Manager installation on office computer

Gyrolab Manager is included in the standard installation of a Gyrolab system. This chapter describes how to install Gyrolab Manager on an office computer to enable remote setup of runs to be executed at Gyrolab instruments, eliminating the need to use the instrument computer for this purpose.

B10.1 Gyrolab Manager installation package

Gyrolab Manager installation package contains the following software:

- Gyrolab Manager
- Gyrolab Manager Release Notes
- Microsoft.Net Framework 4.5.2 or higher
- Gyrolab User Guide
- Software installation instructions

B10.2 Computer requirements

Gyrolab Manager should be installed on a computer with access to the desired Gyrolab instrument(s).

- Minimum computer system specification
 - 4 GB RAM memory.
- Operative system requirement is Windows 10, 64 bit.
- Minimum monitor 1366×768 resolution. A higher vertical resolution is recommended for best user interaction.
- Adobe Reader™ version 10 or higher for opening PDF files.
- Microsoft.Net Framework 4.5.2 or higher. A Microsoft.Net Framework installer is available on the Gyrolab Manager installation CD.
- To work with Sample List files or Microplate Layout files (see chapter B.5.3.3 and B.5.4.2), a spreadsheet program that can handle xls files is required.

B10.3 User requirements

Installation of Gyrolab Manager requires administrator privileges on the computer.

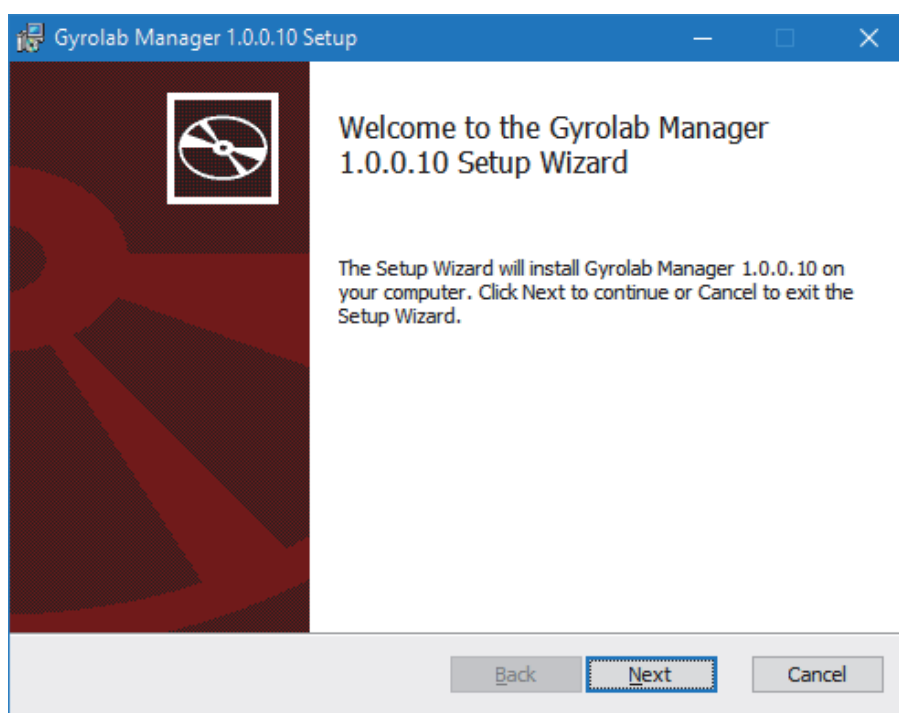
To be able to use Gyrolab Manager, a Username and Password is required for each Gyrolab database to work with. Contact the local Gyrolab system administrator to receive login details for Gyrolab Software.

B10.4 Installation

Before installation start, make sure that the operating system is updated with the latest patches from Microsoft. This can be done from the web site <http://update.microsoft.com>.

Step	Action

1.	Insert Gyrolab Manager Software Package CD in the CD drive.
2.	Gyrolab Manager installation screen opens. If the installation start screen does not appear automatically, browse for the CD folder in Windows Explorer and double-click on the file readme.html.
3.	Verify that the prerequisites listed in section Prerequisites are fulfilled. Some third-party components are available for installation from the installation CD, see section Install Third Party Components .
4.	Consult the section Install Third Party Components to install required components, if not present.
5.	Consult the section Change history to view information on this software release.
6.	Consult the section Install Gyrolab Manager for information on how to start the software installation. Start the installation as described in the section Brief installation instruction . (Accessing the full instructions will guide you to this text.) The steps in the installation of Gyrolab Manager is described in the following steps.
7.	A Gyrolab Manager Setup dialog opens. Click Next .

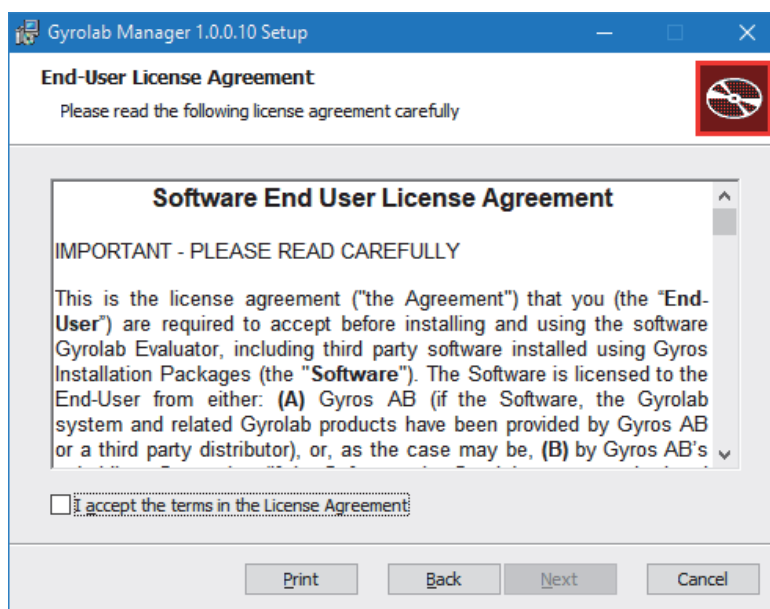


NOTE: During the installation procedure it is possible to cancel installation by clicking *Cancel* and to return to previous step by clicking *Back*.

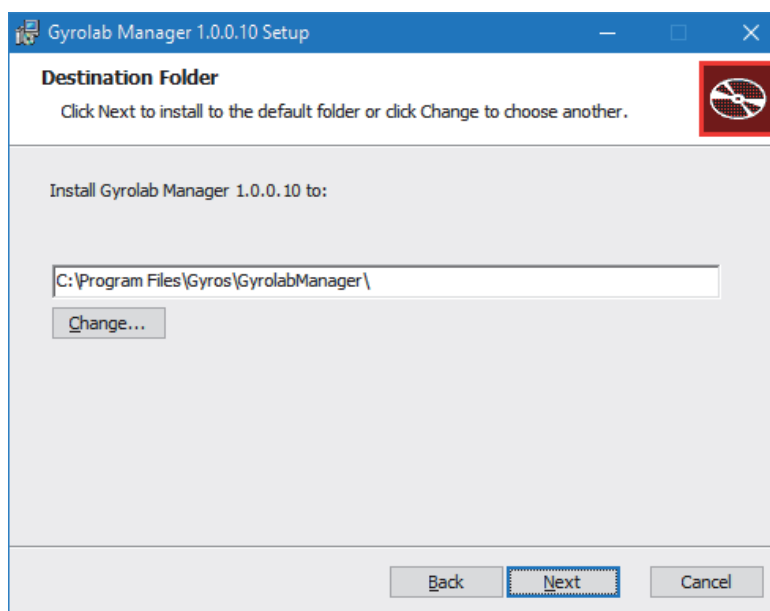
Step Action

8. A dialog opens presenting the End-User License Agreement. Read the license agreement, check **I accept the terms in the License Agreement** and click **Next**.

If the License agreement cannot be accepted, click **Cancel** and contact Gyros Protein Technologies.

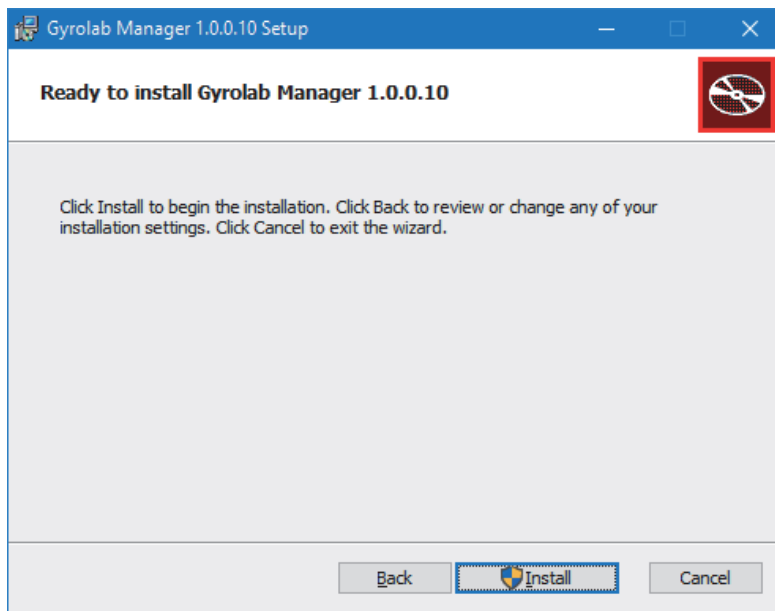


9. A dialog opens presenting the destination for the installation. Click **Next** to accept the default destination, or **Change** to select another destination. After changing destination, click **Next** to continue.

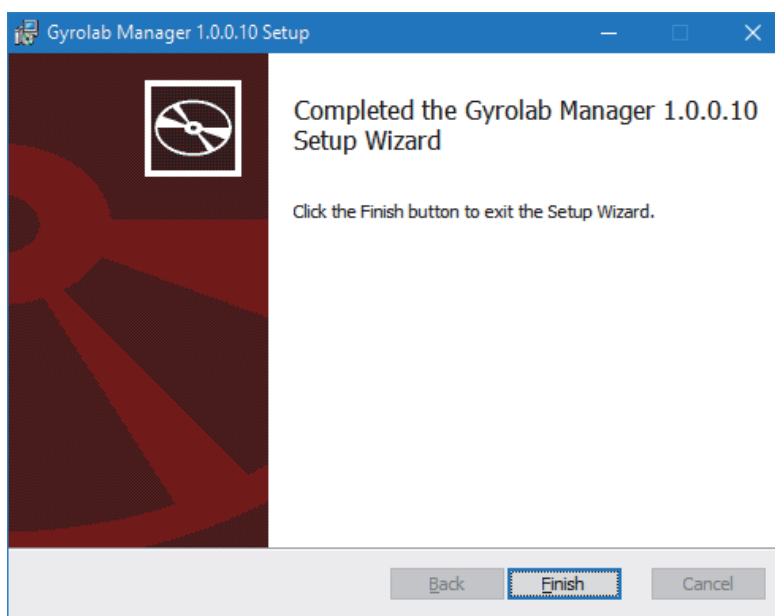


Step Action

10. A new dialog is opened with information that installation can begin. Click **Install** to start the installation.



11. A new dialog is opened, stating that the installation is now complete. Click **Finish** to end the installation.



12. Installation of Gyrolab Manager is now complete. Close any open windows and eject the installation CD.

GYROLAB USER GUIDE

C Perform immunoassays on Gyrolab Instrument



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C1 Labelling of capture and detection reagents

This chapter contains protocols for

- Biotinylation of capture reagent, Chapter C1.1
- Fluorophore labeling of detection reagent, Chapter C1.2
- Buffer exchange/protein concentration, Chapter C1.3

For recipes, refer to Chapter F2.

C1.1 Biotinylation of capture reagent

The following solutions and consumables are required:

- Biotinylation reagent
- Capture reagent
- Milli-Q® water
- PBS
- Protein Desalting Spin Column (Thermo Scientific), cutoff: 7K. For larger proteins consider using Nanosep 30K (Pall Life Sciences).
- 1.5–2.0 ml microcentrifuge collection tube

Step Action

1. Preparation of capture reagent

Refer to supplier-provided instructions for the biotinylation reagent. The protocol in this chapter is based on instructions for EZ-Link Sulpho NHS-LC-Biotin (Thermo Scientific).

Use 100 µl of 1 mg/ml capture reagent (antibody or other suitable capture reagent) for biotinylation labeling. The capture reagent to be biotinylated must be in a buffer free from stabilizing proteins (for example BSA), ammonium ions, primary amines, sodium azide and ProClin-950 to obtain the best possible degree of labeling.

- If the concentration of sodium azide in capture reagent solution is >3 mM (0.02%), remove the sodium azide, refer to Chapter C1.3.
- If the capture reagent solution is in an amine-containing buffer, exchange buffer to PBS (pH 7.2 – 8.0), refer to Chapter C1.3.
- If concentration of capture reagent solution is <1 mg/ml, concentrate capture reagent solution, refer to Chapter C1.3.
- If concentration of capture reagent solution is >1 mg/ml, dilute with PBS.
- If the capture reagent is a powder lyophilized from an appropriate buffer, it is reconstituted in PBS.

Step	Action
2.	Preparation of Biotinylation reagent - Allow biotinylation reagent (EZ-Link Sulfo-NHS-LC-Biotin) to reach room temperature. - Dissolve 0.5–1 mg of the biotinylation reagent in ice-cold deionized/distilled water (Milli-Q water) to a final concentration of 1 mg/ml. - Vortex gently.
3.	Biotin labeling procedure - Mix appropriate volumes of biotinylation reagent and capture reagent solution at a 12 times molar excess of biotinylation reagent compared to capture reagent. TIP: Formula: $\mu\text{mol capture reagent} = \mu\text{g capture reagent} / (\text{g/mol}) \text{ capture reagent}$ $\mu\text{mol Biotin} = 12 \times \mu\text{mol capture reagent}$ $\mu\text{g Biotin} = \mu\text{mol Biotin} \times (\text{g/mol}) \text{ Biotin (MW Biotin} = 556 \text{ g/mol)}$ Example: <i>For 100 μg of 1 mg/ml IgG (MW 150 000 g/mol), add 4.5 μg Biotin reagent</i> $\mu\text{mol IgG} = 100 \mu\text{g} / 150\,000 \text{ g/mol} = 0.000667 \mu\text{mol IgG}$ $\mu\text{mol Biotin} = 12 \times 0.000667 \mu\text{mol IgG} = 0.008 \mu\text{mol Biotin}$ $\mu\text{g Biotin} = 0.008 \mu\text{mol Biotin} \times 556 \text{ g/mol Biotin} = 4.5 \mu\text{g Biotin}$ <i>(4.5 μg Biotin is 4.5 μl of a 1 mg/ml Biotin reagent solution)</i> - Vortex gently for a few seconds. - Incubate 1 hour at room temperature while occasionally shaking the vial gently.
4.	Removal of unbound biotinylated reagent - Invert the Protein Desalting Spin Column (Thermo Scientific) to suspend slurry. - Place the column in a collection tube and centrifuge at 1500 $\times$ g for one minute to remove excess liquid. - Add the biotinylation mixture to the column center of the compacted resin bed. Be careful not to disturb the resin or to allow sample to flow around the resin bed. - Centrifuge at 1500 $\times$ g for two minutes. Biotinylation mixture will be collected in the tube. - Put the tube with biotinylation mixture on ice. - Discard the column only after a proper separation of compounds in the biotinylation mixture is confirmed. NOTE: <i>This protocol step is only valid for proteins larger than 7kD. For smaller proteins use another method for removal of free biotin, for example Nanosep (Pall Life Sciences) with a suitable cutoff.</i>
5.	Concentration measurement of biotinylated reagent - Measure absorbance (A_{280}) of the biotinylated reagent. Dilute an aliquot of the biotinylated reagent 1:10 in PBS for absorbance measurement. - Calculate reagent concentration (mg/ml): $\text{Reagent concentration (mg/ml)} = (A_{280} \times \text{dilution factor}) / \epsilon \times L$ $\epsilon = 1,38 \text{ (cm}^{-1} \text{ (mg/ml)}^{-1}), L = \text{cuvette length in cm (1 cm)}$ NOTE: <i>The extinction coefficient, ϵ, for IgG is 1,38 (cm⁻¹ (mg/ml)⁻¹), other values may be valid for other reagents.</i>

Step	Action
6.	Storage of biotinylated reagent Aliquot and store the biotinylated capture reagent at +4 °C or -20 °C (long-term storage).
7.	Verify biotinylation Perform a Run using 700 nM of the biotinylated molecule (for an antibody this corresponds to 0.1 mg/ml). Evaluate results to verify a successful biotinylation.
TIP: <i>Recalculations of concentration from g/L to molar terms</i> <i>Formula: $M \text{ protein} = \text{g/L protein} / \text{MW (g/mol)} = \text{mol/L protein}$</i> <i>Example: For 1 mg/mL of BSA (MW 67000 g/mol): $M \text{ BSA} = 1 \text{ g/L} / 67000 \text{ g/mol} = 0.0000149 \text{ M} = 14900 \text{ nM}$</i>	
TIP: <i>The concentration of biotinylated capture reagent should be high enough to saturate the streptavidin column. Normally concentrations of around 700 nM of biotinylated protein is enough to saturate the column.</i>	

C1.2 Fluorophore labeling of detection reagent

The following solutions and consumables are required

Desired Fluorophore labeling kit

- Alexa Fluor 647 Monoclonal Antibody Labeling Kit (100 µg), proteins >30 kDa
- Alexa Fluor 647 Microscale Protein Labeling Kit (20–100 µg), proteins 20–150 kDa
- DyLight 649 Microscale Antibody Labeling Kit (100 µg), 50–150 kDa
- Detection reagent

Required solutions and consumables depend on which fluorophore labeling kit is used. Please refer to supplier-provided instructions for the fluorophore labeling kit.

Step Action

1. Preparation of detection reagent

Refer to instructions for the fluorophore labeling kit for details. The protocol in this chapter follows instructions given in Alexa Fluor™ 647 Monoclonal Antibody Labeling Kit (Molecular Probes) for antibodies and proteins > 30 kDa.

Use 100 µl of 1 mg/ml detection reagent (antibody or other suitable detecting reagent) for fluorophore labeling. The reagent to be fluorophore labeled must be in a buffer free of stabilizing proteins (for example BSA), ammonium ions, primary amines, sodium azide and ProClin-950 to obtain the best possible degree of labeling.

- If the concentration of sodium azide in detection reagent solution is >3 mM (0.02%), remove the sodium azide, refer to Chapter C1.3.
- If the detection reagent solution is in amine-containing buffer, exchange buffer to 0.1 M Sodium bicarbonate buffer (pH 7.2 – 8.0), refer to Chapter C1.3.
- If concentration of detection reagent is <1 mg/ml, concentrate detection reagent solution, refer to Chapter C1.3.
- If concentration of detection reagent is >1 mg/ml, dilute with 0.1 M Sodium bicarbonate buffer.
- If the reagent to be labeled is a powder lyophilized from an appropriate buffer, it is reconstituted in 0.1 M Sodium bicarbonate buffer.

2. Fluorophore labeling procedure

- Add 1:10 volume of 1 M Sodium bicarbonate buffer to the 1 mg/ml detection reagent solution.

NOTE: *This is not required if the starting material is lyophilized and already reconstituted in 0.1 M sodium bicarbonate buffer.*

- Transfer 100 µl of detection reagent solution to vial containing Component A (reactive dye). Vortex gently to dissolve the reactive dye.
- Protect vial from light by wrapping it with aluminum foil.
- Incubate 1 hour at room temperature while shaking the vial gently.

3. Preparation of purification column

- Moisten purification column filter with 1 ml PBS. Pressured air may be required to elute the PBS.
- Stir purification resin (Component C) and add 1 ml to the column, allow it to settle.

NOTE: *The purification resin is a 30,000 Mw size-exclusion resin. Do not use for proteins <30 kDa.*

- Add additional purification resin until the bed volume is approximately 1.5 ml.
- Allow the column buffer to drain from the column by gravity.
- Place column in provided collection tube. Centrifuge at 1100 × g for 3 minutes.

4. Purification of fluorophore labeled detection reagent

- Load 100 µl of the labeled reagent onto the purification column.
- Place column in an empty collection tube.
- Centrifuge 1100 × g for 5 minutes.
- Transfer the labeled reagent in the collection tube to a dark vial.

Step	Action
5.	Determination of concentration and labeling efficiency - Measure absorbance of the purified fluorophore labeled detection reagent at A_{280} and A_{650}. Dilute an aliquot of the fluorophore reagent 1:10 in PBS for absorbance measurement. - Calculate detection reagent concentration: $\text{Concentration (M)} = (A_{280} - (A_{650} \times 0.03)) \times \text{dilution factor} / \epsilon,$ $\epsilon = 203000 \text{ (cm}^{-1} \text{ M}^{-1}\text{)}$ NOTE: The extinction coefficient, ϵ, for IgG at $A_{280} = 203000 \text{ (cm}^{-1} \text{ M}^{-1}\text{)}$, other values may be valid for other reagents. - Calculate degree of labeling (moles fluorophore per mole of detection reagent): $\text{Labeling degree} = (A_{650} \times \text{dilution factor}) / \epsilon \times \text{Concentration (M)}$ $\epsilon = 239000 \text{ (cm}^{-1} \text{ M}^{-1}\text{) of fluorophore at } A_{650}$ NOTE: For antibodies a degree of labeling of 3–7 moles of fluorophore dye per mole of antibody is recommended.
6.	Dilution and storage of fluorophore labeled detection reagent - Dilute the fluorophore labeled reagents to 1000 nM in PBS, 0.2% BSA (Calbiochem). - Aliquot and store fluorophore labelled detection reagent at -20°C protected from light.
7.	Verify fluorophore labeling - For all new assays, assay formats and newly labelled reagents, perform a titration Run to find the optimal concentration for the detection reagent, refer to Chapter A2.5.2. - For an established assay, perform a test Run using previously established concentration. Compare the result from the new batch of labelled reagent with results from previous batches in previous titration Runs.

C1.3 Buffer exchange, azide removal and protein concentration protocols

This chapter contains protocols for buffer exchange and reagent concentration.

C1.3.1 Nanosep 30K Protocol

The Nanosep 30K protocol (Pall Life Sciences), is used for buffer exchange and azide removal. Nanosep columns come in different cut off values (3, 10, 30 and 100K). The optimal filter size of the spin column depends on the size of the reagent.

The following solutions and consumables are required

- Nanosep 30K membrane (Pall Life Sciences) and sample reservoir
- Deionized water
- 1×PBS without NaN_3

Step Action

- 1.**
 - Pre-rinse the Nanosep by filtering 500 µl deionized water or buffer through the membrane twice.
 - Spin up to 11 000 × g for a couple of minutes. Do not allow the membrane to dry out prior to use.
- 2.**
 - Pipette the required volume of protein (50 to 500 µl) into the sample reservoir.
 - Fill up to 400 µl with buffer.
 - Cap the Nanosep device.
 - Spin up to 11 000 × g for 2 – 20 minutes.
- 3.**
 - Wash 2–3 times with 200 – 400 µl buffer.
 - Spin up to 11 000 × g for 2 – 20 minutes.
- 4.** If the reagent appears to have spun dry in the device, the reagent is easily recovered by pipetting several times with approximately 50 µl buffer.
- 5.** Dilute the reagent with buffer to get a concentration of 1 mg/ml.

C1.3.2 Thermo Scientific spin column protocol

The protocol is copied from Thermo Scientific Protein Desalting Spin Columns, product number: 89849, which is designed for use on proteins with a $M_W > 7000$ Da.

Follow this protocol when using Desalting spin column for buffer exchange and azide removal.

The following solutions and material are required

- Thermo Scientific Protein Desalting Spin Column
- Variable-speed bench-top microcentrifuge
- 1.5–2 ml microcentrifuge collection tubes
- Equilibration buffer: PBS

A Protein Desalting Spin Columns Preparation

Step	Action
1.	Prepare the protein desalting spin column • Invert column to suspend slurry. • Twist off bottom closure and loosed cap. • Place column in 1.5–2 ml microcentrifuge collection tube. • Centrifuge at $1500 \times g$ for 1 minute to remove excess liquid.
2.	Perform four column washes • Add 400 μl of equilibration buffer to the top of column. • Centrifuge the column at $1500 \times g$ for 1 minute to remove excess liquid. • Discard buffer from the collection tube.

Sample Loading

Step	Action
1.	• Place column in a fresh collection tube and remove the cap. • Apply 30–120 μl of sample (proteins with M_W greater than 7000) to the center of the compacted resin bed. Be careful not to disturb the resin or to allow sample to flow around the resin bed.
2.	Optional: To improve recovery percentage of low molecular weight proteins or for small sample volumes, add 20–40 μ l of equilibration buffer to top of resin. Do not exceed a total of volume of 120 μ l.
3.	Centrifuge column at $1500 \times g$ for 2 minutes. The desalted sample is collected in the collection tube.
4.	Discard the desalting column after use.

C1.3.3 Concentrate reagent solution

This protocol for reagent concentration uses Nanosep 30K (Pall Life Sciences). Nanosep columns come in different cut off values (3, 10, 30 and 100K). The optimal filter size of the spin column depends on the size of the reagent.

The following solutions and consumables are required

- Nanosep 30K membrane (Pall Life Sciences) and sample reservoir
- Deionized water
- 1×PBS without NaN_3 .
- Thermo Scientific spin column protocol

Step	Action

1.	• Pre-rinse the Nanosep by filtering 500 μl deionized water or buffer through the membrane twice. • Spin up to $11\,000 \times g$ for a couple of minutes. Do not allow the membrane to dry out prior to use.
2.	• Pipette the required volume of protein (50 to 500 μl) into the sample reservoir. • Cap the Nanosep device. • Spin up to $11\,000 \times g$ for 2 – 20 minutes.
3.	If the reagent appears to have spun dry in the device, the reagent is easily recovered by pipetting several times with approximately 50 μl buffer.
4.	Dilute the reagent with buffer to get a concentration of 1 mg/ml.

C2 Gyrolab instrument startup procedure

The following steps must be performed prior to start a Run on the Gyrolab instrument

- Turn on the instrument (Chapter C2.1)
- Start Gyrolab Control (Chapter C2.2)
- Initialize the system (Chapter C2.3)
- Prime the system (Chapter C2.4)

The following solutions are required, refer to Chapter F2.2 for recipes

- Bioaffy Pump Liquid
- Bioaffy Wash Station Solution 1

NOTE: *Switching users in Windows: If there is more than one user account on the computer, another person may log on to the computer without logging off the first user. The second user should not start the Gyrolab Control server while the first user is running the server, since this may cause interference with the first user's Gyrolab session. Recommendation: Do not switch user while the instrument is running.*

C2.1 Turn on instrument

Step	Action
1.	Switch on instrument power. The power switch is located at the rear of the Gyrolab instrument. For instruments with an external GL Degasser, also turn on GL Degasser. The power switch is located at the rear of the GL Degasser.
2.	For Gyrolab xPlore and Gyrolab xPand, push the Power button on the front panel of the instrument for 1 second. The button lights up. Wait with any further actions until the Ready LED on the instrument front panel is lit. This may take several minutes.

C2.2 Start Gyrolab Control software

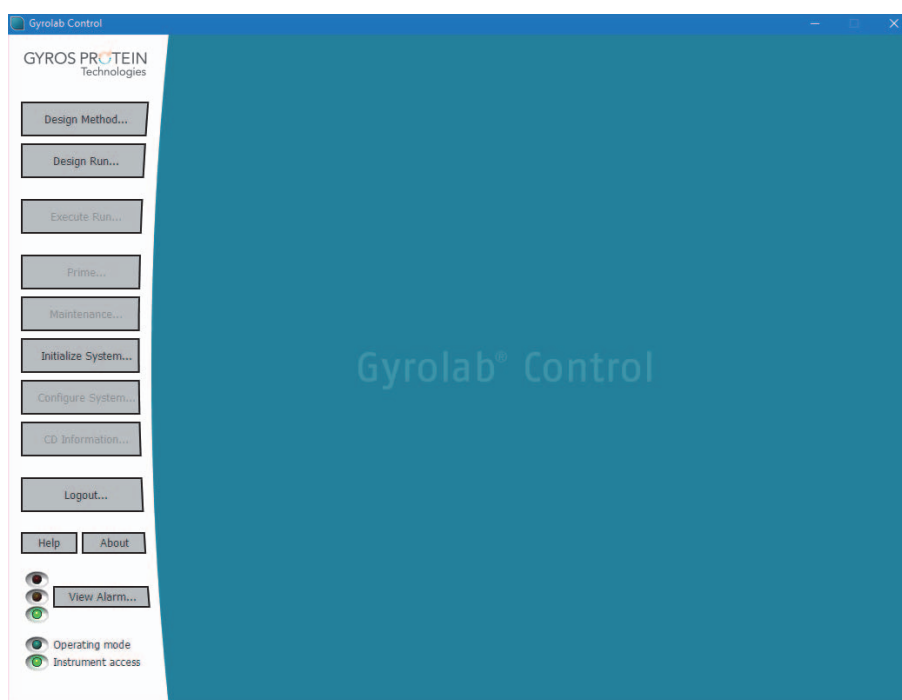
Gyrolab Control software consists of a server software and a client software. The server must be running before the client is started.

Step	Action
1.	Start Gyrolab Server: - Click Start:All Programs:Gyros:Server. Gyrolab Instrument Log is displayed and Gyrolab server icon appears on the task bar.
2.	Start Gyrolab Control software: Select Start:All Programs:Gyros:Client.
3.	Enter Username and Password in the Login dialog box and click OK. The Username and Password is the same for all Gyrolab software. For further information on user and password administration, refer to Chapter B9. Password must be changed if requested by the software. Password may also be changed when desired by the user: To change password: - Mark the check-box Change Password. - Enter current password in Password field, new password in New Password field and confirm new password in Confirm Password field. - Click OK. NOTE: <i>Username and Password are case sensitive.</i>



Step	Action

4.	Once logged in, the main screen appears.



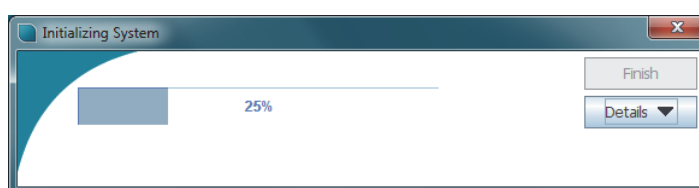
NOTE: *If no instrument access, restart the instrument.*

C2.3 Initialize the system

During initialization hardware tests of the instrument components are performed, for example robot arm movements and CD stations vacuum.

Step	Action

1.	Close the instrument hatch if open. Click Initialize System on the Main menu. The Initializing System dialog box is displayed as initialization proceeds.



Details of the initialization can be viewed by clicking on the **Details** button.

NOTE: *To re-initialize the system, click on Logout in the Main menu. Choose Restart from the drop-down menu in the Shut Down dialog, then click OK.*

2.	On success, the dialog box is automatically closed. On failures, click Finish to close the dialog box.

C2.4 Prime instrument

For optimal results it is important to prime the Gyrolab instrument before the first Run of the day. Gyrolab priming requires 15–20 minutes. Refer to Gyrolab Instrument Guide for priming instructions.

NOTE: *If the instrument has not been used for at least two weeks extra priming must be performed. Refer to Gyrolab Instrument Guide.*

C3 Prepare samples and reagents

This chapter describes sample and reagent preparation when working with Gyrolab Bioaffy CDs. For sample and reagent preparation for Gyrolab Mixing CDs, refer to E2.

This chapter applies both when a Run Design has been prepared for execution in Gyrolab Control, or when a Run Setup has been created in Gyrolab Manager.

Preparation of Capture and Detection reagents, Standard series, Calibration Controls, Quality Controls and Unknown samples for Gyrolab Bioaffy CDs and their loading into microplates is described in this chapter. Refer to Chapter A2.4 for more info on sample types. Minimum required reagent and sample volumes are specified in the Gyrolab Control Loading list.

Gyros Protein Technologies provides REXSIP® buffers for reagent and sample dilution. REXSIP buffers are optimized for all types of applications and CDs and for a variety of molecules with different analytical properties. Suitable REXSIP buffer should be selected considering sample type and species, analyte and assay format. Refer to Product Information Sheet for REXSIP buffers for recommendations on buffer selection.

The following solutions and reagents are required

- PBS-T (for recipe, refer to Chapter F2.2)
- Capture and Detection reagents
- Standard Protein
- REXSIP buffer (Refer to Product information sheet for REXSIP buffers for recommendations on buffer selection)

C3.1 Reagents and samples

C3.1.1 Capture reagent

1. Vortex Capture reagent stock solution gently.
2. Dilute in PBS-T or REXSIP to working concentration (usually 700 nM, for an antibody this corresponds to 0.1 mg/ml). For minimum required reagent volumes, please refer to the Gyrolab Control Loading list, Chapter I2.4.

NOTE: *Use fresh Capture reagent: Use new aliquots from the Capture reagent stock solution (kept in refrigerator or freezer) at least every week and prepare fresh dilutions of Capture reagent daily.*

C3.1.2 Detection reagent

1. Vortex Detection reagent stock solution gently.
2. Spin at 12 000 × g for 4 minutes to pellet any aggregates that may have formed during storage.
3. Dilute the detection reagent in REXSIP buffer (usually REXSIP F) to the optimal working concentration. Use a dark vial to minimize fluorophore exposure to light. Avoid pipetting from the bottom of the detection reagent stock tube to avoid transferring aggregates. Aggregates may affect the performance of the assay. For minimum required reagent volumes, please refer to the Gyrolab Control Loading list, Chapter I2.4.

NOTE: *Prepare fresh dilutions of Detection reagent daily.*

C3.2 Standard series and Calibration Controls

Standard series samples and Calibration Controls are crucial parts of the experiment. They must be prepared and handled with care since errors during this process will affect all concentration values for the Unknown samples.

For minimum required volumes for Standard samples, please refer to the Gyrolab Control Loading list, Chapter I2.4.

1. Take a new vial from the freezer (or from other appropriate storage).
2. Reconstitute lyophilized standards for dilution according to their product data sheet.
3. Make serial dilutions of the Standard sample proteins in appropriate Rxxip buffer.
4. Ensure sufficient mixing but do not shake.

NOTE: *For the Standard series samples used as Calibration Controls one must prepare extra volume during dilution to ensure that the volume is sufficient for both the Standard series and Calibration Control. It is very important that the Standard series sample and Calibration Control are from the identical dilution. Note that identical Standard/Calibration Control concentrations are distributed to separate microplate wells for each CD in experiments using more than one CD.*

C3.2.1 Unknown samples and Quality Controls

Quality Controls are prepared in the same manner as Unknown samples.

Step	Action
1.	Thaw sample vials completely on ice. NOTE: <i>Avoid repeated freeze and thaw cycles of samples. Aliquot samples before freezing.</i>
2.	Vortex the vials gently.
3.	For serum and plasma samples and all other samples that may contain particulate matter with cell debris or pellet, centrifuge 3000 × g for 15 min at 8 °C.
4.	Dilute samples to concentration specified in the Loading List using appropriate Rxxip buffer. The dilution factor needs to be optimized for each analyte, assay format and matrix. Dilution should be made so that buffer characteristics are as similar as possible for all samples.
5.	Ensure sufficient mixing. Use microtubes for mixing of small samples volumes.

C3.3 Load microplates

Step	Action
1.	Add reagents, samples and solutions to microplates. Sample volume, microplate name and microplate well is specified in Gyrolab Control Loading list. • Capture reagent • Detection reagent • Unknown samples • Quality Controls • Standard series samples • Calibration Controls • Blanks • Wash solutions (For recipe, see Chapter F2)
2.	Cover filled wells temporarily during preparation of microplates (for example with PCR lids) to avoid evaporation.
3.	When a microplate is loaded, apply Microplate Foil using a Microplate Foil Adapter. Instruction is supplied together with Microplate Foil Adapter.
4.	Centrifuge microplates at 3000 × g for two minutes. This is done to eliminate bubbles in the microplate wells and to ensure that the samples are at the bottom of the wells. Examine microplates after centrifugation to make sure that no bubbles are present.
NOTE: <i>Do not stack microplate foil-sealed microplates on top of each other. The microplate foil may get perforated which may cause evaporation from wells.</i>	
NOTE: <i>Contamination risk! Microplate wells must not contain more than 100 µl of any solution. Needles are not washed higher than 1 cm.</i>	

C4 Start Run procedures

The procedure for starting a Run depends on how the preparation has been performed.

The recommended way to execute a Run is by creating a Run Setup in Gyrolab Manager, see Chapter B4. How to start the Run in this case is described in Start Run from Run Setup, Chapter C4.1.

If the Run has been prepared using Gyrolab Control, see Chapter I2.4 for Wizard Design type, the start Run procedure is described in Start Run from Gyrolab Control Run Design, Chapter I7. This chapter also applies when starting a Run of another Design type than the Wizard Design type.

C4.1 Start Run from Run Setup

The workflow described in this chapter is used when starting a Run based on a Run Setup which has been created in Gyrolab Manager. A Run Setup includes all information required to start the Run.

Step	Action

1.	Click Execute Run on the Main menu.

2.	Click Run Setup...

Run... is used to execute Runs based on a Run Design created in Gyrolab Control and cannot be used to execute a Run based on a Run Setup.

Step Action

3. A screen is opened:

The screenshot displays a software interface for managing run setups. It features two main panels: 'Queued Run Setups' on the left and 'Run Setups to Execute' on the right. The 'Queued Run Setups' panel contains a list of two items: 'BA4399-003 Gyros AB, 4/13/18 9:14 AM' and 'Reagent R2, QA run Gyros AB, 4/13/18 9:13 AM'. A 'Refresh' button is located above this list. Between the two panels are two arrow buttons (left and right). The 'Run Setups to Execute' panel is currently empty. On the right side of the interface is a blue sidebar with 'OK' and 'Cancel' buttons. Below the main panels is an 'Info' section containing various input fields for metadata: 'Created by', 'Modified by', 'Queued by', 'Nr. of CDs', 'Nr. of MPs', 'Uses cooling' (with a checkbox), 'Description', 'Created at', 'Modified at', 'Queued at', 'Run Setup version nr.', and 'Loading List version nr.'.

A list of all Run Setups that have been queued for execution is presented in **Queued Run Setups**.

Run Setups that are still in development are not listed.

To refresh the list, click Refresh. This is useful if a Run Setup has been queued for execution recently – and does not appear in the list.

Select a Run Setup to display information on it.

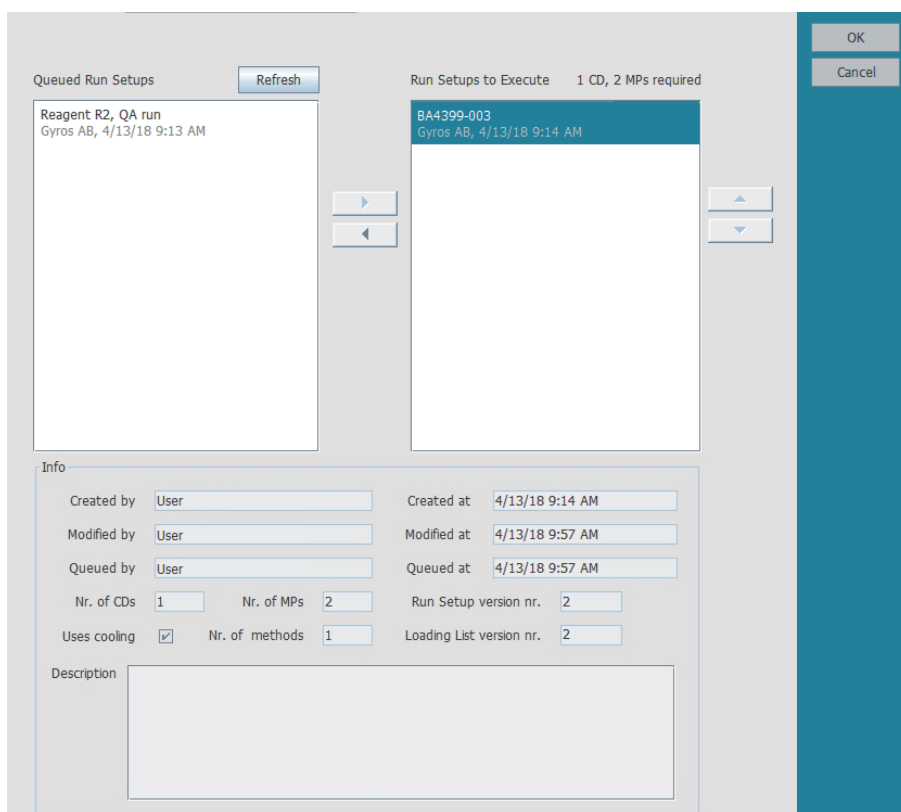
Step Action

4.

Select the Run Setup to execute and click . The selected Run Setup will be moved to the right side, in the list **Run Setups to Execute**.

NOTE: *It is important to verify that the Loading List used to prepare the microplates has the same version number as is presented in the Run Setup information section, in the Loading List version nr. text box. If the version numbers printed on the Loading List differs from the number presented in the information section, please return to Gyrolab Manager and verify that the microplate preparation follows the specification in the latest Loading List for the Run Setup. The Loading List can be opened from the Gyrolab Manager main menu, by right clicking the Run Setup and selecting Loading List...*

Click  to remove a Run Setup from the **Run Setups to Execute** list.



The screenshot displays the Gyrolab Manager interface for configuring a run. It features two main lists: 'Queued Run Setups' on the left and 'Run Setups to Execute' on the right. The 'Queued Run Setups' list contains one entry: 'Reagent R2, QA run' with a timestamp of '4/13/18 9:13 AM'. The 'Run Setups to Execute' list contains one entry: 'BA4399-003' with a timestamp of '4/13/18 9:14 AM'. Between the lists are navigation buttons: a right arrow to move a setup from queued to execute, and a left arrow to move a setup from execute back to queued. Below the lists is an 'Info' section for the selected Run Setup. It includes fields for 'Created by', 'Modified by', 'Queued by', 'Nr. of CDs', 'Nr. of MPs', 'Run Setup version nr.', 'Uses cooling', 'Nr. of methods', 'Loading List version nr.', 'Created at', 'Modified at', and 'Queued at'. The 'Description' field is also present. On the far right, there are 'OK' and 'Cancel' buttons.

To execute a single Run Setup, continue to step 5.

5.

Gyrolab instruments allows multiple Runs to be executed together, in sequence. To do this, select additional Run Setups in the list and add them to the **Run Setups to Execute** list. The Runs will be executed in the order they have in the list. Use the up and down buttons to change the order.

Next to the **Run Setups to Execute** list title, the total number of CDs and microplates in the selected Run Setups is presented. The total must not exceed what the instrument supports.

Step Action

6. When selection of Run Setup(s) is done, click **OK**. A screen is opened presenting the microplates, CDs, and liquids required to start the Run.

If multiple Run Setups were selected, the loading screen will include the microplates and CDs needed for all the Run Setups.

7. The following screen shown is used as a checklist before starting a Run. A green indicator is lit for each step performed.

CDs: 1 x Gyrolab Bioaffy 200

Microplates

Run Setup	Type	Identity	Sector	Nr. of u...	Cooling	Available
test	MP96 PCR	#1MP-1			No	Not Loaded
test	MP96 PCR	#2MP-2			No	Not Loaded

Unload... Load...

CDs

Run Setup	Type	Identity	Segments	Status
test	Gyrolab Bioaffy 200			

Unload... Load...

1 CD is needed, 0 loaded

Wash Station Solutions

Solution	Wash Station
Bioaffy wash station solution 1	1

Confirm Connect...

Pump Liquids

Liquid	Pump
Bioaffy pump liquid	1, 2, 3, 4, 5

Confirm Connect...

Cancel

Start

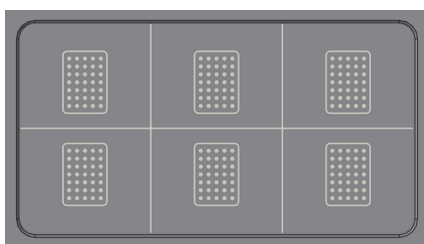
Pause 1st 10 min

Step Action

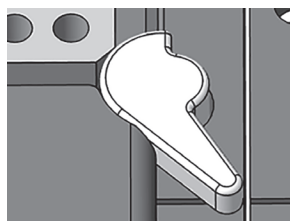
8. Load samples and reagents.
 - Centrifuge microplates (4000 x g for two minutes) to eliminate bubbles and ensure that there is liquid at the bottom of the wells.
 - Click **Load...** button in the **Microplates** section of the screen. The **Microplate ID** dialog opens.
 - Read the bar code of the microplate or enter microplate identity manually.*

NOTE: *The bar code reader is optional and is not provided by Gyros Protein Technologies or included with Gyrolab xPand.*

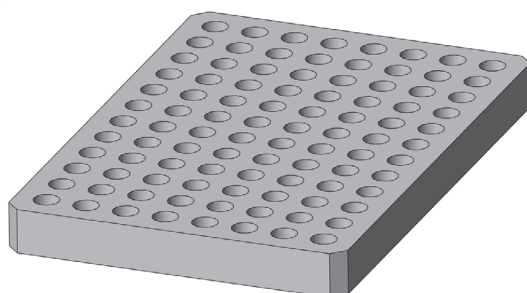
- Place the sample microplate in the microplate position indicated by the lit green LED beside the microplate positions in the instrument, for Gyrolab xP insert the microplate in carousel loading position, and click **Confirm**.



- The microplate locking lever must be opened by pulling it forward while inserting a microplate.
- Make sure that the microplate locking lever is in the locked position, see Instrument Guide for details..



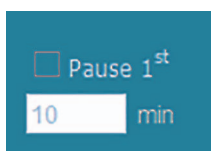
- For Gyrolab xPand, if cooling of microplates is used during the Run, use the metal cooling microplate insert to get optimal cooling of sample and reagents.



9. Repeat step 8 for additional microplates.
10. Load CDs.
 - Click **Load...** in the **CD Data** section of the screen. The **Load** dialog opens.
 - Place the CD on the loading position.
 - For Gyrolab xPlore, close the hatch.
 - Click **Load** button.
11. Repeat step 10 for additional CDs.

Step	Action

12.	Confirm Wash Station Solutions . - Highlight Wash Station Solution. - Click the Confirm button.
13.	Confirm Pump Liquid . - Highlight the Bioaffy Pump Liquid. - Click the Confirm button.
14.	When loading is complete and all green indicators are lit, close the Gyrolab hatch.
15.	Click Start button to start the Run. - Pause an ongoing Run by clicking Pause button. Click Resume button to resume the Run. - Stop an ongoing Run by clicking Abort.
16.	The run can be set up to automatically pause after the first CD is completed.



Responses for this CD can be viewed in Gyrolab Evaluator. The execution will automatically resume after the specified time has elapsed .

- * Ensure the Bar Code Reader is configured so that **Enter** or **Carriage Return** is not added when scanning the identity of a MP.

C5 After Run procedures and result export

C5.1 Finish Run

When the Run is completed microplates and CDs must be unloaded from the instrument.

Unloading is carried out in the same way as the system is loaded, that is by following the instructions on the screen. After each step has been completed, a green indicator is lit on the left side of each section.

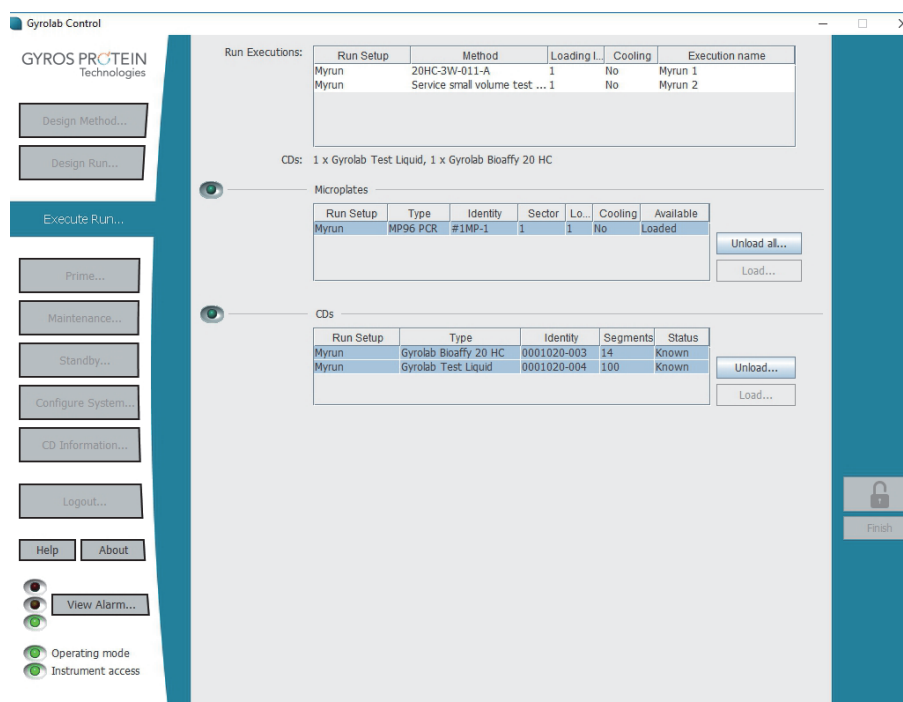
The procedure for finishing a Run depends on how the Run was started.

If the Run was started from a Run Design, see Chapter I7, for information on how to Finish the Run.

Use the workflow below if the Run was started from a Run Setup created in Gyrolab Manager.

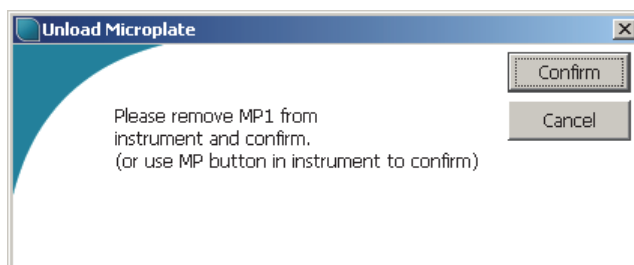
Step Action

1. The system stops automatically when the run is completed. Click **Finish**. The **Execute Run** screen, a checklist for unloading, appears:



Step	Action

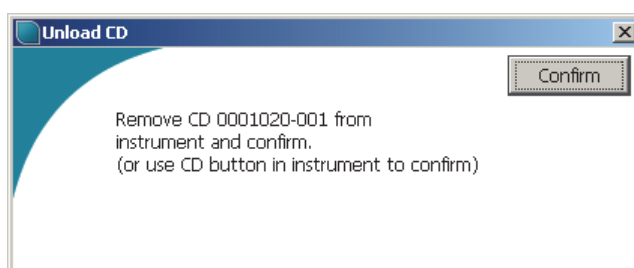
2.	In Microplates section, click Unload all.... The Remove CD and Microplate dialog opens.



- Remove plates.
- Click **Confirm**.

NOTE: For Gyrolab xPlore, the Remove CD and Microplate dialog prompts "Please remove the CD and all of the Microplates and confirm".

3.	In CD Data section, click Unload . The Unload CD dialog opens.

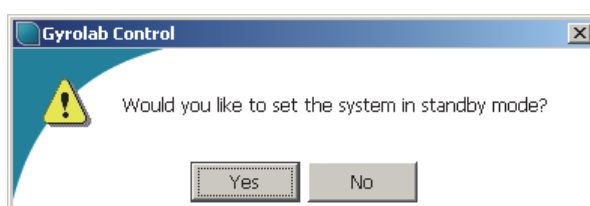


- Remove CD.
- Click **Confirm**.
- Repeat for all CDs.

4.	Click Finish .

NOTE: Finish cannot be activated until all indicators are lit in the screen to indicate that unloading is complete.

The **Standby** dialog opens.



- If another Run is scheduled later during the day, click **No** and start the new run.
- If it is the last Run of the day, click **Yes**. The **Ensure enough standby solution is available** dialog opens. Connect tubings for Standby solutions and click **OK**. Standby procedures will start.

Standby procedures means priming Syringe Pumps and Wash Stations with **Standby Solution**. It is recommended to put system in Standby mode at least three times a week. For more information, refer to Gyrolab Instrument Guide.

Step	Action

5.	For Gyrolab xPand, remove the metal cooling microplate insert. Wipe microplate positions dry if cooling of microplates has been used.

C5.2 How to turn Gyrolab off

For details on how to turn Gyrolab instrument off, see Gyrolab Instrument Guide.

C5.3 Generated Gyrolab Control files

There are several types of files generated by Gyrolab Control. Files are available in the Gyrolab database and accessible through Gyrolab Database Explorer.

Copies of files may be available in other locations as set during run preparations. The locations are displayed in the log panel after a Run.

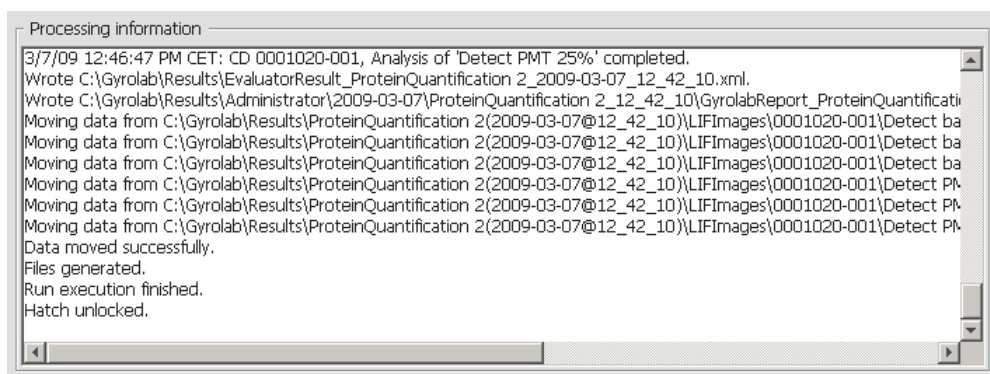


Figure 1: Run log panel showing location of generated files.

GYROLAB USER GUIDE

D Data analysis



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D1 Introduction to data evaluation

This chapter gives an introduction to, and describes structure and functionalities available within Gyrolab Evaluator.

D1.1 Gyrolab Evaluator introduction

Gyros Protein Technologies provides software to facilitate data evaluation of Runs performed on the Gyrolab instrument.

- **Gyrolab Evaluator** is part of the base software package installed on all Gyrolab systems. It is designed analyze data from Gyrolab Runs. Several evaluation functions and setting options are available to achieve optimal quantification results. For an introduction to Gyrolab Evaluator, refer to Chapter D1 and for instructions on how to use Gyrolab Evaluator, refer to Chapter D4.

Available Add-ons and plug-ins:

- **Gyrolab Viewer** is an add-on software module to Gyrolab Evaluator used to study the binding profiles in Bioaffy CD columns produced during data evaluation. This can be useful during assay optimization to help identify suitable reagents, during trouble shooting to investigate outliers and for quality control purposes. For instructions on how to use Gyrolab Viewer, refer to Chapter E1.

D1.2 Gyrolab Evaluator main features

D1.2.1 Data analysis

Using the **Quantification** module, analyses of selected Runs using certain analysis settings are performed. Different analysis settings can be tested to find optimal curve fits. Samples are quantified using the selected Analysis settings. Subsets of Run results are selected for inclusion in Reports and the resulting analysis report is displayed in the Project view under **Analyses:Quantification** (refer to Chapter D4.1).

Different analyses are compared using the **Data Comparison** module (Chapter D4.2). For example it is possible to compare sample data and standard curves from different experiments in the same Run or from different Runs. This can for example be used when comparing different assay development Runs, when comparing routine analyses performed at different occasions or for quality tests. Data to be compared must be quantified in the same Project.

To analyze and monitor any trends in QC data over time in a selected number of quantified Runs, one can use the **QC Trending** module (Chapter D4.3). This can for example be used as an aid during routine assays to analyze if a QC from a batch is performing as expected with no visible trends nor deviations, if an instrument is consistent between runs and comparing how results can differ depending on the operator.

D1.2.2 Analysis settings

There are several settings available for data analysis. Examples of analysis settings for the Quantification module are curve fit models and acceptance criteria. Analysis settings can be set for an entire **Project** (option to lock settings), refer to Chapter D3.8, or for a specific analysis, refer to Chapter D4.1.

D1.2.3 Storage of analyses

In order to store analyses of Run results in a GxP compliant and traceable manner, the following features are used.

- **Project:** Run results from one or more Runs are added to analysis entities named Projects. Within a Project, selected Run results are analyzed using one or several analysis modules. The resulting **Analyses** are included in the Project. Analysis setting may be locked for a Project. All analyses are logged in the **Audit trail**. If the Project is set to **Approved** status it can be opened and viewed but no additional analyses can be made.
- **Folder structure:** In order to organize Projects, a folder structure is available.
- Run result files, Analyses, Projects and Structure folders are stored in a specific Gyrolab database connected to the Gyrolab Evaluator.

D1.2.4 Traceability of analyses

- To ensure data integrity and traceability to comply with GxP requirements, all data modifications are recorded in an **Audit Trail** (Chapter D2.3 and Chapter D3.10).
- To further increase traceability, it is possible to require users to enter change descriptions for Analyses and Projects.

D1.2.5 Export of reports

Analysis reports and Audit trail reports can be exported in different formats, refer to Chapter D2.3 and Chapter D3.11.

D2 Log in, main menu functions and analysis administration

This chapter describes log in procedure and available functions in the main menu of Gyrolab Evaluator.

For instructions on how to install Gyrolab Evaluator on a office computer, refer to Chapter D5.

D2.1 Start and log in

Step	Action

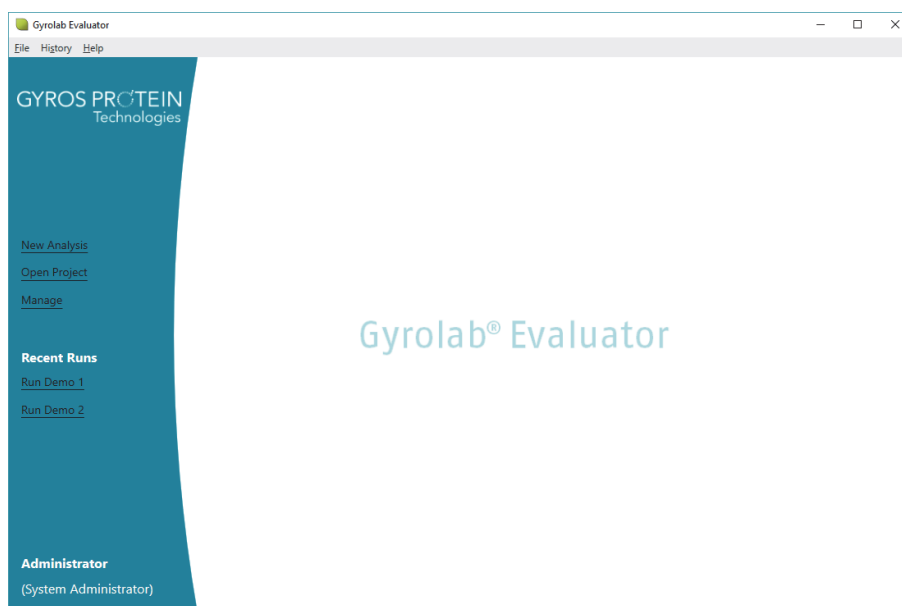
1.	Start Gyrolab Evaluator: Select Start:All Programs:Gyros:Gyrolab Evaluator .
2.	Enter Username and Password in the Login dialog box and click OK . The Username and Password are the same for all Gyrolab software. For further information on user and password administration, refer to Chapter B9 Password must be changed if requested by the software. Password may also be changed when desired by the user. To change Password: • Mark the check-box Change Password. • Enter current password in Password field, new password in New Password field and confirm new password in Confirm Password field. • Click OK.

NOTE: Username and Password are case sensitive.

NOTE: The software will request the user to log in anew when the system has been inactive for a specified time. This time is controlled by system setting "Maximum inactivity time". For more information, see Chapter B10.

Step Action

3. Gyrolab Evaluator Start view opens.



The following options are available:

- Click **New Analysis** to add Run(s) to a new Project, perform analysis and then save or discard the new Project, refer to Chapter D2.2.
- Click **Open Project** to open an existing Project to view or add/remove Runs and analysis in the Project, refer to Chapter D2.2.2.
- Click **Manage** to create a new Project, edit analysis setting for a Project, manage the Folder structure or perform searches within Projects, refer to Chapter D2.2.3.
- Click on desired Run under **Recent Runs** to add this run to a new Project, refer to Chapter NOTE:.

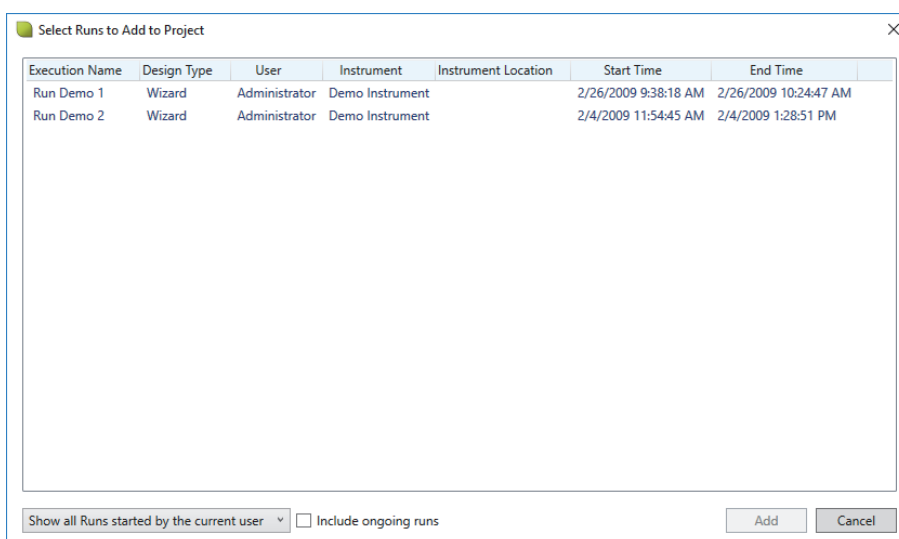
In the lower left corner current user and their user role is shown. Some actions are restricted to certain user roles. For information of user roles, refer to Chapter G2.2.7.

D2.2 Main menu functions

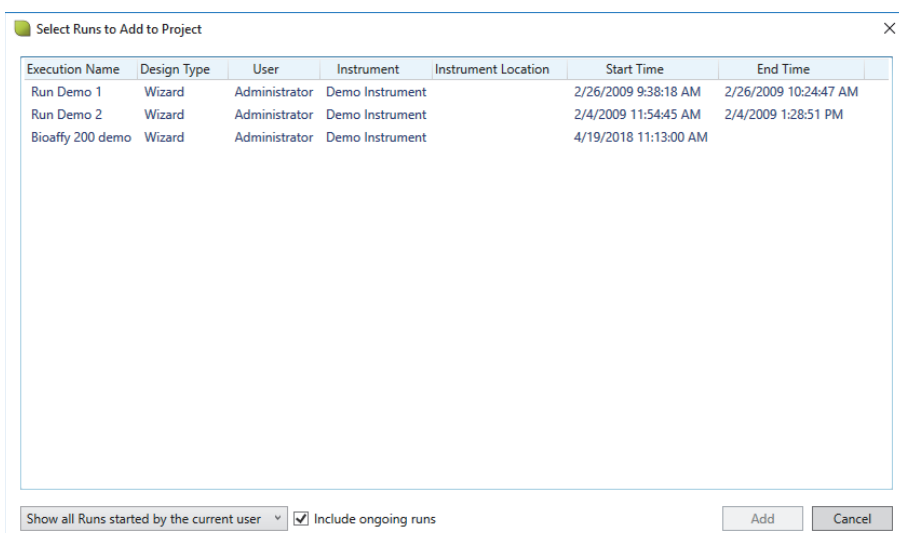
D2.2.1 New Analysis menu

Step Action

1. Click **New Analysis** in Gyrolab Evaluator start view.
2. A dialog opens.
Select one or more Runs to be analyzed and click **Add**.



- Unselect a Run by clicking on the name again.
- Use the drop down list in the lower left corner to view different subsets of Runs or all available Runs.



- When **Include ongoing runs** is checked, the window will also present ongoing runs where at least one CD has been finished. Ongoing runs can be identified by not having any **End Time**. If a project contains an ongoing run then the project cannot be saved. Ongoing runs contains the processed structures from finished CDs. The run must have been executed on a system with Gyrolab Control version 8.0 or higher to evaluate ongoing runs.

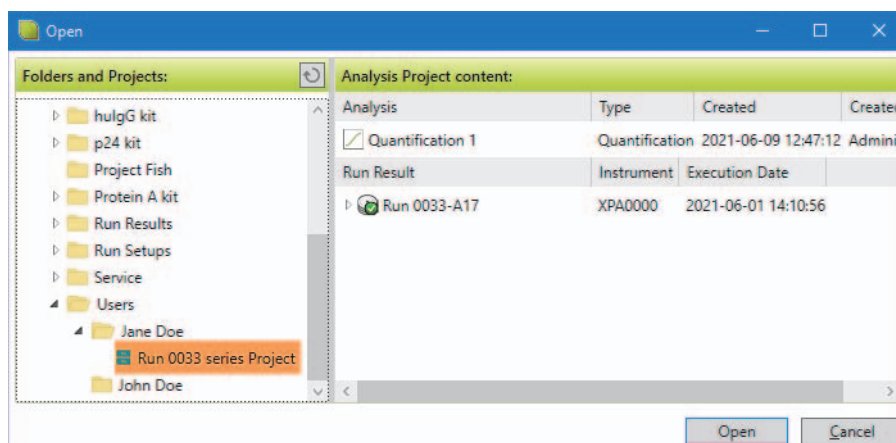
Step Action

3. Gyrolab Evaluator Project view opens.
 - For more information on the Project view and how to manage and save the new Project, refer to Chapter D3.
 - To perform data analysis on a Run, refer to Chapter D4.1 and Chapter D4.2
 - To discard the project, click **File:Close** or the or click Close button  to close the Project.

D2.2.2 Open Project menu

Step Action

1. Click **Open Project** in Gyrolab Evaluator start view.
2. The **Open** widow is displayed. In the Folder structure, browse to find the desired Project.



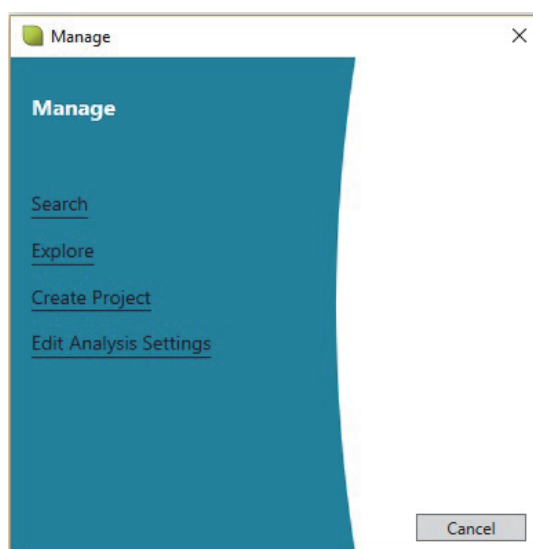
Select Project and click **Open**.

3. Gyrolab Evaluator Project view opens.
 - To manage and save the Project, refer to Chapter D3.
 - To perform data analysis on a Run, refer to Chapter D4.1 and Chapter D4.2.

D2.2.3 Manage menu

The **Manage** menu allows the user to perform administration functions related to Project management.

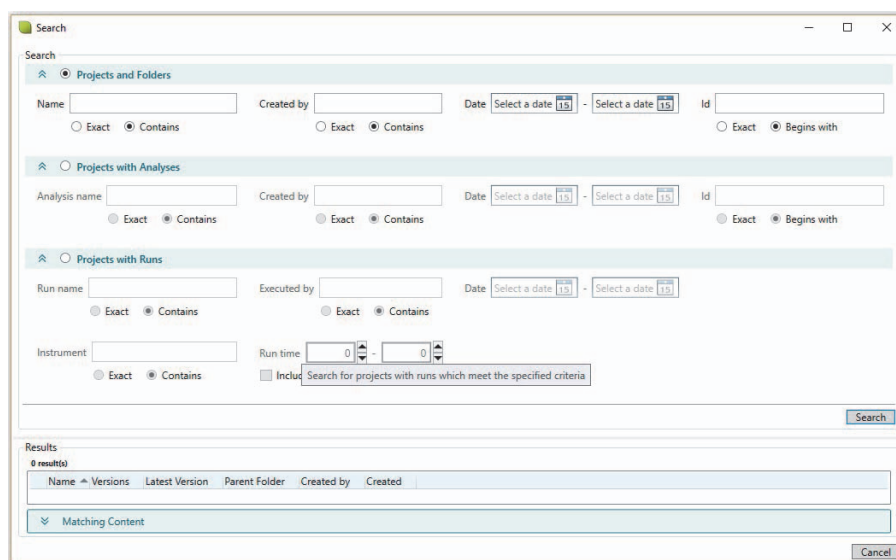
- To search for Project folders , Runs and Analyses, refer to Chapter D2.2.3.1
- To explore and manage Folder structure, refer to Chapter D2.2.3.2
- To create a new Project, refer to Chapter D2.2.3.3
- To edit analysis settings for a Project, refer to Chapter D2.2.3.4



D2.2.3.1 Search for Folders, Projects, Runs and Analyses

Step Action

1. Click **Manage** in Gyrolab Evaluator start view, and click **Search** in the **Manage** window.
2. In the **Search** section, set search criteria for one of the following items:
 - Projects and Folders
 - Projects with Analysis
 - Projects with Runs



3. For Projects and Analyses it is possible to include identity number in search criteria. The identity number is a unique identifier for the Project or Analysis.
 Project identity number is found on Projects that have been printed or been saved to .xps format.
 Analysis identity number is found at the bottom of Analysis reports.

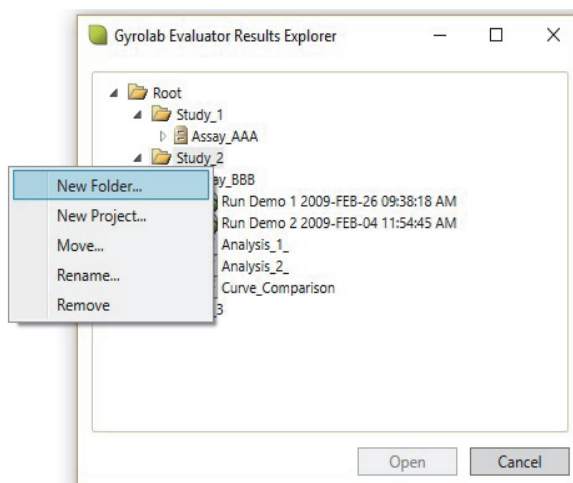
Step	Action

4.	Click Search .
5.	Results are displayed in the Results section. Sort by specific column by clicking on column title.

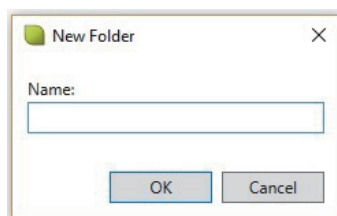
D2.2.3.2 Explore folder structure

Step	Action

1.	Click Manage in Gyrolab Evaluator start view and click Explore in the Manage window.
2.	A window opens where it is possible to browse the folder tree and interact with objects stored in folders. Gyrolab Evaluator uses the same folder tree as Gyrolab Control and Gyrolab Manager. For general information on the folder tree and its operations, see Chapter B3.1. Functions specific to Gyrolab Manager, like creating or editing Run Designs and Run Setups, are not available in Gyrolab Evaluator. On the other hand, some operations not available in Gyrolab Manager, like opening a Gyrolab Evaluator Project, are available. To open a Project, select the Project and click Open .
3.	To create a new Folder or a new Project, right-click on desired parent Folder and select New Folder or New project .



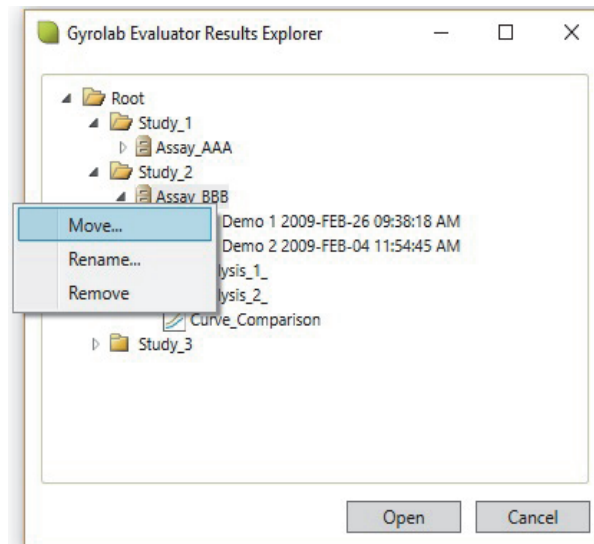
A dialog opens.



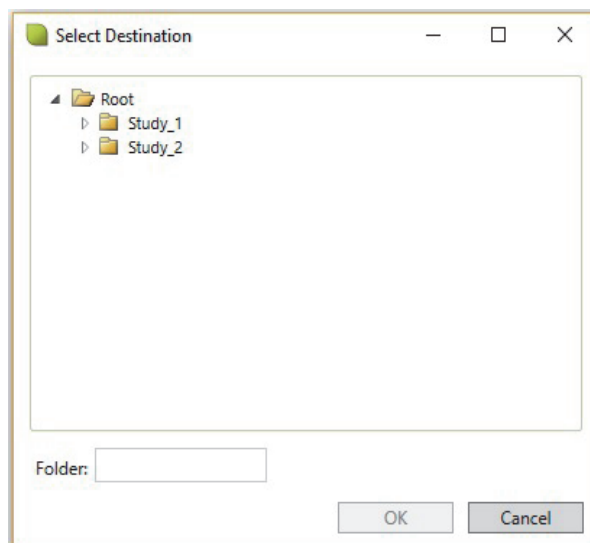
- Enter a name for the new Folder or new Project and click **OK**.
- Click **Cancel** to abort Project/Folder creation.

Step Action

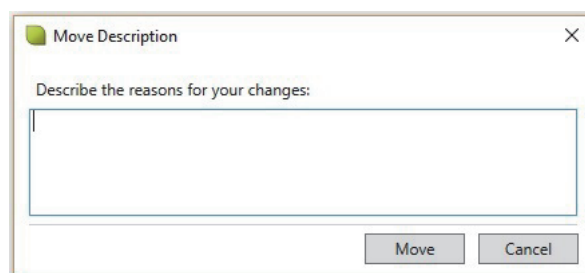
4. To move an existing Folder or Project, right-click on the Folder or the Project and select **Move**.



- Select the new parent Folder and click **OK**.

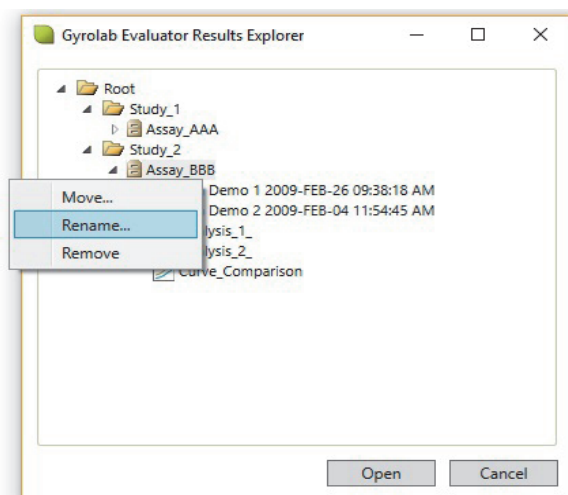


- For Projects: Enter a reason for the move. The description is saved in the Audit trail. Click **Move**.

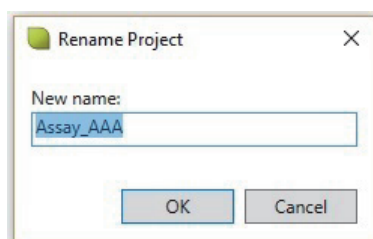


Step Action

5. To rename an existing Folder or Project, right-click on the Folder or the Project and select **Rename**.

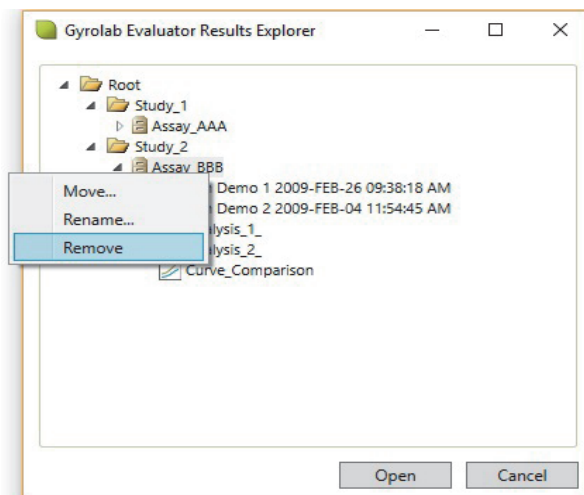


Enter the new Folder or Project name and click **OK**.

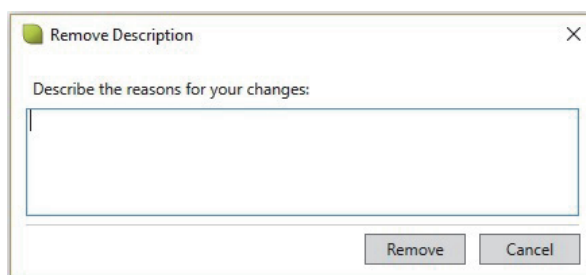


Step Action

6. To remove an existing Folder or Project, right-click on the Folder or the Project and select **Remove**.



For Projects: enter a reason for the removal. The description is saved in the audit trail. Click **Remove**.



NOTE: Folders can only be removed if they are empty.

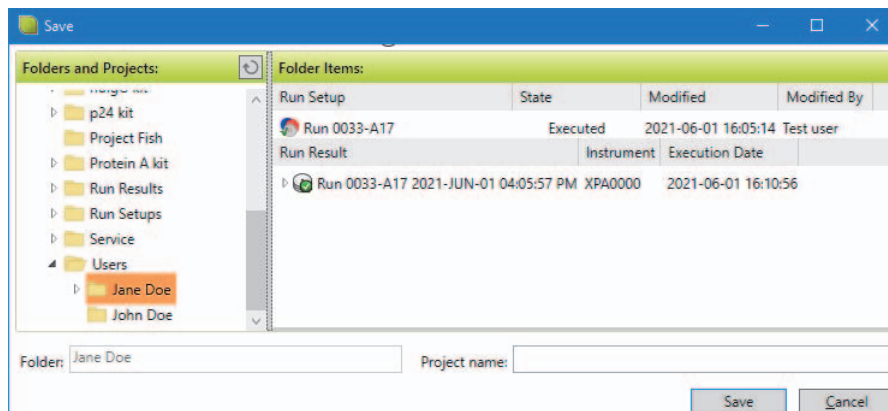
D2.2.3.3 Create new Project

Step Action

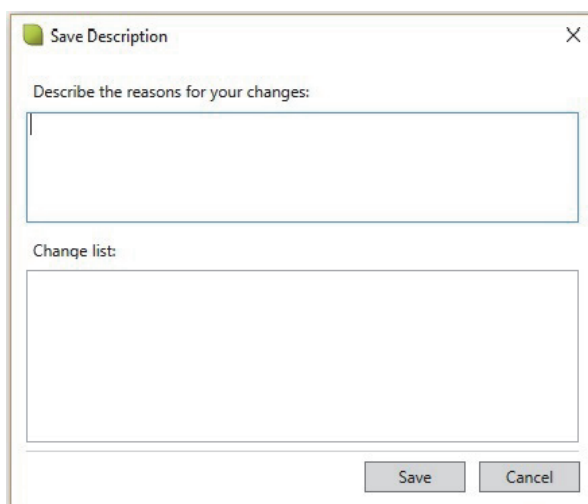
1. Click **Manage** in Gyrolab Evaluator start view, and click **Create Project** in the **Manage** window.

Step Action

2. The **Save** window opens. In the folder structure in the left panel, browse to desired Folder in which the new Project will be placed, and click to highlight that Folder.



3. Enter desired Project name in the **Name:** text box and click **Save**.
4. The **Save Description** window opens.



5. Enter a comment in the text box to describe the Project rationale. The comment is saved in the Audit trail.

D2.2.3.4 Edit analysis settings for Project

Step	Action
1.	Click Manage in Gyrolab Evaluator start view, and click Edit Analysis Settings in the Manage window.
2.	Refer to Chapter D3.8 for further instructions.

D2.2.4 Recent Runs menu

Step	Action
1.	Click on one of the run names displayed below the Recent Runs headline in Gyrolab Evaluator start view.
2.	The Project view opens where the chosen Run has been added to a new Project. - For more information on the Project view and how to manage and save the new Project, refer to Chapter D3. - To perform data analysis on a Run, refer to Chapter D4.1 and Chapter D4.2 - To discard the project, click File:Close or the or click Close button to close the Project.

D2.3 Gyrolab Evaluator Audit trail

All system and Project modifications are logged together with information on user identity, time and, where applicable, version in the Audit trail. This is done to ensure full traceability of results. It is possible to export and print Audit trail reports. This chapter describes Audit trail for Gyrolab Evaluator, refer to Chapter D3.10 for information on Project-specific Audit trail.

Gyrolab Evaluator Audit trail, except for Project-specific Audit trail, is collected and stored in the same way for all Gyrolab software applications¹.

Audit trail for a Gyrolab user can be presented from the User administration tool in Gyrolab Manager. See Chapter B9.1.

D2.4 Close Gyrolab Evaluator

Select **File:Exit**.

1. Gyrolab Evaluator version 3.6 and older used another system for storing non-project audit trail. This information has been migrated to be part of the user audit trail when updating to Gyrolab Evaluator version 3.7. Project-specific audit trail in Gyrolab Evaluator has not been changed.

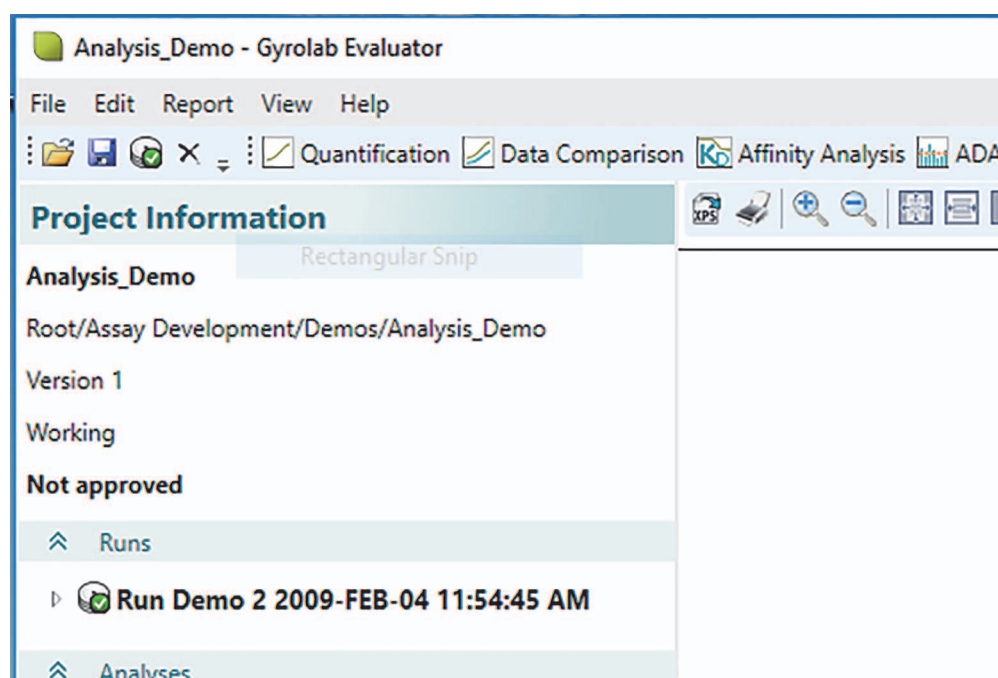
D3 Manage analysis projects

This chapter describes how to handle analysis project functionalities within Gyrolab Evaluator.

All analyses of Gyrolab Runs are organized in Gyrolab Evaluator Projects. For an introduction of how to use Projects, refer to Chapter D1.2.3.

D3.1 Project view

The Project view is reached by selecting **New Analysis** or **Open Project** in the Gyrolab Evaluator Start view described in Chapter D2. In the Project view a number of actions are available, refer to Chapter D3.2 to Chapter D3.11.2 for instructions.



- Runs in the Project are shown under **Runs**.
- Analyses in the Project are shown under **Analyses**.
- Report content for selected Run or Analysis is shown in the right part of the view. To change displayed report, select the desired Run or Analysis.

Project Information item	Name / Status (example from figure above)	Description
Project name	Analysis_Demo	For Projects not yet saved the Project name is missing.
Folder path	Root/Assay Development/Demos/Analysis_Demo	Project position in Folder structure. For Projects not yet saved the folder path is missing.
Project version	Version 1	Version status is increased every time the Project is saved. Version 0 is an unsaved Project.

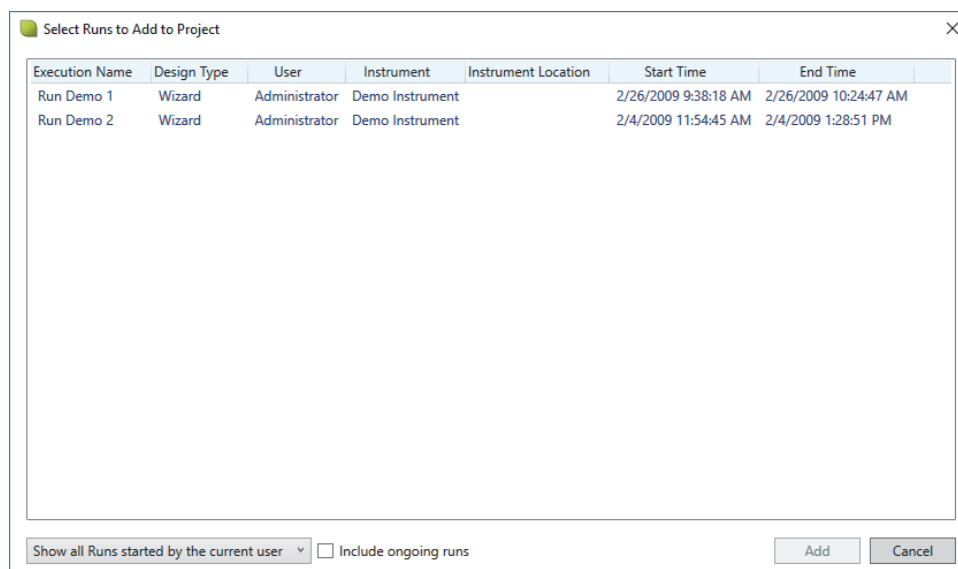
Project Information item	Name / Status (example from figure above)	Description
Project status	Working	Project status Not saved for an unsaved new Project. Project status Working for open Projects. Project status Replaced for earlier versions of a Projects. Refer to Chapter D3.10 for information on how to open previous versions of a Project.
Approval status	Not approved	Not approved status is set for all active Project. Approved status locks the Project for further actions. Only users with user role System Administrator and Project Manager can change approval status to Approved, refer to Chapter NOTE: for more information on user roles.

Runs	Example	Description
Run name	Demo Run 2 2009-FEB-04 11:54:45 AM	The Run name is generated during the Run on a Gyrolab instrument and consists of the execution name filled in before run start in Gyrolab Control and a time stamp. It can not be changed.

Analyses	Example	Note
Quantification analysis name and version	Quantification 1	Each quantification analysis is given a name which can be changed by the user if desired. In brackets the status is given: (nothing is shown or status New or Changed). Version number is available as a tool tip.
Data comparison analysis name and version	Data Comparison 1	Each Data comparison analysis is given a name which can be changed by the user if desired. In brackets the status is given: (nothing is shown or status New or Changed). Version number is available as a tool tip.

D3.2 Add and remove run in Project

- Click **Edit:Add Run** or the button  to add a Run to an open Project.
- A dialog opens.



- Select one or more Runs to be analyzed in the Project and click **Add**.
- Unselect a Run by clicking on the name again.
- Use the drop down list in the down left corner to view different subsets of Runs or all available Runs.
- Select a Run in the **Runs** list and click **Edit:Remove Selected Run** to remove a Run from a Project.

D3.3 Add, remove and export analyses in a Project

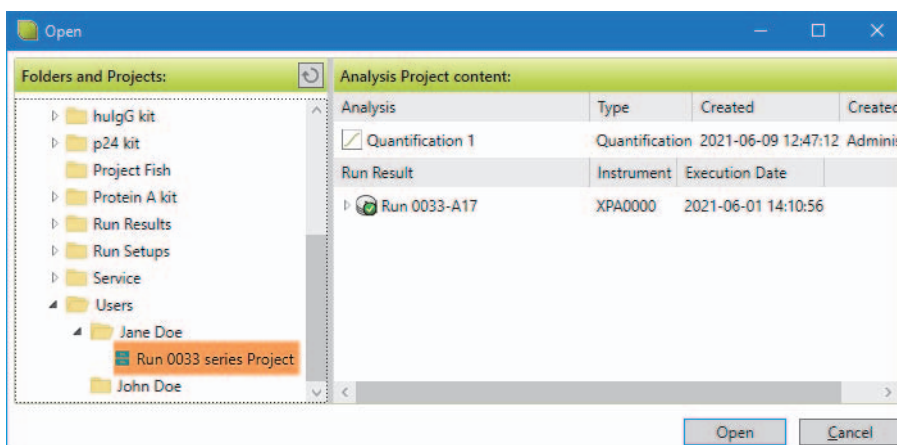
- To add analyses to the project, click **Quantification**  **Quantification** (refer to Chapter D4.1) or click **Data Comparison**  **Data Comparison** (refer to Chapter D4.2).
- To remove an existing analysis from a Project, select the Analysis in the **Analyses** list and select **Edit:Remove Selected Analysis**. This action requires System Administrator or Project Manager user role privileges.
- To export (save to file) an existing analysis, select the Analysis in the **Analyses** list and select **File:Export Selected Analyses**. To perform this step the Project must be saved. All modifications are logged in the Audit Trail.

NOTE: *No further traceability of the file and data is supported by the Gyrolab system when analysis is exported.*

D3.4 Open a Project

Step Action

1. In the project view, select **File:Open Project** or click .
NOTE: *The Open Project dialog is also available from the Gyrolab Evaluator start view.*
2. The **Open** window opens. In the folder structure in the left panel, browse to the Folder in which the desired Project is present.



3. Click to highlight Project name in the right panel and click **Open**.

D3.5 Save a Project

NOTE: *If no change has been made in a Project it is not possible to save it.*

Step Action

1. In the Project view select **File:Save Project** or click .
2. The **Save Description** window opens.

Step	Action

3.	Enter a comment in the text box to describe the reasons for Project changes. The comment is saved in the Audit trail .

4.	Click Save .

D3.6 Close a Project

Step	Action

1.	In the Project view select File:Close or click  .
2.	If the Project has unsaved changes the Save Project dialog opens. - Click Yes to save changes. The Save Description window opens, refer to Chapter D3.5. - Click No if the changes are not to be saved.

D3.7 Approve/Unapprove a Project

Approved Projects are locked for further action. It is possible to open it but no new analyses can be saved. To approve a Project user role Project Manager or System Administrator is required.

Approved projects can be unapproved. It is possible to edit unapproved Projects. To unapprove an approved Project user role System Administrator is required.

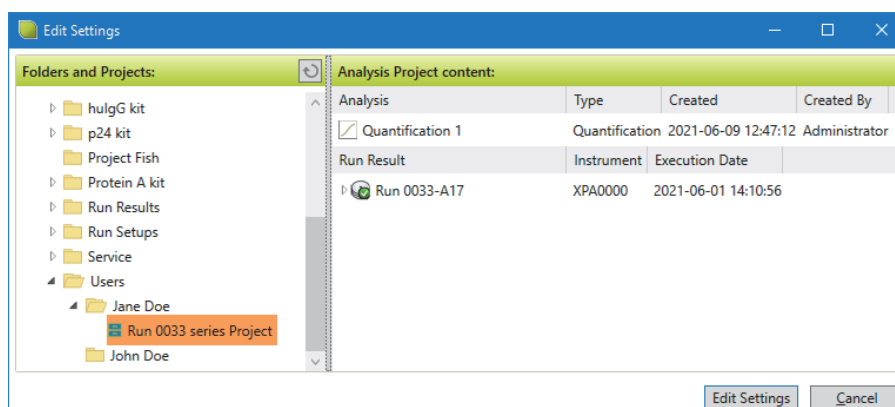
- Select **Edit:Approve Project** to approve a project. The action is logged in the system audit trail (Chapter D2.3).
- Select **Edit:Unapprove Project** to unapprove an approved project. The action is logged in the system audit trail (Chapter D2.3).

D3.8 Set analysis settings for a Project

Analysis settings for a Project determines the default settings for data evaluation for all analyses within the Project. It is possible to lock analysis settings for a Project. This will ensure that all analyses performed within the Project are carried out in a consistent manner.

Step Action

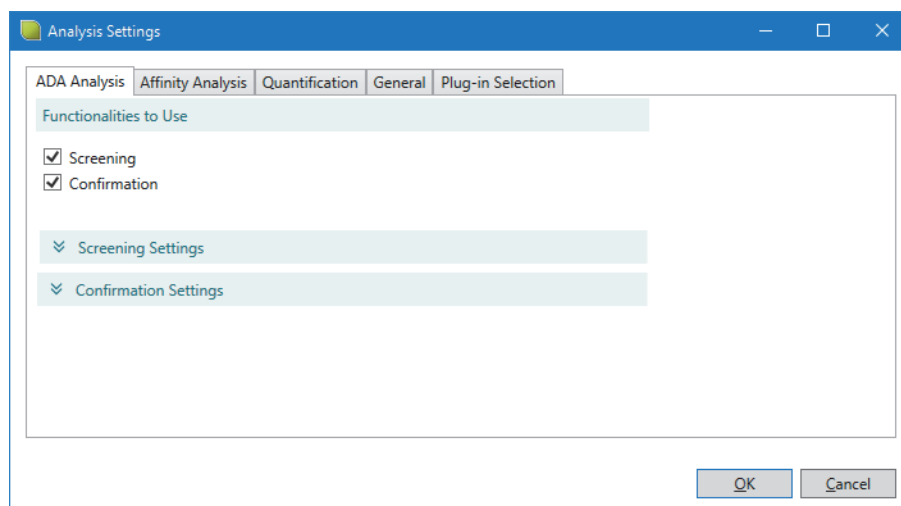
1.
 - To edit and set analysis settings for a Project already opened, click **View:Analysis Settings** and follow step 5 to step 11 below.
 - To edit and set analysis settings for a Project not opened, click **Manage** in Gyrolab Evaluator start view and follow step 2 to step 11 below.
2. Click **Edit Analysis Settings** in the **Manage** window (The Manage window is available from Gyrolab Evaluator main menu).
The **Edit Settings** window opens.
3. In the folder structure, browse to the Folder that contains the Project for which analysis settings are to be changed and click to highlight that Folder.



4. Click to highlight desired Project.
Click **Edit Settings**.

Step Action

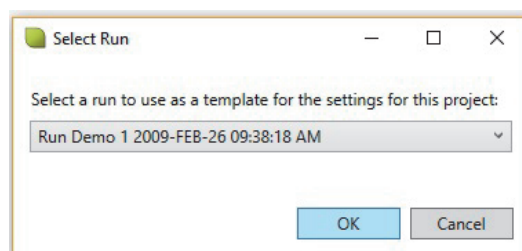
5. The **Analysis Settings** window opens showing a number of tabs.
The ADA Analysis tab is specific for and only used with the Gyrolab ADA Software module.



- **Functionalities to use:** Mark check boxes to select which ADA analysis functionalities to be available in the specific project.
- **Screening settings and Confirmation Settings:** Refer to Chapter E2.4 for information on analysis settings.

To import the settings used in a previous run:

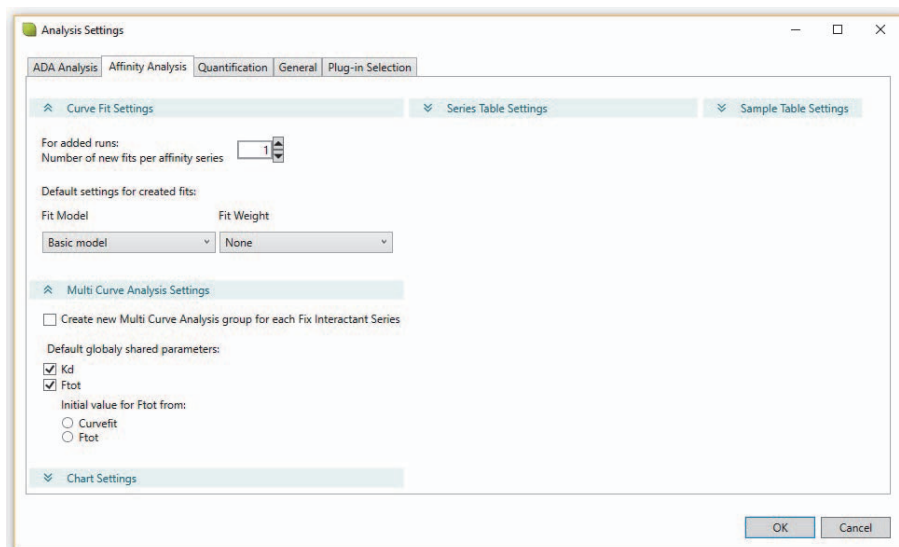
- Click **Template Run** button  in respective analysis section.
- Select a run from which to import analysis settings for the project.



- Select **OK**.

Step Action

6. The **Affinity Analysis** tab is specific for and only used with the Gyrolab Affinity Software module.



- **Curve Fit Settings:** These settings affect the curve fit(s) and thus the calculated fit model parameters.
- **Chart Settings:** Select chart appearance. Click the section header to view the available chart settings.
- **Series Table Settings**, or **Sample Table Settings:** Select which columns to be shown in the respective table. Click the section header to view the available columns.

For detailed description of analysis settings for the Affinity Analysis module, refer to Chapter E5.4.

Step Action

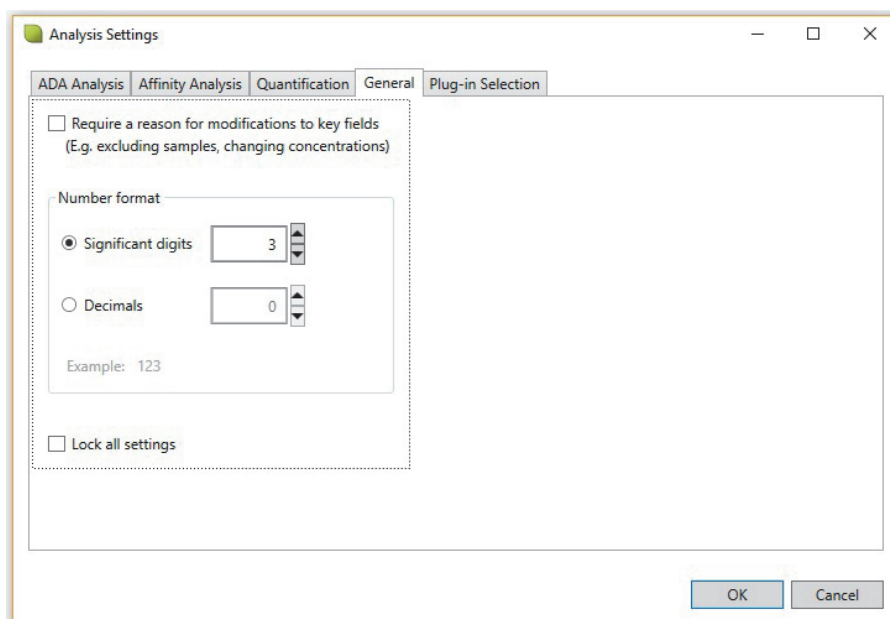
7. In **Quantification** tab, edit settings for the quantification module.

- **Evaluation:** These settings affect curve appearance and limit of detection factor.
- **Evaluation Functionality:** These settings are used to enable or disable the dilution/spike functionality.
- **Acceptance criteria:** These settings are used to determine which result values are considered acceptable. Result that fall outside of acceptance criteria will be highlighted in the result report.
- **Table settings:** It is possible to set which columns that should be visible in the Custom View for an entire project. Every analysis carried out within a project will have those column settings. If Analysis settings are locked, then a user cannot unselect the columns selected in the project view. The user may however add other columns.

For detailed descriptions of analysis settings for the Quantification module, refer to Chapter D4.5.

Step Action

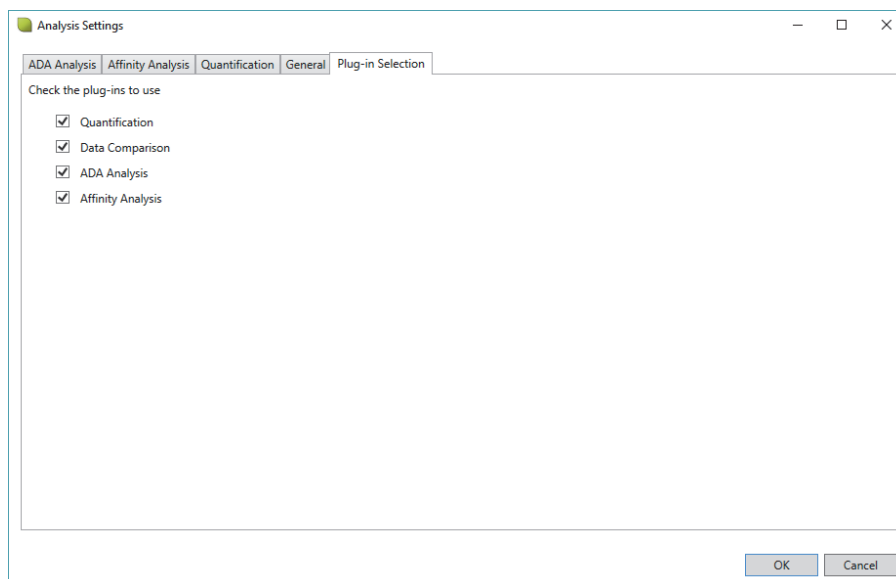
8. In **General** tab, edit general project settings.



- If **Require a reason for modification of key fields** box is ticked, a change description is required if a sample is excluded or included and if concentration or dilution values are changed. The change descriptions are included in the **Audit Trail**.
- Significant digits or number of decimals can be set for the current Project. This setting controls how numeric values are displayed in the GUI, but calculations are performed with full precision. When copying numeric values from the GUI, then the copied value will be limited by this setting. When exporting data to file then the full precision values will be exported.
- If **Lock all settings** box is ticked, the Analysis settings are locked for all analyses within the project and for all users. Only users with user role System Administrator can edit Analysis settings or change **Lock all settings** status.

Step Action

9. In **Plug-in Selection** tab, mark the check-boxes to select what software modules and plug-ins to be available in the specific Project.



10. Click **OK**.
11. The **Save Description** window opens.
 - Enter a change description in the text box.
 - Click **Save**.

The settings made will be applied on all new analyses made within the selected Project.

D3.9 Manage Folder structure

Projects are saved in the Folder structure. Changes to the folder structure are controlled by user role privileges. Refer to Chapter D2.2.3 for more information on Folder structure, and Chapter NOTE: for more information on user roles.

D3.10 Audit trail for Projects

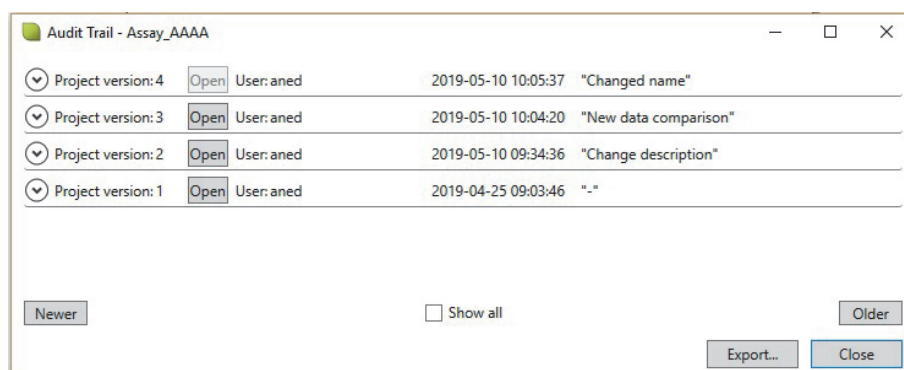
All Projects modifications, for example adding/removing Runs, changing Run data with analysis modules etc, are logged together with information on user identity, time and version in the Audit trail. This is done to ensure full traceability of results. It is possible export and print Audit trail reports. This chapter describes Audit trail for Projects, refer to Chapter D2.3 for information on Audit trail for the Gyrolab Evaluator.

Step Action

1. Select **View: Audit trail** in Gyrolab Evaluator Project view to display the Audit trail log.

Step Action

2. The **Audit Trail** window opens.



- To review details, click the **Open** button for desired **Project Version**. That version of the Project is opened as read-only.
 - To view details of an analysis click analysis expander.
 - To export a copy of the Audit trail in text format, click the **Export** button. Browse for desired location and click **OK**.
3. Click **Close** to go back to Gyrolab Evaluator Project view.

D3.11 Reports and report data export

D3.11.1 Report content

A Run report contains:

- Run name and other Run information.
- Unprocessed data (raw data)
- Version number of the Gyrolab Evaluator
- Version number of the analysis module

An Analysis report contains:

- Analysis name
- Processed data (analyzed data such as Standard curve, quantification data, sample results)
- User-created analysis
- Version number of the Gyrolab Evaluator
- Version number of the analysis module

D3.11.2 View, print and export report data

Step Action

1. Select desired Run (available Runs are shown under **Runs**) or desired analysis (available analyses are shown under **Analyses**).
2. To include all available sample information in the report, select **Report:ViewTables** (Run report only).
3. The selected Run/Analysis report is shown in the right part of Gyrolab Evaluator Project view.

The screenshot displays the Gyrolab Evaluator software interface. On the left, the 'Project Information' pane shows a tree view with 'Runs' and 'Analyses' sections. The 'Runs' section is expanded, showing 'Run Demo 2 2009-FEB-04 11:54:45 AM' selected. The main area on the right displays the 'Run Report' for this specific run. The report includes the Gyros Protein Technologies logo, the title 'Run Report', and the execution name 'Run Demo 2 2009-FEB-04 11:54:45 AM'. Below this, the 'Run Information' section provides details about the run, including date and time, user, method, and instrument.

Run Information	
Date and time:	2009-02-04 11:54:45 (YYYY-MM-DD HH:MM:SS)
Executed by:	Administrator
Run Design name:	Run Demo 2
Method:	Bioaffy 20HC 3-step C-A-D w/z v2
Method description:	Information missing (run was executed with Gyrolab Control version older than 5.3).
Run Design description:	
Design type:	Wizard
Sample list:	C:\DemoSampleList.xls
Reagent list:	BioaffyReagentList
Transfer list:	BioaffyTransferList
Detect operations:	Detect PMT 0.025, processing: Bioaffy Quant Constant Area Size 6.5.3 Detect PMT 0.05, processing: Bioaffy Quant Constant Area Size 6.5.3 Detect PMT 0.1, processing: Bioaffy Quant Constant Area Size 6.5.3
Instrument name:	Demo Instrument
Database name:	GYROLAB_DB
Gyrolab Control version:	5.0.0

Created 5/7/2018 3:20:54 PM by user Administrator using Gyrolab Evaluator version 3.5.1.63.

Step	Action

4.	Use the following buttons to view the report:



	Zoom in.



	Zoom out.



	View Report in actual size.



	View Report in maximal width.



	View one page of the report at the time.



	View two pages of the report at the time.

5.	Use the search field to find specific parts of the report. Several search options are available by clicking the black arrow.



6.	Select File:Print Selected Report or click  button to print the report.

7.	Select File:Save report as Xps... or click on  button to export the report to .xps -format (Microsoft's electronic paper format).

NOTE: *When analyzing data in Quantification or Data Comparison modules it is possible to export the data to .xls or XML format, refer to Chapter D4.1 and Chapter D4.2.*

D4 Analyze data

D4.1 Quantification module

The **Quantification** module is used to quantify samples by analyzing results from Gyrolab Runs. Several evaluation functions and setting options are available to achieve optimal quantification results. For an introduction to quantification analyses of Gyrolab Runs, refer to Chapter D1.

To set analysis parameters and/or to lock the settings for a Project, refer to Chapter D3.8. Analysis parameters can also be set or modified during the quantification analysis procedure, refer to step 2 below.

D4.1.1 Basic view

Basic view is used to quantify samples by analyzing results from Gyrolab Runs. Several evaluation functions and setting options are available to achieve optimal quantification results. For an introduction to quantification analyses of Gyrolab Runs, refer to Chapter D1.

Step Action

1. In Gyrolab Evaluator Project view (Chapter D3.1), click the **Quantification** button

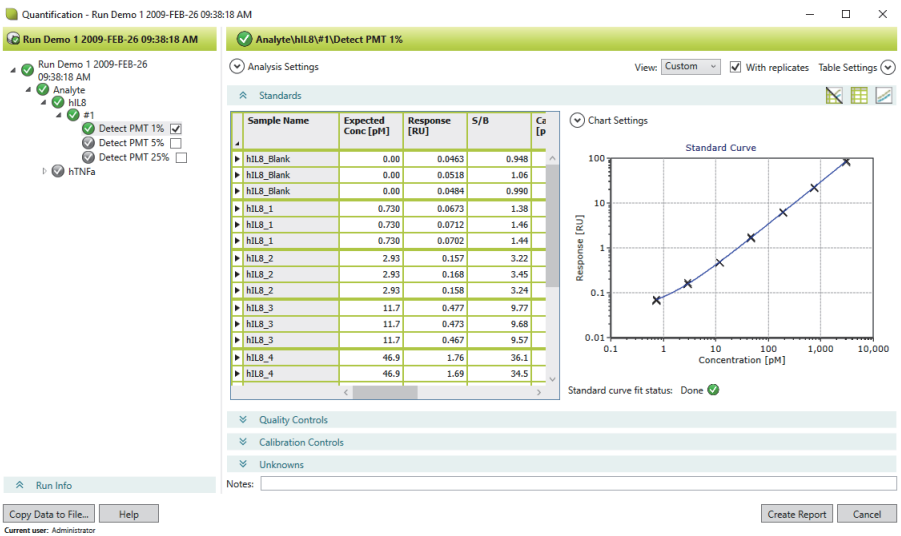


2. The **Quantification:Analysis Setup** window opens.

- In the **Runs** section, select desired Run for quantification analysis.
- In the **Analysis Settings** section, set or edit Analysis setting for Evaluation, Matrix Settings and Acceptance Criteria, refer to Chapter D4.5 for more information
- Click the **Continue** button.

Step Action

3. The Quantification window opens.



Step Action

4. The left panel of the Quantification window displays available experiments in the run. Click on the arrow sign in the tree to expand or collapse the tree structure. Experiment data is structured according to:

Run name

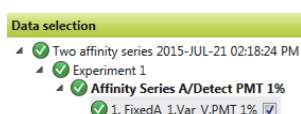
Analyte name

Experiment name

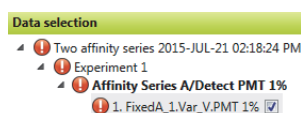
CD number (#1, #2 etc.)

Available PMT setting (Detect PMT X%)

- Green symbols (see below) indicate that the standard curve fit succeeded.



- Red symbols (see below) indicate that the standard curve fit failed.



- Click on the rows with green or red symbols to view results from corresponding data set (bottom level in the tree) in the right panel, refer to steps 6–10.
- The standard curve can have three states:
 - Success will be indicated by the text Standard Curve fit status: Done, followed by a green circle with check-sign.
 - Not ok, will be indicated by the text Standard curve fit status: Not OK! Followed by a red circle with an exclamation mark. This will happen if the curve fit does not converge in a normal way. One of the following reasons is behind this status:
 - The algorithm converged, but the result is not a solution of the problem
 - The maximum number of iterations was exceeded.
 - The maximum number of function evaluations was exceeded.
 - Round-off error prevented the algorithm from achieving a result within the desired tolerance.
 - The algorithm diverges.

In these cases, the algorithm may produce a curve, but the user should be aware that there is something wrong with it.

- No result! Will be indicated by the text: "Standard curve fit status: No result!" Followed by a red Circle with an exclamation mark. No curve will be shown, since the curve fit algorithm has not been executed.
- Click the tick box of one or more experiments (bottom level in the tree) to include that/those experiments in the report.

Click **Run Info** in the bottom of the left panel to display run information such as user and date.

Step Action

5. The right panel of the Quantification window displays collapsable/expandable views for
 - **Analysis settings**, used to view and edit analysis settings, refer to step 6
 - **Standards**, which hold standard curve data table and corresponding graph, refer to step 8
 - **Quality Controls**, **Calibration Control**, **ADA Controls** and **Unknowns**, which hold result data tables refer to steps 9 to 13.

Other available functionalities:

- Options for viewing of data tables and graph, refer to step 7
- Notes, refer to step 13
- Data export, refer to step 14
- Report generation, refer to step 15 to 17.

6. Click **Analysis Settings** (in the right panel) to view and/or edit **Evaluation** and/or **Acceptance Criteria** settings for the analysis, refer to Chapter D4.5 for information on settings parameters. If changes are made only settings for currently opened data set will be changed.

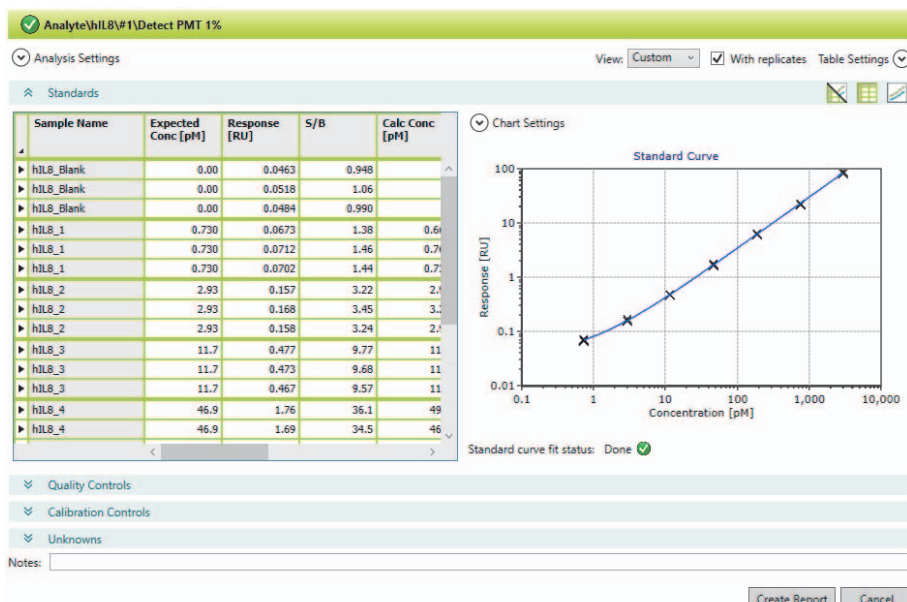
The calculated **Limit of detection** as well as **Fit data** parameter values are displayed in the bottom of this view.

The screenshot shows the 'Analysis Settings' window for a file named 'Analyte\h1L8\#1\Detect PMT 1%'. The window has two main tabs: 'Evaluation' and 'Acceptance Criteria'. The 'Evaluation' tab is active, showing options for 'Include blanks in curve fitting' (unchecked), 'Fit model' (Five parameter logistic curve), 'Weight' (Response), and 'Limit of detection factor' (2). The 'Acceptance Criteria' tab shows 'LOQ matrix' (Neat), 'LLOQ (conc.)', 'ULOQ (conc.)', and 'T-test (%)'. Below these are fields for 'CV conc. (%)' and 'Avg bias (%)' with 'Low', 'Medium', and 'High' selection buttons. A note explains the selection logic. At the bottom, the 'Limit of detection [RU]' is 0.054443 and 'Limit of detection [pM]' is 0.36679. The 'Fit data' section shows the model equation $y = (A - B) / (1 + (x/C)^D)^E + B$ and the parameter values: A = 0.037622; B = 1.8005E+07; C = 6.3402E+09; D = 0.9459; E = 4.5128. The R-squared value is 0.99843.

Click **Analysis Settings** again to collapse the **Analysis Settings** view.

Step Action

7. General commands for **Standards**, **Quality Controls**, **Calibration Controls**, **ADA Controls** and **Unknowns** tables.

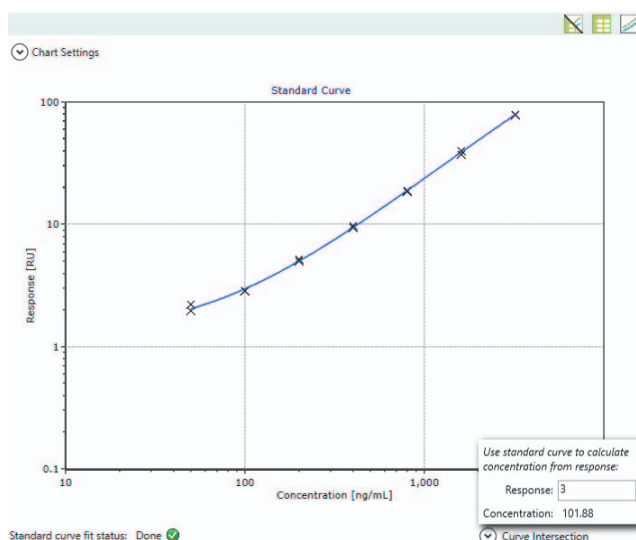


- In the **View** list, select display option for data tables:
 - Custom:** Desired table columns are checked under Table settings (default)
 - Original:** A selected number of data columns (default)
 - Extended:** All available data column
- Refer to Chapter D4.6 for description of data table columns.
- If the **With replicates** box is ticked (default) all replicates for samples are shown. Untick the box to display average values for samples.
- To plot all sample types on the standard curve, go to **Chart Settings** and select which samples to plot. It is possible to view the corresponding sample in data grid by right clicking the data point in chart and selecting **Show in grid**.
- To exclude a data point, right click on the replicate and select **Exclude** in data grid or chart. To perform this **With replicates** must be ticked. If required by Project settings, the reason for exclusion must be specified. The change description is included in the Audit Trail.
- To include an excluded replicate right-click on the sample and select **Include** in data grid or chart. To perform this **With replicates** box must be ticked. If required by Project settings, the reason for inclusion must be specified. The change description is included in the Audit Trail.
- It is possible to edit **Expected Concentration** and **Dilution** values. If required by Project settings, the reason for inclusion must be specified. The change description is included in the Audit Trail.
- It is possible to add notes for individual samples in the right-most column if **With replicates** box is ticked and **View** list is set to **Extended**.

NOTE: The number and titles of columns may differ depending on the Run and if replicates are shown or not.

Step Action

8. Expand sections **Standards** to view Standard samples data and Standard curve.
 - Use buttons to display
 -  Standard samples data and Standard curve
 -  Standard samples data
 -  Standard curve.
 - Standard Samples that fail acceptance criteria are highlighted in the table (Acceptance criteria were set in 6).
 - Click **Chart settings** above the **Standard Curve** to set linear/logarithmic scales on the X-axis and the Y-axis. Click again to close the **Chart settings** window.
 - Standard Curve zooming: Zoom in by clicking in the graph and drag the cursor down and right to select area with the rectangle. Zoom out by clicking in the graph and drag the cursor up and left. The original graph will be shown.
 - Standard points can be excluded/included by right-clicking on the data point in the graph and select **Exclude/Include**.
 - Expand the **Curve Intersection** box and enter a response value to get a concentration value for where that response value intersects with the standard curve.



- Click **Standards** again to close the **Standards** view.
9. Click **Quality Controls** to view Quality Control samples data.
 - If desired: Exclude/include samples, show sample in grid and make notes as described in 7.
 - Click **Quality Controls** again to close the **Quality Controls** view.
 10. Click **Calibration Controls** to view Calibration Control samples data.
 - If desired: Exclude/include samples, show sample in grid and make notes as described in 7.
 - Click **Calibration Controls** again to close the **Calibration Controls** view.

Step	Action

11.	Click ADA Controls to view ADA Control samples data • If desired: Exclude/include samples, show sample in grid and make notes as described in 7. • Click ADA Controls again to close the ADA Controls view.
12.	Click Unknowns to view Unknowns samples data and Standard curve. • If desired: Exclude/include samples, show sample in grid and make notes as described in 7. • Click Unknowns again to close the Unknowns view.
13.	Optional: Add general experiment comments in the Notes text box located at bottom of the right panel.
14.	Optional: To export data from the Quantification module to tab separated text format (.txt) or to Excel XML spreadsheet format (.xls), click Copy Data To File button, browse for desired location and click Save . NOTE: <i>No traceability of results is possible once data is exported using Copy Data to file. In order to fulfill the requirements of 21 CFR part 11 data can only be exported from a saved project, refer to Chapter D3.5.</i>
15.	Click Create Report to save analysis.
16.	Set Analysis Name and click OK .
17.	The analysis is now saved under Analyses:Quantification in Gyrolab Evaluator Project view.

D4.1.2 Dilution/spikes view

Dilution/spikes is a functionality within the Quantification module intended to handle more complex analyte concentration determinations, for example testing assay accuracy and sensitivity by spike recovery studies or analyzing sample dilution linearity.

Step	Action

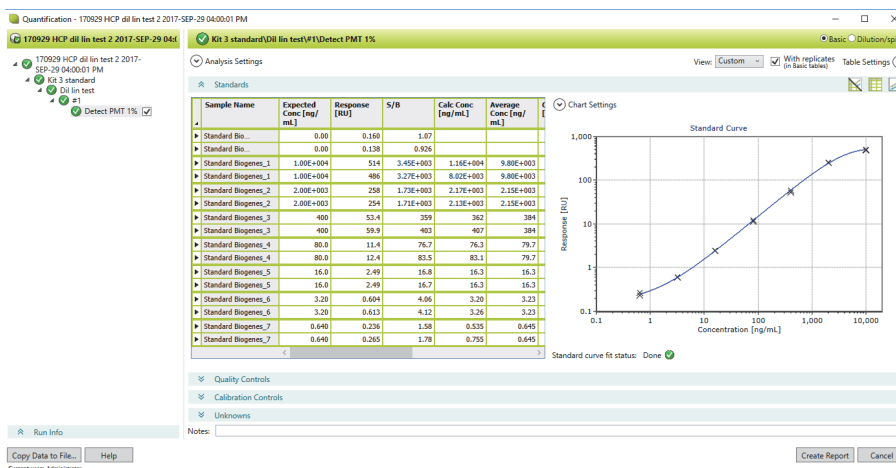
1.	In Gyrolab Evaluator Project view (Chapter D3.1), click the Quantification button. The Quantification:Analysis Setup opens.

Step Action

2. Select desired run under **Runs** section. Check the **Include dilution/spike functionality** under **Analysis Settings** Evaluation Functionality to view and edit acceptance criteria for **Dilutions/spikes** evaluations, refer to Chapter D4.6.

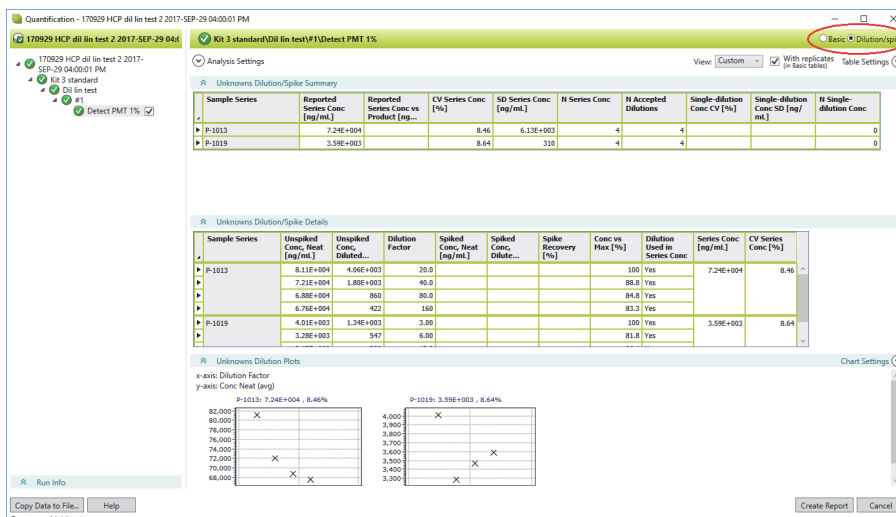
3. Click the **Next** button.

4. The **Quantification:Basic** window opens, refer to Chapter D4.1.



Step Action

- Click the **Dilutions/spikes** button in the upper panel to view the Quantification:Dilutions/spikes window.

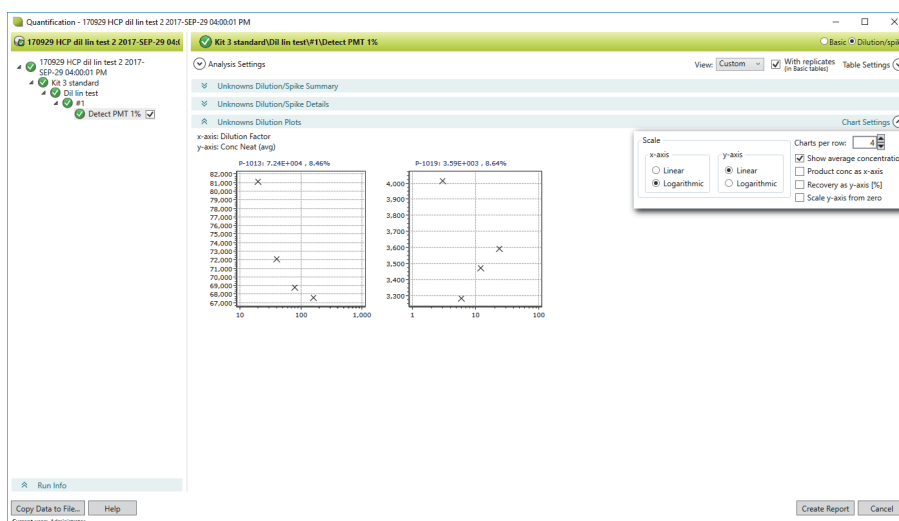


- The left panel displays all available experiments from the run, refer to Chapter D4.1 step 4.
- The right panel displays expandable views for
 - Analysis settings**, used to view and edit Dilutions/Spikes Acceptance Criteria, refer to Chapter D4.6
 - Unknowns Dilution/Spike Summary**, used to summarize sample series data from the Details table, refer to step 8
 - Unknowns Dilution/Spike Details**, used to view detailed data from samples series, refer to step 9
 - Unknowns Dilution Plots**, used to visualize sample dilution series, refer to step 10
 - Chart settings**, used to edit plot settings, refer to step 10
 - Table Settings**, used to edit visible columns in the Custom view, refer to step 11
- The **Unknowns Dilution/Spike Summary** table contains summarized data for each sample series. Table values depend on Acceptance Criteria Settings, refer to Chapter D4.6. Failed acceptance criteria are indicated by a red cell color. Sample series containing failed acceptance criteria are indicated by a light red color. Detailed data for each individual sample included in a sample series is visible in the details table, refer to step 9. Refer to Chapter D4.4.5 for a description of table columns.
- The **Unknowns Dilution/Spike Details** table contains detailed data for all individual samples in a sample series. Table values depend on Acceptance Criteria Settings, refer to Chapter D4.6. Failed acceptance criteria are indicated by a red cell color. Sample series containing failed acceptance criteria are indicated by a light red color. Replicates of individual samples are visible in the Quantification:Basic view, where exclusion of replicates can be performed, refer to step 4. Refer to Chapter D4.6 for a description of table columns.

Step Action

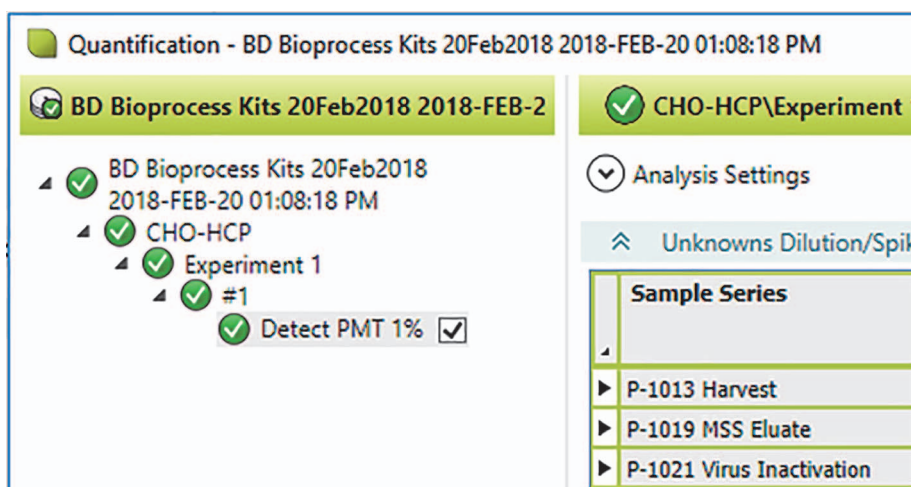
10. The **Unknowns Dilution Plots** visualize individual neat concentrations for sample dilutions included in a sample series. Each graph represents one sample series identified by sample series name, reported series concentration and series CV concentration from the **Unknowns Dilution/Spike Summary** table. Default settings for the x-axis is dilution factor and for the y-axis unspiked neat concentration from the **Unknowns Dilution/Spike Details** table.

Plot settings can be adjusted in the **Chart Settings** expandable view. The scale for x- and y-axis can be altered from linear (default) to logarithmic. The x-axis can be changed from showing dilution factor (default) to product concentration. The y-axis can be changed to show percentage of the unspiked neat concentration compared to the reported series concentration.



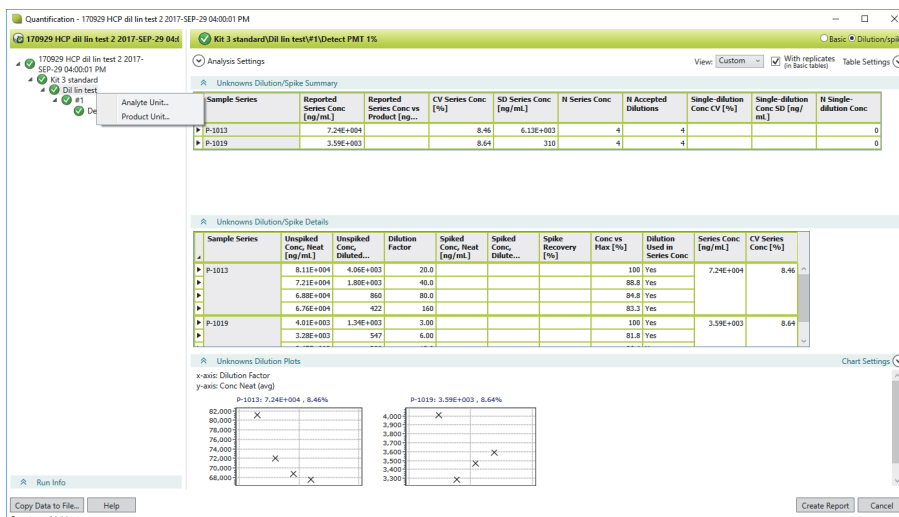
11. In the view list, an option for the **Summary** and **Details** table columns can be selected:

- **Custom** (default): desired table columns are checked under **Table settings**
- **Original**: a selected number of table columns
- **Extended**: all available table columns

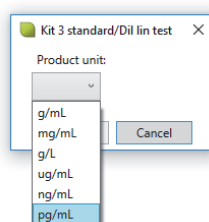


Step Action

12. By right-clicking on the Experiment Node, a context menu is opened where it is possible to select **Analyte Unit** or **Product Unit**.



Changing Product Unit or Analyte Unit will not invoke a unit conversion. It will change the unit without conversion. These units are used when calculating the Series Conc vs Product [ng/mg]. Changing these units will affect this calculation.



D4.2 Data Comparison module

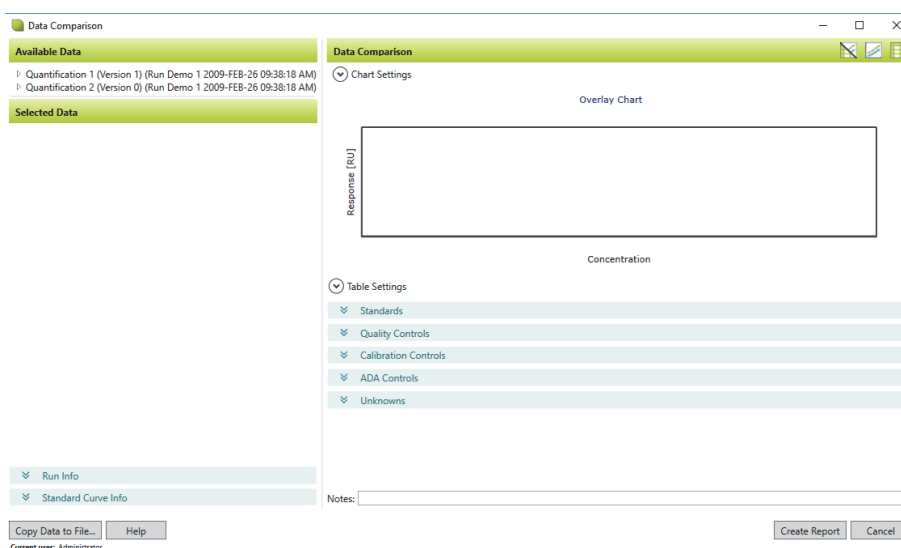
The Data Comparison module is used to compare result data and charts produced by the Quantification module for different data sets. Comparison analyses can be made between **Quantification** module analyses within a Project.

Step Action

1. In Gyrolab Evaluator Project view (Chapter D3.1), click the **Data Comparison** button



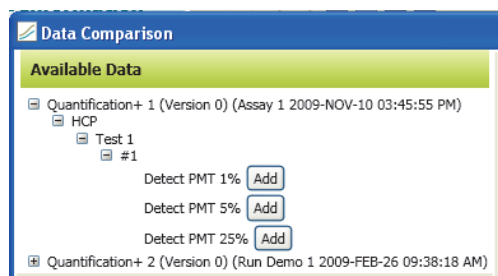
2. The **Data Comparison** window opens.



Three main panels are available:

- **Available Data**
- **Selected Data**
- **Data Comparison**

3. In the **Available Data** panel, browse and select analysis set (**Detect PMT X%** in figure below) for data comparison by clicking the corresponding **Add** button. Repeat until all desired analysis sets are selected.

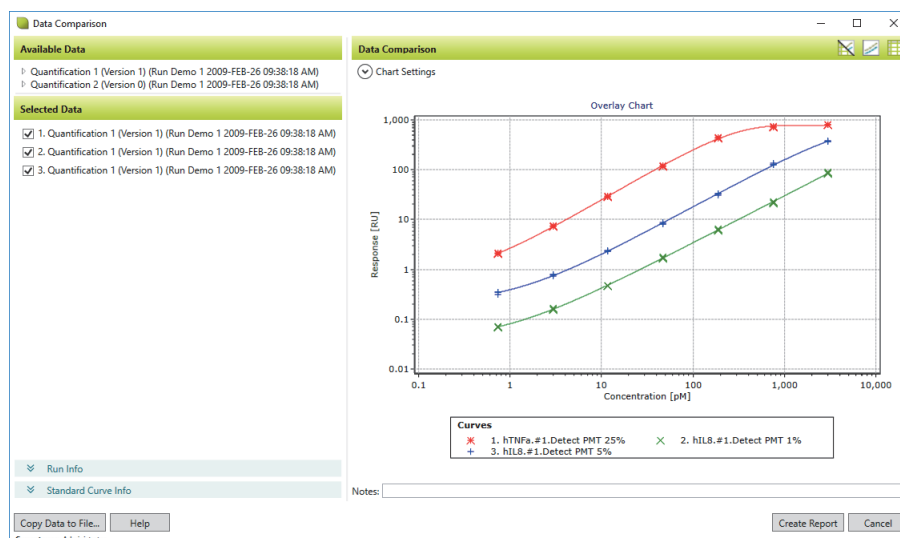


NOTE: The **Add** button will only be available if that specific analysis set is available in an Analysis Report.

Step Action

4. The selected analysis sets are listed in the **Selected Data**, information on analysis set can be found in the tool-tip. Hover with the cursor over selected data to display the tool-tip.

An overlay chart is displayed in the **Data Comparison** panel.



5. To display information for a specific analysis set:
- Click the desired analysis set in the **Selected Data** panel. The selected row in the list is highlighted.
 - Click **Run Info** to display run information such as user and date.
 - Click **Standard Curve Info** to display information on the analysis settings used when the quantification was performed.).

Selected Data

- ☒ 1. Quantification+ 1 (Version 0) (Assay 1 2009-NOV-10 03:45:55 PM)
- ☒ 2. Quantification+ 1 (Version 0) (Assay 1 2009-NOV-10 03:45:55 PM)

Run Info

User: Administrator
 Date: 2009-11-10 15:45:55
 Number of experiments: 1
 Number of CDs: 1

Standard Curve Info

Fit model: Five parameter logistic curve
 Weight: Response
 Blanks included in fit: No
 Model equation: $y = (A - B) / (1 + (x/C)^D)^E + B$
 Fit status: Not OK!
 R²: 0,001334
 Parameters: A = 57,973
 B = 57,973
 C = 3333
 D = 0,00013446
 E = -22,084

6. Untick the box of a specific analysis set in the **Selected Data** panel to remove that analysis set from the **Data Comparison** panel.

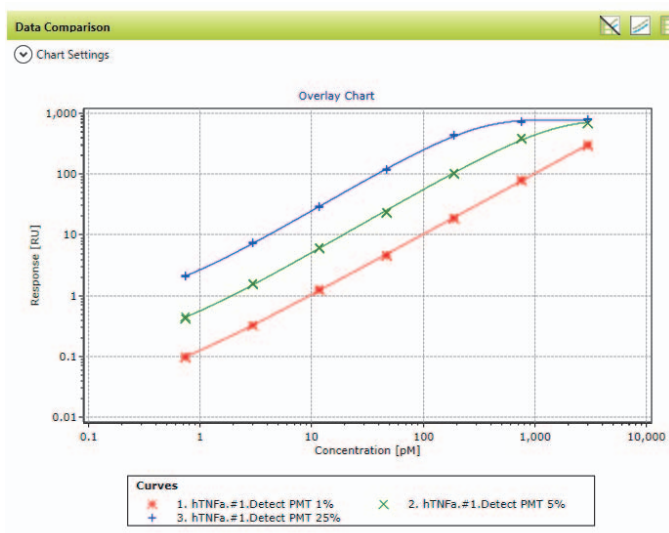
Tick the box again to display the analysis set in the **Data Comparison** panel again.

Step Action

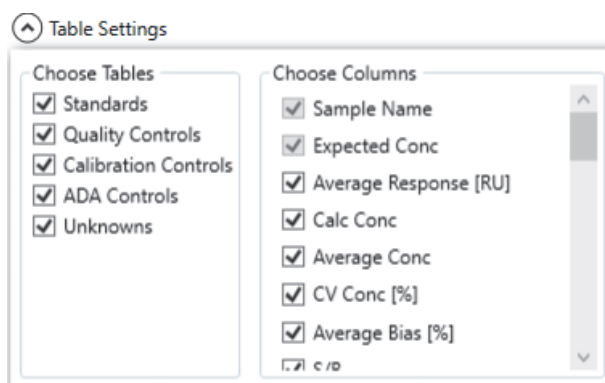
7. In the **Data Comparison** panel use buttons to display:

-  Samples data and overlay chart
-  Overlay chart
-  Samples data

8. **Overlay Chart functionalities:**



- Click **Chart settings** above the **Overlay Chart** to set linear/logarithmic scales on the X-axis and the Y-axis and to edit chart legend. Click again to close the **Chart settings** view.
 - To rename curves, right-click on curve number and select **Rename Legend Item**. Enter new name and click **OK** (to return to default name, click **OK** directly). If the curve is not named only the number of the curve is displayed.
 - **Overlay Chart** zooming: Click in the graph and drag cursor down and right to zoom in. Zoom out by clicking in the graph and dragging the cursor up and left.
 - Place the cursor on a curve to display a tool-tip with the analysis settings used for that curve.
9. Click **Table Settings** to view and edit which **Tables** and **Columns** to display. Note that only selected tables and columns are included in the Report. For data columns definitions, refer to Chapter D4.5.



Step Action

10. To view specific data points, click desired Table (**Standards**, **Quality Controls**, **Calibration Control** and **Unknowns**) to expand. Click again to collapse.

Standards							
Sample Name	Expected Conc	Average Response [RU]	Calc Conc	Average Conc	CV Conc [%]	Average Bias [%]	S/B
1. Quantification 4 (Version 0) (Run Demo 1 2009-FEB-26 09:38:18 AM)\Analyte\hTNFa\#1\Detect PMT 1%							
hTNFa_Blank	0.00	0.0141					0.474
hTNFa_Blank	0.00	0.0141					0.766
hTNFa_Blank	0.00	0.0141					1.76
hTNFa_1	0.730	0.0978	0.729	0.726	0.730	-0.570	6.94
Quality Controls							
Calibration Controls							
ADA Controls							
Unknowns							

TIP: If the entire name of the analysis set is not visible in the Table, increase the column width or decrease number of columns (Refer to step 9 or see complete name under Selected Data).

11. Optional: Add general experiment comments in the **Notes** text box located at bottom of the right panel.
12. Optional: To export data from the **Data Comparison** module to tab separated text format (.txt) or to Excel XML spreadsheet format (.xls), click **Copy Data To File** button, browse for desired location and click **Save**.

NOTE: No traceability of results is possible once data is exported using Copy Data to file. In order to fulfill the requirements of 21 CFR part 11 data can only be exported from a saved project, refer to Chapter D3.5

13. Click **Create Report** to save the analysis.
14. Set **Analysis Name** and click **OK**.
15. The analysis is now saved under **Analyses:Data Comparison** in Gyrolab Evaluator Project view.

D4.3 Result data table descriptions

Data table content is the same for both **Quantification** and **Data Comparison** modules.

In the **Quantification** module it is possible to choose between Original, Custom and Extended view and to view values with or without replicates. If Original view is selected the number of columns displayed may differ depending on available sample results and type of sample.

In Data comparison module replicates are always shown and it is possible to select which columns to view (however **Sample Name** and **Expected conc.** are always shown).

Columns displayed in the **Quantification** and **Data Comparison** modules will be included in reports generated.

Custom view is selected by default, showing the columns selected under **Table Settings**. Original view shows the columns indicated with a Yes in the table below. Selecting Extended view will show all columns.

NOTE: *If a cell in a column is empty a value could not or should not be calculated for that cell. For example a CV-calculation when only one replicate is available and for calculated concentration for a blank sample.*

Column heading	Original view	Description
Sample Name	Yes	Sample identity
Expected conc	Yes	Given for samples with known concentrations such as Standard Samples, Quality Controls and Calibration Controls.
Response (RU)	Yes	Integrated volume of the fluorescent binding surface of a reaction in a microstructure.
S/B	Yes	Signal to background. The ratio between the signal and the absolute value of mean of the blanks' signal.
Calc. Conc	Yes	The neat analyte concentration calculated from a single sample response read from a standard curve. Calc. Conc = Diluted Conc. × Dilution Factor
Average conc	Yes	The neat average calculated analyte concentration of replicates of a sample.
CV Conc (%)	Yes	Coefficient of variation of analyte concentration of a replicate series of a sample.
Bias (%)	Yes	Deviation from the expected value - For Calibration Controls: Bias (%) = $100 \times (\text{Calculated Concentration} - \text{Average calculated concentration for the standard sample(s)}) / \text{Average calculated concentration for the standard sample(s)}$ - For other samples (not Unknown Samples): Bias (%) = $100 \times (\text{Calculated Concentration} - \text{Expected Concentration}) / \text{Expected Concentration}$
Average Bias (%)	Yes	Average Bias for a set of sample replicates.
Average Response (RU)	Yes	Average of response values for replicates of a sample, sample group or sample subgroup.

Column heading	Original view	Description
CV Response (%)	Yes	Coefficient of variation of response of replicates of a sample.
Dilution Factor	Yes	The Dilution Factor for Unknown samples and Quality Control samples. Dilution Factor for Unknown samples is added in the sample list. For Quality Control samples the Dilution Factor is entered when setting up a Run using Design Run (refer to Chapter 12.3). The concentration of the diluted sample is multiplied with the Dilution Factor to obtain the calculated analyte concentration of the neat sample. If no Dilution Factor value has been assigned a factor of 1 will automatically be used.
CD ID	Yes	Identity of Gyrolab CD microlaboratory used to process the samples.
CD Struct	Yes	Identity of structure on Gyrolab CD microlaboratory where the sample was processed.
Diluted Conc	No	The measured (diluted) analyte concentration from a single sample response read from a standard curve, hence the in-well-concentration.
Avg Diluted Conc	No	The average measured (diluted) analyte concentration of replicates of a sample
SD Response (RU)	No	The standard deviation of responses of sample replicates.
SD Conc	No	The standard deviation of calculated concentrations of replicates of a sample.
Recovery (%)	No	Recovery is calculated for samples with known concentration: - Standard sample recovery = $(\text{Calculated concentration} / \text{Expected concentration}) \times 100$ - Calibration Control recovery = $(\text{Calculated concentration} / \text{Average concentration for the standard sample(s) with same concentration}) \times 100$ - Quality Control recovery = $(\text{Calculated concentration} / \text{Expected concentration}) \times 100$
MP ID	No	Identity of the microplate where the sample was placed.
MP Well	No	Well position on the microplate where the sample or standard was placed.
Detect Result	No	- OK: The results are approved - Not OK: The results are not approved. The fluorescence signal is of poor quality which may be caused by inadequate PMT setting (detector is saturated) or errors in sample preparation.
Spiking Conc, at least diluted	No	In-well concentration of spike in the first dilution analyzed in a dilution series (least diluted). NOTE: This column is only shown for Unknown samples

Column heading	Original view	Description
Product Conc Neat	No	Concentration of product (e.g. Drug Substance for bioprocess impurity assays) in undiluted sample. <i>NOTE: This column is only shown for Unknown samples</i>
Sample Type	No	Sample types: Standard, Blank, Quality Control, Calibration Control and Unknown sample. Changing the expected concentration for Standard Samples, to or from 0, will change Sample Type.
T-test	No	The T-test analyzes whether a blank and any single Standard, respectively, belong to the same data population.
Needle ID	No	The needle used to transfer the sample from the MP to the CD structure
Group	No	Optional information of important sample properties such as common source or treatment. Group is only used for Quality Control and Unknown samples (refer to Chapter I2.3). <i>NOTE: This column is only shown for Unknown and Quality Control samples and only if there are any samples with Group information in the Experiment.</i>
Subgroup	No	Optional information of important sample properties such as common source or treatment, which can be used to sub group samples within a group. Subgroup is only used for Quality Control and Unknown samples (refer to Chapter I2.3). <i>NOTE: This column is only shown for Unknown and Quality Control samples and only if there are any samples with Group information in the Experiment.</i>
Group average conc	No	The average calculated analyte concentration of replicates of a sample group or sample subgroup. <i>NOTE: This column is only shown for Unknown samples and only if there are any samples with Group information in the Experiment.</i> <i>NOTE: Even if a group is specified other statistical parameters are calculated for individual replicates.</i>
Exp Diluted Conc	No	The Expected Diluted Concentration is the expected concentration divided by the dilution factor. <i>NOTE: This column is only shown for Quality Control and Calibration Control samples.</i>
Group CV conc (%)	No	Coefficient of variation of analyte concentration of replicates of a sample group or sample subgroup. <i>NOTE: This column is only shown for Unknown and Quality Control samples and only if there are any samples with Group information in the Experiment.</i>
Group SD conc	No	The standard deviation of calculated analyte concentrations of replicates of a sample group or sample subgroup <i>NOTE: This column is only shown for Unknown and Quality Control samples and only if there are any samples with Group information in the Experiment.</i>

Column heading	Original view	Description
Group Average Bias [%]	No	Average Bias for a set of replicates of a sample group or sample subgroup. <i>NOTE: This column is only shown for Unknown samples and only if there are any samples with Group information in the Experiment</i>
Notes	No	It is possible to add comments to individual samples.

D4.4 QC Trending module

The QC Trending module is used to compare QC result data over time produced by the Quantification module for different Runs. This module only works with Runs executed with QC Sets (To set up a Run with QC Sets, refer to Chapter B4.3.4.1). The QC data from the Runs will form one QC Series per QC, plotted in a Levey-Jennings chart.

D4.4.1 Getting started with QC Trending

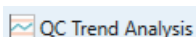
Before being able to use the QC Trending module, we need to set up valid QC data for the module to use.

1. Prepare a Run Design (or Run Setup) with a QC Set selected to one or more experiments. Refer to Chapter B4.3.4.1 on how to do this.
2. Execute several Run Setups using this QC Set.
3. Quantify the results from the Runs by using the Quantification module (Chapter D4.1). Remember to check the box(es) for PMT levels that are approved, to indicate to the software that the data set is evaluated, and any outliers removed.
4. Save the project(s) containing the Quantification analyses.

Now the QC data from these Runs can be analyzed.

D4.4.2 Creating a QC Trend Analysis

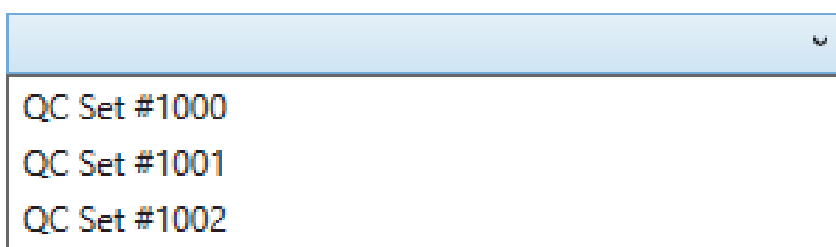
1. In Gyrolab Evaluator Project view (Chapter D3.1), click the QC Trending button.



2. The QC Trending window opens. Select a **QC Set** to analyze. The latest version of the QC set will always be used.

QC Set

Select a quality control sample set to perform analysis on:



3. Upon selecting a QC Set, more detailed information about the QC set will be displayed.

QC Set #1000

Current version: 3
 Created: 2020-09-04 15:31:15 Modified: 2021-06-03 16:22:03
 Created by: Administrator Modified by: Administrator

⬇ Description:
 BatchID SE-123

Replicates: 2

Quality control name	Concentration	Concentration unit	Dilution
▶ QC 1	1.00	g/mL	1.00
▶ QC 2	2.00	g/mL	1.00
▶ QC 3	3.00	g/mL	1.00

Bias tolerance:

Quality control name	Lower limit	Upper limit
▶ QC 1	0.950	1.05
▶ QC 2	0.00	4.00
▶ QC 3		

4. All the Runs executed using this QC Set will be presented. Select all or a subset of Runs to analyze by checking the checkmark.

	Execution Date	Execution Name	Executor	Instrument	Analyses	Analysis	Has New	Updated
▶ ☐	2020-09-10 16:26:53	RUN_10 QCSET_1	Administrator	geya_sim	2	2021-05-11 18:38:16 - study/Quantification 2 (v.1)		
▶ ☐	2020-09-09 16:24:16	RUN_9 QCSET_1	Administrator	geya_sim	1	2021-05-11 18:39:33 - study/Quantification 10 (v.1)		
▶ ☐	2020-09-08 16:21:39	RUN_8 QCSET_1	Administrator	geya_sim	1	2021-05-11 18:39:25 - study/Quantification 9 (v.1)		
▶ ☐	2020-09-07 16:19:01	RUN_7 QCSET_1	Administrator	geya_sim	1	2021-05-11 18:39:18 - study/Quantification 8 (v.1)		
▶ ☐	2020-09-06 16:16:23	RUN_6 QCSET_1	Administrator	geya_sim	1	2021-05-11 18:39:10 - study/Quantification 7 (v.1)		
▶ ☐	2020-09-05 16:10:12	RUN_5 QCSET_1	Administrator	geya_sim	1	2021-05-11 18:39:02 - study/Quantification 6 (v.1)		
▶ ☐	2020-09-04 16:07:35	RUN_4 QCSET_1	Administrator	geya_sim	1	2021-05-11 18:38:53 - study/Quantification 5 (v.1)		
▶ ☐	2020-09-03 16:04:57	RUN_3 QCSET_1	Administrator	geya_sim	1	2021-05-11 18:38:33 - study/Quantification 4 (v.1)		
▶ ☐	2020-09-02 16:02:19	RUN_2 QCSET_1	Administrator	geya_sim	1	2021-05-11 18:38:25 - study/Quantification 3 (v.1)		
▶ ☐	2020-09-01 15:59:43	RUN_1 QCSET_1	Administrator	geya_sim	4	2021-05-11 18:38:08 - study/Quantification 1 (v.1)		

5. The Runs can be filtered on date, executor, and instrument.

From: To: Instrument: Executor:

6. If there are multiple Quantifications on one Run (see column **Analyses** to see the total of Quantification analyses), the most recently created or updated will be selected. To select another Quantification analysis than the preselected, click on the Analysis cell and the other available Quantifications will be listed.

▶ ☒	2020-09-10 16:26:53	RUN_10 QCSET_1	Administrator	geya_sim	2	2021-05-11 18:38:16 - study/Quantification 2 (v.1)		
▶ ☐	2020-09-09 16:24:16	RUN_9 QCSET_1	Administrator	geya_sim	1	2020-11-05 21:07:25 - Other/Quantification (v.1)		
▶ ☐	2020-09-08 16:21:39	RUN_8 QCSET_1	Administrator	geya_sim	1	2021-05-11 18:38:16 - study/Quantification 2 (v.1)		

7. Continue to the **Analysis** page by clicking **Next**. Two main panels are available:
- **Data Selection**
 - **Quality Control Information**

8. Select which QC series to view in **Data Selection**. Details regarding the selected QC series is presented in **QC Sample Properties**.

Data Selection

QC Set #1000

[QC Set 1] QC 1

[QC Set 1] QC 2

[QC Set 1] QC 3

⤴ QC Sample Properties

Name: [QC Set 1] QC 1

Expected concentration: 1.00 g/ml

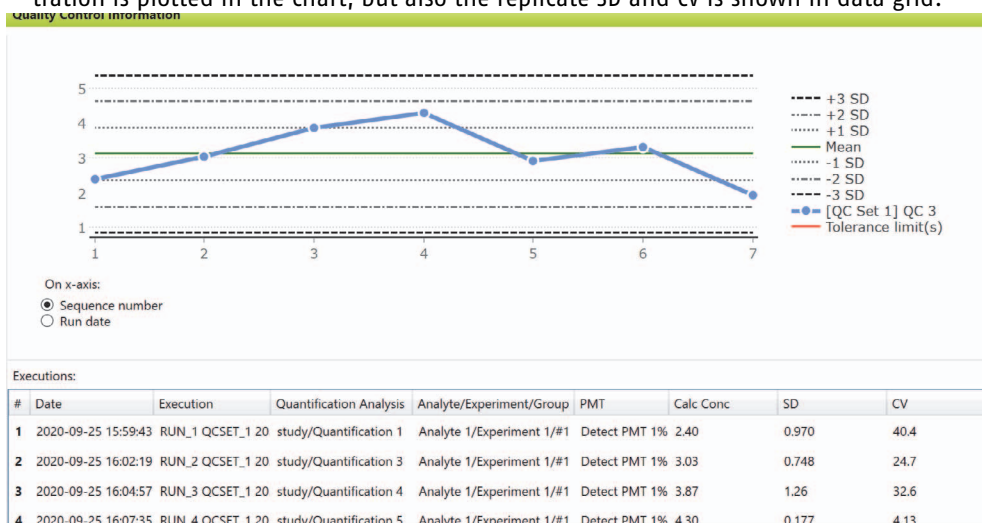
Dilution factor: 1.00

Mean: 1.21 g/ml

Standard deviation: 0.0766 g/ml

Tolerance: 0.950 - 1.05 g/ml

9. In the **Quality Control Information** section, the QC data from the selected quantified Runs are plotted in a Levey Jennings chart and displayed in a data grid. To remove a Run, go Back to the previous page and untick the Run.
- In the Levey Jennings chart, each data point represents one QC data point measured in one PMT level of an experiment. The y-axis represents the concentration and the x-axis the run sequence.
- In the data grid, the QC data from the Quantification analyses are displayed. The concentration is plotted in the chart, but also the replicate SD and CV is shown in data grid.



10. Save the QC Trend analysis by clicking **Create Report**. To export the data to a spreadsheet, click **Copy Data to File...**

D4.4.3 Updating a QC Trend analysis

New QC data will automatically become available whenever a Run is executed with a QC set and then quantified and saved to a project. To know what data is new since the QC trend analysis was last saved, select the filter option Show only new since last saved.

☒ Show only new since last saved [2021-06-07 09:24:28]

All Runs and Quantification analyses that are new or updated will be presented in the list. Whenever an included Run has a new Quantification analysis or an updated version selected, this will be apparent in the Has New / Updated column.

☒	2020-09-09 16:24:16	RUN_9 QCSET_1	Administrator	geya_sim	3	2021-06-07 14:42:05 - aFFINITY/Quantification 7 (v.1)	New
☒	2020-09-10 16:26:53	RUN_10 QCSET_1	Administrator	geya_sim	3	2021-06-07 14:41:40 - aFFINITY/Quantification 5 (v.2)	Updated

D4.4.4 Additional information

By default, the software will calculate the mean and standard deviation of concentration of a QC series. It is possible to override this setting and manually input the mean and standard deviation per QC under **Chart Limit Settings**.

Chart Limit Settings

Specify mean, standard deviation and number of runs:

☐ Use automatic calculation of values based on runs
☒ Manual input

Quality control name	Mean	Standard deviation
QC 1		
QC 2		
QC 3		

When having enabled the Analysis general setting **Require a reason for modification to key fields** and saving a QC trend analysis, the software will ask for a reason for change and present the different changes made. The comments will be visible in the project audit trail.

Describe the reasons for your change in the text box below before continuing:

Change:

New included data:

Run: RUN_10 QCSET_1 2020-SEP-10 04:26:53 PM (New)
 Analysis: "study/Quantification 2" (Version 1, GUID: 960932c0-abfc-4464-8dbf-344f529ebe36)

Removed data:

Run: RUN_1 QCSET_1 2020-SEP-01 03:59:43 PM

D4.4.5 Dilutions/spikes result data table description

In the Quantification Dilutions/spikes functionality two result data tables are shown, **Unknowns Dilution/Spike Summary** and **Unknowns Dilution/Spike Details**.

For the tables it is possible to choose between **Original**, **Extended** and **Custom View**. In the **Original** view only columns indicated with a **Yes** below will be displayed. In the **Extended** view all available columns will be shown. In the **Custom** view any of the desired columns can be displayed.

Column heading	Original view	Description
Unknowns Dilution/Spike Summary		
Sample Series	Yes	Sample series identity
Reported Series Conc	Yes	The neat average concentration for the sample series. The concentration is calculated from unspiked samples accepted by specified dilution/spike criteria, refer to Chapter D4.6.
Reported Series Conc vs Product Conc [ng/mg]	Yes	The ratio between the Reported Series Conc and the given product concentration.
CV Series Conc [%]	Yes	The coefficient of variation (CV) for the sample series concentration. The CV is calculated from the unspiked samples accepted by specified dilution/spike criteria, refer to Chapter D4.6.

Column heading	Original view	Description
SD Series Conc	Yes	The standard deviation (SD) for the sample series concentration. The SD is calculated from unspiked samples accepted by specified dilution/spike criteria, refer to Chapter D4.6.
N Series Conc	Yes	The number of dilutions used to calculate the Series Conc in the Unknowns Dilution/Spike Details table.
N Accepted Dilutions	Yes	The number of dilutions that are accepted by specified dilution/spike criteria, refer to Chapter D4.6.
Single-dilution Conc CV [%]	Yes	The coefficient of variation (CV) for a sample series containing - only one dilution - only one dilution accepted by specified dilution/spike criteria, refer to Chapter D4.6. The CV is calculated from the unspiked dilution replicates visible in the Basic table.
Single-dilution Conc SD	Yes	The standard deviation (SD) for a sample series containing - only one dilution - only one dilution accepted by specified dilution/spike criteria, refer to Chapter D4.6. The SD is calculated from the unspiked dilution replicates visible in the Basic table.
N Single-dilution Conc	Yes	The number of unspiked dilution replicates used in calculations for Single-dilution Conc CV [%] and Single-dilution Conc SD . Replicates can be found in the Quantification Basic view, refer to Chapter D4.1.1 step 4.
Unknowns Dilution/Spike Details		
Sample Series	Yes	Sample series identity
Unspiked Conc, Neat	Yes	The average neat concentration for an unspiked dilution within a sample series. The Unspiked Conc, Diluted multiplied with the Dilution Factor .
Unspiked Conc, Diluted	Yes	The average concentration for the measured unspiked diluted samples within a sample series. The value is based on replicate concentrations visible in the Quantification Basic view, refer to Chapter D4.1.1 step 4.
Dilution Factor	Yes	The dilution factor stated in the Run Design, refer to Chapter B4, or Run Setup, refer to Chapter B5.

Column heading	Original view	Description
Spiked Conc, Neat	Yes	The average neat concentration for a spiked dilution within a sample series. The Spiked Conc, Diluted multiplied with the Dilution Factor .
Spiked Conc, Diluted	Yes	The average concentration for the measured spiked diluted samples within a sample series. The value is based on replicate concentrations visible in the Quantification Basic view, refer to Chapter D4.1.1 step 4.
Spike Recovery [%]	Yes	The spike recovery at a specific dilution and a specific spiking concentration. The value is calculated by subtracting the unspiked concentration from the spiked concentration, then dividing with the spiking concentration.
Conc vs Max [%]	Yes	The ratio between an unspiked dilution's concentration and the maximum unspiked concentration in a sample series.
Dilution Used in Series Conc	Yes	The dilutions within a sample series that are accepted by dilution/spike criteria and included in the Series Conc .
Series Conc	Yes	The neat average concentration for the sample series. The concentration is calculated from unspiked samples accepted by specified dilution/spike criteria, refer to Chapter D4.6. NOTE: <i>The Series Conc may differ from the Reported Series Conc in the Unknowns Dilution/Spike Summary table depending on specified dilution/spike criteria.</i>
CV Series Conc [%]	Yes	The coefficient of variation (CV) for the sample series concentration. The CV is calculated from the unspiked samples accepted by specified dilution/spike criteria, refer to Chapter D4.6.
CV Unspiked Conc [%]	No	The coefficient of variation (CV) for an unspiked concentration within a series. The CV is based on replicate concentration visible in the Quantification Basic view, refer to Chapter D4.1.1 step 4.
N Unspiked Conc	No	The number of replicates used in the calculation of CV Unspiked Conc [%] . Replicates are visible in the Quantification Basic view, refer to Chapter D4.1.1 step 4.

Column heading	Original view	Description
CV Spiked Conc [%]	No	The coefficient of variation (CV) for a spiked concentration within a series. The CV is based on replicate concentration visible in the Quantification Basic view, refer to Chapter D4.1.1 step 4.
N Spiked Conc	No	The number of replicates used in the calculation of CV Spiked Conc [%] . Replicates are visible in the Quantification Basic view, refer to Chapter D4.1.1 step 4.
Spiking Conc, at lowest dilution	No	The spiking concentration in the least diluted sample, stated in the Run Design, refer to Chapter B4.
Spiking Conc, Diluted	No	The diluted spiking concentration in a specific dilution.
N Passed Spike Recovery	No	Number of passed spiked recovery within one dilution. Acceptable spike recovery is stated in acceptance criteria, refer to Chapter D4.6.
Conc vs Product [ng/mg]	No	Ratio between Unspiked Conc, Neat and Product Conc Neat .
Product Conc Neat	No	The product concentration stated in the Run Setup, refer to Chapter B5. Stated product concentration can be altered in the Quantification Basic view, refer to Chapter D4.4.5.
Dilution Accepted by Series Rule	No	States if the dilution is accepted by the selected series rule, refer to Chapter D4.6.
Series Conc vs Product [ng/mg]	No	Ratio between the Series Conc and the Product Conc .
N Accepted Dilutions	No	The number of dilutions that are accepted by specified dilution/spike criteria, refer to Chapter D4.6.

D4.5 Analysis settings

The finding of optimal curve fit model and other analysis settings are important for accurate calculation of results. It is possible to modify different settings and evaluate the analysis results. For example, different algorithms can be selected and outliers in Standard series can be excluded. It is recommended to use similar Settings in routine analyses as was found to be optimal during assay development.

It is possible to lock settings for a Project to ensure identical analysis settings on all samples performed within that project.

We use the Levenberg-Marquardt algorithm (LVM), which minimizes the sum-of-squares of the vertical distance between the observed data and the curve or fitted data (residuals). When weighting is used the following is minimized in order to find best curve fit:

$$\sum [(Y_{data} - Y_{fit})/Weight]^2$$

It can also be expressed as:

$$\sum [(Y_{data} - Y_{fit})^2 \times 1/Weight^2]$$

NOTE: Be careful using any manipulations of analysis settings and exclusions to avoid any undesired implications on reported analyte concentrations.

NOTE: All changes of parameters are recorded in the Audit Trail, Chapter D3.10, to enable full traceability of results.

Parameter	Comment
Evaluation	
Include blanks in curve fitting	Blanks included or excluded in curve fitting.
Fit model	The following fit models are available: • Five parameter logistic curve (default) • Four parameter logistic curve • Straight line • Exponential curve • MMF curve (Morgan–Mercer–Flodin) Refer to Chapter D4.5.1 for descriptions and recommendation when to use which fit model.
Weight	The following options are available: • None • Concentration • Response (default) • Standard deviation response In general a weighted fit is more appropriate than an unweighted fit.
Limit of detection factor	The following options are available: • 2 standard deviations (default value) • 3 standard deviations It is the number of standard deviations of the blank added to the average blank.
Acceptance Criteria	
Neat / Diluted	Set if the acceptance criteria LLOQ and ULOQ represents the back-calculated Neat (i.e. 100% matrix) concentration values or the Diluted concentration values.
LLOQ (conc.)	Lower limit of Quantification: • For Unknown samples, the LLOQ defines the lowest level of analyte concentration measurable. • For Standards, Quality Controls and Calibration Controls, the LLOQ defines the border between Low and Medium ranges for CV conc. (%) and Average Bias (%), refer to table below.

Parameter	Comment
ULOQ (conc.)	Upper limit of Quantification: - For Unknown samples, the ULOQ defines the highest level of analyte concentration measurable. - For Standards, Quality Controls and Calibration Controls, the ULOQ defines the border between Medium and High ranges for CV conc. (%) and Average Bias (%), refer to table below.
T-Test (%)	The T-test analyzes whether a blank and any single Standard, respectively, belong to the same data population.
CV conc. (%)	Coefficient of variation of concentration of replicates of a sample, sample group or sample subgroup. Set acceptance CV conc. (%) values for Standards, Quality Controls and Calibration Controls samples for: - Low: concentration values < LLOQ - Medium: concentration values from LLOQ to ULOQ - High: concentration values > ULOQ NOTE: For Quality Control samples the average concentration is calculated on a sample Group or sample Subgroup if there is any sample with Group information included in the Experiment.
Average Bias (%)	Average Bias from included replicates. Average Bias is the deviation from the expected value, that is: $((\text{Average concentration} - \text{Nominal concentration}) / \text{Nominal concentration}) \times 100$ Set acceptance Average Bias (%) values for Standards, Quality Controls and Calibration Controls samples for: - Low: concentration values < LLOQ - Medium: concentration values from LLOQ to ULOQ - High: concentration values > ULOQ
Evaluation Functionality	
Parameter	Include dilution/spike functionality. NOTE: If checked it is possible to switch to the dilution/spike view from the Quantification window.

D4.5.1 Curve fit models

Dose-response curves are used to calculate concentrations of unknowns in many types of immunoassays. The X-axis shows concentration of an analyte (the substance to be studied). The Y-axis shows the fluorescent response in the assay.

Different biological results will fit to varying extent to different curve fit models. Testing different curve fit models may identify an improved curve fit. With the four parameter logistic curve, the change from the initial value and towards the final value is fairly symmetrical. When the data does not show this symmetry, the resulting fit may not be adequate. The five parameter logistic curve remedies this situation by adding an asymmetry factor.

D4.5.1.1 Four parameter logistic model

A dose-response curve with fairly symmetrical transition from one response level to another.

Model equation:

$$y = (A - B) / (1 + (x/C)^D) + B$$

Model parameters:

- A: The bottom level of the curve i.e. the minimum level of y
- B: The top level of the curve i.e. the maximum level of y
- C: The EC50 value represents the x value at which the middle y value is attained.
- D: The slope factor. A positive value is returned when y is decreasing as x increases and a negative value returned when y is decreasing as x decreases.
- x: The known, original concentrations
- y: The known responses

Fit Method:

Data is fitted using the Levenburg Marquardt algorithm.

D4.5.1.2 Five parameter logistic model

A dose-response curve with asymmetrical transition from one response level to another.

Model equation:

$$y = (A - B) / (1 + (x/C)^D)^E + B$$

Model parameters:

- A: The bottom level of the curve i.e. the minimum level of y
- B: The top level of the curve i.e. the maximum level of y
- C: The EC50 value represents the x (concentration) value at which the middle y (response) value is attained for a symmetric curve (E=1).
- D: The slope factor. A positive value is returned when y is decreasing as x increases and a negative value returned when y is decreasing as x decreases.
- E: The symmetry factor
- x: The known, original concentrations
- y: The known responses

Fit Method:

Data is fitted using the Levenburg Marquardt algorithm.

D4.5.1.3 Exponential model

A curve with exponential growth.

Model equation:

$$y = Ae^{-Bx}$$

Model parameters:

- A: The point where the curve crosses the y axis
- B: The value of a definite physical constant
- x: The known, original concentrations
- y: The known responses

Fit method:

Data is fitted using the Levenburg Marquardt algorithm.

D4.5.1.4 Straight line

Linear model equation:

$$y = A + Bx$$

Model parameters:

- A: Linear factor
- B: Intersect
- x: The known, original concentrations
- y: The known responses

D4.5.1.5 MMF curve

Morgan–Mercer–Flodin curve, a sigmoidal curve with a transition from one response level to another.

Model equation:

$$y = (AB + Cx^D)/(B + x^D)$$

Model parameters:

- A: The level of the curve when x approaches zero.
- B: The EC50 factor. The term half maximal effective concentration (EC50) refers to the concentration of a drug, antibody or toxicant which induces a response halfway between the baseline and maximum after some specified exposure time. It is commonly used as a measure of drug's potency. EC50 value represents the x-value at which the middle y-value is attained and is $B^{1/D}$
- C: The level of the curve when x approaches positive infinity.
- D: The slope factor. D is always positive, A and C values determine if y is decreasing as x increases or y is decreasing as x decreases (fitted using Levenburg Marquardt algorithm).
- x: The known, original concentrations
- y: The known responses

Note that the MMF curve model equation can also be expressed as:

$$y = C - (C - A)/(1 + (Ex)^D)$$

D4.6 Dilutions/spikes

In the **Dilutions/spikes** functionality, spike recovery and dilution linearity studies for sample dilution series can be performed. From sample dilutions passing predefined criteria, an average sample series concentration can be calculated.

Data from sample dilutions are presented in a **Details** table and averaged data for the sample series is presented in a **Summary** table.

Criteria are specified for a sample dilution or sample series back calculated concentration (bcc), meaning measured concentrations adjusted for dilution factor.

Step	Action
1.	Under Dilution criteria two criteria for each sample dilution series can be specified. Each sample dilution, within a series, that don't meet specified Dilution criteria will be highlighted in red in the Details table. - When evaluating spike recovery of a sample dilution series, an acceptable spike recovery interval for each sample dilution can be specified - When evaluating dilution linearity of a sample dilution series, rules for maximum concentration deviations from the highest measured concentration in the series or acceptable sample dilution series precision levels can be specified Refer to Table A (below) for detailed information on Dilution criteria.

Step Action

2. Based on sample dilutions passing **Dilution criteria** an average sample series concentration can be calculated.
 Two choices for the calculation of an average sample series concentration are available:
 - **Dilutions not failing selected criteria** (default):
 The concentration is only based on sample dilutions with accepted **Dilution criteria**. The calculated concentration is visible in the **Reported Series Conc** column in the **Summary** table.
NOTE: *Sample dilutions not passing specified Dilution criteria will be highlighted in red and excluded from the calculation of average sample series concentration.*
NOTE: *If both Dilution criteria are checked, only dilutions passing spike recovery will be evaluated by the dilution rule.*
 - **All dilutions:**
 The concentration is based on all sample dilutions included in the sample dilution series. The calculated concentration is visible in the **Reported Series Conc** column in the **Summary** table.
NOTE: *Sample dilutions not passing specified Dilution criteria will be highlighted in red but included in the calculation of average sample series concentration. Reported Series Conc based on sample dilutions with failed Dilution criteria will be highlighted in red.*
3. Under **Series criteria**, two criteria for the calculated average sample series concentration can be specified. Average sample series concentrations that don't meet specified **Series criteria** will be highlighted in red in the **Summary** table.
 - The minimum number of sample dilutions that must not fail for the average sample series concentration to be calculated.
 - The precision limit for the back calculated concentrations.
 Refer to Table B for detailed information on **Series criteria**.

Table A

Dilution criteria		
Parameter	Comment	Dilution criteria not passed will be highlighted in column:
Minimum number of spikes, for the dilution, with passed spike recovery	For each spiked sample included in a sample series, specify the minimum acceptable number of spikes that passed spike recovery.	N Passed Spike Recovery (Details table, Extended view)
Spike recovery interval (%)	Specify the acceptable spike recovery interval in percent. Spike recovery is calculated by subtracting the unspiked concentration from the spiked concentration, the difference is divided with the spiking concentration.	Spike Recovery [%] (Details table, Original view)

Dilution criteria

Rule for dilution's bcc	Percent Deviation	For each sample dilution included in a sample series, specify the maximum acceptable concentration deviation from the highest measured concentration. Refer to Chapter D4.6.1 for descriptions of rules.	Series Conc (Details table, Original view)
	CV	For the sample dilution series, specify the maximum CV level. Refer to Chapter D4.6.1 for descriptions of rules.	Series Conc (Details table, Original view)
	LLOQ	When selecting the Percent Deviation or CV rule, user can also select the criteria All replicates in at least one dilution in the series must be below LLOQ . Refer to Chapter D4.1 step 6 for specifying LLOQ levels. NOTE: <i>In the Dilution/spike-view's Details table, the values in the column Unspiked Conc, Diluted will read "<LLOQ" when at least one replicate is below the user set LLOQ limit. If some, but not all, replicates are below LLOQ and the user selects the LLOQ rule and that rule fails, then the cell will read "<LLOQ (some repl.)"</i>	Series Conc (Details table, Original view)

Table B

Series criteria		
Parameter	Comment	Dilution criteria not passed will be highlighted in column:
Minimum number of dilutions not failing selected dilution criteria	Specify the minimum number of sample dilutions that should pass specified Dilution criteria. <i>NOTE: Dilutions passing the criteria do not need to be consecutive dilutions.</i>	N Accepted Dilutions (Summary table, Original view) N Accepted Dilutions (Details table, Extended view)
bcc CV (%)	Specify the coefficient of variation (CV) limit for the sample dilution series.	CV Series Conc [%] (Summary table, Original view) CV Series Conc [%] (Details table, Original view)

D4.6.1 Dilutions/spikes rules

D4.6.1.1 Percent deviation

By using the **Max** rule, a maximum concentration deviation between each sample dilution and the highest measured concentration in a sample series can be specified.

The deviation is calculated by dividing a sample dilution concentration with the highest measured concentration within that sample series. The deviations will be specified in the **Conc vs Max [%]** column (Details table, Original view), the highest concentration will be specified as 100. Sample dilutions outside the maximum deviation will be highlighted in red and identified by "No" in the **Dilution Accepted by Series Rule** column (Details table, Extended view).

The maximum acceptable deviation is specified in the **Max deviation from highest bcc (%)**.

D4.6.1.2 CV

By using the **CV** rule, a coefficient of variation (CV) limit for the sample dilution series can be specified. If the sample dilution series CV is higher than specified, the rule will remove the least diluted sample and recalculate the CV until specification is reached. Removed samples will be highlighted in red and identified by "No" in the **Dilution Accepted by Series Rule** column (Details table, Extended view).

D5 Gyrolab Evaluator installation on office computer

The analysis software Gyrolab Evaluator is included in the standard installation of the Gyrolab system. This chapter describes how to install Gyrolab Evaluator on an office computer to enable remote evaluation of run result, eliminating the need to use the instrument computer for data analysis.

D5.1 Gyrolab Evaluator installation package

Gyrolab Evaluator installation package contains the following software:

- Gyrolab Evaluator
- Microsoft .Net Framework 4.5.2 or higher
- Gyrolab User Guide
- Software installation instructions
- Adobe Reader (enables access to Gyrolab User Guide and Software installation instructions)

D5.2 Computer requirements

Gyrolab Analysis Software Package should be installed on a computer with access to desired Gyrolab instrument.

- Minimum computer system specifications are 3 GHz processor and 1 Gb RAM memory.
- Operative system requirement is Windows 10, 64 bit.
- Minimum monitor 1080×1024 resolution, minimum color quality (16 bit).

D5.3 User role requirements

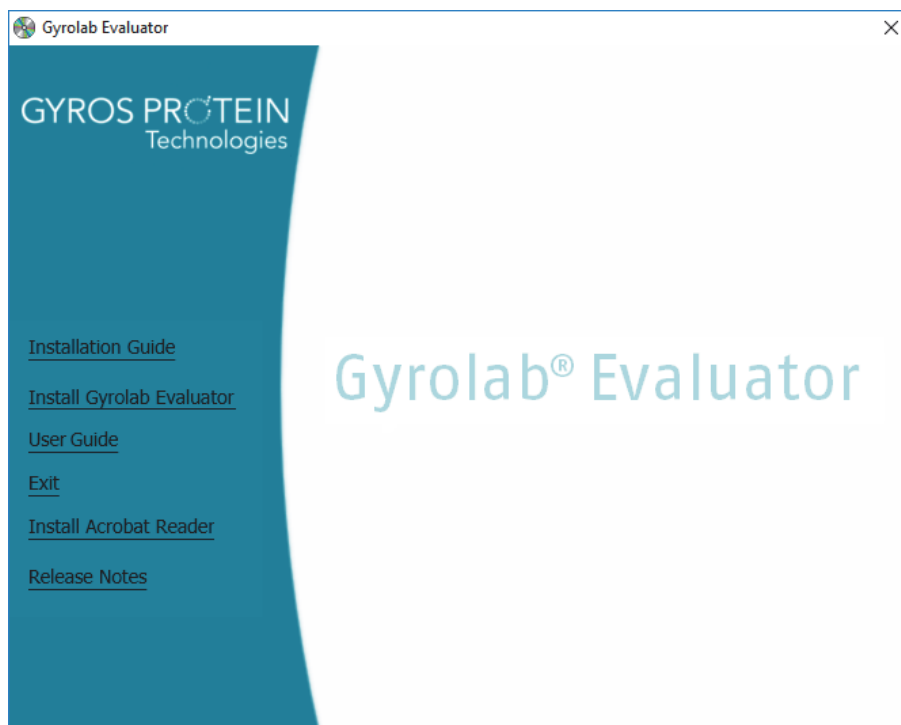
Installation of Gyrolab Analysis Software Package requires administrator privileges on the computer.

To be able to use the Gyrolab software, a Username and Password is required. Contact the local Gyrolab system administrator to receive login details for Gyrolab Software.

D5.4 Installation

Before installation start, make sure that the operating system is updated with the latest patches from Microsoft. This can be done from the web site <http://update.microsoft.com/>

Step	Action
1.	Insert Gyrolab Analysis Software Package CD in the CD drive.
2.	Gyrolab Evaluator installation screen opens.



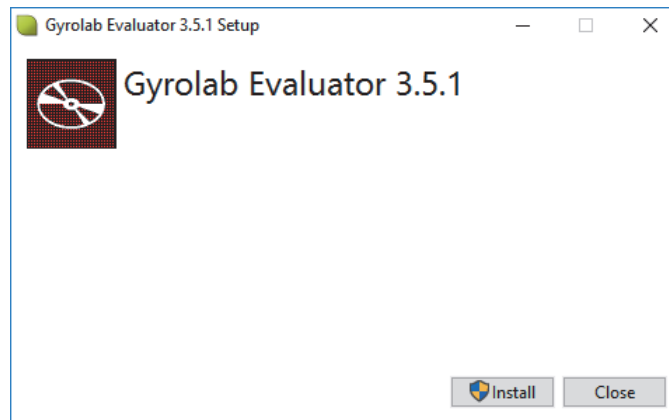
- If the installation start screen does not appear automatically, browse for the CD folder in Windows Explorer and double-click on the file **lsplash\autorun.exe**.
- 3.
- Select **Installation Guide** to view installation instructions.
 - Select **User Manual** to access Gyrolab User Guide.
 - Select **Exit** to exit installation procedures.
 - Select **Install Acrobat Reader** and follow the instructions to install Acrobat Reader. This is needed only if your system does not have a pdf reader already.
 - Select **Release Notes** to view information on this software release.

4. Select **Install Gyrolab Evaluator** to start installation.

If .NET Framework is unavailable or of inadequate version, the installation software will also install required .NET Framework.

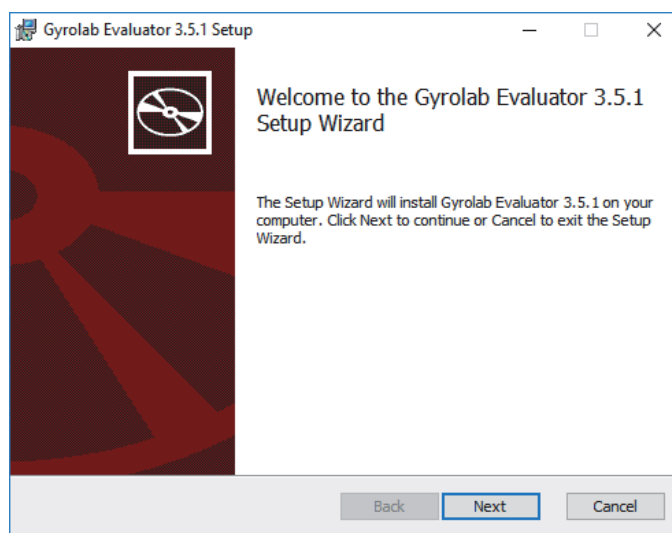
Step Action

5. A **Gyrolab Evaluator** dialog opens. Click **Install**.



NOTE: During the installation procedure it is possible to cancel installation by clicking **Cancel** and to return to previous step by clicking **< Back**.

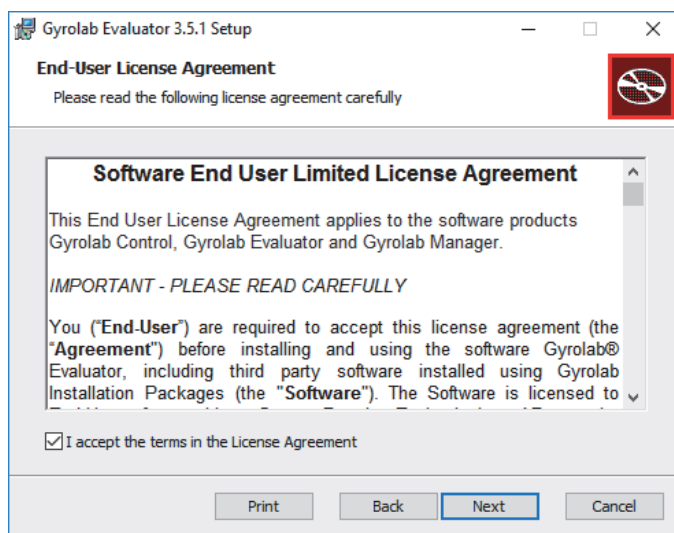
6. A **Gyrolab Evaluator** dialog opens. Click **Next >**.



Step	Action

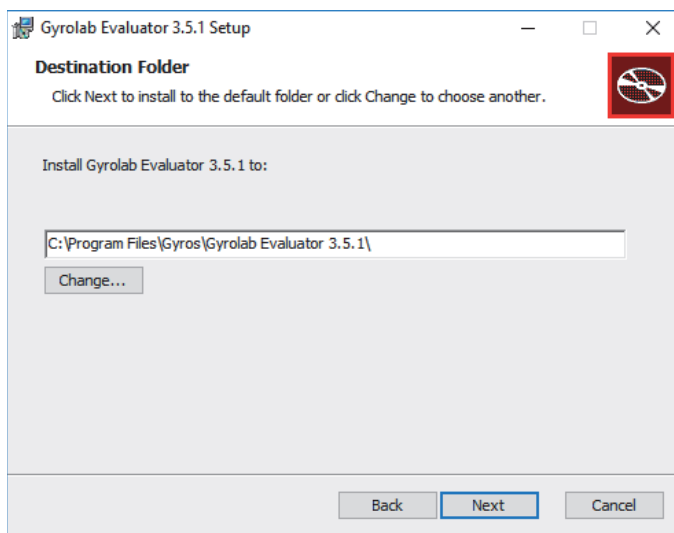
7.	A Gyrolab Evaluator dialog opens. Read the license agreement, select I accept the terms in the Licence Agreement and click Next > .

If the License agreement can not be accepted click **Cancel** and contact Gyros Protein Technologies.



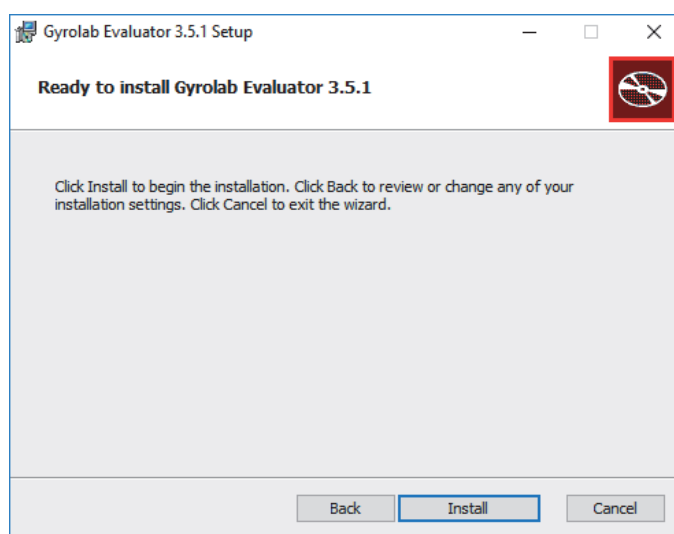
8.	A Gyrolab Evaluator dialog opens.

- Click **Change...** to select folder for installation.
- Click **Next >**.

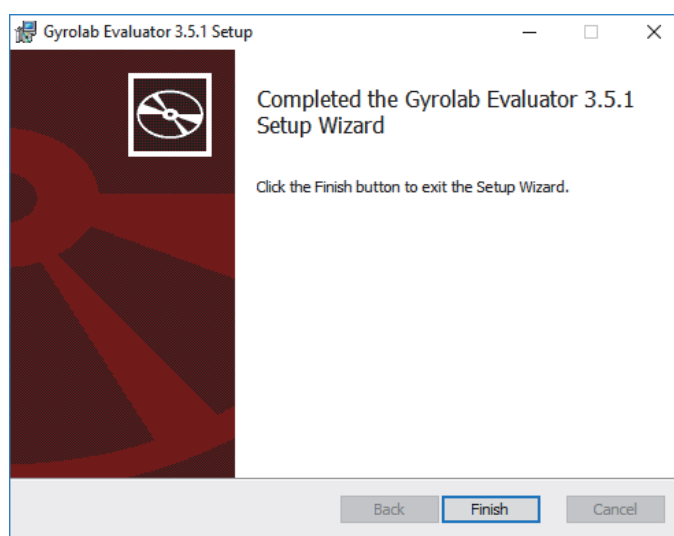


Step Action

9. A **Gyrolab Evaluator** dialog opens. Click **Install** to start the installation.



10. When the installation is completed a **Gyrolab Evaluator** dialog opens. Click **Finish** to exit.



11. Check Windows Update for available updates for Microsoft.NET Framework 4.
12. When the installation is finished, eject the CD.
13. Restart the computer after installation.

D5.5 Database configuration

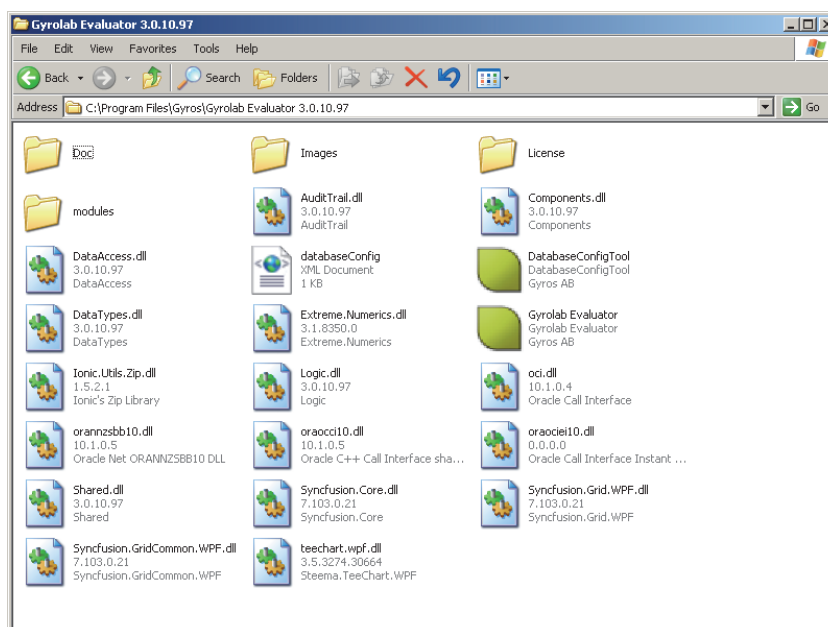
Gyrolab Evaluator is designed to evaluate results processed by Gyrolab Control. The result files are stored in Gyrolab Result Database.

The Gyrolab instrument computer is installed with the Windows firewall enabled. To allow communication between the Gyrolab instrument computer and an office computer, contact the local system administrator.

This chapter describes how to configure and set up Gyrolab database communication between the Gyrolab instrument computer and another computer in the same network.

Step Action

1.
 - In Windows Explorer, browse to the Gyrolab Evaluator installation folder. The location for this folder was set during installation, refer to Chapter D5.4, step 8.
 - Click to open **DatabaseConfigTool**.

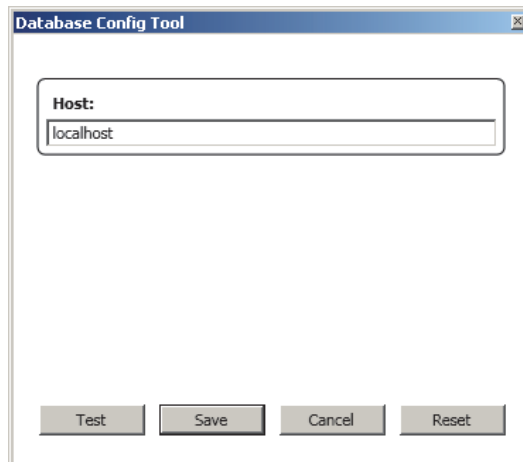


NOTE: *Windows 7, Windows 8 or Windows 7 UAC (User Application Control) may not allow to select DatabaseConfigTool. Right-click on the DatabaseConfigTool icon (administrator user privileges required) to Right-click on the DatabaseConfig-Tool icon (Run as administrator) and select to allow database configuration in the dialogs that follow.*

NOTE: *In order for the Gyrolab Evaluator software to be able to communicate with the workstation database from a remote computer; port 1521 must be configured open for access in the firewall.*

Step	Action

2.	The Database Config Tool opens:



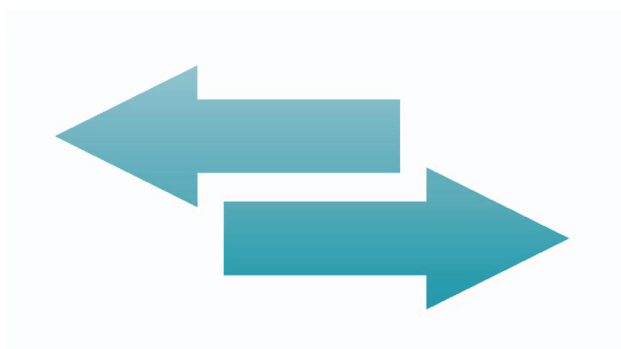
Enter the name of the Gyrolab database in the **Host** field:

- If Gyrolab database is located on the same computer as Gyrolab Evaluator, enter *localhost*
 - if the Gyrolab database is located on a different computer than the Gyrolab Evaluator software, enter the computer network address for the computer that holds the Gyrolab Result Database
 - **Reset** will regenerate the original *localhost* settings.
- | | |
|----|---|
| 3. | Click Save . |
| 4. | Press the Test button to verify the connection. There should be no red text in the result. If there is any text, refer to Chapter H2.3 |

To change database, perform step 1 to 3 above and change to desired database in step 2.

GYROLAB USER GUIDE

E Gyrolab software add-on modules



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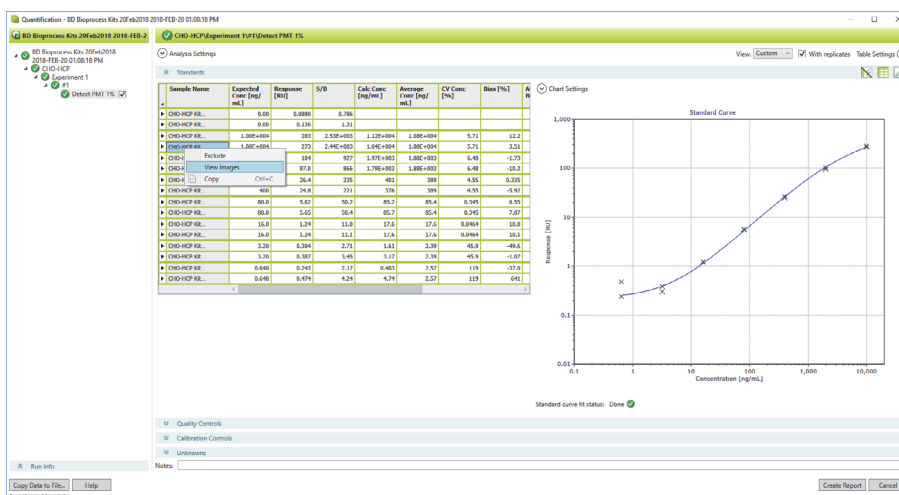
E1.1 Gyrolab Viewer introduction

Gyrolab Viewer is used during assay development to aid in the selection of optimal reagents and during quality control and assay troubleshooting to investigate outliers.

E1.2 View binding profile images

Step	Action

1. In the analysis window, select a sample in a data table. Right-click on the Sample Name and select **View Images...**

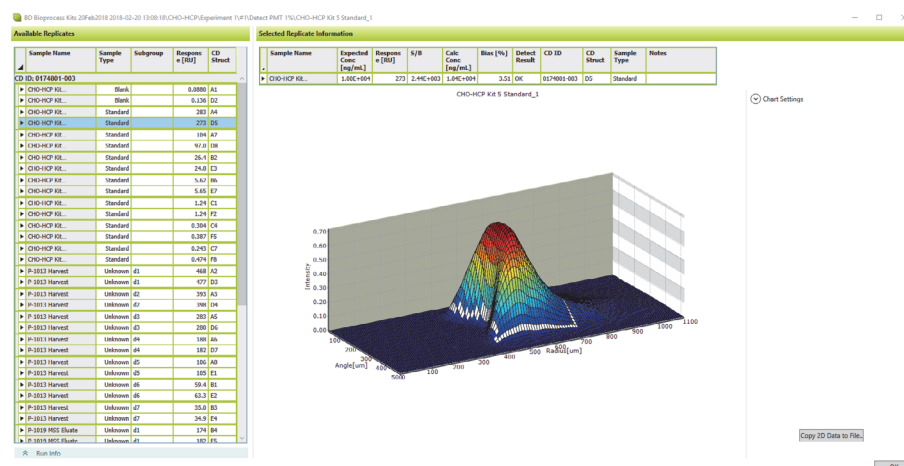


Step Action

2. Gyrolab Viewer window opens.

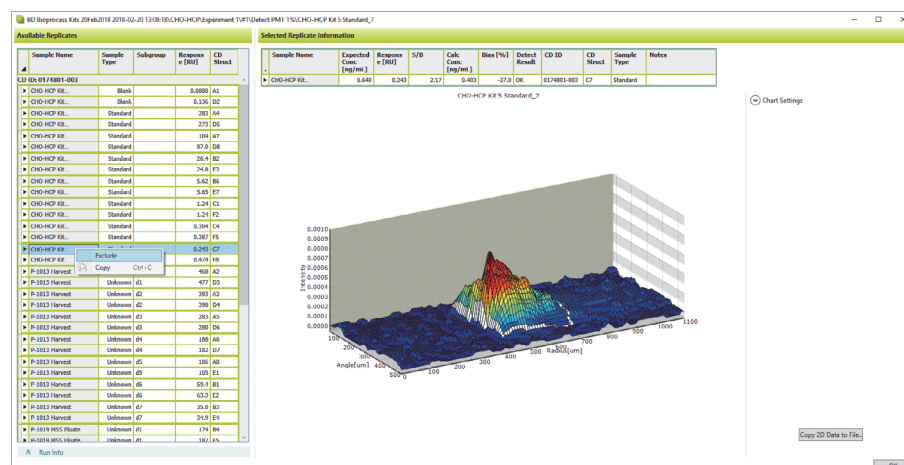
The binding profile is a 3D representation of the response intensity in each Gyrolab CD microstructure. The binding profile color, ranging from dark blue to dark red, corresponds to signal intensity from 0 to 1. For alternative profile coloring, refer to step 3.

For further information on binding profile interpretation, refer to Chapter E1.3.



Replicates can be excluded, if the analysis settings permit it, by right clicking the replicate in the **Available Replicates** table and selecting **Exclude**.

In the **Selected Replicate Information**, the user can comment on a replicate by typing in the **Notes** column.

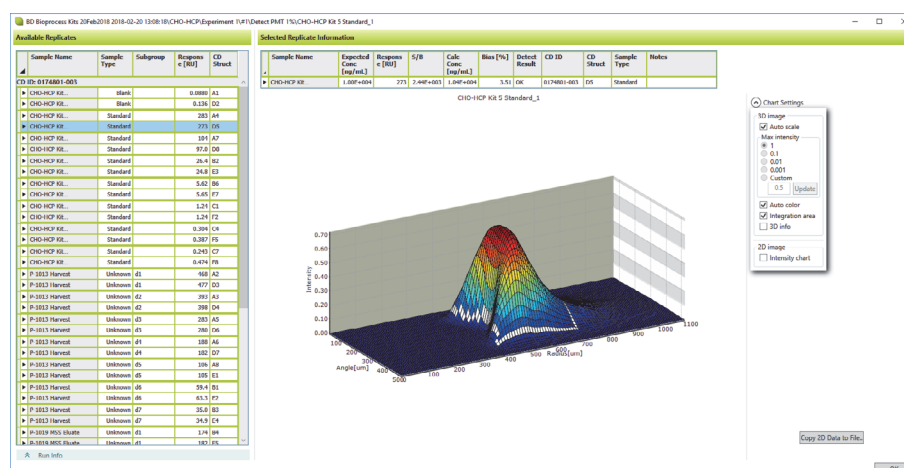


Step Action

3. Click within the 3D image and drag to change the view angle.

To control the 3D binding profile display, click **Chart Settings...**

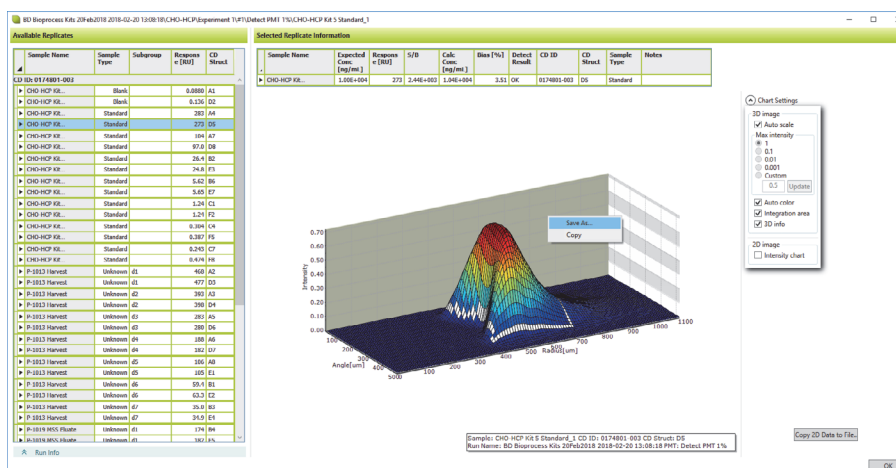
- Select scale for the intensity axis: Choose between **Autoscale** or a fixed **Max intensity**. For fixed intensity axis, choose between default values or set a custom value. Click **Update** for the custom value change to take effect. Available intensity axis value range is 0.001 to 1.
- Mark check box **Integration area** to display the integration area on top of the binding profile. The integration area illustrates the part of the signal included in the calculation of the sample response value.
- Mark check box **Autocolor** to obtain binding profile coloring where colors range from dark blue to dark red corresponding to lowest and highest signal intensity within each specific image.
- Mark check box **Show 3D info** to display a text box with sample, CD structure and run information. This text box is included in the binding profile image when copied or saved to another location.
- Click **Chart Settings** again to close the settings window.



Step Action

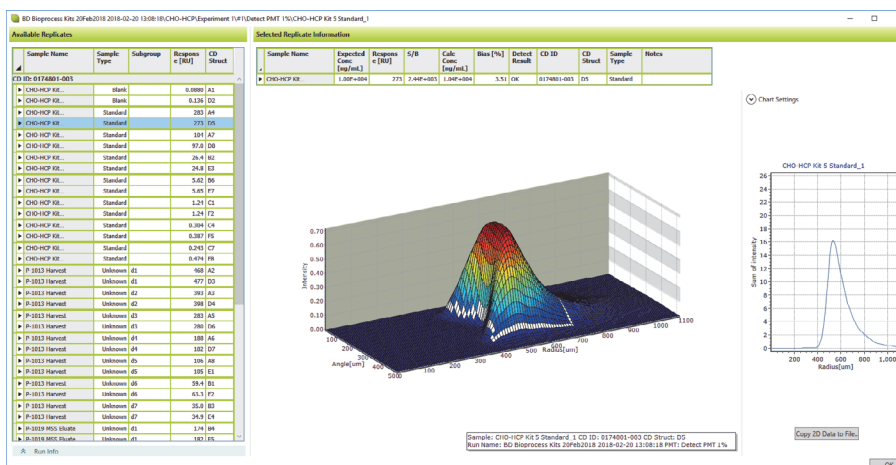
4. To copy or save the 3D image to file, right-click in the image and select:

- **Save As...** to save the 3D image to disc. In the Save As... dialog, enter desired file name and choose between available file formats (.svg, .jpg, .vml, .xaml, .gif, .png, .tiff, .bmp). Click Save.
- **Copy** to place a copy of the image on the clipboard.



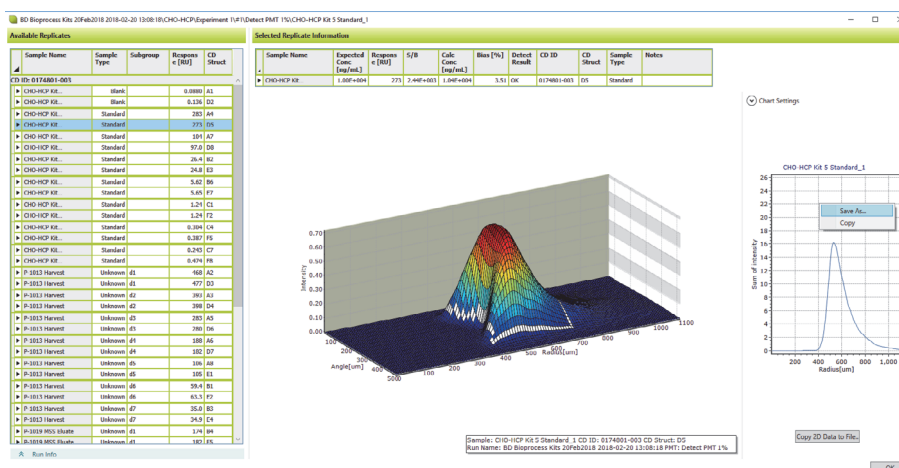
5. To display a 2D image of the binding profile, click **Chart Settings...**

- Mark check box **Show Chart** in the 2D image, Intensity Sum section. Click **Chart Settings** again to close the settings window.
- A two-dimensional contour plot appears. The 2D image displays the sum of the intensity across the microstructure in radial direction.
- Zoom in by clicking in the 2D graph and drag the cursor down and right to select an area with the rectangle. Zoom out by clicking in the graph area and drag the cursor up and left. The original graph will be shown.

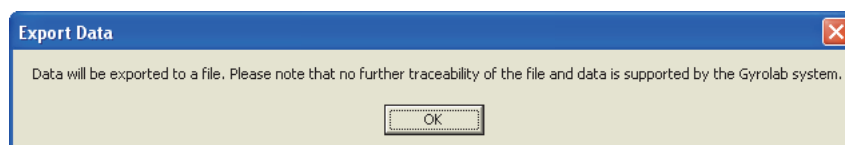


Step Action

6. To copy or save the 2D image to file, right-click in the image and select:
 - **Save As...** to save the 2D image to disc. In the Save As... dialog, enter desired file name and choose between available file formats (.svg, .jpg, .vml, .xaml, .gif, .png, .tiff, .bmp). Click Save.
 - **Copy** to place a copy of the image on the clipboard.



7. To export 2D data to file, click **Copy 2D Data To File** button. A dialog appears:



- The dialog is to remind the user that further analysis of the 2D image data is not supported by the Gyrolab Viewer software. Click **OK**.
 - In the **Save As...** dialog, enter desired file name and choose between available file formats (Excel XML Spreadsheet .xls or Text file .txt). Click **Save**.
 - The exported data can be used to create 2D overlay plots in other analysis software, for example Microsoft® Excel®.
8. Click **OK** to close the Gyrolab Viewer window and return to the analysis module window.

E1.3 Interpreting Gyrolab Viewer images

All interactions in the CD microstructure are generated under controlled flow conditions. The binding profile produced by Gyrolab Viewer is a representation of the signal intensity in each Gyrolab CD microstructure and illustrates the analyte's position in the microstructure.

Interaction between the capture reagent and the analyte molecule affects profile characteristics. Characteristics of an ideal binding profile:

- The signal is not saturated, i.e. the maximum signal intensity within the binding profile is lower than 1.
- The binding profile has a sharp peak and has a narrow distribution in the radial direction, indicating high affinity between capture reagent and analyte.
- No signal spikes are visible within the binding profile.

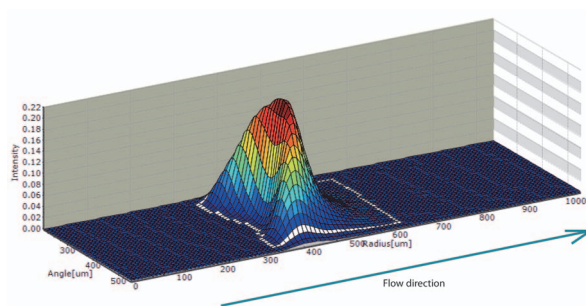


Figure 1: Example of desired binding profile in Gyrolab Viewer

E1.3.1 Using Gyrolab Viewer to optimize PMT setting for a run

The images produced in Gyrolab Viewer are useful when selecting the optimum PMT setting for a Gyrolab Run.

The fluorescent signal from the microstructure column is amplified by a photo multiplier tube (PMT) when the signal reaches the detector. The degree of amplification needed to obtain a sufficient response value depends on the signal intensity of the measured sample. The signal amplification is controlled by the PMT setting in a Gyrolab method.

Since the response signal is dependent on the analyte concentration of the sample as well as the PMT setting, combining a high analyte concentration and high PMT setting may saturate the detector. An example of a saturated signal is given in Figure 2.

To ensure proper quantification of response signal when analyzing run results, use data produced with a PMT setting that does not saturate the detector. If such results are not available within the run, rerun the assay using a lower PMT setting in the Gyrolab method. Contact Gyros for support regarding altering methods or adjust the concentration range of the assay.

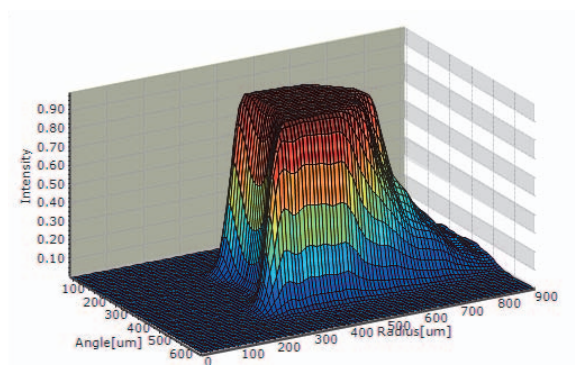


Figure 2: Example of binding profile that indicates saturated detector signal

If the calculated concentration for a sample is very low and Viewer images display low-intensity binding profiles even for samples with highest expected concentration, use data produced with a higher PMT setting. If such results are not available within the run, rerun the assay using a higher PMT setting in the Gyrolab method. Contact Gyros for support regarding altering methods or adjust the concentration range of the assay.

E1.3.2 Using Gyrolab Viewer to characterize binding properties

During assay development different reagents are evaluated to find the most suitable reagent combination for the specific assay. Most often several antibody combinations are tested and compared to achieve an optimal assay performance. The Viewer images can help in the characterization of the binding profiles of the reagents, as reagents with appropriate affinity should be selected for an optimal assay performance.

When the assay is intended to measure low analyte concentrations high affinity reagents are required. For assays with a working range at higher analyte concentrations, reagents with lower affinity can be selected.

- Binding profiles where capture reagent-analyte interaction is weaker normally display a peak that is broader in radial direction i.e. the signal is more widely distributed along the flow direction in the microstructure column (Figure 3 B).
- Binding profiles where capture reagent-analyte interactions are strong display sharp peaks. The reagent is more efficient in enriching the analyte in the top of the column compared to a capture reagent with lower affinity (Figure 3 A).

The Viewer may also help in investigating the binding properties of samples with endogenous analyte vs. the standard analyte as these may in some instances differ, see Figure 3 A&B. Care should be taken to adjust the assay, either by choosing different reagents or adjusting the method so that samples are appropriately measured to the standard analyte.

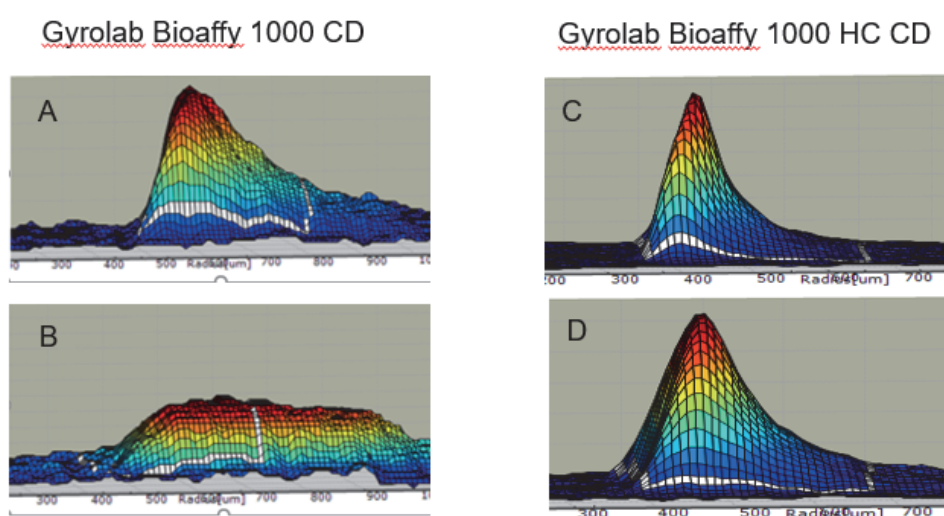


Figure 3: A hormone measured on two different CD types, Gyrolab Bioaffy 1000 CD (A and B) and Gyrolab Bioaffy 1000 HC CD (C and D). The standard analyte, which was a recombinant protein, showed good binding profiles (A and C) on both CD types. The endogenous hormone sample (B and D) could only be accurately measured using the Bioaffy 1000 HC CD (D).

E1.3.3 Using Gyrolab Viewer to investigate outliers

When analyzing assay results, Gyrolab Viewer may assist in assessing outliers caused by fibers or fluorescent spikes that affects the signal intensity in the integration area. Fibers or spikes within the integration area should be excluded from data analysis.

Fluorescent spikes may be caused by contaminations of, or aggregation in samples, reagents or wash solutions and it is therefore important that all liquids are prepared and stored according to their recommendations. Most often aggregates are seen in the detection reagent

and it is therefore recommended to always perform a high-speed spin of the detection reagent prior analysis run. Similarly, highly lipophilic serum samples may also cause increased spikes, and a centrifugation of serum samples may alleviate the problem.

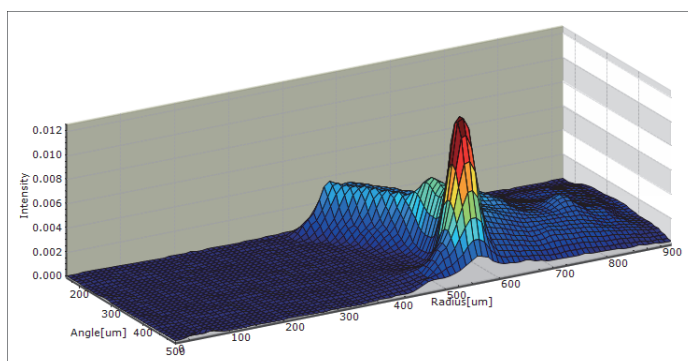


Figure 4: Example of binding profile with spike irregularities

Other suggestions that may help in reducing spikes are to use filtered wash buffers, use fresh reagents and regularly clean the surfaces of the instrument with lint free tissue to reduce accidental introduction of fibers to the CD. See chapter C1 for recommendations on reagent labeling, chapter C3 for recommendations on sample and reagent preparation and to the Gyrolab Instrument Guide for maintenance of your instrument.

E1.4 Compare multiple binding profile images

To get an overview of all the binding profile images and analyze them simultaneously, it is possible to select a set of sample replicates for **Side-by-Side** comparison.

In the section **Available Replicates**, select the replicates to examine by checking them in the **Side-by-Side** column

Sample Name	Sample Type	Response [RU]	CD Struct	Side By Side
CD ID: 0003202-086				
▶ Standard kit 5_Blank	Blank	0.0777	G1	☐
▶ Standard kit 5_Blank	Blank	0.0880	H1	☐
▶ Standard kit 5_Blank	Blank	0.0822	I1	☐
▶ Standard kit 5_1	Standard	0.168	G2	☒
▶ Standard kit 5_1	Standard	0.146	H2	☒
▶ Standard kit 5_1	Standard	0.133	I2	☒

Use the selection filters for a quick selection of all samples or all samples of a specific sample type.

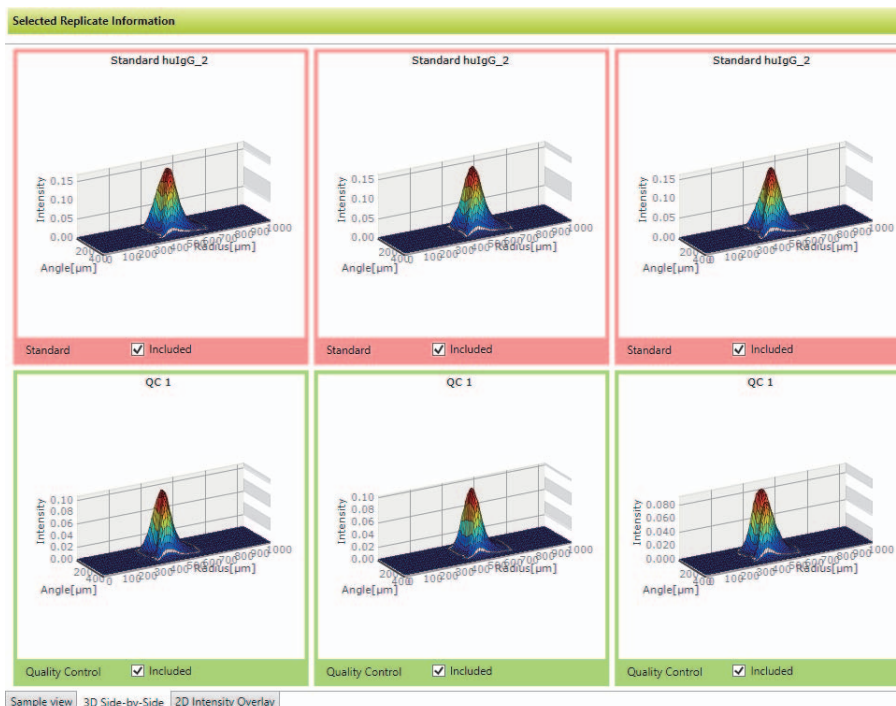
- ☐ All Samples
- ☐ All Standards
- ☐ All Quality Controls
- ☐ All Calibration Controls
- ☐ All Unknowns
- ☒ Selection filters for side by side...

⬆ Run Info

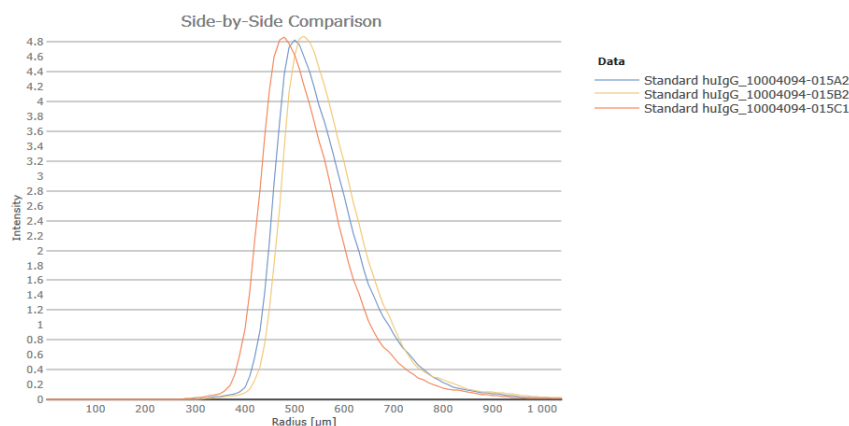
To analyze the binding profile images of the selected replicates simultaneously, select tab **3D Side-by-Side**, or to view an overlay chart of the intensity graphs, select tab **2D Intensity Overlay**.

Sample view 3D Side-by-Side 2D Intensity Overlay

From the 3D-view it is possible to include/exclude replicates by selecting/deselecting the **Included** checkbox. Clicking on an image will select the corresponding sample replicate in the data grid, and vice versa. Refer to Chapter E1.3 on how to interpret the images.



Compare the intensity charts of replicates by overlaying them in **2D Intensity Overlay**.



E1.5 Installation of Gyrolab Viewer

The Gyrolab Viewer software module is available for Gyrolab Evaluator version 3.2 or higher and is activated by the user with a licence key. Licences are instrument specific. Contact Gyros Protein Technologies to purchase Gyrolab Viewer and receive a license.

To register the license: Save the license file to the hard disk of the external instrument computer, at the Gyros license folder, currently C:\ProgramData\Gyros\Licenses.

E2 Gyrolab ADA Software

Visit www.gyrosproteintechnologies.com for the latest updates on available software modules.

E2.1 Introduction to Gyrolab ADA Software

Gyrolab ADA Software is a software add-on module for Gyrolab Control version 5.4 and Gyrolab Evaluator version 3.3 or higher.

The Gyrolab ADA product portfolio enables measurement of anti-drug antibodies (ADAs) in the presence of excess amounts of drug. Samples can be treated with acid in an automated procedure to allow drug-ADA complexes to dissociate, and then neutralized just before analysis, preventing complexes from reforming. The acid pre-treatment of the ADA-drug complex increases the “drug tolerance” of the assay, a term used to describe its capability to detect ADAs in the presence of drug in the sample.

Recommendations on assay development and sample and reagent preparations are found in the Gyrolab ADA assay protocol, included in the purchase of Gyrolab ADA Software.

During clinical ADA analysis samples are screened for ADA positives in a **Screening** assay. **Confirmation** assays are performed to investigate whether positive samples from screening are true positives. Evaluation functionalities are available in Gyrolab ADA Software to support these analyses.

E2.2 ADA Run Design

E2.2.1 Design Method

The Gyrolab Mixing CD contains individual mixing chambers upstream of the capture column. The mixing chamber allows for rapid mixing of liquids added according to the Gyrolab method. Mixing is followed by incubation steps to get the full effect of sample acidification to dissociate ADA-drug complexes or neutralization to form complexes necessary for detection of ADAs.

Two parameters in the ADA methods can be controlled by the user: mixing time and incubation time.

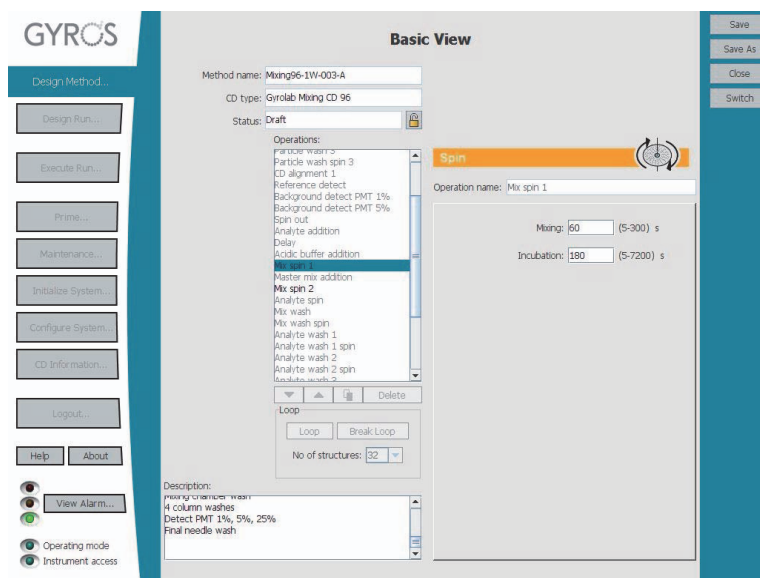
Designing a Method for an ADA run is currently always done in Gyrolab Client, even if the ADA Run Design that will use the Method will be created in Gyrolab Manager. Once a Method has been created, it can be used in all ADA Run Designs having the same method properties, including mixing and incubation times.

NOTE: *User role Method Developer, Project Manager or System Administrator is required to edit methods. For more information on user roles, refer to Chapter NOTE:.*

Step	Action
1.	In the main menu of Gyrolab Control (refer to Chapter G1.2), select Methods...
2.	Select an ADA method in the method list and click Open...

Step Action

3. The **Basic View** for method editing opens.

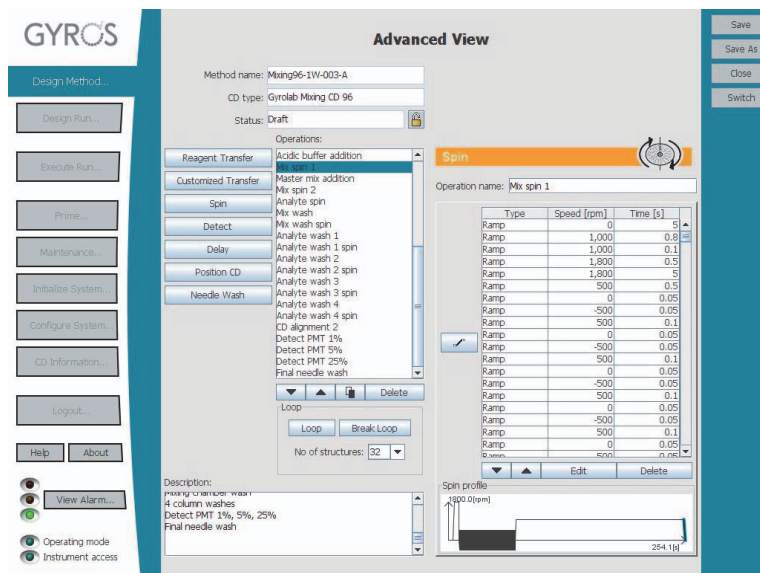


Method steps that are editable are displayed in black in the **Operations** list. Select the method step you wish to edit (in the example above mix spin 1 or mix spin 2).

Enter mixing and incubation times in seconds in the fields **Mixing** and **Incubation**.

- Click **Save** to save the method change.
- Click **Save As** to save the method in a new name.

4. To enable editing of all method steps, click **Switch**. The **Advanced View** for method editing opens.



Advanced editing is a function used for developing customized Methods to suit specific needs. Contact Gyros Protein Technologies for more information.

5. Click **Close** to close the method editor.

E2.2.2 Design Run

The recommended way to design an ADA Run Design is to use Gyrolab Manager, followed by creating a Run Setup based on the Run Design.

An ADA Run Design is very similar to creating a Wizard Run Design, where the main difference is that an ADA Run Design typically includes ADA Controls. ADA Controls are handled quite similar to Quality Control (QC) samples, with some differences

- An ADA Control can be classified as a Negative or Positive Control.
- A concentration value is not assigned to an ADA Control.
- The number of replicates can be set individually for each ADA Control.

The procedure to create a Wizard Run Design is described in chapter B4, specifically addressing ADA controls in Chapter B4.3.5.

To create an ADA Run Design using Gyrolab Client instead, see chapter I4.2.

E2.3 ADA Run Setup

If using Gyrolab Manager to create the ADA Run Design, no special procedure is required to prepare run execution. Create a Run Setup as for a Wizard run, see Chapter B5.

It is also possible to execute an ADA run in the traditional way, using Gyrolab Client. In this case, the ADA Run Design must be created using Gyrolab Client, see chapter I4.2 and execution is described in chapter I4.3.

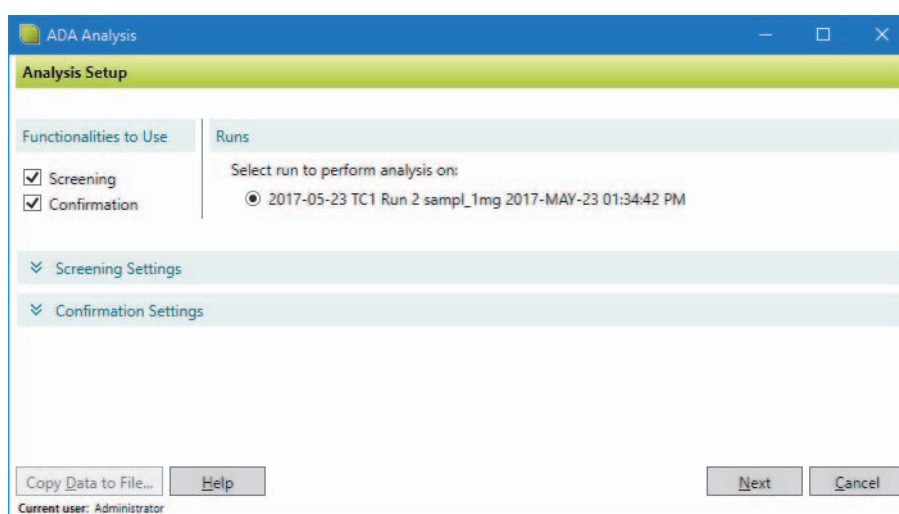
E2.4 Data evaluation

This chapter describes how to evaluate run data from an ADA Run. The data analysis is performed in Gyrolab Evaluator using the software module Gyrolab ADA Software.

Quantification functionality may be used during ADA assay development and validation. To perform a quantification analysis on data from an ADA Run, see Chapter D4.1.¹

Step Action

1. In Gyrolab Evaluator Project view (Chapter D3.1), select an ADA run and click the **ADA Analysis** button  **ADA Analysis**.
2. The **ADA Analysis** window opens.



- Select what analysis **Functionalities to use** by marking check boxes as appropriate.
- In the **Runs** section, select desired Run for analysis.
- Analysis Settings for each functionality are set in the **Screening Settings**, **Confirmation Settings** and the **Quantification Settings** sections. Click on the section to expand it.
 - For **Screening** analysis, continue to Chapter E2.4.1. Screening assays are performed to screen for ADA positive samples. The Screening functionality is used during assay development and validation and for routine analysis.
 - For **Confirmation** analysis, continue to Chapter E2.4.2. Confirmation assays are performed to investigate whether positive samples from screening assays are true positives. Confirmation functionality is used during assay development and validation and for routine analysis.

E2.4.1 Screening

During ADA analysis clinical samples are screened for ADA positives in a **Screening** assay. The Screening functionality is also used during assay development and validation.

1. If an ADA Analysis containing a Quantification was created in an older version of Gyrolab Evaluator, the analysis report can still be viewed, saved to disk, and printed. However, if the ADA Analysis is opened, only Screening and Confirmation will be available. To make a new Quantification, see Chapter D4.1

Step Action

1. In the ADA Analysis window (Chapter E2.4), click on **Screening Settings**. The Screening Settings panel opens.

Screening Settings

Evaluation

Cut point formula: ⌵ AvgNcResp

⌵ Help

You can enter a formula used to calculate the cut point.

The formula may contain numbers and operators (+, -, *, /). Parentheses may be used. In addition, the following predefined parameters can be used:

AvgNcResp: Average of the response of all (included) NC sample replicates.

AvgNcAvgResp: Average of the average response of all NC samples.

SdNcResp: Standard deviation of the response of all (included) NC sample replicates.

SdNcAvgResp: Standard deviation of the average response of all NC samples.

Write the parameters directly in the formula or use the parameter selection and insert button.

Note! All numerical values must be written in American English (e.g. decimal point, not decimal comma).

Acceptance Criteria

ADA Controls:

Sample Name	Type	Max CV (%)	Detect PMT 1%		Detect PMT 5%		Detect PMT 25%	
			Lower Limit	Upper Limit	Lower Limit	Upper Limit	Lower Limit	Upper Limit
NC_SPIKED	NC							
NC_UNSPIKED	NC							
PC800_SPIKED	NC							
PC100_SPIKED	PC							
PC100_UNSPIKED	PC							
PC800_UNSPIKED	PC							

CV unknown samples (%):

- In the **Evaluation** section, enter cut point formula in the **Cut point formula** field. Enter numbers, operators and/or parameters or build your cut point formula using the parameters in the drop-down list. A help section is available with explanations on available functions.

For multi-CD runs: Averages of ADA control response values and standard deviations can be included in the cut point formula. If ADA controls are applied to all CDs in the run (check box **Use on all CDs** is ticked (Chapter E2.2)), the average ADA control responses and standard deviations will be calculated for each CD individually and resulting cut point used to evaluate samples on that specific CD. If ADA Controls are applied only to one CD in the run, the average of ADA control results for this CD will be used to calculate a cut point and the same cut point will be used to evaluate all samples on all CDs.

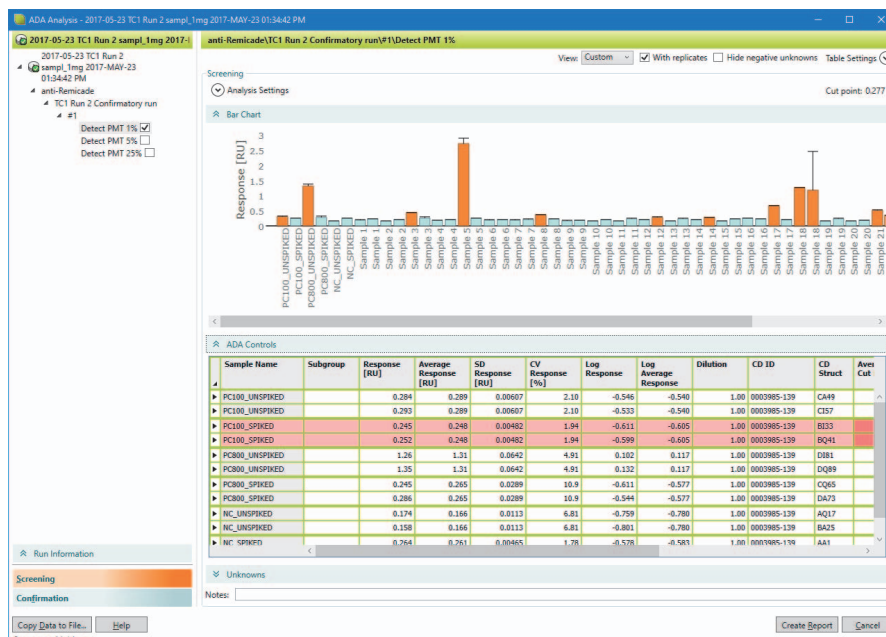
What screening cut point formula to apply for the assay is determined during the assay validation phase. For more information on cut point determination, refer to Gyrolab ADA assay protocol.

NOTE: *Gyros Protein Technologies recommends using floating cut point and to include ADA controls on all CDs in a run.*

- In the **Acceptance Criteria** section, add acceptance criteria for ADA controls for precision in the fields **Max CV (%)** and for response values in fields **Lower Limit** and **Upper Limit**. Add acceptance criteria for Unknown samples in the field **CV unknown samples (%)**. Values for upper and lower limit can be set for each detect operation in the method.
- Click **Next**.

Step Action

- Click **Screening** in the lower left corner. The Screening window opens.



The left panel of the Screening window displays available experiments in the Run and Run information, refer to Chapter D4.1.

The right panel of the Screening window displays collapsable/expandable views for:

- Bar Chart:** Visualizes average response results for ADA controls and unknown samples compared to the screening cut point. Standard deviations are indicated with error bars. Samples above cut point are indicated with orange bar color. Samples below cut point are indicated with blue bar color.
- ADA controls:** Data table with analysis results for ADA controls. ADA controls with results that fall outside of acceptance criteria (as set up in step 1) are high-lighted. Negative controls with response above screening cut point and positive controls with response below screening cut point are highlighted. Refer to Chapter E2.4.1.1 for detailed information on column data.
- Unknowns:** Data table with analysis results for unknown samples. Samples with results that fall outside of acceptance criteria set in step 1 are highlighted. Refer to Chapter E2.4.2.1 for detailed information on column data.

- Click **Analysis settings** to change settings for the Screening functionality.

- To simplify bar chart view and facilitate data evaluation it is possible to hide unknown samples with mean response values below the cut point.

- Mark check box **Hide negative unknowns**.

Step Action

5. General commands for data tables:
 - In the **View** list, select display option for data tables:
 - **Original**: A selected number of data columns (default)
 - **Extended**: All available data columns
 - If the **With replicates** box is ticked (default) all replicates for samples are shown in the table and in the bar chart. Untick the box to display average values for samples.
 - It is possible to include or exclude data points:
 - To exclude a data point, right-click on the sample and select **Exclude**. To perform this With replicates must be ticked. If required by Project settings, the reason for inclusion must be specified. The change description is included in the Audit Trail.
 - To include an excluded sample, right-click on the sample and select **Include**. To perform this With replicates box must be ticked. If required by Project settings, the reason for inclusion must be specified. The change description is included in the Audit Trail.
 - It is possible to edit **Dilution** values. If required by Project settings, the reason for editing must be specified. The change description is included in the Audit Trail.
 - It is possible to add **Notes** for individual samples in the right-most column if With replicates box is ticked and View list is set to Extended.

NOTE: *The number and titles of columns may differ depending on the Run and if replicates are shown or not.*
6. It is possible to add general experiment comments in the **Notes** text box located at bottom of the right panel.
7. To export data or generate analysis report, continue to Chapter E2.4.3.

E2.4.1.1 Data table descriptions – Screening

Columns that are displayed in the **Screening** view will be included in reports generated.

If Original view is selected (refer to Chapter E2.4.1, step 7) only columns indicated with a Yes below will be displayed. If Extended view is selected all available columns are shown.

Column heading	Original view	Description
Sample Name	Yes	Sample identity
Subgroup	Yes	Sample subgroup, as set during Run set-up, refer to Chapter I4.2.
Response (RU)	Yes	Integrated volume of the fluorescent binding surface of a reaction in a microstructure.
Average Response (RU)	Yes	Average of response values for replicates of a sample, sample group or sample subgroup.
SD Response (RU)	Yes	The standard deviation of responses of sample replicates.

Column heading	Original view	Description
CV Response (%)	Yes	Coefficient of variation of response of replicates of a sample.
Dilution	Yes	Dilution factor for Unknown samples is entered in the Sample List. For ADA control samples the dilution factor is entered entered during Run set-up, refer to Chapter E2.2. If no Dilution Factor value has been assigned a factor of 1 will automatically be used.
CD ID	Yes	Identity of Gyrolab CD microlaboratory used to process the samples.
CD Structure	Yes	Identity of structure on Gyrolab CD microlaboratory where the sample was processed.
Average Cut Point	Yes	Describes whether average sample response for replicates of a sample, sample group or sample subgroup are above or below cut point. Negative or positive.
Cut Point	Yes	Describes whether sample response is above or below cut point. Negative or positive.
Log of Response	No	The logarithm of Response value.
Log of Average Response	No	The logarithm of Average Response value.
MP ID	No	Identity of the microplate where the sample was placed.
MP Well	No	Well position on the microplate where the sample or standard was placed.
Detect Result	No	- OK: The results are approved - Not OK: The results are not approved. The fluorescence signal is of poor quality which may be caused by inadequate PMT setting (detector is saturated) or errors in sample preparation.
Sample Type	No	For ADA controls: Negative control or Positive control. For unknown sample: Unknown
Needle ID	No	The needle used to transfer the sample from the MP to the CD structure
Notes	No	It is possible to add comments to individual samples.

E2.4.2 Confirmation

Confirmation assays are performed to investigate whether positive samples from screening assays are true positives.

Step Action

1. In the ADA Analysis window (Chapter E2.4), click on **Confirmation Settings**. The Confirmation Settings panel opens.

Confirmation Settings

Evaluation

Cut point value (%):

Help

You can enter a value for the cut point.

Note! The value must be written in American English (e.g. decimal point, not decimal comma).

Spiked/Unspiked Sample Tags:

Subgroup	Spiked	Unspiked
SPIKED	☒	☐
UNSPIKED	☐	☒

Acceptance Criteria

CV unknown samples (%):

- In the **Evaluation** section, enter cut point value in the **Cut point value** field. A help section is available with explanations on how to enter numerical values.

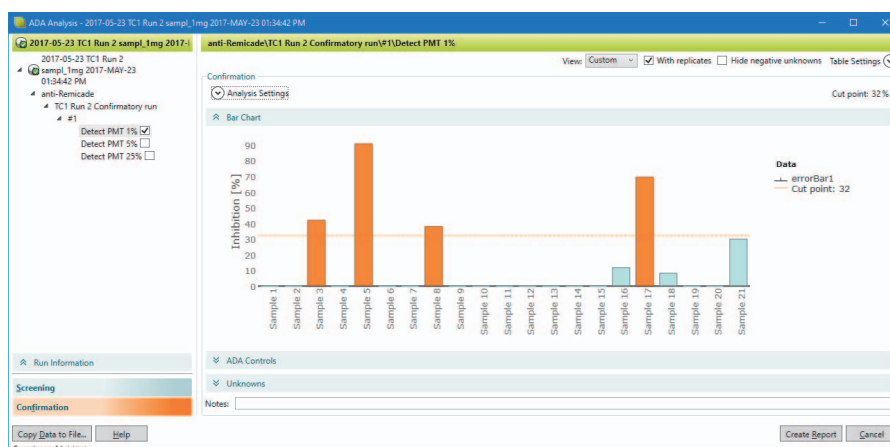
What confirmation cut point to apply for the assay is determined during the assay validation phase. For more information on cut point determination, refer to Gyrolab ADA assay protocol.

NOTE: *The confirmation functionality calculates the "percent inhibition" for samples. This serves as a base to determine the confirmation cut point.*

- In the **Evaluation** section, mark check boxes to indicate sample subgroups that have been spiked and which are unspiked.
- In the **Acceptance Criteria** section, add acceptance criteria for Unknown samples in the field **CV unknown samples (%)**.
- Click **Next**.

Step Action

2. Click **Confirmation** in the lower left corner. The Confirmation window opens.



The left panel of the Confirmation window displays available experiments in the Run and Run information, refer to Chapter D4.1.

The right panel of the Confirmation window displays collapsible/expandable views for:

- **Bar Chart:** Visualizes inhibition value for ADA controls and unknown samples compared to the confirmation cut point. Standard deviations are indicated with error bars. Values above cut point are indicated with orange bar color. Values below cut point are indicated with blue bar color. A true positive should be above confirmation cut point.
- **ADA controls:** Data table with analysis results for ADA controls. ADA control with results that fall outside of acceptance criteria set in step 1 are highlighted. Negative controls with response above confirmation cut point and positive controls with response below confirmation cut point are highlighted. Refer to Chapter E2.4.2.1 for detailed information on column data.
- **Unknowns:** Data table with analysis results for unknown samples. Samples with results that fall outside of acceptance criteria set in step 1 are highlighted. Refer to Chapter E2.4.2.1 for detailed information on column data.

3. Click **Analysis settings** to change settings for the confirmation view.

4. To simplify bar chart view and facilitate data evaluation it is possible to hide unknown samples with inhibition below the cut point.

- Mark check box **Hide negative unknowns**.

Step Action

5. General commands for data tables:
 - In the **View** list, select display option for data tables:
 - **Original**: A selected number of data columns (default)
 - **Extended**: All available data column
 - If the **With replicates** box is ticked (default) all replicates for samples are shown. Untick the box to display average values for samples.
 - It is possible to include or exclude data points:
 - To exclude a data point, right-click on the sample and select **Exclude**. To perform this With replicates must be ticked. If required by Project settings, the reason for exclusion must be specified. The change description is included in the Audit Trail.
 - To include an excluded sample, right-click on the sample and select **Include**. To perform this With replicates box must be ticked. If required by Project settings, the reason for inclusion must be specified. The change description is included in the Audit Trail.
 - It is possible to edit **Dilution** values. If required by Project settings, the reason for editing must be specified. The change description is included in the Audit Trail.
 - It is possible to add **Notes** for individual samples in the right-most column if With replicates box is ticked and View list is set to Extended.

NOTE: *The number and titles of columns may differ depending on the Run and if replicates are shown or not.*
6. Optional: Add general experiment comments in the **Notes** text box located at bottom of the right panel.
7. To export data or generate analysis report, continue to Chapter E2.4.3.

E2.4.2.1 Data table descriptions – Confirmation

Columns that are displayed in the **Confirmation** view will be included in reports generated.

If Original view is selected only columns indicated with a Yes below will be displayed. If Extended view is selected all available columns are shown.

Column heading	Original view	Description
Sample Name	Yes	Sample identity
Subgroup	Yes	Sample subgroup, as set during Run set-up, refer to Chapter I4.2.
Response (RU)	Yes	Integrated volume of the fluorescent binding surface of a reaction in a microstructure.
Average Response (RU)	Yes	Average of response values for replicates of a sample, sample group or sample subgroup.
SD Response (RU)	Yes	The standard deviation of responses of sample replicates.

Column heading	Original view	Description
CV Response (%)	Yes	Coefficient of variation of response of replicates of a sample.
Inhibition (%)	Yes	Inhibition is calculated as: $\%Inhibition = 1 - (\text{response for spiked samples}) / (\text{response for unspiked samples})$
Dilution	Yes	Dilution factor for Unknown samples is entered in the Sample List. For ADA control samples the dilution factor is entered during Run set-up, refer to Chapter E2.2. If no Dilution Factor value has been assigned a factor of 1 will automatically be used.
CD ID	Yes	Identity of Gyrolab CD microlaboratory used to process the samples.
CD Structure	Yes	Identity of structure on Gyrolab CD microlaboratory where the sample was processed.
Cut Point	Yes	Describes whether sample response is above or below cut point. Negative or positive.
Log of Response	No	The logarithm of Response value.
Log of Average Response	No	The logarithm of Average Response value.
MP ID	No	Identity of the microplate where the sample was placed.
MP Well	No	Well position on the microplate where the sample or standard was placed.
Detect Result	No	• OK: The results are approved • Not OK: The results are not approved. The fluorescence signal is of poor quality which may be caused by inadequate PMT setting (detector is saturated) or errors in sample preparation.
Sample Type	No	For ADA controls: Negative control or Positive control. For unknown sample: Unknown
Needle ID	No	The needle used to transfer the sample from the MP to the CD structure
Notes	No	It is possible to add comments to individual samples.

E2.4.3 Data export and report generation

Step	Action
1.	Optional: To export data to tab separated text format (.txt) or to Excel XML spreadsheet format (.xls), click Copy Data To File button, browse for desired location and click Save. This functionality is useful when further data analysis e.g cut point determination calculations are needed. NOTE: <i>No traceability of results is achieved using Copy Data To File. A copy of a Result file is created but this can be done for example before an analysis is saved and it is NOT logged in the Audit Trail. To fulfil the requirements of 21 CFR part 11 data must be exported from a saved Project, refer to Chapter D3.5</i>
2.	Click Create Report to save analysis. All results from chosen included experiments and analysis functionalities (Screening, Confirmation) will be included in the report.
3.	Set Analysis Name and click OK .

E2.5 Installation of Gyrolab ADA Software

The Gyrolab ADA Software module is available for Gyrolab Control version 5.4 or higher and Gyrolab Evaluator version 3.3 and is activated by the user with a license key. Licenses are instrument specific. Contact Gyros Protein Technologies to purchase Gyrolab ADA Software and receive a license.

To register the license: Save the license file to the hard disk of the external instrument computer, at the Gyros license folder, currently C:\ProgramData\Gyros\Licenses.

E3 Gyrolab LIMS Interface

Visit www.gyrosproteintechnologies.com for the latest updates on available software modules.

E3.1 Introduction to Gyrolab LIMS Interface workflow

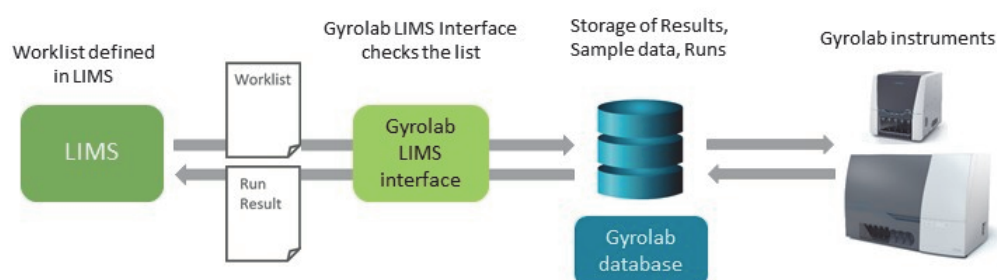
Gyrolab provides several ways for a LIMS to interact with Gyrolab. Current version of Gyrolab Control includes support for the following main workflows

- Manual setup of LIMS Run using Gyrolab software, with information on samples to process provided by the LIMS and returning Run Result to LIMS. See chapter E3.1.1.
- Fully automated process where the LIMS communicates directly with Gyrolab to set up a Run, and to later fetch the Run Results. See Chapter E3.1.2.

E3.1.1 Sample information transfer using LIMS Sequence Files

The characteristics of this interaction between LIMS and Gyrolab is based on transfer of sample information from the LIMS and return of the result (sample responses) back to the LIMS after run execution.

The default file format is the **LIMS Sequence File format**, but other formats can optionally be supported, contact Gyros Protein Technologies for more information.



The typical steps in this workflow are

Step	Action
1.	A Gyrolab User creates a LIMS Run Design specifying information on the Method and reagents to use in the run.
2.	The LIMS generates one or more Worklists in LIMS Sequence File format . A Worklist contains information on the samples to process (Standards, Quality Controls, Unknown samples).
3.	A Gyrolab User creates a LIMS Run Setup by combining the LIMS Run Design with the LIMS Worklist(s).
4.	A Gyrolab User prepares and executes the Run Setup.
5.	After run execution, the Run Result can be transferred back to the LIMS using the same Worklist format with response values appended to the sample list.

The Worklist can be transferred from the LIMS to Gyrolab as a disk file, or from the LIMS directly to the Gyrolab database.

The result file can be transferred from Gyrolab to LIMS in four ways

- Manually copied from Gyrolab Manager to a disk file.
- Automatically exported to a disk file as part of run execution.
- Automatically exported by Gyrolab Result Exporter to a disk file.
- Fetched by the LIMS directly from the Gyrolab database.

The third method, using the Gyrolab Result Exporter, has the advantage that it can be set up to export files to a location not accessible to ordinary users, thereby reducing the risk for unintentional changes to data.¹

The LIMS sequence file format is based on the generic raw data file format for Watson LIMS 6.4.

Due to the limitation in this file format, only one response value per sample can be written to the result file. When creating the LIMS Run Design, the PMT level to export must be selected if the used Method produces results from multiple PMT levels.

Details on the [LIMS Sequence File format](#) can be provided by Gyros on request.

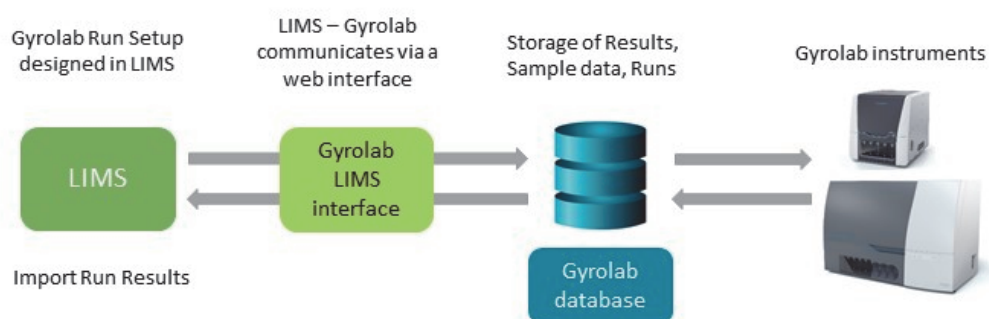
This workflow is also supported by Gyrolab Client, with the limitation that the Worklist can only be loaded from a disk file. See chapter I5.

This workflow when used with Gyrolab Manager is described in more detail starting with chapter E3.2.

E3.1.2 Full Run Setup creation directly from LIMS

Starting with Gyrolab Control 8.1, Gyrolab provides a network interface allowing a LIMS to communicate directly with Gyrolab to create a Run Setup.

If using this workflow there is no need for a user to interact with Gyrolab Manager before starting execution. The entire setup is controlled from the LIMS.



Step Action

1. The LIMS asks Gyrolab for the Methods available for use when creating a Run Setup. The methods available to the LIMS are selected beforehand by a Gyrolab user.
2. The LIMS directly creates a Run Setup within Gyrolab by providing all information required by the Run Setup. This includes
 - The Experiments to process, where each Experiment can specify a separate Method and/or set of reagents.
 - The samples to process, including Standards, Quality Controls, and Unknowns samples

When creating the Run Setup, the LIMS receives a unique identifier for the Run Setup that later is used to fetch the corresponding Run Result.

1. For more information on Gyrolab Result Exporter, see Chapter G7

Step Action

3. A Gyrolab User prepares the samples to be processed based on a Loading List. The Loading List can be opened/printed from Gyrolab Manager and/or fetched and presented/printed by the LIMS.
4. A Gyrolab User executes the Run Setup.
5. After run execution, the LIMS fetches the Run Result based on the Run Setup identifier.

More information on this LIMS workflow is provided by Gyros Protein Technologies on request.

E3.2 LIMS Run Design

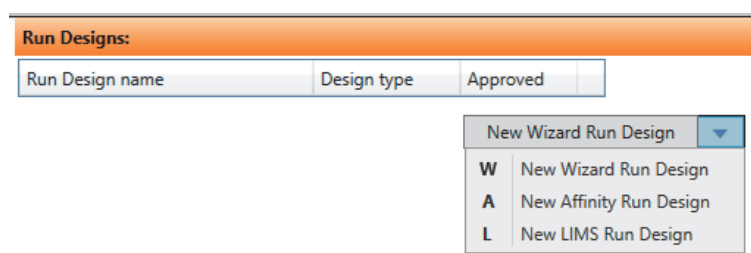
The properties of a LIMS Run Design are similar to a Wizard Run Design, except that the information entered is adapted to the LIMS workflow and limitations.

This chapter describes how to create a LIMS Run Design using Gyrolab Manager. To create a LIMS Run Design using Gyrolab Client, see chapter I5.2.

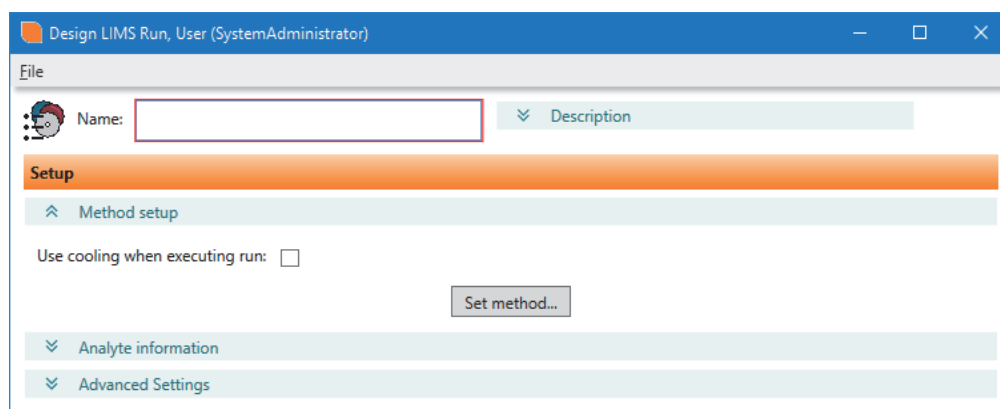
E3.2.1 Overview of workflow

The general steps to create a new or edit an existing LIMS Run Design are similar to creating or editing a Wizard Run Design, described in chapter B4.1.

Note that the button used to create a new Run Design will, by default, create a Wizard Run Design. To create a LIMS Run Design, choose **New LIMS Run Design** from the drop-down list.



After creating a new LIMS Run Design, a new window is displayed.



When creating a new Run Design, a name must be entered in the **Name** field.

A description (comment) on the Run Design can optionally be made in the **Description** section, for example what type of assays the Run Design is intended for.

The following list shows the steps to create a basic LIMS Run Design, with references to applicable chapters for more information. The following chapters explain the parts of a LIMS Run Design in more detail.

Step Action

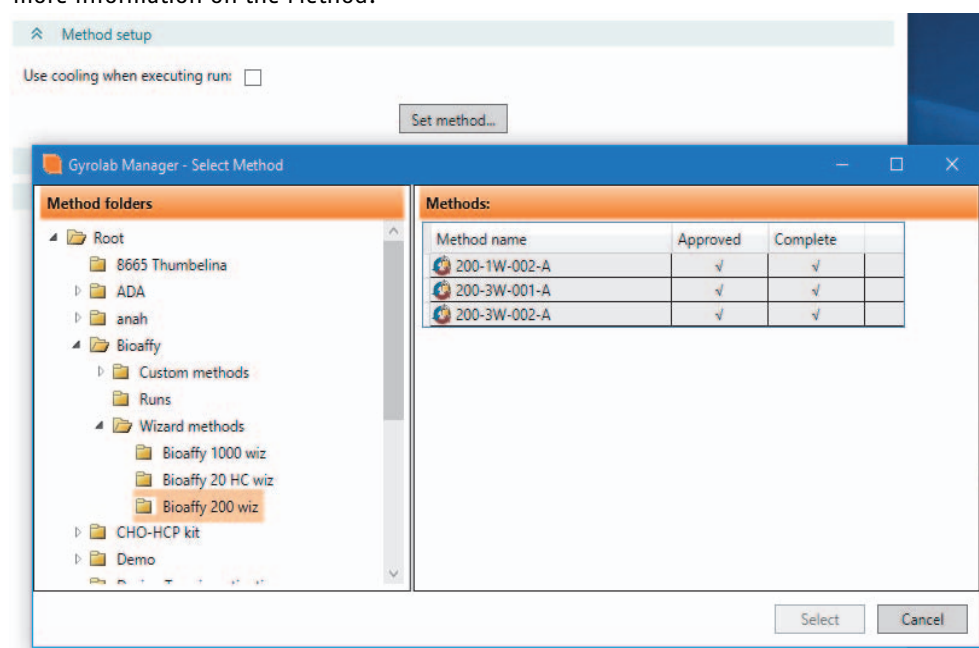
1. Select a suitable folder in the main window folder tree or create a new folder (Chapter B3.1).
2. On the right side of the main window, select **New LIMS Run Design** to create a new LIMS Run Design in the selected folder.
3. A Run Design edit window is opened.
4. Enter a Name for the Run Design.
5. In Method setup, select Set method to select the method to use in the Run Design. (E3.2.2)
6. In Analyte information, provide an analyte name and name the reagents to match the assay. (E3.2.3)
7. An optional feature in Advanced Settings allows the user to specify how replicates are distributed on the CD(s), and whether a non-standard output format is desired. (E3.2.4)
8. Save the Run Design from the File menu, by selecting Save.
9. Close the Design LIMS Run window from the File menu, by selecting Exit.

E3.2.2 Selecting method

A LIMS Run Design must specify one Method. This is done in the **Method setup** section. In contrast to some Design Types, the LIMS Design Type only supports use of one Method per Run Design.

To specify the Method, select **Set method....** A method selection dialog is opened. Browse and select the desired Method. The selected Method must contain W in the name which indicates that it is designed for use with a Wizard run, refer to Chapter A2.3 for more information.

When selecting a Method, it is possible to right click the Method and select **Properties...** to get more information on the Method.



When a method has been selected in a folder, click Select. The selected Method is added to the Run Design and Method information is displayed.

Method setup

Use cooling when executing run: ☐

Set method...

Set data

Detection setting: Detect PMT 1%

Method information

Method: 200-3W-001-A

Full Method path: Root/Bioaffy/Wizard methods/Bioaffy 200 wiz/200-3W-001-A

CD type: Gyrolab Bioaffy 200

Description:

Bioaffy 200 CD
 3-step (capture-analyte-detection) Wizard run
 One Wash solution used for all needle washes
 Initial needle wash
 2 column washes
 Capture addition
 2 column washes
 Analyte addition
 2 column washes
 Background detect
 Detection addition
 4 column washes
 Detect PMT 1%, 5%, 25%

It is also possible to specify whether sample cooling shall be turned on when later executing the run (given that the Gyrolab instrument provides cooling functionality) by selecting **Use cooling when executing run**.

Use cooling when executing run: ☐

E3.2.3 Analyte information

In the Analyte information section, information on Analyte name and reagents is added. The number of reagents to enter corresponds to the number of reagent transfers in the selected Method.

Analyte information

Analyte name :

Capture reagent addition :

Detection reagent addition :

E3.2.4 Advanced Settings

Advanced Settings allows some processing parameters to be specified.

In **Process order on CD**, the order in which replicates from a Worklist are placed within a CD, when later selecting Worklists during Run Setup creation.

Process order on CD: As Work List

Output format

☒ Generic Raw Data ☐ By Gyros

- **As Work List** will place the replicates loaded from a Worklist in the same order as the appear in the Worklist imported from the LIMS.
- **By Gyros** will allow Gyrolab Manager to redistribute the replicates from a Worklist within the CD. The redistribution will attempt to mix the different sample types and replicates from a given sample over the CD.

In **Output format**, the format for the generated Run Result files can be selected.

- **Generic Raw Data** will produce output files in the same format as the loaded Worklist(s). This is the default output format.
- **Basic format** will produce a simplified output as a tab delimited text files with sample names and the corresponding response values.
- **External format** allows a custom output format to be selected. Select **Import Format** to browse and select the desired format. Select **View Format** to view the selected format. Contact Gyros Protein Technologies for more information.

E3.2.5 Using the Run Design to Execute a Run

You may now save the Run Design. Saving a Run Design is done in the same way as for a Wizard Run Design (B4).

To prepare for executing a LIMS run, perform the following steps.

Step	Action
1.	Export information from the LIMS on samples to be processed in the form of one or more Worklists in LIMS Sequence Files format. (E3.3)
2.	Create a LIMS Run Setup based on the Run Design (E3.4). In the Run Setup, add samples to process by selecting Worklist(s) as desired.
3.	Execute the run at a Gyrolab instrument.

E3.3 LIMS worklist generation

In your LIMS, generate one or more worklists to be processed in the LIMS Run. Standards, Quality Controls and Unknown samples and their replicates are defined in the worklists. Note that your LIMS must generate worklists in certain formats in order to be able to interact with Gyrolab software. Contact Gyros Protein Technologies for more information.

It is possible to make one LIMS worklist per CD or one LIMS worklist for all CDs in a Run.

E3.3.1 Controlling distribution of samples between CDs

If one LIMS Worklist is generated for each CD to execute in the run, each Worklist defines the samples for one CD.

If one LIMS common Worklist is generated for all CDs, samples will by default be placed on CDs in the same order as they are found in the Worklist. But depending on information in the Worklist, CD placement can be controlled by ordering and/or naming the samples properly.

If standard samples are not all listed together in the Worklist, each new set of standard samples will cause the layout to start on a new CD. For example, assume that the Worklist contains the following samples, in the given order

- First set of standard samples
- Some quality controls and unknown samples
- Another set of standard samples
- Optionally additional quality controls and unknown samples

In this case, the first set of standard samples, and the following quality controls and unknown samples, will be placed on the first CD. The remaining standards, quality controls and unknown samples will then be placed on the second CD. (The distribution between CDs is also affected by the number of samples/replicates, as CD limitations may require samples to be spread over additional CDs.)

Another option is to control sample placement explicitly through their names. If the names of all samples include the text "CDn", where "n" is a number 1 to 5, the names will control the CD on which the samples are placed. Note that all replicates for a sample must be placed together on the same CD.

Assignment of samples to CDs can also be done manually when loading the Worklist. See chapter E3.4.2.1.

The discussion above regarding distribution of samples does not apply when using a single-CD Gyrolab instrument.

E3.3.2 Transferring Worklists via the Gyrolab database

The simplest way of transferring Worklists from the LIMS to Gyrolab is to write them as disk files from the LIMS, and then read them from disk in Gyrolab.

Starting with Gyrolab Control 8.1, Gyrolab provides a network interface that allows a LIMS to send Worklists directly into the Gyrolab database. The Worklists can then be loaded from the database when creating a LIMS Run Setup. See Chapter E3.4.2.1.

A Gyrolab administrator can decide which of these two alternatives that should be allowed through the **System Settings**. (B10)

E3.4 LIMS Run Setup

In the same way as for the Wizard Run Setup (B5), the main task for the LIMS Run Setup is to add information on samples to process.

E3.4.1 Overview of workflow

The following list shows the steps to create a LIMS Run Setup, with references to applicable chapters for more information. The following chapters explain the process of creating a LIMS Run Setup in more detail.

Step	Action
1.	Select the LIMS Run Design to base the Run Setup on from the main window folder tree.
2.	On the right side of the main window, select Create Run Setup from Design to create a new Run Setup based on the selected LIMS Run Design.
3.	A Run Setup edit window is opened.
4.	Enter a Name and a Description (optional) for the Run Setup.
5.	In the LIMS Data Input tab, decide whether to use one Worklist per CD, or one common Worklist for the entire Run Setup. (E3.4.2)

Step	Action

6.	If using one common Worklist, select the single Worklist to use. If using one Worklist per CD, select as many Worklists as desired, where the samples on each selected Worklist are placed within one CD. Selection of Worklists can be done from a disk location or the database. (E3.4.2)
7.	Go to tab MP Layout . (E3.4.3)
8.	Produce a Loading List to guide the microplate preparation. Navigate to the Loading List section and use Save... , Open... or Print as desired.
9.	Queue the Run Setup from the File menu, by selecting Queue for Execution and Close . If Target and Report Settings dialog is displayed, close it with OK . These steps are the same as for a Wizard Run Setup. See chapters B5 and B6 for details.
10.	Prepare microplates according to Loading List. The Run Setup is now ready for execution at a Gyrolab instrument.

E3.4.2 Defining samples to process

The main purpose for a Run Setup is to add information about the samples to process when executing a run. When creating or opening a Run Setup, the initial view shows the **LIMS Data Input** tab, where samples are specified.

The setup from the underlying Run Design is also available as reference on the **LIMS Design** tab. The information defined by the Run Design can be viewed, but not modified.

The **MP Layout** tab can be used to control how unknown samples, reagents and other liquids are placed on the microplate. For more information, see chapter E3.4.3.

The first decision is whether to use one Worklist for all CDs, or one Worklist per CD. Using one Worklist for all CDs is useful if the number of samples in the Worklist will not fit on one CD.

Select whether to use one Worklist per CD or one for all CDs in the **Worklist** section.

Worklist

☒ One per CD ☐ One for all CDs

Information on how to load one Worklist per CD is found in chapter E3.4.2.1 and how to load one common Worklist for all CDs is found in chapter E3.4.2.2.

How the instrument interprets the contents of a Worklist is defined by a **List Loader**. By default, Gyrolab is distributed with a default List Loader for LIMS Sequence Files. Contact Gyros Protein Technologies in case support for an alternate Worklist format is required.

List Loader: LIMS sequence file List Loader

E3.4.2.1 Using one Worklist per CD

If deciding to use one Worklist per CD, the window will display a list of five CDs, where a Worklist can be loaded for each CD.

CD 1 :

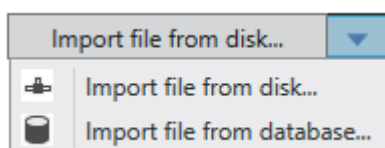
CD 2 :

CD 3 :

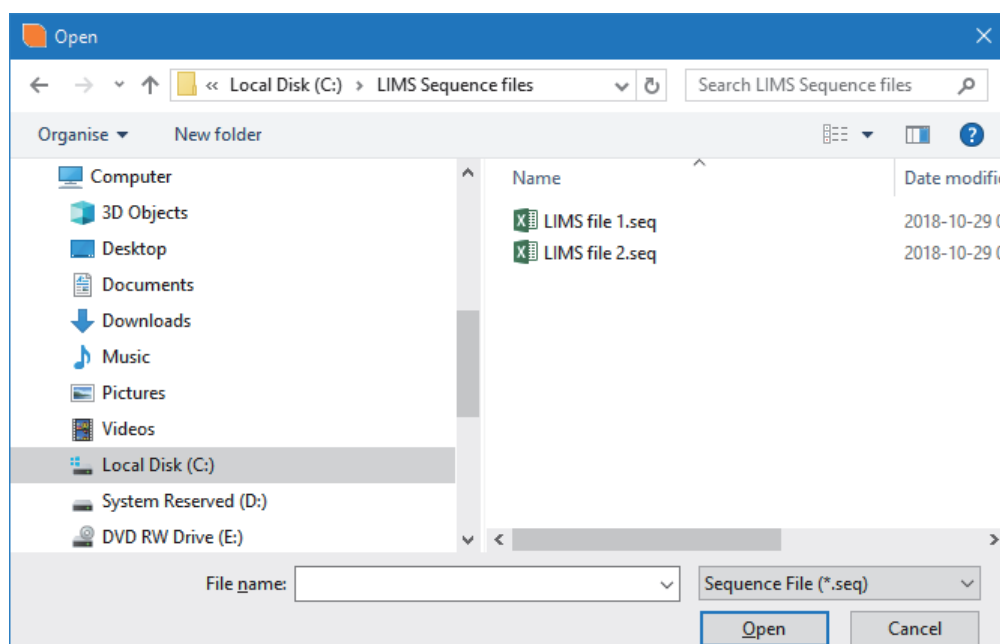
CD 4 :

CD 5 :

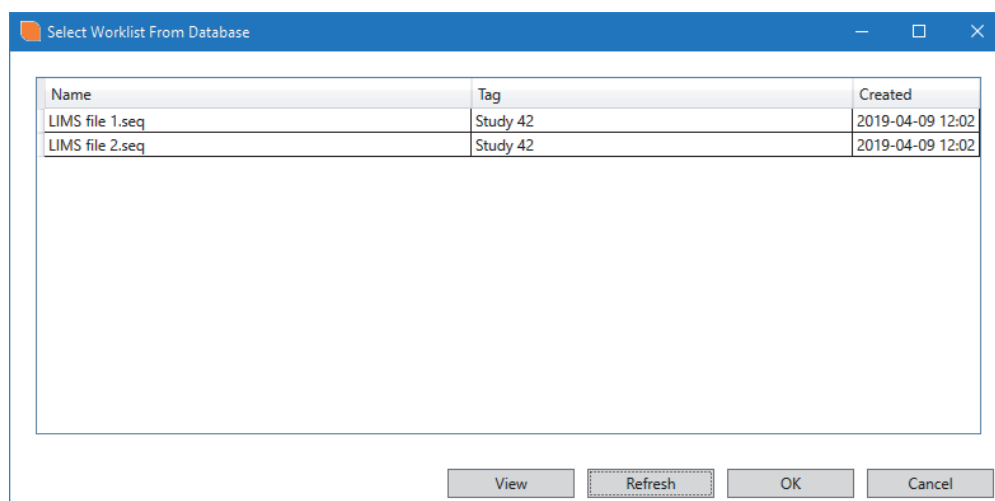
To load a Worklist, use the drop-down list to select the location where the Worklist is found.



If selecting **Import file from disk...**, a file dialog is displayed where the Worklist file can be selected.



If selecting **Import file from database...**, a dialog is displayed where all Worklists that have been added to the database are presented.



The **Tag** column shows an optional mark that the LIMS can assign to a Worklist when adding it to the database. The tag can later be used by the LIMS to find the corresponding Run Results.

The **View** button can be used to present the raw information in the Worklist.

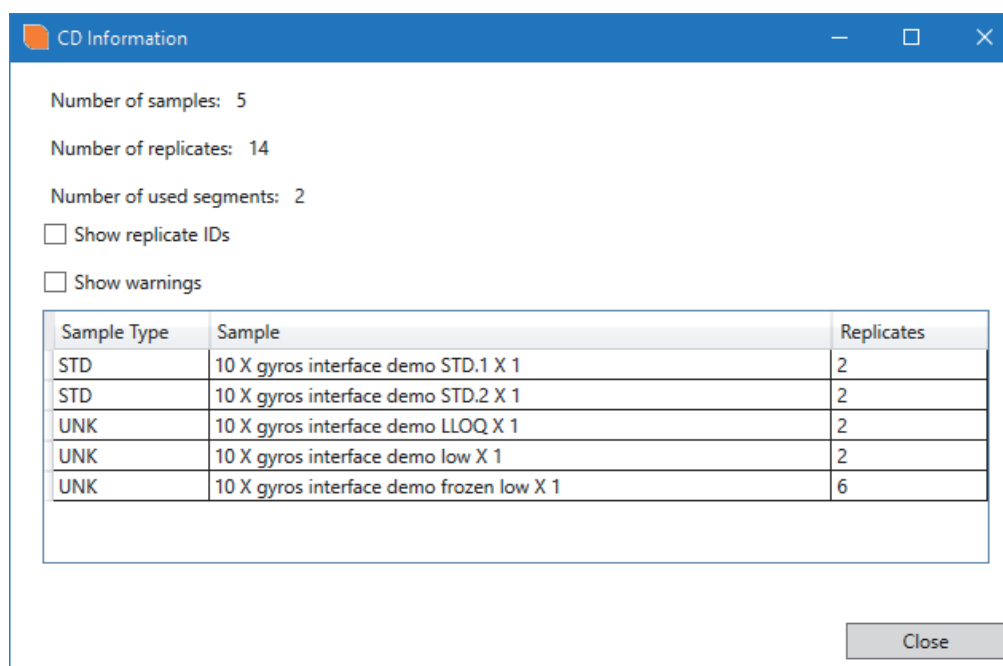
To select a Worklist, mark the Worklist in the display and select **OK**.

Note that either of the location types, disk or database, may be disabled by your system administrator. A location type that has been disabled is not visible in the drop-down list.

Once a Worklist has been selected, the corresponding row is updated to show the name of the Worklist. The CD indicator to the left is updated to show the used part of the CD.



Select **Info** to present the samples loaded from the Worklist in a new **CD Information** window. Information on the individual sample replicates can be displayed by selecting **Show replicate IDs**.



If the Worklist contains errors, warnings are displayed. The warnings field can be turned off by deselecting **Show warnings**.

CD Information

Number of samples: 5

Number of replicates: 14

Number of used segments: 2

☐ Show replicate IDs

☒ Show warnings

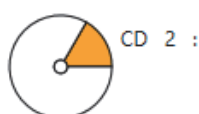
Warnings

The replicates for sample '10 X gyros interface demo STD.2 X 1' are not properly ordered: 1 3

Sample Type	Sample	Replicates
STD	10 X gyros interface demo STD.1 X 1	2
STD	10 X gyros interface demo STD.2 X 1	2
UNK	10 X gyros interface demo LLOQ X 1	2
UNK	10 X gyros interface demo low X 1	2
UNK	10 X gyros interface demo frozen low X 1	6

Close

In addition to the warnings in the CD Information window, the CD indicator in the main window also shows the CD use in yellow.



Select **Clear** to remove a loaded Worklist.

E3.4.2.2 Using one Worklist for all CDs

If deciding to use one common Worklist for all CDs, the window will display only one line where a Worklist can be imported.

Worklist

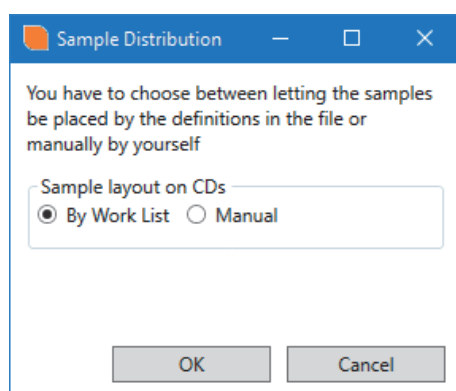
☐ One per CD ☒ One for all CDs

List Loader: LIMS sequence file List Loader

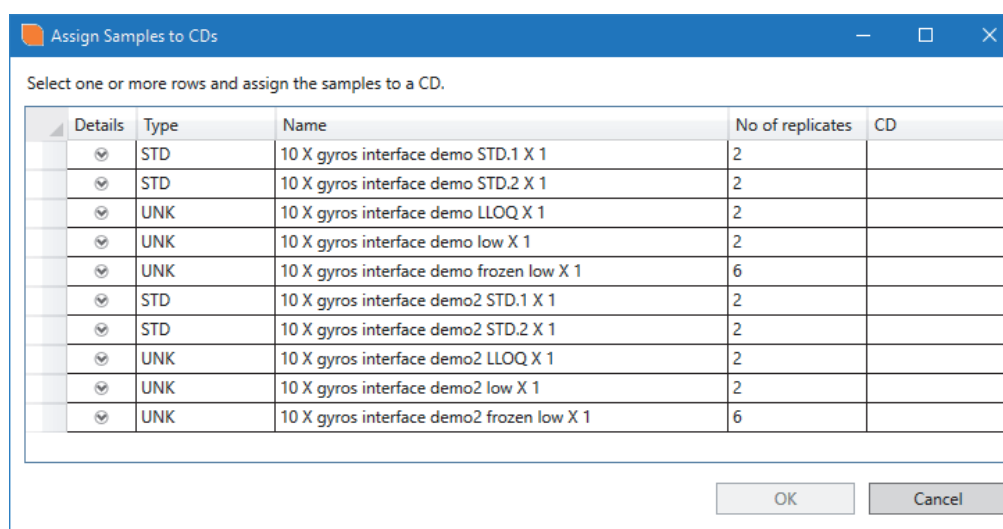
Import file from disk...

The Worklist can be loaded from disk or from the database, in the same way as when using one Worklist per CD.

After selecting to import from disk or database, before selecting the Worklist, a dialog is presented where you can select **By Work List** to let the Worklist determine how the samples are distributed to the CDs, or **Manual** to manually decide how samples are distributed on the CDs. The actual distribution of samples to CDs is performed after selecting the Worklist.

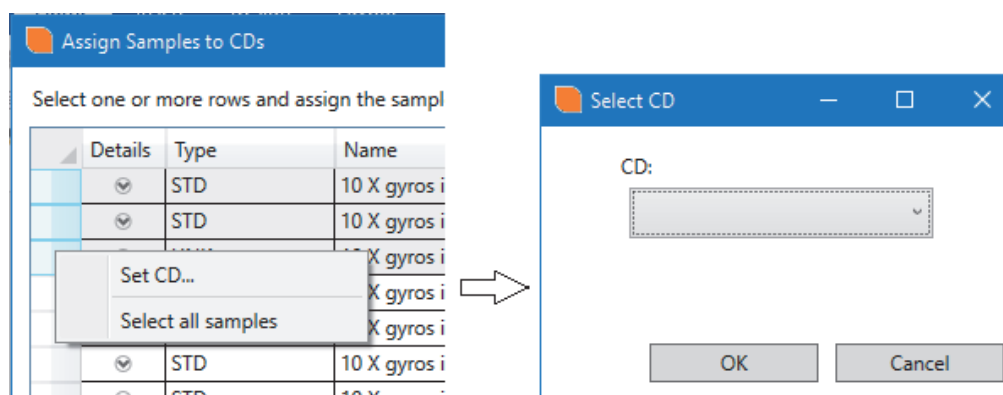


If selecting **Manual** sample distribution, the **Assign Samples to CDs** dialog is displayed after selecting the Worklist.



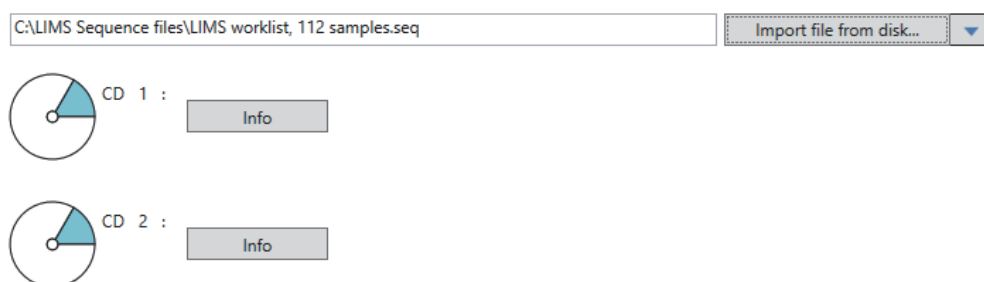
All samples found in the Worklist are presented. Replicate information can be displayed by clicking the icon in the **Details** column.

To assign samples to CDs, use the **CD** column and select a CD for each sample. It is possible to assign a CD to multiple samples at the same time by selecting a range of samples in the leftmost column (to the left of the **Details** column), right clicking and selecting **Set CD...**, when a **Select CD** dialog is displayed where the CD can be selected.



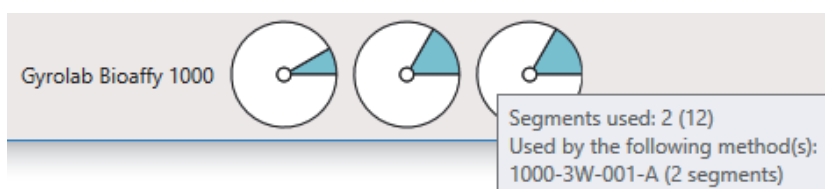
Samples must be assigned to CDs in a way that keeps samples of one type together on the same CD.

After loading the Worklist, the display is updated to show how the Worklist samples are distributed on the CDs. Select **Info** to present information on the samples placed on a specific CD.



E3.4.2.3 Summary of the required amount of CDs

A summary is shown in the lower section of the window which displays information on the number of segments and usage of each CD.



The presentation includes the CD type required by the Method selected in the LIMS Run Design and illustrates the amount of CD segments required. By holding the mouse pointer over a CD, details about the use for that CD is presented.

E3.4.3 MP Layout

The **MP Layout** tab provides information on how samples, and other liquids included in a run, are placed on microplates.

The MP Layout tab is the same as for a Wizard Run Setup, see chapter B5.4.

The only difference is that for a LIMS Run Setup, the default **Well Placement** is **New Plate for each CD**. With this layout, the samples placed on one CD are also placed on a separate microplate. This layout may be especially suitable when using one Worklist per CD.

E3.5 Gyrolab LIMS Interface data output

One or more LIMS Run result files are generated in the format specified in Chapter I5.2 and to location specified in Chapter I5.3. The result files can be imported into a LIMS for analysis.

E3.6 Data evaluation

When using the LIMS workflow, all data analysis is performed using a LIMS system.

E3.7 Installation of Gyrolab LIMS Interface

The Gyrolab LIMS Interface software module is available for Gyrolab Control version 5.2 or higher and is activated by the user with a licence key. Licenses are instrument specific. Contact Gyros Protein Technologies to purchase Gyrolab LIMS Interface and receive a license.

To register the license: Save the license file to the hard disk of the external instrument computer, at the Gyros license folder, currently C:\ProgramData\Gyros\Licenses.

E4 Gyrolab Control Report

Visit www.gyrosproteintechnologies.com for the latest updates on available software modules.

E4.1 Introduction to Gyrolab Control Report

Gyrolab Control Report is a software add-on module for Gyrolab Control version 5.2 or higher that enables automatic generation of a condensed, printable, raw data report in pdf format after each run on the Gyrolab instrument. The generated report is compliant with 21 CFR Part 11 regulations and cannot be edited. The report includes raw data and general information about the run and experimental details.

The software was developed to support users whose workflows require non-editable and printable raw data reports.

If using Gyrolab Manager to prepare a Run, the Gyrolab Report can always be selected, see Chapter B6. But the Gyrolab Report will only be generated when executing the Run on an instrument with a valid license.

E4.2 Perform run using Gyrolab Control Report

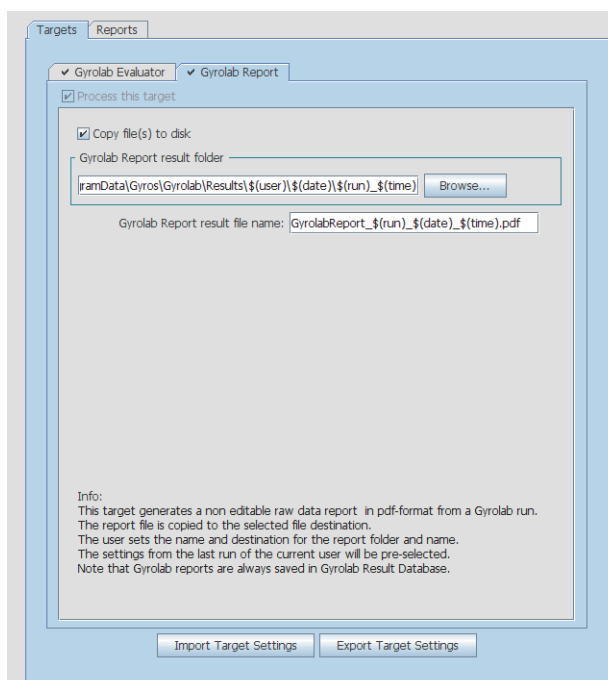
After installation of Gyrolab Control Report module it is necessary to import target settings prior to the first Run. These settings only need to be selected one time for each user unless the user needs to change the location of the Gyrolab Control Report file at a later time.

Gyrolab Control Report can also be automatically copied to disk after Run execution. The steps below describe how to enable it for Gyrolab Control. When using Gyrolab Manager to set up the Run, see Chapter B6.1.

Step Action

1. Prepare the run and edit settings for targets as described in Chapter I2.4. When the target screen is reached, go to target tab **Gyrolab Report**.

Gyrolab Control Report result files from the run are always saved in Gyrolab Result Database. To create local copies of the result files (optional), mark the check box **Copy file(s) to disc**.



2. Files are saved to the location specified in **Gyrolab Report result folder** field and with the name specified in **Gyrolab Report result file name**. Settings are preserved from the user's last Run.

- To import default settings for **Gyrolab Report result folder** and **Gyrolab Report result file name**:
 - Click **Import Target Settings**.
 - In the **Import Settings** dialog, browse to C:\ProgramData\Gyros\Gyrolab\Templates\Default Settings, select **GyrolabReportTargetSettings.xml** and click **Import**.
- To customize settings for **Gyrolab Report result folder** and **Gyrolab Report result file name**:
 - To edit **Gyrolab Report result folder**, click **Browse**. Browse and click **Select** to set new folder in the **Select folder** dialog.
 - To edit **Gyrolab Report result file name**, click in the field and edit.

NOTE: *The maximum number of characters in folder name and file name is 30, including file extension. Do not begin the folder name and/or file name with a number.*

TIP: *Macros can be used to construct file names and locations, refer to Chapter I2.5 for a list of available macros.*

TIP: *The settings in the Targets tab can be exported and imported, which enables settings to be shared between users, instruments and projects.*

Step Action

3. Continue with target settings for other modules as described in step 7 in Chapter I2.4 and with run preparations, start and finish as described throughout Chapter C in Gyrolab User Guide.

When the run has finished, Gyrolab Control will generate an output report file in pdf format including specific information about the run.

E4.3 Gyrolab Control Report output

The report file is automatically placed in the Gyrolab Result Database. If requested by the user a copy of the report is placed at the location specified in the target setting, refer to Chapter E4.2.



The following run, experiment and sample information is included:

Run information
Date and Time
Run by
Method
Design type
Experiments
Sample, reagent, transfer list (file name/s)
Detect operations
Instrument name
Database name
Gyrolab Control version

Experiment information**Sample identity****Replicate number****Sample type****MP id****MP well****CD id****CD structure****Gyrolab response**

E4.4 Installation of Gyrolab Control Report

The Gyrolab Control Report software module is available for Gyrolab Control version 5.2 or higher and is activated by the user with a licence key. Licenses are instrument specific. Contact Gyros Protein Technologies to purchase Gyrolab Control Report and receive a license.

To register the license: Save the license file to the hard disk of the external instrument computer, at the Gyros license folder, currently C:\ProgramData\Gyros\Licenses.

E5 Gyrolab Affinity Software

E5.1 Introduction to Gyrolab Affinity Software

The Gyrolab Affinity Software consists of an add-on module introduced with Gyrolab Evaluator version 3.4 (or higher) including a new Design Type for Gyrolab Control version 7.1.1 (or higher) to facilitate design of in-solution affinity runs.

The support has been extended in Gyrolab Evaluator 3.6 to include Multi Curve Analysis, and the possibility to set up Affinity Runs has been added to Gyrolab Manager 1.1, extending the support from Gyrolab Client to also allow multi-Method setups.

Affinity Runs must be set up using the Affinity Design Type in Gyrolab Manager or Gyrolab Control to enable data analysis in the Gyrolab Evaluator Affinity Software module.

Recommendations and descriptions on how to perform Affinity Runs on Gyrolab are described in Affinity Assay Guidelines, which is included in the Gyrolab Affinity product package or can be downloaded at www.gyrosproteintechnologies.com.

E5.2 Affinity Run Design

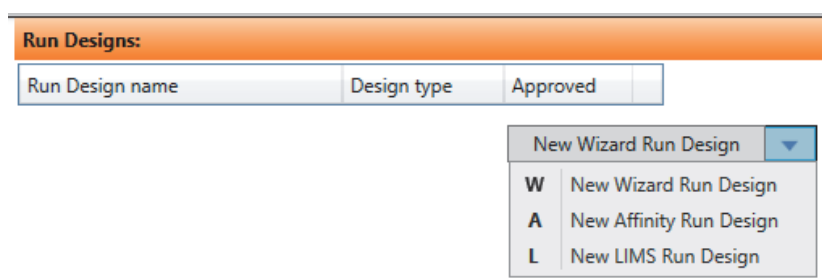
The general properties of an Affinity Run Design are similar to a Wizard Run Design, except that the information entered is adapted to entering data required for an Affinity analysis.

This chapter describes how to create an Affinity Run Design using Gyrolab Manager. To create an Affinity Run Design using Gyrolab Client, see chapter I6.2.

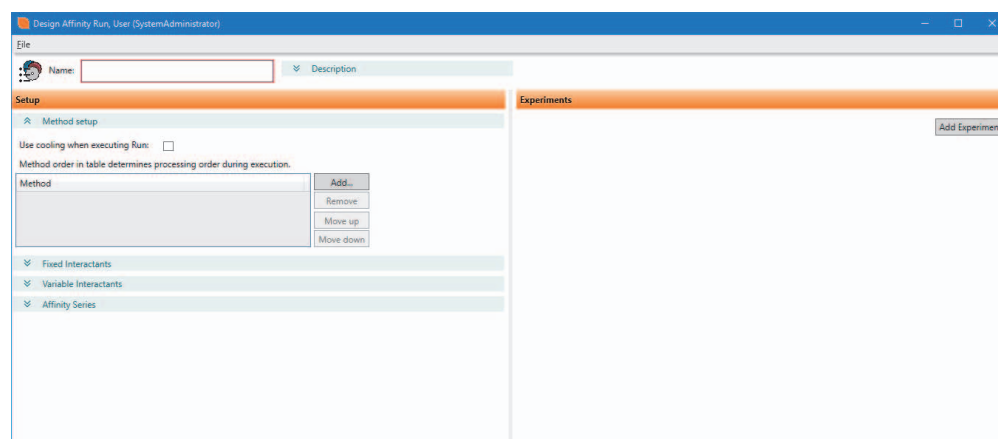
E5.2.1 Overview of workflow

The general steps to create a new or edit an existing Affinity Run Design are similar to creating or editing a Wizard Run Design, described in chapter B4.1.

Note that the button used to create a new Run Design will, by default, create a Wizard Run Design. To create an Affinity Run Design, choose **New Affinity Run Design** from the drop-down list.



After creating a new Affinity Run Design, a new window is displayed.



When creating a new Run Design, a name must be entered in the **Name** field.

A description (comment) on the Run Design can optionally be made in the **Description** section, for example what type of assays the Run Design is intended for.

The following list shows the steps to create a basic Affinity Run Design, with references to applicable chapters for more information. The following chapters explain the parts of a Affinity Run Design in more detail.

Step	Action

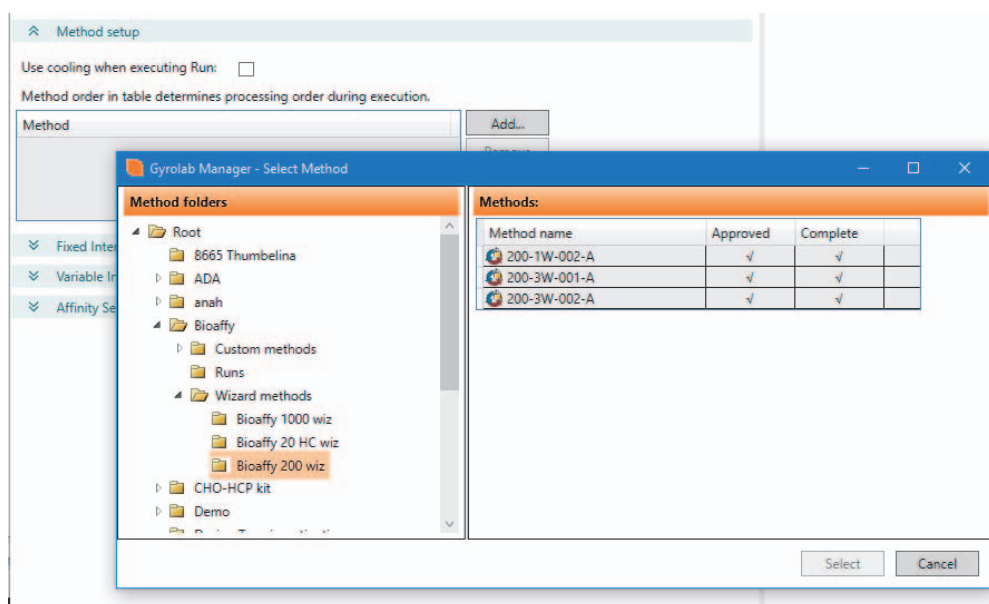
1.	Select a suitable folder in the main window folder tree or create a new folder (Chapter B3.1).
2.	On the right side of the main window, select New Affinity Run Design to create a new Affinity Run Design in the selected folder.
3.	A Run Design edit window is opened.
4.	Enter a Name for the Run Design.
5.	In Method Setup , select Add to select and add a method (E5.2.2).
6.	In Reagents , rename the reagents to match the assay (E5.2.3).
7.	In Fixed Interactants , select Add to create a Fixed Interactant. Select the number of points (concentrations or dilutions) for the Fixed Interactant and adjust the concentration/dilution values for the points. (E5.2.4)
8.	In Variable Interactants , select Add to create a Variable Interactant. Select the number of points (concentrations or dilutions) for the Variable Interactant and adjust the concentration/dilution values for the points. (E5.2.5)
9.	In Affinity Series , select Add to create an Affinity Series and select one concentration/dilution from a Fixed Interactant and one Variable Interactant. Typically, one Affinity Series is created for each combination of Fixed Interactant concentration/dilution and Variable Interactant. (E5.2.6)
10.	Create an Experiment based on the Setup by selecting Add Experiment . In the Experiment, specify reagents to use for the reagent transfer operations in the Method. Also select the Affinity Series to process in the Experiment, and the number of replicates for the Affinity Series points. (E5.2.7).
11.	Save the Run Design from the File menu, by selecting Save .
12.	Close the Design Affinity Run window from the File menu, by selecting Exit .

E5.2.2 Selecting methods

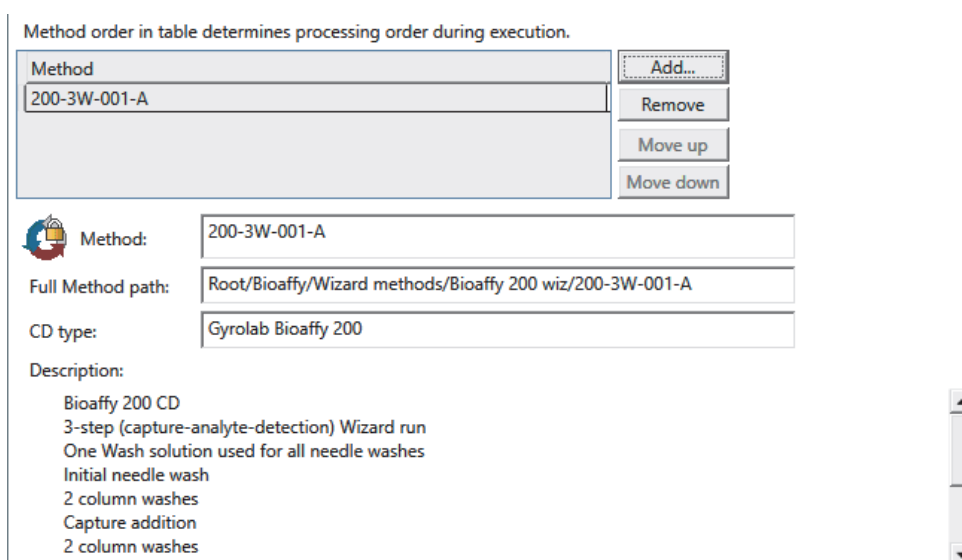
Any Run Design must include at least one Method. This is done in the **Method Setup** section.

To add a method, select **Add...**. A method selection dialog is opened. Browse and select the desired Method. The selected Method must contain W in the name which indicates that it is designed for use with a Wizard or Affinity run, refer to Chapter A2.3 for more information.

When selecting a Method, it is possible to right click the Method and select **Properties...** to get more information on the Method.



When a method has been selected in a folder, click **Select**. The selected Method is added to the Run Design and Method information is displayed.



A Run Design must specify at least one Method, but it is possible to select additional methods. Each Experiment will specify the Method to use, and different Experiments may specify different Methods.

The different Methods will be processed one at a time, including all Experiments specifying that Method, starting with the first Method in the list of Methods.

The processing order can be modified by moving Methods up and down in the list of Methods by selecting a Method and using the **Move up** and **Move down** buttons.

Method order in table determines processing order during execution.

Method	
200-3W-001-A	Add... Remove Move up Move down
1000-3W-001-A	

An added Method can also be removed by selecting the Method and using the **Remove** button.

It is also possible to specify whether sample cooling shall be turned on when later executing the run (given that the Gyrolab instrument provides cooling functionality) by selecting **Use cooling when executing Run**.

Use cooling when executing Run: ☐

E5.2.3 Reagents

For Methods requiring Reagents, the name of the Reagents must be specified.

When initially adding a Method requiring Reagents, a default list of Reagents will be created automatically.

Reagents		
Reagent name	Condition	
Reagent 1		Add Delete
Reagent 2		

Specify the **Reagent name** for the Reagents to use in the run. The **Condition** field is optional and can be used for additional information such as concentration value or matrix.

Click **Add** to add additional Reagents.

To delete a Reagent, select the entire row by clicking the black triangle and then selecting **Delete**. Multiple Reagents can be deleted at the same time by marking multiple lines and selecting **Delete**.

Reagent names and conditions can be copied and pasted. Use Ctrl+C to copy and Ctrl+V to paste, or right click and select **Copy** or **Paste**.

The Reagents can be sorted on name or condition by clicking the table header. Note that this is only a temporary sorting and will not affect the underlying order defined when adding the Reagents.

E5.2.4 Fixed Interactants

A Fixed Interactant is the interaction partner added to each equilibrium mixture in fixed/constant concentration to interact with its partner.

A Fixed Interactant can be used at different concentrations to cover a broad range of affinity properties or to determine active concentration. This series is called a Fixed Interactant series and may involve known concentration or dilution.

Multiple Fixed Interactants can be created. Each Affinity Series will be based on one point (concentration or dilution) of a Fixed Interactant.

Click **Add** to add a Fixed Interactant. Specify the **Fixed Interactant name**.

Fixed Interactants	
Fixed Interactant name	Add
▶ Fixed A	Copy
	Delete

To delete a Fixed Interactant, select the entire row by clicking the black triangle and then selecting **Delete**. Multiple Fixed Interactants can be deleted at the same time by marking multiple lines and selecting **Delete**.

As considerable time may have been spent on creating a Fixed Interactant, you will have to confirm when attempting to delete a Fixed Interactant.

A Fixed Interactant can be copied by selecting the Fixed Interactant and selecting **Copy**. It is possible to copy multiple Fixed Interactants by selecting many Fixed Interactants before selecting **Copy**.

Fixed Interactant names can be copied and pasted. Use Ctrl+C to copy and Ctrl+V to paste, or right click and select **Copy** or **Paste**.

The Fixed Interactants can be sorted on name by clicking the table header. Note that this is only a temporary sorting and will not affect the underlying order defined when adding the Fixed Interactants.

When selecting a Fixed Interactant, details about the Fixed Interactant become visible.

Fixed Interactant name		Add
▶ Fixed A		Copy
		Delete

Fixed A

Number of Fixed Concentrations:

Value type: ☒ Concentration ☐ Dilution

Dilution factor:

Interactant Point name	Concentration [M]
▶ Fixed A_1	0.0

By default, the Fixed Interactant includes one point only. To create a Fixed Interactant Series, select the number of points in the series in **Number of Fixed Concentrations**.

By default, the points are expressed as concentrations. With **Value type**, it is possible to express the points as dilutions instead. A concentration is given in molar and a dilution is given as a reciprocal dilution factor (value . 1).

The concentration/dilution values can be entered manually.

The concentration/dilution values can also be copied and pasted. Use Ctrl+C to copy and Ctrl+V to paste, or right click and select **Copy** or **Paste**.

Additionally, concentration/dilution values can be automatically generated as a series. The values are all based on the concentration/dilution value entered for the first point.

If selecting **High > Low**, the concentration/dilution value of each point will be set to the value of the previous point divided by the value entered as **Dilution Factor**, using the value of the first point as reference value.

If selecting **Low > High**, the concentration/dilution value of each point will be set to the value of the previous point multiplied by the value entered as **Dilution Factor**, using the value of the first point as reference value.

Value type: ☒ Concentration ☐ Dilution

Dilution factor:

Interactant Point name	Concentration [M]
► Fixed A_1	1.0
► Fixed A_2	2.0
► Fixed A_3	4.0
► Fixed A_4	8.0

E5.2.5 Variable Interactants

A Variable Interactant is the interactant partner used in variable concentration to form a concentration series in equilibrium mixtures.

Multiple Variable Interactants can be created. Each Affinity Series will be based on all points (concentration or dilution) from a Variable Interactant.

Click **Add** to add a Variable Interactant. Specify the **Variable Interactant name**.

Variable Interactants	
Variable Interactant name	Add
► Variable A	Copy
	Delete

To delete a Variable Interactant, select the entire row by clicking the black triangle and then selecting **Delete**. Multiple Variable Interactants can be deleted at the same time by marking multiple lines and selecting **Delete**.

As considerable time may have been spent on creating a Variable Interactant, you will have to confirm when attempting to delete a Variable Interactant.

A Variable Interactant can be copied by selecting the Variable Interactant and selecting **Copy**. It is possible to copy multiple Variable Interactants by selecting many Variable Interactants before selecting **Copy**.

Variable Interactant names can be copied and pasted. Use Ctrl+C to copy and Ctrl+V to paste, or right click and select **Copy** or **Paste**.

The Variable Interactants can be sorted on name by clicking the table header. Note that this is only a temporary sorting and will not affect the underlying order defined when adding the Variable Interactants.

When selecting a Variable Interactant, details about the Variable Interactant become visible.

Variable Interactant name	Add
Variable A	Copy
	Delete

Variable A

Number of Variable Concentrations: 8

Value type: ☒ Concentration ☐ DilutionDilution factor: 2.0 High ► Low Low ► High

Interactant Point name	Concentration [M]
Variable A_1	0.0
Variable A_2	0.0
Variable A_3	0.0
Variable A_4	0.0
Variable A_5	0.0
Variable A_6	0.0
Variable A_7	0.0
Variable A_8	0.0

By default, the Variable Interactant includes eight point. To set another number of points, select the number of points in the series in [Number of Variable Concentrations](#).

By default, the points are expressed as concentrations. With [Value type](#), it is possible to express the points as dilutions instead. A concentration is given in molar and a dilution is given as a reciprocal dilution factor (value ≥ 1).

The concentration/dilution values can be entered manually.

The concentration/dilution values can also be copied and pasted. Use Ctrl+C to copy and Ctrl+V to paste, or right click and select [Copy](#) or [Paste](#).

Additionally, concentration/dilution values can be automatically generated as a series. The values are all based on the concentration/dilution value entered for the first point.

If selecting [High > Low](#), the concentration/dilution value of each point will be set to the value of the previous point divided by the value entered as [Dilution Factor](#), using the value of the first point as reference value.

If selecting [Low > High](#), the concentration/dilution value of each point will be set to the value of the previous point multiplied by the value entered as [Dilution Factor](#), using the value of the first point as reference value.

Value type: ☒ Concentration ☐ DilutionDilution factor: 2.0 High ► Low Low ► High

Interactant Point name	Concentration [M]
Variable A_1	1.0
Variable A_2	2.0
Variable A_3	4.0
Variable A_4	8.0
Variable A_5	16.0
Variable A_6	32.0
Variable A_7	64.0
Variable A_8	128.0

E5.2.6 Affinity Series

An Affinity Series is defined by the Affinity samples containing mixtures with one Fixed Interactant concentration and a concentration series of the Variable Interactant.

Click **Add** to add an Affinity Series. Specify the **Affinity Series name**. **Condition** is optional and can be used to add additional information about the series.

Affinity Series			
Affinity Series name	Condition		Add
▶ Affinity Series A			Copy
			Delete

To delete an Affinity Series, select the entire row by clicking the black triangle and then selecting **Delete**. Multiple Affinity Series can be deleted at the same time by marking multiple lines and selecting **Delete**.

As considerable time may have been spent on creating an Affinity Series, you will have to confirm when attempting to delete an Affinity Series.

An Affinity Series can be copied by selecting the Affinity Series and selecting **Copy**. It is possible to copy multiple Affinity Series by selecting many Affinity Series before selecting **Copy**.

Affinity Series names and conditions can be copied and pasted. Use Ctrl+C to copy and Ctrl+V to paste, or right click and select **Copy** or **Paste**.

The Affinity Series can be sorted on name or condition by clicking the table header. Note that this is only a temporary sorting and will not affect the underlying order defined when adding the Affinity Series.

When selecting an Affinity Series, details about the Affinity Series become visible.

Affinity Series name	Condition		Add
▶ Affinity Series A			Copy
			Delete

Affinity Series A

Fixed Interactant:

Fixed Concentration [M]:

Variable Interactant:

Each Affinity Series must include one concentration or dilution from a Fixed Interactant, together with one Variable Interactant.

Select the **Fixed Interactant**, followed by selecting the **Fixed Concentration** or **Fixed Dilution** from that Fixed Interactant.

Then select the **Variable Interactant**. When the Variable Interactant has been selected, the points in the Affinity Series are displayed, with the concentration/dilution values from the Variable Interactant.

Affinity Series A

Fixed Interactant: Fixed A (Concentration) ▾

Fixed Concentration [M]: 1.0 ▾

Variable Interactant: Variable B (Dilution) ▾

Affinity Series Sample name	Dilution
▶ Affinity Series A_1	1.0
▶ Affinity Series A_2	2.0
▶ Affinity Series A_3	4.0
▶ Affinity Series A_4	8.0
▶ Affinity Series A_5	16.0
▶ Affinity Series A_6	32.0
▶ Affinity Series A_7	64.0
▶ Affinity Series A_8	128.0

Either the Fixed Interactant or Variable Interactant must be specified as a concentration to determine affinity.

E5.2.7 Experiments

Selecting Methods and defining Affinity Series provides the building blocks to create Experiments.

Each Experiment defines which of these building blocks to use when executing the run and processing the Experiment in question.

Add an Experiment by selecting **Add Experiment**. The Experiment will be given a default name, which can be changed.

Experiments

Add Experiment

If exactly one Method has been selected in the Run Design, the Experiment will be configured to use that Method. Otherwise, select the Method from **Method to process**.

⤴ Experiment 1

Method to process: 200-3W-001-A ▾

Capture reagent addition ▾

Detection reagent addition ▾

To change Method, select a new **Method to process**. In case the reagent transfer operations match those from the previously selected Method, the software will offer to keep the reagent selection. Otherwise, the list of selected Reagents will be cleared.

The number and types of Reagents are defined by the Method. The specific reagent for each Experiment must be manually selected from the drop down list for each reagent type.

All Affinity Series are presented, together with a summary of the most important parameters for each Affinity Series.

Used Affinity Series:

Affinity Series	Use
Affinity Series A Fixed Interactant: Fixed A (Concentration), 1.0 [M] Variable Interactant: Variable A (Dilution)	☐
Affinity Series B Fixed Interactant: Fixed A (Concentration), 2.0 [M] Variable Interactant: Variable A (Dilution)	☐
Affinity Series C Fixed Interactant: Fixed A (Concentration), 4.0 [M] Variable Interactant: Variable A (Dilution)	☐
Affinity Series D Fixed Interactant: Fixed A (Concentration), 8.0 [M] Variable Interactant: Variable A (Dilution)	☐

It is possible to select what Affinity Series to process for an Experiment. Mark the **Use** checkbox for each Affinity Series to include in the Experiment.

You may want to cover a large number of interactions in an initial Run that can later be repeated with a reduced set of binders. There may be reasons to just run the best binders again or those that did not give reliable results. Instead of entering the same information, creating a new Run Design, it is possible to modify the Experiments in the previous Run Design. You can also modify an Experiment removing certain Affinity Series with a Fixed Interactant that did not give any information in the first Run.

When selecting an Affinity Series from the list, information on all the samples from that Affinity Series is displayed.

Used Affinity Series:

Affinity Series	Use
Affinity Series A Fixed Interactant: Fixed A (Concentration), 1.0 [M] Variable Interactant: Variable A (Dilution)	☒
Affinity Series B Fixed Interactant: Fixed A (Concentration), 2.0 [M] Variable Interactant: Variable A (Dilution)	☐
Affinity Series C Fixed Interactant: Fixed A (Concentration), 4.0 [M] Variable Interactant: Variable A (Dilution)	☐
Affinity Series D Fixed Interactant: Fixed A (Concentration), 8.0 [M] Variable Interactant: Variable A (Dilution)	☐

Affinity Series Sample name	Dilution	Replicates
Affinity Series A_1	1.0	2
Affinity Series A_2	2.0	2
Affinity Series A_3	4.0	2
Affinity Series A_4	8.0	2
Affinity Series A_5	16.0	2
Affinity Series A_6	32.0	2
Affinity Series A_7	64.0	2
Affinity Series A_8	128.0	2

The number of replicates for each sample is specified in **Replicates**. The highest number of replicates is eight. Replicate numbers can be copied and pasted. Use Ctrl+C to copy and Ctrl+V to paste, or right click and select Copy or Paste.

To delete an Experiment, click the corresponding  button.



An Experiment can be copied. Click the  button. This will create a new Experiment with the same setup as the original Experiment.

Experiments can be reorganized within the Run Design. To move an existing Experiment, grab the title bar for the Experiment, to the right of the Experiment name, with the default (normally the left) mouse button, and drag it up and down to the desired destination. When grabbing the Experiment, an icon will initially be displayed showing that the Experiment cannot be dropped. When moving the mouse up and down, a legal destination will be highlighted with a black stripe. Release the mouse button at the desired destination to complete the move.

E5.2.8 Using the Run Design to Execute a Run

You may now save the Run Design. Saving a Run Design is done in the same way as for a Wizard Run Design (B4.4).

Perform the following steps to execute an Affinity run..

Step	Action

1.	Create an Affinity Run Setup based on the Run Design (E5.3).
2.	Typically for an Affinity Run, samples should be incubated. In this case prepare the microplates and leave them for incubation for the desired time.
3.	Execute the run at a Gyrolab instrument.

E5.3 Affinity Run Setup

In contrast to a Wizard Run Setup (B5), all the samples to process have already been defined in the Affinity Run Design when selecting to use Affinity Series in Experiments. The main task for the Affinity Run Setup is to decide whether to use a partially used CD ("limited CD") – and to decide on a suitable microplate layout.

E5.3.1 Overview of workflow

The following list shows the steps to create an Affinity Run Setup, with references to applicable chapters for more information. The following chapters explain the process of creating an Affinity Run Setup in more detail.

Step	Action

1.	Select the Affinity Run Design to base the Run Setup on from the main window folder tree.
2.	On the right side of the main window, select Create Run Setup from Design to create a new Run Setup based on the selected Affinity Run Design.
3.	A Run Setup edit window is opened. The MP Layout tab is displayed.
4.	Enter a Name and optionally a Description for the Run Setup.
5.	In the MP Layout tab, decide on a suitable well placement. (E5.3.2).
6.	Produce a Loading List to guide the microplate preparation from the Loading List section, using either Save... , Open... or Print as desired.

Step	Action

7.	Queue the Run Setup from the File menu, by selecting Queue for Execution and Close . If Target and Report Settings dialog is displayed, close it with OK . These steps are the same as for a Wizard Run Setup. See chapters B5.5 and B6 for details.
8.	Prepare microplates according to Loading List. The Run Setup is now ready for execution at a Gyrolab instrument. Typically for an Affinity Run Setup, microplates are prepared and incubated for some time before starting execution.

E5.3.2 MP Layout

The **MP Layout** tab provides information on how samples, and other liquids included in a run, are placed on microplates.

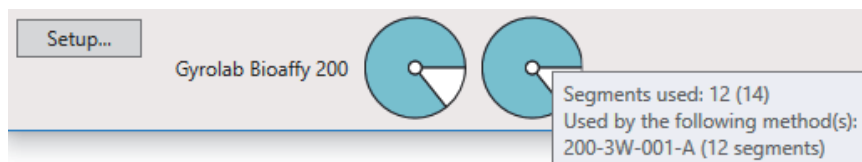
The MP Layout tab is the same as for a Wizard Run Setup, see chapter B5.4.

Note that an Affinity Run does not have unknown samples, so the following selections in **Well Placement** will result in identical layouts

- New Row for Liquid Type
- New Plate for Unknowns
- New Plate for Controls & Unknowns
- Unknowns sorted on Preparation

E5.3.2.1 Summary of the required amount of CDs

A summary in the lower section of the window displays the number of segments and CDs used for the run.



The presentation includes the CD types required by the Methods selected in the Affinity Run Design and illustrates the number of CD segments required. By holding the mouse pointer over a CD, details about the use for that CD is presented.

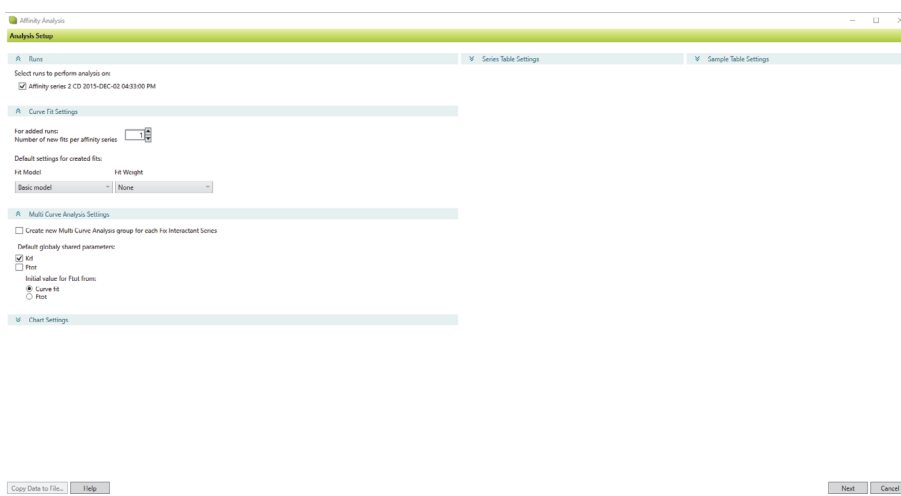
More complex use patterns for CDs can be specified through the Setup... button. See chapter B5.7 for more information.

E5.4 Data evaluation

This chapter describes how to evaluate run data from an Affinity Run. The data analysis is performed in Gyrolab Evaluator using the software module Gyrolab Affinity Software.

Step Action

1. In Gyrolab Evaluator Project view (Chapter D3.1), click the **Affinity Analysis** button  **Affinity Analysis**.
2. The **Affinity Analysis** wizard opens with the page **Analysis Setup** (first page of three).



- In the **Runs** section, select desired Run(s) for the analysis. It is possible to select one or several affinity Runs to analyze. If the Gyrolab Evaluator Project contains Run(s) that are not of type Affinity, such Run(s) will be grayed out in the **Runs** section.
- In the **Curve Fit Settings** section, select **Fit Model** and **Fit Weight** for the curve fit. The **Number of new fits per affinity series** may be changed from the default of one fit, if desired. Refer to Chapter E5.4.4 and E5.4.5 for more information on the available curve fit models and weights, respectively.
- In the **Multi Curve Analysis Settings** section, select which parameters to be globally shared K_d and/or F_{tot} . Create new Multi Curve Analysis group for each Fix Interactant series, will automatically create Multi Curve Analysis groups if it is checked.

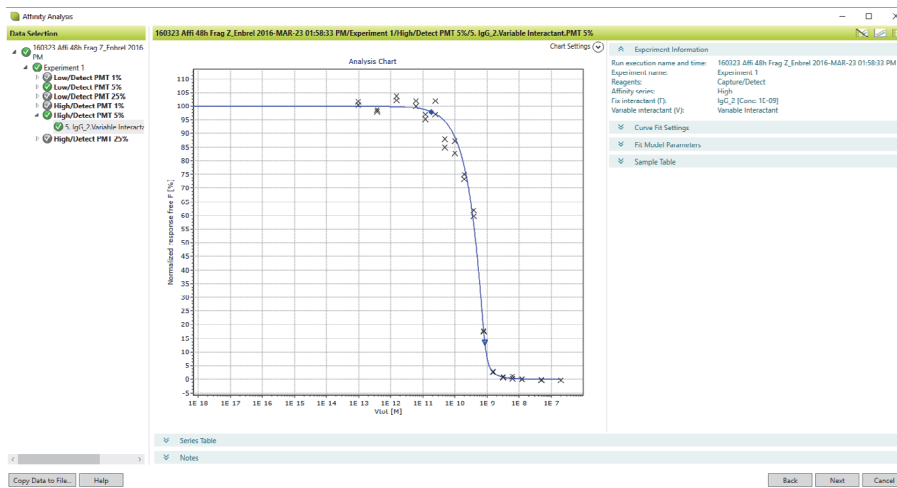
There are two options for initial values for F_{tot}

- Curve fit, Multi Curve Analysis will decide an initial value from the datasets
- F_{tot} , the value for fixed series interactant from the run will be used as initial value. A user can also change the initial value by editing the column for F_{tot} in the series table if this option has been selected.
- It is possible to change the chart and table settings by expanding the **Chart Settings**, **Sample Table Settings** and **Series Table Settings** sections, refer to Chapter E5.4.1, E5.4.2 and E5.4.3, respectively, for more information.
- Click the **Next** button.

NOTE: *If this is not the first time this page is displayed in this specific analysis, the selected curve fit settings will only be applied to Runs that are added since last time going Next from Analysis Setup.*

Step Action

3. The **Affinity Analysis** wizard continues to the **Affinity Analysis** page (second page of three).



TIP: In the Affinity Analysis page, it is possible to adjust the size of the Data Selection area by selecting the splitter line with the left mouse button and dragging it to the desired position. Similarly, it is possible to adjust the size of the chart in proportion to the collapsible/expandable sections to the right. The buttons to the upper right provide a shortcut to moving this second splitter to display both chart and sections , mostly chart , or mostly sections .

Step Action

4. The left panel of the **Affinity Analysis** page, **Data Selection**, displays the Runs selected in step 2. Click on the arrow sign in the tree to expand or collapse the tree structure. The data is structured according to:

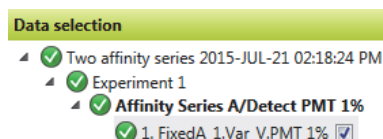
Run name

Experiment name

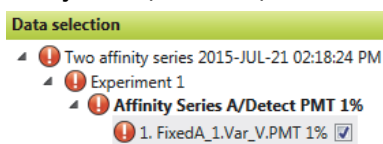
Affinity series name/PMT setting

Affinity fit ID number. Affinity fit curve name

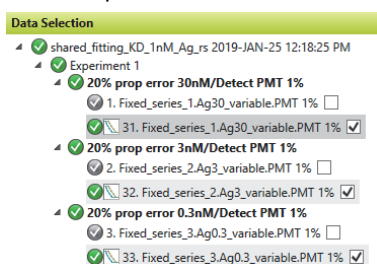
- Green symbols (see below) indicate that the curve fit succeeded.



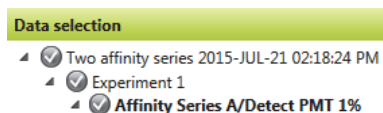
- Red symbols (see below) indicate that the curve fit failed.



- Curve fits that are part of a Multi Curve Analysis Group have a double curve icon next to it, see below.



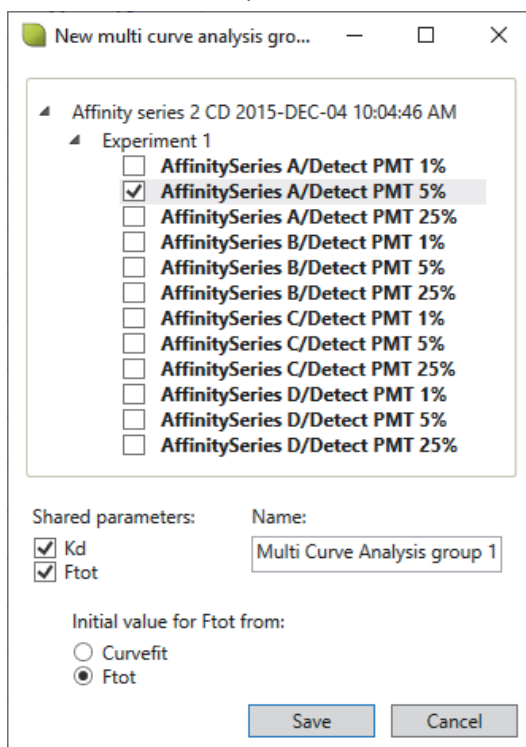
- Selecting a fit that is part of a Multi Curve Analysis group, will highlight all fits that belong to the same group. See above.
- Click on an affinity fit row (bottom level in the tree) to display the corresponding data in the workspace to the right in the wizard page.
- An affinity fit curve may be renamed or removed by right-clicking an affinity fit row (bottom level in the tree) and selecting **Rename** or **Remove**, respectively. To rename, enter the desired name in the dialog that opens, then click **OK**. To remove, confirm by clicking **OK**.
- Note: The ID number cannot be changed, only the curve name.
- A new affinity fit may be created by right-clicking an affinity series row (the level in the tree that is written in bold, see below) and selecting **New Fit**.



- The affinity series can be added to a Multi Curve Analysis group by clicking Multi Curve Analysis and select, or create, a group.

Step Action

- In the dialog for New Multi Curve Analysis group, the affinity series can be selected by ticking the checkbox of the series. Globally shared parameters are decided with the checkboxes for Shared Parameters. Initial value for Ftot decides the origin of the start guess in the curve fitting.
- If curve fit is selected, the Multi Curve Analysis will use the estimated Ftot from a prefit.
- If from Ftot is selected, then the value entered by the user is selected.



- A Multi Curve Analysis group can be edited by right-clicking a Multi Curve Analysis fit and select Edit Group.
- A Multi Curve Analysis group can be deleted by right-clicking a Multi Curve Analysis fit and select remove group. Removing a group will delete all the members in that group.
- Click the tick box of one or more affinity fits to include it/them in the report and to be available in the **Summary** wizard page, step 7. If selecting a fit that is part of a Multi Curve Analysis group all of the fits in that Multi Curve Analysis group will be selected.

Step Action

5. The workspace to the right in the **Affinity Analysis** page displays a chart and a number of collapsible/expandable sections:
- **Analysis Chart**, used to view the fitted curve and to view and exclude/include data points for the selected affinity fit. To exclude/include a data point, right-click it and then select exclude/include. Refer to Chapter E5.4.1 for more information on the chart and the available chart settings.
 - **Experiment Information**, used to view information about the run, experiment and affinity series for the selected affinity fit.
 - **Curve Fit Settings**, used to view and change the fit model and fit weight for the selected affinity fit. Refer to Chapter E5.4.4 and E5.4.5 for more information on the available curve fit models and weights, respectively.
 - **Fit Model Parameters**, used to view the fit result for the selected affinity fit and to view the model equation. The values and the standard deviations for the fitted parameters are displayed as well as R^2 for the fit. The data is available in the **Series Table** as well and is presented in this format for convenience.
 - **Sample Table**, used to view sample data and edit/exclude/include sample points for the selected affinity fit. To edit Vtot Conc or Dilution, click the corresponding table cell and enter the new value (see below). To exclude/include a sample, right-click the corresponding table row and select exclude/include. Refer to Chapter E5.4.2 for more information on the sample table and its settings.

Sample Table

	Sample Name	Vtot Conc [M]	Response [RU]
▶	High_6	6.10E-012	93.3
▶	High_6	6.10E-012	95.1

- **Series Table**, used to view and edit the affinity series data and to view the analysis results for the selected affinity fit. To edit Ftot Conc or Dilution, click the corresponding table cell and enter the new value. Refer to Chapter E5.4.3 for more information on the series table and its settings.
- **Multi Curve Analysis Table**, used to view all the fits that belong to the multifit group selected in the combobox, see below.

Multi Curve Analysis Table

Multicurvefit group: Multi Curve Analysis group 1

Series Name	Multi Curve Analysis Group	Shared Parameters	Ftot Conc [M]	Kd [M]
▶ 31. Fixed_series_1.Ag30_variable.PMT 1%	Multi Curve Analysis group 1	Kd, Ftot	3.00E-008	1.06E-009
▶ 32. Fixed_series_2.Ag3_variable.PMT 1%	Multi Curve Analysis group 1	Kd, Ftot	3.00E-009	1.06E-009
▶ 33. Fixed_series_3.Ag0.3_variable.PMT 1%	Multi Curve Analysis group 1	Kd, Ftot	3.00E-010	1.06E-009

Step Action

- The combobox contains all the Multi Curve Analysis groups in the analysis. Delete group will remove the Multi Curve Analysis group and all of the fits that belongs to it. The button edit group open up the edit group dialog, see below.

Edit multi curve analysis group

▲ Affinity series 2 CD 2015-DEC-04 10:04:46 AM

▲ Experiment 1

- ☐ AffinitySeries A/Detect PMT 1%
- ☒ AffinitySeries A/Detect PMT 5%
- ☐ AffinitySeries A/Detect PMT 25%
- ☐ AffinitySeries B/Detect PMT 1%
- ☒ AffinitySeries B/Detect PMT 5%
- ☐ AffinitySeries B/Detect PMT 25%
- ☐ AffinitySeries C/Detect PMT 1%
- ☒ AffinitySeries C/Detect PMT 5%
- ☐ AffinitySeries C/Detect PMT 25%
- ☐ AffinitySeries D/Detect PMT 1%
- ☐ AffinitySeries D/Detect PMT 5%
- ☐ AffinitySeries D/Detect PMT 25%

Shared parameters: Name:

☒ Kd
☒ Ftot

Initial value for Ftot from:

☒ Curvefit
☐ Ftot

In the Edit multicurve analysis group, the group can be renamed, shared parameters can be edited and affinity series can be added or removed. The **Save as...** button makes a copy of the Group.

Notes, used to view and edit the notes for the selected affinity fit.

- In the context menu, found by right-clicking on the Sample Table columns **Vtot Conc** or **Vtot Dilution** (Vtot Dilution column is by default hidden it can be made visible in the table settings), the user can specify if dilution or concentration is master of sample change. If **Concentration is master** is selected, the software will treat concentration as fixed, and changing one of the dilutions will update all dilutions to accommodate for the change. If **Dilution is master**, the software will treat dilution as fixed, and changing one of the concentrations will update all concentrations according to the dilutions specified.

Sample Table Table Settings

Sample Name	Vtot Conc [M]	Vtot Dilution	Response	CV Response	Norm Resp
Low_13	7.81E-010				
Low_13	7.81E-010				
Low_14	1.56E-009	128	0.0977	1.54	
Low_14	1.56E-009	128	0.0956	1.54	
Low_15	3.13E-009	63.9	0.0918	2.59	
Low_15	3.13E-009	63.9	0.0952	2.59	
Low_16	6.25E-009	32.0	0.171	13.0	
Low_16	6.25E-009	32.0	0.142	13.0	
Low_17	1.25E-008	16.0	0.0767	12.6	
Low_17	1.25E-008	16.0	0.0917	12.6	
Low_18	5.00E-008	4.00	0.0714	10.5	
Low_18	5.00E-008	4.00	0.0829	10.5	
Low_19	2.00E-007	1.00	0.0865	1.13	
Low_19	2.00E-007	1.00	0.0879	1.13	

Step Action

7. When finished reviewing, adjusting and selecting affinity fits/curves in the **Affinity Analysis** page, click the **Next** button.

NOTE: To export data refer to Chapter E5.4.6.

8. The **Affinity Analysis** wizard continues to the **Affinity Summary** page (last page of three).



TIP: In the **Affinity Summary** page, it is possible to adjust the size of the chart area and the table area by selecting the splitter line by the right mouse button and dragging it to the desired position.

- Select which curves to be displayed in the **Summary Chart** by clicking the tick boxes in the **Show in Chart** column in the **Summary Table**.
 - To rename a curve, right-click the name in the chart legend and select **Rename**, then enter the desired name in the dialog that opens, click **OK**.
 - Refer to Chapter E5.4.1 for more information on the chart.
 - Refer to Chapter E5.4.3 for more information on the series data in the **Summary Table**.
9. When finished adjusting the chart and table in the **Affinity Summary** page, click the **Create Report** button to save the analysis and create the **Affinity Analysis Report**.

NOTE: To export data refer to Chapter E5.4.6.

10. Set **Analysis Name** and click **OK**. The analysis is saved under **Analyses: Affinity Analysis** in Gyrolab Evaluator Project view.

E5.4.1 Affinity chart description

The charts show the Gyrolab response on the y-axis and the user-entered V_{tot} on the x-axis (unless the fit model is Unknown V_{tot} , in which case the x-axis is the calculated V_{tot}). Refer to Chapter E5.4.2 and E5.4.4 for more information on V_{tot} . The Gyrolab response is expected to be proportional to the concentration of non-bound F, the interactant with fixed concentration. Refer to Chapter E5.4.4 for more information on F.

The chart settings are displayed by expanding the **Chart Settings** section in the **Analysis Setup** page or in the respective chart by clicking the **Chart Settings** expander in the upper right of the chart area. To collapse the **Chart Settings**, click the expander once more. Available chart settings are:

- **x-axis** and **y-axis**, select **Linear** or **Logarithmic** scale.
- **Response**, select **Absolute** or **Normalized** response.
- **Show K_D** , click the tick box to show/hide the calculated K_D point (diamond).
- **Show F_{tot}** , click the tick box to show/hide the calculated/fixed F_{tot} point (triangle).
- **Show samples**, click the tick box to show/hide the data points (only applicable in the **Summary Chart**).
- **Legend alignment**, select the legend position (only applicable in the **Summary Chart**).

To save a chart to file or to the clipboard, right-click the chart and select:

- **Save As**, to save the chart to disk. In the **Save As...** dialog, enter desired file name and choose between available file formats. Click **Save**.
- **Copy**, to place a copy of the chart on the clipboard.

NOTE:

- K_D and F_{tot} points as well as all normalized responses are only displayed if the curve fit succeeded.
- In the **Analysis Chart**, data points with defined values are always displayed. With **Response** setting **Absolute** any excluded points are grayed out. With **Response** setting **Normalized** any excluded points are hidden.
- In the **Summary Chart**, excluded data points are not displayed.
- To plot data points when only the sample dilutions are known, set one of the sample concentrations in the **V_{tot} Conc [M]** column in the **Sample Table** in the **Affinity Analysis** page, refer to Chapter E5.4.2 for more information on the **Sample Table**.
- A change in the chart settings in one wizard page will be reflected in the other wizard pages and in the **Affinity Analysis Report**.

E5.4.2 Affinity sample table description

The sample table settings are displayed in the [Analysis Setup](#) page or in the [Affinity Analysis](#) page by expanding the [Sample Table](#) section and clicking the [Table Settings](#) expander in the right of the section header. To collapse the [Table Settings](#), click the expander once more. It is possible to select which sample table columns to include in the analysis by clicking the column name tick boxes. It is not possible to exclude the [Sample Name](#) column. A change in the table settings in one wizard page will be reflected in the other wizard pages and in the [Affinity Analysis Report](#).

The available columns in the [Sample Table](#) are:

Column heading	Default	Description
Sample Name	Yes	Sample identity
Vtot Conc [M]	Yes	Total concentration of V*, the interactant with variable concentration in the affinity series
Vtot Dilution	No	V* dilution factor, where V* is the interactant with variable concentration in the affinity series
Calc Vtot Conc [M]	No	Calculated total concentration of V*, the interactant with variable concentration in the affinity series. Applicable when Dcf* is one of the fitted parameters
Response [RU]	Yes	Integrated volume of the fluorescent binding surface of a reaction in a microstructure
Average Response [RU]	No	Average of response values for replicates of a sample
CV Response [%]	Yes	Coefficient of variation of responses of replicates of a sample
SD Response [RU]	No	Standard deviation of responses of sample replicates
Normalized Response [%]	Yes	Response normalized to 100% at Rmax* and 0% at Rmin* from curve fitting
CD ID	No	Identity of Gyrolab CD microlaboratory where the sample was processed
CD Struct	No	Identity of structure on Gyrolab CD microlaboratory where sample was processed
MP ID	No	Identity of the microplate where the sample was placed
MP Well	No	Well position on the microplate where the sample was placed
Needle ID	No	Identity of the needle used to transfer the sample from the MP to the CD structure
Detect Result	No	- OK: The results are approved - Not OK: The results are not approved. The fluorescence signal is of poor quality which may be caused by inadequate PMT setting (detector is saturated) or errors in the sample preparation
Run	No	Name of the Run, in which the sample was contained
Experiment	No	Name of the Experiment, within the Run, where the sample was contained

Column heading	Default	Description
Affinity Series	No	Name of the Affinity Series, within the Run, from which the sample was defined
PMT	No	Name of the PMT operation, in the Gyrolab method of the Run, used to measure the sample response
Instrument ID	No	Identity of the Gyrolab instrument where the Run was executed
Notes	No	It is possible to add comments to individual samples

* Refer to Chapter E5.4.4 for further information on the terms V, Vtot, Rmax, Rmin and Dcf.

NOTE: Excluded samples are shown as grayed-out rows in the table.

E5.4.3 Affinity series table description

The series table settings are displayed in the **Analysis Setup**, the **Affinity Analysis** or **Affinity Summary** pages by expanding the **Series Table** or **Summary Table** section, and then clicking the **Table Settings** expander in the right of the section header. To collapse the **Table Settings**, click the expander once more. It is possible to select which series table columns to include in the analysis by clicking the column name tick boxes. The **Series ID** column is not possible to exclude. A change in the table settings in one wizard page will be reflected in the other wizard pages and in the **Affinity Analysis Report**.

The available columns in the **Series Table** and **Summary Table** are:

Column heading	Default	Description
Series ID	Yes	Curve identity
Multi Curve Analysis Group	Yes	Multi Curve Analysis group that the curve belongs to.
Shared Parameters	Yes	States the parameters that are globally shared within the multicurve analysis group.
Ftot Conc [M]	Yes	Total (active) concentration of F*, the interactant with fixed concentration in the affinity series
Ftot Dilution	No	F* dilution factor, where F* is the interactant with fixed concentration in the affinity series
K_D [M]	Yes	Calculated K _D *
K_D SD [M]	Yes	Standard deviation of the calculated K _D *
K_D Conf 95% Low [M]	No	Lower limit of the 95% confidence interval for calculated K _D *
K_D Conf 95% High [M]	No	Upper limit of the 95% confidence interval for calculated K _D *
Ftot [M]	Yes	Calculated Ftot*, applicable if Ftot* is one of the fitted parameters
Ftot SD [M]	Yes	Standard deviation of the calculated Ftot*, applicable if Ftot* is one of the fitted parameters
Ftot Conf 95% Low [M]	No	Lower limit of the 95% confidence interval for calculated Ftot*, applicable if Ftot* is one of the fitted parameters

Column heading	Default	Description
Ftot Conf 95% High [M]	No	Upper limit of the 95% confidence interval for calculated Ftot*, applicable if Ftot* is one of the fitted parameters
Rmax [RU]	No	Calculated Rmax*
Rmax SD [RU]	No	Standard deviation of the calculated Rmax*
Rmax Conf 95% Low [RU]	No	Lower limit of the 95% confidence interval for calculated Rmax*
Rmax Conf 95% High [RU]	No	Upper limit of the 95% confidence interval for calculated Rmax*
Rmin [RU]	No	Calculated Rmin*
Rmin SD [RU]	No	Standard deviation of the calculated Rmin*
Rmin Conf 95% Low [RU]	No	Lower limit of the 95% confidence interval for calculated Rmin*
Rmin Conf 95% High [RU]	No	Upper limit of the 95% confidence interval for calculated Rmin*
Dcf [M]	No	Calculated Dcf*, applicable if Dcf* is one of the fitted parameters
Dcf SD [M]	No	Standard deviation of the calculated Dcf*, applicable if Dcf* is one of the fitted parameters
Dcf Conf 95% Low [M]	No	Lower limit of the 95% confidence interval for calculated Dcf*, applicable if Dcf* is one of the fitted parameters
Dcf Conf 95% High [M]	No	Upper limit of the 95% confidence interval for calculated Dcf*, applicable if Dcf* is one of the fitted parameters
Standard Error [RU]	No	Standard error of the curve fit
R²	Yes	Linear correlation coefficient squared for the curve fit
Fit Model	Yes	Model used in the curve fit
Fit Weight	Yes	Weight used in the curve fit
Number of Excluded	No	Number of excluded sample points in the curve fit
Fix Interactant (F)	No	Name of F*, the interactant with fixed concentration in the affinity series
Variable Interactant (V)	No	Name of V*, the interactant with variable concentration in the affinity series
Run	No	Name of the Execution of the Run, in which the affinity series was contained
Experiment	No	Name of the Experiment, within the Run, where the affinity series was contained
Affinity Series	No	Name of the Affinity Series, within the Run
PMT	No	Name of the PMT operation, in the Gyrolab method of the Run, used to measure the affinity series responses
Instrument ID	No	Identity of the Gyrolab instrument where the Run was executed

* Refer to Chapter E5.4.4 for further information on the terms K_D , V , F , F_{tot} , R_{max} , R_{min} and Dcf .

NOTE: *In the Summary Table, an additional column Show in Chart is available and is not possible to exclude. The tick boxes in the column is editable and controls which curves are included in the Summary Chart, refer to step 7 in Chapter E5.4.*

E5.4.4 Affinity curve fit models

The equilibrium dissociation constant K_D for a simple one-to-one binding system with two interactants, V and F , can be described as:

$$K_D = [V][F]/[VF], \text{ at equilibrium}$$

If the relation between Gyrolab response and non-bound F is linear for the experimental conditions, the response can be related to the total concentrations of F and V at equilibrium, denoted F_{tot} and V_{tot} respectively, according to:

$$\text{Response} = (\text{Response}_{max} - \text{Response}_{min})(F_{tot} - V_{tot} - K_D + ((F_{tot} - V_{tot} - K_D)^2 + 4K_DF_{tot})^{1/2}) / 2F_{tot} + \text{Response}_{min}$$

E5.4.4.1 Basic model

The basic model is a four parameter model which estimates both K_D and F_{tot} from an affinity series where V_{tot} is varied and F_{tot} is kept fixed.

Model equation:

$$y = (R_{max} - R_{min})(F_{tot} - x - K_D + ((F_{tot} - x - K_D)^2 + 4K_DF_{tot})^{1/2}) / (2F_{tot}) + R_{min}$$

Model parameters:

- K_D : Equilibrium dissociation constant
- F_{tot} : Total concentration of the interactant with fixed concentration
- R_{max} : Gyrolab response corresponding to $[F]=F_{tot}$
- R_{min} : Gyrolab response corresponding to F completely titrated
- x : V_{tot} , total concentration of the interactant with varied concentration
- y : Gyrolab response from free F , the interactant with fixed concentration

E5.4.4.2 Multi Curve Analysis

Multi Curve Analysis use the basic four parameter model which estimates both K_D and F_{tot} from several affinity series where the parameters K_D and F_{tot} can be globally shared between the affinity series. The parameters R_{max} and R_{min} is individually estimated for each curve fit.

A Multi Curve Analysis of N datasets will generate N affinity fits, one for each dataset

Model equation:

$$y = (R_{max} - R_{min})(F_{max}/D - x - K_D + ((F_{max}/D - x - K_D)^2 + 4K_DF_{max}/D)^{1/2}) / (2F_{max}/D) + R_{min}$$

Model parameters

- K_D : Equilibrium dissociation constant
- F_{max} : The least diluted F_{tot} of all the affinity series that belongs to the multicurve analysis group.
- D : The dilution factor between the F_{max} and the F_{tot} of the affinity series.
- F_{tot} : Total concentration of the interactant with fixed concentration. $F_{tot} = F_{max}/D$

- $R_{\max}$: Gyrolab response corresponding to $[F]=F_{\text{tot}}$
- $R_{\min}$: Gyrolab response corresponding to F completely titrated
- x : V_{tot} , total concentration of the interactant with varied concentration
- y : Gyrolab response from free F, the interactant with fixed concentration

Fit Method:

Data is fitted using the Levenburg Marquardt algorithm. If an F_{tot} Conc value is given, it will be used as starting value for the F_{tot} parameter.

E5.4.4.3 Locked F_{tot} model

The locked F_{tot} model is a three parameter model which estimates K_D from an affinity series where V_{tot} is varied and F_{tot} is kept fixed.

Model equation:

$$y = (R_{\max} - R_{\min})(F_{\text{tot}} - x - K_D + ((F_{\text{tot}} - x - K_D)^2 + 4K_DF_{\text{tot}})^{1/2})/2F_{\text{tot}} + R_{\min}$$

where F_{tot} is the total concentration of F, the interactant with fixed concentration.

Model parameters:

- K_D : Equilibrium dissociation constant
- $R_{\max}$: Gyrolab response corresponding to $[F]=F_{\text{tot}}$
- $R_{\min}$: Gyrolab response corresponding to F completely titrated
- x : V_{tot} , total concentration of the interactant with varied concentration
- y : Gyrolab response from free F, the interactant with fixed concentration

Fit Method:

Data is fitted using the Levenburg Marquardt algorithm.

E5.4.4.4 Unknown V_{tot} model

The unknown V_{tot} model is a four parameter model which estimates both K_D and D_{cf} from an affinity series where V_{tot} is varied and F_{tot} is kept fixed.

D_{cf} , the dilution-to-concentration factor, is the value that relates dilution of V to concentration of V, for a sample, according to:

$$V_{\text{tot},i} = D_{\text{cf}}/V_{\text{dilution},i} \text{ for sample } i$$

Thus, the value of D_{cf} corresponds to V_{tot} in a sample with dilution 1.0.

Model equation:

$$y = (R_{\max} - R_{\min})(F_{\text{tot}} - D_{\text{cf}}/x - K_D + ((F_{\text{tot}} - D_{\text{cf}}/x - K_D)^2 + 4K_DF_{\text{tot}})^{1/2})/2F_{\text{tot}} + R_{\min}$$

where F_{tot} is the total concentration of F, the interactant with fixed concentration.

Model parameters:

- K_D : Equilibrium dissociation constant
- D_{cf} : Dilution-to-concentration factor

- R_{max}: Gyrolab response corresponding to $[F]=F_{\text{tot}}$
- R_{min}: Gyrolab response corresponding to F completely titrated
- x: Dilution of V, the interactant with varied concentration
- y: Gyrolab response from free F, the interactant with fixed concentration

Fit Method:

Data is fitted using the Levenburg Marquardt algorithm. If a V_{tot} Conc value is given, it will be used to create the starting value for the D_{cf} parameter.

E5.4.5 Affinity curve fit weights

The weights available in **Affinity Analysis** are:

- Response
- Standard deviation response (defined in Chapter E5.4.2)
- V_{tot} dilution (defined in Chapter E5.4.2)
- None

The default weight is Response.

E5.4.6 Data export

To export data to Excel XML spreadsheet format (.xls), click the **Copy Data To File** button in the **Affinity Analysis** or **Affinity Summary** pages, browse to the desired location and click **Save**. Data for all columns will be exported, not only those selected in **Table Settings**.

NOTE: *No traceability of results is achieved using Copy Data To File. A copy of a Result file is created but this can be done for example before an analysis is saved and it is NOT logged in the Audit Trail. To fulfill the requirements of 21 CFR part 11 data must be exported from a saved Project, refer to Chapter D3.5.*

E5.5 Installation of Gyrolab Affinity Software

The Gyrolab Affinity Software module is available for Gyrolab Control version 7.1.1 or higher and Gyrolab Evaluator version 3.4 and is activated by the user with a license key. Licenses are instrument specific. Contact Gyros Protein Technologies to purchase Gyrolab Affinity Software and receive a license.

To register the license: Save the license file to the hard disk of the external instrument computer, at the Gyros license folder, currently C:\ProgramData\Gyros\Licenses.

GYROLAB USER GUIDE

F Liquids and Recipes

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F1 Liquids

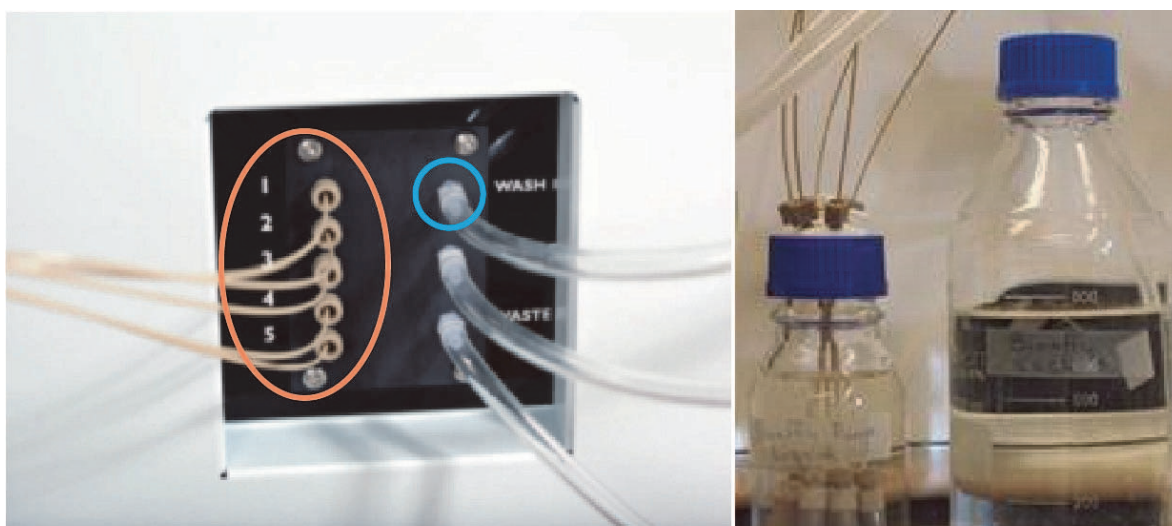
This chapter describes which liquids shall be connected to the instrument.

F1.1 Bioaffy Pump Liquid and Bioaffy Wash Station 1 solution

Prior to a Gyrolab run, Bioaffy Pump Liquid and Bioaffy Wash Station 1 solution shall be prepared and placed in the bottle with tubings for the five syringe pumps and in the bottle for Bioaffy Wash Station 1.

Gyrolab systems are compatible with use of 1 × PBS containing 0.01% Tween 20 and addition of 0.02% NaN₃ or 0.05% Proclin 950 to prevent bacterial growth, see chapter F2 Recipes. It is not recommended to use any other solutions unless it has been approved by Gyros Protein Technologies. Please contact Gyros Protein Technologies if you are considering using other Bioaffy Pump Liquid or Bioaffy Wash Station 1 solutions.

NOTE: *Use of unauthorized solutions may damage the instrument and void warranty or service agreements.*



Connecting panel (Gyrolab xPand) for external tubing. The tubing for the five syringe pumps (encircled in orange) shall be connected to the bottle of Bioaffy Pump Liquid. The tubing for wash station 1 (encircled in blue) shall be connected to the bottle with Bioaffy Wash Station 1.

F1.2 Bioaffy Wash Station Solution 2

For Gyrolab methods including additional needle wash, use any of the recommended Bioaffy Wash Station 2 solutions described in chapter F2 Recipes. Please contact Gyros Protein Technologies if you are considering using another Bioaffy Wash Station 2 solution.

NOTE: *Use of unauthorized solutions may damage the instrument and void warranty or service agreements.*

F1.3 Stand-by solution

Post Run, when the Gyrolab system is put in Standby, the Bioaffy Pump Liquid solution and Bioaffy Wash Station solutions shall be replaced by 20% ethanol standby solution. For recipes, see chapter F2 Recipes.

F2 Recipes

In this chapter F2 recipes for Gyrolab Runs, maintenance and sanitization procedures are provided.

F2.1 Stock solutions

10% Tween 20

To prepare 100 ml	Dissolve 10 g Tween 20 in 90 g deionized/distilled water.
Storage	Store at room temperature up to six months and keep protected from light.

20% sodium azide (NaN₃)



WARNING: Sodium azide (NaN₃) is very toxic. Handle with care.

To prepare 100 ml	- Add 20 g NaN₃ to 100 g Milli-Q water. - Stir for 20 hours.
Storage	Store in a hood at room temperature for up to 1 year.

10x PBS with sodium azide



WARNING: Sodium azide (NaN₃) is very toxic. Handle with care.

Composition	150 mM phosphate buffer, 1.5 M NaCl, 0.2% NaN ₃ , (150 mM PBS):
Chemicals required (1000 ml)	3.4 g NaH₂PO₄ (Mw 120 g/mol) 17.3 g Na₂HPO₄ (Mw 142 g/mol) 87.6 g NaCl (Mw 58.44 g/mol)
To prepare 1000 ml	- Dissolve all chemicals in 1000 ml deionized/distilled water. - Add 10 ml 20% NaN₃.
pH	1x PBS should have pH 7.4.
Storage	Store at room temperature.

10x PBS

Composition	150 mM phosphate buffer, 1.5 M NaCl, (150 mM PBS):
Chemicals required (1000 ml)	• 3.4 g NaH_2PO_4 (Mw 120 g/mol) • 17.3 g Na_2HPO_4 (Mw 142 g/mol) • 87.6 g NaCl (Mw 58.44 g/mol)
To prepare 1000 ml	• Dissolve all chemicals in 1000 ml deionized/distilled water. • Filter buffer through 0.22 μm filter and store at room temperature.
pH	1x PBS should have pH 7.4.
Storage	Store at room temperature.

Use of pre-made PBS (1x or 10x)

Pre-made PBS can be used in the Gyrolab instrument provided that the buffer composition is according to our recommendations stated above.

Additional important aspects regarding pre-made PBS buffer:

- It should be free of Ca^{2+} .
- Add Sodium azide prior to connecting the PBS buffer to the Gyrolab instrument.

NOTE: For PBS buffers, ensure they are filtered through 0.22 μm filter prior to connection to the Gyrolab instrument. Store at room temperature.

1 M Sodium bicarbonate buffer stock

Composition	1 M NaHCO_3
To prepare 1 ml	Add 1 ml deionized water to 85 mg of NaHCO_3 .
Storage	Store at +4 °C for maximum two weeks.

F2.2 Working solutions

F2.2.1 Bioaffy Pump Liquid

1 × PBS, 0.02% NaN₃, 0.01% Tween 20

Purpose	Used for the five Syringe Pumps
Composition	15 mM phosphate buffer, 150 mM NaCl, 0.02% NaN ₃ , 0.01% Tween 20
To prepare 250 ml	- Mix 25 ml 10x PBS with 0.2% NaN₃ with 225 ml deionized/distilled water. - Add 250 µl 10% Tween 20.
Required volume	250 ml for 1–5 CDs

F2.2.2 Bioaffy Wash Station Solution 1

1 × PBS, 0.02% NaN₃, 0.01% Tween 20

Purpose	Used for the Wash Station
Composition	15 mM phosphate buffer, 150 mM NaCl, 0.02% NaN ₃ , 0.01% Tween 20
To prepare 1000 ml	- Mix 100 ml 10x PBS with 0.2% NaN₃ with 900 ml deionized/distilled water. - Add 1 ml 10% Tween 20.
Required volume	1000 ml for 1 CD 2000 ml for 2–5 CDs

F2.2.3 Bioaffy Wash Station Solution 2

Select option depending on application.

Gyrolab Wash Buffer pH 11

Purpose	Used for the Wash Station 2
Composition	Gyrolab Wash Buffer pH 11
To prepare 1000 ml	- Dissolve one pack (10 g) of Gyrolab Wash buffer pH 11 powder in 1000 ml deionized/distilled water. - Filter 0.22 µm or 0.45 µm.
Required volume	1000 ml for 1 CD 2000 ml for 2–3 CDs 3000 ml for 4–5 CDs

50 mM Glycin pH 9.5 with 0.5% Dodecylsulfate sodium salt (SDS)

Purpose	Used for the Wash Station 2
Composition	50 mM Glycin pH 9.5 with 0.5% Dodecylsulfate sodium salt (SDS)
To prepare 1000 ml	• Dissolve 3.75 g Glycin in approximate 800 ml deionized/distilled water. • Adjust to pH 9.5 using sodium hydroxide. • Filter 0.22 µm. • Dissolve 5 g Dodecylsulfate sodium salt (SDS, Mw 288,38 g/mol) and adjust the volume to 1000 ml.
Required volume	• 1000 ml for 1 CD • 2000 ml for 2–5 CDs

1.5 M NaCl, 20% ethanol

Purpose	Used for the Wash Station 2
Composition	1.5 M NaCl in 20% ethanol
To prepare 1000 ml	• Mix 200 ml 95% ethanol with 800 ml deionized/distilled water. • Dissolve 87.66 g NaCl (Mw 58.44 g/mol). • Filter 0.22 µm.
Required volume	• 1000 ml for 1 CD • 2000 ml for 2–5 CDs

0.5% Dodecylsulfate sodium salt (SDS), 20% ethanol

Purpose	Used for the Wash Station 2
Composition	0.5% SDS in 20% ethanol
To prepare 1000 ml	• Mix 200 ml 95% ethanol with 800 ml deionized/distilled water. • Dissolve 5 g SDS (Mw 288.38 g/mol). • Filter 0.22 µm.
Required volume	• 1000 ml for 1 CD • 2000 ml for 2–5 CDs

F2.2.4 Standby Solution

20% ethanol

Purpose	Used in Syringe Pumps and Wash Stations
Composition	20% ethanol
To prepare 250 ml	Prepare 20% solution.
Required volume	250 ml for 1–5 CDs

F2.2.5 Needle Sanitize Solution

3% sodium hypochlorite

Purpose	Used for sanitizing needles
Composition	3% sodium hypochlorite
To prepare 10 ml	Mix sodium hypochlorite with deionized/distilled water. The amount depends upon the concentration of the stock solution.

F2.2.6 Wash Station Sanitize Solution

3% sodium hypochlorite

Purpose	Used for sanitizing Wash Station 1 and 2
Composition	3% sodium hypochlorite
To prepare 600 ml	Mix sodium hypochlorite with deionized/distilled water. The amount depends upon the concentration of the stock solution.

F2.2.7 Needle Desorb Solution

	Gyrolab Wash Buffer pH 11
Purpose	Used for Needle desorb
Composition	Gyrolab Wash Buffer pH 11
To prepare 1000 ml	Dissolve one pack (10 g) of Gyrolab Wash buffer pH 11 powder in 1000 ml deionized/distilled water. Filter through a 0.22 or 0.45 µm filter.

0.5% Dodecylsulfate sodium salt (SDS)

Purpose	Used for Needle desorb
Composition	0.5% SDS
To prepare 100 ml	Dissolve 0.5 g SDS in 99.5 g deionized/distilled water.

50 mM glycine, pH 9.5

Purpose	Used for Needle desorb
Composition	50 mM glycine, pH 9.5
To prepare 100 ml	Dissolve 375 mg glycine (Mw 75.07 g/mol) in 100 ml deionized/distilled water. Adjust to pH 9.5 with sodium hydroxide.

1.5 M NaCl in 20% ethanol

Purpose	Used for Needle desorb
Composition	1.5 M NaCl in 20% ethanol
To prepare 100 ml	Dissolve 8.77 g NaCl (Mw 58.44 g/mol) in 100 ml 20% EtOH. Filter through a 0.22 µm filter.

F2.2.8 General buffers

PBS-T

Purpose	PBS-T is a buffer for dilution of capture antibody and column wash in CDs.
Composition	15 mM phosphate buffer, 150 mM NaCl, 0.02% NaN ₃ , 0.01% Tween 20
To prepare 20 ml	- Mix 2 ml 10x PBS with 0.2% NaN₃, 20 µl 10% Tween 20 and 18 ml with deionized water. - Filter buffer through a 0.22 mm filter.
Storage	Store at +4 °C.

PBS-0.2% BSA

Purpose	Storage buffer: Dilute Detecting reagent to 1000 nM after labeling
Composition	15 mM phosphate buffer, 150 mM NaCl, 0.02% NaN ₃
To prepare 20 ml	- Mix 2 ml 10x PBS with 0.2% NaN₃, 400 µl 10% BSA with 18 ml with deionized water. - Filter buffer through a 0.22 mm filter.
Storage	Store at +4 °C.

1 × PBS

Purpose	During labelling of fluorophore and biotinylation
Composition	15 mM phosphate buffer, 150 mM NaCl
To prepare 20 ml	Mix 2 ml 10x PBS, 20 µl 10% Tween 20 and 18 ml deionized water.
Storage	Store at +4 °C.

GYROLAB USER GUIDE

G System administration and configuration



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G1 Gyrolab Control

G1.1 Start Gyrolab Control

The control software consists of the server and the client. The server must be running before starting the client.

Step	Action
1.	Start Gyrolab Server: - Click Start:All Programs:Gyros:Server. Gyrolab Instrument Log is displayed and Gyrolab server icon appears on the task bar.
2.	Start Gyrolab Control software: Select Start:All Programs:Gyros:Client.
3.	The Login dialog box is displayed. Enter Username and Password in the Login dialog box. NOTE: <i>Username and Password are case sensitive.</i> NOTE: <i>The software will request the user to log in anew when the system has been inactive for a specified time. This time is controlled by system setting "Maximum inactivity time". For more information, see Chapter B9.</i>
4.	Password must be changed when requested by Gyrolab Control. Password may also be changed when desired by a user: The Change Password window opens: - Enter present Password. - Enter New Password. Confirm Password. - Click OK.

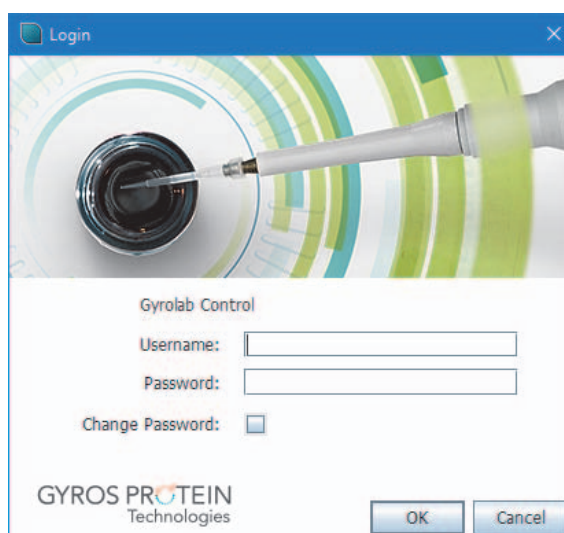
- Click **Start:All Programs:Gyros:Server**.
- Gyrolab Instrument Log** is displayed and Gyrolab server icon appears on the task bar.



- Select **Start:All Programs:Gyros:Client**.

NOTE: *Username and Password are case sensitive.*

NOTE: *The software will request the user to log in anew when the system has been inactive for a specified time. This time is controlled by system setting "Maximum inactivity time". For more information, see Chapter B9.*



The **Change Password** window opens:

- Enter present **Password**.
- Enter **New Password**.
- Confirm Password**.
- Click **OK**.

Step Action

5. Click **OK** to log in or **Exit** to close the dialog box without logging in. Once logged in, the main menu appears.

G1.2 Gyrolab Control main menu

G1.2.1 Main menu overview

The start screen in Gyrolab Control holds the main menu from which all actions are initiated. The main menu also displays instrument access status (refer to Chapter G1.3), instrument mode (refer to Chapter G1.3.14) and functionality for alarm handling.

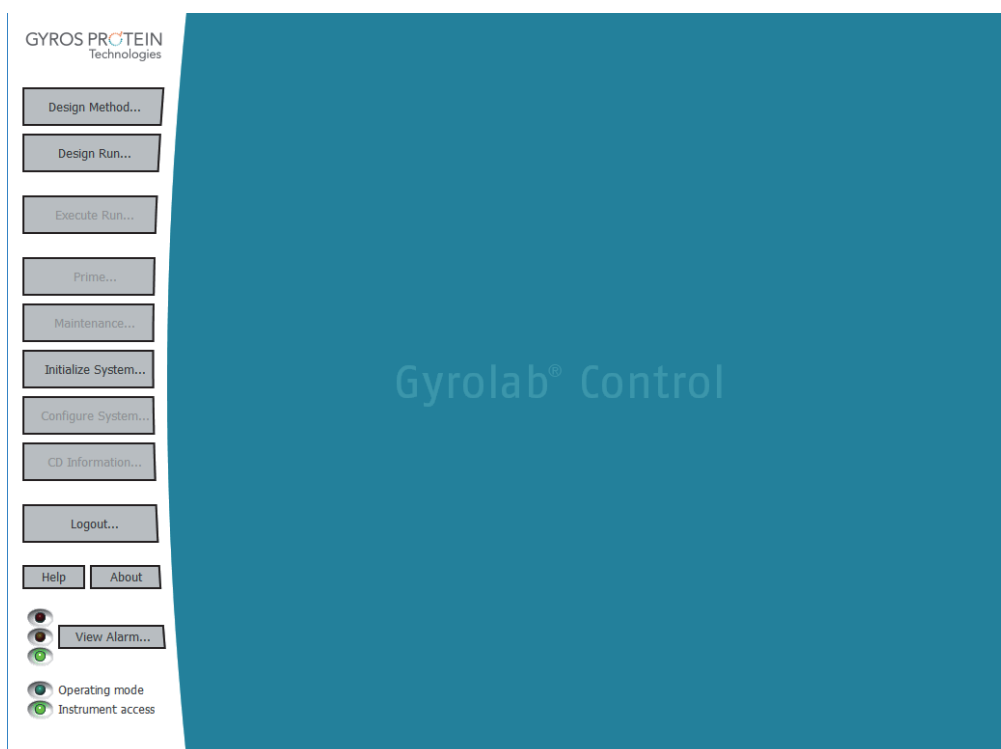


Figure 1: Main menu

The main functions of Gyrolab Control are represented by buttons on the main menu. Only one function at a time can be activated. Select a function by clicking on the function button and the panel for the selected function is displayed on the screen.

Buttons may be accessible (in the example above: **Initialize System**), or inaccessible (grayed out, in the example above: **Execute Run**) when not available. A common case is that operations requiring access to the Gyrolab instrument are inaccessible until the instrument has been initialized.

G1.3 Main menu functions

Button/LED	Function
Design Method	Launches the Design Method screen to create new methods/edit method, refer to Chapter G1.3.1.

Button/LED	Function
Design Run	Launches the Design Run screen to create new/edit/delete Run Designs, refer to Chapter G1.3.2.
Execute Run	Launches the Execute Run screen to prepare and start a Run, Chapter G1.3.3
Prime	Launches the Prime screen to set priming parameters perform instrument priming, refer to Chapter G1.3.4
Maintenance	Launches the Maintenance screen to perform instrument priming and/or a cleaning method, refer to Chapter G1.3.5
Initialize System	Starts system initialization, refer to Chapter G1.3.6
Configure System	Launches the Configure System screen to change the system configuration, refer to Chapter G1.3.7
CD Information	Launches functionality to read information from a CD tag.
Logout	Logout from Gyrolab Control.
Help	Launches the help system, refer to Chapter G1.3.10
About	Displays information on software versions and licences, refer to Chapter G1.3.11
View Alarm	Displays information about alarms, refer to Chapter G1.3.12
Instrument access LED	Indicates instrument access status, refer to Chapter G1.3.13
Instrument mode LED	Indicates instrument mode, refer to Chapter G1.3.14

G1.3.1 Design Method

Design Method function is used for setting up new or edit existing Methods to be used in Runs. Methods can be customized by Gyros Protein Technologies to suit specific needs. Contact Gyros Protein Technologies for more information.

G1.3.2 Design Run

The information required to perform an immunoassay on the Gyrolab instrument is collected in a **Run**. A **Run** is based on a **Method**, and a **Run Design**, which provides the environment for the **Run**, like definition of a Standard series. A **Run** is set up by using a **Run Design** and adding information on Unknown samples.

The function **Design Run** is used to create, edit, and delete **Run Designs**.

The information required for a **Run Design** differs depending on which Design type (which type of **Run**) is used.

A **Run Design** can also be created in Gyrolab Manager, which is the recommended way to work with **Run Designs**. For more information, see Chapter B4.

If using Gyrolab Control to create the **Run**, the Unknown samples are added to the **Run Design** when executing the **Run**. If using Gyrolab Manager, the Unknown samples are added as part of creating a **Run Setup**, see Chapter B5.

G1.3.3 Execute Run

Runs are prepared, loaded, executed, unloaded and finished in the Execute Run function.

When the execution is based on a Run Design created in Gyrolab Control, the Run Design is completed with sample information (using a Sample List) and settings for result and report files. Input data and settings differs depending on which Design type (which type of Run) is

used. See Chapter I, where the workflow for different Design Types using Gyrolab Client is described.

A Run can also be prepared in Gyrolab Manager by creating a Run Setup. In this case, sample information and settings for result and report files are already included in the Run Setup. See Chapter B5 for details on creating a Run Setup. See Chapter C4.1 to start execution from a Run Setup.

G1.3.4 Prime

Instrument priming is performed through this function. Refer to Gyrolab Instrument Guide.

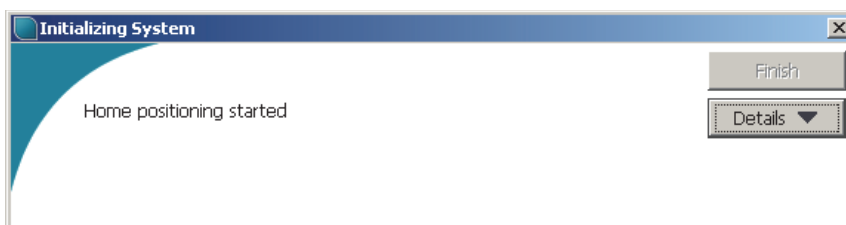
G1.3.5 Maintenance

Maintenance function is used for system maintenance. Refer to Gyrolab Instrument Guide for information about specific methods and procedures.

G1.3.6 Initialize System

Hardware tests of the components are performed during initialization, for example robot arm movements and vacuum of the CD stations when applicable.

Step	Action
1.	Close the Gyrolab instrument hatch if open. Click Initialize System on the Main menu. The Initializing System dialog box is displayed as initialization proceeds. Details of the initialization can be viewed by clicking on the Details button. NOTE: <i>To re-initialize the system, click on Logout in the Main menu. Choose Restart from the drop-down menu in the Shut Down dialog, then click OK.</i>
2.	Click Finish when initialization is complete.



G1.3.7 Configure System

The Gyrolab instrument is delivered with a pre-programmed configuration set-up and system priming protocol. This section explains how to configure the system and alter these settings.

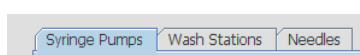
CAUTION: *Contact Gyros Protein Technologies before changing any configuration default settings.*

NOTE: *Only users with user roles Method Developer or System Administrator can configure the system, refer to Chapter NOTE:.*

Access the Configure System screen

Step Action

1. If the instrument is not initialized, click **Initialize** on the main menu.
NOTE: *The system must be initialized in order to access the Configure System screen.*
2. Click the **Configure System** button on the main menu.
3. Select desired tab, refer to chapters "Configure Syringe Pumps" and "Align needles" for further instructions.



Configure Syringe Pumps

The system is equipped with five Syringe Pumps that control two needles each. Pump number 1 controls needles 1 and 2, pump number 2 controls needles 3 and 4 and so on. This set-up is displayed on the **Syringe Pumps** tab in the **Configure System** screen.

NOTE: *Different Syringe Pumps can handle different liquids.*

 A screenshot of the 'Syringe Pumps' configuration tab. It features a table with columns for 'Use pump for: Samples', 'Reagents', 'Syringe Volume', and 'Connected Needles'. Below the table is a 'General pump settings' section with input fields for 'Pump to needle prime volume', 'Minimum needle volume', 'Bottle to pump prime volume', and 'Maximum needle volume'. There is also a 'Standby Liquid...' dropdown and a checkbox for 'Prompt for priming needles before run execution'.

	Use pump for: Samples	Reagents	Syringe Volume	Connected Needles
Pump 1	☒	☐	100.0 ul	1,2
Pump 2	☒	☐	100.0 ul	3,4
Pump 3	☒	☐	100.0 ul	5,6
Pump 4	☒	☐	100.0 ul	7,8
Pump 5	☐	☒	100.0 ul	9,10

General pump settings

Pump to needle prime volume: 2000.0 ul Minimum needle volume: 0.1 ul

Bottle to pump prime volume: 6000.0 ul Maximum needle volume: 60.0 ul

Standby Liquid... Standby solution

Prompt for priming needles before run execution: ☒

Figure 2: Example of syringe pump configuration tab

Syringe Volume shows the syringe volumes for the current instrument configuration. Do not change. **Connected Needles** shows how needles are connected to pumps. Do not change.

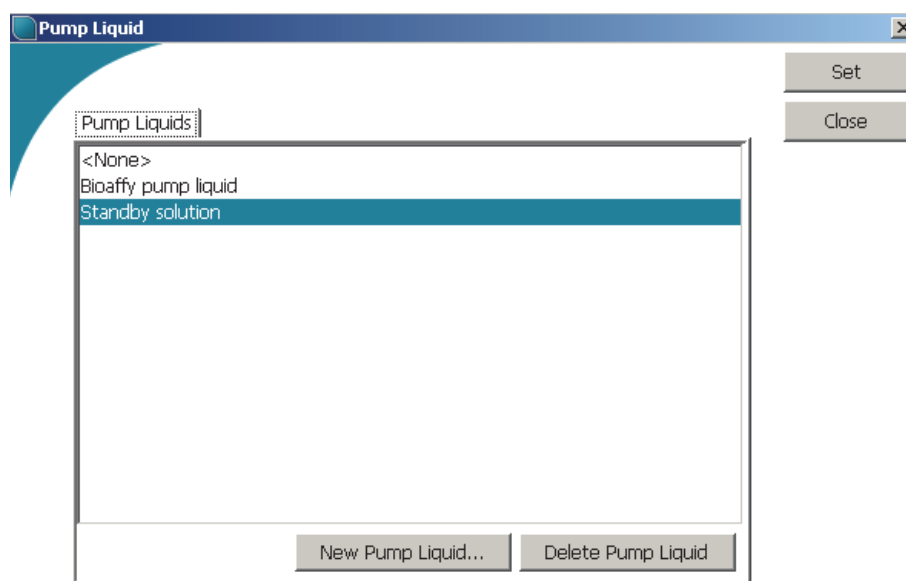
Step Action

1. Indicate the role of the syringe pump by marking one or both of the check boxes, **Samples** and **Reagents**, for each pump.
2. In the General Pump Settings section, enter **Pump to Needle Prime Volume** in µl.
The Pump to Needle Prime Volume is the volume used to rinse the tubing between the syringe pump and its connected needles during priming.

Step	Action

3.	In the General Pump Settings section, enter Bottle to Pump Prime Volume in µl. The Bottle to Pump prime Volume is the volume used to rinse the tubing between the pump liquid bottle and the syringe pump during priming.
4.	Enter the Minimum Needle Volume in µl.
5.	Enter the Maximum Needle Volume in µl.
6.	Click Standby Liquid . The standby liquid is the solution used to put the system in Standby mode.

The **Pump Liquids** dialog displays a list of available liquids:



7.	Select Standby Solution by clicking its name in the list. - To add new liquids to the list, click New Pump Liquid. Type a new name and click OK. - To remove a liquid from the list, select a name in the list and click Delete Pump Liquid and click OK to confirm deletion.
8.	Click Set . The standby liquid appears on the tab.
9.	Click Save to save syringe pump settings.

Configure Wash Stations

The system is equipped with two wash station pumps, one for each Wash Station. The wash station pumps are primed with wash station solutions.

The two Wash Stations are configured on the **Wash Stations** tab in the **Configure System** screen.

The screenshot shows the 'Wash Stations' tab in the 'Configure System' window. It has sub-tabs for 'Syringe Pumps', 'Wash Stations', 'Needles', and 'CD Stations'. Under 'Wash Stations', there are two sections: 'Prime Volume' and 'General wash station settings'. In the 'Prime Volume' section, 'Wash station 1' and 'Wash station 2' both have a value of '100000.0' in a text box followed by 'ul'. In the 'General wash station settings' section, there is a 'Standby Solution...' button and a text box containing 'Standby solution'. At the bottom, there is a checkbox labeled 'Prompt for priming wash stations before run execution:' which is currently unchecked.

Figure 3: Example of Wash Station configuration tab

Step Action

1. Enter the **Prime Volume** in μl for Wash Stations 1 and 2.
The Prime Volume is the volume used to rinse the tubing between the wash station bottle and the Wash Station during priming.
2. Click **Standby Solution** at the bottom of the tab. The standby liquid is the solution used to put the system in Standby mode.
The **Wash Station Solution** dialog is displayed containing a list of available standby solutions.

The screenshot shows the 'Wash Station Solution' dialog box. It has a title bar with a close button. Inside, there is a list box titled 'Wash Station Solutions' containing the following items: '<None>', 'Bioaffy wash station solution 1', 'Bioaffy wash station solution 2', 'Needle desorb solution 1', 'Needle desorb solution 2', 'Needle sanitize solution', 'Standby solution' (which is highlighted with a blue background), and 'Wash station sanitize solution 1'. To the right of the list box are two buttons: 'Set' and 'Close'. At the bottom of the dialog are two buttons: 'New Wash Station Solution...' and 'Delete Wash Station Solution'.

Step Action

3. Select the Standby Solution to be added by clicking its name in the list.
 - To add new liquids to the list, click **New Wash Station Solution**. Type a new name and click **OK**.
 - To remove a standby liquid from the list, select a name in the list and click **Delete Wash Station Solution**.
 - Click **OK** to confirm deletion.
4. Click **Set**. The Standby Solution appears on the tab.
5. Click **Save** to save wash station settings.

Align needles

An alignment procedure can be performed to ensure that the needles are correctly aligned (i.e. on target for the wells of a microplate). This procedure is normally only performed by Gyros Protein Technologies service staff when needles have been replaced.

The alignment procedure is controlled from the **Needles** tab on the **Configure System** screen. The tab holds a list of the needles along with their nominal positions and the allowed deviation ranges.

NOTE: *The nominal positions and allowed deviation ranges are set by the manufacturer and cannot be altered.*

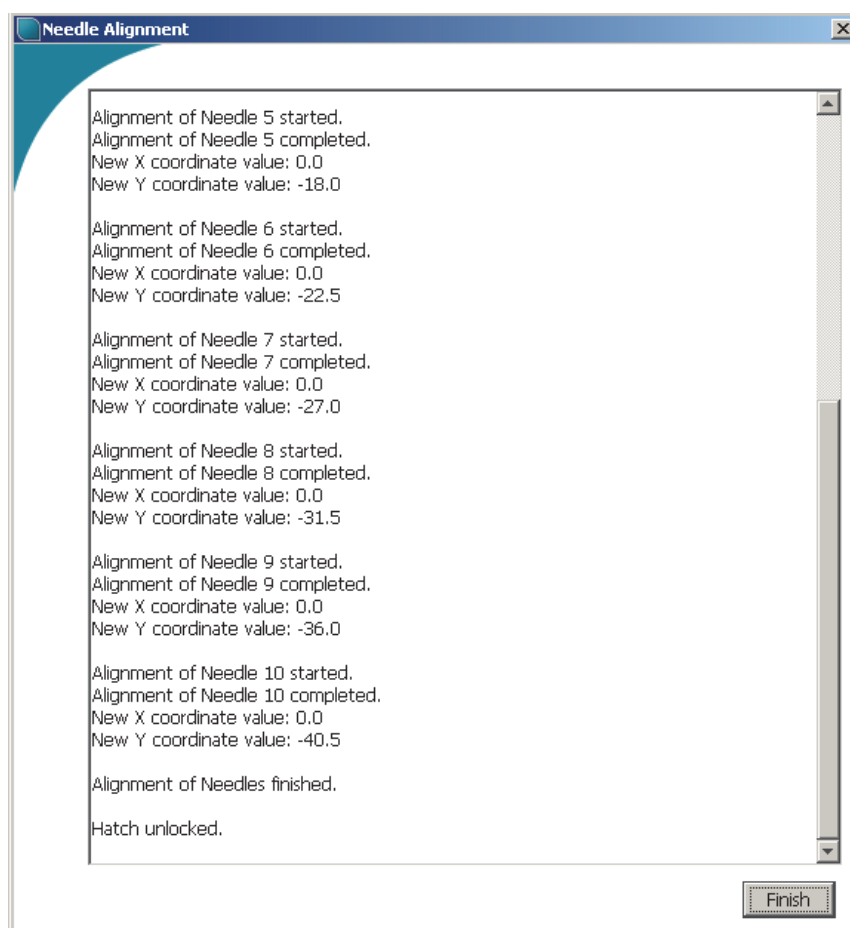
Needle configuration					
Position	X Coordinate	Y Coordinate	Max Deviation	Deviation	Approved
1	Not Measured	Not Measured	0.4	0	☒
2	Not Measured	Not Measured	0.4	0	☒
3	Not Measured	Not Measured	0.4	0	☒
4	Not Measured	Not Measured	0.4	0	☒
5	Not Measured	Not Measured	0.4	0	☒
6	Not Measured	Not Measured	0.4	0	☒
7	Not Measured	Not Measured	0.4	0	☒
8	Not Measured	Not Measured	0.4	0	☒
9	Not Measured	Not Measured	0.4	0	☒
10	Not Measured	Not Measured	0.4	0	☒

Figure 4: Needles tab

Step Action

1. Click **Align**.

The **Aligning Needles** dialog box is displayed:



2. Click **Finish**.

If the alignment process fails repeatedly, please contact your local Gyros Protein Technologies office (refer to www.gyrosproteintechnologies.com for contact details).

G1.3.8 CD information

CD Information is used to read the information stored in the CD tag.

Step Action

1. Click CD information. The CD information screen opens.

Type:	Gyrolab Bioaffy 20 HC
Identity:	0003313-046
Number of free segments:	9
CD is expired:	No
Process status:	Known

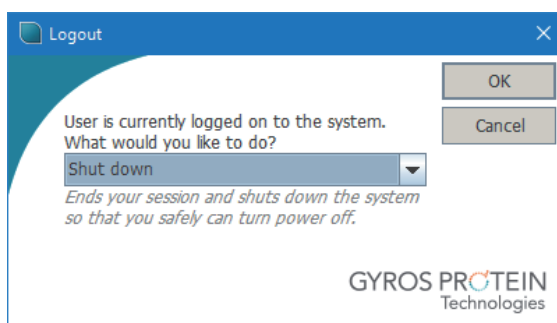
2. Place CD of interest in the instrument CD loading position and close the hatch, refer to Gyrolab Instrument Guide for details.
3. Click **Read CD**. The following information of the CD is given:
 - **Type**: type of CD.
 - **Identity**: identification number of CD.
 - **Number of free segments**: number of unused segments on the CD.
 - **CD is expired**: Do not use the CD if the CD is expired.
 - **Process status**: Do not use the CD if the status is Unknown.
4. Open the hatch and remove the CD from the Gyrolab instrument.
5. Click **Close** to close the CD information screen.

G1.3.9 Logout

Logout is used for shut down, log off or restart of Gyrolab Control:

Step Action

1. Click **Logout**. The **Logout** dialog opens.



2. Select desired function (**Shut down**, **Log off** or **Restart**) and click **OK**.

Step Action

3. Gyrolab Control performs desired function.
Additional windows may open. Select desired function and click **OK** to complete **Shut down**, **Log off** or **Restart**.

G1.3.10 Help

To access the help section (a pdf version of Gyrolab User Guide), click **Help** on the main menu and browse for needed Gyrolab User Guide chapter.

G1.3.11 About

Click **About** to get information about the software versions and licences for Gyrolab Control.

G1.3.12 View Alarm

Gyrolab Control has a built-in warning system. A traffic light icon in the bottom left hand side of the main menu indicates alarm state.



Figure 5: Alarm LEDs

Alarms

LED	Level	Requires action
Green	No active alarm	No.
Yellow	Warning alarm	Optional. A warning means that the system cannot operate according to configuration set-up. A warning does not affect the physical ability of the Gyrolab instrument, but may have an impact on the results.
Red	Normal alarm	Yes. This alarm indicates an error in the physical operation of the Gyrolab instrument. The instrument will either complete a specific operation or pause immediately. It should be possible to resolve the problem and continue with the system in operating mode.
Red flashing	Critical alarm	Yes. This alarm indicates an error in the physical operation of the Gyrolab instrument. The instrument will either complete a specific operation or pause immediately. The problem must be resolved and the system must be re-initialized.

View information on individual alarms

- To display information on current active alarms, click **View Alarm** on the main menu.
- To view detailed information for a specific alarm, select the alarm in the list. The additional information is displayed in the box below the list.

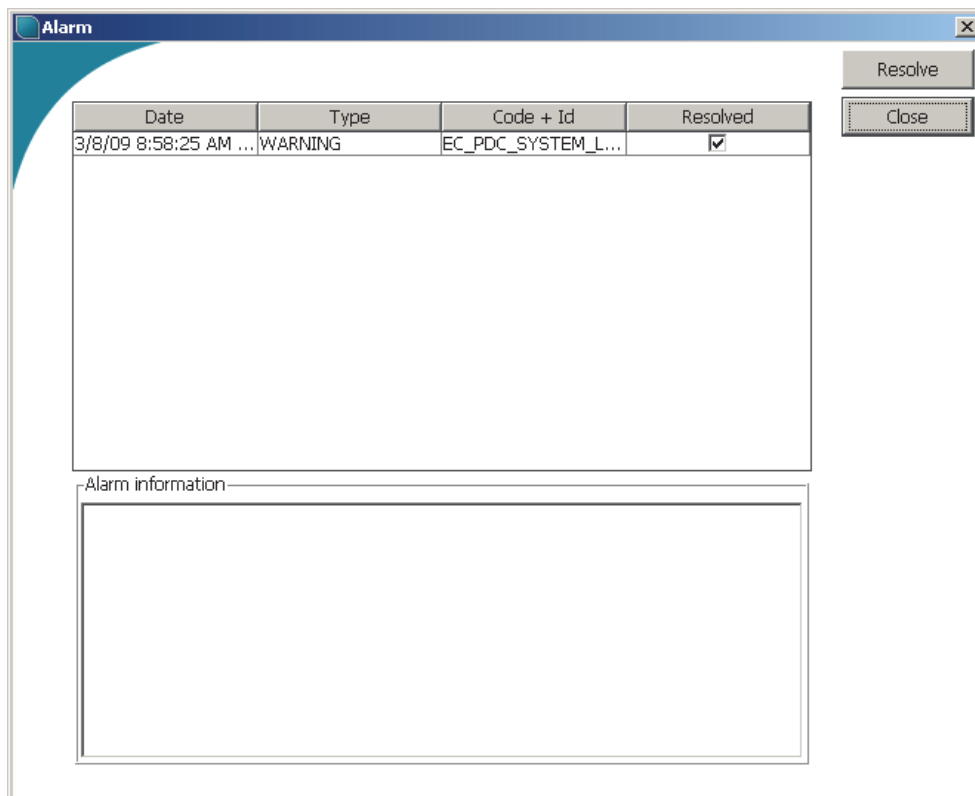


Figure 6: View alarm information

When an alarm occurs, a dialog box is displayed in which the alarm can be confirmed and the **View Alarm** dialog can be accessed.

NOTE: *All Normal (red) and Critical (red flashing) alarms must be confirmed.*

Address the issue displayed in the **View Alarm** dialog and click **Resolve**.

G1.3.13 Instrument access

Instrument access status is indicated by a green LED below the function buttons on the main screen.



When the instrument access LED is lit, the main power is on and the connection between instrument and computer is functioning.

NOTE: *Even if the instrument access LED is not lit (indicating no instrument access), methods and Runs can still be created and edited.*

G1.3.14 Instrument modes

Instrument mode is indicated by a LED below the instrument access LED (refer to Chapter G1.3.13) in the main menu.



Operating Mode

Instrument mode and user privileges (refer to Chapter NOTE:) determine what functions are available in the main menu.

The change of instrument mode is triggered by actions from the user or the control software. These actions differ depending on the status of the Gyrolab instrument.

The instrument modes are applicable when the instrument is Online only.

Gyrolab instrument modes:

Mode	Description	LED appearance	Accessible from	Activated by
Uninitialized	Gyrolab Control software is started. System is ready to be initialized.	Off	- Initializing - Standby - Operating	- Initialization failure - User logout, followed by Shut down or Restart - Critical alarms
Initializing	Hardware tests are being performed.	Not indicated by LED	Uninitialized	Button Initialize System... followed by directions on screen.
Operating	System is ready for use.	On	- Initializing - Standby	- Successful initialization - Starting a Run - Priming the system
Standby	System has been primed with standby solutions.	Flashing	Operating	Button Standby followed by directions on screen.

G2 Gyrolab Result Database Explorer

G2.1 Introduction

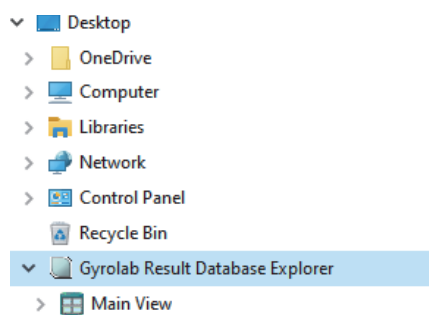
Files that are generated by Gyrolab Control during a Run are saved in **Gyrolab Result Database**. The files are kept in a read only state and cannot be changed, moved, or deleted.

Use Gyrolab Result Database Explorer to:

- generate status reports, Chapter G2.2.
- generate instrument log file reports, Chapter G2.3.

A result report is similar to a status report but also contains run data which in some cases may be considered sensitive. For information on how to generate a result report, see Chapter B3.1.1.4.

Step	Action
1.	To open Gyrolab Result Database Explorer: • Open Windows Explorer. • Click on Gyrolab Result Database Explorer.
2.	Gyrolab Result Database Explorer window opens. If Main View is not visible, click on arrow next to Gyrolab Result Database Explorer .



G2.2 Status Report

A compressed Audit Trail report is called a **Status Report**. Output format is .gyr which is a compressed format suitable to e-mail to Gyros Protein Technologies' support function. Since this report does not contain any run data it can be used for support matters where data can not be shared for some reason.

Step	Action
1.	Open Gyrolab Result Database Explorer as described in Chapter G2.1.
2.	Right-click Main View and select Generate Status Report .

Step	Action

3.	Set Start date and End date for the status report. Default setting is 10 days from current date.

Click **OK**.

4.	In the Save As dialog, name the status report file and browse for desired location. The location must be at the local disc, usually the C disc.

Click **Save**.

5.	The exported status report is now found at its specified location. The file contains the instrument audit trail (system log) and is compressed to .gyr format.

G2.3 Instrument Log File Report

The **Instrument Log File Report** should be generated on request from Gyros Protein Technologies service personnel. Output format is .ZIP. This report contains low level log information from the Gyrolab instrument that may be useful for troubleshooting.

Step	Action

1.	Open Gyrolab Result Database Explorer as described in Chapter G2.1.
2.	Right-click Main View and select Generate Instrument Log File Report .
3.	In the Save As dialog, name the report file and browse for desired location. The location must be at the local disc, usually the C disc. Click Save .
4.	The exported report is now found at its specified location. Send to Gyros Protein Technologies as requested.

G3 Gyrolab Database Backup Manager

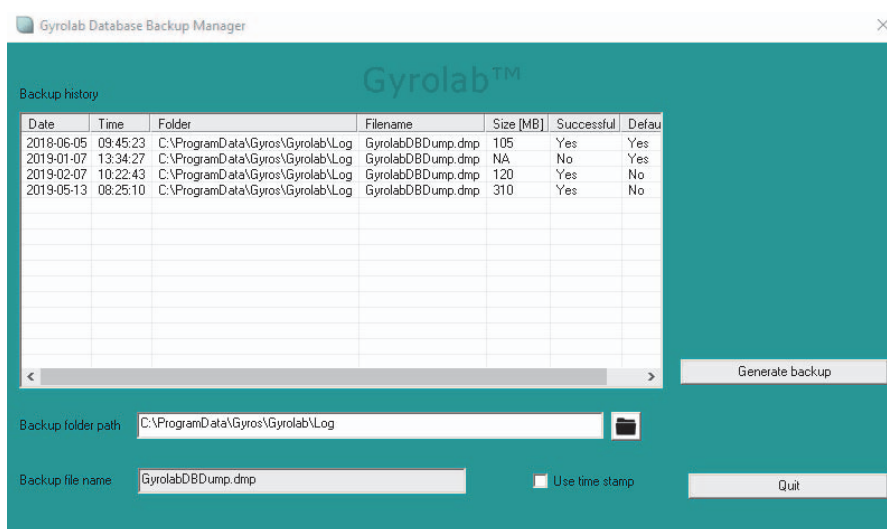
Gyrolab Database Backup Manager is used to back up the data stored in Gyrolab Result Database. Backup of the database is not performed automatically by Gyrolab software. Gyrolab users must create their own routines and set time intervals for data backup. Backup can be performed manually at certain time points or set up as a scheduled, repetitive task.

TIP: *It is strongly recommended to store the backup data at a different location than the Gyrolab computer.*

G3.1 Perform Gyrolab database back up

Step Action

- To open Gyrolab Database Backup Manager:
Select **Start:All Programs:Gyros:Gyrolab Control:Gyrolab DB Backup Manager**.
Gyrolab Database Backup Manager dialog opens. The list displays backup history.



- To set location for database backup, either enter the desired file path in the **Backup folder path** text field or browse for a folder using the button to the right of the text field.

NOTE: *Note that it is recommended to save the backup separate from the C: drive if the C: drive would crash. It is also recommended to put the database backup at a location where regular backup is taken, e.g. on a network server.*

Step	Action

3.	Check or un-check the Use time stamp box: • If Use time stamp is checked, the time and date for the database backup will be included in the database backup file name. Each database backup file will have a unique name and the risk of replacing old back up files is minimized. • If Use time stamp is not checked, the database backup file will be saved under the standard name in the selected folder and any previous database backup files without time stamps in the same folder will be replaced. The name for the database backup file is shown in the Backup file name field.
4.	Click Generate backup. The back up file is not available in the set folder destination.
5.	To close Gyrolab Database Backup Manager: Click Quit.

G3.2 Schedule Gyrolab data base backup

Database backup can be scheduled as a one time event or as a recurring action using the Windows Task Scheduler.

Refer to Windows Help for instructions on how to perform a scheduled task.

Chose Gyrolab Database Backup Manager to run as a recurring task. The path to the software is C:\Program Files (x86)\Gyros\Gyrolab\Bin\GyrolabDbBackupMan.exe.

The backup files will be stored to the location, and file name, set interactively in **Gyrolab DB Backup Manager**.

NOTE: *Please verify that the backup location is accessible to the Windows user specified to run the scheduled backup. If specifying a folder on a mapped network drive as the backup location, it is important that the Windows user running the scheduled backup has access to this location. Please consult your IT department for help.*

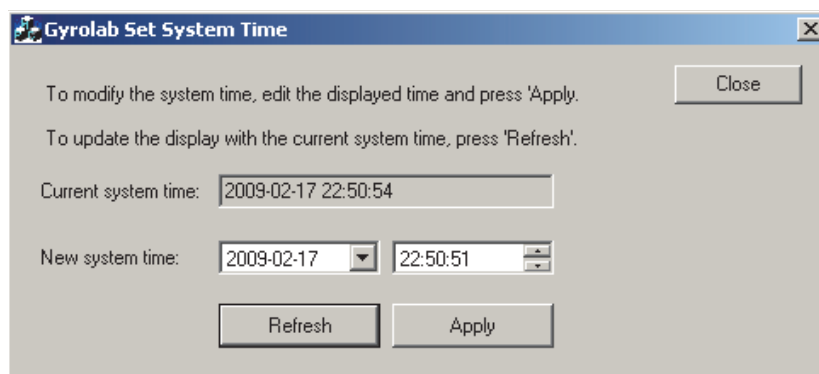
G4 Gyrolab Set System Time

G4.1 Gyrolab Set System Time introduction

Gyrolab Set System Time is a software tool that enables Gyrolab users to change system time in a controlled manner. All changes of system time will be recorded in the audit trail. Only System Administrators can change system time. The System Administrator must also have Windows system privileges for the computer.

G4.2 Perform logged system time change

Step	Action
1.	Close all open Gyrolab software applications open including the server.
2.	Select Start:All Programs:Gyros:Gyrolab Control:Gyrolab Set System Time . <i>NOTE: In order to run the tool, right-click and select to run as administrator.</i>
3.	Enter Username and Password in the Login dialog box and click OK . The Username and Password is the same for all Gyrolab software. For further information on user and password administration, refer to Chapter B9<<new chapter B8. If a Password change is requested by the software, log in to Gyrolab Manager or Gyrolab Evaluator to change Password, then return to Gyrolab Set System Time and log in using the new Password.
4.	Gyrolab Set System Time dialog opens.



- Set **New system time**: (date and time).
- Click **Refresh** to update the fields in New System Time to the current system time.
- Click **Apply**.
- Click **Close**.

G4.3 Non-logged system time changes

System time can also be changed manually using the regular Windows® tools or by automatic updates. However, system time changes will only be added to the audit trail if Gyrolab Set System Time is used.

Automatic updates of system time can occur when:

- The instrument computer is included in a Windows domain where system time is controlled by domain policies.
- The instrument computer is configured to automatically adjust the system time to correlate with an external time server.
- The instrument computer is set to automatically adjust to daylight saving time changes.

If it is vital to include all system time changes in the audit trail, make sure to exclude these time change sources by taking the following steps:

- Do not add the instrument computer to a windows domain, or make sure that there are no policies adjusting the system clock on the instrument computer.
- Disable synchronization with external time servers, and daylight saving adjustments, using the Windows Control Panel **Date and Time** tool.

G5 Gyrolab Control Database Config Tool

From Gyrolab Control version 7.1.1 onwards, the Gyrolab Control database can be located on a different computer than the computer running the Gyrolab Control application. Also, several instruments can be connected to the same database. For example, one Gyrolab xP workstation and one Gyrolab xPlore instrument can be connected to a database located on a third computer. The instruments connected to the same database must have the same software and database versions. This is also described in the separate instruction 'Several Gyrolab systems sharing one database'.

The database to be connected to Gyrolab Control and Gyrolab Result Database Explorer is configured and selected using Gyrolab Control Database Config Tool.

The two main scenarios when this tool is used are:

1. initial configuration of the database, and
2. temporarily switching from the remote database to the local database to view historical data located in the local database.

G5.1 Start and exit Gyrolab Control Database configuration tool

To open Gyrolab Database Config Tool, select:

Start : All Programs : Gyros : Gyrolab Control : Gyrolab Control Database Config Tool.

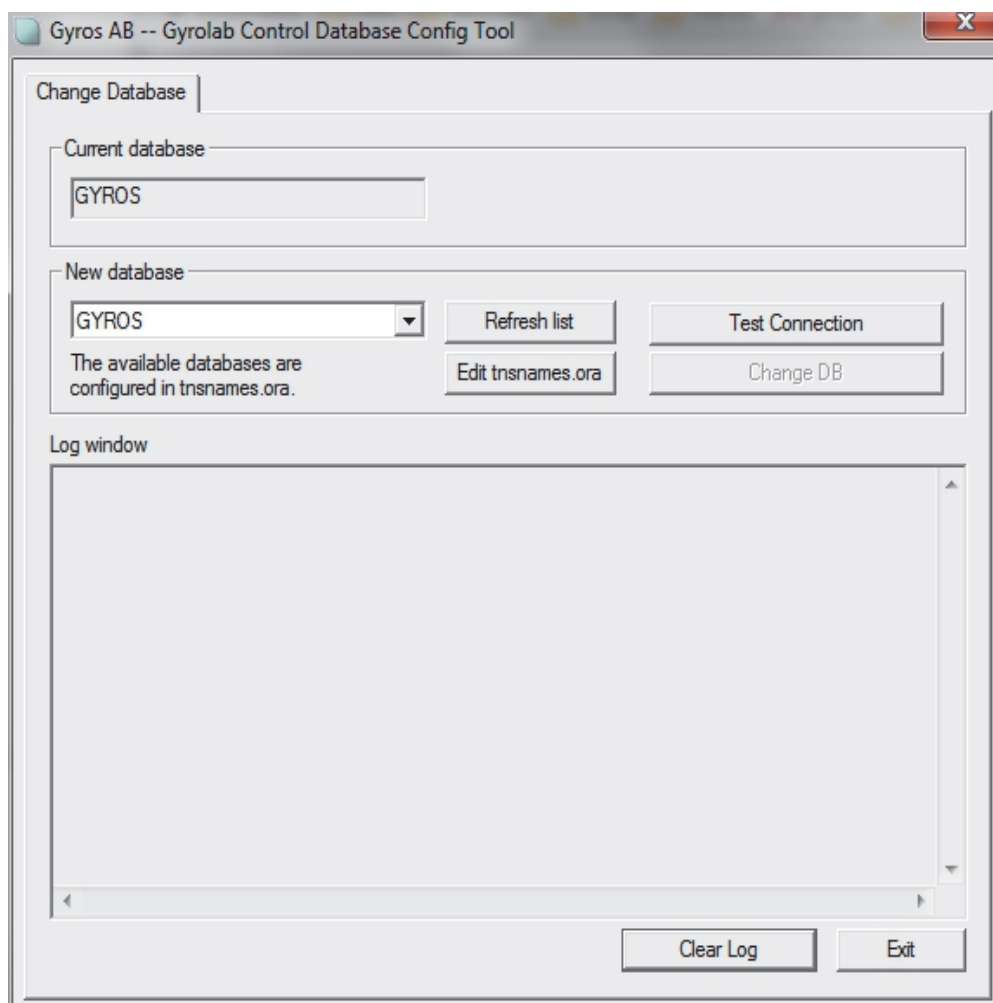
To exit the application, click the button labeled **Exit** or the window's close button.

NOTE: *Administrator privileges are needed to run the application.*

G5.2 Overview of Gyrolab Control Database configuration tool

The main window is divided into three sections:

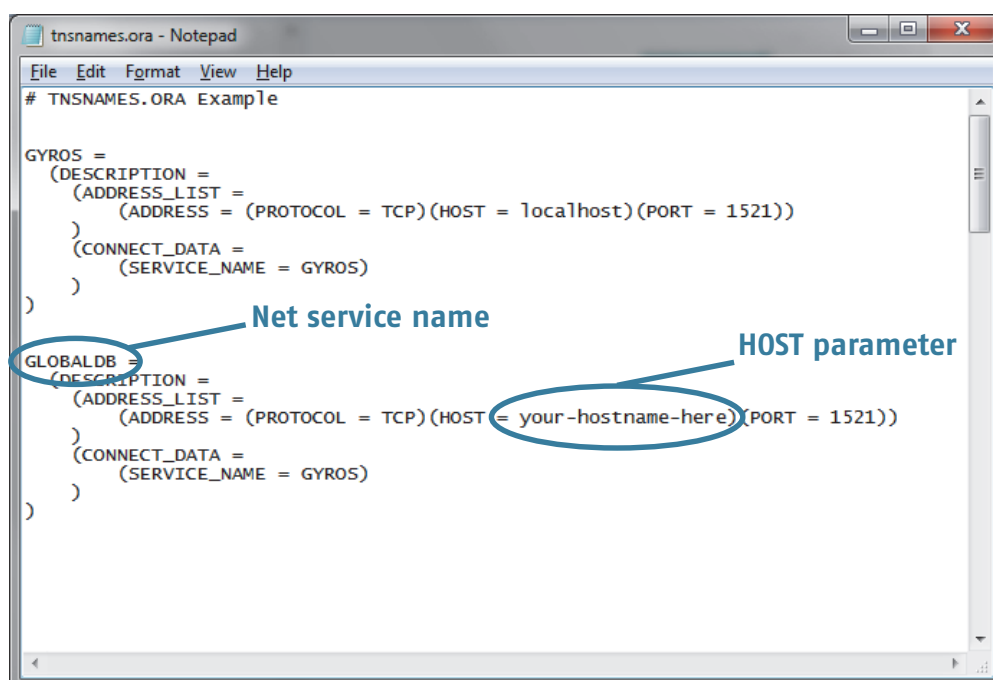
1. The top section displays the currently selected database name.
2. The middle section displays a drop-down list of the available databases. This section also includes four buttons to configure (see Chapter G5.3), test (see Chapter G5.4), and change (see Chapter G5.5) the database.
3. The bottom section shows a log window.



G5.3 Configuring connection to a new database

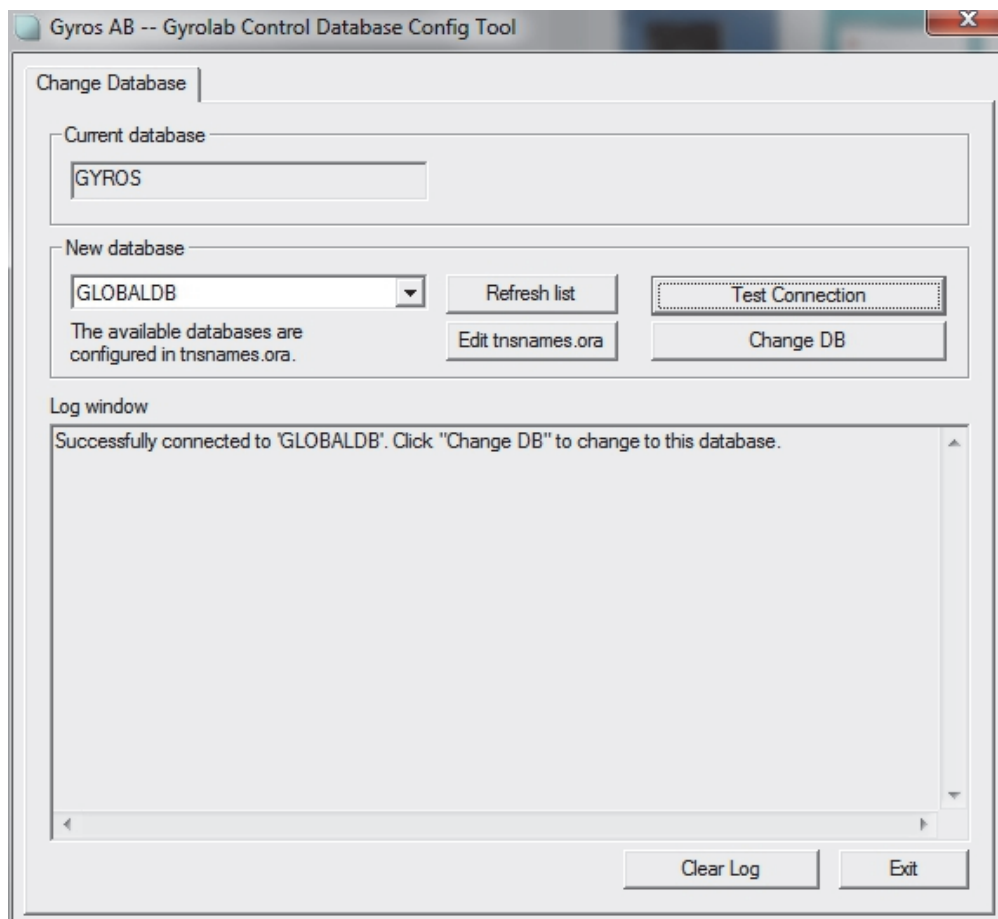
The available databases are configured in the file `tnsnames.ora`. To edit this file, click [Edit tnsnames.ora](#). The syntax of this file can be found at <https://docs.oracle.com>. Basically, `tnsnames.ora` contains database names (technically: "net service names") mapped to descriptions of where the databases are located (technically: "connect descriptors"). The database names will appear in the drop-down list mentioned above.

The easiest way to add a new database configuration is to copy an existing database configuration section, modify the `HOST` parameter and specify a suitable database name. The `HOST` parameter is the name of the computer, possibly including the domain name. Consult with your local IT administrator regarding these settings. When finished, save the file and exit the text editor. This will update the drop-down list of available databases. If `tnsnames.ora` was updated in some other way, the list of available databases can be updated by clicking [Refresh list](#).



G5.4 Test connection to a database

It is highly recommend to test the connection of a newly configured database. To test the connection, select the database from the drop-down list and click **Test Connection**. If the connection attempt was successful, the log window will output **Successfully connected to <database>**. If the connection attempt failed, an error will be displayed. Testing the connection will not change the current database. It is also possible to test the connection of the current database.

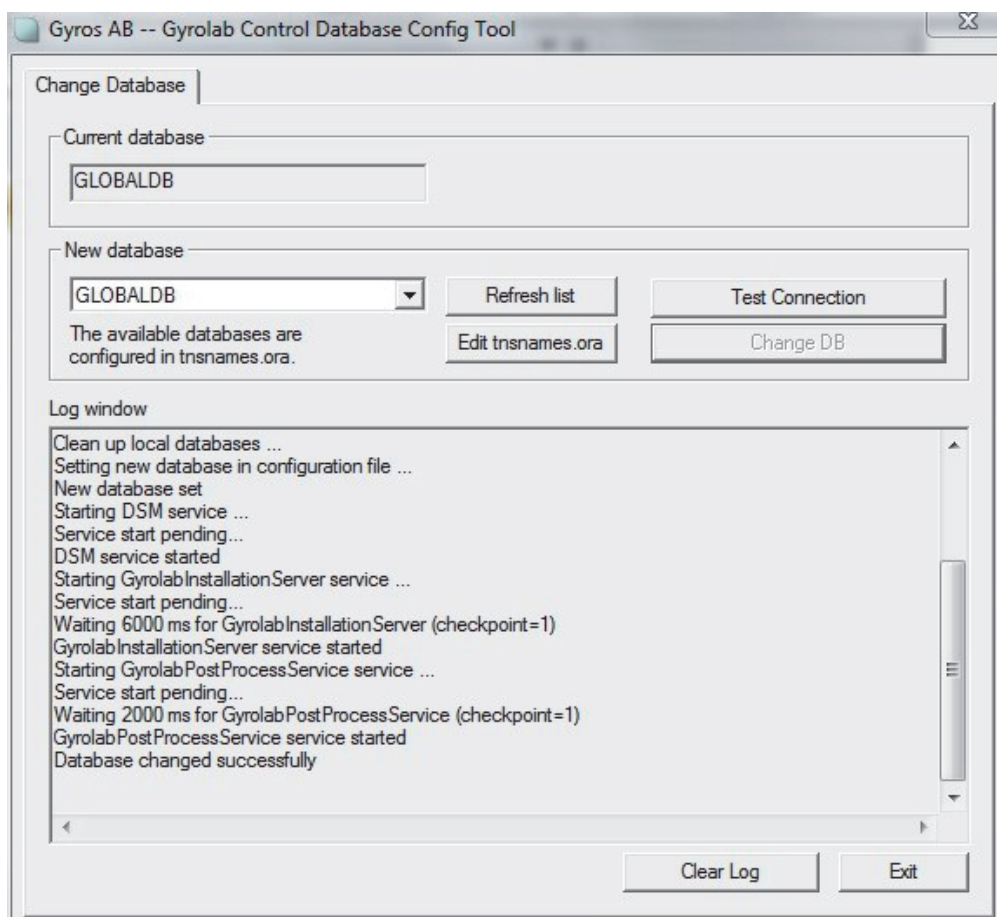


G5.5 Change database connection

To change the database, choose the desired database from the drop-down list and click **Change DB**.

NOTE: *The database cannot be changed while Gyrolab Server is running.*

The log window will display the progress of the operation. If the database change was successful, the text **Database changed successfully** will be displayed and the **Current database** field will be updated with the new database.



The log window can be cleared by clicking **Clear Log**.

G6 Gyrolab Manager

Many functions related to system administration and configurations are found in Gyrolab Manager. For more information on System Settings, see Chapter B9.

G7 Gyrolab Result Exporter

G7.1 Gyrolab Result Exporter introduction

Gyrolab Result Exporter is a utility introduced with Gyrolab Control 8.1 that allows a Gyrolab system administrator to configure an automatized export of Run Results from the Gyrolab database.

To configure exports for Gyrolab Result Exporter, the system administrator must log in as a Gyrolab user with the privilege **Configure System**. Gyrolab Result Exporter runs as a Windows service. To enable and configure the Windows service, Windows system privileges are required.

G7.2 Gyrolab Result Exporter configuration

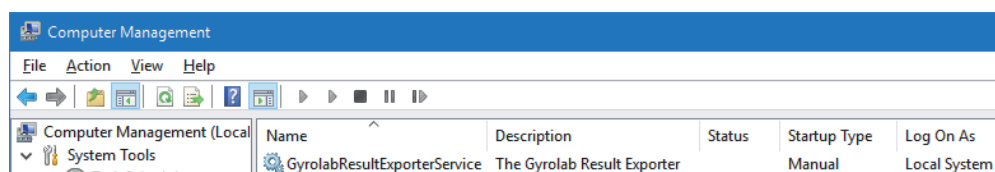
Gyrolab Result Exporter configuration is performed from Gyrolab Manager. The configuration is stored in the Gyrolab database and can be changed by any Gyrolab Manager connected to the database. The configuration need not be performed from the computer hosting the Gyrolab database.

For information on how to configure Gyrolab Result Exporter, see Chapter B9.1.

G7.3 Setting up the Gyrolab Result Exporter Windows service

When Gyrolab Control is installed, a Windows service is created for Gyrolab Result Exporter, named **GyrolabResultExporterService**. The Windows service is installed with the Startup Type **Manual** indicating that it has to be started manually.

The Gyrolab Result Exporter is installed, and must be configured, on the computer where the Gyrolab database is located.



The screenshot shows the Windows 'Computer Management' window. In the left-hand tree, 'System Tools' is expanded, and 'Task Scheduler' is selected. The main pane displays a table of services. The service 'GyrolabResultExporterService' is highlighted. The table has columns for Name, Description, Status, Startup Type, and Log On As.

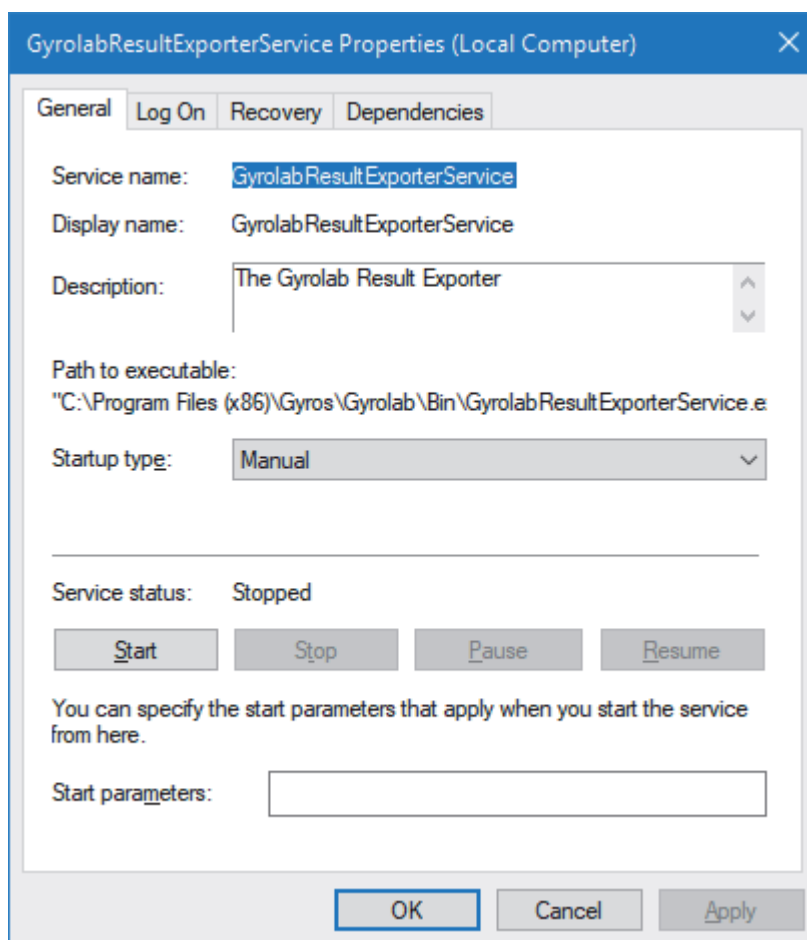
Name	Description	Status	Startup Type	Log On As
GyrolabResultExporterService	The Gyrolab Result Exporter		Manual	Local System

Configuration of the Windows service is described below but assumes a general knowledge about Windows services.

To activate Gyrolab Result Exporter, perform the following steps using a Windows user account with system privileges.

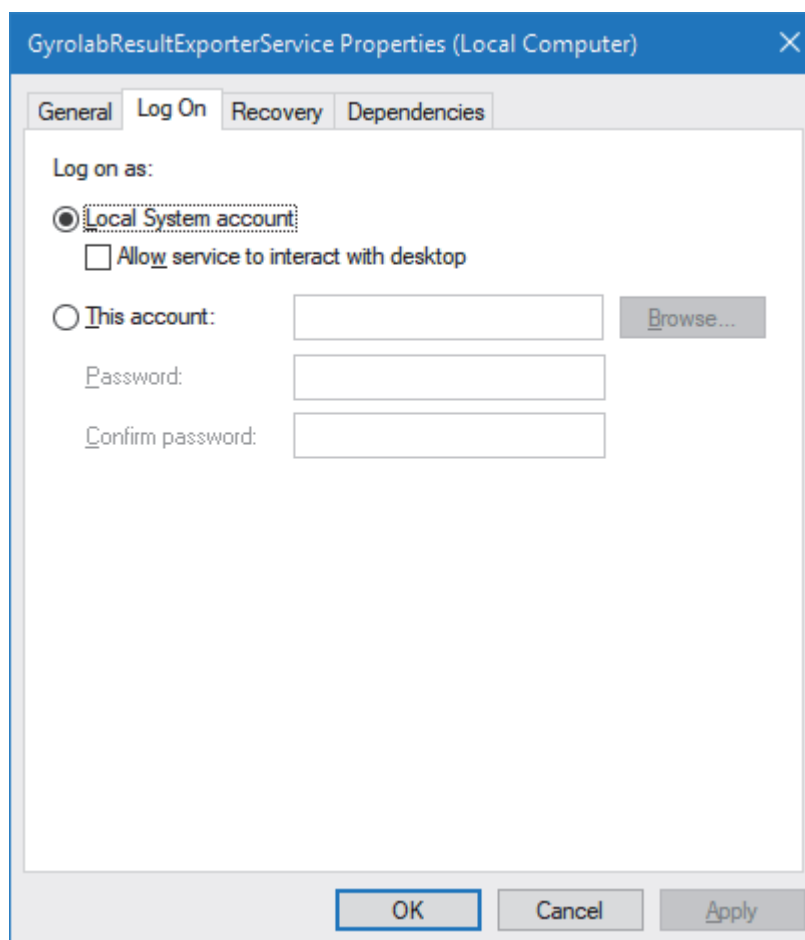
Step Action

1. Open the Windows service dialog, for example by opening Windows Explorer, right clicking **Computer**, and selecting **Manage**.
2. Open the properties dialog for the Gyrolab Result Exporter Windows service by right clicking the **GyrolabResultExporterService** service entry and selecting **Properties**.



3. Change **Startup type** to **Automatic** to make the service start every time the computer is started.

Step	Action
4.	Go to the tab Log On .



5. Configure the Windows account to run the service. Make sure the account to use has access to the folder(s) specified in the Gyrolab Result Exporter configuration, see Chapter B9.1.

6. Select **OK** to save the Windows service configuration.

7. To start the Windows service, either right click the **GyrolabResultExporterService** service entry and select **Start** or restart the computer.

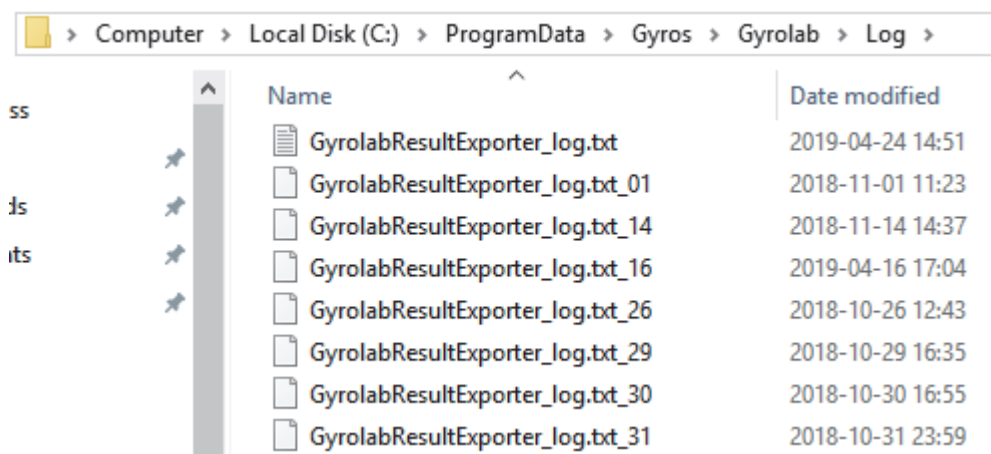
NOTE: *Make sure you have configured at least one export before starting the GyrolabResultExporterService Windows service. Gyrolab Result Exporter may not run properly until at least one export has been configured.*

After setting up the Windows service, it is recommended to monitor that the configured export(s) is/are working as expected.

G7.4 Troubleshooting Gyrolab Result Exporter

If the **GyrolabResultExporterService** Windows service does not start properly or stops unexpectedly, or if expected exports do not appear, Gyrolab Result Exporter can be troubleshooted by reading the log files produced by the utility.

On the instrument computer where the database is located, open folder
C:\ProgramData\Gyros\Gyrolab\Log. Locate the files with names starting with GyrolabResultExporter_log.



The log files can be opened and inspected with a text editor, like Notepad.

The file GyrolabResultExporter_log.txt contains the log files produced by the currently running Gyrolab Result Exporter. Files with a number suffix are from the day in the month given by the number. For example, GyrolabResultExporter_log.txt_14 contains logs from day 14 in the month. Log files are overwritten after one month.

Please note that if Gyrolab Result Exporter is currently running, it will try to add information to the file named GyrolabResultExporter_log.txt. To inspect this file, please take a copy first and inspect the copy to avoid blocking Gyrolab Result Exporter from adding information to the log file.

The log messages in the file should be quite self-explanatory. Please contact Gyros in case help is required to interpret the logs.

GYROLAB USER GUIDE

H Troubleshooting

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H1 Instrument issues

This section contains information on how to diagnose and possibly solve problems related to all Gyrolab instrument. Always start the troubleshooting by checking the connection between the computer and the instrument and restart the instrument and the computer. If you cannot identify the problem, or if the problem remains, please contact Gyros Protein Technologies for support.

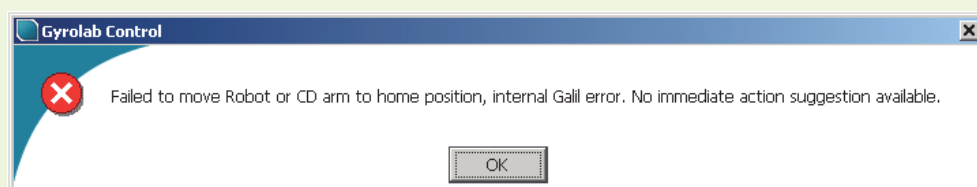
H1.1 Instrument initialization problems

The instrument initialization problems described in this section applies for all Gyrolab Instruments.

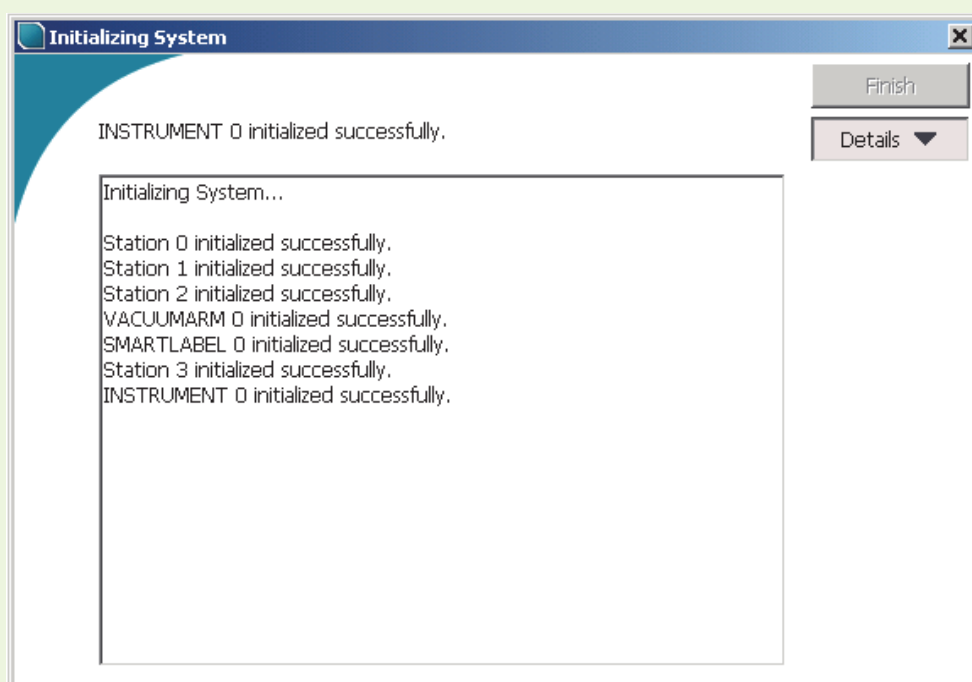
Error message/Possible cause	Action
Example of error message: - No instrument access. - Initialize System button disabled (grayed out). Possible cause: - Gyrolab Control software turned on without restarting the instrument.	- Check the connection between the computer and the instrument. - Restart the instrument. - If still no instrument connection, restart the computer. - If you cannot identify the problem, or if the problem remains, please contact Gyros Protein Technologies for support.

The following applies to Gyrolab xP with serial number GW158 and earlier.

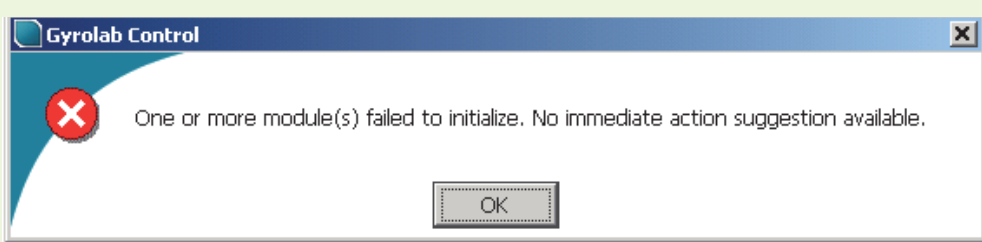
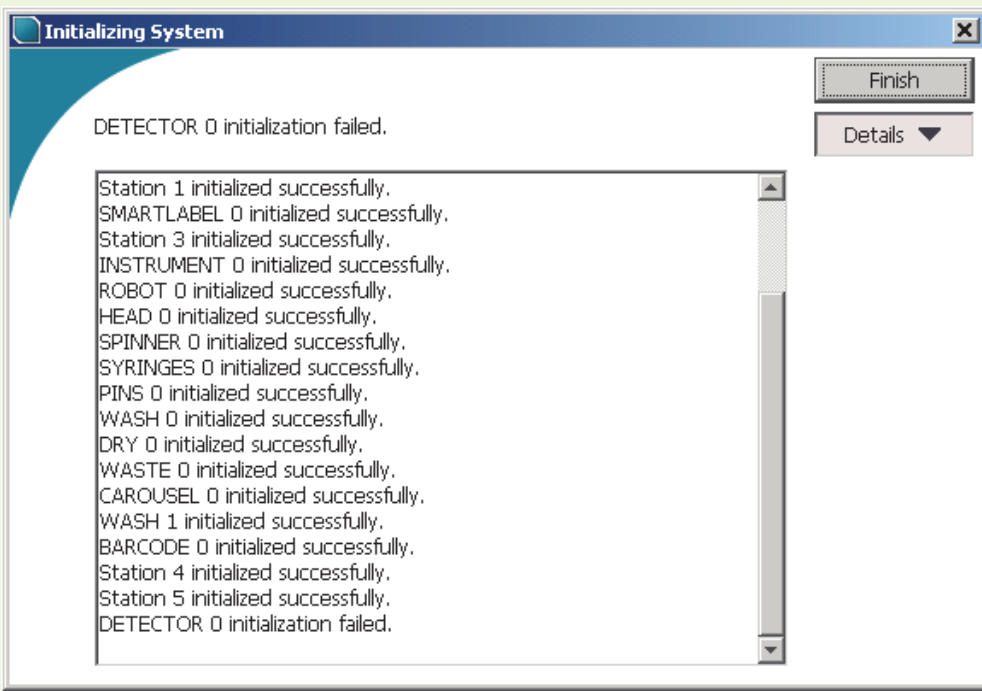
Error message/Possible cause	Action
Examples of error messages: - Robot, Carousel or CD-arm timed out. Software error. No immediate action suggestion available, example in figure below Possible cause: - Dislocated Controller cables	- Check Controller cable 1, refer to Gyrolab Instrument Guide. - Disconnect and reconnect the cable. - Retry instrument initiation. - If problem remains, check and refit other cables (controller cables and USB cable). - If problems still remain, contact Gyros Protein Technologies.



Error message/Possible cause	Action
Examples of error messages: - Needles correlated error messages or that the instrument failures initialization, example in figure below. Possible cause: - Dislocated Controller cables	- Check Controller cable 2, refer to Gyro-lab Instrument Guide. - Disconnect and reconnect the cable. - Retry instrument initiation. - If problem remains, check and refit other cables (controller cables and USB cable). - If problems still remain, contact Gyros Protein Technologies.



Example of error message: - LIF correlated error messages, example in figures below. Possible cause: - Dislocated Controller cables	- Check Controller cable 3, refer to Gyro-lab Instrument Guide. - Disconnect and reconnect the cable. - Retry instrument initiation. - If problem remains, check and refit other cables (controller cables and USB cable). - If problems still remain, contact Gyros Protein Technologies.

Error message/Possible cause	Action
 	
Example of error message: - Examples of error message below. Possible cause: - Dislocated Controller cables	- Check the connection between the computer and the instrument. - Restart the instrument and the computer. - If you cannot identify the problem, or if the problem remains, please contact Gyros Protein Technologies for support.

H1.2 Instrument computer contact

If the instrument loses contact with the computer an ongoing run will continue until it has finished. The user interface on the computer will however not be able to follow the process in the instrument any longer, nor can it be used for unloading once the run has finished. This has to be done manually before a new run is started. Results from a run will be transferred to Gyrolab Results Database once connection between the instrument and the computer is restored.

Lost contact with the instrument may occur in the following scenarios:

- USB cable removed or communication disturbed
- Computer restarted/shutdown
- Gyrolab Control client shutdown

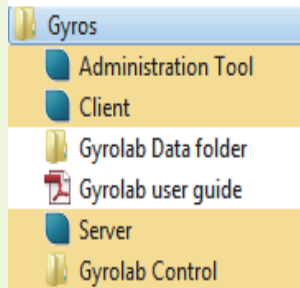
H1.3 Front panel LEDs

Problem	Action
If the Instrument Ready LED to the left on the front does not light up after a couple of minutes, the instrument has failed to start.	This might be resolved by turning off the instrument using the power switch on the rear of the instrument and try to start again.
If the LED on the Power button to the right on the front do not switch off after a couple of minutes when trying to power down the instrument the instrument has failed to power down.	This might be resolved by turning off the instrument using the power switch on the rear of the instrument and try to start again.

H2 Software issues

This section contains information on how to diagnose and possibly solve problems related to software or software installation. If you cannot identify the problem, or if the problem remains, please contact Gyros Protein Technologies for support.

H2.1 Gyrolab Control

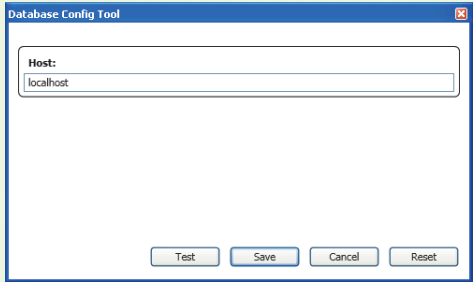
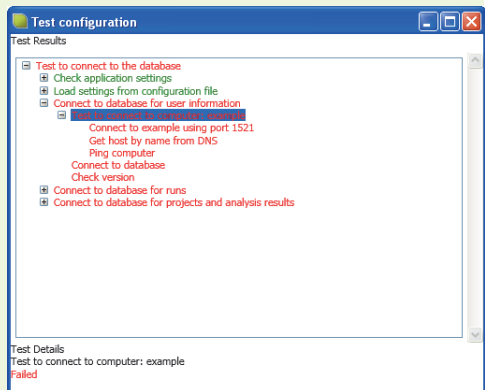
Problem	Possible cause	Action
Software may generate errors like "The entered values generated errors which have to be corrected before proceeding. File ##### not found"	Systems that have been upgraded to version 6.0 may have user preferences stored in the database pointing to other no longer existing folders.	Find the location where the files are placed after upgrade of the software and enter this new path in the software. Gyrolab Control software version 6.0 is installed under a path specified during installation. Default locations for results, templates and licenses are: "C:\ProgramData\Gyros\Gyrolab\Results" "C:\ProgramData\Gyros\Gyrolab\Templates" "C:\ProgramData\Gyros\Licenses" The "ProgramData" folder may be hidden. For easy access to ProgramData, please use the Gyrolab Data folder shortcut under Start menu. 

Problem	Possible cause	Action
Sample list error message during Execute Run in Gyrolab Control.	- Required information missing in the Sample List. - Information missing in Transfer and/or Reagent Lists (Custom Run only).	- Open Sample List and add any missing information. - Open list(s) and add any missing information.
No .gyr file created for status report.	Incorrect file target selected.	The .gyr file must be saved to a location on the local hard disk drive (usually the C: drive).
Results are not visible in Gyrolab Result Database.	One of: a) The run has not finished. b) A synchronization problem has occurred during the transfer of data from the instrument to the database.	Do one of: a) Wait until the run has finished. b) Restart the instrument and computer, see Instrument Guide.

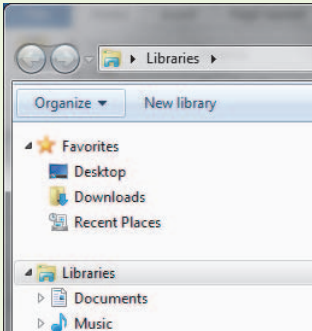
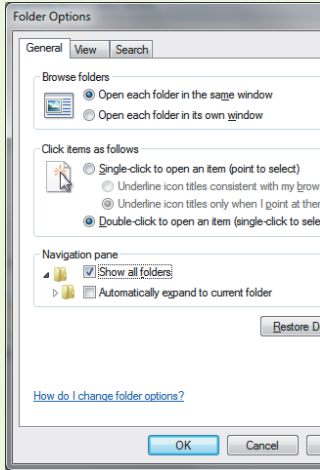
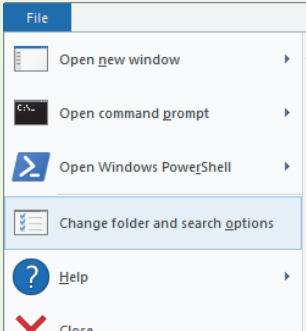
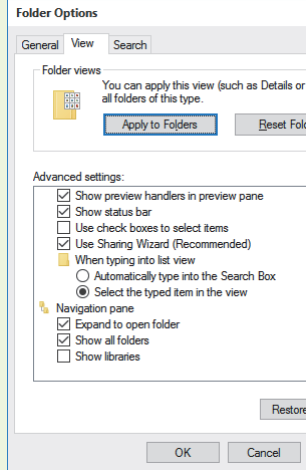
H2.2 Gyrolab Result Database Backup Manager

Problem	Action
Back-up of the Gyrolab Database using Gyrolab Database Backup Manager is scheduled in Windows. The Gyrolab Result Database Manager software opens, but does not automatically start the data back-up. It waits for a confirmation and someone has to physically press the button.	Ensure that the path to Gyrolab Result Database Backup Manager as used in the Windows scheduled task specifies the .exe file and does not include additional parameter.

H2.3 Gyrolab Evaluator

Problem	Action
Installation and/or database communication problems	- Go to the folder C:\Program Files\Gyros\Gyrolab Evaluator N.N.N.N (software version), or the folder that was chosen for the installation, and start the application DatabaseConfigTool.exe:  - Click on Test to check that it is possible to connect to the database and that the communication with the database is working.  - If the communication is working, all text in the dialogue is green. - If there is a database communication problem, the text is colored red. - To find out more, check messages on the innermost red nodes. - In the example shown above it was not possible to connect to the computer using the specified host name. This can be caused by a firewall on the instrument computer, or on the network where the office computer and the instrument computer is placed.

H2.4 Gyrolab Result Database Explorer

Problem	Action
The Gyrolab Result Database Explorer is not visible in Windows Explorer.	Follow the below instructions configure Windows Explorer to make Gyrolab Result Database Explorer visible: In Windows 7: 1. Open Windows Explorer. 2. In the Organize menu, select Folder and search options.  3. Select the General tab, and then check the box Show all folders under Navigation pane. 4. Click OK.  In Windows 10: 1. Open Windows Explorer. 2. In the File menu, select Change folder and search options.  3. Select the View tab, and then select Show all folders under Navigation pane. 4. Click OK. 

H3 Application issues

This section contains information on how to diagnose and possibly solve problems related to immunoassay performance and results. If you cannot identify the problem, or if the problem remains, please contact Gyros Protein Technologies for assistance.

H3.1 No response values are generated

Possible cause	Action
Was the CD positioned upside down?	Make sure the text on CD is readable after loading CD in Gyrolab instrument.
Was the LIF button in pressed-down position? (Only valid for Gyrolab instruments with a LIF button, refer to Gyrolab Instrument Guide.)	Press LIF button. Initialize Gyrolab instrument 30 min before starting experiment. Check instructions in Chapter C2.1.
Were all samples, reagents and solutions placed in microplates according to Loading list?	Check instructions in Chapter C3.3.
Was the microplate foil applied on microplate according to recommendations?	Check that microplate foil is applied according to Microplate foil adapter instructions, supplied with the microplate foil.
Were all microplates correctly loaded in the microplate carousel?	Check instructions in Chapter I7.2 and Chapter I7.3.2.

H3.2 Unexpected appearance of standard curve

H3.2.1 Laboratory and instrument generated errors

Possible cause	Action
Were correct volumes of reagents and samples loaded in microplate wells?	Refer to Chapter C3.1 for details.
Were there air bubbles in microplate wells?	To remove air bubbles, centrifuge microplate at 3000 × g for two minutes. If bubbles still remain, increase time or speed until all bubbles are gone.

Possible cause	Action
Were there any air bubbles in the Syringe Pumps?	• Ensure that the degasser is working, refer to GL Degasser manual. • Inspect the syringes to ensure that there is no leakage. Refer to Gyrolab Instrument Guide. • To remove air bubbles, prime Gyrolab instrument, refer to Chapter C2.4. • If there still are air bubbles in the Syringe Pumps, remove the bubbles as described in Gyrolab Instrument Guide.

H3.2.2 Low response

Possible cause	Action
Were Unknown and Standard series samples handled and stored appropriately?	Frozen samples should be thawed on ice, vortexed and centrifuged before transfer to microplate wells, refer to Chapter C3.1 for details.
Where correct Rexxip buffers and solutions used according to Gyros Protein Technologies recommendations?	Refer to Instruction For Use, supplied with the Rexxip buffer.
Are reagents freshly prepared? Where the reagents stored according to recommendations?	Refer to Chapter C1.1 and Chapter C1.2 for details.
If using a freshly labeled detection reagent: Is the optimal concentration used?	Titrate detection reagent concentration, refer to Chapter A2.5 for details.
If using a freshly labeled detection reagent: Was unbound labeling reagent sufficiently removed?	Remove unbound labeling reagent, refer to Chapter C1.2.
Is the optimal reagent pair used in the assay?	Further assay development and optimization may be needed, refer to Chapter A2.5 for details.

H3.2.3 Extensive variation

Possible cause	Action
Was the detection reagent centrifuged before use?	Refer to Chapter C1.2 for details.
Where the reagent stored according to recommendations?	Refer to Chapter C1.2 for details.
Was enough Wash Station Solution connected to the system?	Refer to Chapter C2.4 for details.

Possible cause	Action
Was the Wash Station pump moving during Run?	Prime Gyrolab instrument to ensure functionality of Wash Station pump. Refer to Chapter C2.4 for details.
Were there air bubbles in microplate wells?	To remove air bubbles, centrifuge microplate at 3000 × g for four min. If bubbles still remain, increase time or speed until all bubbles are gone.
Was enough volume of reagents and sample added to microplate wells?	Ensure that loaded volumes are according to volumes specified in Loading List.
Does the fluorescent signal image in Gyrolab Viewer show extensive variation?	Ensure that each CD contain Unknown/Standard series samples with a concentration larger than the limit of quantification for the assay and at least four structures with Unknown/Standard series samples with a response value of 0.5.
Was an old aliquot of detecting reagent used?	Use a fresh aliquot of detecting reagent.
Did sample to sample carryover interfere with results?	Gyrolab methods with extended wash procedures are available for analytes with specific biochemical properties. Contact Gyros Protein Technologies for support.

H3.2.4 Detect result – Not OK in Gyrolab Evaluator result file

Possible cause	Action
- The fluorescence signal is saturated in the Fluorescence detector - The quantifier fails to calculate the response - The fluorescence signal generated from this particular structure in the CD microlaboratory is of poor quality.	- Results should be disregarded. - Adjust PMT setting.
Were serum or plasma samples analyzed in the Run?	Ensure that recommendations regarding sample preparation were followed. Serum and plasma samples should be thawed on ice, vortexed and centrifuged prior to dilution, refer to Chapter C3.1.
Was a partially used CD used in the Run?	Ensure to follow Instruction For Use for CDs regarding handling of a partly used CD.

H3.2.5 Elevated background

Possible cause	Action
Was the detecting reagent stored and prepared according to recommendations?	Refer to Chapter C1.2 for details. In Figure 1 an example of elevated background caused by ageing of detection reagent during storage at +4 °C is shown. The Figure shows a comparison of results using two different aliquots of detection reagent from the same labeling analyzed after storage for three months in fridge (crosses) and freezer (circles), respectively. There is a significantly elevated background after storage at +4 °C.
If using a freshly labeled detection reagent – is the optimal concentration used?	Titrate detection reagent concentration. Refer to Chapter A2.5.2 for details.
Were the correct Rxxip buffers used?	Refer to Chapter C3.1 for details.
Was enough wash solution added to the microplate wells?	Refer to Chapter C3.3 for details.
Did sample to sample carryover interfere with results?	Gyrolab methods with extended wash procedures are available for analytes with specific biochemical properties. Contact Gyros Protein Technologies for support.

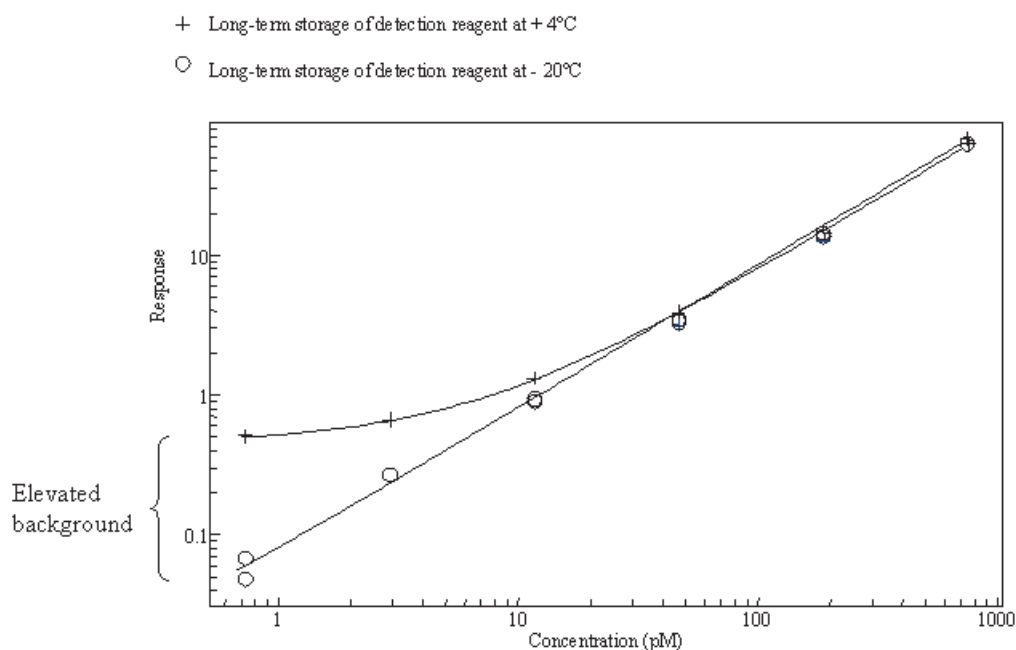


Figure 1: An example of elevated background caused by ageing of detection reagent during storage at +4 °C.

H3.3 Problems with outliers

Possible cause	Action
Contaminated spinner positions (CD and LIF)	Perform Clean surfaces in Gyrolab instrument on all surfaces. Refer to Gyrolab Instrument Guide. It is important also to wipe the LIF spinner position with a fresh lint free cloth without fluorescent material.

H3.4 Poor recovery of proteins after using Nanosep

Possible cause	Action
Protein interaction with Nanosep filter (Pall Life Sciences)	Surface pretreatment can in some situations increase recovery. Contact the supplier for instructions.

H3.5 Poor precision and bad reproducibility between runs

Possible cause	Action
Capture reagent dilution problems	Capture reagent dilution in REXXIP buffer might improve results. This is not applicable for antibodies. The recommended REXXIP buffers for this purpose are (in recommended order): REXXIP F, REXXIP A and REXXIP AN. PBS-T usually works well for monoclonal antibodies.

H3.6 Increased background in lower parts of the CD column

Possible cause	Action
Poor biotinylation. This may cause loss of unbiotinylated capture reagent during loading to the capture column and that an insufficient amount of biotinylated capture reagent being loaded. Unbound biotin may occupy binding sites on the capture column. This will dilute the density of specific capture reagent and usually lead to less efficient analyte capture and a broader fluorescent column profile.	Discard the biotinylated capture reagent batch and make a new biotinylation, refer to chapter Chapter C1.1.

GYROLAB USER GUIDE

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I1 Products, accessories and consumables

I1.1 Gyros Protein Technologies products

Visit www.gyrosproteintechnologies.com or contact your Gyros Protein Technologies sales representative for the latest updates on available products and services.

I1.2 Recommended consumables

Product	Recommended supplier	Product no.
Ethanol 95%	–	–
Albumin, bovine serum, > 95% purity	Calbiochem	126615
Sodium azide	e.g. Aldrich	438456
Sodium chloride	e.g. Merck	106404
Sodium hypochlorite, CAS Number 7681–52–9	e.g. Aldrich	425044
Sodium dihydrogen phosphate NaH_2PO_4	e.g. Merck	106346
Sodium hydrogen phosphate Na_2HPO_4	e.g. Merck	106586
Tween 20	e.g. Merck	822184
Virkon S	DuPont	–
Syringe filter (disposable): 0.45 μm , 0.22 μm	–	–
Syringes: 10 ml, 50 ml	–	–
Alexa Fluor 647 Monoclonal Labeling Kit Monoclonal antibody labeling kit optimized for labeling of 100 μg antibodies and proteins >30 kDa.	Molecular Probes	A-20186
Alexa Fluor 647 Microscale Protein Labeling Kit Protein labeling kit optimized for labeling of 20–100 μg proteins 10–150 kDa.	Molecular Probes	A30009
Dylight™ 649 Microscale Antibody Labeling Kit Antibody labeling kit optimized for labeling of 100 μg antibodies and proteins 50–150 kDa	Thermo Scientific	53051
EZ-Link Sulfo-NHS-LC-Biotin 8 × 1 mg microtubes (No-weight format)	Thermo Scientific	21327
EZ-Link Sulfo-NHS-LC-Biotin 100 mg	Thermo Scientific	21335

Product	Recommended supplier	Product no.
Nanosep 30K OMEGA Centrifugal Devices Note that the size of the filter in the spin column depends on the size of the reagent. Nanosep centrifugal devices exist in 3K, 10K, 30K and 100K.	Pall Life Sciences	0D030C34
Protein Desalting Spin Columns	Thermo Scientific	89849

I2 Wizard Run workflow using Gyrolab Client

To design a run using the Wizard design type, the recommended way is to use Gyrolab Manager. See Chapter B4 to create a Run Design, and Chapter B5 to create a Run Setup where unknown samples have been added.

This chapter describes the how to design runs using the Wizard Design type in Gyrolab Control.

I2.1 Wizard run design introduction

This is an overview of the steps to create a Wizard Run Design using Gyrolab Control, and how to prepare it for execution.

Step	Wizard Run
Create or Edit Run Design Chapter I2.2	• Select Wizard Run design type • Enter experimental parameters • Save Wizard Run Design
Sample List Chapter I2.3	Sample List generated by: • Gyrolab Control, or • manual editing (.xls), or
Prepare Run Chapter I2.4	• Select Wizard Run Design • Select Sample List • Enter experimental parameters • Set name and folder for result files • Set name and folder for reports • Generate Loading List

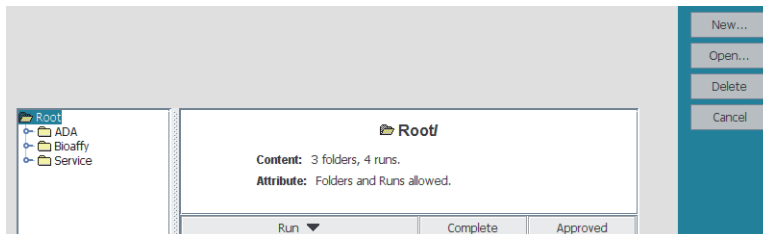
I2.2 Create or edit a Wizard Run Design

There are three options available when setting up a new run:

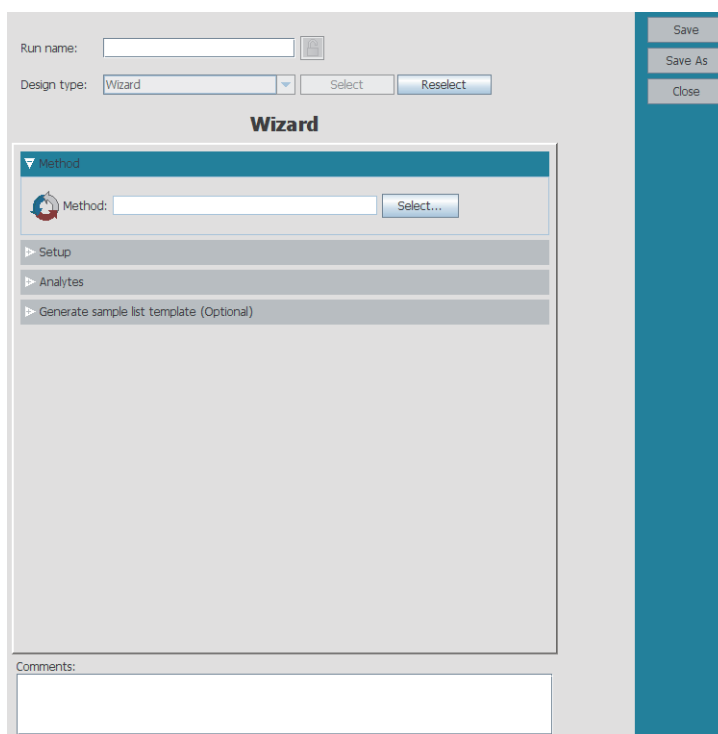
- Create a new Run Design, proceed with Chapter I2.2
- Edit an existing Run Design (use when similar but not identical experiment design is wanted), proceed with Chapter I2.2
- Use an existing Run Design (use when identical experiment design is wanted), go to Chapter I2.4.

Step Action

1. Click **Design Run** on the Main menu. The **Run** screen appears.



2.
 - To create a new Run Design, click **New**. Enter a Run Design name in the **Run Name** field.
 - To edit an existing Run Design, browse and select the desired Run Design and click **Open**.
3.
 - Select Wizard in the **Design Type** list and click **Select**. The **Wizard** panel appears:



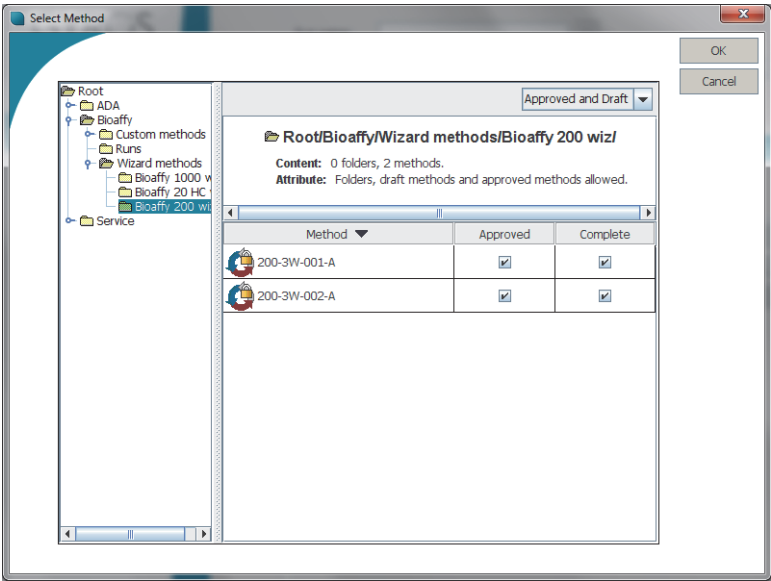
- To change design type, highlight the design type in the **Design Type** list and click **Reselect**.
- Comments for the Run Design can be made in the **Comments** window, for example what type of assays the run is intended for.

Step Action

4. Select **Method** and click **Select**.

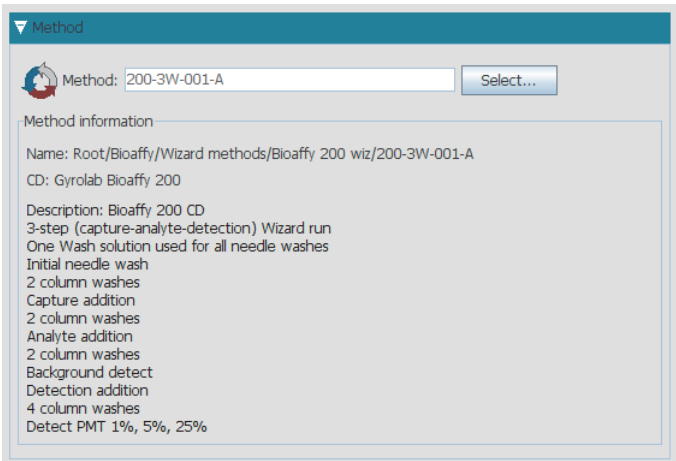


The **Select Method** dialog is opened.



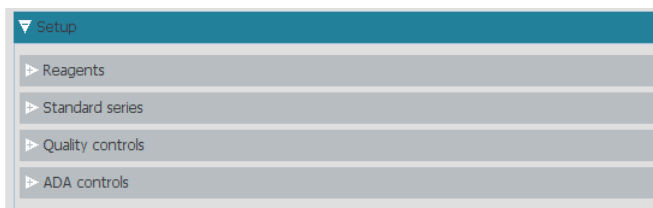
Browse and select desired Method. The selected Method must contain W in the name which indicates that it is designed for use with a Wizard run refer to Chapter A2.3 for more information.

Click **OK**. The selected method is added to the run design and method information is displayed.



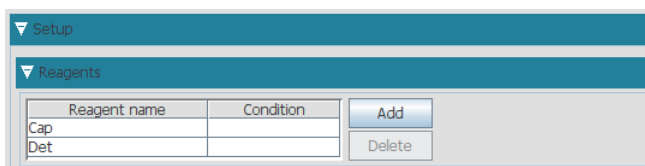
Step Action

5. Select **Setup**.



6. Select **Reagents**.

NOTE: *The software will automatically add reagents to the design depending on selected method (1-step, 2-step, 3-step or 4-step). This can be edited by the user.*



- Specify **Name** for capture (Cap_) and detect (Det_) reagents. The **Condition** field is optional and can be used for additional information such as concentration value or matrix.
- Click **Add** to add more capture and detect reagents. Add and name one reagent in the software for each different reagent required for the design.
- Highlight reagent and click **Delete** to remove reagent.

Step Action

7. Select **Standard series**.

The screenshot shows the 'Standard series' configuration window. It includes a table for existing series, input fields for 'Blank', 'Standard points', and 'Calibration Controls (CC)', and a detailed table for standard points with concentration and calibration control checkboxes.

Standard series name	Condition
Standard A	

	Number	Replicates
Blank:	1	2
Standard points:	7	2
Calibration Controls (CC):	0	2

(CC only used in multi-CD runs)

Standard point name	Concentration	CC
Standard A_Blank	0.0	☐
Standard A_1	0.0	☐
Standard A_2	0.0	☐
Standard A_3	0.0	☐
Standard A_4	0.0	☐
Standard A_5	0.0	☐
Standard A_6	0.0	☐
Standard A_7	0.0	☐

Concentration unit:

- Specify **Name** for Standard series. **Condition** is optional and can be used for additional information such as Standard samples dilution buffer.
- Set **Replicates** for Blank samples. Highest number of replicates is 20.
- Set **Number** and **Replicates** for Standard series samples and Calibration Controls. Highest number of replicates is 8.
- For each Standard series sample, specify the **Concentration**.
- Specify unit in the **Concentration unit** text box.
- For multi-CD runs, the use of calibration controls is added by ticking **Calibration** check boxes for standard samples of choice. A marked check box means that for every CD that does not have a standard curve, calibration control(s) with concentration corresponding to that of the standard sample will be placed instead of the Standard series.

NOTE: Calibration controls are not applicable for the Gyrolab xPlore system.

Additional functions:

- To add additional Standard series, click **Add**.
- To copy settings of one Standard series to a new Standard series, highlight desired Standard series and click **Copy**. The new Standard series can be edited and saved by a new name.
- Highlight Standard series and click **Delete** to remove a Standard series.

NOTE: Maximum 8 replicates for the same needle can be used in a Gyrolab Bioaffy 1000 CD.

Step Action

8. Select **Quality Control**. (This step is optional)

Quality Controls are samples with known concentration. Quality Controls may be used for quality control or when comparing results from different Runs and experiments.

Quality control name	Concentration	Dilution
QC 1	20.0	10.0
QC 2	40.0	10.0
QC 3	80.0	10.0
QC 4	160.0	10.0

- Set number of replicates in the **Replicates** list. Highest number of replicates is 8.
- Specify **Quality control name**, **Concentration** and **Dilution** for each Quality Control sample. The concentration value corresponds to Quality Control sample concentration before dilution. The dilution value corresponds to the dilution of the Quality Control sample. A value of 1 corresponds to an undiluted sample, Dilution values must be 1 or larger.
- Specify the unit in the **Concentration unit** text box.
Note that the same unit must be used as used for the Standard series, refer to Step 7.
- Click **Add** for adding an additional Quality Control sample.
- Highlight Quality control sample and click **Delete** to remove.

9. The **ADA Control** section contains settings specific for the software module Gyrolab ADA Software. Refer to Chapter E2.2 for more information.

10. Select **Analytes**.

For each Run, one or more **Analytes** are defined.

For each Analyte one or more **Experiments** are defined. Experiment settings determine which Reagents, Standard series, Calibration Controls and Quality Controls (defined in Steps 6 to 8 above) to be used for the specific experiment.

To set up an Analyte with one Experiment, continue to next step.

Step Action

11.
 - Select **Analyte: Analyte 1**. Enter a name for the Analyte in the **Name** text field.
 - Select **Experiment: Experiment 1**. Enter a name for the Experiment in the **Name** text field.
 - Select Capture reagent(s) from the **Capture reagent addition** list. Only Capture reagents specified in step 5 are available.
 - Select Detection reagent(s) from the **Detection reagent addition** list. Only Detect reagents specified in step 5 are available.
 - Select number of Standard series in the **Number of Standard series** list.
 - If planning to use Run Design for multi-CD runs: Tick **Use on all CDs** to place Standard series on all CDs included in the Run.
 - When **Use on all CDs** is ticked, unknown samples will be quantified against Standard series on the same CD. One analysis per CD will be created.
 - If **Use on all CDs** is not ticked, all unknown samples are quantified against the same Standard series.

NOTE: *Instead of Standard series on all CDs, Calibration Controls can be used. Refer to step 7. This is not applicable for the Gyrolab xPlore system.*

- Select Standard series in the **Standard series name** list. Only Standard series specified in step 7 are available.
- Select number of Quality Controls in the **Number of Quality controls** list.
- When planning to use Run Design for multi-CD runs: Tick **Use on all CDs** to place Quality Controls on all CDs included in the Run.
 - If **Use on all CDs** is selected, the Quality Controls samples will be applied on all CDs included in the Run.
 - If **Use on all CDs** is not selected, the Quality Controls samples will be applied on one CD even if the experiment is included on several CDs.
- Select Quality Controls in the **Quality control name** list(s). Only Quality Controls specified in step 5 are available.
- The **Number of ADA controls** field is specific for and only used with the software module Gyrolab ADA Software. Refer to Chapter E2.2 for more information.

The screenshot shows the 'Analyte: Analyte 1' and 'Experiment: Experiment 1' configuration windows. The 'Name' field for the experiment is 'Experiment 1'. The 'Capture reagent addition' is set to 'Cap' and 'Detection reagent addition' is set to 'Det'. The 'Number of Standard series' is 1, and 'Standard series name' is 'Standard A'. The 'Number of Quality controls' is 4, and 'Quality control name' is 'QC 1', 'QC 2', 'QC 3', and 'QC 4'. The 'Number of ADA controls' is 0. The 'Use on all CDs (*)' checkbox is checked for Quality controls and ADA controls.

Step	Action

12.	• Add additional Analytes by clicking  in the Analytes bar. • Delete Analytes by clicking  in the Analyte: bar. • Add additional Experiments to an Analyte by clicking  in the Analyte: bar. • Delete Experiment by clicking  in the Experiment: bar.

Step Action

13. Select **Generate Sample List template**.

Generate sample list template (Optional)

Number of unknowns: 0

Unknown replicates: 2

☒ Ensure compatibility with single-CD instrument

Include limited CD: ☐ Number of free segments: 1

Use spiked/unspiked: ☐ (Number of unknowns is doubled and subgroup set to spiked/unspiked in sample list)

Generate Template...

- Save the Run.
 - To save a new Wizard Run, click **Save**. Browse to select folder and click **Save**.
 - To save an edited Wizard Run, click **Save as**. Name the Run, browse to select folder and click **Save**. If **Save** is clicked the information on the original Run will be replaced with the edited information.
 - If any information added to the Wizard Run is incomplete or erratic an error message will be presented. The specified issues must be addressed before it is possible to save.
 - Specify number of samples to be analyzed ("Unknown samples") in the **Number of unknowns** list.
 - Specify number of sample replicates in the **Unknown replicates** list. Highest number of replicates are 8.
 - **Ensure compatibility with single-CD instrument** checkbox. Purpose of this function is to help the user to ensure that the run can be executed on a single CD instrument by limiting the 'Number of unknowns'-dropbox to not exceed the number of structure on the CD. If the checkbox is checked. Then the dropbox is limited to one CD. If not checked the dropbox is limited to 5 CDs.
- Default values for the checkbox are:
- If system is initialized:
 - it will be checked if the client is connected to a Gyrolab xPlore system.
 - Unchecked if connected to Gyrolab xP system.
 - If the system is not initiated:
 - a dialog appears informing the user that configuration is unknown and the checkbox is unchecked.
 - If it is desired to use a CD that previously has been partially used, check **Include limited CD** and define number of available segments in the **Number of free segments** list.
 - The **Use spiked/unspiked** check box is specific for the software module Gyrolab ADA Software. Refer to Chapter E2.2 for more information.
 - Click **Generate template**.
 - Browse to select Sample List location and click **Save**.

A Sample List is generated. The Sample List contains all necessary sample information defined in the run design. It also holds a suggestion for sample placement within the microplate.

NOTE: *The procedure described in this step is the most convenient way to generate a Sample List. Sample Lists can be created manually and automatically generated lists can be edited prior to run start, refer to Chapter I2.3. However, Gyros Protein Technologies recommends using the automatically generated Sample Lists as this will reduce the risk of errors.*

Step Action

14. Save the Run.
15. Click **Close** to finish the Design Run procedure.

I2.3 Sample List completion

A Sample List is designed to transfer important sample information from run design phase to run execution phase in Gyrolab Control. All samples types (Unknown samples, Standard samples, Quality Control samples, Calibration Control samples) defined in the Run are included in the Sample List. The automatically generated Sample list is a template, the final numbers of samples and replicates in a run are set when the Sample list is imported prior to run start, refer to Chapter I2.4.

A Sample List can also be used to define Unknown samples in Gyrolab Manager. See Chapter B5.3.3. The procedure for editing the Sample list is the same as when using a Sample list in Gyrolab Control.

NOTE: *When using a Sample List in Gyrolab Manager, values for Sample Group and Sample Subgroup may only be set for Unknown samples. Sample Group and Sample Subgroup are controlled by Gyrolab Manager for other samples (standard, quality controls etc.).*

Step Action

1. Open the Sample List (location defined in Chapter I2.2 step 10) in Microsoft Excel™. From row 8 and below one row represents one sample. Data is mandatory in columns labelled **(M)** and optional in columns labelled **(O)**. Columns labelled **(N/A)** are not used. Example of automatically generated Sample List:

	A	B	C	D	E	F	G	H
1	Template	Sample3.0	Sample list info					
2	M=Manda	Sample M	MP96	PCR				
3	O=Option	Result File Name	(O)					
4	N/A=Not	Result File Path	(O)					
5								
6								
7	Index (M)	Sample Ty	Sample Id	Sample Gr	Sample Su	Dilution F	MP Ident	Well (M)
8	#1	UNK	Sample 1				MP1	D1
9	#2	UNK	Sample 2				MP1	D2
10	#3	UNK	Sample 3				MP1	D3
11	#4	UNK	Sample 4				MP1	D4
12	#5	UNK	Sample 5				MP1	D5
13	#6	UNK	Sample 6				MP1	D6
14	#7	UNK	Sample 7				MP1	D7
15	#8	UNK	Sample 8				MP1	D8
16		BL	Standard A_Blank				MP1	A1
17		BL	Standard A_Blank				MP1	A2
18		STD	Standard A_1				MP1	A3
19		STD	Standard A_1				MP1	A4
20		STD	Standard A_2				MP1	A5
21		STD	Standard A_2				MP1	A6
22		STD	Standard A_3				MP1	A7
23		STD	Standard A_3				MP1	A8
24		STD	Standard A_4				MP1	A9
25		STD	Standard A_4				MP1	A10
26		STD	Standard A_5				MP1	A11
27		STD	Standard A_5				MP1	A12
28		STD	Standard A_6				MP1	B1
29		STD	Standard A_6				MP1	B2
30		STD	Standard A_7				MP1	B3
31		STD	Standard A_7				MP1	B4

Step Action

2. Edit sample information as desired, make sure that data is in accordance with Table I2-1 on page 17.
 - By default all samples and reagents of all types will be located on the same Sample Microplate. To have Unknown samples on the Sample Microplate and place all other sample types on a Reagent Microplate, delete all samples but unknowns from the generated Sample List. The software will automatically place deleted samples on a Reagent Microplate during Loading List generation, refer to Chapter I2.4.
 - When evaluating results in Gyrolab Evaluator, refer to Chapter D, samples are sorted based on sample identity, group and subgroup, refer to Table I2-2 on page 18 for details. Statistics such as average, standard deviation and CV are available for these groups.

NOTE: Only edit rows 8 and below. Edits in other parts of the Sample list may cause the list to be incompatible with the run.
3. Save the edited Sample List.

Sample List item and column	Mandatory/ Optional	Information
Index Column A	Mandatory for Unknown samples, not used for other sample types.	The index is an identifier for Unknown samples (UNK). The form of the entry is predefined and the entries must be consecutively numbered: #1, #2, #3, and so on. NOTE: Do not use this column for Standard series, Quality Controls or Calibration Controls.
Sample type Column B	Mandatory	• UNK for Unknown samples • QC for Quality Controls • CC for Calibration Controls • STD for Standard series • BL for Blanks
Sample Identity Column C	Mandatory	Enter Sample identity for all unknown samples. Sample identity is used as basis for statistical analysis in Gyrolab Evaluator software. Table I2-2, "Basis for sample statistics", on page 18 below.
Sample Group Column D	Optional	Sample Group is used to group samples with common properties. Sample group is used as basis for statistical analysis in Gyrolab Evaluator software. Table I2-2, "Basis for sample statistics", on page 18 below.

Table I2-1: Details for Sample List items

Sample List item and column	Mandatory/ Optional	Information
Sample Subgroup Column E	Optional	Sample Subgroup is used to subgroup samples within a Sample Group or Sample identity with common properties, for example samples given different treatment or from different time points. Sample subgroup is used as basis for statistical analysis in Gyrolab Evaluator software. Table I2-2, "Basis for sample statistics", on page 18 below.
Dilution Factor Column F	Optional for Unknown samples, not used for other sample types	
MP Identity Column G	Mandatory	A Microplate identity must be entered.
Well Column H	Mandatory	Identity of microplate well where the sample is located.

Table I2-1: Details for Sample List items

Sample identity (Column C)	Sample group (Column D)	Sample subgroup (Column E)	Statistics based on
Used	Not used	Not used	Sample identity
Used	Used	Not used	Sample group
Used	Not used	Used	Sample identity and subgroup
Used	Used	Used	Sample group and subgroup

Table I2-2: Basis for sample statistics

I2.4 Prepare Wizard Run

Step	Action
1.	Click Execute Run on the Main menu.
2.	Click Run... Run Setup... is used to execute Runs defined by a Run Setup created in Gyrolab Manager. See Chapter B5.
3.	Browse and select desired Run Design (as set in Chapter I2.2) from the list and click OK .
4.	A screen is opened:

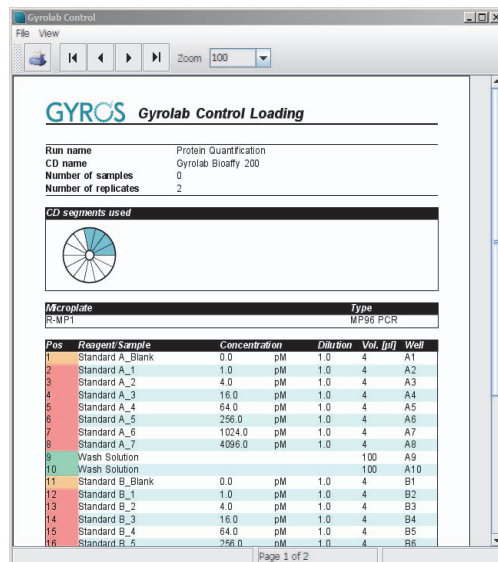
- To load a Sample List, click **Sample List file**, browse and select desired Sample List.
- **List Loader** file sets rules for how to import Sample list. Choose the **SampleList-Loader** option in the drop-down menu.
- Number of Unknown samples will be displayed in the **Number of samples** field when the desired Sample List is loaded.
- The number of Unknown sample replicates was defined during run design (Chapter I2.2) and is displayed in the **Sample replicates** list. Sample replicate number can be changed compared what was defined during the run design.
- **Include limited CD** box is ticked if a partially used (limited) CD was included when the run was designed (Chapter I2.2). It will always be the first CD in the Run that is partially used. It is possible to remove limited CD or change number of available CD segments.

The CD and CD segment consumption is calculated based on number of samples and replicates. For all samples, position on the CD(s) is automatically randomized and distributed by the software. For multiple-CD runs: If Calibration Controls are used, these will be placed on each CD that do not have a corresponding Standard series.

Step Action

5. Click **Loading List**.

Gyrolab Control Loading screen is opened.



- **Gyrolab Control Loading** holds microplate loading information and is used when preparing microplates for a run. Name, concentration, volume, microplate and well position is included for all sample types. An overview of microplates with indication of used wells is also provided.
- Click **Printer** button to print the **Gyrolab Control Loading**.

TIP: Select **File: Export to export the Loading list in PDF or text format**. This is useful when printing from another computer is required.

6. Close **Gyrolab Control Loading**.

Click **OK**.

7. To continue with Targets and Report settings, Start and After Run procedures proceed to Chapter I7.

8. For sample and reagents preparations proceed to Chapter C3.

I2.5 Macros for creating names for folders and files

By using macros, unique names for results files and folders will be created automatically without having to change the settings for different Runs. A selection of macros are provided for this. Insert macros by typing them into folder and result file name fields.

Macro	Description
\$(user)	Expands to the full Username.
\$(run)	Expands to the Run name.
\$(cdid)	Expands to the CD id, for example 1234567-123.
\$(date)	Expands to the executed Run start date.
\$(time)	Expands to the executed Run start time.

I3 Custom Run workflow using Gyrolab Client

This chapter describes how to perform immunoassays in Gyrolab Instrument using the **Custom Run** workflow (design type). Refer to Chapter A2.2 for recommendations of when to use which Run design type.

Only instructions that are unique for Custom Run is included in this chapter. For the parts of the workflow that are identical between Custom Run and Wizard Run, refer to relevant section in Chapter I2.

This chapter describes the Custom workflow using Gyrolab Client. At this time, the Custom workflow is not supported by Gyrolab Manager and it is required to use Gyrolab Client.

I3.1 Introduction

The Custom Run workflow is designed for maximal flexibility and allows the user to customize what samples are quantified towards what reagent set. Custom Run can be used when non-standard transfer from microplates to CD microlaboratories is required or when a variation of replicates for different samples and standard points for example during assay development is required.

No Loading List is generated during experiment set-up. Transfer and Reagent Lists are required to define a Custom Run.

I3.2 Preparation of capture and detection reagents

Please refer to Chapter C1.

I3.3 Gyrolab instrument startup procedure

Please refer to Chapter C2.

I3.4 Experimental design

Chapter I3.7 contains detailed information and examples on how to prepare Sample, Reagent and Transfer lists to achieve intended mapping of samples against standard curves.

I3.4.1 Create Sample List

The Sample List is designed to transfer sample information to Gyrolab Control. Gyros Protein Technologies provides a **Sample List template** in Microsoft Excel format.

Step Action

1. Open the **Sample List Template** Sample_list_template.xls found in C:\ProgramData\Gyros\Gyrolab\Templates\Lists
2. From row 8 and below, one row in the Sample list represents one sample. Columns labelled (M) are mandatory, columns labelled (O) are optional and columns labelled (N/A) are not used.

	A	B	C	D	E	F	G	H
1	Template version:	Sample3.0		Sample list info				
2	M=Mandatory	Sample MP Type (M)	MP96 PCR					
3	O=Optional	Result File Name (O)						
4	N/A=Not Applicable	Result File Path (O)						
5								
6								
7	Index (M)/(N/A)	Sample Type (M)	Sample Identity (M)	Sample Group (O)	Sample Subgroup (O)	Dilution Factor (O)	MP Identity (M)	Well (M)
8								
9								
10								

Figure I3-1: Sample list template

NOTE: Cells with a red mark in the upper right hand corner have a comment attached. The comment is a description of the information to be included in the column/cell.

3. Fill in sample information according to Table I2-1 in Chapter I2.3.
For multi-CD runs: If designing multiple-CD Run where a Standard series/Unknown/Calibration Control/Quality Control sample is repeated on different CDs it must be placed in separate wells in the reagent microplate (and on separate rows in the Sample list) in order to avoid evaporation during the run. The number of wells for each Standard series/Unknown/Calibration Control/Quality Control sample shall correspond to the number of CDs in the Run on which the sample should be used on. Each row in the Sample list must have unique sample identity. Refer to examples in Chapter I3.7.2.
4. Click **File:Save As** to save the Sample list in a folder accessible by the Gyrolab computer.
NOTE: Do not save the file in the C:\ProgramData\Gyros\Gyrolab\Templates\Lists folder. This folder should be kept for list templates only.
5. Click **File:Close** to close the Sample list.

TIP: Print the Sample List and use when preparing sample microplates.

TIP: Quality Control samples are valid only in the reagent list.

I3.4.2 Create Reagent List

The Reagent List contains information about the solutions in the reagent plate, such as type of liquid, concentration (for Standard series samples), dilution factor etc. The Reagent List template must be edited for each new set of reagents used for each new Run.

Step Action

1. Open the **Reagent List Template** Reagent_list_Template.xls found in C:\ProgramData\Gyros\Gyrolab\Templates\Lists.
2. From row 3 and below, one row in the Reagent list represents one reagent. Columns labelled (M) are mandatory, columns labelled (O) are optional and columns labelled (N/A) are not used.

	A	B	C	D	E	F	G
1	MP Type (M)	MP96 PCR	M=Mandatory	O=Optional			Reagent list info
2	Name (M)	Type (M)	Concentration (M)/(N/A)	Unit (M)/(N/A)	Dilution Factor (O)	MP Name (M)	Well (M)
3							
4							
5							
6							

Figure I3-2: Reagent list template

NOTE: Cells with a red mark in the upper right hand corner have a comment attached. The comment is a description of the information to be included in the column/cell.

3. Fill in reagent information according to Table I3-1.
4. Click **File:Save As** to save the Reagent list in a folder accessible by the Gyrolab computer.
Do not save the file in the C:\ProgramData\Gyros\Gyrolab\Templates\Lists folder. This folder should be kept for list templates only.
5. Click **File:Close** to close the Reagent list.

Reagent List item	Mandatory/Optional	Information
MP type	Mandatory	Type of microplate
Cell B1		NOTE: Use only microplates recommended by Gyros Protein Technologies, that is MP96 PCR.

Reagent List item	Mandatory/ Optional	Information
Name Column A	Mandatory	This name is the identity of the reagent and must correspond to the name specified in the transfer list. The name of the reagent is defined by the user. It is case sensitive, so take care to copy it exactly. Enter each reagent name on a new row (Check cell A2 Name for list of allowed characters). For multi-CD runs: If designing multiple-CD Run where a Standard series/Unknown/Calibration Control/Quality Control -sample is repeated on different CDs it must be placed in separate wells in the reagent microplate (and on separate rows in the Reagent list) in order to avoid evaporation during the run. The number of wells for each Standard series/Unknown/Calibration Control/Quality Control sample shall correspond to the number of CDs in the Run on which the sample should be used on. Each row in the Reagent list must have unique name. Refer to examples in Chapter I3.7.2. It is possible to group reagent combination together for subsequent data analysis by use of a common Experiment name, refer to Chapter I3.4.4 and Chapter for details.
Type Column B	Mandatory	Enter reagent type or sample type for reagents and samples. (For more information on sample types, refer to Chapter A2.4.2): • RR = Reagent regular (wash etc.) • RB = Reagent biomolecule (capture or detection reagent) • STD = Standard series • CC = Calibration Control • BL = Blank • QC = Quality Control
Concentration Column C	Mandatory N/A	Enter the concentration for each reagent. • Mandatory for Standard series (STD), Blank (BL), Calibration Control (CC) and Quality Control (QC). • Not applicable for Reagent regular (RR) and Reagent biomolecule (RB) reagents • For Quality Control (QC) samples enter the undiluted concentration if diluted. Enter the dilution factor in column E.
Unit Column D		Enter the unit of concentration for example pM, mg/ml. • Mandatory for Standard series (STD), Blank (BL), Calibration Control (CC) and Quality Control (QC). • Not applicable for Reagent regular (RR) and Reagent biomolecule (RB) reagents

Reagent List item	Mandatory/ Optional	Information
Dilution Column E	Optional	Enter the dilution factor for Quality Control (QC) samples. Undiluted samples have dilution factor = 1. Dilution values must be 1 or higher. If nothing is entered the default value is =1.
MP Name Column F	Mandatory	Identity of microplate where the reagent or standard solutions is located.
Well Column G	Mandatory	Enter the positions of reagents and standard solutions in the microplate, for example A1, A2. For optimal liquid transfer use the same liquid in rows with the same letter (8 well rows). If the MP Type is given, and the MP Name and Well columns are completed, this information will appear in the Execute Run screens for loading Gyrolab instrument.

Table I3-1: Specification for Reagent list

TIP: *Print the Reagent List and use when preparing reagent microplates.*

I3.4.3 Create Transfer List

A Transfer List is required for Custom Run and describes how samples and reagents are transferred to defined microstructures in the CD microlaboratory. The Transfer List template must be edited to match the specific CD type and actual CD to be used. A transfer list can be used for one specific Run. There are several templates available for different types of assays. For each assay type one template is provided for running 1 CD and another template for running up to 5 CD microlaboratories.

Step Action

1. Open a suitable **Transfer List Template** found in C:\Program-Data\Gyros\Gyrolab\Templates\Lists.
2. From row 3 and below, one row represents one inlet on a CD and column from column D and further represent transfer operations in the method. The columns labelled M are mandatory and the columns labelled O are optional.

A	B	C	D	E	F	G	H
Use Exact Mapping (M)	No	Transfer list info	CD Type (O)	Gyrolab Bioaffy 1	M=Mandatory	O=Optional	N/A=Not Applicable
Segment (M)	Structure (M)	Inlet (M)	Op_Capture reagent addition	Op_Analyste addition	Op_Detection reagent addition		
1	Common left	Common inlet					
1	1	Structure inlet					
1	2	Structure inlet					
1	3	Structure inlet					
1	4	Structure inlet					
1	5	Structure inlet					
1	6	Structure inlet					
1	7	Structure inlet					
1	8	Structure inlet					
2	Common left	Common inlet					
2	1	Structure inlet					
2	2	Structure inlet					
2	3	Structure inlet					
2	4	Structure inlet					
2	5	Structure inlet					
2	6	Structure inlet					
2	7	Structure inlet					

Figure I3-3: Transfer List template

NOTE: Cells with a red mark in the upper right hand corner have a comment attached. The comment is a description of the information to be included in the column/cell.

NOTE: The number of columns in the template depends on the number of customized transfers in the used Method.

3. Fill in transfer information according to Table I3-2.
4. Click **File:Save As** to save the Transfer list in a folder accessible by the Gyrolab computer.

NOTE: Do not save the file in the C:\ProgramData\Gyros\Gyrolab\Templates\Lists folder. This folder should be kept for list templates only.
5. Click **File:Close** to close the Transfer list.

Transfer List item	information
Use Exact Mapping Cell B1	Specifies if Exact mapping will be used. This value can be Yes or No. • Yes – the number of samples in the Sample List must match the number stated in the Transfer List. • No – it is possible to enter the same or a lower number of samples in the Sample List than the number stated in the Transfer List.
CD type Cell E1	Specifies the CD type.
Segment Column A	The segment numbers each refer to a specific segment on a CD microlaboratory. The segment are used in order. Segment 1 refers to the first available segment on the CD, segment 2 means the second available segment etc. • For Bioaffy 20 HC and Bioaffy 200 CDs (that have 14 segments on each CD): If more than one CDs are used, segment 15 means the first segment on the second CD, segment 16 means the second segment on the second Bioaffy CD microlaboratory etc. • For Bioaffy 1000 CDs (that have 12 segments on each CD): If more than one CDs are used, segment 13 means the first segment on the second CD, segment 14 means the second segment on the second Bioaffy CD microlaboratory etc. • If partly used CDs are included in the Run, there are less than 14 (12 for Bioaffy 1000) segments available on those CDs and the numbering of segments will be different than normal.
Structure Column B	Structures are either common structures (named Common left or Common right) or individual structures (1–8). For each segment, there are one Common left, one Common right and eight individual structures. • All operations will begin in the first microstructure of the first unused segment of the CD. • Common left is used for adding liquid to all structures in one segment, starting from the left. • Common right is used for adding liquid to all structures in one segment, starting from the right. • The microstructure numbers 1, 2, 3 indicate individual structures in a segment.
Inlet Column C	Inlet specifies where samples and reagents are applied on the CD microlaboratory: either to a common inlet (common distribution channel) or to a structure inlet (individual microstructure).

Transfer List item	information
Op_Capture reagent addition Column D	First operation in the method. The name must be written as Op_<your customized transfer name from method> for example Op_Capture reagent addition. Naming is case sensitive. The entries here are the names from the reagent list, or a number for example #1 if it comes from a Sample List. This specifies where the reagent or sample will be placed on the CD, and in which operation. NOTE: <i>Methods and transfer lists are connected through the Run. The order of operations in the transfer list must follow the same order as the operations in the method. For each customized transfer operation in the method, one column is needed in the Transfer list. Contact Gyros Protein Technologies for more details on method design.</i>
Op_Analyte addition Column E	Second operation in the method. The name must be written as Op_<your customized transfer name from method> for example Op_Analyte addition. Naming is case sensitive. The entries are the reagent or sample name from the Reagent list or Sample list. This specifies where the reagent or sample will be placed on the CD, and in which operation it will be used. NOTE: <i>It is crucial that all replicates of the same Standard series/Unknown/Calibration Control/Quality Control sample are placed on the same CD.</i>
Op_Detect reagent addition Column F	Third operation in the method to be performed. The name must be written as Op_<your customized transfer name from method> for example Op_Detection reagent addition. Naming is case sensitive. The entries are the reagent or sample name from the Reagent list or Sample list. This specifies where the reagent or sample will be placed on the CD, and in which operation it will be used.
Op_ Column G	Forth operation in the method to be performed. The name must be written as Op_<your customized transfer name from method> for example Op_Detection reagent addition. Naming is case sensitive. The entries are the reagent or sample name from the Reagent list or Sample list. This specifies where the reagent or sample will be placed on the CD, and in which operation it will be used.

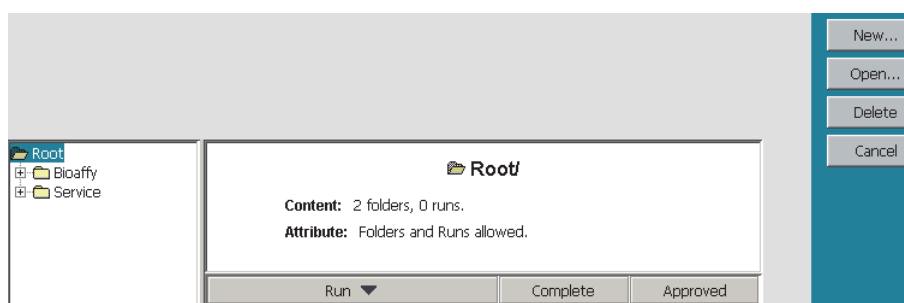
Table I3-2: Specification for Transfer list

I3.4.4 Create or edit Run Design

There are three options available when setting up a new Run Design:

- Create a new Run Design, see below.
- Edit an existing Run Design (use when similar but not identical experiment design is wanted), see below.
- Use an existing Run Design (use when identical experiment design is wanted), go to Chapter I3.5.

Step	Action
1.	Click Design Run on the Main menu. The Design Run screen appears.



2.	• To create a new Run Design, click New. Give the Run Design a name. • To edit an existing Run Design, browse to locate the desired Run Design, select the Run Design and click Open. Follow instructions below from step 4 and edit items to be changed and leave the other items unedited.

Step Action

3. Select **Custom Run** in the **Design type:** list and click **Select** button.
Custom Run panel can now be seen.

Run name:

Design type:

Custom

Method

Reagent list

Transfer list

Experiment mapping

Reagents	Reagent combination	Experiment name

Comments:

4. Click **Set** to select **Method**.
The **Select Method** dialog is opened. Select method and click **OK**.

Select Method

OK Cancel

Approved and Draft

Root/Bioaffy/Custom methods/Bioaffy 200/

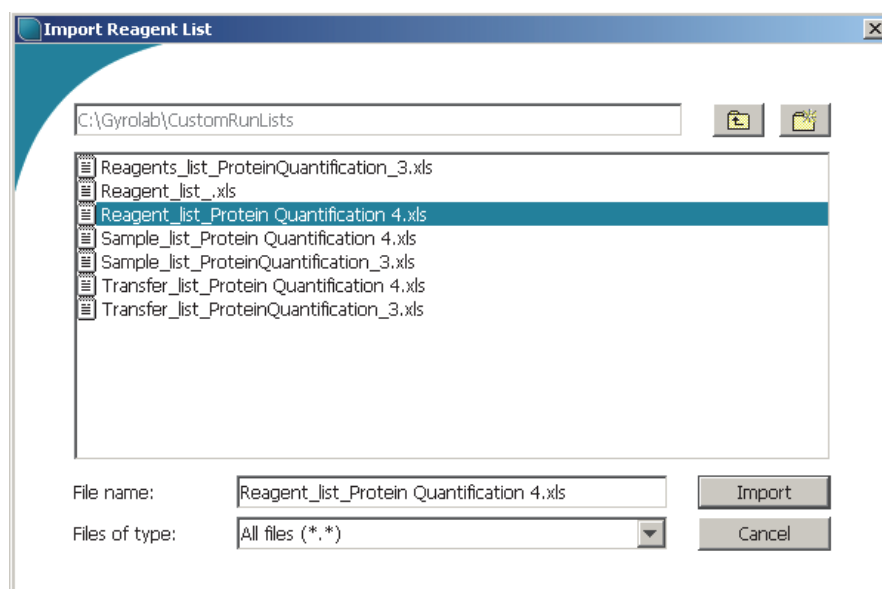
Content: 0 folders, 8 methods.

Attribute: Folders, draft methods and approved methods allowed.

Method	Approved	Complete
Bioaffy 200 1-step v1	☒	☒
Bioaffy 200 2-step C-AD v1	☒	☒
Bioaffy 200 2-step C-D v1	☒	☒
Bioaffy 200 3-step C-A-D low PMT v1	☒	☒
Bioaffy 200 3-step C-A-D v1	☒	☒
Bioaffy 200 4-step (2xC)-A-D v1	☒	☒
Bioaffy 200 4-step C-A-(2xD) v1	☒	☒
Bioaffy 200 wash station 2 v1	☒	☒

Step	Action

5.	Click Import under Reagent List and the Import Reagent List dialog opens. Browse to locate the desired Reagent list file, prepared in Chapter I3.4.2 and click Import.

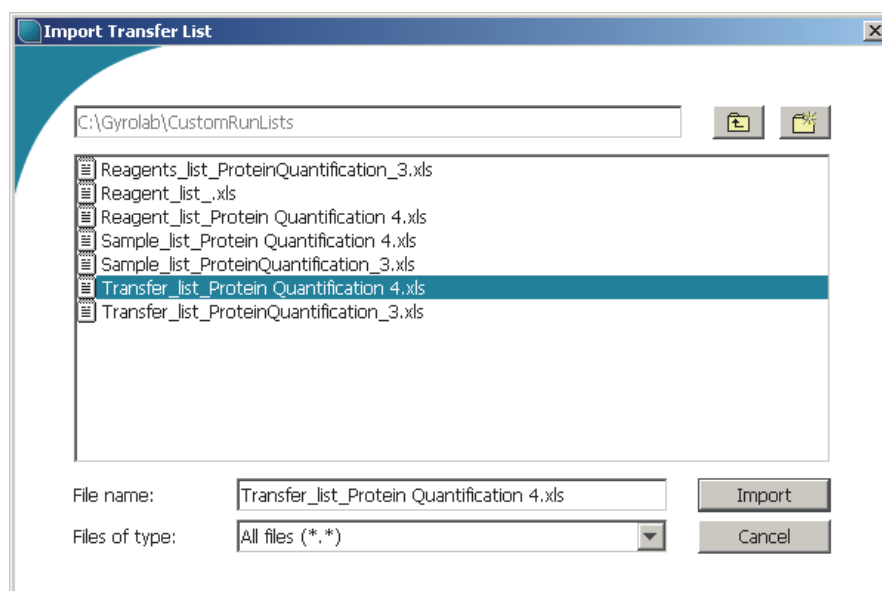


In **Custom Run** panel:

- Click **View** button to view the contents of the imported Reagent List file. Click **Close** after viewing.
- Click **Remove** button to delete the imported Reagent list.

Step	Action

6.	Click Import under Transfer List, the Import Transfer List dialog appears. Browse to locate the desired Transfer list file, prepared in Chapter I3.4.3 and click Import.



In **Custom Run** panel:

- Click **View** button to view the contents of the imported Transfer List file. Click **Close** after viewing.
- Click **Remove** button to delete the imported Transfer list.

Step Action

7. After selecting Method, Reagent list and Transfer list, the **Experiment mapping** section lists information on **Reagent combinations**.

Run name: ProteinQuantification 4

Design type: Custom

Custom

Method
tom methods/Bloaffy 200/Bloaffy 200 3-step C-A-D v1

Reagent list
Reagent_list_ProteinQuantification 4

Transfer list
Transfer_list_ProteinQuantification 4

Experiment mapping

Reagents	Reagent combination	Experiment name
2Cap1_CD1_Det1_CD1		
2Cap1_CD2_Det1_CD2		

Comments:

For multi-CD runs, reagents must be placed in unique microplate wells (one per CD) and have unique identities, even if it is the same reagent. Data analysis in Gyrolab Evaluator are based on which reagents (**Reagent combination**) that are used for the specific sample.

It is possible to group sample made with identical reagents but with different reagents names by giving them a common **Experiment name**. Gyrolab Evaluator will analyze all samples with a common **Experiment name** together if it is present. If not present the **Reagent combination** will be used to group samples.

Another reason for using an Experiment name is that it is possible to use a simple informative name, for example IgG.

To group reagent combinations for subsequent data analysis:

- Enter identical names in the **Experiment name** field for reagent combinations to be grouped together.

Experiment mapping

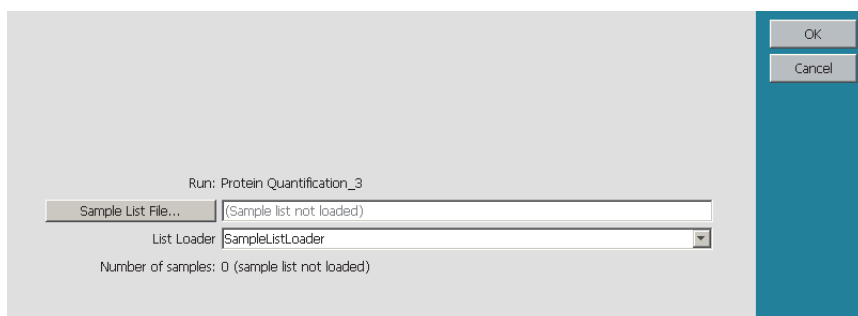
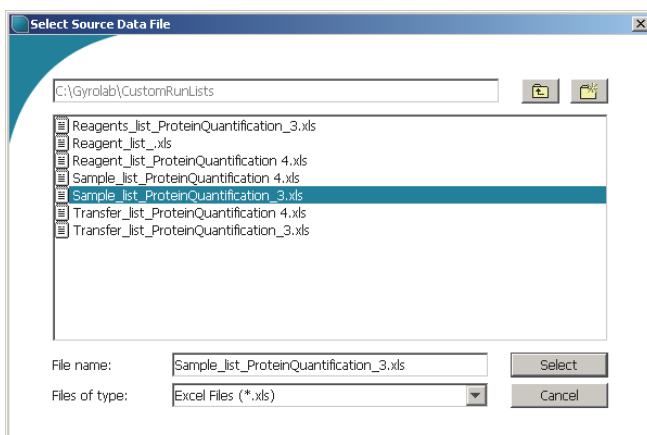
Reagents	Reagent combination	Experiment name
2Cap1_CD1_Det1_CD1		IgG
2Cap1_CD2_Det1_CD2		IgG

- 8.
- To save a new Run Design, click **Save**. Browse to select folder and click **Save**.
 - To save an edited Run Design, click **Save as**. Give the Run Design a name, browse to select folder and click **Save**. If **Save** is clicked the original Run Design will be lost.

NOTE: *If changes are made to the transfer and/or reagent lists, they must be re-imported to the Run Design to be performed.*

I3.5 Prepare Custom Run

Step	Action
1.	Click Execute Run on the Main menu.
2.	Click Run... Run Setup... is used to execute Runs defined by a Run Setup created in Gyrolab Manager. See Chapter B5.
3.	Browse and select desired Run Design from the list and click OK .
4.	Browse and select desired Sample List and click Select .
5.	Number of samples is displayed and the Sample List status is set to Loaded. Click OK .
6.	To continue with Targets and Report settings, Start and After Run procedures proceed to Chapter I7.

Click **Sample List File**.Click **OK**.

I3.6 Sample and reagents preparations

This chapter describes preparation of capture and detection reagents, standard sample series, Calibration Controls, Quality Controls and unknown samples as well as the distribution of samples and reagents in microplates. For preparing reagents for a multi CD Run, refer to Chapter I3.7.2 for details.

The following solutions and reagents are required:

- PBS-T (for recipe, refer to Chapter F2.2)
- Capture and Detection reagents
- Standard Protein
- REXXIP buffer (Refer to Product information sheet for REXXIP buffers for recommendations on buffer selection)

I3.6.1 Capture reagent and detection reagent

Prepare capture reagent and detection reagent according to Chapter I3.6.1 and Chapter I3.6.2 respectively. For minimum required reagent volumes, use formula below:

- $\text{Reagent volume} = (2.5 \mu\text{l} \times \text{Number of segments}) + 10 \mu\text{l}$

For correct number of segments, refer to Transfer list (Chapter I3.4.3).

NOTE: *In multiple-CD Runs reagents that are used on more than one CD must be placed in different microplate wells, one per CD, refer to Chapter I3.4.2. Calculate minimum required volume per well using the formulas above.*

I3.6.2 Standard series and Calibration Controls

Prepare Standard series and Calibration Controls according to Chapter I3.6.2. For minimum required sample volumes, use formulas below:

For **Bioaffy 20 HC and Bioaffy 200:**

- $\text{Standard volume} = (0.5 \mu\text{l} \times \text{Number of replicates}) + 2.5 \mu\text{l}$

For **Bioaffy 1000:**

- Number of replicates is 8 or less:
 $\text{Standard volume} = (2.5 \mu\text{l} \times \text{Number of replicates}) + 5.0 \mu\text{l}$
- Number of replicates is 8 or more
 $\text{Standard volume} = (2.5 \mu\text{l} \times \text{Number of replicates}) + 10.0 \mu\text{l}$

For correct number of replicates, refer to Transfer list prepared in Chapter I3.4.3.

NOTE: *In multiple-CD Runs, samples that are used on more than one CD must be placed in different microplate wells, one per CD, refer to Chapter I3.4.2. Calculate minimum required volume per well using the formulas above.*

NOTE: *Calibration Controls can be used in multiple-CD runs and are selected points in the Standard series. When calibration Controls are used, one must prepare extra volume of Standard series samples to ensure that the volume is sufficient for both the Standard series sample and Calibration Control. It is very important that the Standard series and Calibration Control samples are from the identical Standard series dilution.*

NOTE: *If more than 41 replicates are used on a Bioaffy 1000 CD the sample liquid must be divided into more than one well.*

I3.6.3 Unknown Samples and Quality Controls

Prepare Standard series and Calibration Controls according to Chapter I3.6.3. For minimum required sample volumes, use formula below:

For **Bioaffy 20 HC and Bioaffy 200**:

- Sample volume = $(0.5 \mu\text{l} \times \text{Number of replicates}) + 2.5 \mu\text{l}$

For **Bioaffy 1000**:

- Number of replicates is 8 or less:
Sample volume = $(2.5 \mu\text{l} \times \text{Number of replicates}) + 5.0 \mu\text{l}$
- Number of replicates is 8 or more
Sample volume = $(2.5 \mu\text{l} \times \text{Number of replicates}) + 10.0 \mu\text{l}$

NOTE: *In multiple-CD Runs, samples that are used on more than one CD must be placed in different microplate wells, one per CD, refer to Chapter I3.4.1. Calculate minimum required volume per well using the formulas above.*

NOTE: *If more than 41 replicates are used on a Bioaffy 1000 CD the sample liquid must be divided into more than one well.*

I3.6.4 Microplates

Prepare microplates according to Chapter C3.

Prepare reagent microplate:

Reagent microplate contains:

- Capture reagent
- Detection reagent
- Standard series samples including blank samples
- Quality Control samples
- Calibration Control samples

The volumes and microplate positions are specified in the **Reagent List** Chapter I3.4.2 and **Transfer List**, prepared in Chapter I3.4.3.

Prepare sample microplate:

Sample microplate contains:

- Unknown samples

Transfer the samples, as prepared in Chapter I3.6.3, to wells in the sample microplate according to the order stated in the Sample List prepared in Chapter I3.4.1.

I3.7 Examples of run setup and experiment mapping

Evaluation of results of samples of different types (Standard series/Unknown/Calibration Control/Quality Control) in Gyrolab Evaluator are based on which reagents (**Reagent combination**) that are used for the specific sample.

By using the option of **Experiment mapping** (refer to Chapter I3.5) it is possible to group sample analyses made by identical reagents but with different reagents names by giving them a common **Experiment name**. Gyrolab Evaluator will analyze all samples with a common **Experiment name** together if it is present. If not present the **Reagent combination** will be used.

The following chapters provide examples to high-light how sample naming and experiment mapping will affect sample grouping during data analysis in Gyrolab Evaluator

I3.7.1 Examples of experiment mapping for 1-CD runs

Four examples of run set-up for 1-CD runs are provided.

Example 1: One Reagent combination and one standard curve

Use Exact Mapping (M)	No	Transfer list info	CD Type (O)	Bioafly	M=Mandatory	O=Optional	N/A=Not Applicable
Segment (M)	Structure (M)	Inlet (M)	Op_Capture reagent addition	Op_Analyte addition	Op_Detection reagent addition		
1	Common left	Common inlet	Capture		Detection		
1	1	Structure inlet		Blank			
1	2	Structure inlet		Standard_1			
1	3	Structure inlet		Standard_2			
1	4	Structure inlet		Standard_3			
1	5	Structure inlet		Standard_4			
1	6	Structure inlet		Standard_5			
1	7	Structure inlet		Standard_6			
1	8	Structure inlet		Standard_7			
2	Common left	Common inlet	Capture		Detection		
2	1	Structure inlet		Blank			
2	2	Structure inlet		Standard_1			
2	3	Structure inlet		Standard_2			
2	4	Structure inlet		Standard_3			
2	5	Structure inlet		Standard_4			
2	6	Structure inlet		Standard_5			
2	7	Structure inlet		Standard_6			
2	8	Structure inlet		Standard_7			

Figure 10: One calibration reference and one standard curve in transfer list

A Run using this transfer list will generate following in Gyrolab Evaluator:

- One **Reagent combination**: Capture_Detection.
- One standard curve in duplicates.

Example 2: Two Reagent combinations

Use Exact Mapping (M)	No	Transfer list info	CD Type (O)	Bioaffy	M=Mandatory
Segment (M)	Structure (M)	Inlet (M)	Op_Capture reagent addition	Op_Analyte addition	Op_Detection reagent addition
1	Common left	Common inlet	Capture_1		Detection_1
1	1	Structure inlet		Curve_1_Blank	
1	2	Structure inlet		Curve_1_Standard_1	
1	3	Structure inlet		Curve_1_Standard_2	
1	4	Structure inlet		Curve_1_Standard_3	
1	5	Structure inlet		Curve_1_Blank	
1	6	Structure inlet		Curve_1_Standard_1	
1	7	Structure inlet		Curve_1_Standard_2	
1	8	Structure inlet		Curve_1_Standard_3	
2	Common left	Common inlet	Capture_1		Detection_1
2	1	Structure inlet		#1	
2	2	Structure inlet		#2	
2	3	Structure inlet		#3	
2	4	Structure inlet		#4	
2	5	Structure inlet		#1	
2	6	Structure inlet		#2	
2	7	Structure inlet		#3	
2	8	Structure inlet		#4	
3	Common left	Common inlet	Capture_2		Detection_2
3	1	Structure inlet		Curve_2_Blank	
3	2	Structure inlet		Curve_2_Standard_1	
3	3	Structure inlet		Curve_2_Standard_2	
3	4	Structure inlet		Curve_2_Standard_3	
3	5	Structure inlet		Curve_2_Blank	
3	6	Structure inlet		Curve_2_Standard_1	
3	7	Structure inlet		Curve_2_Standard_2	
3	8	Structure inlet		Curve_2_Standard_3	
4	Common left	Common inlet	Capture_2		Detection_2
4	1	Structure inlet		#1	
4	2	Structure inlet		#2	
4	3	Structure inlet		#5	
4	4	Structure inlet		#6	
4	5	Structure inlet		#1	
4	6	Structure inlet		#2	
4	7	Structure inlet		#5	
4	8	Structure inlet		#6	

Figure 11: Example of two **Reagent combinations** in the transfer list

A Run using this transfer list will generate following in Gyrolab Evaluator:

- Two different **Reagent combinations**:
 - Capture_1_Detection_1
 - Capture_2_Detection_2
- Two standard curves in duplicates. One for each **Reagent combination**.
- Samples 1 and 2 will be quantified against both standard curves 1 and 2 (**Reagent combination 1**= Capture_1_Detection_1 and **Reagent combination 2**= Capture_2_Detection_2)
- Samples 3 and 4 will be quantified against curve 1 (**Reagent combination** = Capture_1_Detection_1)
- Samples 5 and 6 will be quantified against curve 2 (**Reagent combination** = Capture_2_Detection_2)

Example 3: Two different Standard series and one Reagent combination

Use Exact Mapping (M)	No	Transfer list info	CD Type (O)	Bioaffy	M=Mandatory
Segment (M)	Structure (M)	Inlet (M)	Op_Capture reagent addition	Op_Analyte addition	Op_Detection reagent addition
1	Common left	Common inlet	Capture		Detection
1	1	Structure inlet		Curve1_Blank	
1	2	Structure inlet		Curve1_Standard_1	
1	3	Structure inlet		Curve1_Standard_2	
1	4	Structure inlet		Curve1_Standard_3	
1	5	Structure inlet		Curve1_Blank	
1	6	Structure inlet		Curve1_Standard_1	
1	7	Structure inlet		Curve1_Standard_2	
1	8	Structure inlet		Curve1_Standard_3	
2	Common left	Common inlet	Capture		Detection
2	1	Structure inlet		Curve2_Blank	
2	2	Structure inlet		Curve2_Standard_1	
2	3	Structure inlet		Curve2_Standard_2	
2	4	Structure inlet		Curve2_Standard_3	
2	5	Structure inlet		Curve2_Blank	
2	6	Structure inlet		Curve2_Standard_1	
2	7	Structure inlet		Curve2_Standard_2	
2	8	Structure inlet		Curve2_Standard_3	

Figure 12: Two different Standard series with, for example different standard preparations/dilutions, but only one **Reagent combination** will generate one standard curve

A Run using this transfer list will generate following in Gyrolab Evaluator:

- One **Reagent combination**: Capture_Detection.
- One standard curve in 4 replicates.

NOTE: *Even though the Standard series have been given different names in the transfer list, see figure for current example, they will be analyzed against the same Reagent combination and thus they will be evaluated as replicates of the same curve. In order to generate two different standard curves (for example with different standard preparations/dilutions) two different Reagent combination are needed, see figure for example 4.*

Example 4: Two different Standard series and two Reagent combinations

Use Exact Mapping (M)	No	Transfer list info	CD Type (O)	Bioaffy	M=Mandatory
Segment (M)	Structure (M)	Inlet (M)	Op_Capture reagent addition	Op_Analyte addition	Op_Detection reagent addition
1	Common left	Common inlet	Capture_Curve_1		Detection_Curve_1
1	1	Structure inlet		Curve_1_Blank	
1	2	Structure inlet		Curve_1_Standard_1	
1	3	Structure inlet		Curve_1_Standard_2	
1	4	Structure inlet		Curve_1_Standard_3	
1	5	Structure inlet		Curve_1_Blank	
1	6	Structure inlet		Curve_1_Standard_1	
1	7	Structure inlet		Curve_1_Standard_2	
1	8	Structure inlet		Curve_1_Standard_3	
2	Common left	Common inlet	Capture_Curve_2		Detection_Curve_2
2	1	Structure inlet		Curve_2_Blank	
2	2	Structure inlet		Curve_2_Standard_1	
2	3	Structure inlet		Curve_2_Standard_2	
2	4	Structure inlet		Curve_2_Standard_3	
2	5	Structure inlet		Curve_2_Blank	
2	6	Structure inlet		Curve_2_Standard_1	
2	7	Structure inlet		Curve_2_Standard_2	
2	8	Structure inlet		Curve_2_Standard_3	

Figure 13: Two different Standard series, with for example different standard preparations/dilutions, with two different **Reagent combinations** will generate two standard curves

A Run using this transfer list will generate following in Gyrolab Evaluator:

- Two **Reagent combination**:
 - Capture_curve 1_Detection_curve 1
 - Capture_curve 2_Detection_curve 2
- Two standard curves in duplicates. One for each **Reagent combination**.

I3.7.2 Examples of experiment mapping for multi-CD Runs

Three examples for set-up of multi-CD Runs are provided.

NOTE: *In the following examples Transfer Lists where only transfers to segments 14 and 15 are shown. This is to make the examples easy to follow. If present in a real Run the Transfer List must also specify transfers to segments 1–13. Otherwise the transfer will occur to segments 1 and 2 on the first CD since segments with no specified transfer will be ignored during the Run.*

NOTE: *Following examples refers to the use of CDs with 14 segments available.*

Example 1: 2 CDs Run with standard curve repeated for each CD

Figures included in this section show reagent and transfer lists from a Run with the purpose to use the same Standard series on a different CDs in a multiple CD Run. This requires that the Standard series samples and reagents are given different names in the reagent list (different **Reagent combination** names) and are put in different wells in the micro plate even though it has the same content. By giving the different **Reagent combinations** the same **Experiment name** they will be analyzed as one entity in Gyrolab Evaluator.

	A	B	C	D	E	F	G
1	MP Type (M)	MP96 PCR	M=Mandatory	O=Optional			Reagent list info
2	Name (M)	Type (M)	Concentration (M)/(N/A)	Unit (M)/(N/A)	Dilution Factor (O)	MP Name (M)	Well (M)
3	Capture_CD_1	RB				Reagent_MP	A1
4	Capture_CD_2	RB				Reagent_MP	A2
5	Detection_CD_1	RB				Reagent_MP	B1
6	Detection_CD_2	RB				Reagent_MP	B2
7	Curve_CD_1_Blank	BL	0	ng/ml		Reagent_MP	C1
8	Curve_CD_1_Standard_1	STD	1	ng/ml		Reagent_MP	C2
9	Curve_CD_1_Standard_2	STD	10	ng/ml		Reagent_MP	C3
10	Curve_CD_1_Standard_3	STD	100	ng/ml		Reagent_MP	C4
11	Curve_CD_2_Blank	BL	0	ng/ml		Reagent_MP	D1
12	Curve_CD_2_Standard_1	STD	1	ng/ml		Reagent_MP	D2
13	Curve_CD_2_Standard_2	STD	10	ng/ml		Reagent_MP	D3
14	Curve_CD_2_Standard_3	STD	100	ng/ml		Reagent_MP	D4

Figure 14: Reagent list with the same Standard series repeated on a different CD in the same Run

Use Exact Mapping (M)	No	Transfer list info	CD Type (O)	Bioaffy	M=Mandatory
Segment (M)	Structure (M)	Inlet (M)	Op_Capture reagent addition	Op_Analyte addition	Op_Detection reagent addition
14	Common left	Common inlet	Capture_CD_1		Detection_CD_1
14	1	Structure inlet		Curve_CD1_Blank	
14	2	Structure inlet		Curve_CD1_Standard_1	
14	3	Structure inlet		Curve_CD1_Standard_2	
14	4	Structure inlet		Curve_CD1_Standard_3	
14	5	Structure inlet		Curve_CD1_Blank	
14	6	Structure inlet		Curve_CD1_Standard_1	
14	7	Structure inlet		Curve_CD1_Standard_2	
14	8	Structure inlet		Curve_CD1_Standard_3	
15	Common left	Common inlet	Capture_CD_2		Detection_CD_2
15	1	Structure inlet		Curve_CD2_Blank	
15	2	Structure inlet		Curve_CD2_Standard_1	
15	3	Structure inlet		Curve_CD2_Standard_2	
15	4	Structure inlet		Curve_CD2_Standard_3	
15	5	Structure inlet		Curve_CD2_Blank	
15	6	Structure inlet		Curve_CD2_Standard_1	
15	7	Structure inlet		Curve_CD2_Standard_2	
15	8	Structure inlet		Curve_CD2_Standard_3	
3	Common left	Common inlet	Capture_CD_2		Detection_CD_2

Figure 15: Transfer list with the same standard curve repeated on a different CD in the same Run

A 2-CD Run using a reagent and transfer list from current examples will generate following in Gyrolab Evaluator:

If not using an Experiment name

- Capture_CD 1_Detection_CD 1 (processed on CD 1)
- Capture_CD 2_Detection_CD 2 (processed on CD 2)
- Two Standard series in duplicates. One for each **Reagent combination**.

If using an Experiment name

- One combined set of reagents (**Experiment name**)
- One common Standard series in quadruplicates.

Example 2: A two CD Run with a common Experiment name

- One Standard series (CD1)
- Two Calibration Control samples (CD2)
- Eight Unknown samples, four on each CD (Sample List not shown)

The figures included in this example demonstrates Reagent and Transfer lists for a 2 CD Run using one Standard series on CD1 and Calibration Control samples on CD2. Unknown samples are present on both CDs. Using this strategy all Unknown samples will be quantified against the Standard series on CD 1.

	A	B	C	D	E	F	G
1	MP Type (M)	MP96 PCR	M=Mandatory	O=Optional			Reagent list info
2	Name (M)	Type (M)	Concentration (M)/(N/A)	Unit (M)/(N/A)	Dilution Factor (O)	MP Name (M)	Well (M)
3	Capture_CD_1	RB				Reagent_MP	A1
4	Capture_CD_2	RB				Reagent_MP	A2
5	Detection_CD_1	RB				Reagent_MP	B1
6	Detection_CD_2	RB				Reagent_MP	B2
7	Curve_CD_1_Blank	BL	0	ng/ml		Reagent_MP	C1
8	Curve_CD_1_Standard_1	STD	1	ng/ml		Reagent_MP	C2
9	Curve_CD_1_Standard_2	STD	10	ng/ml		Reagent_MP	C3
10	Curve_CD_1_Standard_3	STD	100	ng/ml		Reagent_MP	C4
11	CC1	CC	25	ng/ml		Reagent_MP	D1
12	CC2	CC	50	ng/ml		Reagent_MP	D2

Use Exact Mapping (M)	No	Transfer list info	CD Type (O)	Bioaffy	M=Mandatory
Segment (M)	Structure (M)	Inlet (M)	Op_Capture reagent addition	Op_Analyte addition	Op_Detection reagent addition
14	Common left	Common inlet	Capture_CD_1		Detection_CD_1
14	1	Structure inlet		Curve_CD1_Blank	
14	2	Structure inlet		Curve_CD1_Standard_1	
14	3	Structure inlet		Curve_CD1_Standard_2	
14	4	Structure inlet		Curve_CD1_Standard_3	
14	5	Structure inlet		#1	
14	6	Structure inlet		#2	
14	7	Structure inlet		#3	
14	8	Structure inlet		#4	
15	Common left	Common inlet	Capture_CD_2		Detection_CD_2
15	1	Structure inlet		CC1	
15	2	Structure inlet		CC2	
15	3	Structure inlet		CC1	
15	4	Structure inlet		CC2	
15	5	Structure inlet		#5	
15	6	Structure inlet		#6	
15	7	Structure inlet		#7	
15	8	Structure inlet		#8	
3	Common left	Common inlet	Capture_CD_2		Detection_CD_2

A two CD Run using current lists will generate following in Gyrolab Evaluator

- One Standard series
- Two Calibration Controls
- Eight Unknown samples, quantified against Standard series on CD 1

Example 3: A two CD Run with a common Experiment name

- Two Standard series (CD1 and CD2)
- Eight Unknown samples, four on each CD (Sample List not shown)

The figures included in this example demonstrates Reagent and Transfer lists for a two CD Run using two Standard series on separate CDs. Unknown samples are present on both CDs.

In spite of the use of a common **Experiment name**, using this strategy Unknown sample #1 -4 will be quantified against the Standard series on CD 1 and Unknown sample #5 -8 will be quantified against the Standard series on CD 2.

	A	B	C	D	E	F	G
1	MP Type (M)	MP96 PCR	M=Mandatory	O=Optional			Reagent list info
2	Name (M)	Type (M)	Concentration (M)/(N/A)	Unit (M)/(N/A)	Dilution Factor (O)	MP Name (M)	Well (M)
3	Capture_CD_1	RB				Reagent_MP	A1
4	Capture_CD_2	RB				Reagent_MP	A2
5	Detection_CD_1	RB				Reagent_MP	B1
6	Detection_CD_2	RB				Reagent_MP	B2
7	Curve_CD_1_Blank	BL	0	ng/ml		Reagent_MP	C1
8	Curve_CD_1_Standard_1	STD	1	ng/ml		Reagent_MP	C2
9	Curve_CD_1_Standard_2	STD	10	ng/ml		Reagent_MP	C3
10	Curve_CD_1_Standard_3	STD	100	ng/ml		Reagent_MP	C4
11	Curve_CD_2_Blank	BL	0	ng/ml		Reagent_MP	D1
12	Curve_CD_2_Standard_1	STD	1	ng/ml		Reagent_MP	D2
13	Curve_CD_2_Standard_2	STD	10	ng/ml		Reagent_MP	D3
14	Curve_CD_2_Standard_3	STD	100	ng/ml		Reagent_MP	D4

Segment (M)	Structure (M)	Inlet (M)	Op_Capture reagent addition	Op_Analyte addition	Op_Detection reagent addition
14	Common left	Common inlet	Capture_CD_1		Detection_CD_1
14	1	Structure inlet		Curve_CD_1_Blank	
14	2	Structure inlet		Curve_CD_1_Standard_1	
14	3	Structure inlet		Curve_CD_1_Standard_2	
14	4	Structure inlet		Curve_CD_1_Standard_3	
14	5	Structure inlet		#1	
14	6	Structure inlet		#2	
14	7	Structure inlet		#3	
14	8	Structure inlet		#4	
15	Common left	Common inlet	Capture_CD_2		Detection_CD_2
15	1	Structure inlet		Curve_CD_2_Blank	
15	2	Structure inlet		Curve_CD_2_Standard_1	
15	3	Structure inlet		Curve_CD_2_Standard_2	
15	4	Structure inlet		Curve_CD_2_Standard_3	
15	5	Structure inlet		#5	
15	6	Structure inlet		#6	
15	7	Structure inlet		#7	
15	8	Structure inlet		#8	

A two CD Run using current lists will generate following in Gyrolab Evaluator

- Two Standard series
- Unknown sample #1 -4 will be quantified against the Standard series on CD 1
- Unknown sample #5 -8 will be quantified against the Standard series on CD 2.

I4 ADA Software workflow using Gyrolab Client

I4.1 Introduction

Gyrolab ADA Software is a software add-on module for Gyrolab Control version 5.4 and Gyrolab Evaluator version 3.3 or higher.

The Gyrolab ADA product portfolio enables measurement of anti-drug antibodies (ADAs) in the presence of excess amounts of drug. Samples can be treated with acid in an automated procedure to allow drug-ADA complexes to dissociate, and then neutralized just before analysis, preventing complexes from reforming. The acid pre-treatment of the ADA-drug complex increases the “drug tolerance” of the assay, a term used to describe its capability to detect ADAs in the presence of drug in the sample.

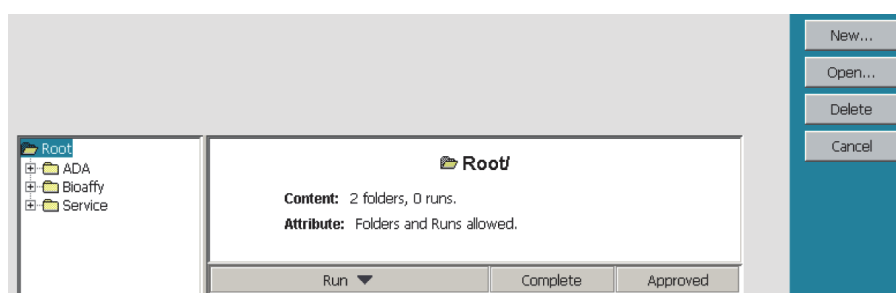
Recommendations on assay development and sample and reagent preparations are found in the Gyrolab ADA assay protocol, included in the purchase of Gyrolab ADA Software.

During clinical ADA analysis samples are screened for ADA positives in a **Screening** assay. **Confirmation** assays are performed to investigate whether positive samples from screening are true positives. Evaluation functionalities are available in Gyrolab ADA Software to support these analyses.

I4.2 Create or Edit an ADA Run

This chapter describes how to create or edit an ADA Run Design using the Wizard workflow in Gyrolab Control. To create an ADA Run Design in Gyrolab Manager, see Chapter E2.

Step	Action
1.	Click Design Run on the Main menu of Gyrolab Control (refer to Chapter G1.2). The Run screen appears.
2.	- To create a new Run Design, click New and continue with 3. - To edit an existing Run Design, browse and select the desired Run Design and click Open. Change desired parameters. For instructions, refer to step 3 to 16.



Step Action

3. Enter a Run Design name in the **Run Name** field.
Select Wizard in the **Design Type** list and click **Select**. The **Wizard** panel appears:

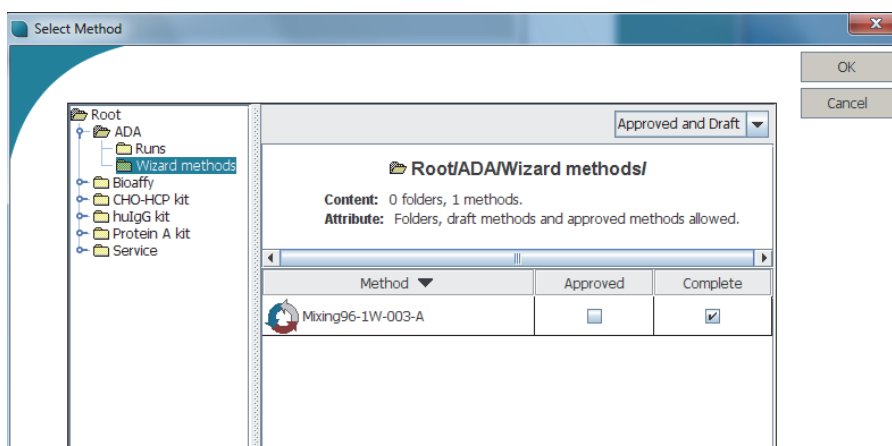
The screenshot shows the 'Wizard' panel in the Gyrolab Client software. At the top, there is a 'Run name:' text box and a 'Design type:' dropdown menu currently set to 'Wizard'. To the right of the dropdown are 'Select' and 'Reselect' buttons. On the far right, a vertical blue bar contains 'Save', 'Save As', and 'Close' buttons. The main area of the wizard is titled 'Wizard' and contains a 'Method' section with a 'Method:' text box and a 'Select...' button. Below this are three expandable sections: 'Setup', 'Analytes', and 'Generate sample list template (Optional)'. At the bottom, there is a 'Comments:' text box.

Step Action

4. In the **Method** section, click **Select**.

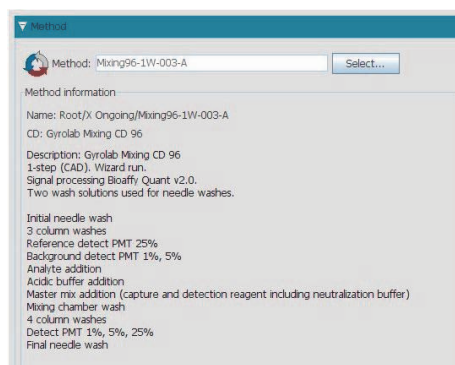


The **Select Method** dialog is opened.

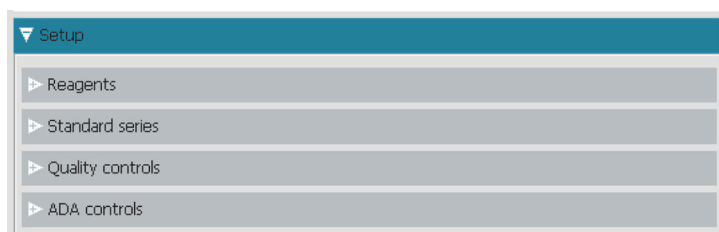


Browse and select desired ADA Method.

Click **OK**. The selected method is added to the run design and method information is displayed.



5. Select **Setup**.



Step Action

6. Select **Reagents**. The number of reagents may differ depending on what assay format and method is used.

NOTE: *The software will automatically add reagents to the design depending on selected method. The number of reagents can be edited by the user.*

Reagent name	Condition
Acid	HAc 300 mM pH 3
Neutralization	Tris pH 8.0

- Enter **Reagent name** for reagents. The **Condition** field is optional and can be used for additional information such as concentration value, matrix or buffer.
 - Click **Add** to add more reagents. Add and name one reagent in the software for each different reagent required for the assay.
 - Highlight reagent and click **Delete** to remove reagent.
7. Select **Standard series** (This step is optional).
- Standard Series set-up is identical to the workflow used with Gyrolab Bioaffy CDs, refer to Chapter I2.2.
8. Select **Quality Control** (This step is optional).
- Quality Control set-up is identical to the workflow used with Gyrolab Bioaffy CDs, refer to Chapter I2.2.
9. Enter **ADA control name** for ADA controls
- Specify **ADA control name** for ADA controls.
 - The **Dilution** field is optional. The dilution value is used for concentration calculations in the evaluation software. The value can be changed during data analysis.
 - Set **Type** to PC (positive control) or NC (negative control)
 - Mark **Use spiked/unspiked** check box when performing confirmation runs. This automatically doubles the number of ADA controls and sample subgroup for ADA controls is set to "spiked" and "unspiked" respectively within each pair.
 - Click **Add** to add more ADA controls.
 - Highlight ADA control and click **Delete** to remove ADA control.

ADA control name	Dilution	Replicates	Type
PC1	1.0	2	PC
PC2	1.0	2	PC
PC3	1.0	2	PC
NC1	1.0	2	NC
NC2	1.0	2	NC
NC3	1.0	2	NC

Step	Action

10.	Select Analytes. - Analyte and experiment set-up is identical to the workflow used with Gyrolab Bioaffy CDs, refer to Chapter I2.2 except for the addition of a new sample type: ADA controls. To set up an Analyte with one Experiment: - Select Analyte: Analyte 1. Enter a name for the Analyte in the Name text field. - Select Experiment: Experiment 1. Enter a name for the Experiment in the Name text field. - Select reagent(s) from the drop-down lists. The number of reagent fields is determined by the number of reagent transfer operations in the method and the reagent field names are determined by the reagent transfer operation names in the method. Only reagents specified in 6 are available in the reagent drop-down lists. In the example in 11, there are two reagent transfer operations in the method and therefore two reagent drop-down lists in the experiment set-up: Acidic reagent addition and Detection reagent mix addition. - Select number of Standard series in the Number of Standard series list. For multi-CD runs: - When Use on all CDs is ticked, unknown samples will be quantified against Standard series on the same CD. One analysis per CD will be created. - If Use on all CDs is not ticked, all unknown samples are quantified against the same Standard series. NOTE: <i>Instead of Standard series on all CDs, Calibration Controls can be used. Refer to step 7.</i> - Select Standard series in the Standard series name list. Only Standard series specified in 7 are available. - Select number of Quality Controls in the Number of Quality controls list. For multi-CD runs: - If Use on all CDs is selected, the Quality Controls samples will be applied on all CDs included in the Run. - If Use on all CDs is not selected, the Quality Controls samples will be applied on one CD even if the experiment is included on several CDs. - Select Quality Controls in the Quality control name list(s). Only Quality Controls specified in 8 are available. - Select number of ADA controls in the Number of ADA controls list. For multi-CD runs: - If Use on all CDs is selected, the ADA control samples will be applied on all CDs included in the Run. - If Use on all CDs is not selected, the ADA control samples will be applied on one CD even if the experiment is included on several CDs. - Select ADA controls in the ADA control name list(s). ADA controls specified in 9 are available.

Step	Action

11.	An example of an experiment set-up is given below:

The screenshot shows the 'Analyte: ADA 1' window. Inside, there is an 'Experiment: Screening homogeneous' section. The 'Name' field is 'Screening homogeneous'. The 'Acidic reagent addition' is 'Acid dissociation_ HAc 300mM pH...' and the 'Detection reagent mix addition' is 'Neutralization_1 M Tris pH 8.0'. The 'Number of Standard series' is 0, and 'Use on all CDs' is unchecked. The 'Number of Quality controls' is 0, and 'Use on all CDs' is unchecked. The 'Number of ADA controls' is 6, and 'Use on all CDs' is checked. Below this, there are six 'ADA control name' fields with values: NC1, NC2, NC3, PC1, PC2, and PC3.

12.	More analytes and experiments can be added: • Add additional Analytes by clicking  in the Analytes bar. • Delete Analytes by clicking  in the Analyte: bar. • Add additional Experiments to an Analyte by clicking  in the Analyte: bar. Delete Experiment by clicking  in the Experiment: bar.

Step	Action

13.	Select Generate Sample List template .

Generate sample list template (Optional)

Number of unknowns: 0 (Same value must be used when executing run)

Unknown replicates: 2 (Same value must be used when executing run)

Include limited CD: ☐ Number of free segments: 1

Use spiked/unspiked: ☐ (Number of unknowns is doubled and subgroup set to spiked/unspiked in sample list)

Generate Template...

- Save the Run Design.
 - To save a new ADA Run Design, click **Save**. Browse to select folder and click **Save**.
 - To save an edited ADA Run Design, click **Save as**. Name the Run Design, browse to select folder and click **Save**. If **Save** is clicked the information on the original Run Design will be replaced with the edited information.
 - If any information added to the ADA Run Design is incomplete or erratic an error message will be presented. The specified issues must be addressed before it is possible to save.
- Specify number of samples to be analyzed ("Unknown samples") in the **Number of unknowns** list.
- Specify number of sample replicates in the **Unknown replicates** list. Highest number of replicates are 8.
- If it is desired to use a CD that previously has been partially used, check **Include limited CD** and define number of available segments in the **Number of free segments** list.
- Mark **Use spiked/unspiked** check box when performing confirmation runs. This will automatically generate a Sample List where the number of unknown samples are doubled and sample subgroup for unknown samples is set to "spiked" and "unspiked" respectively within each pair.
- Click **Generate template**.
- Browse to select Sample List location and click **Save**.

A Sample List is generated. The Sample List contains all necessary sample information defined in the run design. It also holds a suggestion for sample placement within the microplate.

NOTE: *The procedure described in this step is the most convenient way to generate a Sample List. Sample Lists can be created manually and automatically generated lists can be edited prior to run start, refer to Chapter 12.3. However, Gyros Protein Technologies recommends using the automatically generated Sample Lists as this will reduce the risk of errors.*

14.	Comments for the Run Design can be made in the Comments window, for example what type of assays the Run Design is intended for.
15.	Save the Run Design.
16.	Click Close to finish the Design Run procedure.

I4.3 Prepare ADA Run

To prepare an ADA Run, the same procedure is used as when preparing a Wizard Run, see chapter I2.4.

I5 LIMS Software workflow using Gyrolab Client

I5.1 Introduction

The LIMS workflow differs from the workflow for Design Type Wizard using Gyrolab Client (Chapter I2). Sample preparation (C4), run start (I7) and run finish (C5) procedures are the same for both. Hence, only LIMS module specific parts of performing a run is described in this section.

Step	Wizard Run Design	LIMS Run Design
Create or Edit Run Design	- Select Wizard Run Design type - Enter experiment parameters - Save Wizard Run Design Chapter I2.2	- Select LIMS Run Design type - Enter experiment parameters - Set result file output format - Save LIMS Run Design Chapter I5.2
Sample List or Worklist(s)	Sample List generated by: - Gyrolab Control or - manual editing (.xls) Chapter I2.3	Worklist(s) generated by: LIMS Chapter E3.3
Prepare Run	- Select Wizard Run - Select Sample List - Enter experimental parameters - Set name and folder for result files - Set name and folder for reports - Generate Loading List Chapter I2.4	- Select LIMS Run - Select Worklist(s) - Enter experimental parameters - Set name and folder for result files - Set name and folder for reports - Generate Loading List Chapter I5.3

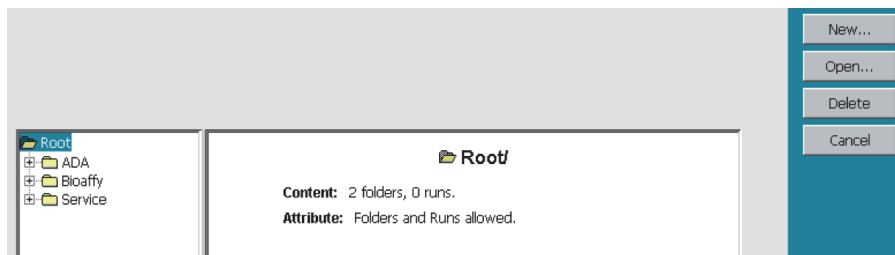
I5.2 Create or edit a LIMS Run

There are three options available when setting up a new Run Design:

- Create a new Run Design, proceed with I5.2
- Edit an existing Run Design (use when similar but not identical experiment design is wanted), proceed with I5.2
- Use an existing Run Design (use when identical experiment design is wanted), go to I5.3

Step Action

1. Click **Design Run** on the Main menu. The **Run** screen appears.



2.
 - To create a new Run Design, click **New**. Enter a Run Design name in the **Run Name** field.
 - To edit an existing Run Design, browse and select the desired Run Design and click **Open**.
3.
 - Select **LIMS** in the **Design Type** list and click **Select**. The **LIMS** panel appears:

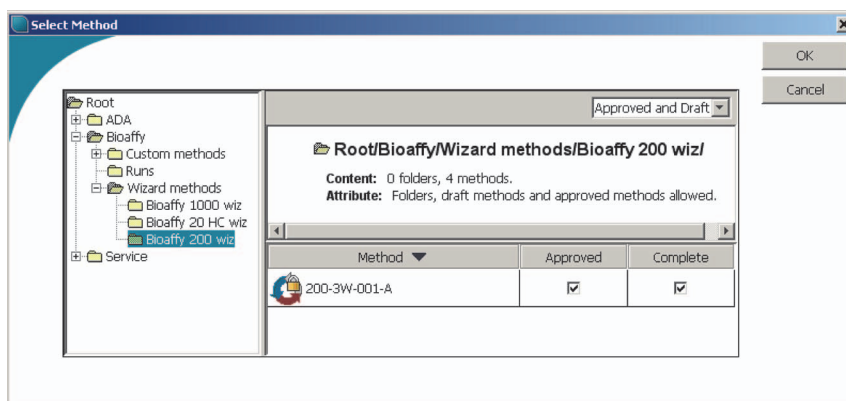
- To change design type, highlight the design type in the **Design type** list and click **Reselect**.
- Comments for the Run Design can be made in the **Comments** window, for example what type of assays the Run Design is intended for.

Step Action

4. Select **Method** and click **Select**.



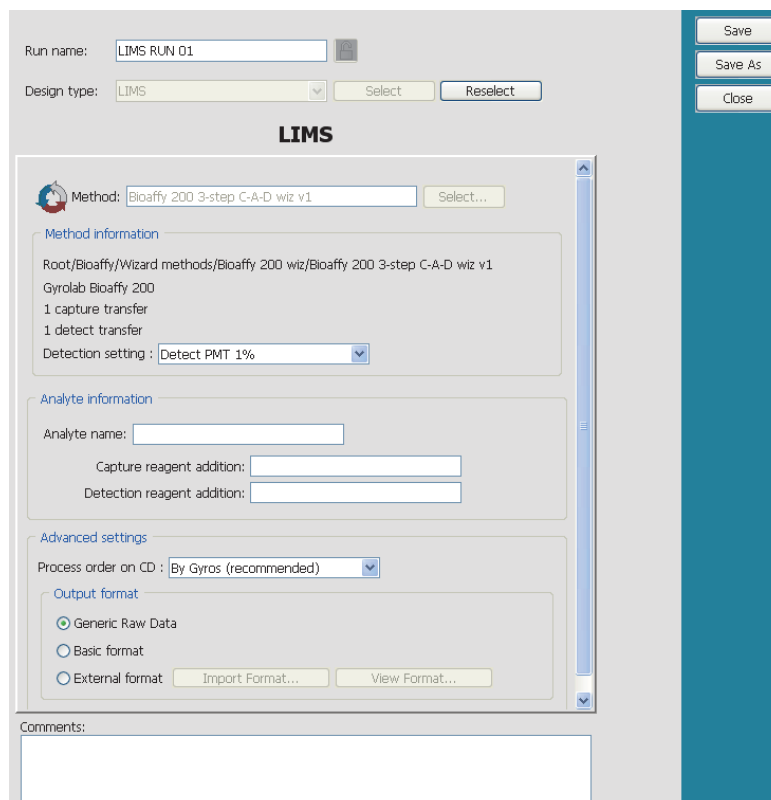
The **Select Method** dialog opens.



Browse and select desired Method in the folder structure. Click **OK**.

NOTE: Use the Method that was used during assay development.

5. It is now possible to add and edit **Method information**, **Analyte information** and **Advanced settings**.



6. In the **Method information** panel, select a detection setting from the **Detection setting** list. Result files will only contain data for the selected detection level.

Step	Action

7.	In Analyte information panel set:

	• Analyte name • Capture reagent name(s) (Capture reagent addition) • Detection reagent name(s) (Detection reagent addition)

	NOTE: <i>The number of capturing and detecting reagents displayed may differ depending on the Method (1-step, 2-step, 3-step or 4-step).</i>

8.	In Advanced settings panel select:

	• Process order on CD. The selection defines how samples are distributed on CDs. Options available: • As Work List. Select this option to place samples in the order defined in the worklist generated in the LIMS. • By Gyros. Gyrolab Control distributes samples on CDs to achieve optimal distribution of sample replicates. • Output format. Options available: • Generic Raw Data (default). All work list information and results are exported in tab delimited text format (.txt) compatible with Watson LIMS. • Basic format. Sample Name and results are exported in tab delimited text format (.txt). • External format. Click Import Format button to browse and select desired format. Click View Format button to view selected format. External format is used when a customized output format is required, contact Gyros Protein Technologies for more information.

9.	• To save a new LIMS Run Design, click Save. In the Save as window, browse to select folder and click Save. • To save an edited LIMS Run Design, click Save as. Name the Run Design, browse to select folder and click Save. If Save is clicked the information on the original Run Design will be replaced with the edited information.

	NOTE: <i>If any information added to the LIMS Run Design is incomplete or erratic an error message will be presented. The specified issues must be addressed before it is possible to save.</i>

10.	Click Close to finish the Design Run procedure.

I5.3 Prepare LIMS Run

Step	Action
1.	Click Execute Run on the Main menu.
2.	Click Run... Run Setup... is used to execute Runs defined by a Run Setup created in Gyrolab Manager. See Chapter B5.
3.	Browse and select desired Run Design from the list and click OK .
4.	A screen is opened. LIMS data is displayed.

- **List Loader** file sets rules for how to import worklists. Choose the **WorkList-Loader** option in the drop-down menu.
- Define number of work lists:
 - Check **One Work List per CD** box if multiple work lists (one per CD) has been defined in the LIMS. Go to step 4.
 - Un-check **One Work List per CD** box if one worklist is used for all CDs. Go to step 5.

Step Action

5. Option "one Work List per CD":

For each CD and worklist:

- Click **Work List File**. In the **Select Work List File** window, browse and select Work List for current CD.
- Required CD segments is shown in the CD symbol.
- Click **Info** for CD of interest to view sample information. Check Show replicate ID:s box to show information about sample replicates.
- Click **Clear** to remove a Work List.
- Continue to step 6.

Run: LIMS Run 001

One Work List per CD ☒

List Loader: WorkListLoader

Number of samples: 44

Segments Used

CD Symbol	Segments	Info	Text Field	Work List File...	Clear
	11	Info	C:\Gyrolab\SEQ\13_88.SEQ	Work List File...	Clear
	0	Info		Work List File...	Clear

6. Option "one Work List for all CDs":

- Click **Work List File**. In the **Select Work List File** window, browse and select Work List.
- Required CD segments per CD are shown in the CD symbols.
- Click **Info** for CD of interest to view sample information. Check Show replicate ID:s box to show information about sample replicates.
- Continue to step 6.

Trial period until Feb 6, 2010

Run: LIMS Run 001

One Work List per CD ☐

Work List File...

List Loader: WorkListLoader

Number of samples: 0

Segments Used

CD Symbol	Segments	Info
	0	Info
	0	Info
	0	Info
	0	Info
	0	Info

One MP per CD ☒

Step Action

7.
 - Check **One MP per CD** to place all samples for one CD on individual microplates.
 - Un-check **One MP per CD** to let the software distribute samples on microplates.

8. Click **Loading List**.

Gyrolab Control Loading screen is opened.

Pos	Reagent/Sample	Concentration	Dilution	Vol. [µl]	Well	
1	Standard A_Blank	0.0	pM	1.0	4	A1
2	Standard A_1	1.0	pM	1.0	4	A2
3	Standard A_2	4.0	pM	1.0	4	A3
4	Standard A_3	16.0	pM	1.0	4	A4
5	Standard A_4	64.0	pM	1.0	4	A5
6	Standard A_5	256.0	pM	1.0	4	A6
7	Standard A_6	1024.0	pM	1.0	4	A7
8	Standard A_7	4096.0	pM	1.0	4	A8
9	Wash Solution			100		A9
10	Wash Solution			100		A10
11	Standard B_Blank	0.0	pM	1.0	4	B1
12	Standard B_1	1.0	pM	1.0	4	B2
13	Standard B_2	4.0	pM	1.0	4	B3
14	Standard B_3	16.0	pM	1.0	4	B4
15	Standard B_4	64.0	pM	1.0	4	B5
16	Standard B_5	256.0	pM	1.0	4	B6

- **Gyrolab Control Loading** holds microplate loading information and is used when preparing microplates for a run. Name, concentration, volume, microplate and well position is included for all sample types. An overview of microplates with indication of used wells is also provided.
- Click **Printer** button to print the **Gyrolab Control Loading**.

TIP: *Select File: Export to export the Loading list in PDF or text format. This is useful when printing from another computer is required.*

9. Close **Gyrolab Control Loading**.

Click **OK**.

10. To continue with Targets and Report settings, Start and After Run procedures proceed to Chapter I7.

11. For sample and reagents preparations proceed to Chapter C3.

I6 Affinity Software workflow using Gyrolab Client

16.1 Introduction

The Gyrolab Affinity Software consists of an add-on module introduced to facilitate design of in-solution affinity runs. For more information on the Affinity software, see Chapter E5.1.

This chapter describes how to create Affinity runs using Gyrolab Client.

16.2 Create or Edit an Affinity Run

16.2.1 Design Method

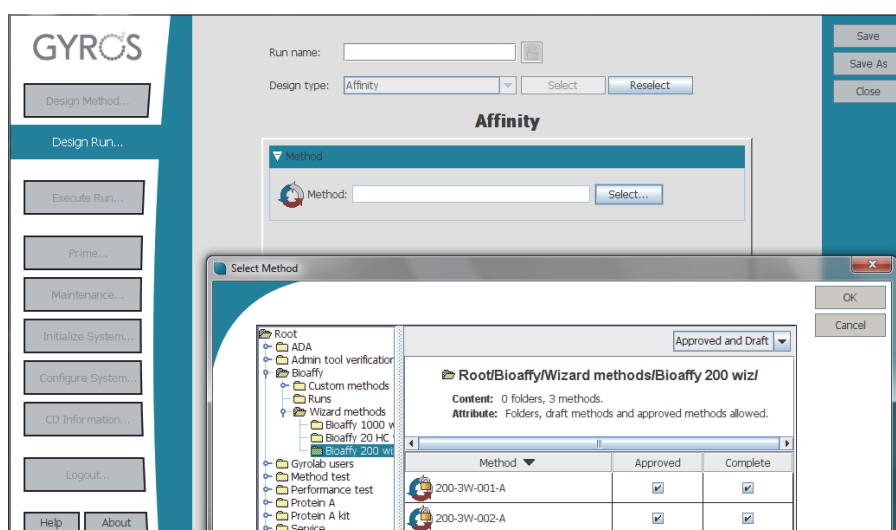
See recommendation in the Affinity Assay Guidelines on which method should be used.

16.2.2 Design Run

This chapter describes how to create or edit an Affinity Run Design using the Affinity Design Type in Gyrolab Client.

Step Action

1. Click **Design Run** on the Main menu of Gyrolab Control. The **Run** screen appears.
2.
 - To create a new Run Design, click **New** and continue with step 3.
 - To edit an existing Run Design, browse and select the desired Run Design and click **Open**. Change desired parameters. For instructions, refer to step 3-14.
3. Enter a Run Design name in the **Run Name** field.
Select Affinity in the **Design Type** list and click **Select**. The **Affinity** panel appears.



Step	Action

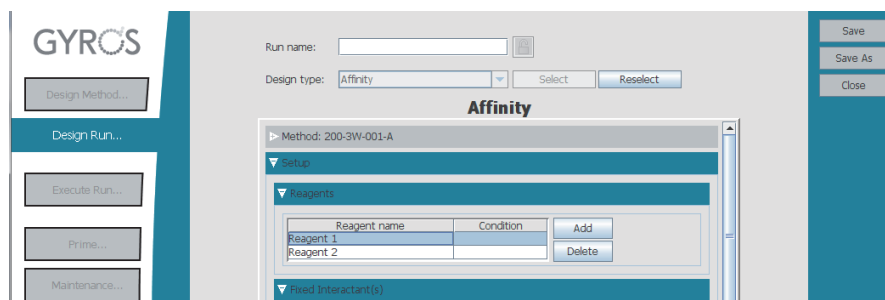
4.	In the Method section, click Select .

The **Select Method** dialog is opens.

Browse and select desired Method. Click **OK**.

The selected method is added to the run design and the method information is displayed. See the Affinity assay protocol for recommendation on which of the Gyros Protein Technologies default methods should be used.

5.	Select Setup .



6.	Select Reagents . The number of reagents may differ depending on what assay format and method is selected.

NOTE: *The software will automatically add reagents to the design depending on the selected method. The number of reagents can be edited by the user.*

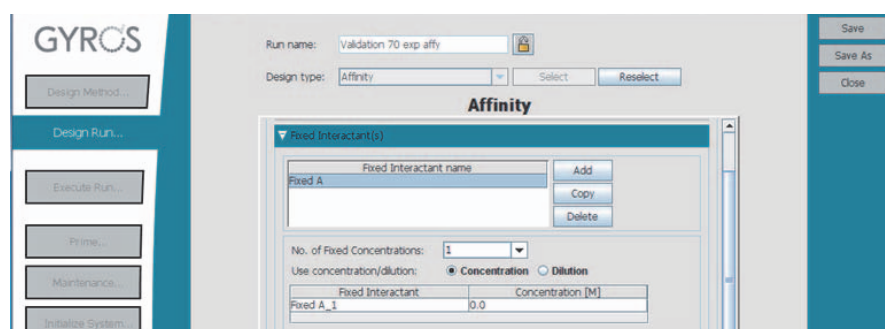
- Enter **Reagent name** for reagents. The **Condition** field is optional and can be used for additional information such as concentration value, matrix or buffer.
- Click **Add** to add additional reagents. Add and name each different reagent required for the assay.
- Highlight reagent and click **Delete** to remove reagent.

Step Action

7. Select **Fixed Interactant(s)**.

Here the Fixed Interactant(s) used in the affinity analysis is/are defined.

- As default the software will automatically define one fixed interactant, Fixed A. It is possible to rename the Fixed Interactant.
- Click **Add** to add additional Fixed Interactants.
- To copy settings of one Fixed Interactant to a new, highlight desired Fixed Interactant and click **Copy**. The new Fixed Interactant can be edited.
- Highlight a Fixed Interactant and click **Delete** to remove a Fixed Interactant.



- To set the number of fixed concentrations or dilutions for a Fixed Interactant click and highlight the Fixed Interactant and use the **No. of Fixed Concentrations/Dilutions** drop-down menu. A maximum of 10 Concentrations or Dilutions can be set.
- To set Concentration or Dilution for the Fixed Interactant click and highlight the Fixed Interactant and use the **Use Concentration/Dilution** radio buttons.
- Enter the Concentration or Dilution for a Fixed Interactant in the Fixed Interactant table. The software will automatically name the individual Fixed Interactants in the table.

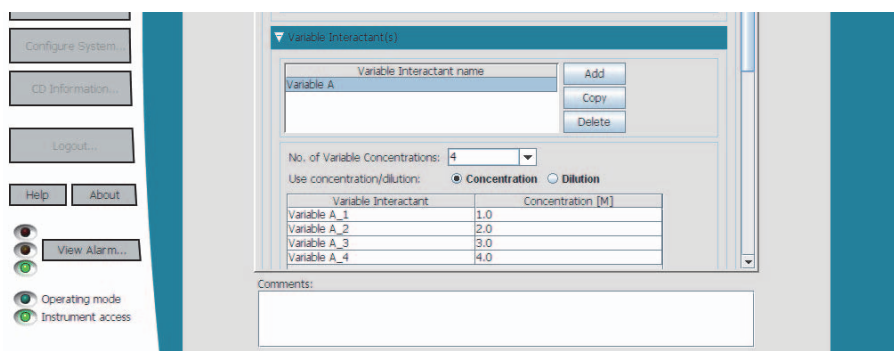
NOTE: *The concentration is given in molar and the dilution is given as reciprocal dilution factor (value ≥ 1).*

Step Action

8. Select **Variable Interactant(s)**.

Here the Variable Interactant(s) used in the affinity analysis is/are defined.

- As default the software will automatically define one Variable Interactant, Variable A. It is possible to rename the Variable Interactant.
- Click **Add** to add additional Variable Interactants.
- To copy settings of one Variable Interactant to a new, highlight desired Variable Interactant and click **Copy**. The new Variable Interactant can be edited.
- Highlight a Variable Interactant and click **Delete** to remove a Variable Interactant.



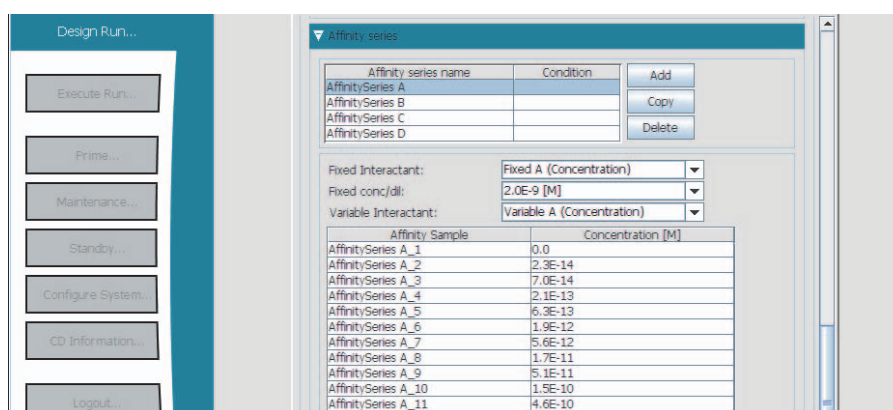
- To set the number of variable concentrations or dilutions for a Variable Interactant click and highlight the Variable Interactant and use the **No. of Variable Concentrations/Dilutions** drop-down. A maximum of 32 concentrations or dilutions can be set per Variable Interactant.
- To set Concentration or Dilution for the Variable Interactant click and highlight the Variable Interactant and use the **Use Concentration/Dilution** radio buttons.
- Enter the concentration or dilution factor for a Variable Interactant in the Variable Interactant table. The software will automatically name the individual Variable Interactant samples.

Step Action

9. Select **Affinity Series**.

Here the Affinity series is/are defined.

- As default the software will automatically define one Affinity series, Affinity Series A. It is possible to rename the Affinity series.
- Click **Add** to add additional Affinity series.
- To copy settings of one Affinity series to a new, highlight desired Affinity Series and click **Copy**. The new Affinity series can be edited.
- Highlight an Affinity series and click **Delete** to remove an Affinity series.



- Set the Fixed Interactant and concentration or dilution for the Affinity Series in the Fixed Interactant and **Fixed conc/dil** drop-downs.
- Set the Variable Interactant for the Affinity series in the **Variable Interactant** drop-down. Only Fixed Interactants and Variable Interactants specified can be chosen.

Step Action

10. Select **Experiments** to set up one or several Affinity Experiments.

Affinity series name	Condition	Use
AffinitySeries A		☒
AffinitySeries B		☐
AffinitySeries C		☐
AffinitySeries D		☐

Fixed Interactant: Fixed A
Fixed Interactant Concentration: 2.0E-9 [M]
Variable Interactant: Variable A

Affinity Sample	Concentration [M]	Replicates
AffinitySeries A_1	0.0	2
AffinitySeries A_2	2.3E-14	2
AffinitySeries A_3	7.0E-14	2
AffinitySeries A_4	2.1E-13	2
AffinitySeries A_5	6.3E-13	2
AffinitySeries A_6	1.9E-12	2
AffinitySeries A_7	5.6E-12	2
AffinitySeries A_8	1.7E-11	2
AffinitySeries A_9	5.1E-11	2
AffinitySeries A_10	1.5E-10	2
AffinitySeries A_11	4.6E-10	2
AffinitySeries A_12	1.4E-9	2
AffinitySeries A_13	4.1E-9	2

Enter a name for the Experiment in the **Name** field.

- Select reagent(s) from the drop-down lists. The number of reagent fields is determined by the number of reagent transfer operations in the method.
- The reagent field names are determined by the reagent transfer operation names in the method.
- Select the Affinity series that shall be included in the Experiment by marking the check box in the table.
- Information of the Affinity Series can be obtained by highlighting an Affinity Series in the table. The information presented is selected Fixed Interactant, Fixed Interactant concentration or dilution and Variable Interactant.

NOTE: Only specified reagents and Affinity Series are available.

The individual Affinity samples are presented in a table with concentration or dilution and number of replicates.

NOTE: It is possible to set the number of replicates for each Affinity sample.

- To set the number of replicates for a specific affinity sample click on a cell in the Replicates column for an Affinity sample.

TIP: By right-clicking on the Replicates heading in the table all replicates can be set at once.

Add additional Experiments to an Analyte by clicking **+** on the **Experiments** bar.

Delete Experiment by clicking **X** on the specific **Experiment** bar.

When the experimental setup is complete, **Save** the Run Design.

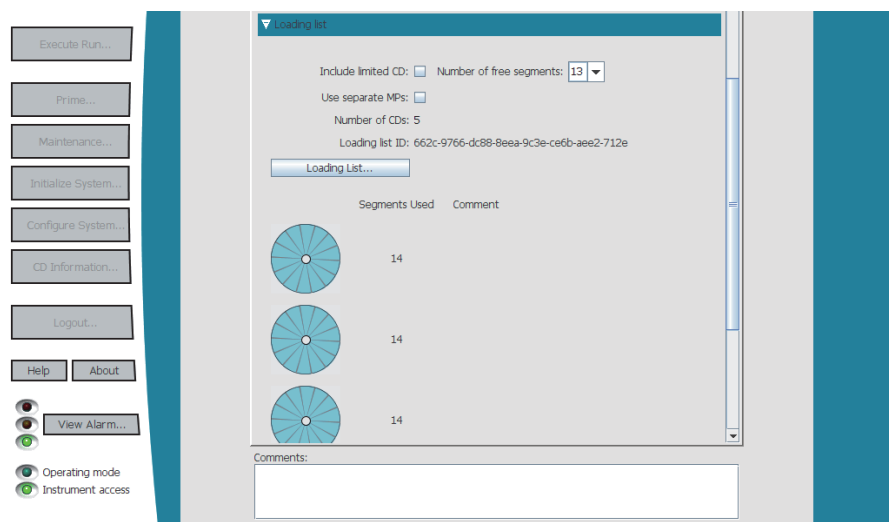
Step Action

11. Select **Loading List**.

The **Loading list** screen is opened.

The user can view the microplate well positions of samples and reagents, volume requirements and number of CDs needed for the Run. It is also possible to view the microplate overview which can be useful in the preparation for the Run.

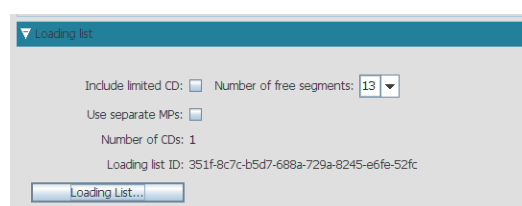
NOTE: *This can be very useful when preparing Affinity experiments where the samples need a longer incubation before the Run.*



NOTE: *To be able to see the loading list information the Run needs to be saved.*

- If it is desired to use a CD that previously has been partially used, check **Include limited CD** and define number of available segments in the **Number of free segments** list.
- To use separate microplates for Affinity sample and reagents (including wash solutions) check the **Use separate MPs** check box.

A **Loading list ID** is shown for the saved Run. This ID can be used to check that the loading list shown in the Execute run procedure is the same as shown when the run was designed.



To view the **Gyrolab Loading List** click on **Loading List....**

Gyrolab Loading List screen is opened.

Gyrolab Loading List holds microplate loading information and is used when preparing microplates for a Run. Name, concentration, volume, microplate and well position are included for all sample and reagent types. An overview of microplates with indication of used wells is also provided.

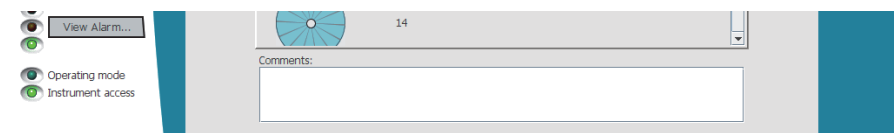
Step Action

Click on the **Printer** button to print the **Gyrolab Control Loading**.

TIP: *Select File: Export to export the Loading list in PDF format. This is useful if printing from another computer.*

GYROS Gyrolab Loading List					
Run name	User Guide				
CD name	Gyrolab Bioaffy 200				
Number of samples	8				
Used CD	No				
Separate MP	No				
Loading list ID	351f-8c7c-b5d7-688a-729a-8245-e6fe-52fc				
Affinity Series	Fixed interactant	Conc. [M]	Dilution	Variable interactant	
AffinitySeries C	Fixed B	1.0E-10		Variable A	
CD segments used					
					
Microplate	Type				
R-MP1	MP96 PCR				
Pos	Reagent/Sample	Conc. [M]	Dilution	Vol. [µl]	Well
1	AffinitySeries_C_1	0.0		4	A1
2	AffinitySeries_C_2	1.0		4	A2
3	AffinitySeries_C_3	2.0		4	A3
4	AffinitySeries_C_4	3.0		4	A4
5	AffinitySeries_C_5	4.0		4	A5
6	AffinitySeries_C_6	5.0		4	A6
7	AffinitySeries_C_7	6.0		4	A7
8	AffinitySeries_C_8	7.0		4	A8
9	Wash Solution			100	A9
10	Reagent 1			16	B1
11	Reagent 2			16	B2

12. Comments for the Run Design can be made in the **Comments** window, for example what type of assays the Run Design is intended for.



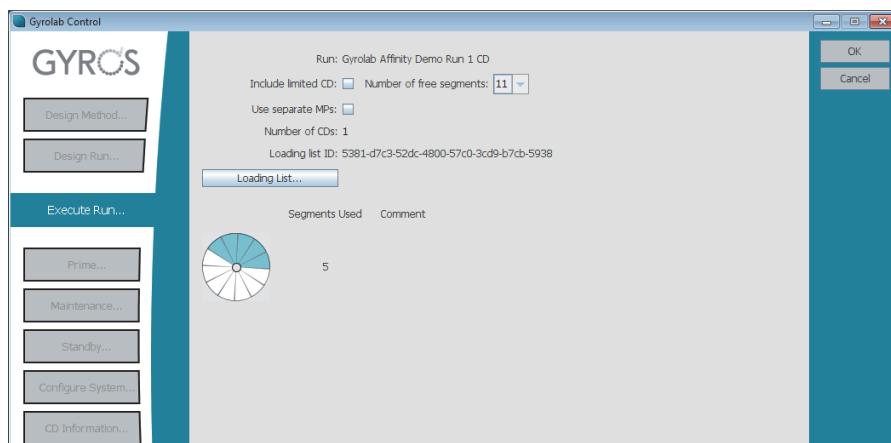
13. **Save** the Run Design.
14. Click **Close** to finish the Design Run procedure.

I6.3 Prepare Affinity Run

Sample preparation is carried out as described in the Affinity Assay Guidelines. The protocol is included in the purchase of Gyrolab Affinity Software. This chapter describes run preparation for an Affinity Run.

Step Action

1. Click **Execute Run** in the Main menu of Gyrolab Control (refer to Chapter G1.2).
2. Click **Run...**
Run Setup... is used to execute Runs defined by a Run Setup created in Gyrolab Manager. See Chapter B5.
3. Browse and select desired **Run Design** from the list and click **OK**.
4. The Execute Run screen is opened.



Click **Loading List**.

Gyrolab Control Loading screen is opened.

- **Gyrolab Control Loading** holds microplate loading information and is used when preparing microplates for a run. Name, concentration, volume, microplate and well position is included for all sample types. An overview of microplates with indication of used wells is also provided.
- Click on the **Printer** button to print the **Gyrolab Control Loading**.

TIP: *Select File: Export to export the Loading list in PDF format. This is useful when printing from another computer is required.*

Close **Gyrolab Control Loading**.

TIP: *Check that the Loading List ID generated during this step is the same as the Loading list generated in the design of the run*

5. Click **OK**.
To continue with Targets and Report settings, Start and After Run procedures proceed to Chapter I7.
6. Prepare samples and reagents as described in the Affinity Assay protocol.

I7 Start and Finish Run from Gyrolab Control Run Design

The workflow described in this chapter is used when starting a Run based on a Run Design, where unknown samples are added as part of starting run Execution.

The first steps after clicking **Execute Run** are different for the different Design types and are described in I2.4, I3.5, I4.3, I5.3, I6.3.

I7.1 Targets and Reports

The workflow below begins with **Targets** and **Reports** settings.

Step Action

- NOTE:** *The workflow is the same for all targets, the names of fields and folders differ. This workflow describes Gyrolab Evaluator.*

In the **Targets** tab, choose **Gyrolab Evaluator**.

Result files from the run are always saved in Gyrolab Result Database. To create local copies of the result files (optional), mark the check box **Copy file(s) to disc**.

Files are saved to the location specified in **Gyrolab Evaluator result folder** field and with the name specified in **Gyrolab Evaluator result file name**. Settings are pre-served from the user's last Run.

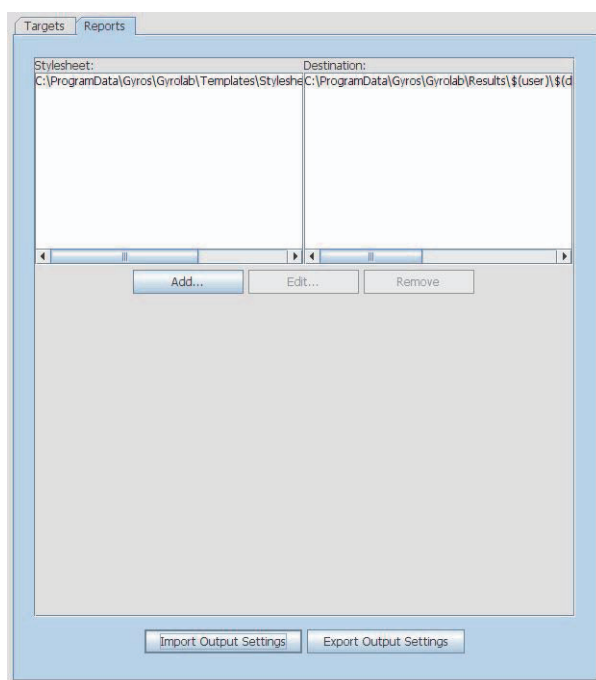
- To import default settings for **Gyrolab Evaluator result folder** and **Gyrolab Evaluator result file name**:
 - Click **Import Target Settings**.
 - In the **Import Settings** dialog, browse to C:\ProgramData\Gyros\Gyrolab\Templates\Default Settings, select **GyrolabEvaluatorTargetSettings.xml** and click **Import**.
- To customize settings for **Gyrolab Evaluator result folder** and **Gyrolab Evaluator result file name**:
 - To edit **Gyrolab Evaluator result folder**, click **Browse**. Browse and click **Select** to set new folder in the **Select folder** dialog.
 - To edit **Gyrolab Evaluator result file name**, click in the field and edit.

TIP: *Macros can be used to construct file names and locations, refer to Chapter I2.5 for a list of available macros.*

TIP: *The settings in the **Targets** tab can be exported and imported, which enables settings to be shared between users, instruments and projects.*

Step Action

2. The Targets tab, **Gyrolab Report** section contains settings specific for the software module Gyrolab Control Report and is only available if a licence for Gyrolab Control Report has been acquired. Refer to Chapter E4.2 for more information.
3. Open **Reports** tab.



A report file that holds method information can be generated.

- To import default settings for report file **Stylesheet** and **Destination**:
 - Click **Import Output Settings**.
 - In the **Import Settings** dialog, browse to C:\ProgramData\Gyros\Gyrolab\Templates\Default Settings, select **ReportSettings.xml** and click **Import**.
- If no report file is wanted, select the file present in **Stylesheet** and click on **Remove** button.

TIP: *Customized reports can be generated. Contact Gyros Protein Technologies for information.*

Click **OK**.

I7.2 Load Gyrolab Instrument

Step Action

1. The following screen is shown after the clicking **OK** in the last step in Chapter I7.1

Run: ProteinQuantification 2
 CD type: Gyrolab Bioaffy 200
 Execution name:
 MP cooling: ☐ Enable cooling for sample and reagent MPs

Samples

MP type:

Identity	Loaded	No. of Samples
MP1	No	26

CD data

Identity	Segments	CD Status

1 CD is needed, 0 loaded.

Wash Station Solutions

Solution	Wash Station
Bioaffy wash station solution 2	2
Bioaffy wash station solution 1	1

Pump Liquids

Liquid	Pump
Bioaffy pump liquid	1, 2, 3, 4, 5

Reagents

Name	Identity	Available
g-MP1		Not Loaded

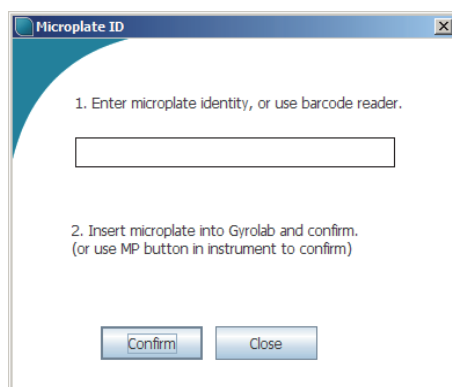
The screen is a check list for the loading steps. Upon completion of each step, the corresponding green indicators on the left panel is lit. A Run cannot be started until all indicators are lit.

Click **MP cooling** to enable cooling of loaded microplates during Run execution.

I7.2.1 Load sample microplates

Step	Action

1.	Click Load in the Samples section. The Microplate ID dialog appears:



- Either scan the barcode ID, or click **Enter ID Manually** and enter microplate ID as stated in the Loading List.*
- Place the sample microplate in the microplate position indicated by the lit green LED beside the microplate positions in the instrument. See Gyrolab Instrument Guide for details.

NOTE: *If cooling of microplates is used during the Run, use the metal cooling microplate insert to get optimal cooling of sample and reagents.*

- Click **Confirm**. The microplate ID appears in the list on screen.

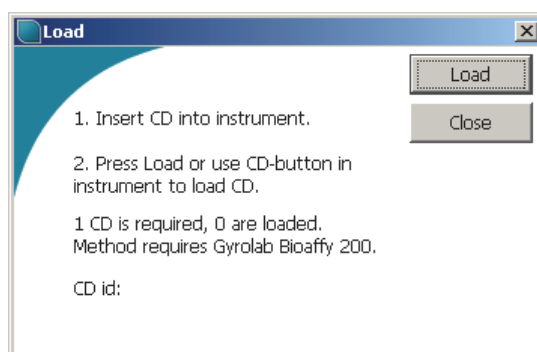
2.	Repeat for each sample microplate until all sample microplates are loaded.

* Ensure the BCR is configured so that **Enter** or **Carriage Return** is not added when scanning the identity of a MP

I7.3 Load CDs

Step	Action

1.	Put CDs in room temperature for 30 minutes (in the unopened aluminum pouches).
2.	Click Load in the CD Data section. The Load (CD) dialog opens.



Step Action

3. Open the aluminum pouch and place the CD in loading position. See Gyrolab Instrument Guide for details. Touch only the outer edge of the CDs. Do not touch the surface of the CD. Start the Run within 15 minutes after the CD has been taken out from its pouch. Protect the CD from extended illumination from indoor lighting or sunlight since this may affect data quality.

Click **Load** in **Load** dialog or press **CD** button on the instrument. See Gyrolab Instrument Guide for details. The system identifies the CD and the CD identity appears in the list on screen.

Repeat for all CDs.

NOTE: *The number of CDs required and the number that have been loaded are displayed at the bottom of the screen. The LED will not be lit until all required CDs have been loaded.*

I7.3.1 Confirm Wash Station Solutions and Pump Liquid

If solutions and liquids are available:

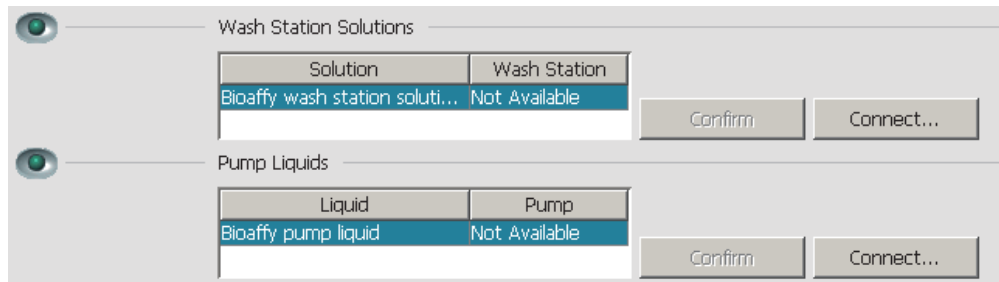
Wash Station Solutions	
Solution	Wash Station
Bioaffy wash station soluti...	1

Pump Liquids	
Liquid	Pump
Bioaffy pump liquid	1, 2, 3, 4, 5

Step Action

1. Make sure tubings for wash station solution and pump liquid are connected and system is primed according to Chapter C2.4.
2. Under **Wash Station Solutions**: Highlight the Wash Station Solution and click **Confirm**.
3. Under **Pump Liquid** section: Highlight the Bioaffy Pump Liquid and click **Confirm**.

If solutions and liquids are not available:



Step Action

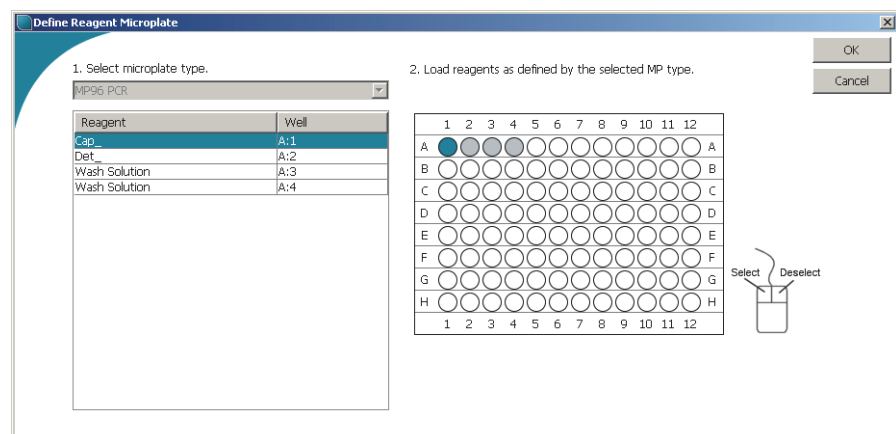
1. Make sure tubings for wash station solution and pump liquid are connected and system is primed according to Chapter C2.4.
2. Under **Wash Station Solutions**
 - Click **Connect**.

Click **OK** in the **Connect Wash Station** dialog that opens.
3. Under **Pump Liquids**
 - Click **Connect**.
 - Click **Confirm** in the **Pump Liquid** dialog that opens.

I7.3.2 Load reagent microplate

Step Action

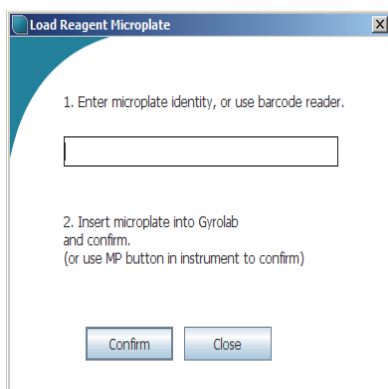
1. Click **Load** in the **Reagents** section. The **Define Reagent Microplate** dialog box is displayed.



2. Verify that the reagents are placed correctly in the microplate according to the Gyrolab Control Loading list.

Step	Action

3.	Click OK . The load reagent microplate dialog appears:



- Either scan the barcode ID, or click **Enter ID Manually** and enter microplate ID as stated in the Loading List.*
- Place the reagent microplate in the microplate position indicated by the lit green LED beside the microplate positions in the instrument. See Gyrolab Instrument Guide for details.

NOTE: *If cooling of microplates is used during the Run, use the metal cooling microplate insert to get optimal cooling of sample and reagents.*

- Click **Confirm**. The microplate ID appears in the list on screen.

4.	Repeat for each reagent microplate until all reagent microplates are loaded.

* Ensure the BCR is configured so that **Enter** or **Carriage Return** is not added when scanning the identity of a MP

I7.4 Start Run

When loading is completed, as confirmed by all green indicators being lit on screen, the Run can be started.

Step Action

1. Close the instrument hatch. A lock indicator indicates if the hatch has been properly locked.

If the hatch has not been properly locked, press down the hatch to activate the lock.

The lock indicator can be clicked to unlock the hatch again, in case some step in the loading must be corrected.

Hatch unlocked:

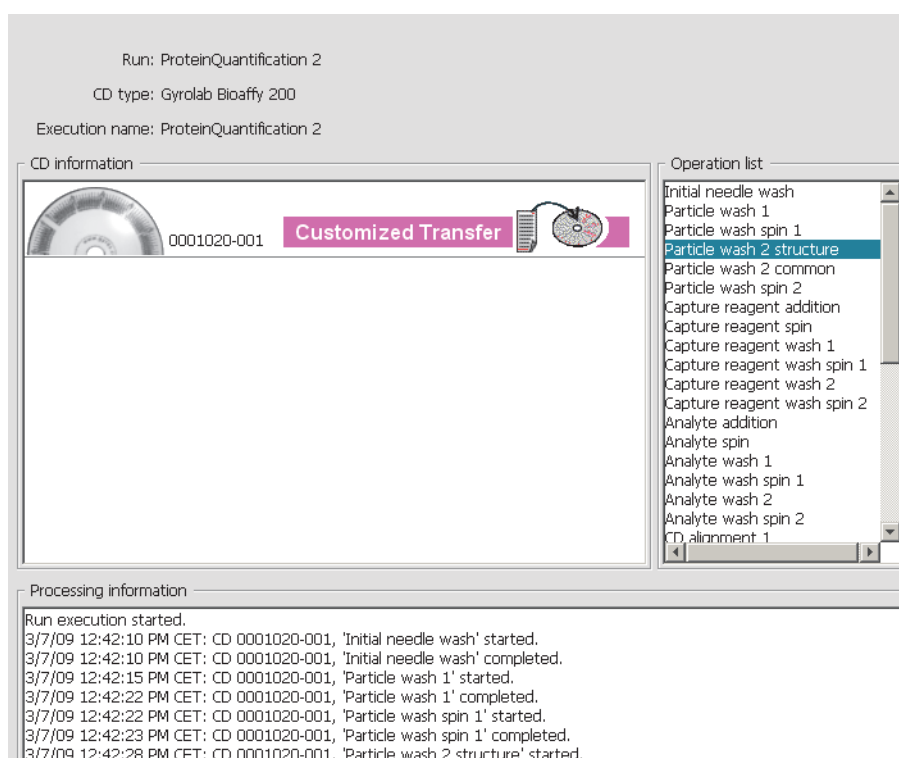


Hatch locked:



2. Click **Start**.

An event log is displayed where all steps of the Run are registered along with event time.



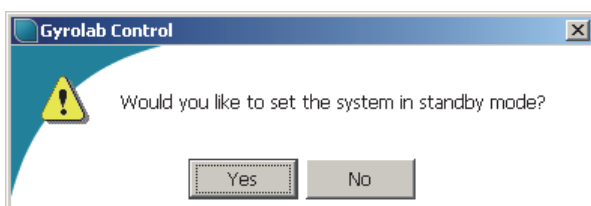
3. It is possible to pause or abort an ongoing run:
 - To stop an ongoing Run, click **Abort**. The Run is immediately terminated and cannot be resumed. Remove all CDs and microplates as described in Chapter C5.1. Do not use results or CDs from aborted Runs as there is a risk that data or the CDs may have been corrupted.
 - The pause an ongoing run, click **Pause**. To resume the Run, click **Resume**.
4. The system stops automatically when the run is completed. Click **Finish**.

17.5 Finish Run

When the Run is completed microplates and CDs must be unloaded from the instrument. Unloading is carried out in the same way as the system is loaded, that is by following the instructions on the screen.

After each step has been completed, a green indicator is lit on the left side of each section.

Step	Action
1.	Click Finish. NOTE: <i>Finish cannot be activated until all indicators are lit in the screen to indicate that unloading is complete.</i> The Standby dialog opens. - If another Run is scheduled later during the day, click No and start the new run. - If it is the last Run of the day, click Yes. The Ensure enough standby solution is available dialog opens. Connect tubings for Standby solutions and click OK. Standby procedures will start. Standby procedures means priming Syringe Pumps and Wash Stations with Standby Solution. It is recommended to put system in Standby mode at least three times a week. For more information, refer to Gyrolab Instrument Guide.
2.	For Gyrolab xPand, remove the metal cooling microplate insert. Wipe microplate positions dry if cooling of microplates has been used.



I8 Default User Roles and User Privilege Descriptions

This chapter describes default User Roles provided with Gyrolab. It also describes all User Privileges and how these are assigned to the default User Roles. Custom User Roles can be created. For more information, see Chapter B8.2.

System Administrators have unlimited user privileges. They can perform all actions of all other pre-defined user roles as well as some actions unique to System Administrators, such as creating and editing other users. Complete user role privileges are indicated by ticked boxes below.

An **Operator** can perform runs, including creating Run Setups in Gyrolab Manager, but cannot create or edit Run Designs or configure the system. Complete user role privileges are indicated by ticked boxes below.

An **Executor** is similar to **Operator** but can only execute runs setup by some other user. This includes executing a Run Setup created from Gyrolab Manager (**Execute Run:Run Setup**), but excludes executing a run directly from a Run Design (**Execute Run:Run**). An **Executor** is not allowed to define the Unknown samples to process in a run. Complete user role privileges are indicated by ticked boxes below.

A **Method Developer** can develop methods and configure or align the system. In addition, a **Method Developer** can perform all actions of **Operators**. Complete user role privileges are indicated by ticked boxes below.

A **Project Manager** can perform administrative tasks such as creating folders, importing and exporting objects and approve projects in Gyrolab Evaluator. In addition, a **Project Manager** can perform all actions of **Operators** and **Method Developers**. Complete user role privileges are indicated by ticked boxes below.

An **Auditor** can inspect different records and items in the software, but cannot create, execute or edit existing runs or configure the system. Complete user role privileges are indicated by ticked boxes below.

There is also a **Service** user role used by Gyros during service.

The first table below describes the privileges common for all Gyrolab software, followed by a table specific to Gyrolab Evaluator. These chapters describe privileges in more detail and show the privileges for the default roles. Some privileges also have dependencies on each other, which is shown after the privilege table in each chapter.

Gyrolab Control and Gyrolab Manager

NOTE: Some privileges are related to Run Design (new terminology in Gyrolab Manager and in selected sections of Gyrolab Control 8.0). In many sections of Gyrolab Control, the former term "Run" is still used. Below, the term "run design" is used.

Privilege name	Description	System Administrator	Operator	Method Developer	Project Manager	Executor	Auditor
Archive QC set	Grants the user the privilege to archive a QC set.	X		X	X		
Configure instrument	Grants the user the privilege to configure syringe pumps and wash stations on the panel "Configure System" in Gyrolab Control Client.	X		X			

Privilege name	Description	System Administrator	Operator	Method Developer	Project Manager	Executor	Auditor
Configure system	Grants the user the privilege to change system settings (e.g. password properties, timeout, import LIMS-related data).	X					
Create new method	Grants the user the privilege to create a new method on the panel "Design Method" in Gyrolab Control Client. This privilege also allows the user to save an existing method to a new name (i.e. "Save as...").	X		X	X		
Create new run design	Grants the user the privilege to create a new run design on the panel "Design Run" in Gyrolab Control Client or in Gyrolab Manager. This privilege also allows the user to save an existing run design with a new name (i.e. "Save as..."). In Gyrolab Manager, it also grants the user the privilege to create a run setup without basing it on a run design	X		X	X		
Create new user	Grants the user the privilege to create a new user in Gyrolab Manager's User Administration. Note that a user with this privilege can create a user with any role, including System Administrator.	X					
Create new user role	Grants the user the privilege to create a new user role and assign privileges to it in Gyrolab Manager's User Administration. Note that a user with this privilege can create a role with any privileges.	X					

Privilege name	Description	System Administrator	Operator	Method Developer	Project Manager	Executor	Auditor
Create run setup	Grants the user the privilege to create, edit (including rename and move) and/or delete run setups in Gyrolab Manager, including saving with a new name (i.e. "Save as..."). This does not however apply to run setups that is not created from a run design. To create and save such a run setup with a new name, the 'Create new run design' privilege is required. Similarly, to edit it, the 'Edit run design' privilege is required. Lastly, to delete such a run setup, the 'Delete run design ' privilege is required. In Gyrolab Control Client, the operation that corresponds to creating a run setup is to execute a run based on a run design, and adding samples to be processed. Consequently, the Create run setup privilege is required to execute runs that way. (In contrast, to start execution for an already created run setup, it is sufficient to have the Start run privilege.)	X	X	X	X		
Create QC set	Grants the user the privilege to create a new QC set to be selectable in a Run Design and used for QC trending.	X		X	X		
Delete approved methods	Grants the user the privilege to delete approved methods by right-click and selecting delete in Gyrolab Manager Approved methods cannot be deleted in Gyrolab Control Client.	X			X		
Delete method	Grants the user the privilege to delete methods on "Design Method" in Gyrolab Control Client and by right-clicking and selecting delete in Gyrolab Manager.	X		X	X		

Privilege name	Description	System Administrator	Operator	Method Developer	Project Manager	Executor	Auditor
Delete run design	Grants the user the privilege to delete runs designs on "Design Run" in Gyrolab Control Client, and in Gyrolab Manager. In Gyrolab Manager, it also grants the user the privilege to delete a run setup that is not based on a run design.	X		X	X		
Disable user	Grants the user the privilege to disable an existing user in Gyrolab Manager's User Administration. Note that users cannot be deleted.	X					
Edit all folders	Grants the user the privilege to edit (including edit and view access properties to a restricted folder tree) and add any folder below root (i.e. add any level 1, 2, 3, ... folder), and delete folders on the panel "Folders" in Gyrolab Manager. The root folder (level 0), however, cannot be deleted, renamed or edited.	X					
Edit level 1 folders	Grants the user the following privileges: 1. Edit any level 1, 2, 3... folder (the root folder is level 0). Including edit and view access properties to a restricted folder tree. 2. Add any folder below level 1 folders (i.e. add any level 2, 3, 4, ... folder). 3. Delete any level 2, 3, 4, ... folder. The right to Add and Delete folders control the right to Move to and Move from. 4. Archive a level 1 folder.	X			X		

Privilege name	Description	System Administrator	Operator	Method Developer	Project Manager	Executor	Auditor
Edit level 2 folders	Grants the user the following privileges: 1. Edit any level 2, 3, 4, ... folder (the root folder is level 0). 2. Add any folder below level 2 folders (i.e. add any level 3, 4, 5, ... folder). 3. Delete any level 3, 4, 5, ... folder. The right to Add and Delete folders control the right to Move to and Move from.	X		X	X		
Edit method	Grants the user the privilege to edit, save and approve already existing methods on the panel "Design Method" in Gyrolab Control Client.	X		X	X		
Edit run design	Grants the user the privilege to edit (including rename in Gyrolab Manager), save and approve already existing run designs on the panel "Design Run" in Gyrolab Control Client, and in Gyrolab Manager. In Gyrolab Manager, it also grants the user the privilege to edit a run setup that is not based on a run design.	X		X	X		
Edit user	Grants the user the privilege to modify an existing user in Gyrolab Manager's User Administration, i.e. changing its role, login name, password, etc. Note that user roles supplied by Gyros cannot be modified. Note that a user with this privilege can assign any user role to any user, including System Administrator.	X					
Edit user role	Grants the user the privilege to modify an existing customer defined user role in Gyrolab Manager's User Administration. A change to an existing user role will affect all users assigned that role. Note that user roles supplied by Gyros cannot be modified. Note that a user with this privilege can set any privileges for all customer defined roles.	X					

Privilege name	Description	System Administrator	Operator	Method Developer	Project Manager	Executor	Auditor
Edit QC set	Grants the user privilege to edit an existing QC set, and therefore updating the version of the QC set.	X		X	X		
Export method	Grants the user the privilege to export methods in Gyrolab Manager.	X		X	X		X
Export readable method	Grants the user the privilege to export methods in a readable format in Gyrolab Manager.	X					X
Export readable run design	Grants the user the privilege to export run designs in a readable format from Gyrolab Manager.	X					X
Export run design	Grants the user the privilege to export run designs from Gyrolab Manager.	X		X	X		X
Export user list	Grants the user the privilege to export a list of users in PDF format in Gyrolab Manager's User Administration.	X			X		X
Export user role list	Grants the user the privilege to export a list of user roles in PDF format in Gyrolab Manager's User Administration.	X			X		X
Import method	Grants the user the privilege to import methods in Gyrolab Manager	X		X	X		
Import run design	Grants the user the privilege to import run designs in Gyrolab Manager.	X		X	X		
Instrument shutdown	Grants the user the privilege to shut down the instrument. Without this privilege the only option in the "Log Out"-dialog will be "Log off".	X	X	X	X	X	
Instrument startup	Grants the user the privilege to initialize the instrument.	X	X	X	X	X	
Manage CD	Grants the user the privilege to view CD information on the panel "CD information" in Gyrolab Control Client.	X	X	X	X	X	
Move method	Grants the user the privilege to move methods in Gyrolab Manager.	X		X	X		

Privilege name	Description	System Administrator	Operator	Method Developer	Project Manager	Executor	Auditor
Move run design	Grants the user the privilege to move run designs in Gyrolab Manager.	X		X	X		
Move Run Result	Grants the user the privilege to move Run Results in Gyrolab Manager.	X		X	X		
Perform maintenance	Grants the user the privilege to perform maintenance functions on the panel "Maintenance" in Gyrolab Control Client.	X	X	X	X	X	
Prime system	Grants the user the privilege to prime the system. This function is available from the menu items "Prime..." and "Standby..." in Gyrolab Control Client.	X	X	X	X	X	
Resolve warnings	Grants the user the privilege to resolve warnings on the alarm dialog in Gyrolab Control Client.	X	X	X	X	X	
Start run	Grants the user the privilege to start execution of runs on the panel "Execute Run" in Gyrolab Control Client. (Starting execution by selecting a Run Design and adding samples also requires Create run setup privilege. To start execution of a Run Setup, the Start run privilege is sufficient.)	X	X	X	X	X	
System alignment	Grants the user the privilege to align needles on the panel "Configure System" in Gyrolab Control Client.	X		X	X		
View method	Grants the user the privilege to view methods on the panel "Design Method" in Gyrolab Control Client.	X	X	X	X	X	X
View run design	Grants the user the privilege to view run designs on the panel "Design Run" in Gyrolab Control Client, or view content of run designs in Gyrolab Manager.	X	X	X	X	X	X
View run setup	Grants the user the privilege to view content of run setups in Gyrolab Manager.	X	X	X	X	X	X
View user audit trail	Grants the user the privilege to view and export the audit trail for a user. This is available in Gyrolab Manager.	X			X		X

Privilege name	Description	System Administrator	Operator	Method Developer	Project Manager	Executor	Auditor
View user role audit trail	Grants the user the privilege to view and export the audit trail for actions performed on a user role. This is available in Gyrolab Manager.	X			X		X

Gyrolab Control and Gyrolab Manager have the following privilege dependencies:

- "Start run" requires "Prime system" and "View run setup" (and thus, implicitly, "View run design").
- "Create new run design" and "Edit run design" require "View run design".
- "Create run setup" requires "View run setup".
- "Create run setup" and "View run setup" require "View run design".

Gyrolab Evaluator

Note that for Gyrolab Evaluator, the role Executor does not have any privileges. That is as intended, as the intended task for this role is (only) to execute runs on Gyrolab. Consequently, there is no column for role Executor below.

Privilege name	Description	System Administrator	Operator	Method Developer	Project Manager	Auditor
Administrate project	Grants the user the privilege to remove projects and recreate projects from earlier versions (not implemented) in Gyrolab Evaluator.	X			X	
Analyze	Grants the user the privilege to create, edit, include/exclude samples, add comments for samples, and add notes for, analyses in Gyrolab Evaluator.	X	X	X	X	
Approve project	Grants the user the privilege to approve Gyrolab Evaluator projects.	X			X	
Configure analysis	Grants the user the privilege to configure an analysis in Gyrolab Evaluator.	X	X	X	X	
Configure presentation	Grants the user the privilege to edit and show/hide graph legends in presentations in Gyrolab Evaluator.	X	X	X	X	
Configure report	Grants the user the privilege to configure report content (not implemented), view sample data w/ or w/o replicates, show/hide columns, add/remove columns (not implemented) in Gyrolab Evaluator.	X	X	X	X	
Edit project	Grants the user the privilege to save projects and add runs to a Gyrolab Evaluator project.	X	X	X	X	
Edit analysis samples	Grants the user the privilege to change parameters for samples, e.g. expected concentration, in Gyrolab Evaluator.	X		X	X	
Edit settings	Grants the user the privilege to edit general settings and global analysis settings in Gyrolab Evaluator.	X	X	X	X	
Export analysis result	Grants the user the privilege to export analysis data to file from project view in Gyrolab Evaluator.	X	X	X	X	X

Privilege name	Description	System Administrator	Operator	Method Developer	Project Manager	Auditor
Exporting project	Grants the user the privilege to export projects (not implemented) in Gyrolab Evaluator.	X	X	X	X	X
Export analysis data	Grants the user the privilege to export analysis data to file from analysis view in Gyrolab Evaluator.	X	X	X	X	X
Export report	Grants the user the privilege to print report and save report as PDF or XPS in Gyrolab Evaluator.	X	X	X	X	X
Lock settings	Grants the user the privilege to lock all analysis settings in Gyrolab Evaluator.	X	X	X	X	
Manage analysis	Grants the user the privilege to rename an analysis (not implemented) in Gyrolab Evaluator.	X		X	X	
Manage project	Grants the user the privilege to create, remove runs from, remove analysis from, move, and rename projects in Gyrolab Evaluator.	X		X	X	
Unapprove project	Grants the user the privilege to unapprove projects in Gyrolab Evaluator.	X				
Unlock settings	Grants the user the privilege to unlock all analysis settings in Gyrolab Evaluator.	X			X	
View project	Grants the user the privilege to open and view projects in Gyrolab Evaluator.	X	X	X	X	X

The following table shows the dependencies for the privileges in Gyrolab Evaluator. For each privilege listed on a row, X and (X) indicate which required privilege is needed.

X Directly dependent

(X) Implicitly dependent

E.g. the privilege "Configure analysis" is directly dependant on "Edit settings". And since "Edit settings" is directly dependant on "View project", then "Configure analysis" is also implicitly dependant on "View project".

Depending on Privilege	Analyze	Configure analysis	Edit project	Edit settings	View project
Administrate project					X
Analyze					X
Approve project					X
Configure analysis				X	(X)
Configure presentation					X
Configure report	X				(X)
Edit project					X
Edit settings					X
Export analysis data	X				(X)
Export analysis result					X
Export project					X
Export report					X
Lock settings		X	X	(X)	(X)
Manage project			X		(X)
Unapprove project					X
Unlock settings					X

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