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QIAlink™ Software User Manual



Sample & Assay Technologies

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1 Introduction

Thank you for choosing QIAlink software. We are confident that this software will become an integral part of your laboratory.

This manual describes how to operate QIAlink software. Before using QIAlink software, it is essential that you read this user manual carefully.

1.1 About this user manual

This user manual provides information about QIAlink software in the following sections:

- Introduction
- Safety Information
- Installation
- General Description
- QIAlink Interface Engine
- QIAlink Result Manager
- Workflow with QIAlink
- Maintaining the Database
- Troubleshooting
- License Terms

1.2 General information

1.2.1 Scope of delivery

The delivery includes the following:

- QIAlink software package
- *QIAlink Software User Manual* (available on CD)

1.2.2 License versions

QIAlink is available in two license versions.

- QIAlink, Standard Implementation:
Includes connectivity of QIASymphony® and Rotor-Gene Q® (both Rotor-Gene Q Software and Rotor-Gene AssayManager®)
- QIAlink, RGQ Implementation:
Includes connectivity of Rotor-Gene Q (both Rotor-Gene Q Software and Rotor-Gene AssayManager)

1.2.3 Technical assistance

At QIAGEN, we pride ourselves on the quality and availability of our technical support. Our Technical Services Departments are staffed by experienced scientists with extensive practical and theoretical expertise in molecular biology and the use of QIAGEN® products. If you have any questions or experience any difficulties regarding QIAlink software or QIAGEN products in general, do not hesitate to contact us.

QIAGEN customers are a major source of information regarding advanced or specialized uses of our products. This information is helpful to other scientists as well as to the researchers at QIAGEN. We therefore encourage you to contact us if you have any suggestions about product performance or new applications and techniques.

For technical assistance, contact QIAGEN Technical Services Department.

For up-to-date information about QIAlink software, visit www.qiagen.com/p/QIAlink.

1.2.4 Policy statement

It is the policy of QIAGEN to improve products as new techniques and components become available. QIAGEN reserves the right to change the specifications of products at any time.

In an effort to produce useful and appropriate documentation, we appreciate your comments on this user manual. Please contact QIAGEN Technical Services Department with any feedback.

1.2.5 Version management

This document is the QIALink user manual, version 1.1 for use with QIALink software version 1.1.

1.3 Intended use of QIALink software

QIALink is a middleware software that is intended to provide bi-directional connectivity with a Laboratory Information Management System (LIMS) and specific QIAGEN instruments and software — QIASymphony SP/AS, Rotor-Gene Q instruments, and the Rotor-Gene AssayManager. QIALink software will create work lists and transfer results between the specific QIAGEN instruments and the LIMS.

QIALink is intended for use by professional users, and trained in the operation of QIASymphony SP/AS instruments and software, Rotor-Gene Q instruments and software, the laboratory's particular LIMS, and QIALink.

1.3.1 Training for QIALink users

Customers are trained by a QIAGEN representative upon installation of the QIALink software. The training covers general operation of the system, Iguana service including channel concept and logs, QIALink Result Manager with user management, interface setup, test orders and archive.

QIAGEN can also provide retraining, for example after software updates, or for new laboratory personnel. Please contact QIAGEN Technical Services to get more information about retraining.

2 Safety Information

The instructions and safety information in this user manual must be followed to ensure safe operation of QIAlink software.

The following types of safety information appear throughout the *QIAlink Software User Manual*.

<p>WARNING</p> 	<p>The term WARNING is used to inform you about situations that could result in personal injury to other persons. Details about these circumstances are given in a box like this one.</p>
---	---

The advice given in this manual is intended to supplement, not supersede, the normal safety requirements prevailing in the user's country.

2.1 Proper use

Important

QIAlink software must be operated by personnel familiar with the use of the associated QIAGEN instrumentation. Personnel must have been trained in its use or have read and demonstrated an understanding of this manual.

QIAlink software may only be installed by QIAGEN Technical Services.

The *QIAlink Software User Manual* describes features which are not part of QIAGEN validated assay workflows. When using QIAlink software, it is recommended that you consult the assay kit handbook for a description of the validated workflow to determine the appropriate application of a feature.

WARNING**Deselection of invalid results**

[W1]

Samples with invalid results must be deselected in Rotor-Gene Q software prior to data transfer by QIAlink. Otherwise, invalid results may be exported to LIMS.

If a result is designated as invalid, the sample must be deselected from the sample list.

3 Installation

3.1 QIAlink software installation

Note: QIAlink software may only be installed by QIAGEN Technical Services.

Note: Updates of QIAlink Interface Engine may only be installed by QIAGEN Technical Services.

Note: Updates of QIAlink Result Manager can be installed by the user.

3.2 System requirements

The computer system running the QIAlink software package must fulfill these minimum requirements.

Description	System requirement
Operating system	Microsoft® Windows® XP 32-bit Microsoft Windows 7 32-bit
Browser	Internet Explorer® 8
Processor	600 MHz or higher, Pentium® III or higher
Main memory	Minimum 512 MB
Hard disk space	Minimum 30 GB
Ports	Ethernet adapter

The QIAlink software package should be installed on the computer running the QIASymphony Management Console (QMC).

3.2.1 **Additional software on computers running QIAlink**

No software other than the QMC, the Rotor-Gene Q software, or Rotor-Gene AssayManager should be running on the same computer as QIAlink software.

Note: Rotor-Gene Q software or Rotor-Gene AssayManager should be used on the QIAlink computer for result evaluation only, and must not be used to control the Rotor-Gene Q instrument.

3.2.2 **Virus scanners**

We strongly recommend disabling virus scanner activity during the use of QIAlink software.

4 General Description

4.1 Software modules

The QIALink software package contains three software modules:

- QIALink Interface Engine (see Section 5)
- QIALink Result Manager (see Section 6)
- LIMS export package for Rotor-Gene Q software (see Section 7.2)

4.1.1 QIALink Interface Engine

QIALink Interface Engine connects QIASymphony, Rotor-Gene Q, and Rotor-Gene AssayManager to any Laboratory Information System (LIS) and Laboratory Information Management System (LIMS). It incorporates the middleware solution Iguana™ from iINTERFACEWARE™ and runs as a Windows service in the background. The Iguana web interface enables status monitoring from any computer within the network.

Note: Rotor-Gene Q refers to Rotor-Gene Q and Rotor-Gene Q MDx instruments.

4.1.2 QIALink Result Manager

QIALink Result Manager ensures complete traceability of all steps of the QIASymphony RGQ workflow. It offers features for convenient and fast retrieval of instrument result files.

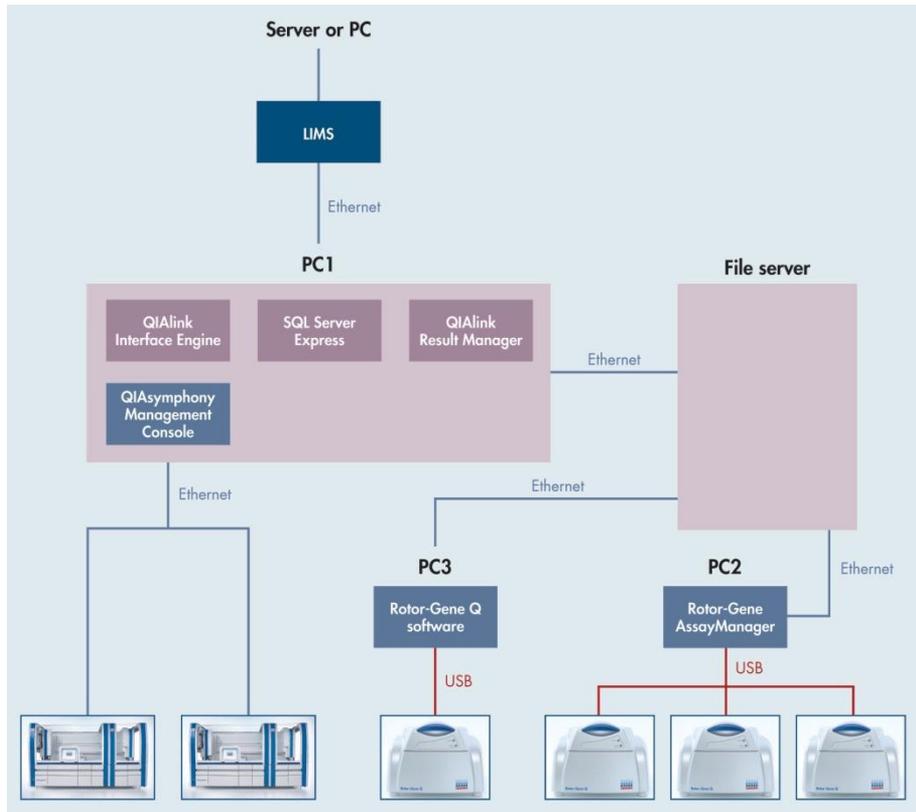
QIALink Result Manager allows configuration of instrument- and assay-specific parameters for QIALink Interface Engine.

4.2 System setup

QIALink software performs the following tasks:

- QIALink Interface Engine receives test orders from LIMS and generates QIASymphony work lists based on the orders (see Section 7.1). It stores the LIMS test order and the QIASymphony work list into a SQL Server® Express database.
- QIALink Interface Engine creates LIMS responses from the results of Rotor-Gene Q software (see Section 7.2) and Rotor-Gene AssayManager (see Section 7.3). Additionally, it stores the LIMS output of Rotor-Gene AssayManager and the LIMS export files from Rotor-Gene Q software into a SQL Server Express database.
- QIALink Interface Engine archives the result files from QIASymphony into a SQL Server Express database (see Section 7.1).
- QIALink Interface Engine transfers QIASymphony rack files from QIASymphony SP to all connected QIASymphony instruments (see Section 7.1).
- QIALink Interface Engine processes the QIASymphony start batch confirmation and stores the information in the SQL Server Express database (see Section 7.1). This information is used by the QIALink Result Manager to create an overview of samples that are waiting to be processed (see Section 6.5).
- QIALink Result Manager offers various filter functions to retrieve, display and print the archived instrument result files from the SQL Server Express database (see Section 6.6).

The following figure shows a typical hardware deployment of the software components that are required for the QIASymphony RGQ workflow with QIALink.



A typical hardware deployment of software components for the QIASymphony RGQ workflow with QIAlink software.

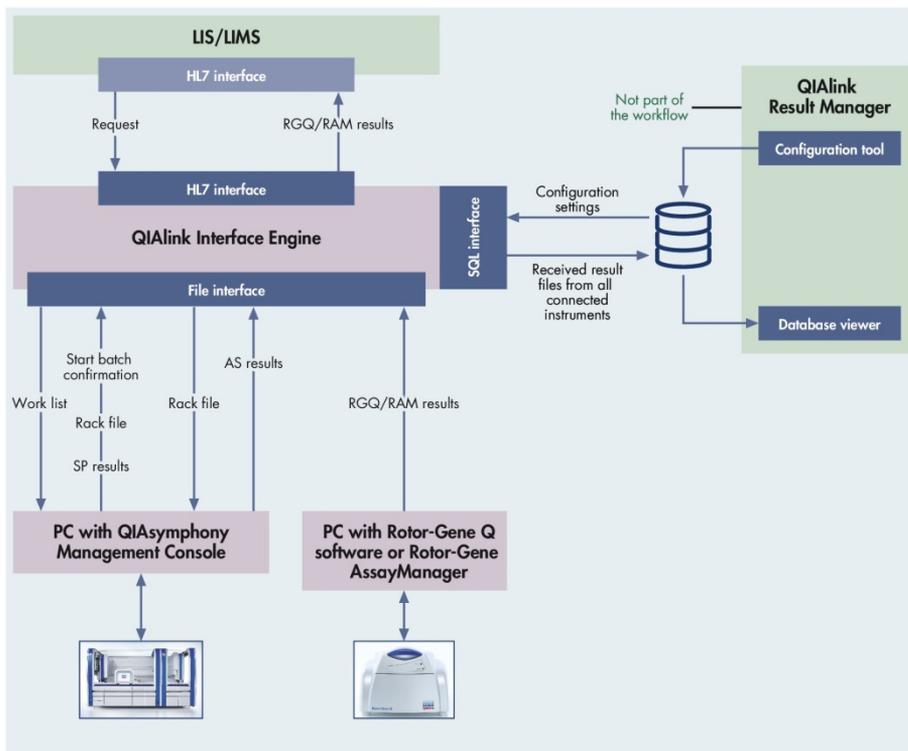
Typically, QIAlink Interface Engine, QIAlink Result Manager, the SQL Server Express installation, and QIASymphony Management Console are located on the same computer (“PC1” in the figure above). This computer is connected to the lab network to allow communication with the LIMS, the QIASymphony instruments, and a file server which is used to exchange files between PC1, PC2, and PC3.

Note: The figure above shows one example. The deployment can be different depending on the infrastructure of the laboratory, especially if an existing SQL Server is used instead of a local SQL Server Express installation.

General Description

During installation, QIAGEN Technical Services, in collaboration with your IT personnel, will create the system setup that best fits the laboratory.

An overview of the integration of QIALink software in the QIASymphony RGQ system and with LIMS is illustrated in the figure below. The exchange of data between the software components is also shown.



Overview of the integration of QIALink software in the QIASymphony RGQ system.

5 QIALink Interface Engine

5.1 Iguana

iINTERFACEWARE Iguana is an integral part of QIALink Interface Engine. Iguana is an integration engine that enables healthcare applications to easily exchange electronic information.

QIALink Interface Engine utilizes Iguana specifically for the interface between QIAGEN instrumentation and LIMS.

5.2 Start and stop service

Iguana runs as a Windows service. To start or stop the Iguana service, follow these steps:

1. From the Windows "Start" menu, select "Control Panel", then "Administrative Tools".
2. Double-click "Services".
3. Right-click the Service "iINTERFACEWARE Iguana".
4. Select "START" to start the service, or "STOP" to stop the service.

QIALink Interface Engine will be active while the Iguana service is running.

5.3 Logging in to the web interface

The Iguana service runs in the background and does not require any user interaction. The Iguana web interface can be used to monitor the status of the interface.

Log in as follows:

1. Open Internet Explorer and enter the IP address and port of the computer that is running the Iguana service.

- To log in on the computer that runs Iguana, the address is `http://localhost:6543`.
- To log in from another computer in the network, the address is `http://<IP>:6543` where <IP> is the Iguana computer's IP address.

2. Click "Enter".

The user is directed to the Iguana log in page.



QIAGEN Technical Services create accounts for two different user roles during installation:

- LabUser
- LabAdmin

Depending on requirements, one or more accounts are created for each user role. To log in to the web interface, use the credentials provided by QIAGEN Technical Services and follow these steps.

3. Enter the user name in the left dialog field.
4. Enter the password in the right dialog field.
5. Click "LOG IN".

After a successful login, the user will be directed to the Dashboard (see Section 5.6).

5.4 User roles

- | | |
|----------|---|
| LabUser | <ul style="list-style-type: none">■ Start/Stop channels (see 5.6.1)■ View log files (see 5.7.2)■ Export log files (see 5.7.3) |
| LabAdmin | <ul style="list-style-type: none">■ Start/Stop channels (see 5.6.1)■ Edit channels (see 5.8.1)■ View log files (see 5.7.2)■ Export log files (see 5.7.3) |

5.5 Channel concept

Iguana uses so called “channels” to transport data from one point to another.

These channels exist within QIAlink Interface Engine.

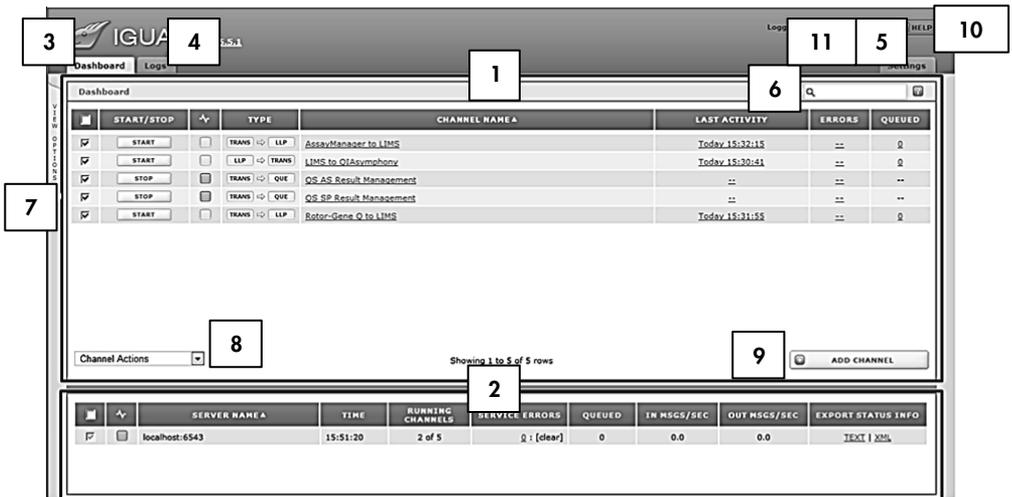
Channel name	Description
LIMS to QIAsymphony	Creates a QIAsymphony work list for each LIMS request received. The work lists are transferred to all connected QIAsymphony instruments.
QS SP Result Management	Archives the QIAsymphony SP result files in the result database and processes the start batch confirmation file. In addition, it transfers the QIAsymphony SP rack file to all connected QIAsymphony AS instruments.
QS AS Result Management	Archives the QIAsymphony AS result files in the result database.
AssayManager to LIMS	Creates a LIMS response for each LIMS output file that has been exported from Rotor-Genie AssayManager.
Rotor-Genie Q to LIMS	Creates a LIMS response for each LIMS export file that has been exported from Rotor-Genie Q software.

Each channel can be started and stopped individually. Working with the channels is described in Section 5.6.

5.6 Dashboard tab screen

5.6.1 General overview

The Dashboard is the central monitoring screen for Iguana. This section gives an overview about the Dashboard's elements and their purposes.



The following table describes the different numbered areas and control elements of the Dashboard.

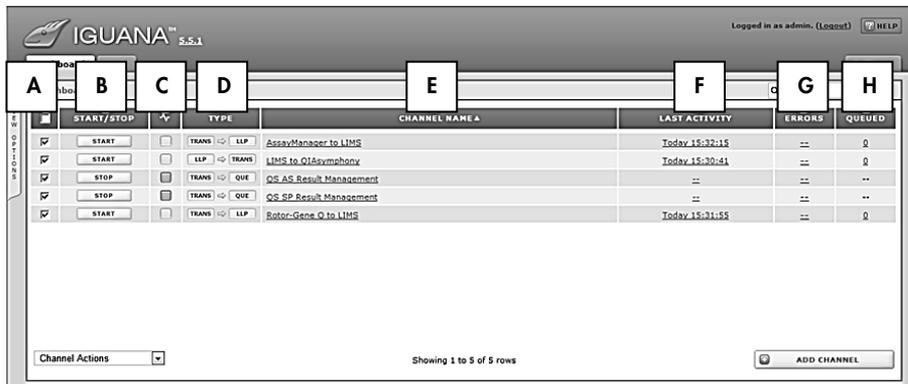
No.	Name	Description
1	Top Dashboard panel	Shows all the channels. For an overview of the available channels, see Section 5.5.
2	Bottom Dashboard panel	Shows the Server List that the Dashboard is monitoring. QIAlink Interface Engine uses only one server.
3	“Dashboard” tab	Returns the user to the Dashboard screen.
4	“Logs” tab	Opens the Logs screen (see Section 5.7).
5	“Settings” tab	This tab is for use by QIAGEN Technical Services only.
6	Search box	Use the Search box to filter for visible channels, based on name and description.

Table continued on next page

Table continued

No.	Name	Description
7	View Options	View Options opens a selector for customizing the columns in the top and bottom panels. For details, refer to the Iguana online help.
8	Channel Actions	Allows bulk actions to be performed on channels that have been selected. These actions are available in a drop-down list: <ul style="list-style-type: none"> ■ Start Channel(s) ■ Stop Channel(s) ■ Clear/Mark Channel Errors ■ Clear Channel Queue(s)
9	Add Channel	Only accessible for QIAGEN Technical Services, otherwise disabled.
10	Help	Access to Iguana online help.
11	Logout	Logout of current user from the web interface.

5.6.2 View of available channels



The following table describes the Dashboard panel columns.

ID	Name	Description	Click on the element	Tooltips
A	Checkbox	Select multiple channels for bulk operations: clear channel errors, stop and start etc.	To activate or deactivate checkbox.	n/a
B	Start/Stop	Stop and start channels.	To stop or start channel.	n/a
C	Activity light	For details, see section 5.6.3.	n/a	Summary of channel activity.
D	Type	"Source" and "Destination" components.	To open the configuration screen for the component.	Configuration for each component and runtime statistics.
E	Channel name	Name of the channel.	To open configuration of the channel.	Description and channel groups.
F	Last activity	Last recorded transaction for the channel or "-" if no activity since channel last started.	To go to the Logs screen with that transaction.	Summary of transactions processed.
G	Errors	Number of errors on the channel.	To go to the Logs screen showing those errors.	n/a

Table continued on next page

Table continued

ID	Name	Description	Click on the element	Tooltips
H	Queued	Number of unprocessed transactions remaining for the channel.	To go to the Logs screen showing the queued messages and those already processed; this allows repositioning of the queue.	n/a

5.6.3 Status monitoring with the Dashboard

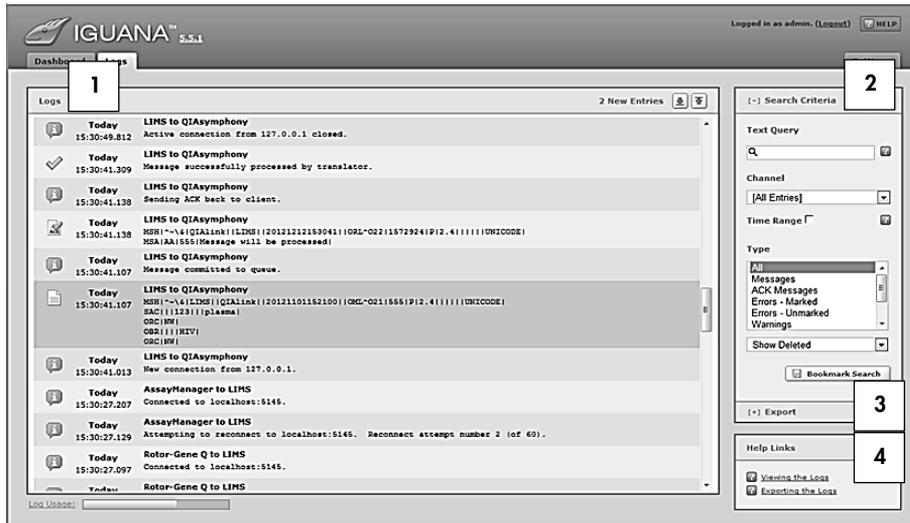
The Dashboard is mainly used to monitor the status of the LIMS interface. Therefore, the relevant indicator is the Activity Light (see section 5.6.1). This section explains the meaning of the different Activity Light statuses.

Status	Meaning	Actions
 Inactive (white)	The channel is idle; no data are currently being processed by this channel.	To start the channel, click "Start".
 Active (green)	The channel is running; no problems occurred.	To stop the channel, click "Stop".
 Pending (yellow)	No connection could be established to LIMS. OR A warning occurred, but the channel is still processing data.	Check the Logfile for this channel (see Section 5.7). Check the Logfile for this channel (see Section 5.7).
 Error (red)	An error occurred; the channel has stopped processing data.	Resolve the error situation (see Section 9, "Troubleshooting"). Restart the channel with the "Start/Stop" button.

5.7 Logs tab screen

5.7.1 Overview

The Logs screen of the Iguana web interface gives an overview of information, warnings, and error messages.



This table describes the different sections and control items of the Logs screen.

No.	Name	Description
1	Logs	Overview of all messages matching the filter criteria.
2	Search Criteria	Various criteria to search and filter the messages; for details, refer to the Iguana online help.
3	Export	Export function for the log messages.
4	Help Links	Hyperlinks to access relevant sections of the online help.

5.7.2 Logs identification

Each message contains, along with the message text itself, information about the type, the time, and the component or channel that produced the message.

Icon	Meaning	Description
	Error (unmarked)	<p>A service or channel error, or an error that has occurred while processing a message; errors will appear on the Dashboard or the Control Panel unless they are marked.</p> <p>Error messages indicate a severe problem; the channel has been stopped and no further data are processed until the root cause has been resolved and the channel has been restarted with the "START" button on the Dashboard.</p>
	Error (marked)	<p>An error that has been marked; marked errors do not appear on the Dashboard or the Control Panel.</p> <p>Error messages indicate a severe problem; the channel has been stopped and no further data are processed until the root cause has been resolved and the channel has been restarted with the "START" button on the Dashboard.</p>
	Warning	Warning messages indicate a problem during data processing; the channel continues to operate.
	Success	A log entry indicating that Iguana has processed a message successfully.
	Informational	A log entry that informs the user of a task performed by the channel.

Table continued on next page

Table continued

Icon	Meaning	Description
	Message	A message sent through the channel.
	Unqueued message	Indicates a message that has been received but was not added to the queue of messages to be processed; examples of unqueued messages are messages that could not be processed because they contain errors.
	Warning	A message sent to the LIMS to acknowledge the reception of an order, or a message received from LIMS to acknowledge reception of results.
	Success	An internal debugging log entry.

5.7.3 Export logs

The Export Logs function is helpful for transferring the logs to QIAGEN Technical Services Department in case of any problems. Follow these steps to export the log files.

1. Click  to expand the "Export" dialog box.

[+] Search Criteria

[-] Export

Format

One entry per line.
 An annotated text file.
 A CSV file.

Options

Related messages.

2. Click "A CSV file".
3. Check "Related messages".
4. Click "Export" and save the generated file.

5.8 Configuration

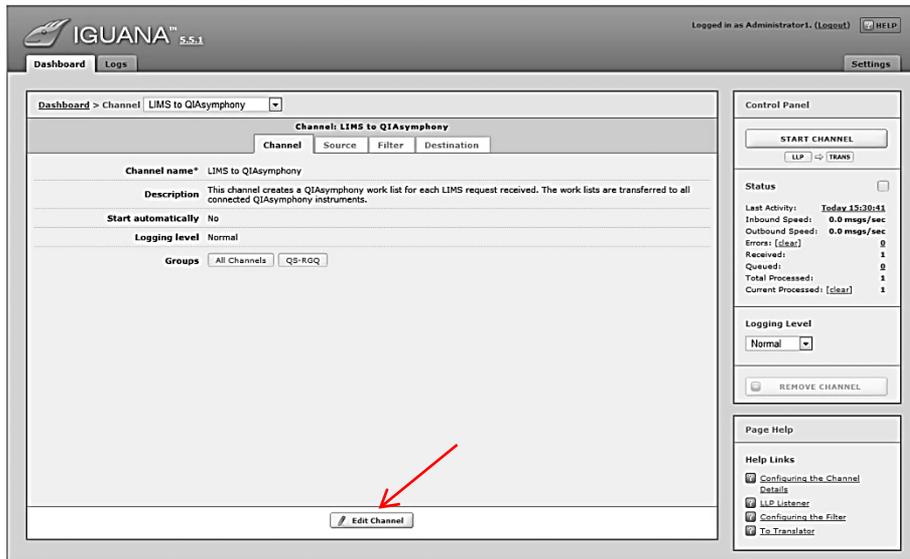
5.8.1 Channel configuration

The channels are configured by QIAGEN Technical Services during installation. The user only needs to change the channel configuration if the IP address and/or ports used by LIMS are changed.

Dashboard		Logs			
Dashboard					
<input type="checkbox"/>	START/STOP	<input type="checkbox"/>	TYPE	CHANNEL NAME ▲	
<input checked="" type="checkbox"/>	<input type="button" value="START"/>	<input type="checkbox"/>	TRANS ⇌ LLP	AssayManager to LIMS	
<input checked="" type="checkbox"/>	<input type="button" value="START"/>	<input type="checkbox"/>	LLP ⇌ TRANS	LIMS to QIAsymphony	
<input checked="" type="checkbox"/>	<input type="button" value="STOP"/>	<input type="checkbox"/>	TRANS ⇌ QUE	QS AS Result Management	
<input checked="" type="checkbox"/>	<input type="button" value="STOP"/>	<input type="checkbox"/>	TRANS ⇌ QUE	QS SP Result Management	
<input checked="" type="checkbox"/>	<input type="button" value="START"/>	<input type="checkbox"/>	TRANS ⇌ LLP	Rotor-Gene Q to LIMS	

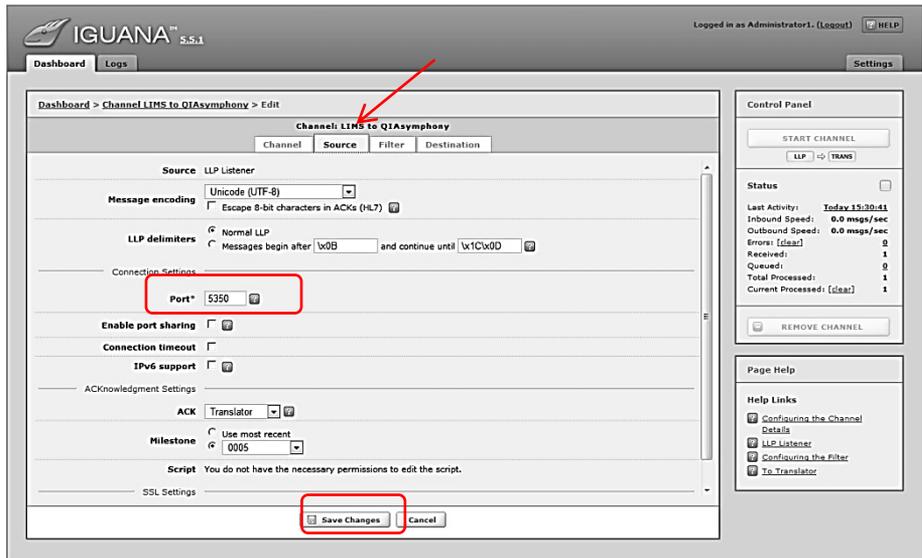
To change the channel configuration, select “LIMS to QIAsymphony” from the “Channel Name” column of the Dashboard screen.

The following screen opens.



Proceed as follows:

1. Click “Edit Channel”.
2. Select the “Source” tab in the following screen.

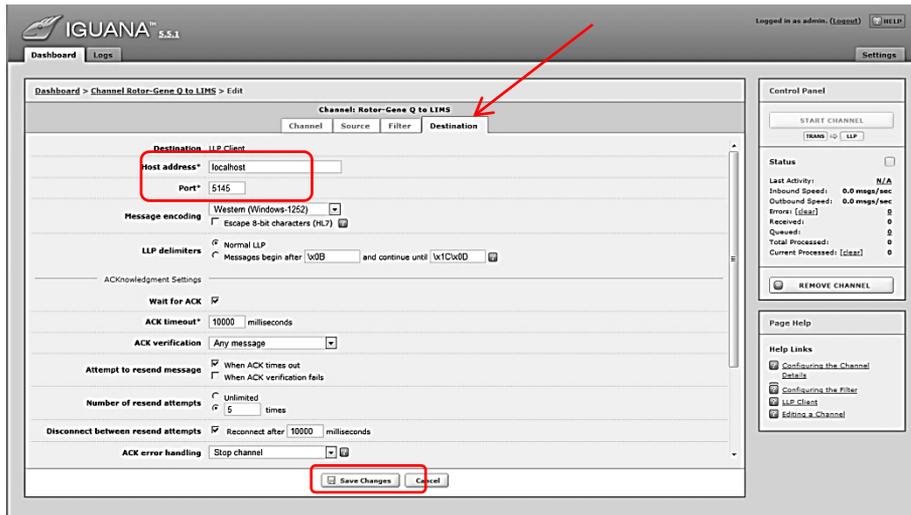


3. Enter the correct port for the LIMS connection in the "Port" field.
4. Click "Save Changes".
5. Select the "Dashboard" tab.



6. Select the channel name "Rotor-Gene Q to LIMS".
7. Click "Edit Channel".
8. Select the "Destination" tab.

The following screen appears.



9. Enter the correct value for the LIMS IP address in the "Host address" field.
10. Enter the correct value for the port in the "Port" field.
11. Click "Save Changes".
12. Select the "Dashboard" tab.
13. Repeat steps 6 to 11 for the channel "AssayManager to LIMS".
14. Log out.

Note: The LIMS interface cannot operate properly if other channel configuration parameters as described above are modified.

5.8.2 Instrument configuration

Configuration of the instrument connection settings and assay specific settings in QIALink Interface Engine can be carried out using the interface setup environment of QIALink Result Manager (see Section 6.7).

5.9 Settings tab

The "Settings" tab is for use by QIAGEN Technical Services only.

The "Settings" tab contains configuration for Iguana. If it is selected, only existing settings will be displayed.

5.10 Iguana help

The Iguana "HELP" function operates if the system running QIALink software is connected to the internet.

All relevant "HELP" information may be found in the corresponding sections in this user manual, or is listed in Section 9, "Troubleshooting".

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6 QIAlink Result Manager

6.1 Overview

QIAlink Result Manager provides features to manage QIAlink configuration settings. The functionality is split into different environments:

Test orders (see Section 6.5)

Archive (see Section 6.6)

Interface setup (see Section 6.7)

- Configuration of instrument connection settings
- Configuration of assay specific settings
- Import and export of settings specific to an instrument or assay

Configuration (see Section 6.8)

- User management
- Archive management

Support (see Section 6.9)

- Audit trail

6.2 General software usage

The following chapter describes the general software usage concept of QIAlink Result Manager.

6.2.1 Use of color

For optimal user interaction, QIAlink Result Manager uses a specific color concept for presenting information.

The following table provides a summary of the colors used in the software together with a description of their meanings.

Color	Description
Light blue	The field is interactive and clickable.
Dark blue	The field is selected or focused.
Gray	The field is read-only and can neither be selected nor activated.
Yellow	The field requires input.

Example

The following dialog box gives an example of the color concept. The field "LIMS target name" (yellow) requires input. See text in "Messages" in the right panel.

Add Target

Assay profile name: AP

Assay profile version: 1 0 0

Plug-in name: UDTBasic

AssayManager target name: target

LIMS target name: (Yellow background)

Export to LIMS

Messages

Enter an LIMS target name. (170068)

Ok Cancel

6.2.2 Displaying warnings

Errors and warnings are essential information for the user. These messages highlight a problem, or alert the user to an erroneous situation. QIAlink Result Manager differentiates among 4 different problem levels.

Priority	Name	Icon	Description	Action
1	System error		A combination of unacceptable incidents.	User interaction required.
2	Validation error		An error due to a missing or invalid user input.	User interaction required.
3	Warning		Situation could be optimized by further input.	User interaction possible, but not mandatory.
4	Information		A message containing additional information about the current situation.	User interaction not possible.

All existing errors and warnings are displayed with the corresponding icon either in a separate messages area or as a pop-up window. If applicable, the messages area lists all currently existing errors and warnings sorted with descending priority.

6.2.3 “Messages” panel

The following screenshot shows an example of a validation error during configuration of QIASymphony parameters.

Messages are displayed with the corresponding icon and the error text, and include the error ID in brackets.

The screenshot shows a dialog box titled "Add QIASymphony parameter". It features a blue header with a pencil icon. The main area contains four text input fields: "LIMS test name" (containing "Test A"), "LIMS specimen name" (containing "Specimen 1"), "Assay control set" (empty), and "Assay parameter set" (containing "APS"). Below these fields is a checked checkbox labeled "Activate Configuration". On the right side, a "Messages" window is open, displaying a yellow pencil icon and the text: "Comb nation of LIMS test name and LIMS specimen name must be unique. (170020)". At the bottom of the dialog are "Ok" and "Cancel" buttons.

6.2.4 Sorting tables

It is possible in some tables in QIALink Result Manager to sort contained data by columns. Sortable tables can be recognized by the "Sort" icon (▲) in one of the column headers. The rows in the table are sorted according to the data in this column.

Two icons are used to indicate either ascending (▲) or descending (▼) sorting order:

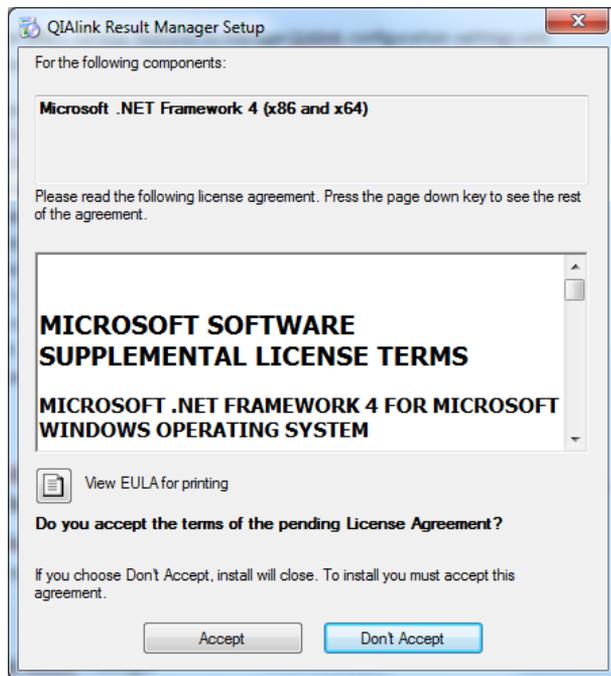
To toggle the sorting order from ascending to descending, or vice versa, click the column header with the "Sort" icon. To sort the data in the table according to another column, click the column header of that column.

6.3 Installation and updates

6.3.1 Install QIALink Result Manager

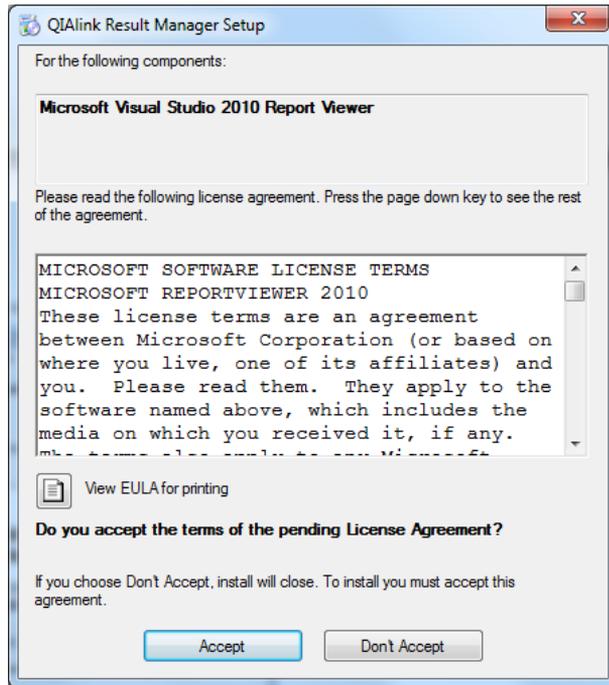
To start the installation of QIALink Result Manager, proceed as follows:

1. Insert the QIALink Software CD into the corresponding CD drive.
2. Go to the folder “QIALink Result Manager”.
3. Double-click **setup.exe** and follow these steps.



4. Click “Accept” to accept the license agreement for the Microsoft .NET Framework 4.

Note: This dialog box is not displayed if Microsoft .NET Framework 4 is already installed.

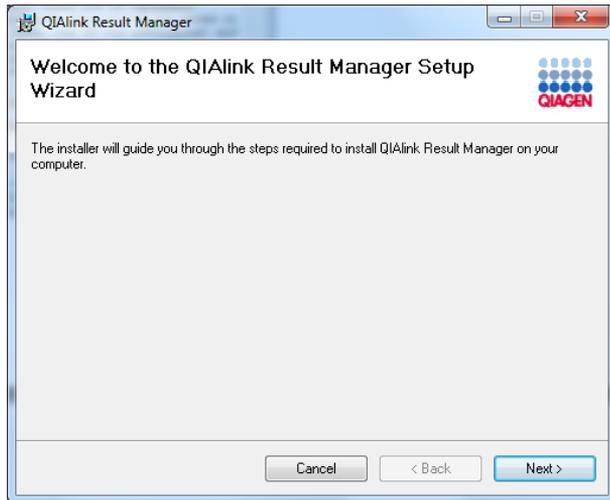


5. Click "Accept" to accept the license agreement for the Microsoft Visual Studio® 2010 Report Viewer.

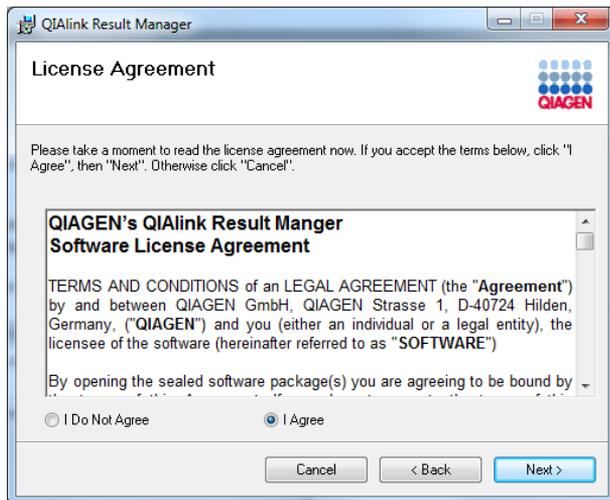
Note: This dialog box is not displayed if Microsoft Visual Studio 2010 Report Viewer is already installed.

Microsoft .NET Framework 4 and the Visual Studio 2010 Report Viewer will be installed if not already present.

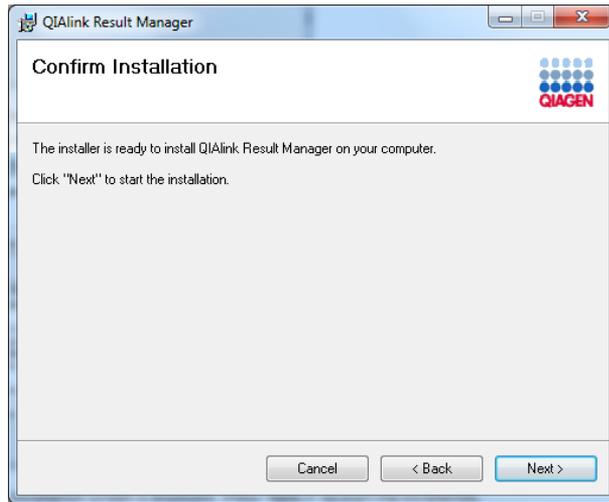
The welcome dialog box of QIAlink Result Manager Setup Wizard opens.



6. Click "Next" to proceed.

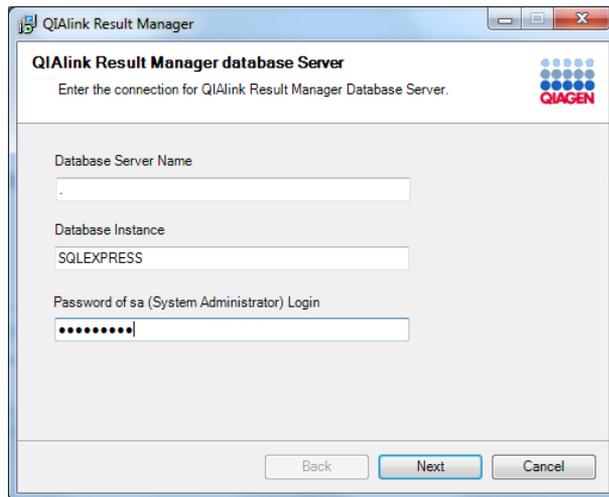


7. Accept the license agreement of QIAlink Result Manager by selecting "I Agree", then click "Next".



8. Click "Next" in the Confirm Installation dialog box to start the installation.

After installation of QIAlink Result Manager, the settings dialog box for the connection to the SQL Server, or SQL Server Express database, is displayed.



9. Enter information in the dialog fields as follows:

“Database Server Name”

- Enter “.”, if the database is located on this computer.
- Enter the IP address of the database server if the database is located on a remote server.

“Database Instance”

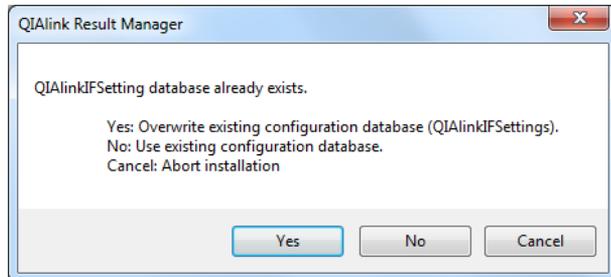
- Enter the name of the database instance (e.g., “QIALINK”).

“Password of sa (System Administrator) Login”

- Enter the Administrator password for the SQL Server or SQL Server Express database.

10. Click “Next”.

If a QIAlink configuration database already exists, this dialog box is displayed.



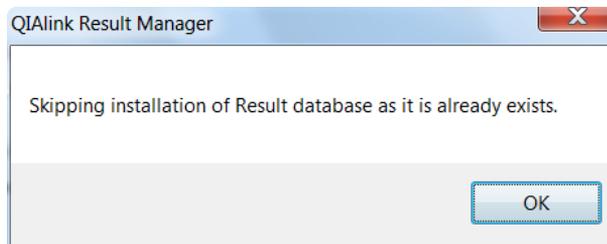
11. Click “Yes” to delete the existing database and create a new database.

Note: This results in loss of all existing configuration data!

Click “No” to keep the existing database and continue to work with it.

Click “Cancel” to cancel the installation.

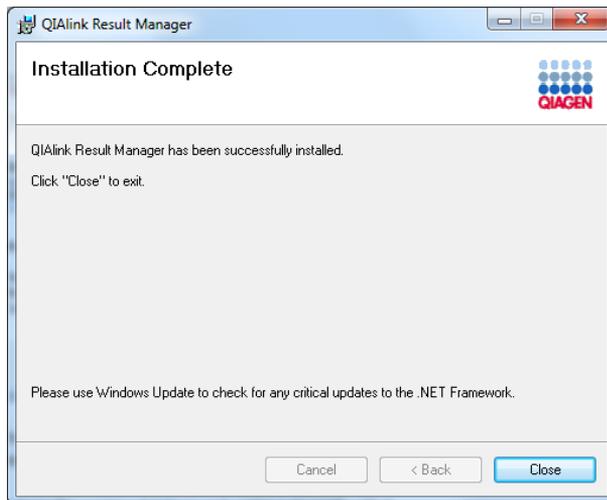
If the QIAlink result database already exists, this dialog box is displayed.



12. Click "OK".

Note: The result database cannot be deleted during installation.

After a successful installation, the Installation Complete dialog box is displayed.



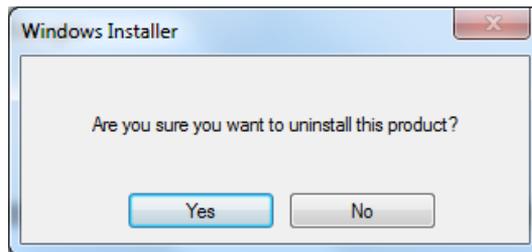
13. Click "Close" to exit the setup.

QIAlink Result Manager is now ready to be used.

6.3.2 Uninstall QIAlink Result Manager

Follow these steps to uninstall QIAlink Result Manager from the computer.

1. Open the Windows "Start" menu. Select "All Programs/QIAGEN" then "QIAlink Result Manager". Launch "Uninstall QIAlink Result Manager".



2. Click "Yes" to confirm removal of the software. QIAlink Result Manager will be uninstalled.

6.4 Logging in to QIAlink Result Manager

The following dialog box opens when QIAlink Result Manager is started.



1. Enter user ID and password in the dialog fields, then click "OK" to log into the software, or click "Cancel" to cancel the log in.

Note: Initial user credentials for the Administrator are provided by QIAGEN Technical Services after installation. To create additional user accounts, see Section 6.8.2.

2. To log out from QIALink Result Manager, click the logout icon in the lower right corner of the screen.



The login dialog box is displayed for a new user.

6.5 Test orders environment

6.5.1 Overview

The test orders environment can be used to generate an overview of the tests that have been requested by LIMS. It allows either a list of samples that are currently waiting to be processed to be displayed, or a list of tests that have been requested by LIMS in a specific time frame.

The test orders environment consists of filter options (1) and result selection (2).

Filter options (1)

- Pending requests
 - 7 Past days
- Time frame
 - Start: 01.06.2013
 - End: 01.07.2013
 - Reset filter
 - Apply filter

Result selection (2)

Sample ID	Test ID	Assay control set	Assay parameter set
1583454784258	Virus A	Custom_ACS_DNA_v1	Custom_APS_VirA_v2
1583454784258	Virus B	Custom_ACS_DNA_v1	Custom_APS_VirB_v3
1583454949258	Virus A	Custom_ACS_DNA_v1	Custom_APS_VirA_v2
1583454949258	Virus B	Custom_ACS_DNA_v1	Custom_APS_VirB_v3
1583782186949	Virus A	Custom_ACS_DNA_v1	Custom_APS_VirA_v2
1583782186949	Virus B	Custom_ACS_DNA_v1	Custom_APS_VirB_v3
1583955689245	Virus A	Custom_ACS_DNA_v1	Custom_APS_VirA_v2
1583955689245	Virus B	Custom_ACS_DNA_v1	Custom_APS_VirB_v3
1583956009565	Virus A	Custom_ACS_DNA_v1	Custom_APS_VirA_v2
1583956009565	Virus B	Custom_ACS_DNA_v1	Custom_APS_VirB_v3
1583956186001	Virus A	Custom_ACS_DNA_v1	Custom_APS_VirA_v2
1583956186158	Virus A	Custom_ACS_DNA_v1	Custom_APS_VirA_v2
1583956186555	Virus A	Custom_ACS_DNA_v1	Custom_APS_VirA_v2
1583956186555	Virus B	Custom_ACS_DNA_v1	Custom_APS_VirB_v3
1583956186565	Virus A	Custom_ACS_DNA_v1	Custom_APS_VirA_v2
1583956186565	Virus B	Custom_ACS_DNA_v1	Custom_APS_VirB_v3
1583956186949	Virus A	Custom_ACS_DNA_v1	Custom_APS_VirA_v2
1583956186949	Virus B	Custom_ACS_DNA_v1	Custom_APS_VirB_v3

Print

July 1, 2013 John Smith

The following filter options are available.

Field/button	Meaning
Pending requests (button)	If the radio button is selected, test requests for samples not yet being processed are displayed.
Past days (dialog box)	This figure specifies the number of days, counting back from the current date, for which the pending requests are displayed.
Time frame (button)	If this radio button is selected, all test requests from the specified time frame are displayed.
Start	Specifies the start date for test requests to be displayed.
End	Specifies the end date for test requests to be displayed.
"Reset Filter"	Resets all parameters of the filter dialog to their default values.
"Apply Filter"	A list of test requests is generated based on the filter parameters.

Click "Print" to print the displayed list.

The following table explains the columns in the result selection dialog.

Column	Meaning
Sample ID	ID of the sample.
Test ID	Assay name as requested by the LIMS.
Assay control set	The Assay Control Set (ACS) to be used by the QIASymphony SP.
Assay parameter set	The Assay Parameter Set (APS) to be used by the QIASymphony AS.

6.5.2 Display pending requests

This feature allows a list to be displayed of all test requests sent by LIMS. These are requests for which corresponding samples are not yet being processed.

1. Select the button "Pending requests" in filter options.
2. Specify the number of days, counting back from the current day, for which the pending requests are displayed. The number of days includes the current day.
3. Select "Apply filter".
4. The list containing all pending requests from the specified number of days is displayed in the result selection dialog.

6.5.3 Display requests from a specific time frame

This feature generates a list of all test requests sent by LIMS within a specific time frame.

1. Click the radio button "Time frame" in filter options.
2. Specify the start date and the end date. The start and end dates are included in the search.

3. Click "Apply filter".
4. The list containing all requests from the specified time frame is displayed in the result selection dialog.

6.5.4 Print request list

Click "Print" on the lower right corner of the test order environment screen to print the displayed list. The Windows printer dialog is opened to generate the print-out.

6.6 Archive environment

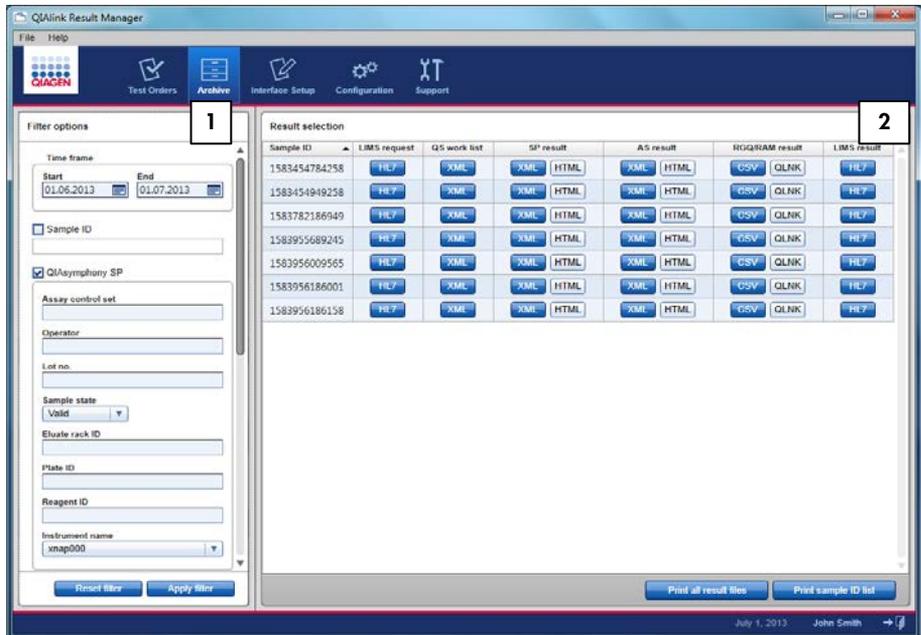
6.6.1 Overview

The archive environment allows the user to retrieve, display and print:

- LIMS requests
- QIASymphony work lists
- QIASymphony result files
- Rotor-Gene LIMS export files
- Rotor-Gene AssayManager LIMS output files
- LIMS results.

Note: the QIALink archive environment does not fully comply with U.S. FDA 21 CFR part 11 regulations. We recommend maintaining an additional archive of the QIASymphony result files.

The archive environment consists of filter options dialog (1) and result selection (2).



The following filter options are available.

Field/button	Meaning
--------------	---------

Start	Specifies the start date for data to be displayed.
End	Specifies the end date for data to be displayed.
Sample ID (box)	Check to display data related to the specific sample ID.
Sample ID (field)	Enter a specific sample ID.
QIAsymphony SP (box)	Check to apply the parameters specified in the QIAsymphony SP parameter group to the search.

Field/button	Meaning
Assay control set (field)	Name of the assay control set (ACS).
Operator (field)	Name of the QIAsymphony SP operator.
Lot No. (field)	Lot number of purification reagents.
Sample state (drop-down list)	Status of the sample on QIAsymphony SP; possible values are <empty>, valid, invalid, or unclear.
Eluate rack ID (field)	Identifier of the eluate rack.
Plate ID (field)	Identifier of the SP output plate.
Reagent ID (field)	Identifier from the bar code of the SP reagents box.
Instrument name (field)	Name of the QIAsymphony SP instrument.
QIAsymphony AS (box)	Check to apply the parameters specified in the QIAsymphony AS parameter group to the search.
Assay parameter set (field)	Name of the assay parameter set (APS).
Operator (field)	Name of the QIAsymphony AS operator
Lot No. (field)	Lot number of assay reagents.
Sample state (drop down list)	Status of the sample on QIAsymphony AS; possible values are <empty>, valid, invalid, or unclear.

Field/button	Meaning
Input plate ID (field)	Identifier of the AS input plate.
Output plate ID (field)	Identifier of the AS output plate.
Reagent ID (field)	Identifier from the barcode of the AS reagents box.
Instrument name (field)	Name of the QIA Symphony AS instrument.
LIMS request (box)	Check to apply the parameters specified in the LIMS request parameter group to the search.
Test ID (field)	Test identifier used by the LIMS to request a test.
Specimen (field)	Specimen descriptor used by the LIMS to request a test.
“Reset Filter”	Resets all parameters of the filter dialog to their default values.
“Apply Filter”	A list of test requests is generated based on the filter parameters.

The table below explains the items in the result selection dialog.

Button/column	Meaning
Sample ID (column)	ID of the sample. The result table has one row per sample. Each sample that matches the filter criteria is listed in the table.
LIMS request (column)	If one or more LIMS requests for this sample are stored in the database, "HL7" will appear in this column. If not, the column is empty.
QS work list (column)	If one or more QIASymphony work lists for this sample are stored in the database, "XML" will appear in this column. If not, the column is empty.
SP result (column)	If one or more QIASymphony SP result files for this sample are stored in the database, "XML" and "HTML" will appear in this column. If not, the column is empty.
AS result (column)	If one or more QIASymphony AS result files for this sample are stored in the database, "XML" and "HTML" appear in this column. If not, the column is empty.
RGQ/RAM result (column)	If one or more LIMS export files from the Rotor-Gene Q Software for this sample are stored in the database, "CSV" and "QLNK" appear. If one or more LIMS output files from Rotor-Gene AssayManager for this sample are stored in the database, the "ILE" button is displayed. If neither of those files is stored, the column is empty.

Button/column Meaning

LIMS result (column)	If one or more LIMS results for this sample are stored in the database, "HL7" appears in this column. If not, the column is empty.
"XML"	If only one file in XML format is present for the sample, clicking "XML" opens the file viewer dialog with the contents of the .xml file. If more than one file is present, clicking "XML" opens the file selection dialog.
"HTML"	If only one file in HTML format is present for the sample, clicking "HTML" opens the file viewer dialog with the contents of the .html file. If more than one file is present, clicking "HTML" opens the file selection dialog.
"HL7"	If only one file in HL7 (Health Level 7) format is present for the sample, clicking "HL7" opens the file viewer dialog with the contents of the .HL7 file. If more than one file is present, clicking "HL7" opens the file selection dialog.
"CSV"	If only one file in CSV format is present for the sample, clicking "CSV" opens the file viewer dialog with the contents of the .csv file. If more than one file is present, clicking "CSV" opens the file selection dialog.

Button/column	Meaning
"QLNK"	If only one file in QLNK format is present for the sample, clicking "QLNK" opens the Rotor-Gene Q software if installed on the computer and loads the run data. If more than one file is present, clicking "QLNK" button opens the file selection dialog.
"ILE"	If only one file in ILE format is present for the sample, clicking "ILE" opens the file viewer dialog with the contents of the .ile file. If more than one file is present, clicking "ILE" opens the file selection dialog.
"Print all result files"	Generates printouts of data for all samples displayed in the result selection dialog.
"Print sample ID list"	Generates a printout of the sample ID list with the samples displayed in the result selection dialog.

The table below lists the different file types.

File type	Meaning
*.xml	The XML format (Extensible Markup Language) is used for QIASymphony work lists and QIASymphony SP/AS result files. XML files are primarily intended for troubleshooting by QIAGEN Technical Services.
*.html	The HTML format (Hypertext markup language) is used for QIASymphony SP/AS result files. HTML is displayed in the file viewer dialog similarly to a web browser. HTML files are primarily intended for user-friendly display of the QIASymphony results.
*.HL7	The HL7 format (Health Level 7) is used for communication between LIMS and QIALink. HL7 files are primarily intended for troubleshooting by QIAGEN Technical Services.
*.csv	The CSV format (comma separated values) is used for exporting result data from the Rotor-Gene Q software to QIALink. CSV files are primarily intended for troubleshooting by QIAGEN Technical Services.

File type	Meaning
*.qlnk	The QLNK format (QIAGEN specific format) is used for exporting analysis data from the Rotor-Gene Q software to QIALink. QLNK files can be used to display the analyzed PCR curves in the Rotor-Gene Q software.
*.ile	The ILE format (QIAGEN specific format) is used for exporting result data from the Rotor-Gene AssayManager to QIALink. ILE files are primarily intended for troubleshooting by QIAGEN Technical Services.

6.6.2 Filter function

The Archive environment is intended to facilitate quality control by:

- Identifying all samples that share one or more common characteristic (e.g., that have been processed with the same reagent lot, or on the same plate)
- Accessing all QIASymphony *.html result files belonging to those samples

Additionally, the Archive environment can be used to support troubleshooting by QIAGEN Technical Services. It offers access to files tracing the communication between QIALink and LIMS as well as between the instruments and QIALink.

To search for sample IDs, enter all desired filter parameters. All the nominated filter parameters are combined for the search, i.e., only samples for which all parameters are valid are displayed in the result.

Click "Apply Filter" to execute the search.

“Reset Filter” can be used to reset all filter parameters to their default values.

Note: Applying a very long time frame to the search filter will increase the search time. We recommend specifying a reasonable time frame for the purpose of the search.

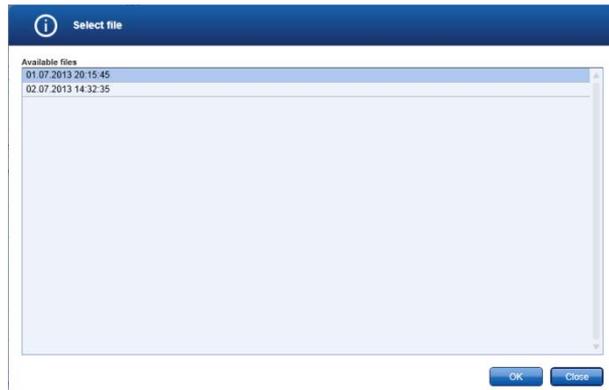
6.6.3 Result selection dialog

After application of the filter parameters, an overview of the sample IDs matching the search parameters is displayed in the “Result selection” view, together with the available result files.

- There is one row in the table for each sample matching the filter parameters.
- An empty column means that no result file of the corresponding type is available for this sample.
- The presence of a button means that one or more result files of the corresponding type is available for this sample.

Selecting single result files

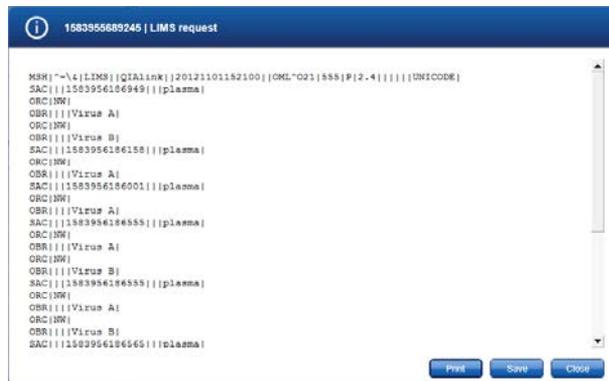
1. Click the button which represents the desired file type (e.g., click “HTML” in column “SP Results” to display the SP result file in HTML format).
2. If only one result file of the desired type is present for that sample, the file is displayed directly.
Files with file types ***.html**, ***.xml**, ***.HL7**, ***.csv**, or ***.ile** are displayed in the file viewer dialog.
Files with type ***.qlnk** are opened in the Rotor-Gene Q Software.
Note: For this feature, the Rotor-Gene Q software must be installed on the computer running QIAlink.
3. If more than one result file is present, the “Select file” dialog box opens. Each file is identified by its creation date.



4. To open a single file, select the corresponding row and click "OK".
5. Click "Close" to close the dialog box.

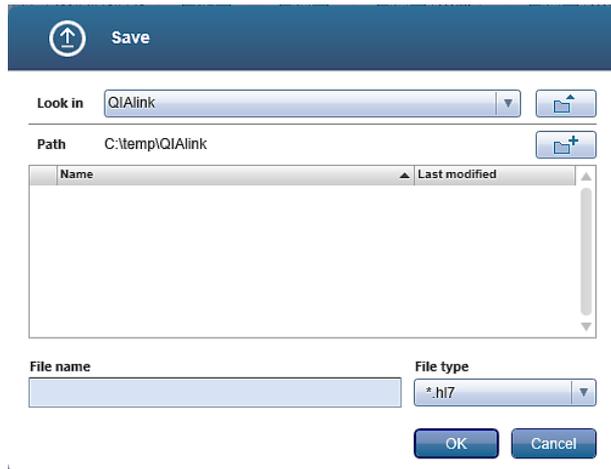
Printing and saving single files from the file viewer

The file viewer is used to display files with file type ***.html**, ***.xml**, ***.HL7**, ***.csv**, or ***.ile**.



1. Click "Close" to close the dialog box without saving the file.
2. To save the file to hard disk, click "Save".

The file save dialog box is opened.



3. Chose the appropriate location, enter the file name, and click "OK" to save the file.
4. To print the file, click "Print". The standard Windows printer dialog is opened.
5. To close the file viewer, click "Close".

Print sample ID list

To print a list of all sample IDs matching the filter parameters, click "Print sample ID list". The standard Windows printer dialog is opened.

Print all result files

To print a list with all result files that belong to samples matching the filter parameters, follow these steps.

1. Click "Print all result files".
2. The "Select file type" dialog box opens. Check all file types to be printed.



3. Click "OK" to print.

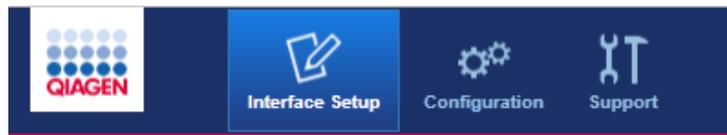
Note: A result file referencing more than one sample included in the search results is only printed once.

4. Click "Close" to close the dialog box without printing.

6.7 Interface setup environment

6.7.1 Overview

To access the Interface Setup, select the icon "Interface Setup" in the main navigation bar.



The setup environment is divided into screens that are accessed by using the navigation bar of the Interface Setup Environment.

For users with the user role "Operator", the settings are read-only. Creation of new settings, and modification, activation, and deactivation of existing settings are disabled.

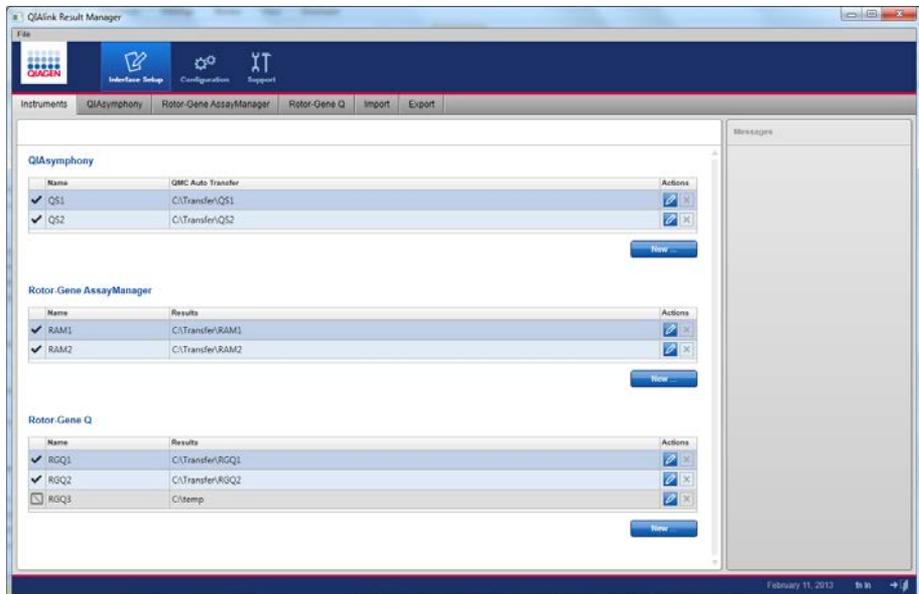
Users with the user role "Administrator" can create new settings and modify, activate, and deactivate existing settings.

Only QIAGEN Technical Services may delete existing settings.

The screens are explained within the following sections.

6.7.2 Instruments dialog

The Instruments dialog is used to configure the directories for data exchange between the instruments and QIAlink software. Only instruments that are configured in this dialog will be supported.



The screen is divided into different areas based on instrument types.

QIAsymphony

The QIAsymphony area allows configuration of up to 10 QIAsymphony instruments. A unique name must be assigned for each instrument. The instrument name can be freely chosen (e.g., *QSSPAS Lab1*). In the column "QMC Auto Transfer", the root directory of the transfer folder created by the QIAsymphony Management Console (QMC) is entered.

For details on the Auto Transfer feature of the QMC, refer to the QMC user manual supplied with your instrument.

Rotor-Gene AssayManager

The Rotor-Gene AssayManager area allows configuration of up to 10 instances of the Rotor-Gene AssayManager software. The name of the Rotor-Gene AssayManager instance can be freely chosen (e.g., *RAM1*). In the column "Results", the LIMS output folder of Rotor-Gene AssayManager is entered. For details on the configuration of the LIMS output folder in Rotor-Gene AssayManager, refer to the Rotor-Gene AssayManager documentation.

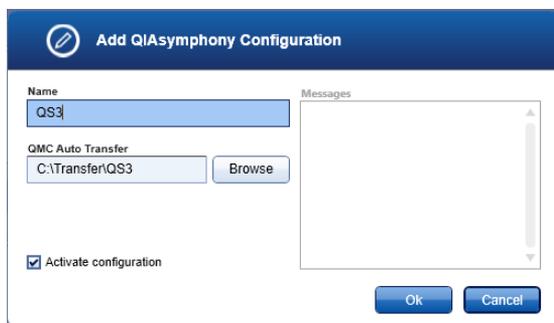
Rotor-Gene Q

The Rotor-Gene Q area allows configuration of up to 10 exchange folders for Rotor-Gene Q LIMS export files. The name of the Rotor-Gene Q instance can be freely chosen (e.g., *RGQ Lab1*). In the column "Results", the directory that is used during the LIMS Export of the results from the Rotor-Gene Q software is entered.

Add a new directory

1. To add a directory to a table, click the "New" button below the table.

The following dialog box opens.



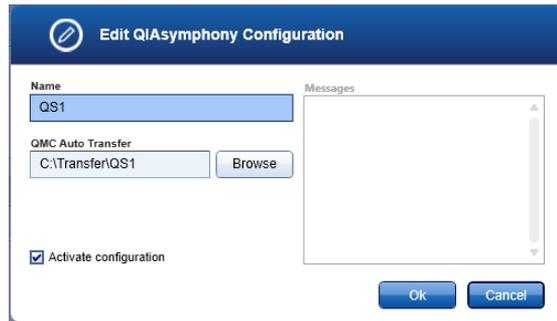
2. In the "Name" field, enter a name for the instrument that will use the file exchange directory.

Note: This name can be freely chosen, but must be unique (e.g., *QIASymphony Lab1*).

3. For local directories:
Click on the "Browse" button to browse to the desired folder.
4. For remote directories:
The full network path must be specified. Use of mapped network drives is not supported by QIALink. It is necessary to enter the network path into one of the dialog fields, "QMC Auto Transfer" for QIASymphony or "Results" for Rotor-Gene Q software and Rotor-Gene AssayManager.
Copy the path name to the clipboard then paste it into the dialog field.
5. Ensure that the box "Activate configuration" is checked.
6. Click "OK" to save the configuration.

Modify an existing directory

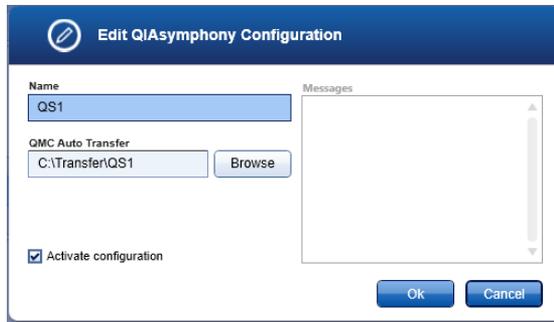
1. Click  of the directory to be modified.



2. Modify the desired parameters in the fields "Name" and "QMC Auto Transfer" or "Results".
3. Click "OK" to save the configuration.

Deactivate or activate an existing directory

1. Click  of the directory to be modified.



2. To activate a directory, check the box "Activate configuration".
3. To deactivate a directory, uncheck the box "Activate configuration".
4. Click "OK" to save the configuration.

6.7.3 QIASymphony dialog

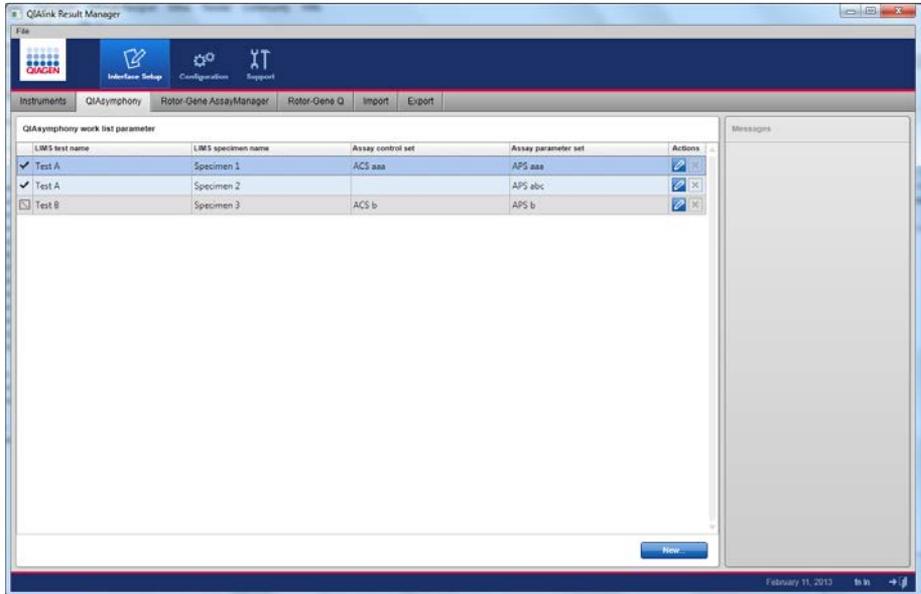
The QIASymphony screen is used to configure the assay specific parameters required for the generation of the QIASymphony work lists.

The desired QIASymphony parameters (Assay Control Set and Assay Parameter Set) must be configured in the QIASymphony screen for each possible combination of Test ID and Specimen that can be ordered by LIMS for processing on QIASymphony. Available Assay Control Set and Assay Parameter Set names can be found by using the QIASymphony Management Console (QMC). For details, refer to the QIASymphony user documentation.

The combination of Test ID and Specimen must be unique.

Note: If the LIMS requests a test for a combination of Test ID and Specimen that is not configured, QIAlink will not

generate a QIAAsymphony work list and a warning will be displayed in the Logs screen (see Section 5.7).

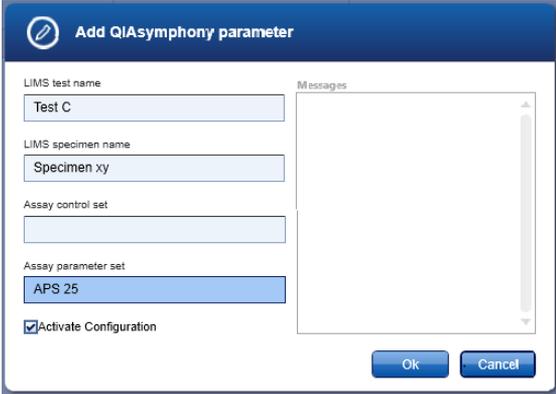


Column	Meaning
Active/inactive (First column)	  <p>The configuration is active/inactive. An inactive configuration will not be used by the QIALink Interface Engine.</p>
LIMS test name	<p>The test identifier transferred from LIMS to QIALink (e.g., "HCV").</p> <p>Please contact your LIMS provider for an overview of the used test identifiers.</p> <p>Note: The test identifier that is transmitted from LIMS to QIALink may differ from the name that is used on the LIMS user interface!</p>
LIMS specimen name	<p>The specimen type transferred from LIMS to QIALink (e.g., "plasma").</p> <p>Please contact your LIMS provider for an overview of the used specimen types.</p> <p>Note: The specimen type that is transmitted from LIMS to QIALink may differ from the name that is used on the LIMS user interface!</p>
Assay control set	<p>The Assay Control Set (ACS) to be used by the QIASymphony SP (e.g., "ACS_Cellfree1000_V6_DSP_default_IC").</p>
Assay parameter set	<p>The Assay Parameter Set (APS) to be used by the QIASymphony AS (e.g., "QIAGEN-PCR-96 (15+10) V1.0").</p>
Actions	 Edit configuration.  Delete configuration. <p>"Delete configuration" is enabled for QIAGEN Technical Service only.</p>

Add a new configuration

1. To add a new configuration, click "New".

The following dialog box appears.



2. Enter the test identifier provided by your LIMS provider in the field "LIMS test name" (case sensitive).
3. Enter the specimen name provided by your LIMS provider in the field "LIMS specimen name" (case sensitive).
4. In the "Assay control set" field, enter the name of the Assay Control Set (case sensitive) to be used on QIAsymphony for the purification of samples with the given test identifier and specimen name.

Note: If the "integrated run" feature is used on QIAsymphony, the "Assay control set" field can be empty.

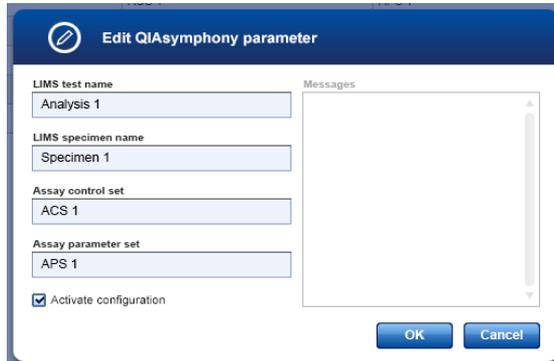
Note: If the "Assay control set" field is left empty, only "integrated run" will be possible with this configuration.

5. In the "Assay parameter set" field, enter the name of the Assay Parameter Set to be used on QIAsymphony for the assay setup of samples with the given test identifier and specimen name.
6. Ensure that the box "Activate configuration" is checked.

7. Click "OK" to save the configuration.

Modify an existing configuration

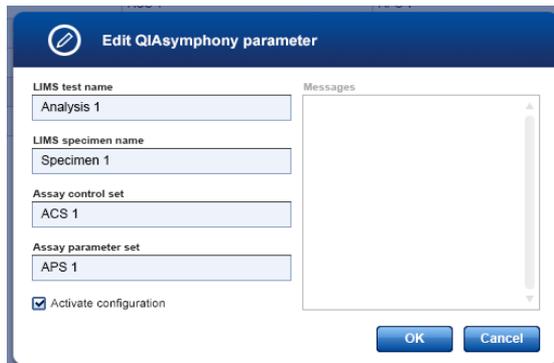
1. Click  of the configuration to be modified.



2. Modify the desired parameters in the fields "LIMS test name", "LIMS specimen name", "Assay control set", and "Assay parameter set".
3. Click "OK" to save the configuration.

Deactivate or activate an existing configuration

1. Click  of the configuration to be modified.



2. To activate a configuration, check the box "Activate configuration".

3. To deactivate a configuration, uncheck the box "Activate configuration".
4. Click "OK" to save the configuration.

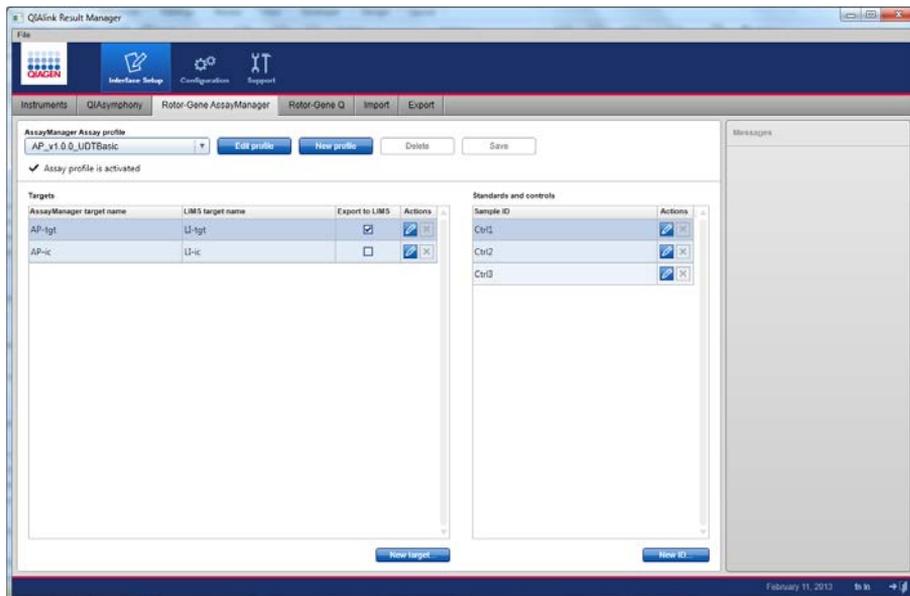
Important note: If the Assay Control Set (ACS) and/or Assay Parameter Set (APS) are updated on QIASymphony, the QIALink configuration must be updated to match the new ACS/APS names. If this is not done, the new ACS/APS will not be used in the QIASymphony work list.

6.7.4 Rotor-Gene AssayManager dialog

The Rotor-Gene AssayManager screen is used to configure the assay specific parameters required for creation of LIMS responses from the LIMS output files of Rotor-Gene AssayManager.

Each assay profile used in Rotor-Gene AssayManager and exported to LIMS must be configured in this screen.

Note: No LIMS response will be generated if results are exported from Rotor-Gene AssayManager to QIALink for an assay profile that is not configured. An error will be displayed in the Logs screen (see Section 5.7).



Meanings of items in the “Rotor-Gene AssayManager” tab are explained in the following table.

Column/field name	Meaning
AssayManager Assay profile (field)	Contains the following information about the Rotor-Gene AssayManager assay profile: <ul style="list-style-type: none"> ■ Assay profile name ■ Assay profile version ■ Plug-in name
Targets (table)	Contains all targets belonging to the assay profile.
AssayManager target name	Name of the target as configured in the Rotor-Gene AssayManager assay profile.

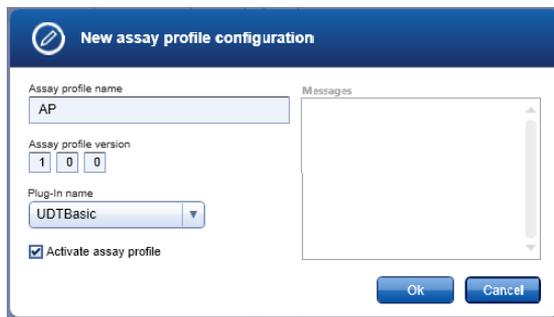
Table continued on next page

Table continued

Column/field name	Meaning
LIMS target name	<p>Target name for export to LIMS.</p> <p>Please contact your LIMS provider for an overview of the supported target names.</p> <p>Note: The target name that is expected by LIMS may differ from the name that is used on the LIMS user interface!</p>
Export to LIMS	<p>Unchecked: No results for this target will be transferred to LIMS. (This is intended to be used, for example, for internal controls.)</p> <p>Checked: Results for this target will be transferred to LIMS.</p>
Actions	<p> Edit configuration for target.</p> <p> Delete target from configuration.</p>
Standards and controls (table)	<p>Contains all standards and external controls belonging to the assay profile.</p> <p>Results for standards and external controls will not be transferred to LIMS.</p>
Sample ID	<p>Names of the standards and external controls as configured in the Rotor-Gene AssayManager assay profile.</p>
Actions	<p> Edit configuration for standard/control.</p> <p> Delete standard/control from configuration.</p>

Configure a new assay profile

1. Click the “New profile” button.
2. The following dialog box opens.



3. Enter the name of the Rotor-Gene AssayManager assay profile as defined in the Rotor-Gene AssayManager.
4. Enter the version of the Rotor-Gene AssayManager assay profile.
5. In the “Plug-in name” field, select the name of the Rotor-Gene AssayManager plug-in for the assay profile.
Note: Only plug-ins in the drop-down list are supported by QIALink.
6. Click “OK” to confirm the new configuration.

Configure the targets

1. Click the “New target” button.
The following dialog box opens.

The screenshot shows the 'Add Target' dialog box. The title bar is blue with a pencil icon and the text 'Add Target'. The main area is white. On the left, there are several input fields: 'Assay profile name' (text box with 'AP'), 'Assay profile version' (three small boxes with '1', '0', '0'), 'Plug-in name' (text box with 'UDTBasic'), 'AssayManager target name' (text box with 'AP-tgt2'), and 'LIMS target name' (text box with 'LI-tgt2'). Below these is a checkbox labeled 'Export to LIMS' which is checked. On the right, there is a 'Messages' text area. At the bottom right, there are two buttons: 'OK' and 'Cancel'.

Note: The name, version, and plug-in name of the assay profile are read-only and cannot be changed in this dialog box.

2. Enter the name of the target as it is configured in the Rotor-Gene AssayManager assay profile.
3. Enter the target name to be exported to LIMS.

This name is defined by your LIMS provider. For targets not exported to LIMS, the name can be freely chosen.

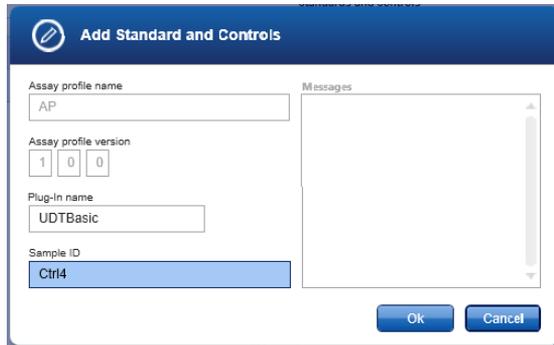
Note: Targets that are not exported to LIMS (e.g., internal controls) must also be configured. If not, warnings will be displayed in the Logs screen (see Section 5.7) during processing of Rotor-Gene AssayManager LIMS output files.

4. Check the "Export to LIMS" box if results for this target are exported to LIMS.
Uncheck the "Export to LIMS" box if results for this target are not exported to LIMS (e.g., for internal controls).
5. Click "OK" to confirm the configuration and close the dialog box.
6. Repeat steps 1 to 5 for each target in the assay profile.

Configure standards and controls

1. Click the “New ID” button.

The following dialog box opens.



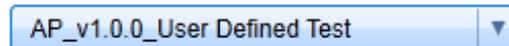
Note: The name, version, and plug-in name of the assay profile are read-only and cannot be changed in this dialog box.

2. In the “Sample ID” field, enter the name of the standard/external control as it is configured in the Rotor-Gene AssayManager assay profile.
3. Click “OK” to confirm the configuration and close the dialog box.
4. Repeat steps 1 to 3 for each standard/external control belonging to the assay profile.
5. Click “Save” to save the assay profile configuration.

Modify the name, version, or plug-in name of an existing assay profile configuration

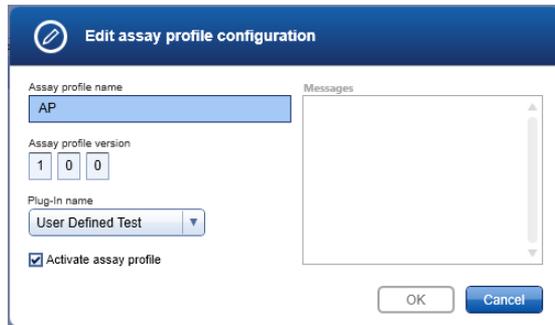
1. Select the assay profile from the “AssayManager assay profile” drop-down list.

AssayManager assay profile



2. Click the “Edit profile” button.

The following dialog box opens.

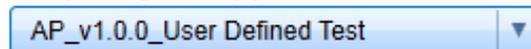


3. Modify the desired values.
4. Click “OK” to confirm the changes and close the dialog box.
5. Click “Save” to save the changes.

Modify targets in an existing assay profile configuration

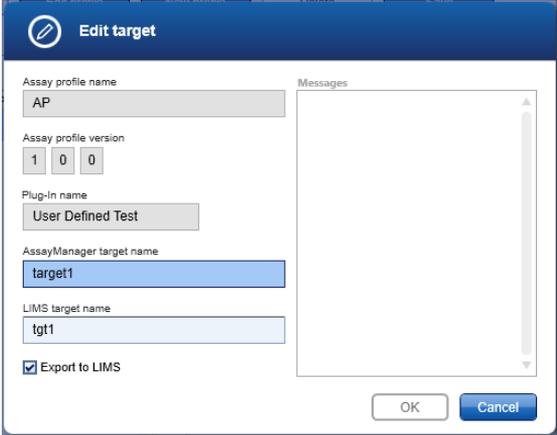
1. Select the assay profile from the “AssayManager assay profile” drop-down list.

AssayManager assay profile



2. To add a target, follow steps 1 to 6 from “Configure a new assay profile”.
3. To modify an existing target, click  of the target to be modified.

The following dialog box opens.

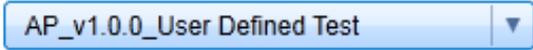


4. Modify the parameters.
5. Click "OK" to confirm the modifications and close the dialog box.
6. Click "Save" to save the changes.

Modify standards and controls in an existing assay profile configuration

1. Select the assay profile from the "AssayManager assay profile" drop-down list.

AssayManager assay profile



2. To add a standard/external control, follow steps 1 to 6 from "Configure a new assay profile" above.
3. To modify an existing standard/external control, click  of the standard/external control to be modified.

The following dialog box opens.

4. Modify the "Sample ID" field.
5. Click "OK" to confirm the modifications and close the dialog box.
6. Click "Save" to save the changes.

Deactivate or activate an existing assay profile configuration

1. Select the assay profile from the "AssayManager assay profile" drop-down list.

AssayManager assay profile

2. Click the "Edit profile" button.

The following dialog box opens.

3. Uncheck "Activate assay profile" to deactivate the configuration.
Check "Activate assay profile" to activate the configuration.
4. Click "OK" to confirm the changes and close the dialog box.
5. Click "Save" to save the changes.

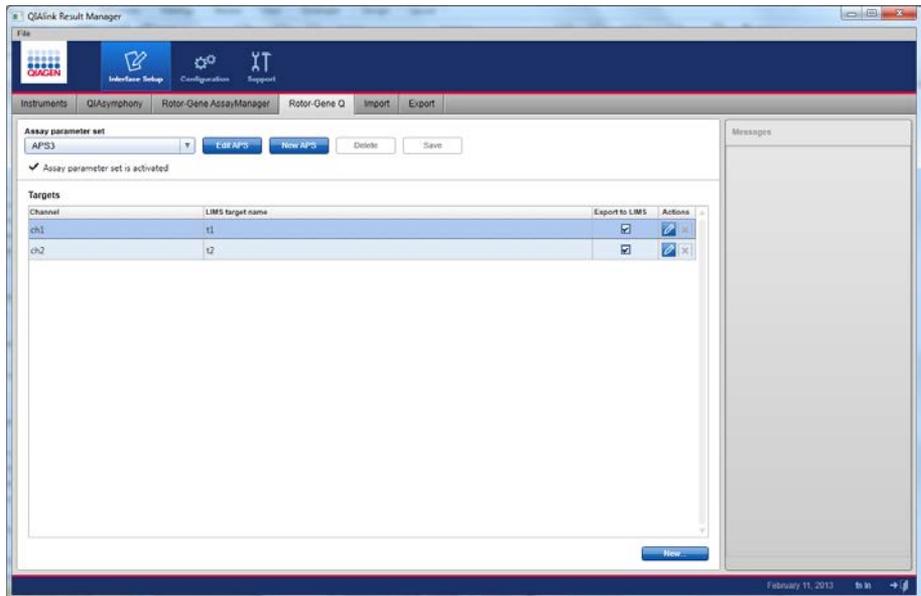
Note: Configurations for Rotor-Gene AssayManager assay profiles (closed mode) will be provided by QIAGEN and can be imported into QIALink (see Section 6.7.6). After import of a profile, the LIMS target name for each target must be entered to comply with LIMS. (See step "Modify targets in an existing assay profile configuration" in the description above.)

6.7.5 Rotor-Gene Q dialog

The Rotor-Gene Q screen is used to configure the assay specific parameters that are required for creation of LIMS responses from the Rotor-Gene Q LIMS export files.

Each assay processed on the Rotor-Gene Q and exported to LIMS must be configured in this screen.

No LIMS response will be generated if results are exported to QIAlink for an assay that has not been configured. An error will be displayed in the Logs screen (see Section 5.7).



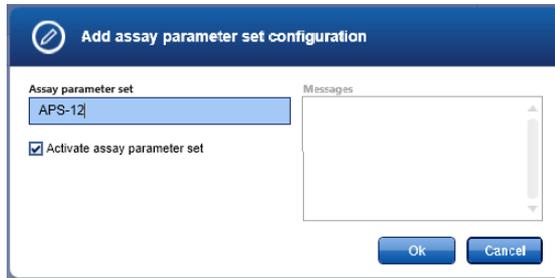
Meanings of items in the “Rotor-Gene Q” tab are explained in the following table.

Column/field name	Meaning
Assay parameter set (field)	The name of the assay parameter set (e.g., "QIAGEN-PCR-96 (15+10) V1.0"). For each assay parameter set, a list of targets can be configured in the "Targets" table.
Channel	Channel used by Rotor-Gene Q to detect the target (e.g., "Cycling A.Green").
LIMS target name	Target name for export to LIMS. Contact your LIMS provider for an overview of the supported target names. Note: The target name that is expected by LIMS may differ from the name that is used on the LIMS user interface!
Export to LIMS	Unchecked: no results for this target will be transferred to LIMS. (This is intended to be used, for example, for internal controls.) Checked: results for this target will be transferred to LIMS.
Actions	 Edit target.  Delete target from configuration.

Configure a new assay parameter set

1. Click the “New APS” button.

The following dialog box opens.

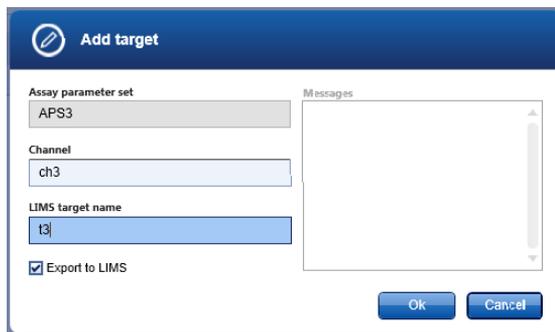


2. Enter the name of the assay parameter set.
3. Click “OK” to confirm and close the dialog box.

Configure the targets

1. Click the “New” button.

The following dialog box opens.



Note: The name of the assay parameter set is read-only and cannot be changed in this dialog box.

2. In the “Channel” field, enter the name of the Rotor-Gene Q channel used to detect the target (e.g., “Cycling A.Green”).
3. In the “LIMS target name” field, enter the target name for export to LIMS. This name needs to be defined by your

LIMS provider. For targets not exported to LIMS, the name can be freely chosen.

Note: Targets that are not exported to LIMS (e.g., internal controls) must also be configured. If this is not done, warnings will be displayed in the Logs screen (see Section 5.7) during processing of Rotor-Gene Q software LIMS export files.

4. Check "Export to LIMS" if results for this target are exported to LIMS.
Uncheck "Export to LIMS" if results for this target are not exported to LIMS (e.g., for internal controls).
5. Click "OK" to confirm the configuration and close the dialog box.
6. Repeat steps 1 to 5 for each target.
7. Click "Save" to save the changes.

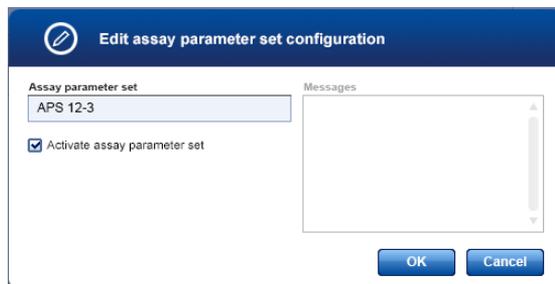
Change the name of an existing assay parameters set

1. Select the assay parameter set from the drop-down list.



2. Click the "Edit APS" button.

The following dialog box opens.



3. Change the name in the "Assay parameter set" field.

4. Click "OK" to confirm the changes and close the dialog box.
5. Click "Save" to save the changes.

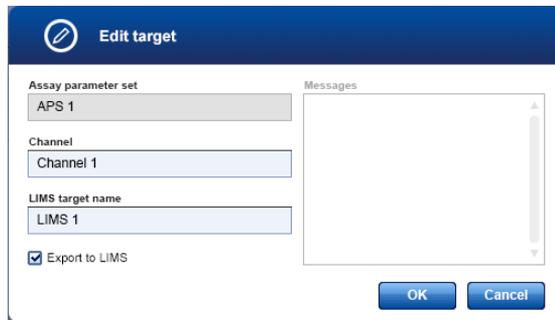
Modify an existing assay parameter set

1. Select the assay parameter set from the drop-down list.



2. To add a target, follow steps from "Configure a new assay parameter set".
3. To modify an existing target, click  of the target to be modified.

The following dialog box opens.



4. Enter the modified parameters.
5. Click "OK" to confirm the changes and close the dialog box.
6. Click "Save" to save the changes.

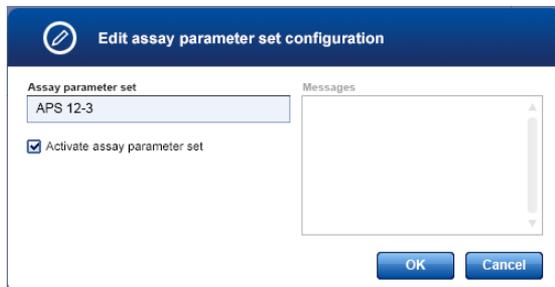
Deactivate or activate an existing configuration

1. Select the assay parameter set from the drop-down list.



2. Click the “Edit APS” button.

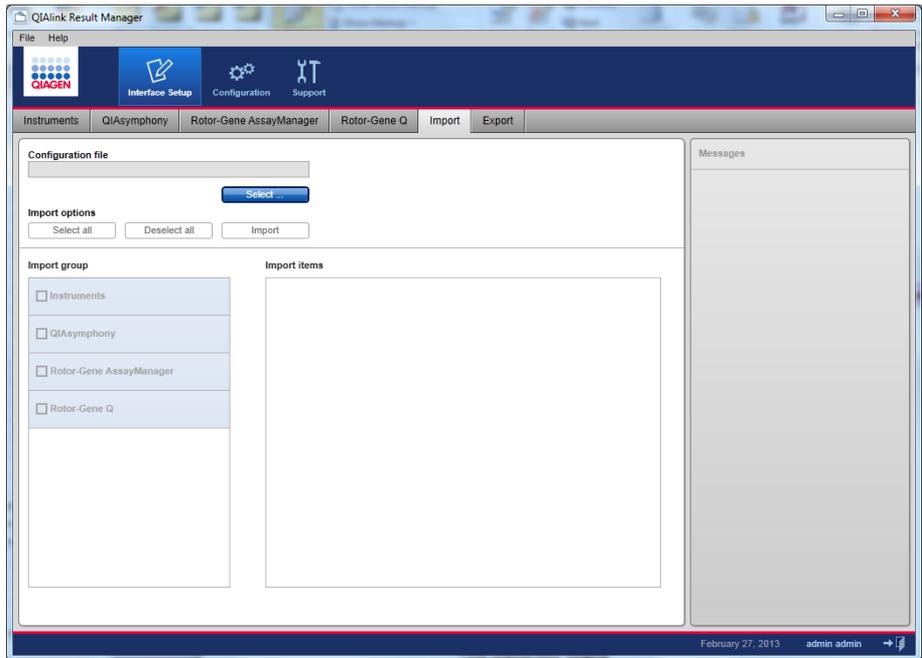
The following dialog box opens.



3. Uncheck “Activate assay parameter set” to deactivate the configuration.
Check “Activate assay parameter set” to activate the configuration.
4. Click “OK” to confirm the changes and close the dialog box.
5. Click “Save” to save the changes.

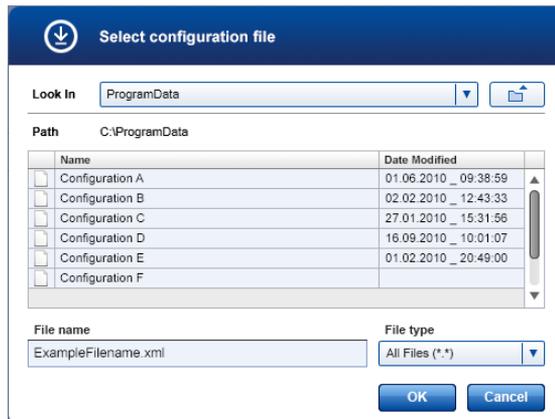
6.7.6 Import

The import function can be accessed by choosing “Import” from the navigation bar of the Interface Setup Environment. The function enables the import of existing configurations into QIALink. The imported configurations can be either standard configurations provided by QIAGEN or configurations created with another QIALink installation.



1. Click "Select".

The following dialog box opens.



2. In the "Look In" field, browse through the drop-down list to the directory that contains the configuration file.

3. Select the file to import.

Look In 

Path C:\ProgramData

4. Click "OK".

The available configurations from the import file are displayed.

Configuration

Import options

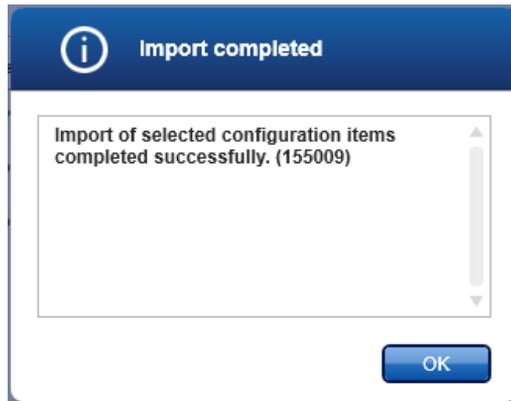
Import group	Import items
<input type="checkbox"/> Instruments >	QIAsymphony <input type="checkbox"/> QS 1 <input type="checkbox"/> QS 2 <input checked="" type="checkbox"/> QS 3
<input type="checkbox"/> QIAsymphony	Rotor-Gene AssayManager <input checked="" type="checkbox"/> RAM 1 <input checked="" type="checkbox"/> RAM 2 <input checked="" type="checkbox"/> RAM 3 <input checked="" type="checkbox"/> RAM 4
<input checked="" type="checkbox"/> Rotor-Gene AssayManager	Rotor-Gene Q <input type="checkbox"/> RGQ 1 <input type="checkbox"/> RGQ 2 <input type="checkbox"/> RGQ 3 <input type="checkbox"/> RGQ 4
<input type="checkbox"/> Rotor-Gene Q	

5. Click "Select all" to import all configurations contained in the configuration file.

To import a subset of the configurations, check the desired configurations in the "Import group" and "Import items" panels.

6. Click "Import".

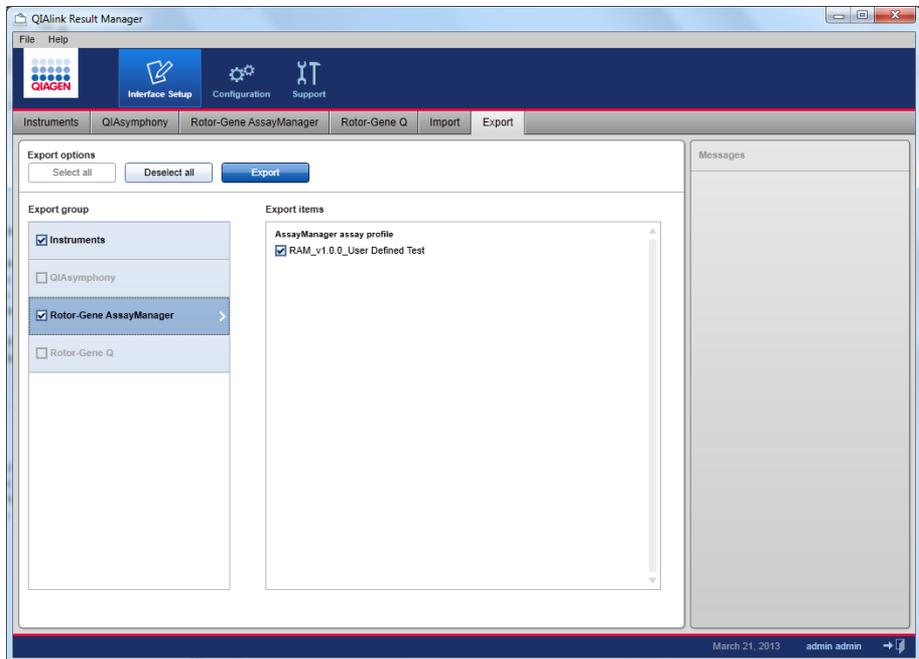
The chosen configuration is imported and becomes active immediately. An "Import completed" message is displayed.



7. Click "OK" to close the message.

6.7.7 Export

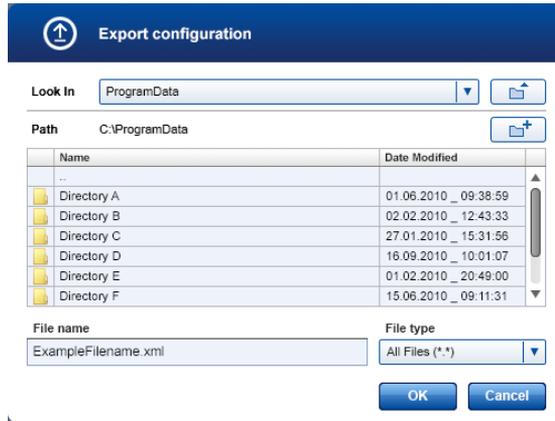
The export function is accessed by selecting "Export" in the navigation bar of the Interface Setup Environment. The function enables the export of existing configurations to a file.



Export all configurations

1. Click "Select all".
2. Click "Export".

The following dialog box opens.



3. Browse to the desired directory. Enter a file name.
4. Click "OK".
All configuration settings are saved to file.

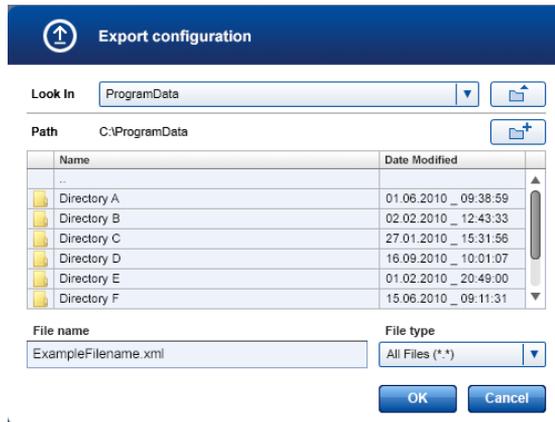
Export a subset of the available configurations

1. Select the items for export by clicking the corresponding box.



2. Click "Export".

The following dialog box opens.

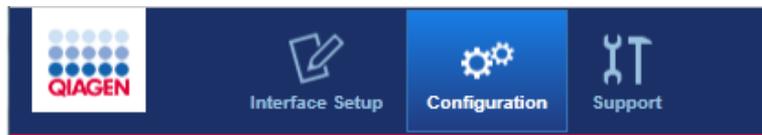


3. Browse to the desired directory.
4. Enter a file name in the “File name” field.
5. Click “OK”.
The selected settings are saved to file.

6.8 Configuration environment

6.8.1 Overview

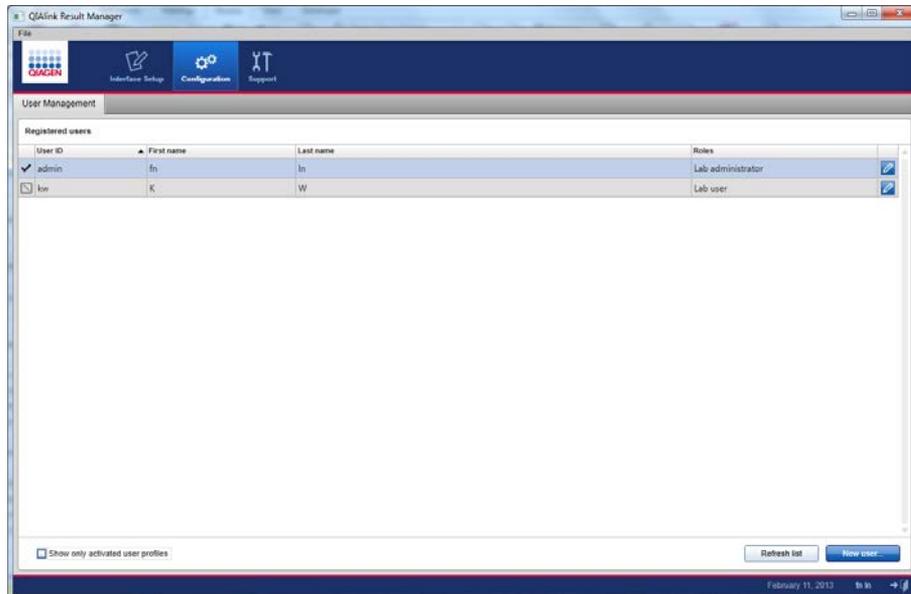
The Configuration environment is accessed by selecting “Configuration” in the main navigation bar. It enables user management for QIAlink Result Manager.



6.8.2 User management

A user assigned the role of Lab Administrator is able to add new user profiles. The Lab Administrator is also able to activate, deactivate, and modify existing user profiles. User profiles cannot be deleted. They may only be deactivated, if necessary.

Users are managed in the “User Management” tab of the Configuration environment.



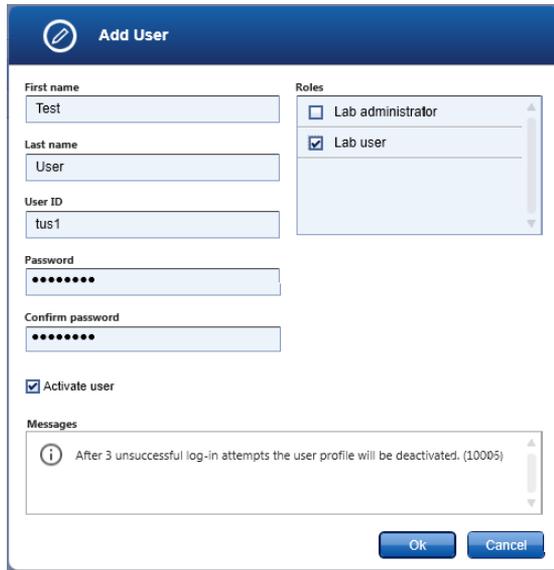
Meanings of items in the “User Management” tab are explained in the following table.

Item	Meaning
Active/inactive (first column)	<input checked="" type="checkbox"/> The user account is active. <input type="checkbox"/> The user account is inactive and cannot be used to log into the software.
User ID	The user ID for logging into the software.
First name/Last name	First and family names of the user.
Roles	Assigned user roles. Possible roles are: <input type="checkbox"/> LabUser <input type="checkbox"/> LabAdmin
Edit (last column)	 Edit user.
"Show only activated user profiles" (box)	Checked: only active user accounts are displayed. Unchecked: active and inactive user accounts are displayed.
"Refresh list"	To refresh list after checking/unchecking "Show only activated user profiles" box.
"New user..."	Create new user account.

Create new user

1. Click the “New user” button.

The following dialog box opens.



2. Enter first name, last name, and a user ID into the appropriate fields.
3. Enter a password in the “Password” field. Enter the same password again in the “Confirm password” field.

The password must comply with the following rules:

- Minimum length 8 characters
- Minimum 2 upper case characters
- Minimum 2 lower case characters
- Minimum 2 numeric characters
- Minimum 2 special characters

The “Activate user” checkbox is checked by default.

4. Check the required roles in the “Roles” panel.

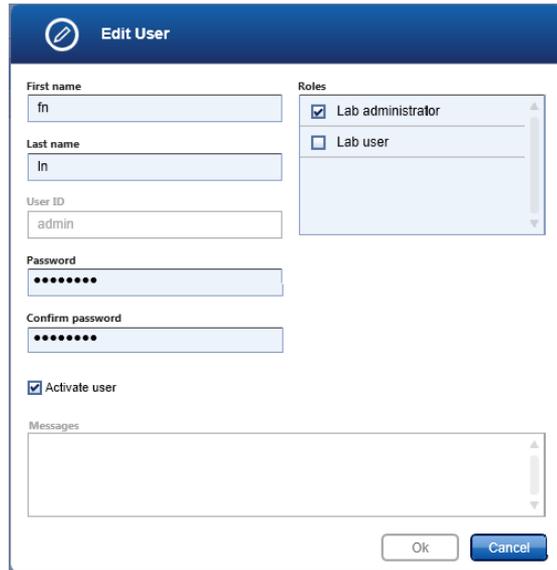
5. Confirm and close the dialog box by clicking “OK”.

The new user is created immediately.

Modify details of an existing user

1. Click  of the user to be modified.

The “Edit User” dialog box opens.



2. Modify the user’s details.

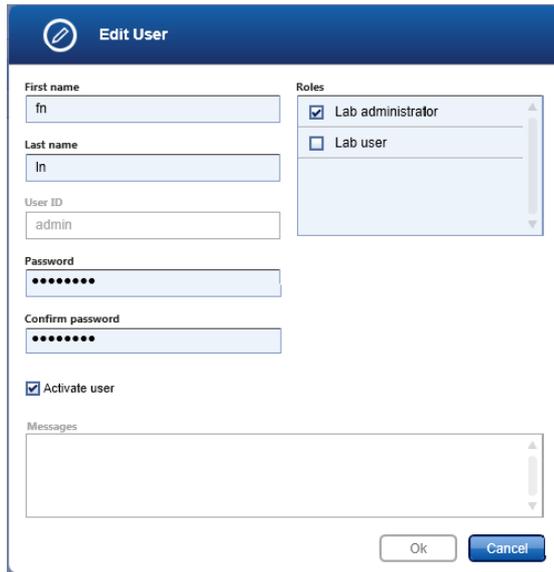
3. Click “OK” to confirm the changes and close the dialog box.

The modifications are saved.

Deactivate or activate an existing user

1. Click  of the user account to be deactivated or activated.

The Edit User dialog box opens.



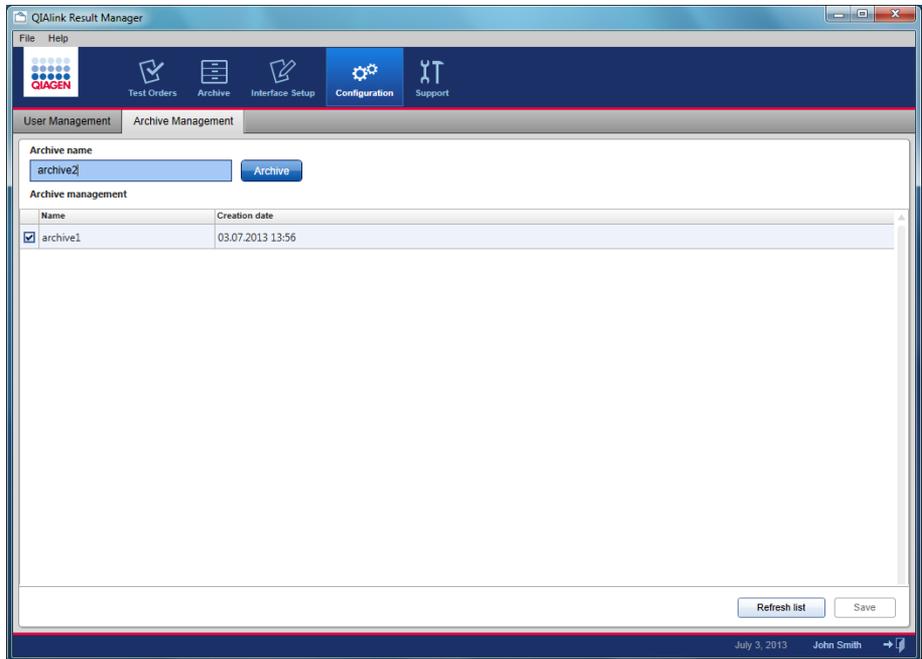
The screenshot shows the 'Edit User' dialog box. It has a blue header with a pencil icon and the text 'Edit User'. The dialog contains several input fields: 'First name' with 'fn', 'Last name' with 'ln', 'User ID' with 'admin', 'Password' with masked characters, and 'Confirm password' with masked characters. There is a 'Roles' section with two checkboxes: 'Lab administrator' (checked) and 'Lab user' (unchecked). At the bottom, there is a checked 'Activate user' checkbox and a 'Messages' text area. 'OK' and 'Cancel' buttons are at the bottom right.

2. Uncheck the "Activate user" box to deactivate the user account.
To activate the user account, check the "Activate user" checkbox.
3. Click "OK" to confirm the changes and close the dialog box.

6.8.3 Archive management

The archive management environment is accessible by users with the role "Lab administrator". It allows management of archives of the QIALink result database. The result database contains all data that can be viewed in the archive environment (see section 6.6). Archive management allows

activation or deactivation of existing archives and creation of a new archive from the current working database.



Meanings of items in the “Archive Management” tab are explained in the following table.

Item	Meaning
"Archive name" (text box)	Field to enter the name of a new archive.
"Archive"	To create an archive from the current working database.
Archive management table	Table containing all available archives.
Checkbox column	To activate/deactivate an archive.
Name	Contains the name of the archive.
Creation date	Contains the creation date of the archive.
"Refresh list"	To refresh the list of existing archives
"Save"	To save changes to the active/inactive section.

Create a new archive

Since the size of an individual SQL Server Express database is limited, it is required that stored result data be moved to an archive from time to time.

The following steps are required:

1. Specify the name of the new archive in the "Archive name" text box.

Note: The name must be unique.

2. Click "Archive".

An information message is displayed after successful creation of the archive.

The archive management table is updated with the new archive and the "Archive name" text box is cleared.

Activation/deactivation of archives

The activate/deactivate archive function allows the user to select the archived databases that will be used in the archive management environment. Data from deactivated archives is not accessible in the archive management environment.

Note: Reducing the number of active archives increases the performance of searches in the archive environment.

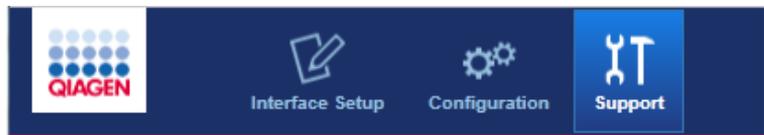
To change the activation status of an archive, follow these steps.

1. Check the box in the first column of the archive management table for an archive to be activated.
2. Uncheck the checkbox in the first column of the archive management table for an archive to be deactivated.
3. Click "Save" to activate/deactivate the archives according to the selections.

6.9 Support environment

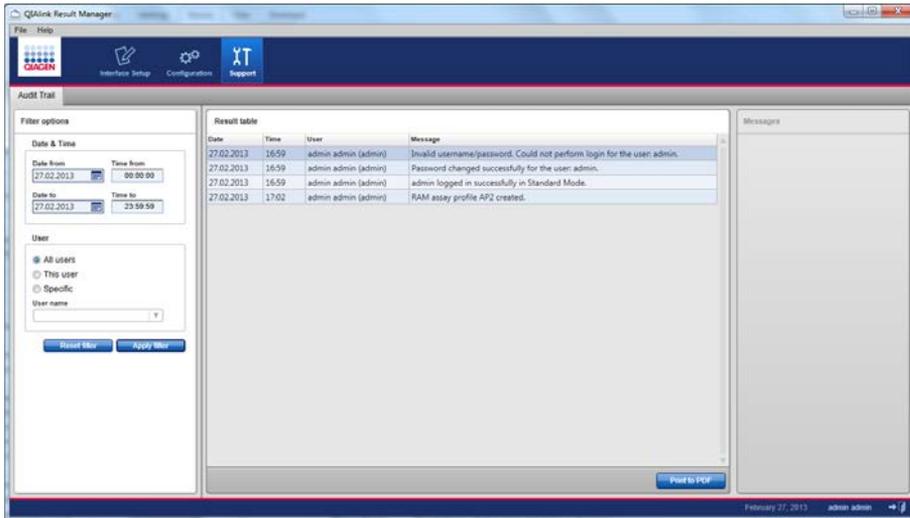
6.9.1 Overview

The Support environment is accessed by selecting "Support" in the main navigation bar. It contains the audit trail.



6.9.2 Audit trail

The "Audit Trail" tab of the Support environment gives access to the audit trail. All changes to configuration are tracked and displayed in this view.



The “Filter Options” panel on the left of the screen enables filtering of displayed messages. The following options are available:

Field/button	Meaning
--------------	---------

Date from	Start date of the required time frame.
-----------	--

Time from	Start time of the required time frame.
-----------	--

Date to	End date of the required time frame.
---------	--------------------------------------

Time to	End time of the required time frame.
---------	--------------------------------------

User	User modifying a configuration: Possible values are:
------	---

- All users
- This user
- Specific (select user name from drop-down list)

Field/button	Meaning
--------------	---------

"Reset Filter"	Reset filter values to default settings.
"Apply Filter"	Initiate filtering of messages based on the required filter options.

The following information is displayed in a table on the right hand panel:

Column	Meaning
--------	---------

Date	Date when a change took place.
Time	Time when a change took place.
User	User ID of the user who made the change.
Message	Description of the configuration change.

To filter the messages:

1. Enter the required values for date, time, and user.
2. Click "Apply Filter".
3. Click "Print PDF" to print the displayed audit trail messages to a PDF file.

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7 Workflow with QIALink

This chapter provides information about using QIALink software in combination with QIASymphony, the Rotor-Gene Q software, and Rotor-Gene AssayManager.

7.1 QIASymphony in combination with QIALink

7.1.1 Overview

QIALink software supports QIASymphony software versions 4.0.2 and higher.

QIALink uses the QIASymphony Management Console (QMC) to communicate with QIASymphony instruments.

Note: The Auto Transfer function of the QMC must be activated to enable QIALink to work. See QIASymphony user documentation for more information.

The interactions between QIALink software and the QIASymphony are described in the following sections.

7.1.2 Work list generation

After receiving a test order from LIMS, QIALink creates a QIASymphony work list. Therefore, the parameters contained in the LIMS order must be configured in QIALink (see Section 6.7.3).

The created work lists are transferred to all connected and configured QIASymphony instruments.

For more information on working with work lists on QIASymphony, refer to QIASymphony user documentation.

7.1.3 Archiving of QIASymphony result files

The result files from QIASymphony SP and AS are archived within a SQL Server Express database.

7.1.4 Processing of QIASymphony SP batch confirmation

QIASymphony SP batch confirmation is evaluated by QIALink software.

7.1.5 Transfer of QIASymphony rack files

The rack files from QIASymphony SP are transferred by QIALink to all connected QIASymphony AS instruments. This makes it possible to move eluate racks to a different QIASymphony instrument for assay setup.

7.1.6 Required QIASymphony settings

The user with the "Supervisor" ID can change a range of QIASymphony configuration settings with the QIASymphony "Configuration" menu. For a detailed description of the QIASymphony configuration, please refer to QIASymphony user documentation.

The following configuration settings of QIASymphony are strongly recommended for use in combination with QIALink:

Configuration/General process

Number of days for which a work list is valid?

This setting defines the number of days for which a work list is valid on QIASymphony. After this time, the work list is automatically deleted from QIASymphony.

Configuration/Process SP3

Write start batch confirmation files?

= Yes This setting activates sending of a start batch confirmation after start of the SP process.

Allow partial use of work lists?

= Yes It is possible to use a work list even if not all samples from the work list are present in the batch.

7.2 Rotor-Gene Q software in combination with QIAlink

7.2.1 General

QIAlink software supports Rotor-Gene Q software versions 2.0.3 and higher.

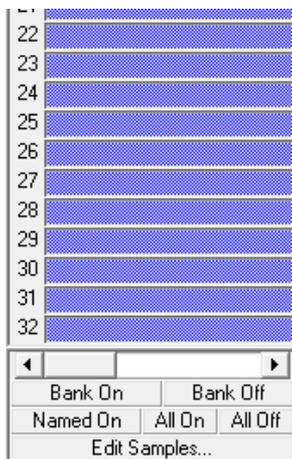
Note: Rotor-Gene Q software is not supported by QIAlink when operated in closed mode. To enable QIAlink support of Rotor-Gene Q software, the export package “LIMS Export” must be installed. This will be done by QIAGEN Technical Services during installation of QIAlink software.

7.2.2 Page definition

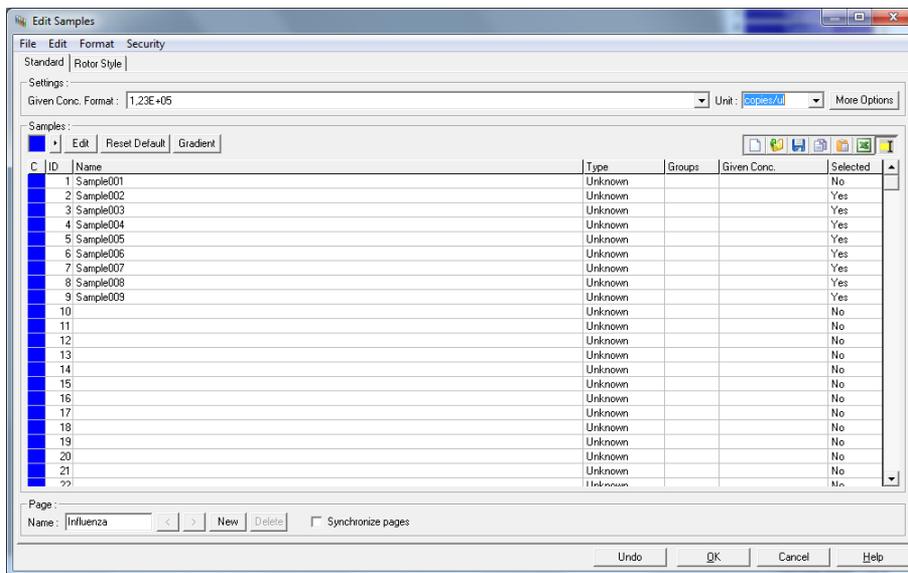
We recommend using the QIASymphony AS cycler file to define the Rotor-Gene Q run. The pages are automatically named according to the used Assay Parameter Set.

If it is not possible to use the cycler file (e.g., if QIASymphony AS was not used for assay setup), it is necessary to define the page names manually.

1. Click “Edit Samples” at the lower, right-hand corner of the page, at the end of the samples list.



The “Edit Samples” screen opens.

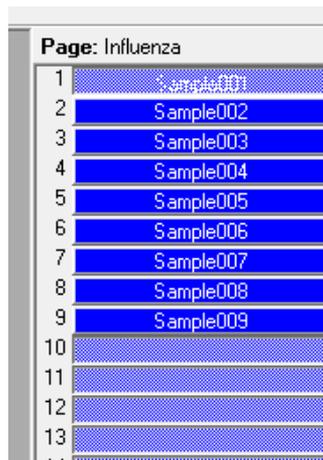


2. Enter the desired page name in the “Name” field in the lower left corner of the “Edit Samples” screen.

Note: The name of the page must be identical to the value “Assay parameter set” configured in the Rotor-Gene Q dialog in QIAlink Result Manager (see Section 6.7.5).

3. Click “OK”.

The page name is now displayed at the top of the samples list.



For more information on the use of pages, please refer to the user manual of the Rotor-Gene Q instrument.

7.2.3 Release of results

Follow these steps to export results from the Rotor-Gene Q software through QIAlink to LIMS.

1. Evaluate the results in Rotor-Gene Q software.
2. Deselect any invalid samples/results by clicking the corresponding sample name.

WARNING 	<p>Deselection of invalid results [W1]</p> <p>Samples with invalid results must be deselected in Rotor-Gene Q software prior to data transfer by QIAlink. Otherwise, invalid results may be exported to LIMS.</p>
---	---

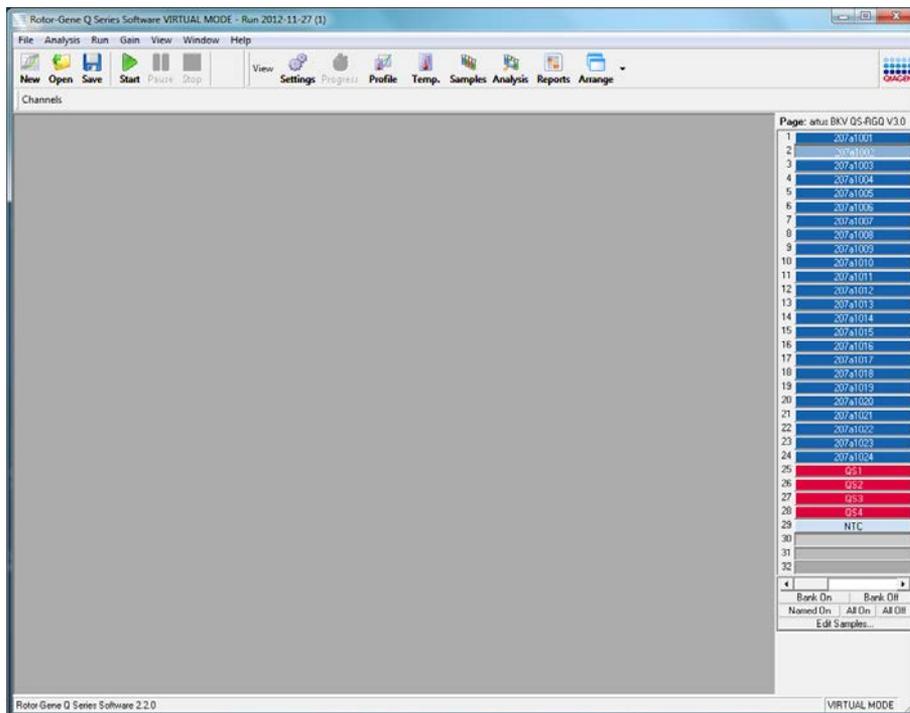
If a result is designated as invalid, the sample must be deselected from the sample list on the right panel.

Reporting results to LIMS

- Deselected sample: no result will be exported to LIMS; instead, the information that no valid result could be obtained for this sample is sent to LIMS.

- Selected sample: the corresponding result will be exported to LIMS.

The screenshot shows an example where sample 2 has been deselected.



QIALink software will transfer the information to LIMS that no valid result could be obtained for the deselected sample.

3. To initiate the export of the results, select "File/Save As...", then "LIMS Export..." in Rotor-Gene Q software.

Choose a directory that is configured in QIALink for Rotor-Gene Q software LIMS export files (see Section 6.7.5).

The file name may be freely chosen. The file type must be set to ***.xml**.

If the results are exported inadvertently to another folder, the export to LIMS can be triggered by performing steps 1 to 3 again.

QIALink forwards the exported results automatically to LIMS. The results are also archived in the SQL Server Express database.

7.3 Rotor-Genes AssayManager in combination with QIALink

7.3.1 General

QIALink software supports version 1.0 and higher of Rotor-Genes AssayManager.

To activate export of Rotor-Genes AssayManager results to LIMS, the option "Export results to LIMS" must be activated in the "Settings" tab of the Rotor-Genes AssayManager "Configuration" environment. For details, refer to the Rotor-Genes AssayManager user documentation.

Configure the QIALink Results folder (see Section 6.7.4) to the same directory as the LIMS output folder specified in Rotor-Genes AssayManager Local Settings.

Upon release of results in Rotor-Genes AssayManager, a LIMS output file will be exported to QIALink. QIALink transfers the results from the LIMS output file automatically to LIMS. The rules described below apply for the transfer of Rotor-Genes AssayManager results to LIMS.

7.3.2 Handling of rejected results

Results that have been rejected in Rotor-Genes AssayManager will not be transferred to LIMS. Instead, QIALink will transmit the information to LIMS that no valid result could be obtained for this sample.

7.3.3 Handling of invalid results

If a target is marked with an error flag in Rotor-Gene AssayManager and is declared invalid, no result for this target will be transferred to LIMS. Instead, QIALink will transmit the information to LIMS that no valid result could be obtained for this sample.

7.3.4 Rotor-Gene AssayManager plug-ins

QIALink supports the following plug-ins:

- *artus*[®] Basic plug-in
- *artus* Basic (US) plug-in
- *artus* MRSA/SA plug-in
- *artus* MRSA/SA (US) plug-in
- JAK2 plug-in
- UDT Basic plug-in

If a plug-in is used that is not supported, no results will be transferred to LIMS. A warning will be displayed in the Logs screen (see Section 5.7).

8 Maintaining the Database

QIAlink is a software package and does not need general maintenance. However, the databases do need to be maintained.

8.1 Backing up

Important: It is important to back up the databases. In case of a computer failure, data may be recovered from the most recent backup.

Note: A special software tool is needed for creating a backup of the QIAlink databases. The Microsoft SQL Server 2008 Management Studio Express (SSMSE) is a graphical management tool for SQL Server 2008 R2 Express used as database in QIAlink.

Go to www.microsoft.com for instructions on how to download and installing SSMSE.

8.2 Hints for backing up a database

Before backing up the database, close QIAlink Result Manager and stop the Iguana service (see Section 5.2).

Back up the following databases:

- aspnetdb
- QIAlinkIFSettings
- QIAlinkResultArchive

To access the backup option dialog, select the context menu entry for the desired database and choose "Tasks/Back Up".

Further information can be obtained from the "Help" function of SSMSE, or refer to www.microsoft.com for setting up the backup of the database according to your laboratory's requirements.

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9 Troubleshooting

The table lists errors, warnings and info messages that can occur in the Logs screen of the QIAlink Interface Engine (see Section 5.7). It contains information about possible root causes and actions to resolve the problem.

Error code	Possible cause	Comments and suggestions
<p>001</p> <p>Could not read from configuration database. Check the database settings. Restart the channel when the problem is resolved.</p>	<p>SQL Server database on a remote server is used. Connection to remote server is disrupted.</p>	<p>Check server availability.</p> <p>Restart the channel.</p>
<p>002</p> <p>Could not write to result database. Check the database settings. Restart the channel when the problem is resolved</p>	<p>SQL Server database on a remote server is used. Connection to remote server is disrupted.</p>	<p>Check server availability.</p> <p>Restart the channel.</p>
<p>003</p> <p>Could not write to file <FILE>. Check that the directory is available and write permissions are set properly. Restart the channel when the problem is resolved.</p>	<p>Directory refers to a network drive. Network drive is not accessible.</p> <p>Directory allows no write access.</p>	<p>Check availability of the network drive.</p> <p>Restart the channel.</p> <p>Enable write access in Windows settings.</p> <p>Restart the channel.</p>

004

Could not read from file <FILE>. Check that the directory is available and read permissions are set properly. Restart the channel when the problem is resolved.

Directory refers to a network drive.
Network drive is not accessible.

Directory allows no read access.

Check availability of the network drive.

Restart the channel.

Enable read access in Windows settings.

Restart the channel.

005

Received a message with unknown recipient <RECEIVING_APP>. The message will be ignored.

LIMS transmitted a test order to QIALink with a recipient other than QIALink. The LIMS message does not comply with QIAGEN interface specification.

Contact your LIMS vendor.

006

Received a message with unsupported encoding <ENCODING>. The message will be ignored.

LIMS transmitted a test order with a character set that is not supported. The LIMS message does not comply with QIAGEN interface specification.

Contact your LIMS vendor.

Error code	Possible cause	Comments and suggestions
<p>007</p> <p>Received an unsupported message of type <MSGTYPE>. The message will be ignored.</p>	<p>LIMS transmitted a message with a message type that does not comply with QIAGEN interface specification.</p>	<p>Contact your LIMS vendor.</p>
<p>008</p> <p>Received a message with an unsupported HL7 version (<VERSION>). The message will be ignored.</p>	<p>LIMS transmitted a message with a HL7 protocol version that does not comply with QIAGEN interface specification.</p>	<p>Contact your LIMS vendor.</p>
<p>009</p> <p>Received order with unsupported value for order control (<OCVALUE>). The order will be ignored.</p>	<p>LIMS transmitted a test order with an order control value that does not comply with QIAGEN interface specification.</p>	<p>Contact your LIMS vendor.</p>

Error code	Possible cause	Comments and suggestions
<p>010</p> <p>No configuration for <SERVICE_IDENTIFIER> and specimen <SPECIMEN>. The order for sample <SAMPLE_ID> will be ignored. Check the configuration and resend the order from the LIMS.</p>	<p>LIMS transmitted a test order that contained an unknown test ID or an unknown specimen.</p>	<p>Correct configuration of QIAsymphony parameters (see Section 6.7.3).</p> <p>Resend order from LIMS.</p>
<p>011</p> <p>Found multiple configurations for <SERVICE_IDENTIFIER> and specimen <SPECIMEN>. Check the configuration and restart the channel.</p>	<p>The QIAlink configuration contains more than one configuration for the same LIMS test ID and specimen.</p>	<p>Correct configuration of QIAsymphony parameters (see Section 6.7.3).</p> <p>Resend order from LIMS.</p>
<p>012</p> <p>No configuration for QIAsymphony work list directory. Check the configuration and restart the channel.</p>	<p>No directory is configured for QIAsymphony.</p>	<p>Configure QIAsymphony directory (see Section 6.7.3).</p> <p>Restart the channel.</p>
<p>013</p> <p>No configuration for Rotor-Gene AssayManager result directory. Check the configuration and restart the channel.</p>	<p>No directory is configured for Rotor-Gene AssayManager.</p>	<p>Configure Rotor-Gene AssayManager directory (see Section 6.7.4).</p> <p>Restart the channel.</p>

Error code	Possible cause	Comments and suggestions
<p>014</p> <p>No configuration for Assay Profile <AP> of version <VERSION>. The result file <FILE> will be ignored.</p>	<p>A result file has been exported from Rotor-Gene AssayManager containing an assay profile that is not configured in QIAlink. The channel stops processing until the error is resolved.</p>	<p>Configure assay profile (see Section 6.7.4). Go to the LIMS output folder. Move the result file that caused the problem from the Error folder to the LIMS output folder. The file will be processed again.</p>
<p>015</p> <p>Found multiple configurations for Assay Profile <ASSAYPROFILENAME> of version <ASSAYPROFILEVERSION>. Check the configuration and restart the channel.</p>	<p>The QIAlink configuration contains more than one configuration for the same assay profile.</p>	<p>Correct configuration of assay profiles (see Section 6.7.4). Go to the LIMS output folder. Move the result file that caused the problem from the Error folder to the LIMS output folder. The file will be processed again.</p>
<p>016</p> <p>Result file for unsupported plug-in <PLUGINNAME> found. The result file <FILE> will be ignored.</p>	<p>The plug-in used by Rotor-Gene AssayManager is not supported by the installed version of QIAlink.</p>	<p>Contact QIAGEN Technical Services to inquire about a QIAlink software update to support the plug-in.</p>

Error code	Possible cause	Comments and suggestions
017 Result file with unknown target <TARGET> for Assay Profile <AP> of version <VERSION> found. Check the configuration and restart the channel.	Not all targets are configured in the assay profile configuration.	Correct configuration of assay profile (see Section 6.7.4).
018 Result file with target <TARGET> for Assay Profile <ASSAYPROFILENAME> of version <ASSAYPROFILEVERSION> has multiple mappings configured. Check the configuration and restart the channel.	The assay profile configuration contains a target more than one time.	Correct configuration of assay profile (see Section 6.7.4). Go to the LIMS output folder. Move the result file that caused the problem from the Error folder to the LIMS output folder. Restart the channel. The file will be processed again.
019 No sample result to export in file <FILE>. The file will be ignored. (Continued on next page.)	A result file has been exported from the Rotor-Gene Q software or Rotor-Gene AssayManager that does not contain a result.	No action required.

Error code	Possible cause	Comments and suggestions
<p>019 (continued)</p> <p>No sample result to export in file <FILE>. The file will be ignored.</p>	<p>A result file has been exported that contains only targets configured to be excluded from LIMS export in QIAlink (see Section 6.7.4 or 6.7.5).</p>	<p>No action required.</p>
<p>020</p> <p>Result file with unknown mapping for Assay Parameter Set <APS> and Channel <CHANNEL>. Check the configuration and restart the channel.</p>	<p>The Rotor-Gene Q result file contains a combination of assay parameter set and channel that is not configured in QIAlink.</p>	<p>Correct configuration of assay parameter set (see Section 6.7.5).</p>
<p>021</p> <p>Found multiple mappings for Assay Parameter Set <ASSAYPARAMETERSET> and channel <CHANNEL>. Check the configuration and restart the channel.</p>	<p>The QIAlink configuration contains more than one configuration for the same assay parameter set and channel.</p>	<p>Correct the configuration of assay parameter set (see Section 6.7.4). Go to Rotor-Gene Q software export folder. Move result file that caused the problem from the Error folder to the export folder.</p> <p>Restart the channel. The file will be processed again.</p>

Error code	Possible cause	Comments and suggestions
<p>022</p> <p>Rotor-Gene Q software result directory is not configured. Check the configuration and restart the channel.</p>	<p>No directory is configured for Rotor-Gene Q software.</p>	<p>Configure Rotor-Gene Q software export directory (see Section 6.7.5).</p> <p>Restart the channel.</p>
<p>023</p> <p>An unexpected error occurred. Please contact QIAGEN Technical Services.</p>	<p>An unexpected error occurred.</p>	<p>Contact QIAGEN Technical Services.</p>
<p>024</p> <p>Rotor-Gene Q result file with unknown Assay Parameter Set <ASSAYPARAMETERSET>. Check the configuration and restart the channel.</p>	<p>The used Assay Parameter Set is not configured in QIAlink.</p>	<p>Correct configuration of assay parameter set (see Section 6.7.5).</p> <p>Restart the channel.</p>
<p>025</p> <p>Found multiple configurations for Assay Parameter Set <ASSAYPARAMETERSET>. Check the configuration and restart the channel.</p>	<p>The same combination of Assay Parameter Set and Rotor-Gene Q channel is configured multiple times in QIAlink.</p>	<p>Correct the configuration of assay parameter set (see Section 6.7.5).</p> <p>Restart the channel.</p>

Error code	Possible cause	Comments and suggestions
<p>026</p> <p>Result database is currently using <SIZE> % of its maximum size. Archive the database from QIAlink Result Manager.</p>	<p>The QIAlink result database has reached more than 80% of the maximum size.</p>	<p>Archive the database (see Section 6.6).</p>
<p>027</p> <p>Order without sample ID and/or universal service ID received. The order has been ignored</p>	<p>LIMS transmitted a message without sample ID or test identifier.</p>	<p>Contact your LIMS vendor.</p>
<p>028</p> <p>An unknown export format has been found in Rotor-Gene Q result file <FILE>. The file has been ignored and will be moved to error folder.</p>	<p>An incorrect export format has been used in the Rotor-Gene Q software.</p>	<p>Go back to the Rotor-Gene Q software. Export the results using “LIMS Export” (see Section 7.2).</p>

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10 License Terms

The license terms for all software that is used within QIAlink, including QIAGEN software components, commercial software components, and open source software components, are provided in the file **licenses.txt** found on the QIAlink CD.

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