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QIAlink[®] Software User Manual

For use only in the United States of America

Revision 3 For QIAlink software version 2.0.2

REF

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Document Revision History

Revision 3 HB-1936-003 06/2018	Update instructions, images and screenshots to reflect software upgrade to version 2.0.2. Software version 2.0.2 is Windows® 10 compatible and supports additional Rotor-Gene® AssayManager® plug-ins.
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Introduction

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

About this user manual

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

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

- Introduction
- Safety Information
- General Description
- Installation
- QIAlink Result Manager
- Workflow with QIAlink
- Troubleshooting
- License Terms

General information

Scope of delivery

The delivery includes the following:

- QIAlink software package
- *QIAlink Software User Manual* (available for download at www.qiagen.com/p/QIAlink)

License versions

QIALink is available in two license versions.

- QIALink, Standard Implementation:
Includes connectivity of QIASymphony® and Rotor-Gene Q MDx with Rotor-Gene AssayManager
- QIALink, RGQ MDx Implementation:
Includes connectivity of Rotor-Gene Q MDx with Rotor-Gene AssayManager

Technical assistance

At QIAGEN we pride ourselves on the quality and availability of our technical support. 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 valuable source of information regarding our products. We encourage you to contact us if you have any suggestions or feedback concerning our products.

For technical assistance, contact QIAGEN Technical Services.

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

Policy statement

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

Intended use of QIALink software

QIALink is middleware software that is intended to provide bidirectional connectivity with a Laboratory Information Management System (LIMS) and specific QIAGEN instruments and software:

- QIASymphony SP/AS with QIASymphony Management Console
- Rotor-Gene Q MDx instrument with Rotor-Gene AssayManager

The QIALink software creates work lists and transfers results between the instruments and the LIMS. The QIALink software archives instrument result files from the above-mentioned instruments and software.

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

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 including the QIALink Interface Engine with channel concept and logs, and QIALink Result Manager with user management, interface setup, test orders, archive and backup management.

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

Safety Information

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

The following type of safety information appears in this user manual.

WARNING 	The term WARNING is used to inform you about situations that could result in personal injury to you or others. Note: Details about these circumstances are given in a box like this one.
---	--

The guidance given in this manual is intended to supplement, not supersede, the normal safety requirements prevailing in your country.

Proper use

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.

IMPORTANT: It is the responsibility of the user to validate QIAlink in the context of their laboratory environment and the LIMS or LIS utilized.

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 	Rotor-Gene AssayManager result configuration Wrong mapping of the Rotor-Gene AssayManager result values to the LIMS result values can induce incorrect results.
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General Description

Software modules

The QIALink software package contains three software modules:

- QIALink Interface Engine (see “Interface channels”, page 94; “Interface log”, page 97)
- QIALink Result Manager (see page 41)

QIALink Interface Engine

QIALink Interface Engine connects QIASymphony and Rotor Gene Q MDx using Rotor-Gene AssayManager to any Laboratory Information System (LIS) and Laboratory Information Management System (LIMS). It incorporates the middleware solution Iguana™ from iINTERFACEWARE™ that runs as a Microsoft® Windows service in the background.

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.

QIALink Result Manager

QIALink Result Manager supports chain of custody for sample data when using the QIASymphony RGQ MDx workflow or individual modules (e.g., RGQ MDx). It offers features for convenient and fast retrieval of instrument result files.

QIALink Result Manager allows configuration of instrument-specific and assay-specific parameters for QIALink Interface Engine. It allows the monitoring of the interface channel status and interface log of the QIALink Interface Engine.

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 “QIASymphony in combination with QIALink”, page 106). It stores the LIMS test order and the QIASymphony work list into a Microsoft SQL Server® Express database.
- QIALink Interface Engine creates LIMS responses from the results of Rotor-Gene AssayManager (see page 108). Additionally, it stores the LIMS output of Rotor-Gene AssayManager into a SQL Server Express database.
- QIALink Interface Engine archives the result files from QIASymphony into a SQL Server Express database (see page 106).
- QIALink Interface Engine transfers QIASymphony rack files from QIASymphony SP to all connected QIASymphony AS instruments (see page 106).
- QIALink Interface Engine processes the QIASymphony start batch confirmation and stores the information in the SQL Server Express database (see page 106). This information is used by the QIALink Result Manager to create an overview of samples that are waiting to be processed (see page 46).
- QIALink Result Manager offers various filter functions to retrieve, display and print the archived instrument result files from the SQL Server Express database (see “Archive environment”, page 49).
- QIALink Result Manager provides a backup function to securely back up the QIALink database and all configuration files.
- QIALink Result Manager creates a support package that can be sent to QIAGEN Technical Service for troubleshooting.

The following figure (Figure 1) shows a typical hardware deployment of the software components that are required for the QIASymphony RGQ MDx workflow with QIALink.

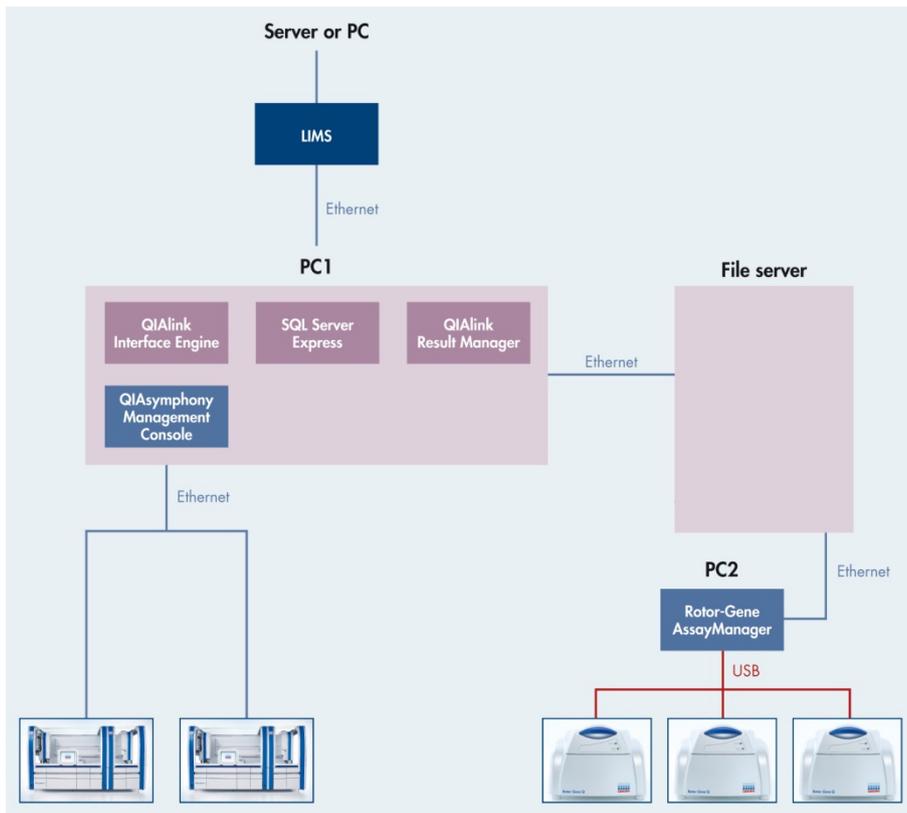


Figure 1. A typical hardware deployment of software components for the QIASymphony RGQ MDx workflow with QIAlink software.

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 and PC2.

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.

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 MDx system and with LIMS is illustrated in Figure 2 below. The exchange of data between the software components is also shown.

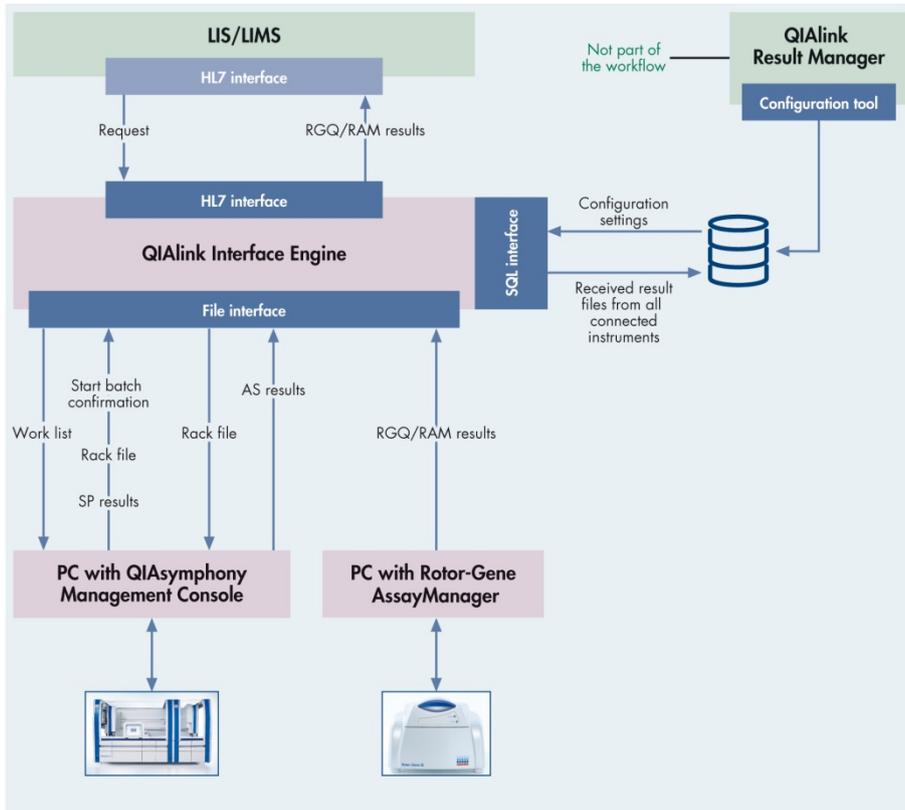


Figure 2. Overview of the integration of QIALink software in the QIASymphony RGQ MDx system.

Note: The files transferred between QIALink file interface and QIAGEN instruments depend on the software version of the connected instruments.

Installation

QIALink software installation

Note: Initial installation of QIALink software may only be performed by QIAGEN Technical Services as LIMS connection must be established.

Note: Updates of QIALink can be installed by the user.

System requirements

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

Description	System requirement
Operating system	Microsoft Windows 7 32-bit Microsoft Windows 7 64-bit Microsoft Windows 10 32-bit Microsoft Windows 10 64-bit
Browser	Internet Explorer® 8 and above
Processor	600 MHz or higher, Pentium® III-compatible 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).

Additional software on computers running QIALink

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

Note: In the event that Rotor-Gene AssayManager is located on the same computer as the QIALink software, Rotor-Gene AssayManager should be used for result evaluation only and must not be used to control the Rotor-Gene Q MDx instrument. Failure to follow this instruction may result in performance issues for the control of the Rotor-Gene Q MDx instrument.

Virus scanners

We are aware of the threat of viruses to any computer that exchanges data with other computers. QIALink software is primarily installed in environments where local policies exist to minimize this threat. These policies usually require use of a particular anti-virus tool. QIALink software has been tested on a computer using Microsoft Security Essentials. Due to the sheer number of anti-virus tools available, it is not possible for QIAGEN to predict the possible impact on QIALink software if such a tool is active. As a result, system administrators should therefore ensure that during the use of QIALink software:

- File access is not intercepted by a virus scanner
- Updates to the virus database are not performed
- File scans are not performed

We strongly recommend disabling virus scanner activity during laboratory working hours to prevent interference of the virus scan with the operation of QIALink software. The virus scanner tasks described above can only be safely carried out when QIALink software is not running. Otherwise there is a risk of adverse impact on the performance of the software.

Installing QIALink software components

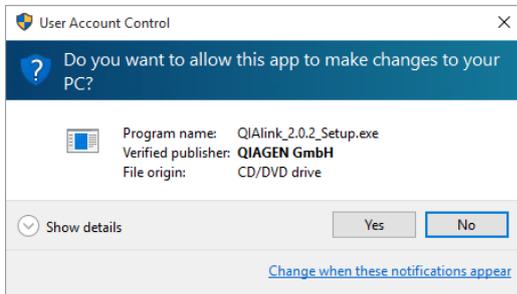
IMPORTANT: Initial installation of QIALink software may only be performed by QIAGEN Technical Services as a LIMS connection must be established.

Note: Microsoft SQL Server 2008 R2 Express or Microsoft SQL Server Express 2014 must be installed before the start of installation of QIALink Result Manager or QIALink Interface Engine, unless an existing Microsoft SQL Server installation is used. The installation package for Microsoft SQL Server Express 2014 is located on the QIALink Software CD.

To start the installation of QIALink software components, proceed as follows:

1. Insert the QIALink Software CD into the corresponding CD drive.
2. Double-click **QIALink_2.0.2_Setup.exe**.

If **User Account Control** is enabled on the machine, the following dialog appears:

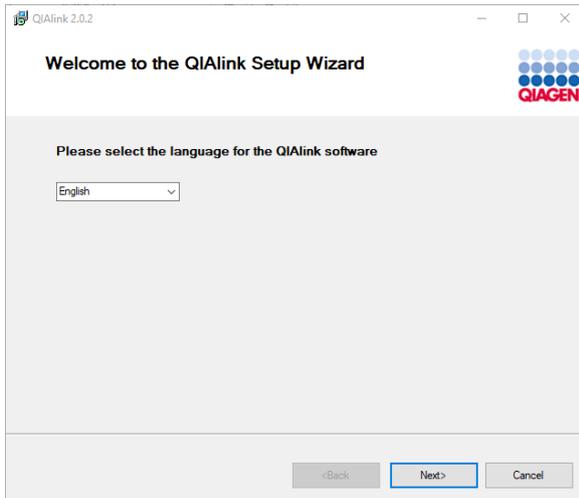


3. Click **Yes** to confirm the installation.

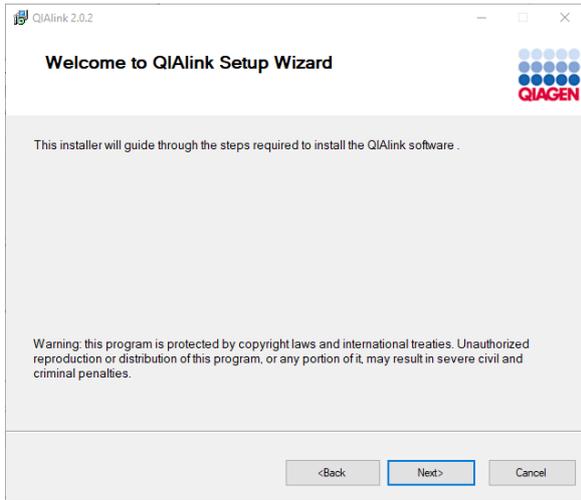
Note: The User Account Control dialog may show a warning for “unknown publisher” indicating that the code signing certificate might not be installed on the QIAlink machine. The certificate can be found on the QIAlink Software CD in the “Prerequisites” folder, or may be downloaded from the VeriSign® web site under:

https://knowledge.verisign.com/library/VERISIGN/ALL_OTHER/Certificates/Code2010/VeriSign_Class_3_Code_Signing_2010_CA.cer .

4. Follow these steps when the QIAlink Setup Wizard opens.

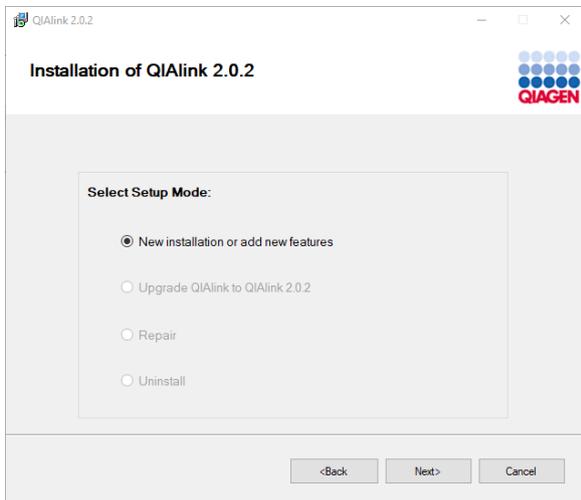


5. Select the language for the QIAlink software installation and click **Next** to continue.



6. Click **Next** to proceed.

If no QIAlink software is installed on the system, the only enabled option is **New Installation or add new features**.



7. Click **Next** to continue.

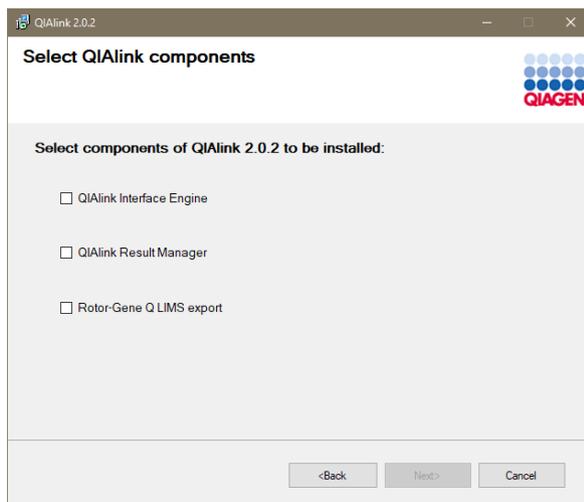
8. The **License Agreement** dialog is displayed.



9. Accept the license agreement of QIAlink software by selecting **I Agree**, then click **Next**.

10. Click **Next** to continue the QIAlink Software installation.

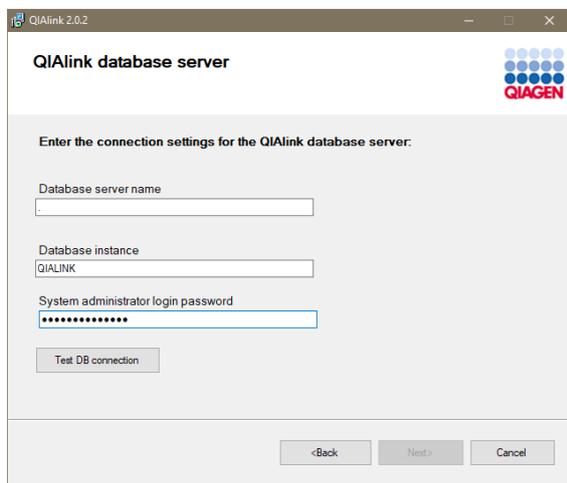
The dialog for selection of the software components is displayed.



Note: The option **Rotor-Gene Q LIMS export** is not supported in the U.S.

11. Select the QIAlink software components to be installed and click **Next**.

The settings dialog for connection to the SQL Server or SQL Server Express database opens.



12. 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”).

System administrator login password

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

13. Click **Test DB connection**.

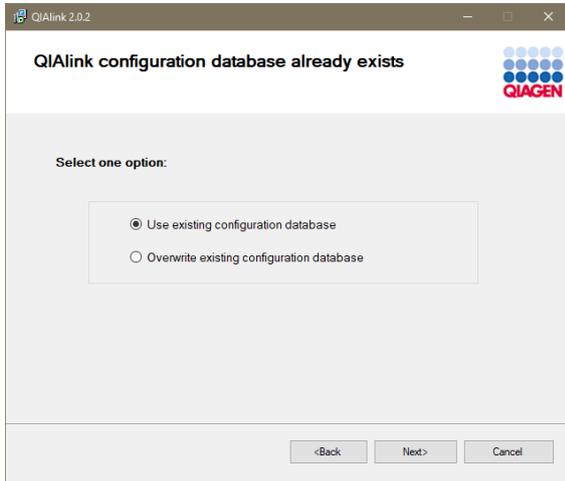
If connection is established, **DB connection successful** is displayed and the **Next** button is enabled.

If connection to the database could not be established, **DB connection failed** is displayed together with a **Details** link.

Click **Details** to view details of the reason for the connection error. Correct entry of the settings accordingly and click **Test DB connection** again.

14. Click **Next**.

15. **Optional:** If a QIAlink configuration database already exists, the following dialog is displayed:



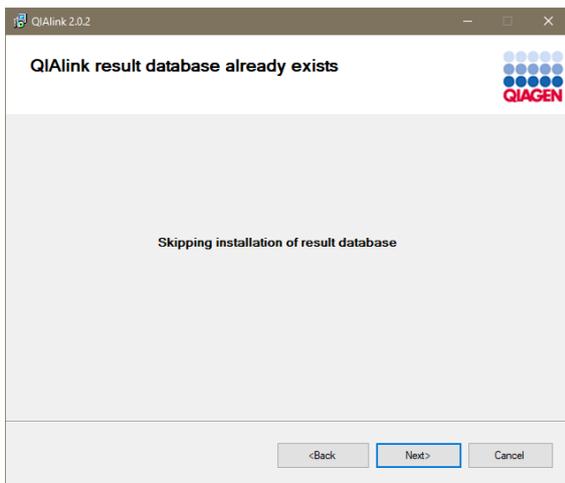
Select **Use existing configuration database** to keep the existing configuration database and continue to work with it.

Select **Overwrite existing configuration database** to delete the existing configuration database and create a new database.

IMPORTANT: Selection of the “overwrite” option results in loss of all existing configuration data!

16. Click **Next** to continue the installation.

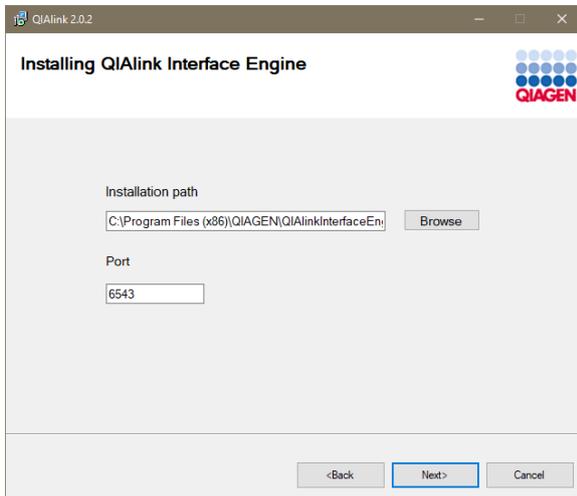
17. **Optional:** If the QIAlink result database already exists, this information dialog is displayed:



18. Click **Next**.

Note: The result database cannot be deleted during installation.

19. If QIALink Interface Engine has been selected for installation, the dialog **Installing QIALink Interface Engine** is displayed:



Note: If QIALink Interface Engine has been installed before, this step is optional.

Enter information in the dialog fields as follows:

Installation path

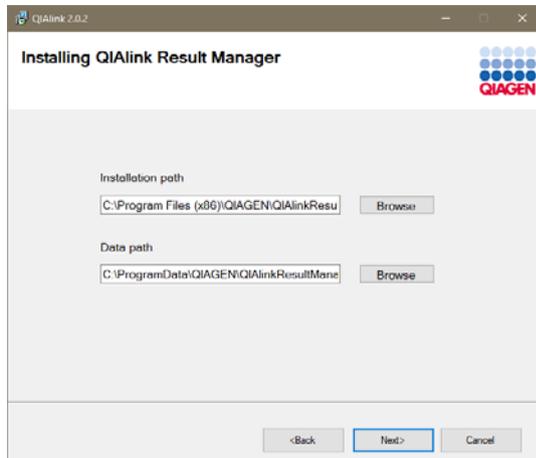
- Either use the installation path shown as default,
- Or click **Browse** to open a file explorer window and navigate to the directory where QIALink Interface Engine should be installed.

Port

- Enter the Port for the QIALink Interface Engine (default: 6543).

20. Click **Next** to continue.

21. If QIAlink Result Manager has been selected for installation, the dialog **Installing QIAlink Result Manager** is displayed:



Note: If QIAlink Result Manager has been installed before, this step is optional.

Enter information in the dialog fields as follows:

Installation path

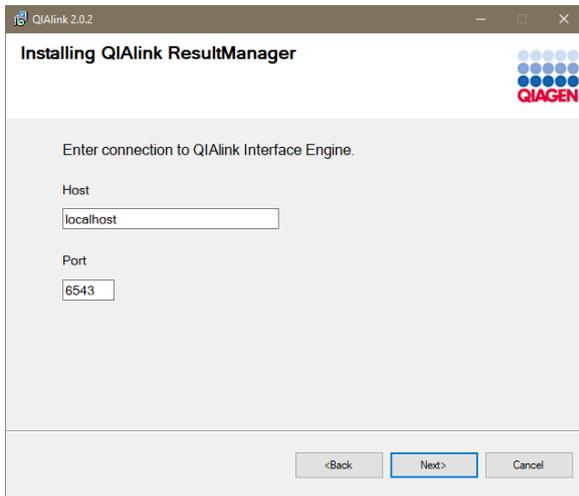
- Either use the installation path shown as default,
- Or click **Browse** to open a file explorer window and navigate to the directory where QIAlink Result Manager should be installed.

Log path

- Either use the Log path shown as default,
- Or click **Browse** to open a file explorer window and navigate to the directory where QIAlink Result Manager should write the log files.

22. Click **Next** to continue.

23. **Optional:** If QIALink Result Manager without QIALink Interface Engine has been selected for installation in step 11, the dialog for entering Interface Engine connection data is displayed:



Note: If QIALink Interface Engine has been installed before, this step is optional.

Enter information in the dialog fields as follows:

Host

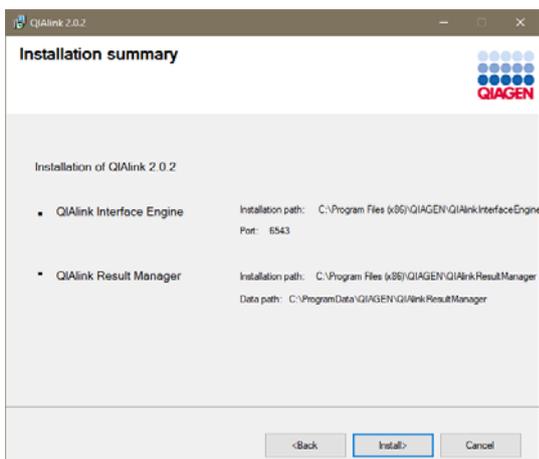
- Either enter "localhost" if QIALink Interface Engine is running on the same machine,
- Or enter the host name or IP address of the host where the component QIALink Interface Engine is running.

Port

- Enter the Port used by QIALink Interface Engine (default: 6543).

24. Click **Next** to proceed.

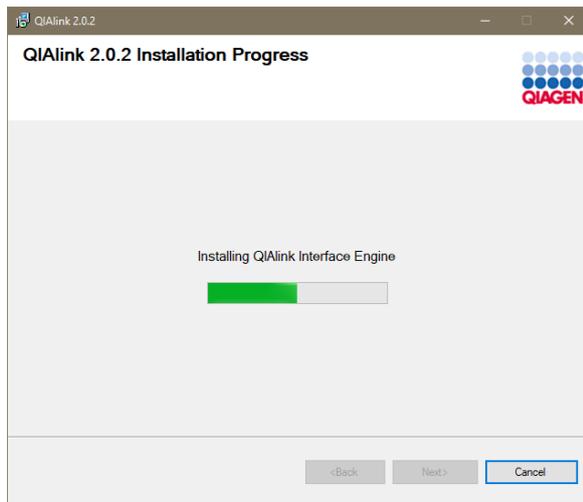
25. The **Installation summary** dialog listing the selected software components is displayed.



Note: The option **Rotor-Gene Q LIMS export** is not supported in the U.S.

26. Click **Install** to start the installation of the selected QIALink software components.

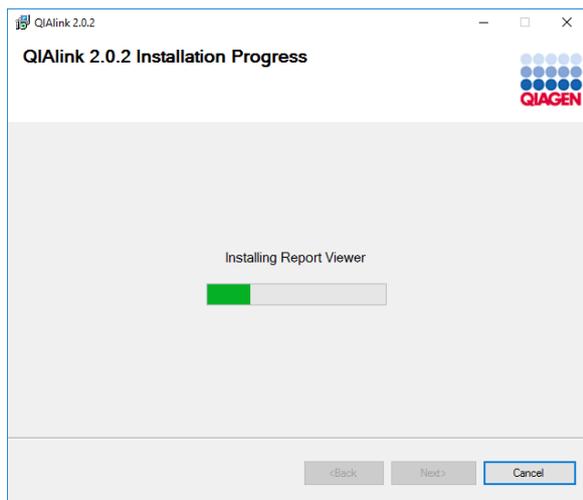
27. **Optional:** If QIALink Interface Engine has been selected for installation in step 11, the dialog showing installation progress for the QIALink Interface Engine is displayed.



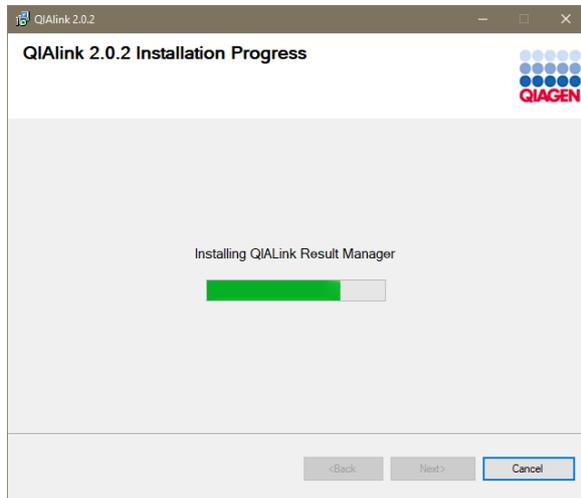
28. Click **Next** after installation is done.

29. **Optional:** If QIALink Result Manager has been selected for installation and Visual Studio® Report Viewer is not installed on the computer, the dialog showing installation progress for the Report Viewer is displayed.

The software is needed by the QIALink Result Manager to display result files.

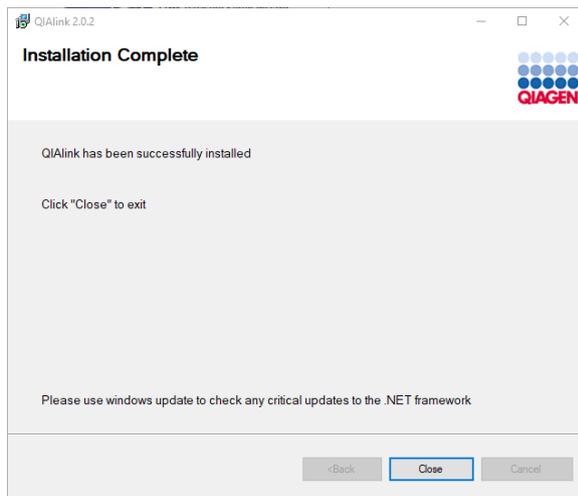


30. If QIALink Result Manager has been selected for installation in step 11, the dialog showing installation progress for QIALink Result Manager is displayed.



31. Click **Next** after installation is done.

32. After successful installation, the **Installation Complete** dialog is displayed.



33. Click **Close** to exit the setup.

QIALink software is now ready to be used.

Upgrading to QIALink 2.0.2

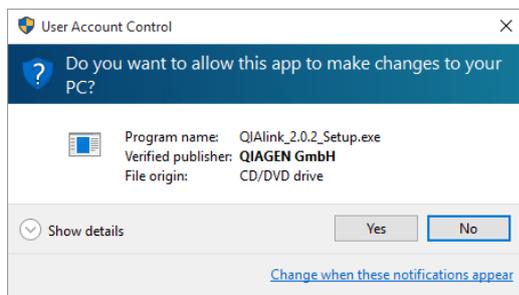
IMPORTANT: Do not perform an upgrade of the QIALink software during lab operations! Please observe the following preconditions for upgrading QIALink software:

- Process all pending test orders.
Note: To view test orders, open the QIALink Result Manager and navigate to **Test Order**.
- Make sure that all instrument result files from QIASymphony SP/AS and Rotor-Gene Q MDx are processed.
- Do not send LIMS requests to QIALink during upgrade as the QIALink Interface Engine has to be stopped.
- **IMPORTANT:** Make sure QIALink Result Manager and QIALink Interface Engine are installed before starting the QIALink upgrade.

To start upgrading QIALink, proceed as follows:

1. Insert the QIALink Software CD into the corresponding CD drive.
2. Double-click **QIALink_2.0.2_Setup.exe**.

If **User Account Control** is enabled on the machine, the following dialog appears:

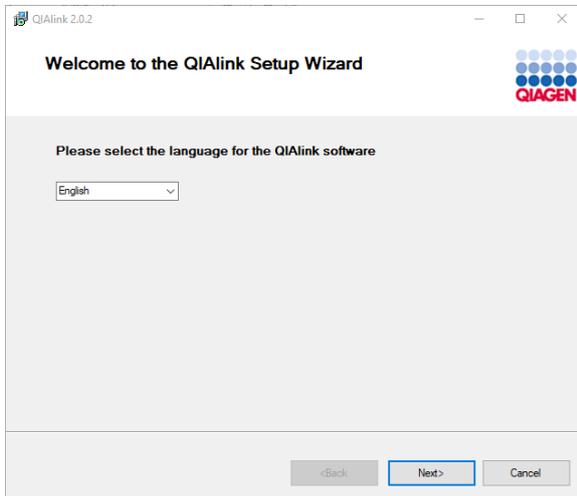


3. Click **Yes** to confirm the installation.

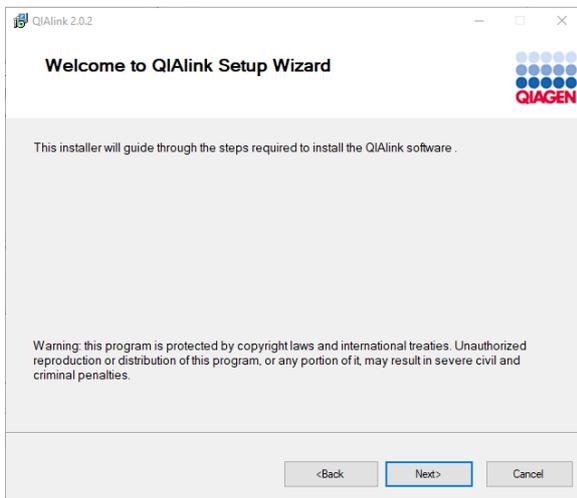
Note: The User Account Control dialog may show a warning for “unknown publisher”.

See page 15 for more information on installing the appropriate certificate.

4. Follow these steps when the QIAlink Setup Wizard opens.



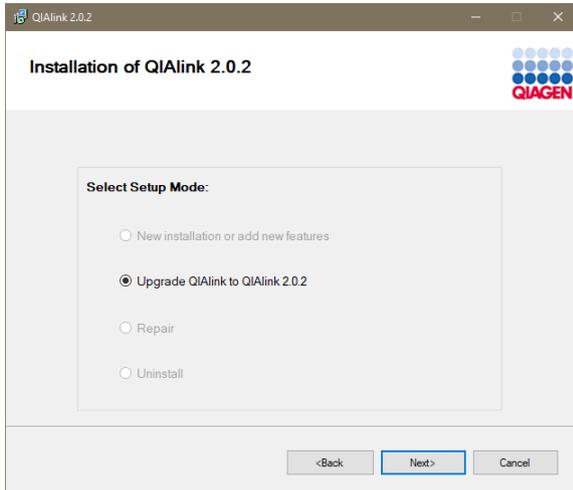
5. Select the language for the QIAlink software installation and click **Next** to continue.



6. Click **Next** to proceed.

The installation dialog is displayed.

If QIAlink 1.1.x or QIAlink 2.0.1 software is detected on the system, **Upgrade QIAlink to QIAlink 2.0.2** is the only enabled option.



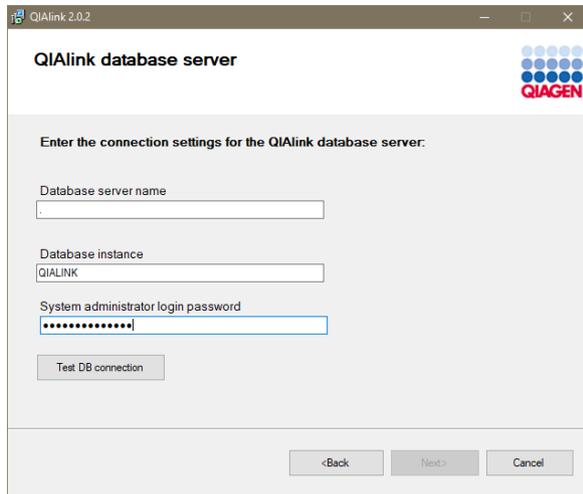
7. Click **Next** to continue with the upgrade.

The license agreement dialog is displayed.



8. Accept the license agreement of QIAlink Software by selecting **I Agree**, then click **Next**.

The settings dialog 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”).

Note: Make sure to enter the correct database instance name, otherwise an update is not possible.

System administrator login password

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

10. Click **Test DB connection**.

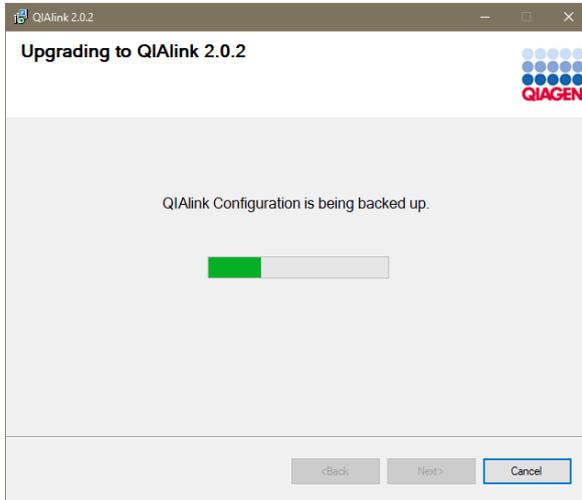
If connection is established, **DB connection successful** is displayed and the **Next** button is enabled.

If the connection to the database could not be established, **DB connection failed** is displayed together with a **Details** link.

Click **Details** to view details of the reason for the connection error. Correct entry of the settings accordingly and click **Test DB connection** again.

11. Click **Next** to continue.

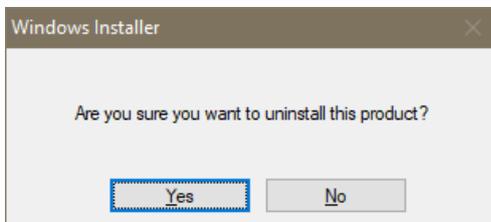
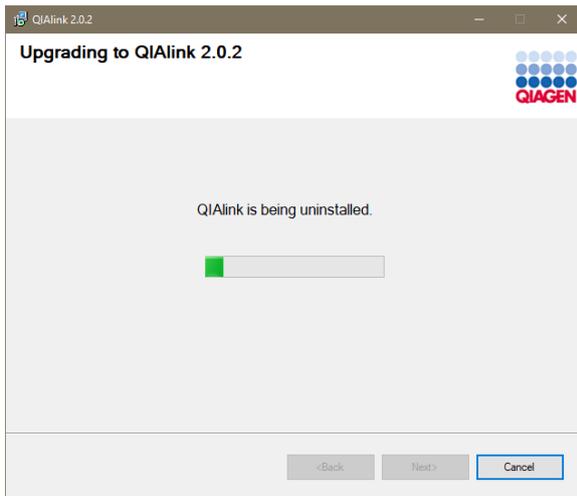
The backup dialog is displayed.



The backup file will be stored under **C:\ProgramData\QIAGEN\QIAlink**.

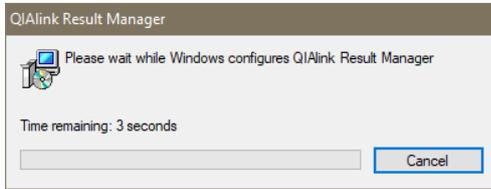
12. After backup is finished, click **Next** to continue.

The dialog for uninstalling the existing QIAlink version is displayed.



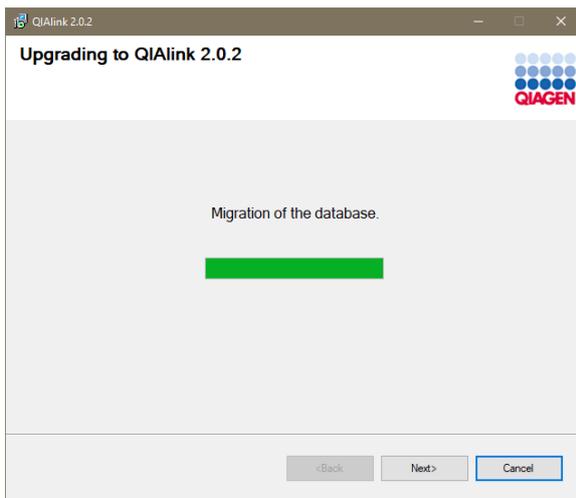
13. The Windows Installer dialog opens. Click **Yes** to uninstall the QIAlink software.

The QIAlink Result Manager configuration dialog is displayed.



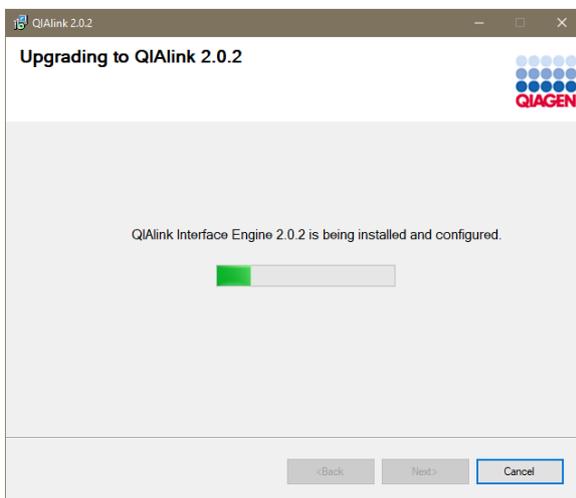
14. After uninstallation is finished, click **Next** to continue.

The dialog showing **Migration of the database** is displayed.



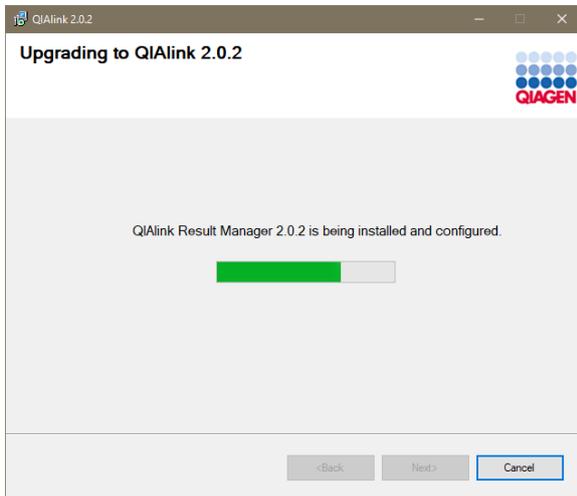
15. Click **Next** when migration of the database is finished.

16. If QIAlink Interface Engine is upgraded, the dialog showing installation and configuration of QIAlink Interface Engine is displayed.



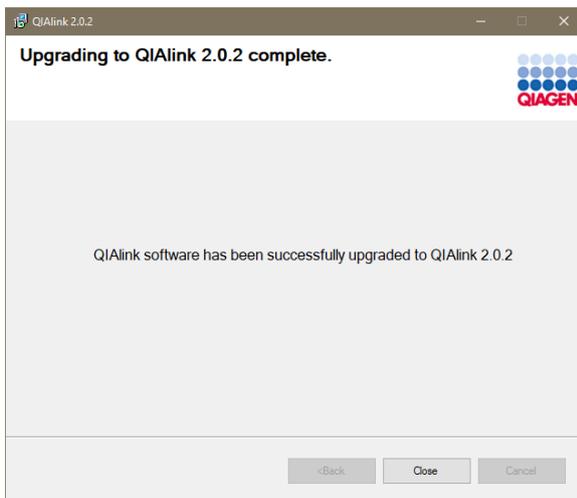
17. Click **Next** to proceed after installation and configuration are finished.

18. If QIAlink Result Manager is upgraded, the dialog showing installation and configuration of QIAlink Result manager is displayed.



19. Click **Next** to proceed after installation and configuration are finished.

After a successful upgrade, the dialog **Upgrading to QIAlink 2.0.2 complete** is displayed.



20. Click **Close** to exit.

IMPORTANT: After the upgrade has been completed successfully, the Rotor-Gene AssayManager export parameters in the **Interface Setup** environment of the QIAlink Result Manager must be checked by the user (see page 75).

During the migration from QIALink 1.1 to QIALink 2.0, the Rotor-Gene AssayManager export parameters are defaulted as follows:

- Export standards and controls = false
- Export internal controls = false

As a result, internal controls and standard and controls will no longer be exported to LIMS. If the export is needed, please start QIALink Result Manager, navigate to the **Rotor-Gene AssayManager** tab and enable **Export standard and controls** and **Export internal controls** (see “Rotor-Gene AssayManager dialog”, page 67).

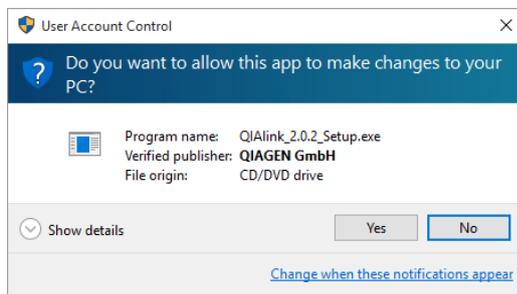
Note: After the migration, all rack files will be sent again. This may take some time. QIAGEN recommends removing outdated rack files from the QIASymphony instrument and the QMC transfer folder.

Repairing QIALink software components

To start the repair of QIALink software components, proceed as follows:

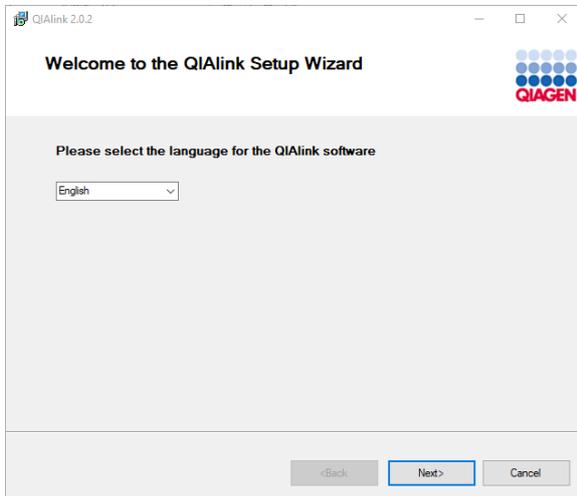
1. Insert the QIALink software CD into the corresponding CD drive.
2. Double-click **QIALink_2.0.2_Setup.exe**.

If **User Account Control** is enabled on the machine, the following dialog appears:

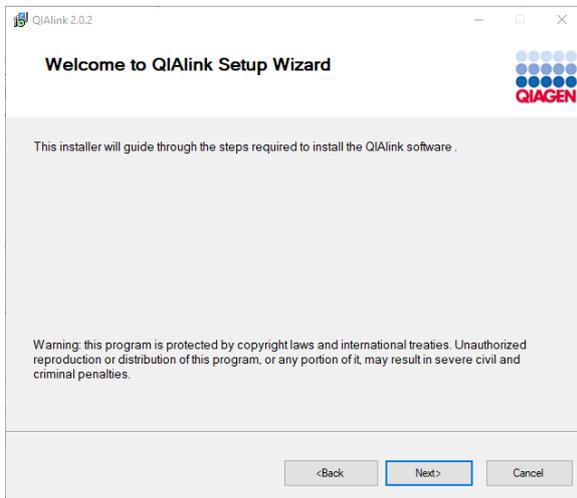


3. Click **Yes** to confirm the installation.
4. Follow these steps when the QIALink Setup Wizard opens.

The **Welcome to the QIAlink Setup Wizard** dialog is displayed.

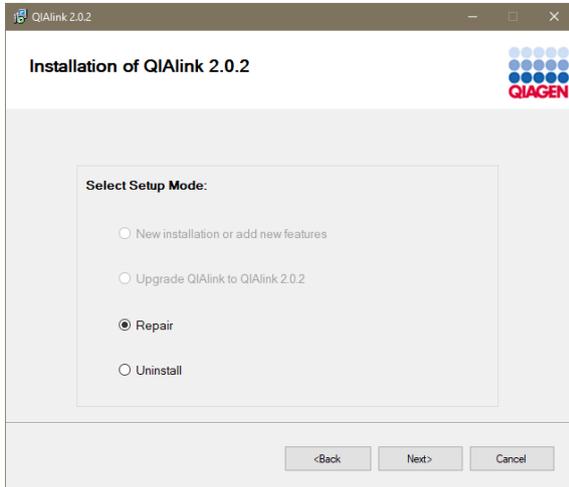


5. Select the language for the QIAlink software installation and click **Next** to continue.



6. Click **Next** to proceed.

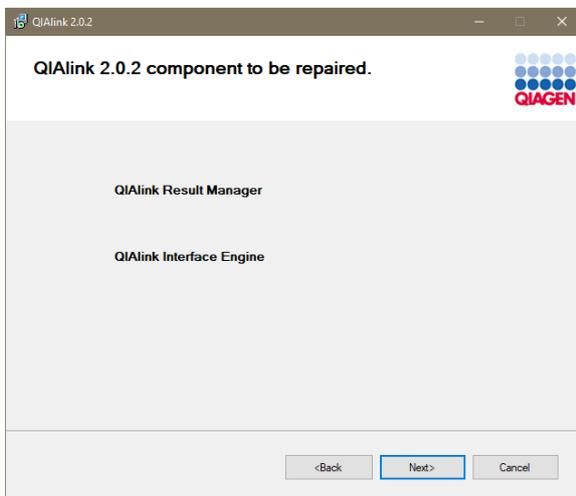
The following dialog is displayed.



The **New installation or add new features** option is only enabled if not all QIAlink software components are installed.

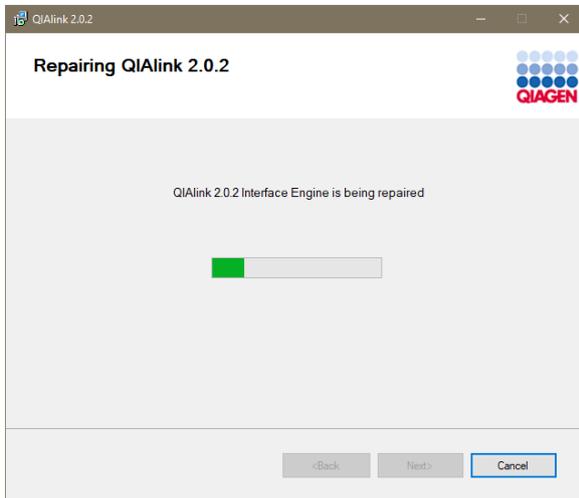
7. Select **Repair** and click **Next** to proceed.

The following dialog is displayed. QIAlink software components are highlighted depending on the components installed.



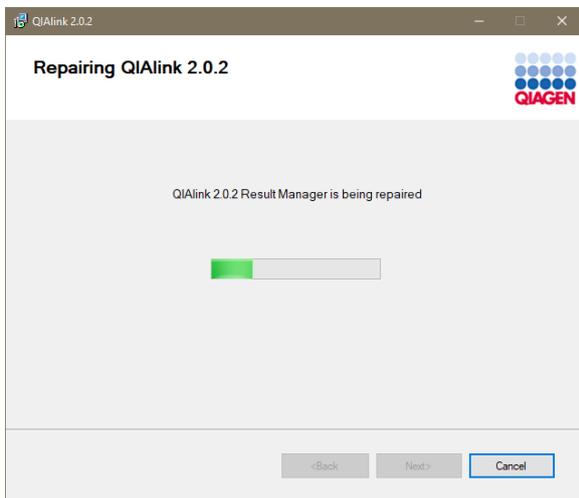
8. Click **Next** to continue.

9. If QIAlink Interface Engine is installed, the following dialog is displayed.



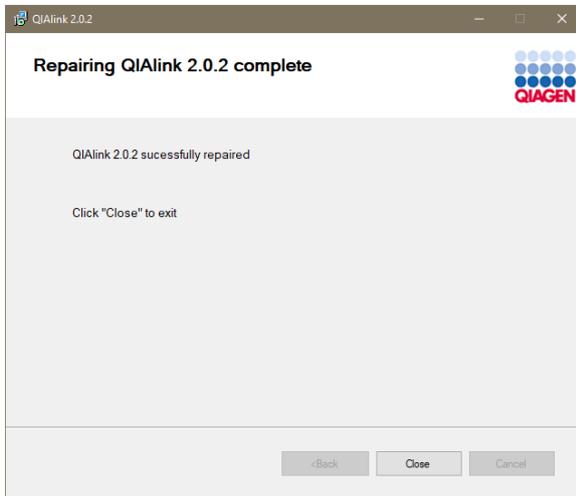
10. Click **Next** in the **Repairing QIAlink 2.0.2** dialog to continue.

11. If QIAlink Result Manager is installed the following dialog is displayed.



12. Click **Next** in the **Repairing QIAlink 2.0.2** dialog to continue.

The following dialog is displayed.



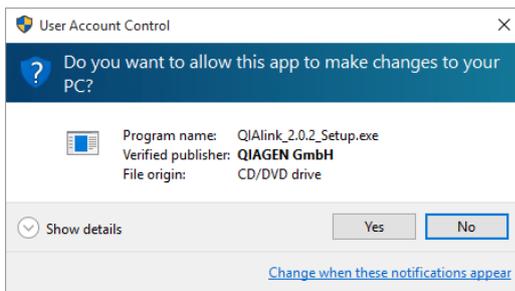
13. Click **Close** to exit the repair.

Uninstalling QIAlink software components

To start the uninstallation of QIAlink software components, proceed as follows:

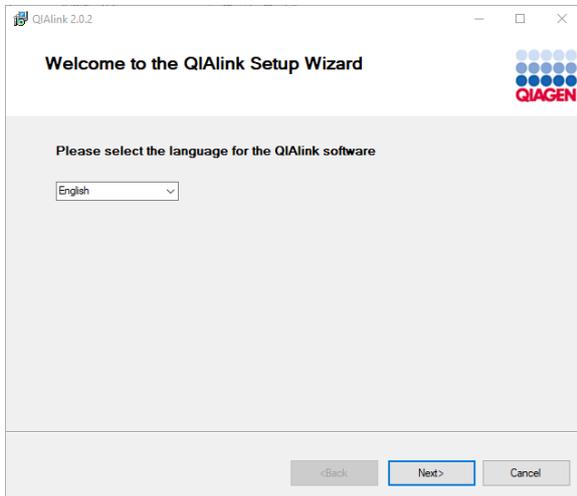
1. Insert the QIAlink software CD into the corresponding CD drive.
2. Double-click **QIAlink_2.0.2_Setup.exe**.

If **User Account Control** is enabled on the machine, the following dialog appears:

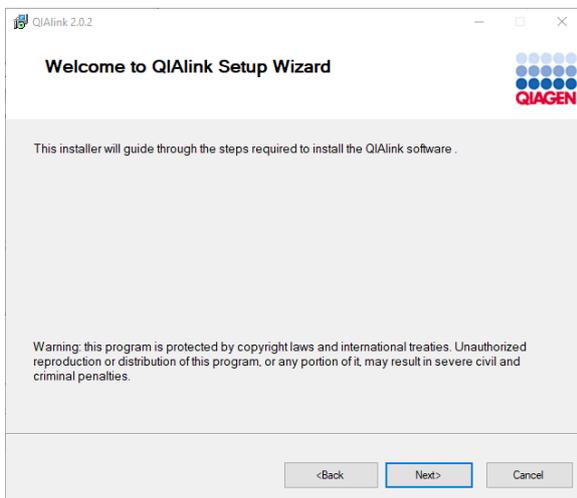


3. Click **Yes** to confirm the uninstallation.

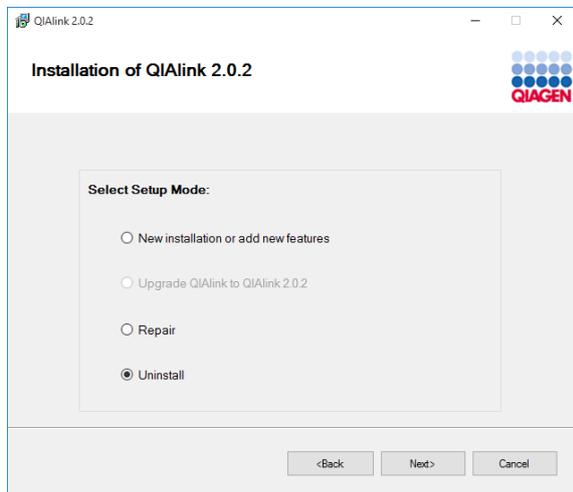
4. Follow these steps when the QIAlink Setup Wizard opens.



5. Select the language for the QIAlink software uninstallation and click **Next** to continue.

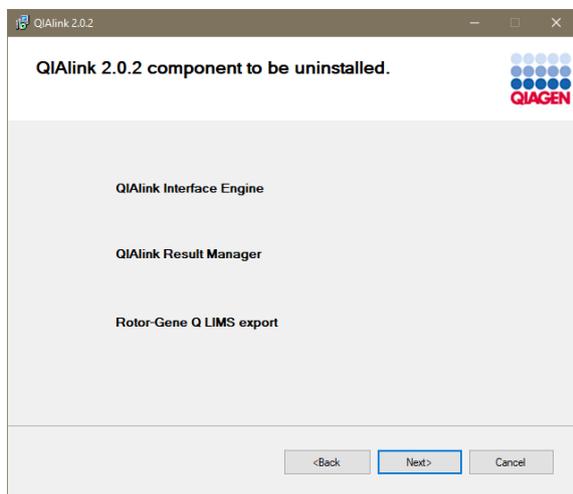


6. Click **Next** to proceed.



7. Select **Uninstall** and click **Next** to proceed.

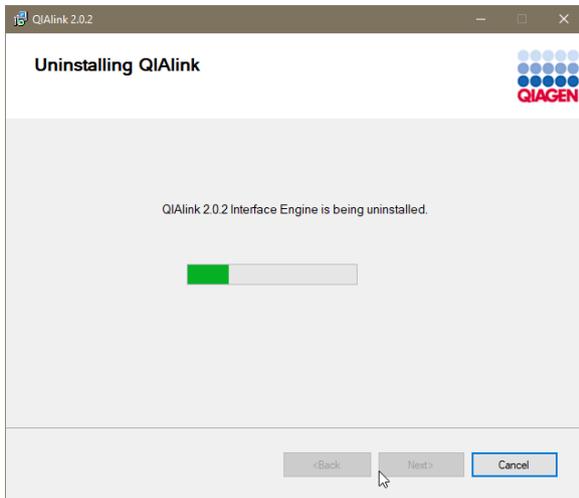
QIAlink software components are highlighted depending on the components installed.



Note: The option **Rotor-Gene Q LIMS export** is not supported in the U.S.

8. Click **Next** to proceed.

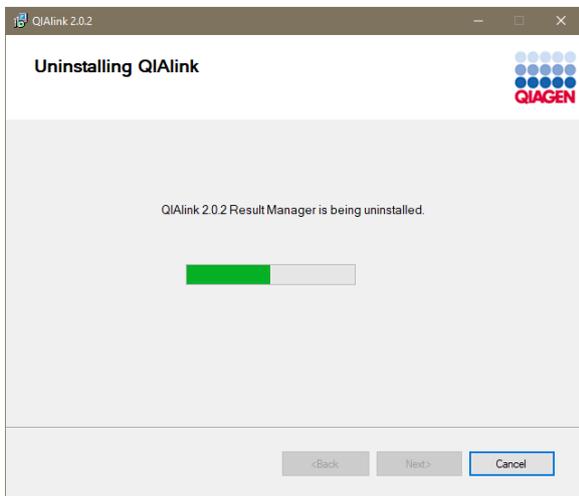
9. If QIAlink Interface Engine is installed, the dialog showing progress of uninstallation of QIAlink Interface Engine is displayed.



10. Click **Next** when uninstallation is finished.

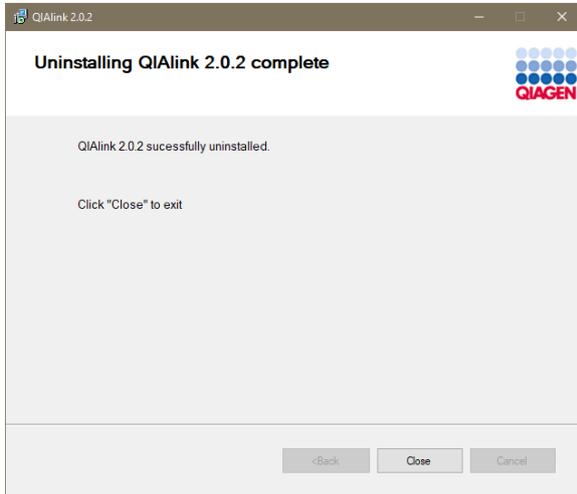
11. If QIAlink Result Manager is installed, the dialog showing progress of uninstallation of QIAlink Result Manager is displayed.

Note: This step is optional if QIAlink Result Manager was uninstalled via Microsoft Windows System settings.



Click **Next** when uninstallation is finished.

12. After successful uninstallation, the **Uninstalling QIAlink 2.0.2 complete** dialog is displayed.



13. Click **Close** to exit.

Note: The QIAlink user, configuration, and result databases will not be deleted.

Note: During uninstalling, the QIAlink 2.0.2 setup creates a backup file in **C:\ProgramData\QIAGEN\QIAlink**.

Note: The QIAlink software components can also be uninstalled via Microsoft Windows system settings. However, this method is not recommended because a backup file will not be created.

QIAlink Result Manager

Overview

QIAlink Result Manager provides features to manage QIAlink configuration settings and provide access to the test results. It allows monitoring of the interface channel status and the interface log of the QIAlink Interface Engine.

IMPORTANT: It is the responsibility of the user to validate QIAlink in the context of their laboratory environment and the LIMS or LIS utilized.

The QIAlink Result Manager functionality is split into different environments:

Test orders (see page 46)

Archive (see page 49)

Interface setup (see page 60)

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

Configuration (see page 78)

- User management
- Archive management
- Backup management
- Settings

Support (see page 94)

- Interface channels
- Interface log
- Audit trail
- Support package

General software usage

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. A validation error has occurred.

Example

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

The screenshot shows a dialog box titled "Add Instrument". It contains several fields and controls:

- Instrument type:** A dropdown menu with "QIASymphony" selected.
- Instrument name:** A text input field that is highlighted in yellow, indicating it requires input.
- Transfer folder:** Radio buttons for "Local" (selected) and "Network".
- Path field:** A text input field that is highlighted in yellow, with a "Browse" button next to it.
- Messages panel:** A scrollable list of error messages, each with a yellow pencil icon:
 - "Enter a name. (160009)"
 - "Enter a path. (160011)"
- Buttons:** "OK" and "Cancel" buttons at the bottom.
- Checkbox:** "Activate configuration" is checked.

Displaying warnings

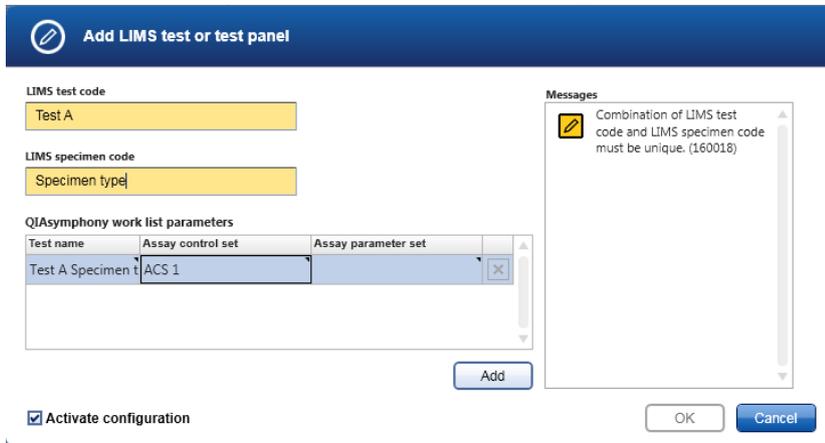
Errors and warnings are essential information for the user. These messages highlight a problem, or alert the user to an erroneous situation. QIALink Result Manager differentiates among 4 different problem levels.

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.

Messages panel

The following screenshot shows an example of a validation error during configuration of LIMS test parameters. Messages are displayed with the corresponding icon and the error text, and include the error ID in brackets.



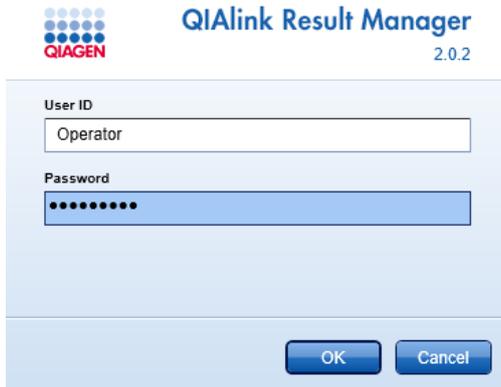
Sorting tables

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.

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.
2. 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 "User management", page 78.
3. 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.

Test Orders environment

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. In addition it allows filtering according to selected criteria.

The **Test Orders** environment consists of filter options (panel 1) and test orders (panel 2).

Sample ID	Test name	Assay control set	Assay parameter set
Test_Sample 1	LIMStest Blood	ACS1	APS1
Test_Sample 2	LIMStest Blood	ACS1	APS1
Test_Sample 3	LIMStest Blood	ACS1	APS1
Test_Sample 4	LIMStest Blood	ACS1	APS1
Test_Sample 5	LIMStest Blood	ACS1	APS1
Test_Sample 6	LIMStest Blood	ACS1	APS1
Test_Sample 7	LIMStest Blood	ACS1	APS1

The following filter options are available. The text fields support the wildcards "*" and "?".

Field/button	Meaning
Pending test orders (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.
All test orders (button)	If this radio button is selected, all test requests from the specified time frame are displayed.
Start date	Specifies the start date for test requests to be displayed.
End date	Specifies the end date for test requests to be displayed.
Sample ID	ID of the sample.
Test name	Test 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.
QIASymphony work list	Specifies name of QIASymphony work list assigned to 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.

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 name	Test name requested by the LIMS, as defined in the QIASymphony work list parameters dialog.
Assay control set	The Assay Control Set (ACS) to be used by QIASymphony SP.
Assay parameter set	The Assay Parameter Set (APS) to be used by QIASymphony SP.
QIASymphony work list	Specifies name of QIASymphony work list transferred to the QIASymphony SP/AS instruments.

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 test orders** 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**.

The list containing all pending requests from the specified number of days is displayed in the result selection dialog.

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 **All test orders** 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**.

The list containing all requests from the specified time frame is displayed in the test orders dialog.

Print request list

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

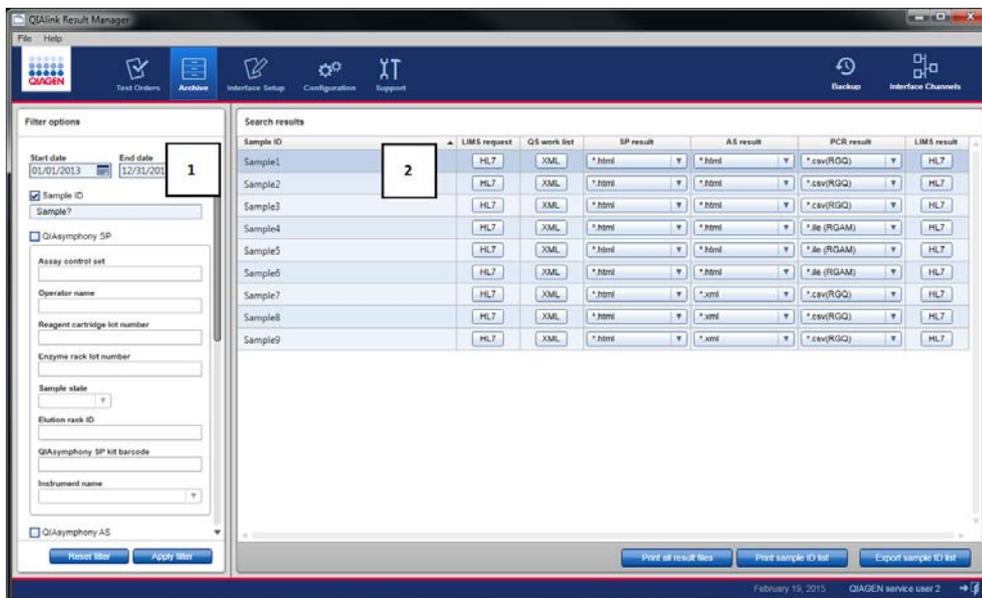
Archive environment

Overview

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

- LIMS requests
- QIASymphony work lists
- QIASymphony SP results
- QIASymphony AS results
- PCR results
- LIMS results

The **Archive** environment consists of filter options dialog (panel 1) and result selection (panel 2).



The following filter options are available. The text fields support the wildcards "*" and "?".

Field/button	Meaning
Start date	Specifies the start date for data to be displayed.
End date	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.
Assay control set (field)	Name of the Assay Control Set (ACS).
Operator name (field)	Name of the QIASymphony SP operator.
Reagent cartridge lot number (field)	Lot number of purification reagents.
Enzyme rack lot number (field)	Lot number read from the enzyme rack bar code.
Sample state (drop-down list)	Status of the sample on QIASymphony SP; possible values are <empty>, valid, invalid, or unclear.
Elution rack ID (field)	Identifier of the elution rack.
QIASymphony SP kit barcode (field)	Bar code of the QIASymphony SP kit.
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).

Field/button	Meaning
Operator name (field)	Name of the QIA Symphony AS operator.
Assay kit lot number (field)	Lot number of assay reagents.
Sample state (drop-down list)	Status of the sample on QIA Symphony AS; possible values are <empty>, valid, invalid, or unclear.
Elution rack ID (field)	Identifier of the elution rack.
Assay rack ID (field)	Identifier of the assay rack.
Assay kit bar code (field)	Bar code of the QIA Symphony assay kit.
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.
LIMS test code (field)	Test code used by the LIMS to request a test.
LIMS Specimen code (field)	Specimen code used by the LIMS to request a test.
Reset filter (button)	Resets all parameters of the filter dialog to their default values.
Apply filter (button)	A list of test requests and results is generated based on the filter parameters. Note: If search results contain entries for more than 100 samples, the following message is displayed: "Too many records. The search returned more than 100 matches. Adjust the filter parameters to reduce the number of matches. (190034)" In this situation, the search results table will not be updated (i.e., the results of the previous search will still be displayed).

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

Item	Meaning
Sample ID (column)	<p>ID of the sample.</p> <p>The result table has one row per sample. Each sample that matches the filter criteria is listed in the table.</p>
LIMS request (column)	<p>If one or more LIMS requests for the specified time frame are stored in the database for this sample, HL7 will appear in this column.</p> <p>If not, the column is empty.</p>
QS work list (column)	<p>If one or more QIASymphony work lists for the specified time frame are stored in the database for this sample, XML will appear in this column.</p> <p>If not, the column is empty.</p>
SP result (column)	<p>If one or more QIASymphony SP result files for the specified time frame are stored in the database for this sample, a drop-down list with *.xml and *.html, and (optionally) *.qdef, will appear in this column.</p> <p>If not, the column is empty.</p>
AS result (column)	<p>If one or more QIASymphony AS result files for the specified time frame are stored in the database for this sample, a drop-down list with *.xml and *.html, and (optionally) *.qdef, will appear in this column.</p> <p>If not, the column is empty.</p>
PCR result (column)	<p>If one or more LIMS output files from Rotor-Gene AssayManager for the specified time frame are stored in the database for this sample, the *.ile (RGAM) can be selected from the drop-down list.</p> <p>If not, the column is empty.</p>
LIMS result (column)	<p>If one or more LIMS results for the specified time frame are stored in the database for this sample, HL7 appears in this column.</p>

Item	Meaning
XML	<p>If not, the column is empty.</p> <p>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.</p> <p>If more than one file is present, clicking XML opens the file selection dialog.</p>
HL7	<p>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.</p> <p>If more than one file is present, clicking HL7 opens the file selection dialog.</p>
*.html	<p>If only one file in HTML format is present for the sample, selecting *.html from the drop down list opens the file viewer dialog with the contents of the *.html file.</p> <p>If more than one file is present, selecting *.html opens the file selection dialog.</p>
*.xml	<p>If only one file in XML format is present for the sample, selecting *.xml from the drop down opens the file viewer dialog with the contents of the *.xml file.</p> <p>If more than one file is present, selecting *.xml opens the file selection dialog.</p>
*.ile	<p>If only one file in ILE format is present for the sample, selecting *.ile from the drop down list opens the file viewer dialog with the contents of the *.ile file.</p> <p>If more than one file is present, selecting *.ile opens the file selection dialog.</p>
*.qdef	<p>If only one file in QDEF format is present for the sample, selecting *.qdef from the drop down list opens the file viewer dialog with the contents of the *.qdef file.</p> <p>If more than one file is present, selecting *.qdef opens the file selection dialog.</p>

Item	Meaning
Print all result files (button)	<p>Generates printouts of data for all samples displayed in the result selection dialog.</p> <p>Note: After selecting the file types to be printed, an additional message box displaying all files selected for printing must be confirmed. The larger the number, the longer QIALink will be inactive (i.e., Result Manager will be inactive but Interface Engine will continue running).</p> <p>Note: HTML files are printed via Microsoft Internet Explorer with a predefined page setup (e.g., including orientation, print color, scale, etc.). Check the page setup within the Print settings of Internet Explorer to ensure proper printing. Selecting the “Shrink to fit” option is recommended.</p> <p>In addition, if page setup is configured to print the current date on the header or footer, the date is printed according to the language setting for Internet Explorer. This printed date format may appear differently than the actual file date format. For example, a QIASymphony result file that uses the date format “yyyy-mm-dd hh:mm:ss” may be printed with a different date format (e.g., mm/dd/yy) in the header/footer.</p>
Print sample ID list (button)	Generates a printout of the sample ID list with the samples displayed in the result selection dialog.
Export sample ID list (button)	Exports the sample IDs displayed in the results table as *.csv file.

The table below lists the different file types.

File type	Meaning
*.xml	<p>The XML format (Extensible Markup Language) is used for QIASymphony work lists and QIASymphony SP/AS result files.</p> <p>XML files are primarily intended for troubleshooting by</p>

File type	Meaning
	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.
*.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.
*.qdef	The QDEF format (QIAGEN specific XML format) is used for QIASymphony SP and AS result files.

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.

All filter parameters support the wildcards "*" and "?".

Click **Apply Filter** to execute the search.

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

Search results dialog

After application of the filter parameters, an overview of the sample IDs matching the search parameters is displayed in the **Search results** 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 for the specified time frame.
- The presence of a button or drop-down list means that one or more result files of the corresponding type is available for this sample for the specified time frame.

Selecting a single result file

1. Click the button or drop down list which represents the desired file type
For example, click **HL7** in column **LIMS request** to display the LIMS request in HL7 format, or click ***.html** in the drop-down list of 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**, ***.ile** or ***.qdef** are displayed in the file viewer dialog.
3. If more than one result file is present, the **Select file** dialog box opens. Each file is identified by its creation date.

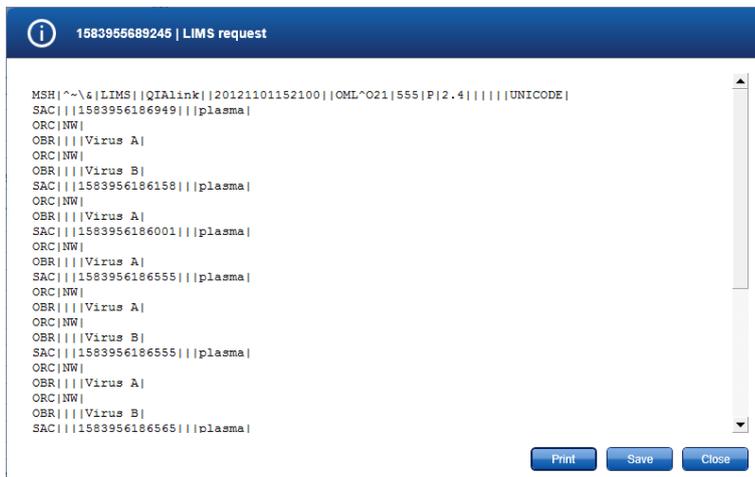


4. To open a single file, select the corresponding row and click **OK**.

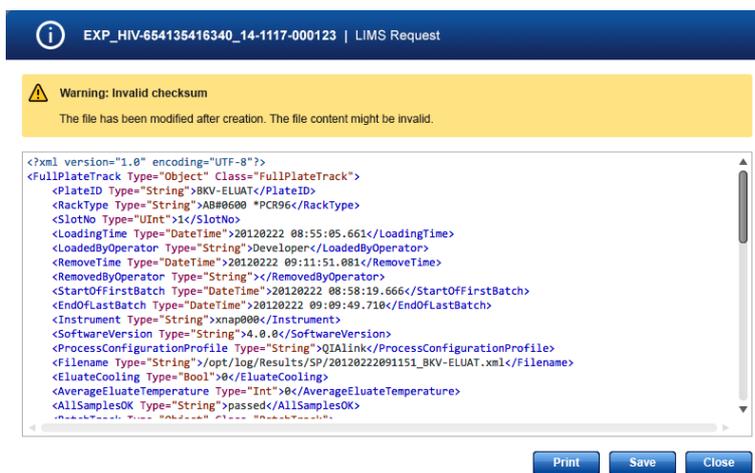
5. Click **Close** to close the dialog box.

Printing and saving single files from the file viewer

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



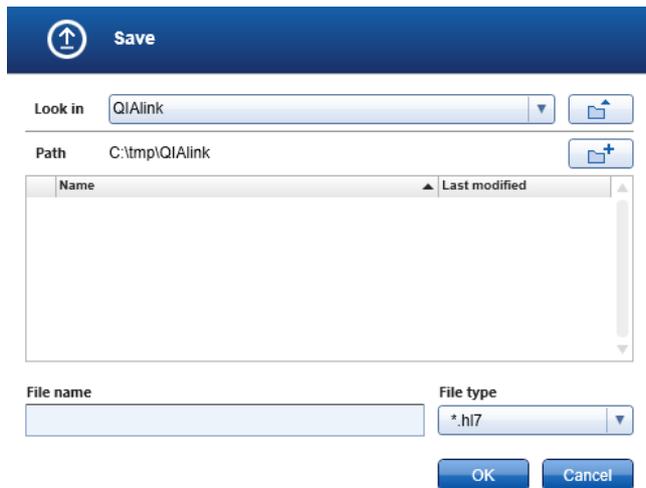
QIAGEN instruments use a checksum to trace if instrument result files have been modified after creation. QIALink uses this checksum functionality to identify records that have been modified. A warning is displayed indicating that the record has been altered whenever an instrument result file does not match the checksum.



1. Click **Close** to close the dialog box without saving the file.

2. Click **Save** to save the file to hard disk.

The file save dialog box is opened.



3. Choose 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**.

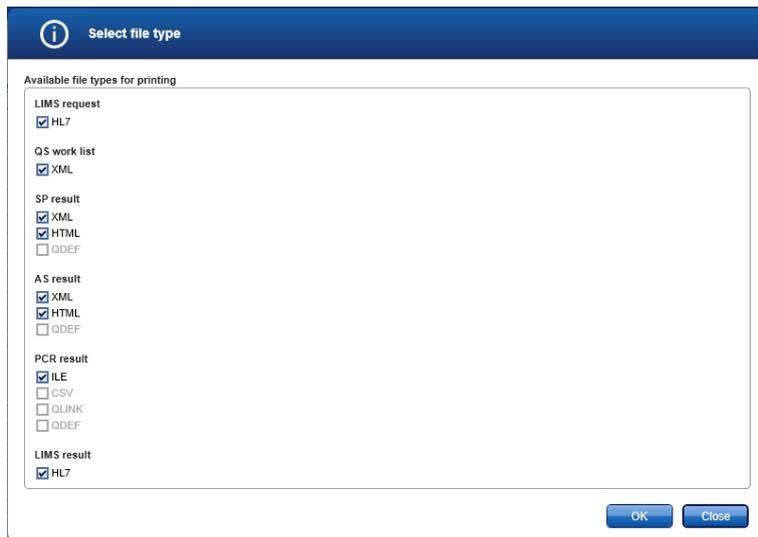
Print sample ID list

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

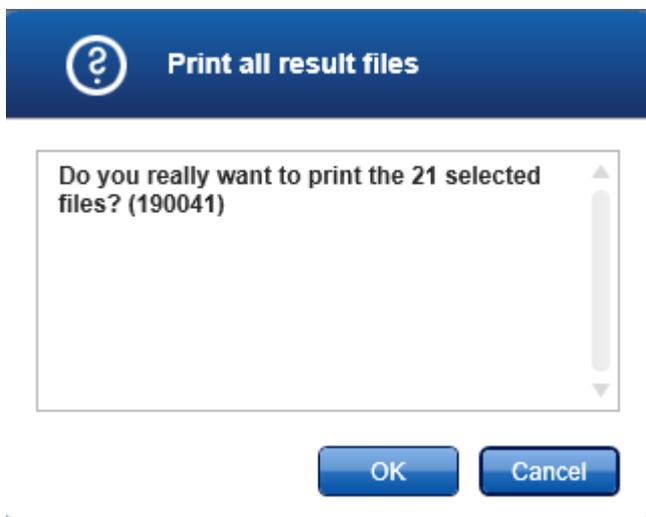
Print all result files

To print 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 or click **Close** to close the dialog box without printing. Upon clicking **OK**, a dialog box specifying the number of files to be printed will open.



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

4. Click **OK** to print (the Windows print dialog will open) or click **Cancel** to close the dialog box without printing.

Export sample ID list

To export a list of all sample IDs matching the filter parameter, click **Export sample ID list**. The Microsoft Excel® application is opened containing the exported sample ID list.

Interface Setup environment

Overview

To access the interface setup, select the **Interface Setup** icon in the main navigation bar.



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

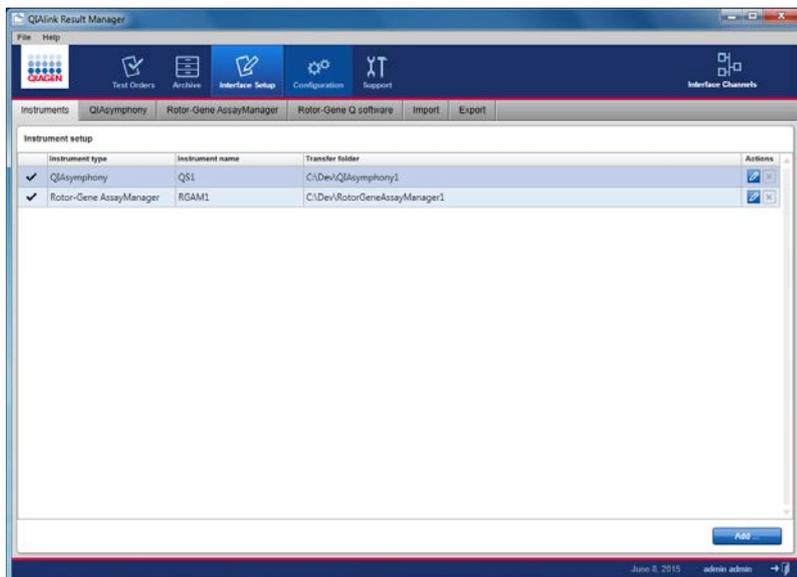
For users with the user role “Lab user”, the settings are read-only. Creation of new settings, and modification, activation and deactivation of existing settings are disabled.

Users with the user role “Lab 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.

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 instrument configuration of up to 20 instruments per instrument type is allowed.



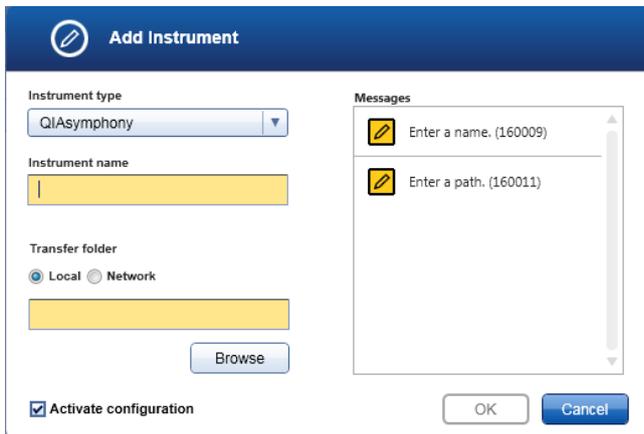
Note: The option **Rotor-Gene Q Software** is not supported in the U.S.

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>
Instrument type	The type of the instrument (e.g., "QIA Symphony", "Rotor-Gene AssayManager").
Instrument name	The name of the instrument for which the configuration is done (e.g., "QIA Symphony Lab1"). The name of the instrument must be unique.
Transfer folder	The root directory of the transfer folder that is used to exchange the files for QIA Symphony. This directory shall point to the transfer folder of the "QMC Auto Transfer".
Actions	 Edit configuration  Delete configuration (enabled for QIAGEN Technical Services only)

Add instrument

- To add a new instrument, click **Add...** below the table.

The following dialog box opens.



- Choose an instrument type from the drop-down list.

3. In the **Instrument 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 Lab 1).

4. For local directories:

Click **Browse** to navigate to the desired folder.

5. 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 the dialog field **Transfer folder**.

Copy the path name to the clipboard and then paste it into the dialog field.

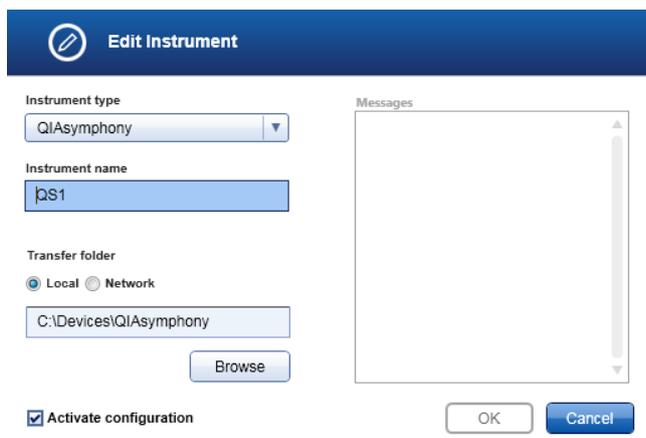
6. Make sure that the **Activate configuration** box is checked.

7. Click **OK** to save the configuration.

Modify an existing instrument configuration

1. Click  of the configuration to be modified.

The **Edit instrument** dialog opens.



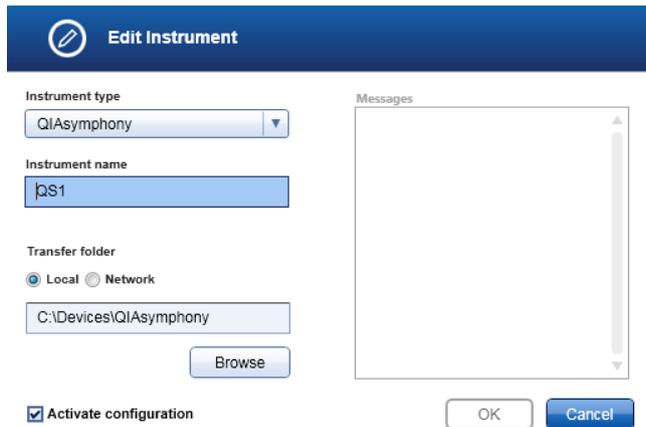
2. Modify the parameters as desired in the fields **Instrument type**, **Instrument name** and **Transfer folder**.

3. Click **OK** to save the modification and close the dialog box.

Deactivate or activate an existing directory

1. Click  of the directory to be modified.

The Edit instrument dialog opens.



2. To activate a directory, check the **Activate configuration** box.
3. To deactivate a directory, uncheck the **Activate configuration** box.
4. Click **OK** to save the modification and close the dialog box.

QIAsymphony dialog

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

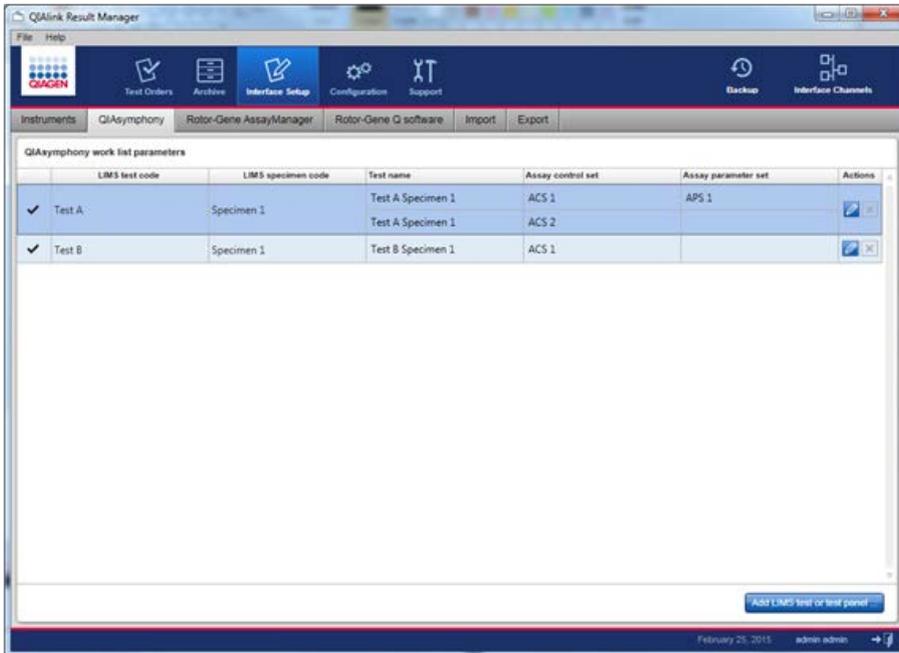
The desired QIAsymphony work list parameters (Assay Control Set and Assay Parameter Set) must be configured in the QIAsymphony screen for each possible combination of LIMS test code and LIMS specimen code that can be ordered by LIMS for processing on QIAsymphony. Available Assay Control Set and Assay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

The combination of LIMS test code and LIMS specimen code must be unique.

Note: If the LIMS requests a test for a combination of LIMS test code and LIMS specimen code that is not configured, QIALink will not generate a QIAsymphony work list and a warning will be displayed in the **Interface log** screen (see page 97).

The **QIAsymphony** screen can be used to configure tests and test panels.

- For a test, the combination of LIMS test code and LIMS specimen code is mapped to one set of QIAsymphony work list parameters.
- For a test panel, the combination of LIMS test code and LIMS specimen code is mapped to multiple QIAsymphony work list parameters.



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

Active/inactive (first column)	<div style="display: flex; align-items: center;"> <input checked="" type="checkbox"/> <input type="checkbox"/> </div> <p>The configuration is active/inactive.</p> <p>An inactive configuration will not be used by the QIAlink Interface Engine.</p>
LIMS test code	<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>

Column	Meaning
LIMS specimen code	<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>
Test name	User-defined name of the test as requested by the LIMS. Test name is defaulted to the test identifier and specimen code and can be overwritten by the user.
Assay control set	The Assay Control Set (ACS) to be used by the QIAsymphony SP (e.g., "ACS_Cellfree1000_V6_DSP default IC").
Assay parameter set	The Assay Parameter Set (APS) to be used by the QIAsymphony AS (e.g., "QIAGEN-PCR-96 (15+10) V1.0").
Actions	<p> Edit configuration.</p> <p> Delete configuration (enabled for QIAGEN Technical Services only).</p>

Add a new LIMS test or test panel

- To add a new LIMS test or test panel, click **Add LIMS test or test panel**.

The following dialog box appears.

2. Enter the test identifier provided by your LIMS provider in the field **LIMS test code** (case sensitive).
3. Enter the specimen type provided by your LIMS provider in the field **LIMS specimen code** (case sensitive).
4. Modify the default value for the test name if desired.
5. In the **Assay control set** field, enter the name of the Assay Control Set (case sensitive) to be used on QIAAsymphony for the purification of samples with the given test identifier and specimen type.

Note: If the “integrated run” feature is used on QIAAsymphony, the **Assay control set** field can be empty.

6. In the **Assay parameter set** field, enter the name of the Assay Parameter Set to be used on QIAAsymphony for the assay setup of samples with the given LIMS test code and LIMS specimen code.

Note: The **Assay parameter set** field can be left empty. If the **Assay parameter set** is left empty, only a QIAAsymphony SP stand-alone run will be possible.

Note: For a test, one set of QIAAsymphony work list parameters is defined. For a test panel, additional sets of QIAAsymphony work list parameters are added.

7. Click **Add** to add multiple tests to define a test panel.
8. Click  to delete a test from the QIAAsymphony work list parameters.
9. Ensure that the **Activate configuration** box is checked.
10. Click **OK** to save the configuration and close the dialog box.

Modify a LIMS test or test panel

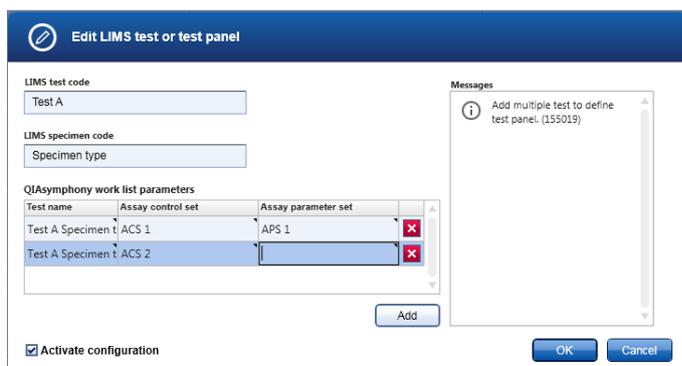
1. Click  of the configuration to be modified.

2. Modify the desired parameters in the fields **LIMS test code**, **LIMS specimen code**, **Test name**, **Assay control set** and **Assay parameter set**.

3. Click **Add** to add multiple tests to define a test panel.
4. Click  to delete a test from the QIAsymphony work list parameters.
5. Click **OK** to save the configuration and close the dialog box.

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 and close the dialog box.

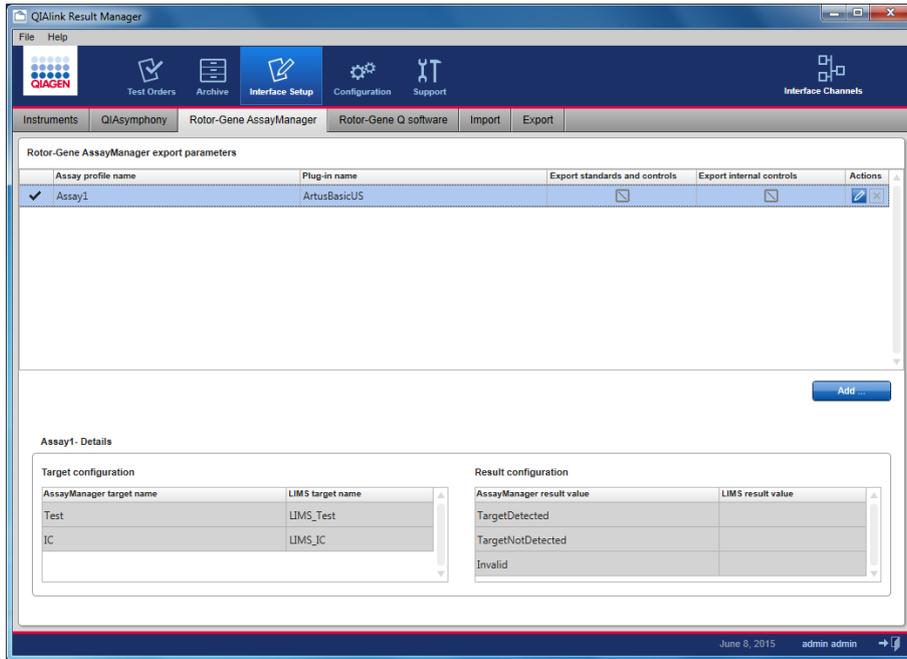
IMPORTANT: If the Assay Control Set (ACS) and/or Assay Parameter Set (APS) are updated on QIAsymphony, the QIAlink configuration must be updated to match the new ACS/APS names. If this is not done, the new ACS/APS will not be used in the QIAsymphony work list.

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. A warning will be displayed in the **Interface log** screen (see page 97).



Item	Meaning
Active/inactive (first column)	  The configuration is active/inactive. An inactive configuration will not be used by the QIAlink Interface Engine.
Assay profile name (column)	Name of the Rotor-Gene AssayManager profile.
Plug-in name (column)	Name of the plug-in for Rotor-Gene AssayManager.
Export standards and controls (column/box)	Unchecked: No standard controls are exported to LIMS. Checked: Standard controls are exported to LIMS.
Export internal controls (column/box)	Unchecked: No internal controls are exported to LIMS. Checked: Internal controls are exported to LIMS.

Item	Meaning
Actions (column/box)	 Edit configuration for target.  Delete configuration (enabled for QIAGEN Technical Services only).
Target configuration (table)	Contains all targets belonging to the assay profile.
AssayManager target name (column)	Name of the target as configured in the Rotor-Gene AssayManager assay profile.
LIMS target name (column)	Target name for export to LIMS. Please 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!
Result configuration (table)	Contains the Rotor-Gene AssayManager result values supported by the plug-in.
AssayManager result value (column)	Rotor-Gene AssayManager result values for qualitative results supported by the Rotor-Gene AssayManager plug-in.
LIMS result value (column)	Result values exported to LIMS.

Add an assay profile configuration

1. Click **Add...**

The following dialog box opens.

The dialog box titled "Add assay profile configuration" contains the following elements:

- Assay profile name:** A text input field and a "Select assay profile..." button.
- Plug-in name:** A text input field and two checkboxes: "Export standards and controls" and "Export internal controls".
- Target configuration:** Two dropdown menus labeled "AssayManager target name" and "LIMS target name".
- Result configuration:** Two dropdown menus labeled "AssayManager result value" and "LIMS result value".
- Messages:** A list of error messages: "Select an assay profile. (160031)" and "Plug-in name cannot be blank. (160041)".
- Buttons:** "OK" and "Cancel" buttons at the bottom right.
- Checkbox:** "Activate configuration" (checked) at the bottom left.

2. Click **Select assay profile** to browse to an assay profile file (*.iap).

Note: Please consult the Rotor-Gene AssayManager user manual for instructions on exporting assay profile files from Rotor-Gene AssayManager software.

3. Enter a LIMS target name for each Rotor-Gene AssayManager target name.
4. Enter LIMS result values for the Rotor-Gene AssayManager result values.
This is not mandatory.

WARNING 	Rotor-Gene AssayManager result configuration Wrong mapping of the Rotor-Gene AssayManager result values to the LIMS result values can induce incorrect results.
---	---

Example: If "TargetDetected" is mapped to "TargetNotDetected", all positive results are changed into negative results.

5. Check the box **Export standards and controls** to export the results for standards and controls to LIMS.
Uncheck the box **Export standards and controls** to export only the results for actual samples to LIMS (no standards and controls are exported).
6. Check the box **Export internal controls** to export the result values for internal control targets to LIMS.

Uncheck the box **Export internal controls** to only export result values for the main targets to LIMS (no internal controls are exported).

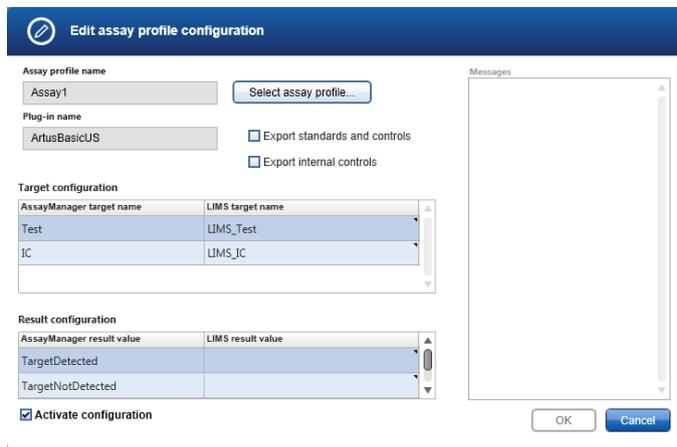
7. Click **OK** to save the new assay profile configuration and close the dialog box.

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

Modify an assay profile configuration

1. To modify an existing assay profile configuration, click  of the assay profile configuration to be modified.

The following dialog box opens.



AssayManager target name	LIMS target name
Test	LIMS_Test
IC	LIMS_IC

AssayManager result value	LIMS result value
TargetDetected	
TargetNotDetected	

2. Modify the desired parameters in the:

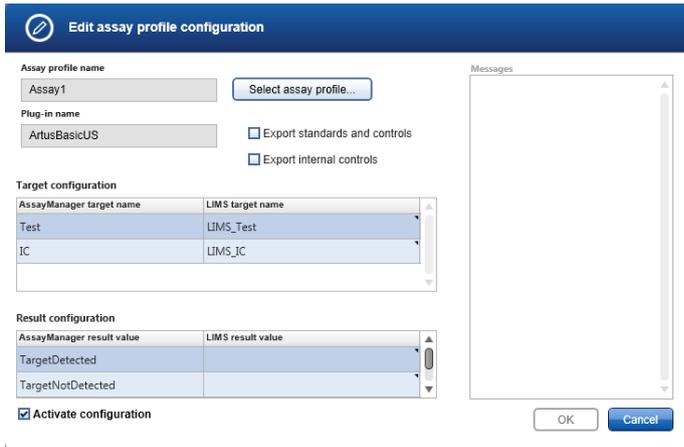
- **Target configuration** table
- **Result configuration** table
- Checkboxes for **Export standards and controls** or **Export internal controls**

3. Click **OK** to save the modifications and close the dialog box.

Deactivate or activate an existing assay profile configuration

1. Click  of the configuration to be modified.

The following dialog box opens.



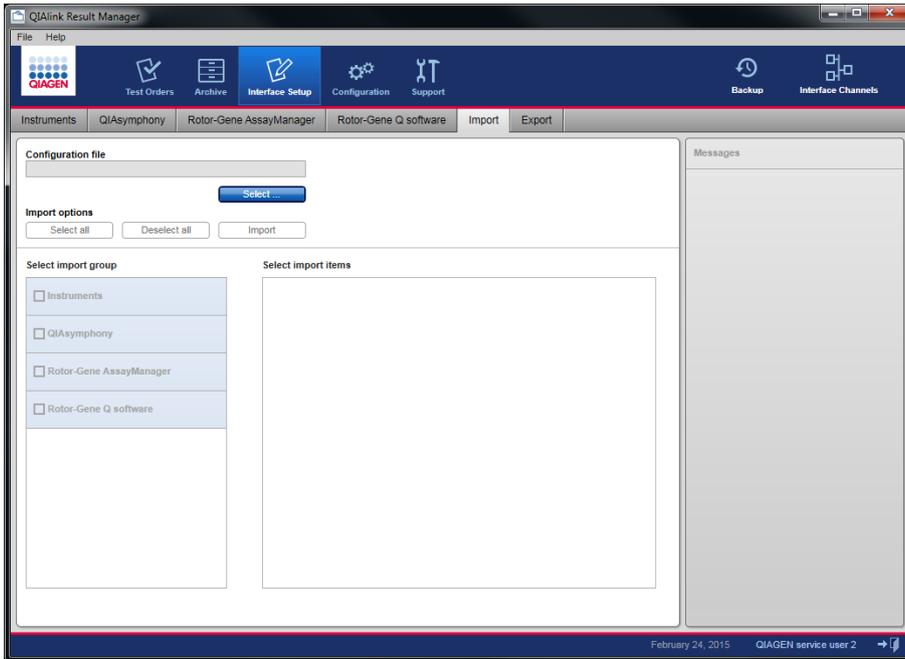
2. Uncheck **Activate configuration** to deactivate the configuration.
Check **Activate configuration** to activate the configuration.
3. Click **OK** to confirm the changes and close the dialog box.

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:

- A configuration file saved during backup
- A configuration file created with another QIALink installation

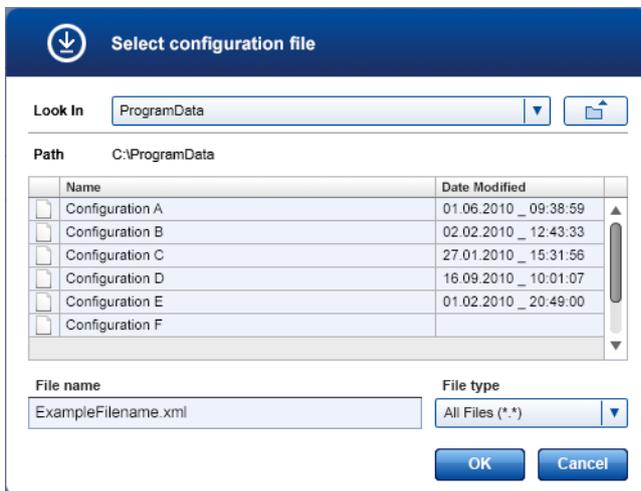
Note: *.xrm files of QIALink versions 1.1 and 2.0.x are incompatible. This means they cannot be used across versions of QIALink and all configuration settings will be migrated to a new data format during the upgrade. It is recommended to export a new *.xrm file after upgrading QIALink (see page 75).



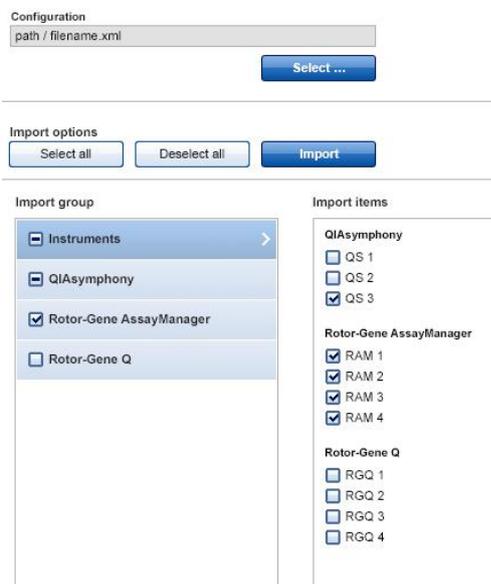
Note: The option **Rotor-Gene Q software** is not supported in the U.S.

1. Click **Select**.

The following dialog box opens.

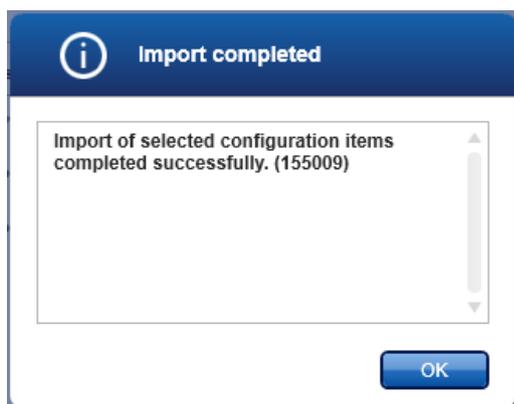


2. Browse through the drop-down list in the **Look In** field to the directory that contains the configuration file.
Select the file to import.
3. Click **OK**.
The available configurations from the import file are displayed.



Note: The option **Rotor-Gene Q** is not supported in the U.S.

4. 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.
5. Click **Import**. The chosen configuration is imported and becomes active immediately.
6. The **Import completed** message is displayed.



7. Click **OK** to close the message.
An import configuration conflict may occur. The **Import configuration conflict** dialog is shown in cases where a configuration already exists.



Import configuration conflict

There is already a QIASymphony work list parameter configuration with LIMS test code Test A and LIMS specimen code Specimen 1 defined.

Repeat for next 2 conflicts.

Import and overwrite

Keep existing configuration

Cancel

It is possible to overwrite the existing configuration by clicking **Import and overwrite**.

Keep the current configuration by clicking **Keep existing configuration**.

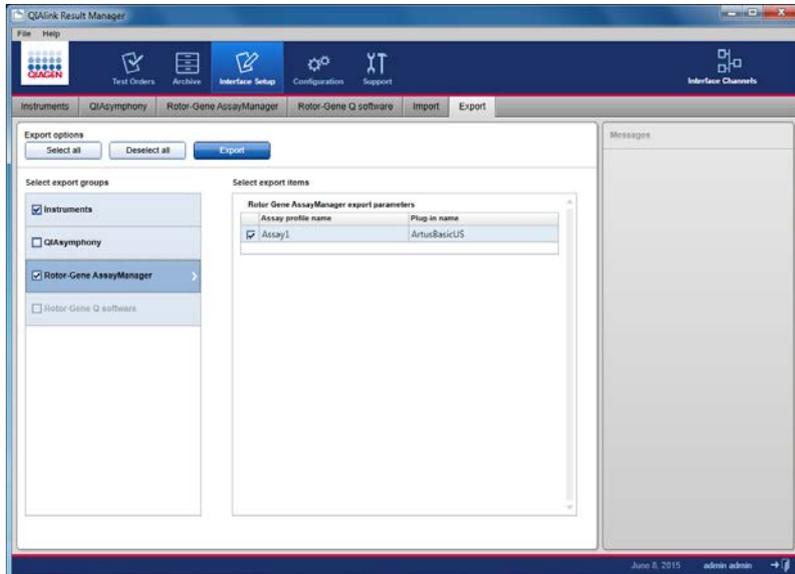
The decision to import and overwrite can be repeated for all similar configuration conflicts by checking **Repeat for next x conflicts**. Otherwise every conflict must be resolved separately.

Click **Cancel** to cancel and reverse the import.

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.

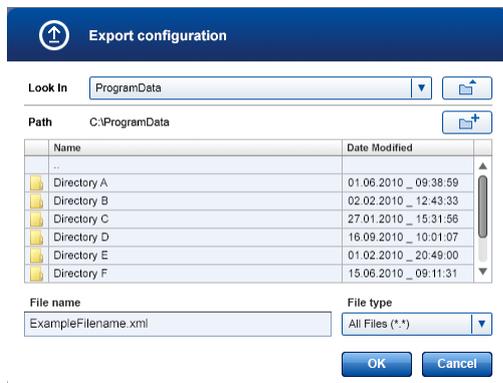
Export all configurations



Note: The option **Rotor-Gene Q software** is not supported in the U.S.

1. Click **Select all**.
2. Click **Export**.

The following dialog box opens.

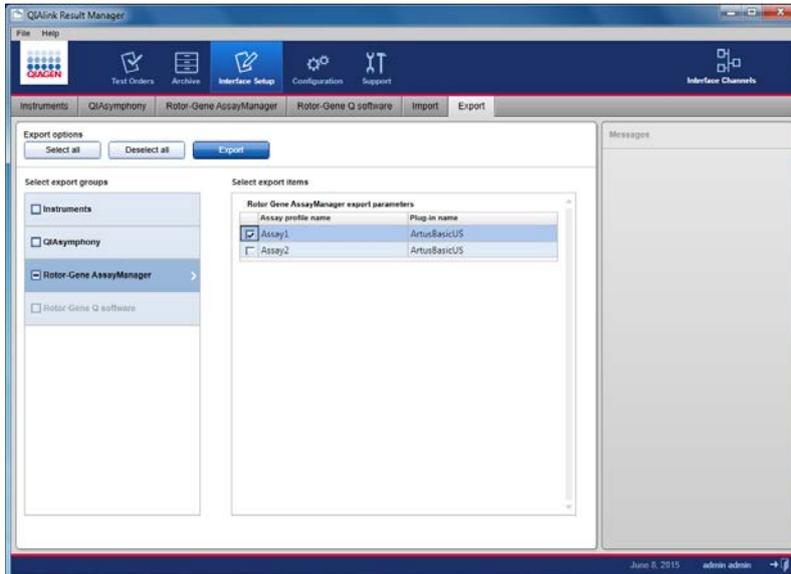


3. Navigate to the desired directory. Enter a file name.
4. Click **OK**.

All configuration settings are saved to file.

Export a subset of the available configurations

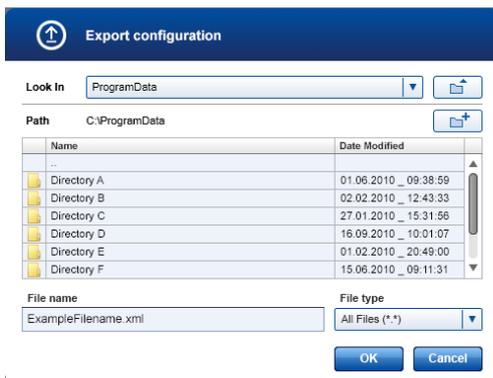
1. Select the items for export by clicking the corresponding box.



Note: The option **Rotor-Gene Q software** is not supported in the U.S.

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.

Configuration environment

Overview

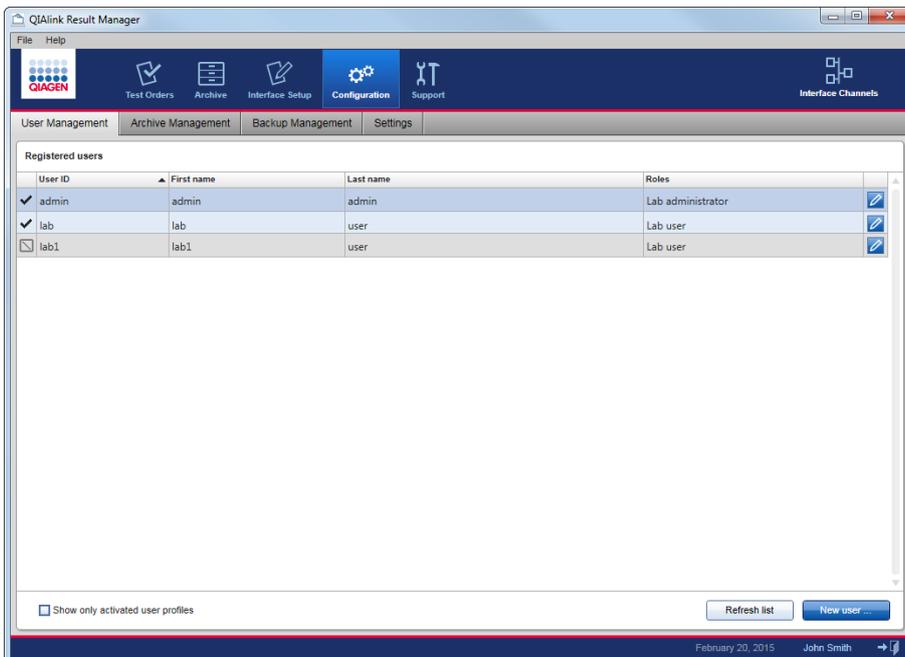
The **Configuration** environment is accessed by selecting **Configuration** in the main navigation bar. It enables user management, archive management, backup management and general settings for QIAlink Result Manager.



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	The first and family names of the user.
Roles	Assigned user roles. Possible roles are: <ul style="list-style-type: none">• Lab user• Lab administrator
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 (button)	Click to refresh list after checking/unchecking Show only activated user profiles box.
New user... (button)	Click to create new user account.

Create new user

1. Click **New user**.

The following dialog box opens.

The screenshot shows a dialog box titled "Add user" with a pencil icon. It contains the following fields and options:

- First name:** test
- Last name:** user
- User ID:** tester
- Password:** masked with dots
- Confirm password:** masked with dots
- Roles:**
 - Lab administrator
 - Lab user
- Activate user
- Messages:** After 3 unsuccessful log-in attempts the user profile will be deactivated. (120006)

Buttons: OK, Cancel

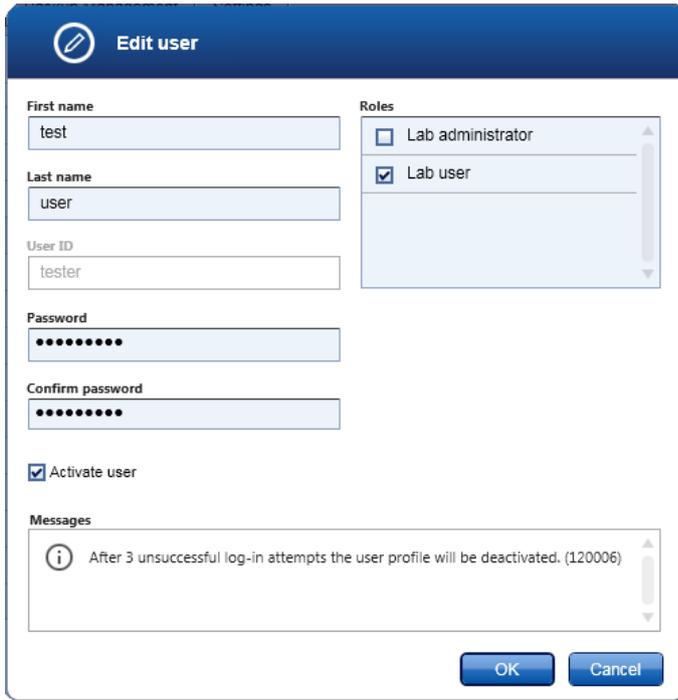
2. Enter first name, last name, and a user ID into the appropriate fields.
3. Enter a password in the **Password** field.
4. Enter the same password again in the **Confirm password** field.
- The **Activate user** checkbox is checked by default.
5. Check the required roles in the **Roles** panel.
6. 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.



Edit user

First name: test

Last name: user

User ID: tester

Password: ●●●●●●

Confirm password: ●●●●●●

Activate user

Roles:

- Lab administrator
- Lab user

Messages:

i After 3 unsuccessful log-in attempts the user profile will be deactivated. (120006)

OK Cancel

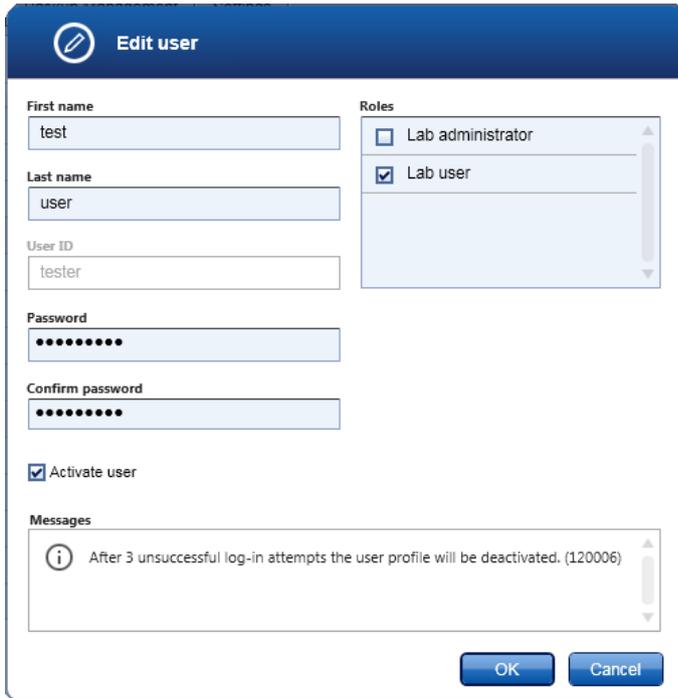
2. Modify the user's details.
3. Click **OK** to confirm the changes and close the dialog box.

The modifications are saved.

Deactivate or activate an existing user

1. Click  of the user to be modified.

The **Edit user** dialog box opens.



Edit user

First name: test

Last name: user

User ID: tester

Password: ●●●●●●

Confirm password: ●●●●●●

Activate user

Roles:

- Lab administrator
- Lab user

Messages:

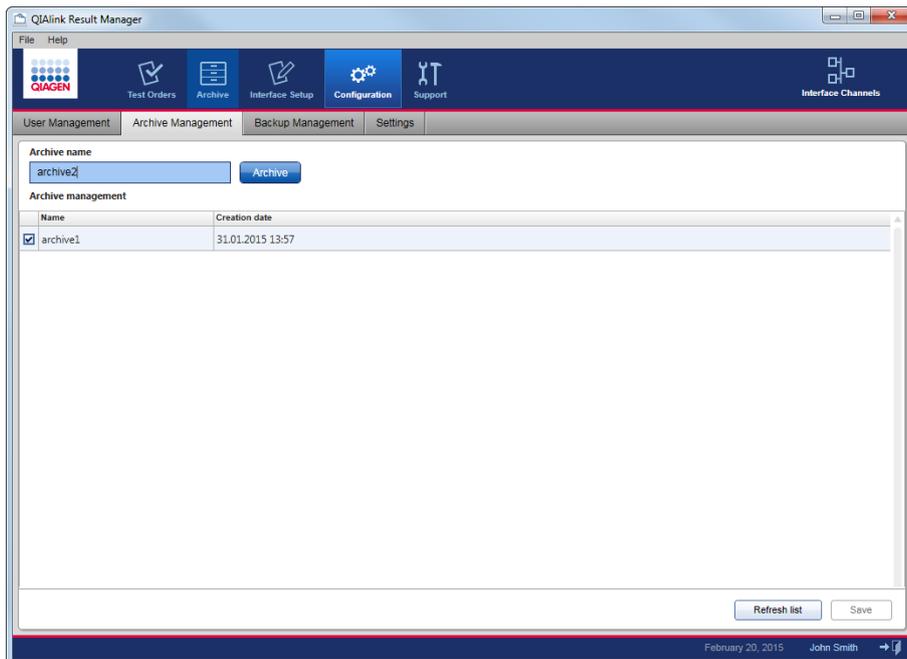
i After 3 unsuccessful log-in attempts the user profile will be deactivated. (120006)

OK Cancel

2. Uncheck the **Activate user** box to deactivate the user account.
Check the **Activate user** checkbox to activate the user account.
3. Click **OK** to confirm the changes and close the dialog box.

Archive management

The **Archive Management** tab 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 page 49). 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 field)	Field to enter the name of a new archive.
Archive (button)	Click to create an archive from the current working database.
Archive management (table)	Table containing all available archives.
Active/inactive (box)	Checked: Archive activated. Unchecked: Archive inactivated.

Item	Meaning
Name	Name of the archive.
Creation date	The creation date of the archive.
Refresh list (button)	Click to refresh the list of existing archives.
Save (button)	Click to save changes to the active/inactive.

Create a new archive

Since the size of an individual SQL Server Express database is limited, it is necessary 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** field.

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** field is cleared.

Activation/deactivation of archives

The activate/deactivate archive function allows the user to select the archived databases that will be searchable in the archive environment (see page 49). Data from deactivated archives is not accessible in the archive environment.

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

Follow these steps to change the activation status of an archive.

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

Backup management

Backup management can be accessed by selecting the **Configuration** icon and clicking the **Backup Management** tab. Alternatively, backup management can be accessed by clicking the shortcut **Backup** icon in the main navigation bar.

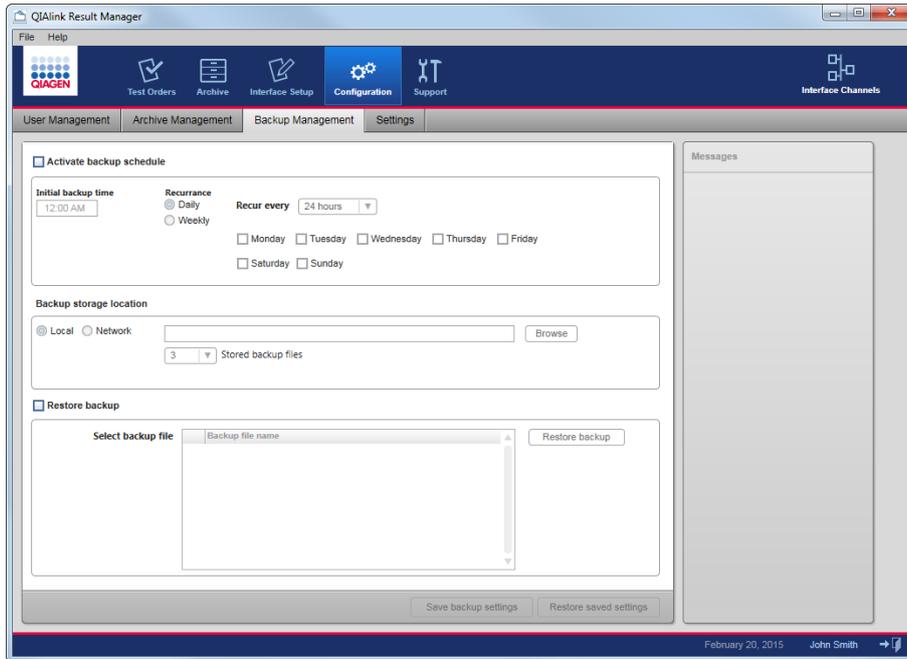


Note: The **Backup** shortcut icon is not visible until the first backup has been configured.

Where errors have occurred during backup, the icon will be colored yellow for a warning or red if an error occurred during the last backup execution.

All users can access the backup management view. Only a user with the assigned role of “Lab administrator” is able to activate and restore backups.

The **Backup Management** screen is divided into two areas. The **Activate backup schedule** region displays and defines backup schedules. The **Restore backup** region allows the user to restore the QIAlink system from a backup file.



Meanings of items in the **Backup Management** tab are explained in the following table.

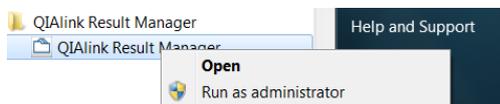
Item	Meaning
Activate backup schedule (box)	To activate/deactivate the backup schedule parameters.
Initial backup time	Time when the backup will be executed the first time.
Daily (button)	Selection indicates the backup will be executed daily.
Recur every x hours (drop-down list)	The backup will be executed daily every x hours. Possible values are: 2, 4, 8, 12 and 24 hours.
Weekly (button)	Selection indicates the backup will be executed weekly.
Days of the week (boxes)	The backup will be executed on the selected weekday(s).
Local (button)	If the button is selected, the backup is stored on a local directory. [Not recommended].
Network (button)	The backup is stored on a network directory.

Item	Meaning
Text field	Shows the directory where the backup file is stored.
Browse (button)	Navigate to the directory where the backup file is stored.
Stored backup files (drop-down list)	Select the number of stored backup files. Possible values are: 1–12.
Restore backup (checkbox)	Check to enable the restore backup.
Select backup file (list)	List of stored backup files which are available for restore backup.
Restore backup (button)	Restores the database, configuration settings and log files from the selected backup file.
Save backup settings (button)	Click to save changes.
Restore saved settings (button)	All modifications entered in the screen will be reset and the settings are read from database.
Messages (panel)	Contains information about the last backup and the next scheduled backup. It also lists errors and warnings which occur during backup.

Activate backup schedule

IMPORTANT: QIAlink Result Manager must be started as administrator to grant the Backup scheduling process sufficient privileges when activating a backup schedule.

1. From the Windows **Start** menu select **All Programs**.
2. Right-click **QIAlink Result Manger** and select "Run as administrator".



If QIAlink Result Manager is not running with administrator rights when the backup schedule is entered, the following warning text is displayed:

⚠️ "Warning (120043) The backup task has been created without the highest privileges due to insufficient rights."

The backup process will complete with errors as it has insufficient privileges to start and stop the Iguana service.

3. To activate the backup schedule, navigate to **Backup Management** by selecting the **Configuration** environment and clicking the **Backup Management** tab.
4. Check **Activate backup schedule** to activate a backup schedule.
5. Enter the initial backup time.

Initial backup time

12:00 AM

The backup will be executed for the first time at the initial backup time. Consecutive backups are performed at the end of every recurrence interval.

6. Choose daily or weekly recurrence for the backup.
7. For daily backup:

Select the backup interval from the drop-down list.

Recurrence
 Daily **Recur every** 24 hours ▼
 Weekly

- 2 hours
- 4 hours
- 8 hours
- 12 hours
- 24 hours

8. For weekly backup:

Recurrence
 Daily **Recur every** 24 hours ▼
 Weekly

Monday Tuesday Wednesday Thursday Friday
 Saturday Sunday

Check the weekday(s) to select the backup recurrence interval.

9. Select the backup storage location. This can be either a local or remote directory.

Local Network C:\Backup **Browse**

IMPORTANT: QIAGEN strongly recommends using a remote directory for backup. Only data on a remote directory is protected in the event of a system crash. The following warning is displayed if a local directory is chosen:

⚠️ "Warning (160117) The backup storage is on a local drive. The backup may not be secure in case of hard drive failure."

10. Select from the drop-down list the number of backup files to be stored.

Supported values are 1–12.



The oldest file will be overwritten when the indicated number of backup files is reached.

11. Click **Save backup settings** to save the settings.

Click **Restore saved settings** to reset the changes to the last saved settings.

IMPORTANT: QIALink Result Manager does not support the backup of remote databases. QIALink Result Manager and the SQL Server Express installation must reside on the same computer for backup. If QIALink Result Manager is connected to a remote database, the following warning is displayed:

 "Warning (160126) Backup of remote databases is not supported."

Note: Close QIALink Result Manager and reopen it as regular user after a backup schedule has been activated.

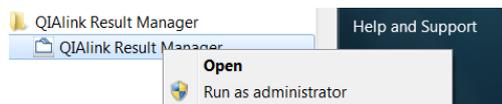
IMPORTANT: When using QIALink backup, the Windows user must not be logged off from the QIALink computer, and the QIALink computer must not hibernate during scheduled backup time. To prevent the computer from hibernating, select **Control Panel** from the Windows **Start** menu, go to **Power Options** in **All Control Panel Items**, click **Change plan settings** and select **Never** from the drop-down list in the setting **Put the computer to sleep**.

IMPORTANT: To ensure correct backup settings, do not use Microsoft Windows system settings to change the QIALink backup settings.

Restore backup

IMPORTANT: QIALink Result Manager must be started as administrator to grant the restore process sufficient privileges to restore a backup.

1. From the Windows **Start** menu select **All Programs**.
2. Right-click **QIALink Result Manger** and select "Run as administrator".

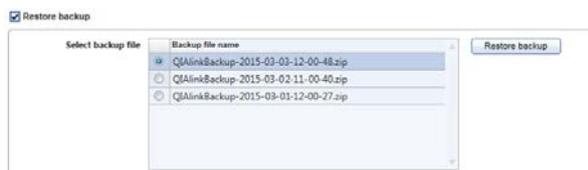


If QIALink Result Manager is not running with administrator rights the restore process will return an error as it has insufficient privileges to start and stop the Iguana service. The backup will not be restored.

3. To restore the backup, navigate to **Backup Management** by selecting the **Configuration** environment and clicking the **Backup Management** tab.
4. Check the **Restore backup** box.
5. Select a backup file from the list.

The list displays all available backup files ordered by backup time.

The latest backup file is displayed at the top of the list.



6. Click **Restore backup** to start restoring the QIALink system from the selected backup file.

IMPORTANT: Once initiated, **Restore backup** will overwrite all data in the databases, configuration files and logs. It will roll back the QIALink system to the state of the selected backup file.

We recommend using the restore function with great care and only after data loss.

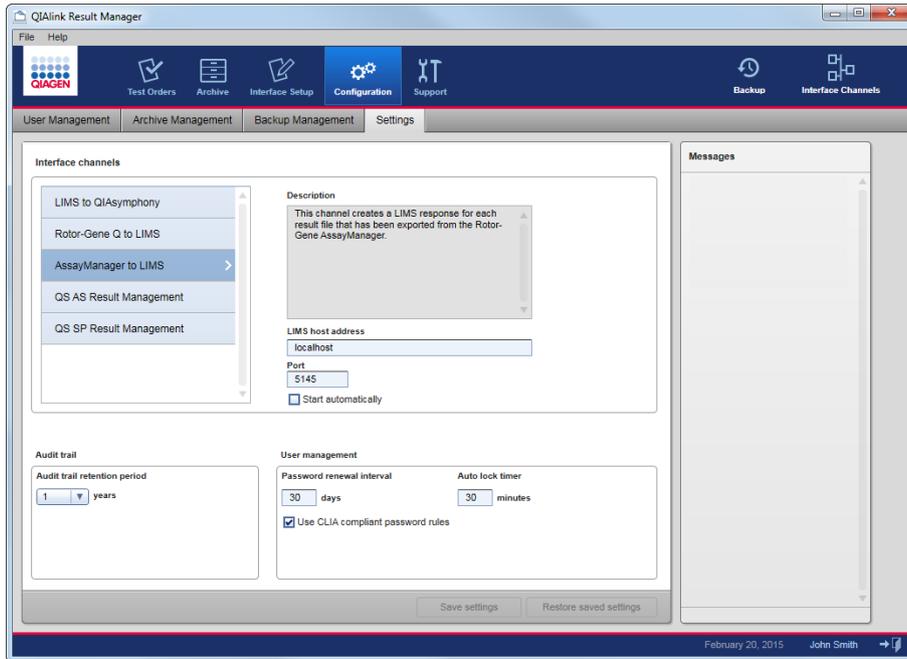
Note: It is not possible to interact with the QIALink Result Manager during the restoring process.

Note: Due to incompatible database settings, it is not possible to restore a backup created with a previous QIALink version.

Note: QIALink Result Manager will be closed after backup is restored.

Settings

The **Settings** screen can be accessed by choosing **Settings** from the navigation bar of the **Configuration** environment. The **Settings** view is accessible for all users, but only users with the assigned role of "Lab administrator" can edit the parameters.

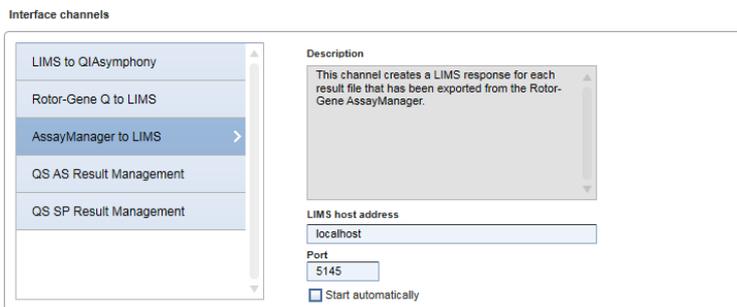


Note: The option **Rotor-Gene Q to LIMS** is not supported in the U.S.

The **Settings** screen is divided into three regions:

- Interface channels
- Audit trail
- User management

Interface channels



Note: The option **Rotor-Gene Q to LIMS** is not supported in the U.S.

Interface channels are listed on the left side of the panel.

The meanings of items in the **Interface channels** panel are explained in the following table.

Item	Meaning
Description (read-only field)	Contains a description of the selected interface channel as it is stored in the QIALink Interface Engine.
LIMS host address (text field)	Enter the host address where LIMS is running. The field is enabled for the channel "AssayManager to LIMS".
Port (text field)	Enter the LIMS TCP port for the selected interface channel. The field is enabled for the channels "LIMS to QIASymphony", and "AssayManager to LIMS".
Start automatically (box)	<p>Check/uncheck to activate/deactivate the automatic start of the selected interface channel during startup of the QIALink Interface Engine.</p> <p>The checkbox is enabled for all channels.</p> <p>Note: This option also needs to be deactivated if a channel should be permanently deactivated. Otherwise, the channel will automatically be restarted after a backup or OS restart, and potentially generate errors.</p>

Audit trail

Audit trail

Audit trail retention period

1 ▼ years

Select from the drop-down list the number of years for the **Audit trail** information to be stored in the SQL Server Express database.

User management

Three parameters can be configured in the **User management** region.

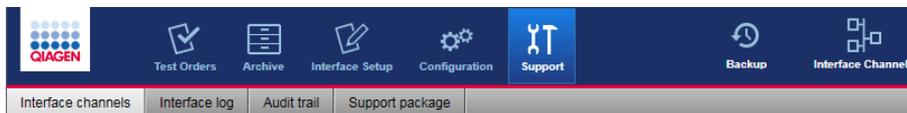
The screenshot shows a configuration panel titled "User management". It contains two input fields: "Password renewal interval" with a value of "30" and the unit "days", and "Auto lock timer" with a value of "30" and the unit "minutes". Below these fields is a checked checkbox labeled "Use CLIA compliant password rules".

- Password renewal interval
Enter the interval (in days) for renewal of passwords.
 - Auto lock timer
Enter the length of elapsed time before QIALink Result Manager is automatically locked. The user must re-enter his password to unlock the application.
 - Use CLIA compliant password rules
Check the box if user passwords are required to follow CLIA compliant rules. If this checkbox is selected, user passwords 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
 - Must not contain white spacesIf this checkbox is unselected, user passwords must comply with the following rules:
 - Minimum length 8 characters
 - Must not contain white spaces
1. Click **Save settings** to save changed settings.
 2. Click **Restore saved settings** to reset changes to the last saved settings.

Support environment

Overview

The **Support** environment is accessed by selecting **Support** in the main navigation bar. It contains the **Interface channels**, **Interface log**, **Audit trail** and **Support package** views.



Interface channels

The **Interface channels** screen can be accessed by selecting the **Support** environment and clicking the **Interface channels** tab. The screen can also be opened by clicking the **Interface Channels** icon in the upper right corner of the main navigation bar.

If the **Interface Channels** icon is not present on the navigation bar, the Iguana service has to be started.

Start and stop Iguana service

Iguana runs as a Windows service. Follow these steps to start or stop the Iguana service.

1. From the Windows **Start** menu, select **Control Panel**, then **Administrative Tools**.
2. Double-click **Services**.
3. Right-click the Service **iNTERFACEWARE 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.

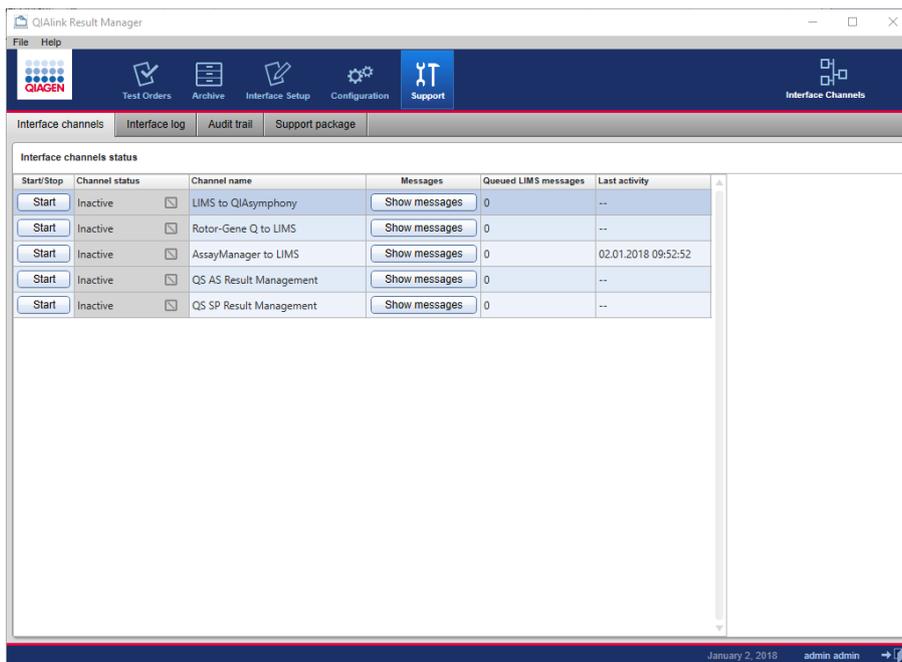
Channel concept

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

These channels exist within QIAlink Interface Engine.

Channel	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-Gene AssayManager.

Each channel can be started and stopped individually in the **Interface channel** view.



Note: The channel **Rotor-Gene Q to LIMS** is not supported in the U.S.

If no channels are listed in the **Interface channel status** table of the **Interface channels** screen, the Iguana service has to be started.

The meanings of the columns and buttons of the **Interface channel status** table are explained below.

Column/button	Meaning
Start/Stop	Toggle button to start or stop the channel of the QIALink Interface Engine.
Channel status	Displays the current status of the channel: inactive, running, warning or error.
Channel name	Specifies the name of the channel for which the status is displayed.
Messages/Show messages	Opens the Interface log tab and displays the message of the corresponding channel by preselecting the channel name in the filter options.
Queued LIMS messages	Shows the number of the queued LIMS messages. For channels without a LIMS connection, “-” is displayed.
Last activity	Shows the date and time of the last channel activity. For channels without activities, “-” is displayed.

Monitoring status of interface channels with the Interface channels view

The **Interface channels** view is mainly used to monitor the status of the LIMS interface. The relevant indicator is the channel status icon. The following table explains the meaning of the channel status icons.

Status	Icon	Meaning	Action
Inactive		The channel is idle; no data are currently being processed by this channel.	Click Start to start the channel.
Running (green)		The channel is running; no problems occurred.	Click Stop to stop the channel.
Warning (yellow)		No connection could be established to LIMS. OR A warning occurred, but the channel is still processing data.	Check the channel log for this channel (see page 97).
Error (red)		An error occurred; the channel has stopped processing data.	Check the channel log for this channel (see page 97). Resolve the error situation (see "Troubleshooting", page 110). Restart the channel with the Start/Stop button.

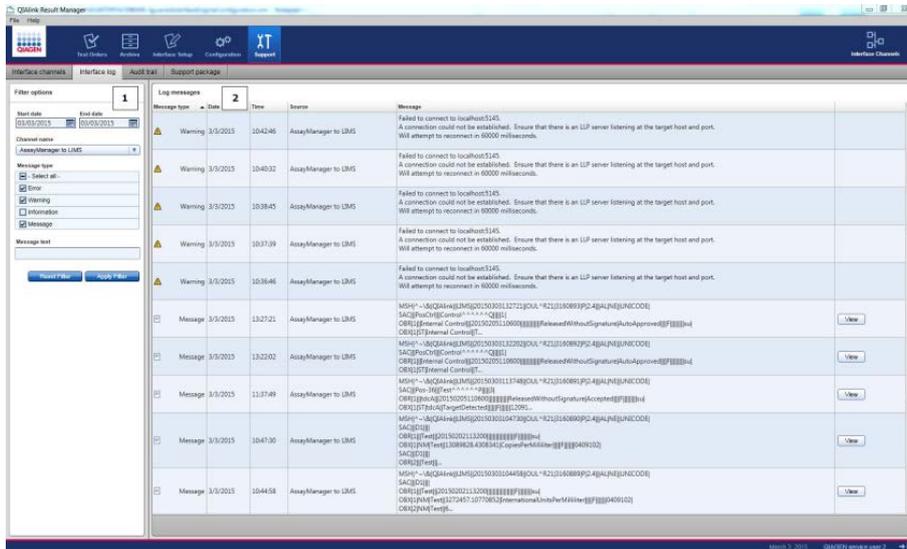
The coloring of the **Interface channel** icon in the navigation bar reflects the status of the interface channels.

- The icon is red if at least one channel is in an error state.
- The icon is yellow if at least one channel is in the warning state.
- The icon is blue if all channels are running or inactive.

Interface log

The **Interface log** tab of the **Support** environment displays the log information of the QIALink interface engine. In addition, it allows filtering according to certain filter criteria.

The Interface log consists of the **Filter options** dialog (1) and the **Log messages** panel (2).



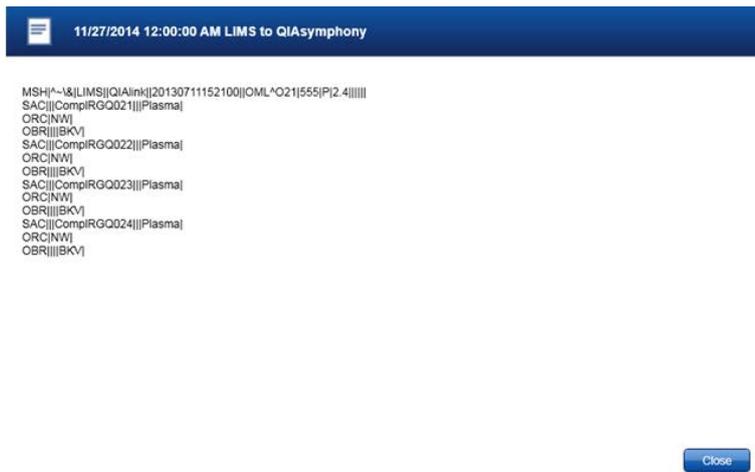
The following **Filter options** are available.

Field/button	Meaning
Start date	Start date for log messages to be displayed.
End date	End date for log messages to be displayed.
Channel name	Specifies the name of the channel for which the log messages are displayed.
Message type (checkboxes)	Message types to be displayed in the Log messages table.
Message text	Specifies the text that is applied to search the message texts. (The wildcards “*” and “?” are supported but may not be entered at the beginning or end of the search string.)
Reset filter (button)	Resets all parameters of the filter dialog to their default values.
Apply filter (button)	Displays a list of Log messages based on the filter parameters.

The following table explains the columns in the **Log messages** dialog.

Column	Meaning
Message type	Message type according to QIALink Result Manager: Error, Warning, Message and Information.
Date	Date when the message was sent.
Time	Time when the message was sent.
Source	The Iguana channel or service that issued the message.
Message	The first 255 characters of the message text.
(Last column)	If the message is longer than 255 characters, the View button opens a window displaying the complete message text in a new dialog box.

Click **View** to open a window displaying the complete message text.



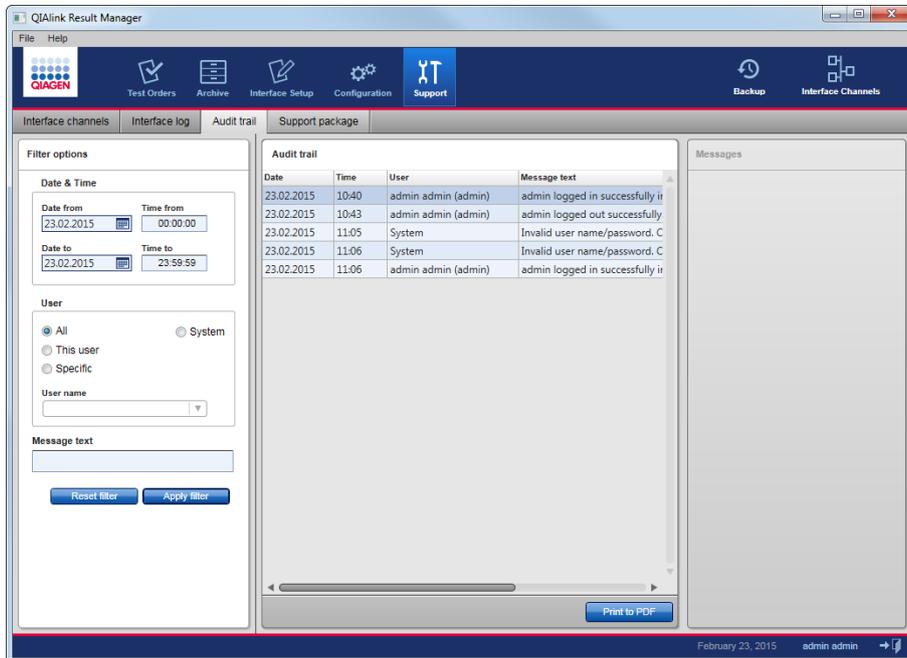
Click **Close** to exit the dialog.

Each message is a specific message type. Meanings of the message type icons are explained in the following table.

Icon	Meaning	Description
	Error	A service or channel error, or an error that has occurred while processing a message. 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.
	Warning	Warning messages indicate a problem during data processing; the channel continues to operate.
	Message	A message sent through the channel.
	Information	A log entry that informs the user of a task performed by the channel.

Audit trail

The **Audit trail** tab of the **Support** environment gives access to the audit trail. All changes to configuration are tracked and can be 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/list	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.

Field/button/list	Meaning
User	User modifying a configuration: Possible values are: <ul style="list-style-type: none"> ● All ● System (used for all actions that cannot be associated with a user) ● This user ● Specific (select user name from drop-down list)
Message text (field)	Searches the message text for a string.
Reset filter (button)	Resets filter values to default settings.
Apply filter (button)	Initiates filtering of messages based on the required filter options.

The following information is displayed in a table on the right-hand panel of the **Audit trail** screen.

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 text	Description of the configuration change.

To print the audit trail messages:

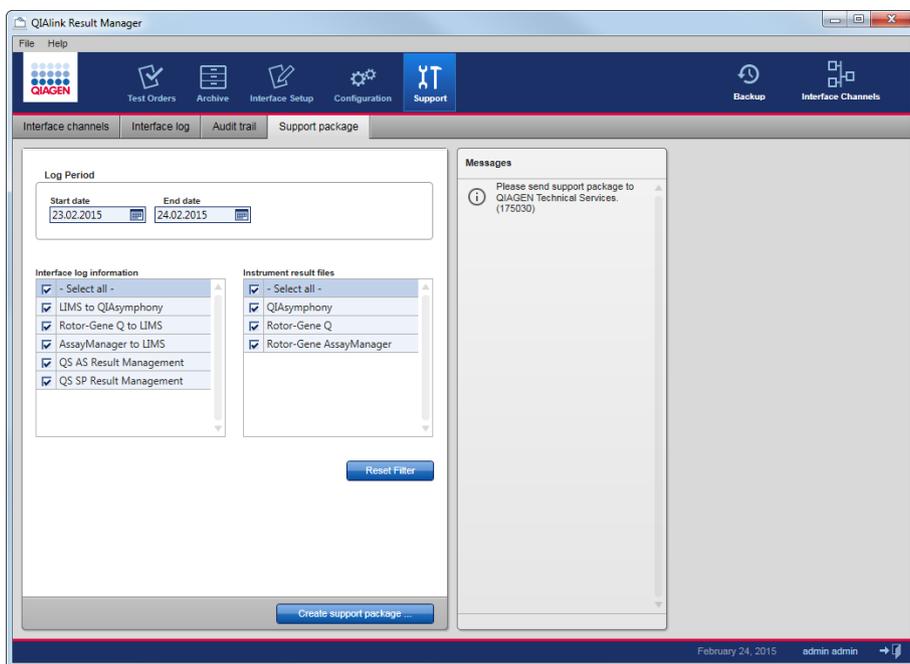
1. Enter the required values for date, time, user, and message text.
2. Click **Apply filter**.
3. Click **Print to PDF** to print the displayed audit trail messages to a PDF file.

Support package

The **Support package** tab of the **Support** environment allows the user to create a support package. The **Support package** view can be accessed by all users.

The support package can be created when a problem occurs within QIAlink that requires support from QIAGEN Technical Services.

Note: The amount of data collected in the support package may be large. Use one or more filters to limit the data included in the support package.



Note: The option **Rotor-Gene Q to LIMS** is not supported in the U.S.

The following **Support package** filter options are available.

Field/button/box	Meaning
Start date	Start date of the required time frame.
End date	End date of the required time frame.
Interface log information (boxes)	Check the box to include the interface channel log in the support package. All log messages created within the log period for the selected channel are added to the support package.
Interface result files (boxes)	Check the box to include the result files of the instrument in the support package. All instrument result files from all transfer folders specified for the selected instrument type are added to the support package.
Reset filter (button)	Resets the filter to the default values.
Create support package (button)	Creates the support package.

Create a support package

1. Select **Start date** and **End date** for the log period.
2. Select the **Interface log information** to be included.
3. Select the **Instrument result files** to be included.
4. Click **Create support package**.
5. In the **Save support package** dialog, select a destination folder to store the support package.
The default name of the support package file is
QIAlinkSupportPackage_YYYYMMDD_hh24mmss.zip
6. Open Windows Explorer, navigate to the location of the support package, and send the support package to QIAGEN Technical Services.

The support package contains the following information:

File	Description
IguanaYYYYMMDD_YYYYMMDD.log	Iguana log file
Log (folder)	QIAlink Result Manager log files
AuditTrailMessages.xml	Audit trail messages from the selected log interval
QIAlinkConfigurations.xrm	Interface setup configuration
Devices (folder)	Contains instrument folders for the selected instruments with result files according to the log period
iINTERFACEWARE-Iguana/InterfaceEngineConfiguration.xml	QIAlink Interface Engine configuration file
iINTERFACEWARE-Iguana/IguanaConfiguration.xml	Iguana configuration file

Workflow with QIALink

This section provides information about using QIALink software in combination with QIASymphony and Rotor-Gene AssayManager.

QIASymphony in combination with QIALink

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.

Work list generation

After receiving a test order from LIMS, QIALink creates a QIASymphony work list. The parameters contained in the LIMS order must be configured in QIALink (see “QIASymphony dialog”, page 63).

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.

Archiving of QIASymphony result files

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

Processing of QIASymphony SP batch confirmation

QIASymphony SP batch confirmation is evaluated by QIALink software.

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.

Required QIASymphony settings

A user with a "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 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 QIASymphony 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.

Rotor-Gene AssayManager in combination with QIALink

General

QIALink software supports Rotor-Gene AssayManager version 1.0.4 and higher.

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

Configure the QIALink Results folder (see “Rotor-Gene AssayManager dialog”, page 67) to the same directory as the LIMS output folder specified in Rotor-Gene AssayManager Local Settings.

Upon release of results in Rotor-Gene 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-Gene AssayManager results to LIMS.

Handling of rejected results

Results that have been rejected in Rotor-Gene 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 (default configuration of QIALink LIMS interface). Alternatively, a result marked as “Invalid” will be transferred to the LIMS if configured accordingly by QIAGEN Technical Services during initial system setup.

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.

Alternatively, a result marked as “Invalid” will be transferred to the LIMS if configured accordingly by QIAGEN Technical Service during initial system setup.

Rotor-Gene AssayManager plug-ins *

QIAlink supports the following plug-ins:

- UDT Basic Plug-in
- Rotor-Gene AssayManager Epsilon (US) Plug-in
- Rotor-Gene AssayManager v2.1 Gamma MDx (US) Plug-in

In the future, there may be additional plug-ins made available for FDA cleared or approved assays.

If a plug-in is used that is not supported, no results will be transferred to LIMS. A warning will be displayed in the **Interface log** screen (see page 97).

* Rotor-Gene AssayManager plug-ins may not be available in all countries.

Troubleshooting

The table lists errors, warnings and information messages that can occur in the **Interface log** screen of the QIALink Interface Engine (see page 97). It contains information about possible root causes and actions to resolve the problem.

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

004

Could not read from file <FILE>. Check that the file exists 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

LIMS order message with unknown receiving application <RECEIVING_APP> [MSH-5] received. The message will be ignored.

Contact your LIMS provider to set receiving application [MSH-5] to "QIALink" and resend LIMS order message.

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 provider to set receiving application [MSH-5] to "QIALink" and resend LIMS order message.

006

LIMS order message with unsupported character set <ENCODING>. [MSH-18] received. The message will be ignored.

Contact your LIMS provider to set character set [MSH-18] to a supported character set and resend LIMS order message.

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 provider to set character set [MSH-18] to a supported character set and resend LIMS order message.

007

LIMS order message with unsupported combination of version id <VERSION> [MSH-12] and message type <MSGTYPE> [MSH-9] received. The message will be ignored.

Contact your LIMS provider to set version id [MSH-12] and message type [MSH-9] to a supported combination of HL7 version and message type and resend LIMS order message.

LIMS transmitted a message with a message type that does not comply with QIAGEN interface specification.

Contact your LIMS provider to set version id [MSH-12] and message type [MSH-9] to a supported combination of HL7 version and message type and resend LIMS order message.

008

LIMS order message with unsupported version id <VERSION> [MSH-12] received. The message will be ignored.

Contact your LIMS provider to set version id [MSH-12] to a supported HL7 version and resend LIMS order message.

LIMS transmitted a message with a HL7 protocol version that does not comply with QIAGEN interface specification.

Contact your LIMS provider to set version id [MSH-12] to a supported HL7 version and resend LIMS order message.

009

LIMS order message with unsupported order control <OCVALUE> [ORC-1] received. The order will be ignored.

Contact your LIMS provider to set order control [ORC-1] to a supported value and resend LIMS order message.

LIMS transmitted a test order with an order control value that does not comply with QIAGEN interface specification.

Contact your LIMS provider to set order control [ORC-1] to a supported value and resend LIMS order message.

010

There is no QIASymphony work list parameter configuration with LIMS test code <SERVICE_IDENTIFIER> and LIMS specimen code <SPECIMEN> defined. The LIMS request for sample <SAMPLE_ID> will be ignored.

Contact your QIALink lab administrator to add the QIASymphony work list parameter configuration. Resend the LIMS order message.

LIMS transmitted a test order that contained an unknown test ID or an unknown specimen.

Correct configuration of QIASymphony parameters (see page 63).
Resend order from LIMS.

011

Found multiple configurations for LIMS test code <SERVICE_IDENTIFIER> and LIMS specimen code <SPECIMEN>.

Contact your QIALink lab administrator to resolve the ambiguous QIASymphony work list parameter configuration. Restart the channel and resend LIMS order message.

The QIALink configuration contains more than one configuration for the same LIMS test ID and specimen.

Correct configuration of QIASymphony parameters (see page 63).
Resend order from LIMS.

012

No QIASymphony instrument defined in instrument setup.

Contact your QIALink lab administrator to add the configuration for at least one QIASymphony instrument and restart the channel.

No directory is configured for QIASymphony.

Configure QIASymphony directory (see page 63).
Restart the channel.

013

(Not in use)

014

There is no Rotor-Gene AssayManager export parameter configuration for assay profile name <ASSAYPROFILENAME> and plug-in name <PLUGIN>.

Contact your QIALink lab administrator to add the Rotor-Gene AssayManager export parameter configuration.

A result file has been exported from Rotor-Gene AssayManager containing an assay profile that is not configured in QIALink. The channel issues a warning and the file is moved to the Pending folder.

Configure assay profile (see page 67). Go to the LIMS output folder. Move the result file that caused the problem from the Pending folder to the LIMS output folder. Restart the channel to dismiss the warning status. The file will be processed again.

015

Found multiple Rotor-Gene AssayManager export parameter configurations for assay profile name <ASSAYPROFILENAME> and plug-in name <PLUGIN>.

Contact your QIALink lab administrator to resolve the ambiguous Rotor-Gene AssayManager export parameter configuration.

The QIALink configuration contains more than one configuration for the same assay profile. The channel issues a warning and the file is moved to the Pending folder.

Correct configuration of assay profiles (see page 67). Go to the LIMS output folder. Move the result file that caused the problem from the Pending folder to the LIMS output folder. Restart the channel to dismiss the warning status. The file will be processed again.

016

Rotor-Gene AssayManager plug-in <PLUGIN> is not supported by QIALink. The AssayManager result file %s will be ignored.

Contact QIAGEN technical service to obtain a QIALink update.

The plug-in used by Rotor-Gene AssayManager is not supported by the installed version of QIALink.

Contact QIAGEN Technical Services to inquire about a QIALink software update to support the plug-in.

017

There is no Rotor-Gene AssayManager export parameter configuration with target <TARGET> for assay profile name <ASSAYPROFILENAME> and plug-in name <PLUGIN>.

Contact your QIAlink lab administrator to add the Rotor-Gene AssayManager export parameter configuration.

Not all targets are configured in the assay profile configuration. The channel issues a warning and the file is moved to the Pending folder.

Correct configuration of assay profile (see page 67). Move the result file that caused the problem from the Pending folder to the LIMS output folder. Restart the channel to dismiss the warning status. The file will be processed again.

018

Found multiple Rotor-Gene AssayManager export parameter configurations with target <TARGET> for assay profile name <ASSAYPROFILENAME> and plug-in name <Plugin>.

Contact your QIAlink lab administrator to reconfigure the Rotor-Gene AssayManager export parameter configuration.

The assay profile configuration contains a target more than one time. The channel issues a warning and the file is moved to the Pending folder.

Correct configuration of assay profile (see page 67). Go to the LIMS output folder. Move the result file that caused the problem from the Pending folder to the LIMS output folder. Restart the channel to dismiss the warning status. The file will be processed again.

019

No sample result to export in file <FILE>. The file will be ignored.

A result file has been exported from Rotor-Gene AssayManager that does not contain a result.

No action required.

020

(Not in use)

021

(Not in use)

022

(Not in use)

023

An unexpected error occurred. Original error was: "<ERRORMESSAGE>".

Restart the channel. Please contact QIAGEN technical services if the problem persists.

An unexpected error occurred. The channel has stopped. The error message is displayed in the channel log.

Restart the channel. If the problem persists contact QIAGEN Technical Services.

024

(Not in use)

025

(Not in use)

026

Result database is currently using <SIZE> % of its maximum size.

Contact your QIALink lab administrator to archive the QIALink Result Manager database.

The QIALink result database has reached more than 80% of the maximum size.

Archive the database (see page 83).

027

LIMS order message without sample ID and/or LIMS test code received. The LIMS request will be ignored.

Contact your LIMS provider to set sample ID and LIMS test code and resend LIMS order message.

LIMS transmitted a message without sample ID or test identifier.

Contact your LIMS vendor to set sample ID and LIMS test code and resend LIMS order message.

028

(Not in use)

029

An instrument folder <FOLDER> could not be accessed.

Check that the folder exists and the permissions are set properly.

Directory allows no read access.

Enable read access in Windows settings.

033

Result database is currently using <SIZE> % of its maximum size.

Contact your QIALink lab administrator to archive the QIALink Result Manager database. Restart the channel when the problem is resolved.

The QIALink result database has reached more than 95% of the maximum size. The channel has stopped.

Archive the QIALink Result Manager database (see page 83).
Restart the channel.

034

Checksum in result file <FILE> is missing.

An instrument result file without checksum was detected. The file has been altered after creation by the instrument. The channel issues a warning.

Check if the instrument result file is correct.

035

Checksum in result file <FILE> is wrong.

An instrument result file does not match the checksum. The file has been altered after creation by the instrument. The channel issues a warning.

Check if the instrument result file is correct.

036

(Not in use)

037

(Not in use)

038

(Not in use)

039

Cannot move file <FILE> to <FOLDER>. Original error was: "<ERRORMESSAGE>".

Check if the file is locked by any other process.

File is locked by other process.

Identify the process that has locked the file and release the lock.

040

Invalid QIAsymphony StartBatchConfirmation file <FILE>. File moved to error folder.

Restart the channel. Please contact QIAGEN technical services if the problem persists.

Wrong configuration of QIAsymphony Management Console.

Restart the channel. Please contact QIAGEN Technical Services if the problem persists.

041

Rotor-Gene AssayManager result file <FILE> does not provide sample types. File was moved to error folder.

Please contact QIAGEN technical services to update Rotor-Gene AssayManager software to version 1.0.4 or higher.

The Rotor-Gene AssayManager LIMS export file was generated using Rotor-Gene AssayManager version 1.0.3 and below.

Please contact QIAGEN Technical Services to update Rotor-Gene AssayManager software to version 1.0.4 or higher.

042

Rotor-Gene AssayManager result file <FILE> does not provide target types. File was moved to error folder.

Please contact QIAGEN technical services to update Rotor-Gene AssayManager software to version 1.0.4 or higher.

The Rotor-Gene AssayManager LIMS export file was generated using Rotor-Gene AssayManager version 1.0.3 and below.

Please contact QIAGEN Technical Services to update Rotor-Gene AssayManager software to version 1.0.4 or higher.

043

Invalid Rotor-Gene AssayManager result file <FILE>. File was moved to error folder.

Restart the channel. Please contact QIAGEN technical services if the problem persists.

Wrong file format for Rotor-Gene AssayManager LIMS export.

Restart the channel.
Please contact QIAGEN Technical Services if the problem persists.

044

QIAsymphony sample state <STATE> not supported.

Restart the channel. Please contact QIAGEN technical services if the problem persists.

Unsupported sample state in QIAsymphony result file.

Restart the channel.
Please contact QIAGEN Technical Services if the problem persists.

045

QIAsymphony reagent rack <RACK> of sample <SAMPLE> not found.

Restart the channel. Please contact QIAGEN technical services if the problem persists.

Unsupported reagent rack in QIAsymphony result file.

Restart the channel.
Please contact QIAGEN Technical Services if the problem persists.

047

RAMPluginType <TYPE> has a sample result, but no sample result name.

Restart the channel. Please contact QIAGEN technical services if the problem persists.

Wrong configuration of QIALink database.

Restart the channel.
Please contact QIAGEN Technical Services if the problem persists.

048

Checksum missing in file <FILE>. File was moved to error folder.

Restart the channel. Please contact QIAGEN technical services if the problem persists.

An instrument result file without checksum was detected. The file has been altered after creation by the instrument. The channel issues an error and moves the file to the error folder.

Check why the instrument result file has been modified. Transfer original instrument result file to QIALink.
Restart the channel.

049

Checksum wrong in file <FILE>. File was moved to error folder.

Restart the channel. Please contact QIAGEN technical services if the problem persists.

An instrument result file does not match the checksum. The file has been altered after creation by the instrument. The channel issues an error and moves the file to the error folder.

Check why the instrument result file has been modified. Transfer original instrument result file to QIALink. Restart the channel.

050

Rotor-Gene AssayManager export parameter configuration for assay profile name <ASSAYPROFILENAME> and plug-in name <PLUGIN>. is inactive.

Contact your QIALink lab administrator to activate the Rotor-Gene AssayManager export parameter configuration.

A result file has been exported from Rotor-Gene AssayManager containing an assay profile that is inactive in QIALink. The channel issues a warning and the file is moved to the Pending folder.

Activate assay profile (see page 67). Go to the LIMS output folder. Move the result file that caused the problem from the Pending folder to the LIMS output folder. Restart the channel to dismiss the warning status. The file will be processed again.

051

(Not in use)

052

File <FILE> was moved to Pending.

See accompanying warning messages.

When the problem causing this warning is solved, move the file from the Pending folder to the LIMS output folder. Restart the channel to dismiss the warning status.

053

File <FILE> could not be processed.

See accompanying error messages.

Follow the corrective action of the accompanying error message.
Restart the channel.

054

Configuration database is not available: <DATABASENAME>. Retry <NUMBEROFRETRY>.

SQL server connection is disrupted.

Check server availability.

055

Configuration database is not available. Retry <NUMBEROFRETRY>.

SQL server connection is disrupted.

Check server availability.

056

Result database is not available: <DATABASENAME>. Retry <NUMBEROFRETRY>.

SQL server connection is disrupted.

Check server availability.

057

Result database is not available. Retry <NUMBEROFRETRY>.

SQL server connection is disrupted.

Check server availability.

058

The result file <FILE> is invalid. The following error occurred: <ERRORMESSAGE>.

A file with invalid format is processed.

Restart the channel. Please contact QIAGEN Technical Services if the problem persists.

059

(Not in use)

060

(Not in use)

061

The QDEF file <FILE> is invalid. The following error occurred: <ERRORMESSAGE>. Please contact QIAGEN Technical Services if the problem persists.

Invalid file format. This file does not comply with the definition of QIAGEN Data Exchange Format.

Please contact QIAGEN Technical Services if the problem persists.

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