QIAGEN

QIAlink

Service Manual

SM-5000-0011-002, QFS, QTS, QL

QIAGEN

Document Information

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COMPANY:	QIAGEN
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Document Change Control

Adaptations and updates of the present document are a consequence of technical improvements and amendments of QIAlink. Any changes within this document are to be controlled.

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Trademarks

Trademarks: QIAGEN®, QIAsymphony® SP/AS, Rotor-Gene® Q MDx, and the Rotor-Gene AssayManager®, Adobe®, Reader® (Adobe Systems Incorporated); Microsoft®, Windows®, Pentium® (Microsoft Corporation); Pentium® (Intel Corporation).

1 Introduction

1.1 General Information

QIAGEN Global Product support (GPS) is responsible for the creation and maintenance of Instrument Service documentation. 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 welcome your comments and suggestions on this publication.

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If an error is found in this Service Manual please contact Global Product Support immediately (see contact details above).

1.1.1 Purpose

This Service Manual represents an integral part of QIAlink.This service manual provides detailed information regarding the operation, maintenance and function check of QIAlink. The instructions contained in the manual regarding operation, maintenance and the function check are to be strictly observed. Pay particular attention to any safety information. The information is presented in the following chapters:

1 Introduction (this chapter)
2 Hazards and Precautions
3 General Information
4 Installation
5 Configuring the Result Manager
6 Troubleshooting
7 Customer Training
8 Appendix

1.1.2 Scope

This document is the QIAlink Service manual revision 002 for use with QIAlink version 1.1.

1.2 Intended Use

1.2.1 QIAlink Expected Use

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

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

1

1.2.2 Requirements for working with QIAlink

This section covers the general level of competence and training necessary for installation, use and maintaining of QIAlink.

Appropriate training for all levels can be arranged with QIAGEN.

Task	Personnel	Knowledge
Delivery	No special requirements	No special requirements
Installation	**QIAGEN Field Service Specialists only**	Technically skilled with an good knowledge of the system and application.
Routine Use	Laboratory technicians or equivalent	Appropriately trained and experienced personnel, familiar with use of lab equipment and computers.
Routine Maintenance	Laboratory technicians or equivalent	Appropriately trained and experienced personnel, familiar with use of lab equipment and computers.
Upgrading	**QIAGEN Field Service Specialists only**	Technically skilled with an good knowledge of the system and application.

Table 1.2-1 Requirements for personnel

2 Hazards and Precautions

2.1 Introduction

Before using QIAlink, it is essential that you read this Service Manual as well as the current User Manual carefully and pay particular attention to the safety information. The handbooks contain information and warnings that must be followed by the user and Field Service Specialist to ensure safe operation of the software.

The following safety conventions will be used throughout this manual.

WARNING 	The term WARNING is used to inform you about situation that could result in **personal injury** to you or other persons. Details about these circumstances are given in a box like this one. [W0]

INFORMATION 	The term INFORMATION is used to inform you about **hints and tricks**. Details about these circumstances are given in a box like this one.

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

2.2 Safety Information

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

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

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

2.3 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.

QIAlink may only be installed by a QIAGEN Field Service Specialist.

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

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

3 General Information

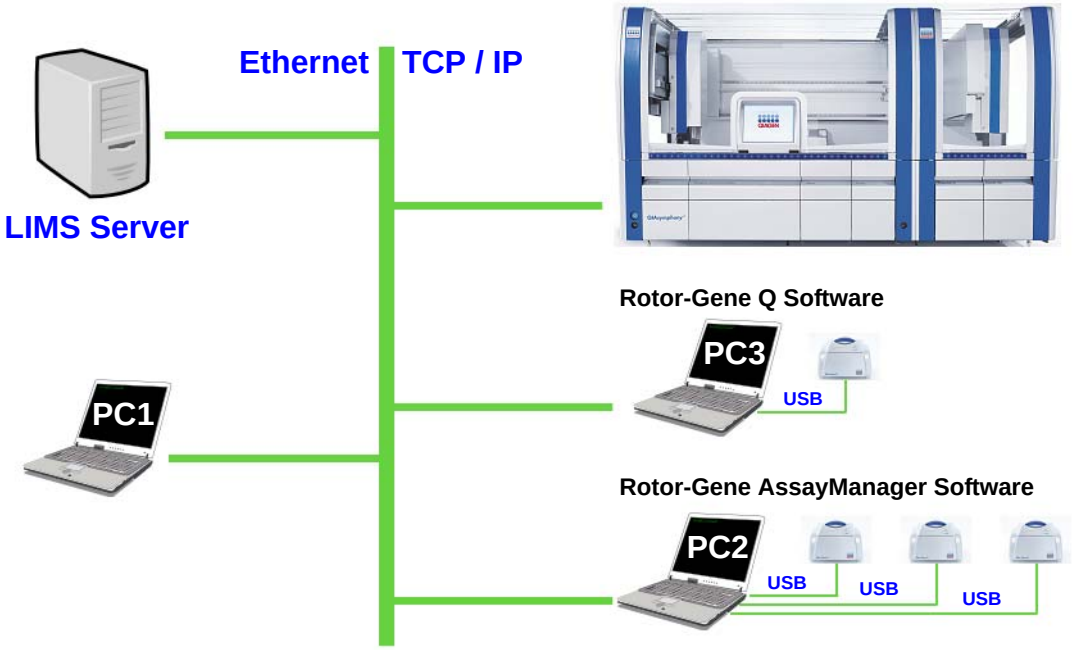
3.1 Principle of operation

3.1.1 Channel concept

The QIAlink Interface Engine uses a Windows service named “**Iguana**” to ensure the communication between the LIMS and the QIAGEN Instrumentation. Iguana uses so called “channels” to transport data from one point to another. The following channels exist within the 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 and starts batch confirmation in the results database and processes* the start batch confirmation file. In addition, it transfers the QIAsymphony SP rack file to all connected QIAsymphony AS instruments. (* the start batch confirmation isn’t archived, it is only processed.)
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.
Rotor-Gene Q to LIMS	Creates a LIMS response for each LIMS export file that has been exported from Rotor-Gene Q software.

3.1.2 Overview

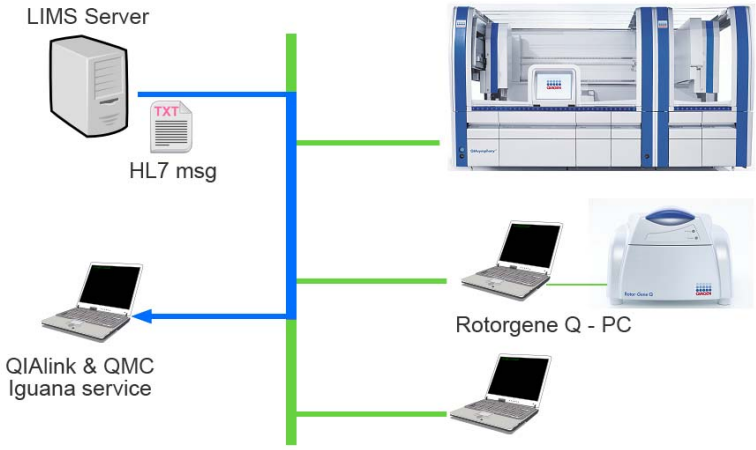


Typically, QIAlink Interface Engine, QIAlink Result Manager, the SQL Server Express installation, and QIAsymphony Management Console are located on the same computer (“PC1” in the figure above). This computer is connected to the lab network to allow communication with the LIMS, the QIAsymphony instruments,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

The following sections describes the steps for one order coming from the LIMS. The figure has been simplified to a setup with a single RGQ as this is representative of any QIAlink implementation.

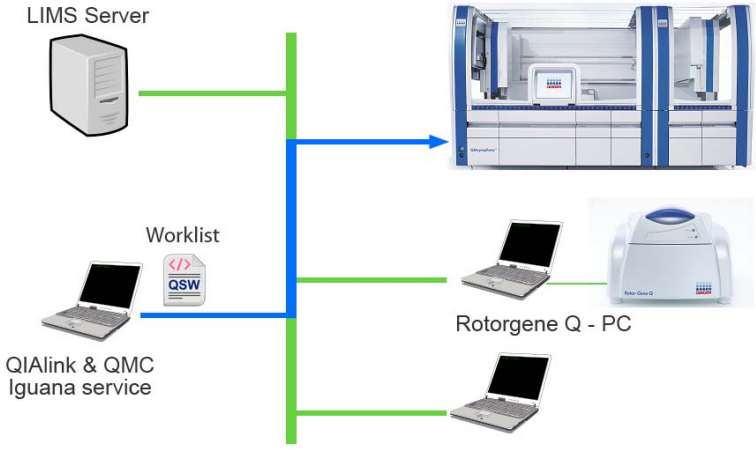
NOTE	The figure above shows an example. The deployment can be different depending on the infrastructure of the laboratory, especially if an existing SQL Server is used instead of a local SQL Server Express installation. During installation you will have to establish the system setup that best fits the laboratory in collaboration with the customer’s IT. An overview of the integration of QIAlink software in the QIAsymphony RGQ system and with LIMS is illustrated in the following sections of the manual. The exchange of data between the software components is also shown.

3.2 LIMS order



In the first step, the LIMS orders tests. QIAlink listens to the broadcast.

3.3 QIAlink listens, parses and translates



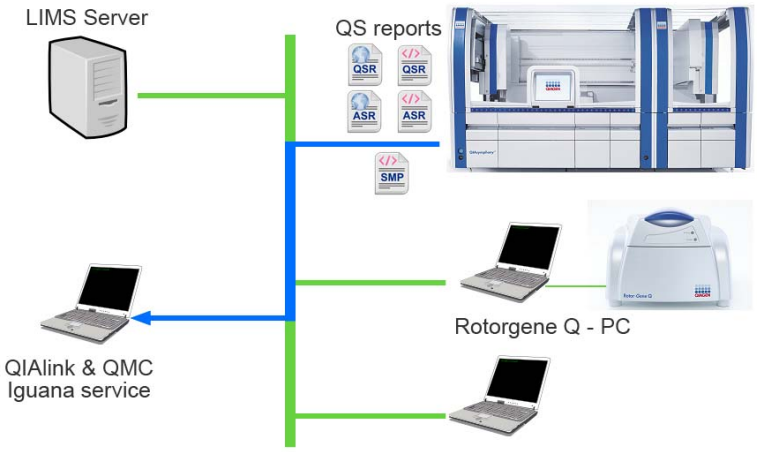
After receiving a test order from the LIMS, QIAlink creates a QIAsymphony work list. Therefore, the parameters contained in the LIMS order must be configured in QIAlink.

The created work lists are transferred via the QMC auto transfer to all connected and configured QIAsymphony instruments.

3.4 Instruments process

For more information on working with work lists on QIAsymphony, refer to the QIAsymphony user documentation. Basically, during this step the operator loads the samples and as soon as the sample ID's

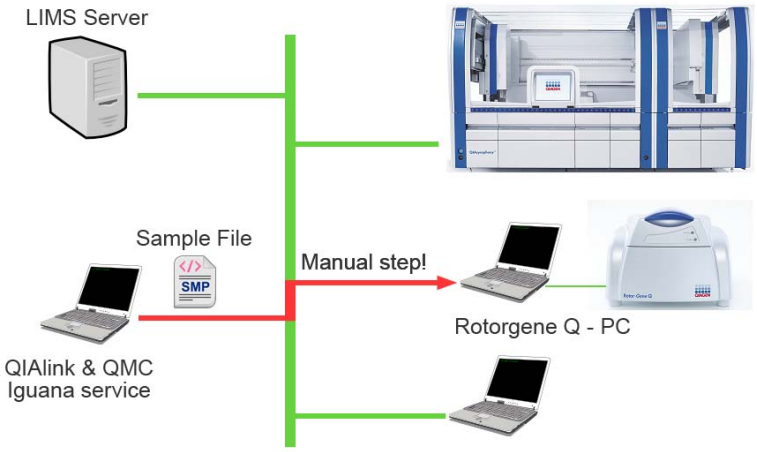
have been successfully read the tests are assigned using the work lists that have been transferred to the device(s) by the QMC software:



Once the run is finished result files from QIAsymphony SP and AS are archived within a SQL Server Express database.

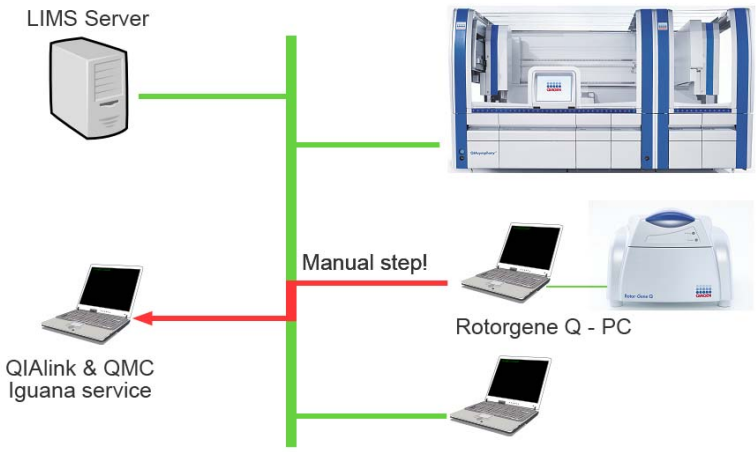
The rack files from QIAsymphony SP are transferred by QIAlink to all connected QIAsymphony AS instruments. This makes it possible to move eluate racks to a different QIAsymphony instrument for assay setup.

3.5 Rotor-Gene Q run



The cycler file is transferred automatically by the QMC to the QIAlink PC, the operator just has to open it and start the cycler run. The folder where the cycler files go to shall be shared on the network and the RGQ PC shall have read/write authorization in this folder. Check with the local IT what best fits their architecture.

Just keep in mind that the drive **has to be reachable from the RGQ PC and that the read and write rights must be given**.



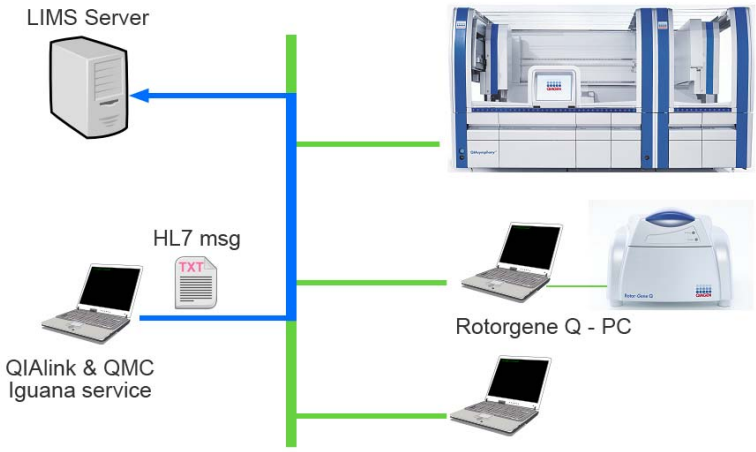
When using the Rotor-Gene Q software the LIMS export of the results is done manually into a “Rotor-Gene Q LIMS export files” folder (configured in the QIAlink Result Manager).

The file name may be freely chosen but the file type must be *.xml.

When using the Rotor-Gene Assay Manager the results are automatically exported to the LIMS export files folder upon release. The transfer from this folder to the LIMS is then carried out by QIAlink.

If the results are exported inadvertently to another folder, the export to the LIMS can be triggered by re-exporting the results into the correct folder.

3.6 Software Operation



QIAlink automatically forwards the exported results to the LIMS and the results are **also archived in the SQL Server Express database**.

4 Installation

Before the installation can start the QIAlink Pre-Installation Form (PIF-5000-0002) has to be completely filled in by a SAS and passed to the FSS in charge of the installation via the local dispatch group.

4.1 Requirements

To allow the installation of QIAlink the following requirements must be fulfilled.

4.1.1 Personal skills

To perform the installation of QIAlink it is mandatory to be certified in:

- QIAsymphony RGQ applications.
- Rotor-Gene Q Applications

Strong PC knowledge, some IT (networks) are a big asset too. If you are not feeling too comfortable with IT/ PC matters you will have to count on stronger IT support from the customer's IT during the installation.

4.1.2 Hardware / PC

4.1.2.1 QIAlink PC

The PC used to run QIAlink has to fulfil the following minimal requirements:

- Operating System: Microsoft® Windows® XP 32 bit, Microsoft® Windows® 7 32 bit
- Browser: Internet Explorer 8
- Main memory: Min. 512 MB
- Harddisk space: Min. 30 GB of free disk space
- Ports: Ethernet
- Software: MS SQL Server 2008 R2, SQL Server Management Studio,.NET 4.0 or higher

4.1.3 Site Survey

NOTE	The **QIAlink Pre-Installation Form** (PIF-5000-0002) has been filled in and communicated to the FSS in charge of the installation. If this hasn't been done the installation might need to be re scheduled until this input is available.

4.1.4 Software

QIAlink archives data (settings and results) in different SQL inter relational databases. This requires the following Microsoft components, if not already installed, then install:

NOTE	Windows 7 users: Powershell and Microsoft Windows Installer 4.5 are part of the standard Windows Installation.

- **.NET framework 4.0** by running:
  "\bin\DotNetFX40\dotNetFx40_Full_x86_x64.exe" ...from the QIAlink CD.
- **Microsoft® Powershell 1.0** (or higher) by running:
  "bin\Powershell10\WindowsXP-Powershell-x86-ENU.exe" ...from the QIAlink CD.
- **Microsoft® Windows Installer 4.5** (or higher) by running:
  "bin\WindowsInstaller45\WindowsXP-WinInstaller-x86.exe" ...from the QIAlink CD.

4.2 Installation procedure

This chapter describes the installation procedure for new installations.

If upgrading from QIAlink 1.0 to 1.1 refer to chapter **4.4 Upgrading QIAlink 1.0 to QIAlink 1.1.**

4.2.1 Installation Overview

QIAlink requires different software components to operate. The table below presents the “macro steps” of the installation:

NOTE	Go directly to **section 4.4** if you are upgrading QIAlink 1.0 to 1.1.

Step	Action	Section
1	Proposed Folders Setup	4.2.2
2	Microsoft® SQL Server 2008 R2 Installation	4.2.3
3	Microsoft SQL Server 2008 R2 Configuration	4.2.4
4	Installation of the QIAlink Result Manager Software	4.2.5
5	Installation of QIAlink Interface Engine (aka Iguana)	4.2.6
6	Iguana login - Starting the GUI	4.2.7
7	Licensing	4.2.8
8	Iguana Channels Settings	4.2.9
9	QIAsymphony settings (required for use with QIAlink)	4.2.10
10	Patching the RGQ software for the LIMS export	4.2.11
11	Configuring the AssayManager for the LIMS export	4.2.12
12	Configuring the QMC software	4.2.13
13	Post installation activities	4.3
14	Monitor / check QIAlink operation	4.3.1
15	Backups	4.3.2
16	Logging	4.3.3

Table 4.2-1 Overview of the QIAlink installation “macro steps”.

NOTE	The procedure reflects the order required to install the different software pieces for a new installation, disregarding this order **will lead to issues!** Refer to section 4.4 if upgrading an existing QIAlink 1.0 system.

4.2.2 Proposed Folders Setup

QIAlink requires a specific IT setup of shared network drives. Usually customers won’t let anybody work alone on their network. **IT support will be required in most cases to implement a functional architecture for the file transfer required by QIAlink**.

If needed some information about this is available in section “8.3 8.3 Windows tips & tricks” of this manual.

The PC(s) operating the Rotor-Gene Q has to be able to read/write data on the QIAlink PC. For this purpose we need to define 2 network folders on the QIAlink PC that must be accessible to the RGQ PC. If both PC are in the same domain this is pretty straightforward.

On the **C:** drive of the QIAlink PC create a folder named: "**QQL_dir**" (QIAGEN QIAlink Directory).

Create 3 sub-folders:

1. **FileTransfer**: this folder stores **all files transferred via the manual transfer**, it must be setup in the QMC software.
2. **AutoTransfer**: this folder is used for the **automated file transfer via QMC**.
3. **RotorGene**: this folder must contain 2 sub-folders named as follows:
   3.1 **RQSNxxxx**: folder receiving **all results** from the **Rotor-Gene Q** with the **serial number "xxxx"**.
   3.2 **RAM-<hostname>**: folder receiving **all results** from the **AssayManager** operated Rotor-Gene Q connected to the PC named **<hostname>**.

There is no real official naming recommendation for the folders or for the PC's, very often the customers IT has the authority over PC naming, so you cannot choose it on your own. Concerning folders, the name are at the engineers option (the setup has to work) and the names must be logged in the **QIAlink Installation Check Sheet** (ICS-5000-0002).

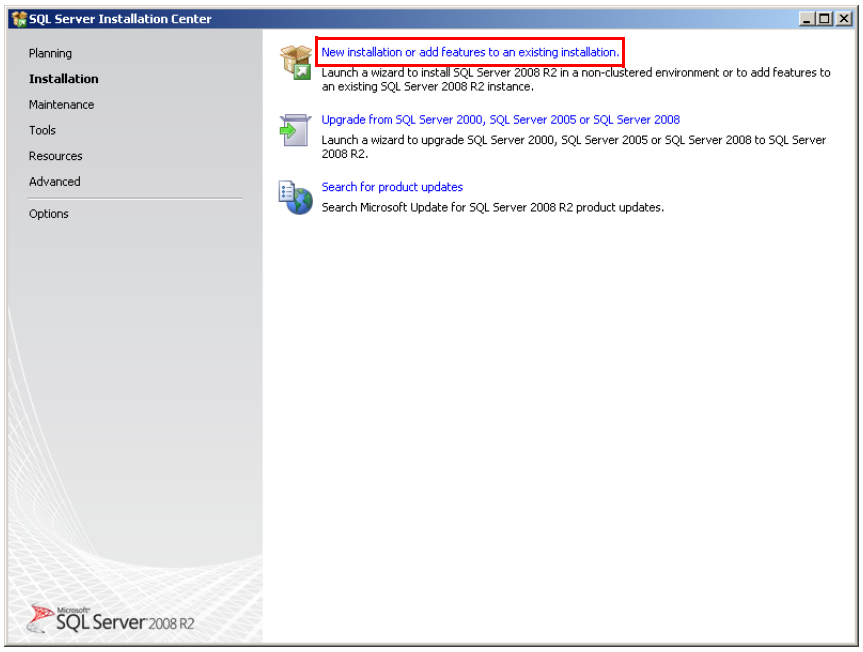
NOTE	Keep in mind that PC's in a network may not have the same host name!

4.2.3 Microsoft® SQL Server 2008 R2 Installation

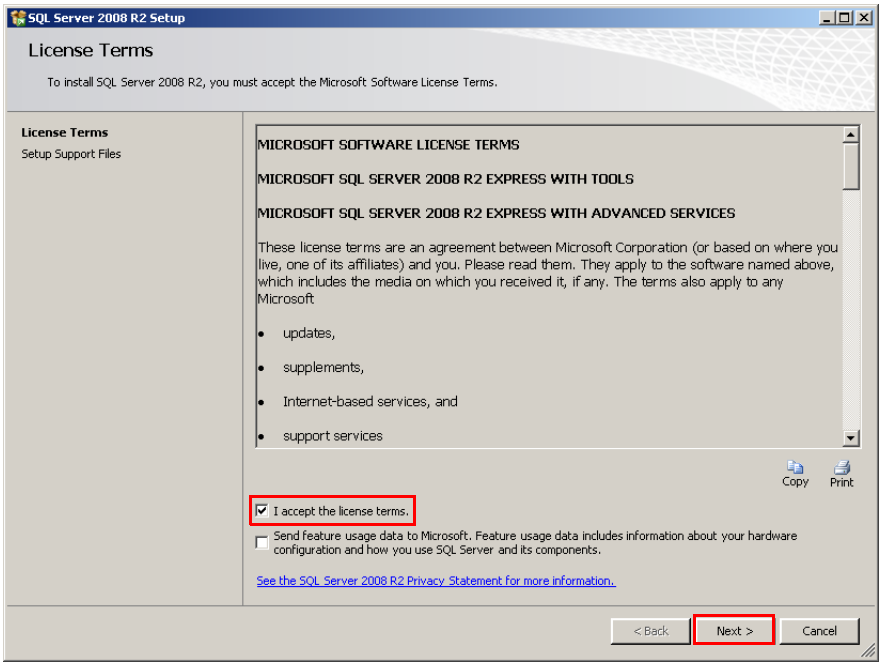
NOTE	If installing on a PC already running a SQL Server instance, go directly to section "**4.2.3.1 4.2.3.1 Installation if another SQL Server Express instance is already present on PC**"

1. Go to directory „**bin\SqlExpress2008R2**" on the QIAlink CD
2. Run "**SQLEXPR_x86_ENU.EXE**"

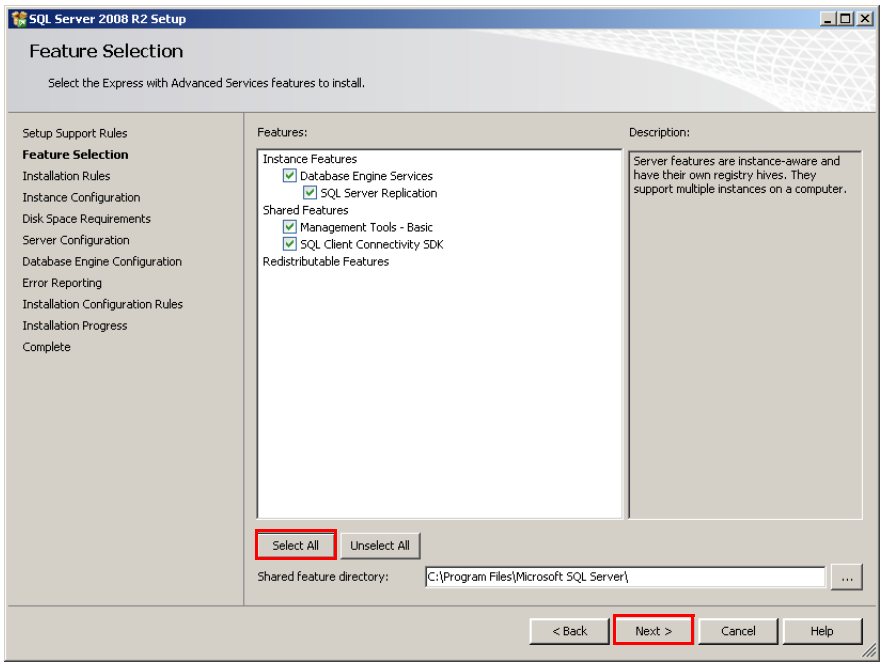
3. Click on “**New installation or add features to an existing installation**”



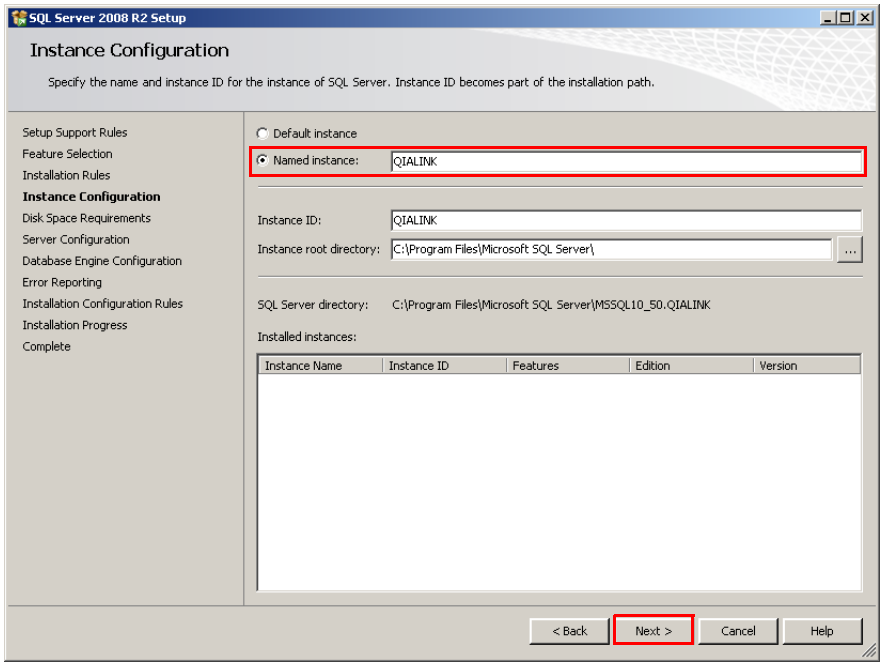
4. Accept the license terms and click “Next >”



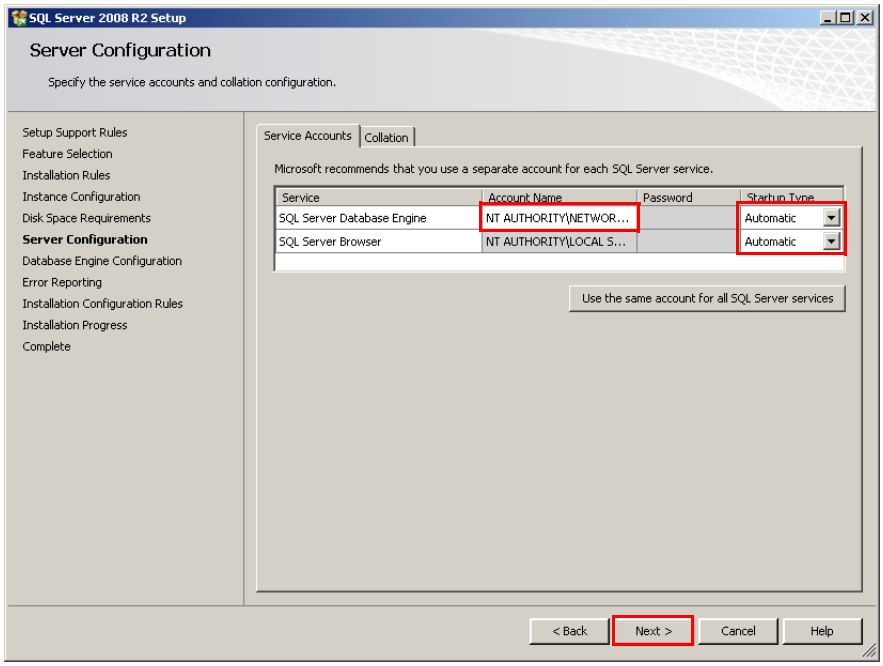
5. Click “**Select All**” and then “**Next >**”



6. Create a named instance with name “**QIALINK**” and click “**Next >**”

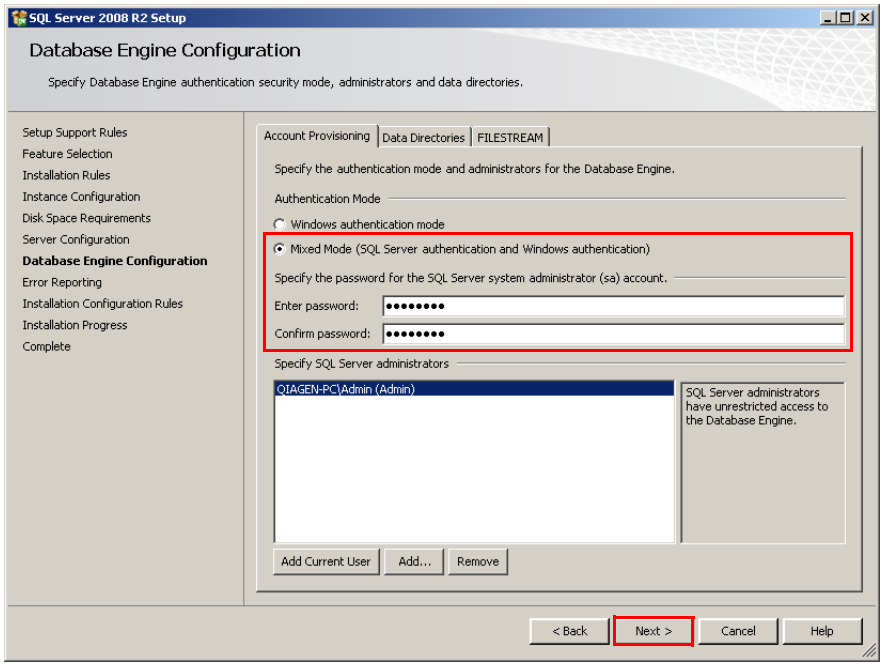


7. Set “Startup Type” for “**SQL Server Database Engine**” and “**SQL Server Browser**” to “**Automatic**”.



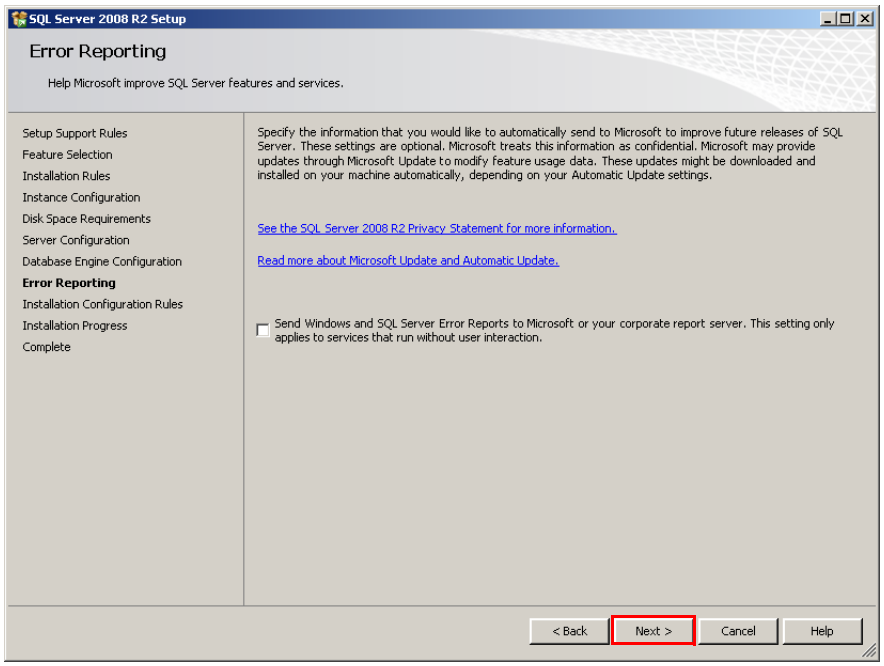
Enter an Account Name for both Services:
Male sure the account name is “**Network Service**” for the SQL Server Database Engine.
(check in the pop-up that it is set to “NT AUTHORITY\NETWORK SERVICE”).
Keep the **default** for the SQL Server Browser. Click “**Next >**”

8. Choose “**Mixed Mode**” authentication. Enter and confirm the administrator password and click “**Next >**”.

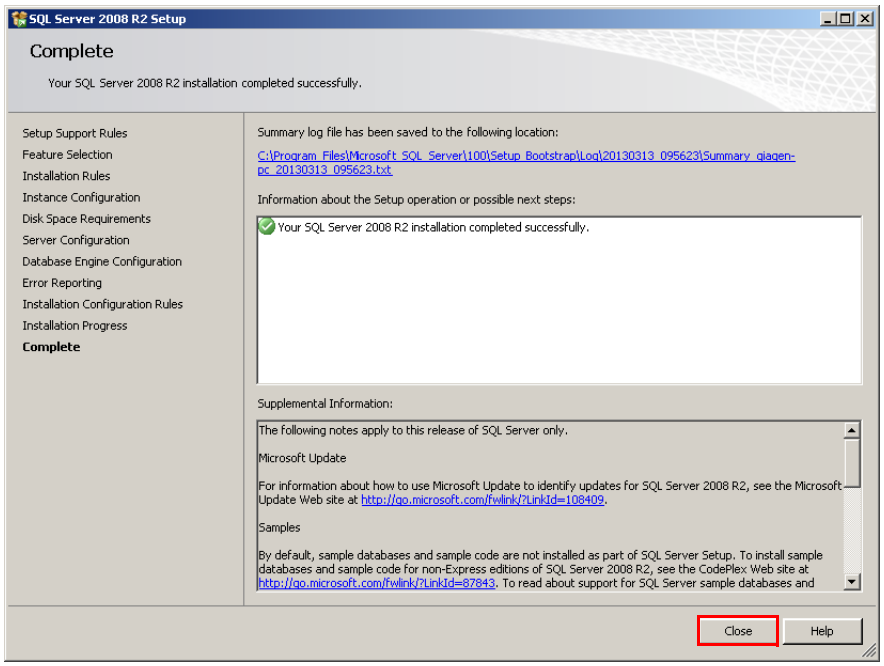


INFORMATION	During this step the SQL Server Administrator password **is set to**: **QIAsqlserv2013** This password will be required during the installation of the QIAlink Result Manager!

9. Click “**Next >**”



10. The SQL Server instance is installed.



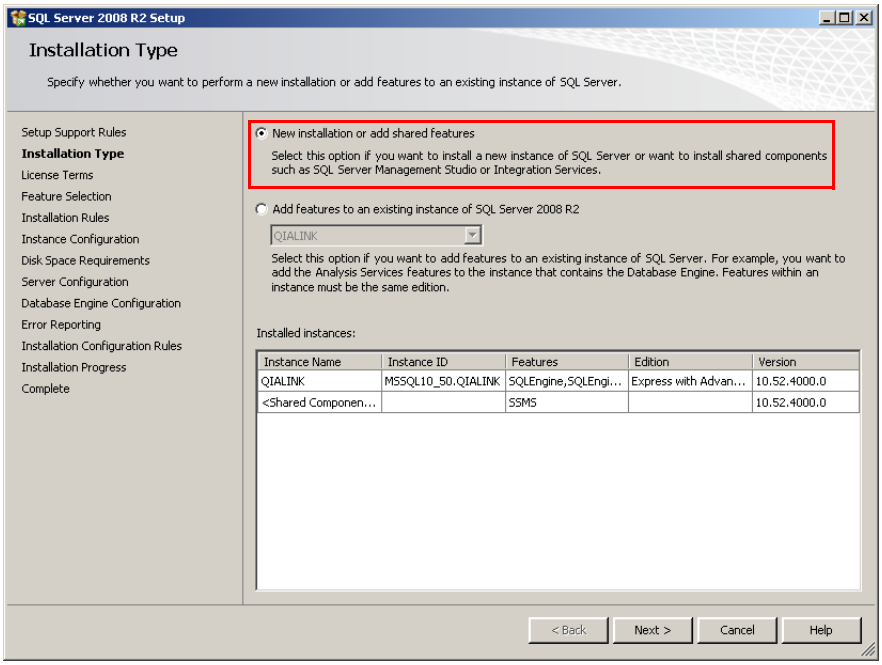
11. Click “**Close**” to leave the installation wizard.

NOTE	In some cases you will need to install **a second SQL server instance** (i.e. the QIAlink PC from the customer already uses a SQL Server instance). To learn how to do it refer to **section 4.2.3.1**.

4.2.3.1 Installation if another SQL Server Express instance is already present on PC

In some cases you will need to install a second SQL server instance (i.e. the QIAlink PC from the customer already uses a SQL Server instance).

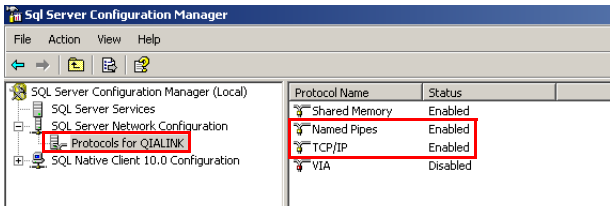
1. To do so follow step 1 - 3 from “4.2.3 Microsoft® SQL Server 2008 R2 Installation”, select “**New installation or add shared features**”:



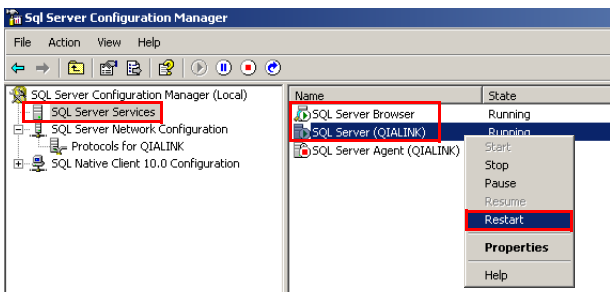
2. Then simply follow steps 4 - 15 from “4.2.3 Microsoft® SQL Server 2008 R2 Installation”, and **make sure to use an unique different name for the new instance**.

4.2.4 Microsoft SQL Server 2008 R2 Configuration

1. Go to: “**All Programs\Microsoft SQL Server 2008 R2\Configuration Tools\SQL Server Configuration Manager**”.
2. Go to “S**QL Server Network Configuration\Protocols for QIALINK**” and enable “**Named Pipes and TCP/IP**” by right clicking and choosing “**Enable**”



3. Go to page “**SQL Server Services**” and restart “**SQL Server Browser**” and “**SQL Server (QIALINK)**” by right-clicking and choosing “**Restart**”

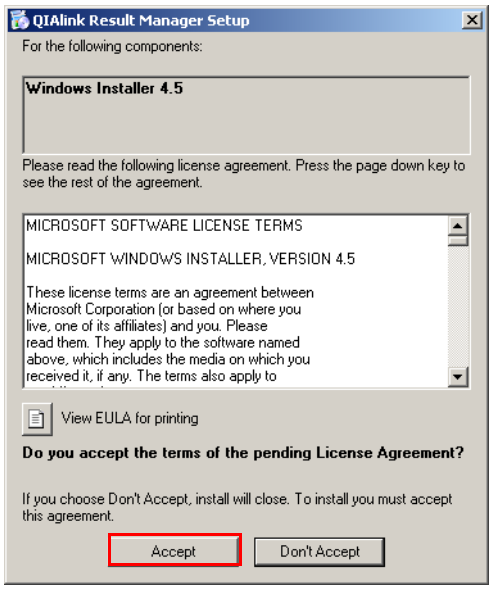


4.2.5 Installation of the QIAlink Result Manager Software

NOTE	If upgrading from QIAlink 1.0 to 1.1 refer to chapter **4.4 Upgrading QIAlink 1.0 to QIAlink 1.1.**

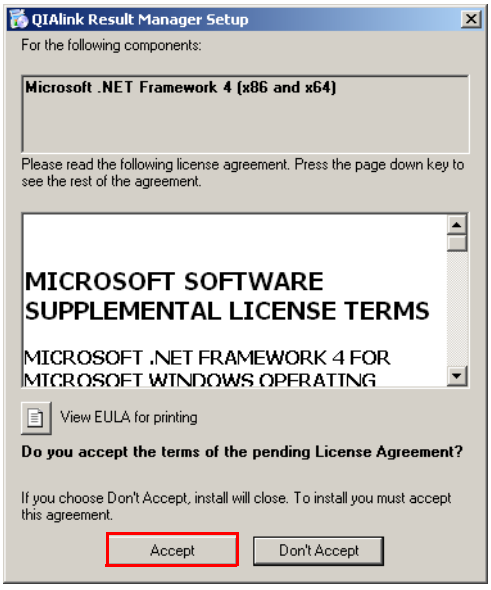
To start the installation of the QIAlink Result Manager, proceed as follows:

1. Insert the **QIAlink Software CD** into the CD drive.
2. Got to the folder "**QIAlink Result Manager**".
3. Double click "**setup.exe**" and follow these steps.
4. Click "**Accept**" to accept the license agreement for the Microsoft Windows Installer 4.5



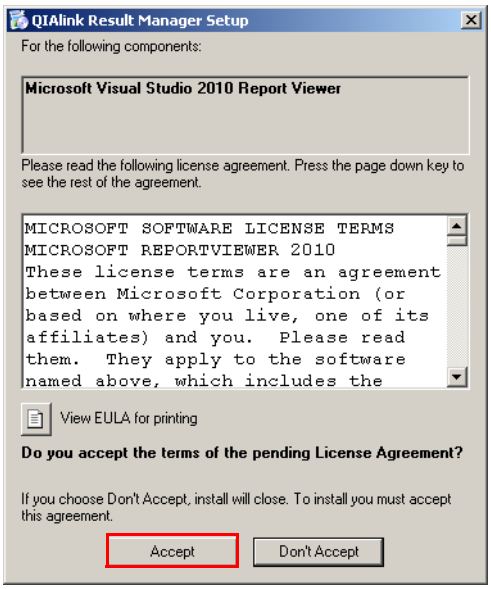
NOTE	This screen is not displayed if Microsoft Windows Installer 4.5 (or higher) is already installed.

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



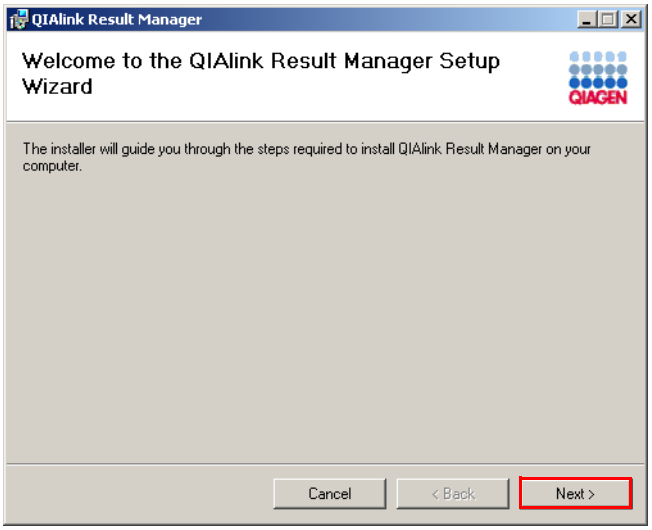
NOTE	This screen is not displayed if Microsoft .NET Framework 4 is already installed.

6. Click “**Accept**” to accept the license agreement for the Microsoft Visual Studio® 2010 Report Viewer.



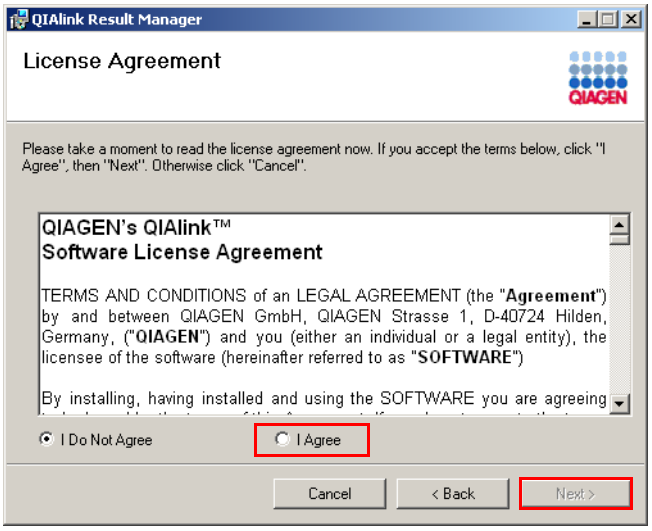
NOTE	This screen is not displayed if Microsoft Visual Studio 2010 Report Viewer is already installed.

7. Depending on which elements needed to be installed a pop-up recommending to restart the PC will be displayed, if so reboot the PC. After reboot the welcome screen of the QIAlink Result Manager Setup Wizard opens.

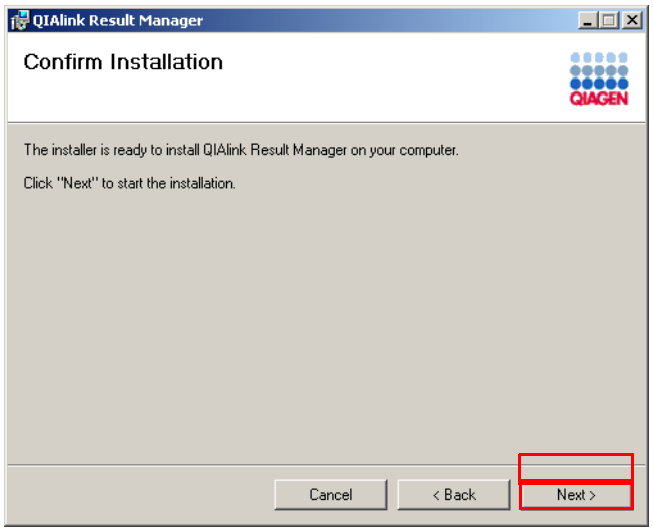


8. Click “**Next >**” to proceed.

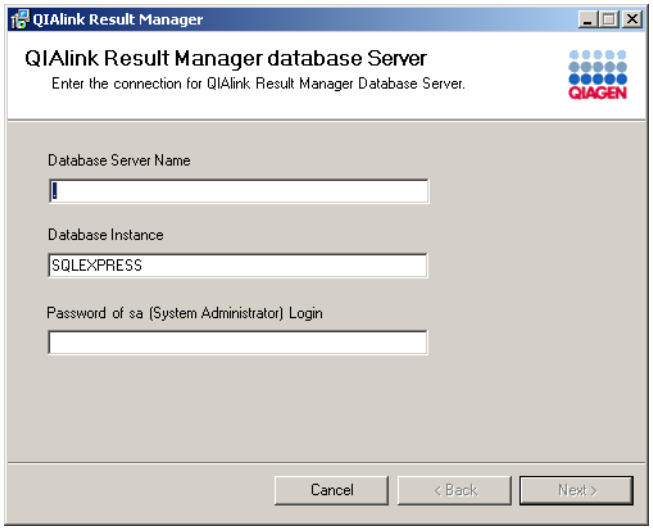
9. Accept the license agreement of QIAlink Result Manager by selecting “**I Agree**”, then click “**Next >**”.



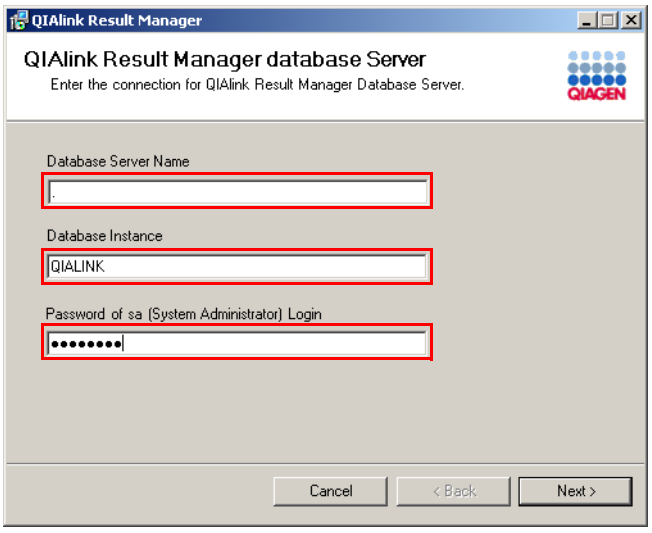
10. Click “**Next >**” on the Confirm Installation screen to start the installation.



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

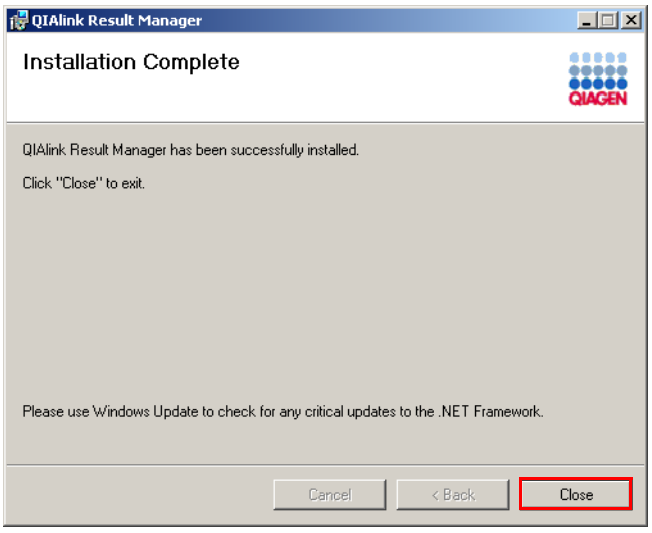


12. Enter the required information in the dialog fields as follows:



INFORMATION	The **SQL Server Administrator password** is required at this stage. It has been defined during the installation of the QIAlink SQL Server instance (see 4.2.3, step 8) and should be: **QIAsqlserv2013**

13. "**Database Server Name**"
    13.1 Enter "**.**", if the database is located on this computer.
    13.2 Enter the IP address of the database server if the database is located on a remote server.
14. "**Database Instance**"
    14.1 Enter the name of the database instance (e.g. "**QIALINK**").
15. "**Password of sa (System Administrator) Login**"
    15.1 Enter the Administrator password for the SQL Server or SQL Server Express database.
16. Click "**Next >**".
17. After a successful installation, the "**Installation Complete**" screen is displayed.

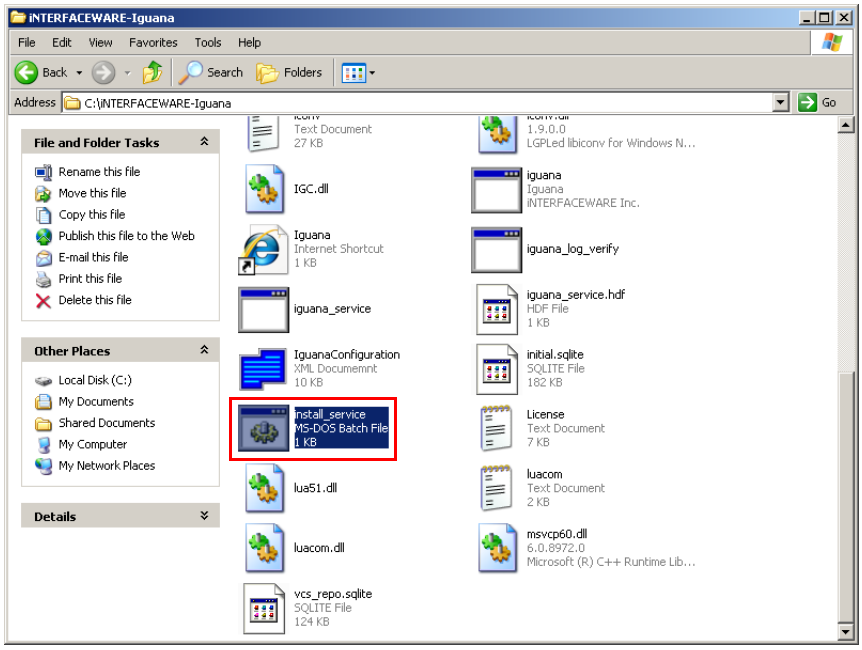


18. Click "**Close**" to exit the setup.
19. QIAlink Result Manager is now ready to be configured.

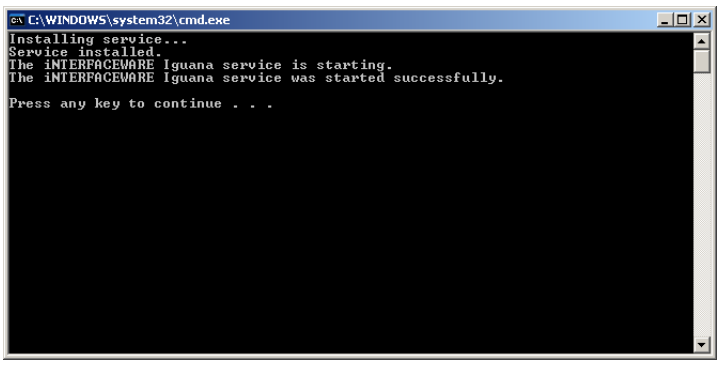
4.2.6 Installation of QIAlink Interface Engine (aka Iguana)

NOTE	If upgrading from QIAlink 1.0 to 1.1 refer to chapter **4.4 Upgrading QIAlink 1.0 to QIAlink 1.1.**

1. Copy the "**iNTERFACEWARE-Iguana**" directory into the "**QQL_dir**" (see 4.2.2).
   The "iNTERFACEWARE-Iguana" directory is located in the "**QIAlink Interface Engine**" folder of the QIAlink CD.



2. Double-click the batch file named "**install_service.bat**"



3. Press any key to close the shell window.

4.2.7 Iguana login - Starting the GUI

All interactions of the user with Iguana occur through a web GUI. To start the GUI:

Open your browser and type in the following address:

- **http://localhost:6543/**

  OR if not logging in on the machine running Iguana:

  http://xxx.xxx.xxx.xxx:6543/, where xxx.xxx.xxx.xxx is the IP address of the QIAlink / Iguana computer.

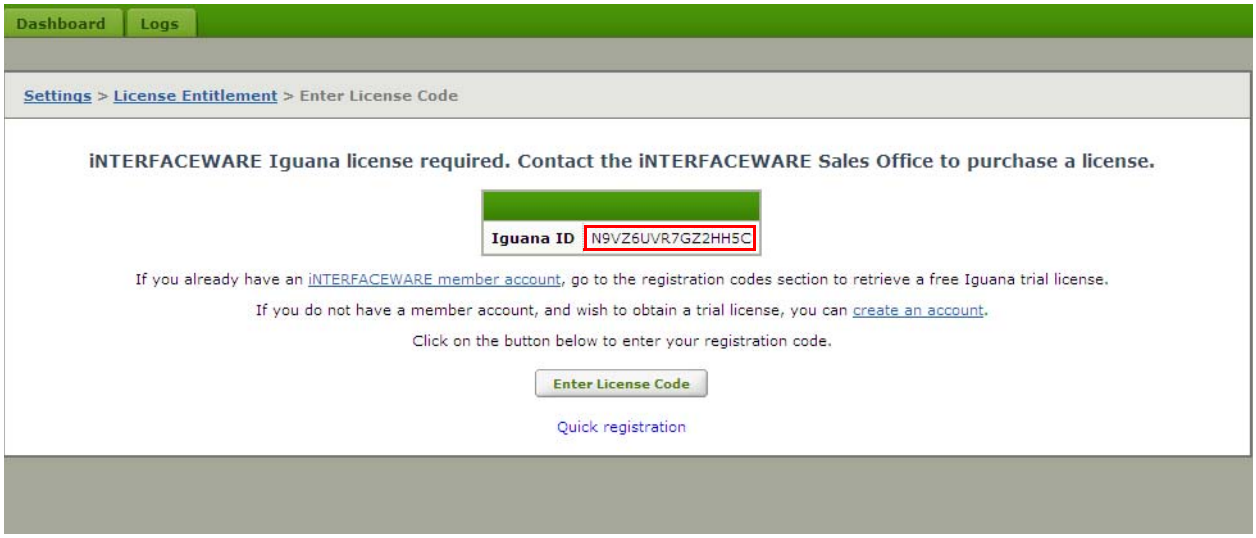
The Iguana GUI will open and the following login window will appear:

1. The login credentials for QIAGEN service are:

INFORMATION	User name: admin Password: QIAserv2013 These credentials are strictly for QIAGEN use and may never be communicated to customers.

4.2.8 Licensing

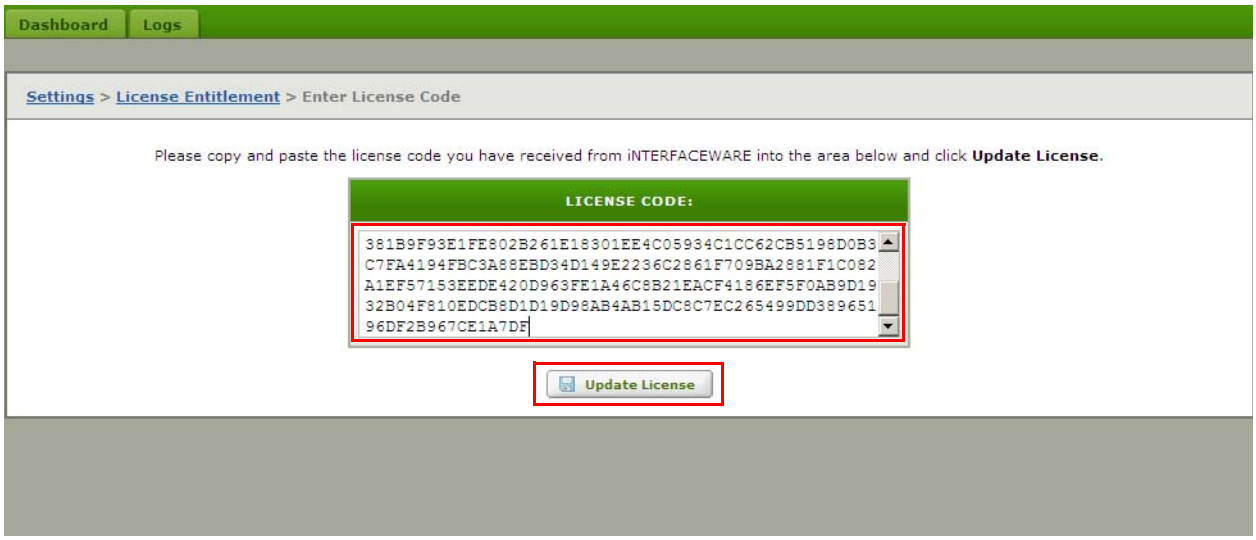
1. In Iguana go to Settings\License Entitlement\Enter License Code



2. The screen above will be displayed. Copy the Iguana ID and send it to your dispatch:

Region	Email
EMEA	dispatch-eu@qiagen.com
NA	AASteam-na@qiagen.com
APAC/Japan	GAsiaPacBackOfficeFieldService1@qiagen.com

3. Once you have received the answer containing the license code from the dispatch, copy the code and paste it into the designated area in the Iguana settings.



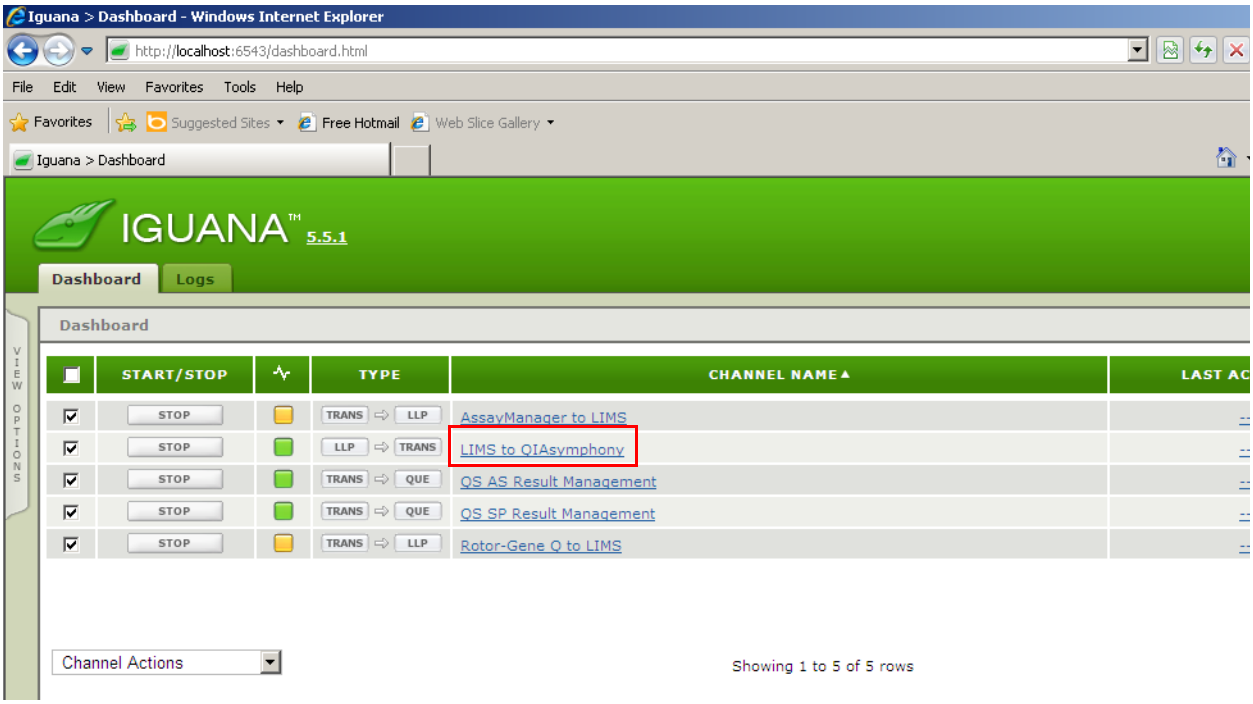
4. Iguana can now be configured.

4.2.9 Iguana Channels Settings

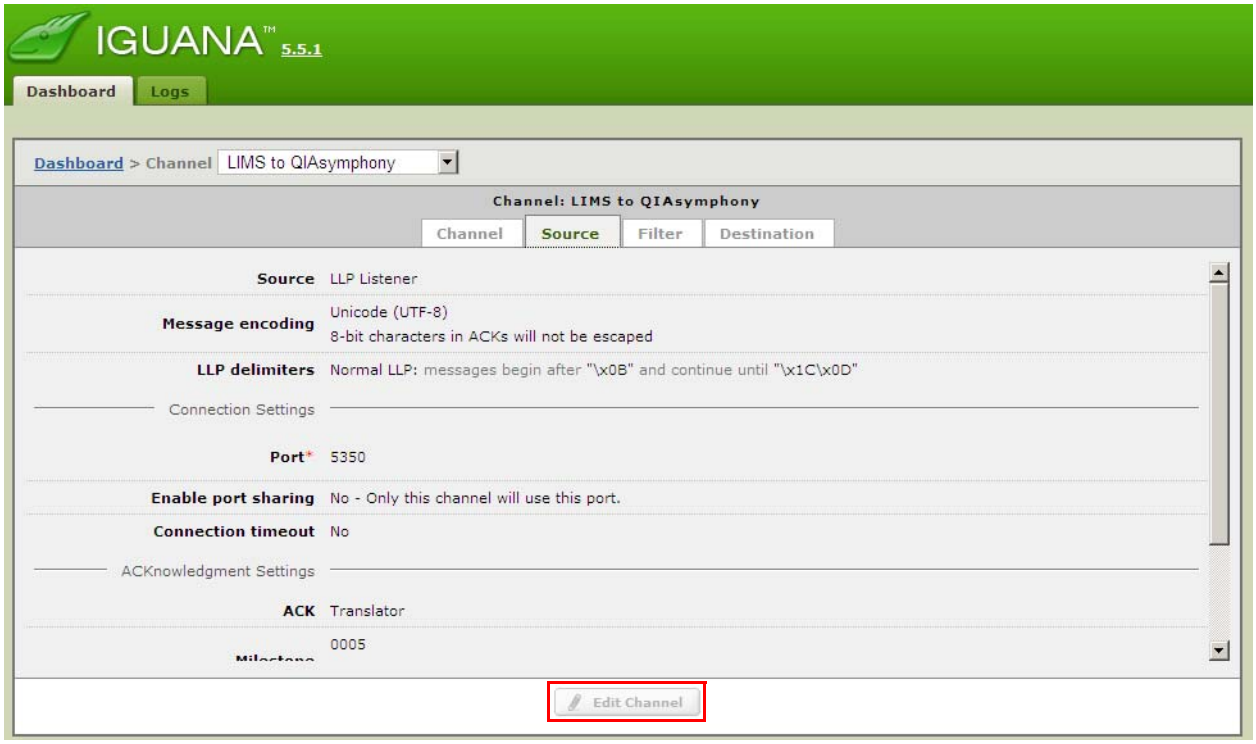
NOTE	Before channel settings can be edited the concerned channel has to be stopped. Usually all channels are stopped when first starting the Iguana GUI after installing.

Some Iguana settings have to be made during the installation. These settings are first the I/O ports to use for the incoming/outgoing HL7 messages from/to the LIMS as well as the machine name/IP address of the LIMS computer. Usually only the LabAdmin / Supervisor needs to change the channel configuration if the IP address and/or ports used by the LIMS are changed.

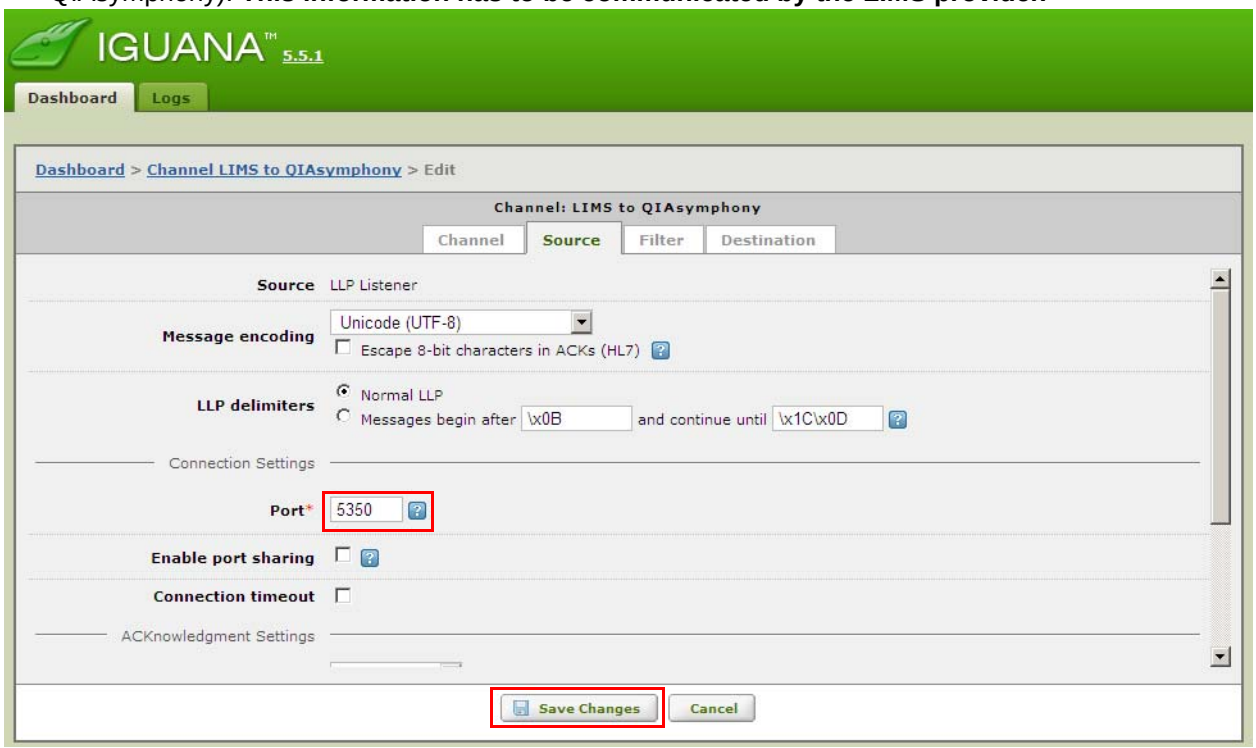
4.2.9.1 Source Tab: Iguana I-port



1. Usually all channels are stopped when first starting the Iguana GUI.
2. Click on the channel you want to configure in the “**Channel Name**” column.



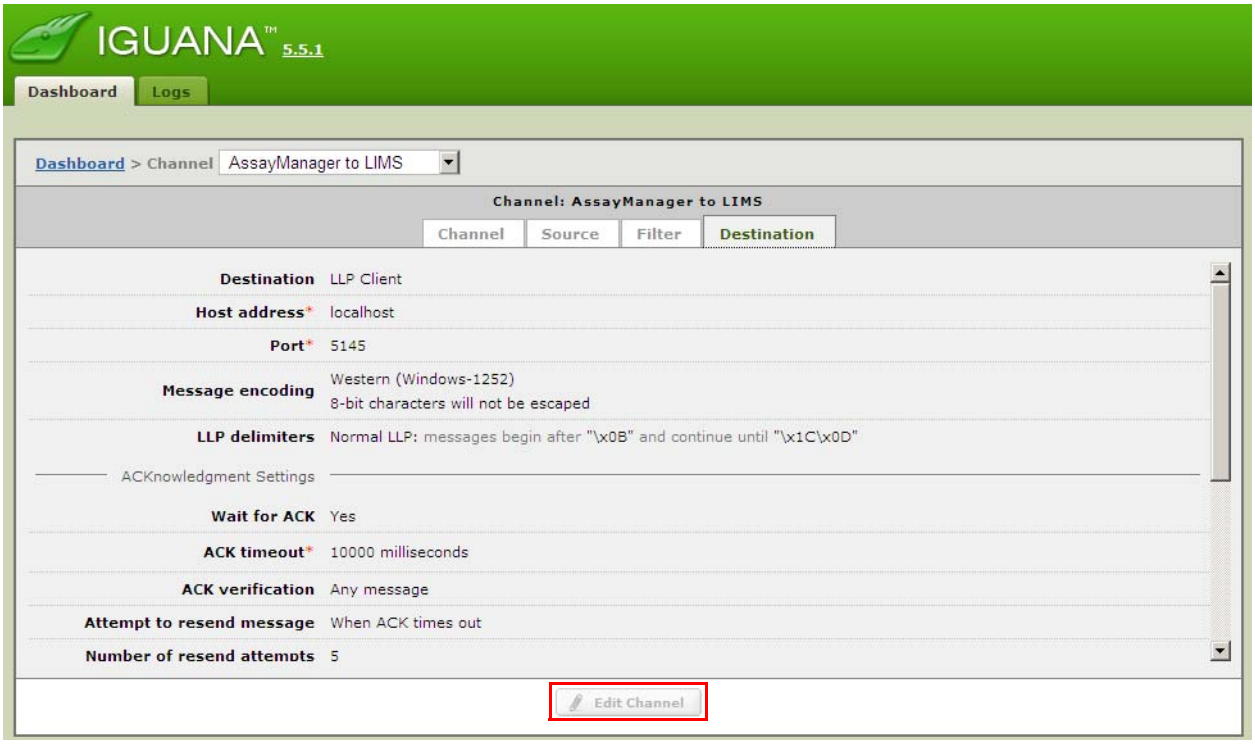
3. Move to the “**Source”** tab and click the “**Edit Channel**” button to activate the fields.
4. Enter the port number to use for the incoming messages (messages coming from the LIMS to the QIAsymphony). **This information has to be communicated by the LIMS provider.**



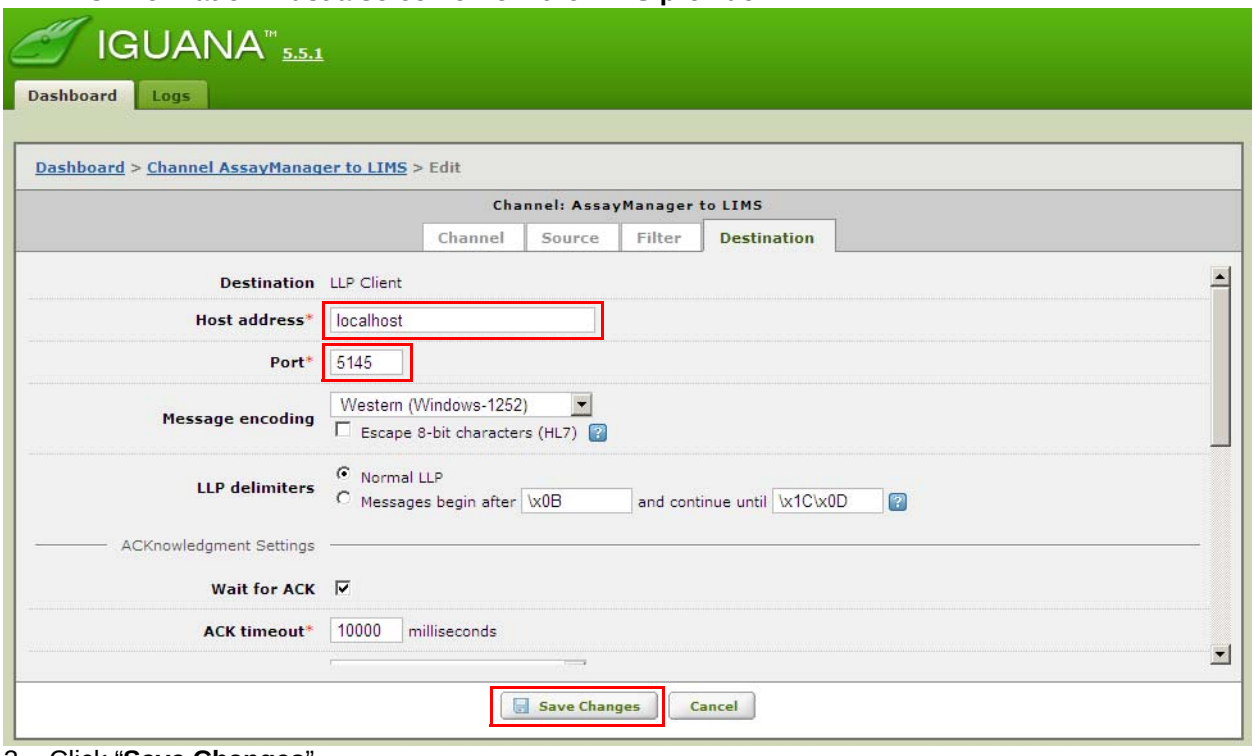
5. Click “**Save Changes**”.
6. **Log this information** in the adequate field of the “QIAlink Installation Check Sheet” (ICS-5000-0002).

4.2.9.2 Destination tab: O-port and IP address of the LIMS server

1. Proceed similarly for the output port (port to use for outgoing messages, RGQ/AssayManager to LIMS).



2. Enter the "**Host address**": this is the machine name or IP address of the LIMS computer. **This information must also come from the LIMS provider.**

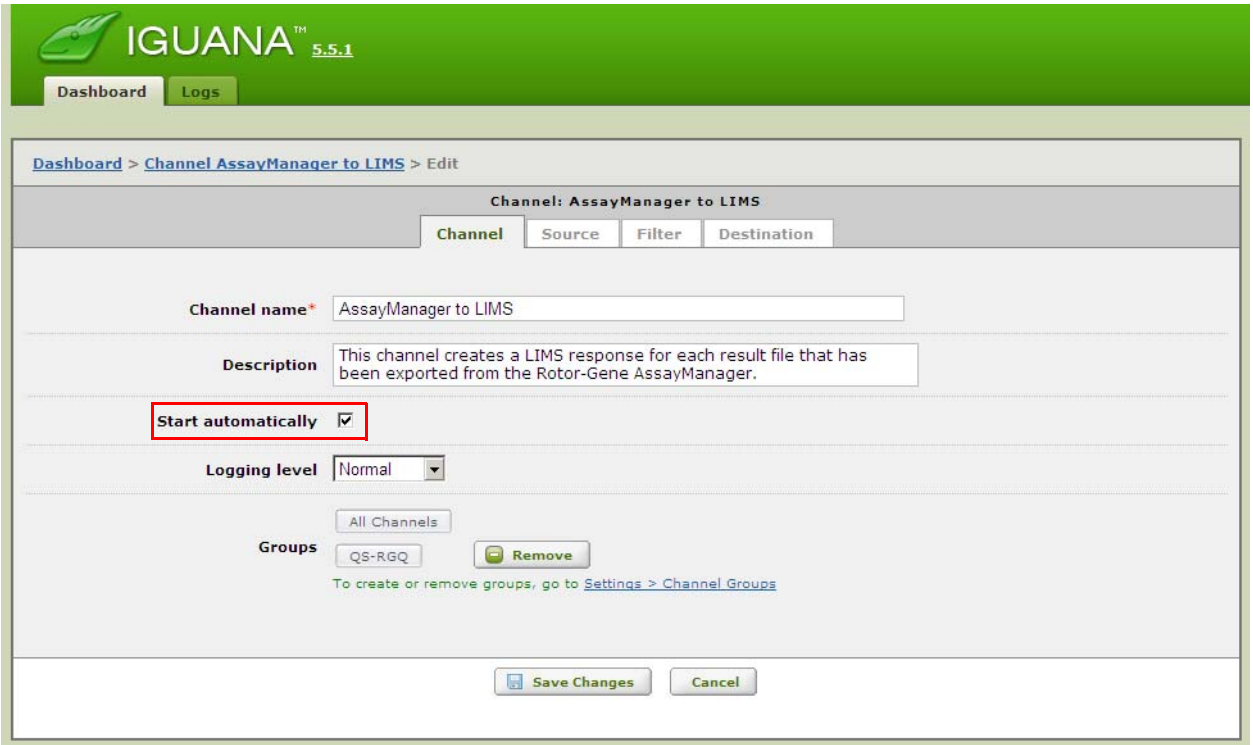


3. Click "**Save Changes**".
4. **Log this information** in the adequate field of the "QIAlink Installation Check Sheet" (ICS-5000-0002).

4.2.9.3 Channels autostart

1. In the channels settings click on the "**Channel**" tab and make sure the "**Start automatically**" check box is checked. This will start automatically the services on system startup. Make sure **all used channel** are

set to start automatically.

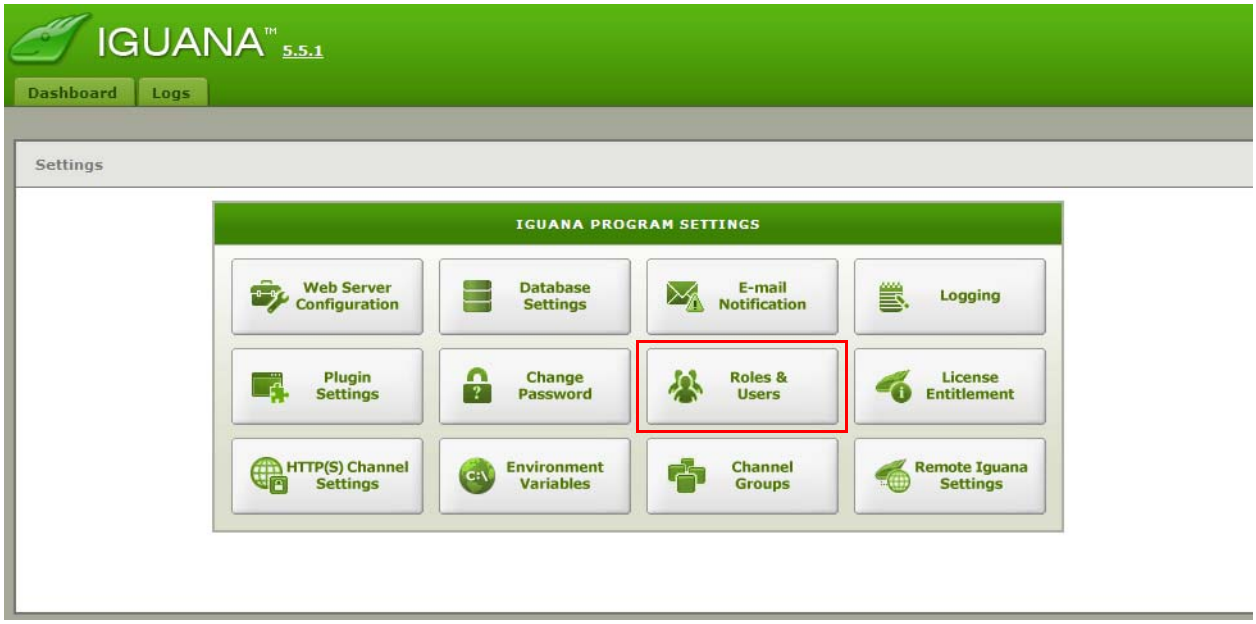


4.2.9.4 Setting up user accounts in Iguana

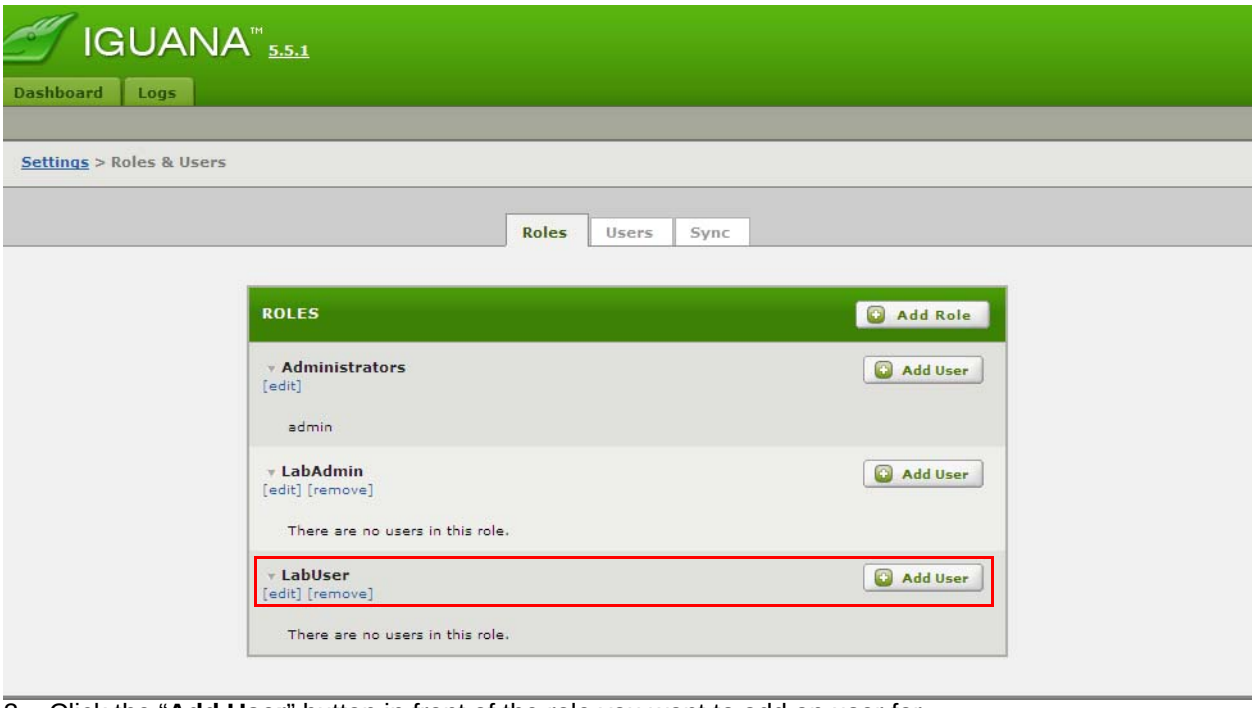
The following steps are an integral part of the installation, make sure to receive the customer's input concerning the accounts they want to have activated in Iguana web GUI.

To setup user accounts proceed as follows:

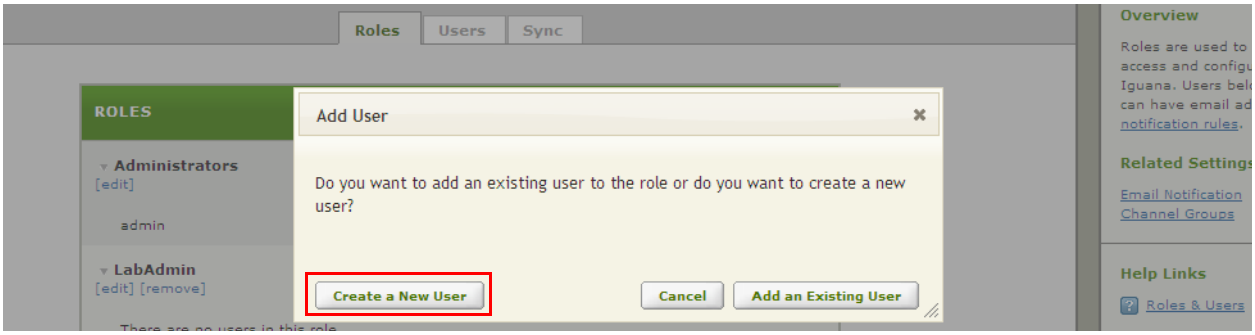
1. Click on the "**Settings**" tab.



2. Click “**Roles & Users**”.

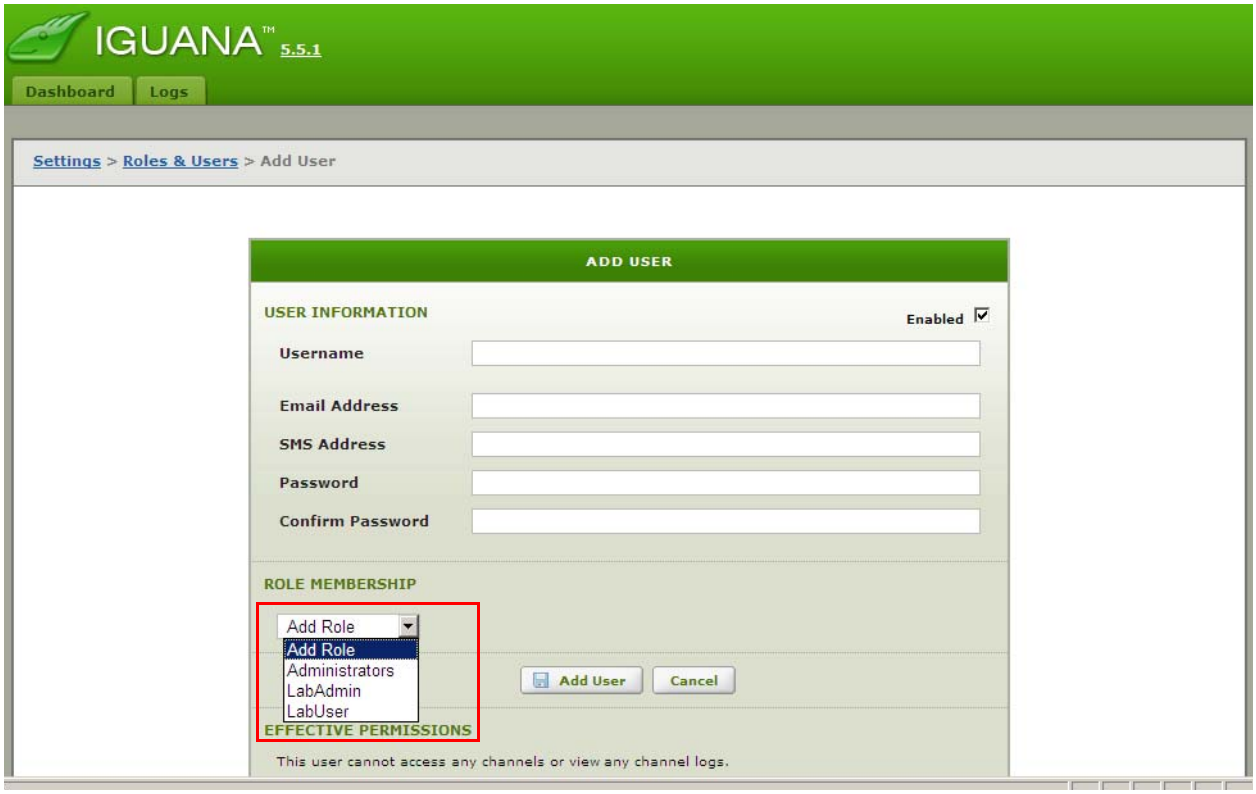


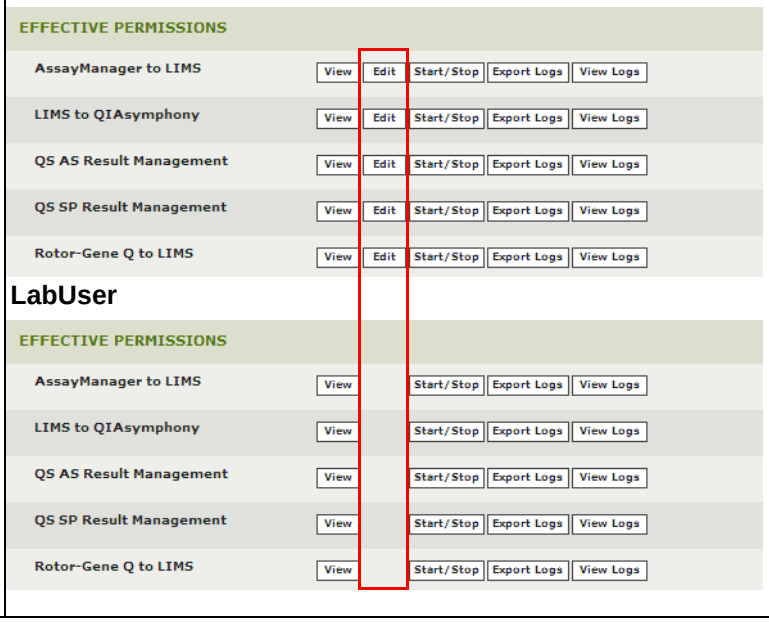
3. Click the “**Add User**” button in front of the role you want to add an user for.



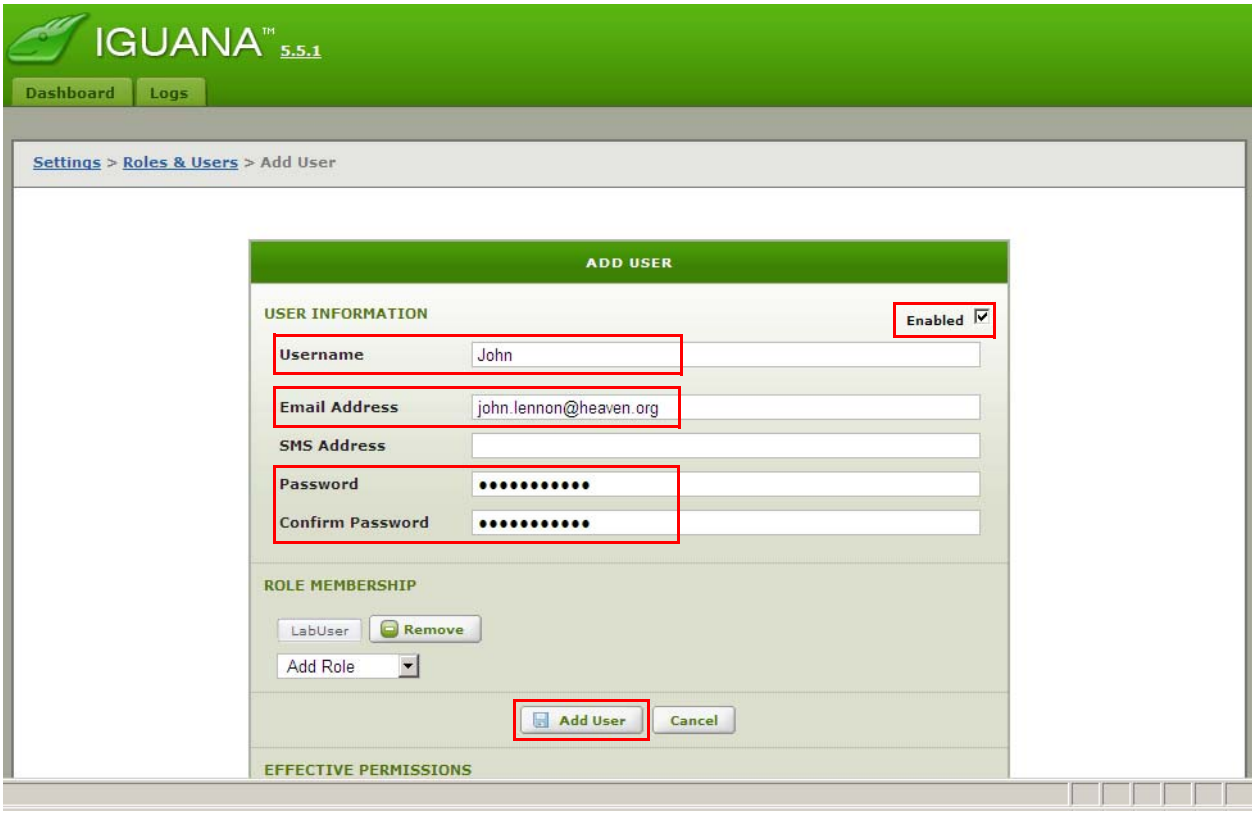
4. Choose “**Create a New User**”.

5. Once the mask below is displayed, choose a role for the new user (i.e. LabUser).

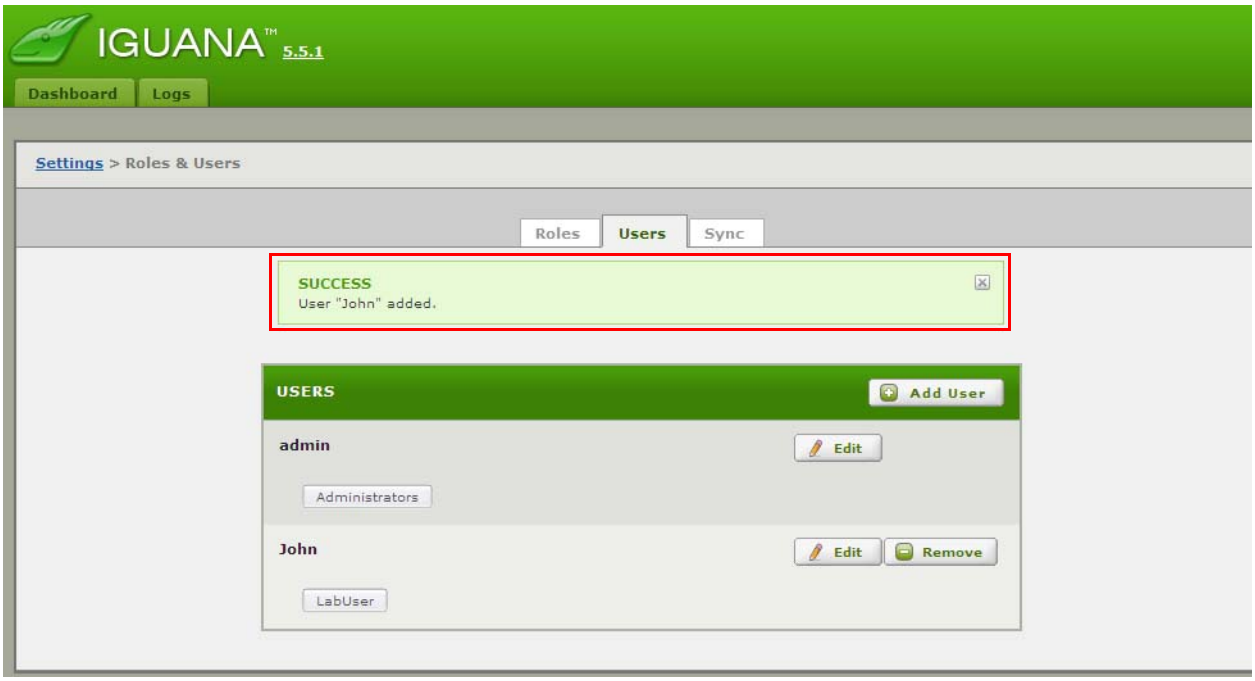


NOTE	The **LabAdmin** and **LabUser** roles only have one main difference: - the LabAdmin can edit parameters whereas the LabUser can only view them. Whenever creating accounts the effective permissions are displayed at the bottom of the window. **LabAdmin**  **LabUser**

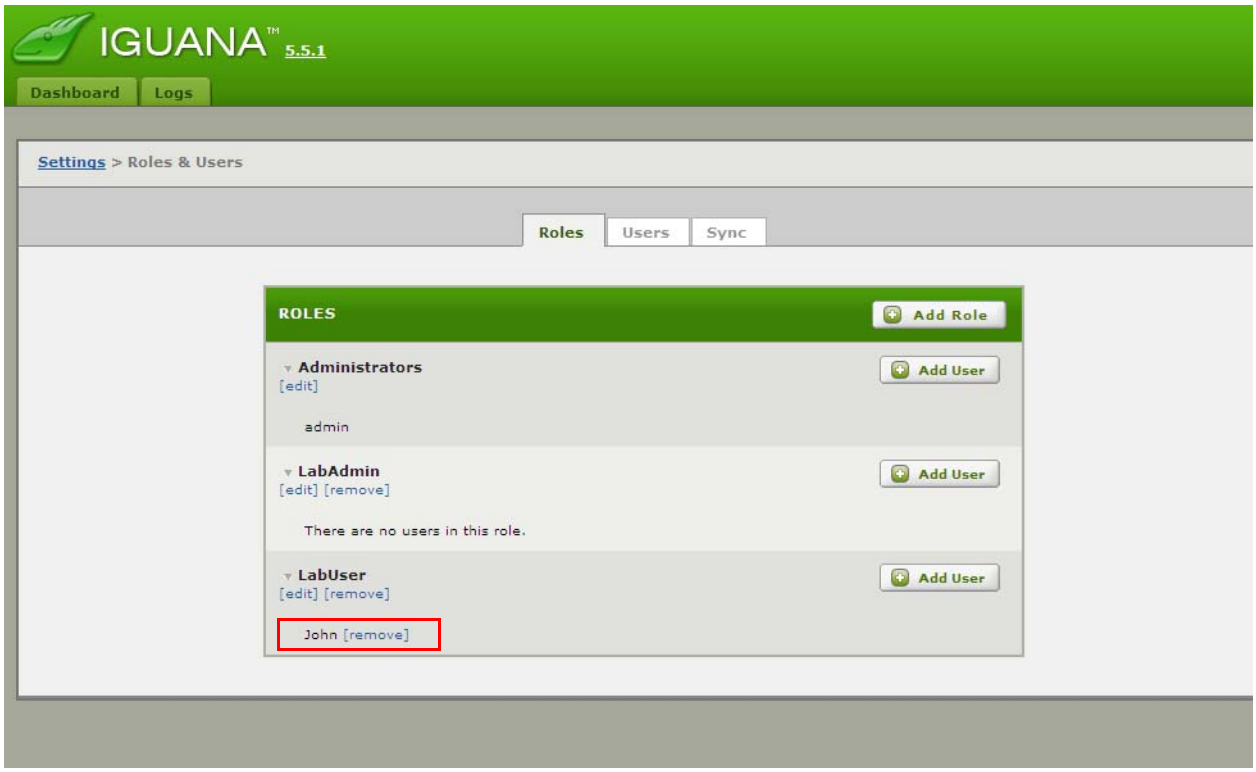
6. Fill in the required information according to the inputs of the customer and make sure the user is enabled.



7. Click the "**Add User**" button, Iguana should report that the user has been added successfully.



8. If you go back to the “Roles” the display now should look like this:



4.2.10 QIAsymphony settings (required for use with QIAlink)

The user with the “Supervisor” user 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 the QIAsymphony user documentation.

4.2.10.1 Configuration / General process

1. **Number of days for which a work list is valid?**
   This setting should be “5”: Setting this value to “5” ensures that the work list will expire after 5 days. After expiration, the work list will automatically be deleted from the QIAsymphony instrument. Manual deletion of work lists is not required.

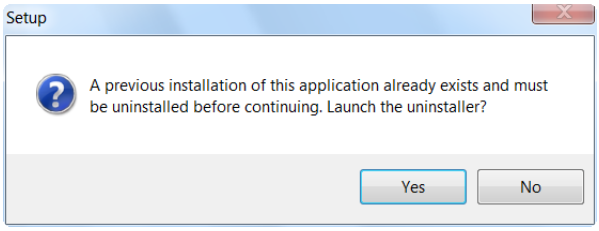
4.2.10.2 Configuration/Process SP3

1. **Write start batch confirmation files?**
   Yes, This setting activates sending of a start batch confirmation after start of the SP process.
2. **Allow partial use of work lists?**
   Yes, It is possible to use the work list and to process the batch even if there are samples defined in the work list, but not present. Entries for missing samples will be ignored.

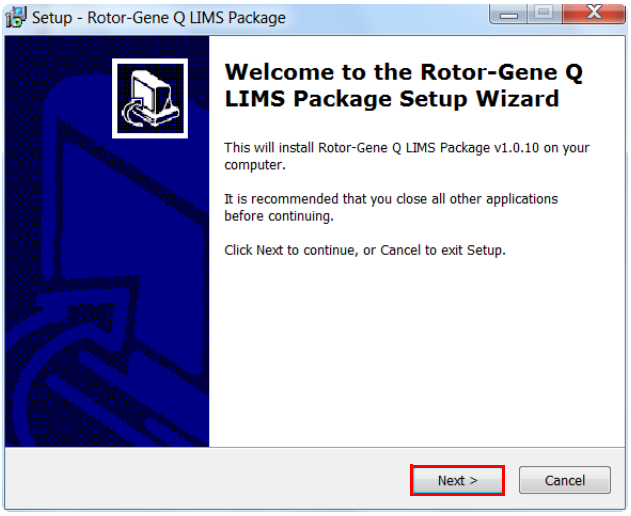
4.2.11 Patching the RGQ software for the LIMS export

The Rotor-Gene Q software has to be patched before it can generate a LIMS export file. Patch all Rotor-Gene Q software used in combination with QIAlink.

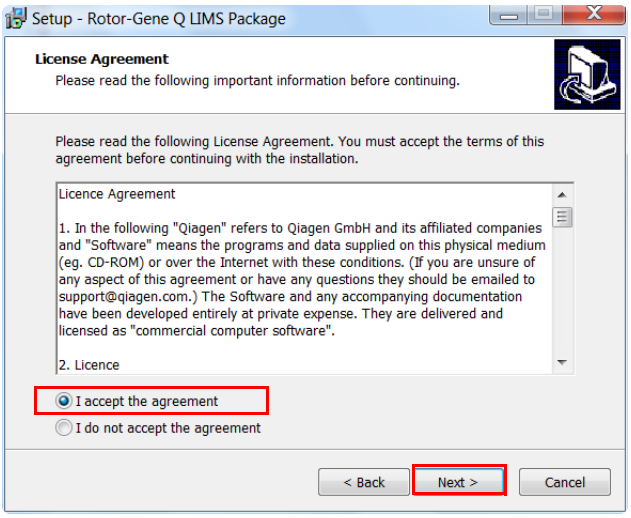
1. In the folder named “**Rotor-Gene Q LIMS Export**” locate and double-click the installer named “**Rotor-Gene_LIMS_Package_v1.0.10**”.
2. If a previous installation of the patch exists, the following message is displayed:



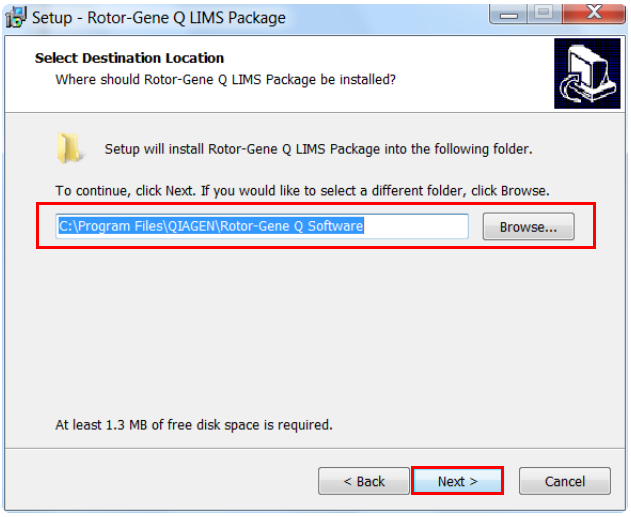
3. **Uninstall** any previously installed patch by clicking “**Yes**” before going on with the installation.



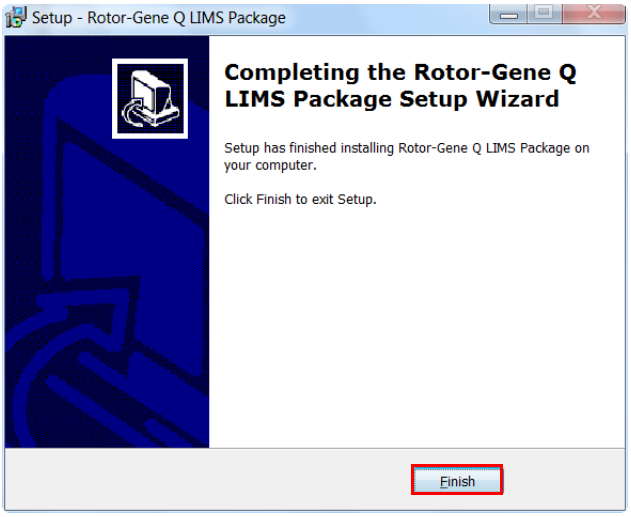
4. Click “**Next >**”.



5. Choose “**I accept the agreement**” and click “**Next >**”.



6. Confirm the path, make sure this is the path to the RG-Q software!

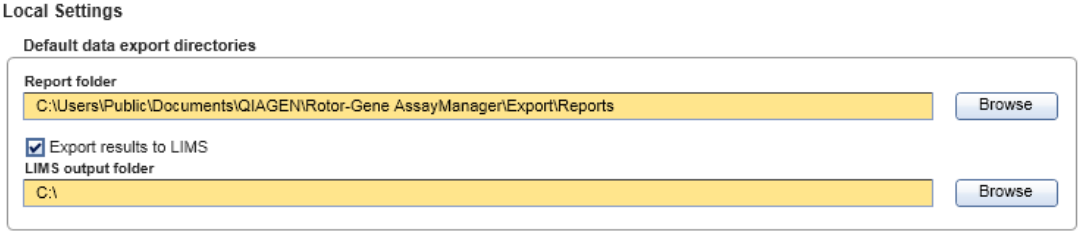


7. Click “**Finish**” to close the installer.

4.2.12 Configuring the AssayManager for the LIMS export

QIAlink software supports version 1.0 of the Rotor-Gene AssayManager but the “Export results to LIMS” feature is disabled by default.

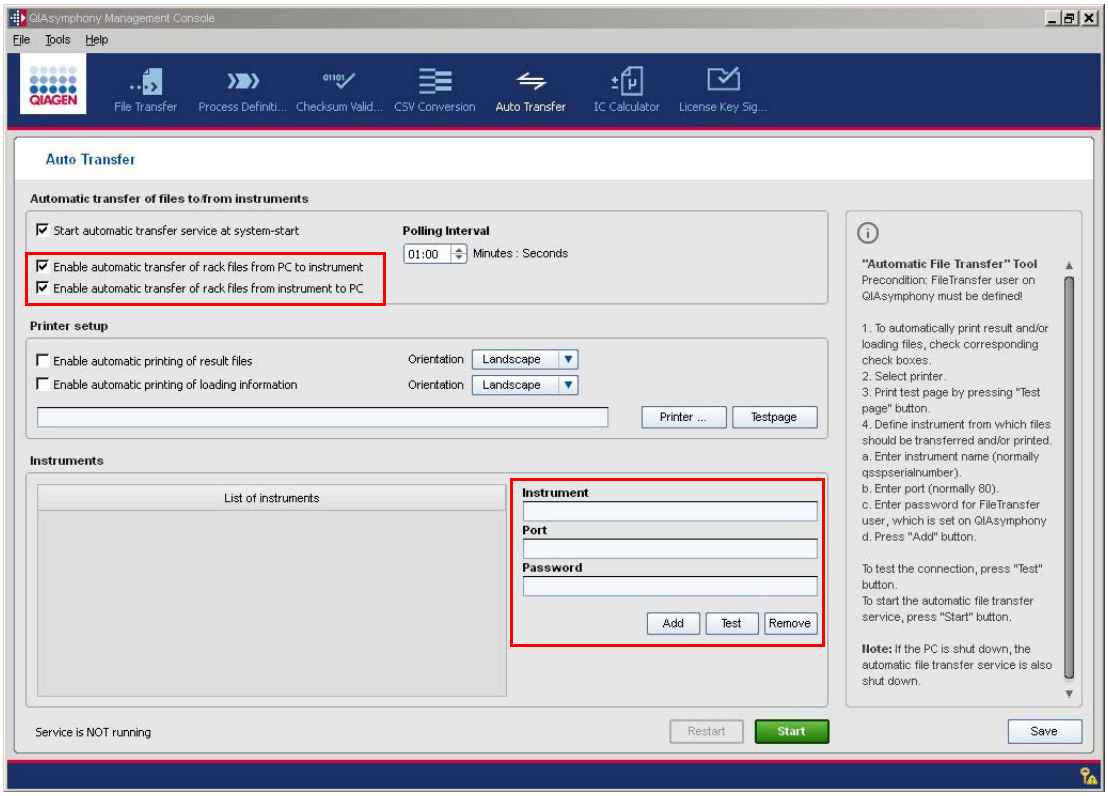
To activate the export of the Rotor-Gene AssayManager results to the LIMS, the option “Export results to LIMS” must be activated in the Rotor-Gene AssayManager Settings. For details, refer to the Rotor-Gene AssayManager user documentation.



Configure the QIAlink Results folder to the same directory as the LIMS output folder in the Rotor-Gene AssayManager Settings. If this check box is activated, results released in the “Approval” environment are exported in a LIMS compatible file to the specified directory. QIAlink must be configured in a way that it searches for new files in the same directory as specified here.

4.2.13 Configuring the QMC software

In the QMC software make sure that the autotransfer is configured correctly and that the service is started.



See also the QIAsymphony Management Console user documentation for detailed information about the configuration of the “auto transfer” feature.

4.3 Post installation activities

NOTE	During the function check of QIAlink you might need support from a lab operator, the IT and the LIMS provider in some cases!

4.3.1 Monitor / check QIAlink operation

- Monitor the incoming LIMS messages and control correct QIAlink behaviour / treatment of the messages from the LIMS.
- Check that work lists are generated and forwarded to all QIAsymphony connected via QMC.
- Check that work lists contain the correct ACS/APS with the operator.
- Check that results are sent back to the LIMS (RGQ and RGAM) using a fake RGQ results file (csv). (make up a csv file manually containing the sample ID’s used in the LIMS order to report results).

- Check that the results are recognized (shouldn't be an issue, we respect HL7 norm) if they aren't recognized check on both the LIMS and the QIAlink side that the messages are in specification and that they are sent into the correct folders.
- Check with the customer that the results are reported in the correct format (copies/ml, IU/ml, ...).
- Discuss the possibilities with customer's IT and/or LIMS provider, and setup scheduled virus scan to minimize impact on QIAlink (lower activity, night?). This is going to be different from customer to customer and has to be addressed.
- The release recommendation QIAlink recommends not to run the antivirus together with QIAlink! Hint: discuss the use a scheduled Windows task with IT, the task should turn the Iguana service OFF, trigger the virus scan, and re start the Iguana service optimally during idle time / maintenance of the LIMS.

4.3.2 Backups

- Backup the Iguana files: **see 8.1.3**.
- Backup the QIAlink Result Manager configuration (see User Manual, chapter 6.5.7 Export).

4.3.3 Logging

Fill in the "**QIAlink Installation Check Sheet**" (ICS-5000-0002) completely.

4.3.4 Finalize the installation

1. Train the customer(s) (according to chapter 7) and fill in the "**Customer Training Checklist**" (CTC-5000-0002).
2. Upload the "**QIAlink Installation Check Sheet**" and the "**Customer Training Checklist**" as attachment to the CRM Installation SI.

4.4 Upgrading QIAlink 1.0 to QIAlink 1.1

4.4.1 Upgrade class

The upgrade policy for this upgrade is "*Class II - Active*".
This upgrade must be implemented during the next service visit.

4.4.2 Requirements

The upgrade requires **both the original QIAlink 1.0 CD (or installer) and the new QIAlink 1.1 CD**.

NOTE	The upgrade procedure has been optimised to reduce the time lines, and to mitigate some known migration issues related to cross compatibility issues of QIAlink 1.0 and QIAlink 1.1. **Follow this procedure step wise if upgrading from QIAlink 1.0 to QIAlink 1.1.**

See **chapter 6 Troubleshooting** for details about "Known issues" (section 6.3 Known Issues).

4.4.3 Procedure

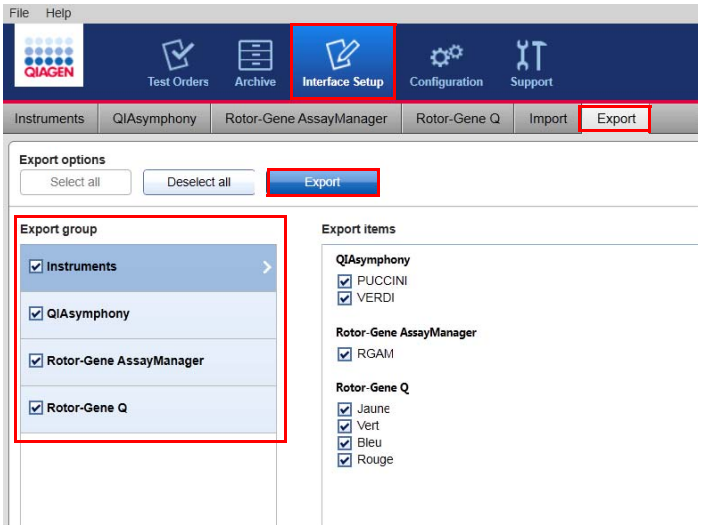
4.4.3.1 Upgrade overview

Step	Action	Section
1	Export the QIAlink Result Manager configuration data	4.4.3.2
2	Convert the configuration data manually	4.4.3.3
3	Upgrade the Iguana service	4.4.3.4
4	Uninstall QIAlink Result Manager	4.4.3.5
5	Install the new QIAlink Result Manager	4.4.3.6
6	Import the manually converted Configuration Data	4.4.3.7
7	Check the QIAsymphony settings	4.4.3.8
8	Patching the RGQ software	4.4.3.9
9	Archiving the results	4.4.3.10
10	Train new features	4.4.3.11

4.4.3.2 Export the QIAlink Result Manager configuration data

1. Open the QIAlink Result Manager.
2. Go to "**Interface Setup**" and click the "**Export**" tab.

3. Select **ALL** export groups (Instruments, QIAsymphony, Rotor-Gene AssayManager, Rotor-Gene Q).

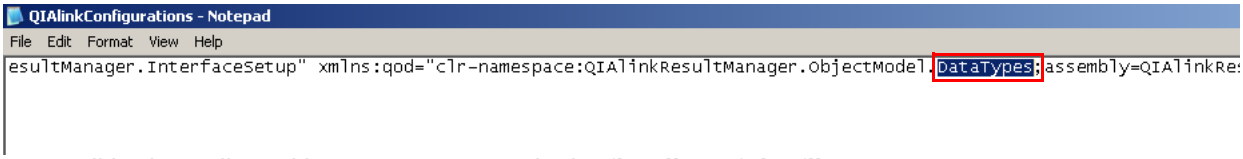


4. Click on the "**Export**" tab.
5. Save the configuration data to a file where the application has write permission e.g. *QIAlinkConfigurations.xrm*.
6. Close the QIAlink Result Manager.

4.4.3.3 Convert the configuration data manually

See chapter **6 Troubleshooting** (section 6.3 Known Issues) for details about the reason why this needed.

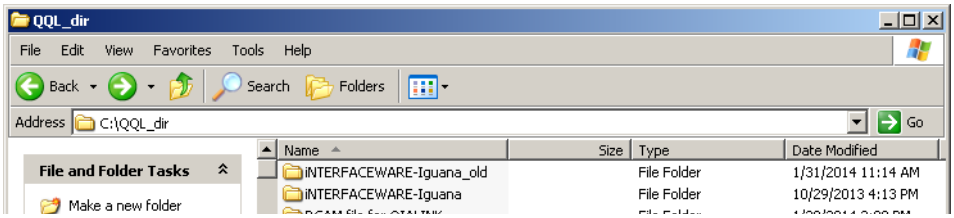
1. Open the configuration data file using Notepad (or any text editor):



2. Scroll horizontally and locate "**Datatypes**" in the **first line of the file**.
3. Change "**Datatypes**" to "**DataTypes**", save the file.

4.4.3.4 Upgrade the Iguana service

1. Stop the Iguana service (see **8.1.1 Start / stop the Iguana service**).
2. Rename the **iNTERFACEWARE-Iguana** folder to "**iNTERFACEWARE-Iguana_old**"

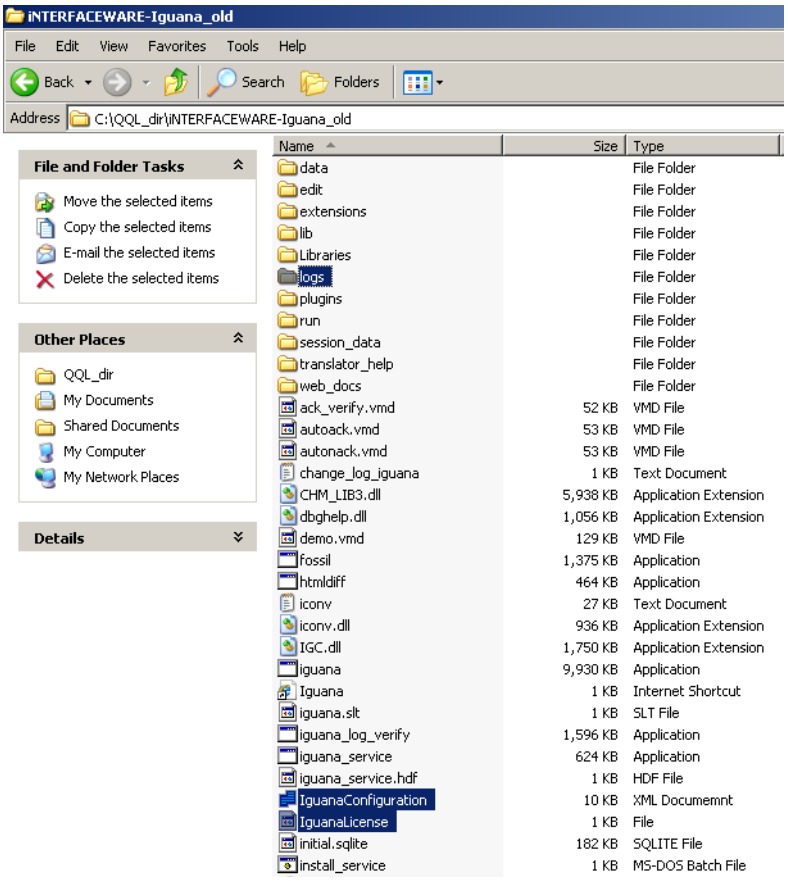


NOTE	**Do not delete the folder: rename it!** It contains all Iguana **logfiles**, the **license code** as well as the Iguana **configuration data**!

3. Install the new version of the Iguana from the QIAlink 1.1 CD, according to section **4.2.6 Installation of QIAlink Interface Engine (aka Iguana)**.

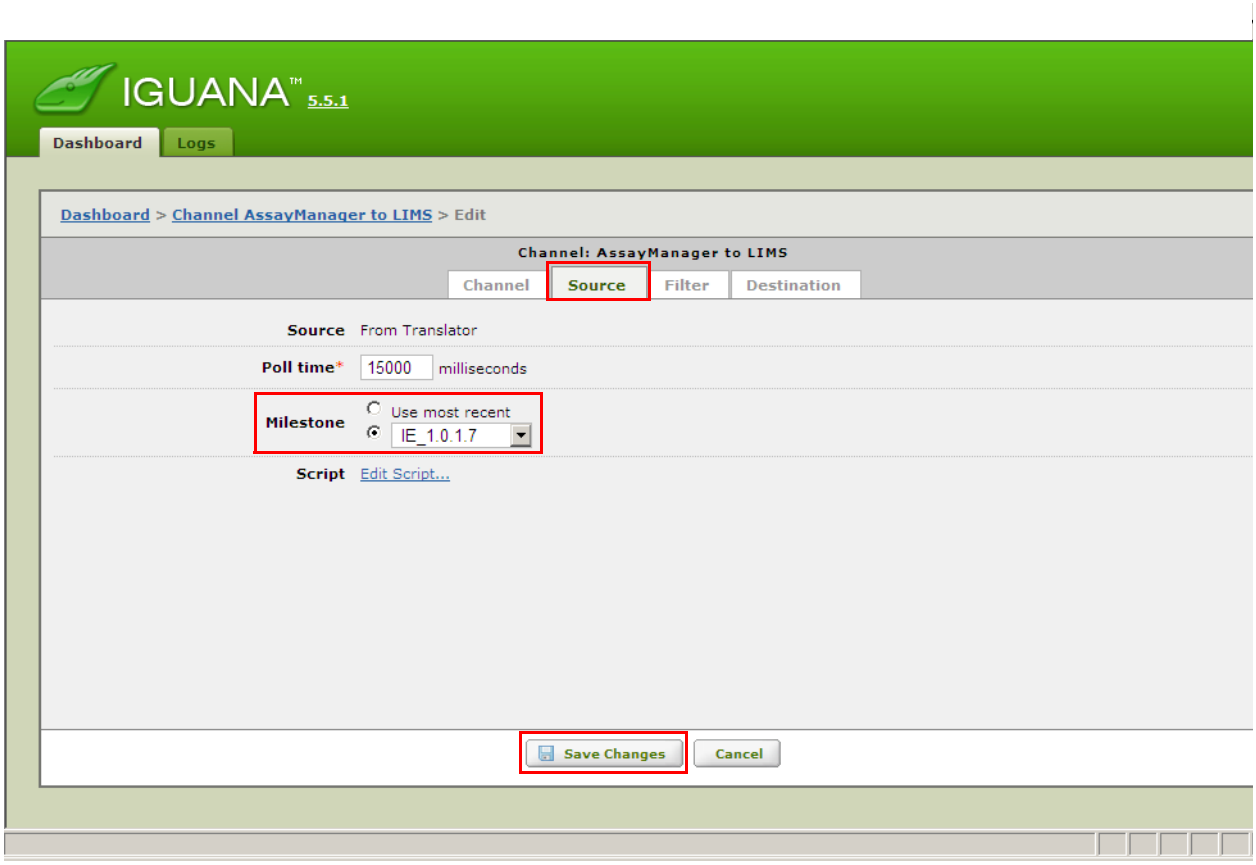
NOTE	**Make sure to place the new iNTERFACEWARE-Iguana folder in the exact same location as the old version on the hard drive.** Disregarding this point will make your license code invalid because the algorithm uses the path of the Iguana folder to generate the license code!

4. Copy the following files **from the iNTERFACEWARE-Iguana_old folder into the newly installed iNTERFACEWARE-Iguana folder**. Use copy/paste, to keep the original data!
   4.1 the **logs** folder
   4.2 IguanaLicense
   4.3 IguanaConfiguration.xml



5. Go to the Iguana "**Dashboard**"

6. For each channel, click on the channel's name, move to the "**Source**" tab, click the "**Edit Channel**" button and directly "**Save Changes**": This will automatically refresh the "**Milestone**" to use the latest version: 1.0.1.7.



7. Re start the Iguana service (see 8.1.1 Start / stop the Iguana service).
8. Check in the dashboard that all channels are setup correctly.
   - 8.1 Check that all channels are set to start automatically
   - 8.2 Check that the LIMS configuration is correct
   - 8.3 Check that the configuration is in accordance with data saved during backup Milestone to V1.0.1.7.
   - 8.4 Check that all user accounts are present

4.4.3.5 Uninstall QIAlink Result Manager

NOTE	Make sure you have performed the steps described in section **4.4.3.2 Export the QIAlink Result Manager configuration data** and **4.4.3.3 Convert the configuration data manually** before going on with the following steps.

1. Insert the **QIAlink 1.0** Software CD into the CD drive.

NOTE	Uninstall the QIAlink Result Manager using the original **QIAlink 1.0** CD! (or an electronic copy of the software pack version 1.0, available from the GPS intranet)

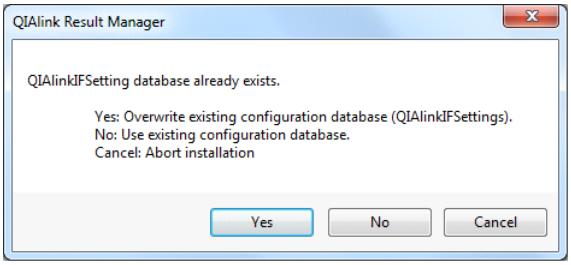
2. Go to the folder "**QIAlink Result Manager**".
3. Double click "**setup.exe**" and follow these steps:

3.1 Select “**Remove QIAlink Result Manager**” and click “**Next**”.
3.2 Click on “**Finish**”

The QIAlink Result Manager is uninstalled, the **database is unchanged**.

4.4.3.6 Install the new QIAlink Result Manager

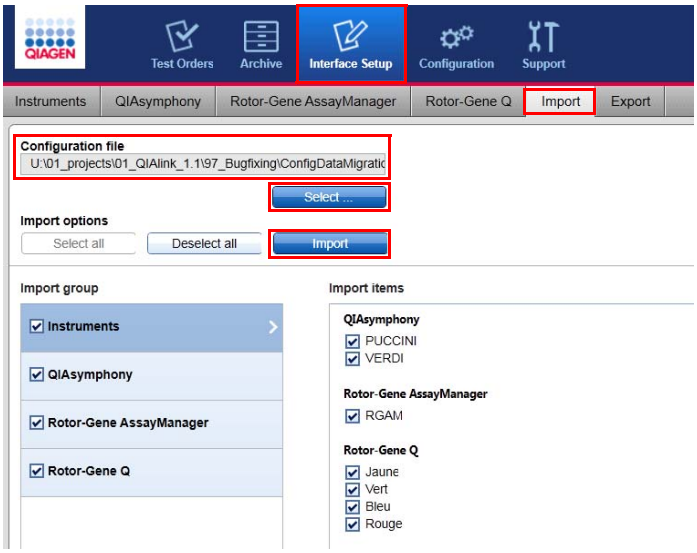
1. Now insert the **QIAlink 1.1** Software CD into the CD drive
2. Go to the folder “**QIAlink Result Manager**”.
3. Double click “**setup.exe**”.
4. The following window will pop up:



5. Click “**Yes**”, the configuration Database (QIAlinkIFSettings) is updated to the new schema and all data is deleted. The result database remains unchanged.

4.4.3.7 Import the manually converted Configuration Data

1. Open the **QIAlink Result Manager**.
2. Go to “**Interface Setup**” and click the “**Import**” tab.
3. Select the file that you have converted manually according to section 4.4.3.3.



4. Click on “**Import**”
5. Check that all the configuration data is imported properly.
6. Verify the data in the following tabs:
   6.1 Instruments
   6.2 QIAsymphony
   6.3 Rotor-Gene AssayManager
   6.4 Rotor-Gene Q
7. Close the QIAlink Result Manager

4.4.3.8 Check the QIAsymphony settings

Check that the QIAsymphony settings are according to section 4.2.10.

4.4.3.9 Patching the RGQ software

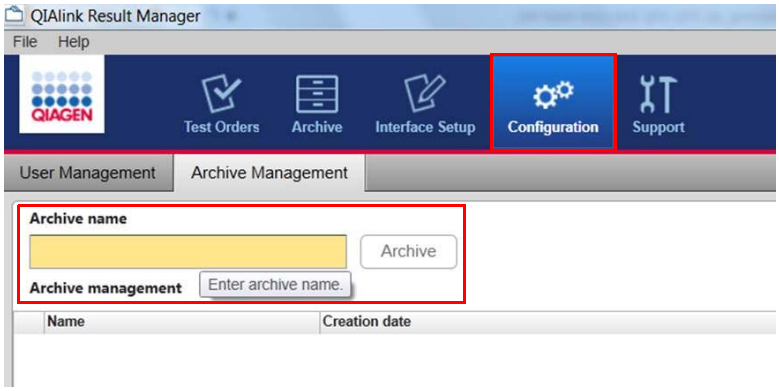
Patch the Rotor-Gene Q software as indicated in section 4.2.11

4.4.3.10 Archiving the results

Explain the issues described in section **6.3.5 Interface Engine processes only first plate from AS result file** to the customer and discuss the 2 possible strategies QIAGEN proposes.

To archive the results that the customer has generated before the upgrade, proceed as follows:

1. Open the QIAlink Result Manager.
2. Go to “Configuration” and click the “Archive Management” tab



3. Enter a new “**Archive name**”.
4. Click the “**Archive**” button.

The archive management features in QIAlink allow to choose if archives are visible or not in the “**Archive view**”.

The “**Lab Administrator**” can decide and select which archives should be visible and which not.

Once the results are archived, discuss this point with the customer, the 2 possibilities QIAGEN proposes are:

- If the customer chooses to accept the **missing AS data** (see 6.3.5 Interface Engine processes only first plate from AS result file), then **select** the archive to be displayed in the “**Archive View**”.
- If the customer chooses not to accept the missing AS (see 6.3.5 Interface Engine processes only first plate from AS result file) data then **deselect** the archive to be displayed in the “**Archive View**”

4.4.3.11 Train new features

After upgrading QIAlink 1.0 to QIAlink 1.1 train the customer on the new available features:

1. Train the Operator on the new features available in QIAlink 1.1 according to **7.3.1.1 Operator training** (Table items 7.4 & 7.5).
2. Train the Supervisor on the new features available in QIAlink 1.1 according to **7.3.1.2 Supervisor training**.

5 Configuring the Result Manager

5.1 Service Login

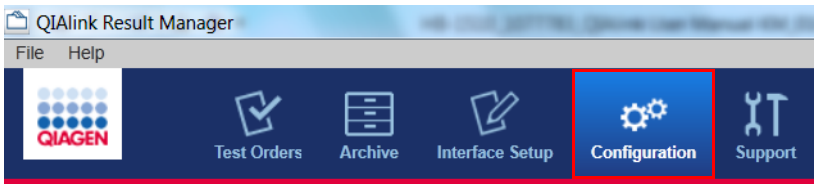
1. Launch QIAlink Result Manager.

2. Plug in your QIAsymphony service USB stick.
3. Click “**Cancel**” on the login window.
4. Click “**Browse**” and locate the **QIAGEN Service File** (e.g. \\login\service).
5. Enter your personal **QIAsymphony PIN Code** in the PIN field.
6. Browse to QSY service stick > login > service.
7. Click “**OK**”.
8. You are logged in as “**QIAGEN Service**”.

NOTE	
	Using the service login only adds one feature to the ones available to supervisors: It allows to delete configurations. The main advantage of the service login is that it allows to login without supervisor password.

5.1.1 User management

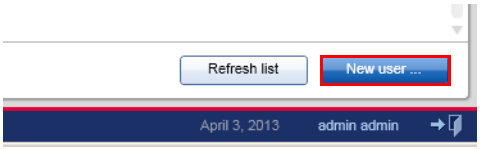
The Configuration environment is accessed by clicking on “**Configuration**” in the main navigation bar. It allows user management for the QIAlink Result Manager.



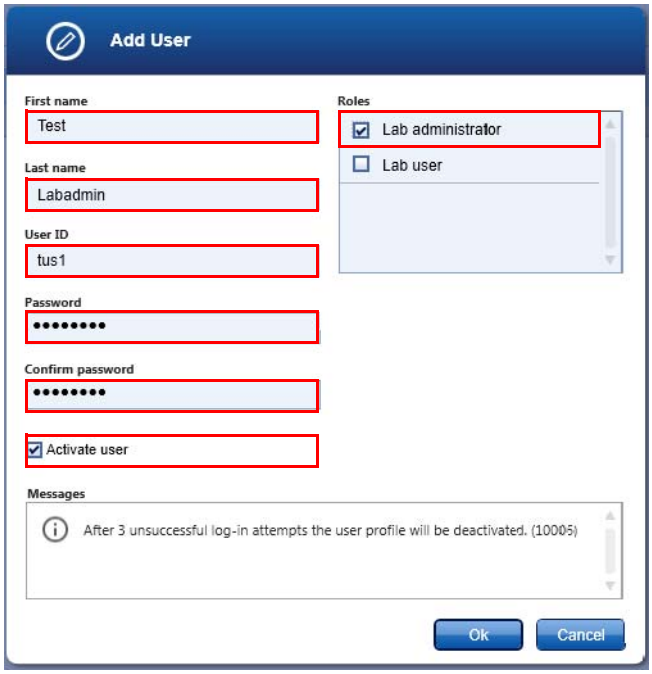
A user with the role “**Lab Administrator**” is able to add new user profiles. The Lab Administrator is also able to activate, deactivate, and modify existing user profiles. User profiles cannot be deleted, but can be deactivated, if needed.

5.1.1.1 Adding a new user

To add a new user profile, go to the Configuration environment and click the “New user” button located at the bottom right corner of the window:



Fill in the fields and once this is done click “Ok”



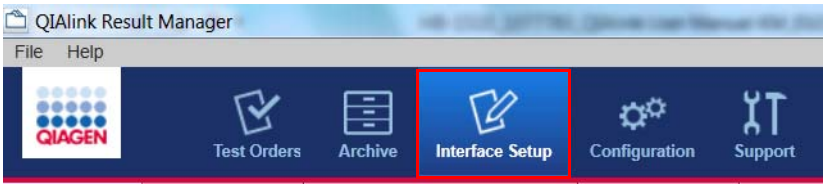
5.1.1.2 Edit existing User profiles

To edit an existing user profile: click on the located on the right hand side on the concerned user profile line.

5.2 Configuring the QIAlink Result Manager

Refer to the QIAGEN Result Manager User Manual to configure the software according to the needs of your customer. The Assays list will help you in this task.

To access the Interface Setup, select the icon “**Interface Setup**” in the main navigation bar.



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

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

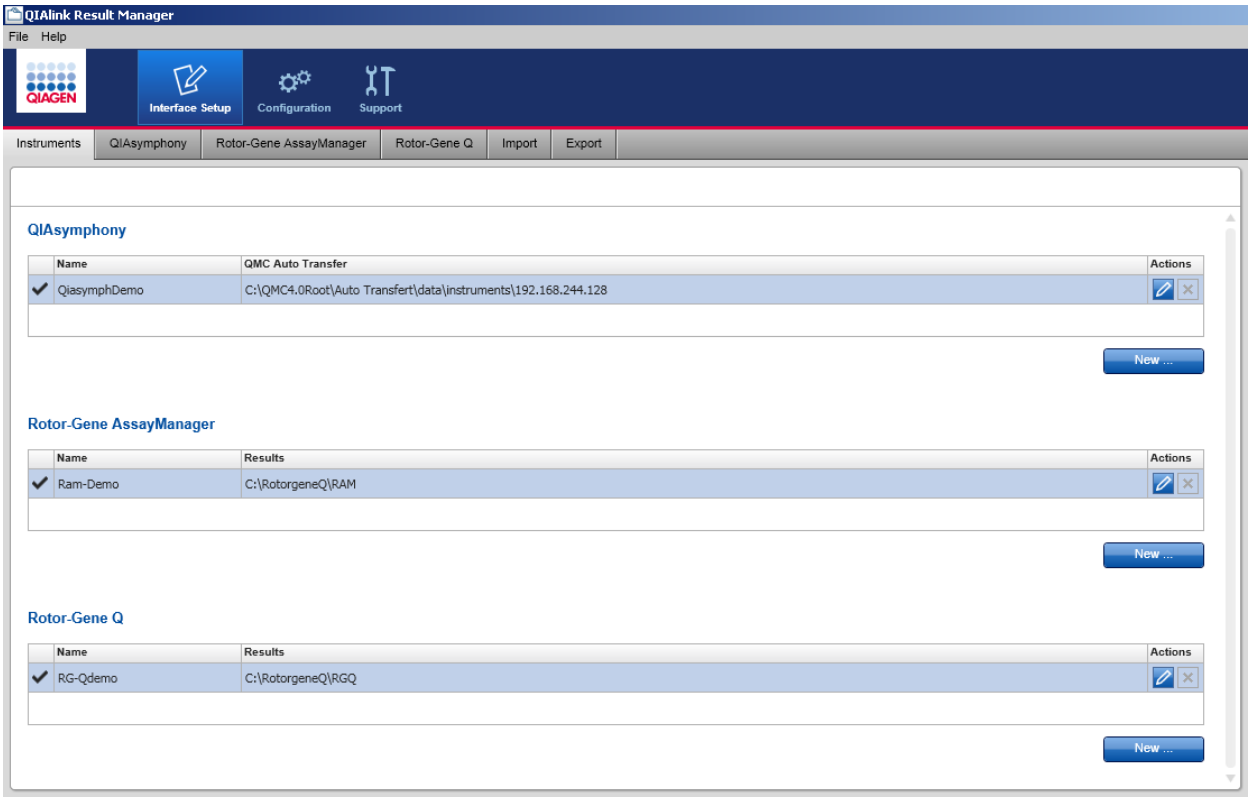
Users with the user role “**Lab Administrator**” can create new settings, modify, activate and deactivate existing settings.

Only QIAGEN Technical Service may delete existing settings.

The screens are explained within the following sections.

5.2.1 Instruments dialog

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



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

5.2.1.1 QIAsymphony

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

For details on the Auto Transfer feature of the QMC, refer to the QMC user manual.

5.2.1.2 Rotor-Gene AssayManager

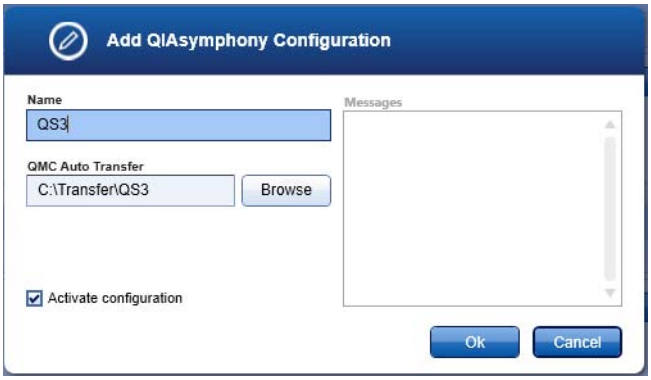
The Rotor-Gene AssayManager area allows configuration of up to 10 instances of the Rotor-Gene AssayManager software. The name of the Rotor-Gene AssayManager instance can be freely chosen (e.g., RAM1). In the column “Results”, the LIMS output folder of the Rotor-Gene AssayManager is entered. For details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

5.2.1.3 Rotor-Gene Q

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

5.2.1.4 Add a new directory

1. To add a directory to a table, click the “New” button below the table. The following dialog box opens.



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

NOTE	This name can be freely chosen, but must be unique (e.g., qssp5612).

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

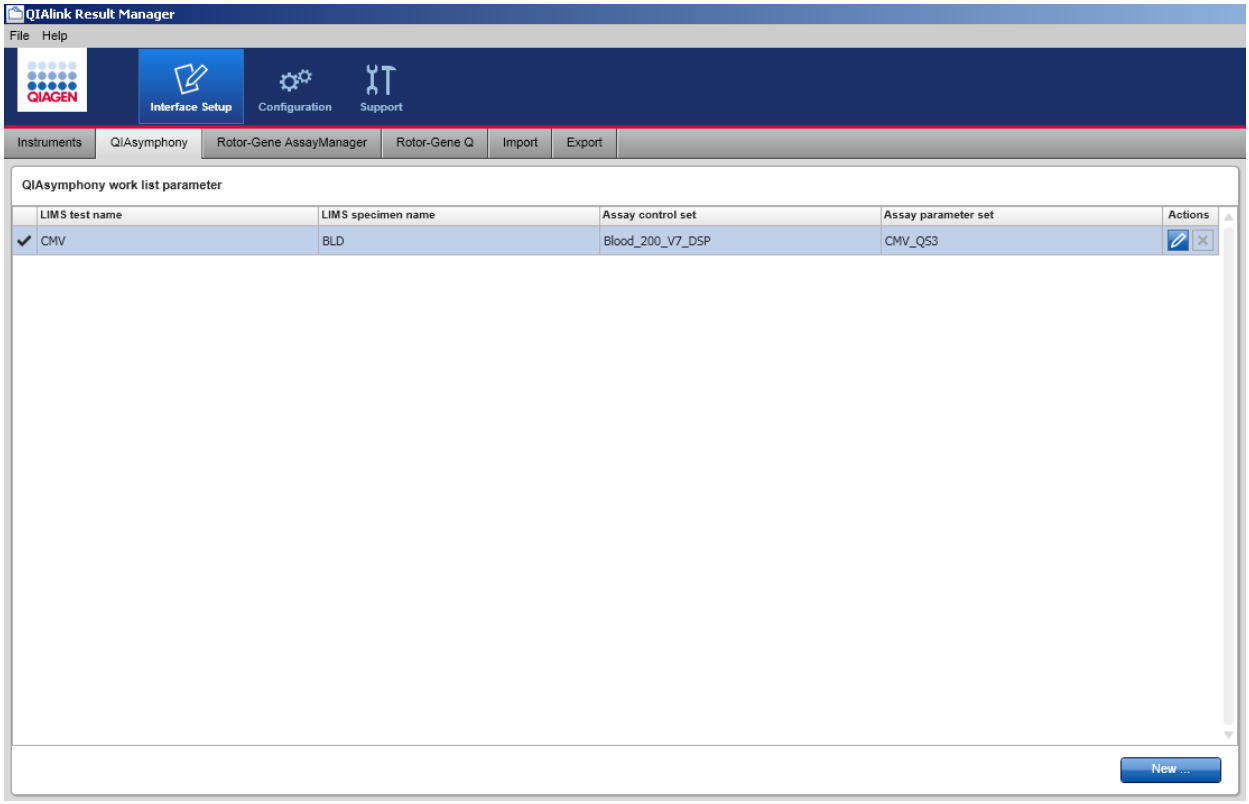
5.2.1.5 Editing an existing configuration

To edit an existing configuration: click on the located on the right hand side on the concerned configuration line.

5.2.2 Configuring the QIAsymphony worklist parameters.

NOTE	For the following steps you will need to have the Assays List on hand. Make sure it has been completely filled in.

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



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

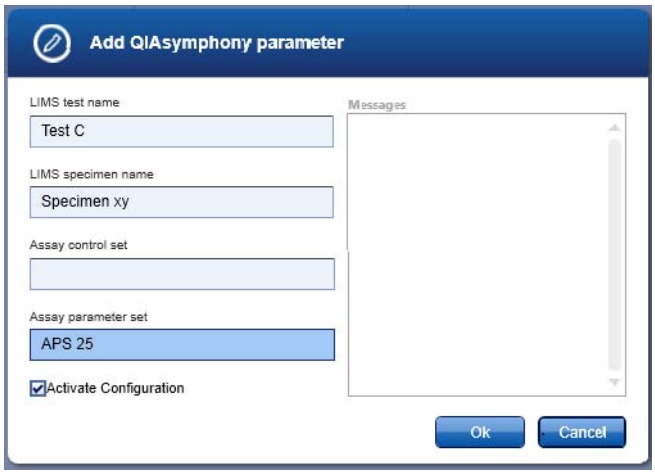
The combination of Test ID and Specimen must be unique.

NOTE	If the LIMS requests a test for a combination of Test ID and Specimen that is not configured, QIAlink will not generate a QIAsymphony work list and a warning will be displayed in the Iguana logs.

5.2.2.1 Add a new configuration

1. Click “**New ...**”

2. The following window is displayed:



3. Enter the following parameters:
   3.1 **LIMS test name**: Enter the test identifier provided by your LIMS provider in this field (case sensitive)
   3.2 **LIMS specimen name**: Enter the specimen name provided by your LIMS provider in this field (case sensitive)
   3.3 **Assay control set**: enter the name of the Assay control set (case sensitive) to be used on QIAsymphony for the purification of samples with this given test identifier and specimen name in this field.

NOTE	This field can be left empty if the “integrated run” feature is used on the QIAsymphony. If this field is empty then only “integrated runs” can be preformed with this configuration.

   3.4 **Assay parameter set**: enter the name of the Assay parameter set to be used on QIAsymphony for the assay setup of samples with this given test identifier and specimen name in this field.
4. Make sure the configuration is active (check box) before closing with “**OK**”.

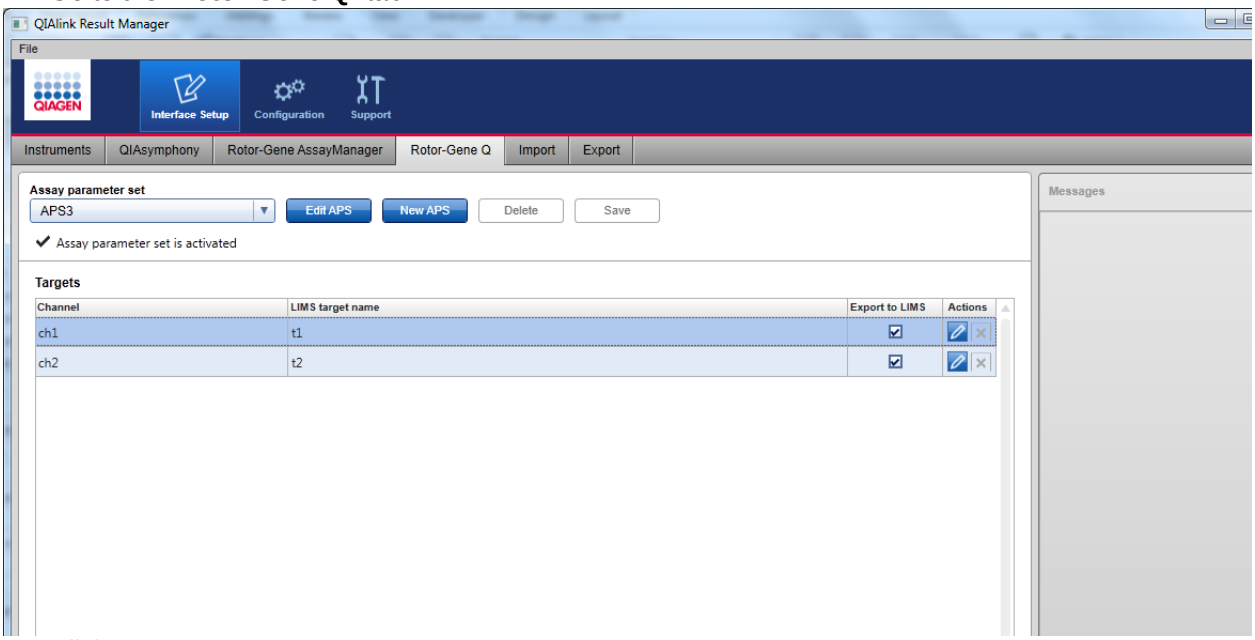
5.2.3 Adding a new APS / Rotor-Gene Q software

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

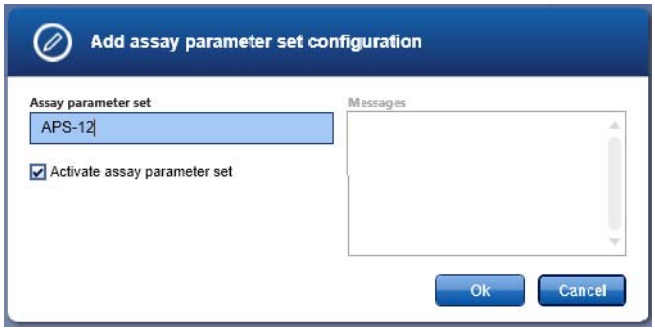
Each assay processed on the Rotor-Gene Q and exported to the LIMS must be configured in this screen.

No LIMS response is generated if results are exported to QIAlink for an assay that has not been configured but a warning is displayed in the logs.

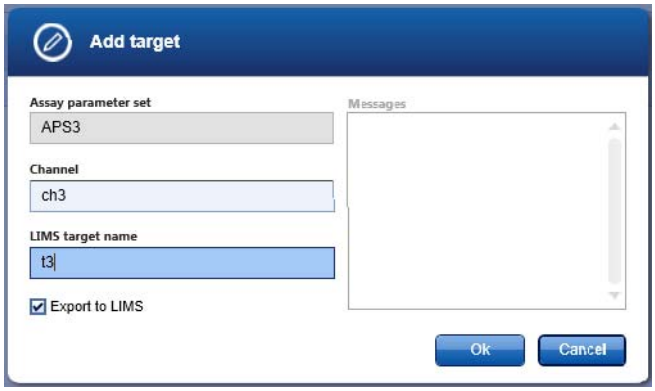
1. Go to the "**Rotor-Gene Q**" tab



2. Click "**New APS ...**"



3. The window above will open, name the new APS and click "**OK**" to close the window and click "**Save**" to save the changes.
4. Click "**New ...**" in the bottom right corner of the window to add a target

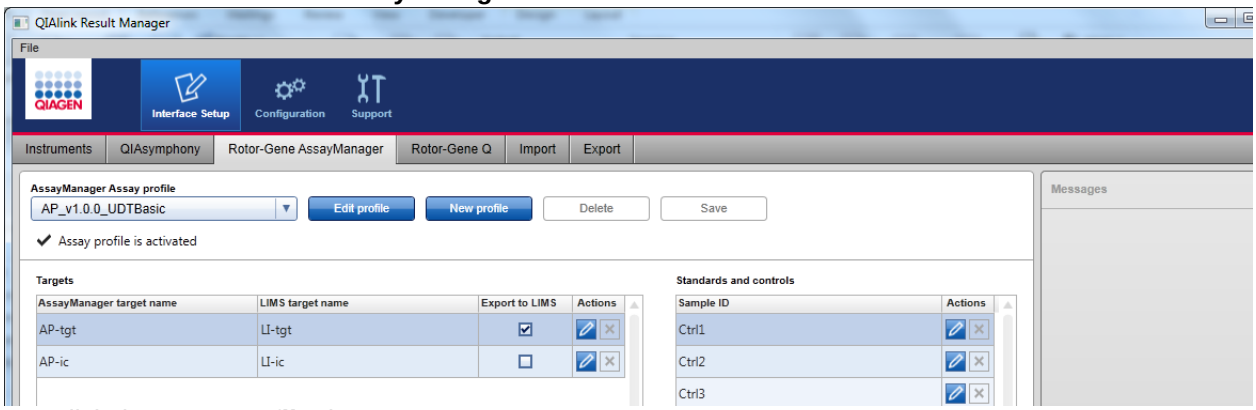


5. Enter the following parameters:
   5.1 **Channel**: enter the name of the Rotor-Gene Q channel used to detect the target (e.g., "Cycling A. Green")
   5.2 **LIMS target name**: enter the target name for export to the LIMS in this field. This name needs to be defined by the LIMS provider. For targets not exported to the LIMS, the name can be freely chosen.
6. Check "**Export to LIMS**" if results for this target are to be exported to the LIMS. Uncheck it if the results for this target needn't be exported to the LIMS (for example: internal controls).
7. Click "**OK**" to close the window and **Save**" to save the changes.

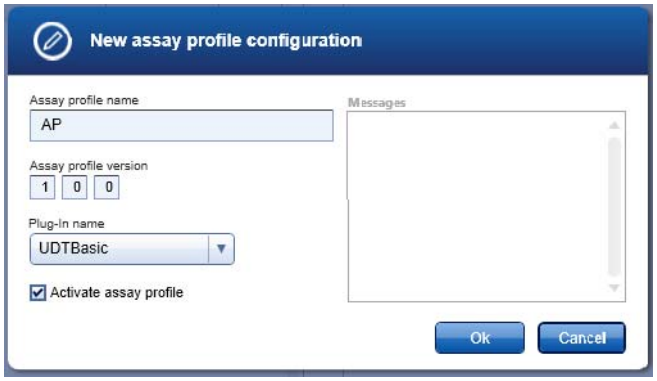
8. Repeat steps 4 to 7 for each target.

5.2.4 Adding a new Assay Profile / AssayManager software

1. Go to the “**Rotor-Gene AssayManager**” tab



2. Click the “**New profile**” button.

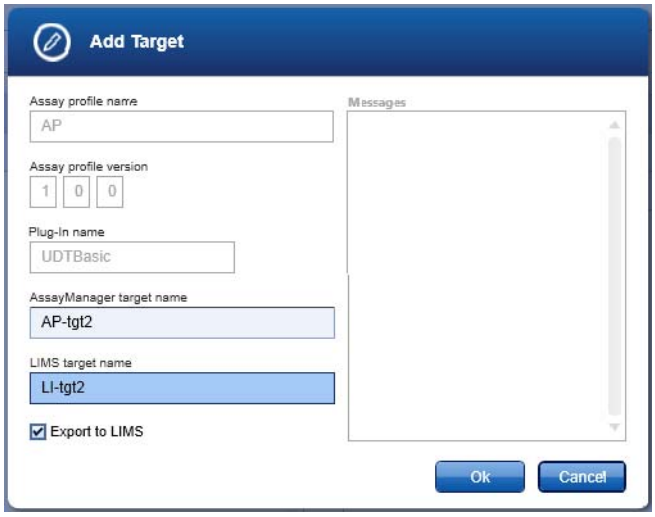


3. Enter the following parameters:
   - 3.1 **Assay profile name**: Enter the name of the Rotor-Gene AssayManager assay profile as defined in the Rotor-Gene AssayManager software.
   - 3.2 **Assay profile version**: Enter the version of the Rotor-Gene AssayManager assay profile.
   - 3.3 **Plug-in name**: select the name of the Rotor-Gene AssayManager plug in used by the assay profile.

NOTE	Only plug-ins in the drop-down list are supported by QIAlink.

   - 3.4 Click “**OK**” and “**Save**” to confirm the new configuration and save the changes.

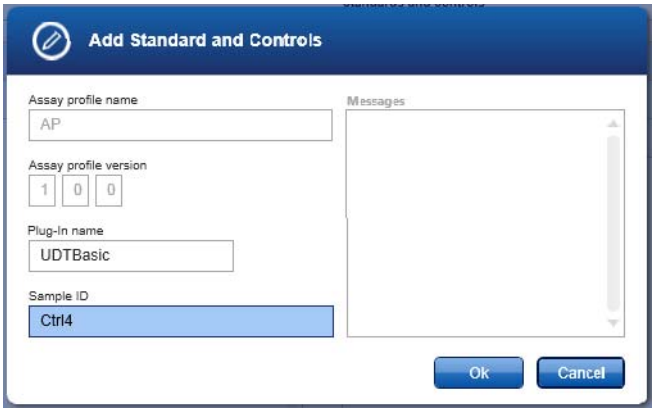
4. Click “**New target**”



5. Enter the following parameters:
   5.1 AssayManager target name: enter the name of the target as it is configured in the Rotor-Gene AssayManager assay profile in this field.
   5.2 LIMS target name: enter the name of the target as it is configured in the Rotor-Gene AssayManager assay profile in this field.
6. This name is defined by your LIMS provider. For targets not exported to the LIMS, the names can be chosen freely.

NOTE	Targets that are not exported to the LIMS (e.g., internal controls) must also be configured. If not, warnings will be displayed in the logs of Iguana during processing of Rotor-Gene AssayManager LIMS output files.

7. Check the “**Export to LIMS**” box if results for this target are to be exported to the LIMS.
   Uncheck the “**Export to LIMS**” box if results for this target needn’t be exported to the LIMS (for example: internal controls).
8. Click “**OK**” to close the window and “**Save**” to save the changes.
9. Repeat steps 3 to 7 for each target of the assay profile.
10. To configure the standards and controls, click “**New ID...**”



11. Enter the following parameters:
    11.1 **Sample ID**: enter the name of the standard/external control as it is configured in the Rotor-Gene AssayManager assay profile in this field.
12. Click “**OK**” to confirm the configuration and “**Save**” to save the changes.
13. Repeat steps 9 to 11 for each standard/external control of the assay profile.

6 Troubleshooting

6.1 Remote support / phone support

If the customer has an established remote support solution and if you are enabled to use it, then this is surely the method of choice to troubleshoot QIAlink issues.
Connect to the customer's QIAlink PC and perform the checks recommended in the next sections. If no remote access is available, then assist the customer on the phone to perform a check.

6.1.1 Iguana Checkpoints

Before escalating to FSS there are things that can be checked with the customer over the phone.
Use chapter 9 of Qialink user manual for basic configuration trouble shooting. For any issues control the following check points before going deeper in TS. This will provide a picture upon QIALINK current status:

1. Check the **channel status**

   1.1 **Green**: the channel is running, check the last activity and **go to 2**.
   1.2 **White**: the channel is idle (has been stopped manually or never started): start the channel and check status again and **go to 1**.
   1.3 **Red**: the channel stopped and is in error state: check error message in the logs and **go to 3**.
   1.4 **Yellow**: The channel is running but there is a warning: Check the logs to identify reason to the warning.

2. Check the last activities of channels: **LIMS to QIAsymphony** & **"Cycler"* to LIMS** in the logs (see also QIAlink UM chapter 5-1):
   2.1 If there was **no activity** and the LIMS was also idle: no orders, **no action**.
   2.2 If there was **an activity**, that indicates QIAlink has processed data: **go to 5**.
   2.3 If there was **no activity** and QIAlink hasn't processed any data despite LIMS activities: no messages received: Check connections: **go to 4**.

3. Check the **errors in the logs**: Check the error(s) reported in the chapter 9 of the User Manual and take appropriate actions.

4. Check **instruments paths** in QIAlink Result Manager (QIAlink UM chapter 6.5.2)
   4.1 Confirm that the path to the auto transfer folder in the QIAlink Result Manager settings matches the path to this same folder defined in the QMC.
   4.2 Confirm that the path of the export folder for the Rotor-Gene Assay Manager (see 4.2.15) matches the path set in the QIAlink Result Manager in the Interface Setup\Instruments.
   4.3 Confirm that the customer can successfully export RAM/RG-Q file to the shared results folder(s).

5. Ensure needed **network computers** can be reached through the network.
   To do this: look up the LIMS server IP address in the settings of the Iguana channel **"Cycler"* to LIMS** (see 4.2.12.2) and ping this IP address: Refer to 8.3.3 to learn how to make a ping.
   5.1 The **Ping works**: check the ports settings in the Iguana settings and port numbers given by the LIMS provider.
   5.2 The **Ping fails**: the LIMS server cannot be reached through the network: inform local IT/LIMS provider.

6. Look up the QIAsymphony IP address in the QMC (hostname or IP address) and ping the QIAsymphony from the QIAlink PC.
   6.1 The **Ping works**: check QMC, **go to 5**.
   6.2 The **Ping fails**: check the QIAsymphony TCP / IP settings (FSS)

7. Look up the QIAlink IP address and ping the QIAlink PC from the RG-Q/RAM PC. 7.1 The **Ping works**: check folder sharing (go to step 4.) 7.2 The **Ping fails**: check the TCP / IP settings of both QIAlink and RG-Q/RAM PC's. (FSS)
8. Check the **presence of network drives**: make sure that the Auto Transfer folder for cycler files export and the RG-Q/RAM results folder (located on the QIAlink PC) are shared over the network (see QIAlink UM 6.5.2). 8.1 If the folders **aren't visible/reachable** from the RG-Q/RAM PC: start the sharing (ask the local IT support if needed). 8.2 If the folders **are visible/reachable**: control read / write permissions (ask the local IT if needed).
9. Check QMC: Check that the Auto Transfer service is started (see QMC user manual) 9.1 If QMC Auto Transfer is stopped, then re start it. 9.2 If QMC Auto Transfer was started, check the settings (see QMC user manual / QIAlink configuration) and **go to 10**.
10. Check the **QMC settings**: open the Auto Transfer work list folder on the QIAlink PC: 10.1 If the **folder contains work lists**: the work lists haven't been sent to the QIAsymphony, check the Auto Transfer settings (QMC user manual). 10.2 If the **folder is empty**: the work lists have been sent to the QIAsymphony, **go to 11**.
11. Use the QMC software to check the content of the internal QIAsymphony work list folder: 11.1 If this **folder is empty** as well despite LIMS activity, **go to 2**. 11.2 If this **folder contains work lists**, make sure they are originating from recent LIMS activity. At this stage everything looks normal so QIAlink should operate normally, discuss possible issue with customer, escalate to the next level if problems persist.

** Whichever is used "Rotor-Gene Q to LIMS or AssayManager to LIMS*

6.2 Transfer an Iguana license to another computer

Customers sometimes need to transfer an installation of **Iguana** to another computer. You can easily do this by providing **your DISPATCH** with the Iguana IDs of both your old and new installations, so that the license may be transferred accordingly.

6.2.1 Procedure

To transfer the **Iguana** license:

1. Install **Iguana** on your new computer and start it. The new version of **Iguana** will display the Iguana ID for your new installation, and will ask for a license to run it.
2. Contact your local Dispatch (Licensing) at:

Region	Email
EMEA	dispatch-eu@qiagen.com
NA	AASteam-na@qiagen.com
APAC/Japan	GAsiaPacBackOfficeFieldService1@qiagen.com

3. Provide both the Iguana ID for the installation you are currently licensed on and the Iguana ID for the new installation.
4. Once your mail is received and processed a new registration code will be mailed to you.

6.3 Known Issues

- After training assist customer during the complete workflow, to be able to address any need, question.
- Fill in the CTC (Customer Training Checklist) and attach it to the Installation CRM SI.

6.3.1 WL bug I - preventive measures

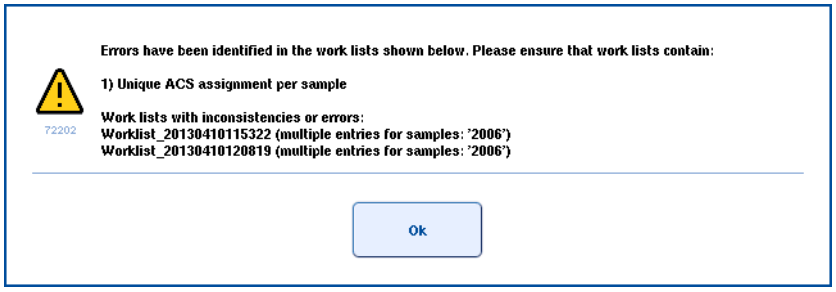
WARNING	**More than 600 work lists on QIAsymphony** c2 The presence of more than 600 work lists on QIAsymphony running QIAsymphony software version up to 4.0.1 may lead to software failure during startup of the QIAsymphony instrument. When this error occurs, the QIAsymphony instrument will not start. This error can only be resolved by a QIAGEN Field Service Specialist.

After or during training discuss the deletion of work lists with the customer(s). It is required to instruct them how to delete work lists on a **predefined regular basis given in the table below**

Number of work lists / day	Setting “old files” [d]	Recommended deletion interval (“Delete old files”)
no WL < 10	28	**once / month**
11 < no WL < 50	14	**once / week**
51 < no WL < 100	7	
101 or more	**QIAsymphony connection only possible using QS 4.0.2.** It is possible to connect RGQ/RGQM already and activate QS connection after update of the QS software.	

6.3.2 WL bug II - preventive measures

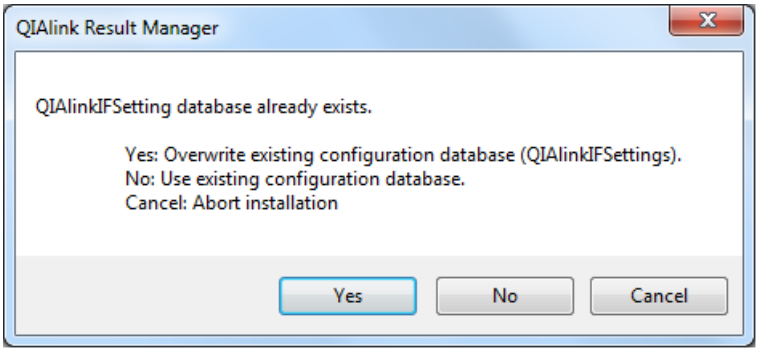
If 2 (or more) tests / assays are ordered for the same sample and the order are in the same work list, QIAsymphony isn’t able to automatically assign the assays and generates the following error:



In this case the ACS must be assigned manually, for more detail refer to the QIAsymphony User Documentation.

6.3.3 QIAlink Result Manager setup does not upgrade DB schema when choosing “use existing configuration database”

QIAlink Result Manager setup does not update the database schema when choosing “Use **existing configuration database”**:



Current behaviour
During setup of the QIAlink result manager the user can choose to overwrite the existing **QIAlinkIFSetting** database:

- When choosing **YES** the **DB is updated to the new schema and all data is deleted.**
- When choosing **NO** the **data is kept**, but the **DB schema is not updated**.

Expected behaviour

- When choosing **YES** the **DB is updated to the new schema and all data is deleted.**
- When choosing **NO** the **data is kept and the DB is updated to the new schema.**

As a result of this issue **the configuration database cannot be updated to the new DB schema while the configuration data is kept**.

NOTE	Select “**Yes**” during the upgrade process from QIAlink 1.0 to QIAlink 1.1! Before clicking “**Yes**” make sure you have performed the steps described in section **4.4.3.2 Export the QIAlink Result Manager configuration data** and **4.4.3.3 Convert the configuration data manually**.

6.3.4 QIAlink 1.0 export cannot be imported in QIAlink 1.1

When exporting the configuration data from QIAlink 1.0, the resulting file cannot be imported in QIAlink 1.1.

The reason for this is that “Data**t**ypes” (QIAlink 1.0) was substituted by “Data**T**ypes” (QIAlink 1.1) in the configuration export file (*QIAlinkConfigurations.xrm).* This can be corrected manually (see 4.4.3.3) by field service during the upgrade (see 4.4).

6.3.5 Interface Engine processes only first plate from AS result file

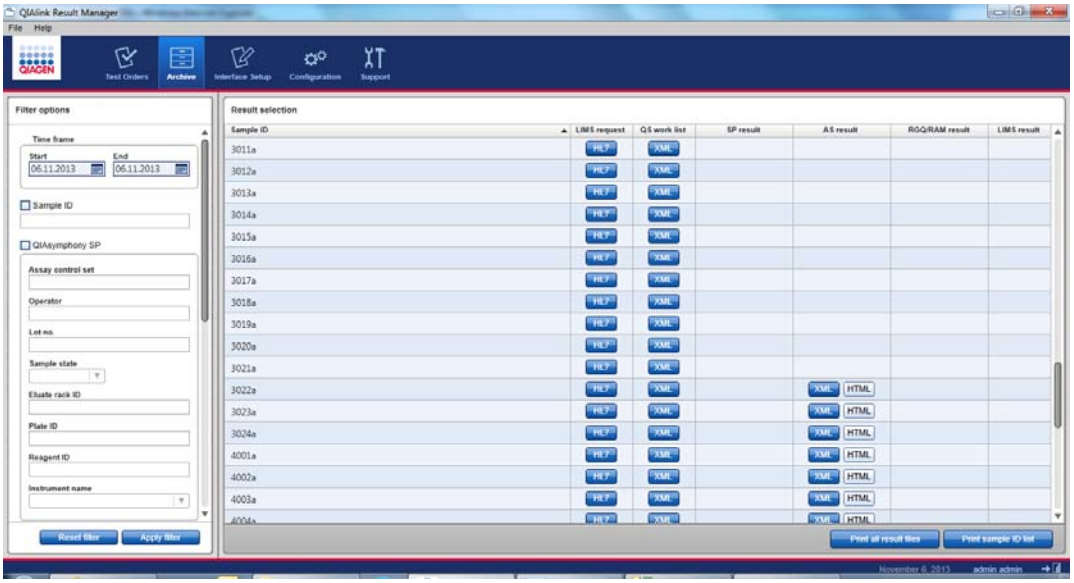
Current behaviour
An AS result file can have multiple output plates. The Interface Engine processes only the first plate in the AS result file. Only samples results from the first plate are stored in the database (and displayed by the QIAlink Result Manager).

Expected behaviour
All output plates and all samples should be processed.

This bug was fixed with the QIAlink release 1.1. However, it is already in QIAlink version 1.0, but not visible to the customer because the “Archive View” isn’t available to the customer in release 1.0. When the customer upgrades to version 1.1 it becomes visible that data is missing.

NOTE	Only the AS results are affected. All other results are archived correctly For AS result files this issue only occurs when multiple output plates were used in one run on QIAsymphony AS. When only one output plate is used, the AS result files are archived correctly.

In case the problem occurs (AS run with multiple output plates) the archive view looks as follows:



Picture 6.3-1 This is a snapshot from an integrated run. In this case the AS result file is release before the SP result file is released. SP result files, RGQ/RAM result files and LIMS result files are not affected by this issue. At the time when the snapshot was taken, these files have not been processed yet. That is why they are missing.

- **Samples 3011a – 3021a:** are on the second output plate → the AS result file is not linked to the sample ID.
- **Samples 3022a – 4004a:** are on the first output plate → the AS result file is linked to the sample ID.

7 Customer Training

7.1 Time lines

The customer training will take approx. 1/2 day to perform.

7.2 Learning Objectives

7.2.1 User / operator

- Must be able to use QIAlink in the routine workflow.
- Must be able to login in Iguana interface using Internet Explorer 8.
- Must be able to check if channels are started, and on “green” in Iguana web GUI.
- Must be able to determine if WL are generated. They should know where to find the new ones and processed ones.
- Must be able to send us the required information for troubleshooting.

7.2.2 Supervisor

- Must be able to use the QIAlink Result Manager.
- Must be able to manage users.
- Must be able to configure new devices/new assays using the QIAlink Result Manager software.
- Must be able to perform basic troubleshooting (export log files, export configuration)

7.3 Procedure

7.3.1 Introduction

Depending on people’s availability and needs it might make sense to make 2 separate training, for example:

1. User / operator training: focussing on routine use.
2. Supervisor training: focussing on configuration, user management and troubleshooting.

The reference document for the customer training is the User Manual.

7.3.1.1 Operator training

1. **Principle of Operation**: based on user manual introduction + marketing presentation.
2. **IT Setup**: Explain actual hardware setup briefly to explain where data will be located (folders structure). Give the big picture, no need to go in detail.
3. Explain that **Iguana is a Windows service**: show how to start / stop the service.
4. **Web GUI**: login in Iguana using the Operators account. Give him his/her specific login information. 4.1 Explain User roles, effective permissions, and demonstrate how to manage user profiles.
5. Channels concept: 5.1 Explain channel concept 5.2 Demonstrate how to START/STOP channels. Explain status indicator of the channels 5.3 Explain where the hostname of the LIMS server can be edited/changed. 5.4 Explain that users mainly use the GUI for monitoring status, explain all items of the dashboard main view.
6. Logs 6.1 Show where log can be read 6.2 Show usage of filters 6.3 Explain show logs identification (Error, Warning, Success, Informational. Unmarked / marked. 6.4 Explain based on some examples. 6.5 Show how to export logs.

7. QIAlink Result Manager 7.1 Explain login 7.2 Explain how to configure the interface. 7.3 Explain how to configure assay specific settings, explain how to import / export settings. 7.4 Explain the Test orders environment according to chapter **6.5 Test orders environment** of the QIAlink User Manual. 7.5 Explain the Archive view.
8. **QIAlink Limitations**: 8.1 Explain that invalid results must be deselected before the export of results with the RGQ software (see 2.2).

7.3.1.2 Supervisor training

1. Explain Iguana / QIAlink Result Manager **login & user management**.
2. Explain QIAlink Result Manager **configuration of instruments and specific assays**.
3. Explain that in case the **LIMS IP address / hostname** changes, then the setting needs to be propagated in Iguana. Demonstrate.
4. Explain the Archive management according to chapter **6.7 Archive environment** of the QIAlink User Manual. Explain the SQL Server Express limitation: the maximum database size is limited to 4 GB therefore QIAGEN recommends to perform regular archiving.
5. Explain basic **troubleshooting**: reading the logs, using the filter, exporting the logs, exporting configurations.

8 Appendix

8.1 Iguana

8.1.1 Start / stop the Iguana service

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

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.

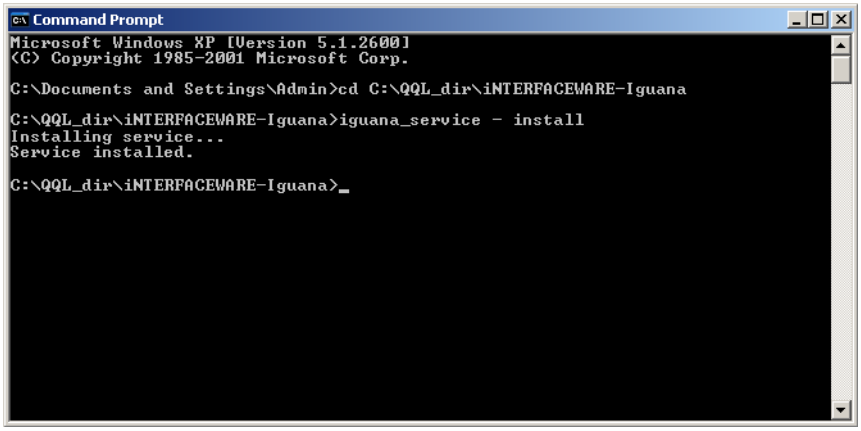
QIAlink Interface Engine will be active while the Iguana service is running.

8.1.2 "Manual" installation of the Iguana service

Under Windows 7 it can happen that the batch file used to install the Iguana service doesn't t work.

If this happens try the following:

1. Copy the "**iNTERFACEWARE-Iguana**" directory into the "**QQL_dir**" (see 4.2.4).
   The "iNTERFACEWARE-Iguana" directory is located in the "**QIAlink Interface Engine**" folder of the QIAlink CD.
2. Run the command prompt as administrator: Start\Programs\Accessories\Command Prompt locate the command prompt, right-click and choose "**Run as...**" and run it as the administrator.
3. Copy the path to the iNTERFACEWARE folder to the clipboard.
4. In the command prompt type **cd** and paste the path to the iNTERFACEWARE folder by right-click and paste.



5. Type "**iguana_service - install**" followed by "**Enter**" in the command prompt.
6. The Iguana service is now installed, **make sure to start it manually** (see 8.1.1).

8.1.3 Backup Iguana

To make a backup of Iguana, backup the following Iguana files:

1. <working directory>**IguanaConfiguration.xml**
2. <working directory>**vcs_repo.sqlite**
3. <log directory>\log\<YYYMMDD>**.log**
4. Log backup must not be run at the time the logs are being purged.
5. All VMD files that are used by Legacy components in your channels.

Legacy components are: From Database, To Database and Legacy Filter components

All Translator component VMDs are stored in Fossil (vcs_repo.sqlite) and will be recreated automatically

6. All databases that are used in your channels.

7. Optional: backup the sample data for channels, located in <install dir>\data.

It's important that your backup process does not backup these files:

- <log directory>\log\index*.*
- <log directory>\log\meta*.*

These files are index files for the logs which Iguana can re generate from scratch from the *.log files. There is no benefit in backing them up. **If you do back them up it can stop Iguana from functioning since the backup process will generate an error.**

8.1.4 Restore Iguana

Follow these steps:

1. Install or reinstall Iguana.
2. To install in a different directory you must update the log_directory entry in IguanaConfiguration.xml to match.
3. If you need a new license code follow the procedure for transferring a license to another computer.
4. Stop the iNTERFACEWARE Iguana service.
5. Replace the default "**IguanaConfiguration.xml**" file with your saved backup copy.
6. Edit "**IguanaConfiguration.xml**" change any instance of StartAutomatically or start_automatically from true to false
7. Restore all other backed up files:
   7.1 vcs_repo.sqlite
   7.2 <YYYMMDD>.log
   7.3 All VMD files that are used by Legacy components in your channels.
   7.4 All databases that are used by your channels.
   7.5 Optionally sample data for channels.
   7.6 Test channels by starting each one manually.
8. Once everything works configure the channels to start automatically, or simply reverse the edits made in step 7.

NOTE	If your backup (or antivirus) software locks the index files for over 30 seconds, this error is generated and all channels will be stopped. *The log index commit system has failed. Possible reasons:* • *The disk has run out of space.* • *An external process (such as antivirus or backup software) is locking files in the log system, or has changed the file permissions.* • *Some other unknown I/O error occurred, please provide this error to GPS.* Database backup and restore procedures will differ, speak to whoever is responsible for the databases you are using. The *.log files are designed to be backup friendly - they are append only. However ensure that your backup software does not exclusively lock these files.

8.2 LIMS

8.2.1 How to check validity of LIMS messages

Go to the log files of the Iguana services and pick the messages you want to check.

If a message doesn't comply with the HL7 specification you will find an error related to this message in the logs view, for more details about the correct syntax, refer to the QIAGEN Health Level Seven (HL7) Documentation and check that messages are formatted according to specifications.

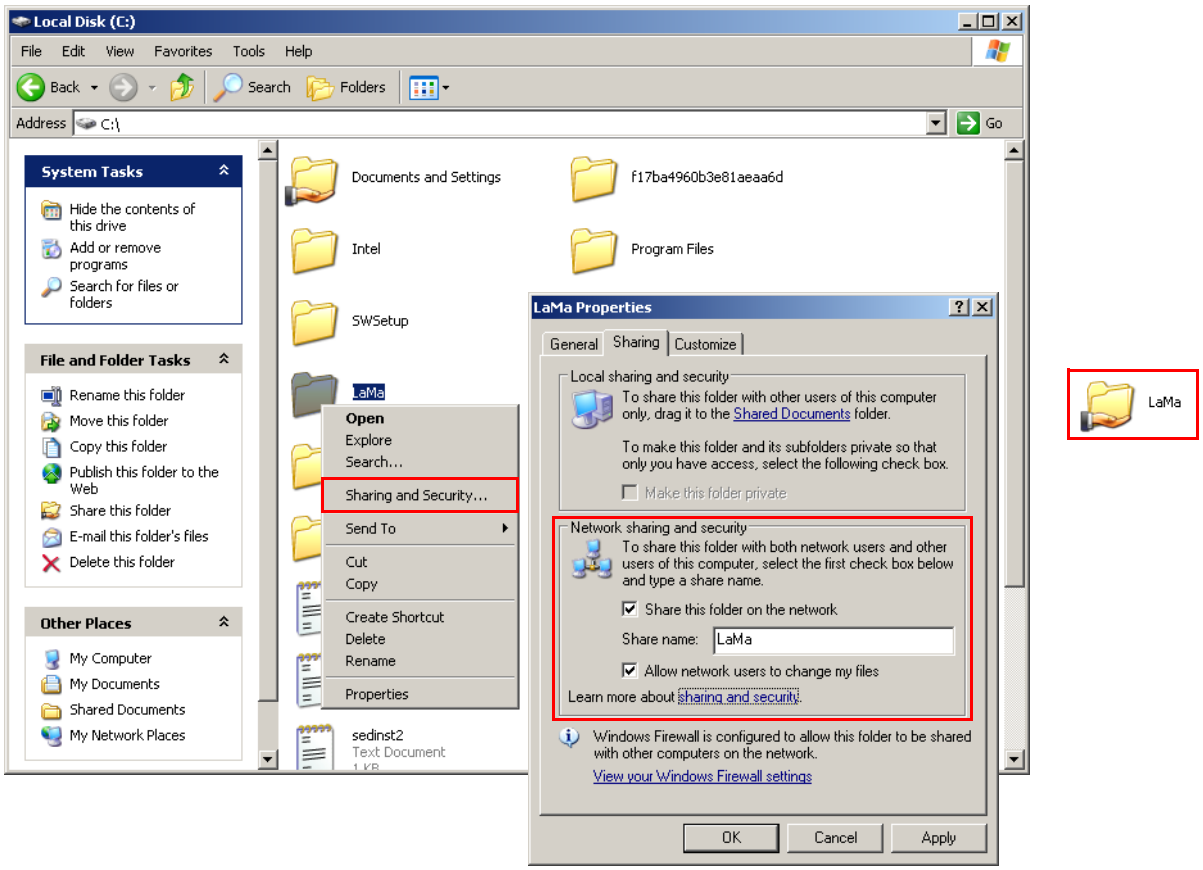
HL7 is an international norm used to code LIMS requests messages. QIAGEN has only implemented a subset of transactions allowing integration of QIAsymphony RGQ in an existing LIMS. For full HL7 specification make a literature review, for the minimal needed to install QIAlink refer to the QIAGEN document mentioned before.

8.3 Windows tips & tricks

8.3.1 Network drives

Right-click the folder you want to share, select "**Sharing and Security**", check the boxes "**Share this folder on the network**" and "**Allow network users to change my files**"

How to create a shared network drive in a workgroup:

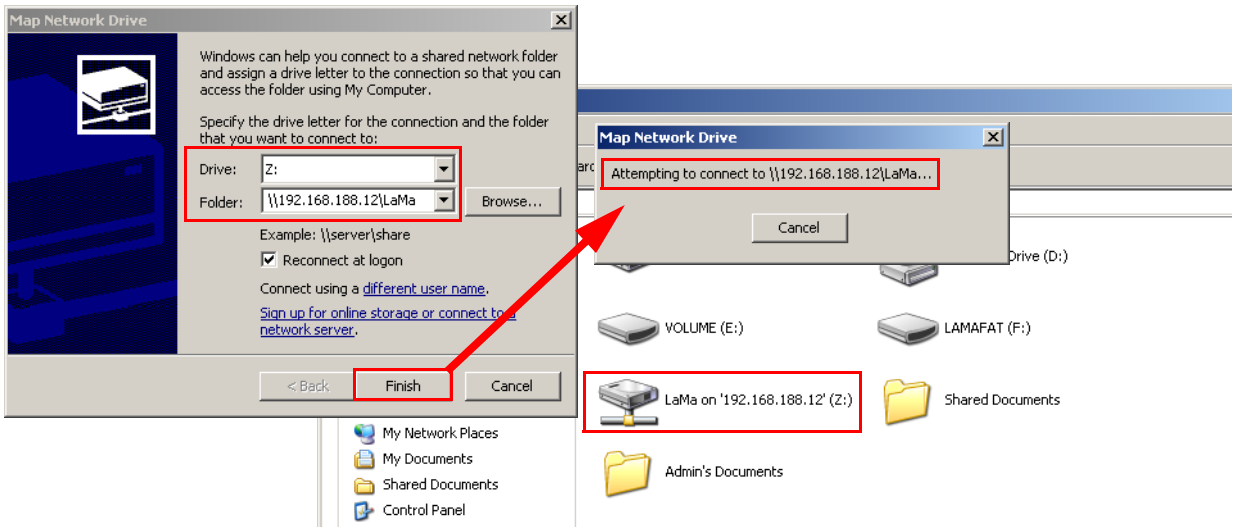


Choose a letter to map the folder as a network drive (Windows usually uses **Z:** as default) and then enter the path to the desired folder (you must know the machine name/IP address of the computer hosting the concerned folder):

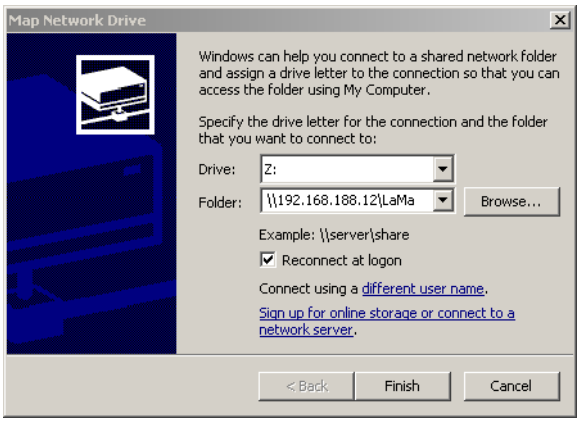
- \\192.168.188.12\LaMa, in our example.

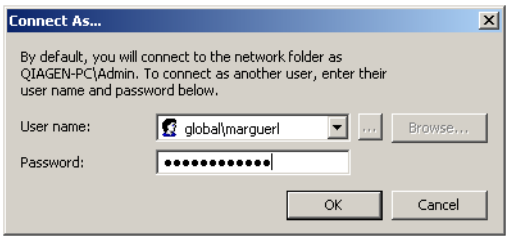
A window should briefly popup "**Attempting to connect to \\192.168.188.12\LaMa...**" and then the if the operation is successful windows will directly open the newly setup shared folder.

If you open “**My Computer**” you should now see the new shared folder.



If you are trying to share a drive located on a PC requiring another user logon, then click on “Connect using a different user name.” and enter the user’s login information in the window that as opened.

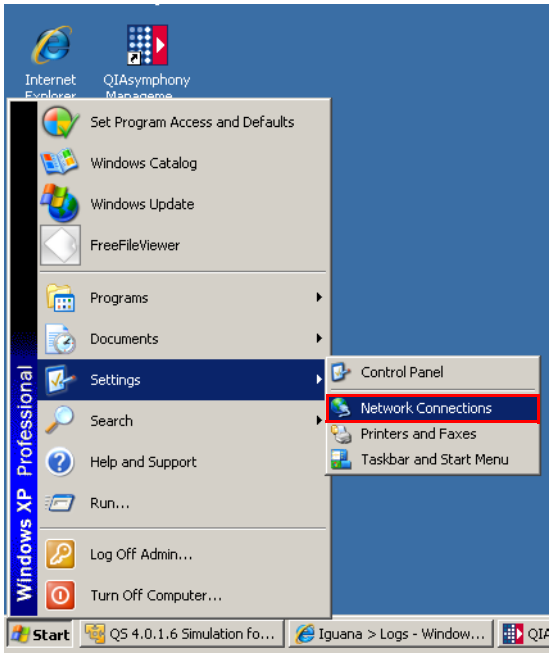




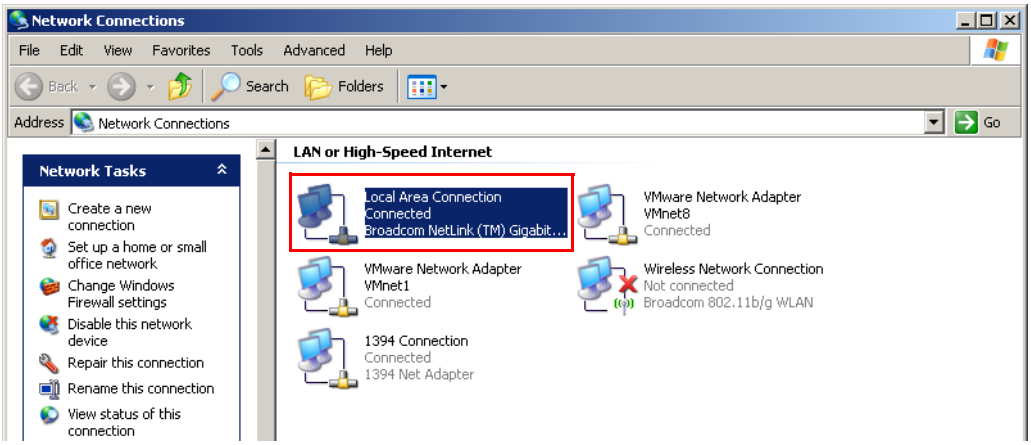
8.3.2 De activate firewalls

In some cases it will be required to disable the firewall to allow connections, to do it proceed as follows:

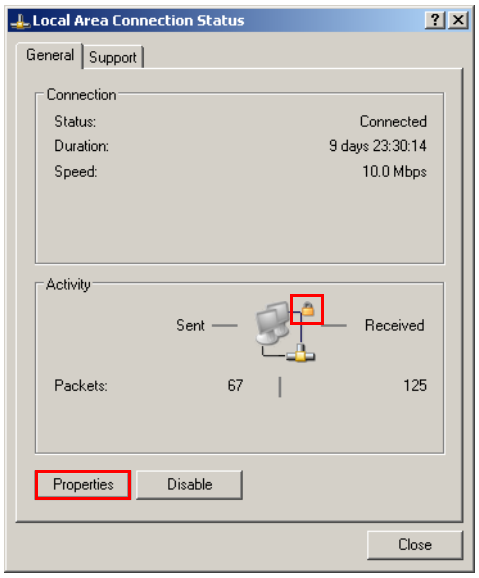
1. In the “Start” menu, select “Settings\Network Connections”.



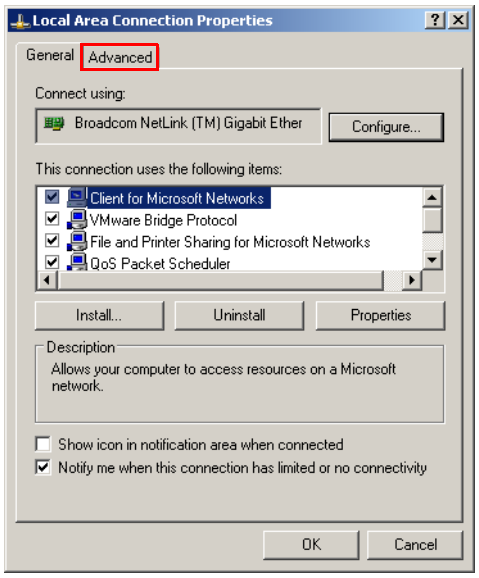
2. Choose the connection you want to disable the firewall for:



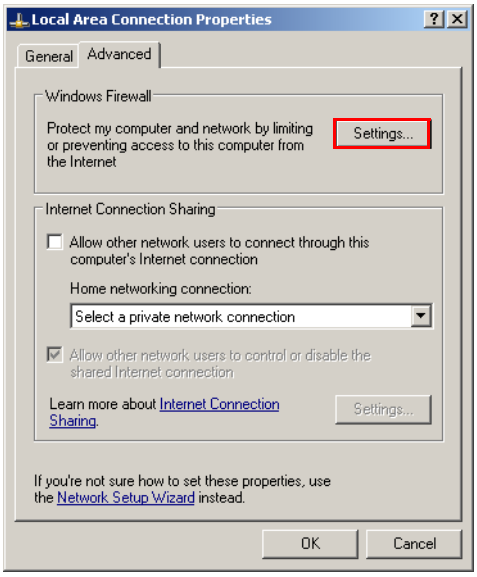
3. Note the little lock indicating that the firewall is “**ON**” on the picture below:



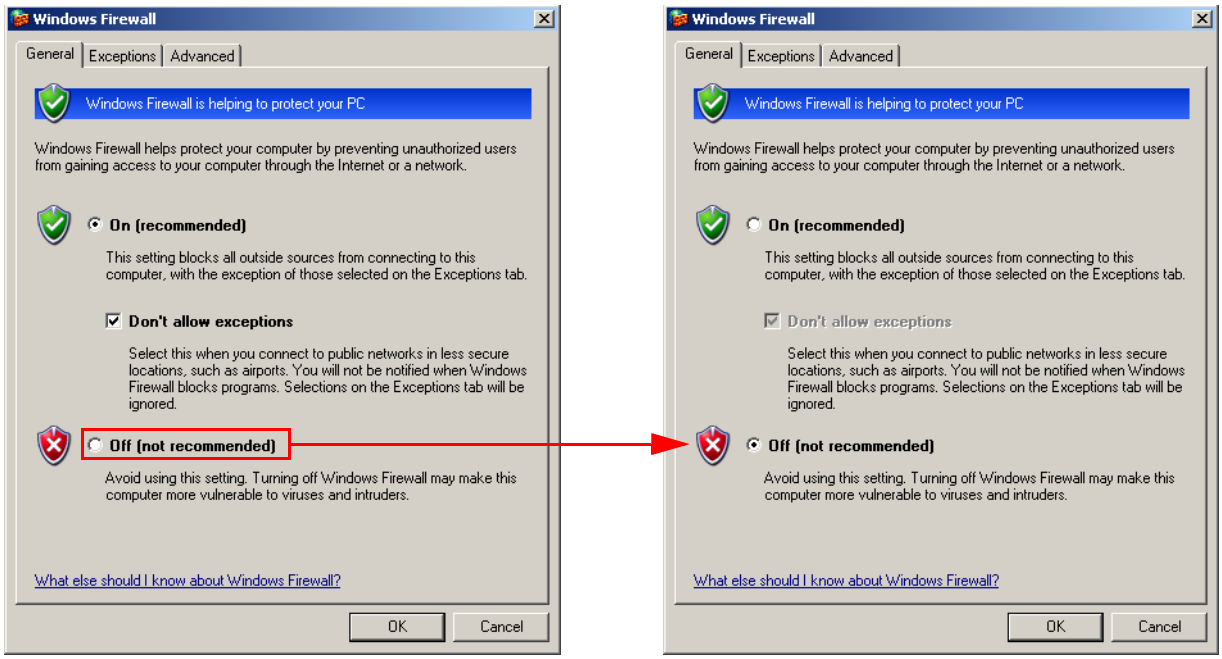
4. Click on “**Properties**”, the following window will open:



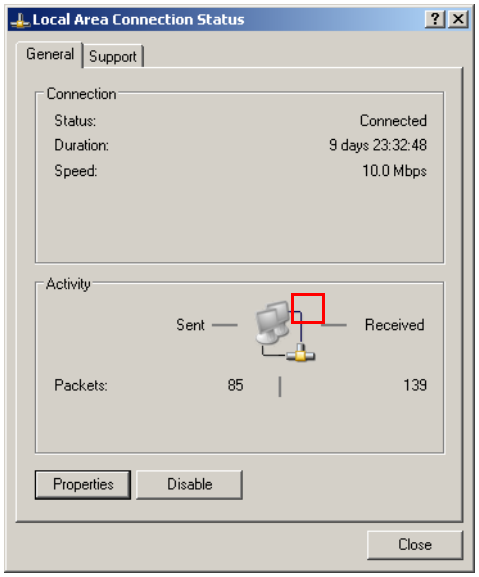
5. Select the "**Advanced**" tab and click "**Settings**".



6. Turn the firwall "**OFF**".



7. The “Local Area Connection Status” window should now look as on the picture below:
(the little lock should have disappeared)



8. The firewall is now inactive.

8.3.3 ping <IP>

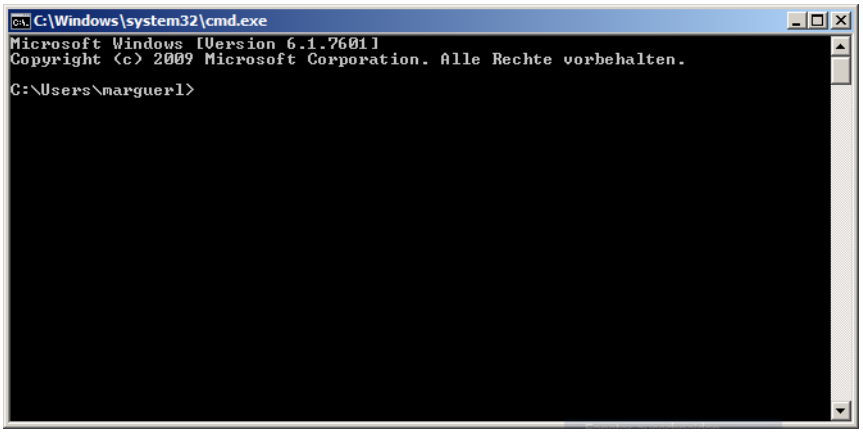
PING tests the connection between two network nodes by sending packets to a host and then reporting the time it takes to get a response. The nodes can be in a Local Area Network, Wide Area Network or anywhere on the internet.

Ping operates by sending echo request packets to the target host and waiting for a response. The time from transmission to reception (round-trip time) is measured and packet losses are recorded.

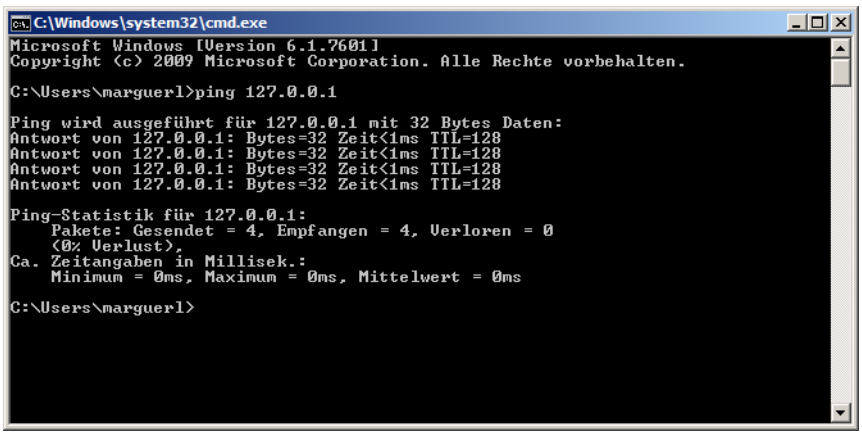
The results of the test are then displayed in the form of a statistical summary of the response packets received, including the minimum, maximum, and the mean round-trip times.

To check if a remote host can be reached via a router, follow these instructions:

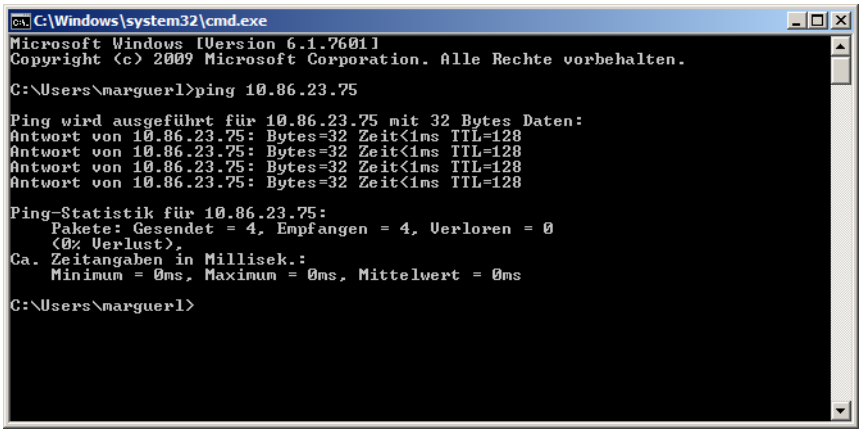
9. Start \ cmd



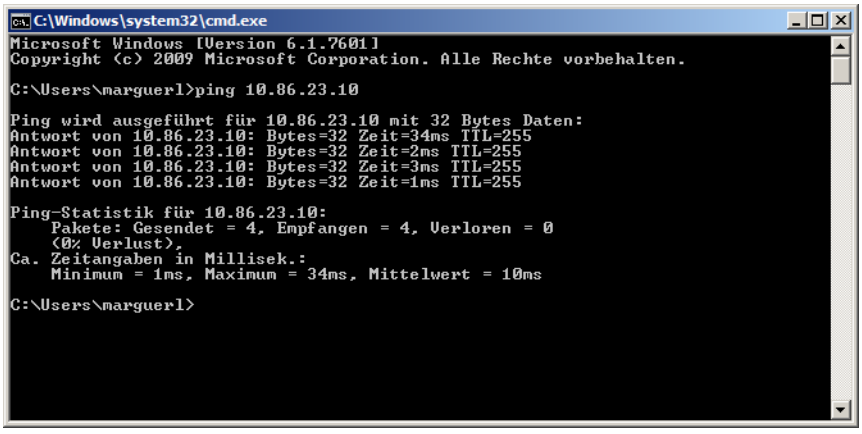
10. First type “PING 127.0.0.1” (loop back address) to verify that TCP/IP is installed and configured correctly on the local computer.



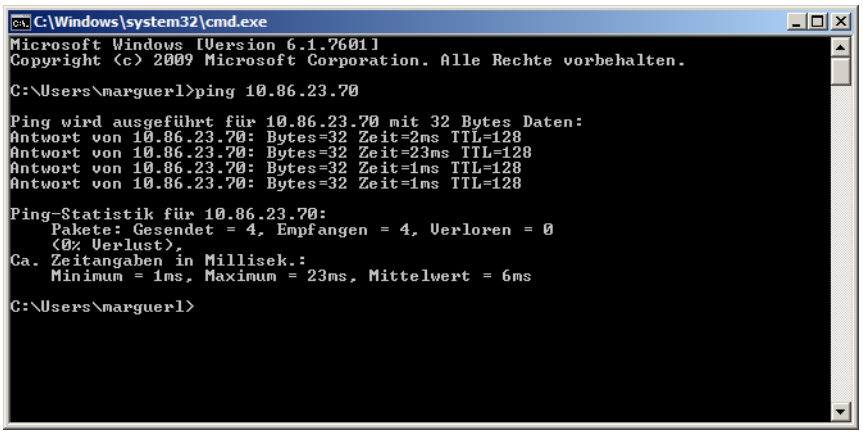
11. Then ping the IP of the local computer to verify that it was added to the network correctly:



12. Ping the IP address of the default gateway to verify that it is functioning and that you can communicate with a local host on the local network:

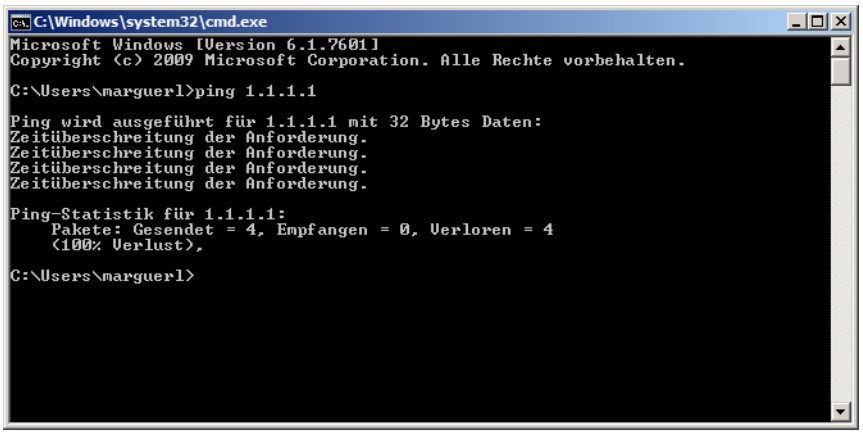


13. Finally ping the IP address of the remote host to verify that you can communicate through a router:



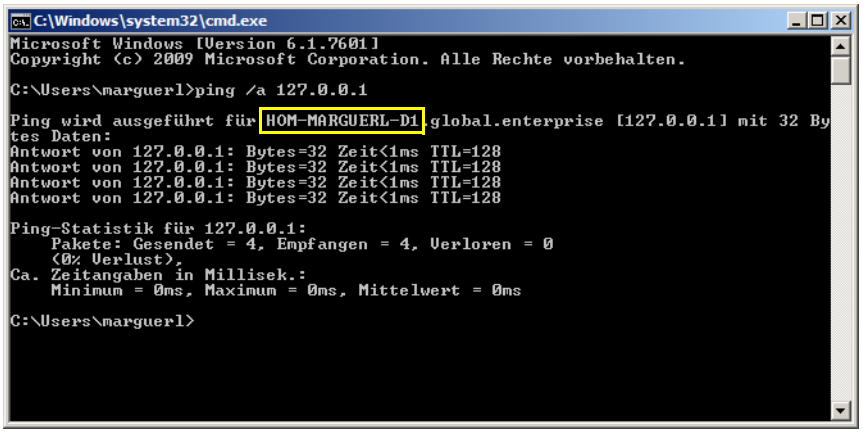
8

If the ping returns time out, and the IP you are trying to reach exists then there is a problem with the connection. Ask the customer's IT to support re establishing a reliable connection.



8.3.3.1 ping /a <IP>

Another useful usage of ping: ping /a <IP address>, when using this command the following will be returned:

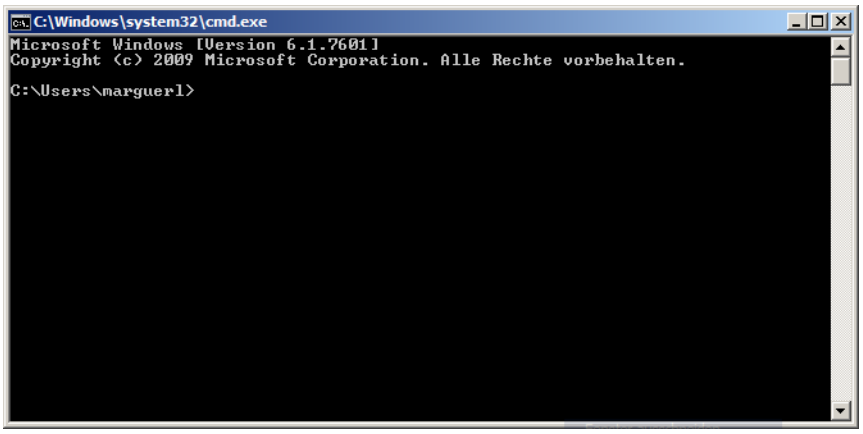


This is a quick way to check the reachability of a remote computer and to get the hostname of the local computer.

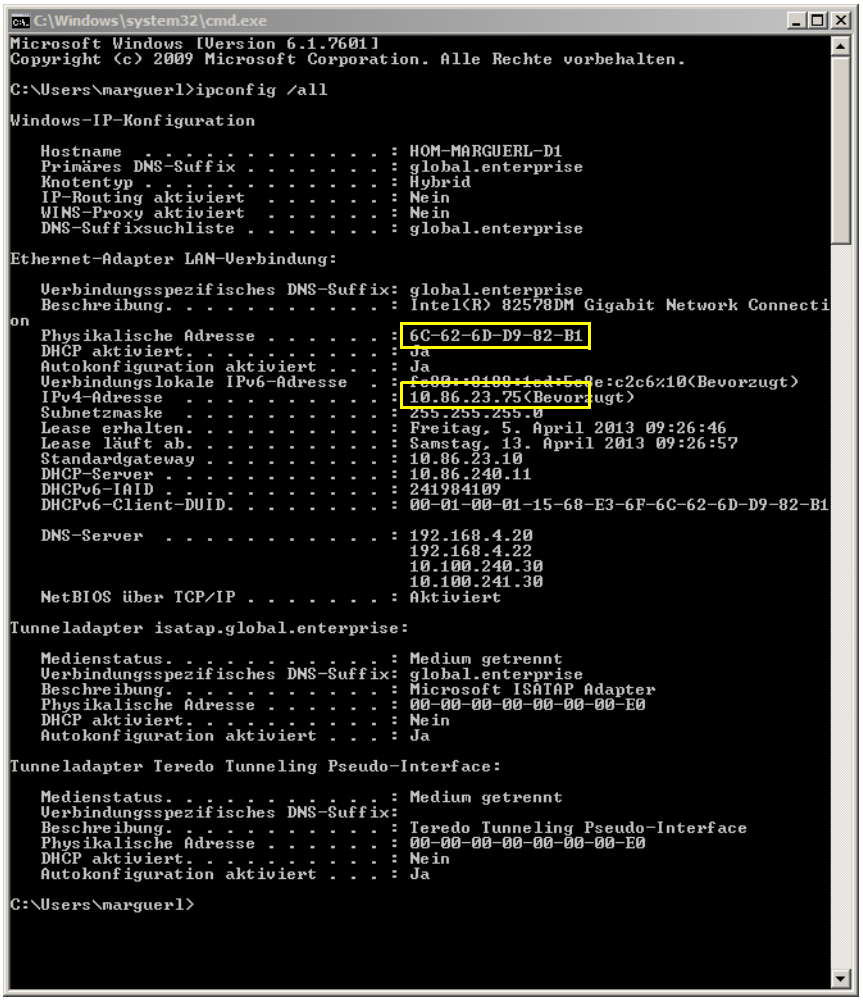
8.3.4 ipconfig

A quick way to find the IP address, the hostname and other TCP /IP parameter is to open a command shell:

14. Start \ cmd



15. Type “**ipconfig /all**”



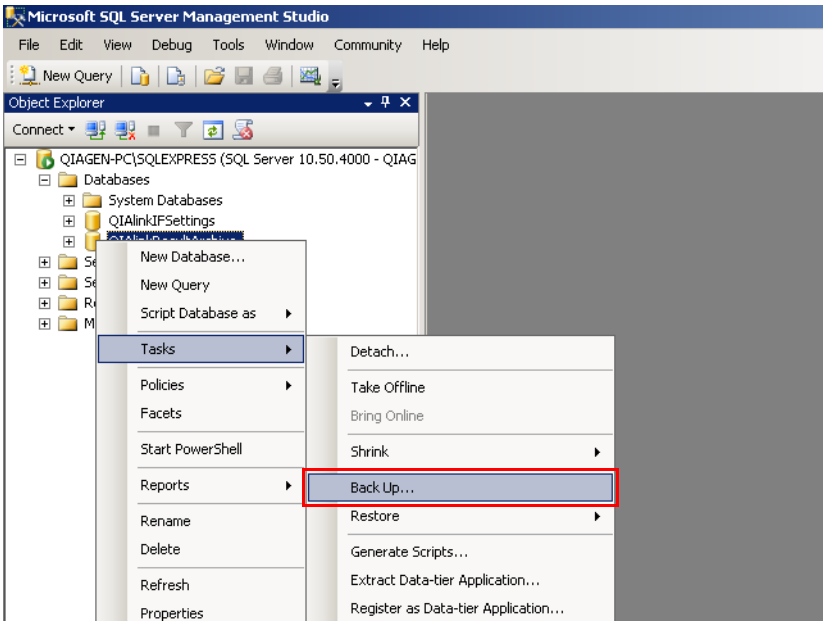
8.4 Backup / restore SQL Databases

8.4.1 How to backup a SQL database

This procedure requires the **SQL Server Management Studio**, this utility can be downloaded for free from the Microsoft website.

1. Open **SQL Server Management Studio** and connect to the appropriate instance of **Microsoft SQL Server Database Engine** in **Object Explorer** (QIAGEN-PC\QIALINK, SQLEXPRESSS). It has to be the server used to store the QIAlink data.

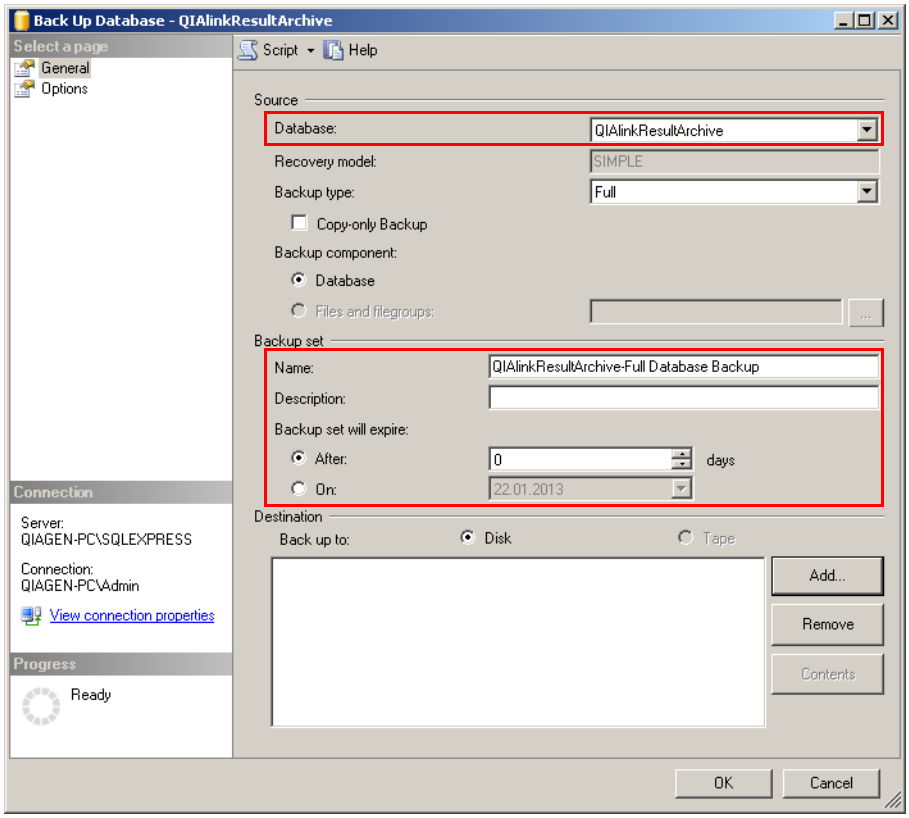
2. Expand **Databases** node and then right click the database which you want to take a full backup and point to **Tasks**, and then click **Back Up…** option as shown in the below screenshot to open up **Back Up Database** dialog box.



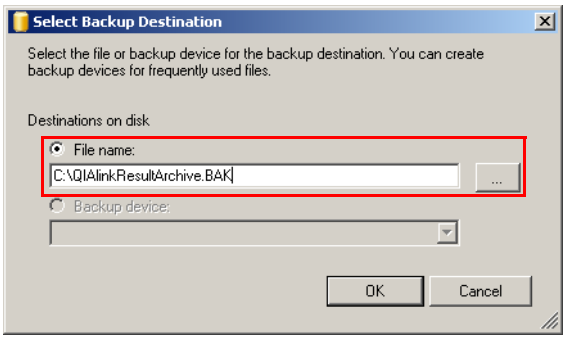
3. In **Back Up Database** Dialog box, in Database List box, verify the database name. Optionally you can even select a different database to backup. You will be able to perform a Full Backup of a database which is **FULL, BULK_LOGGED** or **Simple** recovery model.

4. In **Backup type** list box select Full. Once you have taken a full backup of a database then you can perform **Differential backup** or **Transactional log backups**. However, if your database is in Simple recovery model you will not be able to take a Transactional log backup. This is by design from Microsoft.

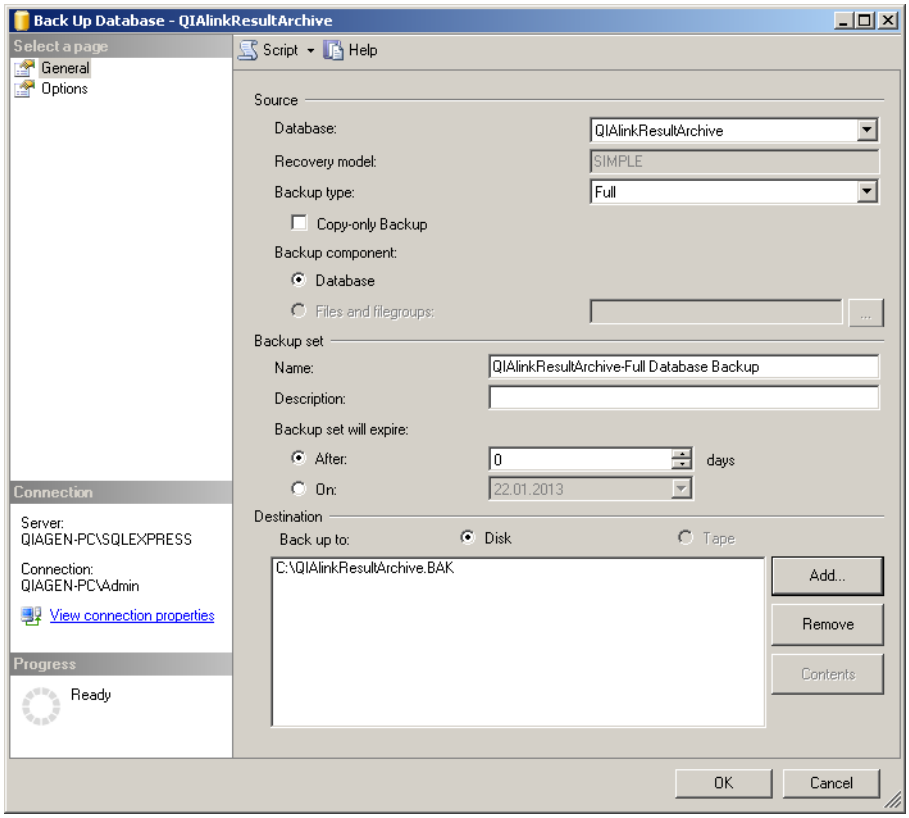
5. If you want to perform a **Copy-Only** backup of a database then choose **Copy-Only Backup** option in Back Up Database Dialog box. Using copy-only backup option you can take a full, differential or transactional log backup which is independent of the sequence of conventional SQL Server backups. The copy-only backup option was introduced in SQL Server 2005.
6. In **Backup Component** select **Databases** and in **Backup** set leave the default Name and optionally enter Description. Leave the default value as 0 days for **Backup set will expire after** option



7. Click the **Add** button to **select the file or backup device for the backup destination** as shown in the below screenshot and click OK to return to Backup Database Dialog box.

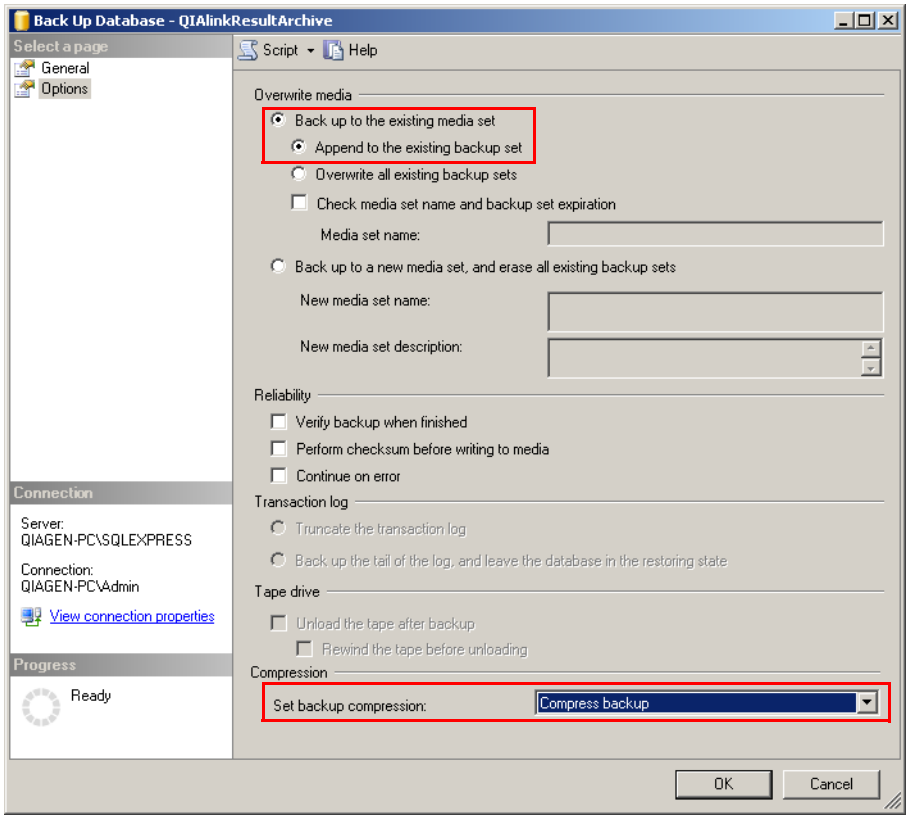


8. Once you have completed the **General settings** you will be able to see a screen similar to below screenshot.

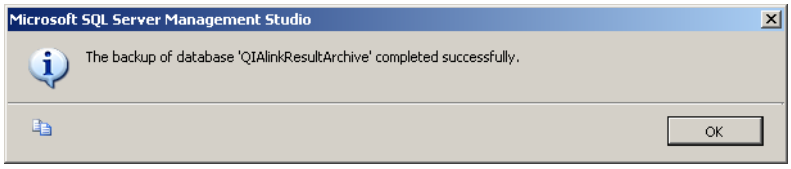


9. Select **Options** in the **Select a page** panel to view the advanced options. In **Overwrite Media** choose **Back up to the existing media** set and **Append to the existing backup** set option as shown in the below screenshot.

10. Under **Reliability** section, you can select the checkbox **Verify backup when finished** option. By selecting this option you can make sure the database backup is good.

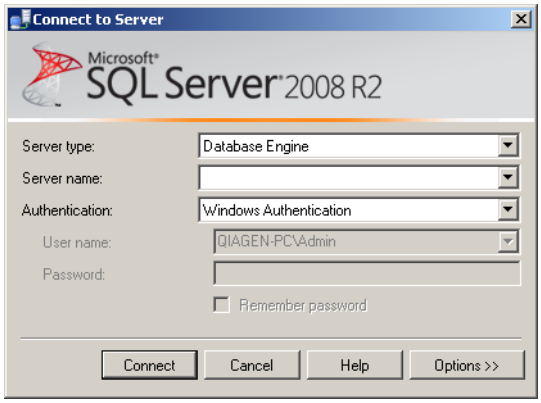


11. Under **Compression** section, you can select the Compress backup from the drop down list as shown in the below screenshot. Microsoft introduced Database Backup Compression Feature in SQL Server 2008 for Enterprise Edition.
12. Once the database is successfully backed up you will get a popup message similar to the one shown in below screenshot.

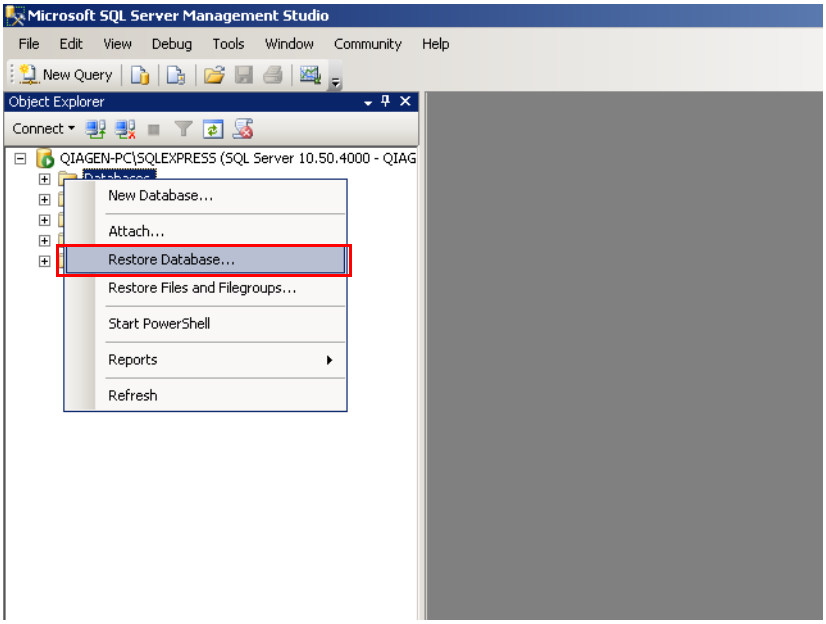


8.4.2 How to restore a SQL database

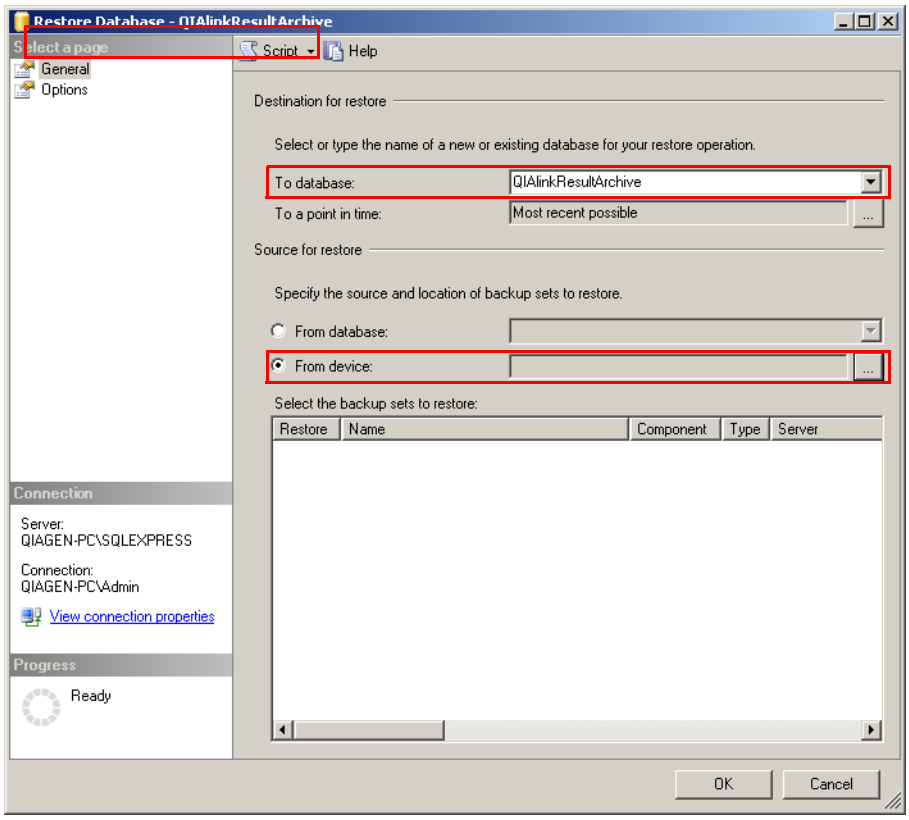
1. Open **SQL Server Management Studio** and connect to the appropriate instance of **Microsoft SQL Server Database Engine** in **Object Explorer**.



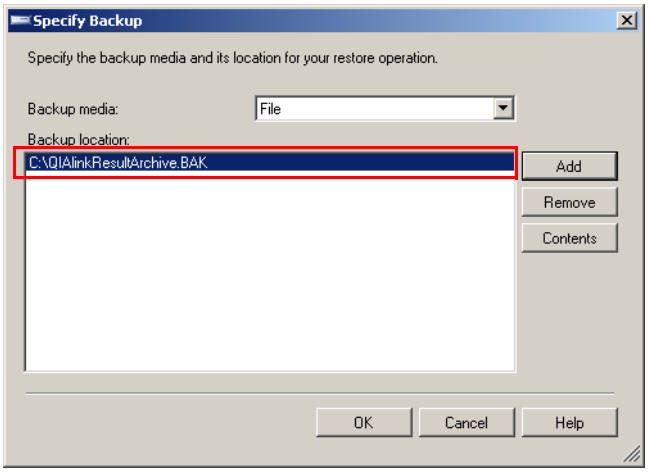
2. Right click **Databases** node and then select **Restore Database…** option from the drop down list as shown in the below screenshot to open up **Restore Database** dialog box.



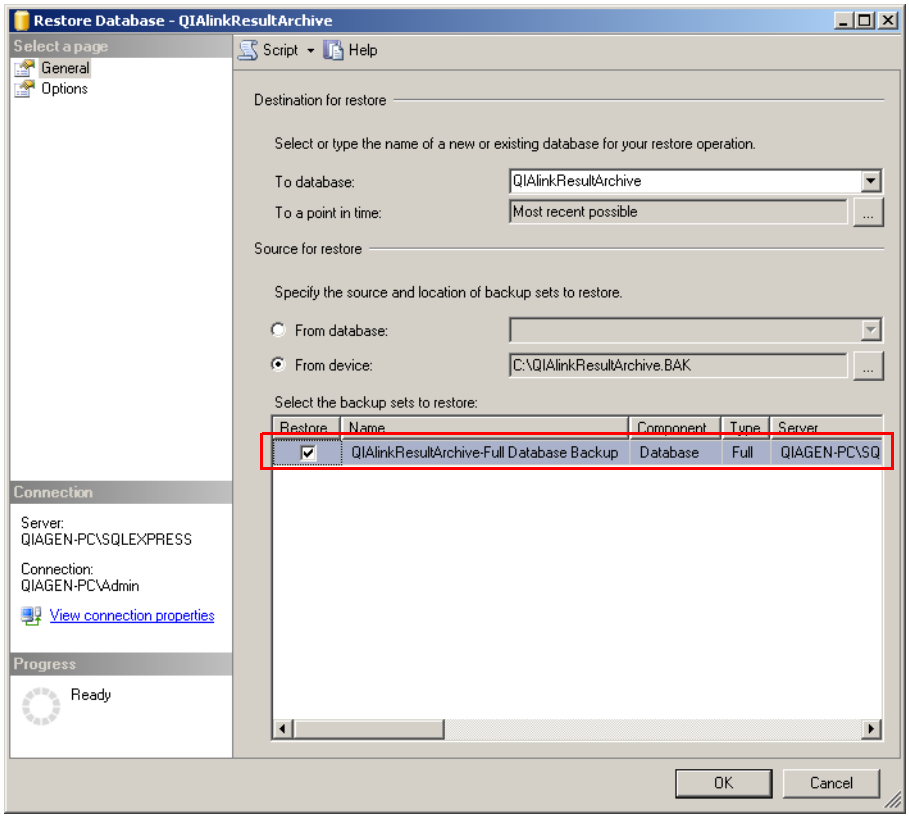
3. In **General Page** of Restore Database dialog box, select or type the name of a new or existing database for your restore operation. In **Source for restore** specify the source and location of backup sets to restore. Choose **From Device** radio button and then click the "**…**" button to specify backup file location.



4. In **Specify Backup** dialog box choose **File** as **Backup Media** and then click the **Add** button to choose the **location of database backup file** from which you want to restore the database as shown in the below screenshot. Click **OK** to return to **Restore Database** dialog box.

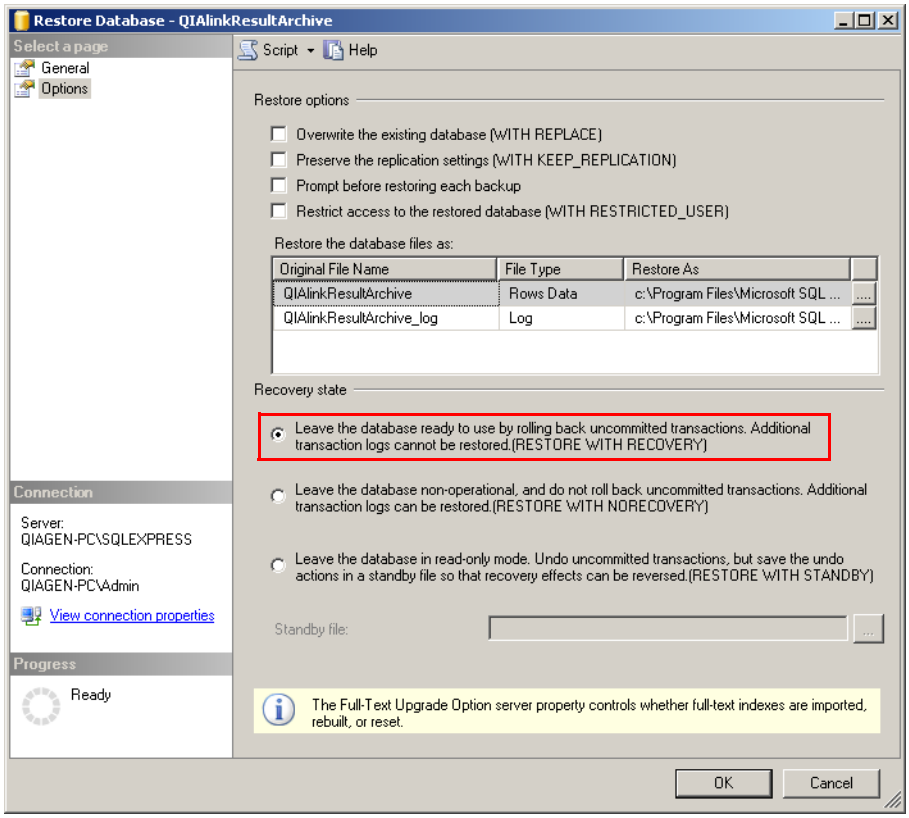


5. In **Restore Database Dialog box** select the **checkbox** under **Restore** as shown in the below screenshot and then select **Option Page** from the left panel.

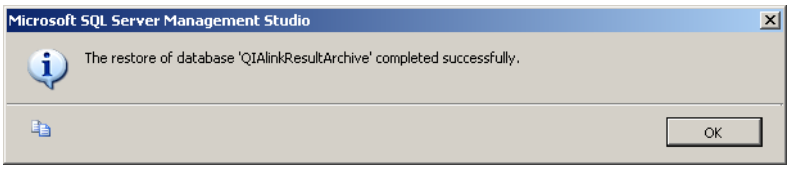


6. In **Options Page** of **Restore Database** dialog box select the **checkbox** next to **Overwrite the existing database (WITH REPLACE)** and choose the radio button next to **Leave the database ready to use by rolling back uncommitted transactions. Additional transactional logs cannot be restored.**

(RESTORE WITH RECOVERY) as shown in the below snippet. Finally, click **OK** to start restoring the SQL Server Database.



7. Once the database is successfully restored you will get a popup message similar to the one shown in below screenshot.



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