

May 2019

Rotor-Gene AssayManager[®] v2.1 Core Application User Manual



REF

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R2

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Rotor-Gene AssayManager v2.1 Core Application User Manual

1 Rotor-Gene AssayManager v2.1 Core Application User Manual - May 2019



QIAGEN Rotor-Gene AssayManager v2.1 Online Help Recommended readings

For all users

- ▶ Introduction
- ▶ Basic concepts
- ▶ Using Rotor-Gene AssayManager v2.1
- ▶ Troubleshooting
- ▶ Abbreviations
- ▶ Glossary
- ▶ Appendices

For operators

Operators set up and start a run.

- ▶ Setting up a run
- ▶ Starting a run
- ▶ Finishing/releasing a run

For administrators

Administrators are responsible for the initial installation. They manage all assets (e.g., cyclers, assay profiles, users) necessary for working with Rotor-Gene AssayManager v2.1.

- ▶ Getting started
- ▶ Managing assay profiles
- ▶ Managing report profiles
- ▶ Managing users
- ▶ Managing cyclers

For approvers

Approvers assess the results of a run, make decisions on the validity of an experiment and releases the results.

The decision on the validity is not made for most of the plug-ins.

- ▶ Approving a run
- ▶ Working with reports

1.1 Safety Information

The user-friendly Rotor-Gene AssayManager v2.1 software has been specifically developed for use with up to four different Rotor-Gene® Q instruments. Before using Rotor-Gene AssayManager v2.1 software, it is essential that you carefully read this user manual, paying particular attention to the "Safety Information" chapter. The instructions and safety information must be followed to ensure safe operation of the cyclor and to maintain the instrument in a safe condition.

Rotor-Gene AssayManager v2.1 Core Application User Manual does not provide detailed information about Rotor-Gene Q instrument hardware and maintenance. The user manual only describes the functionality of the Rotor-Gene AssayManager v2.1 software in combination with Rotor-Gene Q instruments.

Note

The terms "Rotor-Gene Q" and "Rotor-Gene Q instrument", used in this manual, apply to all Rotor-Gene Q and Rotor-Gene Q MDx instruments (not available in all countries) unless otherwise specified.

Safety information for the Rotor-Gene Q cyclor

The following types of safety information appear throughout the Rotor-Gene Q cyclor manual.

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

<p>CAUTION</p> 	<p>The term CAUTION is used to inform you about situations that could result in damage to the instrument or other equipment. Details about these circumstances are given in a box like this one.</p>
--	--

The advice given in the Rotor-Gene Q cyclor manual is intended to supplement, not supersede, the normal safety requirements prevailing in the user's country.

Proper use

<p>WARNING/ CAUTION</p> 	<p>Risk of personal injury and material damage [W1] Improper use of the Rotor-Gene Q may cause personal injuries or damage to the instrument. The Rotor-Gene Q must only be operated by qualified personnel who have been appropriately trained. Servicing of the Rotor-Gene Q must only be performed by QIAGEN Field Service Specialists.</p>
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QIAGEN charges for repairs that are required due to incorrect maintenance.

<p>WARNING/ CAUTION</p> 	<p>Risk of personal injury and material damage [W2] Rotor-Gene Q is a heavy instrument. To avoid personal injury or damage to the instrument, take care when lifting.</p>
---	--

<p>WARNING/ CAUTION</p> 	<p>Risk of personal injury and material damage [W3] Do not attempt to move the Rotor-Gene Q during operation.</p>
---	--

<p>CAUTION</p> 	<p>Damage to the instrument [C1] Avoid spilling water or chemicals onto the Rotor-Gene Q. Damage caused by water or chemical spillage will void your warranty.</p>
--	---

Note

In case of emergency, switch off the Rotor-Gene Q at the power switch at the back of the instrument and unplug the power cord from the power supply port.

<p>WARNING/ CAUTION</p> 	<p>Risk of personal injury and material damage [W4] Do not try to open the lid during an experiment or while the Rotor-Gene Q is spinning. Otherwise, if you overcome the lid lock and reach inside, you risk contact with parts that are hot, electrically live, or moving at high speed, and you may injure yourself and damage the instrument.</p>
---	--

<p>WARNING/ CAUTION</p> 	<p>Risk of personal injury and material damage [W5] If you need to stop an experiment quickly, turn off the power to the instrument, then open the lid. Let the chamber cool before reaching inside. Otherwise you risk injury by touching parts that are hot.</p>
---	---

<p>WARNING/ CAUTION</p> 	<p>Risk of personal injury and material damage [W6] If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.</p>
---	--

<p>WARNING/ CAUTION</p> 	<p>Risk of personal injury and material damage [W7] Loose paper underneath the Rotor-Gene Q interferes with instrument cooling. It is recommended that the area beneath the instrument is kept free of clutter.</p>
---	--

<p>CAUTION</p> 	<p>Damage to the instrument [C2] Always use a locking ring on the rotor. This stops caps from coming off tubes during an experiment. If caps come off during an experiment, they may damage the chamber.</p>
--	---

If you touch the Rotor-Gene Q during an experiment, while you are charged with static electricity, in severe cases the Rotor-Gene Q may reset. However, the software will restart the Rotor-Gene Q and continue the experiment.

Electrical safety

Disconnect the line power cord from the power supply port before servicing.

<p>WARNING</p> 	<p>Electrical hazard [W8] Any interruption of the protective conductor (earth/ground lead) inside or outside the instrument or disconnection of the protective conductor terminal is likely to make the instrument dangerous. Intentional interruption is prohibited. Lethal voltages inside the instrument. When the instrument is connected to line power, terminals may be live, and opening covers or removing parts is likely to expose live parts.</p>
--	--

To ensure satisfactory and safe operation of the Rotor-Gene Q, follow the advice below:

- The line power cord must be connected to a line power outlet that has a protective conductor (earth/ground).
- Do not adjust or replace internal parts of the instrument.
- Do not operate the instrument with any covers or parts removed.
- If liquid has spilled inside the instrument, switch off the instrument, disconnect it from the power outlet, and contact QIAGEN Technical Services.

If the instrument becomes electrically unsafe, prevent other personnel from operating it, and contact QIAGEN Technical Services; the instrument may be electrically unsafe when:

- It or the line power cord appears to be damaged.
- It has been stored under unfavorable conditions for a prolonged period.
- It has been subjected to severe transport stresses.

<p>WARNING</p> 	<p>Electrical hazard [W9] The instrument has an electrical compliance label which indicates the voltage and frequency of the power supply as well as fuse ratings. The equipment should only be operated under these conditions.</p>
--	---

Environment

Operating conditions

WARNING 	Explosive atmosphere [W10] The Rotor-Gene Q is not designed for use in an explosive atmosphere.
---	---

WARNING 	Risk of explosion [W11] The Rotor-Gene Q is intended for use with reagents and substances supplied with QIAGEN kits. Use of other reagents and substances may lead to fire or explosion.
---	--

CAUTION 	Damage to the instrument [C3] Direct sunlight may bleach parts of the instrument and cause damage to plastic parts. The Rotor-Gene Q must be located out of direct sunlight.
--	---

Biological safety

Specimens and reagents containing materials from biological sources should be treated as potentially infectious. Use safe laboratory procedures as outlined in publications such as *Biosafety in Microbiological and Biomedical Laboratories*, HHS
▶ <http://www.cdc.gov/biosafety>.

Samples

Samples may contain infectious agents. You should be aware of the health hazard presented by such agents and should use, store, and dispose of such samples according to the required safety regulations.

<p>WARNING</p> 	<p>Samples containing infectious agents [W12] Some samples used with this instrument may contain infectious agents. Handle such samples with the greatest of care and in accordance with the required safety regulations. Always wear safety glasses, 2 pairs of gloves, and a lab coat. The responsible body (e.g., laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe, and that the instrument operators are suitably trained and not exposed to hazardous levels of infectious agents as defined in the applicable Safety Data Sheets (SDSs) or OSHA,* ACGIH,† or COSHH‡ documents. Venting for fumes and disposal of wastes must be in accordance with all national, state, and local health and safety regulations and laws.</p>
--	--

- * OSHA Occupational Safety and Health Administration (United States of America).
- † ACGIH American Conference of Government Industrial Hygienists (United States of America).
- ‡ COSHH Control of Substances Hazardous to Health (United Kingdom).

Chemicals

<p>WARNING</p> 	<p>Hazardous chemicals [W13] Some chemicals used with this instrument may be hazardous or may become hazardous after completion of the protocol run. Always wear safety glasses, gloves, and a lab coat. The responsible body (e.g., laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe and that the instrument operators are not exposed to hazardous levels of toxic substances (chemical or biological) as defined in the applicable Safety Data Sheets (SDSs) or OSHA,* ACGIH,† or COSHH‡ documents. Venting for fumes and disposal of wastes must be in accordance with all national, state, and local health and safety regulations and laws.</p>
--	--

- * OSHA Occupational Safety and Health Administration (United States of America).
- † ACGIH American Conference of Government Industrial Hygienists (United States of America).
- ‡ COSHH Control of Substances Hazardous to Health (United Kingdom).

<p>WARNING</p> 	<p>Risk of fire [W14] When cleaning the Rotor-Gene Q with alcohol-based disinfectant, leave the Rotor-Gene Q door open to allow flammable vapors to disperse. Only clean the Rotor-Gene Q when worktable components have cooled down.</p>
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Toxic fumes

If working with volatile solvents or toxic substances, you must provide an efficient laboratory ventilation system to remove vapors that may be produced.

Waste disposal

Used consumables and plasticware may contain hazardous chemicals or infectious agents. Such wastes must be collected and disposed of properly according to local safety regulations.

Mechanical hazards

The lid of the Rotor-Gene Q must remain closed during operation of the instrument.

WARNING 	Moving parts [W15] To avoid contact with moving parts during operation of the Rotor-Gene Q, the instrument must be operated with the lid closed.
--	---

WARNING/ CAUTION 	Risk of personal injury and material damage [W16] Open and close the lid of the Rotor-Gene Q carefully to avoid trapping fingers or clothing.
--	--

CAUTION 	Damage to the instrument [C4] Make sure that the rotor and locking ring are installed correctly. If the rotor or locking ring show signs of mechanical damage or corrosion, do not use the Rotor-Gene Q; contact QIAGEN Technical Services.
--	--

CAUTION 	Damage to the instrument [C5] The Rotor-Gene Q must not be used if the lid is broken or if the lid lock is damaged. Make sure that the rotor and locking ring are installed correctly. Only use rotors, locking rings, and consumables designed for use with the Rotor-Gene Q. Damage caused by use of other consumables will void your warranty.
--	---

<p>CAUTION</p> 	<p>Damage to the instrument [C6] When Rotor-Gene Q is started immediately after delivery in cold climates, mechanical parts can block. Allow the instrument to acclimatize to room temperature for at least one hour before turning the instrument on.</p>
--	---

<p>WARNING</p> 	<p>Moving parts [W17] In case of breakdown caused by power failure, remove the power cord and wait 10 minutes before attempting to manually open the lid.</p>
--	---

<p>WARNING</p> 	<p>Risk of overheating [W18] To ensure proper ventilation, maintain a minimum clearance of 10 cm at the sides and rear of the Rotor-Gene Q. Slits and openings that ensure the ventilation of the Rotor-Gene Q must not be covered.</p>
--	--

Heat hazard

<p>WARNING</p> 	<p>Hot surface [W19] The Rotor-Gene Q chamber can reach temperatures above 120°C (248°F). Avoid touching it when it is hot.</p>
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<p>WARNING</p> 	<p>Hot surface [W20] When a run is paused, the Rotor-Gene Q will not be cooled completely to room temperature. Exercise caution before handling the rotor or any tubes in the instrument.</p>
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1.2 Introduction

Thank you for choosing Rotor-Gene AssayManager v2.1. We are confident it will become an integral part of your laboratory.

Rotor-Gene AssayManager v2.1 is a software for routine testing in combination with Rotor-Gene Q instruments. Rotor-Gene AssayManager v2.1 is able to read in sample information, set up experiments, control up to four different Rotor-Gene Q cyclers, acquire data from these instruments, automatically analyze results, and create reports.

Rotor-Gene AssayManager v2.1 consists of different components working together. The core application v2.1 is complemented by different plug-ins that contain assay type specific analysis and visualization of the results. The core application v2.1 is mandatory for working with Rotor-Gene AssayManager v2.1 and at least one plug-in must be installed. Optionally, additional plug-ins can be installed. Not all plug-ins may be available in all countries. Refer to www.qiagen.com/Products/Rotor-GeneAssayManager_v2_1.aspx to discover our continuously expanding range of plug-ins.

1.2.1 Provided User Manuals

The core application v2.1 as well as every available plug-in has its own user manual with specific information about the functionality of the different Rotor-Gene AssayManager v2.1 components. Rotor-Gene AssayManager v2.1 provide a context sensitive help that can be started by simply pressing the "F1" key. components. When installing additional plug-ins, the corresponding user manuals are automatically added to the existing help system. Alternatively the different user manuals can be accessed, read, and printed as *.pdf files.

Rotor-Gene AssayManager v2.1 Core Application User Manual	Provides a description of the software and describes functions that are the same for the core application and all different plug-ins. Information about troubleshooting is also provided.
Rotor-Gene AssayManager v2.1 Plug-in User Manuals	Provide details on how to use the assay type specific plug-ins and their functionalities.

1.2.2 About this User Manual

This user manual provides information about Rotor-Gene AssayManager v2.1 Core Application in the following sections:

1. ▶ Introduction
2. ▶ Intended use of Rotor-Gene AssayManager v2.1
3. ▶ Getting started including installing Rotor-Gene AssayManager v2.1
4. ▶ Basic concept and general software usage
5. ▶ Using Rotor-Gene AssayManager v2.1
6. ▶ Maintenance
7. ▶ Troubleshooting
8. ▶ Abbreviations
9. ▶ Glossary

The ▶ appendices contain the following:

- ▶ File endings
- ▶ Liability clause
- ▶ License terms

Note

The screenshots show examples of how to use the Rotor-Gene AssayManager v2.1 software. Some of the names used in this manual are only examples and may look different in the lab of the end user. This particularly applies to the use of cyclers names.

In this manual, the cycler names "Cycler 1", "Cycler 2", "Cycler 3", and "Cycler 4" are used. Further information about how to configure cycles can be found under ▶ Managing cyclers and ▶ Cycler management.

1.2.3 General Information

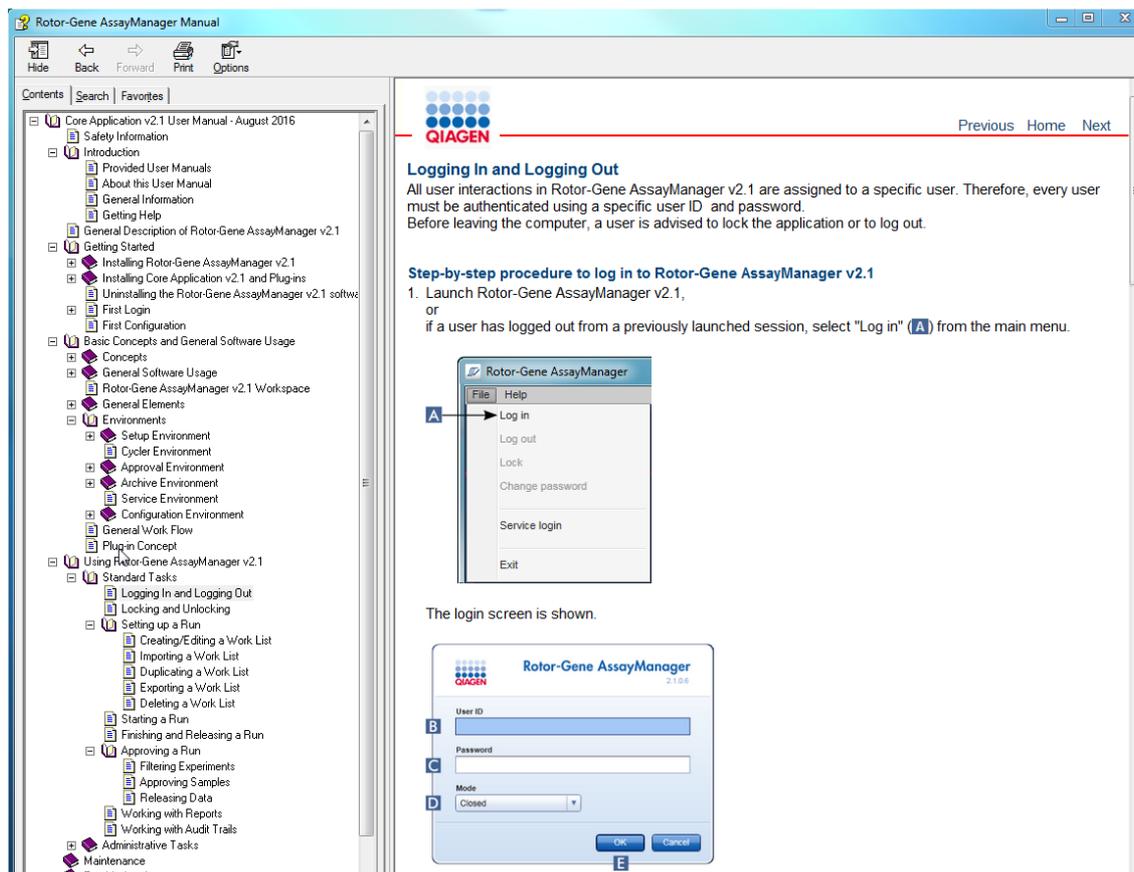
Policy Statement

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

In an effort to produce useful and appropriate documentation, we appreciate your comments on this user manual. Therefore contact the QIAGEN Technical Services.

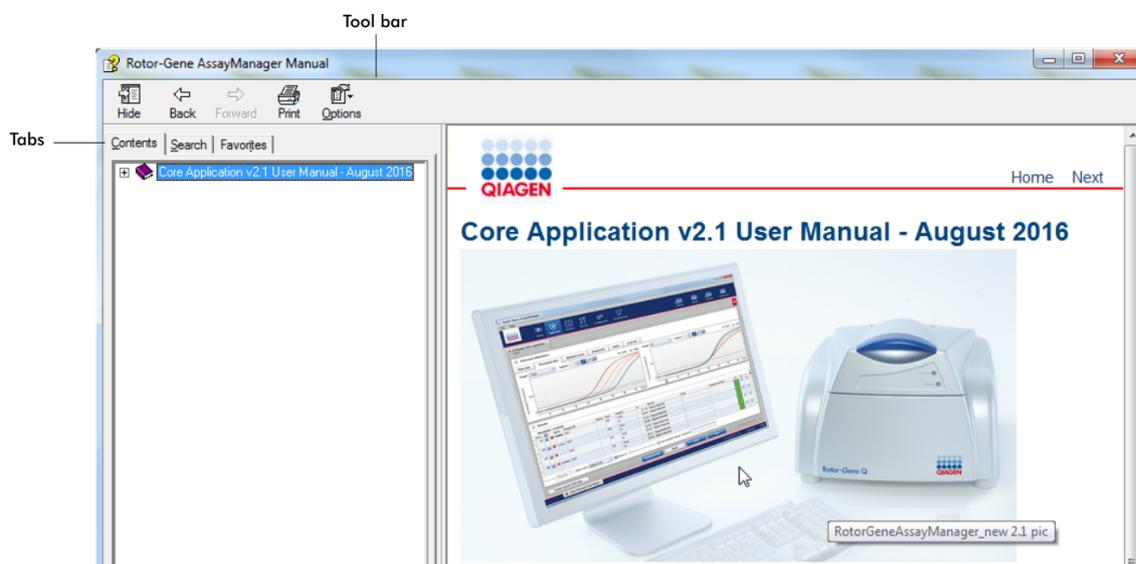
1.2.4 Getting Help

Rotor-Gene User AssayManager v2.1 comes with a detailed help system. The help is provided as *.pdf file and as *.chm file (compiled help file). The following image shows the help page corresponding to the login screen as an example:



Rotor-Gene AssayManager v2.1 has a context-sensitive help system. After pressing the "F1" key in dialogs, a context-sensitive help page is shown.

Using Rotor-Gene AssayManager v2.1 Help



The help file contains two functional areas:

- Tool bar
- Tabs

The tool bar contains the following buttons:

Name	Icon	Description
"Hide" or "Show"		Hides the left-hand side navigation tab. To display the navigation tab again, click "Show". This button appears instead of "Hide".
"Back"		Returns to the previous screen.
"Forward"		Returns to the screen displayed before using the "Back" button.

"Print"		The user has the choice: 1) Print the selected topic. 2) Print the selected heading and all subtopics. Select one option and confirm with "OK" or select "Cancel" to go back.
"Options"		Opens the options menu with the following entries:

Hide Tabs
Back
Forward
Home
Stop
Refresh
Internet Options...
Print...
Search Highlight Off

The navigation tab contains the following tabs:

Name	Description
"Contents"	In the "Contents" tab the help content can be browsed by topics.
"Search"	Specific help topics can be found by entering search terms.
"Favorites"	Shortcuts to individual help topics can be added and managed

1.3 General Description of Rotor-Gene AssayManager v2.1

Product Configuration

Rotor-Gene AssayManager v2.1 is a software for routine testing in combination with the Rotor-Gene Q real-time PCR instruments.

The software consists of a core application v2.1 and modular plug-ins and assay profiles. The specific combination of core application v2.1, plug-in and assay profile determines a specific routine testing application. Rotor-Gene AssayManager v2.1 allows control and operation of the Rotor-Gene Q instrument and contains algorithms for analysis of data generated with the Rotor-Gene Q. Rotor-Gene AssayManager v2.1 supports the user in importing sample specific information and in performing all aspects of the experiment result analysis procedure. The result analysis is started and

processed fully automatically after finishing an experiment, and appropriate result reports can be generated.

Rotor-Gene AssayManager v2.1 does not replace the standard Rotor-Gene Q software with its full breadth of functionalities. Rather it allows running and analyzing PCR tests in a highly controlled environment making use of assay profiles dedicated to specific PCR assays, as well as automated result reporting, thus giving maximum process safety and reliability.

Product Functions

Rotor-Gene AssayManager v2.1 includes these 3 main functionalities:

1) **Cycler control:** Rotor-Gene AssayManager v2.1 controls the Rotor-Gene Q cycler, i.e., the software will provide all functions to set up, start, and run real-time PCR experiments on up to 4 Rotor-Gene Q cyclers in parallel. Rotor-Gene AssayManager v2.1 can also be used for experiment result approval and reporting only. In this case the software can be installed on a computer not necessarily connected to a Rotor-Gene Q cycler.

2) **Data analysis:** Rotor-Gene AssayManager v2.1 analyzes the real-time PCR raw data according to well defined assay specific rules and generates result reports comprising information on the validity or invalidity of the assay and individual samples.

3) **Data management:** Rotor-Gene AssayManager v2.1 imports sample-specific information from QIASymphony® software version 5.0 or via a LIMS. Data from the PCR experiment are then used for analysis. After release of the results the system is able to export data.

Note

The Rotor-Gene AssayManager v2.1 is only compatible with the results files of the QIASymphony software version 5.0.

Modes of Operation

For cyclers control and data analysis, Rotor-Gene AssayManager v2.1 offers 2 modes of operation to the user, the Closed Mode and the User Defined Test Mode.

Closed Mode	User Defined Test Mode (UDT mode)
The Closed Mode is used for assays that have been created and validated by QIAGEN. These assays can only be modified by QIAGEN.	The User Defined Test Mode is used for assays that have been created and validated by a user of the Rotor-Gene AssayManager v2.1 with the user role "Assay Developer".
In Closed Mode, assays are run and analyzed without the permission to modify the corresponding assay profiles.	In User Defined Test Mode, assays are run and analyzed without the permission to modify the corresponding assay profiles.
The analysis in Closed Mode includes core analysis, assay and sample analysis, and, depending on plug-in, also a fully automatic data scan (AUDAS).	The analysis in UDT mode includes only the core analysis and the assay and sample analysis.
To run and analyze an assay in Closed Mode a corresponding closed mode plug-in is required.	To create, run, and analyze an assay in UDT mode a corresponding UDT mode plug-in is required.

Note

For usage of the User Defined Test Mode (UDT mode) functionalities a compatible UDT mode plug-in is required to be installed. A log-in in UDT mode without installation of the corresponding plug-in will give you no access to administrative tasks and you will not be able to perform experiments or analysis.

Requirements for Rotor-Gene AssayManager v2.1 software users

The following table covers the general level of competence and training necessary for delivery, installation, routine use, maintenance, and servicing of the Rotor-Gene AssayManager v2.1 software.

Task	Personnel	Training and experience
Delivery	No special requirements	No special requirements
Installation	Laboratory technicians or equivalent, IT personnel	Basic IT knowledge of installing software
Routine use	Laboratory technicians or equivalent	Professional users such as technicians or physicians, trained in molecular biology techniques and the functionalities of the Rotor-Gene Q
Maintenance	Laboratory technicians or equivalent, IT personnel	Professional users such as technicians or physicians, trained in molecular biology techniques and the functionalities of the Rotor-Gene Q
Service	QIAGEN Technical or Field Service Specialists only	Regularly trained personnel, certified, and authorized by QIAGEN

Training for Rotor-Gene AssayManager v2.1 software users

To use the Rotor-Gene AssayManager v2.1 software no additional special training is required. The user has to read the accompanying documentation before using the Rotor-Gene AssayManager v2.1 software.

1.4 Getting Started

This section of the user manual describes the system requirements for Rotor-Gene AssayManager v2.1 and how to install and configure Rotor-Gene AssayManager v2.1 before the software can be used.

If you download software from the QIAGEN website on a different computer to the one on which the software is to be installed, please make sure that the flash drive used to transfer the software is free of viruses. QIAGEN strongly recommends a virus scan is performed using an up-to-date virus scanner on the flash drive to avoid contamination.

Note: Checksum confirmation is required to secure software integrity after web download was successfully completed and before subsequent handling of the software. Therefore, software checksum verification is requested before installation of any downloaded file is started. For detailed information on confirmation of software integrity during download and file transfer, please check the “QIAGEN software integrity verification process” description document, which is provided on the QIAGEN webpage.

1.4.1 Installing Rotor-Gene AssayManager v2.1

Rotor-Gene AssayManager v2.1 and the corresponding plug-ins are available on QIAGEN.com. The data carrier provides installation, update, and uninstall process for Rotor-Gene AssayManager v2.1, the Rotor-Gene AssayManager database, and the Rotor-Gene AssayManager v2.1 plug-ins (plug-ins are delivered with different data carriers).

Rotor-Gene AssayManager v2.1 uses a database (Microsoft® SQL Server® Express) to store all data. The database can be installed locally or on a remote system. The Microsoft SQL Server database provides backup and restore mechanisms. For detailed information about backup and restore instructions, refer to the “Maintenance” section in the Rotor-Gene AssayManager v2.1 MDx Core Application User Manual .

Note

Future updates of Rotor-Gene AssayManager v2.1 will be provided on the QIAGEN webpage.

Note

Most screenshots in this document were created using Windows 7. If there is no difference between Windows 7 and Windows 10, no additional screenshots were created for Windows 10. A separate description has been added only where the behavior differs between the operating system versions.

Note

Plug-ins cannot be uninstalled. In case you want to uninstall a plug-in, the core application must be uninstalled together with the plug-in. See ► Uninstalling the Rotor-Gene AssayManager v2.1 for details.

Note

It is not possible to install Rotor-Gene AssayManager v2.1 on a computer or an existing database server which already has Rotor-Gene AssayManager v1.0 installed. Rotor-Gene AssayManager v1.0 and v2.1 are independent products and cannot be used in parallel on one system. In addition, Rotor-Gene AssayManager v2.1 does not replace Rotor-Gene AssayManager v1.0.

Rotor-Gene AssayManager v2.1 uses a database (Microsoft SQL Server Express) to store all data. The database can be installed locally or on a remote system.

Rotor-Gene AssayManager v2.1 can be installed with 3 different configurations:

Task	Description
Install on stand-alone computer*	<ul style="list-style-type: none">• A user with local system administration privileges installs the database (Microsoft SQL Server Express) including initial data, the Rotor-Gene AssayManager v2.1 application, and at least one Rotor-Gene AssayManager v2.1 plug-in on a computer.• The user is completely guided by the installation wizard and will be prompted for input, if necessary.

<p>Setup a stand-alone computer*, which is connected to a network and install Rotor-Gene AssayManager v2.1 on additional computers* connected to the first</p>	<ul style="list-style-type: none"> • Proceed as described in "Install on stand-alone computer*". • The computer* is connected to the local area network. • Rotor-Gene AssayManager v2.1 and at least one Rotor-Gene AssayManager v2.1 plug-in is installed on additional computers by a user with local administration privileges. During installation the user is prompted for connection to the database, which has to be provided by the database administrator.
<p>Use existing database server and install Rotor-Gene AssayManager v2.1 on additional computers*</p>	<ul style="list-style-type: none"> • A user with all required database administration privileges uses the installation wizard to install only a new database instance including initial data on an existing database server. • The database administrator is responsible to check whether the database server fulfills the Rotor-Gene AssayManager v2.1 requirements. He is also responsible to perform all database administration tasks necessary to back up the system before installation. Furthermore, the database administrator must guarantee the functionality of the system after the successful installation or a failed installation. • Rotor-Gene AssayManager v2.1 and at least one Rotor-Gene AssayManager v2.1 plug-in is installed on additional computers by a user with local administration privileges. During installation the user is prompted for connection to the database, which has to be provided by the database administrator.

* The term "computer" is used to describe a notebook or a PC, and not a server.

1.4.1.1 Requirements

A computer with the required specifications for operating the Rotor-Gene Q MDx instrument and Rotor-Gene AssayManager v2.1 is supplied as part of the Rotor-Gene Q MDx instrument which is referred to as “QIAGEN laptop” in the following text. In general, the following minimum requirements must be fulfilled to run Rotor-Gene AssayManager v2.1:

Description	Minimum requirements
Display	1024 x 768 pixel resolution or higher
Supported operating systems	Windows 7 Professional (32- or 64-bit) with Service Pack 1 Windows 10 with version 1709 or newer (32- or 64-bit)
Disk space	250 GB
Processor	Intel® Core™ i3-380M Processor or higher
Memory	4 GB RAM recommended.
USB interface	1 to 4 USB 2.0 ports or higher. Contact www.qiagen.com for details regarding a USB Hub if necessary.
Pointing device	Touchpad or mouse or equivalent is required.
Service packs required	Microsoft Windows 7: Service Pack 1
Bluetooth®	Has to be switched off
PDF viewer or similar	Already installed
Power options	Never turn off hard disks, hibernate, or go to standby

Note

The installation of Rotor-Gene AssayManager v2.1 can only be performed with administrator privileges.

Note

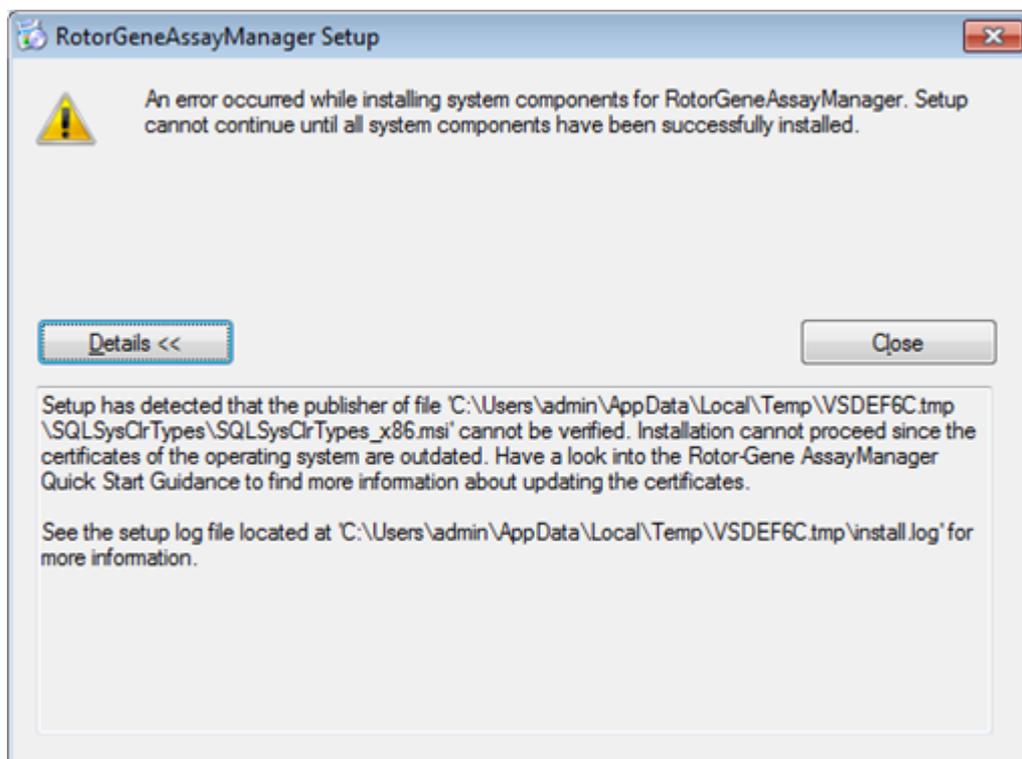
Only use original material, e.g., cables etc., supplied by QIAGEN.

1.4.1.2 Outdated certificates on Windows 7

All installation packages, contained in the Rotor-Gene AssayManager v2.1 installer are signed with validated certificates, trusted by Microsoft. This validity is checked by the operating system for every new program which shall be installed on the system. To be able to verify the validity of installer packages, the operating system maintains a list of trusted root certification authorities which is updated automatically by the so-called “automatic root update mechanism” introduced by Microsoft during the lifetime of Windows 7.

If your operating system or the list of trusted root certification authorities is in an outdated state, Microsoft cannot verify the validity of the pre-requisite packages, installed by the Rotor-Gene AssayManager v2.1 installer. This will result in the following error message during installation:

“Setup has detected that the publisher of file ‘...’ cannot be verified. Installation cannot proceed since the certificates of the operating system are outdated.” (see screenshot below – note: the error message is only shown if you click on “Details <<” button).



Visit the QIAGEN website for updates and instructions to solve this problem.

1.4.1.3 Internationalization

The standard language on a notebook delivered by QIAGEN is set to English (American). The language of the software itself is English. Rotor-Gene AssayManager v2.1 uses the computer language settings to display dates and decimal separators in the corresponding format. To change the language settings of the computer, select "Control Panel" from the windows start menu and select "Local language settings".

1.4.2 Installing Core Application v2.1 and Plug-ins

The following chapters provide you with details about the installation of the software in 3 different configurations:

- Install on stand-alone computer*
- Setup a stand-alone computer* which is connected to a network and install Rotor-Gene AssayManager v2.1 on one or two further computers* connected to the first
- Use existing database server and install Rotor-Gene AssayManager v2.1 on additional computers*

* The term "computer" is used to describe a notebook or a PC, and not a server.

For computer system requirements, refer to ► Requirements.

Note

If Rotor-Gene AssayManager v2.1 is being installed on any client or server in a shared database environment, the user must close all connected Rotor-Gene AssayManager v2.1 instances before installation.

Note

It is not possible to install Rotor-Gene AssayManager v2.1 on a computer or an existing database server, which already has Rotor-Gene AssayManager v1.0 installed. Rotor-Gene AssayManager v1.0 and v2.1 are independent products and cannot be used in parallel on one system. In addition, Rotor-Gene AssayManager v2.1 does not replace Rotor-Gene AssayManager v1.0.

Note

Plug-ins for Rotor-Gene AssayManager v1.0 are not compatible with Rotor-Gene AssayManager v2.1.

1.4.2.1 Installing the Core Application v2.1

For computer system requirements, refer to ► Requirements.

Note

Rotor-Gene AssayManager v2.1 uses several software packages provided by third parties. If not already installed on the system, these software packages are automatically installed at the beginning of the Rotor-Gene AssayManager v2.1 software setup. Depending on the installed software packages, a reboot of the system may be required before proceeding with the setup.

Note

The system must be virus and spyware free to install the Rotor-Gene AssayManager v2.1 software.

Rotor-Gene AssayManager v2.1 requires an MS SQL Server 2014 Express instance with mixed mode authentication and tcp/ip network protocol activated for installation. The installation process depends on whether MS SQL Server 2014 Express already is installed or should be installed on the local system or whether Rotor-Gene AssayManager v2.1 shall be installed with a remote connection to an existing SQL Server on an external system:

- If MS SQL Server 2014 Express is already installed on the local system or a remote connection to an existing SQL server or an external system, the installation of MS SQL Server 2014 Express is skipped and the installation continues with the installation of Rotor-Gene AssayManager v2.1 application.
- If MS SQL Server 2014 Express was not installed previously, the first step in the installation process is the installation of MS SQL Server Express 2014 and then the Rotor-Gene AssayManager v2.1 application is installed.

Note

During installation process, click "Back" to go a step back in the installation process.

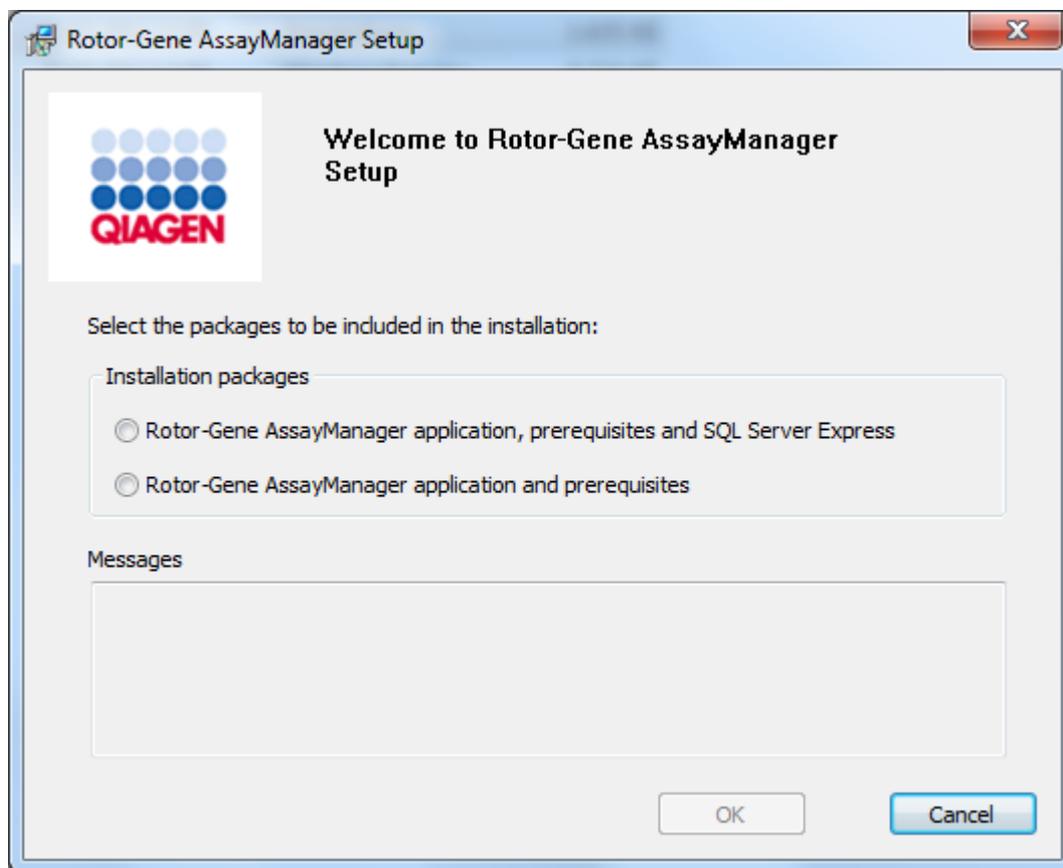
Step-by-step procedure to install the Rotor-Gene AssayManager v2.1 on stand-alone computer*

1. Download the Rotor-Gene AssayManager v2.1 Core Application from the QIAGEN website.

Note: Checksum confirmation is required to secure software integrity after web download is successfully completed and before subsequent handling of the software. Therefore, software checksum verification is requested before installation of the downloaded software is started. For detailed information on confirmation of software integrity during download and file transfer, please check the QIAGEN software integrity verification process description document, which is provided together with the software package on the QIAGEN webpage. If you download software from the QIAGEN website on a different computer than that one on which the software shall be installed, please make sure that the used flash drive to transfer the software is free of viruses. QIAGEN strongly recommends to perform a virus scan using an up-to-date virus scanner on the flash drive to avoid a contamination.

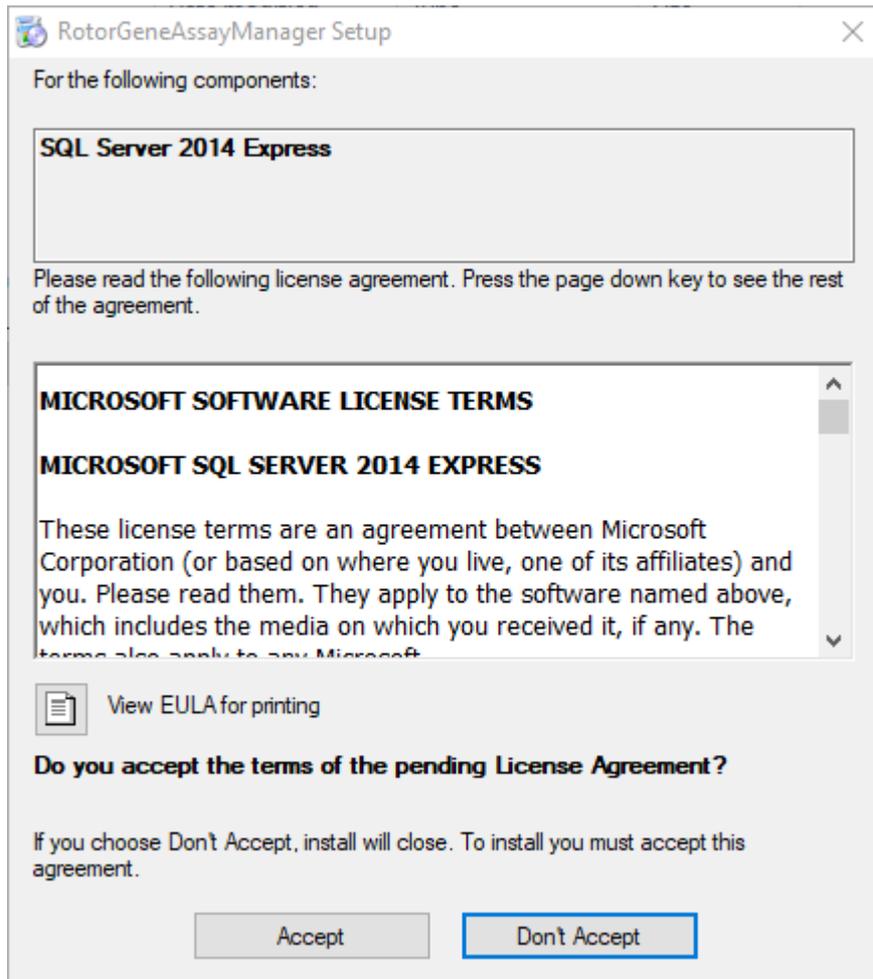
2. Start the installation of Rotor-Gene AssayManager v2.1 by double-clicking on setup.exe.

The setup wizard automatically opens the "Rotor-Gene AssayManager Setup" window.

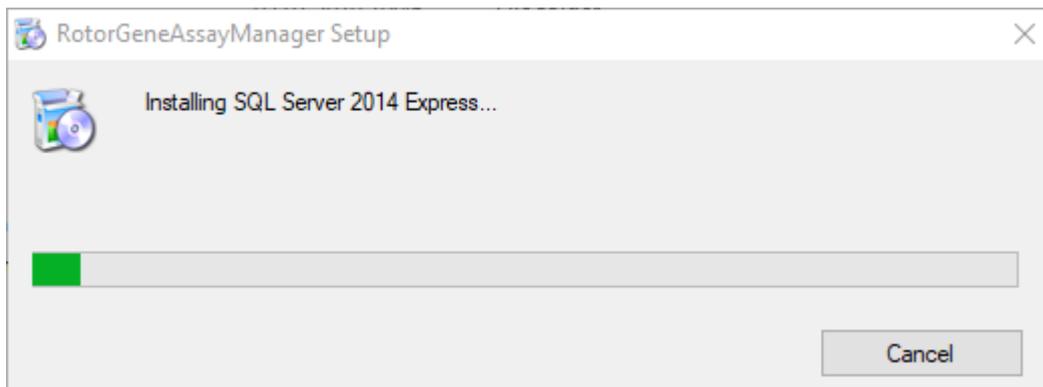


* The term "computer" is used to describe a notebook or a PC, and not a server.

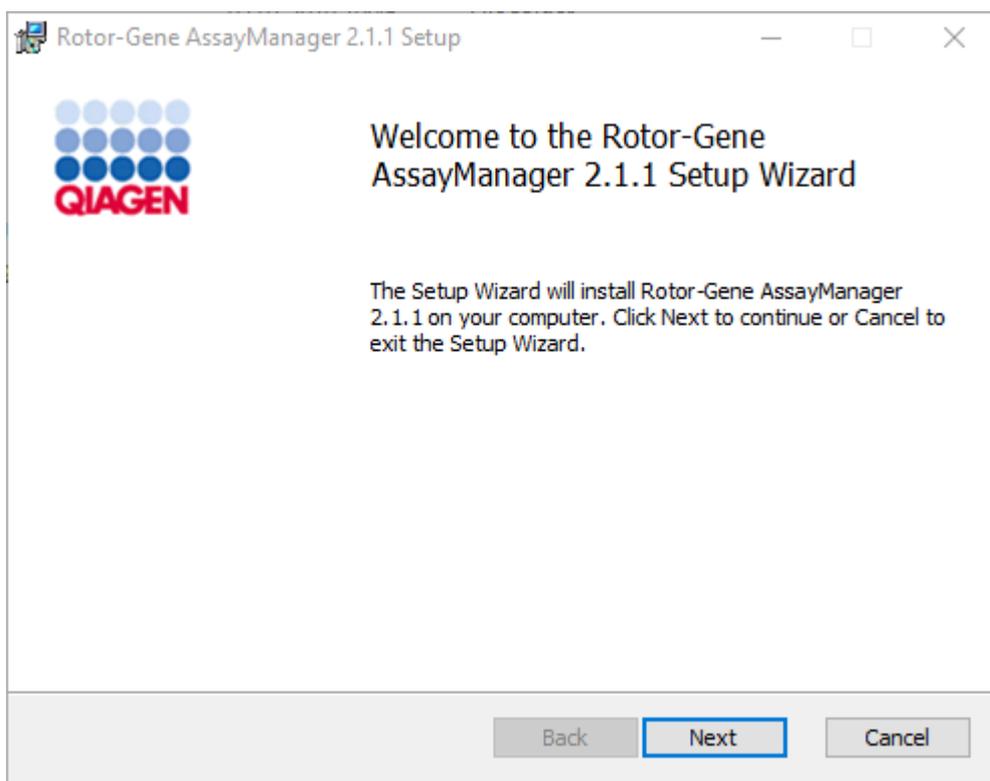
3. Select the Rotor-Gene AssayManager v2.1 application, prerequisites, and SQL Server Express to install the SQL Server locally on your system.
4. Click "OK" to proceed.
5. Click "Accept" to start the installation of MS SQL Server 2014 Express.



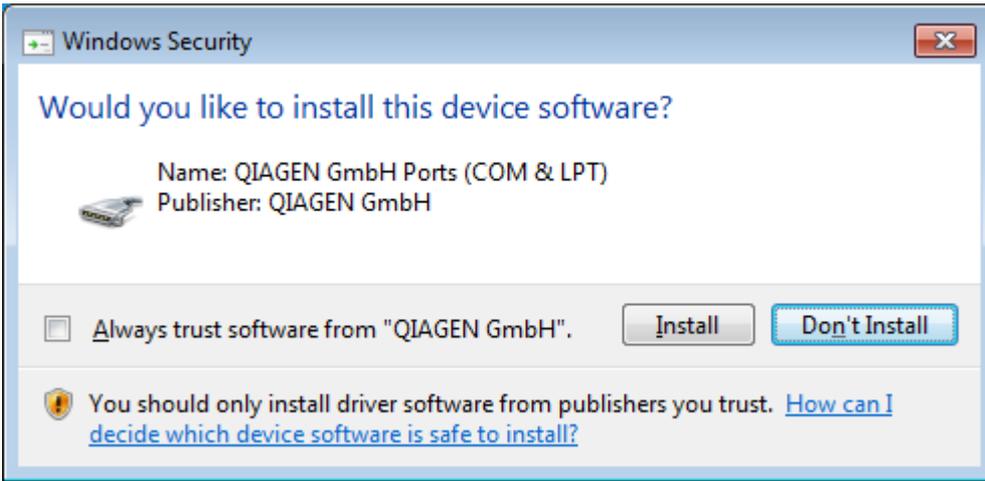
The installation progress windows is displayed:



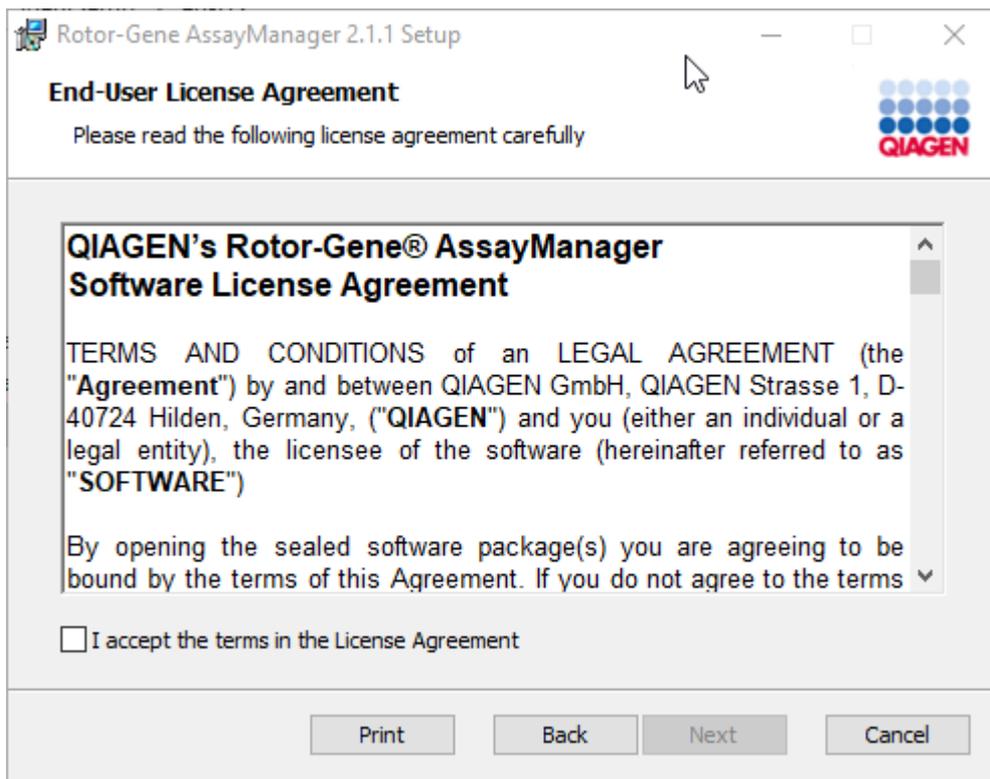
6. The Rotor-Gene AssayManager v2.1 welcome screen will automatically be opened.



7. Click "Next" to start the installation procedure.
8. The following windows security message may appear during the installation process. Click "Install".

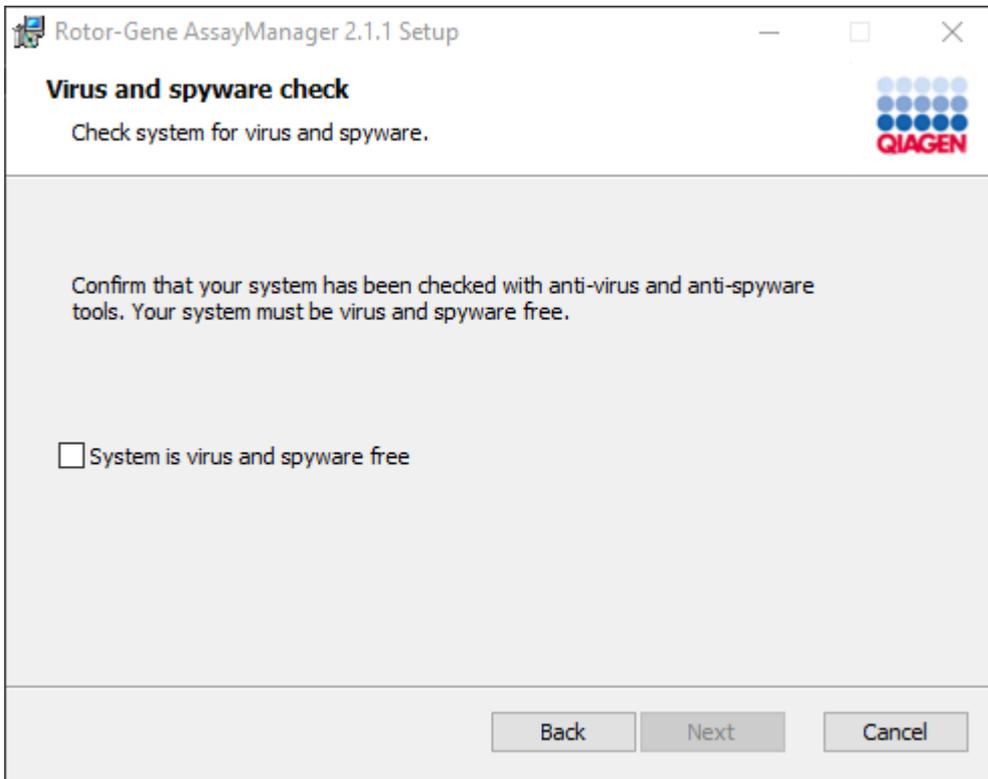


9. Depending on the software packages already installed on the system, different license agreements for the required software packages will be displayed.



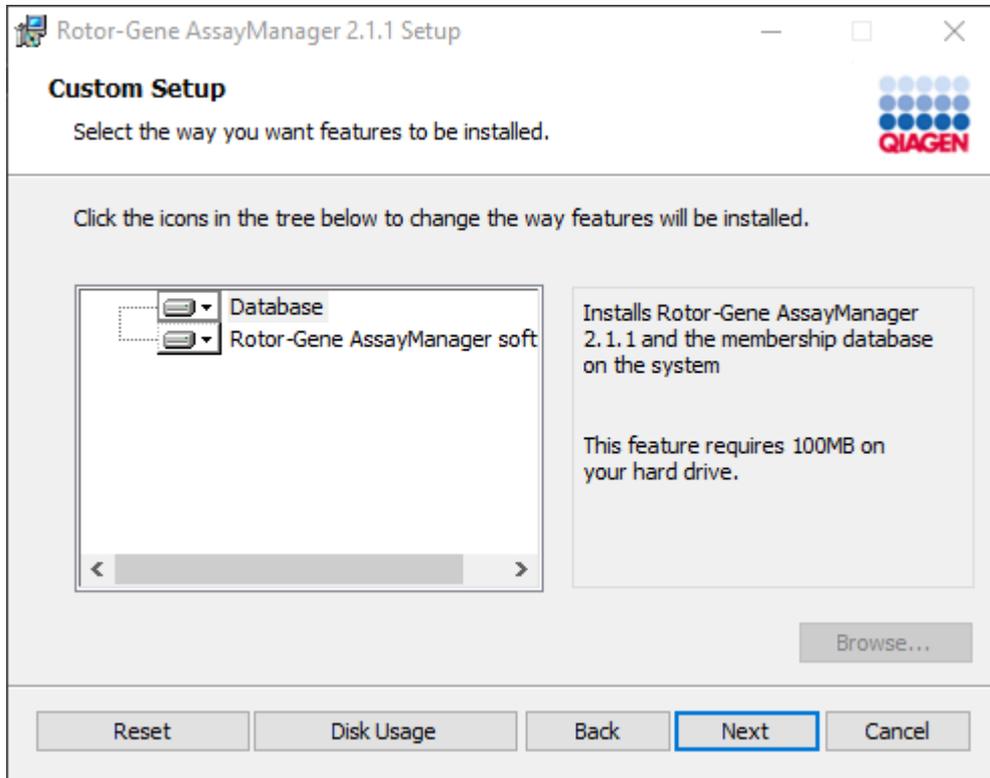
Read and accept the license agreements by checking "I accept the terms in the License Agreement" and click "Next".

10. The "Virus and spyware check" window is opened:



Confirm that the system is virus free by activating the "System is virus and spyware free" option and click "Next".

11.The "Custom Setup" screen is displayed.

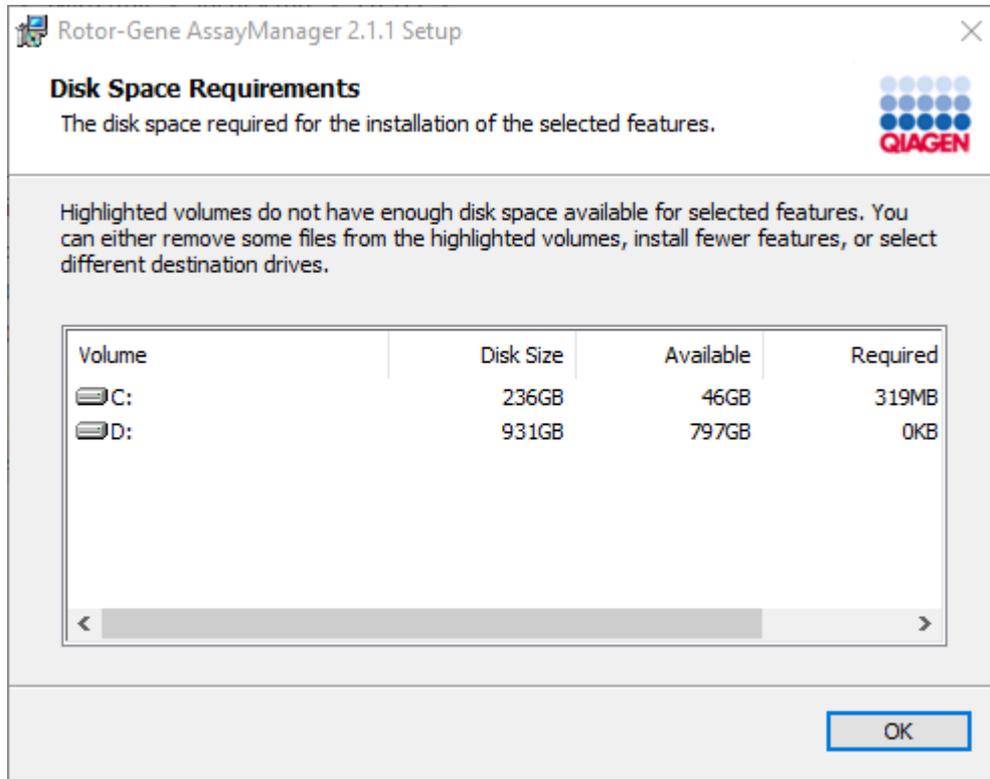


12.For a stand-alone desktop scenario with application and database on one computer, the features "Database" and "Rotor-Gene AssayManager software" must stay selected.

Note

Do not deselect any feature.

13. Click "Disc Usage" to get an overview of the available and required disc space.

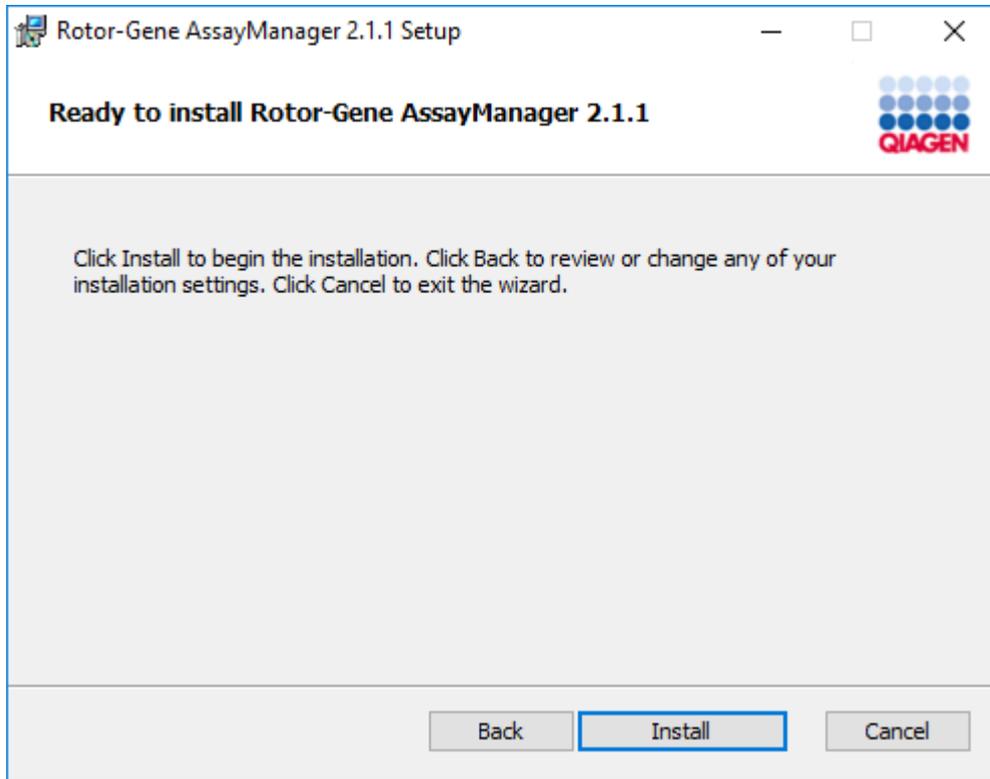


Click "OK" to close the window.

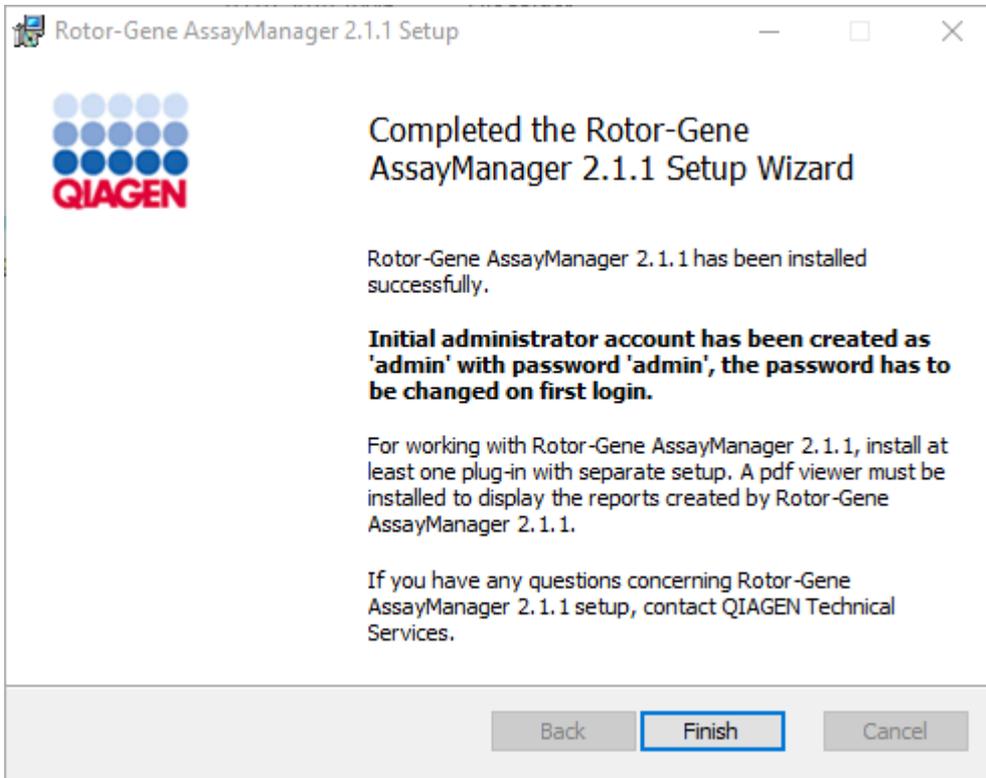
14. Click "Next" to proceed with the installation of the selected features.

15. To proceed with the installation click "Next".

16. Click "Install" to start the installation.



17. After the installation is completed click "Finish" to close the window.



18. After the installation Rotor-Gene AssayManager v2.1 can be started either from the Windows start menu under **QIAGEN/Rotor-Gene AssayManager** or using the desktop icon.



Step-by-step procedure to setup a stand alone computer and install Rotor-Gene AssayManager v2.1 on additional computers*

As a prerequisite for this installation scenario, install the Rotor-Gene AssayManager v2.1 on a computer which is connected to the local area network according the previous section (installed with an SQL Server Express installation).

Note

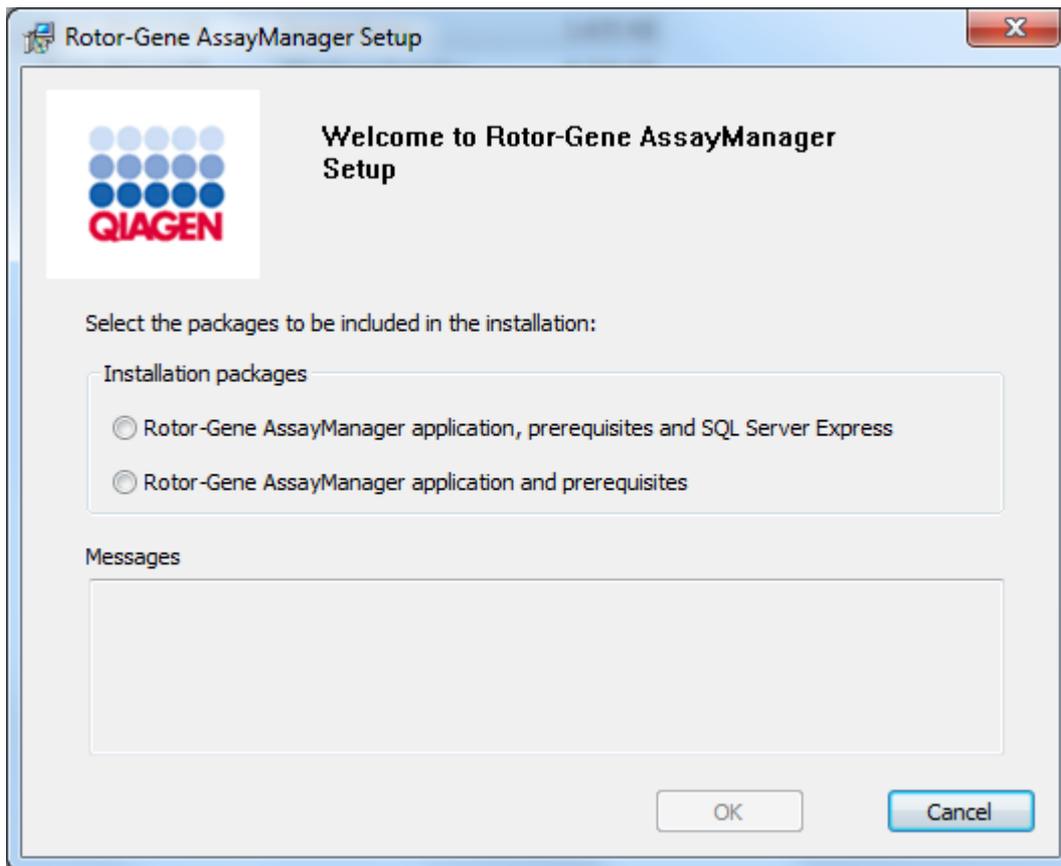
If Rotor-Gene AssayManager v2.1 is being installed on any client or server in a shared database environment, the user must close all connected RGAM instances before installation.

1. Download the Rotor-Gene AssayManager v2.1 Core Application from the QIAGEN website.

Note: Checksum confirmation is required to secure software integrity after web download is successfully completed and before subsequent handling of the software. Therefore, software checksum verification is requested before installation of the downloaded software is started. For detailed information on confirmation of software integrity during download and file transfer, please check the QIAGEN software integrity verification process description document, which is provided together with the software package on the QIAGEN webpage. If you download software from the QIAGEN website on a different computer than that one on which the software shall be installed, please make sure that the used flash drive to transfer the software is free of viruses. QIAGEN strongly recommends to perform a virus scan using an up-to-date virus scanner on the flash drive to avoid a contamination.

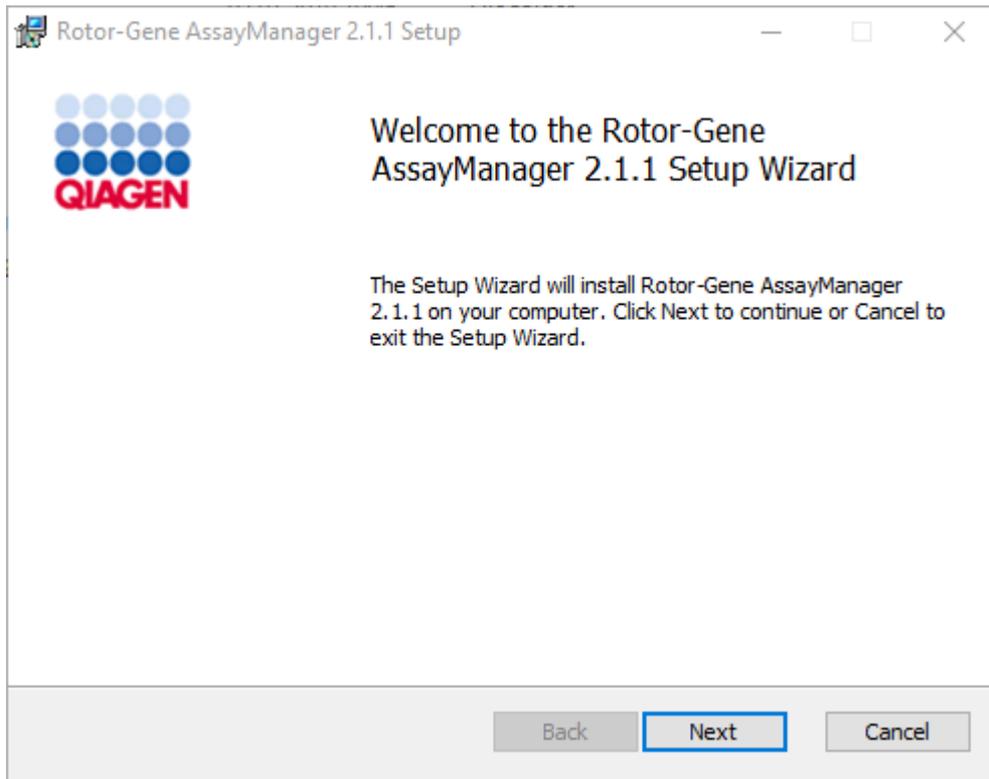
2. Start the installation of Rotor-Gene AssayManager v2.1 by double-clicking on setup.exe.

The setup wizard automatically opens the "Rotor-Gene AssayManager Setup" window.

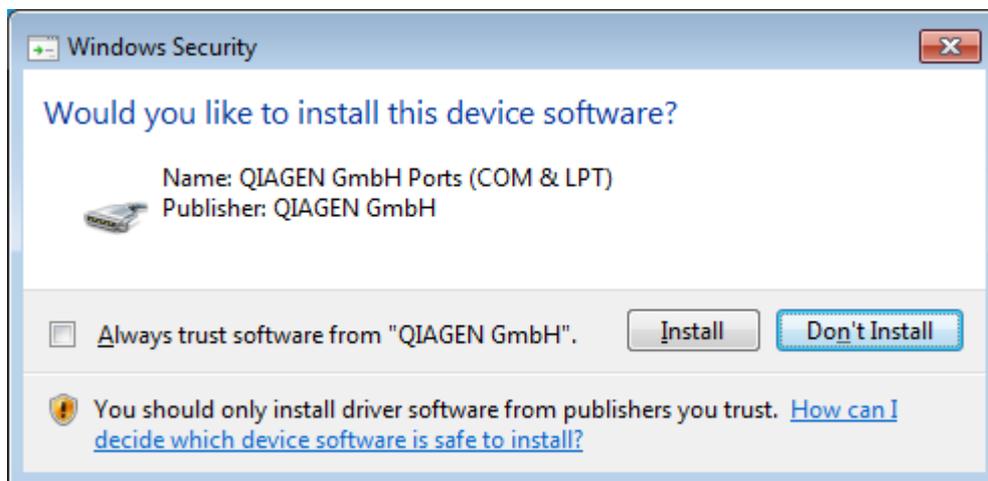


* The term "computer" is used to describe a notebook or a PC, and not a server.

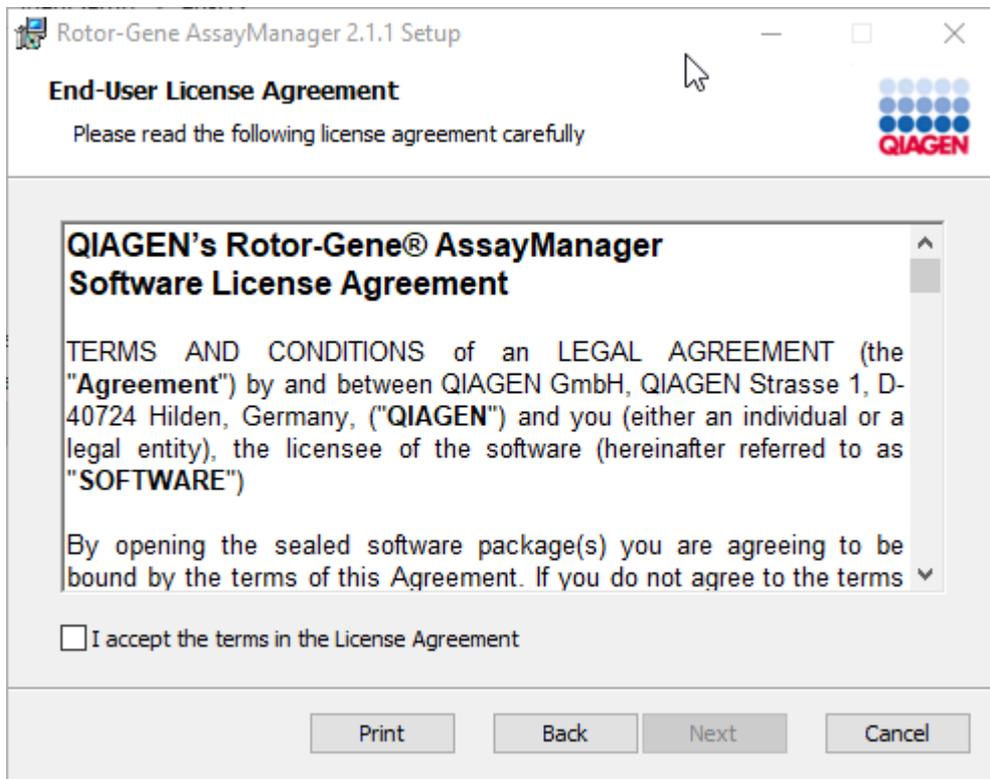
3. Select the Rotor-Gene AssayManager v2.1 application and prerequisites.
4. Click "OK" to proceed.
5. The Rotor-Gene AssayManager v2.1 welcome screen will automatically be opened.



6. Click "Next" to start the installation procedure.
7. The following windows security message may appear during the installation process. Click "Install".

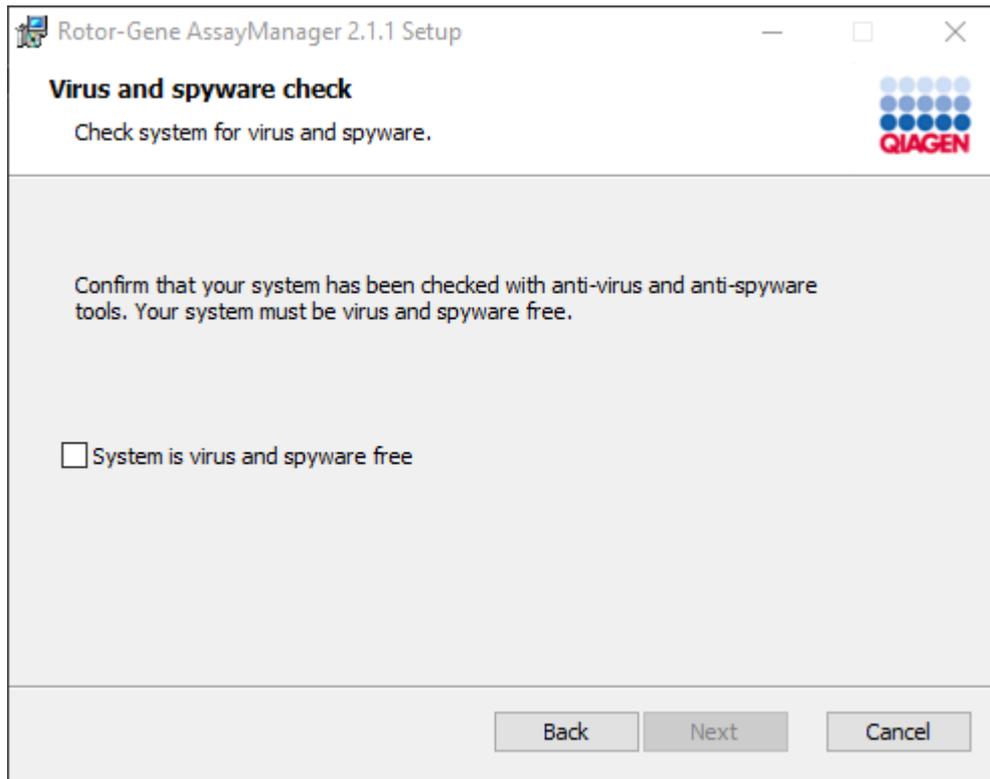


8. Depending on the software packages already installed on the system, different license agreements for the required software packages will be displayed.



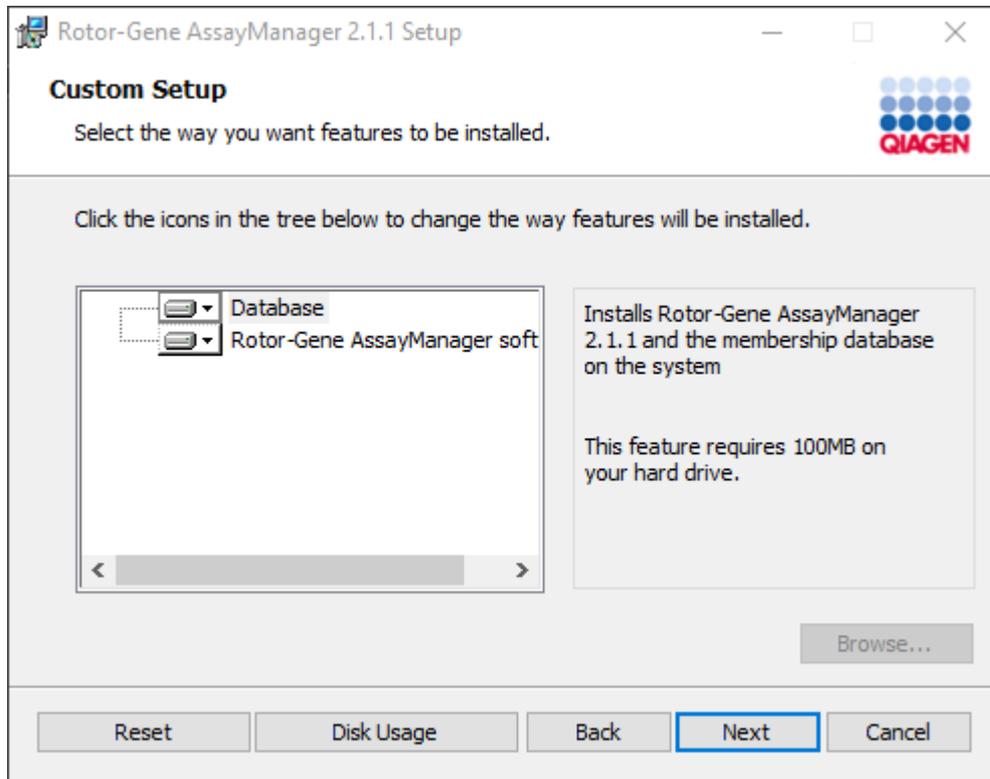
Read and accept the license agreements by checking "I accept the terms in the License Agreement" and click "Next".

9. The "Virus and spyware check" window is opened:



Confirm that the system is virus free by activating the "System is virus and spyware free" option and click "Next".

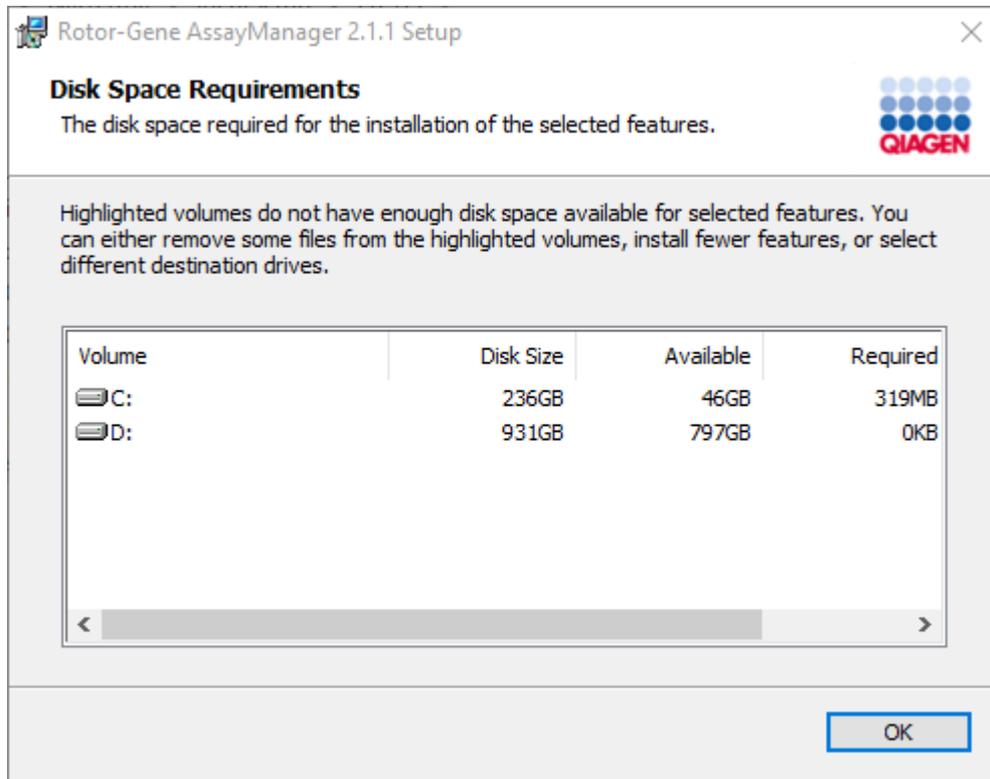
10. The "Custom Setup" screen is displayed.



Note

Do not deselect any feature.

11. Click "Disc Usage" to get an overview of the available and required disc space.

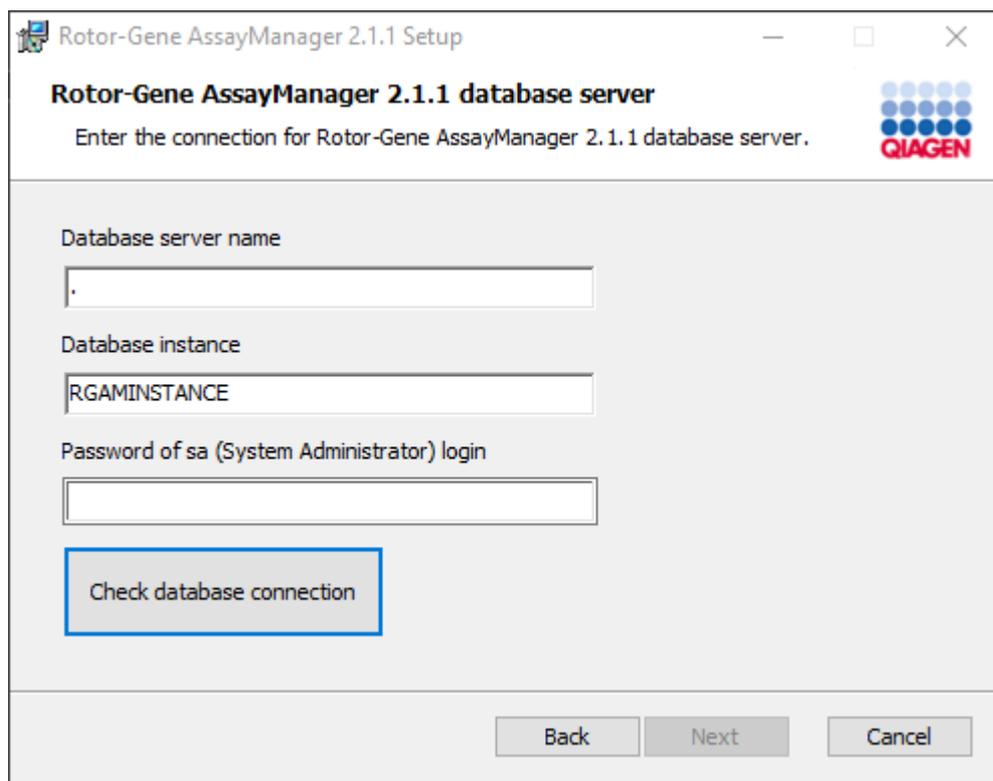


Click "OK" to close the window.

12. Click "Next" to proceed with the installation of the selected feature.

13. Fill in the required parameters. If the remote "Database server" is a computer with a local installation of the Rotor-Gene AssayManager v2.1, fill in the computer name, leave the instance name ("RGAMINSTANCE") as it is, and leave the field of the "Password of sa" blank.

To check the database connection, click "Check database connection". If you encounter problems during the connection process to the database server, contact your local system administrator.



The screenshot shows a Windows-style dialog box titled "Rotor-Gene AssayManager 2.1.1 Setup". The main heading is "Rotor-Gene AssayManager 2.1.1 database server" with the QIAGEN logo to the right. Below the heading, it says "Enter the connection for Rotor-Gene AssayManager 2.1.1 database server." The dialog contains three input fields: "Database server name" (containing a single dot), "Database instance" (containing "RGAMINSTANCE"), and "Password of sa (System Administrator) login" (which is empty). A blue-bordered button labeled "Check database connection" is positioned below the password field. At the bottom of the dialog are three buttons: "Back", "Next", and "Cancel".

14. To proceed with the installation click "Next".

15. Install the Rotor-Gene AssayManager v2.1 as described in the following chapter.

Step-by-step procedure to use existing database server and install Rotor-Gene AssayManager v2.1 on additional computers*

Note

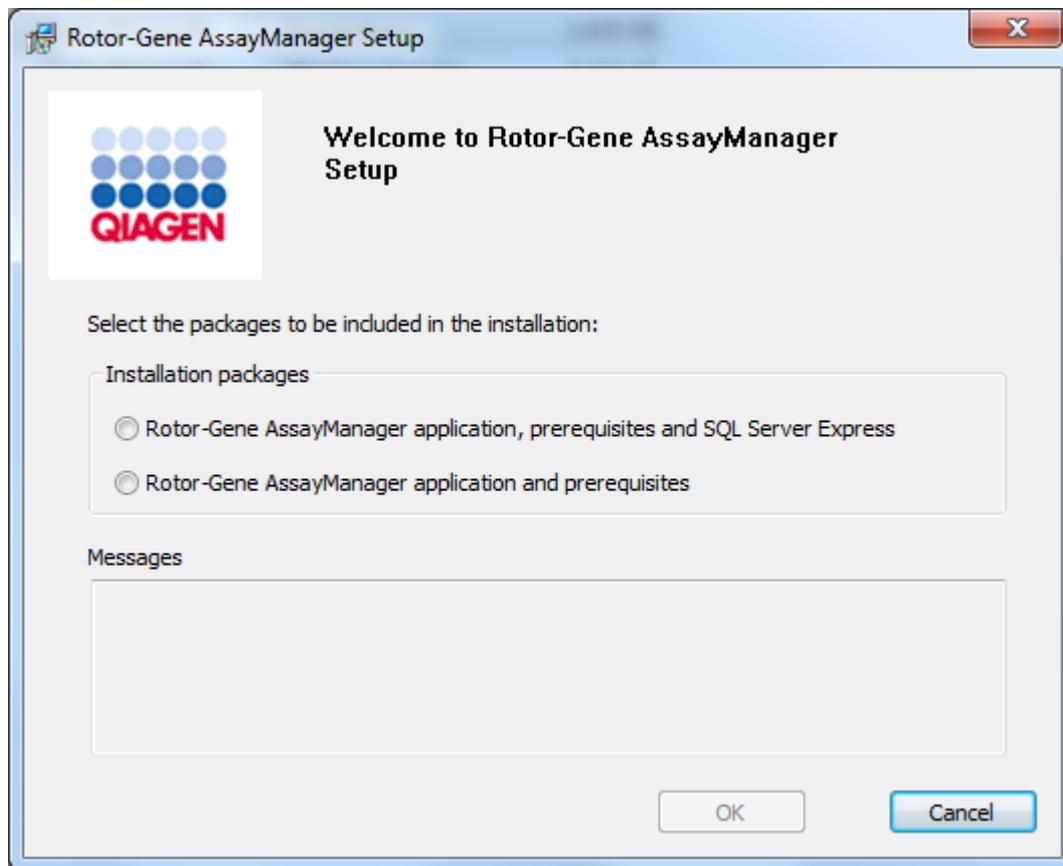
If Rotor-Gene AssayManager v2.1 is being installed on any client or server in a shared database environment, the user must close all connected RGAM instances before installation.

1. Download the Rotor-Gene AssayManager v2.1 Core Application from the QIAGEN website.

Note: Checksum confirmation is required to secure software integrity after web download is successfully completed and before subsequent handling of the software. Therefore, software checksum verification is requested before installation of the downloaded software is started. For detailed information on confirmation of software integrity during download and file transfer, please check the QIAGEN software integrity verification process description document, which is provided together with the software package on the QIAGEN webpage. If you download software from the QIAGEN website on a different computer than that one on which the software shall be installed, please make sure that the used flash drive to transfer the software is free of viruses. QIAGEN strongly recommends to perform a virus scan using an up-to-date virus scanner on the flash drive to avoid a contamination.

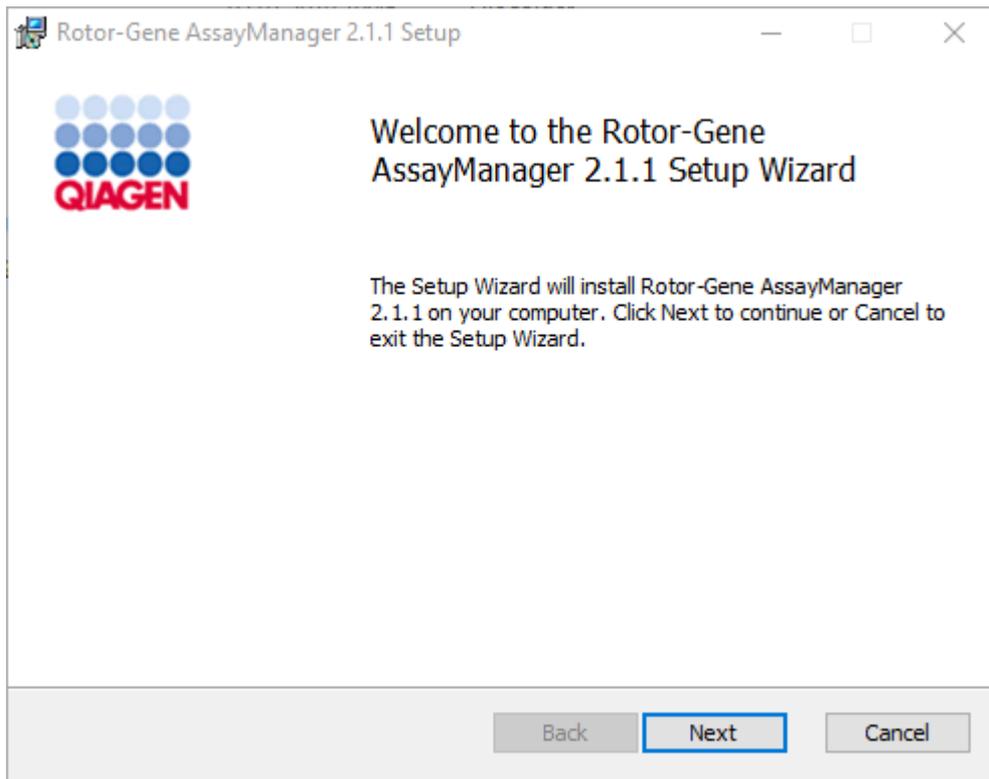
2. Start the installation of Rotor-Gene AssayManager v2.1 by double-clicking on setup.exe.

The setup wizard automatically opens the "Rotor-Gene AssayManager Setup" window.



* The term "computer" is used to describe a notebook or a PC, and not a server.

3. Select the Rotor-Gene AssayManager v2.1 application, prerequisites, if you want to install Rotor-Gene AssayManager v2.1 with a remote connection to an existing SQL Server on an external system.
4. Click "OK" to proceed.
5. The Rotor-Gene AssayManager v2.1 welcome screen will automatically be opened.

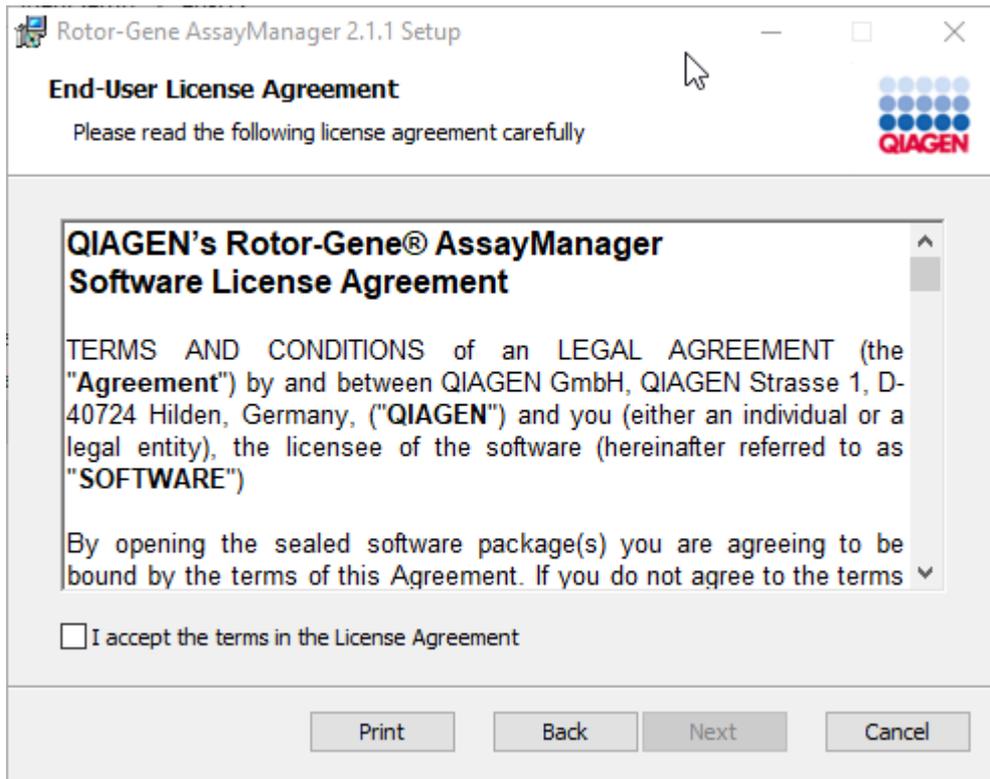


6. Click "Next" to start the installation procedure.

7. The following windows security message may appear during the installation process. Click "Install".

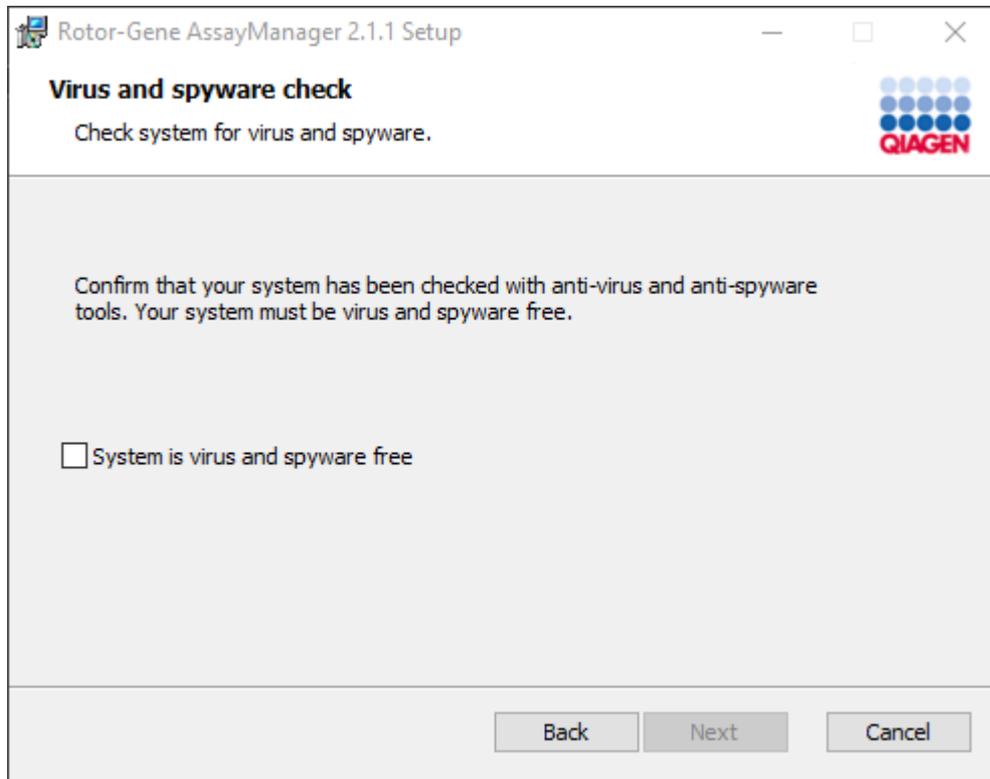


8. Depending on the software packages already installed on the system, different license agreements for the required software packages will be displayed.



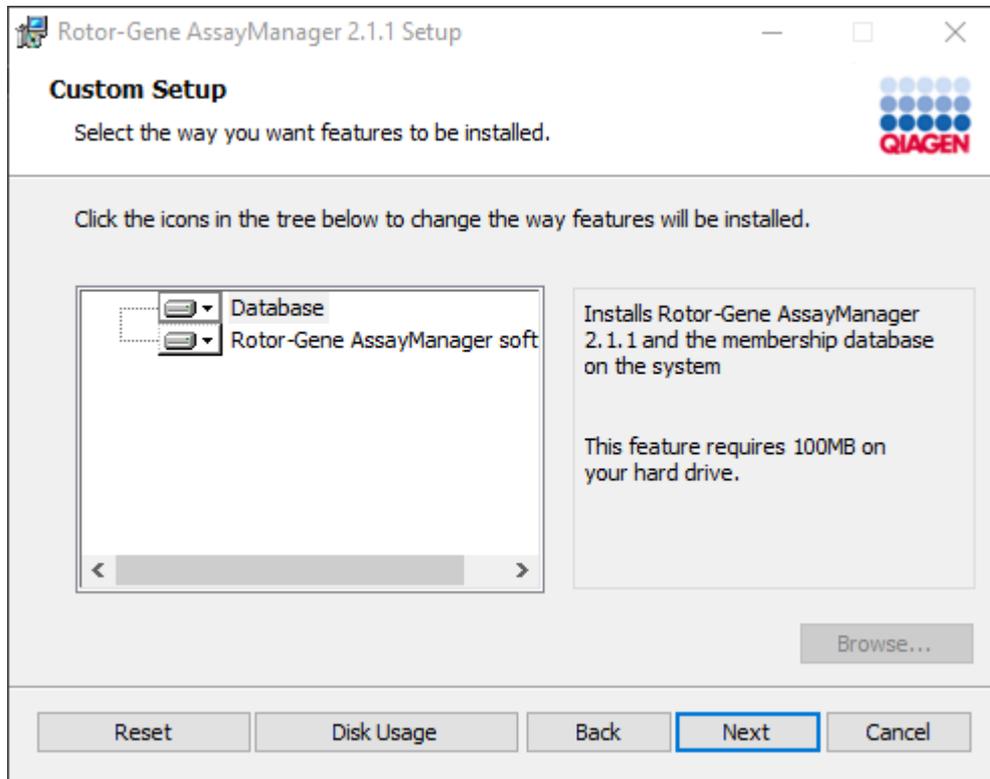
Read and accept the license agreements by checking "I accept the terms in the License Agreement" and click "Next".

9. The "Virus and spyware check" window is opened:



Confirm that the system is virus free by activating the "System is virus and spyware free" option and click "Next".

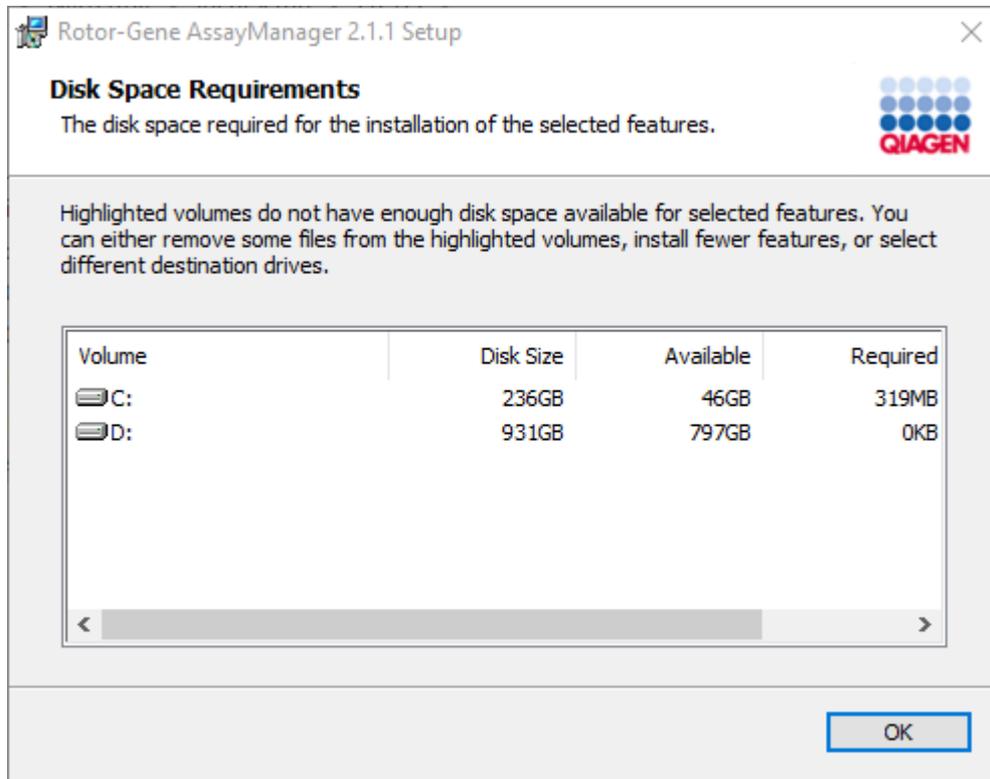
10. The "Custom Setup" screen is displayed.



Note

Do not deselect any feature.

11. Click "Disc Usage" to get an overview of the available and required disc space.



Click "OK" to close the window.

12. Click "Next" to proceed with the installation of the selected feature.

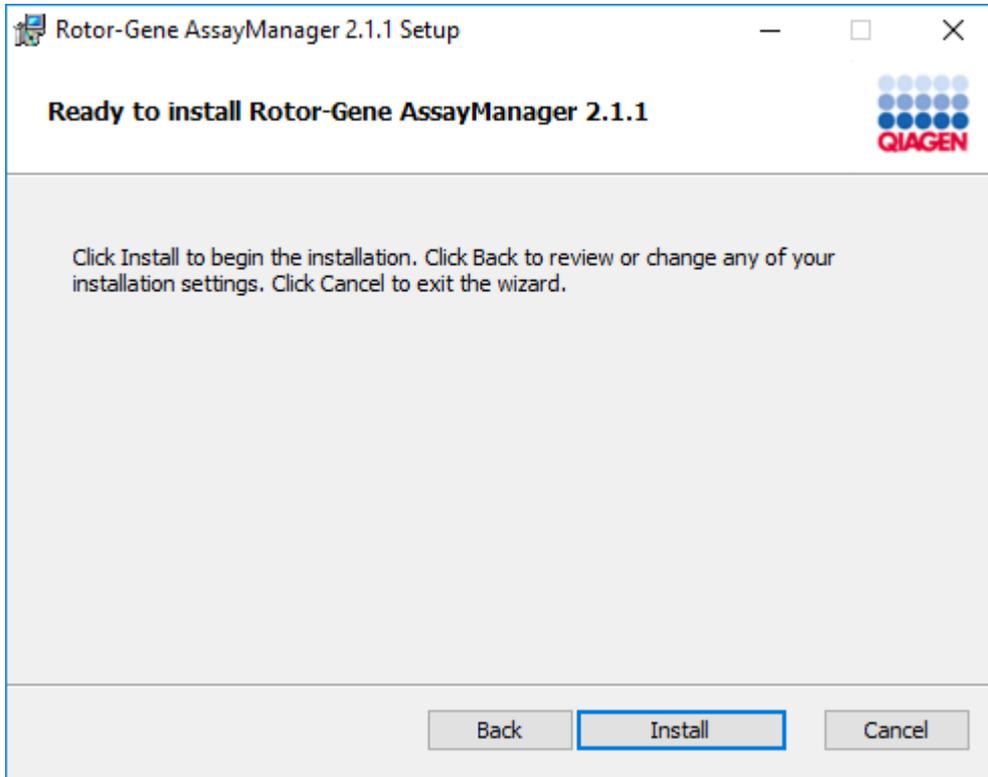
13. Fill in the required parameters.

To check the database connection, click "Check database connection". If you encounter problems during the connection process to the database server, contact your local system administrator.

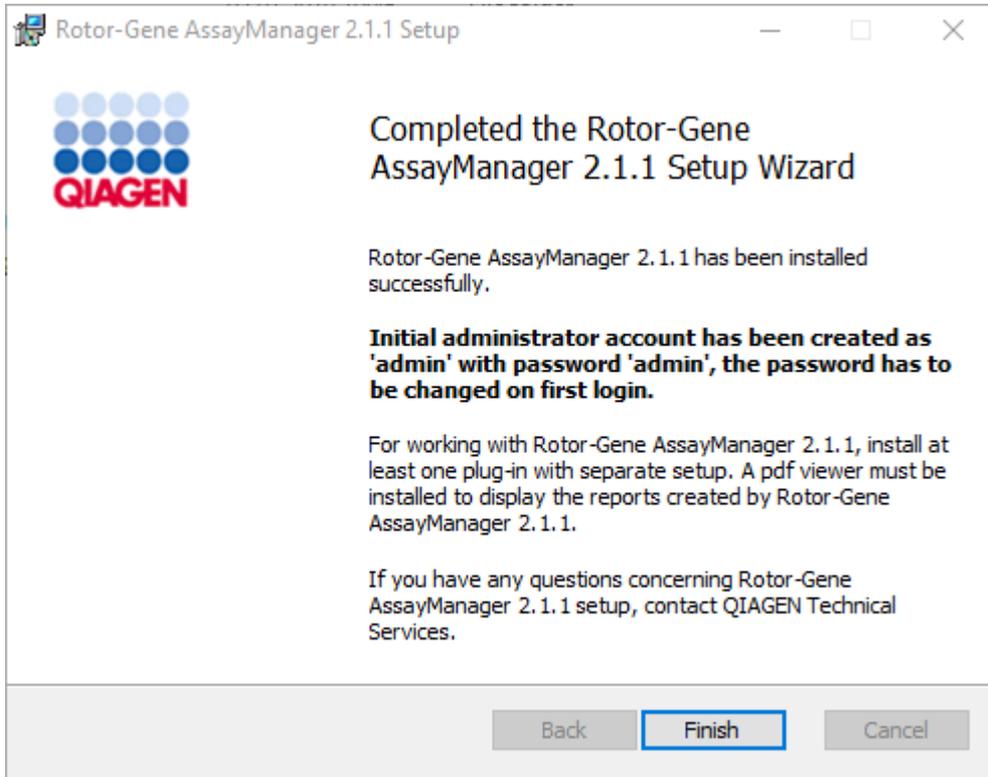
The screenshot shows a Windows-style dialog box titled "Rotor-Gene AssayManager 2.1.1 Setup". The main heading is "Rotor-Gene AssayManager 2.1.1 database server" with the QIAGEN logo to the right. Below the heading is the instruction "Enter the connection for Rotor-Gene AssayManager 2.1.1 database server." The dialog contains three input fields: "Database server name" with a single period "." entered, "Database instance" with "RGAMINSTANCE" entered, and "Password of sa (System Administrator) login" which is empty. A blue-bordered button labeled "Check database connection" is positioned below the password field. At the bottom right, there are three buttons: "Back", "Next", and "Cancel".

14.To proceed with the installation click "Next".

15. Click "Install" to start the installation.



16. After the installation is completed click "Finish" to close the window.



17. After the installation Rotor-Gene AssayManager v2.1 can be started either from the Windows start menu under **QIAGEN/Rotor-Gene AssayManager** or using the desktop icon.



Note: Future updates to Rotor-Gene AssayManager v2.1 will be provided on the QIAGEN webpage.

1.4.2.2 Installing Plug-ins

For the use of Rotor-Gene AssayManager v2.1 at least one plug-in has to be installed. Plug-ins are provided on QIAGEN.com.

Note

Plug-ins for Rotor-Gene AssayManager v1.0 are not compatible with Rotor-Gene AssayManager v2.1.

Note

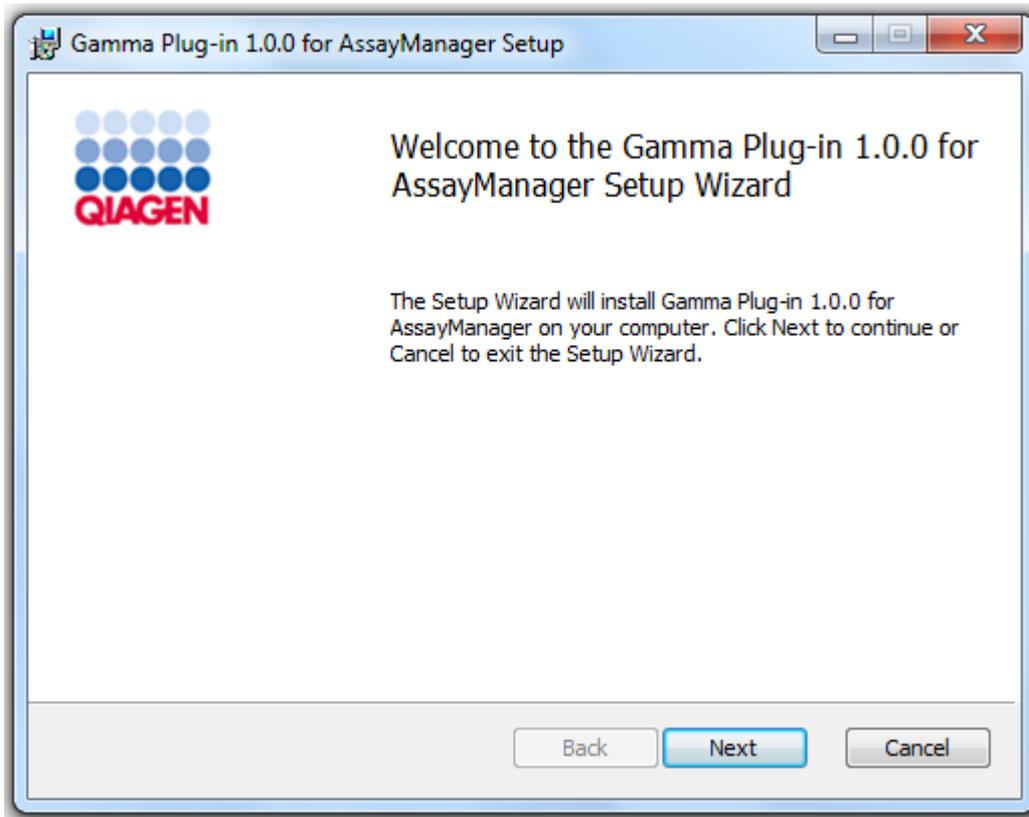
Only after the same plug-ins have been successfully installed on all related clients, should the user log in again.

Note

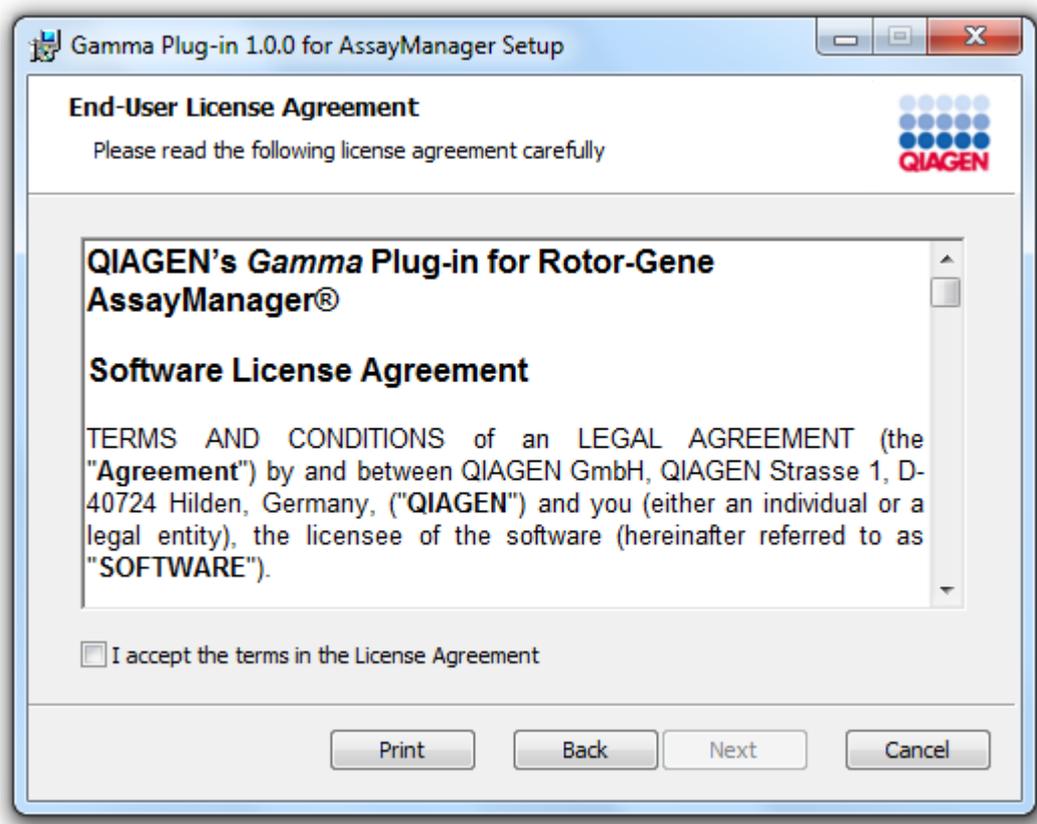
The installation of the Gamma Plug-in is provided as an example for the installation of any plug-in.

Step-by-step procedure to install a Rotor-Gene AssayManager v2.1 plug-in

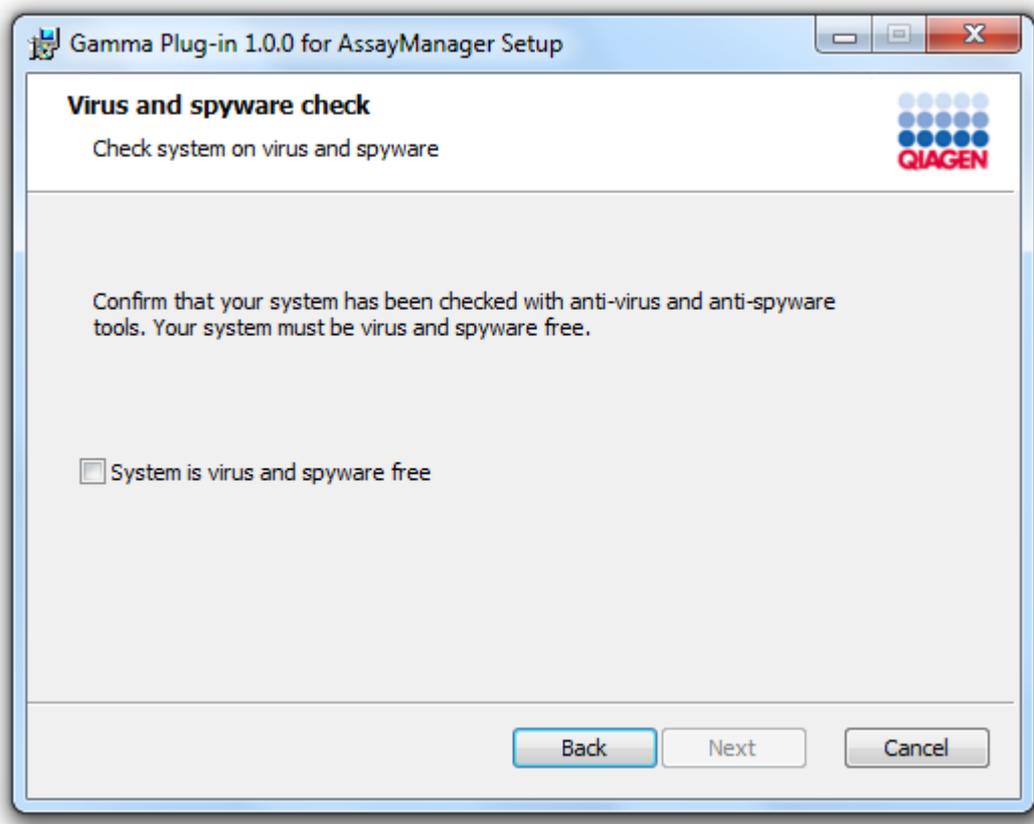
1. Download the plug-in from the QIAGEN website.
2. Start the installation of the plug-in by double-clicking on setup.exe.



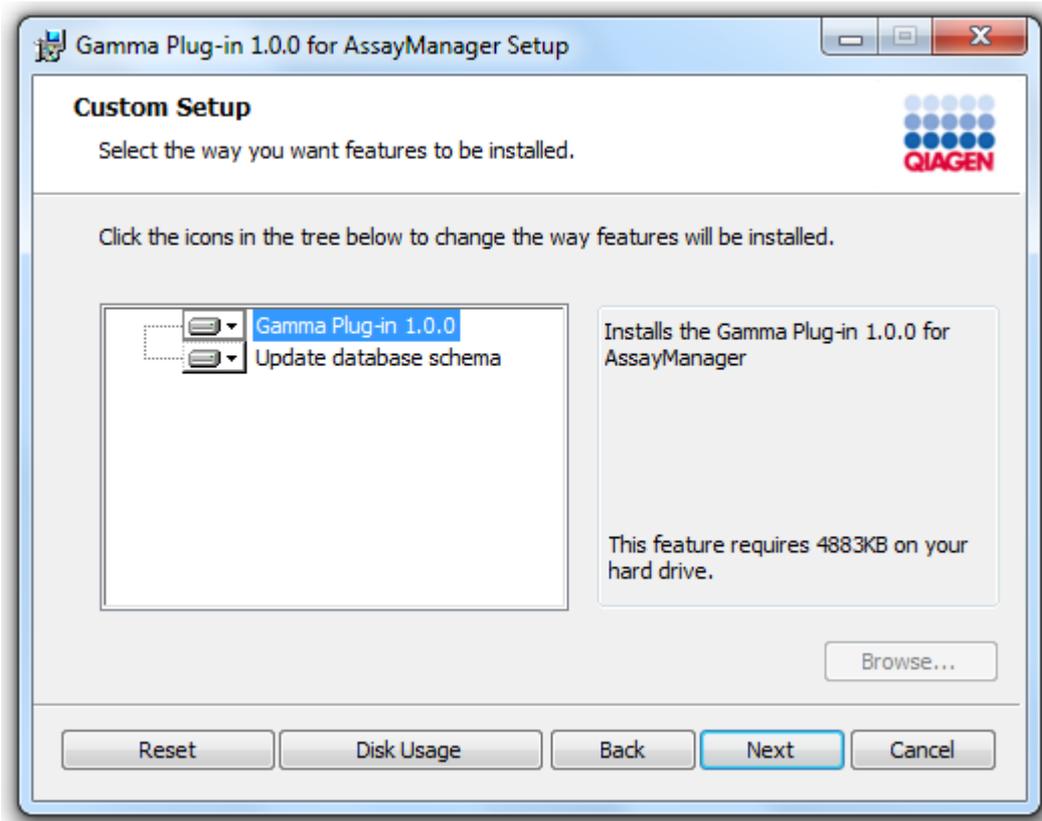
3. Read and accept the license agreement by clicking the checkbox and click "Next".



4. Confirm that your system is virus and spyware free by checking the corresponding check box and click "Next".



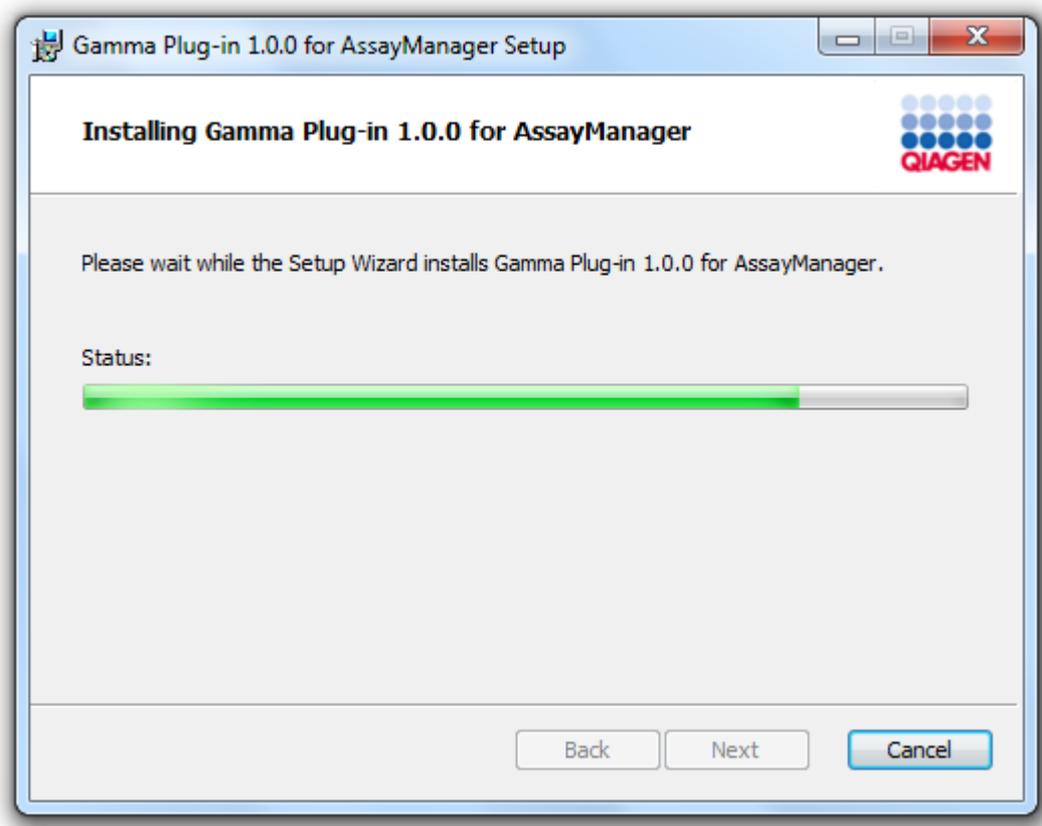
5. Select the features to be installed.



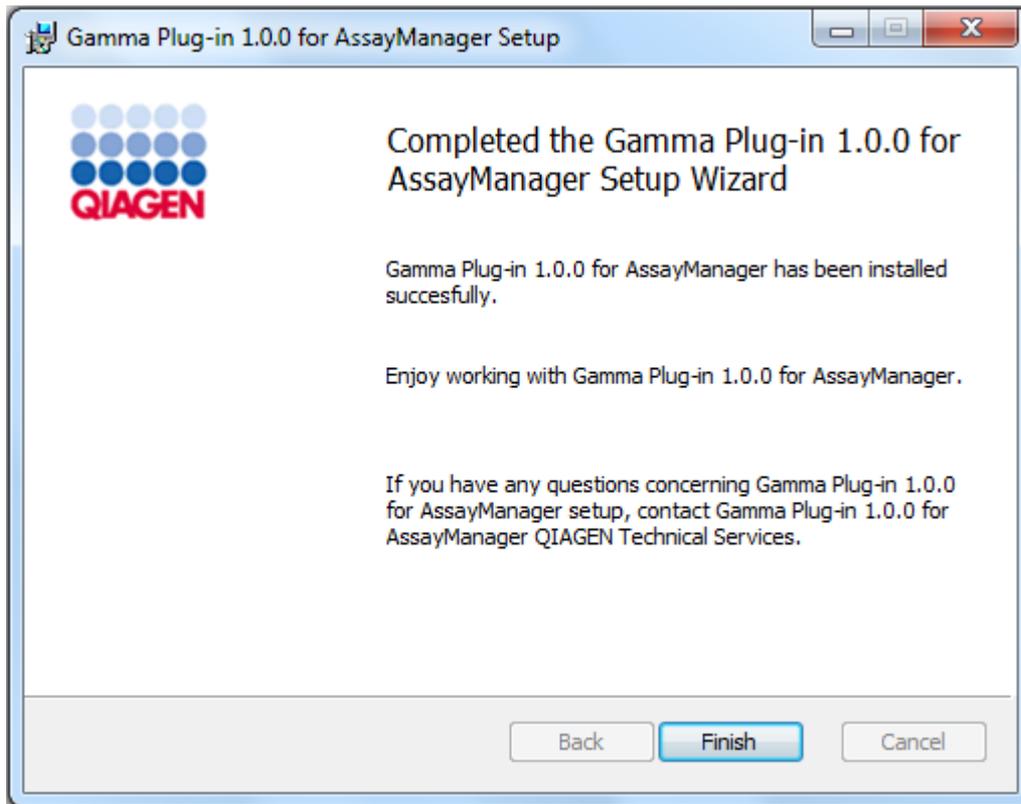
Note

Do not deselect any feature.

6. Click "Disc Usage" to get an overview of the available and required disc space. Click "OK" to close the window. Click "Next" to proceed with the installation of the selected features.
7. Click "Install" to start the installation of the plug-in.



8. Wait until the installation process has finished.



9. After the installation is completed click "Finish" to close the window.
10. After next restart of Rotor-Gene AssayManager v2.1 the installed plug-in is available.

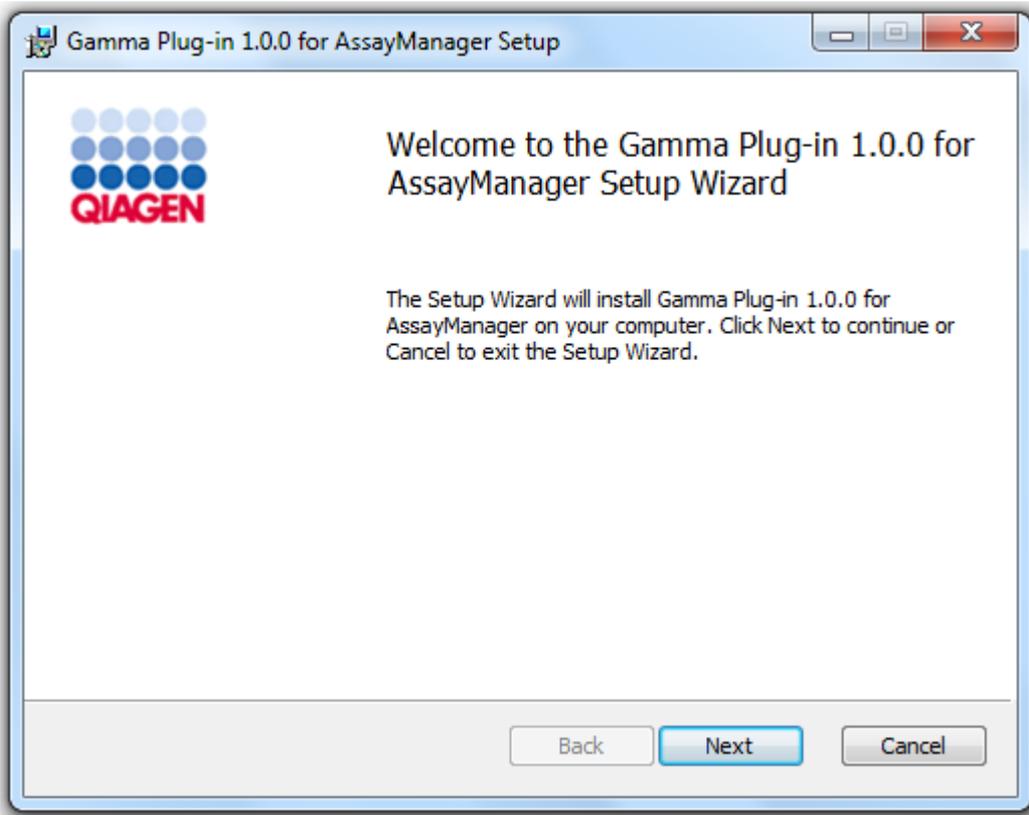
Related topics

- ▶ Installing the core application v2.1

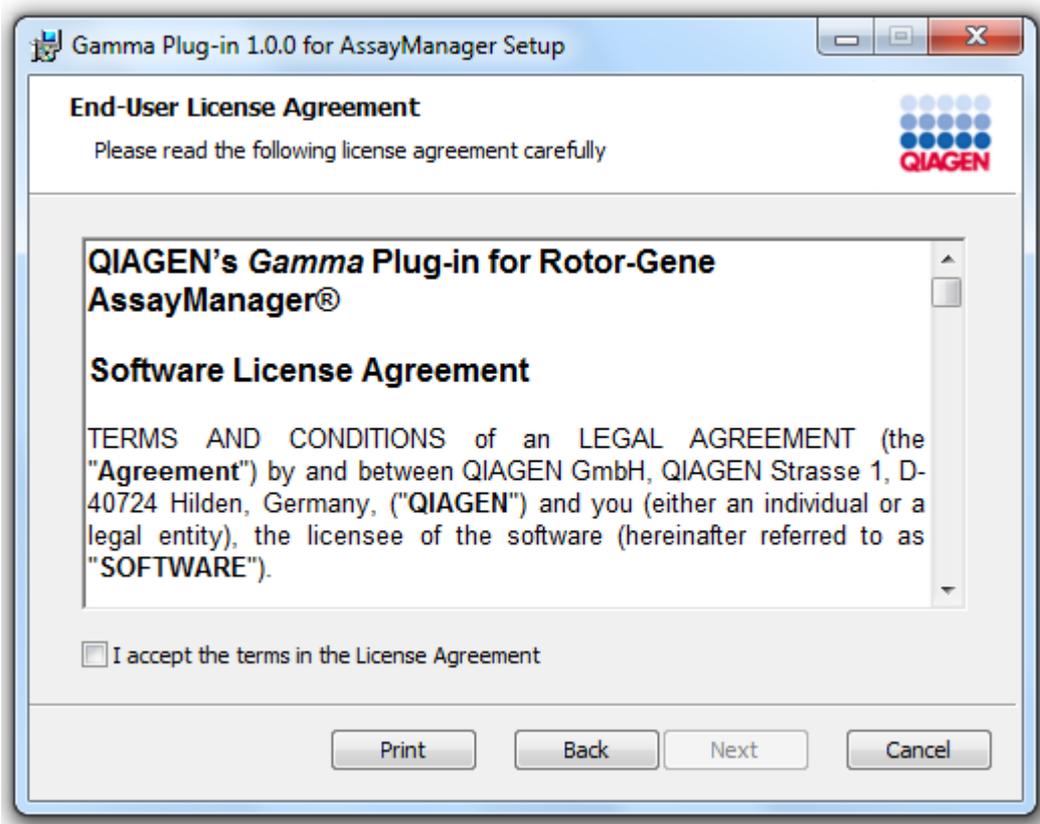
Step-by-step procedure to install Rotor-Gene AssayManager v2.1 plug-in using a central database server

As a prerequisite for this installation scenario, the plug-in installation will be started on a computer on which the SQL Server Express database was deselected during core application installation.

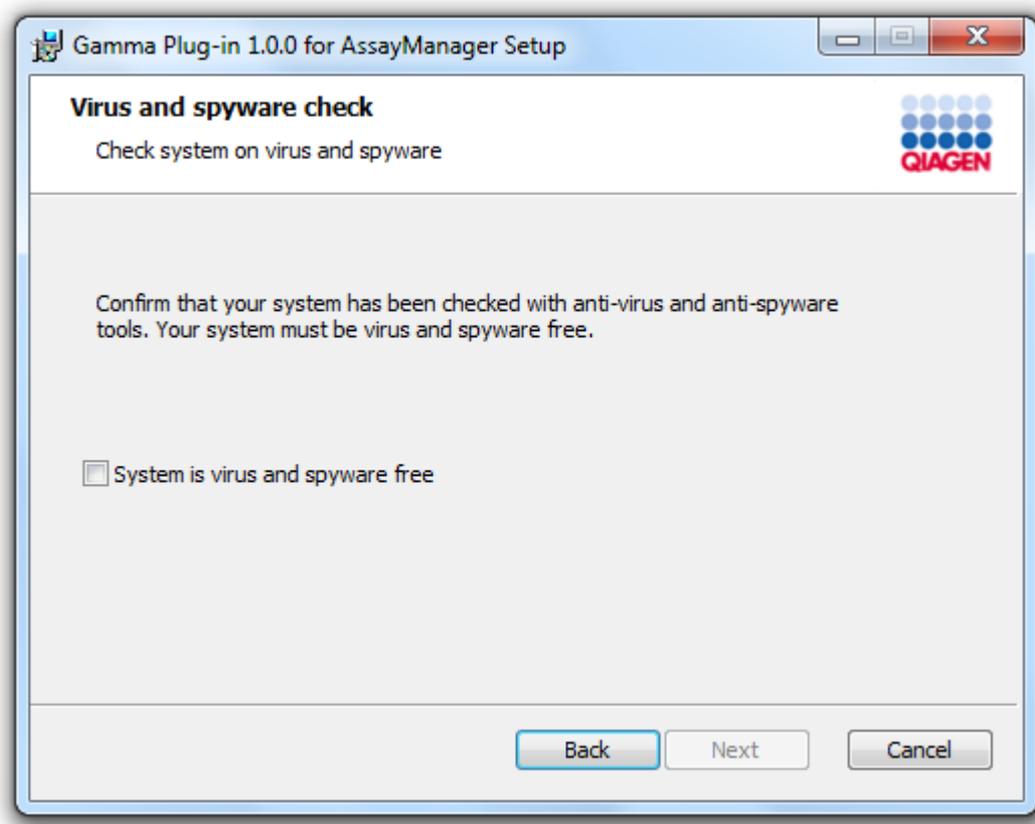
1. Download the plug-in from the QIAGEN website.
2. Start the installation of the plug-in by double-clicking on setup.exe.



3. Read and accept the license agreement by clicking the checkbox and click "Next".

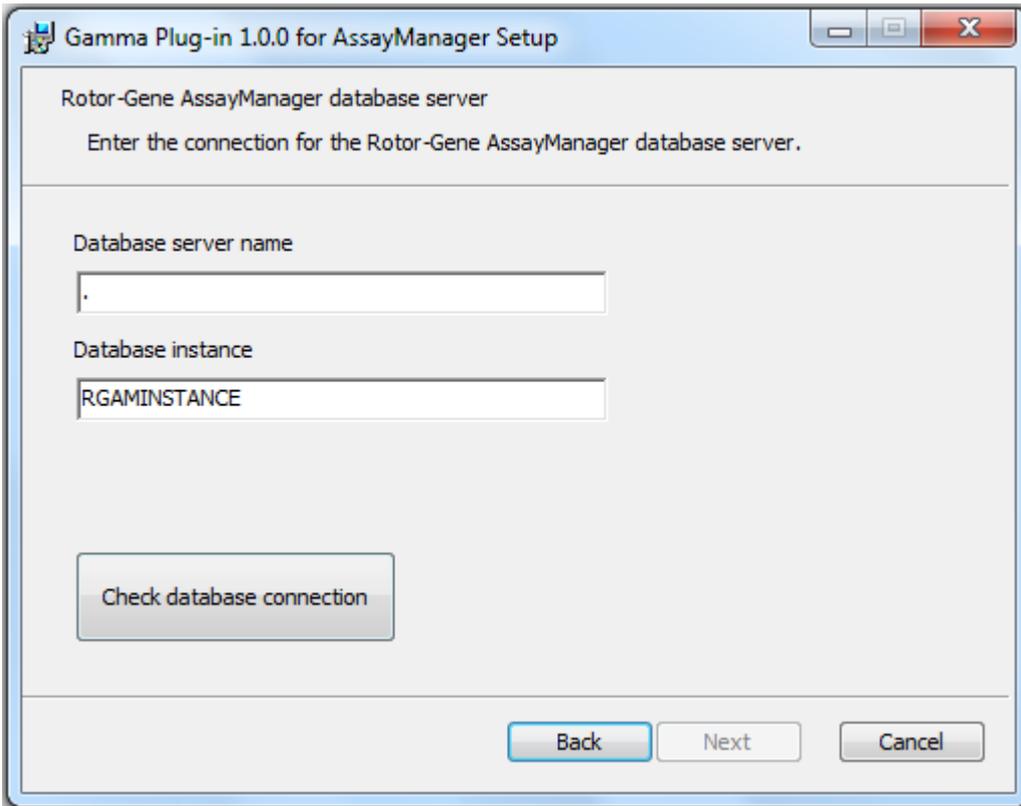


4. Confirm that your system is virus and spyware free by checking the corresponding check box and click "Next".

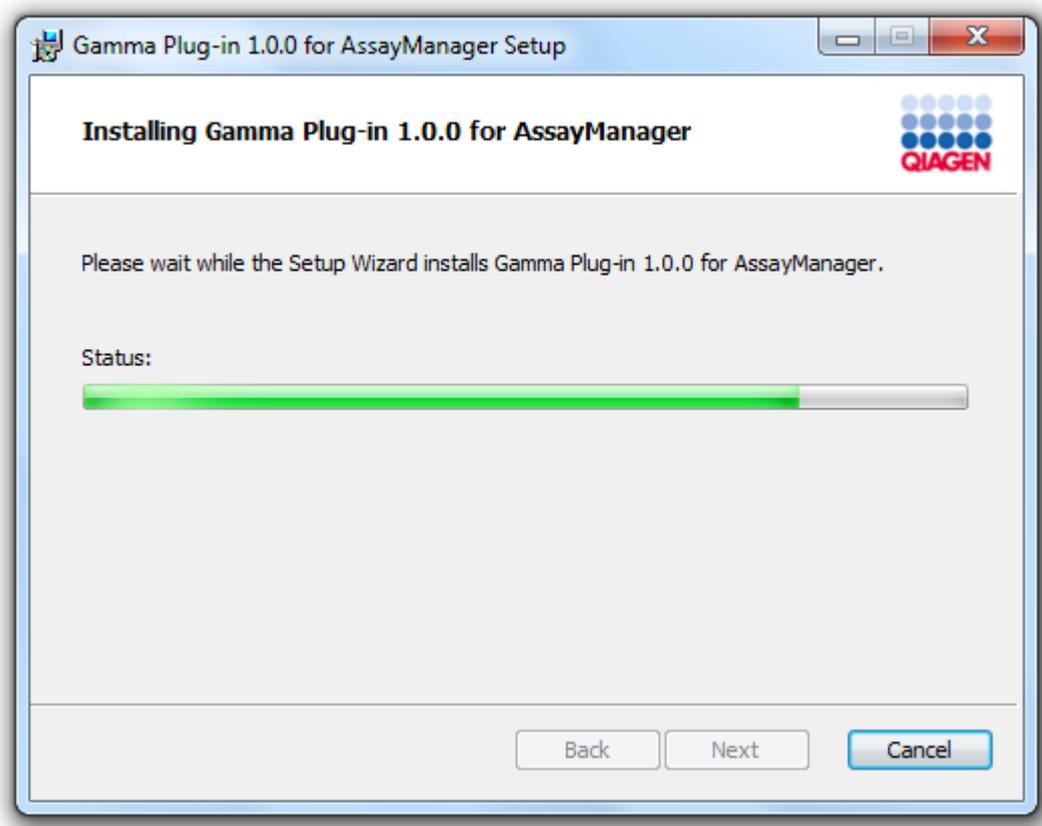


5. Fill in the required parameters.

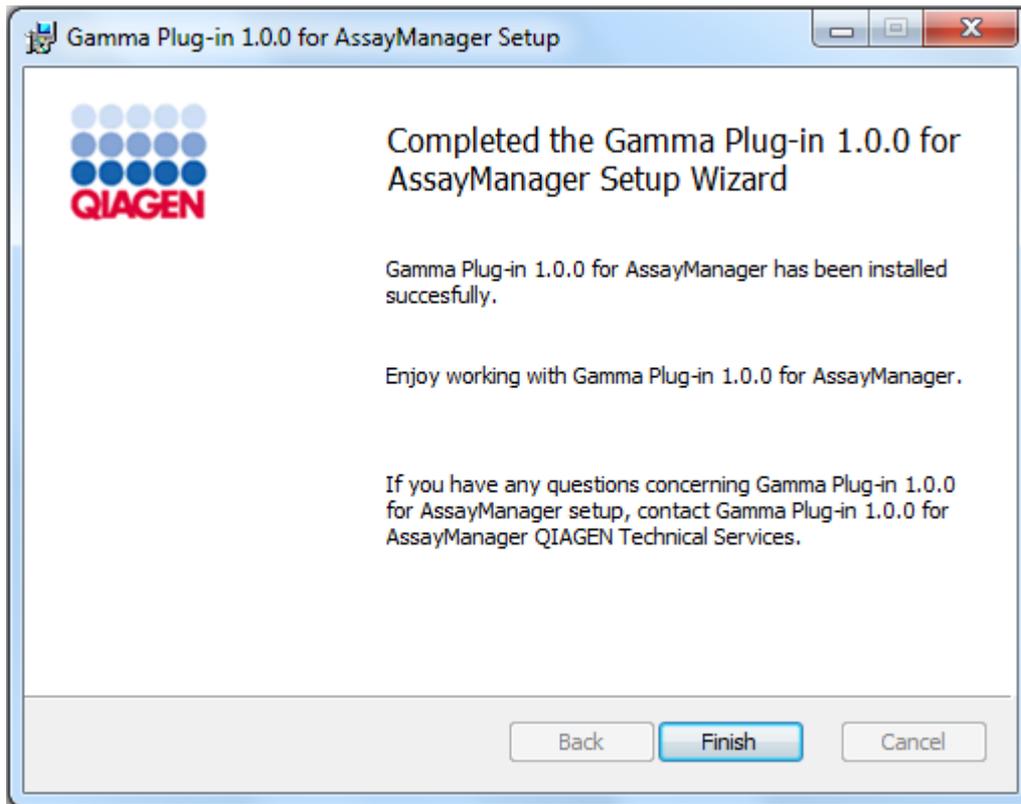
- a) If the remote "Database server" is a computer with a local installation of the Rotor-Gene AssayManager v2.1, fill in the computer name and leave the instance name ("RGAMINSTANCE") unchanged.
- b) If the "Database server" is a SQL server, fill in the your customer database instance name, provided by our database administrator.



6. Click "Next" to start the installation of the plug-in.



7. Wait until the installation process has finished.



8. After the installation is completed click "Finish" to close the window.
9. After the next restart of Rotor-Gene AssayManager v2.1 the installed plug-in will be available.

1.4.3 Additional Software on Connected Computers

Rotor-Gene AssayManager v2.1 software manages time-critical processes during the PCR run and the data acquisition process. For this reason, it is important to ensure that no other processes use significant system resources and thus slow down the Rotor-Gene AssayManager v2.1 software. It is particularly important to pay attention to the points listed in the subsections below.

System administrators are advised to consider any impact that a modification to the system may have on the resources before implementing it.

1.4.3.1 Configuration of Windows Security

The laptop computers that are provided by QIAGEN for use with your Rotor-Gene® Q instrument have Microsoft Windows 7 or 10 pre-installed and are configured with a standard (non-administrative) Windows user account and with an administrator

account. In routine usage of the system, the standard account shall be used, since Rotor-Gene AssayManager v2.1 is designed to run without administrator rights. The administrator account shall only be used to install the Rotor-Gene AssayManager v2.1 software and a virus scanner (please see chapter for anti-virus software). Using the administrator account is indicated by a red desktop background. Please make sure, that you always log-in as standard-user for routine use.

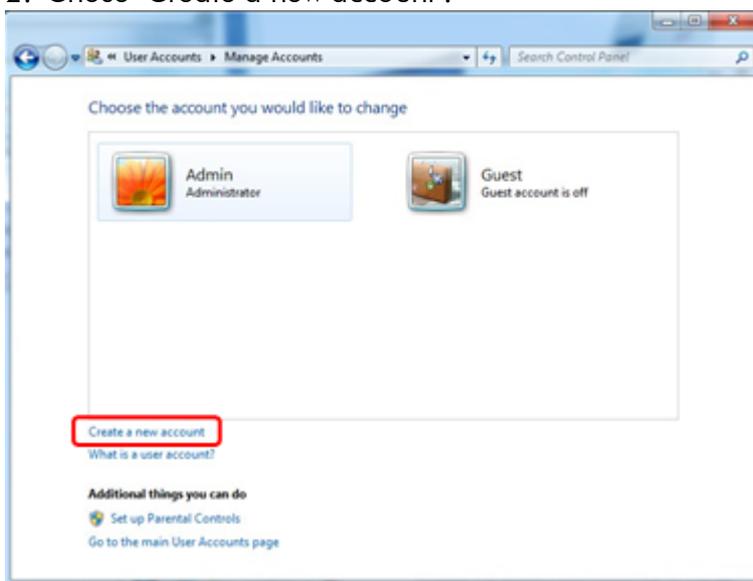
The default password of the administrator account is as follows: "Q1a#g3n!A6". Please change the administrator password after first login. Please make sure that the password is secure and does not get lost. There is no password for the operator account.

If your configuration is different and no non-administrative account is available, a system administrator should setup an additional standard Windows user account to prevent access to critical system areas, such as "Program Files", "Windows" directory (e.g. access to installation or uninstallation functionality, including applications, operating system components, date/time settings, Windows updates, firewall, user rights & roles, anti-virus activation), or performance relevant settings like power saving. Multiple users can then be configured within the Rotor-Gene AssayManager v2.1 user management.

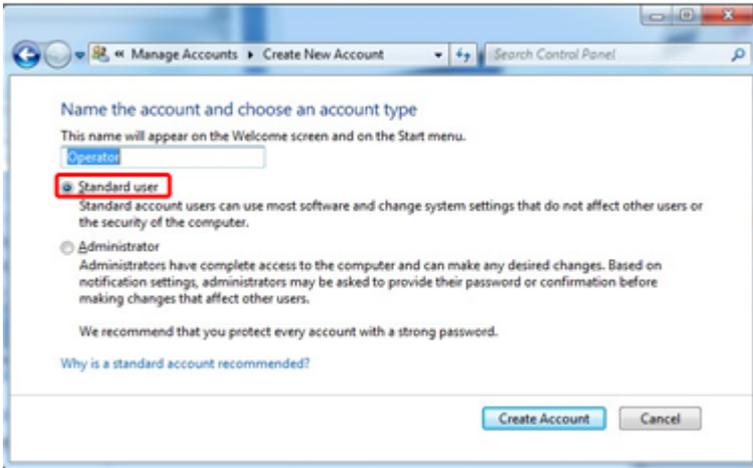
1.4.3.1.1 Configuration for Windows 7 security

To create a standard user account, please follow these steps:

1. Open the windows control panel via the "Start" menu and select the "User Accounts/Manage Accounts".
2. Chose "Create a new account".



3. Name the account and select "Standard User" as the account type.

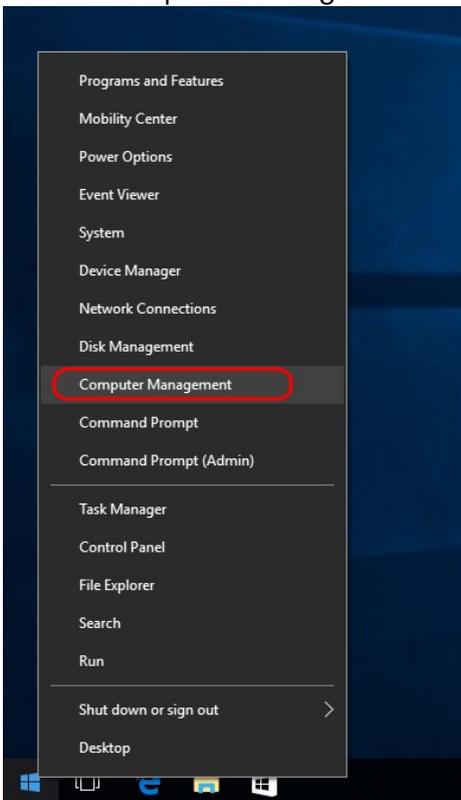


4. Click "Create Account"

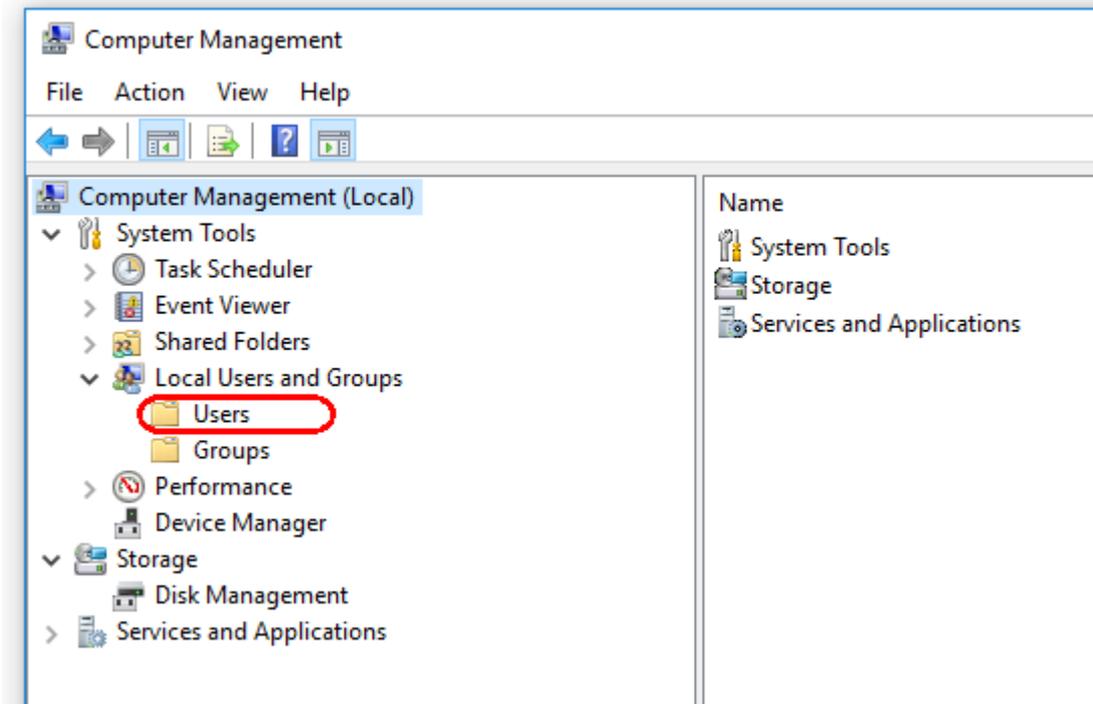
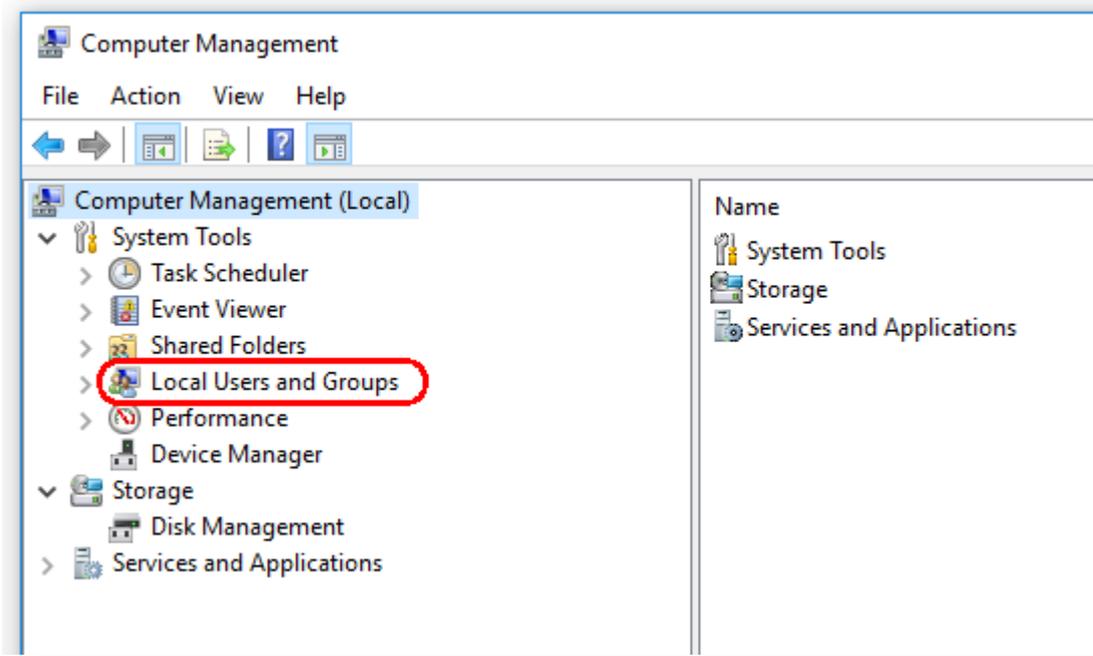
1.4.3.1.2 Configuration for Windows 10 security

To create a standard user account in Windows 10, please follow these steps:

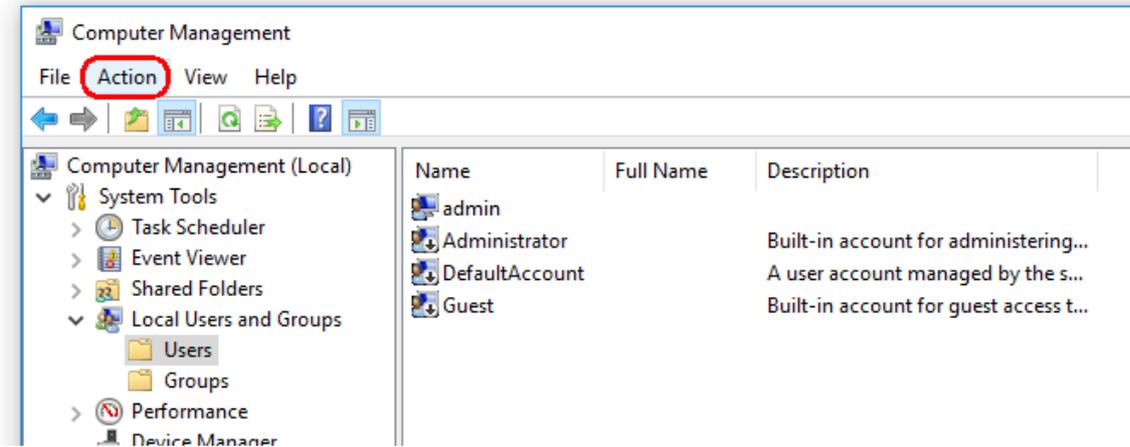
1. Right-click on the Windows icon in the lower-left corner of the screen. Select "Computer Management".



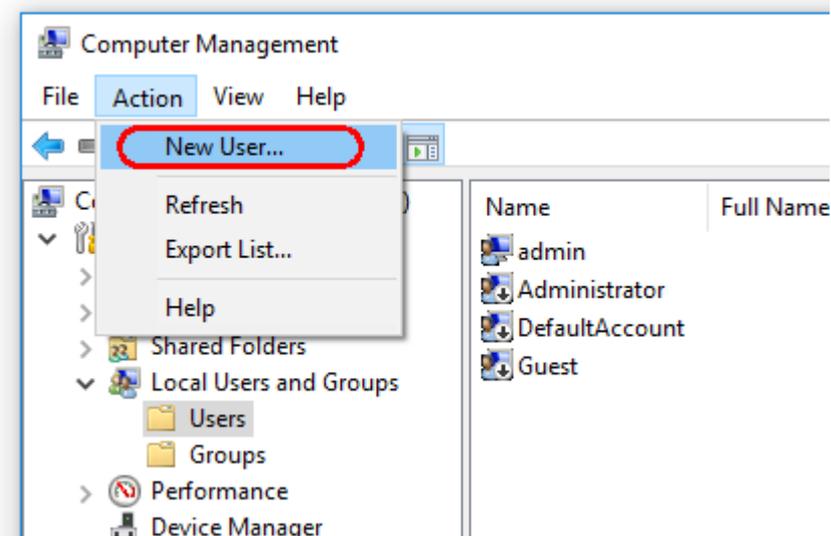
2. Expand Local Users and Groups.



3. Select "Users". With "Users" highlighted, click "Action".



4. Select "New User...".



New User

User name: Operator

Full name:

Description:

Password: ●●●●●●

Confirm password: ●●●●●●

User must change password at next logon

User cannot change password

Password never expires

Account is disabled

Help Create Close

5. Enter the user name "Operator" and set a password that is compliant with your security rules.

6. Uncheck "User must change password at next logon" to allow more options.

The screenshot shows a "New User" dialog box with the following fields and options:

- User name: Operator
- Full name: [Empty]
- Description: [Empty]
- Password: [Masked with 8 dots]
- Confirm password: [Masked with 8 dots]
- User must change password at next logon
- User cannot change password
- Password never expires
- Account is disabled

Buttons at the bottom: Help, Create, Close.

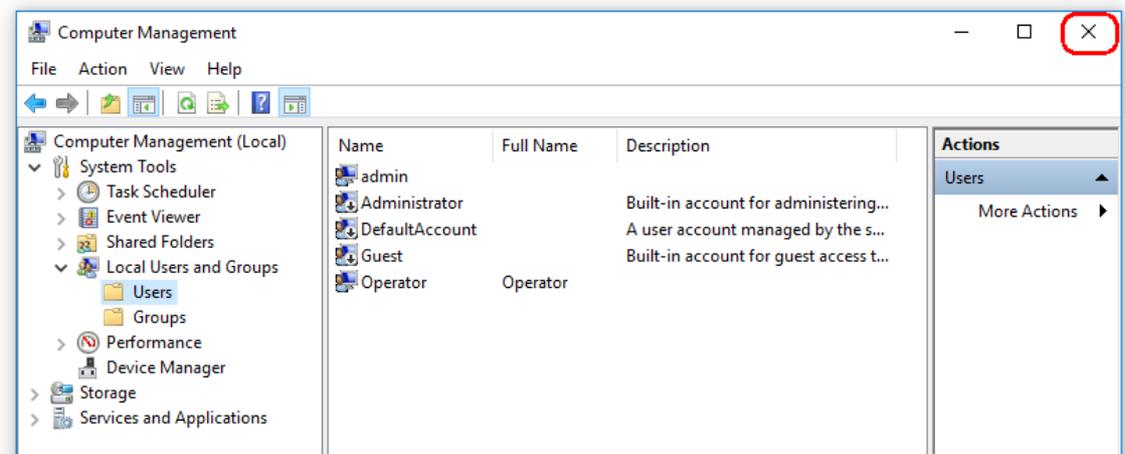
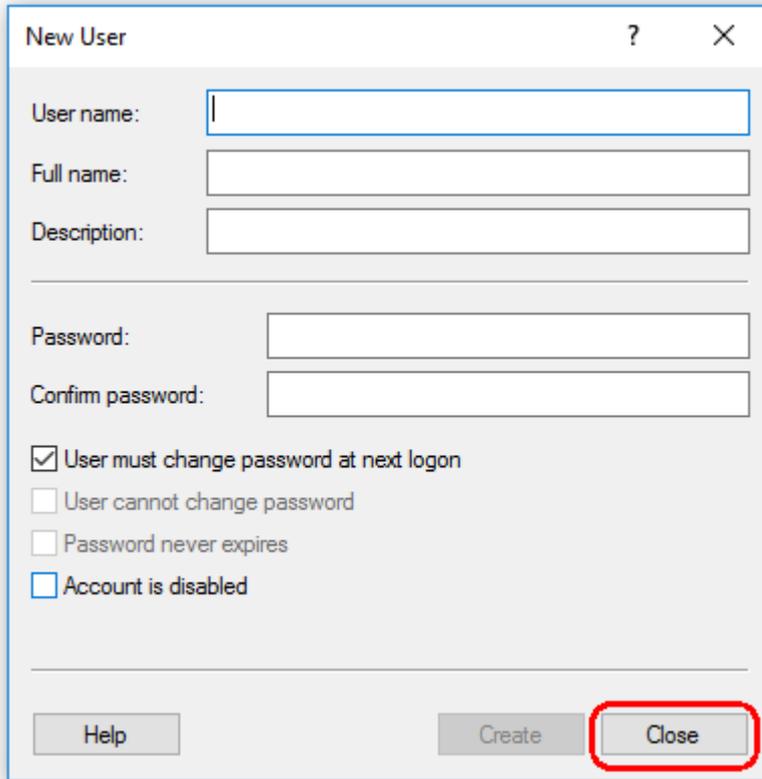
7. Click "Create" to finish.

The image shows a 'New User' dialog box with the following fields and options:

- User name: Operator
- Full name: (empty)
- Description: (empty)
- Password: (masked with dots)
- Confirm password: (masked with dots)
- User must change password at next logon
- User cannot change password
- Password never expires
- Account is disabled

Buttons at the bottom: Help, Create (highlighted with a red circle), Close.

8. Add another user or click "Close". All existing local users are shown in the "Users" list.

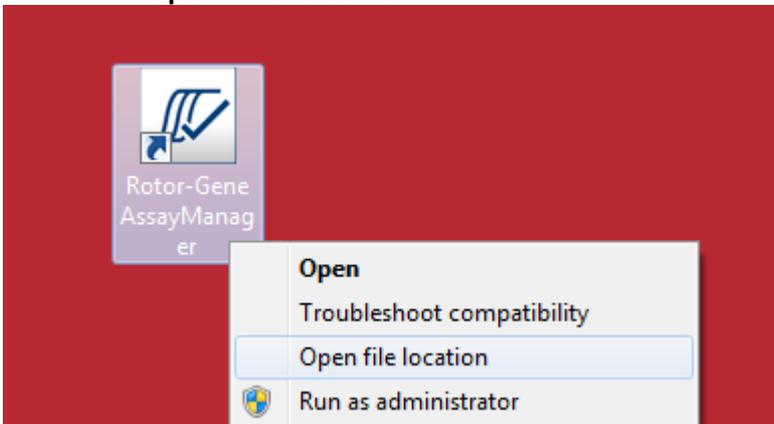


9. Close "Computer Management".
Change the password of the currently logged-in user by pressing the key combination CTRL + ALT + DELETE and selecting "Change a password" from the available options.

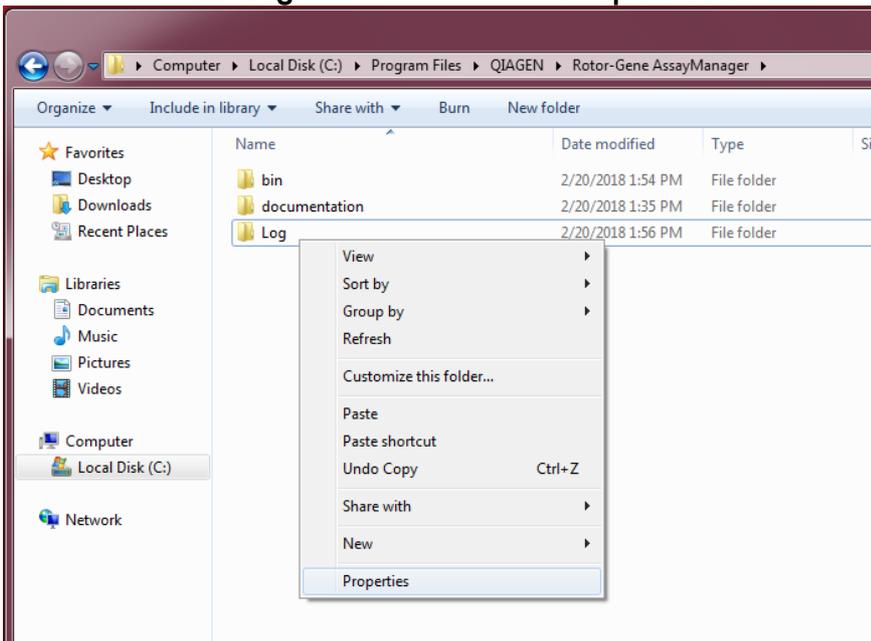
1.4.3.2 Setting up properties for log folder

If you are using Rotor-Gene AssayManager v2.1 in a multi-user windows environment, you must manually setup permissions for the “log” folder after installing RGAM. Otherwise it will not be possible for RGAM to create new log files if the windows user is changed.

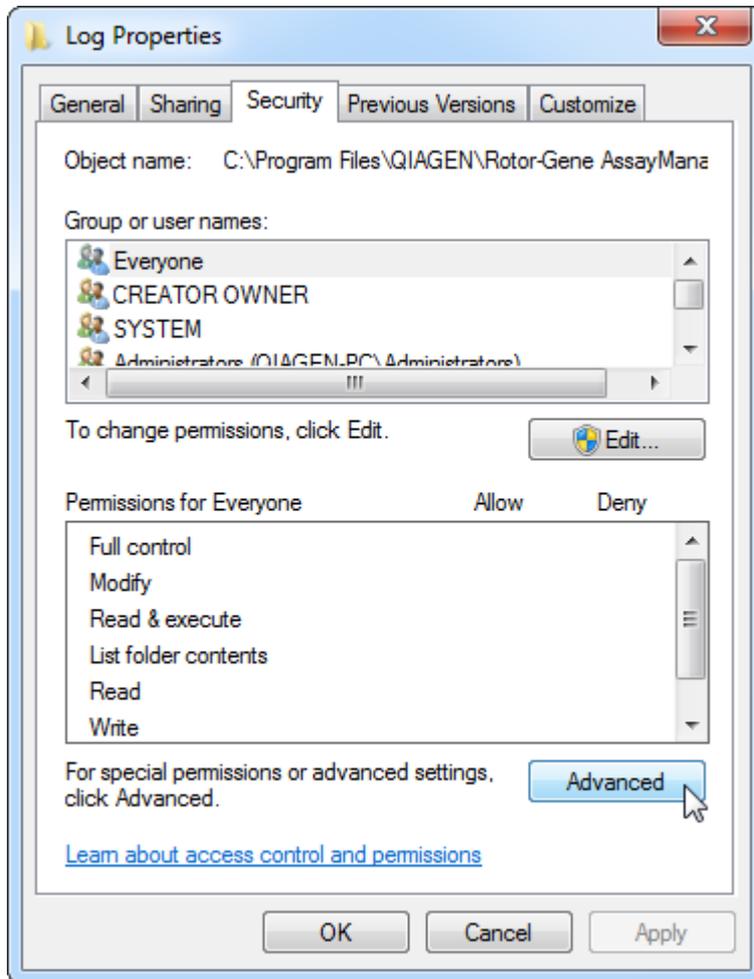
1. Log in as administrator, right click on the Rotor-Gene AssayManager icon and select “**Open file location**”.



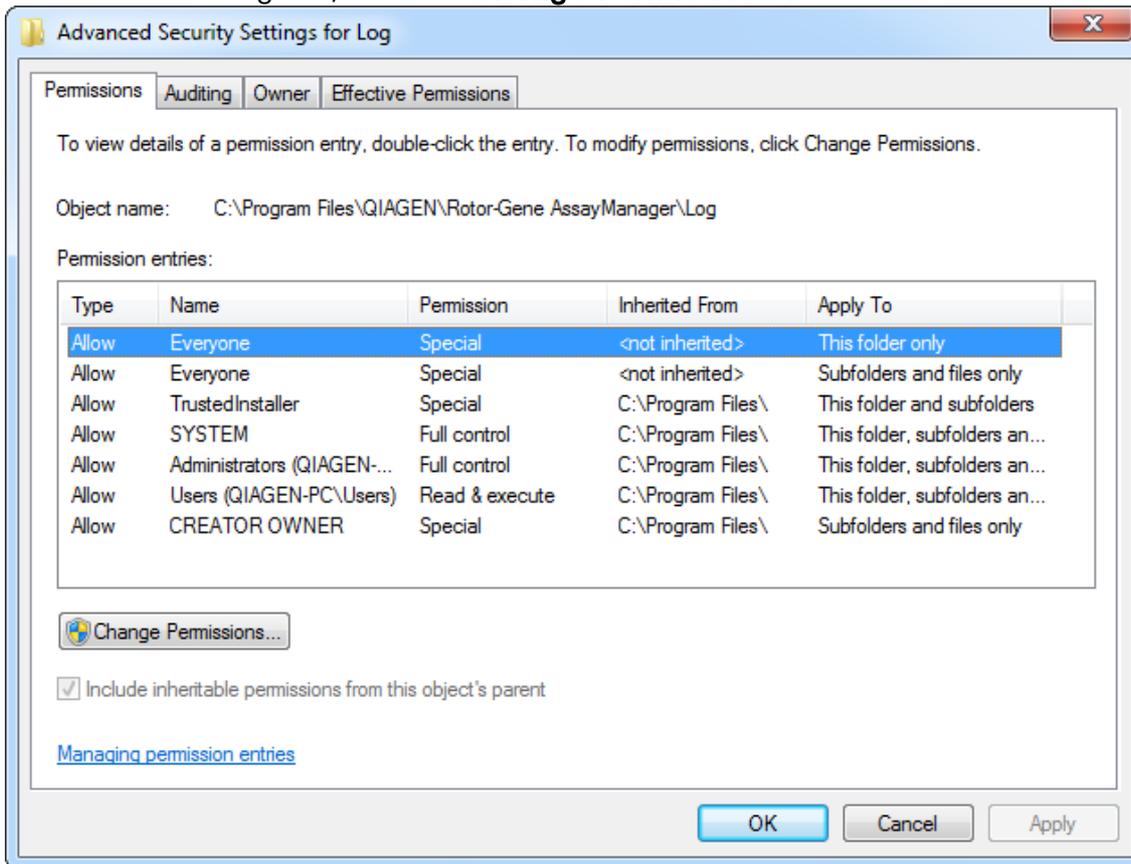
2. The file explorer will open the Rotor-Gene AssayManager/bin folder. Navigate up one folder to the Rotor-Gene AssayManager top folder. Click with the right mouse button on the “**Log**” folder and select “**Properties**”:



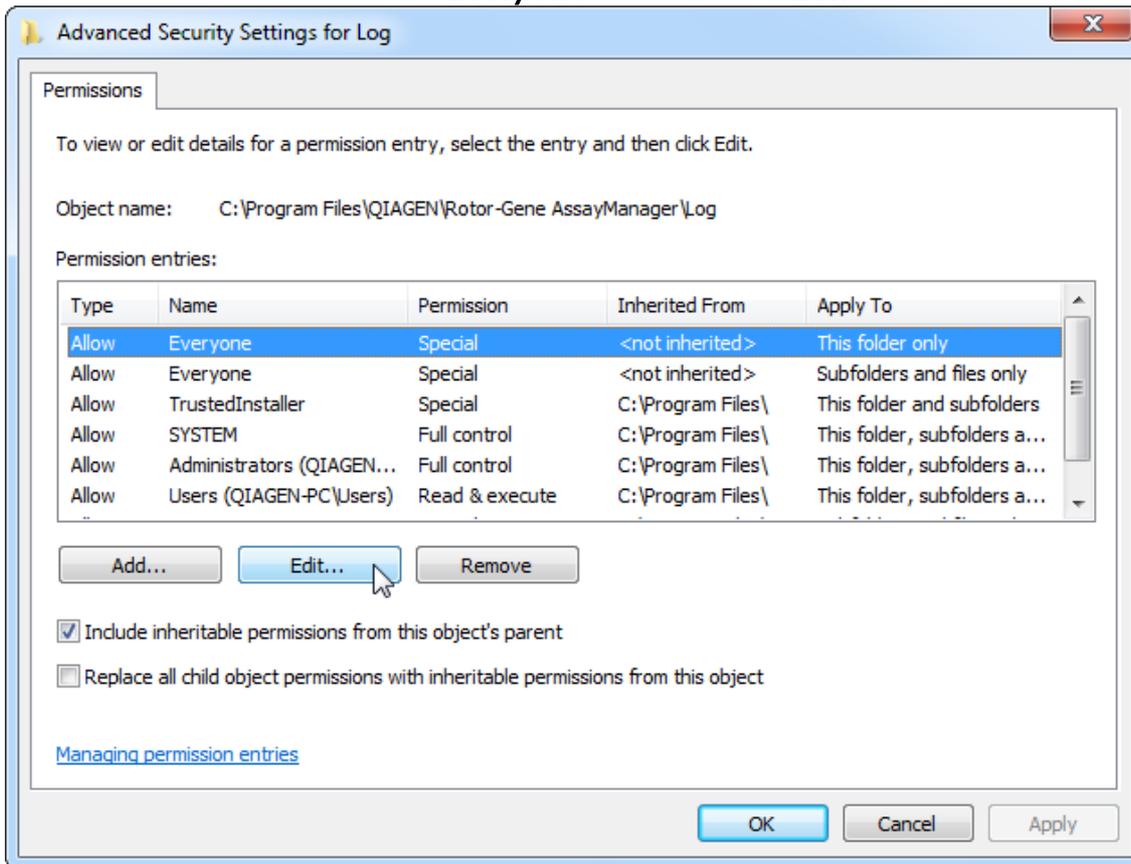
3. In the new dialog box, click on the **“Security”** tab and then select the **“Advanced”** button:



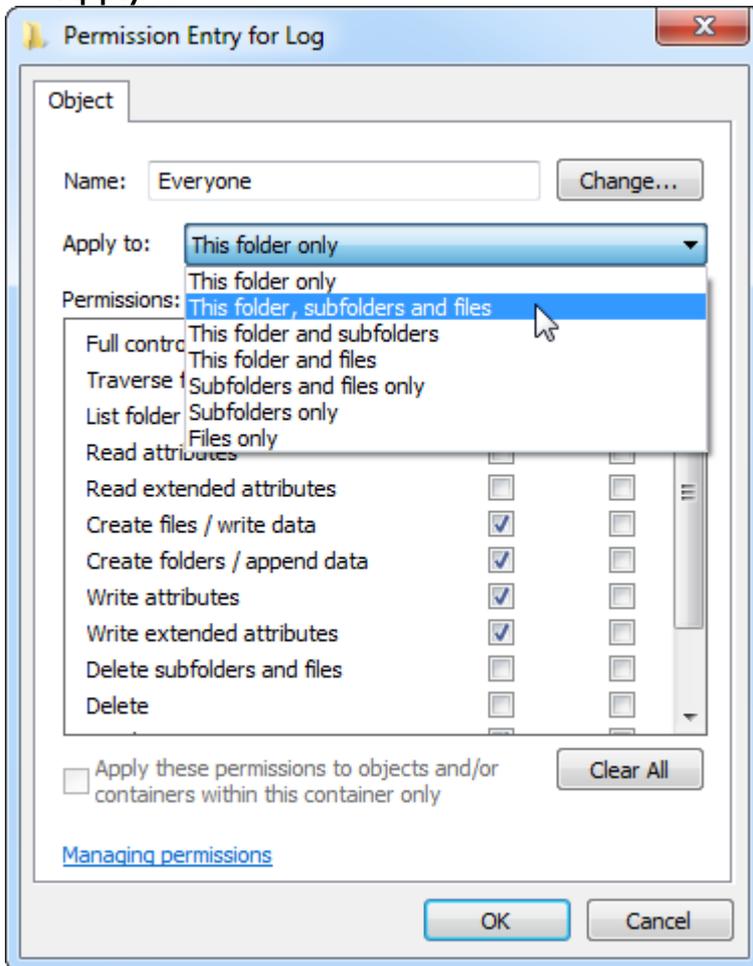
4. In the new dialog box, click on “**Change Permissions...**”:



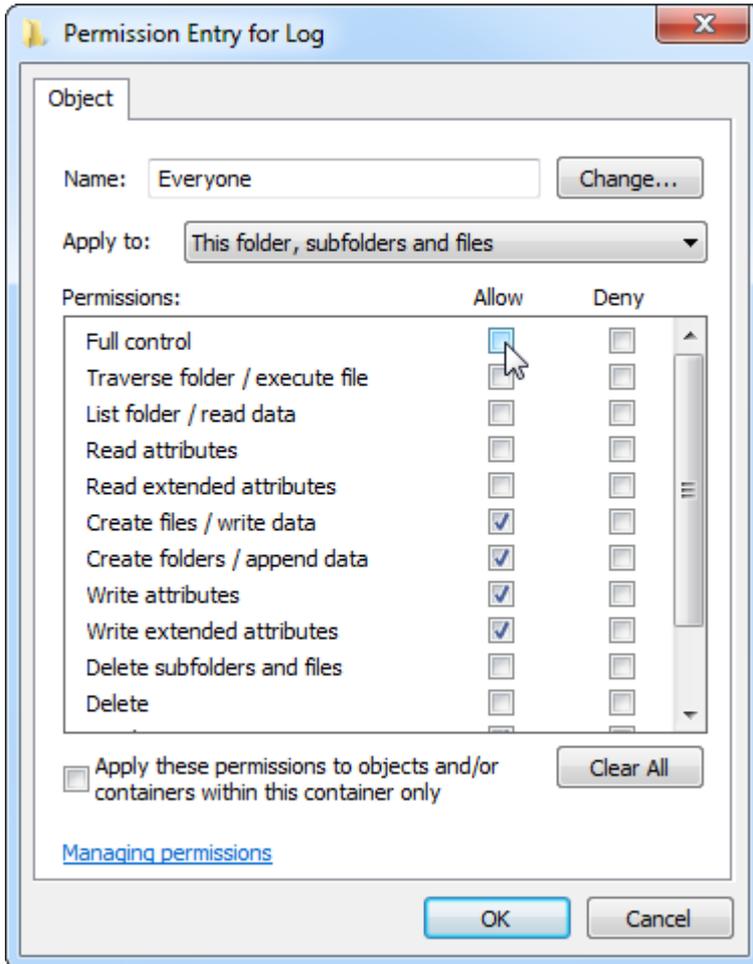
5. Select the user with the name **"Everyone"** and click on **"Edit"**.



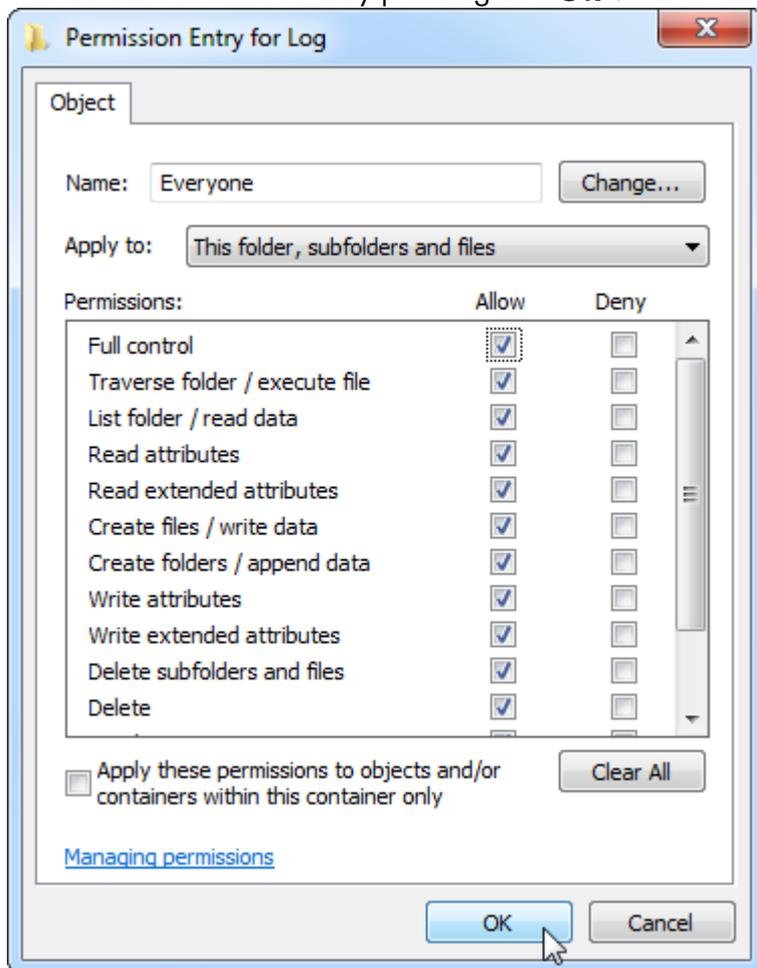
6. Select the entry **"This folder, subfolders and files"** from the drop-down menu **"Apply to"**:



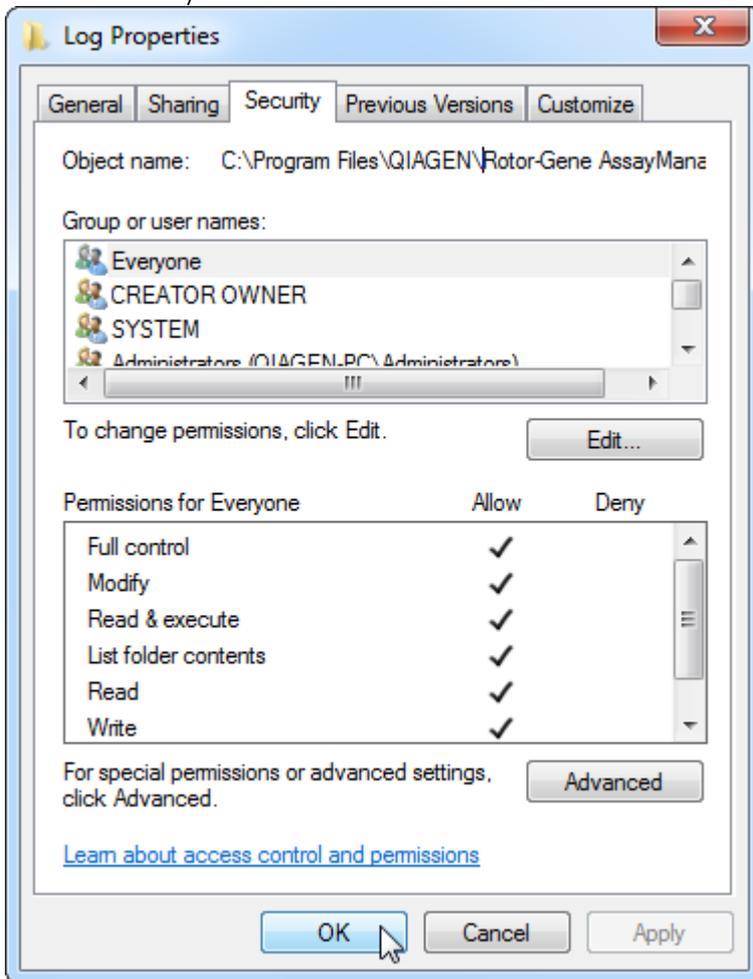
7. Click on “**Click**” on the checkbox “**Full Control**” in the column under “**Allow**”:



8. Afterwards, **“Allow”** should be checked for all permissions. Confirm this dialog and close the window by pressing on **“Ok”**.



9. Close the remaining dialogs with a click on the “**Ok**” Button as well. The last dialog box should look like the one on the following page (User “**Everyone**” has full control):



1.4.3.3 Anti-virus software

QIAGEN is aware of the threat that computer viruses cause to any computer that exchanges data with other computers. Rotor-Gene AssayManager v2.1 software is expected to be primarily installed in environments where local policies are in place to minimize this threat. However, QIAGEN recommends the use of a virus scanner. The selection and installation of an appropriate virus scanning tool is in the customer's responsibility. However, QIAGEN has validated the Rotor-Gene AssayManager with the QIAGEN laptop in combination with the following two virus scanners to show compatibility:

- Symantec Endpoint Protection V12.1.6
- Microsoft Security Essentials V4.10.209

Note: After installation of “Microsoft Security Essentials”, you should check that Windows updates are deactivated since the installation might activate this setting (please read chapter “Operating system updates”).

Please refer to the product page on www.QIAGEN.com for the latest versions of anti-virus software that have been validated in combination with Rotor-Gene AssayManager v2.1.

If a virus scanner is selected, make sure that it can be configured in a way that the database folder path can be excluded from the scan. Otherwise, there is the risk of database connection errors. As Rotor-Gene AssayManager v2.1 creates new database archives dynamically, it is required to exclude the folder path to the files and not single files. We do not recommend the use of virus scanners where only single files can be excluded, e.g. McAfee Antivirus Plus V16.0.5. If the computer is used in an environment without network access, please also make sure that the virus scanner supports offline updates.

The selection of an appropriate virus scanning tool is the customer’s responsibility. To get consistent results after installation of a virus scanner, a system administrator should ensure the following:

- As explained above, the database folder path of the Rotor-Gene AssayManager v2.1 needs to be excluded from file scans which is as follows: C:\Program Files\Microsoft SQL Server\MSSQL10_50.RGAMINSTANCE\MSSQL\DATA or C:\Program Files\Microsoft SQL Server\MSSQL14.RGAMINSTANCE\MSSQL\DATA depending on the MS SQL server version which initially created the database
- Updates to the virus database are not performed when the Rotor-Gene AssayManager v2.1 is in use
- Please make sure that full or partial scans of the hard drive are disabled during real-time PCR data acquisition. Otherwise there is a risk of adverse impact on the performance of the instrument.

Please read the manual of your selected virus scanner for configuration details.

1.4.3.4 System tools

Many system tools may use significant system resources even without any user interaction. Typical examples of such tools are:

- File indexing, which is performed as a background task by many contemporary office applications
- Disk defragmentation, which often also employs a background task
- Any software that checks for updates on the Internet
- Remote monitoring and management tools

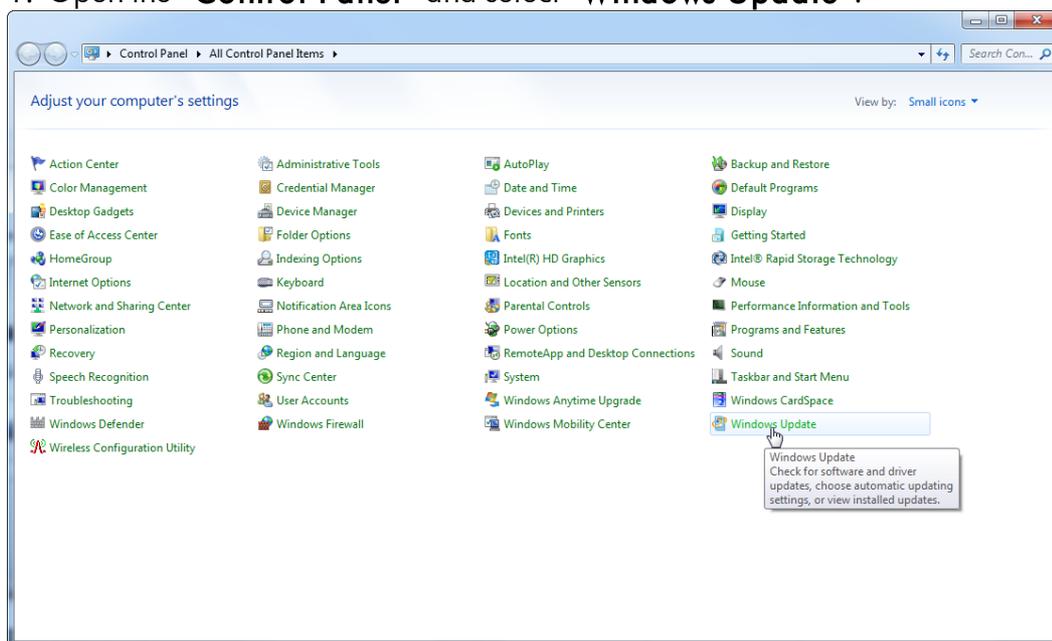
Note: Due to the dynamic nature of information technology products and systems, this list may be incomplete. Tools may be released that are not known at the time of

writing. It is important that system administrators take care that such tools are not active on the computer while Rotor-Gene AssayManager v2.1 is performing a PCR run.

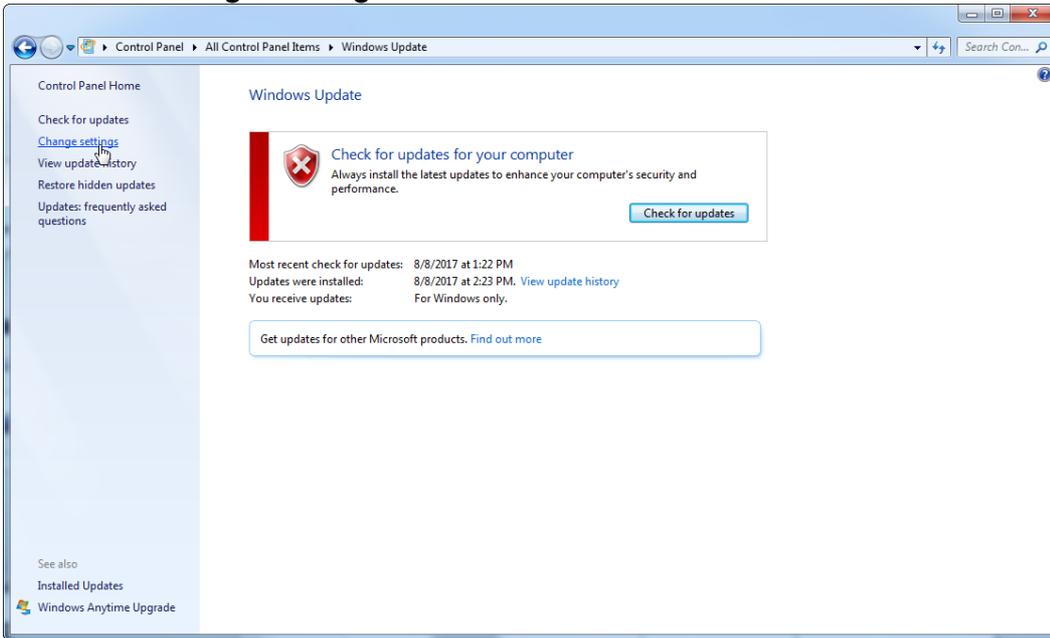
1.4.3.5 Operating system updates

The laptop computers provided by QIAGEN is configured in a way that automatic updates to the operating system are disabled. If your configuration is different, a system administrator must disable any automatic updates to the operating system. This can be performed as follows.

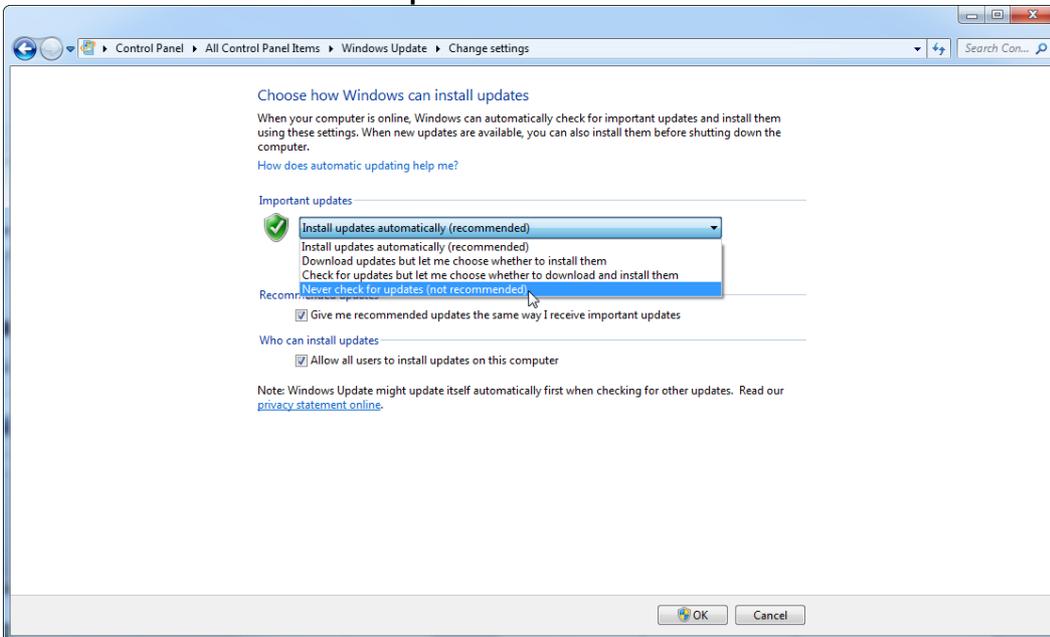
1. Open the “**Control Panel**” and select “**Windows Update**”.



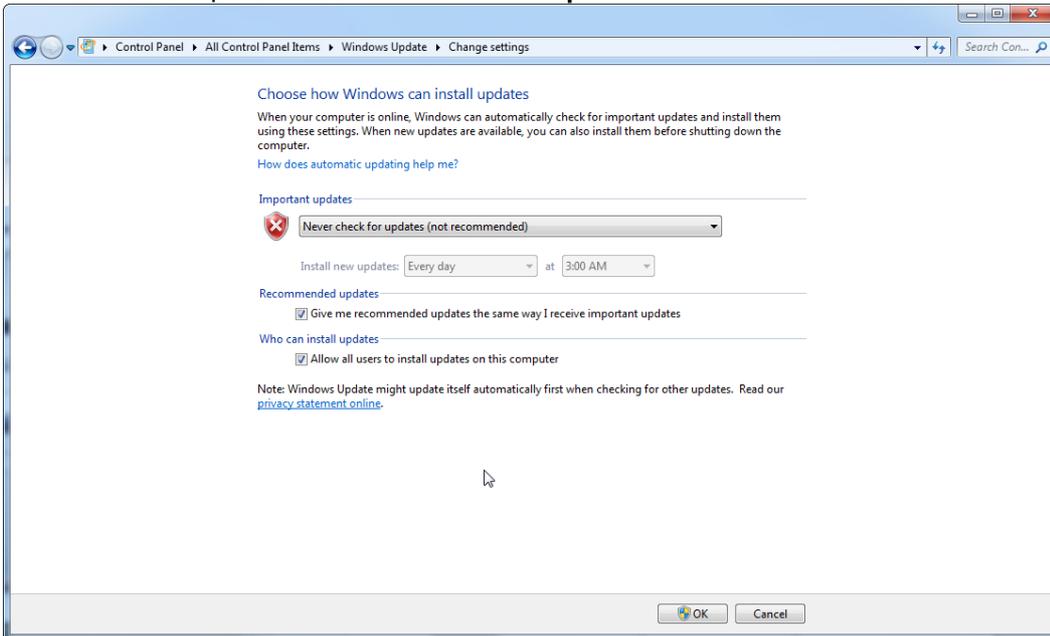
2. Select "Change settings".



3. Select "Never check for updates".



4. Check that option “Never check for updates” is active.



In case updates are required due to uncovered security vulnerabilities, QIAGEN provides mechanisms to install a defined set of validated Windows security patches either online (if an internet connection is available on the QIAGEN laptop), or as offline package, prepared on a separate computer with internet connection.

Please visit the product page on www.qiagen.com/support/technical-support/qiagen-system-updater/ for more information

To maintain the highest level of system security, you can be notified when a new release of the QIAGEN System Updater is available. Register at <https://go.qiagen.com/QIAGENSysUpdaterSignUp> to receive updates regarding the QIAGEN System Updater. If you choose to not register, email notification of updates will be sent to the contacts QIAGEN has listed for your account. Once registered, QIAGEN will send you an email when a new release of the QIAGEN System Updater is available for download.

1.4.3.6 Firewall and Networks

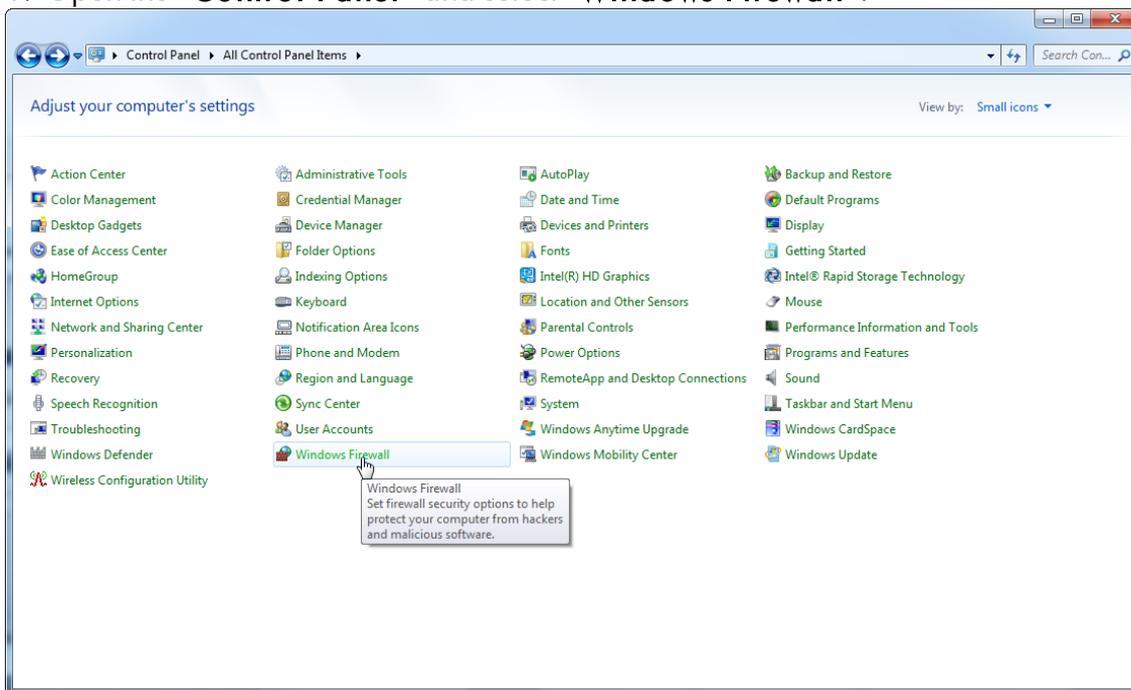
The Rotor-Gene AssayManager v2.1 can run either on computers without network access, if the database is located on the same computer that controls the Rotor-Gene Q MDx instrument, or can run in a network environment, if a remote database server is used. For networked operation, the firewall on the laptop computer provided by QIAGEN is configured in a way that inbound traffic is blocked for all ports except those ones required to establish a network connection.

Please note that blocking incoming connections does not affect responses to requests triggered by the user such as updating anti-virus definition files, or connecting the

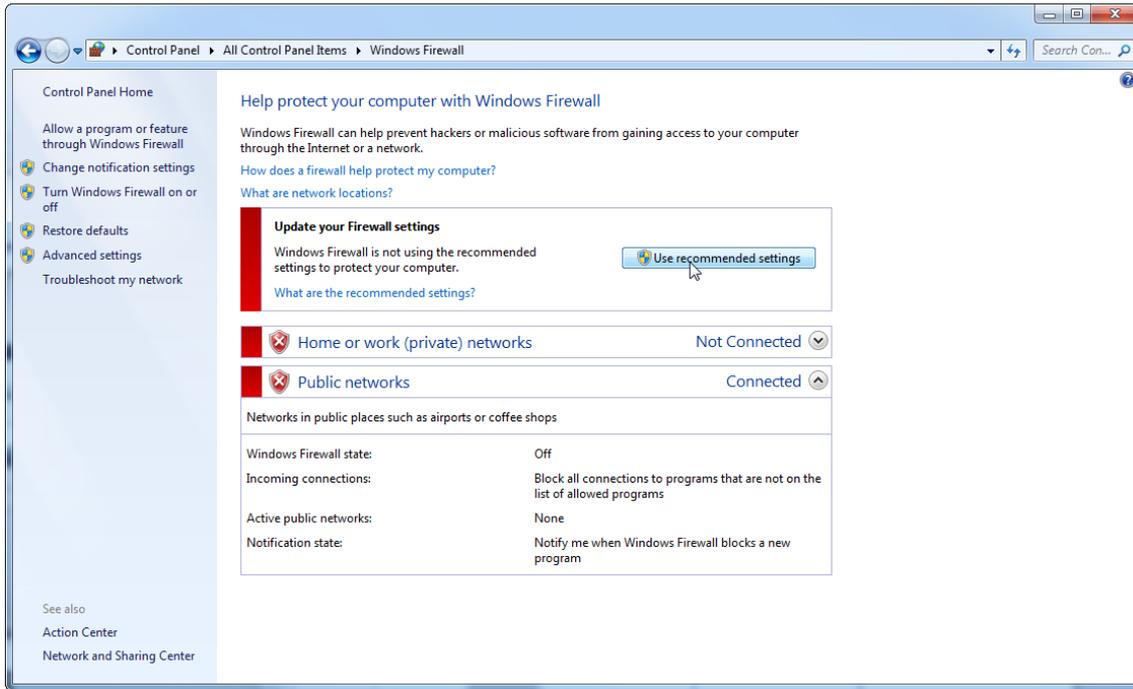
Rotor-Gene AssayManager v2.1 to the centralized database server. Outgoing connections are allowed as this may be required for retrieving updates or when the Rotor-Gene AssayManager v2.1 is configured to work with a centralized database server. For security and reliability reasons in such cases, a cable-based local area networks instead of wireless network connections should be used.

If your configuration is different, QIAGEN recommends you configure the firewall in the same way as described above. To this end, a system administrator has to login and has to perform the following steps:

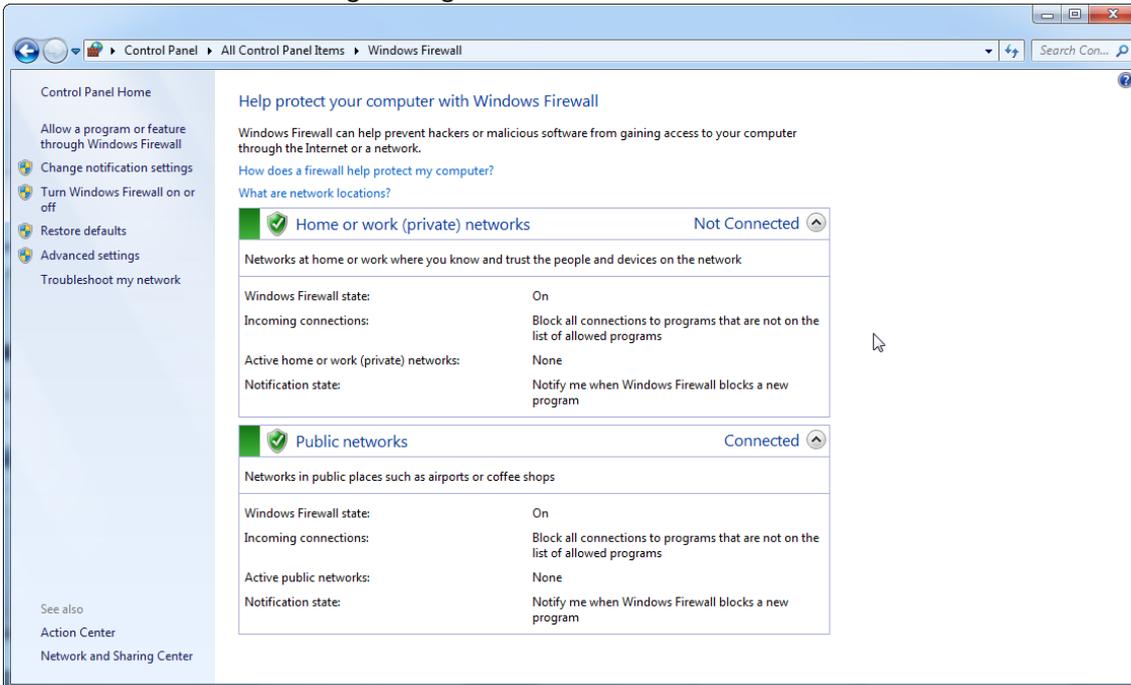
1. Open the “**Control Panel**” and select “**Windows Firewall**”.



2. Select “**Use recommended settings**”.



3. Check that the following settings are active:

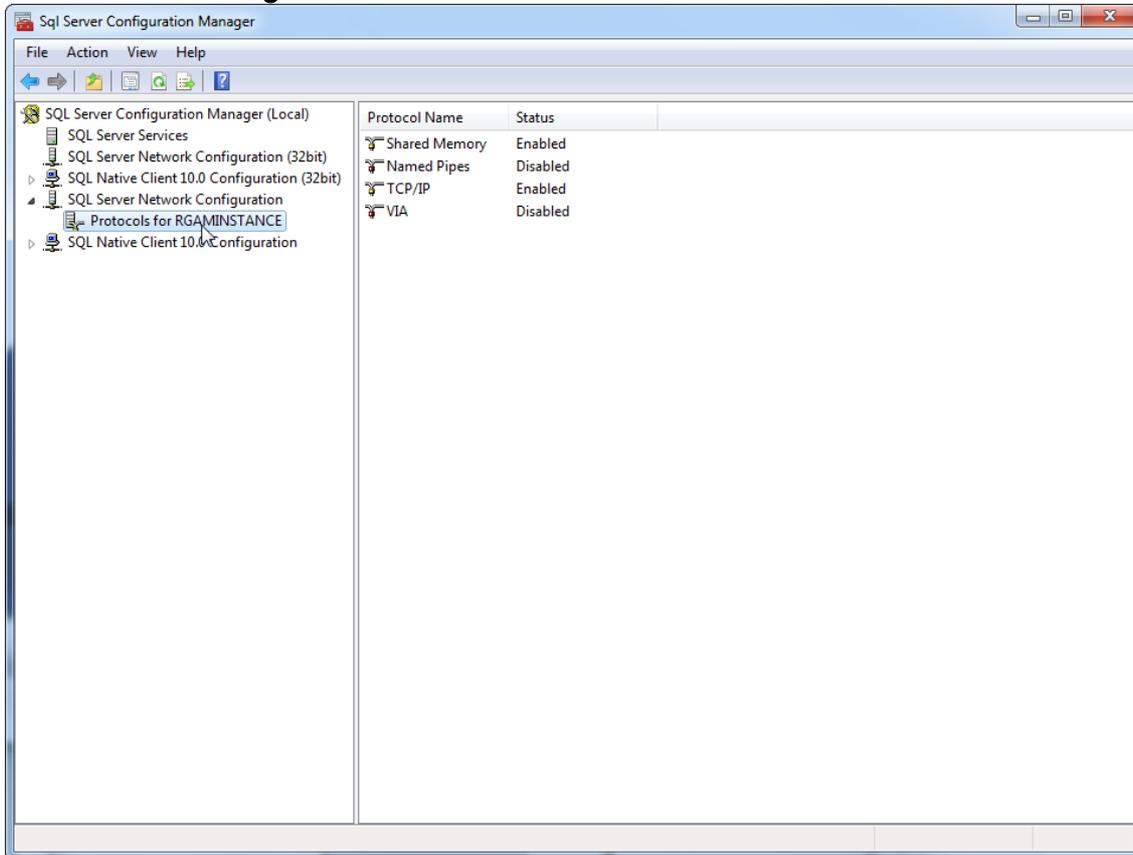


If you use a stand-alone computer that is connected to a network and you want to install Rotor-Gene AssayManager v2.1 on another computer to connect to the first (cf. configuration, page 36), a system administrator must create an exception in the firewall configuration. This exception can be created by executing the following steps:

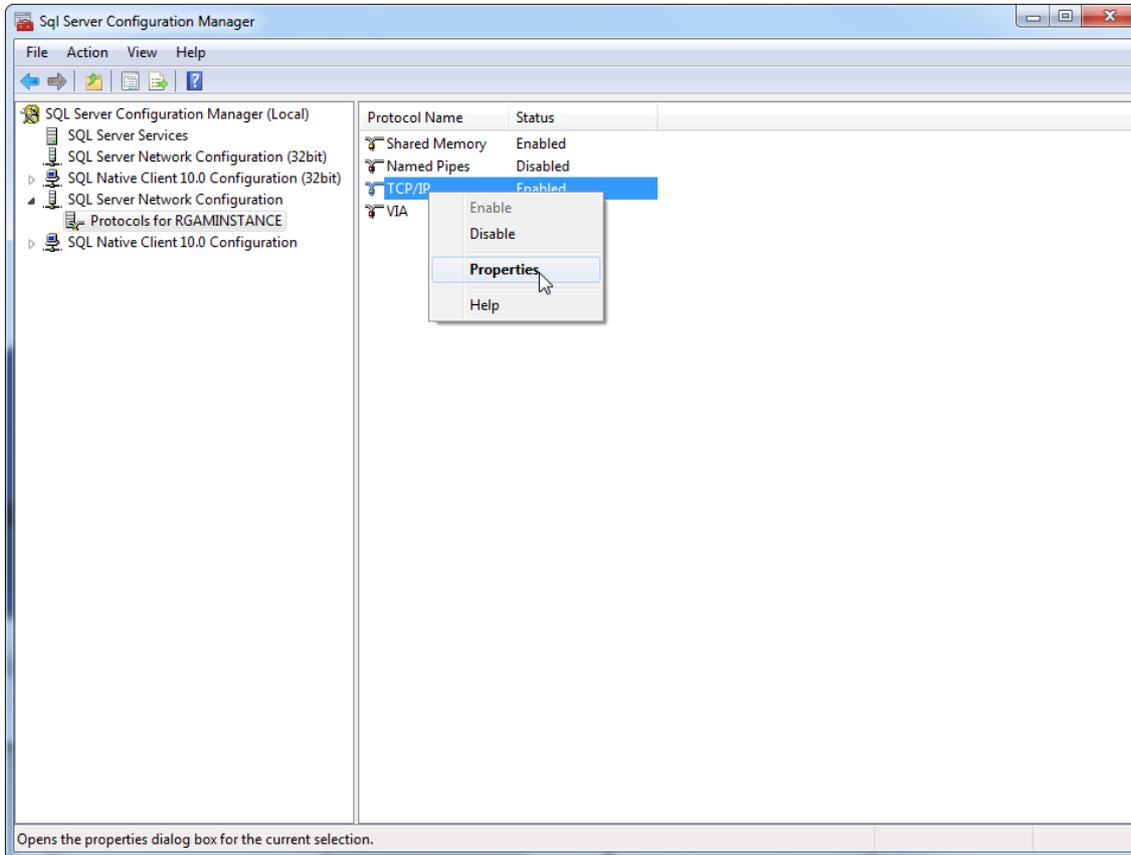
1. Select **"SQL Server Configuration Manager"** from the start menu.



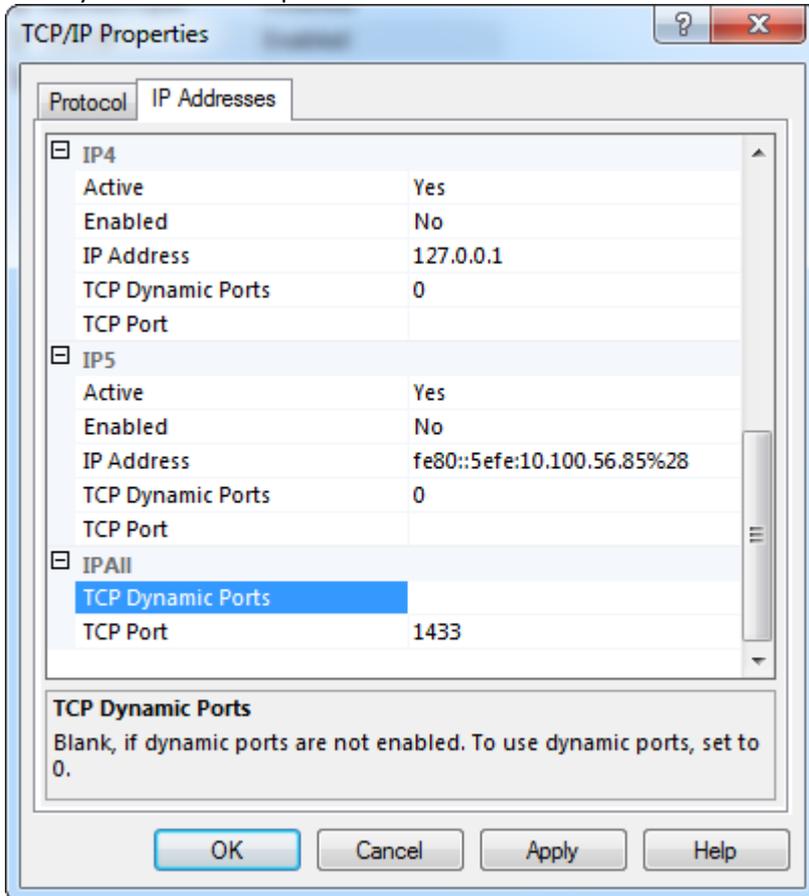
2. Select **“Protocols for RGAMINSTANCE”** which is a sub-item of **“SQL Server Network Configuration”**



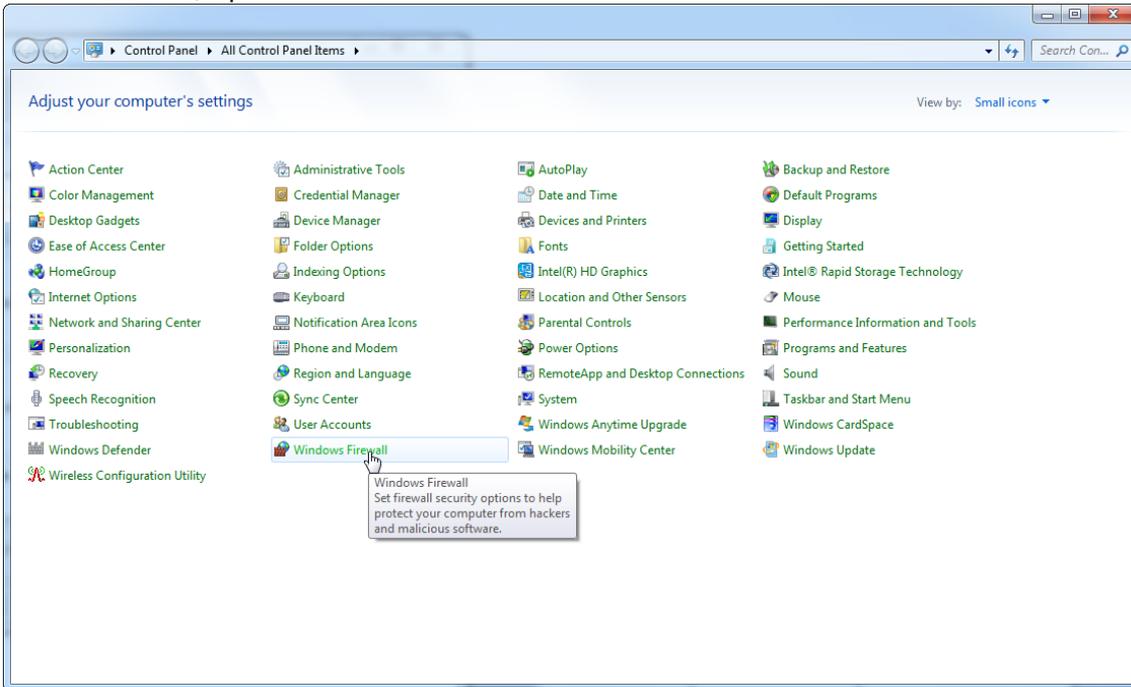
3. Hover over **"TCP/IP"**, press the right mouse button, and select **"Properties"** from the context menu.



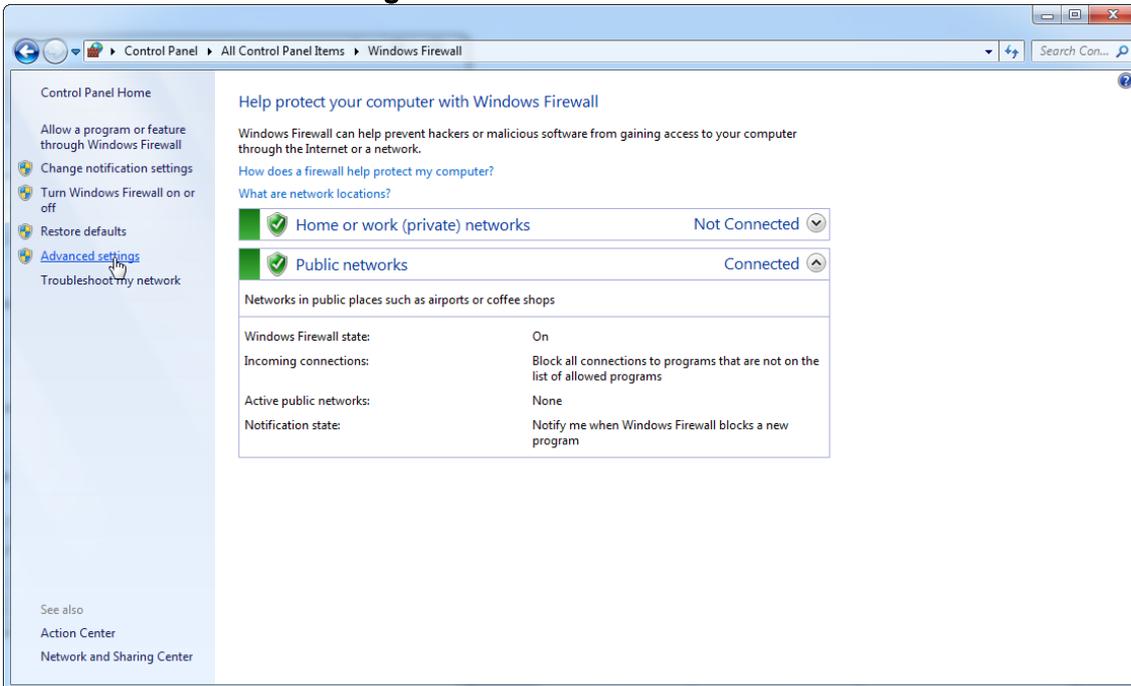
4. Remove the random number at “**TCP Dynamic Port**” if this is predefined and add the SQL-standard port 1433 at “**TCP Port**”. If this port is in use, you can use any other unused port.



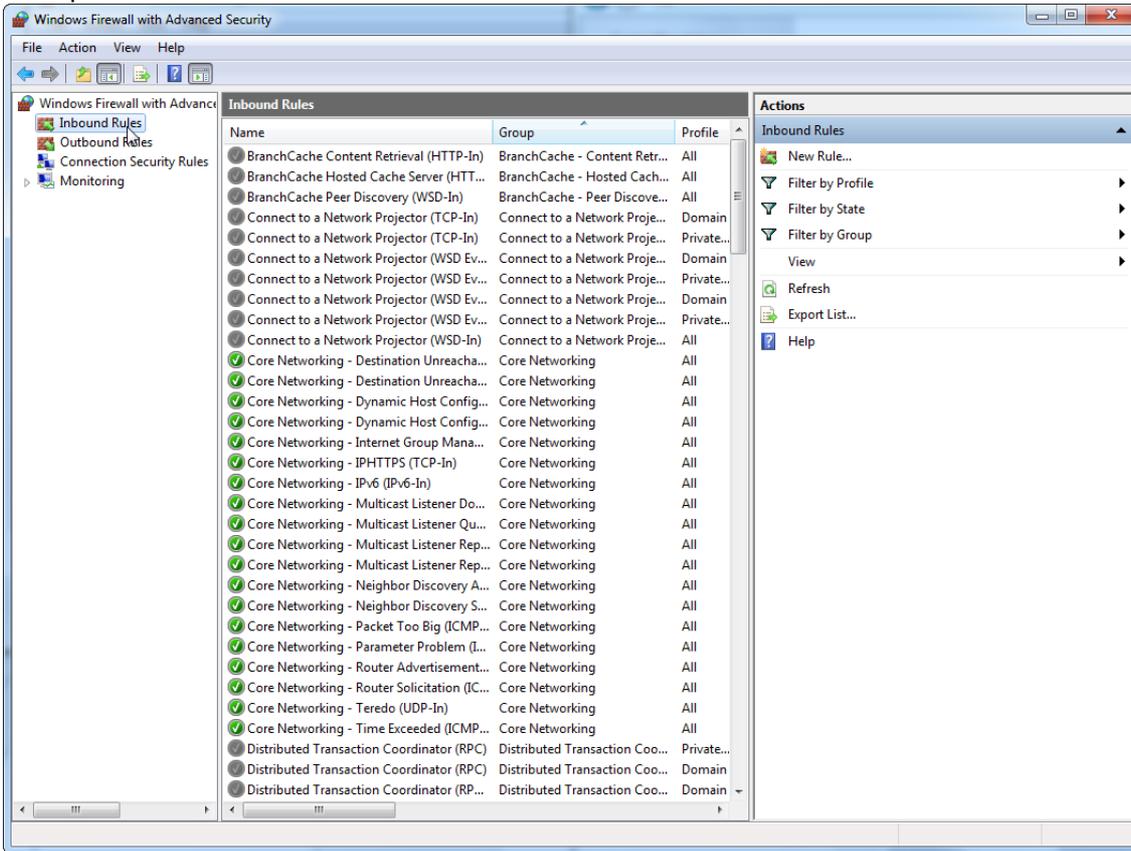
5. Press "OK", open the "Control Panel" and select "Windows Firewall".



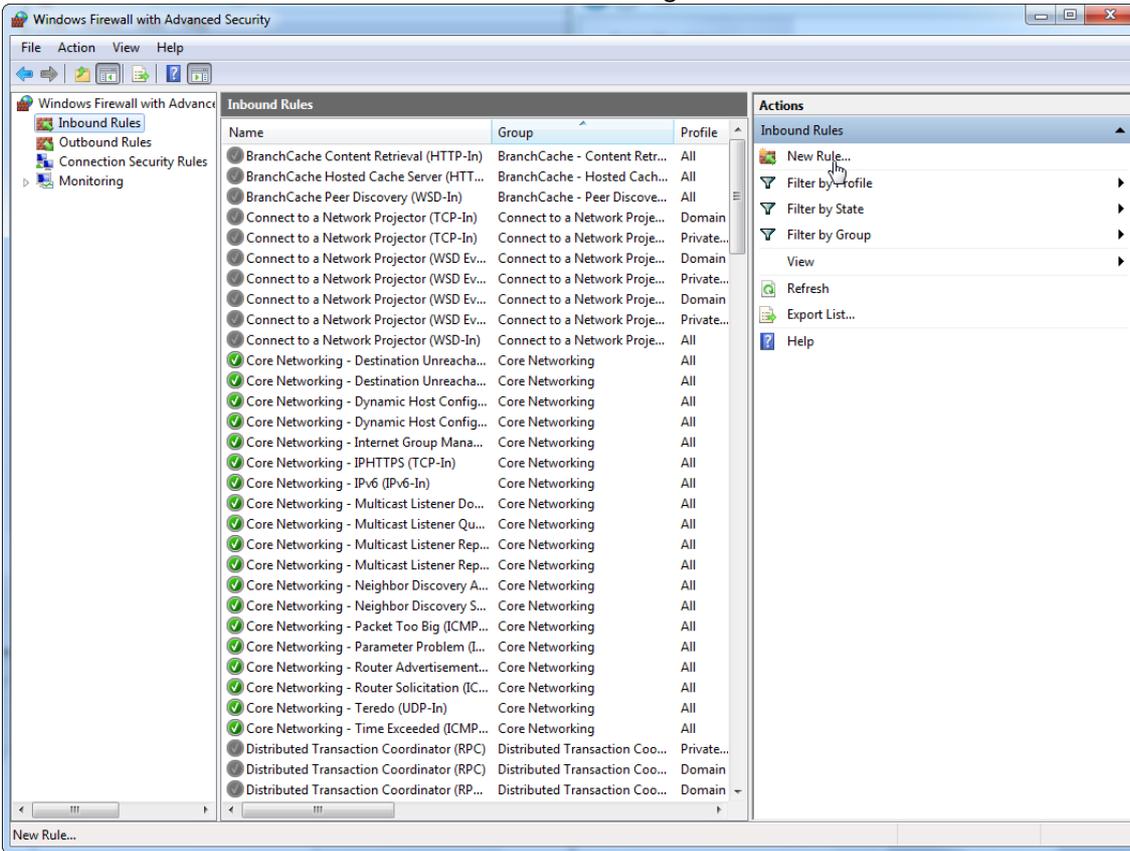
6. Select "Advanced settings".



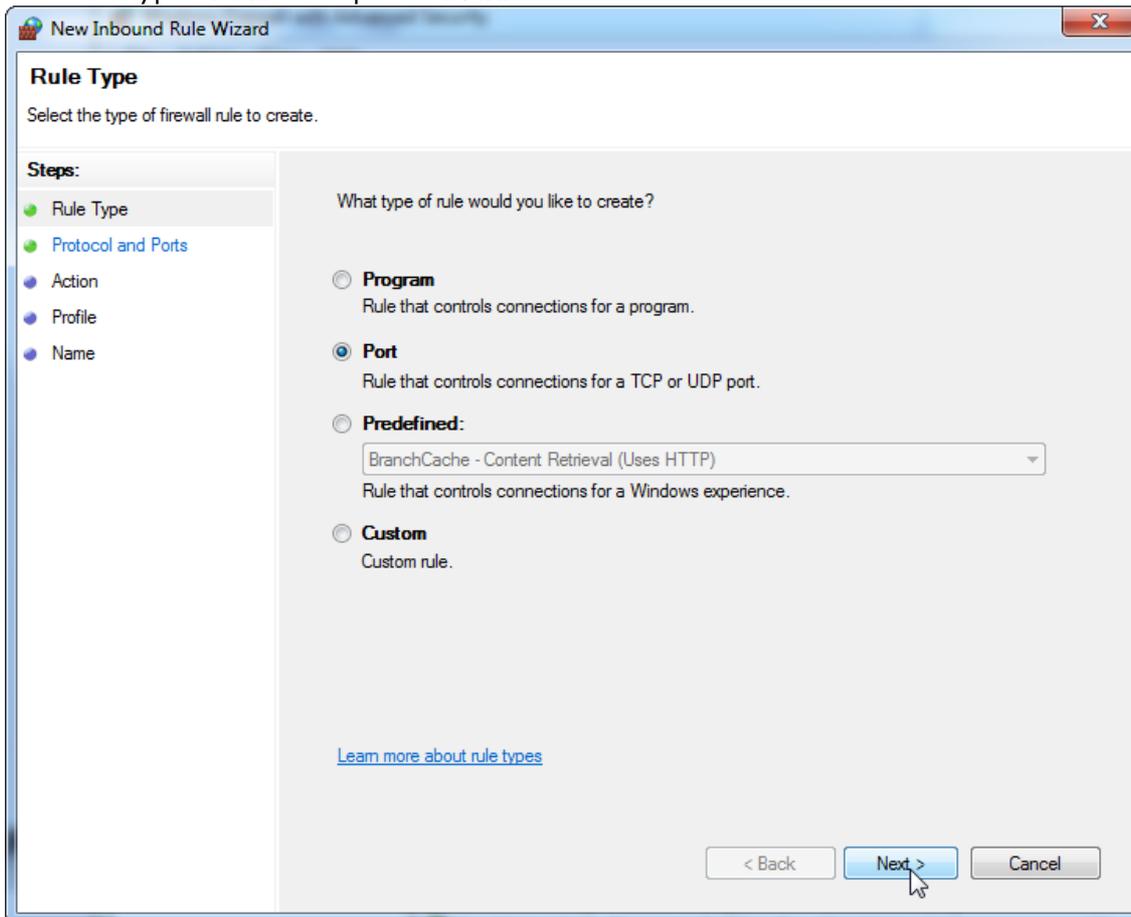
7. Open “Inbound rules”.



8. Select "New Rule..." from "Actions" on the right-hand side.



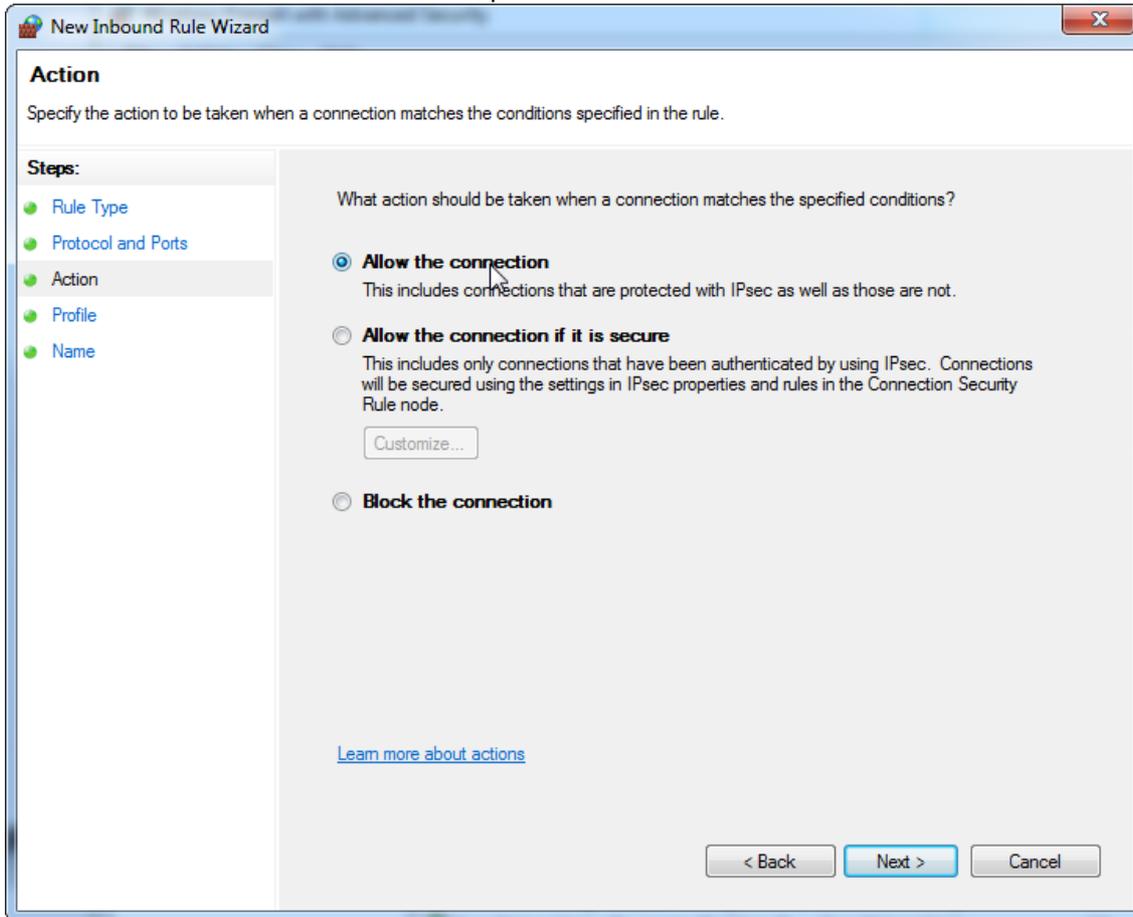
9. Select type “**Port**” and press “**Next**”.



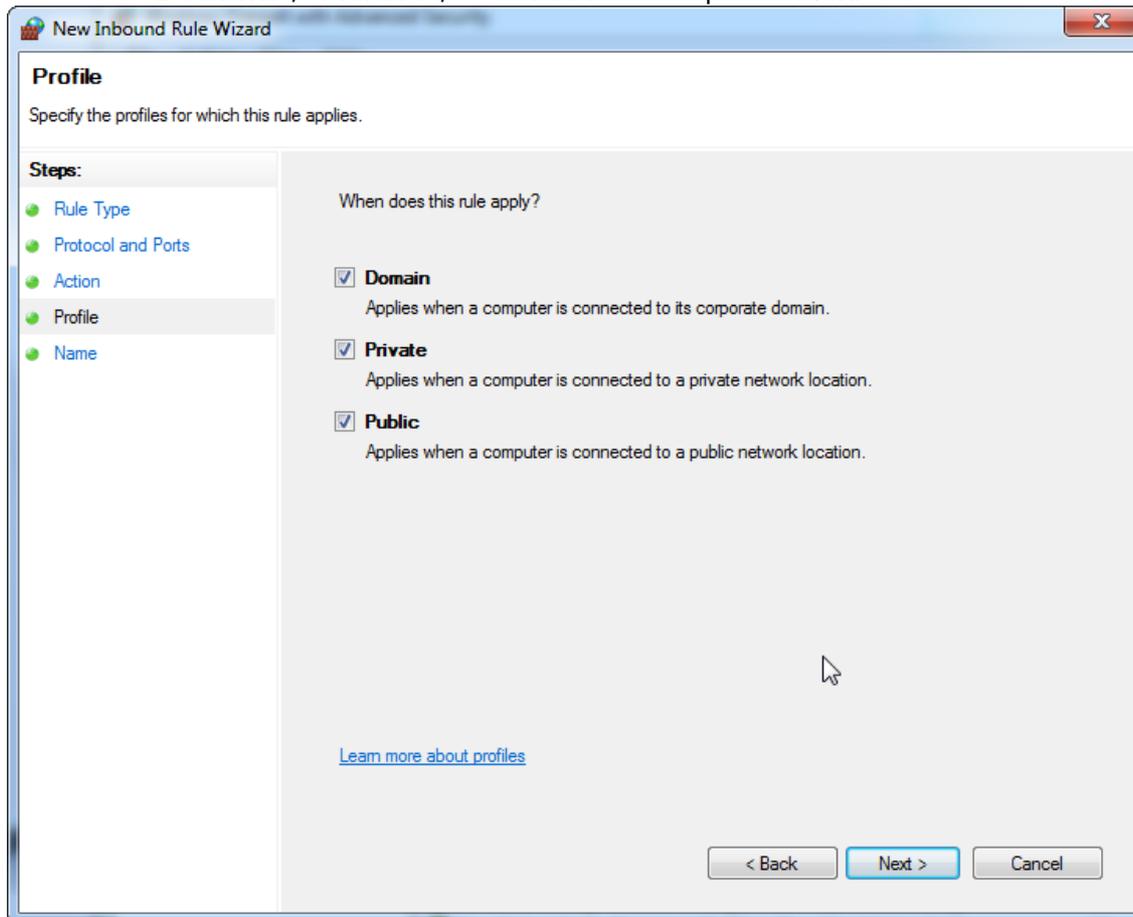
10. Select **"TCP"** and define the specific local port **"1433"** corresponding to the database. If you have defined a different port in step 4, enter this port. Press **"Next"**.

The screenshot shows a window titled "New Inbound Rule Wizard" with a close button in the top right corner. The main heading is "Protocol and Ports" with the instruction "Specify the protocols and ports to which this rule applies." On the left, a "Steps:" sidebar lists "Rule Type", "Protocol and Ports", "Action", "Profile", and "Name", with "Protocol and Ports" selected. The main area contains two questions: "Does this rule apply to TCP or UDP?" with radio buttons for "TCP" (selected) and "UDP"; and "Does this rule apply to all local ports or specific local ports?" with radio buttons for "All local ports" and "Specific local ports:" (selected). A text input field next to "Specific local ports:" contains the value "1433" and has an example "Example: 80, 443, 5000-5010" below it. At the bottom, there are three buttons: "< Back", "Next >" (highlighted in blue), and "Cancel". A link "Learn more about protocol and ports" is located above the buttons.

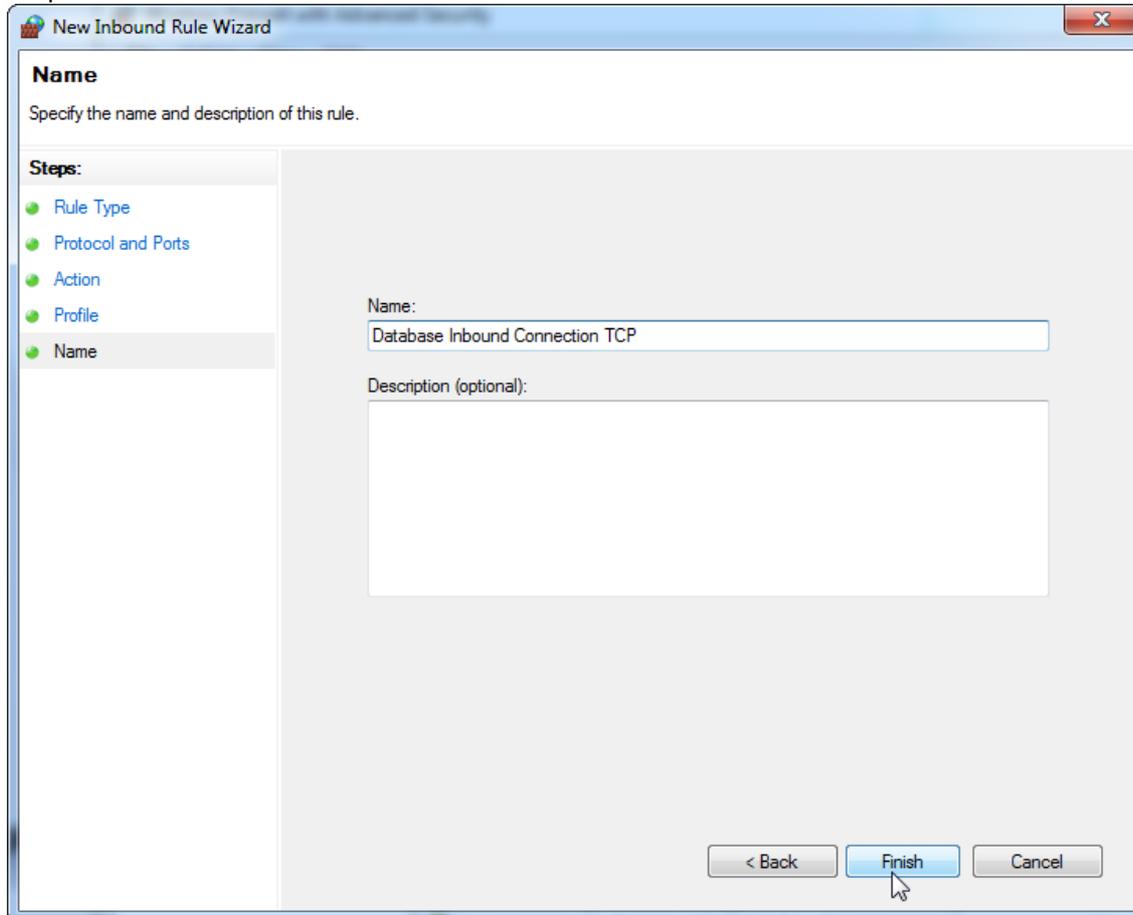
11. Select **“Allow connection”** and press **“Next”**.



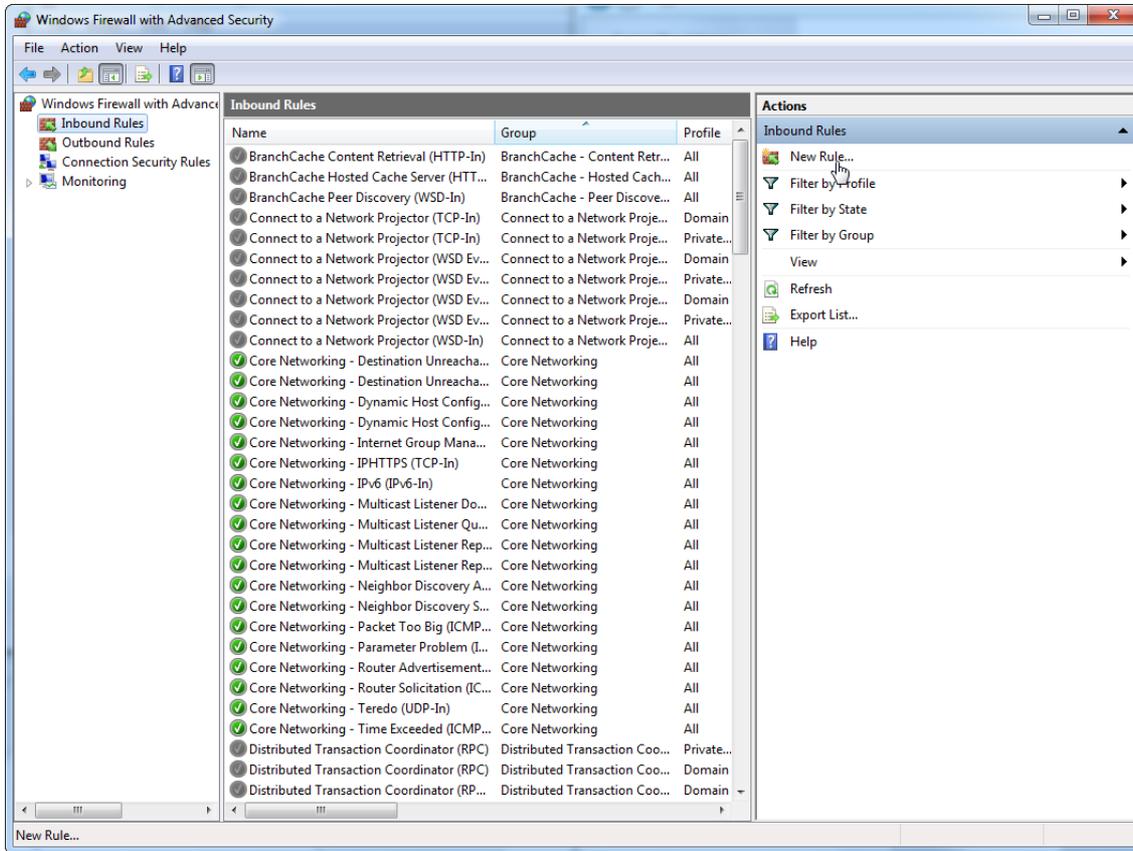
12. Check **“Domain”**, **“Private”**, and **“Public”** and press **“Next”**.



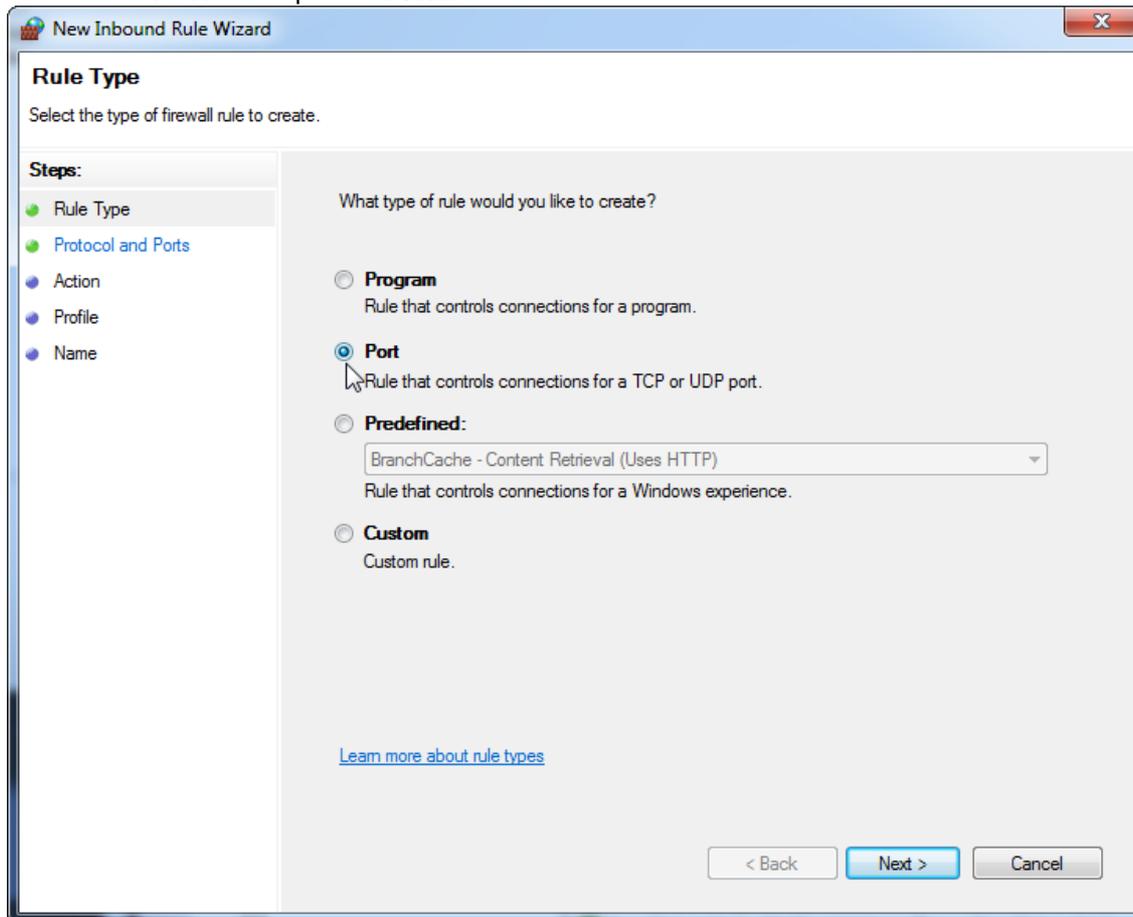
13. Define a name for the rule, e.g. **“Database Inbound Connection TCP”** and press **“Finish”**.



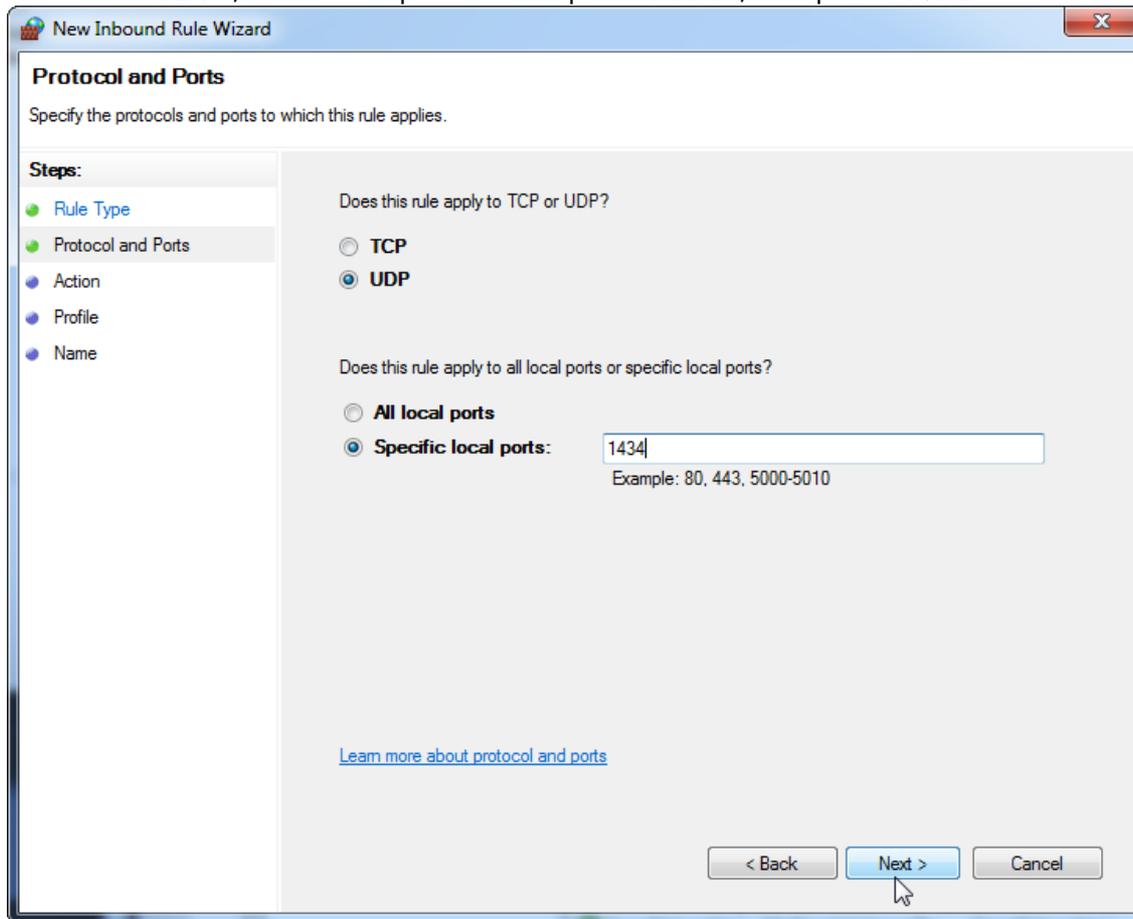
14. After the creation of the rule for the “TCP” protocol, you must define another rule for “UDP” which is set to port 1434 per default. Select again “New Rule...” from “Actions”.



15. Select **Port** and press **Next**.



16. Select **“UDP”**, define the specific local port **“1434”**, and press **“Next”**.



17. Select **“Allow the connection”** and press **“Next”**.

New Inbound Rule Wizard

Specify the name and description of this rule.

Steps:

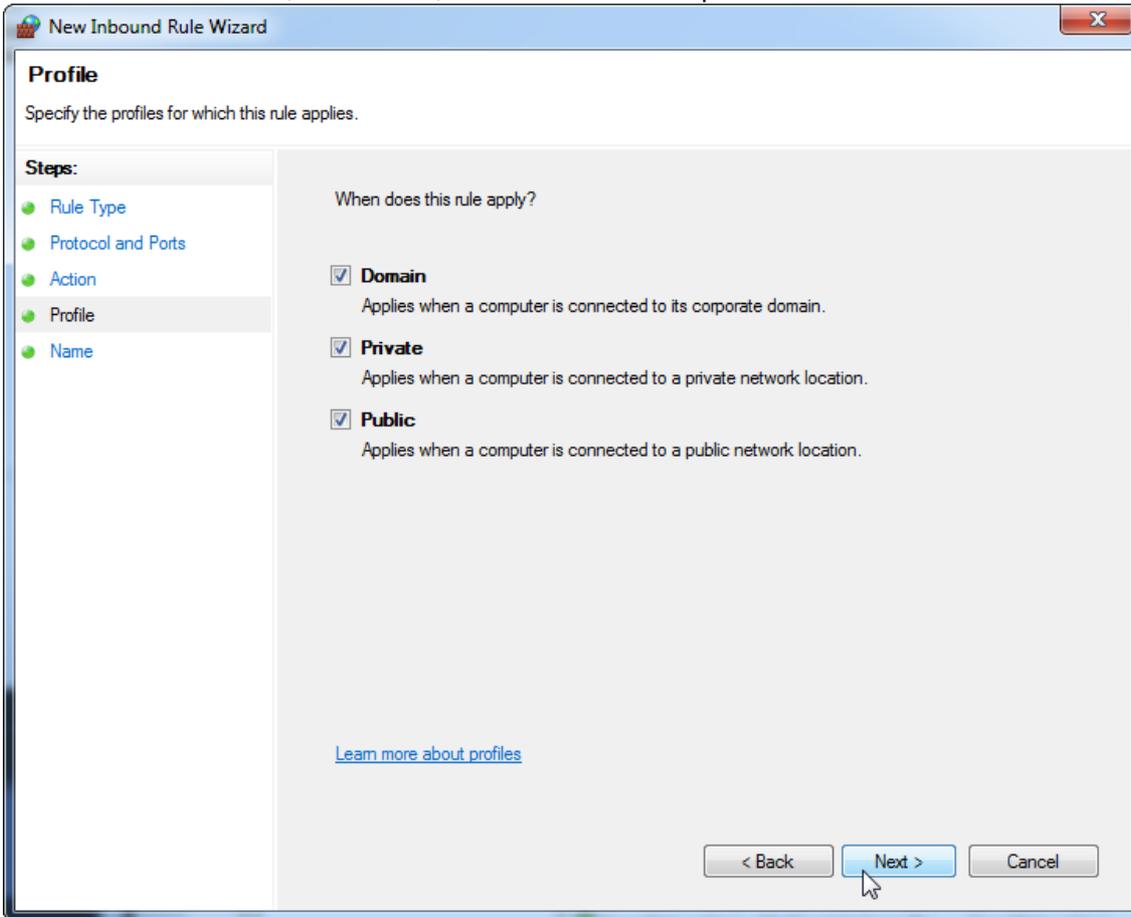
- Rule Type
- Protocol and Ports
- Action
- Profile
- **Name**

Name:
Database Inbound Connection UDP

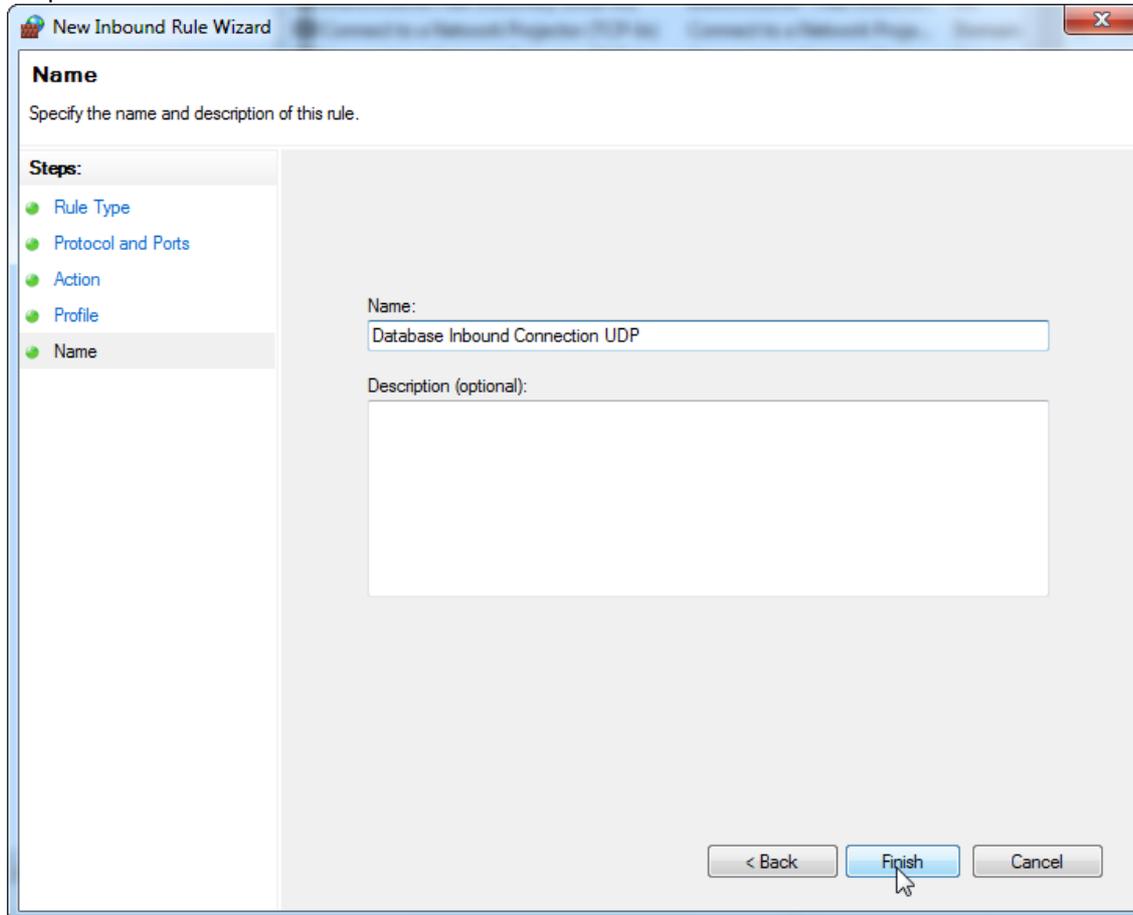
Description (optional):

< Back **Finish** Cancel

18. Check **“Domain”**, **“Private”**, and **“Public”** and press **“Next”**.

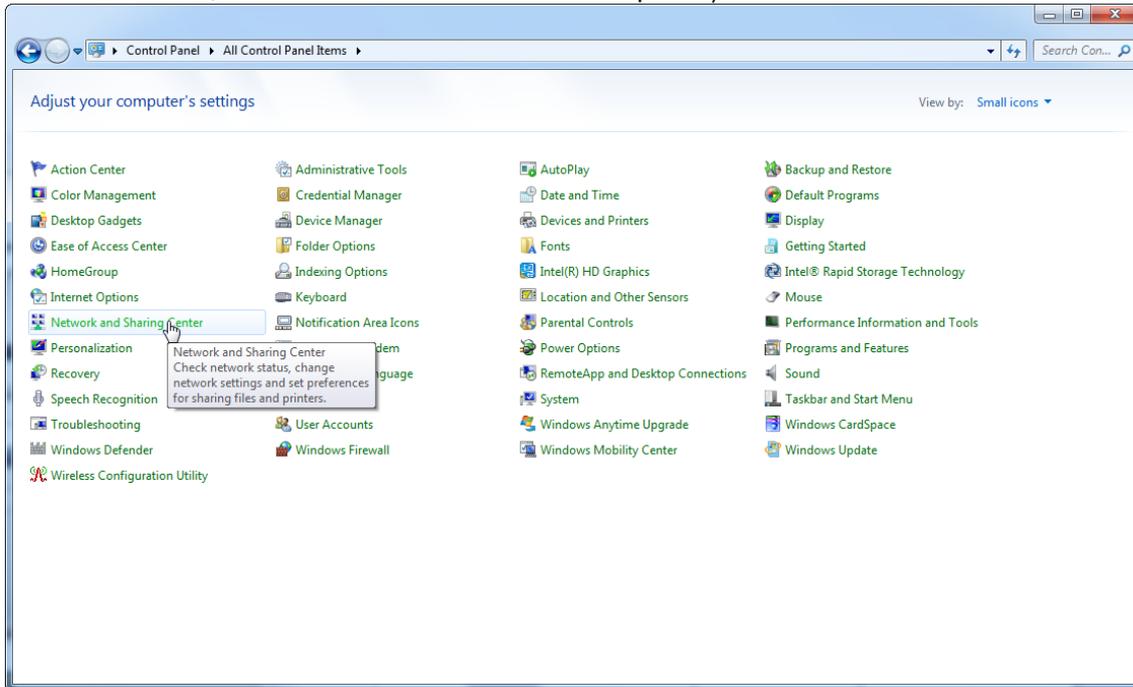


19. Define a name for the rule, e.g. **“Database Inbound Connection UDP”** and press **“Finish”**.

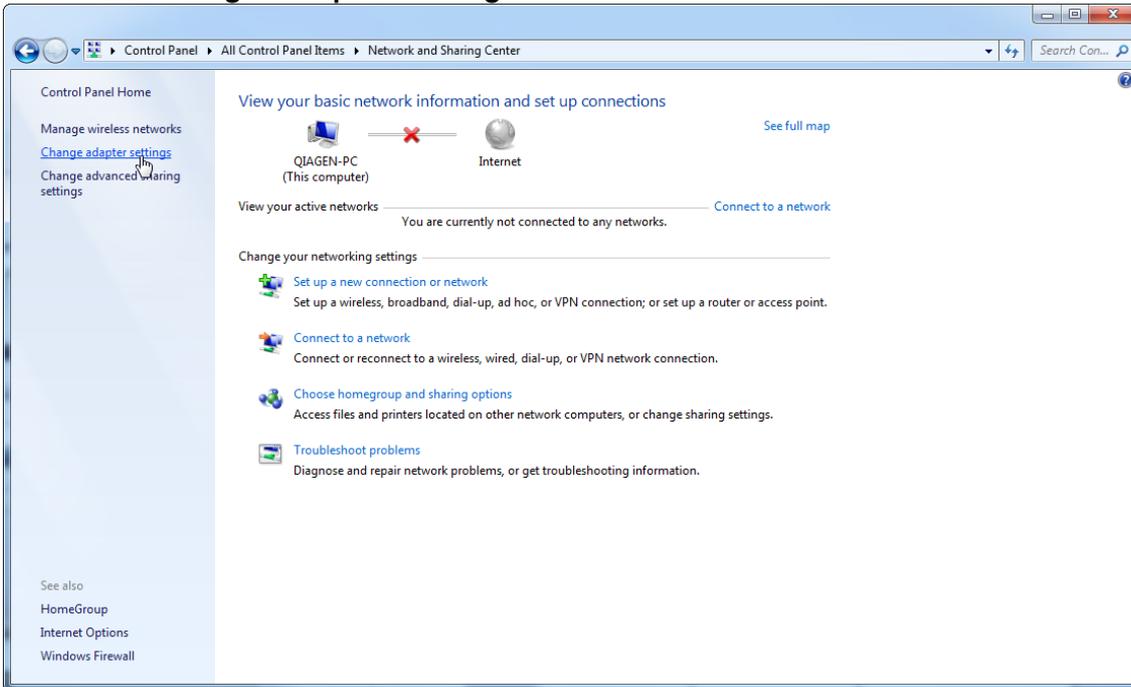


For security and reliability reasons cable-based network access instead of Wi-Fi shall be used. The laptop computers that are provided by QIAGEN have a disabled Wi-Fi adapter. If your configuration is different, a system administrator must disable the Wi-Fi adapter manually which can be done by the following steps:

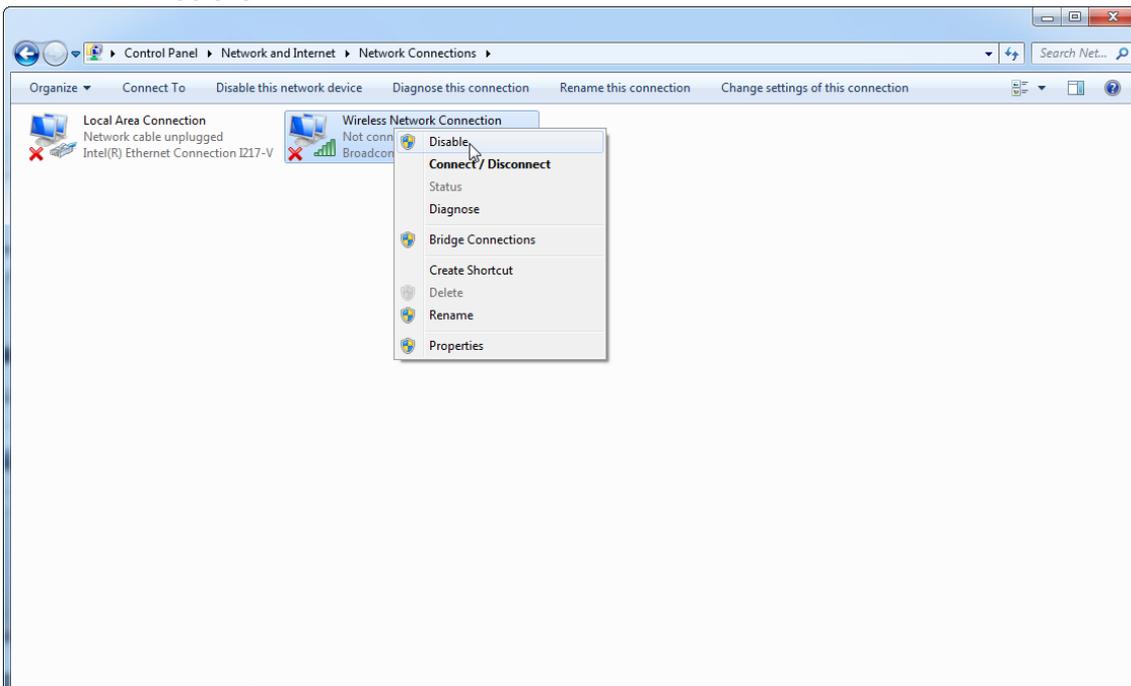
1. Open the “**Control Panel**” and select “**Network and Sharing Center**” (on Windows 10, search for “Control Panel” to open it).



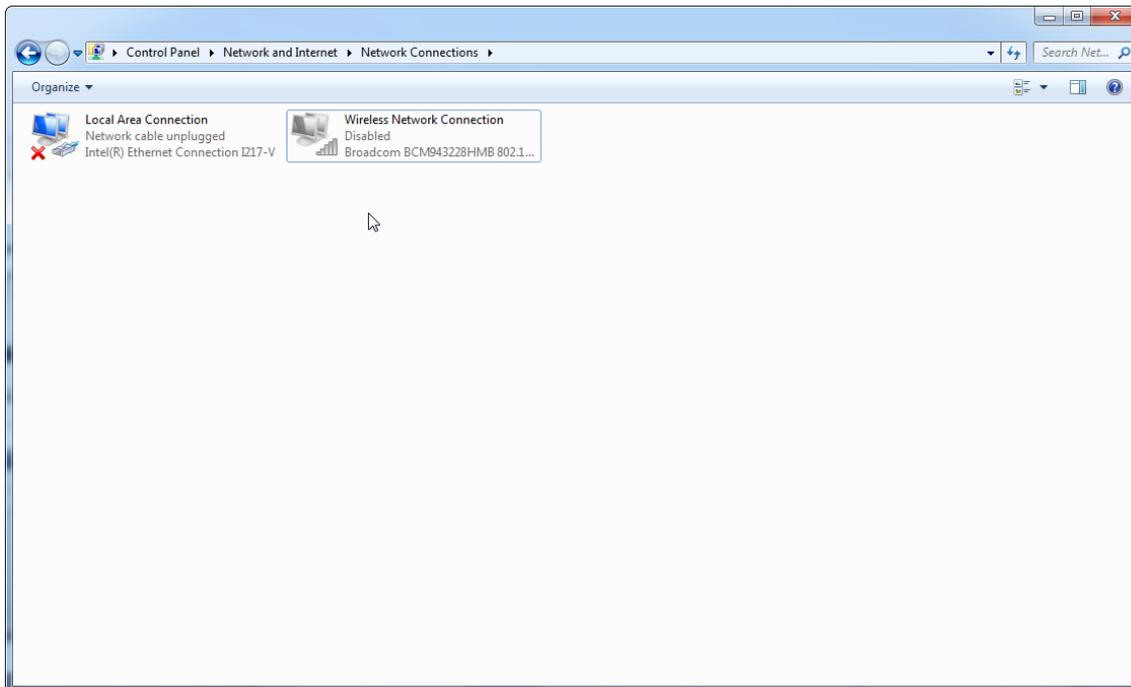
2. Select "Change adapter settings".



3. Hover over "Wireless Network Connection", press the right mouse button, and select "Disable" from the context menu.



4. Check that the Wireless Network Connection is disabled.



1.4.4 Uninstalling the Rotor-Gene AssayManager v2.1 software

Note

The uninstall process of the Rotor-Gene AssayManager v2.1 software will remove the core application as well as all installed plug-ins. It is not possible to uninstall only a plug-in, as this will create inconsistencies in the database and ceases further access to corresponding datasets.

Step-by-step procedure to uninstall Rotor-Gene AssayManager v2.1 and all installed plug-ins from your computer.

Note

If you want to uninstall Rotor-Gene AssayManager v2.1, close the application first. Otherwise Rotor-Gene AssayManager v2.1 might not be uninstalled completely.

1. Select **QIAGEN/Rotor-Gene AssayManager/Uninstall Rotor-Gene AssayManager** from the Windows Start Menu.
2. Confirm that you want to uninstall the product by clicking "Yes".



3. The windows installer program starts to uninstall the entire Rotor-Gene AssayManager v2.1.

1.4.5 First Login

After successful installation or update of Rotor-Gene AssayManager v2.1, the system administrator needs to log in for a first configuration of the software.

1. Enter user ID *admin* and password *admin*.
2. Select an appropriate mode (Closed Mode or User Defined Test Mode) and confirm with "OK".
3. Change the default password to a new, secure password.
4. The "Settings" tab in the "Configuration" environment will be opened.

Note

For usage of the User Defined Test Mode (UDT mode) functionalities a compatible UDT mode plug-in is required to be installed. A log-in in UDT mode without installation of the corresponding plug-in will give you no access to administrative tasks and you will not be able to perform experiments or analysis.

Note

All users without the "Administrator" role can ask the administrator to reset the password. However, if the administrator forgets the administrator password, they have to contact QIAGEN Technical Services to reset the password, which requires an on-site visit by a QIAGEN service engineer.

Note

It is strongly recommended to create at least one additional user account, without an "Administrator" role, at first login. If a single user of Rotor-Gene AssayManager aggregates different user roles including the "Administrator" role, there is a high risk that the access to the software will be completely blocked if this user forgets the password!

Note

The administrator after installation does not have the access rights for the "Setup environment". This environment can be accessed for users with the role "Operator".

Related topics

- ▶ Logging in and logging out
- ▶ User management
- ▶ "Setup" environment
- ▶ "Configuration" environment

1.4.5.1 Licence Key file**Introduction**

To run the Rotor-Gene AssayManager v2.1, a license key file is required. Create and submit the key file to QIAGEN to obtain a license before the application can be used productively. For contact information consult ▶ www.qiagen.com/Products/Rotor-GeneAssayManager_v2_1.aspx.

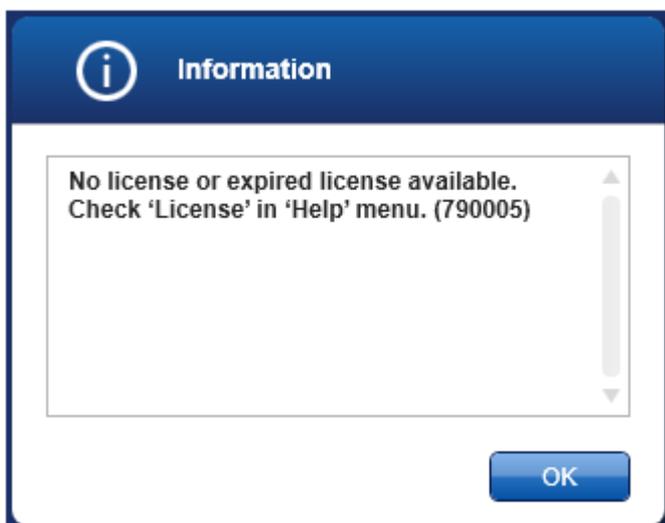
There are two types of licenses available.

- The trial license
The **trial license** is limited to a certain **period of time**. It can be used on any computer where the Rotor-Gene AssayManager v2.1 is installed.
- The regular license
The **regular (perpetual) license** can only be used with a **dedicated computer**. It cannot be transferred between computers. The customer creates a file containing information which clearly identifies the computer. This information is incorporated into the "license key" which is sent back.

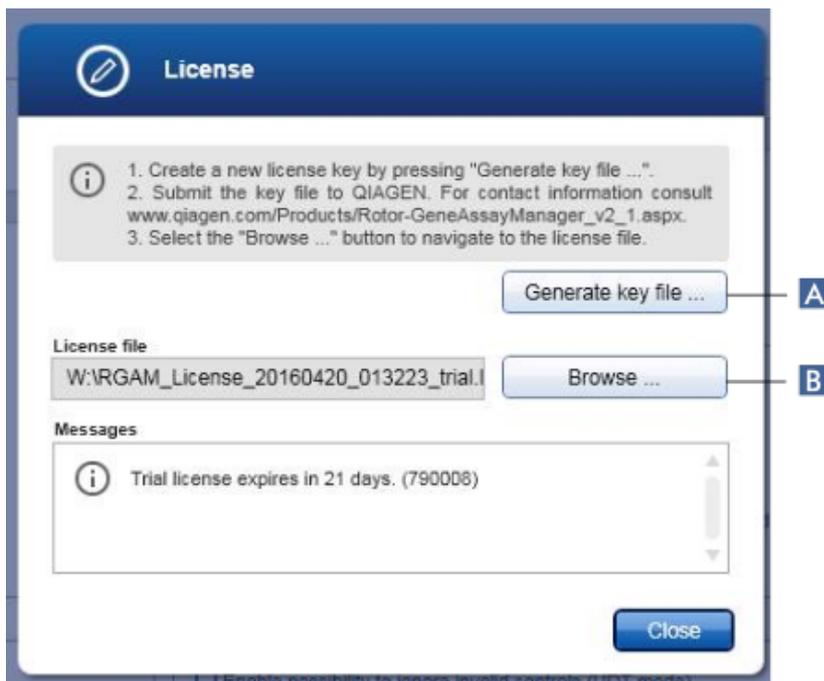
License key generation

The following chapter provides you with details about receiving a license for use of the Rotor-Gene AssayManager v2.1 from QIAGEN.

After Rotor-Gene AssayManager v2.1 installation the following information regarding a necessary license is displayed.



The appropriate dialog for handling the licenses is reachable via the 'License' entry in the 'Help' menu as stated in the missing license dialog. Create a license file via the "Generate key file" button (A) for each computer on which Rotor-Gene AssayManager v2.1 has been installed and submit it to QIAGEN to receive a license key.



Note

For each computer with Rotor-Gene AssayManager v2.1 installation an independent license key is necessary.

License file loading

After receiving your computer specific Rotor-Gene AssayManager v2.1 license key from the QIAGEN, select the 'License' entry in the 'Help' menu and click on 'Browse' (B) to load the provided license file.

1.4.6 First Configuration

Before Rotor-Gene AssayManager v2.1 can be used, the creation of user profiles and the registration of one or several Rotor-Gene Q cyclers in the "Configuration" environment is essential. For details about these tasks refer to:

- ▶ Managing users
- ▶ Managing cyclers

1.5 Basic Concepts and General Software Usage

In the following chapter the concepts and the general software usage of Rotor-Gene AssayManager v2.1 are described.

1.5.1 Concepts

Rotor-Gene AssayManager v2.1 uses multiple concepts to facilitate tasks and processes. The following topics describe these concepts in detail:

- Modes
- User Management
- Session Management
- Rotor-Gene AssayManager v2.1 and other QIAGEN products
- Clarification of terms experiment and assay

1.5.1.1 Modes

Rotor-Gene AssayManager v2.1 can be operated in 2 separate modes of operation with individual characteristics:

- Closed Mode
- User Defined Test Mode (UDT mode)

Closed Mode	User Defined Test Mode (UDT mode)
The Closed Mode is used for assays that have been created and validated by QIAGEN. These assays can only be modified by QIAGEN.	The User Defined Test Mode is used for assays that have been created and validated by a user of Rotor-Gene AssayManager v2.1 with the user role "Assay Developer".
In Closed Mode, assays are run and analyzed without the permission to modify the corresponding assay profiles.	In User Defined Test Mode, assays are run and analyzed without the permission to modify the corresponding assay profiles.
The analysis in Closed Mode includes core analysis, assay and sample analysis, and	The analysis in UDT mode includes only the core analysis and the assay

depending on plug-in, also a fully automatic data scan (AUDAS).

and sample analysis.

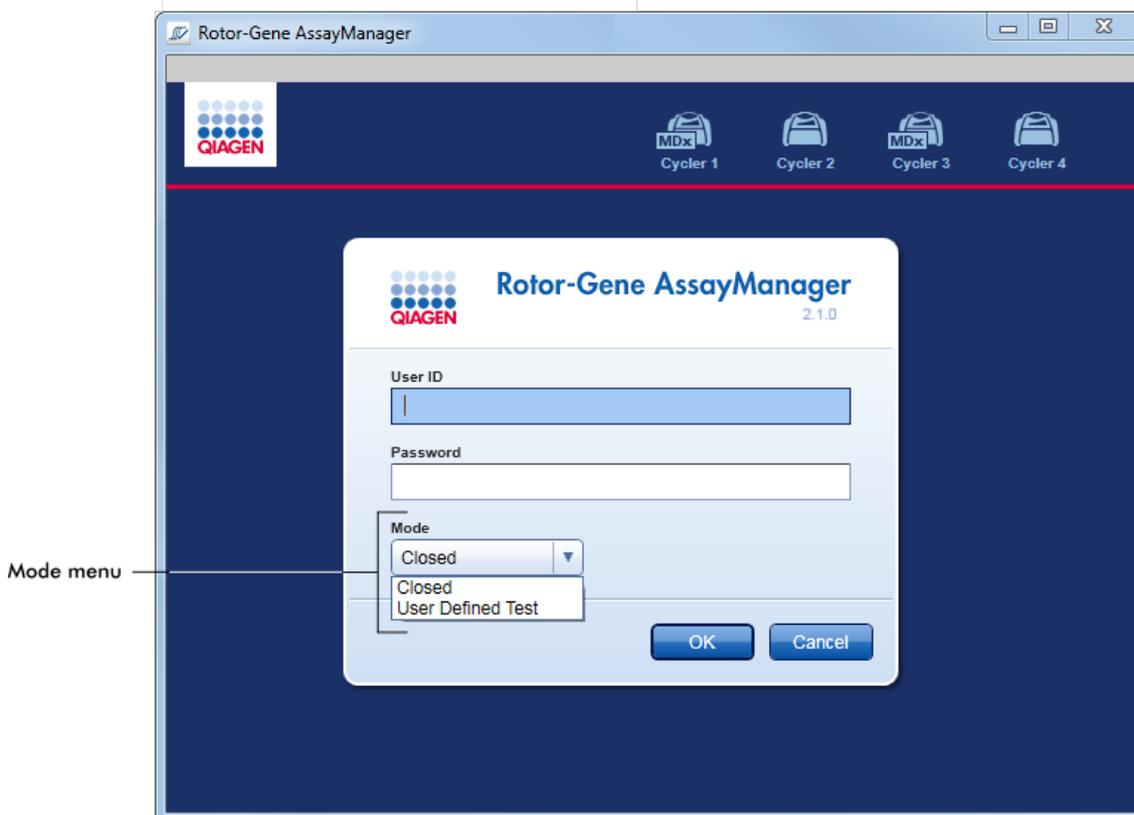
To run and analyze an assay in Closed Mode a corresponding closed mode plug-in is required.

To create, run, and analyze an assay in UDT mode a corresponding UDT mode plug-in is required.

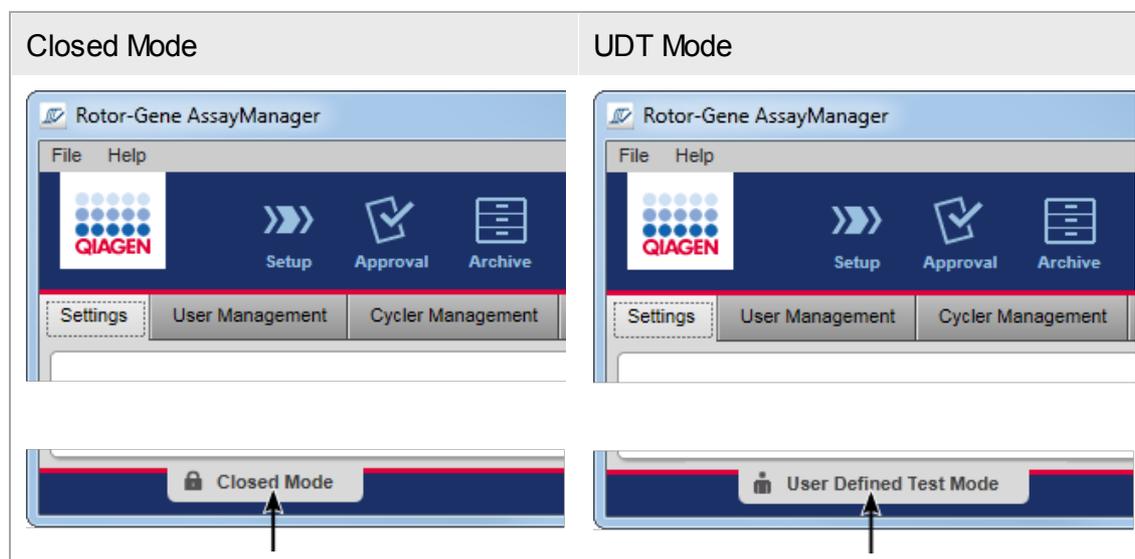
Note

For usage of the User Defined Test Mode (UDT mode) functionalities a compatible UDT mode plug-in is required to be installed. A log-in in UDT mode without installation of the corresponding plug-in will give you no access to administrative tasks and you will not be able to perform experiments or analysis.

The mode is selected from the Rotor-Gene AssayManager v2.1 login screen. The login screen contains 2 fields to enter the user ID and the password, as well as an additional drop-down menu to select the mode of operation.



After the user has logged in, the selected mode is displayed in the status bar:



1.5.1.2 User Management

User interactions with the system must be assignable to an individual person. Therefore, each user must log in before the Rotor-Gene AssayManager v2.1 software can be used. After finishing work the user should log out or lock the application.

A role must be assigned to every user. It is also possible to assign multiple roles to a single user. The following properties are stored in the database for a user:

- First name
- Last name
- User ID
- Password
- Role(s)

Related tasks

- ▶ Creating a user profile
- ▶ Changing user profile settings
 - Changing name/last name
 - Changing password
 - Changing role

- ▶ Activating/deactivating a user profile
- ▶ Setting password policies and auto lock timer

1.5.1.2.1 User Roles

Different Rotor-Gene AssayManager v2.1 functions can only be accessed by users with certain roles. All available user roles and their permissions are listed in the following table:

Role	Description
Administrator	The administrator has permissions to <ul style="list-style-type: none"> • configure the system, • manage users, • create and edit report profiles, • manage archives.
Assay developer	The assay developer has all needed permissions to create an assay profile in UDT mode.
Operator	The operator has permissions necessary to <ul style="list-style-type: none"> • create a worklist, • apply the worklist, • view the analysis results. <p>The operator cannot approve or release assay results.</p>
Approver	The approver is the only user with permissions to approve and release assay results.
Super User	The super user has all available permissions of all available rules as a convenient way to grant all permissions to one user, i.e., Administrator, Assay Developer, Operator, and Approver.

The following actions can be performed by every role

- ▶ Logging in and logging out
- ▶ Locking and unlocking
- ▶ Changing user profile settings

The following table gives an overview about permissions of the different user roles in the different environments:

Environment	Task	Description	Admin	AD	Op	Ap	SU*
"Setup"	Access "Setup" environment	User can enter the "Setup" environment.	-	-	+	-	+
	Apply runs	User can apply runs in the "Setup" environment.	-	-	+	-	+
"Approval"	Access "Approval" environment	User can access the "Approval" environment.	+	-	+	+	+
	Approve test results Release of test results	User can approve the test results in the "Approval" environment.	-	-	-	+	+
	Create support package	User can create support packages in the "Approval" environment.	+	-	+	+	+
"Archive"	Access "Archive" environment	User can enter the "Archive" environment.	+	-	+	+	+
	Create support package	User can create support packages in the "Archive" environment.	+	-	+	+	+
"Service"	Access "Service" environment	User can enter the "Service" environment.	+	-	-	+	+

Environment	Task	Description	Admin	AD	Op	Ap	SU*
	View audit trail	User can access the Audit Trail tab in the "Service" environment.	+	-	-	+	+
"Configuration"	Access "Config." environment	User can enter the "Config." environment.	+	+	-	-	+
	Configure system settings	User can configure all settings in the "Config." environment.	+	-	-	-	+
	Manage cyclers	User can access the "Cycler Management" tab in the "Config." environment.	+	-	-	-	+
	Manage users	User can access the "User Management" tab in the "Config." environment.	+	-	-	-	+
	Manage assay profiles	User can access the "Assay Profiles" tab in the "Config." environment.	+	-	-	-	+
	Manage report profiles	User can access the "Report	+	+	-	-	+

Environment	Task	Description	Admin	AD	Op	Ap	SU*
		Profiles" tab in the "Config." environment.					
"Development"	Access "Development" environment	User can enter the "Development" environment.	-	+	-	-	+
	Develop assay profiles	User can develop assay profiles in the "Development" environment.	-	+	-	-	+
"Cycler"	Access "Cycler" environment	User can enter the "Cycler" environment.	+	-	+	-	+
	Release cyclers	User can add a comment, release a cycler, stop a process, and close pop-ups in the "Cycler" environment.	-	-	+	-	+

* **Admin**: Administrator; **AD**: Assay Developer; **Op**: Operator; **Ap**: Approver; **SU**: Super User.

Note

For usage of the User Defined Test Mode (UDT mode) functionalities a compatible UDT mode plug-in is required to be installed. A log-in in UDT mode without installation of the corresponding plug-in will give you no access to administrative tasks and you will not be able to perform experiments or analysis.

1.5.1.2.2 Password Policy

Unless otherwise defined the password must be between 8 and 40 characters long. An administrator can also define, in the settings of the "Configuration" environment, if using Clinical Laboratory Improvement Amendments (CLIA) complaint password rules is mandatory. According to CLIA, a password has to contain at least:

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

An administrator can also define the password renewal interval. A user must renew his password after the renewal interval has passed. Note that the last 10 passwords cannot be reused.

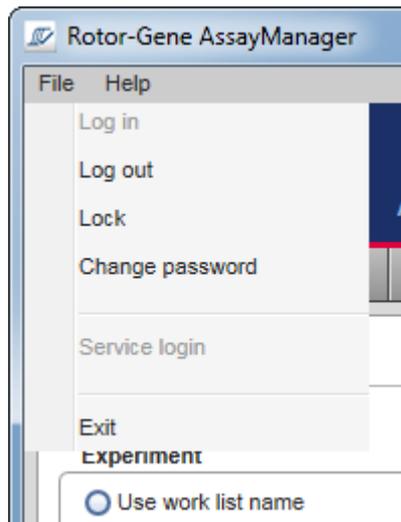
Related topics

- ▶ [Setting password policies and auto-lock timer](#)

1.5.1.3 Session Management

To start working with Rotor-Gene AssayManager v2.1, a user has to start a new session by logging in. Logging in is possible from the login screen either after the application was started or after a previous session was finished. Logging out is possible using the command from the main menu or the logout button in the status bar.

Log out from
main menu



Log out from
status bar



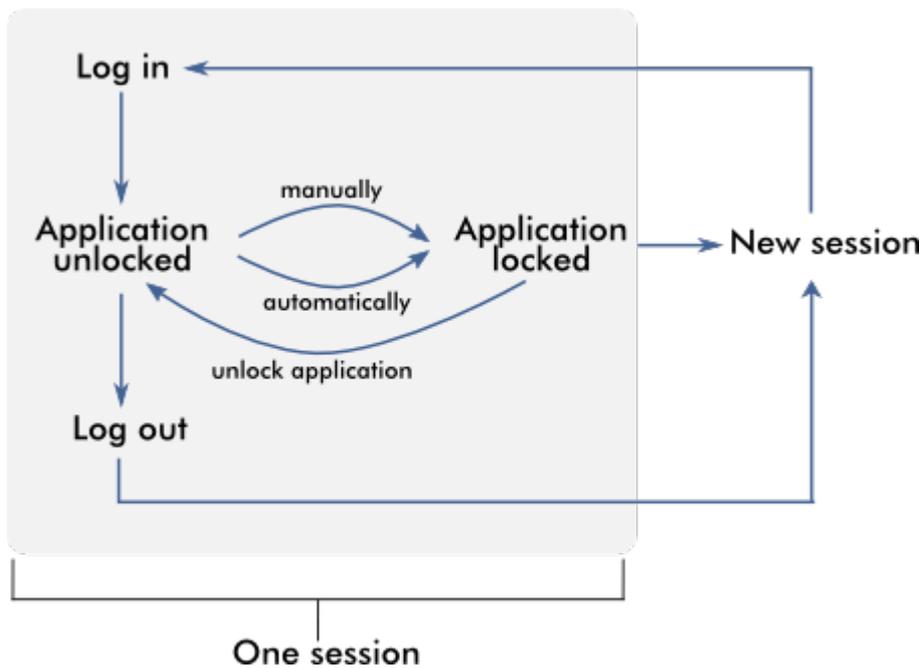
To prevent misuse, a user can lock the application. Rotor-Gene AssayManager v2.1 also has an auto-lock timer that locks the application automatically after a predefined time without user interaction (an administrator can customize the auto-lock feature, see ► Setting up the auto-lock timer). If locked, the user can either continue working by unlocking the application or alternatively another user can start a new session.

The automatic locking feature does not interrupt or impact the operation of the cyclers.

Started runs are not interrupted or impacted if:

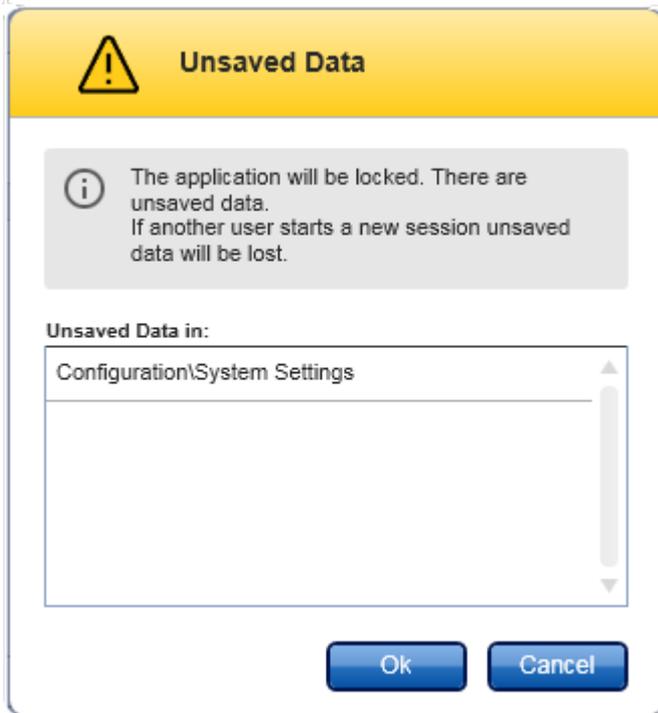
- a user logs out,
- another user starts a new session,
- or the application is locked (automatically or manually).

The following graphic illustrates the session, locking concepts, and their interdependencies:

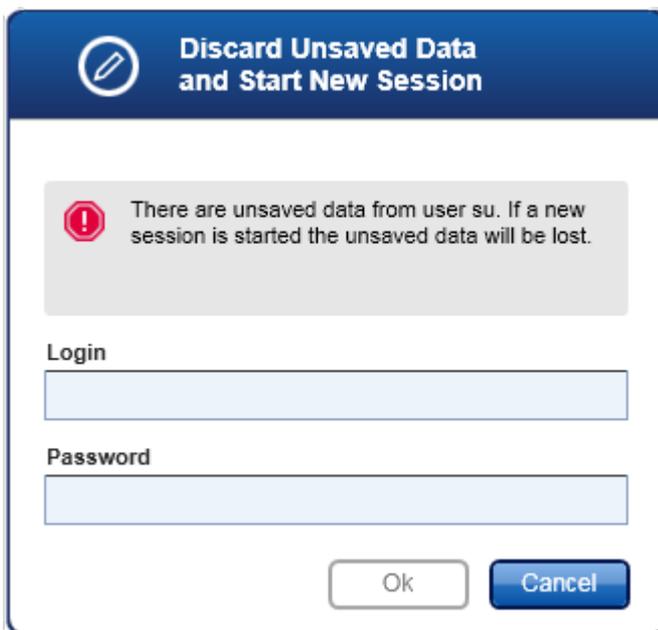


Behavior if unsaved data exist

If a user locks the application and unsaved data exist, a dialog is opened containing a list of all environments with unsaved data:



If another user wants to start a new session, a dialog is shown containing a warning that unsaved data from the previous user exist, and the unsaved data are lost if the new session is started.



Related topics

- ▶ Logging in and logging out
- ▶ Locking and unlocking
- ▶ Setting password policies and auto-lock timer

1.5.1.4 Rotor-Gene AssayManager v2.1 and other QIAGEN Products

Rotor-Gene AssayManager v2.1 has different interfaces and data exchange features with other QIAGEN products and external Laboratory Information Management Systems (LIMS).

With Rotor-Gene AssayManager v2.1, up to 4 different Rotor-Gene Q instruments can be controlled simultaneously. Each connected cyclers can send raw acquisition data back to Rotor-Gene AssayManager v2.1.

Note

The Rotor-Gene AssayManager v1.0 and v2.1 are independent products and cannot be used in parallel on one system. In addition, Rotor-Gene AssayManager v2.1 does not replace the Rotor-Gene AssayManager v1.0.

Note

Rotor-Gene AssayManager v2.1 and Rotor-Gene Q software may be installed on the same computer in parallel. But only one of the programs can have an active connection to a Rotor-Gene Q at a particular time.

Scenario 1:

In case the Rotor-Gene Q software is started prior to Rotor-Gene AssayManager v2.1 and connected to a cyclers first, Rotor-Gene AssayManager v2.1 is not able to set up a connection to the cyclers. Shut down the Rotor-Gene Q software. Restart Rotor-Gene AssayManager v2.1 to control the cyclers with Rotor-Gene AssayManager v2.1.

Scenario 2:

In case Rotor-Gene AssayManager v2.1 is started prior to the Rotor-Gene Q software and connected to a cyclers first, the Rotor-Gene Q software is not able to set up a connection to the cyclers. Shut down Rotor-Gene AssayManager v2.1. Restart the Rotor-Gene Q software to control the cyclers with the Rotor-Gene Q software.

Result files from the QIASymphony AS software version 5.0 can be used to generate worklists in Rotor-Gene AssayManager v2.1. All relevant sample and assay related

information are automatically set, and manual input during worklist setup is minimized.

Rotor-Gene AssayManager v2.1 can be linked to a Laboratory Information Management System (LIMS) directly or via a dedicated middleware solution (QIAlink™),* which easily connects QIAGEN instruments with a LIMS. (Contact QIAGEN for availability of QIAlink middleware.)

Related topics

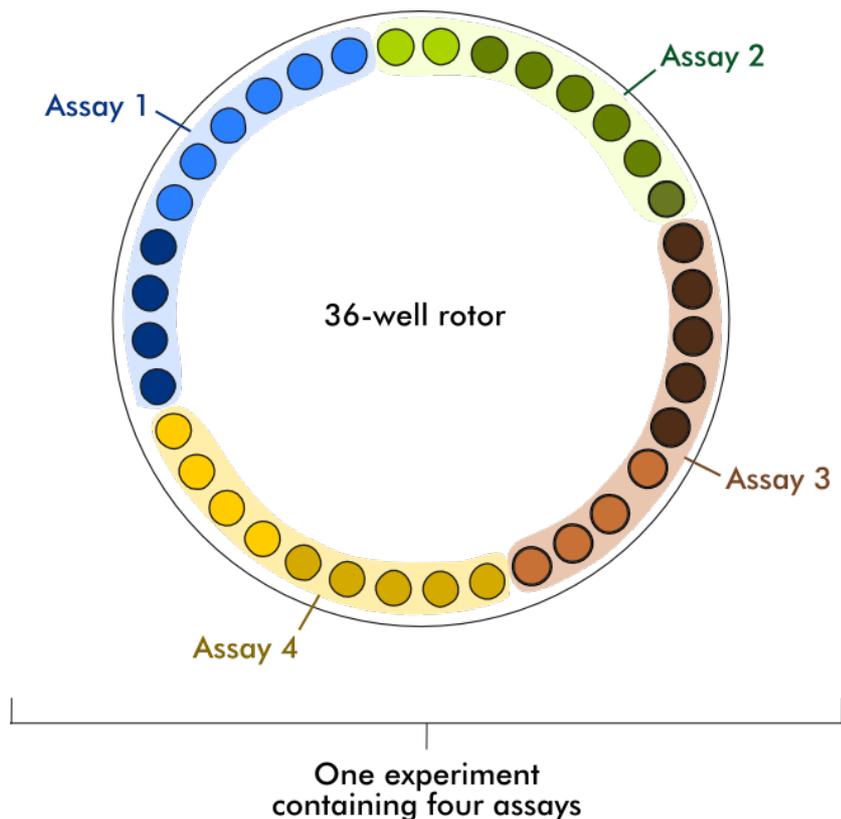
- ▶ Importing a worklist
- ▶ Exporting a *.rex file
- ▶ Setting up a run

1.5.1.5 Experiment vs. Assay

The terms "experiment" and "assay" are used with different meanings in Rotor-Gene AssayManager v2.1. Rotor-Gene AssayManager v2.1 allows multiple assays to run in one experiment by creating a worklist with multiple compatible assay profiles. All assays within one run define an experiment.

Example

The following graphic gives an example. A worklist is created consisting of 4 different assays. The brighter colors represent test samples; the darker colors, non-test samples, such as external controls. A 36-Well Rotor is used for the worklist.



After the run has finished, all individual assays of the experiment are listed in the "Approval" environment. All test samples of an assay have to be approved (accepted or rejected) and released. An experiment is defined as fully released only if all test samples of all assays of an experiment have been released. The data are then transferred to the "Archive" environment, and the LIMS output (optionally) and the report (optionally) are created.

Related topics

- ▶ Creating/editing a worklist
- ▶ Starting a run
- ▶ Finishing and releasing a run

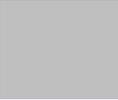
1.5.2 General Software Usage

The following chapter describes the general software usage concept of Rotor-Gene AssayManager v2.1.

1.5.2.1 Use of Color

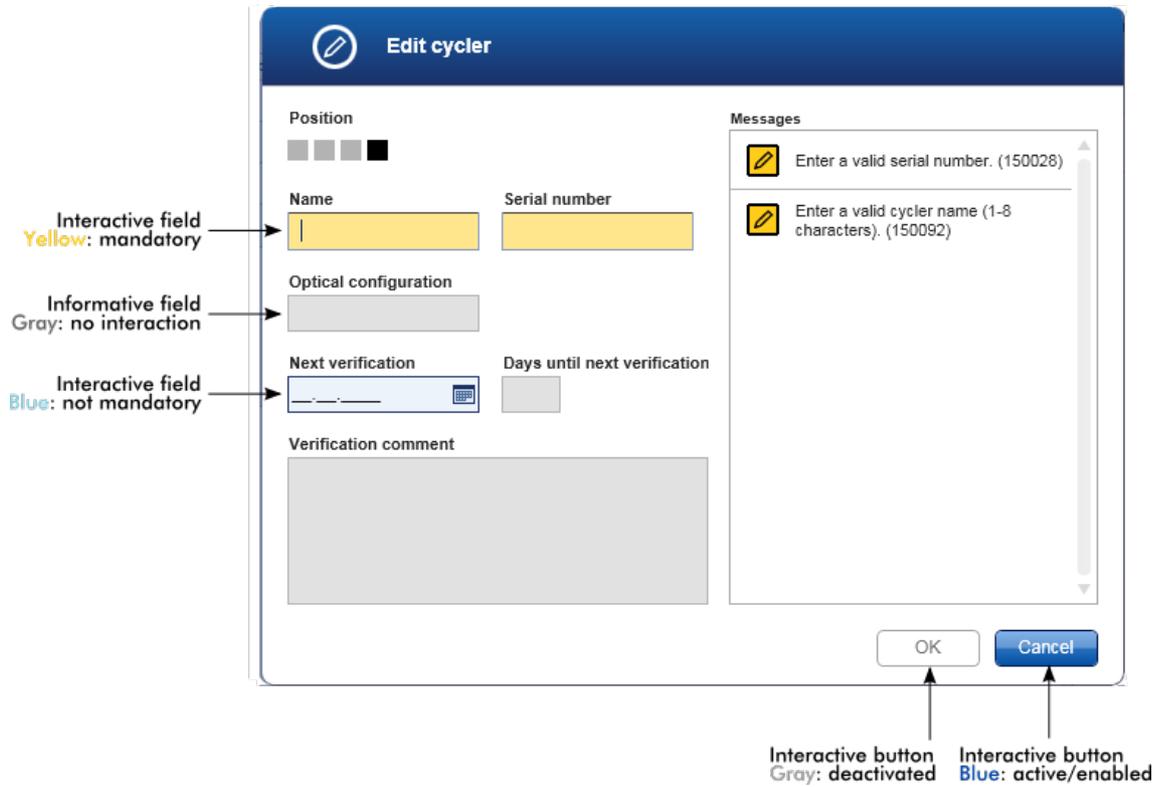
For an optimal user interaction Rotor-Gene AssayManager v2.1 has a specific color concept for presenting information and intuitive guiding.

The following table provides an overview about the different colors used in the software and their dedicated meaning:

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

Example 1

The following dialog example gives an explanation of the color concept.



Example 2

When creating a new worklist in the "Setup" environment, there are 4 step buttons ("Assays", "Kit information", "Samples", and "Properties") for the different steps to complete. The coloring concept of the step buttons is shown in the following table:

Status of step	Colors	Example
Disabled	Grayed out	
Currently active without error	Gray background, white font	
Currently active with error	Dark yellow background, yellow font	
Not currently active without error	Blue background, dark blue font	
Not currently active with error	Yellow background, dark brown font	

1.5.2.2 Displaying Errors and Warnings

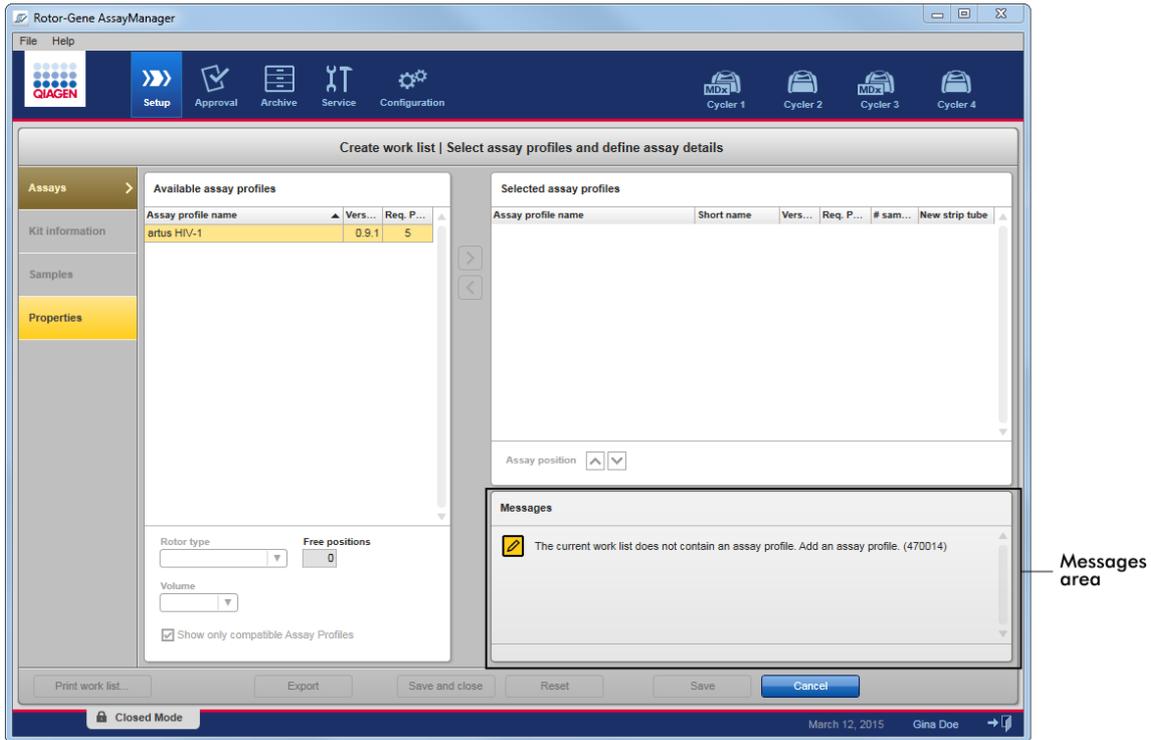
Errors and warnings are essential information for the user. These messages point to a problem or an erroneous situation. Rotor-Gene AssayManager v2.1 differentiates between 4 different problem levels:

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

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

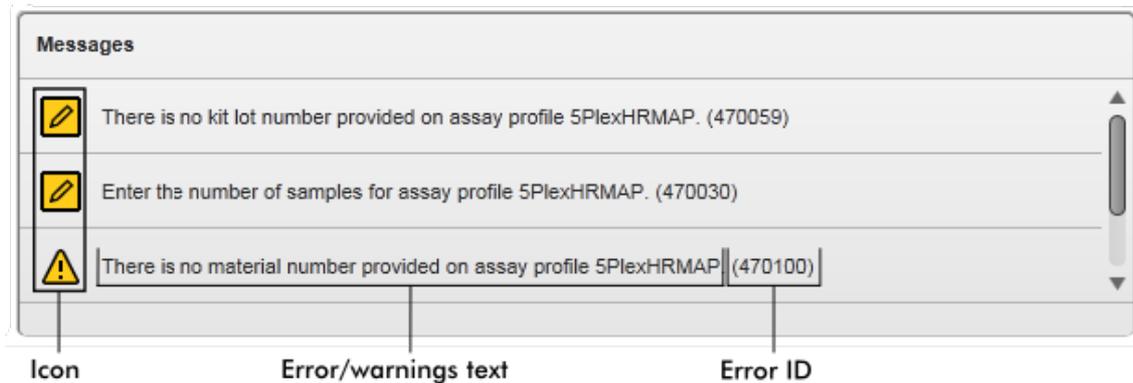
"Messages" area

The following screenshot shows possible errors and warnings during worklist creation in the "Setup" environment. The messages are displayed with the corresponding icon, the error text, and the error ID in brackets.

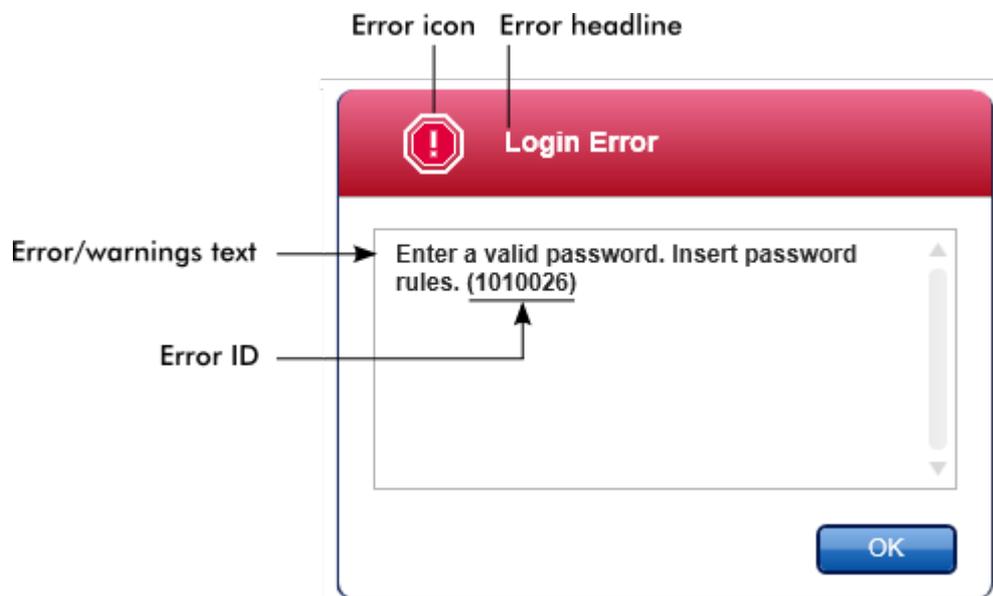


Messages area

Detailed view of the "Messages" area:



Error messages pop-up window



Each error ID is unique. In case QIAGEN Technical Services needs to be contacted for troubleshooting, have the error ID ready. Further more screenshots of the error containing GUI can be useful.

1.5.2.3 Entering Data

Shortcuts

The following hot keys are available in Rotor-Gene AssayManager v2.1:

- "F1" to open the help file
- Copy and paste operations ("CTRL"+"C" and "CTRL"+"V")
- Navigation (tab key, cursor keys)

While entering data, the following keyboard shortcuts can be used:

- "F2" to start editing
- "Escape" to cancel the input
- "Return" to commit an input

Identifying interactive fields

All interactive elements where a user can enter data are marked with a black triangle symbol (▾) in their upper right corner.

The following example is taken from the worklist creation step in the "Setup" environment:

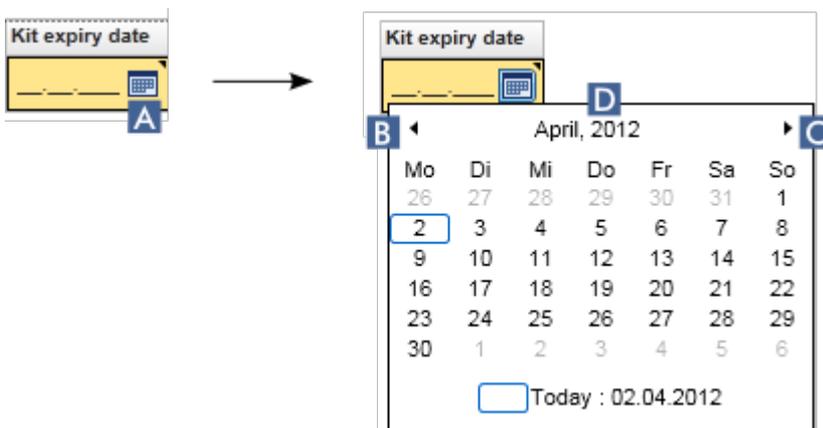
Selected assay profiles					
Assay profile name	Short name	Vers...	Req. P...	# sam...	New strip tube
artus HIV-1	HIV_a	0.9.1	5		<input checked="" type="checkbox"/>

Interactive fields:
 Yellow = mandatory field
 Blue = not mandatory

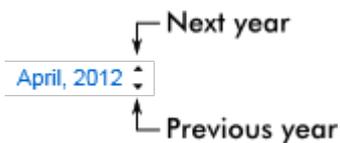
Date picker: Entering date in date fields

Dates can either be entered manually into date fields using the keyboard or using an interactive date picker in form of a pop-up calendar. A calendar icon (📅) is positioned at the right of every date field.

Clicking the calendar icon (A) opens the pop-up calendar.



Change to the previous/next month by clicking the arrow icons (B) and (C). Hovering over the year label (D) displays additional control arrows, which are used to quickly jump to the next (up arrow) respectively previous year (down arrow):



Step-by-step procedure to enter a date using the date picker

1. Click the calendar icon  (A) next to the date field.

The calendar pop-up is shown.

2. Continue using the following scheme:

To	Do this
Change the year	Hover the mouse over the year (D). Date is displayed in blue. Additional control arrows are shown. Click the "up" arrow to change to the next year. Click the "down" arrow to change to the previous year.
Change the month/day	Click the "left" arrow (B) to change to the previous month. Click the "right" arrow (C) to change to the next month. Click the date of the desired day.

The date picker disappears and the date field is populated with the selected date.

1.5.2.4 Working with Tables

Sorting tables

Some tables in Rotor-Gene AssayManager v2.1 give the possibility to sort the contained data by column. Sortable tables can be recognized by the Sort indicator icon (▲) in one of the column headers. The data in the table are sorted according to this column. Two different icons exist to visualize an ascending or descending sorting order:



Ascending sorting:

The table is sorted by the selected column is ascending order.

- ▼ Descending sorting:
The table is sorted by the selected column in descending order.

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

In the example below, the "Assay selection" table is sorted by the "Experiment" column in ascending order.

Sort indicator icon



Assay selection				
	<input type="checkbox"/>	Experiment	Assay	# samples
▶	<input type="checkbox"/>	QF Pat_20120417_0949	QuantiFast Pathogen PCR...	66
▶	<input type="checkbox"/>	QF Pat_20120417_0959	QuantiFast Pathogen PCR...	66
▶	<input type="checkbox"/>	QF Pat_20120417_1009	QuantiFast Pathogen PCR...	66

Selecting cells

A certain cell area can be selected by clicking in the first cell, holding down the left mouse button, and dragging to the last cell of the area. Selected cells are highlighted in dark blue color. To make multiple selection of non-adjacent cells, hold down the "CTRL" key and click the cells to select.

Copying data from a table

Copying data from a table is possible by first selecting the cells to be copied and then using "CTRL"+"C". The contents of the selected cells are copied to the clipboard. The copied cells can easily be pasted to another area within Rotor-Gene AssayManager v2.1 or to another software for further processing using "CTRL"+"V".

Assay selection			
<input type="checkbox"/>	Experiment	Assay	# samples
<input type="checkbox"/>	QF Pat_20120417_0949	QuantiFast Pathogen PCR...	66
<input type="checkbox"/>	SYBR_20120417_0953	Rotor-Gene SYBR Green...	48
<input type="checkbox"/>	QF Pat_20120417_0959	QuantiFast Pathogen PCR...	66
<input type="checkbox"/>	SYBR_20120417_1007	Rotor-Gene SYBR Green...	48
<input type="checkbox"/>	QF Pat_20120417_1009	QuantiFast Pathogen PCR...	66



1. Select cells to be copied
2. CTRL-C to copy the content
3. Paste in spreadsheet application

	SYBR_20120417_0953	Rotor-Gene SYBR Green PCR Demo Kit	
	QF Pat_20120417_0959	QuantiFast Pathogen PCR +IC	
	SYBR_20120417_1007	Rotor-Gene SYBR Green PCR Demo Kit	
	QF Pat_20120417_1009	QuantiFast Pathogen PCR +IC	

Context menu

Tables have context menus with varying commands. The context menu in Rotor-Gene AssayManager v2.1 is opened with a right-click on selected cells. In tables with a row selector there is an additional context menu when first selecting rows by clicking the row selector of the row and then clicking the right mouse button.



1.5.2.5 Working with Graphs

Rotor-Gene AssayManager v2.1 provides graph viewing functions, such as zooming, panning, and selecting samples to easily examine a graph in detail. The following topics describe how to use these functionalities.

Tasks related to working with graphs

- ▶ Zooming in
- ▶ Zooming out
- ▶ Panning
- ▶ Selecting/deselecting samples
- ▶ Sample information in graphs

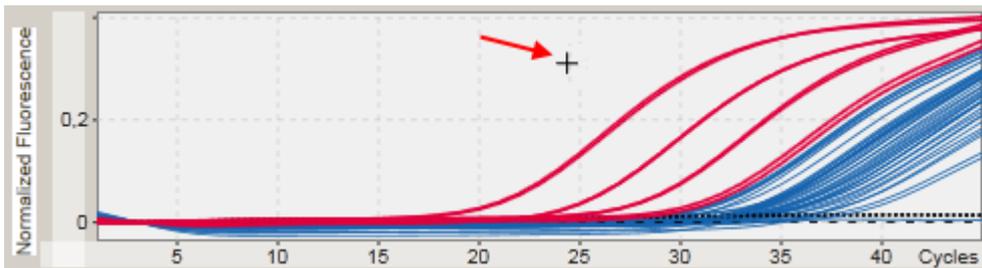
1.5.2.5.1 Zooming in a Graph

Overview

For zooming in a graph in Rotor-Gene AssayManager v2.1, an individual zoom area can be selected as in the following example of an amplification plot from the "Approval" environment.

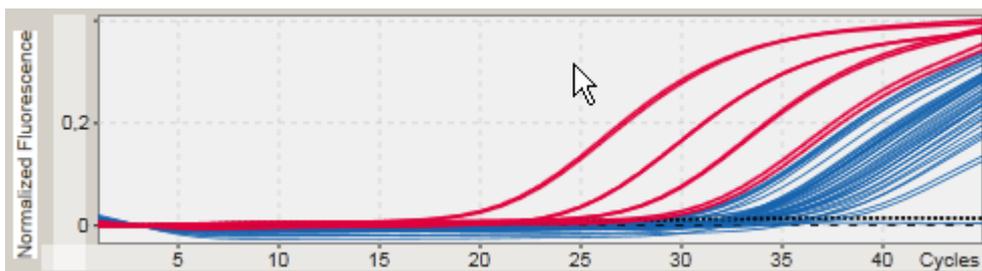
Step-by-step procedure to zoom in a graph

1. Move the cursor over the graph's area. The cursor changes to cross hairs.

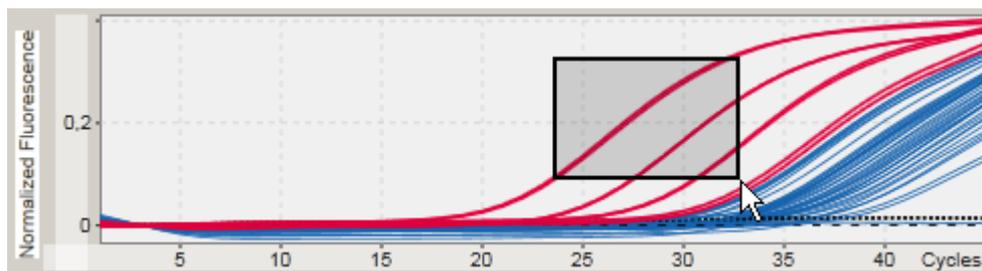


- 2.

- a) Click and hold down the left mouse button. The mouse icon changes from cross hairs to the cursor icon.



- b) Drag the cursor until the end of the area to zoom in. A dark gray rectangle visualizes the selected area, as long as the left mouse button is held down.



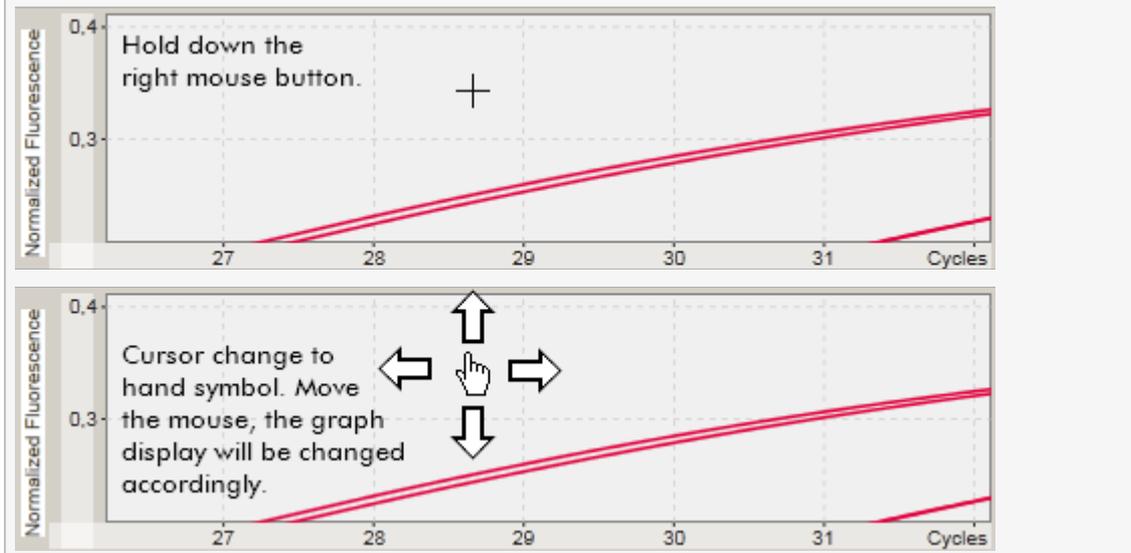
- c) Release the left mouse button. The following menu pops up:



3. Left-click "Zoom". The graph will be zoomed to the selected area.
4. To scroll in the zoomed graph in vertical or horizontal direction just click right in the graph area, hold down the right mouse button, and move the mouse.

Example

Holding down the right mouse button and moving the mouse will change the graph's display accordingly.



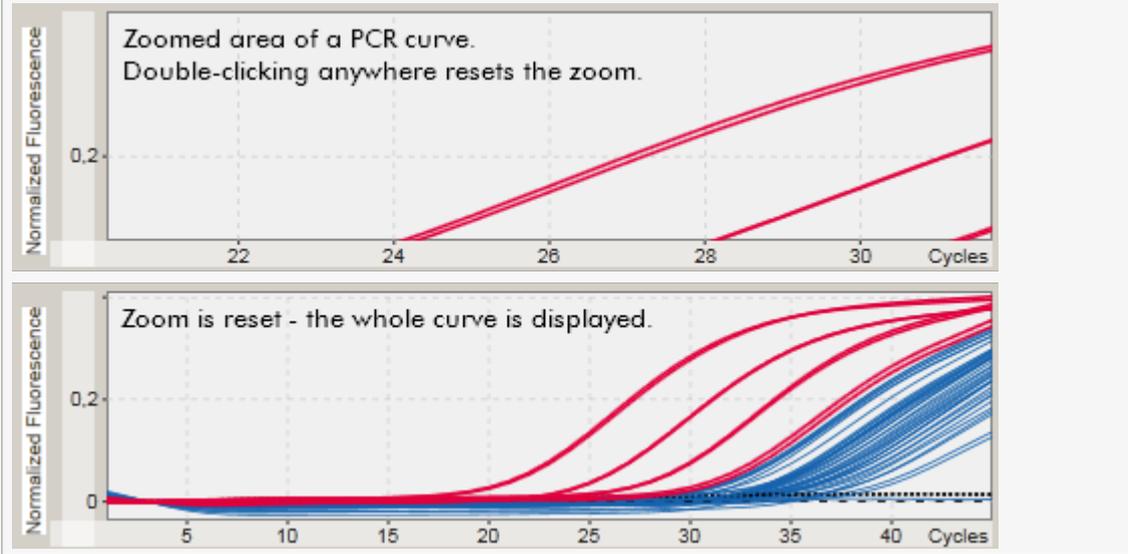
1.5.2.5.2 Zooming out a Graph

Step-by-step procedure to zoom out a graph

Double-click anywhere in a graph area to reset the zoom function to default-scale and see the whole graph.

Example

The graph shows a zoomed area of an amplification plot. Double-clicking anywhere in the graph area will reset the zoom.



1.5.2.5.3 Selecting/Deselecting Samples

Overview

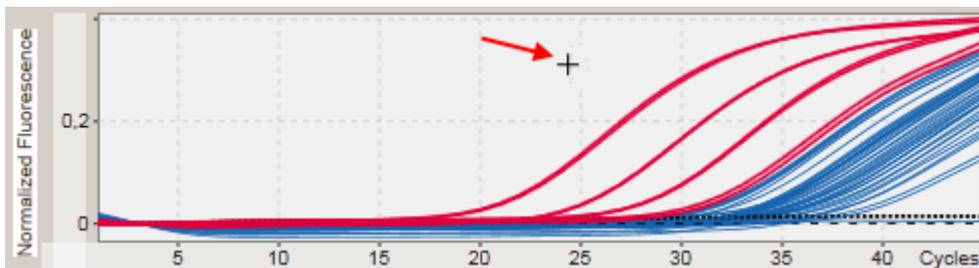
Rotor-Gene AssayManager v2.1 provides 2 methods to select or deselect samples in an amplification plot:

- Using a graph
- Using check boxes

Step-by-step procedure to select/deselect samples using a graph

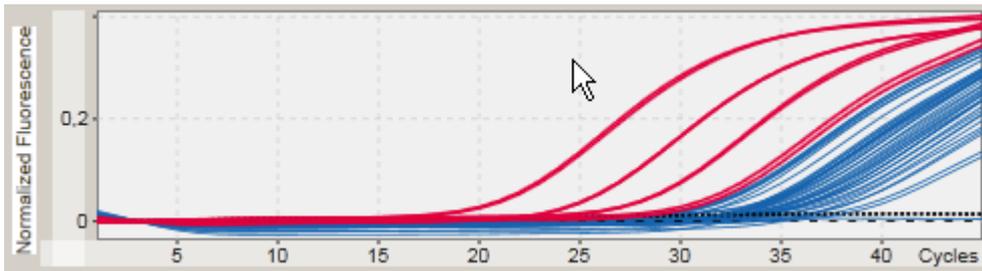
1. Move the cursor over the graph area.

The mouse cursor icon changes to cross hairs.

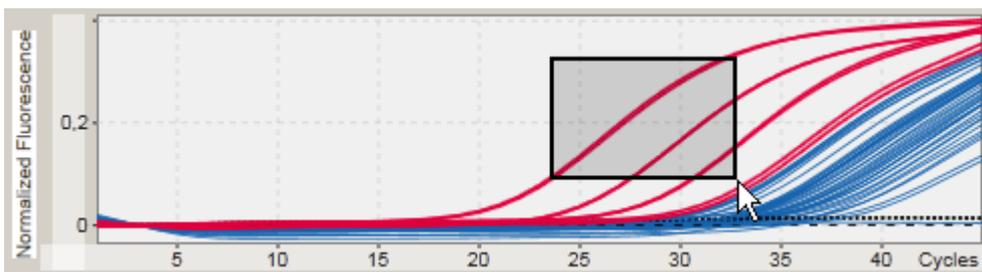


2.

a) Click and hold down the left mouse button. The mouse icon changes from cross hairs to the cursor icon.



b) Drag the cursor until the end of the area to zoom in. A dark gray rectangle visualizes the selected area, as long as the left mouse button is held down.



c) Release the left mouse button. The following menu pops up:



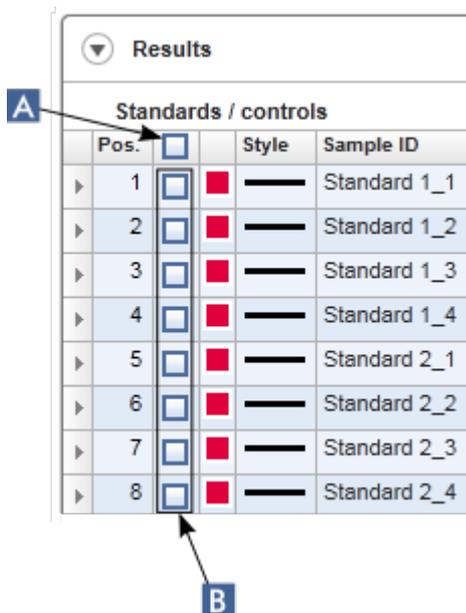
2. Left-click at the desired option

To	Click
Select all samples within the selected area	 Select corresponding samples
Deselect all samples within the selected area	 Deselect corresponding samples

To	Click
Cancel the process	Cancel

Select/deselect samples using check boxes

Samples are selected or deselected by activating or deactivating the corresponding check boxes in the results table.



To	Do
Select all samples in the table	Activate the check box in the column header (A).
Select a specific sample in the table	Activate the check box in the corresponding sample row (B).
Deselect all samples in the table	Deactivate the check box in the column header (A).
Deselect a specific sample in the table	Deactivate the check box in the corresponding sample row (B).

Note

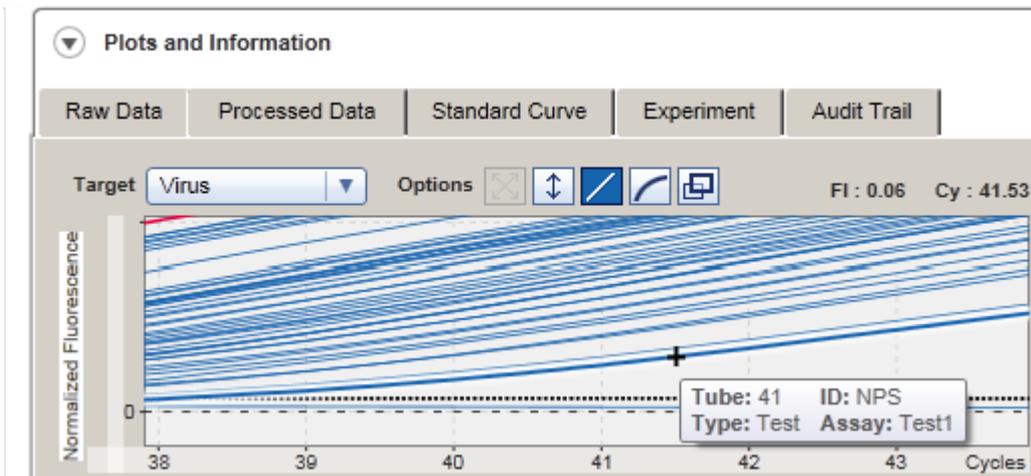
The check box icon in the column header changes depending on the number of selected samples.

Icon	Description
<input type="checkbox"/>	No sample is selected
<input type="checkbox"/>	One or more samples are selected
<input checked="" type="checkbox"/>	All samples are selected

1.5.2.5.4 Sample information in Graphs

To get sample information corresponding to a specific curve, hover the mouse over the curve. The curve will be highlighted, and a tooltip containing the following information will be displayed:

- Tube number
- Sample ID
- Assay type
- Assay short name



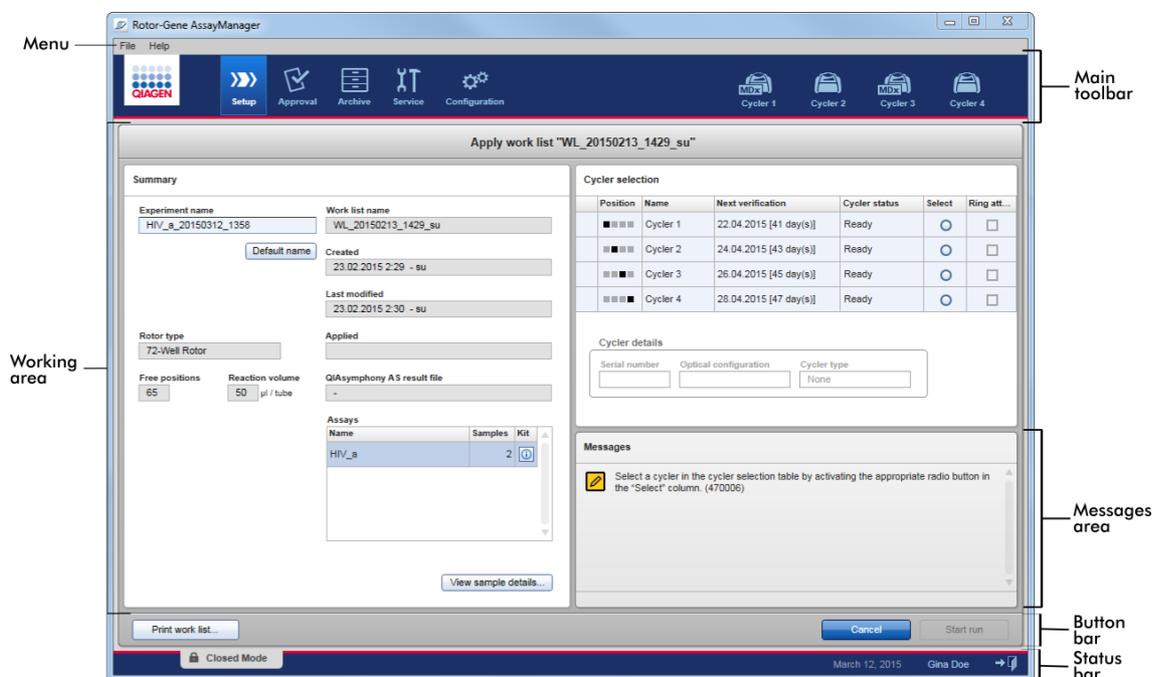
1.5.3 Rotor-Gene AssayManager v2.1 Workspace

Rotor-Gene AssayManager v2.1 is divided into different environments. These environments can be accessed by using the dedicated icons in the main toolbar. The following environments are available:

- ▶ "Setup" environment
- ▶ "Approval" environment
- ▶ "Archive" environment
- ▶ "Service" environment
- ▶ "Configuration" environment
- ▶ "Cycler" environment

Note

If working in the User Defined Test Mode (UDT mode) the "Development" environment is additionally available. For usage of the UDT mode functionalities a compatible UDT mode plug-in is required to be installed.



The workspace of an environment consists of an environment-specific working area and of the following general elements:

- Menu
- Main toolbar
- Working area
- "Messages" area
- Button bar
- Status bar

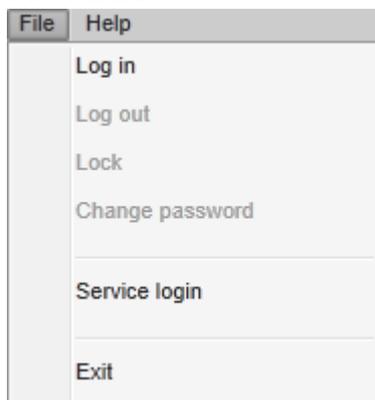
1.5.4 General Elements

The following general graphic user interface elements are described in this section:

- ▶ Menu
- ▶ Main toolbar
- ▶ "Messages" area
- ▶ Button bar
- ▶ Status bar

1.5.4.1 Menu

File menu

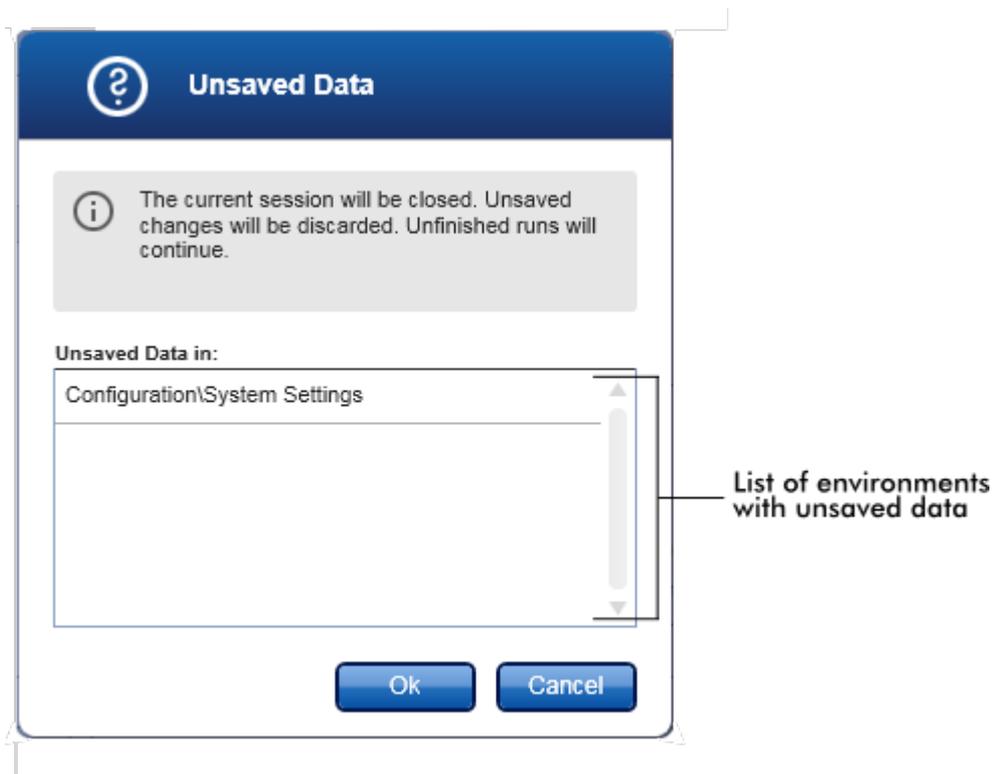


Log in

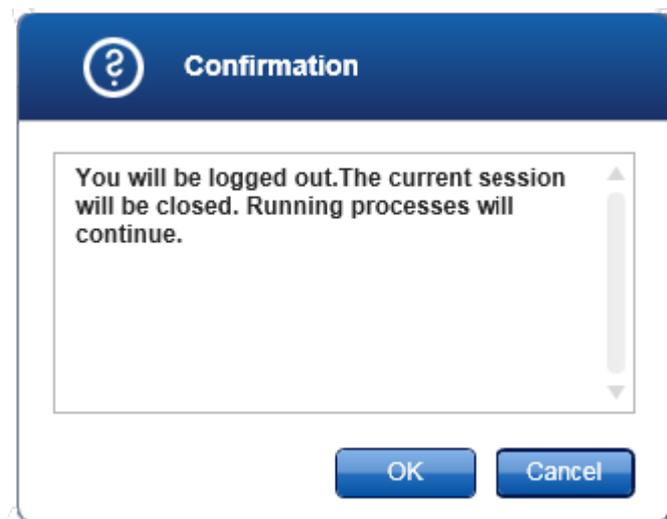
Select "Log in" to log in to Rotor-Gene AssayManager v2.1. This option is grayed out if a user is already logged in.

Log out

This enables the current user to log out. If there are unsaved data, the following warning is shown with a list of environments where unsaved data exist.



If there are no unsaved data, the following dialog is shown:



Lock

This locks the current session. To unlock, the logged in user has to enter the password.

Change password

This opens a dialog to change the password. The old password has to be entered, followed by the new password and a confirmation of the new password.

Service login

This option is for login of a QIAGEN Field Service Engineer. This field is grayed out if a user is already logged in.

Exit

Closes Rotor-Gene AssayManager v2.1. If there are unsaved data, a warning will appear.

Help menu

Open Rotor-Gene AssayManager v2.1 help file

This opens the help file for Rotor-Gene AssayManager v2.1 core application.

Open Gamma Plug-in help file

This opens the help file dedicated for functions related to the Gamma Plug-in. If other plug-ins are installed, there may be more help files.

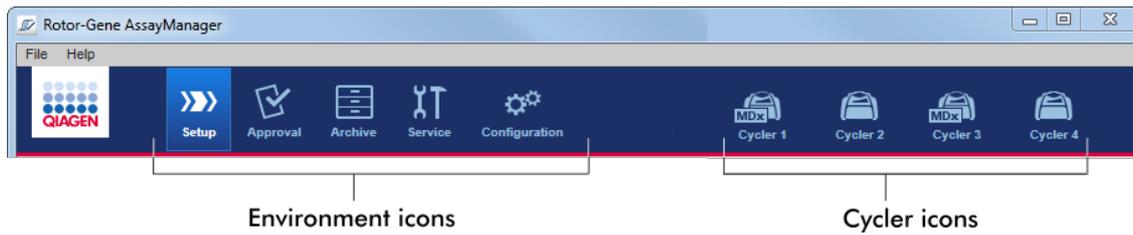
About

The "About Rotor-Gene AssayManager" dialog box appears and displays information about the Rotor-Gene AssayManager v2.1 and the loaded plug-ins including the version numbers.

1.5.4.2 Main Toolbar

The main toolbar contains 2 areas:

- Environment icons
- Cyclor icons



Environment icons

The environment icons are used to change to the corresponding environment. The currently active environment is highlighted.

Rotor-Gene AssayManager v2.1 has 6 different environments. To get detailed information about a specific environment, click its name in the list.

- ▶ "Setup" environment
- ▶ "Approval" environment
- ▶ "Archive" environment
- ▶ "Service" environment
- ▶ "Configuration" environment

Note

If working in the User Defined Test Mode (UDT mode) the "Development" environment is additionally available. For usage of the UDT mode functionalities a compatible UDT mode plug-in is required to be installed.

Cycler icons

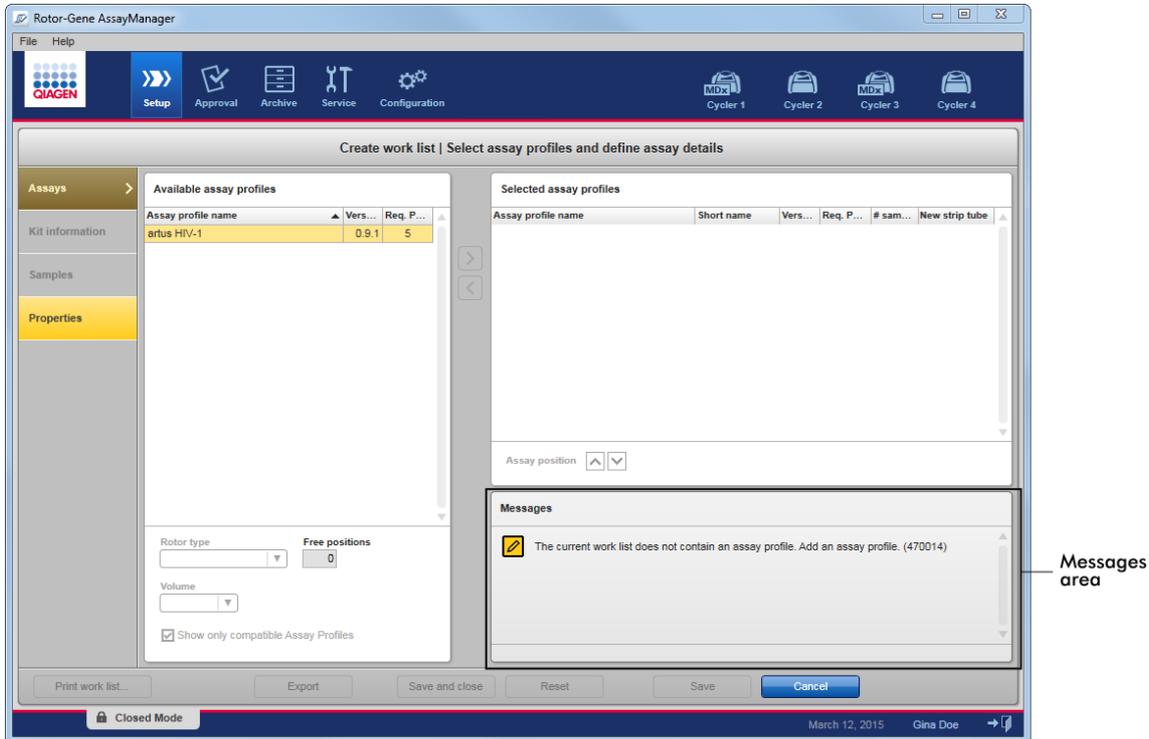
The cycler icons visualize the up to 4 registered cyclers managed by Rotor-Gene AssayManager v2.1. Clicking a cycler icon changes to the corresponding cycler screen.

For details, see ▶ "Cycler" environment.

1.5.4.3 Messages Area

Depending on the selected environment and the corresponding dialog within the environment, there is a "Messages" area containing all warnings, errors, and information related to the current operation.

Example: "Messages" area in the "Setup" environment

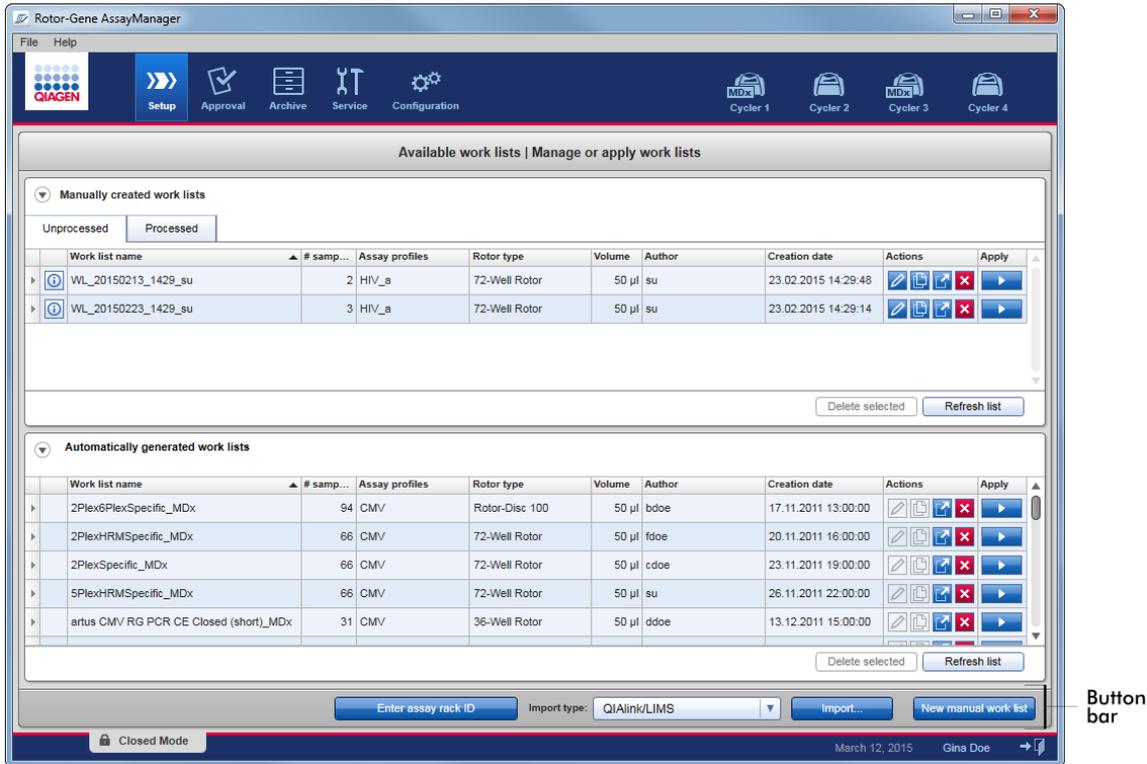


Related topics

- ▶ Using colors
- ▶ Displaying errors and warnings

1.5.4.4 Button Bar

The button bar is placed at the bottom of the screen. It contains buttons specific for the selected environment.



1.5.4.5 Status Bar

The status bar is always visible and gives an overview about the session status.



Status bar element	Explanation
Mode indicator	Indicates the current user mode, i.e., Closed Mode or User Defined Test Mode (UDT mode). If the user is logged in in Closed Mode, the label "Closed Mode" and the corresponding icon is shown:



If the user is logged in in User Defined Test Mode, the label "User Defined Test Mode" and the corresponding icon is shown:



Date	Shows the current date.
User name	Shows first and last name of the user currently logged in.
Log out button	Logs out the current user. If there are unsaved data, a warning will appear.

Note

For usage of the UDT mode functionalities a compatible UDT mode plug-in is required to be installed.

Related topics

- ▶ The two different modes in Rotor-Gene AssayManager v2.1
- ▶ Logging in and logging out

1.5.5 Environments

Rotor-Gene AssayManager contains 4 different environments.

An overview of access rights for different user roles can be found under ▶ User roles.

You can switch to another environment by clicking the appropriate button. The icon of the currently active environment is highlighted with white font and a blue gradient background color.

Environment	Description
	Used for creation, management and application of worklists.
	Used to search for unreleased or partially released assays and for the approval of dedicated samples. Experiment reports are created on release of a sample.
	Used to search for fully and partially released experiments and to generate experiment reports using predefined report profiles.
	Used to adjust the settings of Rotor-Gene AssayManager.
	Used to stop or finish a run and to release a cycler after a run is finished.

Note

If working in the User Defined Test Mode (UDT mode) the "Development" environment is additionally available. For usage of the UDT mode functionalities a compatible UDT mode plug-in is required to be installed.

1.5.5.1 Setup Environment

Overview

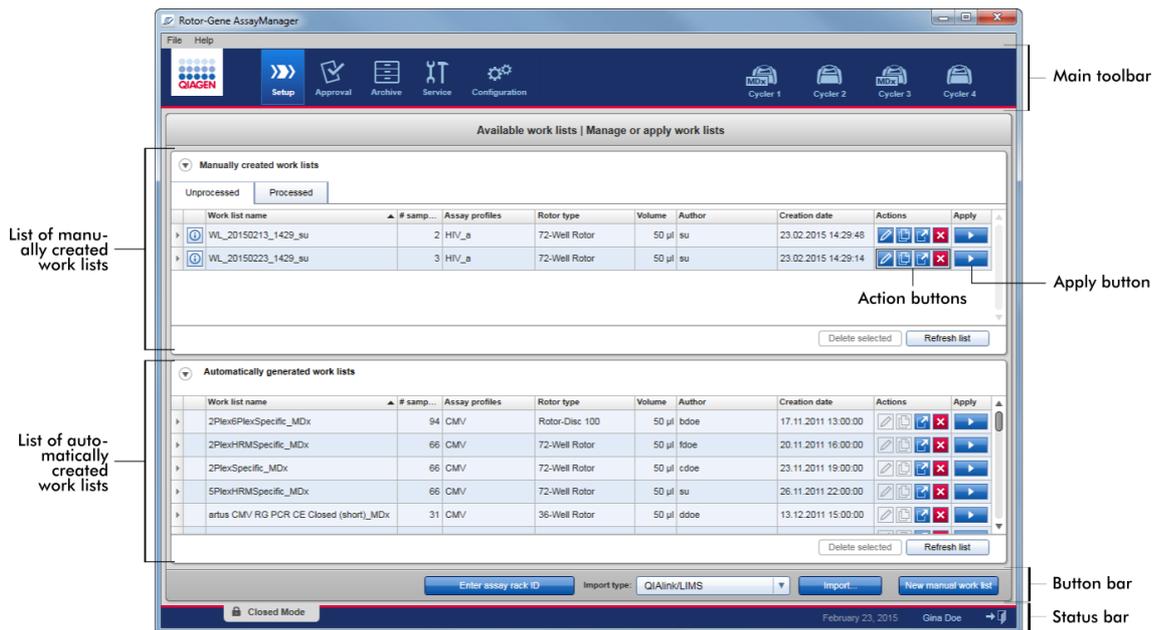
The "Setup" environment is one of the core parts of the Rotor-Gene AssayManager v2.1 application. It automatically appears after a user with the assigned role of an Operator successfully logs in to Rotor-Gene AssayManager v2.1. The "Setup" environment consists of 3 different screens where tasks can be assigned:

Screen	Assigned tasks
"Available worklists" <ul style="list-style-type: none">• "Manually created worklists"• "Automatically generated worklists"	<ul style="list-style-type: none">• Creating a new worklist• Importing a worklist• Editing a worklist• Duplicating a worklist• Exporting a worklist• Deleting a worklist• Applying a worklist
"Create new worklist" <ul style="list-style-type: none">• "Assays" step• "Kit information" step• "Samples" step• "Properties" step	Create a new worklist: <ul style="list-style-type: none">• Appears after clicking "New worklist"• Starts the process to create a new worklist
"Apply worklist"	<ul style="list-style-type: none">• Setup run and apply a worklist

1.5.5.1.1 Available Worklists View

The "Available worklists" view contains 3 areas:

- A table with available manually created worklists (stored in the internal database).
- A table with automatically created worklists (imported by QIASymphony software version 5.0, QIALink/LIMS or Rotor-Gene AssayManager v2.1).
- The button bar at the bottom of the screen.



Note

The Rotor-Gene AssayManager v2.1 is only compatible with the results files of the QIA Symphony software version 5.0.

The "Available Worklists" Tables

The "Available worklists" table displays the following information for all currently available worklists:

- Status icon
- worklist name
- Number of samples
- Assay profiles
- Rotor type
- Reaction volume
- Author
- Creation date
- Last applied

The table with available manually created worklists is further subdivided into unprocessed and processed worklists. By clicking at the corresponding tab the processed and the unprocessed worklists are displayed respectively.

The data in both tables are sortable. By clicking at the column header, the table's data is sorted in ascending order. By clicking at the column header again, the table's data is sorted in descending order.

A status icon is displayed in the very left column of a worklist in case of existing warnings or errors. Possible icons are:

Icon	Description
	Deactivated assay profile or expired kit
	Message: "This worklist contains invalid samples" A worklist contains invalid samples. This message is used only for imported worklists.
	The worklist is currently locked.

Note

Moving the mouse over the icon reveals a tooltip with detailed information about the problem.

The screenshot shows a tooltip titled "Available work lists | Manage or apply work lists" over a table row. The tooltip text reads: "This work list contains the deactivated assay profile QuantiFast Pathogen PCR +IC version 2.0.0. Activate the assay profile and update the work list."

Work list name	# samples	Assay profiles	Rotor type	Volume	Author	Creation date	La
WL_20120417_0858_su	66	QF Pat	72-Well Rotor	25 µl	su	17.04.2012 08:58:58	17

In the very right columns of a worklist, the Action buttons and the Apply button can be found.

The screenshot shows a table with columns: Work list name, # samples, Assay profiles, Rotor type, Volume, Author, Creation date, Last applied, Actions, and Apply. Callouts point to the 'Assay profiles' column (Detailed work list information), the 'Actions' column (Action buttons), and the 'Apply' column (Apply button).

Work list name	# samples	Assay profiles	Rotor type	Volume	Author	Creation date	Last applied	Actions	Apply
WL_20120417_0858_su	66	QF Pat	72-Well Rotor	25 µl	su	17.04.2012 08:58:58	17.04.2012 10:38:20		
WL_20120417_0900_su	48	SYBR	72-Well Rotor	25 µl	su	17.04.2012 09:00:43	17.04.2012 10:38:39		

Type	Icon	Label/Title	Description	Link to
Action buttons		"Edit worklist"	<p>Editing a worklist means modifying its parameters in the "Edit worklist" view. The parameters of the worklist can be modified using the "Edit worklist" view.</p> <p>Note: This button is only enabled if the option "is editable" was set during worklist setup and the worklist is not locked. worklists imported from QIASymphony or LIMS to the software cannot be edited.</p>	 Creating/editing a worklist
		"Duplicate worklist"	<p>Creates a copy of the selected worklist. A copy of the selected worklist is created. This copy can subsequently be edited in the "Edit worklist" view.</p> <p>Note: All modifications are temporary until the new worklist is saved.</p> <p>Note: This icon is disabled for worklists imported from QIASymphony or LIMS.</p>	 Creating/editing a worklist
		"Export worklist"	<p>Exports the worklist as *.iwl file. The intended use of this function is to exchange worklists between different Rotor-Gene AssayManager v2.1 installations using the import/export function.</p>	–
		"Remove worklist"	<p>Removes the worklist from the system. A warning must be confirmed before the worklist is deleted.</p>	–
		"Apply worklist"	<p>The worklist is applied (i.e., the run is performed) and further details have</p>	 Apply worklist view

"Apply" button

to be entered in the "Run worklist" view.

Note: This button is enabled if the worklist is set as "ready to be applied" and the worklist is not locked.

Note

The "Available worklists tables" might become very long and confusing: this table might contain a number of worklists that you do not need anymore.

Remove the worklists you do not need anymore at regular periods:

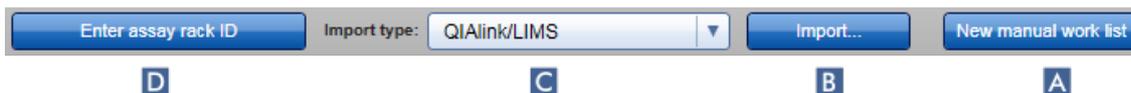
1. Click the "Remove worklist" button (✖).
2. Confirm the warning "Worklist Removal" by clicking "OK". The deleted worklist disappears from the "Available worklists table".
3. Repeat these steps for any other worklist you want to remove.

Note

The automatically created worklist table cannot be either edited as duplicated since it was automatically generated based on a AS result file.

The Button Bar

The button bar is arranged at the bottom of the screen:



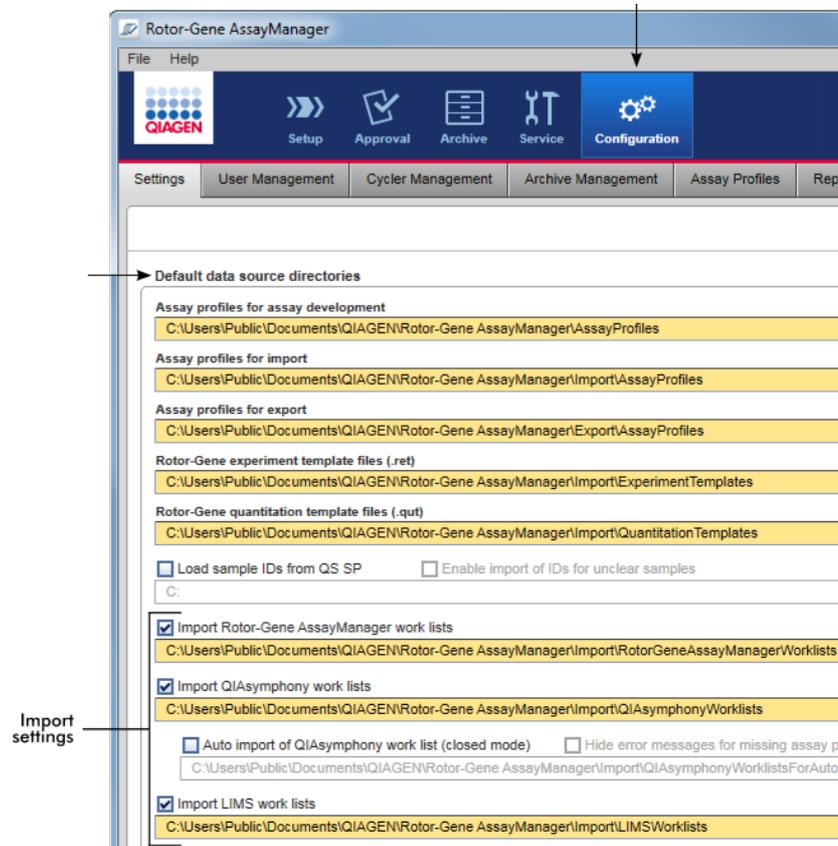
	Label/Title	Description
A	"New worklist"	Create a new worklist. This button links to the "Create new worklist" screen.
B	"Import"	Import a worklist from a file. A file selection dialog is opened where the worklist to be imported can be selected. The source type is determined by the item selected in the drop-down menu C .

C "Import type"

Drop-down menu to select the import source file type for the import worklist command. Rotor-Gene AssayManager v2.1 can import worklists from QIAlink/LIMS, QIASymphony, and other Rotor-Gene AssayManager v2.1 installations. In addition, also an automatically QIASymphony worklist functionality can be defined.

Possible values: QIAlink/LIMS
QIASymphony
Rotor-Gene AssayManager

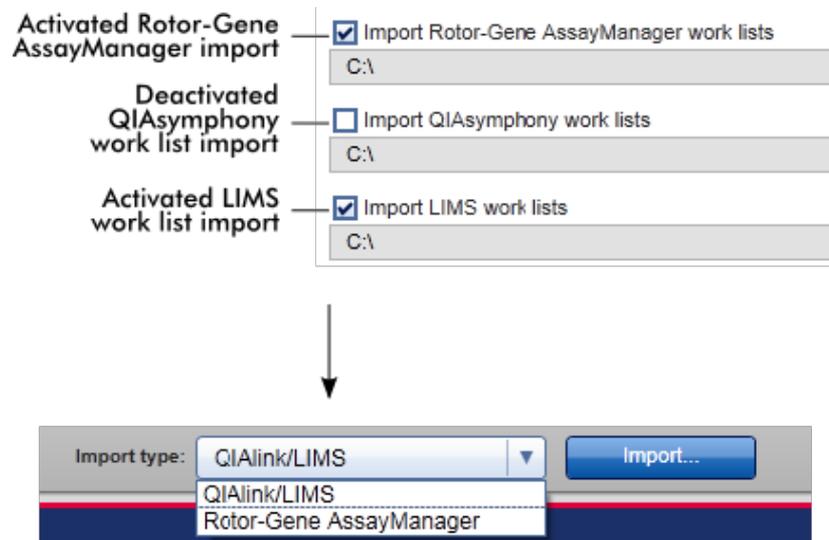
The entries in this menu depend on the import settings in the "Configuration" environment.



The group box "Default data source directories" in the "Settings" tab of the "Configuration" environment defines whether the import of external worklists (from Rotor-Gene AssayManager v2.1, QIASymphony, or a LIMS) is possible and determines the source directory.

A check box in front of the 3 import settings determines if the corresponding import setting is activated or not. If the check box is activated, the import of this specific worklist is enabled. The "Import type" drop-down menu in the "Setup" environment is populated with this import option.

Example:



The "Import QIASymphony worklists" option is deactivated in the example above. The QIASymphony import option is removed from the "Import type" menu.

For QIASymphony worklists also an automatic import functionality can be selected. By checking "Auto import QIASymphony worklist (closed mode)" the software checks automatically in the defined source directory every minute if a worklist is available and imports this automatically.

<p>D</p>	<p>"Enter assay rack ID"</p>	<p>Enter manually or scan an assay rack ID, which was used in QIASymphony AS and the corresponding worklist will be automatically selected. Note: The corresponding worklist must be imported before to use this functionality.</p>
-----------------	------------------------------	---

Tasks related to the "Available worklists" view

- ▶ Creating a new worklist

- ▶ Editing/modifying a worklist
- ▶ Exporting a worklist
- ▶ Importing a worklist
- ▶ Applying a worklist

1.5.5.1.2 Apply Worklist View

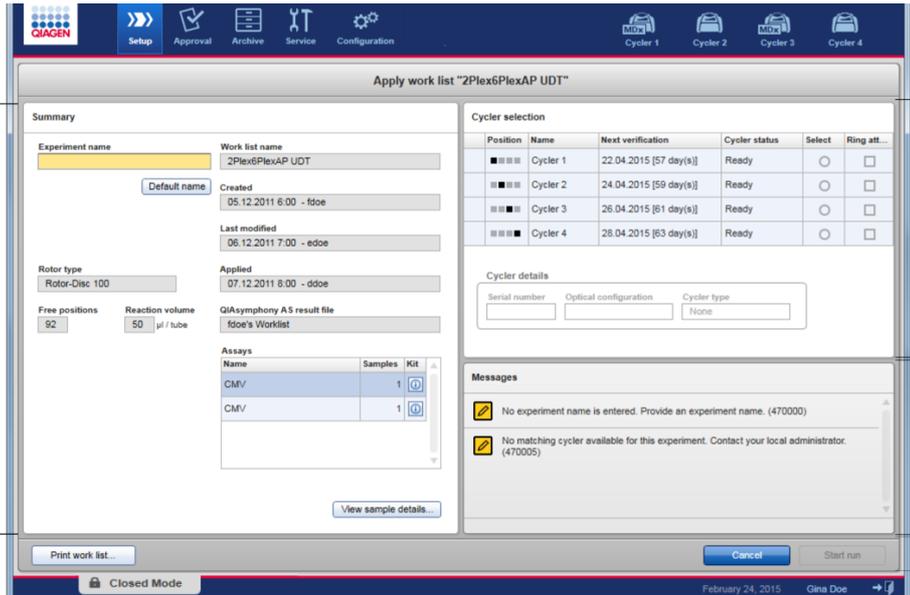
Selecting the "Apply" button either in the "Available worklists" view or in the "Create New/Edit worklist" view links to the "Apply worklist" view.

In the "Apply worklist view" the following tasks can be accomplished to start a run:

- Define an experiment name
- View sample details
- Print a worklist
- Select a cycler
- Confirm that the locking ring has been attached to the rotor
- Start the run

Furthermore detailed information about the worklist and the cycler are displayed:

worklist information	Cycler information
<ul style="list-style-type: none"> • worklist name • Creation date • Last modification date • Last application date • Rotor type • Number of free positions • Reaction volume • Assays used in the worklist <ul style="list-style-type: none"> • Assay name • Number of samples • Material number • Kit expiry date • Lot number 	<ul style="list-style-type: none"> • Position • Name • Next verification date • Cycler status • Serial number • Optical configuration



Summary area

Cycler selection area

Messages area

Button bar

Summary area

The "Summary" area is intended to enter a mandatory experiment name. The "Summary" area also provides detailed information about the worklist and its incorporated assay(s). Sample details can be displayed in a secondary table.

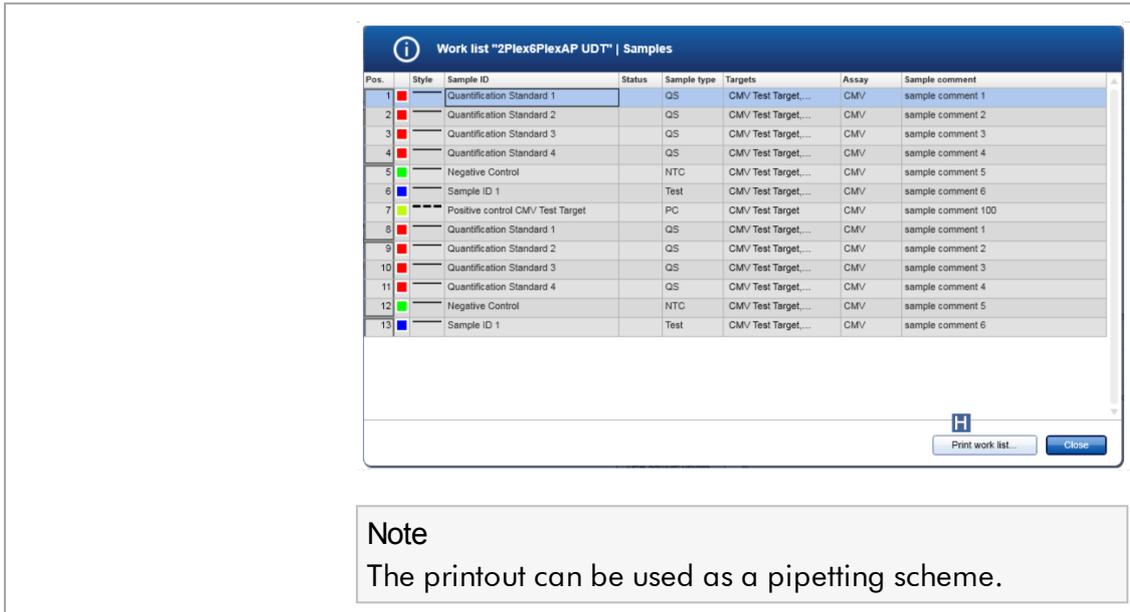
The screenshot displays the 'Summary' section of a software interface. It contains several input fields and a table. Callout boxes A through G highlight specific elements:

- A:** Points to the 'Experiment name' input field, which is highlighted in yellow.
- B:** Points to a 'Default name' button.
- C:** Points to the 'Rotor type' field, which contains '72-Well Rotor'.
- D:** Points to the 'Work list name' field, which contains '2PlexAP UDT', and the 'Created' and 'Last modified' fields.
- E:** Points to the 'Assays' table.
- F:** Points to the 'View sample details...' button.
- G:** Points to the 'View sample details...' button.

The 'Assays' table is as follows:

Name	Samples	Kit
CMV	66	

	Label/Title	Description
A	"Experiment name"	Input box to enter a mandatory experiment name. The experiment name must fulfill 2 requirements: <ul style="list-style-type: none"> • The experiment name must not exceed 80 characters. • The experiment name must be unique.
B	"Default name" button	A default name is entered automatically in the experiment name input box using the name pattern defined in the "Configuration" environment. Further information can be found under ► "Configuration" environment - "Settings"
C	Data field: <ul style="list-style-type: none"> • "Free positions" • "Reaction volume" 	Shows the following data: <ul style="list-style-type: none"> • Number of free positions • Reaction volume
D	Data field: <ul style="list-style-type: none"> • "worklist name" • "Created" • "Last modified" • "Applied" • QIASymphony AS result file" 	Shows the following data: <ul style="list-style-type: none"> • worklist name • Creation date • Last modification date • Last application date • QIASymphony AS result file
E	"Assays" table	Table with a list of all assays incorporated in the worklist. For every assay the following data is shown: <ul style="list-style-type: none"> • Assay name • Number of samples
F	"Kit information"	Dialog shows following kit information: <ul style="list-style-type: none"> • Kit bar code • Material number • Kit expiry date • Lot number
G	"View sample details..."	Overview of the samples in the worklist in the form of a table. This table can be printed by clicking "Print worklist..." (H).



Pos.	Style	Sample ID	Status	Sample type	Targets	Assay	Sample comment
1	Quantification Standard 1	Quantification Standard 1	QS	CMV Test Target...	CMV/	sample comment 1	
2	Quantification Standard 2	Quantification Standard 2	QS	CMV Test Target...	CMV/	sample comment 2	
3	Quantification Standard 3	Quantification Standard 3	QS	CMV Test Target...	CMV/	sample comment 3	
4	Quantification Standard 4	Quantification Standard 4	QS	CMV Test Target...	CMV/	sample comment 4	
5	Negative Control	Negative Control	NTC	CMV Test Target...	CMV/	sample comment 5	
6	Sample ID 1	Sample ID 1	Test	CMV Test Target...	CMV/	sample comment 6	
7	Positive control CMV Test Target	Positive control CMV Test Target	PC	CMV Test Target...	CMV/	sample comment 100	
8	Quantification Standard 1	Quantification Standard 1	QS	CMV Test Target...	CMV/	sample comment 1	
9	Quantification Standard 2	Quantification Standard 2	QS	CMV Test Target...	CMV/	sample comment 2	
10	Quantification Standard 3	Quantification Standard 3	QS	CMV Test Target...	CMV/	sample comment 3	
11	Quantification Standard 4	Quantification Standard 4	QS	CMV Test Target...	CMV/	sample comment 4	
12	Negative Control	Negative Control	NTC	CMV Test Target...	CMV/	sample comment 5	
13	Sample ID 1	Sample ID 1	Test	CMV Test Target...	CMV/	sample comment 6	

Note
The printout can be used as a pipetting scheme.

"Cycler selection" area

The "Cycler selection" area mainly consists of the "Cycler selection" table, which lists all available and usable cyclers with the following data:

- Position of cycler
- Name of cycler
- Next temperature verification date (residual days in brackets)
- Status of cycler

The "Cycler details" table below displays the "Serial number" and the "Optical configuration" of the selected cycler.

Cycler selection

	Position	Name	Next verification	Cycler status	Select	Ring att...
Cycler selection table	■ ■ ■ ■	Cycler 1	22.04.2015 [57 day(s)]	Ready	<input type="radio"/>	<input type="checkbox"/>
	■ ■ ■ ■	Cycler 2	24.04.2015 [59 day(s)]	Ready	<input type="radio"/>	<input type="checkbox"/>
	■ ■ ■ ■	Cycler 3	26.04.2015 [61 day(s)]	Ready	<input type="radio"/>	<input type="checkbox"/>
	■ ■ ■ ■	Cycler 4	28.04.2015 [63 day(s)]	Ready	<input type="radio"/>	<input type="checkbox"/>

Cycler details

Serial number

Optical configuration

Cycler type

The "Cycler selection" table has 4 rows, representing the maximum of 4 cyclers that can be operated by Rotor-Gene AssayManager v2.1. If fewer than 4 cyclers are configured, residual table rows will be disabled.

All compatible cyclers with the status "Ready" can be selected for the worklist to be applied using the "Select" radio button. After successful cycler selection, the dedicated "Ring attached" check box will become active. Confirm that the locking ring is attached to the rotor by activating the "Ring attached" check box to start the cycler.

Note

A successful cycler selection requires at least that the optical configuration of a cycler matches the configuration defined by the assay profiles referenced in the worklist.

Cycler selection					
Position	Name	Next verification	Cycler status	Select	Ring attached
■ ■ ■ ■	Cycler 1	16.06.2012 [60 day(s)]	Ready	<input type="radio"/>	<input type="checkbox"/>
■ ■ ■ ■	Cycler 2	18.06.2012 [62 day(s)]	Ready	<input checked="" type="radio"/>	<input type="checkbox"/>
■ ■ ■ ■	Cycler 3	20.06.2012 [64 day(s)]	Ready	<input type="radio"/>	<input type="checkbox"/>
■ ■ ■ ■	Cycler 4	22.06.2012 [66 day(s)]	Ready	<input type="radio"/>	<input type="checkbox"/>



Status of "Start run" button changes when "Ring attached" option is activated



Cycler selection					
Position	Name	Next verification	Cycler status	Select	Ring attached
■ ■ ■ ■	Cycler 1	16.06.2012 [60 day(s)]	Ready	<input type="radio"/>	<input type="checkbox"/>
■ ■ ■ ■	Cycler 2	18.06.2012 [62 day(s)]	Loaded	<input checked="" type="radio"/>	<input checked="" type="checkbox"/>
■ ■ ■ ■	Cycler 3	20.06.2012 [64 day(s)]	Ready	<input type="radio"/>	<input type="checkbox"/>
■ ■ ■ ■	Cycler 4	22.06.2012 [66 day(s)]	Ready	<input type="radio"/>	<input type="checkbox"/>



Button bar

The button bar contains 3 interactive buttons:



	Label/Title	Description
A	"Print worklist..."	Generation of a worklist report in *.pdf format with the following structure:

worklist name

Creation date and time, user name

Rotor information

- Rotor type
- Volume

Assays

- Assay profile name
- Version
- Kit information:
 - Material number
 - Expiry date
 - Lot number

Sample details

- Position
- Sample ID
- Target(s)
- Type
- Assay
- Comment

Note

The worklist can also be printed by clicking the "View sample details..." button; see ▶ Printing worklist using view sample details button.

Note

The printout can be used as a pipetting scheme.

B "Cancel"

- The application process is canceled.
- The "Apply worklist" screen is closed without saving any changes.
- The "Available worklists" screen is shown.

C "Start run"

After the start of the cycling process, the cycler screen of the selected cycler is displayed.

Note: The "Start run" button is disabled by default. This button is activated if the user has selected a cycler in the

"Cycler selection" table and has confirmed that the locking ring has been attached.

When the user clicks the "Start run" button, the following actions are performed:

- The experiment is saved in the database.
- The run is started.
- Rotor-Gene AssayManager v2.1 switches to the "Cycler" environment of the selected cycler.

Tasks related to the "Run worklist" view

- ▶ Starting a run
- ▶ Managing cyclers
- ▶ Setting worklist naming options

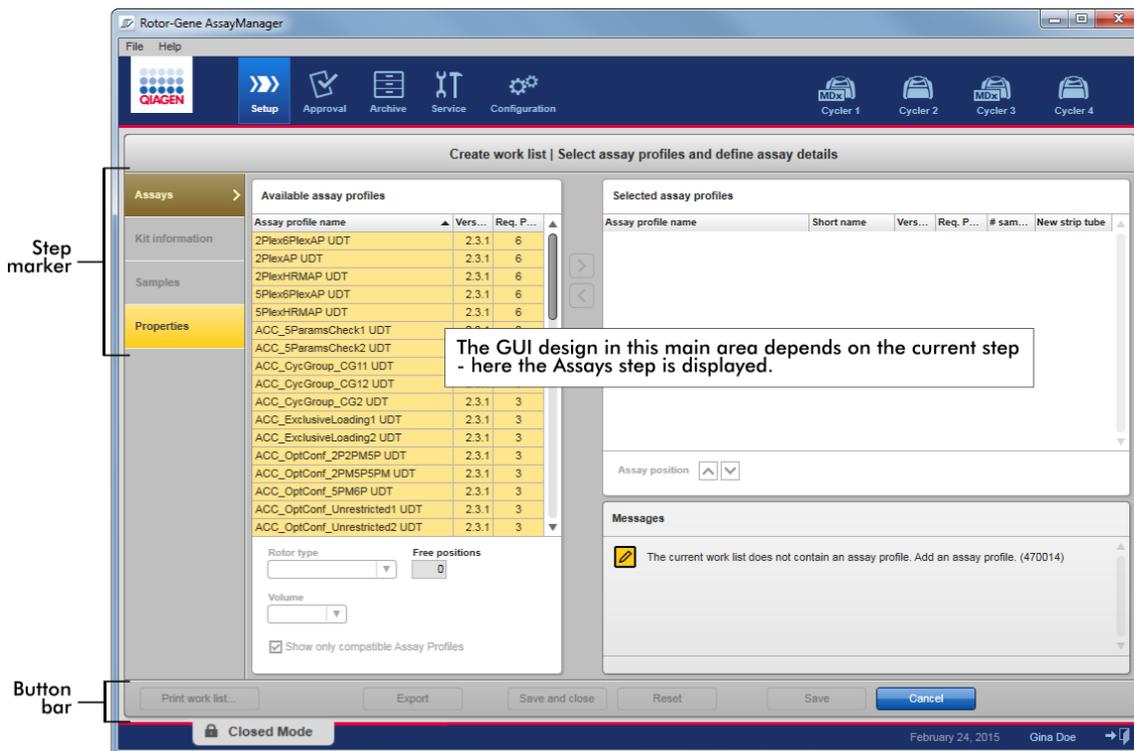
1.5.5.1.3 Create New/Edit Worklist View

The "Create new worklist" view and the "Edit worklist" view share the same design — therefore the description below is valid for both, creating and editing a worklist.

The task of creating a new worklist/editing a worklist is subdivided into 4 steps:

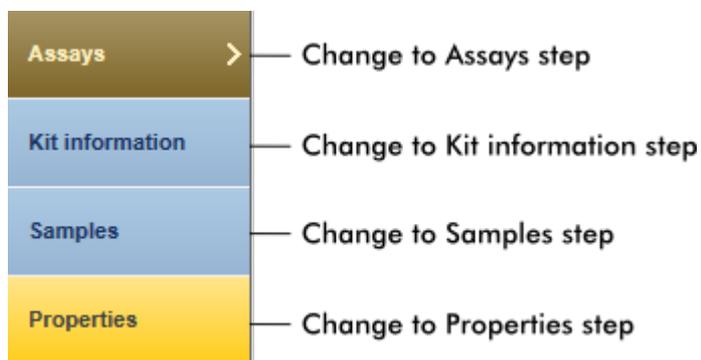
- "Assays"
- "Kit information"
- "Samples"
- "Properties"

The screen layouts for these steps have 2 static elements in common: the step marker and the button bar. These elements remain unchanged if the user changes from one step to another — with the exception that the "Properties" step contains an additional "Apply" button. The main screen area varies according to the current step. The step marker is used to change between these 4 steps.



Step marker

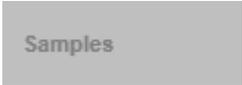
The step marker is used to change between the 4 different steps.



Note

It is not necessary to follow the 4 steps one after another. The steps can be accessed arbitrarily. Unsaved changes are maintained if the user changes to another step.

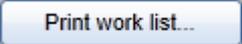
The coloring of the step marker changes, depending on whether errors occur and if the step is currently active or not.

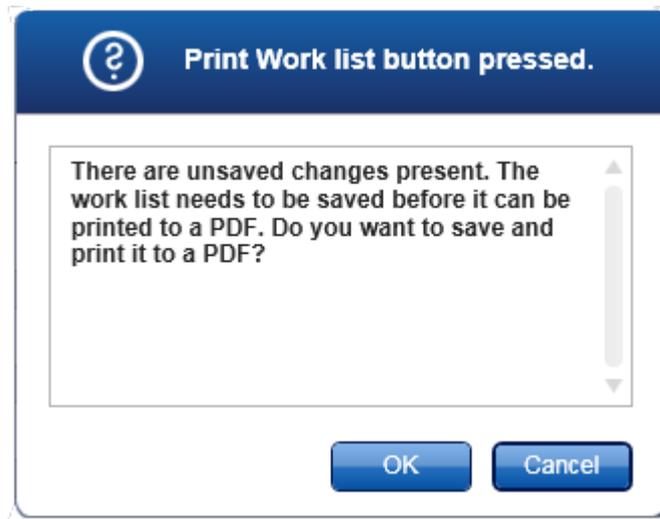
Status	Coloring	Example
Disabled step	Grayed out	
Currently active step without error	Gray background white font	
Currently active step with error	Brown background yellow font	
Currently not active step without error	Blue background dark blue font	
Currently not active step with error	Yellow background dark brown font	

Button bar

The button bar is arranged at the bottom of the screen.



Label/Title	Description
	<p>Note: Button is only enabled if the worklist is valid and contains no errors.</p> <p>Task: Generate a worklist report in *.pdf format. In case unsaved changes are present, the following warning must be confirmed before the *.pdf file can be generated. A worklist must be saved in the database before it can be printed.</p>



The generated *.pdf has the following structure:

worklist name

Creation date and time, user name

Rotor information

- Rotor type
- Volume

Assays	<ul style="list-style-type: none"> • Assay profile name • Version 	Kit information: <ul style="list-style-type: none"> • Material number • Expiry date • Lot number
--------	---	---

Sample details table

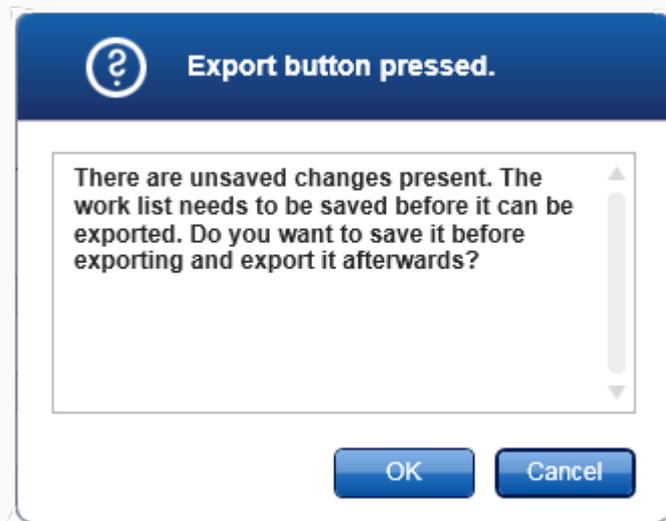
- Position
- Sample ID
- Target(s)
- Assay type
- Comment

Export

Note: Button is enabled if at least the worklist name is valid.

Task: Export the worklist as *.iwl file.
 The *.iwl file can be imported to other Rotor-Gene AssayManager installations (exchange functionality). If

unsaved changes are present, the following warning must be confirmed.

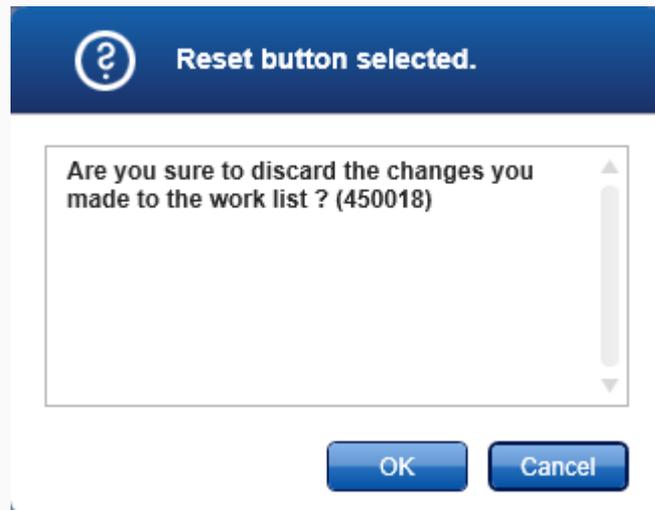


Save and close

Task: Save the current progress and return to the available worklists table.

Reset

Task: Reset the current creation process. If a new worklist was created, all fields are reset to their default value. If an existing worklist was edited, unsaved changes of the worklist are discarded. After clicking "Reset", the following warning must be confirmed.



Save

Note: Button is only enabled if unsaved changes exist and a valid worklist name has been entered.

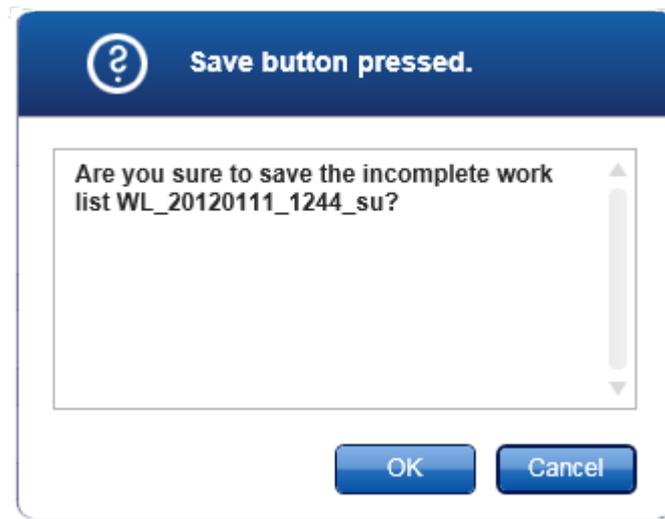
Task: Save the worklist.

The current worklist is saved to the database under the worklist name entered in the "Properties" step. The worklist is subsequently available in the "Available worklists" table.

If a worklist was edited, the "Last modified" field is set to the current date, time, and user.

If a new worklist was created, the "Created" field is set to the current date, time, and user.

Clicking "Save" if the worklist is still incomplete opens the following dialog:

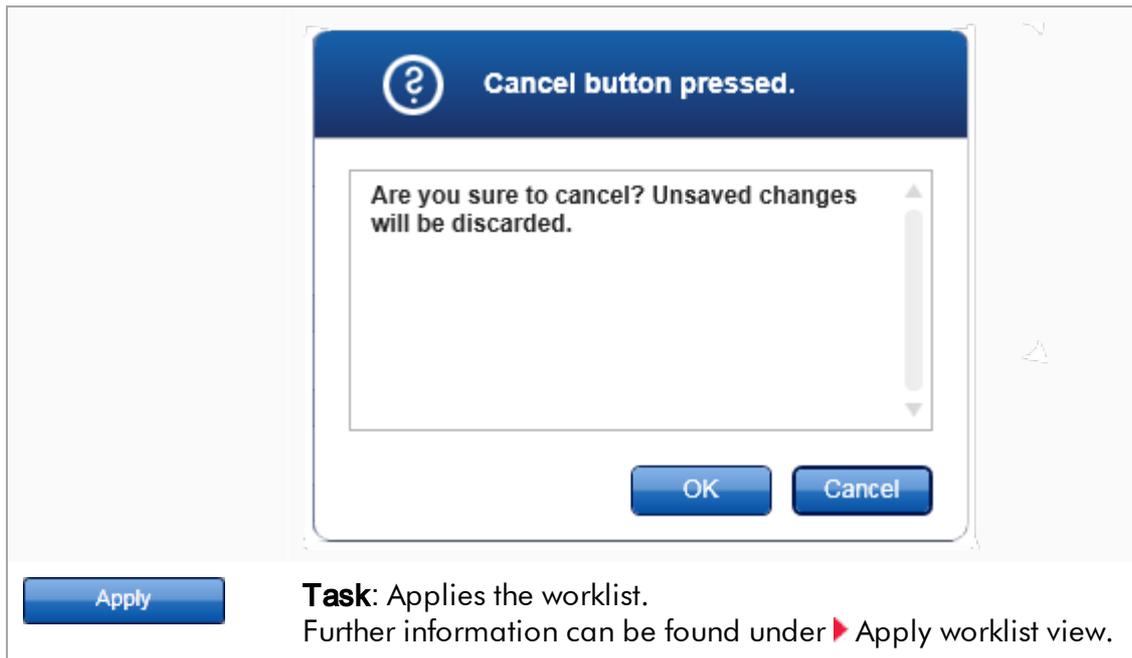


Note: An incomplete worklist can be saved if at least a valid worklist name was entered. If an incomplete worklist is saved, Rotor-Gene AssayManager v2.1 displays a warning that has to be confirmed.

Cancel

Task: Cancel the creation process.

All entries are deleted and the "Available worklists" table is shown. After clicking "Cancel", the user must confirm that unsaved data will be discarded.



Assays step

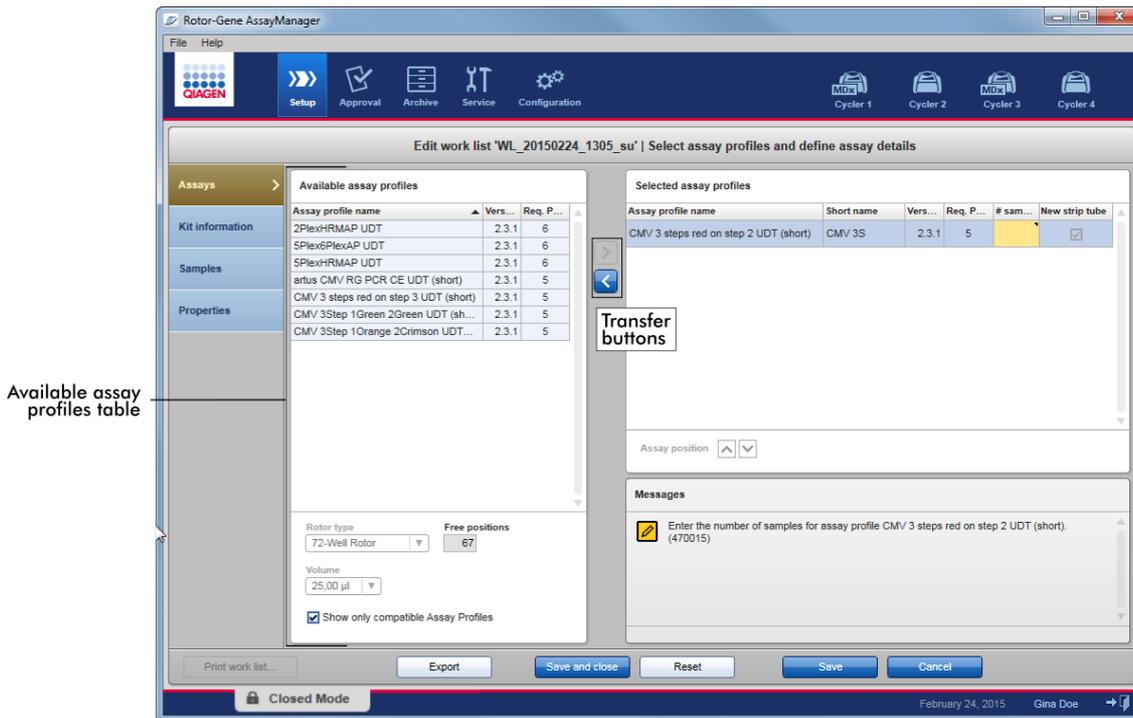
In this step, the user assembles a worklist by adding assay profiles to the worklist. In its simplest form, only one assay profile is added to the worklist. It is also possible to add multiple, compatible assay profiles.

The following requirements must be fulfilled when assay profiles are combined:

- The assay profiles must be compatible (compatibility of assay profiles is defined in the ► [Assay profile editor](#)).
- The maximum number of tubes for the selected rotor is not exceeded.

The assays step consists of 4 areas:

- "Available assay profiles" table
- "Selected assay profiles" table
- "Messages" area
- Transfer buttons



Select and edit assay profiles:

- Select one assay profile for the worklist from the "Available assay profiles" table and add it; in case the worklist contains multiple assay profiles, select a compatible assay profile and add it.
- Select the rotor type and the reaction volume.
- Transfer the assay(s) to the "Selected assay profiles" table.

The number of samples have to be entered in the selected assay profiles table for every selected assay.

Note

These data (except the number of samples) can either be entered manually in the individual boxes or by using a bar code scanner. The bar code of the dedicated QIAGEN kit can be scanned. Therefore click on the "Kit information" step and enter manually or scan the QIAGEN kit bar code. The values for material number, kit expiry date, and kit lot number will be automatically populated with the values from the scan. Only the number of samples has to be entered manually.

Note

For a description of how to install and use a handheld bar code scanner, please refer to the corresponding device manual.

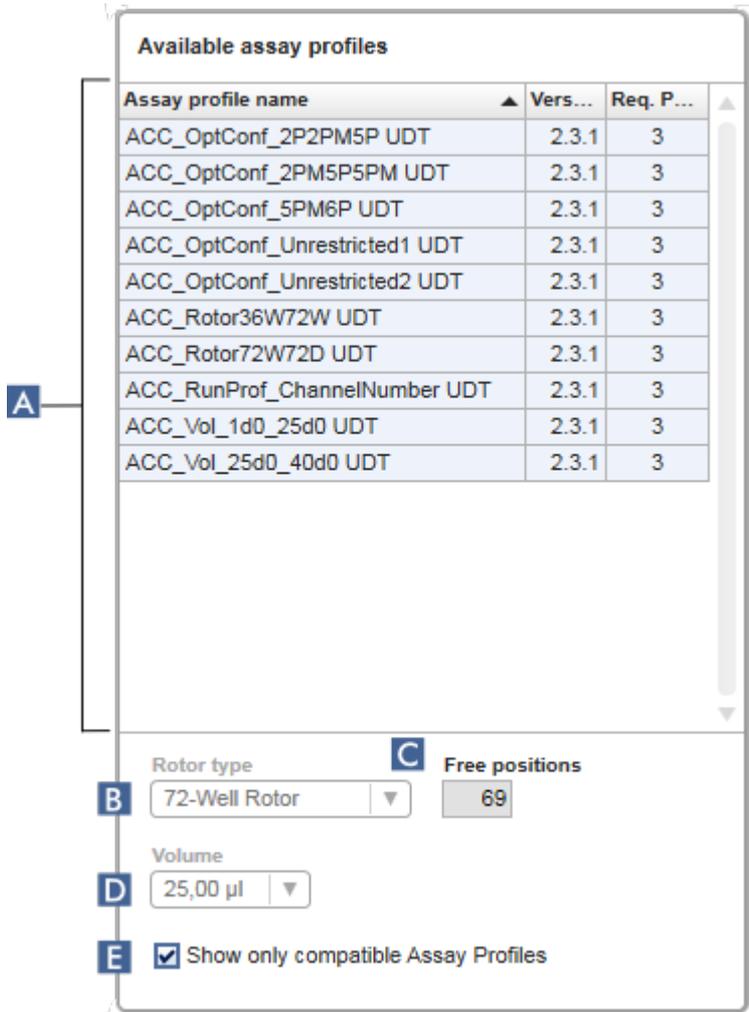
Transfer buttons

The transfer buttons are used to add and remove assay profiles to/from the selected assay profiles table.

Icon	Description
	<p>Transfer the selected assay profile from the "Available assay profiles" table to the "Selected assay profiles" table.</p> <p>This button is enabled if:</p> <ul style="list-style-type: none">• An assay profile is selected in the "Available assay profiles" table.• Sufficient free wells are available on the selected rotor.• The selected assay profile is compatible with assay profiles already in the "Selected assay profiles" table.
	<p>Remove the selected assay profile from the "Selected assay profiles" table.</p> <p>This button is enabled if an entry is selected in the "Selected assay profiles" table.</p>

"Available assay profiles" table

List with all available assay profile names, sorted alphabetically in ascending order.



	Label/Title	Description
A	"Available assay profiles" table	Table of all available assay profiles with the following columns: <ul style="list-style-type: none"> • Name of assay profile • Version number • Number of external controls used by the corresponding assay.
B	"Rotor type" overview	Drop-down menu for selection of one rotor type for the new worklist.

The "Rotor type" selection menu displays the selected value. This menu becomes disabled after an assay profile has been transferred from the "Available assay profiles" table to the "Selected assay profiles" table.

To re-enable this menu, all assay profiles have to be removed from the "Selected assay profiles" using the transfer button <.

The rotor type for each assay is predefined in the corresponding assay profile.

C "Free positions" info field

Info about the number of free positions on the rotor.

The value in this read-only field depends on the selected rotor. This value is calculated by subtracting the mandatory assay positions (i.e., external controls) and the number of samples from the number of rotor wells.

Example:

The assay requires 1 NTC (no template control) and 4 quantitation standards. 12 samples shall be processed in a 72-well rotor.

1 NTC + 4 standards = 5 required positions
5 required positions + 12 samples = 17 reserved positions
72 wells – 17 reserved positions = 55 free positions

The example above is valid for assays where one sample is applied into one tube. In case of tube splitting, i. e., one sample is split to multiple tubes, the number of test samples has to be multiplied by the number of necessary tubes.

For example, if a sample is split to 5 tubes, then the number of necessary test samples is determined by multiplying the number of test samples by 5.

D "Volume selection" menu

Drop-down menu with predefined reaction volumes for the new worklist. Select the appropriate reaction volume from the drop-down menu.

25,00 µl
40,00 µl
50,00 µl
100,00 µl

Note

The screenshot above is an example. The available reaction volumes are defined by the assay profile.

The "Volume selection" menu displays the selected value. This menu becomes disabled after an assay profile has been transferred from the "Available assay profiles" table to the "Selected assay profiles" table.

To re-enable this menu, all assay profiles have to be removed from the "Selected assay profiles" using the transfer button "<".

The reaction volume is predefined in each assay profile.

E

"Compatible assay profiles" check box

If not activated: List all available assay profiles.

Incompatible assay profiles are grayed out.

If activated:

If an assay profile has already been added to the "Selected assay profiles" table, only compatible assay profiles will be listed.

Note

Multiple assay profiles are defined as being compatible if all of the following requirements are fulfilled:

- The thermal cycling profiles are identical.
- The auto-gain settings are identical.
- They share at least one rotor type.
- They share at least one reaction volume.
- The optical configuration restrictions allow the usage of at least one cycler type, and they share at least one optical configuration.
- They are generally allowed to run with other assays.
- They share the same cycling group, or they are not part of a cycling group at all.

"Selected assay profiles" table

Assay profiles added to the worklist (one or multiple) are listed in the "Selected assay profiles" table. This table is not sortable.

Selected assay profiles					
Assay profile name	Short name	Vers...	Req. P...	# sam...	New strip tube
ACC_Standardprofile UDT	ACC	2.3.1	3		<input checked="" type="checkbox"/>

This table contains data given by the respective assay profile and data that has to be entered manually or with a bar code scanner. The following table shows the source for every column:

Column	Source for column data
"Assay profile name"	Values given by the assay profile
"Short name"	
"Version"	
"# controls"	
"# samples"	Manual input required
"New strip tube"	Manual choice (if more than one assay is defined).

Note

The setting, whether a valid product number, etc., is required, is set in the "Settings" screen of the "Configuration" environment.

The screenshot shows a configuration window titled "Work list". It contains several sections:

- Format of generated work list names:** A text field containing "WL_20110513_0430_Operator".
- User-definable section:** A text field containing "WL".
- Checkboxes:**
 - Date
 - Time
 - Operator
 - Enable analysis of unclear samples
 - Enable checksum for LIMS import
- Closed mode:**
 - Material number required
 - Valid expiration date required
 - Lot number required
- UDT mode:**
 - Material number required
 - Valid expiration date required
 - Lot number required

Below the "Closed mode" and "UDT mode" sections, there are two labels: "Requirements settings for work lists in Closed Mode" and "Requirements settings for work lists in UDT Mode". Lines connect these labels to the respective "Closed mode" and "UDT mode" sections.

These requirements can be set independently for the Closed Mode and the UDT Mode.

If the setting is set to be "required" for one of the three options (checkbox is activated), then the operator must provide the information. It is not possible to leave void the respective input fields in that case.

Further details can be found in the description of the ► "Configuration" environment under ► "Settings".

Note

For usage of the User Defined Test Mode (UDT mode) functionalities a compatible UDT mode plug-in is required to be installed.

"Assay position" control buttons

The "Assay position" control buttons are placed below the "Selected assay profiles" table.

Selected assay profiles					
Assay profile name	Short name	Vers...	Req. P...	# sam...	New strip tube
ACC_Standardprofile UDT	ACC	2.3.1	3	5 (5 P...	<input checked="" type="checkbox"/>
ACC_OptConf_Unrestricted2 UDT	ACC	2.3.1	3	5 (5 P...	<input type="checkbox"/>
ACC_Rotor36W72W UDT	ACC	2.3.1	3	5 (5 P...	<input type="checkbox"/>

Assay position

Assay position controls

Two arrow buttons are used to change the position of the "Selected assay profiles" in the table. Click the up arrow to move an assay profile up. Click the down arrow to move it down. This will also affect the assay position on the rotor.

"Samples" step

The "Samples" step shows the sample details in tabular form. All sample types from all selected assay profiles are displayed here. In case multiple assay profiles were added, they are listed subsequently.

Note

The order of the samples within one specific assay profile is determined by the order specified during the creation of the assay profile. The order of multiple assay profiles is defined by their order in the "Assays" step.

The number of displayed samples depends on:

- The number of test samples entered in the "Assays" step
- Required samples given by the assay profile
- The number of assay profiles added in the "Assays" step

Pos.	Style	Sample ID	Status	Sample type	Targets	Assay	Sample com
1	---			Test	Test 1	ACC	
2	---			Test	Test 1	ACC	
3	---			Test	Test 1	ACC	
4	---			Test	Test 1	ACC	
5	---			Test	Test 1	ACC	
6	---	Positive Control		PC	IC 1	ACC	
7	---	Negative Control		EC-	IC 1	ACC	
8	---	Positive control Test 1		PC	Test 1	ACC	

The editable columns of the samples details table (line color, line style, ID, and comment) have a pop-up menu, which can be accessed by a right click in the respective column. The columns are described in the following table:

Column	Description
Row selector	The row selector is intended to select single or multiple rows. If a row is selected, the column will be marked in blue and the row selector icon will change:
	<p>Unselected row </p>

Selected row

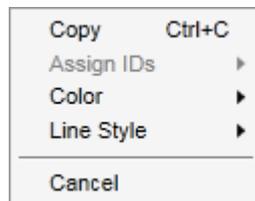


To select several consecutive rows, click the first row selector, hold down the left mouse button, and drag the cursor to the last desired row. To add a single row to a selection, hold down the Control button and click the row selector.

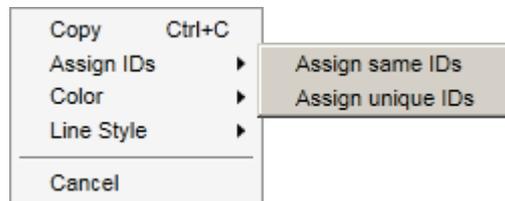
Pop-up menu:

Note: A row must be selected using the row selector before the corresponding pop-up menu can be opened. If a single row is selected, the "Assign IDs" menu entry is disabled. This entry is only activated if multiple rows are selected.

Open the pop-up menu by right clicking in any area of a selected row.



Pop-up menu for a single row selection



Pop-up menu for multiple row selection

Label/Title	Description
"Assign ID" "Assign same IDs"	Assigns the ID value from the first cell of the selection to all other selected cells.
"Assign unique IDs"	Based on the ID of the first selected cell, an incremental number is added to all selected cells. Example: If first cell has the ID <i>Sample</i> , the generated values

	<p>are <i>Sample 1</i> , <i>Sample 2</i> , <i>Sample 3</i> , etc.</p> <p>If the first selected cell is empty, an incremental number is added to all selected cells. Example: If the first cell is empty, the generated values are <i>1</i> , <i>2</i> , <i>3</i> , etc.</p>
"Color"	<p>Open a color palette where the user can select a specific color for the amplification curve of the selected samples.</p> 
"Line Style"	<p>Open a style palette where the user can select a specific line style for the amplification curve of the selected samples.</p> 
"Pos."	<p>Displays the position of the sample in the rotor. The position of a sample is determined by the assay profile and the order of the assay profiles in the "Assays" step (in case the worklist consists of multiple assay profiles). The maximum position number is restricted by the selected rotor type.</p>
Line color	<p>The color of a sample's amplification curve in the PCR plot can be set by opening the color palette and selecting one out of 20 predefined colors.</p>



Pop-up menu:

It is possible to select multiple samples and assign them the same line color using this pop-up menu.

"Style"

The line style of a sample's amplification curve in the PCR plot can be set by opening the line style palette and selecting one out of 6 predefined styles.



Pop-up menu:

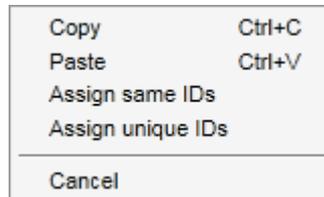
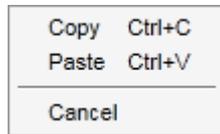
It is possible to select multiple samples and assign them the same line color using this pop-up menu.

"Sample ID"

The sample ID can't not be empty and must have 1 to 40 characters.

Pop-up menu:

The sample ID pop-up menu depends on whether a single or multiple cells are selected.



Pop-up menu for a single ID cell selection

Pop-up menu for multiple ID cells selection

Label/Title	Description
-------------	-------------

	<table border="1"> <tr> <td>"Copy"</td> <td>Copy the content of the selected ID cells — single or multiple — to the clipboard.</td> </tr> <tr> <td>"Paste"</td> <td>Paste the content of the clipboard to the selected cell. A warning is displayed before data is overwritten.</td> </tr> <tr> <td>"Assign same IDs"</td> <td>Assign the ID value from the first cell of the selection to all other selected cells. Note: For some assay profiles it is not allowed to have the same ID for different samples. In this case "Assign same IDs" entry is disabled in the context menu.</td> </tr> <tr> <td>"Assign unique IDs"</td> <td>Based on the ID of the first selected cell, an incremental number is added to all selected cells. Example: If first cell has the ID <i>Sample</i> , the generated values are <i>Sample 1</i> , <i>Sample 2</i> , <i>Sample 3</i> , etc.</td> </tr> <tr> <td>"Cancel"</td> <td>Close the pop-up menu.</td> </tr> </table>	"Copy"	Copy the content of the selected ID cells — single or multiple — to the clipboard.	"Paste"	Paste the content of the clipboard to the selected cell. A warning is displayed before data is overwritten.	"Assign same IDs"	Assign the ID value from the first cell of the selection to all other selected cells. Note: For some assay profiles it is not allowed to have the same ID for different samples. In this case "Assign same IDs" entry is disabled in the context menu.	"Assign unique IDs"	Based on the ID of the first selected cell, an incremental number is added to all selected cells. Example: If first cell has the ID <i>Sample</i> , the generated values are <i>Sample 1</i> , <i>Sample 2</i> , <i>Sample 3</i> , etc.	"Cancel"	Close the pop-up menu.
"Copy"	Copy the content of the selected ID cells — single or multiple — to the clipboard.										
"Paste"	Paste the content of the clipboard to the selected cell. A warning is displayed before data is overwritten.										
"Assign same IDs"	Assign the ID value from the first cell of the selection to all other selected cells. Note: For some assay profiles it is not allowed to have the same ID for different samples. In this case "Assign same IDs" entry is disabled in the context menu.										
"Assign unique IDs"	Based on the ID of the first selected cell, an incremental number is added to all selected cells. Example: If first cell has the ID <i>Sample</i> , the generated values are <i>Sample 1</i> , <i>Sample 2</i> , <i>Sample 3</i> , etc.										
"Cancel"	Close the pop-up menu.										
"Status"	<p>Note: This column is used only if a QIASymphony worklist is imported.</p> <p>Possible statuses of samples from a QIASymphony worklist are:</p> <ul style="list-style-type: none"> • Valid • Invalid • Unclear • None (empty field) is the status if QIASymphony has not been used. 										
"Sample type"	<p>The sample type is listed in this field.</p> <p>Possible values are:</p> <ul style="list-style-type: none"> • Test Test sample • NTC No template control 										

	<ul style="list-style-type: none"> • PC Positive control • EC+ Positive extraction control • EC- Negative extraction control • QS Quantitation standard • FPC+ Positive full process control • FPC- Negative full process control
"Targets"	Acquisition target given by assay profile
"Assay profile name"	Short assay profile name given by assay profile. Hovering over the short assay profile name shows a tooltip with the full assay profile name.
"Comment"	The comment column may be empty. If a comment is filled in, it must contain no more than 256 characters.

"Properties" step

The properties step is used to assign the new worklist a name, either by entering the name manually or by using a generated default name. Furthermore, 2 options may be set (worklist "is editable" and "is applicable").

Properties

Work list name

A

B Default name

Work list

C is editable **D** is applicable

Created

E

Last modified

F

Last applied

G

External order ID

H

	Label/Title	Description
A	"worklist name"	Text field to enter a name for the new worklist. Note Maximum length for the name is 40 characters. The entered name must be unique (in case a new worklist is created).
B	"Default name"	Automatically generate a name for the worklist. The pattern for the generated name is defined in the ► "Configuration" environment under ► "Settings".
C	"Is editable" check box	Determines whether a worklist can be modified later. This check box is disabled by default. It is enabled when the "worklist is ready to be applied" check box is activated.

If not activated: worklist cannot be modified later.
The "Edit worklist" icon in the action bar is deactivated: 

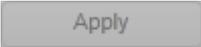
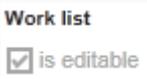
If activated: worklist can be modified later.
The "Edit worklist" icon in the action bar is activated: 

D "worklist is complete" check box

Determines whether a worklist can be applied:

If not activated: worklist cannot be applied.
If activated: worklist can be applied.

When this check box is activated, the (disabled) "Apply" button in the button bar and the "Is editable" check box get activated:

"Is applicable" unchecked	"Is applicable" checked
	
"Apply" button in button bar is disabled.	"Apply" button in button bar is disabled.
	
"Is editable" check box is disabled.	"worklist is complete" check box is enabled.

E "Created" info field

Displays who created the worklist and when (field is populated upon saving).

F "Last modified" info field

Displays who modified the worklist and when (field is populated upon saving).

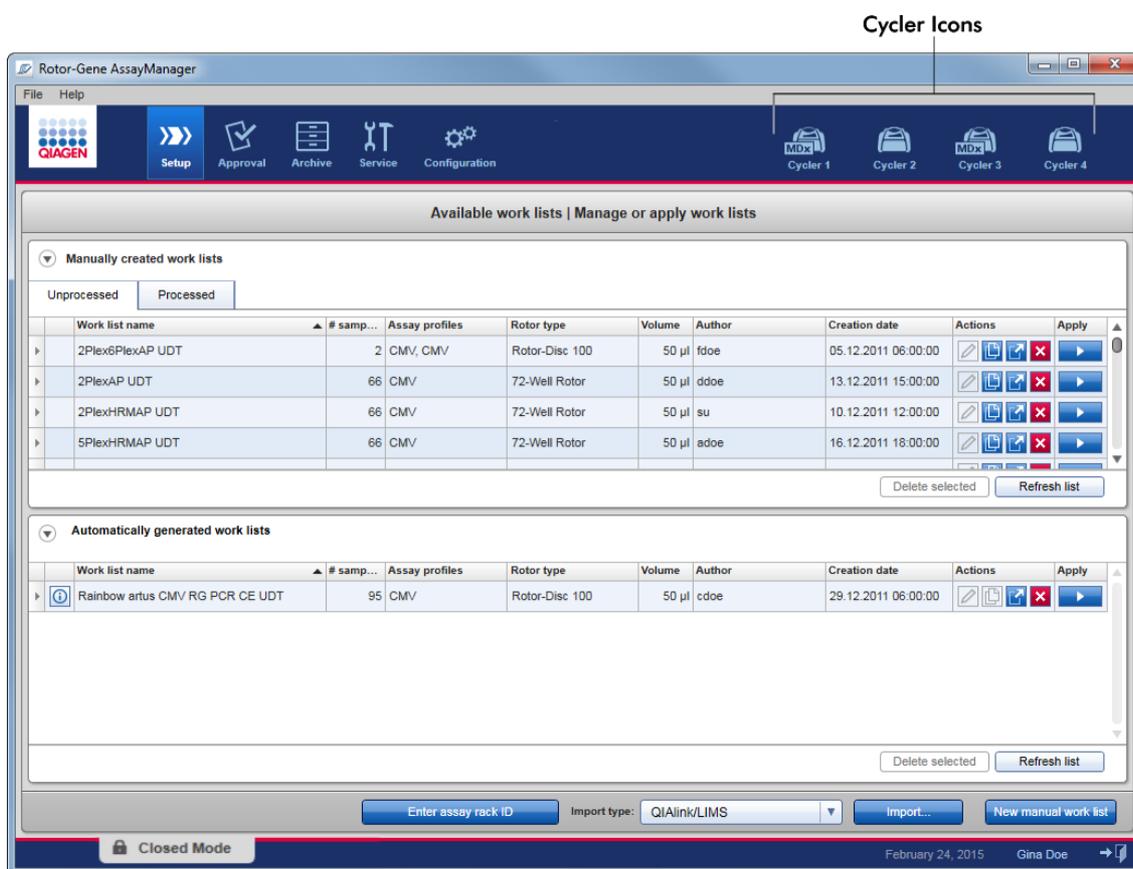
G "Last applied" info field

Displays when the worklist was last applied.

H "External order ID" Optional field that can be used for worklists imported from a LIMS. The order ID will also be written to the LIMS output so that the LIMS can map the results to the initial order. Check whether your LIMS supports this kind of order IDs.

1.5.5.2 Cyclers Environment

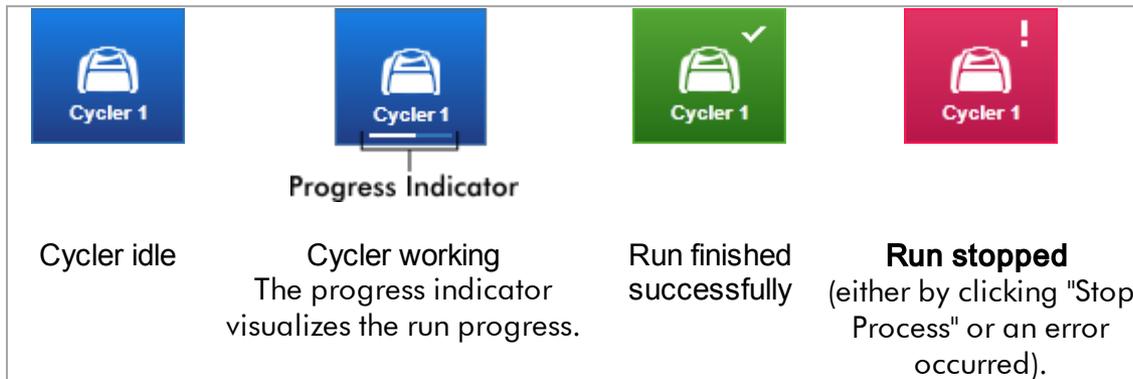
The "Cycler" environment is used for the cyclers and gives an overview about all Rotor-Gen Q instruments accessible by Rotor-Gen AssayManager v2.1. Up to 4 different Rotor-Gen Q cyclers can be registered and subsequently controlled by Rotor-Gen AssayManager v2.1 in parallel. The different cyclers are represented by individual "Cycler" icons, which are always displayed at the very top right of the Rotor-Gen AssayManager v2.1 screen.



The content of the "Cycler" environment depends on whether a cycler is currently idle, in operation, or whether a run has been stopped but not yet released. The visual appearance of the cycler icon indicates the current state of the cycler.

"Cycler" icon

The "Cycler" icon changes its appearance depending on the progress and the result of the run.

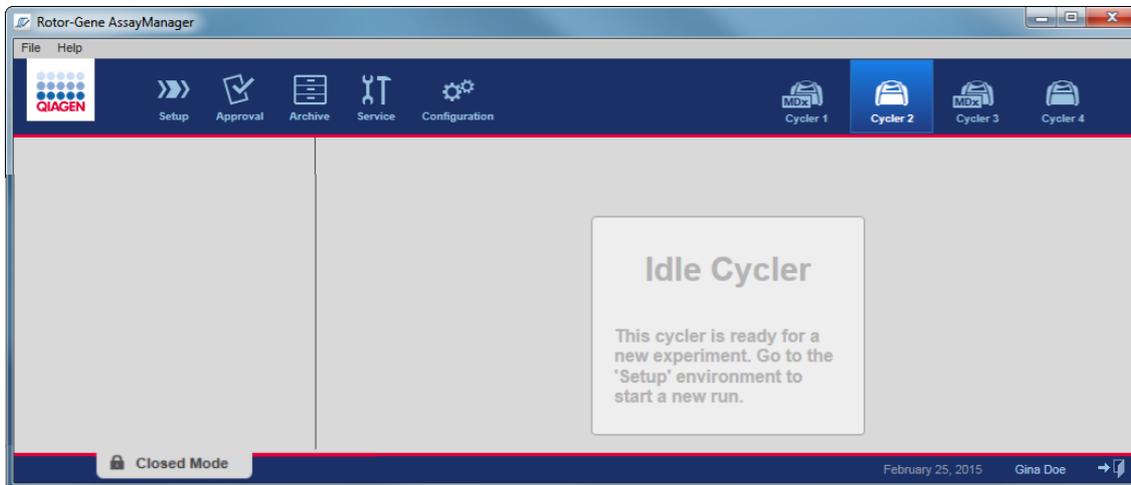


Further cycler icons are listed below:



"Idle Cycler" screen

In case a cycler is idle, clicking the corresponding icon displays the following screen:

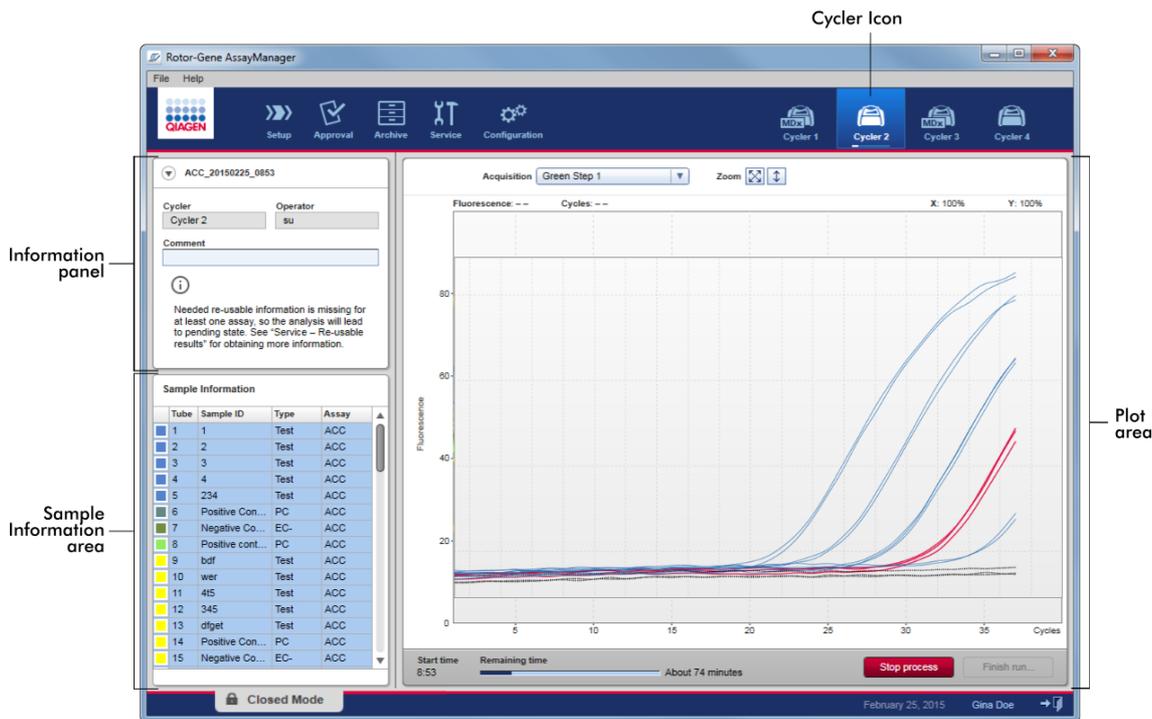


There are two alternatives to start a run on an idle cycler:

- Apply an existing worklist from the "Available Worklists" table.
- Create a new worklist and apply it.

"Active Cycler" screen

If a cycler is active, a run has been finished or stopped manually and has not yet been released, a plug-in specific screen will be displayed.



The amplification of the samples is displayed in real time in the plot area. After the run process has finished, the run is released and the sample results can be approved.

It is possible to stop the process before it is finished. If the "Stop process" button is clicked during the run, a confirmation dialog with the message "The run will be stopped." appears. Click "OK". The run is stopped as soon as the device has finished a profile step. This can take up to 60 seconds. The experiment is stored on the database with the result status "Run stopped". Afterwards, the "Finish run" button is enabled and the "Stop process" button is disabled.

The cycler screen consists of 4 areas:

- Information panel
- "Sample information" area
- Plot area
- "Cycler" icon

Information panel

Label	Explanation
Collapse icon	The collapse icon is used to collapse the Information panel to a single row to gain screen space to enlarge the "Sample information" area. If the area is collapsed, only the experiment name is shown.
Experiment name	Experiment name as defined during worklist setup.
A	Name of the cycler
B	Comment field, maximum 256 characters are allowed
C	Operator name

"Sample information" area

The "Sample information" area lists all samples of the run in a table with the following columns:

- Line color (derived from the worklist)
- Sample position on rotor
- Sample ID
- Sample type:
 - Test Test sample
 - NTC No template control
 - PC Positive control
 - EC+ Positive extraction control
 - EC- Negative extraction control

- QS Quantitation standard
- FPC+ Positive full process control
- FPC- Negative full process control

- Assay short name

Sample Information				
	Tube	Sample ID	Type	Assay
Non-Test samples	1	PC_1	PC	QF Pat
Non-Test samples	2	PC_2	PC	QF Pat
Non-Test samples	3	PC_3	PC	QF Pat
Test samples	4	1	Test	QF Pat
	5	2	Test	QF Pat
	6	3	Test	QF Pat
	7	4	Test	QF Pat
	8	5	Test	QF Pat
	9	6	Test	QF Pat
	10	7	Test	QF Pat
	11	8	Test	QF Pat
	12	9	Test	QF Pat
	13	10	Test	QF Pat
	14	11	Test	QF Pat
	15	12	Test	QF Pat
	16	13	Test	QF Pat
	17	14	Test	QF Pat
	18	15	Test	QF Pat
	19	16	Test	QF Pat
	20	17	Test	QF Pat
	21	18	Test	QF Pat

The number of rows is equal to the number of wells on the rotor. If the number of samples used is less than the number of wells on the rotor, the sample type "Empty" is assigned to unused rotor positions.

Multiple assays

In case multiple assays were used to set up an experiment, the assays are arranged one after the other.

Sample Information				
	Tube	Sample ID	Type	Assay
■	1	1	Test	ACC
■	2	2	Test	ACC
■	3	3	Test	ACC
■	4	4	Test	ACC
■	5	5	Test	ACC
■	6	6	Test	ACC
■	7	Positive Con...	PC	ACC
■	8	Negative Co...	EC-	ACC
■	9	1	Test	ACC
■	10	2	Test	ACC
■	11	3	Test	ACC
■	12	4	Test	ACC
■	13	Positive Con...	PC	ACC
■	14	Negative Co...	EC-	ACC
■	15		Empty	
■	16		Empty	
■	68		Empty	
■	69		Empty	
■	70		Empty	
■	71		Empty	
■	72		Empty	

Samples from Assay A

Samples from Assay B

"Empty" type samples up to the number of wells on the rotor (here a 72-well-rotor is used)

Behavior of the "Sample information" area

The acquisition plots for specific samples can be hidden or shown in the plot area. Click in the row of the designated sample. By default, all samples used are shown and hence highlighted in a dark blue color. Rows of disabled samples (i.e., hidden acquisition plot) are colored in brighter blue.

Sample Information				
	Tube	Sample ID	Type	Assay
■	1	PC_1	PC	QF Pat
■	2	PC_2	PC	QF Pat
■	3	PC_3	PC	QF Pat
■	4	1	Test	QF Pat
■	5	2	Test	QF Pat
■	6	3	Test	QF Pat
■	7	4	Test	QF Pat



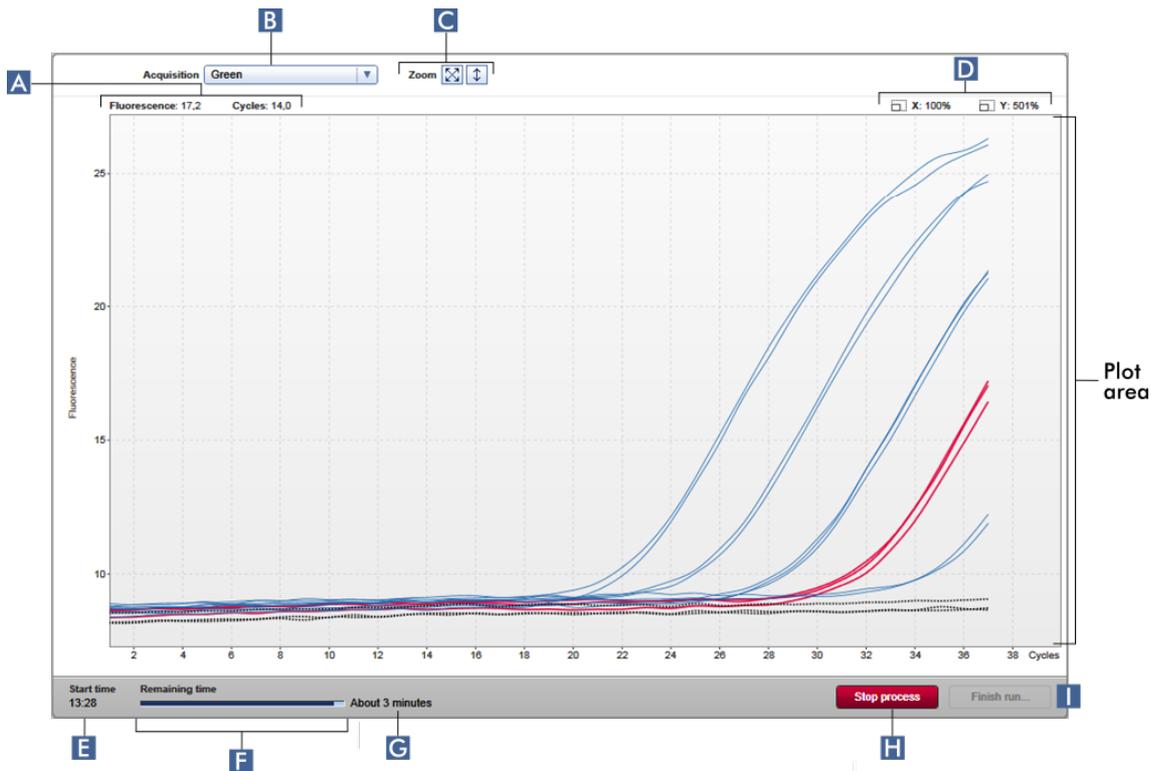
Sample Information				
	Tube	Sample ID	Type	Assay
■	1	PC_1	PC	QF Pat
■	2	PC_2	PC	QF Pat
■	3	PC_3	PC	QF Pat
■	4	1	Test	QF Pat
■	5	2	Test	QF Pat
■	6	3	Test	QF Pat
■	7	4	Test	QF Pat

Acquisition plots are enabled by default for all samples. The row is colored in dark blue.

In the example above, the amplification curves of tubes 2, 3, and 5 have been disabled. These rows are colored in brighter blue.

Plot area

The plot area displays the amplification curves for a selected acquisition of the different samples recorded by the Rotor-Gene Q in real time.



Label	Explanation
A Coordinates	Shows the coordinates of the current mouse position. If the mouse cursor is within the plot area, the mouse cursor changes to cross hairs (+). The current coordinates are displayed in this field. The coordinates are shown as "Fluorescence" and "Cycles" values.
B Target selection menu	Selects the acquisition target used for the plots.
C Graph options	Displays options to modify the scaling of the plot. <div style="display: flex; align-items: center;">  <p>The plot is scaled to 100%. The whole plot is displayed fitted in the graph area. The scale is reset to display from 0 to 100 fluorescence units. The x-axis is set to a maximum value equal to the number of cycles in the run profile, and the y-axis is set to 100.</p> </div>

The auto scale button fits the scale to the maximum and minimum readings in the data.



The y-axis range is restricted to the lowest and highest measured fluorescence value. The x-axis is set to a maximum value equal to the number of cycles in the run profile.

D Zoom factors Displays zoom factors separately for the x-axis and the y-axis.

E "Start time" Displays the start time of the run.

F Progress indicator bar Displays the progress of the experiment. The indicator bar visualizes the acquisition progress: the dark blue colored part of the bar visualizes the elapsed time; the brighter blue colored part, the remaining time of the experiment.



The text over the progress indicator changes depending on the current status of the run:

Text	Explanation
"Remaining time"	Ongoing experiment
"Analyzing"	Experiment was finished, analysis has started
"Ready"	Experiment analysis finished

G "Remaining time" estimation Displays the estimated remaining time.

H "Stop process" Stops the run.

After clicking the "Stop process" button, a warning dialog must be confirmed to stop the run. The run will be stopped as soon as the device has finished a profile step. This can take up to 60 seconds. The status "Run stopped" is assigned to the experiment in the internal database.

I "Finish run"

Finish the run.
The following dialog is opened:

The screenshot shows a dialog box titled "Finish run" with a blue header bar containing a white checkmark icon. The dialog is divided into several sections: a top section with three columns labeled "Position", "Name", and "Run status"; a section for "Experiment name" with a text input field; a section for "Errors during run" with a scrollable area; a section for "Comment" with a text area; and a section for "Password" with a text input field. At the bottom of the dialog, there are three buttons: "Release", "Release and go to approval", and "Cancel".

The behavior of this dialog depends on the "Finish run" setting defined in the "Configuration" environment. The administrator can set the option that a run has to be released before it can be approved. If this option is activated, the administrator can further define that the release must be signed:

Finish run

Run has to be released before starting approval

Release of run has to be signed

If this setting is deactivated, the run can be approved in the "Approval" environment without releasing the run.

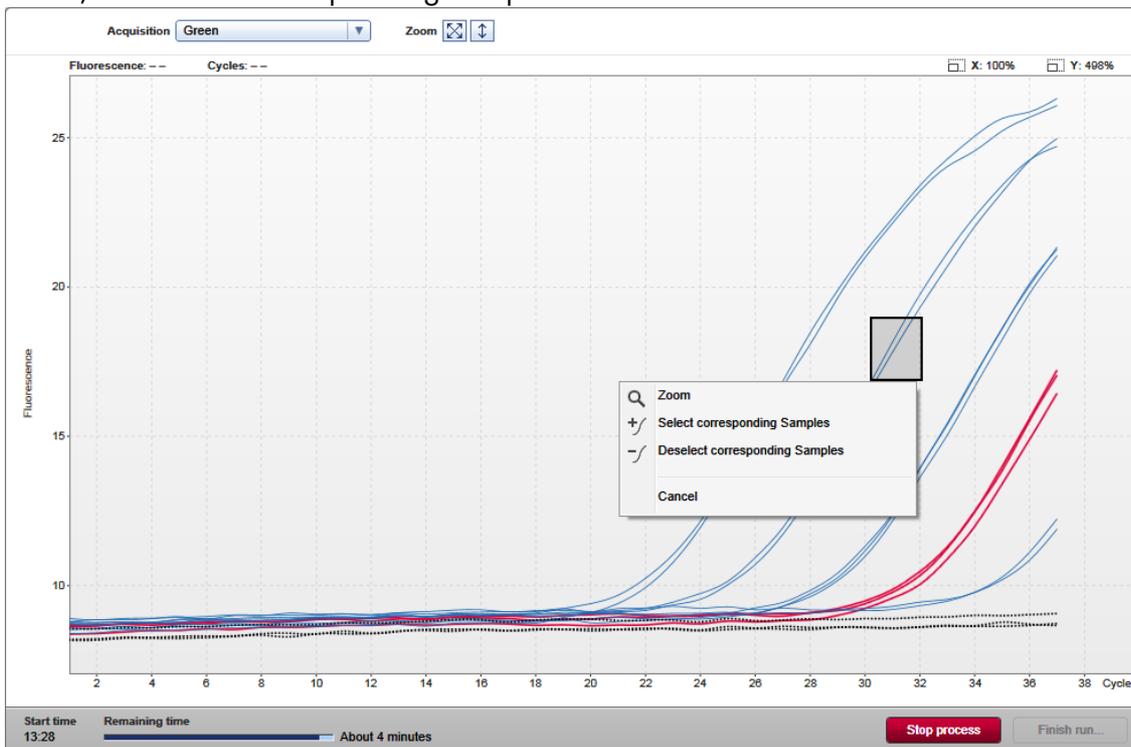
For further information, see ► "Configuration" environment.

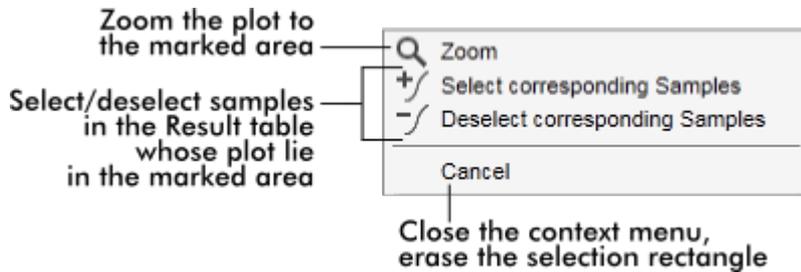
Behavior of the Plot area

The plot area has interactive functionalities:

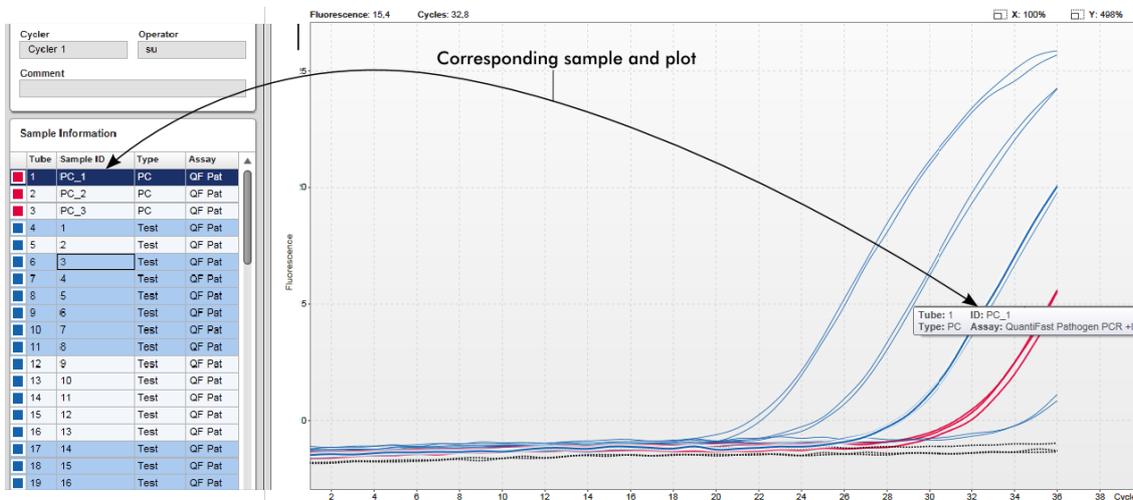
- **Context menu:**

An area of the amplification plot can be selected. Click and hold the left mouse button and drag the mouse pointer. A context menu appears with the options to zoom, select, or deselect corresponding samples.





- Zoom:**
 Clicking "Zoom" in the context menu zooms the amplification plot to the selected area. By right-clicking and holding down the mouse button, the cursor changes to a hand symbol (🖱️). The amplification plot area can be scrolled in all directions by moving the mouse. Double-click anywhere in the amplification plot area to reset the zoom to 100%.
- Identification of amplification curves:**
 Hovering the mouse over an individual amplification curve highlights the curve in the amplification plot and displays a tooltip with the following data:
 - Tube number
 - Sample type
 - Sample ID
 - Assay type



The corresponding sample in the "Sample information" table is highlighted in darker blue to visualize its position in the table.

Tasks related to the "Cycler" view

- ▶ Managing cyclers
- ▶ Finishing and releasing a run

1.5.5.3 Approval Environment

The "Approval" environment is used to search for unreleased or partially released assays and to approve and release every single test sample of the assay. The "Approval" environment mainly consists of 2 different screens:

- "Filter" screen: Used for filtering and selecting specific assays for the approval and release process
- "Approval" screen: Used for checking the assay result and approving and releasing every individual test sample

Note

All functions of the "Approval" environment can be used by users with the user role "Approver". A user with the user role "Operator" can also access this environment, but without rights to approve or release data.

Assays intended to be approved can be filtered by defining search criteria. After applying the filter options, the corresponding assays are displayed in the table next to the filter options section. To start the approval and release process, the assays to be approved are selected by checking the corresponding check box and clicking "Start approval".

The results of every individual test sample and, depending on the plug-in, even the external controls have to be checked and approved separately. Depending on the status of the individual samples, the status of the experiment will change accordingly.

Possible sample status	Possible assay status
<ul style="list-style-type: none">• Undefined• Accepted• Rejected	<ul style="list-style-type: none">• Unreleased• Partially released• Fully released

Dependency between sample status and assay status:

• All samples undefined	→	Experiment unreleased
• Samples sporadically accepted or rejected	→	Experiment partially released
• All samples accepted or rejected	→	Experiment fully released

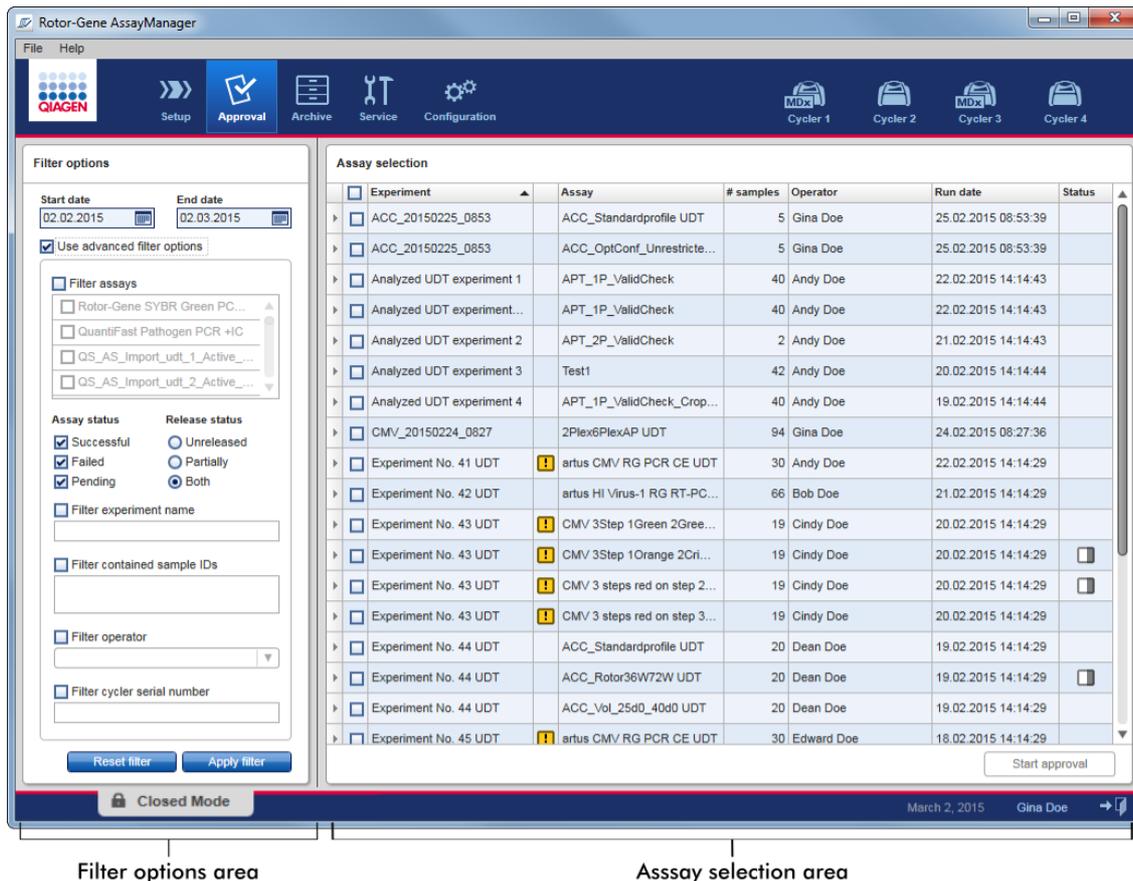
1.5.5.3.1 Filter Screen

The "Filter" screen is intended to

- Filter for not yet released or partially released assays
- Select assays to start the approval process

It consists of 2 parts:

- "Filter options" area at the left hand side of the screen
- "Assay selection" area at the right hand side of the screen



Initially, the "Assay selection" area is empty. Specific criteria in the filter options have to be defined and applied to search for specific assays. All assays matching these criteria will be listed in the "Assay selection" area. Using the check boxes, the user selects one or multiple assays to be approved. By clicking the "Start approval" button the "Approval" screen appears.

"Filter options" area

Filter options

Start date: 02.02.2015 End date: 02.03.2015

Use advanced filter options (A)

Filter assays

- Rotor-Gene SYBR Green PC...
- QuantiFast Pathogen PCR +IC
- QS_AS_Import_udt_1_Active_...
- QS_AS_Import_udt_2_Active_...

Assay status **Release status**

Successful Unreleased

Failed Partially

Pending Both

Filter experiment name

Filter contained sample IDs

Filter operator

Filter cyler serial number

Reset filter (B) Apply filter (C)

By default the filter options are set to search for assays of the last month. All other filter options are disabled. To enable the advanced filter options, the check box "Use advanced filter options" (A) must be checked.

Note

Filtering for text is not case sensitive. For example, if *sample01* is entered in the "Filter contained sample IDs" box, samples with IDs *Sample01* and *SAMPLE01* are also considered as matching samples.

Label/Title	Description						
Date filter options	<p>Enter a start date and an end date in the corresponding fields to filter for assays with a run start date in the defined date interval.</p> <p>Dates can either be manually entered or using the date picker.</p> <p>Restrictions:</p> <ul style="list-style-type: none">• Wildcard characters are not allowed.• Dates must be entered completely.						
A "Use advanced filter options" check box	Click in the check box next to "Use advanced filter options" to activate the advanced filter options.						
Advanced Filter Criteria	<table border="1"><thead><tr><th>Filter Criterion</th><th>Explanation</th></tr></thead><tbody><tr><td>"Filter assays"</td><td>To filter for specific assays, activate the "Filter assays" check box. All assays are displayed in a list. A check box in front of every assay row allows to select individual assays. Multiple assay selections are possible to search simultaneously for different assays.</td></tr><tr><td>"Assay status"</td><td>Filter for the assay status using the radio buttons. Possible values are:<ul style="list-style-type: none">• Successful• Failed• Both</td></tr></tbody></table>	Filter Criterion	Explanation	"Filter assays"	To filter for specific assays, activate the "Filter assays" check box. All assays are displayed in a list. A check box in front of every assay row allows to select individual assays. Multiple assay selections are possible to search simultaneously for different assays.	"Assay status"	Filter for the assay status using the radio buttons. Possible values are: <ul style="list-style-type: none">• Successful• Failed• Both
	Filter Criterion	Explanation					
	"Filter assays"	To filter for specific assays, activate the "Filter assays" check box. All assays are displayed in a list. A check box in front of every assay row allows to select individual assays. Multiple assay selections are possible to search simultaneously for different assays.					
"Assay status"	Filter for the assay status using the radio buttons. Possible values are: <ul style="list-style-type: none">• Successful• Failed• Both						

		<ul style="list-style-type: none"> • Pending
	"Release status"	Filter for the release status using the radio buttons. Possible values are: <ul style="list-style-type: none"> • Unreleased • Partially • Both
	"Filter experiment name"	Filter for the experiment name by activating the check box and entering an experiment name.
	"Filter contained sample IDs"	Filter for specific sample IDs by activating the check box and entering one or multiple sample IDs. Multiple sample IDs have to be entered in individual rows without any separators.
	"Filter operator"	Filter for a specific operator by activating the check box and selecting an operator from the list.
	"Filter cyler serial number"	Filter for a cyler serial number by activating the check box and entering a cyler serial number (only digits).
B	"Reset filter" button	Resets all filter options to the default values.
C	"Apply filter" button	Starts the filter process. All experiments matching the filter criteria will be listed in the "Assay selection" area.

"Assay selection" area

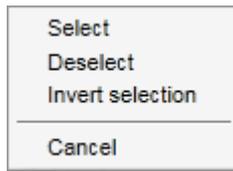
The "Assay selection" area consists of a table containing experiments. These experiments meet the search criteria defined in the "Filter options" area.

Assay selection

<input type="checkbox"/> Experiment ▲	Assay	# samples	Operator	Run date	Status
▶ <input type="checkbox"/> ACC_20150225_0853	ACC_Standardprofile UDT	5	Gina Doe	25.02.2015 08:53:39	
▶ <input type="checkbox"/> ACC_20150225_0853	ACC_OptConf_Unrestricte...	5	Gina Doe	25.02.2015 08:53:39	
▶ <input type="checkbox"/> Analyzed UDT experiment 1	APT_1P_ValidCheck	40	Andy Doe	22.02.2015 14:14:43	
▶ <input type="checkbox"/> Analyzed UDT experiment...	APT_1P_ValidCheck	40	Andy Doe	22.02.2015 14:14:43	

B
Start approval

Column	Explanation				
Row selector ▶	<p>The row selector is a tool to select and deselect assays in the assay selection table.</p> <p>Single assays are selected by activating the check box (<input type="checkbox"/>) of the corresponding experiment. Use multiple check boxes to select multiple assays.</p> <p>Clicking the row selector highlights the current row in dark blue. The row selector icon changes:</p> <table style="width: 100%; text-align: center;"> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>Deactivated row selector</td> <td>Activated row selector</td> </tr> </table> <p>To highlight adjacent rows, click the first element's row selector, hold down the left mouse button, and move the cursor to the last element to be highlighted. All rows in between are highlighted. Use the Control key to make multiple selections of non-adjacent rows.</p> <p>Context menu The context menu of the row selector is used to select or deselect the highlighted assay:</p>	<input type="checkbox"/>	<input type="checkbox"/>	Deactivated row selector	Activated row selector
<input type="checkbox"/>	<input type="checkbox"/>				
Deactivated row selector	Activated row selector				



Label/Title	Description
"Select"	Activates the check box for all highlighted assays.
"Deselect"	Deactivates the check box for all highlighted assays.
"Invert selection"	Inverts the status of the check box for all highlighted assays, i.e., selected assays are unselected and vice versa.
"Cancel"	Closes the context menu.

Assays selector check box



The assay selector check box is used to select the assays to be approved. To select all assays for the approval process, activate the check box in the column header (A).

The column select icon (A) changes according to the number of selected assays.

- No assay selected
- One or more assay selected, but not all
- All assays selected

"Experiment"

Experiment name defined before starting the run

Assay validity



Shows the assay's validity status:

- If the assay is valid, this field is empty.
- In case an assay is invalid, this is indicated by a warning icon: !

	<p>The reason for invalidity is shown in a tooltip. Possible reasons are:</p> <table border="0"> <tr> <td>Run failed</td> <td>A problem with the cyclers or the cycler connection.</td> </tr> <tr> <td>Run stopped</td> <td>A run was stopped manually.</td> </tr> <tr> <td>Assay invalid</td> <td>Invalid external controls can lead to an invalid assay. For details refer to the detailed analysis.</td> </tr> <tr> <td>Analysis failed</td> <td>Various reasons. Contact QIAGEN Technical Services.</td> </tr> </table>	Run failed	A problem with the cyclers or the cycler connection.	Run stopped	A run was stopped manually.	Assay invalid	Invalid external controls can lead to an invalid assay. For details refer to the detailed analysis.	Analysis failed	Various reasons. Contact QIAGEN Technical Services.
Run failed	A problem with the cyclers or the cycler connection.								
Run stopped	A run was stopped manually.								
Assay invalid	Invalid external controls can lead to an invalid assay. For details refer to the detailed analysis.								
Analysis failed	Various reasons. Contact QIAGEN Technical Services.								
"Assay"	Full name of the assay(s) used for this experiment								
"# samples"	Number of samples								
"Operator"	Name of the operator								
"Run date"	Run date of the experiment								
"Status"	<p>Release status of the assay</p> <p>If this field is empty, no samples from this assay have been released yet.</p> <p>If not all samples have been released, this assay has the status "Partially released". This is indicated by the  icon.</p> <p>If an assay is locked, the column shows a lock icon .</p> <p>If an assay is pending, this is indicated by the  icon</p>								
"Start approval" button	<p>Starts the approval process of the selected assays. This button is enabled if at least one assay is selected.</p> <p>By clicking this button, the "Approval" screen is displayed. All selected assays get the status "Locked".</p>								

1.5.5.3.2 Approval Screen

Note

The approval procedure and appearance of the approval screen may be different depending on the plug-in of the assay used. For details regarding different approval procedures, refer to the corresponding Rotor-Gene AssayManager v2.1 plug-in user manuals. In this manual, example screens and procedures for the Gamma Plug-in are shown.

The "Approval" screen is used to:

- Check the result of an assay
- Approve (accept or reject) the result of every sample
- Release individual sample results and whole assays
- Create a support package to facilitate support in case of problems

The results of the samples of the previously selected assay can be checked and have to be accepted or rejected and finally released. Assays where not all sample results have been released are saved as partially released assays. Only if all sample results have been released and no test sample has the status "undefined", the assay is defined as "fully released". A fully released assay will no longer be available in the "Approval" environment. This assay will be moved to the "Archive" environment.

The screenshot displays the Rotor-Gene AssayManager software interface. The top menu bar includes 'File' and 'Help'. The toolbar contains icons for 'Setup', 'Approval', 'Archive', 'Service', and 'Configuration', along with buttons for 'Cycler 1', 'Cycler 2', 'Cycler 3', and 'Cycler 4'. The main window is titled 'Rotor-Gene AssayManager' and shows a 'Tab list' with 'Experiment-6359356604...' and 'Demo Assay'. The 'Plots and information area' contains fields for 'Experiment name', 'Reaction volume', 'Rotor type', 'Run start', 'End of run', 'Run on SW version', 'Cyclor serial no.', 'Run operator', and 'Run released by'. The 'Results area' contains a table with columns for 'Pos.', 'Style', 'Sample...', 'Type', 'Sample com...', 'Output', 'Ct', 'Value', 'Individual target result', and 'Flags'. The table shows results for positions 37, 38, 39, and 40, with various targets and their Ct values. The 'Button bar' at the bottom contains buttons for 'Create support package...', 'Save and close', 'Reset', 'Save', 'Close', and 'Release / report data...'. The status bar at the bottom indicates 'Closed Mode', the date 'February 25, 2015', and the user 'Gina Doe'.

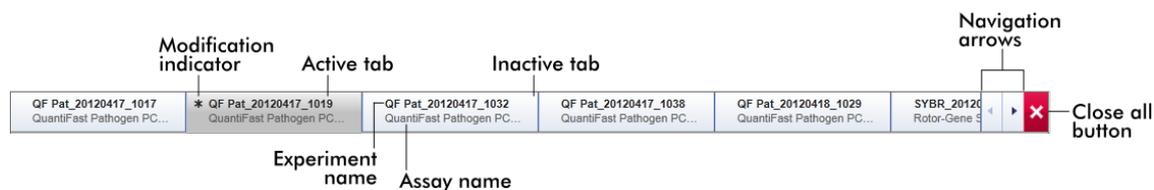
The "Approval" screen consists of the following 4 areas:

Area	Functionality/Tasks
Tab list	All assays selected in the previous step are displayed in the tab list. This allows the user to work on multiple assays simultaneously. In case the screen space is insufficient to fit all assays, navigation arrows are added to the tab list.
"Plots and information" area	This area contains various data about an experiment. This area is subdivided in up to 6 separate tabs (depending on the selected assay and the currently used plug-in).
"Results" area	This area contains details about the samples and radio buttons to approve or reject individual sample results.
Button bar	This area contains buttons to save, close, reset, and finally release the selected sample results of the assay.

Tab list

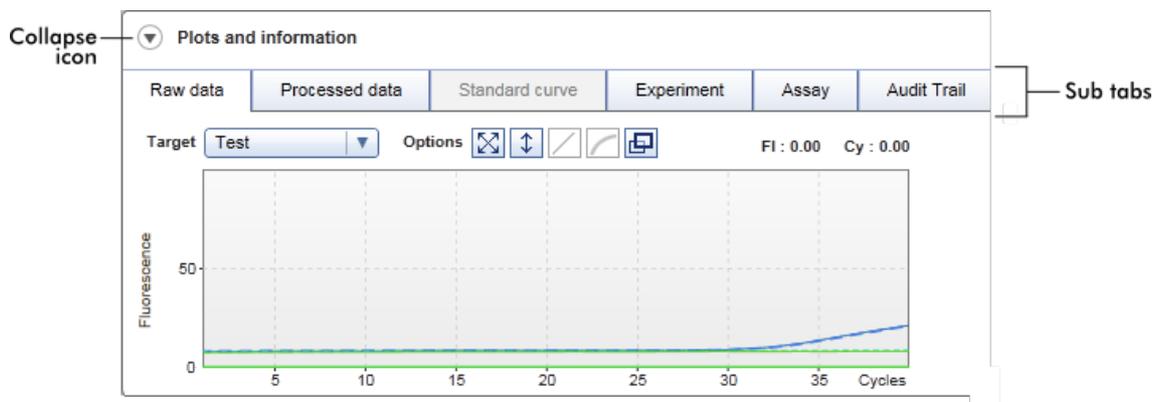
All assays chosen for approval in the previous "Assay selection" step are listed in the tab list. Every selected assay is displayed as a tab with the experiment name and the assay name in the tab header. The currently active tab is highlighted gray. The inactive tab(s) are light blue. If an experiment contains unsaved modifications, this will be indicated by a * symbol beside the experiment name.

A tab is closed by clicking the "Close" button in the button bar. The red close button at the very right of the tab list is used to close all tabs. In case the screen size is not sufficient to display all assay tabs, a left and right arrow symbol is displayed to navigate between the tabs.



"Plots and information" area

The "Plots and information" area is subdivided into 6 sub tabs:



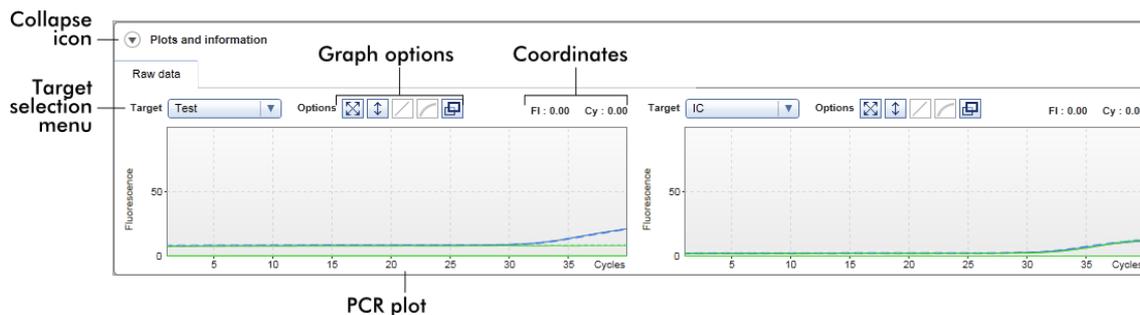
1.	"Raw data"	}	Graphic focused: Shows amplification plots of raw and processed data as well as the standard curve, respectively (depending on the selected assay and the currently used plug-in).
2.	"Processed data"		
3.	"Standard curve"		
4.	"Experiment"	}	Data focused: Shows detailed data about the experiment and the assay.
5.	"Assay"		
6.	"Audit Trail"		
			Shows all actions that are recorded in the audit trail.

Note

The collapse icon (▼) is used to collapse the "Plots and information" or the "Results" area to gain screen space for the other area. If an area is collapsed to a single row, the icon changes to ▶ for expanding the area back to the default size.

"Raw data" sub tab

The "Raw data" sub tab displays a plot of the fluorescence measured during the assay run. The line styles and colors used in the plots are defined during the creation of the corresponding assay profile. The availability of raw data depends on the currently used plug-in.

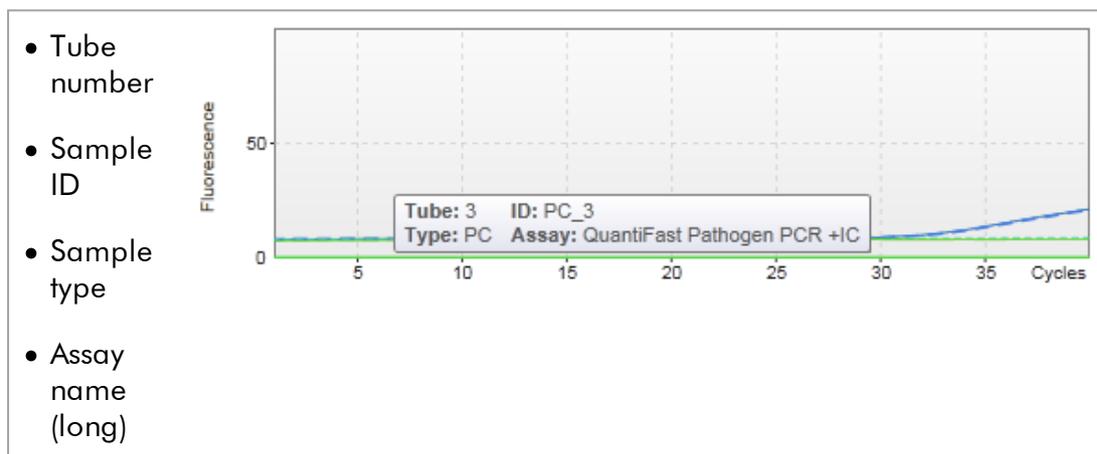


Label/Title	Icon	Description
Collapse icon		Collapses the "Plots and information" or the "Results area" to gain screen space for the other area.
Target selection menu		Selects the target source used for the corresponding plot.
Graph options		This button resets the scale of the y-axis (visualization of the fluorescence) from 0 to 100 fluorescence units. The x-axis is set to a maximum value equal to the number of cycles in the run profile.
		The auto-scale button attempts to fit the scale of the y-axis to the maximum and minimum readings in the data. The x-axis is set to a maximum value equal to the number of cycles in the run profile.
		Disabled in "Raw data" tab.
		Disabled in "Raw data" tab.
		Clicking the "Full screen" button enlarges the amplification plot to maximum size. Clicking it again will scale down the amplification plot back to normal size.
Coordinates		Shows the coordinates of the mouse pointer (cross hairs) in the amplification plot area in the amplification plot. First, the fluorescence value on the y-axis is displayed, followed by the cycle value on the x-axis.

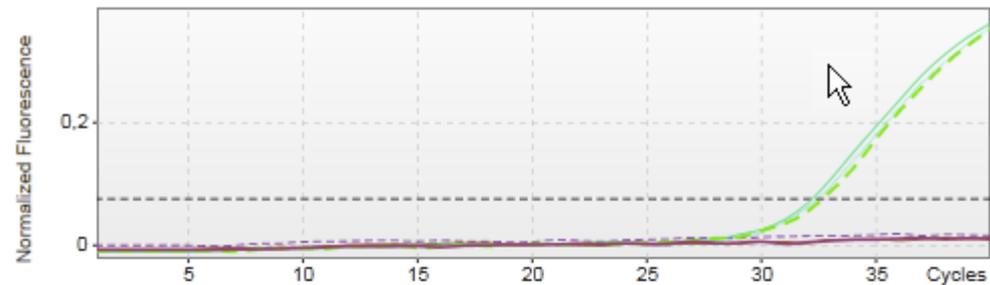
Coordinates are displayed only if the cursor is over the amplification plot. Otherwise the coordinate values are set to 0.

Behavior of the plot area

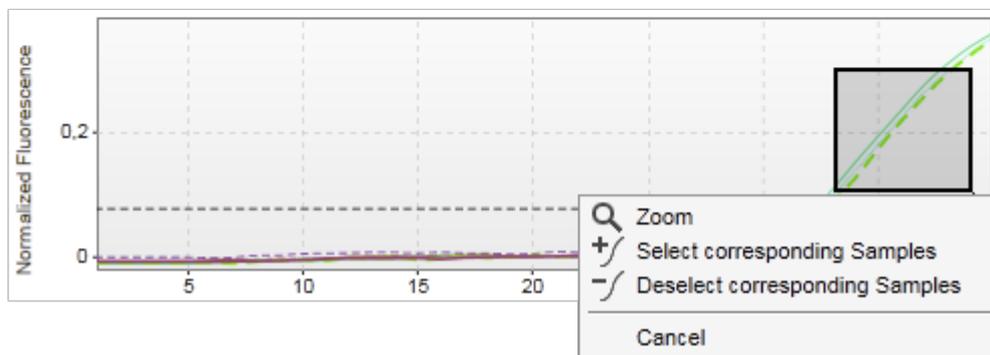
- When the mouse is hovered over the amplification plot, the cursor changes to cross hairs (+).
- The current position of the mouse cursor over the amplification plot is displayed in real time in the coordinates field.
- Hovering with the mouse over the amplification curve of a specific sample opens a tooltip displaying the following information:



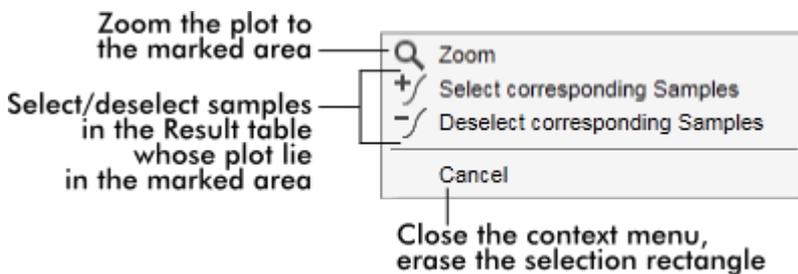
An area of the amplification plot can be selected by clicking and holding the left mouse button and dragging the mouse pointer. A context menu with several options appears.



1. Hold down left mouse button
2. Drag mouse to end point



Description of the context menu's functions:



Note

Navigation in a zoomed amplification plot

- By right-clicking and holding down the mouse button the cursor changes to a hand symbol (). The plot area can be scrolled in all directions by moving the mouse.
- Double-click anywhere in the amplification plot area to reset the zoom to 100%.

Processed Data

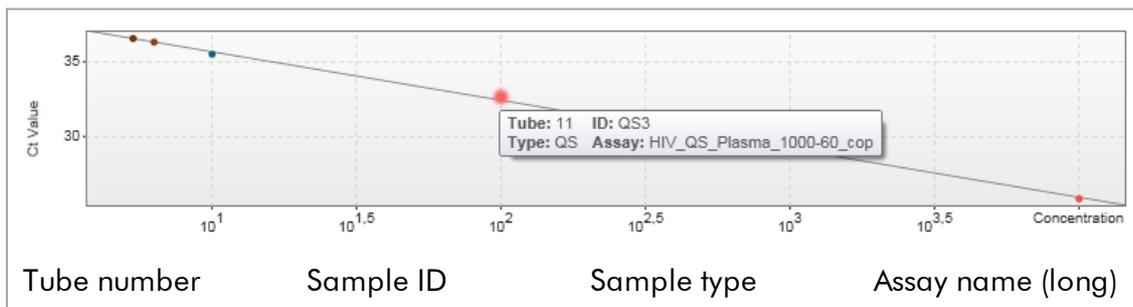
The availability of processed data depends on the currently used plug-in. The "Processed data" sub tab has the same elements and the same behavior as the "Raw data" sub tab with only a few differences:

1. The raw fluorescence data are normalized using the internal algorithm of Rotor-Gene AssayManager v2.1 according to the settings of the corresponding assay profile.
2. The graph options are partially different. The following table describes only the differences to the raw data tab:

Graph options	Icon	Description
		Disabled in "Processed data" tab
		By clicking the "Linear scale" button, the amplification plot is displayed using a linear scale. If this option is selected, the "Linear scale" button is highlighted in dark blue color.
		By clicking the "Logarithmic scale" button, the amplification plot is displayed using a logarithmic scale. If this option is selected, the "Logarithmic scale" button is highlighted in dark blue.

Standard Curve

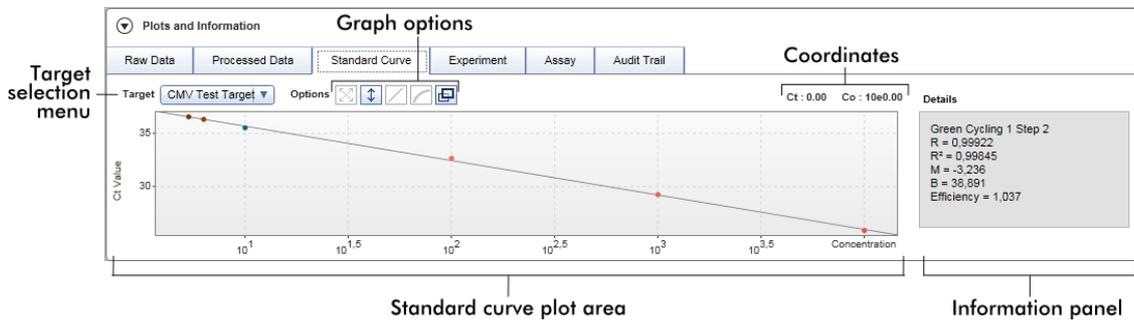
The standard curve sub tab displays the standard curve as a result of plotting the C_T values of the quantitation standards on the y-axis against their concentration on the x-axis. For easy identification the color of the data points corresponds with the style for the individual samples selected in the assay profile. Additionally, hovering with the mouse over the data point of a specific sample opens a tooltip displaying the following information:



Note

The standard curve is only available for quantitative assays and certain plug-ins.

The "Plots and information" area consists of a standard curve plot area where the curve is displayed, and an information panel with statistical information about the curve.



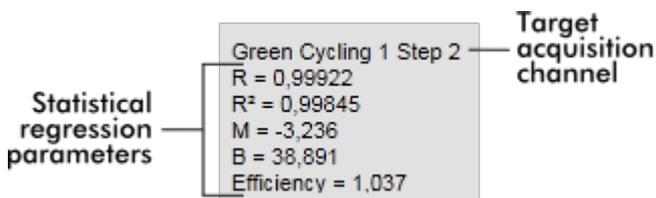
Standard curve plot area

The layout is similar to the "Raw data" and "Processed data" sub tabs:

- A drop-down menu to select the target
- Graph option buttons to manage the plot
- A coordinates field, displaying C_T and concentration values of the current cursor position in the plot

Information panel

The informational panel provides information about the acquisition channel and statistical parameters describing the parameter values of the regression analysis:



The statistical regression parameters are:

Parameter	Explanation
R	Root extracted from R ²
R ²	The correlations coefficient R ² is a statistical parameter to measure the fit of the data points to the regressed line. In general, the standard curve should have an R ² value ≥ 0.990 . However, the individual limit for this value can be set during assay profile creation.
M	Curve slope
B	Curve offset
Efficiency	Describes the amplification efficiency in a PCR.

Experiment

The "Experiment" sub tab provides detailed information about the experiment.

Plots and information

Raw data | Processed data | Standard curve | **Experiment** | Assay | Audit Trail

Run comment	Run operator su	External order ID	Messages
	Run released by	Work list source Manual	Work list locked No
Experiment name QF Pat_20120417_0949	Reaction volume 25	Rotor type 72-Well Rotor	Created from worklist WL_20120417_0858_su
Run start 17.04.2012 09:49:42	End of run 17.04.2012 09:52:17	Run on SW version 0.8.6.2	Cycler Serial No. 0112101
	Work list last changed by su	Work list created on 17.04.2012 08:58:58	Work list last changed on 17.04.2012 08:58:58

Assay

The "Assay" sub tab provides detailed information about the selected assay.

Plots and information

Raw data | Processed data | Standard curve | Experiment | **Assay** | Audit Trail

Assay profile name Quantifast Pathogen PCR +IC	# standards and controls 6	Material number
Short name QF Pat	# test samples 66	Kit expiration date
Version 2.0.0	Reserved rotor positions 72	Kit lot number 139264899

Audit Trail

The "Audit trail" sub tab contains detailed information about any substantial events of the experiment in adjacent order.

Example:

Plots and information					
Raw data	Processed data	Standard curve	Experiment	Assay	Audit Trail
Date and time	User ID	Message ID	Message		Signed
11.05.2012 09:31:22	su	540015	Approval: Experiment Experiment-634716579113812101 assay QuantiFast Pathogen PCR +IC sample PC_1 in tube position 1 state set from Undefined to Accepted.		
11.05.2012 09:31:22	su	540015	Approval: Experiment Experiment-634716579113812101 assay QuantiFast Pathogen PCR +IC sample PC_2 in tube position 2 state set from Undefined to Accepted.		

"Results" table

All samples and external controls are listed in separate rows of the results table. If a sample has multiple targets, the row is further split and the results of every individual target are displayed. Any test sample results provided by Rotor-Gene AssayManager v2.1 must be investigated as being correct or incorrect and must be approved (accepted or rejected) accordingly. Accepted or rejected samples must be released as a final step.

Note

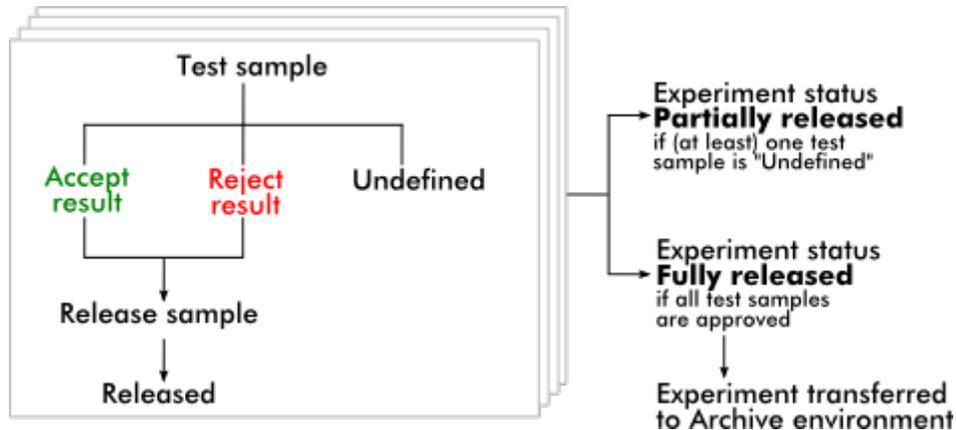
The approval procedure may be different depending on the plug-in currently used. For details regarding the approval procedure, refer to the corresponding Rotor-Gene AssayManager v2.1 plug-in user manual.

Results											
Standards / controls											
Pos.	<input checked="" type="checkbox"/>	Style	Sample ID	Status	Type	Targets	Ct	Result	Flags	Sample comment	
1	<input checked="" type="checkbox"/>	---	PC_1		PC	Test	-	INVALID	MULTIPLE_THRESHO...		
						IC	-	INVALID	MULTIPLE_THRESHO...		
2	<input checked="" type="checkbox"/>	---	PC_2		PC	Test	-	INVALID	MULTIPLE_THRESHO...		
						IC	-	INVALID	MULTIPLE_THRESHO...		
3	<input checked="" type="checkbox"/>	---	PC_3		PC	Test	-	INVALID	MULTIPLE_THRESHO...		
						IC	-	INVALID	MULTIPLE_THRESHO...		

Results table options: Conc. in: [] Conc. unit: [] Show IC Ignore invalid controls Use scientific format Comment: []

Assays with at least one undefined test sample get the status "Partially released". If all test samples of an experiment have been released, the experiment status is set to "Fully released". The experiment is transferred to the "Archive" environment. Future

access to the data of the experiment is possible from the "Archive" environment, but decisions made during approval are fixed to the samples.



Results table

The results table contains the following columns:

Column	Explanation
Row selector	<p>The row selector enables the user to select and deselect samples in the results table and to approve the status of multiple test samples simultaneously.</p> <p>Selecting single assays is simply done by activating the check box <input type="checkbox"/> of the corresponding sample. Use the row selector to select multiple samples.</p> <p>Clicking the row selector highlights the current row. The row selector icon changes. The highlighted row will be colored in dark blue.</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> <input type="checkbox"/> <p>Deactivated row selector</p> </div> <div style="text-align: center;"> <input checked="" type="checkbox"/> <p>Activated row selector</p> </div> </div> <p>To highlight adjacent rows, click the first element's row selector, hold down the left mouse button, and move the cursor to last element to be highlighted. All rows in between are highlighted.</p>

Use the "Control" key to make multiple selections of non-adjacent rows.

Context menu

The context menu of the row selector is used to select/deselect the highlighted sample experiment:

Copy	Ctrl+C
Show curves	
Hide curves	
Invert selection	
Accept	
Reject	
Reset to undefined	
Cancel	

Label/title	Description
"Copy"	Copies the content of the selected rows to the clipboard (the individual cells are separated by tab characters, the row start is characterized with a carriage return)
"Show curves"	Shows the curves of the selected samples in the amplification plot
"Hide curves"	Hides the curves of the selected samples in the amplification plot
"Invert selection"	Inverts the row selection
"Accept"	Sets the approval status of the selected samples to "Accept"
"Reject"	Sets the approval status of the selected samples to "Reject"
"Reset to undefined"	Resets the approval status of the selected samples to "Undefined". This is only possible if the sample result is not released yet.

"Cancel" Closes the context menu

Graph selector check box

The graph selector check box is used to show or hide the amplification curve of the selected sample.

- Hide the amplification curve of the sample
- Show the amplification curve of the sample

The column select icon in the table header changes according to the number of selected samples.

Column select icon

Results				
Standards / controls				
	Pos.	<input type="checkbox"/>	Style	Sample ID
▶	6	<input type="checkbox"/>	—	Positive Control
▶	7	<input type="checkbox"/>	—	Negative Control
▶	8	<input type="checkbox"/>	—	Positive control Test 1

- No sample selected
- Samples selected sporadically
- All samples selected

Click the column select icon to easily select or deselect all samples.

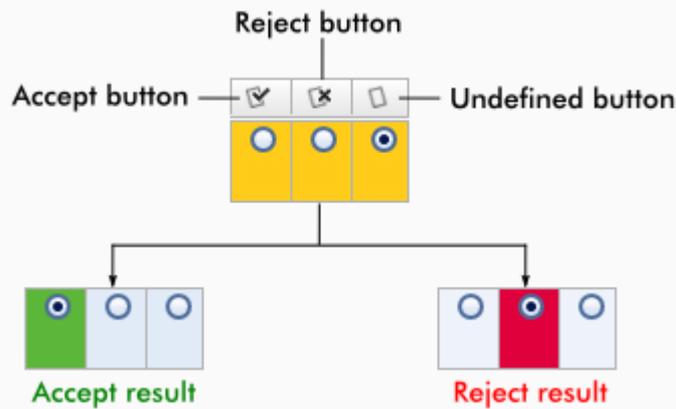
- Line color Line color of the amplification curve used for the sample
- Line style Line style of the PCR amplification curve used for the sample
- Sample ID Sample ID of the sample (as defined during worklist setup)
- Status Upstream status of the sample.

Possible values are:

- QIASymphony sample status valid

	<p> QIASymphony sample status unclear</p> <p> QIASymphony sample status invalid</p>
Target	Display all targets related to the sample. The sample row is split, and every target is displayed in a separate row.
Ct	Calculated Ct value for the target
Results	<p>Rotor-Gene AssayManager v2.1 sample evaluation result. Possible results are:</p> <ul style="list-style-type: none"> • Concentration value including a concentration unit • Signal detected • No signal • Invalid
Flags	Exceptions identified by Rotor-Gene AssayManager v2.1 analysis. Possible flags are listed in the corresponding Rotor-Gene AssayManager v2.1 plug-in user manual.
Sample comment	For every sample a comment can be entered. Maximum 256 characters are allowed. Comments already entered during worklist setup are shown.
Approval status	<p>The last 3 columns are reserved for the approval buttons. Here the approval status of the test samples has to be defined using three radio buttons.</p> <p>Note: The approval procedure may be different depending on the plug-in currently used. For details regarding the approval procedure, refer to the corresponding Rotor-Gene AssayManager v2.1 plug-in user manual.</p> <p>Initially, the approval status of all test samples is set to "undefined". This means that the undefined radio button is activated and the background color of all 3 approval buttons is set to yellow.</p> <p>When the result of a test sample is set to "Accepted" by clicking the "Accept" button, the background changes to green and the background color of the 2 other buttons changes to blue.</p>

When the result of a test sample is set to "Rejected" by clicking the "Reject" button, the background changes to **red** and the background color of the 2 other buttons is set to **blue**.



Results table options

Note

The results table options differ from plug-in to plug-in. Refer to the relevant plug-in manual for details.

Button bar

Title/label	Explanation
	Saves all changes and closes the current assay. No test results will be released.
	Discards all unsaved changes. Note: Visualization options, such as "Show IC", check boxes of samples, etc., are not changed.
	Saves all changes; remains in this dialog. No test results will be released.
	Closes the selected experiment. If there are unsaved changes, a warning will be displayed.

Release / report data...

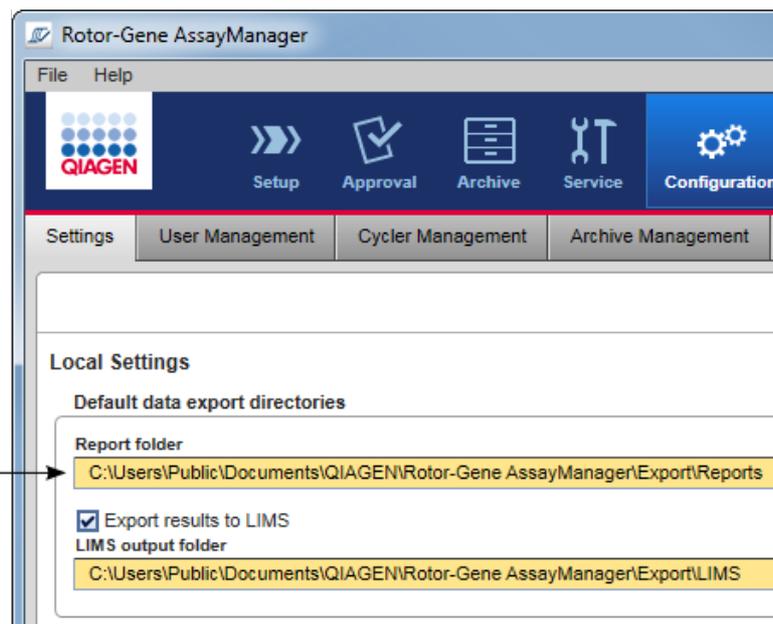
Opens a dialog to release test results and optionally create a report using a report profile selected from the "Report profile" drop-down menu.

The status of the assay is set to:

- "Fully released" if all test samples were released and no test sample has the status "Undefined".
- "Partially released" if at least one test sample is approved and released while at least one test sample still is not yet released.
- "Pending" if some re-usable data are missing.

The *.pdf report file is saved in the folder defined in the ► "Configuration" environment, under

Settings ► Local Settings ► Folders for exporting ► Report folder.



1.5.5.4 Archive Environment

The "Archive" environment is used to search for released assays, to generate experiment reports using predefined report profiles and to import run experiment data into the the Archive. Note that filtering in the "Archive" environment is limited to the

currently active archives. Inactivated archives are not included in the filtering. Different archives can be activated or deactivated using the "Archive Management" tab in the "Configuration" environment.

The "Archive" and the "Approval" environments have a very similar layout.

Note

After finishing, an assay can have one of the following statuses:

- Unreleased No sample has been released yet.
- Partially released At least one, but not all test samples have been released.
- Fully released All test samples have been released.
- Pending Mandatory re-usable data are missing.

Unreleased and pending experiments can be accessed in the "Approval" environment; fully released experiments in the "Archive" environment. Partially released experiments can be accessed in both environments.

Approval environment	Archive environment
Unreleased	Fully released <input checked="" type="checkbox"/>
Pending <input type="checkbox"/>	<input type="checkbox"/>
Partially released <input type="checkbox"/>	

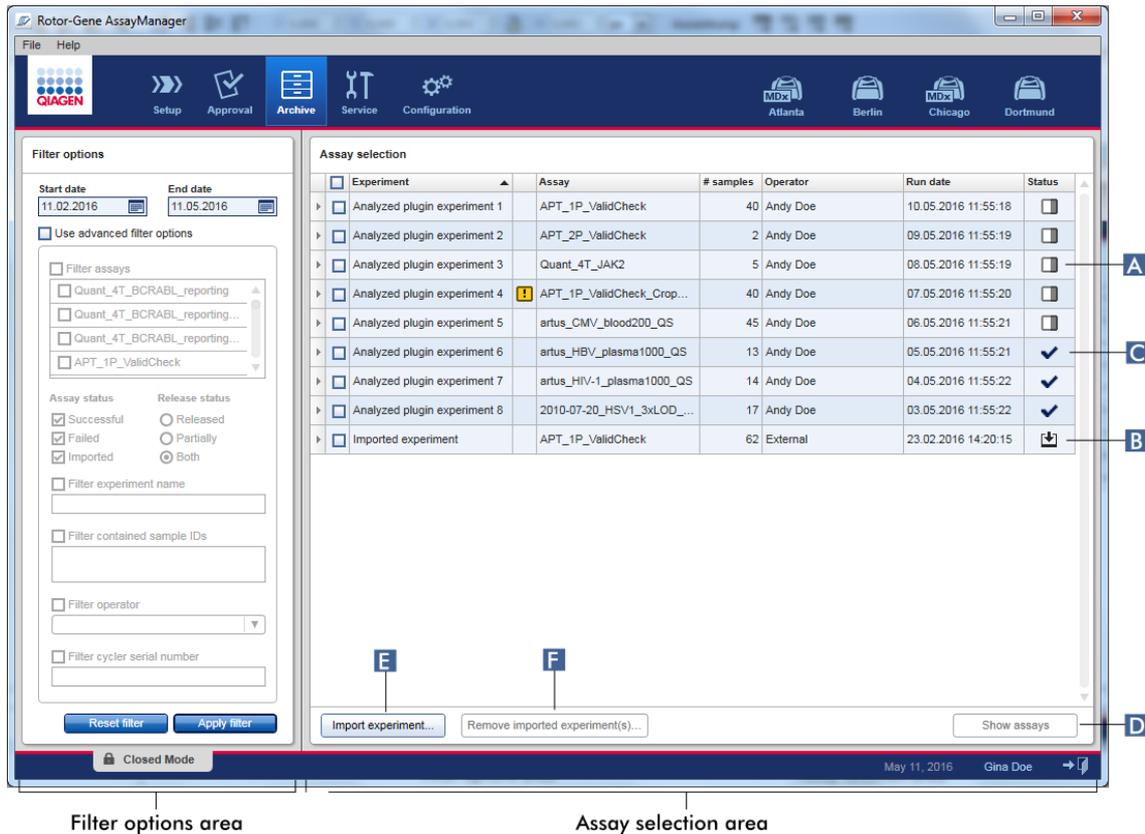
The main tasks (searching and reporting data) are carried out in 2 different screens:

- ▶ Filter options and assay selection screen
- ▶ Showing assays screen

1.5.5.4.1 Filter Screen

The Filter screen is used to search for and select partially or fully released experiments. The layout and behavior is identical to the Filter screen of the ▶ "Approval" environment. The only differences are:

- Experiments with either status "partially released" (A), "imported" (B) or "fully released" (C) are shown.
- The "Show assays" button (D) is shown instead of the "Start approval" button.



In addition, it is possible to import Rotor-Gene AssayManager v2.1 experiments e.g. from another computer or database via the "Import experiment" button (E). Select the *.rgam file of interest and export the complete experiment into the archive. Imported experiments can be removed via the "Remove imported experiment(s)" button (F).

For experiment import .rgam files are necessary. Refer to ► Show Assay screen to export experiment raw data.

Note

The "Remove imported experiment(s)" button is only visible if at least one experiment was imported.

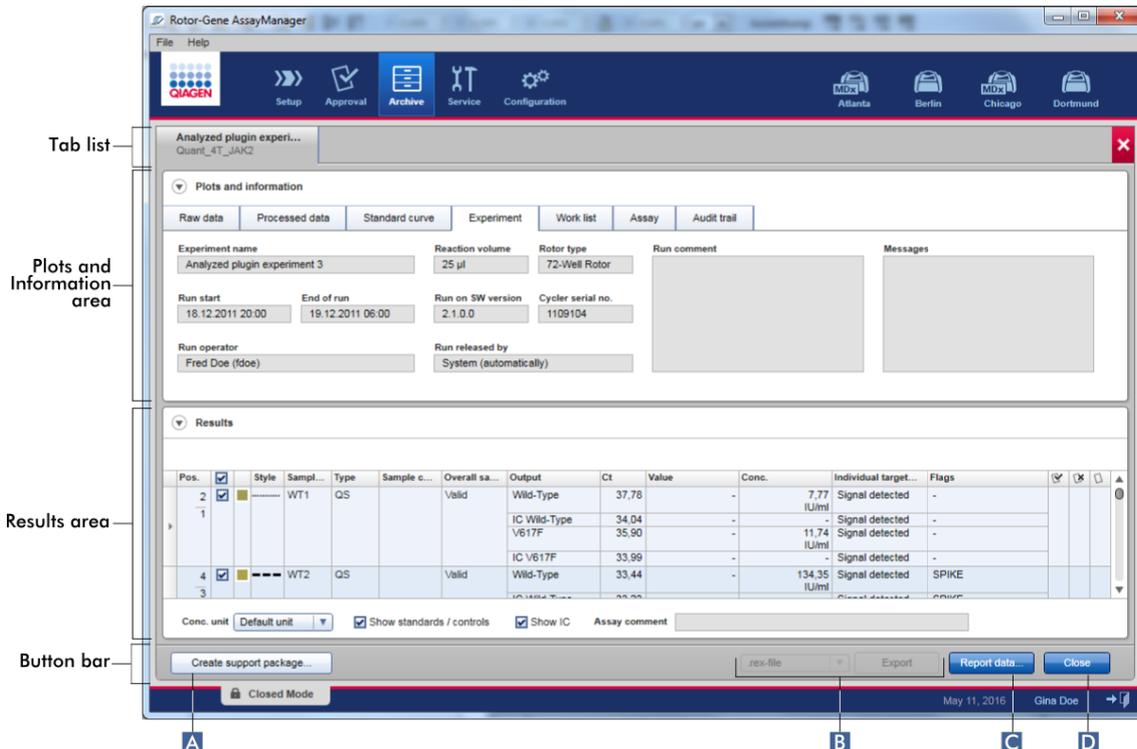
For details about the functionality of the Filter screen, see ► "Approval" environment.

1.5.5.4.2 Show Assays Screen

The Show Assays screen of the "Archive" environment is used for the following tasks:

- Check experiment data of partially or fully released experiments
- Create a support package to facilitate support in case of problems
- Print reports as *.pdf file using report profiles

The layout of this screen is very similar to the "Approval" screen in the ► "Approval" environment. Some functions are disabled here, for example the approval buttons in the results table as well as the assay comment field. Released assays cannot be modified.



Label/Title	Description
-------------	-------------

A "Create support package..."

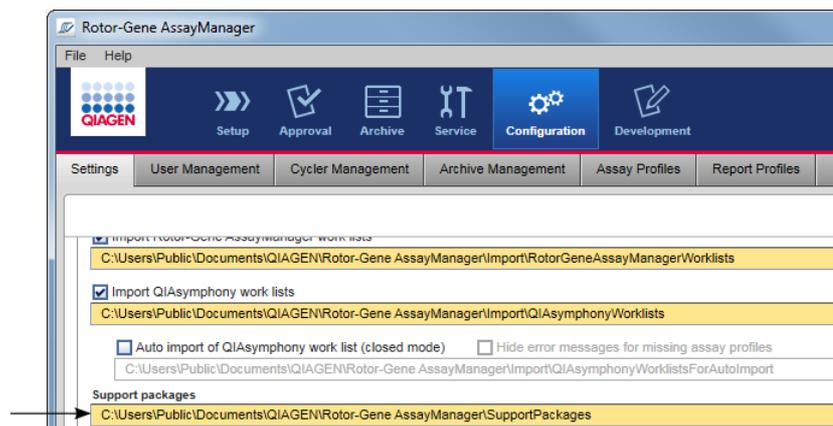
Rotor-Gene AssayManager v2.1 has a built-in support function. In case problems with a specific experiment occur a support package can be generated. This file can be sent via email to QIAGEN Technical Services.

The name of the generated support package has the format:

<Experiment name>_<Assay name>_<Timestamp>.zip

Upon clicking "Create support package..." (**A**), the support package will be generated. A save file dialog is opened to select the target directory for the support package.

The default directory for saving the support package file is set in the "Configuration" environment under the ► "Settings" tab in the support packages option.



B "Export"

Exports raw data of experiment/s to a *.rex file, *All .rex files, *.rgam-file, *All .rgam-files, *.zip-archive or *All .zip-archives.

C "Report data..."

Creates a report of the experiment as *.pdf file. The report is generated using the report profile selected from the "Report Profile" (**C 2**) menu. Reports can be generated using the scientific format (**C 1**), the reporting unit can be selected (**C 3**) and the concentration can be defined (**C 4**).

Note
For the Gamma Plug-in, no user defined report profiles are applicable. The experiment data which will be included in the report are pre-defined by the assay.

Note
The scientific format function is not available for all Rotor-
Gene AssayManager v2.1 Plug-ins.

D "Close" Closes the "Show Assays" screen and returns to the Filter screen of the "Archive" environment.

1.5.5.5 Service Environment

The "Service" environment contains the "Audit Trail" and the "Re-usable Data" tab.

"Audit Trail" tab

The audit trail is a record of all user actions. All actions are traced in the audit trail and can be filtered and printed out. The Rotor-Gene AssayManager v2.1 audit trail is designed based on guidelines in FDA CFR Title 21, Part 11 Electronic Records, Electronic Signatures.

All activities of a user are logged in an audit trail categorized in 8 different contexts:

- Installation

- User
- Session
- Profile
- Settings
- Cyclor
- worklist
- Experiment

The content of the audit trail can be accessed using the "Service" environment. Here, various filter criteria can be selected and applied. The "Audit Trail" tab contains 2 areas:

- "Filter" area
- "Results" table
- "Print to PDF" button

The user defines filter criteria in the "Filter" area and applies the filter. All entries in the audit trail matching the filter criteria will be listed in the "Results" table.

The screenshot displays the Audit Trail interface. On the left, a vertical label "Filter area" points to the filter configuration section. This section includes:

- Date & time:** Date from (02.03.2015), Time from (00:00:00), Date to (02.03.2015), Time to (23:59:59).
- User:** Radio buttons for "All users", "This user", and "Specific". A "User ID" input field is present.
- Experiment:** Radio buttons for "All" and "Specific". An "Experiment name" input field is present.
- Context:** A list with checkboxes for "Installation", "User", and "Session".
- Computer:** Radio buttons for "This computer" and "All computers".
- Signed actions:** Radio buttons for "All actions" and "Signed only".
- Message ID:** Radio buttons for "All" and "Specific". An "ID" input field is present.
- Language:** Radio buttons for "System language" and "English".
- Buttons for "Reset filter settings" and "Apply filter".

On the right, a vertical label "Results table" points to the table below. The table has columns: Context, Date & Time, User, Experiment, Message ID, Text, and Signed. It contains three rows of data:

Context	Date & Time	User	Experiment	Message ID	Text	Signed
Session	02.03.2015 08:15:23	Gina Doe (su)		1030012	su logged in successfully in User Defined Test Mode.	
Session	02.03.2015 10:36:13	Gina Doe (su)		1030016	Application unlocked successfully for the user: su.	
Session	02.03.2015 11:22:34	Gina Doe (su)		1030016	Application unlocked successfully for the user: su.	

At the bottom right of the interface, there is a "Print to PDF" button. A "Messages" panel on the right side contains an information icon and a note: "The messages are shown in the system language. If the language file was not found, the messages will be shown in English. (920002)".

The content of the matching entries in the "Results" table are not editable, the table cannot be sorted. It is possible to select a row and copy the content to the clipboard using the "CTRL" + "C" shortcut. A *.pdf report file of the matching entries can be generated by clicking the "Print to PDF" button.

Filter area

Explanation

A Filter for date and time
Enter a date in the "Date from" and "Date to" fields either manually or using the date picker. Enter a time in the "Time from" and "Time to" fields.

B Filter for a user name

To	Do this
Filter for all users	Activate "All users".
Filter for the current user	Activate "This user".
Filter for a specific user	Activate "Specific" and enter a user ID in the "User ID" field.

C Filter for an experiment name

To	Do this
Filter for all experiments	Activate "All".

To	Do this
Filter for a specific experiment	Activate "Specific" and enter an experiment name in the "Experiment name" field.

D Filter for a specific context

Select a context to filter for from the "Context" menu by activating the corresponding check box. Multiple selections are possible. By default all check boxes are activated.

- Installation
- User
- Session
- Profile
- Settings
- Cyclor
- Worklist
- Experiment
- Licensing

E Filter for a computer

If Rotor-Gene AssayManager v2.1 is installed in a network on multiple computers, this setting allows to filter for a specific computer name. It can only be switched between all messages and those messages related to the local computer. In a single computer installation environment, this setting is less useful.

To	Do this
Filter for the computer in use	Activate "This computer".
Filter for all computers	Activate "All computers".

F Filter for signed actions

The administrator can define in the "Settings" tab of the "Configuration" environment that the release of a run and the release of test results have to be signed: see ► Signing release of a run option, ► Signing release of test results option. This filter option is used to filter for signed actions only.

To	Do this
Filter for all actions	Activate "All actions".
Filter for signed actions only	Activate "Signed only".

G Filter for messages

To	Do this
Filter for all messages	Activate "All".
Filter for a specific message	Activate "Specific" and enter a message ID in the "Message ID" field.

H Select a language.

I Reset the "Filter" settings to the default values.

The default values and selection of control are as follows:

"Date & time"	Date from: Current date	Date to: Current date
	Time from: 00:00:00	Time to: 23:59:59
"User"	All users activated	
"Computer"	All activated	
"Signed actions"	All actions activated	
"Message ID"	All activated	
"Experiment"	All activated	
"Context"	All check boxes are selected.	

J Apply the selected filter criteria. All entries in the audit trail matching the filter criteria are listed in the results table.

Results table

The results table lists all entries in the audit trail matching the filter criteria.

Results						
Context	Date & Time	User	Experiment	Message ID	Text	Signed
Session	02.03.2015 08:15:23	Gina Doe (su)		1030012	su logged in successfully in User Defined Test Mode.	
Session	02.03.2015 10:36:13	Gina Doe (su)		1030016	Application unlocked successfully for the user: su.	
Session	02.03.2015 11:22:34	Gina Doe (su)		1030016	Application unlocked successfully for the user: su.	

[Print to PDF](#)

The contents of the matching entries in the "Results" table are not editable, and the table cannot be sorted. It is possible to select a row and copy the content to the clipboard using "CTRL" + "C".

Column	Description
"Context"	Context of the entry. Possible values are: <ul style="list-style-type: none">• Installation• User• Session• Profile• Settings• Cycler• worklist• Experiment
"Date & Time"	Date and time
"User"	Name of the user logged in the audit trail
"Experiment"	Name of the experiment logged in the audit trail
"Message ID"	ID of the message
"Text"	Text of the audit trail message
"Signed"	Indication if the audit trail entry is signed or not

"Print to PDF" button



Print the audit trail messages to a *.pdf file.

Tasks related to the "Service" environment

▶ Working with audit trails

"Re-usable Data" tab

Please refer to the plug-in specific manuals.

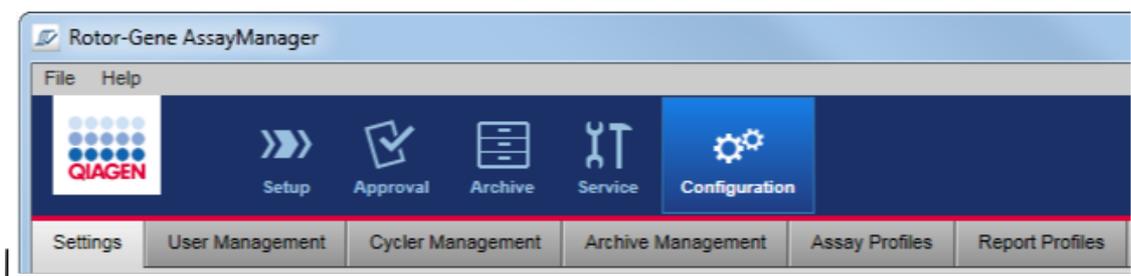
1.5.5.6 Configuration Environment

In the "Configuration" environment, the settings of Rotor-Gene AssayManager v2.1 can be adjusted. Furthermore, different users, cyclers, archives, assay profiles, and report profiles can be managed.

Note

Only users with the role "Administrator" can access this environment.

The "Configuration" environment is organized in 6 different tabs.



Configuration environment is organized in six tabs

The following table shows the tabs and their assigned tasks.

Tab	Assigned tasks
▶ "Settings"	<ul style="list-style-type: none"> • Define global settings • Define local settings
▶ "User Management"	<ul style="list-style-type: none"> • Add user • Edit user data • Modify user roles • Change password • Activate/deactivate user
▶ "Cycler Management"	<ul style="list-style-type: none"> • Set up new cyclers • Remove cyclers • Enter next verification date
▶ "Archive Management"	<ul style="list-style-type: none"> • Activate/deactivate archives
▶ "Assay Profiles"	<ul style="list-style-type: none"> • Activate/deactivate assay profiles • Import assay profiles
▶ "Report Profiles"	<ul style="list-style-type: none"> • Create or adapt report profiles • Import report profiles • Export report profiles • Delete report profiles • Select content sections

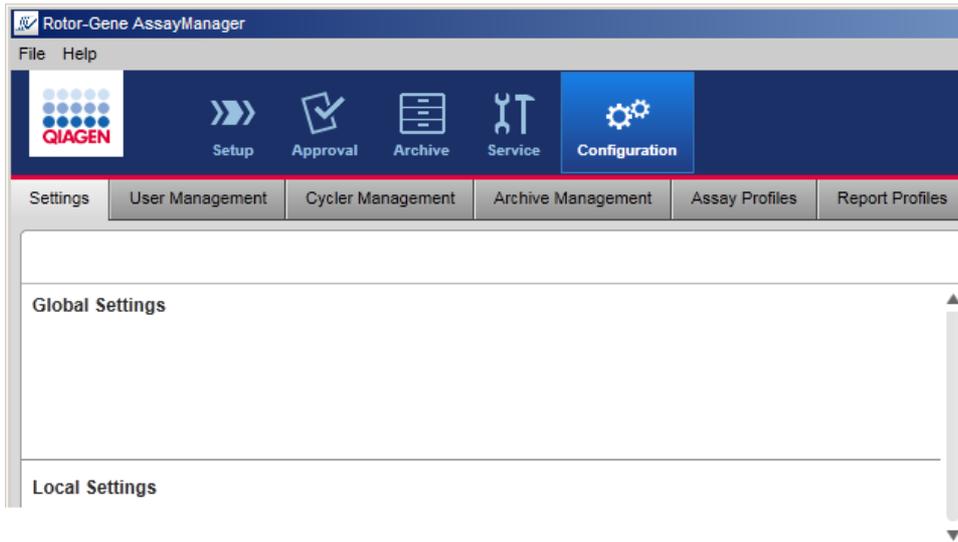
Tasks related to the "Configuration" environment

▶ Administrative tasks

1.5.5.6.1 Settings

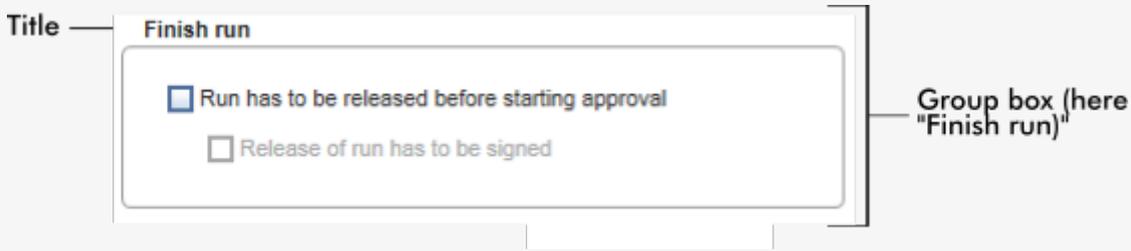
The "Settings" tab is divided in 2 sections:

- "Global Settings": Global settings are stored in the database. They are "global" for all clients connected to the database.
- "Local Settings": Local settings are only applied to the currently used computer.



Note

Thematically associated settings are bundled in group boxes. Every group box has a title.



Global settings

Miscellaneous settings are defined in the global settings. These are bundled in 7 group boxes.

Global Settings

Experiment A

Use work list name
 Select pattern

Format of generated experiment names
AS1_AS2_AS3_20110513_0430

User-definable section

Assay profile short names
 Date
 Time
 Operator

Work list D

Format of generated work list names
WL_20110513_0430_Operator

User-definable section

Date
 Time
 Operator

Enable processing of unclear samples
 Enable checksum for LIMS import

Closed mode	UDT mode
<input type="checkbox"/> Material number required	<input type="checkbox"/> Material number required
<input type="checkbox"/> Valid expiry date required	<input type="checkbox"/> Valid expiration date required
<input type="checkbox"/> Lot number required	<input type="checkbox"/> Lot number required

Finish run B

Run has to be released before starting approval
 Release of run has to be signed

Analysis / Approval E

Enable possibility to ignore invalid controls (UDT mode)
 Release of test results has to be signed

Reporting C

Page header image

Report concluding image

Cycler verification management F

Disable unverified cyclers

User management G

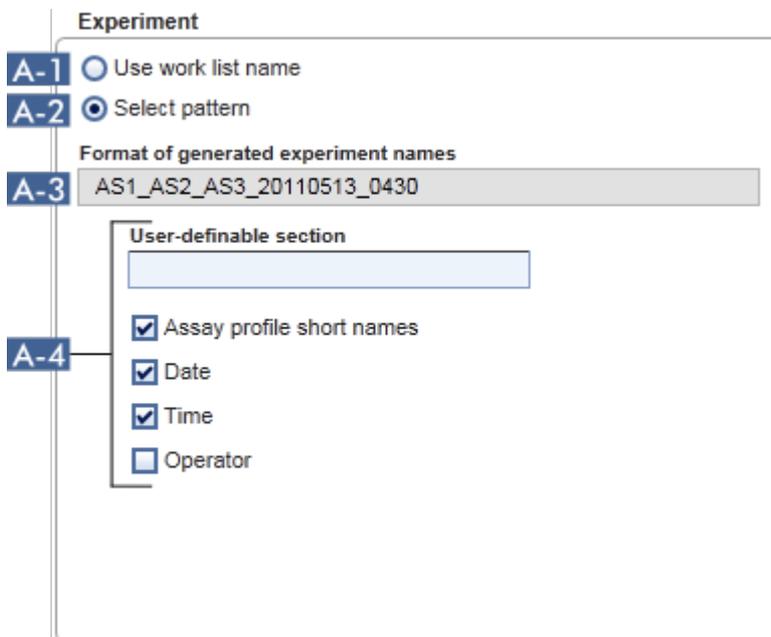
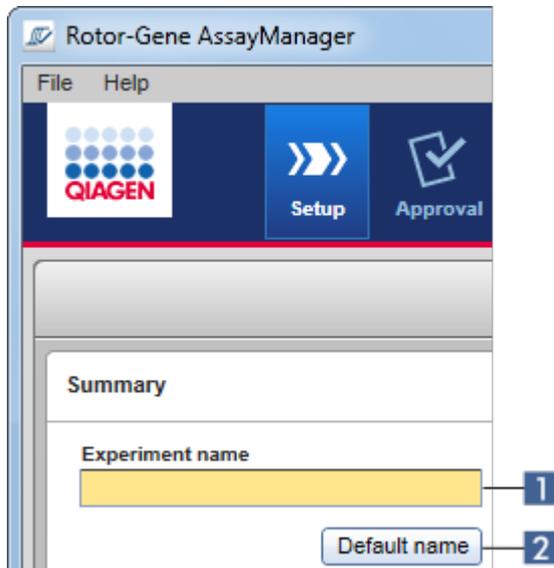
Password renewal interval
 days
 Use CLIA compliant password rules

Auto-lock timer
 minutes

- | | |
|----------|--|
| A | Group box "Experiment" |
| B | Group box "Finish run" |
| C | Group box "Reporting" |
| D | Group box "worklist" |
| E | Group box "Analysis/Approval" |
| F | Group box "Cycler verification management" |
| G | Group box "User management" |

Group box "Experiment"

The settings in the "Experiment" group box define the default naming scheme for experiments. To apply a worklist, an experiment name must be entered. The user can either enter an arbitrary name in the "Experiment name" field (1) or let Rotor-Gene AssayManager v2.1 automatically generate a default name by clicking (2) "Default name". This default name can be configured in the "Experiment" group box.



	Explanation
A-1	Activate "Use worklist name" to use the same name as given to the worklist that is applied.
A-2	Activate "Select pattern" to define a specific naming scheme.
A-3	<p>Display the current worklist name definition. This field is empty if "Use worklist name" is selected. If "Select pattern" is selected, the resulting experiment name is shown.</p> <p>Example:</p>  <p>The experiment name is set to be the same as the worklist name, hence the field is empty.</p>
A-4	<p>The scheme for the default name consists of 5 options:</p> <ul style="list-style-type: none"> • "User-definable section" • "Assay profile short names" • "Date" • "Time" • "Operator" <p>Activating the check box in front of the last 4 options includes these information in the experiment name. The options are separated by a "_" character in the experiment name. A user definable section with a maximum of 15 characters is entered directly in the corresponding field. The order of the individual information cannot be changed. If a user definable section is defined, the resulting experiment name will always start with this section.</p> <p>Rotor-Gene AssayManager v2.1 is delivered with the following default settings:</p>

Format of generated experiment names
 Exp_AS1_AS2_AS3_20120327_1359

User-definable section
 Exp

Assay profile short names
 Date
 Time
 Operator

The text in the field "Format of generated experiment names", here *Exp_AS1_AS2_AS3_20120327_1359* , results from the input in the "User-definable section" *Exp*, the "Assay profile short names" *AS1_AS2_AS3* , the current date *20120327* , and the current time *1359* .

Group box "Finish run"

Option to set

- If a user must release a run before the approval can be started.
- If a user must sign the run release by entering the password.

Finish run

B-1 Run has to be released before starting approval

B-2 Release of run has to be signed

	Explanation
B-1	If activated, the user must click "Release" (or "Release and go to approval") after a run has finished to transfer the experiment to the "Approval" environment. As long as an experiment is not released this way, it will not be listed in the "Approval" environment and cannot be approved.

User must release experiment

B-2 This option is available only if **B-1** was activated before.

If this option is activated, the "Release" and "Release and go to approval" buttons are disabled after the run has finished. The user must sign the release by entering his password in the "Password" field. Only if the correct password is entered, then the "Release" and "Release and go to approval" buttons are enabled. The user can then release the experiment to the "Approval" environment.

Finish run

Position	Name	Run status
■ ■ ■ ■	Cycler 1	Run Successful

Experiment name
QF Pat_20120425_1334

Errors during run

Comment

Password

Release Release and go to approval Cancel

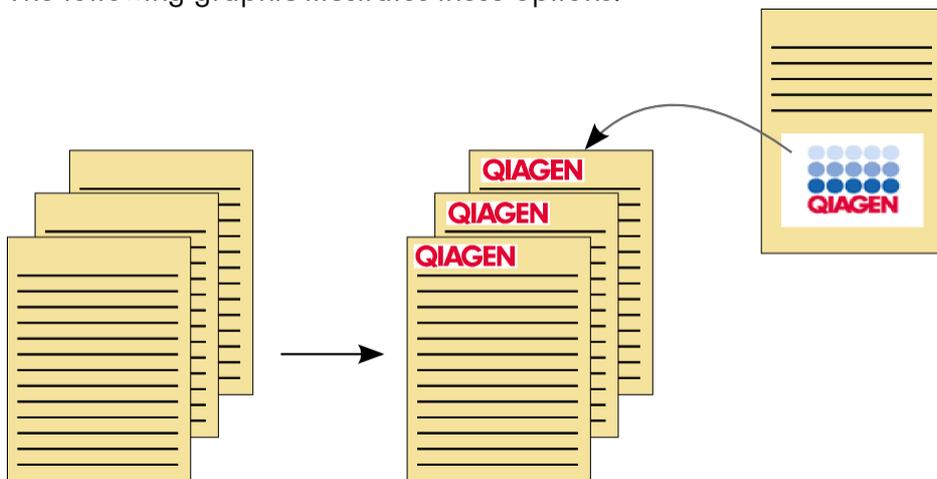
Buttons disabled initially; they are enabled after user has signed with a valid password.

Group box "Reporting"

The "Reporting" group box is used to customize the layout of reports using images. Rotor-Gene AssayManager v2.1 provides 2 different options:

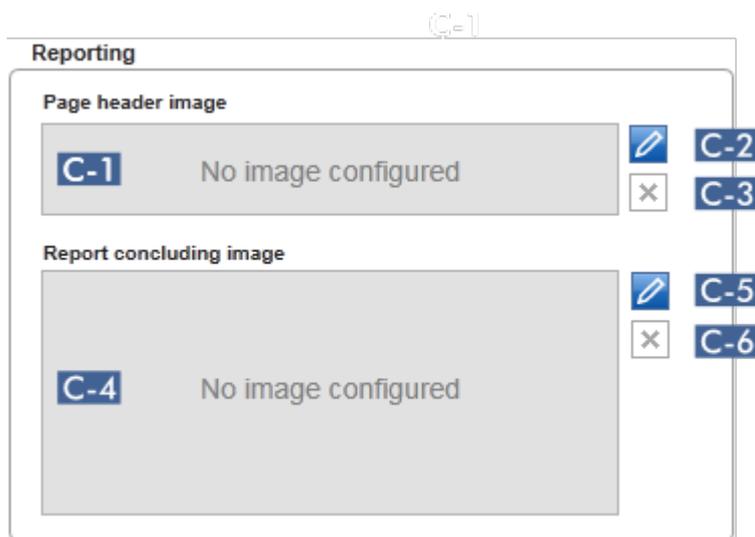
- Image in the header of every report page
- Image at the last page of the report

The following graphic illustrates these options:



The images must have one of the following formats:

- *.bmp
- *.jpg
- *.png



	Explanation
C-1	Displays a preview of the selected header image. If no image is selected, the message "No image configured" is shown.

C-2

Use to select a header image. The size of the header image must not exceed 1900 x 300 pixels.

Step-by-step procedure to select a header image

1. Click the pencil icon (**C-2**).

The file dialog opens.

2. Navigate to the directory with the image file and select it.
3. Click "OK".

The selected image is loaded and displayed in **C-1**. All generated reports will contain the selected image in its header.

Note

Select the appropriate image type in the file open dialog using the "File type" drop-down menu.



C-3

Remove a previously selected header image. After confirming a warning, the image preview will be removed from field **C-1**. The text "No image configured" is displayed.

C-4

Displays a preview of the selected finishing image. If no image is selected, the message "No image configured" is shown.

C-5

Use to select a finishing image.

Used to select a finishing image. The size of the finishing image must not exceed 1900 x 828 pixels.

Step-by-step procedure to select a finishing image

1. Click the pencil icon (**C-5**).

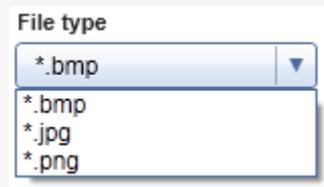
The file dialog opens.

2. Navigate to the directory with the image file and select it.
3. Click "OK".

The selected image is loaded and displayed in (C-4). All generated reports will contain the selected image on its last page.

Note

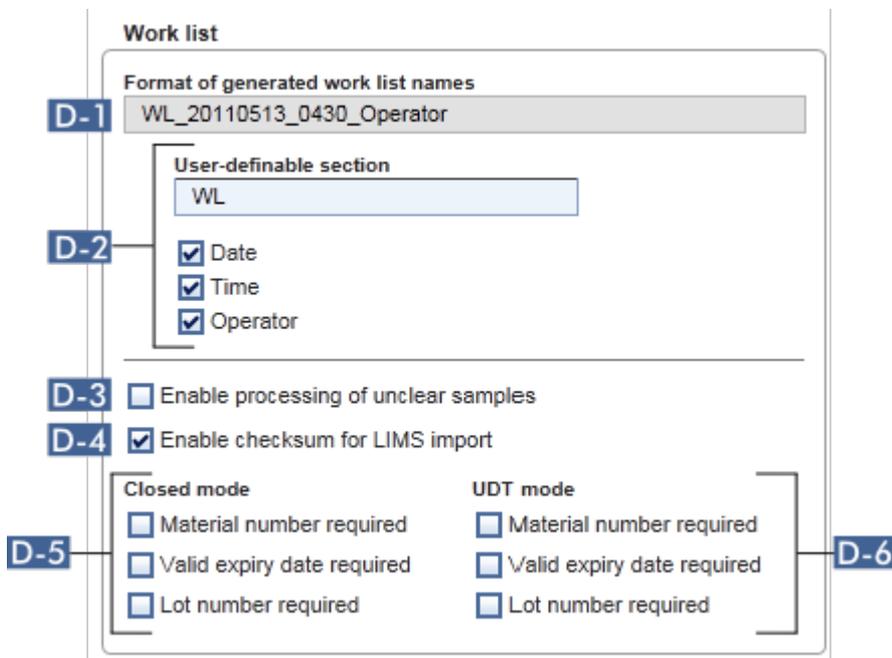
Select the appropriate image type in the file open dialog using the "File type" drop-down menu.



- C-6** Remove a previously selected finishing image. After confirming a warning, the image preview will be removed from field C-4. The text "No image configured" is displayed.

Group box "worklist"

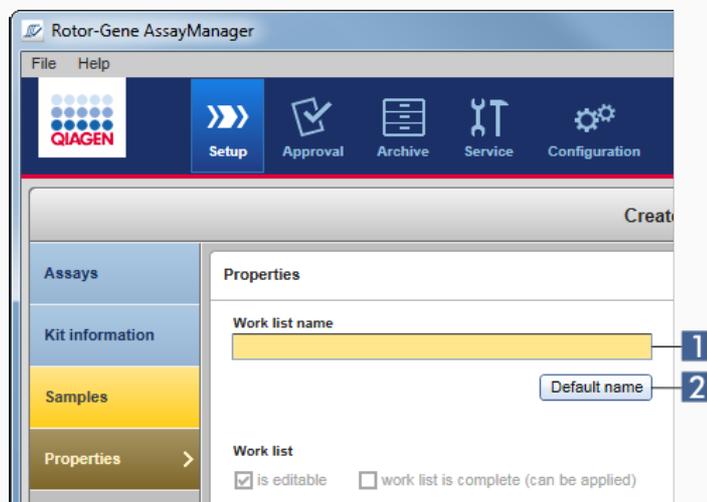
The "worklist" group box bundles various options concerning worklists, e.g., the naming scheme for default names, requirements for material numbers, etc.



Explanation

D-1 Displays the current default worklist name definition, as it results from the selected options in **D-2**.

D-2 When the user manually creates a new worklist in the "Setup" environment, a worklist name must be entered in the "Properties" step. The user can either enter an arbitrary name in the "worklist name" field (**1**) or let the Rotor-Gene AssayManager v2.1 automatically generate a default name by clicking the "Default name" (**2**) button.



The scheme for the default name can consist of up to 4 options:

- "User-definable section"
- "Date"
- "Time"
- "Operator"

Activating the check box in front of the last 3 options includes these information in the worklist name. The options are separated by a "_" character in the worklist name. A user definable section with a maximum of 15 characters is entered directly in the corresponding field. The order of the individual information cannot be changed. If a user definable section is defined, the resulting worklist name will always start with this section.

Rotor-Gene AssayManager v2.1 is delivered with the following default settings:

The screenshot shows a software interface with the following elements:

- A label "Format of generated work list names" above a text input field containing "WL_20120327_1319".
- A label "User-definable section" above a text input field containing "WL".
- Three checkboxes: "Date" (checked), "Time" (checked), and "Operator" (unchecked).

The text in the field "Format of generated worklist names", here `WL_20120327_1319`, results from the input in the user-definable section `WL`, the current date `20120327`, and the current time `1319`.

D-3 If this check box is activated, samples flagged as "unclear" during sample preparation or assay setup by QIASymphony software 5.0 will be handled as valid. An "UNCLEAR" flag is assigned to the valid sample result as a warning.

If the check box is not activated, unclear samples will be handled as "invalid" samples and no usable results are assigned by Rotor-Gene AssayManager v2.1 after the run is finished. Affected samples will get an "INVALID" flag as result.

Note

The QIASymphony sample flag "unclear" implies that there was a problem during sample preparation or assay setup (e.g., cooling temperature was not reached or the run was paused). Enabling the processing of unclear samples may cause doubtful sample results.

Note

The Rotor-Gene AssayManager v2.1 is only compatible with the results files of the QIASymphony software version 5.0.

D-4 If activated, the checksum algorithm is applied for worklist import from a LIMS. If not activated, Rotor-Gene AssayManager v2.1 does not verify the checksum of a worklist to be imported from a LIMS.

D-5 The options in **D-5** and **D-6** refer to the creation of a new worklist. In this first step of the worklist creation process, the user enters the number

D-6

of test samples. Optionally, the user can enter the material number, kit expiry date, and the lot number in the kit information dialog. If the check boxes in front of the options in the worklist group box are activated, the associated entries are mandatory during worklist setup. If the check boxes are not activated, the associated entries are optional. These options can be set independently for worklist setup in Closed Mode (options in **D-5**) and UDT Mode (options in **D-6**).

Note

For usage of the User Defined Test Mode (UDT mode) functionalities a compatible UDT mode plug-in is required to be installed.

Group box "Analysis/approval"

These settings influence the "Approval" environment.

Analysis / Approval

E-1 Enable possibility to ignore invalid controls (UDT mode)

E-2 Release of test results has to be signed

Explanation**E-1**

By checking the check box "Enable possibility to ignore invalid controls (UDT mode)", the "Set assay to be valid" check box in the "Approval" environment of the UDT mode (which is deactivated by default) can be activated.

The "Enable possibility to ignore invalid controls (UDT mode)" check box has the following functionality:

- If an assay in UDT mode is invalid, it can be manually set to be valid by checking the "Enable possibility to ignore invalid controls (UDT mode)" check box. Using this functionality, individual external controls that were evaluated as invalid by Rotor-Gene AssayManager v2.1 are excluded from the analysis. The test sample results are set to valid. Invalid quantitation standards will be excluded from standard curve calculation.

- If the "Enable possibility to ignore invalid controls (UDT mode)" check box is used for assay approval, this will be mentioned on the result report.

Note

For usage of the User Defined Test Mode (UDT mode) functionalities a compatible UDT mode plug-in is required to be installed.

E-2

If the check box is activated, the release of test results in the "Approval" environment has to be signed with the approver's password.

The following table illustrates this behavior by comparing the deactivated/activated check box and the resulting dialog in the release step of the "Approval" environment.

User must sign release of approved test results User must sign release of approved test results

✓
Release / Report Data

Create Report

Report Profile

Password

Messages

i The once released data can't be reset. (550197)

✓
Release / Report Data

Create Report

Report Profile

Password

Messages

✎ Enter your password to sign your approval electronically. (550201)

i The once released data can't be reset. (550197)

← Password field

User releases test samples simply by clicking "OK".

The approver's password must be entered before test samples are released. The "OK" button is disabled by default and will be activated once the correct password is entered.

Note

For the Gamma Plug-in, no user defined report profiles are applicable. The experiment data which will be included in the report are pre-defined by the assay.

Group box "Cycler verification management"

Cycler verification management

F-1 Disable unverified cyclers

	Explanation
F-1	<p>Rotor-Gene AssayManager v2.1 continuously checks the status of connected cyclers concerning verification.</p> <p>The option F-1 determines if cyclers with a verification status past due are automatically disabled or not.</p>
Activated 	<p>If the verification of a cycler is already expired, the cyclers' status is set to "Needs verification". This cycler is no longer available for experiments.</p> <p>To enable a cycler again, a temperature verification needs to be performed. An administrator needs to enter a valid, future "Next verification" date in the ► "Edit cycler" dialog.</p>

The image shows a software interface with two parts. On the right is a dialog box titled "Edit cyclers" with a pencil icon. It contains several fields: "Position" (four grey squares), "Cyclers type" (RGQ MDx), "Name" (Cycler 1), "Serial number" (0112101), "Optical configuration" (6plex), "Distribution channel" (255), "Next verification" (22.04.2015 with a calendar icon), "Days until next verification" (50), and a "Verification comment" text area. There are "OK" and "Cancel" buttons at the bottom right. On the left is a "Deactivated" section under "Cycler verification management" with a checkbox labeled "Disable unverified cyclers".

Deactivated
Cycler verification management
 Disable unverified cyclers

If the check box is deactivated, cyclers can be used for experiments even if the verification is already expired.

Group box "User management"

The settings in this group box influence the password renewal interval, password rules, and the auto-lock timer.

The image shows a "User management" group box with three settings:

- G-1** Password renewal interval: 30 days
- G-2** Use CLIA compliant password rules
- G-3** Auto-lock timer: 30 minutes

Explanation	
G-1	Defines the time interval for a renewal of user passwords. The value must be in the range of 0–999 days.

Note: If the value is set to 0, the password never expires.

G-2

If activated

Users must use CLIA compliant passwords. This means a password has to contain at least 2 upper case characters, 2 lower case characters, 2 numerical characters, and 2 special characters.

If deactivated

Password must have at least 8 and no more than 40 characters.

G-3

If there is no user interaction, the application will be locked automatically after the time defined here. The value must be in the range of 0–60 minutes.

Note: If the value is set to 0, the auto-lock is deactivated and the application will never be locked automatically.

Local settings

The user defines export directories and source directories for the local installation. These defined settings are applicable only to the local computer. The user can define a specific directory by clicking and selecting the specific export/source directory.

Local Settings

Default data export directories

A Report folder
C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Export\Reports Browse

Export results to LIMS

B LIMS output folder
C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Export\LIMS Browse

Export directories

Default data source directories

C Assay profiles for assay development
C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\AssayProfiles Browse

D Assay profiles for import
C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Import\AssayProfiles Browse

E Assay profiles for export
C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Export\AssayProfiles Browse

F Rotor-Gene experiment template files (.ret)
C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Import\ExperimentTemplates Browse

G Rotor-Gene quantitation template files (.qut)
C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Import\QuantitationTemplates Browse

Load sample IDs from QS SP Enable import of IDs for unclear samples

H C: Browse

Import Rotor-Gene AssayManager work lists

I C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Import\RotorGeneAssayManage Browse

Import QIASymphony work lists

J C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Import\QIASymphonyWorklists Browse

Auto import of QIASymphony work list (closed mode) Hide error messages for missi

C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Import\QIASymphonyWorklik Browse

Import LIMS work lists

K C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Import\LIMSWorklists Browse

L Experiments for import (closed mode)
C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Import\ExperimentsforClosedMode Browse

M Experiments for import (user defined test mode)
C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Import\ExperimentsforUDTMode Browse

N Exported experiments (closed mode)
C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Export\ExperimentsforClosedMode Browse

O Exported experiments (user defined test mode)
C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Export\ExperimentsforUDTMode Browse

P Report profiles
C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\ReportProfiles Browse

Q Support packages
C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\SupportPackages Browse

R Rotor-Gene experiments (.rex) for assay profile testing
C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\RexForAssayTest Browse

Source directories

	Explanation
A	Target directory where reports generated in the "Approval" or "Archive" environment are saved.
B	<p>Target directory where export data for a LIMS are saved. Initially, this option is disabled. To enable this option, the check box "Export results to LIMS" must be activated:</p> <p><input type="checkbox"/> Export results to LIMS</p> <p>If this check box is activated, results released in the "Approval" environment are exported in a LIMS compatible file to the specified directory. The target LIMS system must be configured in a way that it searches for new files in the same directory as specified here.</p>
C	<p>Source directory for assay profiles for development in UDT mode.</p> <div data-bbox="252 974 1273 1110" style="border: 1px solid #ccc; padding: 5px;"> <p>Note For usage of the User Defined Test Mode (UDT mode) functionalities a compatible UDT mode plug-in is required to be installed.</p> </div>
D	Source directory for assay profiles to be imported into the Rotor-Gene AssayManager v2.1 database via the "Assay Profiles" tab in the "Configuration" environment.
E	Source directory for assay profiles to be exported of the Rotor-Gene AssayManager v2.1 database via the "Assay Profiles" tab in the "Configuration" environment.
F	<p>Source directory for Rotor-Gene experiment template files (*.ret) used in the "Development" environment of the UDT mode.</p> <div data-bbox="252 1519 1273 1655" style="border: 1px solid #ccc; padding: 5px;"> <p>Note For usage of the User Defined Test Mode (UDT mode) functionalities a compatible UDT mode plug-in is required to be installed.</p> </div>
G	Source directory for Rotor-Gene quantitation template files (*.qut) used in the "Development" environment of the UDT mode.

Note

For usage of the User Defined Test Mode (UDT mode) functionalities a compatible UDT mode plug-in is required to be installed.

- H** Source directory for QIASymphony sample IDs to be imported into the Rotor-Gene AssayManager v2.1 with the option to import "unclear" sample IDs.

Load sample IDs from QS SP Enable import of IDs for unclear samples

Note

The Rotor-Gene AssayManager v2.1 is only compatible with the results files of the QIASymphony software version 5.0.

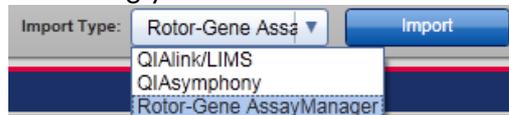
- I** Import Rotor-Gene AssayManager work lists

- J** Import QIASymphony work lists

In the closed mode an auto import of the QIASymphony software 5.0 worklist is possible each minute. Error messages for missing assay profiles can also be hidden.

Auto import of QIASymphony work list (closed mode)
 Hide error messages for missing assay profiles

Rotor-Gene AssayManager v2.1 can import worklists from other Rotor-Gene AssayManager v2.1 installations, QIASymphony software version 5.0, and LIMS. The user can select which of these 3 import options shall be available by activating the check boxes **I** – **K**. The import type menu in the "Setup" environment will be populated with the selected import options accordingly.



- K** Import LIMS work lists

- L** Source directory for closed mode experiments to be imported into the Rotor-Gene AssayManager v2.1 database via the "Import experiments" function in the "Archive" environment.

- M** Source directory for user defined test mode experiments to be imported into the Rotor-Gene AssayManager v2.1 database via the "Import experiments" function in the "Archive" environment.

- N** Destination for *.rex-files exported from the "Archive" environment (closed mode).

- O** Destination for *.rex-files exported from the "Archive" environment (user defined test mode).

Note

For usage of the User Defined Test Mode (UDT mode) functionalities a compatible UDT mode plug-in is required to be installed.

P Directory for importing and exporting report profiles.

Q Destination for support packages created from the "Approval" or "Archive" environment.

R Source directory for Rotor-Gene experiments (*.rex-files) to be tested in the "Development" environment of the UDT mode.

Note

For usage of the User Defined Test Mode (UDT mode) functionalities a compatible UDT mode plug-in is required to be installed.

Tasks related to the "Settings" environment

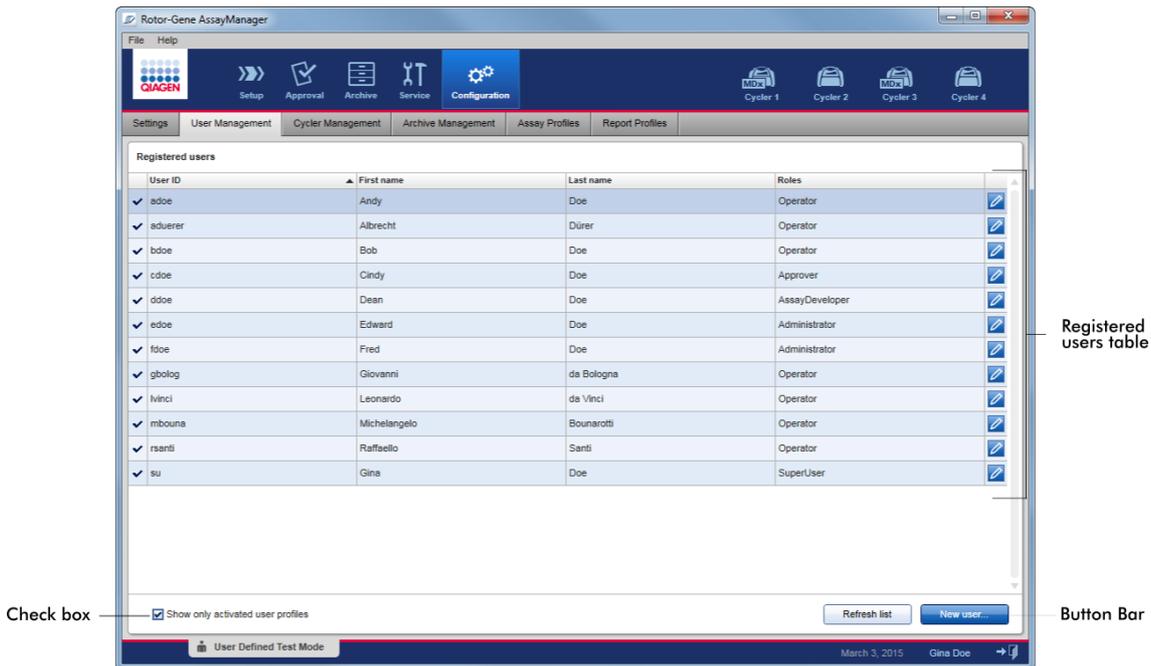
- ▶ Managing cyclers
- ▶ Managing report profiles
- ▶ Creating/editing a worklist
- ▶ Finishing and releasing a run
- ▶ Managing users

1.5.5.6.2 User Management

The "User Management" tab provides an overview of all configured user profiles and the possibility to manage these user profiles. For details about users and their roles refer to ▶ Concepts - user management.

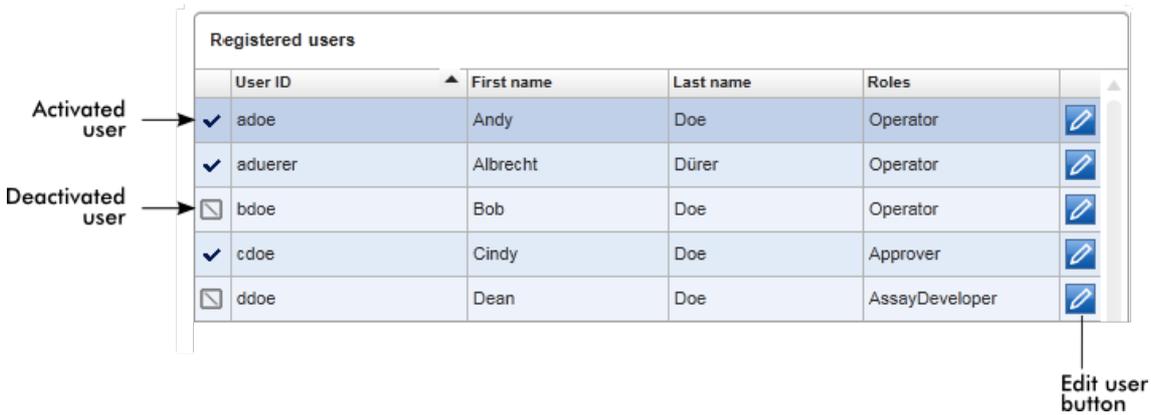
The "User Management" tab consists of 2 parts:

- "Registered users" table
- Button bar



"Registered users" table

The "Registered users" table lists all user profiles already configured in Rotor-Gene AssayManager v2.1. A user profile can be activated or deactivated. To display a deactivated user profile in the table, the "Show only activated user profiles" check box must be deactivated. The activation status of a user profile is displayed in the first column of the table.



Column	Explanation
User status	<p>Status of the user profile. A user profile can be deactivated or activated. The activation status is displayed by the icon in the first column of the table.</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> User is activated. <input type="checkbox"/> User is deactivated. <div style="border: 1px solid gray; padding: 5px; margin-top: 10px;"> <p>Note Deactivated user profiles will only be shown in the table if the "Show only activated user profiles" checkbox is deactivated. If the checkbox is activated, only activated users profiles will be shown.</p> </div>
"User ID"	Shows the user ID
"First name"	Shows the user's first name
"Last name"	Shows the user's last name
"Roles"	Shows the user's roles. In case multiple roles are assigned to a user, all roles are listed sequentially and separated by comma.
	<p>Example</p> <div style="display: flex; align-items: center;"> <div style="margin-right: 10px;"> <p>User with single role</p> <ul style="list-style-type: none"> Administrator Operator <p>User with single role</p> </div> <div style="border-left: 1px solid gray; border-right: 1px solid gray; padding: 5px; margin-right: 10px;"> <ul style="list-style-type: none"> Approver, AssayDeveloper, Operator AssayDeveloper, Operator </div> <div style="margin-left: 10px;"> <p>Users with multiple roles</p> </div> </div>
"Edit user" button	The "Edit user" button opens the "Edit User" dialog where properties and settings can be modified for a user.
	

	Label/Title	Description
A	"First name" field	Maximum 50 characters
B	"Last name" field	Maximum 50 characters
C	"User ID" field	ID must be unique and may not exceed a maximum of 40 characters. User IDs containing the words <i>QIAGEN</i> , <i>Service</i> , and <i>User</i> in combination are not allowed.
D	"Password" fields	Sets a new password for the user The password must be in the range of 8–40 characters. If CLIA complaint password rules are activated in the "Settings" tab, the password has to contain at least 2 upper

		<p>case characters, 2 lower case characters, 2 numerical characters, and 2 special characters.</p> <p>The password must be re-entered exactly in the "Confirm password" field.</p>
E	"Activate user" check box	<p>Activates or deactivates a user profile by clicking this check box</p> <p><input checked="" type="checkbox"/> Activate user User profile is activated.</p> <p><input type="checkbox"/> Activate user User profile is deactivated.</p>
F	"Messages" box	Displays information, warnings, and errors.
G	"Roles" selection list	<p>Assigns roles to a user profile. Activate the check box in front of a role to assign this role to the current user profile.</p> <p>It is possible to assign multiple roles to a user profile. For details see ► User roles.</p>
H	"OK" button	Confirms the current settings, closes the dialog, and goes back to the "User Management" tab.
I	"Cancel" button	Cancels the current settings, closes the dialog, and goes back to the "User Management" tab.

Button bar



	Label/Title	Description
A	"Refresh list"	This button is always enabled. Updates the "Registered users" table by retrieving the list of users from the internal database.
B	"New user..."	This button is always enabled. Creates a new user profile. The following "Add user" dialog is opened: <div data-bbox="459 942 1173 1672" data-label="Image"> </div> Characteristics upon opening the dialog: <ul style="list-style-type: none"> • All fields are initially empty

- The following mandatory fields are colored in yellow:
 - "First name"
 - "Last name"
 - "User ID"
 - "Password"
- The Activate user check box is activated
- No role is selected
- "OK" button is deactivated

All elements in this dialog are equal to the dialog described in the table above.

Confirm all entries with "OK" to go back to the "User Management" tab.

- Activated () The new user profile is added to the "Registered users" table and is selected.
- Deactivated () The new user profile is added to the internal database but not shown in the "Registered users" table.

Tasks related to the "User Management" tab

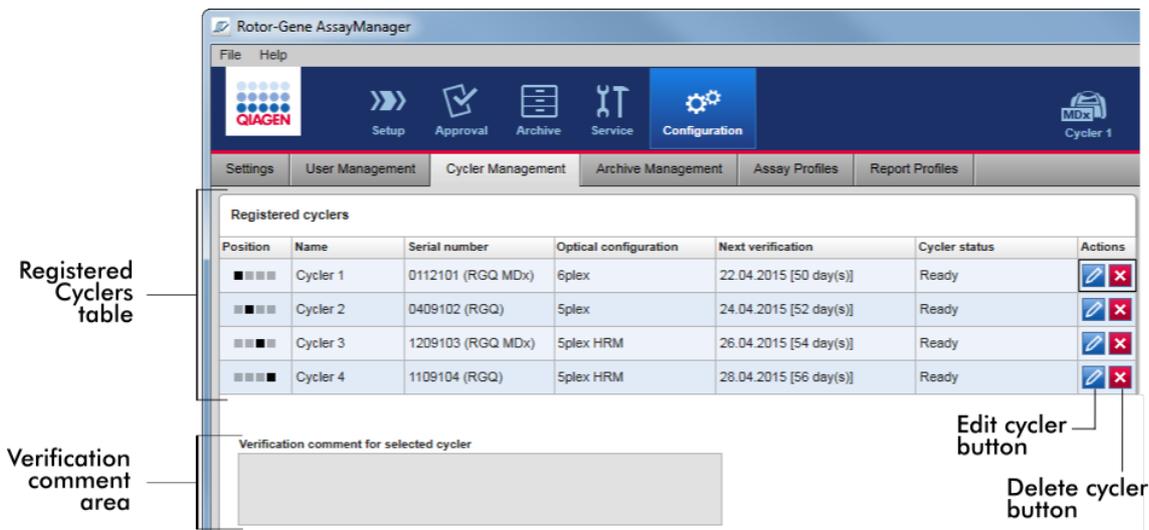
- ▶ Creating a user profile
- ▶ Changing user profile settings
- ▶ Activate/deactivate a user profile

1.5.5.6.3 Cyclor Management

The "Cyclor Management" tab gives an overview of the configured cyclers, their properties, and their current status.

The "Cyclor Management" tab mainly consists of 2 parts:

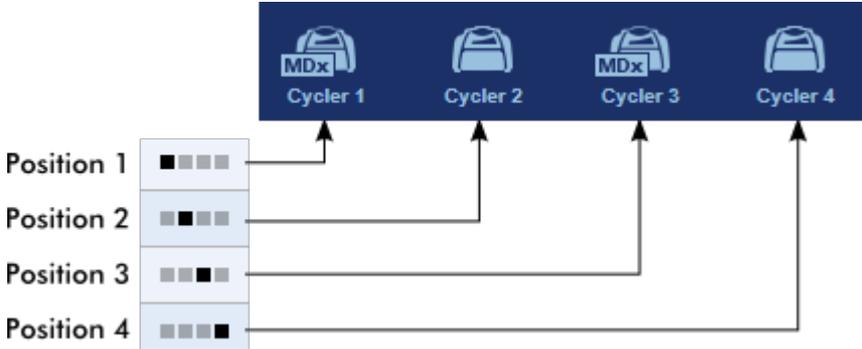
- "Registered Cyclers" table with 2 buttons for every cycler
 - "Edit cyclor" button
 - "Delete cyclor" button
- "Verification comment for selected cyclor" area



"Registered Cyclers" table

The "Registered Cyclers" table consists of 4 rows. Every row represents one of the up to 4 configurable cyclers. If no cyclers are configured yet, all columns except the position column are empty. The following graphic shows an example configuration with cyclers registered in positions 2 and 4. Positions 1 and 3 do not contain any data.

Registered cyclers						
Position	Name	Serial number	Optical configuration	Next verification	Cycler status	Actions
■ ■ ■ ■	---	---	---	---	---	 
■ ■ ■ ■	Cycler 2	0409102	5plex	18.06.2012 [61 day(s)]	Ready	 
■ ■ ■ ■	---	---	---	---	---	 
■ ■ ■ ■	Cycler 4	1109104	5plex HRM	22.06.2012 [65 day(s)]	Ready	 

Column	Explanation
"Position"	<p>A graphical illustration represents the configurable cyclers. The current cycler position is indicated by a black square.</p> <p>Example:</p>  <p>In the illustration above, the first and third cycler positions are not registered. Their icons are inactive.</p>
"Name"	<p>Name of a registered cycler.</p> <p>Characteristics</p> <ul style="list-style-type: none"> • Must not be empty • Must have 1–8 characters • Must be unique within a Rotor-Gene AssayManager v2.1 installation
"Serial number"	<p>Serial number of a registered cycler.</p> <p>Characteristics</p> <ul style="list-style-type: none"> • Must not be empty • Must be unique within a Rotor-Gene AssayManager v2.1 installation • Must match a connected cycler that is switched on <p>After entering the serial number of a connected cycler, its optical configuration is automatically checked by the Rotor-Gene AssayManager v2.1 and displayed in the "Optical configuration" box. This box remains empty if no cycler with the entered serial number is connected.</p>

Note: If the instrument is an RGQ MDx cyler the "MDx" symbol is automatically added to the serial number and the corresponding cyler symbol.

"Optical configuration"

Optical configuration of a registered cyler.

"Next verification"

Next temperature verification date and remaining days until that date.

Characteristics

- This field can be empty.
- If it is set to empty, the "Verification comment" text box is disabled and its content is cleared.
- If the date is expired, the "Verification comment" text box is disabled.
- If a date is set, the date must be in the future.

"Cyler status"

Shows the current status of a registered cyler. Possible values are:

Offline	Cyler is not connected or connected but not switched on.
Ready	Cyler is ready.
Needs verification	Verification has expired.
Loaded	The cyler is loaded and ready to be run.
Running	Cyler is currently running.
Run stopped	User has stopped a run while the cyler was running.
Run complete	Run has finished successfully.
Run failed	Error occurred during the run.
Run stopped, cyler disconnected	Cyler was disconnected when it had the status "Run stopped".
Run complete, cyler disconnected	Cyler was disconnected when it had the status "Run complete".

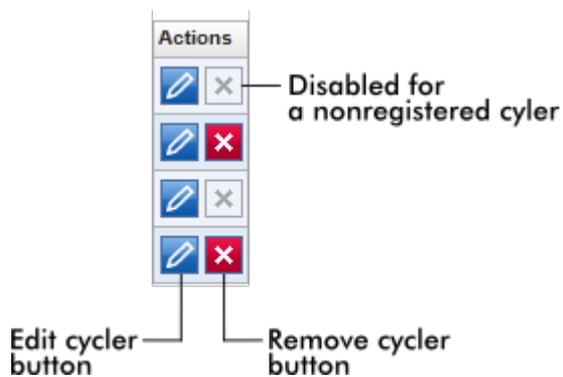
Run failed, cycler disconnected

Cyclor was disconnected during a run or when it had the status "Run failed".

"Actions"

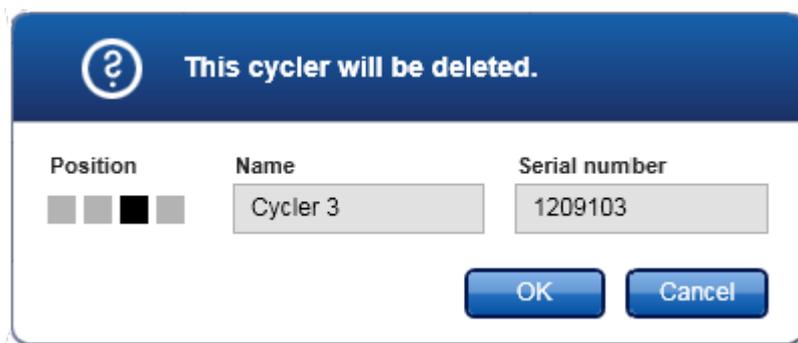
The actions column contains 2 buttons for:

- Editing the cyclor's properties
- Removing a cyclor



"Remove cyclor" button

If the "Remove cyclor" button is clicked, the following dialog will be displayed and has to be confirmed with "OK" to remove a cyclor finally:



"Edit cyclor" button

If the "Edit cyclor" button is clicked, the "Edit cyclor" dialog will be displayed.

Explanation

- A** A graphical illustration representing the up to 4 configurable cyclers. The current cyclers position is indicated by a black square.
- B** Name of the cyclers. The field can be edited.
- C** Optical configuration of the cyclers. The field cannot be edited; it is read-only.
- D** Next verification date. The date can either be entered manually or using the date picker (📅).
- E** Text field to enter an optional verification comment.
- F** Displays the cyclers type. The field will be automatically filled after serial number edition.
- G** Serial number of the cyclers. The field can be edited
- H** Distribution channel of the cyclers. The field cannot be edited; it is read-only.

I Displays the number of remaining days until the verification date. The field cannot be edited.

Tasks related to the "Cycler Management" tab

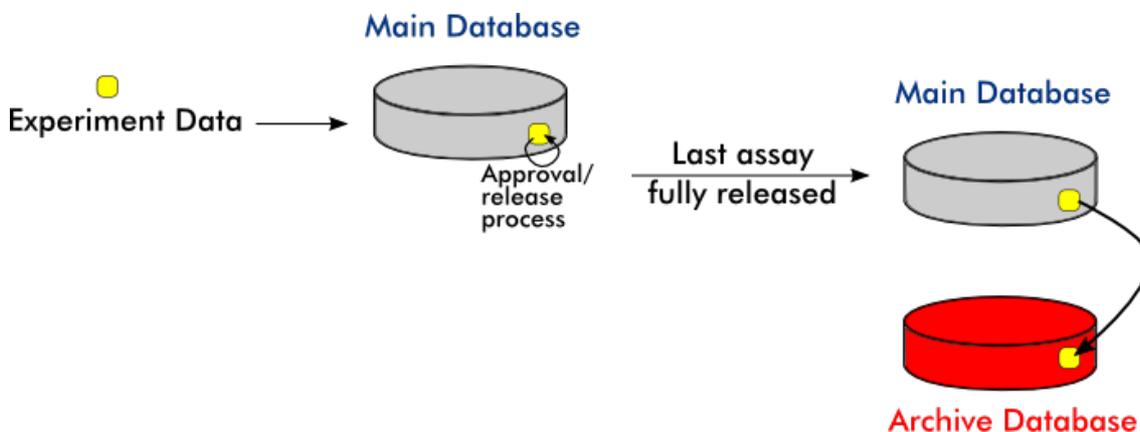
- ▶ Adding a cycler
- ▶ Editing cycler settings
- ▶ Removing a cycler

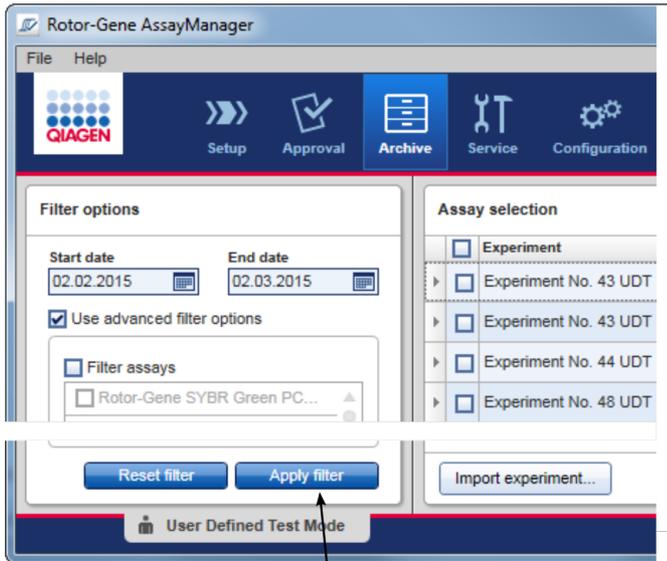
1.5.5.6.4 Archive Management

In the "Archive Management" tab, it can be defined which archives are browsed for experiment data during assay selection in the "Archive" environment.

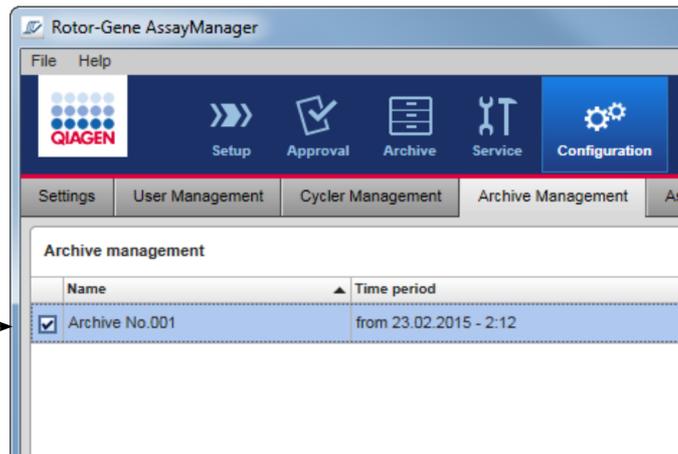
Background information

After finishing a run, all experiment data and audit trails are stored in the main database until all sample results of the experiment are released in the "Approval" environment. After release of the sample results the experiment data are accessible via the "Archive" environment.





Only archives activated in the Archive management are used to search for assays



Characteristics of an archive database

- An archive database covers a certain time span that is defined by the date of the first and the last audit trail message stored in the database.

Archive Management

	Name	Time period
<input checked="" type="checkbox"/>	Archive No.001	from 19.04.2008 - 19:30 to 31.12.2008 - 19:17

Time period of archive

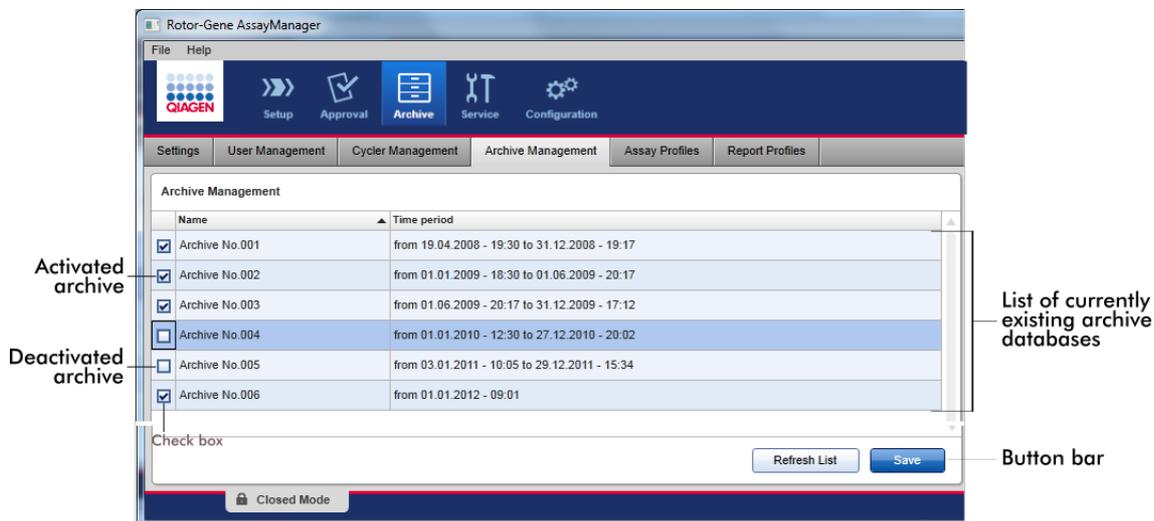
- An archive database has a size of 10 GB. If a database is close to its maximum capacity, the database is marked as "closed" and a new archive database is created automatically.

All these processes concerning the creation and management of archive databases are automatically performed in the background. The main database only contains data from current, non-released, or not fully released experiments.

Tasks related to the "Archive Management" tab

The "Archive Management" tab consists of 2 parts:

- "Archive Management" table
- Button bar



"Archive Management" table

The "Archive Management" table lists all currently existing archive databases.

Column	Explanation
Check box	A check box column indicates if an archive database is currently active or inactive. Only active archive databases will be browsed for experiment data searched from the "Archive" environment. Deactivated databases will not be included in a search. In addition, audit trail messages related to the archived experiments will not be shown in the "Service" environment if the dedicated archive database is deactivated.

- Activated
- The corresponding archive database will be browsed for experiment data when searched from the "Archive" environment.
 - Audit trail messages related to the experiments stored in the corresponding archive database can be found in the "Service" environment.
- Deactivated
- The corresponding archive database will not be browsed for experiment data when searched from the "Archive" environment.
 - Audit trail messages related to the experiments stored in this database and other audit trail messages in the time span of the database cannot be found in the "Service" environment.

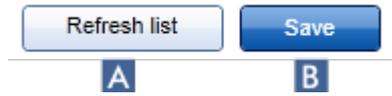
"Name" Name of the archive database.

"Time period" Time period covering all experiments in the archive.

Start date Creation date of the first audit trail entry in the database.

End date Creation date of the latest audit trail entry in the database.
The end date of the active archive is empty.

Button bar



	Label/Title	Description
A	"Refresh list"	Unsaved modifications are discarded.
B	"Save"	Saves all modifications.

Tasks related to the "Archive Management" tab

► Managing archives

1.5.5.6.5 Assay Profiles

The "Assay Profiles" tab in the "Configuration" environment is used to manage assay profiles, i.e., importing, exporting, activating, and deactivating assay profiles. Assay profiles cannot be edited in this tab.

Assay profiles can clearly be identified by their name and a version number. It is possible to have several assay profiles with the same name but different version numbers — but only one can be active. All other assay profiles with this name are automatically deactivated. User defined assay profiles have to be imported into the database within this tab to be accessible for experiment setup.

Note

Only assay profiles compatible to Rotor-Gene AssayManager v2.1 can be imported.

Example:

The following screenshot shows an example where an assay profile "Rotor-Gene SYBR® Green PCR Demo Kit" exists in two different versions, 3.0.0 and 5.0.0. Only one version can be active. Version 3.0.0 is deactivated (icon ) , and version 5.0.0 is activated (icon ).

<input type="checkbox"/>	Rotor-Gene SYBR Green PCR Demo Kit	3.0.0	SYBR
<input checked="" type="checkbox"/>	Rotor-Gene SYBR Green PCR Demo Kit	5.0.0	SYBR

The "Assay Profiles" tab consists of 2 parts:

- "Assay profiles management" table
- Button bar

List of available assay profiles

Name	Version	Short name	Plug-in type and version	Creation date
<input checked="" type="checkbox"/> 2Plex6PlexAP UDT	2.3.1	CMV	UDTBasic 2.0.0 UserDefin...	23.02.2015 15:14:23
<input checked="" type="checkbox"/> 2PlexAP UDT	2.3.1	CMV	UDTBasic 2.0.0 UserDefin...	23.02.2015 15:14:23
<input checked="" type="checkbox"/> 2PlexHRMAP UDT	2.3.1	CMV	UDTBasic 2.0.0 UserDefin...	23.02.2015 15:14:23
<input checked="" type="checkbox"/> 5Plex6PlexAP UDT	2.3.1	CMV	UDTBasic 2.0.0 UserDefin...	23.02.2015 15:14:23
<input checked="" type="checkbox"/> 5PlexHRMAP UDT	2.3.1	CMV	UDTBasic 2.0.0 UserDefin...	23.02.2015 15:14:23
<input checked="" type="checkbox"/> ACC_5ParamsCheck1 UDT	2.3.1	ACC	UDTBasic 2.0.0 UserDefin...	23.02.2015 15:14:23
<input checked="" type="checkbox"/> ACC_5ParamsCheck2 UDT	2.3.1	ACC	UDTBasic 2.0.0 UserDefin...	23.02.2015 15:14:23
<input checked="" type="checkbox"/> ACC_CycGroup_CG11 UDT	2.3.1	ACC	UDTBasic 2.0.0 UserDefin...	23.02.2015 15:14:23
<input checked="" type="checkbox"/> ACC_CycGroup_CG12 UDT	2.3.1	ACC	UDTBasic 2.0.0 UserDefin...	23.02.2015 15:14:23
<input checked="" type="checkbox"/> ACC_CycGroup_CG2 UDT	2.3.1	ACC	UDTBasic 2.0.0 UserDefin...	23.02.2015 15:14:23
<input checked="" type="checkbox"/> ACC_ExtlusiveLoading1 UDT	2.3.1	ACC	UDTBasic 2.0.0 UserDefin...	23.02.2015 15:14:23
<input checked="" type="checkbox"/> ACC_ExtlusiveLoading2 UDT	2.3.1	ACC	UDTBasic 2.0.0 UserDefin...	23.02.2015 15:14:23
<input checked="" type="checkbox"/> ACC_OptConf_2P2PM5P UDT	2.3.1	ACC	UDTBasic 2.0.0 UserDefin...	23.02.2015 15:14:23
<input checked="" type="checkbox"/> ACC_OptConf_2PM5P5PM UDT	2.3.1	ACC	UDTBasic 2.0.0 UserDefin...	23.02.2015 15:14:23
<input checked="" type="checkbox"/> ACC_OptConf_5PM6P UDT	2.3.1	ACC	UDTBasic 2.0.0 UserDefin...	23.02.2015 15:14:23
<input checked="" type="checkbox"/> ACC_OptConf_Unrestricted1 UDT	2.3.1	ACC	UDTBasic 2.0.0 UserDefin...	23.02.2015 15:14:23
<input checked="" type="checkbox"/> ACC_OptConf_Unrestricted2 UDT	2.3.1	ACC	UDTBasic 2.0.0 UserDefin...	23.02.2015 15:14:23
<input checked="" type="checkbox"/> ACC_Rotor36W72W UDT	2.3.1	ACC	UDTBasic 2.0.0 UserDefin...	23.02.2015 15:14:23
<input checked="" type="checkbox"/> ACC_Rotor72D100D UDT	2.3.1	ACC	UDTBasic 2.0.0 UserDefin...	23.02.2015 15:14:23
<input checked="" type="checkbox"/> ACC_Rotor72W72D UDT	2.3.1	ACC	UDTBasic 2.0.0 UserDefin...	23.02.2015 15:14:23

Check box

Button bar

"Assay profiles management" table

The "Assay profile management" table lists all available assay profiles, i.e., all assay profiles stored in the current Rotor-Gene AssayManager v2.1 installation. Every assay profile is displayed in a separate row. The table is sortable: Clicking the corresponding column header will sort the table according to the selected column. A row in the header of the corresponding column indicates the sorting column (▲ icon for ascending order, ▼ icon for descending order).

Assay profiles management					
	Name ▲	Version	Short name	Plug-in type and version	Creation date ▲
✓	QuantiFast Pathogen PCR +IC	2.0.0	QF Pat	UDTBasic 0.8.5 UserDefi...	23.03.2012 17:00:52
✓	Rotor-Gene SYBR Green PCR Demo Kit	3.0.0	SYBR	UDTBasic 0.8.5 UserDefi...	23.03.2012 16:54:04

Note

With the check box "Show only active profile versions" it can be determined if deactivated assay profiles are shown in the table or not.

Show only active profile versions

If activated Only activated assay profiles are shown; deactivated assay profiles are hidden.

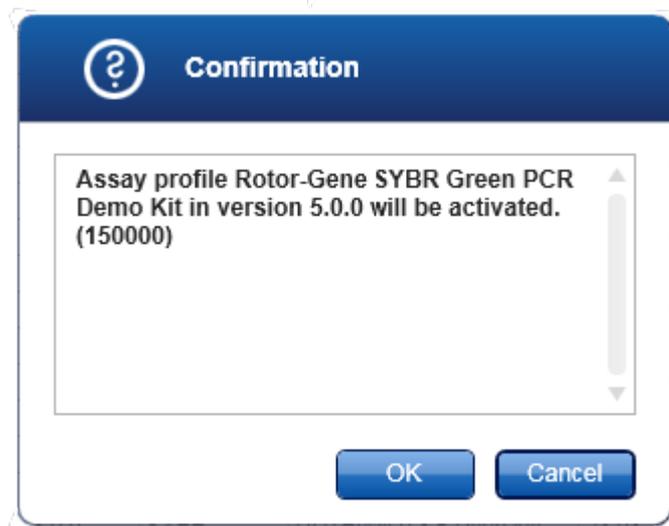
If deactivated Both activated and deactivated assay profiles are shown.

Column	Explanation
Status	<p>Status of the assay profile.</p> <ul style="list-style-type: none"> <input type="checkbox"/> Deactivated assay profile <input type="checkbox"/> Expired assay profile <input checked="" type="checkbox"/> Activated assay profile <div style="border: 1px solid gray; padding: 5px; margin-top: 10px;"> <p>Note In case that Rotor-Gene AssayManager v2.1 has been updated from an older version, there are also deactivated (expired) assay profiles. It is not possible to activated them.</p> </div>
"Name"	Name of the assay profile.
"Version"	Version number of the assay profile.
"Short name"	Short name of the assay profile.
"Plug-in type and version"	Plug-in type and version the assay profile was created with.
"Creation date"	Creation date of the assay profile.

Button bar



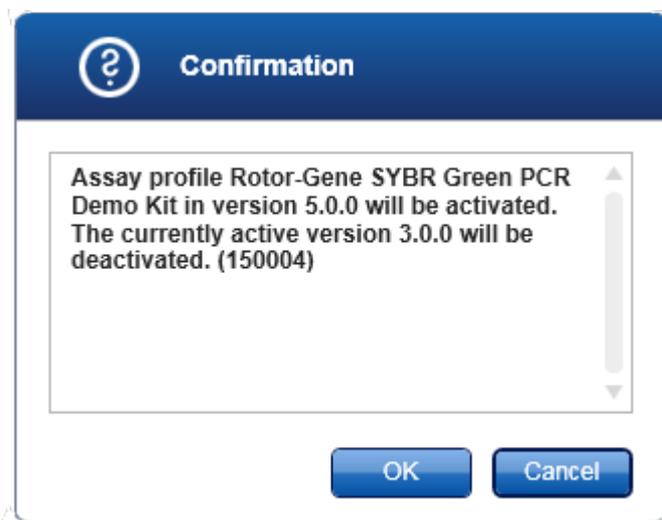
	Label/Title	Description
A	"Refresh list"	Updates the list of all available assay profiles.
B	"Deactivate"	<p>Deactivates the selected assay profile. A confirmation dialog must be confirmed by clicking "OK" before the selected assay profile is deactivated.</p> <div data-bbox="459 910 1129 1430" data-label="Image"> </div> <ul style="list-style-type: none"> • If the check box "Show only active profile versions" is deactivated, the deactivated assay profile is listed in the table with an <input type="checkbox"/> icon in its status column. • If the check box is activated, the deactivated assay profile is not listed in the table anymore.
C	"Activate"	Activates the selected assay profile. A confirmation dialog must be confirmed by clicking "OK" before the selected assay profile is activated.



The icon of the assay profile changes from deactivated () to activated ()

The check box "Show only active profile versions" must be deactivated to list activated and deactivated assay profiles in parallel in the table.

If another version of the assay profile is active, the following dialog is displayed.



Confirm with "OK" to disable the other version.

D

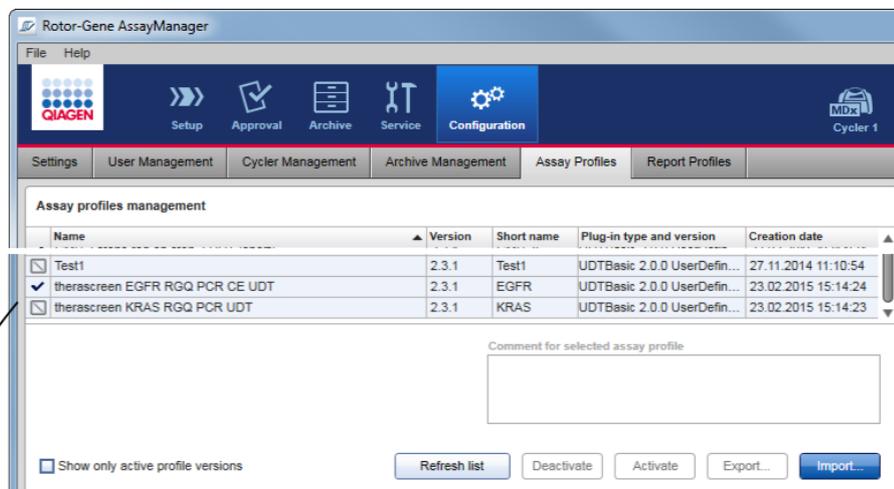
"Export..."

Exports an assay profile (file extension *.iap). A dialog is opened to select the destination directory and a file name.

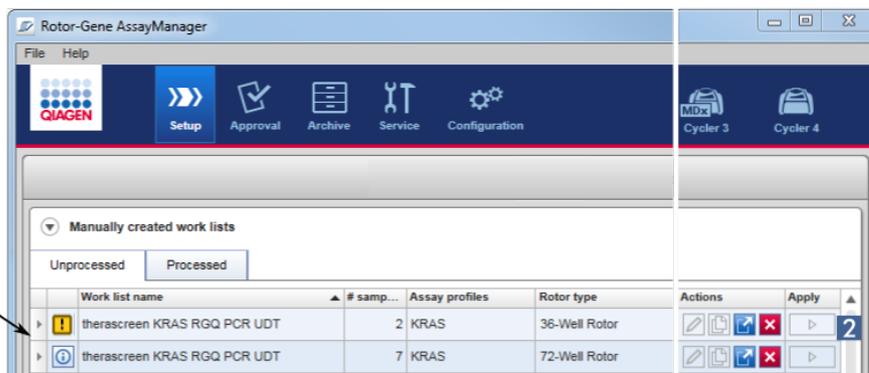
The selected assay profile will be exported accordingly.

- E** "Import..." Imports an assay profile. A dialog is opened to select the assay profile (file extension *.iap). The selected assay profile will be imported to the assay profile management table.

Explanation: Relationship between deactivating assay profiles in the "Configuration" environment and worklists in the "Setup" environment.



Assay profile deactivated in the **Configuration** environment



Consequence in the **Setup** environment:
Work lists containing the deactivated assay profile are displayed with a warning icon (1) and cannot be applied (2).

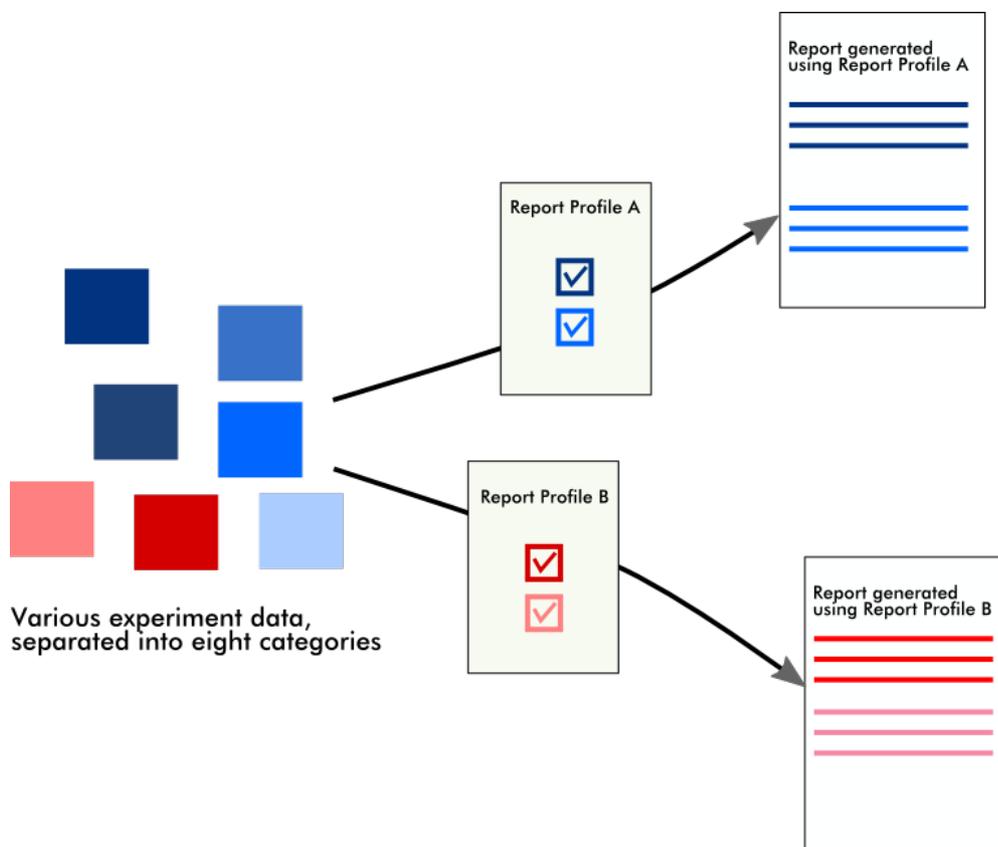
If an assay profile is deactivated in the "Configuration" environment, worklists in the "Setup" environment containing this assay profile cannot be applied anymore.

Tasks related to the "Assay Profiles" tab

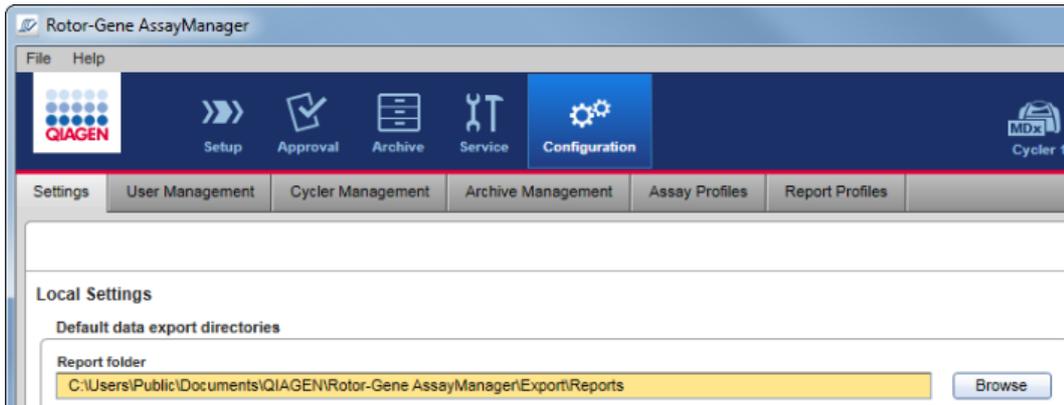
- ▶ Activating/deactivating an assay profile
- ▶ Importing/exporting an assay profile

1.5.5.6.6 Report Profiles

A report containing various data about an experiment can be generated by Rotor-Gene AssayManager v2.1 in a *.pdf file format. Depending on the individual needs, it is not always useful to include all available experiment information in a report. Therefore the content of a report can be tailored by configuring and applying different report profiles. In the "Report Profiles" tab different report profiles can be configured. This is done by selecting the useful information from 8 main categories and its subordinated content options. By applying the configured report profiles in the "Approval" or "Archive" environment, reports are created containing only the desired experiment information.



Report profiles are stored in the internal database. Report profiles can be exported to and imported from other Rotor-Gen AssayManager v2.1 installations. The default export and import directories for report profiles can be configured in the "Settings" tab of the "Configuration" environment.

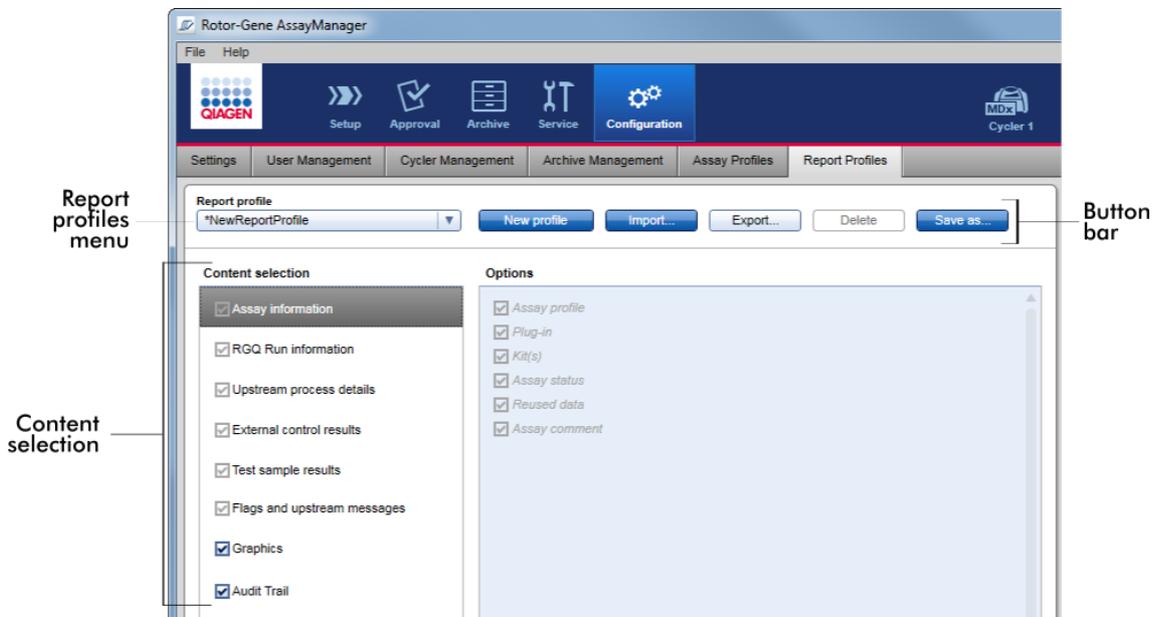


Note

QIAGEN specific report profiles cannot be copied or exported.

The "Report Profiles" screen consists of 3 elements:

- "Report profiles" menu
- Button bar
- "Content selection" area



"Report profile" menu

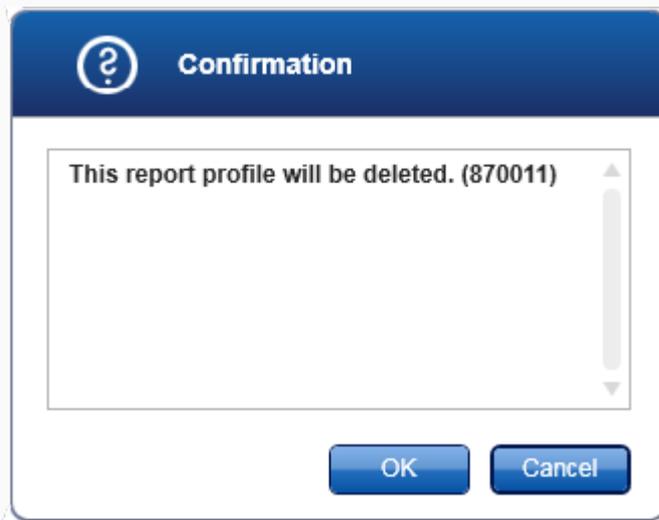
The "Report profile" drop-down menu contains all configured report profiles. The currently selected report profile is displayed in the menu. Clicking the menu arrow (▼) shows a full listing of all currently available report profiles.



Button bar

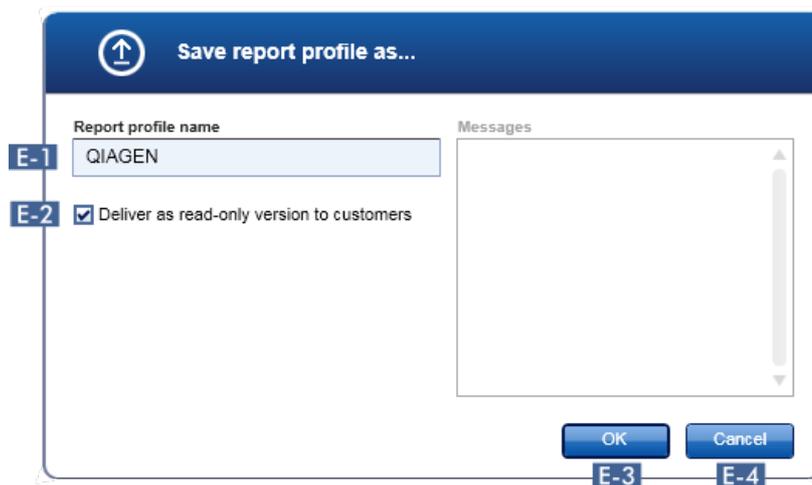


	Label/Title	Description
A	"New profile"	Creates a new report profile. All content selection options are activated by default for a new report profile.
B	"Import..."	Imports a report profile file (file extension *.irp). An import file dialog is shown where the report profile file to be imported can be selected.
C	"Export..."	Exports the currently selected report profile (file extension *.irp). An export file dialog is shown where the destination directory and file name for the report profile to be exported can be specified.
D	"Delete"	Deletes the currently selected report profile. A confirmation dialog must be approved.



Clicking "OK" removes the report profile from the internal database.

- E** "Save as..." Saves the configured report profile. The following dialog is opened:



- E-1** Field to enter a name for the report profile file.
- E-2** Saves the report file in the internal database using the name entered in field **E-1**.
- E-3** Cancels the process and closes this dialog.

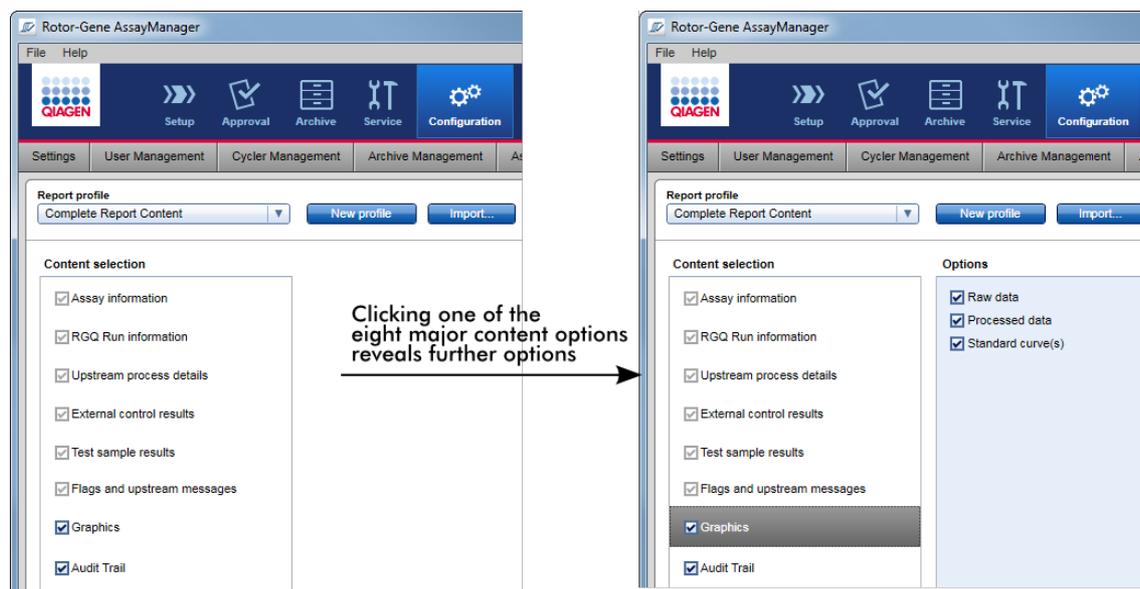
"Content selection" area

In the "Content selection" area, different experiment information can be selected to be included in a report profile by activating or deactivating the respective check boxes and radio buttons.

All available content options are grouped in 8 major categories:

- "Assay Information"
- "RGQ Run information"
- "Upstream process details"
- "External control results"
- "Test sample results"
- "Flags and upstream messages"
- "Graphics"
- "Audit Trail"

Clicking one of these major content categories opens the corresponding detailed content options. These are minor content options that allow a finer adjustment of the resulting report contents.



Some of the options for external controls and test samples (ID or position for example) are mandatory fields and cannot be deselected. These are always activated. All content options in the "Audit trail" major category are also mandatory and cannot be deselected.

Content selection

- Assay information
- RGQ Run information
- Upstream process details
- External control results
- Test sample results**
- Flags and upstream messages
- Graphics
- Audit Trail

Options

Table columns

- Position
- Color
- Style
- Sample ID
- Sample result
- Comment
- Approval
- Target
- Ct value
- Plug-in specific information
- Target result
- Flags

Deactivated option: mandatory, cannot be deselected

Check boxes: activate/deactivate an option

Content selection

- Assay information
- RGQ Run information
- Upstream process details
- External control results
- Test sample results
- Flags and upstream messages
- Graphics
- Audit Trail**

Options

- Time
- User
- Action
- Signed

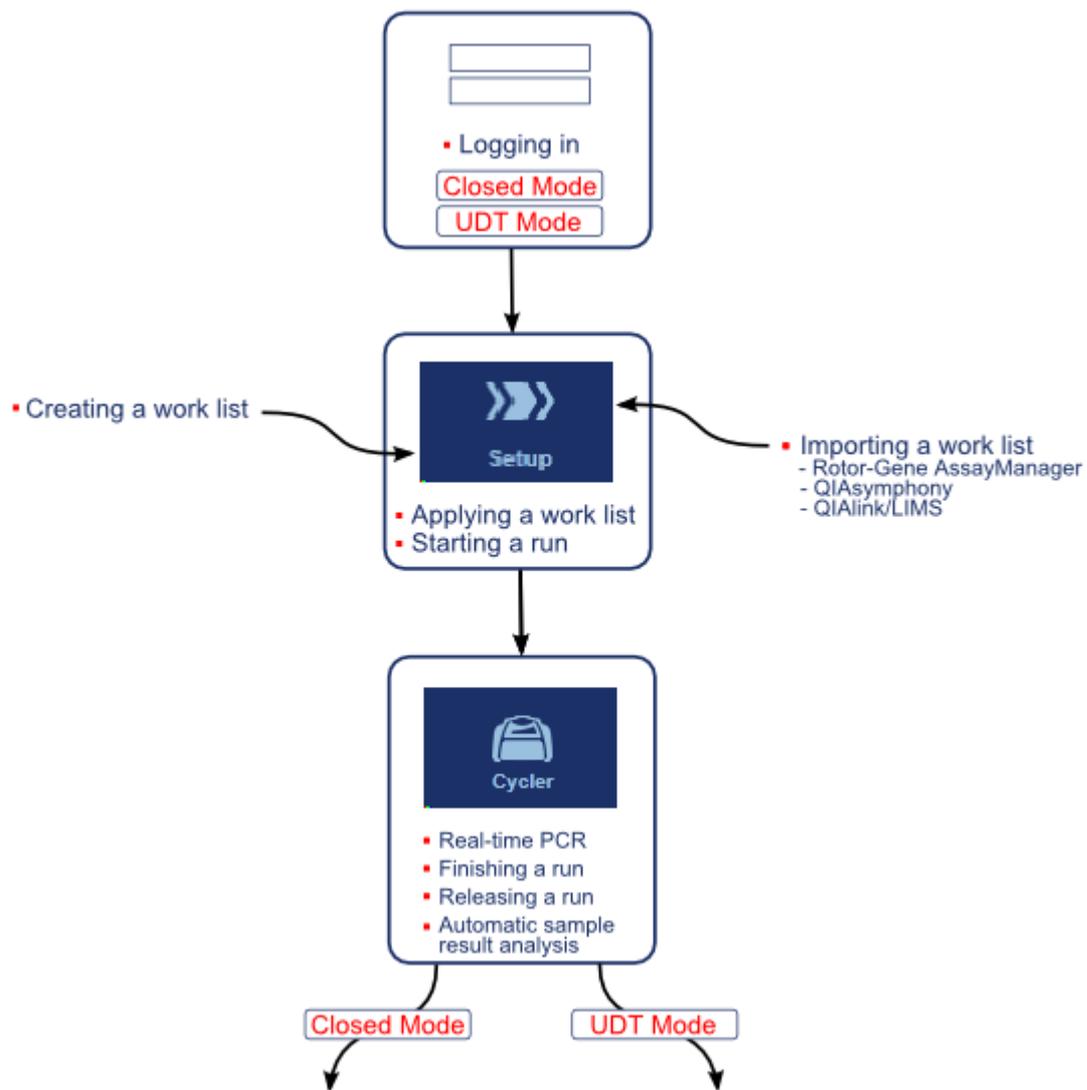
Audit trail: Mandatory entries, cannot be deselected

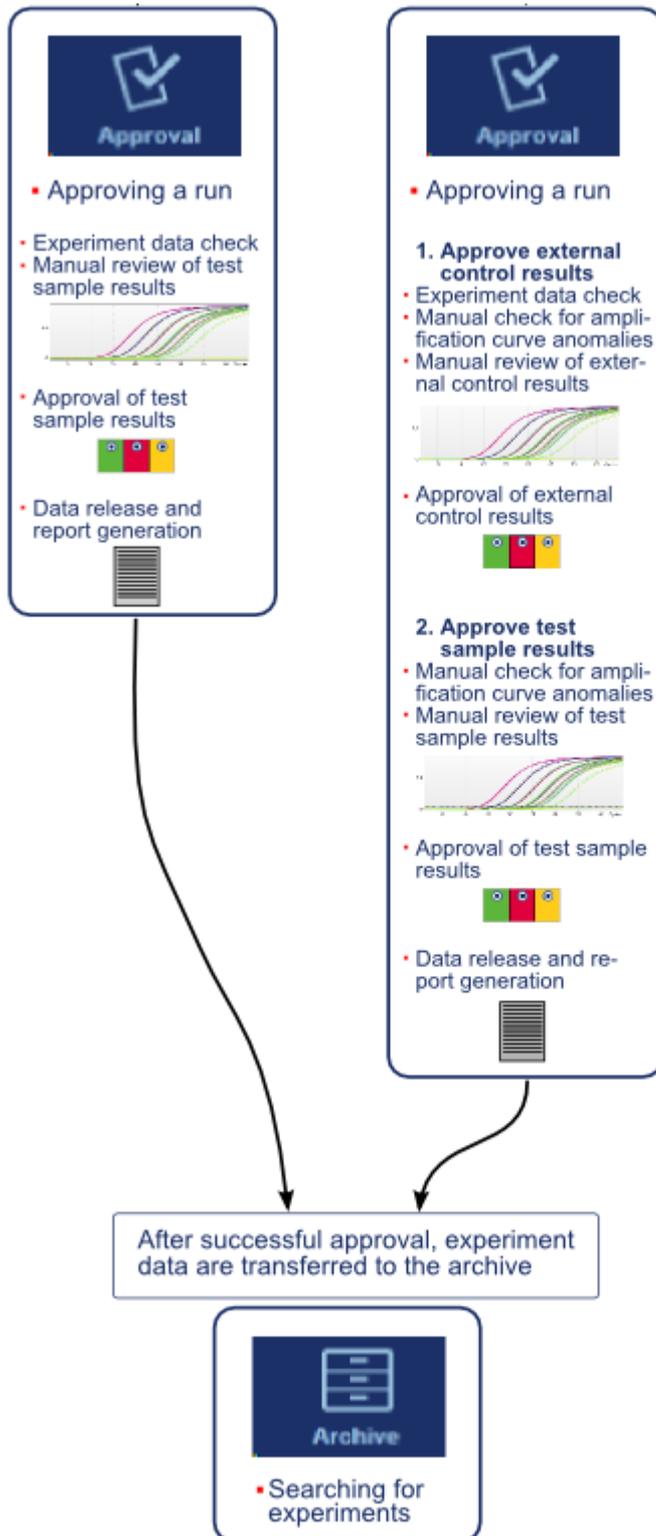
Tasks related to the report profiles tab

- ▶ Creating a new report profile
- ▶ Importing/exporting a report profile
- ▶ Deleting a report profile

1.5.6 General Work Flow

The following graphic summarizes the work flow in Rotor-Gene AssayManager v2.1.





Note

For usage of the User Defined Test Mode (UDT mode) functionalities a compatible UDT mode plug-in is required to be installed.

Note

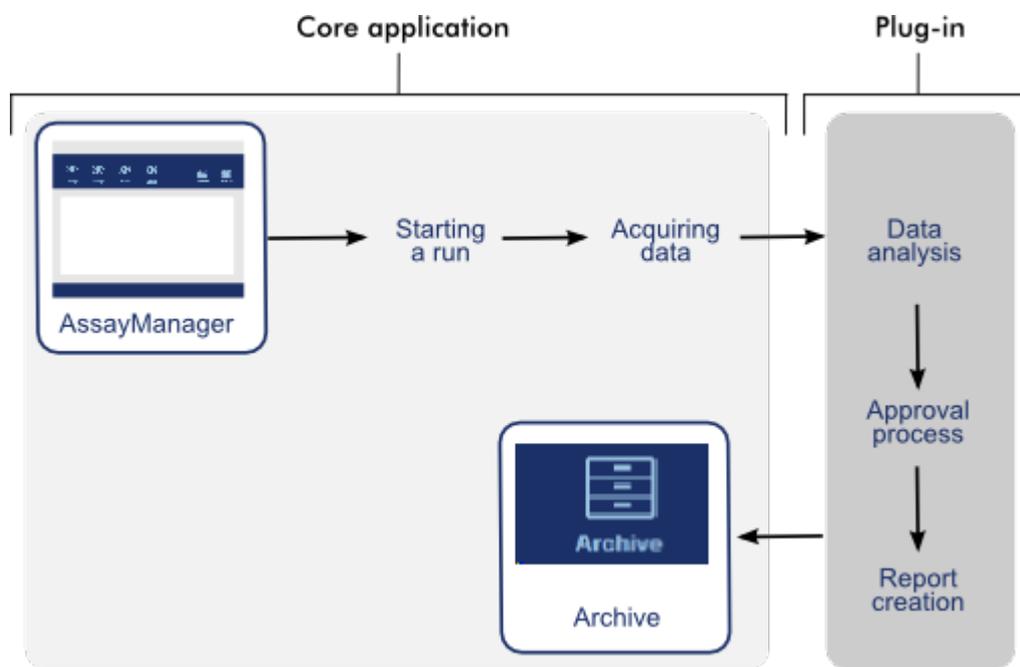
The Rotor-Gene AssayManager v2.1 is only compatible with the results files of the QIAAsymphony software version 5.0.

1.5.7 Plug-in Concept

Rotor-Gene AssayManager v2.1 is a versatile application with a plug-in architecture. With every plug-in the number of supported assays can be extended. The general work flow is provided by the core application and its frame work. The work flow for specific assays — including analysis — is provided by plug-ins. Plug-ins cover the control of the following tasks:

- Processing of acquired data
- Analysis algorithms
- Presentation of results (GUI layout of the approval work flow)
- Layout and structure of report contents
- Output to LIMS

The following graphic illustrates the plug-in concept:



1.6 Using Rotor-Gene AssayManager v2.1

The work flow in Rotor-Gene AssayManager v2.1 can be divided in 2 sections:

- ▶ Standard tasks
- ▶ Administrative tasks

Standard tasks are tasks that are performed on a daily basis.

Administrative tasks are tasks performed to manage and configure the work flow.

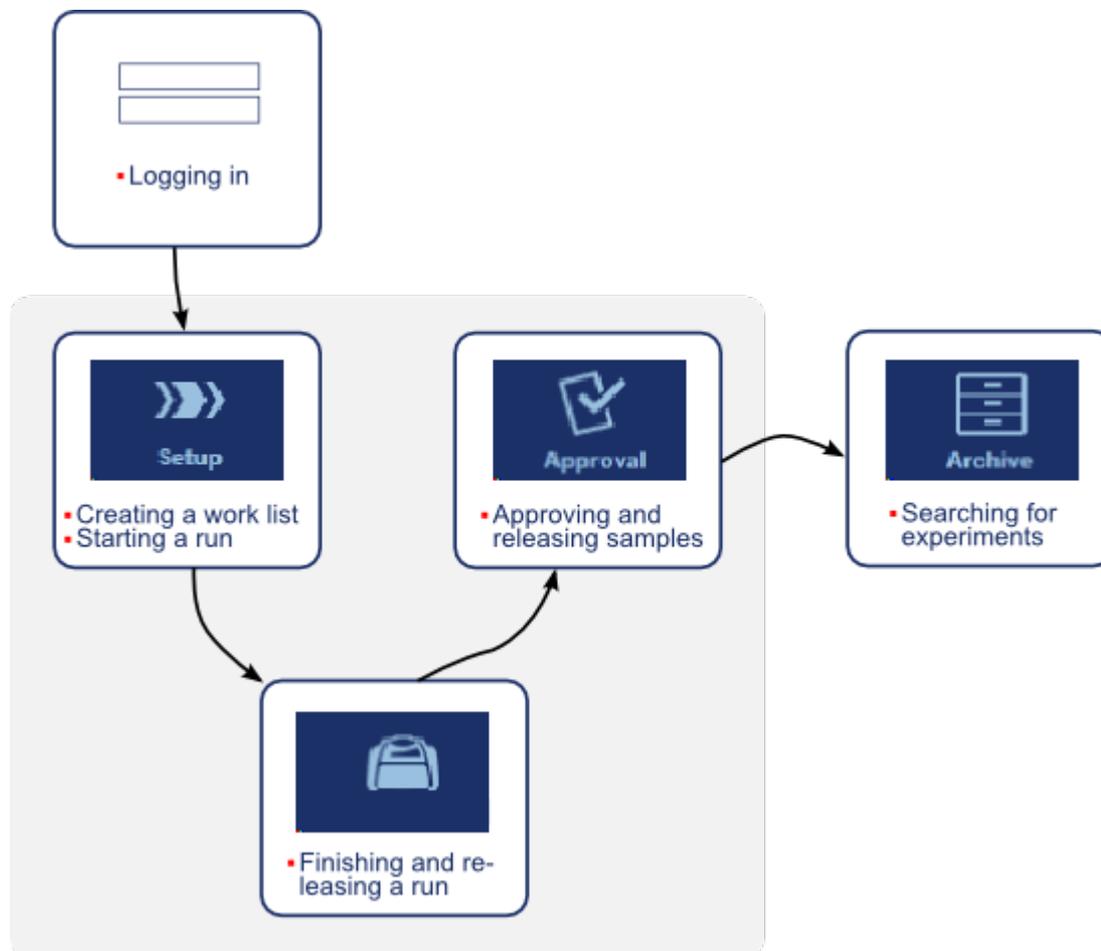
1.6.1 Standard Tasks

The following tasks are performed by users who are involved in the routine work of a lab, i.e., running experiments and analyzing data.

- ▶ Logging in and logging out
- ▶ Locking and unlocking
- ▶ Setting up a run
- ▶ Starting a run
- ▶ Finishing and releasing a run

- ▶ Approving a run
- ▶ Working with reports
- ▶ Working with audit trails

The following graphic gives an overview of the work flow in Rotor-Gene AssayManager v2.1:

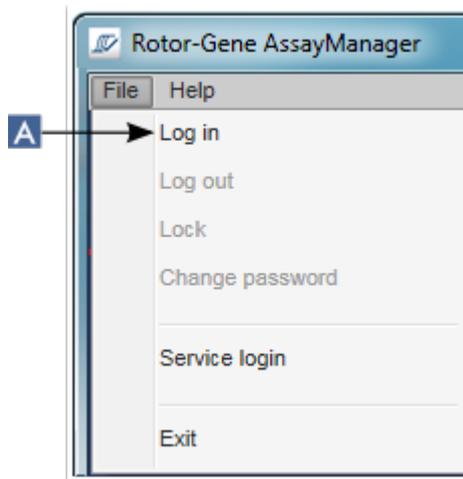


1.6.1.1 Logging In and Logging Out

All user interactions in Rotor-Gene AssayManager v2.1 are assigned to a specific user. Therefore, every user must be authenticated using a specific user ID and password. Before leaving the computer, a user is advised to lock the application or to log out.

Step-by-step procedure to log in to Rotor-Gene AssayManager v2.1

1. Launch Rotor-Gene AssayManager v2.1,
or
if a user has logged out from a previously launched session, select "Log in" (A)
from the main menu.



The login screen is shown.



2. Enter the user ID in "User ID" field (B).
3. Enter the password in the "Password" field (C).
4. Select *Closed* or *User Defined Test* from the "Mode" menu (D).
5. Click "OK" (E).

Note

For usage of the User Defined Test Mode (UDT mode) functionalities a compatible UDT mode plug-in is required to be installed. A log-in in UDT mode without installation of the corresponding plug-in will give you no access to administrative tasks and you will not be able to perform experiments or analysis.

The user is logged in and forwarded to the default screen that matches their role as listed in the table below. Users with multiple roles are forwarded to the default screen of their first matching role. For example, a user with the role Administrator is forwarded to the "Settings" tab in the "Configuration" environment. A user with roles Operator and Approver will be forwarded to the "Setup" environment.

Role	Environment	Screen/tab
Operator	"Setup" environment	"Available worklists" screen
Approver	"Approval" environment	Filter assays screen
Assay developer (if Closed Mode is selected)	"Configuration" environment	"Report Profiles" tab
Assay developer (if UDT mode is selected)	"Development" environment	Assay profile step
Administrator	"Configuration" environment	"Settings" tab
SuperUser	"Configuration" environment	"Settings" tab

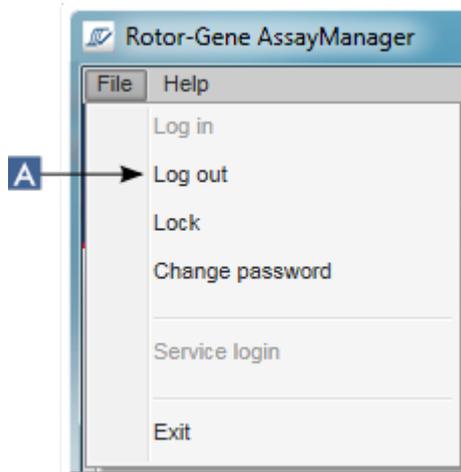
The selected mode is indicated at the bottom left of the screen:



Step-by-step procedure for logging out of Rotor-Gene AssayManager v2.1

The user can choose between 2 alternative methods to log out: The user can either use the log out command in the main menu or the log out button in the status bar.

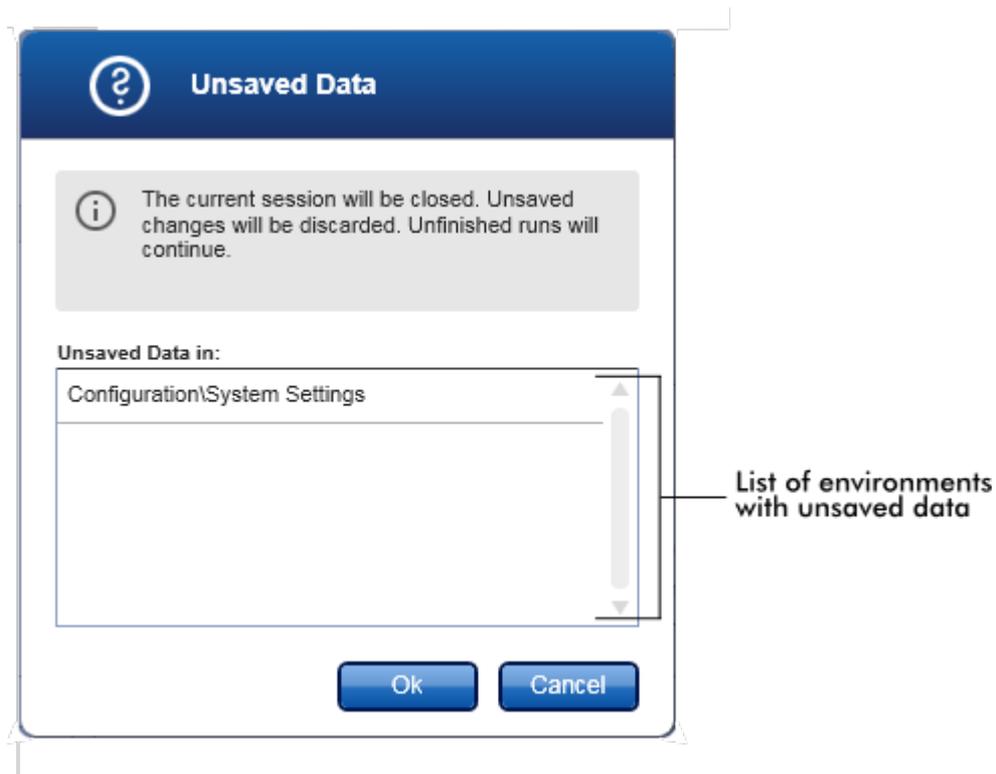
1. Click "Log out" (A) in the main menu,



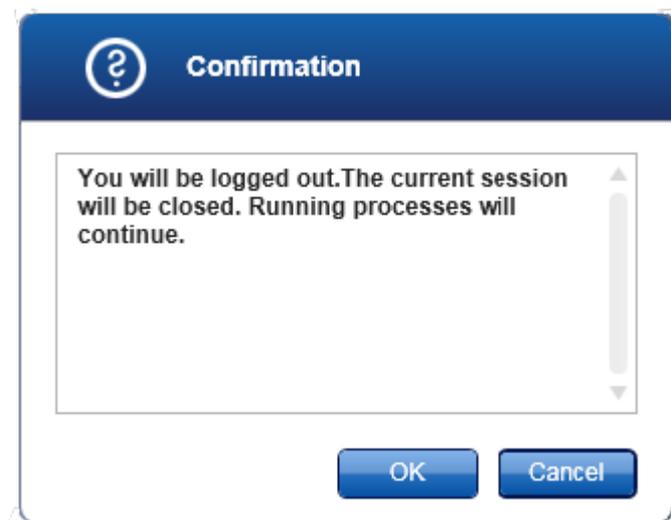
or
click "Log out" (B) in the status bar.



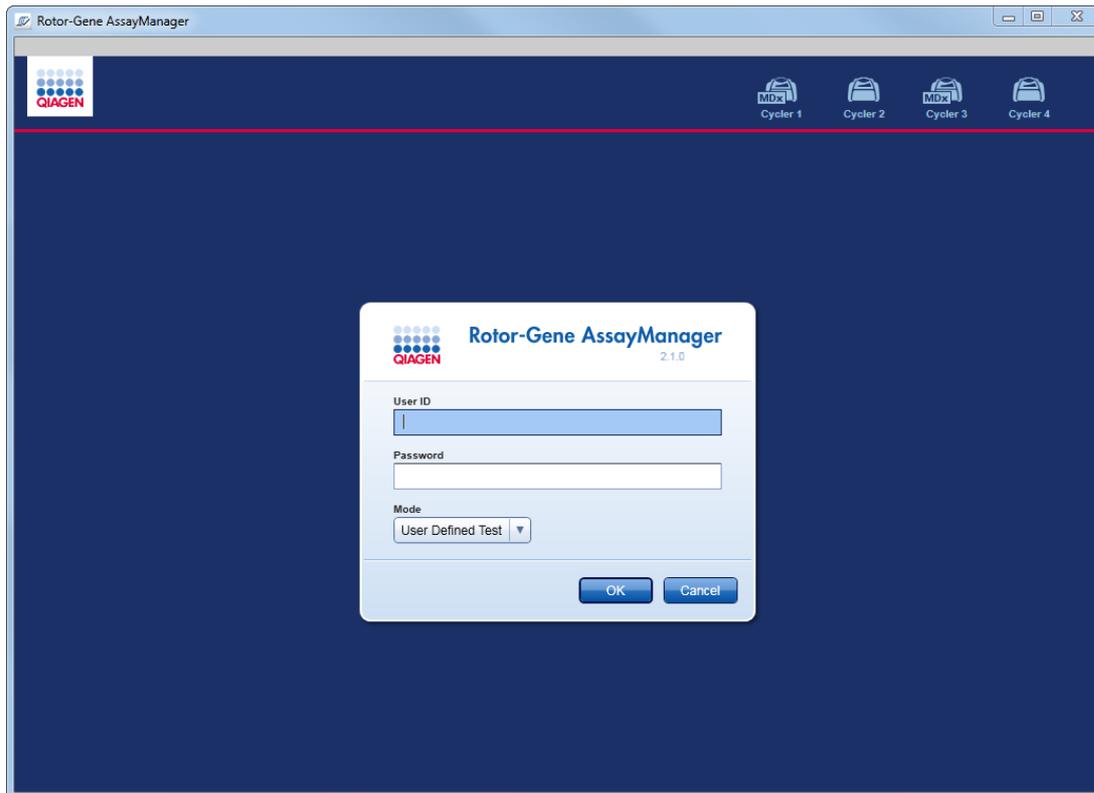
2. A confirmation dialog is shown. If unsaved data exist, an "Unsaved Data" dialog is shown with a list of all environments containing unsaved data:



Otherwise a standard confirmation log out dialog is shown:



3. Click "OK" (clicking "Cancel" cancels the log out and closes the dialog). The user is logged out and the login screen is shown.



Note

If a user logs out, active cyclers will continue.

Related topics

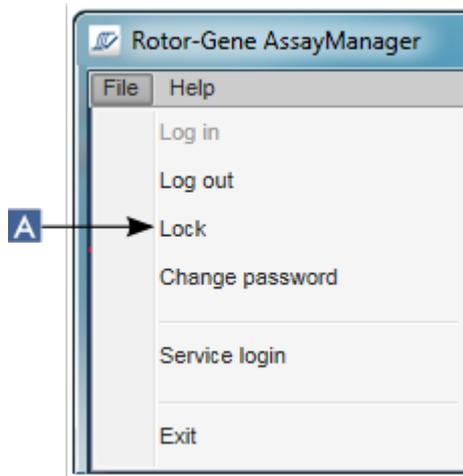
- ▶ Managing users
- ▶ Modes in Rotor-Gene AssayManager v2.1
- ▶ Session management
- ▶ Main toolbar
- ▶ Status bar

1.6.1.2 Locking and Unlocking

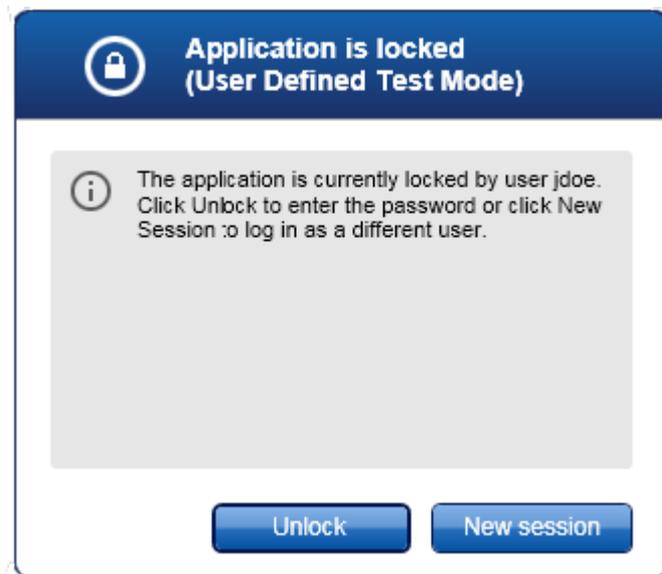
The application can be locked to restrict access. The locked application can be either unlocked by the user who has locked it, or a new session can be started.

Step-by-step procedure to lock Rotor-Gene AssayManager v2.1

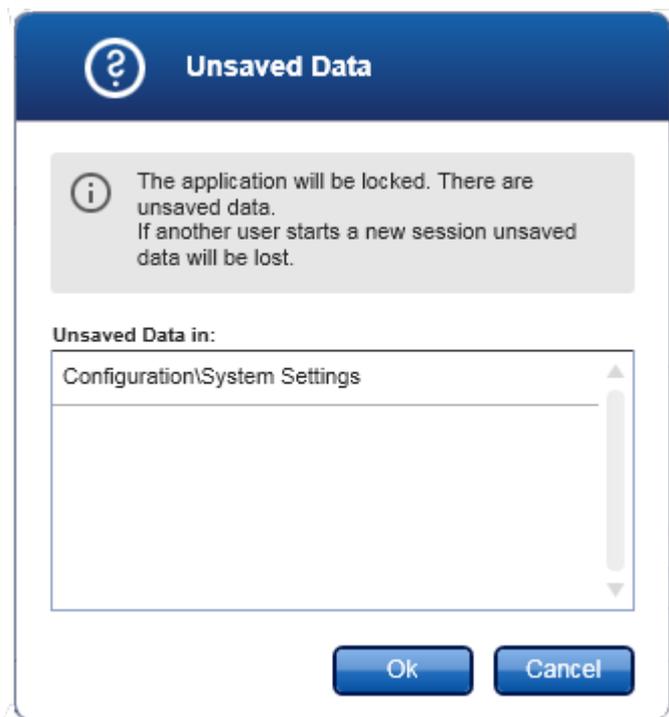
1. Click "Lock" in the main menu.



- If no unsaved data exist, the application is locked and the following dialog is displayed:



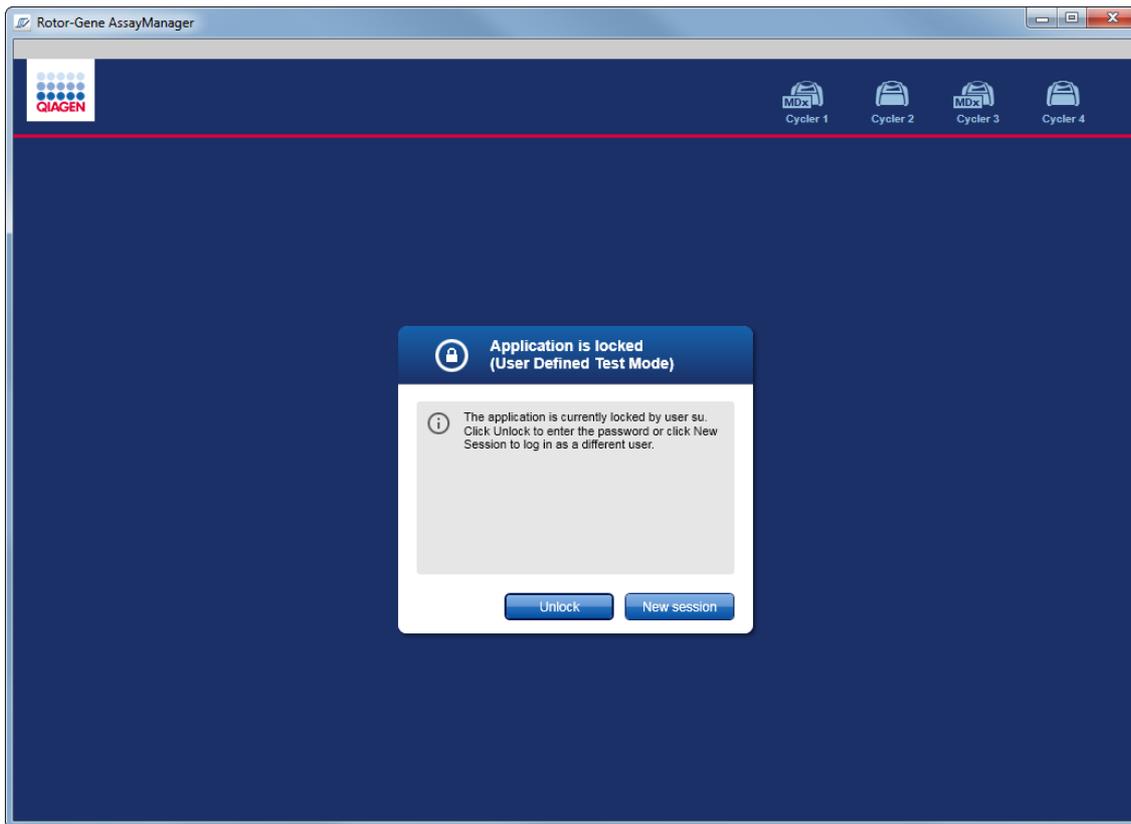
- If unsaved data exist, an "Unsaved Data" dialog is shown with a list of all environments containing unsaved data.



2. Confirming by clicking "OK" locks the application. The dialog above is shown.

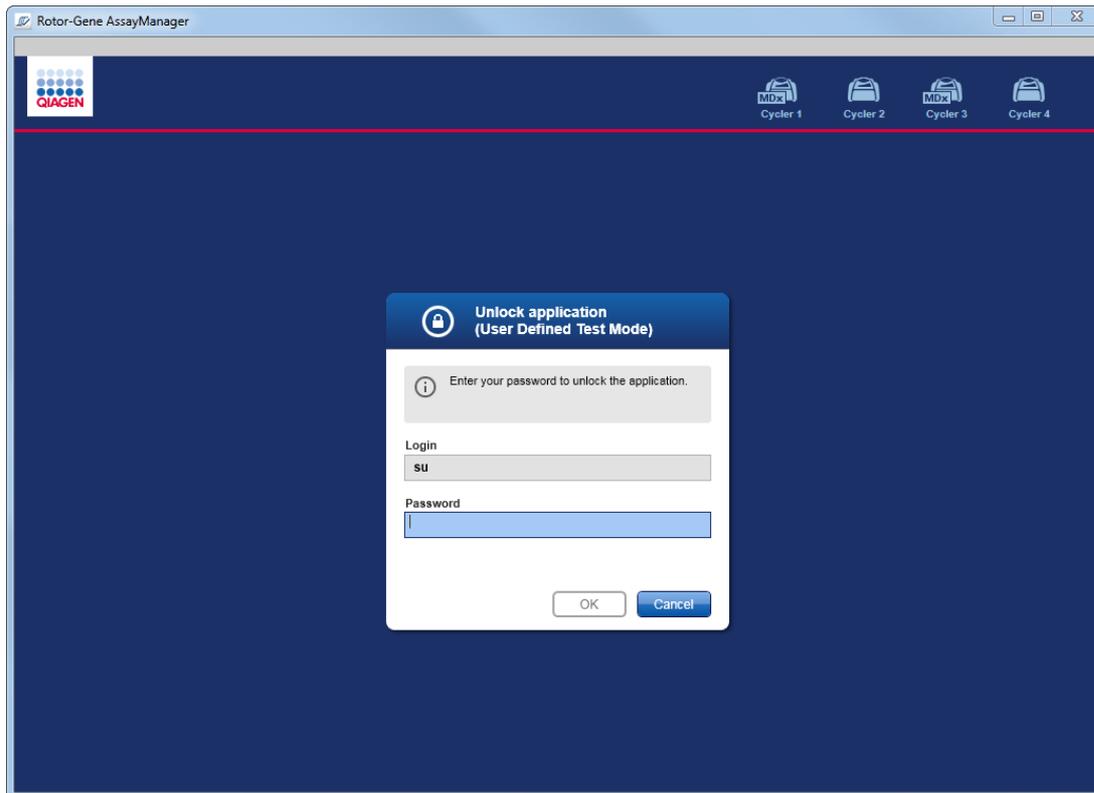
Step-by-step procedure to unlock Rotor-Gene AssayManager v2.1

Precondition is that the application was locked before. The following screen is shown:



1. Click "Unlock".

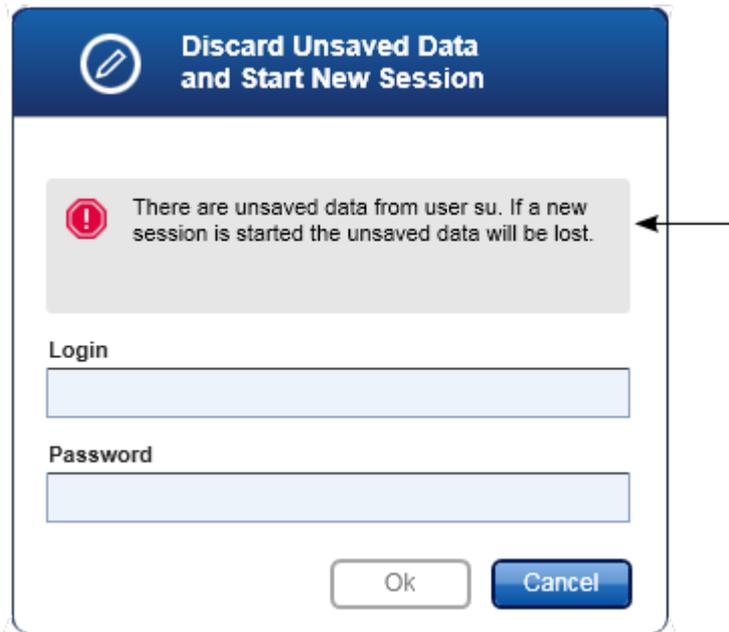
The following dialog is opened. Note that the user name in the login field is set to the user who locked the application prior. Only this user is allowed to unlock the application.



2. Enter the password in the "Password" field.
3. Click "OK".

The application is unlocked.

It is possible to start a new session if the application is locked by another user by clicking "New session". If the previously logged in user did not save all data, the following dialog is shown:



Related topics

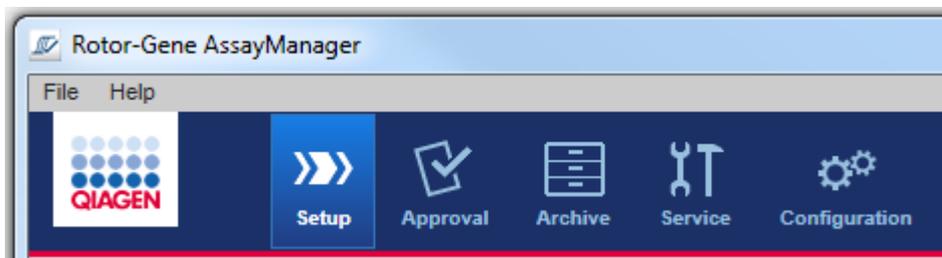
- ▶ Managing users
- ▶ Session management

1.6.1.3 Setting up a Run

Overview

A worklist is used to define an experiment, i.e., which assays shall be applied, their order, the number of samples, etc.

All tasks related to worklists are carried out in the "Setup" environment.



Tasks related to worklists

- ▶ Creating/editing a worklist
- ▶ Importing a worklist
- ▶ Duplicating a worklist
- ▶ Exporting a worklist
- ▶ Deleting a worklist

Note

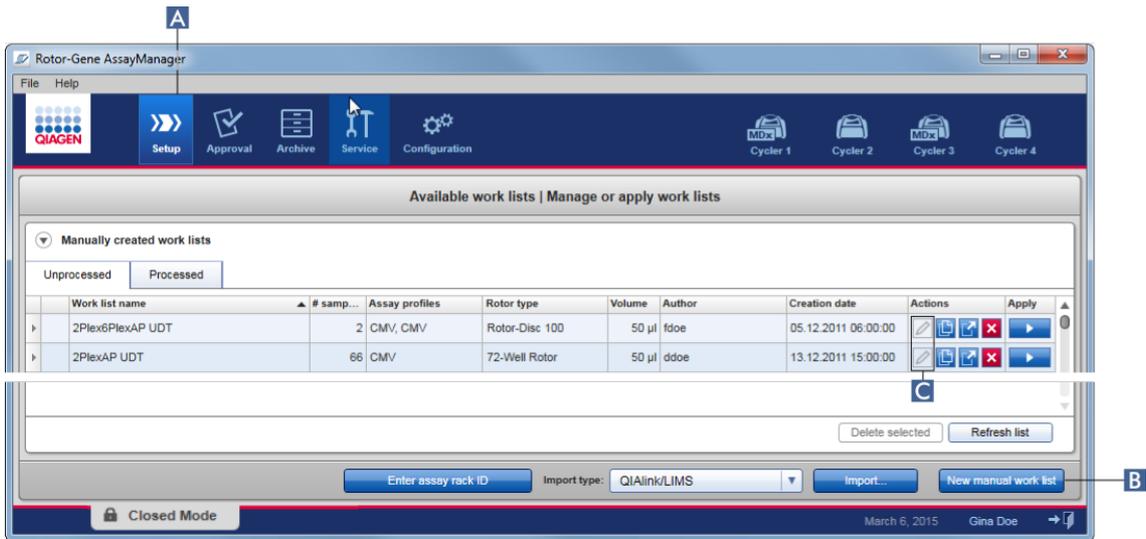
Use only assay kits with the same lot number for setting up an assay.

1.6.1.3.1 Creating/Editing a Worklist

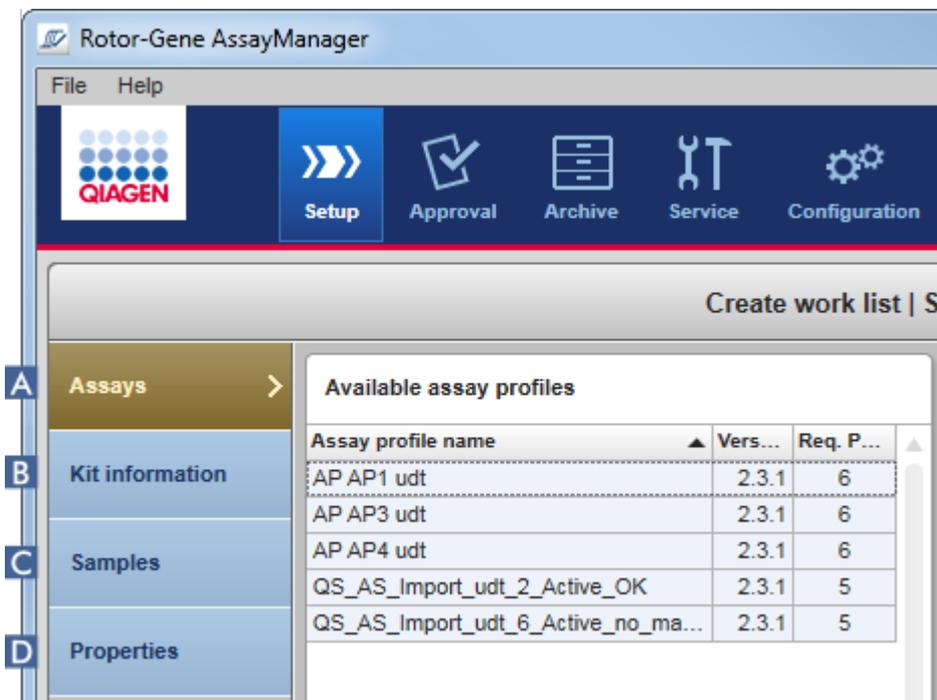
Overview

worklists combine one or more assay profiles that are intended to run in an experiment. The user creates a worklist by first selecting one or multiple compatible assay profiles. Optionally the user can adjust the material number, the kit expiration date, and the lot number. After defining the number of samples for the worklist, each individual sample has to get an ID. Finally, the user defines the name of the worklist, sets its properties, and saves the worklist. The user can save an unfinished worklist at any time and continue with the definition later.

A worklist is created and imported in the "Setup" environment (A). This environment automatically appears on login for users with the role of an operator. Initially, the "Available worklists" screen is shown with a list of all manually created worklists (further subdivided into "Unprocessed" and "Processed" worklist), and a list with all automatically generated and available worklists on the system. Clicking the "New manual worklist" button (B) at the bottom right of the screen changes to the "Create new worklist" screen where the new worklist is set up.



The "Create new worklist" screen comprises 4 different steps:



	Name	Description
A	"Assays"	<p>Select or enter the following data:</p> <ul style="list-style-type: none"> • One (or multiple, compatible) assay profile(s) • Rotor type • Reaction volume • Number of samples • Chose if new strip tubes shall be used (option for multi-assays)
B	"Kit information"	<p>Scan or enter the kit information manually. The kit information contains following data:</p> <ul style="list-style-type: none"> • Kit bar code • Material number • Kit expiration date • Lot number
C	"Samples"	<p>The assay setup is displayed as defined in the assay profile. Enter IDs for each test sample. Optionally add a comment. Line colors and line styles for amplification curves can be adapted.</p> <p>The order of the samples cannot be changed. The order is defined by the assay profile and the order of different assay profiles selected in the "Assays" step, if applicable.</p>
D	"Properties"	<p>The creation of a worklist process is finalized by activating 2 different options:</p> <ul style="list-style-type: none"> • "worklist is editable" • "worklist is complete (can be applied)"

Note

- Unsaved changes will not be lost if the user changes to another environment.
- The "Setup" environment is not a wizard, i.e., the steps do not need to be followed in a specific order.
- A new worklist can be saved in an uncompleted state. It is sufficient that at least a valid worklist name is provided.

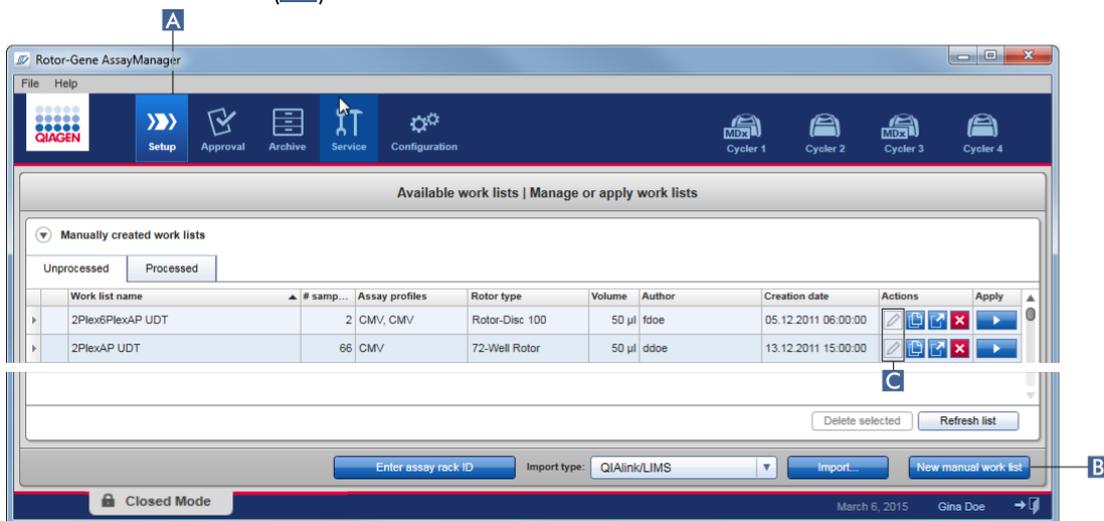
Step-by-step procedure to create a new worklist

Creating a new worklist comprises 6 steps:

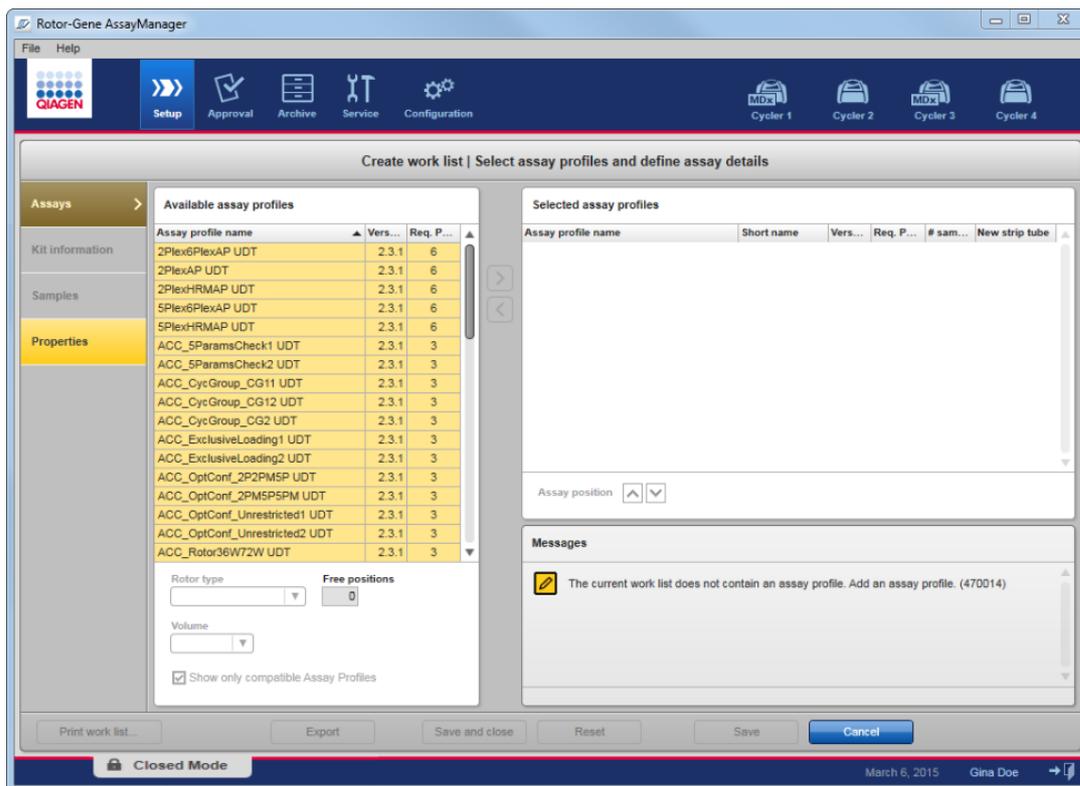
1. Create a new, empty worklist.
2. Add one (or multiple) assay profile(s) to the worklist ("Assays" step).
3. Scan or enter the kit information
4. Assign sample IDs ("Samples" step).
5. Define the properties of the worklist ("Properties" step).
6. Save the worklist.

Step 1: Create a new, empty worklist

- a) If it is not active yet, change to the "Setup" environment by clicking the "Setup" icon in the main toolbar (A).



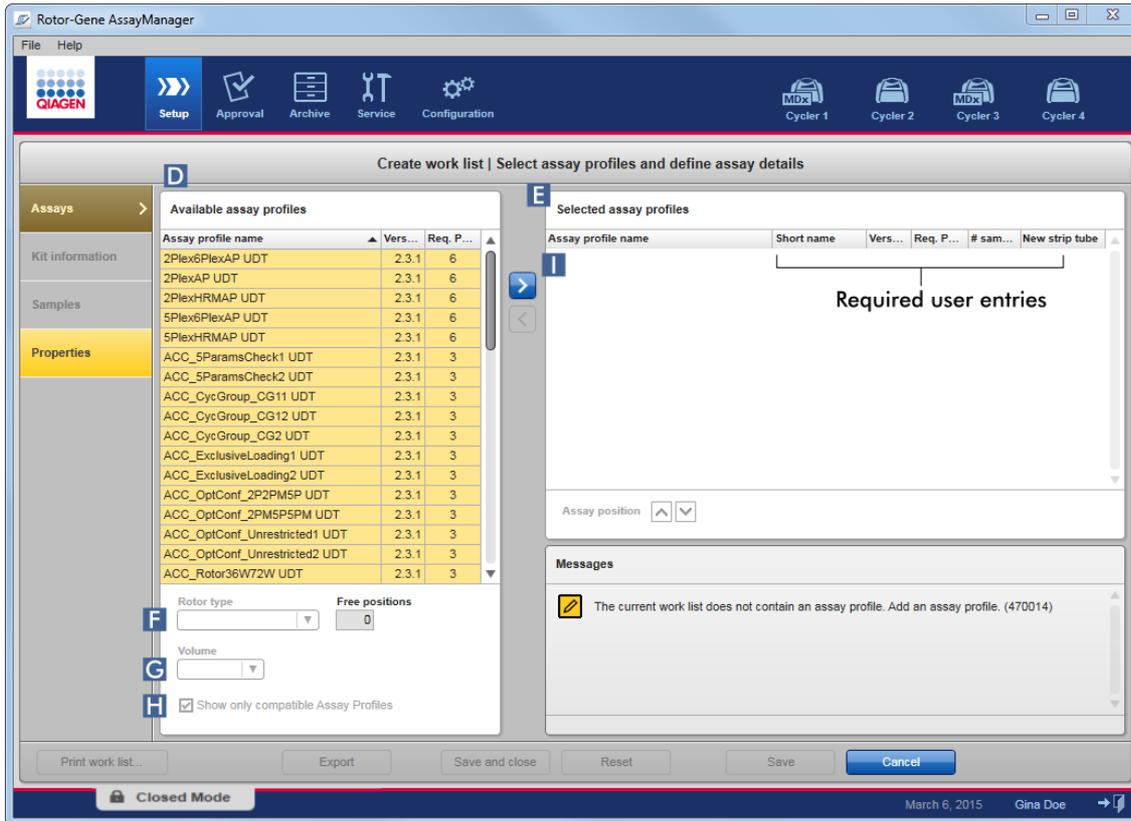
- b) Click the "New manual worklist" button (B) at the bottom right of the screen. The "Create worklist" screen is opened. The "Assays" step marker is activated, as indicated in dark yellow.



Step 2: Add one (or multiple) assay profile(s) to the worklist ("Assays" step)

In this step, the user adds one or multiple compatible assays to the worklist. Multiple assay profiles can only be added if enough positions are available on the rotor. The "Assays" step lists all available assay profiles in the "Available assay profiles" table at the left in alphabetical order. The selected assays will be added and shown in the "Selected assay profiles" table at the right.

The order in which assays are added defines their order on the rotor. The order can be changed by using the assay position arrows below the right table, i.e., the assays can be moved up and down in the table.



a) In the "Available assay profiles" table (D) click the assay you want to be included in the "Selected assay profiles" table (E). Only one entry can be selected at a time. If an entry is selected, the corresponding row is highlighted blue. Depending on the assay profile the "Rotor type" (F) and "Volume" (G) drop-down menus may be colored in yellow to indicate a mandatory entry.

b)

Note

The check box "Show only compatible assay profiles" (H) determines the behavior of the "Available assay profiles" table:

- If not activated: All available assay profiles are listed. Incompatible assay profiles are grayed out.
- If activated: If an assay profile has been added to the "Selected assay profiles" table, only compatible assay profiles will be listed.

c) Click the "Rotor type" drop-down menu (F) to select the rotor type that will be used.

Note

Assay profiles that require more tube positions than available on the selected rotor are grayed out in the table.

- d) Click the "Volume" drop-down menu (**G**) to select the reaction volume that will be used.

The "Add assay to worklist" (**I**) button is set to active.

- e) Click the "Add assay to worklist" (**I**) button to transfer the selected assay to the "Selected assay profiles" table at the right.

The first 4 columns in the "Selected assay profiles" table ("Assay profile name", "Short name", "Version", "Required Position") are populated with data from the assay profile.

The "New strip tube" option can be activated manually for multi-assay usage. If a second assay is selected, the user has the option to start the new assay in a new 4-strip tube.

Note

If only one assay is selected, the option "New strip tube" is automatically selected.

- f) Enter the number of test samples in the "# samples" column.

Note

Enter the number of different sample IDs. If the selected assay profile analyzes each sample ID for x different targets in individual rotor positions, x rotor positions will automatically be grouped per sample ID. Replicates are classified as individual sample IDs.

The sample IDs themselves have to be entered in the following "Samples" step.

Step 3: Scan or enter kit information

In this step, the material number, kit expiration date and the lot number can either be entered manually or by scanning the kit bar code.

- Alternative 1: Manual entry of material number, kit expiration date, and lot number

Select the option "Enter kit information manually" and enter the material number, the kit expiration date, and the lot number. Use the date picker (📅) to enter the date using an interactive calendar.

- Alternative 2 (for QIAGEN kits only): Automatic entry of material number, kit expiration date, and lot number by scanning the kit bar code

Click on "Use kit bar code" icon and scan the QIAGEN kit bar code.

Use kit bar code
 Enter kit information manually

Kit information

Kit bar code

Material number <input type="text"/>	Kit expiry date <input type="text" value="MM/DD/YYYY"/> 📅
--	---

Lot number

Note

The document only describes the general functionality of the "Scan or enter kit information" dialog. For detailed information refer to the corresponding plug-in user manual.

Note

If you run out of chemicals and need a new kit box, use only assay kits with the same lot number for setting up an assay.

Repeat steps 2 and 3 for all other assay profiles you want to be included in the worklist.

Note

Incompatible assay profiles cannot be selected. These are disabled and grayed out by Rotor-Gene AssayManager.

Hint

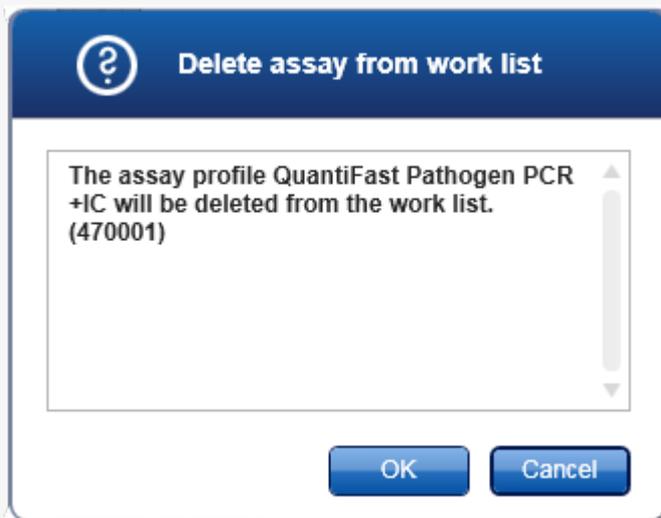
To remove an assay profile from the worklist:

1. Click the assay profile in the "Selected assay profiles" table.

The name is marked and the "Remove selected assay from worklist" button  is activated.

2. Click the "Remove selected assay from worklist" button.

The following confirmation dialog is displayed:



3. Click "OK" to remove the assay profile from the worklist. Click "Cancel" to close the dialog without removing the assay profile from the worklist.

Step 4: Assign sample IDs to assay profiles ("Samples" step)

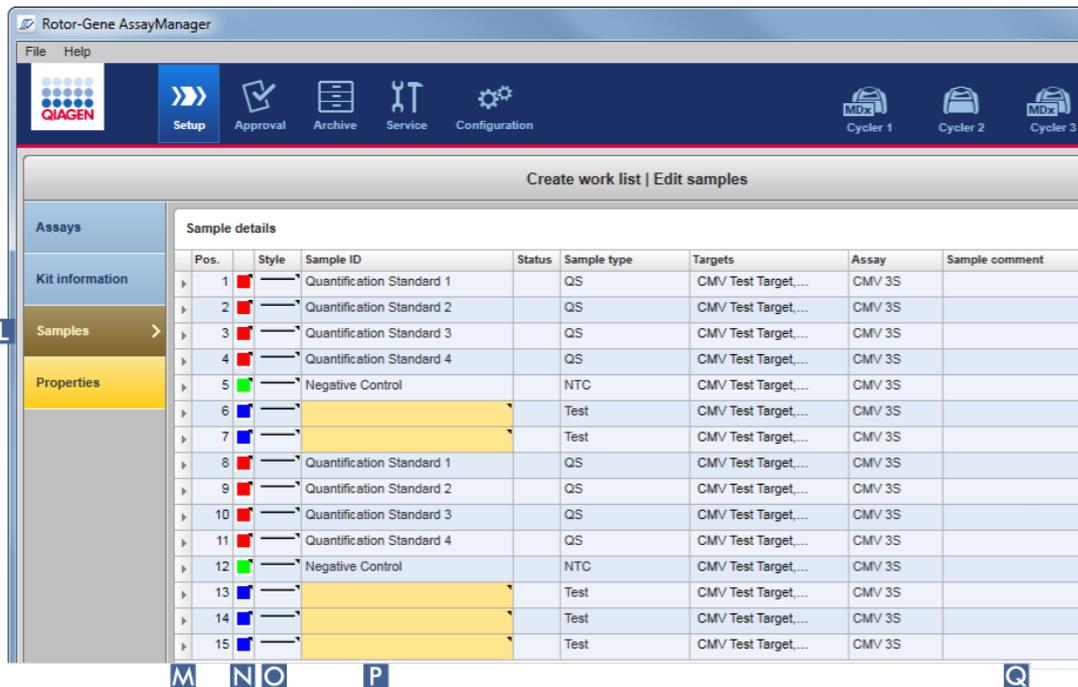
<p>WARNING</p> 	<p>Do not enter patient specific data into the sample ID</p>
--	--

In the previous step ("Assays") one or multiple, compatible assays were added to the worklist. The number of test samples was defined in the "# samples" field of the selected assay profiles table. The position and quantity of external controls, such as quantitation standards and NTC, are derived from the assay profile.

The main purpose in the "Samples" step is to assign IDs to the test samples, select line styles and line colors for samples, and (optionally) enter a comment. The "Sample

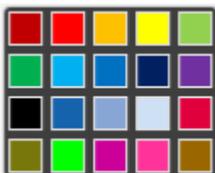
details" table lists all test samples and non-test samples. In case multiple assay profiles were added, the order of the assay profiles is determined by their order defined in the "Assays" step.

a) Change to the "Samples" step by clicking "Samples" (L) in the step bar.



The "Sample details" table is displayed with a visualization of the current assay design. The ID field of the test samples is colored yellow because these entries are mandatory.

b) If supported by the plug-in currently used, a color for the respective amplification curve can be selected. To select a color for an amplification curve, right-click the color icon of the corresponding row (N). A color palette is opened.



Click a color to select it.

c) If supported by the plug-in currently used, a line style for the respective amplification curve can be selected. To select a line style for an amplification curve, right-click the line style icon of the corresponding row (O). A line style

palette is opened.



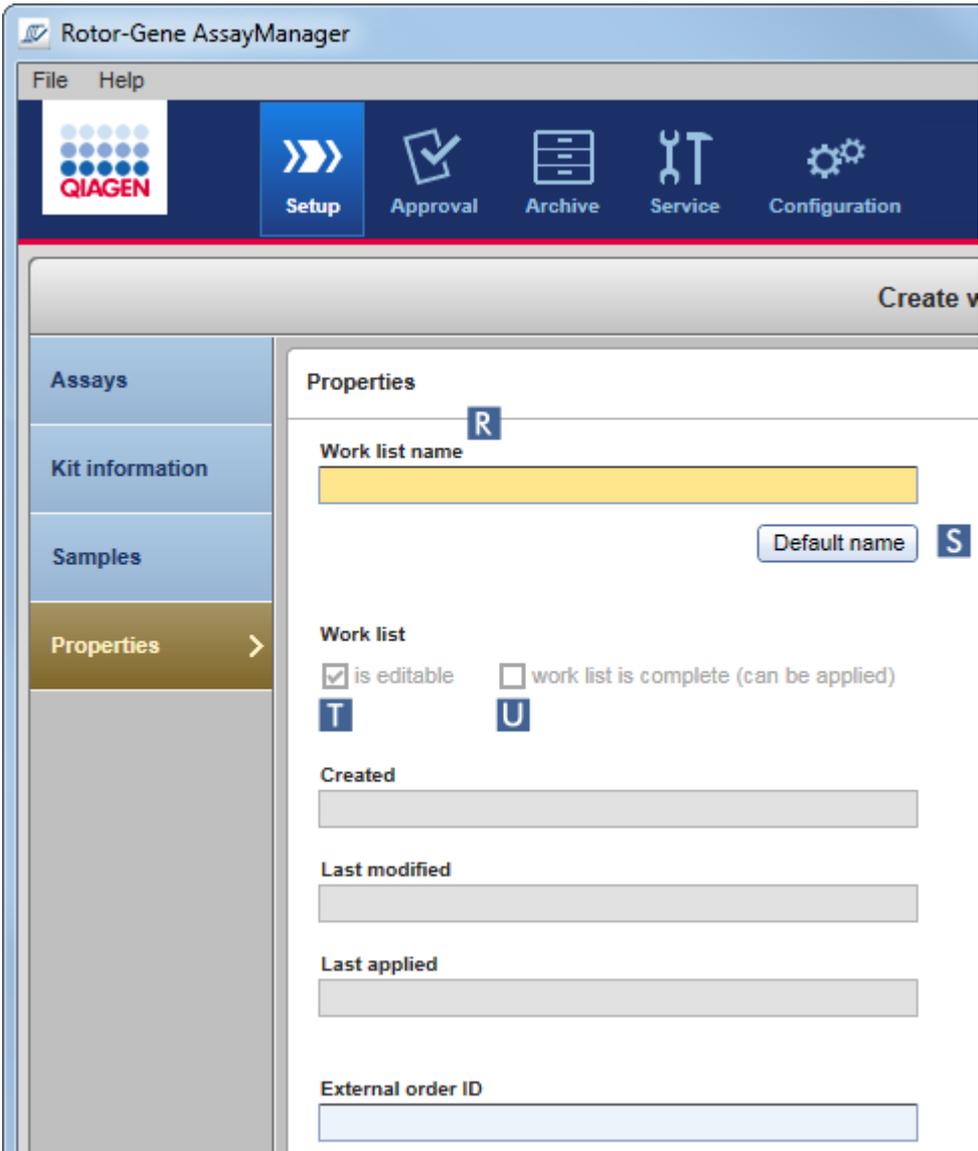
Click a style to select it.

- d) Enter an ID into the ID field **(P)** for every test sample. The ID must be between 1 and 40 characters long. The sample IDs can either be identical or unique. However, some assay profiles restrict the use of the same IDs.
- e) **Optional:** Enter a comment in the "Sample comment" field **(Q)**. The comment must not exceed 256 characters.

Step 5: Define the properties of the worklist ("Properties" step).

This screen is intended to enter the worklist name and to review information about when it was created, modified, and last applied. The user can also specify if a worklist can be edited or applied.

- a) Change to the "Properties" step by clicking the "Properties" step marker **(R)**.



- b) Enter the desired worklist name into the "worklist name" field (R). To let Rotor-Gene AssayManager v2.1 automatically generate a worklist name, click "Default name" (S). Rotor-Gene AssayManager v2.1 automatically creates a default name using a user-defined pattern (see ► Settings) and populates the field.
- c) Activate the desired options:

To	Do this	Explanation
Define a worklist as being editable	Activate check box T <input checked="" type="checkbox"/> is editable	The worklist can be edited, i.e., modified, later. If this option is

To	Do this	Explanation
		deactivated, the worklist cannot be changed.
Mark a worklist as being applicable	Activate check box <input type="checkbox"/> U <input checked="" type="checkbox"/> work list is complete (can be applied)	If the "is applicable" option is deactivated, the worklist cannot be applied. To start a run, this option must be activated.

Note

The field "External order ID" is optional.

Step 6: Finish creating the worklist

Finish creating a worklist by clicking one of the buttons in the button bar:



To	Click
Print the worklist to PDF after having saved the worklist	
Export the worklist to a folder after having saved the worklist	
Save the worklist and go back to the start screen of the "Setup" environment.	
Cancel your entries and set properties to default	
Save the worklist	
Cancel your entries	
Apply your worklist	

Related topics

- ▶ Managing assay profiles
- ▶ Managing cyclers

- ▶ Entering data
- ▶ Using colors
- ▶ "Setup" environment

1.6.1.3.2 Importing a Worklist

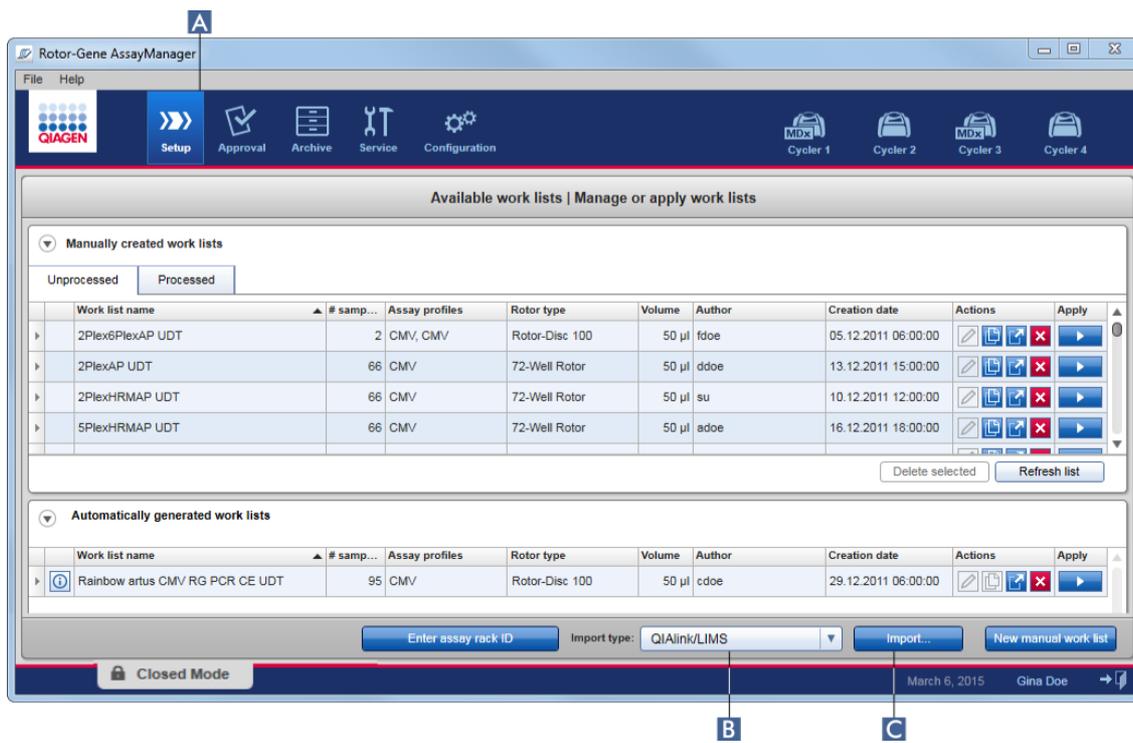
Importing a worklist is a function used either to exchange worklists between different Rotor-Gene AssayManager v2.1 installations or to import worklists from an upstream laboratory device (for example a LIMS or QIA Symphony). For the QIA Symphony software version 5.0 worklist an automatic import functionality can be configured (see ▶ Step-by-step procedure to configure an automatic worklist import).

Note

The Rotor-Gene AssayManager v2.1 is only compatible with the results files of the QIA Symphony software version 5.0.

The import command is placed in the "Setup" environment (A) and consists of 2 elements:

- A drop-down menu (B) to select the source of the file
- The "Import" button (C) for manual import



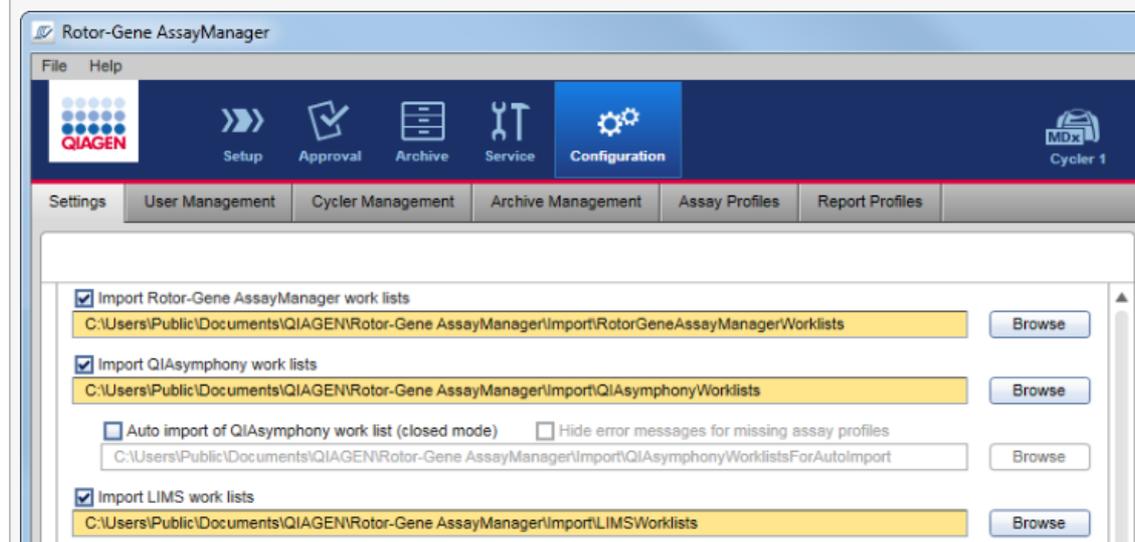
A worklist can be imported from the following sources (entries from the drop-down menu **B**):

Source	File extension	Description
Rotor-Gene AssayManager v2.1	*.iwl	Exported Rotor-Gene AssayManager v2.1 worklist
QIASymphony	*.xml	Result file from QIASymphony AS software version 5.0
QIALink/LIMS	*.lwl	worklists from QIALink or a LIMS

After a worklist to be imported has been selected, Rotor-Gene AssayManager v2.1 internally checks its syntax and signature. If the check is successful, the worklist will be imported and added to the "Available worklists" table. Otherwise the worklist will be rejected with a corresponding error message.

Note

The entries in the import drop-down menu (**B**) depend on the settings set in the "Settings" tab of the "Configuration" environment. An administrator can activate/deactivate each of the 3 possible import options.



Step-by-step procedure to import a worklist manually

1. If it is not active yet, change to the "Setup" environment by clicking the "Setup" icon in the main toolbar (A).
2. Select the source for the worklist to be imported from the "Import type" drop-down menu (B). If the menu is disabled or necessary entries are missing, these can be customized in the "Configuration" environment in the ► "Settings" tab. If necessary, save the changes in the settings.
3. Click "Import" (C).
The "Select file" dialog opens. By default, the directory set for this import type in the ► "Configuration" environment is shown.
4. Change to the directory where the file to be imported is located. Select it and click "Open".
Rotor-Gene AssayManager v2.1 internally checks the signature and the syntax of the worklist.
5. The worklist is imported and added to the list of available worklists.

Note

The names of worklists imported from QIASymphony software version 5.0 are automatically created with the following information separated by an underscore:

- "QS" as identifier for worklists imported from QIASymphony
- Batch ID of the QIASymphony AS run
- "S" + slot number of QIASymphony AS, where the assay was set up
- Rack ID of QIASymphony AS run
- Start date of QIASymphony AS run in format "YYYYMMDD"
- Start time of QIASymphony AS run in format "HHMMSS"

In case that the QIASymphony AS result file contains information about several batches, this information will be separated in different worklists.

Step-by-step procedure to configure an automatic worklist import

In Rotor-Gene AssayManager v2.1 an automatic import of QIASymphony worklists can be configured. Each minute the software automatically checks if QIASymphony worklists are available in a predefined source directory and imports them automatically.

For activation of the automatic worklist import function:

1. Select the "Settings" tab of the "Configuration" environment (see ► Settings)
2. Check the "Auto import of QIASymphony worklist (closed mode)" button.
3. Define the source directory.

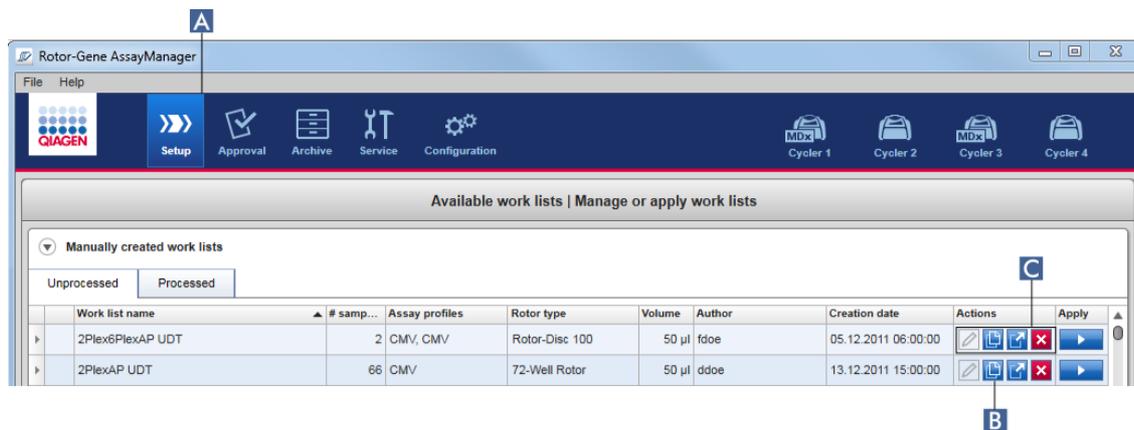
Related topics

- ▶ Settings
- ▶ Setting up worklist name options
- ▶ Rotor-Gene AssayManager v2.1 and other QIAGEN products
- ▶ Available worklists view

1.6.1.3.3 Duplicating a Worklist

General

A specific manually generated worklist is duplicated from the "Setup" environment (A) by clicking the "Duplicate worklist" button (B) in the "Actions" bar (C) of the corresponding worklist.



The "Duplicate worklist" button is always enabled for manually created worklist. Clicking this button creates a copy of the selected worklist. The "worklist modification" screen is displayed. This screen is analog to the "Creating a worklist" dialog. The copy is not saved to the database until "Save" is clicked.

The duplicated worklist has the following properties:

- The fields "# samples", "Material number", "Kit expiry date", and "Lot number" are editable.
- The "is editable" check box is enabled. The "is applicable" check box of duplicated worklists is not activated.
- The "Last applied" and "Last modified" fields are empty and will be set when the worklist is saved for the first time.

Step-by-step procedure to duplicate a worklist

1. If it is not active yet, change to the "Setup" environment by clicking the "Setup" icon in the main toolbar (A).
All available worklists are displayed in the table.
2. Locate the worklist you want to duplicate of the manually created worklists, and click the corresponding "Duplicate worklist" button (B) in the "Actions" bar (C).
The "Edit duplicated worklist" screen is shown.
3. Modify those parameters you need to change according to the steps described in steps 2 to 5 of the procedure ► Creating/editing a worklist.

Note

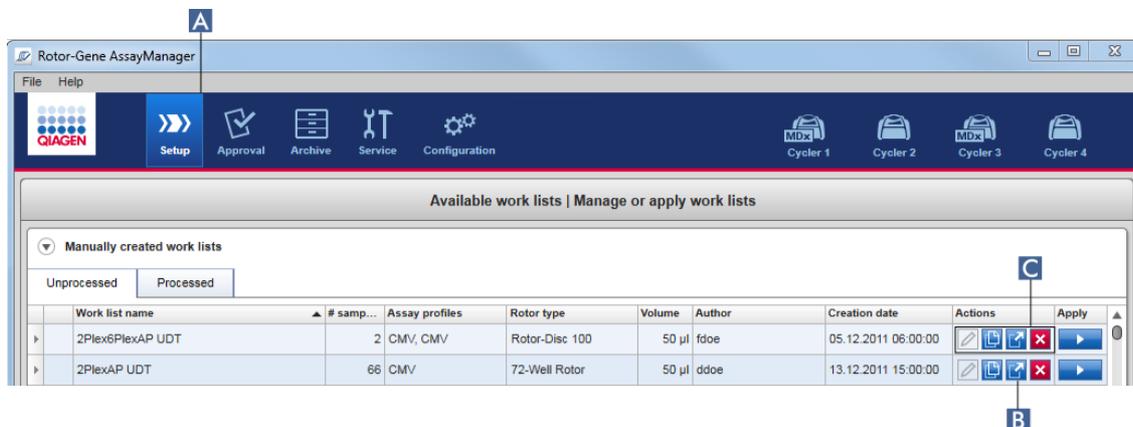
Automatically generated worklist are not duplicable.

Related topic

- Available worklists view

1.6.1.3.4 Exporting a Worklist

Exporting a worklist is used to exchange worklists between different Rotor-Gene AssayManager v2.1 installations that are using different databases. The export functionality can be found in the "Setup" environment (A). The "Actions" bar (C) in the "Available worklists" table includes the "Export worklist" button (B).

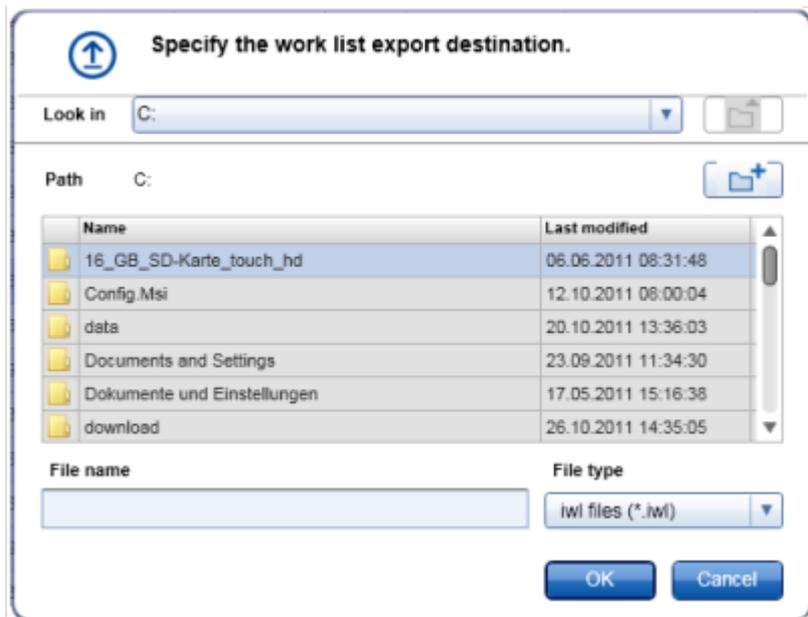


Step-by-step procedure to export a worklist

1. If it is not active yet, change to the "Setup" environment by clicking the "Setup" icon in the main toolbar (A).
2. Move the mouse cursor to the "Actions" bar (C) of the worklist you want to export.

3. Click the "Export worklist" button (B).

A dialog opens to select the target directory and the file name. By default, the directory set in the "Configuration" environment is preselected.



4. Browse to the designated directory.
5. Enter a file name for the exported worklist.
6. Click "OK".

The worklist will be saved under the entered file name and with the extension *.iwl.

Note

Both manually and automatically created worklists can be exported.

Related topic

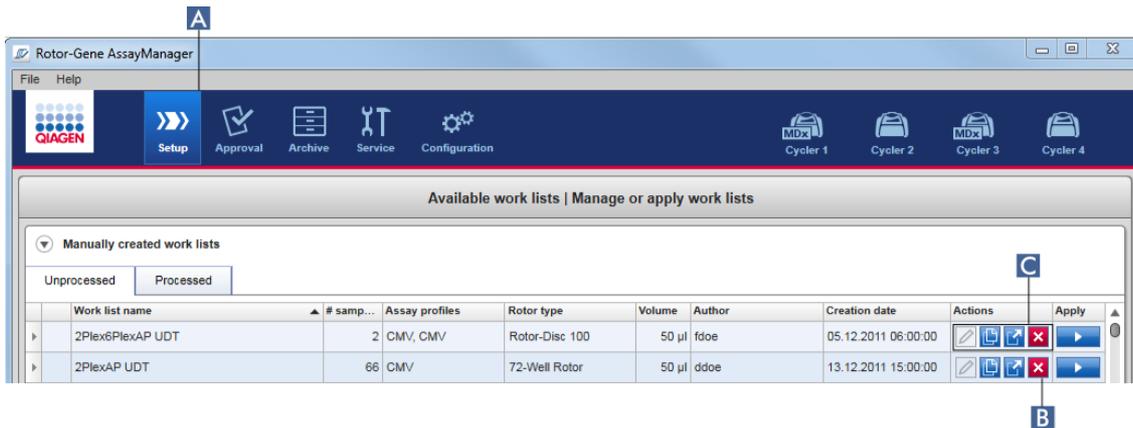
- ▶ Available worklists view

1.6.1.3.5 Deleting a Worklist

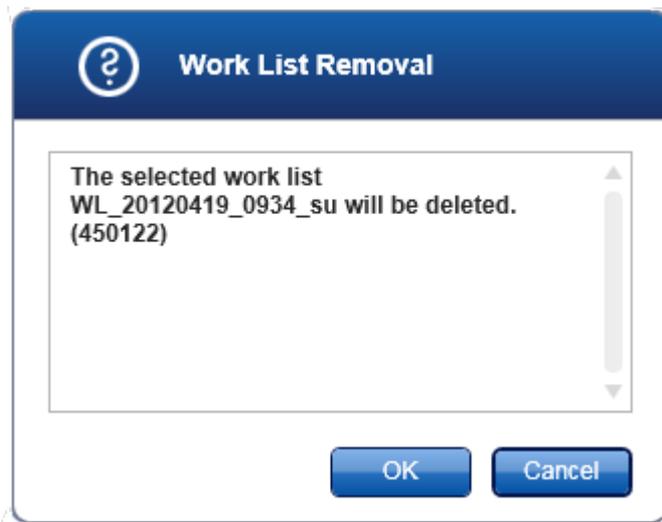
Step-by-step procedure to delete a worklist

1. If it is not active yet, change to the "Setup" environment by clicking the "Setup" icon in the main toolbar (A).

All available worklists are displayed in the table.



2. Locate the worklist you want to delete, and click the corresponding "Delete worklist" (B) button in the "Actions" bar (C) of the appropriate row of the table. The following confirmation dialog is shown:



3. Click the appropriate button:

To	Click
Delete a worklist and return to the "Setup" start screen.	 The selected worklist entry will be deleted from the database and then disappears from the worklist table.
Cancel the delete process and return to the "Setup" start screen	 The selected worklist entry will remain as before.

Note

Both manually and automatically created worklist can be deleted.

Related topic

▶ Available worklists view

1.6.1.4 Starting a Run

A run can be started from the "Available worklists" table in the "Setup" environment (A) by clicking the "Apply" button (B) in the button bar of the appropriate worklist entry. An alternative is to start a run after a new worklist has been successfully created. Details can be found under ▶ Creating/editing a worklist.

After the run is triggered, the "Apply worklist" screen is opened. The user must enter an experiment name and select a cycler. Furthermore, an overview of the samples can be displayed and printed to a *.pdf file (command "View sample details", then "Print worklist"). This printout can be used as a pipetting scheme.

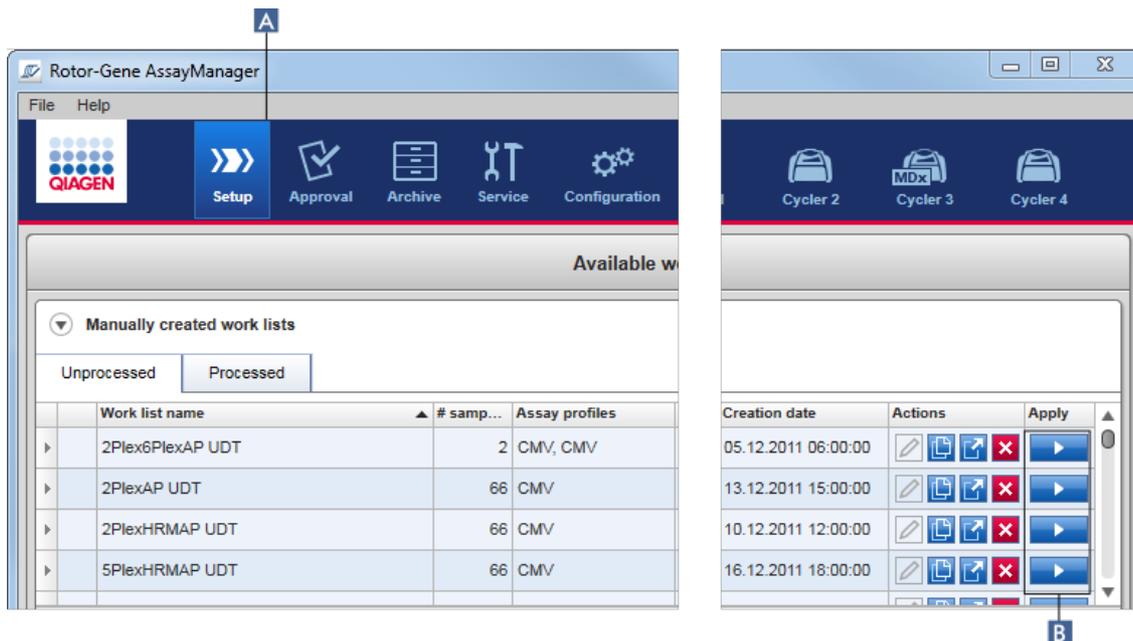
Note

- An experiment name must be entered.
- The length of the experiment name is limited to 80 characters.
- The experiment name must be unique in the database.

The default name is defined under ▶ "Settings" in the ▶ "Configuration" environment. Upon delivery, the default name for the experiment name is defined as follows:

<Assay profile short names>_<YYYYMMDD>_<HHMM>, e.g.,
AS1_AS2_AS3_20120327_1359 .

It may happen that the default name exceeds 80 characters. In this case you have to shorten the name manually to meet the requirements.



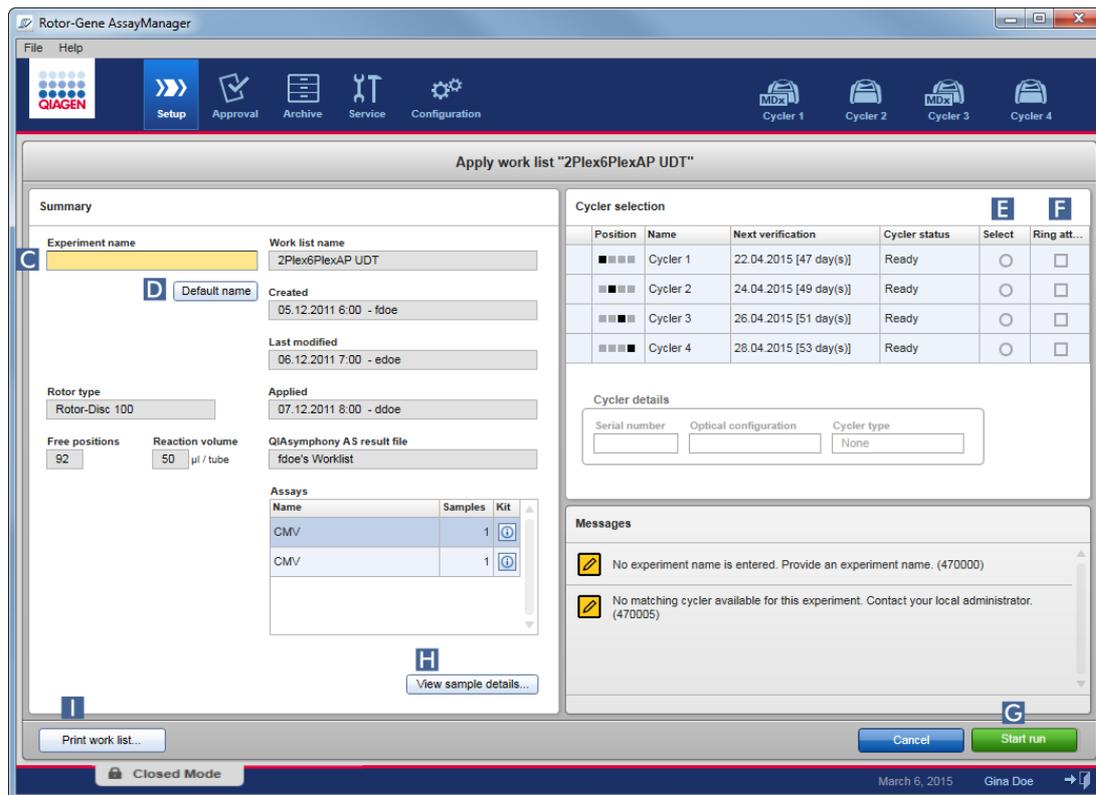
Step-by-step procedure to apply a worklist

1. If it is not active yet, change to the "Setup" environment by clicking the "Setup" icon in the main toolbar (A).

The "Setup" environment is opened. All available worklists are displayed.

2. Select the worklist you want to apply (manually or automatically created). Click "Apply worklist" in the last column of the row (B).

The "Apply worklist" screen is shown. It consists of 3 areas: "Summary", "Cycler selection", and the "Messages" section.

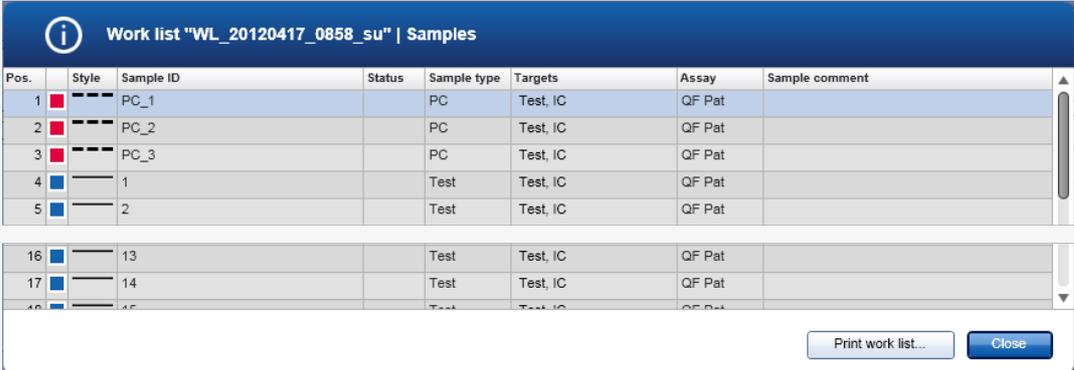


3. Enter the name of the experiment in the "Experiment name" field (C), or click "Default name" (D) to generate a name automatically.
 4. Click the "Select" radio button (E) to select a cycler with the status "Ready".
 5. Activate the "Ring attached" check box (F) to confirm you have attached the locking ring.
The "Start run" button (G) is now activated.
 6. Click the green "Start run" button (G) to start and apply the run. Click "Cancel" to abandon the preparation of the run. In this case this screen will be closed and the "Available worklists" screen is shown.
- After clicking the "Start run" button, the following happens:
- The experiment is saved to the database.
 - The run is started.
 - The application switches to the cycler environment of the cycler selected for the run.

Optional Step

The user can get detailed information about the samples using the "View sample details..." (H) and "Print worklist..." buttons (I).

Clicking "View sample details..." opens a scrollable list with detailed information about the samples:



Pos.	Style	Sample ID	Status	Sample type	Targets	Assay	Sample comment
1	■	PC_1		PC	Test, IC	QF Pat	
2	■	PC_2		PC	Test, IC	QF Pat	
3	■	PC_3		PC	Test, IC	QF Pat	
4	■	1		Test	Test, IC	QF Pat	
5	■	2		Test	Test, IC	QF Pat	
16	■	13		Test	Test, IC	QF Pat	
17	■	14		Test	Test, IC	QF Pat	
18	■	15		Test	Test, IC	QF Pat	

A *.pdf file with this data can be generated either by clicking "Print worklist..." from this screen or from the "Apply worklist" screen. This file can be used as a pipetting scheme.

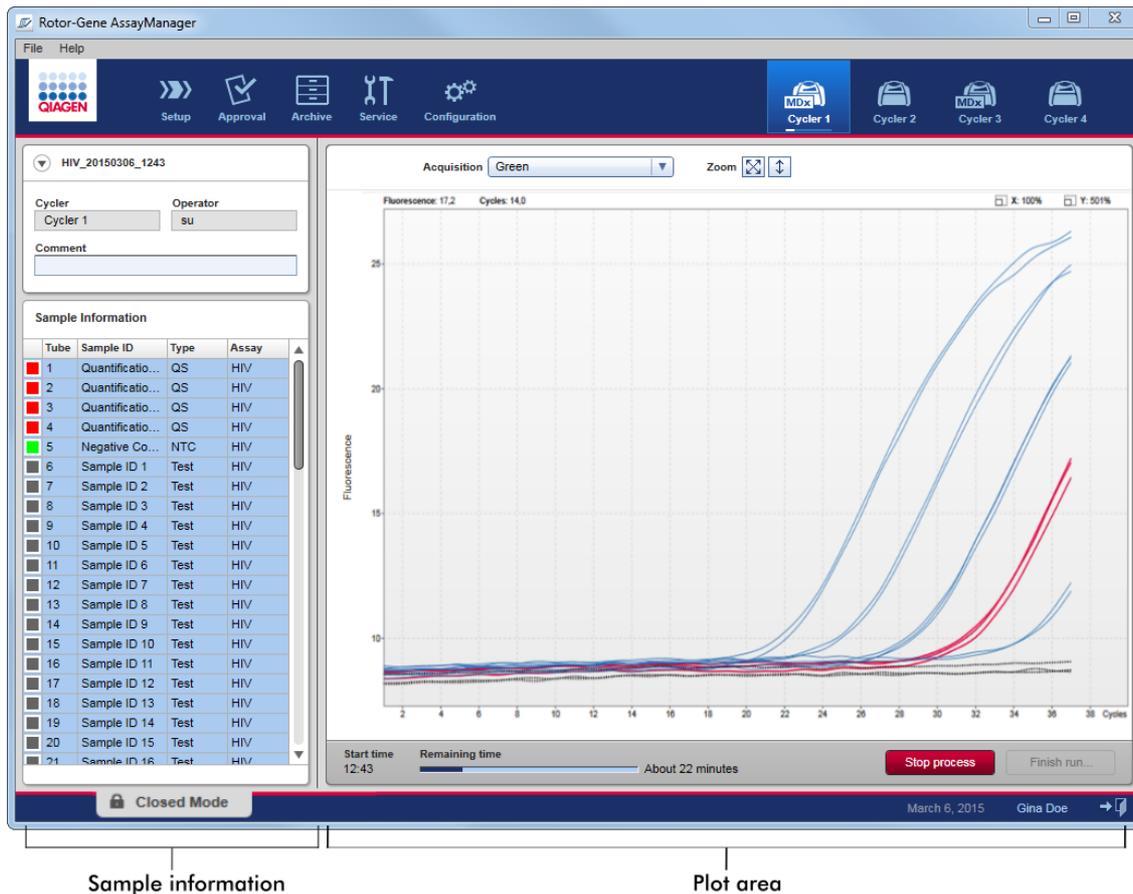
Related topics

- ▶ Creating a worklist
- ▶ Managing cyclers
- ▶ Settings
- ▶ Available worklists view

1.6.1.5 Finishing and Releasing a Run

During a run:

After a run is started, the environment of the selected cycler is displayed. This screen mainly consists of the sample information at the left and the plot area at the right.



During the run process and depending on the currently used plug-in, the amplification curves will be displayed and updated in real time. A progress indicator at the bottom left and a progress indicator placed underneath the cycler's icon show the run progress. It is possible to stop the run by clicking "Stop process".

Both sample information and plot area provide interactive functionalities to check the amplification curves of single (or multiple) samples.

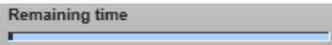
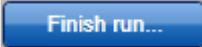
Note

Upon starting the run, all samples are selected and marked blue and all amplification curves are shown.

Click a single sample row in the sample information table to select/deselect a sample. To make multiple selections, move to the first sample to be selected, hold down the left mouse button, and drag the mouse to the last sample. The status of the first selected sample defines whether these samples are selected or deselected: if the first sample was initially selected, all samples will be deselected and vice versa.

Finishing a run:

When the run has finished, the cycler icon will change. The stop process button will change its label to finish run. The following table gives an overview how the button label and cycler icons change from start to the end of a run.

	Cycler idle	Run started	Run finished
Cycler Icon		 Progress Indicator	
Progress Indicator	–		
Label of button	–		

The operator must click "Finish run" to finalize the run.

Note

If "Stop Process" is clicked during the run or an error occurs, the run is stopped and the cycler icon changes to:



For further details, see ► "Cycler" environment

Step-by-step procedure to finish a run

1. If it is not open yet, change to the corresponding "Cycler" screen by clicking its icon in the main toolbar.

The "Cycler" screen is displayed.

2. To finish a run, click "Finish run".

The "Finish run" dialog is opened. It provides details about the position and the name of the cycler, the run status, the experiment name, errors during run, and a comment. Depending on the run properties, some of the fields may be empty.

Finish run

Position: [Black] [Grey] [Grey] [Grey] Name: Cycler 1 Run status: Run Successful

Experiment name: QF Pat_20120419_0940

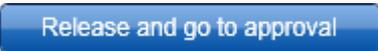
Errors during run: [Empty text area]

Comment: [Empty text area]

Password: [Empty text box]

Buttons: Release, Release and go to approval, Cancel

3. Select the desired option:

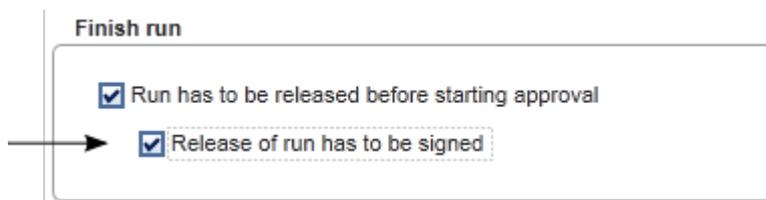
To	Click
Release the cycler	
Release the cycler and change to the "Approval" environment	
Cancel the release process and change to the "Cycler" view	

When the user releases the cyclus, the following processes are triggered:

- The cyclus is released and ready for a new run.
- The run is stored in the internal database with all experiment data (sample information, etc.).

Difference if release of run has to be signed

The administrator can determine that the release of a run must be signed. This option is set in the "General settings" tab of the ► "Configuration" environment.



If the option was set, the run has to be signed with a password (user profile password). The buttons "Release" and "Release and go to approval" are initially disabled. These buttons are enabled only if a valid password is entered in the "Password" field.

Note
 After a run is finished and the cycler is released, open the lid, remove the rotor, and discard the samples immediately.

Related topics

- ▶ Making a release mandatory
- ▶ "Cycler" environment

1.6.1.6 Approving a Run

Overview

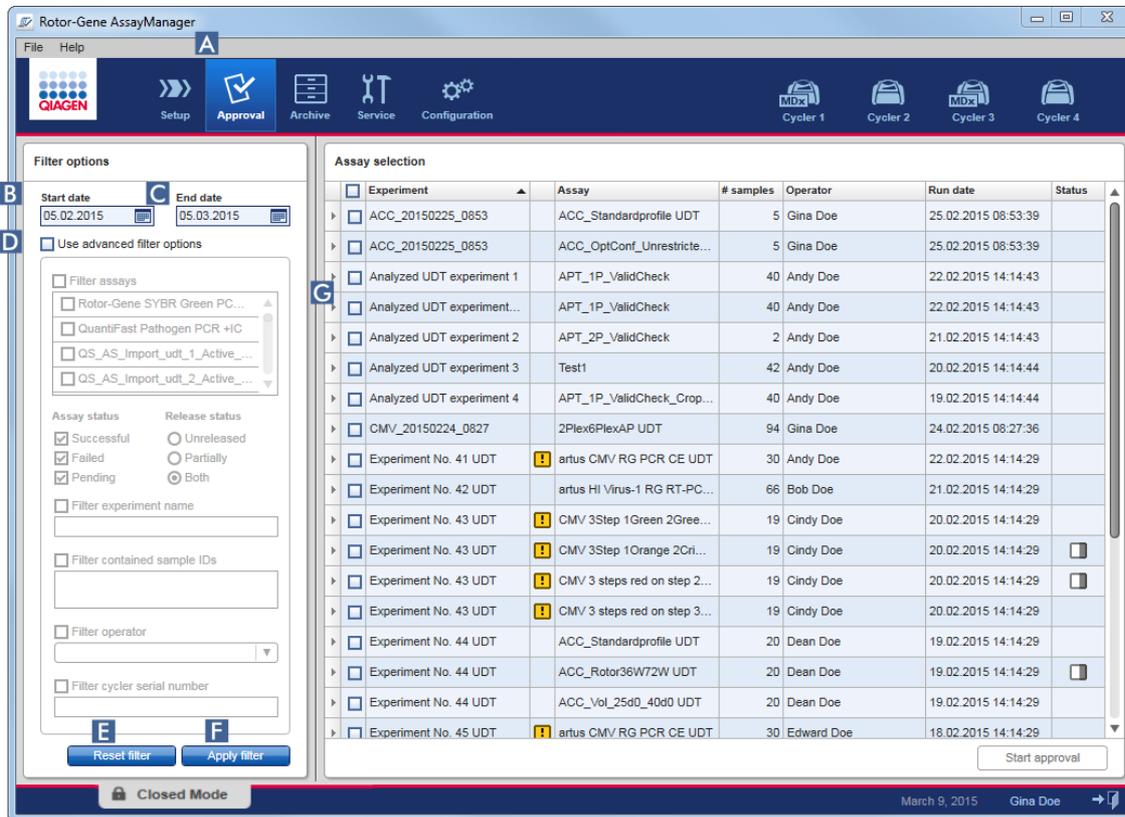
After a run has finished and the cycler has been released, the experiment will be stored in the internal database. The analysis of the acquired data is performed automatically depending on the plug-in corresponding to the assay profile and the rules and parameter values defined by the assay profile.

Rotor-Gene AssayManager v2.1 provides test results that must be approved and released by a user with the role of an approver. Depending on which Rotor-Gene AssayManager v2.1 plug-in is currently used, the individual approval process may differ.

In this section only the general functions are described. For details about the individual approval process, refer to the corresponding plug-in user manual.

1.6.1.6.1 Filtering Experiments

The first step in the approval process is to filter the assay to be approved. This is done by using filter criteria in the "Approval" environment.



This environment mainly consists of 2 parts: the "Filter options" at the left and the "Assay selection" table at the right. The filter criteria are defined in the "Filter options" area. All assays matching the criteria will be listed in the "Assay selection" table at the right.

The most simple filter is the search for assays within a certain date range. Advanced filter options allow to define further filter criteria.

The following table provides an explanation of the filter criteria:

Filter Criteria	Comment
Date range	<p>Enter a start date and an end date in the corresponding fields to filter for assays with a run start date in the defined date interval. Dates can either be manually entered or using the date picker.</p> <p>Restrictions:</p> <ul style="list-style-type: none"> • Wildcard characters are not allowed. • Dates must be entered completely.
"Filter assays"	<p>To filter for specific assays, activate the "Filter assays" check box. All assays are displayed in a list. A check box in front of every assay row allows to select for individual assays. Multiple assay selections are possible to search simultaneously for different assays.</p>
"Assay status"	<p>Filter for the assay status using the radio buttons. Possible values are:</p> <ul style="list-style-type: none"> • Successful • Failed • Both • Pending
"Release status"	<p>Filter for the release status using the radio buttons. Possible values are:</p> <ul style="list-style-type: none"> • Unreleased • Partially • Both
"Filter experiment name"	<p>Filter for certain assays by activating the check box and entering an experiment name.</p>
"Filter contained sample IDs"	<p>Filter for specific sample IDs by activating the check box and entering one or multiple sample IDs. Multiple sample IDs must be entered in individual rows without any separators.</p>

"Filter operator"	Filter for a specific operator by activating the check box and selecting an operator from the list.
"Filter cyler serial number"	Filter for a cyler serial number by activating the check box and entering a cyler serial number (only digits).

Step-by-step procedure to filter assays

1. If it is not active yet, change to the "Approval" environment by clicking the "Approval" (A) icon in the main toolbar.
2. In the "Filter options" section in the left part of the screen, select the appropriate filter criteria.
3. Enter a start and an end date in the "Start date" (B) and "End date" (C) fields either manually or using the date picker.

To use advanced search criteria:

4. Activate the "Use advanced filter options" (D) check box.
5. Select the appropriate filter options. Multiple selections are possible.
6. Click "Apply filter" (F) to search the internal database for experiments meeting the criteria defined in the previous step.

All assays meeting the filter criteria will be listed in the "Assay selection" table (G) in the right half of the "Approval" environment.

7. Activate the check box in front of the assay to approve. It is possible to select multiple assays.

Assay selection		
<input type="checkbox"/>	Experiment ▲	Assay
<input type="checkbox"/>	CMV 7cyc_20120321_0953	2Plex6PlexAP
<input type="checkbox"/>	CMV_20120321_1222	⚠ 2Plex6PlexAP

An arrow points to the checkbox in the first row of the table body.

The "Start approval" button is activated when at least one assay is selected:



8. Click "Start approval".

Note

Click "Reset filter" (E) to reset the selected filter options to the default values, i.e., start date set to one month ago, end date set to today, advanced filter options deactivated.

1.6.1.6.2 Approving Samples

Depending on which Rotor-Gene AssayManager v2.1 plug-in is currently used, the individual approval process may differ. For details about the individual approval process, refer to the corresponding plug-in user manual.

1.6.1.6.3 Releasing Data

After the approval of sample results, the data must be released. If a sample result is released, its approval status and the comment cannot be changed anymore.

Step-by-step procedure to release data

1. After approving the sample results, click "Release/report data" in the button bar.
The following dialog will be opened:

Release / report data

A Create report

Password

B

Messages

i After release, the approval state of data cannot be changed. (2270158)

C OK **D** Cancel

Note

The release process of the Gamma Plug-in is taken as an example for screenshots.

2. To create a report, activate the "Create report" option (A).
3. If the release must be signed, enter the Rotor-Gene AssayManager v2.1 login password in the "Password" field (B). This option is set by the administrator in the ▶ "Configuration" environment.
4. To release the data, click "OK" (C). To cancel and go back to the "Results" table click "Cancel" (D).

All approved sample results with the status "Accepted" or "Rejected" that have not been released before will now be released. The data will be stored in the internal database of Rotor-Gene AssayManager v2.1. If at least one sample result has not been approved and still has the status "Undefined", the experiment will be marked as "Partially released". If all sample results have been approved, the status "Fully released" is assigned to the assay. As a result, the assay will no longer be available in the "Approval" environment but can be accessed from the "Archive" environment.

Note

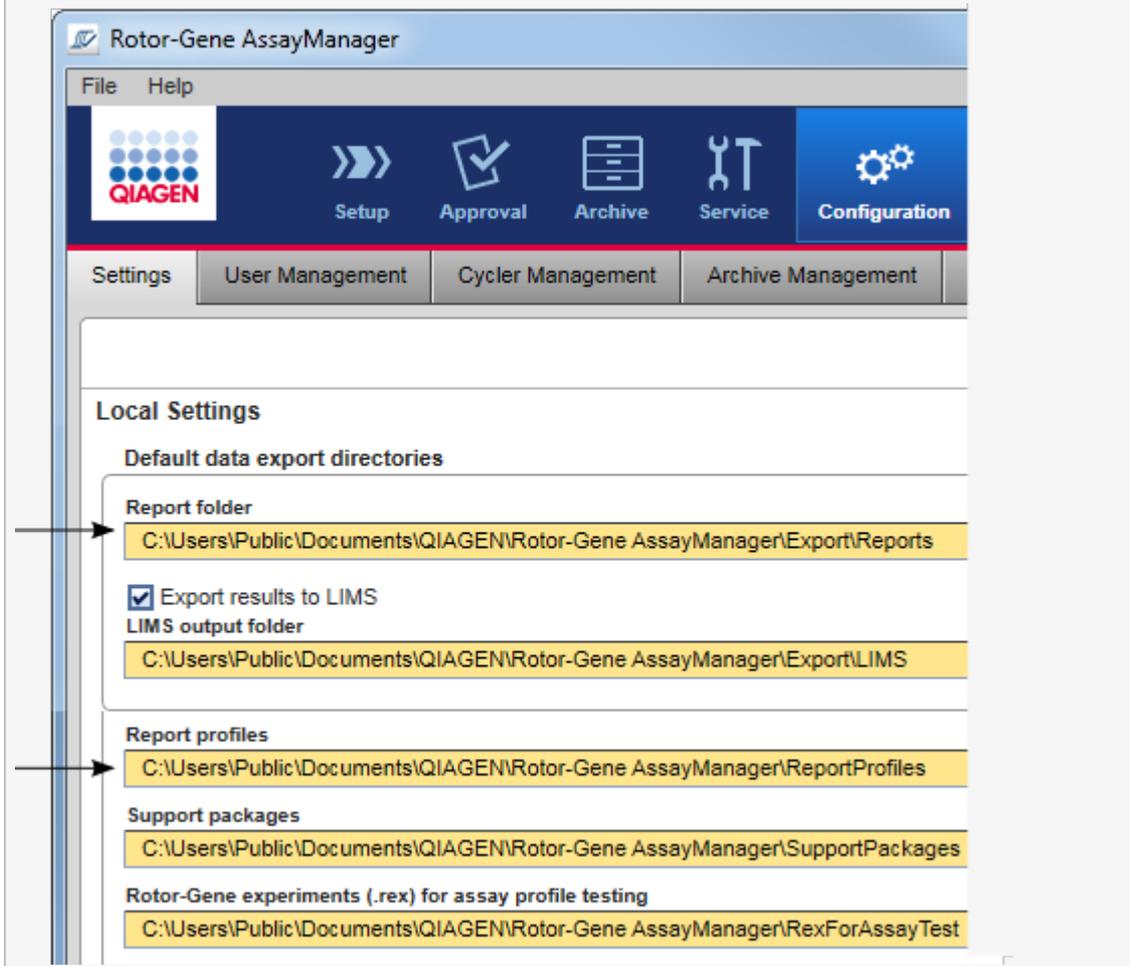
LIMS output is generated during release if configured.

1.6.1.7 Working with Reports

A report can be generated either during the release of sample results in the ▶ "Approval" environment (see ▶ Approving a run) or for already released experiments from the "Archive" environment. The content of a report is defined by individual report profiles that can be configured in the ▶ "Report profiles" tab of the ▶ "Configuration" environment.

Note

The target directory to save the generated report and the source directory for report profiles are defined in the ► "Settings" tab of the ► "Configuration" environment.

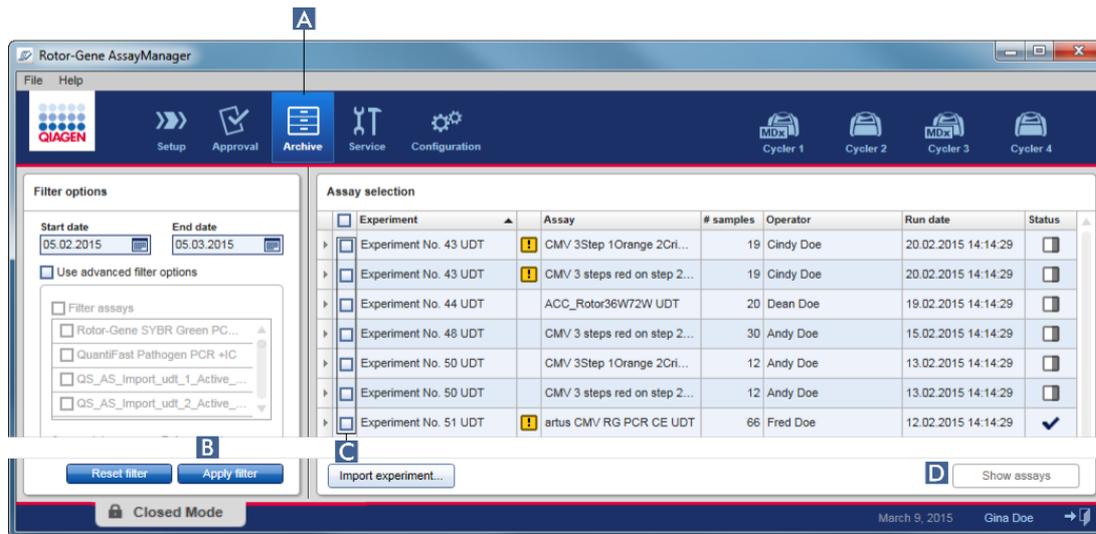


Note

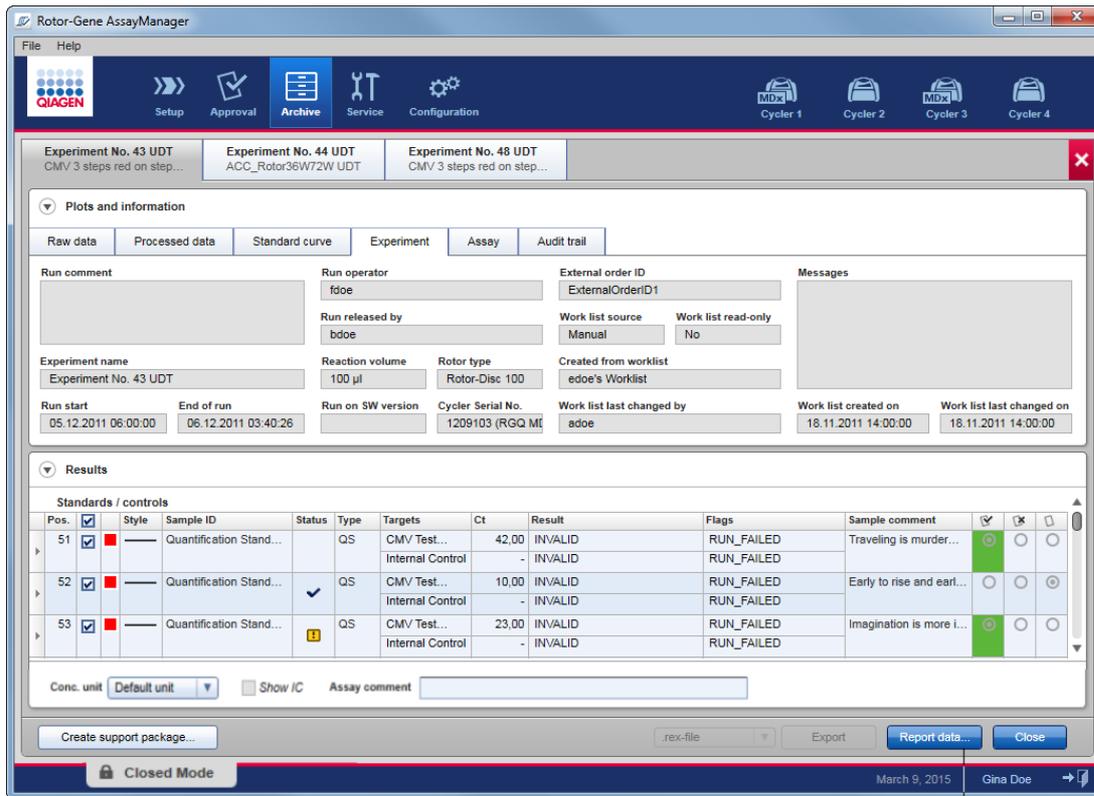
For the Gamma Plug-in, no user defined report profiles are applicable. The experiment data which will be included in the report are pre-defined by the assay.

Step-by-step procedure to create a report in the Archive environment

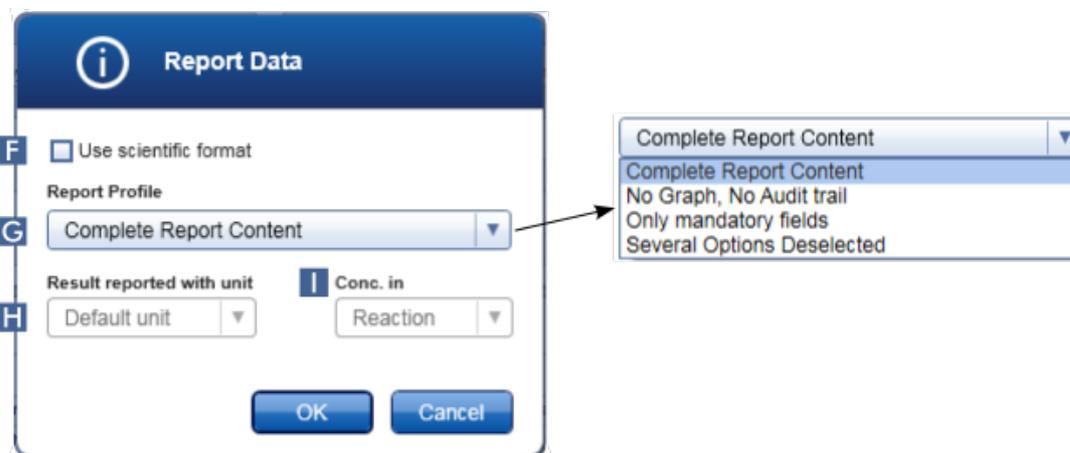
1. Click "Archive" (A) in the main toolbar to change to the "Archive" environment.
The "Assay selection" screen is displayed.



2. Select the appropriate filter options and click "Apply filter" (B).
- A list with assays matching the filter options is displayed.
3. Select one or multiple assays by activating the corresponding check boxes (C).
 4. Click "Show assays" (D) button, which is activated if at least one experiment is selected.



- Click "Report data..." (E) in the button bar.
The "Report Data" dialog is opened.



Note

The scientific format function is not available for all Rotor-Gene AssayManager v2.1 Plug-ins.

6. Decide if the scientific format shall be used (**F**).
7. Select a report profile from the "Report Profile" drop-down menu (**G**).
8. Select a result unit from the "Result reported with unit" drop-down menu (**H**).
9. Select the desired reporting concentration (**I**).
10. Click "OK" to create the report. Click "Cancel" to cancel and return to the approval screen.

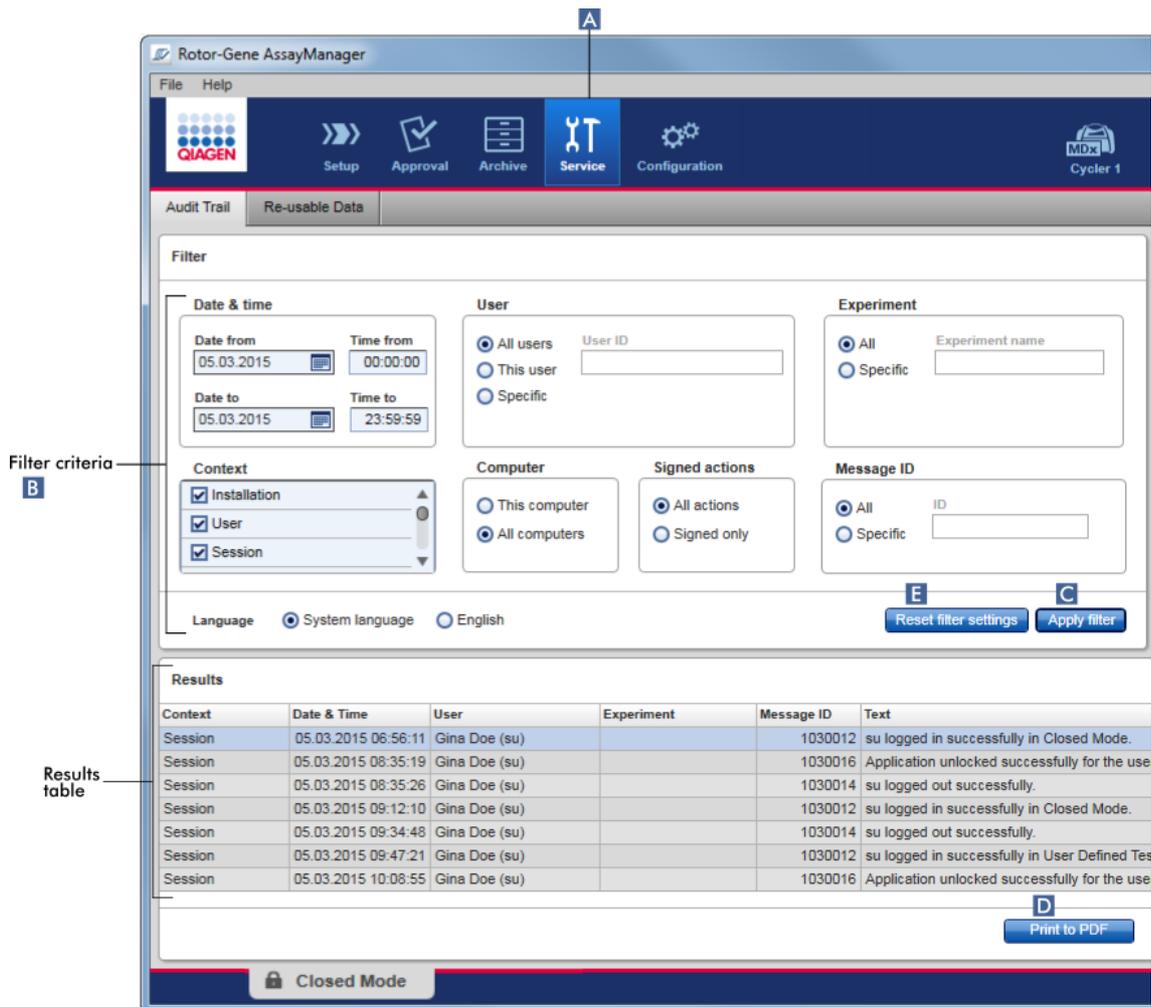
A report of the selected experiment is generated as a *.pdf file using the selected report profile and saved in the report folder defined in the "Configuration" environment.

Related topics

- ▶ Managing report profiles
- ▶ Setting target directory for report profiles
- ▶ "Archive" environment
- ▶ "Approval" environment

1.6.1.8 Working with Audit Trails

The audit trail logs all actions performed in Rotor-Gene AssayManager v2.1. In the "Service" environment, various filter criteria can be selected to filter the audit trail entries. All entries matching the filter criteria are listed in the "Results" table.



Step-by-step procedure to filter for audit trail entries

1. Click "Service" (A) in the main toolbar.

The "Service" environment contains an "Audit trail" tab containing a "Filter area" to apply various filter criteria and a results table where matching audit trail entries are listed.

2. Select filter criteria from the group boxes in the "Filter criteria" area (B). Different filter criteria can be combined. The following filtering options can be used:

- Date
- User
- Experiment
- Context

- Computer location
 - Signed actions
 - Message ID
3. Click "Apply filter" (**C**). All entries in the audit trail matching the filter criteria are listed in the "Results" table. Click "Reset filter settings" (**E**) to set default filter options.
 4. Click "Print to PDF" (**D**) to create a *.pdf file containing the filter criteria and the dedicated audit trail entries. This *.pdf file has to be saved manually, if necessary.

Note

If the number of entries matching the filter criteria exceeds 1200 entries, an error message is shown. Adjust the filter settings.

Related topics

- ▶ "Service" environment

1.6.2 Administrative Tasks

The following administrative tasks can be performed by those users logged in as administrators.

Warning

Rotor-Gene AssayManager v2.1 shall not be used with the admin account of Microsoft Windows operating system.

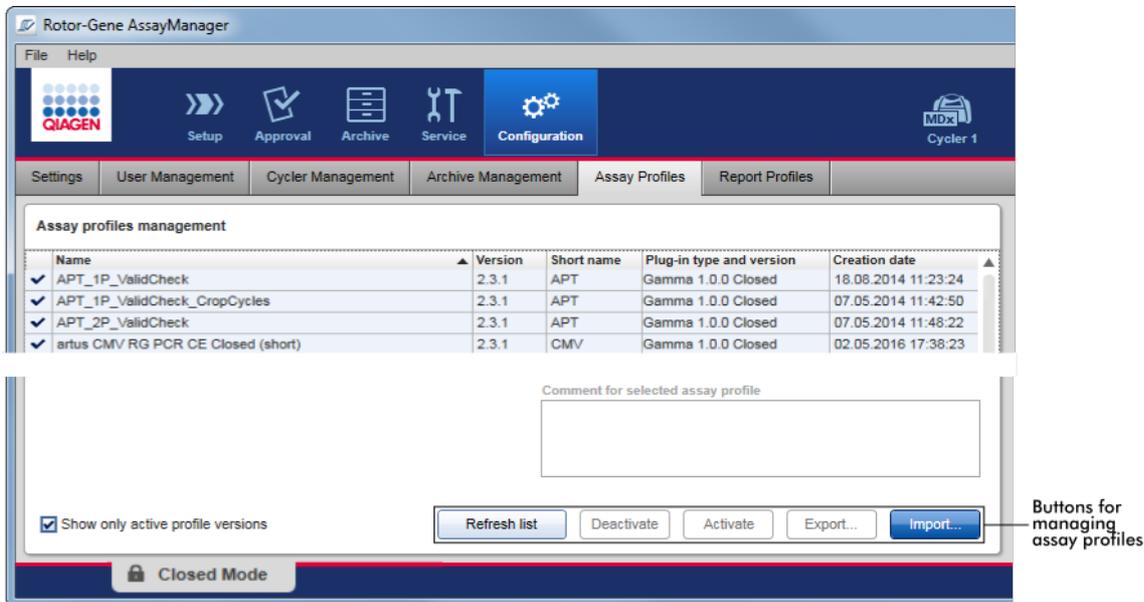
- ▶ Managing assay profiles
- ▶ Customizing reports using report profiles
- ▶ Managing cyclers
- ▶ Managing users
- ▶ Managing archives
- ▶ Working with audit trails
- ▶ Customizing settings

1.6.2.1 Managing Assay Profiles

Overview

Assay profiles can be managed in the "Assay Profiles" tab of the "Configuration" environment. All previously imported assay profiles are listed in a table. A button bar

at the bottom of the screen contains all commands to manage assay profiles. Assay profiles can be activated, deactivated, imported, and exported.

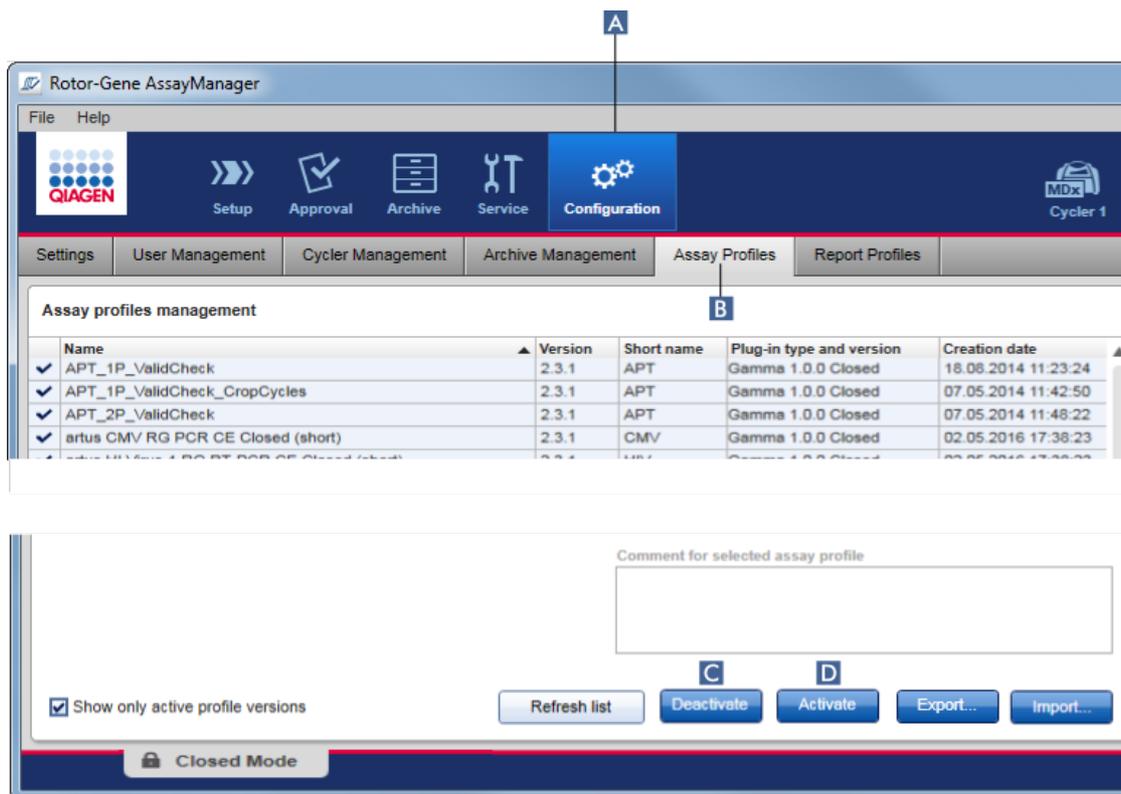


Tasks related to managing assay profiles

- ▶ Importing/exporting an assay profile
- ▶ Activating/deactivating an assay profile

1.6.2.1.1 Importing/Exporting an Assay Profile

Rotor-Gene AssayManager v2.1 provides an import/export feature for assay profiles to exchange assay profiles between different Rotor-Gene AssayManager v2.1 installations. An imported assay profile will be added to the list of "Available worklists" in the "Setup" environments. The imported assay profile is available for the creation of new worklists. This is done in the "Setup" environment. Newly developed assay profiles have to be imported before they can be used in Rotor-Gene AssayManager v2.1.



Step-by-step procedure to export an assay profile

1. Change to the "Assay profiles management" screen:
 - a) Click "Configuration" (A) in the main toolbar.
 - b) Click "Assay Profiles" (B) tab.
2. Select the assay profile to export by clicking in the corresponding table row.
The selected row is marked blue.
3. Click "Export" (C).
The file dialog is opened.
4. Select the target directory, enter a file name for the assay profile, and click "OK".
The selected assay profile is saved to the selected directory. The file extensions is *.iap.

Step-by-step procedure to import an assay profile

1. Change to the "Assay profiles management" screen:
 - b) Click "Configuration" (A) in the main toolbar.

- c) Click "Assay Profiles" (B) tab.
2. Click "Import" (D).
- The select file dialog is opened.
3. Change to the directory containing the assay profile you want to import. Select it, and click "Open".
- The selected assay profile is loaded and added to the list of available assay profiles.

Note

The same version of an assay profile cannot be imported twice.

Related topics

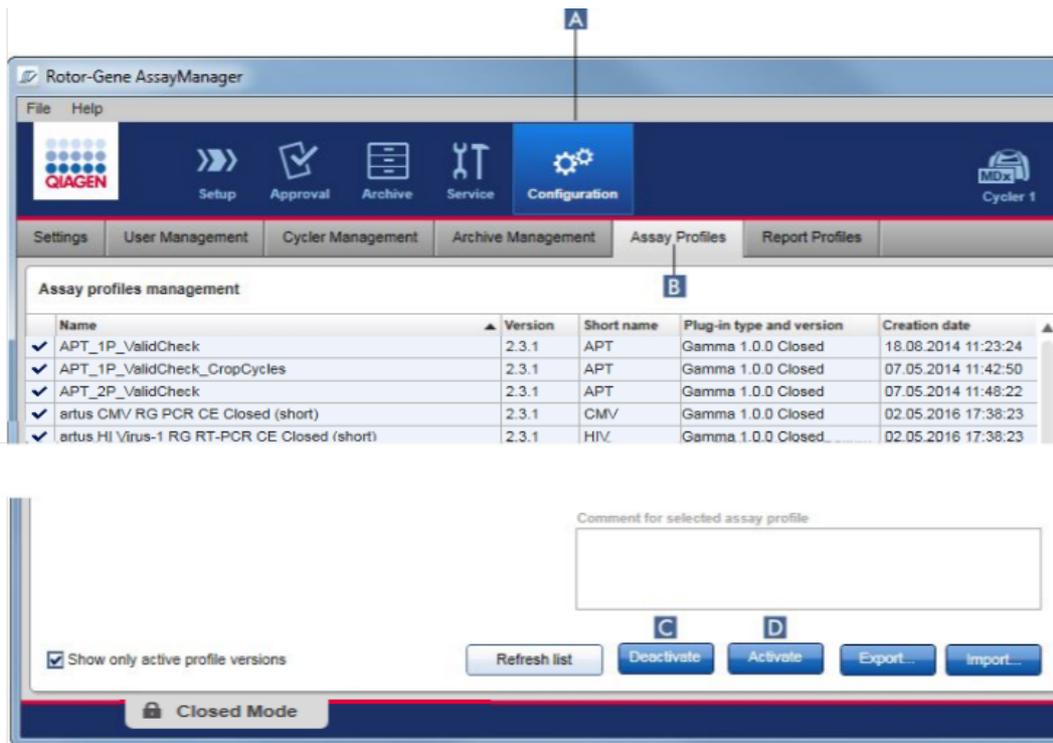
- ▶ Configuration - assay profiles
- ▶ Setting up a run
- ▶ "Setup" environment

1.6.2.1.2 Activating/Deactivating an Assay Profile

Assay profiles can be activated and deactivated. Only activated assay profiles are available for creating and applying worklists in the "Setup" environment. Deactivated assay profiles cannot be used but can be reactivated by an administrator if required. Existing worklists containing a deactivated assay profile cannot be applied anymore, which is indicated in the status column of the "Setup" environment.

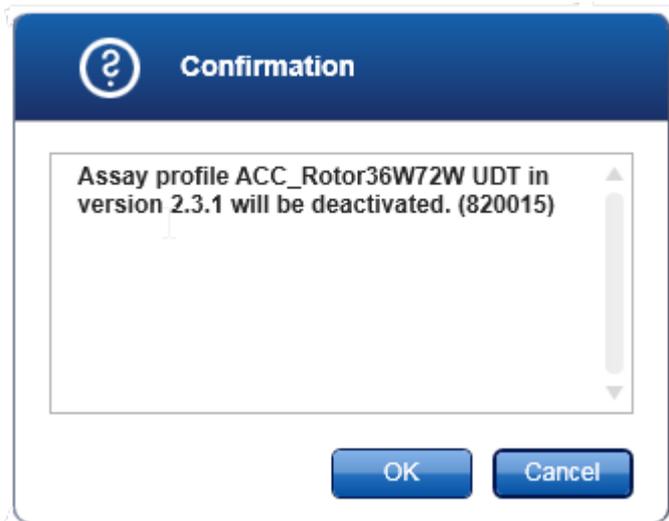
By default the "Show only active profile versions" check box at the bottom left of the screen is activated. To see activated, deactivated and expired assay profiles in parallel in the list, deactivate the check box. Activated, deactivated and expired assay profiles can be differentiated by the following icons:

Icon	Assay profile status
	Activated
	Deactivated
	Expired



Step-by-step procedure to deactivate an assay profile

1. Change to the "Assay profiles management" screen:
 - a) Click "Configuration" (A) in the main toolbar.
 - b) Click "Assay Profiles" (B) tab.
2. Select the assay profile to be deactivated by clicking in the corresponding table row.
The selected row is marked blue.
3. Click "Deactivate" (C).
The following confirmation dialog is opened:



4. Click "OK".

The selected assay profile will be deactivated. The icon of the assay profile changes from to in the assay profiles table.

Assay profiles management	
	Name
<input checked="" type="checkbox"/>	QuantiFast Pathogen PCR +IC
<input checked="" type="checkbox"/>	Rotor-Gene SYBR Green PCR Demo Kit

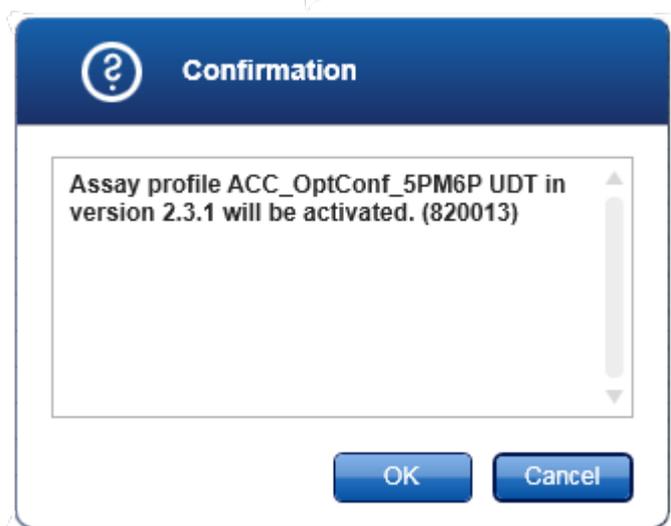
→

Assay profiles management	
	Name
<input checked="" type="checkbox"/>	QuantiFast Pathogen PCR +IC
<input type="checkbox"/>	Rotor-Gene SYBR Green PCR Demo Kit

Step-by-step procedure to activate an assay profile

1. Change to the "Assay profiles management" screen:
 - a) Click "Configuration" (**A**) in the main toolbar.
 - b) Click "Assay Profiles" (**B**) tab.
2. Ensure that the "Show only active profile versions" check box is deactivated. Otherwise deactivated assay profiles are not shown and cannot be activated.

Show only active profile versions
3. Select the assay profile to activate by clicking in the corresponding table row. The selected row is marked blue.
4. Click "Activate" (**D**). The following confirmation dialog is opened:



5. Click "OK".

The selected assay profile will be activated. The icon of activated assay profile changes from to in the assay profiles table.

Note

Only one version of an assay profile can be active. If another version of an active assay profile is activated, the previous one is automatically deactivated.

Related topics

- ▶ Configuration - assay profiles

1.6.2.2 Managing Report Profiles

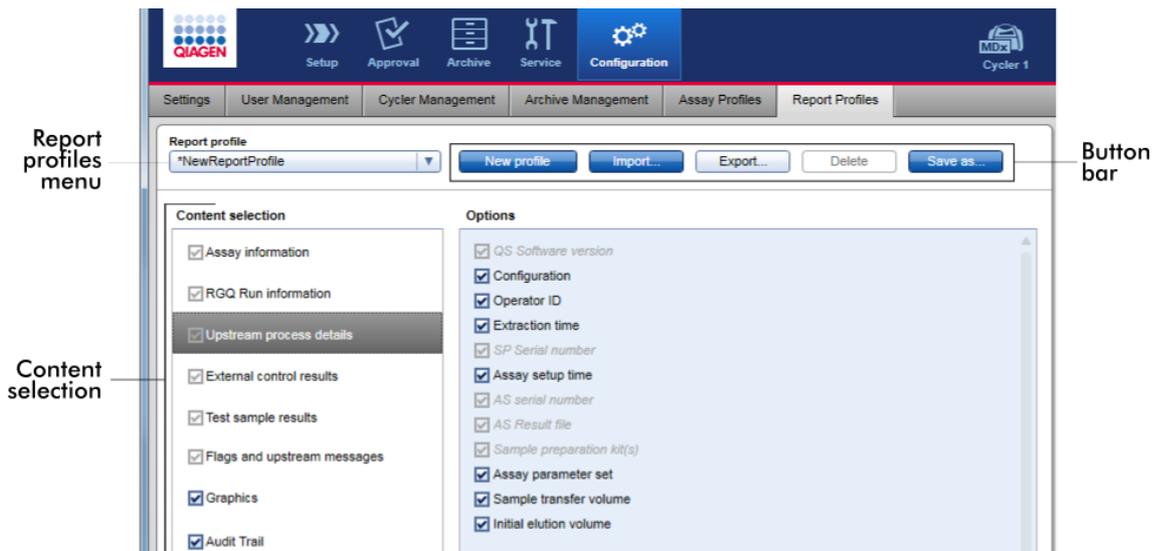
Report profiles define which experiment data will be included in a report. Before creating a report, a specific report profile has to be selected from a list of all available report profiles. Depending on the individual needs, different report profiles can be configured in the "Report Profiles" tab of the "Configuration" environment. For plugin based approaches appropriate report profiles depending on the plugin and assay profile can be downloaded.

Note

Some plug-ins contain a specific report profile that is mandatory.

Note

For the Gamma Plug-in, no user defined report profiles are applicable. The experiment data which will be included in the report are pre-defined by the assay.



All available report profiles are listed in the "Report profile" drop-down menu. The content to be included in a report when using a specific report profile can be selected in the content selection area. A button bar at the top of the screen contains all commands to manage report profiles.

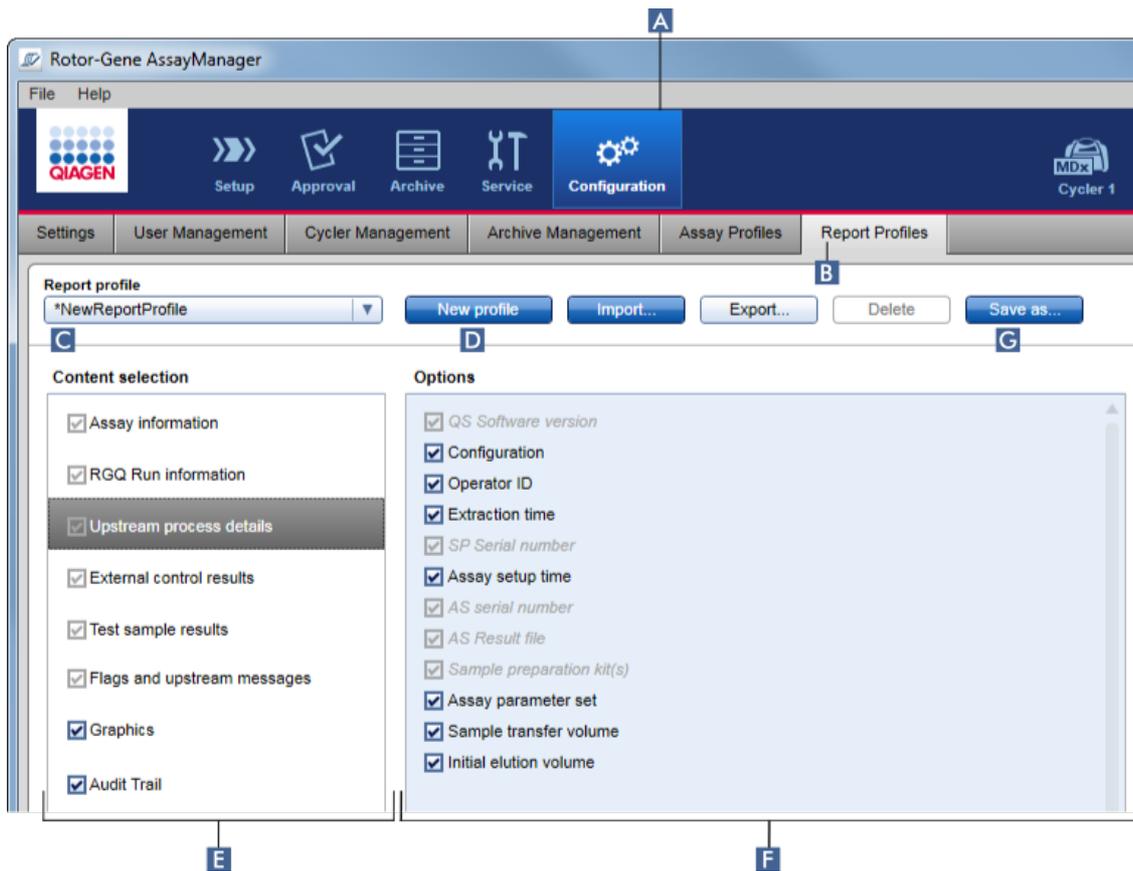
Tasks related to managing report profiles

- ▶ Creating a new report profile
- ▶ Importing/exporting a report profile
- ▶ Deleting a report profile

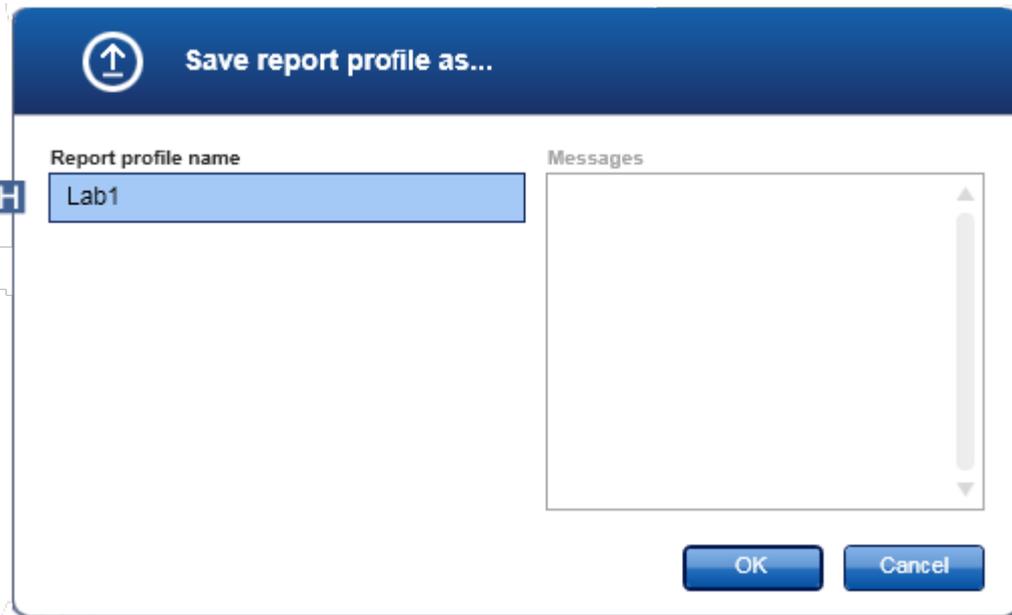
1.6.2.2.1 Creating a New Report Profile

Step-by-step procedure to create a new report profile

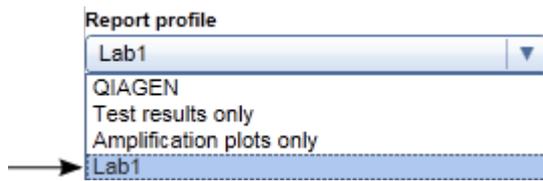
1. Change to the "Report Profiles" management screen:
 - a) Click "Configuration" (A) in the main toolbar.
 - b) Click the "Report Profiles" (B) tab.



2. By default a new report profile template is selected in the "Report profile" drop-down menu (C) called **NewReportProfile* with all content selection options activated. If another report profile was selected before, a new report profile can be generated by clicking "New profile" (D).
3. Deactivate the check box of an item in the content selection or options area to exclude it from the report file. Only items with activated check box will be included in the report. Note: Some content selection options are mandatory and cannot be deactivated.
4. Click "Save as..." (G) to save the report profile.
5. The "Save report profile as..." dialog is displayed:



6. Enter a name for the new profile in the "Report profile name" field (H).
7. Click "OK".
8. The report profile is created and listed in the report profiles list (C).



Note

Report profiles delivered by QIAGEN are read-only, i.e., they can only be imported or deleted.

Note

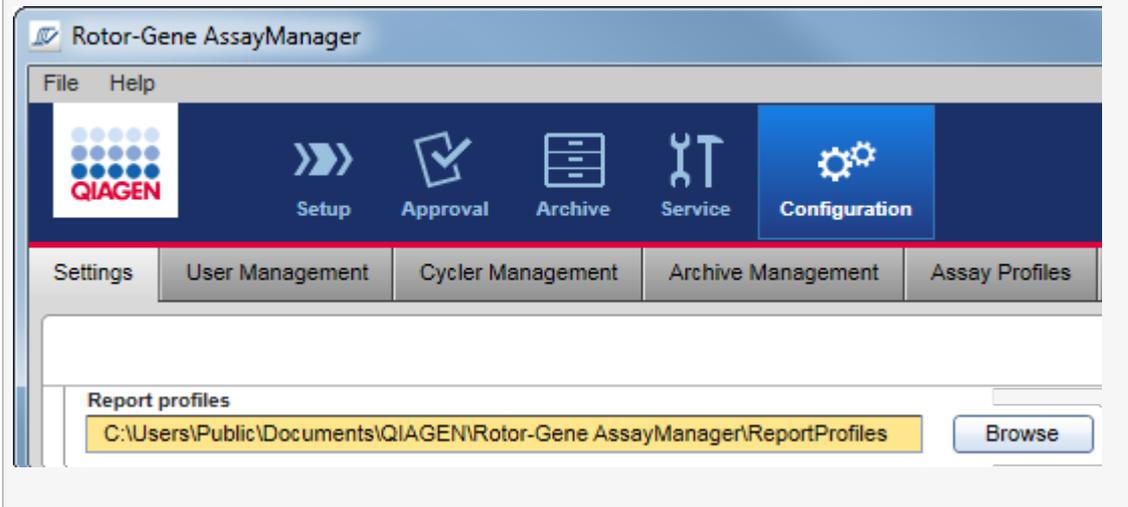
For the Gamma Plug-in, no user defined report profiles are applicable. The experiment data which will be included in the report are pre-defined by the assay.

1.6.2.2.2 Importing/Exporting a Report Profile

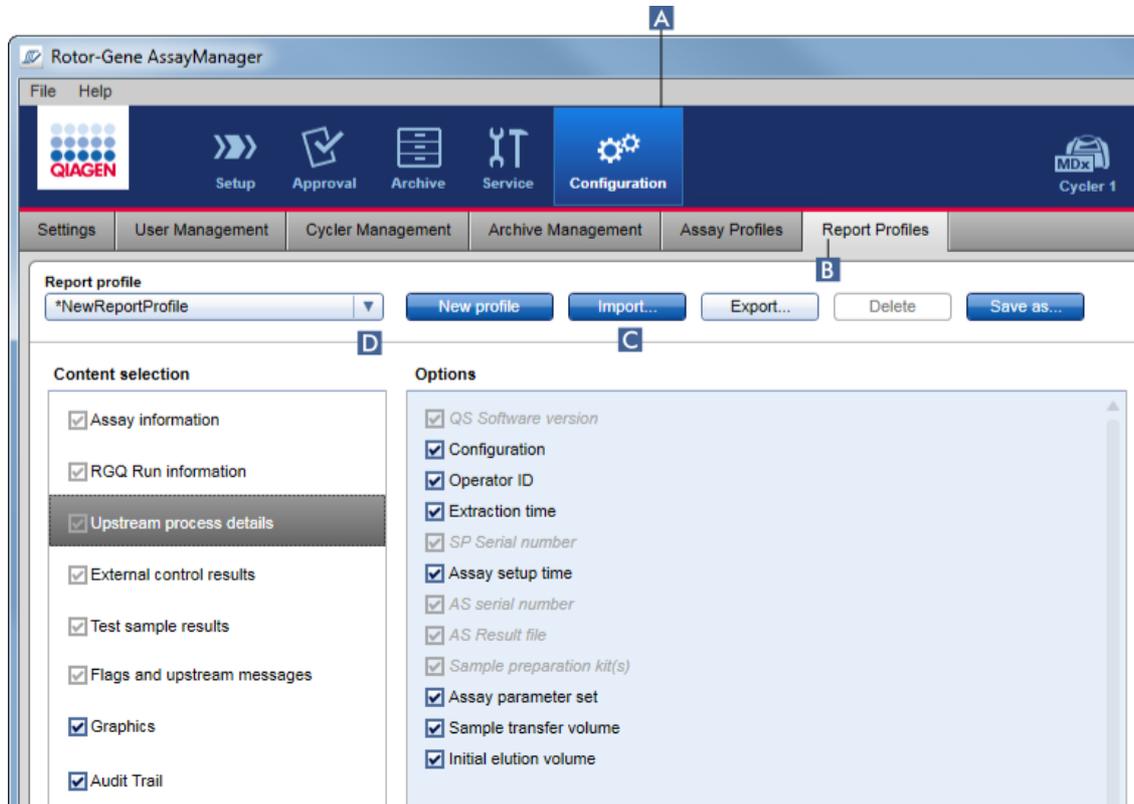
Report profiles can be exchanged between different Rotor-Gene AssayManager v2.1 installations using the report profile import and export function.

Note

The default directory for report profile import and export is set in the ► "Settings" tab of the ► "Configuration" environment.

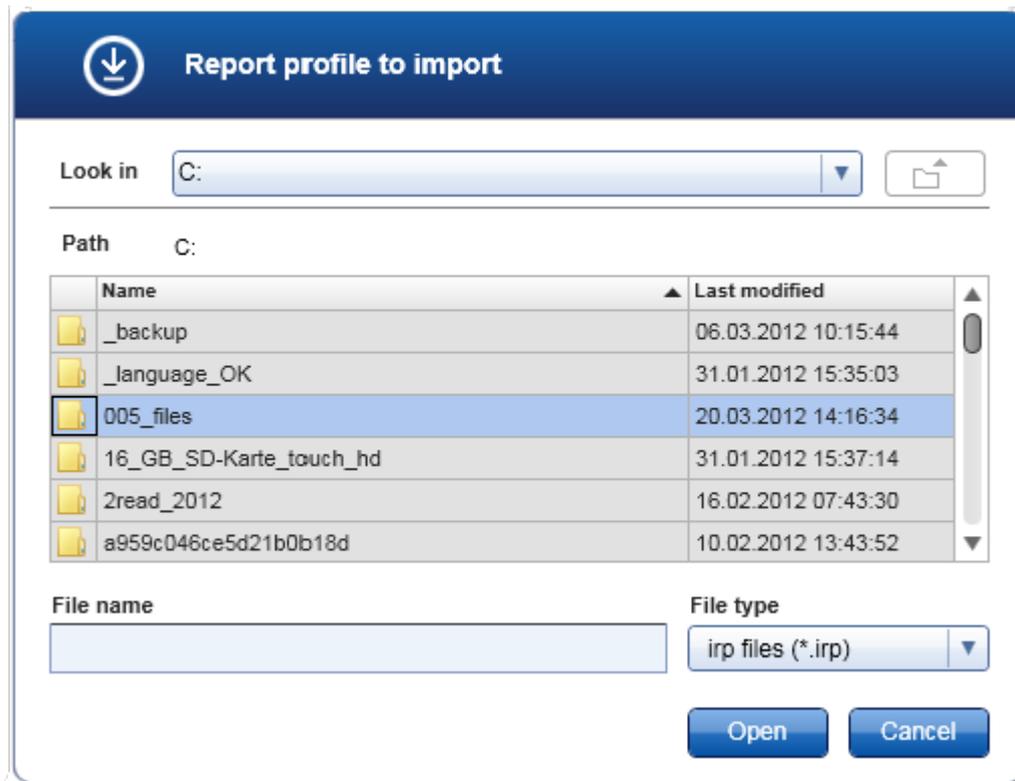


Step-by-step procedure to import a report profile



1. Change to the "Report Profiles" management screen:
 - a) Click "Configuration" (A) in the main toolbar.
 - b) Click the "Report Profiles" (B) tab.
2. Click "Import" (C).

The file dialog is opened.



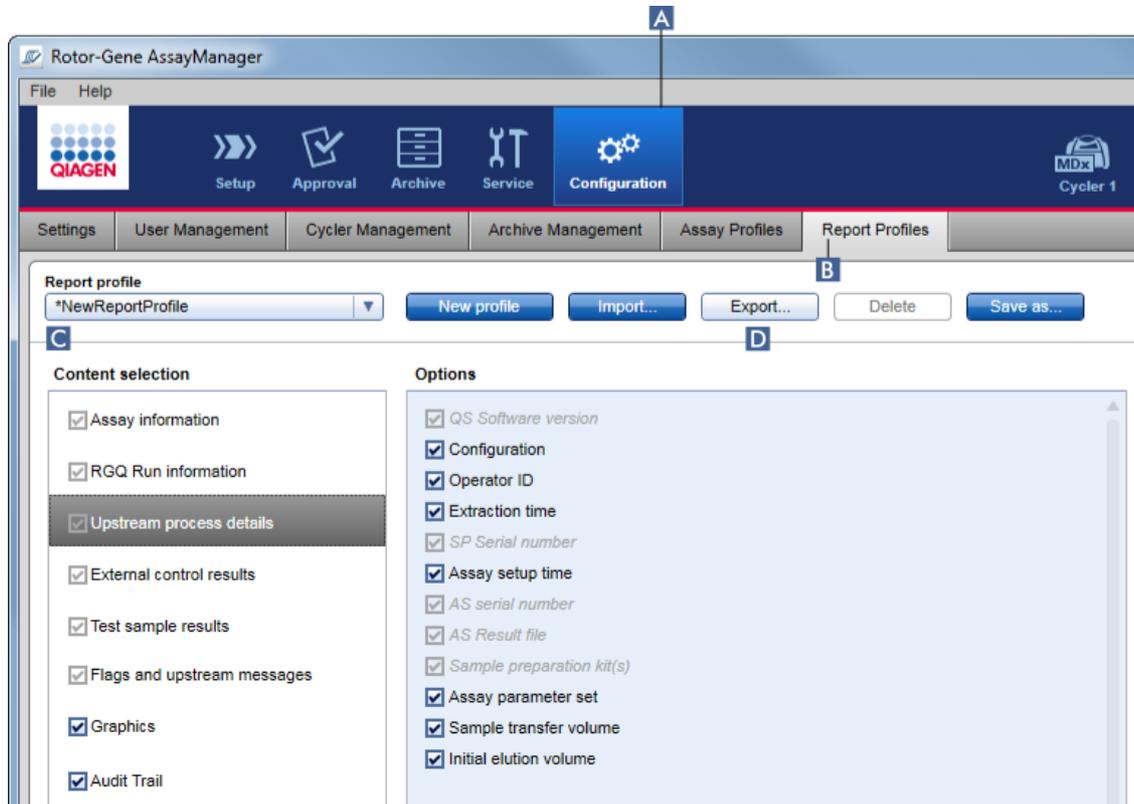
3. Change to the directory containing the report profile you want to import. Select the report profile and click "Open".

The selected report profile is loaded and added to the list of available report profiles in the drop-down menu (D).

Note

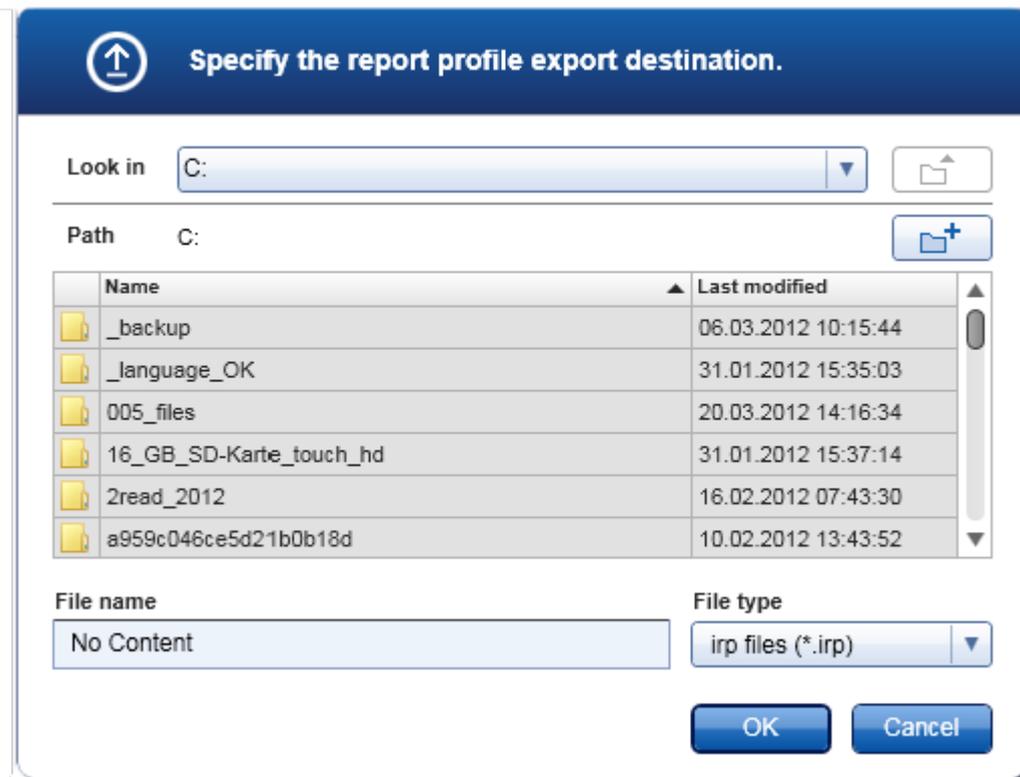
The maximum path length including the report file name must not exceed 256 characters.

Step-by-step procedure to export a report profile



1. Change to the "Report profiles" management screen:
 - b) Click "Configuration" (A) in the main toolbar.
 - c) Click "Report Profiles" (B) tab.
2. Select the report profile to be exported from the "Report profile" drop-down menu (C).
3. Click "Export" (D).

The file dialog is opened.



4. Change to the target directory, and click "OK".

The report profile is saved to the selected directory. The file extensions is *.irp.

Note

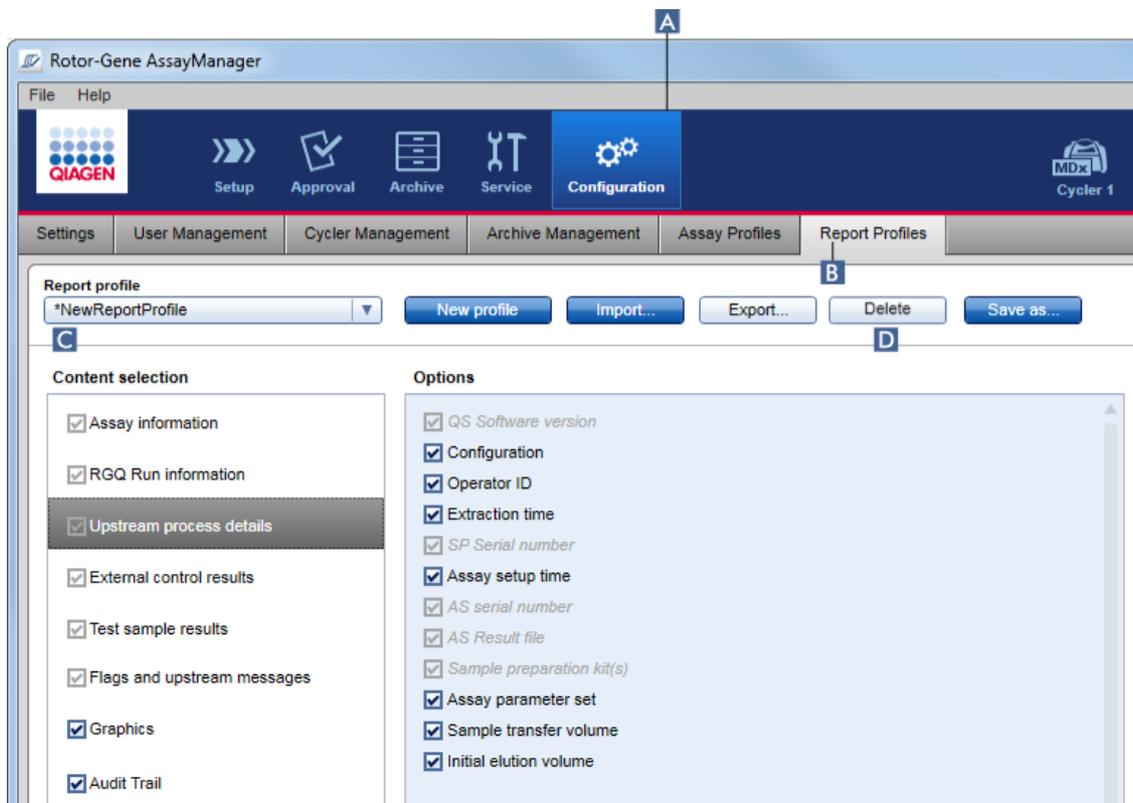
Report profiles delivered by QIAGEN are read-only and cannot be exported.

Note

For the Gamma Plug-in, no user defined report profiles are applicable. The experiment data which will be included in the report are pre-defined by the assay.

1.6.2.2.3 Deleting a Report Profile

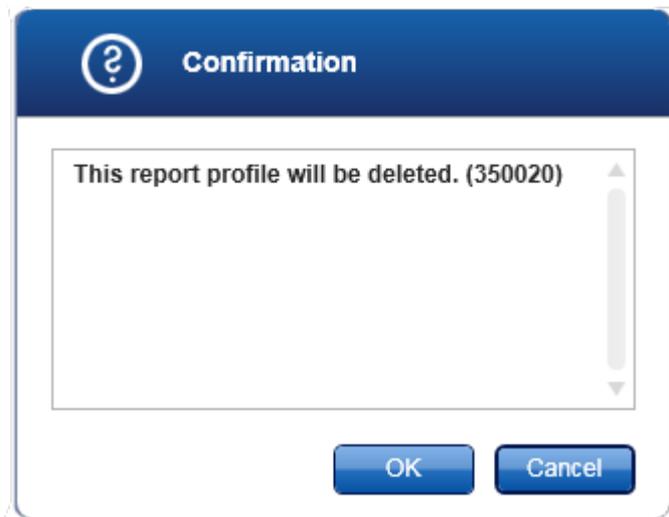
Obsolete report profiles can be removed using the delete function.



Step-by-step procedure to delete a report profile

1. Change to the "Report Profiles" management screen:
 - a) Click "Configuration" (A) in the main toolbar.
 - b) Click the "Report Profiles" (B) tab.
2. Select the report profile to be exported from the report profile menu (C).
3. Click "Delete" (D).

The following confirmation dialog is opened:

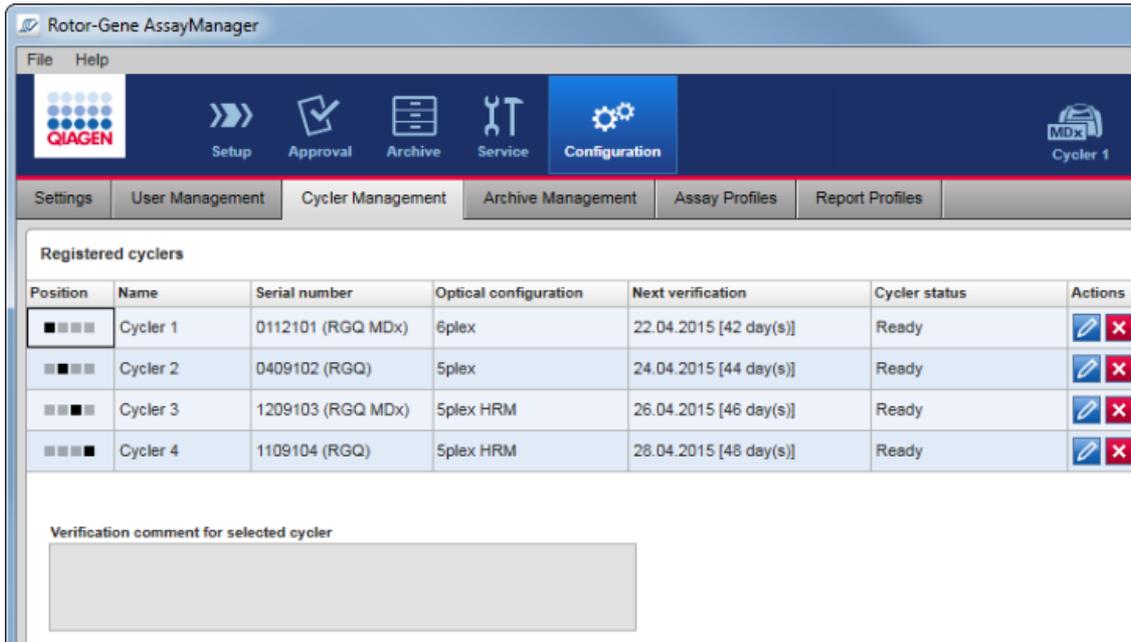


4. Click "OK".

The selected report profile is deleted and removed from the report profile drop-down menu (C).

1.6.2.3 Managing Cyclers

Rotor-Gene AssayManager v2.1 can manage and operate up to 4 different Rotor-Gene Q instruments in parallel. The cyclers can be configured and managed in the "Cycler Management" tab of the "Configuration" environment.



Tasks related to managing cyclers

- ▶ Adding a cycler
- ▶ Editing cycler settings
- ▶ Removing a cycler

Possible cycler states are:

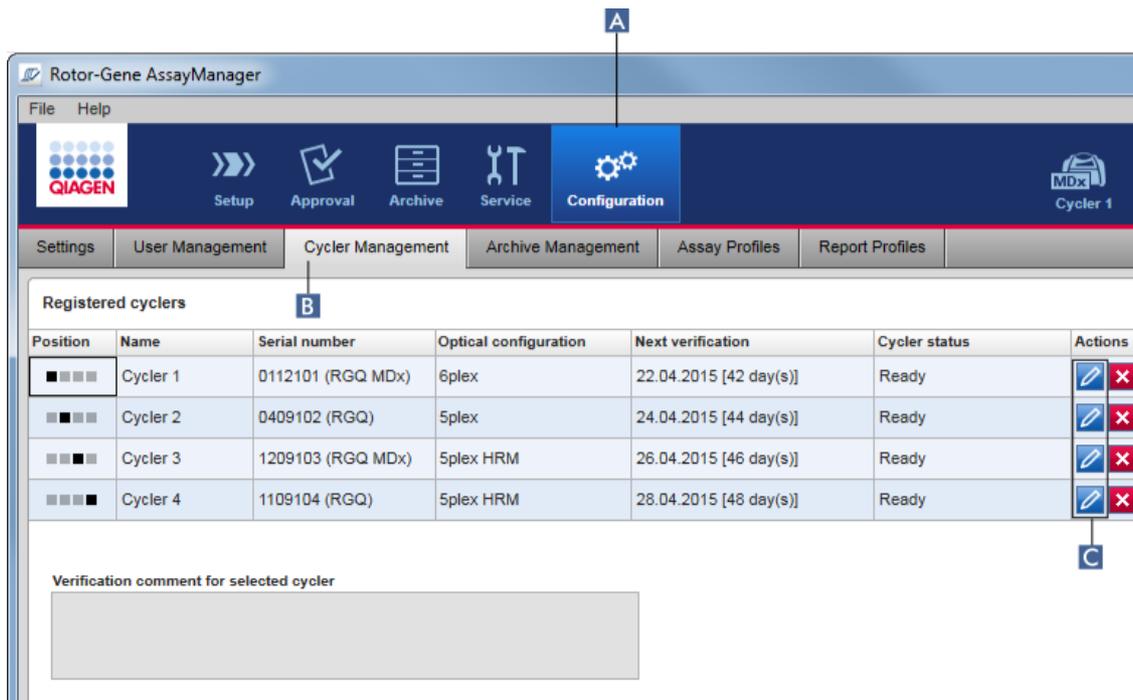
Status	Description
Offline	The cycler is either connected or not connected but not turned on.
Ready	The cycler is activated and ready.
Loaded	The cycler is loaded.
Needs verification	The cycler needs to be verified.
Running	The cycler is performing a run.
Run stopped	The cycler was stopped, but has not been released yet.

Run complete	The run finished successfully.
Run failed	An error occurred during the run.
Run stopped, cycler disconnected	The cycler has been disconnected after the run has been stopped but has not been released yet.
Run complete, cycler disconnected	The cycler was disconnected after the run had been completed.
Run failed, cycler disconnected	The cycler was disconnected after the run had failed.

1.6.2.3.1 Adding a Cycler

Step-by-step procedure to add a cycler

1. Connect the USB cable supplied to the USB hub or a USB port of the computer.
2. Connect the USB cable or the USB hub to the back of the Rotor-Gene Q.
3. Connect the Rotor-Gene Q to the power supply. Connect one end of the AC power cord to the socket located at the rear of the Rotor-Gene Q and the other end to the AC power outlet.
4. If not already done, install Rotor-Gene AssayManager v2.1 software. The driver is installed automatically with the software.
5. Once the software has been installed, switch on the Rotor-Gene Q by moving the switch, located at the back on the right hand side, to the "On" position.
6. Open Rotor-Gene AssayManager v2.1.



7. Change to the "Cyclers Management" screen:
 - a) Click "Configuration" (A) in the main toolbar.
 - b) Click the "Cyclers Management" (B) tab.

Note

The cycler must be connected to the computer and switched on before it can be registered in Rotor-Gene AssayManager v2.1. The software automatically detect if a Rotor-Gene Q MDx device is connected.

8. Click the "Edit cycler" icon (C) of an empty row.
9. The "Edit cycler" dialog is shown:

10. Enter a name with up to eight characters in the "Name" field (D) and the serial number of the connected Rotor-Gene Q in the "Serial number" field (E). The optical configuration of the cycler will automatically be recognized by the Rotor-Gene AssayManager v2.1 once the name and serial number are entered. Also a possible MDx status will be assigned automatically.
11. Optional: Enter a date when the cycler needs next verification in the "Next verification" field (F) and a verification comment. The comment field can be used to specify what kind of verification shall be performed at the defined date.
12. Click "OK" to add the Rotor-Gene Q to the "Registered cyclers" table.

Note

If more than one cycler is registered in Rotor-Gene AssayManager v2.1, we highly recommend labeling each cycler prominently on the front instrument housing with the specific name given during registration. This eases identification of cyclers when loading or when several cyclers are running in parallel and omits to refer back each time to the serial number on the type plate.

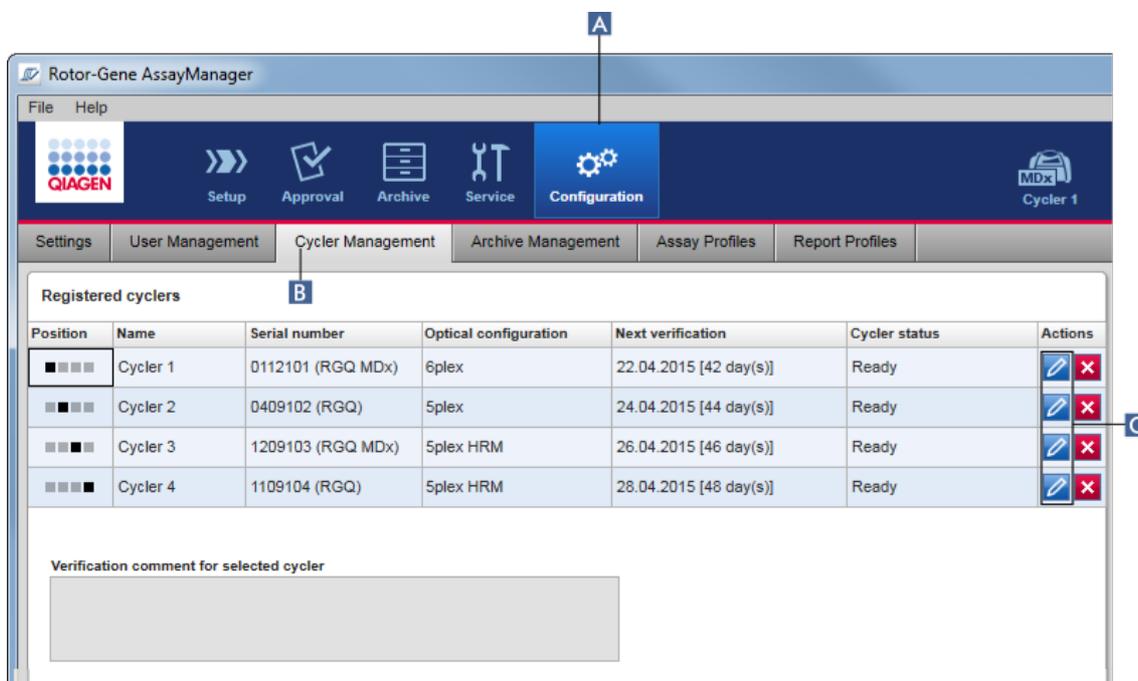
Related topics

- ▶ Setting up a run
- ▶ "Cycler" environment

1.6.2.3.2 Editing Cyclers Settings

Step-by-step procedure to modify a cycler's settings

1. Change to the "Cycler Management" screen:
 - a) Click "Configuration" (A) in the main toolbar.
 - b) Click the "Cycler Management" (B) tab.



2. Click the "Edit cycler" icon (C) of an already registered cycler.
3. The "Edit cycler" dialog is shown.
4. The cycler name, the next verification date, and the verification comment may be edited.
5. Click "OK" to update the cycler configuration.

Related topics

- ▶ Setting up a run
- ▶ "Cycler" environment

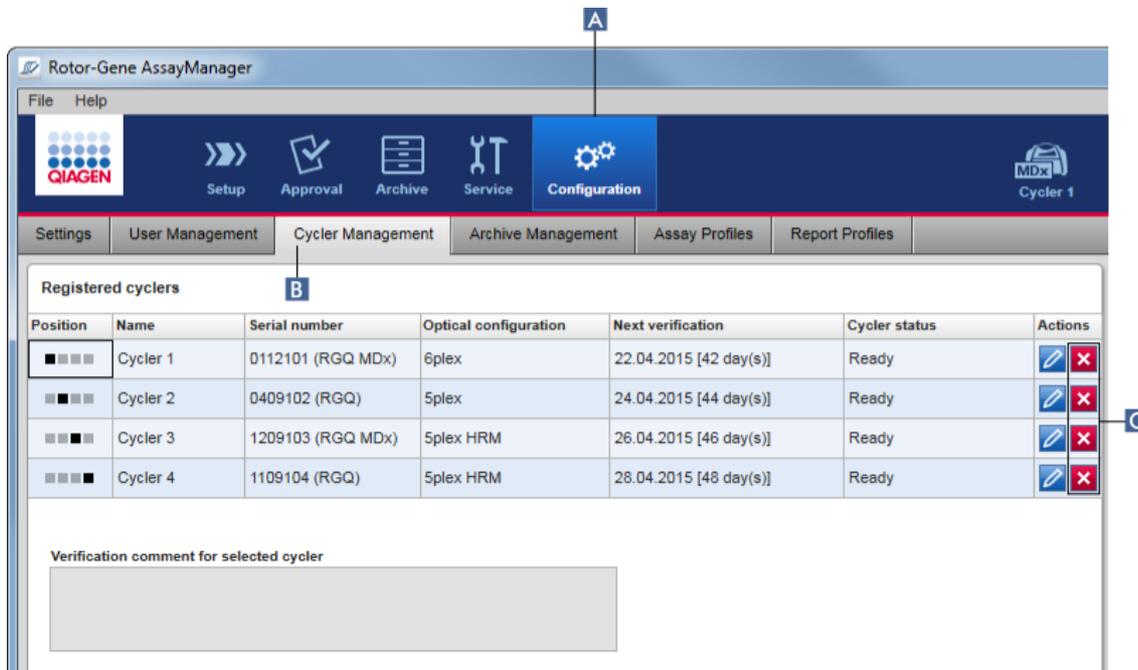
1.6.2.3.3 Removing a Cyclor

Note

Cyclers can only be removed if they are offline, ready, or in status "needs verification".

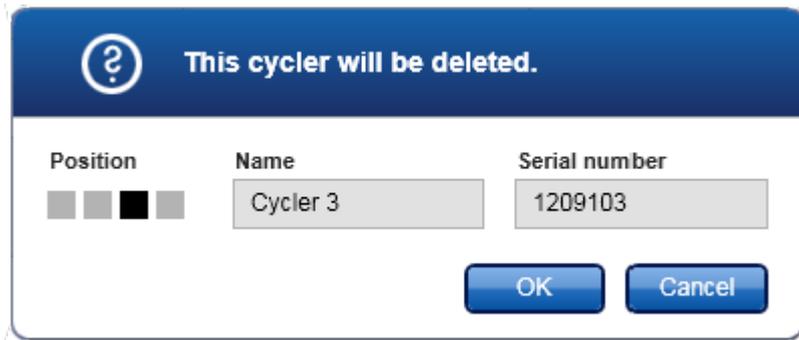
Step-by-step procedure to remove a cyclor

1. Change to the "Cyclor Management" screen:
 - a) Click "Configuration" (A) in the main toolbar.
 - b) Click the "Cyclor Management" (B) tab.



2. Move the mouse to the row containing the cyclor to be removed from the "Registered cyclers" table.
3. Click the "Remove cyclor" button (C).

The following confirmation dialog is opened.



4. Click "OK". The selected cycler is removed from the "Registered cyclers" table and cannot be used anymore.

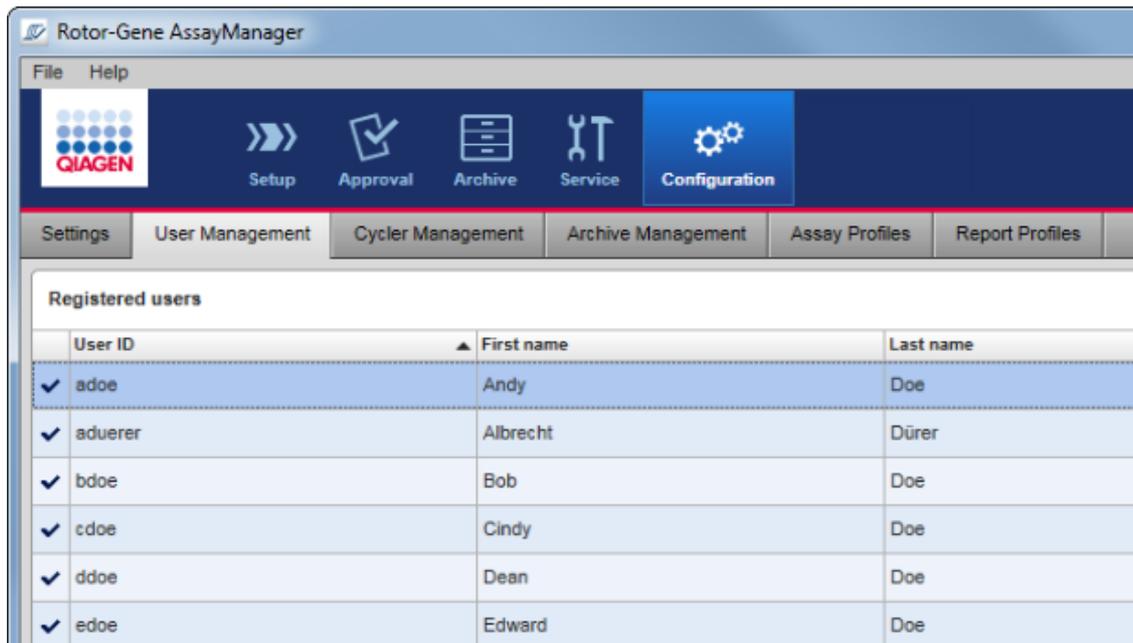
Related topics

- ▶ Setting up a run
- ▶ "Cycler" environment

1.6.2.4 Managing Users

A user with the assigned role "Administrator" can add new user profiles or activate, deactivate, and modify existing user profiles. User profiles cannot be deleted but only deactivated, if necessary.

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



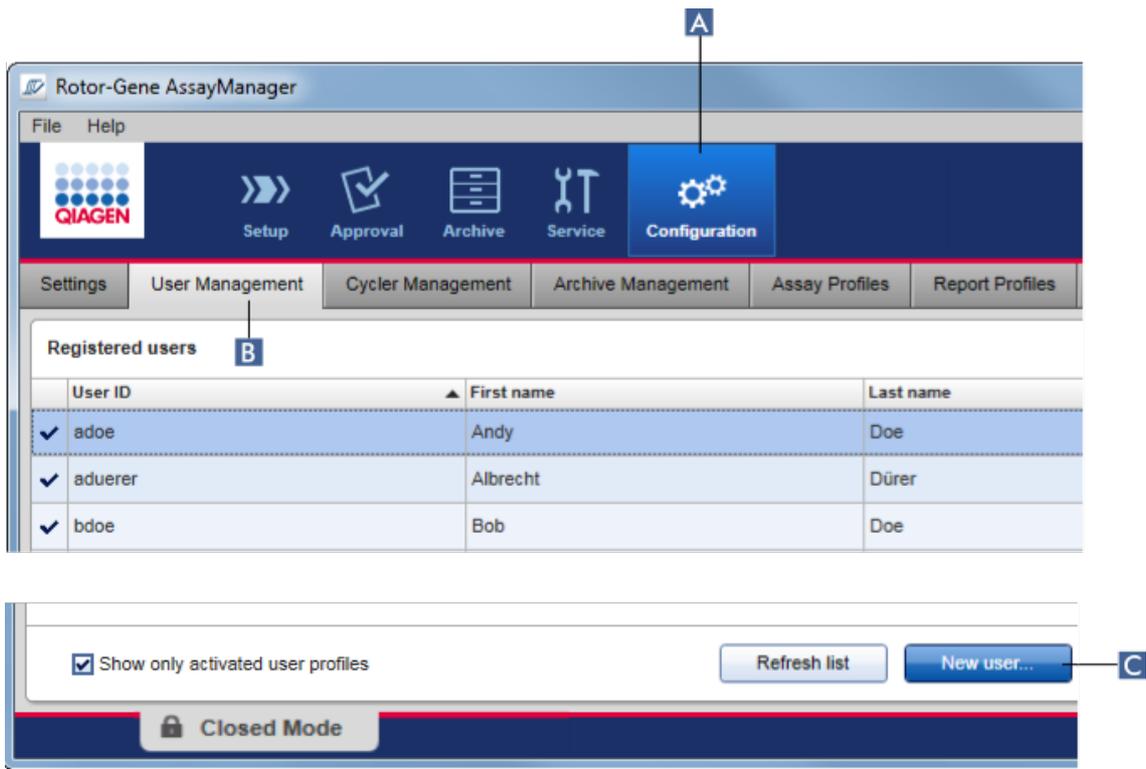
Tasks related to managing users

- ▶ Creating a user profile
- ▶ Changing user profile settings
- ▶ Activating/deactivating a user profile
- ▶ Setting password policies and auto-lock timer

1.6.2.4.1 Creating a User Profile

Step-by-step procedure to create a user profile

1. Change to the "User Management" screen:
 - a) Click "Configuration" (A) in the main toolbar.
 - b) Click the "User Management" (B) tab.



2. Click "New user..." (C).
3. The "Add user" dialog is shown:

4. Enter the first name, the last name, and a user ID in the corresponding fields **D**, **E**, and **F**.
5. Enter a password in the "Password" field (**G**), and enter it again in the "Confirm password" field (**H**).

Note

The password must be in the range of 8–40 characters. If CLIA complaint password rules are activated in the "Settings" tab of the Configuration environment, the password has to contain at least 2 upper case characters, 2 lower case characters, 2 numerical characters, and 2 special characters.

6. The "Activate user" check box (I) is activated by default. To create a deactivated user profile, deactivate this check box.
7. Activate the check boxes of the role in the "Roles" table that will be assigned to the user (J). It is possible to assign multiple roles to a user.
8. Click "OK".
The new user profile is added to the "Registered users" table.

Note

- The user must change the password at the first login.
- Password rules can be set up in the ► "Configuration" environment in the ► "Settings" tab.

Related topics

- Configuration - managing users
- User roles

1.6.2.4.2 Changing User Profile Settings

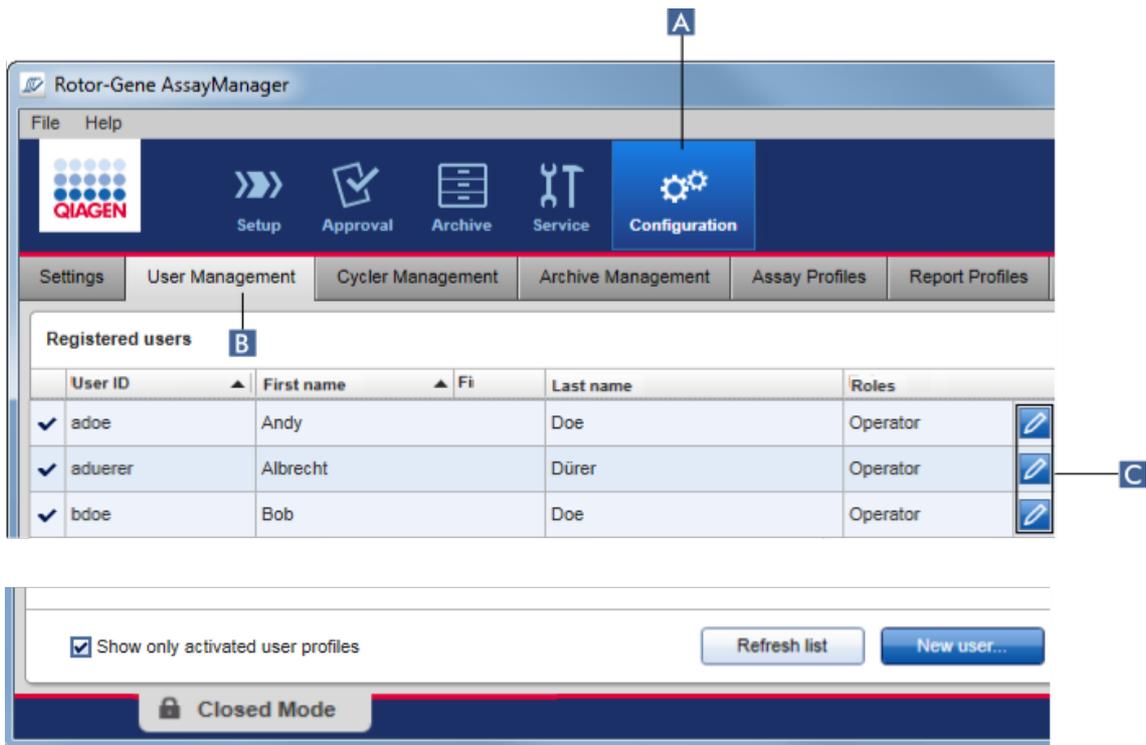
Note

A user ID can never be edited or removed. However, the following data can be modified:

- First name
- Last name
- Password
- Roles

Step-by-step to modify user settings

1. Change to the "User Management" screen:
 - a) Click "Configuration" (A) in the main toolbar.
 - b) Click the "User Management" (B) tab.



2. Click the "Edit User" icon (C) of a user profile.
3. The "Edit User" dialog is shown:

Edit User

D First name: John

E Last name: Doe

User ID: SU

F Password: ●●●●●●

G Confirm password: ●●●●●●

H Activate user

Messages

Roles	
<input type="checkbox"/> Administrator	
<input type="checkbox"/> Approver	
<input type="checkbox"/> AssayDeveloper	
<input type="checkbox"/> Operator	
<input checked="" type="checkbox"/> SuperUser	

OK Cancel

4. If applicable, modify the name of the user in the fields **D** and **E**.
5. If applicable, enter a new password in the "Password" field (**F**), and enter it again in the "Confirm password" field (**G**).
6. Toggle the "Activate user" check box (**H**) to change the activation status of the user.
7. If applicable, modify the check boxes in the "Roles" table (**I**) according to the needs. It is possible to assign multiple roles to a user.
8. Click "OK". The user profile will be updated according to the modifications made.

Note

The user must change the password at the next login.

Related topics

- ▶ Configuration - managing users
- ▶ User roles

1.6.2.4.3 Activating/Deactivating a User Profile

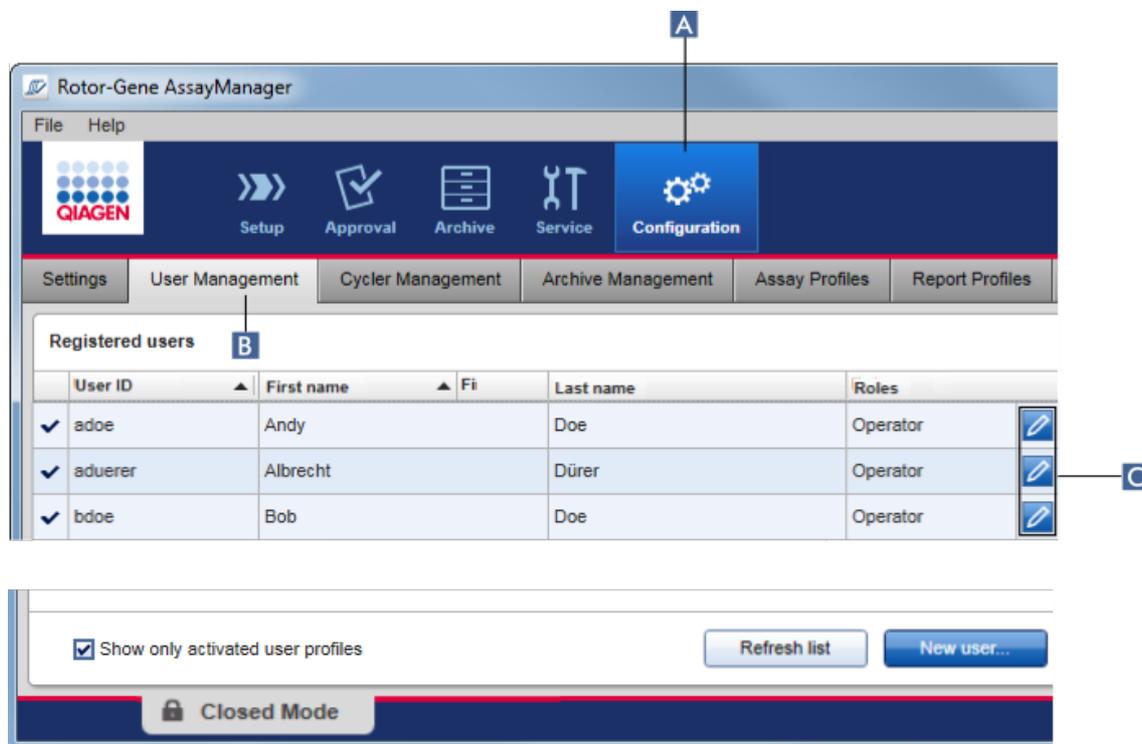
A user profile can never be deleted but only deactivated. This ensures that actions in the audit trails can always be tracked back to a specific user.

Note

Only the status of a user who is currently not logged in can be changed.

Note

To make deactivated user profiles visible under "Registered users", deselect "Show only activated user profiles".



Step-by-step to deactivate a user

1. Change to the "User Management" screen:

- a) Click "Configuration" (A) in the main toolbar.
- b) Click the "User Management" (B) tab.
2. Click the "Edit User" icon (C) of a user profile.
3. The "Edit User" dialog is shown:

The "Edit User" dialog box is shown. It features a blue header with a pencil icon and the text "Edit User". The dialog contains several input fields: "First name" (John), "Last name" (Doe), "User ID" (SU), "Password" (masked with dots), and "Confirm password" (masked with dots). To the right is a "Roles" section with a list of roles: Administrator, Approver, AssayDeveloper, Operator, and SuperUser. The "SuperUser" role is checked. Below the roles is a "Messages" text area. At the bottom left, there is a checked checkbox labeled "Activate user" with a blue "D" next to it. At the bottom right are "OK" and "Cancel" buttons.

4. Uncheck the "Activate user" check box (D) to deactivate the user profile.
 5. Click "OK".
- The user profile is deactivated. Its status icon in the "Registered users" table changes from ✓ to ☐.

Step-by-step to activate a user

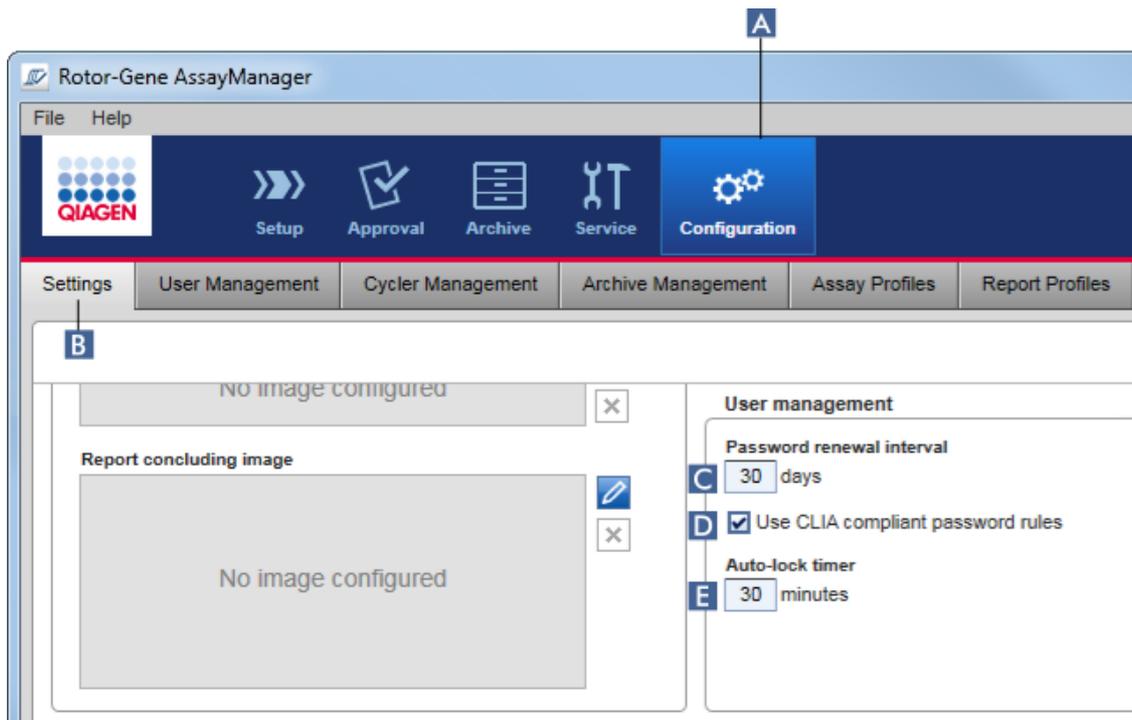
1. Change to the "User Management" screen:
 - a) Click "Configuration" (A) in the main toolbar.
 - b) Click the "User Management" (B) tab.
2. Ensure that the check box "Show only activated user profiles" is unchecked to make deactivated user profiles visible.
3. Click the "Edit user" icon (C) of a deactivated user profile.
4. The "Edit User" dialog is shown:
 - a) Activate the "Activate user" check box (D) to activate the user profile.
 - b) Click "OK". The status icon in the "Registered users" table changes from  to .

1.6.2.4.4 Setting Password Policies and Auto Lock Timer

A user with assigned role "Administrator" can set up password policies and the auto-lock timer in the "Settings" tab of the "Configuration" environment.

Passwords for user profiles have to be changed after the specified number of days. The administrator can also define that  CLIA compliant password rules must be applied for password creation.

The auto-lock timer locks the application after a certain time without user interaction.



Step-by-step to set the password renewal interval

1. Change to the "Settings" screen:
 - a) Click "Configuration" (A) in the main toolbar.
 - b) Click the "Setting" (B) tab.
2. Go to the "User management" group box. Enter the number of days in the "Password renewal interval" field (C) after which the password for user profiles should expire.

Note

Entering a value of 0 means the password will never expire.

Step-by-step to activate CLIA compliant password rules

1. Change to the "Settings" screen:
 - b) Click "Configuration" (A) in the main toolbar.
 - c) Click the "Setting" (B) tab.
2. Go to the "User management" group box, and activate the check box "Use CLIA compliant password rules" (D).
The user is required to use CLIA compliant passwords.

Further information on password rules can be found under ► Password policy.

Step-by-step to set up the auto-lock timer

1. Change to the "Settings" screen:
 - a) Click "Configuration" (**A**) in the main toolbar.
 - b) Click the "Setting" (**B**) tab.
2. Go to the "User management" group box, and enter the number of minutes after which the application will be locked in the "Auto-lock timer" field (**E**). After the specified time without user interaction, the application will be locked.

Note

Entering a value of 0 means the auto-lock timer is deactivated and the user is never logged out automatically.

Related topics

- Configuration - managing users
- User roles

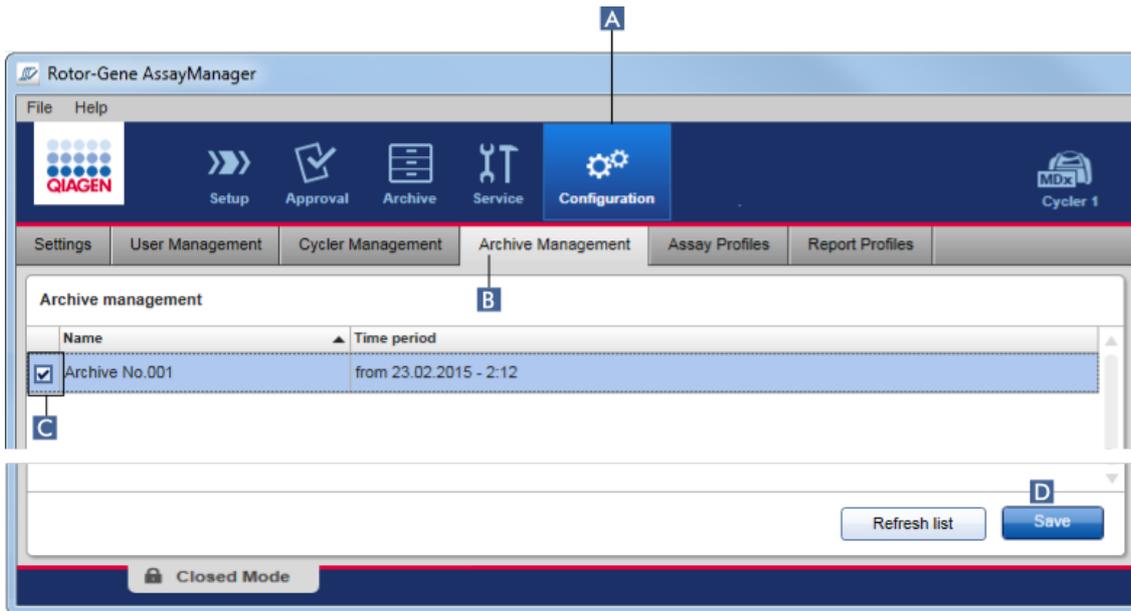
1.6.2.5 Managing Archives

Rotor-Gene AssayManager v2.1 creates archives to save and archive experiment data with a size of up to 10 GB each. A new archive is created automatically when the archive currently used is full.

When filtering for specific experiments in the "Archive" environment, only activated archives will be browsed. By default this is the archive currently in use. If searching becomes too slow due to increasing data sizes, archives can be deactivated. It is possible to include deactivated archives in the browsing process by reactivating them in the "Archive Management" tab of the "Configuration" environment.

Note

Browsing in several archives will slow down the search time of Rotor-Gene AssayManager v2.1.



Step-by-step procedure to activate or deactivate an archive

1. Change to the "Archive Management" screen:
 - a) Click "Configuration" (A) in the main toolbar.
 - b) Click the "Archive Management" (B) tab.

The "Archive Management" screen contains a table listing all existing archives. A check box at the beginning of every row (C) indicates if an archive is activated or deactivated.

If check box is...	Archive is...
Checked	Activated
Unchecked	Deactivated

2. Check the check box of archives to be activated. Uncheck the check boxes of archives to be deactivated.
3. Click "Save" (D).

Related topics

- ▶ Configuration - managing archives
- ▶ Filtering for experiments

1.6.2.6 Customizing Settings

A user with the assigned role "Administrator" can customize the settings in the "Configuration" environment. The settings are divided into two sections, "Global settings" and "Local settings":

- "Global settings": Global settings are stored in the database and affect all clients using the database.
- "Local settings": Local settings affect only the specific computer.

For details, see [▶ Settings](#).

1.7 Maintenance

Both the Rotor-Gene Q cycler and the computer running the Rotor-Gene AssayManager v2.1 need to be maintained. Details can be found in the relevant manuals.

Rotor-Gene AssayManager v2.1 is a software and does not need to be maintained in general. However, the database may need to be maintained.

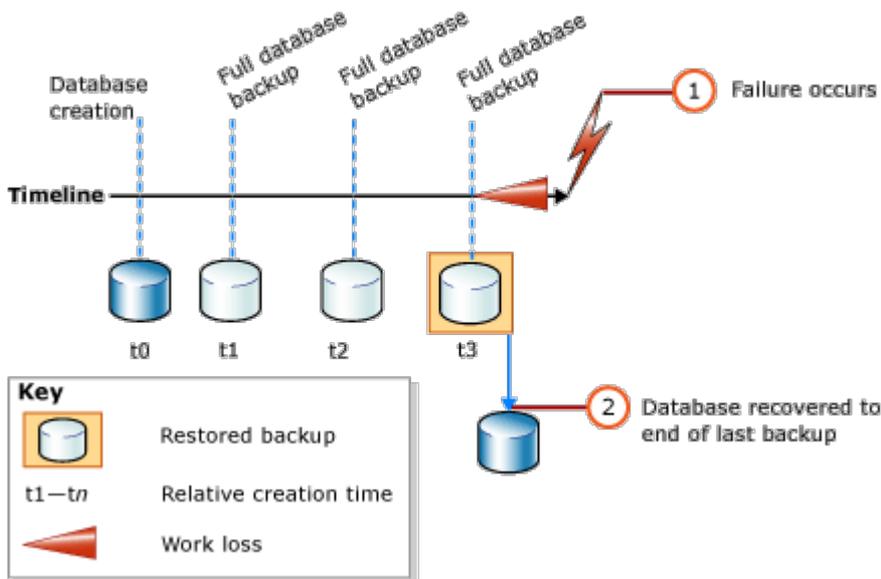
Maintaining the database

Note

- It is important to back up the database: in case of a computer failure you are able to recover your data from your last back up.
- It is not possible to back up the content of the computer's hard disc directly to get a back up of the database.

The following guidelines are designed to help you with creation of database back ups as well as re-expansion of a compressed Rotor-Gene AssayManager v2.1 database.

It is important to explicitly back up the database of the Rotor-Gene AssayManager v2.1. In the case of the computer crashing you are able to recover your data from your last back up and minimize the loss of data.



It is not possible to simply back up the database of the Rotor-Gene AssayManager v2.1 by restoring the content of the computer's hard disc.

Note

Due to the fact the backup of a database is a snap shot of the content at a certain point in time, the amount of a data loss increases with the time difference to the point in time of the last back-up. Perform the back-up according to your requirements for the availability of data and the protection of data from loss.

Installing the Tools

With the SQL Server Management Studio Express (SSMSE) Microsoft provides a graphical management tool for the used SQL Server 2014 Express to perform database back-ups. See <http://www.microsoft.com/en-US/download/details.aspx?id=42299> for detailed instruction how to download and install the SSMSE. Click "Download" and select "SQLManagementStudio_x86_ENU.exe" to download the installer of the management studio.

Download and install as prerequisites:

1. Microsoft .Net Framework 4.7 (<https://www.microsoft.com/en-us/download/details.aspx?id=55170>).

It is assumed that the Rotor-Gene AssayManager v2.1 is already installed. It includes further prerequisites of the management studio.

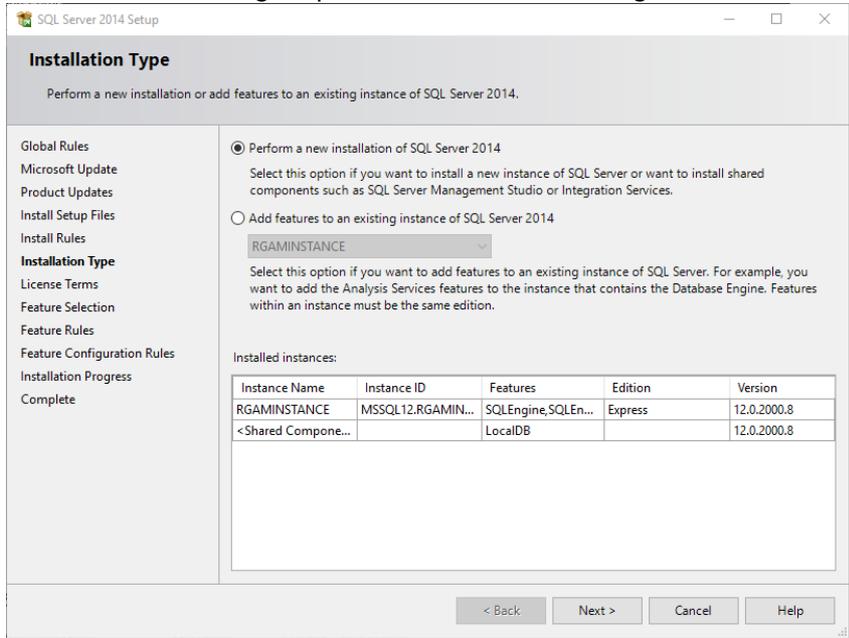
You need administration rights for processing installations.

SQL Server Management Studio Express installation details

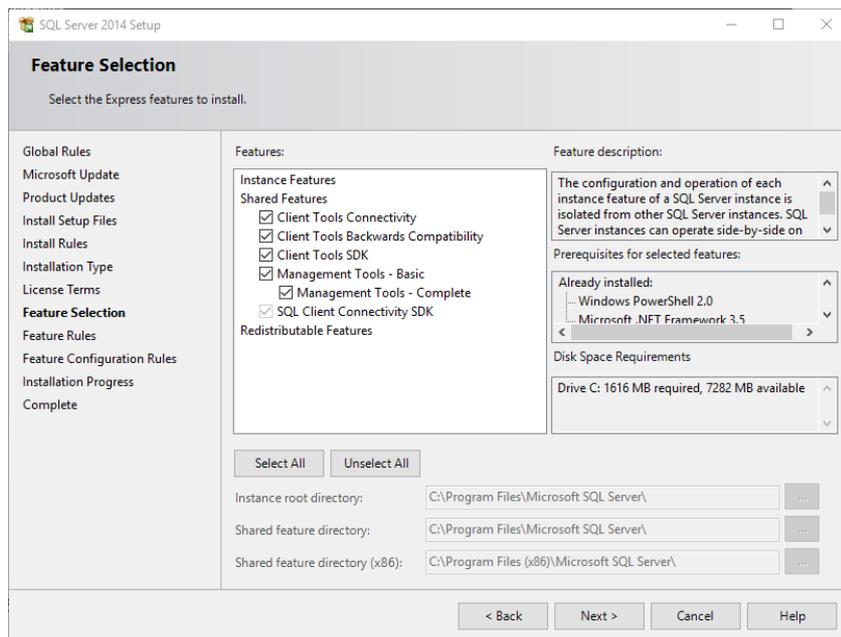
When starting the setup of the management studio select the entry as marked in the figure.



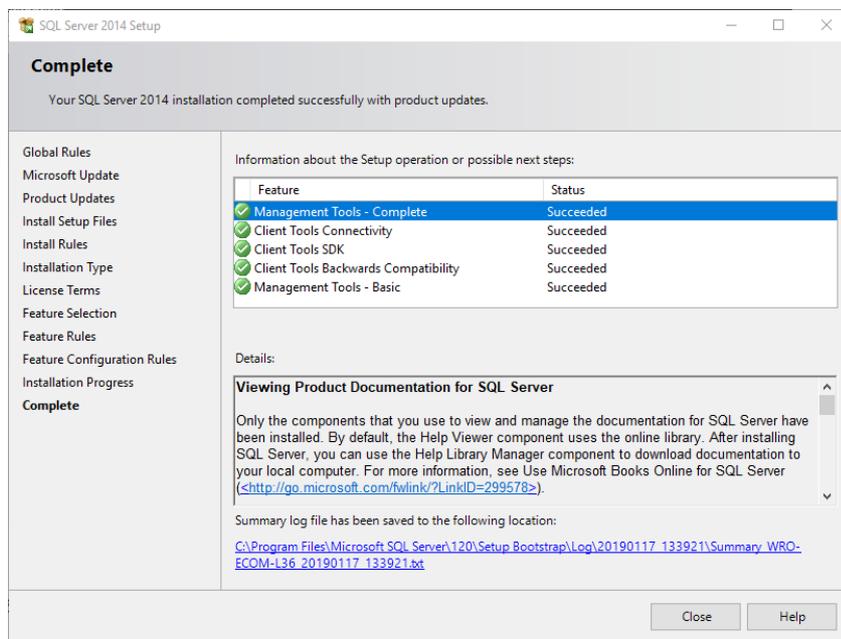
Confirm the following steps with the default settings until the following screen:



Select the first option as marked in the figure above. Confirm and accept the following steps with the default settings until the following screen:



Tick the check box as marked in the figure above. Confirm and accept the following steps with the default settings until the successful completion of the installation.



Backing up Rotor-Gen AssayManager v2.1 databases

You need appropriate rights for working with the SSMSE. It is crucial for working with the management studio that the Windows account which was taken to perform the installation task of the Rotor-Gen AssayManager v2.1 is used.

First you have to establish a connection to the SQL Server system. The required server name is a combination of computer name and SQL Server instance name. The name of the used instance is *RGAMINSTANCE*. In an environment where the SQL Server Management Tool is installed in which the Rotor-Gene AssayManager v2.1 is installed, you can insert “.\RGAMINSTANCE”.

Hints for backing up a database

Before backing up the database you have to close the Rotor-Gene AssayManager v2.1. Be sure that no runs are active and all changes are saved. Ensure also that all remotely connected Rotor-Gene AssayManager v2.1 are shut down.

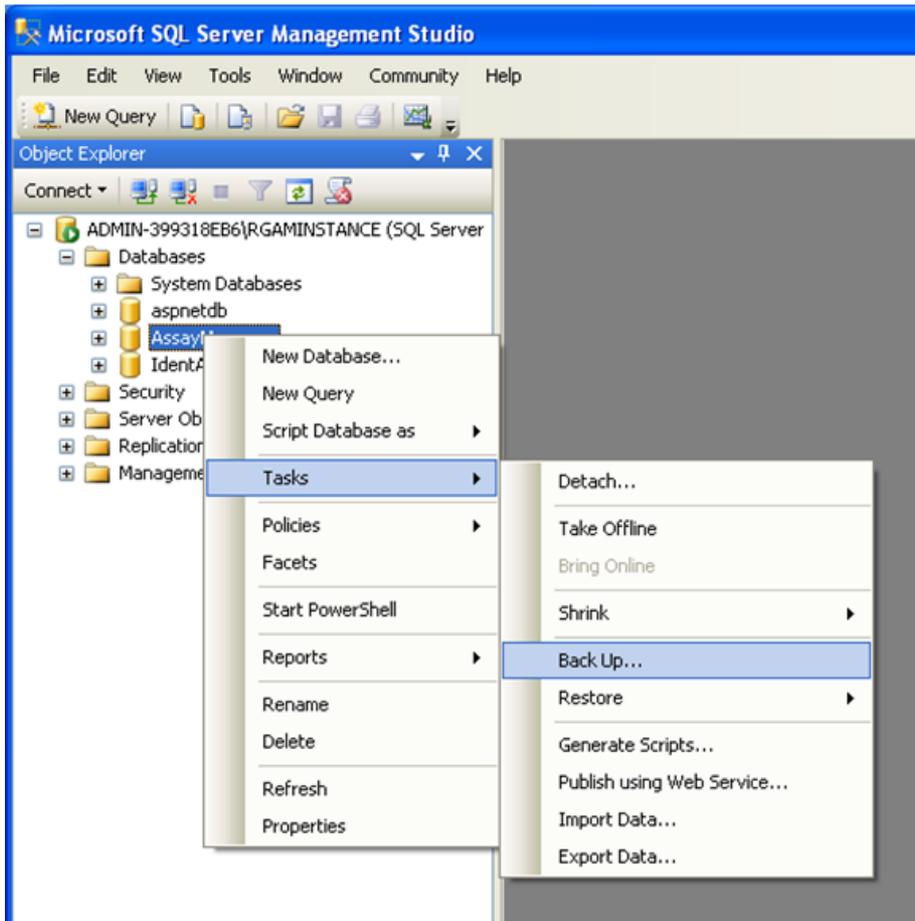
Note

With the installation of the Rotor-Gene AssayManager v2.1, a system of databases was installed to cover all necessary tasks. It is important that all databases are always backed up as a package. This is necessary since these databases are interconnected and represent a certain state of the system at each point in time.

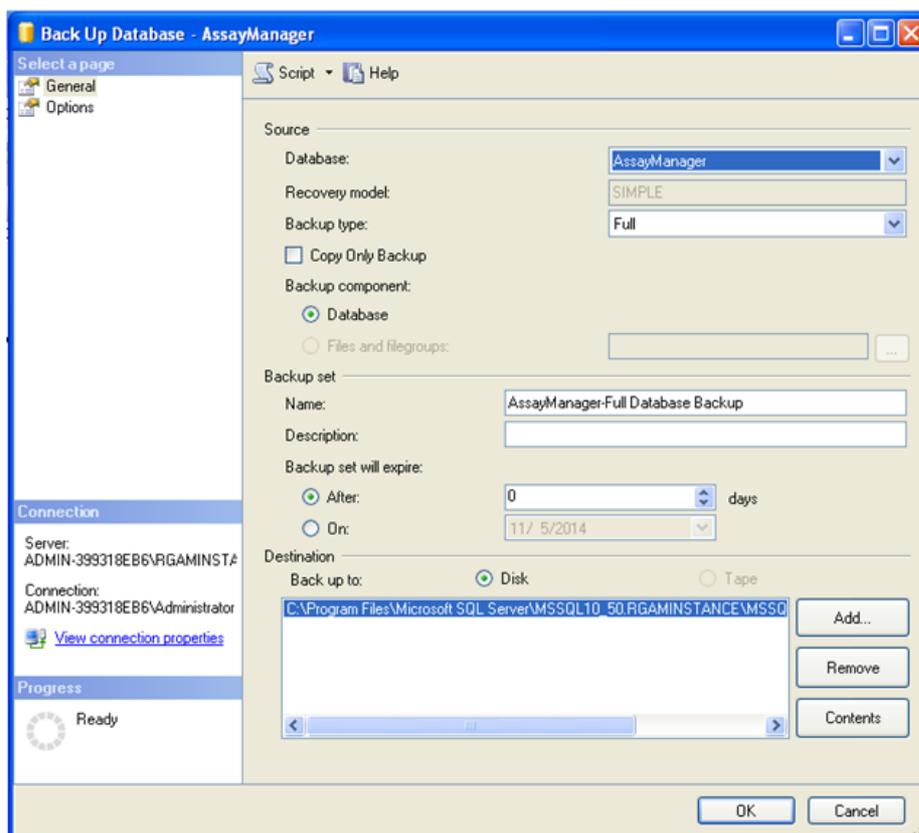
Back up the following databases:

- aspnetdb
- AssayManager
- All databases starting with “IdentArchive”

To access the option dialog, select the context menu entry for the desired database according the following figure.



1. The “Back Up Database” dialog opens with the “General” page by default. Check that the correct database name is displayed in the “Database” list box.
2. Select “Full” in the “Backup type” list box.
3. Enter a name for the backup and optionally enter a description.
4. Set “Backup set will expire” to 0 days in order to ensure that the back up will not expire.



- The default destination of the back up is "c:\Program Files\Microsoft SQL Server\MSSQL14.RGAMINSTANCE\MSSQL\Backup\" plus the database name with the file extension ".bak" (e.g. "AssayManager.bak"). It is not recommended to change the paths.

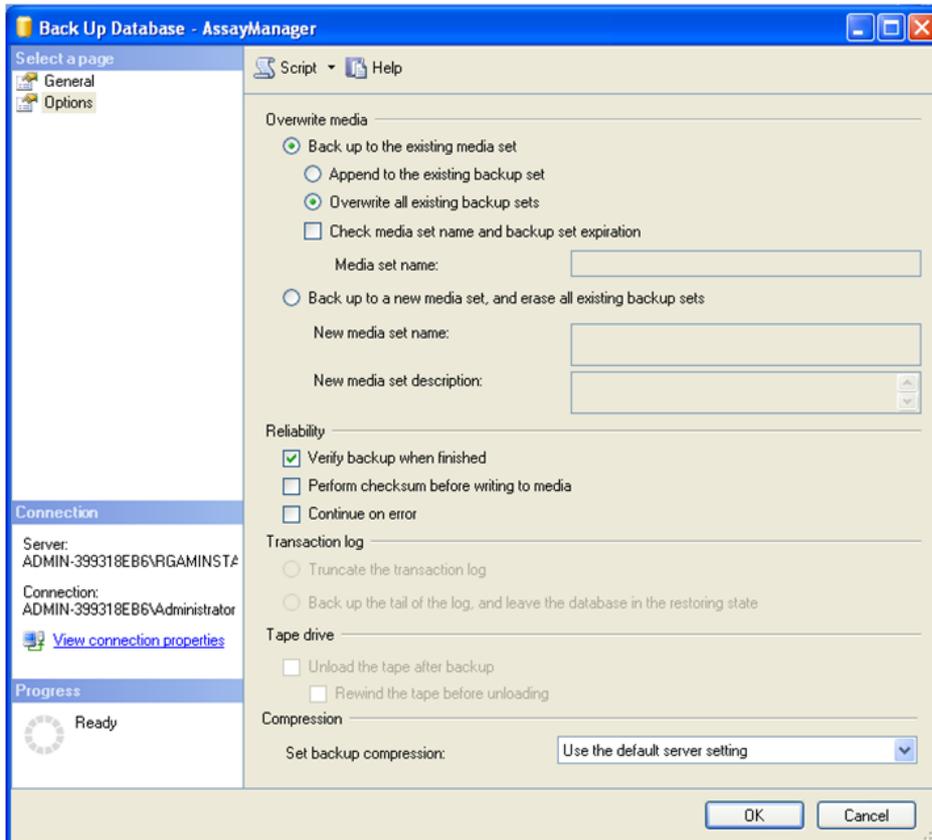
Note

The file name has to be identical to the database name with the file extension ".bak":

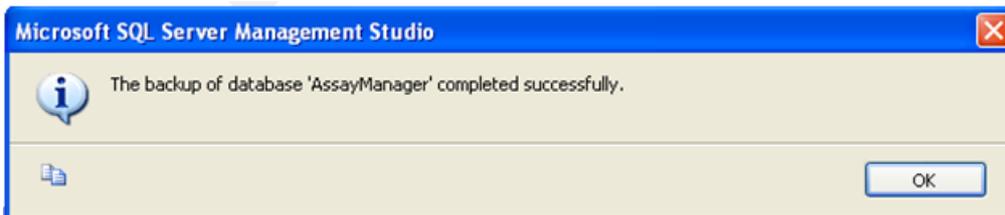
- aspnetdb
- AssayManager
- IdentArchive<three digit no>-<UUID>

Copy the content of the Name field of the Backup set section without the default extension "-Full Database Backup" and add ".bak".

- In the "Back Up Database" select "Options" in the "Select a page" panel to view the advanced options. In "Overwrite Media" choose the "Back up to the existing media set" and "Overwrite all existing backup sets" options.



7. Select "Verify backup when finished" in the "Reliability" section.
8. Click "OK".
9. Once the database is successfully backed up you will get a popup message similar to the one shown in the below screenshot.



10. Proceed similarly with the other databases.

Note

Ensure that the back-up files are stored at a secure location after completion. The files have to be handled as a bundle since the related databases are interconnected. Performing a database recovery has to be done with the entire bundle. Otherwise unpredictable behavior may occur.

Restoring a Rotor-Gene AssayManager v2.1 database back up

With the recovery of the databases of the Rotor-Gene AssayManager v2.1 you should be able to recreate the application, e.g. after a crash of the hard disc.

Precondition

Before restoring the databases of the Rotor-Gene AssayManager v2.1 you need a successful installation of the application and all previously installed plug-ins. The successful installation ensures that the necessary structures in the SQL Server are set up correctly. Keep in mind that the recovery will overwrite all data, like worklists or experiments, which were created since the installation. Furthermore, all data since the last back up are lost.

Note

It is important to set up the system with the version which was used before the recovery.

Note

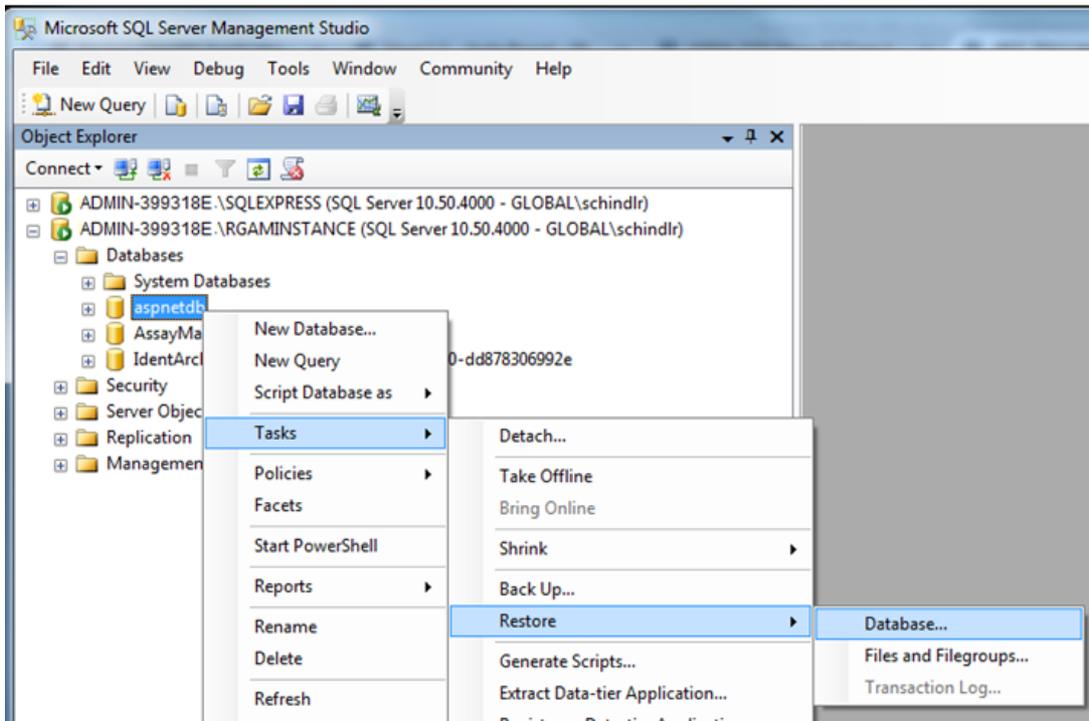
You have to restore all database packages resulting from a backup (described in the preceding sections). The databases are interconnected internally. Just restoring a single SQL Server database can lead to unpredictable behavior or malfunction of the Rotor-Gene AssayManager v2.1.

Before restoring the databases you have to close the Rotor-Gene AssayManager. Ensure also that all remotely connected Rotor-Gene AssayManager v2.1 instances are shut down.

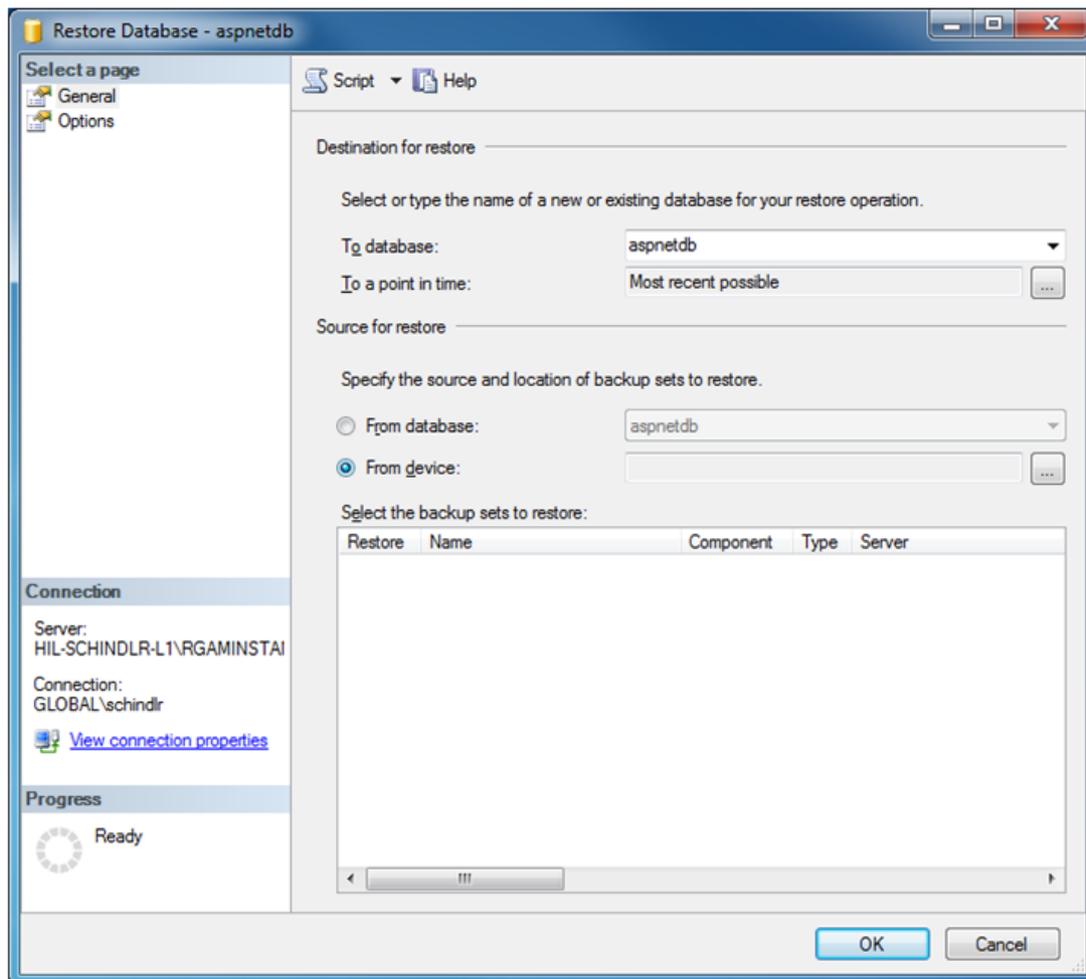
Restore a database

The following steps describe how to restore a database.

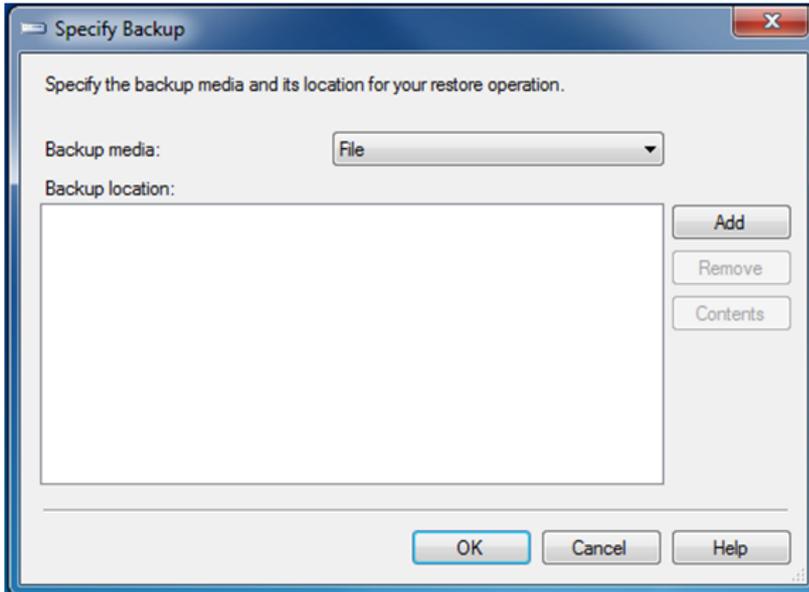
1. Open the SQL Server Management Studio and connect the SQL Server instance "RGAMINSTANCE". See section "Backing up Rotor-Gene AssayManager databases" for details.
2. In the object explorer expand the instance and the "Databases" entry. The relevant databases are
 - "aspnetdb",
 - "AssayManager", and
 - "IdentArchive...". Multiple archives can exist, depending on the number of processed assays.
3. Initialize the recovery of a database by opening the context menu of the database and selecting the corresponding menu entry as shown in the figure below.

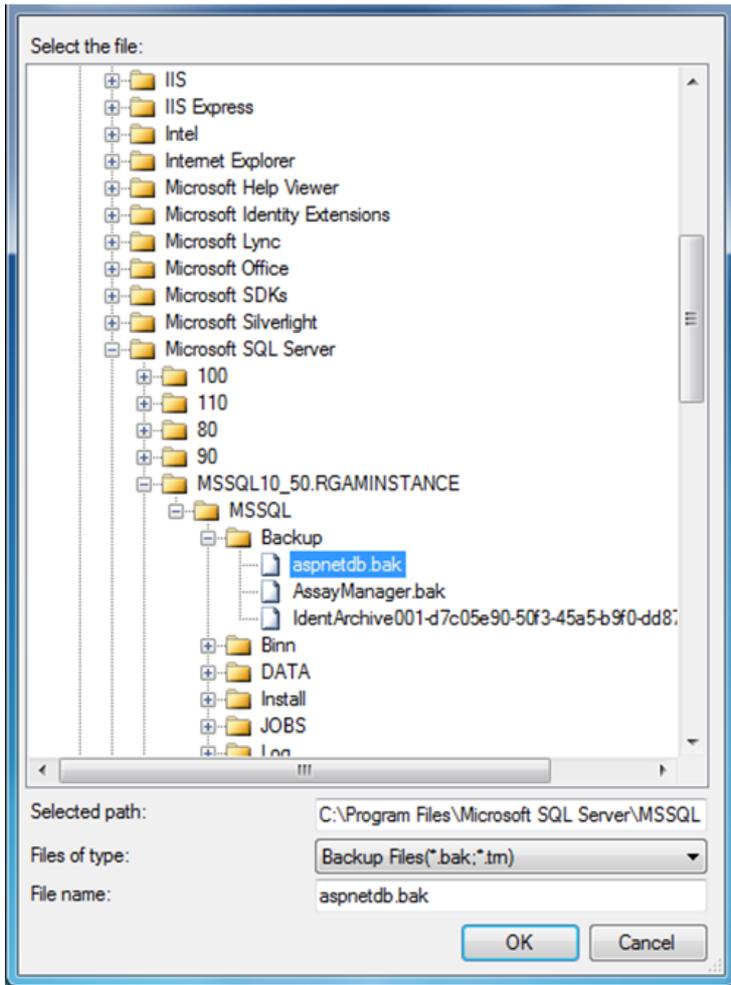


This opens the “Restore Database” dialog:

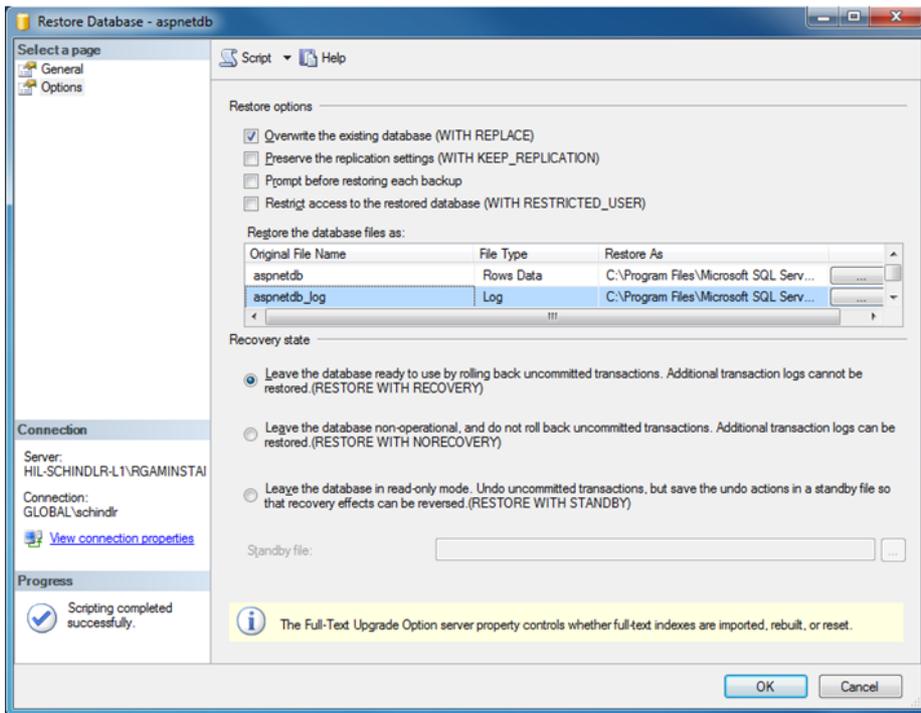


4. Leave the section "Destination for restore" untouched.
5. In the section "Source for restore", select the option "From device"
6. Locate the backup via the browse button 
7. In the dialog "Specify Backup" open the file selection dialog by clicking the "Add" button.



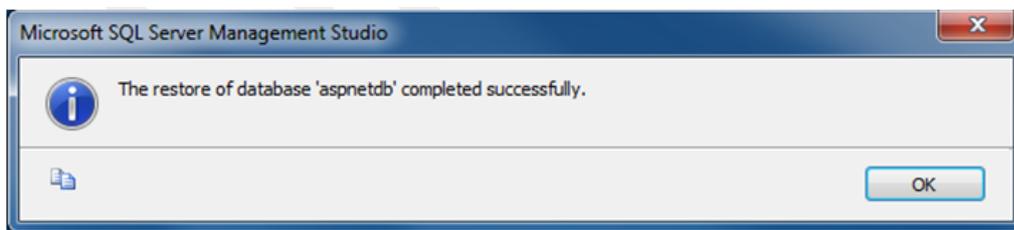


8. Navigate to the .bak file of the selected database (here aspnetdb.bak) and confirm with the “OK” button.
9. Confirm the selection in the “Specify Backup” dialog as well.
10. Select the backup by ticking the check box in the list
11. Select “Options” in the “Select a page” pane (left side) and set the options as shown in the next figure.
The entries of the section “Restore the database files as:” have to be left untouched. They are set through the steps 5 to 10.



12. Confirm the settings by clicking the “OK” button.

The successful recovery is confirmed with:

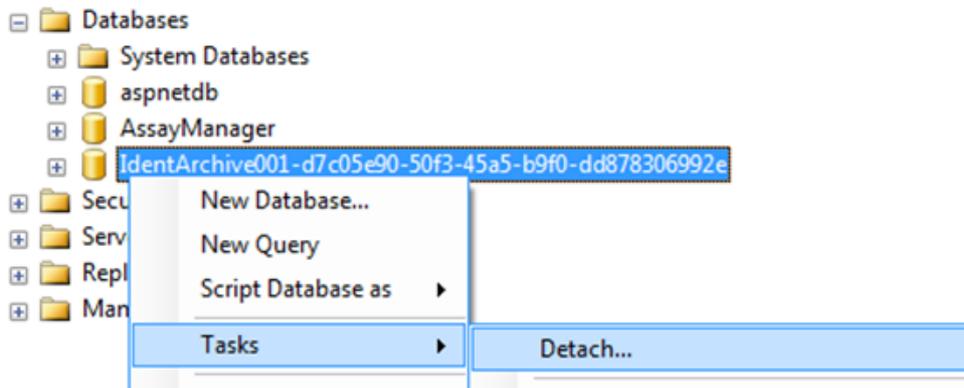


Perform these steps with the “aspnetdb” and “AssayManager” database.

Restore an archive database

The archive databases need special treatment because of their unique naming property. After a fresh installation of the Rotor-Gene AssayManager v2.1, no archive database is created until the application is started. The first start of the application creates an (empty) archive database. This archive database has to be removed since the backup of the “AssayManager” database references (an-) other database(s).

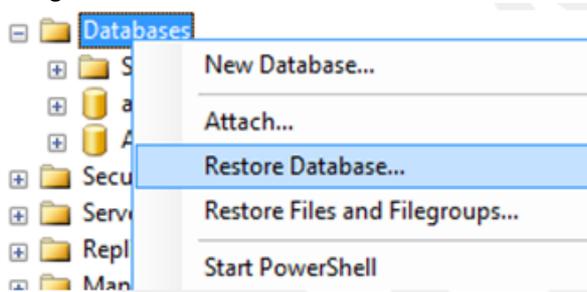
1. To remove the useless default archive of the current installation open the context menu by pointing to the archive database and clicking the right mouse button and select "Detach...".



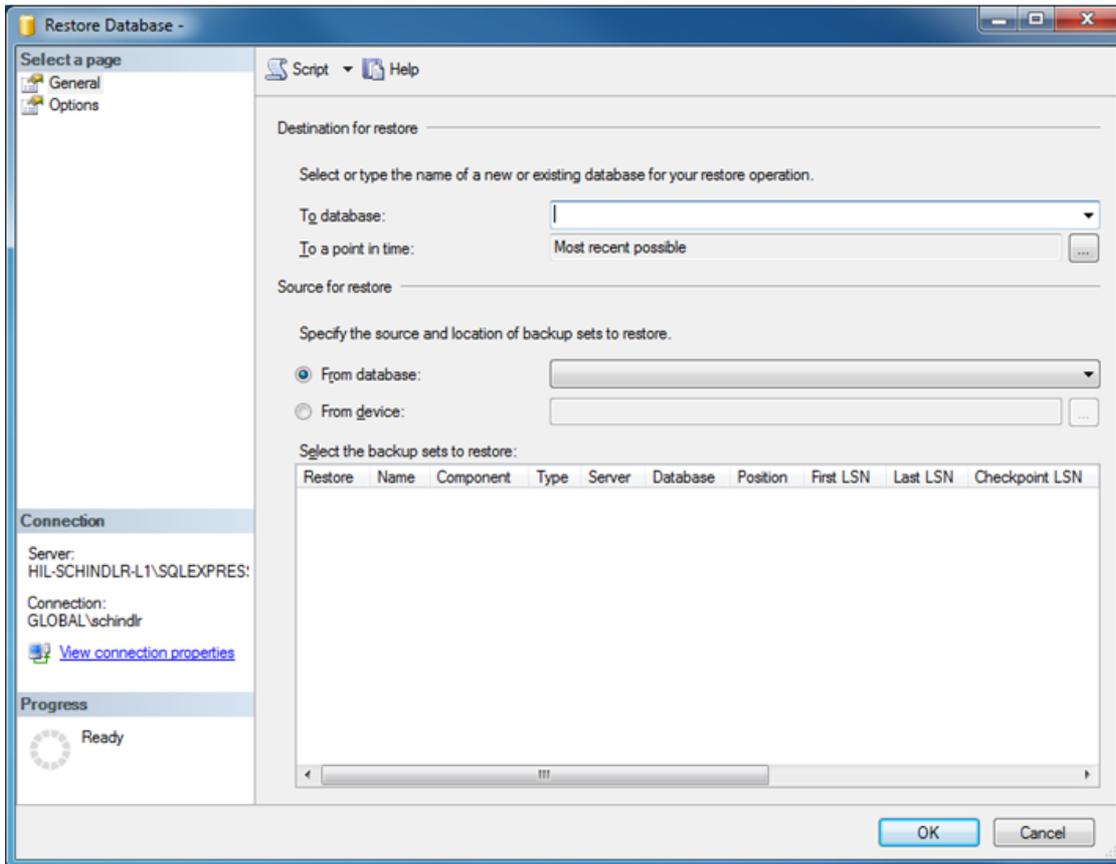
2. In the opening "Detach database dialog" click "OK".

For restoring the appropriate backup of an archive database related to an "AssayManager" database:

3. Open the context menu of the "Databases" entry in the object explorer pane via right mouse button click and select the "Restore Database..." menu entry.



This opens the "Restore Databases" dialog (see section "Restore a database") without a preselected database.



4. Provide the correct archive database name in the “To database” field in the “Destination for restore” section.

Note

It is crucial to copy the name of .bak backup file without the .bak file extension (e.g. IdentArchive001-d7c05e90-50f3-45a5-b9f0-dd878306992e)

5. Proceed from here on as described in section “Restore a database” step 5

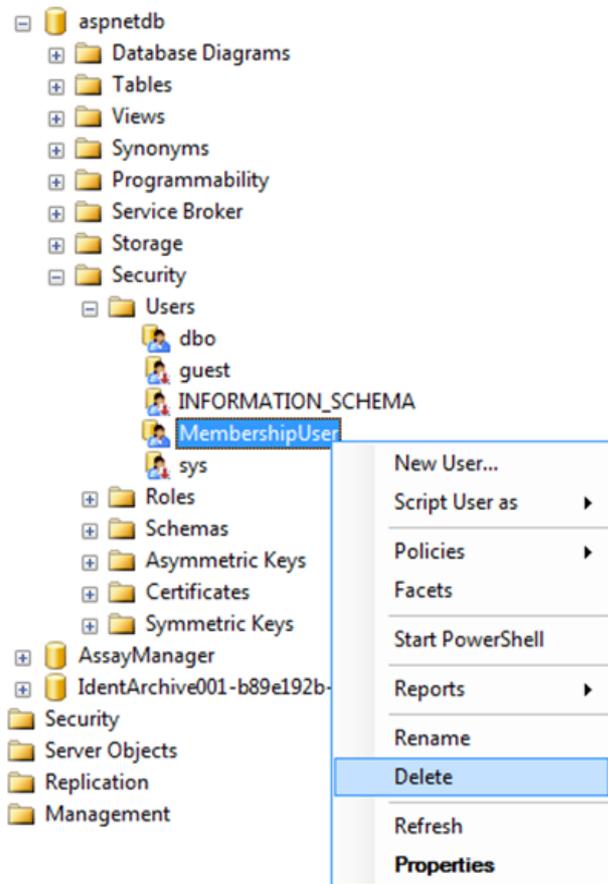
Final steps

In the last step the restored databases must be set up in a way that the access from the Rotor-Gene AssayManager v2.1 is possible.

Prepare aspnetdb database

In the first step, the original SQL Server user “MembershipUser” has to be cleared.

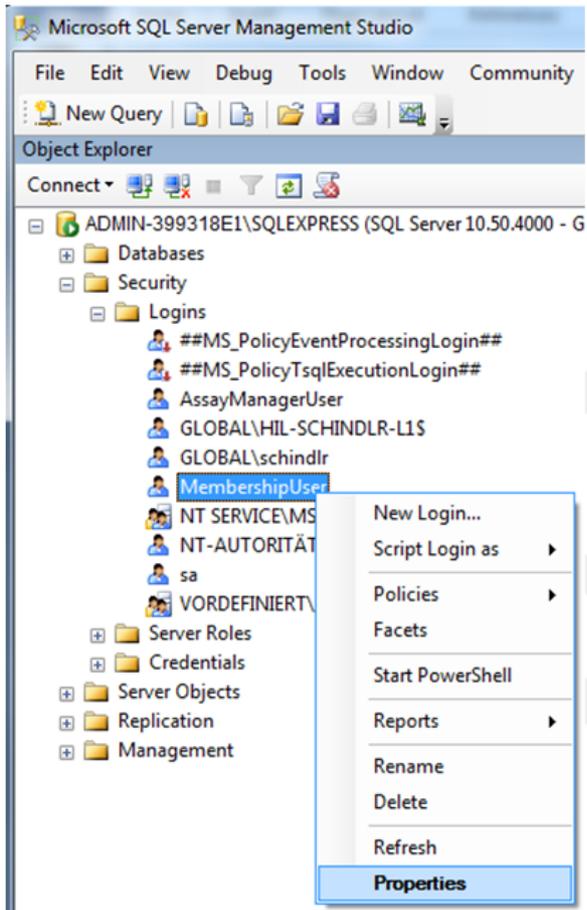
1. Expand in the object explorer the “aspnetdb” database according to the following figure



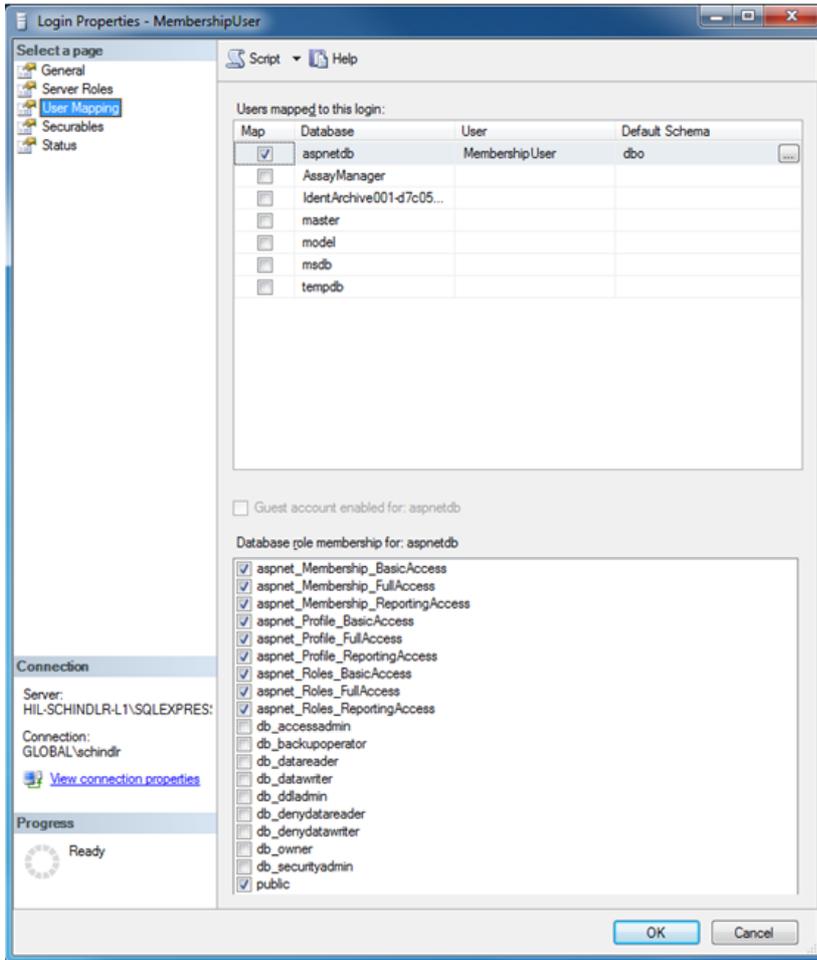
2. Select the “Delete” entry of the context menu for the “MembershipUser” item
3. In the opened dialog confirm the deletion by clicking the “OK” button.

The next steps associate the SQL Server login with the database. Do not mix up the Logins folder with the Users folder.

1. Expand the “Security” entry on the first level under the database instance and the subsequent “Logins” entry in the “Object explorer” pane
2. Select “MembershipUser” entry, open the context menu, and click the “Properties” menu item.



3. In the opened "Login Properties" dialog, click the "User Mapping" entry in the "Select a page" pane.
4. Adjust the "User mapped to this login" section and "Database role membership for: aspnetdb" section according the following figure:

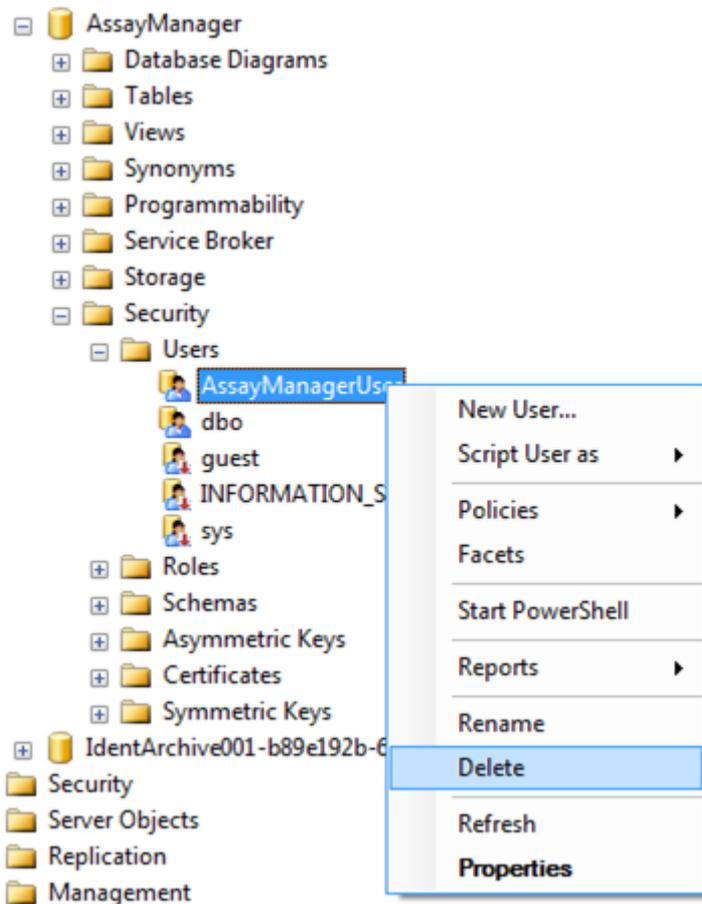


5. Confirm the settings by clicking “OK”

Prepare AssayManager and the archive databases

In the first step, the original SQL Server user “AssayManagerUser” has to be cleared.

1. In the object explorer expand the “AssayManager” database according to the following figure

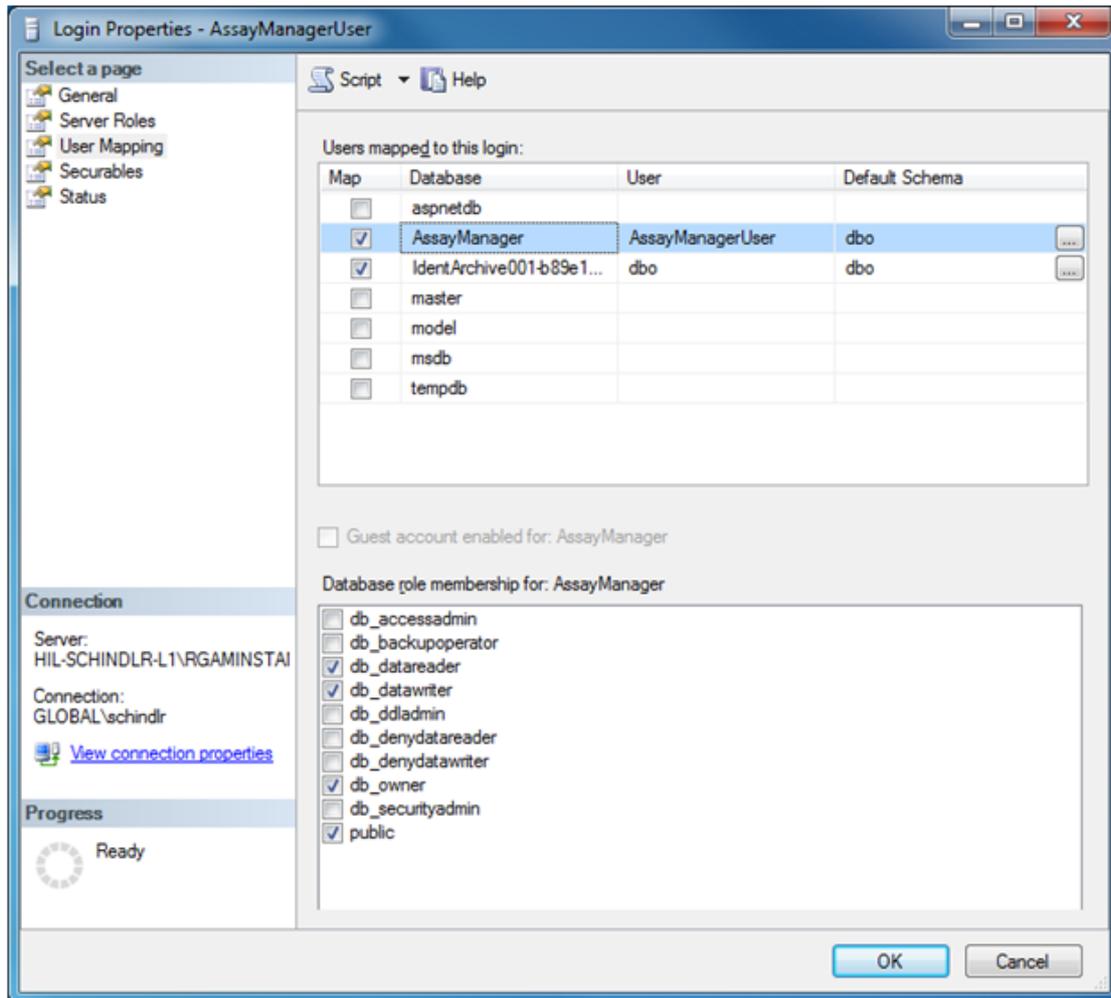


2. Select the "Delete" entry of the context menu for the "AssayManagerUser" item
3. In the opened dialog confirm the deletion by clicking the "OK" button.

In the next step associate the SQL Server login with the database. Do not mix up the *Logins* folder with the *Users* folder.

1. Expand the "Security" entry and subsequent "Logins" entry in the "Object explorer" pane
2. Select "AssayManagerUser" entry, open the context menu, and click the "Properties" menu item (similar to "Prepare *aspnetdb* database").
3. In the opened "Login Properties" dialog, click the "User Mapping" entry in the "Select a page" pane.

- Adjust the “User mapped to this login” section and “Database role membership for: AssayManager” section according the following figure:



- Leave the settings for all databases whose names start with “IdentArchive” untouched.
- Confirm the settings by clicking “OK”.

1.8 Troubleshooting

This section provides information about what to do if an error occurs when using Rotor-Gene AssayManager v2.1.

Resolving error messages and warnings

Error messages and warnings are displayed when a problem occurs during the operation of Rotor-Gene AssayManager v2.1. All messages have an error ID, which is displayed at the end of the error message. It is possible that several errors are combined in only one message. Refer to the error IDs listed in this section if an error message or warning appears. If error messages or warnings appear that are not listed here or if the error cannot be resolved, note the error ID, the error text, and the steps leading to the error. Then contact QIAGEN Technical Services.

Note

If QIAGEN Technical Services needs to be consulted for troubleshooting of an error, note the steps leading to the error and the information from any dialog boxes that appear (or at least the error IDs). This will help the QIAGEN Technical Service Specialist to resolve the error.

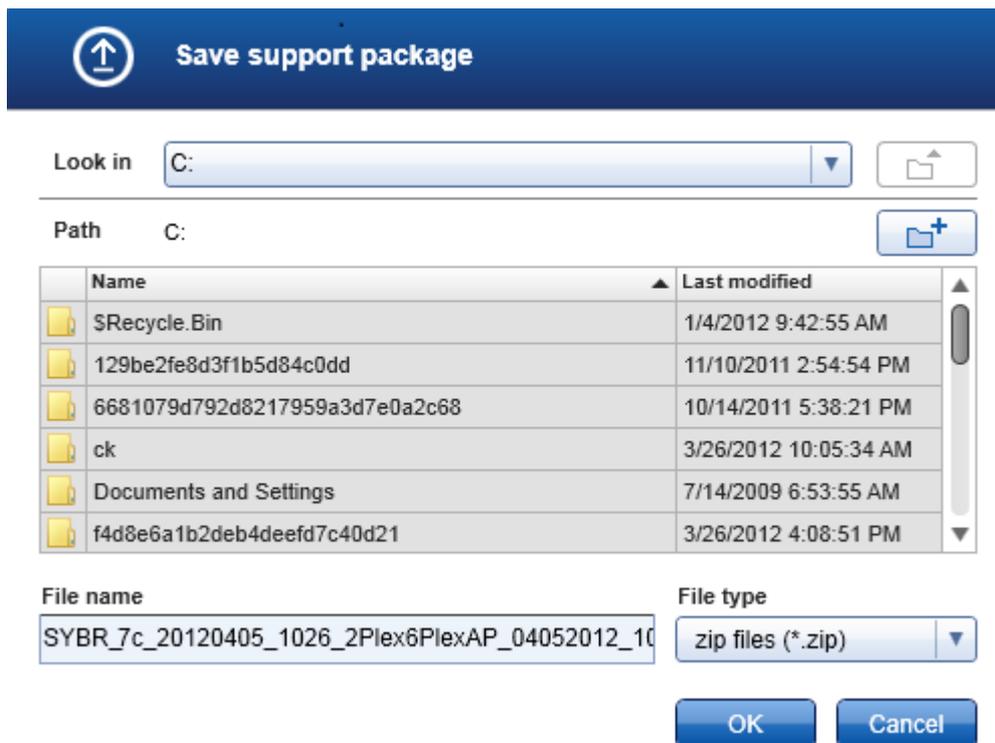
If there are problems with a specific experiment, create a support package and send it to QIAGEN Technical Services.

Creating a support package

Rotor-Gene AssayManager v2.1 provides the possibility to create support packages containing all relevant information about a specific experiment. Depending on the approval status of the erroneous experiment, either go to the "Approval" or "Archive" environment, select the correct experiment, and start the approval process or let the assay data be displayed, respectively. Click "Create support package..." at the bottom left of the screen to create a support package for the selected experiment.



A dialog opens for selecting a file name and the directory where the support package will be saved. The default support package file name contains the experiment name followed by the assay profile name, the current date, and time.



The support package will be saved as a single file containing all relevant information about the experiment. This file can be attached to an email and sent to QIAGEN Technical Services for troubleshooting.

Note for laboratories using several installations of Rotor-Gene AssayManager v2.1
 A support package should always be created at the computer that was connected to the Rotor-Gene Q during processing the erroneous experiment to ensure that all relevant information are included.

1.8.1 System Setup

This section contains information about potential errors during system setup.

Error description	Comments and suggestions
Computer or Rotor-Gene Q does not turn on	Check the power connection. The power cable might be loose or faulty. Reconnect or replace the cable.

Rotor-Gene AssayManager v2.1 cannot communicate with the cyclor	Check the cable connection between Rotor-Gene Q and the computer. The USB cable might be loose or faulty. Reconnect or replace the cable. Only use cables and accessories supplied by QIAGEN that are dedicated for connecting the Rotor-Gene Q. Switch off the Rotor-Gene Q and switch it back on again. Close the Rotor-Gene Software, if applicable. Restart Rotor-Gene AssayManager v2.1.
Rotor-Gene AssayManager v2.1 does not start	
a) Rotor-Gene AssayManager v2.1 is not installed	Install Rotor-Gene AssayManager v2.1.
b) Old version of Microsoft Windows	Rotor-Gene AssayManager v2.1 can only be operated with Windows 7 or 10.
c) No plug-in installed	Rotor-Gene AssayManager v2.1 consists of the core software and plug-ins with application specific components. Besides the core software, at least one plug-in must be installed to be able to use Rotor-Gene AssayManager v2.1.
d) Different versions of core application/plug-in	All Rotor-Gene AssayManager v2.1 installations that use the same database must have installed: <ul style="list-style-type: none"> • the same plug-in versions • the same core version. Note: "Same version" means all 3 parts of the version number must be the same. Even maintenance upgrades must be executed simultaneously on all machines.
Rotor-Gene AssayManager 2.1 does not work properly and freezes before the user can log-in	Rotor-Gene AssayManager 2.1 is compatible with 32-bit and 64-bit versions of Windows 7 or 10. Update your computer to Windows 7 or Windows 10, or install Rotor-Gene AssayManager v2.1 on another computer with a compatible Windows version.

1.8.2 Operation

This section contains information about potential errors during operation of Rotor-Gene AssayManager v2.1.

Instrument-related errors

Error description	Comments and suggestions
No or weak fluorescence signal detected	Open the lid of the Rotor-Gene Q and ensure that the lenses, located at both the emission and the detection source, are clean. This is achieved by gently wiping a cotton tip applicator, moistened with ethanol, over the lenses. For details see the Maintenance section of the Rotor-Gene Q user manual.
Erroneous instrument performance	Keep the work bench area clean and free from dust and sheets of paper. The air inlet of the Rotor-Gene Q is at the bottom. Loose material such as paper or dust may compromise performance.
Run cannot be started	Close the lid of the Rotor-Gene Q before starting a run.

Software-related errors

Error description	Comments and suggestions
Second Rotor-Gene AssayManager v2.1 installation cannot access data from another installation	If several Rotor-Gene AssayManager v2.1 installations are used, ensure that core software and plug-ins of all installations have exactly the same version. Software upgrades have to be applied simultaneously to all computers sharing Rotor-Gene AssayManager v2.1 data.

<p>QIASymphony AS result file cannot be imported to Rotor-Gene AssayManager v2.1</p>	<p>Rotor-Gene AssayManager v2.1 is only compatible with QIASymphony software version 5.0. Update your QIASymphony system to the latest software version. Furthermore the QIASymphony AS result file has to match an assay profile in the Rotor-Gene AssayManager v2.1 database.</p>
<p>The background in plots is printed in black</p>	<p>Some printer drivers are configured in a way that transparent background colors, which are used in the Rotor-Gene AssayManager v2.1 plots, are printed in black. Check the manual of your printer how to change this configuration.</p> <p>Technical background: To ensure that the displayed results of the plots are exactly the same as the printed reports, the background colors need to be transparent.</p>

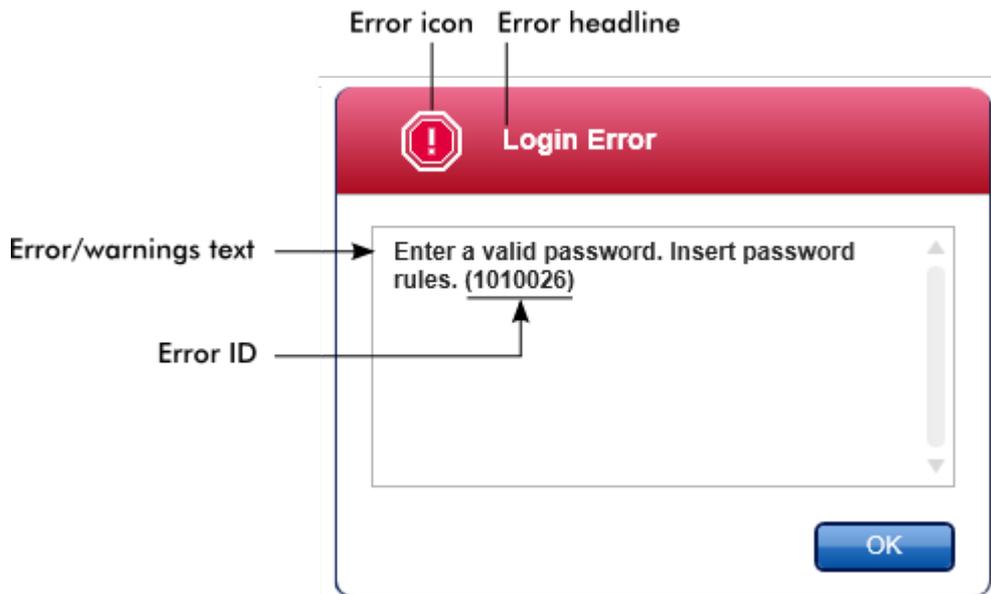
General errors

Error description	Comments and suggestions
<p>Incorrect rotor loading</p>	<p>Load tubes and Rotor-Discs® in the correct orientation into the rotor ensuring that each tube sits correctly in place. Samples will not optimally be aligned over the detection system if not placed correctly in the rotor. This could result in a reduction of the acquired fluorescence signal and the detection sensitivity.</p>
<p>Missing locking ring</p>	<p>Always attach the dedicated locking ring to the rotor before starting a run. The locking ring ensures that caps remain on tubes during a run and that tubes or Rotor-Discs sit correctly in place.</p>

Rotor not completely filled	To achieve maximum temperature uniformity, each position in the rotor must contain a tube. Filling all positions in the rotor ensures even airflow to every tube. Keep a set of empty capped tubes available that can be used to fill any unused positions.
The bar code of a QIAGEN kit cannot be read using the handheld bar code scanner	Make sure that the handheld bar code scanner is correctly connected to the computer and configured properly, e.g., data will be sent after pressing "Enter". Try to read other bar codes with the scanner. Ensure that all bar codes can be easily read.
Login error	Check whether the user name is correct. Make sure to enter the correct password. Note that after 3 unsuccessful log-in attempts the user profile will be locked. In that case another registered user with the role of an administrator has to re-activated the user profile.
Sample position is incorrect	When setting up an experiment be sure to place the reaction tubes in the correct positions of the rotor. During worklist setup, the sample details and their respective positions can be displayed or printed using the "View sample details..." or the "Print worklist..." button, respectively. If using strip tubes, 0.1 ml, be sure not to invert the strip tubes during transfer from assay setup to the rotor.

1.8.3 Error Messages and Error Codes

The source of a message is indicated in the error ID. The general structure of an error ID is:



The following list provides all error messages that might occur during operation of Rotor-Gene AssayManager v2.1. In case QIAGEN Technical Services needs to be contacted, provide the service specialist with the following information:

- Actions performed before the error message occurred
- Error ID

Note

The error ID is unique and helps QIAGEN Technical Services to clearly identify the error message.

Error ID Error Text

30000	Failed reading the permissions file {0}.
30001	Wrong Silicon Laboratories CP210x driver version was found on the system. Only CP210x driver of version 6.5.3 should be installed. Please remove the wrong CP210x drivers and restart the application. The application will exit now.
30002	The permissions file {0} has an invalid document format.
30003	Silicon Laboratories CP210x driver of version 6.5.3 was not found on the system. Please install the driver and restart the application. The application will exit now.
30004	Unexpected error with user activity timer. Application has to terminate. Please contact your administrator.
30005	License check has failed. Contact QIAGEN support.
30006	Could not find the permissions file {0}.
30007	Assign at least one role to user {0}.

- 30008 The following roles in the database are obsolete: {0}. Contact QIAGEN Technical Services.
- 30009 Could not find the following role '{0}' in the database. Contact QIAGEN Technical Services.
- 30011 The database connection is lost. Running experiments will continue; they will be saved automatically into the database as soon as the connection is restored. Log in again. If the problem persists, contact your system administrator.
- 30012 No valid license file is selected.
- 30013 The application initialization failed because the database connection is not available. The application will exit now. Contact your local administrator.
- 30014 License key file generated successfully.
- 30015 Trial license has been expired.
- 30016 Access to the following path is denied: '{0}'. Select another path.
- 30017 Rotor-Gene AssayManager is already started on this computer
- 70000 The analysis of assay with name {0} (version {1}, application mode {2}) failed.
- 70001 There is not assay profile available with name {0}, version {1} and application mode {2}.
- 70002 Plug-in {0} (version {1}, application mode {2}) does not provide an analysis service.
- 150000 At least one error still exists (see messages). Please fix the error first, before settings can be saved.
- 150001 There is already a profile in the database with the same name and version. The file you selected will not be imported.
- 150002 The selected assay profile is based on the plug-in "{0}" in version {1}. Install or update to the most recent, compatible version of this plug-in and repeat the import of the assay profile.
- 150003 Enter a valid user ID (User ID must not contain comma).
- 150008 The resource has an invalid document format. Contact QIAGEN Technical Services.
- 150009 {0} must not be empty.
- 150022 This cycler name is already in use. Enter a different cycler name.
- 150023 There is no cycler with the serial number {0} connected. Enter the correct serial number.
- 150024 The cycler with the serial number {0} is already registered as {1}.
- 150028 Enter a valid serial number.
- 150029 The file contains an incomplete or invalid assay profile. The file will not be imported.
- 150030 Enter a valid assay profile path.
- 150032 The file cannot be read. It will not be imported.
- 150035 In Closed Mode, you can only import profiles distributed by QIAGEN. The file you selected will not be imported. Log in in User Defined Test Mode to import this file.

- 150036 In User Defined Test Mode, you cannot import profiles distributed by QIAGEN for the Closed Mode. The file you selected will not be imported. Log in in Closed Mode to import this file.
- 150040 Enter a valid first name (1-50 characters).
- 150041 Enter a valid last name (1-50 characters).
- 150042 Enter a valid user ID (1-40 characters).
- 150043 Assay Profile could not be imported.
- 150045 A user profile with the same user ID already exists. Enter a different user ID.
- 150047 The entered passwords do not match. Enter and confirm password again.
- 150048 The connected cyler reports a firmware version ({0}.{1}.{2}) that is not supported. The cyler cannot be used.
- 150049 Enter an initial password.
- 150050 The password must not be the same as the user ID. Enter a different password.
- 150069 Enter a valid number in the „Auto-Lock timer“ field (0-60). 0 means the application is never locked.
- 150070 Enter a valid password renewal interval (0-999 days). 0 means the password never expires.
- 150076 Define the default for the worklist name.
- 150077 Define a default for the experiment name.
- 150078 Enter a valid password renewal interval (0-999 days). 0 means the password never expires.
- 150084 Enter a valid number in the „Auto-Lock timer“ field (0-60). 0 means the application is never locked.
- 150087 Enter a valid password renewal interval (0-999 days). 0 means the password never expires.
- 150088 The connected cyler reports an optical configuration that is not stored in the database. The cyler cannot be used. Select another cyler.
- 150092 Enter a valid cyler name (1-8 characters).
- 150093 Select a date in the future for the next verification date. Keep the field empty if the verification notifier shall not be used.
- 150095 Shorten the verification comment to max. 256 characters.
- 150113 {0} could not be loaded. The file reading failed. Select a different image file.
- 150114 The assay profile could not be activated. It refers to assay parameter set names already present in the following active assay profile(s): {0}
- 150115 The assay profile could not be imported. It refers to assay parameter set name and volume pair combinations already present in the following active assay profile(s): {0}.
- 150118 The combination of first name and last name must not contain all the three words "QIAGEN", "Service", and "User" together.
- 150119 The user ID must not contain all the three words "QIAGEN", "Service", and "User" together.
- 150120 The assay profile is not finalized. Finalize the assay profile.
- 150127 Enter a valid password (8-40 characters).

- 150131 Shorten the user-definable section for experiment name to max. {0} characters.
- 150132 Shorten the user-definable section for worklist name to max. {0} characters.
- 150138 Assay Profile export failed because:
- 150140 The user ID must not contain white spaces.
- 150141 Failed to read administration data.
- 150142 Enter a valid user ID with at least one non-numerical character (1-40 characters).
- 150148 An error occurred during report generation. Retry report generation.
- 190000 The unique application ID is not stored in the registry. Contact your local administrator.
- 190001 Cannot read the unique application ID that is stored in the registry. Contact your local administrator.
- 190002 Cannot write Rotor-Gene AssayManager unique application ID to the registry. Start the application again with administration rights.
- 190005 Rex file export canceled. No file was written.
- 190006 Rex channel reference key not found.
- 190007 The experiment {0} was removed in the meantime.
- 190008 The file codec differs to the expected codec UTF-8
- 190009 The product license has been removed. To continue with Rotor-Gene AssayManager provide a valid license file.
- 190011 No valid license
- 190012 No valid license file is selected.
- 190014 Trial license has been expired.
- 190015 File {0} does not exist.
- 190017 The provided file path is invalid. Enter a valid path.
- 190018 Path too long. : {0}
- 190019 The resource has an invalid document format. Contact QIAGEN Technical Services.
- 190023 Rex file export failed. Reason: {0}
- 190028 Specify experiment to export.
- 190034 Signature could not be validated.
- 190035 Failed reading the file
- 190036 Signature could not be validated.
- 190038 The access to the selected file or folder is denied. Select a different file or folder.
- 190039 Unexpected I/O error with file {0}. Contact QIAGEN Technical Services.
- 190040 A unsupported operation was called on the file-system or memory resources. Contact QIAGEN Technical Services.
- 190045 File {0} does not exist.
- 190049 The provided file path is invalid. Enter a valid path.
- 190051 XML signature invalid.
- 190053 Path too long. : {0}
- 190054 The resource has an invalid document format. Contact QIAGEN Technical Services.

- 190055 The access to the selected file or folder is denied. Select a different file or folder.
- 190056 Unexpected I/O error with file {0}. Contact QIAGEN Technical Services.
- 190057 A unsupported operation was called on the file-system or memory resources. Contact QIAGEN Technical Services.
- 190067 The file was created using Rotor-Gene AssayManager {0}, it cannot be opened. Make sure the versions are the same.
- 190162 File {0} not found.
- 190163 Failed to open the file {0} in the default viewer.
- 190205 The Experiment '{0}' cannot be exported. The following error occurred: {1}
- 190207 The given run profiles are not cycling compatible. Therefore, these profiles cannot be merged.
- 190208 One of the run profiles contains a run profile entry of an unsupported type. Select another run profile.
- 230000 Enter a correct amount of steps per cycle: {0}. Max. 5 steps are supported.
- 230002 Tube position {0} is missing in the tube list.
- 230003 The tube positions do not start at 1. Start with tube position 1.
- 230004 The tube position {0} occurs more than once in the tube list. Enter a unique tube position in the tube list.
- 230005 The profile name is too long.
- 230006 Run profile must contain at least one run profile entry.
- 230010 The worklist assay {0} must contain at least one test sample.
- 230011 The worklist assay {0} does not contain a valid assay kit. Enter a valid assay kit.
- 230012 The worklist tube at position {0} is marked as invalid.
- 230013 Enter a valid worklist name (1 to 80 characters).
- 230014 A worklist needs to contain at least one assay.
- 230015 Enter a valid reaction volume (min. 1).
- 230016 The sample {0} does not contain a target. Define a target for sample {0}.
- 230017 The given {0} path does not exist. Select another existing path.
- 230019 Enter a valid name of the detector ({3} to {5} characters).
- 230020 Enter a valid position of the detector (min. {3}).
- 230021 Enter a valid name of the emitter ({3} to {5} characters).
- 230022 Enter a valid position of the emitter (min. {3}).
- 230023 Enter a valid name of the optical configuration ({3} to {5} characters).
- 230055 Auto import QIASymphony worklists
- 270000 The public token of the plug-in does not match with the public token configured in the database. Plug-in: {0}.
- 270001 The following plug-ins are missing in the plug-in manager: {0}. Contact your system administrator to upgrade your installation. The application will exit now.
- 270002 Unexpected length for an array of doubles!
- 270003 Rotor-Gene AssayManager is needed in version {0}, you have installed version {1}. Please contact your system administrator to upgrade your installation. The

application will exit now

- 270004 The following plug-in is not found on this system {0}. Please contact your system administrator to upgrade your installation. The application will exit now.
- 310001 Could not load the plug-in assembly.
- 310006 Plug-in not found for provided key.
- 310007 Assembly name information does not match with the configuration of the plug-in.
- 350000 Entered profile name is invalid because this name is always used to show a new report profile. Enter a different name.
- 350001 Enter report profile name.
- 350002 Enter a valid report profile name (1-50 characters).
- 350003 Entered profile name is invalid, because it is a reserved device name. Enter another name.
- 350004 The following characters are not allowed: / " > < | : * ? \ . Enter a different name without special characters.
- 350005 Failed to generate report.
- 350008 The entered profile name is already used. Enter a unique name.
- 350009 Report cannot be rendered as it is not generated.
- 350010 Failed to generate audit trail report.
- 350011 File {0} not found.
- 350012 The report profile name must not contain leading and/or trailing white spaces.
- 350013 Failed to create file {0}.
- 350014 Failed to open the file {0} in the default viewer.
- 350015 The import of the report profile failed. Reason: {0}
- 350016 The export of the report profile failed. Reasons: {0}
- 350019 Failed to delete the report profile.
- 350034 Selected report profile is already deleted. Select another report profile.
- 350038 The data cannot be used.
- 350039 The export of the QIALink/LIMS result file failed. The samples were only saved but not released.
- 390000 Select at least one assay profile.
- 390001 Enter a cycler serial number.
- 390002 Enter a valid cycler serial number (1-{0} digits).
- 390003 Enter a valid end date.
- 390004 The end date must be after {0}.
- 390005 Enter an experiment name.
- 390006 Enter a valid experiment name (1-{0} characters).
- 390008 Enter at least one sample ID. Separate multiple sample ID's using the enter key.
- 390009 Following assays could not be removed:
- 390011 Enter a valid sample ID (1-{0} characters).
- 390015 Enter max. {0} sample IDs to filter.

- 390016 The Rotor-Gene AssayManager Experiment from file '{0}' cannot be imported. The following error occurred: {1}
- 390017 The experiment {0} was removed in the meantime.
- 390018 The assay(s) of experiment {0} will be closed as the experiment was removed in the meantime.
- 390019 The assay(s) of the deleted experiment will be closed.
- 390021 The experiment cannot be imported as the following assay profiles are missing: {0}
- 390022 Could not find a matching assay profile in the database for the given experiment. Select another experiment.
- 390023 The assay(s) have already been deleted.
- 390024 In {0} mode, you can only import experiments belonging to the {0} mode. Log in in {1} mode to import this file.
- 390026 The environment '{0}' is not supported.
- 390034 Select at least one assay status
- 390039 Report generation failed. Reason: {0}
- 390040 Failed to create support package. Reason: {0}
- 390052 Failed to create log file. Reason: {0}
- 390054 Copy operation is cancelled. Selected cell(s) should be contiguous.
- 390065 RGAM Experiment export failed because:{0}
- 430000 The channel {0} does neither have gain nor auto gain. The run cannot be started.
- 430001 The required channel {0} on the selected cycler could not be found. The run cannot be started.
- 430003 Initialize the experiment summary view before preparation.
- 430004 This worklist cannot be used in {0} mode.
- 430006 No cycler device could be found. Restart the application or, if necessary, the computer and the application. Scan again for connected devices.
- 430008 COM port {0} is either unknown or no device is connected. Restart the application or, if necessary, the computer and the application. Scan again for connected devices.
- 430010 The process cannot be started. The instrument {0} is already busy with another process.
- 430011 The cycler {0} is not connected to the system. Connect the cycler with the system.
- 430012 The run could not be started on the cycler with the serial number {0}. Make sure the lid is closed.
- 430013 No cycler environment controller is available. Contact QIAGEN Technical Services.
- 430015 Initialize the view model {0} before reaching the Prepared state.
- 430016 The CyclerEnvironmentController must be initialized before any operation.
- 430023 The merged contains a wrong acquisition type: {0}. Expected {1}. The run cannot be started.

-
- 430024 Within one cycle, the runProfileEntryIndex must not change. The run cannot be started.
- 430030 The run was stopped. For more information see experiment error log.
- 430032 The cycler with the serial number {0} cannot be modified in the current state. The current cycler state is: {1}. Contact QIAGEN Technical Services.
- 430033 The optical configuration with the ID '{0}' is not supported by the system. Select another optical configuration.
- 430035 The optical configuration does not match with a previously connected instrument with this serial number. Check the combination of serial number and optical configuration of the cycler and remove potentially wrong configured cycler from the cycler list.
- 430037 No assay profile was found for tube position {0}. Check the worklist setup and the assay profile for consistency.
- 430038 No sample was found for tube position {0}. Check the worklist setup and the assay profile for consistency.
- 430039 The number of tubes configured in the samples exceeds the capacity of the rotor. Reduce the number of tubes for that rotor.
- 430040 The tube positions assigned to the sample are not in the right range. Check worklist setup and assay profile for consistency.
- 430041 The analysis of experiment {0} failed.
- 430042 Enter a valid password.
- 430043 This user is deactivated. Contact your local administrator.
- 430049 One or more assays are currently open in Approval. Close them in order to go to Approval directly from here.
- 430050 This user was deactivated because the password was entered wrong too many times. Contact your local administrator. The current session will be closed.
- 430051 An error occurred during the initialization of the device. Re-initialize the cycler.
- 430055 The Experiment has been run in {0} mode. Please log out and log in in the {0} mode to start the approval.
- 430056 The run has been interrupted by Windows Hibernate mode.
- 430057 The connected cycler reports a firmware version ({0}.{1}.{2}) that is not supported. The cycler cannot be used.
- 430058 Persistence Exception
- 470000 No experiment name is entered. Provide an experiment name.
- 470001 The specified experiment name is a reserved name. Select a different name.
- 470002 The selected cycler is not available. Select a different cycler which is ready to use.
- 470003 The selected cycler is not available because it has not yet been released. Release the cycler first.
- 470004 There is no cycler configured at the selected position. Select a different cycler or contact your local administrator.
- 470005 No matching cycler available for this experiment. Contact your local administrator.

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- 470006 Select a cyler in the cyler selection table by activating the appropriate radio button in the "Select" column.
- 470007 The entered experiment name is invalid. Enter a unique experiment name (1-80 characters)
- 470008 The chosen experiment name has already been used in the meantime. Select a different experiment name.
- 470010 No assay profile present in the worklist. Complete the worklist setup before continuing.
- 470011 The worklist has been removed by another user in the meantime. Check available worklists.
- 470012 Enter a valid external order ID (1-40 characters).
- 470013 The number of samples for assay profile {0} exceeds the number of free positions on the rotor. Decrease the number of samples accordingly.
- 470014 The current worklist does not contain an assay profile. Add an assay profile.
- 470015 Enter the number of samples for assay profile {0}.
- 470016 The assays of this worklist contain more samples than the rotor has capacity for. Reduce the number of samples for that rotor.
- 470017 The selected assay profile {0} is not compatible to the current worklist. The rotor types are not identical.
- 470018 The available assay profile {0} is not compatible to the current worklist. Not all assay profiles define a cycling group. Check assay profiles and worklist setup for consistency.
- 470019 The available assay profile {0} is not compatible to the current worklist. Reason: Either the available assay profile or the already selected assay profile is marked as to run exclusively.
- 470020 The assay profile {0} is not compatible to the current worklist. Assay profiles are not assigned to the same cycling group. At least one selected assay profile has been defined as "exclusive use only".
- 470021 The selected assay profile {0} is not compatible to the current worklist.
- 470022 The selected assay profile {0} is not compatible to the current worklist. The reaction volumes are not identical.
- 470023 The selected assay profile {0} is not compatible to the current worklist. The thermal cycling profiles are not identical.
- 470024 The available assay profile {0} is already added to the current worklist. Proceed with the worklist setup.
- 470025 There are not enough free positions on the current rotor to fit the initial tubes of the assay profile. Check the assay profile and the selected rotor for consistency.
- 470026 The assay profile {0} is deactivated.
- 470027 The current worklist contains the deactivated assay profile {0} version {1}. Select an activated assay profile.
- 470028 The entered bar code contains an expired kit expiration date.

- 470029 The entered bar code is invalid. Scan or enter a bar code with 17-23 digits. Other characters like letters or special characters are not allowed.
- 470030 The entered bar code is invalid. Enter the bar code again.
- 470031 Scan or enter a valid bar code (17 – 23 digits).
- 470032 The current worklist contains an expired assay kit on assay profile {0}.
- 470033 Enter a valid kit lot number (4-10 digits) in the worklist.
- 470034 There is no valid kit expiration date provided in the worklist.
- 470035 Enter a kit lot number in the worklist either by scanning the kit barcode or by manual input.
- 470036 The entered material number does not fit to assay profile {0}. It might be that either a wrong assay profile was selected or a wrong kit.
- 470037 The entered material number is invalid. Enter a valid material number (exactly 7 digits).
- 470038 The kit lot number is invalid. Enter a valid kit lot number in the worklist (1-40 characters).
- 470039 The material number in the worklist can contain a maximum of 40 characters.
- 470040 The selected cyler has not an optical configuration which is compatible with the worklist. Contact your local administrator.
- 470041 The entered bar code contains invalid characters within the lot number. The lot number starts at digit 14 and can be up to 10 digits long. Enter a valid bar code.
- 470042 The entered bar code contains invalid characters within the material number. The material number starts at digit 1 and must be 7 digits long. Enter a valid bar code.
- 470043 There is no material number provided in the worklist.
- 470044 The list of allowed material numbers of the assay profile does not contain the extracted material number.
- 470045 A worklist with the name '{0}' already exists. The existing worklist cannot be replaced by the imported worklist.
- 470046 Sample ID is not valid. Sample IDs for this assay must be unique.
- 470047 The cyler cannot be used because it is due for verification. Select a different cyler or contact your local administrator.
- 470048 The selected assay(s) cannot be run on this cyler, as the cyler comes from a different distributor.
- 470049 The selected assay(s) cannot be run on this cyler, as they are not compatible to {0} cyclers.
- 470050 The assay profile does not contain material numbers.
- 470051 The assay profile {0} does not contain material numbers.
- 470052 An error occurred during report generation. Retry report generation.
- 470053 Copying of the selected cells failed. Only adjacent cells can be copied. Copy and paste the selected cells individually.
- 470054 Paste operation is cancelled. Selected cell(s) must be editable for pasting.
- 470055 Paste operation is cancelled. Selected cell(s) must be contiguous cell(s) of one column.

- 470056 Paste operation is cancelled. Selected cell(s) must be contiguous cell(s) of one column.
- 470057 Paste operation is cancelled. Select some cell(s).
- 470058 There is not enough space for the information to be pasted.
- 470059 The database is full. Approve and release experiments in the Approval dialog to allow new runs.
- 470060 The run cannot be started. The assay profile(s) contained in the worklist might have been deactivated or the worklist settings have been changed.
- 470061 Cyclor type of the selected assay profile {0} is not compatible to cyclor type of the assay profile(s) in the current worklist .
- 470062 Distributed channel of the selected assay profile {0} is not compatible to distributed channel of the assay profile(s) in the current worklist.
- 470063 The sample comment must not exceed 256 characters.
- 470064 Enter a valid sample ID (1-40 characters).
- 470065 The sample ID must be filled in, not only with space characters.
- 470066 Confirm that you have loaded the selected cyclor and attached the locking ring to the rotor.
- 470067 The Rotor-Gene AssayManager Worklist '{0}' cannot be exported. The following error occurred: {1}
- 470068 A Rotor-Gene AssayManager worklist from file {0} cannot be imported. The worklist was exported with a different application mode. Make sure the application modes are the same.
- 470069 The Rotor-Gene AssayManager worklist from file {0} cannot be imported. Reason: The assay {1} contains an invalid assay kit. Select a worklist with a valid assay kit.
- 470070 The Rotor-Gene AssayManager worklist from file {0} cannot be imported. It contains assay profiles which are either not installed or deactivated.
- 470071 The Rotor-Gene AssayManager worklist from file '{0}' cannot be imported. It contains assay profiles which are not available. Select another file.
- 470072 The Rotor-Gene AssayManager Worklist from file '{0}' cannot be imported. The following error occurred: {1}
- 470073 The Rotor-Gene AssayManager Worklist from file '{0}' cannot be imported, because it contains a rotor type that is not available.
- 470074 The referenced assay profiles '{0}' are not compatible to each other. Reasons:
- 470075 The assay kit information check of APS '{0}' produced the following errors:
- 470076 The assay profile '{0}' referenced by APS '{1}' does not refer to exactly one rotor type.
- 470077 The QIASymphony AS result file '{0}' cannot be imported: Reason: '{1}'
- 470078 The QIASymphony AS result file at '{0}' contains an invalid checksum. The file cannot be imported.
- 470079 The file '{0}' does not match the QIASymphony AS result file specification. The file cannot be imported.

- 470080 The number of assay points ({0}) exceeds the number of tube positions on the rotor.
- 470081 The unknown assay point state '{0}' of assay point '{1}' at position '{2}' is not supported by Rotor-Gene AssayManager.
- 470082 The unknown sample type '{0}' of assay point '{1}' at position '{2}' is not supported by Rotor-Gene AssayManager. Select another sample type.
- 470083 The unknown slot name '{0}' is not supported by Rotor-Gene AssayManager.
- 470084 No active assay profile matches the APS '{0}', major version '{1}', the QIAGEN original setting 'not required' and the volume pair '{2} µl, {3} µl' explicitly.
- 470085 No active assay profile matches the APS '{0}', major version '{1}', the QIAGEN original setting 'required' and the volume pair '{2} µl, {3} µl' explicitly.
- 470086 The pipetting scheme is not supported by Rotor-Gene AssayManager.
- 470087 The reaction volume of the APS '{0}' is not supported by the corresponding assay profile '{1}'.
- 470088 The APS '{0}' do not specify identical reaction volumes.
- 470089 The created worklist test samples contain replicated sample IDs, but the referenced Assay Profile '{0}' does not allow this.
- 470090 The number of assay points is '{0}'. This number exceeds the number of tubes on the rotor of the referenced assay profiles '{1}'.
- 470091 The assay point arrangement does not match the assay profile '{0}'. At position '{1}' the type '{2}' was expected, but the type '{3}' was found.
- 470092 The specified sample input volume and the eluate volume pair do not match the assay profile '{0}'. At position '{1}' the type '{2}' specifies '{3} µl' and '{4} µl', respectively, but '{5} µl' and '{6} µl' were expected.
- 470093 A matching assay profile was found for APS '{0}', but it is not designed for use in integrated workflows.
- 470094 A worklist with the name '{0}' already exists in the database. The file '{1}' may already have been imported. Create a worklist with a unique name.
- 470095 The assay profile {0} does not allow replicates. Remove the replicates.
- 470096 The LIMS file at '{0}' does not match the interface specification. The LIMS file cannot be imported.
- 470097 The resource has an invalid document format. Contact QIAGEN Technical Services.
- 470098 The referenced assay profiles are not cycling compatible. Reasons: {0}.
- 470099 The referenced assay profiles are not assay compatible. Reason: The rotor types do not match.
- 470100 The QIALink/LIMS result file does not specify identical reaction volumes.
- 470101 The referenced assay profiles are not assay compatible. Reason: The reaction volumes do not match.
- 470102 Your login mode : {0} does not match to the login mode {1} of the imported worklist.
- 470103 The sample arrangement does not match the assay profile '{0}'.
- 470104 The required assay profile '{0}, {1}. {2}. {3}' is not available in this system.

- 470105 The QIALink/LIMS worklist at {0} contains an invalid checksum.
- 470106 The unknown login mode "{0}" is not supported by Rotor-Gene AssayManager.
- 470107 The rotor type is not available in this system.
- 470108 The unknown sample type "{0}" is not supported by Rotor-Gene AssayManager.
- 470109 The unknown upstream status "{0}" is not supported by Rotor-Gene AssayManager.
- 470110 The file cannot be read. It will not be imported.
- 470111 The resource has an invalid document format. Contact QIAGEN Technical Services.
- 470112 The file cannot be read. The system supports interface version {0}, but the file is designed for version {1}.
- 470113 Automatic import of following QIASymphony AS result file(s) failed. The file(s) must be imported manually.{0}
- 470114 The path {0} could not be accessed. Automatic import of QIASymphony AS result files is not possible.
- 470115 The path {0} could not be found. Automatic import of QIASymphony AS result files is not possible.
- 470116 {0} (Slot {1})
- 470117 Automatic import of QIASymphony AS result file {0} (Slot {1}) failed.
- 470118 Automatic import of QIASymphony AS result file {0} failed.
- 470119 The file '{0}' does not match the QIASymphony SP result file specification. The file cannot be imported.
- 470120 The QIASymphony SP result file '{0}' contains an invalid checksum. The file cannot be imported.
- 470121 The QIASymphony SP result file '{0}' cannot be imported: Reason: '{1}'
- 470122 More sample IDs selected then available positions. Deselect {0} sample IDs.
- 470123 The specified path {0} does not exist any more. Please update the configuration setting path with correct path.
- 470124 No valid samples contained in QIASymphony AS result file.
- 470125 The Rotor-Gene AssayManager worklist from file {0} cannot be imported. It contains samples with invalid ids.
- 470126 The Rotor-Gene AssayManager worklist from file {0} cannot be imported. It contains assay(s) with invalid assay profile name.
- 470127 The QIALink/LIMS worklist at {0} contains assay(s) with invalid assay profile name.
- 470128 The QIALink/LIMS worklist at {0} contains samples with invalid ids.
- 470130 No worklist with assay rack ID {0} available.
- 470131 {0} Sample IDs will be overwritten.
- 470132 The applied worklist does not contain the entered assay rack ID {0}.
- 470133 Paste operation is cancelled. Selected cell(s) must not contains empty tube.
- 470134 "The file '{0}' cannot be imported. The Rotor-Gene AssayManager only support QIASymphony 5.0 and above file version. Make sure the versions are the same."

- 470135 "More than one worklists match the given rack ID. Select worklist manually."
470136 Report cannot be rendered as it is not generated.
470137 Failed to generate report.
470138 The Kit reference '{0}' of sample '{1}' does not match any of the given Kit references.
470139 The SP Batch ID '{0}' of sample '{1}' does not match any of the given Batch ID.
470140 The ICKitRef '{0}' of sample '{1}' does not match any of the given Kit references.
470141 The QIASymphony AS result file contains samples which are not expected by the referenced assay profile.
470142 The Rotor type '{0}' defined in the worklist does not fit to the assay profile.
470143 The Reaction volume '{0}' defined in the worklist does not fit to the assay profile.
470144 The associated assay profile contains multiple rotor types or reaction volumes. An unambiguous worklist cannot be created. Create and import assay profiles with a unique combination of rotor type and reaction volume.
470145 This worklist contains the outdated assay profile {0} version {1}. Create a new worklist with an updated assay profile.
470146 The kit expiration date for assay {0} is invalid. Provide valid kit expiration date.
510001 Fatal exception error occurred during command execution: {0}
510002 Make sure custom exception supports constructor with signature 'Exception(String, Exception)'
510003 Cycler-device generated an error with error code {0}. Switch off the cycler, switch it back on again, and restart application. If the error persists, contact QIAGEN Technical Services.
510004 Device was disconnected. Reconnect the device and retry.
510005 Fatal exception error occurred during Optical Temperature Verification (OTV) run: {0}
510006 Fatal exception error occurred during assay profile execution: {0}
510007 Reset cycler status failed. Switch off the cycler, switch it back on again, and restart application. If the error persists, contact QIAGEN Technical Services.
510008 Fatal exception error occurred during command execution. Switch off the cycler, switch it back on again, and restart application. If the error persists, contact QIAGEN Technical Services.
510009 Assay profile execution failed with error code {0}. Check the assay profile for inconsistencies and retry the execution.
510010 Update of OTV-calibration failed!
510011 The air temperature has gone over 140° C. Check if the heater or the thermistor are working properly. Contact QIAGEN Technical Services.
510012 A communication error occurred. Contact QIAGEN Technical Services.
510013 The machine's detector motor jammed. Contact QIAGEN Technical Services.
510014 The communication with the cycler was lost. Switch off the cycler, switch it back on again. If error persists, contact QIAGEN Technical Services.
510015 Enter a valid verification date.

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- 510016 The lid has been opened during the run. Close the lid and restart the run.
- 510017 Error cause that was previously flagged was solved.
- 510018 The rotor has stalled or stopped.
- 510019 The machine's source motor jammed. Contact QIAGEN Technical Services.
- 510020 The cycler is taking too long to reach temperature. This can affect the assay performance.
- 510021 The temperature measurement thermistor has gone open circuit. Contact QIAGEN Technical Services.
- 510022 Undefined error. Switch off the cycler, switch it back on again, and restart the application. If the error persists, contact QIAGEN Technical Services.
- 510023 An unexpected exception occurred during the run. Switch off the cycler, switch it back on again, and restart the application. If the error persists, contact QIAGEN Technical Services.
- 510024 The watchdog timer on the machine has reset it.
- 510025 Melt acquisition cannot be performed with settings 'keep LED on' on more than one acquisition channel selected. Check the assay profile for inconsistencies.
- 510026 No rotors have been added. Run cannot be started. Check the rotor configuration and the retry.
- 510027 No shoots have been added. Run can't be started!
- 510028 The requested rotor is not configured for this device. Check the rotor configuration and retry.
- 670000 Enter a user ID.
- 670001 Enter a valid user ID (1-40 characters).
- 670002 Enter an experiment name (1-{0} characters).
- 670003 Enter a valid experiment name (1-{0} characters).
- 670011 Select at least one context parameter.
- 670016 The number of messages in the audit trail table to print exceeds {0} messages. Adjust the filter settings.
- 670020 An error occurred during report generation. Retry report generation.
- 880039 The export has failed for: {0}
- 900010 The data from slot '{0}' in QIASymphony AS result file '{1}' cannot be imported to a worklist.
- 1010000 The access to the selected file or folder is denied. Select a different file or folder.
- 1010001 File not found. Check the file name and repeat the procedure.
- 1010002 The entered file name is invalid. Enter a valid file name without invalid characters, i.e. / | ? * " < >.
- 1010003 File path must be less than 260 characters.
Path too long: {0}.
- 1010004 Reserved Device Name
{0} is a reserved device name and cannot be used for a folder. Enter a different folder name.
- 1010006 Enter folder name.

- 1010007 The folder name is invalid. Enter a valid folder name (1-{0} characters)
- 1010008 Invalid folder name.
Entered value is a reserved device name. Enter a different name.
- 1010009 Invalid folder name.
Do not use special characters. Especially the following characters are not acceptable:
/ > < " : * | ? \
- 1010010 Folder {0} could not be created. Either the permission was denied, or a folder with this name already exists. Enter a different folder name.
- 1010011 Failed to create the Unlock file.
- 1010012 {0}
This file exists with Read Only attributes.
Use a different file name.
- 1010014 The entered file/directory name is invalid. Directory name must be less than 248 characters.
Path too long: {0}.
- 1010016 User name is unknown or password is incorrect. Enter user name and password again.
- 1010018 The confirmation password does not match the new password.
- 1010019 Confirm the new password.
- 1010020 Enter the new password.
- 1010022 The new and the old password must be different.
- 1010023 Enter the old password.
- 1010026 Enter a valid password.
- 1010028 Invalid password. The old password for the user is incorrect.
- 1010029 Invalid user name or password. Enter user name and password again.
- 1010031 The entered name is reserved. It cannot be used as folder name. Enter a different folder name.
- 1010032 The entered folder name is invalid. Enter a valid folder name.
- 1010033 This user is deactivated. Contact your local administrator.
- 1010034 Assign at least one role to user {0}.
- 1010035 The new password must be different from the previous {0} passwords. Enter a unique password.
- 1010044 {0} is not accessible. Directory not found. Check the network connection or create a new directory.
- 1010047 Could not log-in to the application. The database connection is lost. Contact your local administrator.
- 1010048 Enter a new password (8-40 characters).
- 1010049 The entered password is not valid. Enter a password that fulfills the following criteria:
8-40 characters, 2 upper case characters, 2 lower case characters, 2 numerical characters, 2 special characters and must not contain white spaces.

- 1010054 The entered password is not valid. Enter a password that fulfills the following criteria:
8-40 characters, 2 upper case characters, 2 lower case characters, 2 numerical characters, 2 special characters and must not contain white spaces.
- 1010055 A specified {0} name is a reserved name. Select a different name.
- 1010056 The {0} name must not contain leading and/or trailing white spaces.
- 1010057 The password must not contain white spaces.
- 1010058 The entered file name is invalid. File name must be less than 248 characters.
- 1110012 Signature not found.

1.9 Abbreviations

Note

Further information can be found in the [► Glossary](#).

APS	Assay parameter set
AUDAS	Automatic data scan
CAL	Calibrator
CFR	Code of Federal Regulations
CLIA	Clinical Laboratory Improvement Amendments
COC	Cut-off control
Ct	Cycle threshold
EC-	Negative extraction control
EC+	Positive extraction control
FDA	Food and Drug Administration
FPC+	Positive full process control
FPC-	Negative full process control
GMP	Good Manufacturing Practice
GUI	Graphical User Interface
IC	Internal control

LIMS	Laboratory Information Management System
LOQ	Limit of quantification
NTC	No template control
OTV	Optical temperature verification
PCR	Polymerase chain reaction
PC	Positive control
R	Root extracted from R^2
R^2	Correlations coefficient
QS	Quantitation standard
S	Test sample
UDT Mode	User Defined Test Mode of operation

1.10 Glossary

A B C D E F G I K L M N O P Q R S T U V W

Click a letter to jump to the topics starting with the corresponding letter.

A

Acquisition	Acquisition is the collection of fluorescent data during a PCR run. Each acquisition step is related to a certain channel and a certain cycling step.
Administrator	User role which has the permissions to configure the software, add and delete assay profiles, report profiles, and to manage cyclers and users.
Amplification plot	Plot showing one or more amplification curves.
Analysis	See "PCR analysis".
Analysis parameters	Parameters to define the different analysis steps (e.g., fluorescence thresholds, allowed ranges of C_T values).
Anomaly	Deviation from an ideal amplification curve (e.g., peaks, baseline dips, or rising/decreasing plateaus).
Application	Used here as a synonym for Rotor-Gene AssayManager v2.1.
Approval (approve)	The process by which the approver accepts or rejects sample results. After approval of a sample result, it can be released so that the related information can be printed into a report or submitted to a LIMS.

Approver	User role which gives the user the right to approve and release sample results in Closed Mode or in UDT Mode.
APS	See "Assay Parameter Set".
Archive (noun)	Part of the experiment repository that contains experiments with completely released sample results.
Assay	General molecular biology test (term used here for real-time PCR assays). In the context of the Rotor-Gene AssayManager v2.1 software the term "assay" defines the collection of all samples (including external controls) and their corresponding sample results that are related to one assay performed in one run.
Assay and sample analysis	Analysis step that contains various rule based checks to create the final results for each sample by incorporating all targets (including the internal control and the external controls).
Assay developer	Role for a developer that gives the user the right to develop assay profiles with the assay profile editor. Users can only develop assay profiles in UDT Mode. Closed Mode assays are developed and validated by QIAGEN.
Assay Parameter Set (APS)	File from QIASymphony. The combination of an Assay Definition with additional parameters defined (e.g., number of replicates and assay standards). In Integrated run mode, it is also connected to the Assay Control Set.
Assay profile	Consists of general information, e.g., about cycling compatibility, structural information about targets and samples, a run profile, and an analysis profile.

Assay profile editor	Environment in the UDT mode of Rotor-Gene AssayManager v2.1 to support the assay developer to create an assay profile.
Assay status	The assay status describes whether run and analysis were successful or failed. Reasons for failed can be "run failed", "run stopped", or "assay invalid" (according to failed analysis rules).
AUDAS	See "Automatic Data Scan (AUDAS)".
Audit trail	A record of user actions.
Auto gain	Method to determine an appropriate gain value for a PCR run. Thereby, the gain is selected in a manner that the background fluorescence is within a defined interval (a typical interval is fluorescence between 5 and 10 on the measurement scale of the cycler) with the intention to get a signal over the full dynamic range but without driving into saturation (>100).
Automatic Data Scan (AUDAS)	AUDAS is the name for the analysis step of the real-time PCR analysis that tests each curve for anomalies. Curves with anomalies are flagged as invalid. Unproblematic anomalies can be flagged by a warning flag that does not lead not to an invalid result.
Auto-lock (verb)	Locks the application after a predefined time without any user interaction to prevent misuse. Started runs are neither interrupted nor impacted if a user logs out, another user starts a new session, or if the application is locked (automatically or manually).
Auto-lock timer	The auto-lock timer locks the application after a predefined time without user

interaction.

B

Bar code

See "QIAGEN kit bar code".

C

CFR

Code of Federal Regulations.
See "FDA CFR Title 21 Part 11".

Channel

A channel consists of a light-emitting diode (LED) with an excitation filter paired with an emission filter. The LED and excitation filter excite samples at a given wavelength. Fluorescence emitted by samples is passed through the emission filter, before being detected by a photomultiplier.

CLIA

Clinical Laboratory Improvement Amendments.

CLIA compliant password rules

According to CLIA, a password must contain at least:

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

Closed mode

In Closed mode of operation only validated QIAGEN assays can be processed. The user does not have permission to modify the assay profile.

Computer

In Rotor-Gene AssayManager v2.1 the term "computer" is used for a notebook or a PC, not a server.

Concentration factor	Factor to convert the calculated target concentration within an eluate (i.e., the quantitative result of the analysis) into the concentration within the original sample. The concentration factor is optional for analysis but necessary if one is interested in the target concentration within the sample.
Conversion factor	Factor to convert the calculated target concentration from the default unit to another unit.
Core analysis	This term describes a part of the analysis comprising the normalization, C_T value calculation, and (for quantitative assays) the quantification. This analysis is identical to the analysis used by the Rotor-Gene Q software.
Core application	The Rotor-Gene AssayManager v2.1 software consists of different components working together. The core application is complemented by different plug-ins that contain assay type-specific, analysis-specific options. The core application is mandatory for working with Rotor-Gene AssayManager v2.1. At least one plug-in must be installed.
C_t	See "Cycle threshold".
Curve	Unprocessed (raw data) or processed data measured by an acquisition with the cycler in a series of an assay-specific number of cycles. Technically, the curve is a discrete series of fluorescence measurements. However, these measurements are typically connected and displayed as a curve. A curve corresponds to one target of a specific sample.
Cycle threshold (C_t)	Fractional cycle at which a curve reaches a predefined normalized fluorescence

	threshold.
Cycler	See "Rotor-Gene Q Cycler".
Cycler verification	General term for a maintenance method to check whether the device works properly.
Cycling compatible assays	Cycling compatible assays are assays that can be used in different tubes during the same PCR run in parallel. Assays are cycling compatible if they are defined and validated to be cycling compatible. A cycling group can be set up, which contains assays defined to be cycling compatible. It is necessary that at least the thermal profiles (part of the run profile with number of cycles, steps, step length, temperatures etc.) of cycling compatible assays are identical. Other run parameters (e.g., acquisitions) and the analysis profiles can be, however, individual for each assay.

D

Date picker	 Calendar icon to help you selecting the required date. Alternative to entering the date manually.
Default name	Automatically generated name for a newly created worklist or an experiment. The pattern for the generated name is defined in the Configuration environment.

E

EC-	Sample type (external controls): Negative extraction control.
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EC+	Sample type (external controls): Positive extraction control.
Eluate	Purified nucleic acids from a sample.
Environment	The Rotor-Gene AssayManager v2.1 software consists of several environments ("Setup", "Approval", "Archive", "Service", "Configuration", and "Cycler"). In these environments, certain tasks can be performed, such as setting up a run.
Error	See "System error".
Experiment	The process composed of a PCR run and a PCR analysis yielding test results.
Experiment data	All data that are collected during an experiment: worklist, assay profiles, raw data, processed data, logs, assay status, approvals, release status, sample result, and comments.
Experiment status	The 3 states of an experiment are initialized, run performed, and run failed.
Expiration date	Every kit has an expiration date. If a kit has expired, QIAGEN will not guarantee that the kit performs according to its specification anymore.
Expiry date	Used here as a synonym for expiration date.
Export	The process of transferring any kind of data from Rotor-Gene AssayManager v2.1 to an external destination.
External controls	Collection of standards and controls (such as the quantitation standard, the negative control, or the positive control) defined by an individual assay profile. External controls are always located in other tubes than the test samples of the assay.

External control result Assay-dependent final test outcome of an external control summarizing all corresponding target results.

External source/external destination Location outside of the Rotor-Gene AssayManager v2.1 software.

F

FDA Food and Drug Administration is an agency of the United States Department of Health and Human Services responsible for the safety regulation of most types of foods, dietary supplements, drugs, vaccines, biological medical products, blood products, medical devices, radiation-emitting devices, veterinary products, and cosmetics.

FDA CFR Title 21 Part 11 FDA CFR Title 21 Part 11 regulations define the criteria for considering electronic records and electronic signatures to be trustworthy, reliable, and equivalent to paper records. Part 11 requires drug makers, medical device manufacturers, biotech companies, biologics developers, and other FDA-regulated industries (with some specific exceptions), to implement controls, including audits, system validations, audit trails, electronic signatures, and documentation for software and systems involved in processing many forms of data as part of business operations and product development.

Flag Annotation that may occur during the run or the analysis. There are two types of flags: Warning flags are just extra information while invalid flags set the corresponding target to invalid.

FPC+	Positive full process control.
FPC-	Negative full process control.
G	
Gain	The Rotor-Gene Q uses a photomultiplier to collect fluorescence photons and convert them to electronic signals. The gain is a setting that determines the sensitivity of the photomultiplier. If the gain is set too high, the signal is oversaturated. If the gain is set too low, it is not possible to differentiate signal from background noise. A method to determine the gain is the auto-gain function. See "Auto gain".
Gain Optimization	Gain Optimization is a process that dynamically adjusts the gain setting, allowing an appropriate setting to be selected, which results in optimal signal detection.
Global settings	Global settings are stored in the database and affect all clients using this database. These settings can be configured in the "Configuration" environment.
GUI	Graphical User Interface.
I	
*.iap	File extension for a Rotor-Gene AssayManager v2.1 Assay Profile.
IC	See "Internal control".
Import	The process of transferring any kind of data from an external source into Rotor-Gene AssayManager v2.1.

Internal control (IC)	A standard reaction that is run simultaneously with the sample within the same tube and detected by a certain acquisition. It is used to verify that the PCR process was successfully performed and has not been inhibited. Technically, the IC is one of the targets of an assay and is present in the test sample tubes as well as in the external control tubes. In some assays the internal control is located in a different tube than the test, for example, for SYBR® Green assays where only one color channel can be detected. In such cases the "internal" control can be tested with the same sample but in a separate tube.
Invalid sample	Sample flagged as "invalid". If a sample is invalid, all its targets are invalid.
*.irp	File extension for a Rotor-Gene AssayManager v2.1 report profile.
*.iwl	File extension for a Rotor-Gene AssayManager v2.1 worklist.
 K	
Kit	A kit is a box with reagents sold by QIAGEN to perform a biological application. In the context of Rotor-Gene AssayManager v2.1, a kit contains all reagents to perform a PCR run with eluates. PCR kits can contain master mix components, positive and negative controls, etc.
Kit bar code	See "QIAGEN kit bar code".
Kit information	A kit is labeled with, among others, the following information: material number, lot number, and expiration date.

L

LIMS	Laboratory Information Management System. If configured, Rotor-Gene AssayManager v2.1 exports results in a file to be read by a LIMS.
Local settings	Local settings are stored on the local computer and affect no other clients using the same database (in comparison to the global settings). These settings can be configured in the "Configuration" environment.
Lock (verb)	Make the application inaccessible for other users without logging out. Started runs are neither interrupted nor impacted if a user logs out, another user starts a new session, or if the application is locked (automatically or manually).
Locking ring	Locking rings are metal rings that fit onto the rotor to prevent tubes and caps from coming loose during operation of the Rotor-Gene Q. Loose caps and tubes could cause damage to the instrument.
Log file	Log of the technical software behavior that can be interpreted by the QIAGEN Technical Services.
Lot number	Part of the kit information.

M

Material number	Part of the kit information.
Mode	See "Closed Mode of operation". See "User Defined Test Mode of operation".

Mode of operation	See "Closed Mode of operation". See "User Defined Test Mode of operation".
Multiplex assay	Multiplex assays are multi-target assays that simultaneously test multiple targets in single tubes by using different primers and probes. The probes are labeled with specific dyes, which anneal to the different target sequences. The detection is performed by different color channels. However, internal controls, which are technically targets as well, are typically not regarded in this context.
Multi-target assay	General term for an assay that can detect more than one target in parallel. Thereby, internal controls, which are technically targets as well, are typically not regarded in this context. The multiple targets can be independent or interdependent or a combination of both. Multi-target assays can be either multiplex assays, multi-tube assays, or a combination of both.
Multi-tube assay	Multi-tube assays are multi-target assays that simultaneously test multiple targets in more than one tube. Before the PCR process, the sample to be tested is split and distributed over the different tubes.
N	
Normalization	In this context, normalization is an analysis step used for curve preprocessing prior to Ct value calculation and the quantitation. It includes typically a smoothing of the curves and a removal of the background noise by subtracting the baselines.
NTC	No template control.

O

Operator

User role with the rights to perform a PCR run and to view the results (not allowed to approve).

Optical configuration

The optical configuration of a Rotor-Gene Q cycler is described by the available excitation diodes that excite the fluorescence and the emission filters letting pass the emitted light. The optical configuration differs between different types of the Rotor-Gene Q. It can be read out from the firmware.

OTV

Optical Temperature Verification.

OTV calibration run

The OTV calibration run is a special run that measures the in-tube temperature in the Rotor-Gene Q cycler and calibrates the cycler according to the measurements afterwards. A special rotor is used for this run, which contains 3 thermochromatic liquid crystals that change their transparency according to the temperature. OTV calibration can be performed with the Rotor-Gene Q software but not with Rotor-Gene AssayManager.

P

PC

Sample type (external controls): Positive control.

PCR

Polymerase chain reaction.

PCR analysis

Processing of the raw PCR data, for example, by applying AUDAS, normalization, Ct value calculation, quantification, and assay and sample

	analysis algorithms to obtain a quantitative or qualitative result.
PCR run	PCR process performed in a thermocycler (e.g., the Rotor-Gene Q). In this context PCR is always a real-time PCR.
Plug-in	A plug-in allows Rotor-Gene AssayManager to support a specific type of assays. Plug-ins may not be available in all countries.
Processed curve	Raw data that have been changed during PCR analysis.
Processed data	Collection of processed curves.
Q	
QIAGEN kit bar code	Identifies the QIAGEN kit. The bar code consists of the material number (7 digits), the expiry date (6 digits), and the lot number (4–10 digits).
QIALink	Middleware at QIAGEN to support specific LIMS systems. Contact QIAGEN Technical Services for details.
QIAsymphony	QIAGEN platform for automatic sample preparation and assay setup.
QS	Sample type (external controls): quantitation standard.
Qualitative result	Information whether a signal has been detected for a target or not or whether the target is invalid.
Quantification	Analysis step to determine the initial concentration of a target.
Quantitative result	Information of the initial target concentration of a result.

Quantitation standard	Reference sample with a given target concentration used for quantification. Note: In the Rotor-Gene Q software the term “quantitation” may even be used instead of the term “quantification”.
*.qut	File extension for Rotor-Gene quantitation analysis template used by the Rotor-Gene Q software. The file contains all values to parameterize the absolute quantification analysis. Note: In the Rotor-Gene Q software the term “quantitation” may be used instead of the term “quantification”.
R	
R	Root extracted from R^2 .
R^2	Correlations coefficient: The correlations coefficient is a statistical parameter to measure the fit of the data points to the regressed line. In general, the standard curve should have an R^2 value ≥ 0.990 . The individual limit for the R^2 value can be defined in the assay profile.
Raw curve	Unprocessed fluorescence data measured in one tube on one channel by the cycler in a series of an assay-specific number of cycles.
Raw data	Collection of unprocessed amplification curves.
Reaction volume	Volume of liquid in the PCR tubes.
Real-time PCR	PCR with real-time monitoring of the reaction products.
Regression line	In this context, a regression line is a linear function derived from a regression

	analysis between the C_T values and given concentrations of quantitation standards. It is also known as the standard curve. See "Standard curve".
Release	The process of publishing previously approved sample results by generating a report and optionally transferring the data to a LIMS.
Release status	The release status is the status of an assay that can be "not released", "partially released", and "fully released" where "fully released" means that all sample results contained in the assay have been released.
Renewal interval	Days until a password must be renewed.
Replicate	See "Sample replicate".
Report	Summary of selected sample results (external control results are always included) of one assay as a secure *.pdf-file, which cannot be manipulated.
Report profile	Profile describing which information shall be included in the report.
*.ret	File extension for a Rotor-Gene Q run template file used by the Rotor-Gene Q software. The file contains all values to parameterize a PCR run.
*.rex	File extension for a Rotor-Gene Q experiment file format used by the Rotor-Gene Q software. It can be imported for testing an assay profile in the "Development" environment of the UDT mode.
*.rgam	Contains all data of one Rotor-Gene AssayManager v2.1 experiment.
Role	User rights are summarized in a certain role: administrator, approver, operator,

	assay developer, and super user are available.
Rotor	The metal rotor holds tubes or Rotor-Discs in the Rotor-Gene Q. It enables samples to spin in the instrument chamber and ensures that samples are correctly aligned with the optical system. The rotor is secured with a locking ring.
Rotor-Disc	Rotor-Discs are circular plates of vertically oriented reaction wells. Rotor-Disc formats for 72 and 100 reactions are available. Rotor-Discs are sealed using Rotor-Disc® Heat Sealing Film and the Rotor-Disc Heat Sealer.
Rotor-Gene Q Cyclor	The real-time PCR cyclor supported by Rotor-Gene AssayManager v2.1.
Rotor-Gene Q Software	Open mode software to control the Rotor-Gene Q cyclor and to analyze the acquired data.
Rotor type	See "Rotor".
Row selector	Specific table column to select complete rows.
Run	See "PCR run".
Run parameters	Parameters specifying a PCR run (e.g., number of cycles, temperature, acquisitions, rotor type, tube volume, etc.).
Run profile	Set of all run parameters. It is part of the assay profile.

S

S	Sample type: test sample
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Sample	Test sample or external control to be analyzed.
Sample ID	Identifier of a sample. The sample ID must not be empty and must consist of 1–40 characters.
Sample information	Annotations describing one sample. It contains sample ID, reaction volume, sample volume, sample type, flags set by an upstream platform, and process history.
Sample replicate	One sample split on several tubes to do the same test in parallel in order to get an estimate for the variance.
Sample result	General term for test result and external control result.
Sample result status	The sample result status describes a qualitative result by different assay-dependent states corresponding to a test result or an external control result.
Sample type	A sample can be of the following types: test sample (S) or one of the following external controls: quantitation standard (QS), no template control (NTC), positive control (PC), negative extraction control (EC–), positive extraction control (EC+), negative full process controls (FPC–) and positive full process controls (FPC+). Not all assays include all types of external controls. This is assay dependent.
Sample volume	Volume of the initial amount of material for the sample preparation procedure.
Service user	User role that has all necessary permissions to maintain the software at customer site. The service user has no permission to approve analysis results.

Session	Contains all user actions from login until logout.
Standard curve	A standard curve is a linear function derived from a regression analysis between the Ct values and given concentrations of quantitation standards.
Super user	The super user has all available permissions of all available roles as a convenient way to grant all permissions to one user.
Support package	Information wrapped up in a *.zip file to be sent via an email program to QIAGEN Technical Services to inform QIAGEN what went wrong at the customer's site and how to help the customer. The support package can be created in the "Approval" and in the "Archive" environment.
System error	Technical errors (e.g., process errors, software malfunctions, cyclers errors) that are not acceptable. User interaction is required. Note: Do not confuse with invalid results.
T	
Target	Specific DNA sequence (or RNA before reverse transcription step) to be amplified during the PCR.
Target result	The result of the analysis of one target for one specific sample.
Test	Synonym of assay.
Test sample	Unknown sample to be tested with an assay.

Test sample result	Assay-dependent final test outcome of an assay for one test sample summarizing all corresponding target results.
Threshold	Predefined fluorescence value used to calculate the cycle threshold (Ct) of a curve.
Tube	Small container for liquids, in which the PCR reaction takes place. A sample can be split over multiple tubes.

U

UDT Mode	See "User Defined Test Mode of operation (UDT mode)".
Upstream process	From the PCR point of view, the upstream process consists of the sampling, the sample disruption, the purification, and the assay setup.
Upstream status	Status which is set by QIASymphony system. It can be "valid", "unclear", or "invalid". If it is "invalid" or if Rotor-Gene AssayManager v2.1 is configured in a way that "unclear" samples are processed as if they are "invalid", a special invalid flag is set. Sample result are not provided for samples with an "invalid" upstream status.
User Defined Test Mode (UDT mode)	This is the mode of operation for assays that are created and validated by a user of Rotor-Gene AssayManager v2.1 software.
User role	See "Role".

V

Validation error	An error that occurs due to a missing or invalid user input. User interaction is required.
Verification	See "Cycler verification".

W

Warning	A situation could be optimized by further input. User interaction is possible, but not mandatory.
worklist	Sample information for all samples to be analyzed and a reference to an assay profile for each sample. When using an upstream platform, the worklist contains flags as well.

1.11 Appendices

The appendices contain a ► list of file endings, the ► liability clause, and ► license terms.

1.11.1 File Endings

Note

Further information can be found in the ► Glossary.

*.iap	Rotor-Gene AssayManager v2.1 Assay Profile file.
*.irp	Rotor-Gene AssayManager v2.1 report file.
*.iwl	Rotor-Gene AssayManager v2.1 worklist.
*.qut	Rotor-Gene quantitation analysis template used by the Rotor-Gene Q software.
*.ret	Rotor-Gene Q run template file used by the Rotor-Gene Q software.
*.rex	Rotor-Gene Q experiment file format used by the Rotor-Gene Q software.

*.rgam All data of one Rotor-Gene AssayManager v2.1 experiment.

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1.11.3.5 Log4Net

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1.11.3.8 Microsoft SQL Server 2014 Express

Microsoft SQL Server 2014 Express

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1.11.3.9 NHibernate

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