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Rotor-Gene AssayManager® v1.0 Core Application User Manual

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Sample to Insight

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1.1 Safety Information

The user-friendly Rotor-Gene AssayManager™ v1.0 has been specifically developed for use with up to 4 different Rotor-Gene® Q instruments. Before using Rotor-Gene AssayManager v1.0, it is essential that you read this user manual carefully and pay particular attention to the safety information. The instructions and safety information in the user manual must be followed to ensure safe operation of the cycler and to maintain the instrument in a safe condition.

The Rotor-Gene AssayManager v1.0 user manual does not provide detailed information about the Rotor-Gene Q instrument hardware and maintenance. The Rotor-Gene AssayManager v1.0 manual only describes the functionality of the Rotor-Gene AssayManager v1.0 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 cycler

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

WARNING ⚠	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.

CAUTION ⚠	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.

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

Proper use

WARNING/ CAUTION ⚠	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.

QIAGEN charges for repairs that are required due to incorrect maintenance.

WARNING/ CAUTION ⚠	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.

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

CAUTION ⚠	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.

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 outlet.

WARNING/ CAUTION ⚠	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.

WARNING/ CAUTION ⚠	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.

WARNING/ CAUTION ⚠	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.

WARNING/ CAUTION ⚠	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.

CAUTION ⚠	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.

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 outlet before servicing.

WARNING ⚠	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.

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.

WARNING ⚠	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.

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 ▶ www.cdc.gov/labs/BMBL.html.

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.

WARNING ☣	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.

[*] 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

WARNING ⚠	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.

*	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).

WARNING ⚠	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.

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.

CAUTION ⚠	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.

WARNING ⚠	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.

WARNING ⚠	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.

Heat hazard

WARNING ⚠	Hot surface [W19] The Rotor-Gene Q chamber can reach temperatures above 120°C (248°F). Avoid touching it when it is hot.

WARNING ⚠	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.

1.2 Introduction

Thank you for choosing Rotor-Gene AssayManager v1.0. We are confident it will become an integral part of your laboratory.

Rotor-Gene AssayManager v1.0 is a software for routine testing in combination with Rotor-Gene Q instruments. Rotor-Gene AssayManager v1.0 is able to read in sample information, set up experiments, control up to 4 different Rotor-Gene Q cyclers, acquire data from these instruments, automatically analyze results, and create reports.

Rotor-Gene AssayManager v1.0 consists of different components working together. The core application is complemented by different plug-ins that contain assay type specific analysis and visualization of the results. The core application is mandatory for working with Rotor-Gene AssayManager v1.0. Optionally additional plug-ins can be installed. At least one plug-in must be installed. Not all plug-ins are available in all countries. Refer to the www.qiagen.com/Products/Rotor-GeneAssayManager.aspx to discover our continuously expanding range of plug-ins.

1.2.1 Provided User Manuals

The core application and every available plug-in have their own user manual with specific information about the functionality of the different Rotor-Gene AssayManager v1.0 components. Rotor-Gene AssayManager v1.0 provides a context sensitive help that can be started by simply pressing the "F1" key.
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 from the product web page, read, and printed as *.pdf files.

Rotor-Gene AssayManager v1.0 core application user manual	▪ Provides a description of the software ▪ Describes functions that are the same for the core application and all different plug-ins ▪ Provides information about troubleshooting
Rotor-Gene AssayManager v1.0 plug-in user manuals	Provide details on ▪ How to use the assay type specific plug-ins ▪ Their functionalities.

1.2.2 About this User Manual

This user manual provides information about Rotor-Gene AssayManager v1.0 Core Application in the following sections:

1. Introduction
2. General Description of Rotor-Gene AssayManager v1.0
3. Getting started including installing Rotor-Gene AssayManager v1.0
4. Basic concept and general software usage
5. Using Rotor-Gene AssayManager v1.0
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 v1.0 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 cycler names. In this manual, the cycler names "Cycler 1", "Cycler 2", "Cycler 3", and "Cycler 4" are used. Further information about how to configure cyclers 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.

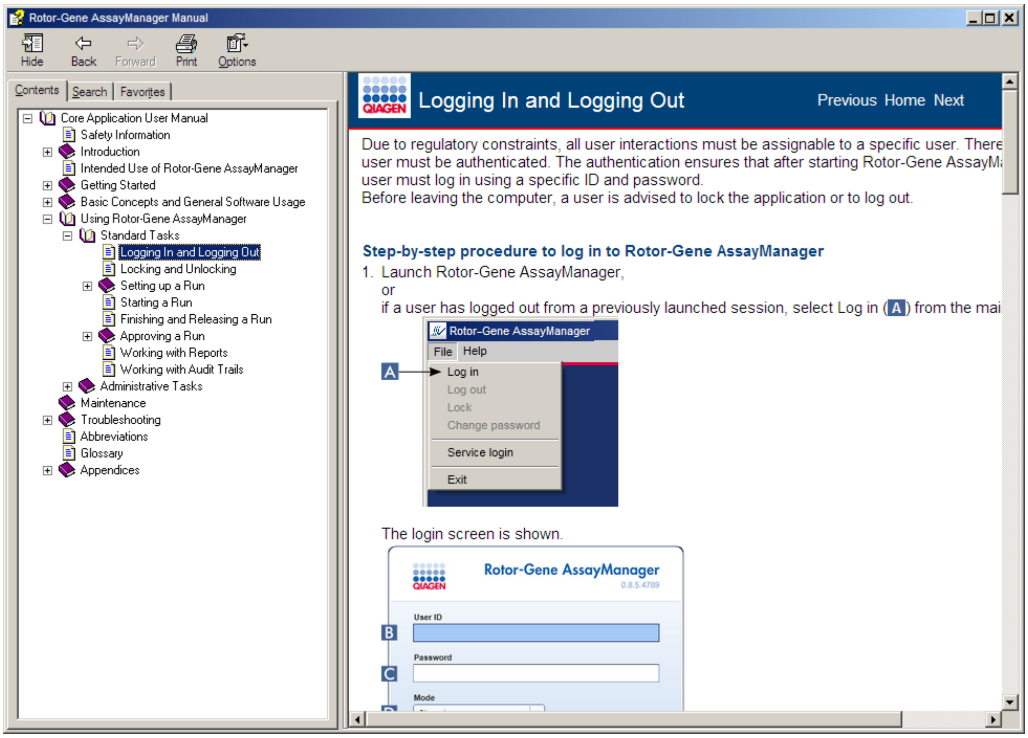
In an effort to produce useful and appropriate documentation, we appreciate your comments on this user manual. Please contact QIAGEN Technical Services.

Version Management

This document is the Rotor-Gene AssayManager v1.0 Core Application User Manual, which provides information about Rotor-Gene AssayManager v1.0 Core Application version 1.0.x (x ≥ 5).

1.2.4 Getting Help

Rotor-Gene AssayManager v1.0 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, after pressing the "F1" key in dialog. For example:



Logging In and Logging Out

Due to regulatory constraints, all user interactions must be assignable to a specific user. There
user must be authenticated. The authentication ensures that after starting Rotor-Gene AssayM
user must log in using a specific 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

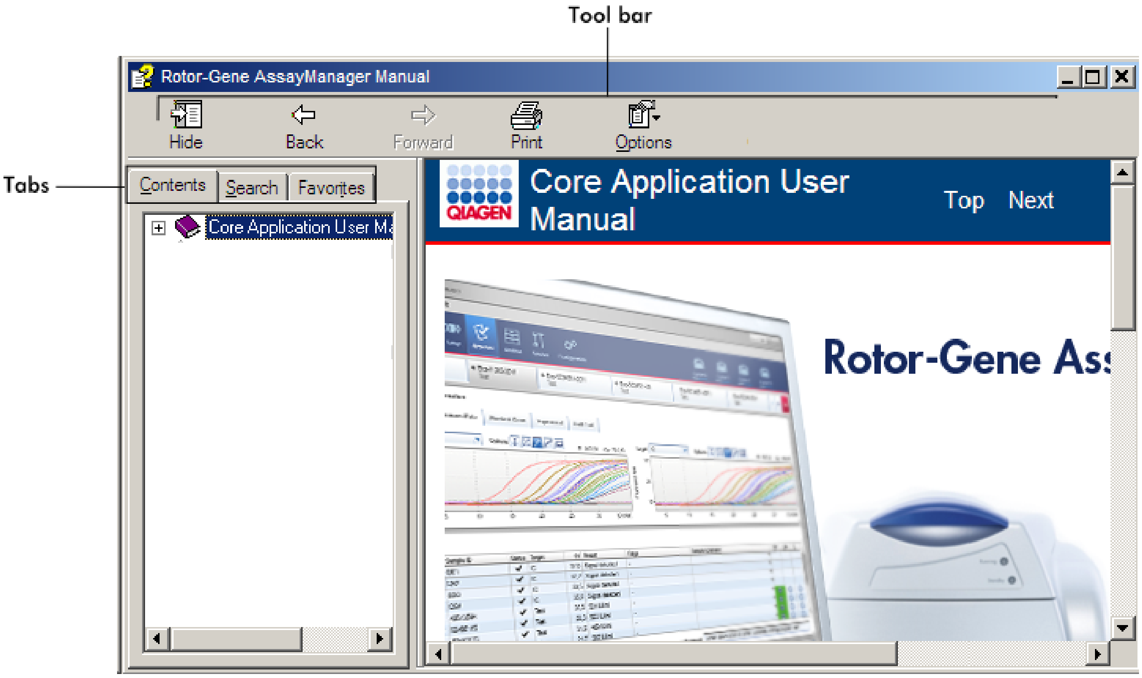
1. Launch Rotor-Gene AssayManager,
   or
   if a user has logged out from a previously launched session, select Log in (A) from the mai

   The login screen is shown.

   User ID

   Password

Using Rotor-Gene AssayManager v1.0 Help

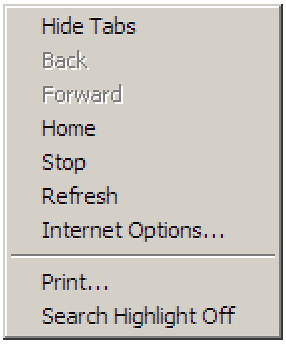


The help file contains two functional areas:

- Tool bar
- Tabs

The tool bar contains the following buttons:

Name	Icon	Description
"Hide" or "Show"	Hide	Hides the left-hand side navigation tab. To display the navigation tab again, click "Show". This button appears instead of "Hide".
"Back"	Back	Returns to the previous screen.
"Forward"	Forward	Returns to the screen displayed before using the "Back" button.
"Print"	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"	Options	Opens the options menu with the following entries: 

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 V1.0

Product Configuration

Rotor-Gene AssayManager v1.0 is a software for routine testing in combination with the Rotor-Gene Q real-time PCR instruments.
The software consists of a core application and modular plug-ins and assay profiles. The specific combination of core application, plug-in and assay profile determines a specific routine testing application. Rotor-Gene AssayManager v1.0 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 v1.0 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 v1.0 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 v1.0 includes these 3 main functionalities:

1) Cycler control: Rotor-Gene AssayManager v1.0 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 v1.0 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 v1.0 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 v1.0 imports sample-specific information from QIAsymphony® or via a LIMS. Data from the PCR experiment are then used for analysis. After analysis the system is able to export data.

Modes of Operation

For cycler control and data analysis, Rotor-Gene AssayManager v1.0 offers 2 modes of operation to the user, the Closed Mode and the User Defined Test Mode, described fully in section 1.5.1.1.

Requirements for Rotor-Gene AssayManager v1.0 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 v1.0 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	Trained personnel, certified, and authorized by QIAGEN

Training for Rotor-Gene AssayManager v1.0 software users

To use the Rotor-Gene AssayManager software no additional special training is required. The user has to read the accompanying documentation before using the Rotor-Gene AssayManager v1.0 software.

1.4 Getting Started

This section of the user manual describes the system requirements for Rotor-Gene AssayManager v1.0 and how to install and configure Rotor-Gene AssayManager v1.0 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 v1.0

Rotor-Gene AssayManager v1.0 and the corresponding plug-ins are available on Removable Media. The data carrier provides installation, update, and uninstall process for Rotor-Gene AssayManager v1.0, the Rotor-Gene AssayManager v1.0 database, and the Rotor-Gene AssayManager v1.0 plug-ins (plug-ins are delivered with different data carriers).

Rotor-Gene AssayManager v1.0 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 Core Application User Manual.

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 v1.0 for details.

Note

It is not possible to install Rotor-Gene AssayManager v1.0 on a computer or an existing database server, that already has Rotor-Gene AssayManager v2.1 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.

Rotor-Gene AssayManager v1.0 can be installed with 3 different configurations:

Task	Description
Install on stand-alone computer*	▪ A user with local system administration privileges installs the database (Microsoft® SQL Server Express) including initial data, the Rotor-Gene AssayManager v1.0 application, and at least one Rotor-Gene AssayManager v1.0 plug-in on a computer. ▪ The user is completely guided by the installation wizard and will be prompted for input, if necessary.
Create new central database and install Rotor-Gene AssayManager v1.0 on additional computers*	▪ A user with all required database administration privileges installs only the database (Microsoft SQL Server Express) including initial data on a server. ▪ The server is connected via local area network to the computers of the application users. ▪ Rotor-Gene AssayManager v1.0 and at least one Rotor-Gene AssayManager v1.0 plug-in is installed on one or multiple 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.
Use existing database server and install Rotor-Gene AssayManager v1.0 on one or multiple computers*	▪ 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 v1.0 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 v1.0 and at least one Rotor-Gene AssayManager v1.0 plug-in is installed on one or multiple 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 v1.0 is supplied as part of the Rotor-Gene Q instrument which is referred to as a “QIAGEN laptop” in the following text. In general, the following minimum requirements must be fulfilled to run Rotor-Gene AssayManager v1.0:

Description	Minimum requirements
Display	1024 x 768 pixel resolution or higher
Supported operating systems	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	2 USB 2.0 ports. If necessary, USB Hub can be ordered through QIAGEN. Contact ▶ www.qiagen.com for details.
Removable Media drive	1
Pointing device	Touchpad or mouse or equivalent is required.
Bluetooth®	Must be switched off
PDF viewer or similar	Already installed
Power options	Never turn off hard disks, hibernate, or go to standby

WARNING ⚠	Hard disk turn off, hibernation, and standby must be deactivated to prevent interference with experiment which could resulting in incorrect results.

Note

Any outstanding Windows update needs to be applied before installing Rotor-Gene AssayManager v1.0. Otherwise the installation procedure might fail.

Note
The installation of Rotor-Gene AssayManager v1.0 can only be performed with administrator privileges.

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

Note
A stable power connection is required. Unstable power connections can cause loss of data.

1.4.1.2 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 v1.0 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 v1.0 and Plug-ins

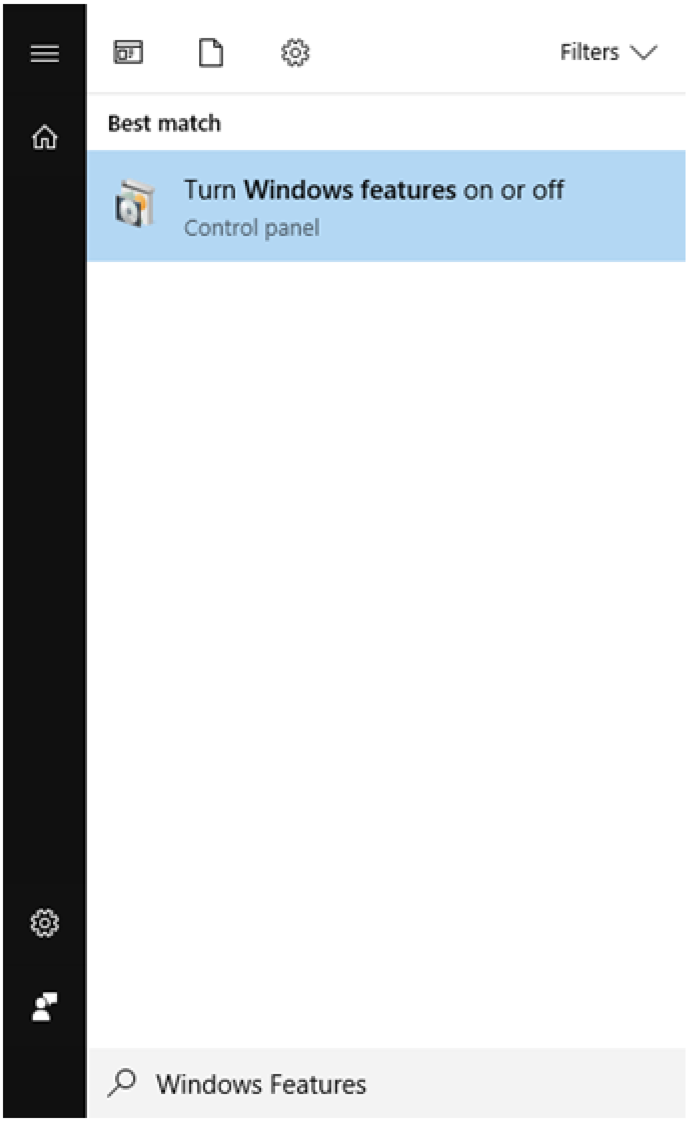
The following chapters provide you with details about the installation of the software.

1.4.2.1 Installation Pre-Requisites on Windows 10

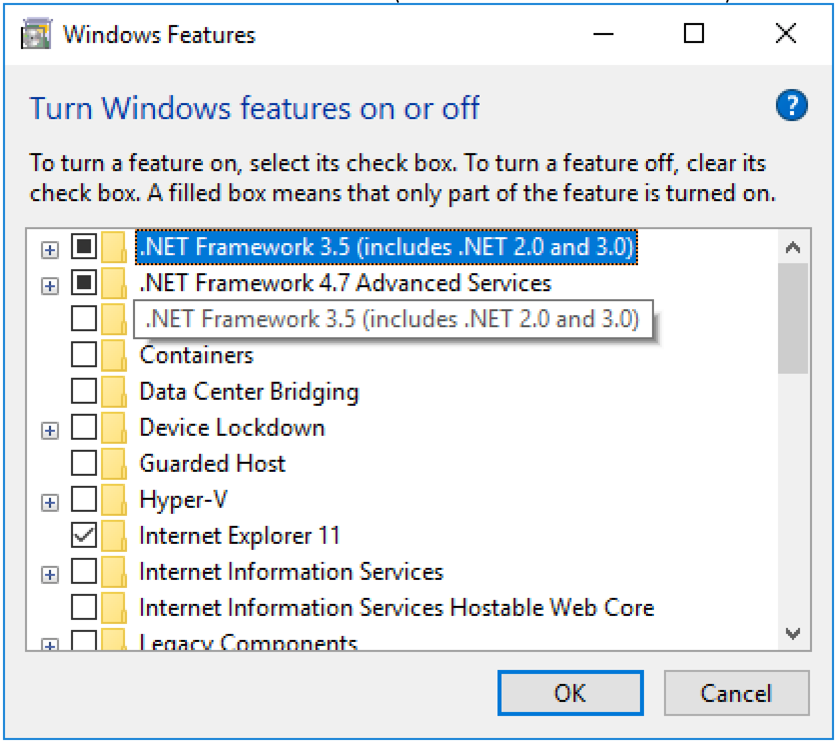
The Microsoft SQL Server installed together with Rotor-Gene AssayManager v1.0 needs a pre-installed Microsoft .NET Framework in version 3.5. If you use a laptop, distributed by QIAGEN, this installation is already done. If your configuration is different, you may have to install the .NET Framework 3.5 manually on Windows 10 operating systems. There are two options to do so:

1.4.2.1.1 Installation with the feature manager (active internet connection required)

1. Click on “Start” and type “Windows Features”.
2. Click on “Turn Windows features on or off”.



3. Select the .NET Framework 3.5 (includes .NET 2.0 and 3.0) check box and click on OK.



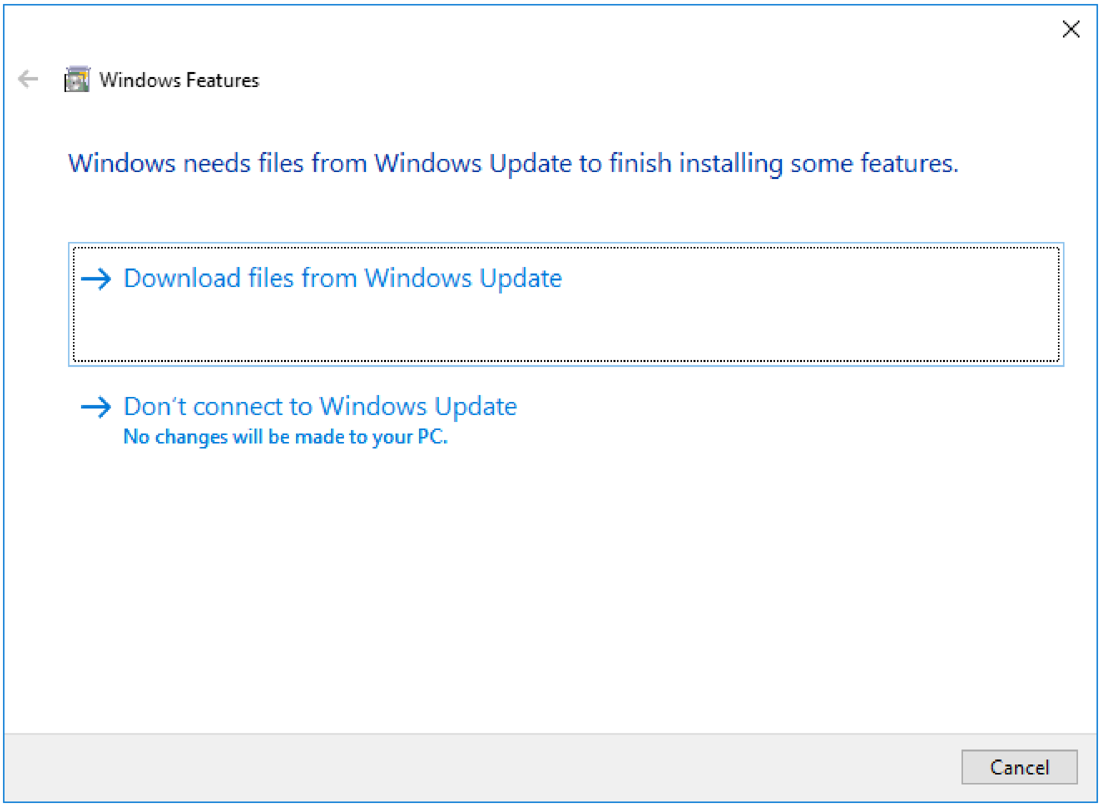
Windows Features

Turn Windows features on or off

To turn a feature on, select its check box. To turn a feature off, clear its check box. A filled box means that only part of the feature is turned on.

- ■ .NET Framework 3.5 (includes .NET 2.0 and 3.0)
- ■ .NET Framework 4.7 Advanced Services
- ☐ .NET Framework 3.5 (includes .NET 2.0 and 3.0)
- ☐ Containers
- ☐ Data Center Bridging
- ☐ Device Lockdown
- ☐ Guarded Host
- ☐ Hyper-V
- ☑ Internet Explorer 11
- ☐ Internet Information Services
- ☐ Internet Information Services Hostable Web Core
- ☐ Legacy Components

4. On the next screen select “Download files from Windows Update”. Please note: You must be connected to the internet.

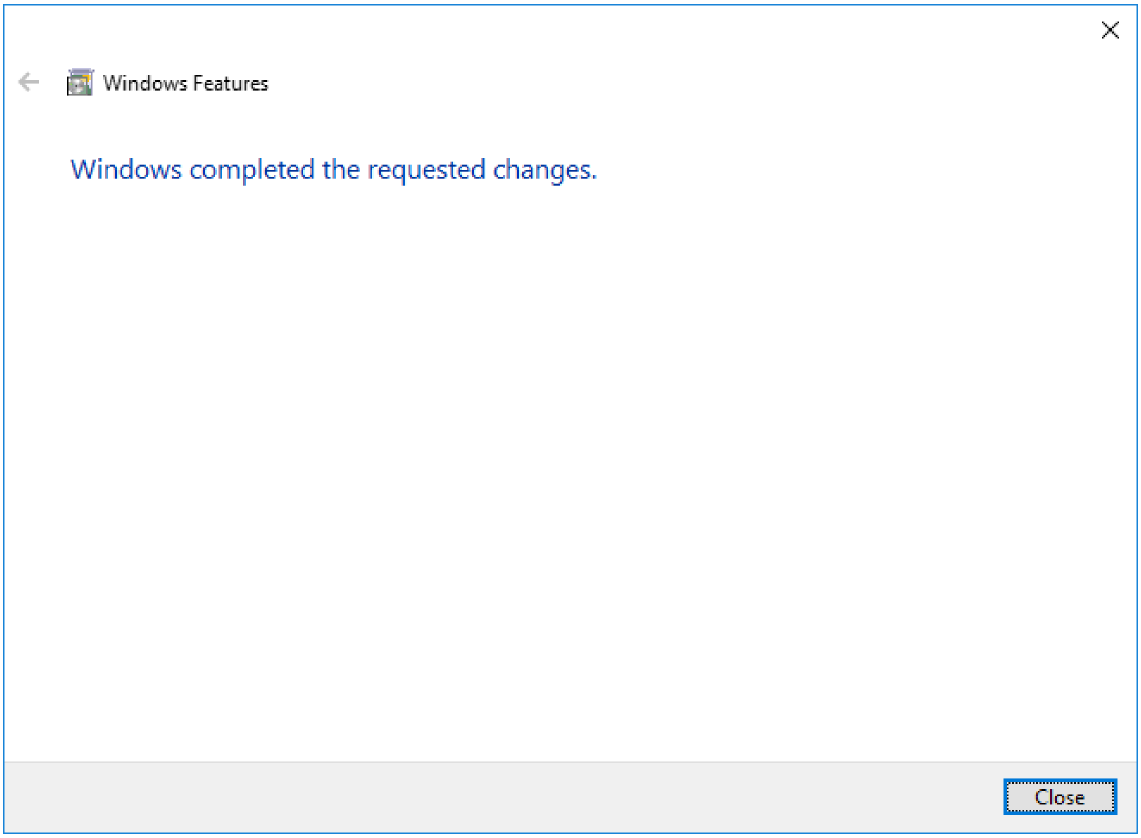


Windows needs files from Windows Update to finish installing some features.

→ Download files from Windows Update

→ Don’t connect to Windows Update
No changes will be made to your PC.

5. If you see the message "Windows completed the requested change", the installation process is completed successfully. You can continue installing Rotor-Gene AssayManager v1.0.



Windows completed the requested changes.

1.4.2.2 Installing the Core Application v1.0

For computer system requirements, refer to ▶ Requirements.

Note
Rotor-Gene AssayManager v1.0 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 v1.0 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 v1.0 software.

Rotor-Gene AssayManager v1.0 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 is already installed or if this will be installed on the local system, or if Rotor-Gene AssayManager v1.0 needs to 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 v1.0 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 v1.0 application is installed.

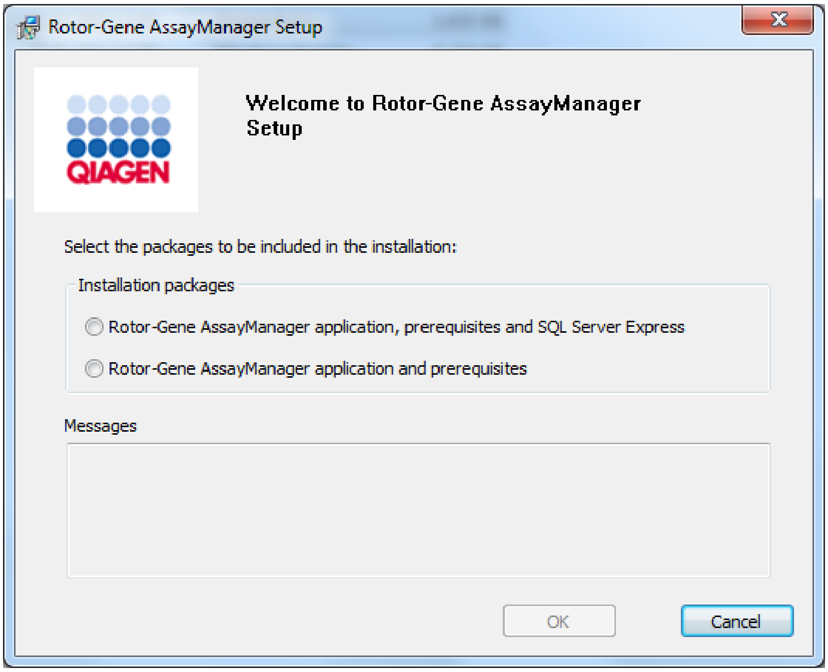
Note

During installation process, click "Back" to go a step back in the installation process. Click "Cancel" to stop and end the installation process.

Step-by-step procedure to install the Rotor-Gene AssayManager v1.0

1. Place the Removable Media in the computer.

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



Welcome to Rotor-Gene AssayManager Setup

Select the packages to be included in the installation:

Installation packages

○ Rotor-Gene AssayManager application, prerequisites and SQL Server Express

○ Rotor-Gene AssayManager application and prerequisites

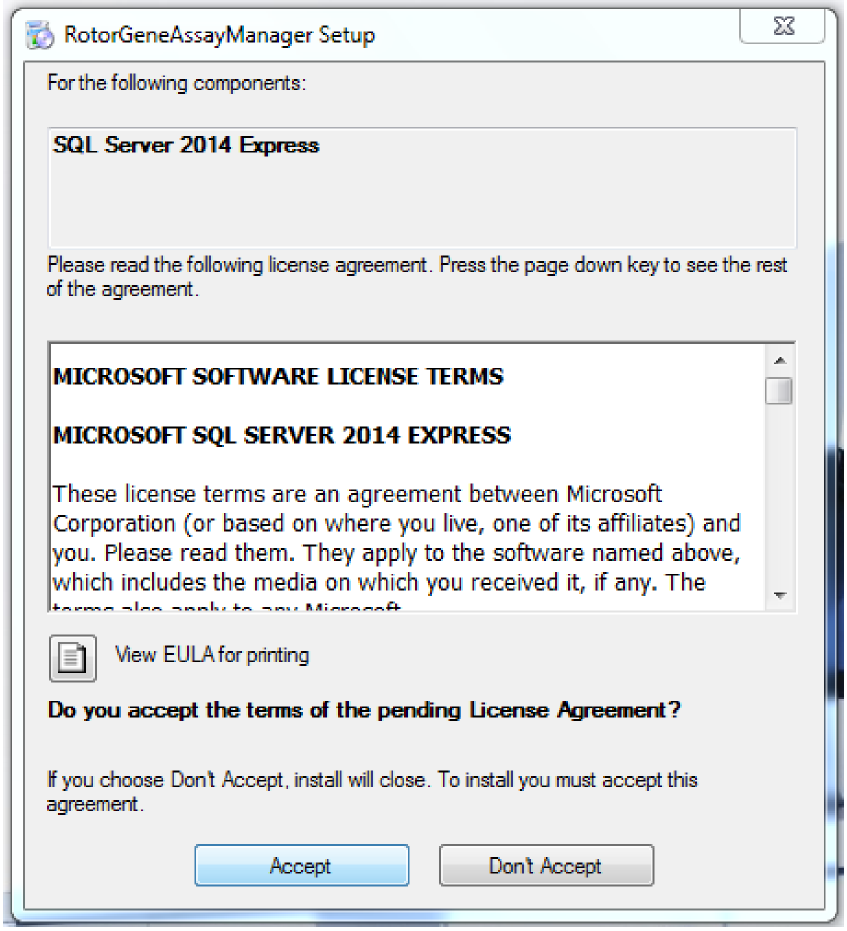
Messages

Note

If the setup wizard does not start automatically, double-click "My Computer" and select the Removable Media drive. Double-click "setup.exe" to start Rotor-Gene AssayManager v1.0 installation.

2. The further installation process depends on whether SQL Server 2014 instance with mixed mode authentication and tcp/ip network protocol is activated for installation.
   - If the installation wizard could not detect an SQL Server installed on your system and you want to install the SQL Server locally on your system, select "Rotor-Gene AssayManager application, prerequisites, and SQL Server Express" and proceed with step 4.
   - If the installation wizard detects an existing SQL Server on your system, a corresponding message will be shown in the messages box below. The upper option "Rotor-Gene AssayManager application, prerequisites, and SQL Server Express" is disabled.
   - If you want to install Rotor-Gene AssayManager v1.0 with a remote connection to an existing SQL Server on an external system, select the option "Rotor-Gene AssayManager application and prerequisites".
3. Click "OK" to proceed.

4. If applicable, the SQL Server will be installed. Click "Accept" to start the installation of MS SQL Server 2014 Express.



For the following components:

SQL Server 2014 Express

Please read the following license agreement. Press the page down key to see the rest of the agreement.

MICROSOFT SOFTWARE LICENSE TERMS

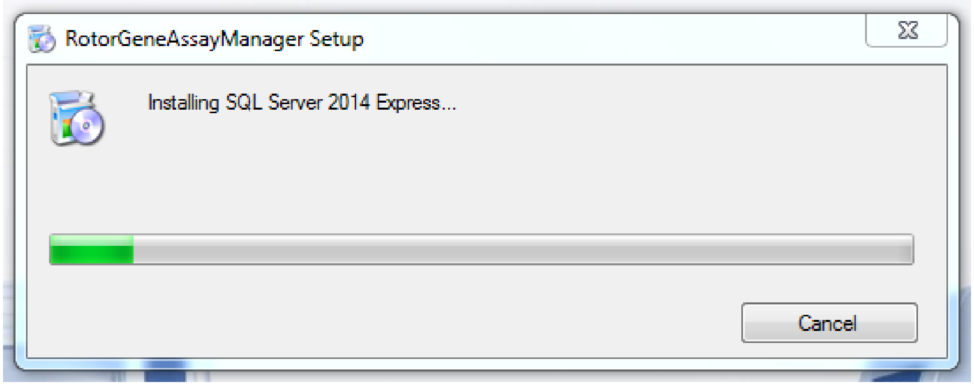
MICROSOFT SQL SERVER 2014 EXPRESS

These license terms are an agreement between Microsoft Corporation (or based on where you live, one of its affiliates) and you. Please read them. They apply to the software named above, which includes the media on which you received it, if any. The

Do you accept the terms of the pending License Agreement?

If you choose Don't Accept, install will close. To install you must accept this agreement.

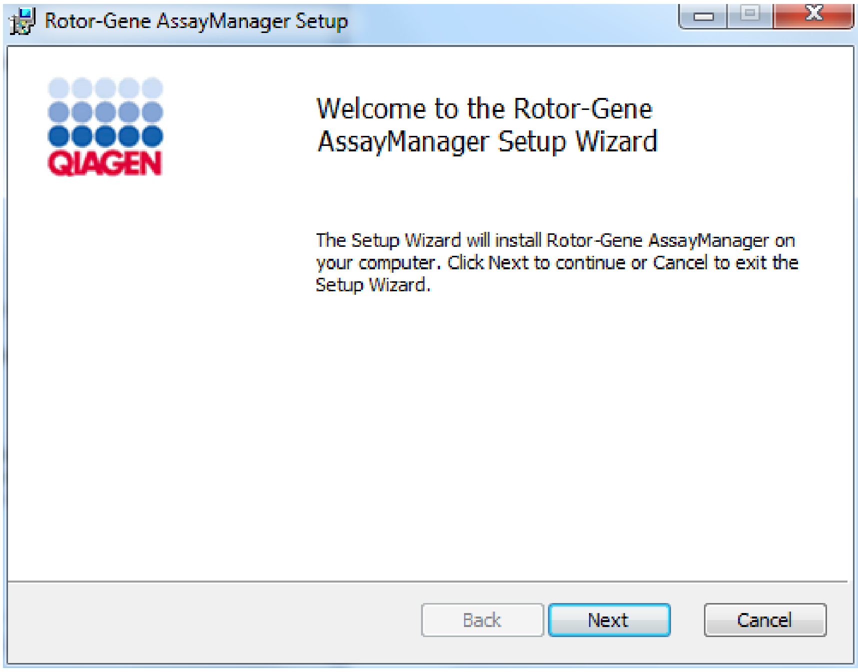
The installation progress windows is displayed:



RotorGeneAssayManager Setup

Installing SQL Server 2014 Express...

5. The Rotor-Gene AssayManager v1.0 Welcome screen will automatically be opened.



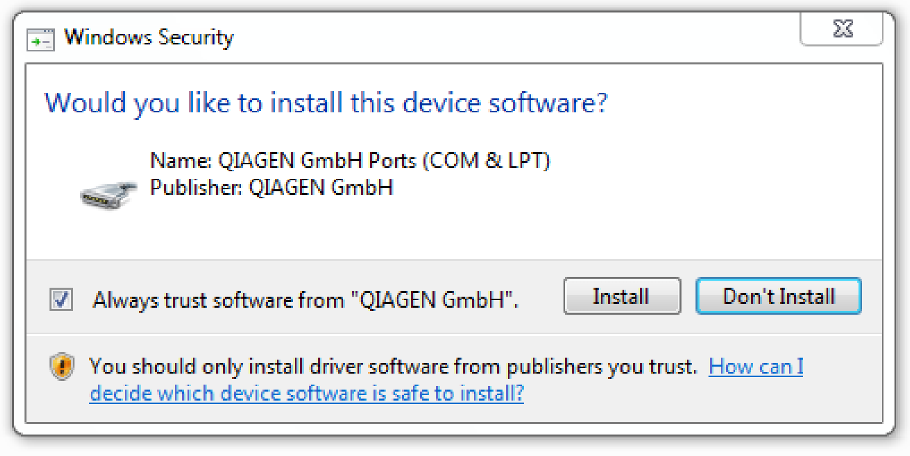
Rotor-Gene AssayManager Setup

Welcome to the Rotor-Gene AssayManager Setup Wizard

The Setup Wizard will install Rotor-Gene AssayManager on your computer. Click Next to continue or Cancel to exit the Setup Wizard.

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

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



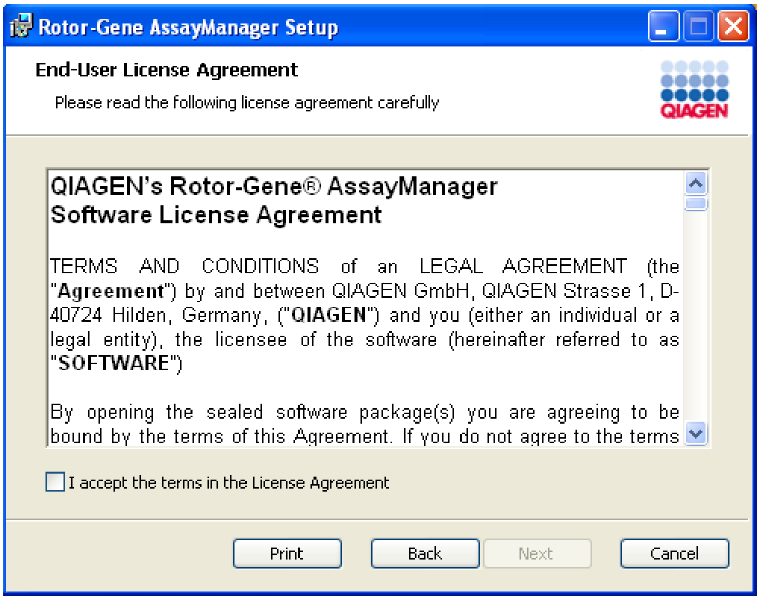
Would you like to install this device software?

Name: QIAGEN GmbH Ports (COM & LPT)
Publisher: QIAGEN GmbH

☑ Always trust software from "QIAGEN GmbH".

You should only install driver software from publishers you trust. How can I decide which device software is safe to install?

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



End-User License Agreement

Please read the following license agreement carefully

QIAGEN's Rotor-Gene® AssayManager Software License Agreement

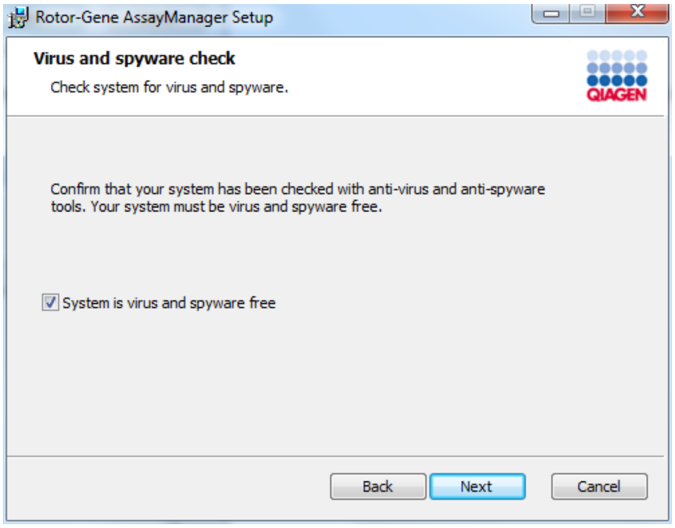
TERMS AND CONDITIONS of an LEGAL AGREEMENT (the "**Agreement**") by and between QIAGEN GmbH, QIAGEN Strasse 1, D-40724 Hilden, Germany, ("**QIAGEN**") and you (either an individual or a legal entity), the licensee of the software (hereinafter referred to as "**SOFTWARE**")

By opening the sealed software package(s) you are agreeing to be bound by the terms of this Agreement. If you do not agree to the terms

☐ I accept the terms in the License Agreement

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

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



Virus and spyware check

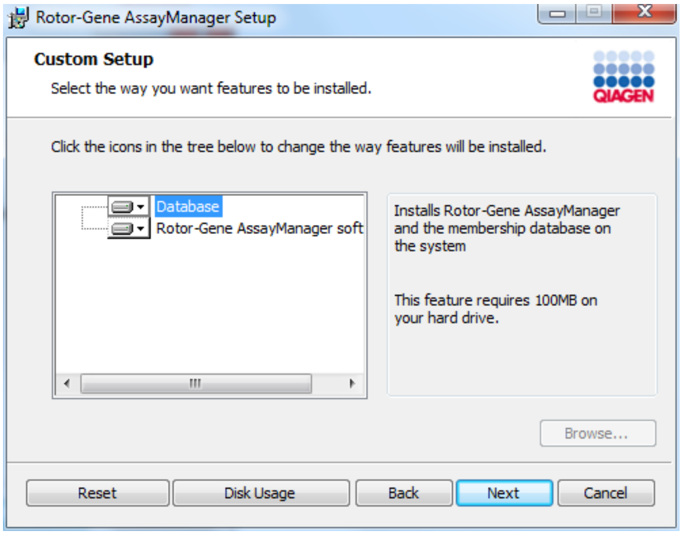
Check system for virus and spyware.

Confirm that your system has been checked with anti-virus and anti-spyware tools. Your system must be virus and spyware free.

☑ System is virus and spyware free

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.



Custom Setup

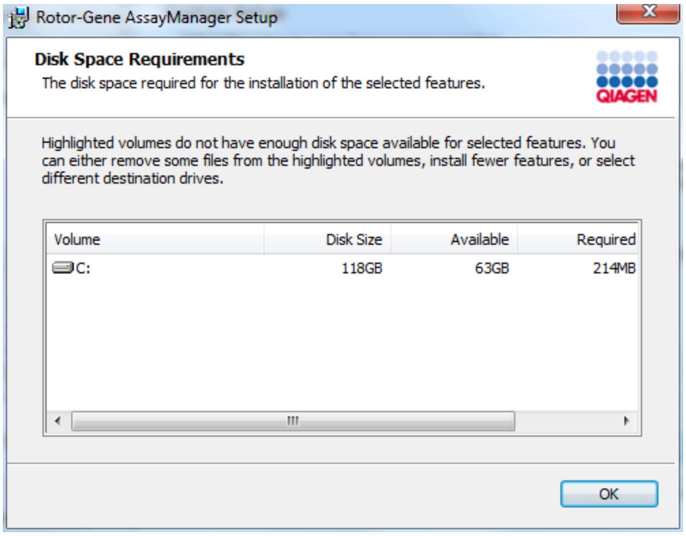
Select the way you want features to be installed.

Click the icons in the tree below to change the way features will be installed.

Installs Rotor-Gene AssayManager and the membership database on the system

This feature requires 100MB on your hard drive.

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



Disk Space Requirements

The disk space required for the installation of the selected features.

Highlighted volumes do not have enough disk space available for selected features. You can either remove some files from the highlighted volumes, install fewer features, or select different destination drives.

Volume	Disk Size	Available	Required
C:	118GB	63GB	214MB

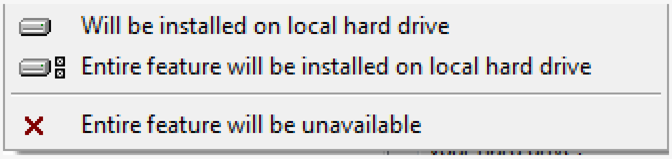
Click "OK" to close the window.

12.Select the features to be installed.

- **Features "Database" and "Rotor-Gene AssayManager software" both selected**
  For a stand-alone desktop scenario with application and database on one computer, both features must stay selected.
- **Feature "Rotor-Gene AssayManager software" only selected**
  For the installation of the application accessing a central database server, the “Database” feature must be deselected and the “Rotor-Gene Assay Manager software” feature must stay selected.
- **Feature "Database" only selected**
  For installation of a central database server only, the “Rotor-Gene Assay Manager software” feature must be deselected and the feature “Database” must stay selected.

Note

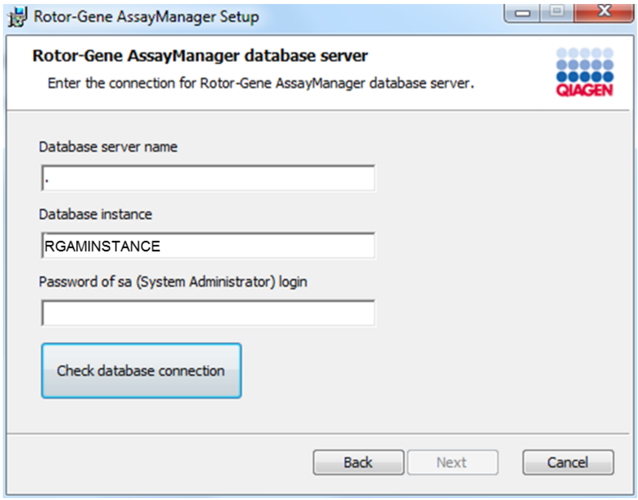
For selection or deselection of features, use the drop-down menu.



The first 2 options displayed here are identical. Select the corresponding feature.
The third option deselects the corresponding feature.

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

14. Optional: This step is necessary only if no SQL Server “RGAMINSTANCE” was detected or if the “Database” feature has been deselected in step 12. Otherwise, this screen will be skipped.



Rotor-Gene AssayManager Setup

Rotor-Gene AssayManager database server

Enter the connection for Rotor-Gene AssayManager database server.

Database server name: .

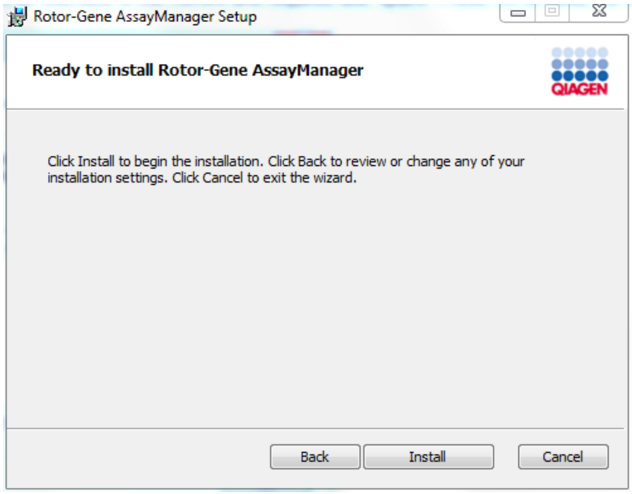
Database instance: RGAMINSTANCE

Password of sa (System Administrator) login:

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.

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

16. Click "Install" to start the installation.

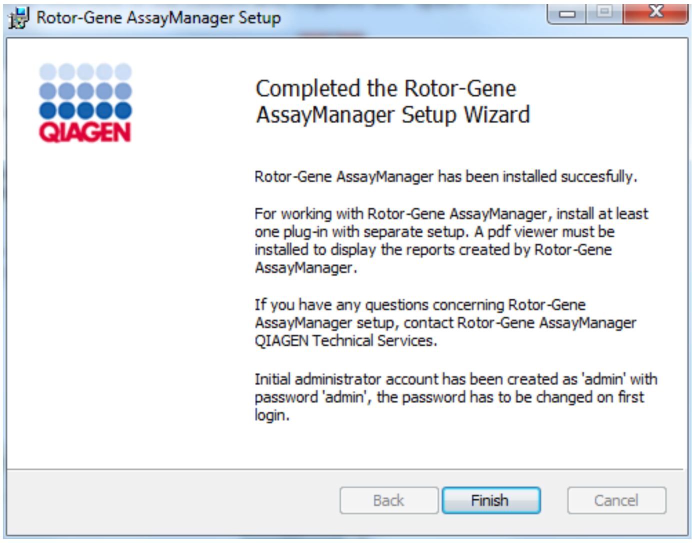


Rotor-Gene AssayManager Setup

Ready to install Rotor-Gene AssayManager

Click Install to begin the installation. Click Back to review or change any of your installation settings. Click Cancel to exit the wizard.

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



Completed the Rotor-Gene AssayManager Setup Wizard

Rotor-Gene AssayManager has been installed succesfully.

For working with Rotor-Gene AssayManager, install at least one plug-in with separate setup. A pdf viewer must be installed to display the reports created by Rotor-Gene AssayManager.

If you have any questions concerning Rotor-Gene AssayManager setup, contact Rotor-Gene AssayManager QIAGEN Technical Services.

Initial administrator account has been created as 'admin' with password 'admin', the password has to be changed on first login.

18.After the installation, Rotor-Gene AssayManager v1.0 can be started either from the Windows start menu under **QIAGEN/Rotor-Gene AssayManager** or using the desktop icon.

Note
Future updates will be provided on the QIAGEN webpage and/or distributed by QIAGEN on Removable Media to the customer.

1.4.2.3 Installing Plug-ins

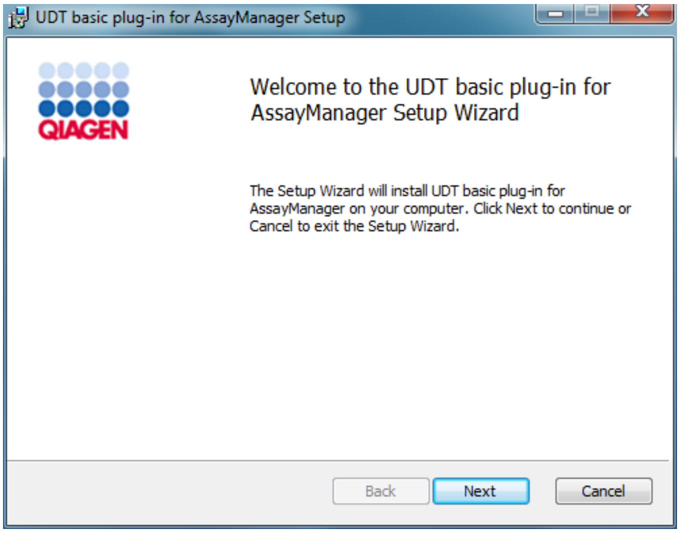
For the use of Rotor-Gene AssayManager v1.0 at least one plug-in must be installed.

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

Note
The installation of the UDT basic plug-in is taken as an example for the installation of any plug-in.

Step-by-step procedure to install a Rotor-Gene AssayManager v1.0 plug-in

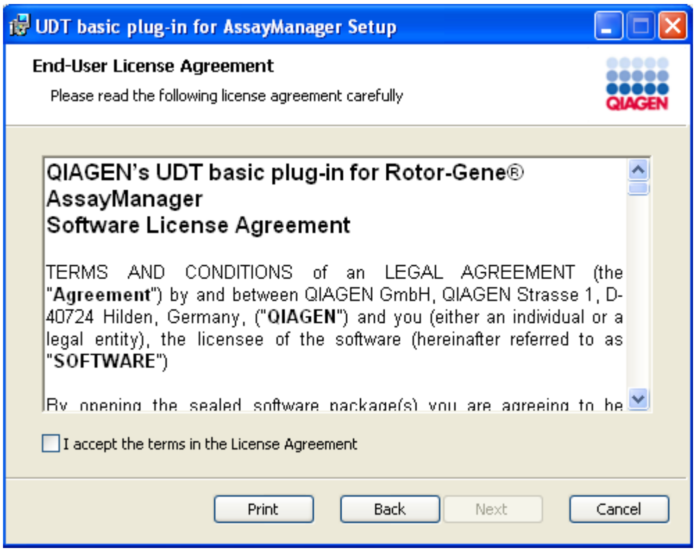
1. Place the plug-in installation Removable Media (provided with the software) into the computer or download the plug-in from the QIAGEN website, if available.
2. Double-click **My Computer** and select the Removable Media drive. Double-click **UDTBasic.Installation.msi** to start the UDT basic plug-in setup wizard. Click "Next" to proceed.



Welcome to the UDT basic plug-in for AssayManager Setup Wizard

The Setup Wizard will install UDT basic plug-in for AssayManager on your computer. Click Next to continue or Cancel to exit the Setup Wizard.

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



End-User License Agreement

Please read the following license agreement carefully

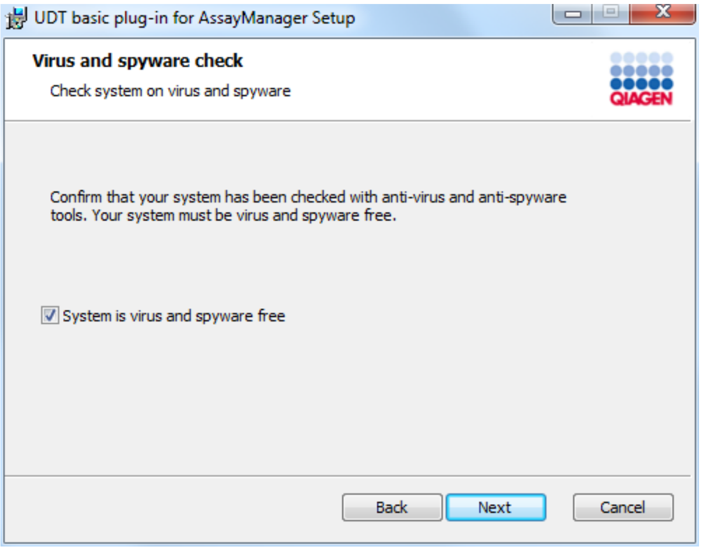
QIAGEN's UDT basic plug-in for Rotor-Gene® AssayManager
Software License Agreement

TERMS AND CONDITIONS of an LEGAL AGREEMENT (the "**Agreement**") by and between QIAGEN GmbH, QIAGEN Strasse 1, D-40724 Hilden, Germany, ("**QIAGEN**") and you (either an individual or a legal entity), the licensee of the software (hereinafter referred to as "**SOFTWARE**")

By opening the sealed software package(s) you are agreeing to be

☐ I accept the terms in the License Agreement

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



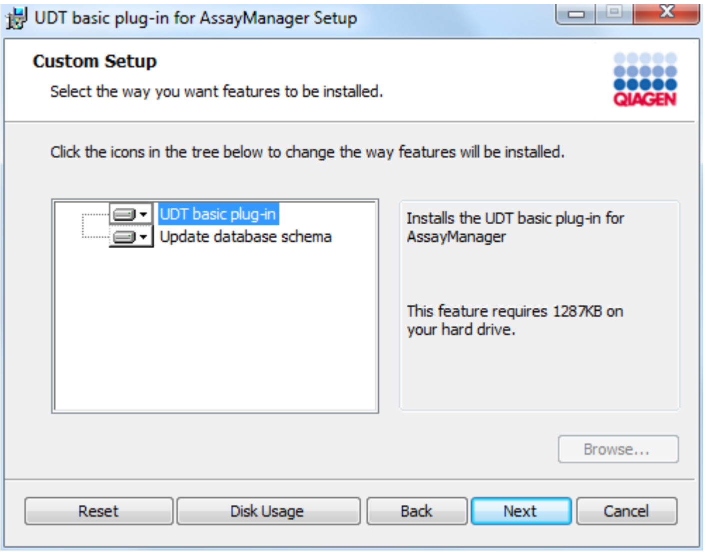
Virus and spyware check

Check system on virus and spyware

Confirm that your system has been checked with anti-virus and anti-spyware tools. Your system must be virus and spyware free.

☑ System is virus and spyware free

5. Select the features to be installed.


UDT basic plug-in for AssayManager Setup

Custom Setup

Select the way you want features to be installed.

Click the icons in the tree below to change the way features will be installed.

UDT basic plug-in
Update database schema

Installs the UDT basic plug-in for AssayManager

This feature requires 1287KB on your hard drive.

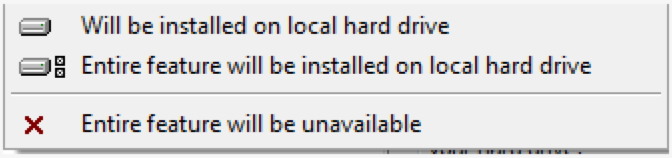
- Features "UDT basic plug-in" and "Update database schema" selected
  For a stand-alone desktop scenario with application and database on one computer, both features must stay selected.

- Feature "UDT basic plug-in" selected
  This feature updates the Rotor-Gene AssayManager v1.0 application with the UDT basic plug-in. It is needed always if the Rotor-Gene AssayManager v1.0 and its database are installed on one system. The feature can be deselected only if a database server without the Rotor-Gene AssayManager v1.0 application is to be updated.

- Feature "Update database schema" selected
  After the Rotor-Gene AssayManager v1.0 installation, the database schema contains unspecified Rotor-Gene AssayManager v1.0 tables only. This feature adds the UDT-specific tables.
  This feature is needed if the Rotor-Gene AssayManager v1.0 and its database are installed on one system. The feature can be deselected only if the database is installed on a separate server and was updated by a prior UDT basic plug-in installation.

Note

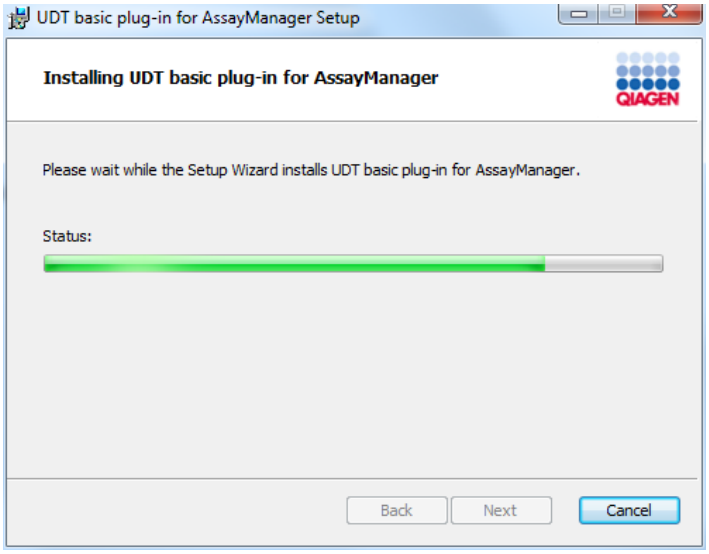
For selection or deselection of features, use the drop-down menu.



The first 2 options displayed here are identical. Select the corresponding feature.
The third option deselects the corresponding 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.



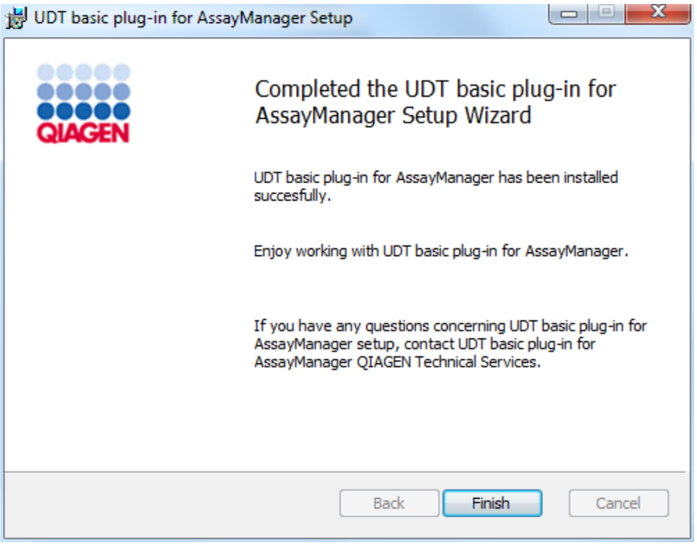
UDT basic plug-in for AssayManager Setup

Installing UDT basic plug-in for AssayManager

Please wait while the Setup Wizard installs UDT basic plug-in for AssayManager.

Status:

8. Wait until the installation process has finished.



UDT basic plug-in for AssayManager Setup

Completed the UDT basic plug-in for AssayManager Setup Wizard

UDT basic plug-in for AssayManager has been installed succesfully.

Enjoy working with UDT basic plug-in for AssayManager.

If you have any questions concerning UDT basic plug-in for AssayManager setup, contact UDT basic plug-in for AssayManager QIAGEN Technical Services.

9. After the installation is completed click "Finish" to close the window.
10. After next restart of Rotor-Gene AssayManager v1.0 the installed plug-in is available.

Related topics

▶ Installing the core application

1.4.2.4 Additional software on connected computers

Rotor-Gene AssayManager v1.0 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 v1.0 software. It is particularly important to pay attention to the points listed below.
System administrators are advised to consider any impact that a modification to the system may have on the resources before implementing it.

1.4.2.5 Configuration for Windows security

The laptop computers that are provided by QIAGEN for use with your Rotor-Gene® Q instrument have Microsoft Windows 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 v1.0 is designed to run without administrator rights. The administrator account shall only be used to install the Rotor-Gene AssayManager v1.0 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.

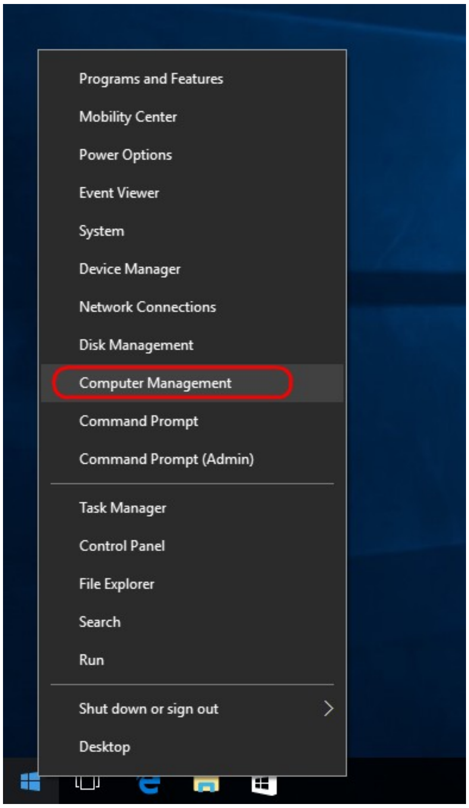
The default password of the administrator account is as follows: “Q1a#g3n!A6”. Please change the administrator password after first login. Please make sure that the password is secure and does not get lost. There is no password for the standard account.

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 v1.0 user management.

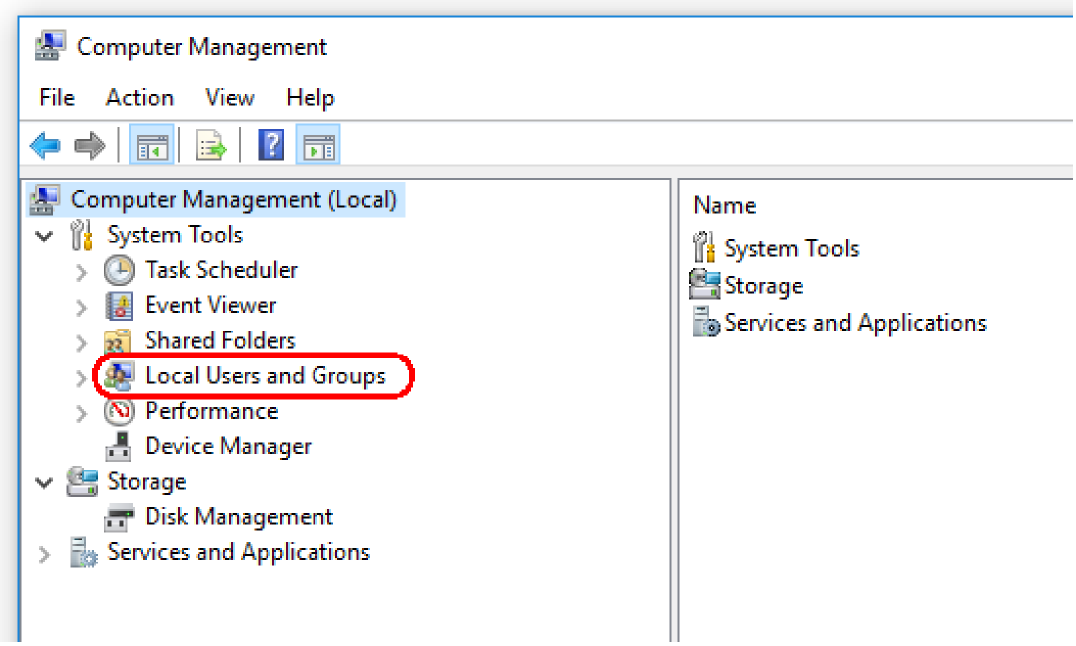
1.4.2.5.1 **Windows 10 security**

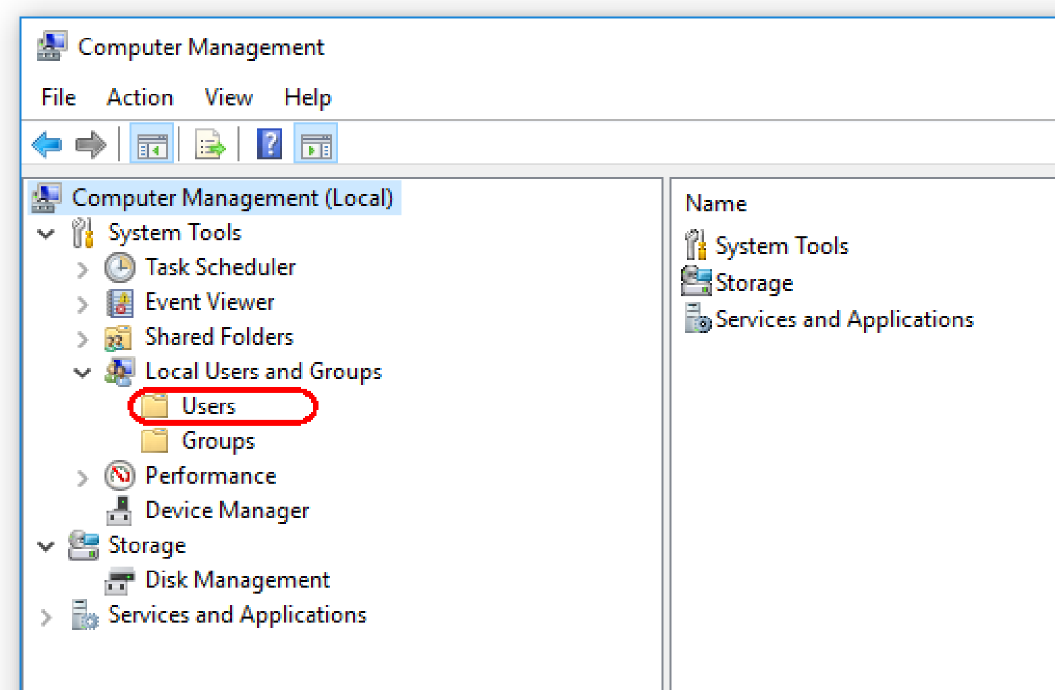
To create a standard user account in Windows 10, please follow these steps:

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

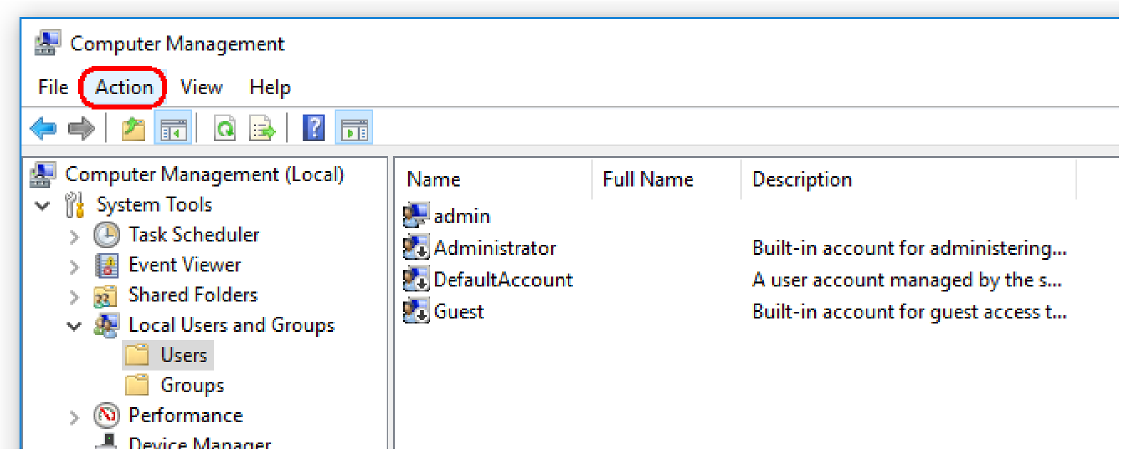


2. Expand Local Users and Groups.



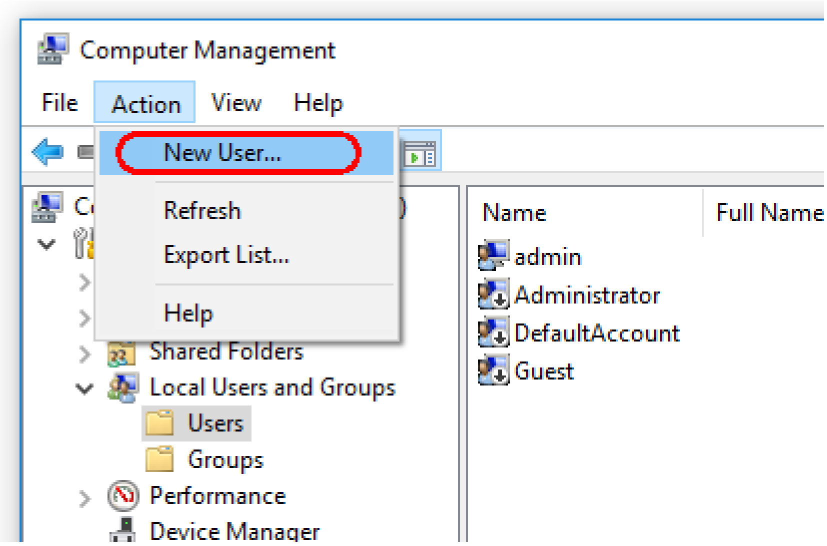


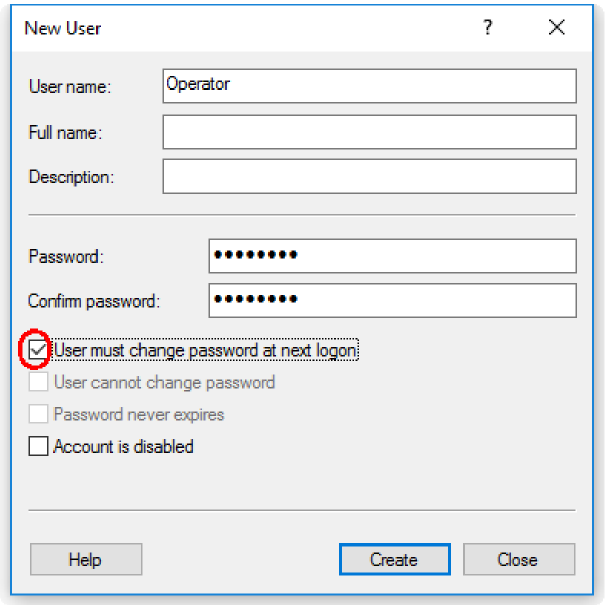
3. Select Users. With Users highlighted, click Action.



Name	Full Name	Description
admin		
Administrator		Built-in account for administering...
DefaultAccount		A user account managed by the s...
Guest		Built-in account for guest access t...

4. Select New User….





User name: Operator

Full name:

Description:

Password: ••••••••

Confirm password: ••••••••

☑ User must change password at next logon

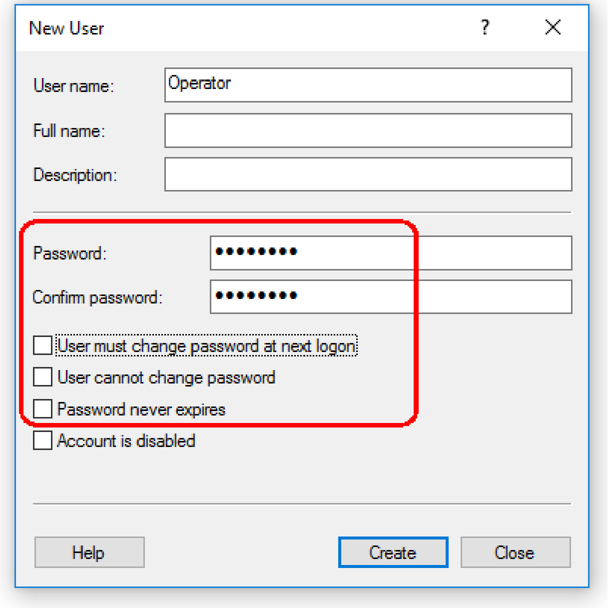
☐ User cannot change password

☐ Password never expires

☐ Account is disabled

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.



User name: Operator

Full name:

Description:

Password: ••••••••

Confirm password: ••••••••

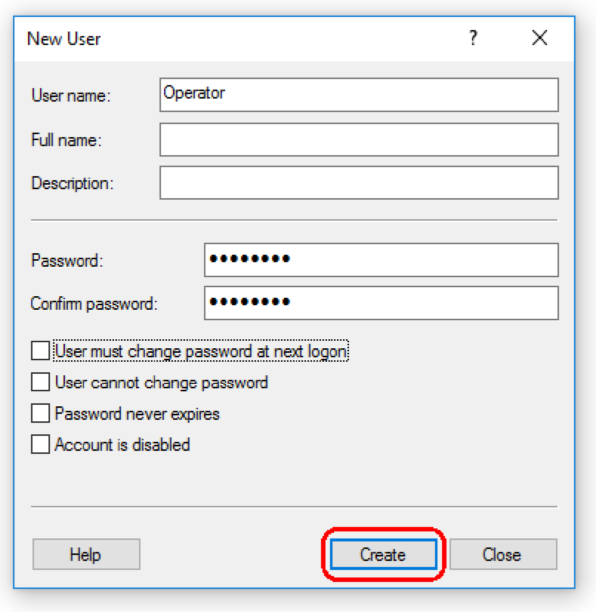
☐ User must change password at next logon

☐ User cannot change password

☐ Password never expires

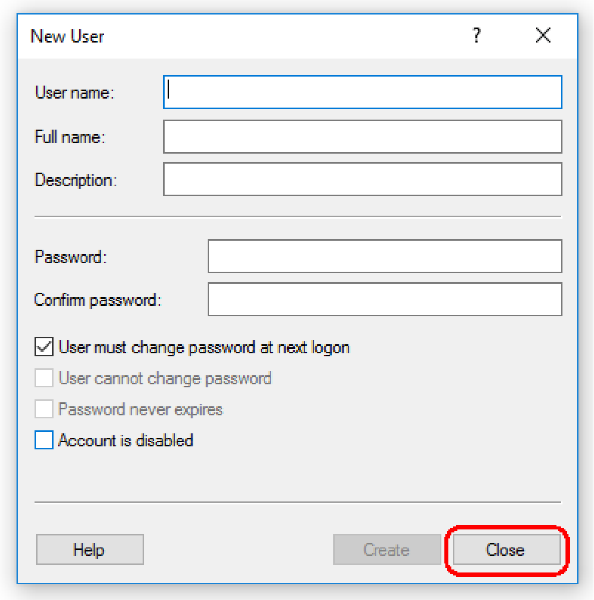
☐ Account is disabled

7. Click Create to finish.

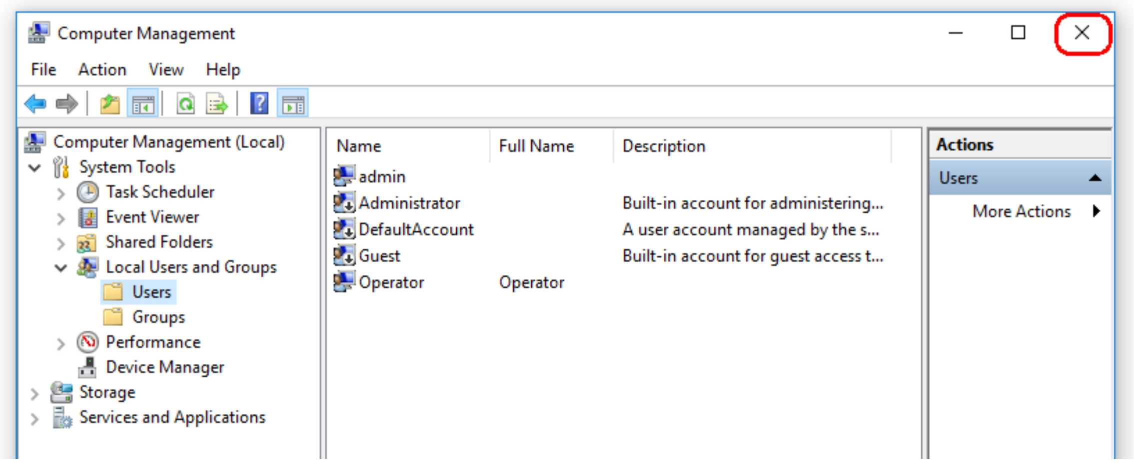


User name: Operator
Full name:
Description:
Password: ••••••••
Confirm password: ••••••••
☐ User must change password at next logon
☐ User cannot change password
☐ Password never expires
☐ Account is disabled

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



User name:
Full name:
Description:
Password:
Confirm password:
☑ User must change password at next logon
☐ User cannot change password
☐ Password never expires
☐ Account is disabled



Name	Full Name	Description
admin		
Administrator		Built-in account for administering...
DefaultAccount		A user account managed by the s...
Guest		Built-in account for guest access t...
Operator	Operator	

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.

1.4.2.6 **Anti-virus scanners**

QIAGEN is aware of the threat that computer viruses cause to any computer that exchanges data with other computers. Rotor-Gene AssayManager v1.0 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 in any case. 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 QIAGEN.com for the latest versions of anti-virus software that have been validated in combination with Rotor-Gene AssayManager v1.0.
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. Since Rotor-Gene AssayManager v1.0 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 v1.0 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\MSSQL12.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 v1.0 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.

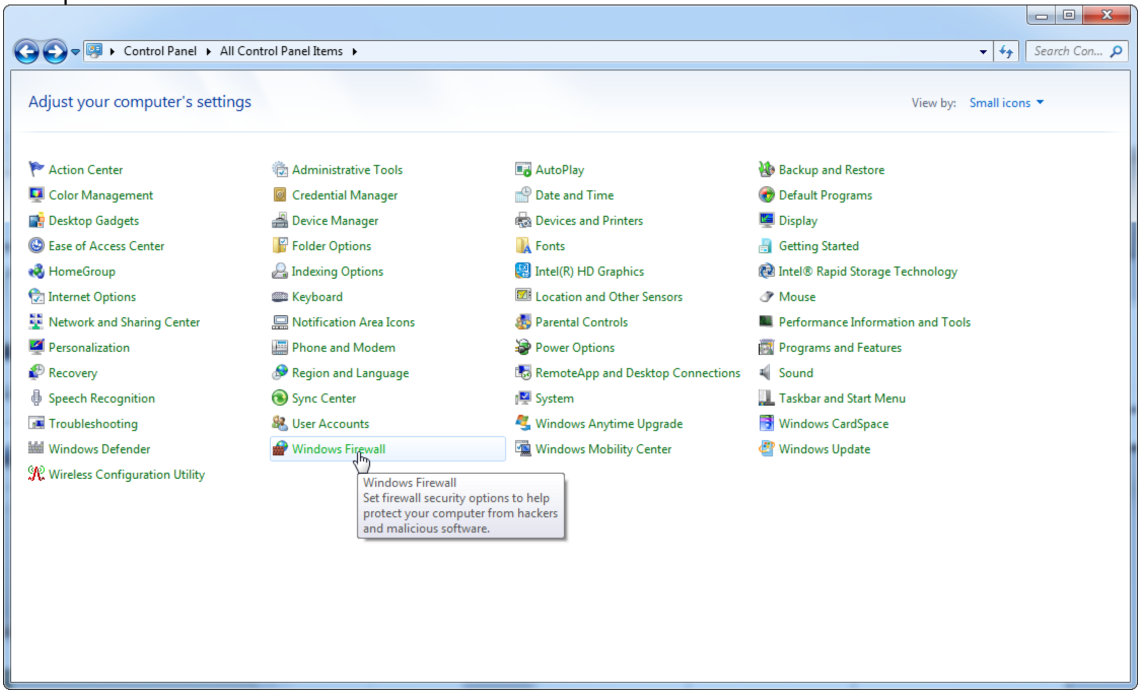
1.4.2.7 Firewall and networks

The Rotor-Gene AssayManager v1.0 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 v1.0 to the centralized database server. Outgoing connections are allowed as this may be required for retrieving updates or when the Rotor-Gene AssayManager v1.0 is configured to work with a centralized database server.

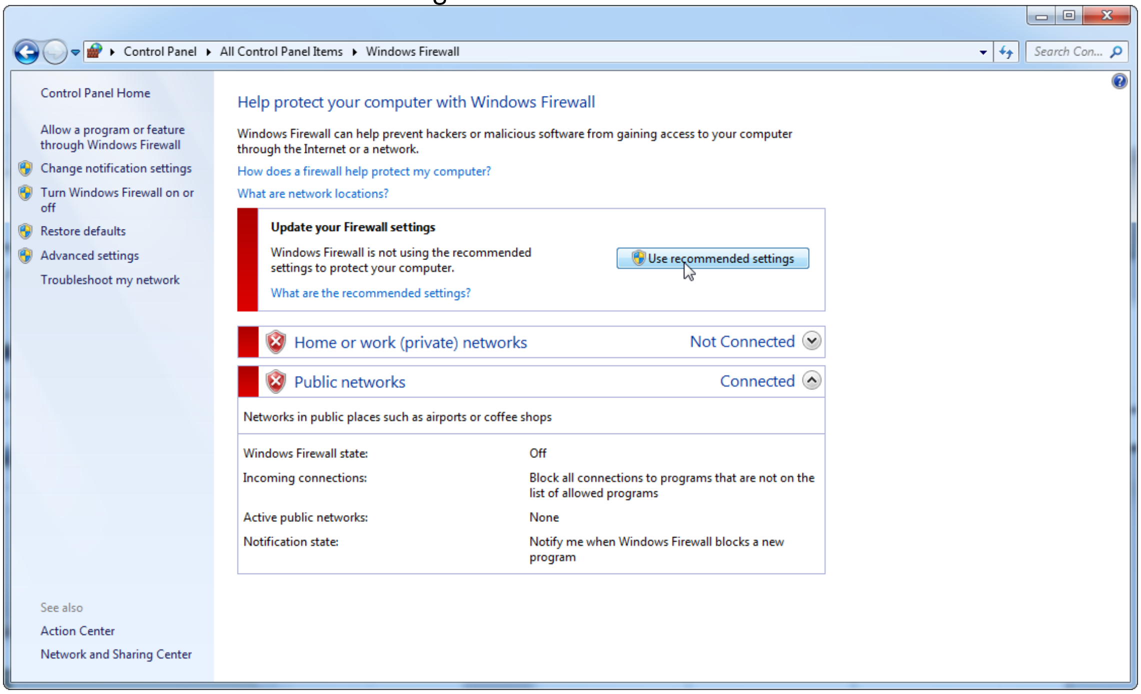
If your configuration is different, QIAGEN recommends to configurate the firewall in the same way as described above. To this end, a system administrator has to login and has to perform the following steps:

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



Windows Firewall
Set firewall security options to help protect your computer from hackers and malicious software.

2. Select “Use recommended settings”.



Help protect your computer with Windows Firewall

Windows Firewall can help prevent hackers or malicious software from gaining access to your computer through the Internet or a network.

How does a firewall help protect my computer?

What are network locations?

Update your Firewall settings

Windows Firewall is not using the recommended settings to protect your computer.

What are the recommended settings?

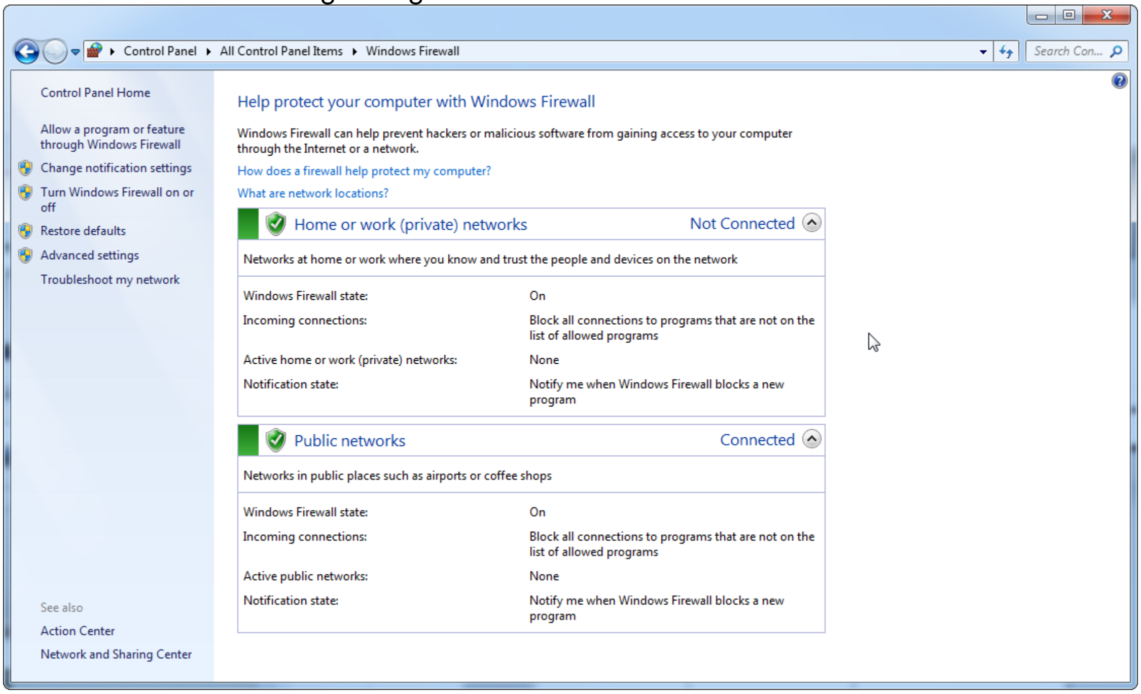
Home or work (private) networks — Not Connected

Public networks — Connected

Networks in public places such as airports or coffee shops

Windows Firewall state:	Off
Incoming connections:	Block all connections to programs that are not on the list of allowed programs
Active public networks:	None
Notification state:	Notify me when Windows Firewall blocks a new program

3. Check that the following settings are active:



Help protect your computer with Windows Firewall

Windows Firewall can help prevent hackers or malicious software from gaining access to your computer through the Internet or a network.

How does a firewall help protect my computer?

What are network locations?

Home or work (private) networks — Not Connected

Networks at home or work where you know and trust the people and devices on the network

Windows Firewall state:	On
Incoming connections:	Block all connections to programs that are not on the list of allowed programs
Active home or work (private) networks:	None
Notification state:	Notify me when Windows Firewall blocks a new program

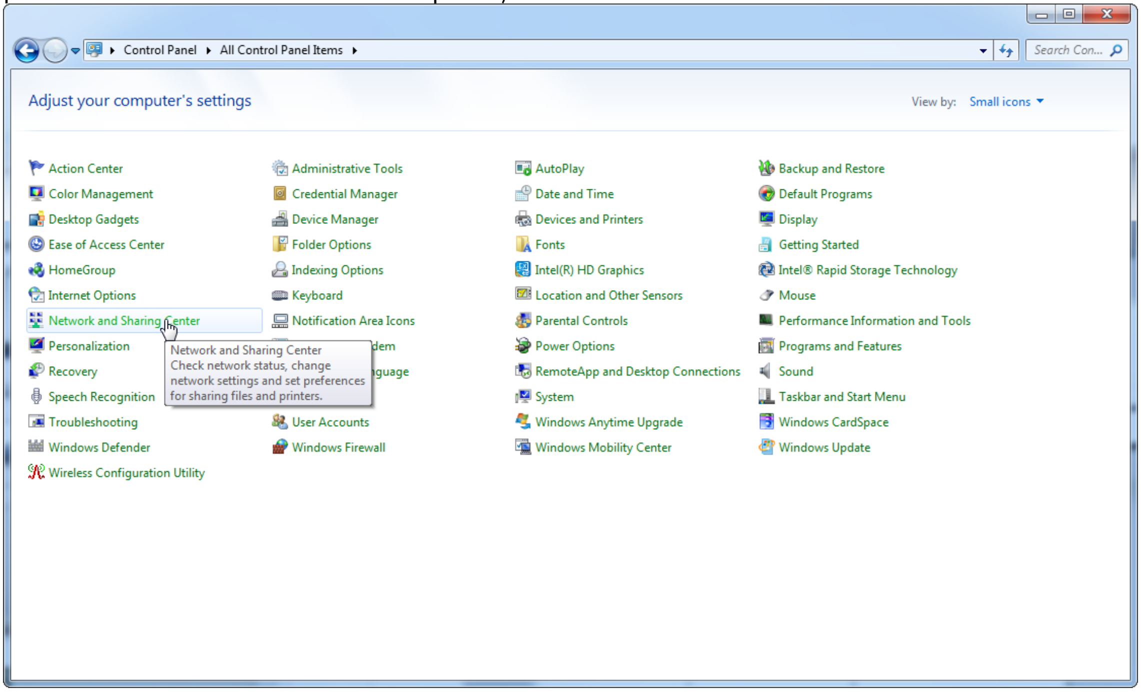
Public networks — Connected

Networks in public places such as airports or coffee shops

Windows Firewall state:	On
Incoming connections:	Block all connections to programs that are not on the list of allowed programs
Active public networks:	None
Notification state:	Notify me when Windows Firewall blocks a new program

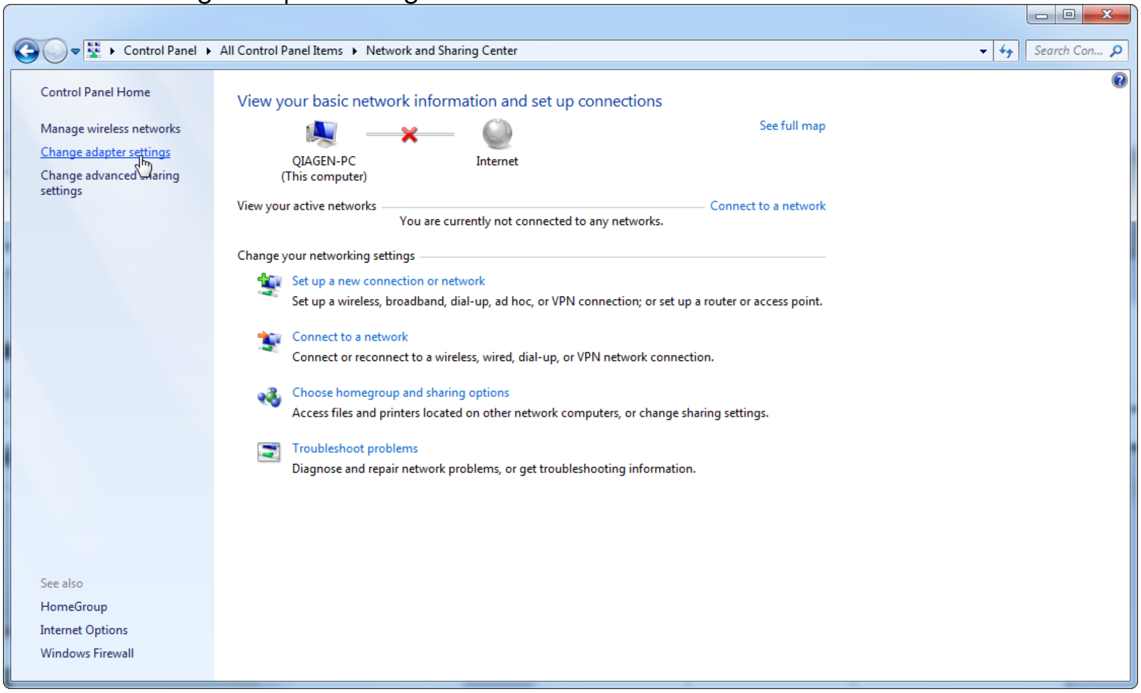
For security and reliability reasons cable-based network access instead of Wi-Fi shall be used. The laptop computers that are provided by QIAGEN have a disabled Wi-Fi adapter. If your configuration is different, a system administrator must disable the Wi-Fi adapter manually which can be done by the following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

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



Network and Sharing Center
Check network status, change network settings and set preferences for sharing files and printers.

2. Select “Change adapter settings”.



View your basic network information and set up connections

View your active networks

You are currently not connected to any networks.

Change your networking settings

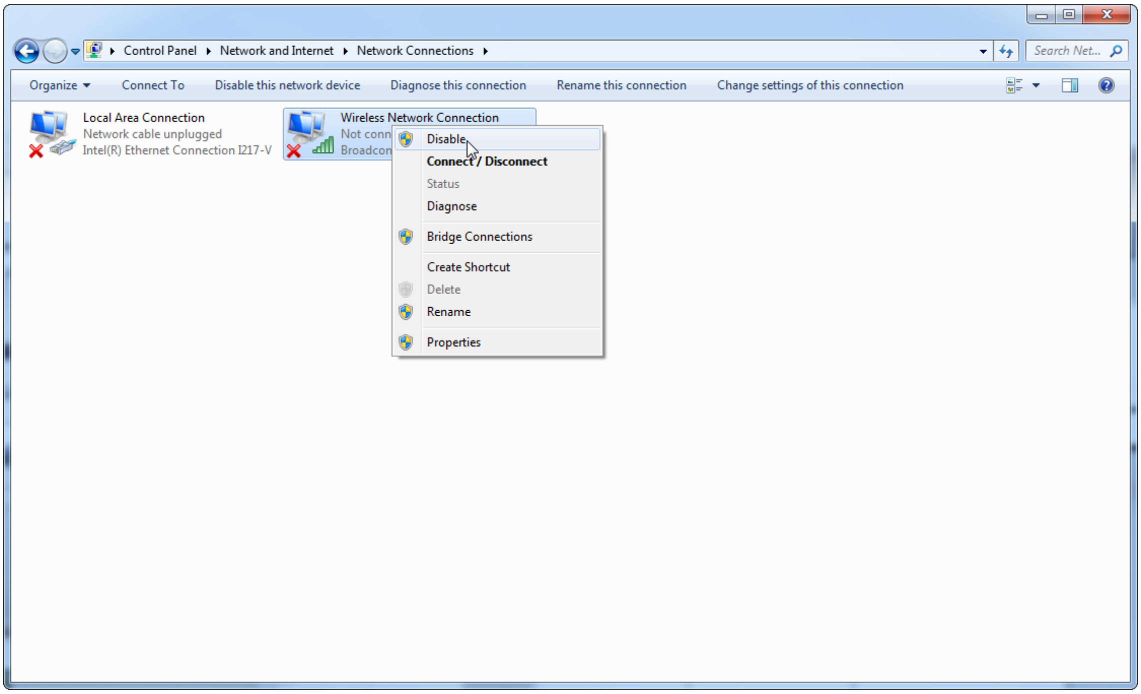
Set up a new connection or network
Set up a wireless, broadband, dial-up, ad hoc, or VPN connection; or set up a router or access point.

Connect to a network
Connect or reconnect to a wireless, wired, dial-up, or VPN network connection.

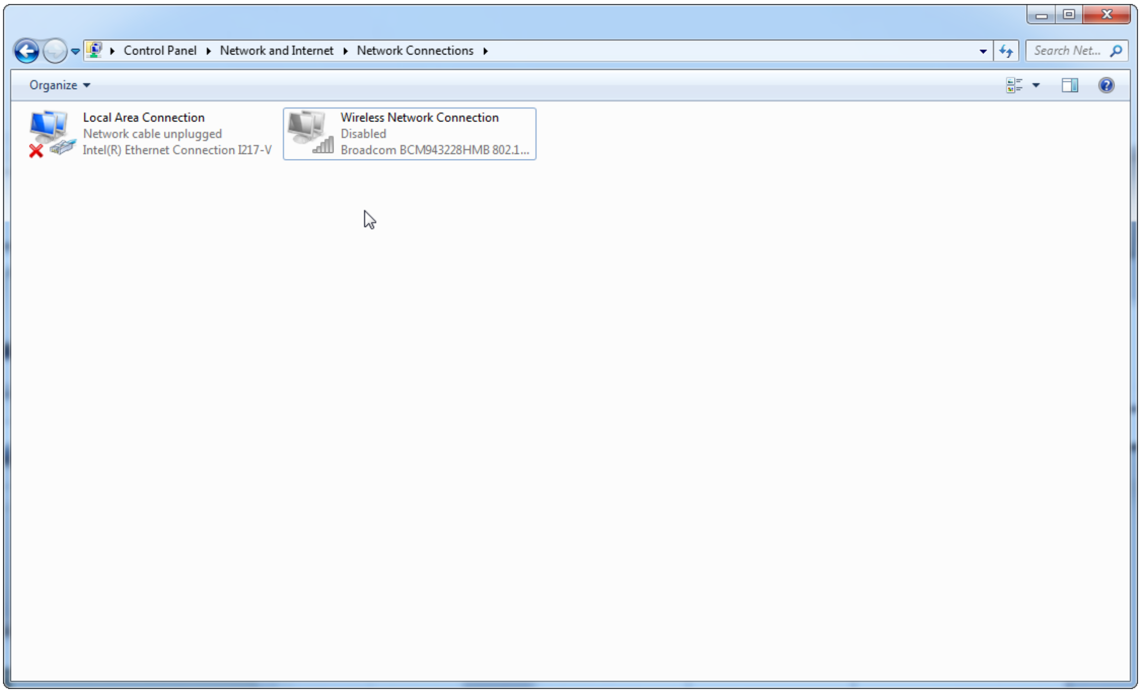
Choose homegroup and sharing options
Access files and printers located on other network computers, or change sharing settings.

Troubleshoot problems
Diagnose and repair network problems, or get troubleshooting information.

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.



Local Area Connection
Network cable unplugged
Intel(R) Ethernet Connection I217-V

Wireless Network Connection
Disabled
Broadcom BCM943228HMB 802.1...

1.4.2.8 **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 runs in the background
- 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 v1.0 performing a PCR run.

1.4.2.9 Operating system updates

1.4.2.9.1 Instructions for Windows 10

If you are using Windows 10, please visit the product page on QIAGEN.com for more information.

1.4.3 Uninstalling the Rotor-Gene AssayManager V1.0

Note
The uninstall process of the Rotor-Gene AssayManager v1.0 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 v1.0 and all installed plug-ins from your computer.

Note
If you want to uninstall Rotor-Gene AssayManager v1.0, close the application first. Otherwise Rotor-Gene AssayManager v1.0 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".

Are you sure you want to uninstall this product?

3. The windows installer program starts to uninstall the entire Rotor-Gene AssayManager v1.0.

1.4.4 First Login

After successful installation of Rotor-Gene AssayManager v1.0, the system administrator needs to log 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**
> All users without the "Administrator" role can ask the administrator to reset the password. However, if the administrator forgets the administrator password, they must 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 v1.0 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 First Configuration

Before Rotor-Gene AssayManager v1.0 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 v1.0 are described.

1.5.1 Concepts

Rotor-Gene AssayManager v1.0 uses multiple concepts to facilitate tasks and processes. The following topics describe these concepts in detail:

- Modes
- User Management
- Session Management
- Rotor-Gene AssayManager v1.0 and other QIAGEN products
- Clarification of terms experiment and assay

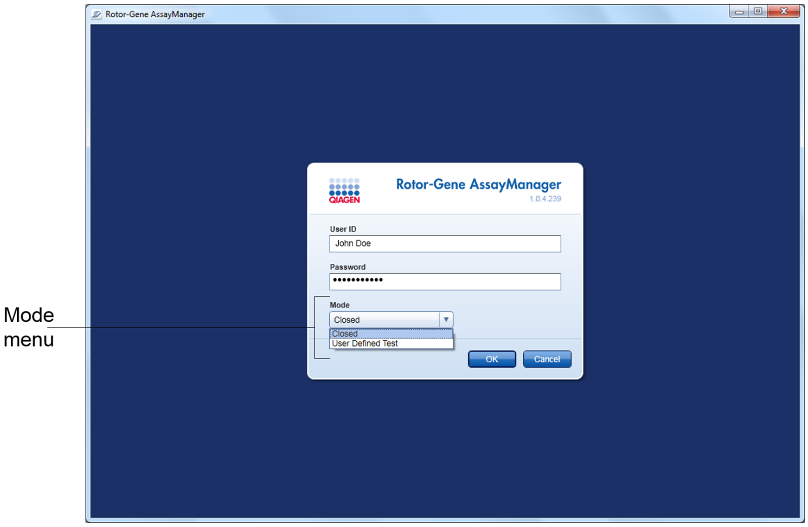
1.5.1.1 Modes

Rotor-Gene AssayManager v1.0 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 Assay Manager with the user role “UDT Mode 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.

The mode is selected from the Rotor-Gene AssayManager v1.0 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.



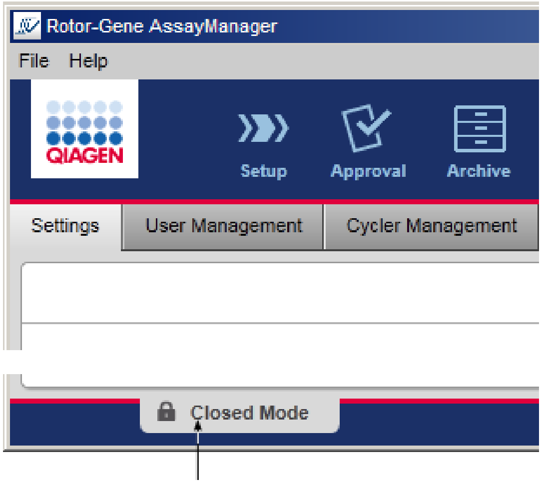
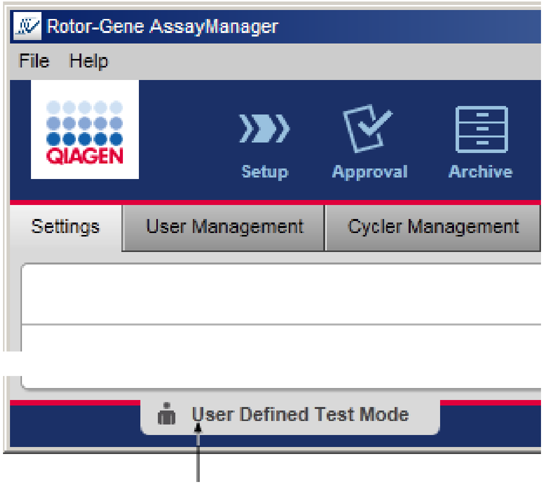
User ID: John Doe

Password: ●●●●●●●●●●●●

Mode: Closed

Closed
User Defined Test

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

Closed Mode	UDT Mode
	

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 v1.0 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 v1.0 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 only permissions to ▪ configure the system, ▪ manage users, ▪ create and edit report profiles, ▪ manage archives.
Assay developer	The assay developer has all necessary permissions to create an assay profile in UDT Mode.
Operator	The operator has all permissions necessary to ▪ create a work list, ▪ apply the work list,

	▪ view the analysis results. The operator cannot approve or release assay results.
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.	–	–	–	+	+

Environment	Task	Description	Admin	AD	Op	Ap	SU*
	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.	+	–	–	+	+
	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.	+	–	–	–	+

Environment	Task	Description	Admin	AD	Op	Ap	SU*
	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 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.

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 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.

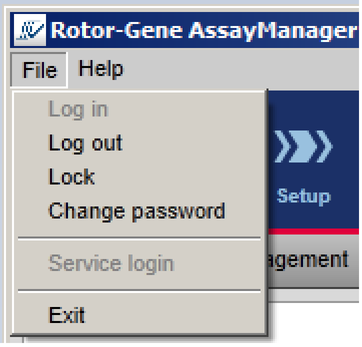
Related topics

▶ Setting password policies and auto-lock timer

1.5.1.3 Session Management

To start working with Rotor-Gene AssayManager v1.0, 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



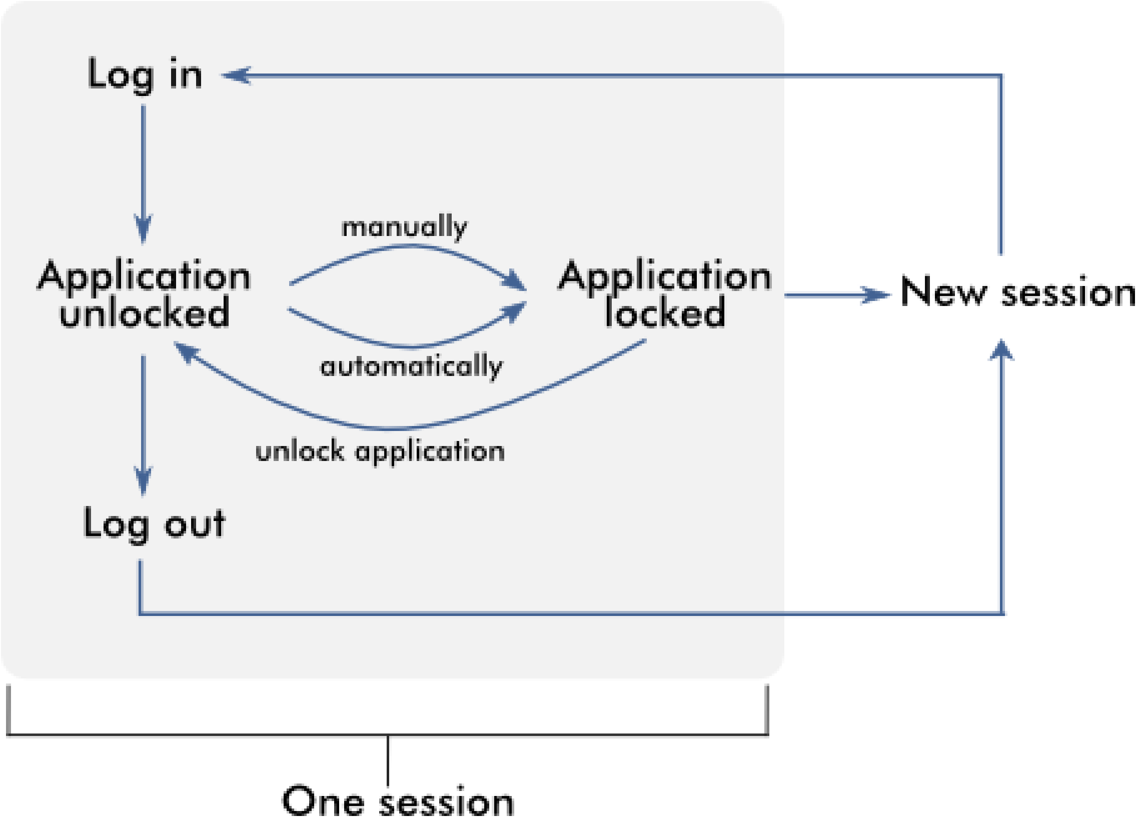
Log out from status bar

To prevent misuse, a user can lock the application. Rotor-Gene AssayManager v1.0 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.

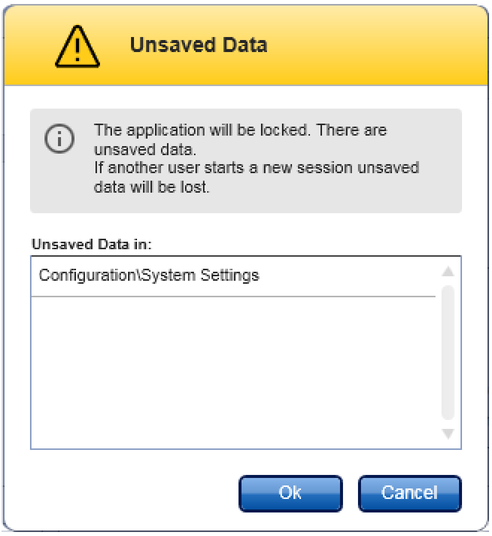
The automatic locking feature does not interrupt or impact the operation of the cyclers. Started runs are not interrupted or impacted if:

- 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:



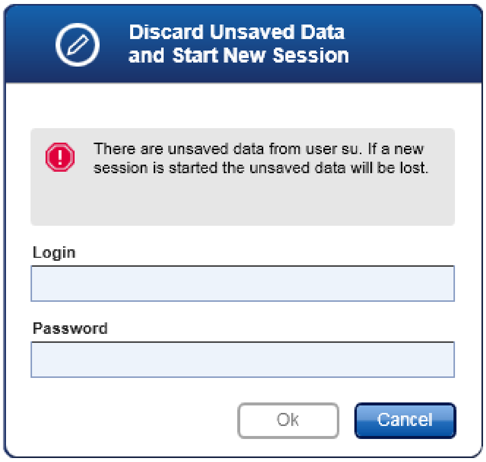
Behavior if unsaved data exist
If a user locks the application and unsaved data exist, a dialog is opened containing a list of all environments with unsaved data:



The application will be locked. There are unsaved data.
If another user starts a new session unsaved data will be lost.

Unsaved Data in:
Configuration\System Settings

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.



There are unsaved data from user su. If a new session is started the unsaved data will be lost.

Related topics

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

1.5.1.4 Rotor-Gene AssayManager v1.0 and other QIAGEN Products

Rotor-Gene AssayManager v1.0 has different interfaces and data exchange features with other QIAGEN products and external Laboratory Information Management Systems (LIMS).

With Rotor-Gene AssayManager v1.0, up to 4 different Rotor-Gene Q instruments can be controlled simultaneously. Each connected cycler can send raw acquisition data back to Rotor-Gene AssayManager v1.0.

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 v1.0 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.

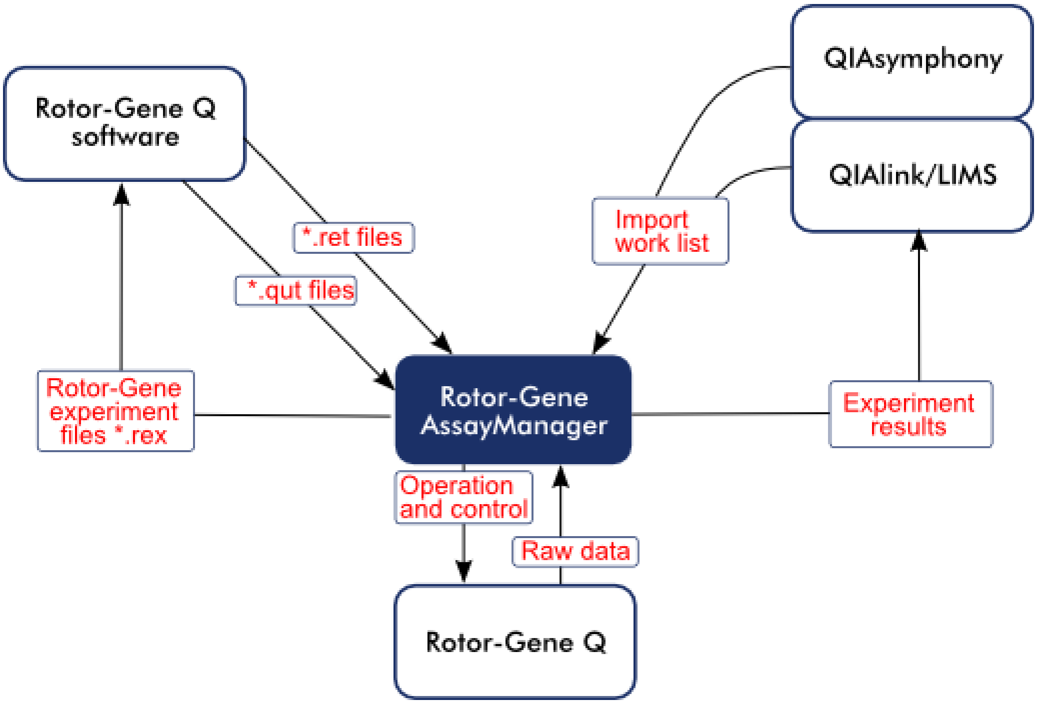
Scenario 1:
Where the Rotor-Gene Q software is started prior to Rotor-Gene AssayManager v1.0 and connected to a cycler first, Rotor-Gene AssayManager v1.0 is not able to set up a connection to the cycler. Shut down the Rotor-Gene Q software. Restart Rotor-Gene AssayManager v1.0 to control the cycler with Rotor-Gene AssayManager v1.0.

Scenario 2:
Where Rotor-Gene AssayManager v1.0 is started prior to the Rotor-Gene Q software and connected to a cycler first, the Rotor-Gene Q software is not able to set up a connection to the cycler. Shut down Rotor-Gene AssayManager v1.0. Restart the Rotor-Gene Q software to control the cycler with the Rotor-Gene Q software.

Rotor-Gene template files (*.ret files) can be imported in Rotor-Gene AssayManager v1.0 to create assay profiles in UDT Mode. Result files from the QIAsymphony AS can be used to generate work lists in Rotor-Gene AssayManager v1.0. All relevant sample and assay related information are automatically set, and manual input during work list setup is minimized.

Rotor-Gene AssayManager v1.0 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.)

The following graphic illustrates the possible interactions between Rotor-Gene AssayManager v1.0 and other instruments and external software:



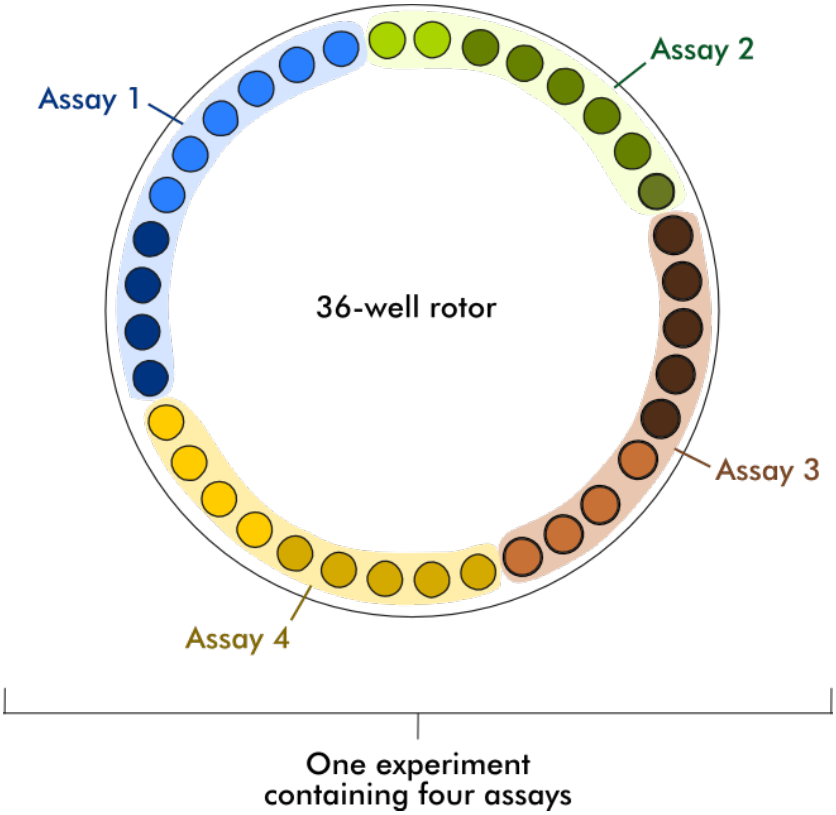
Related topics

- Importing a work list
- 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 v1.0. Rotor-Gene AssayManager v1.0 allows multiple assays to run in one experiment by creating a work list with multiple compatible assay profiles. All assays within one run define an experiment.

Example
The following graphic gives an example. A work list 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 work list.



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 and released. An experiment is defined as fully released only if all test samples (and external controls in case of UDT plug-in) 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 work list
- 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 v1.0.

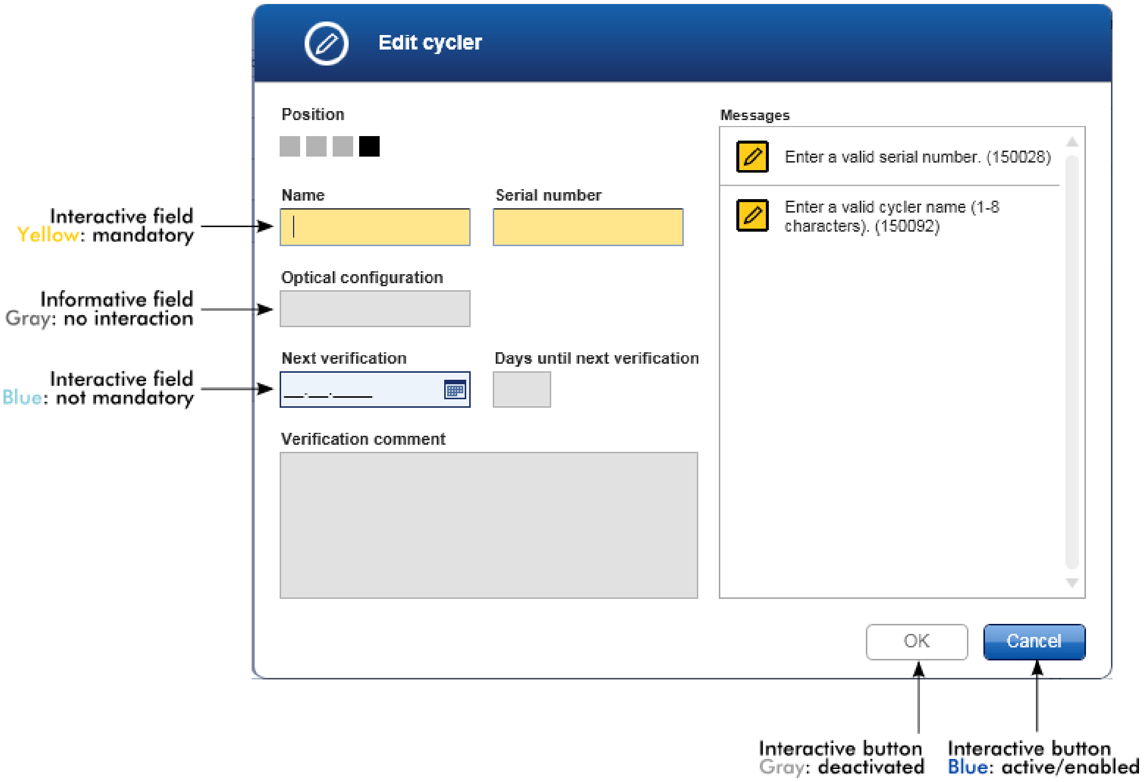
1.5.2.1 Use of Color

For an optimal user interaction Rotor-Gene AssayManager v1.0 has a specific color concept for presenting information.
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.



Edit cycler

Position

Name

Serial number

Optical configuration

Next verification

Days until next verification

Verification comment

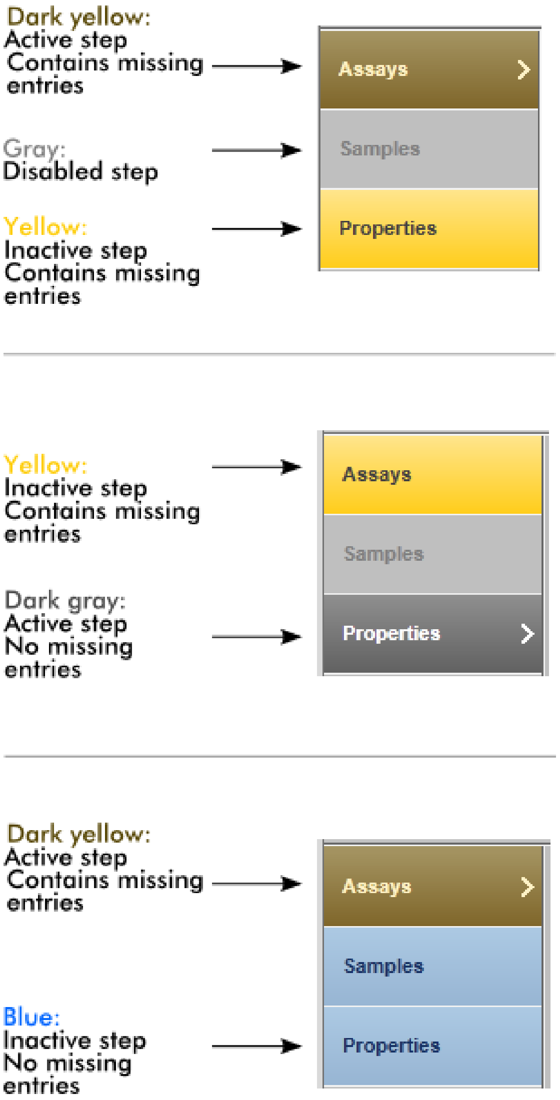
Messages

Enter a valid serial number. (150028)

Enter a valid cycler name (1-8 characters). (150092)

Example 2

When creating a new work list in the "Setup" environment, there are 3 step buttons ("Assays", "Samples", and "Properties") for the different steps to complete. The coloring concept of the step buttons is shown in the following graphic:



1.5.2.2 Displaying Errors and Warnings

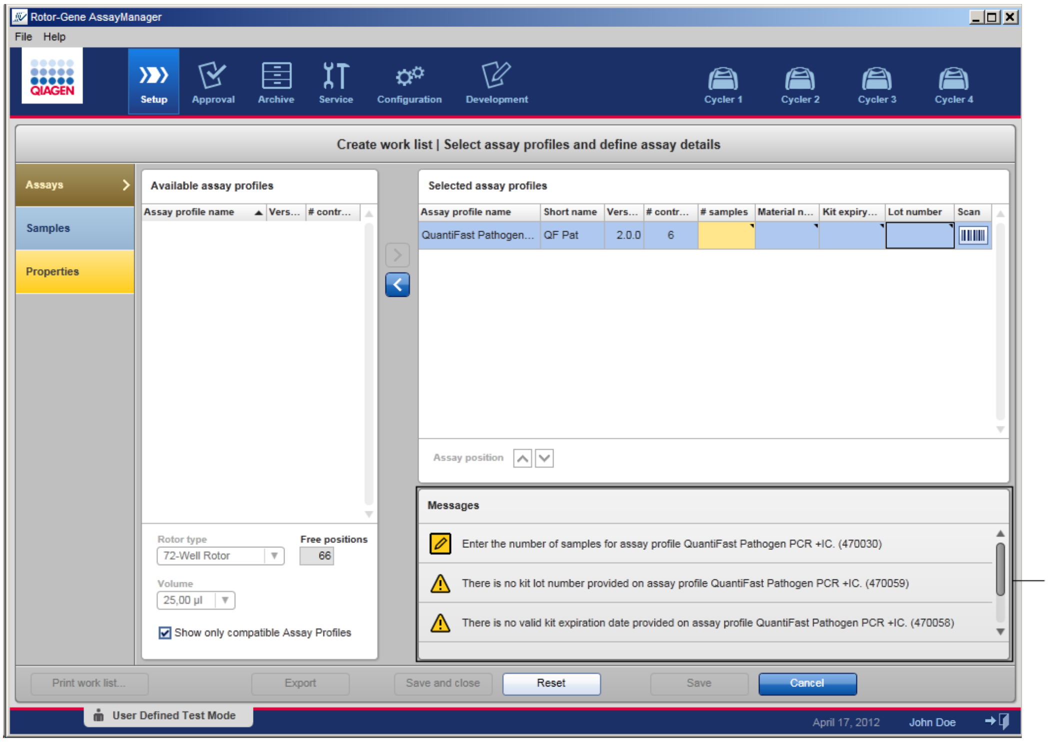
Errors and warnings are essential information for the user. These messages point to a problem or an erroneous situation. Rotor-Gene AssayManager v1.0 differentiates between 4 different problem levels:

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 work list creation in the "Setup" environment. The messages are displayed with the corresponding icon, the error text, and the error ID in brackets.



Assay profile name	Short name	Vers...	# contr...	# samples	Material n...	Kit expiry...	Lot number	Scan
QuantiFast Pathogen...	QF Pat	2.0.0	6					

Rotor type: 72-Well Rotor

Free positions: 66

Volume: 25,00 µl

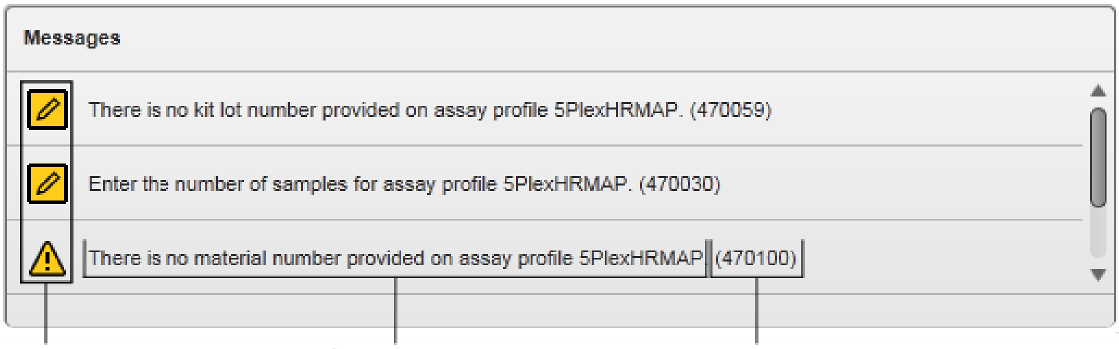
☑ Show only compatible Assay Profiles

Messages

- Enter the number of samples for assay profile QuantiFast Pathogen PCR +IC. (470030)
- There is no kit lot number provided on assay profile QuantiFast Pathogen PCR +IC. (470059)
- There is no valid kit expiration date provided on assay profile QuantiFast Pathogen PCR +IC. (470058)

Messages area

Detailed view of the "Messages" area:


Messages

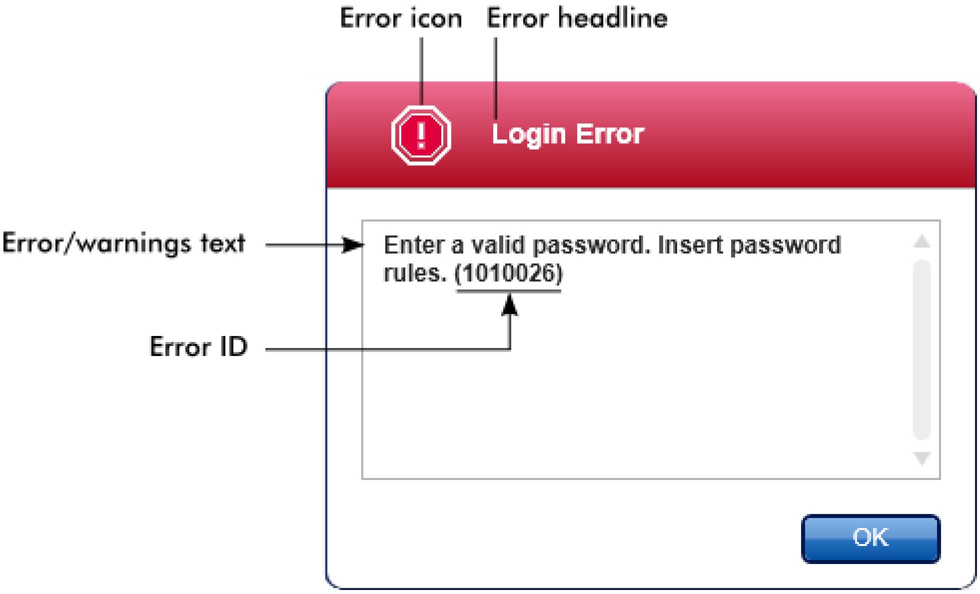
- There is no kit lot number provided on assay profile 5PlexHRMAP. (470059)
- Enter the number of samples for assay profile 5PlexHRMAP. (470030)
- There is no material number provided on assay profile 5PlexHRMAP (470100)

Icon

Error/warnings text

Error ID

Error messages pop-up window



Enter a valid password. Insert password rules. (1010026)

Each error ID is unique. in case QIAGEN Technical Services needs to be contacted for troubleshooting, have the error ID ready.

1.5.2.3 Entering Data

Shortcuts

The following hot keys are available in Rotor-Gene AssayManager v1.0:

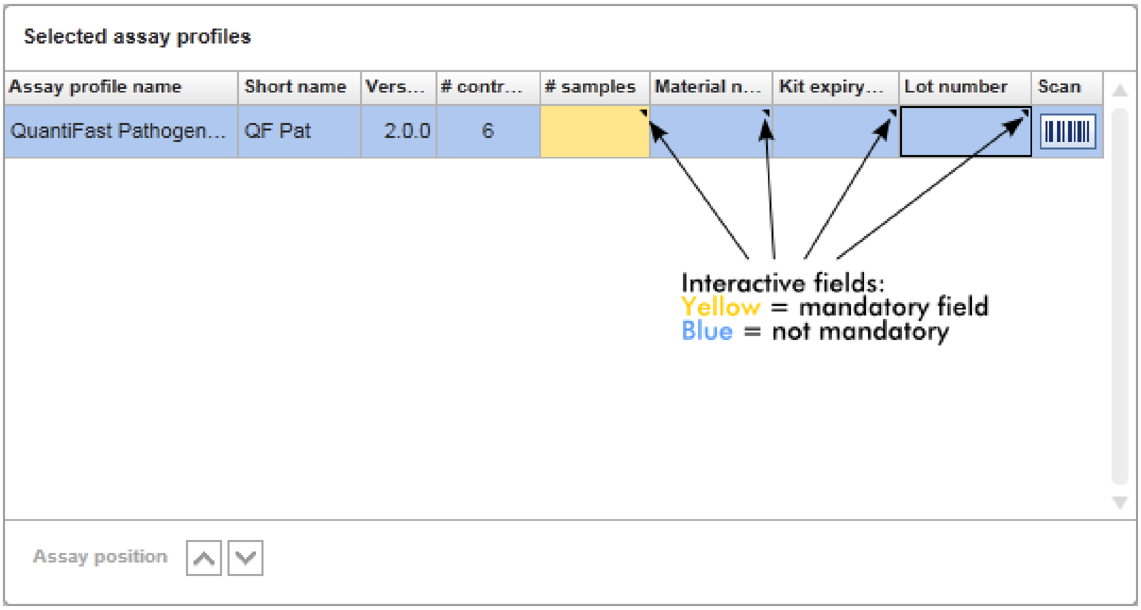
- "F1" to open the help file
- Copy and paste operations ("CTRL"+"C" and "CTRL"+"V")
- Navigation (tab key, cursor keys)

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 work list creation step in the "Setup" environment:



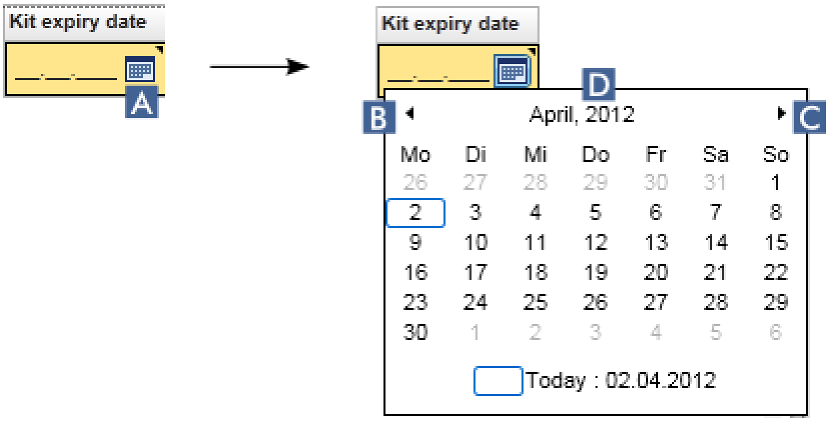
Selected assay profiles

Assay profile name	Short name	Vers...	# contr...	# samples	Material n...	Kit expiry...	Lot number	Scan
QuantiFast Pathogen...	QF Pat	2.0.0	6					

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.

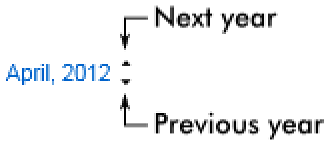


April, 2012

Mo	Di	Mi	Do	Fr	Sa	So
26	27	28	29	30	31	1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	1	2	3	4	5	6

Today : 02.04.2012

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

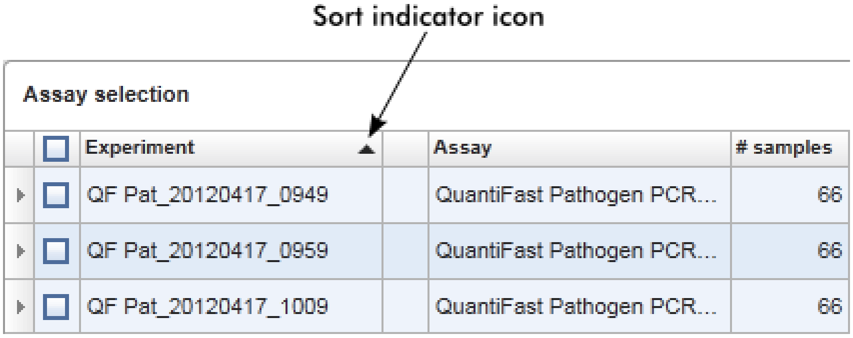
Sorting tables

Some tables in Rotor-Gene AssayManager v1.0 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.



Assay selection

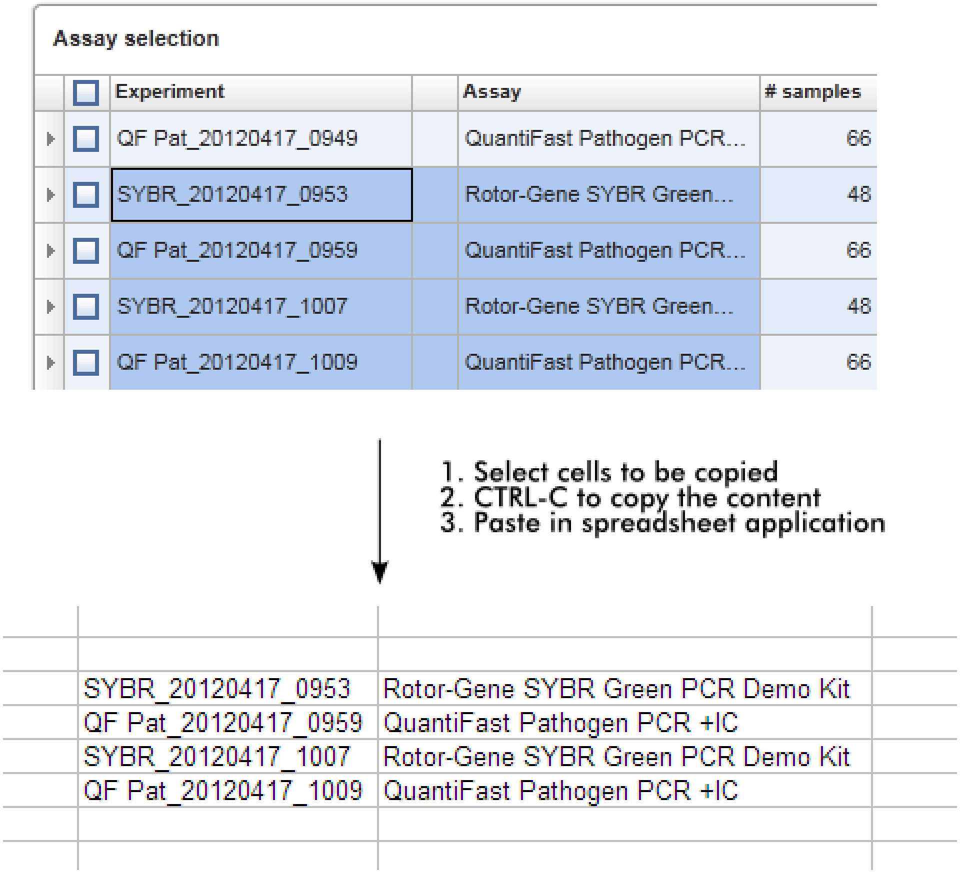
	☐	Experiment ▲		Assay	# samples
▸	☐	QF Pat_20120417_0949		QuantiFast Pathogen PCR...	66
▸	☐	QF Pat_20120417_0959		QuantiFast Pathogen PCR...	66
▸	☐	QF Pat_20120417_1009		QuantiFast Pathogen PCR...	66

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 v1.0 or to another software for further processing using "CTRL"+"V".



Assay selection

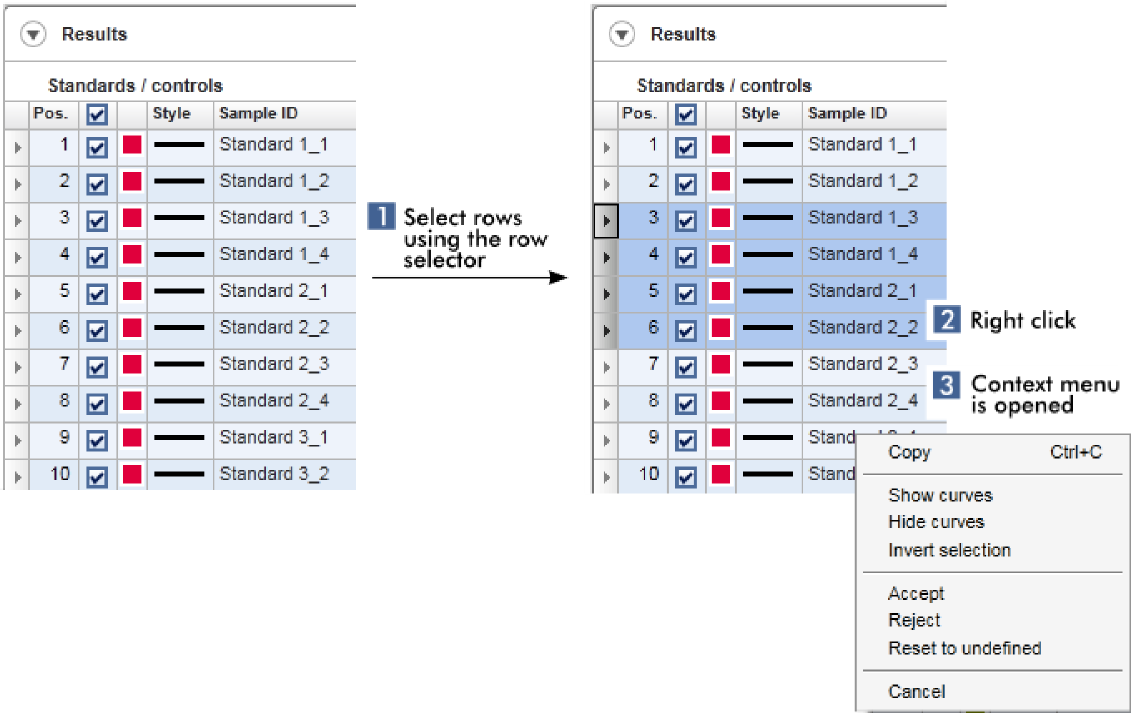
☐	Experiment		Assay	# samples
☐	QF Pat_20120417_0949		QuantiFast Pathogen PCR...	66
☐	SYBR_20120417_0953		Rotor-Gene SYBR Green...	48
☐	QF Pat_20120417_0959		QuantiFast Pathogen PCR...	66
☐	SYBR_20120417_1007		Rotor-Gene SYBR Green...	48
☐	QF Pat_20120417_1009		QuantiFast Pathogen PCR...	66

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 v1.0 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.



Results

Standards / controls

Pos.	☑		Style	Sample ID
1	☑	🟥	—	Standard 1_1
2	☑	🟥	—	Standard 1_2
3	☑	🟥	—	Standard 1_3
4	☑	🟥	—	Standard 1_4
5	☑	🟥	—	Standard 2_1
6	☑	🟥	—	Standard 2_2
7	☑	🟥	—	Standard 2_3
8	☑	🟥	—	Standard 2_4
9	☑	🟥	—	Standard 3_1
10	☑	🟥	—	Standard 3_2

1.5.2.5 Working with Graphs

Rotor-Gene AssayManager v1.0 provides graph 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

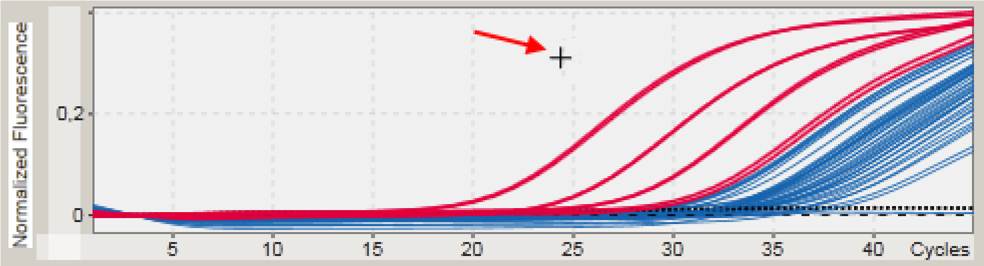
1.5.2.5.1 Zooming in a Graph

Overview

For zooming in a graph in Rotor-Gene AssayManager v1.0, an individual zoom area can be selected as in the following example of an amplification plot from the "Approval" environment.

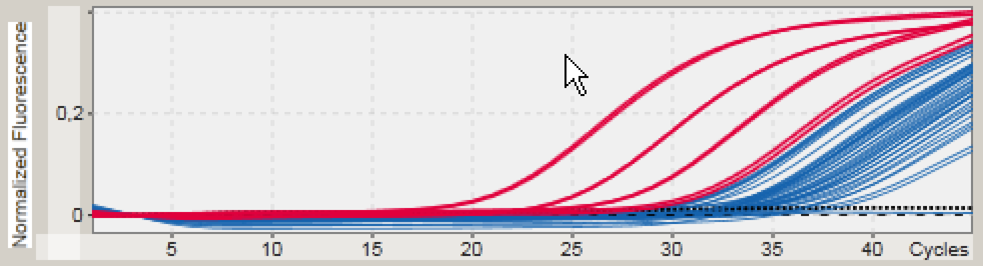
Step-by-step procedure to zoom in a graph

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

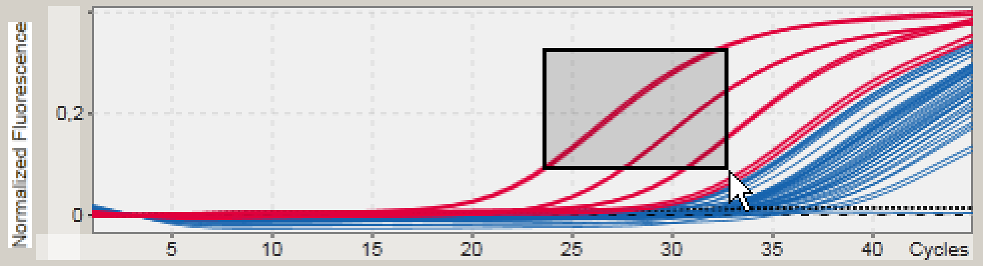


2.

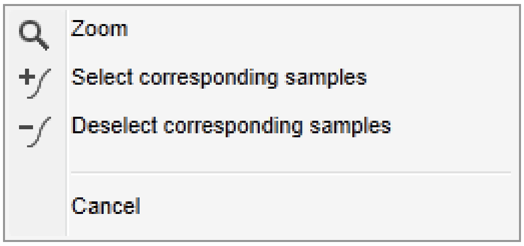
   a) Click and hold down the left mouse button. The mouse icon changes from cross hairs to the cursor icon.



   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.



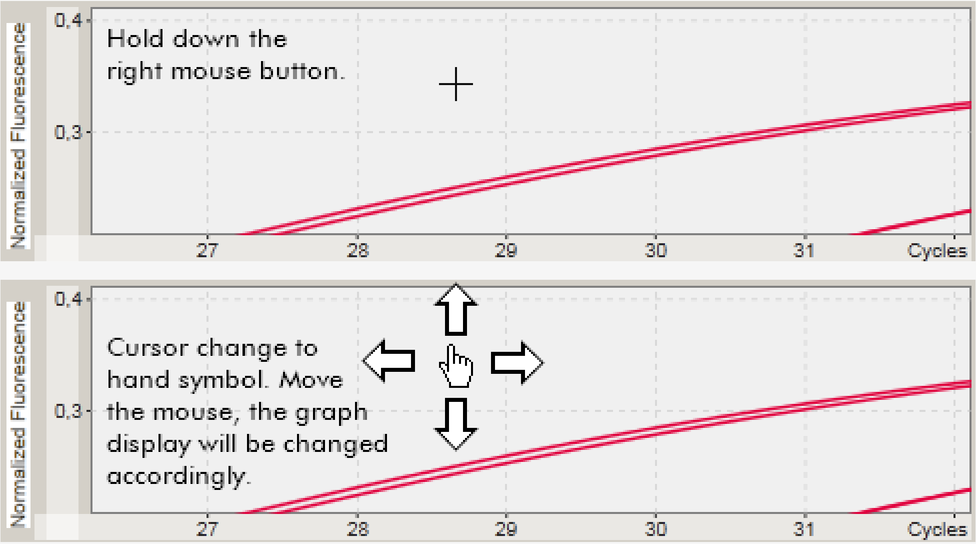
   c) Release the left mouse button. The following menu pops up:



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.


Hold down the right mouse button.

Cursor change to hand symbol. Move the mouse, the graph display will be changed accordingly.

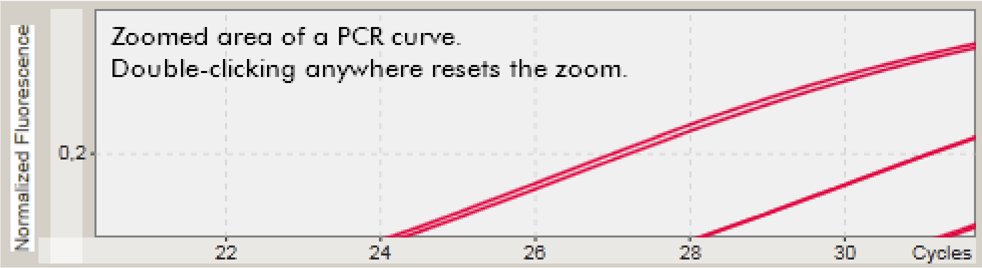
1.5.2.5.2 Zooming out a Graph

Step-by-step procedure to zoom out a graph

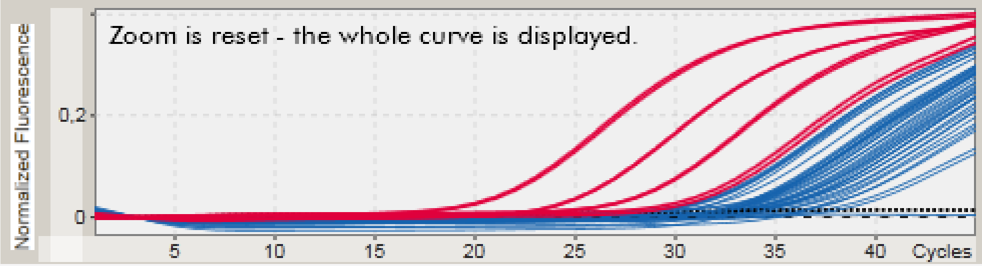
Double-click anywhere in a graph area to reset the zoom function to default-scale and see the whole graph.

Example

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



Zoomed area of a PCR curve.
Double-clicking anywhere resets the zoom.



Zoom is reset - the whole curve is displayed.

1.5.2.5.3 Selecting/Deselecting Samples

Overview

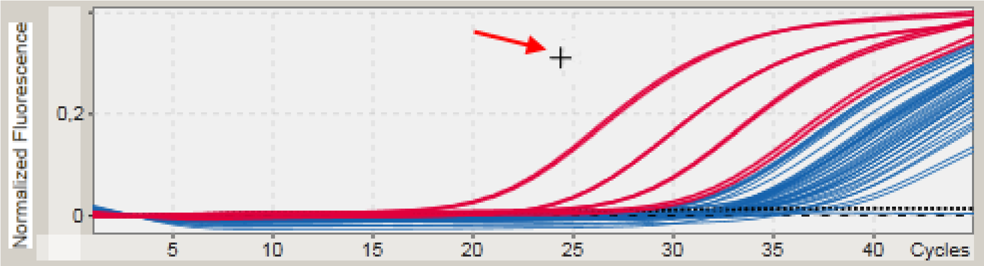
Rotor-Gene AssayManager v1.0 provides 2 methods to select or deselect samples in an amplification plot:

- Using a graph
- Using check boxes

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

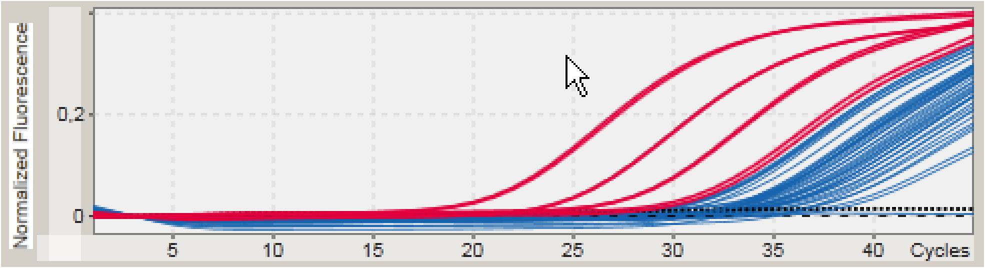
1. Move the cursor over the graph area.

   The mouse cursor icon changes to cross hairs.

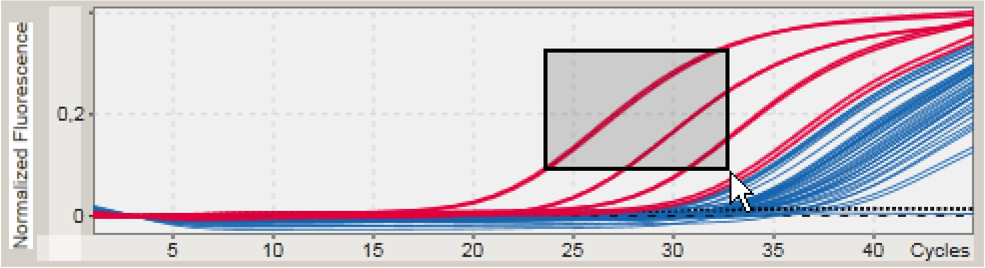


2.

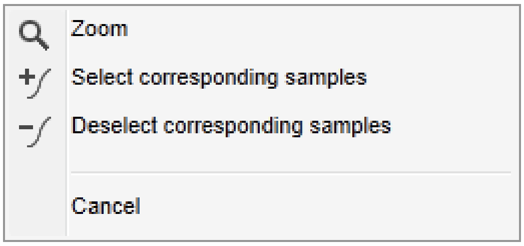
a) Click and hold down the left mouse button. The mouse icon changes from cross hairs to the cursor icon.



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:

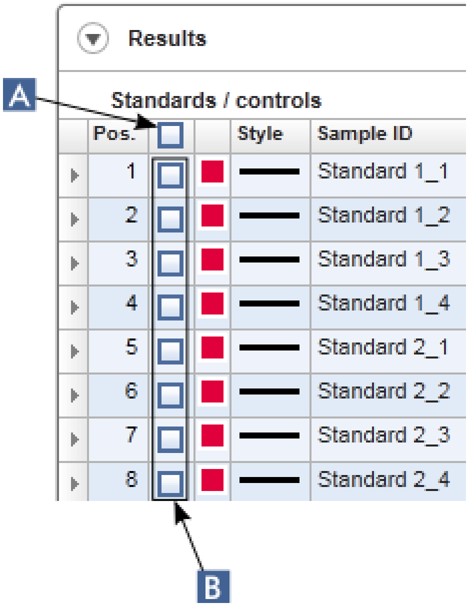


2. Left-click at the desired option

To	Click
Select all samples within the selected area	+∫ Select corresponding samples
Deselect all samples within the selected area	−∫ Deselect corresponding samples
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.



Standards / controls

	Pos.	☐		Style	Sample ID
▸	1	☐	🟥	—	Standard 1_1
▸	2	☐	🟥	—	Standard 1_2
▸	3	☐	🟥	—	Standard 1_3
▸	4	☐	🟥	—	Standard 1_4
▸	5	☐	🟥	—	Standard 2_1
▸	6	☐	🟥	—	Standard 2_2
▸	7	☐	🟥	—	Standard 2_3
▸	8	☐	🟥	—	Standard 2_4

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).

To	Do
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).

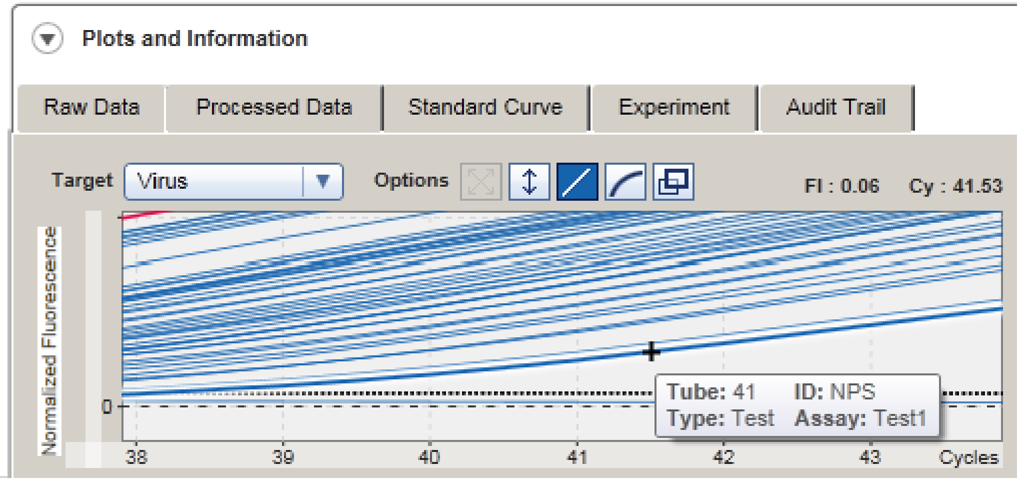
Note
The check box icon in the column header changes depending on the number of selected samples.

Icon	Description
☐	No sample is selected
⊟	One or more samples are selected
☑	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
- ID
- Assay type
- Assay short name



Target: Virus

FI : 0.06 Cy : 41.53

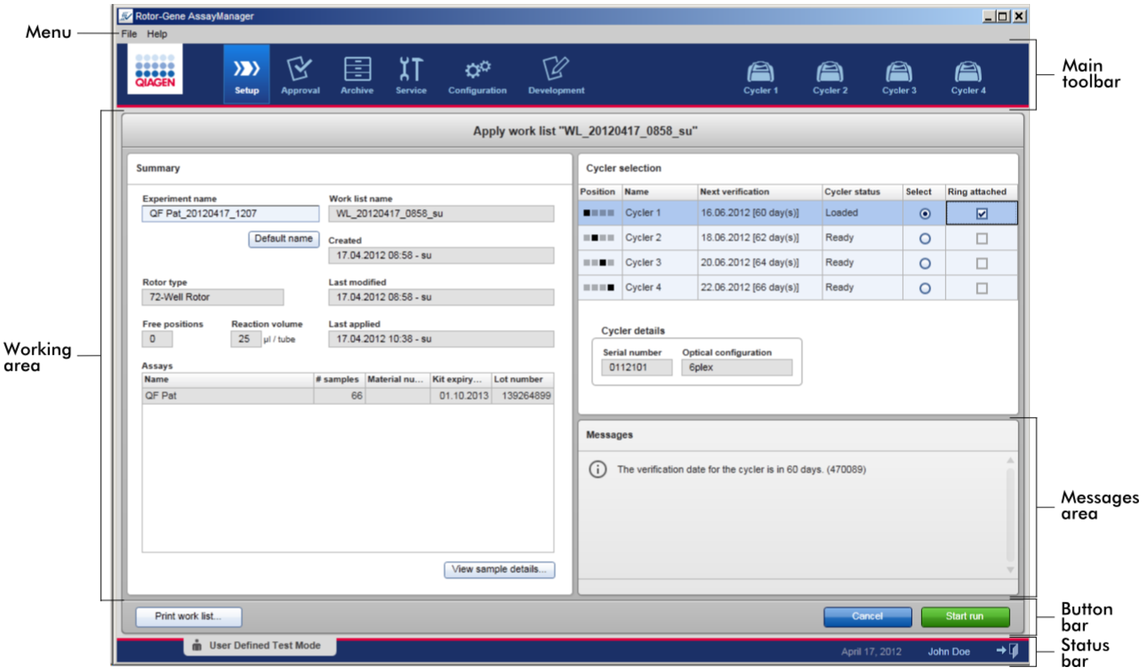
Tube: 41 ID: NPS
Type: Test Assay: Test1

1.5.3 Rotor-Gene AssayManager v1.0 Workspace

Rotor-Gene AssayManager v1.0 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
- "Development" environment

Note
The "Development" environment is only available if a UDT mode plug-in is installed.



Apply work list "WL_20120417_0858_su"

Summary

Experiment name: QF Pat_20120417_1207
Work list name: WL_20120417_0858_su
Created: 17.04.2012 08:58 - su
Rotor type: 72-Well Rotor
Last modified: 17.04.2012 08:58 - su
Free positions: 0
Reaction volume: 25 µl / tube
Last applied: 17.04.2012 10:38 - su

Assays

Name	# samples	Material nu...	Kit expiry...	Lot number
QF Pat	66		01.10.2013	139264899

Cycler selection

Position	Name	Next verification	Cycler status	Select	Ring attached
■□□□	Cycler 1	16.06.2012 [60 day(s)]	Loaded	●	☑
□■□□	Cycler 2	18.06.2012 [62 day(s)]	Ready	○	☐
□□■□	Cycler 3	20.06.2012 [64 day(s)]	Ready	○	☐
□□□■	Cycler 4	22.06.2012 [66 day(s)]	Ready	○	☐

Cycler details

Serial number: 0112101
Optical configuration: 6plex

Messages

The verification date for the cycler is in 60 days. (470089)

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

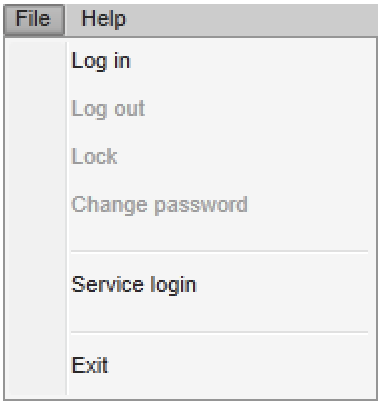
1.5.4 General Elements

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

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

1.5.4.1 Menu

File menu

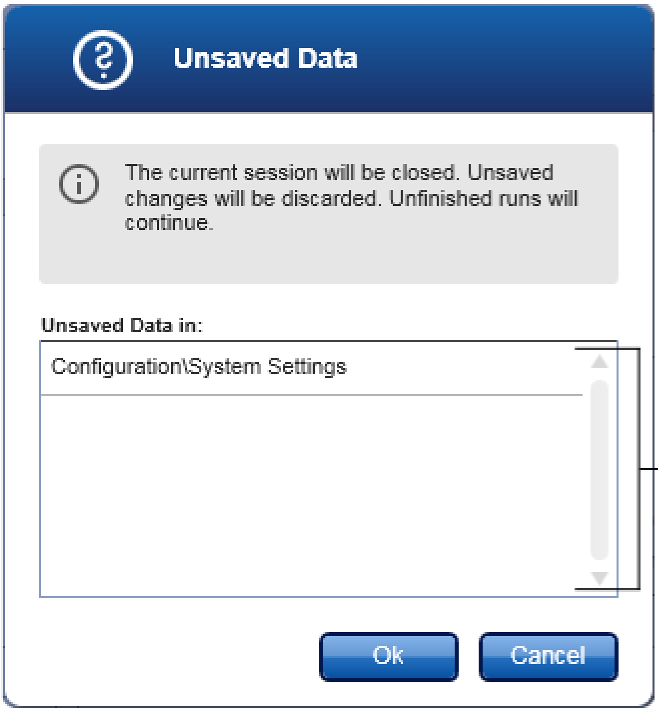


Log in

Select "Log in" to log in to Rotor-Gene AssayManager v1.0. 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.

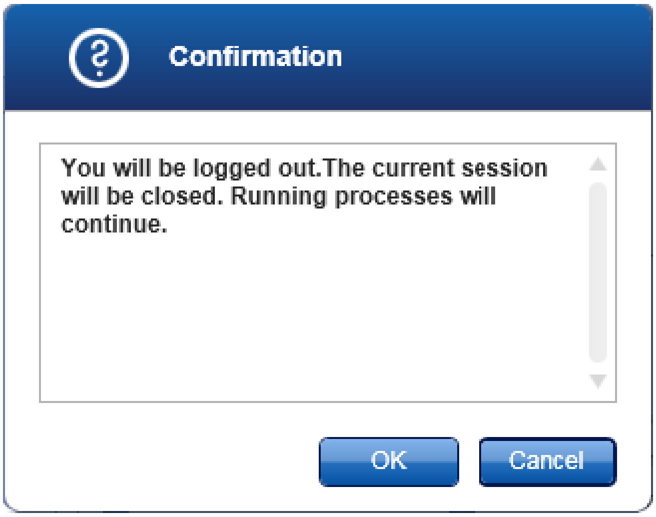


The current session will be closed. Unsaved changes will be discarded. Unfinished runs will continue.

Unsaved Data in:

Configuration\System Settings

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



You will be logged out.The current session will be closed. Running processes will continue.

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 v1.0. If there are unsaved data, a warning will appear.

Help menu

Open Rotor-Gene AssayManager v1.0 help file

This opens the help file for Rotor-Gene AssayManager v1.0 core application.

Open UDT basic Plug-in help file

This opens the help file dedicated for functions related to the UDT basic plug-in. If other plug-ins are installed, there will be more help files available.

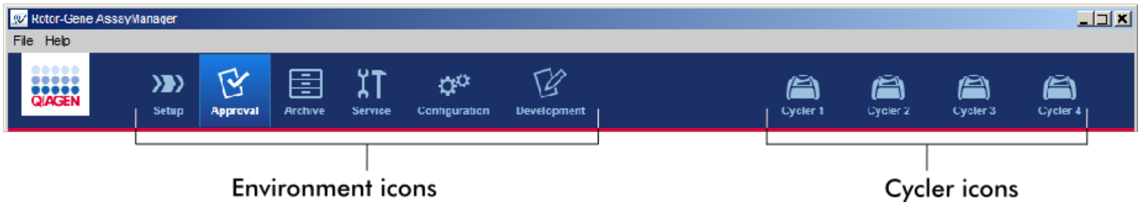
About

The “About Rotor-Gene AssayManager” dialog box appears and displays information about the Rotor-Gene AssayManager v1.0 and the loaded plug-ins including the version numbers.

1.5.4.2 Main Toolbar

The main toolbar contains 2 areas:

- Environment icons
- Cycler icons



Environment icons

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

Rotor-Gene AssayManager v1.0 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

The "Development" environment is only available if a plug-in for UDT mode is installed.

Cycler icons

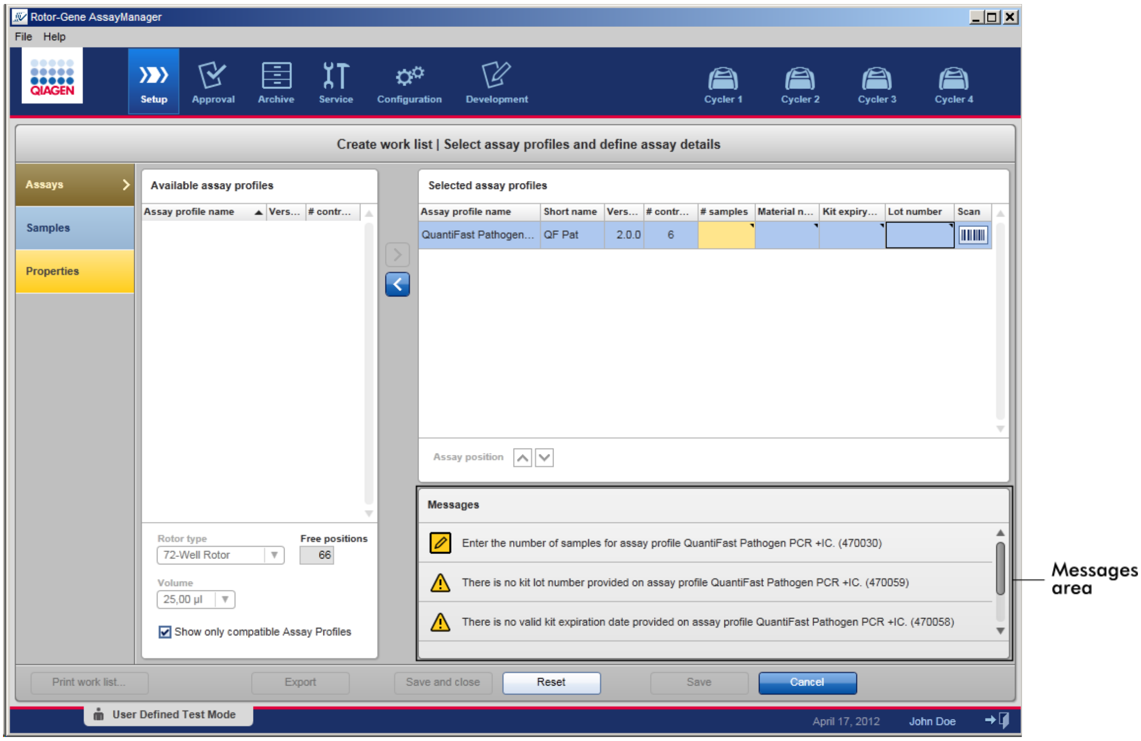
The cycler icons visualize the up to 4 registered cyclers managed by Rotor-Gene AssayManager v1.0. Clicking a cycler icon changes to the corresponding cycler screen.

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



Assay profile name	Short name	Vers...	# contr...	# samples	Material n...	Kit expiry...	Lot number	Scan
QuantiFast Pathogen...	QF Pat	2.0.0	6					

Rotor type: 72-Well Rotor
Free positions: 66
Volume: 25,00 µl
☑ Show only compatible Assay Profiles

Messages

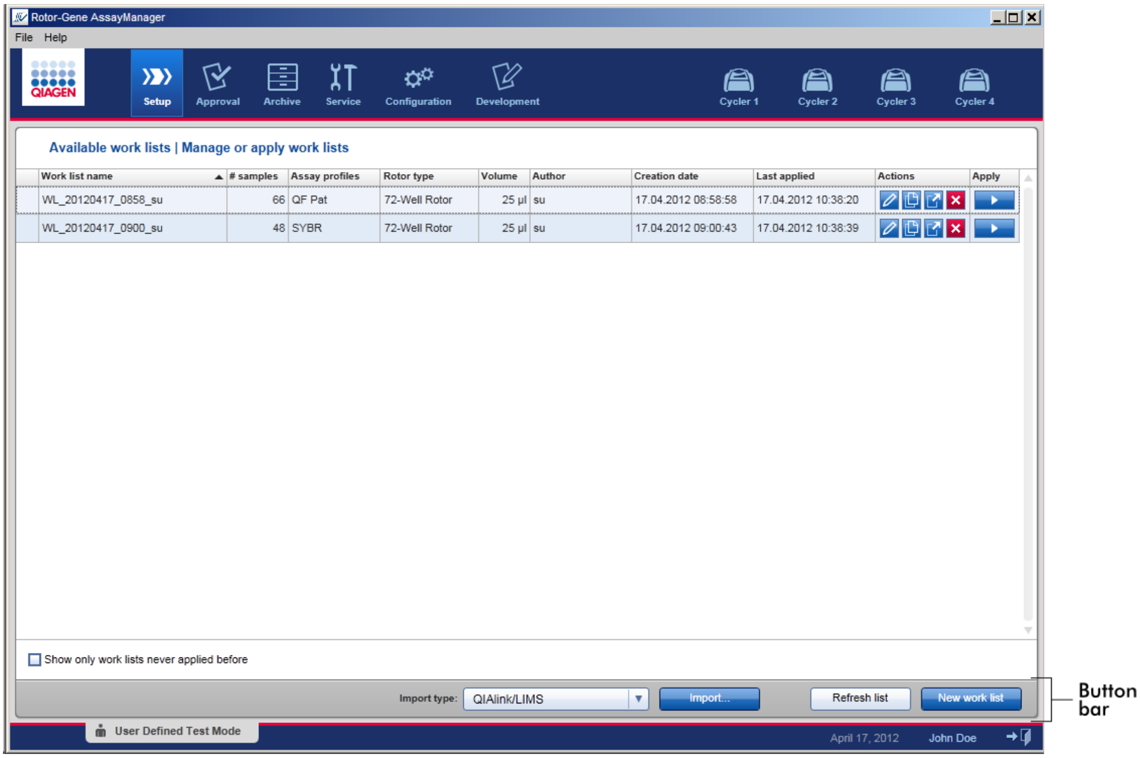
- Enter the number of samples for assay profile QuantiFast Pathogen PCR +IC. (470030)
- There is no kit lot number provided on assay profile QuantiFast Pathogen PCR +IC. (470059)
- There is no valid kit expiration date provided on assay profile QuantiFast Pathogen PCR +IC. (470058)

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.



Available work lists | Manage or apply work lists

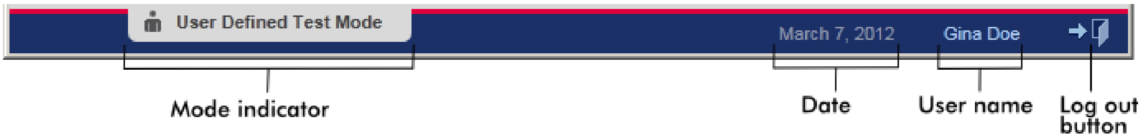
Work list name	# samples	Assay profiles	Rotor type	Volume	Author	Creation date	Last applied	Actions	Apply
WL_20120417_0858_su	66	QF Pat	72-Well Rotor	25 µl	su	17.04.2012 08:58:58	17.04.2012 10:38:20	✎ ⧉ ↗ ✕	▶
WL_20120417_0900_su	48	SYBR	72-Well Rotor	25 µl	su	17.04.2012 09:00:43	17.04.2012 10:38:39	✎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

☐ Show only work lists never applied before

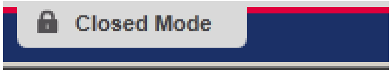
Import type: QIAlink/LIMS

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.

Related topics

- The two different modes in Rotor-Gene AssayManager
- Logging in and logging out

1.5.5 Environments

Rotor-Gene AssayManager v1.0 contains 6 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 work lists.
	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.

Archive	Used to search for fully released experiments and to generate experiment reports using predefined report profiles.
Configuration	Used to adjust the settings of Rotor-Gene AssayManager v1.0.
Development	Used to develop new assay profiles in User Defined Test Mode.
Cycler 1	Used to stop or finish a run and to release a cycler after a run is finished.

1.5.5.1 Setup Environment

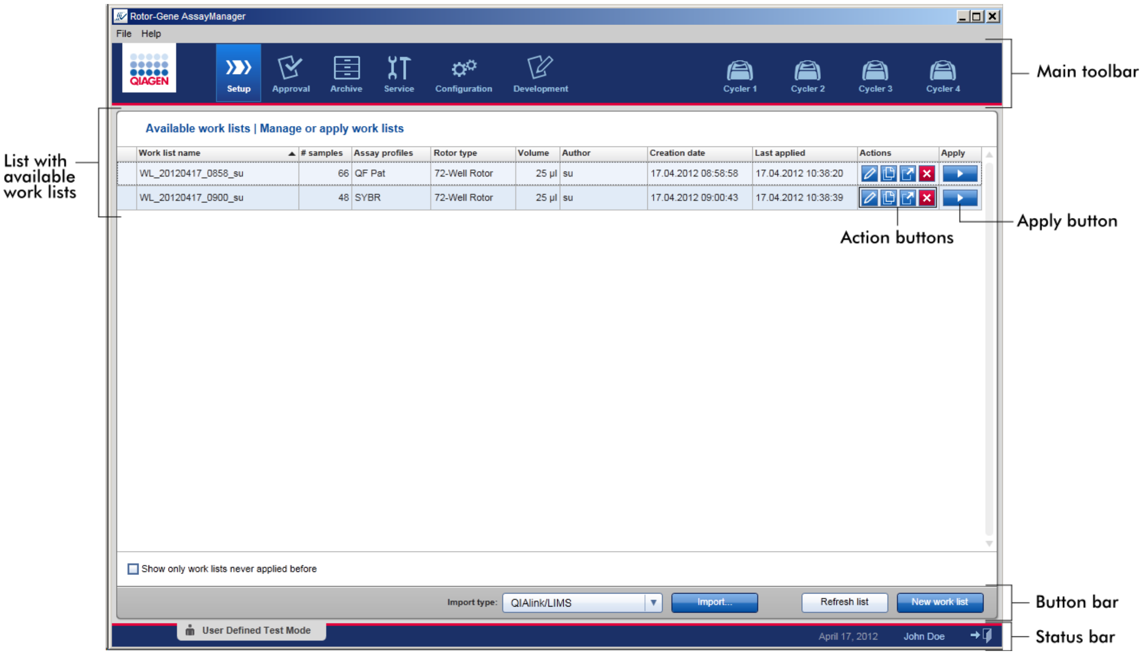
Overview
The "Setup" environment is one of the core parts of the Rotor-Gene AssayManager v1.0 application. It automatically appears after a user with the assigned role of an Operator successfully logs in to Rotor-Gene AssayManager v1.0. The "Setup" environment consists of 3 different screens where tasks can be assigned:

Screen	Assigned tasks
"Available work lists"	▪ Creating a new work list ▪ Importing a work list ▪ Editing a work list ▪ Duplicating a work list ▪ Exporting a work list ▪ Deleting a work list ▪ Applying a work list
"Create new work list" ▪ "Assays" step ▪ "Samples" step ▪ "Properties" step	Create a new work list: ▪ Appears after clicking "New work list" ▪ Starts the process to create a new work list
"Apply work list"	▪ Setup run and apply a work list

1.5.5.1.1 Available Work Lists View

The "Available work lists" view contains 2 areas:

- A table with available work lists (stored in the internal database).
- The button bar at the bottom of the screen



Available work lists | Manage or apply work lists

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		

☐ Show only work lists never applied before

Import type: QIAlink/LIMS

April 17, 2012 John Doe

The "Available Work Lists" Table

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

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

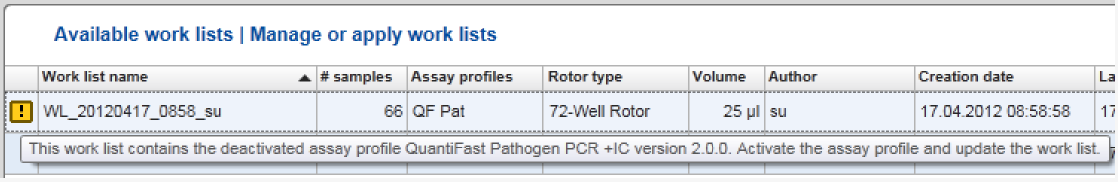
The data in the table is sortable. By clicking at the column header, the table's data is sorted in ascending order. By clicking at the column header again, the table's data is sorting in descending order.

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

Icon	Description
!	Deactivated assay profile or expired kit
?	Message: "This work list contains invalid samples" A work list contains invalid samples. This message is used only for imported work lists.
🔒	The work list is currently locked.

Note

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

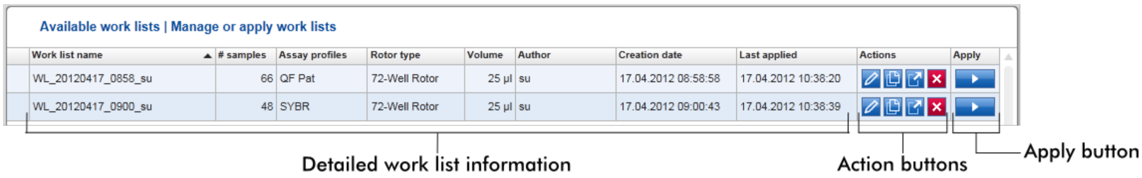


Available work lists | Manage or apply work lists

	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

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.

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



Available work lists | Manage or apply work lists

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 work list"	Editing a work list means modifying its parameters in the "Edit work list" view. The parameters of the work list can be modified using the "Edit work list" view. Note: This button is only enabled if the option "is editable" was set during work list setup and the work list is not locked. Work lists imported from QIAsymphony or LIMS to the software cannot be edited.	▶ Creating/editing a work list
	⧉	"Duplicate work list"	Creates a copy of the selected work list. A copy of the selected work list is created. This copy can subsequently be edited in the "Edit work list" view. Note: All modifications are temporary until the new work list is saved. Note: This icon is disabled for work lists imported from QIAsymphony or LIMS.	▶ Creating/editing a work list
	↗	"Export work list"	Exports the work list as *.iwl file. The intended use of this function is to exchange work lists between different Rotor-Gene AssayManager v1.0 installations using the import/export function.	–
	☒	"Remove work list"	Removes the work list from the system. A warning must be confirmed before the work list is deleted.	–
▶ "Apply" button		"Apply work list"	The work list is applied (i.e., the run is performed) and further details have to be entered in the "Run work list" view. Note: This button is enabled if the work list is set as "ready to be applied" and the work list is not locked.	▶ Apply work list view
☐ Show only work lists never applied before			If not activated: Displays all work lists, regardless if they already have been applied or not.	

	If activated:	Displays only work lists which have not been applied yet.	

Note

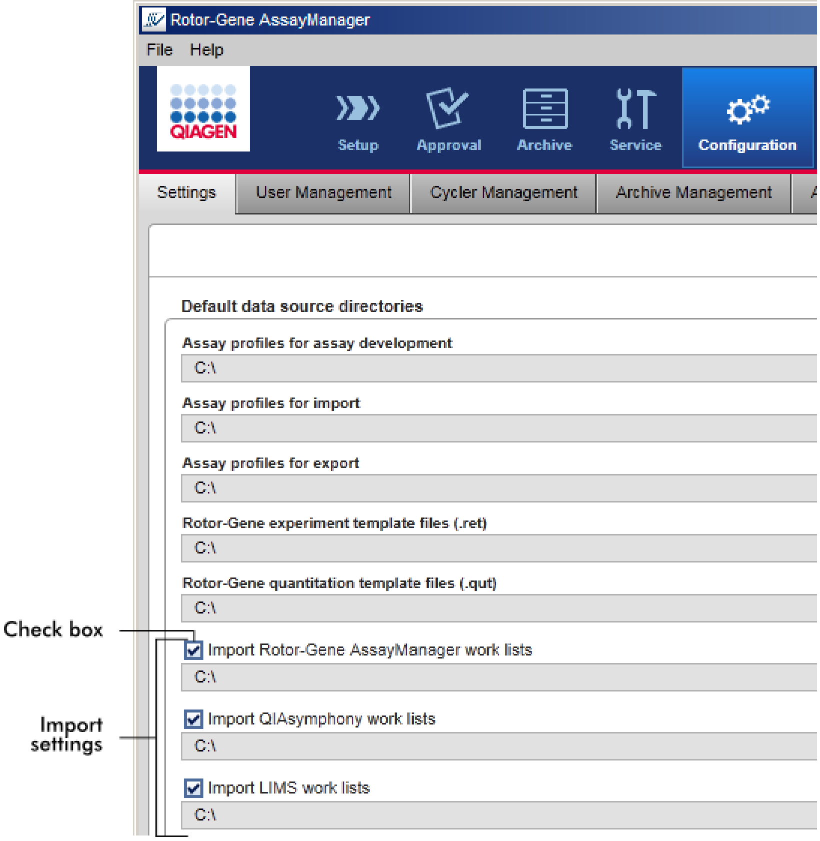
The "Available work lists table" might become very long and confusing: this table might contain a number of work lists that you do not need anymore.
Remove the work lists you do not need anymore at regular periods:

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

The Button Bar

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

	Label/Title	Description
A	"New work list"	Create a new work list. This button links to the "Create new work list" screen.
B	"Import"	Import a work list from a file. A file selection dialog is opened where the work list 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 work list command. Rotor-Gene AssayManager v1.0 can import work lists from QIAlink/LIMS, QIAsymphony, and other Rotor-Gene AssayManager v1.0 installations. Possible values: QIAlink/LIMS QIAsymphony Rotor-Gene AssayManager The entries in this menu depend on the import settings in the "Configuration" environment.



Default data source directories

Assay profiles for assay development
C:\

Assay profiles for import
C:\

Assay profiles for export
C:\

Rotor-Gene experiment template files (.ret)
C:\

Rotor-Gene quantitation template files (.qut)
C:\

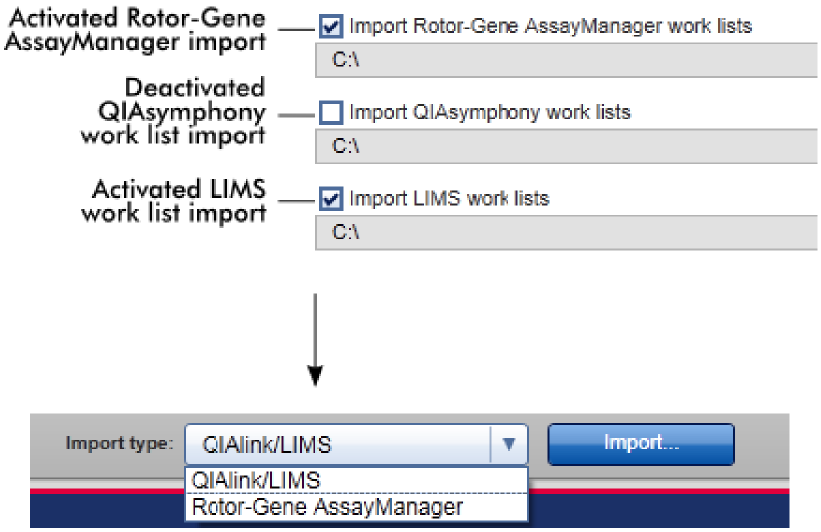
☑ Import Rotor-Gene AssayManager work lists
C:\

☑ Import QIAsymphony work lists
C:\

☑ Import LIMS work lists
C:\

The group box "Default data source directories" in the "Settings" tab of the "Configuration" environment defines whether the import of external work lists (from Rotor-Gene AssayManager v1.0, 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 work list is enabled. The "Import type" drop-down menu in the "Setup" environment is populated with this import option.

Example:



☑ Import Rotor-Gene AssayManager work lists
C:\

☐ Import QIAsymphony work lists
C:\

☑ Import LIMS work lists
C:\

Import type: QIAlink/LIMS

The "Import QIAsymphony work lists" option is deactivated in the example above. The QIAsymphony import option is removed from the "Import type" menu.

Tasks related to the "Available work lists" view

- Creating a new work list
- Editing/modifying a work list
- Exporting a work list
- Importing a work list
- Applying a work list

1.5.5.1.2 Apply Work List View

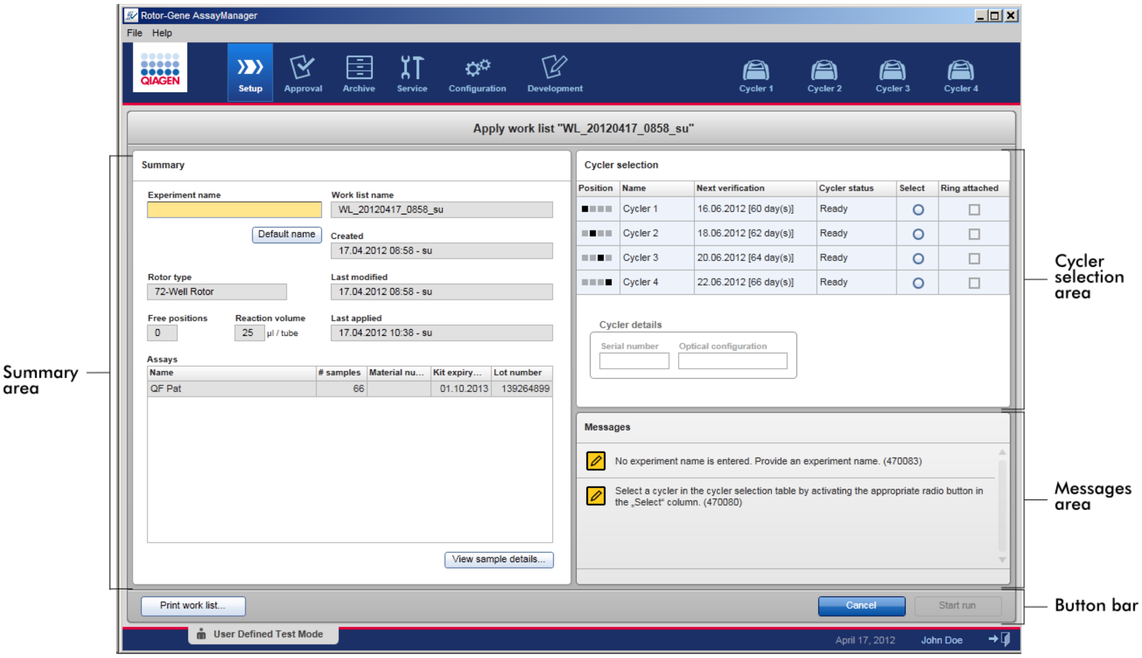
Selecting the "Apply" button either in the "Available work lists" view or in the "Create New/Edit work list" view links to the "Apply work list" view.

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

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

Furthermore detailed information about the work list and the cycler are displayed:

Work list information	Cycler information
▪ Work list name ▪ Creation date ▪ Last modification date ▪ Last application date ▪ Rotor type ▪ Number of free positions ▪ Reaction volume ▪ Assays used in the work list • Assay name • Number of samples • Material number • Kit expiry date • Lot number	▪ Position ▪ Name ▪ Next verification date ▪ Cycler status ▪ Serial number ▪ Optical configuration



Apply work list "WL_20120417_0858_su"

Summary

Experiment name:

Work list name: WL_20120417_0858_su

Created: 17.04.2012 08:58 - su

Rotor type: 72-Well Rotor

Last modified: 17.04.2012 08:58 - su

Free positions: 0

Reaction volume: 25 µl / tube

Last applied: 17.04.2012 10:38 - su

Assays

Name	# samples	Material nu...	Kit expiry...	Lot number
QF Pat	66		01.10.2013	139264899

Cycler selection

Position	Name	Next verification	Cycler status	Select	Ring attached
■□□□	Cycler 1	16.06.2012 [60 day(s)]	Ready	○	☐
□■□□	Cycler 2	18.06.2012 [62 day(s)]	Ready	○	☐
□□■□	Cycler 3	20.06.2012 [64 day(s)]	Ready	○	☐
□□□■	Cycler 4	22.06.2012 [66 day(s)]	Ready	○	☐

Cycler details

Serial number:

Optical configuration:

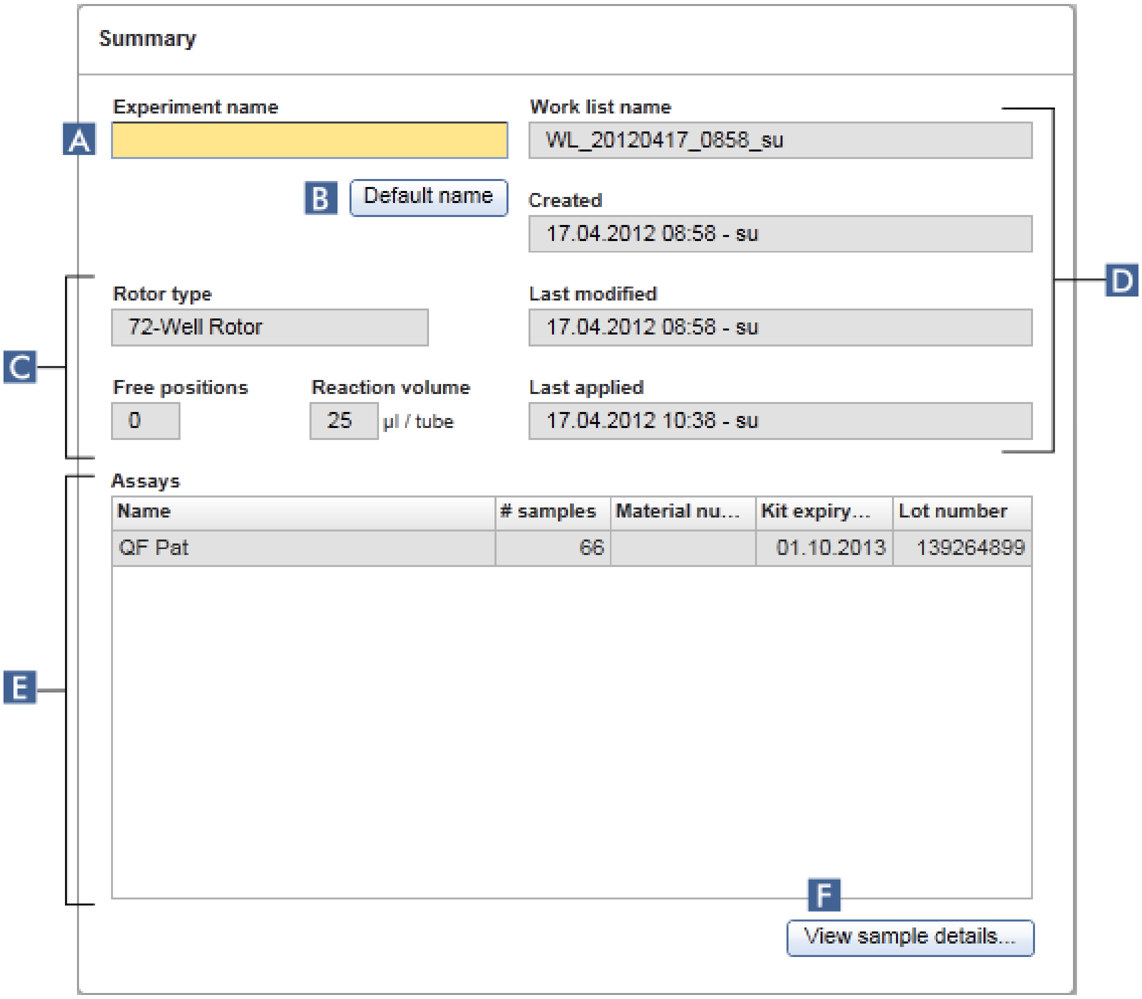
Messages

No experiment name is entered. Provide an experiment name. (470083)

Select a cycler in the cycler selection table by activating the appropriate radio button in the „Select“ column. (470080)

Summary area

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



Summary

Experiment name

Work list name: WL_20120417_0858_su

Created: 17.04.2012 08:58 - su

Rotor type: 72-Well Rotor

Last modified: 17.04.2012 08:58 - su

Free positions: 0

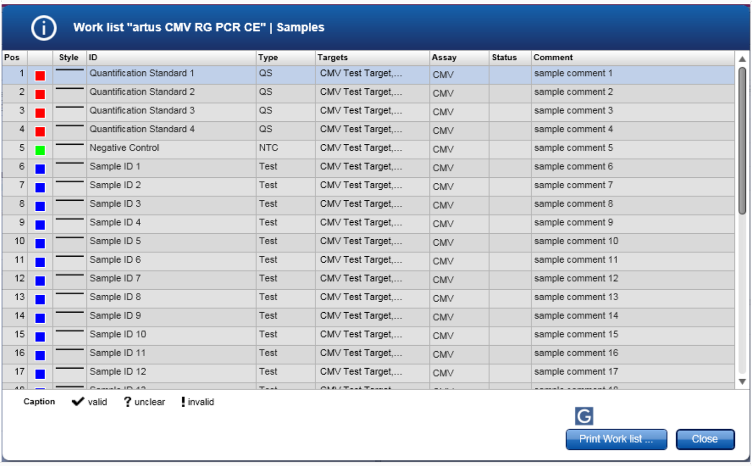
Reaction volume: 25 µl / tube

Last applied: 17.04.2012 10:38 - su

Assays

Name	# samples	Material nu...	Kit expiry...	Lot number
QF Pat	66		01.10.2013	139264899

	Label/Title	Description
A	"Experiment name"	Input box to enter a mandatory experiment name. The experiment name must fulfill 2 requirements: ▪ 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:	Shows the following data:

<table>
<tr><td></td><td>"Free positions"
"Reaction volume"</td><td>Number of free positions
Reaction volume</td></tr>
<tr><td>D</td><td>Data field:
"Work list name"
"Created"
"Last modified"
"Last applied"</td><td>Shows the following data:
Work list name
Creation date
Last modification date
Last application date</td></tr>
<tr><td>E</td><td>"Assays" table</td><td>Table with a list of all assays incorporated in the work list. For every assay the following data is shown:
Assay name
Number of samples
Material number
Kit expiry date
Lot number</td></tr>
<tr><td>F</td><td>"View sample details..."</td><td>Overview of the samples in the work list in form of a table. This table can be printed by clicking "Print work list..." (G).

Work list "artus CMV RG PCR CE" | Samples
<table>
<tr><th>Pos</th><th></th><th>Style</th><th>ID</th><th>Type</th><th>Targets</th><th>Assay</th><th>Status</th><th>Comment</th></tr>
<tr><td>1</td><td>🟥</td><td>—</td><td>Quantification Standard 1</td><td>QS</td><td>CMV Test Target,...</td><td>CMV</td><td></td><td>sample comment 1</td></tr>
<tr><td>2</td><td>🟥</td><td>—</td><td>Quantification Standard 2</td><td>QS</td><td>CMV Test Target,...</td><td>CMV</td><td></td><td>sample comment 2</td></tr>
<tr><td>3</td><td>🟥</td><td>—</td><td>Quantification Standard 3</td><td>QS</td><td>CMV Test Target,...</td><td>CMV</td><td></td><td>sample comment 3</td></tr>
<tr><td>4</td><td>🟥</td><td>—</td><td>Quantification Standard 4</td><td>QS</td><td>CMV Test Target,...</td><td>CMV</td><td></td><td>sample comment 4</td></tr>
<tr><td>5</td><td>🟩</td><td>—</td><td>Negative Control</td><td>NTC</td><td>CMV Test Target,...</td><td>CMV</td><td></td><td>sample comment 5</td></tr>
<tr><td>6</td><td>🟦</td><td>—</td><td>Sample ID 1</td><td>Test</td><td>CMV Test Target,...</td><td>CMV</td><td></td><td>sample comment 6</td></tr>
<tr><td>7</td><td>🟦</td><td>—</td><td>Sample ID 2</td><td>Test</td><td>CMV Test Target,...</td><td>CMV</td><td></td><td>sample comment 7</td></tr>
<tr><td>8</td><td>🟦</td><td>—</td><td>Sample ID 3</td><td>Test</td><td>CMV Test Target,...</td><td>CMV</td><td></td><td>sample comment 8</td></tr>
<tr><td>9</td><td>🟦</td><td>—</td><td>Sample ID 4</td><td>Test</td><td>CMV Test Target,...</td><td>CMV</td><td></td><td>sample comment 9</td></tr>
<tr><td>10</td><td>🟦</td><td>—</td><td>Sample ID 5</td><td>Test</td><td>CMV Test Target,...</td><td>CMV</td><td></td><td>sample comment 10</td></tr>
<tr><td>11</td><td>🟦</td><td>—</td><td>Sample ID 6</td><td>Test</td><td>CMV Test Target,...</td><td>CMV</td><td></td><td>sample comment 11</td></tr>
<tr><td>12</td><td>🟦</td><td>—</td><td>Sample ID 7</td><td>Test</td><td>CMV Test Target,...</td><td>CMV</td><td></td><td>sample comment 12</td></tr>
<tr><td>13</td><td>🟦</td><td>—</td><td>Sample ID 8</td><td>Test</td><td>CMV Test Target,...</td><td>CMV</td><td></td><td>sample comment 13</td></tr>
<tr><td>14</td><td>🟦</td><td>—</td><td>Sample ID 9</td><td>Test</td><td>CMV Test Target,...</td><td>CMV</td><td></td><td>sample comment 14</td></tr>
<tr><td>15</td><td>🟦</td><td>—</td><td>Sample ID 10</td><td>Test</td><td>CMV Test Target,...</td><td>CMV</td><td></td><td>sample comment 15</td></tr>
<tr><td>16</td><td>🟦</td><td>—</td><td>Sample ID 11</td><td>Test</td><td>CMV Test Target,...</td><td>CMV</td><td></td><td>sample comment 16</td></tr>
<tr><td>17</td><td>🟦</td><td>—</td><td>Sample ID 12</td><td>Test</td><td>CMV Test Target,...</td><td>CMV</td><td></td><td>sample comment 17</td></tr>
</table>

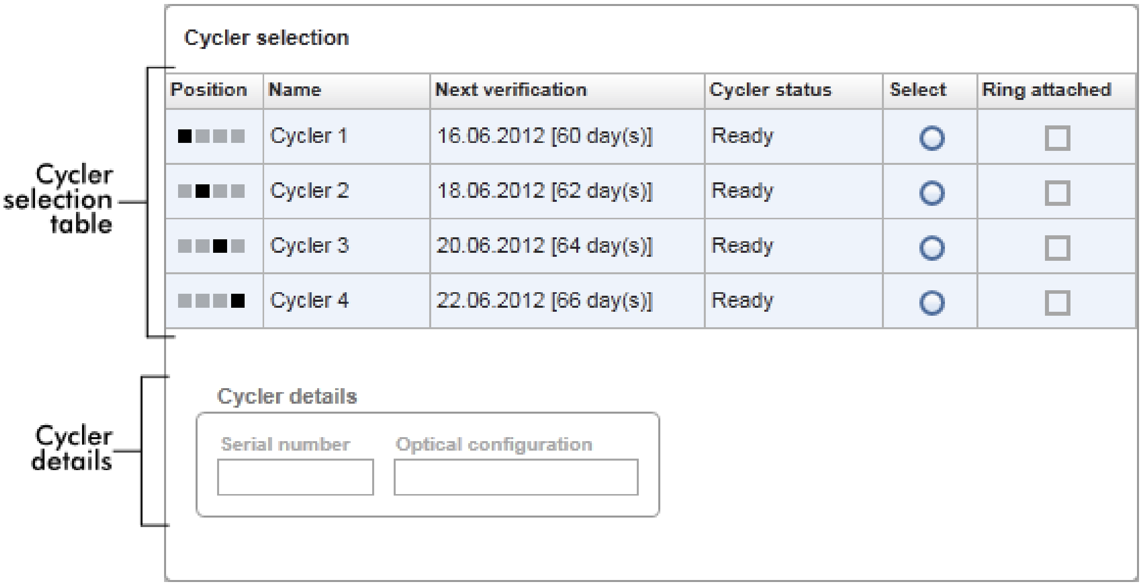
Note
The printout can be used as a pipetting scheme.</td></tr>
</table>

"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 attached
■□□□	Cycler 1	16.06.2012 [60 day(s)]	Ready	○	☐
□■□□	Cycler 2	18.06.2012 [62 day(s)]	Ready	○	☐
□□■□	Cycler 3	20.06.2012 [64 day(s)]	Ready	○	☐
□□□■	Cycler 4	22.06.2012 [66 day(s)]	Ready	○	☐

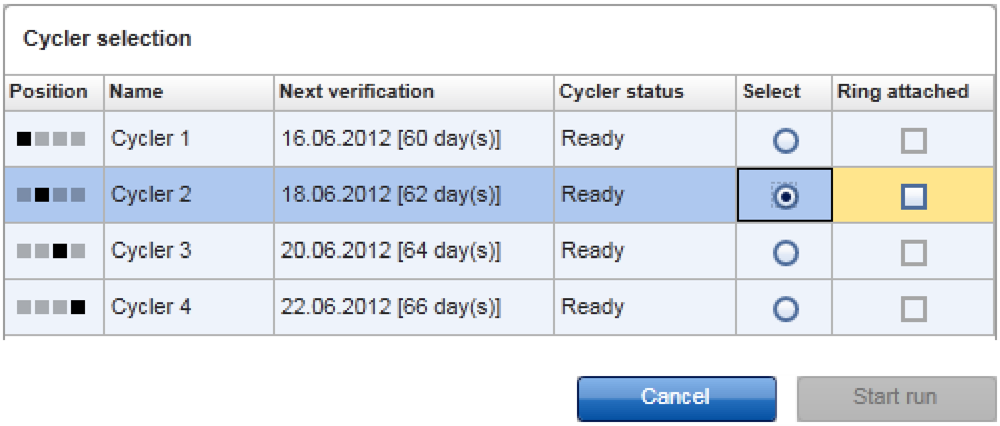
Cycler details

Serial number	Optical configuration

The "Cycler selection" table has 4 rows, representing the maximum of 4 cyclers that can be operated by Rotor-Gene AssayManager v1.0. 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 work list 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.

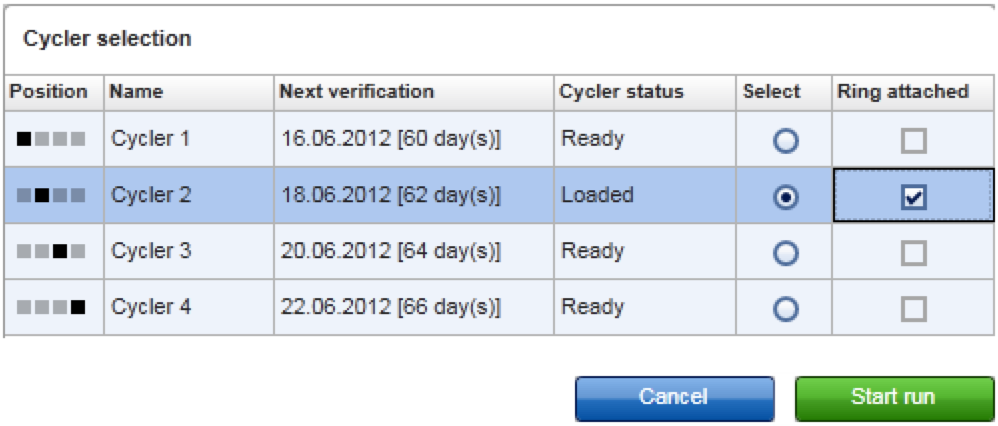
Note
A successful cycler selection requires at least that the optical configuration of a cycler matches the configuration defined by the assay profiles referenced in the work list.



Cycler selection

Position	Name	Next verification	Cycler status	Select	Ring attached
■□□□	Cycler 1	16.06.2012 [60 day(s)]	Ready	○	☐
□■□□	Cycler 2	18.06.2012 [62 day(s)]	Ready	●	☐
□□■□	Cycler 3	20.06.2012 [64 day(s)]	Ready	○	☐
□□□■	Cycler 4	22.06.2012 [66 day(s)]	Ready	○	☐

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

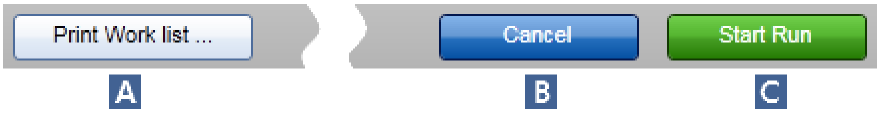


Cycler selection

Position	Name	Next verification	Cycler status	Select	Ring attached
■□□□	Cycler 1	16.06.2012 [60 day(s)]	Ready	○	☐
□■□□	Cycler 2	18.06.2012 [62 day(s)]	Loaded	●	☑
□□■□	Cycler 3	20.06.2012 [64 day(s)]	Ready	○	☐
□□□■	Cycler 4	22.06.2012 [66 day(s)]	Ready	○	☐

Button bar

The button bar contains 3 interactive buttons:



	Label/Title	Description
A	"Print work list..."	Generation of a work list report in *.pdf format with the following structure: Work list 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 work list can also be printed by clicking the "View sample details..." button; see ▶ Printing work list using view sample details button. Note The printout can be used as a pipetting scheme.
B	"Cancel"	▪ The application process is canceled.

		▪ The "Apply work list" screen is closed without saving any changes. ▪ The "Available work lists" 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 v1.0 switches to the "Cycler" environment of the selected cycler.

Tasks related to the "Run work list" view

- Starting a run
- Managing cyclers
- Setting work list naming options

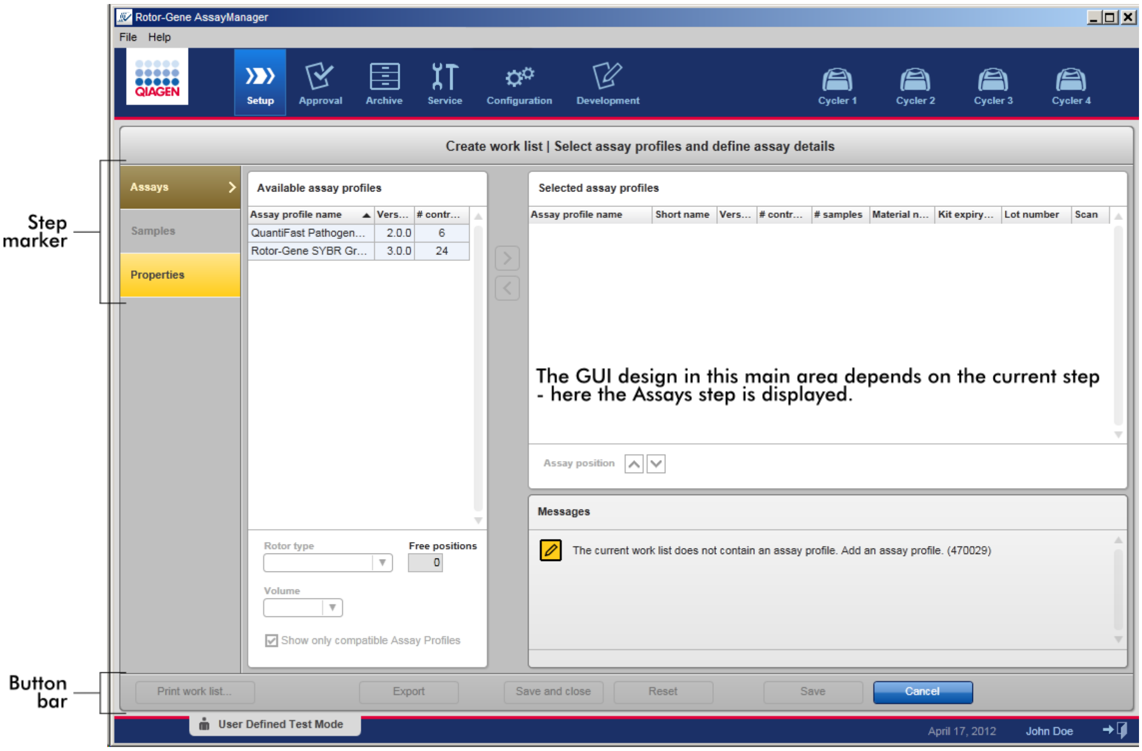
1.5.5.1.3 Create New/Edit Work List View

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

The task of creating a new work list/editing a work list is subdivided into 3 steps:

- "Assays"
- "Samples"
- "Properties"

The screen layout 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 3 steps.



Create work list | Select assay profiles and define assay details

Available assay profiles

Assay profile name	Vers...	# contr...
QuantiFast Pathogen...	2.0.0	6
Rotor-Gene SYBR Gr...	3.0.0	24

Rotor type:

Free positions: 0

Volume:

☑ Show only compatible Assay Profiles

Selected assay profiles

Assay profile name	Short name	Vers...	# contr...	# samples	Material n...	Kit expiry...	Lot number	Scan

The GUI design in this main area depends on the current step - here the Assays step is displayed.

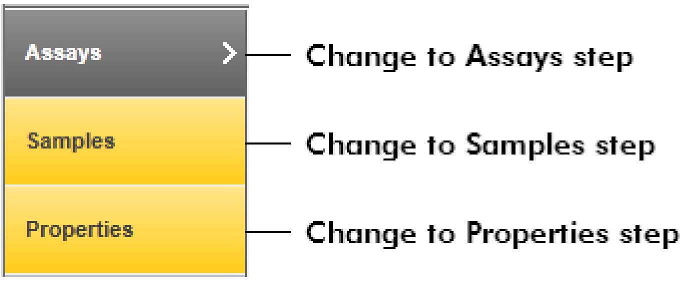
Assay position

Messages

The current work list does not contain an assay profile. Add an assay profile. (470029)

Step marker

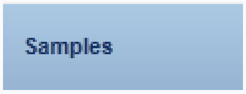
The step marker is used to change between the 3 different steps.



Note

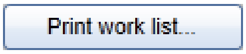
It is not necessary to follow the 3 steps one after another. The steps can be accessed arbitrarily. Unsaved changes are maintained if the user changes to another step.

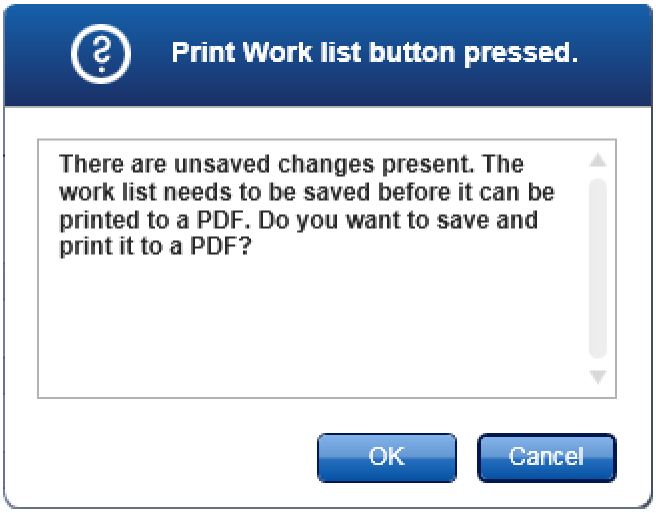
The coloring of the step marker changes, depending on whether errors occur and if the step is currently active or not.

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



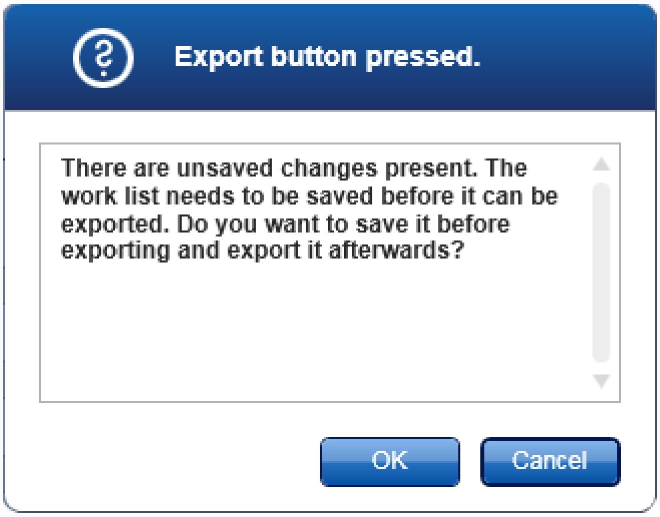
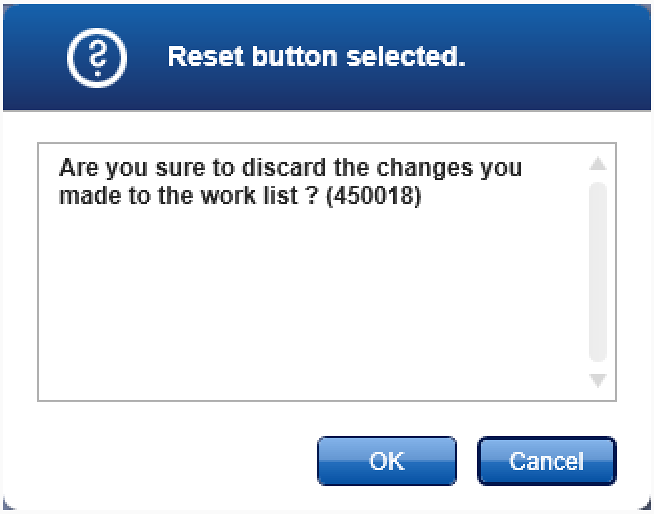
Print Work list button pressed.

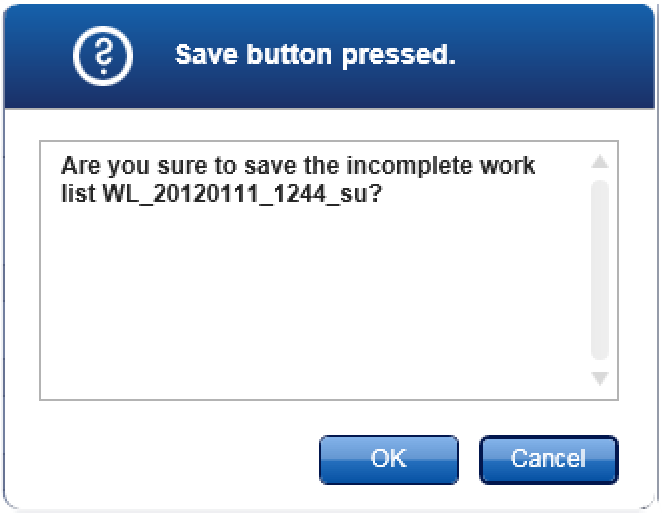
There are unsaved changes present. The work list needs to be saved before it can be printed to a PDF. Do you want to save and print it to a PDF?

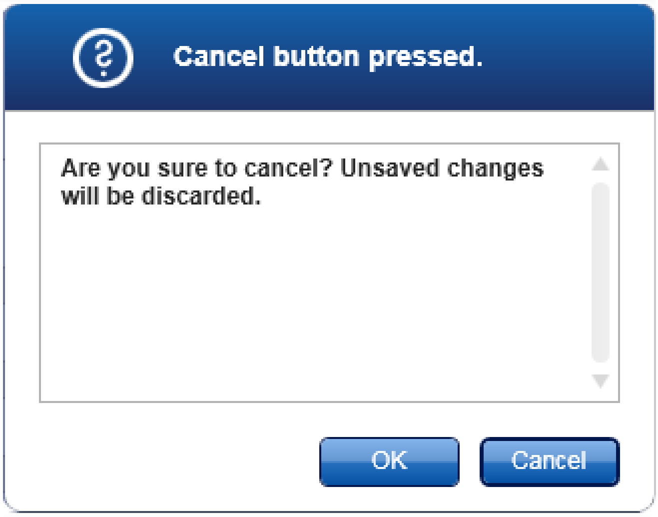
The generated *.pdf has the following structure:

Work list 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 table	▪ Position ▪ Sample ID ▪ Target(s) ▪ Assay type ▪ Comment	

Export	Note: Button is enabled if at least the work list name is valid. Task: Export the work list as *.iwl file. The *.iwl file can be imported to other Rotor-Gene AssayManager v1.0 installations (exchange functionality). If unsaved changes are present, the following warning must be confirmed.

	 Export button pressed. There are unsaved changes present. The work list needs to be saved before it can be exported. Do you want to save it before exporting and export it afterwards?
Save and close	Task: Save the current progress and return to the available work lists table.
Reset	Task: Reset the current creation process. If a new work list was created, all fields are reset to their default value. If an existing work list was edited, unsaved changes of the work list are discarded. After clicking "Reset", the following warning must be confirmed.  Reset button selected. Are you sure to discard the changes you made to the work list ? (450018)
Save	Note: Button is only enabled if unsaved changes exist and a valid work list name has been entered.

	Task: Save the work list. The current work list is saved to the database under the work list name entered in the "Properties" step. The work list is subsequently available in the "Available work lists" table. If a work list was edited, the "Last modified" field is set to the current date, time, and user. If a new work list was created, the "Created" field is set to the current date, time, and user. Clicking "Save" if the work list is still incomplete opens the following dialog:  **Save button pressed.** Are you sure to save the incomplete work list WL_20120111_1244_su? Note: An incomplete work list can be saved if at least a valid work list name was entered. If an incomplete work list is saved, Rotor-Gene AssayManager v1.0 displays a warning that has to be confirmed.
Cancel	Task: Cancel the creation process. All entries are deleted and the "Available work lists" table is shown. After clicking "Cancel", the user must confirm that unsaved data will be discarded.



Cancel button pressed.

Are you sure to cancel? Unsaved changes will be discarded.

Apply	**Task**: Applies the work list. Further information can be found under ▶ Apply work list view.

Assays step

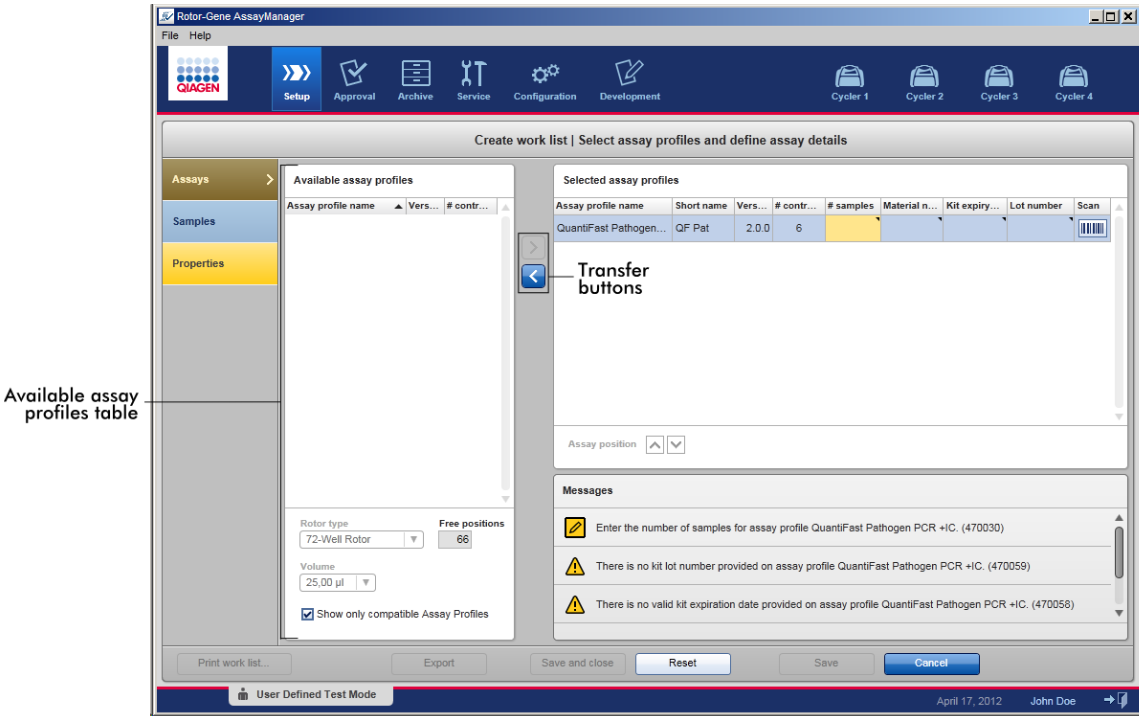
In this step, the user assembles a work list by adding assay profiles to the work list. In its simplest form, only one assay profile is added to the work list. It is also possible to add multiple, compatible assay profiles.

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



Create work list | Select assay profiles and define assay details

Available assay profiles

Assay profile name	Vers...	# contr...

Rotor type: 72-Well Rotor

Free positions: 66

Volume: 25,00 µl

☑ Show only compatible Assay Profiles

Selected assay profiles

Assay profile name	Short name	Vers...	# contr...	# samples	Material n...	Kit expiry...	Lot number	Scan
QuantiFast Pathogen...	QF Pat	2.0.0	6					

Messages

- Enter the number of samples for assay profile QuantiFast Pathogen PCR +IC. (470030)
- There is no kit lot number provided on assay profile QuantiFast Pathogen PCR +IC. (470059)
- There is no valid kit expiration date provided on assay profile QuantiFast Pathogen PCR +IC. (470058)

April 17, 2012 John Doe

Select and edit assay profiles:

- Select one assay profile for the work list from the "Available assay profiles" table and add it; in case the work list 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.

Depending on the settings in the ▸ "Configuration" environment, the following data might have to be entered in the selected assay profiles table for every selected assay:

- Number of samples
- Material number
- Kit expiry date
- Lot number

Note

These data (except the number of samples) can either be entered manually in the individual boxes or by using a bar code scanner.
To activate the bar code scanning function, click the bar code symbol in the very right column. The "Scan QIAGEN Kit Bar code" dialog opens. The bar code of the dedicated QIAGEN kit can be scanned. 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.

We recommend the bar code scanner delivered with QIAsymphony instruments, which can be ordered separately from QIAGEN (Handscanner Touch 65-PRO m.CAB-412/USB A, cat. no. 9241227).

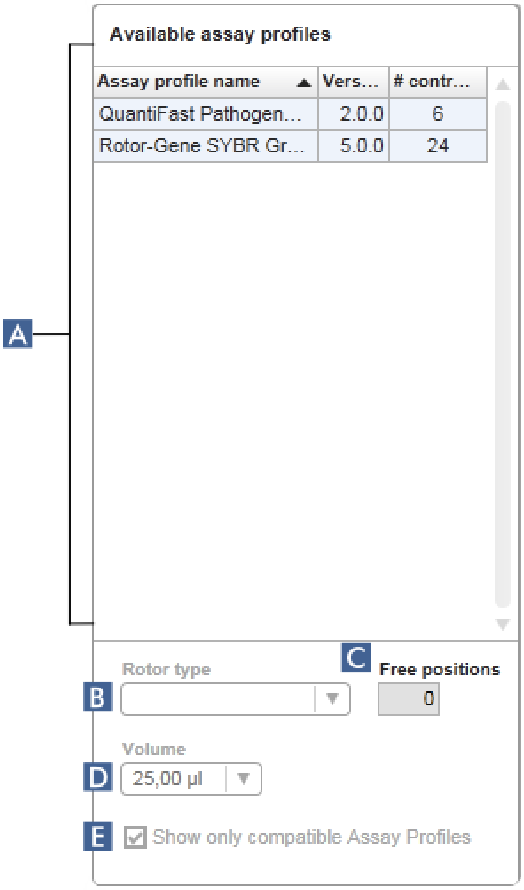
Transfer buttons

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

Icon	Description
>	Transfer the selected assay profile from the "Available assay profiles" table to the "Selected assay profiles" table. This button is enabled if: ▪ 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.
<	Remove the selected assay profile from the "Selected assay profiles" table. This button is enabled if an entry is selected in the "Selected assay profiles" table.

"Available assay profiles" table

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



Available assay profiles

Assay profile name ▲	Vers...	# contr...
QuantiFast Pathogen...	2.0.0	6
Rotor-Gene SYBR Gr...	5.0.0	24

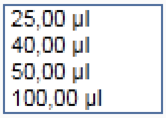
Rotor type

Free positions: 0

Volume: 25,00 µl

☑ Show only compatible Assay Profiles

	Label/Title	Description
A	"Available assay profiles" table	Table of all available assay profiles with the following columns: ▪ Name of assay profile ▪ Version number ▪ Number of external controls used by the corresponding assay.
B	"Rotor type" selection menu	Drop-down menu with predefined rotor types. Select one rotor type for the new work list.

		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 must be removed from the "Selected assay profiles" using the transfer button <.
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 work list. 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 "<".
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.

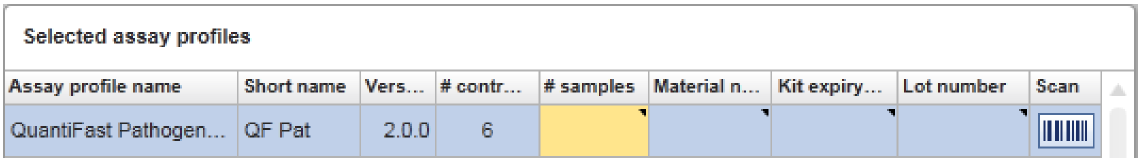
Note

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 work list (one or multiple) are listed in the "Selected assay profiles" table. This table is not sortable.

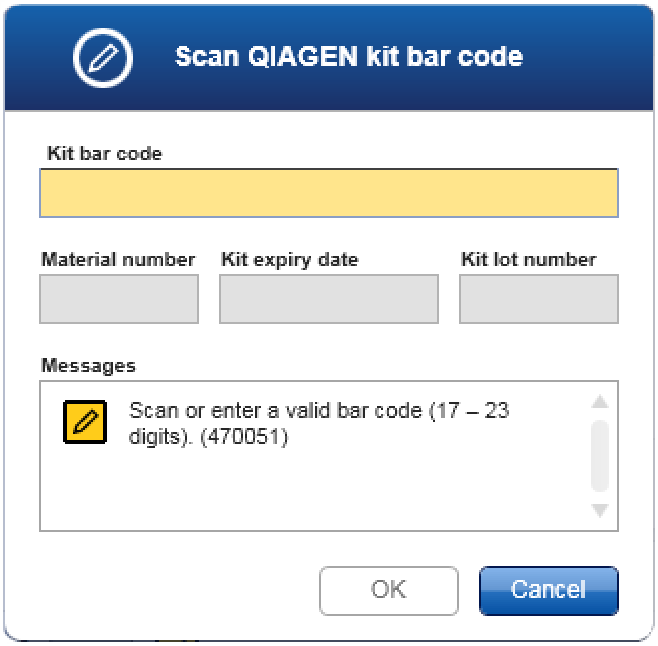


Selected assay profiles

Assay profile name	Short name	Vers...	# contr...	# samples	Material n...	Kit expiry...	Lot number	Scan
QuantiFast Pathogen...	QF Pat	2.0.0	6					

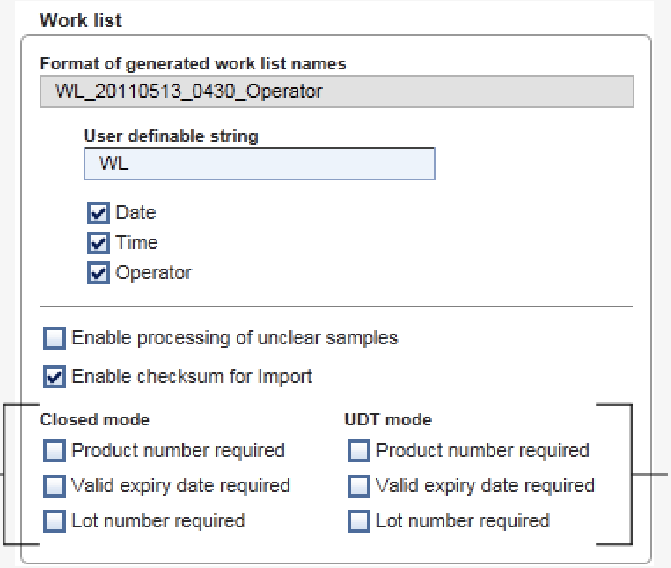
This table contains data given by the respective assay profile and data that has to be entered manually or with a bar code scanner. The following table shows the source for every column:

Column	Source for column data
"Assay profile name"	Values given by the assay profile
"Short name"	
"Version"	
"# controls"	
"# samples"	Manual input required
"Material number"	Input required either manually or by using a bar code scanner
"Kit expiry date"	
"Lot number"	
"Scan"	Values are entered either manually or via scanning the bar code of the respective QIAGEN kit. Click ▥ in the very right column to open the following "Scan QIAGEN kit bar code" dialog:

Column		Source for column data
		 Scan or enter a valid bar code (17 – 23 digits). (470051) Using the bar code dialog facilitates the tedious task of manually entering the material number, expiry date, and lot number of the kit. The bar codes of QIAGEN kits contain the information as bar code itself and as a sequence of digits. The user can either scan the bar code using a bar code scanner or enter the bar code digits into the "Kit bar code" field.

Note

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



Work list

Format of generated work list names

WL_20110513_0430_Operator

User definable string

WL

☑ Date
☑ Time
☑ Operator

☐ Enable processing of unclear samples
☑ Enable checksum for Import

Closed mode
☐ Product number required
☐ Valid expiry date required
☐ Lot number required

UDT mode
☐ Product number required
☐ Valid expiry date required
☐ Lot number required

Requirements settings for work lists in Closed Mode

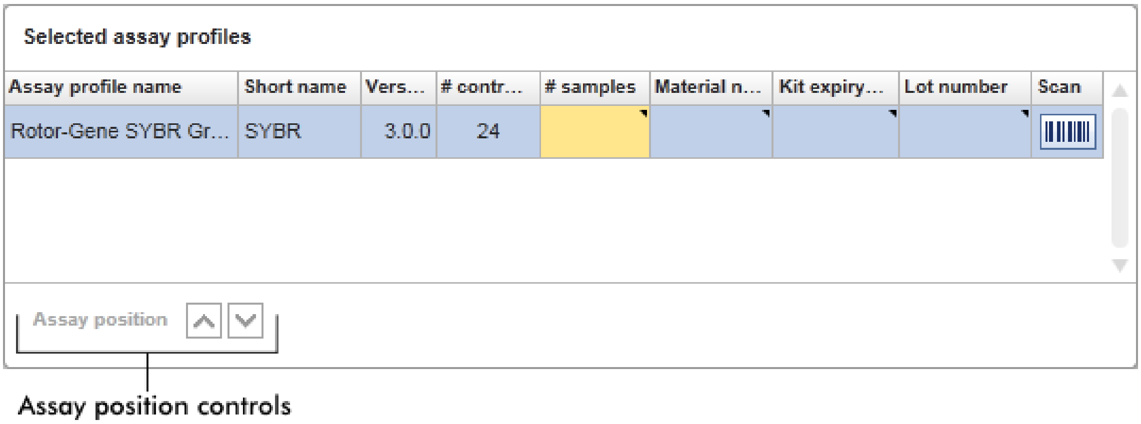
Requirements settings for work lists in UDT Mode

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 (check box 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".

"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...	# contr...	# samples	Material n...	Kit expiry...	Lot number	Scan
Rotor-Gene SYBR Gr...	SYBR	3.0.0	24					

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

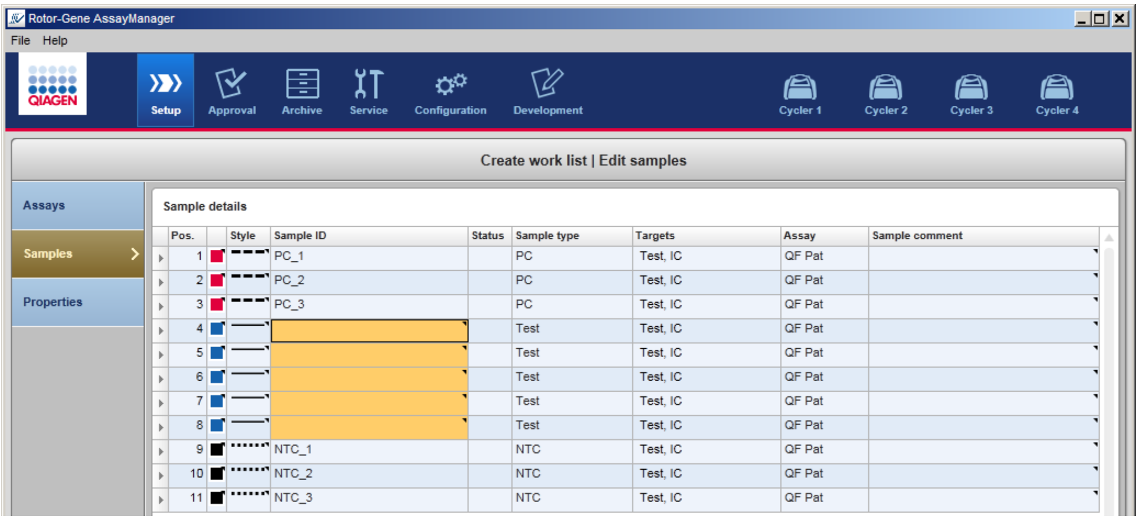
The "Samples" step shows the sample details in tabular form. All sample types from all selected assay profiles are displayed here. In case multiple assay profiles were added, they are listed subsequently.

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

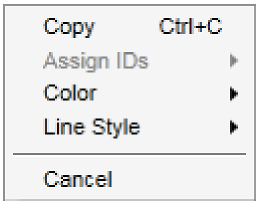


Pos.		Style	Sample ID	Status	Sample type	Targets	Assay	Sample comment
1	🟥	- - -	PC_1		PC	Test, IC	QF Pat	
2	🟥	- - -	PC_2		PC	Test, IC	QF Pat	
3	🟥	- - -	PC_3		PC	Test, IC	QF Pat	
4	🟦	—			Test	Test, IC	QF Pat	
5	🟦	—			Test	Test, IC	QF Pat	
6	🟦	—			Test	Test, IC	QF Pat	
7	🟦	—			Test	Test, IC	QF Pat	
8	🟦	—			Test	Test, IC	QF Pat	
9	⬛	······	NTC_1		NTC	Test, IC	QF Pat	
10	⬛	······	NTC_2		NTC	Test, IC	QF Pat	
11	⬛	······	NTC_3		NTC	Test, IC	QF Pat	

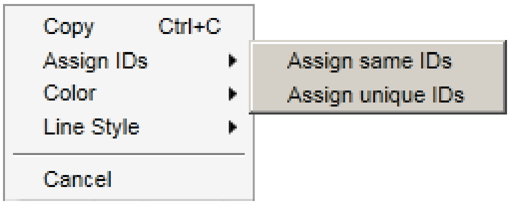
The editable columns of the samples details table (line color, line style, ID, and comment) have a pop-up menu, which can be accessed by a right click in the respective column. The columns are described in the following table:

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: Unselected row ▹ 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.

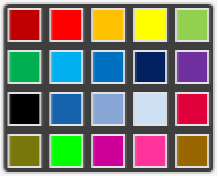
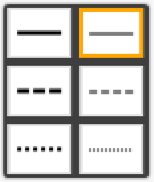


Pop-up menu for a single row selection



Pop-up menu for multiple row selection

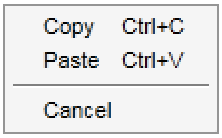
Label/Title		Description
"Assign ID"	"Assign same IDs"	Assigns the ID value from the first cell of the selection to all other selected cells.
	"Assign unique IDs"	Based on the ID of the first selected cell, an incremental number is added to all selected cells. Example: If first cell has the ID *Sample*, the generated values are *Sample 1*, *Sample 2*, *Sample 3*, etc. 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 *1*, *2*, *3*, etc.
"Color"		Open a color palette where the user can select a specific color for the amplification curve of the selected samples. 
"Line Style"		Open a style palette where the user can select a specific line

	style for the amplification curve of the selected samples. 
"Pos."	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 work list consists of multiple assay profiles). The maximum position number is restricted by the selected rotor type.
Line color	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.  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.

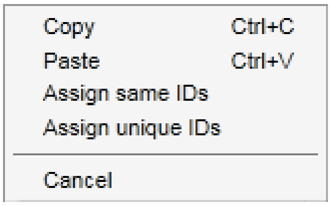
<table>
<tr><td>"Sample ID"</td><td>

The sample ID must 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

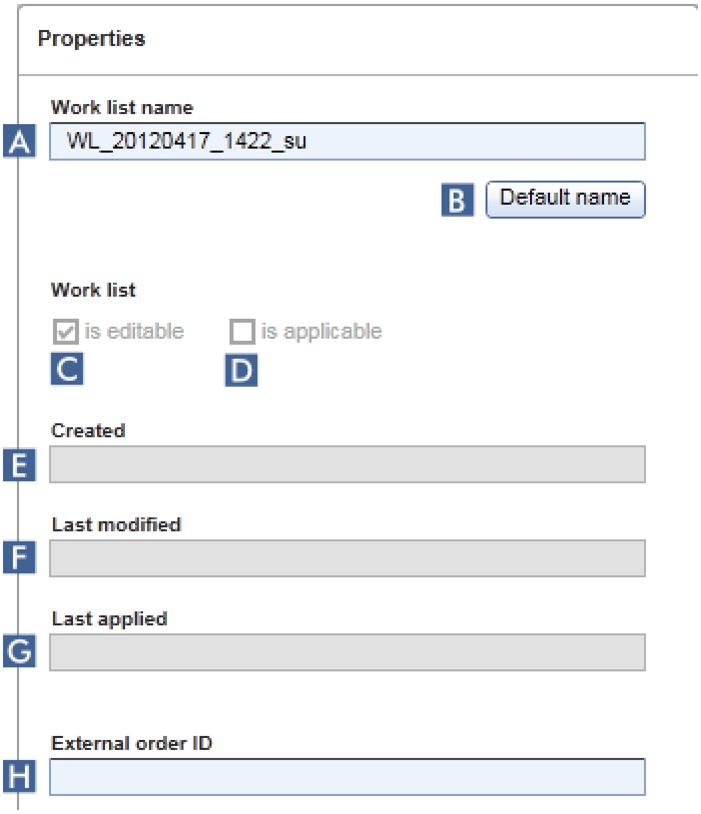
<table>
<tr><th>Label/Title</th><th>Description</th></tr>
<tr><td>"Copy"</td><td>Copy the content of the selected ID cells — single or multiple — to the clipboard.</td></tr>
<tr><td>"Paste"</td><td>Paste the content of the clipboard to the selected cell. A warning is displayed before data is overwritten.</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>

</td></tr>
<tr><td>"Status"</td><td>Note: This column is used only if a QIAsymphony work list is imported.</td></tr>
</table>

	Possible statuses of samples from a QIAsymphony work list are: ▪ Valid ▪ Invalid ▪ Unclear ▪ None (empty field) is the status if QIAsymphony has not been used.
"Sample type"	The sample type is listed in this field. Possible values are: ▪ Test — Test sample ▪ NTC — No template control ▪ PC — Positive control ▪ EC+ — Positive extraction control ▪ EC- — Negative extraction control ▪ QS — Quantitation standard
"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 work list a name, either by entering the name manually or by using a generated default name. Furthermore, 2 options may be set (work list "is editable" and "is applicable").



Properties

Work list name: WL_20120417_1422_su

Work list

☑ is editable
☐ is applicable

Created:

Last modified:

Last applied:

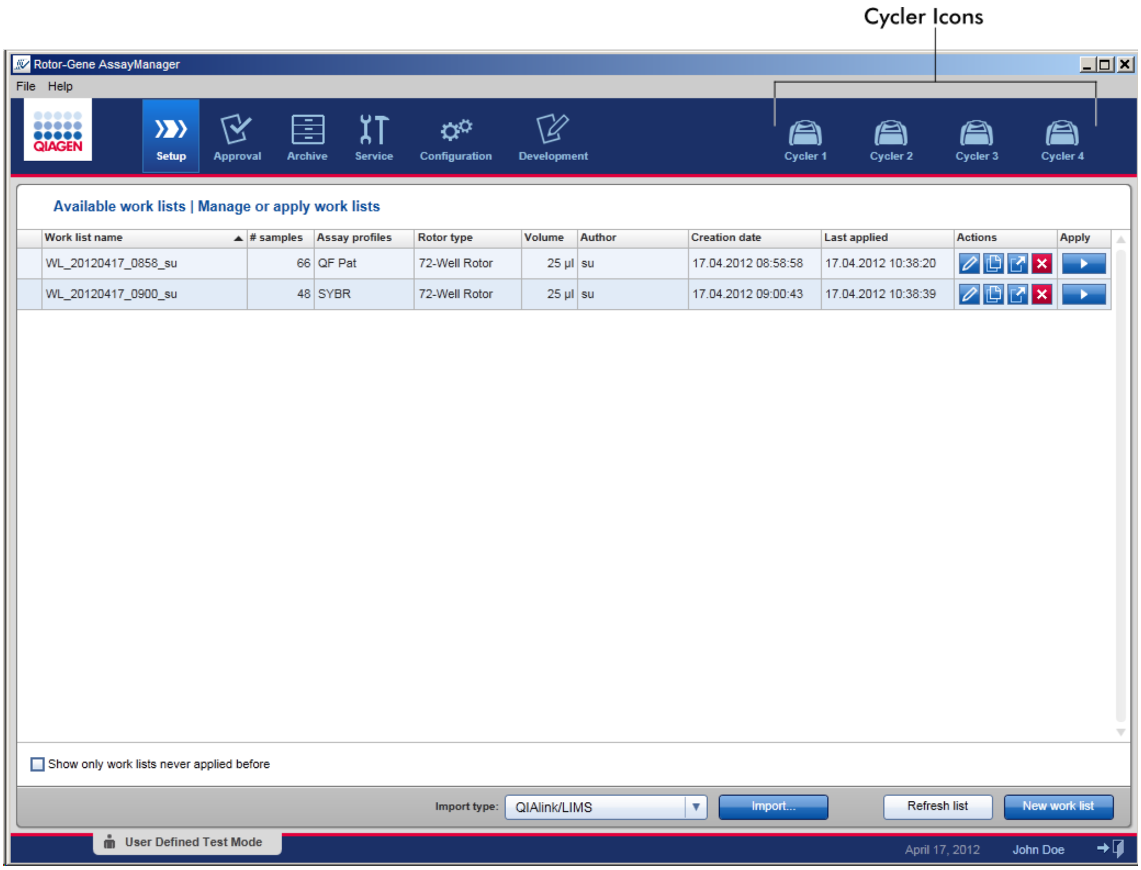
External order ID:

<table>
<tr><th></th><th>Label/Title</th><th>Description</th></tr>
<tr><td>A</td><td>"Work list name"</td><td>Text field to enter a name for the new work list.
Note
Maximum length for the name is 40 characters. The entered name must be unique (in case a new work list is created).</td></tr>
<tr><td>B</td><td>"Default name"</td><td>Automatically generate a name for the work list. The pattern for the generated name is defined in the ▶ "Configuration" environment under ▶ "Settings".</td></tr>
<tr><td>C</td><td>"Is editable" check box</td><td>Determines whether a work list can be modified later. This check box is disabled by default. It is enabled when the "work list is ready to be applied" check box is activated.
If not activated: Work list cannot be modified later. The "Edit work list" icon in the action bar is deactivated: ✎
If activated: Work list can be modified later. The "Edit work list" icon in the action bar is activated: ✎</td></tr>
<tr><td>D</td><td>"Is applicable" check box</td><td>Determines whether a work list can be applied:
If not activated: Work list cannot be applied.
If activated: Work list 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:
<table>
<tr><th>"Is applicable" unchecked</th><th>"Is applicable" checked</th></tr>
<tr><td>Apply</td><td>Apply</td></tr>
<tr><td>"Apply" button in button bar is disabled.</td><td>"Apply" button in button bar is disabled.</td></tr>
<tr><td>Work list
☑ is editable</td><td>Work list
☑ is editable</td></tr>
</table>
</td></tr>
</table>

		"Is editable" check box is disabled. "Is editable" check box is enabled.
E	"Created" info field	Displays who created the work list and when (field is populated upon saving).
F	"Last modified" info field	Displays who modified the work list and when (field is populated upon saving).
G	"Last applied" info field	Displays when the work list was last applied.
H	"External order ID"	Optional field that can be used for work lists 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 Cycler Environment

The "Cycler" environment is used for the cyclers and gives an overview about all Rotor-Gene Q instruments accessible by Rotor-Gene AssayManager v1.0. Up to 4 different Rotor-Gene Q cyclers can be registered and subsequently controlled by Rotor-Gene AssayManager v1.0 in parallel. The different cyclers are represented by individual "Cycler" icons, which are always displayed at the very top right of the Rotor-Gene AssayManager v1.0 screen.


Cycler Icons

Available work lists | Manage or apply work lists

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		

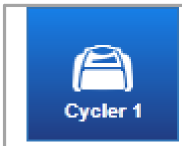
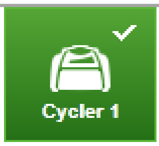
☐ Show only work lists never applied before

Import type: QIAlink/LIMS

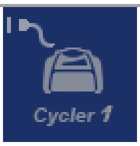
The content of the "Cycler" environment depends on whether a cycler is currently idle, in operation, or whether a run has been stopped but not yet released. The visual appearance of the cycler icon indicates the current state of the cycler.

"Cycler" icon

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

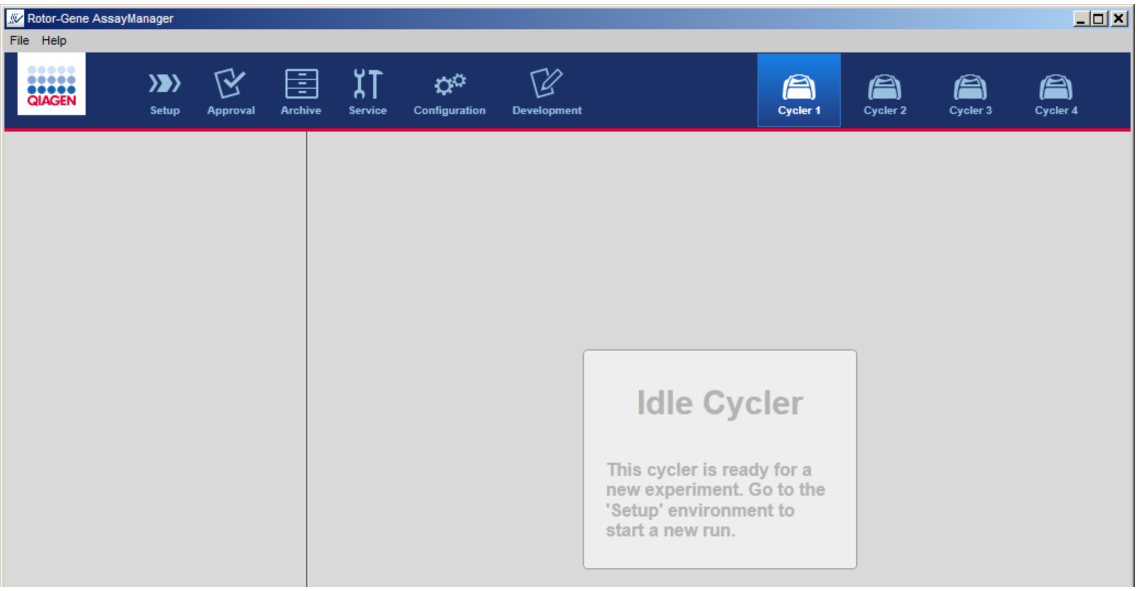
			
Cycler idle	Cycler working The progress indicator visualizes the run progress.	Run finished successfully	**Run stopped** (either by clicking "Stop Process" or an error occurred).

Further cycler icons are listed below:

			
Cycler offline	Cycler activated	Invalid verification	Run stopped and cycler offline

"Idle Cycler" screen

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



Idle Cycler

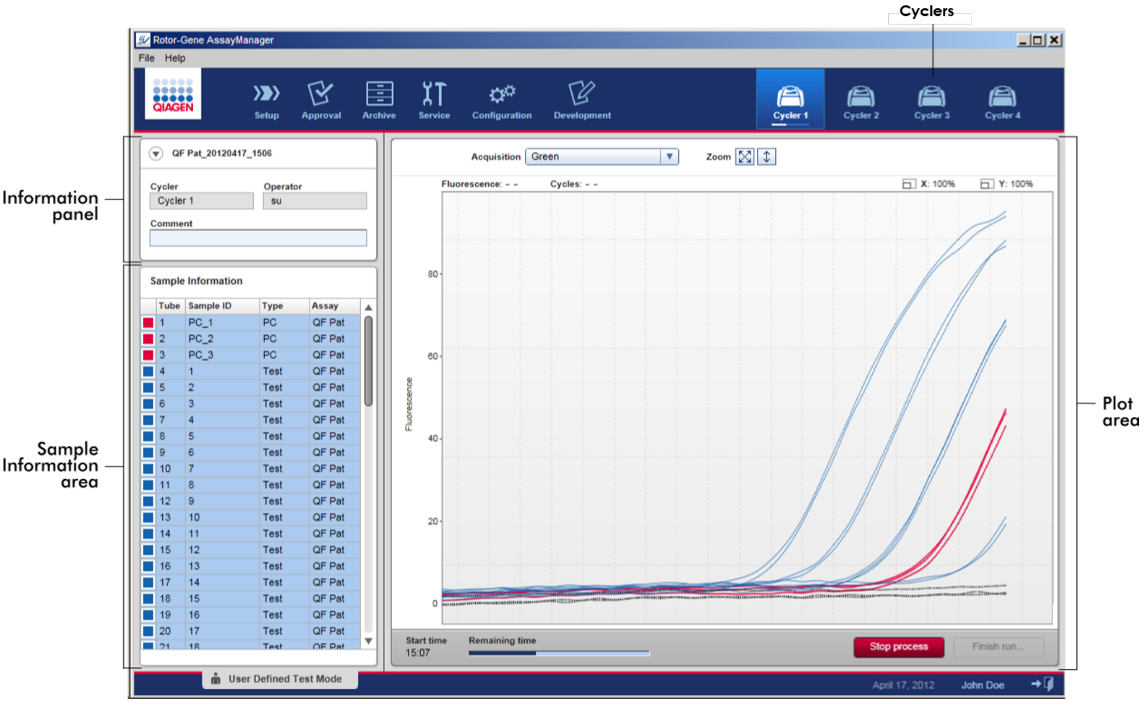
This cycler is ready for a new experiment. Go to the 'Setup' environment to start a new run.

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

- Apply an existing work list from the "Available Work Lists" table.
- Create a new work list 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.



QF Pat_20120417_1506

Cycler: Cycler 1

Operator: su

Comment:

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
🟦	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

User Defined Test Mode

Acquisition: Green

Zoom

Fluorescence: - -   Cycles: - -

X: 100%   Y: 100%

Start time: 15:07

Remaining time

April 17, 2012   John Doe

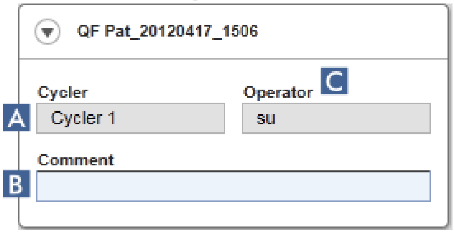
The amplification of the samples is displayed in real time in the plot area. After the run process has finished, the run is released and the sample results can be approved.

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



QF Pat_20120417_1506

Cycler: Cycler 1

Operator: su

Comment:

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 work list setup.
A	Name of the cycler
B	Comment field, maximum 256 characters are allowed
C	Operator name

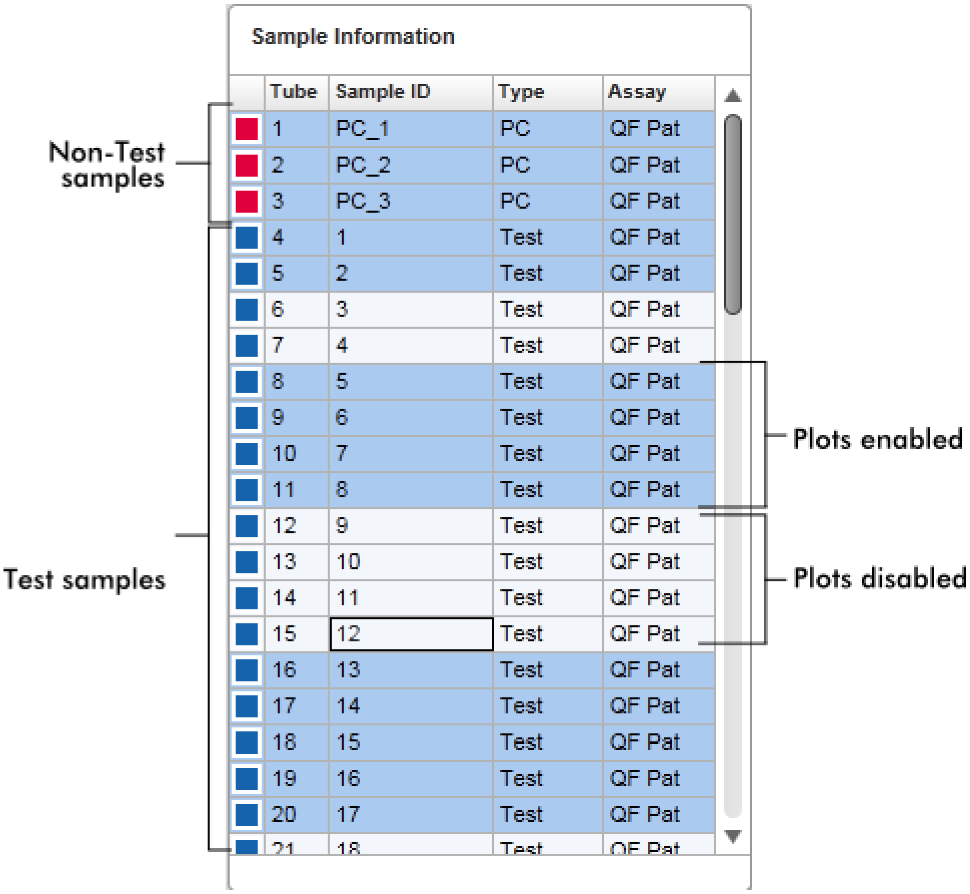
"Sample information" area

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

- Line color (derived from the work list)
- 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

- Assay short name

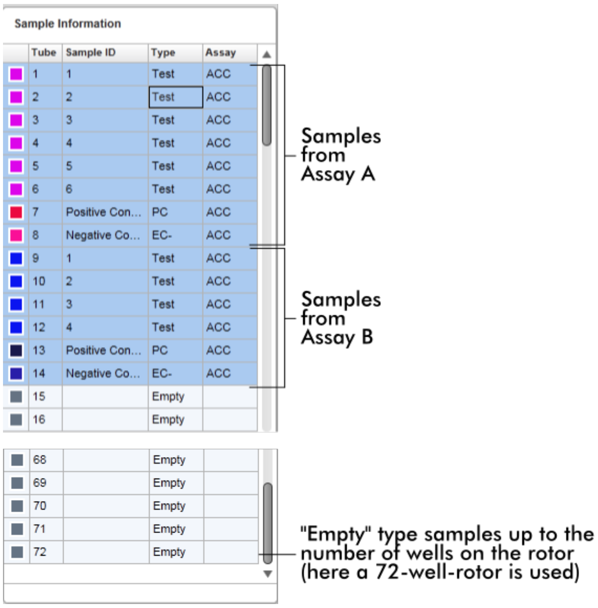


Sample Information

	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
🟦	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	

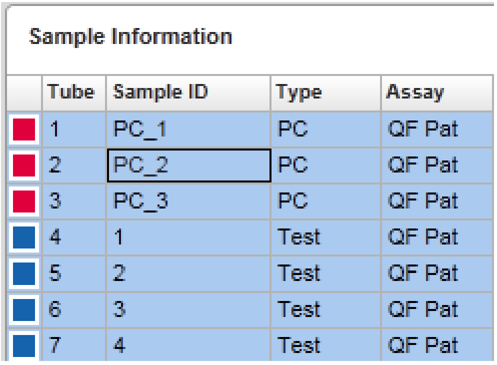
Samples from Assay A

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

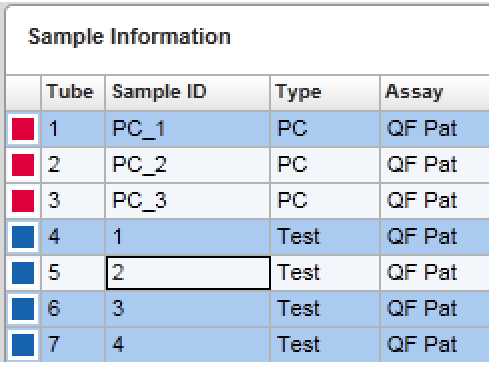
The acquisition plots for specific samples can be hidden or shown in the plot area. Click in the row of the designated sample. By default, all samples used are shown and hence highlighted in a dark blue color. Rows of disabled samples (i.e., hidden acquisition plot) are colored in brighter blue.



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

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



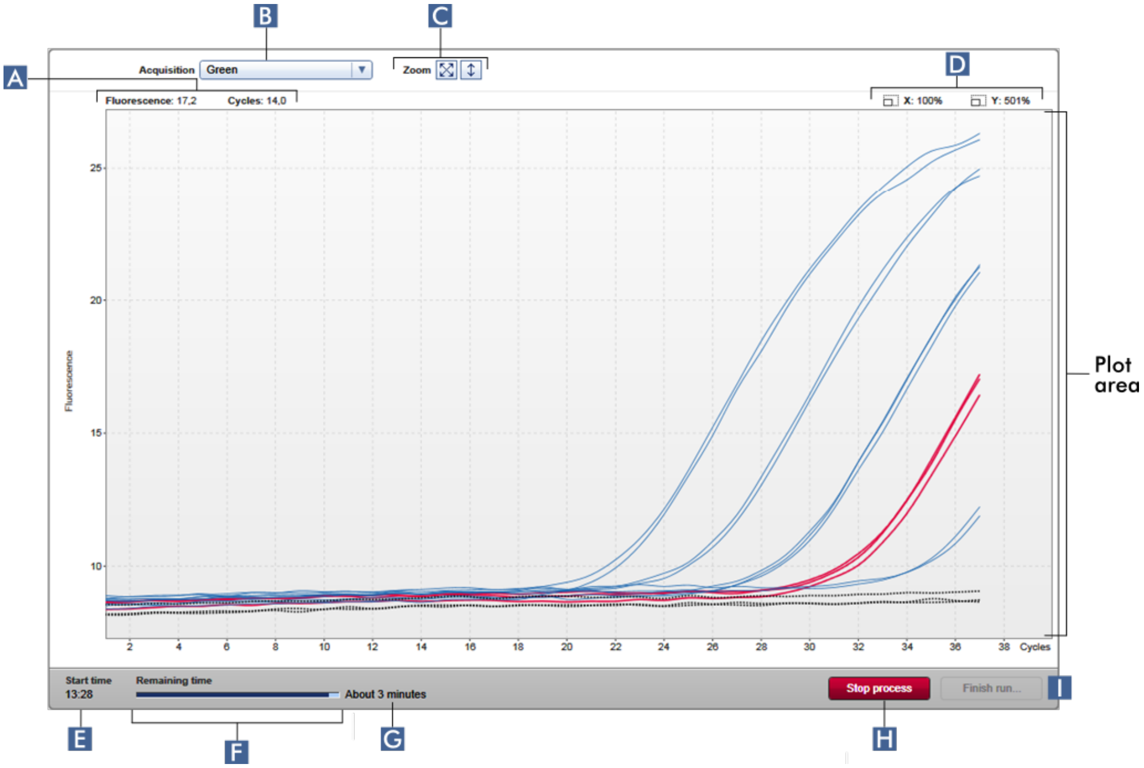
Sample Information

	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

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.



Acquisition: Green

Fluorescence: 17,2 Cycles: 14,0

X: 100% Y: 501%

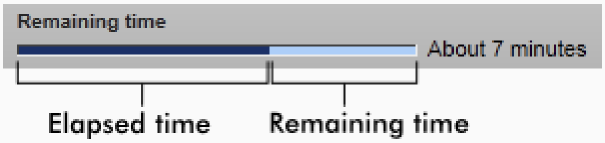
Start time 13:28

Remaining time About 3 minutes

	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. ⤢ 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

<table>
<tr><td></td><td></td><td>the number of cycles in the run profile, and the y-axis is set to 100.

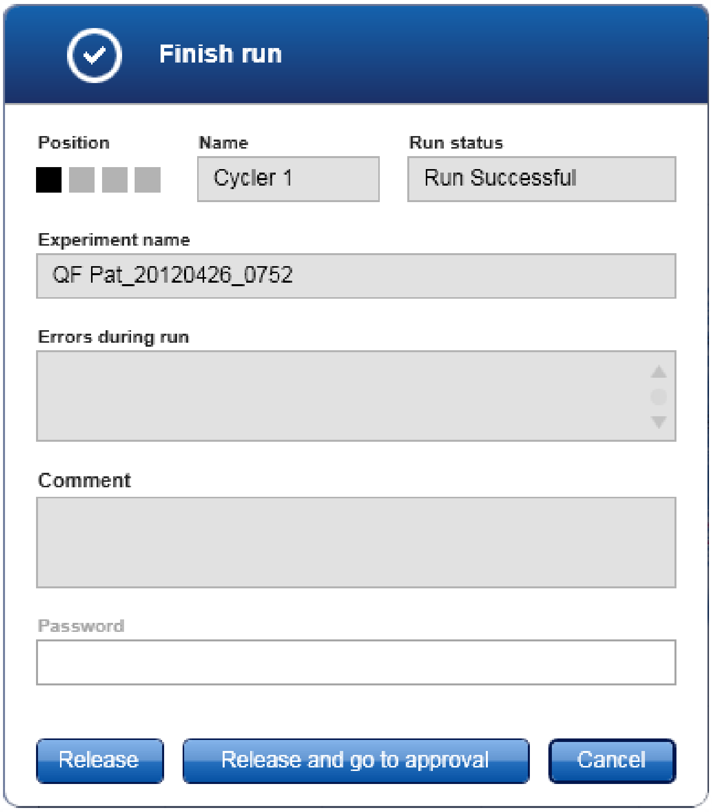
↕ The auto scale button fits the scale to the maximum and minimum readings in the data. The y-axis range is restricted to the lowest and highest measured fluorescence value. The x-axis is set to a maximum value equal to the number of cycles in the run profile.</td></tr>
<tr><td>D</td><td>Zoom factors</td><td>Displays zoom factors separately for the x-axis and the y-axis.</td></tr>
<tr><td>E</td><td>"Start time"</td><td>Displays the start time of the run.</td></tr>
<tr><td>F</td><td>Progress indicator bar</td><td>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:

<table>
<tr><th>Text</th><th>Explanation</th></tr>
<tr><td>"Remaining time"</td><td>Ongoing experiment</td></tr>
<tr><td>"Analyzing"</td><td>Experiment was finished, analysis has started</td></tr>
<tr><td>"Ready"</td><td>Experiment analysis finished</td></tr>
</table></td></tr>
<tr><td>G</td><td>"Remaining time" estimation</td><td>Displays the estimated remaining time.</td></tr>
<tr><td>H</td><td>"Stop process"</td><td>Stops the run.

After clicking the "Stop process" button, a warning dialog must be confirmed to stop the run. The run will be stopped</td></tr>
</table>

		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:  **Finish run** Position: ■ ■ ■ ■ Name: Cycler 1 Run status: Run Successful Experiment name: QF Pat_20120426_0752 Errors during run: Comment: Password: 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

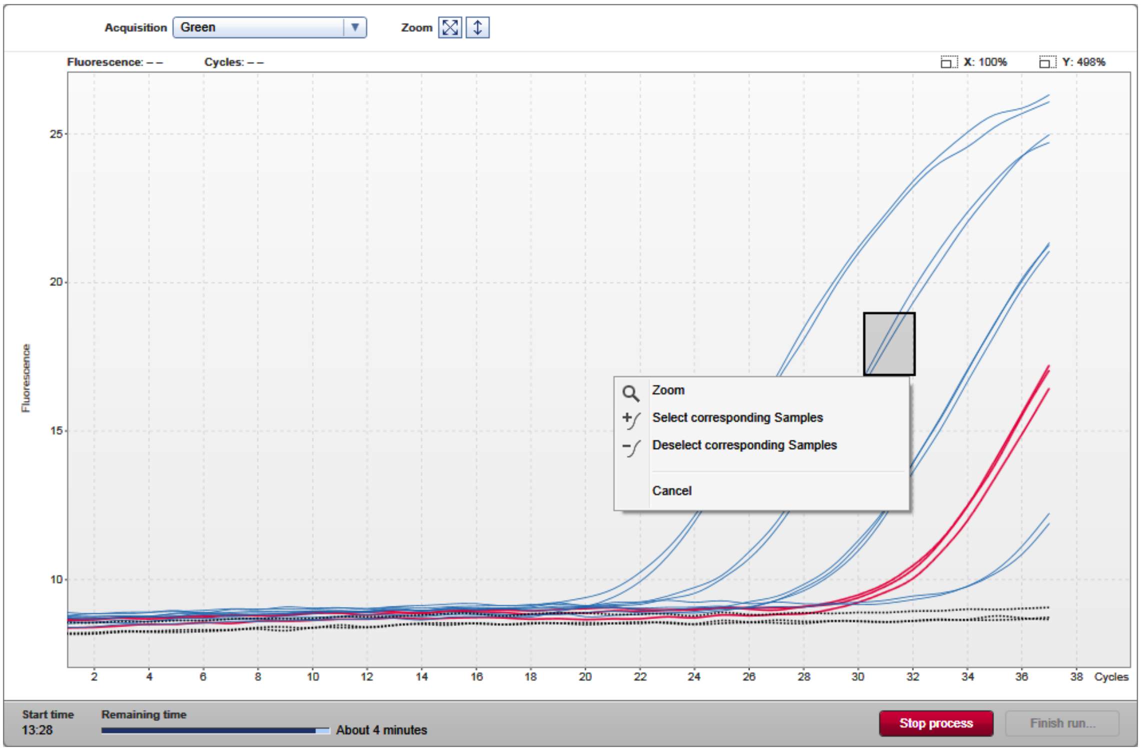
	If this setting is deactivated, the run can be approved in the "Approval" environment without releasing the run. For further information, see ▶ "Configuration" environment.

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.



Acquisition: Green

Fluorescence: – –

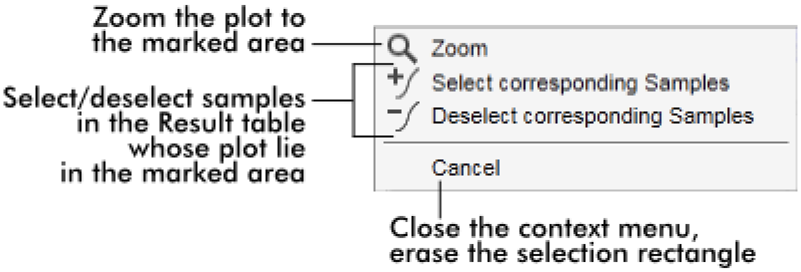
Cycles: – –

X: 100%

Y: 498%

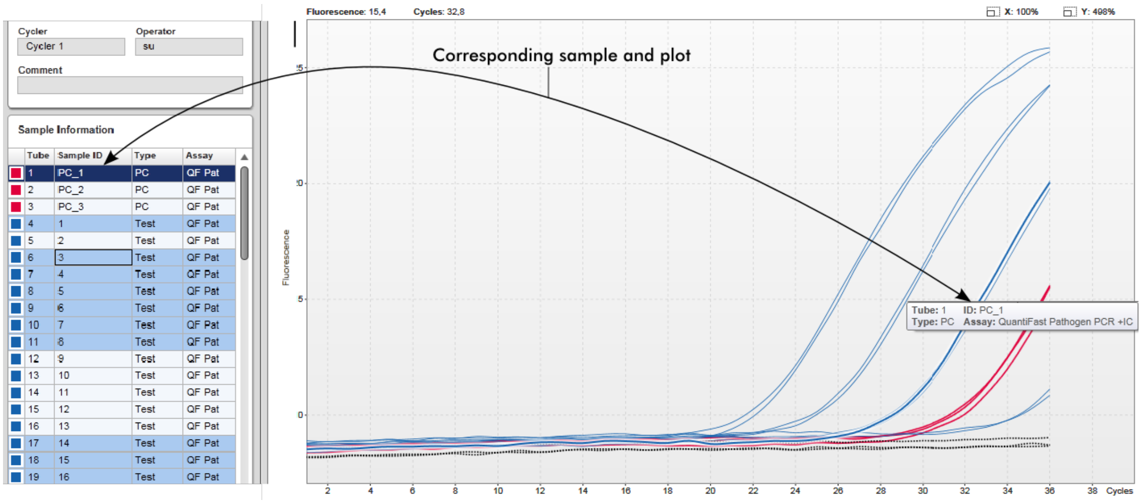
Start time 13:28

Remaining time About 4 minutes



- 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



Cycler: Cycler 1
Operator: su
Comment:

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
🟦	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

Fluorescence: 15,4 Cycles: 32,8 X: 100% Y: 498%

Tube: 1 ID: PC_1
Type: PC Assay: QuantiFast Pathogen PCR +IC

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
▪ Undefined ▪ Accepted ▪ Rejected	▪ 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

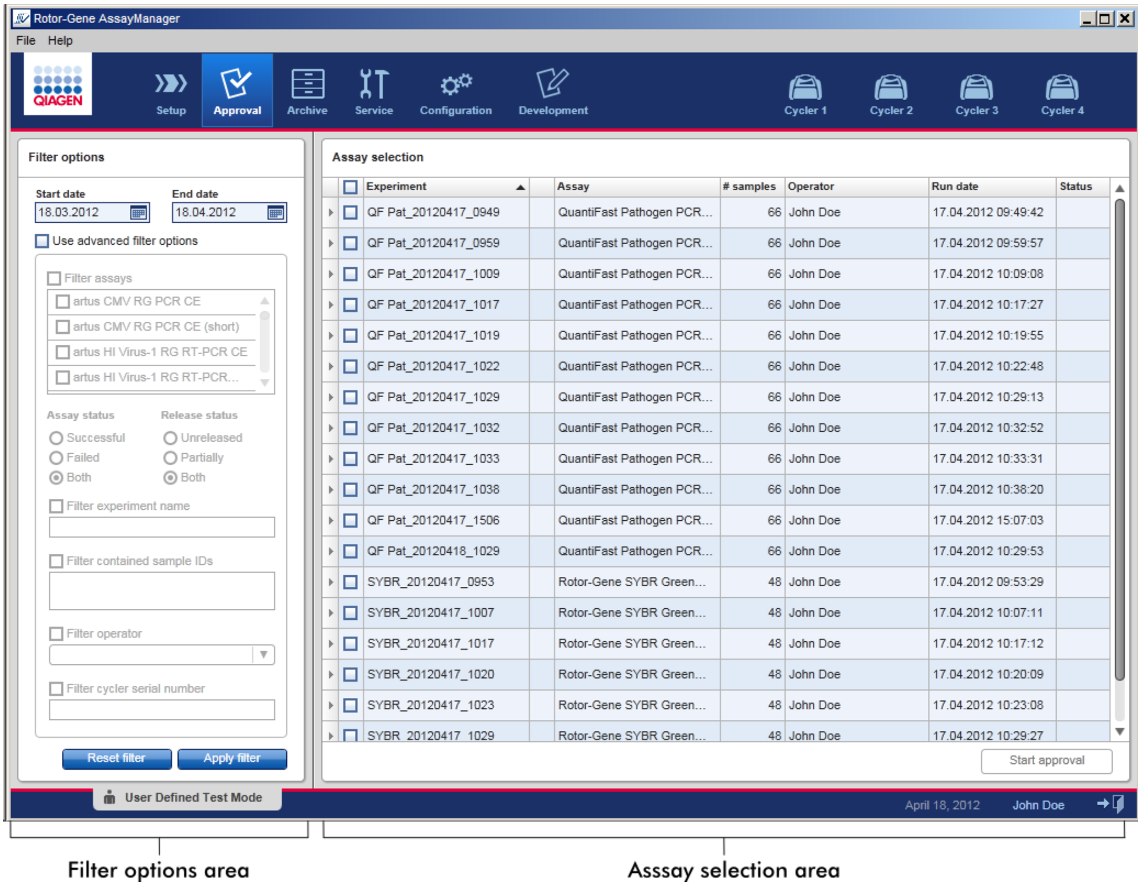
1.5.5.3.1 Filter Screen

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



Start date: 18.03.2012
End date: 18.04.2012

☐ Use advanced filter options

☐ Filter assays
☐ artus CMV RG PCR CE
☐ artus CMV RG PCR CE (short)
☐ artus HI Virus-1 RG RT-PCR CE
☐ artus HI Virus-1 RG RT-PCR...

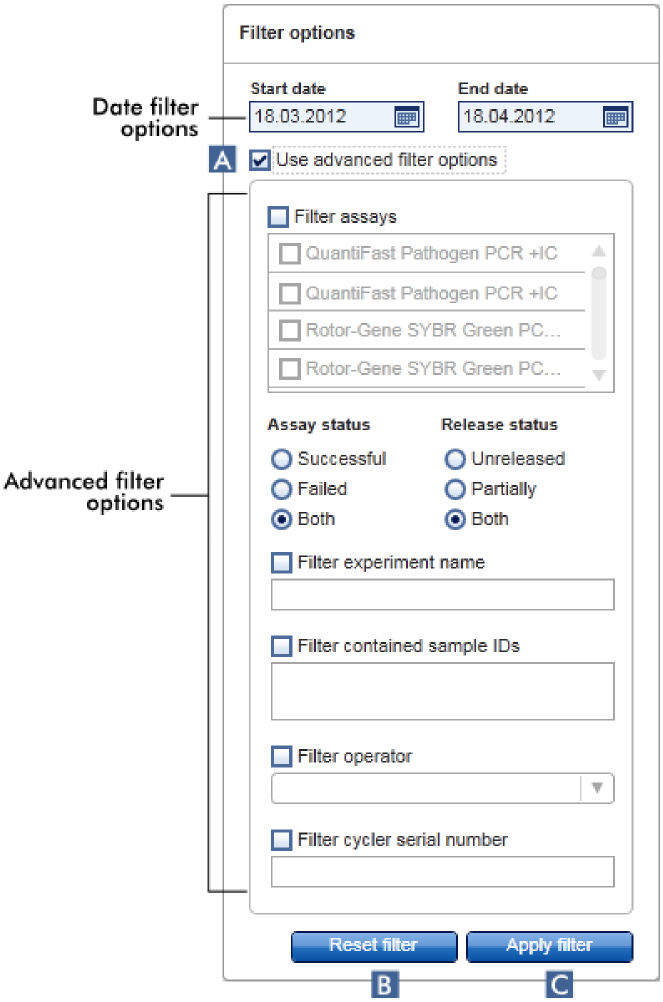
Assay status: ○ Successful ○ Failed ● Both
Release status: ○ Unreleased ○ Partially ● Both

☐ Filter experiment name
☐ Filter contained sample IDs
☐ Filter operator
☐ Filter cycler serial number

☐	Experiment	Assay	# samples	Operator	Run date	Status
☐	QF Pat_20120417_0949	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 09:49:42	
☐	QF Pat_20120417_0959	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 09:59:57	
☐	QF Pat_20120417_1009	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 10:09:08	
☐	QF Pat_20120417_1017	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 10:17:27	
☐	QF Pat_20120417_1019	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 10:19:55	
☐	QF Pat_20120417_1022	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 10:22:48	
☐	QF Pat_20120417_1029	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 10:29:13	
☐	QF Pat_20120417_1032	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 10:32:52	
☐	QF Pat_20120417_1033	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 10:33:31	
☐	QF Pat_20120417_1038	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 10:38:20	
☐	QF Pat_20120417_1506	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 15:07:03	
☐	QF Pat_20120418_1029	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 10:29:53	
☐	SYBR_20120417_0953	Rotor-Gene SYBR Green...	48	John Doe	17.04.2012 09:53:29	
☐	SYBR_20120417_1007	Rotor-Gene SYBR Green...	48	John Doe	17.04.2012 10:07:11	
☐	SYBR_20120417_1017	Rotor-Gene SYBR Green...	48	John Doe	17.04.2012 10:17:12	
☐	SYBR_20120417_1020	Rotor-Gene SYBR Green...	48	John Doe	17.04.2012 10:20:09	
☐	SYBR_20120417_1023	Rotor-Gene SYBR Green...	48	John Doe	17.04.2012 10:23:08	
☐	SYBR_20120417_1029	Rotor-Gene SYBR Green...	48	John Doe	17.04.2012 10:29:27	

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: 18.03.2012
End date: 18.04.2012

☑ Use advanced filter options

☐ Filter assays
☐ QuantiFast Pathogen PCR +IC
☐ QuantiFast Pathogen PCR +IC
☐ Rotor-Gene SYBR Green PC...
☐ Rotor-Gene SYBR Green PC...

Assay status
○ Successful
○ Failed
● Both

Release status
○ Unreleased
○ Partially
● Both

☐ Filter experiment name

☐ Filter contained sample IDs

☐ Filter operator

☐ Filter cycler serial number

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.

<table>
<tr><th></th><th>Label/Title</th><th>Description</th></tr>
<tr><td></td><td>Date filter options</td><td>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.

Restrictions:
▪ Wildcard characters are not allowed.
▪ Dates must be entered completely.</td></tr>
<tr><td>A</td><td>"Use advanced filter options" check box</td><td>Click in the check box next to "Use advanced filter options" to activate the advanced filter options.</td></tr>
<tr><td></td><td>Advanced Filter Criteria</td><td>
<table>
<tr><th>Filter Criterion</th><th>Explanation</th></tr>
<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:

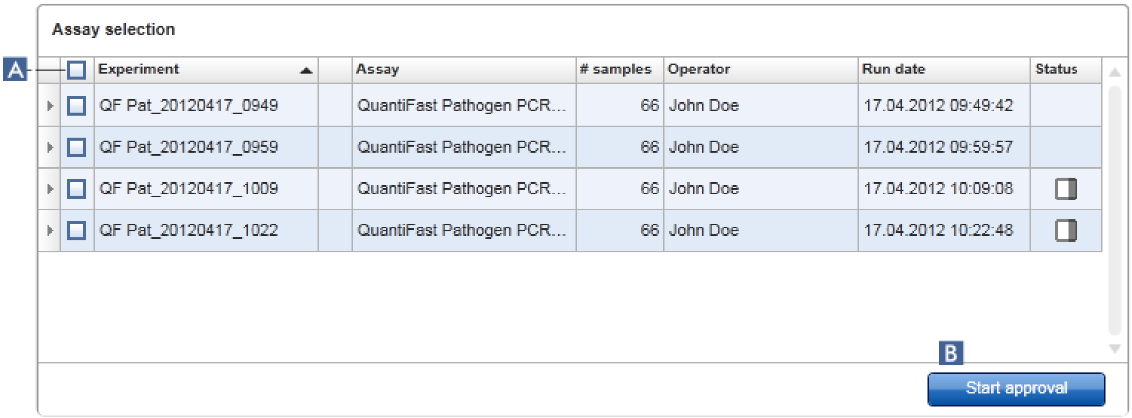
▪ Successful
▪ Failed
▪ Both</td></tr>
<tr><td>"Release status"</td><td>Filter for the release status using the radio buttons. Possible values are:

▪ Unreleased
▪ Partially
▪ Both</td></tr>
<tr><td>"Filter experiment name"</td><td>Filter for the experiment name by activating the check box and entering an experiment name.</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td></td><td></td><td><table>
<tr><td>"Filter contained sample IDs"</td><td>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.</td></tr>
<tr><td>"Filter operator"</td><td>Filter for a specific operator by activating the check box and selecting an operator from the list.</td></tr>
<tr><td>"Filter cycler serial number"</td><td>Filter for a cycler serial number by activating the check box and entering a cycler serial number (only digits).</td></tr>
</table></td></tr>
<tr><td>B</td><td>"Reset filter" button</td><td>Resets all filter options to the default values.</td></tr>
<tr><td>C</td><td>"Apply filter" button</td><td>Starts the filter process.
All experiments matching the filter criteria will be listed in the "Assay selection" area.</td></tr>
</table>

"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.

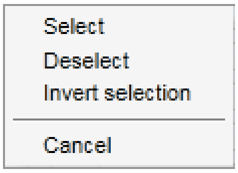


Assay selection

	☐	Experiment ▲	Assay	# samples	Operator	Run date	Status
▸	☐	QF Pat_20120417_0949	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 09:49:42	
▸	☐	QF Pat_20120417_0959	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 09:59:57	
▸	☐	QF Pat_20120417_1009	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 10:09:08	◧
▸	☐	QF Pat_20120417_1022	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 10:22:48	◧

Column	Explanation
Row selector ▸	The row selector is a tool to select and deselect assays in the assay selection table. Single assays are selected by activating the check box (☐) of the corresponding experiment. Use multiple check boxes to select multiple assays. Clicking the row selector highlights the current row in dark blue. The row selector icon changes: ▸ Deactivated row selector ▶ Activated row selector 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. Context menu

The context menu of the row selector is used to select or deselect the highlighted assay:



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: ⚠

<table>
<tr><td></td><td>The reason for invalidity is shown in a tooltip. Possible reasons are:<table><tr><td>Run failed</td><td>A problem with the cycler 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></td></tr>
<tr><td>"Assay"</td><td>Full name of the assay(s) used for this experiment</td></tr>
<tr><td>"# samples"</td><td>Number of samples</td></tr>
<tr><td>"Operator"</td><td>Name of the operator</td></tr>
<tr><td>"Run date"</td><td>Run date of the experiment</td></tr>
<tr><td>"Status"</td><td>Release status of the assay

If this field is empty, no samples from this assay have been released yet.
If not all samples have been released, this assay has the status "Partially released". This is indicated by the ◨ icon.
If an assay is locked, the column shows a lock icon 🔒.</td></tr>
<tr><td>"Start approval" button (B)</td><td>Starts the approval process of the selected assays. This button is enabled if at least one assay is selected.

By clicking this button, the "Approval" screen is displayed. All selected assays get the status "Locked".</td></tr>
</table>

1.5.5.3.2 Approval Screen

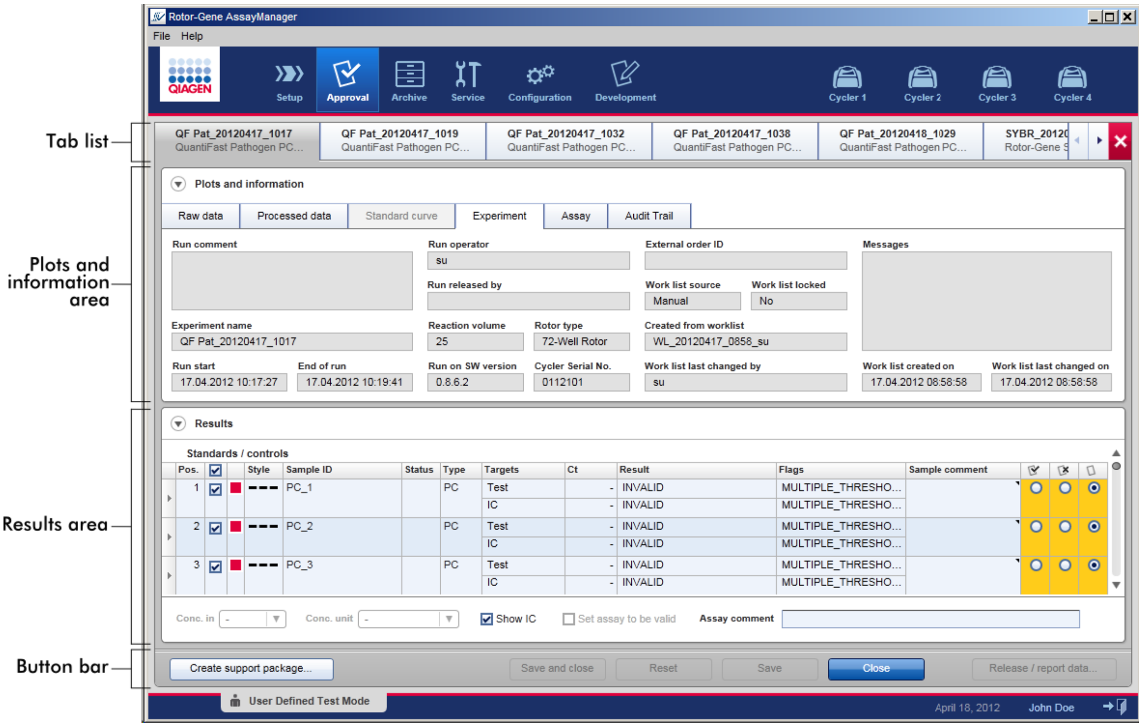
Note

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 v1.0 plug-in user manuals. In this manual, example screens and procedures for the UDT basic 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.



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_1017
Reaction volume: 25
Rotor type: 72-Well Rotor
Created from worklist: WL_20120417_0858_su
Run start: 17.04.2012 10:17:27
End of run: 17.04.2012 10:19:41
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

Pos.	☑		Style	Sample ID	Status	Type	Targets	Ct	Result	Flags	Sample comment			
1	☑	🟥	▬ ▬ ▬	PC_1		PC	Test	-	INVALID	MULTIPLE_THRESHO...		○	○	●
							IC	-	INVALID	MULTIPLE_THRESHO...				
2	☑	🟥	▬ ▬ ▬	PC_2		PC	Test	-	INVALID	MULTIPLE_THRESHO...		○	○	●
							IC	-	INVALID	MULTIPLE_THRESHO...				
3	☑	🟥	▬ ▬ ▬	PC_3		PC	Test	-	INVALID	MULTIPLE_THRESHO...		○	○	●
							IC	-	INVALID	MULTIPLE_THRESHO...				

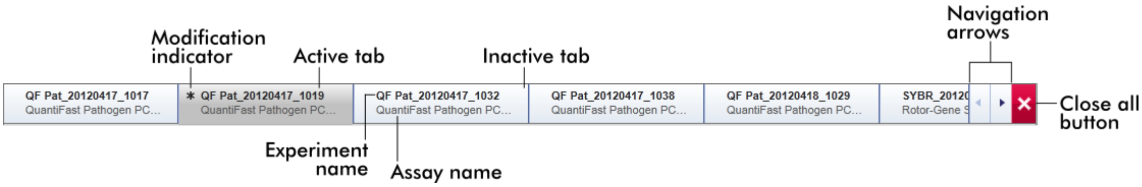
Conc. in: -
Conc. unit: -
☑ Show IC
☐ Set assay to be valid
Assay comment:

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.

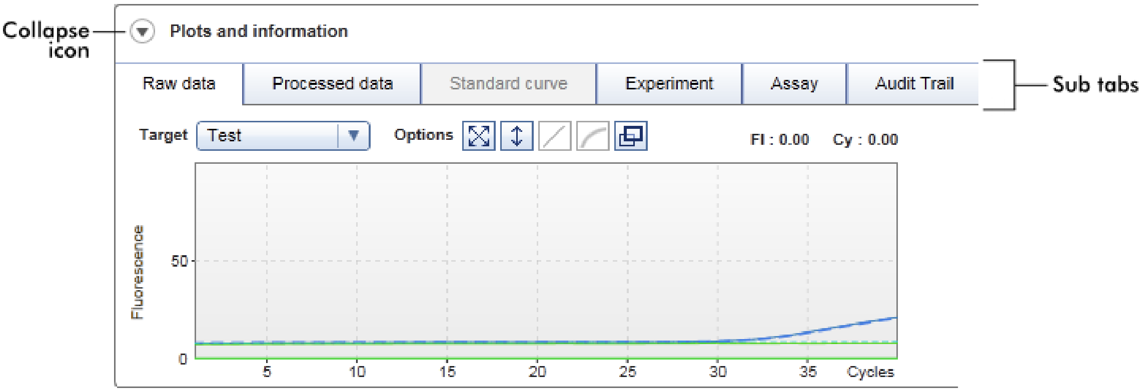
Tab list

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 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"	

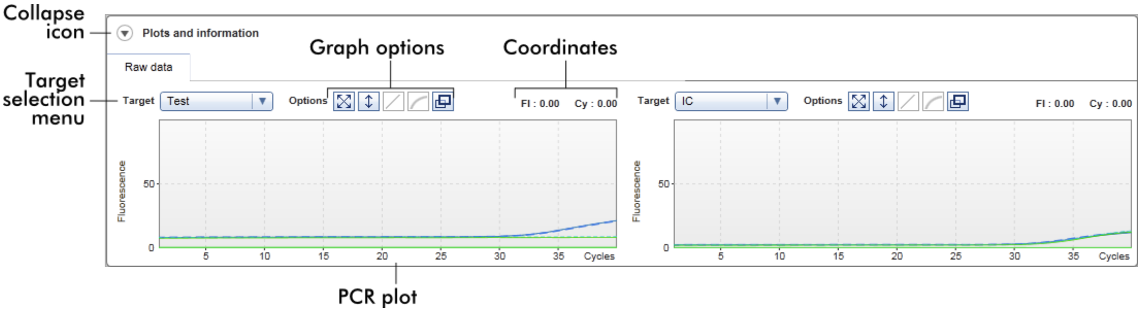
6.	"Audit Trail"	Shows all actions that are recorded in the audit trail.

Note

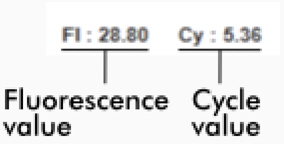
The collapse icon (▼) is used to collapse the "Plots and information" or the "Results" area to gain screen space for the other area. If an area is collapsed to a single row, the icon changes to ▶ for expanding the area back to the default size.

"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.



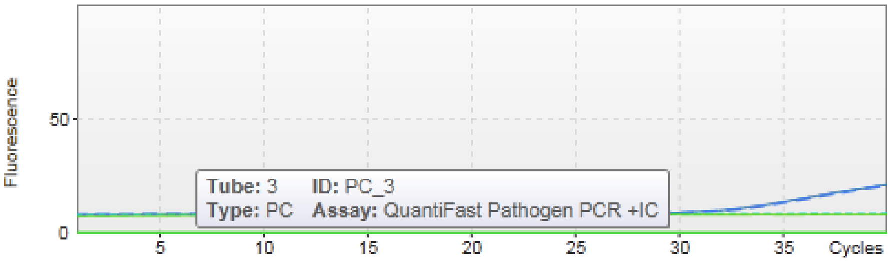
Label/Title	Icon	Description
Collapse icon	▼	Collapses the "Plots and information" or the "Results area" to gain screen space for the other area.
Target selection menu		Selects the target source used for the corresponding plot.
Graph options	⤢	This button resets the scale of the y-axis (visualization 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

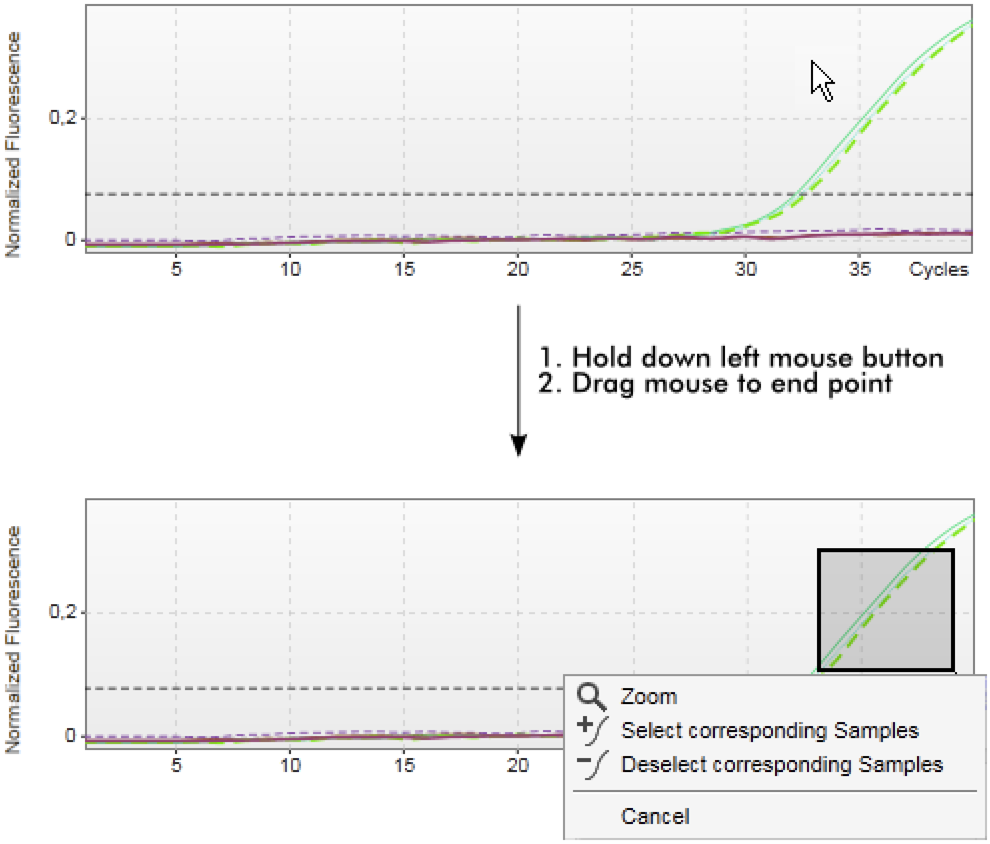
- When the mouse is hovered over the amplification plot, the cursor changes to cross hairs (+).
- The current position of the mouse cursor over the amplification plot is displayed in real time in the coordinates field.
- Hovering with the mouse over the amplification curve of a specific sample opens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

- Tube number
- Sample ID
- Sample type
- Assay name (long)



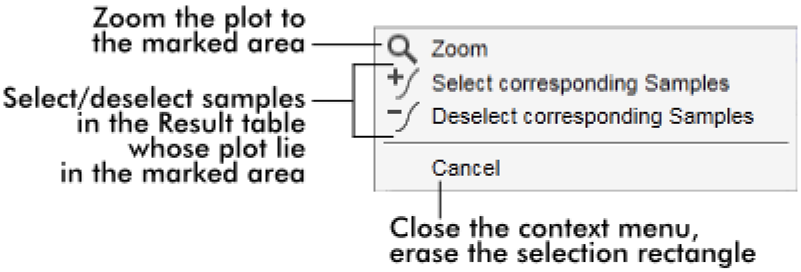
Tube: 3 **ID:** PC_3
Type: PC **Assay:** QuantiFast Pathogen PCR +IC

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

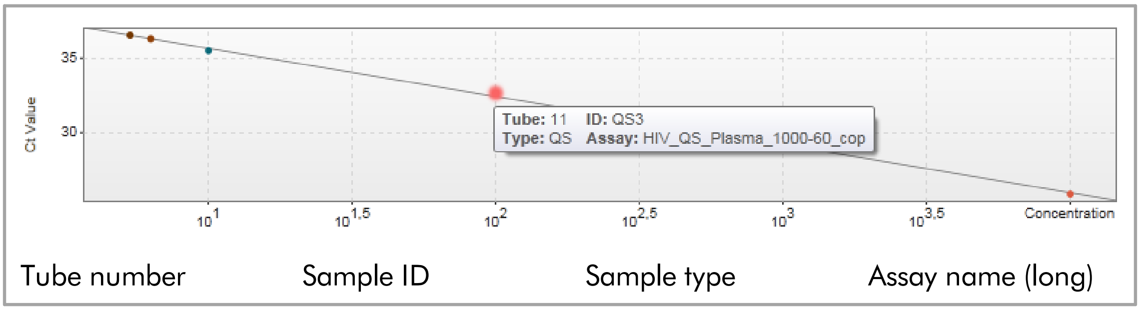
The availability of processed data depends on the currently used plug-in. The "Processed data" sub tab has the same elements and the same behavior as the "Raw data" sub tab with only a few differences:

1. The raw fluorescence data are normalized using the internal algorithm of Rotor-Gene AssayManager v1.0 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	⤢	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

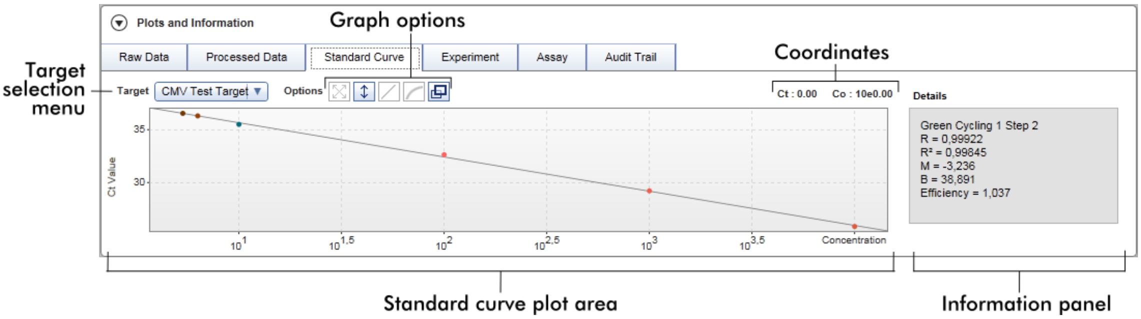
The standard curve sub tab displays the standard curve as a result of plotting the C_T values of the quantitation standards on the y-axis against their concentration on the x-axis. For easy identification the color of the data points corresponds with the style for the individual samples selected in the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



Tube: 11 ID: QS3
Type: QS Assay: HIV_QS_Plasma_1000-60_cop

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.



Target: CMV Test Target

Ct : 0.00 Co : 10e0.00

Details

Green Cycling 1 Step 2
R = 0,99922
R² = 0,99845
M = -3,236
B = 38,891
Efficiency = 1,037

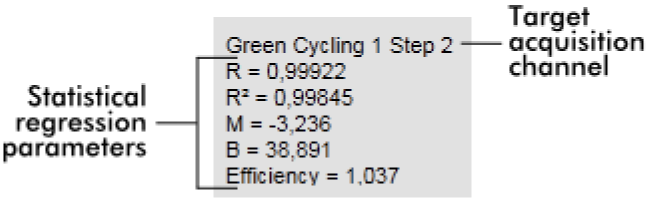
Standard curve plot area

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:



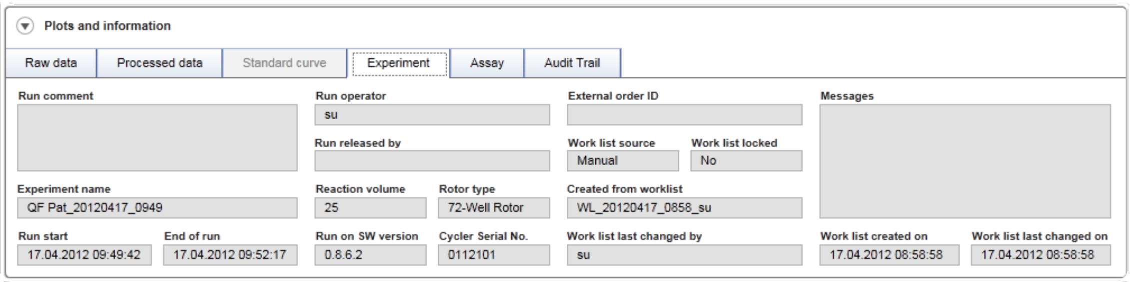
Green Cycling 1 Step 2
R = 0,99922
R² = 0,99845
M = -3,236
B = 38,891
Efficiency = 1,037

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

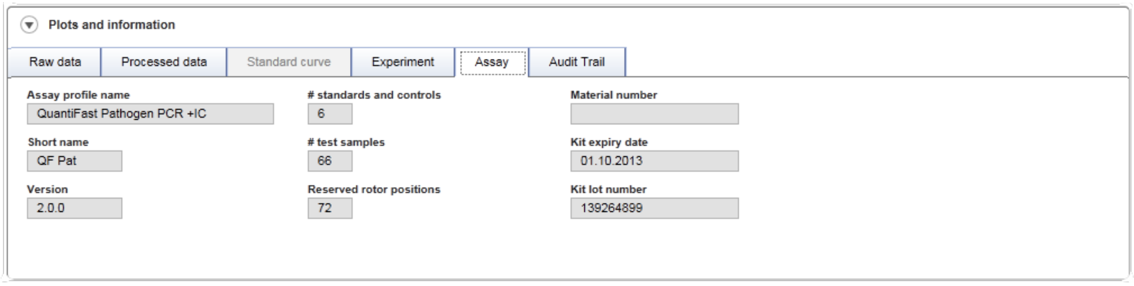
The "Experiment" sub tab provides detailed information about the experiment.



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.



Assay profile name: QuantiFast Pathogen PCR +IC

Short name: QF Pat

Version: 2.0.0

standards and controls: 6

test samples: 66

Reserved rotor positions: 72

Material number:

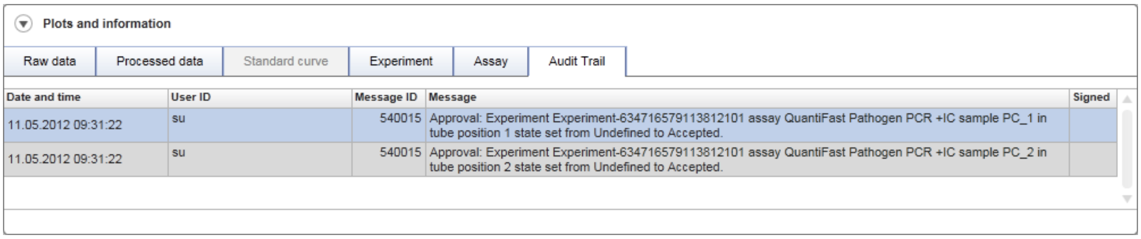
Kit expiry date: 01.10.2013

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:



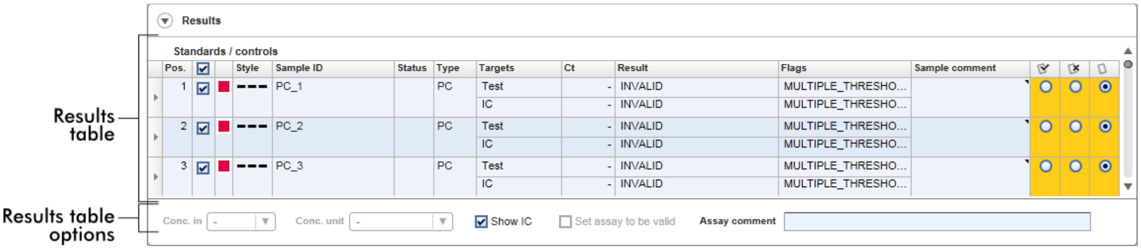
Date and time	User ID	Message ID	Message	Signed
11.05.2012 09:31:22	su	540015	Approval: Experiment Experiment-634716579113812101 assay QuantiFast Pathogen PCR +IC sample PC_1 in tube position 1 state set from Undefined to Accepted.	
11.05.2012 09:31:22	su	540015	Approval: Experiment Experiment-634716579113812101 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 v1.0 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 v1.0 plug-in user manual.



Standards / controls

Pos.	☑		Style	Sample ID	Status	Type	Targets	Ct	Result	Flags	Sample comment	☑	☒	☐
1	☑	🟥	---	PC_1		PC	Test	-	INVALID	MULTIPLE_THRESHO...		○	○	●
							IC	-	INVALID	MULTIPLE_THRESHO...				
2	☑	🟥	---	PC_2		PC	Test	-	INVALID	MULTIPLE_THRESHO...		○	○	●
							IC	-	INVALID	MULTIPLE_THRESHO...				
3	☑	🟥	---	PC_3		PC	Test	-	INVALID	MULTIPLE_THRESHO...		○	○	●
							IC	-	INVALID	MULTIPLE_THRESHO...				

Conc. in: -

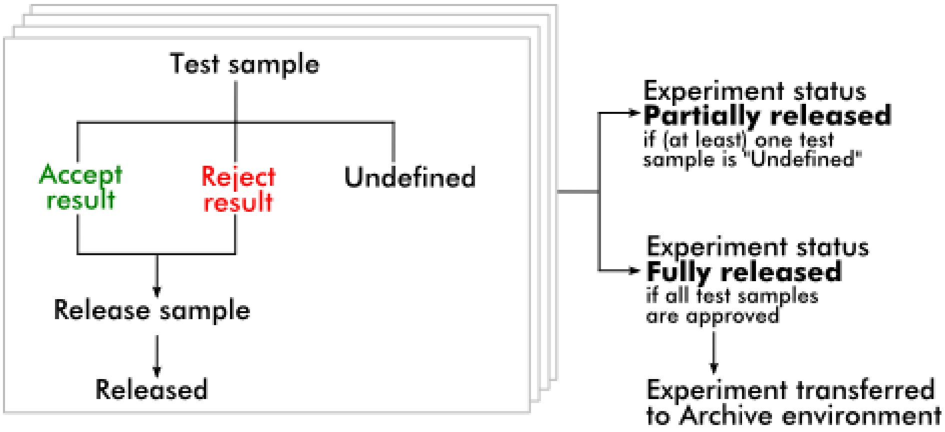
Conc. unit: -

☑ Show IC

☐ Set assay to be valid

Assay 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.



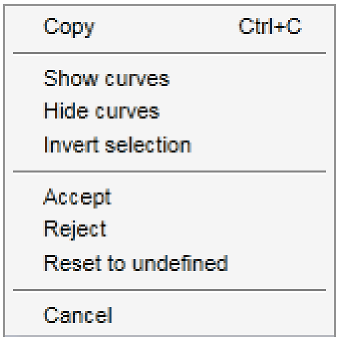
Results table

The results table contains the following columns:

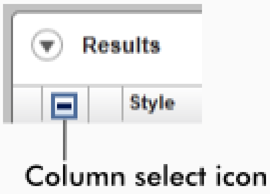
Column	Explanation
Row selector ▸	The row selector enables the user to select and deselect samples in the results table and to approve the status of multiple test samples simultaneously. Selecting single assays is simply done by activating the check box (☐) of the corresponding sample. Use the row selector to select multiple samples. Clicking the row selector highlights the current row. The row selector icon changes. The highlighted row will be colored in dark blue. ▸ Deactivated row selector ▸ Activated row selector

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

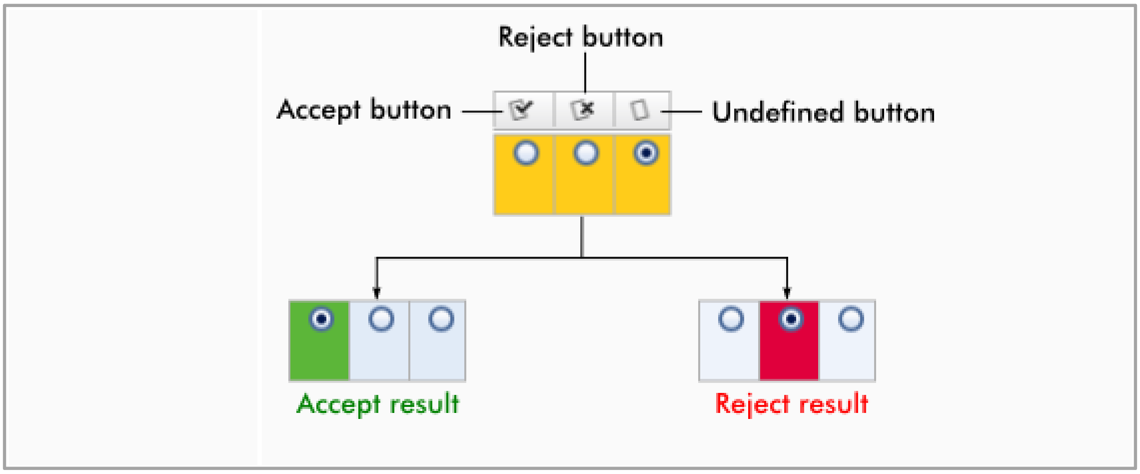
Context menu
The context menu of the row selector is used to select/deselect the highlighted sample experiment:



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.  ☐ 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 work list setup)
Status		Upstream status of the sample. Possible values are: ✓ QIAsymphony sample status valid ? QIAsymphony sample status unclear ! QIAsymphony sample status invalid
Target		Display all targets relating to the sample. The sample row is split, and every target is displayed in a separate row.

C_T	Calculated C_T value for the target
Results	Rotor-Gene AssayManager v1.0 sample evaluation result. Possible results are: ▪ Concentration value including a concentration unit ▪ Signal detected ▪ No signal ▪ Invalid
Flags	Exceptions identified by Rotor-Gene AssayManager v1.0 analysis. Possible flags are listed in the corresponding Rotor-Gene AssayManager v1.0 plug-in user manual.
Sample comment	For every sample a comment can be entered. Maximum 256 characters are allowed. Comments already entered during work list setup are shown.
Approval status	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. **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 v1.0 plug-in user manual. 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. 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. 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.

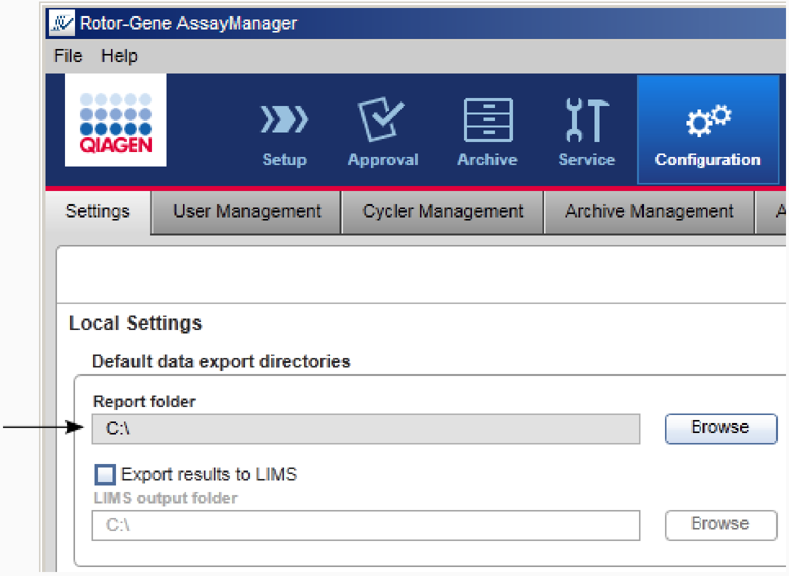
Button bar

Title/label	Explanation
Save and close	Saves all changes and closes the current assay. No test results will be released.
Reset	Discards all unsaved changes. Note: Visualization options, such as "Show IC", check boxes of samples, etc., are not changed.
Save	Saves all changes; remains in this dialog. No test results will be released.
Close	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.

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

Settings 4 Local Settings 4 Folders for exporting 4 Report folder.



Local Settings

Default data export directories

Report folder
C:\

☐ Export results to LIMS

LIMS output folder
C:\

1.5.5.4 Archive Environment

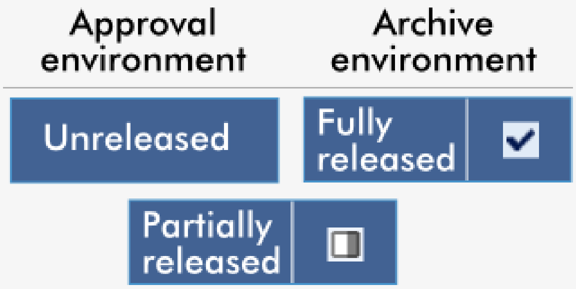
The "Archive" environment is used to search for released assays and to generate experiment reports using predefined report profiles. Note that filtering in the "Archive" environment is limited to the currently active archives. Inactivated archives are not included in the filtering. Different archives 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.

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

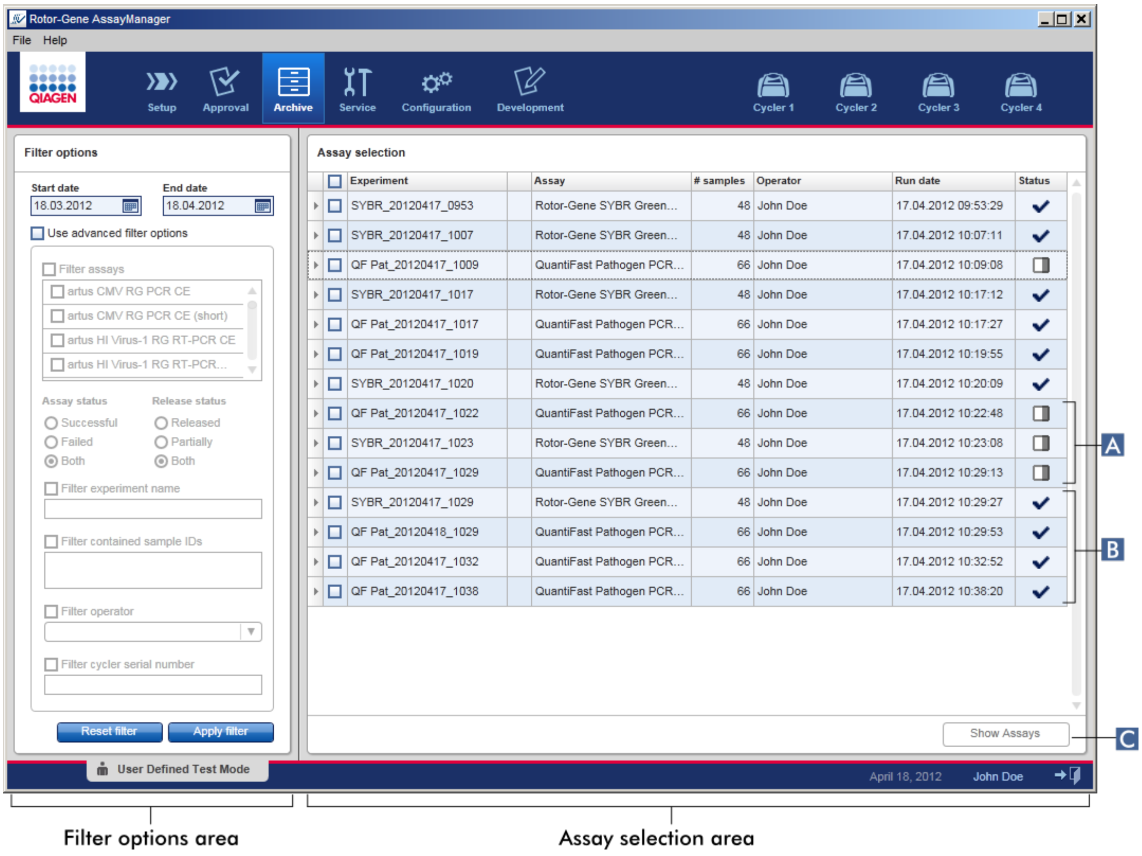


The main tasks (searching and reporting data) are carried out in 2 different screens:
- Filter options and assay selection screen
- Showing assays screen

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:

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



Start date: 18.03.2012
End date: 18.04.2012
☐ Use advanced filter options
☐ Filter assays
☐ artus CMV RG PCR CE
☐ artus CMV RG PCR CE (short)
☐ artus HI Virus-1 RG RT-PCR CE
☐ artus HI Virus-1 RG RT-PCR...
Assay status: ○ Successful ○ Failed ● Both
Release status: ○ Released ○ Partially ● Both
☐ Filter experiment name
☐ Filter contained sample IDs
☐ Filter operator
☐ Filter cycler serial number

☐	Experiment	Assay	# samples	Operator	Run date	Status
☐	SYBR_20120417_0953	Rotor-Gene SYBR Green...	48	John Doe	17.04.2012 09:53:29	✓
☐	SYBR_20120417_1007	Rotor-Gene SYBR Green...	48	John Doe	17.04.2012 10:07:11	✓
☐	QF Pat_20120417_1009	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 10:09:08	◨
☐	SYBR_20120417_1017	Rotor-Gene SYBR Green...	48	John Doe	17.04.2012 10:17:12	✓
☐	QF Pat_20120417_1017	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 10:17:27	✓
☐	QF Pat_20120417_1019	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 10:19:55	✓
☐	SYBR_20120417_1020	Rotor-Gene SYBR Green...	48	John Doe	17.04.2012 10:20:09	✓
☐	QF Pat_20120417_1022	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 10:22:48	◨
☐	SYBR_20120417_1023	Rotor-Gene SYBR Green...	48	John Doe	17.04.2012 10:23:08	◨
☐	QF Pat_20120417_1029	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 10:29:13	◨
☐	SYBR_20120417_1029	Rotor-Gene SYBR Green...	48	John Doe	17.04.2012 10:29:27	✓
☐	QF Pat_20120418_1029	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 10:29:53	✓
☐	QF Pat_20120417_1032	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 10:32:52	✓
☐	QF Pat_20120417_1038	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 10:38:20	✓

April 18, 2012 John Doe

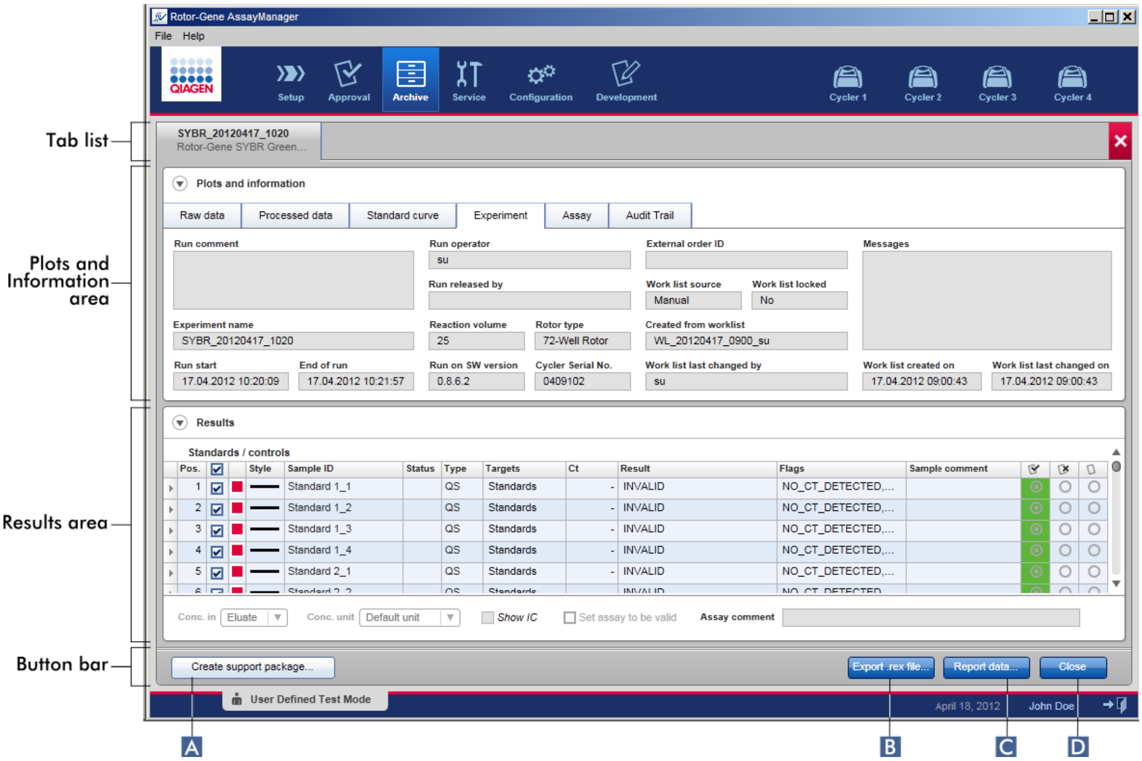
For details about the functionality of the Filter screen, see ▶ "Approval" environment.

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.

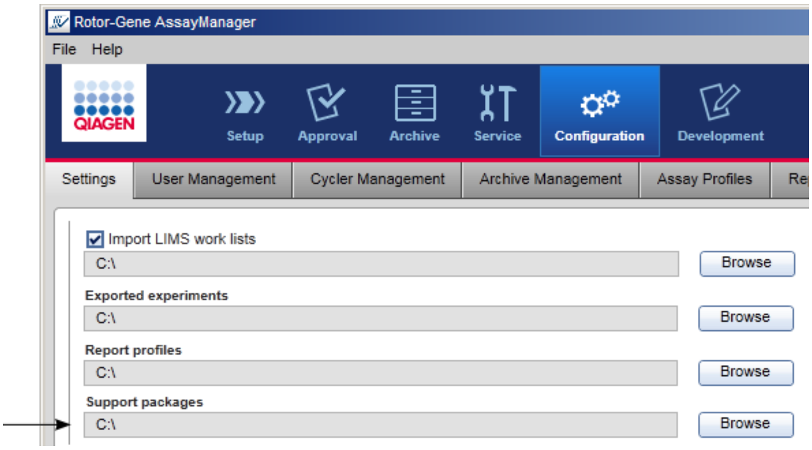


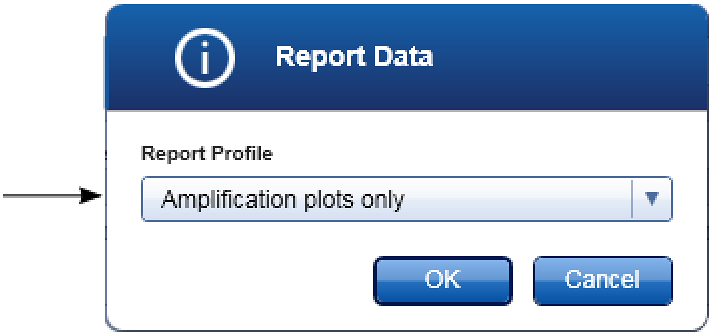
Run comment:
Run operator: su
Run released by:
External order ID:
Work list source: Manual
Work list locked: No
Messages:
Experiment name: SYBR_20120417_1020
Reaction volume: 25
Rotor type: 72-Well Rotor
Created from worklist: WL_20120417_0900_su
Run start: 17.04.2012 10:20:09
End of run: 17.04.2012 10:21:57
Run on SW version: 0.8.6.2
Cycler Serial No.: 0409102
Work list last changed by: su
Work list created on: 17.04.2012 09:00:43
Work list last changed on: 17.04.2012 09:00:43

Standards / controls

Pos.	☑	Style	Sample ID	Status	Type	Targets	Ct	Result	Flags	Sample comment	✓	✗	☐
1	☑	🟥 ▬	Standard 1_1		QS	Standards	-	INVALID	NO_CT_DETECTED,...		●	○	○
2	☑	🟥 ▬	Standard 1_2		QS	Standards	-	INVALID	NO_CT_DETECTED,...		●	○	○
3	☑	🟥 ▬	Standard 1_3		QS	Standards	-	INVALID	NO_CT_DETECTED,...		●	○	○
4	☑	🟥 ▬	Standard 1_4		QS	Standards	-	INVALID	NO_CT_DETECTED,...		●	○	○
5	☑	🟥 ▬	Standard 2_1		QS	Standards	-	INVALID	NO_CT_DETECTED,...		●	○	○

Conc. in: Eluate
Conc. unit: Default unit
☐ Show IC
☐ Set assay to be valid
Assay comment:

	Label/Title	Description
A	"Create support package..."	Rotor-Gene AssayManager v1.0 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.  ☑ Import LIMS work lists C:\ Exported experiments C:\ Report profiles C:\ Support packages C:\
B	"Export *.rex file..."	Exports raw data of all assays from an experiment to a *.rex file. This button is only enabled if all assays of the experiment are completely released.
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" menu.

		 **Report Data** Report Profile: Amplification plots only
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" tab.

"Audit Trail" tab

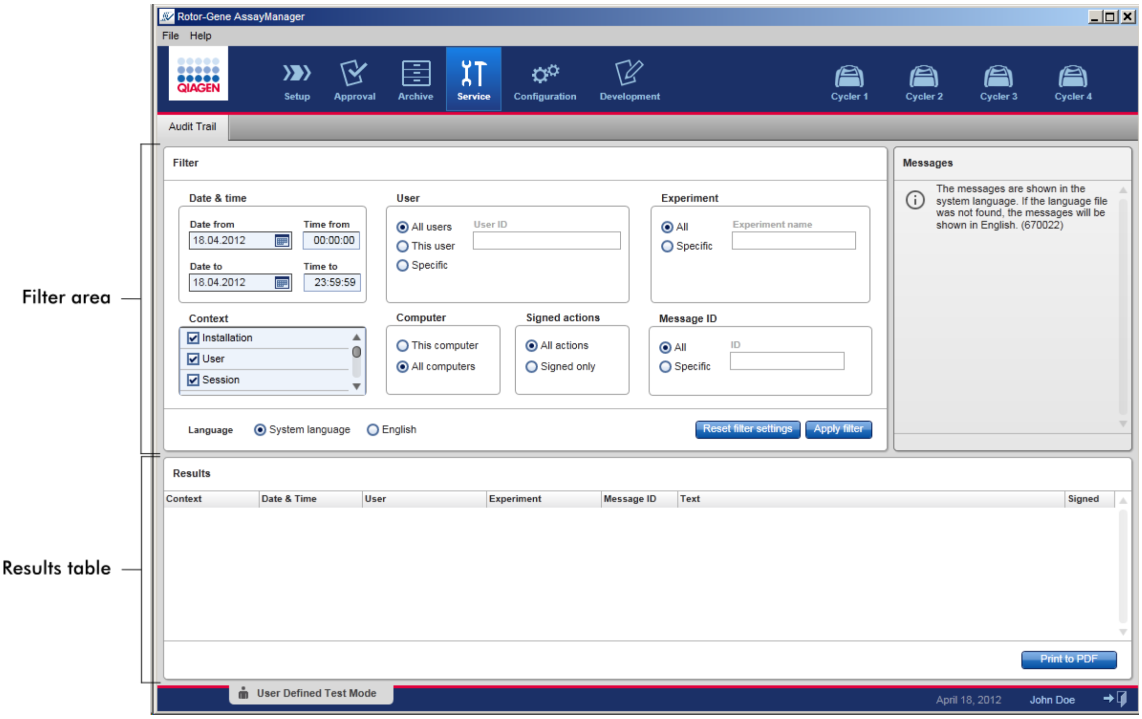
The audit trail is a record of all user actions. All actions are traced in the audit trail and can be filtered and printed out. The Rotor-Gene AssayManager v1.0 audit trail is designed based on guidelines in FDA CFR Title 21, Part 11 Electronic Records, Electronic Signatures.

All activities of a user are logged in an audit trail categorized in 8 different contexts:
- Installation
- User
- Session
- Profile
- Settings
- Cycler
- Work list
- 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.



Date & time
Date from 18.04.2012
Time from 00:00:00
Date to 18.04.2012
Time to 23:59:59

User
● All users
○ This user
○ Specific
User ID

Experiment
● All
○ Specific
Experiment name

Context
☑ Installation
☑ User
☑ Session

Computer
○ This computer
● All computers

Signed actions
● All actions
○ Signed only

Message ID
● All
○ Specific
ID

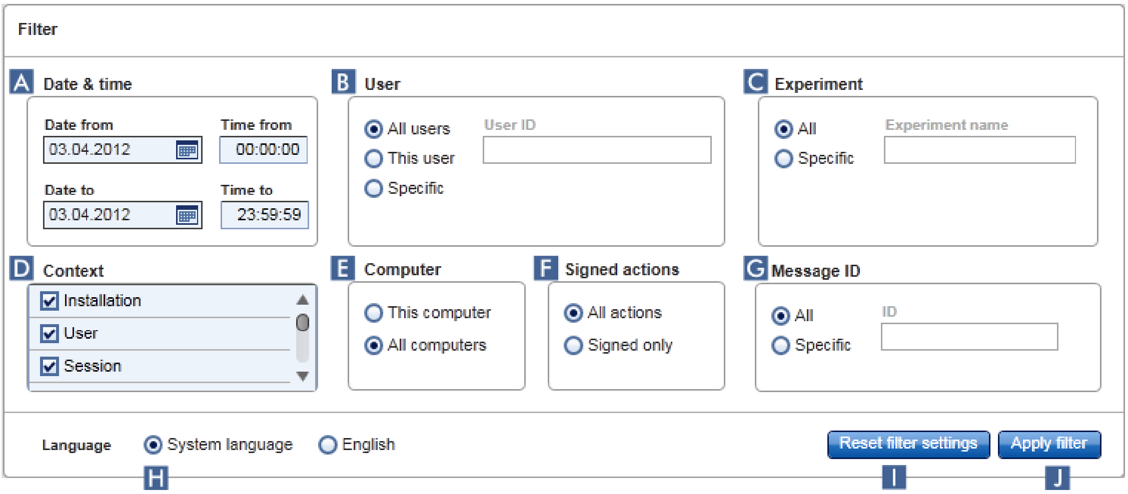
Language ● System language ○ English

The messages are shown in the system language. If the language file was not found, the messages will be shown in English. (670022)

April 18, 2012 John Doe

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



Date from 03.04.2012
Time from 00:00:00
Date to 03.04.2012
Time to 23:59:59

● All users
○ This user
○ Specific
User ID

● All
○ Specific
Experiment name

☑ Installation
☑ User
☑ Session

○ This computer
● All computers

● All actions
○ Signed only

● All
○ Specific
ID

Language ● System language ○ English

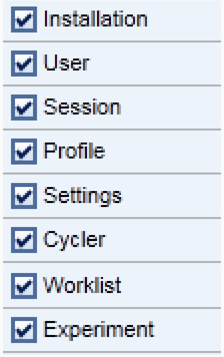
<table>
<tr><th></th><th>Explanation</th></tr>
<tr><td>A</td><td>Filter for date and time
Enter a date in the "Date from" and "Date to" fields either manually or using the date picker. Enter a time in the "Time from" and "Time to" fields.</td></tr>
<tr><td>B</td><td>Filter for a user name
<table>
<tr><th>To</th><th>Do this</th></tr>
<tr><td>Filter for all users</td><td>Activate "All users".</td></tr>
<tr><td>Filter for the current user</td><td>Activate "This user".</td></tr>
<tr><td>Filter for a specific user</td><td>Activate "Specific" and enter a user ID in the "User ID" field.</td></tr>
</table></td></tr>
<tr><td>C</td><td>Filter for an experiment name
<table>
<tr><th>To</th><th>Do this</th></tr>
<tr><td>Filter for all experiments</td><td>Activate "All".</td></tr>
</table></td></tr>
</table>

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
- ☑ Cycler
- ☑ Worklist
- ☑ Experiment

E

Filter for a computer
If Rotor-Gene AssayManager v1.0 is installed in a network on multiple computers, this setting allows to filter for a specific computer name. 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".

To	Do this
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.

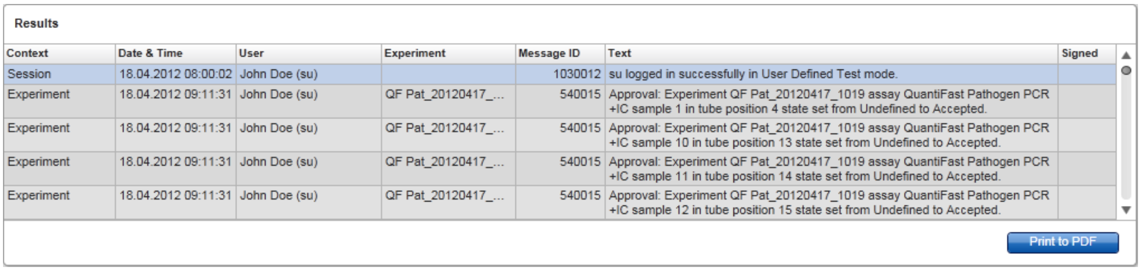
The default values and selection of control are as follows:

"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	18.04.2012 08:00:02	John Doe (su)		1030012	su logged in successfully in User Defined Test mode.	
Experiment	18.04.2012 09:11:31	John Doe (su)	QF Pat_20120417_...	540015	Approval: Experiment QF Pat_20120417_1019 assay QuantiFast Pathogen PCR +IC sample 1 in tube position 4 state set from Undefined to Accepted.	
Experiment	18.04.2012 09:11:31	John Doe (su)	QF Pat_20120417_...	540015	Approval: Experiment QF Pat_20120417_1019 assay QuantiFast Pathogen PCR +IC sample 10 in tube position 13 state set from Undefined to Accepted.	
Experiment	18.04.2012 09:11:31	John Doe (su)	QF Pat_20120417_...	540015	Approval: Experiment QF Pat_20120417_1019 assay QuantiFast Pathogen PCR +IC sample 11 in tube position 14 state set from Undefined to Accepted.	
Experiment	18.04.2012 09:11:31	John Doe (su)	QF Pat_20120417_...	540015	Approval: Experiment QF Pat_20120417_1019 assay QuantiFast Pathogen PCR +IC sample 12 in tube position 15 state set from Undefined to Accepted.	

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: ▪ Installation ▪ User ▪ Session ▪ Profile ▪ Settings ▪ Cycler ▪ Work list ▪ 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 to PDF

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

Tasks related to the "Service" environment

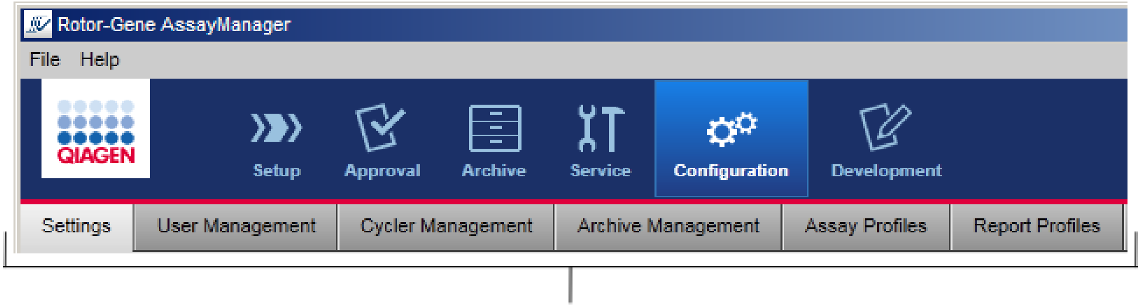
- Working with audit trails

1.5.5.6 Configuration Environment

In the "Configuration" environment, the settings of Rotor-Gene AssayManager v1.0 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"	▪ Define global settings ▪ Define local settings
"User Management"	▪ Add user ▪ Edit user data ▪ Modify user roles ▪ Change password

	- Activate/deactivate user
"Cycler Management"	- Set up new cyclers - Remove cyclers - Enter next verification date
"Archive Management"	- Activate/deactivate archives
"Assay Profiles"	- Activate/deactivate assay profiles - Import assay profiles
"Report Profiles"	- Create or adapt report profiles - Import report profiles - Export report profiles - Delete report profiles - Select content sections

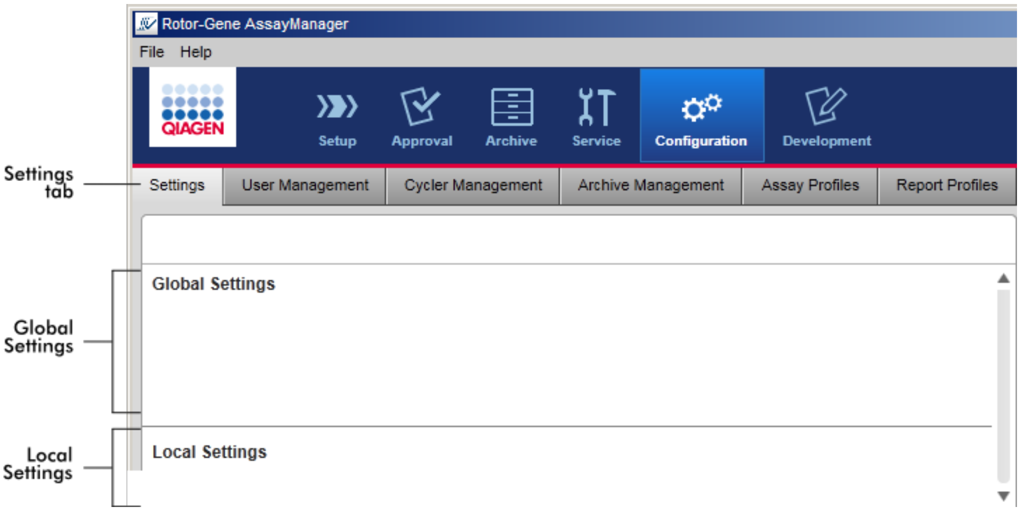
Tasks related to the "Configuration" environment

Administrative tasks

1.5.5.6.1 Settings

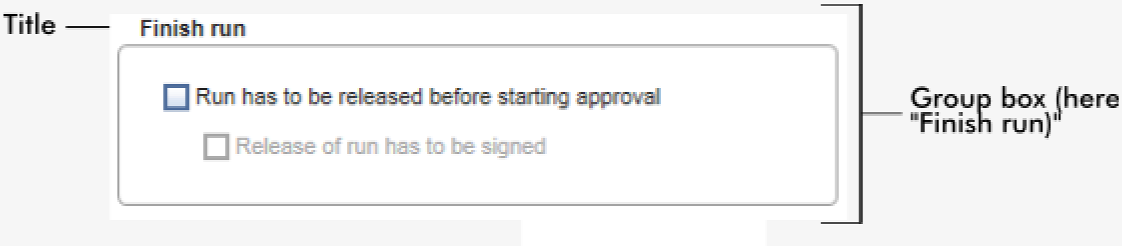
The "Settings" tab is divided in 2 sections:

- "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.

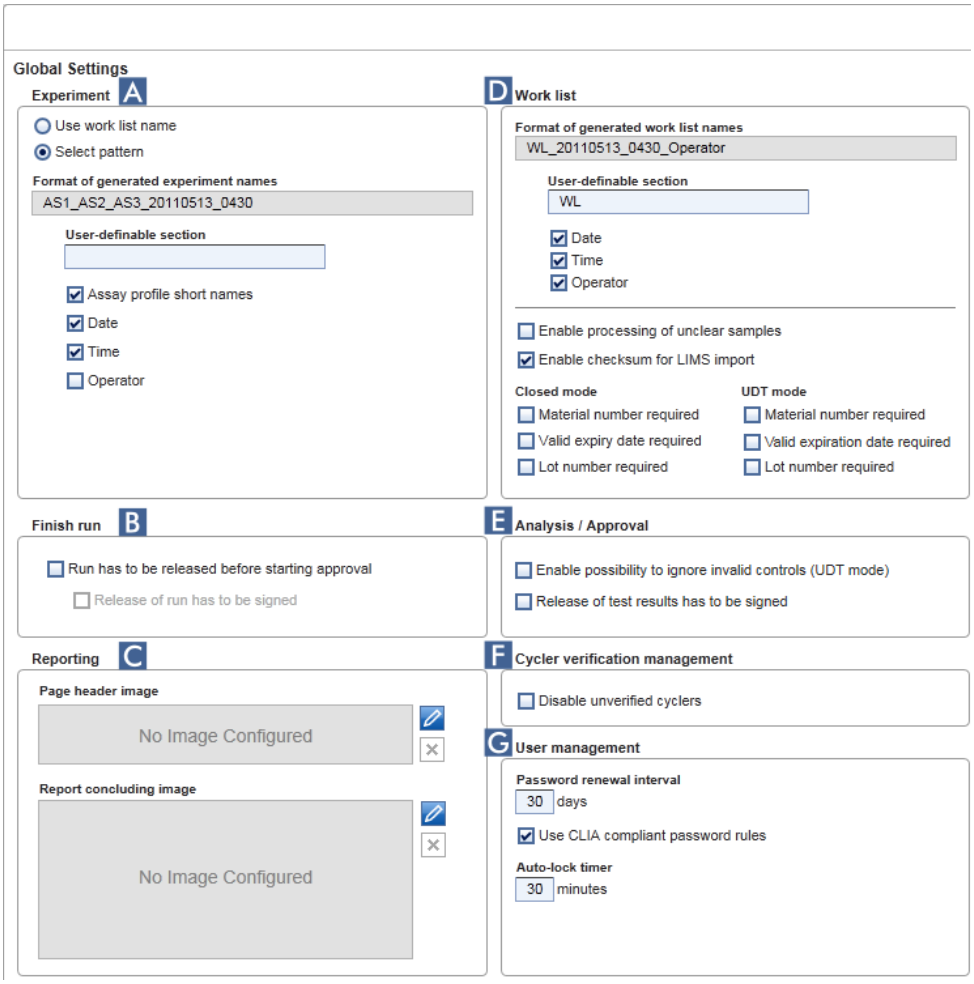


☐ Run has to be released before starting approval

☐ Release of run has to be signed

Global settings

Miscellaneous settings are defined in the global settings. These are bundled in 7 group boxes.



Global Settings

A Experiment

○ 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

B Finish run

☐ Run has to be released before starting approval
☐ Release of run has to be signed

C Reporting

Page header image: No Image Configured

Report concluding image: No Image Configured

D Work list

Format of generated work list names: WL_20110513_0430_Operator

User-definable section: WL

☑ Date
☑ Time
☑ Operator

☐ Enable processing of unclear samples
☑ Enable checksum for LIMS import

Closed mode
☐ Material number required
☐ Valid expiry date required
☐ Lot number required

UDT mode
☐ Material number required
☐ Valid expiration date required
☐ Lot number required

E Analysis / Approval

☐ Enable possibility to ignore invalid controls (UDT mode)
☐ Release of test results has to be signed

F Cycler verification management

☐ Disable unverified cyclers

G User management

Password renewal interval: 30 days

☑ Use CLIA compliant password rules

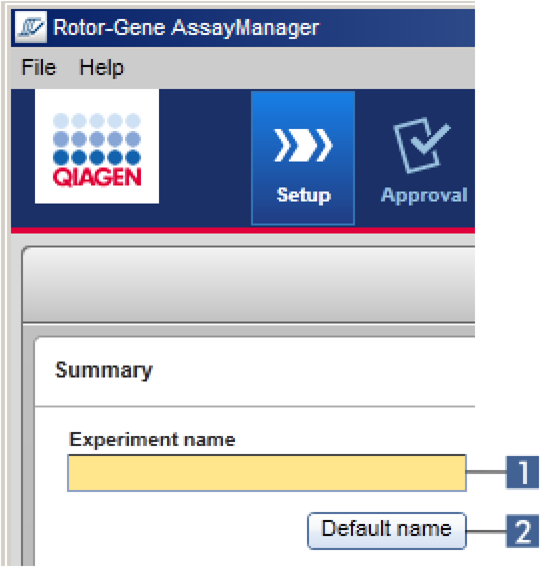
Auto-lock timer: 30 minutes

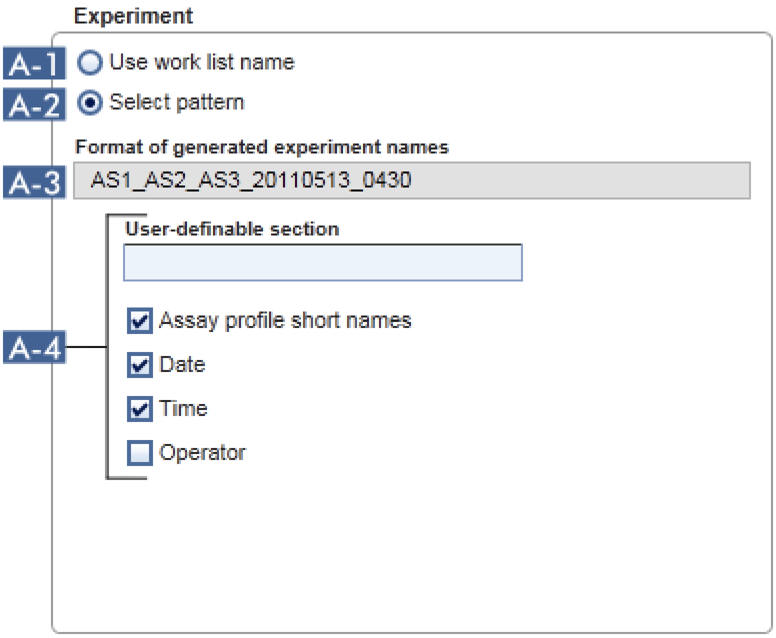
A	Group box "Experiment"
B	Group box "Finish run"
C	Group box "Reporting"
D	Group box "Work list"
E	Group box "Analysis/Approval"
F	Group box "Cycler verification management"

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 work list, 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 v1.0 automatically generate a default name by clicking "Default name" (2). This default name can be configured in the "Experiment" group box.





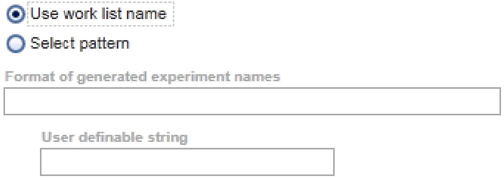
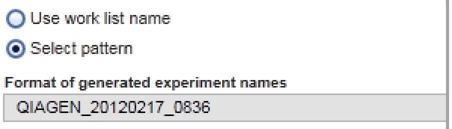
Experiment

○ Use work list name
● Select pattern

Format of generated experiment names
AS1_AS2_AS3_20110513_0430

User-definable section

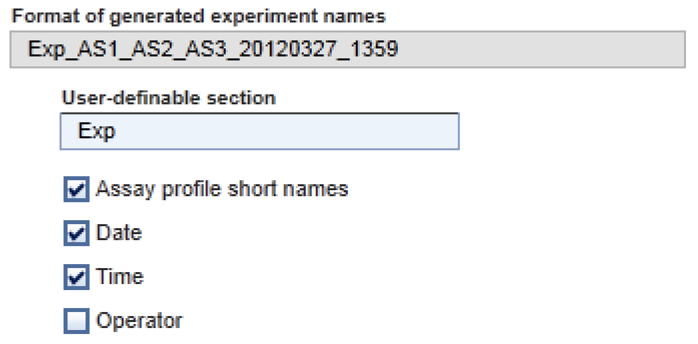
☑ Assay profile short names
☑ Date
☑ Time
☐ Operator

	Explanation
A-1	Activate "Use work list name" to use the same name as given to the work list that is applied.
A-2	Activate "Select pattern" to define a specific naming scheme.
A-3	Display the current work list name definition. This field is empty if "Use work list name" is selected. If "Select pattern" is selected, the resulting experiment name is shown. Example:  ● Use work list name ○ Select pattern Format of generated experiment names User definable string The experiment name is set to be the same as the work list name, hence the field is empty.  ○ Use work list name ● Select pattern Format of generated experiment names QIAGEN_20120217_0836 The resulting experiment name is displayed.
A-4	The scheme for the default name consists of 5 options: ▪ "User-definable section" ▪ "Assay profile short names"

- "Date"
- "Time"
- "Operator"

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.

Rotor-Gene AssayManager v1.0 is delivered with the following default settings:


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

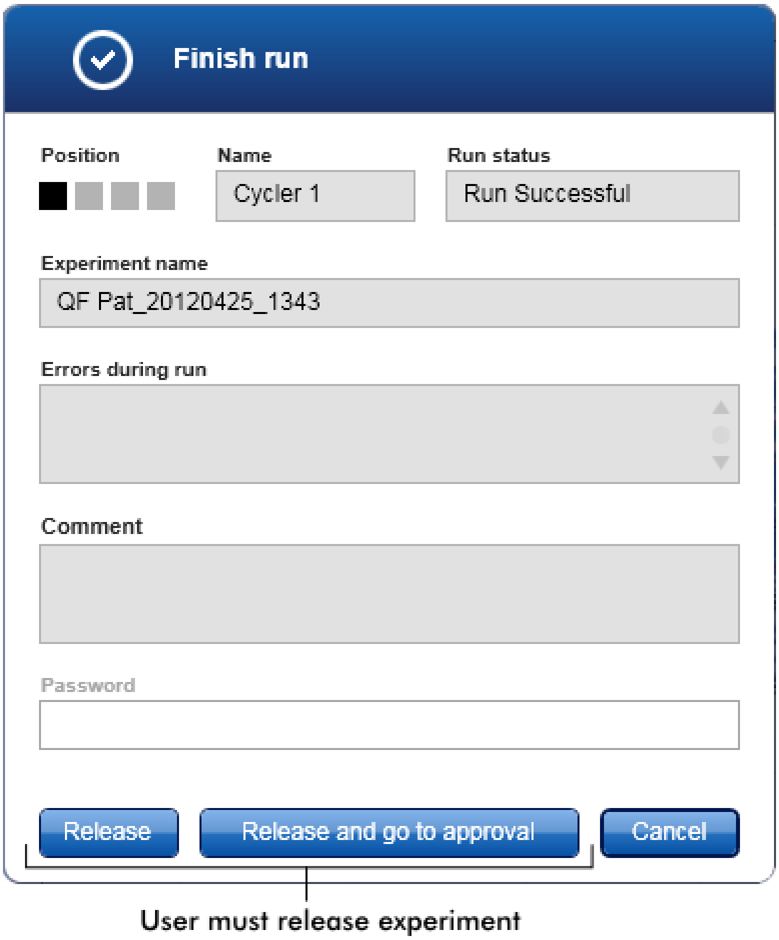
- If a user must release a run before the approval can be started.
- If a user must sign the run release by entering the password.

Finish run

☐ Run has to be released before starting approval
☐ 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.



Position

Name: Cycler 1

Run status: Run Successful

Experiment name: QF Pat_20120425_1343

Errors during run

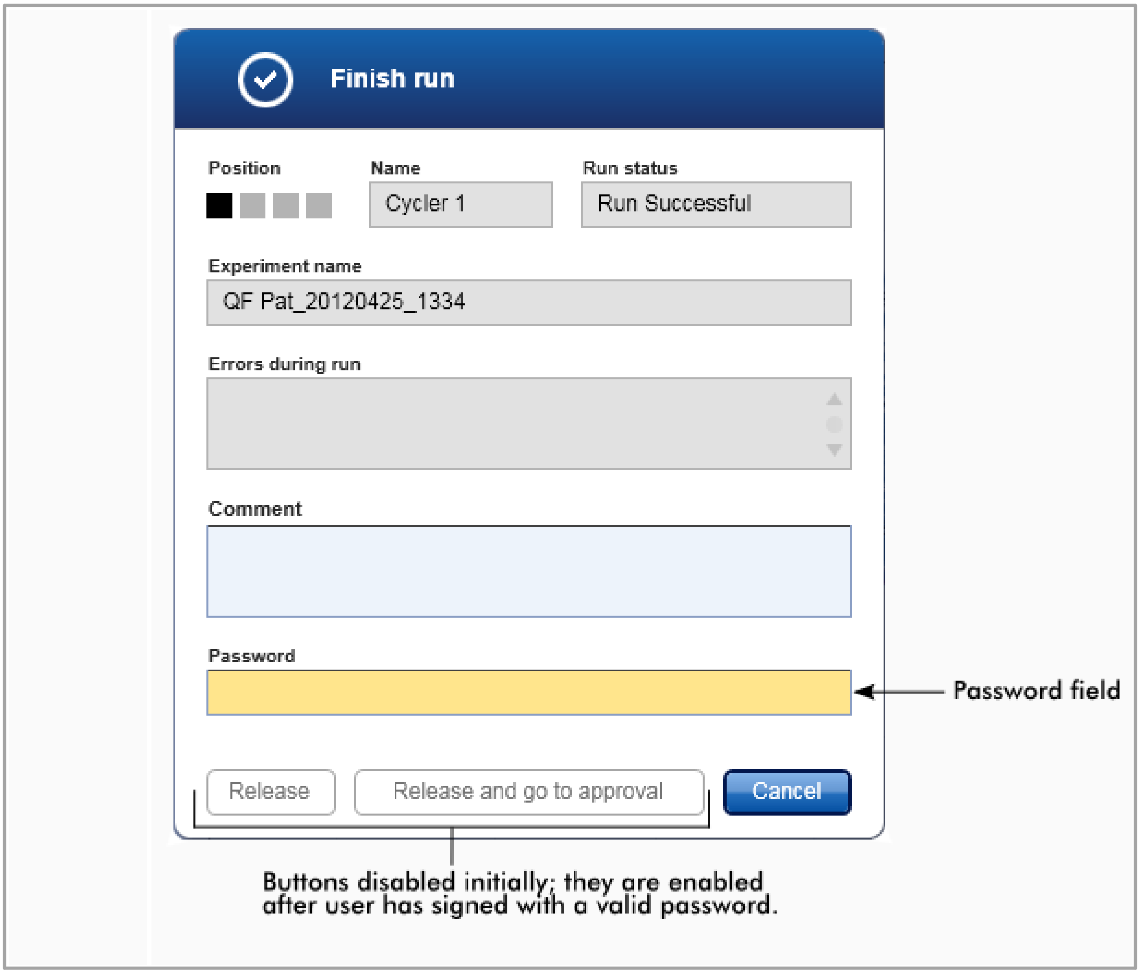
Comment

Password

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.



Name: Cycler 1
Run status: Run Successful
Experiment name: QF Pat_20120425_1334

Password field

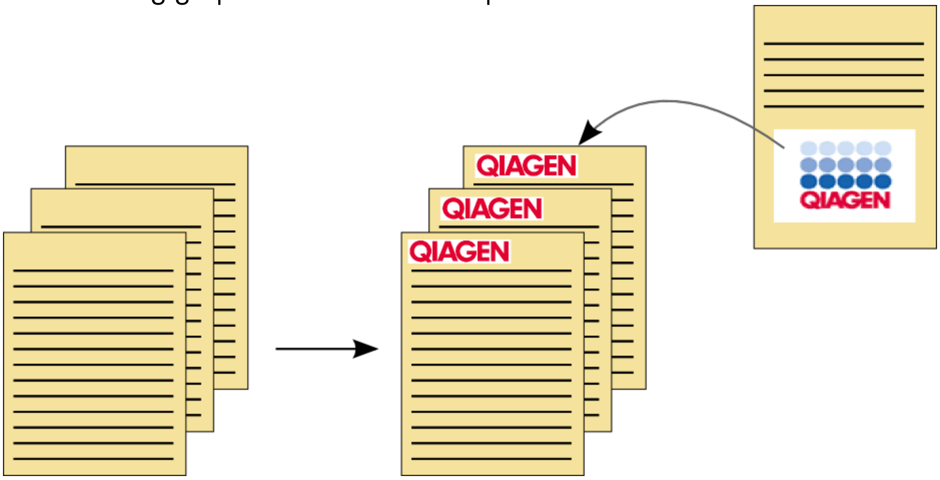
Buttons disabled initially; they are enabled after user has signed with a valid password.

Group box "Reporting"

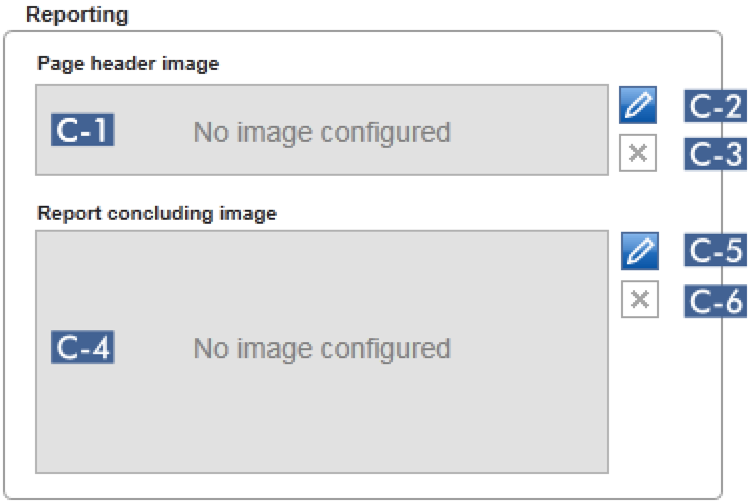
The "Reporting" group box is used to customize the layout of reports using images. Rotor-Gene AssayManager v1.0 provides 2 different options:

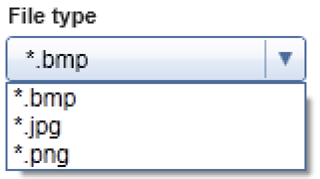
- Image in the header of every report page
- Image at the last page of the report

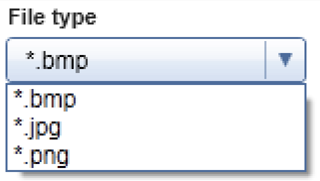
The following graphic illustrates these options:



The images must have one of the following formats:
- *.bmp
- *.jpg
- *.png

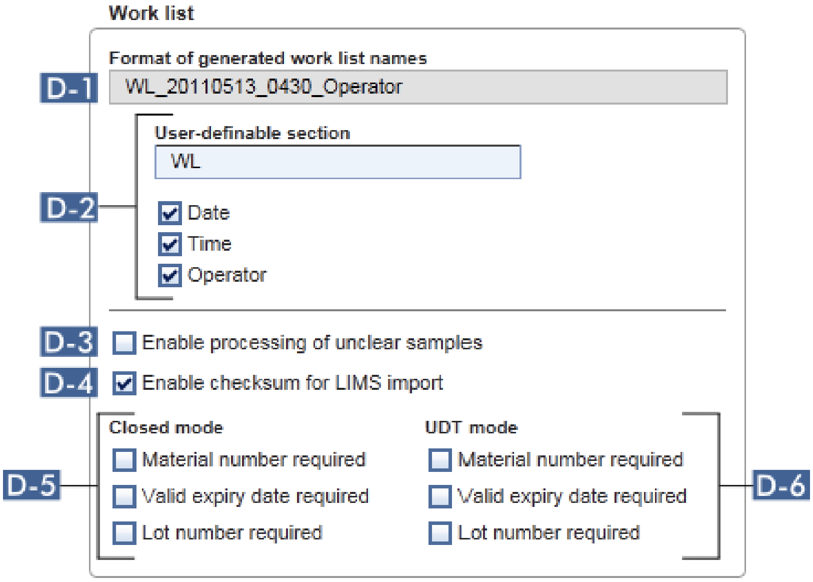


	Explanation
C-1	Displays a preview of the selected header image. If no image is selected, the message "No image configured" is shown.
C-2	Use to select a header image. The size of the header image must not exceed 1900 x 300 pixels. Step-by-step procedure to select a header image 1. Click the pencil icon (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 . 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 ( ). 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 ( ). 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 "Work list"

The "Work list" group box bundles various options concerning work lists, e.g., the naming scheme for default names, requirements for material numbers, etc.



Work list

Format of generated work list names

WL_20110513_0430_Operator

User-definable section

WL

☑ Date

☑ Time

☑ Operator

☐ Enable processing of unclear samples

☑ Enable checksum for LIMS import

Closed mode

☐ Material number required

☐ Valid expiry date required

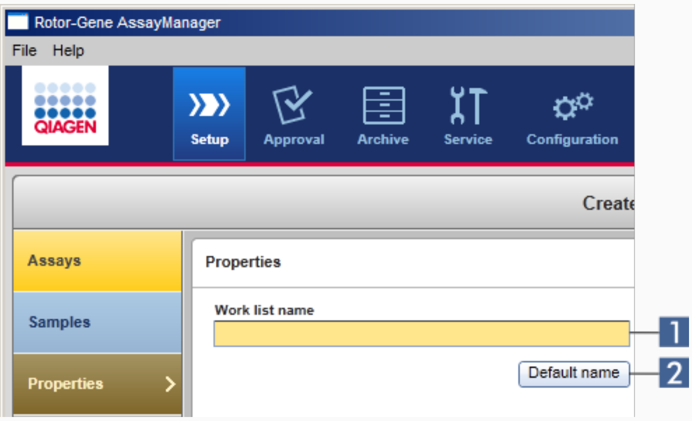
☐ Lot number required

UDT mode

☐ Material number required

☐ Valid expiry date required

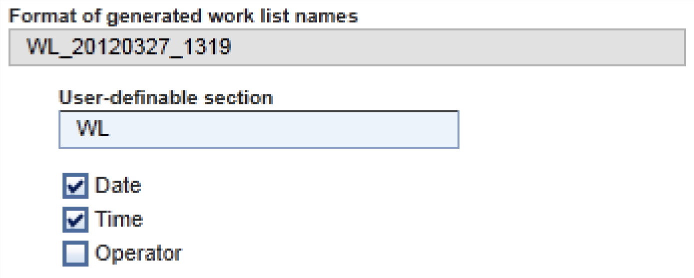
☐ Lot number required

	Explanation
D-1	Displays the current default work list name definition, as it results from the selected options in .
D-2	When the user manually creates a new work list in the "Setup" environment, a work list name must be entered in the "Properties" step. The user can either enter an arbitrary name in the "Work list name" field (1) or let the Rotor-Gene AssayManager v1.0 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 work list name. The options are separated by a "_" character in the work list 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 work list name will always start with this section.

Rotor-Gene AssayManager v1.0 is delivered with the following default settings:



Format of generated work list names

WL_20120327_1319

User-definable section

WL

☑ Date
☑ Time
☐ Operator

The text in the field "Format of generated work list 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 will be handled as valid. An "UNCLEAR" flag is assigned to the valid sample result as a warning.

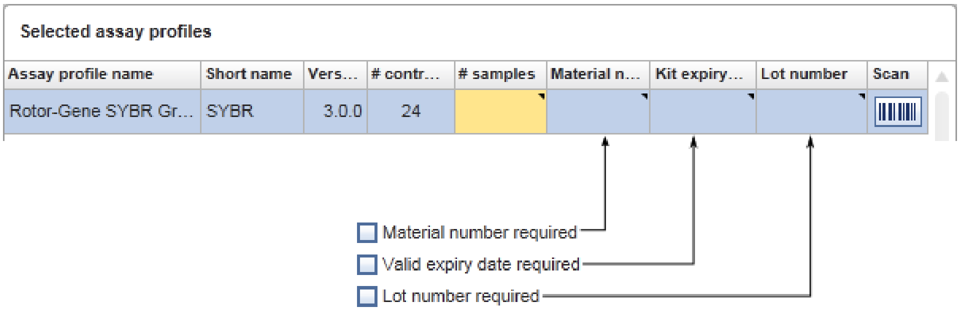
If the check box is not activated, unclear samples will be handled as "invalid" samples and no usable results are assigned by Rotor-Gene AssayManager v1.0 after the run is finished. Affected samples will get an "INVALID" flag as result.

> 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.

D-4 If activated, the checksum algorithm is applied for work list import from a LIMS. If not activated, Rotor-Gene AssayManager v1.0 does not verify the checksum of a work list to be imported from a LIMS.

D-5
D-6

The options in and refer to the creation of a new work list. In this first step of the work list creation process, the user enters the number of test samples. Optionally, the user can enter the material number, kit expiry date, and the lot number.
If the check boxes in front of the options in the work list group box are activated, the associated entries are mandatory during work list setup. If the check boxes are not activated, the associated entries are optional.


Selected assay profiles

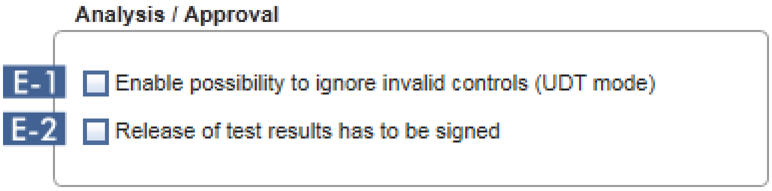
Assay profile name	Short name	Vers...	# contr...	# samples	Material n...	Kit expiry...	Lot number	Scan
Rotor-Gene SYBR Gr...	SYBR	3.0.0	24					

☐ Material number required
☐ Valid expiry date required
☐ Lot number required

These options can be set independently for work list setup in Closed Mode (options in) and UDT Mode (options in).

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

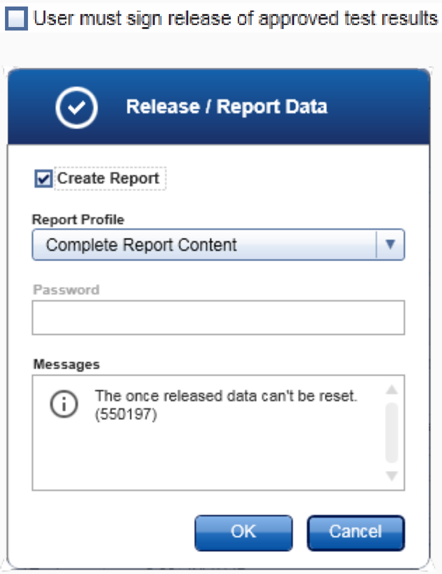
	Explanation
E-1	By checking the check box "Enable possibility to ignore invalid controls (UDT Mode)", the "Ignore invalid controls" check box in the "Approval" environment of the UDT Mode (which is deactivated by default) can be activated. The "Ignore invalid controls" check box has the following functionality: ▪ If an assay in UDT Mode is invalid, it can be manually set to be valid by checking the "Ignore invalid controls" check box. Using this functionality, individual external controls that were evaluated as invalid by Rotor-Gene

AssayManager v1.0 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 "Ignore invalid controls" check box is used for assay approval, this will be mentioned on the result report.

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

Release / Report Data

☑ Create Report

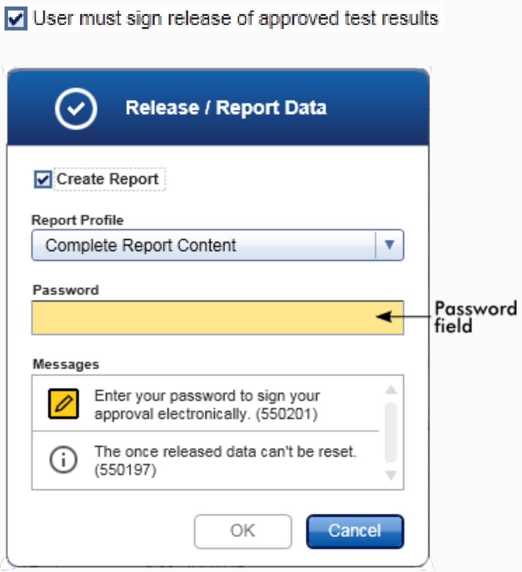
Report Profile: Complete Report Content

Password:

Messages:

The once released data can't be reset. (550197)

User releases test samples simply by clicking "OK".


☑ User must sign release of approved test results

Release / Report Data

☑ Create Report

Report Profile: Complete Report Content

Password:

Messages:

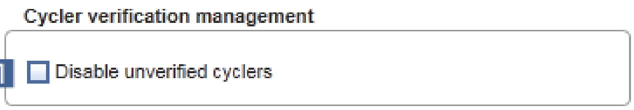
Enter your password to sign your approval electronically. (550201)

The once released data can't be reset. (550197)

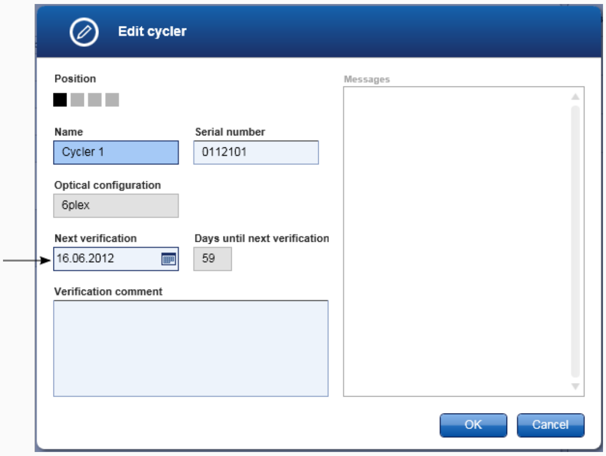
The approver's password must be entered before test samples are released. The "OK" button is disabled by default and will be activated once the correct password is entered.

Group box "Cycler verification management"

F-1

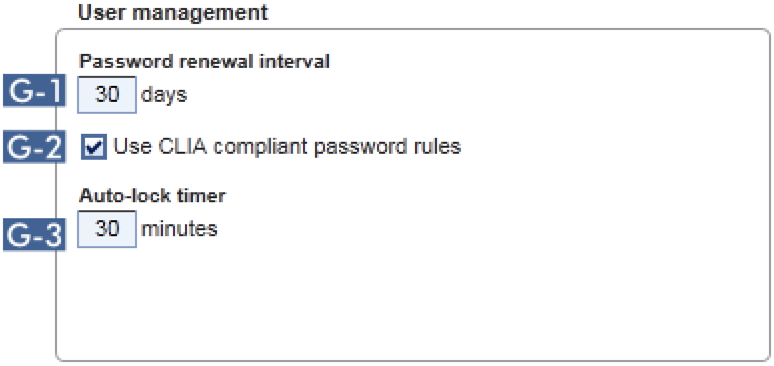

Cycler verification management

☐ Disable unverified cyclers

	Explanation	
F-1	Rotor-Gene AssayManager v1.0 continuously checks the status of connected cyclers concerning verification. The option determines if cyclers with a verification status past due are automatically disabled or not.	
	Activated  Cycler verification management ☑ Disable unverified cyclers	If the verification of a cycler has expired, the cycler's status is set to “Needs verification”. This cycler is no longer available for experiments. 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 cycler management tab ▶ "Edit cycler" dialog.  Name: Cycler 1 Serial number: 0112101 Optical configuration: 6plex Next verification: 16.06.2012 Days until next verification: 59 Verification comment
	Deactivated  Cycler verification management ☐ Disable unverified cyclers	If the check box is deactivated, cyclers can be used for experiments even if the verification has expired.

Group box "User management"

The settings in this group box influence the password renewal interval, password rules, and the auto-lock timer.



User management

Password renewal interval

30 days

☑ Use CLIA compliant password rules

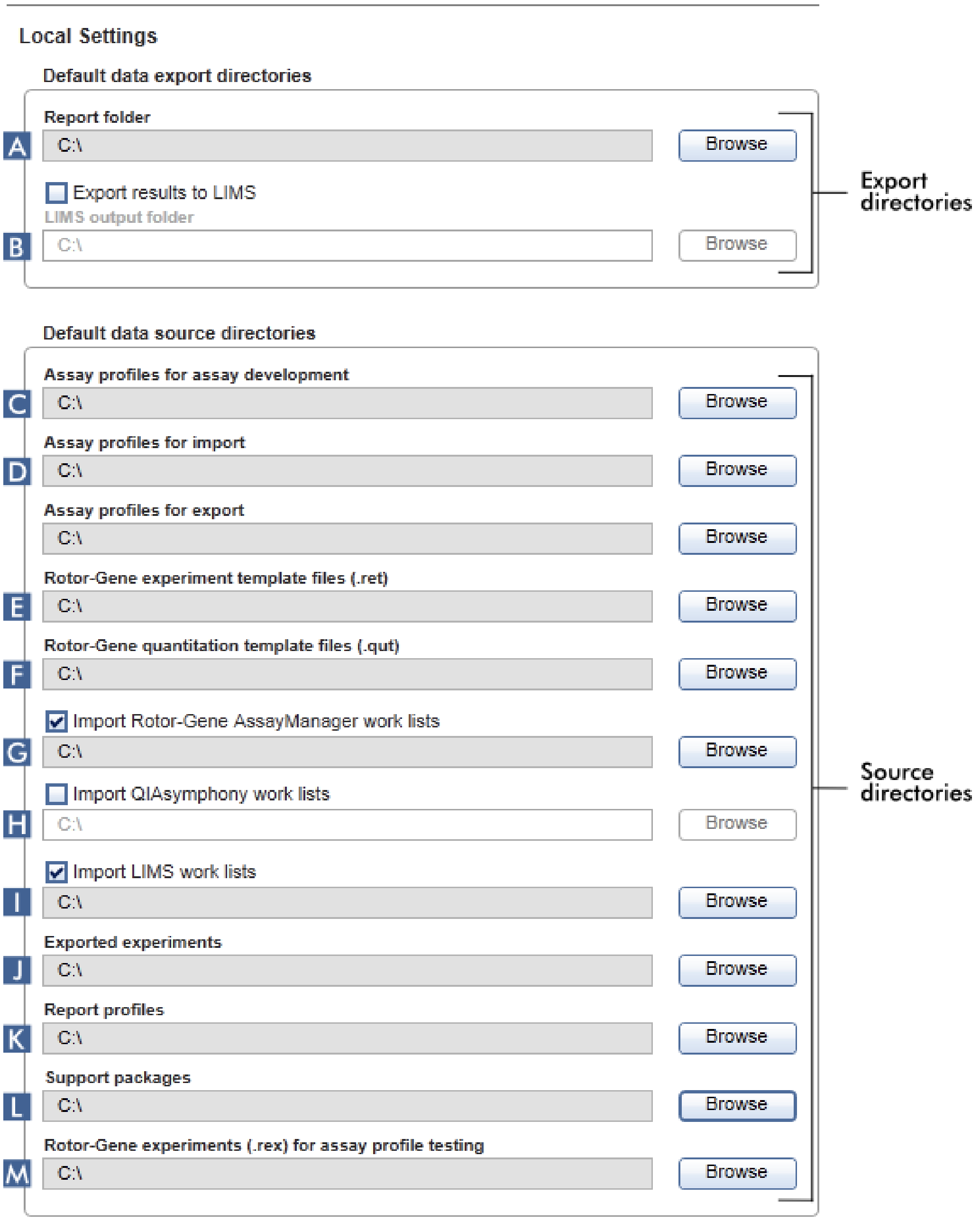
Auto-lock timer

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 Browse and selecting the specific export/source directory.



Local Settings

Default data export directories

A Report folder: C:\ Browse

☐ Export results to LIMS

B LIMS output folder: C:\ Browse

Default data source directories

C Assay profiles for assay development: C:\ Browse

D Assay profiles for import: C:\ Browse

Assay profiles for export: C:\ Browse

E Rotor-Gene experiment template files (.ret): C:\ Browse

F Rotor-Gene quantitation template files (.qut): C:\ Browse

G ☑ Import Rotor-Gene AssayManager work lists: C:\ Browse

H ☐ Import QIAsymphony work lists: C:\ Browse

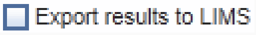
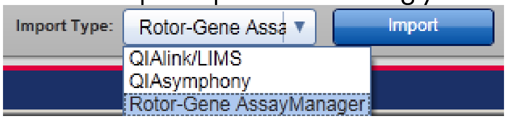
I ☑ Import LIMS work lists: C:\ Browse

J Exported experiments: C:\ Browse

K Report profiles: C:\ Browse

L Support packages: C:\ Browse

M Rotor-Gene experiments (.rex) for assay profile testing: C:\ Browse

	Explanation
A	Target directory where reports generated in the "Approval" or "Archive" environment are saved.
B	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:  ☐ Export results to LIMS 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.
C	Source directory for assay profiles for development in UDT mode.
D	Source directory for assay profiles to be imported into the Rotor-Gene AssayManager v1.0 database via the "Assay Profiles" tab in the "Configuration" environment.
E	Source directory for Rotor-Gene experiment template files (*.ret) used in the "Development" environment of the UDT mode.
F	Source directory for Rotor-Gene quantitation template files (*.qut) used in the "Development" environment of the UDT mode.
G	 ☑ Import Rotor-Gene AssayManager work lists Rotor-Gene AssayManager v1.0 can import work lists from other Rotor-Gene AssayManager v1.0 installations, QIAsymphony, and LIMS. The user can select which of these 3 import options shall be available by activating the check boxes G – I. The import type menu in the "Setup" environment will be populated with the selected import options accordingly. 
H	 ☑ Import QIAsymphony work lists
I	 ☑ Import LIMS work lists
J	Destination for *.rex-files exported from the "Archive" environment.
K	Directory for importing and exporting report profiles

L	Destination for support packages created from the "Approval" or "Archive" environment.
M	Source directory for Rotor-Gene experiments (*rex-files) to be tested in the "Development" environment of the UDT mode.

Tasks related to the "Settings" environment

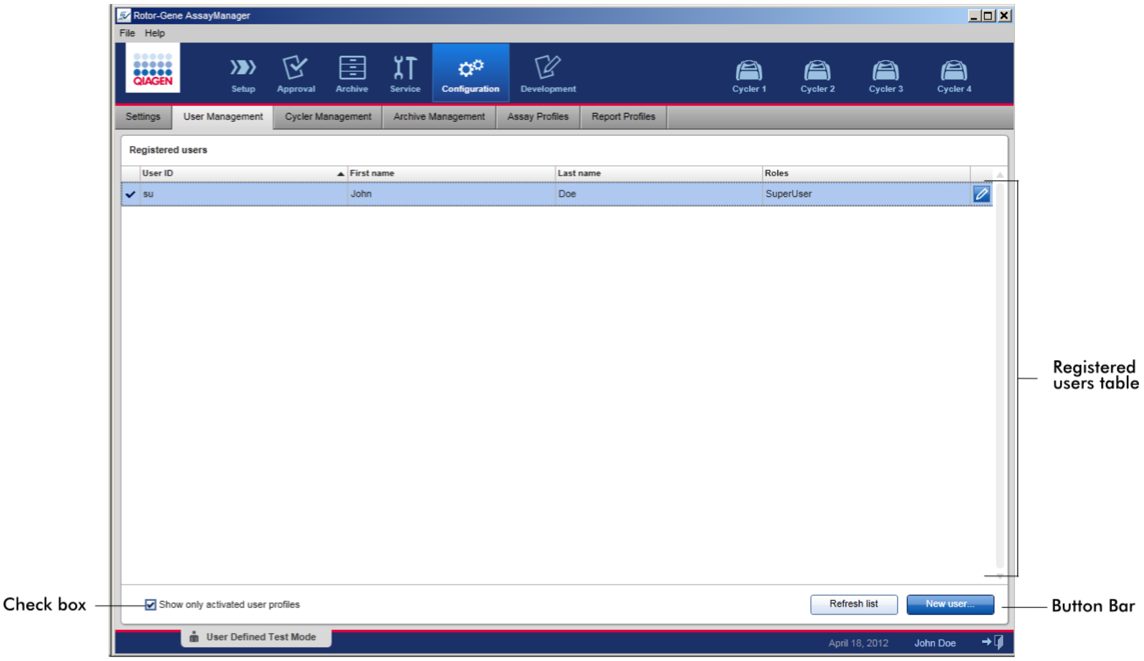
- Managing cyclers
- Managing report profiles
- Creating/editing a work list
- Finishing and releasing a run
- Managing users

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

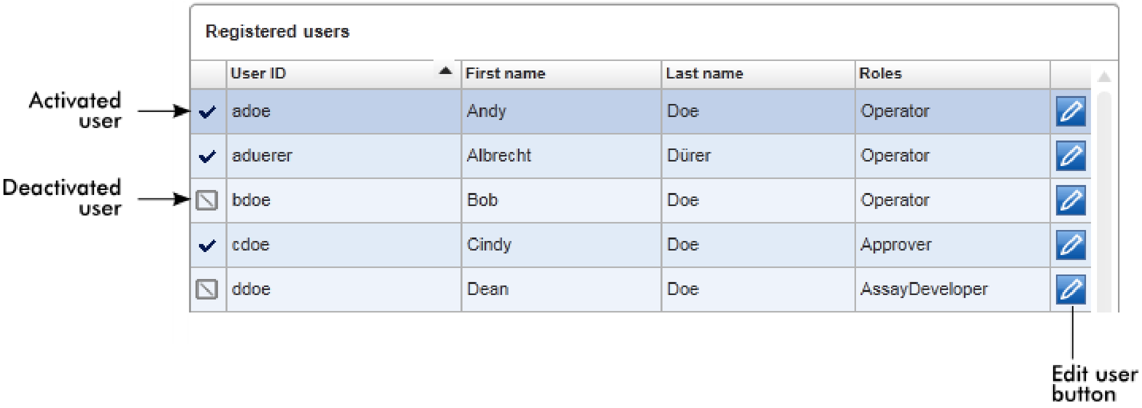


	User ID	First name	Last name	Roles
✓	su	John	Doe	SuperUser

☑ Show only activated user profiles

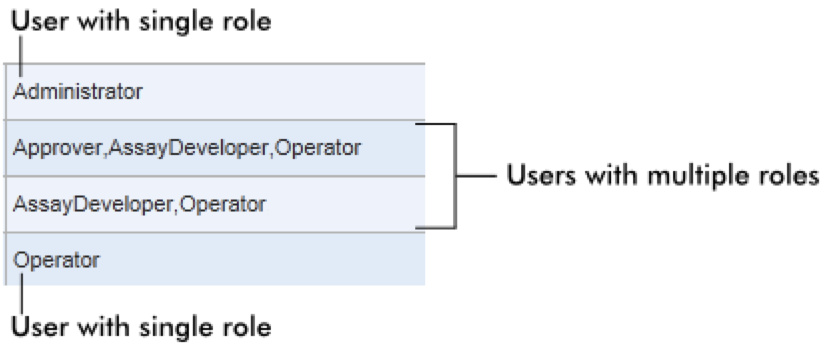
"Registered users" table

The "Registered users" table lists all user profiles already configured in Rotor-Gene AssayManager v1.0. 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.



Registered users

	User ID	First name	Last name	Roles	
✓	adoe	Andy	Doe	Operator	✎
✓	aduerer	Albrecht	Dürer	Operator	✎
⊘	bdoe	Bob	Doe	Operator	✎
✓	cdoe	Cindy	Doe	Approver	✎
⊘	ddoe	Dean	Doe	AssayDeveloper	✎

Column	Explanation
User status	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. ✓ User is activated. ▧ User is deactivated. 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.
"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. **Example**  Administrator Approver,AssayDeveloper,Operator AssayDeveloper,Operator Operator
"Edit user" button ✎	The "Edit user" button opens the "Edit User" dialog where properties and settings can be modified for a user.

First name: John

Last name: Doe

User ID: su

Password: ••••••••

Confirm password: ••••••••

☑ *Activate user*

Messages

Roles

☐ Administrator

☐ Approver

☐ AssayDeveloper

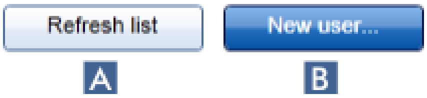
☐ Operator

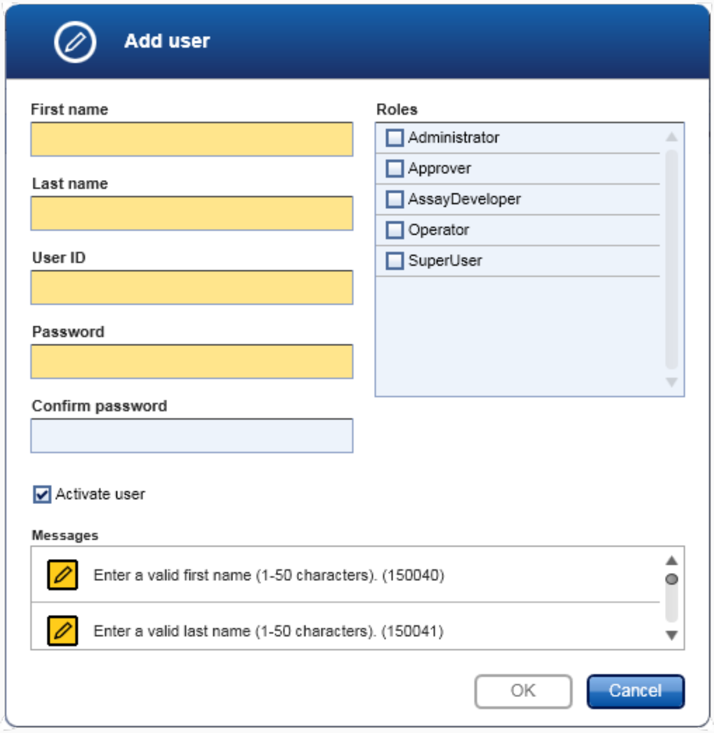
☑ SuperUser

	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 *QIAGEN*, *Service*, and *User* 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 case characters, 2 lower case characters, 2

		numerical characters, and 2 special characters. The password must be re-entered exactly in the "Confirm password" field.
E	"Activate user" check box	Activates or deactivates a user profile by clicking this check box ☑ Activate user — User profile is activated. ☐ Activate user — User profile is deactivated.
F	"Messages" box	Displays information, warnings, and errors.
G	"Roles" selection list	Assigns roles to a user profile. Activate the check box in front of a role to assign this role to the current user profile. It is possible to assign multiple roles to a user profile. For details see ▶ User roles.
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:  Add user First name Last name User ID Password Confirm password ☑ Activate user Roles ☐ Administrator ☐ Approver ☐ AssayDeveloper ☐ Operator ☐ SuperUser Messages Enter a valid first name (1-50 characters). (150040) Enter a valid last name (1-50 characters). (150041) OK Cancel Characteristics upon opening the dialog: ▪ 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

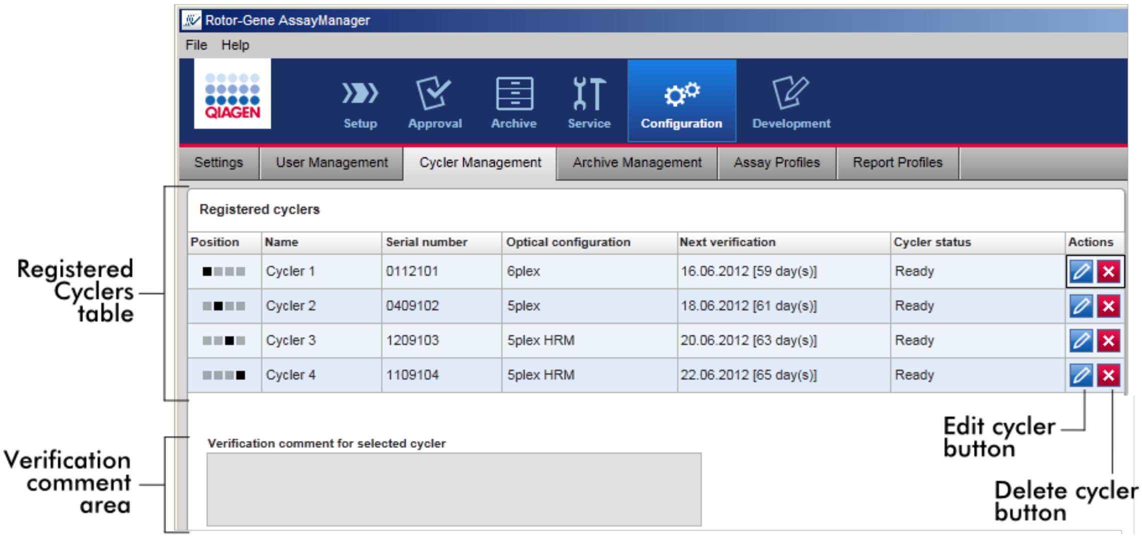
- Creating a user profile
- Changing user profile settings
- Activate/deactivate a user profile

1.5.5.6.3 Cycler Management

The "Cycler Management" tab gives an overview of the configured cyclers, their properties, and their current status.

The "Cycler Management" tab mainly consists of 2 parts:

- "Registered Cyclers" table with 2 buttons for every cycler
    - "Edit cycler" button
    - "Delete cycler" button
- "Verification comment for selected cycler" area



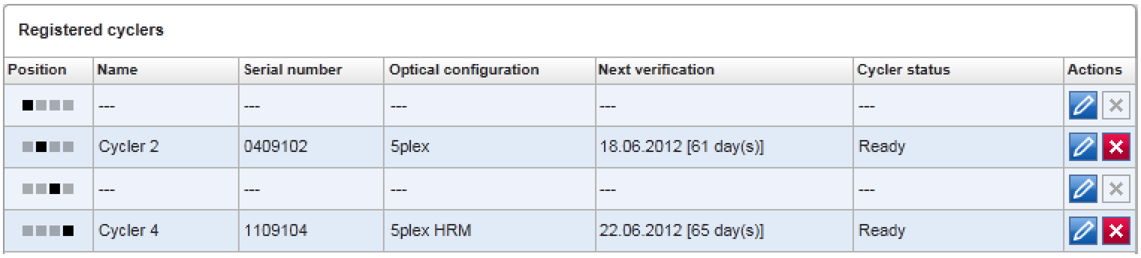
Registered cyclers

Position	Name	Serial number	Optical configuration	Next verification	Cycler status	Actions
■□□□	Cycler 1	0112101	6plex	16.06.2012 [59 day(s)]	Ready	✎ ✕
□■□□	Cycler 2	0409102	5plex	18.06.2012 [61 day(s)]	Ready	✎ ✕
□□■□	Cycler 3	1209103	5plex HRM	20.06.2012 [63 day(s)]	Ready	✎ ✕
□□□■	Cycler 4	1109104	5plex HRM	22.06.2012 [65 day(s)]	Ready	✎ ✕

Verification comment for selected cycler

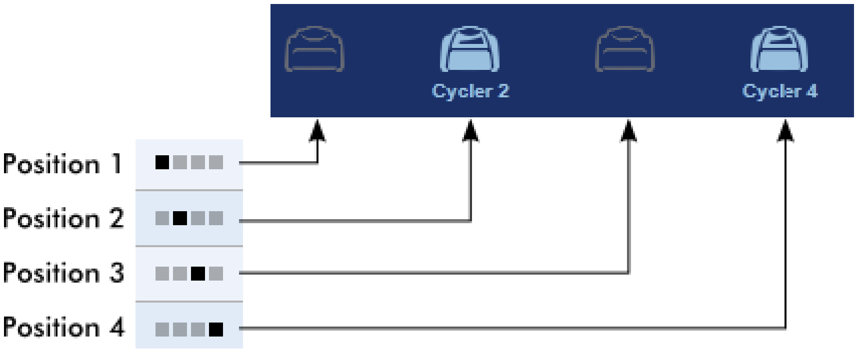
"Registered Cyclers" table

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"	A graphical illustration represents the configurable cyclers. The current cycler position is indicated by a black square. Example:  In the illustration above, the first and third cycler positions are not registered. Their icons are inactive.
"Name"	Name of a registered cycler. Characteristics ▪ Must not be empty ▪ Must have 1–8 characters ▪ Must be unique within a Rotor-Gene AssayManager v1.0 installation
"Serial number"	Serial number of a registered cycler.

<table>
<tr><th></th><th></th></tr>
<tr><td></td><td>Characteristics
▪ Must not be empty
▪ Must be unique within a Rotor-Gene AssayManager v1.0 installation
▪ Must match a connected cycler that is switched on

After entering the serial number of a connected cycler, its optical configuration is automatically checked by the Rotor-Gene AssayManager v1.0 and displayed in the "Optical configuration" box. This box remains empty if no cycler with the entered serial number is connected.</td></tr>
<tr><td>"Optical configuration"</td><td>Optical configuration of a registered cycler.</td></tr>
<tr><td>"Next verification"</td><td>Next temperature verification date and remaining days until that date.

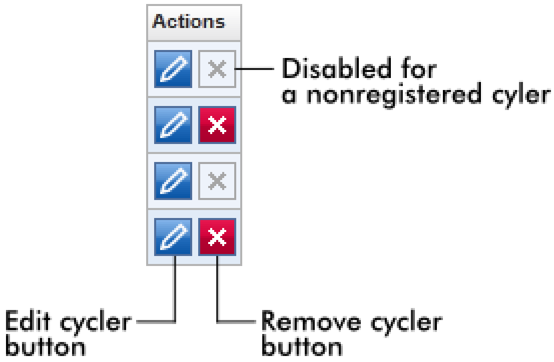
Characteristics
▪ This field can be empty.
▪ If it is set to empty, the “Verification comment” text box is disabled and its content is cleared.
▪ If the date is expired, the "Verification comment" text box is disabled.
▪ If a date is set, the date must be in the future.</td></tr>
<tr><td>"Cycler status"</td><td>Shows the current status of a registered cycler. Possible values are:
<table>
<tr><td>Offline</td><td>Cycler is not connected or connected but not switched on.</td></tr>
<tr><td>Ready</td><td>Cycler is ready.</td></tr>
<tr><td>Needs verification</td><td>Verification has expired.</td></tr>
<tr><td>Loaded</td><td>The cycler is loaded and ready to be run.</td></tr>
<tr><td>Running</td><td>Cycler is currently running.</td></tr>
<tr><td>Run stopped</td><td>User has stopped a run while the cycler was running.</td></tr>
<tr><td>Run complete</td><td>Run has finished successfully.</td></tr>
<tr><td>Run failed</td><td>Error occurred during the run.</td></tr>
</table></td></tr>
</table>

	Run stopped, cycler disconnected	Cycler was disconnected when it had the status "Run stopped".
	Run complete, cycler disconnected	Cycler was disconnected when it had the status "Run complete".
	Run failed, cycler disconnected	Cycler was disconnected during a run or when it had the status "Run failed".

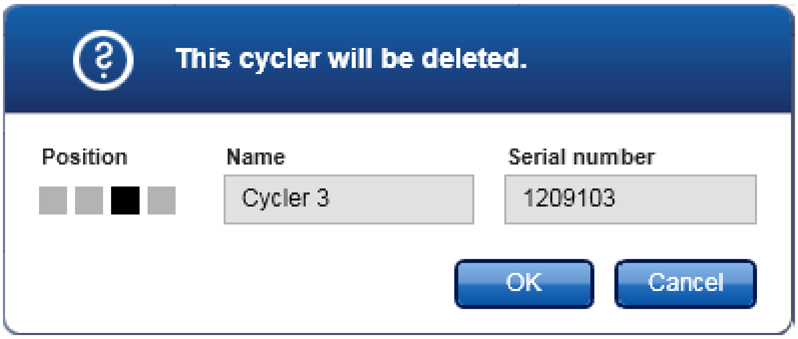
"Actions"

The actions column contains 2 buttons for:

- Editing the cycler's properties
- Removing a cycler



"Remove cycler" button
If the "Remove cycler" button is clicked, the following dialog will be displayed and has to be confirmed with "OK" to remove a cycler finally:

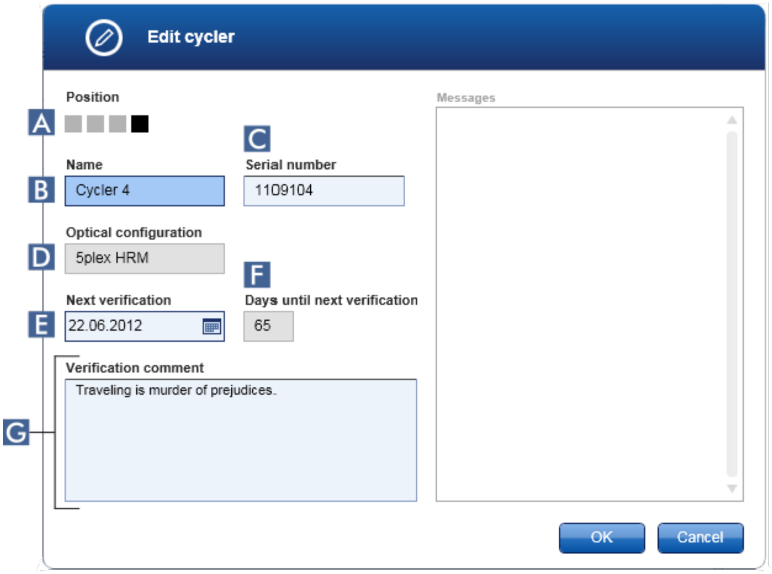

This cycler will be deleted.

Position

Name: Cycler 3

Serial number: 1209103

"Edit cycler" button
If the "Edit cycler" button is clicked, the "Edit cycler" dialog will be displayed.



Position

Name: Cycler 4

Serial number: 1109104

Optical configuration: 5plex HRM

Next verification: 22.06.2012

Days until next verification: 65

Verification comment: Traveling is murder of prejudices.

	Explanation
A	A graphical illustration representing the up to 4 configurable cyclers. The current cycler position is indicated by a black square.
B	Name of the cycler. The field can be edited.
C	Serial number of the cycler. The field can be edited.
D	Optical configuration of the cycler. The field cannot be edited; it is read-only.
E	Next verification date. The date can either be entered manually or using the date picker (▦).
F	Displays the number of remaining days until the verification date. The field cannot be edited.
G	Text field to enter an optional verification comment.

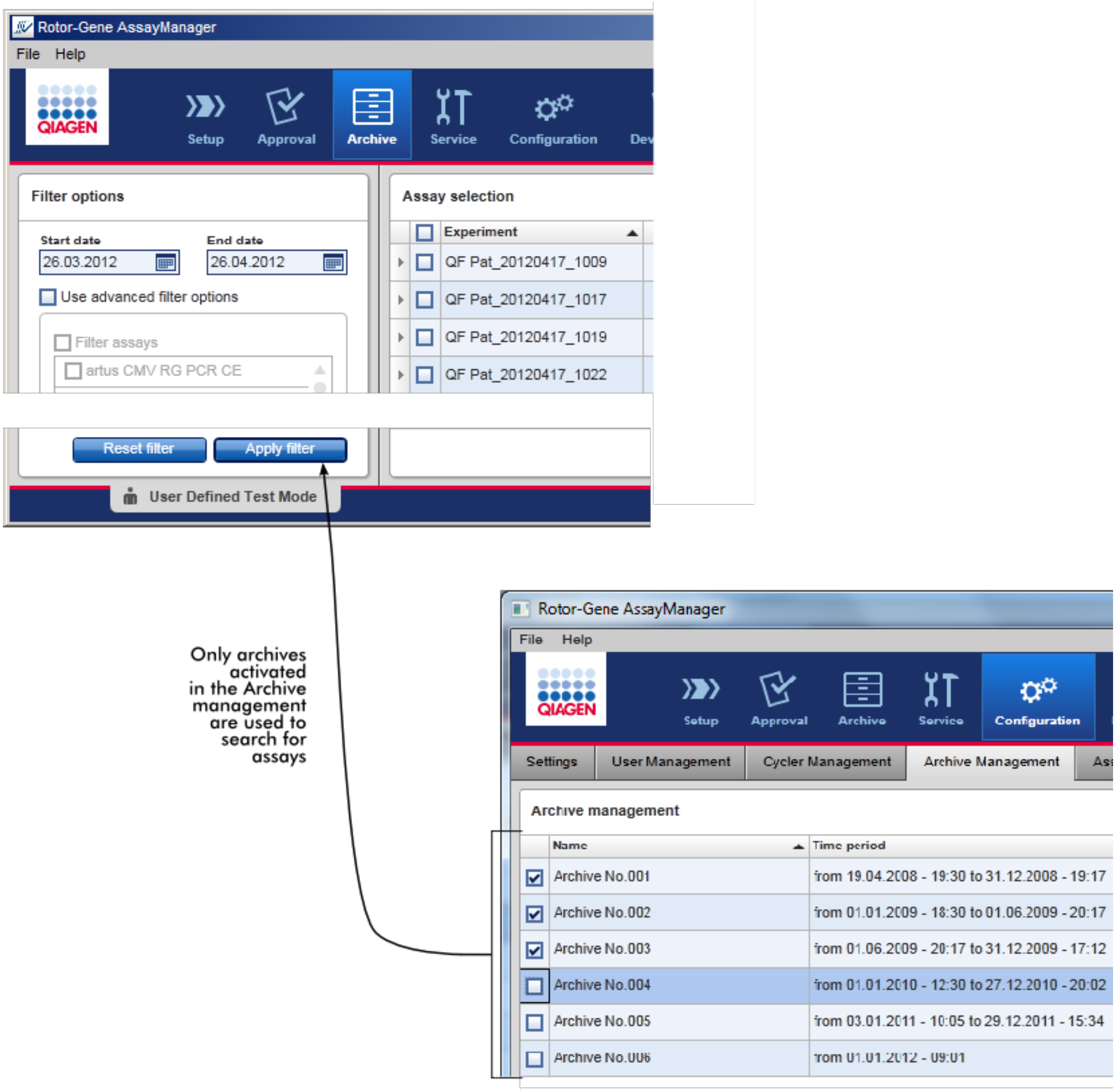
Tasks related to the "Cycler Management" tab

- 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.



Filter options

Start date: 26.03.2012

End date: 26.04.2012

☐ Use advanced filter options

☐ Filter assays

☐ artus CMV RG PCR CE

Assay selection

☐	Experiment
☐	QF Pat_20120417_1009
☐	QF Pat_20120417_1017
☐	QF Pat_20120417_1019
☐	QF Pat_20120417_1022

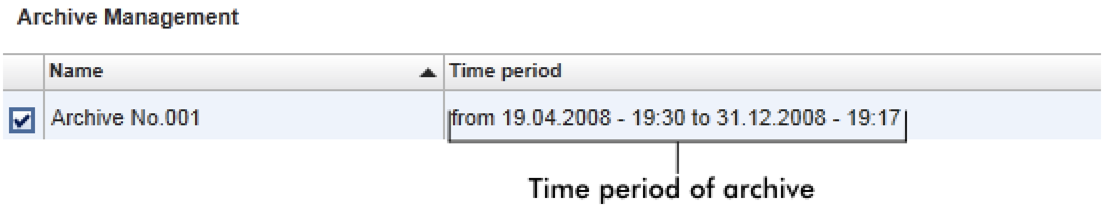
Archive management

	Name	Time period
☑	Archive No.001	from 19.04.2008 - 19:30 to 31.12.2008 - 19:17
☑	Archive No.002	from 01.01.2009 - 18:30 to 01.06.2009 - 20:17
☑	Archive No.003	from 01.06.2009 - 20:17 to 31.12.2009 - 17:12
☐	Archive No.004	from 01.01.2010 - 12:30 to 27.12.2010 - 20:02
☐	Archive No.005	from 03.01.2011 - 10:05 to 29.12.2011 - 15:34
☐	Archive No.006	from 01.01.2012 - 09:01

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
☑	Archive No.001	from 19.04.2008 - 19:30 to 31.12.2008 - 19:17

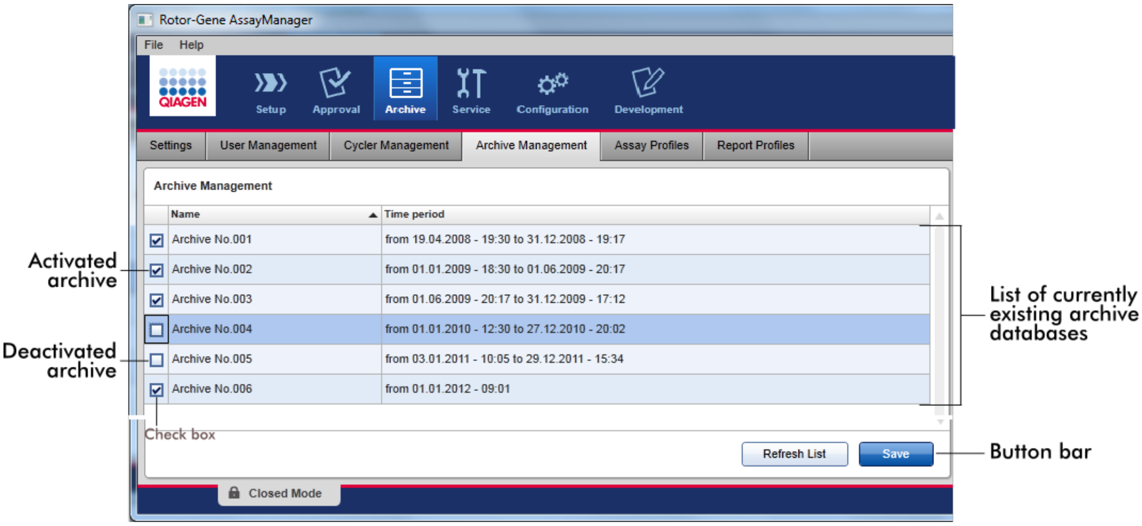
Time period of archive

- 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



	Name	Time period
☑	Archive No.001	from 19.04.2008 - 19:30 to 31.12.2008 - 19:17
☑	Archive No.002	from 01.01.2009 - 18:30 to 01.06.2009 - 20:17
☑	Archive No.003	from 01.06.2009 - 20:17 to 31.12.2009 - 17:12
☐	Archive No.004	from 01.01.2010 - 12:30 to 27.12.2010 - 20:02
☐	Archive No.005	from 03.01.2011 - 10:05 to 29.12.2011 - 15:34
☑	Archive No.006	from 01.01.2012 - 09:01

"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 relating 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

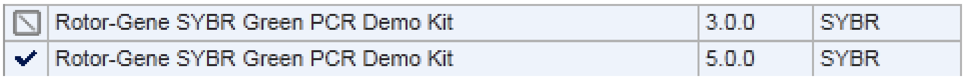
- Managing archives

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.

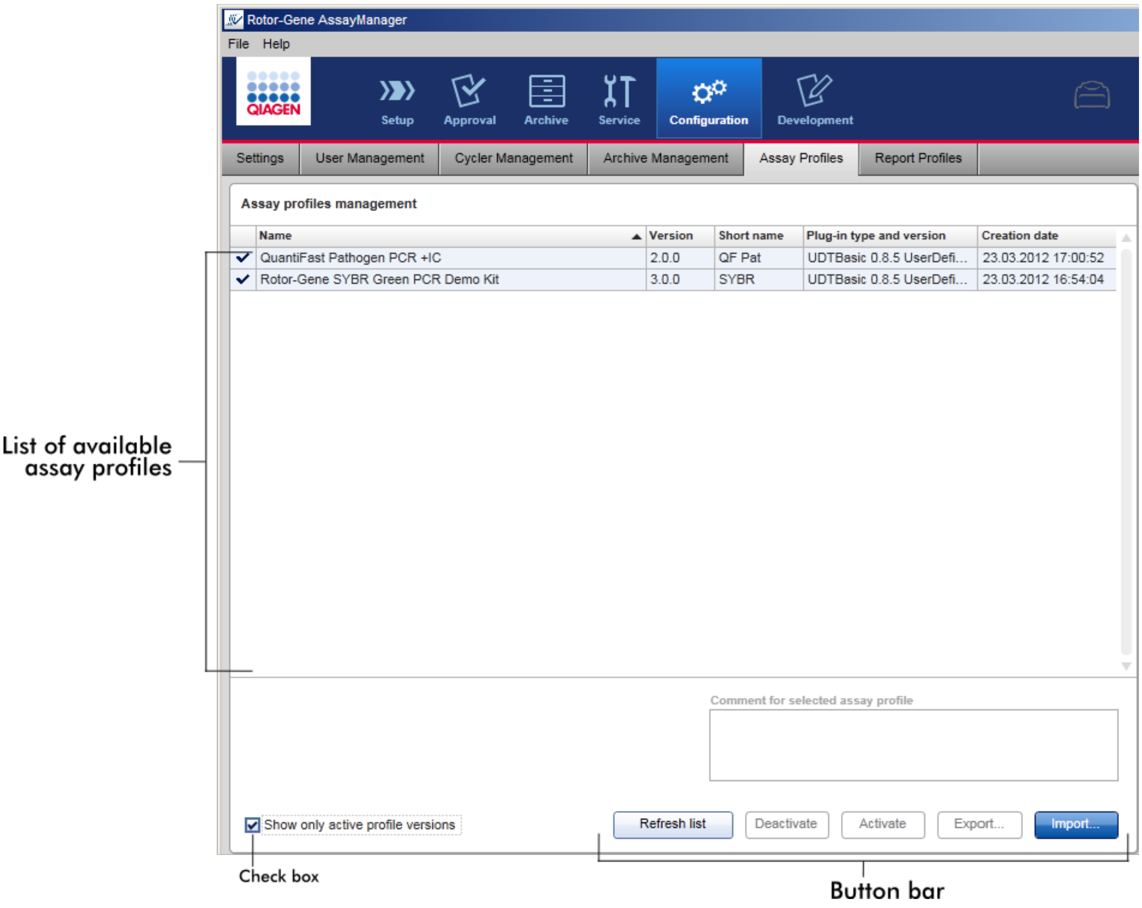
Example**:**
The following screenshot shows an example where an assay profile "Rotor-Gene SYBR Green PCR Demo Kit" exists in two different versions, 3.0.0 and 5.0.0. Only one version can be active. Version 3.0.0 is deactivated (icon ⧅), and version 5.0.0 is activated (icon ✓).



⧅	Rotor-Gene SYBR Green PCR Demo Kit	3.0.0	SYBR
✓	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



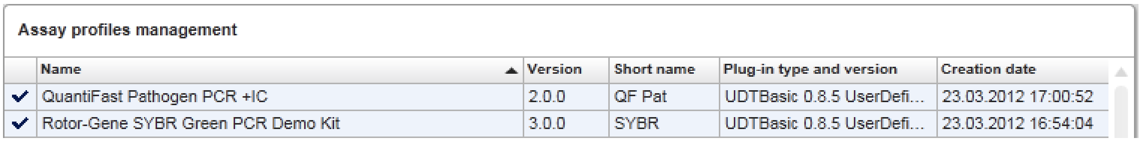
Assay profiles management

	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

☑ Show only active profile versions

"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 v1.0 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 cell 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

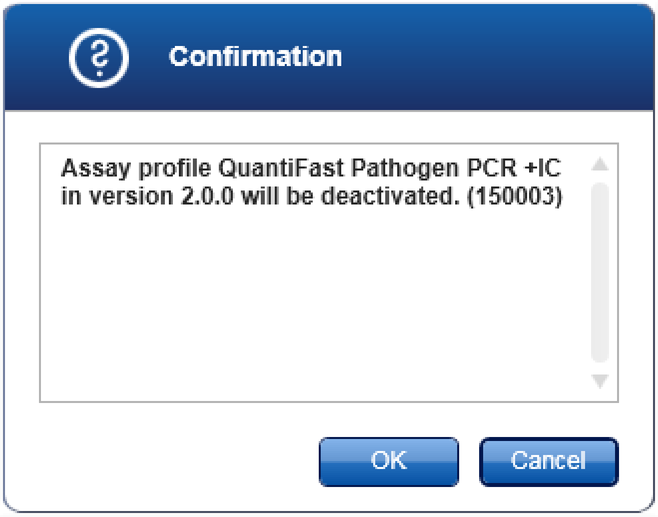
With the check box "Show only active profile versions" it can be determined if deactivated assay profiles are shown in the table or not.

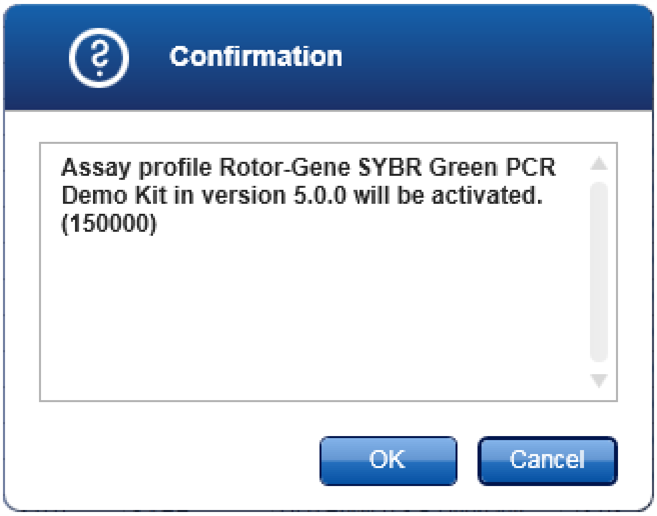
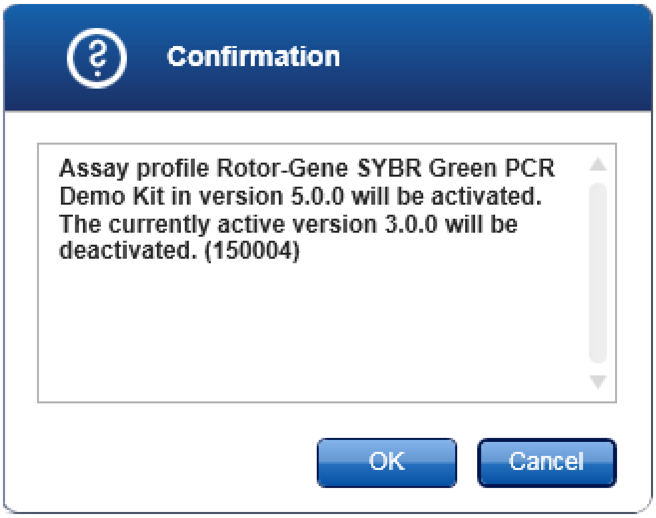
☐ Show only active profile versions

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	Status of the assay profile. ▨ Deactivated assay profile ✓ Activated assay profile
"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.

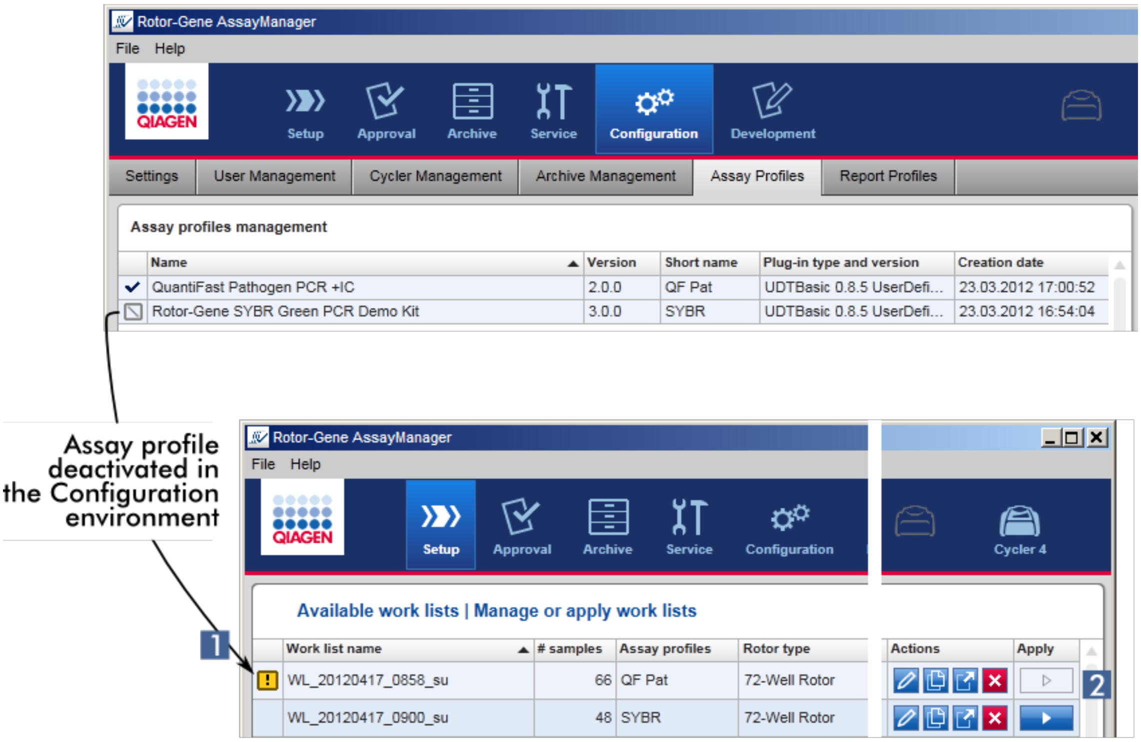
Button bar

	Label/Title	Description
A	"Refresh list"	Updates the list of all available assay profiles.
B	"Deactivate"	Deactivates the selected assay profile. A confirmation dialog must be confirmed by clicking "OK" before the selected assay profile is deactivated.  Assay profile QuantiFast Pathogen PCR +IC in version 2.0.0 will be deactivated. (150003) ▪ If the check box "Show only active profile versions" is deactivated, the deactivated assay profile is listed in the table with an ▨ 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.

		 Assay profile Rotor-Gene SYBR Green PCR Demo Kit in version 5.0.0 will be activated. (150000) 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.  Assay profile Rotor-Gene SYBR Green PCR Demo Kit in version 5.0.0 will be activated. The currently active version 3.0.0 will be deactivated. (150004) 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 work lists in the "Setup" environment.



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

Assay profile deactivated in the Configuration environment

Available work lists | Manage or apply work lists

	Work list name	# samples	Assay profiles	Rotor type	Actions	Apply
!	WL_20120417_0858_su	66	QF Pat	72-Well Rotor		▷
	WL_20120417_0900_su	48	SYBR	72-Well Rotor		▶

Consequence in the Setup environment:
Work lists containing the deactivated assay profile are displayed with a warning icon (1) and cannot be applied (2).

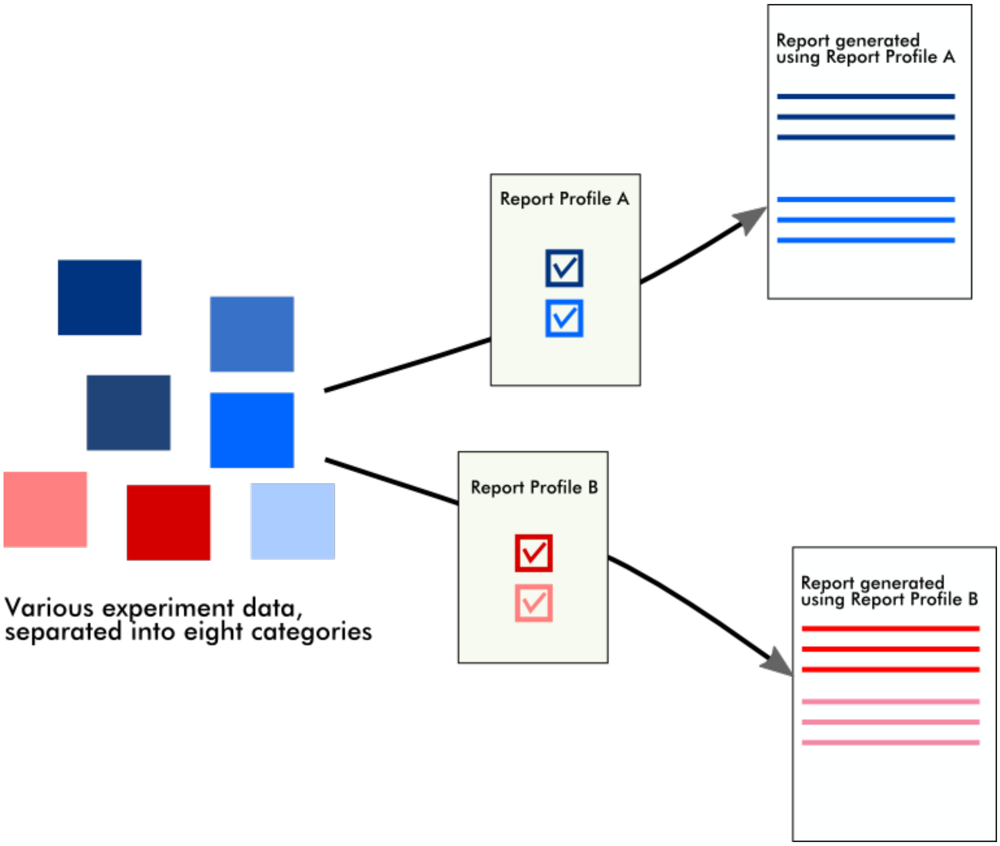
If an assay profile is deactivated in the "Configuration" environment, work lists in the "Setup" environment containing this assay profile cannot be applied anymore.

Tasks related to the "Assay Profiles" tab

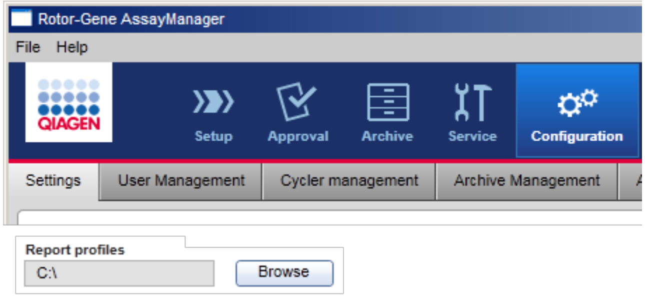
- Activating/deactivating an assay profile
- Importing/exporting an assay profile

1.5.5.6.6 **Report Profiles**

A report containing various data about an experiment can be generated by Rotor-Gene AssayManager v1.0 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-Gene AssayManager v1.0 installations. The default export and import directories for report profiles can be configured in the "Settings" tab of the "Configuration" environment.



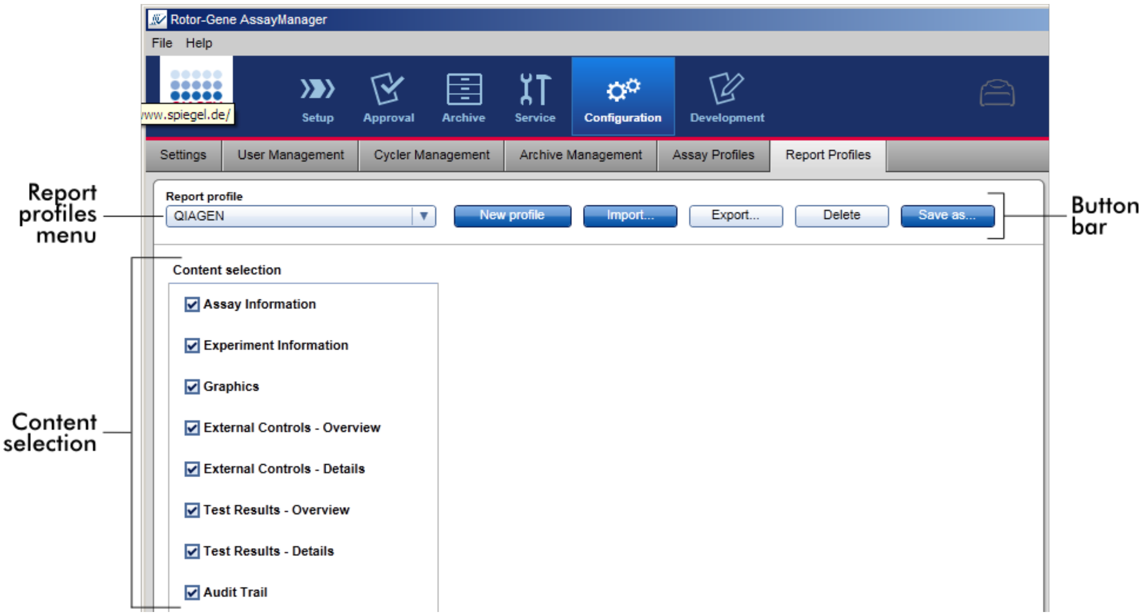
Report profiles

C:\

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

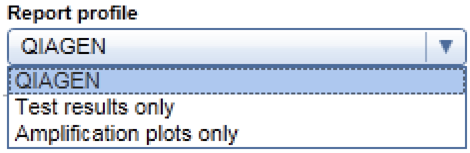
QIAGEN

Content selection

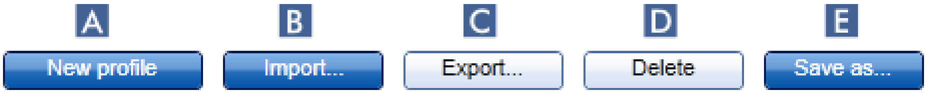
- ☑ Assay Information
- ☑ Experiment Information
- ☑ Graphics
- ☑ External Controls - Overview
- ☑ External Controls - Details
- ☑ Test Results - Overview
- ☑ Test Results - Details
- ☑ Audit Trail

"Report profile" menu

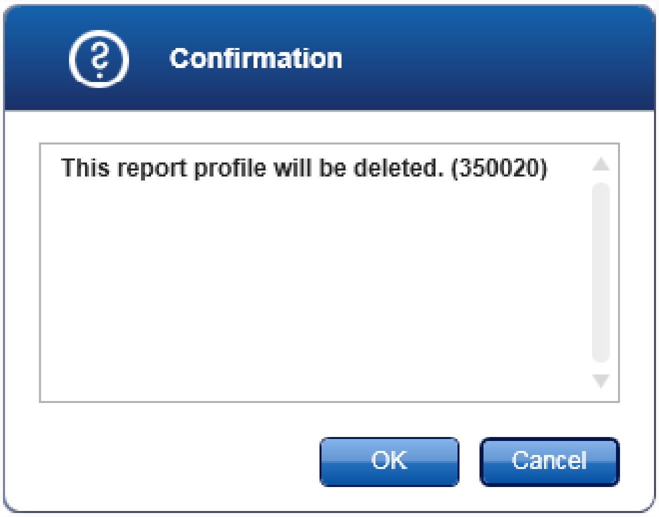
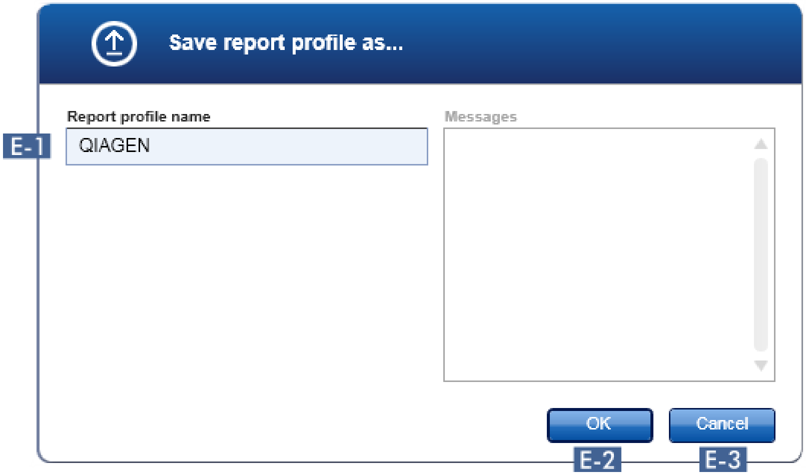
The "Report profile" drop-down menu contains all configured report profiles. The currently selected report profile is displayed in the menu. Clicking the menu arrow (▼) shows a full listing of all currently available report profiles.



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.

		 This report profile will be deleted. (350020) Clicking "OK" removes the report profile from the internal database.
E	"Save as..."	Saves the configured report profile. The following dialog is opened:  Report profile name: QIAGEN Field to enter a name for the report profile file. Saves the report file in the internal database using the name entered in field . Cancels the process and closes this dialog.

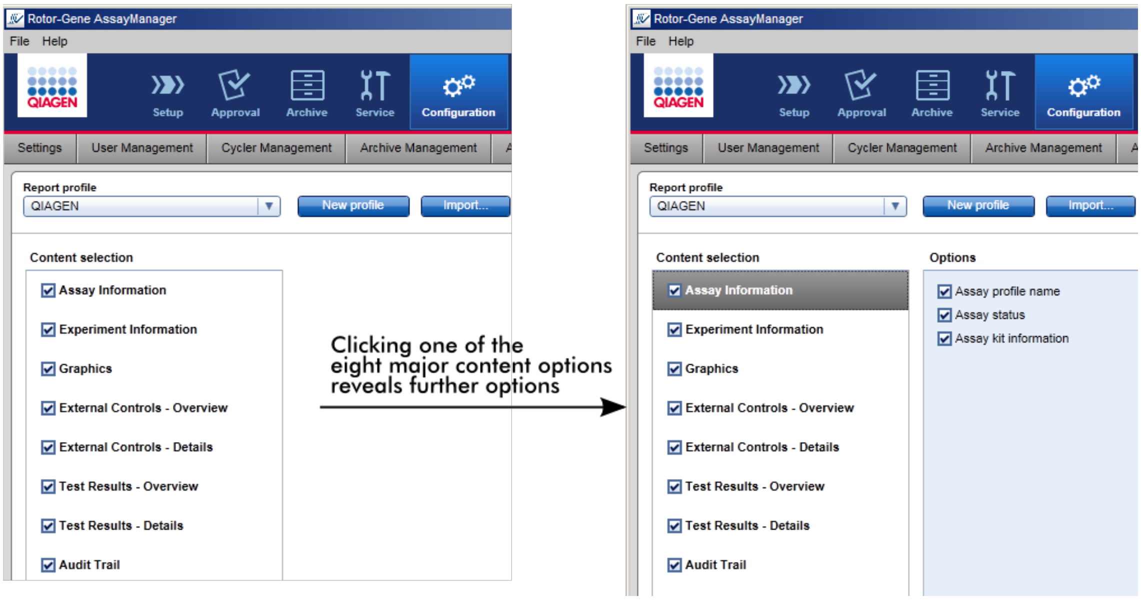
"Content selection" area

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"
- "Experiment Information"
- "Graphics"
- "External Controls - Overview"
- "External Controls - Details"
- "Test Results - Overview"
- "Test Results - Details"
- "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.



Report profile: QIAGEN

Content selection

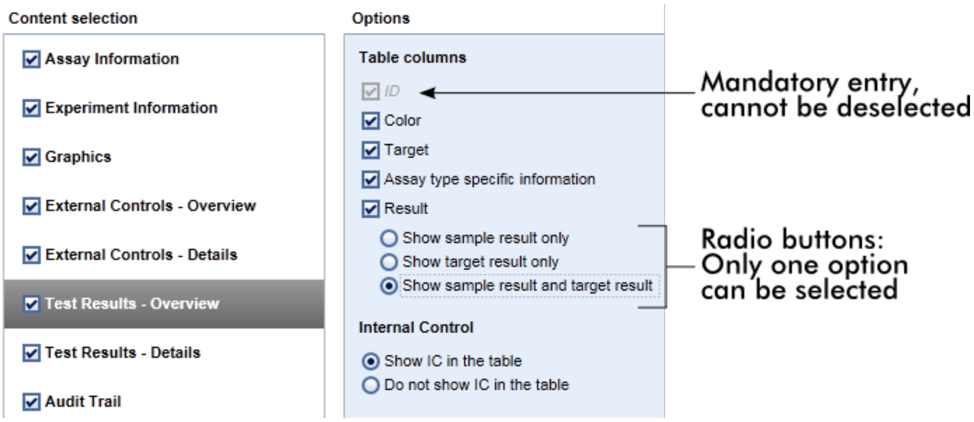
☑ Assay Information
☑ Experiment Information
☑ Graphics
☑ External Controls - Overview
☑ External Controls - Details
☑ Test Results - Overview
☑ Test Results - Details
☑ Audit Trail

Clicking one of the eight major content options reveals further options

Options

☑ Assay profile name
☑ Assay status
☑ Assay kit information

The ID of external controls and test samples are mandatory fields and cannot be deselected. The ID is always activated. Even all content options in the "Audit trail" major category are also mandatory and cannot be deselected.



Content selection

☑ Assay Information
☑ Experiment Information
☑ Graphics
☑ External Controls - Overview
☑ External Controls - Details
☑ Test Results - Overview
☑ Test Results - Details
☑ Audit Trail

Options

Table columns

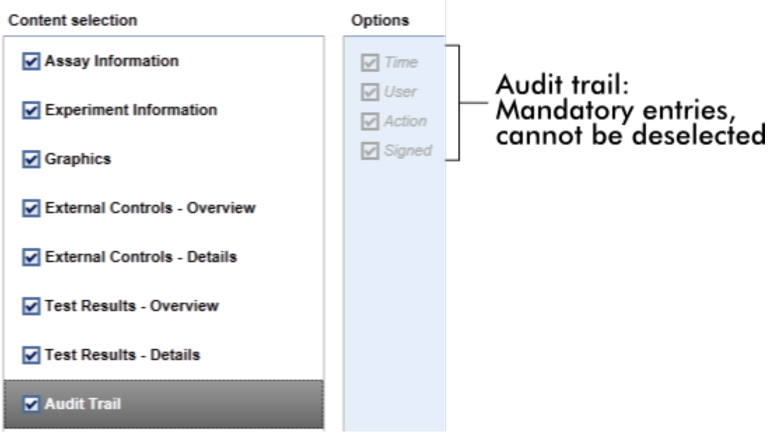
☑ *ID*
☑ Color
☑ Target
☑ Assay type specific information
☑ Result
○ Show sample result only
○ Show target result only
● Show sample result and target result

Internal Control

● Show IC in the table
○ Do not show IC in the table

Mandatory entry, cannot be deselected

Radio buttons: Only one option can be selected



Content selection

☑ Assay Information
☑ Experiment Information
☑ Graphics
☑ External Controls - Overview
☑ External Controls - Details
☑ Test Results - Overview
☑ Test Results - Details
☑ Audit Trail

Options

☑ *Time*
☑ *User*
☑ *Action*
☑ *Signed*

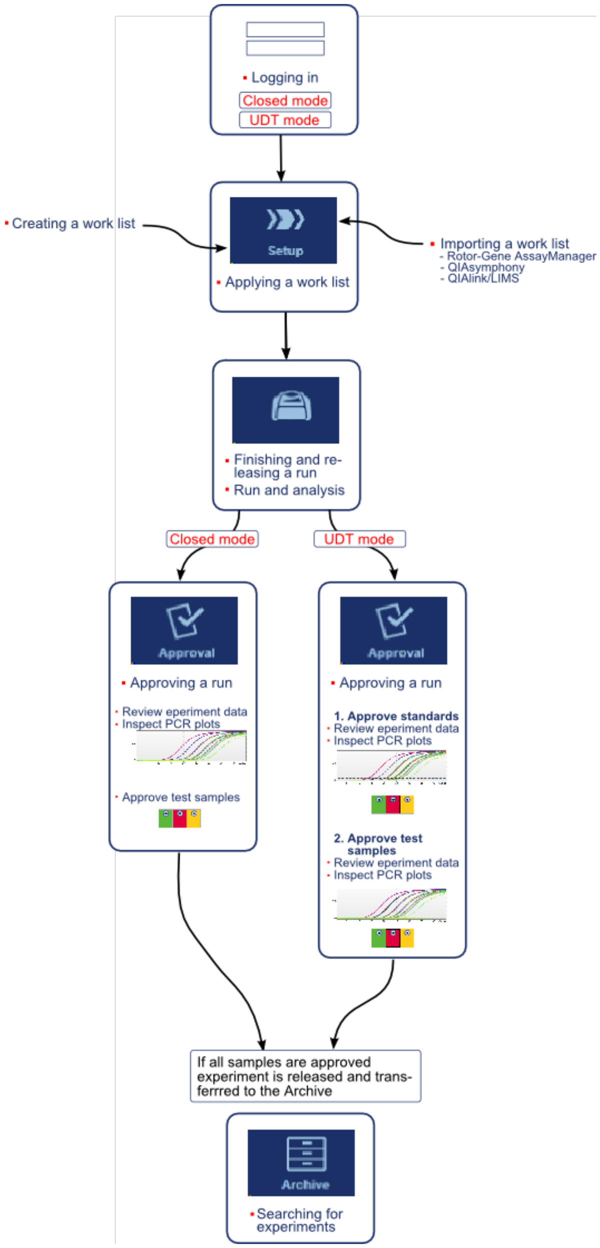
Audit trail: Mandatory entries, cannot be deselected

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 v1.0.

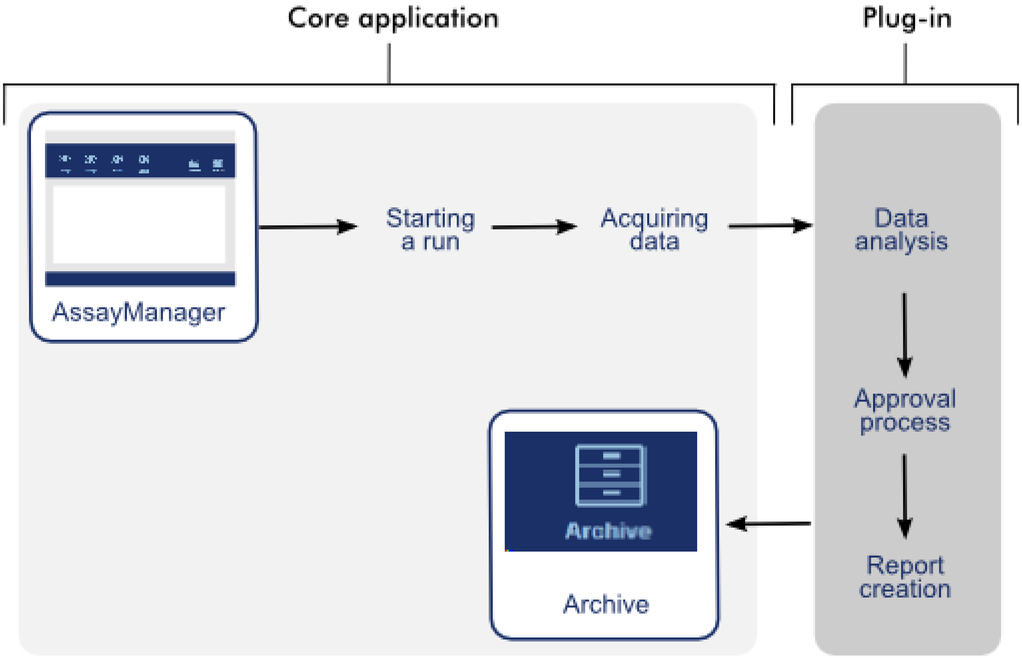


1.5.7 Plug-in Concept

Rotor-Gene AssayManager v1.0 is a versatile application. The number of assay types that can be processed can be expanded with its plug-in architecture.
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 v1.0

The work flow in Rotor-Gene AssayManager v1.0 can be divided in 2 sections:

- Standard tasks
- Administrative tasks

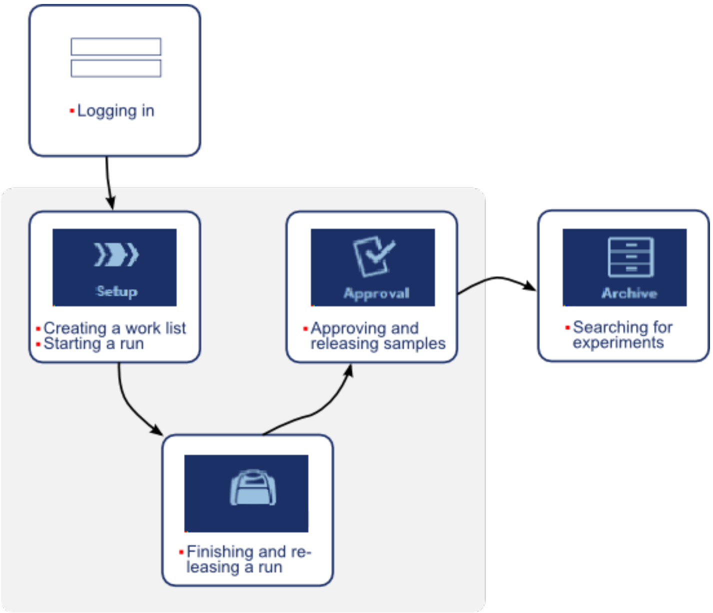
Standard tasks are tasks that are performed on a daily basis.
Administrative tasks are tasks performed to manage and configure the work flow.

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 v1.0:

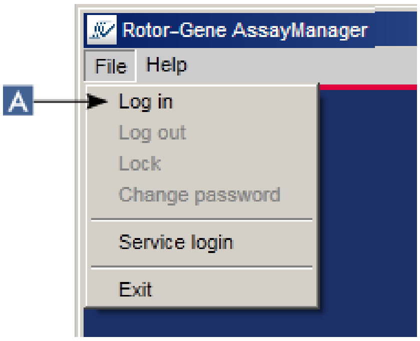


1.6.1.1 Logging In and Logging Out

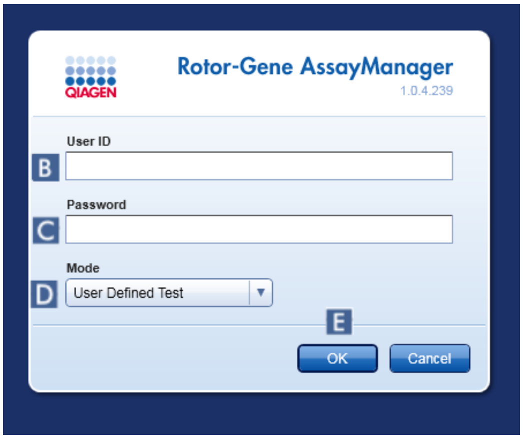
All user interactions in Rotor-Gene AssayManager v1.0 are assigned to a specific user. Therefore, every user must be authenticated using a specific user ID and password. Before leaving the computer, a user is advised to lock the application or to log out.

Step-by-step procedure to log in to Rotor-Gene AssayManager v1.0

1. Launch Rotor-Gene AssayManager v1.0,
   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.



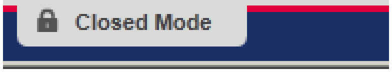
2. Enter the user ID in "User ID" field (B).
3. Enter the password in the "Password" field (C).
4. Select *Closed* or *User Defined Test* from the "Mode" menu (D).
5. Click "OK" (E).

> **Note**
> Closed mode plug-ins may not be available in all countries. If no Closed mode plug-ins are installed, a log in in Closed mode will give you only very limited access to adminstrative tasks, but you can neither perform experiments nor any analysis.

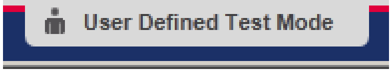
The user is logged in and forwarded to the default screen that matches their role as listed in the table below. Users with multiple roles are forwarded to the default screen of their first matching role. For example, a user with the role Administrator is forwarded to the "Settings" tab in the "Configuration" environment. A user with roles Operator and Approver will be forwarded to the "Setup" environment.

Role	Environment	Screen/tab
Operator	"Setup" environment	"Available work lists" 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:



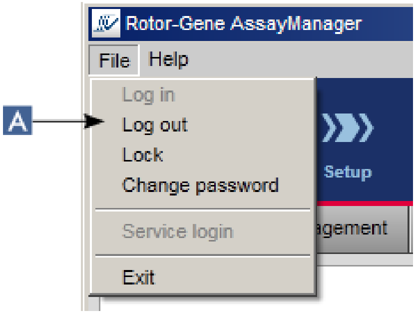
or



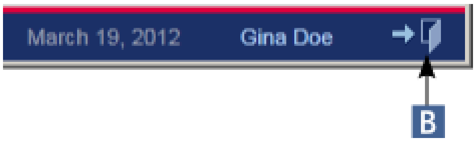
Step-by-step procedure for logging out of Rotor-Gene AssayManager v1.0

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.

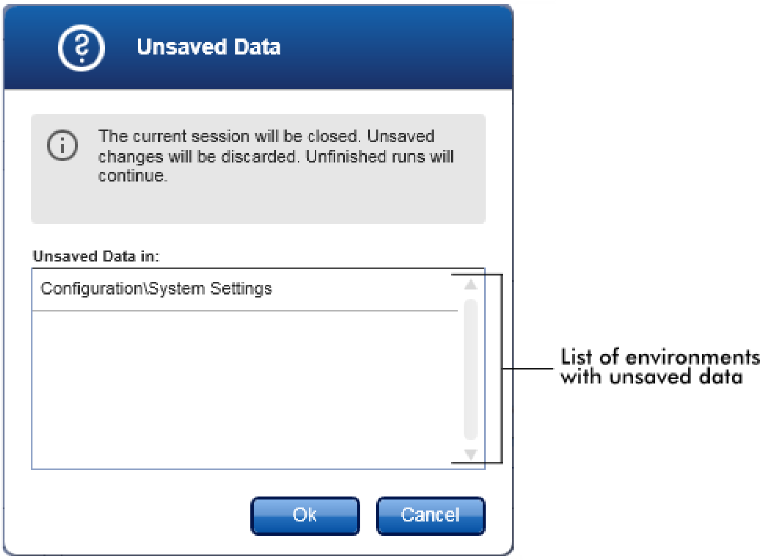
1. Click "Log out" ( ) in the main menu,



or click "Log out" ( ) 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:



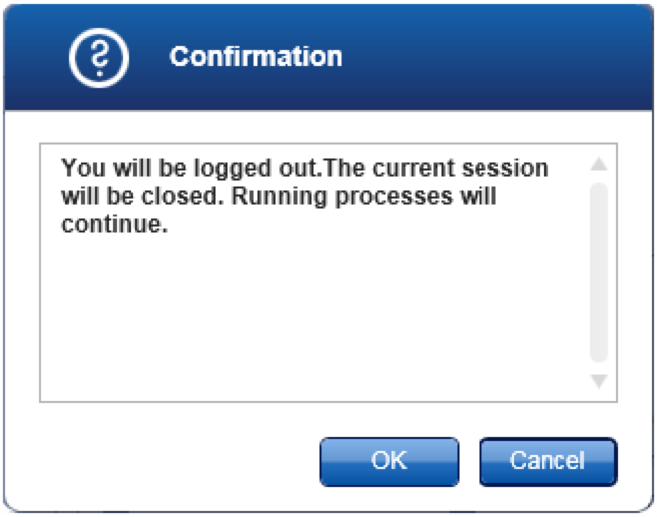
The current session will be closed. Unsaved changes will be discarded. Unfinished runs will continue.

Unsaved Data in:

Configuration\System Settings

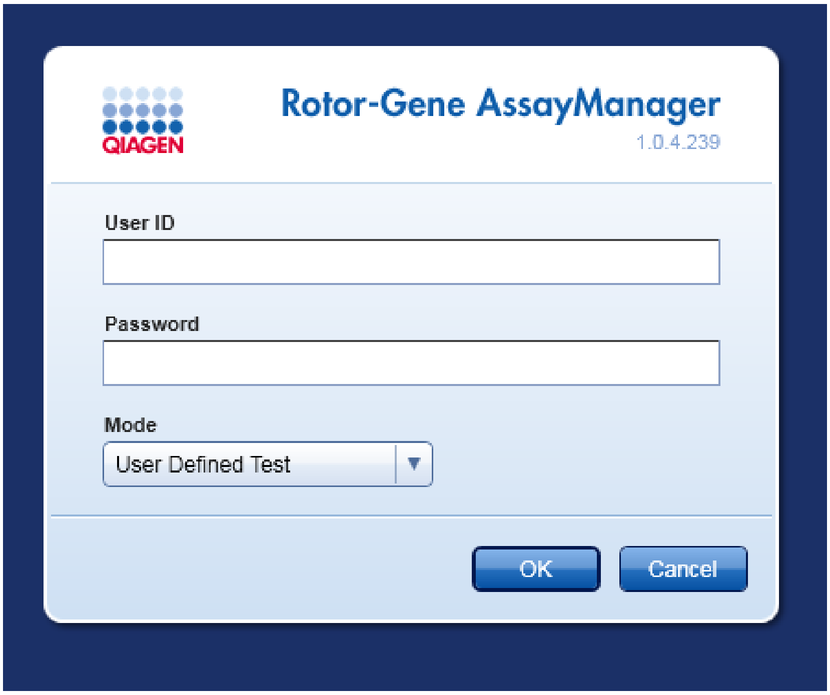
List of environments with unsaved data

Otherwise a standard confirmation log out dialog is shown:



You will be logged out.The current session will be closed. Running processes will continue.

3. Click "OK" (clicking "Cancel" cancels the log out and closes the dialog).
   The user is logged out and the login screen is shown.



Mode: User Defined Test

Note
If a user logs out, active cyclers will continue.

Related topics

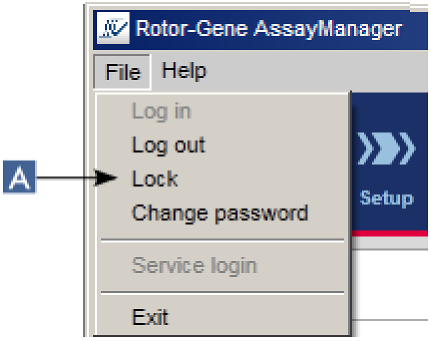
- Managing users
- Modes in Rotor-Gene AssayManager
- Session management
- Main toolbar
- Status bar

1.6.1.2 Locking and Unlocking

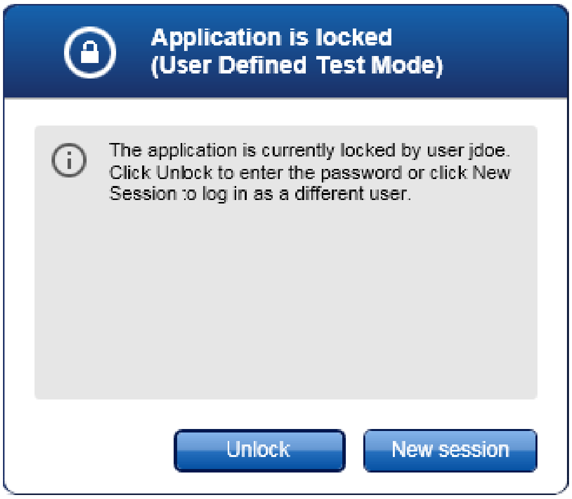
The application can be locked to restrict access. The locked application can be either unlocked by the user who has locked it, or a new session can be started.

Step-by-step procedure to lock Rotor-Gene AssayManager v1.0

1. Click "Lock" in the main menu.



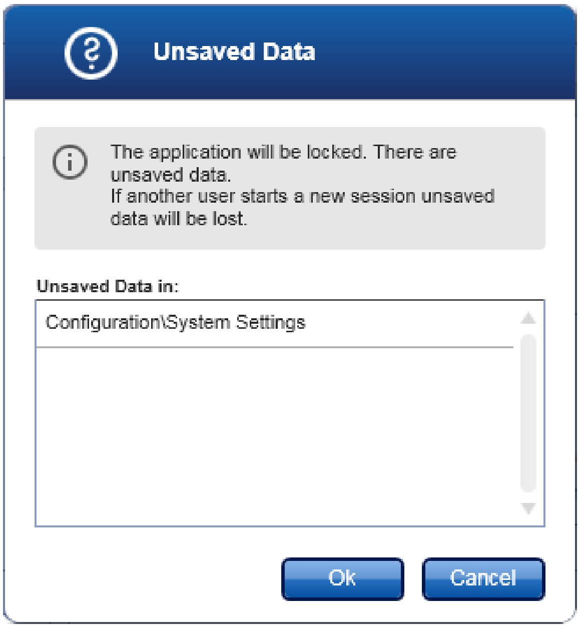
- If no unsaved data exist, the application is locked and the following dialog is displayed:



Application is locked
(User Defined Test Mode)

The application is currently locked by user jdoe. Click Unlock to enter the password or click New Session to log in as a different user.

- If unsaved data exist, an "Unsaved Data" dialog is shown with a list of all environments containing unsaved data.



Unsaved Data

The application will be locked. There are unsaved data.
If another user starts a new session unsaved data will be lost.

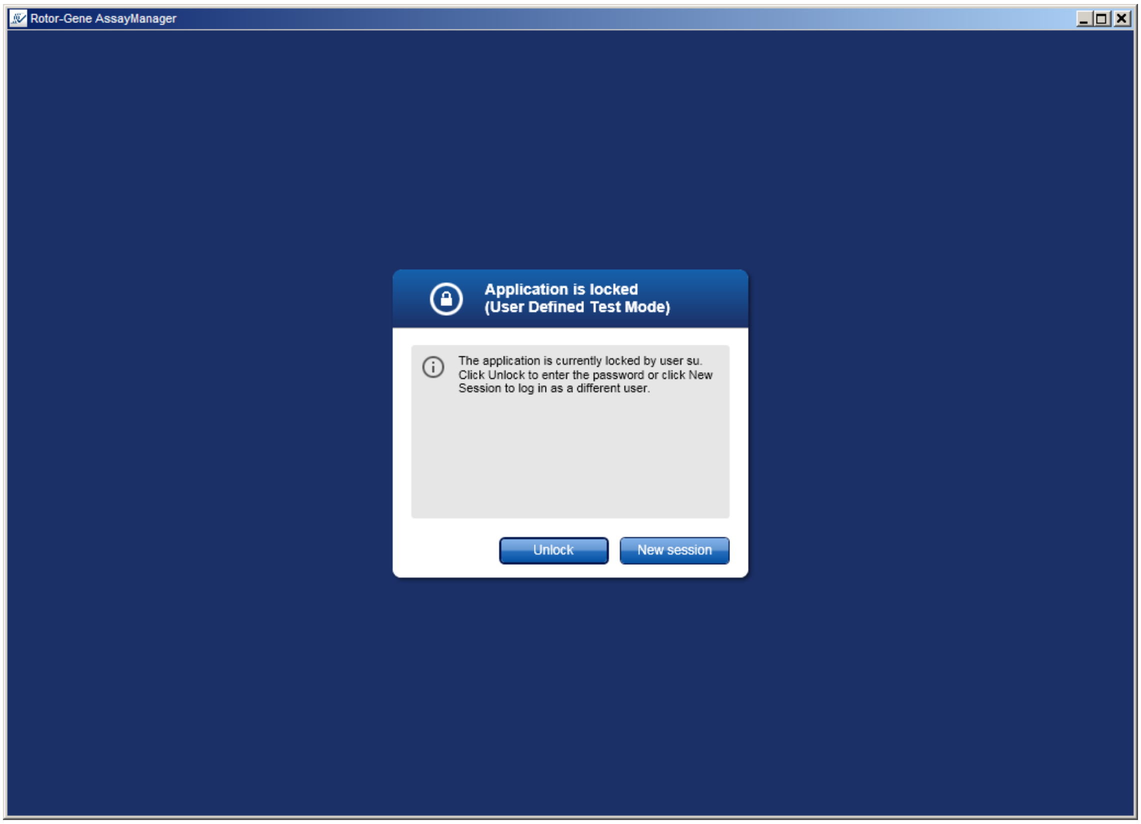
Unsaved Data in:

Configuration\System Settings

2. Confirming by clicking "OK" locks the application. The dialog above is shown.

Step-by-step procedure to unlock Rotor-Gene AssayManager v1.0

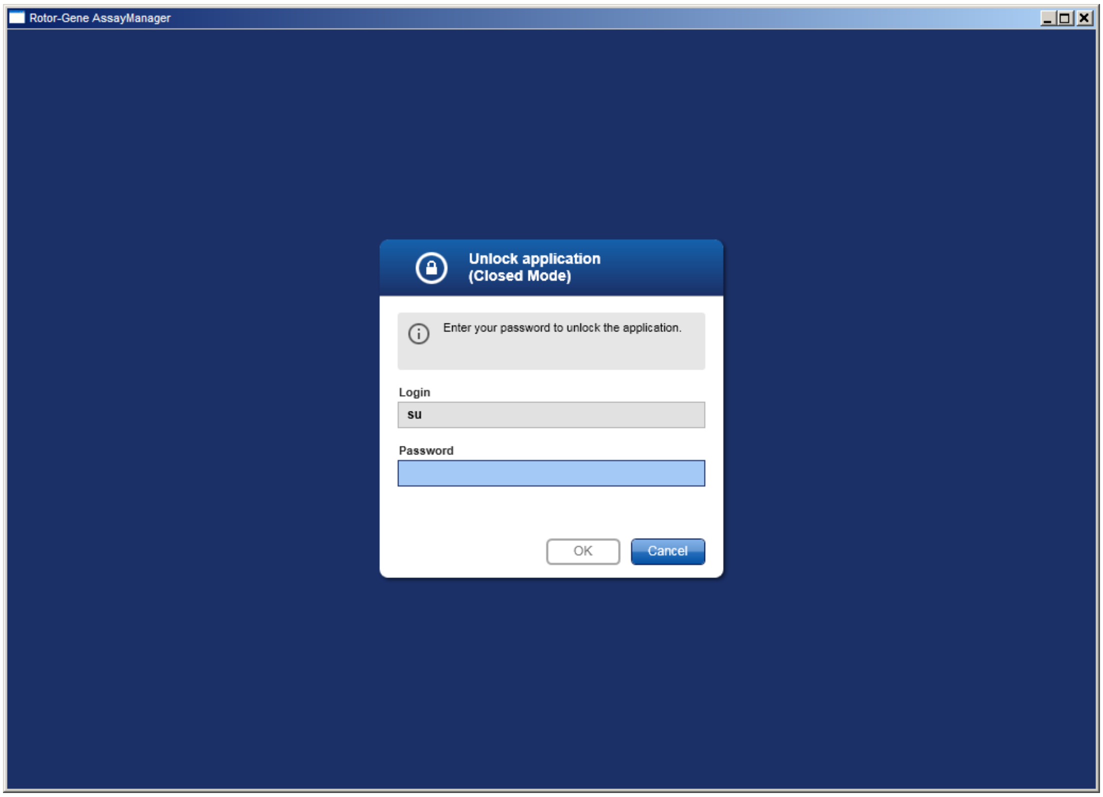
Precondition is that the application was locked before. The following screen is shown:



The application is currently locked by user su. Click Unlock to enter the password or click New Session to log in as a different user.

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.



Enter your password to unlock the application.

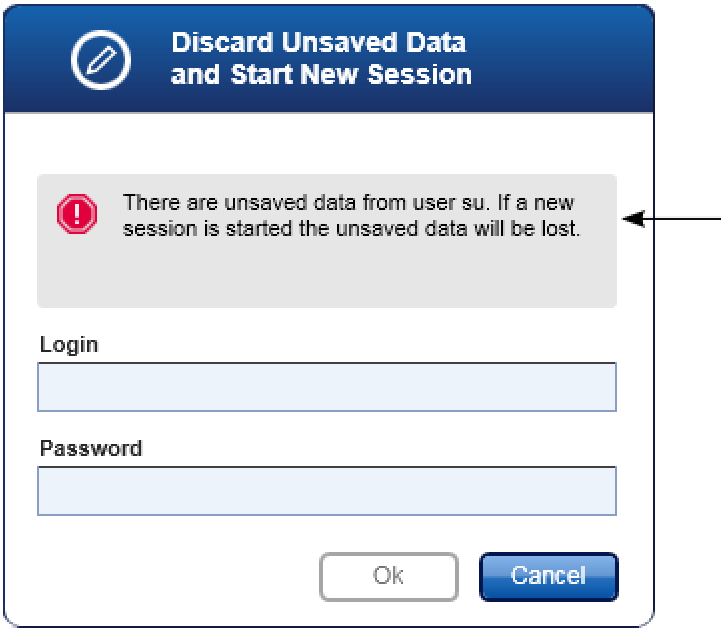
Login
su

Password

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:



There are unsaved data from user su. If a new session is started the unsaved data will be lost.

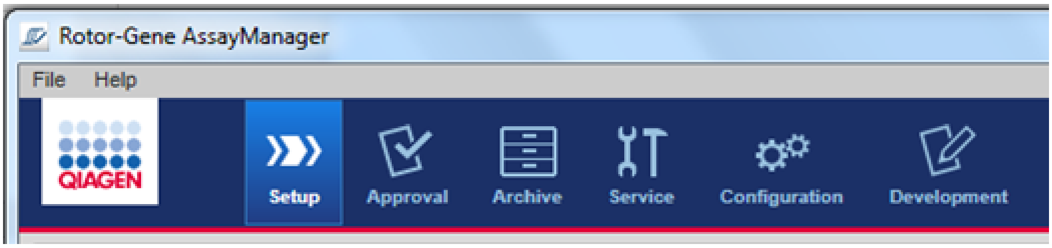
Related topics

- Managing users
- Session management

1.6.1.3 Setting up a Run

Overview

A work list is used to define an experiment, i.e., which assays shall be applied, their order, the number of samples, etc.
All tasks related to work lists are carried out in the "Setup" environment.



Tasks related to work lists

- Creating/editing a work list
- Importing a work list
- Duplicating a work list
- Exporting a work list
- Deleting a work list

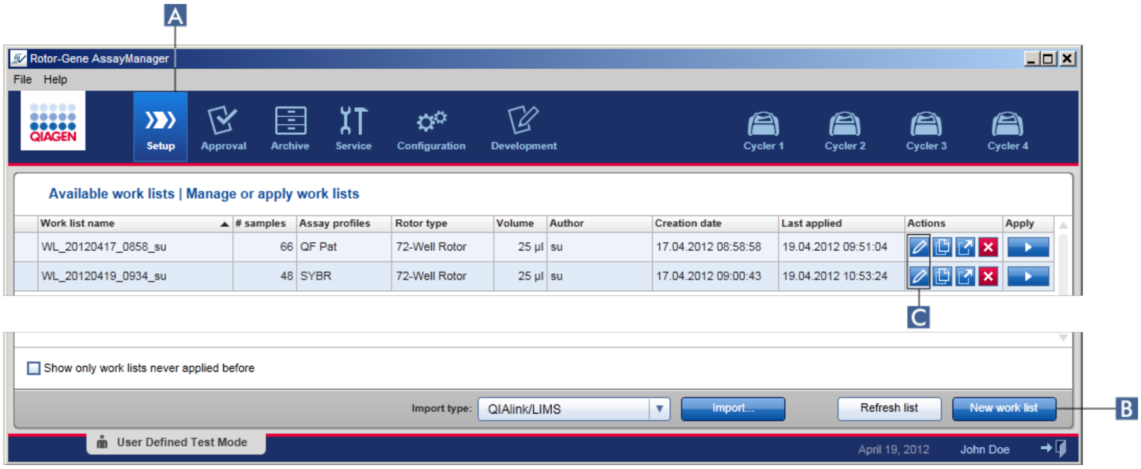
Note
Use only assay kits with the same lot number for setting up an assay.

1.6.1.3.1 Creating/Editing a Work List

Overview

Work lists combine one or more assay profiles that are intended to run in an experiment. The user creates a work list 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 work list, each individual sample has to get an ID. Finally, the user defines the name of the work list, sets its properties, and saves the work list. The user can save an unfinished work list at any time and continue with the definition later.

A work list is created in the "Setup" environment (A). This environment automatically appears on login for users with the role of an operator. Initially, the "Available work lists" screen is shown with a list of all currently available work lists on the system. Clicking the "New" button (B) at the bottom right of the screen changes to the "Create new work list" screen where the new work list is set up.



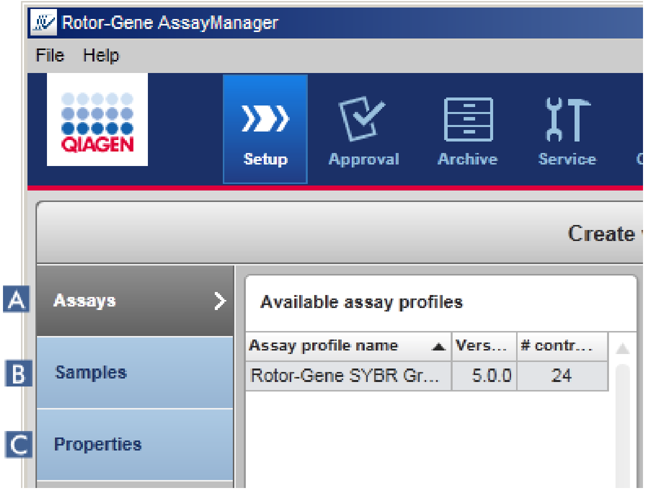
Available work lists | Manage or apply work lists

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	19.04.2012 09:51:04		▶
WL_20120419_0934_su	48	SYBR	72-Well Rotor	25 µl	su	17.04.2012 09:00:43	19.04.2012 10:53:24		▶

☐ Show only work lists never applied before

Import type: QIAlink/LIMS

The "Create new work list" screen comprises 3 different steps:



Assay profile name	Vers...	# contr...
Rotor-Gene SYBR Gr...	5.0.0	24

	Name	Description
A	"Assays"	Select or enter the following data: ▪ One (or multiple, compatible) assay profile(s) ▪ Rotor type ▪ Reaction volumes ▪ Number of samples ▪ Material number ▪ Kit expiration date ▪ Lot number
B	"Samples"	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. 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.
C	"Properties"	The creation of a work list process is finalized by activating 2 different options: ▪ "Work list is editable" ▪ "Is applicable"

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 work list can be saved in an uncompleted state. It is sufficient that at least a valid work list name is provided.

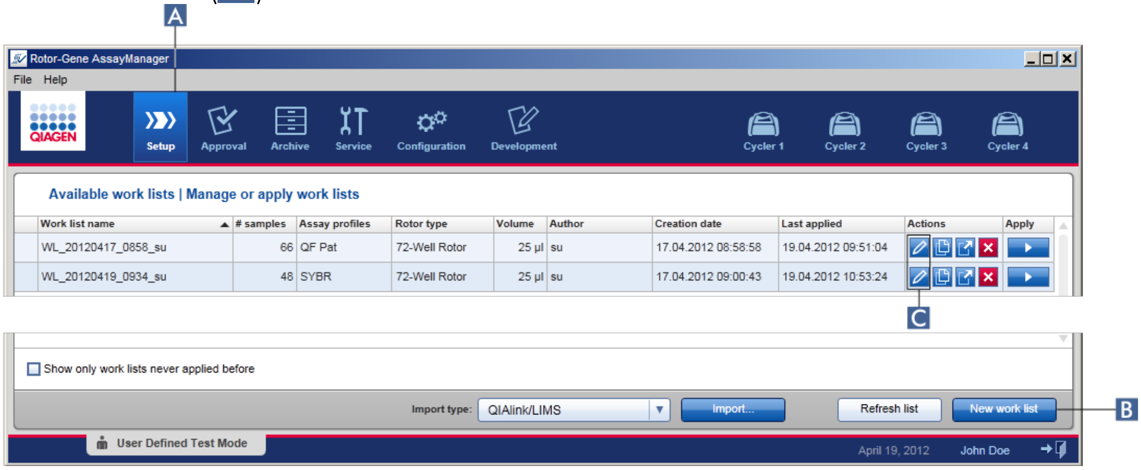
Step-by-step procedure to create a new work list

Creating a new work list comprises 5 steps:

1. Create a new, empty work list (see ▶ Settings)
2. Add one (or multiple) assay profile(s) to the work list ("Assays" step).
3. Assign sample IDs ("Samples" step).
4. Define the properties of the work list ("Properties" step).
5. Save the work list.

Step 1: Create a new, empty work list

a) If it is not active yet, change to the "Setup" environment by clicking the "Setup" icon in the main toolbar (**A**).



Available work lists | Manage or apply work lists

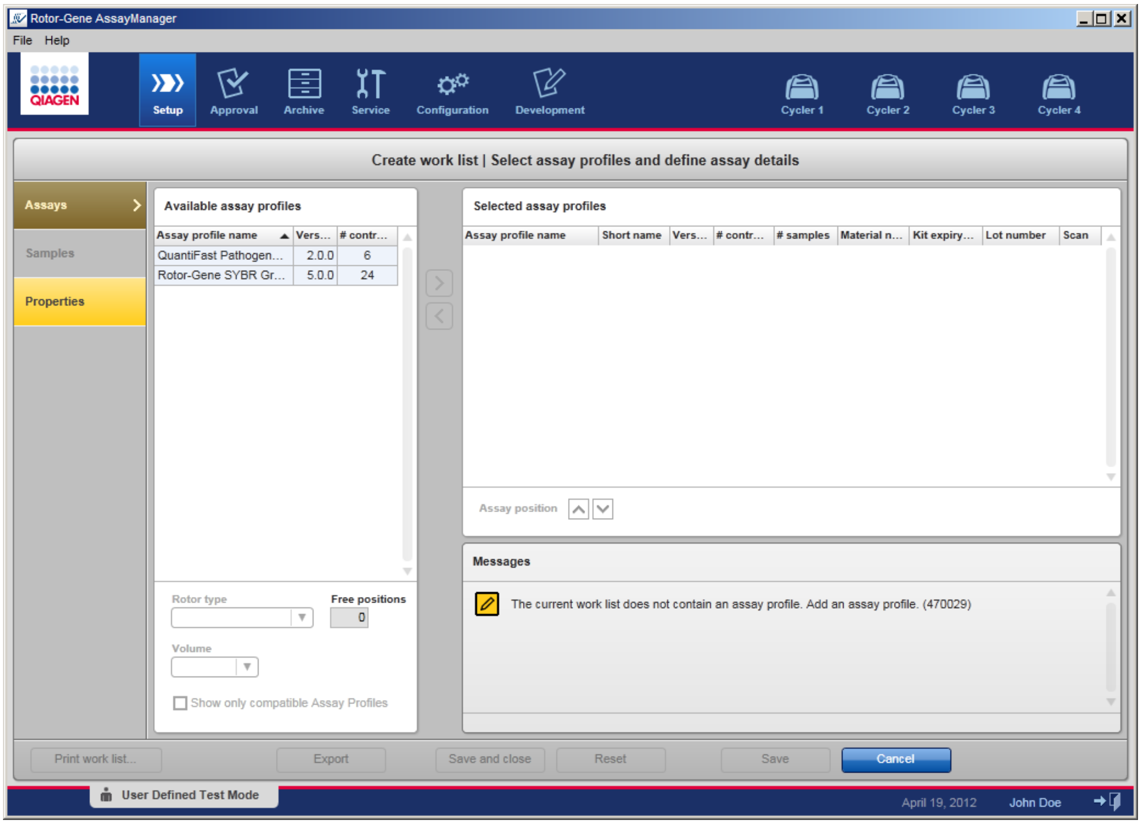
Work list name	# samples	Assay profiles	Rotor type	Volume	Author	Creation date	Last applied	Actions	Apply
WL_20120417_0858_su	66	QF Pat	72-Well Rotor	25 µl	su	17.04.2012 08:58:58	19.04.2012 09:51:04		▶
WL_20120419_0934_su	48	SYBR	72-Well Rotor	25 µl	su	17.04.2012 09:00:43	19.04.2012 10:53:24		▶

☐ Show only work lists never applied before

Import type: QIAlink/LIMS

b) Click the "New work list" button (**B**) at the bottom right of the screen.

The "Create work list" screen is opened. The "Assays" step marker is activated, as indicated in dark yellow.



Create work list | Select assay profiles and define assay details

Available assay profiles

Assay profile name	Vers...	# contr...
QuantiFast Pathogen...	2.0.0	6
Rotor-Gene SYBR Gr...	5.0.0	24

Rotor type:
Free positions: 0
Volume:
☐ Show only compatible Assay Profiles

Selected assay profiles

Assay profile name	Short name	Vers...	# contr...	# samples	Material n...	Kit expiry...	Lot number	Scan

Messages

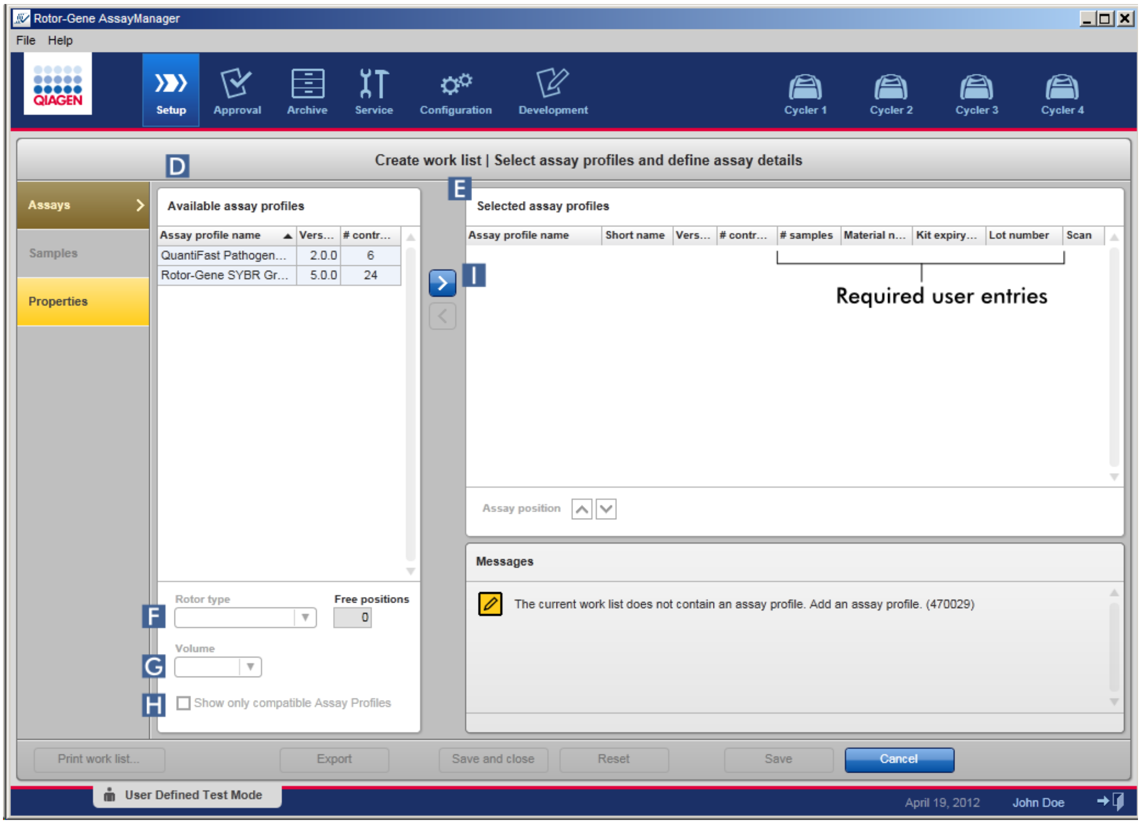
The current work list does not contain an assay profile. Add an assay profile. (470029)

User Defined Test Mode
April 19, 2012
John Doe

Step 2: Add one (or multiple) assay profile(s) to the work list ("Assays" step)

In this step, the user adds one or multiple compatible assays to the work list. 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.



Create work list | Select assay profiles and define assay details

Assay profile name	Vers...	# contr...
QuantiFast Pathogen...	2.0.0	6
Rotor-Gene SYBR Gr...	5.0.0	24

Free positions: 0

The current work list does not contain an assay profile. Add an assay profile. (470029)

a) In the "Available assay profiles" table (**D**) click the assay you want to be included. 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.

> **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. |

b) 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.

c) Click the "Volume" drop-down menu (G) to select the reaction volume that will be used.
The "Add assay to work list" (I) button is set to active.
d) Click the "Add assay to work list" (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", "# controls") are populated with data from the assay profile. The "# samples", "Material number", "Kit expiry date", and "Lot number" columns must be entered manually.
e) 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.

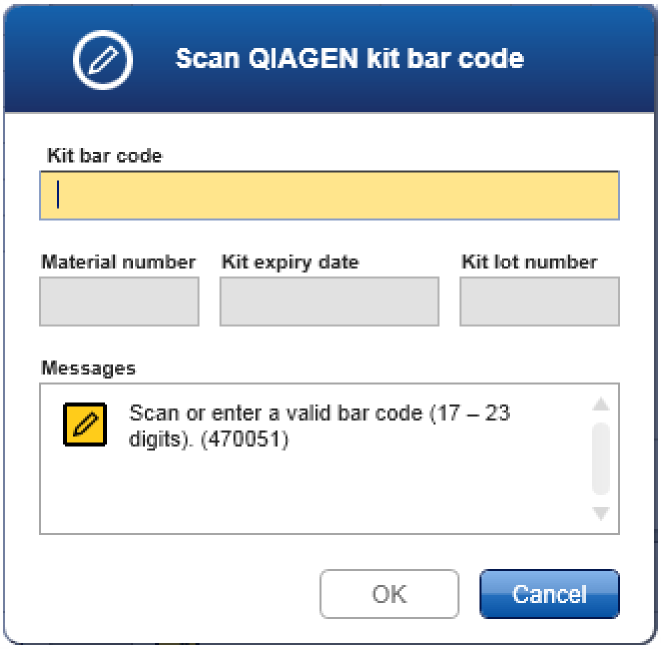
f) The material number, kit expiration date, and the lot number can either be entered manually or scanned.

- Alternative 1: Manual entry of material number, kit expiration date, and lot number

Enter the material number, the kit expiration date, and the lot number manually. 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 the "bar code" icon in the scan column.
The "Scan QIAGEN kit bar code" window opens.



Scan or enter a valid bar code (17 – 23 digits). (470051)

Either scan the bar code with a scanner or type in the kit bar code into the "Kit bar code" field. Material number, kit expiration date, and kit lot number will automatically be populated.

Note

Use only assay kits with the same lot number for setting up an assay.

Repeat steps a–f for all other assay profiles you want to be included in the work list.

Note

Incompatible assay profiles cannot be selected. These are disabled and grayed out by Rotor-Gene AssayManager v1.0.

Hint

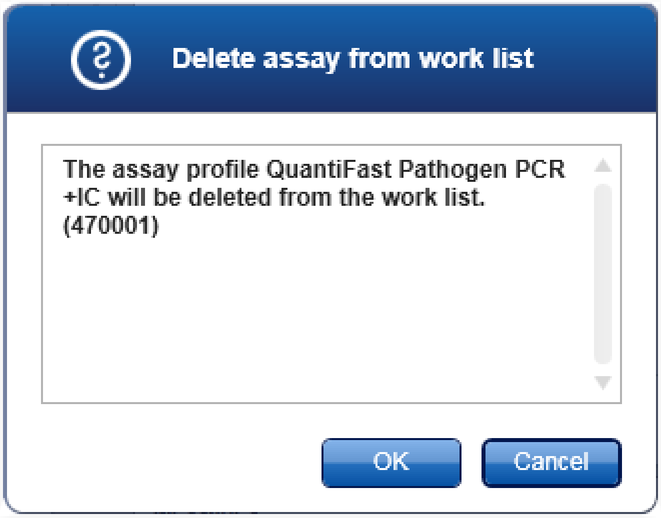
To remove an assay profile from the work list:

1. Click the assay profile in the "Selected assay profiles" table.

The name is marked and the "Remove selected assay from work list" button < is activated.

2. Click the "Remove selected assay from work list" button.

The following confirmation dialog is displayed:



The assay profile QuantiFast Pathogen PCR +IC will be deleted from the work list. (470001)

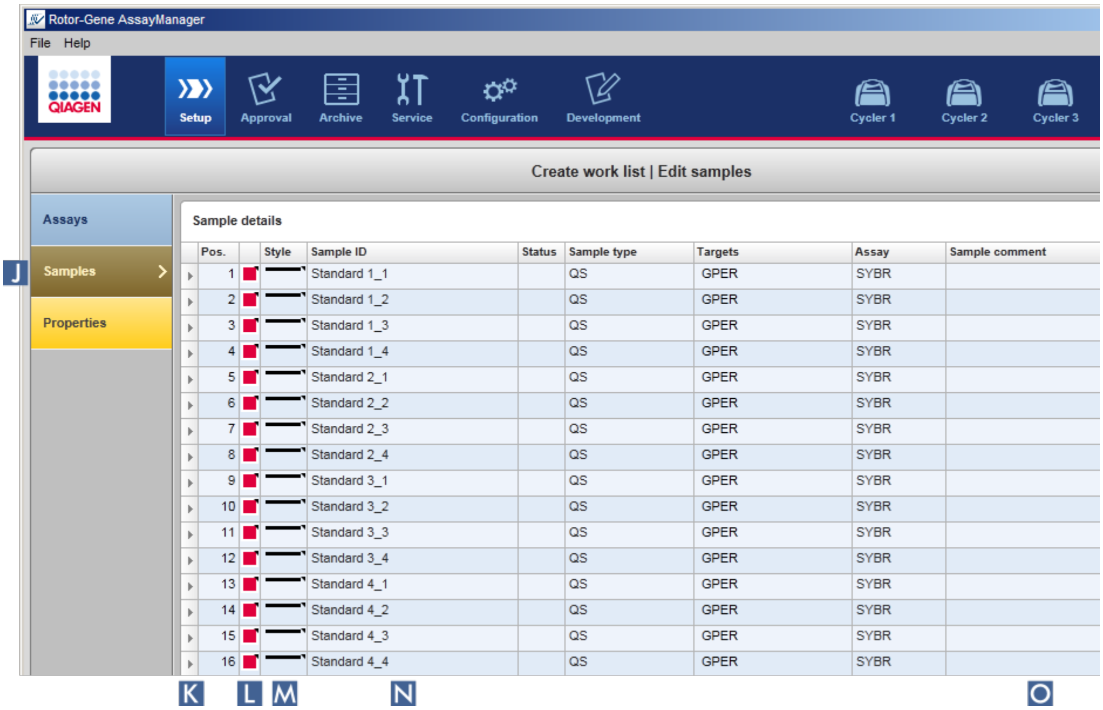
3. Click "OK" to remove the assay profile from the work list. Click "Cancel" to close the dialog without removing the assay profile from the work list.

Step 3: Assign sample IDs to assay profiles ("Samples" step)

In the previous step ("Assays") one or multiple, compatible assays were added to the work list. 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" (**J**) in the step bar.

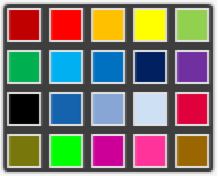


Sample details

Pos.		Style	Sample ID	Status	Sample type	Targets	Assay	Sample comment
1	🟥	—	Standard 1_1		QS	GPER	SYBR	
2	🟥	—	Standard 1_2		QS	GPER	SYBR	
3	🟥	—	Standard 1_3		QS	GPER	SYBR	
4	🟥	—	Standard 1_4		QS	GPER	SYBR	
5	🟥	—	Standard 2_1		QS	GPER	SYBR	
6	🟥	—	Standard 2_2		QS	GPER	SYBR	
7	🟥	—	Standard 2_3		QS	GPER	SYBR	
8	🟥	—	Standard 2_4		QS	GPER	SYBR	
9	🟥	—	Standard 3_1		QS	GPER	SYBR	
10	🟥	—	Standard 3_2		QS	GPER	SYBR	
11	🟥	—	Standard 3_3		QS	GPER	SYBR	
12	🟥	—	Standard 3_4		QS	GPER	SYBR	
13	🟥	—	Standard 4_1		QS	GPER	SYBR	
14	🟥	—	Standard 4_2		QS	GPER	SYBR	
15	🟥	—	Standard 4_3		QS	GPER	SYBR	
16	🟥	—	Standard 4_4		QS	GPER	SYBR	

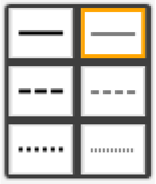
The "Sample details" table is displayed with a visualization of the current assay design. The ID field of the test samples is colored yellow because these entries are mandatory.

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 (**L**). 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 (M). A line style palette is opened.



Click a style to select it.

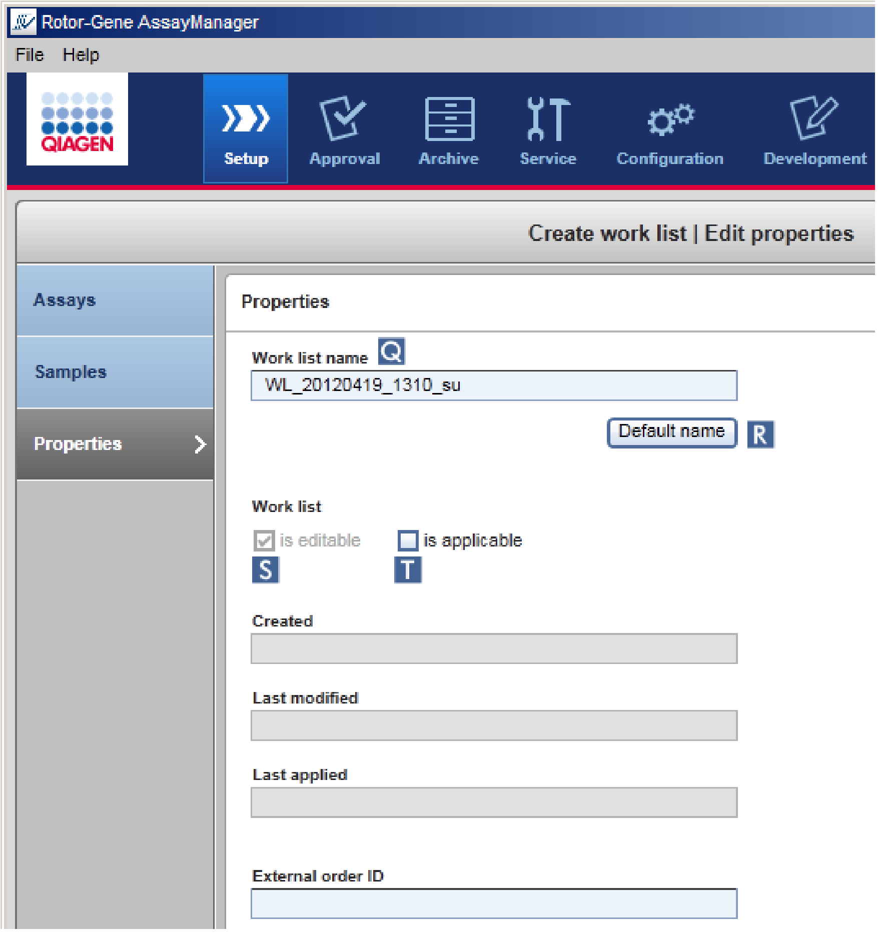
d) Enter an ID into the ID field (N) for every test sample. The ID must be between 1 and 40 characters long. The sample IDs can either be identical or unique. However, some assay profiles restrict the use of the same IDs.

e) **Optional**: Enter a comment in the "Comment" field (O). The comment must not exceed 256 characters.

Step 4: Define the properties of the work list ("Properties" step).

This screen is intended to enter the work list name and to review information about when it was created, modified, and last applied. The user can also specify if a work list can be edited or applied.

a) Change to the "Properties" step by clicking the "Properties" step marker.



Properties

Work list name
WL_20120419_1310_su

Work list
☑ is editable ☐ is applicable

Created

Last modified

Last applied

External order ID

b) Enter the desired work list name into the "Work list name" field (Q). To let Rotor-Gene AssayManager v1.0 automatically generate a work list name, click "Default name" (R). Rotor-Gene AssayManager v1.0 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 work list as being editable	Activate check box S ☑ is editable	The work list can be edited, i.e., modified, later. If this option is deactivated, the work list cannot be changed.
Mark a work list as being applicable	Activate check box T ☐ is applicable	If the "is applicable" option is deactivated, the work list cannot be applied. To start a run, this option must be activated.

Note

The field "External order ID" is optional.

Step 5: Finish creating the work list

Finish creating a work list by clicking one of the buttons in the button bar:

To	Click
Print the work list to PDF after having saved the work list	Print work list...
Export the work list to a folder after having saved the work list	Export
Save the work list and go back to the start screen of the "Setup" environment.	Save and close
Cancel your entries and set properties to default	Reset
Save the work list	Save
Cancel your entries	Cancel
Apply your work list	Apply

Related topics

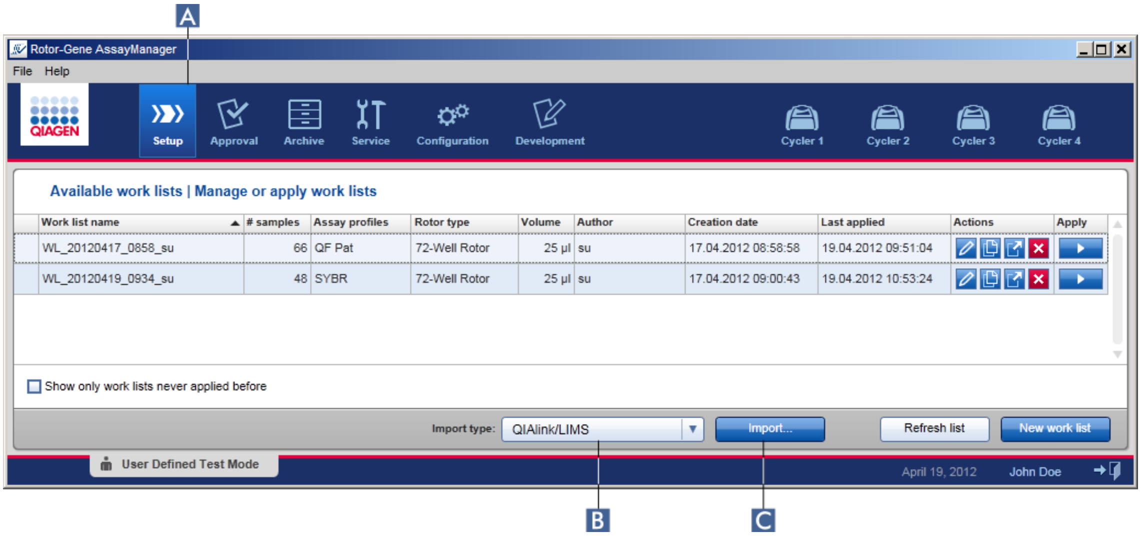
- Managing assay profiles
- Managing cyclers
- Entering data
- Using colors
- "Setup" environment

1.6.1.3.2 Importing a Work List

Importing a work list is a function used either to exchange work lists between different Rotor-Gene AssayManager v1.0 installations or to import work lists from an upstream laboratory device (for example a LIMS or QIAsymphony).

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**)



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	19.04.2012 09:51:04		
WL_20120419_0934_su	48	SYBR	72-Well Rotor	25 µl	su	17.04.2012 09:00:43	19.04.2012 10:53:24		

☐ Show only work lists never applied before

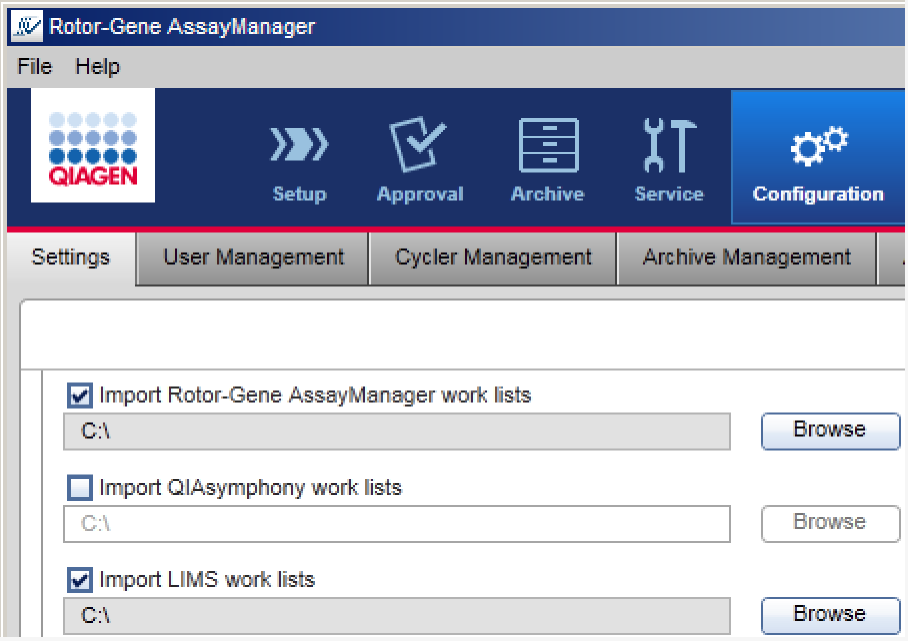
A work list can be imported from the following sources (entries from the drop-down menu **B**):

Source	File extension	Description
Rotor-Gene AssayManager v1.0	*.iwl	Exported Rotor-Gene AssayManager v1.0 work list
QIAsymphony	*.xml	Result file from QIAsymphony AS
QIAlink/LIMS	*.lwl	Work lists from QIAlink or a LIMS

After a work list to be imported has been selected, Rotor-Gene AssayManager v1.0 internally checks its syntax and signature. If the check is successful, the work list will be imported and added to the "Available work lists" table. Otherwise the work list 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.



☑ Import Rotor-Gene AssayManager work lists
C:\

☐ Import QIAsymphony work lists
C:\

☑ Import LIMS work lists
C:\

Step-by-step procedure to import a work list

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 work list 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 v1.0 internally checks the signature and the syntax of the work list.
5. The work list is imported and added to the list of available work lists ▶ Creating/editing a work list.

Note

The name of work lists imported from QIAsymphony is automatically created with the following information separated by an underscore:

- "QS" as identifier for work lists 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 the QIAsymphony AS result file contains information about several batches, this information will be separated in different work lists.

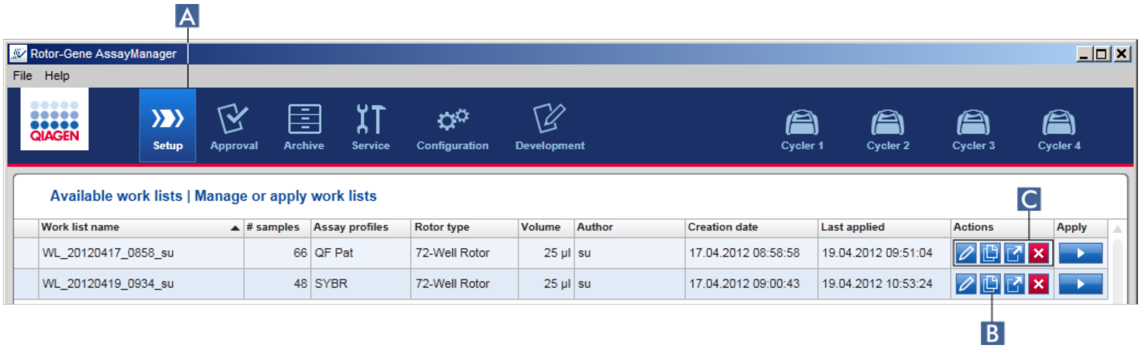
Related topics

- Settings
- Setting up work list name options
- Rotor-Gene AssayManager and other QIAGEN products
- Available work lists view

1.6.1.3.3 Duplicating a Work List

General

A specific work list is duplicated from the "Setup" environment (A) by clicking the "Duplicate work list" button (B) in the "Actions" bar (C) of the corresponding work list.



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	19.04.2012 09:51:04		
WL_20120419_0934_su	48	SYBR	72-Well Rotor	25 µl	su	17.04.2012 09:00:43	19.04.2012 10:53:24		

The "Duplicate work list" button is always enabled. Clicking this button creates a copy of the selected work list. The "Work list modification" screen is displayed. This screen is analog to the "Creating a work list" dialog. The copy is not saved to the database until "Save" is clicked.

The duplicated work list 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 work lists is not activated.

- The "Last applied" and "Last modified" fields are empty and will be set when the work list is saved for the first time.

Step-by-step procedure to duplicate a work list

1. If it is not active yet, change to the "Setup" environment by clicking the "Setup" icon in the main toolbar (A).

   All available work lists are displayed in the table.
2. Locate the work list you want to duplicate, and click the corresponding "Duplicate work list" button (B) in the "Actions" bar (C).

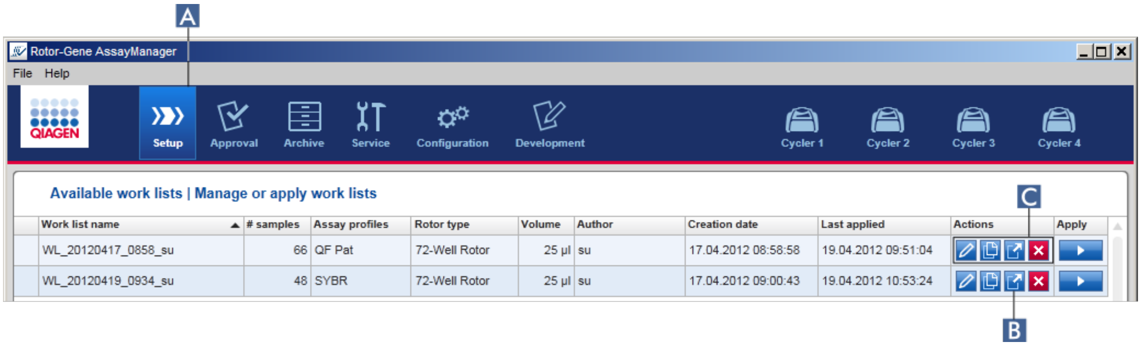
   The "Edit duplicated work list" screen is shown.
3. Modify those parameters you need to change according to the steps described in steps 2 to 5 of the procedure and save ▶ Creating/editing a work list.

Related topic

- Available work lists view

1.6.1.3.4 Exporting a Work List

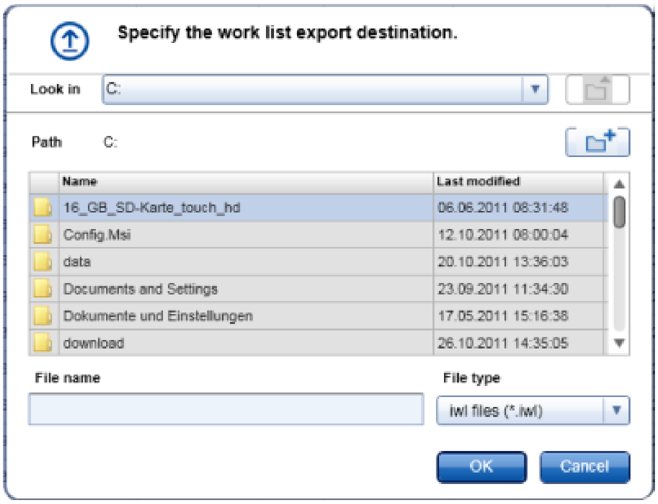
Exporting a work list is used to exchange work lists between different Rotor-Gene AssayManager v1.0 installations that are using different databases.
The export functionality can be found in the "Setup" environment (**A**). The "Actions" bar (**C**) in the "Available work lists" table includes the "Export work list" button (**B**).



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	19.04.2012 09:51:04		
WL_20120419_0934_su	48	SYBR	72-Well Rotor	25 µl	su	17.04.2012 09:00:43	19.04.2012 10:53:24		

Step-by-step procedure to export a work list

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 work list you want to export.
3. Click the "Export work list" 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.



Specify the work list export destination.

Look in C:

Path C:

Name	Last modified
16_GB_SD-Karte_touch_hd	06.06.2011 08:31:48
Config.Msi	12.10.2011 08:00:04
data	20.10.2011 13:36:03
Documents and Settings	23.09.2011 11:34:30
Dokumente und Einstellungen	17.05.2011 15:16:38
download	26.10.2011 14:35:05

File name

File type iwl files (*.iwl)

4. Browse to the designated directory.

5. Enter a file name for the exported work list.
6. Click "OK".

   The work list will be saved under the entered file name and with the extension *.iwl.

Related topic

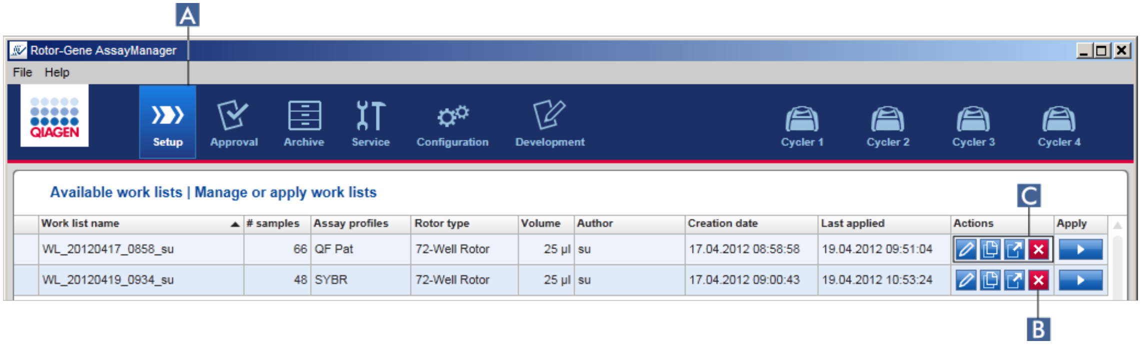
- Available work lists view

1.6.1.3.5 Deleting a Work List

Step-by-step procedure to delete a work list

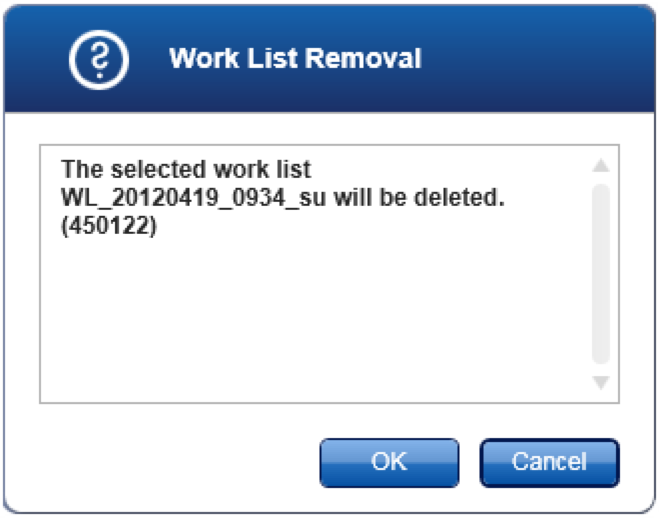
1. If it is not active yet, change to the "Setup" environment by clicking the "Setup" icon in the main toolbar (A).

   All available work lists are displayed in the table.



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	19.04.2012 09:51:04		
WL_20120419_0934_su	48	SYBR	72-Well Rotor	25 µl	su	17.04.2012 09:00:43	19.04.2012 10:53:24		

2. Locate the work list you want to delete, and click the corresponding "Delete work list" (B) button in the "Actions" bar (C) of the appropriate row of the table. The following confirmation dialog is shown:



The selected work list WL_20120419_0934_su will be deleted. (450122)

3. Click the appropriate button:

To	Click	
Delete a work list and return to the "Setup" start screen.	OK	The selected work list entry will be deleted from the database and then disappears from the work list table.
Cancel the delete process and return to the "Setup" start screen	Cancel	The selected work list entry will remain as before.

Related topic

Available work lists view

1.6.1.4 Starting a Run

A run can be started from the "Available work lists" table in the "Setup" environment (A) by clicking the "Apply" button (B) in the button bar of the appropriate work list entry. An alternative is to start a run after a new work list has been successfully created. Details can be found under Creating/editing a work list.

After the run is triggered, the "Apply work list" 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 work list"). This printout can be used as a pipetting scheme.

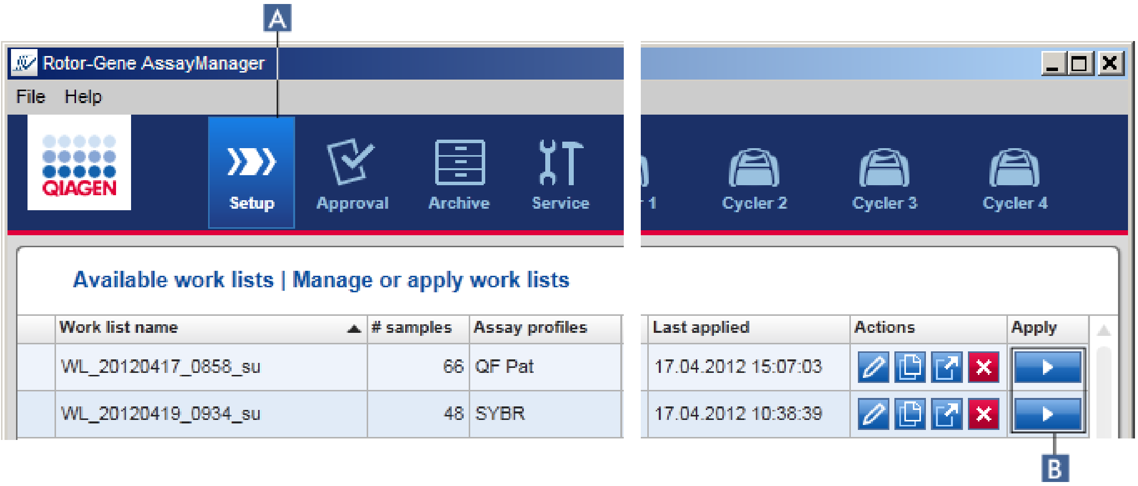
Note

- 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.



Available work lists | Manage or apply work lists

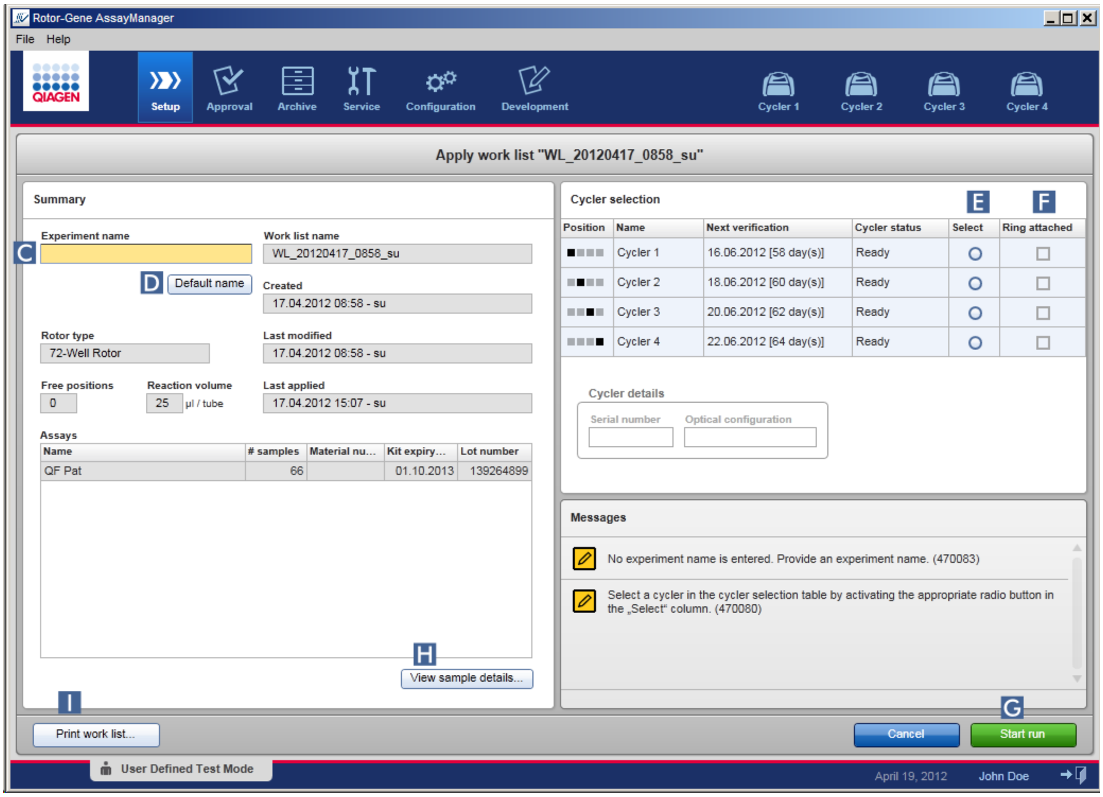
Work list name	# samples	Assay profiles	Last applied	Actions	Apply
WL_20120417_0858_su	66	QF Pat	17.04.2012 15:07:03		
WL_20120419_0934_su	48	SYBR	17.04.2012 10:38:39		

Step-by-step procedure to apply a work list

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 work lists are displayed.
2. Select the work list you want to apply. Click "Apply work list" in the last column of the row (B).

   The "Apply work list" screen is shown. It consists of 3 areas: "**Summary**", "**Cycler selection**", and the "**Messages**" section.



Apply work list "WL_20120417_0858_su"

Summary

Experiment name:

Work list name: WL_20120417_0858_su

Created: 17.04.2012 08:58 - su

Rotor type: 72-Well Rotor

Last modified: 17.04.2012 08:58 - su

Free positions: 0

Reaction volume: 25 µl / tube

Last applied: 17.04.2012 15:07 - su

Assays

Name	# samples	Material nu...	Kit expiry...	Lot number
QF Pat	66		01.10.2013	139264899

Cycler selection

Position	Name	Next verification	Cycler status	Select	Ring attached
■▪▪▪	Cycler 1	16.06.2012 [58 day(s)]	Ready	○	☐
▪■▪▪	Cycler 2	18.06.2012 [60 day(s)]	Ready	○	☐
▪▪■▪	Cycler 3	20.06.2012 [62 day(s)]	Ready	○	☐
▪▪▪■	Cycler 4	22.06.2012 [64 day(s)]	Ready	○	☐

Cycler details

Serial number:

Optical configuration:

Messages

No experiment name is entered. Provide an experiment name. (470083)

Select a cycler in the cycler selection table by activating the appropriate radio button in the „Select“ column. (470080)

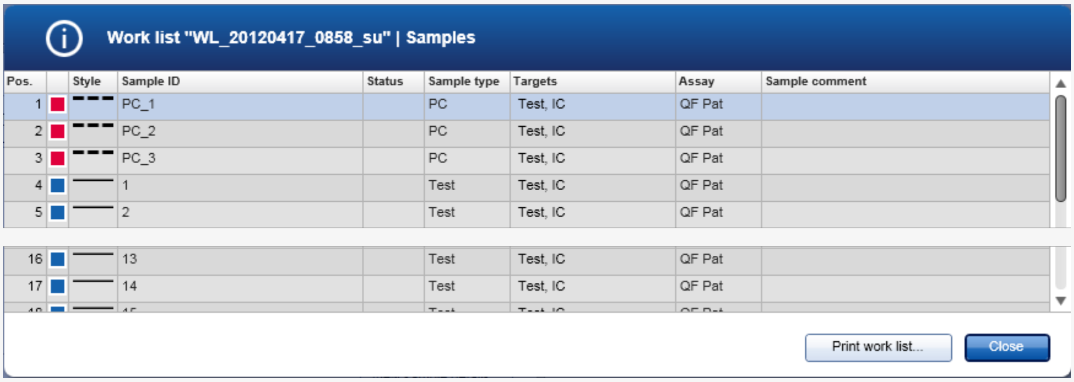
3. Enter the name of the experiment in the "Experiment name" field (**C**), or click "Default name" (**D**) to generate a name automatically.
4. Click the "Select" radio button (**E**) to select a cycler with the status "Ready".
5. Activate the "Ring attached" check box (**F**) to confirm you have attached 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 work lists" 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 work list..." buttons (**I**).
Clicking "View sample details..." opens a scrollable list with detailed information about the samples:



Work list "WL_20120417_0858_su" | 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	

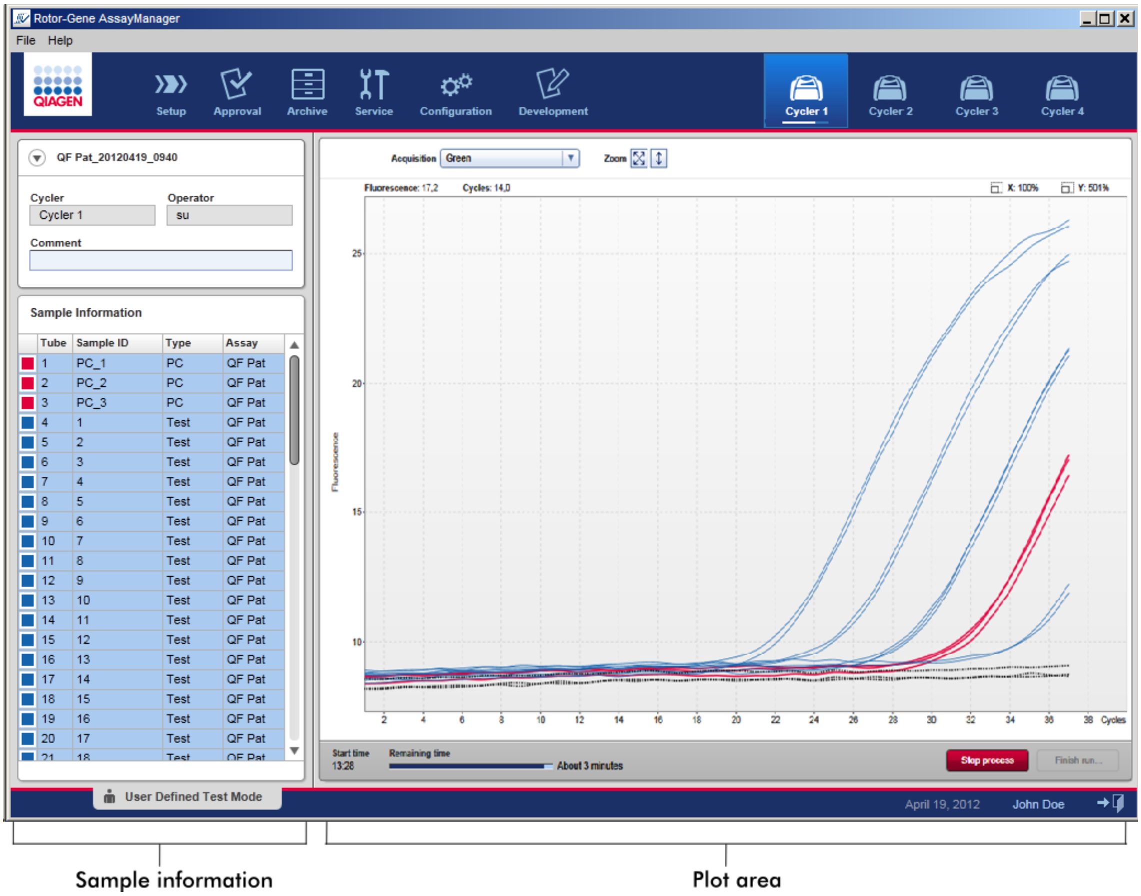
A *.pdf file with this data can be generated either by clicking "Print work list..." from this screen or from the "Apply work list" screen. This file can be used as a pipetting scheme.

Related topics

- Creating a work list
- Managing cyclers
- Settings
- Available work lists 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.



QF Pat_20120419_0940

Cycler: Cycler 1
Operator: su
Comment:

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
🟦	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

User Defined Test Mode

Acquisition: Green
Zoom

Fluorescence: 17,2 Cycles: 14,0
X: 100% Y: 501%

Start time: 13:28
Remaining time: About 3 minutes

April 19, 2012 John Doe

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.

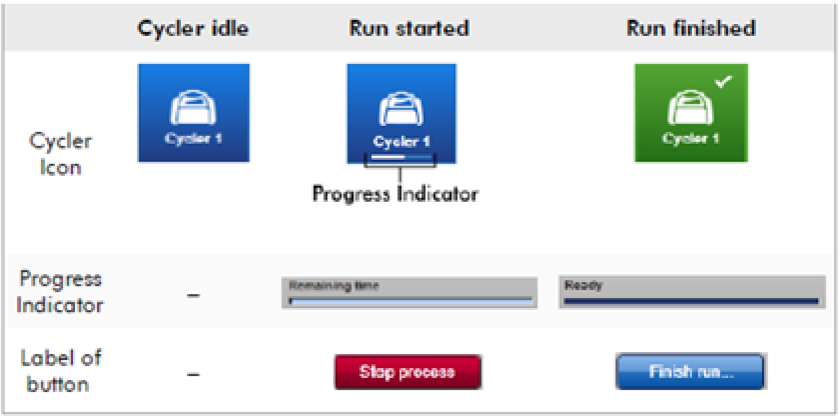
Note

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	Cycler 1	Cycler 1 Progress Indicator	Cycler 1 ✓
Progress Indicator	–	Remaining time	Ready
Label of button	–	Stop process	Finish run...

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:

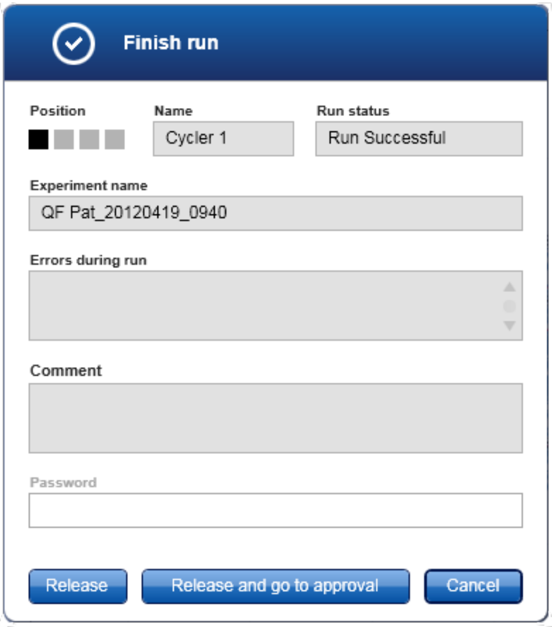
For further details, see ▶ "Cycler" environment

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: ■ ■ ■ ■

Name: Cycler 1

Run status: Run Successful

Experiment name: QF Pat_20120419_0940

Errors during run:

Comment:

Password:

3. Select the desired option:

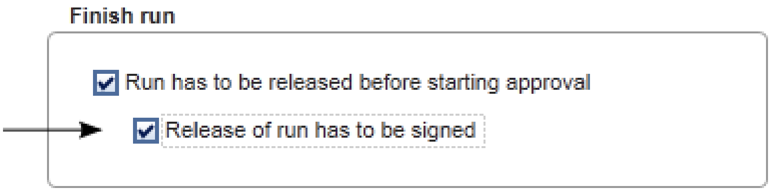
To	Click
Release the cycler	Release
Release the cycler and change to the "Approval" environment	Release and go to approval
Cancel the release process and change to the "Cycler" view	Cancel

When the user releases the cycler, the following processes are triggered:

- The cycler 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.

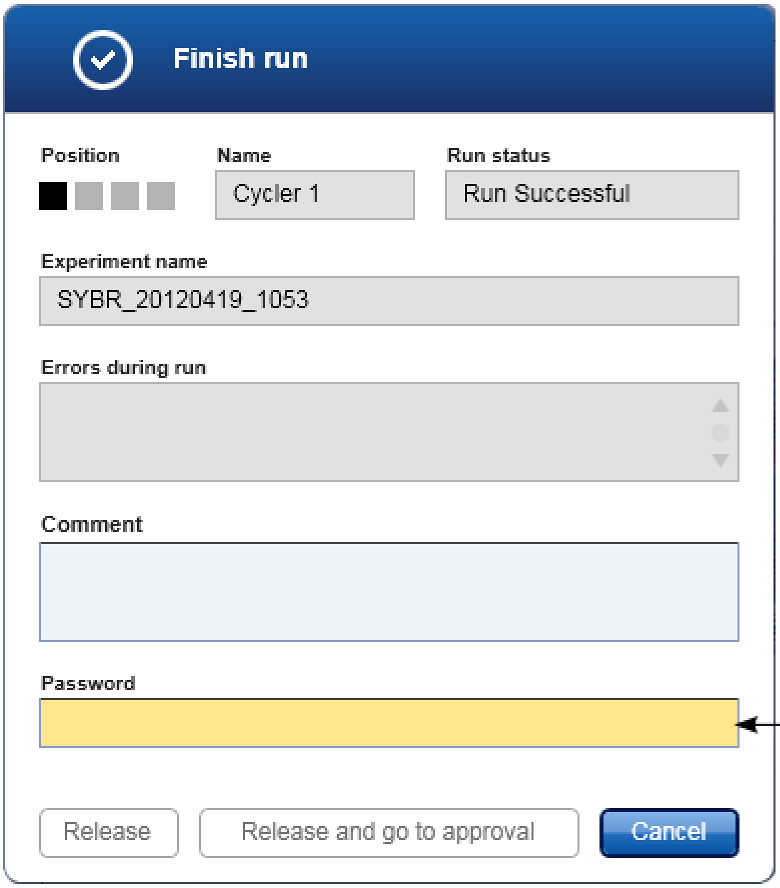


Finish run

☑ Run has to be released before starting approval

☑ Release of run has to be signed

When this option is selected, the run must be signed with a password (user profile password). The buttons "Release" and "Release and go to approval" are initially disabled. These buttons are only enabled if a valid password is entered in the "Password" field.



Finish run

Name: Cycler 1

Run status: Run Successful

Experiment name: SYBR_20120419_1053

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

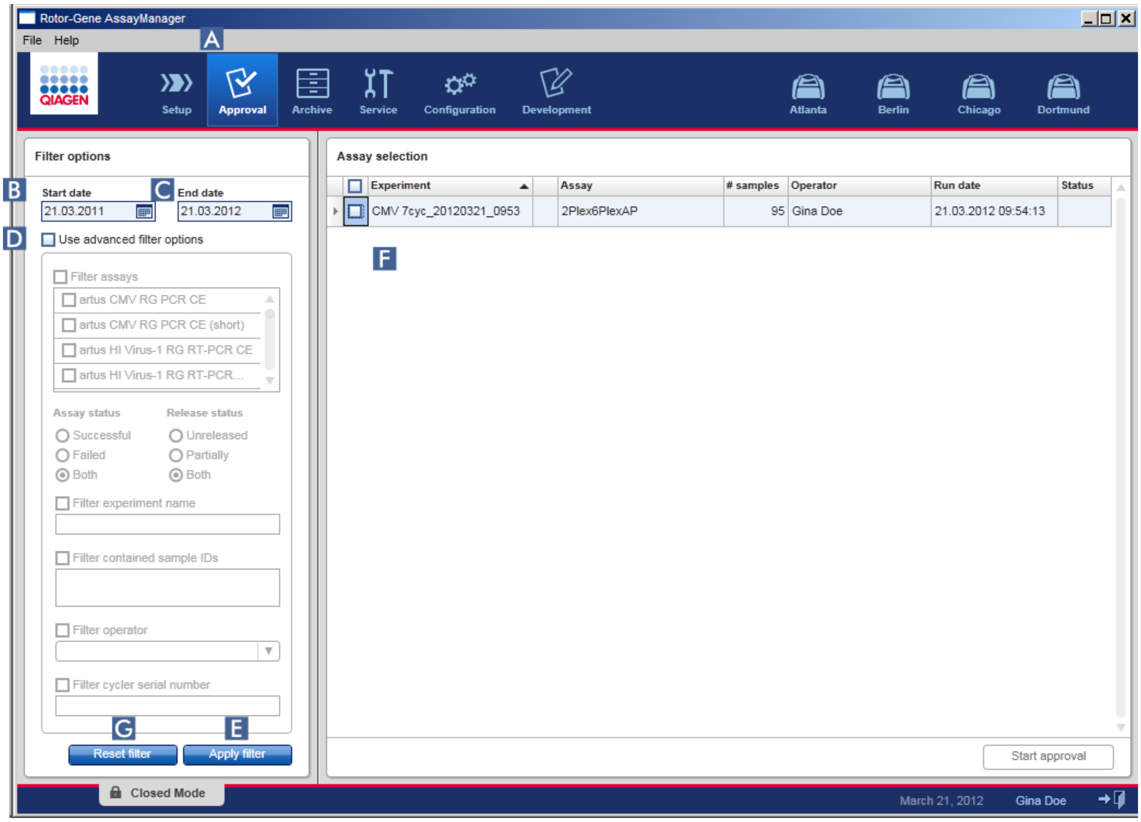
After a run has finished and the cycler has been released, the experiment will be stored in the internal database. The analysis of the acquired data is performed automatically depending on the plug-in corresponding to the assay profile and the rules and parameter values defined by the assay profile.

Rotor-Gene AssayManager v1.0 provides test results that must be approved and released by a user with the role of an approver. Depending on which Rotor-Gene AssayManager v1.0 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.



Start date: 21.03.2011

End date: 21.03.2012

☐	Experiment	Assay	# samples	Operator	Run date	Status
☐	CMV 7cyc_20120321_0953	2Plex6PlexAP	95	Gina Doe	21.03.2012 09:54:13	

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		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. Restrictions: ▪ Wildcard characters are not allowed. ▪ Dates must be entered completely.
Advanced Criteria	"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 for 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: ▪ Successful ▪ Failed ▪ Both
	"Release status"	Filter for the release status using the radio buttons. Possible values are: ▪ Unreleased ▪ Partially ▪ Both
	"Filter experiment name"	Filter for certain assays 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 must 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 cycler serial number"	Filter for a cycler serial number by activating the check box and entering a cycler serial number (only digits).

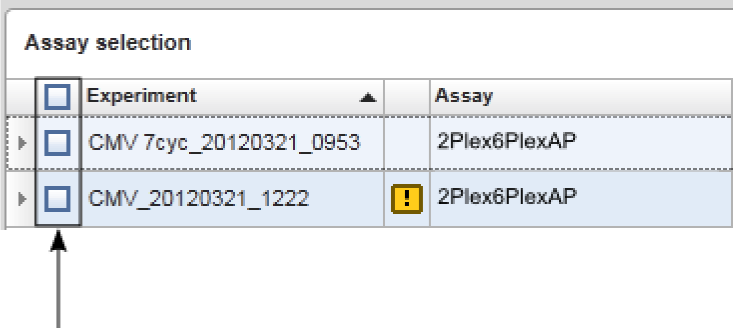
Step-by-step procedure to filter assays

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" (E) to search the internal database for experiments meeting the criteria defined in the previous step.

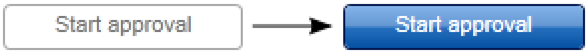
   All assays meeting the filter criteria will be listed in the "Assay selection" table (F) in the right half of the "Approval" environment.
7. Activate the check box in front of the assay to approve. It is possible to select multiple assays.



Assay selection

☐	Experiment		Assay
☐	CMV 7cyc_20120321_0953		2Plex6PlexAP
☐	CMV_20120321_1222	!	2Plex6PlexAP

The "Start approval" button is activated when at least one assay is selected:



8. Click "Start approval".

Note

Click "Reset filter" (G) 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

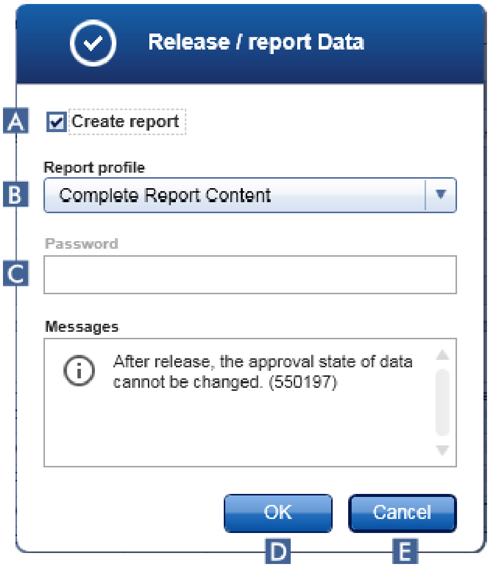
Depending on which Rotor-Gene AssayManager v1.0 plug-in is currently used, the individual approval process may differ. For details about the individual approval process, refer to the corresponding plug-in user manual.

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

☑ Create report

Report profile

Complete Report Content

Password

Messages

After release, the approval state of data cannot be changed. (550197)

2. To create a report, activate the "Create report" option (A) and select a report profile from the drop-down list (B).
3. If the release must be signed, enter the Rotor-Gene AssayManager v1.0 login password in the "Password" field (C). This option is set by the administrator in the ▶ "Configuration" environment.
4. To release the data, click "OK" (D). Click "Cancel" (E) to cancel and go back to the "Results" table.

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 v1.0. 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.

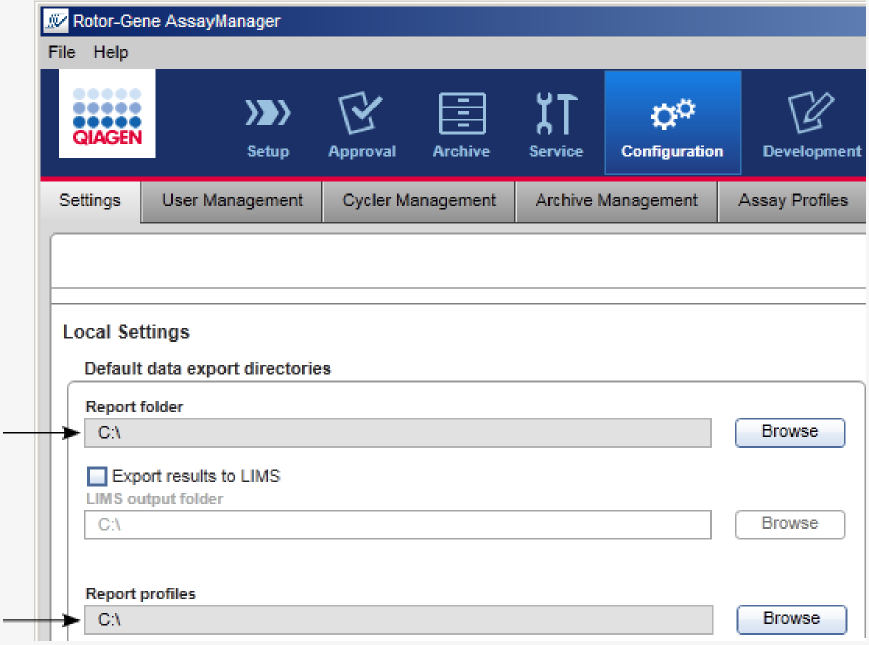
Note
LIMS output is generated during release if configured.

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 foralready 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.



Local Settings

Default data export directories

Report folder: C:\

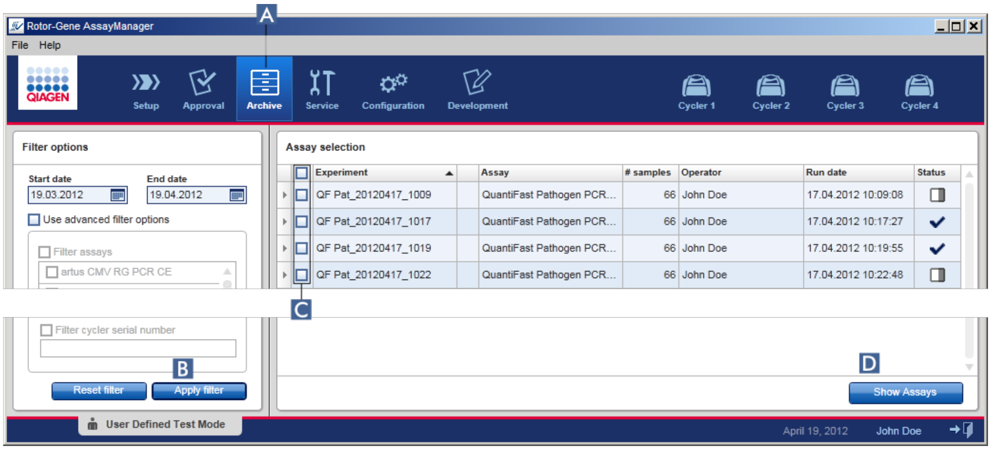
☐ Export results to LIMS

LIMS output folder: C:\

Report profiles: C:\

Step-by-step procedure to create a report in the Archive environment

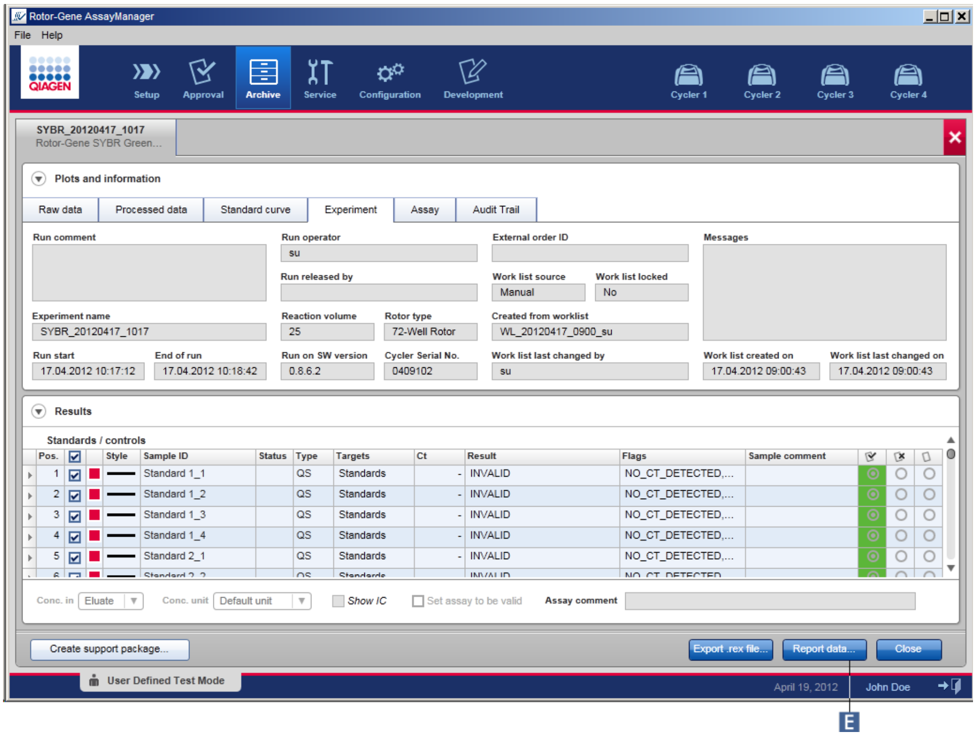
1. Click "Archive" (A) in the main toolbar to change to the "Archive" environment.
   The "Assay selection" screen is displayed.



Start date: 19.03.2012
End date: 19.04.2012
☐ Use advanced filter options

	☐	Experiment	Assay	# samples	Operator	Run date	Status
▸	☐	QF Pat_20120417_1009	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 10:09:08	☐
▸	☐	QF Pat_20120417_1017	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 10:17:27	✓
▸	☐	QF Pat_20120417_1019	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 10:19:55	✓
▸	☐	QF Pat_20120417_1022	QuantiFast Pathogen PCR...	66	John Doe	17.04.2012 10:22:48	☐

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).



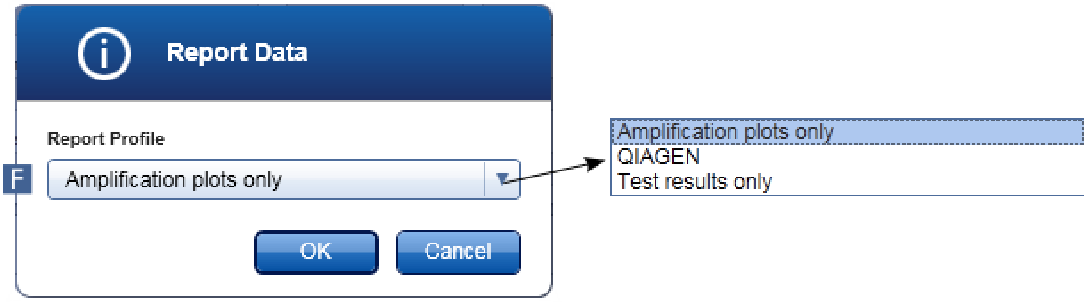
Run comment:
Run operator: su
External order ID:
Messages:
Run released by:
Work list source: Manual
Work list locked: No
Experiment name: SYBR_20120417_1017
Reaction volume: 25
Rotor type: 72-Well Rotor
Created from worklist: WL_20120417_0900_su
Run start: 17.04.2012 10:17:12
End of run: 17.04.2012 10:18:42
Run on SW version: 0.8.6.2
Cycler Serial No.: 0409102
Work list last changed by: su
Work list created on: 17.04.2012 09:00:43
Work list last changed on: 17.04.2012 09:00:43

	Pos.	☑		Style	Sample ID	Status	Type	Targets	Ct	Result	Flags	Sample comment			
▸	1	☑	🟥	—	Standard 1_1		QS	Standards	-	INVALID	NO_CT_DETECTED,...		●	○	○
▸	2	☑	🟥	—	Standard 1_2		QS	Standards	-	INVALID	NO_CT_DETECTED,...		●	○	○
▸	3	☑	🟥	—	Standard 1_3		QS	Standards	-	INVALID	NO_CT_DETECTED,...		●	○	○
▸	4	☑	🟥	—	Standard 1_4		QS	Standards	-	INVALID	NO_CT_DETECTED,...		●	○	○
▸	5	☑	🟥	—	Standard 2_1		QS	Standards	-	INVALID	NO_CT_DETECTED,...		●	○	○

Conc. in: Eluate
Conc. unit: Default unit
☐ *Show IC*
☐ Set assay to be valid
Assay comment:

5. Click "Report data..." (E) in the button bar.

The "Report Data" dialog is opened.



Report Profile: Amplification plots only

6. Select a report profile from the "Report Profile" drop-down menu (F) .
7. Click "OK" to create the report. Click "Cancel" to cancel and return to the approval screen.

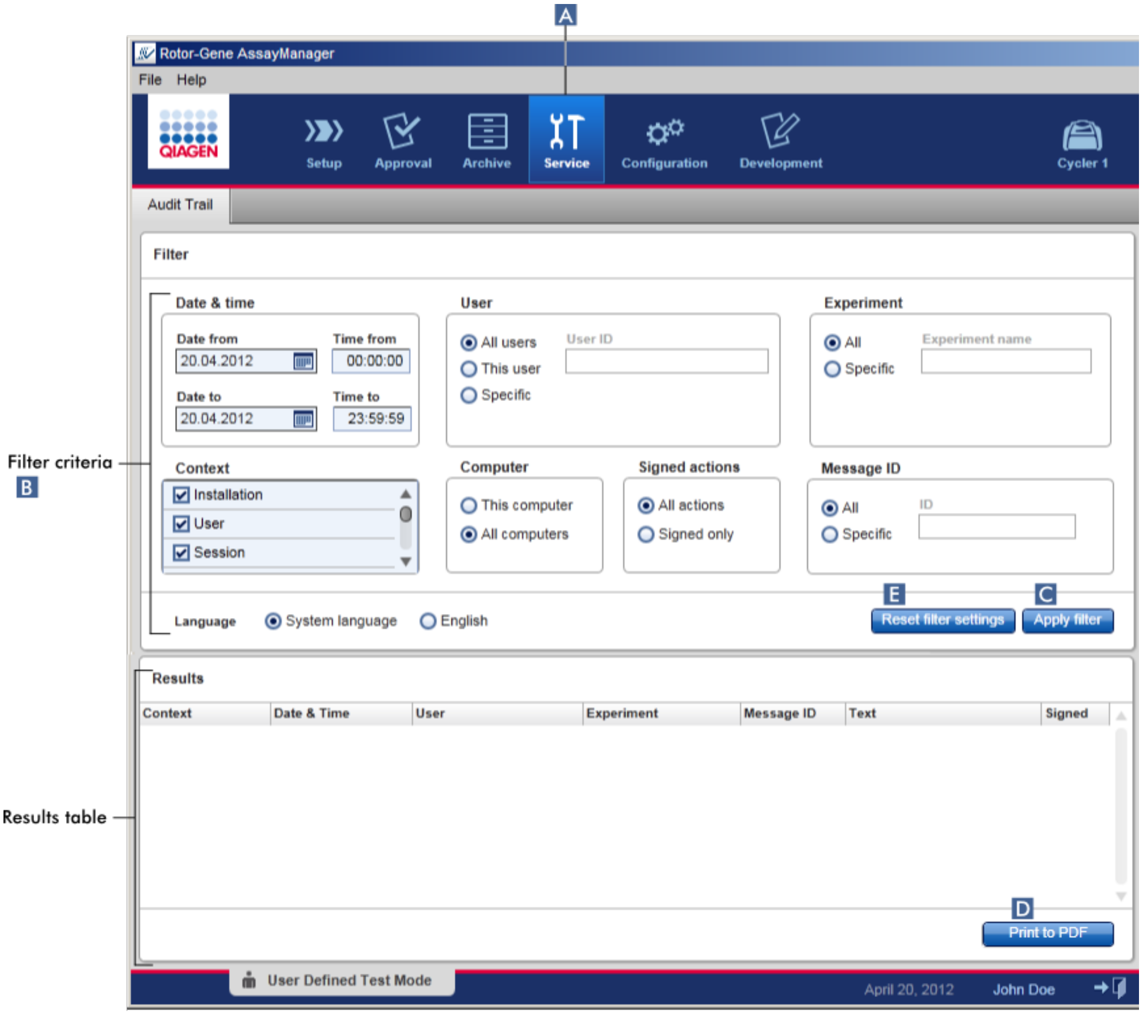
   A report of the selected experiment is generated as a *.pdf file using the selected report profile and saved in the report folder defined in the "Configuration" environment.

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 v1.0. 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.



Date & time
Date from 20.04.2012
Time from 00:00:00
Date to 20.04.2012
Time to 23:59:59

User
● All users
○ This user
○ Specific
User ID

Experiment
● All
○ Specific
Experiment name

Context
☑ Installation
☑ User
☑ Session

Computer
○ This computer
● All computers

Signed actions
● All actions
○ Signed only

Message ID
● All
○ Specific
ID

Language ● System language ○ English

April 20, 2012 John Doe

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.

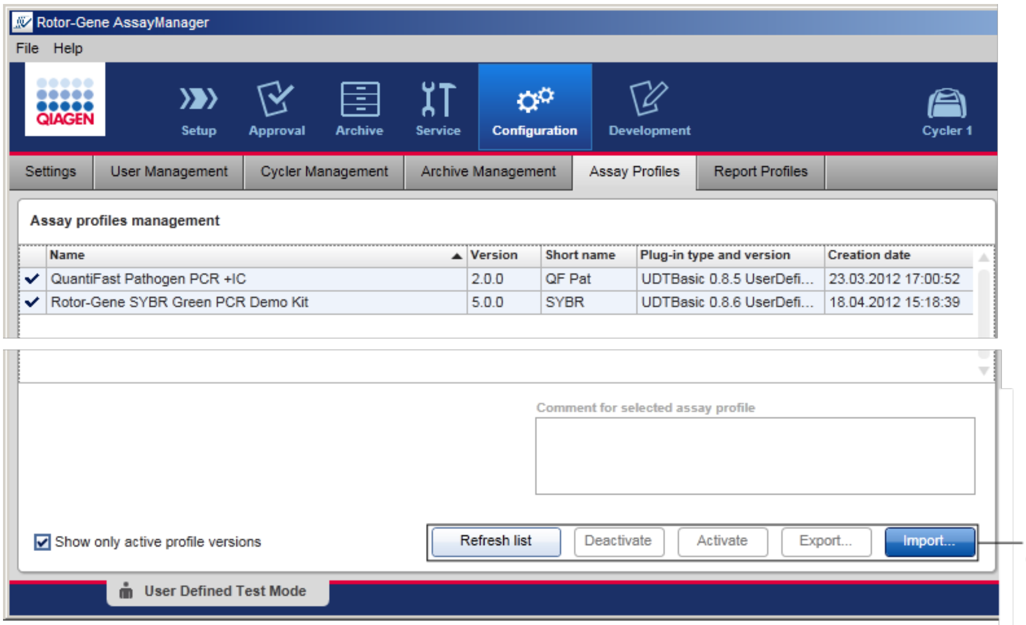
> **Warning**
> Rotor-Gene AssayManager v1.0 shall not be used with the admin account of Microsoft Windows operating system.

▸ 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.



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	5.0.0	SYBR	UDTBasic 0.8.6 UserDefi...	18.04.2012 15:18:39

☑ Show only active profile versions

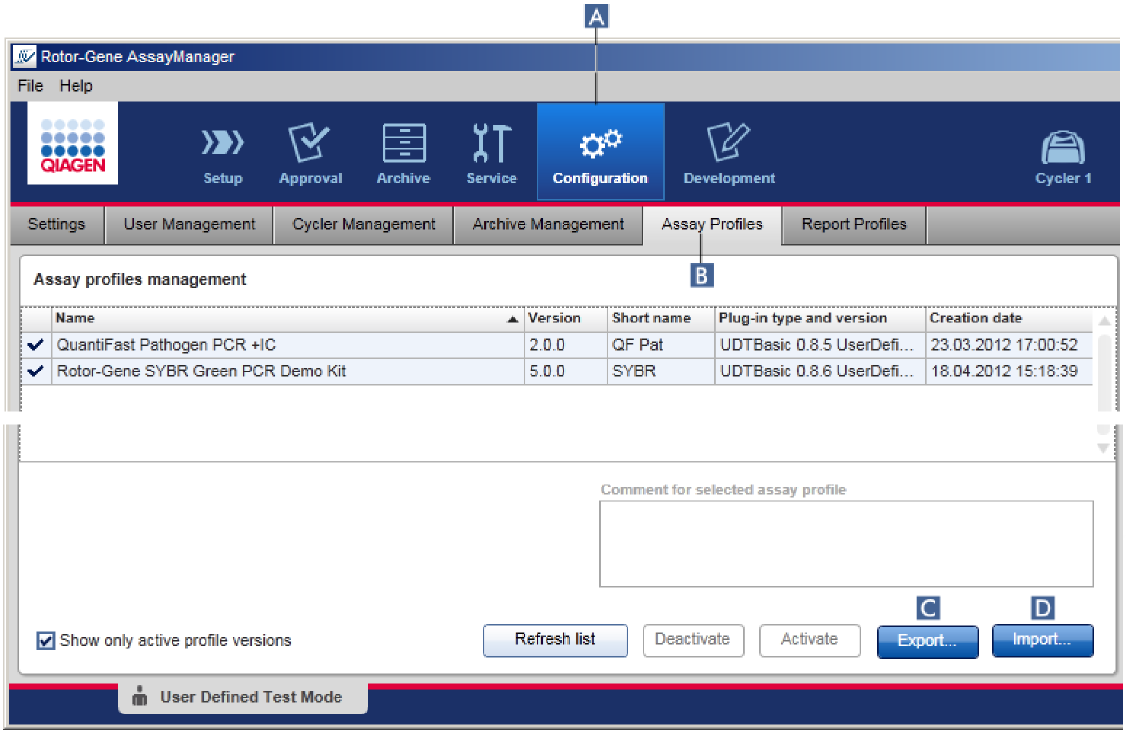
Buttons for managing assay profiles

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 v1.0 provides an import/export feature for assay profiles to exchange assay profiles between different Rotor-Gene AssayManager v1.0 installations. An imported assay profile will be added to the list of "Available work lists" in the "Setup" environments. The imported assay profile is available for the creation of new work lists. This is done in the "Setup" environment. Newly developed assay profiles have to be imported before they can be used in Rotor-Gene AssayManager v1.0.



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	5.0.0	SYBR	UDTBasic 0.8.6 UserDefi...	18.04.2012 15:18:39

☑ Show only active profile versions

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

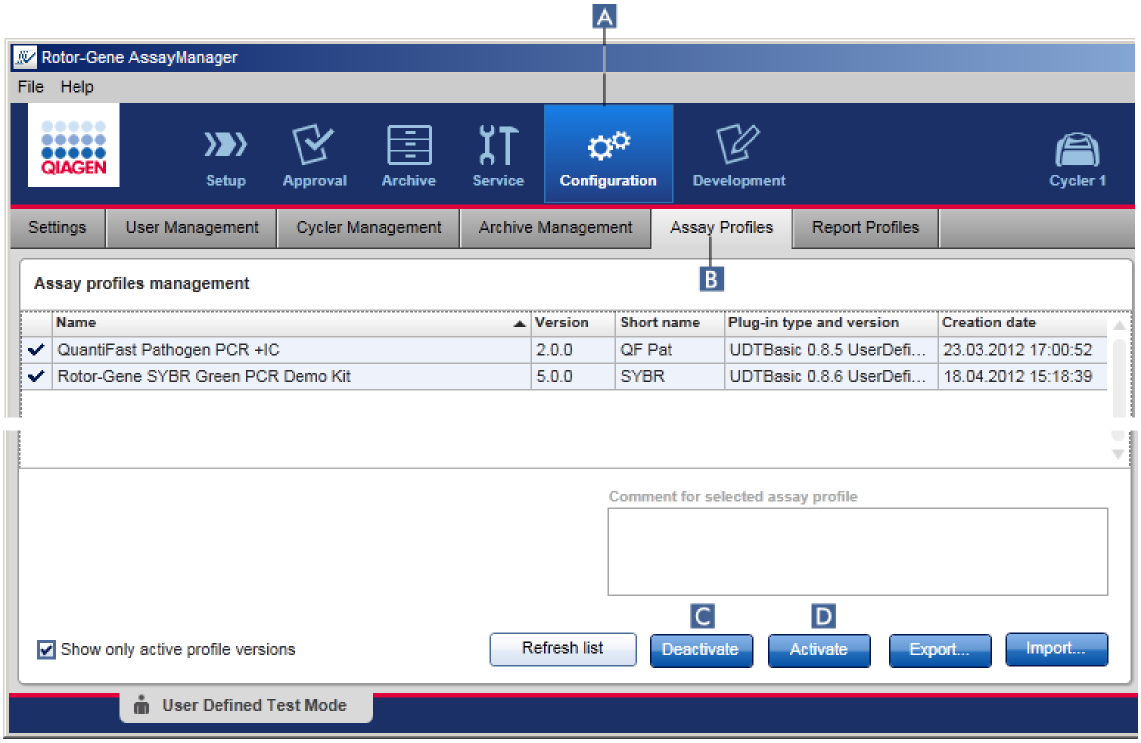
- Configuration - assay profiles
- Setting up a run
- "Setup" environment

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 work lists in the "Setup" environment. Deactivated assay profiles cannot be used but can be reactivated by an administrator if required. Existing work lists 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 and deactivated assay profiles in parallel in the list, deactivate the check box. Activated and deactivated assay profiles can be differentiated by the following icons:

Icon	Assay profile status
✓	Activated
▧	Deactivated



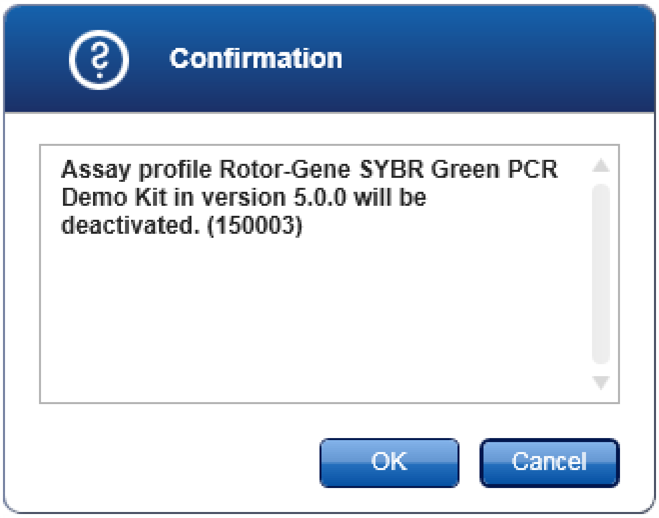
Assay profiles management

	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	5.0.0	SYBR	UDTBasic 0.8.6 UserDefi...	18.04.2012 15:18:39

☑ Show only active profile versions

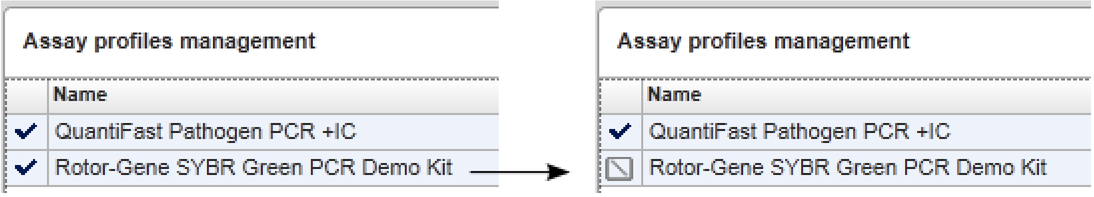
Step-by-step procedure to deactivate an assay profile

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:



Assay profile Rotor-Gene SYBR Green PCR Demo Kit in version 5.0.0 will be deactivated. (150003)

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

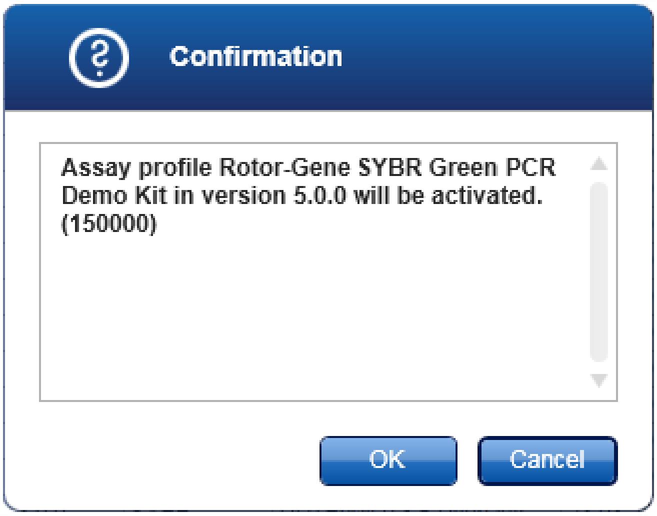
	Name
✓	QuantiFast Pathogen PCR +IC
✓	Rotor-Gene SYBR Green PCR Demo Kit

Assay profiles management

	Name
✓	QuantiFast Pathogen PCR +IC
⧅	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:



Assay profile Rotor-Gene SYBR Green PCR Demo Kit in version 5.0.0 will be activated. (150000)

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.

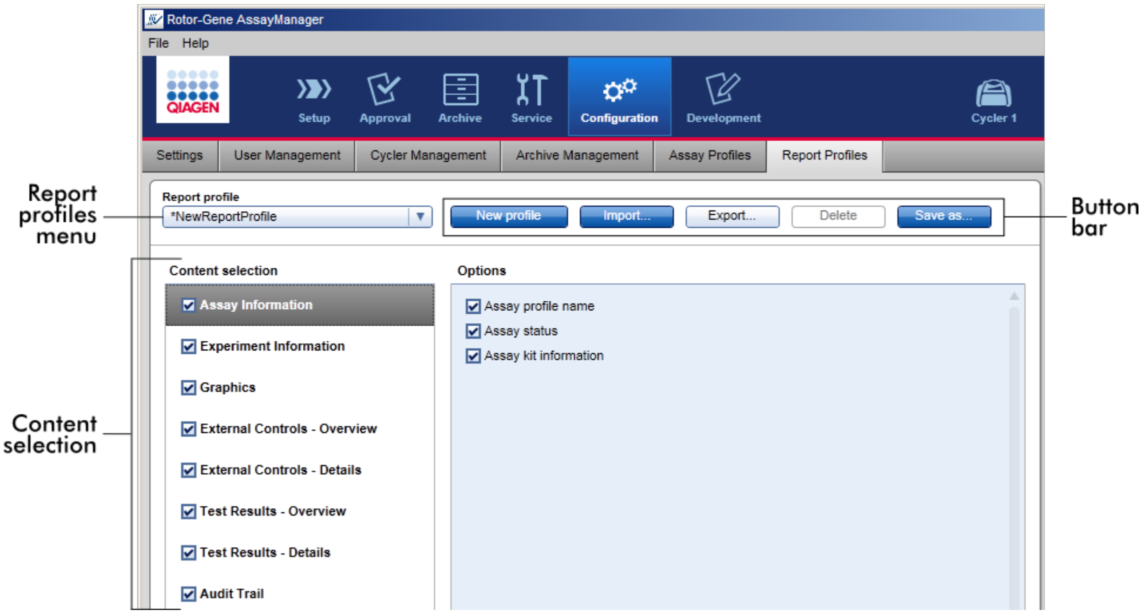
Related topics

- 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.

> **Note**
> Some plug-ins contain a specific report profile that is mandatory.



Report profile: *NewReportProfile

Content selection
- ☑ Assay Information
- ☑ Experiment Information
- ☑ Graphics
- ☑ External Controls - Overview
- ☑ External Controls - Details
- ☑ Test Results - Overview
- ☑ Test Results - Details
- ☑ Audit Trail

Options
- ☑ Assay profile name
- ☑ Assay status
- ☑ Assay kit information

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.

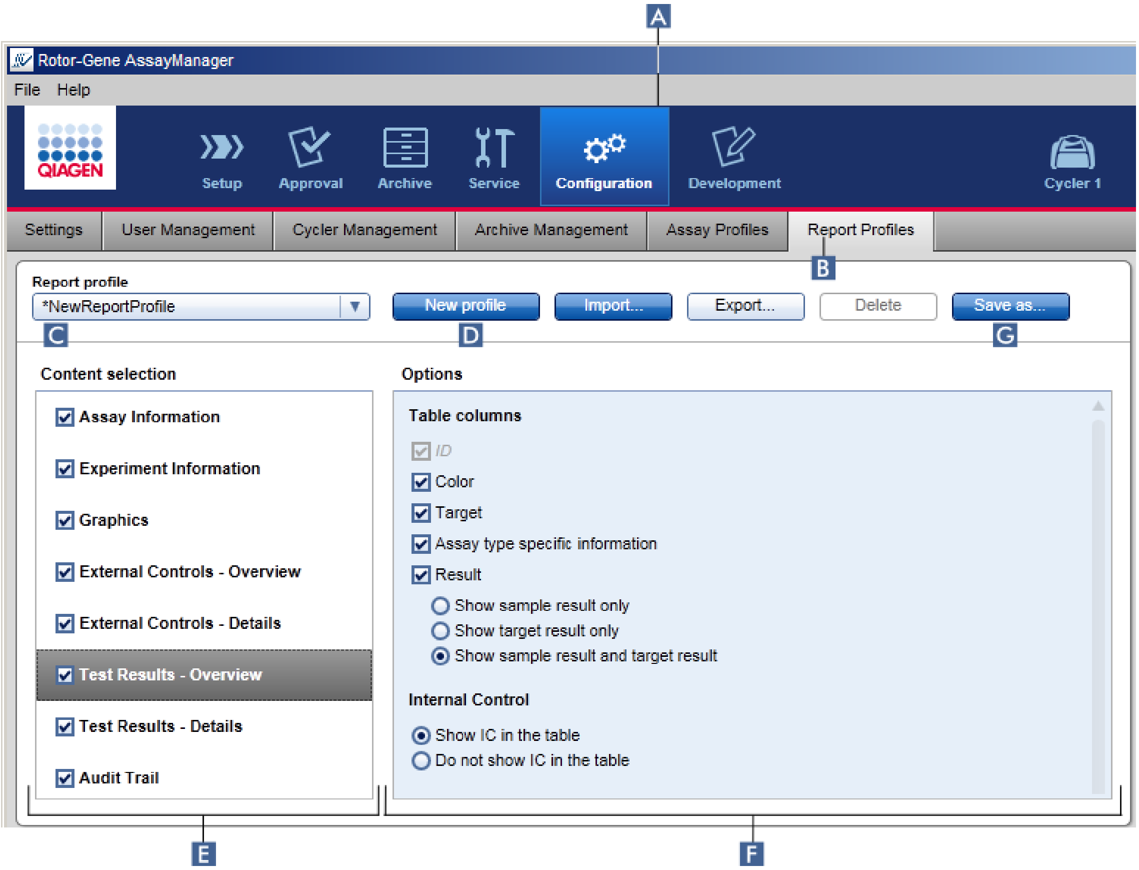
Tasks related to managing report profiles

- 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.



Report profile: *NewReportProfile

Content selection

☑ Assay Information
☑ Experiment Information
☑ Graphics
☑ External Controls - Overview
☑ External Controls - Details
☑ Test Results - Overview
☑ Test Results - Details
☑ Audit Trail

Options

Table columns

☑ *ID*
☑ Color
☑ Target
☑ Assay type specific information
☑ Result
  - ○ Show sample result only
  - ○ Show target result only
  - ● Show sample result and target result

Internal Control

● Show IC in the table
○ Do not show IC in the table

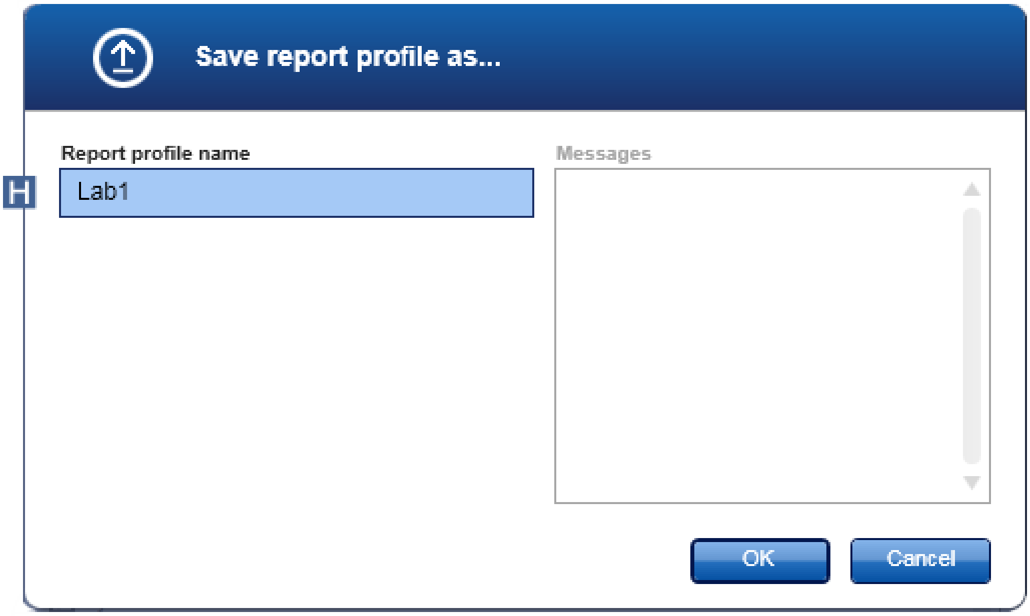
2. By default a new report profile template is selected in the "Report profile" drop-down menu (C) called **NewReportProfile* with all content selection options activated. If another report profile was selected before, a new report profile can be generated by clicking "New profile" (D).
3. Deactivate 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

The option "**Sample result**" is only useful for experiments where Rotor-Gene AssayManager v1.0 has to evaluate a result for a certain sample ID over different assays in several rotor positions.

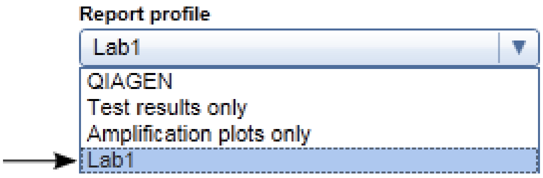
For standard or multiplex assays with one rotor position per sample ID, select the "**Show target result only**" radio button in the "External Controls - Overview" and "Test Results - Overview" sections and **deselect the "Sample result" check box** in the "External Contorols - Details" and "Test Results - Details" sections. Otherwise the report will contain a "Sample result not supported" warning for every single sample.

4. Click "Save as..." (G) to save the report profile.
5. The "Save report profile as..." dialog is displayed:



Report profile name: Lab1

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).



Report profile: Lab1

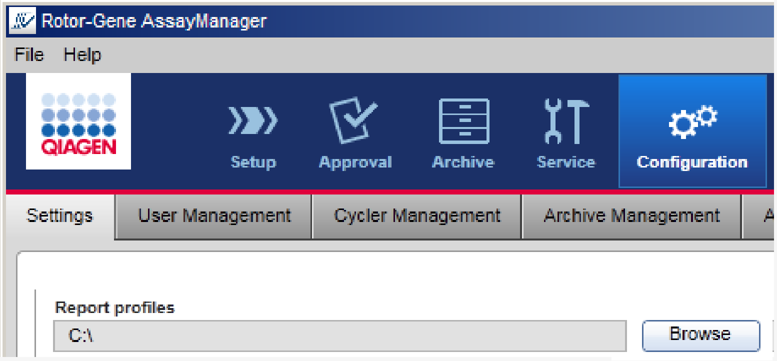
> **Note**
> Report profiles delivered by QIAGEN are read-only, i.e., they can only be imported or deleted.

1.6.2.2.2 **Importing/Exporting a Report Profile**

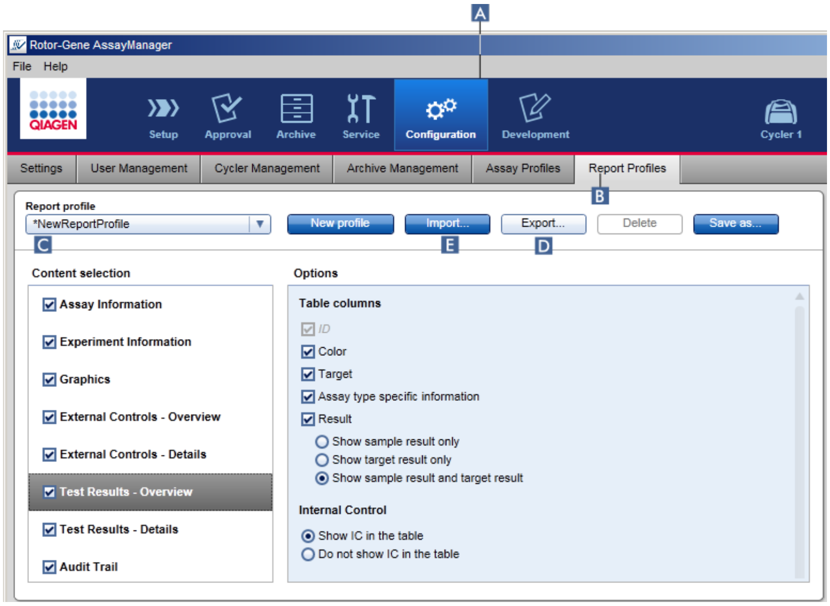
Report profiles can be exchanged between different Rotor-Gene AssayManager v1.0 installations using the report profile import and export function.

Note

The default directory for report profile import and export is set in the ▶ "Settings" tab of the ▶ "Configuration" environment.



Report profiles: C:\



Report profile: *NewReportProfile

Content selection

☑ Assay Information
☑ Experiment Information
☑ Graphics
☑ External Controls - Overview
☑ External Controls - Details
☑ Test Results - Overview
☑ Test Results - Details
☑ Audit Trail

Options

Table columns

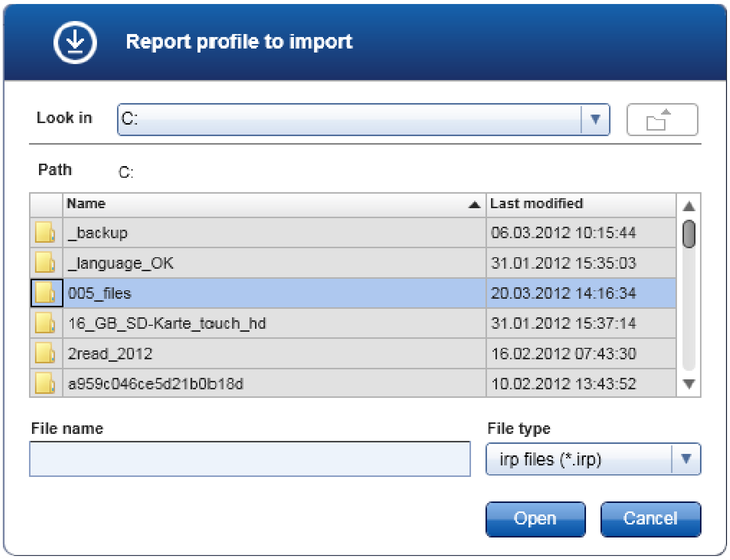
☑ ID
☑ Color
☑ Target
☑ Assay type specific information
☑ Result
○ Show sample result only
○ Show target result only
● Show sample result and target result

Internal Control

● Show IC in the table
○ Do not show IC in the table

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" (E).
   The file dialog is opened.



Look in: C:

Path: C:

Name	Last modified
_backup	06.03.2012 10:15:44
_language_OK	31.01.2012 15:35:03
005_files	20.03.2012 14:16:34
16_GB_SD-Karte_touch_hd	31.01.2012 15:37:14
2read_2012	16.02.2012 07:43:30
a959c046ce5d21b0b18d	10.02.2012 13:43:52

File name:

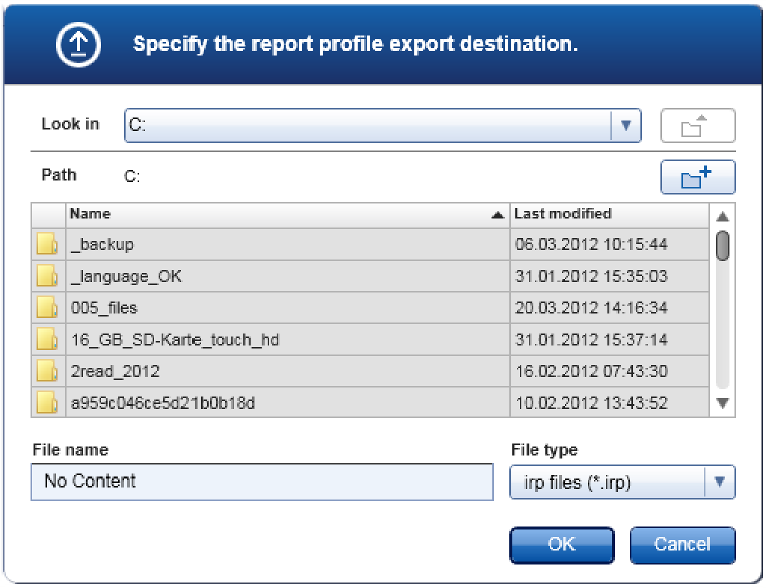
File type: irp files (*.irp)

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 (C).

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.



Specify the report profile export destination.

Look in: C:

Path: C:

Name	Last modified
_backup	06.03.2012 10:15:44
_language_OK	31.01.2012 15:35:03
005_files	20.03.2012 14:16:34
16_GB_SD-Karte_touch_hd	31.01.2012 15:37:14
2read_2012	16.02.2012 07:43:30
a959c046ce5d21b0b18d	10.02.2012 13:43:52

File name: No Content

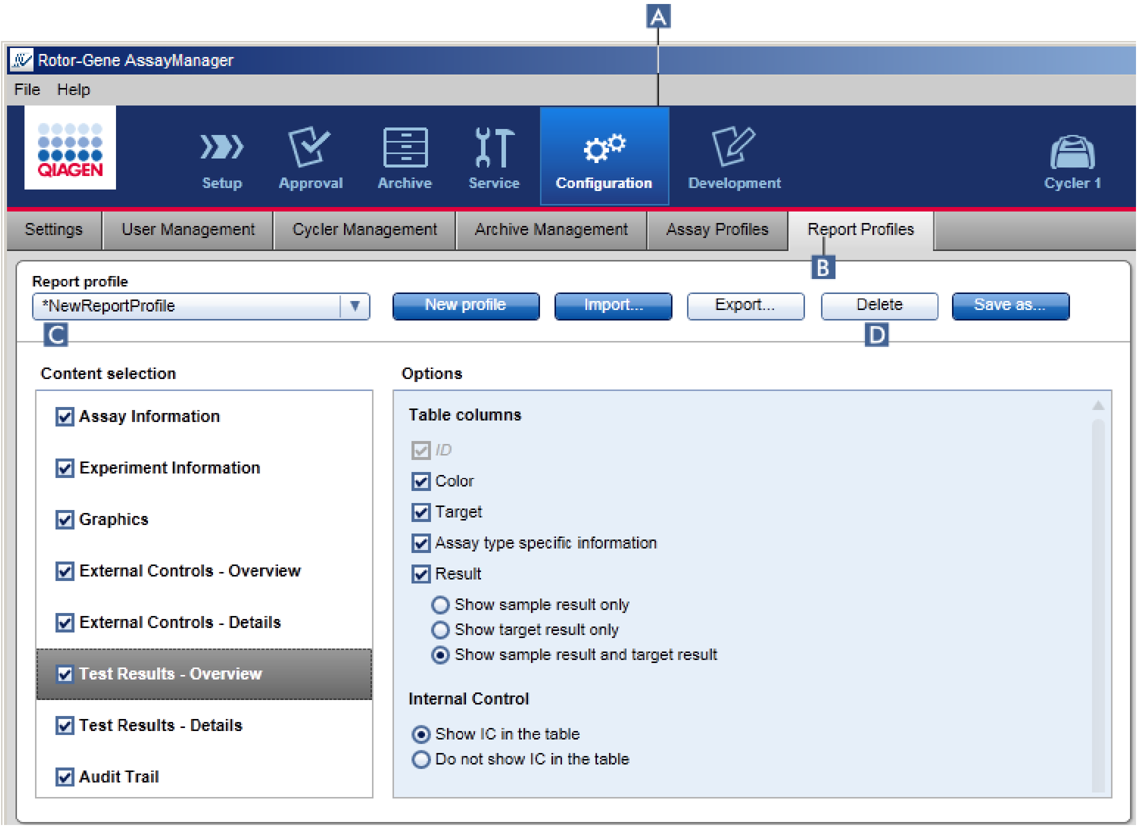
File type: irp files (*.irp)

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.

1.6.2.2.3 Deleting a Report Profile

Obsolete report profiles can be removed using the delete function.



Report profile: *NewReportProfile

Content selection
- ☑ Assay Information
- ☑ Experiment Information
- ☑ Graphics
- ☑ External Controls - Overview
- ☑ External Controls - Details
- ☑ Test Results - Overview
- ☑ Test Results - Details
- ☑ Audit Trail

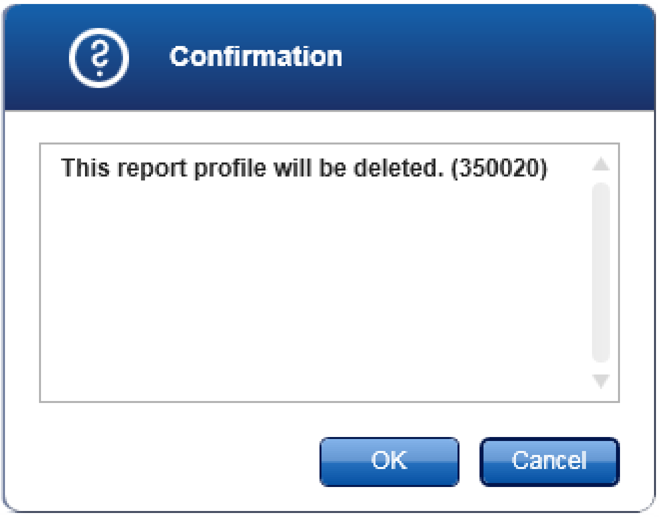
Options

Table columns
- ☑ *ID*
- ☑ Color
- ☑ Target
- ☑ Assay type specific information
- ☑ Result
  - ○ Show sample result only
  - ○ Show target result only
  - ● Show sample result and target result

Internal Control
- ● Show IC in the table
- ○ Do not show IC in the table

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:

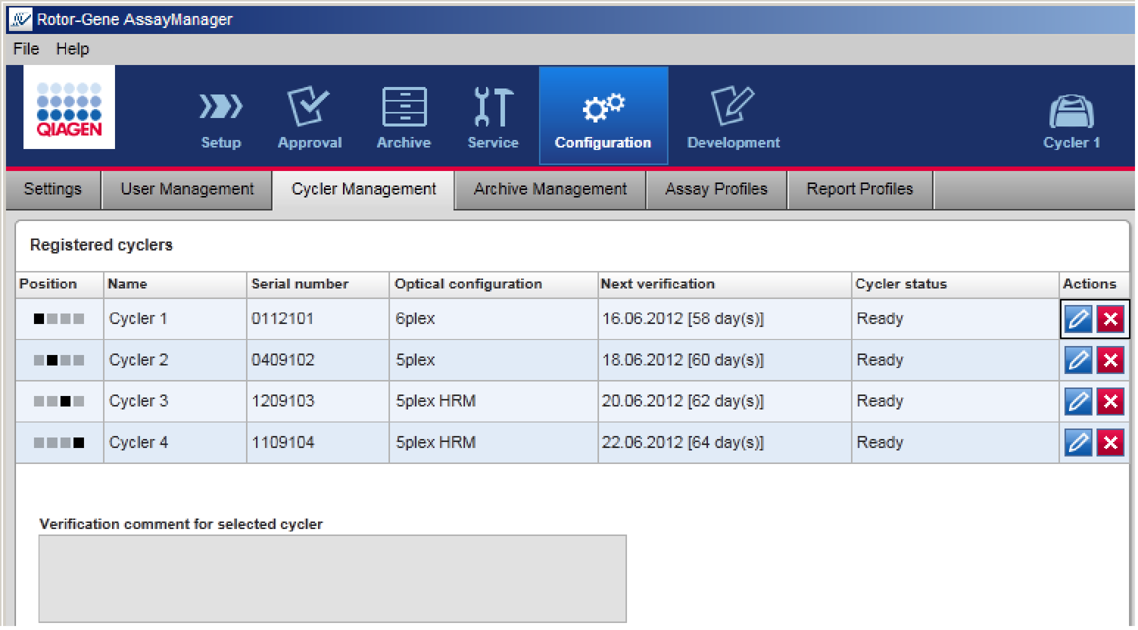


This report profile will be deleted. (350020)

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 v1.0 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.



Registered cyclers

Position	Name	Serial number	Optical configuration	Next verification	Cycler status	Actions
■□□□	Cycler 1	0112101	6plex	16.06.2012 [58 day(s)]	Ready	✎ ✖
□■□□	Cycler 2	0409102	5plex	18.06.2012 [60 day(s)]	Ready	✎ ✖
□□■□	Cycler 3	1209103	5plex HRM	20.06.2012 [62 day(s)]	Ready	✎ ✖
□□□■	Cycler 4	1109104	5plex HRM	22.06.2012 [64 day(s)]	Ready	✎ ✖

Verification comment for selected cycler

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

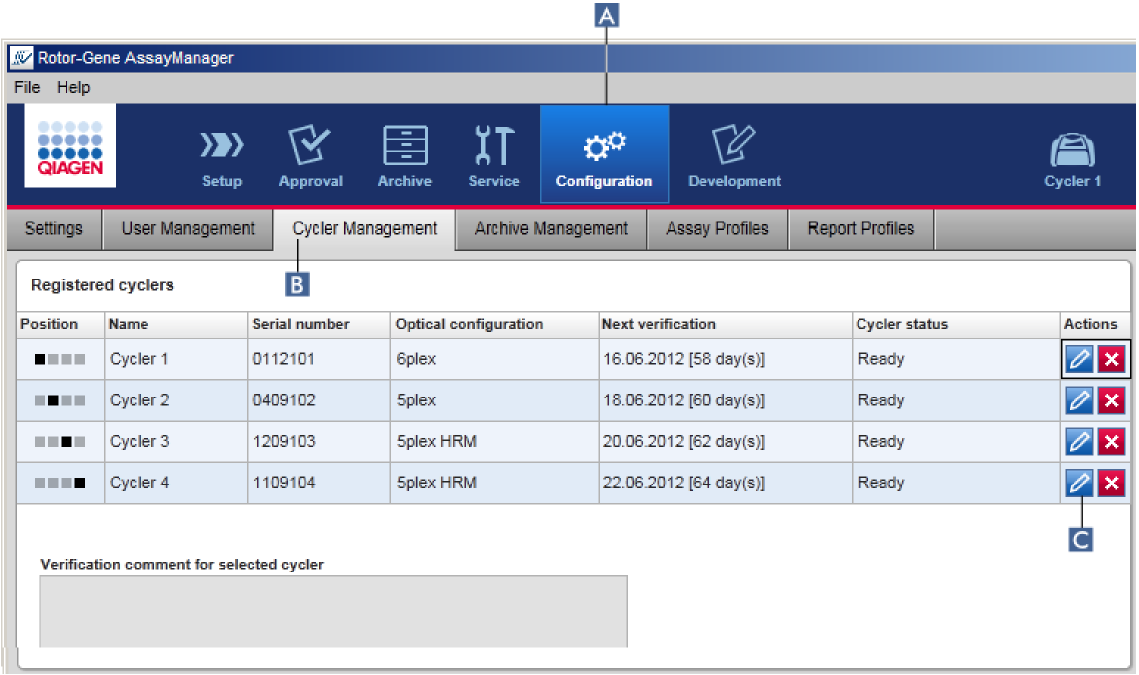
Step-by-step procedure to add a cycler

1. Connect the USB cable supplied to a USB port of the computer.
2. Connect the USB cable 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 Q software version 2.1, or higher. 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.

> **Note**
> For details about hardware installation and the installation of the Rotor-Gene Q software, refer to the Rotor-Gene Q user manual.

6. Open Rotor-Gene AssayManager v1.0.



Registered cycters

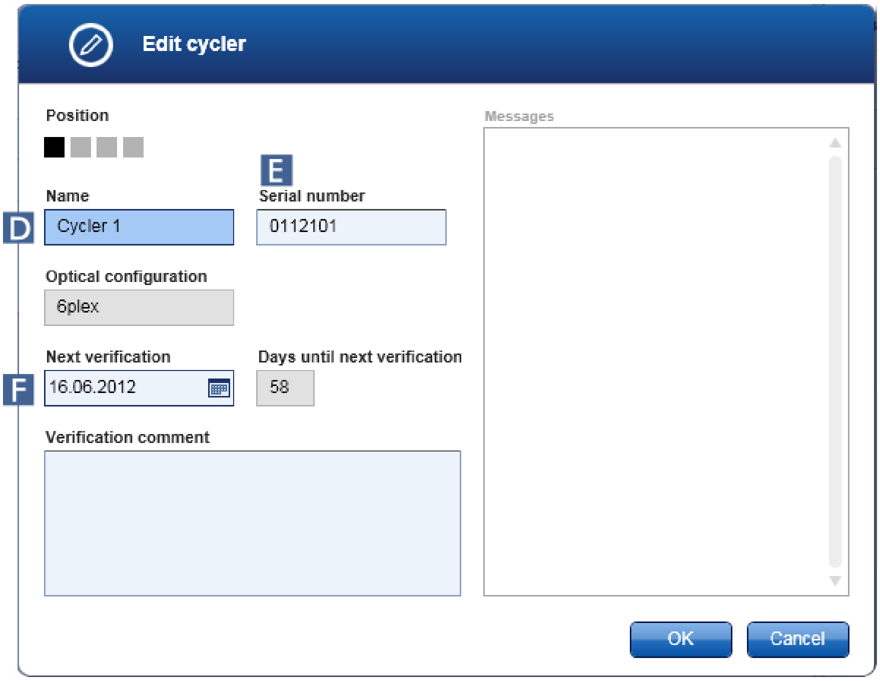
Position	Name	Serial number	Optical configuration	Next verification	Cycler status	Actions
■□□□	Cycler 1	0112101	6plex	16.06.2012 [58 day(s)]	Ready	✎ ✖
□■□□	Cycler 2	0409102	5plex	18.06.2012 [60 day(s)]	Ready	✎ ✖
□□■□	Cycler 3	1209103	5plex HRM	20.06.2012 [62 day(s)]	Ready	✎ ✖
□□□■	Cycler 4	1109104	5plex HRM	22.06.2012 [64 day(s)]	Ready	✎ ✖

Verification comment for selected cycler

7. Change to the "Cycler Management" screen:
   a) Click "Configuration" (A) in the main toolbar.
   b) Click the "Cycler Management" (B) tab.

> **Note**
> The cycler must be connected to the computer and switched on before it can be registered in Rotor-Gene AssayManager v1.0.

6. Click the "Edit cycler" icon (C) of an empty row.
7. The "Edit cycler" dialog is shown:



Position

Name: Cycler 1

Serial number: 0112101

Optical configuration: 6plex

Next verification: 16.06.2012

Days until next verification: 58

Verification comment

8. 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 v1.0 once the name and serial number are entered.
9. 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.
10. 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 v1.0, 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.

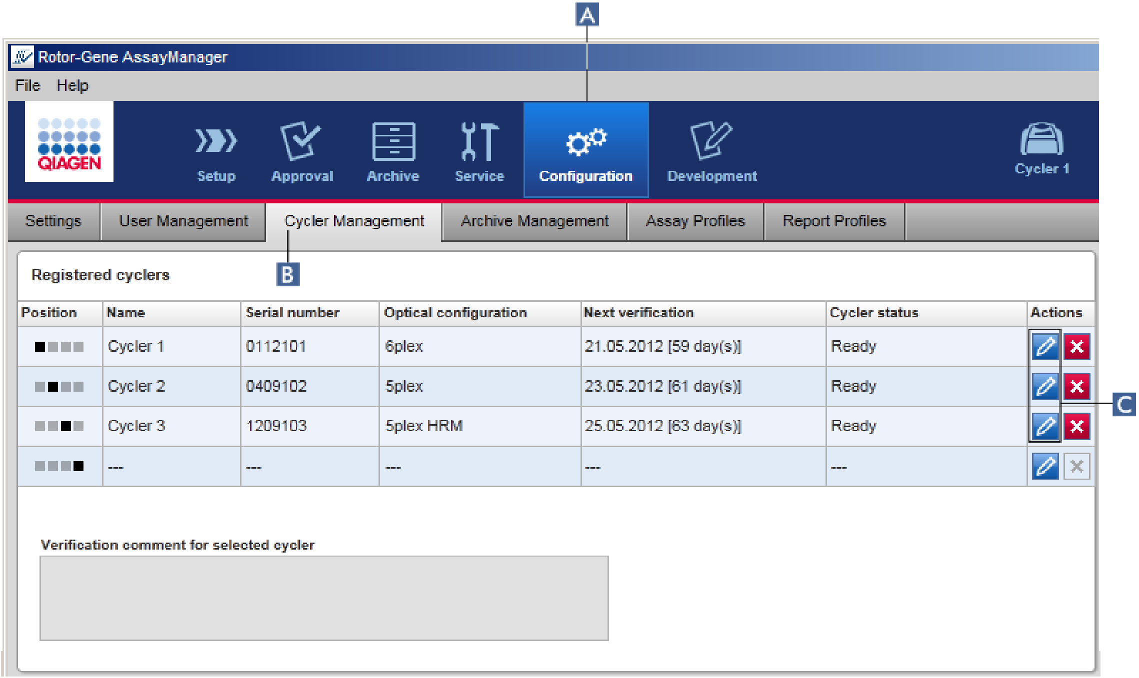
Related topics

- Setting up a run
- "Cycler" environment

1.6.2.3.2 Editing Cycler 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.



Registered cyclers

Position	Name	Serial number	Optical configuration	Next verification	Cycler status	Actions
■□□□	Cycler 1	0112101	6plex	21.05.2012 [59 day(s)]	Ready	✎ ✕
□■□□	Cycler 2	0409102	5plex	23.05.2012 [61 day(s)]	Ready	✎ ✕
□□■□	Cycler 3	1209103	5plex HRM	25.05.2012 [63 day(s)]	Ready	✎ ✕
□□□■	---	---	---	---	---	✎ ✕

Verification comment for selected cycler

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

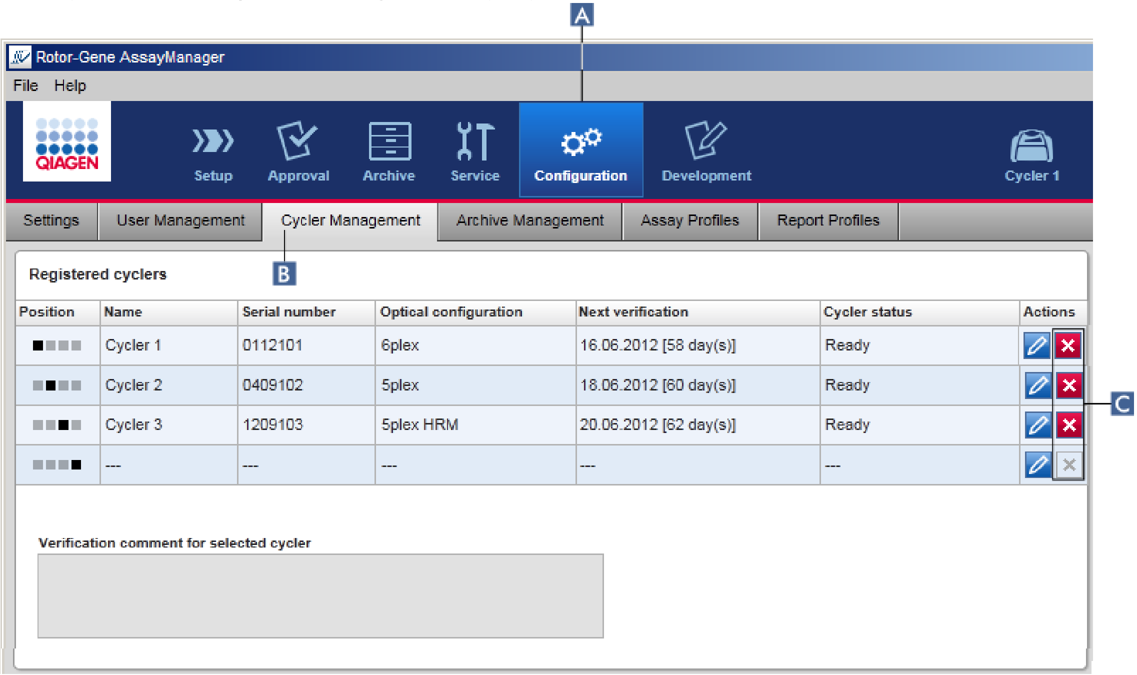
1.6.2.3.3 Removing a Cycler

Note
Cyclers can only be removed if they are offline, ready, or in status "needs verification".

Step-by-step procedure to remove a cycler

1. Change to the "Cycler Management" screen:

a) Click "Configuration" (A) in the main toolbar.
b) Click the "Cycler Management" (B) tab.

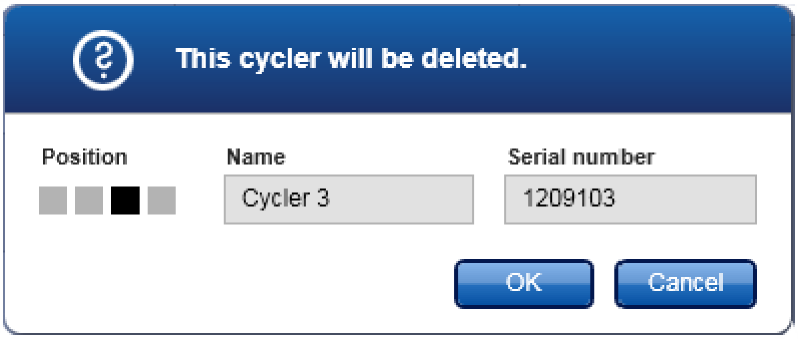


Registered cyclers

Position	Name	Serial number	Optical configuration	Next verification	Cycler status	Actions
■□□□	Cycler 1	0112101	6plex	16.06.2012 [58 day(s)]	Ready	
□■□□	Cycler 2	0409102	5plex	18.06.2012 [60 day(s)]	Ready	
□□■□	Cycler 3	1209103	5plex HRM	20.06.2012 [62 day(s)]	Ready	
□□□■	---	---	---	---	---	

Verification comment for selected cycler

2. Move the mouse to the row containing the cycler to be removed from the "Registered cyclers" table.
3. Click the "Remove cycler" button (C).
   The following confirmation dialog is opened.



This cycler will be deleted.

Position	Name	Serial number
□□■□	Cycler 3	1209103

4. Click "OK". The selected cycler is removed from the "Registered cyclers" table and cannot be used anymore.

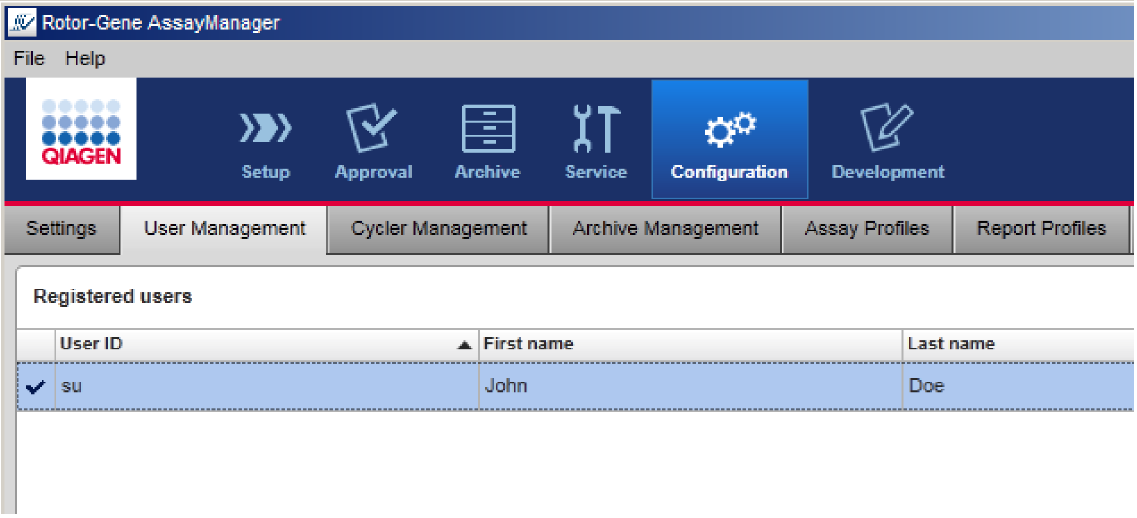
Related topics

- 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.



User ID	First name	Last name
✓ su	John	Doe

Tasks related to managing users

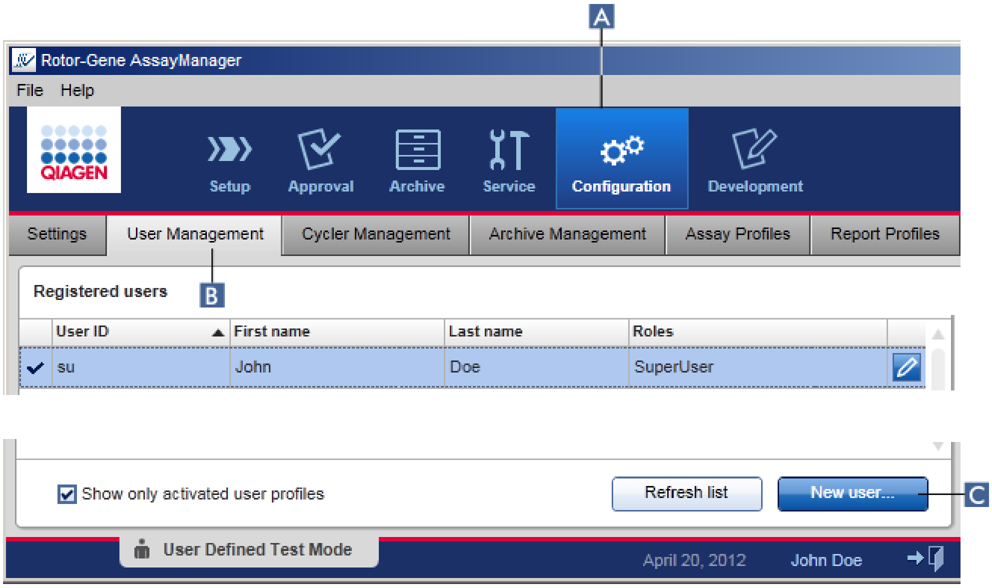
- Creating a user profile
- Changing user profile settings
- Activating/deactivating a user profile
- Setting password policies and auto-lock timer

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.

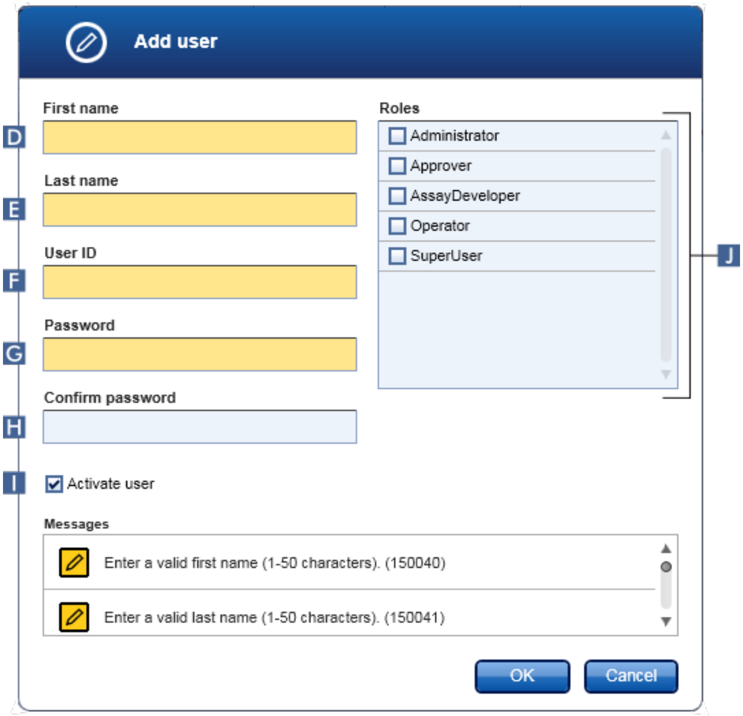
c)



	User ID	First name	Last name	Roles
✓	su	John	Doe	SuperUser

☑ Show only activated user profiles

2. Click "New user..." (C).
3. The "Add user" dialog is shown:



☑ Activate user

Enter a valid first name (1-50 characters). (150040)

Enter a valid last name (1-50 characters). (150041)

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

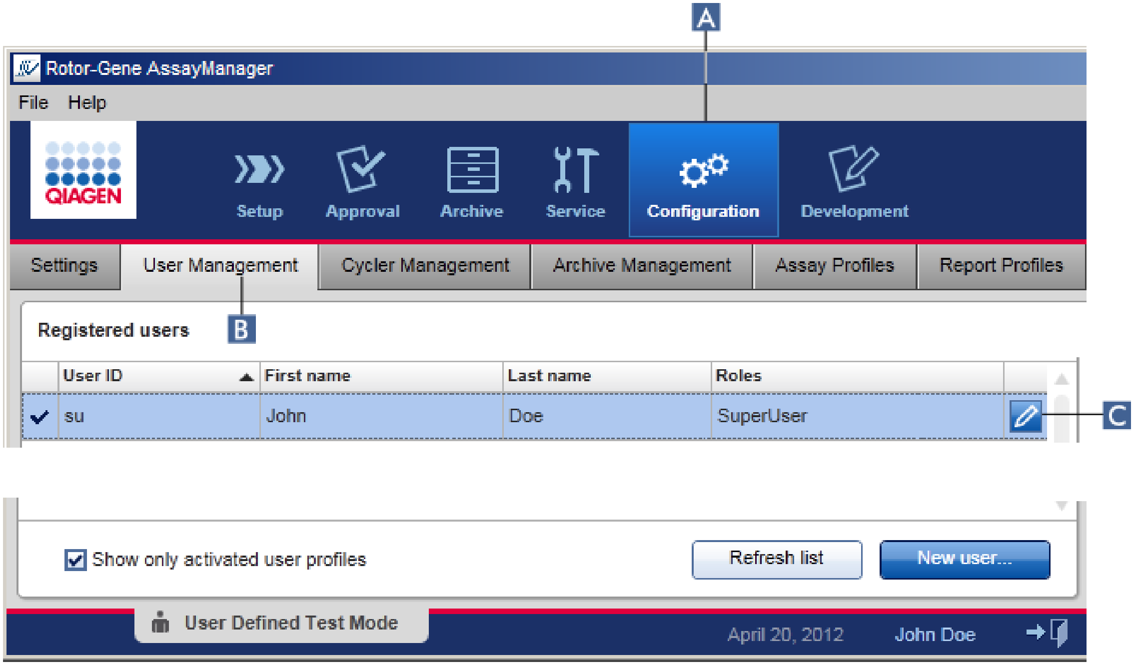
▶ Configuration - managing users
▶ User roles

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

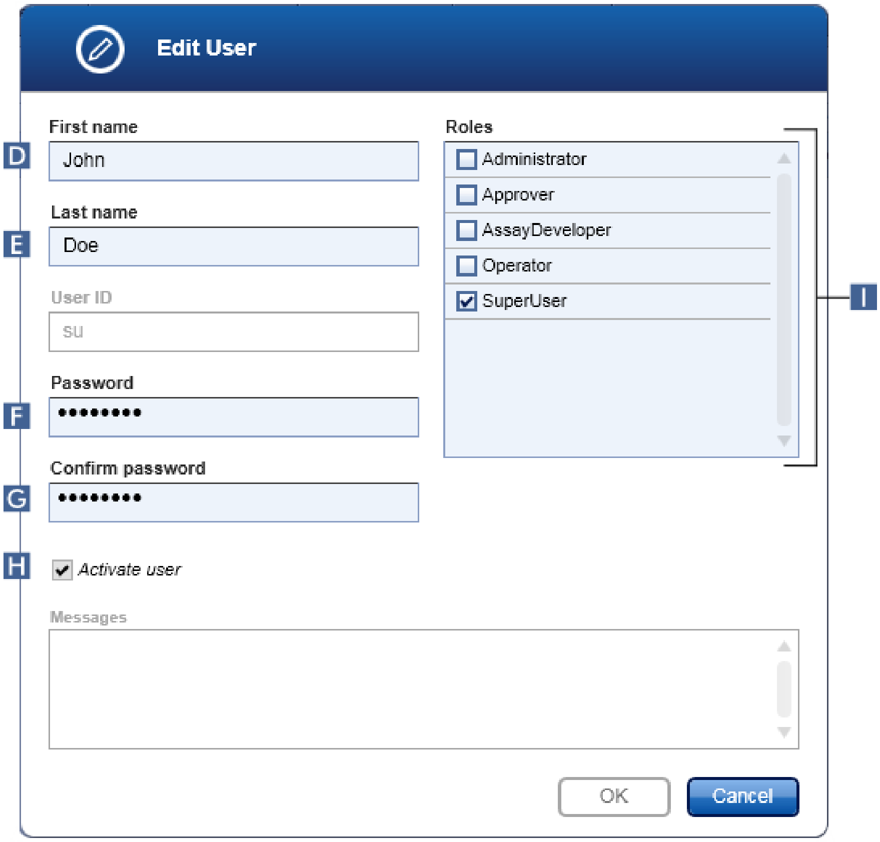
1. Change to the "User Management" screen:
    a) Click "Configuration" (A) in the main toolbar.
    b) Click the "User Management" (B) tab.



	User ID	First name	Last name	Roles
✓	su	John	Doe	SuperUser

☑ Show only activated user profiles

2. Click the "Edit User" icon (C) of a user profile.
3. The "Edit User" dialog is shown:



First name: John

Last name: Doe

User ID: su

Password: ••••••••

Confirm password: ••••••••

☑ Activate user

Roles:
- ☐ Administrator
- ☐ Approver
- ☐ AssayDeveloper
- ☐ Operator
- ☑ SuperUser

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

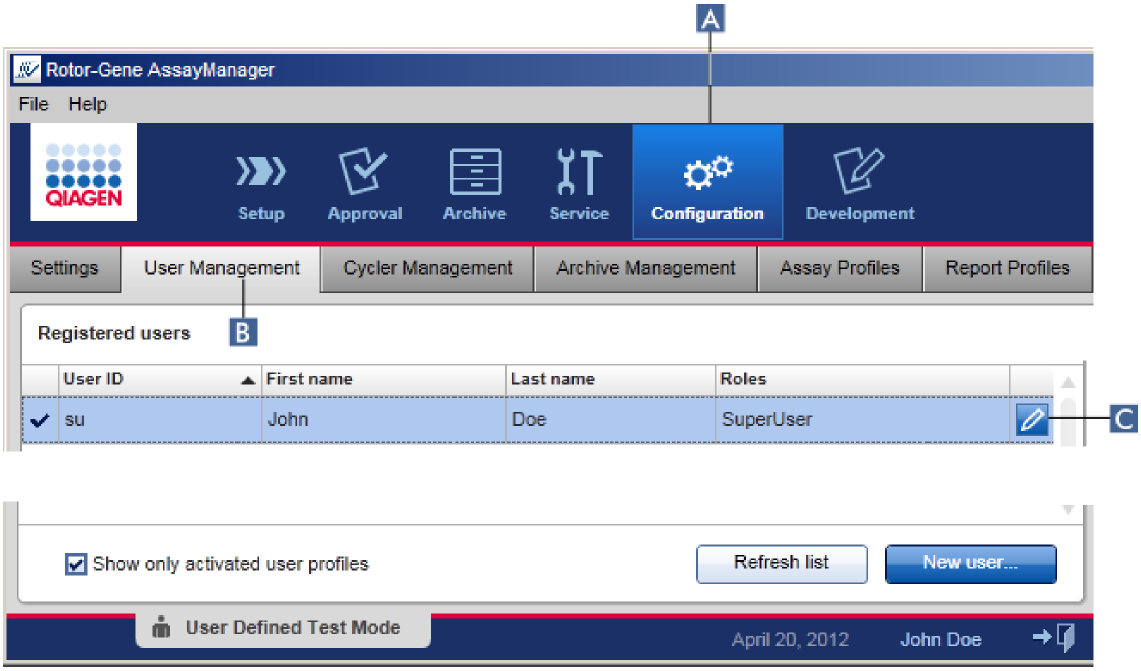
A user profile can never be deleted but only deactivated. This ensures that actions in the audit trails can always be tracked back to a specific user.

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".



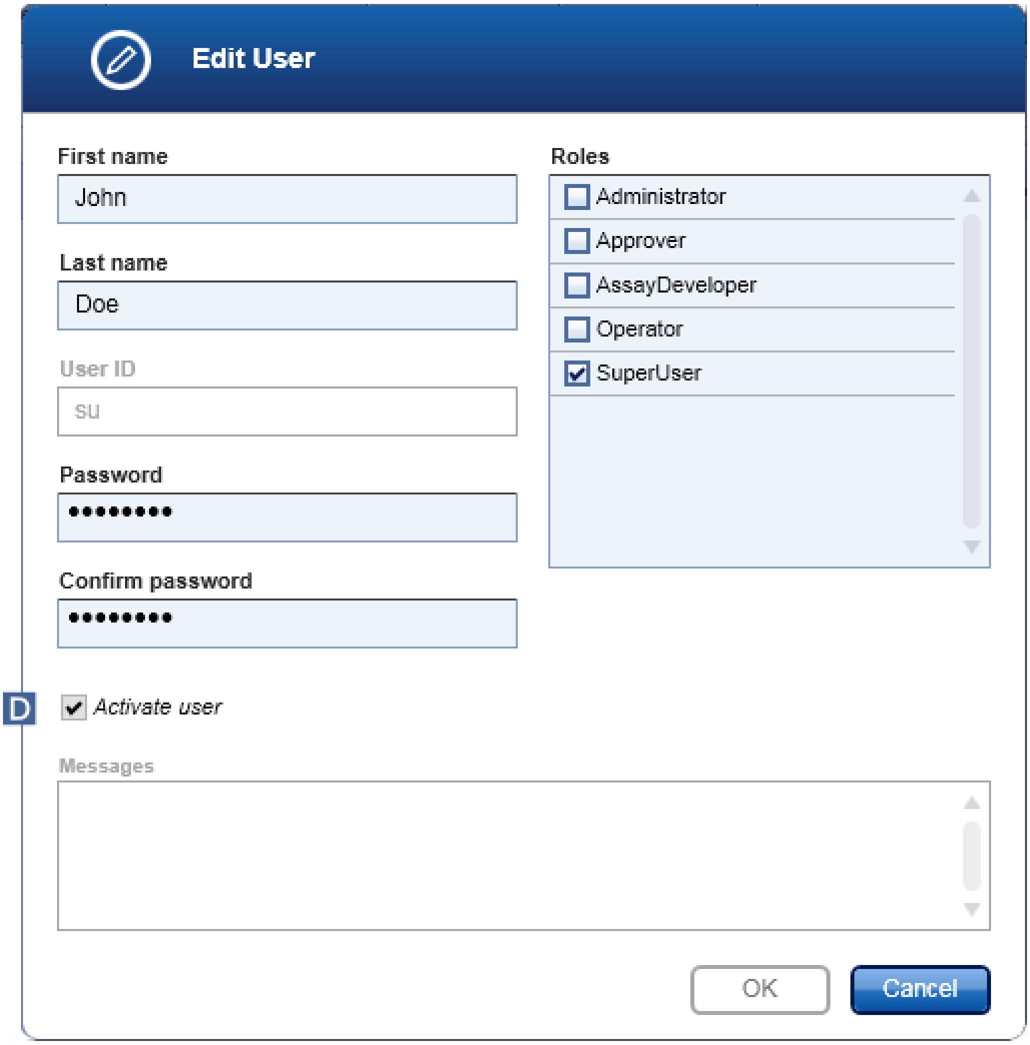
Registered users

User ID	First name	Last name	Roles
✓ su	John	Doe	SuperUser

☑ 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:



Edit User

First name: John

Last name: Doe

User ID: su

Password: ••••••••

Confirm password: ••••••••

Roles:
- ☐ Administrator
- ☐ Approver
- ☐ AssayDeveloper
- ☐ Operator
- ☑ SuperUser

☑ *Activate user*

Messages

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.

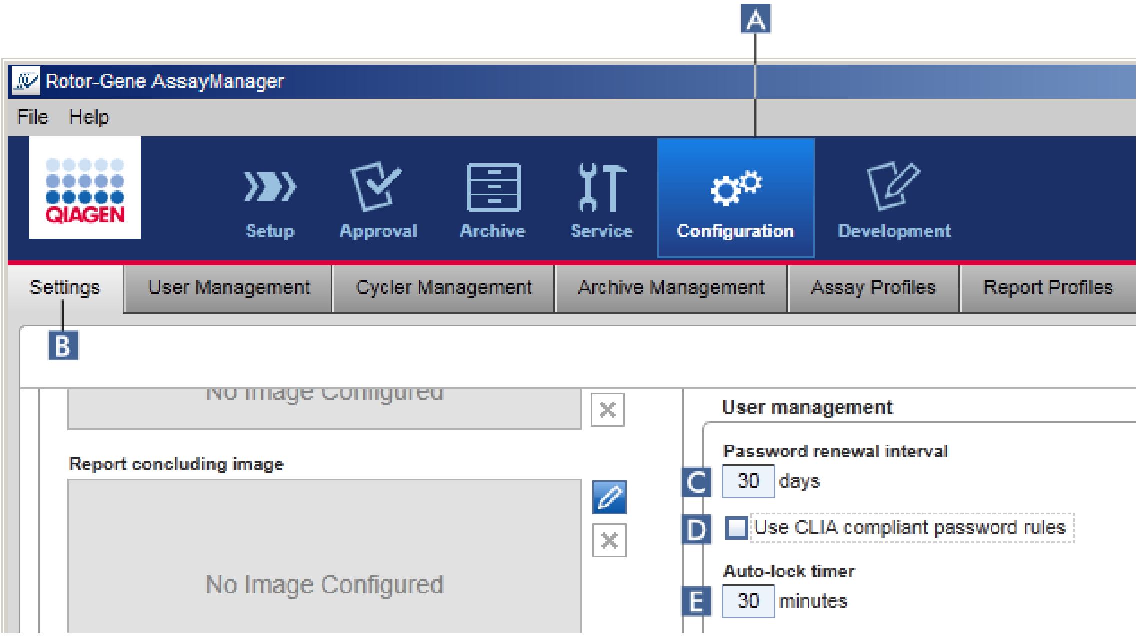
3. Click the "Edit user" icon (C) of a deactivated user profile.
4. The "Edit User" dialog is shown:
    a) Activate the "Activate user" check box (D) to activate the user profile.
    b) Click "OK". The status icon in the "Registered users" table changes from ⧅ to ✓.

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.



Password renewal interval
30 days

☐ Use CLIA compliant password rules

Auto-lock timer
30 minutes

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

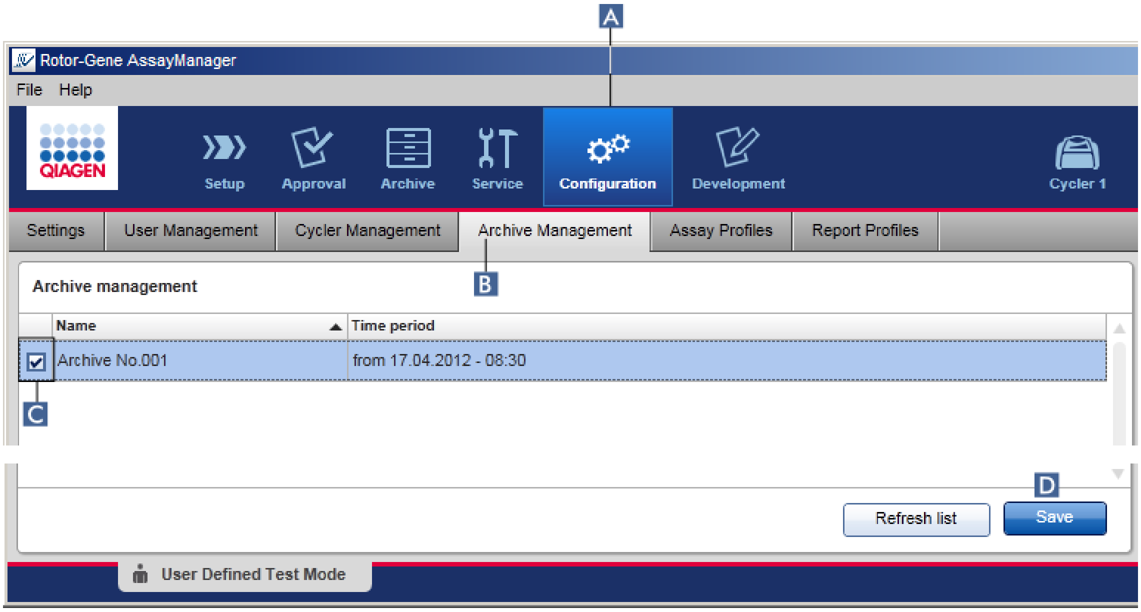
▶ Configuration - managing users
▶ User roles

1.6.2.5 Managing Archives

Rotor-Gene AssayManager v1.0 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 v1.0.



Archive management

	Name	Time period
☑	Archive No.001	from 17.04.2012 - 08:30

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 v1.0 need to be maintained. Details can be found in the relevant manuals.

Rotor-Gene AssayManager v1.0 is a software and does not need to be maintained in general. However, the database may need to be maintained.

Maintaining the database

Important

- It is important to back up the database: in case of a computer failure you are able to recover your data from your last backup.
- It is not possible to backup the content of the computer's hard disc directly to get a backup of the database.

The Rotor-Gene AssayManager (RGAM) Backup Tool software has been specifically developed for use with the Rotor-Gene AssayManager v1.0 software.

RGAM Database Backup Tool is software for automatic backup creation of the Rotor-Gene AssayManager database (Microsoft® SQL Server® Express) using Windows® Task Scheduler. The RGAM Database Backup Tool has the functionality to restore previously created backup files automatically.

For maintaining the database, download the RGAM Database Backup Tool software on the QIAGEN webpage. Refer to the RGAM Database Backup Tool User Manual for further information.

1.8 Troubleshooting

This section provides information about what to do if an error occurs when using Rotor-Gene AssayManager v1.0.

Resolving error messages and warnings

Error messages and warnings are displayed when a problem occurs during the operation of Rotor-Gene AssayManager v1.0. 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

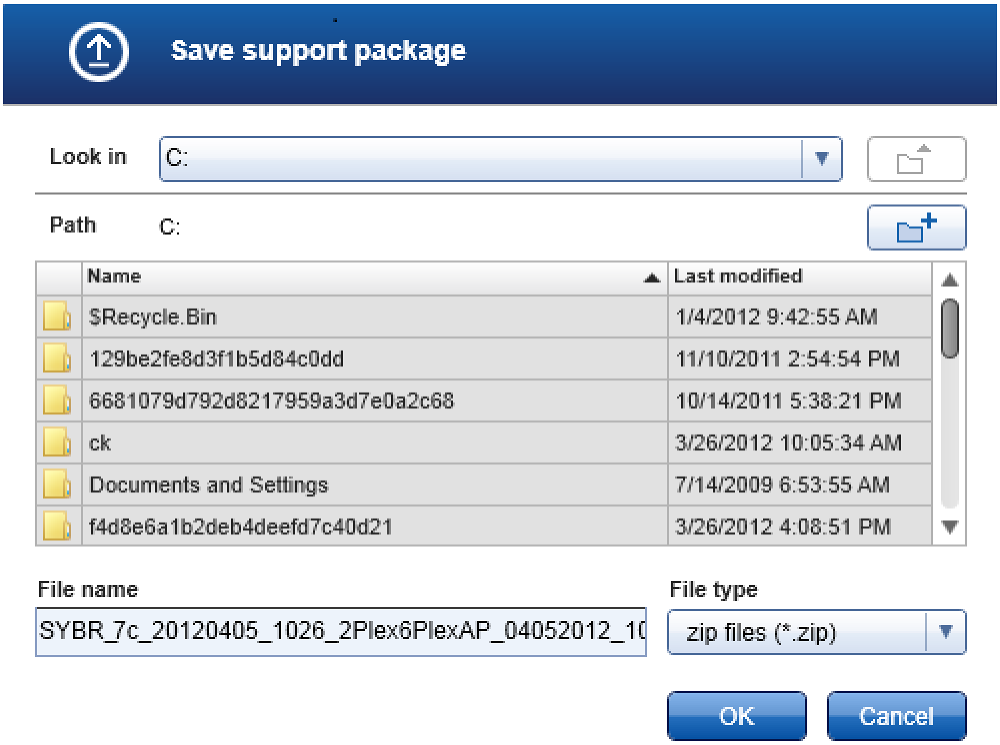
If QIAGEN Technical Services needs to be consulted for troubleshooting of an error, note the steps leading to the error and the information from any dialog boxes that appear (or at least the error IDs). This will help the QIAGEN Technical Service Specialist to resolve the error.

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 v1.0 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.



Look in: C:

Path: C:

Name	Last modified
$Recycle.Bin	1/4/2012 9:42:55 AM
129be2fe8d3f1b5d84c0dd	11/10/2011 2:54:54 PM
6681079d792d8217959a3d7e0a2c68	10/14/2011 5:38:21 PM
ck	3/26/2012 10:05:34 AM
Documents and Settings	7/14/2009 6:53:55 AM
f4d8e6a1b2deb4deefd7c40d21	3/26/2012 4:08:51 PM

File name: SYBR_7c_20120405_1026_2Plex6PlexAP_04052012_1(

File type: zip files (*.zip)

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 v1.0

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 v1.0 cannot communicate with the cycler	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 v1.0.
Rotor-Gene AssayManager v1.0 does not start	
a) Rotor-Gene AssayManager v1.0 is not installed	Install Rotor-Gene AssayManager v1.0.
b) Old version of Microsoft Windows	Rotor-Gene AssayManager v1.0 can only be operated with Windows 10.
c) No plug-in installed	Rotor-Gene AssayManager v1.0 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 v1.0.
d) Different versions of core application/plug-in	All Rotor-Gene AssayManager v1.0 installations that use the same database must have installed: ▪ 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 v1.0 does not work properly and freezes before the user can log-in	Rotor-Gene AssayManager v1.0 is only compatible with Windows 10. Update your computer to Windows 10, install Rotor-Gene AssayManager v1.0 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 v1.0.

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 v1.0 installation cannot access data from another installation	If several Rotor-Gene AssayManager v1.0 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 v1.0 data.
QIAsymphony AS result file cannot be imported to Rotor-Gene AssayManager v1.0	Rotor-Gene AssayManager v1.0 is only compatible with QIAsymphony software version 4.0 or higher. 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 v1.0 database.
The background in plots is printed in black	Some printer drivers are configured in a way that transparent background colors, which are used in the Rotor-Gene Assay Manager plots, are printed in black. Check the manual of your printer how to change this configuration. 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.

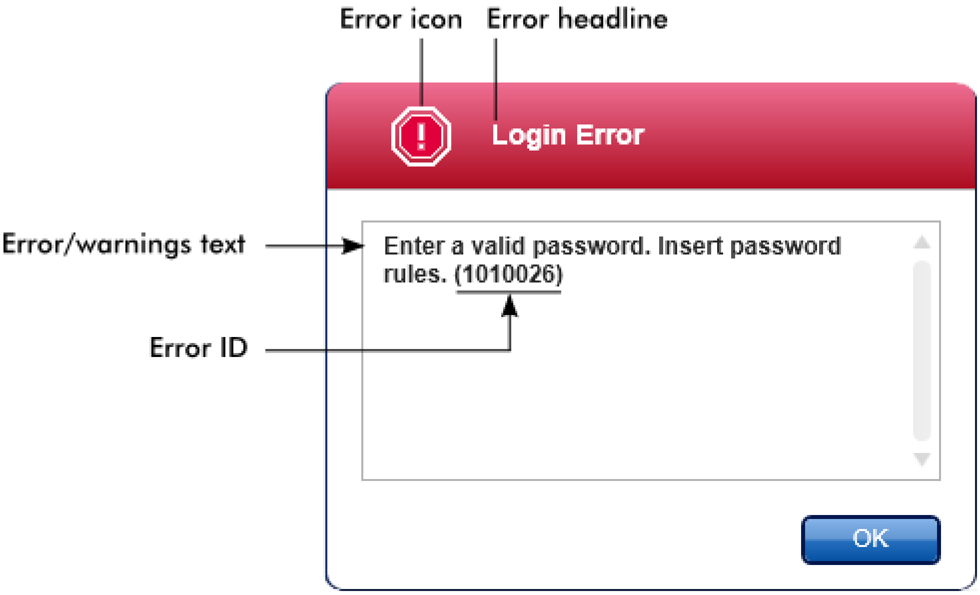
General errors

Error description	Comments and suggestions
Incorrect rotor loading	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.
Missing locking ring	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.
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 work list setup, the sample details and their

	respective positions can be displayed or printed using the "View sample details..." or the "Print work list..." 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:



Enter a valid password. Insert password rules. (1010026)

The following list provides all error messages that might occur during operation of Rotor-Gene AssayManager v1.0. 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}.
30002	The permissions file {0} has an invalid document format.
30006	Could not find the permissions file {0}.

Error ID	Error Text
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. The session has to be closed. Unsaved data are discarded. Contact your system administrator to fix the problem and log in again. Running experiments will continue; they will be saved automatically into the database as soon as the connection is restored.
30013	The application initialization failed because the database connection is not available. The application will exit now. Contact your local administrator.
30014	Could not log-in to the application. The database connection is lost. Contact your local administrator.
30015	Runs which were not finished during the time of the database connection loss will now finish and all data will be stored to the database.
30017	Rotor-Gene AssayManager is already started on this computer
30018	Wrong Silicon Laboratories CP210x driver version was found on the system. CP210x driver of either version 5.4.29 or 6.5.3 should be installed. Please remove the wrong CP210x drivers and restart the application. The application will exit now.
30019	Silicon Laboratories CP210x driver of version 5.4.29 or 6.5.3 was not found on the system. Please install the driver and restart the application. The application will exit now.
30020	Rotor-Gene AssayManager requires at least the following plug-in versions: {0} Please update the plug-ins to the listed version.
30023	Wrong Silicon Laboratories CP210x driver version was found on the system. CP210x driver of either version 6.5.3 or 6.7.4 should be installed. Please remove the wrong CP210x drivers and restart the application. The application will exit now.
30024	Silicon Laboratories CP210x driver of version 6.5.3 or 6.7.4 was not found on the system. Please install the driver and restart the application. The application will exit now.
30025	Wrong Silicon Laboratories CP210x driver version was found on the system. CP210x driver of either version 6.7.4 should be installed. Please remove the wrong CP210x drivers and restart the application. The application will exit now.
30026	Silicon Laboratories CP210x driver of version 6.7.4 was not found on the system. Please install the driver and restart the application. The application will exit now.
110000	The new assay profile failed. Check the assay profile content and load again.
110003	The entered assay profile name is invalid. Enter a valid assay profile name (1-50 characters).

Error ID	Error Text
110004	The entered short name is invalid. Enter a valid short name (1-6 characters).
110005	Assay profile could not be loaded.
110006	The assay profile could not be saved. The system could not write to file system. Contact your local administrator.
110007	The required plug-in {0}, version {1}, for the selected assay profile is not available. Ask your software administrator to install the plug-in.
110008	In Closed Mode only assay profiles distributed by QIAGEN can be loaded. The selected file is not a QIAGEN original file. Switch to User Defined Test Mode to open the selected assay profile.
110009	In User Defined Test Mode (UDT Mode), you cannot load profiles distributed by QIAGEN for Closed Mode. The file will not be loaded. Log in in Closed Mode to load this file.
110010	The signature of the file is invalid. It will not be loaded. Provide a valid signature.
110019	The selected assay profile contains an unknown rotor type. Select a different assay profile.
110020	The incomplete assay profile will be saved but cannot be used until finished.
110035	The given concentration must be between 0.000000001 and 999999999999999.
110036	The selected run template cannot be used with the selected plug-in "{0} {1} {2}".
110038	The run profile could not be loaded. The optical configuration does not match any of the cyclers currently available.
110039	The run profile could not be loaded.
110040	The optical configuration is unknown.
110043	Enter a valid number for the relative tube position. The relative tube position must not be greater than the number of tubes defined in the sample.
110044	The run template of the current assay profile does not match the run settings of the .rex-file.
110048	One or more steps in the assay profile editor are invalid. Correct these invalid steps to start the assay profile tester.
110049	The .rex file at {0} cannot be accessed. Check if the .rex file path is correct.
110055	The color channels of the run profile of the current assay profile do not match the .rex file color channel {0}. Select another assay profile or .rex file.
110056	The samples of an assay must be arranged without gaps. At .rex file tube position {0} on page {1} a sample is positioned after a gap.
110057	Based on the assay profile, a {0} sample is expected in .rex file tube {1} but the .rex file contains a {2} sample. Adjust the assay profile or select another .rex file.
110058	There is no plug-in available with name {0}, version {1} and application mode {2}.

Error ID	Error Text
110059	The signature of .rex file {0} is invalid. It cannot be loaded. Select another .rex file.
110060	The samples of an assay must be arranged without gaps. The .rex file page {0} contains empty tubes that do not reach the end of the file.
110061	Not all control samples of the current assay profile are specified in .rex file. Adjust the assay profile or select another .rex file.
110072	A .rex file was loaded, but the analysis cannot be started. Reasons:
110073	The selected .rex file could not be loaded. Reasons:
110083	The assay name must be filled in, not only with space characters.
110084	The assay short name must be filled in, not only with space characters.
110085	The Target name must not contain only space characters.
110086	The sample name must not contain only space characters.
110088	Assay profile version '{0}' does not match with the current Rotor-Gene AssayManager version.
110092	This assay profile was created with plug-in {0} version {1} and application version '{2}' and cannot be upgraded.
110093	The assay profile could not be mapped to the .rex file. Adjust the assay profile or select another .rex file.
130220	At least one error still exists (see messages). Please fix error(s) 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.
150006	File {0} does not exist.
150007	The signature of the file is invalid. The file will not be imported. Provide a valid signature.
150008	The resource has an invalid document format. Contact QIAGEN Technical Services.
150012	Enter a valid path to the startup directory of the dialog.
150021	The profile name is too long.
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.
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.
150033	The signature of the file is invalid. The file will not be imported. Provide a valid signature.

Error ID	Error Text
150034	The plug-in required by the selected assay profile is not installed. Install the required plug-in and repeat the import of the assay profile.
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.
150037	Assay profile could not be loaded.{0}
150038	The selected assay profile contains an unknown rotor type. Select a different assay profile.
150043	Assay Profile could not be imported.
150047	The entered passwords do not match. Enter and confirm password again.
150050	The password must not be the same as the user ID. Enter a different password.
150065	Enter a valid e-mail address with the format: name@example.com.
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.
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}.
150120	The assay profile is not finalized. Finalize the assay profile.
150134	The Assay profile was created with RotorGene AssayManager version {0}, which is not compatible to the currently installed version {1}.
150138	Assay Profile export failed because: {0}
150142	Enter a valid user ID with at least one non-numerical character (1-40 characters).
150143	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.
160000	Failed to read application mode.
160001	Plugin name cannot be empty.
160002	Invalid version information.
160003	Reader cannot be null.

Error ID	Error Text
160004	Sub tree reader cannot be null.
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.
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.
190021	Rex channel reference key not found.
190023	Rex file export failed. Reason: {0}
190024	Experiment validation failed. Reason: {0}
190026	The experiment validity check failed.
190027	Failure to get acquisition channel reference.
190031	The .rex file import created an invalid experiment: {0}. Retry or select another .rex file.
190032	The .rex file specifies a rotor which is unknown to the system. Select another .rex file.
190034	Signature could not be validated.
190035	Failed reading the file
190036	Signature could not be validated.
190037	The resource has an invalid document format. Contact QIAGEN Technical Services.
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.
190041	The directory path to the file {0} does not exist. Select another path.
190043	Destination file {0} already exists at the path {1}.
190044	The file {0} is already used.
190045	File {0} does not exist.
190046	File {0} does not exist at the path {1}.
190047	Invalid argument used.
190048	Path must not contain /.":|?><\ and leading white spaces.
190049	The provided file path is invalid. Enter a valid path.

Error ID	Error Text
190050	Invalid path {0} accessed. Access a valid path.
190051	XML signature invalid.
190052	Not supported operation called on the file-system or memory resources.
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.
190060	The sample ID must be filled in, not only with space characters.
190061	A Rotor-Gene AssayManager work list from file {0} cannot be imported. The work list was exported with a different application mode. Make sure the application modes are the same.
190062	The Rotor-Gene AssayManager work list from file '{0}' cannot be imported. It contains assay profiles which are not available. Select another file.
190063	The Rotor-Gene AssayManager work list from file {0} cannot be imported. It contains assay profiles which are either not installed or deactivated.
190064	The Rotor-Gene AssayManager Work List from file '{0}' cannot be imported, because it contains a rotor type that is not available.
190065	The Rotor-Gene AssayManager Work List from file '{0}' cannot be imported. The following error occurred: {1}
190066	The Rotor-Gene AssayManager Work List '{0}' cannot be exported. The following error occurred: {1}
190067	The file was created using Rotor-Gene AssayManager {0}, it cannot be opened. Make sure the versions are the same.
190069	Schema validation failed: {0}
190070	Failed reading the file.
190071	XML signature invalid.
190072	The resource has an invalid document format. Contact QIAGEN Technical Services.
190073	Signature could not be validated.
190074	The optical configuration is unknown. Select a compatible run profile.
190080	This work list cannot be used in {0} mode.
190081	One of the run profiles contains a run profile entry of an unsupported type. Select another run profile.
190096	The sample transfer volume is invalid. Enter a valid volume (1 – 999 999 999).
190098	The initial elution volume is invalid. Enter a valid volume (1 – 999 999 999).

Error ID	Error Text
190104	The entered reaction volume is invalid. Enter a reaction volume (1 - 100 µl).
190105	The entered reaction volume is already available. Enter a unique reaction volume.
190121	The file '{0}' does not match the QIAsymphony AS result file specification. The file cannot be imported.
190123	No active assay profile matches the APS '{0}', the QIAGEN original setting 'not required' and the volume pair '{1} µl, {2} µl' explicitly.
190124	No active assay profile matches the APS '{0}', the QIAGEN original setting 'required' and the volume pair '{1} µl, {2} µl' explicitly.
190125	The referenced assay profiles '{0}' are not compatible to each other. Reasons:
190126	The assay kit information check of APS '{0}' produced the following errors:
190127	The number of assay points is '{0}'. This number exceeds the number of tubes on the rotor of the referenced assay profiles '{1}'.
190128	The assay profile '{0}' referenced by APS '{1}'does not refer to exactly one rotor type.
190129	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.
190131	The QIAsymphony AS result file '{0}' cannot be imported: Reason: '{1}'
190132	The created work list test samples contain replicated sample IDs, but the referenced Assay Profile '{0}' does not allow this.
190134	The QIAsymphony AS result file at '{0}' contains an invalid checksum. The file cannot be imported.
190135	The unknown slot name '{0}' is not supported by Rotor-Gene AssayManager.
190136	The number of assay points is '{0}'. This number is not supported.
190137	The unknown sample type '{0}' of assay point '{1}' at position '{2}' is not supported by Rotor-Gene AssayManager. Select another sample type.
190138	The unknown assay point state '{0}' of assay point '{1}' at position '{2}' is not supported by Rotor-Gene AssayManager.
190139	The output position sequence of the assay points contains gaps, positions multiple times or do not start at 1. This is not supported by Rotor-Gene AssayManager.
190140	The reaction volume of the APS '{0}' is not supported by the corresponding assay profile '{1}'.
190141	The resource has an invalid document format. Contact QIAGEN Technical Services.
190142	The LIMS file at '{0}' does not match the interface specification. The LIMS file cannot be imported.
190143	The rotor type is not available in this system.

Error ID	Error Text
190144	The required assay profile '{0}, {1}.{2}.{3}' is not available in this system. Select another assay profile.
190145	Enter a valid lot number for assay '{0}'.
190146	The kit expiry date for assay {0} is expired or not specified. Use a non expired kit.
190148	The referenced assay profiles are not assay compatible. Reason: The rotor types do not match.
190149	The QIAlink/LIMS worklist at {0} contains an invalid checksum.
190150	The unknown login mode "{0}" is not supported by Rotor-Gene AssayManager.
190151	The unknown sample type "{0}" is not supported by Rotor-Gene AssayManager.
190152	The unknown upstream status "{0}" is not supported by Rotor-Gene AssayManager.
190153	The export of the QIALink/LIMS result file failed. The samples were only saved but not released.
190154	The sample arrangement does not match the assay profile '{0}'.
190156	The assay profile {0} does not allow replicates. Remove the replicates.
190157	The file cannot be read. It will not be imported.
190158	The referenced assay profiles are not cycling compatible. Reasons: .
190159	The status of at least one sample is unclear or invalid.
190160	No active Assay Profile matches the APS {0}.
190161	The Rotor-Gene AssayManager work list from file {0} cannot be imported. Reason: The assay {1} contains an invalid assay kit. Select a work list with a valid assay kit.
190162	File {0} not found.
190165	The data cannot be used.
190175	There are no test samples, positive or negative extraction controls specified, but the referenced assay profile ‘{0}’ specifies a sample eluate volume pair.
190176	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, {4} µl' but '{5} µl, {6} µl' was expected.
190178	A work list with the name '{0}' already exists in the database. The file '{1}' may already have been imported. Create a work list with a unique name.
190180	The file was created using Rotor-Gene AssayManager {0}, it cannot be opened. Make sure the versions are the same.
190183	The file cannot be read. The system supports interface version {0}, but the file is designed for version {1}.
190184	The resource has an invalid document format. Contact QIAGEN Technical Services.

Error ID	Error Text
190187	Autogain is not defined for all channels which are used for acquisitions.
190191	The QIALink/LIMS result file does not specify identical reaction volumes.
190192	The referenced assay profiles are not assay compatible. Reason: The reaction volumes do not match.
190193	The APS '{0}' do not specify identical reaction volumes.
190194	The Rotor-Gene AssayManager work list from file {0} cannot be imported. It contains assay(s) with invalid assay profile name.
190195	The Rotor-Gene AssayManager work list from file {0} cannot be imported. It contains samples with invalid ids.
190196	The QIAlink/LIMS work list at {0} contains samples with invalid ids.
190197	The QIAlink/LIMS work list at {0} contains assay(s) with invalid assay profile name.
230047	Run Successful
230052	The sample names of assay profile {0} must be unique.
230053	Enter a unique target name.
230060	The profile name is too long.
230062	Enter a valid number for the relative tube position (1 to number of tubes).
230063	Each target can only be assigned once.
230066	The work list assay {0} must contain at least one test sample.
230075	The sample {0} does not contain a target. Define a target for sample {0}.
230077	Assay profile must contain at least one reaction volume entry.
230078	Assay profile must contain at least one rotor type name.
230079	Run profile must contain at least one run profile entry.
230083	The customer support mail address must be between {3} and {5} characters long.
230089	The given path must be between {3} and {5} characters long.
230090	The given path does not exist. Select another existing path.
230091	The given concentration must be a positive number.
230092	The entered number of tubes is invalid. Enter a valid # tubes (1-100).
230100	Enter a valid number for the given concentration.
230101	Enter a valid number for the relative tube position.
230110	Enter a valid number for the relative tube position. The relative tube position must not be greater than the number of tubes defined in the sample.
230163	The specified number of repetitions of the cycling run profile must be between 1 and 100.
230164	The specified cycling step duration must be between 1 and 60 seconds.
230165	The specified number of long range cycles of the cycling step must be between 0 and 100.

Error ID	Error Text
230166	The specified long range duration of the cycling step must be between 0 and 1 seconds.
230167	The specified cycling step temperature must be between 25 and 99 degrees Celsius.
230168	The specified number of touchdown cycles of the cycling step must be between 0 and 100.
230169	The specified touchdown temperature of the cycling step must be between 0.1 and 2.0 degrees Celsius.
230170	The specified melt temperature step size must be between 0.02 and 2 degrees Celsius.
230171	The specified melt temperature must be between 25 and 99 degrees Celsius.
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.
270003	RotorGene 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.
310002	Could not find the IModule derived class to initialize the plug-in.
310003	The public token of the assembly does not match with the public token in the list.
310005	Could not find experiment {0}
310006	Plug-in not found for provided key.
310007	Assembly name information does not match with the configuration of the plug-in.
310011	Error occurred during report generation. Retry report generation.
310015	Failed to create file {0}.
350000	Entered profile name is invalid because this name is always used to show a new report profile. Enter a different name.
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.

Error ID	Error Text
350010	Failed to generate audit trail report.
350011	File {0} not found.
350013	Failed to create file {0}.
350015	The import of the report profile failed. Reason: {0}
350016	The export of the report profile failed. Reasons: {0}
350018	The resource has an invalid document format. Contact QIAGEN Technical Services.
350019	Failed to delete the report profile.
350023	The report profile version {0} does not match with the current Rotor-Gene AssayManager version {1}. Update your report profile version.
350034	Selected report profile is already deleted. Select another report profile.
350035	This profile was supplied by QIAGEN. It cannot be edited.
390000	Select at least one assay profile.
390004	The end date must be after {0}.
390009	Empty sample IDs are not allowed. Enter sample IDs.
390010	At least one sample ID occurs more than once. Enter a unique sample ID.
390013	The start date must be before or equal to the end date.
390014	The start date must be after {0}.
390018	Could not find experiment {0}.
390019	Experiment name is already in use. Use a unique experiment name.
390022	Could not find a matching assay profile in the database for the given experiment. Select another experiment.
390028	The experiment {0} assay {1} is locked by user {2}.
390029	The assay is locked by user {0}.
390030	The lock for experiment {0} assay {1} was lost. Close the assay and open it again.
390034	The settings were exported at the time when the support package was created. Therefore, it is possible that the following settings may differ to the ones which were active during the run.
390038	Selected assay already released The assay {0} of experiment {1} has already been released. The approval cannot be started. The assay data can be found in the archive environment.
390039	Report generation failed. Reason: {0}
390040	Failed to create support package. Reason: {0}
390043	The QIAGEN-Hardware.log was not included in the support package. Reason: The run was performed on a different machine.
390052	Failed to create log file. Reason: {0}
390054	Copy operation is cancelled. Selected cell(s) should be contiguous.
390063	The .iap file is not included in the support package.

Error ID	Error Text
390064	The settings file is not included in the support package.
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.
430002	More tubes per sample than expected {0}. The run cannot be started. Reduce the number of tubes per sample. v
430004	The currently running instrument {0} was disconnected. All experiment data are invalid. Switch off the cycler, remove the ring, and set up again the assay.
430005	Missing instrument object, when asking for cycling engine.
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.
430012	The run could not be started on the cycler with the serial number {0}. Make sure the lid is closed.
430020	Persisting the experiment failed. See error log for details.
430021	Unknown error during run profile execution.
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.
430025	The experiment comment must not exceed 256 characters.
430030	The run was stopped. For more information see experiment error log.
430031	The application cannot be closed. Release all instruments before closing the application.
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.
430039	The number of tubes configured in the samples exceeds the capacity of the rotor. Reduce the number of tubes for that rotor.
430041	The analysis of experiment {0} failed.

Error ID	Error Text
430042	Enter a valid password.
430043	This user is deactivated. Contact your local administrator.
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.
430053	The run cannot be stopped. Switch off the cycler, switch it back on again, and restart the application.
430057	The connected cycler reports a firmware version ({0}.{1}.{2}) that is not supported. The cycler cannot be used.
440000	Invalid input value
440002	Serial number string is null or empty. A valid serial number is expected.
470003	An Experiment with this name already exists in the database.
440009	An error occurred, while updating the experiment after the run was finished. Error: {0}
470017	No compatible cycler is available at the moment. Wait for a cycler to finish and release it for further eyperiments.
470018	The chosen experiment name has already been used in the meantime. Select a different experiment name.
470020	No assay profile present in the work list. Complete the work list setup before continuing.
470021	The work list has been removed by another user in the meantime. Check availbale work lists.
470049	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.
470050	The entered bar code is invalid. Enter the bar code again.
470052	The entered bar code is too long. Enter a valid bar code (17-23 digits).
470053	The entered bar code is too short. Enter a valid bar code (17-23 digits).
470057	The kit lot number is invalid. Enter a valid kit lot number (4-10 digits).
470058	There is no valid kit expiration date provided on assay profile {0}.
470059	There is no kit lot number provided on assay profile {0}.
470063	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.
470083	No experiment name is entered. Provide an experiment name.
470084	The experiment name is already in use. Enter a unique experiment name (1-80 characters).
470085	Valid experiment name, set the current experiments name to {0}.

Error ID	Error Text
470086	The list of experiment names is not yet initialized. This could lead to a database connection error. Check the database connection or contact QIAGEN Technical Services.
470087	Sample ID is not valid. Sample IDs for this assay must be unique.
470095	The data from slot '{0}' in QIAsymphony AS result file '{1}' cannot be imported to a work list.
470098	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.
470101	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.
470102	The entered material number is invalid. Enter a valid material number (exactly 7 digits).
470103	The material number in the assay profile {0} can contain a maximum of 40 alphanumerical characters.
470104	The kit lot number is invalid. Enter a valid kit lot number on assay profile {0} (1-40 alphanumeric characters).
470105	The kit lot number is invalid. Enter a valid kit lot number. The kit lot number on assay profile {0} must contain only alphanumeric characters (1-40).
470106	The material number is invalid on assay profile {0}. Enter a valid material number (1-40 alphanumerical characters).
470107	The assay profile does not contain material numbers.
470108	The assay profile {0} does not contain material numbers.
470110	Error occurred during report generation. Retry report generation.
470111	Failed to create file {0}.
470115	There are unsaved changes present. The work list needs to be saved before it can be printed to a PDF. Do you want to save and print it to a PDF?
470116	Copying of the selected cells failed. Only adjacent cells can be copied. Copy and paste the selected cells individually.
470118	Paste operation is cancelled. Selected cell(s) must be editable for pasting.
470119	Pasting failed. The selected target area is smaller than the clipboard entry. Select a different target area or reduce data to be copied.
470121	Paste operation is cancelled. Selected cell(s) must be contiguous.
470122	Paste operation is cancelled. Selected cell(s) must be contiguous.
470123	Paste operation is cancelled. Select some cell(s).
470124	Selected work list locked The work list {0} has been locked for editing by user {1} since the table has been updated. The work list cannot be accessed.
470125	The access protection of work list {0} has been lost due to network problems. Close and reopen the work list.
470128	There is not enough space for the information to be pasted.

Error ID	Error Text
470129	The database is full. Approve and release experiments in the Approval dialog to allow new runs.
470131	The work list {0} has already been created in the meantime. Select a different work list name.
470134	The run cannot be started. The assay profile(s) contained in the work list might have been deactivated or the work list settings have been changed.
510000	Fatal exception error occured during command execution: {0} Switch off the cycler, switch it back on again, and restart application. If the error persists, contact QIAGEN Technical Services.
510001	Fatal exception error occured during command execution: {0} Switch off the cycler, switch it back on again, and restart application. If the error persists, contact QIAGEN Technical Services.
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 occured during Optical Temperature Verification (OTV) run: {0} Switch off the cycler, switch it back on again, and restart application. If the error persists, contact QIAGEN Technical Services.
510006	Fatal exception error occured during assay profile execution: {0} Switch off the cycler, switch it back on again, and restart application. If the error persists, contact QIAGEN Technical Services.
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 occured 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.
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.

Error ID	Error Text
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.
510026	No rotors have been added. Run cannot be started. Check the rotor configuration and the retry.
510028	The requested rotor is not configured for this device. Check the rotor configuration and retry.
550016	Schema validation failed: {0}
550017	Quantitation template could not be loaded. File reading failed. Check Rotor-Gene .qut-file and retry.
550018	Quantitation template could not be loaded. The file does not contain all mandatory fields. Create a file where all fields including the threshold are set.
550033	The run template does not contain any cycling parameters.
550034	The run profile must only contain "Cycling" and "Hold" steps. Check the run profile and the assay profile for consistency.
550036	The loaded rex-file contains a melt step. The assay profile does not allow melt steps. Check the rex-file and the assay profile for consistency.
550070	Failed to generate report. Reason: {0}
550073	Failed to launch the application {0}. Reason:
550188	Run profile must contain at least 7 cycles in the "Cycling" entries.
550199	Enter a valid password.
550200	This user is deactivated. Contact your local administrator.
550212	Copying of the selected cells failed. Only adjacent cells can be copied. Copy and paste the selected cells individually.
550215	Paste operation is cancelled. Selected cell(s) must be contiguous.
550216	Paste operation is cancelled. Selected cell(s) must be editable for pasting.
550217	Paste operation is cancelled. Select some cell(s).
550218	Paste operation is cancelled. Selected cell(s) must be contiguous.
550219	Pasting failed. The selected target area is smaller than the clipboard entry. Select a different target area or reduce data to be copied.
550229	There is not enough space for the information to be pasted.
550231	This user was deactivated because the password was entered wrong too many times. Contact your local administrator. The current session will be closed.
550233	The release was not performed.
550237	The release was not performed but data was saved.

Error ID	Error Text
570016	Schema validation failed: {0}
570017	Quantitation template could not be loaded. File reading failed. Check Rotor-Gene .qut-file and retry.
570018	Quantitation template could not be loaded. The file does not contain all mandatory fields. Create a file where all fields including the threshold are set.
570033	The run template does not contain any cycling parameters.
570034	The run profile must only contain "Cycling" and "Hold" steps. Check the run profile and the assay profile for consistency.
570036	The loaded rex-file contains a melt step. The assay profile does not allow melt steps. Check the rex-file and the assay profile for consistency.
570070	Failed to generate report. Reason: {0}
570073	Failed to launch the application {0}. Reason:
570202	Enter a valid password.
570203	This user is deactivated. Contact your local administrator.
570220	Copying of the selected cells failed. Only adjacent cells can be copied. Copy and paste the selected cells individually.
570222	Paste operation is cancelled. Selected cell(s) must be contiguous.
570223	Paste operation is cancelled. Selected cell(s) must be contiguous.
570224	Paste operation is cancelled. Selected cell(s) must be editable for pasting.
570225	Pasting failed. The selected target area is smaller than the clipboard entry. Select a different target area or reduce data to be copied.
570226	Paste operation is cancelled. Select some cell(s).
570229	There is not enough space for the information to be pasted.
570231	This user was deactivated because the password was entered wrong too many times. Contact your local administrator. The current session will be closed.
570233	The release was not performed.
570237	The release was not performed but data was saved.
670016	The number of messages in the audit trail table to print exceeds {0} messages. Adjust the filter settings.
670018	File {0} not found.
670020	An error occurred during report generation. Retry report generation.
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}.

Error ID	Error Text
1010004	Reserved Device Name {0} is a reserved device name and cannot be used for a folder. Enter a different folder name.
1010005	The directory {0} does not exist. Select an existing directory.
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.
1010012	{0} This file exists with Read Only attributes. Use a different file name.
1010013	Cannot create a new folder at the currently selected path. Directory path must be less than 248 characters.
1010016	User name is unknown or password is incorrect. Enter user name and password again.
1010018	Invalid user name or password. Enter user name and password again.
1010027	The new password has been used before. Use a different one.
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.
1010035	The new password must be different from the previous {0} passwords. Enter a unique password.
1010037	Enter a valid PIN.
1010039	QIAGEN service file could not be loaded. Unauthorized access to the file system or a memory resource. Contact your local administrator.
1010040	QIAGEN service file could not be loaded. Signature is not valid. Contact QIAGEN Technical Services.
1010041	QIAGEN service file could not be loaded. The resource provided has an invalid document format. Contact QIAGEN Technical Services.
1010042	QIAGEN service file could not be loaded. The file was not found. Contact QIAGEN Technical Services.
1010043	QIAGEN service file could not be loaded. Signature is not valid. Contact QIAGEN Technical Services.
1010044	{0} is not accessible. Directory not found. Check the network connection or create a new directory.
1010046	This user was deactivated because the old password has been entered wrong too many times. Contact your local administrator. The current session will be closed.
1010047	Could not log-in to the application. The database connection is lost. Contact your local administrator.
1010050	This user was deactivated because the password has been entered wrong too many times. Contact your local administrator.

Error ID	Error Text
1010054	Invalid name. Do not use special characters. Especially the following characters are not acceptable: / > < " : * | ? \
1010055	A specified {0} name is a reserved name. Select a different name.
1010057	The password must not contain whitespaces.
1010058	The entered file name is invalid. File name must be less than 256 characters.
1110000	Login error. Unknown user name or invalid password. Repeat login procedure.
1110007	Verification failed. No signature was found in the XML file. Retry with an originally signed XML file.
1110008	Verification failed: More that one signature was found for the XML file. Retry with an originally signed XML file.
1110009	File not found.
1110010	The folder you selected is not available or does not have memory space left. The access is denied. Select a different folder.
1110011	Signature could not be validated.
1110012	Signature not found.
1110014	The resource has an invalid document format. Contact QIAGEN Technical Services.
1110015	File not found.
1110016	Signature could not be validated.
1110017	The resource has an invalid document format. Contact QIAGEN Technical Services.
1110018	Signature not found.
1110019	The folder you selected is not available or does not have memory space left. The access is denied. Select a different folder.

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
C_T	Cycle threshold
EC-	Negative extraction control
EC+	Positive extraction control
FDA	Food and Drug Administration
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 v1.0.
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 v1.0 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 v1.0 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 v1.0 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 v1.0 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 v1.0. 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 work list or an experiment. The pattern for the generated name is defined in the Configuration environment.

E

EC-	Sample type (external controls): Negative extraction control.
EC+	Sample type (external controls): Positive extraction control.
Eluate	Purified nucleic acids from a sample.
Environment	The Rotor-Gene AssayManager v1.0 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: work list, 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 v1.0 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 v1.0 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.

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 v1.0 Assay Profile.
IC	See "Internal control".
Import	The process of transferring any kind of data from an external source into Rotor-Gene AssayManager v1.0.

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 v1.0 report profile.
*.iwl	File extension for a Rotor-Gene AssayManager v1.0 work list.

K

Kit	A kit is a box with reagents sold by QIAGEN to perform a biological application. In the context of Rotor-Gene AssayManager v1.0, 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 v1.0 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 C_T 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 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. 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 v1.0.

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, C_T 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 v1.0 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 $\geq$ 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.
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 Cycler	The real-time PCR cycler supported by Rotor-Gene AssayManager v1.0.
Rotor-Gene Q Software	Open mode software to control the Rotor-Gene Q cycler 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
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–), and positive extraction control (EC+). 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 C_T 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, cycler 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 (C_T) 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 v1.0 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 v1.0 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.
Work list	Sample information for all samples to be analyzed and a reference to an assay profile for each sample. When using an upstream platform, the work list 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 v1.0 Assay Profile file.
*.irp	Rotor-Gene AssayManager v1.0 report file.
*.iwl	Rotor-Gene AssayManager v1.0 work list.
*.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.

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Document Revision History	
R4 04/2022	This version has been updated to remove Windows 7 as an operating system, to remove Symantec Endpoint Protection and Microsoft Essentials from listed compatible anti-virus scanners, and to add a note regarding the necessity to prevent hard disk turn off, hibernation and standby.

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