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



US version

IVD

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Safety Information

The user-friendly Rotor-Gene AssayManager v2.1 software has been specifically developed for use with up to 4 different Rotor-Gene® Q MDx instruments. Before using Rotor-Gene AssayManager v2.1 software, it is essential that you carefully read this user manual, paying particular attention to this “Safety Information” chapter. The instructions and safety information must be followed to ensure safe operation of the cyclers and to maintain the instrument in a safe condition.

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

Safety information for the Rotor-Gene Q MDx cycler

The following types of safety information appear throughout the Rotor-Gene Q MDx 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 instruments** or other equipment.



Details about these circumstances are given in a box like this one.

The advice given in the Rotor-Gene Q MDx user 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

Improper use of the Rotor-Gene Q MDx may cause personal injuries or damage to the instrument.

The Rotor-Gene Q MDx must only be operated by qualified personnel who have been appropriately trained.

Servicing of the Rotor-Gene Q MDx 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

Rotor-Gene Q MDx 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

Do not attempt to move the Rotor-Gene Q MDx during operation.

CAUTION



Damage to the instrument

Avoid spilling water or chemicals onto the Rotor-Gene Q MDx. Damage caused by water or chemical spillage will void your warranty.

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

**WARNING/
CAUTION**



Risk of personal injury and material damage

Do not try to open the lid during an experiment, or while the Rotor-Gene Q MDx 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

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

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

Loose paper underneath the Rotor-Gene Q MDx interferes with instrument cooling. It is recommended that the area beneath the instrument is kept free of clutter.

CAUTION



Damage to the instrument

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

Electrical safety

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

WARNING



Electrical hazard

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 MDx, 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

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.

Operating conditions

WARNING



Explosive atmosphere

The Rotor-Gene Q MDx is not designed for use in an explosive atmosphere.

WARNING



Risk of explosion

The Rotor-Gene Q MDx 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

Direct sunlight may bleach parts of the instrument and cause damage to plastic parts.

The Rotor-Gene Q MDx 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/biosafety).

Samples

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

WARNING**Samples containing infectious agents**

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* or ACGIH† documents.

Venting for fumes and disposal of wastes must be in accordance with all national, state and local health and safety regulations and laws.

Chemical safety**WARNING****Hazardous chemicals**

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* or ACGIH† documents.

Venting for fumes and disposal of wastes must be in accordance with all national, state and local health and safety regulations and laws.

WARNING**Risk of fire**

When cleaning the Rotor-Gene Q MDx with alcohol-based disinfectant, leave the Rotor-Gene Q MDx door open to allow flammable vapors to disperse.

Only clean the Rotor-Gene Q MDx when worktable components have cooled down.

* OSHA: Occupational Safety and Health Administration (United States of America).

† ACGIH: American Conference of Government Industrial Hygienists (United States of America).

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 MDx must remain closed during operation of the instrument.

WARNING



Moving parts

To avoid contact with moving parts during operation of the Rotor-Gene Q MDx, the instrument must be operated with the lid closed.

WARNING/ CAUTION



Risk of personal injury and material damage

Open and close the lid of the Rotor-Gene Q MDx carefully to avoid trapping fingers or clothing.

CAUTION



Damage to the instrument

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 MDx; contact QIAGEN Technical Services.

CAUTION



Damage to the instrument

The Rotor-Gene Q MDx 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 MDx. Damage caused by use of other consumables will void your warranty.

CAUTION**Damage to the instrument**

When the Rotor-Gene Q MDx is started immediately after delivery in cold climates, mechanical parts can block. Allow the instrument to acclimatize to room temperature for at least 1 hour before turning the instrument on.

WARNING**Moving parts**

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**

To ensure proper ventilation, maintain a minimum clearance of 10 cm (3.94 in.) at the sides and rear of the Rotor-Gene Q MDx. Slits and openings that ensure the ventilation of the Rotor-Gene Q MDx must not be covered.

Heat hazard**WARNING****Hot surface**

The Rotor-Gene Q MDx chamber can reach temperatures above 120°C (248°F). Avoid touching it when it is hot.

WARNING**Hot surface**

When a run is paused, the Rotor-Gene Q MDx will not be cooled completely to room temperature. Exercise caution before handling the rotor or any tubes in the instrument.

Introduction

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

Rotor-Gene AssayManager v2.1 is a software for routine testing in combination with Rotor-Gene Q MDx instruments. Rotor-Gene AssayManager v2.1 is able to read in sample information, set up experiments, control up to 4 different Rotor-Gene Q MDx cyclers, acquire data from these instruments, automatically analyze results and create reports.

Rotor-Gene AssayManager v2.1 consists of different components working together. The core application v2.1 is complemented by different plug-ins that contain assay type specific analysis and visualization of the results. The core application v2.1 is mandatory for working with Rotor-Gene AssayManager v2.1 and at least one plug-in must be installed. Optionally, additional plug-ins can be installed. Not all plug-ins are available in all countries. Refer to www.qiagen.com/rotor-gene-assaymanager-21-us to discover our continuously expanding range of plug-ins.

About this user manual

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

- Safety Information
- Introduction
- General Description of Rotor-Gene AssayManager v2.1
- Getting Started (including installing Rotor-Gene AssayManager v2.1)
- Basic Concepts and General Software Usage
- Rotor-Gene AssayManager v2.1 environments: Setup, Cycler, Approval, Archive, Service, Configuration
- Work Flow
- Standard Tasks (including audit trails and setting up, finishing and releasing runs)
- Administrative Tasks (managing assay profiles and cyclers, users and archives)
- Maintenance (including database maintenance)
- Troubleshooting
- Abbreviations and File Extensions
- Glossary

Other sections contain the following:

- Liability Clause
- Software License Terms

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

Note: 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,**” page 272, and “**Cycler Management** tab,” page 213.

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 v2.1 MDx Core Application User Manual*, which provides information about Rotor-Gene AssayManager Core Application version 2.1.

General Description of Rotor-Gene AssayManager v2.1

Product configuration

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

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

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

Product functions

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

1) Cycler control: Rotor-Gene AssayManager v2.1 controls the Rotor-Gene Q MDx cyler, 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 MDx cyclers in parallel. Rotor-Gene AssayManager v2.1 can also be used for experiment result approval and reporting only. In this case, the software can be installed on a computer not necessarily connected to a Rotor-Gene Q MDx cyler.

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

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

Note: Rotor-Gene AssayManager v2.1 is only compatible with the QIASymphony AS result files of the QIASymphony software version 5.0.

Modes of operation

Closed mode

Rotor-Gene AssayManager v2.1 offers the Closed mode of operation for IVD applications.

The Closed mode is used for assays that have been created and validated by QIAGEN. These assays can only be modified by QIAGEN.

In Closed 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).

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

Requirements for Rotor-Gene AssayManager v2.1 software users

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

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

Training for Rotor-Gene AssayManager v2.1 software users

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

Getting Started

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

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

Note: Checksum confirmation is required to secure software integrity after web download has been successfully completed and before subsequent handling of the software. Therefore, software checksum verification is requested before installation of the downloaded software is started.

Installing Rotor-Gene AssayManager v2.1

Rotor-Gene AssayManager v2.1 and the corresponding plug-ins are available on the QIAGEN webpage. The data file provides installation, update and uninstall process for Rotor-Gene AssayManager v2.1, the Rotor-Gene AssayManager database, and the Rotor-Gene AssayManager v2.1 plug-ins.

For a diagnostic application, an assay specific assay profile is required. See "Importing/exporting an assay profile," page 268, for details.

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

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

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

Note: Plug-ins cannot be uninstalled. If you want to uninstall a plug-in, the core application must be uninstalled together with the plug-in. See "Uninstalling the Rotor-Gene AssayManager v2.1 software," page 62, for details.

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

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

| Task | Description |
|--|---|
| Install on stand-alone computer* | <ul style="list-style-type: none"> ● A user with local system administration privileges installs the database (Microsoft SQL Server Express) including initial data, the Rotor-Gene AssayManager v2.1 core application and at least one Rotor-Gene AssayManager v2.1 plug-in on a computer. ● The user is completely guided by the installation wizard and will be prompted for input, if necessary. |
| Set up a stand-alone computer* connected to a network and install Rotor-Gene AssayManager v2.1 on an additional computer* connected to the first | <ul style="list-style-type: none"> ● Proceed as described in "Install on stand-alone computer*". ● The computer* is connected to the local area network. ● Rotor-Gene AssayManager v2.1 and at least one Rotor-Gene AssayManager v2.1 plug-in is installed on additional computers by a user with local administration privileges. During installation, the user is prompted for connection to the database, which has to be provided by the database administrator. |

| Task | Description |
|---|--|
| Use an existing database server and install Rotor-Gene AssayManager v2.1 on additional computers* | <ul style="list-style-type: none"> ● A user with all required database administration privileges uses the installation wizard to install only a new database instance including initial data on an existing database server. ● The database administrator is responsible for checking whether the database server fulfills the Rotor-Gene AssayManager v2.1 requirements. He is also responsible for performing all database administration tasks necessary to back up the system before installation. Furthermore, the database administrator must guarantee the functionality of the system after the successful installation or a failed installation. ● Rotor-Gene AssayManager v2.1 and at least one Rotor-Gene AssayManager v2.1 plug-in is installed on additional computers by a user with local administration privileges. During installation, the user is prompted for connection to the database, which has to be provided by the database administrator. |

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

Requirements

A computer with the required specifications for operating the Rotor-Gene Q MDx instrument and Rotor-Gene AssayManager v2.1 is supplied as part of the Rotor-Gene Q MDx instrument which is referred to as "QIAGEN laptop" in the following text.

In general, the following minimum requirements must be fulfilled to run Rotor-Gene AssayManager v2.1:

PC system requirements

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

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

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

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

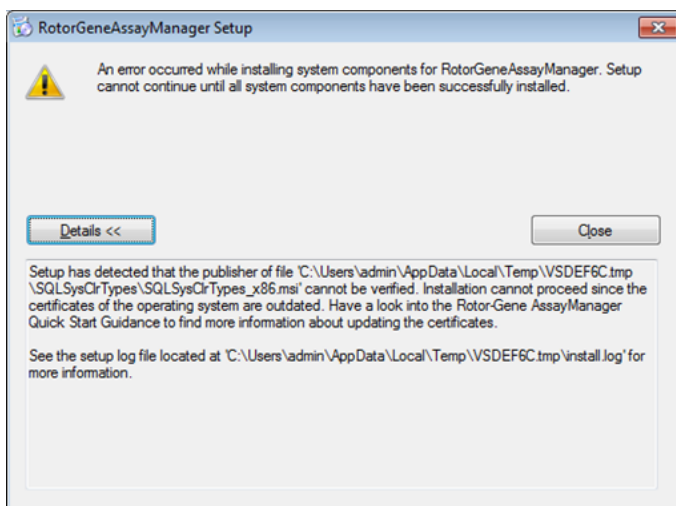
Note: Do not directly connect any network device, such as a computer or QIAsymphony SP/AS, to the computer hosting the Rotor-Gene AssayManager v2.1 via an Ethernet crossover cable or using Auto-MDIX. Do not apply any changes to network-related elements of the computer or any other operation system-related actions while the Rotor-Gene AssayManager v2.1 is started. This may result in data loss or indefinable behavior.

Outdated certificates on Windows 7

All installation packages contained in the Rotor-Gene AssayManager v1.0 installer are signed with validated certificates, trusted by Microsoft. This validity is checked by the operating system for every new program which shall be installed on the system. To be able to verify the validity of installer packages, the operating system maintains a list of trusted root certification authorities which is updated automatically by the so-called “automatic root update mechanism” introduced by Microsoft during the lifetime of Windows 7.

If your operating system or the list of trusted root certification authorities is in an outdated state, Microsoft cannot verify the validity of the pre-requisite packages, installed by the Rotor-Gene AssayManager v1.0 installer. This will result in the following error message during installation: “Setup has detected that the publisher of file ‘...’ cannot be verified. Installation cannot proceed since the certificates of the operating system are outdated.” (See screenshot below.)

Note: The error message is only shown if you click on the **Details <<** button.



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

Additional software on connected computers

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

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

Internationalization

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

Configuration for Windows security

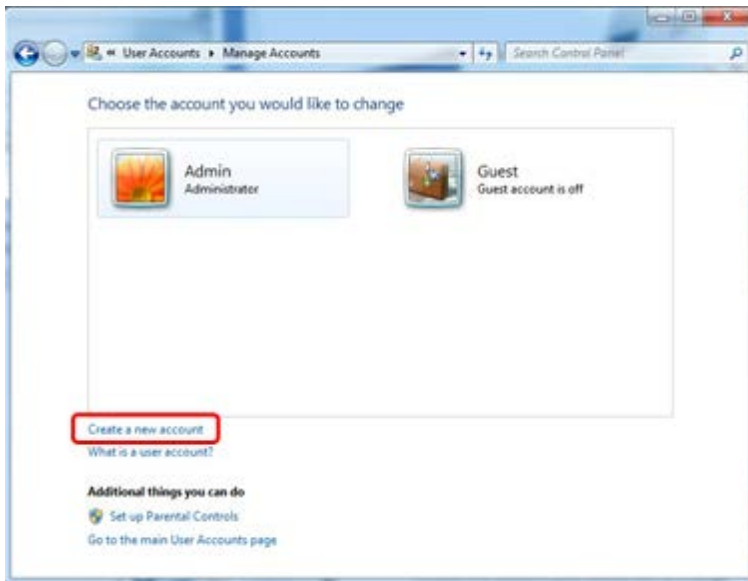
The laptop computers that are provided by QIAGEN for use with your Rotor-Gene Q MDx instrument have Microsoft Windows 7 or 10 pre-installed and are configured with a standard (non-administrative) Windows user account and with an administrator account. In routine usage of the system, the standard account shall be used, since Rotor-Gene AssayManager v2.1 is designed to run without administrator rights. The administrator account shall only be used to install the Rotor-Gene AssayManager v2.1 software and a virus scanner (please see section "Anti-virus scanners"). Using the administrator account is indicated by a red desktop background. Please make sure, that you always log in as standard-user for routine use.

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

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

Configuration for Windows 7 security

1. To create a standard user account, please follow these steps: Open the Windows control panel via the **Start** menu and select the **User Accounts/Manage Accounts**.
2. Choose **Create a new account**.



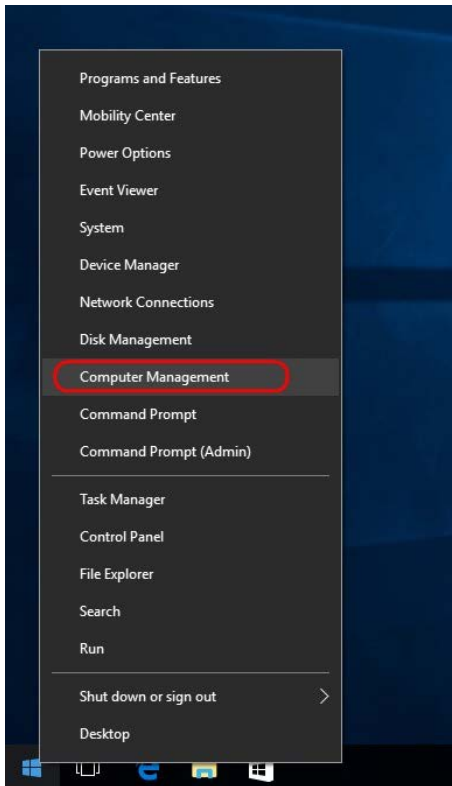
3. Name the account and select **Standard user** as the account type.



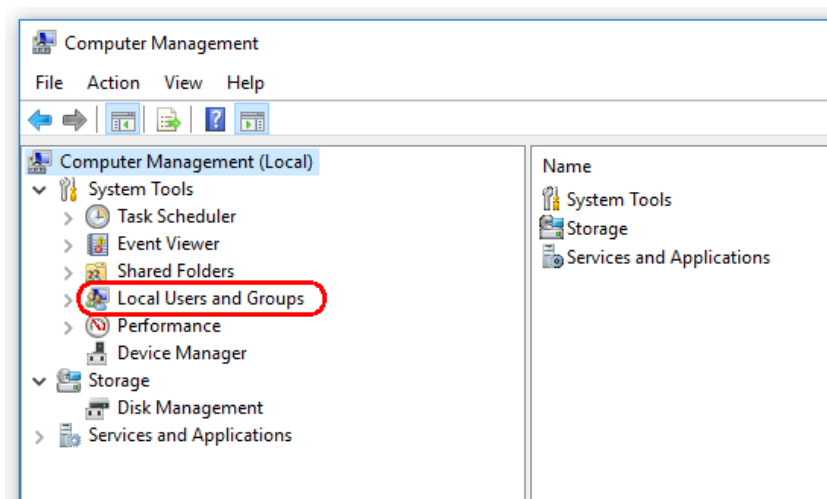
4. Click **Create Account**.

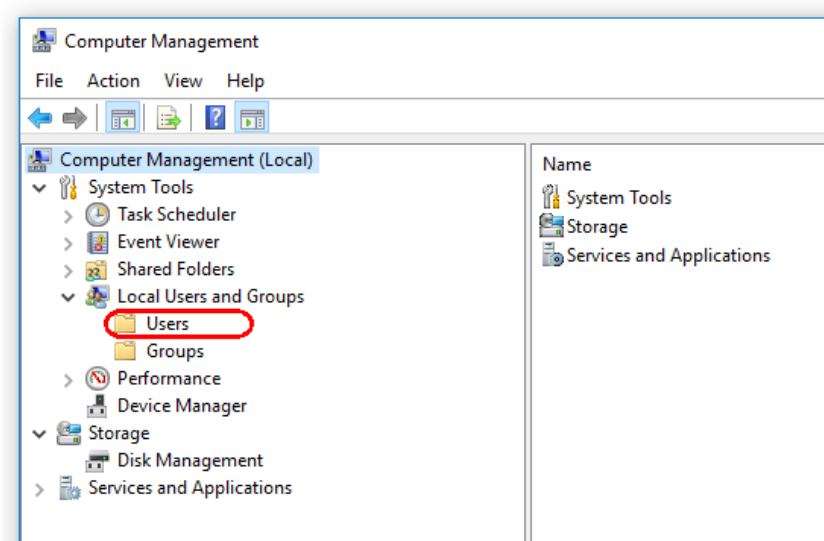
Creation of standard user account for Windows 10

1. Right-click on the Windows-button and select **Computer Management**.

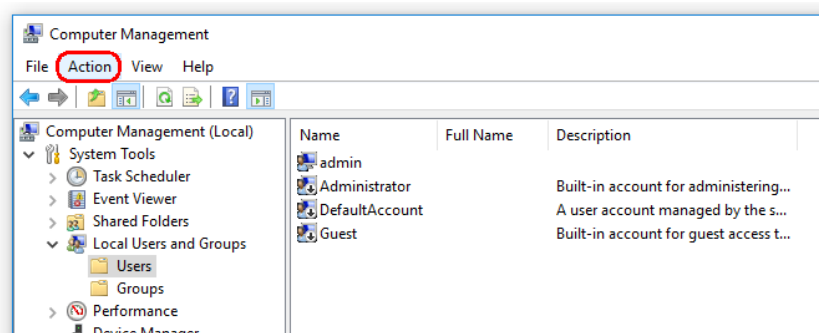


2. Expand **Local Users and Groups**.

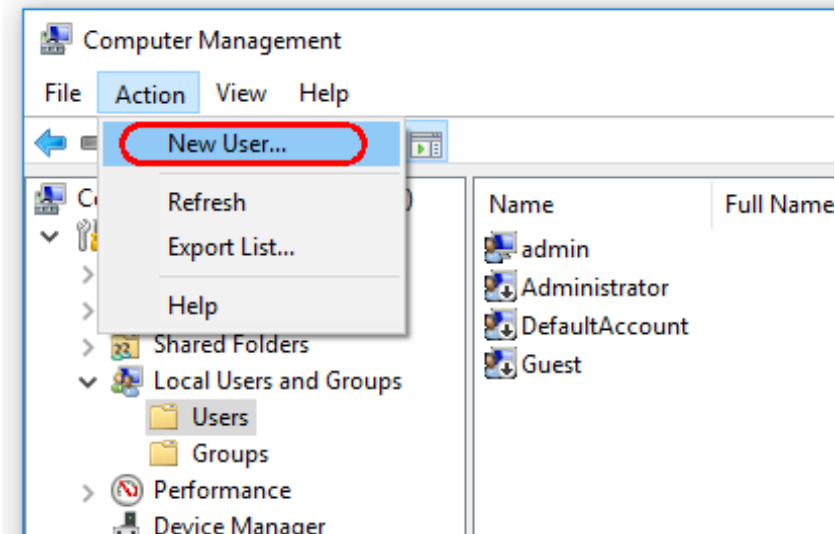




3. Select **Users**. With **Users** highlighted, click **Action**.



4. Select **New User...**



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

- User name: Operator
- Full name: (empty)
- Description: (empty)
- Password: (masked with 8 dots)
- Confirm password: (masked with 8 dots)
- User must change password at next logon
- User cannot change password
- Password never expires
- Account is disabled

Buttons at the bottom: Help, Create, Close.

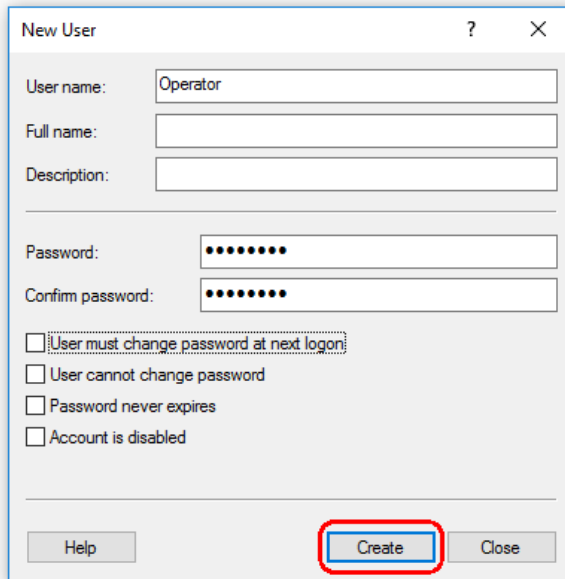
5. Enter the user name "Operator" and set a password that is compliant with your security rules.
6. Uncheck **User must change password at next logon** to allow more options.

The screenshot shows the same 'New User' dialog box, but with the 'User must change password at next logon' checkbox unchecked. A red box highlights the password fields and the unchecked checkbox.

- User name: Operator
- Full name: (empty)
- Description: (empty)
- Password: (masked with 8 dots)
- Confirm password: (masked with 8 dots)
- User must change password at next logon
- User cannot change password
- Password never expires
- Account is disabled

Buttons at the bottom: Help, Create, Close.

7. Click **Create** to finish.

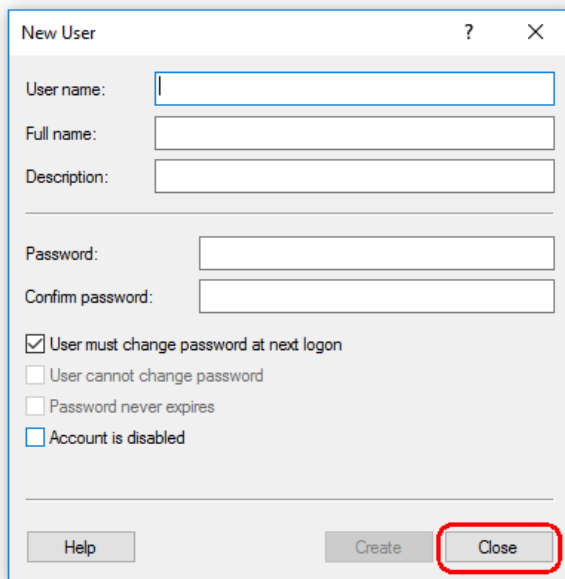


The screenshot shows a 'New User' dialog box with the following fields and options:

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

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

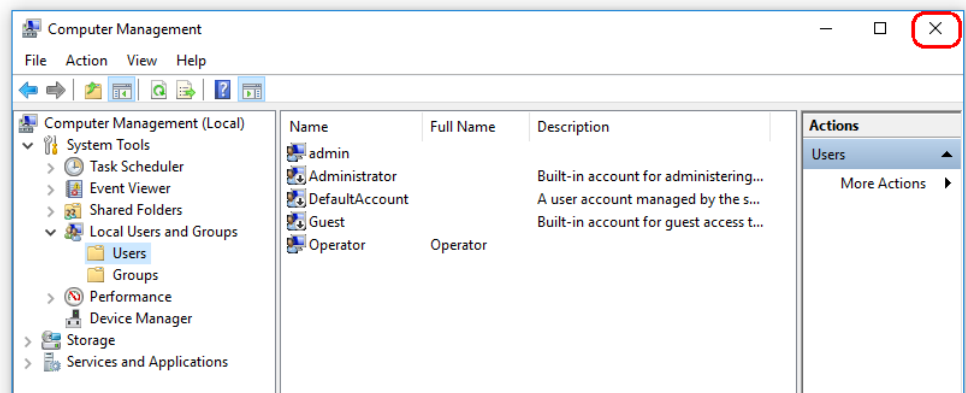
8. Add another user or click **Close**. All existing local users are shown in the **Users** list.



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

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

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



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.

Configuring the installation of Rotor-Gene AssayManager v2.1

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

- Install on stand-alone computer*
- Set up a stand-alone computer* connected to a network and install Rotor-Gene AssayManager v2.1 on o additional computers* connected to the first
- Use an existing database server and install Rotor-Gene AssayManager v2.1 on one or multiple computers*

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

For computer system requirements, refer to "Requirements," page 24.

Note: The system must be virus and spyware free to install the Rotor-Gene AssayManager v2.1 software. Please perform a virus scan using an up-to-date virus scanner to avoid a contamination.

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

Note: It is not possible to install Rotor-Gene AssayManager v2.1 on a computer or an existing database server where Rotor-Gene AssayManager v1.0 is already installed. Rotor-Gene AssayManager v1.0 and v2.1 are independent products and cannot be used in parallel on one system. **In addition, please note that 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.

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

Rotor-Gene AssayManager v2.1 requires a Microsoft 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 should be installed on the local system, or whether Rotor-Gene AssayManager v2.1 shall be installed with a remote connection to an existing SQL Server on an external system:

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

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

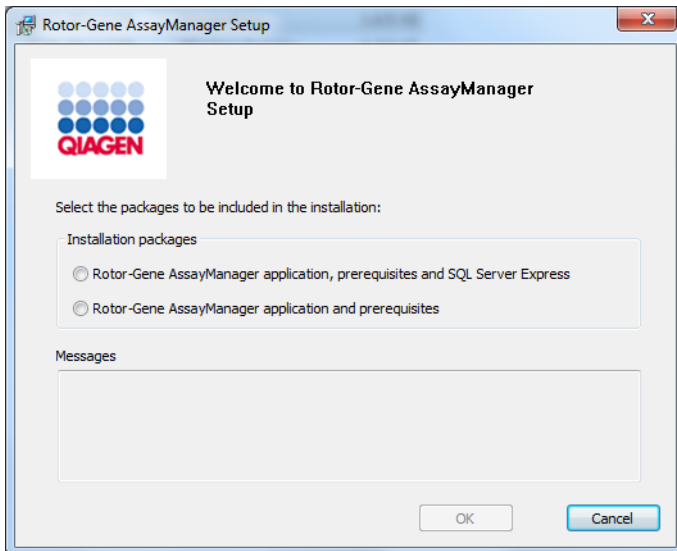
Installation on a stand-alone computer*

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

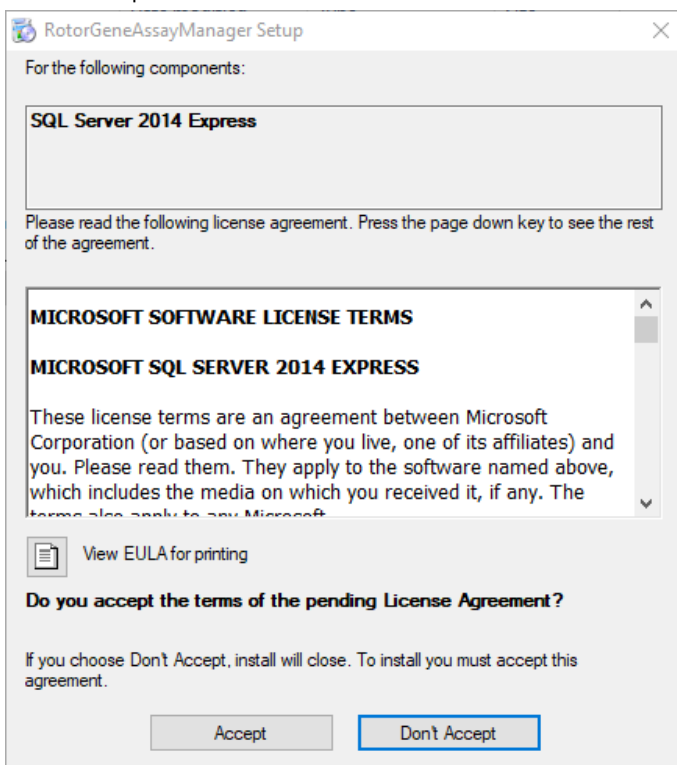
Note: Checksum confirmation is required to secure software integrity after web download is successfully completed and before subsequent handling of the software. Therefore, software checksum verification is requested before installation of the downloaded software is started. For detailed information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

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

2. Start the installation of Rotor-Gene AssayManager v2.1 by double-clicking on **setup.exe**.
The setup wizard automatically opens the **Rotor-Gene AssayManager Setup** window.

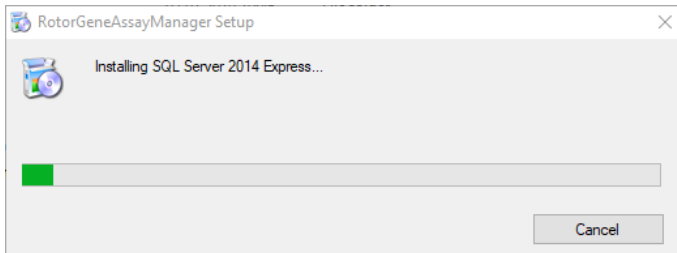


3. Select **Rotor-Gene AssayManager v2.1 application, prerequisites and SQL Server Express** to install the SQL Server locally on your system.
4. Click **OK** to proceed.

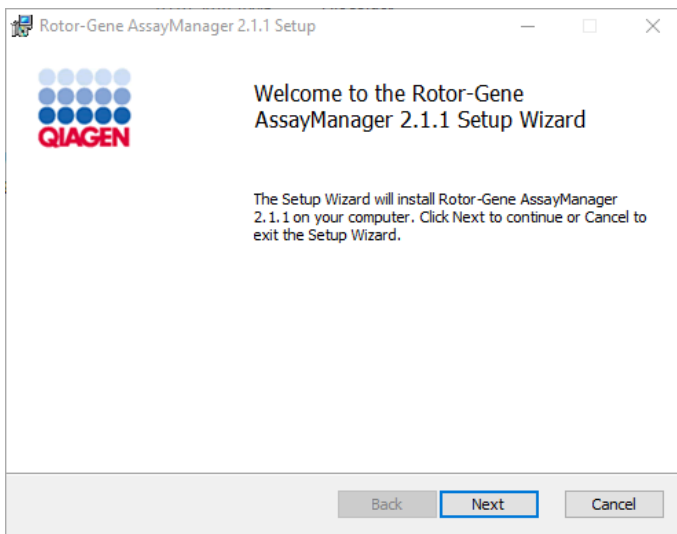


5. Click **Accept** to start the installation of MS SQL Server 2014 Express.

The installation progress window is displayed:

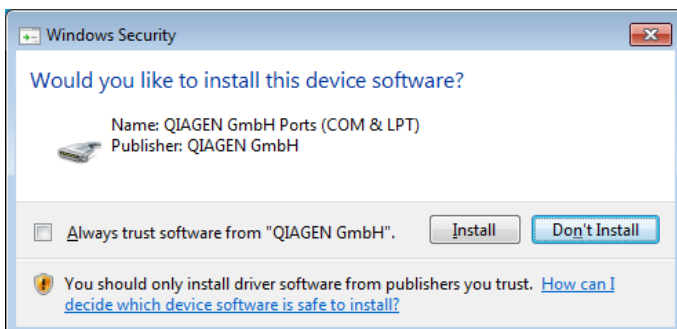


The Rotor-Gene AssayManager v2.1 welcome screen is automatically opened.



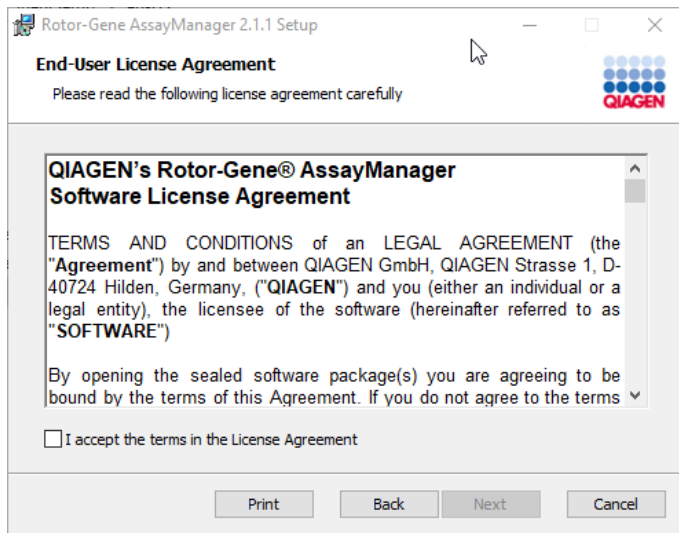
6. Click **Next** to start the installation procedure.

The following **Windows Security** message may appear during the installation process.



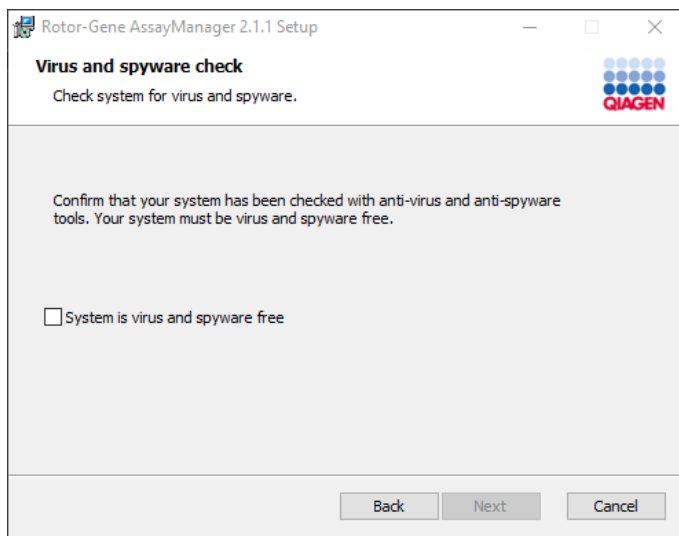
7. Click **Install**.

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



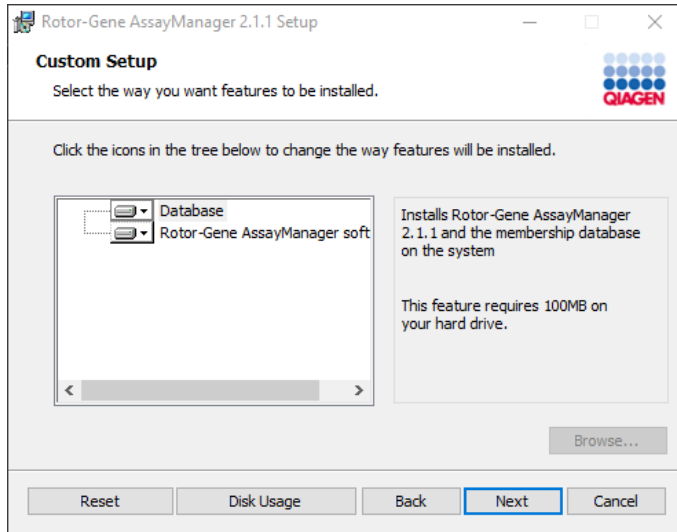
8. Read and accept the license agreements by checking "I accept the terms in the License Agreement" and click **Next**.

The **Virus and spyware check** window is opened:



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

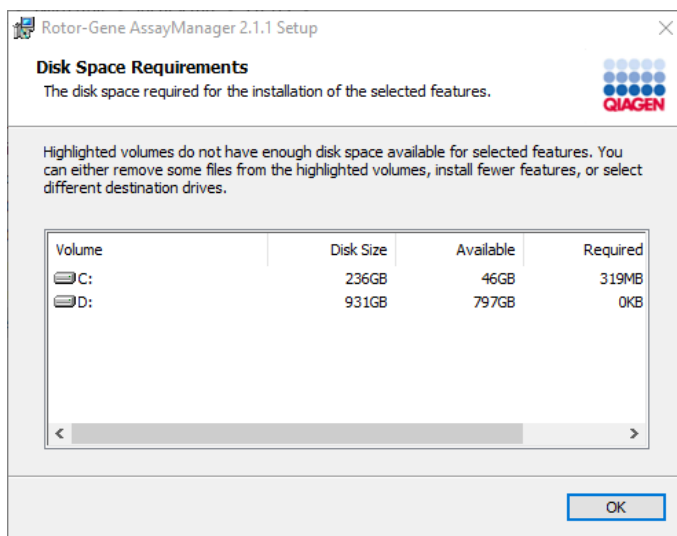
The **Custom Setup** screen is displayed.



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

Note: Do not deselect any feature.

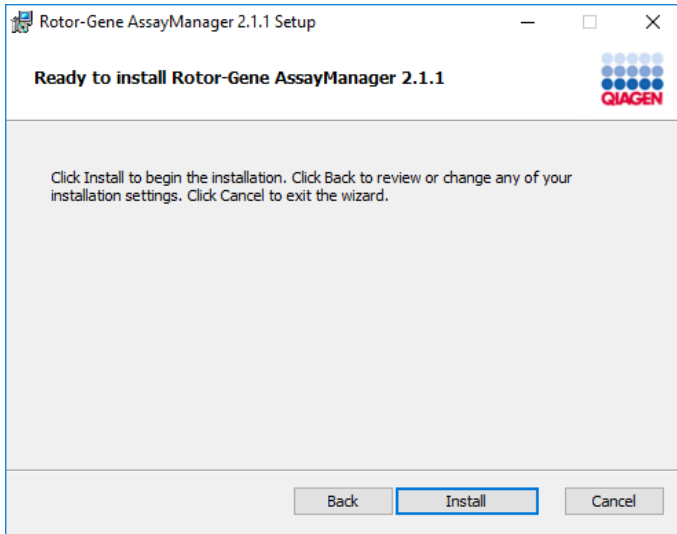
10. Click **Disk Usage** for an overview of the available and required disk space.



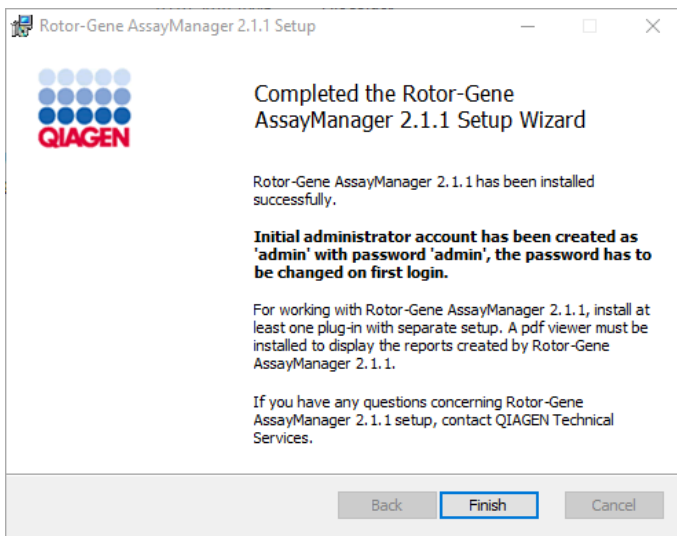
11. Click **OK** to close the window.

12. Click **Next** to proceed with the installation of the selected features.

13. To proceed with the installation, click **Next**.



14. Click **Install** to start the installation.



15. After the installation is completed, click **Finish** to close the window.

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



Installation on a stand-alone computer plus additional computers*

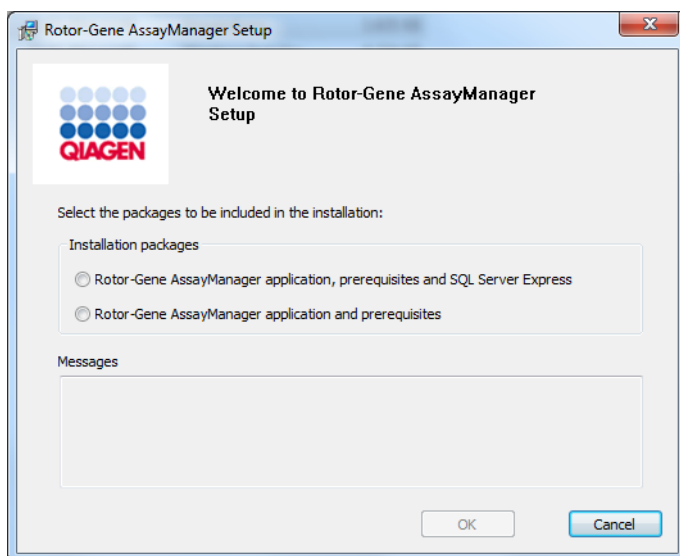
A prerequisite for this scenario is installation of Rotor-Gene AssayManager v2.1 on a computer with SQL Server Express installed and that is connected to the local area network.

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

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

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

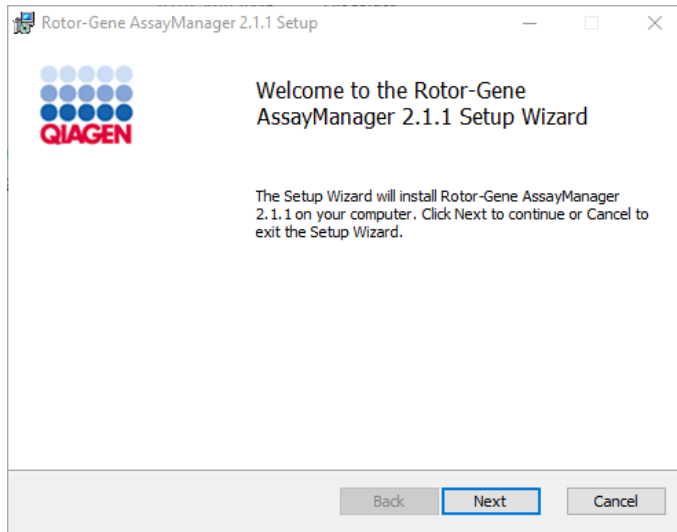
2. Start the installation of Rotor-Gene AssayManager v2.1 by double-clicking on **setup.exe**.
3. The setup wizard automatically opens the **Rotor-Gene AssayManager Setup** window.



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

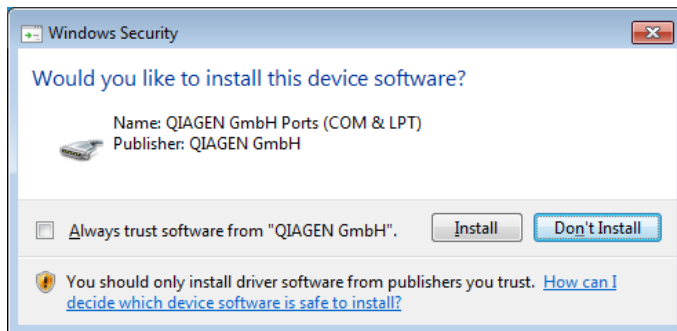
4. Select **Rotor-Gene AssayManager v2.1 application and prerequisites.**
5. Click **OK** to proceed.

The Rotor-Gene AssayManager v2.1 welcome screen is automatically opened.



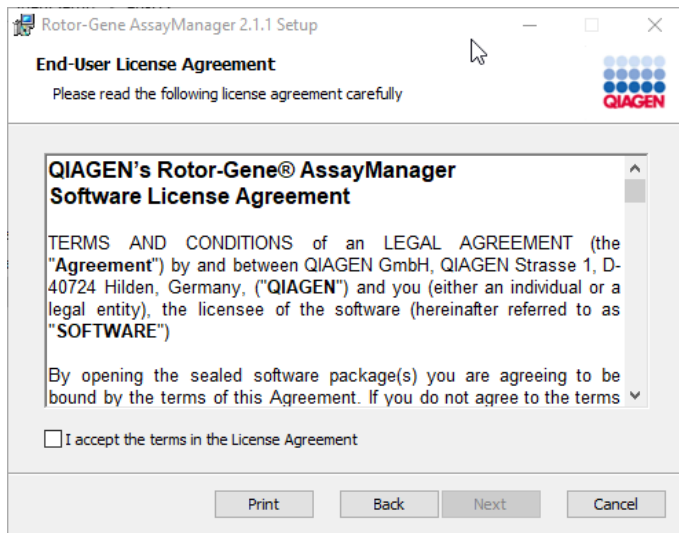
6. Click **Next** to start the installation procedure.

The following **Windows Security** message may appear during the installation process.



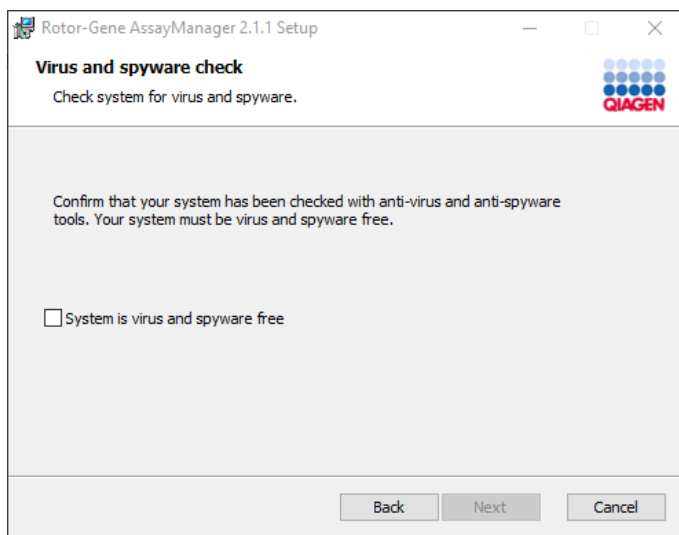
7. Click **Install**.

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



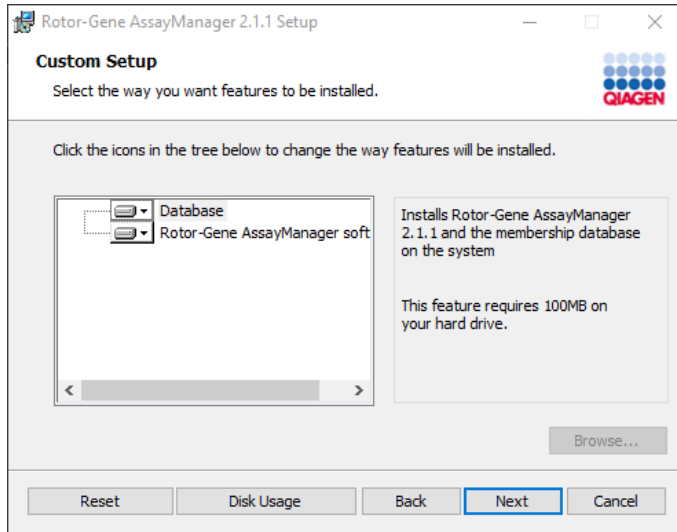
8. Read and accept the license agreements by checking "I accept the terms in the License Agreement" and click **Next**.

The **Virus and spyware check** window is opened:



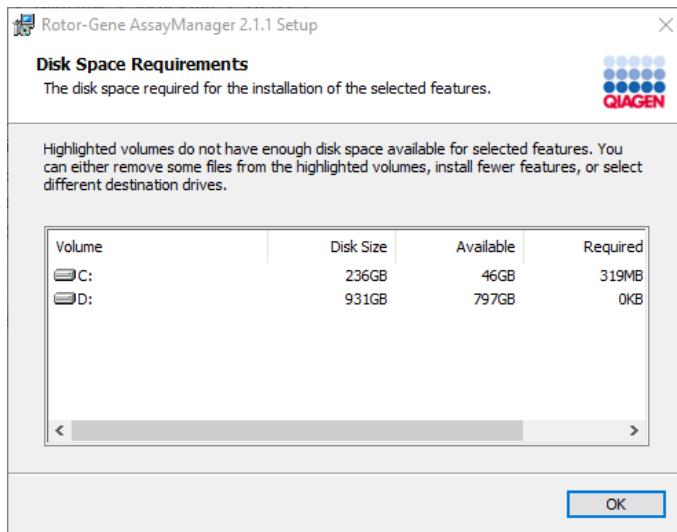
9. Confirm that the system is virus free by activating the **System is virus and spyware free** option and click **Next**.

The **Custom Setup** screen is displayed.



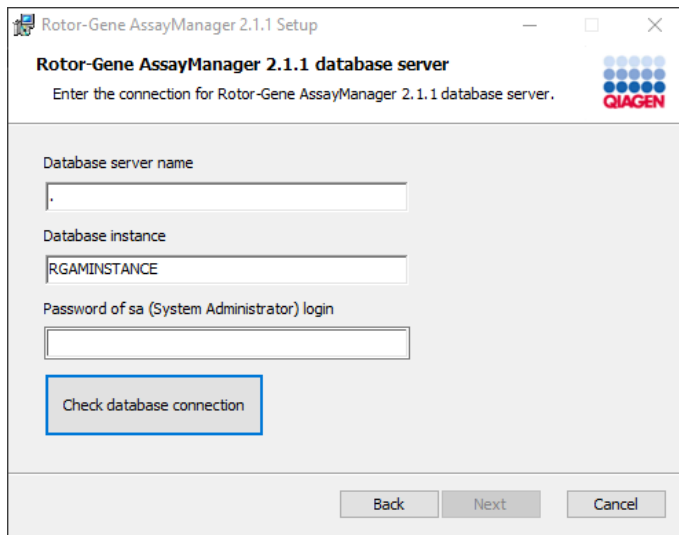
Note: Do not deselect any feature.

10. Click **Disk Usage** for an overview of the available and required disk space.



11. Click **OK** to close the window.

12. Click **Next** to proceed with the installation of the selected features.

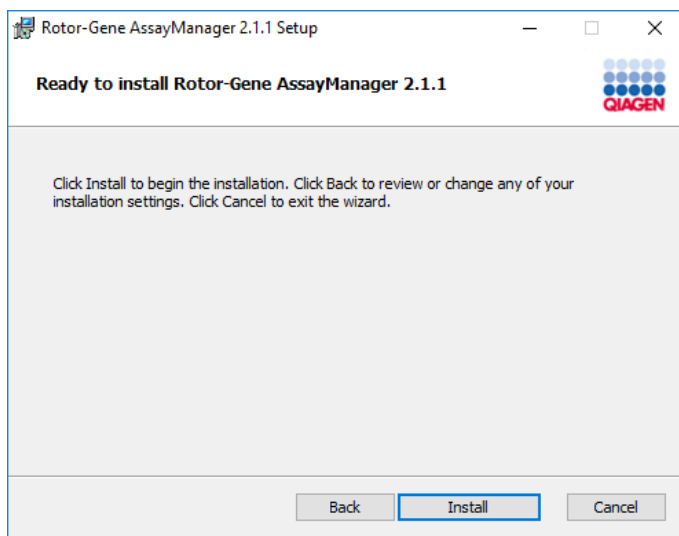


13. Fill in the required parameters.

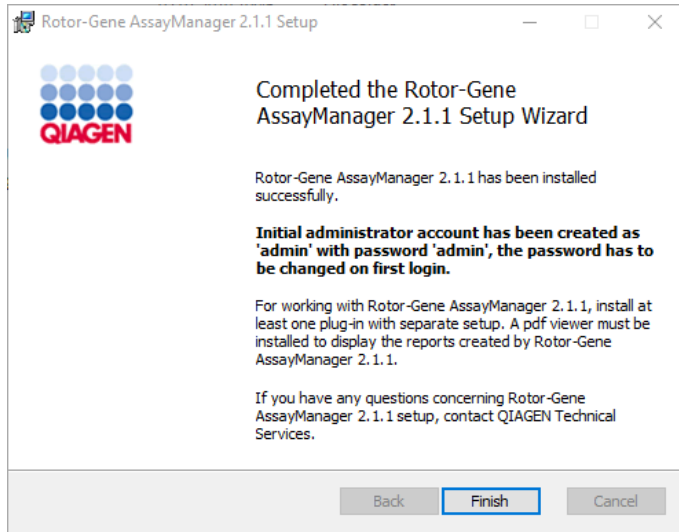
If the remote database server is a computer with a local installation of Rotor-Gene AssayManager v2.1, fill in the computer name as the database server name, leave the instance name ("RGAMINSTANCE") as it is, and leave the field **Password of sa (System Administrator) login** blank.

14. Click **Check database connection** to check the database connection. To access the remote "Database server" on the other computer, a system administrator must create an exception in the firewall configuration of that computer. Please read the chapter "Firewall and networks". If you encounter problems during the connection process to the database server, contact your local system administrator.

15. Click **Next** to proceed with the installation.



16. Click **Install** to start the installation.



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

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



Installation on an existing database server and on additional computers*

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

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

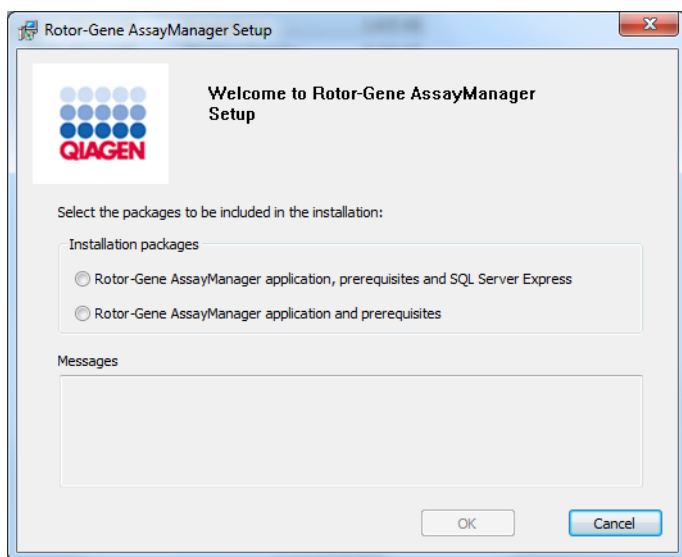
Note: Checksum confirmation is required to secure software integrity after web download is successfully completed and before subsequent handling of the software. Therefore, software checksum verification is requested before installation of the downloaded software is started. For detailed information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

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

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

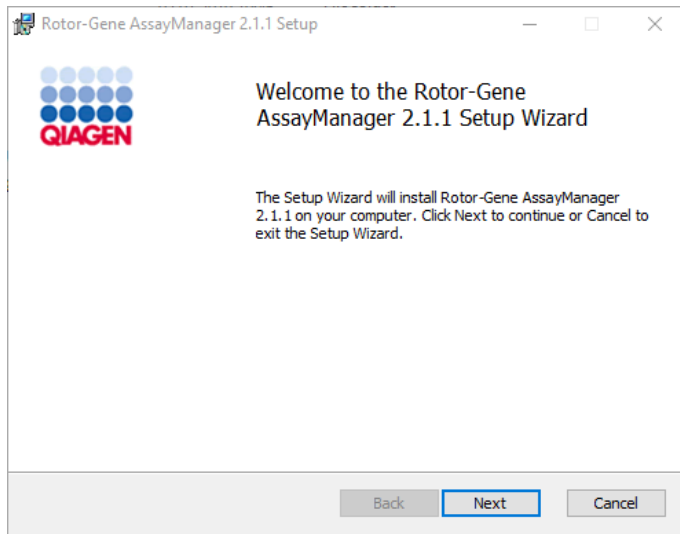
2. Start the installation of Rotor-Gene AssayManager v2.1 by double-clicking on **setup.exe**.

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



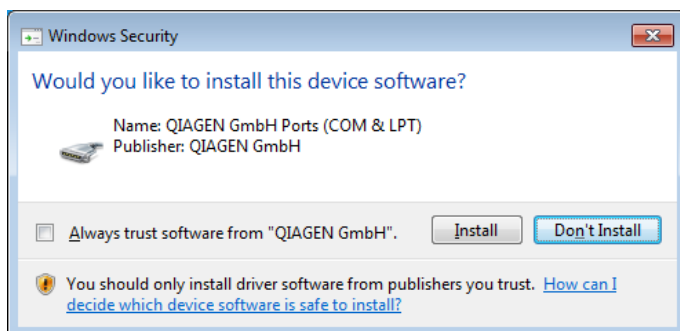
3. Select **Rotor-Gene AssayManager v2.1 application and prerequisites** if you want to install Rotor-Gene AssayManager v2.1 on a computer with a remote connection to an existing SQL Server Express on an external system.
4. Click **OK** to proceed.

The Rotor-Gene AssayManager v2.1 welcome screen is automatically opened.



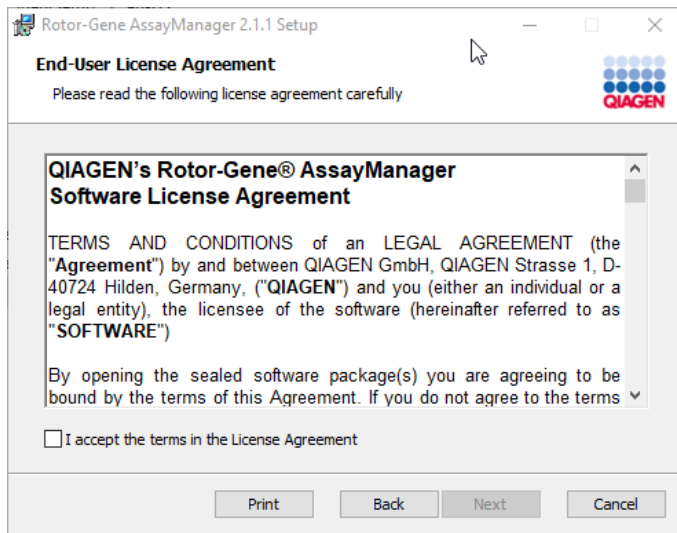
5. Click **Next** to start the installation procedure.

The following **Windows Security** message may appear during the installation process.



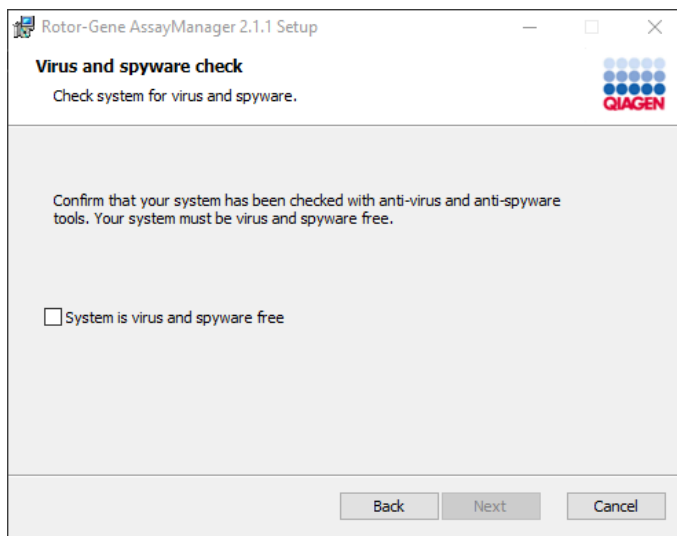
6. Click **Install**.

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



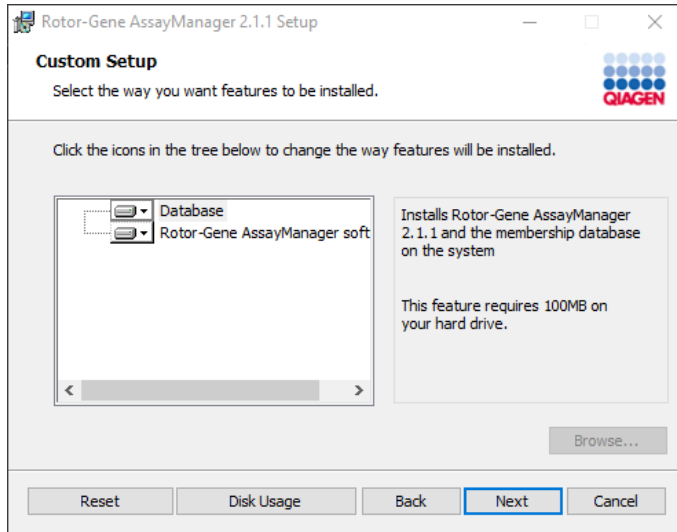
7. Read and accept the license agreements by checking "I accept the terms in the License Agreement" and click **Next**.

The **Virus and spyware check** window is opened:



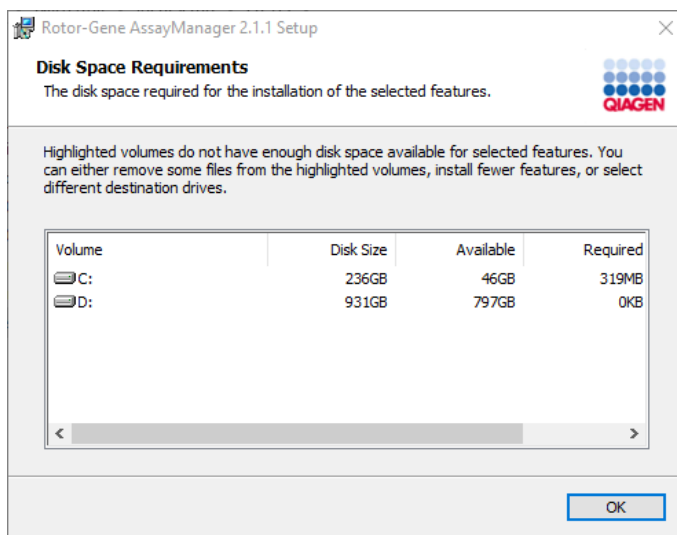
8. Confirm that the system is virus free by activating the **System is virus and spyware free** option and click **Next**.

The **Custom Setup** screen is displayed.

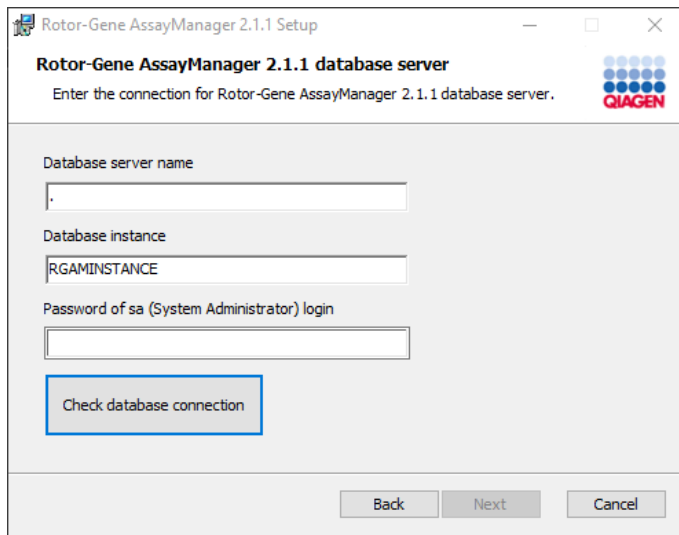


Note: Do not deselect any feature.

9. Click **Disk Usage** for an overview of the available and required disk space.



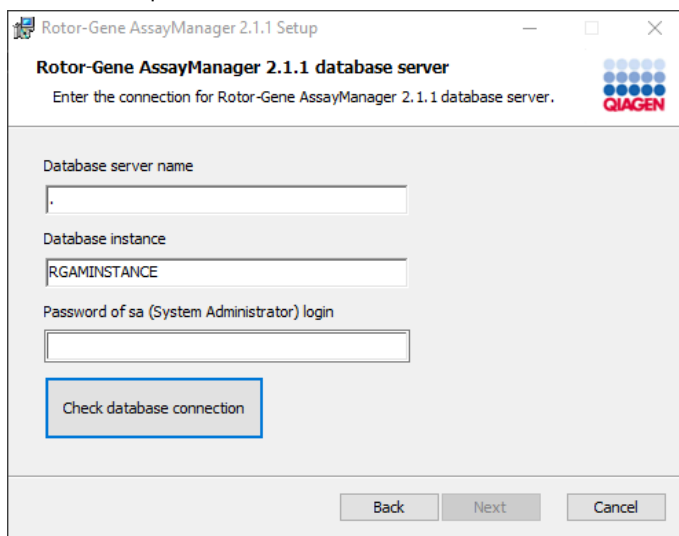
10. Click **OK** to close the window.
11. Click **Next** to proceed with the installation of the selected features.



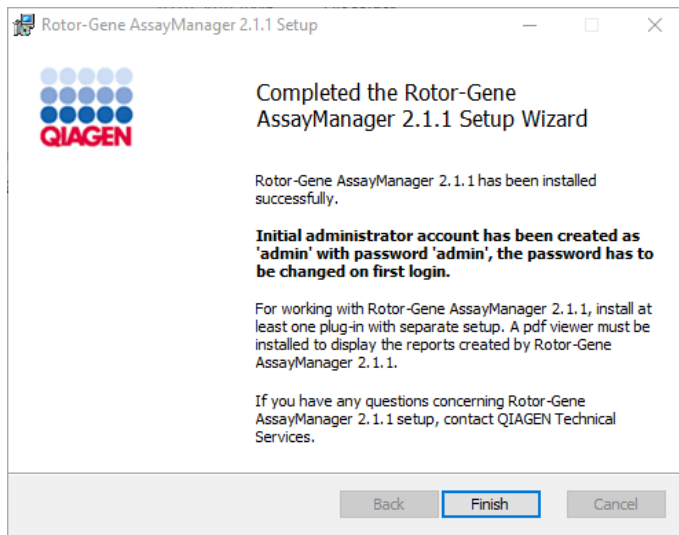
12. Fill in the required parameters.

13. Click **Check database connection** to check the database connection. To access the remote "Database server" on the other computer, a system administrator must create an exception in the firewall configuration of that computer. Please read the chapter "Firewall and networks". If you encounter problems during the connection process to the database server, contact your local system administrator.

14. Click **Next** to proceed with the installation.



15. Click **Install** to start the installation.



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

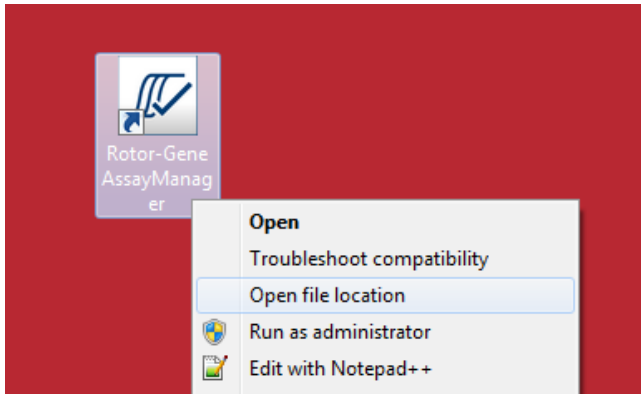
After installation, Rotor-Gene AssayManager v2.1 can be started either from the Windows **Start** menu under **QIAGEN/Rotor-Gene AssayManager** or by using the desktop icon.



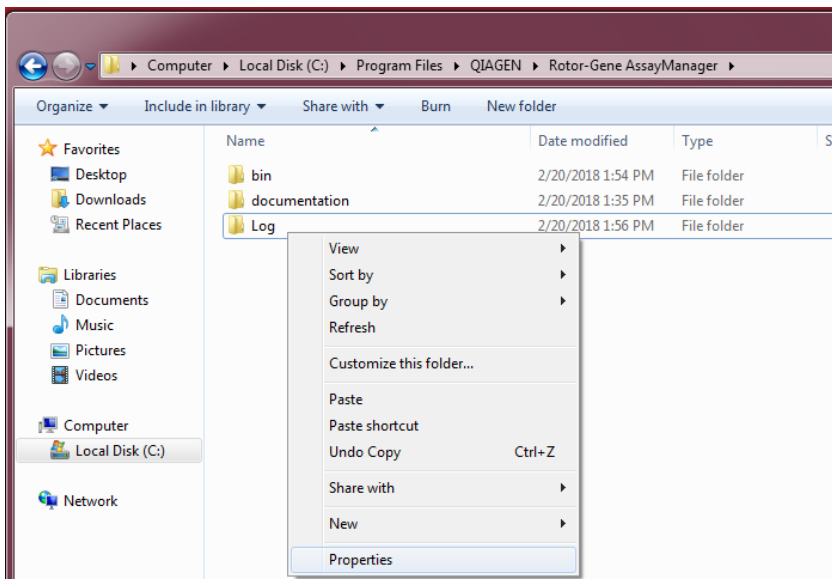
Setting up properties for log folder

If you are using Rotor-Gene AssayManager v2.1.1 in a multi-user windows environment, you must manually setup permissions for the “log” folder after installing RGAM. Otherwise it will not be possible for RGAM to create new log files if the windows user is changed.

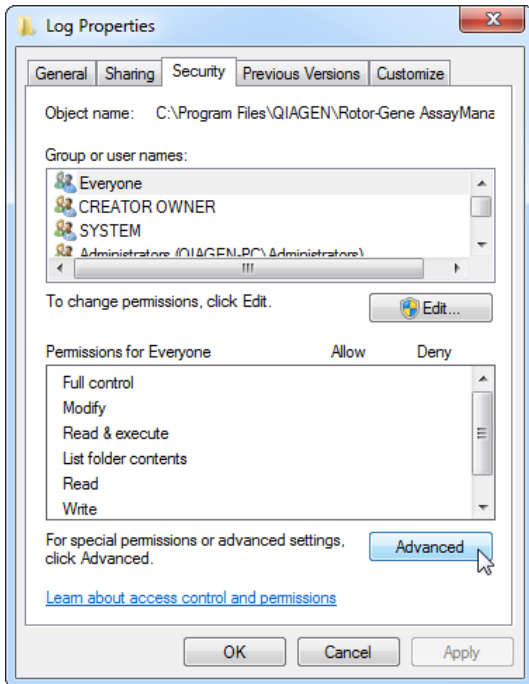
1. Log in as Administrator, right click on the Rotor-Gene AssayManager icon and select **Open file location**.



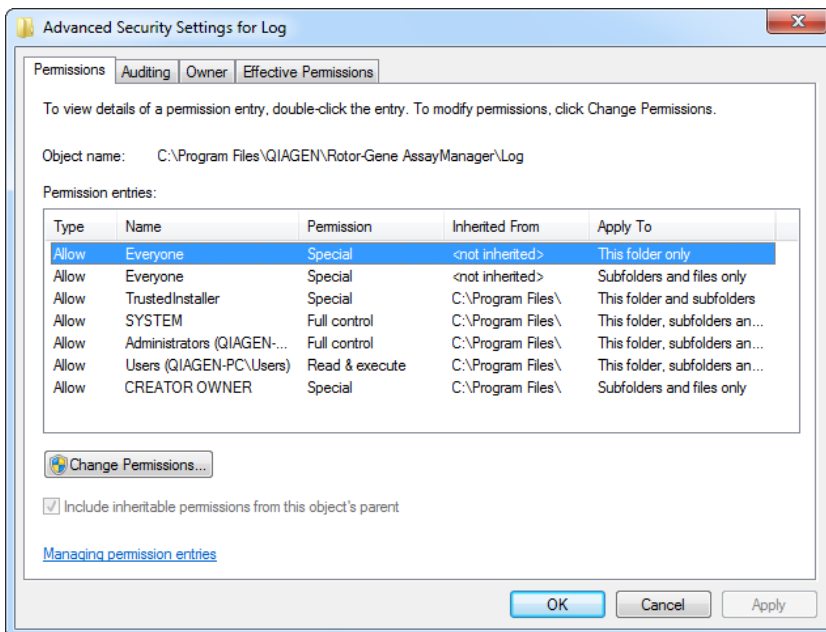
2. The file explorer will open the Rotor-Gene AssayManager/bin folder. Navigate up one folder to the Rotor-Gene AssayManager top folder. Right-click on the **Log** folder and select **Properties**.



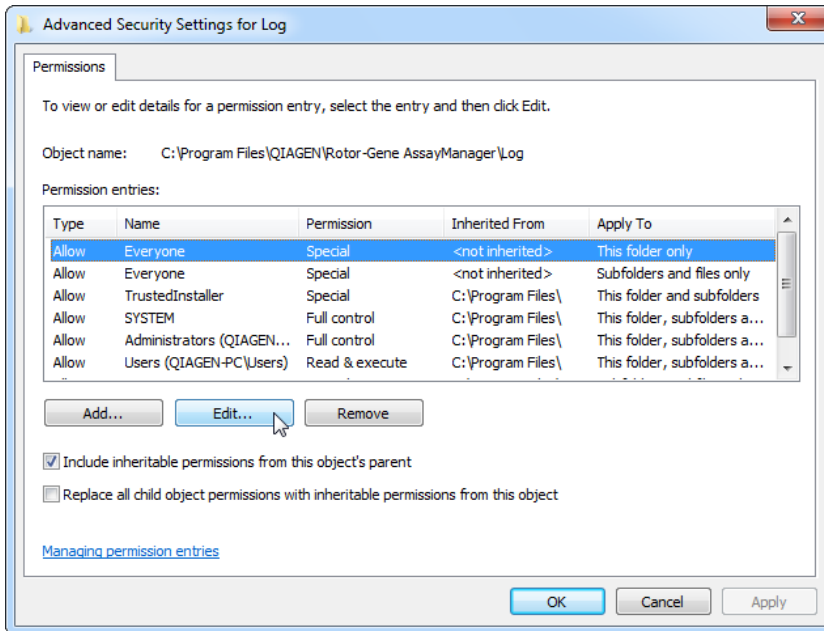
3. In the new dialog box, click on the **Security** tab and then select the **Advanced** button.



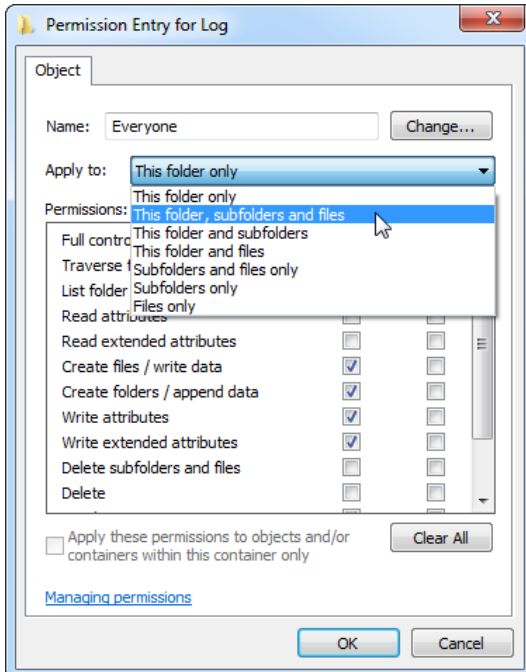
4. In the new dialog box, click on **Change Permissions....**



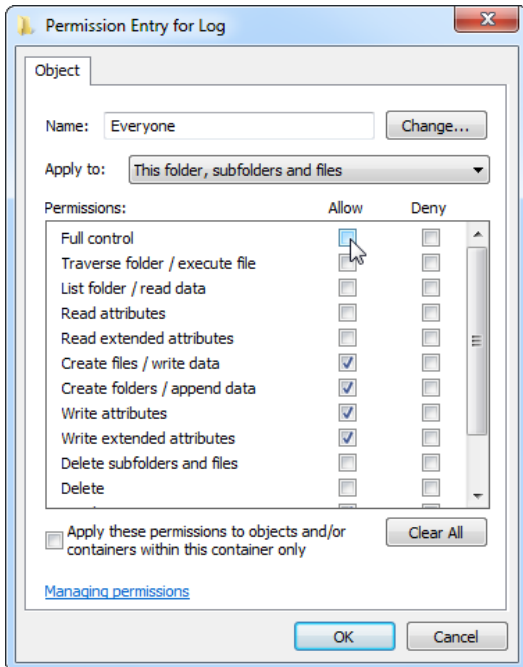
- Select the user with the name **Everyone** and click on **Edit**.



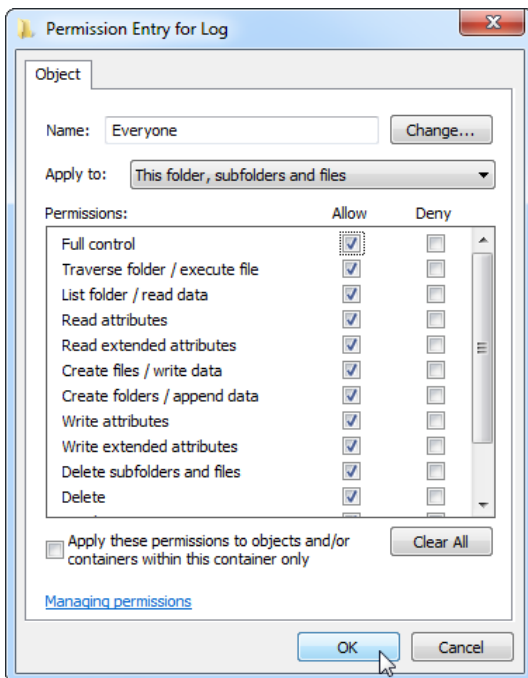
- Select the entry **This folder, subfolders and files** from the drop-down menu **Apply to**.



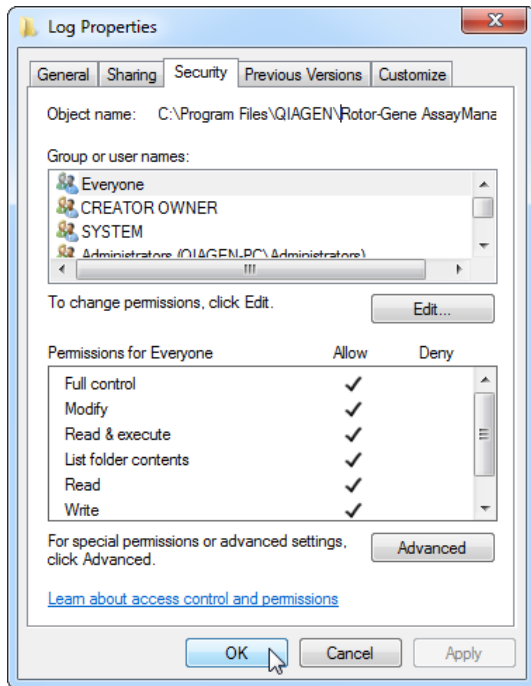
7. Click on the checkbox **Full control** in the column under **Allow**.



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



9. Close the remaining dialogs with a click on the **OK** button as well. The last dialog box should look like the one below. (User “Everyone” has full control.)



Installing plug-ins

At least one plug-in must be installed before Rotor-Gene AssayManager v2.1 can be used. Plug-ins are provided via web download.

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

Note: The user should log in again only after the same plug-ins have been successfully installed on all related clients.

Installing a plug-in on a computer with SQL Server Express installed locally

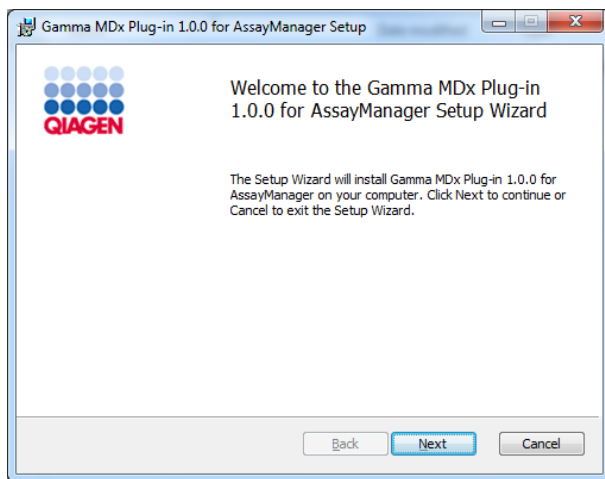
Note: The following installation of the Gamma MDx Plug-in is provided as an example for installation of any plug-in.

1. Download the plug-in from the QIAGEN website.

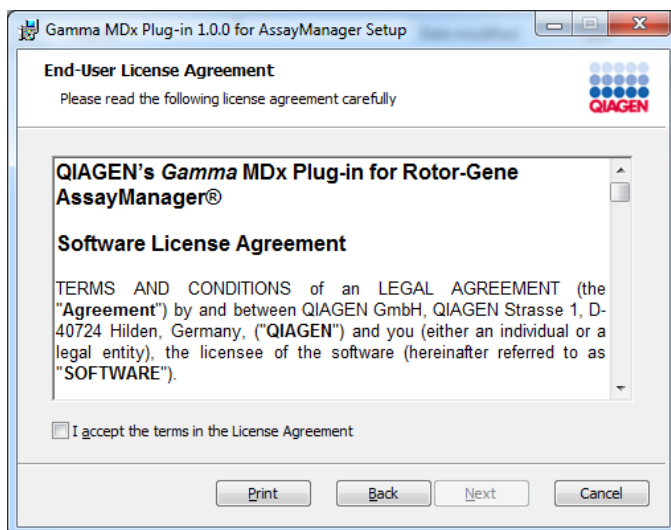
Note: Checksum confirmation is required to secure software integrity after web download is successfully completed and before subsequent handling of the software. Therefore, software checksum verification is requested before installation of the downloaded plug-in is started. For

detailed information on confirmation of software integrity during download and file transfer, please check the *QIAGEN software integrity verification process description* document, which is provided together with the software package on the QIAGEN webpage. If you download software from the QIAGEN website on a different computer to the one on which the software is to be installed, please make sure that the flash drive you use to transfer the software is free of viruses. QIAGEN strongly recommends you perform a virus scan using an up-to-date virus scanner on the flash drive prior to use to avoid contamination.

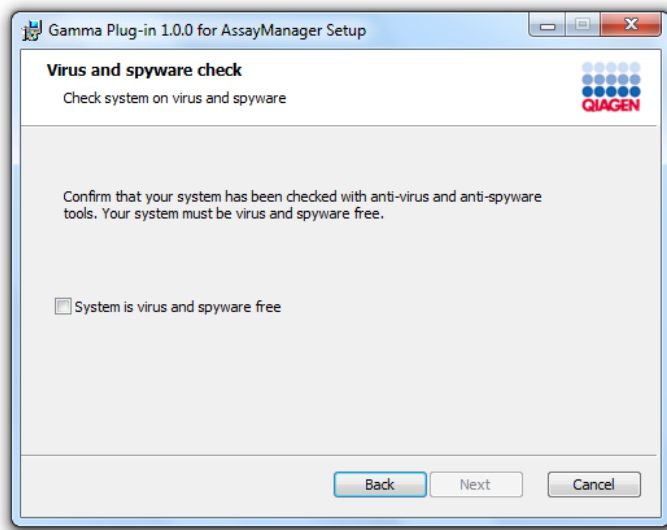
2. Double-click **RGAM_V2_1_Gamma_MDx_Plug-in.Installation.V1_0_0.msi** to start the Gamma MDx Plug-in setup wizard.



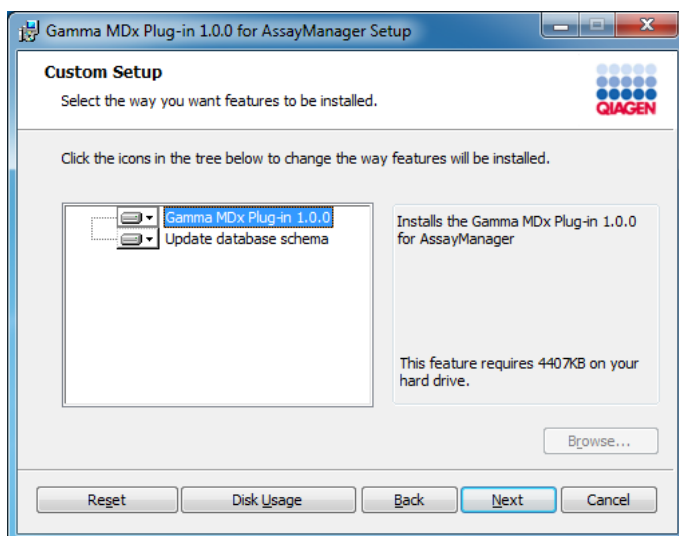
3. Click **Next** to proceed.



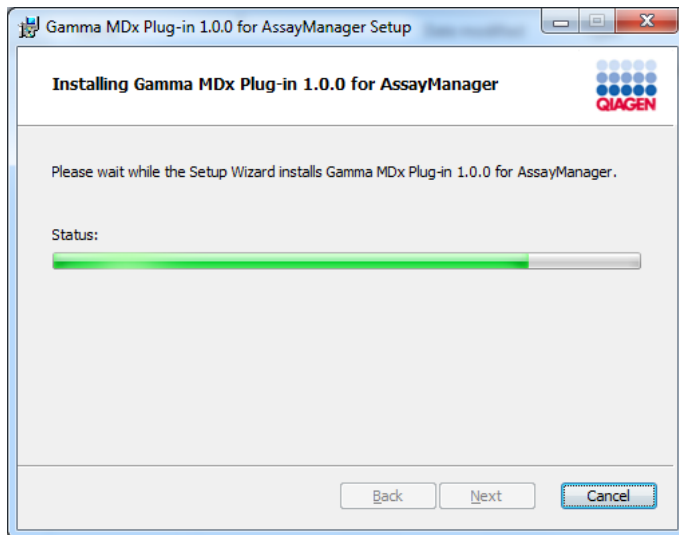
4. Read and accept the license agreement by clicking the checkbox and click **Next**.



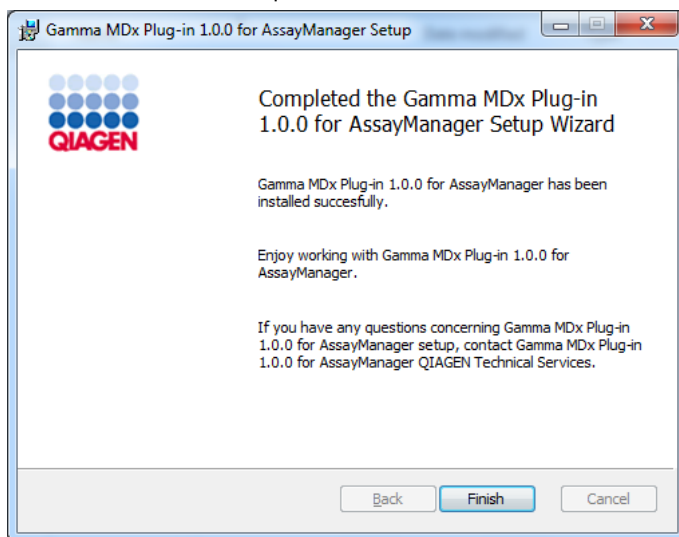
5. Confirm that your system is virus and spyware free by checking the corresponding check box and click **Next**.



6. Select the features to be installed.
Note: Do not deselect any features.
7. Click **Disk Usage** for an overview of the available and required disk space. Click **OK** to close the window.
8. Click **Next** to proceed with the installation of the selected features.
9. Click **Install** to start the installation of the plug-in.



Wait until the installation process has finished.



10. After the installation is completed, click **Finish** to close the window.

The installed plug-in is available after a restart of Rotor-Gene AssayManager v2.1.

Related topics

"Configuring the installation of Rotor-Gene AssayManager v2.1," page 32.

Installing a plug-in on a computer using a central database server

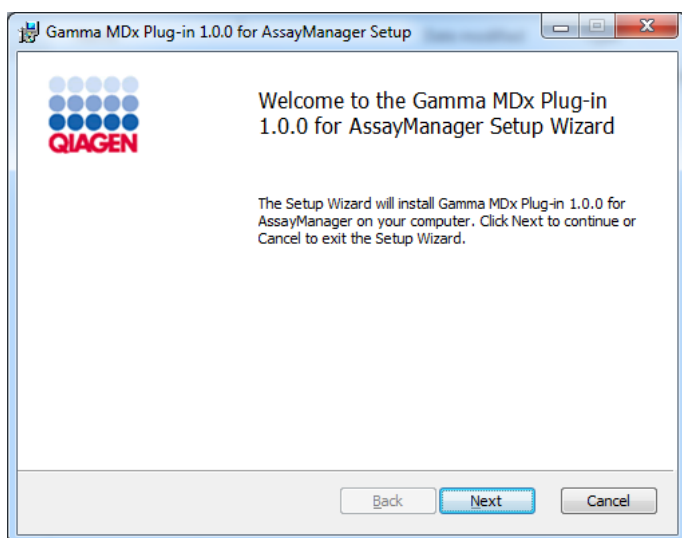
As a prerequisite for this installation scenario, the plug-in is installed on a computer where the SQL Server Express database was deselected during core application installation.

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

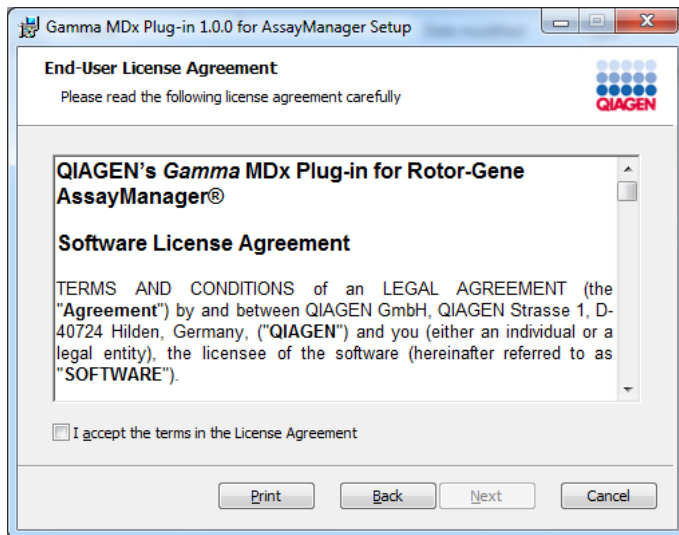
1. Download the plug-in from the QIAGEN website.

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

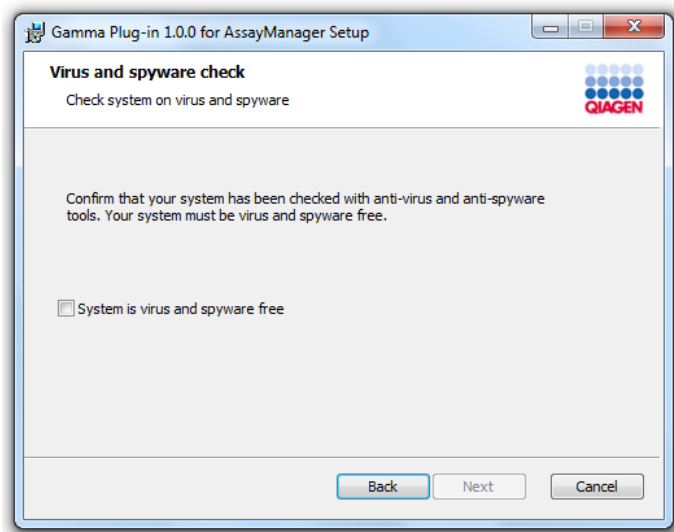
2. Double-click **RGAM_V2_1_Gamma_MDx_Plug-in.Installation.V1_0_0.msi** to start the Gamma MDx Plug-in setup wizard.



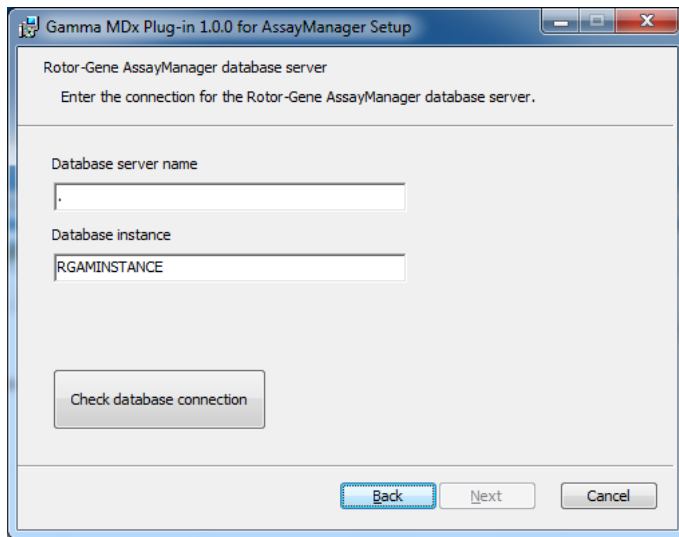
3. Click **Next** to proceed.



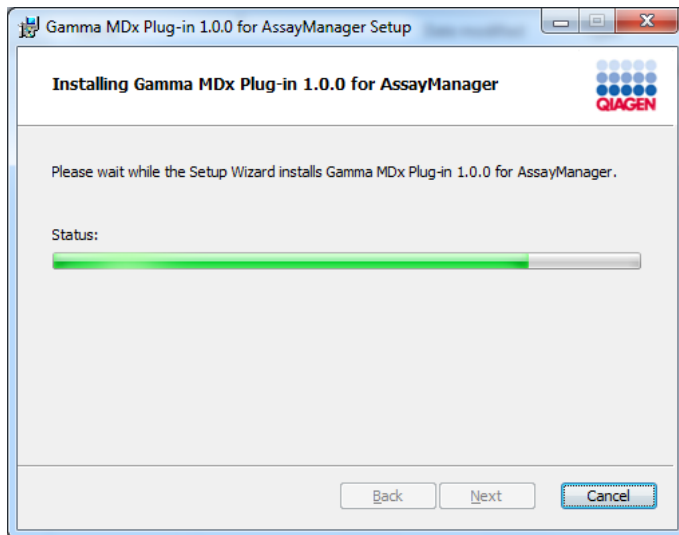
4. Read and accept the license agreement by clicking the checkbox and click **Next**.



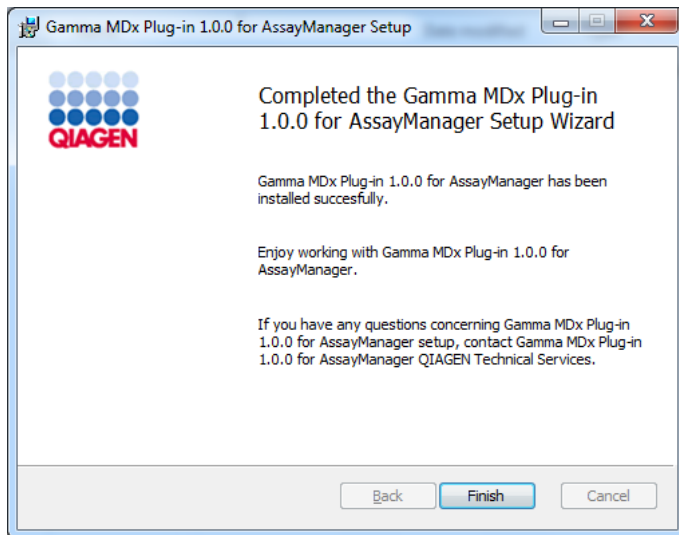
5. Confirm that your system is virus and spyware free by checking the corresponding check box and click **Next**.



6. Fill in the required parameters.
 - 6a. If the remote database server is a computer with a local installation of Rotor-Gene AssayManager v2.1, fill in the computer name and leave the instance name ("RGAMINSTANCE") unchanged.
 - 6b. If the database server is a SQL server, enter the customer database instance name provided by your database administrator.
7. Click **Next** to start the installation of the plug-in.



Wait until the installation process has finished.



8. After the installation is completed, click **Finish** to close the window.

The installed plug-in is available after a restart of Rotor-Gene AssayManager v2.1.

Related topics

“Configuring the installation of Rotor-Gene AssayManager v2.1,” page 32.

Uninstalling the Rotor-Gene AssayManager v2.1 software

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

Note: Close the application before uninstalling Rotor-Gene AssayManager v2.1. Otherwise Rotor-Gene AssayManager v2.1 might not be uninstalled completely.

1. Select **QIAGEN/Rotor-Gene AssayManager/Uninstall Rotor-Gene AssayManager** from the Windows Start menu.



2. Click **Yes** to confirm that you want to uninstall the product.

The Windows installer program uninstalls the entire Rotor-Gene AssayManager v2.1 software.

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

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

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

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

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

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

* After installation of "Microsoft Security Essentials", you shall check that Windows updates are deactivated since the installation might activate this setting (please read chapter "Operating system updates").

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

System tools

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

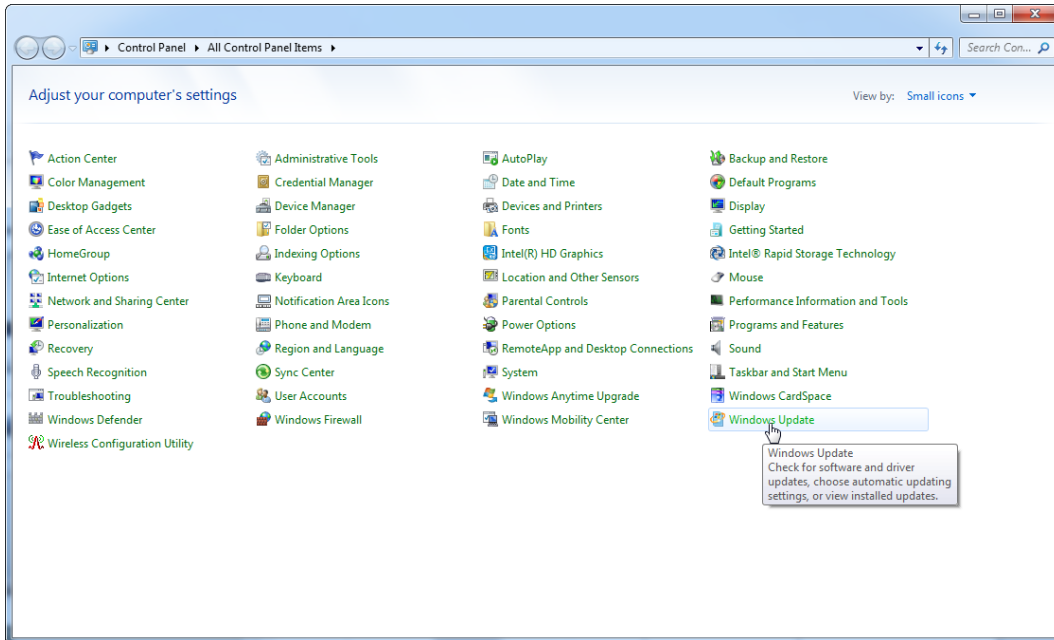
- File indexing, which is performed as a background task by many contemporary office applications
- Disk defragmentation, which often also employs a background task
- Any software that checks for updates on the Internet
- Remote monitoring and management tools

Note: Due to the dynamic nature of information technology products and systems, this list may be incomplete. Tools may be released that are not known at the time of writing. It is important that system administrators take care that such tools are not active on the computer while Rotor-Gene AssayManager v2.1 is performing a PCR run.

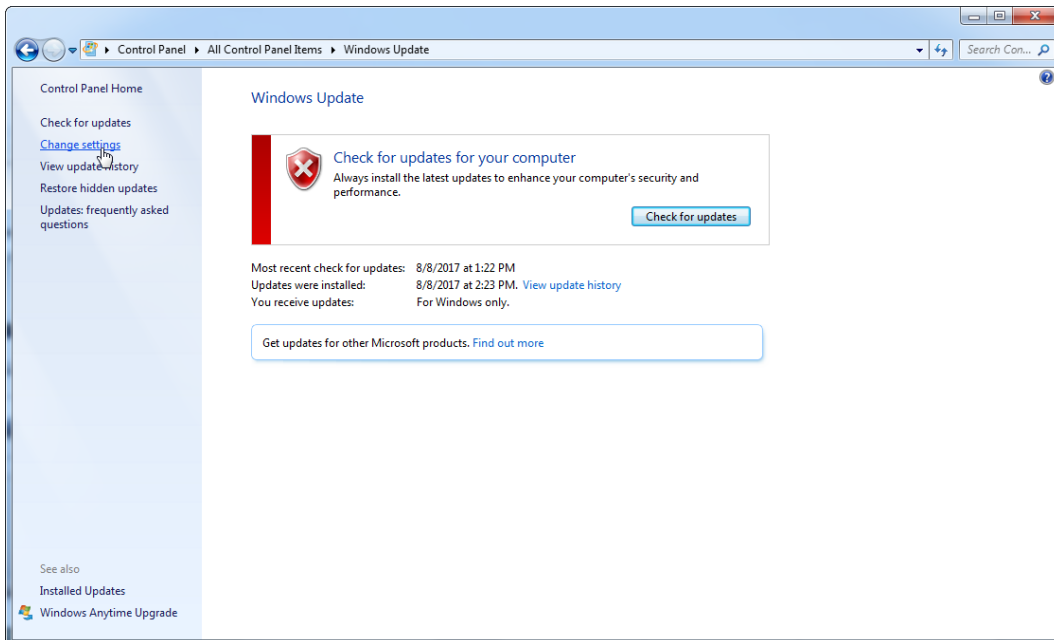
Operating system updates

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

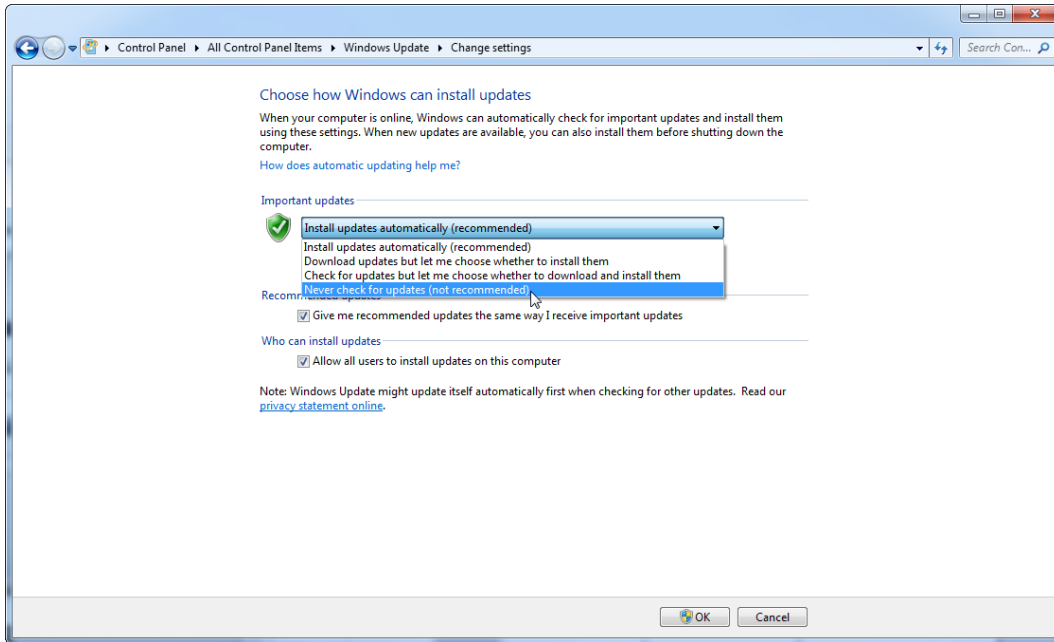
1. Open the **Control Panel** and select **Windows Update**.



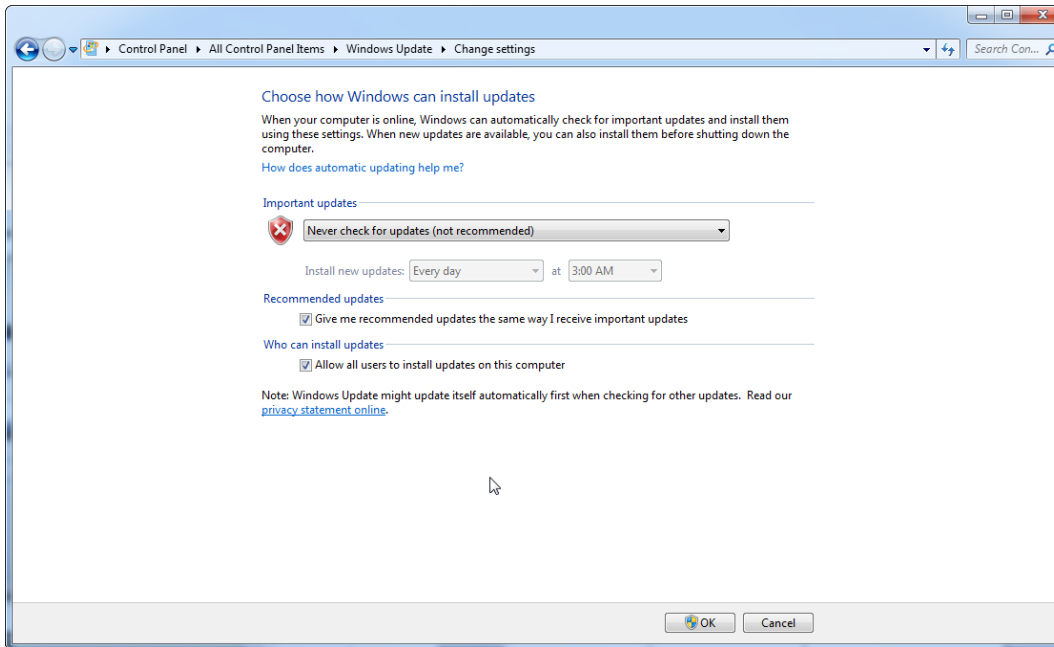
2. Select **Change settings**.



3. Select **Never check for updates**.



4. Check that option **Never check for updates** is active.



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

Please visit the product page on www.qiagen.com for more information.

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

Once registered, QIAGEN will send you an email when a new release of the QIAGEN System Updater is available for download.

Firewall and networks

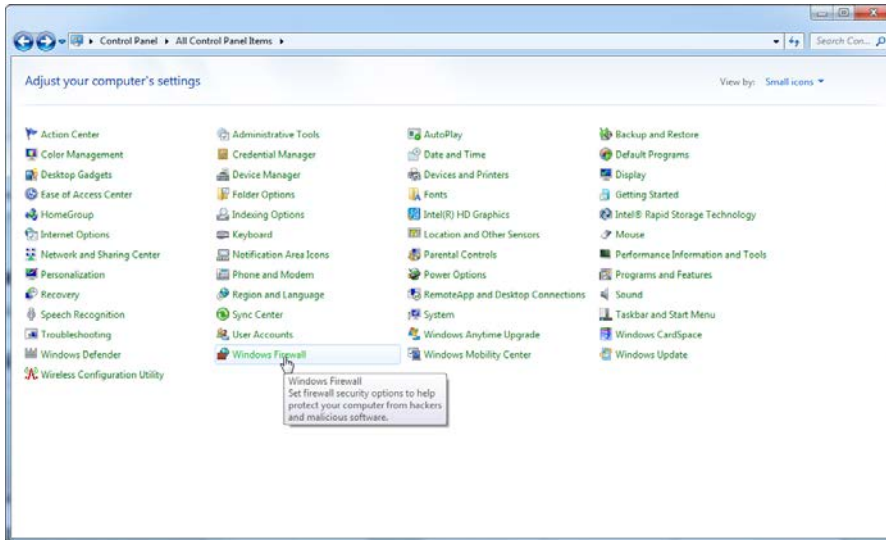
Rotor-Gene AssayManager v2.1 can run on computers without network access, if the database is located on the same computer that controls the Rotor-Gene Q MDx instrument, or can run in a network environment, if a remote database server is used. For networked operation, the firewall on the laptop computer 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 Rotor-Gene AssayManager v2.1 to the centralized database server. Outgoing connections are allowed as this may be required for retrieving updates or when Rotor-Gene AssayManager v2.1 is configured to work with a centralized database server. For security and reliability reasons in such cases, a cable-based local area networks instead of wireless network connections should be used.

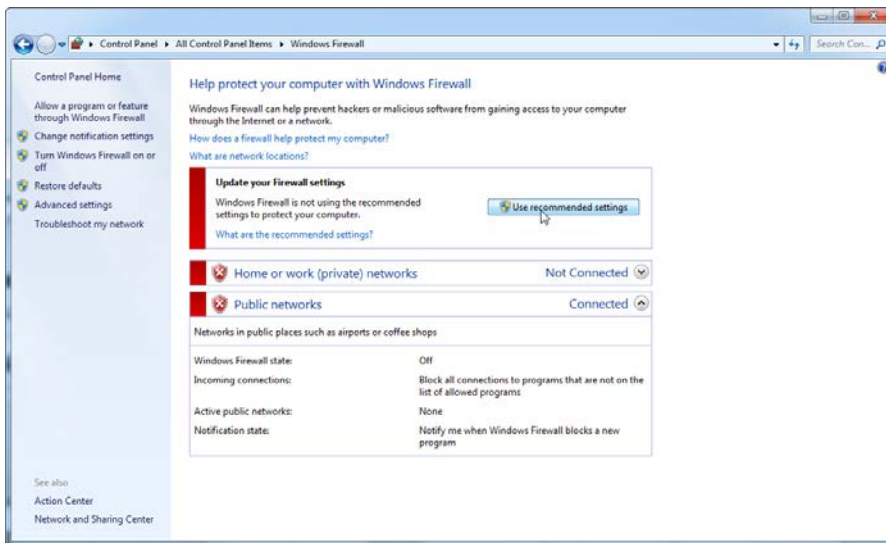
Firewall configuration

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

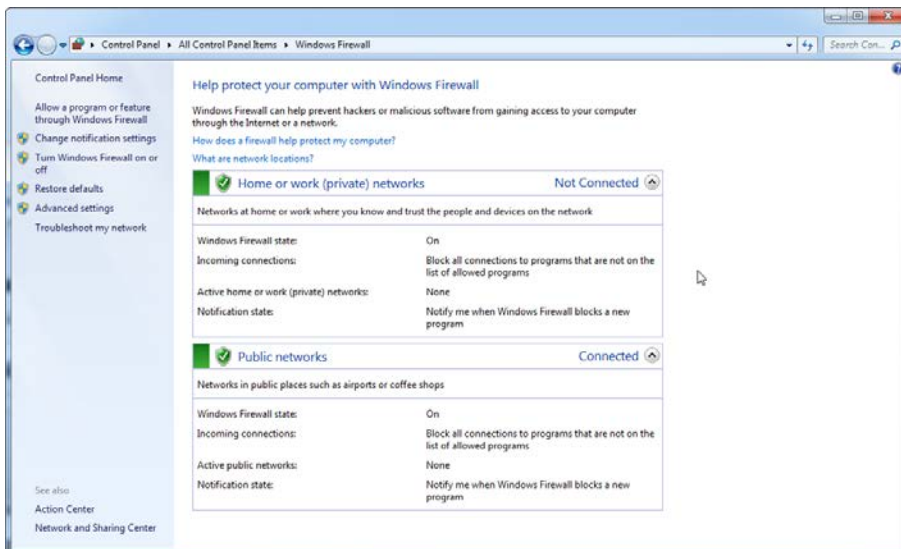
1. Open the **Control Panel** and select **Windows Firewall**.



2. Select **Use recommended settings**.



3. Check that the following settings are active:



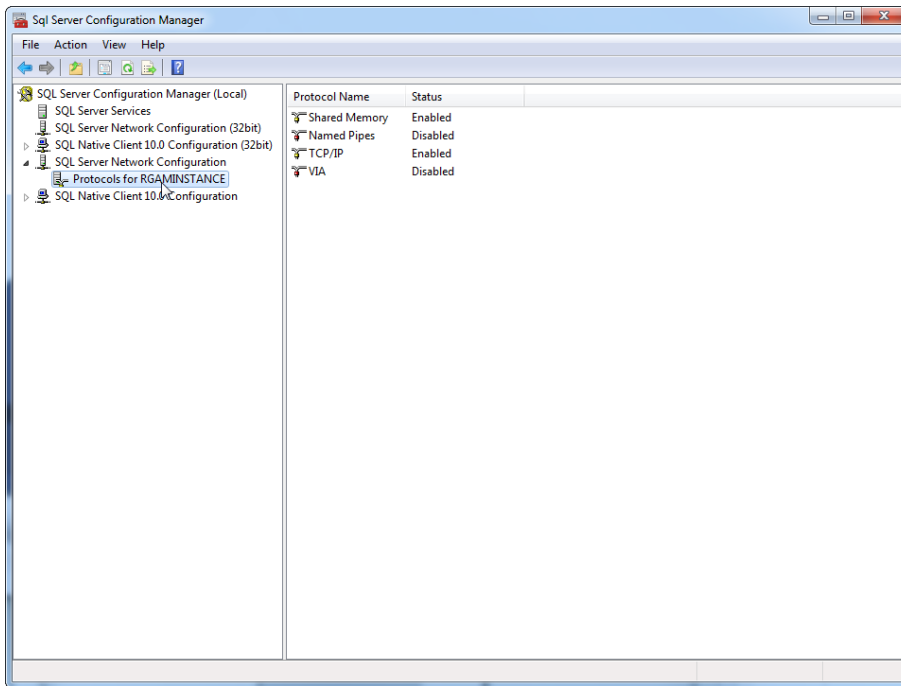
Exception in the firewall configuration

If you use a stand-alone computer that is connected to a network and you want to install Rotor-Gene AssayManager v2.1 on another computer to connect to the first (see “Configuration for Windows security”, page 26), a system administrator must create an exception in the firewall configuration. This exception can be created by executing the following steps.

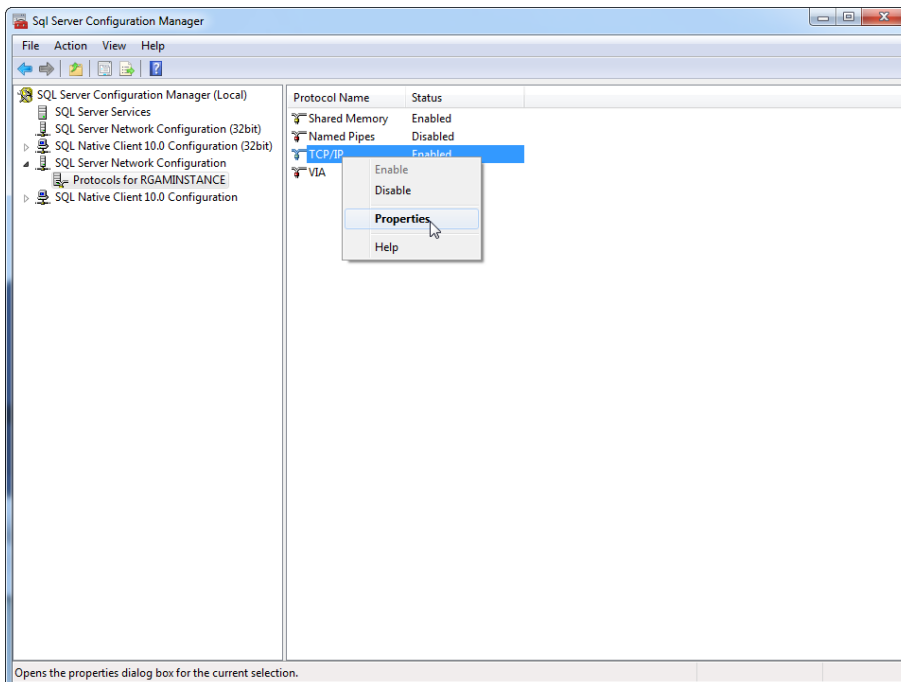
1. Select **SQL Server Configuration Manager** from the start menu.



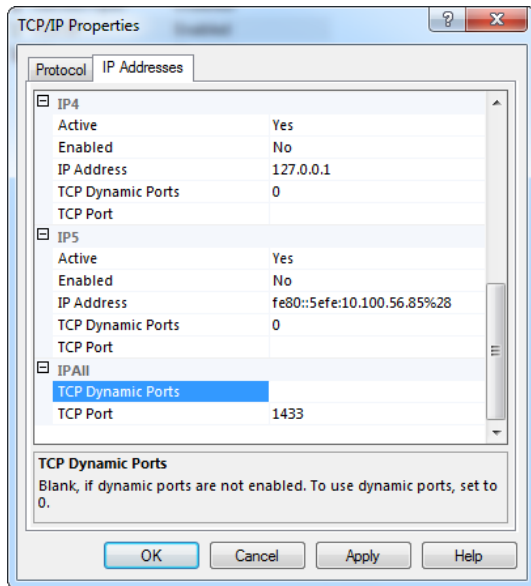
2. Select **Protocols for RGAMINSTANCE** which is a sub-item of **SQL Server Network Configuration**.



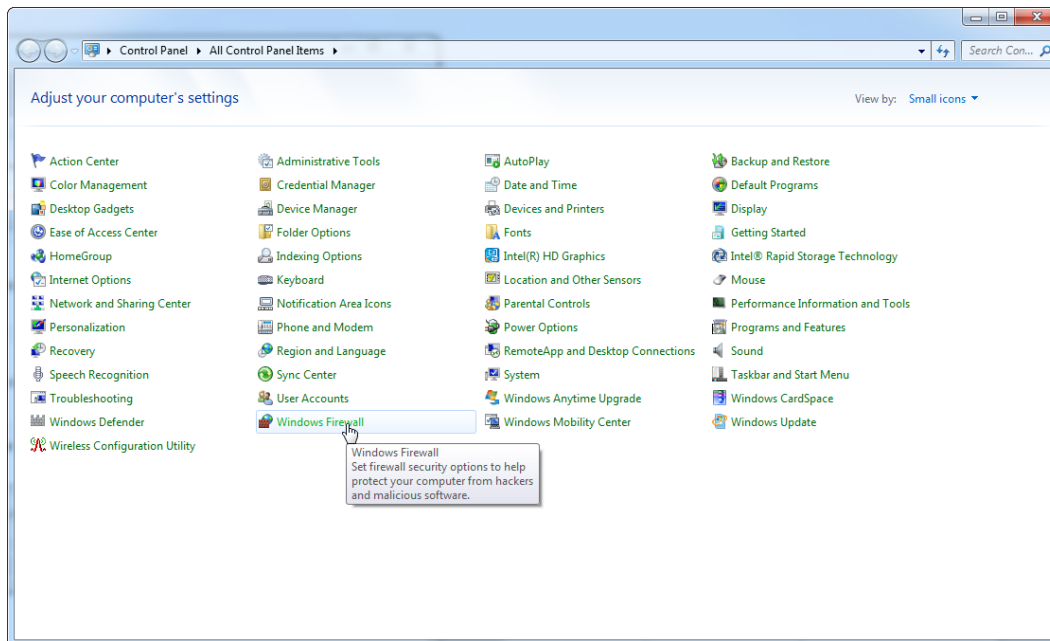
3. Hover over **TCP/IP**, right-click, then select **Properties** from the context menu.



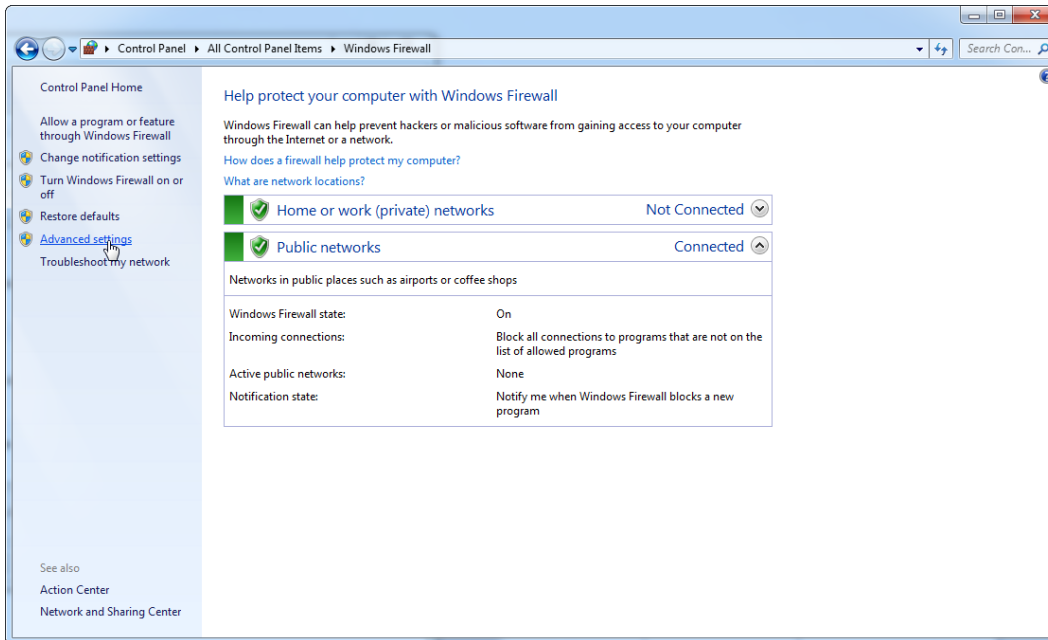
- Remove the random number at **TCP Dynamic Port** if this is predefined and add the SQL-standard port 1433 at **TCP Port**. If this port is in use, you can use any other unused port.



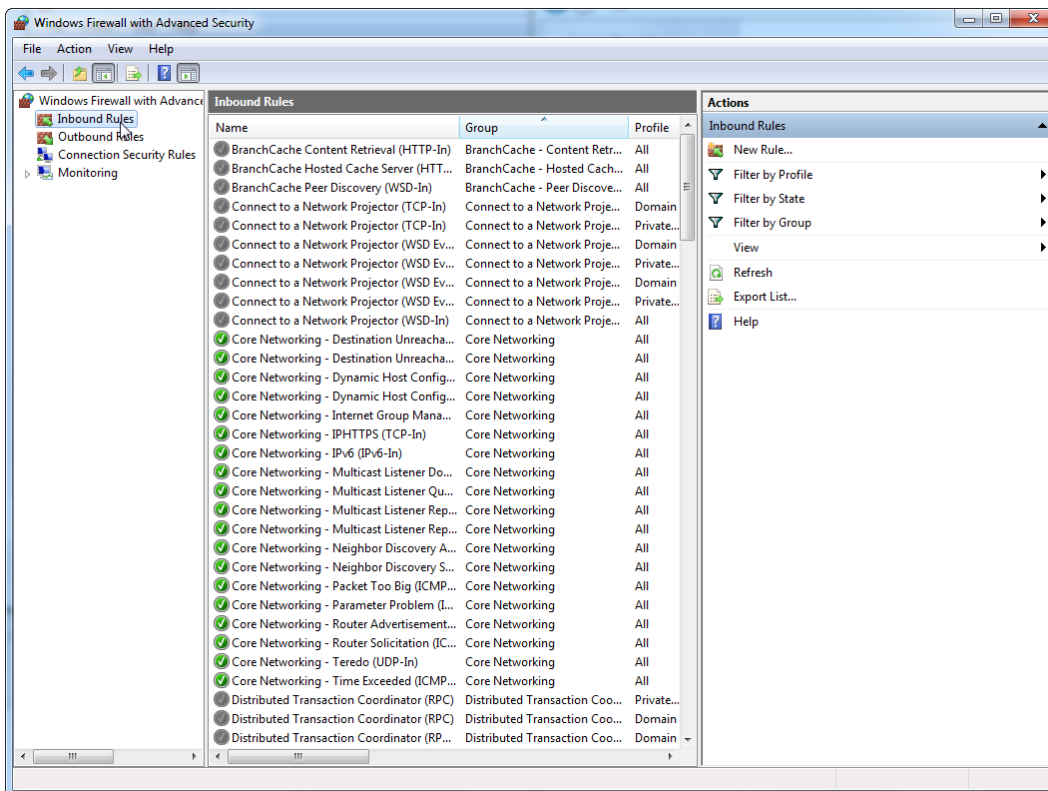
- Press **OK**, open the **Control Panel** and select **Windows Firewall**.



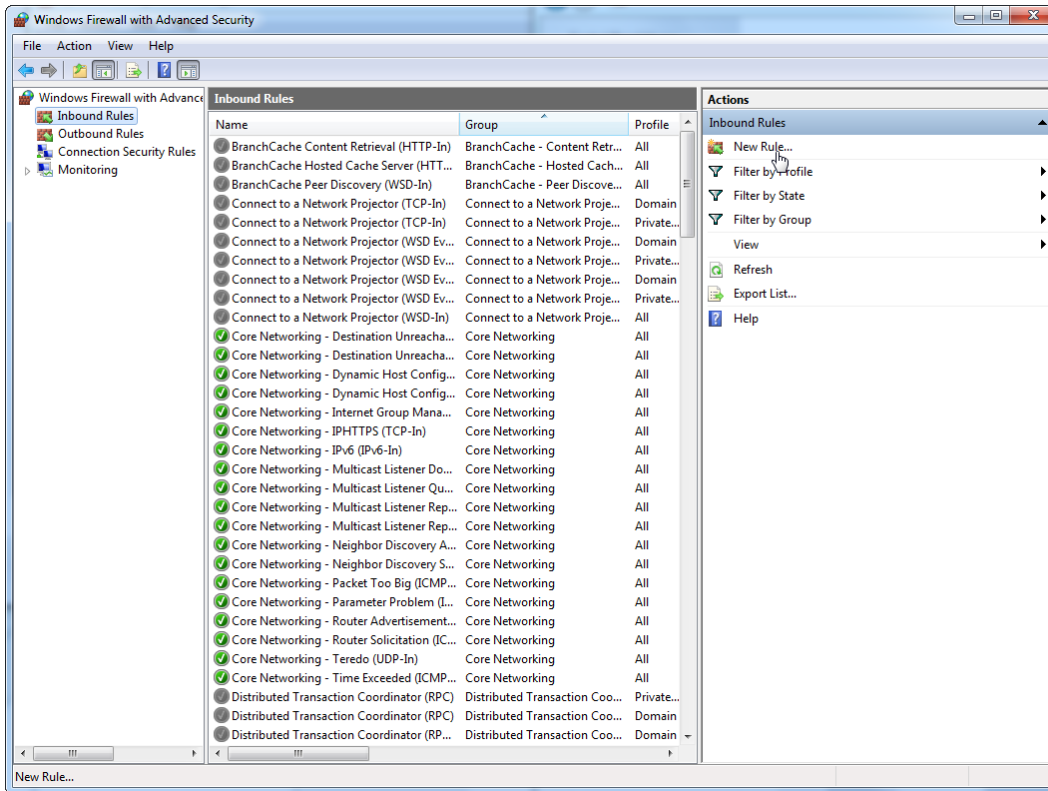
6. Select **Advanced settings**.



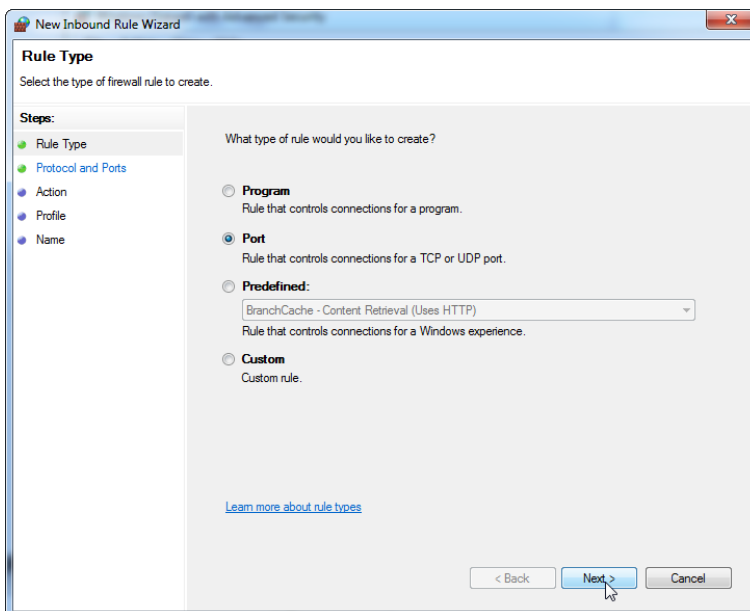
7. Open **Inbound Rules**.



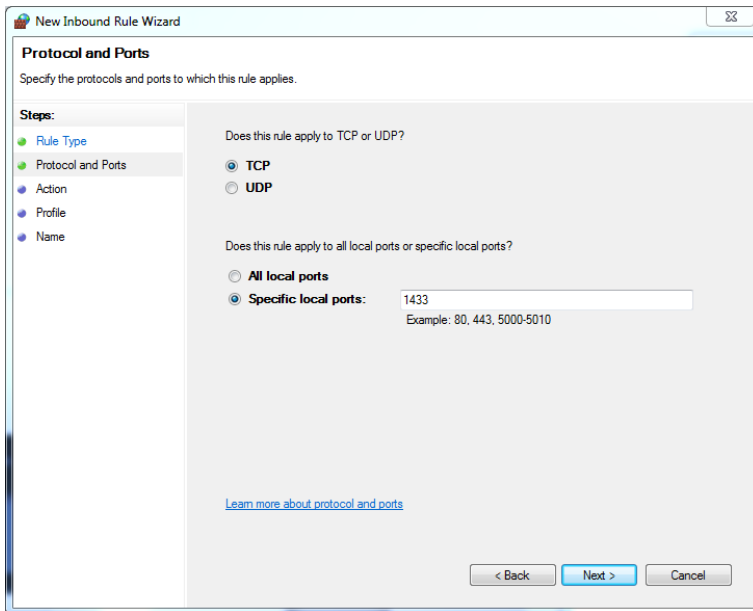
8. Select **New Rule...** from **Actions** on the right-hand side.



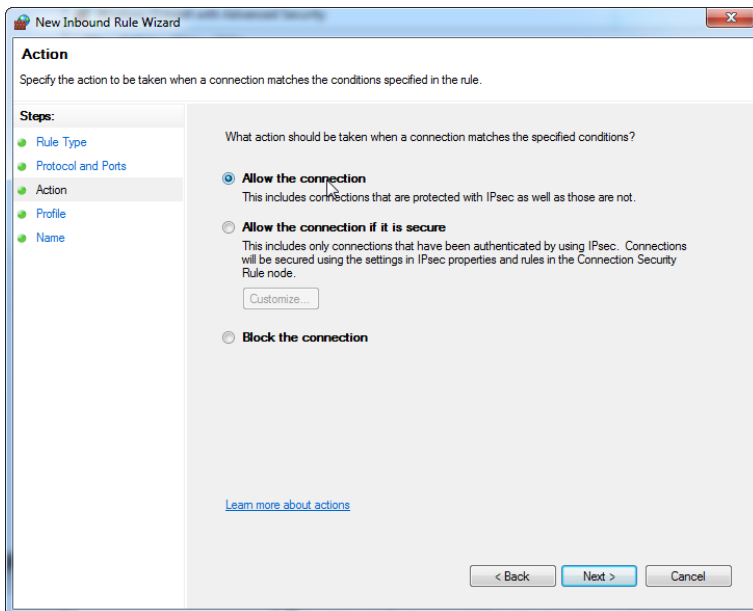
9. Select type **Port** and press **Next**.



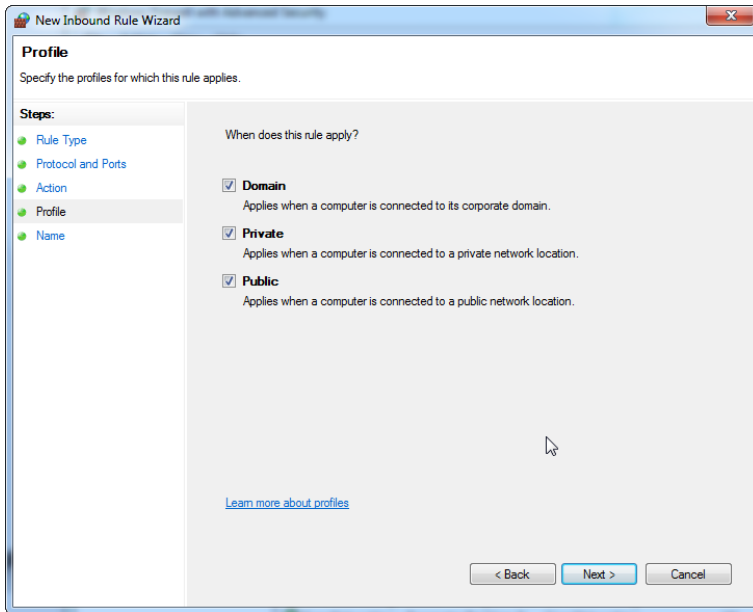
10. Select **TCP** and define the specific local port **1433** corresponding to the database. If you have defined a different port in step 4, enter this port. Press **Next**.



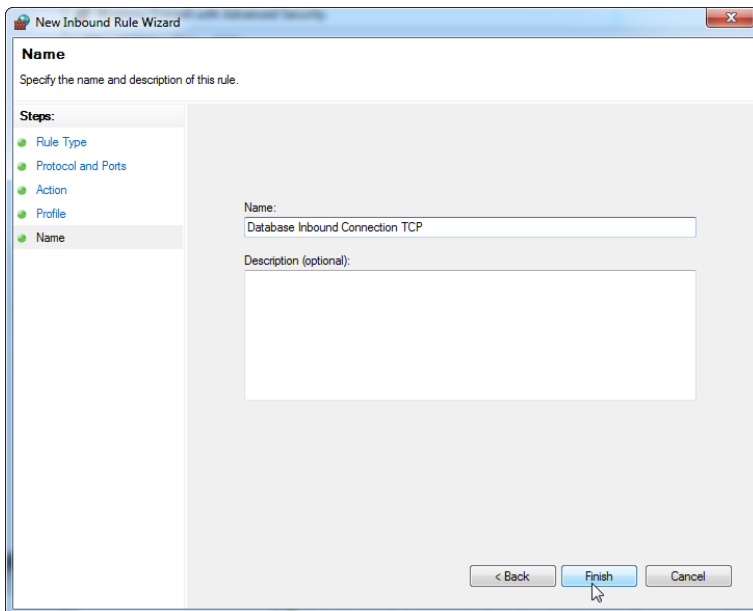
11. Select **Allow connection** and press “Next”.



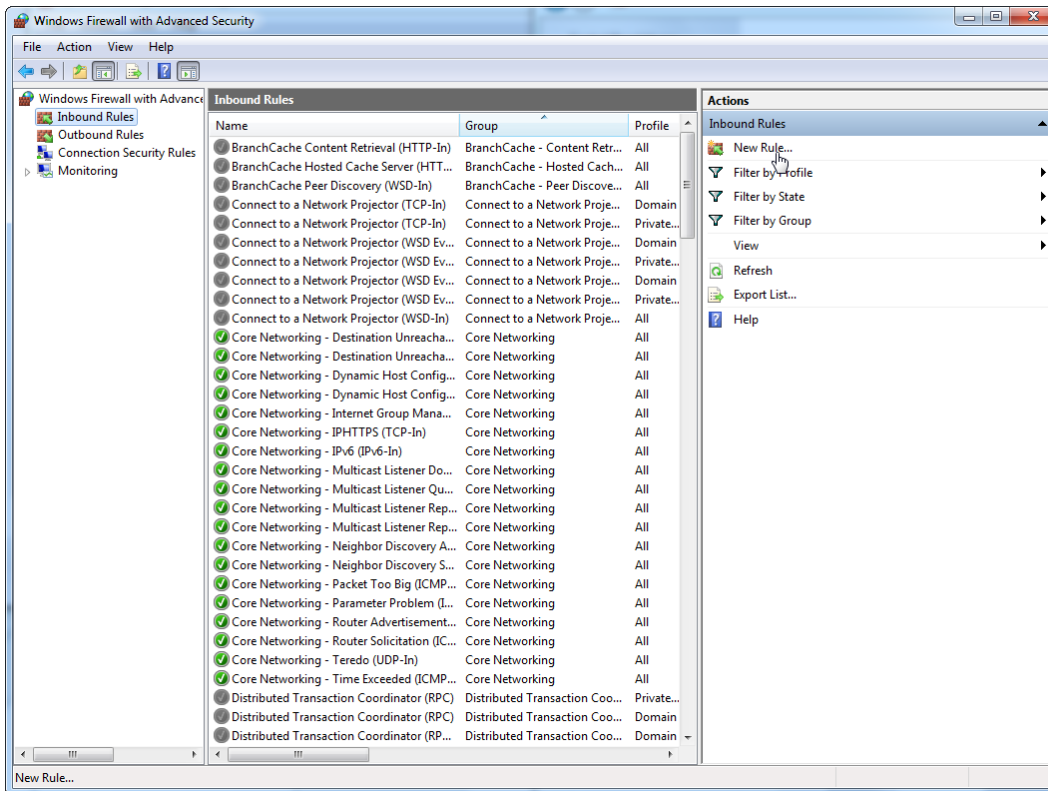
12. Check **Domain**, **Private** and **Public** and press **Next**.



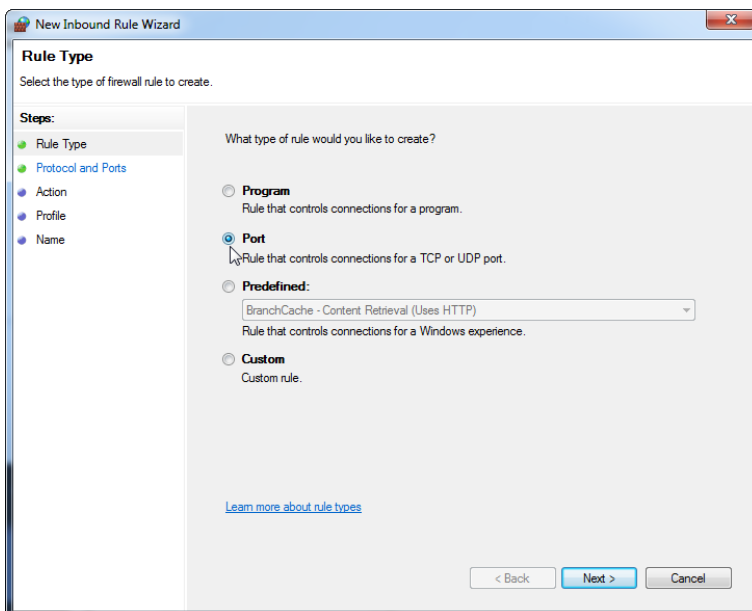
13. Define a name for the rule, e.g. "Database Inbound Connection TCP" and press **Finish**.



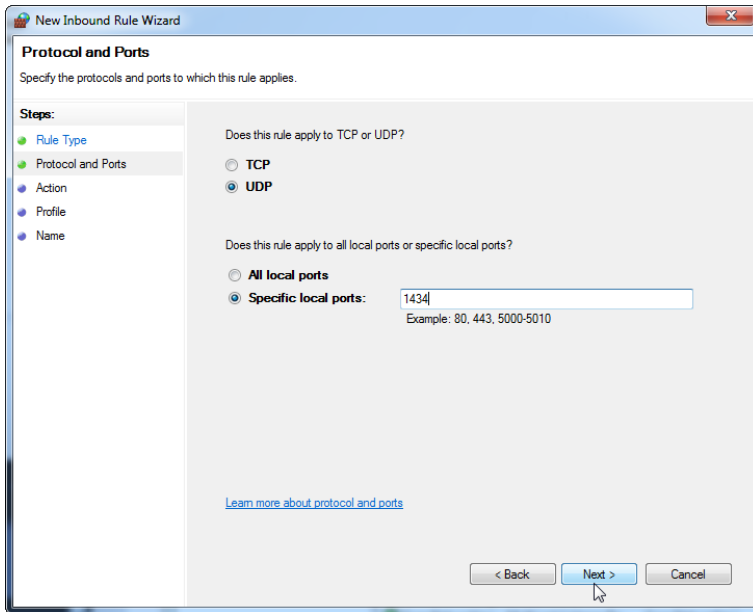
14. After the creation of the rule for the **TCP** protocol, you must define another rule for **UDP** which is set to port 1434 per default. Select again **New Rule...** from **Actions**.



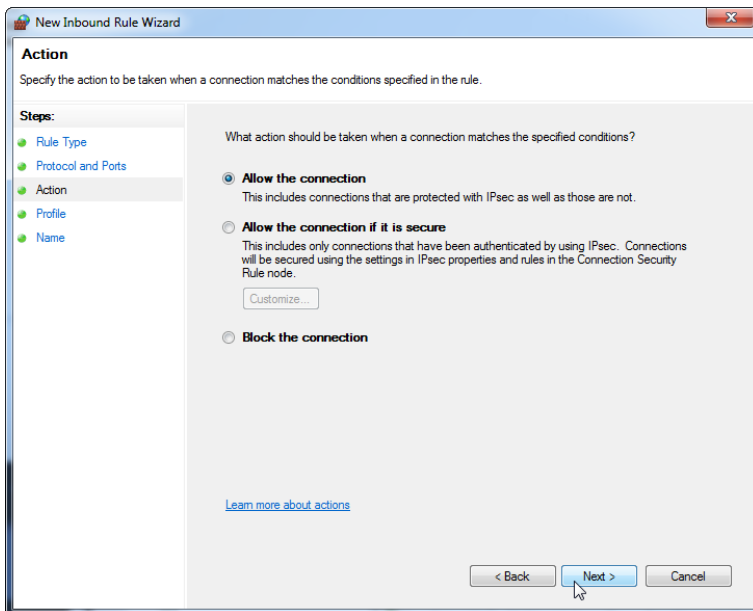
15. Select **Port** and press **Next**.



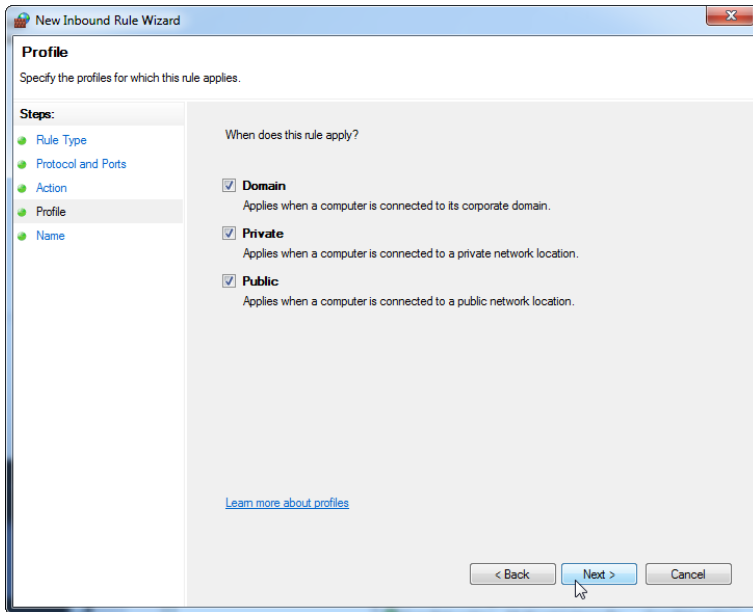
16. Select **UDP**, define the specific local port **1434** and press **Next**.



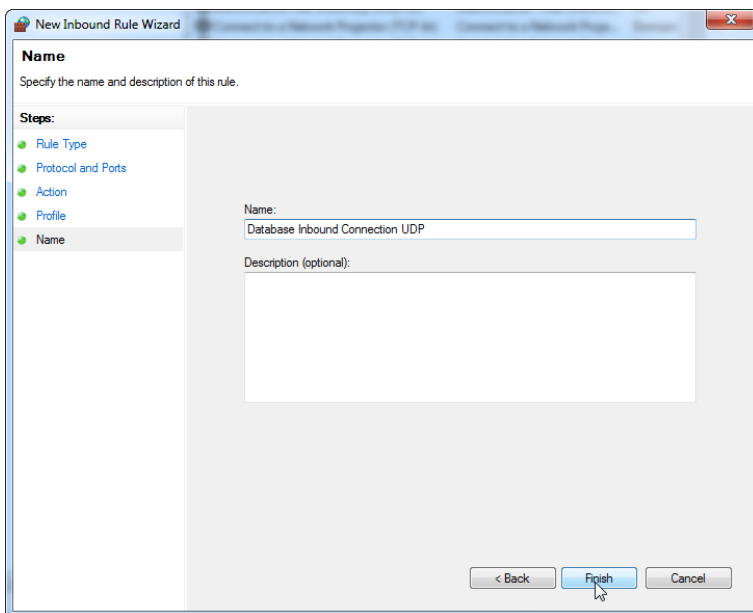
17. Select **Allow the connection** and press **Next**.



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



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

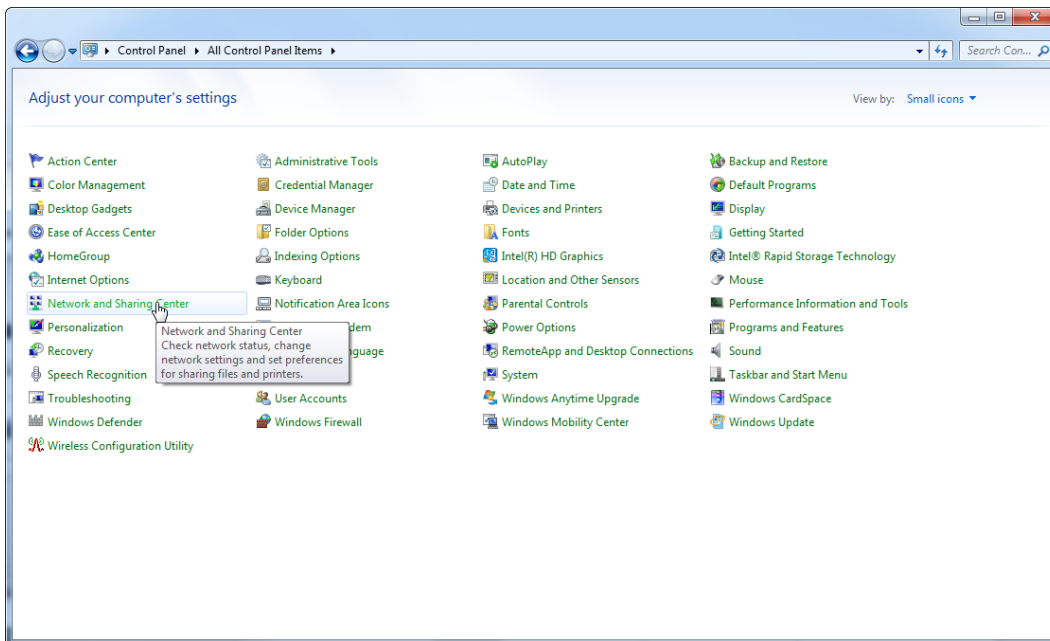


Disabling the Wi-Fi adapter

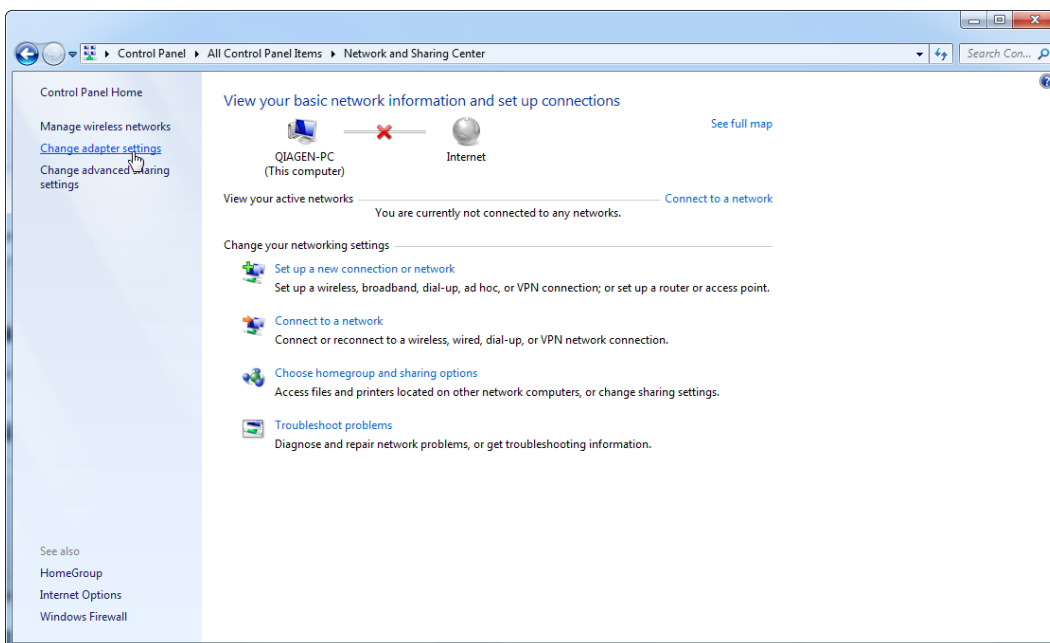
For security and reliability reasons cable-based network access instead of Wi-Fi shall be used. The laptop computers that are provided by QIAGEN have a disabled Wi-Fi adapter. If your

configuration is different, a system administrator must disable the Wi-Fi adapter manually which can be done by the following steps.

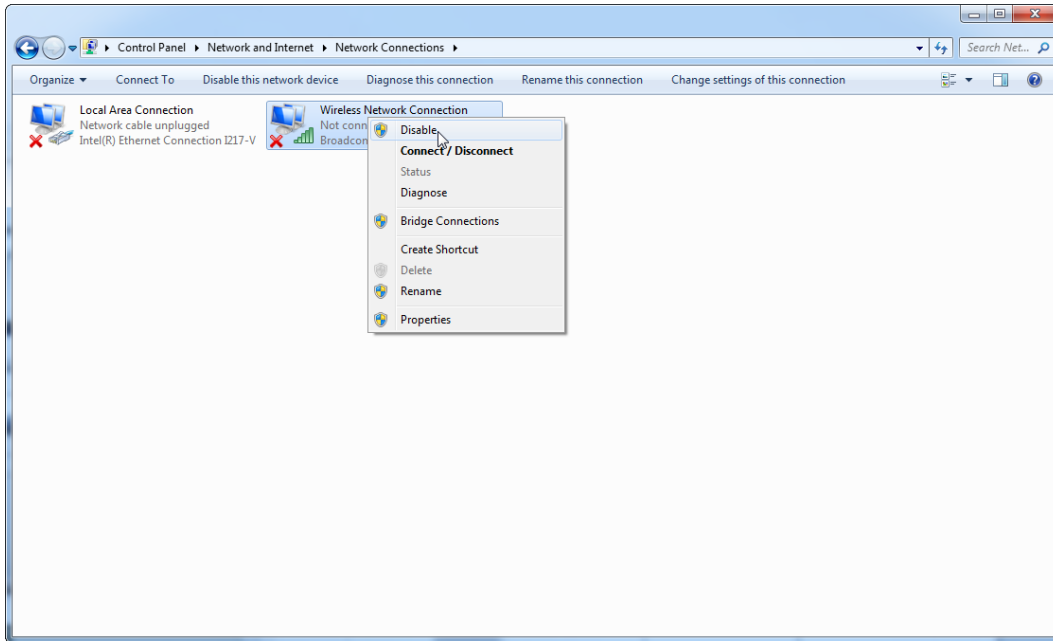
1. Open the **Control Panel** and select **Network and Sharing Center**. (On Windows 10, search for **Control Panel** to open it.)



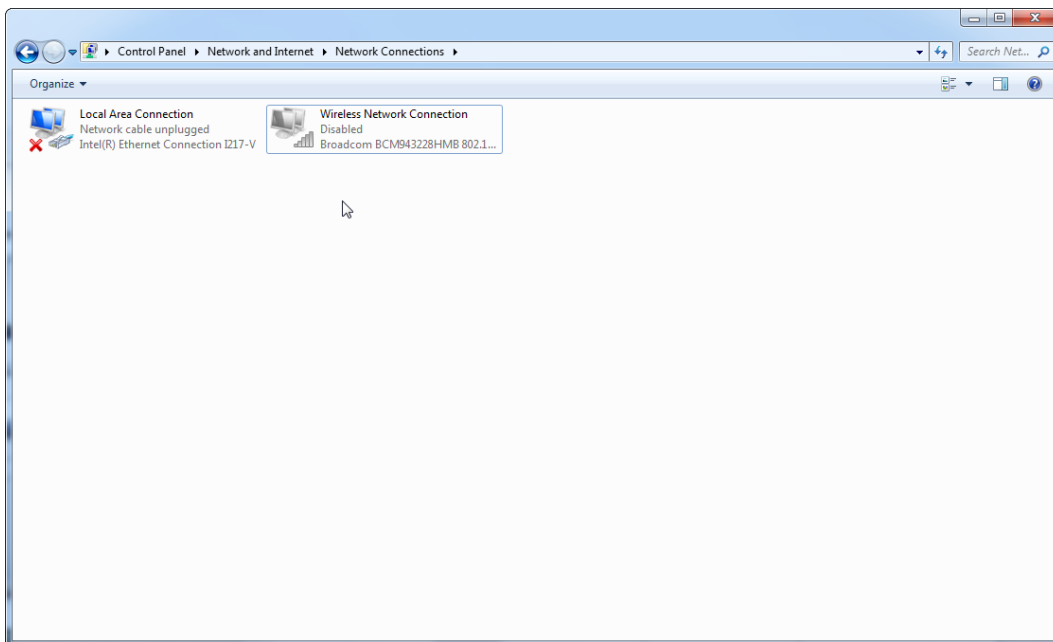
2. Select **Change adapter settings**.



3. Hover over **Wireless Network Connection**, right-click, and select **Disable** from the context menu.



4. Check that the Wireless Network Connection is disabled.



First login

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

1. Enter user ID “**admin**” and password “**admin**”.
2. Select an appropriate mode (Closed Mode or User Defined Test Mode) and confirm with **OK**.
3. Change the default password to a new, secure password.

The **Settings** tab in the **Configuration** environment will be opened.

Note: All users who do not have the “Administrator” role can ask the administrator to reset the password. If the administrator forgets the administrator password, QIAGEN Technical Services must be contacted to reset the password requiring 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 v2.1 aggregates different user roles including the “Administrator” role, there is a high risk that 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 by users with the role “Operator”.

Related topics

“Logging in and logging out” page 230.

“User management” page 87.

“**Setup** Environment,” page 117.

“**Configuration** Environment,” page 192.

License key file

A license key file is required to run Rotor-Gene AssayManager v2.1. Create and submit the key file to QIAGEN to obtain a license before the application can be used productively. Consult www.qiagen.com/Products/Rotor-GeneAssayManager_v2.1.aspx for contact information.

There are 2 types of licenses available:

- The trial license

The trial license is limited to a certain period of time. It can be used on any computer where Rotor-Gene AssayManager v2.1 is installed.

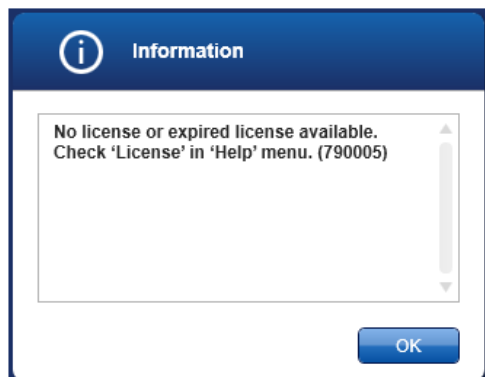
- The regular license

The regular (perpetual) license can only be used with a dedicated computer. It cannot be transferred between computers. The customer creates a file containing information which clearly identifies the computer. This information is incorporated into the "license key" which is sent back.

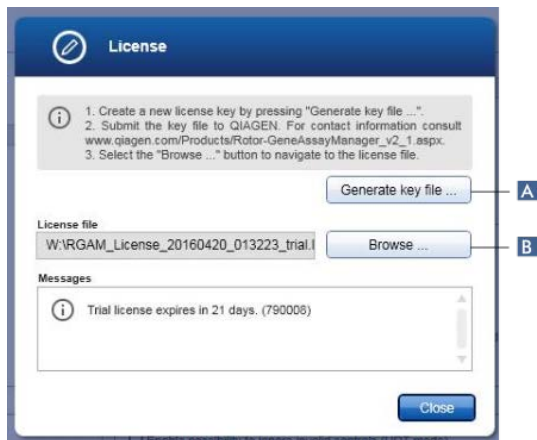
Note: An independent license key is necessary for each computer with Rotor-Gene AssayManager v2.1 installed.

License key generation

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



The appropriate dialog for handling the licenses is reachable via the **License** entry in the **Help** menu as stated in the "missing license" dialog. Click **OK** to close the window.



Create a license file via the **Generate key file** button (A) for each computer on which Rotor-Gene AssayManager v2.1 has been installed and submit it to QIAGEN to receive a license key.

License key loading

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

Basic Concepts and General Software Usage







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

Environments

Rotor-Gene AssayManager v2.1 contains different environments.

Overviews of access rights to these environments for different user roles can be found in “User roles,” page 88.

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

| Environment | Description |
|---|---|
|  Setup | Used for creation, management and application of work lists. |
|  Approval | Used to search for unreleased assays and for the release of dedicated runs. Experiment reports are created on release of run. |
|  Archive | Used to search for fully released experiments and to generate experiment reports. |
|  Service | Used to access the audit trail. |
|  Configuration | Used to adjust the settings of Rotor-Gene AssayManager v2.1. |
|  Cycler 1 | Used to stop or finish a run and to release a cycler after a run is finished. |

First configuration

Before Rotor-Gene AssayManager v2.1 can be used, the creation of user profiles and the registration of one or several Rotor-Gene Q MDx cyclers in the **Configuration** environment are essential.

For details about these tasks refer to:

“Managing users,” page 277.

“Managing cyclers,” page 272.

Concepts

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

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

Modes

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

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

Note: The UDT mode is not intended for use with FDA cleared or approved nucleic acid tests.

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

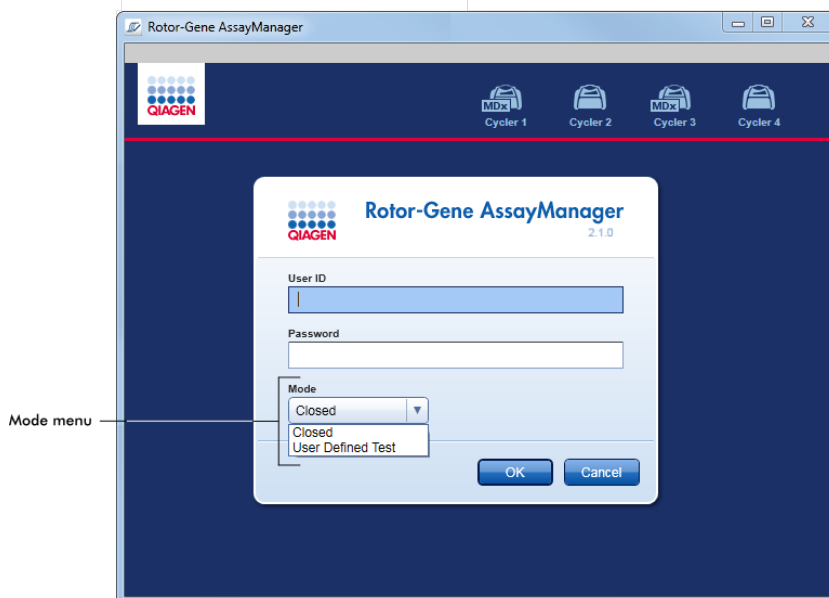
Closed mode

The Closed mode is used for assays that have been created and validated by QIAGEN. These assays can only be modified by QIAGEN. In Closed mode, assays are run and analyzed without the permission to modify the corresponding assay profiles.

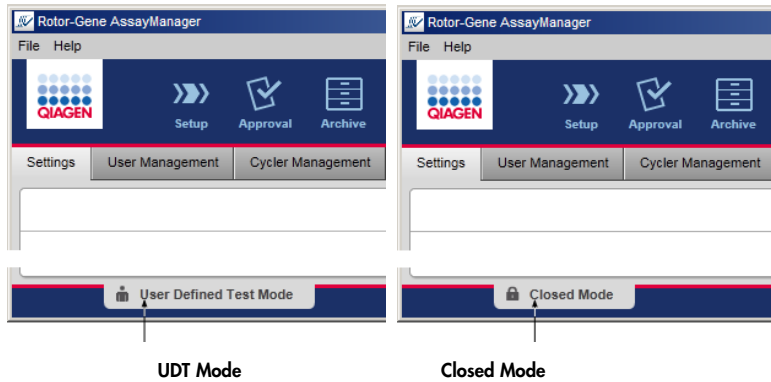
The analysis in Closed mode includes core analysis, assay and sample analysis, and depending on plug-in, also a fully automatic data scan (AUDAS).

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

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



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



Note: The UDT mode is not intended for use with FDA cleared or approved nucleic acid tests.

User management

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

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

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

Related tasks

“Creating a user profile,” page 278.

“Changing user profile settings,” page 279.

- Changing name/last name
- Changing password
- Changing role

“Activating/deactivating a user profile,” page 280.

“Setting password policies and auto-lock timer,” page 282.

User roles

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

| Role | Description |
|-----------------|--|
| Administrator | The administrator has permissions to: <ul style="list-style-type: none">● configure the system● manage users● create and edit report profiles● manage archives |
| Assay Developer | The assay developer has all necessary permissions to create an assay profile in UDT mode. Note: The assay developer has no permissions to create or modify assay profiles for FDA cleared or approved nucleic acid tests in Closed mode. |
| Operator | The operator has permissions necessary to: <ul style="list-style-type: none">● create a work list● apply the work list● view the analysis results The operator cannot release assay results. |
| Approver | The approver is the only user with permissions to release assay results. |
| Super User | The super user has all available permissions of all available roles 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 (page 230)
- Locking and unlocking (page 234)
- Changing user profile settings (page 279)

The following tables give an overview about permissions of the different user roles in the different environments.

Setup environment

| Task | Description | Admin* | Op* | Ap* | SU* |
|---------------------------------|---|--------|-----|-----|-----|
| Access Setup environment | User can enter the Setup environment | - | + | - | + |
| Apply runs | User can apply runs in the Setup environment | - | + | - | + |

* Admin: Administrator; Op: Operator; Ap: Approver; SU: Super User

Approval environment

| Task | Description | Admin* | Op* | Ap* | SU* |
|------------------------------------|---|--------|-----|-----|-----|
| Access Approval environment | User can enter the Approval environment | + | + | + | + |
| Release test results | User can release test results in the Approval environment | - | - | + | + |
| Create support package | User can create support packages in the Approval environment | + | + | + | + |

* Admin: Administrator; Op: Operator; Ap: Approver; SU: Super User

Archive environment

| Task | Description | Admin* | Op* | Ap* | SU* |
|-----------------------------------|---|--------|-----|-----|-----|
| Access Archive environment | User can enter the Archive environment | + | + | + | + |
| Create support package | User can create support packages in the Approval environment | + | + | + | + |

* Admin: Administrator; Op: Operator; Ap: Approver; SU: Super User

Service environment

| Task | Description | Admin* | Op* | Ap* | SU* |
|-----------------------------------|---|--------|-----|-----|-----|
| Access Service environment | User can enter the Service environment | + | - | + | + |
| View audit trail | User can access the audit trail in the Service environment | + | - | + | + |

* Admin: Administrator; Op: Operator; Ap: Approver; SU: Super User

Cycler environment

| Task | Description | Admin* | Op* | Ap* | SU* |
|----------------------------------|--|--------|-----|-----|-----|
| 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; Op: Operator; Ap: Approver; SU: Super User

Configuration environment

| Task | Description | Admin* | Op* | Ap* | SU* |
|---|--|--------|-----|-----|-----|
| Access Configuration environment | User can enter the Configuration environment | + | - | - | + |
| Configure system settings | User can configure all settings in the Configuration environment | + | - | - | + |
| Manage cyclers | User can access the Cycler Management tab in the Configuration environment | + | - | - | + |
| Manage users | User can access the User Management tab in the Configuration environment | + | - | - | + |
| Manage assay profiles | User can access the Assay Profiles tab in the Configuration environment | + | - | - | + |
| Manage report profiles | User can access the Report Profiles tab in the Configuration environment | + | - | - | + |

* Admin: Administrator; Op: Operator; Ap: Approver; SU: Super User

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 it is mandatory to use Clinical Laboratory Improvement Amendments (CLIA) compliant password rules. 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.

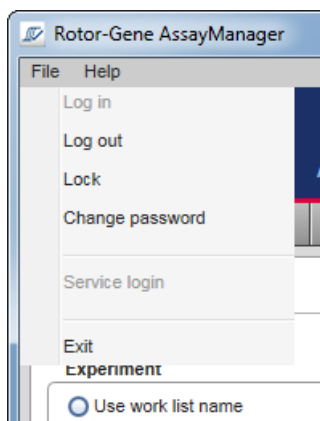
Related topics

“Setting password policies and auto-lock timer,” page 282.

Session management

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

Logging out is possible using the command from the main menu or the logout button in the status bar.



Log out from main menu



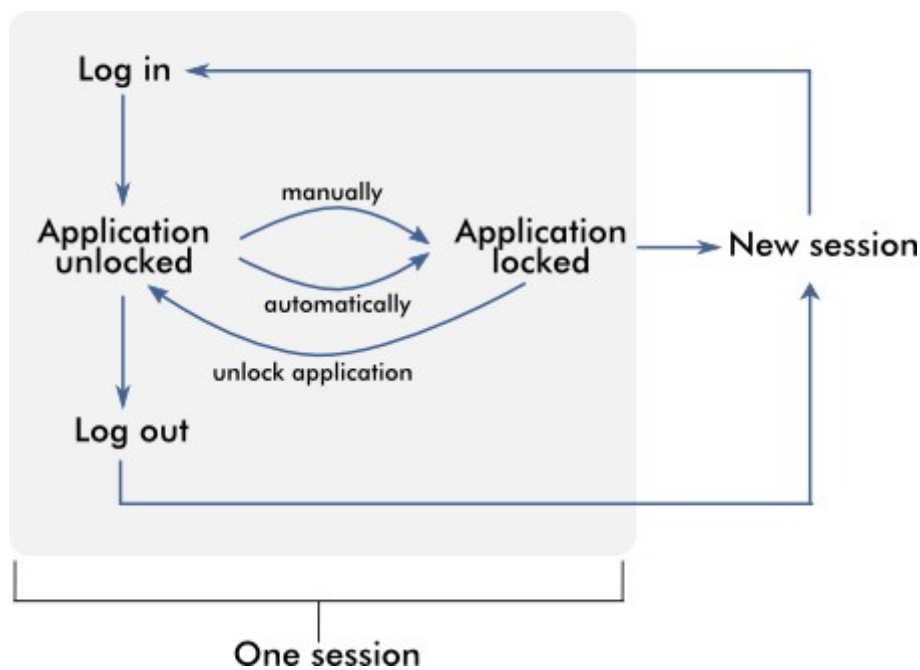
Log out from status bar

To prevent misuse, a user can lock the application. Rotor-Gene AssayManager v2.1 also has an auto-lock timer that locks the application automatically after a predefined time without user interaction (an administrator can customize the auto-lock feature (see "Setting up the auto-lock timer", page 283). If locked, the user can either continue working by unlocking the application or alternatively another user can start a new session.

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

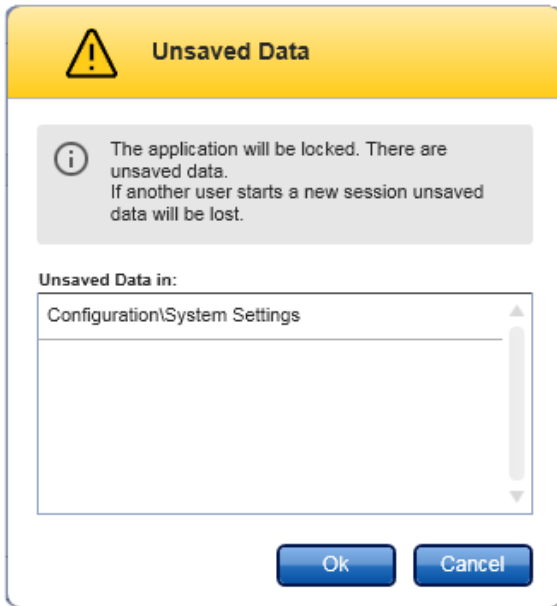
- a user logs out
- another user starts a new session
- or the application is locked (automatically or manually)

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

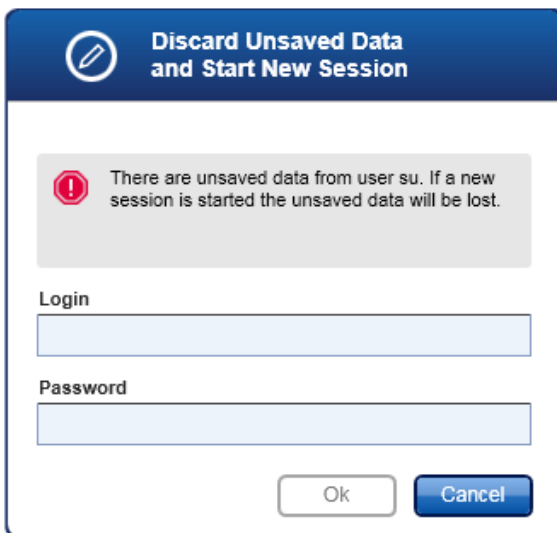


Behavior if unsaved data exist

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



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



Rotor-Gene AssayManager v2.1 and other QIAGEN products

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

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

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

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

Scenario 1:

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

Scenario 2:

If Rotor-Gene AssayManager v2.1 is started before 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 v2.1. Restart the Rotor-Gene Q software to control the cycler with the Rotor-Gene Q software.

Related topics

"Creating/editing a work list," page 237.

"Setting up a run," page 237.

Experiment vs. assay

Note: For FDA cleared or approved nucleic acid tests, an “experiment” contains 1 “assay”.

General software usage

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

Use of color

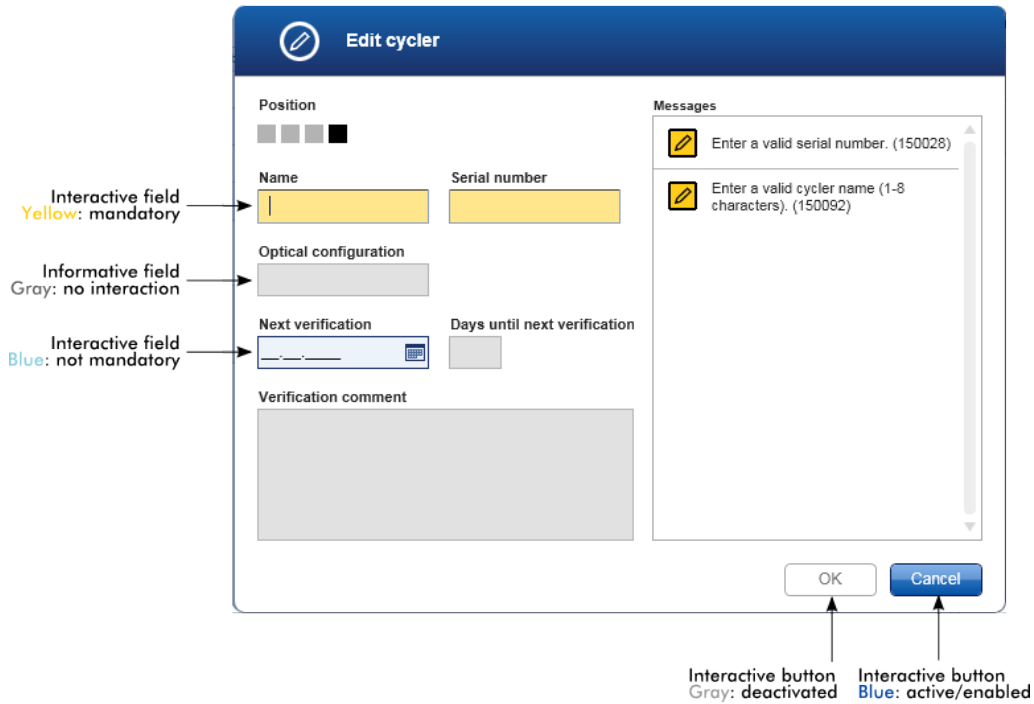
For an optimal user interaction, Rotor-Gene AssayManager v2.1 has a specific color concept for presenting information and intuitive guiding.

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

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

Example 1

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







Example 2

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

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

Displaying errors and warnings

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

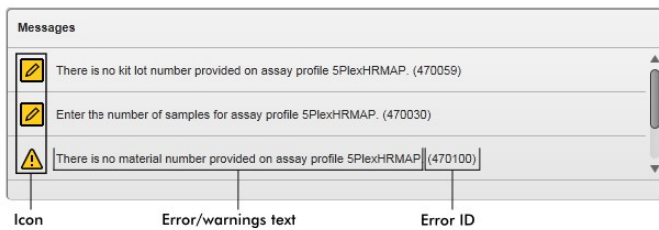
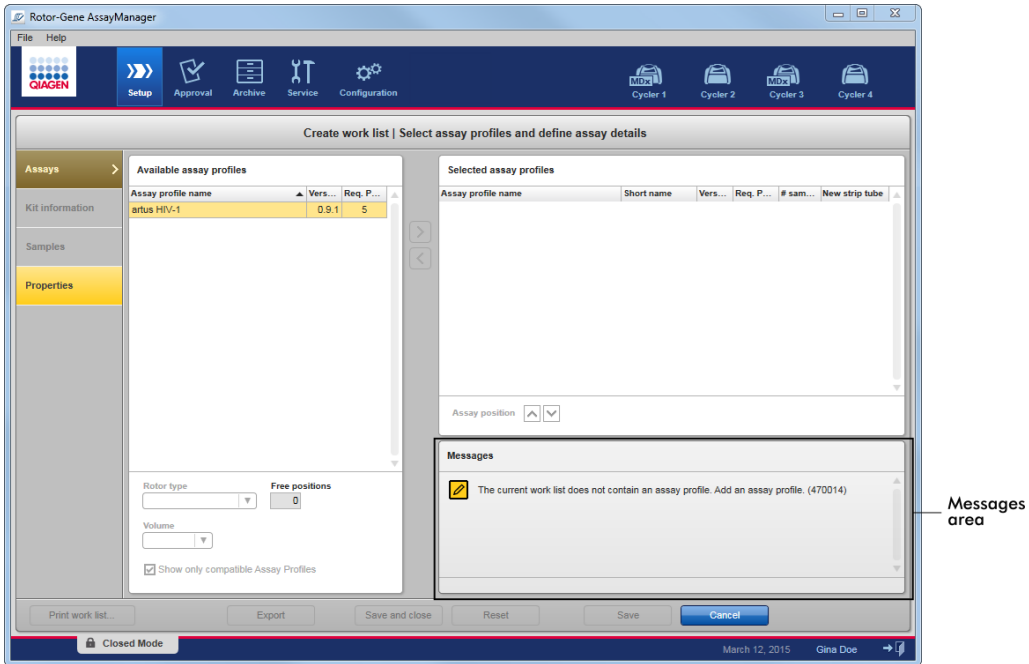
| Priority | Name | Icon | Description | Action by user |
|----------|------------------|--|--|---|
| 1 | System error |  | A combination of not acceptable incidents. | User interaction required. |
| 2 | Validation error |  | An error that occurs due to a missing or invalid user input. | User interaction 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.

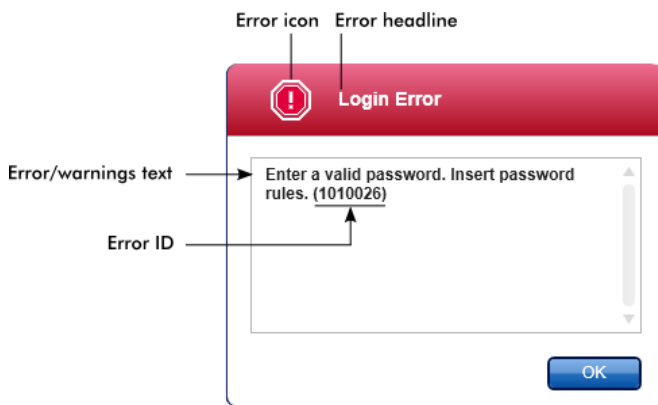
Messages area

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.

Note: The screenshots are shown as examples and may appear differently.



Detailed view of the Messages area



Error messages pop-up window

Note: Each error ID is unique. In case QIAGEN Technical Services needs to be contacted for troubleshooting, have the error ID ready. Screenshots of the error-containing GUI can be useful.

Entering data

Shortcuts

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

- 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:

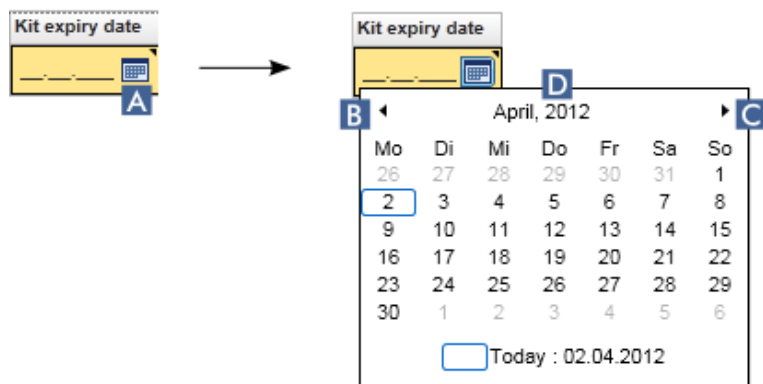
| Selected assay profiles | | | | | |
|-------------------------|------------|---------|-----------|----------|-------------------------------------|
| Assay profile name | Short name | Vers... | Req. P... | # sam... | New strip tube |
| artus HIV-1 | HIV_a | 0.9.1 | 5 | | <input checked="" type="checkbox"/>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

Interactive fields:
Yellow = mandatory field
Blue = not mandatory

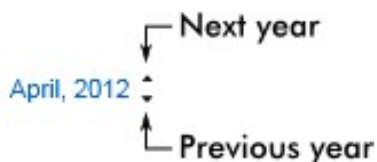
Date picker: Entering date in date fields

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

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



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



Entering a date using the date picker

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

The calendar pop-up is shown.


Continue using the following scheme:

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

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

Working with tables

Sorting tables

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



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

Ascending sorting



The table is sorted by the selected column in descending order.

Descending sorting

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

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

Sort indicator icon

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

Selecting cells

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

Copying data from a table

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

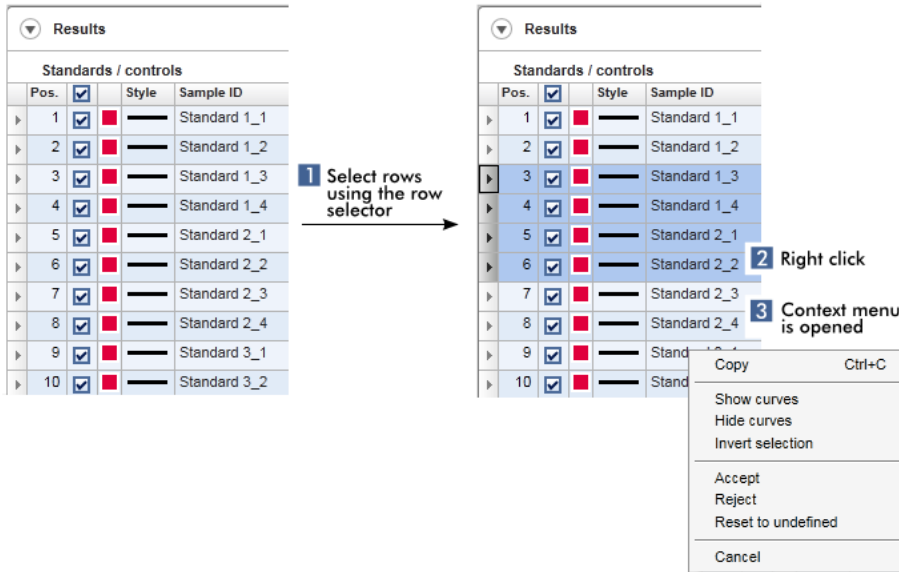
| Assay selection | | | |
|----------------------------|----------------------|----------------------------|-----------|
| <input type="checkbox"/> | Experiment | Assay | # samples |
| ▶ <input type="checkbox"/> | QF Pat_20120417_0949 | QuantiFast Pathogen PCR... | 66 |
| ▶ <input type="checkbox"/> |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

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

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

Context menu

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



Working with graphs

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

Tasks covered in this section related to working with graphs:

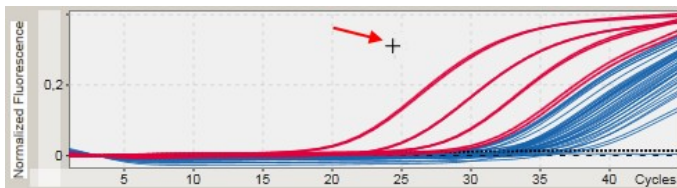
- Zooming in
- Zooming out
- Panning
- Selecting/deselecting samples
- Sample information in graphs

Zooming in a graph

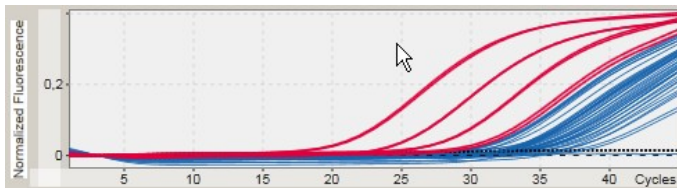
For zooming in a graph in Rotor-Gene AssayManager v2.1, an individual zoom area can be selected as in the following example of an amplification plot from the **Approval** environment.

Zooming in a graph

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

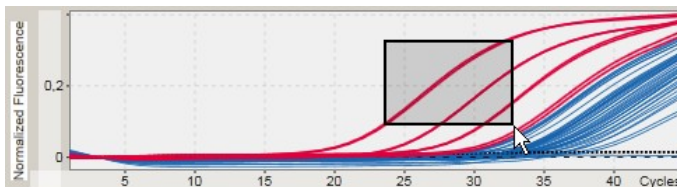


2. (a) Click and hold down the left mouse button. The mouse icon changes from cross hairs to the cursor icon.



- (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.



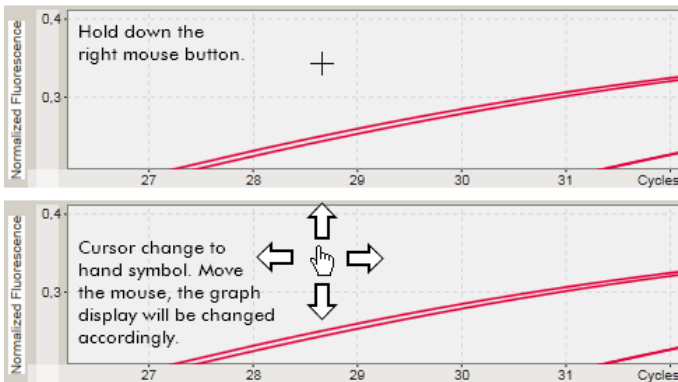
- (c) Release the left mouse button. The following menu pops up:



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.

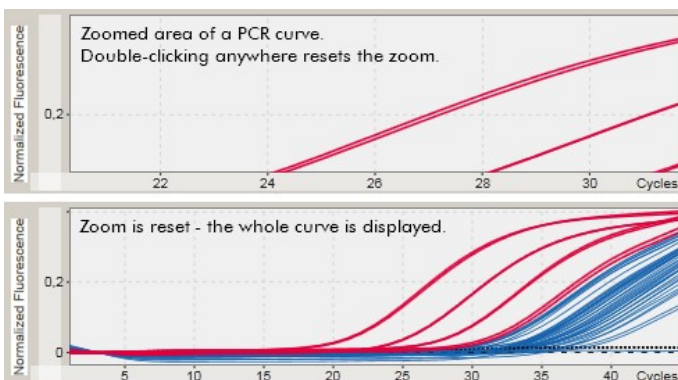


Zooming out a graph

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.



Selecting/deselecting samples

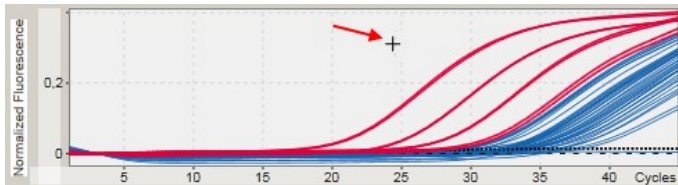
Rotor-Gene AssayManager v2.1 provides 2 methods to select or deselect samples in an amplification plot:

- Using a graph
- Using check boxes

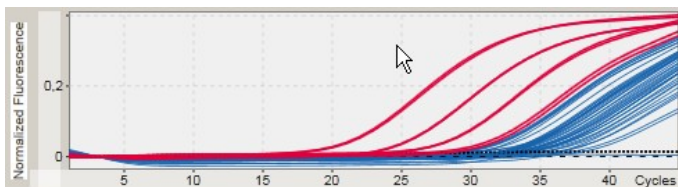
Selecting/deselecting samples using a graph

1. Move the cursor over the graph area.

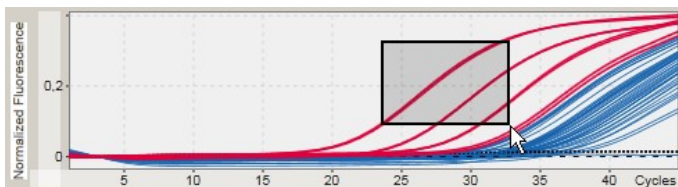
The mouse cursor icon changes to cross hairs.



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





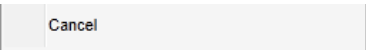
- (b) Drag the cursor until the end of the area to zoom in. A dark gray rectangle visualizes the selected area, as long as the left mouse button is held down.



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



3. 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 |  |

Select/deselect samples using check boxes

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

| Results | | | |
|----------------------|--------------------------|-------|--------------|
| Standards / controls | | | |
| Pos. | | Style | Sample ID |
| ▶ 1 | <input type="checkbox"/> | ■ | Standard 1_1 |
| ▶ 2 | <input type="checkbox"/> | ■ | Standard 1_2 |
| ▶ 3 | <input type="checkbox"/> | ■ | Standard 1_3 |
| ▶ 4 | <input type="checkbox"/> | ■ | Standard 1_4 |
| ▶ 5 | <input type="checkbox"/> | ■ | Standard 2_1 |
| ▶ 6 | <input type="checkbox"/> | ■ | Standard 2_2 |
| ▶ 7 | <input type="checkbox"/> | ■ | Standard 2_3 |
| ▶ 8 | <input type="checkbox"/> | ■ | Standard 2_4 |

To

Select all samples in the table

Select a specific sample in the table

Deselect all samples in the table

Deselect a specific sample in the table

Do

Activate the check box in the column header **(A)**

Activate the check box in the corresponding sample row **(B)**

Deactivate the check box in the column header **(A)**

Deactivate the check box in the corresponding sample row **(B)**

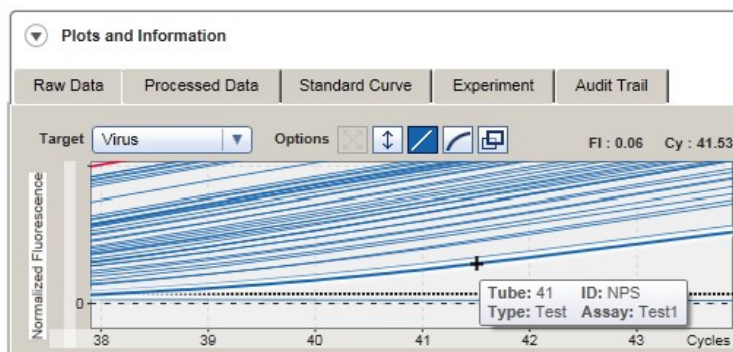
Note: The check box icon in the column header changes depending on the number of selected samples.

- No sample is selected
- One or more samples are selected
- All samples are selected

Sample information in graphs

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

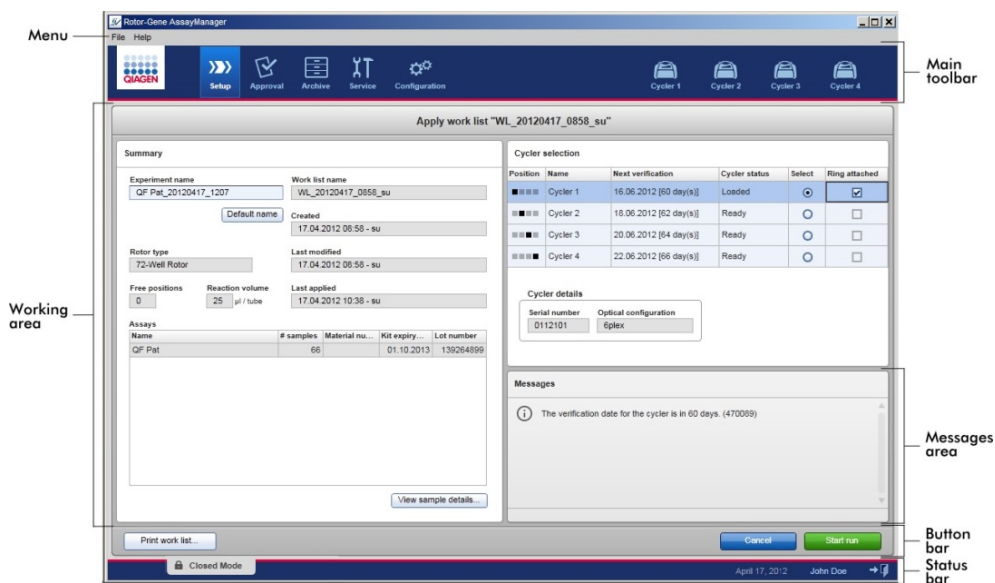
- Tube number
- Sample ID
- Assay type
- Assay short name



Rotor-Gene AssayManager v2.1 workspace

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

- **Setup** environment
- **Approval** environment
- **Archive** environment
- **Service** environment
- **Configuration** environment
- **Cycler** environment



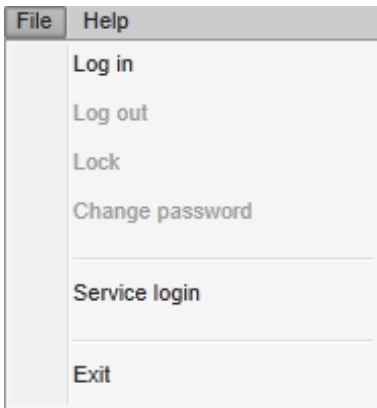
The workspace of an environment consists of an **environment-specific working area** and of the following general elements:

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

These general graphic user interface elements are described in the following sections.

Menu

File menu

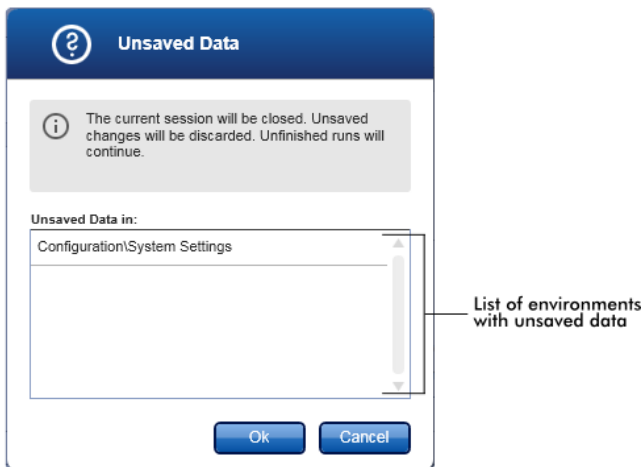


Log in

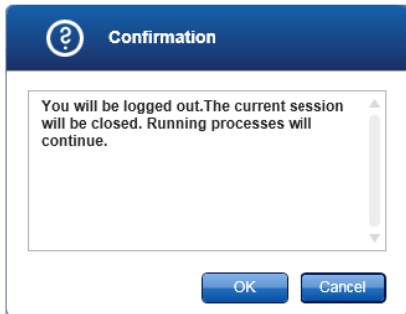
Select **Log in** to log in to Rotor-Gene AssayManager v2.1. This option is grayed out if a user is already logged in.

Log out

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



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



Lock

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

Change password

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

Service login

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

Exit

Selecting **Exit** closes Rotor-Gene AssayManager v2.1. If there are unsaved data, a warning will appear.

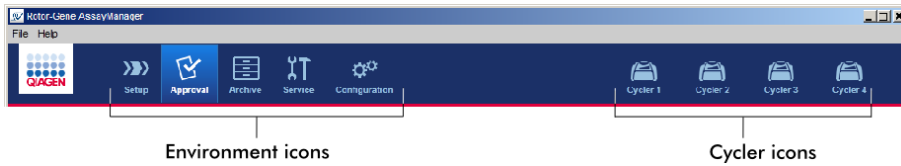
Help menu

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

Main toolbar

The main toolbar contains 2 areas:

- Environment icons
- Cyclor icons



Environment icons

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

Rotor-Gene AssayManager v2.1 has a number of different environments.

- **Setup** environment (page 117)
- **Approval** environment (page 161)
- **Archive** environment (page 182)
- **Service** environment (page 186)
- **Configuration** environment (page 192)

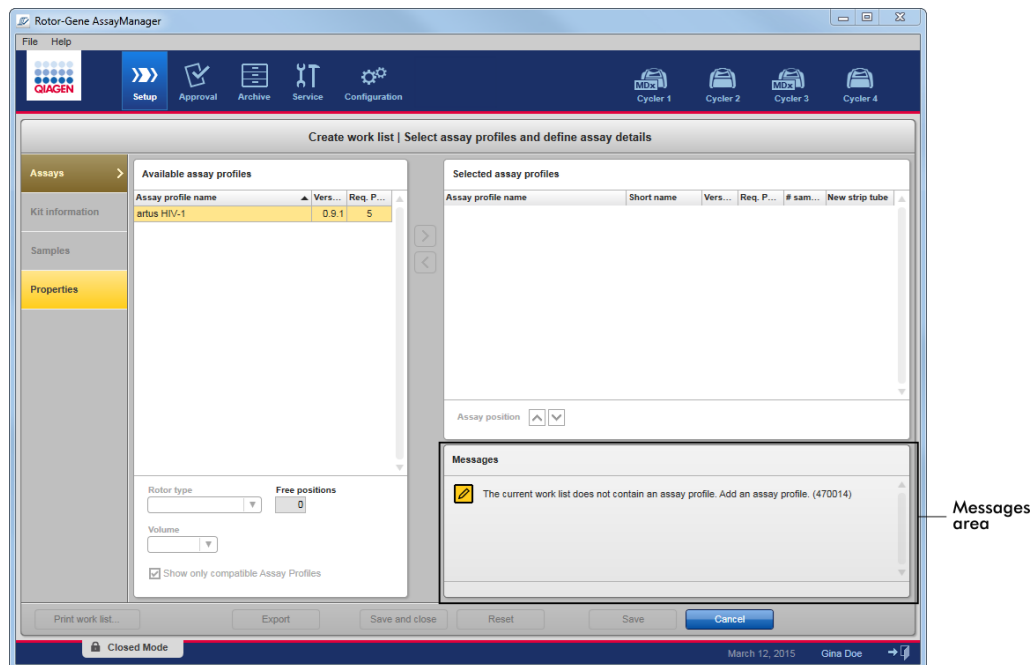
Cycler icons

The cycler icons visualize the up to 4 registered cyclers managed by Rotor-Gene AssayManager v2.1. Clicking a cycler icon changes the screen to the corresponding cycler screen. For details, see “**Cycler Environment**,” page 150.

Messages area

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

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



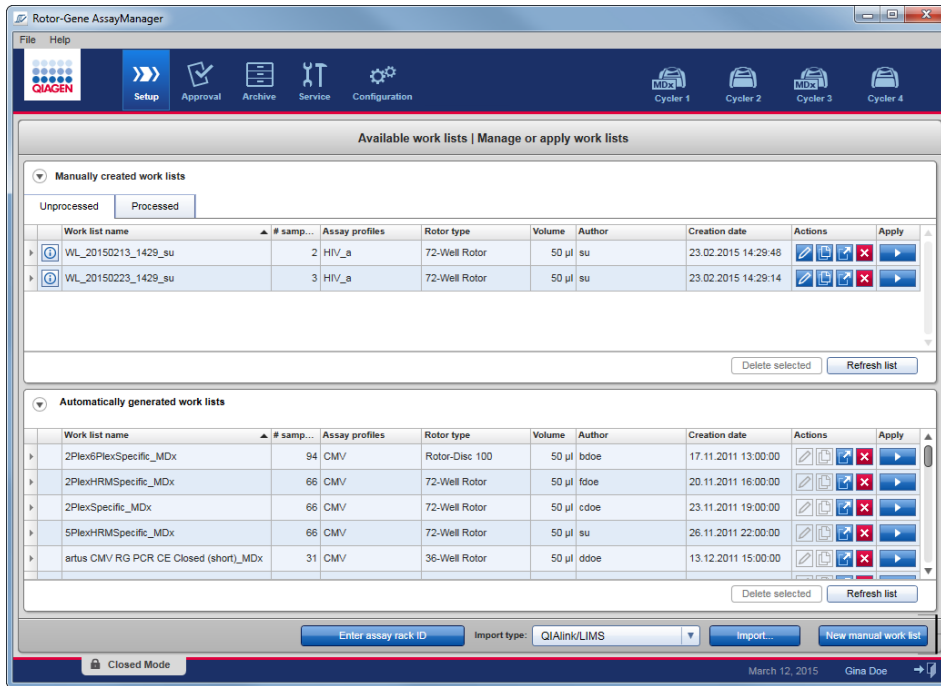
Related topics

"Use of color," page 96.

"Displaying errors and warnings," page 98.

Button bar

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

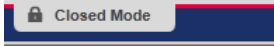
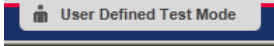


Button bar

Status bar

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



| Status bar element | Explanation |
|--------------------|--|
| Mode indicator | <p>Indicates the current user mode, i.e., Closed mode or User Defined Test mode (UDT mode)</p> <p>If the user is logged in in Closed mode, the label Closed Mode and the corresponding icon is shown.</p>  <p>If the user is logged in in User Defined Test mode, the label User Defined Test Mode and the corresponding icon is shown.</p>  <p>Note: The User Defined Test mode is not intended for use with FDA cleared or approved nucleic acid tests.</p> |
| 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

“Modes,” page 85.

“Logging in and logging out,” page 230.

Setup Environment

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

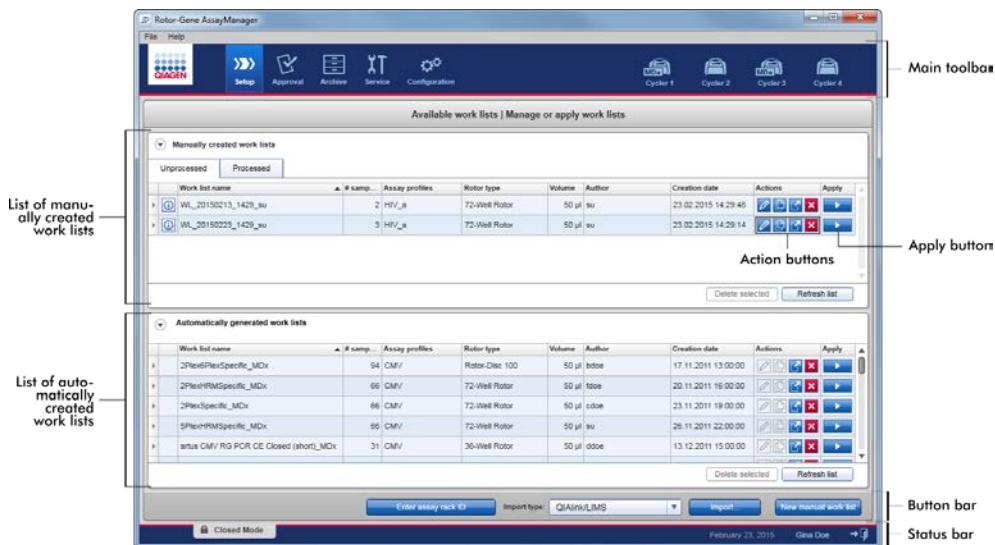
| Screen | Assigned tasks |
|---|--|
| Available work lists | <ul style="list-style-type: none">● Creating a new work list |
| <ul style="list-style-type: none">● Manually created work lists● Automatically generated work lists | <ul style="list-style-type: none">● Importing a work list*● Editing a work list● Duplicating a work list● Exporting a work list● Deleting a work list● Applying a work list |
| Apply work list | Set up run and apply a work list |
| Create/Edit work list | Create (or edit) a work list: |
| <ul style="list-style-type: none">● Assays step● Kit information step● Samples step● Properties step | <ul style="list-style-type: none">● Appears after clicking New manual work list● Starts the process to create a work list |

***Note:** The task "Importing a work list" is not intended for use with FDA cleared or approved nucleic acid tests.

Available work lists view

The **Available work lists** view contains 3 areas:

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



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 table with available manually created work lists is further subdivided into unprocessed and processed work lists. Click on the corresponding tab to display the **Unprocessed** and **Processed** work lists.

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

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

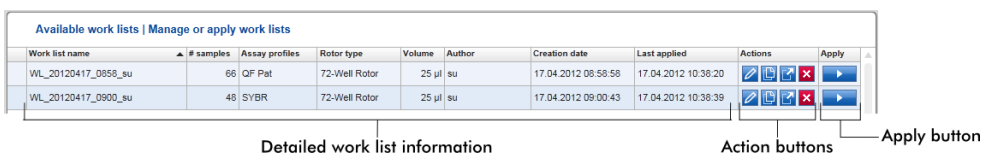
| Icon | Description |
|---|--|
|  | Deactivated assay profile or expired kit |
|  | Message: "This work list contains invalid samples" A work list contains invalid samples. This message is used only for imported work lists. |
|  | The work list is currently locked |





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




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




In the far-right columns of a work list, the **Actions** buttons and the **Apply** button can be found.




| 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 |  |  |

Actions buttons

| Icon | Label/title | Description |
|---|-----------------------|---|
|  | 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 QIA Symphony or LIMS to the software cannot be edited. See "Creating/editing a work list," page 237. |


| Icon | Label/title | Description |
|---|----------------------------|---|
|  | Duplicate work list | <p>Creates a copy of the selected work list. This copy can subsequently be edited in the Edit work list view.</p> <p>Note: All modifications are temporary until the new work list is saved.</p> <p>Note: This icon is disabled for work lists imported from QIASymphony or LIMS.</p> <p>See “Creating/editing a work list,” page 237.</p> |
|  | Export work list | <p>Exports the work list as an *.iwl file. The intended use of this function is to exchange work lists between different Rotor-Gene AssayManager v2.1 installations using the import/export function.</p> |
|  | Remove work list | <p>Removes the work list from the system. A warning must be confirmed before the work list is deleted.</p> |

Apply work list button

| Icon | Label/title | Description |
|---|------------------------|--|
|  | Apply work list | <p>The work list is applied (i.e., the run is performed) and further details have to be entered in the Run work list view.</p> <p>Note: This button is enabled if the work list is set as ready to be applied and if the work list is not locked.</p> <p>See “Apply work list view,” page 124.</p> |

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 at regular intervals:

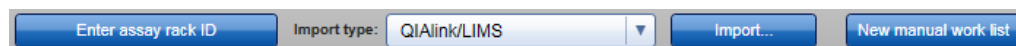
1. Click the **Remove work list** button (.
2. Confirm the warning **Work List Removal** by clicking **OK**. The deleted work list disappears from the **Available work lists** table.

3. Repeat these steps for any other work list you want to remove.

Note: The **Automatically created work lists** table cannot be edited or duplicated; it is generated automatically based on a QIASymphony AS result file.

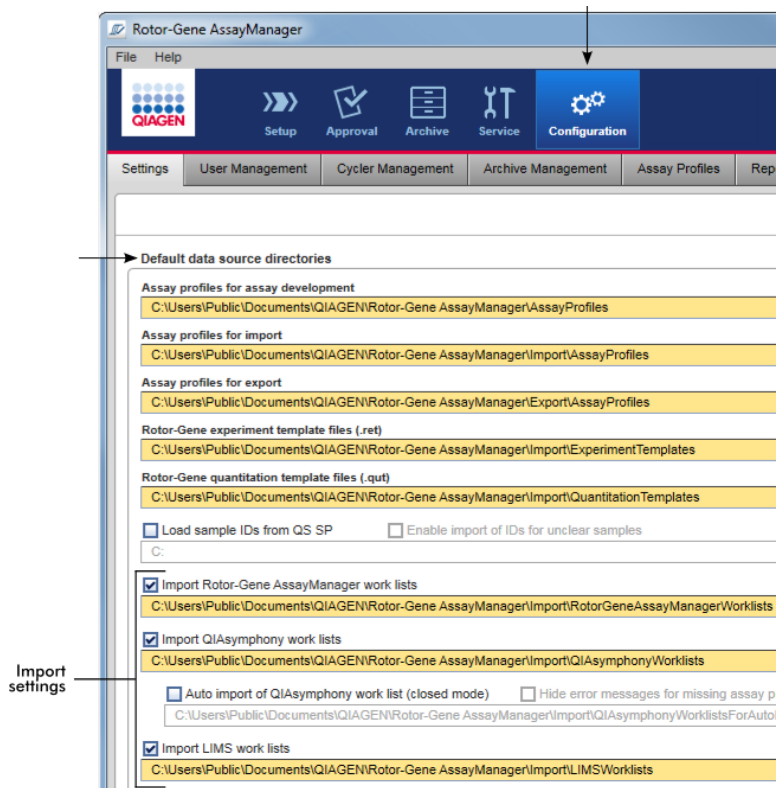
Button bar

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



| Label/title | Description |
|-----------------------------|---|
| Enter assay rack ID | <p>Enter manually or scan an assay rack ID used in QIASymphony AS. The corresponding work list will be automatically selected.</p> <p>Note: The corresponding work list must be imported to use this functionality.</p> <p>Note: QIASymphony work list import is not intended for use with FDA cleared or approved nucleic acid tests.</p> |
| New manual work list | <p>Create a work list. This button links to the Create work list screen.</p> |
| Import | <p>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 Import type.</p> |
| Import type | <p>Drop-down menu to select the import source file type for the import work list command. Rotor-Gene AssayManager v2.1 can import work lists from QIAlink/LIMS, QIASymphony and other Rotor-Gene AssayManager 2.1 installations. In addition, an automatic QIASymphony work list functionality can be defined.</p> <p>Possible values:</p> <ul style="list-style-type: none">QIAlink/LIMSQIASymphonyRotor-Gene AssayManager <p>Note: QIASymphony work list import is not intended for use with FDA cleared or approved nucleic acid tests.</p> |

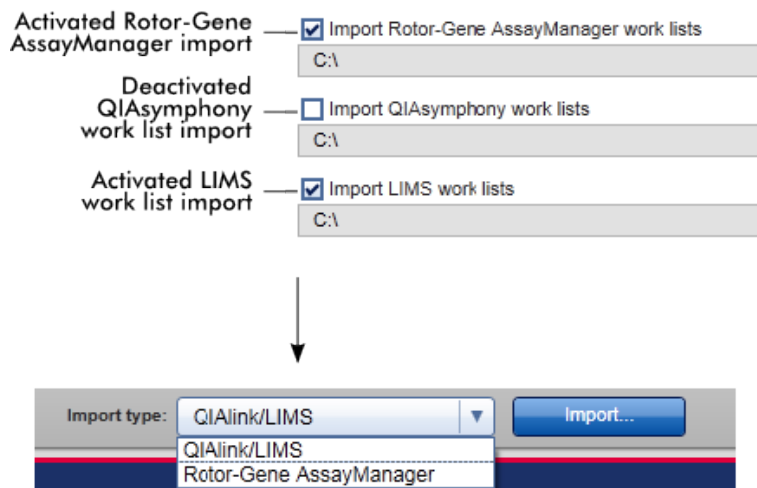
The entries in the **Import type** menu depend on the import settings in the **Configuration** environment.



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

A check box related to each of the 3 import settings activates the corresponding import setting. If the check box is activated, the import of this specific work list is enabled. The **Import type** drop-down list in the **Setup** environment is populated with these import setting options.

Example:



The **Import QIASymphony work lists** option is deactivated in the example above. The QIASymphony import option does not appear in the **Import type** menu.

A function can be selected for automatic import of QIASymphony work lists. By checking **Auto import QIASymphony work list (closed mode)**, the software checks every minute in the defined source directory and imports an available work list automatically.

Note: QIASymphony work list import is not intended for use with FDA cleared or approved nucleic acid tests.

Tasks related to the **Available work lists** view

“Creating/editing a work list,” page 237.

“Importing a work list,” page 247.

“Exporting a work list,” page 250.

Apply work list view

Select the **Apply** button either in the **Available work lists** view or in the **Create /Edit work list** view to link to the **Apply work list** view.

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

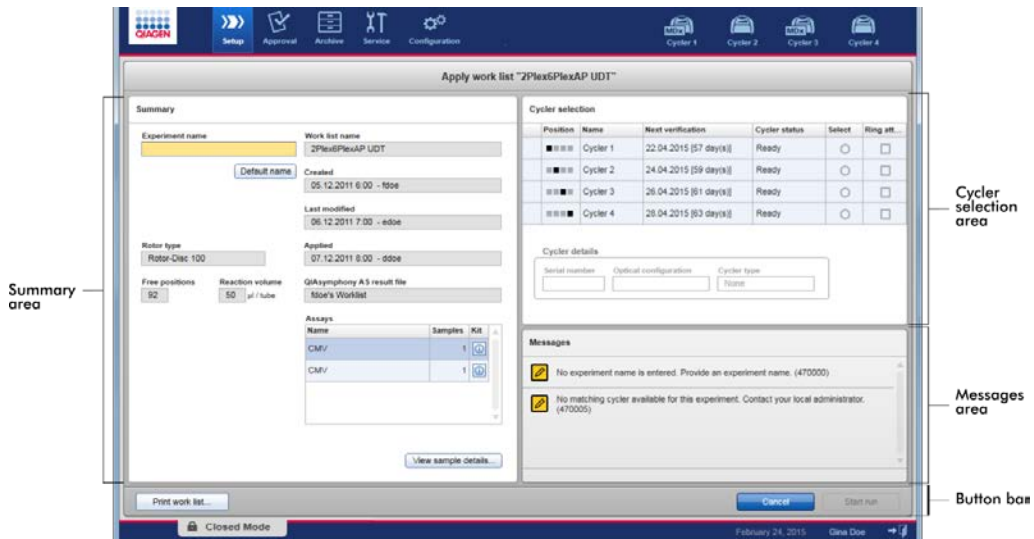
- Define an experiment name
- View sample details
- Print a work list
- Select a cycler
- Confirm that the locking ring has been attached to the rotor
- Start the run

Further detailed information about the work list and the cycler is displayed.

Work list information

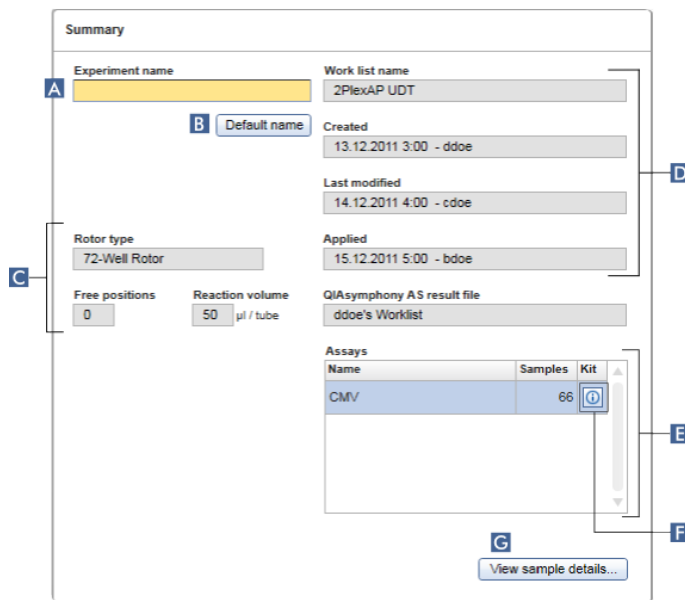
Cycler information

-
- | | |
|---|--|
| <ul style="list-style-type: none">● 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<ul style="list-style-type: none">● Assay name● Number of samples● Material number● Kit expiry date● Lot number | <ul style="list-style-type: none">● Position● Name● Next verification date● Cycler status● Serial number● Optical configuration |
|---|--|



Summary area

The **Summary** area includes a field 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.



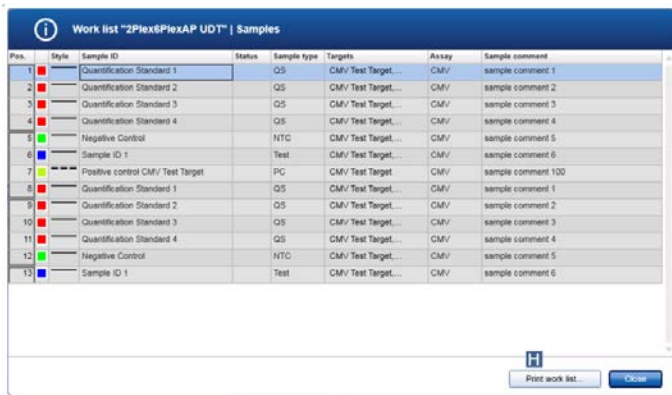
| Label/title | Description |
|--|--|
| A Experiment name | <p>Input box to enter a mandatory experiment name. The experiment name must fulfill 2 requirements:</p> <ul style="list-style-type: none"> • The experiment name must not exceed 80 characters • The experiment name must be unique |
| B Default name button | <p>A default name is entered automatically in the experiment name input box using the name pattern defined in the Configuration environment.</p> <p>Further information can be found in Configuration environment/Settings tab, page 193.</p> |
| C Data field | Shows the following data: |
| <ul style="list-style-type: none"> • Free positions • Reaction volume | <ul style="list-style-type: none"> • Number of free positions • Reaction volume |
| D Data field | Shows the following data: |
| <ul style="list-style-type: none"> • Work list name • Created • Last modified • Applied • QIASymphony AS result file | <ul style="list-style-type: none"> • Work list name • Creation date • Last modification date • Last application date • QIASymphony AS result file |
| Note: QIASymphony work list import is not intended for use with FDA cleared or approved nucleic acid tests. | |
| E Assays table | <p>Table with a list of all assays incorporated in the work list. For every assay the following data is shown:</p> <ul style="list-style-type: none"> • Assay name • Number of samples |
| F Kit information | <p>Dialog shows the following kit information:</p> <ul style="list-style-type: none"> • Kit bar code • Material number • Kit expiry date • Lot number |

Label/title


Description

View sample details button

Overview of the samples in the work list in the form of a table.



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

The table can be printed by clicking **Print work list** .

Note: The printout can be used as a pipetting scheme.

Cycler selection area

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

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

Note: Temperature verification is optional. If no date for temperature verification is defined, this field will be empty.

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 | <input type="radio"/> | <input type="checkbox"/> |
| ■ ■ ■ ■ | Cycler 2 | 18.06.2012 [62 day(s)] | Ready | <input type="radio"/> | <input type="checkbox"/> |
| ■ ■ ■ ■ | Cycler 3 | 20.06.2012 [64 day(s)] | Ready | <input type="radio"/> | <input type="checkbox"/> |
| ■ ■ ■ ■ | Cycler 4 | 22.06.2012 [66 day(s)] | Ready | <input type="radio"/> | <input type="checkbox"/> |

| Cycler details | |
|----------------------|-----------------------|
| Serial number | Optical configuration |
| <input type="text"/> | <input type="text"/> |

The **Cycler selection** table has 4 rows, representing the maximum of 4 cyclers that can be operated by Rotor-Gene AssayManager v2.1. If fewer than 4 cyclers are configured, unused table rows are 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 | <input type="radio"/> | <input type="checkbox"/> |
| ■ ■ ■ ■ | Cycler 2 | 18.06.2012 [62 day(s)] | Ready | <input checked="" type="radio"/> | <input type="checkbox"/> |
| ■ ■ ■ ■ | Cycler 3 | 20.06.2012 [64 day(s)] | Ready | <input type="radio"/> | <input type="checkbox"/> |
| ■ ■ ■ ■ | Cycler 4 | 22.06.2012 [66 day(s)] | Ready | <input type="radio"/> | <input type="checkbox"/> |

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



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

Button bar

The button bar contains 3 interactive buttons.



| Label/title | Description |
|------------------------|---|
| Print work list | <p>Generation of a work list report in *.pdf format with the following structure:</p> <p>Work list name</p> <p>Creation date and time, user name</p> <p>Rotor information</p> <ul style="list-style-type: none"> ● Rotor type ● Volume <p>Assays</p> <ul style="list-style-type: none"> ● Assay profile name ● Version <p>Kit information</p> <ul style="list-style-type: none"> ● Material number ● Expiry date ● Lot number <p>Sample details</p> <ul style="list-style-type: none"> ● Position ● Sample ID ● Target(s) ● Type ● Assay ● Comment <p>Note: The work list can also be printed by clicking the View sample details... button.</p> |
| Cancel | <ul style="list-style-type: none"> ● The application process is canceled. ● The Apply work list screen is closed. ● The Available work lists screen is shown. |

| Label/title | Description |
|------------------|--|
| Start run | <p>After the start of the cycling process, the cycler screen of the selected cycler is displayed.</p> <p>Note: The Start run button is disabled by default. This button is activated if the user has selected a cycler in the Cyclers selection table and has confirmed that the locking ring has been attached.</p> <p>When the user clicks the Start run button, the following actions are performed:</p> <ul style="list-style-type: none"> • The experiment is saved in the database. • The run is started. • Rotor-Gene AssayManager v2.1 switches to the Cyclers environment of the selected cycler. |

Create/Edit work list view

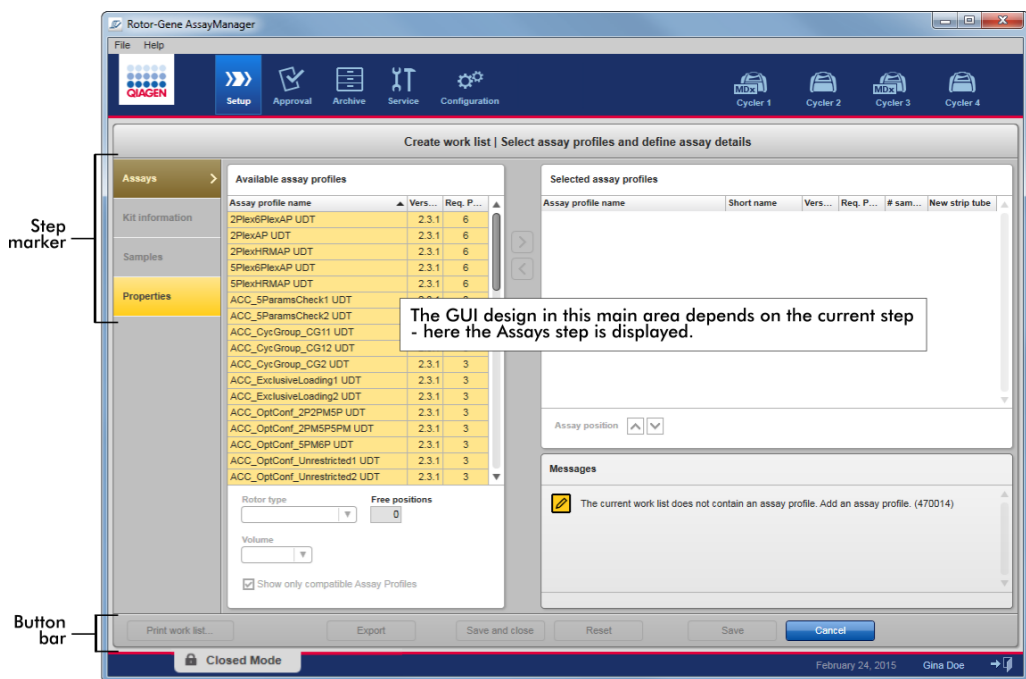
The **Create work list** view and the **Edit work list** view share the same design. The description that follows is valid for creating a new work list or editing a work list.

The tasks of creating a new work list or editing a work list are subdivided into 4 steps:

- **Assays**
- **Kit information**
- **Samples**
- **Properties**

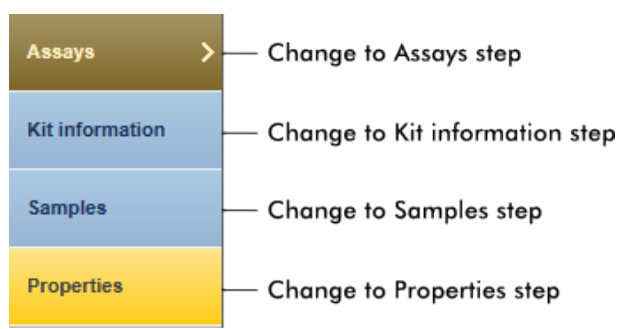
The screen layouts for these steps have 2 static elements in common: the step marker and the button bar. These elements remain unchanged when the user moves from one step to another. There is one exception: The **Properties** step contains an additional **Apply** button on the button bar.

The main screen area varies according to the currently selected step. The step marker is used to change between steps.






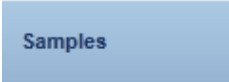
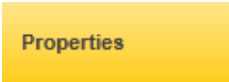
Step markers

The step marker is selected to change between steps.



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

The colors of the step marker and the font change, depending on the occurrence of errors and if the step is currently active.

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

Button bar

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

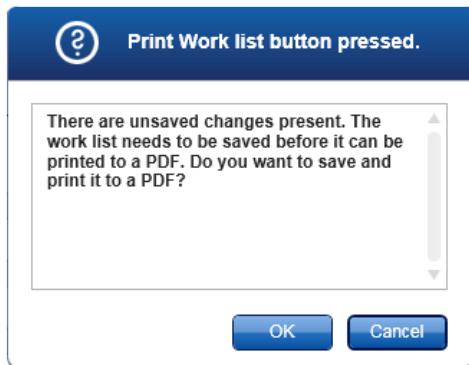


Print work list button

Note: This button is enabled only if the work list is valid and contains no errors.

Select **Print work list** to generate a work list report in *.pdf format.

A work list must be saved before it can be printed. If unsaved changes are present, the following warning must be confirmed before the *.pdf file can be generated.



The generated work list has the following structure:

- | | |
|--|------------------------|
| Work list name | Kit information |
| Creation date and time, user name | ● Material number |
| Rotor information | ● Expiry date |
| ● Rotor type | ● Lot number |
| ● Volume | Sample details |
| Assays | ● Position |
| ● Assay profile name | ● Sample ID |
| ● Version | ● Target(s) |
| | ● Type |
| | ● Assay |
| | ● Comment |

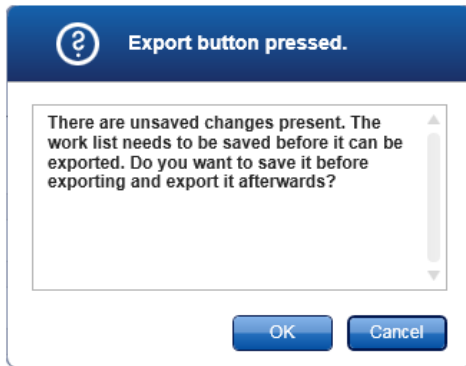
Export button

Note: A valid work list name is the minimum requirement for this button to be enabled.

Select **Export** to export the work list as an *.iwl file.

The *.iwl file can be imported to other Rotor-Genie AssayManager v2.1 installations (exchange functionality).

The following warning must be confirmed by clicking **OK** if unsaved changes are present.



Save and close button

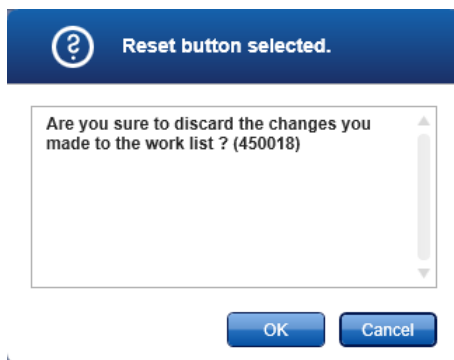
Select **Save and close** to save the current progress on the work list and return to the **Available work lists** table.

Reset button

Select the **Reset** button to reset the current work list creation process.

- Creating a new work list:
 - All fields are reset to their default value
- Editing an existing work list:
 - Unsaved changes to the work list are discarded

After **Reset** is clicked, the following warning must be confirmed.



Save button

Note: The **Save** button is enabled if unsaved changes exist and a valid work list name has been entered.

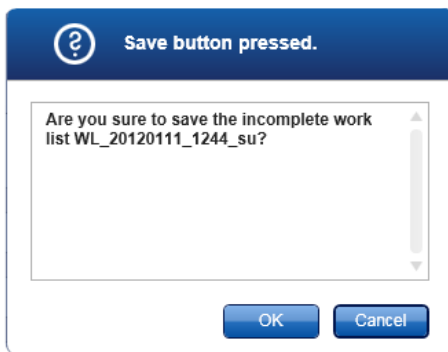
Select the **Save** button to save the new/edited work list.

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.

If the new/edited work list is incomplete, clicking **Save** opens the following dialog:

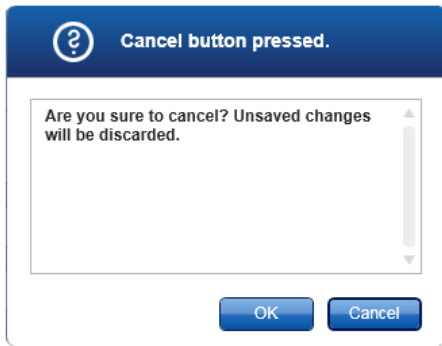


Note: An incomplete work list can be saved if at least a valid work list name has been entered. If an incomplete work list is saved, Rotor-Gene AssayManager v2.1 displays the warning shown above. Click **OK** to confirm.

Cancel button

Select **Cancel** to cancel the creation process. All entries are deleted and the **Available work lists** table opens.

After **Cancel** is clicked, the user must confirm that unsaved data will be discarded.



Apply button

Select the **Apply** button to apply the new/edited work list.

For further information, see “**Apply work list** view,” page 124.

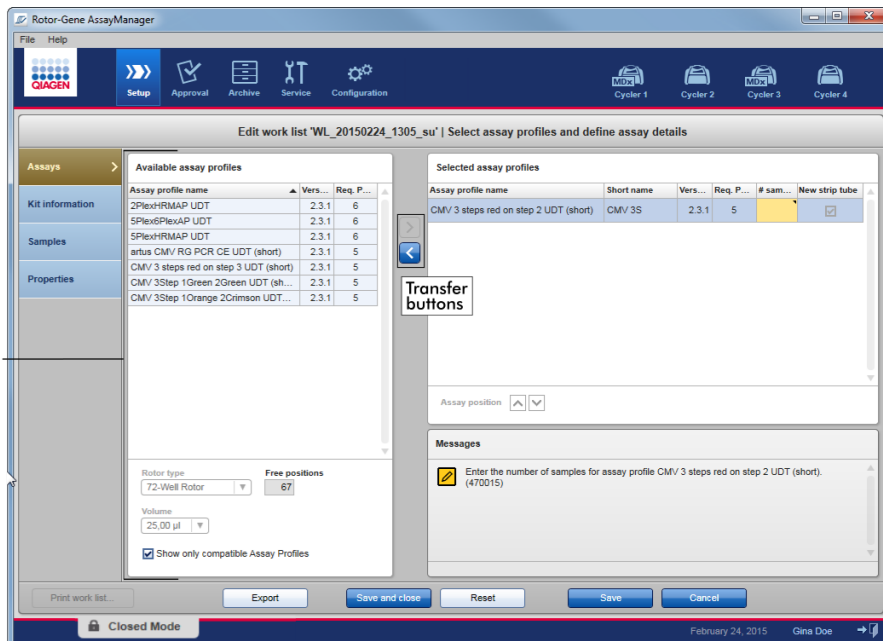
Assays step

In this step of creating a new work list or editing a work list, the user assembles or edits a work list by adding one or more available assay profiles to a new or edited 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.

Note: For FDA cleared and approved nucleic acid tests, only one assay profile can be added to a work list.

The **Assays** step consists of 4 areas:

- Transfer buttons
- **Available assay profiles** area
- **Selected assay profiles** table
- **Messages** panel



Available assay profiles table

Transfer buttons

Transfer buttons

The transfer buttons are used to add and remove assay profiles to/from the table of **Available assay profiles** to/from the **Selected assay profiles** table.

| Transfer button | Description |
|-----------------|-------------|
|-----------------|-------------|



Click to transfer the selected assay profile from the table of **Available assay profiles** to the **Selected assay profiles** table.

This button is enabled if:

- An assay profile is selected in the table of **Available assay profiles**
- Sufficient free wells are available in the selected rotor
- The selected assay profile is compatible with assay profiles already in the **Selected assay profiles** table



Click to 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 area

The **Available assay profiles** area includes a table with all available assay profiles sorted alphabetically in ascending order. The area also contains information on the Rotor-Gene Q MDx rotor and sample volume.

| Assay profile name | Vers... | Req. P... |
|-------------------------------|---------|-----------|
| ACC_OptConf_2P2PM5P UDT | 2.3.1 | 3 |
| ACC_OptConf_2PM5P5PM UDT | 2.3.1 | 3 |
| ACC_OptConf_5PM6P UDT | 2.3.1 | 3 |
| ACC_OptConf_Unrestricted1 UDT | 2.3.1 | 3 |
| ACC_OptConf_Unrestricted2 UDT | 2.3.1 | 3 |
| ACC_Rotor36W72W UDT | 2.3.1 | 3 |
| ACC_Rotor72W72D UDT | 2.3.1 | 3 |
| ACC_RunProf_ChannelNumber UDT | 2.3.1 | 3 |
| ACC_Vol_1d0_25d0 UDT | 2.3.1 | 3 |
| ACC_Vol_25d0_40d0 UDT | 2.3.1 | 3 |

Rotor type: 72-Well Rotor Free positions: 69

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

Drop-down menu of rotor types for the new work list. The **Rotor type** field displays the selected value.

The menu is disabled when an assay profile is transferred from **Available assay profiles** to **Selected assay profiles**. This menu is re-enabled when all assay profiles are removed from the **Selected assay profiles** using the  transfer button.

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

| Label/title | Description |
|----------------------------------|---|
| C Free positions field | <p>Shows the number of free positions on the rotor.</p> <p>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.</p> <p>Example: The assay requires 1 NTC (no template control) and 4 quantitation standards. 12 samples shall be processed in a 72-well rotor.</p> <p>1 NTC + 4 standards = 5 required positions 5 required positions + 12 samples = 17 reserved positions 72 wells – 17 reserved positions = 55 free positions</p> <p>This example is valid for assays where 1 sample is applied into 1 tube. In cases where 1 sample is split to multiple tubes, the number of test samples is multiplied by the number of necessary tubes.</p> <p>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.</p> |
| D Volume field | <p>Drop-down menu with predefined reaction volumes for the new work list. Select the appropriate reaction volume for the assay.</p> <div data-bbox="454 1308 614 1415" style="border: 1px solid black; padding: 5px; width: fit-content;"> <p>25,00 µl 40,00 µl 50,00 µl 100,00 µl</p> </div> <p>Note: This screenshot is an example. The available reaction volumes are defined by the assay profile.</p> <p>The Volume field displays the selected value. This menu is disabled after an assay profile has been transferred from the table of Available assay profiles to the Selected assay profiles table.</p> <p>This menu is re-enabled when all assay profiles are removed from the Selected assay profiles using the  transfer button.</p> <p>The reaction volume is predefined in each assay profile.</p> |

| Label/title | Description |
|---|---|
| E Show only compatible Assay Profiles checkbox | <p>If checkbox not activated: All available assay profiles are listed. Incompatible assay profiles are grayed out.</p> <p>If checkbox activated: Only compatible assay profiles will be listed if an assay profile has already been added to the Selected assay profiles table.</p> <p>Note: For FDA cleared and approved nucleic acid tests, only one assay profile can be added to a work list.</p> |

Selected assay profiles table

An available assay profile added to the work list is listed in the **Selected assay profiles** table.

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

The **Selected assay profiles** table contains data derived from the respective assay profile and data that are entered manually or with a bar code scanner. The following table shows the source for every column.

| Column | Data source |
|---------------------------|---|
| Assay profile name | Assay profile |
| Short name | Assay Profile |
| Version | Assay profile |
| Req. Position | Assay profile |
| # samples | Manual input required |
| New strip tube | Manual choice (if more than one assay is defined) |

Messages panel

The **Messages** panel contains all warnings, errors and information related to the **Assays** step. For more information, see “Messages area,” page 113, and “Displaying errors and warnings,” page 98.

Kit information step

The kit information contains the following data:

- Kit bar code
- Material number
- Kit expiration date
- Lot number

Kit information data can be entered manually in the individual boxes or by using a bar code scanner.

Click on the **Kit information** step and enter the data manually or scan the QIAGEN kit bar code. The values for material number, kit expiration date and kit lot number will be automatically populated with the kit values from the scan. Only the number of samples has to be entered manually.

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

Note: The kit information settings are defined in the **Work list** panel of the **Settings** screen in the **Configuration** environment. (See “**Global Settings** area,” page 194, for more information.)

Work list

Format of generated work list names
 WL_20110513_0430_Operator

User-definable section
 WL

Date
 Time
 Operator

Enable analysis of unclear samples
 Enable checksum for LIMS import

| | |
|---|---|
| Closed mode | UDT mode |
| <input type="checkbox"/> Material number required | <input type="checkbox"/> Material number required |
| <input type="checkbox"/> Valid expiration date required | <input type="checkbox"/> Valid expiration date required |
| <input type="checkbox"/> Lot number required | <input type="checkbox"/> 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.

Note: The UDT mode is not intended for use with FDA cleared or approved nucleic acid tests.

If the information is “required” for an option, the check box is activated and the operator must provide the information. It is not possible to leave the respective input fields void if it is “required”.

Further details can be found in the description of the **Configuration** environment, page 192.

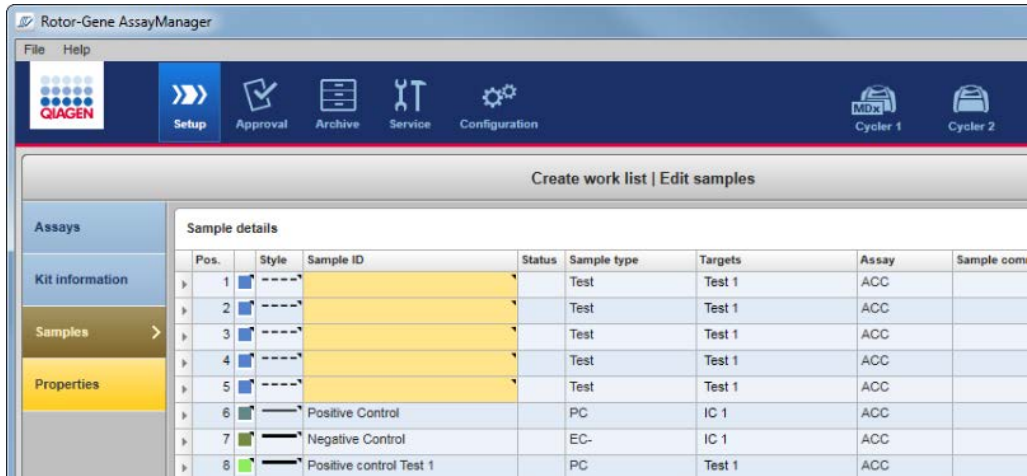
Samples step

The **Samples** step shows the sample details in tabular form. All sample types from all selected assay profiles are displayed here. Added multiple assay profiles are also listed here.

Note: The order of the samples within an 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



The editable columns of the **Sample details** table (line color, line style, sample ID) have pop-up menus that can be accessed by a right-click in the respective column or cell.

Row selector column

The row selector selects single or multiple rows. If a row is selected, it will be marked in blue and the row selector icon will change:

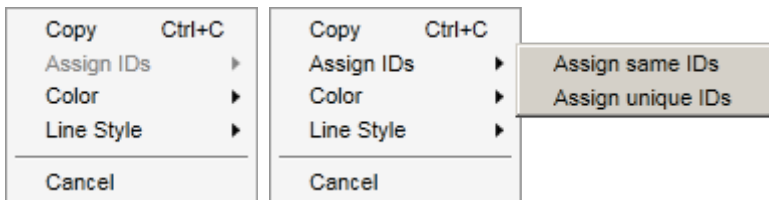
- Unselected row 
- Selected row 

To select several consecutive rows, click the selector of the first row, 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.

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

Note: A row must be selected using the row selector before the corresponding pop-up menu for the row can be opened.

Pop-up menus for selected rows



Single row selected

Multiple rows selected

Copy Ctrl+C copies the content of the selected ID row(s) — single or multiple — to the clipboard.

Assign IDs is disabled if a single row is selected. This option is activated only if multiple rows are selected.

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 opens a color palette for the user to select a specific color for the amplification curve of the selected samples.



Line Style opens a style picker for the user to select a specific line style for the amplification curve of the selected samples.



Pos. column

The position of the sample in the rotor is displayed in this column. The position of a sample is determined by the assay profile and the order of the assay profiles in the **Assays** step if the work list consists of multiple assay profiles.

The maximum position number is restricted by the selected rotor type.

Color column

The color of a sample's amplification curve in the PCR plot can be set by opening the color palette in the pop-up menu and selecting 1 of 20 predefined colors. It is possible to select multiple samples and assign them the same line color using this pop-up menu.



Style column

The line style of a sample's amplification curve in the PCR plot can be set by opening the line style picker in the pop-up menu and selecting 1 out of 6 predefined styles. It is possible to select multiple samples and assign them the same line color using this pop-up menu.

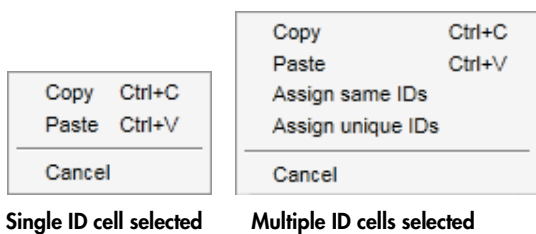


Sample ID column

A sample ID field cannot be empty. The field must contain an ID of 1 to 40 characters.

Options in the pop-up menu of the **Sample ID** field depend on whether a single cell or multiple cells is/are selected.

Pop-up menus for selected sample ID cells



Single ID cell selected

Multiple ID cells selected

Copy Ctrl+C copies the content of the selected ID cell(s) — single or multiple — to the clipboard.

Paste Ctrl+V pastes the content of the clipboard to the selected cell. A warning is displayed before data is overwritten.

Assign same IDs: Assigns the ID value from the first cell of the selection to all other selected cells.

Note: For some assay profiles it is not permitted to have the same ID for different samples. In this case, the **Assign same IDs** option is disabled in the context menu.

Assign unique IDs: Based on the ID of the first selected cell, an incremental number is added to all selected cells.

Example: If first cell has the ID "Sample", the generated values are "Sample 1", "Sample 2", "Sample 3", etc.

Cancel closes the pop-up menu.

Status column

Note: This column is used only if a QIA Symphony work list is imported. QIA Symphony work list import is not intended for use with FDA cleared or approved nucleic acid tests.

Sample type column

Sample types are listed in the fields of this column.

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 column

This is the acquisition target given by the assay profile.

Assay column

The **Assay** column contains a short assay profile name given by the assay profile. Hovering over the short assay profile name shows a tooltip with the full assay profile name.

Sample comment column

The **Sample comment** column may be empty. A comment with a maximum of 256 characters may be included.

Properties step

The **Properties** step is used to assign a name and other properties to the new work list. The name may be entered manually or may be a default name generated by the assay profile. There are also 2 options to mark that the work list “is editable” and “is applicable” (i.e., is ready to be applied).

Properties

Work list name

A WL_20120417_1422_su

B Default name

Work list

is editable is applicable

C D

Created

E

Last modified

F



Last applied

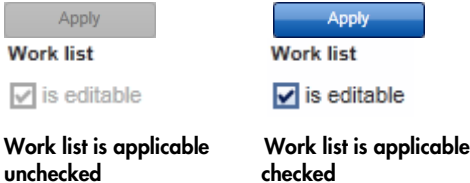
G

External order ID

H

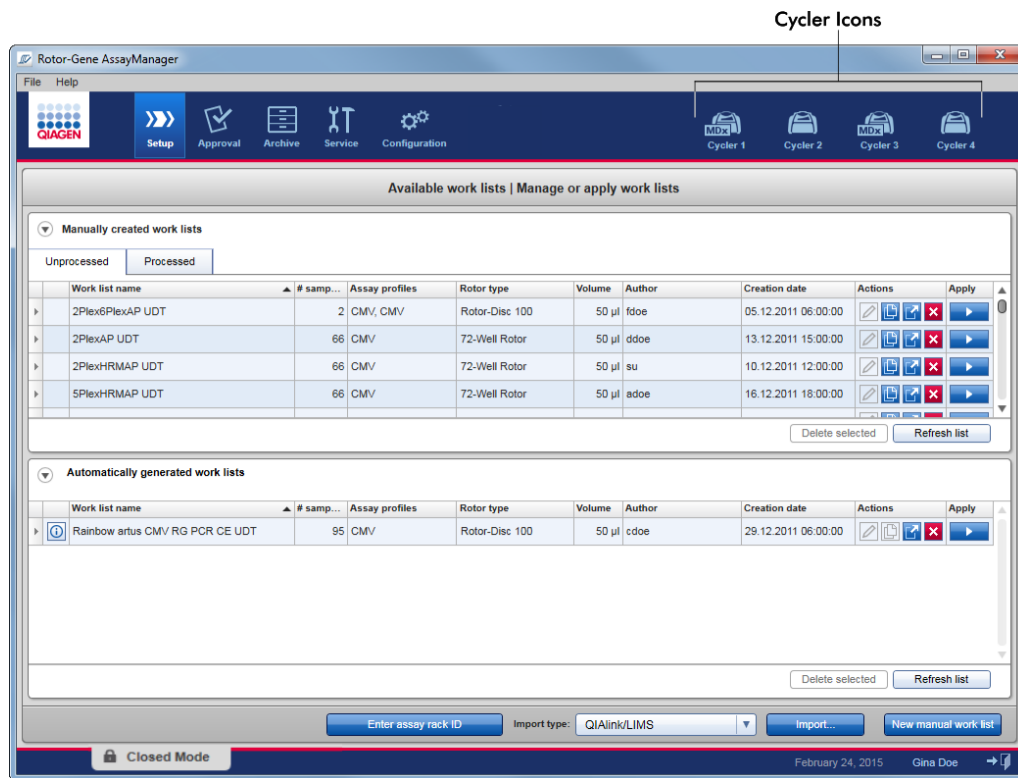
| Label/title | Description |
|--|--|
| A Work list name | Text field to enter a name for the new work list. Maximum length for the name is 40 characters. The entered name for a new work list must be unique. |
| B Default name button | Click to enter an automatically generated name for the work list. The pattern for the generated name is defined in the settings entered in the Work list panel of the Settings screen in the Configuration environment. (See “ Global Settings area,” page 194, for more information.) |
| C Work list is editable check box | Determines whether a work list can be modified later. This check box is disabled by default. It is enabled when the Work list is applicable check box is activated. Not activated: The work list cannot be modified later. |

| Label/title | Description |
|--|---|
| D Work list is applicable check box | <p>The Edit work list icon in the Actions column in the Available work lists table is deactivated: </p> <p>Activated: The work list can be modified later.</p> <p>The Edit work list icon in the Actions column is activated: </p> <p>Indicates that a work list can be applied.</p> <p>Not activated: The work list cannot be applied.</p> <p>Activated: The work list can be applied.</p> <p>When this check box is activated, the previously disabled Apply button in the button bar and the Work list is editable check box are activated.</p> |
| E Created field | Displays who created the work list and when. (This field is populated when the work list is saved.) |
| F Last modified field | Displays who modified the work list and when (This field is populated when the work list is saved.) |
| G Last applied field | Displays when the work list was last applied. |
| H External order ID field | This is an 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 these kinds of order IDs. |



Cycler Environment





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







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

Cycler icon

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

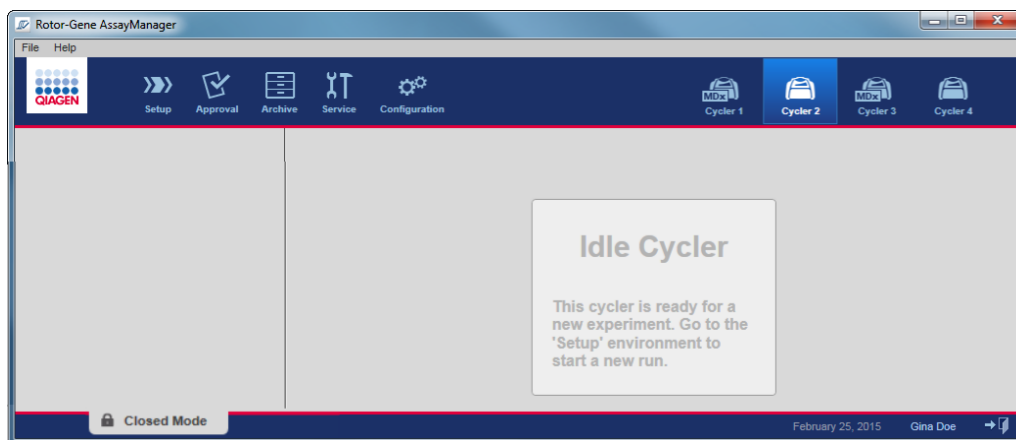
| Icon | Description |
|---|--|
|  | Cycler idle |
|  Progress Indicator | Cycler working (The progress indicator visualizes the run progress.) |
|  | Run finished successfully |
|  | Run stopped (either by clicking Stop Process , or an error occurred) |

Further cycler icons are listed below.

| Icon | Description |
|---|--------------------------------|
|  | Cycler offline |
|  | Cycler activated |
|  | Invalid verification |
|  | Run stopped and cycler offline |

Idle cycler screen

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

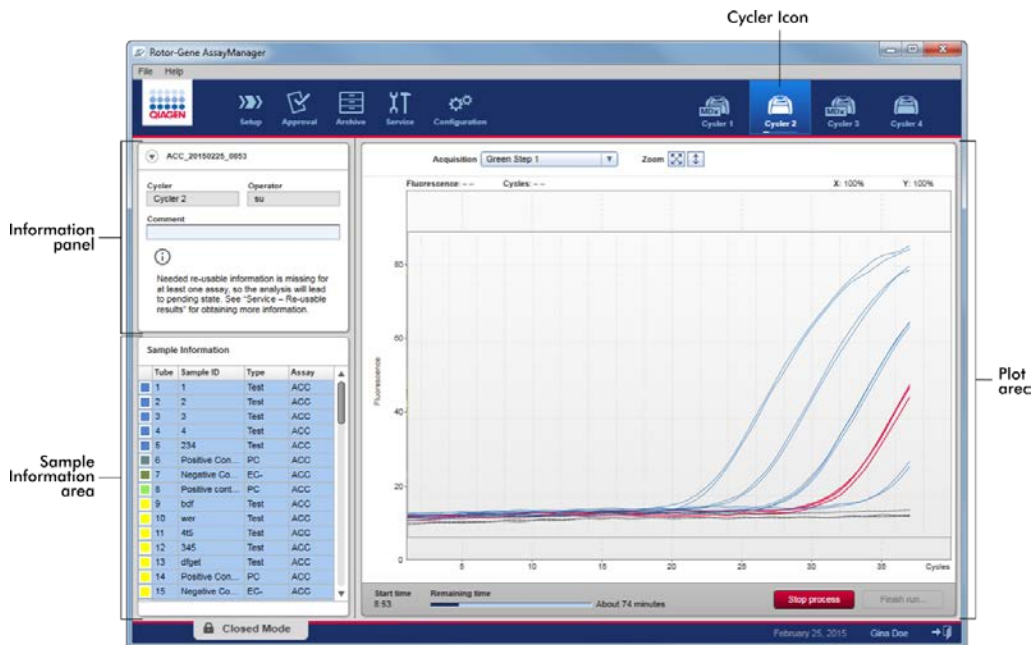


There are 2 ways to start a run on an idle cycler:

- Apply an existing work list from the **Available work lists** table.
- Create a work list and apply it.

Active cyclus screen

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



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

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

The cyclus screen consists of 4 areas:

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

Information panel

| Label | Explanation |
|-----------------|--|
| "Collapse" icon | The collapse icon is used to collapse the information panel to a single row to gain screen space to enlarge the Sample information area. If the area is collapsed, only the experiment name is shown. |
| Experiment name | Experiment name as defined during 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 (**Tube**)
- **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.

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 lighter 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 |

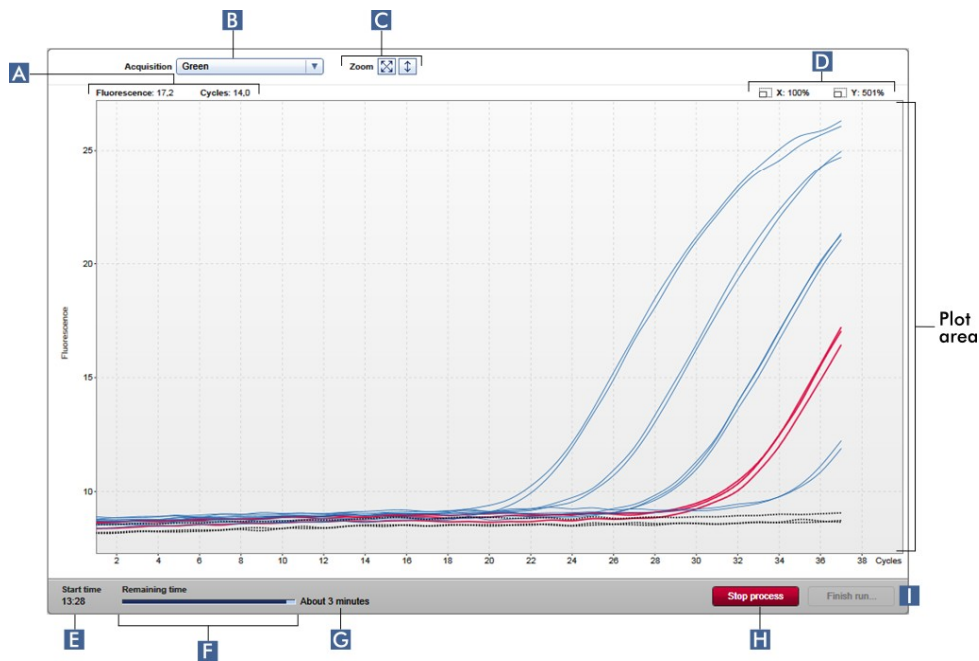
Acquisition plots are enabled by default for all samples. The row is colored in dark blue.

| 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 lighter blue.

Plot area

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





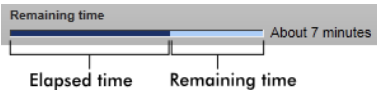
Label

Explanation

A Coordinates

Shows the coordinates of the current mouse position. If the mouse cursor is within the plot area, the mouse cursor changes to cross hairs (+). The current coordinates are displayed in this field.

The coordinates are shown as **Fluorescence** and **Cycles** values.

| Label | Explanation |
|---|--|
| 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 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. |
| D Zoom factors | Displays zoom factors separately for the x-axis and the y-axis. |
| E Start time | Displays the start time of the run. |
| F Progress indicator bar | Displays the progress of the experiment. The indicator bar visualizes the acquisition progress: the dark blue colored part of the bar visualizes the elapsed time; the brighter blue colored part, the remaining time of the experiment. |
| |  <p>The text over the progress indicator changes depending on the current status of the run:</p> <ul style="list-style-type: none"> ● Remaining time: Ongoing experiment ● Analyzing: Experiment was finished, analysis has started ● Ready: Experiment analysis finished |
| G Remaining time estimation | Displays the estimated remaining time. |

| Label | Explanation |
|-----------------------|---|
| H Stop process | <p>Stops the run.</p> <p>After clicking the Stop process button, a warning dialog must be confirmed to stop the run. The run will be stopped as soon as the device has finished a profile step. This can take up to 60 seconds.</p> <p>The status Run stopped is assigned to the experiment in the internal database.</p> |
| I Finish run | Finish the run. |

Finishing a run

After clicking **Finish run** the following dialog is opened:

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:

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

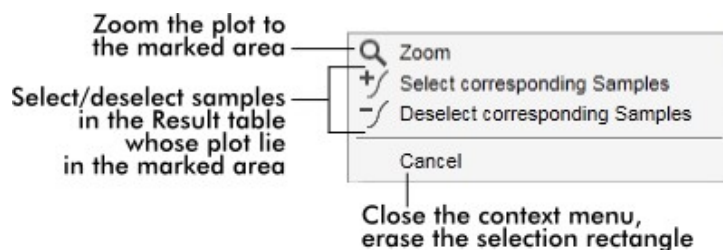
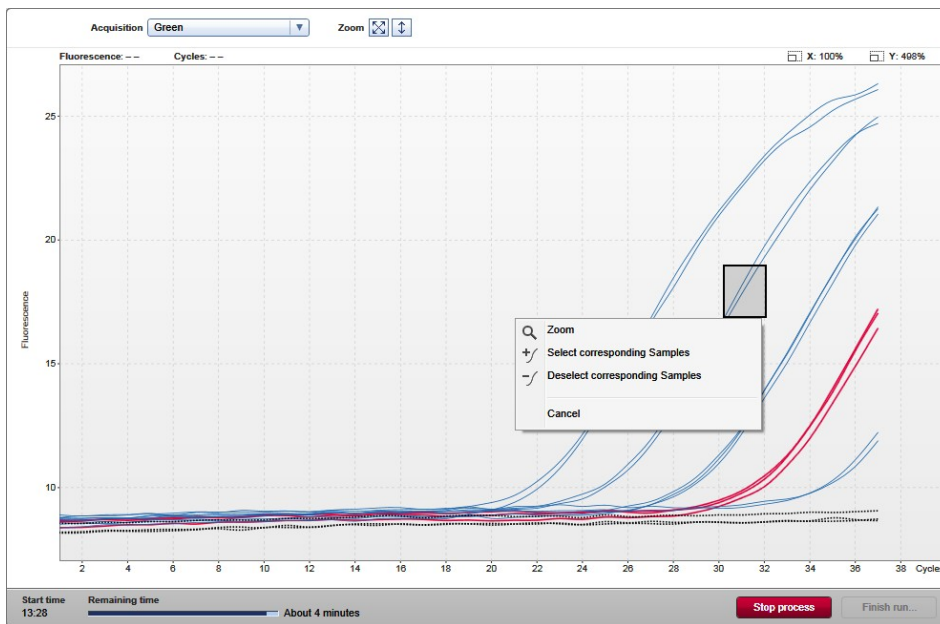
For further information, see the **Configuration** environment, page 192.

Behavior of the plot area

The plot area has interactive functionalities:

Context menu

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



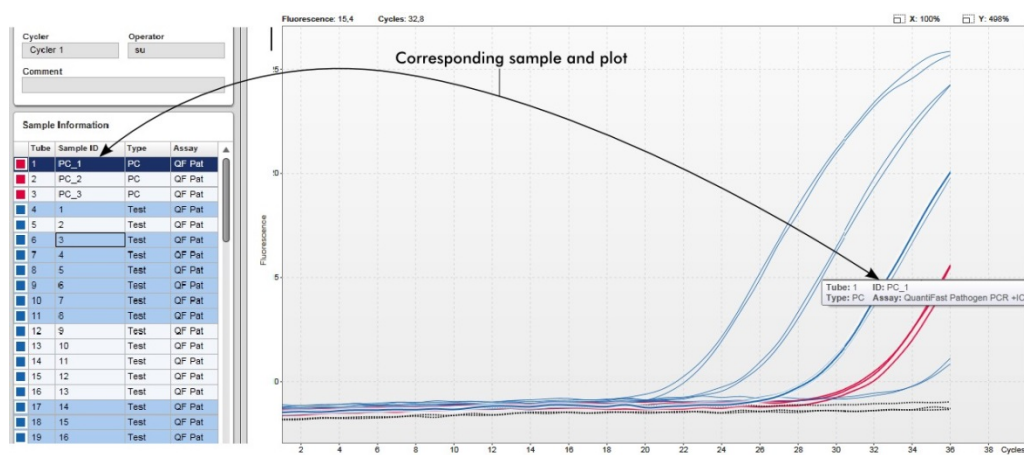
Zoom

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

Identification of amplification curves

Hovering the mouse over an individual amplification curve highlights the curve in the amplification plot and displays a tooltip with the following data:

- Tube number
- Sample type
- Sample ID
- Assay type



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

Tasks related to the Cycler view

"Managing cyclers," page 272."

"Finishing and releasing a run," page 255.

Approval Environment

The **Approval** environment is used to search for unreleased assays and to release all samples of the assay. The **Approval** environment mainly consists of 2 different screens:

- **Filter** screen: Used for filtering and selecting specific assays for the release process
- **Approval** screen: Used for checking the assay result and releasing all samples

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 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 release process, the assays to be approved are selected by checking the corresponding check box and clicking **Start approval**.

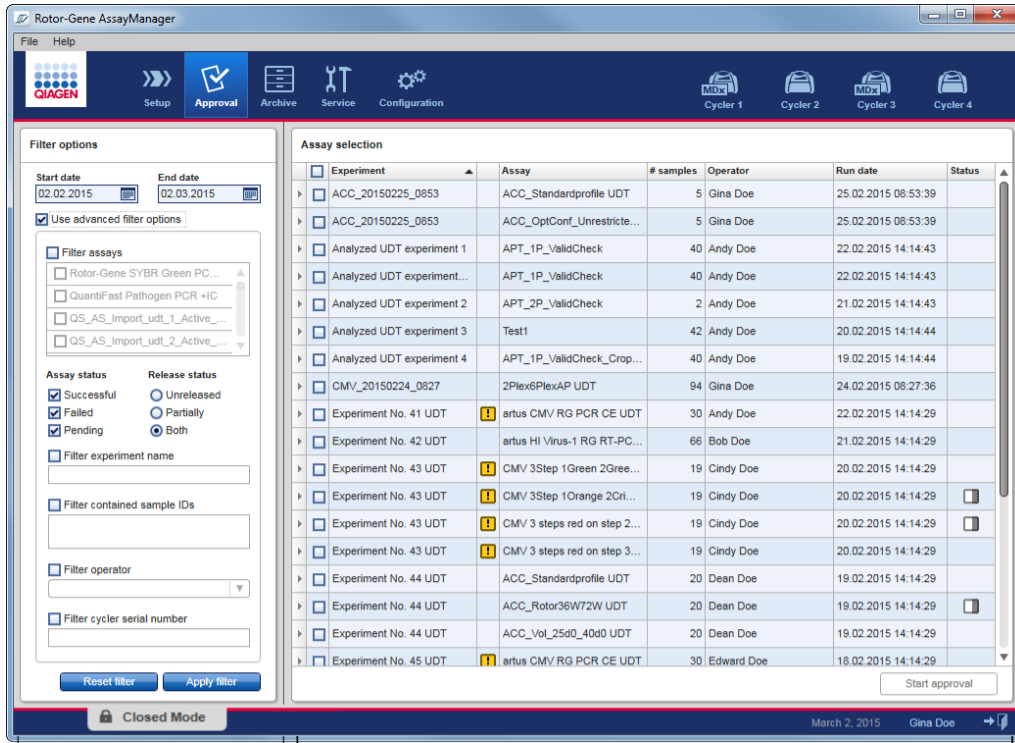
Filter screen

The **Filter** screen is intended to

- Filter for not yet 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



Filter options area

Assay selection area

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

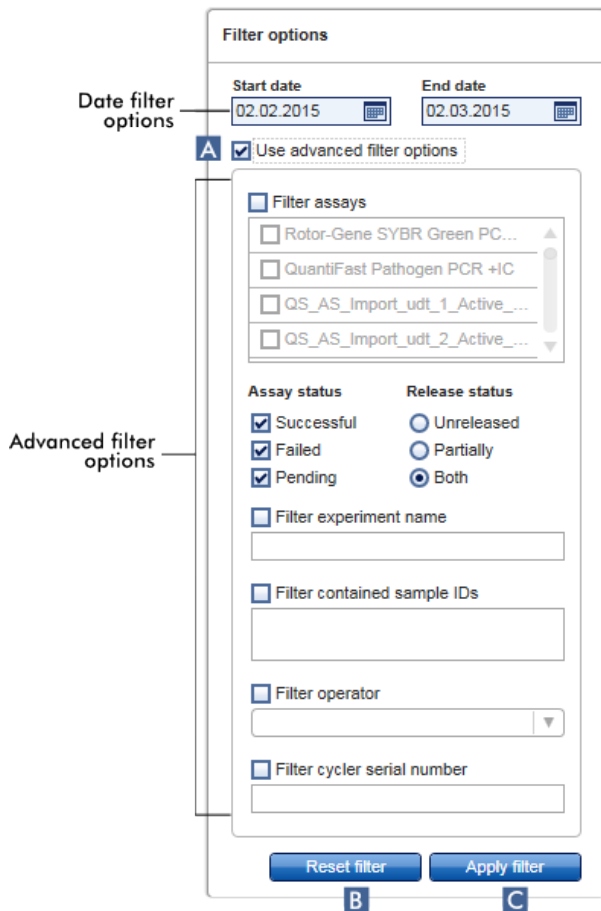
By default, the filter options are set to search for assays of the last month. All other filter options are disabled.

Date filter options

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.

There are restrictions:

- Wildcard characters are not allowed
- Dates must be entered completely



Using the advanced filter options

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.

Advanced filter options

Click in the check box next to **Use advanced filter options** (A) to activate the advanced filter options.

| Filter criterion | Explanation |
|-------------------------------|---|
| Filter assays | <p>To filter for specific assays, activate the Filter assays check box. All assays are displayed in a list. A check box in front of every assay row allows selection of individual assays.</p> <p>Multiple assay selections are possible to search simultaneously for different assays.</p> |
| Assay status | <p>Filter for the assay status using the radio buttons. Possible values are:</p> <ul style="list-style-type: none">● Successful● Failed● Both● Pending <p>Note: The assay status "Pending" is not applicable for FDA cleared or approved nucleic assay tests.</p> |
| Release status | <p>Filter for the release status using the radio buttons. Possible values are:</p> <ul style="list-style-type: none">● Unreleased● Partially● Both <p>Note: The release status Partially released is not applicable for FDA cleared or approved nucleic acid tests.</p> |
| Filter experiment name | <p>Filter for the experiment name by activating the check box and entering an experiment name.</p> |

| Filter criterion | Explanation |
|------------------------------------|--|
| Filter contained sample IDs | Filter for specific sample IDs by activating the check box and entering one or multiple sample IDs. Multiple sample IDs have to be entered in individual rows without any separators. |
| Filter operator | Filter for a specific operator by activating the check box and selecting an operator from the list. |
| Filter cyler serial number | Filter for a cyler serial number by activating the check box and entering a cyler serial number (only digits). |

Reset filter button

The **Reset filter** button (B) resets all filter options to the default values.

Apply filter button

The **Apply filter** button (C) starts the filter process.

All experiments matching the filter criteria will be listed in the **Assay selection** area.


Assay selection area


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

| Experiment | Assay | # samples | Operator | Run date | Status |
|----------------------------|----------------------------|-----------|----------|---------------------|--------|
| ACC_20150225_0853 | ACC_Standardprofile UDT | 5 | Gina Doe | 25.02.2015 08:53:39 | |
| ACC_20150225_0853 | ACC_OptConf_Unrestricte... | 5 | Gina Doe | 25.02.2015 08:53:39 | |
| Analyzed UDT experiment 1 | APT_1P_ValidCheck | 40 | Andy Doe | 22.02.2015 14:14:43 | |
| Analyzed UDT experiment... | APT_1P_ValidCheck | 40 | Andy Doe | 22.02.2015 14:14:43 | |

Start approval


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:

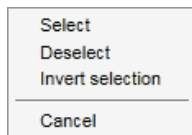
 Deactivated row selector

 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. |


Assay 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 .

The column select icon  changes according to the number of selected assays:

 No assay selected

 One or more assay(s) selected, but not all

 All assays selected

Experiment column

The **Experiment** column has the name defined before starting the run.

Assay validity

This column shows the validity status of an assay.

This field is empty if the assay is valid.

If an assay is invalid, this is indicated by a warning  icon

The reason for an invalid status is indicated in a tooltip.

| Label/title | Description |
|------------------------|---|
| Run failed | A problem with the cycler or the cycler connection. |
| Run stopped | A run was stopped manually. |
| Assay invalid | Invalid external controls can lead to an invalid assay. For details refer to the detailed analysis. |
| Analysis failed | Various reasons. Contact QIAGEN Technical Services. |

Assay

The **Assay** column has the full name of the assay(s) used for this experiment.

samples

This column contains the number of samples.

Operator

This is the operator's name.


Run date


This is the run date of the experiment.


Status column

This column indicates the release status of the experiment.

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.

If an assay is pending, this is indicated by the  icon.

Note: The release statuses “Partially released” and “Pending” are not applicable for FDA cleared or approved nucleic acid tests.

Start approval button

Click the **Start approval** button to start 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**.

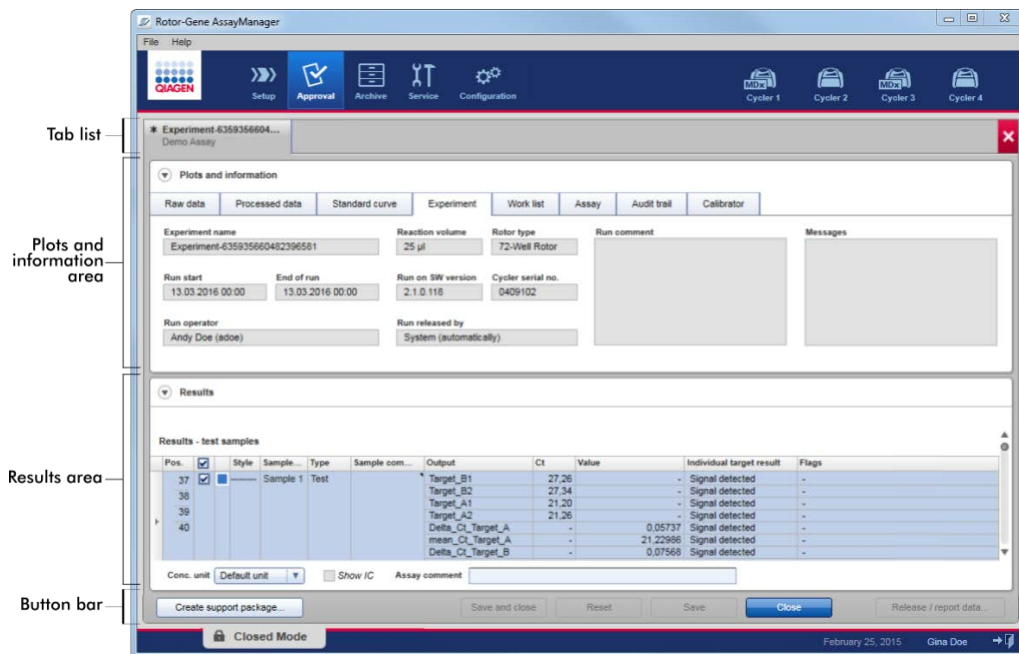
Approval screen

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

The **Approval** screen is used to:

- View the result of an assay
- Release 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. If all sample results have been released and no test sample has the status “undefined”, then 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 (see “**Archive** Environment,” page 182).




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

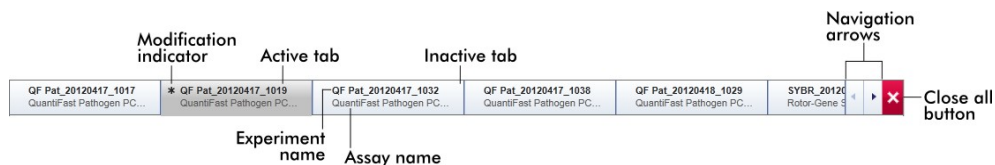
| Area | Functionality/tasks |
|-----------------------------------|--|
| Tab list | All assays selected in the previous step are displayed in the tab list. This allows the user to work on multiple assays simultaneously. In case the screen space is insufficient to fit all assays, navigation arrows are added to the tab list |
| Plots and information area | This area contains various data about an experiment. This area is subdivided into a number of separate tabs depending on the selected assay and the currently used plug-in. |
| Results table | This area contains a table with details about the samples. |
| 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

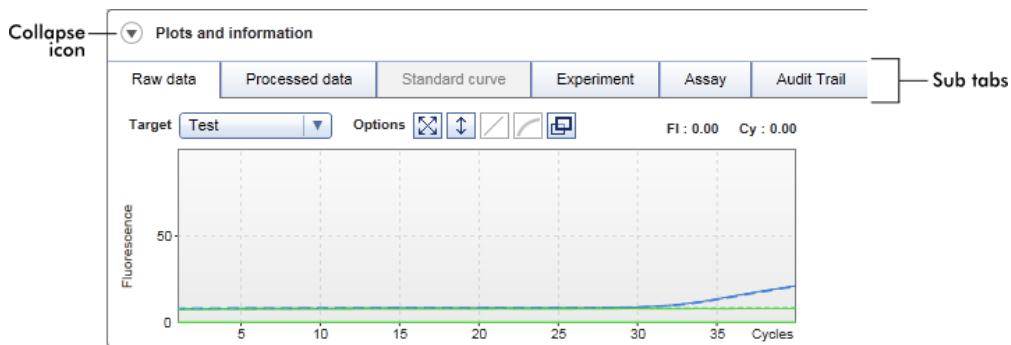
header. The currently active tab is highlighted gray. The inactive tab(s) are light blue. If an experiment contains unsaved modifications, this will be indicated by a  symbol beside the experiment name.

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 a number of separate tabs depending on the selected assay and the currently used plug-in (6 tabs in this example.)



Raw data

Processed data

Standard curve

These tabs are graphic focused.

They show 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).

Experiment

Assay

These tabs are data focused.

They show detailed data about the experiment and the assay.

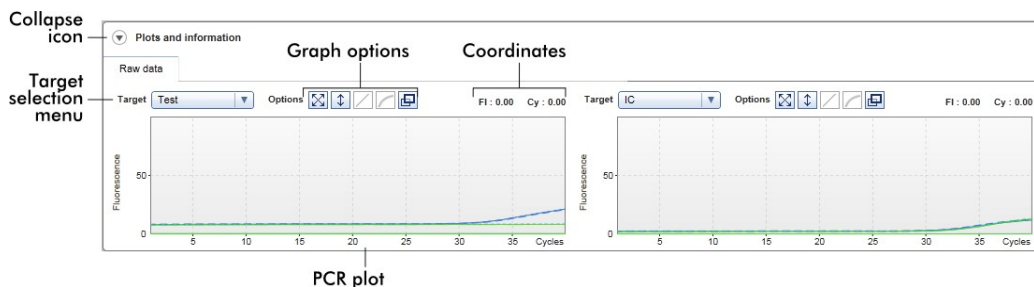
Audit Trail

This tab shows all actions that are recorded on the audit trail.




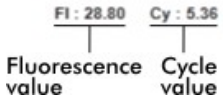
Note: The collapse icon (▼) is used to collapse the **Plots and information** or the **Results** area to gain screen space for the other area. If an area is collapsed to a single row, the icon changes to (▶) for expanding the area back to the default size.

Raw data tab

The **Raw data** 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.



| Icon | Label/title | 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 option | 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. |
| | Graph option | 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. |

| Icon | Label/title | Description |
|---|--------------|--|
|  | Graph option | Disabled in Raw data sub tab. |
|  | Graph option | Disabled in Raw data sub tab. |
|  | Graph option | 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. <div style="text-align: center; margin: 10px 0;">  </div> 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

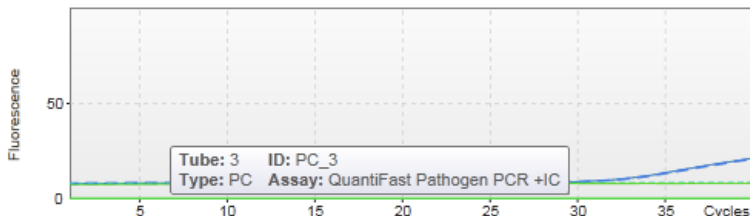
The cursor changes to cross hairs (⊕) when the mouse is hovered over the amplification plot.

The current position of the mouse cursor over the amplification plot is displayed in real time in the coordinates field.

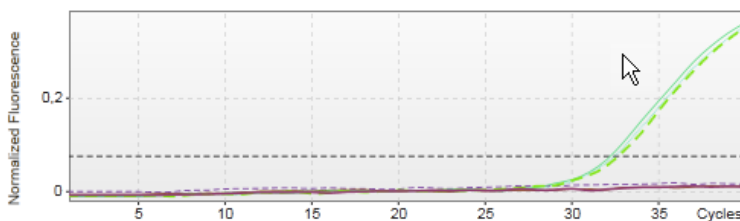
Hovering with the mouse over the amplification curve of a specific sample opens a tooltip displaying the following information:

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

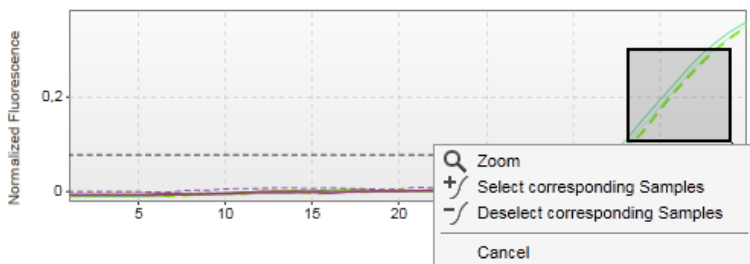
Example:



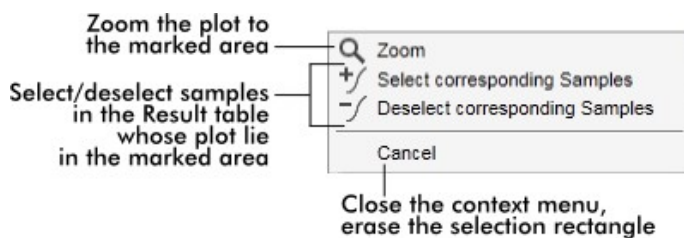
An area of the amplification plot can be selected by clicking and holding the left mouse button and dragging the mouse pointer. A context menu with several options appears.



Hold down the left mouse button and drag the mouse to the end point.



Functions of the context menu






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 tab

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

- The raw fluorescence data are normalized using the internal algorithm of Rotor-Gene AssayManager v2.1 according to the settings of the corresponding assay profile.
- The graph options are partially different.

The following table describes only the differences to the **Raw data** tab.

| Icon | Label/title | Description |
|---|--------------|--|
|  | Graph option | Disabled in Processed data tab. |
|  | Graph option | 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. |
|  | Graph option | 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. |

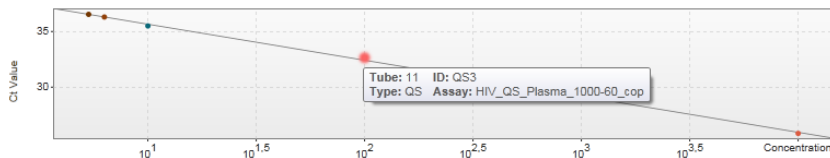
Standard curve tab

The **Standard curve** 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:

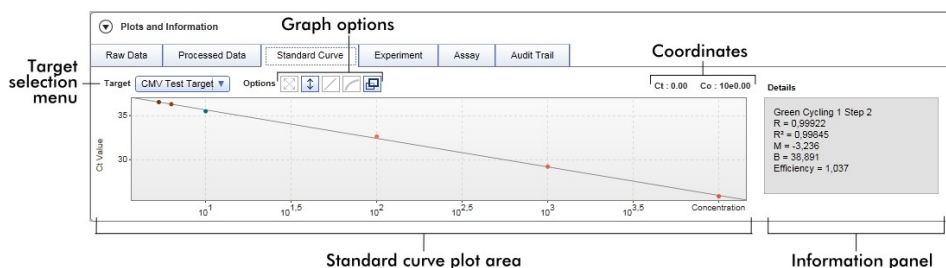
- Tube number
- Sample ID
- Sample type
- Assay name (long)

Example:



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

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



Standard curve plot area

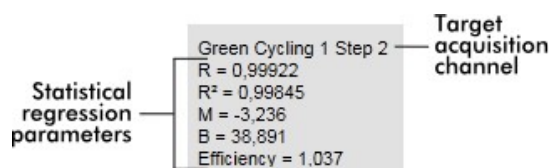
The layout is similar to the **Raw data** and **Processed data** tabs:

- A drop-down menu to select the target
- Graph option buttons to manage the plot
- A coordinates field

The coordinates field displays C_T and concentration values of the current cursor position in the plot.

Information panel

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



The statistical regression parameters are described in the following table.

| Parameter | Explanation |
|----------------|---|
| R | Root extracted from R ² |
| R ² | The correlation 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 | Slope of curve. |
| B | Curve offset. |
| Efficiency | Describes the amplification efficiency in a PCR. |

Experiment tab

The **Experiment** tab provides detailed information about the experiment.

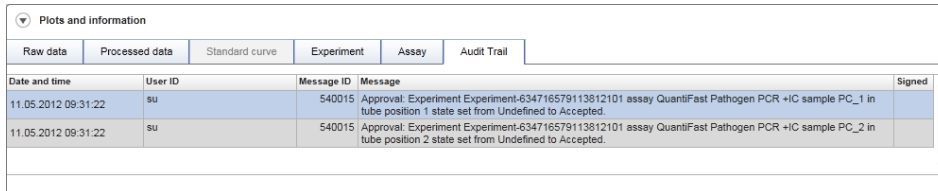
Assay tab

The **Assay** tab provides detailed information about the selected assay.

Audit trail tab

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

An example is shown.



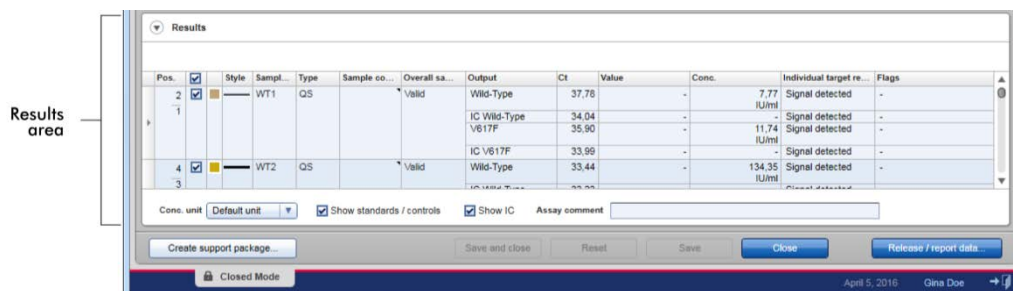
The screenshot shows a window titled "Plots and information" with several tabs: "Raw data", "Processed data", "Standard curve", "Experiment", "Assay", and "Audit Trail". The "Audit Trail" tab is active, displaying a table with the following data:

| 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.

Note: The appearance of the **Results** table may be different depending on the plug-in currently used. For details, refer to the corresponding Rotor-Gene AssayManager v2.1 plug-in user manual.




The screenshot shows a window titled "Results" with a table containing the following columns: Pos., Style, Sampl., Type, Sample co..., Overall sa..., Output, Ct, Value, Conc., Individual target re..., and Flags. The table has two main rows for samples WT1 and WT2, each with multiple target rows. A "Results area" label points to the table. Below the table are several controls: "Conc. unit", "Default unit", "Show standards / controls", "Show IC", and "Assay comment". At the bottom, there are buttons for "Create support package...", "Save and close", "Reset", "Save", "Close", and "Release / report data...". The status bar at the bottom shows "Closed Mode", "April 5, 2016", and "Gina Doe".

The **Results** table in this example contains the following columns.


Row selector

The row selector  enables the user to select and deselect samples in the results table.

Selecting single samples 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 and the row selector icon changes. The highlighted row will be colored in dark blue.

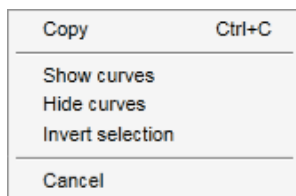
 Deactivated row selector

 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 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 |
|-------------------------|---|
| 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. |
| 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 changes according to the number of selected samples.

Column select icon

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

- No sample selected
- One or more sample(s) selected, but not all
- All samples selected

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

Line color and line style

These columns are used to display the line color and style of the PCR amplification curve used for the sample.

Sample ID

This column displays the sample ID of the sample (as defined during work list setup).

Type

This column displays the type of sample. Possible values are:

- Test Test sample
- NTC No template control
- PC Positive control
- EC+ Positive extraction control
- EC- Negative extraction control
- QS Quantitation standard

Note: Some sample types are only available for certain assays and plug-ins.

Sample comment

A comment can be entered for every sample. A maximum of 256 characters is allowed. Comments already entered during work list setup are shown.

Overall sample result

The overall sample result from analysis of the external control or test sample. Possible values are "Valid", "Invalid" or an assay specific overall sample result.

Output

All targets relating to the external control or test sample. Each target is displayed in a separate row and appears in the order defined in the assay profile.

C_T

Calculated C_T value for the target.

Value

The value for the target defined in "Output" determined according to calculations defined in the assay profile.

Conc. (concentration)

The concentration of the target, if the assay is quantitative.

Individual target result

This field displays the analysis result as "Signal detected", "No signal", "INVALID", or as an assay specific target result.

Flags

Flags are exceptions identified by Rotor-Gene AssayManager v2.1 analysis. Possible flags are listed in the corresponding Rotor-Gene AssayManager v2.1 plug-in user manual.


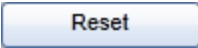



Results table options

Note: The **Results** table options differ from plug-in to plug-in. Refer to the relevant plug-in manual for details. An example is shown:

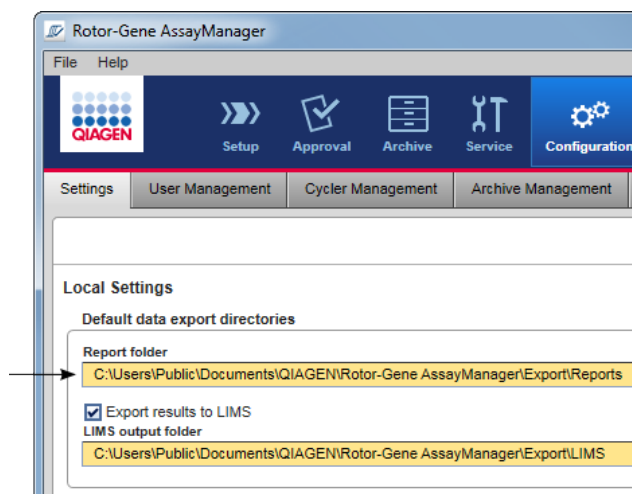
Conc. in Conc. unit Show standards / controls Show IC Assay comment

Button bar

Note: The available functions in the button bar differ from plug-in to plug-in. Refer to the relevant plug-in manual for details.

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

A *.pdf report file is saved in the folder defined in the **Configuration** environment, under **Setting/Local Settings/Folders for exporting/Report folder**.



Archive Environment

The **Archive** environment is used to search for released assays, to generate experiment reports using predefined report profiles and to import run experiment data into the Archive. Note that filtering in the **Archive** environment is limited to the currently active archives. Inactivated archives are not included in the filtering. Different archives can be activated or deactivated using the **Archive Management** tab in the **Configuration** environment.

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

Note: After finishing, the status of an assay can be one of the following:

- Unreleased: assay has not been released yet
- Fully released: assay has been released

Unreleased experiments can be accessed in the **Approval** environment.

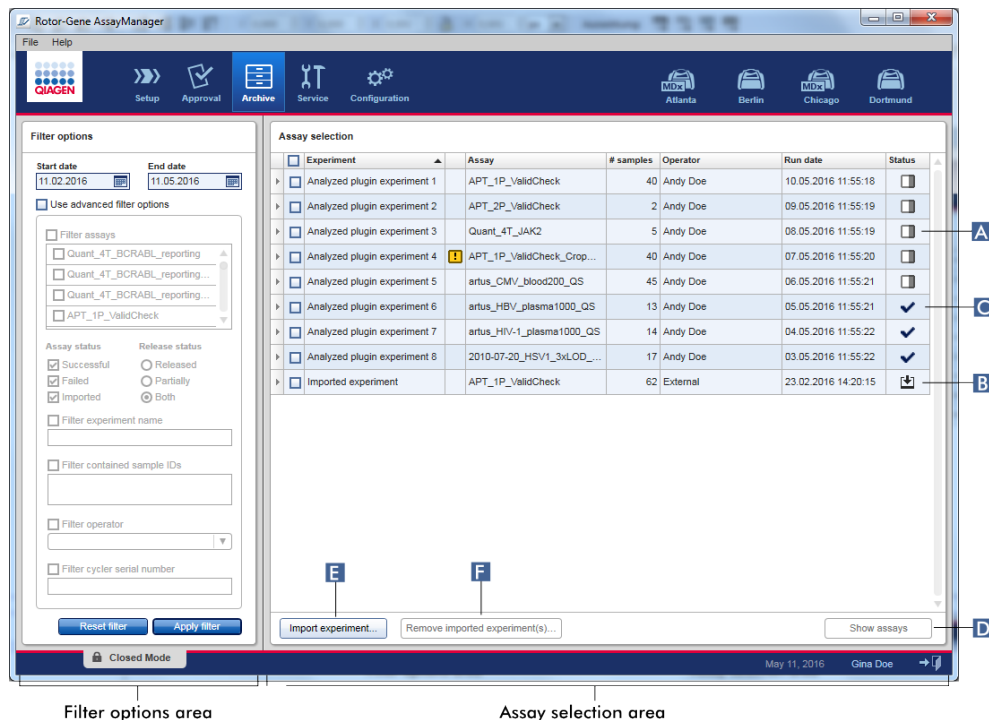
Fully released experiments can be accessed in the **Archive** environment.

Note: FDA cleared or approved nucleic acid test can only exhibit the status “fully released” in the **Archive** environment.

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

- Filter options and assay selection screen
- Showing assays screen

Filter screen



The **Filter** screen is used to search for and select partially or fully released experiments. The layout and behavior is identical to the **Filter** screen of the **Approval** environment.

The only differences are:

- Experiments with a status of “partially released” (A), “imported” (B) or “fully released” (C) are shown.

Note: The release status “partially released” is not applicable for FDA cleared or approved nucleic acid tests.

- The **Show assays** button (D) is shown instead of the **Start approval** button.

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

For experiment import, *.rgam files are necessary. Refer to the **Show Assays** screen (page 184) to export experiment raw data.

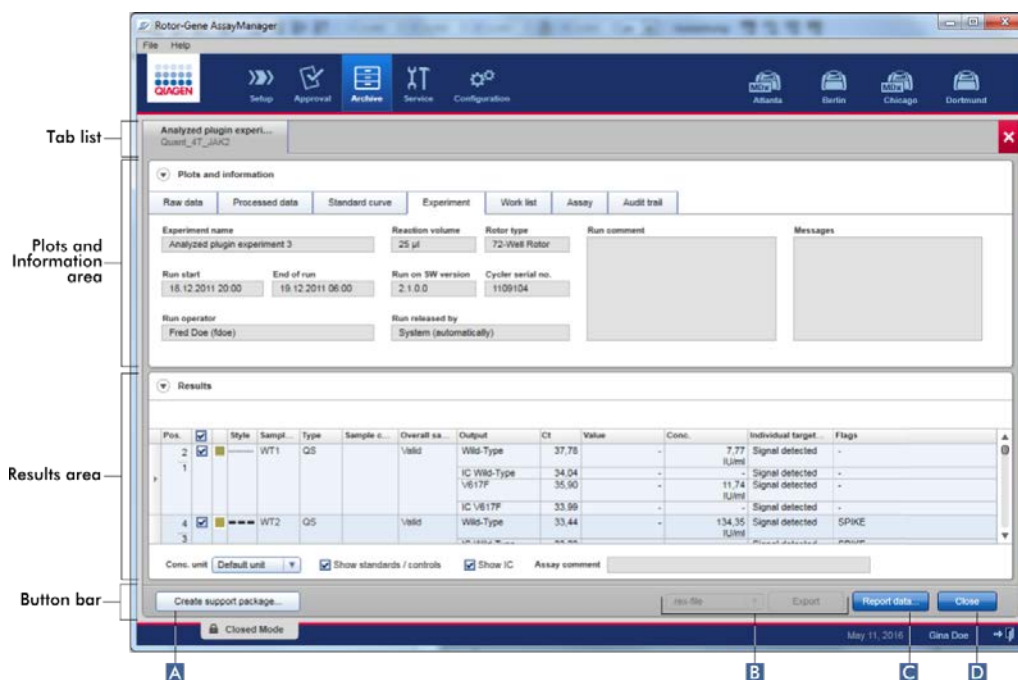
For details about the functionality of the **Filter options** area, see “**Filter options** area,” in the **Approval** environment, page 162.

Show Assays screen

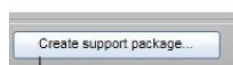
The **Show Assays** screen of the **Archive** environment is used for the following tasks:

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

The layout of this screen is very similar to the **Approval** screen in the **Approval** environment. Some functions are disabled here, e.g., the approval buttons in the results table and the assay comment field. Released assays cannot be modified.



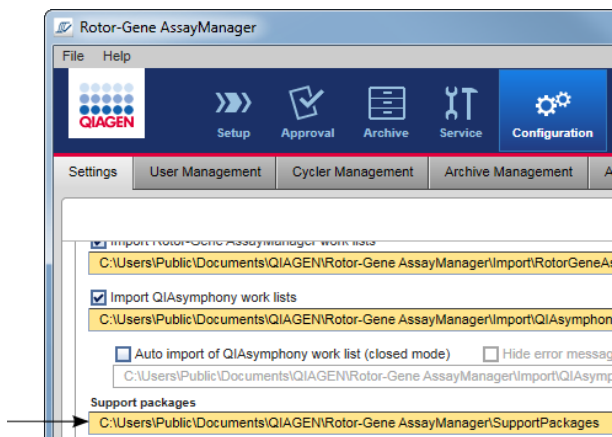
Button bar



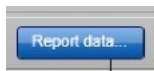
Rotor-Gene AssayManager v2.1 has a built-in support function. In case problems with a specific experiment occur, a support package can be generated. This file can be sent via email to QIAGEN Technical Services. Click **Create support package** (A), to generate the support package. A save file dialog is opened to select the target directory for the support package.

The name of the generated support package has the format: **<Experiment name>_<Assay name>_<Timestamp>.zip**

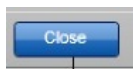
The default directory for saving the support package file is set in the **Configuration** environment under the **Settings** tab, **Local Settings** area, in the **Support packages** option (page 204).



The **Export** button (B) exports raw data of experiment/s to a *.rex file, *All .rex files, *.rgam-file, *All .rgam-files, *.zip-archive or *All .zip-archives (selected from drop-down list).



The **Report data** button (C) creates a report of the experiment as a *.pdf file.



The **Close** button (D) closes the **Show Assays** screen and returns to the **Filter** screen of the **Archive** environment.

Service Environment

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

Audit Trail tab

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

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

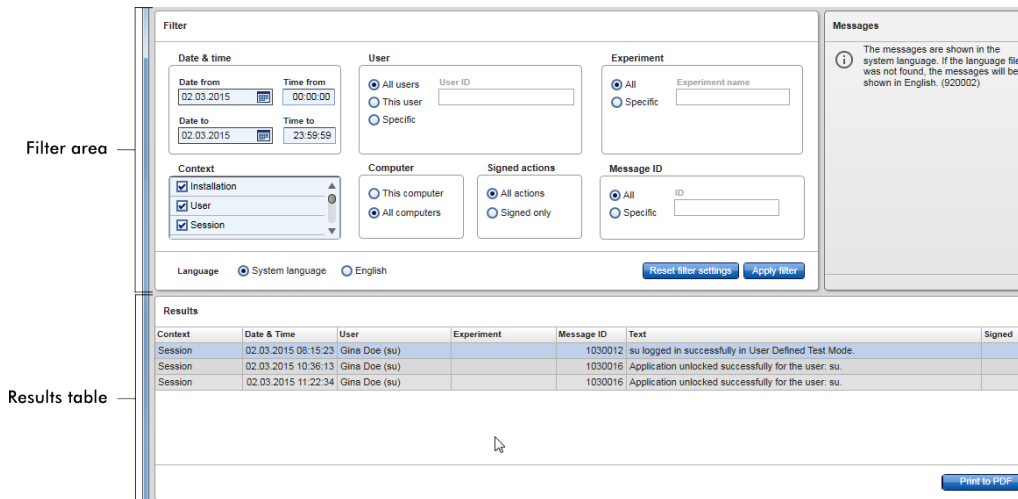
- Installation
- User
- Session
- Profile
- Settings
- Cyclor
- Work list
- Experiment

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

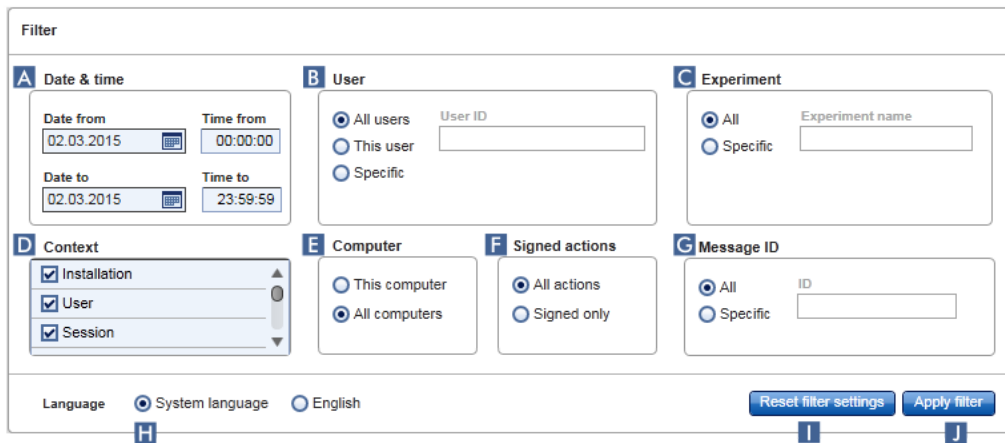
There is a **Print to PDF** button

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



The 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



The features of the **Filter** area are described in the following table.

| Filter | Explanation |
|----------------------|--|
| A Date & 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. |

| Filter | Explanation |
|-------------------------|--|
| B User | |
| All users | Activate to filter for all users. |
| This user | Activate to filter for the current user. |
| Specific | Activate and enter a user ID in the User ID field. |
| C Experiment | |
| All | Activate to filter for all experiments. |
| Specific | Activate and enter a name in the Experiment name field. |
| D 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. |
| | <input checked="" type="checkbox"/> Installation <input checked="" type="checkbox"/> User <input checked="" type="checkbox"/> Session <input checked="" type="checkbox"/> Profile <input checked="" type="checkbox"/> Settings <input checked="" type="checkbox"/> Cyclor <input checked="" type="checkbox"/> Worklist <input checked="" type="checkbox"/> Experiment |
| E Computer | |
| | If Rotor-Gene AssayManager v2.1 is installed in a network on multiple computers, this setting allows filtering for a specific computer name. It can only be switched between all messages and those messages related to the local computer. In a single computer installation environment, this setting is less useful. |
| This computer | Activate to filter for the computer in use. |
| All computers | Activate to filter for all computers. |
| F 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, page 197, and Signing release of test results option, page 201). This filter option is used to filter for signed actions only. |

| Filter | Explanation |
|--------------------------------|--|
| All actions | Activate to filter for all actions. |
| Signed only | Activate to filter for signed actions only. |
| G Message ID | |
| All | Activate to filter for all messages. |
| Specific | Activate to filter for specific message(s) and enter a message ID in the Message ID field. |
| H Language | |
| | Select a language. |
| I Reset filter settings | |
| | Reset the Filter settings to the default values (see below). |
| J Apply filter | |
| | Apply the selected filter criteria. All entries in the audit trail matching the filter criteria are listed in the results table. |

The default values and selections for the **Filter** area are as follows:

| Filter | Default setting |
|-----------------------|--------------------------------|
| Date from | Current date |
| Date to | Current date |
| Time from | 00:00:00 |
| Time to | 23:59:59 |
| User | All users activated |
| Computer | All computers activated |
| Signed actions | All actions activated |
| Message ID | All activated |
| Experiment | All activated |
| Context | All check boxes are selected |

Results table

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

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

[Print to PDF](#)

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

Columns of the **Results** table are described in the following table.

| Column | Description |
|------------------------|---|
| Context | Context of the entry Possible values are: <ul style="list-style-type: none">● Installation● User● Session● Profile● Settings● Cyclor● 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 |

| Column | Description |
|--------|--|
| Signed | Indication if the audit trail entry is signed or not |

Print to PDF button



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

Re-usable Data tab

Note: The **Re-usable Data** tab is not intended for use with FDA cleared or approved nucleic acid test.

Tasks related to the **Service** environment

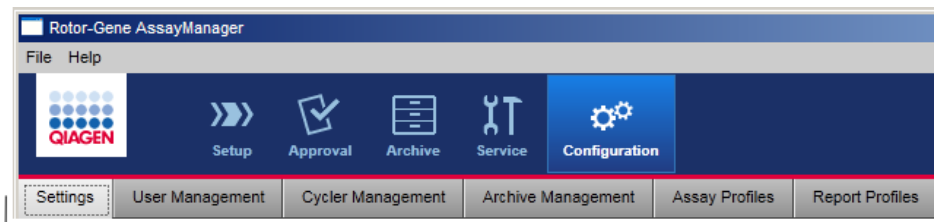
"Working with audit trails," page 265.

Configuration Environment

The settings of Rotor-Gene AssayManager v2.1 can be adjusted in the **Configuration** environment. 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 functions.

| Tab | Assigned functions |
|---------------------------|--|
| Settings | <ul style="list-style-type: none">● Define global settings● Define local settings |
| User Management | <ul style="list-style-type: none">● Add user● Edit user data● Modify user roles● Change password● Activate/deactivate user |
| Cycler Management | <ul style="list-style-type: none">● Set up new cyclers● Remove cyclers● Enter next verification date |
| Archive Management | Activate/deactivate archives |
| Assay Profiles | <ul style="list-style-type: none">● Activate/deactivate assay profiles● Import assay profiles |

| Tab | Assigned functions |
|-----------------|--|
| Report Profiles | Note: FDA cleared or approved nucleic acid tests provide a fixed content and layout for the report. Report profiles are not applicable. |

Tasks related to the Configuration environment

"Administrative Tasks," page 267.

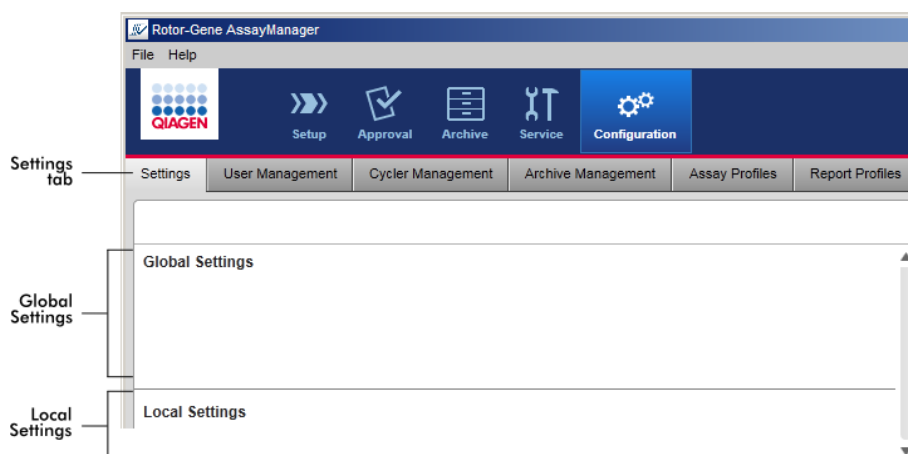
Settings tab

The **Settings** tab is divided in 2 areas:

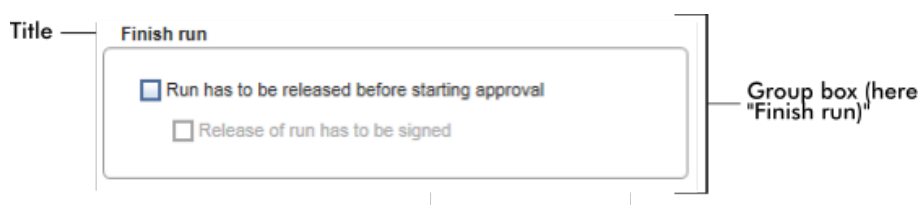
- **Global Settings**
- **Local Settings**

Global Settings are stored in the database. They are "global" for all clients connected to the database.

Local Settings are only applied to the currently used computer.



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



Global Settings area

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

The screenshot displays the 'Global Settings' interface with seven distinct group boxes, each containing various configuration options:

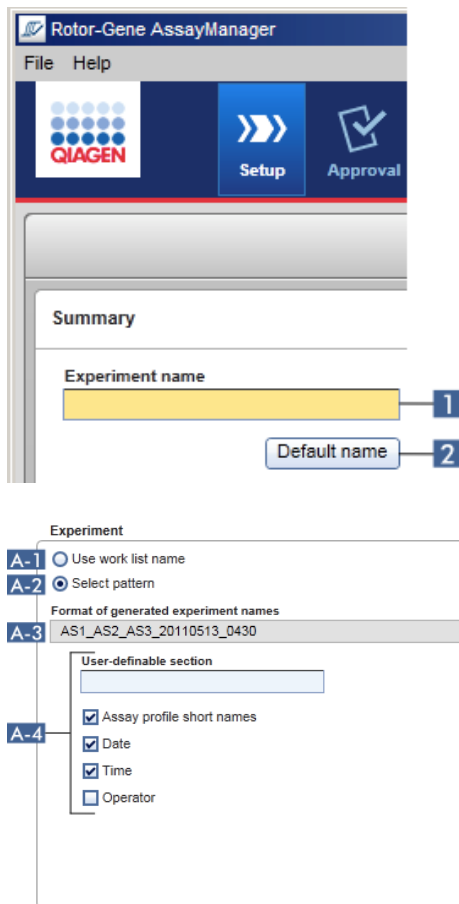
- Group A: Experiment**
 - Radio buttons for 'Use work list name' and 'Select pattern'.
 - Text field for 'Format of generated experiment names' with value 'AS1_AS2_AS3_20110513_0430'.
 - Text field for 'User-definable section'.
 - Checkboxes for 'Assay profile short names', 'Date', 'Time', and 'Operator'.
- Group B: Finish run**
 - Checkboxes for 'Run has to be released before starting approval' and 'Release of run has to be signed'.
- Group C: Reporting**
 - Image placeholder for 'Page header image' with 'No Image Configured' text and edit/delete icons.
 - Image placeholder for 'Report concluding image' with 'No Image Configured' text and edit/delete icons.
- Group D: Work list**
 - Text field for 'Format of generated work list names' with value 'WL_20110513_0430_Operator'.
 - Text field for 'User-definable section' with value 'WL'.
 - Checkboxes for 'Date', 'Time', and 'Operator'.
 - Checkboxes for 'Enable processing of unclear samples' and 'Enable checksum for LIMS import'.
 - Two columns of checkboxes for 'Closed mode' and 'UDT mode', including 'Material number required', 'Valid expiry date required', and 'Lot number required'.
- Group E: Analysis / Approval**
 - Checkboxes for 'Enable to set assay to valid (UDT mode)' and 'Release of test results has to be signed'.
- Group F: Cycler verification management**
 - Checkbox for 'Disable unverified cyclers'.
- Group G: User management**
 - Text field for 'Password renewal interval' with value '30' and unit 'days'.
 - Checkbox for 'Use CLIA compliant password rules'.
 - Text field for 'Auto-lock timer' with value '30' and unit 'minutes'.

The group boxes are:

- **A Experiment**
- **B Finish run**
- **C Reporting**
- **D Work list**
- **E Analysis/Approval**
- **F Cycler verification management**
- **G 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 v2.1 automatically generate a default name by clicking **Default name** (2). This default name can be configured in the **Experiment** group box.



Activate **Use work list name** (A-1) to use the same name as given to the work list that is applied.

Activate **Select pattern** (A-2) to define a specific naming scheme.

The **Format of generated experiment names** field (A-3) displays the current work list name definition.

The **Format of generated experiment names** field is empty if the **Use work list name** button is selected.

Use work list name
 Select pattern

Format of generated experiment names

User definable string

If the **Select pattern** button is selected, the resulting experiment name is shown in this field.

Use work list name
 Select pattern

Format of generated experiment names

The scheme for the default name (**A-4**) 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 in the experiment name. The options are separated by a “_” (underscore) 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 entered, the resulting experiment name will always start with this section.

Rotor-Gene AssayManager v2.1 is delivered with the following default settings:

Format of generated experiment names

User-definable section

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:

- Exp: the input in the **User definable section**
- AS1_AS2_AS3: the **Assay profile short names**
- 20120327: the current date
- 1359: the current time

Group box **Finish run**

The user can set this option for finishing a run:

- 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

The image shows a screenshot of a software interface titled "Finish run". It contains two checkboxes. The first checkbox is checked and is labeled "B-1" with a line pointing to it; the text next to it is "Run has to be released before starting approval". The second checkbox is unchecked and is labeled "B-2" with a line pointing to it; the text next to it is "Release of run has to be signed".

If the check box **Run has to be released before starting approval** (**B-1**) is 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.

Unless an experiment is released this way, it will not be listed in the **Approval** environment and cannot be approved.

User must release experiment

The check box **Release of run has to be signed (B-2)** is available only if the check box **Run has to be released before starting approval (B-1)** was activated before.

If the **Release of run has to be signed** option is activated, the **Release** and **Release and go to approval** buttons are disabled until the correct password is entered.

The user must sign the release by entering his password in the **Password** field. 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.

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. This is not supported for FDA cleared or approved nucleic acid tests.

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.

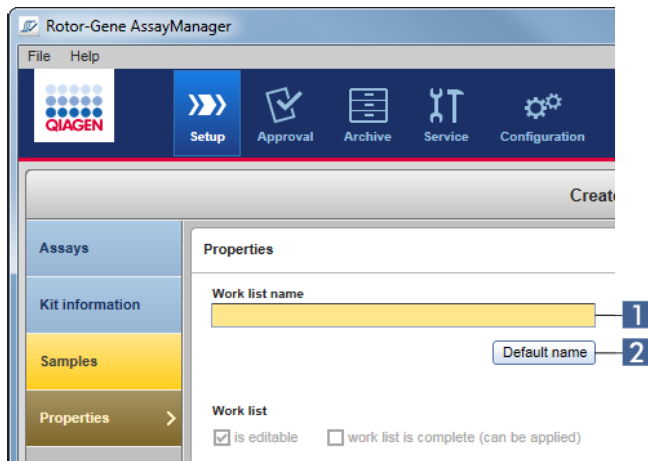
The screenshot shows the 'Work list' configuration dialog box. It contains the following elements:

- Format of generated work list names (D-1):** A text field containing 'WL_20110513_0430_Operator'.
- User-definable section (D-2):** A text field containing 'WL'.
- Checkboxes (D-2):** Three checked checkboxes labeled 'Date', 'Time', and 'Operator'.
- Enable processing of unclear samples (D-3):** An unchecked checkbox.
- Enable checksum for LIMS import (D-4):** A checked checkbox.
- Closed mode (D-5):** Three unchecked checkboxes: 'Material number required', 'Valid expiry date required', and 'Lot number required'.
- UDT mode (D-6):** Three unchecked checkboxes: 'Material number required', 'Valid expiry date required', and 'Lot number required'.

The field **Format of generated work list names** (D-1) displays the current default work list name definition, as it results from the selected options with the **User definable section** (D-2).

The entry and selections in D-2 define the default name for manually created work lists.

When the user manually creates a 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 Rotor-Gene AssayManager v2.1 automatically generate a default name by clicking the **Default name** button (2).

The scheme for the default name in D-2 can consist of up to 4 options:

- User-definable section
- Date
- Time
- Operator

Activating a check box for any or all of the 3 latter options includes this information in the work list name. The options are separated by a “_” (underscore) 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 entered, the resulting work list name will always start with this section.

Rotor-Gene AssayManager v2.1 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.

Note: The **Enable processing of unclear samples** check box function (D-3) is not applicable for FDA cleared or approved nucleic acid tests.

If the **Enable checksum for LIMS import** check box (D-4) is activated, the checksum algorithm is applied for work list import from a LIMS. If not activated, Rotor-Gene AssayManager v2.1 does not verify the checksum of a work list to be imported from a LIMS.

The options in D-5 and D-6 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 in the kit information dialog.

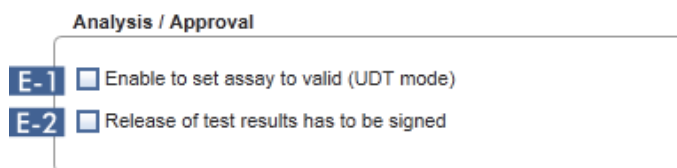
If the check boxes (D-5 and D-6) in front of the options material number, kit expiry date, and the lot number in the work list group box are activated, the associated entries in the imported work lists are mandatory during work list setup. If the check boxes are not activated, the associated entries are optional.

These options can be set independently for work list setup in Closed mode (options in D-5) and UDT mode (options in D-6).

Note: The UDT mode is not intended for use with FDA cleared or approved nucleic acid tests.

Group box **Analysis/approval**

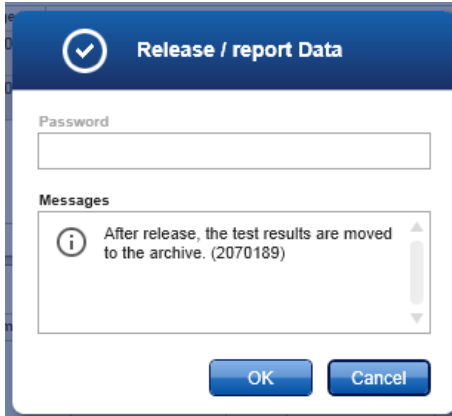
These settings influence the **Approval** environment.



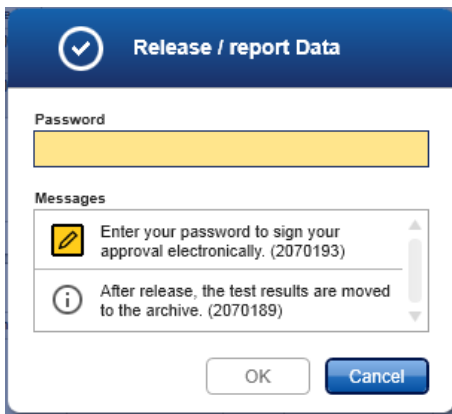
The option of the check box **Enable to set assay to valid (UDT mode)** (E-1) is only available in the UDT mode and not intended for use with FDA cleared or approved nucleic acid tests.

If the check box **Release of test results has to be signed** (E-2) is activated, the release of test results in the **Approval** environment has to be signed with the approver's password.

The following examples illustrate this behavior by comparing the deactivated/activated **Release of test results has to be signed** (E-2) check box and the resulting dialog in the release step of the **Approval** environment.



User releases test samples simply by clicking **OK**.



The approver's password must be entered before test samples are released.

The **OK** button is disabled by default and is activated once the correct password is entered.

Group box **Cycler verification management**



Rotor-Gene AssayManager v2.1 continuously checks the status of connected cyclers concerning verification.

The option **Disable unverified cyclers** check box (**F-1**) determines if cyclers with a verification status past due are automatically disabled or not.

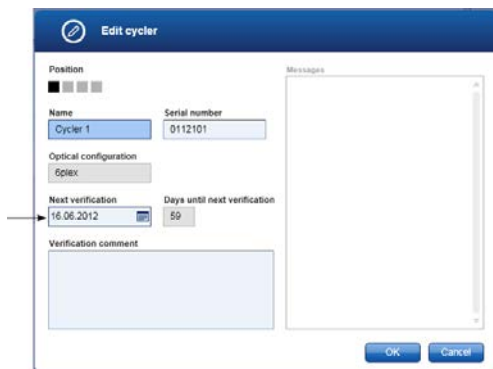
Check box **Disable unverified cyclers** activated

Cycler verification management

Disable unverified cyclers

If the verification of a cycler is already 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 **Edit cycler** dialog (see arrow). See "Editing cycler settings," page 275.



Check box **Disable unverified cyclers** deactivated

Cycler verification management

Disable unverified cyclers

If the check box is deactivated, cyclers can be used for experiments even if the verification is already expired.

Group box **User management**

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

User management

G-1 Password renewal interval
30 days

G-2 Use CLIA compliant password rules

G-3 Auto-lock timer
30 minutes

The **Password renewal interval** setting (**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.

If the **Use CLIA compliant password rules** checkbox (**G-2**) is 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 the **Use CLIA compliant password rules** checkbox is deactivated, a password must have at least 8 and no more than 40 characters.

The **Auto-lock timer** setting (**G-3**) controls the auto-lock function. If there is no user interaction, the application will be locked automatically after the time defined in this field. 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 area

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:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Export\Reports | Browse | Export directories |
| | <input checked="" type="checkbox"/> Export results to LIMS | | | |
| B | LIMS output folder | C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Export\LIMS | Browse | |

Default data source directories

| | | | | |
|----------|--|--|--------|--------------------|
| C | Assay profiles for assay development | C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\AssayProfiles | Browse | Source directories |
| D | Assay profiles for import | C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Import\AssayProfiles | Browse | |
| E | Assay profiles for export | C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Export\AssayProfiles | Browse | |
| F | Rotor-Gene experiment template files (.ret) | C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Import\ExperimentTemplates | Browse | |
| G | Rotor-Gene quantitation template files (.qut) | C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Import\QuantitationTemplates | Browse | |
| H | <input type="checkbox"/> Load sample IDs from QS SP <input type="checkbox"/> Enable import of IDs for unclear samples | C: | Browse | |
| I | <input checked="" type="checkbox"/> Import Rotor-Gene AssayManager work lists | C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Import\RotorGeneAssayManage | Browse | |
| J | <input checked="" type="checkbox"/> Import QIASymphony work lists | C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Import\QIASymphonyWorklists | Browse | |
| | <input type="checkbox"/> Auto import of QIASymphony work list (closed mode) <input type="checkbox"/> Hide error messages for missi | C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Import\QIASymphonyWorkli | Browse | |
| K | <input checked="" type="checkbox"/> Import LIMS work lists | C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Import\LIMSWorklists | Browse | |
| L | Experiments for import (closed mode) | C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Import\ExperimentsforClosedMode | Browse | |
| M | Experiments for import (user defined test mode) | C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Import\ExperimentsforUDTMode | Browse | |
| N | Exported experiments (closed mode) | C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Export\ExperimentsforClosedMode | Browse | |
| O | Exported experiments (user defined test mode) | C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\Export\ExperimentsforUDTMode | Browse | |
| P | Report profiles | C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\ReportProfiles | Browse | |
| Q | Support packages | C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\SupportPackages | Browse | |
| R | Rotor-Gene experiments (.rex) for assay profile testing | C:\Users\Public\Documents\QIAGEN\Rotor-Gene AssayManager\RexForAssayTest | Browse | |

A Report folder

Target directory where reports generated in the **Approval** or **Archive** environment are saved.

B LIMS output folder

Target directory where export data for a LIMS are saved. Initially, this option is disabled. To enable this option, the associated 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 Assay profiles for assay development

Source directory for assay profiles for development in UDT mode.

Note: This is not relevant for Closed mode assays (i.e. FDA cleared or approved nucleic acid tests).

D Assay profiles for import

Source directory for assay profiles to be imported into the Rotor-Gene AssayManager v2.1 database via the **Assay Profiles** tab in the **Configuration** environment.

E Assay profiles for export

Source directory for assay profiles to be exported into the Rotor-Gene AssayManager v2.1 database via the **Assay Profiles** tab in the **Configuration** environment.

F Rotor-Gene experiment template files (.ret)

Source directory for Rotor-Gene experiment template files (*.ret) used in the **Development** environment of the UDT mode.

Note: This is not relevant for Closed mode assays (i.e., FDA cleared or approved nucleic acid tests).

G Rotor-Gene quantitation template files (.qut)

Source directory for Rotor-Gene quantitation template files (*.qut) used in the **Development** environment of the UDT mode.

Note: This is not relevant for Closed mode assays (i.e. FDA cleared or approved nucleic acid tests).

H Directory

Source directory for QIASymphony sample IDs to be imported into Rotor-Gene AssayManager v2.1 with the option to import “unclear” samples.

Load sample IDs from QS SP

Enable import of IDs for unclear samples

I Import Rotor-Gene AssayManager work lists

Import Rotor-Gene AssayManager work lists

J Import QIASymphony work lists

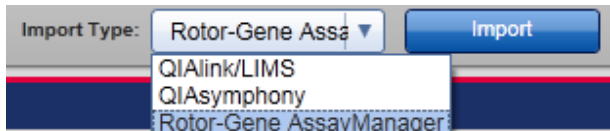
Import QIASymphony work lists

K Import LIMS work lists

Import LIMS work lists

Rotor-Gene AssayManager v2.1 can import work lists from other Rotor-Gene AssayManager installations, QIA Symphony and LIMS. The user can select which of these 3 import options shall be available by activating the check boxes **I**, **J** and **K**.

The import type menu in the **Setup** environment will be populated with the selected import options accordingly.



L Experiments for import (closed mode)

Source directory for closed mode experiments to be imported into the Rotor-Gene AssayManager v2.1 database via the **Import experiments** function in the **Archive** environment.

M Experiments for import (user defined test mode)

Source directory for user defined test mode experiments to be imported into the Rotor-Gene AssayManager v2.1 database via the **Import experiments** function in the **Archive** environment.

N Exported experiments (closed mode)

Destination for *.rex-files exported from the **Archive** environment (Closed mode).

O Exported experiments (user defined test mode)

Destination for *.rex-files exported from the **Archive** environment (User Defined Test mode).

Note: This is not relevant for Closed mode assays (i.e. FDA cleared or approved nucleic acid tests).

P Report profiles

Directory for importing and exporting report profiles.

Q Support packages

Destination for support packages created from the **Approval** or **Archive** environment.

R Rotor-Gene experiments (.rex) for assay profile testing

Source directory for Rotor-Gene experiments (*.rex files) to be tested in the **Development** environment of the UDT mode.

Note: This is not relevant for Closed mode assays (i.e. FDA cleared or approved nucleic acid tests).

Tasks related to the **Settings** tab

“Managing cyclers,” page 272.

“Creating/editing a work list,” page 237.

“Finishing and releasing a run,” page 255.

“Managing users,” page 277.

User Management tab

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 “User roles,” page 88.

The **User Management** tab consists of 2 parts:

- **Registered users** table
- Button bar

The screenshot shows the Rotor-Gene AssayManager application window. The 'User Management' tab is active, displaying a table of registered users. The table has columns for User ID, First name, Last name, and Roles. Below the table is a 'Show only activated user profiles' checkbox and a 'Refresh list' button. A 'New user' button is also visible in the bottom right corner of the table area.

| User ID | First name | Last name | Roles |
|----------|--------------|------------|----------------|
| ✓ adoe | Ashly | Doe | Operator |
| ✓ aduser | Albrecht | Dier | Operator |
| ✓ bdoe | Bob | Doe | Operator |
| ✓ cdoe | Cindy | Doe | Approver |
| ✓ ddoe | Dean | Doe | AssayDeveloper |
| ✓ edoe | Edward | Doe | Administrator |
| ✓ fdoe | Fred | Doe | Administrator |
| ✓ gbolog | Giovanni | de Bologna | Operator |
| ✓ leinci | Leonardo | de Vinci | Operator |
| ✓ mbouna | Michelangelo | Bounarotti | Operator |
| ✓ rsanti | Raffaello | Santi | Operator |
| ✓ su | Gina | Doe | SuperUser |

Registered users table

Check box Show only activated user profiles

Button Bar

Registered users table

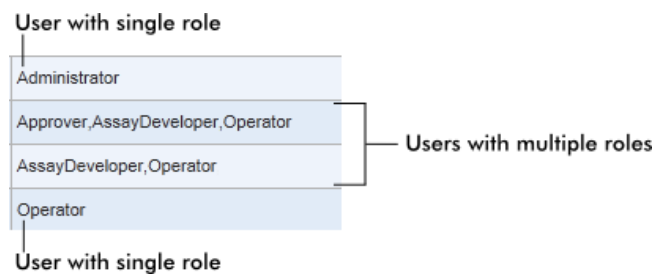
The **Registered users** table lists all user profiles already configured in Rotor-Gene AssayManager v2.1. A user profile can be activated or deactivated. To display a deactivated user profile in the table, the **Show only activated user profiles** check box must be deactivated. The activation status of a user profile is displayed in the first column of the table.


| Registered users | | | | | | |
|------------------|-------------------------------------|------------|-----------|-------|----------------|--|
| | User ID | First name | Last name | Roles | | |
| Activated user | <input checked="" type="checkbox"/> | adoc | Andy | Doe | Operator | |
| | <input checked="" type="checkbox"/> | aduerer | Albrecht | Dürer | Operator | |
| Deactivated user | <input type="checkbox"/> | bdoc | Bob | Doe | Operator | |
| | <input checked="" type="checkbox"/> | cdoc | Cindy | Doe | Approver | |
| | <input type="checkbox"/> | ddoc | Dean | Doe | AssayDeveloper | |

Edit user button

| Column | Explanation |
|-------------|--|
| User status | <p>Status of the user profile.</p> <p>A user profile can be deactivated or activated. The activation status is displayed by the icon in the first column of the table.</p> <p><input checked="" type="checkbox"/> User is activated <input type="checkbox"/> User is deactivated</p> <p>Note: Deactivated user profiles will only be shown in the table if the Show only activated user profiles checkbox is deactivated. If the checkbox is activated, only profiles of activated users will be shown.</p> |
| 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



| Column | Explanation |
|--|---|
| Edit user button  | The Edit user button opens the Edit User dialog where properties and settings can be modified for a user. |



A First name

There is a maximum of 50 characters in this field.

B Last name

There is a maximum of 50 characters in this field.

C User ID

ID must be unique and may not exceed a maximum of 40 characters. User IDs containing the words QIAGEN, Service, and User in combination are not allowed.

D Password fields

These fields are used to set 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

Click this check box to activate or deactivate a user.

F **Messages**

Messages, warnings, and errors are displayed.

G **Roles**

The check boxes are used to assign roles to a user profile. Activate the selection 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," page 88.

H **OK** button

Click to confirm the current settings, close the dialog, and go back to the **User Management** tab.

I **Cancel** button

Click to cancel the current settings, close the dialog, and go back to the **User Management** tab.

User Management button bar



These buttons are always enabled.

Click **Refresh list** to update the **Registered users** table by retrieving the list of users from the internal database.

Click the **New user** button to create a new user profile.

The following **Add user** dialog is opened:

The screenshot shows the 'Add user' dialog box. The title bar is blue with a pencil icon and the text 'Add user'. The dialog contains the following elements:

- First name:** A text input field highlighted in yellow.
- Last name:** A text input field highlighted in yellow.
- User ID:** A text input field highlighted in yellow.
- Password:** A text input field highlighted in yellow.
- Confirm password:** A text input field.
- Roles:** A list box with checkboxes for Administrator, Approver, AssayDeveloper, Operator, and SuperUser.
- Messages:** A scrollable area containing two error messages:
 - Enter a valid first name (1-50 characters). (150040)
 - Enter a valid last name (1-50 characters). (150041)
- Buttons:** 'OK' and 'Cancel' buttons at the bottom right.

Characteristics upon opening the dialog are:

- All fields are empty
- The following mandatory fields are colored in yellow:
 - **First name**
 - **Last name**
 - **User ID**
 - **Password**
- **Activate user** check box is activated
- No role is selected
- **OK** button is deactivated

All elements in the **Add user** dialog are equal to those in the **Edit user** dialog described above.

Click **OK** to confirm all entries and go back to the **User Management** tab.

If the **Activate user** check box is checked, the new user profile is added to the **Registered users** table and is selected.

If the **Activate user** check box is unchecked, 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,” page 278.

“Changing user profile settings,” page 279.

“Activating/deactivating a user profile,” page 280.

Cycler Management tab

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

| Position | Name | Serial number | Optical configuration | Next verification | Cycler status | Actions |
|----------|----------|-------------------|-----------------------|------------------------|---------------|-----------------|
| ■ ■ ■ ■ | Cycler 1 | 0112101 (RGQ MDx) | 6plex | 22.04.2015 [50 day(s)] | Ready | [Edit] [Delete] |
| ■ ■ ■ ■ | Cycler 2 | 0409102 (RGQ) | 5plex | 24.04.2015 [52 day(s)] | Ready | [Edit] [Delete] |
| ■ ■ ■ ■ | Cycler 3 | 1209103 (RGQ MDx) | 5plex HRM | 26.04.2015 [54 day(s)] | Ready | [Edit] [Delete] |
| ■ ■ ■ ■ | Cycler 4 | 1109104 (RGQ) | 5plex HRM | 28.04.2015 [56 day(s)] | Ready | [Edit] [Delete] |

Registered cyclers table

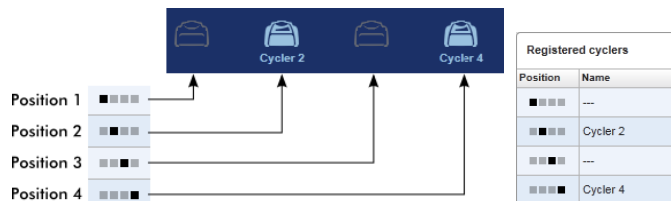
The **Registered cyclers** table consists of 4 rows. Every row represents 1 of the up to 4 configurable cyclers. If no cyclers are configured yet, all columns except the position column are empty. The following graphic shows an example configuration with cyclers registered in positions 2 and 4. Positions 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. |
|----------|---|

Examples:



In the illustrations 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 v2.1 installation

| | |
|---------------|---------------------------------------|
| Serial number | Serial number of a registered cycler. |
|---------------|---------------------------------------|

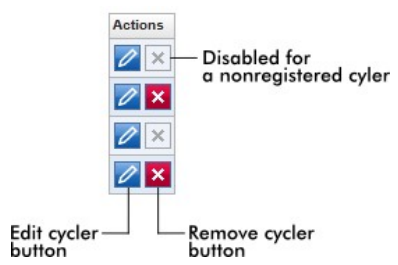
Characteristics:

- Must not be empty
- Must be unique within a Rotor-Gene AssayManager v2.1 installation
- Must match a connected cycler that is switched on

After the user enters the serial number of a connected cycler, its optical configuration is automatically checked by Rotor-Gene AssayManager v2.1 and displayed in the **Optical configuration**

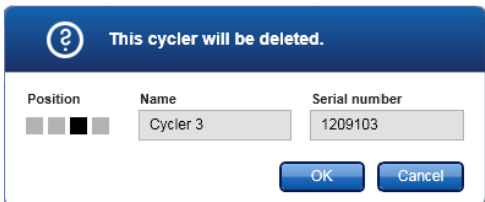
| Column | Explanation |
|------------------------------|--|
| | <p>column. This cell remains empty if no cyclers with the entered serial number is connected.</p> <p>Note: If the instrument is a Rotor-Gene Q MDx cycler, the “MDx” symbol is automatically added to the serial number and the corresponding cycler icon.</p> |
| Optical configuration | Optical configuration of a registered cycler. |
| Next verification | <p>Next temperature verification date; days remaining until that date.</p> <p>Characteristics:</p> <ul style="list-style-type: none"> ● This field can be empty. ● If it is set to empty, the Verification comment for selected cycler area is disabled and its content is cleared. ● If the date has expired, the Verification comment for selected cycler area is disabled. ● If a date is set, the date must be in the future. |
| Cycler status | <p>Shows the current status of a registered cycler. Possible values are:</p> <ul style="list-style-type: none"> ● Offline: cycler is not connected or connected but not switched on ● Ready: cycler is ready ● Needs verification: verification has expired ● Loaded: cycler is loaded and ready to be run ● Running: cycler is currently running ● Run stopped: user has stopped a run while the cycler was running ● Run complete: run has finished successfully ● Run failed: error occurred during the run ● 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 |

| Column | Explanation |
|----------------|---|
| Actions | <p>The actions column contains buttons for:</p> <ul style="list-style-type: none"> • Editing the cyclers's properties • Removing a cycler |



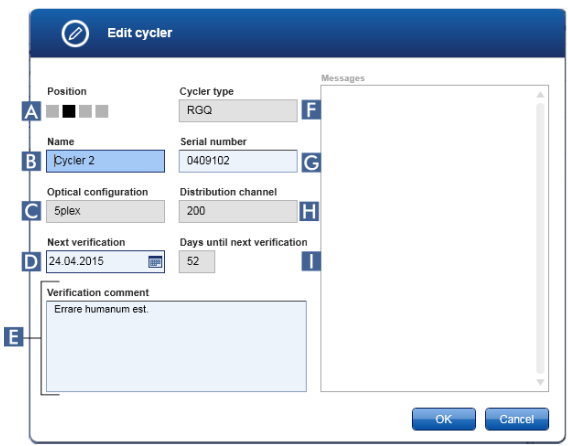
Remove cycler button

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



Edit cycler button

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



Position (A)

This graphical illustration represents 1 of up to 4 configurable cyclers. The current cycler position is indicated by a black square.

Name (B)

The name of the cycler in this field can be edited.

Optical configuration (C)

The optical configuration of the cycler cannot be edited; it is read-only.

Next verification (D)

The next verification date can be entered manually or using the date picker .

Verification comment (E)

This text field is used to enter an optional verification comment.

Cycler type (F)

This field displays the cycler type and is automatically filled after a serial number is entered.

Serial number (G)

The serial number of the cycler can be edited.

Distribution channel (H)

The distribution channel of the cycler cannot be edited; it is read-only.

Days until next verification (I)

This field displays the number of remaining days until the verification date. The field cannot be edited.

Tasks related to the Cycler Management tab

“Adding a cycler,” page 273.

“Editing cycler settings,” page 275.

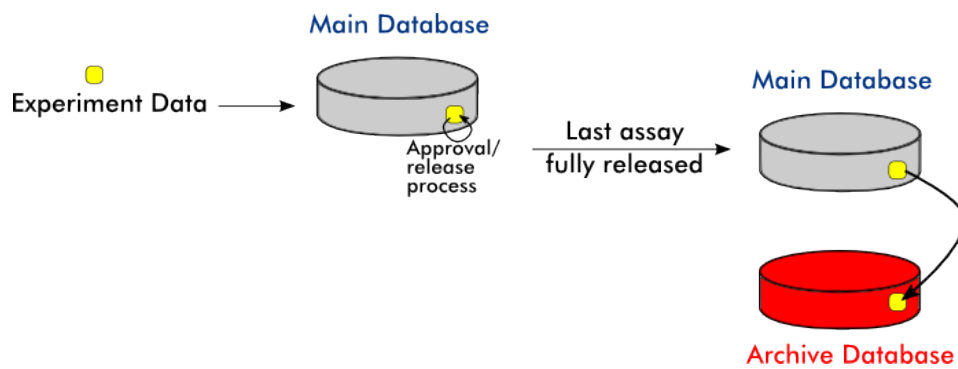
“Removing a cycler,” page 276.

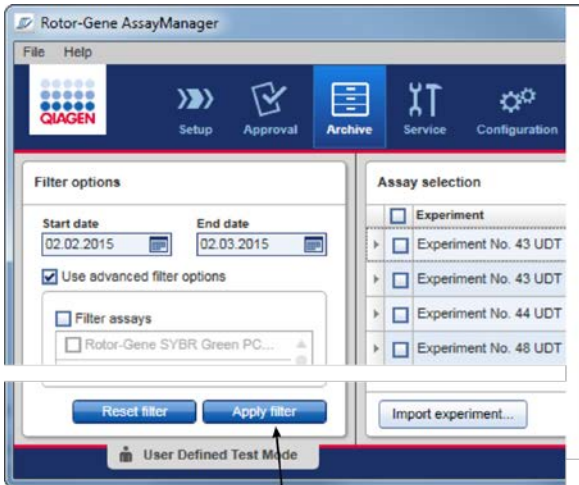
Archive Management tab

The **Archive Management** tab is used to define which archives are browsed for experiment data during assay selection in the **Archive** environment.

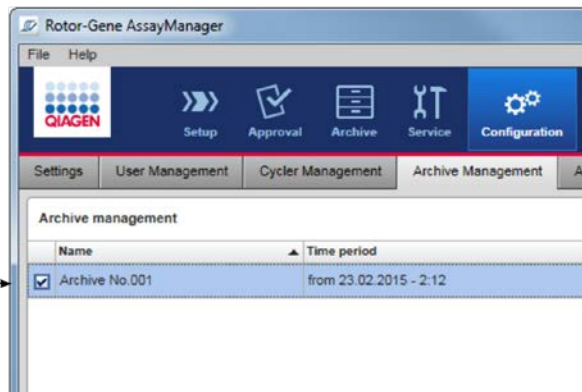
Background information

When a run is finished, all experiment data and audit trails are stored in the main database until all sample results of the experiment are released in the **Approval** environment. After release of the sample results the experiment data are accessible via the **Archive** environment.





Only archives activated in the Archive management are used to search for assays



Characteristics of an archive database

An archive database covers a certain time span that is defined by the date of the first and the last audit trail message stored in the database.

Archive Management

| | Name | Time period |
|-------------------------------------|----------------|---|
| <input checked="" type="checkbox"/> | Archive No.001 | from 19.04.2008 - 19:30 to 31.12.2008 - 19:17 |

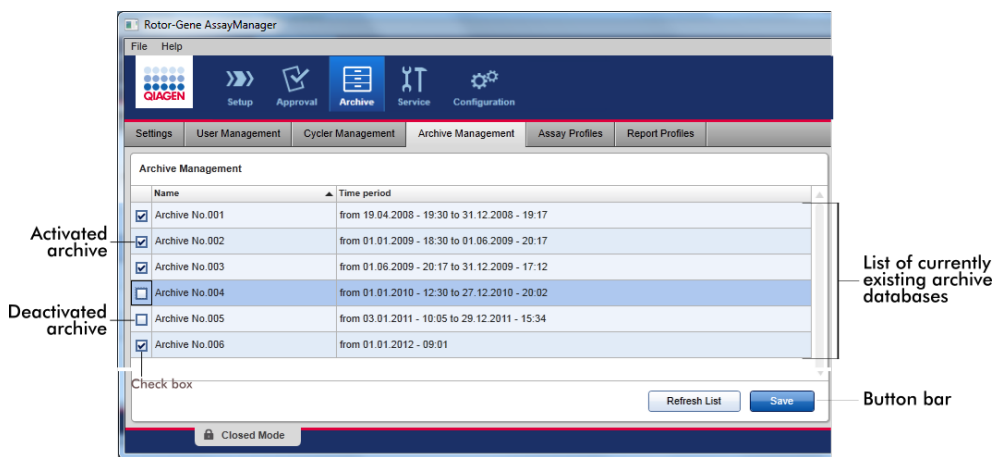
Time period of archive

An archive database has a size of 10 GB. If a database is close to its maximum capacity, the database is marked as "closed" and a new archive database is created automatically.

All these processes concerning the creation and management of archive databases are automatically performed in the background. The main database only contains data from current, non-released or not fully released experiments.


The **Archive Management** tab consists of 2 parts:


- **Archive Management** table
- Button bar



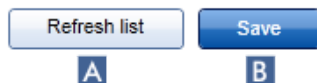
Archive Management table

The **Archive Management** table lists all currently existing archive databases.

| Column | Explanation |
|--|--|
| Check box | <p>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.</p> <p>Deactivated databases will not be included in a search. In addition, audit trail messages related to the archived experiments will not be shown in the Service environment if the dedicated archive database is deactivated.</p> |
|  Activated | <ul style="list-style-type: none"> ● 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. |

| Column | Explanation |
|--|---|
|  Deactivated | <ul style="list-style-type: none"> 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 ("from"): Creation date of the first audit trail entry in the database. End date ("to"): Creation date of the latest audit trail entry in the database. The end date of the active archive is empty. |

Archive Management button bar



Click **Refresh list** (A) to discard unsaved modifications.

Click **Save** (B) to save all modifications.

Tasks related to the Archive Management tab

"Managing archives," page 284.

Assay Profiles tab

The **Assay Profiles** tab in the **Configuration** environment is used to manage assay profiles, i.e., importing, exporting, activating and deactivating assay profiles. Assay profiles cannot be edited in this tab.

Assay profiles can clearly be identified by their name and a version number. It is possible to have several assay profiles with the same name but different version numbers — but only one can be

active. All other assay profiles with this name are automatically deactivated. User defined assay profiles have to be imported into the database within this tab to be accessible for experiment setup.

Note: Only assay profiles compatible to Rotor-Gene AssayManager v2.1 can be imported.

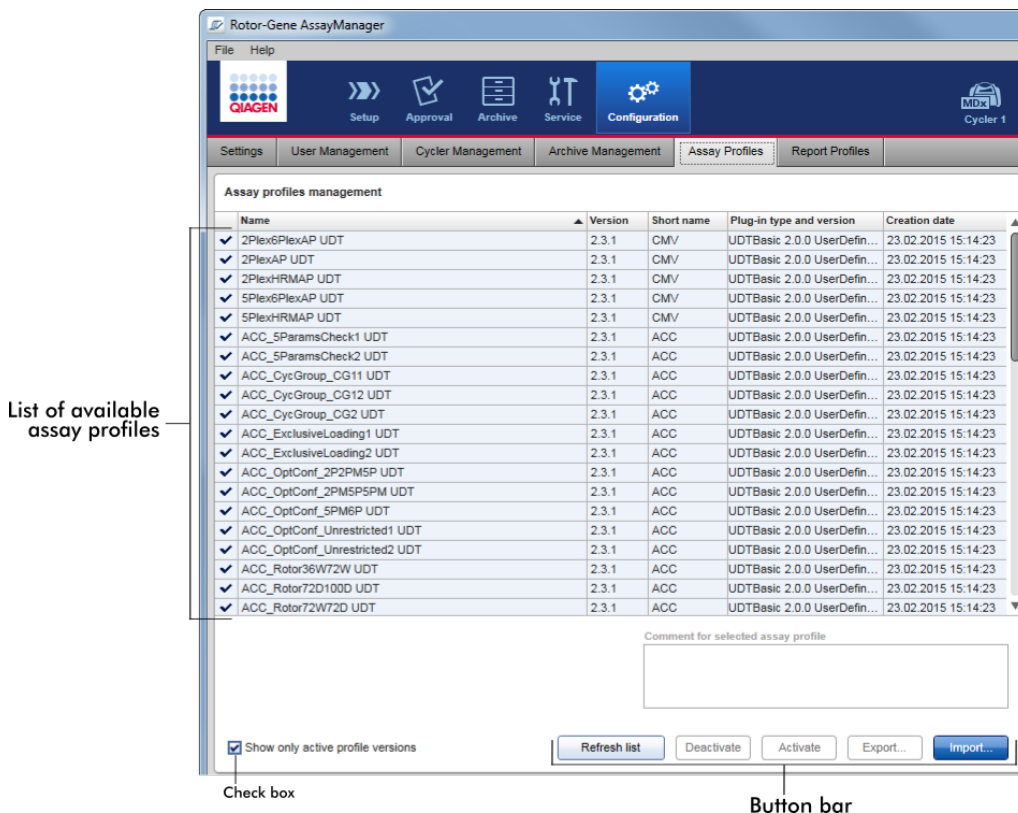
Example

The following screenshot shows an example where an assay profile “Rotor-Gene SYBR® Green PCR Demo Kit” exists in 2 different versions, 3.0.0 and 5.0.0. Only one version can be active. Version 3.0.0 is deactivated () , and version 5.0.0 is activated () .

| | | | |
|-------------------------------------|------------------------------------|-------|------|
| <input type="checkbox"/> | Rotor-Gene SYBR Green PCR Demo Kit | 3.0.0 | SYBR |
| <input checked="" type="checkbox"/> | Rotor-Gene SYBR Green PCR Demo Kit | 5.0.0 | SYBR |

The **Assay Profiles** tab consists of 2 parts:

- **Assay profiles management** table (and check box)
- **Assay Profiles** button bar



Assay profiles management table

The **Assay profiles management** table lists all available assay profiles, i.e., all assay profiles stored in the current Rotor-Gene AssayManager v2.1 installation. Every assay profile is displayed in a separate row. The table is sortable: Clicking the corresponding column header will sort the table according to the selected column. A row in the header of the corresponding column indicates the sorting column (▲ icon for ascending order, ▼ icon for descending order).

| Assay profiles management | | | | | |
|--|-----------|------------|----------------------------|---------------------|--|
| Name | ▲ Version | Short name | Plug-in type and version | Creation date | |
| <input checked="" type="checkbox"/> Quantifast Pathogen PCR +IC | 2.0.0 | QF Pat | UDTBasic 0.8.5 UserDefi... | 23.03.2012 17:00:52 | |
| <input checked="" type="checkbox"/> Rotor-Gene SYBR Green PCR Demo Kit | 3.0.0 | SYBR | UDTBasic 0.8.5 UserDefi... | 23.03.2012 16:54:04 | |

Note: The check box **Show only active profile versions** determines if deactivated assay profiles are shown in the table or not.

Show only active profile versions

If the box is activated () , only activated assay profiles are shown; deactivated assay profiles are hidden.

If the box is deactivated () , both activated and deactivated assay profiles are shown.

| Column | Explanation |
|--------------------------|--|
| Status | Status of the assay profile. <input type="checkbox"/> Deactivated assay profile <input checked="" type="checkbox"/> Expired assay profile <input checked="" type="checkbox"/> Activated assay profile Note: If Rotor-Gene AssayManager v2.1 has been updated from an older version, there are also deactivated (expired) assay profiles. It is not possible to activate them. |
| 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. |

Assay Profiles button bar

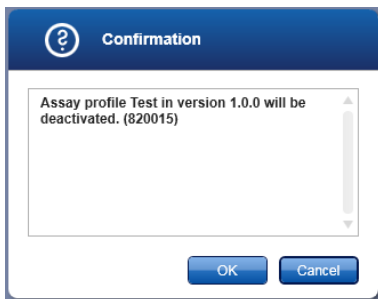


Refresh list (A)

Click to update the list of all available assay profiles.

Deactivate (B)

Click to deactivate the selected assay profile. A confirmation dialog opens.



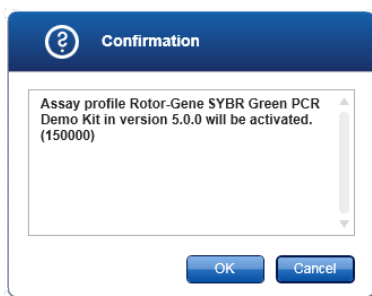
Click **OK** to confirm before the selected assay profile is deactivated.

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 no longer listed in the table.

Activate (C)

Click to activate the selected assay profile. A confirmation dialog opens.

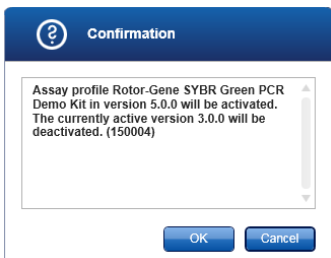


Click **OK** to confirm before the selected assay profile is activated.

The icon of the assay profile changes from deactivated () to activated ()

The check box **Show only active profile versions** must be deactivated to list activated and deactivated assay profiles in parallel in the table.

If another version of the assay profile is active, the following dialog is displayed.



Click **OK** to confirm and disable the other version.

Export (D)

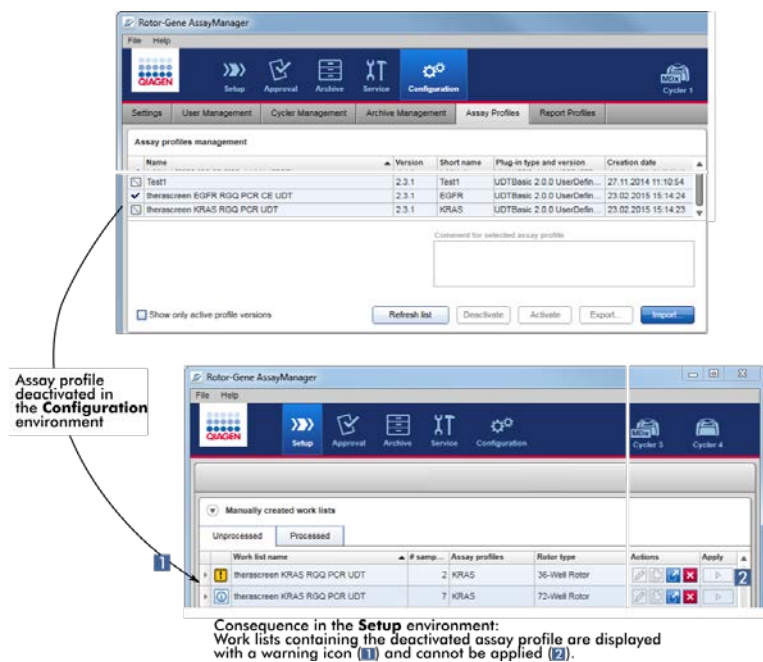
Click to export an assay profile (file extension *.iap). A dialog is opened to select the destination directory and a file name. The selected assay profile will be exported accordingly.

Note: The export functionality is only available for UDT Assay Profiles (not for FDA cleared or approved assays).

Import (E)

Click to import an assay profile. A dialog is opened to select the assay profile (file extension *.iap). The selected assay profile is imported to the **Assay profiles management** table.

Note: The relationship between the deactivation of assay profiles in the **Configuration** environment and work lists in the **Setup** environment is explained in the following figure.



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,” page 269.

“Importing/exporting an assay profile,” page 268.

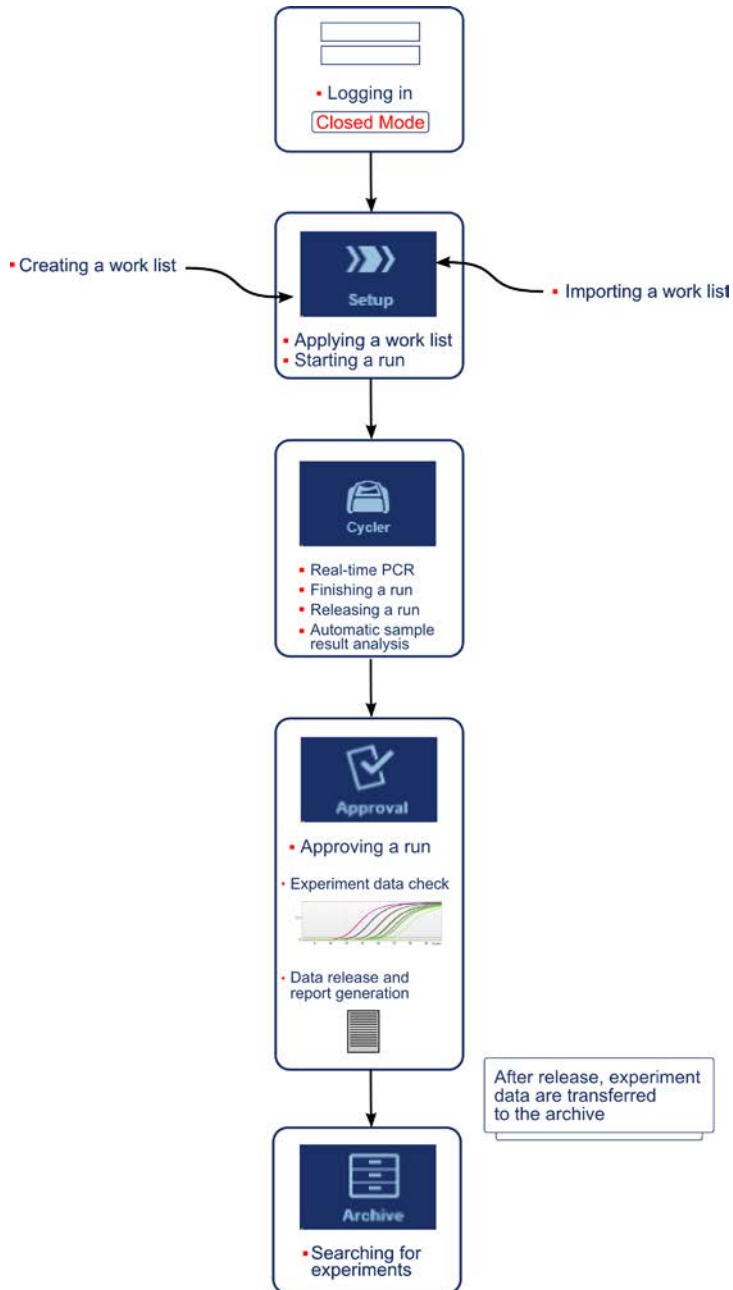
Report Profiles tab

A report containing various data about an experiment can be generated by Rotor-Gene AssayManager v2.1 in a *.pdf file format.

Note: FDA cleared or approved nucleic acid tests come with a fixed content and layout for the report. Report profiles are not applicable.

Work Flow

The following graphic summarizes the work flow in Rotor-Gene AssayManager v2.1.



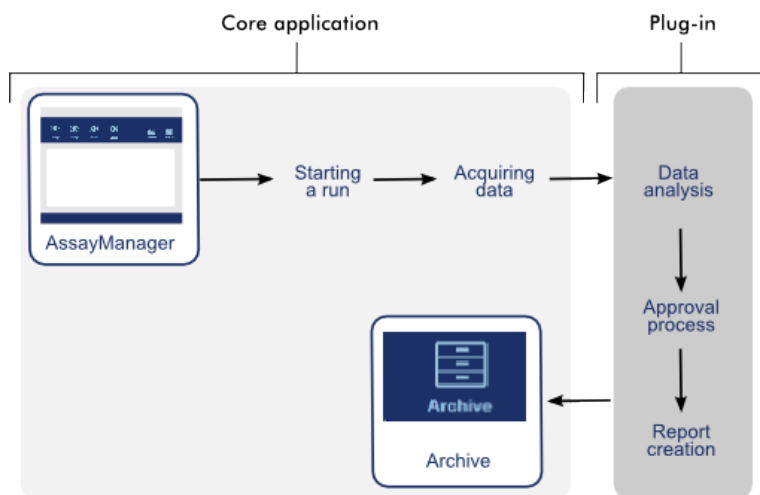
Plug-in concept

Rotor-Gene AssayManager v2.1 is a versatile application with a plug-in architecture. With every plug-in the number of supported assays can be extended.

The general work flow is provided by the core application and its framework. 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:



Using Rotor-Gene AssayManager v2.1

The work flow in Rotor-Gene AssayManager v2.1 can be divided in 2 sections:

- Standard tasks
- Administrative tasks

Standard tasks are tasks that are performed on a daily basis.

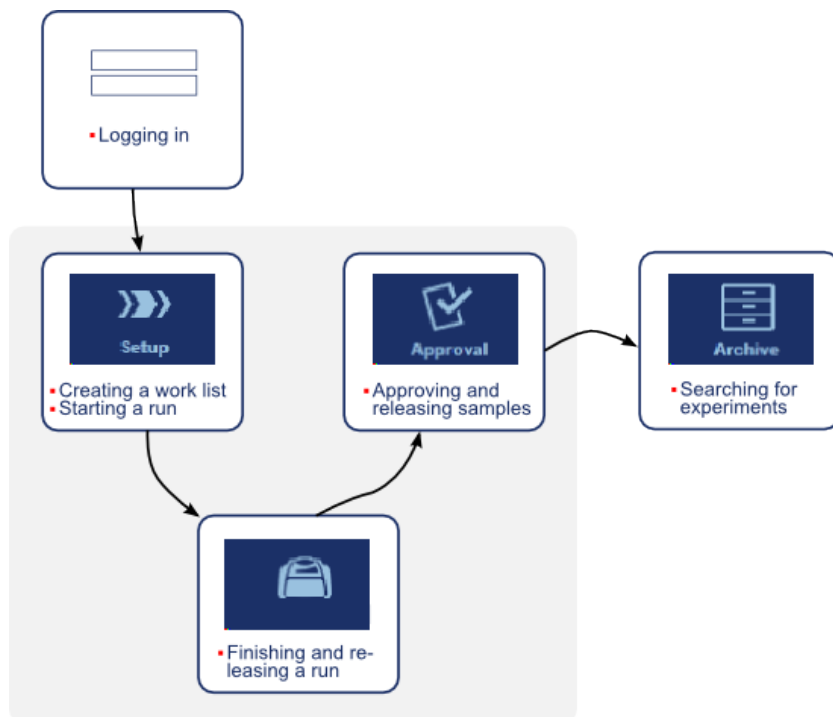
Administrative tasks are tasks performed to manage and configure the work flow.

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 this work flow in Rotor-Gene AssayManager v2.1:



Logging in and logging out

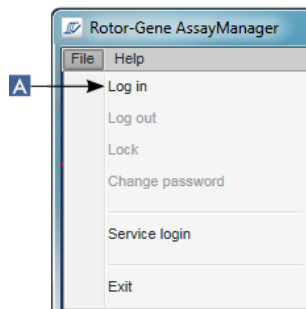
All user interactions in Rotor-Gene AssayManager v2.1 are assigned to a specific user. Therefore, every user must be authenticated using a specific user ID and password.

Before leaving the computer, a user is advised to lock the application or to log out.

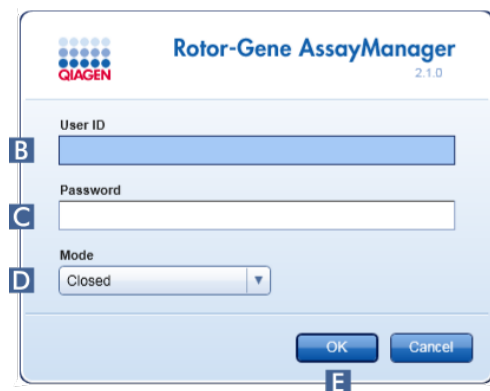
Logging in to Rotor-Gene AssayManager v2.1

1. Launch Rotor-Gene AssayManager v2.1.

If a user has logged out from a previously launched session, select **Log in (A)** from the **File** menu.



The login screen opens.



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

Note: The User Defined Test mode is not for use with FDA cleared or approved assays.

5. Click **OK (E)**.

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 | Available work list screen |
| Approver | Approval | Filter assays screen |
| Assay developer (Closed mode) | Configuration | Report Profiles tab |
| Assay developer (UDT mode) | Development | Assay Profile |
| Note: This is not relevant for Closed mode assays (i.e. FDA cleared or approved nucleic acid tests). | | |
| Administrator | Configuration | Settings tab |
| Super User | Configuration | Settings tab |

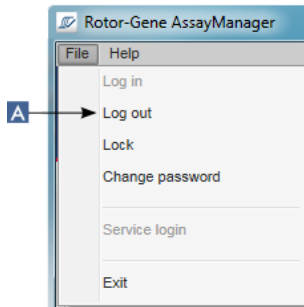
The selected mode is indicated at the bottom of the screen.



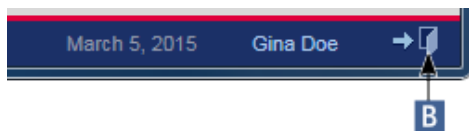
Logging out of Rotor-Gene AssayManager v2.1

The user can choose between 2 alternative methods to log out. The user can either use the log out command in the main menu or the log out button in the status bar.

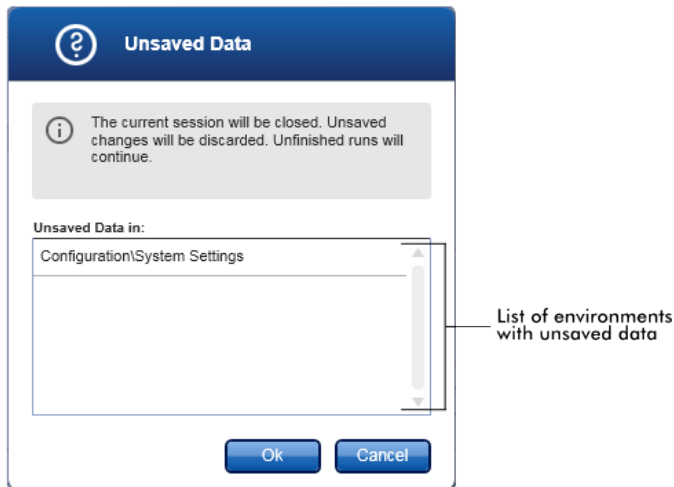
1. Click **Log out** (A) in the **File** menu.



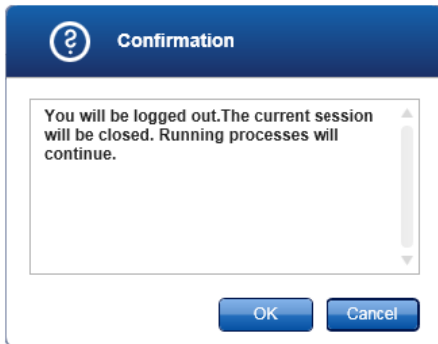
Alternatively, click the log out button (B) in the status bar.



A confirmation dialog is shown. If unsaved data exist, an **Unsaved Data** dialog is shown with a list of all environments containing unsaved data.



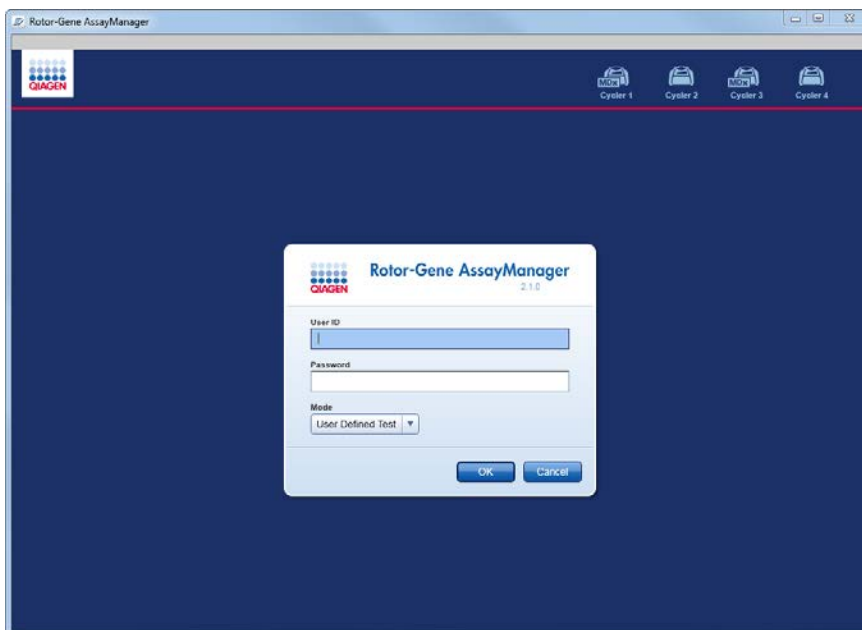
If there are no unsaved data, a standard **Confirmation** log out dialog is shown.



2. Click **OK**. (Clicking **Cancel** cancels the log out and closes the dialog).

The user is logged out and the login screen is shown.

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



Related topics

"Managing users," page 277.

"Modes," page 85.

"Session management," page 92.

"Main toolbar," page 112.

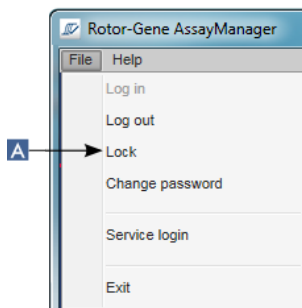
"Status bar," page 116.

Locking and unlocking

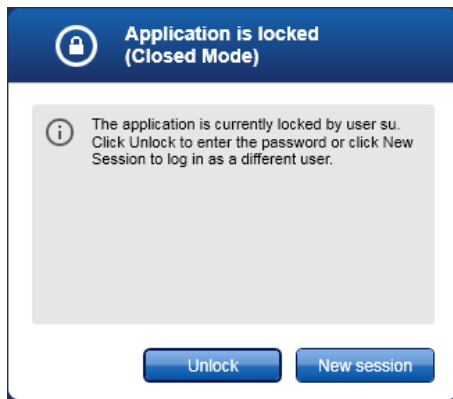
The application can be locked to restrict access. The locked application can be unlocked by the user who has locked it, or a new session can be started.

Locking Rotor-Gene AssayManager v2.1

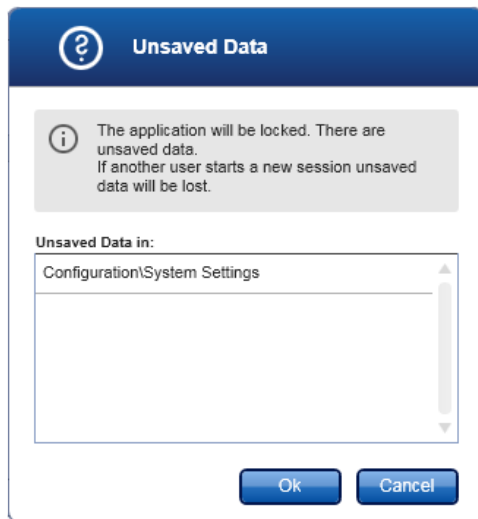
1. Click **Lock** (A) in the **File** menu.



If no unsaved data exist, the application is locked and the **Application is locked** dialog is displayed:



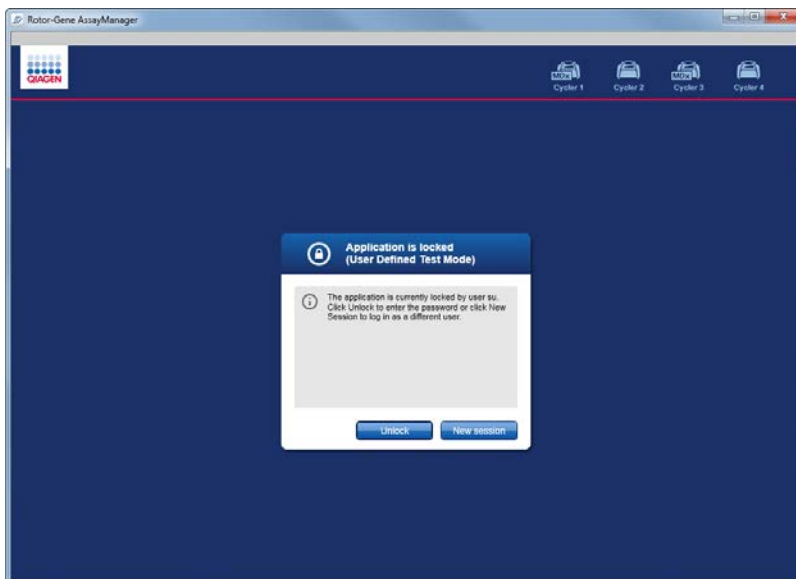
If unsaved data exist, an **Unsaved Data** dialog is shown with a list of all environments containing unsaved data.



2. Click **OK** to confirm that unsaved data will be lost and the application locks. The **Application is locked** dialog above is shown.

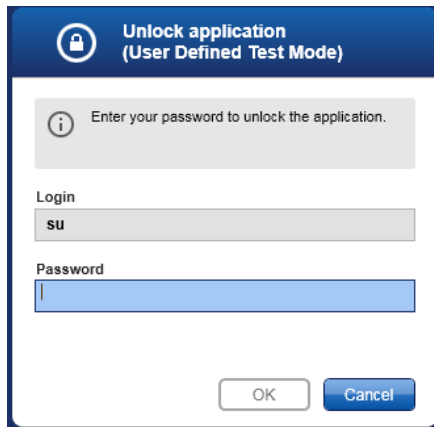
Unlocking Rotor-Gene AssayManager v2.1

A precondition before unlocking the application is that the application is locked. The following screen is shown:



1. Click **Unlock**.

The following dialog is opened. Note that the user name in the login field is set to the user who locked the application. Only this user is able to unlock the application.

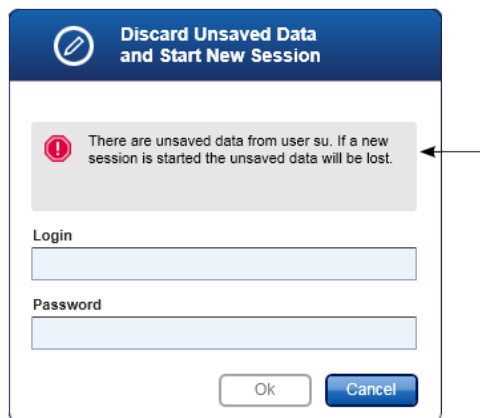


2. Enter the password in the **Password** field.
3. Click **OK**.

The application is unlocked.

4. 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:



5. Enter the login and password for the new user in the fields.
6. Click **OK**.

The application is unlocked and any unsaved data are lost.

Related topics

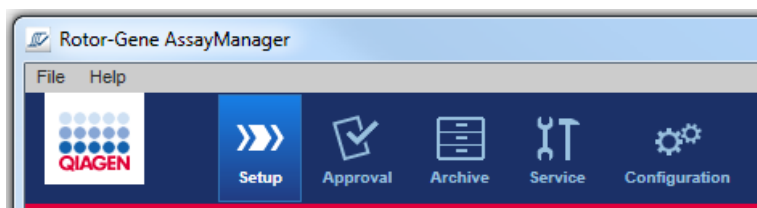
"Managing users," page 277.

"Session management," page 92.

Setting up a run

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,” page 237.

“Importing a work list,” page 247.

“Duplicating a work list,” page 249.

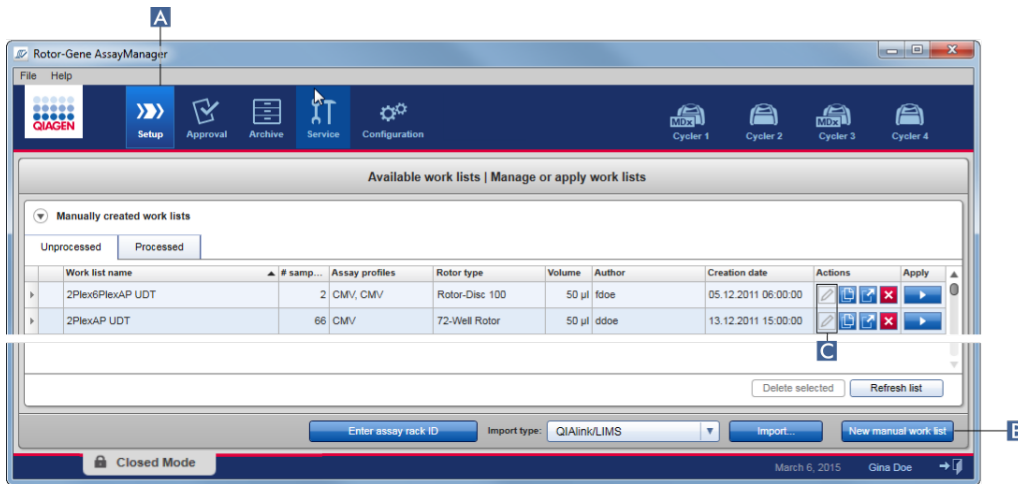
“Exporting a work list,” page 250.

“Deleting a work list,” page 251.

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

Creating/editing a work list

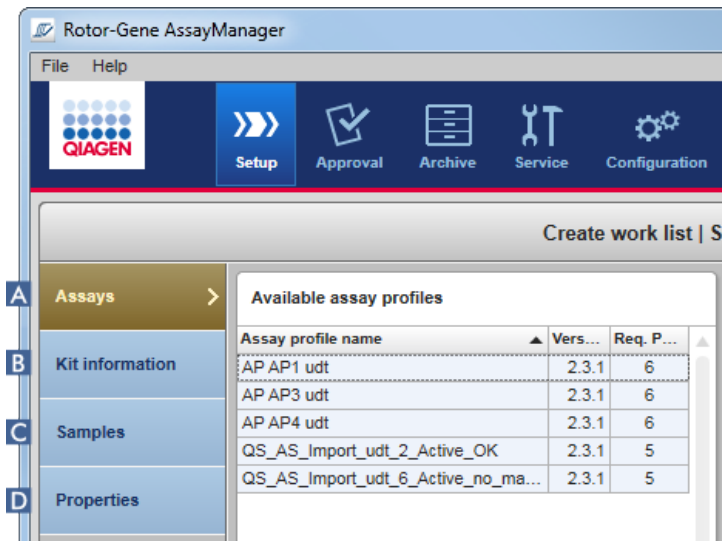
Work lists combine one or more assay profiles that are intended to run in an experiment. The user creates a work list by first selecting one or multiple compatible assay profiles. Optionally the user can adjust the material number, the kit expiration date and the lot number. After defining the number 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 and imported 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 manually created work lists (further subdivided into tabs for **Unprocessed** and **Processed** work lists), and a list with all automatically generated and available work lists on the system.

Clicking the **New manual work list** button (B) at the bottom right of the screen changes the screen to the **Create work list** screen where the new work list is set up. If the work list was saved as “editable”, click the action button (C) to edit the functionality of the work list.

The **Create work list** screen comprises 4 different steps:



| Step | Description |
|--------------------------|--|
| A Assays | <p>Select or enter the following data:</p> <ul style="list-style-type: none"> ● One (or multiple, compatible) assay profile(s) ● Rotor type ● Reaction volume ● Number of samples ● Chose if new strip tubes shall be used (option for multi-assays) |
| B Kit information | <p>Scan or enter the kit information manually. The kit information contains following data:</p> <ul style="list-style-type: none"> ● Kit bar code ● Material number ● Kit expiration date ● Lot number |
| C Samples | <p>The assay setup is displayed as defined in the assay profile. Enter IDs for each test sample. Optionally add a comment. Line colors and line styles for amplification curves can be adapted.</p> <p>The order of the samples cannot be changed. The order is defined by the assay profile and the order of different assay profiles selected in the Assays step (A), if applicable.</p> |
| D Properties | <p>The creation of a work list process is finalized by activating 2 different options:</p> <ul style="list-style-type: none"> ● Work list is editable ● Work list is complete (can be applied) |

Note:

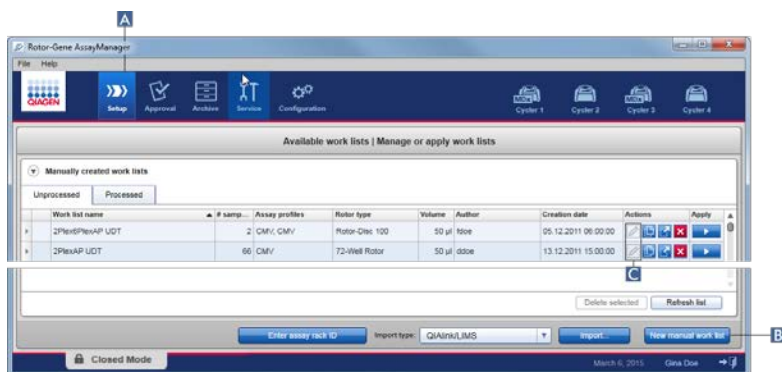
- Unsaved changes will not be lost if the user changes to another environment.
- The **Setup** environment is not a wizard, i.e., the steps do not need to be followed in a specific order.
- A new work list can be saved in an uncompleted state. It is sufficient that at least a valid work list name is provided.

Creating a new work list comprises 6 steps:

- Create a new, empty work list.
- Add one (or multiple) assay profile(s) to the work list (**Assays** step).
- Scan or enter the **Kit information**
- Assign sample IDs (**Samples** step).
- Define the properties of the work list (**Properties** step).
- Save the work list.

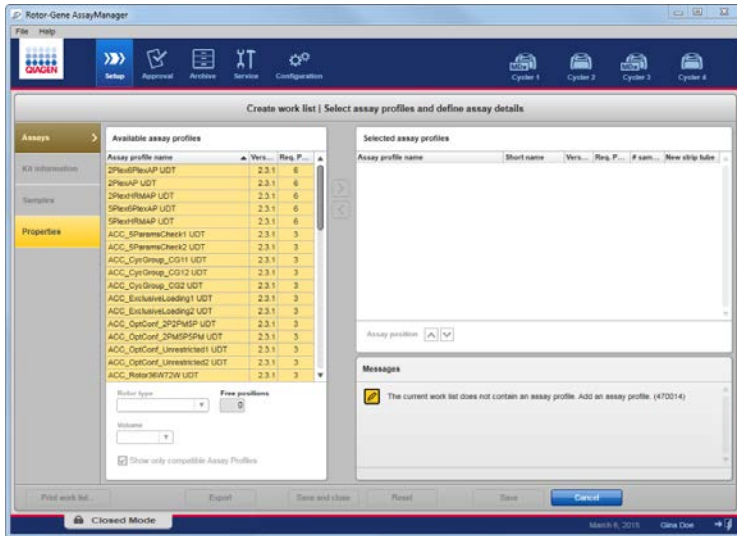
Step 1: Create a new, empty work list

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



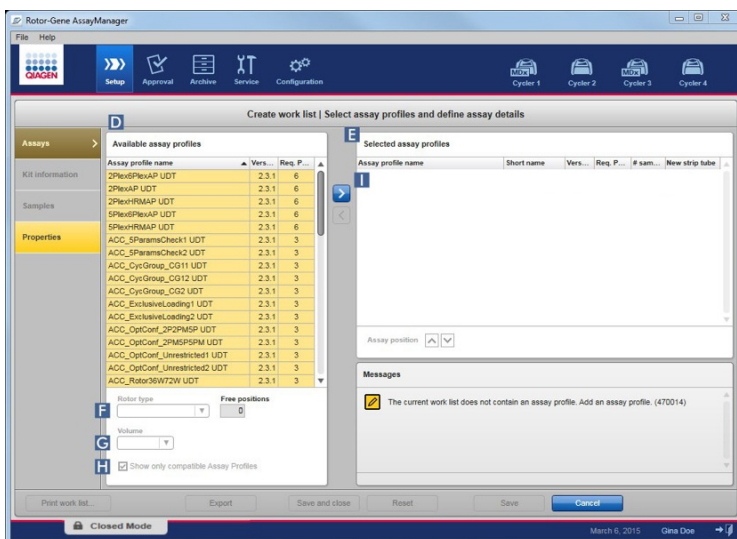
2. Click the **New manual work list** button (B) at the bottom-right of the screen.

The **Create work list** screen is opened. The **Assays** step marker is activated (with an error), as indicated in dark yellow.



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

In this step, the user adds one assay to the work list. The **Assays** step lists all available assay profiles in the **Available assay profiles** table at the left in alphabetical order. Selected assays are added to and shown in the **Selected assay profiles** table at the right.

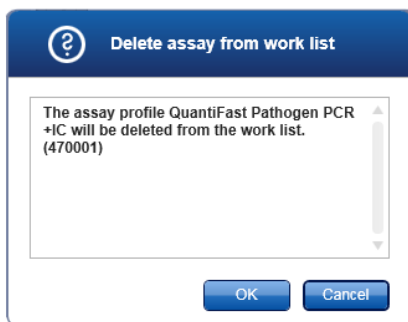


1. In the **Available assay profiles** table (D), click the assay you want to be included. Only one entry can be selected at a time. If an entry is selected, the corresponding row is highlighted blue. Depending on the assay profile, the **Rotor type** (F) and **Volume** (G) drop-down menus may be colored in yellow to indicate a mandatory entry.
2. Click the **Rotor type** drop-down menu (F) to select the rotor type that will be used.

- Click the **Volume** drop-down menu (G) to select the reaction volume that will be used.
The **Add assay to work list** button (I) becomes active.
- Click the button (I) to transfer the selected assay to the **Selected assay profiles** table (E) at the right (see page 141).
The first 4 columns in the **Selected assay profiles** table (**Assay profile name**, **Short name**, **Version** and **Req. Position**) are populated with data from the assay profile.
The **New strip tube** option can be activated manually for multi-assay usage.
Note: Multiple assay usage is not intended for FDA cleared or approved nucleic acid tests.
- 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 are entered in step 4, the **Samples** step.

Remove an assay profile from the work list

- Click on the assay profile in the **Selected assay profiles** table.
The name is highlighted and the button (L) to remove a selected assay from the work list is activated.
- Click the (L) button.
The **Delete assay from work list** confirmation dialog is displayed.



- 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: Scan or enter kit information

In this step, the material number, kit expiration date and the lot number can be entered manually or by scanning the kit bar code.

Manual entry of material number, kit expiration date and lot number

Select the option **Enter kit information manually** and enter the material number, the kit expiration date and the lot number. Use the date picker () to enter the date using an interactive calendar.

Automatic entry of material number, kit expiration date and lot number by scanning the kit bar code (for QIAGEN kits only)

Select the option **Use kit bar code** and scan the QIAGEN kit bar code.

Use kit bar code
 Enter kit information manually

Kit information

Kit bar code

Material number Kit expiry date

Lot number

Note: This user manual describes the general functionality of the **Use kit bar code** dialog. For detailed information, refer to the user manual of the corresponding plug-in.

Note: If you run out of reagents and need a new kit box, use only assay kits with the same lot number for setting up an assay.

Step 4: Assign sample IDs

WARNING



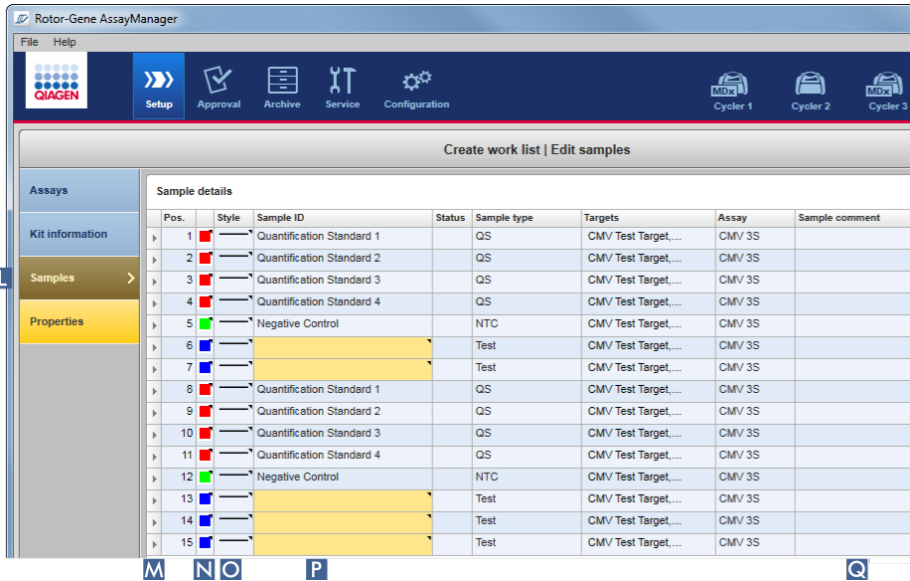
Risk of personal injury

Do not enter patient-specific data as part of a sample ID.

An assay profile is added to the work list in the **Assays** step. The number of test samples is defined in the **# samples** column of the **Selected assay profiles** table.

The position, type and number 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 sample 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. If multiple assay profiles were added, the order of the assay profiles is determined by their order defined in the **Assays** step.



1. Change to the **Samples** step by clicking **Samples** (L) in the step bar.

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

2. If the plug-in currently in use supports it, a color for the respective amplification curve can be selected. Right-click the color icon of the corresponding row (N). A color palette opens.



3. Click on a color to select it.
4. If the plug-in currently in use supports it, a line style for the respective amplification curve can be selected. Right-click the line style icon of the corresponding row (O). A line style palette opens.



5. Click on a style to select it.
6. Enter a sample ID into the **Sample ID** field (P) for every test sample.

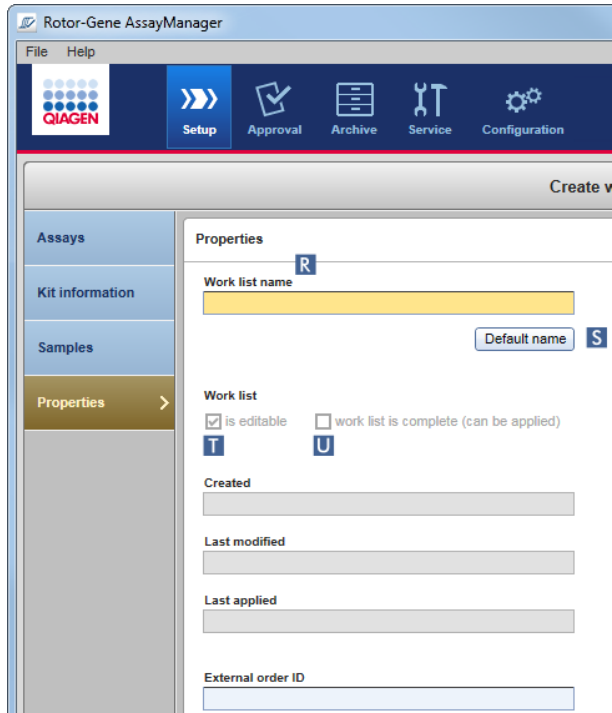
The sample ID must be between 1 and 40 characters long. The sample IDs can be unique or identical. (Some assay profiles restrict the use of a sample ID to a single sample.)

- Optional: Enter a comment in the **Sample comment** field (Q). The comment must not exceed 256 characters.

Step 5: Define the properties of the work list

The **Properties** step is the area where the user enters the work list name and reviews information about when a work list was created, modified and last applied. The user also specifies if a work list can be edited or applied.

- Change to the **Properties** screen by clicking the **Properties** step tab.



- Enter the desired work list name into the **Work list name** field (R).
- For Rotor-Gene AssayManager v2.1 to generate a work list name automatically, click **Default name** (S). Rotor-Gene AssayManager v2.1 creates a default name using a user-defined pattern and populates the field. (For more details, see “**Global Settings** area,” page 194.)

4. Activate the desired options:

| To | Do this | Explanation |
|--------------------------------------|---|---|
| Define a work list as being editable | Activate check box (T) <input checked="" type="checkbox"/> 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 (U) <input checked="" type="checkbox"/> work list is complete (can be applied) | If this 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 6: Save the work list

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



Click **Print work list** to print the work list to PDF after having saved the work list.

Click **Export** to export the work list to a folder after having saved the work list.

Click **Save and close** to save the work list and return to the start screen of the **Setup** environment.

Click **Reset** to cancel your entries and set the properties to default.

Click **Save** to save the work list.

Click **Cancel** to cancel your entries.

Click **Apply** to apply the work list.

Related topics

"Managing assay profiles," page 267.

"Managing cyclers," page 272.

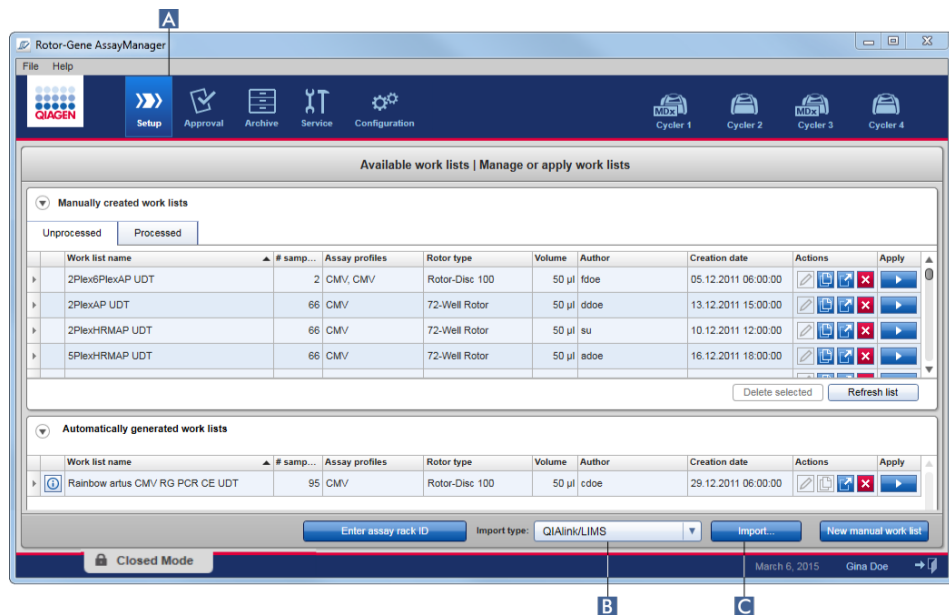
"Entering data," page 100.

"Use of color," page 96.

"**Setup** Environment," page 117.

Importing a work list

Importing a work list is a function used to exchange work lists between different Rotor-Gene AssayManager v2.1 installations or to import work lists from an upstream laboratory device (for example a LIMS or QIAsymphony).



The import function is placed in the **Setup** environment (A) and consists of 2 elements:

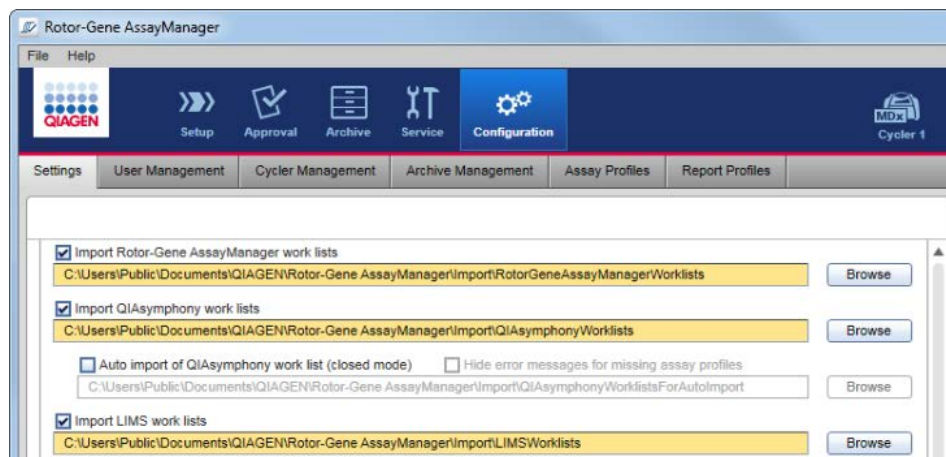
- The drop-down **Import type:** menu (B) to select the source of the file
- The **Import** button (C) for manual import

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

| Source | File extension | Description |
|------------------------------|----------------|--|
| Rotor-Gene AssayManager v2.1 | *.iwl | Exported Rotor-Gene AssayManager v2.1 work list |
| QIAsymphony | *.xml | Result file from QIAsymphony AS software version 5.0 |
| QIALink/LIMS | *.lwl | Work lists from QIALink or a LIMS |

After a work list to be imported has been selected, Rotor-Gene AssayManager v2.1 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 type:** drop-down menu (B) depend on the settings made in the **Settings** tab of the **Configuration** environment. An administrator can activate/deactivate each of the 3 possible import options.



Importing a work list manually

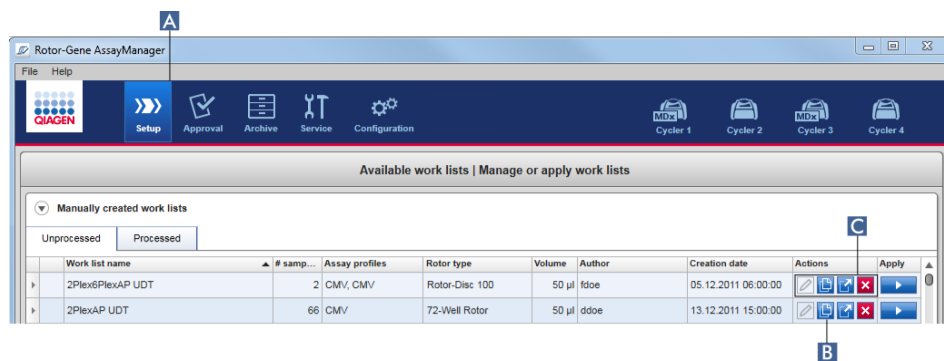
1. If it is not active, change to the **Setup** environment by clicking the **Setup** icon in the main toolbar (A).
2. Select the source for the work list to be imported from the **Import type:** drop-down menu (B).
If the menu is disabled or necessary entries are missing, these can be customized in the **Configuration** environment in the **Settings** tab. Save the changes to the settings if necessary.
3. Click **Import** (C).
The **Select file** dialog opens. The default directory is the one set for this import type in the **Configuration** environment.
4. Browse to the directory where the file to be imported is located. Select the file and click **Open**.
Rotor-Gene AssayManager v2.1 internally checks the signature and the syntax of the work list.
The work list is imported and added to the list of available work lists.

Configuring automatic import of a work list

Note: The automatic import of a work list is not intended for use with FDA cleared or approved nucleic acid tests.

Duplicating a work list

A specific manually generated work list is duplicated from the **Setup** environment (A) by clicking the **Duplicate work list** button (B) in the **Actions** button area (C) of the corresponding work list.



The **Duplicate work list** button is always enabled for a manually created work list. Clicking this button creates a copy of the selected work list. The **Edit duplicated work list** screen is displayed. This screen is analogous to the **Create work list** dialog. The duplicate work list 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 **work list is complete (can be applied)** check box is not activated for duplicated work lists.
- The **Last modified** and **Last applied** fields are empty and are populated when the work list is saved for the first time.

1. 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 manually created work list you want to duplicate and click the corresponding **Duplicate work list** button (B) in the **Actions** buttons area (C).
The **Edit duplicated work list** screen is shown.
3. Modify those parameters you need to change according to the steps described in the procedure "Creating/editing a work list," page 237.

Note: Automatically generated work lists are not able to be duplicated and are not intended for use with FDA cleared or approved nucleic acid tests.

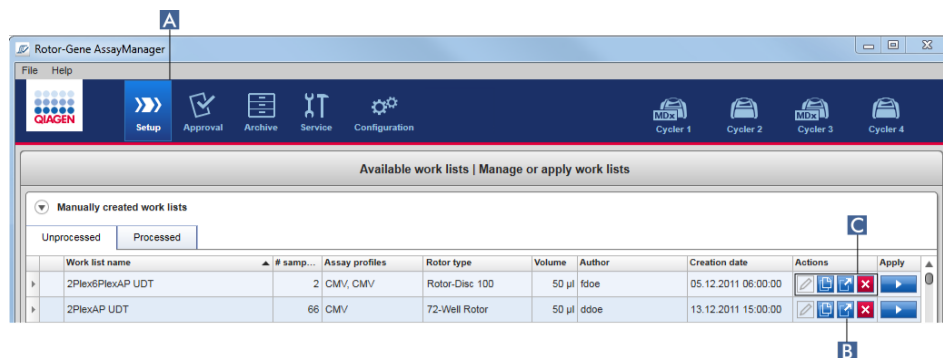
Related topic

“**Available work lists** view,” page 117.

Exporting a work list

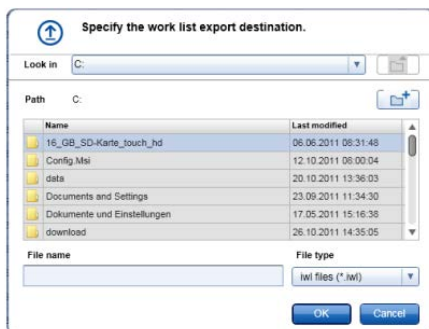
Exporting a work list is used to exchange work lists between different Rotor-Gene AssayManager v2.1 installations that are using different databases.

The export functionality can be found in the **Setup** environment (A). The **Actions** button bar (C) in the **Available work lists** table includes the **Export work list** button (B).



1. If it is not active, change to the **Setup** environment by clicking the **Setup** icon in the main toolbar (A).
2. Move the mouse cursor to the **Actions** button 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.



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.

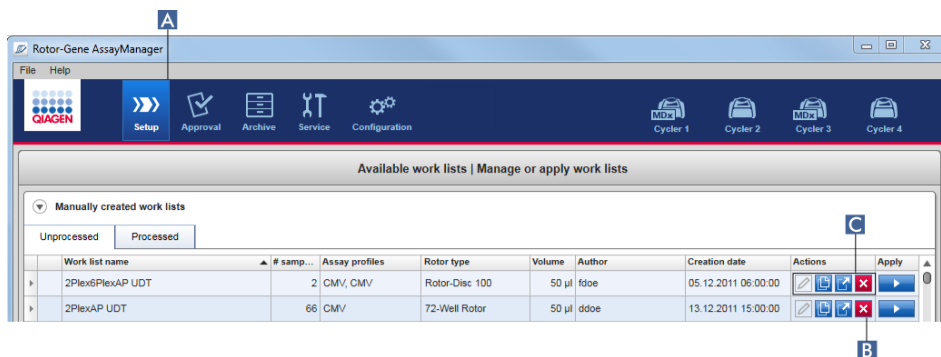
Related topic

“Available work lists view,” page 117.

Deleting a work list

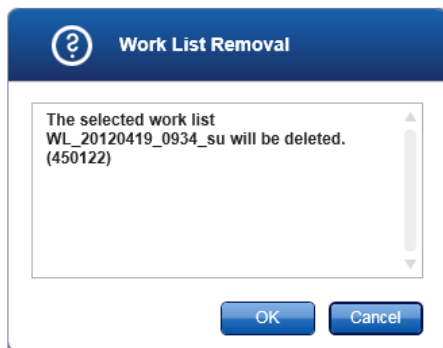
1. If it is not active, change to the **Setup** environment by clicking the **Setup** icon in the main toolbar (A).

All **Available work lists** are displayed in the table.



2. Locate the work list you want to delete and click the corresponding **Remove work list** button (B) in the **Actions** button bar (C) of the appropriate row of the table.

The following confirmation dialog is shown:



3. Click **OK** to remove a work list and return to the **Setup** start screen.

The selected work list entry will be deleted from the database and then disappears from the work list table.

Click **Cancel** to cancel the process to remove the work list and return to the **Setup** start screen.

The selected work list entry will remain as before.

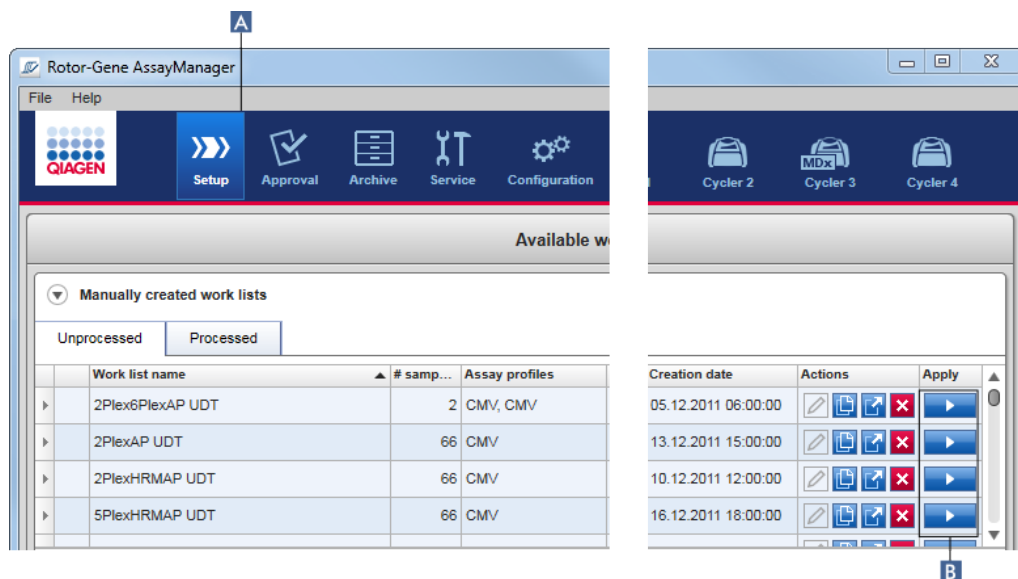
Related topic

“Available work lists view,” page 117.

Starting a run

A run can be started from the **Available work lists** table in the **Setup** environment (A) by clicking the **Apply work list** button (B) in the **Apply** button bar of the appropriate work list entry.

Alternatively, a run can be started after a new work list has been successfully created. Details can be found in the section “Creating/editing a work list,” page 237.



After the run is triggered, the **Apply work list** screen opens.

The user must enter an experiment name and select a cycler. If required, an overview of the samples can be displayed and then printed to a *.pdf file. In the **Summary** area, select **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** (page 195). The default name for the experiment name is defined as follows:

<Assay profile short names>_<YYYYMMDD>_<HHMM>, e.g.,
AS1_AS2_AS3_20120327_1359.

The default name may exceed 80 characters. In this case, shorten the name manually to meet the requirements.

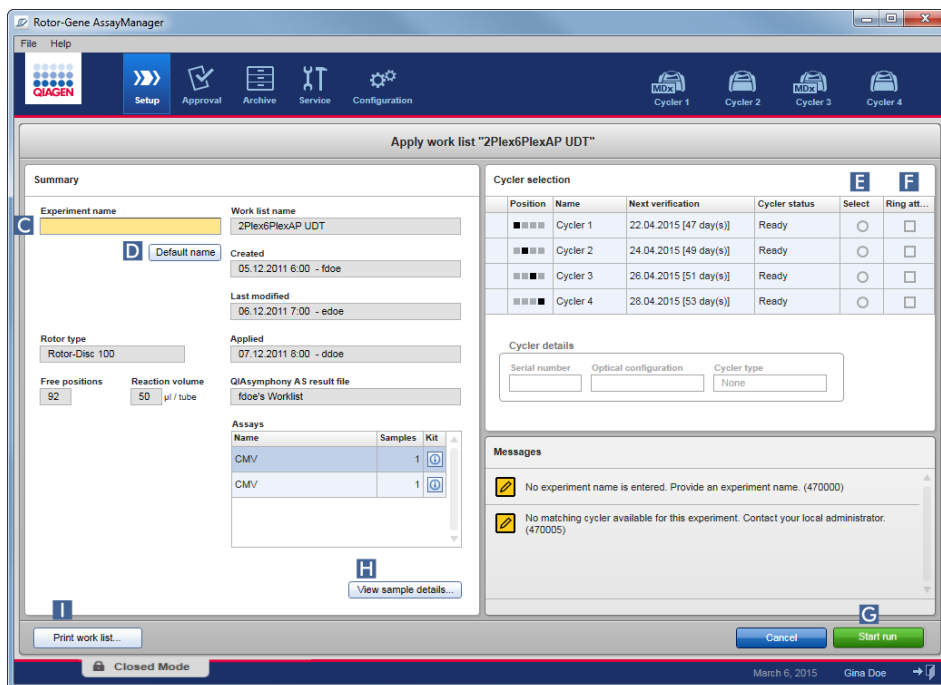
Applying a work list

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

The **Setup** environment opens. All **Available work lists** are displayed.

- Select the work list you want to apply (manually or automatically created).
- Click the **Apply work list** button (B) in the **Apply** button bar.

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



- Enter the name of the experiment in the **Experiment name** field (C), or click **Default name** (D) to generate a name automatically.

- In the **Cycler selection** area, click the **Select** radio button (E) to select a cycler with a **Cycler status** of **Ready**.
- Activate the **Ring attached** check box (F) to confirm you have attached the locking ring.
The **Start run** button (G) is now activated.
- 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 closes and the **Available work lists** screen opens.

The following steps happen after the **Start run** button is clicked:

- 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).

Click **View sample details** to open a scrollable list with detailed information about the samples:

| Pos. | Style | Sample ID | Status | Sample type | Targets | Assay | Sample comment |
|------|-------|-----------|--------|-------------|----------|--------|----------------|
| 1 | PC_1 | | | PC | Test, IC | QF Pat | |
| 2 | PC_2 | | | PC | Test, IC | QF Pat | |
| 3 | PC_3 | | | PC | Test, IC | QF Pat | |
| 4 | 1 | | | Test | Test, IC | QF Pat | |
| 5 | 2 | | | Test | Test, IC | QF Pat | |
| 16 | 13 | | | Test | Test, IC | QF Pat | |
| 17 | 14 | | | Test | Test, IC | QF Pat | |
| 18 | 15 | | | Test | Test, IC | QF Pat | |

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

Related topics

"Creating/editing a work list," page 237.

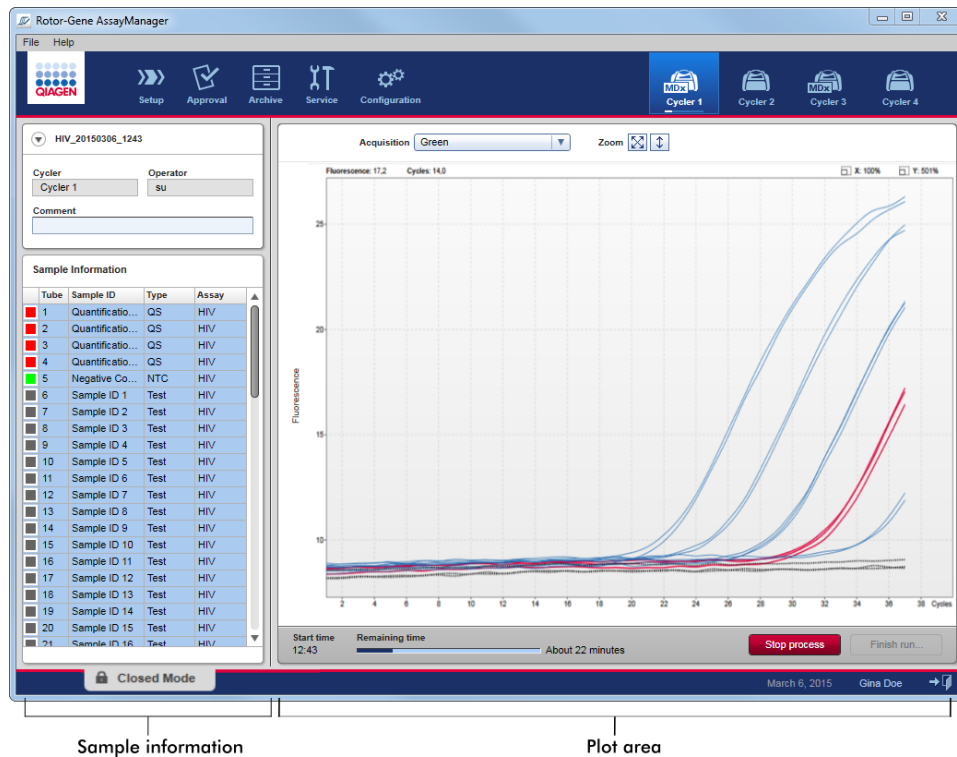
"Managing cyclers," page 272.

"Settings tab," page 193.

"Available work lists view," page 117.

Finishing and releasing a run

After a run is started, the environment of the selected cyclers is displayed. This screen mainly consists of the sample information at the left and the plot area at the right.



During the run process and depending on the currently used plug-in, the amplification curves will be displayed and updated in real time. A progress indicator at the bottom left and a progress indicator located under the cycler's icon show the run's progress. It is possible to stop the run by clicking **Stop process**.

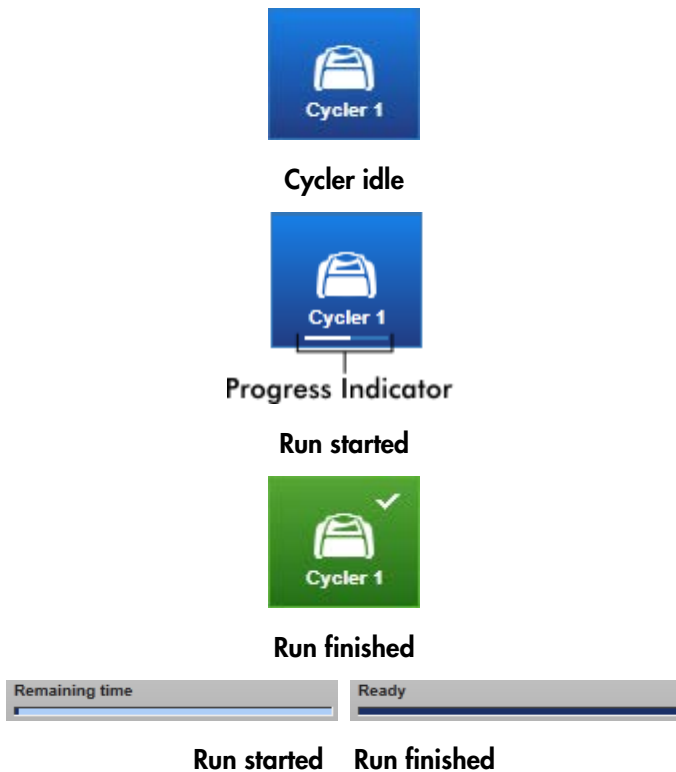
Both sample information and plot area provide interactive functionalities to check the amplification curves of single (or multiple) samples.



Note: When the run is started, 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

The cycler icon and progress indicator, **Remaining time** bar and button labels change from the start to the end of a run. When the run has finished, the cycler icon will change.



The **Stop process** button  changes its label to **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 cyclotron icon changes to:



For more information, see "**Cyclotron Environment**", page 150.

1. 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.

The screenshot shows a dialog box titled "Finish run" with a blue header and a white body. The dialog contains the following fields and controls:

- Position:** A progress indicator showing 1 out of 4 steps completed (one black square, three grey squares).
- Name:** A text field containing "Cycler 1".
- Run status:** A text field containing "Run Successful".
- Experiment name:** A text field containing "QF Pat_20120419_0940".
- Errors during run:** A scrollable text area.
- Comment:** A text area.
- Password:** A text field.
- Buttons:** Three buttons at the bottom: "Release", "Release and go to approval", and "Cancel".

3. Select the desired option.

Click **Release** to release the cycler.

Click **Release and go to approval** to release the cycler and change to the **Approval** environment.

Click **Cancel** to cancel the release process and change to the **Cycler** view.

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.).

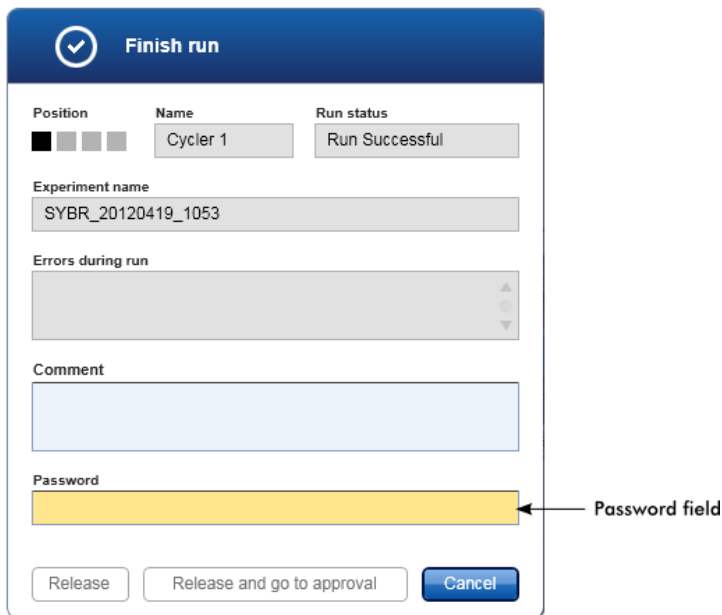
Difference if release of run has to be signed

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.



If the option was set, the run has to be signed with a password (user profile password).

The buttons **Release** and **Release and go to approval** are disabled. These buttons are enabled only if a valid password is entered in the **Password** field of the **Finish run** dialog.



Note: After a run is finished and the cycler is released, open the lid, remove the rotor and discard the samples immediately.

Related topics

"Settings tab," page 193.

"Cycler Environment," page 150.

Approving a run

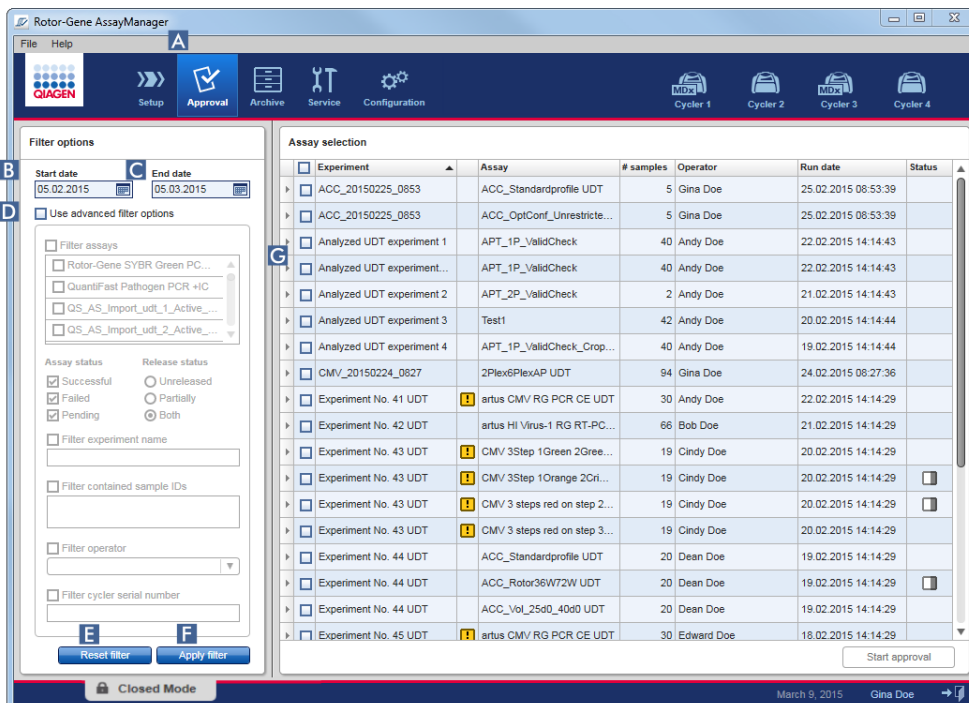
After a run has finished and the cycler has been released, the experiment will be stored in the internal database. The analysis of the acquired data is performed automatically depending on the plug-in corresponding to the assay profile and the rules and parameter values defined by the assay profile.

Rotor-Gene AssayManager v2.1 provides test results that must be approved and released by a user with the role of an approver. Depending on which Rotor-Gene AssayManager v2.1 plug-in is currently used, the individual approval process may differ.

In this section, only the general functions are described. For details about the individual approval process, refer to the corresponding plug-in user manual.

Filtering experiments

The first step in the approval process is to filter the assay to be approved. This is done by using filter criteria in the **Approval** environment.



This environment mainly consists of 2 parts: A **Filter options** panel 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 simplest filter is the search for assays within a certain date range. Advanced filter options allow the user to define further filter criteria.

The following tables provide explanations of the filter criteria.

Simple filter

| Criterion | Comment |
|------------------|--|
| Date range | <p>Enter a start date and an end date in the corresponding fields to filter for assays with a run start date in the defined date interval.</p> <p>Dates can either be manually entered or entered using the date picker.</p> <p>Restrictions:</p> <ul style="list-style-type: none">● Wildcard characters are not allowed● Dates must be entered completely |

Advanced filter options

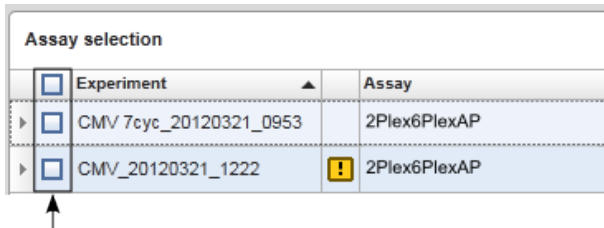
| Criteria | Comment |
|----------------------|---|
| Filter assays | <p>To filter for specific assays, activate the Filter assays check box. All assays are displayed in a list. A check box in front of every assay row allows selection for individual assays.</p> <p>Multiple assay selections are possible to search simultaneously for different assays.</p> |
| Assay status | <p>Filter for the assay status using the radio buttons. Possible values are:</p> <ul style="list-style-type: none">● Successful● Failed● Both● Pending <p>Note: The assay status Pending is not applicable for FDA cleared or approved nucleic acid tests.</p> |

| Criteria | Comment |
|------------------------------------|---|
| Release status | <p>Filter for the release status using the radio buttons. Possible values are:</p> <ul style="list-style-type: none"> ● Unreleased ● Partially ● Both <p>Note: The release status Partially released is not applicable for FDA cleared or approved nucleic acid tests.</p> |
| 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). |

1. If it is not active, change to the **Approval** environment by clicking the **Approval (A)** icon in the main toolbar.
2. Select the appropriate filter criteria in the **Filter options** section in the left part of the screen.
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.
4. To use the advanced search criteria, activate the **Use advanced filter options** check box **(D)**.
5. Select the appropriate filter options. Multiple selections are possible.
6. Click **Apply filter (F)** to search the internal database for experiments meeting the criteria defined in the previous step.

All assays meeting the filter criteria will be listed in the **Assay selection** table **(G)** in the right-hand area of the **Approval** environment.

7. Activate the check box in front of the assay for approval. It is possible to select multiple assays.



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



8. Click **Start approval**.

Note: Click **Reset filter** (E) to reset the selected filter options to the default values, i.e., start date set to 1 month ago, end date set to today, advanced filter options deactivated.

Approving samples

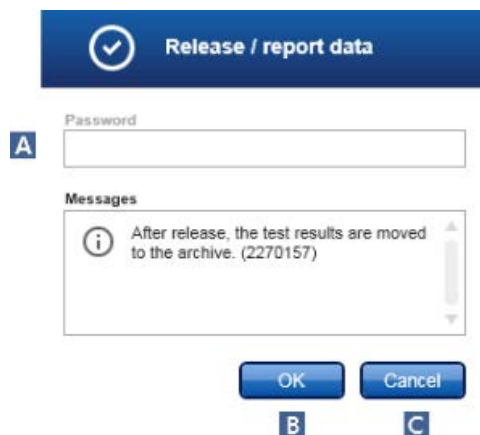
Depending on which Rotor-Gene AssayManager v2.1 plug-in is currently used, the individual approval process may differ. For details about the individual approval process, refer to the corresponding plug-in user manual.

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.

1. After approving the sample results, click **Release/report data** in the button bar.

The following dialog opens:



Note: The release process of the Gamma Plug-in is taken as an example for screenshots.

- If the release must be signed, enter the Rotor-Gene AssayManager v2.1 login password in the **Password** field (A). This option is set by the administrator in the **Configuration** environment.
- To release the data, click **OK** (B).
- To cancel and go back to the **Results** table click **Cancel** (C).

The data will be stored in the internal database of Rotor-Gene AssayManager v2.1. As a result, the assay will no longer be available in the **Approval** environment but can be accessed from the **Archive** environment.

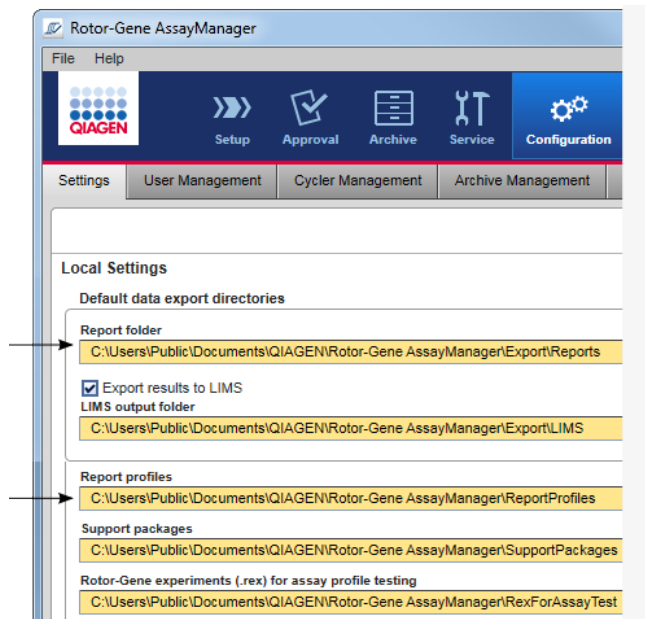
Note: LIMS output is generated during release if configured.

Working with reports

A report can be generated during the release of sample results in the **Approval** environment (see “Approving a run,” page 259, for more information). For experiments that are already released, a report can be generated from the **Archive** environment.

Note: For FDA cleared or approved nucleic acid tests, the content and layout of the report is set by the assay profile.

Note: The target directory for saving the generated report and the source directory for report profiles are defined in the **Settings** tab (see page 204).

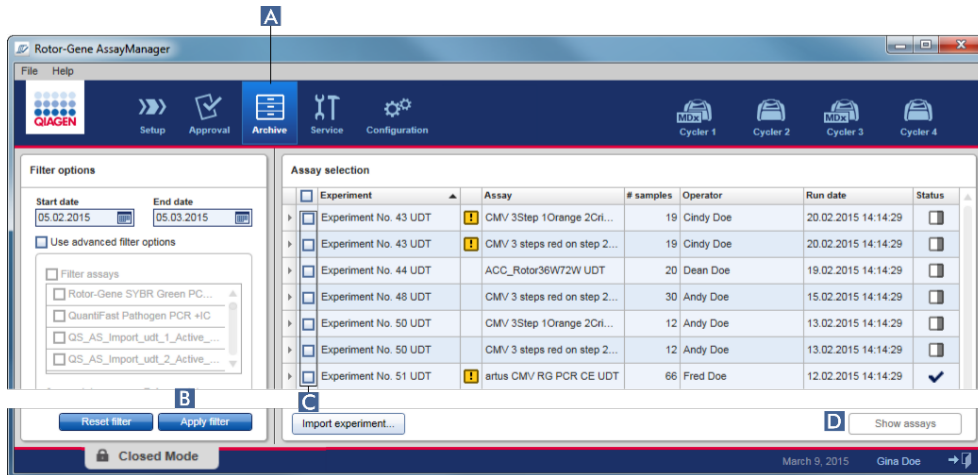


Note: For the Gamma Plug-in, no user defined report profiles are applicable. The experiment data included in the report are predefined by the assay.

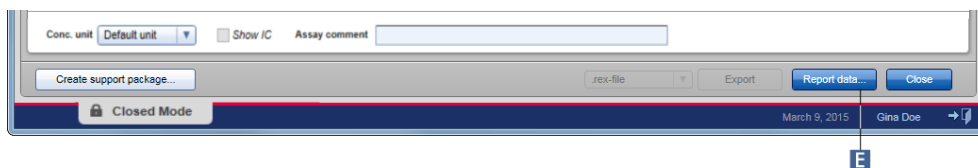
Creating a report in the **Archive** environment

1. Click **Archive** (A) in the main toolbar to change to the **Archive** environment.

The **Assay selection** screen is displayed.



2. Select the appropriate filter options and click **Apply filter** (B).
- A list with assays matching the filter options is displayed.
3. Select one or multiple assays by activating the corresponding check boxes (C).
4. Click the **Show assays** button (D). The button is activated if at least one experiment is selected.



5. Click **Report data** (E) in the button bar and the report is generated.

Related topics

"**Archive** Environment," page 182.

"**Approval** Environment," page 161.

Working with audit trails

The audit trail logs all actions performed in Rotor-Gene AssayManager v2.1. Various filter criteria can be selected in the **Service** environment to filter the audit trail entries. All entries matching the filter criteria are listed in the **Results** table.

The screenshot shows the Rotor-Gene AssayManager interface. The top toolbar includes buttons for Setup, Approval, Archive, Service (highlighted with callout A), and Configuration. The main window is divided into two tabs: Audit Trail (selected) and Re-usable Data. The Audit Trail tab contains a Filter area (callout B) with several sections: Date & time (Date from: 05.03.2015, Time from: 00:00:00, Date to: 05.03.2015, Time to: 23:59:59), User (radio buttons for All users, This user, Specific; User ID field), Experiment (radio buttons for All, Specific; Experiment name field), Context (checkboxes for Installation, User, Session), Computer (radio buttons for This computer, All computers), Signed actions (radio buttons for All actions, Signed only), and Message ID (radio buttons for All, Specific; ID field). Below the filter area are Language options (System language, English) and buttons for Reset filter settings (callout E) and Apply filter (callout C). The Results table (callout D) displays the following data:

| Context | Date & Time | User | Experiment | Message ID | Text |
|---------|---------------------|---------------|------------|------------|---|
| Session | 05.03.2015 08:56:11 | Gina Doe (su) | | 1030012 | su logged in successfully in Closed Mode. |
| Session | 05.03.2015 08:35:19 | Gina Doe (su) | | 1030016 | Application unlocked successfully for the use |
| Session | 05.03.2015 08:35:26 | Gina Doe (su) | | 1030014 | su logged out successfully. |
| Session | 05.03.2015 09:12:10 | Gina Doe (su) | | 1030012 | su logged in successfully in Closed Mode. |
| Session | 05.03.2015 09:34:48 | Gina Doe (su) | | 1030014 | su logged out successfully. |
| Session | 05.03.2015 09:47:21 | Gina Doe (su) | | 1030012 | su logged in successfully in User Defined Tes |
| Session | 05.03.2015 10:08:55 | Gina Doe (su) | | 1030016 | Application unlocked successfully for the use |

At the bottom of the Results table is a Print to PDF button (callout D). The status bar at the bottom shows Closed Mode.

Filtering for audit trail entries

1. Click **Service** (A) in the main toolbar.

The **Audit trail** tab in the **Service** environment contains a **Filter** area with various filter criteria. These criteria are used to generate the **Results** table where audit trail entries matching the filter are listed.

2. Select filter criteria from the group boxes in the **Filter** area (B).

Different filter criteria can be combined. The following filtering options can be used:

- Date & time
- User
- Experiment
- Context
- Computer
- 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.

Note: If the number of entries matching the filter criteria exceeds 1200 entries, an error message is shown. Adjust the filter settings.

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 can be saved manually, if necessary.

Related topics

“Service Environment,” page 186.

Administrative Tasks

The following administrative tasks can be performed by those users logged in as administrators.

Warning: Rotor-Gene AssayManager v2.1 shall not be used with the admin account of Microsoft Windows operating system.

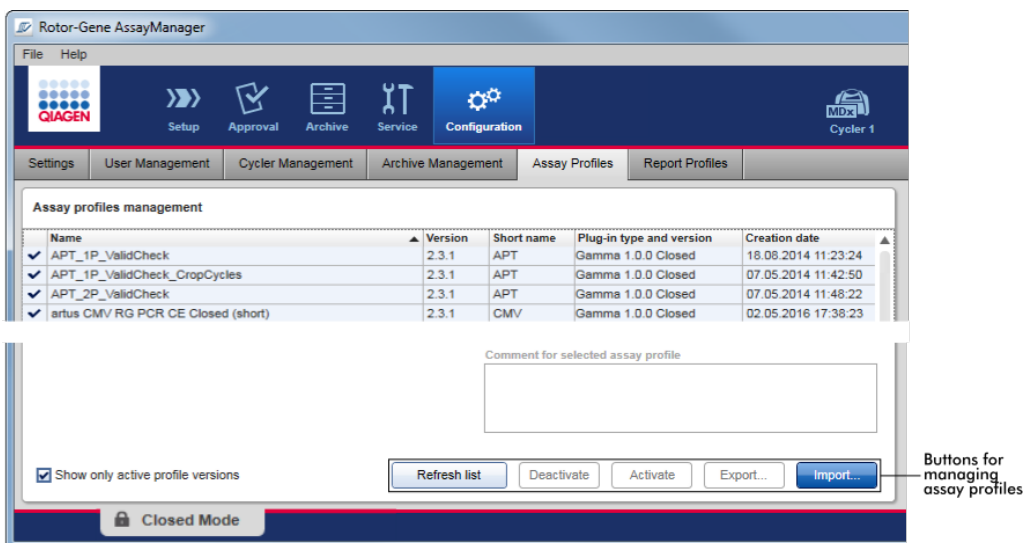
This section covers the following administrative topics:

- Managing assay profiles
- Managing report profiles
- Managing cyclers
- Managing users
- Managing archives
- Customizing settings

Managing assay profiles

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.

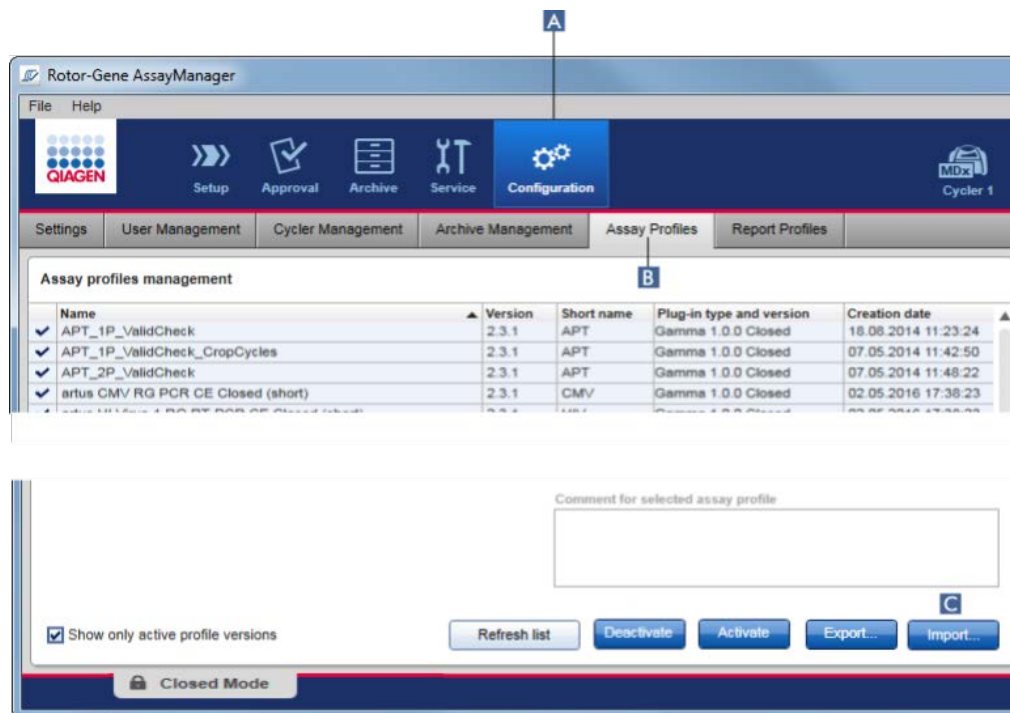


The following tasks related to managing assay profiles are covered in this section:

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

Importing/exporting an assay profile

Rotor-Gene AssayManager v2.1 provides an import/export feature for assay profiles to exchange assay profiles between different Rotor-Gene AssayManager v2.1 installations. An imported assay profile will be added to the list of **Available work lists** in the **Setup** environment. 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 v2.1.



Exporting an assay profile

The export of Closed mode assay profiles (i.e. FDA cleared or approved nucleic acid tests) is not possible. The **Export** button is deactivated.

Importing an assay profile

1. Click **Configuration** (A) in the main toolbar.
2. Select the **Assay Profiles** tab (B).
3. Click **Import** (C).

The **Select file** dialog is opened.

4. Go to the directory containing the assay profile you want to import.
5. Select the assay profile, 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 environment/**Assay Profiles** tab, page 221.


“Setting up a run,” page 237.

“**Setup** Environment,” page 117.

Activating/deactivating an assay profile

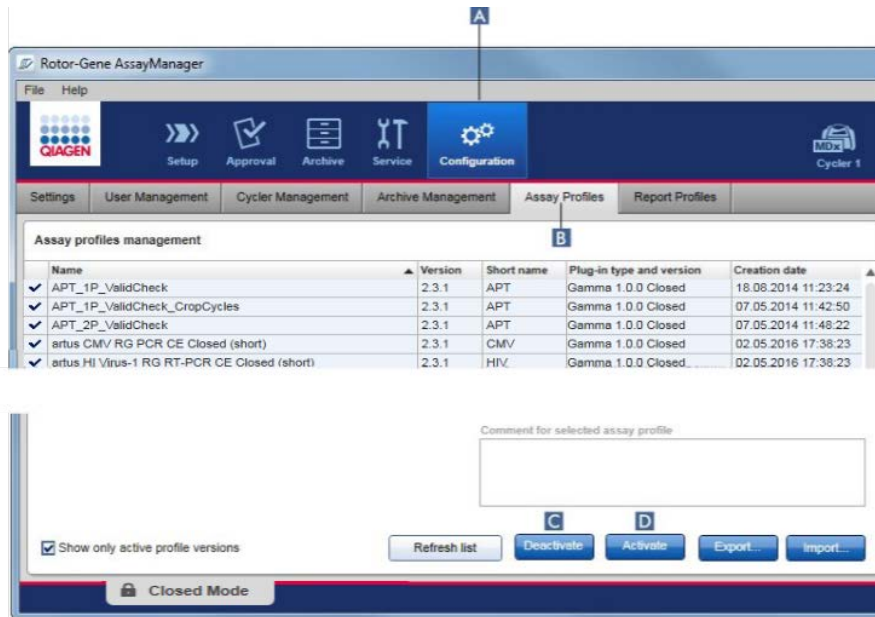
Assay profiles can be activated and deactivated. Only activated assay profiles are available for creating and applying work lists in the **Setup** environment. Deactivated assay profiles cannot be used but can be reactivated by an administrator, if required. Existing work lists containing a deactivated assay profile cannot be applied anymore; this is indicated by an icon  in the **Status** column of the **Available work lists** table in the **Setup** environment.

By default, the **Show only active profile versions** check box at the bottom-left of the screen is activated. To see activated, deactivated and expired assay profiles in parallel in the list, deactivate the check box. Activated, deactivated and expired assay profiles can be differentiated by the following icons:

-  Activated
-  Deactivated
-  Expired

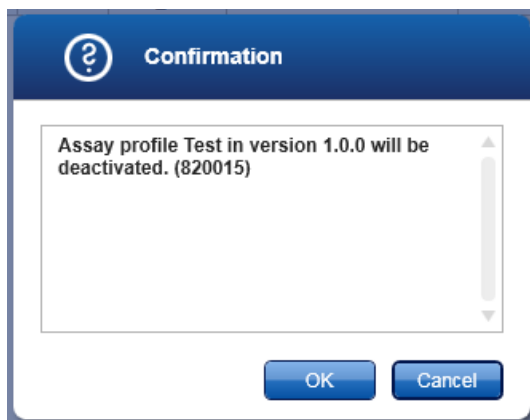
Deactivating an assay profile

1. To open the **Assay profiles management** screen, click **Configuration** (A) in the main toolbar and then click the **Assay Profiles** tab (B).





2. Select the assay profile to be deactivated by clicking in the corresponding table row. The selected row is marked blue.
3. Click **Deactivate** (C).

The following confirmation dialog is opened:



4. Click **OK**.

The selected assay profile will be deactivated. The icon of the assay profile changes from  to  in the assay profiles table.

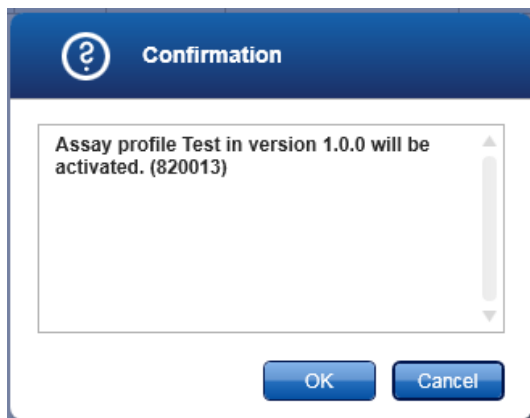




| Assay profiles management | |
|--------------------------------------|--|
| Name | |
| ✓ QuantiFast Pathogen PCR +IC | |
| ✓ Rotor-Gene SYBR Green PCR Demo Kit | |

| Assay profiles management | |
|--------------------------------------|--|
| Name | |
| ✓ QuantiFast Pathogen PCR +IC | |
| ☐ Rotor-Gene SYBR Green PCR Demo Kit | |

Activating an assay profile

1. Click **Configuration** (A) in the main toolbar.
 2. Select the **Assay Profiles** tab (B).
 3. 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
 4. Select the assay profile to activate by clicking in the corresponding table row.
The selected row is marked blue.
 5. Click **Activate** (D).
- The following confirmation dialog is opened:



6. 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

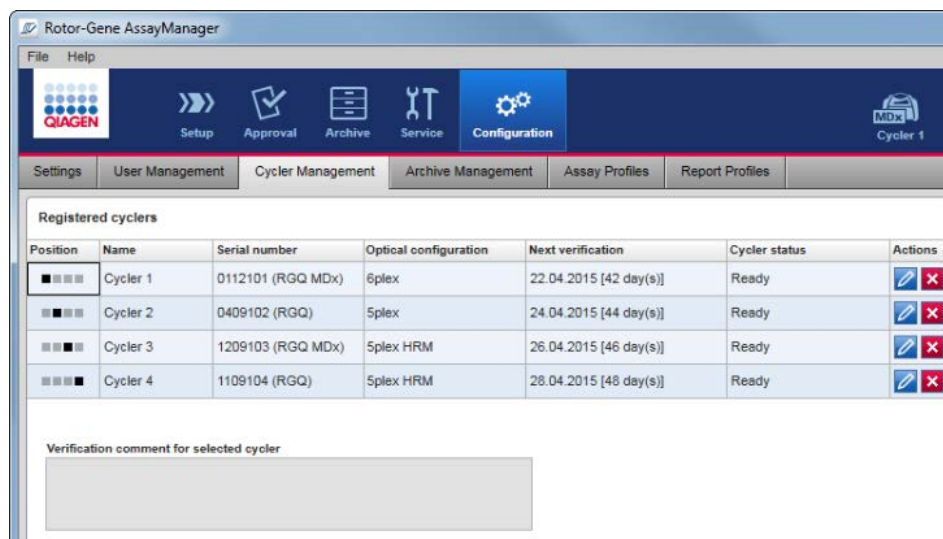
Configuration environment/**Assay Profiles** tab, page 221.

Managing report profiles

Note: For FDA cleared or approved nucleic acid tests, the content and layout of the report is set by each assay.

Managing cyclers

Rotor-Gene AssayManager v2.1 can manage and operate up to 4 different Rotor-Gene Q MDx instruments in parallel. The cyclers can be configured and managed in the **Cycler Management** tab of the **Configuration** environment.



The following tasks related to managing cyclers are covered in this section:

- 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. |

| Status | Description |
|--|--|
| Needs verification | The cycler needs to be verified. |
| Running | The cycler is performing a run. |
| Run stopped | The cycler was stopped but has not yet been released. |
| 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. |

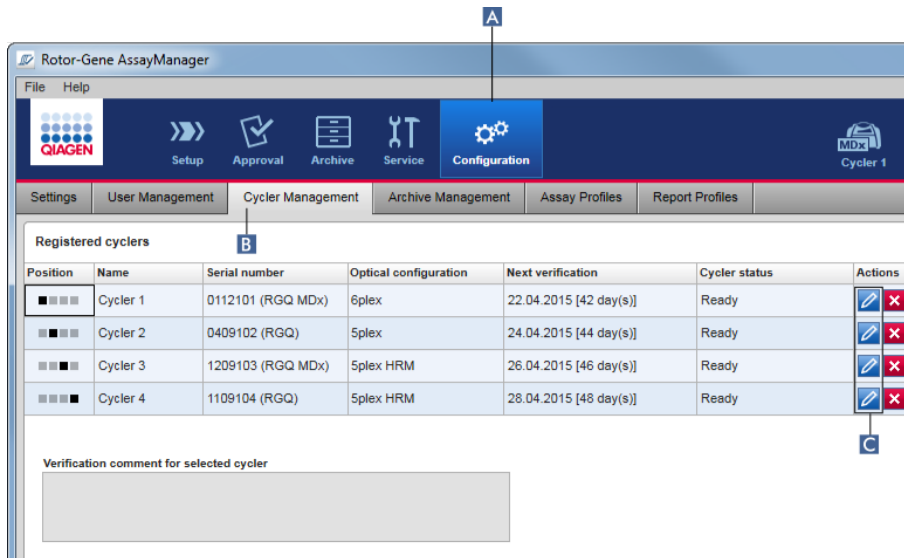
Adding a cycler

1. Connect the USB cable supplied to the USB hub or a USB port of the computer.
2. Connect the USB cable or the USB hub to the back of the Rotor-Gene Q MDx.
3. Connect the Rotor-Gene Q MDx to the power supply. Connect one end of the AC power cord to the socket located at the rear of the Rotor-Gene Q MDx and the other end to the AC power outlet.
4. If not already done, install Rotor-Gene AssayManager v2.1 software. The driver is installed automatically with the software.
5. Once the software has been installed, switch on the Rotor-Gene Q MDx by moving the switch, located at the back on the right-hand side, to the "On" position.

Note: Each Rotor-Gene Q MDx has to be registered by Windows before it can be used by Rotor-Gene AssayManager v2.1. The registration is performed automatically when a connected cycler is switched on.

6. Open Rotor-Gene AssayManager v2.1.

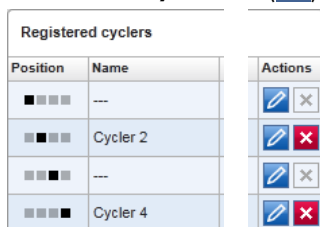
Note: If Rotor-Gene AssayManager v2.1 was previously open, switch off the Rotor-Gene Q MDx and switch it on again.



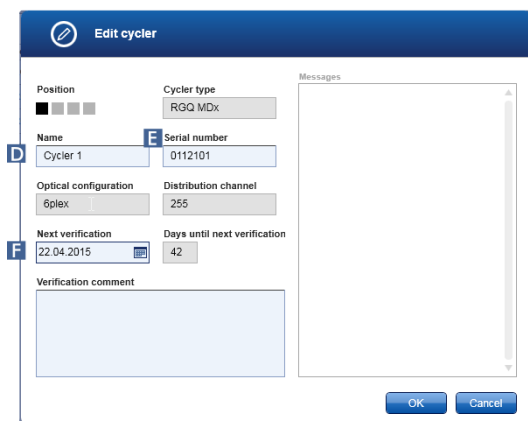
- To open the **Registered cyclers** table, click **Configuration** (A) in the main toolbar, then click the **Cyclor Management** tab (B).

Note: The cyclor must be connected to the computer and switched on before it can be registered in Rotor-Gene AssayManager v2.1. The software will automatically detect if a Rotor-Gene Q MDx device is connected.

- Click the **Edit cyclor** icon (C) in the **Actions** bar of an empty row.



The **Edit cyclor** dialog is shown:



9. Enter a name with up to 8 characters in the **Name** field (D) and the serial number of the connected Rotor-Gene Q MDx in the **Serial number** field (E). The optical configuration of the cyclers will automatically be recognized by Rotor-Gene AssayManager v2.1 when the name and serial number are entered; MDx status is assigned automatically.
10. Optional: Enter a date when the cycler needs its next verification in the **Next verification** field (F) and add a **Verification comment**. The comment field can be used to specify what kind of verification shall be performed at the defined date.
11. Click **OK** to add the Rotor-Gene Q MDx to the **Registered cyclers** table.

Note: If more than one cycler is registered in Rotor-Gene AssayManager v2.1, we highly recommend labeling each cycler prominently on the front of the instrument housing with the specific name given during registration. This facilitates identification of cyclers when loading, or when several cyclers are running in parallel, and avoids the need to refer back each time to the serial number on the type plate.

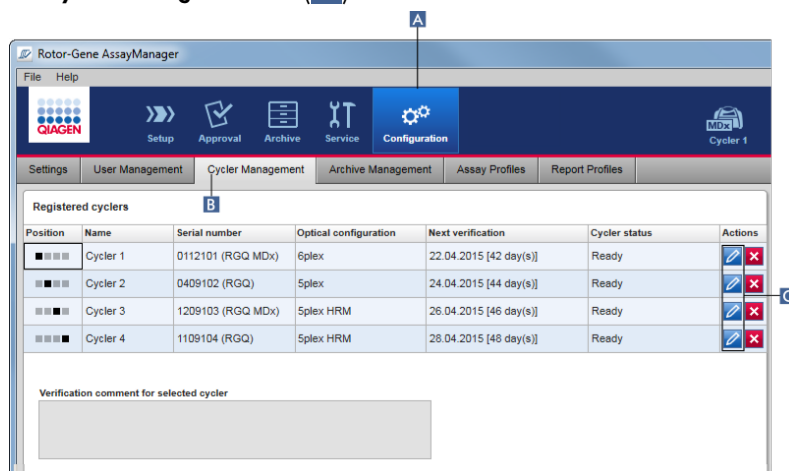
Related topics

“Setting up a run,” page 237.

“Cycler Environment,” page 150.

Editing cycler settings

1. To open the **Registered cyclers** table, click Configuration (A) in the main toolbar, then click the **Cycler Management** tab (B).

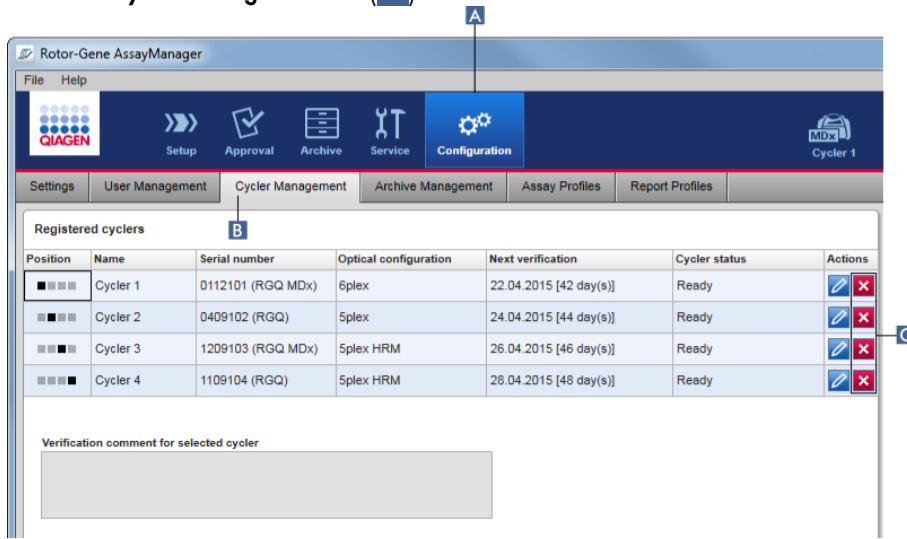


2. Click the **Edit cycler** icon (C) of a cycler that is already registered.
The **Edit cycler** dialog opens.
3. Edit the cycler name, the next verification date, and (optionally) a verification comment.
4. Click **OK** to update the cycler configuration.

Removing a cyler

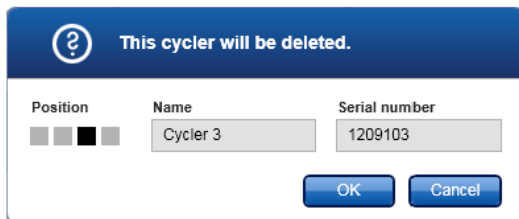
Note: Cyclers can only be removed if they are offline, ready or with the status **Needs verification**.

1. Click **Configuration** (A) in the main toolbar.
2. Select the **Cycler Management** tab (B).



3. Move the mouse to the row containing the cycler to be removed from the **Registered cyclers** table.
4. Click the **Remove cycler** button (C).

The following confirmation dialog is opened:



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

Related topics

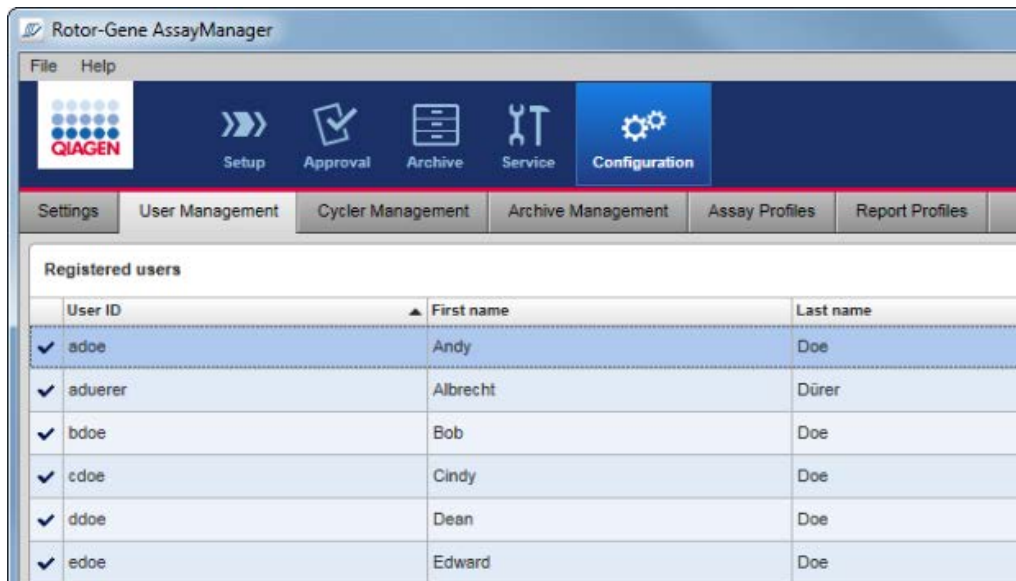
“Setting up a run,” page 237.

“Cycler Environment,” page 150.

Managing users

A user with the assigned role of 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.

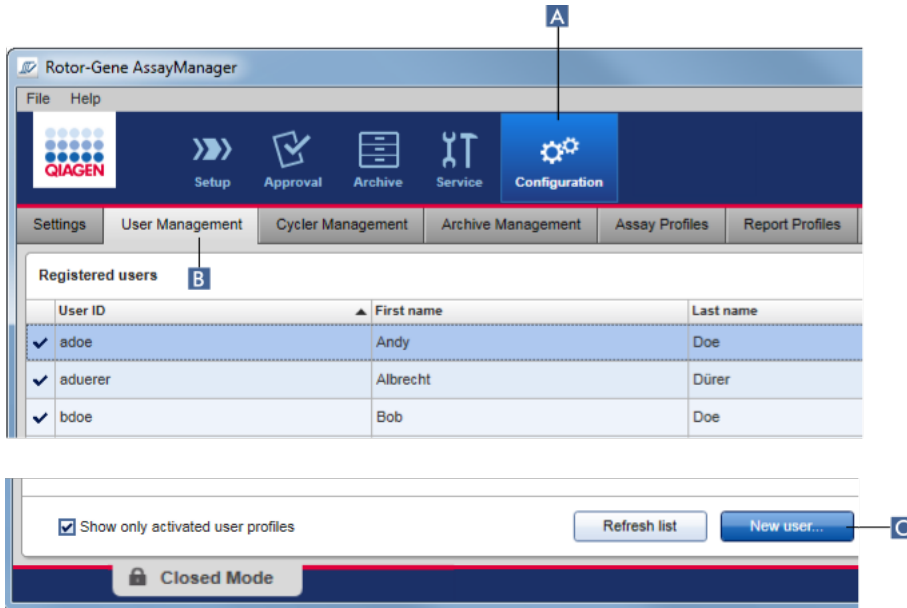


The following topics are covered in this section:

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

Creating a user profile

1. To open the **Registered users** table, click **Configuration** (A) in the main toolbar, then click the **User Management** tab (B).



2. Click **New user** (C).

The **Add user** dialog is shown:

The "Add user" dialog box is shown. It has a title bar with a pencil icon and the text "Add user". The dialog contains several input fields and a list of roles. The fields are: First name (D), Last name (E), User ID (F), Password (G), and Confirm password (H). There is a checkbox for "Activate user" (I) which is checked. To the right of the fields is a list of roles (J) with checkboxes: Administrator, Approver, AssayDeveloper, Operator, and SuperUser. At the bottom, there is a "Messages" section with two error messages: "Enter a valid first name (1-50 characters). (150040)" and "Enter a valid last name (1-50 characters). (150041)". At the bottom right, there are "OK" and "Cancel" buttons.

3. Enter the first name, the last name and a user ID in the corresponding fields (D), (E) and (F).

4. 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 compliant 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.

5. The **Activate user** check box (I) is activated by default. To create a deactivated user profile, deactivate this check box.
6. In the **Roles** table (J), activate the check boxes of the role that will be assigned to the user. It is possible to assign multiple roles to a user.
7. Click **OK**.

The new user profile is added to the **Registered users** table.

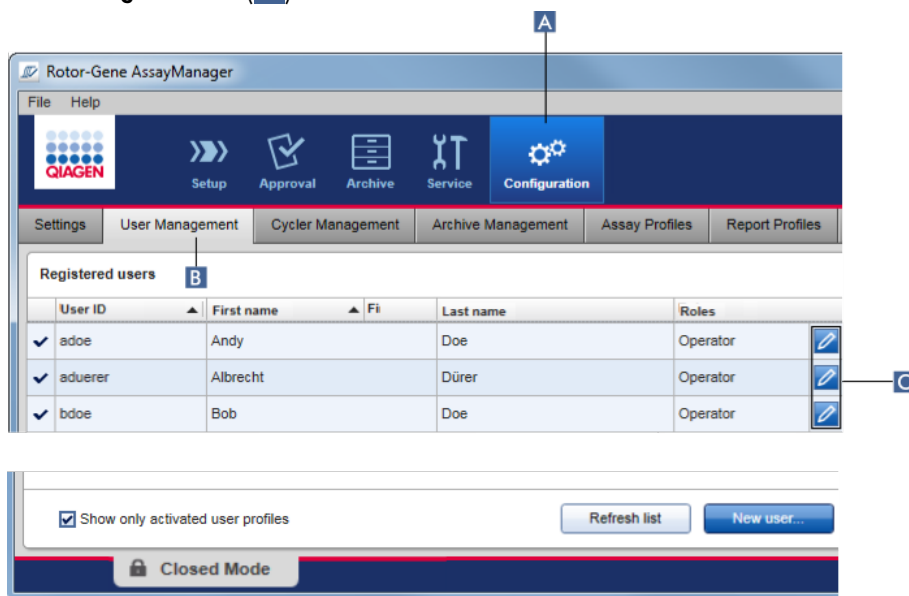
Note:

- The user must change the password at the first login.
- Password rules can be set up in the **Configuration** environment in the **Settings** tab.

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** and **Roles**.

1. To open the **Registered users** table, click **Configuration** (A) in the main toolbar, then click the **User Management** tab (B).



2. Click the **Edit user** icon (C) of a user profile.

The **Edit User** dialog is shown:

| Field | Value |
|----------------------|--|
| First name (D) | John |
| Last name (E) | Doe |
| User ID | SU |
| Password (F) | ***** |
| Confirm password (G) | ***** |
| Activate user (H) | <input checked="" type="checkbox"/> |
| Roles (I) | <input type="checkbox"/> Administrator <input type="checkbox"/> Approver <input type="checkbox"/> AssayDeveloper <input type="checkbox"/> Operator <input checked="" type="checkbox"/> SuperUser |

3. If applicable, modify the name of the user in the fields (D) and (E).
4. If applicable, enter a new password in the **Password** field (F) and enter it again in the **Confirm password** field (G).
5. Toggle the **Activate user** check box (H) to change the activation status of the user.
6. If applicable, modify the check boxes in the **Roles** table (I). It is possible to assign multiple roles to a user.
7. 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 environment/**User Management** tab, page 208.

"User roles," page 88.

Activating/deactivating a user profile

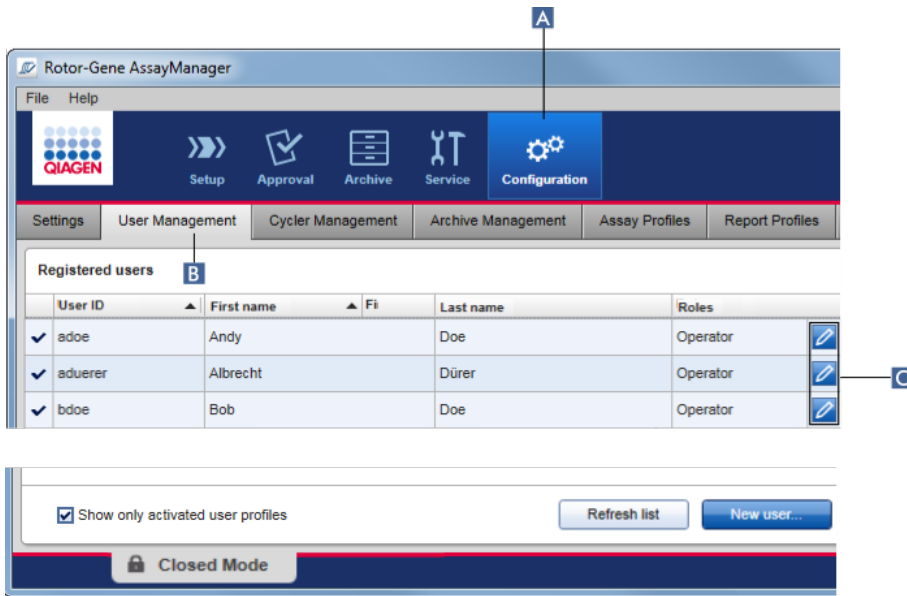
A user profile can never be deleted but only deactivated. This ensures that actions in the audit trails can always be tracked back to a specific user.

Note: Only the status of a user who is not currently logged in can be changed.

Note: Deselect **Show only activated user profiles** to make deactivated user profiles visible in the **Registered users** table.

Deactivating a user profile

1. To open the **Registered users** table, click **Configuration** (A) in the main toolbar, then click the **User Management** tab (B).



2. Click the **Edit user** icon (C) of a user profile.

The **Edit User** dialog is shown:

The "Edit User" dialog box is shown. It has a title bar with an edit icon and the text "Edit User". The dialog contains several input fields: "First name" (John), "Last name" (Doe), "User ID" (SU), "Password" (masked with dots), and "Confirm password" (masked with dots). To the right of these fields is a "Roles" section with a list of roles: Administrator, Approver, AssayDeveloper, Operator, and SuperUser. The SuperUser role is checked. At the bottom left, there is a checkbox labeled "Activate user" (D) which is currently checked. Below this is a "Messages" text area. At the bottom right, there are "OK" and "Cancel" buttons.

3. Uncheck the **Activate user** check box (D) to deactivate the user profile.
4. Click **OK**.



The user profile is deactivated. The status icon in the **Registered users** table changes from ✓ to ☐.

Activating a user profile

1. To open the **Registered users** table, click **Configuration** (A) in the main toolbar, then click the **User Management** tab (B).
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.

The **Edit User** dialog is shown.

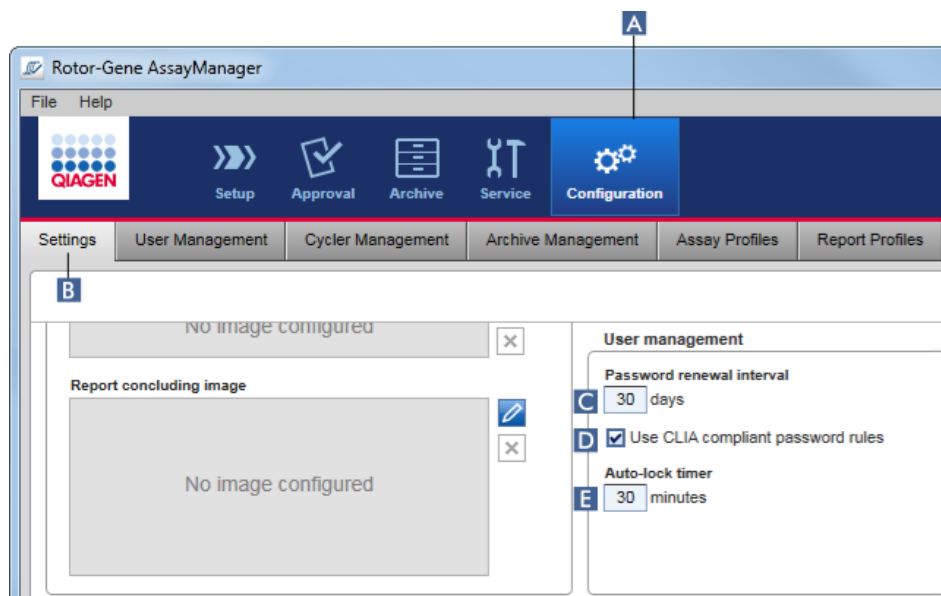
4. Check the **Activate user** check box (D) to activate the user profile.
5. Click **OK**.

The user profile is activated. The status icon in the **Registered users** table changes from  to .

Setting password policies and auto-lock timer

A user with the assigned role of Administrator can set up password policies and the auto-lock timer in the **User management** group box located in the **Global Settings** area of the **Settings** tab in 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.



Setting the password renewal interval

1. To open the **Global Settings** area, click **Configuration** (A) in the main toolbar then click the **Settings** tab (B).
2. Go to the **User management** group box. Enter the number of days in the **Password renewal interval** field (C). This is the interval after which the password for user profiles expires.

Note: Entering a value of "0" (zero) means passwords will never expire.

Activating CLIA compliant password rules

1. To open the **Global Settings** area, click **Configuration** (A) in the main toolbar then click the **Settings** tab (B).
2. Go to the **User management** group box and activate the check box **Use CLIA compliant password rules** (D).

Users are required to use CLIA compliant passwords.

Further information on password rules can be found in "Password policy," page 92.

Setting up the auto-lock timer

1. To open the **Global Settings** area, click **Configuration** (A) in the main toolbar then click the **Settings** tab (B).
2. Go to the **User management** group box. In the **Auto-lock timer** field (E), enter the number of minutes after which the application will be locked. The application will be locked if there is no user interaction after the specified time.

Note: Entering a value of "0" (zero) means the auto-lock timer is deactivated and a user is never logged out automatically.

Related topics

Configuration environment/**User Management** tab, page 208.

"User roles," page 88.

Managing archives

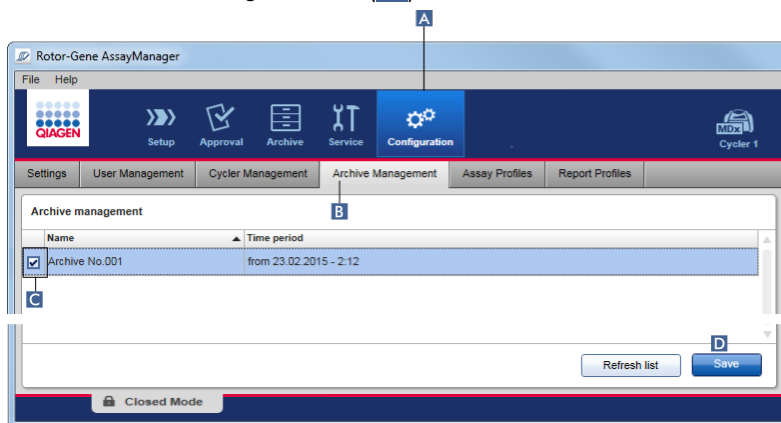
Rotor-Gene AssayManager v2.1 creates archives to save and archive experiment data with a size of up to 10 GB each. A new archive is created automatically when the archive currently in use is full.

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 slows down the search time of Rotor-Gene AssayManager v2.1.

Activating/deactivating an archive

1. To open the **Archive management** area, click **Configuration** (A) in the main toolbar, then click the **Archive Management** tab (B).



The **Archive management** table lists all existing archives. There is a check box at the beginning of every row (C). If the check box is checked, the archive is activated. If the check box is unchecked, the archive is 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 environment/**Archive Management** tab, page 218.

Filter screen, page 183.

Customizing settings

A user with the assigned role of Administrator can customize settings in the **Settings** tab of the **Configuration** environment. The settings are divided into 2 areas: **Global Settings** and **Local Settings**.

Global Settings are stored in the database and affect all clients using the database.

Local Settings affect only the specific computer. For details, see “**Settings** tab,” page 193.

Maintenance

Hardware maintenance

Both the Rotor-Gene Q MDx cyclers and the computer running the Rotor-Gene AssayManager v2.1 need to be maintained. Details can be found in the relevant manuals.

Database Backup Tool for maintaining the database

Important: It is important to back up the database as this will mean you are able to recover the data from your last back up if there is a computer failure.

Note: It is not possible to back up the content of the computer's hard disc directly to create a backup copy of the database.

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

Database maintenance without the Database Backup Tool

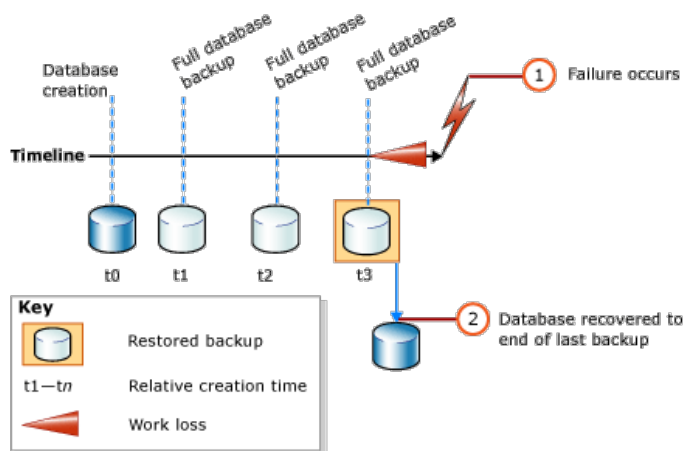
Rotor-Gene AssayManager v2.1 is a software and does not need to be maintained in general. However, the database may need to be maintained.

Note:

- It is important to back up the database. If a computer fails, you are able to recover your data from your last backup.
- A backup of the content of the computer's hard disk does not directly lead to a backup of the database.

The following guidelines are designed to help you with creation of database backups as well as re-expansion of a compressed Rotor-Gene AssayManager v2.1 database.

It is important to explicitly back up the database of Rotor-Gene AssayManager v2.1. In the case of the computer crashing, you are able to recover your data from your last backup and minimize the loss of data.



It is not possible to simply back up the database of Rotor-Gene AssayManager v2.1 by restoring the content of the computer's hard disc.

Note: The backup of a database is a snapshot of the content at a certain point in time. Therefore, the amount of a data loss increases with the time difference to the time point of the last backup. Perform the backup according to your requirements for the availability of data and the protection of data from loss.

Installing the tools

You need administration rights for processing installations.

Prerequisites

Rotor-Gene AssayManager v2.1 must already be installed. It includes further prerequisites of the management studio (see below).

Download and install Microsoft .Net Framework 4.7

(<https://www.microsoft.com/en-us/download/details.aspx?id=55170>).

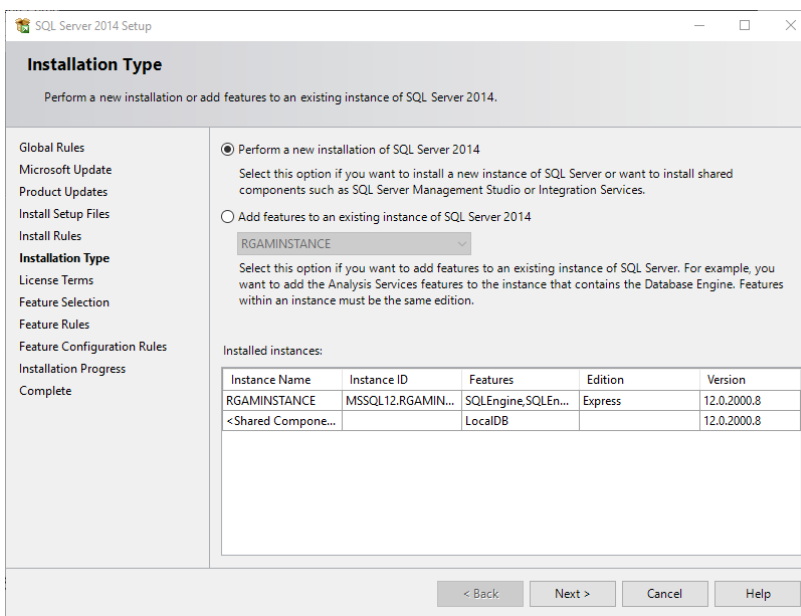
SQL Server Management Studio Express installation

With the SQL Server Management Studio Express (SSMSE), Microsoft provides a graphical management tool for SQL Server 2014 — Express Edition to perform database back-ups.

1. See <http://www.microsoft.com/en-US/download/details.aspx?id=55170> for detailed instructions on downloading and installing the SSMSE.
2. Click **Download** and select **SQLManagementStudio_x86_ENU.exe** (for 32-bit operating systems) to download the installer of the management studio.
3. When starting the setup of the management studio, select the entry as marked in the figure.

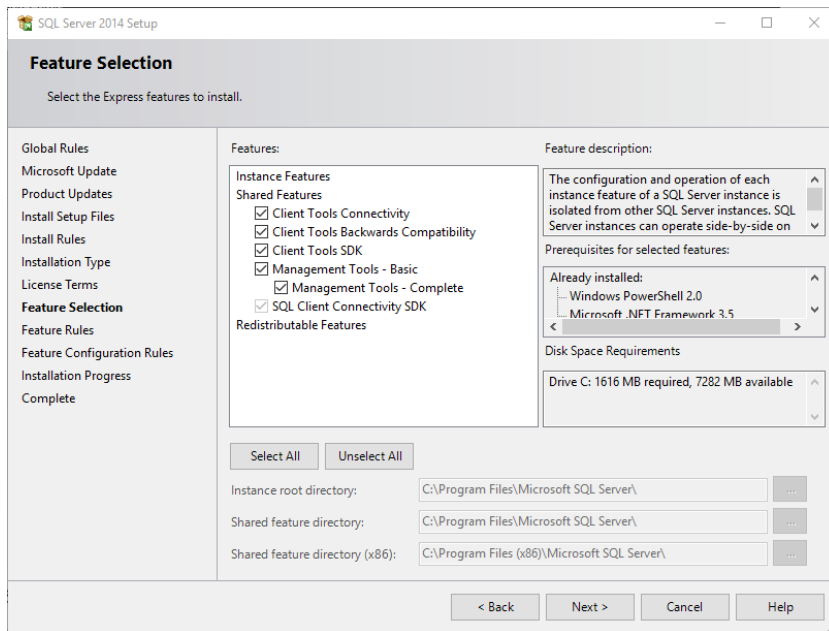


4. Confirm the steps that follow with the default settings until this screen opens:



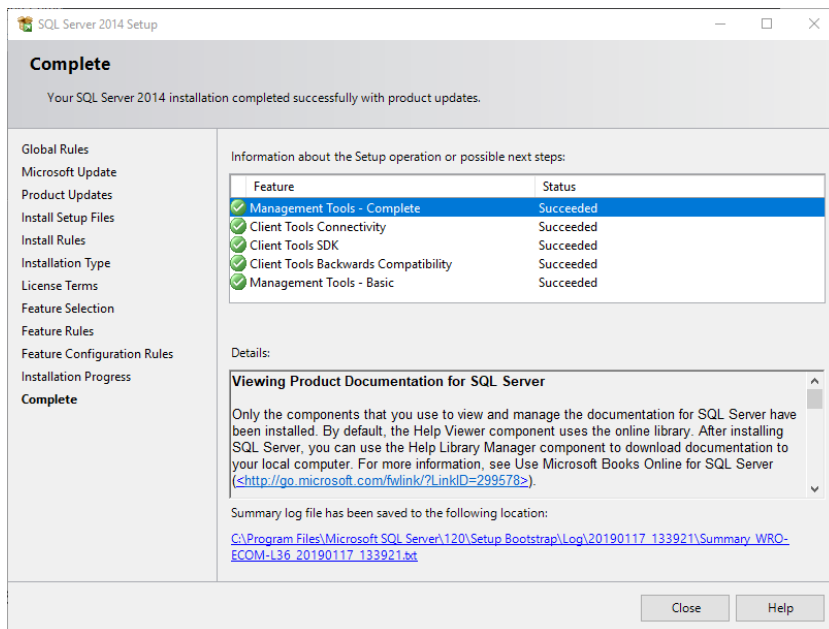
5. Select the first option as marked in the figure above.

6. Confirm and accept the steps that follow with the default settings until this screen opens:



7. Tick the check box as marked in the figure above.

8. Confirm and accept the steps that follow with the default settings until the successful completion of the installation.



Backing up Rotor-Gene AssayManager v2.1 databases

IMPORTANT: You need appropriate rights to work with the SSMSE. It is crucial that the Windows account used to perform the installation of Rotor-Gene AssayManager v2.1 is used for working with the management studio.

The first step is to establish a connection to the SQL Server system. The required server name is a combination of the computer name and the SQL Server instance name. The name used for the instance is RGAMINSTANCE. In an environment where the SQL Server Management Tool is installed and Rotor-Gene AssayManager v2.1 is installed, you can insert “.\RGAMINSTANCE”.

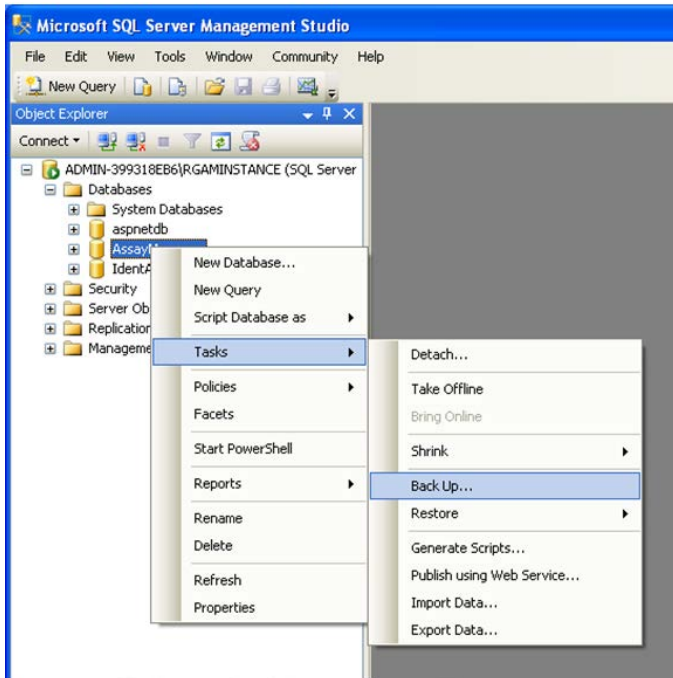
Note: Close Rotor-Gene AssayManager v2.1 before backing up the database. Make sure that no runs are active and that all changes are saved. Make sure also that all remotely connected installations of Rotor-Gene AssayManager v2.1 are shut down.

Note: A system of databases was installed to cover all necessary tasks when Rotor-Gene AssayManager v2.1 was installed. It is important that all databases are always backed up as a package. This is necessary since these databases are interconnected and represent a certain state of the system at each point in time.

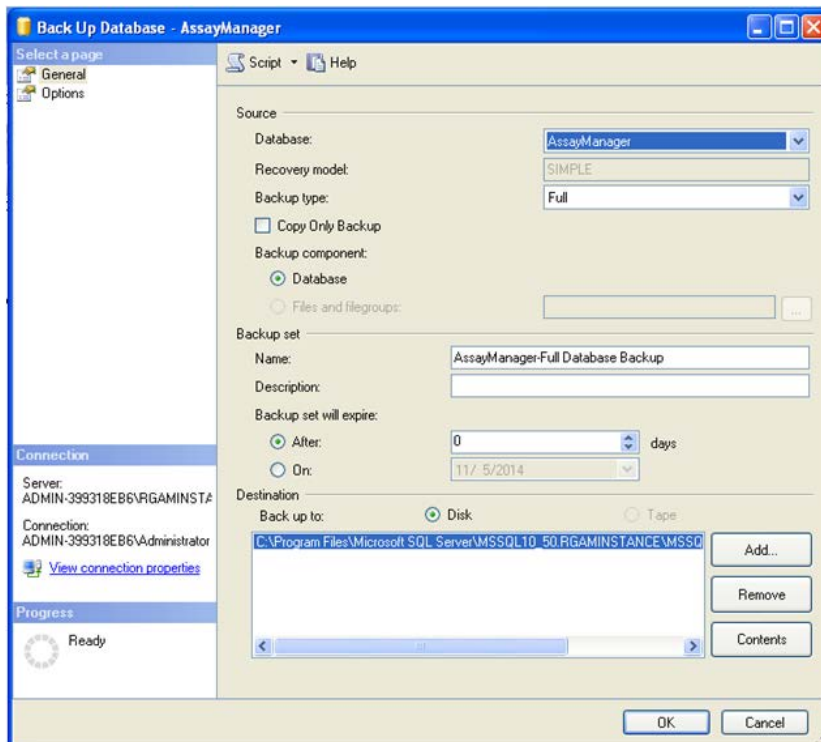
Back up the following databases:

- aspnetdb
- AssayManager
- All databases starting with “IdentArchive”

1. To access the option dialog, select the context menu entry for the desired database according the following figure:



2. The **Back Up Database** dialog opens with the **General** page by default. Check that the correct database name is displayed in the **Database** list box.



3. Select **Full** in the **Backup type** list box.
4. Enter a **Name** for the backup and optionally enter a description.
5. Set **Backup set will expire** to **After "0"** (zero) days so that the backup will not expire.

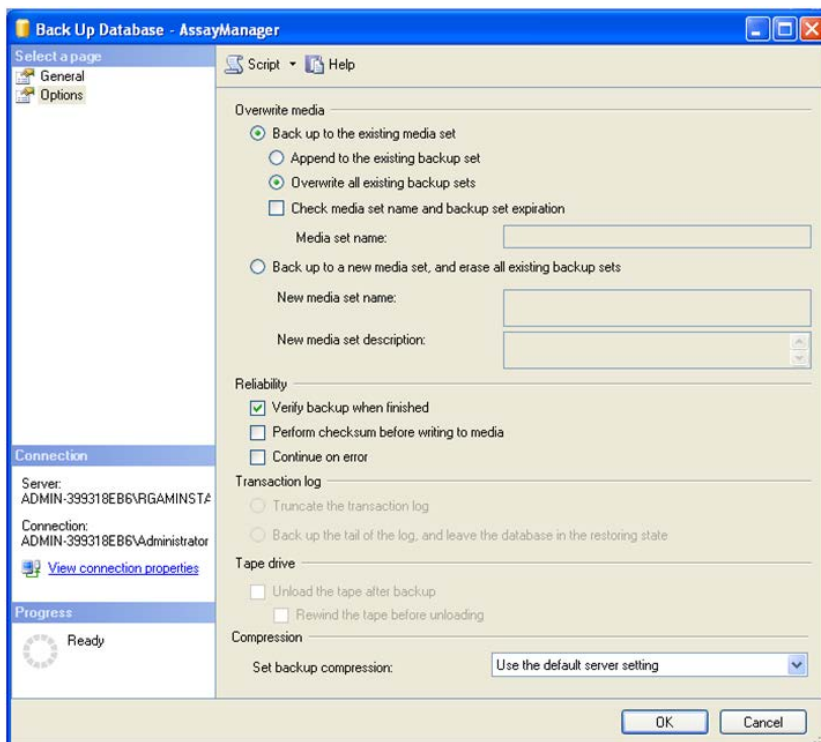
The default destination of the backup is **c:\Program Files\Microsoft SQL Server\MSSQL14.RGAMINSTANCE\MSSQL\Backup** plus the database name with the file extension .bak (e.g., "AssayManager.bak"). It is not recommended to change the paths.

Note: The file name has to be identical to the database name with the file extension .bak:

- aspnetdb
- AssayManager
- IdentArchive<3 digit no>-<UUID>

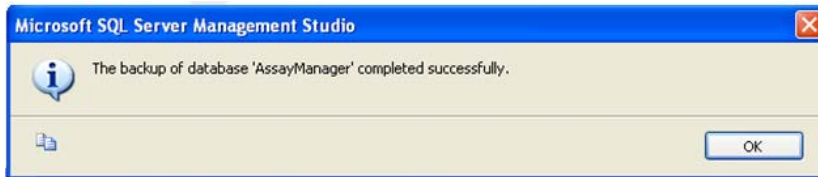
Copy the content of the **Name** field of the **Backup set** area without the default extension "-Full Database Backup" and add ".bak".

6. In the **Back Up Database** dialog, select **Options** in the **Select a page** panel to view the advanced options.



7. In the **Overwrite media** area, choose the options **Back up to the existing media set** and **Overwrite all existing backup sets**.
8. In the **Reliability** area, select the check box **Verify backup when finished**.
9. Click **OK**.

When the database is successfully backed up, a pop-up message will appear similar to the one shown in the screenshot below.



10. Follow a similar procedure with the other databases.

Note: Make sure that the backup files are stored at a secure location after completion. The files must be handled as a bundle since the related databases are interconnected. A database recovery is performed with the entire bundle, otherwise unpredictable behavior may occur.

Restoring a Rotor-Gene AssayManager v2.1 database backup

Recovery of the databases of Rotor-Gene AssayManager v2.1 should allow you to recreate the application, e.g., after a crash of the hard disk.

Precondition

A successful installation of the application and all previously installed plug-ins is required before restoring the databases of Rotor-Gene AssayManager v2.1. The successful installation ensures that the necessary structures in the SQL Server are set up correctly. Keep in mind that the recovery will overwrite all data, such as work lists or experiments, created since the installation. Furthermore, all data since the last backup are lost.

Note: It is important that the system is set up with the version of the application used before the recovery.

Note: All database packages resulting from a backup (described in the preceding sections) must be restored. The databases are interconnected internally. Restoring a single SQL Server database can lead to unpredictable behavior or malfunction of Rotor-Gene AssayManager v2.1.

Close Rotor-Gene AssayManager v2.1 before restoring the databases. Also make sure that all remotely connected Rotor-Gene AssayManager v2.1 instances are shut down.

Database restoration

1. Open the SQL Server Management Studio and connect to the SQL Server instance "RGAMINSTANCE".

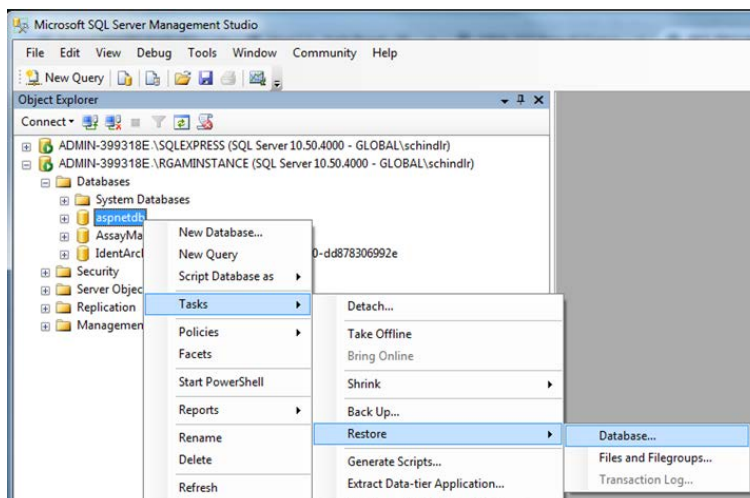
See "Backing up Rotor-Gene AssayManager v2.1 databases," page 290, for details.

2. In the **Object Explorer** panel, expand the instance and then the **Databases** entry. The relevant databases are:

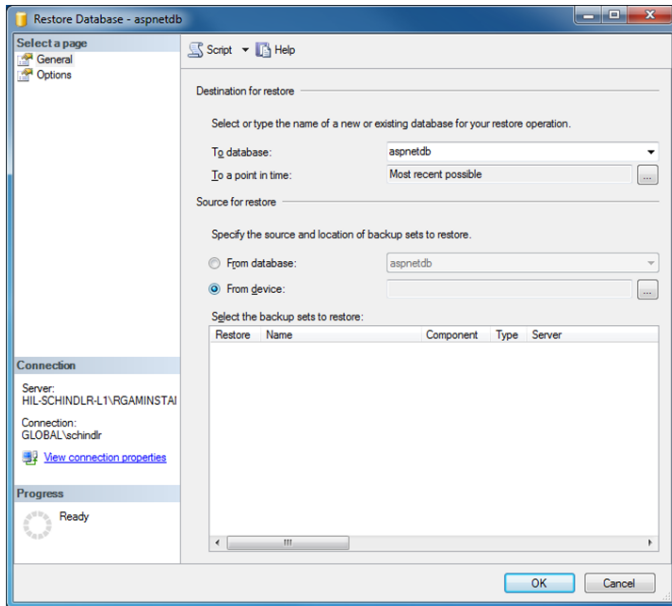
- aspnetdb
- AssayManager
- IdentArchive


(Multiple archives can exist, depending on the number of processed assays.)

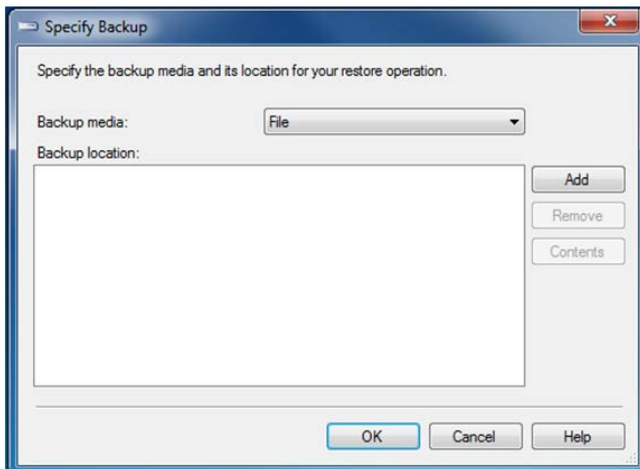
3. Initialize the recovery of a database by opening the context menu of the database and selecting the corresponding menu entry as shown in the figure below:



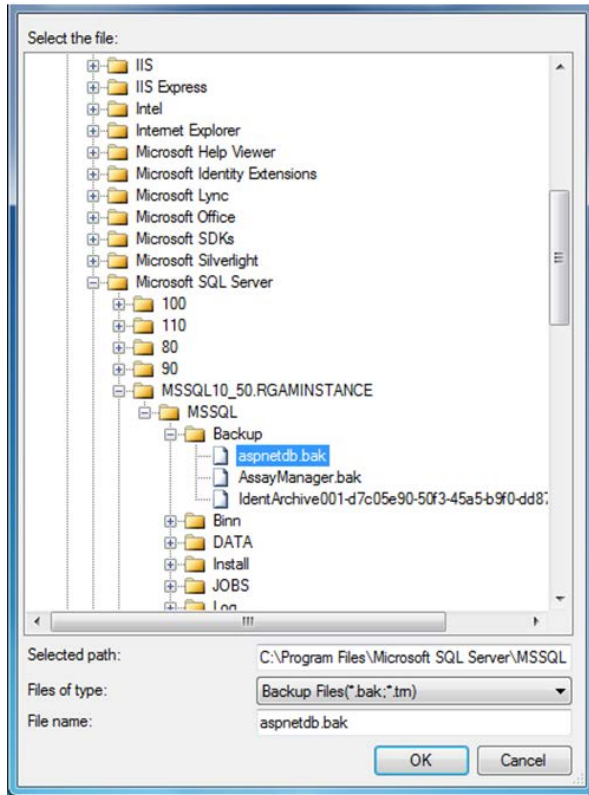
The **Restore Database** dialog opens:



4. Leave the section **Destination for restore** untouched.
5. In the section **Source for restore**, select the option **From device**.
6. Locate the backup via the browse button .

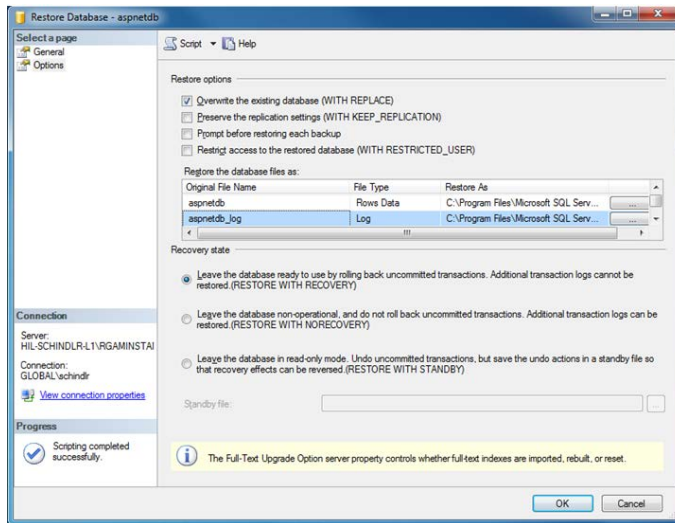


7. In the **Specify Backup** dialog, open the file selection dialog by clicking the **Add** button.



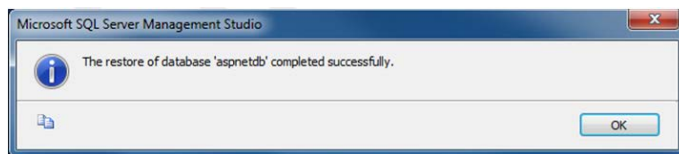
8. Navigate to the .bak file of the selected database (here "aspnetdb.bak"). Confirm with **OK**.
9. Confirm the selection in the **Specify Backup** dialog.
10. Select the backup by ticking the check box in the list.
11. In the **Select a page** panel (left side), select **Options**.
12. Set the options as shown in the **Restore Database** dialog below.

Entries in the table **Restore the database files as:** are left untouched. They are set through the previous steps.



13. Confirm the settings by clicking **OK**.

The successful recovery is confirmed with the pop-up message:

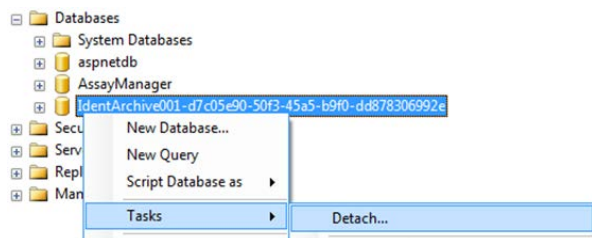


Perform these steps to restore the “AssayManager” database.

Removing a default archive database

The archive databases need special treatment because of their unique naming property. After a fresh installation of Rotor-Gene AssayManager v2.1, no archive database is created until the application is started. The first start of the application creates an (empty) archive database. This archive database has to be removed since the backup of the “AssayManager” database references (an-)other database(s).

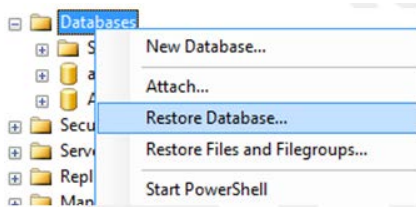
1. To remove the useless default archive of the current installation, open the context menu by pointing to the archive file database and right-clicking the mouse button. Select **Detach**.



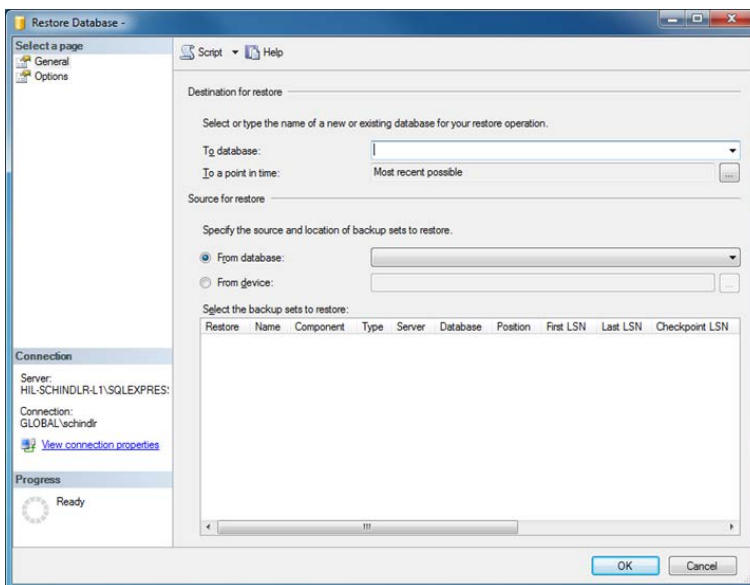
2. The **Detach database** dialog opens. Click **OK**.

Restoring an archive database

1. To restore the appropriate backup of an archive database that is related to an “AssayManager” database, open the context menu of the **Databases** entry in the **Object Explorer** panel via a right-click of the mouse button
2. Select the **Restore Database** menu entry.



This opens the **Restore Database** dialog without a preselected database.



3. In the **Destination for restore** section, provide the correct archive database name in the **To database** field.

Note: It is crucial to copy the name of .bak backup file without the .bak file extension (e.g., “IdentArchive001-d7c05e90-50f3-45a5-b9f0-dd878306992e”)

4. Proceed as described from step 10 in **Database restoration** (page 296).

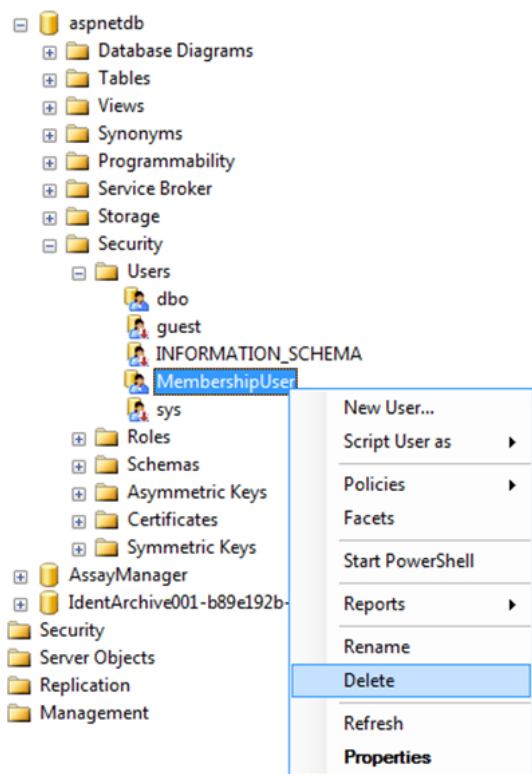
Final steps in database restoration

In the last step, a restored database must be set up in a way that access from Rotor-Gene AssayManager v2.1 is possible.

Preparing the aspnetdb database

In the first step, the original SQL Server user **MembershipUser** has to be cleared.

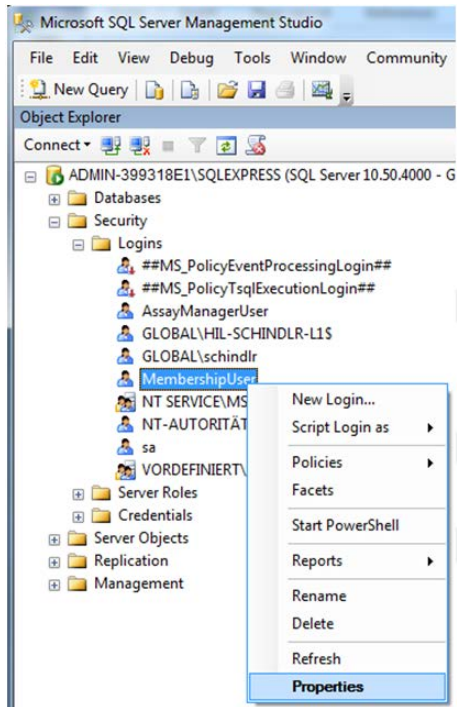
1. In the **Object Explorer** panel, expand the **aspnetdb** database according to the following figure:



2. Select the **Delete** entry of the context menu for **MembershipUser**.
3. A dialog opens. Confirm the deletion by clicking the **OK** button.

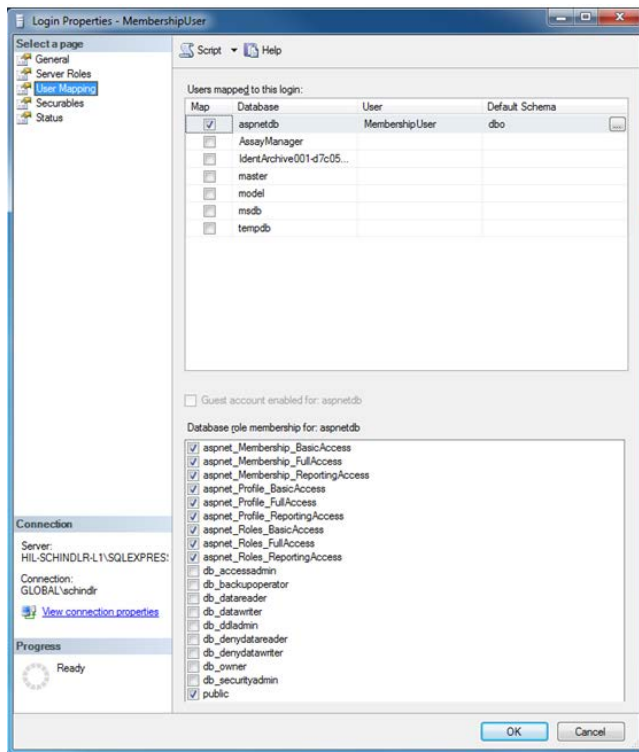
The next step associates the SQL Server login with the database. Do not mix up the **Logins** folder with the **Users** folder.

4. In the **Object Explorer** panel, expand **Security** on the first level under the database instance and then expand the **Logins** entry.



5. Select **MembershipUser**. Open the context menu and click **Properties**.

- The **Login Properties - MembershipUser** dialog opens. Click the **User Mapping** entry in the **Select a page** panel.

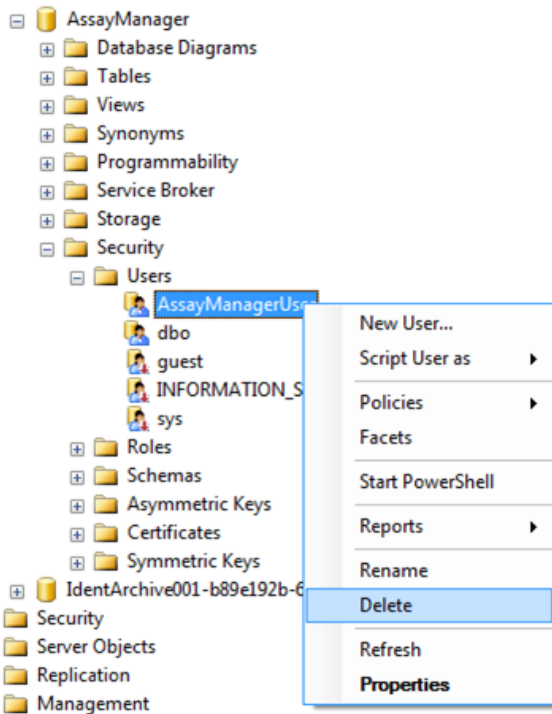


- Adjust the settings in the sections **User mapped to this login** and **Database role membership for: aspnetdb** according the figure above.
- Click **OK** to confirm the settings.

Preparing the AssayManager and archive databases

In the first step, the original SQL Server user **AssayManagerUser** has to be cleared.

1. In the **Object Explorer** panel, expand the **AssayManager** database entry according to the following figure:

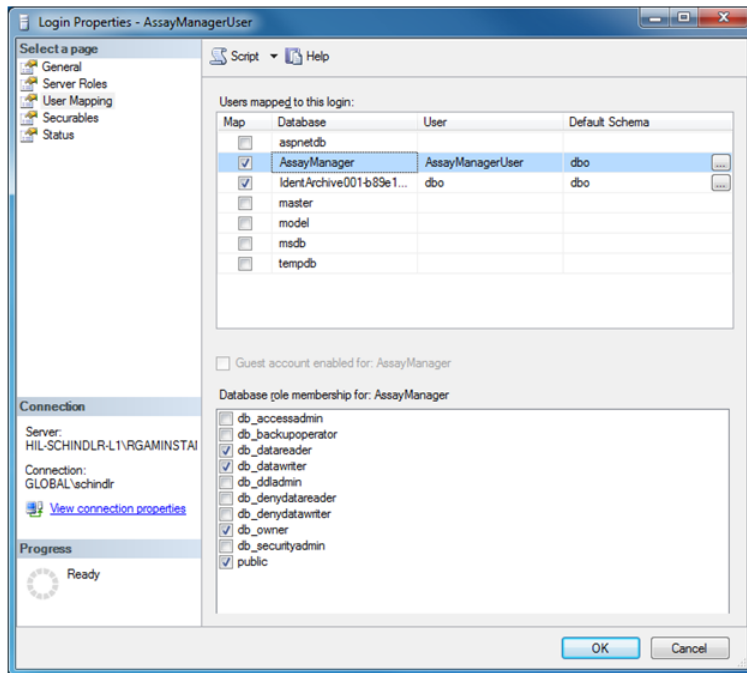


2. Select the **Delete** entry of the context menu for the **AssayManagerUser** item.
3. A dialog opens. Confirm the deletion by clicking the **OK** button.

The next step associates the SQL Server login with the database. Do not mix up the **Logins** folder with the **Users** folder.

4. In the **Object Explorer** panel, expand **Security** and then the **Logins** entry.
5. Select **AssayManagerUser**, open the context menu and click the **Properties** menu item (similar to the procedure in "Preparing the aspnetdb database," page 299).

- The **Login Properties – AssayManagerUser** dialog opens. In the **Select a page** panel, click the **User Mapping** entry.



- Adjust the sections **User mapped to this login** and **Database role membership for: AssayManager** according to the figure above.
- Leave untouched the settings for all databases with names starting with "IdentArchive".
- Click **OK** to confirm the settings.

Troubleshooting

This section provides information about what to do if an error occurs when using Rotor-Gene AssayManager v2.1.

Resolving error messages and warnings

Error messages and warnings are displayed when a problem occurs during the operation of Rotor-Gene AssayManager v2.1. All messages have an error ID, which is displayed at the end of the error message. It is possible that several errors are combined in only one message. Refer to the error IDs listed in this section if an error message or warning appears. If error messages or warnings appear that are not listed here or if the error cannot be resolved, note the error ID, the error text and the steps leading to the error. Then contact QIAGEN Technical Services.

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

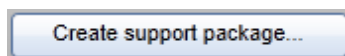
If there are problems with a specific experiment, create a support package and send it to QIAGEN Technical Services.

Creating a support package

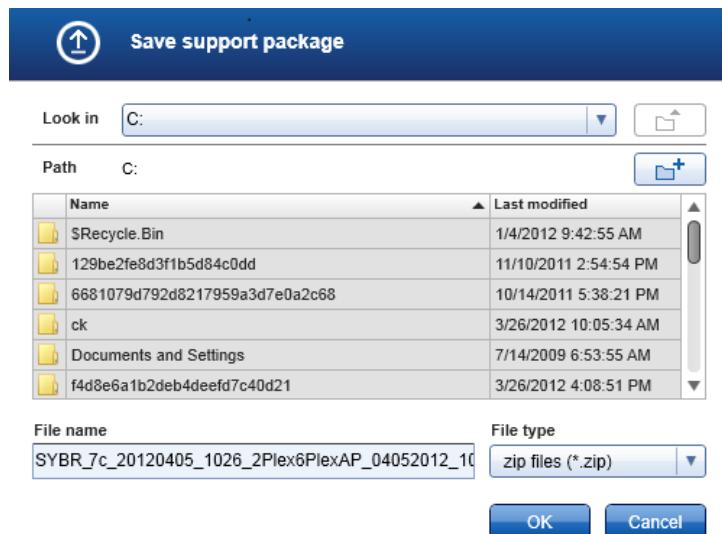
Rotor-Gene AssayManager v2.1 provides the possibility to create support packages containing all relevant information about a specific experiment.

Depending on the approval status of the erroneous experiment, go to the **Approval** environment, select the correct experiment and start the approval process, or go to the **Archive** environment and let the assay data be displayed.

Click **Create support package** at the bottom left of the screen to create a support package for the selected experiment.



A dialog opens for selecting a file name and the directory where the support package will be saved. The default support package file name contains the experiment name followed by the assay profile name, the current date, and time.



The support package will be saved as a single file containing all relevant information about the experiment. This file can be attached to an email and sent to QIAGEN Technical Services for troubleshooting.

Note for laboratories using several installations of Rotor-Gene AssayManager v2.1: A support package should always be created at the computer that was connected to the Rotor-Gene Q MDx during processing the erroneous experiment to ensure that all relevant information is included.

System setup

This section contains information about potential errors during system setup.

| Error description | Comments and suggestions |
|--|---|
| Computer or Rotor-Gene Q MDx does not turn on | Check the power connection. The power cable might be loose or faulty. Reconnect or replace the cable. |
| Rotor-Gene AssayManager v2.1 cannot communicate with cyclser | Check the cable connection between Rotor-Gene Q MDx 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 MDx. Switch off the Rotor-Gene Q MDx and switch it back on again. Close the Rotor-Gene Software, if applicable. Restart Rotor-Gene AssayManager v2.1. |
| Rotor-Gene AssayManager v2.1 does not start | |
| (a) Rotor-Gene AssayManager v2.1 is not installed | Install Rotor-Gene AssayManager v2.1 |
| (b) Old version of Microsoft Windows | Rotor-Gene AssayManager v2.1 can only be operated with Windows 7 or 10. |
| (c) No plug-in installed | Rotor-Gene AssayManager v2.1 consists of the core software and plug-ins with application specific components. In addition to the core application, at least one plug-in must be installed to be able to use Rotor- Gene AssayManager v2.1. |
| (d) Different versions of core application/plug-in | All Rotor-Gene AssayManager v2.1 installations that use the same database must have installed: <ul style="list-style-type: none">● The same plug-in versions● The same core version <p>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.</p> |

| Error description | Comments and suggestions |
|--|---|
| Rotor-Gene AssayManager v2.1 does not work properly and freezes before the user can log in | Rotor-Gene AssayManager 2.1 is compatible with 32-bit and 64-bit versions of Windows 7 and 10. Update your computer to Windows 7 or Windows 10 or install Rotor-Gene AssayManager v2.1 on another computer with a compatible Windows version. |

Operation

This section contains information about potential errors during operation of Rotor-Gene AssayManager v2.1.

Instrument-related errors

| Error description | Comments and suggestions |
|---|--|
| Weak or no fluorescence signal detected | Open the lid of the Rotor-Gene Q MDx and ensure that the lenses, located at both the emission and the detection sources, 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 <i>Rotor-Gene Q MDx User Manual</i> . |
| 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 MDx 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 MDx before starting a run. |

Software-related errors

| Error description | Comments and suggestions |
|---|--|
| Second Rotor-Gene AssayManager v2.1 installation cannot access data from another installation | If several Rotor-Gene AssayManager v2.1 installations are used, ensure that core software and plug-ins of all installations have exactly the same version. Software upgrades have to be applied simultaneously to all computers sharing Rotor-Gene AssayManager v2.1 data. |
| The background in plots is printed in black | <p>Some printer drivers are configured in a way that the transparent background colors used in the Rotor-Gene AssayManager v2.1 plots are printed in black. Check the manual of your printer how to change this configuration.</p> <p>Technical background: To ensure that the displayed results of the plots are exactly the same as the printed reports, the background colors need to be transparent.</p> |

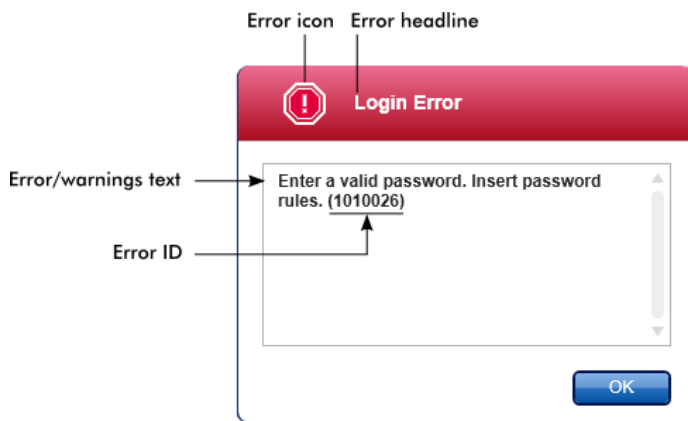
General errors

| Error description | Comments and suggestions |
|--------------------------|---|
| Incorrect rotor loading | Load tubes 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 sit correctly in place. |

| Error description | Comments and suggestions |
|---|--|
| 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., that 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 | <p data-bbox="544 870 963 900">Check whether the user name is correct.</p> <p data-bbox="544 927 1110 1112">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 reactivate the user profile.</p> |
| Sample position is incorrect | <p data-bbox="544 1157 1086 1225">When setting up an experiment be sure to place the reaction tubes in the correct positions of the rotor.</p> <p data-bbox="544 1240 1123 1464">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 buttons respectively. If using strip tubes, 0.1 ml, be sure not to invert the strip tubes during transfer from assay setup to the rotor.</p> |

Error messages and error codes

The source of a message is indicated in the error ID. The general structure of an error ID is shown in an example of an error dialog.



The following table lists all error messages that might occur during operation of Rotor-Gene AssayManager v2.1. If QIAGEN Technical Services needs to be contacted, provide the service specialist with the following information:

- Actions performed before the error message occurred
- Error ID

Note: The error ID is unique and helps QIAGEN Technical Services to clearly identify the error message.

| Error ID | Error text |
|----------|---|
| 30000 | Failed reading the permissions file {0}. |
| 30001 | Wrong Silicon Laboratories CP210x driver version was found on the system. Only CP210x driver of version 6.5.3 should be installed. Please remove the wrong CP210x drivers and restart the application. The application will exit now. |
| 30002 | The permissions file {0} has an invalid document format. |
| 30003 | Silicon Laboratories CP210x driver of version 6.5.3 was not found on the system. Please install the driver and restart the application. The application will exit now. |
| 30004 | Unexpected error with user activity timer. Application has to terminate. Please contact your administrator. |

| Error ID | Error text |
|-----------------|---|
| 30005 | License check has failed. Contact QIAGEN support. |
| 30006 | Could not find the permissions file {0}. |
| 30007 | Assign at least one role to user {0}. |
| 30008 | The following roles in the database are obsolete: {0}. Contact QIAGEN Technical Services. |
| 30009 | Could not find the following role '{0}' in the database. Contact QIAGEN Technical Services. |
| 30011 | The database connection is lost. Running experiments will continue; they will be saved automatically into the database as soon as the connection is restored. Log in again. If the problem persists, contact your system administrator. |
| 30012 | No valid license file is selected. |
| 30013 | The application initialization failed because the database connection is not available. The application will exit now. Contact your local administrator. |
| 30014 | License key file generated successfully. |
| 30015 | Trial license has been expired. |
| 30016 | Access to the following path is denied: '{0}'. Select another path. |
| 30017 | Rotor-Gene AssayManager is already started on this computer |
| 70000 | The analysis of assay with name {0} (version {1}, application mode {2}) failed. |
| 70001 | There is not assay profile available with name {0}, version {1} and application mode {2}. |
| 70002 | Plug-in {0} (version {1}, application mode {2}) does not provide an analysis service. |
| 150000 | At least one error still exists (see messages). Please fix the error first, before settings can be saved. |
| 150001 | There is already a profile in the database with the same name and version. The file you selected will not be imported. |

| Error ID | Error text |
|-----------------|---|
| 150002 | The selected assay profile is based on the plug-in "{0}" in version {1}. Install or update to the most recent, compatible version of this plug-in and repeat the import of the assay profile. |
| 150003 | Enter a valid user ID (User ID must not contain comma). |
| 150008 | The resource has an invalid document format. Contact QIAGEN Technical Services. |
| 150009 | {0} must not be empty. |
| 150022 | This cyclor name is already in use. Enter a different cyclor name. |
| 150023 | There is no cyclor with the serial number {0} connected. Enter the correct serial number. |
| 150024 | The cyclor with the serial number {0} is already registered as {1}. |
| 150028 | Enter a valid serial number. |
| 150029 | The file contains an incomplete or invalid assay profile. The file will not be imported. |
| 150030 | Enter a valid assay profile path. |
| 150032 | The file cannot be read. It will not be imported. |
| 150035 | In Closed Mode, you can only import profiles distributed by QIAGEN. The file you selected will not be imported. Log in in User Defined Test Mode to import this file. |
| 150036 | In User Defined Test Mode, you cannot import profiles distributed by QIAGEN for the Closed Mode. The file you selected will not be imported. Log in in Closed Mode to import this file. |
| 150040 | Enter a valid first name (1-50 characters). |
| 150041 | Enter a valid last name (1-50 characters). |
| 150042 | Enter a valid user ID (1-40 characters). |
| 150043 | Assay profile could not be imported. |
| 150045 | A user profile with the same user ID already exists. Enter a different user ID. |
| 150047 | The entered passwords do not match. Enter and confirm password again. |

| Error ID | Error text |
|-----------------|---|
| 150048 | The connected cycler reports a firmware version {{0}.{1}.{2}} that is not supported. The cycler cannot be used. |
| 150049 | Enter an initial password. |
| 150050 | The password must not be the same as the user ID. Enter a different password. |
| 150069 | Enter a valid number in the "Auto-Lock timer" field (0-60). 0 means the application is never locked. |
| 150070 | Enter a valid password renewal interval (0-999 days). 0 means the password never expires. |
| 150076 | Define the default for the work list name. |
| 150077 | Define a default for the experiment name. |
| 150078 | Enter a valid password renewal interval (0-999 days). 0 means the password never expires. |
| 150084 | Enter a valid number in the "Auto-Lock timer" field (0-60). 0 means the application is never locked. |
| 150087 | Enter a valid password renewal interval (0-999 days). 0 means the password never expires. |
| 150088 | The connected cycler reports an optical configuration that is not stored in the database. The cycler cannot be used. Select another cycler. |
| 150092 | Enter a valid cycler name (1-8 characters). |
| 150093 | Select a date in the future for the next verification date. Keep the field empty if the verification notifier shall not be used. |
| 150095 | Shorten the verification comment to max. 256 characters. |
| 150113 | {0} could not be loaded. The file reading failed. Select a different image file. |
| 150114 | The assay profile could not be activated. It refers to assay parameter set names already present in the following active assay profile(s): {0} |
| 150115 | The assay profile could not be imported. It refers to assay parameter set name and volume pair combinations already present in the following active assay profile(s): {0} |

| Error ID | Error text |
|-----------------|---|
| 150118 | The combination of first name and last name must not contain all the three words "QIAGEN", "Service", and "User" together. |
| 150119 | The user ID must not contain all the three words "QIAGEN", "Service", and "User" together. |
| 150120 | The assay profile is not finalized. Finalize the assay profile. |
| 150127 | Enter a valid password (8-40 characters). |
| 150131 | Shorten the user-definable section for experiment name to max. {0} characters. |
| 150132 | Shorten the user-definable section for work list name to max. {0} characters. |
| 150138 | Assay Profile export failed because: {0} |
| 150140 | The user ID must not contain white spaces. |
| 150141 | Failed to read administration data. |
| 150142 | Enter a valid user ID with at least one non-numerical character (1-40 characters). |
| 150148 | An error occurred during report generation. Retry report generation. |
| 190000 | The unique application ID is not stored in the registry. Contact your local administrator. |
| 190001 | Cannot read the unique application ID that is stored in the registry. Contact your local administrator. |
| 190002 | Cannot write Rotor-Gene AssayManager unique application ID to the registry. Start the application again with administration rights. |
| 190005 | Rex file export canceled. No file was written. |
| 190006 | Rex channel reference key not found. |
| 190007 | The experiment {0} was removed in the meantime. |
| 190008 | The file codec differs to the expected codec UTF-8. |
| 190009 | The product license has been removed. To continue with Rotor-Gene AssayManager provide a valid license file. |
| 190011 | No valid license. |

| Error ID | Error text |
|-----------------|---|
| 190012 | No valid license file is selected. |
| 190014 | Trial license has been expired. |
| 190015 | File {0} does not exist. |
| 190017 | The provided file path is invalid. Enter a valid path. |
| 190018 | Path too long. : {0} |
| 190019 | The resource has an invalid document format. Contact QIAGEN Technical Services. |
| 190023 | Rex file export failed. Reason: {0} |
| 190028 | Specify experiment to export. |
| 190034 | Signature could not be validated. |
| 190035 | Failed reading the file. |
| 190036 | Signature could not be validated. |
| 190038 | The access to the selected file or folder is denied. Select a different file or folder. |
| 190039 | Unexpected I/O error with file {0}. Contact QIAGEN Technical Services. |
| 190040 | A unsupported operation was called on the file system or memory resources. Contact QIAGEN Technical Services. |
| 190045 | File {0} does not exist. |
| 190049 | The provided file path is invalid. Enter a valid path. |
| 190051 | XML signature invalid. |
| 190053 | Path too long. : {0} |
| 190054 | The resource has an invalid document format. Contact QIAGEN Technical Services. |
| 190055 | The access to the selected file or folder is denied. Select a different file or folder. |
| 190056 | Unexpected I/O error with file {0}. Contact QIAGEN Technical Services. |
| 190057 | A unsupported operation was called on the file system or memory resources. Contact QIAGEN Technical Services. |

| Error ID | Error text |
|-----------------|---|
| 190067 | The file was created using Rotor-Gene AssayManager {0}, it cannot be opened. Make sure the versions are the same. |
| 190162 | File {0} not found. |
| 190163 | Failed to open the file {0} in the default viewer. |
| 190205 | The Experiment '{0}' cannot be exported. The following error occurred: {1}. |
| 190207 | The given run profiles are not cycling compatible. Therefore, these profiles cannot be merged. |
| 190208 | One of the run profiles contains a run profile entry of an unsupported type. Select another run profile. |
| 230000 | Enter a correct amount of steps per cycle: {0}. Max. 5 steps are supported. |
| 230002 | Tube position {0} is missing in the tube list. |
| 230003 | The tube positions do not start at 1. Start with tube position 1. |
| 230004 | The tube position {0} occurs more than once in the tube list. Enter a unique tube position in the tube list. |
| 230005 | The profile name is too long. |
| 230006 | Run profile must contain at least one run profile entry. |
| 230010 | The work list assay {0} must contain at least one test sample. |
| 230011 | The work list assay {0} does not contain a valid assay kit. Enter a valid assay kit. |
| 230012 | The work list tube at position {0} is marked as invalid. |
| 230013 | Enter a valid work list name (1 to 80 characters). |
| 230014 | A work list needs to contain at least one assay. |
| 230015 | Enter a valid reaction volume (min. 1). |
| 230016 | The sample {0} does not contain a target. Define a target for sample {0}. |
| 230017 | The given {0} path does not exist. Select another existing path. |
| 230019 | Enter a valid name of the detector ({3} to {5} characters). |
| 230020 | Enter a valid position of the detector (min. {3}). |

| Error ID | Error text |
|----------|---|
| 230021 | Enter a valid name of the emitter ({3} to {5} characters). |
| 230022 | Enter a valid position of the emitter (min. {3}). |
| 230023 | Enter a valid name of the optical configuration ({3} to {5} characters). |
| 230055 | Auto import QIA Symphony work lists. |
| 270000 | The public token of the plug-in does not match with the public token configured in the database. Plug-in: {0}. |
| 270001 | The following plug-ins are missing in the plug-in manager: {0}. Contact your system administrator to upgrade your installation. The application will exit now. |
| 270002 | Unexpected length for an array of doubles! |
| 270003 | Rotor-Gene AssayManager is needed in version {0}, you have installed version {1}. Please contact your system administrator to upgrade your installation. The application will exit now. |
| 270004 | The following plug-in is not found on this system {0}. Please contact your system administrator to upgrade your installation. The application will exit now. |
| 310001 | Could not load the plug-in assembly. |
| 310006 | Plug-in not found for provided key. |
| 310007 | Assembly name information does not match with the configuration of the plug-in. |
| 350000 | Entered profile name is invalid because this name is always used to show a new report profile. Enter a different name. |
| 350001 | Enter report profile name. |
| 350002 | Enter a valid report profile name (1-50 characters). |
| 350003 | Entered profile name is invalid, because it is a reserved device name. Enter another name. |
| 350004 | The following characters are not allowed: / " > < : * ? \ . Enter a different name without special characters. |
| 350005 | Failed to generate report. |
| 350008 | The entered profile name is already used. Enter a unique name. |

| Error ID | Error text |
|-----------------|---|
| 350009 | Report cannot be rendered as it is not generated. |
| 350010 | Failed to generate audit trail report. |
| 350011 | File {0} not found. |
| 350012 | The report profile name must not contain leading and/or trailing white spaces. |
| 350013 | Failed to create file {0}. |
| 350014 | Failed to open the file {0} in the default viewer. |
| 350015 | The import of the report profile failed. Reason: {0} |
| 350016 | The export of the report profile failed. Reasons: {0} |
| 350019 | Failed to delete the report profile. |
| 350034 | Selected report profile is already deleted. Select another report profile. |
| 350038 | The data cannot be used. |
| 350039 | The export of the QIALink/LIMS result file failed. The samples were only saved but not released. |
| 390000 | Select at least one assay profile. |
| 390001 | Enter a cyclor serial number. |
| 390002 | Enter a valid cyclor serial number (1-{0} digits). |
| 390003 | Enter a valid end date. |
| 390004 | The end date must be after {0} |
| 390005 | Enter an experiment name. |
| 390006 | Enter a valid experiment name (1-{0} characters). |
| 390008 | Enter at least one sample ID. Separate multiple sample ID`s using the enter key. |
| 390009 | Following assays could not be removed: |
| 390011 | Enter a valid sample ID (1-{0} characters). |
| 390015 | Enter max. {0} sample IDs to filter. |
| 390016 | The Rotor-Gene AssayManager Experiment from file '{0}' cannot be imported. The following error occurred: {1}. |

| Error ID | Error text |
|----------|---|
| 390017 | The experiment {0} was removed in the meantime. |
| 390018 | The assay(s) of experiment {0} will be closed as the experiment was removed in the meantime. |
| 390019 | The assay(s) of the deleted experiment will be closed. |
| 390021 | The experiment cannot be imported as the following assay profiles are missing: {0} |
| 390022 | Could not find a matching assay profile in the database for the given experiment. Select another experiment. |
| 390023 | The assay(s) have already been deleted. |
| 390024 | In {0} mode, you can only import experiments belonging to the {0} mode. Log in in {1} mode to import this file. |
| 390026 | The environment '{0}' is not supported. |
| 390034 | Select at least one assay status |
| 390039 | Report generation failed. Reason: {0} |
| 390040 | Failed to create support package. Reason: {0} |
| 390052 | Failed to create log file. Reason: {0} |
| 390054 | Copy operation is cancelled. Selected cell(s) should be contiguous. |
| 390065 | RGAM Experiment export failed because:{0} |
| 430000 | The channel {0} does neither have gain nor auto gain. The run cannot be started. |
| 430001 | The required channel {0} on the selected cycler could not be found. The run cannot be started. |
| 430003 | Initialize the experiment summary view before preparation. |
| 430004 | This work list cannot be used in {0} mode. |
| 430006 | No cycler device could be found. Restart the application or, if necessary, the computer and the application. Scan again for connected devices. |
| 430008 | COM port {0} is either unknown or no device is connected. Restart the application or, if necessary, the computer and the application. Scan again for connected devices. |

| Error ID | Error text |
|-----------------|--|
| 430010 | The process cannot be started. The instrument {0} is already busy with another process. |
| 430011 | The cycler {0} is not connected to the system. Connect the cycler with the system. |
| 430012 | The run could not be started on the cycler with the serial number {0}. Make sure the lid is closed. |
| 430013 | No cycler environment controller is available. Contact QIAGEN Technical Services. |
| 430015 | Initialize the view model {0} before reaching the Prepared state. |
| 430016 | The CyclerEnvironmentController must be initialized before any operation. |
| 430023 | The merged contains a wrong acquisition type: {0}. Expected {1}. The run cannot be started. |
| 430024 | Within one cycle, the runProfileEntryIndex must not change. The run cannot be started. |
| 430030 | The run was stopped. For more information see experiment error log. |
| 430032 | The cycler with the serial number {0} cannot be modified in the current state. The current cycler state is: {1}. Contact QIAGEN Technical Services. |
| 430033 | The optical configuration with the ID '{0}' is not supported by the system. Select another optical configuration. |
| 430035 | The optical configuration does not match with a previously connected instrument with this serial number. Check the combination of serial number and optical configuration of the cycler and remove potentially wrong configured cycler from the cycler list. |
| 430037 | No assay profile was found for tube position {0}. Check the work list setup and the assay profile for consistency. |
| 430038 | No sample was found for tube position {0}. Check the work list setup and the assay profile for consistency. |
| 430039 | The number of tubes configured in the samples exceeds the capacity of the rotor. Reduce the number of tubes for that rotor. |
| 430040 | The tube positions assigned to the sample are not in the right range. Check work list setup and assay profile for consistency. |

| Error ID | Error text |
|-----------------|--|
| 430041 | The analysis of experiment {0} failed. |
| 430042 | Enter a valid password. |
| 430043 | This user is deactivated. Contact your local administrator. |
| 430049 | One or more assays are currently open in Approval. Close them in order to go to Approval directly from here. |
| 430050 | This user was deactivated because the password was entered wrong too many times. Contact your local administrator. The current session will be closed. |
| 430051 | An error occurred during the initialization of the device. Reinitialize the cyclers. |
| 430055 | The Experiment has been run in {0} mode. Please log out and log in in the {0} mode to start the approval. |
| 430056 | The run has been interrupted by Windows Hibernate mode. |
| 430057 | The connected cycler reports a firmware version ({0}.{1}.{2}) that is not supported. The cycler cannot be used. |
| 430058 | Persistence Exception |
| 470000 | No experiment name is entered. Provide an experiment name. |
| 470001 | The specified experiment name is a reserved name. Select a different name. |
| 470002 | The selected cycler is not available. Select a different cycler which is ready to use. |
| 470003 | The selected cycler is not available because it has not yet been released. Release the cycler first. |
| 470004 | There is no cycler configured at the selected position. Select a different cycler or contact your local administrator. |
| 470005 | No matching cycler available for this experiment. Contact your local administrator. |
| 470006 | Select a cycler in the cycler selection table by activating the appropriate radio button in the "Select" column. |
| 470007 | The entered experiment name is invalid. Enter a unique experiment name (1-80 characters). |

| Error ID | Error text |
|-----------------|--|
| 470008 | The chosen experiment name has already been used in the meantime. Select a different experiment name. |
| 470010 | No assay profile present in the work list. Complete the work list setup before continuing. |
| 470011 | The work list has been removed by another user in the meantime. Check available work lists. |
| 470012 | Enter a valid external order ID (1-40 characters). |
| 470013 | The number of samples for assay profile {0} exceeds the number of free positions on the rotor. Decrease the number of samples accordingly. |
| 470014 | The current work list does not contain an assay profile. Add an assay profile. |
| 470015 | Enter the number of samples for assay profile {0}. |
| 470016 | The assays of this worklist contain more samples than the rotor has capacity for. Reduce the number of samples for that rotor. |
| 470017 | The selected assay profile {0} is not compatible to the current work list. The rotor types are not identical. |
| 470018 | The available assay profile {0} is not compatible to the current work list. Not all assay profiles define a cycling group. Check assay profiles and work list setup for consistency. |
| 470019 | The available assay profile {0} is not compatible to the current work list. Reason: Either the available assay profile or the already selected assay profile is marked as to run exclusively. |
| 470020 | The assay profile {0} is not compatible to the current work list. Assay profiles are not assigned to the same cycling group. At least one selected assay profile has been defined as "exclusive use only". |
| 470021 | The selected assay profile {0} is not compatible to the current work list. |
| 470022 | The selected assay profile {0} is not compatible to the current work list. The reaction volumes are not identical. |
| 470023 | The selected assay profile {0} is not compatible to the current work list. The thermal cycling profiles are not identical. |

| Error ID | Error text |
|-----------------|---|
| 470024 | The available assay profile {0} is already added to the current work list. Proceed with the work list setup. |
| 470025 | There are not enough free positions on the current rotor to fit the initial tubes of the assay profile. Check the assay profile and the selected rotor for consistency. |
| 470026 | The assay profile {0} is deactivated. |
| 470027 | The current work list contains the deactivated assay profile {0} version {1}. Select an activated assay profile. |
| 470028 | The entered bar code contains an expired kit expiration date. |
| 470029 | The entered bar code is invalid. Scan or enter a bar code with 17-23 digits. Other characters like letters or special characters are not allowed. |
| 470030 | The entered bar code is invalid. Enter the bar code again. |
| 470031 | Scan or enter a valid bar code (17 – 23 digits). |
| 470032 | The current work list contains an expired assay kit on assay profile {0}. |
| 470033 | Enter a valid kit lot number (4-10 digits) in the work list. |
| 470034 | There is no valid kit expiration date provided in the work list. |
| 470035 | Enter a kit lot number in the work list either by scanning the kit barcode or by manual input. |
| 470036 | The entered material number does not fit to assay profile {0}. It might be that either a wrong assay profile was selected or a wrong kit. |
| 470037 | The entered material number is invalid. Enter a valid material number (exactly 7 digits). |
| 470038 | The kit lot number is invalid. Enter a valid kit lot number in the work list (1-40 characters). |
| 470039 | The material number in the work list can contain a maximum of 40 characters. |
| 470040 | The selected cyler has not an optical configuration which is compatible with the worklist. Contact your local administrator. |
| 470041 | The entered bar code contains invalid characters within the lot number. The lot number starts at digit 14 and can be up to 10 digits long. Enter a valid bar code. |

| Error ID | Error text |
|-----------------|---|
| 470042 | The entered bar code contains invalid characters within the material number. The material number starts at digit 1 and must be 7 digits long. Enter a valid bar code. |
| 470043 | There is no material number provided in the work list. |
| 470044 | The list of allowed material numbers of the assay profile does not contain the extracted material number. |
| 470045 | A work list with the name '{0}' already exists. The existing work list cannot be replaced by the imported work list. |
| 470046 | Sample ID is not valid. Sample IDs for this assay must be unique. |
| 470047 | The cycler cannot be used because it is due for verification. Select a different cycler or contact your local administrator. |
| 470048 | The selected assay(s) cannot be run on this cycler, as the cycler comes from a different distributor. |
| 470049 | The selected assay(s) cannot be run on this cycler, as they are not compatible to {0} cyclers. |
| 470050 | The assay profile does not contain material numbers. |
| 470051 | The assay profile {0} does not contain material numbers. |
| 470052 | An error occurred during report generation. Retry report generation. |
| 470053 | Copying of the selected cells failed. Only adjacent cells can be copied. Copy and paste the selected cells individually. |
| 470054 | Paste operation is cancelled. Selected cell(s) must be editable for pasting. |
| 470055 | Paste operation is cancelled. Selected cell(s) must be contiguous cell(s) of one column. |
| 470056 | Paste operation is cancelled. Selected cell(s) must be contiguous cell(s) of one column. |
| 470057 | Paste operation is cancelled. Select some cell(s). |
| 470058 | There is not enough space for the information to be pasted. |
| 470059 | The database is full. Approve and release experiments in the Approval dialog to allow new runs. |

| Error ID | Error text |
|-----------------|---|
| 470060 | 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. |
| 470061 | Cycler type of the selected assay profile {0} is not compatible to cycler type of the assay profile(s) in the current worklist. |
| 470062 | Distributed channel of the selected assay profile {0} is not compatible to distributed channel of the assay profile(s) in the current worklist. |
| 470063 | The sample comment must not exceed 256 characters. |
| 470064 | Enter a valid sample ID (1-40 characters). |
| 470065 | The sample ID must be filled in, not only with space characters. |
| 470066 | Confirm that you have loaded the selected cycler and attached the locking ring to the rotor. |
| 470067 | The Rotor-Gene AssayManager Work List '{0}' cannot be exported. The following error occurred: {1} |
| 470068 | 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. |
| 470069 | 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. |
| 470070 | The Rotor-Gene AssayManager work list from file {0} cannot be imported. It contains assay profiles which are either not installed or deactivated. |
| 470071 | The Rotor-Gene AssayManager work list from file '{0}' cannot be imported. It contains assay profiles which are not available. Select another file. |
| 470072 | The Rotor-Gene AssayManager Work List from file '{0}' cannot be imported. The following error occurred: {1} |
| 470073 | The Rotor-Gene AssayManager Work List from file '{0}' cannot be imported, because it contains a rotor type that is not available. |
| 470074 | The referenced assay profiles '{0}' are not compatible to each other. Reasons: |
| 470075 | The assay kit information check of APS '{0}' produced the following errors: |

| Error ID | Error text |
|----------|---|
| 470076 | The assay profile '{0}' referenced by APS '{1}' does not refer to exactly one rotor type. |
| 470077 | The QIAAsymphony AS result file '{0}' cannot be imported: Reason: '{1}' |
| 470078 | The QIAAsymphony AS result file at '{0}' contains an invalid checksum. The file cannot be imported. |
| 470079 | The file '{0}' does not match the QIAAsymphony AS result file specification. The file cannot be imported. |
| 470080 | The number of assay points ({0}) exceeds the number of tube positions on the rotor. |
| 470081 | The unknown assay point state '{0}' of assay point '{1}' at position '{2}' is not supported by Rotor-Gene AssayManager. |
| 470082 | The unknown sample type '{0}' of assay point '{1}' at position '{2}' is not supported by Rotor-Gene AssayManager. Select another sample type. |
| 470083 | The unknown slot name '{0}' is not supported by Rotor-Gene AssayManager. |
| 470084 | No active assay profile matches the APS '{0}', major version '{1}', the QIAGEN original setting 'not required' and the volume pair '{2} µl, {3} µl' explicitly. |
| 470085 | No active assay profile matches the APS '{0}', major version '{1}', the QIAGEN original setting 'required' and the volume pair '{2} µl, {3} µl' explicitly. |
| 470086 | The pipetting scheme is not supported by Rotor-Gene AssayManager. |
| 470087 | The reaction volume of the APS '{0}' is not supported by the corresponding assay profile '{1}'. |
| 470088 | The APS '{0}' do not specify identical reaction volumes. |
| 470089 | The created work list test samples contain replicated sample IDs, but the referenced Assay Profile '{0}' does not allow this. |
| 470090 | The number of assay points is '{0}'. This number exceeds the number of tubes on the rotor of the referenced assay profiles '{1}'. |
| 470091 | The assay point arrangement does not match the assay profile '{0}'. At position '{1}' the type '{2}' was expected, but the type '{3}' was found. |

| Error ID | Error text |
|----------|---|
| 470092 | The specified sample input volume and the eluate volume pair do not match the assay profile '{0}'. At position '{1}' the type '{2}' specifies '{3} μ l' and '{4} μ l', respectively, but '{5} μ l' and '{6} μ l' were expected. |
| 470093 | A matching assay profile was found for APS '{0}', but it is not designed for use in integrated workflows. |
| 470094 | 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. |
| 470095 | The assay profile {0} does not allow replicates. Remove the replicates. |
| 470096 | The LIMS file at '{0}' does not match the interface specification. The LIMS file cannot be imported. |
| 470097 | The resource has an invalid document format. Contact QIAGEN Technical Services. |
| 470098 | The referenced assay profiles are not cycling compatible. Reasons: {0}. |
| 470099 | The referenced assay profiles are not assay compatible. Reason: The rotor types do not match. |
| 470100 | The QIALink/LIMS result file does not specify identical reaction volumes. |
| 470101 | The referenced assay profiles are not assay compatible. Reason: The reaction volumes do not match. |
| 470102 | Your login mode : {0} does not match to the login mode {1} of the imported work list. |
| 470103 | The sample arrangement does not match the assay profile '{0}'. |
| 470104 | The required assay profile '{0}, {1}.{2}.{3}' is not available in this system. |
| 470105 | The QIALink/LIMS worklist at {0} contains an invalid checksum. |
| 470106 | The unknown login mode "{0}" is not supported by Rotor-Gene AssayManager. |
| 470107 | The rotor type is not available in this system. |
| 470108 | The unknown sample type "{0}" is not supported by Rotor-Gene AssayManager. |
| 470109 | The unknown upstream status "{0}" is not supported by Rotor-Gene AssayManager. |

| Error ID | Error text |
|-----------------|---|
| 470110 | The file cannot be read. It will not be imported. |
| 470111 | The resource has an invalid document format. Contact QIAGEN Technical Services. |
| 470112 | The file cannot be read. The system supports interface version {0}, but the file is designed for version {1}. |
| 470113 | Automatic import of following QIASymphony AS result file(s) failed. The file(s) must be imported manually.{0} |
| 470114 | The path {0} could not be accessed. Automatic import of QIASymphony AS result files is not possible. |
| 470115 | The path {0} could not be found. Automatic import of QIASymphony AS result files is not possible. |
| 470116 | {0} (Slot {1}) |
| 470117 | Automatic import of QIASymphony AS result file {0} (Slot {1}) failed. |
| 470118 | Automatic import of QIASymphony AS result file {0} failed. |
| 470119 | The file '{0}' does not match the QIASymphony SP result file specification. The file cannot be imported. |
| 470120 | The QIASymphony SP result file '{0}' contains an invalid checksum. The file cannot be imported. |
| 470121 | The QIASymphony SP result file '{0}' cannot be imported: Reason: '{1}' |
| 470122 | More sample IDs selected then available positions. Deselect {0} sample IDs. |
| 470123 | The specified path {0} does not exist anymore. Please update the configuration setting path with correct path. |
| 470124 | No valid samples contained in QIASymphony AS result file. |
| 470125 | The Rotor-Gene AssayManager work list from file {0} cannot be imported. It contains samples with invalid ids. |
| 470126 | The Rotor-Gene AssayManager work list from file {0} cannot be imported. It contains assay(s) with invalid assay profile name. |
| 470127 | The QIALink/LIMS worklist at {0} contains assay(s) with invalid assay profile name. |

| Error ID | Error text |
|-----------------|---|
| 470128 | The QIAlink/LIMS worklist at {0} contains samples with invalid ids. |
| 470130 | No work list with assay rack ID {0} available. |
| 470131 | {0} Sample IDs will be overwritten. |
| 470132 | The applied work list does not contain the entered assay rack ID {0}. |
| 470133 | Paste operation is cancelled. Selected cell(s) must not contains empty tube. |
| 470134 | “The file '{0}' cannot be imported. The Rotor-Gene AssayManager only supports QIAAsymphony 5.0 and above file version. Make sure the versions are the same.” |
| 470135 | “More than one work lists match the given rack ID. Select work list manually.” |
| 470136 | Report cannot be rendered as it is not generated. |
| 470137 | Failed to generate report. |
| 470138 | The Kit reference '{0}' of sample '{1}' does not match any of the given Kit references. |
| 470139 | The SP Batch ID '{0}' of sample '{1}' does not match any of the given Batch ID. |
| 470140 | The ICKitRef '{0}' of sample '{1}' does not match any of the given Kit references. |
| 470141 | The QIAAsymphony AS result file contains samples which are not expected by the referenced assay profile. |
| 470142 | The Rotor type '{0}' defined in the work list does not fit to the assay profile. |
| 470143 | The Reaction volume '{0}' defined in the work list does not fit to the assay profile. |
| 470144 | The associated assay profile contains multiple rotor types or reaction volumes. An unambiguous work list cannot be created. Create and import assay profiles with a unique combination of rotor type and reaction volume. |
| 470145 | This work list contains the outdated assay profile {0} version {1}. Create a new work list with an updated assay profile. |

| Error ID | Error text |
|-----------------|---|
| 470146 | The kit expiration date for assay {0} is invalid. Provide valid kit expiration date. |
| 510001 | Fatal exception error occurred during command execution: {0} |
| 510002 | Make sure custom exception supports constructor with signature 'Exception(String, Exception)' |
| 510003 | Cycler-device generated an error with error code {0}. Switch off the cycler, switch it back on again, and restart application. If the error persists, contact QIAGEN Technical Services. |
| 510004 | Device was disconnected. Reconnect the device and retry. |
| 510005 | Fatal exception error occurred during Optical Temperature Verification (OTV) run: {0} |
| 510006 | Fatal exception error occurred during assay profile execution: {0} |
| 510007 | Reset cycler status failed. Switch off the cycler, switch it back on again, and restart application. If the error persists, contact QIAGEN Technical Services. |
| 510008 | Fatal exception error occurred during command execution. Switch off the cycler, switch it back on again, and restart application. If the error persists, contact QIAGEN Technical Services. |
| 510009 | Assay profile execution failed with error code {0}. Check the assay profile for inconsistencies and retry the execution. |
| 510010 | Update of OTV-calibration failed! |
| 510011 | The air temperature has gone over 140° C. Check if the heater or the thermistor are working properly. Contact QIAGEN Technical Services |
| 510012 | A communication error occurred. Contact QIAGEN Technical Services. |
| 510013 | The machine's detector motor jammed. Contact QIAGEN Technical Services. |
| 510014 | The communication with the cycler was lost. Switch off the cycler, switch it back on again. If error persists, contact QIAGEN Technical Services. |
| 510015 | Enter a valid verification date. |
| 510016 | The lid has been opened during the run. Close the lid and restart the run. |
| 510017 | Error cause that was previously flagged was solved. |

| Error ID | Error text |
|-----------------|---|
| 510018 | The rotor has stalled or stopped. |
| 510019 | The machine's source motor jammed. Contact QIAGEN Technical Services. |
| 510020 | The cycler is taking too long to reach temperature. This can affect the assay performance. |
| 510021 | The temperature measurement thermistor has gone open circuit. Contact QIAGEN Technical Services. |
| 510022 | Undefined error. Switch off the cycler, switch it back on again, and restart the application. If the error persists, contact QIAGEN Technical Services. |
| 510023 | An unexpected exception occurred during the run. Switch off the cycler, switch it back on again, and restart the application. If the error persists, contact QIAGEN Technical Services. |
| 510024 | The watchdog timer on the machine has reset it. |
| 510025 | Melt acquisition cannot be performed with settings 'keep LED on' on more than one acquisition channel selected. Check the assay profile for inconsistencies. |
| 510026 | No rotors have been added. Run cannot be started. Check the rotor configuration and the retry. |
| 510027 | No shoots have been added. Run can't be started! |
| 510028 | The requested rotor is not configured for this device. Check the rotor configuration and retry. |
| 670000 | Enter a user ID. |
| 670001 | Enter a valid user ID (1-40 characters). |
| 670002 | Enter an experiment name (1-{0} characters). |
| 670003 | Enter a valid experiment name (1-{0} characters). |
| 670011 | Select at least one context parameter. |
| 670016 | The number of messages in the audit trail table to print exceeds {0} messages. Adjust the filter settings. |
| 670020 | An error occurred during report generation. Retry report generation. |
| 880039 | The export has failed for: {0} |

| Error ID | Error text |
|-----------------|--|
| 900010 | The data from slot '{0}' in QIAAsymphony AS result file '{1}' cannot be imported to a work list. |
| 1010000 | The access to the selected file or folder is denied. Select a different file or folder. |
| 1010001 | File not found. Check the file name and repeat the procedure. |
| 1010002 | The entered file name is invalid. Enter a valid file name without invalid characters, i.e. / ? * " < >. |
| 1010003 | File path must be less than 260 characters. Path too long: {0}. |
| 1010004 | Reserved Device Name {0} is a reserved device name and cannot be used for a folder. Enter a different folder name. |
| 1010006 | Enter folder name. |
| 1010007 | The folder name is invalid. Enter a valid folder name (1-{0} characters) |
| 1010008 | Invalid folder name. Entered value is a reserved device name. Enter a different name. |
| 1010009 | Invalid folder name. Do not use special characters. Especially the following characters are not acceptable: / > < " : * ? \ |
| 1010010 | Folder {0} could not be created. Either the permission was denied, or a folder with this name already exists. Enter a different folder name. |
| 1010011 | Failed to create the Unlock file. |
| 1010012 | {0} This file exists with Read Only attributes. Use a different file name. |
| 1010014 | The entered file/directory name is invalid. Directory name must be less than 248 characters. Path too long: {0}. |
| 1010016 | User name is unknown or password is incorrect. Enter user name and password again. |
| 1010018 | The confirmation password does not match the new password. |
| 1010019 | Confirm the new password. |
| 1010020 | Enter the new password. |
| 1010022 | The new and the old password must be different. |
| 1010023 | Enter the old password. |

| Error ID | Error text |
|-----------------|--|
| 1010026 | Enter a valid password. |
| 1010028 | Invalid password. The old password for the user is incorrect. |
| 1010029 | Invalid user name or password. Enter user name and password again. |
| 1010031 | The entered name is reserved. It cannot be used as folder name. Enter a different folder name. |
| 1010032 | The entered folder name is invalid. Enter a valid folder name. |
| 1010033 | This user is deactivated. Contact your local administrator. |
| 1010034 | Assign at least one role to user {0}. |
| 1010035 | The new password must be different from the previous {0} passwords. Enter a unique password. |
| 1010044 | {0} is not accessible. Directory not found. Check the network connection or create a new directory. |
| 1010047 | Could not log-in to the application. The database connection is lost. Contact your local administrator. |
| 1010048 | Enter a new password (8-40 characters). |
| 1010049 | The entered password is not valid. Enter a password that fulfills the following criteria: 8-40 characters, 2 upper case characters, 2 lower case characters, 2 numerical characters, 2 special characters and must not contain white spaces. |
| 1010054 | The entered password is not valid. Enter a password that fulfills the following criteria: 8-40 characters, 2 upper case characters, 2 lower case characters, 2 numerical characters, 2 special characters and must not contain white spaces. |
| 1010055 | A specified {0} name is a reserved name. Select a different name. |
| 1010056 | The {0} name must not contain leading and/or trailing white spaces. |
| 1010057 | The password must not contain white spaces. |
| 1010058 | The entered file name is invalid. File name must be less than 248 characters. |
| 1110012 | Signature not found. |

Abbreviations and File Extensions

Abbreviations

Note: Further information can be found in "Glossary," page 336.

| | |
|----------|--|
| APS | Assay Parameter Set |
| AUDAS | Automatic Data Scan |
| CAL | Calibrator |
| CFR | Code of Federal Regulations |
| CLIA | Clinical Laboratory Improvement Amendments |
| COC | Cut-off control |
| Ct | Cycle threshold |
| EC- | Negative extraction control |
| EC+ | Positive extraction control |
| FDA | Food and Drug Administration |
| 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 | Correlation coefficient |
| QS | Quantitation standard |
| S | Test sample |
| UDT mode | User Defined Test mode of operation |

File extensions

- *.iap Rotor-Gene AssayManager v2.1 Assay Profile file
- *.irp Rotor-Gene AssayManager v2.1 report file
- *.iwl Rotor-Gene AssayManager v2.1 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
- *.rgam All data of one Rotor-Gene AssayManager v2.1 experiment.

Glossary

A B C D E F G I K L M N O P Q R S T U V W

Control-click on a letter to jump to the topics starting with the corresponding letter.

A

| | |
|---------------------|---|
| Acquisition | Acquisition is the collection of fluorescent data during a PCR run. Each acquisition step is related to a certain channel and a certain cycling step. |
| Administrator | User role which has the permissions to configure the software, add and delete assay profiles, report profiles, and to manage cyclers and users. |
| Amplification plot | Plot showing one or more amplification curves. |
| Analysis | See "PCR analysis". |
| Analysis parameters | Parameters to define the different analysis steps (e.g., fluorescence thresholds, allowed ranges of C_T values). |
| Anomaly | Deviation from an ideal amplification curve (e.g., peaks, baseline dips, or rising/decreasing plateaus). |
| Application | Used here as a synonym for Rotor-Gene AssayManager v2.1. |
| Approval (approve) | The process by which the approver accepts or rejects sample results. After approval of a sample result, it can be released so that the related information can be printed into a report or submitted to a LIMS. |
| Approver | User role which gives the user the right to approve and release sample results in Closed mode or in UDT mode. |
| APS | See "Assay Parameter Set". |


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|---------------------------|---|
| Archive (noun) | Part of the experiment repository that contains experiments with completely released sample results. |
| Assay | <p>General molecular biology test (term used here for real-time PCR assays).</p> <p>In the context of the Rotor-Gene AssayManager v2.1 software the term "assay" defines the collection of all samples (including external controls) and their corresponding sample results that are related to one assay performed in one run.</p> |
| Assay and sample analysis | Analysis step that contains various rule based checks to create the final results for each sample by incorporating all targets (including the internal control and the external controls). |
| Assay developer | Role for a developer that gives the user the right to develop assay profiles with the assay profile editor. Users can only develop assay profiles in UDT mode. Closed mode assays are developed and validated by QIAGEN. |
| Assay Parameter Set (APS) | File from QIASymphony. The combination of an Assay Definition with additional parameters defined (e.g., number of replicates and assay standards). In Integrated run mode, it is also connected to the Assay Control Set. |
| Assay profile | Consists of general information, e.g., about cycling compatibility, structural information about targets and samples, a run profile, and an analysis profile. |
| Assay profile editor | Environment in the UDT mode of Rotor-Gene AssayManager v2.1 to support the assay developer to create an assay profile. |
| Assay status | The assay status describes whether run and analysis were successful or failed. Reasons for failed can be "run failed", "run stopped", or "assay invalid" (according to failed analysis rules). |
| AUDAS | See "Automatic Data Scan (AUDAS)". |

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| 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. |

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|-------------------------------|---|
| CLIA | Clinical Laboratory Improvement Amendments. |
| CLIA compliant password rules | <p>According to CLIA, a password must contain at least:</p> <ul style="list-style-type: none"> ● 8 characters ● 2 upper case characters ● 2 lower case characters ● 2 numeric characters ● 2 special characters |
| Closed mode | In Closed mode of operation only validated QIAGEN assays can be processed. The user does not have permission to modify the assay profile. |
| Computer | In Rotor-Gene AssayManager v2.1 the term “computer” is used for a notebook or a PC, not a server. |
| Concentration factor | Factor to convert the calculated target concentration within an eluate (i.e., the quantitative result of the analysis) into the concentration within the original sample. The concentration factor is optional for analysis but necessary if one is interested in the target concentration within the sample. |
| Conversion factor | Factor to convert the calculated target concentration from the default unit to another unit. |
| Core analysis | This term describes a part of the analysis comprising the normalization, C_T value calculation, and (for quantitative assays) the quantification. This analysis is identical to the analysis used by the Rotor-Gene Q software. |
| Core application | The Rotor-Gene AssayManager v2.1 software consists of different components working together. The core application is complemented by different plug-ins that contain assay type-specific, analysis-specific options. The core application is mandatory for working with Rotor-Gene AssayManager v2.1. At least one plug-in must be installed. |

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| Ct | 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 (Ct) | Fractional cycle at which a curve reaches a predefined normalized fluorescence threshold. (May be written as C_T .) |
| Cycler | See "Rotor-Gene Q MDx Cycler". |
| Cycler verification | General term for a maintenance method to check whether the device works properly. |

D

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|--------------|---|
| 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

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| EC- | Sample type (external controls): Negative extraction control. |
| EC+ | Sample type (external controls): Positive extraction control. |
| Eluate | Purified nucleic acids from a sample. |

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| Environment | The Rotor-Gene AssayManager v2.1 software consists of several environments (Setup, Approval, Archive, Service, Configuration and Cycler). In these environments, certain tasks can be performed, such as setting up a run. |
| Error | See "System error". |
| Experiment | The process composed of a PCR run and a PCR analysis yielding test results. |
| Experiment data | All data that are collected during an experiment: 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 v2.1 to an external destination. |
| External controls | Collection of standards and controls (such as the quantitation standard, the negative control or the positive control) defined by an individual assay profile. External controls are always located in other tubes than the test samples of the assay. |
| External control result | Assay-dependent final test outcome of an external control summarizing all corresponding target results. |
| External source/external destination | Location outside of the Rotor-Gene AssayManager v2.1 software. |

F

FDA Food and Drug Administration is an agency of the United States Department of Health and Human Services responsible for the safety regulation of most types of foods, dietary supplements, drugs, vaccines, biological medical products, blood products, medical devices, radiation-emitting devices, veterinary products and cosmetics.

FDA CFR Title 21 Part 11 FDA CFR Title 21 Part 11 regulations define the criteria for considering electronic records and electronic signatures to be trustworthy, reliable, and equivalent to paper records. Part 11 requires drug makers, medical device manufacturers, biotech companies, biologics developers and other FDA-regulated industries (with some specific exceptions) to implement controls, including audits, system validations, audit trails, electronic signatures and documentation for software and systems involved in processing many forms of data as part of business operations and product development.

Flag Annotation that may occur during the run or the analysis. There are 2 types of flags: Warning flags are just extra information while invalid flags set the corresponding target to invalid.

G

Gain The Rotor-Gene Q MDx 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.

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|-----------------------|---|
| Global settings | Global settings are stored in the database and affect all clients using this database. These settings can be configured in the Configuration environment. |
| GUI | Graphical User Interface. |
| I | |
| *.iap | File extension for a Rotor-Gene AssayManager v2.1 Assay Profile. |
| IC | See "Internal control". |
| Import | The process of transferring any kind of data from an external source into Rotor-Gene AssayManager v2.1. |
| Internal control (IC) | A standard reaction that is run simultaneously with the sample within the same tube and detected by a certain acquisition. It is used to verify that the PCR process was successfully performed and has not been inhibited. Technically, the IC is one of the targets of an assay and is present in the test sample tubes as well as in the external control tubes. In some assays the internal control is located in a different tube than the test, for example, for SYBR® Green assays where only one color channel can be detected. In such cases the "internal" control can be tested with the same sample but in a separate tube. |
| Invalid sample | Sample flagged as "invalid". If a sample is invalid, all its targets are invalid. |
| *.irp | File extension for a Rotor-Gene AssayManager v2.1 report profile. |
| *.iwl | File extension for a Rotor-Gene AssayManager v2.1 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 v2.1, a kit contains all reagents to perform a PCR run with eluates. PCR kits can contain master mix components, positive and negative controls, etc.

Kit bar code See "QIAGEN kit bar code".

Kit information A kit is labeled with, among others, the following information: material number, lot number, and expiration date.

L

LIMS Laboratory Information Management System. If configured, Rotor-Gene AssayManager v2.1 exports results in a file to be read by a LIMS.

Local settings Local settings are stored on the local computer and affect no other clients using the same database (in comparison to the global settings). These settings can be configured in the **Configuration** environment.

Lock (verb) Make the application inaccessible for other users without logging out. Started runs are neither interrupted nor impacted if a user logs out, another user starts a new session, or if the application is locked (automatically or manually).

Locking ring Locking rings are metal rings that fit onto the rotor to prevent tubes and caps from coming loose during operation of the Rotor-Gene Q MDx. 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". See "User Defined Test mode (UDT mode)". |
| Mode of operation | See "Closed mode". See "User Defined Test mode (UDT mode)". |
| Multiplex assay | Multiplex assays are multi-target assays that simultaneously test multiple targets in single tubes by using different primers and probes. The probes are labeled with specific dyes which anneal to the different target sequences. The detection is performed by different color channels. However, internal controls, which are technically targets as well, are typically not regarded in this context. |
| Multi-target assay | General term for an assay that can detect more than one target in parallel. Thereby, internal controls, which are technically targets as well, are typically not regarded in this context. The multiple targets can be independent or interdependent or a combination of both. Multi-target assays can be either multiplex assays, multi-tube assays, or a combination of both. |
| Multi-tube assay | Multi-tube assays are multi-target assays that simultaneously test multiple targets in more than one tube. Before the PCR process, the sample to be tested is split and distributed over the different tubes. |

N

| | |
|---------------|---|
| Normalization | In this context, normalization is an analysis step used for curve preprocessing prior to Ct value calculation and the quantitation. It includes typically a smoothing of the curves and a removal of the background noise by subtracting the baselines. |
| NTC | No template control. |

O

| | |
|-----------------------|--|
| Operator | User role with the rights to perform a PCR run and to view the results (not allowed to approve). |
| Optical configuration | The optical configuration of a Rotor-Gene Q MDx cyclers is described by the available excitation diodes that excite the fluorescence and the emission filters letting pass the emitted light. The optical configuration differs between different types of the Rotor-Gene Q MDx. 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 MDx cyclers and calibrates the cyclers 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 v2.1. |

P

| | |
|--------------|--|
| PC | Sample type (external controls): Positive control. |
| PCR | Polymerase chain reaction. |
| PCR analysis | Processing of the raw PCR data, for example, by applying AUDAS, normalization, Ct value calculation, quantification and assay and sample analysis algorithms to obtain a quantitative or qualitative result. |
| PCR run | PCR process performed in a thermocycler (e.g., the Rotor-Gene Q MDx). In this context, PCR is always a real-time PCR. |

| | |
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| Plug-in | A plug-in allows Rotor-Gene AssayManager v2.1 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 | Correlation coefficient: The correlation coefficient is a statistical parameter to measure the fit of the data points to the regressed line. In general, the standard curve should have an R^2 value ≥ 0.990 . The individual limit for the R^2 value can be defined in the assay profile. |
| Raw curve | Unprocessed fluorescence data measured in one tube on one channel by the cycler in a series of an assay-specific number of cycles. |
| Raw data | Collection of unprocessed amplification curves. |
| Reaction volume | Volume of liquid in the PCR tubes. |
| Real-time PCR | PCR with real-time monitoring of the reaction products. |
| Regression line | In this context, a regression line is a linear function derived from a regression analysis between the C_T values and given concentrations of quantitation standards. It is also known as the standard curve. See “Standard curve”. |
| Release | The process of publishing previously approved sample results by generating a report and optionally transferring the data to a LIMS. |
| Release status | The release status is the status of an assay that can be “not released”, “partially released” and “fully released” where “fully released” means that all sample results contained in the assay have been released. |
| Renewal interval | Days until a password must be renewed. |

| | |
|-------------------------|---|
| Replicate | See "Sample replicate". |
| Report | Summary of selected sample results (external control results are always included) of one assay as a secure *.pdf-file, which cannot be manipulated. |
| Report profile | Profile describing which information shall be included in the report. |
| *.ret | File extension for a Rotor-Gene Q MDx 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 MDx experiment file format used by the Rotor-Gene Q software. It can be imported for testing an assay profile in the Development environment of the UDT mode. |
| *.rgam | Contains all data of one Rotor-Gene AssayManager v2.1 experiment. |
| Role | User rights are summarized in a certain role: Administrator, Approver, Operator, Assay Developer and Super User are available. |
| Rotor | The metal rotor holds tubes or Rotor-Discs® in the Rotor-Gene Q MDx. 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-Gene Q MDx cycler | The real-time PCR cycler supported by Rotor-Gene AssayManager v2.1. |
| Rotor-Gene Q software | Software to control the Rotor-Gene Q MDx cycler and to analyze the acquired data depending on assay being used. |
| 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 | 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 over several tubes to do the same test in parallel to estimate 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 environments. |
| System error | Technical errors (e.g., process errors, software malfunctions, cyclers errors) that are not acceptable. User interaction is required. Note: Do not confuse with invalid results. |
| T | |
| Target | Specific DNA sequence (or RNA before reverse transcription step) to be amplified during the PCR. |
| Target result | The result of the analysis of one target for one specific sample. |
| Test | Synonym of assay. |
| Test sample | Unknown sample to be tested with an assay. |
| Test sample result | Assay-dependent final test outcome of an assay for one test sample summarizing all corresponding target results. |

Threshold Predefined fluorescence value used to calculate the cycle threshold (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 (UDT mode)".

Upstream process From the PCR point of view, the upstream process consists of the sampling, the sample disruption, the purification, and the assay setup.

Upstream status Status which is set by QIASymphony system. It can be "valid", "unclear", or "invalid". If it is "invalid" or if Rotor-Gene AssayManager v2.1 is configured in a way that "unclear" samples are processed as if they are "invalid", a special invalid flag is set. Sample results are not provided for samples with an "invalid" upstream status. Not applicable for FDA cleared or approved nucleic acid tests.

User Defined Test mode (UDT mode) This is the mode of operation for assays that are created and validated by a user of Rotor-Gene AssayManager v2.1 software.

User role See "Role".

V

Validation error An error that occurs due to a missing or invalid user input. User interaction is required.

Verification See "Cycler verification".

W

| | |
|-----------|---|
| Warning | A situation could be optimized by further input. User interaction is possible, but not mandatory. |
| 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. |

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The following section lists the license texts displayed during installation. These texts are also available in the Rotor-Gene AssayManager v2.1 software.

QIAGEN's Rotor-Gene AssayManager v2.1

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- delay,
- compensation due to defect,
- compensation for wasted expenses.

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Microsoft .NET Framework 4

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NHibernate

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Revision History

| Revision | Description |
|-------------|--|
| R2, 05/2019 | <p data-bbox="373 476 1145 534">Updated the following parts for the new Rotor-Gene AssayManager 2.1.1 version:</p> <ul data-bbox="373 555 1145 895" style="list-style-type: none"><li data-bbox="373 555 927 578">● Added support and descriptions for Windows 10<li data-bbox="373 600 1145 678">● Added prerequisites for the installation of Rotor-Gene AssayManager on Windows 10 systems<li data-bbox="373 700 895 723">● Added creation of Windows 10 user accounts<li data-bbox="373 744 1102 823">● Updated and extended description of recommended virus scanner settings<li data-bbox="373 844 1145 902">● Added information on Windows system updates via QIAGEN system updater |

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