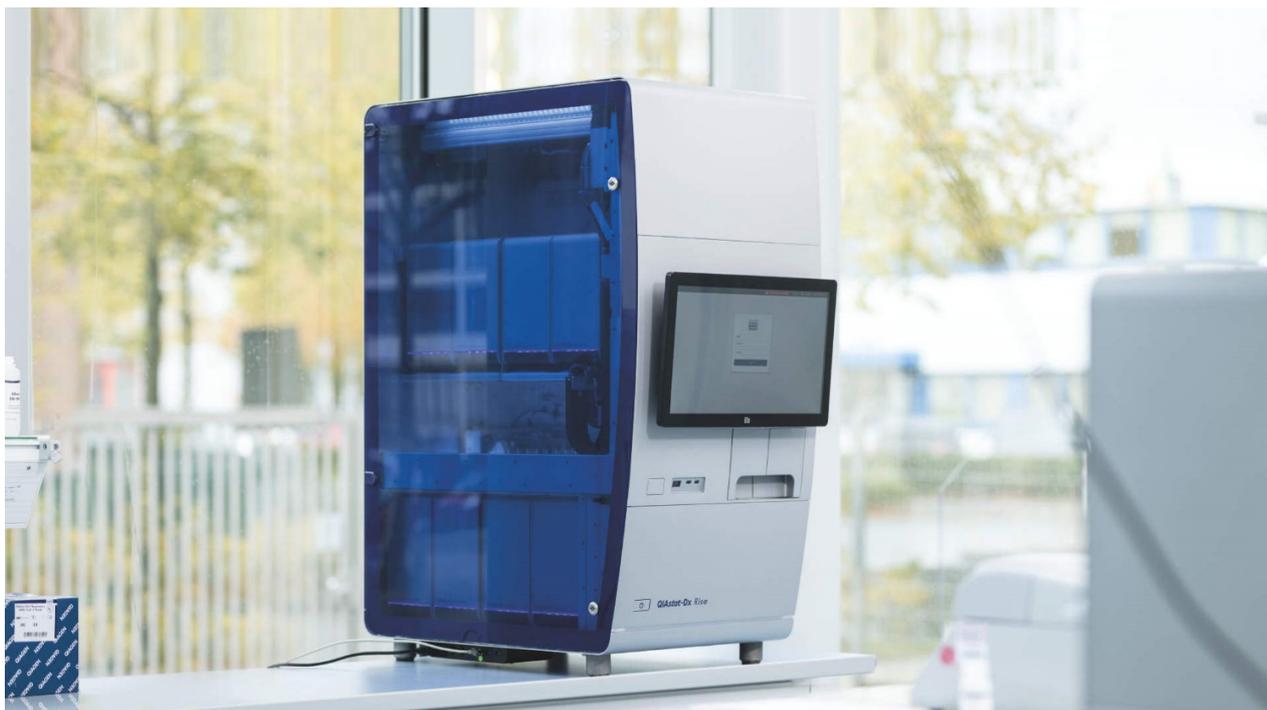


QIAstat-Dx[®] Rise[™] User Manual

For use with software version 2.4



IVD

For in vitro diagnostic use only



REF

9003163



QIAGEN, GmbH, QIAGEN Strasse 1, 40724 Hilden, GERMANY

MAT

R4

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1. Introduction

Thank you for choosing the QIAstat-Dx Rise. We are confident that this system will become an integral part of your laboratory.

This manual describes how to operate the QIAstat-Dx Rise with software version 2.4. Before using the QIAstat-Dx Rise, it is essential to read this user manual carefully and pay particular attention to the safety information. The instructions and safety information in the user manual must be followed to ensure safe operation of the instrument and to maintain it in a safe condition.

Note: The figures of the software screens shown in this user manual are only examples and may differ from assay to assay.

1.1. About this user manual

This user manual provides information about the QIAstat-Dx Rise in the following sections:

- Introduction
- Safety Information
- General Description
- Installation Procedures
- Running a Test and Viewing Results
- Operating Procedures
- HIS/LIS Connectivity
- Maintenance
- Troubleshooting
- Technical Specifications
- Appendices
- Document Revision History

The appendices contain the following information:

- License Terms
- License agreements of third-party software
- Waste Electrical and Electronic Equipment (WEEE)
- Appendix A
- Glossary
- Ordering information

1.2. General information

1.2.1. Technical assistance

At QIAGEN®, we pride ourselves on the quality and availability of our technical support. Our Technical Services Departments are staffed by experienced scientists with extensive practical and theoretical expertise in molecular biology and the use of QIAGEN products. If you have any questions or experience any difficulties regarding the QIAstat-Dx Rise or QIAGEN products in general, do not hesitate to contact us.

QIAGEN customers are a major source of information regarding advanced or specialized uses of our products. This information is helpful to other scientists as well as to the researchers at QIAGEN. We therefore encourage you to contact us if you have any suggestions about product performance or new applications and techniques.

For technical assistance, contact QIAGEN Technical Services.

Website: support.qiagen.com

When contacting QIAGEN Technical Services about errors, please have the following information ready:

- QIAstat-Dx Rise serial number as provided on the instrument type plate
- Support package
- Error code (if applicable)
- Timepoint when the error occurred for the first time
- Frequency of error occurrence (i.e., intermittent or persistent error)

1.2.2. 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.

1.3. Intended use of the QIAstat-Dx Rise

The QIAstat-Dx Rise system is intended as an in-vitro diagnostic device for use with QIAstat-Dx assays and provides full automation from sample preparation to real-time PCR detection for molecular applications. The system is designed for professional use only and it is not a device for self-testing or near-patient testing.

1.3.1. Limitations of use

- The QIAstat-Dx Rise can only be used in combination with at least two QIAstat-Dx Analytical Modules (AM) processing QIAstat-Dx assay cartridges according to the instructions contained in this user manual and in the QIAstat-Dx assay instructions for use.
- When connecting the QIAstat-Dx Rise, use only the cables supplied with the system.
- Any service or repairs should be performed only by personnel authorized by QIAGEN.
- The QIAstat-Dx Rise should only be operated on a flat, horizontal surface that withstands at least 300 kg with no angles or tilts
- Do not re-run a QIAstat-Dx assay cartridge if it has already been used successfully, or if it has been associated with an error or an incomplete run.
- Allow the following minimum clearance to ensure adequate ventilation:
 - **Left side:** 90 cm
 - **Top:** 32 cm
 - **Front:** 150 cm
- The QIAstat-Dx Rise can be used in the following environmental conditions:
 - **Temperature:** 15–27°C
 - **Relative humidity:** 20–80%
 - **Altitude:** maximum 2200 m above sea level
- Make sure that the QIAstat-Dx Rise is positioned away from any air conditioning outlets or heat exchangers.
- Do not change the system configuration during a run.
- Do not use the touchscreen to lift or move the QIAstat-Dx Rise.
- Do not lean on the drawers, the display, or the door to avoid tilting of the instrument.
- User must check if all the samples are loaded to AMs after confirming the run.

1.3.2. Requirements for QIAstat-Dx Rise

Table 1 covers the general level of competence and training necessary for transportation, installation, use, maintenance, and servicing of the QIAstat-Dx Rise.

Table 1. Level of expertise required to perform tasks

Task	Personnel	Training and experience
Delivery	Carrier	Professional carrier, experienced with transportation of heavy equipment
Installation	QIAGEN field service specialists only	Trained and authorized by QIAGEN
Routine use and maintenance	Laboratory technicians or equivalent	Appropriately trained and experienced personnel familiar with use of computers and automation in general
Servicing and annual maintenance	QIAGEN field service specialists only	Trained and authorized by QIAGEN

1.4. Materials provided

- Power cord
- Door key

Note: Only use accessories supplied by QIAGEN.

1.5. Materials required but not provided

- Ethernet cable
- USB storage device (USB 3.0 with 64 GB memory capacity and exFAT file system format and 64 GB memory capacity is recommended)

2. Safety Information

Before using the QIAstat-Dx Rise, it is essential that you read this user manual carefully and pay particular attention to the safety information. The instructions and safety information in the user manual must be followed to ensure safe operation of the instrument and to maintain the instrument in a safe condition.

The following types of safety information appear throughout the *QIAstat-Dx Rise User Manual*.

WARNING The term **WARNING** is used to inform you about situations that could result in personal injury to you or others.



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 an instrument** or other equipment.



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

Note The term **Note** is used for information that explains or clarifies a specific case or task.

Important The term **Important** is used to highlight information that is critical for the completion of a task or optimal performance of the system.

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

Please be aware that you may be required to consult your local regulations for reporting serious incidents that have occurred in relation to the device to the manufacturer and/or its authorized representative and the regulatory authority in which the user and/or the patient is established.

2.1. Proper use

Perform the maintenance as described in Section 8 Maintenance. QIAGEN charges for repairs that are required due to incorrect maintenance.

WARNING **Risk of personal injury and material damage**



The QIAstat-Dx Rise is too heavy to be lifted by one person. To avoid personal injury or damage to the instrument, do not lift the instrument alone. Contact QIAGEN Technical Services to relocate the instrument.

WARNING **Risk of personal injury and material damage**



Improper use of the QIAstat-Dx Rise may cause personal injuries or damage to the instrument. The QIAstat-Dx Rise must only be operated by qualified personnel who have been appropriately trained. Servicing of the QIAstat-Dx Rise must only be performed by a QIAGEN field service specialist.

WARNING **Risk of personal injury and material damage**



Do not attempt to move the QIAstat-Dx Rise during operation.

WARNING Risk of personal injury and material damage



Do not lean on the drawers of the QIAstat-Dx Rise. This may cause tilting of the instrument.

CAUTION Damage to the instrument



Avoid spilling water or chemicals onto the QIAstat-Dx Rise. Instrument damage caused by water or chemical spillage will void your warranty.

CAUTION Risk of material damage



Do not place any items on top of the instrument.

In case of emergency, power **OFF** the QIAstat-Dx Rise using the power switch at the rear connection box on the left side of the instrument.

Note: This will shut down the instrument immediately and result in sample and data loss. Sample and data loss can result from power failures as well.

CAUTION Damage to the instrument



Only use QIAstat-Dx cartridges as described in the respective assay handbook with the QIAstat-Dx Rise. Damage caused by use of other types of consumables will void your warranty.

CAUTION Risk of material damage



Do not place the QIAstat-Dx Rise close to prototype instruments. Effects like electromagnetic emissions, vibration, and heat may cause the instrument to fail, resulting in damage or data or material loss.

WARNING Explosive atmosphere



The QIAstat-Dx Rise is not designed for use in an explosive atmosphere.

CAUTION Interference with direct sunlight



Direct sunlight may interfere with optical modules inside the instrument. The QIAstat-Dx Rise must not be placed in direct sunlight.

2.2. Electrical safety

Disconnect the line power cord from the power outlet 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.

WARNING **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.

CAUTION **Damage to electronics**



Before powering ON the instrument, make sure that the correct supply voltage is used.

Use of incorrect supply voltage may damage the electronics.

To check the recommended supply voltage, refer to the specifications indicated in the type plate of the instrument.

WARNING **Risk of electric shock**



Do not open the instrument cover or any service flap on the QIAstat-Dx Rise.

WARNING **Risk of personal injury and material damage**



Only perform maintenance that is specifically described in this user manual.

To ensure satisfactory and safe operation of the QIAstat-Dx Rise, follow the advice below:

- The line power cord must be connected to a line power outlet that has a protective conductor (earth/ground).
- Place instrument in a location so that the power cord is accessible and can be connected/disconnected.
- Use only the power cord delivered by QIAGEN.
- 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.

2.3. Biological safety

The QIAstat-Dx Rise, Analytical Modules, and cartridges do not themselves contain biohazardous materials. However, samples and reagents containing materials from biological sources should generally be handled and disposed of as potentially biohazardous. Use safe laboratory procedures as outlined in publications such as *Biosafety in Microbiological and Biomedical Laboratories*, from the Centers for Disease Control and Prevention and the National Institutes of Health.

Samples tested on the QIAstat-Dx Rise may contain infectious agents. Users 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. Wear personal protective equipment and disposable powder-free gloves when handling reagents or samples and wash hands thoroughly thereafter.

Avoid contamination of the QIAstat-Dx Rise and workspace by handling samples and QIAstat-Dx assay cartridges with care. In the event of contamination (e.g., a leak from a cartridge), clean and decontaminate the affected area and the instrument as described in Section 8.3.

WARNING Biological hazard



Use caution when loading or removing QIAstat-Dx assay cartridges containing infectious samples into or from the QIAstat-Dx Rise. A break in the cartridge could contaminate the QIAstat-Dx Rise and the surrounding area.

All QIAstat-Dx assay cartridges should always be handled as if they contain potentially infectious agents.

CAUTION Risk of contamination



Contain and clean contamination from a broken or visibly damaged QIAstat-Dx assay cartridge immediately. Contents, though not infectious, can be spread by normal activity and may contaminate further analytical results, leading to false positives.

For instructions on cleaning and decontaminating the QIAstat-Dx Rise, refer to the respective sections in this user manual.

Always observe safety precautions as outlined in relevant guidelines, such as the Clinical and Laboratory Standards Institute® (CLSI) *Protection of Laboratory Workers from Occupationally Acquired Infections, Approved Guidelines (M29)*, or other appropriate documents provided by:

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

2.4. Chemicals

Used QIAstat-Dx assay cartridges and plasticware may contain hazardous chemicals or infectious agents. Such waste must be collected and disposed of properly in accordance with all national, state, and local health and safety regulations and laws.

For disposal of waste electrical and electronic equipment (WEEE), see Appendix A.

WARNING **Hazardous chemicals**



Chemicals may leak from the cartridge in the event that the cartridge housing is damaged. Some chemicals used in QIAstat-Dx assay cartridges may be hazardous or may become hazardous. Always wear eye protection, gloves, and a lab coat.

CAUTION **Damage to the instrument**



Avoid spilling water or chemicals onto the QIAstat-Dx Rise. Instrument damage caused by water or chemical spillage will void your warranty.

2.5. Waste disposal

Used QIAstat-Dx assay cartridges and plasticware may contain hazardous chemicals or infectious agents. Such waste must be collected and disposed of properly in accordance with all national, state, and local health and safety regulations and laws.

Waste drawer must be checked regularly for spilled liquids and cleaned as described in the Section 8 Maintenance.

For more information about how to dispose of the QIAstat-Dx Rise, see “Waste Electrical and Electronic Equipment (WEEE)”.

WARNING **Hazardous chemicals and infectious agents**



The waste contains samples and reagents. This waste may contain toxic or infectious material and must be disposed of properly. Refer to your local safety regulations for proper disposal procedures.

2.6. Mechanical hazards

The side door of the QIAstat-Dx Rise must remain closed during operation of the instrument. Only handle the input and waste drawer when they have been released by the system. Ensure to only operate the system with both the input and the waste tray inserted into their respective drawer positions.

WARNING Biological hazard



To avoid contact with moving parts during operation of the QIAstat-Dx Rise, the instrument must be operated with the door closed. Only open the side door when instructed by the instrument. In the unlikely event that manual recovery of the instrument is required, carefully follow the instructions provided on the graphical user interface of the instrument.

If the door sensor is not functioning correctly, contact QIAGEN Technical Services.

WARNING Closing drawers



To avoid jamming operators' finger between drawer and display, use only the handles to close the waste and input drawers.

WARNING Risk of overheating



To ensure proper ventilation, maintain the following minimum clearance:

- **Left side:** 90 cm
- **Top:** 32 cm
- **Front:** 150 cm

Slits and openings that ensure the ventilation of the QIAstat-Dx Rise must not be covered.

2.7. Electromagnetic safety information (Electromagnetic compatibility; EMC)

CAUTION Risk of data and material loss



Electromagnetic (EM) disturbances might cause the instrument or the Analytical Module (AM) to fail resulting in data loss and/or loss of the sample.

CAUTION Electromagnetic interference



Do not place or use the QIAstat-Dx Rise in close proximity of sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), as these can interfere with proper operation.

CAUTION Risk of data and material loss



Do not expose the instrument to strong magnetic fields.

Magnetic fields can affect the unit by triggering the sensors on the drawers or the side door without cause, thus stopping the robotic handler's movements. This may trigger sample and data loss. However, operator safety is not affected.

CAUTION Risk of data and material loss



Do not use any other power cable than the one supplied with the instrument. In case of damage or loss contact QIAGEN service for a replacement.

Other cables might negatively affect the electromagnetic compatibility (EMC) performance of the instrument.

CAUTION Risk of data and material loss



Do not use portable radio frequency communications equipment (including antennas) closer than 30 cm (12 in.) to any part of the QIAstat-Dx Rise – including cables specified by QIAGEN.

CAUTION Risk of electromagnetic emission



QIAstat-Dx Rise uses (radiofrequency) (RF) energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

CAUTION Risk of electromagnetic emission



QIAstat-Dx Rise suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

CAUTION Risk of electromagnetic immunity



Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

CAUTION Risk of electromagnetic immunity



The signal lines (e.g., Ethernet) must not be longer than 30 m in order to avoid impairments due to surge voltages.

CAUTION Risk of electromagnetic immunity



If the user of QIAstat-Dx Rise requires continued operation during power mains interruptions, it is recommended that the product is powered from an un-interruptible power supply or a battery. UT is the a. c. mains voltage prior to application of the test level.

CAUTION Risk of electromagnetic immunity



Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

2.8. Maintenance safety

WARNING Risk of personal injury and material damage



Only perform maintenance that is specifically described in this user manual.

WARNING Risk of fire



When cleaning the QIAstat-Dx Rise with alcohol-based disinfectant, leave the QIAstat-Dx Rise door open to allow flammable vapors to disperse. For the plastic door, use only distilled water and mild detergents without alcohol.

CAUTION Damage to the instrument



Do not use bleach, solvents, or reagents containing acids, alkalis, or abrasives to clean the QIAstat-Dx Rise.

2.9. Data security

Note: It is strongly recommended to create a support package and archive it according to your organization's policy for the availability of data and the protection of data from loss. The support package contains the database and can be restored by a QIAGEN Service Technician in the event of data loss on the QIAstat-Dx Rise instrument. For creation of a support package refer to Section 5.9 Creating a support package.

USB storage devices should preferably be used for short term data storage and general data transfer (e.g., saving support package and test results, file imports).

Note: The use of a USB storage device is subject to restrictions (e.g., the memory capacity or the risk of overwriting, which should be considered before usage.) It is recommended to use USB 3.0 with 64 GB memory capacity and exFAT file system format to decrease the transfer time of files to and from the storage device.

For long-term data security, follow your organization's data storage and security policies for credential retention.

2.10. Cybersecurity

It is highly recommended to follow the cybersecurity recommendations listed below when using the QIAstat-Dx Rise:

- Operate the QIAstat-Dx Rise in a secured environment and secured network.
- The support package contains a database backup. Extract the support package in regular intervals and keep them at a secure, ideally offline storage. For information on how to create a support package, refer to Section 5.9.
- Always ensure that you use a malware-free USB storage device.
- Use personal user accounts for the QIAstat-Dx Rise and follow the principle of least privileges (Assigning an account to a user according to their work profile). For more information about User management, refer to Section User management.
- Follow the policy of your organization regarding setting-up complex passwords and the frequency when they are changed.
- Always log out when you leave the QIAstat-Dx Rise unattended. For more information on logging out, refer to Section 6.2.2.
- Do not use freely editable fields to enter personal information or protected health information.
- Events related to Cybersecurity are recorded in the System Log.
- In case you suspect that your QIAstat-Dx Rise security may have been compromised, please immediately inform your IT or Cybersecurity department and follow local guidance. Such guidance may vary greatly, depending on local priorities and could include disconnecting the device from the network, shutting down the device, or leaving the device untouched and getting a local response team to investigate. In addition, please inform your QIAGEN Technical Service representative as soon as possible for further guidance and support.

Patches for the QIAstat-Dx Rise are part of the regular system update. They contain updates and vulnerability remediation for the application software and the underlying operating system. These updates undergo the established verification and validation process according to QIAGEN's global quality management system.

Customers are informed when updates, including cybersecurity patches, are available. System updates will be provided and installed by QIAGEN Technical Services.

In addition, *QIAstat-Dx Rise Security and Privacy Guide* will help you safely and securely install, configure, operate, and maintain your instrument in compliance with data protection regulations. The *QIAstat-Dx Rise Security and Privacy Guide* is available on www.qiagen.com.

2.11. Symbols on the QIAstat-Dx Rise

Symbol	Location	Description
	Type plate on the instrument	Mechanical hazard – avoid contact with moving parts.
	Type plate on the instrument	WEEE about the disposal of waste electrical and electronic equipment for Europe and rest of the world.
	Type plate on the instrument	Legal manufacturer.
	Type plate on the instrument	Consult instructions for use
	Type plate on the instrument	CE mark for Europe
	Type plate on the instrument	RCM (former C-Tick) for Australia (supplier identification N17965)
	Type plate on the instrument	Instrument serial number
	Type plate on the instrument	In vitro diagnostic medical device
	Type plate on the instrument	TÜV mark of the TÜV SÜD Product Service for testing
	Type plate on the instrument	Unique Device Identifier
	Type plate on the instrument	Date of manufacturing
	Type plate on the instrument	Catalog number

3. General Description

3.1. System description

The QIAstat-Dx Rise is a diagnostic system leveraging molecular capabilities based on fluorescence techniques providing clinical results.

It works only in combination with QIAstat-Dx assay cartridges and uses real-time PCR to detect pathogen nucleic acids in human biological samples. The QIAstat-Dx Rise and cartridges are designed as a closed system that enables hands-off sample preparation followed by detection and identification of pathogen nucleic acids. Samples are inserted into a QIAstat-Dx assay cartridge that contains all reagents necessary to isolate and amplify nucleic acids from the sample. Detected real-time amplification signals are interpreted by the integrated software and are reported via an intuitive user interface.

3.2. QIAstat-Dx Rise description

The QIAstat-Dx Rise is a regular bench-top usage increased throughput system that incorporates up to 8 QIAstat-Dx Analytical Modules on a small footprint and is designed to process up to 128 cartridges/day (may vary depending on the assay type). The instrument allows queuing of up to 18 cartridges scheduled for processing and loaded into an AM by an integrated robotic handler.

The QIAstat-Dx Rise includes the following elements:

- Touchscreen for user interaction
- Barcode reader for sample and QIAstat-Dx assay cartridge identification
- USB ports for assay and system upgrades
- Input drawer for inserting QIAstat-Dx assay cartridges into the QIAstat-Dx Rise
- Waste drawer for wasting QIAstat-Dx assay cartridges after ejected from an Analytical Module (AM)
- Module Ethernet connector for network connectivity

3.3. QIAstat-Dx Rise workflow

After the cartridge is prepared (sample is loaded and a unique sample ID barcode is applied) and loaded into the input drawer, the system calculates the queue. Next, the queue is confirmed by the user and the QIAstat-Dx Rise automatically performs the following steps:

- Scanning of the cartridge in the scan station
- Picking up the cartridge from the input tray and loading it into the Analytical Module (AM) via a robotic handler
- Processing the cartridge in the AM
- Removal of the cartridge from the AM and transferring it to the waste drawer via robotic handler when the test is completed
- Providing a test result

During the run, users can open the input drawer and load new cartridges for continuous loading.

3.4. QIAstat-Dx Rise assay cartridge description

The QIAstat-Dx assay cartridge is a disposable plastic device that allows performance of fully automated molecular assays. The main features of the QIAstat-Dx assay cartridge include compatibility with various sample types (e.g., fluids or swabs) and hermetic containment of all preloaded reagents necessary for testing and true walk-away operation. All sample preparation and assay testing steps are performed within the QIAstat-Dx assay cartridge as described in the respective assay handbook.

All reagents required for the complete execution of a test run are pre-loaded and self-contained in the QIAstat-Dx assay cartridge. The user does not need to come in contact with and/or manipulate any reagents. During the test, reagents are handled in the Analytical Module (AM) by pneumatically operated microfluidics and make no direct contact with the QIAstat-Dx Rise.

The QIAstat-Dx Rise houses air filters for incoming air, further safeguarding the environment. After testing, the QIAstat-Dx assay cartridge stays hermetically closed at all times, greatly enhancing its safe disposal.

Within the QIAstat-Dx assay cartridge, multiple steps are automatically performed in sequence using pneumatic pressure to transfer samples and fluids via the transfer chamber to their intended destinations. After the QIAstat-Dx assay cartridge is introduced into the QIAstat-Dx Rise, the following assay steps occur automatically:

Execution of the protocol, including:

- Resuspension of internal control
- Cell lysis using mechanical and/or chemical means
- Membrane-based nucleic acid purification
- Mixing of the purified nucleic acid with lyophilized master mix reagents
- Transfer of defined aliquots of eluate/master mix to different reaction chambers
- Performance of real-time, multiplex PCR testing within each reaction chamber. An increase in fluorescence, indicating presence of the target analyte, is detected directly within each reaction chamber.

The general layout of the cartridge and its features are illustrated in QIAstat-Dx assay cartridge features.. This is only a general description of the cartridge, please refer to the respective assay instructions for use for a detailed description of functions and how to prepare and load the samples.

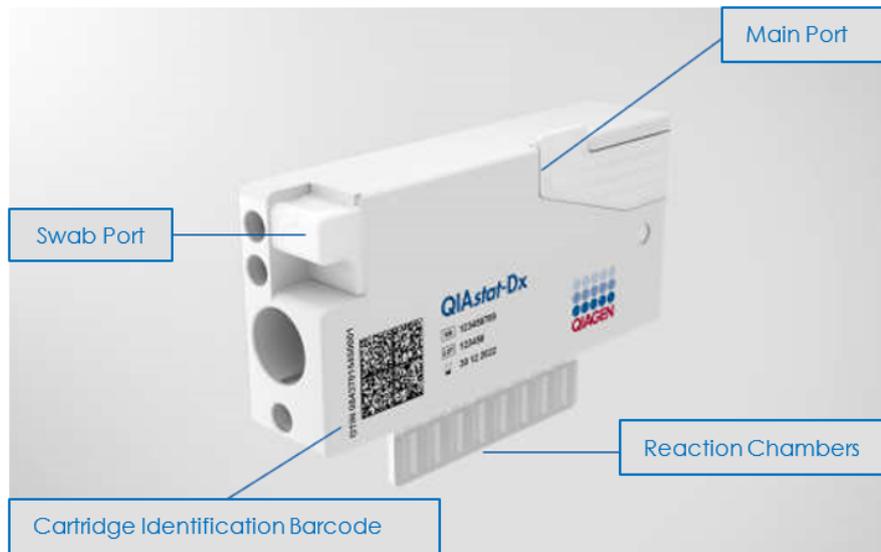


Figure 1. QIAstat-Dx assay cartridge features.

3.5. QIAstat-Dx application software

The QIAstat-Dx application software (SW) is pre-installed on the system. This manual describes the software version 2.4 only.

It implements three main groups of functionalities:

- General operation functions allow easy setup, execution, and visualization of a test and its associated results
- Configuration functions allow configuration of the system (user management, HIS/LIS settings, and hardware/software configuration management)
- Test execution control to perform necessary automated analytical steps that comprise a test execution

3.6. External features of the QIAstat-Dx

Instrument view:



Figure 2. QIAstat-Dx Rise features.

- | | | | |
|---|--------------------|---|----------------------|
| 1 | Upper service flap | 5 | Lower service flap |
| 2 | Display | 6 | LED status indicator |
| 3 | Input drawer | 7 | Side door |
| 4 | Waste drawer | | |

Rear connection box:

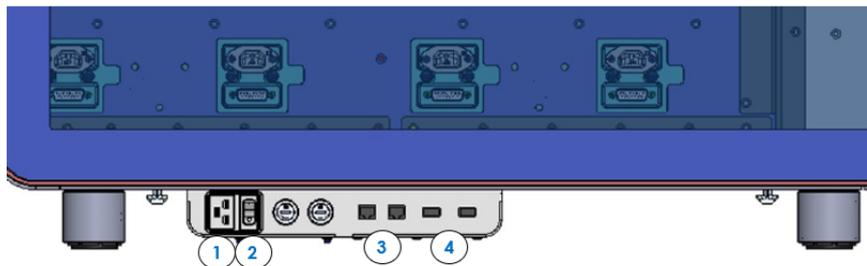


Figure 3. QIAstat-Dx Rise rear connection box.

- | | | | |
|---|---------------------------|---|--------------------|
| 1 | Connection to power cable | 3 | Two ethernet ports |
| 2 | Power switch | 4 | Two USB ports |

3.7. Internal features of the QIAstat-Dx Rise

Internal view:

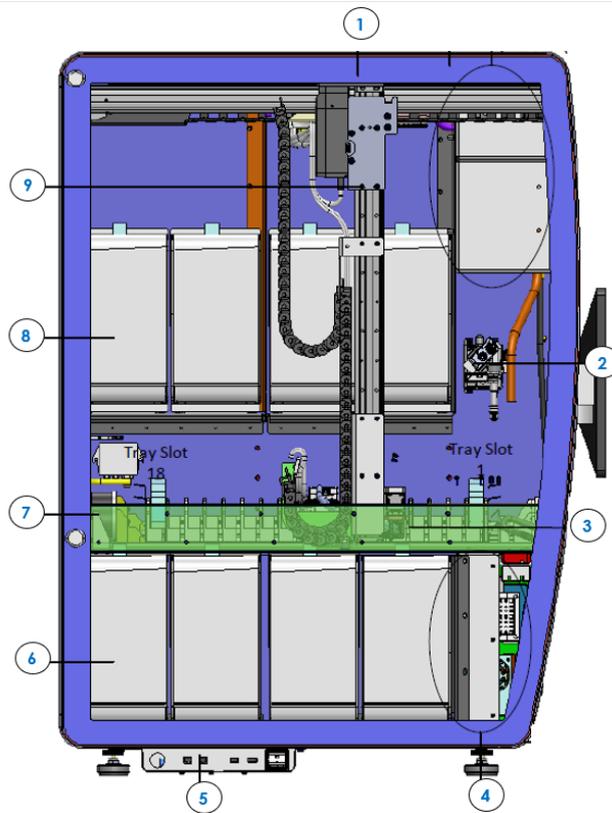


Figure 4. Internal view of the QIAstat-Dx Rise.

- | | | | |
|---|--------------------------|---|---------------------------------------|
| 1 | Main fan | 6 | Analytical Module (AM in position 4) |
| 2 | Scan station | 7 | Input and waste drawer magnetic locks |
| 3 | Input and waste drawer | 8 | Analytical Module (AM in position 8) |
| 4 | Lower electronic cabinet | 9 | Robotic arm |
| 5 | Side connection box | | |

4. Installation Procedures

4.1. System delivery and installation

The unpacking and installation of the QIAstat-Dx Rise is performed by a certified QIAGEN field service specialist. A person who is familiar with your laboratory and computer equipment should be present during the installation.

The following items are delivered:

- QIAstat-Dx Rise
- QIAstat-Dx Rise software (will be installed by QIAGEN field service specialist during initial set up)

An ethernet cable is required to connect the QIAstat-Dx Rise to your local network (not provided). Up to 8 Analytical Modules (AM) are required to operate the QIAstat-Dx Rise (not provided).

4.2. Site requirements

Select a flat, dry, and clean workbench space for the QIAstat-Dx Rise. Make sure that the space is free of excessive drafts, moisture, and dust, as well as protected from direct sunlight, large temperature fluctuations, heat sources, vibration, and electrical interference.

Note: The QIAstat-Dx Rise is heavy. The total weight including eight Analytical Modules (AM) is approximately 260 kg. Please ensure that the workbench supports at least 300 kg. Refer to Section 10.1 for the weight and dimensions of the QIAstat-Dx Rise and the correct operating conditions (temperature and humidity). The QIAstat-Dx Rise should have sufficient clearance on all sides to enable proper ventilation and to allow unimpeded access to the input and the waste drawer, the side of the QIAstat-Dx Rise, the power switch at the side connection box, the ON/OFF button at the front, the barcode reader, the Analytical Modules, and the touchscreen. The side door must be opened in a 90-degree angle for installation and troubleshooting purposes.

Note: Space of 1.5 m is required for installation, service interventions, and troubleshooting in front of the instrument and the left side of the instrument.

For more details regarding the site requirements and safety information, refer to Section 2 Safety Information.

4.3. Unpacking and installing the QIAstat-Dx Rise

Unpacking and installation of the QIAstat-Dx Rise shall only be performed by a qualified QIAGEN field service engineer. Do not install the system on your own.

4.3.1. Software upgrade

If necessary, software updates will be done during the installation procedure. Contact QIAGEN Technical Services at support.qiagen.com for future software updates.

4.4. Repacking and shipping the QIAstat-Dx Rise

Repacking of the QIAstat-Dx Rise shall only be performed by a qualified QIAGEN field service engineer. Do not repack the system on your own.

When repacking the QIAstat-Dx Rise for shipping, the original packaging materials must be used. If the original packaging materials are not available, contact QIAGEN Technical Services.

Make sure that the instrument has been properly prepared prior to packing and that it poses no biological or chemical hazard. For more information, refer to Section 8 on page 76 Maintenance.

5. Running a Test and Viewing Results

Note: The figures shown in this user manual are only examples and may differ from assay to assay.

5.1. Starting the QIAstat-Dx Rise

1. First make sure the power switch at the side connection box of the instrument must be set in the "I" position (Figure 3). Then press the **ON/OFF** button on the front of the QIAstat-Dx Rise to start the unit (Figure 5).



Figure 5. ON/OFF button on the QIAstat-Dx Rise.

Important: Please note that you must restart the instrument once a week.

2. After successful initial installation of the QIAstat-Dx Rise, the system administrator needs to create a password for the default administrator (Figure 6).

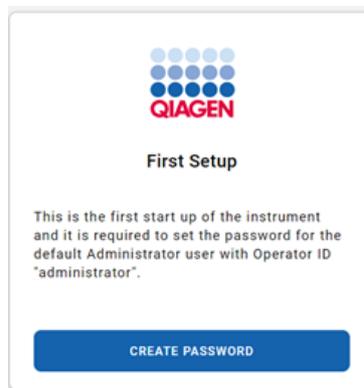


Figure 6. First Setup screen.

Press the **CREATE PASSWORD** button on the upper right of the screen and create a password according to the password requirements shown in Figure 7. The password can be changed after log-in as described in Section 6.3.6.

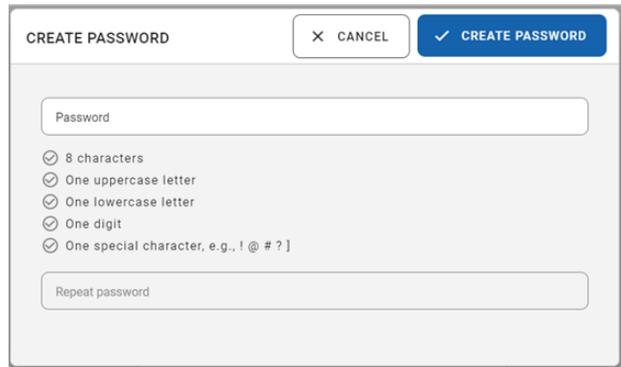


Figure 7. Create password screen.

Note: The password for the operator ID “administrator” must not be forgotten.

Note: Follow your organization’s cybersecurity policies for credential custody.

Note: It is recommended to use a strong password following your organization’s password policies.

Important: Do not use the “+” symbol when creating a password, in particular not for the Administrator role. Using a “+” symbol will block the user from accessing the system or changing the password.

Note: All users shall log out before leaving the device unattended.

3. After creating the password, log in to the system once the LOGIN screen appears (Figure 8).

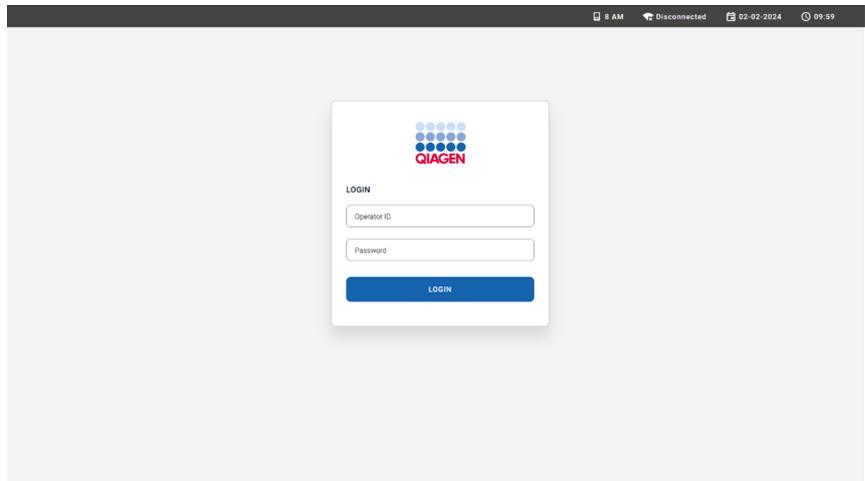


Figure 8. Log in screen.

5.2. Preparing the QIAstat-Dx assay cartridge

Remove the QIAstat-Dx assay cartridge from its packaging. For details about adding the sample to the QIAstat-Dx assay cartridge and for information specific to the assay to be run, refer to the instructions for use for the specific assay.

Always make sure that both sample lids are firmly closed after adding a sample to the QIAstat-Dx assay cartridge.

Important: Follow the assay instructions for the maximum time allowed before the cartridge is loaded to the QIAstat-Dx Rise instrument.

5.2.1. Adding a sample barcode to the QIAstat-Dx cartridge

Place a barcode on the top right side of the QIAstat-Dx cartridge indicated by the arrow (Figure 9).



Figure 9. Placing sample ID barcode.

Important: To process samples on the QIAstat-Dx Rise, it is required to provide a machine-readable sample ID barcode on the QIAstat-Dx cartridge. The sample ID barcode should not contain any special characters or non-ASCII symbols. The maximum barcode size is 22 mm x 35 mm.

Important: The barcode must always be on the right side of the cartridge when looking at it from the side of the label (as it is shown below with blue marked area). The barcode label must not be placed beyond 35 mm from the right side of the cartridge (Figure 10).

Important: Please keep the left side of the cartridge clear in order not to inhibit sample autodetection.

Important: Do not use the same sample ID for different sample type and assay type otherwise the system may not process the sample correctly.



Figure 10. Positioning sample ID barcode.

For QIAstat-Dx Rise, 1D and 2D barcodes can be used. Usable 1D barcodes are the following: EAN-13 and EAN-8, UPC-A and UPC-E, Code128, Code39, Code 93, and Codabar. Usable 2D barcodes are Aztec Code, Data Matrix, and QR code.

Make sure that the barcode quality is sufficient. The system is capable of reading a printing quality of grade C or better, as defined in ISO/IEC 15416 (linear) or ISO/IEC 15415 (2D).

If the system reports barcode scanning errors (e.g., sample ID is not readable), ensure that the barcode position and size are correct and improve the quality of the barcode.

5.3. Procedure to run a test

All operators should wear appropriate personal protective equipment, such as gloves, lab coat, and protective glasses when handling the QIAstat-Dx Rise touchscreen and cartridges.

To run a test, start the instrument, log in and wait for initialization to complete.

When initialization is complete, please check the following:

- The QIAstat-Dx Rise is correctly initialized.
- All installed Analytical Modules (AM) are operational.
- The connectivity is available.
- The HIS/LIS Settings are available.
- Assay Definition File (ADF) is available.
- Check if time and date settings are correct.
- Check if patient ID is activated (If the use of patient ID is preferred, it must be enabled in the **SETTINGS** menu. Go to **SETTINGS > General Settings > TEST SETTINGS > Require Patient ID** and tap on **EDIT** select **Require Patient ID** and press the **SAVE** button (see Section 6.3.2 General settings).

To run a test, follow the steps below:

1. Press the **OPEN WASTE DRAWER** button at the lower right corner of the main test screen (Figure 11) and remove used cartridges from previous runs. Check the waste drawer for spilled liquids. If necessary, clean the waste drawer as described in Section 8 Maintenance.
2. Close the waste drawer. The system will scan the tray and return to the main screen. If the waste tray was removed for maintenance purposes, make sure it is correctly inserted before closing the drawer.
3. Press the **OPEN INPUT DRAWER** button at the lower right corner of the main test screen (Figure 11).

Note: The **OPEN INPUT DRAWER** button is only active when the system is initialized and there is at least one available AM.

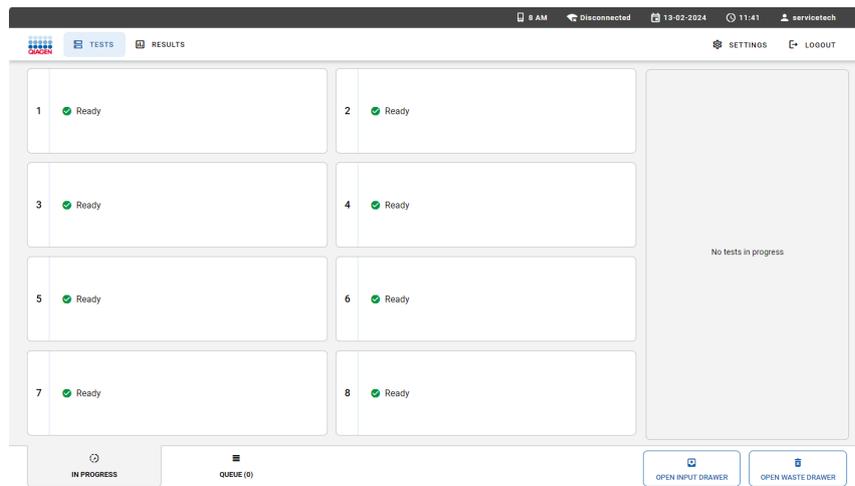


Figure 11. Main test screen.

4. Wait until the input drawer is unlocked (Figure 12).

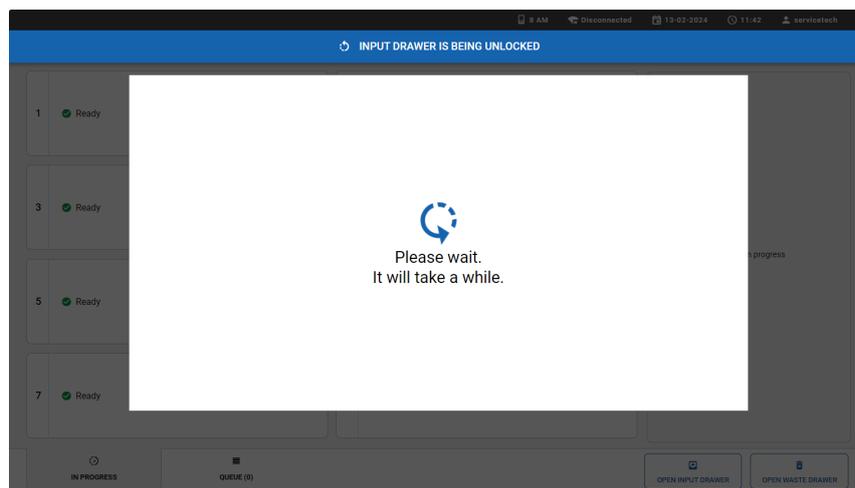


Figure 12. Input drawer waiting dialog.

- When prompted, pull the input drawer to open (Figure 13). Depending on instrument status it can take a moment for the drawer to unlock. Note that the input drawer will be automatically locked, if no interaction is performed.

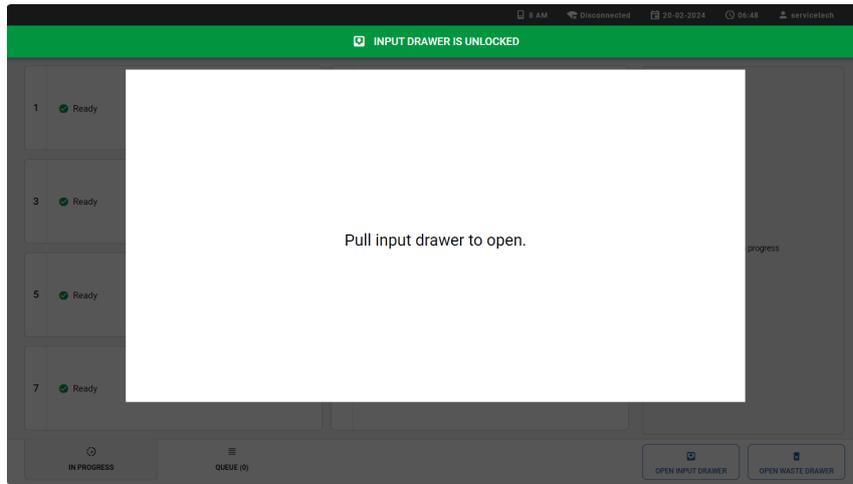


Figure 13. Input drawer open dialog.

Starting with the cartridge loading step, the test setup in QIAstat-Dx Rise may differ depending on the HIS/LIS connection status and the **Test Orders** and **Force Orders** functionality of the HIS/LIS connection (Table 2). The details of the HIS/LIS settings can be found in Section 7 HIS/LIS Connectivity. For more information on **Test Orders** and **Force Orders** functionality refer to Section 7.3 Querying test orders from HIS/LIS .

In case the QIAstat-Dx Rise instrument is not connected to the HIS/LIS system, it is recommended to enter the data to run the test manually, following the manual test setup (Section 5.3.1 Manual test setup).

When the QIAstat-Dx Rise instrument is connected to the HIS/LIS system and both Test Orders and Force Orders are enabled, the data to run the test will always be queried automatically (“LIS orders enforced” section). Samples where no order is available in HIS/LIS cannot be processed in this setup.

If the QIAstat-Dx Rise instrument is connected to the HIS/LIS system and **Test Orders** is enabled, **Force Orders** is disabled, the data to run the test can be either entered manually or can be queried automatically from HIS/LIS (“LIS orders optional” section). Samples without test order that are loaded without manual data entry will undergo full scan by the system before the queue is confirmed.

Table 2. Test setup options

HIS/LIS connection	Test orders	Force orders	Test setup	Reference section
No	n/a	n/a	Manual Test setup	Manual test setup
Yes	Disabled	Disabled	Manual Test setup	Manual test setup
Yes	Enabled	Enabled	Test setup with HIS/LIS connection	LIS orders enforced
Yes	Enabled	Disabled	Test setup with HIS/LIS connection	LIS orders optional

5.3.1. Manual test setup

If the QIAstat-Dx Rise is not connected to your HIS/LIS system, the test order data must be entered manually. To do so, please scan the sample ID barcode and the cartridge ID barcode and enter the relevant test data as described below.

1. The Add cartridge dialog appears and the scanner at the front will be activated. Scan the sample ID barcode attached to the top of the QIAstat-Dx assay cartridge (position is indicated by the arrow) (Figure 14).

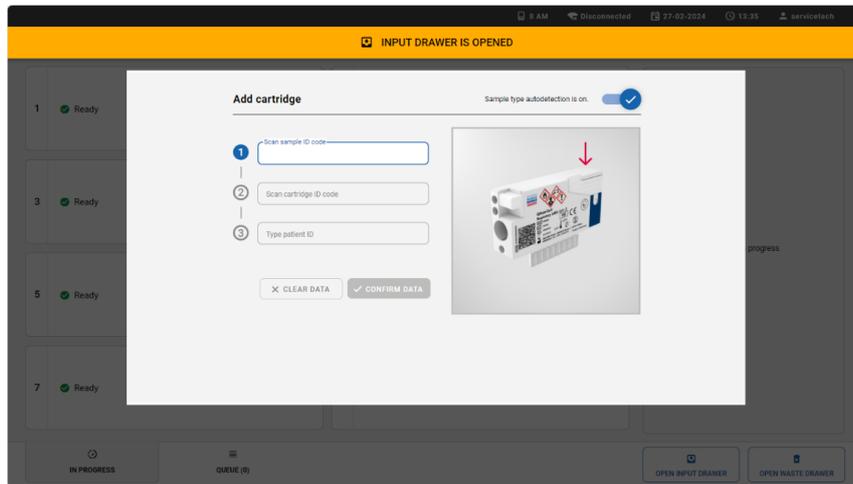


Figure 14. Scan sample ID screen.

2. Scan the cartridge ID barcode. The QIAstat-Dx Rise automatically recognizes the assay to be run, based on the QIAstat-Dx assay cartridge barcode (Figure 15).

If sample type autodetection is enabled, the system will automatically recognize the sample type used. The sample type will be shown as autodetected on the test details section of the sample queue screen. If sample type autodetection is not feasible for the assay used, the sample type has to be chosen manually. If sample type autodetection is disabled, you might need to select the appropriate sample type manually. The sample type will be shown on the test details section of the sample queue screen (Figure 23).

Important: Note that there are QIAstat-Dx assays for which the QIAstat-Dx Rise cannot automatically detect the sample type. Check the respective assay handbook accordingly.

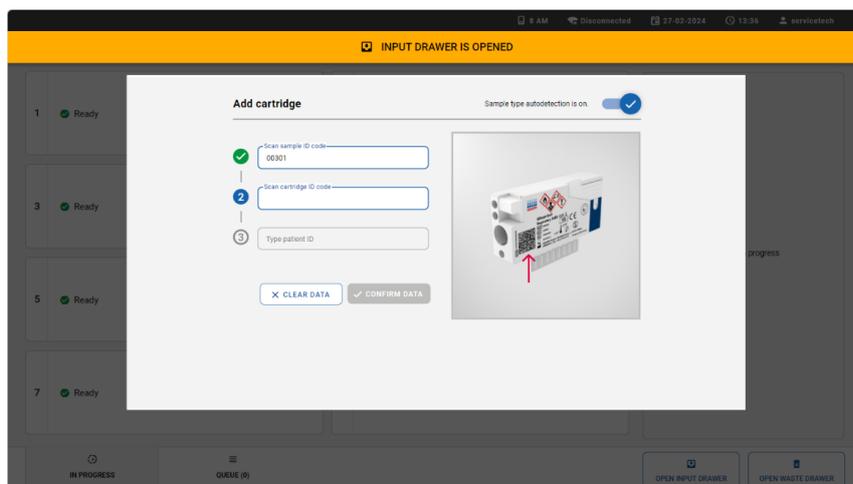


Figure 15. Scan cartridge ID screen.

Note: The QIAstat-Dx Rise will not accept QIAstat-Dx assay cartridges with lapsed expiration dates and onboard stability time, aborted cartridges, cartridges that were already used for a complete test run, or cartridges for assays that are not installed on the instrument. An error message will be shown in these cases.

3. Select the sample type for assays where sample type autodetection is not feasible or in case sample type autodetection is deselected (Figure 16).

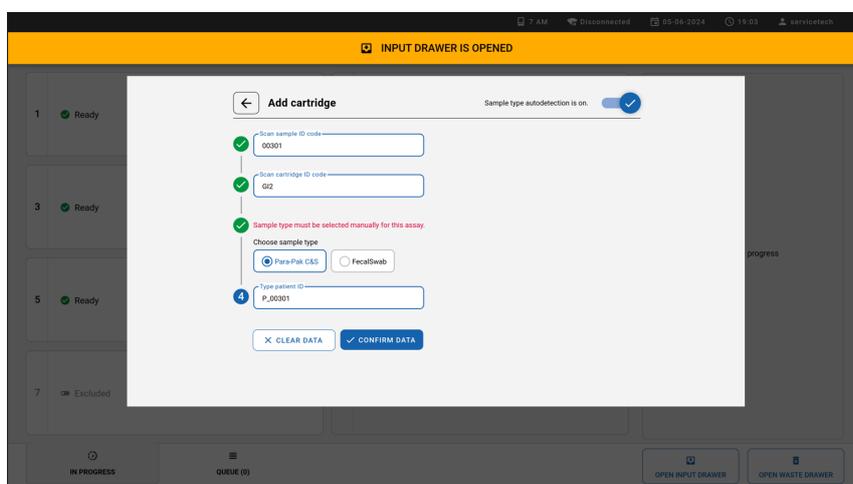


Figure 16. Select sample type screen.

4. Enter the patient ID and push the **CONFIRM DATA** button (Figure 17).

Note: To enable the use of the patient, ID refer to the Section 5.3.

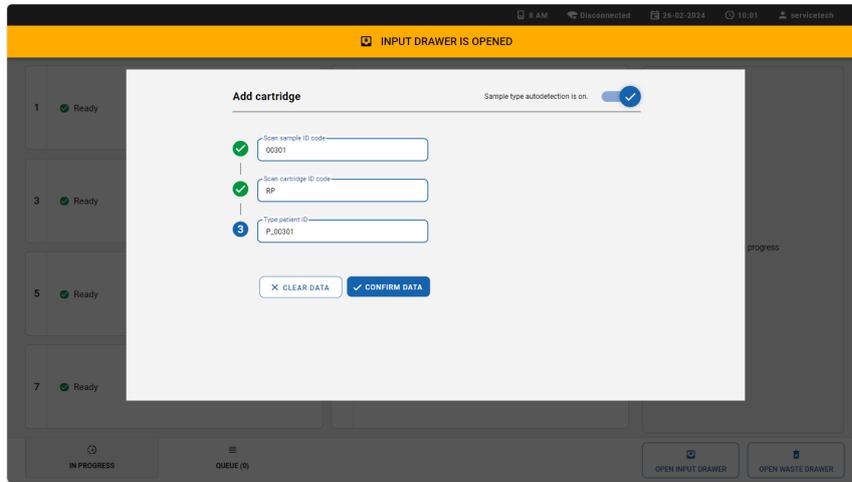


Figure 17. Type patient ID then confirm the data screen.

5. After successful data entry, the following message bar appears briefly at the top of the screen (Figure 18).

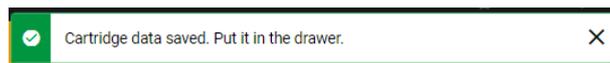


Figure 18. Cartridge saved dialog.

6. Place the cartridge into the input drawer. Make sure the cartridge is inserted properly into the tray.
7. Continue scanning and inserting cartridges following previous steps. You can load up to 18 cartridges into the drawer.
8. Close the input drawer when all cartridges have been manually scanned and inserted. The system will scan the cartridges and prepare a queue (Figure 19).

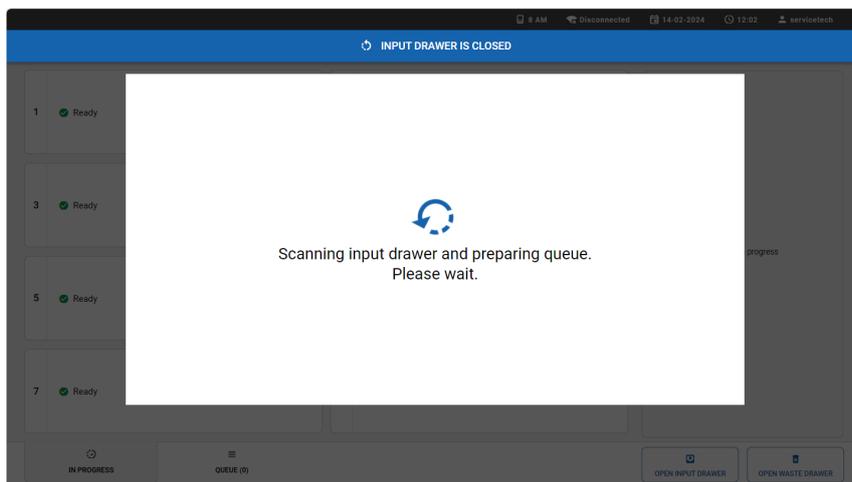


Figure 19. Preparing queue screen.

9. Continue with reviewing the test queue in Section 5.3.3.

Note: It is possible to load cartridges into the input tray without scanning them beforehand. In this case, the time for the queue preparation may take up to 30 minutes depending on the number of loaded cartridges and is therefore not recommended.

5.3.2. Test setup with HIS/LIS connection

When the QIAstat-Dx Rise instrument is connected to your HIS/LIS system, the test order data can be retrieved from the HIS/LIS fully automatically. The cartridges can be loaded without manual data entry as described below.

When connected to HIS/LIS the QIAstat-Dx Rise can be operated in two modes. When **Force Orders** is enabled, the test will only be executed when a matching LIS order can be retrieved from the LIS system. When **Force Orders** is disabled, the user can enter the test data manually and run tests where no LIS order is available. For more information on Force Orders functionality refer to Section 7.3.

LIS orders enforced

When **Force Orders** is enabled, the Load Cartridge(s) dialog appears as seen below (Figure 20).

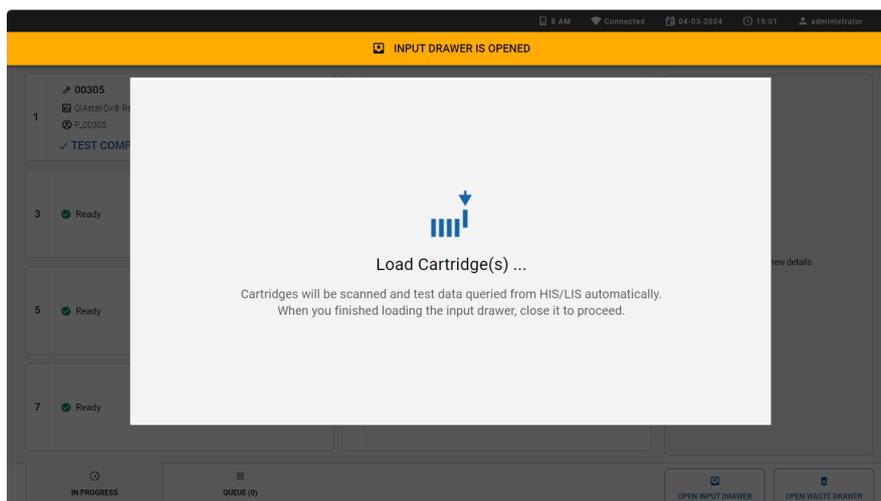


Figure 20. The load cartridge dialog when both test order and force orders are enabled.

1. Place the cartridges into the input drawer (see Section 5.2 and the respective assay handbook for correct cartridge preparation). Make sure all the cartridges are inserted properly into the tray and the sample ID barcode is placed correctly.
2. Close the input drawer. The system will scan the sample ID barcode of the cartridges and prepare a queue (Figure 22).
3. Continue with reviewing the test queue in Section 5.3.3.

Note: If Force Orders is enabled and the test order is not successfully retrieved from the LIS, the system will issue an error and not run the test. If a sample must be urgently run for which no test order is created yet, an administrator must temporarily turn off the Force Orders functionality as described in Section 7.

LIS orders optional

When Force Orders is disabled, the Load Cartridge(s) dialog appears as seen below (Figure 21).

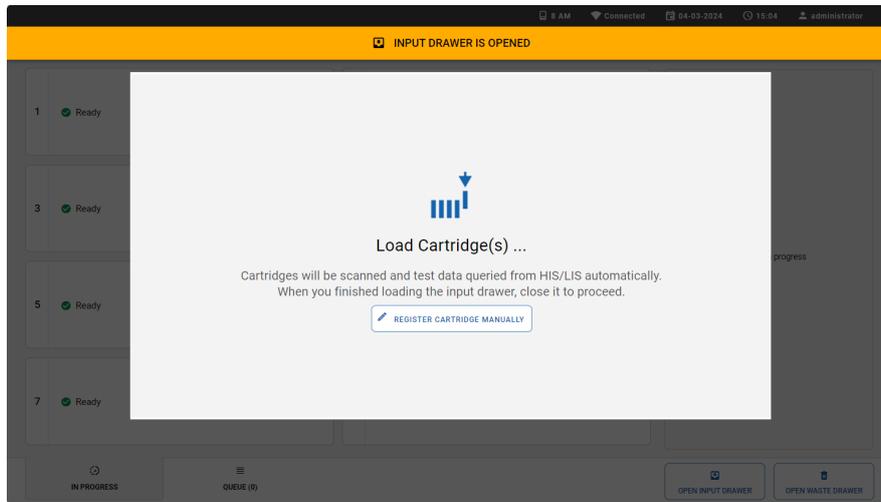


Figure 21. The load cartridge dialog when the test order functionality is enabled and force order disabled.

When a test order can be retrieved from the LIS system for a sample, the cartridge can be loaded without entering the test data manually.

1. Place the cartridges into the input drawer (see Section 5.2 and the respective assay handbook for correct cartridge preparation). Make sure all the cartridges are inserted properly into the tray.
2. Close the input drawer. The system will scan the sample ID barcode of the cartridges and prepare a queue (Figure 22).
3. Continue with reviewing the test queue in Section 5.3.3.

When no test order can be retrieved from the LIS system for a sample, the user can enter the test data manually to run the test.

1. Press the **REGISTER CARTRIDGE MANUALLY** button to switch to manual test setup.
2. Enter the test data and load the cartridges as described within Section 5.3.1.

The system can process tests that were registered manually and tests where the test order is retrieved from LIS in parallel.

Note: For samples where no test order was created in the HIS/LIS system, the manual data entry is strongly recommended. Otherwise, the time for the queue preparation may take up to 30 minutes depending on the number of loaded cartridges and is therefore not recommended.

5.3.3. Review and confirm the test queue to run

When calculated, the test queue is shown as below (Figure 22). Review the data shown in the queue. In case of an error, the respective cartridge will be moved to the waste tray after confirming the queue.

Important: If LIS orders is enabled and a cartridge was previously canceled, the onboard stability time cannot be shown correctly by the system during confirmation of the queue. The correct onboard stability time will only be shown once the cartridge is scanned in the scan station. In this case, it is required that the user tracks the onboard stability time of the sample as cartridges with exceeded onboard stability time might lead to false results.

Important: Do not change the position of a cartridge in the input drawer when re-loading cartridges (continuous loading). If LIS orders is enabled and a cartridge position is changed, the sample stability time will be reset.

Note: If LIS orders is enabled and the user removes a cartridge from the input drawer before the queue is confirmed, the time the cartridge resided in the input drawer is not considered when calculating the onboard stability time when the cartridge is reloaded into the system.

Note: Some errors cannot be detected at this stage, for example, if cartridge data are not matching with data retrieved from the HIS/LIS order. In this case and because cartridges with exceeded onboard stability might lead to false results, the system will issue an error at a later processing step and waste the cartridge at that point in time.

In either case, a detailed error message about the error can be seen in the test results.

Alternatively, the cartridge can be taken out from the input drawer. This is not recommended because the detailed error message is lost once the cartridge is taken out. It also takes longer to process cartridges when the input drawer is opened a second time before the queue confirmation.

It is possible to prioritize a sample at that point (see Section 5.5).

Note: If you need to open the input drawer during a run for any reason (e.g., to load/unload cartridges) the system will prepare the queue again. The queue needs to be confirmed again.

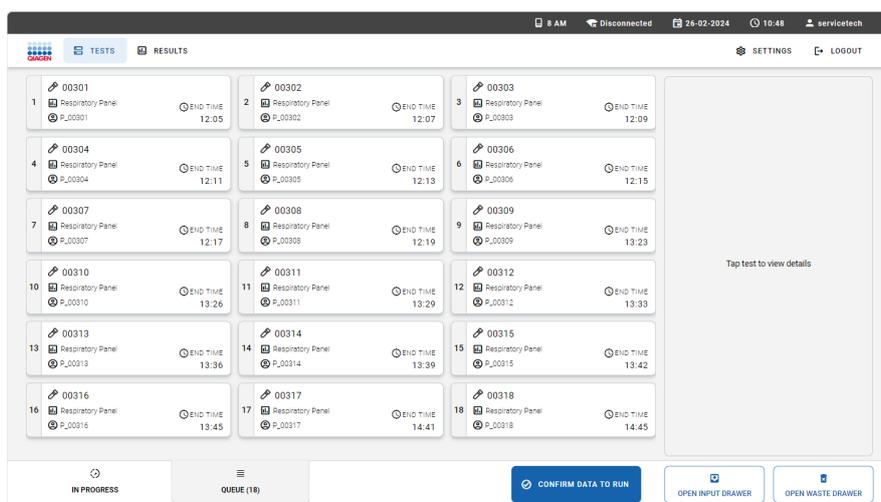


Figure 22. Sample queue screen.

Note: The sample order on the screen may not match the cartridge order in the input drawer. The sample queue/processing order is generated by QIAstat-Dx Rise based on the following rules:

- Samples marked as URGENT will be processed first.
- Stability time/onboard time: Assays with the shortest remaining stability time will be prioritized over samples with longer stability time irrespective of the position in the loading tray.
- Within the same assay type the position in the loading tray determines the order in the queue.

Note: The terms “stability time” and “onboard time” are used synonymously in this document. Please refer to the assay instructions for use for the maximum allowed stability time once the sample is loaded into the cartridge.

If you select a test on the touchscreen, additional information is displayed in the view details section of the screen (Figure 23).

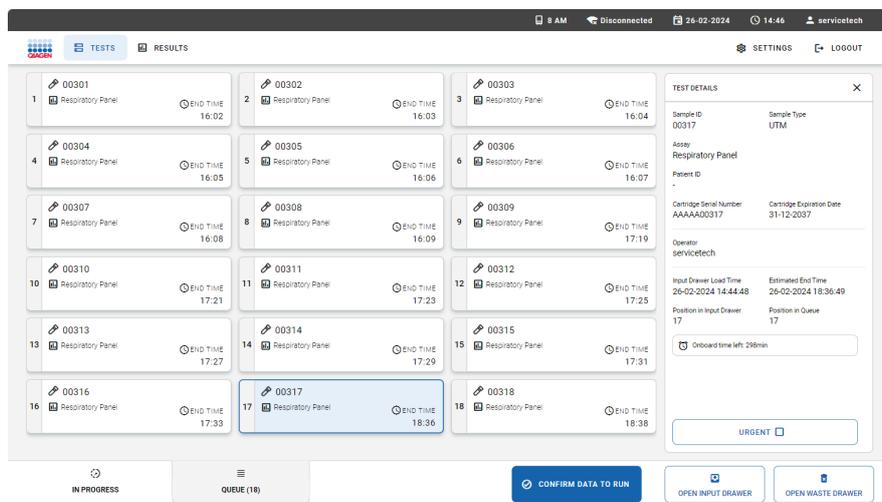


Figure 23. Sample queue screen with selected assay showing additional information.

The following information is shown in the test details section:

- Sample ID
- Sample Type (depends on assay and sample autodetection function)
- Assay
- Patient ID (if applicable)
- Cartridge Serial Number
- Cartridge Expiration Date
- Operator
- Input Drawer Load Time
- Estimated End Time
- Position in Input drawer
- Position in Queue (**Note:** the position may differ, based on sample or assay stability time/onboard time)
- Onboard time left

- **URGENT** icon for prioritization functionality
- Error messages, warnings (if applicable)

Note: In case that a cartridge was loaded using the automatic test setup (see Section 5.3.2), some of the information above (such as the cartridge serial number) may not yet be shown displayed.

Press the **CONFIRM DATA TO RUN** button on the bottom of the screen when all the displayed data are correct (Figure 23). Thereafter, one final confirmation is required from the operator to run the tests, press **RUN TEST** button. (Figure 24).



Figure 24. Confirm queue dialog.

5.4. Test execution

After the queue was confirmed the **IN PROGRESS** tab is displayed. The **IN PROGRESS** tab provides instant information about each of the eight Analytical Module (AM) and the sample being tested by each of the AM.

While the tests are running, the remaining run time and other information for all tests in process are displayed on the touchscreen (Figure 25).

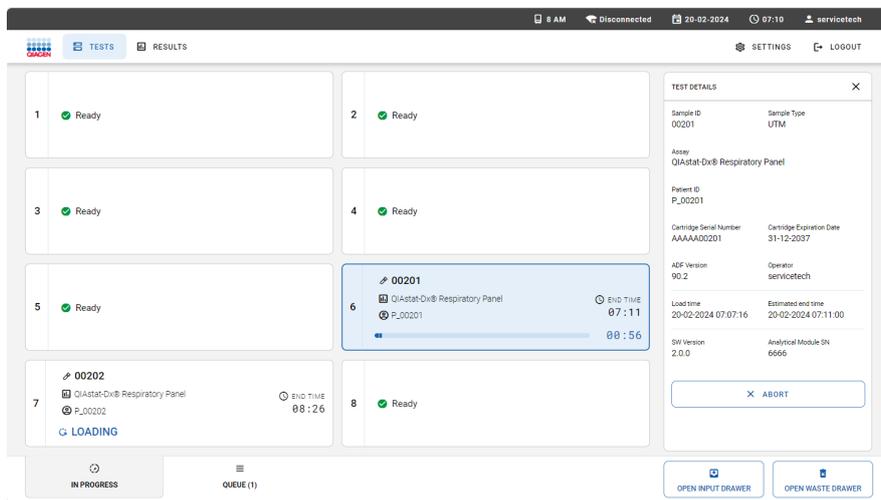


Figure 25. Test execution information on TESTS screen.

When the cartridge is scanned on the scan station the state CHECKING is displayed (Figure 26).

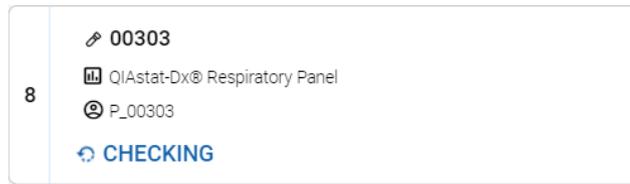


Figure 26. Cartridge checking message.

When the cartridge is being loaded into an AM, a test “LOADING” message and the estimated end time are displayed (Figure 27).

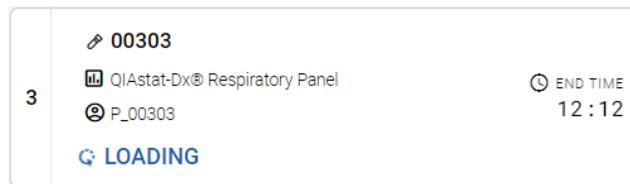


Figure 27. Test loading message and end time.

When the test is running, the elapsed run time and the approximate end time are being displayed (Figure 28).

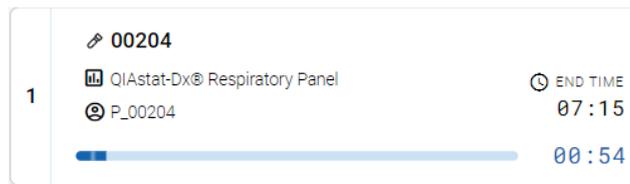


Figure 28. Elapsed run time and approximate end time view.

If the test is completed, a “TEST COMPLETED” message and the run end time is displayed (Figure 29).

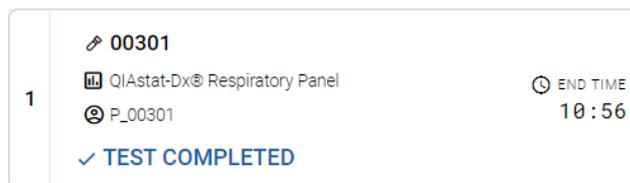


Figure 29. Test completed view.

If an error occurs during test execution the error message will be displayed instead of the “TEST COMPLETED” message.

5.5. Prioritizing samples

5.5.1. Prioritizing samples before starting the run

If one sample needs to be run urgently, it is possible to select this sample on the sample queue screen and run as a first sample. Please note that it is not possible to prioritize a sample after confirmation of the queue. If you need to prioritize a sample after the queue was confirmed, it is required to open and close the input drawer again to create a new queue and prioritize the sample prior to confirming the queue.

Note: Opening the input drawer will trigger a rescan of the cartridges in the input drawer that will take approximately the same time as the original scan.

The urgent sample is selected on the queue screen and marked urgent from right-hand side of the sample queue screen before confirm data to run (Figure 30). Following this, the sample is moved to the first position of the queue and will be processed before all other cartridges in the first available AM (Figure 31).

Note: Only one sample can be prioritized at a time.

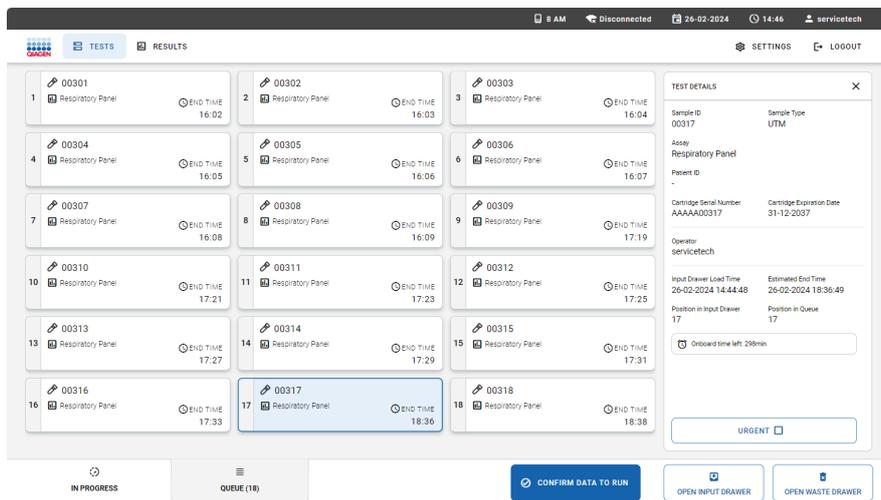


Figure 30. Sample queue screen while selecting sample to be prioritized.

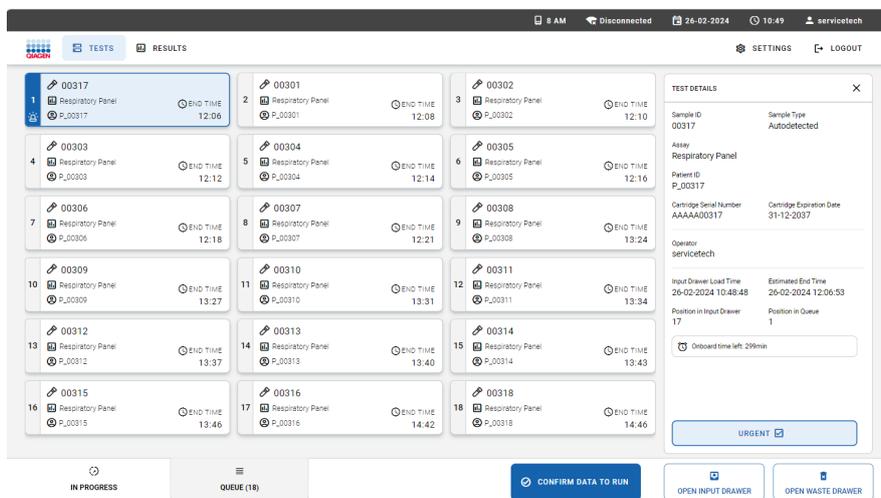


Figure 31. Sample queue screen after a sample is prioritized.

Some other samples may run out of stability time due to prioritization of a sample. The system marks samples that may run out of stability time with a red  icon and show the remaining onboard time in the TEST DETAILS area (Figure 32).

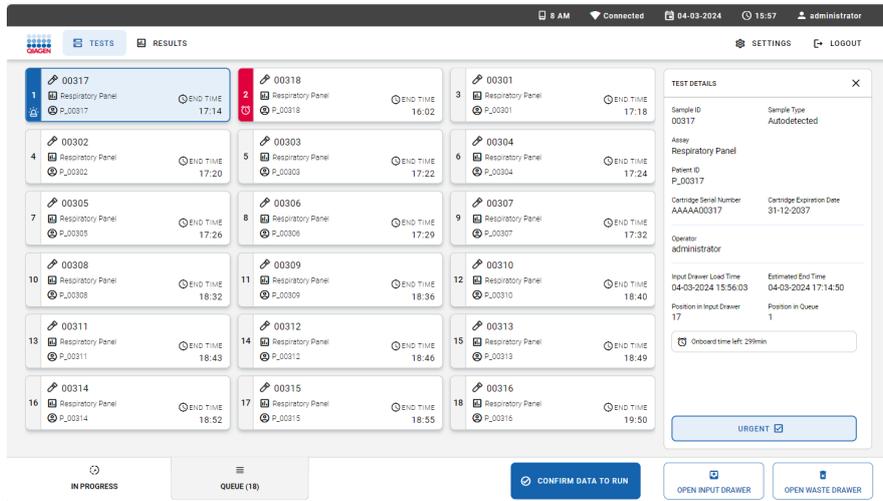


Figure 32. Sample queue screen after a sample is prioritized and one sample may run out of stability time.

After confirmation of the queue the run can be started (Figure 33).

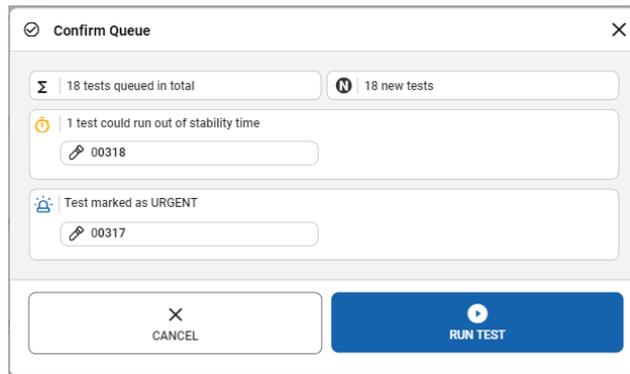


Figure 33. Confirmation of the run screen.

5.5.2. Prioritizing sample during run

If you need to prioritize a sample during the run, it is required to open and close the input drawer and prioritize the sample before confirming the queue. The **URGENT** sample will be processed in the next available Analytical Module (AM).

Note: Opening the input drawer will trigger a rescan of the cartridges in the input drawer that will take approximately the same time as the original scan.

In case the **URGENT** sample needs to be processed immediately and all Analytical Modules are executing tests, any other ongoing test needs to be aborted to start the test execution of the **URGENT** sample (Figure 34).

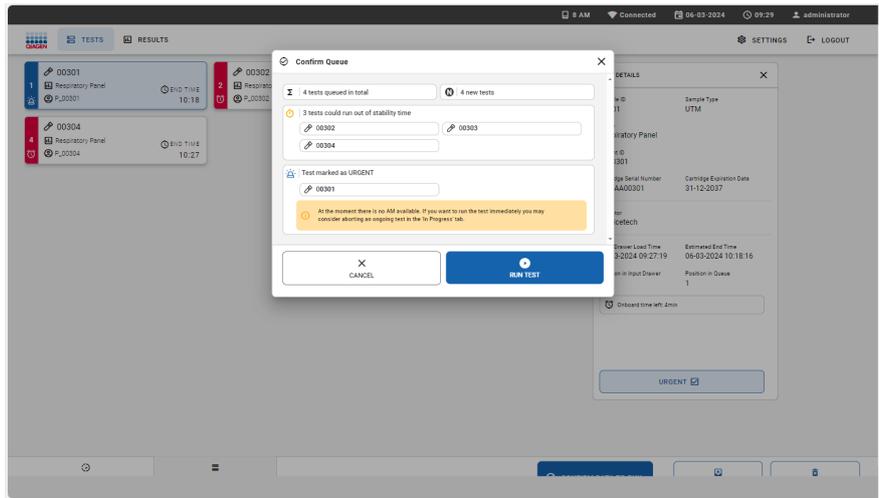


Figure 34. Confirmation when there is no available AM.

5.6. Cancellation and abortion of samples

5.6.1. Cancellation and abortion of samples by the system

Samples can be canceled or aborted by QIAstat-Dx Rise when the test run cannot be started due to an error that occurs before the cartridge is inserted into an Analytical Module.

A cancellation occurs when a sample/cartridge cannot be run due to an error that does not affect the sample. (For example, if the sample ID barcode cannot be read by the system). Because the sample is not affected, the canceled cartridge can be reloaded into the instrument provided the error is corrected and the stability time is not exceeded.

A sample/cartridge is aborted if the sample is affected, so that the result is at risk. (For example, if the temperature inside the instrument is too high). The aborted cartridge can no longer be used.

Result records are created for both canceled (Figure 35) and aborted (Figure 36) cartridges. The test status shows whether a test was canceled or aborted. A detailed error message describes the error. For canceled samples, the message also indicates how to resolve the error so that the cartridge can be reloaded into the instrument. For aborted samples, the test result is transferred to LIS when the system is setup accordingly. In both cases, the cartridge can be taken out of the instrument from the waste drawer.

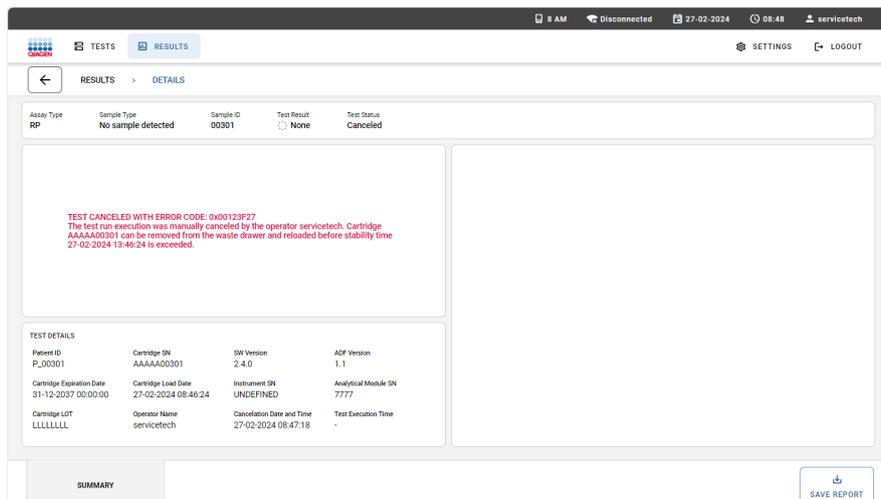


Figure 35. Result of a canceled sample.

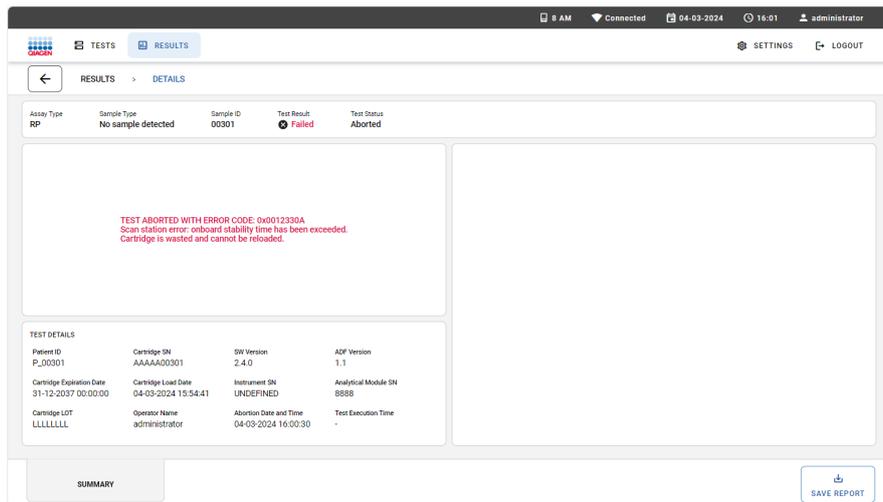


Figure 36. Result of an aborted sample.

In addition to the test cancellations and abortions performed by the system, users can also manually cancel or abort a sample, depending on the status of the run.

5.6.2. Cancellation of a sample by user

A sample can be canceled during transfer to the scan station and cartridge check performed in the scan station (Figure 37). Once the sample is loaded into the AM, it is no longer possible to cancel the test and therefore the cancel option is no longer visible on the touchscreen. After this point, the cartridge can only be aborted (see Section 5.6).

To cancel a sample, go to the **IN PROGRESS** tab of the screen, then select the sample and press the **CANCEL** button on the bottom right corner of the screen (Figure 37).

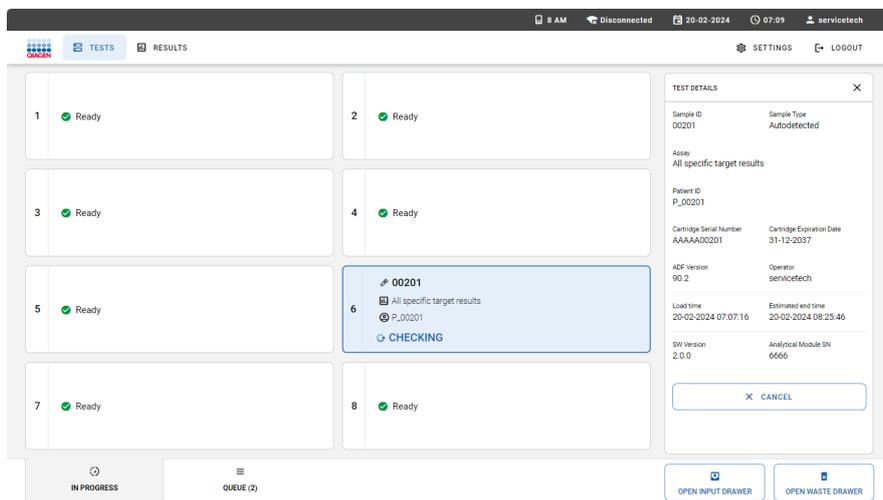


Figure 37. Cancellation of a sample.

Press the **CONFIRM CANCELATION** button to proceed with the cancellation (Figure 38).

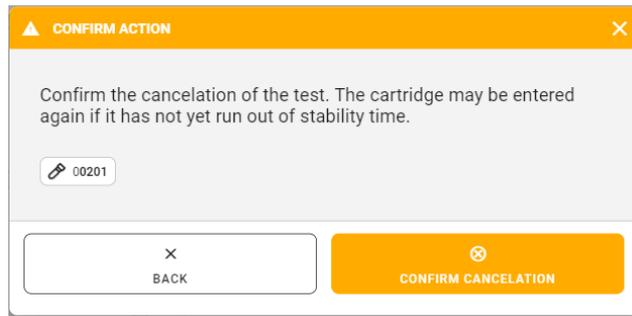


Figure 38. Confirmation dialog of sample cancelation.

The canceled sample can be reloaded into the instrument if the onboard stability time is not exceeded (Figure 39).

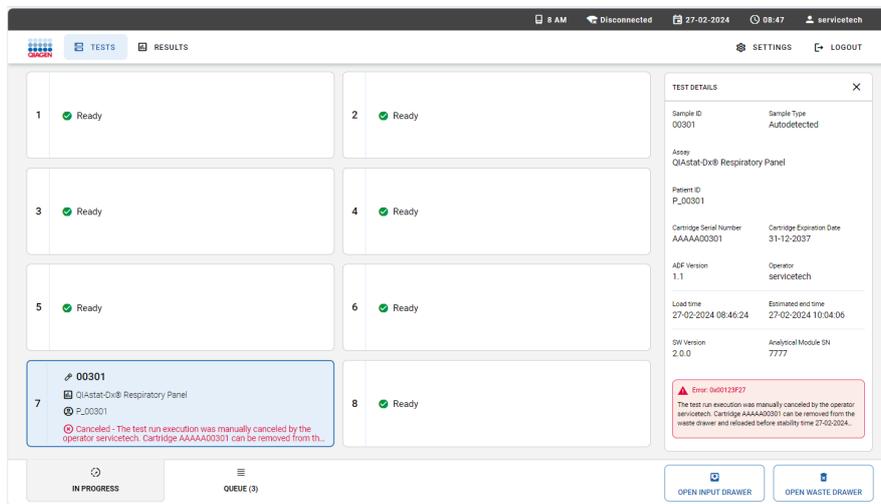


Figure 39. Canceled sample screen.

5.6.3. Abortion of a sample by user

A sample can be aborted while the test is running inside the Analytical Module (AM). To abort a sample, go to the **IN PROGRESS** tab of the **TESTS** screen, then select the sample and press the **ABORT** button on the bottom right corner of the screen (Figure 40).

Important: The sample cannot be used again once it is aborted.

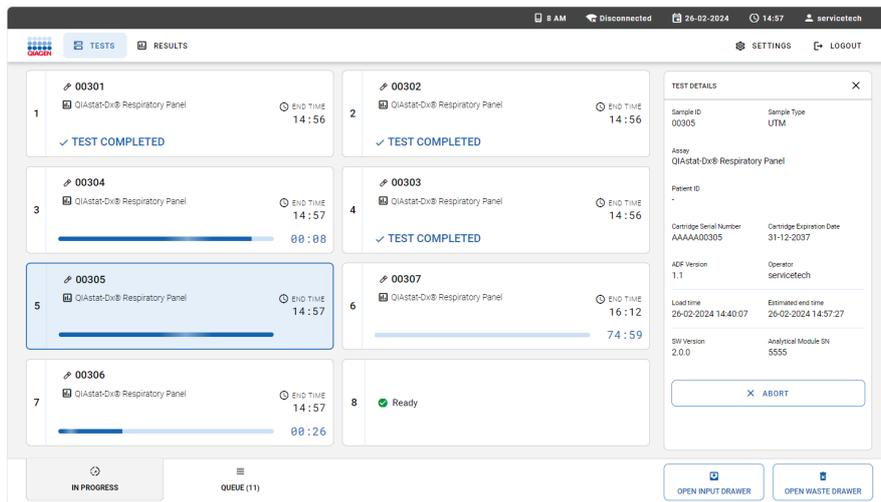


Figure 40. Abortion of a running sample.

Press the **CONFIRM ABORTION** button to proceed with aborting the sample (Figure 41).

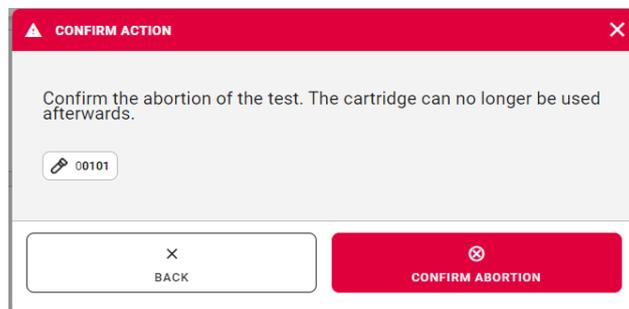


Figure 41. Confirmation dialog to abort running sample.

After confirmation the system aborts the run, ejects the cartridge, and moves it to the waste drawer. After a while the sample can be seen as aborted on the screen (Figure 42 and Figure 43).

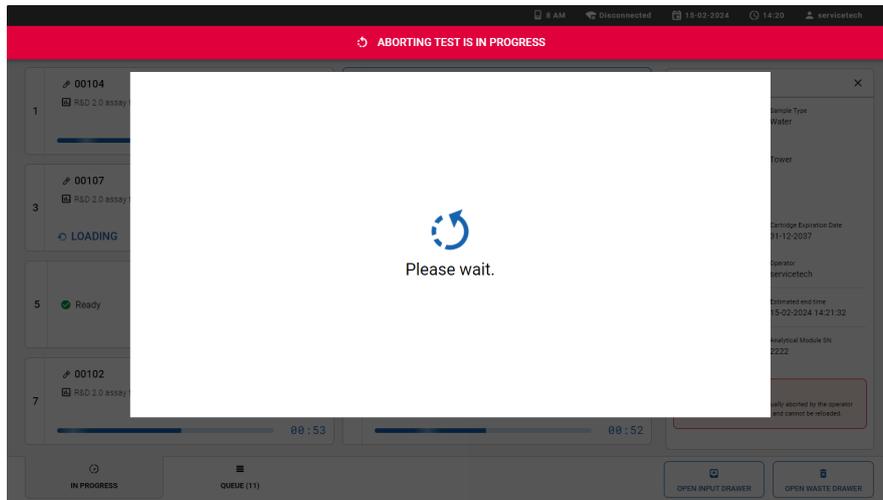


Figure 42. Sample abortion waiting dialog.

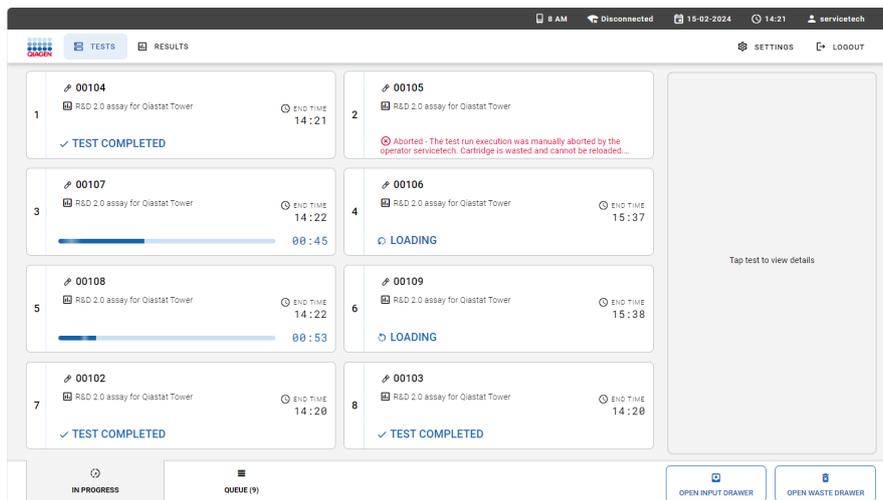


Figure 43. Aborted sample after confirmation of the abortion.

5.7. Continuous operation

5.7.1. Continuous loading

Continuous operation of the QIAstat-Dx Rise allows the user to easily and safely open the input drawer and load new cartridges to be tested during their testing routine while a test run is being performed for other cartridges.

Note: During continuous loading, do not exchange an existing cartridge with another cartridge containing the same sample ID.

5.7.2. Empty the waste drawer during continuous run

Note: The user must check and unload the waste drawer when the new cartridges are loaded to the instrument.

QIAstat-Dx Rise always checks the total number of cartridges in the input tray, waste tray, and all available AM right after the input drawer or waste drawer is closed by the user.

If the total number of the cartridges exceeds the available slots in the waste drawer and available AM, the QIAstat-Dx Rise will show the “Empty The Waste Drawer” warning dialog right after the scan of input tray and load check of waste tray. The warning dialog contains the number of available slots for waste tray and AM and occupied slots for input tray (Figure 44).

The warning dialog can simply be closed by the user by pressing the **CLOSE** button on the screen.



Figure 44. Empty waste drawer dialog.

When there are 7 empty slots in the waste tray, the warning dialog appears on the upper side of the screen and the status indicators (LEDs) of the system starts blinking blue. This additional warning is automatically updated by the system, and it is permanent on the screen until the waste drawer is emptied (Figure 45).



Figure 45. Waste drawer warning.

If the waste tray is not emptied, the system will be blocked and the two warning dialogs appear on the screen (Figure 46). The user can select **OPEN WASTE DRAWER** option on the warning and empty the waste drawer. Please note that this warning

will disappear after a few seconds, but the warning on the upper side (Figure 47) will stay until the waste drawer is emptied. The user can still open the waste drawer and empty at any time.

Note: When the system is blocked, the status indicators (LEDs) of the system starts red blinking.

When the system is blocked, running samples will be completed. However, Analytical Modules cannot be unloaded and remaining samples in the input tray are at risk to exceed their stability time.

After emptying the waste drawer, the warning will disappear, the remaining processed samples in the AM will be transferred to the waste drawer, and the system will be active again.

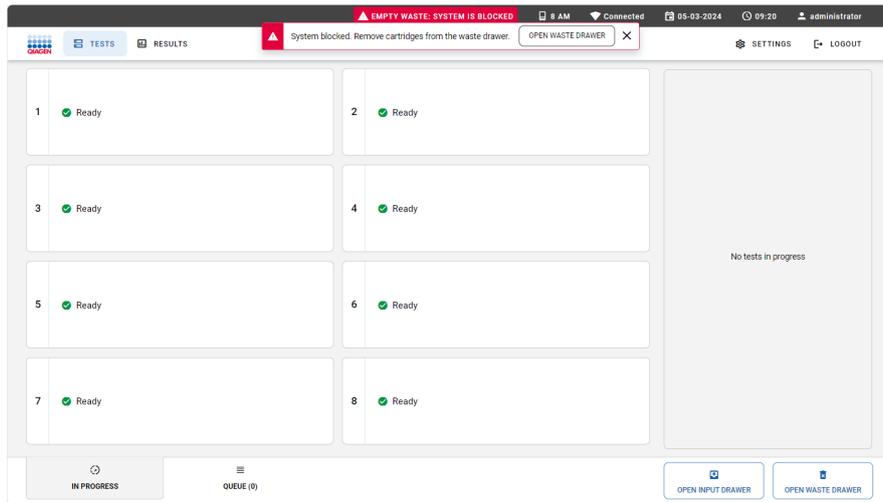


Figure 46. System is blocked warnings.



Figure 47. System is blocked warning.

5.8. Viewing results

The QIAstat-Dx Rise automatically interprets and saves test results. After the run is completed, the results can be seen in the **RESULTS** summary screen (Figure 48).

Note: The figures shown in this user manual are only examples and may differ from assay to assay.

Note: Refer to assay-specific instructions for use for possible results and instructions on how to interpret assay results.

Sample ID / Patient ID	Operator ID	LIS	End time / Date	Assay Type	Result
00320 P_00320	administrator	Ⓜ	21-02-2024 13:31:02	G1	NEGATIVE
00319 P_00319	administrator	Ⓜ	21-02-2024 13:30:36	G1	NEGATIVE
00312 P_00312	administrator	Ⓜ	21-02-2024 13:25:03	RP	POSITIVE
00311 P_00311	administrator	Ⓜ	21-02-2024 13:24:43	RP	POSITIVE
00310 P_00310	administrator	Ⓜ	21-02-2024 13:24:05	RP	POSITIVE
00309 P_00309	administrator	Ⓜ	21-02-2024 13:23:42	RP	POSITIVE
00304 P_00304	administrator	Ⓜ	21-02-2024 13:15:41	G1	NEGATIVE
00303 P_00303	administrator	Ⓜ	21-02-2024 13:14:59	G1	NEGATIVE
00302 P_00302	administrator	Ⓜ	21-02-2024 13:14:43	G1	NEGATIVE
00301 P_00301	administrator	Ⓜ	21-02-2024 13:13:59	G1	NEGATIVE

Figure 48. The RESULTS summary screen.

The main part of the screen provides an overview of the completed, canceled, and aborted runs and uses color-coding and symbols to indicate the results:

- If at least one pathogen is detected in the sample, the term **POSITIVE** is shown in the result column, preceded by a  sign.
- If no pathogen is detected, and the internal control is valid, the term **NEGATIVE** is shown in the result column, preceded by a  sign.
- If at least one pathogen is detected in the sample, and the internal control was invalid, the term **POSITIVE WITH WARNING** is shown in the result column, preceded by a  sign.
- If the test did not complete successfully, the term **FAILED** is shown in the result column, preceded by a  sign. When viewing the details of such a test, a specific error code followed by an error message is shown.
- If a test is canceled before running in an AM, the term **NONE** is shown in the result column, preceded by a  sign. When viewing the details of such a test, a specific error message displays the reason for the cancelation and steps how to resolve it. The cartridge of a canceled test can be reloaded into the instrument again within the stability time.
- If a test is aborted before running in an AM, the term **ABORTED** is shown in the result column, preceded by a  sign. When viewing the details of such a test, a specific error message displays the reason for the abortion. The cartridge of an aborted test cannot be reloaded into the instrument.

The **RESULTS** summary screen shows the following information:

- **Sample ID/Patient ID** (if applicable)
- **Operator ID**
- **LIS** (HIS/LIS upload state, if applicable)
- **End time/Date**
- **Assay Type**
- Result

The **SEARCH** option is available with **Patient ID/Sample ID**. **FILTERS** are available by **Start Day/End Day**, **Results**, **Assay Type** and **Operator ID** and **LIS Upload State**. Filters can be removed by pressing the **CLEAR ALL FILTERS** button.

5.8.1. Viewing test details

For the summary of the data press **DETAILS** button at the right side of the screen (Figure 48). The upper part of the screen shows general information about the test. It includes **Assay Type**, **Sample Type**, **Sample ID**, **Test Result**, status of the **Internal Control**, **Test Status** and **LIS Upload Status** (Figure 49).

On the left side of the screen, all positive and equivocal pathogens are shown, the right part of the screen shows all pathogens defined by the assay and their detection status. For positive and equivocal pathogens, the Ct value and the endpoint fluorescence is shown.

On the bottom left side of the screen, the test details are presented:

- Patient ID (if applicable)
- Cartridge SN (serial number)
- SW Version (software version)
- ADF Version
- Cartridge Expiration Date
- Cartridge Load Date
- Instrument SN
- Analytical Module SN
- Cartridge LOT
- Operator Name
- Test Start Date and Time
- Test Execution Time
- LIS Upload Status (if applicable)
- LIS Order Number (if applicable),
- LIS Order Date and Time (if applicable).

Note: Categories and type of pathogens displayed depend on the assay used.

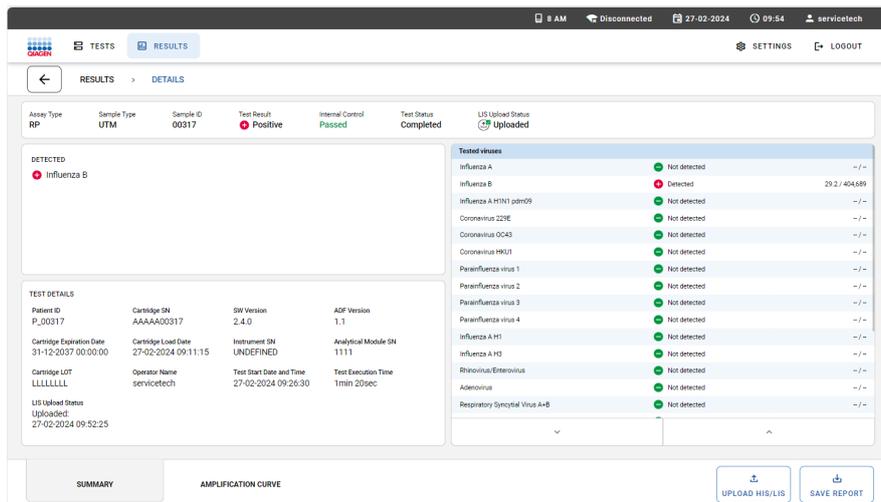


Figure 49. The test details screen.

5.8.2. Viewing amplification curves

To view the test amplification curves, press the **AMPLIFICATION CURVE** tab at the bottom of the screen (Figure 50).

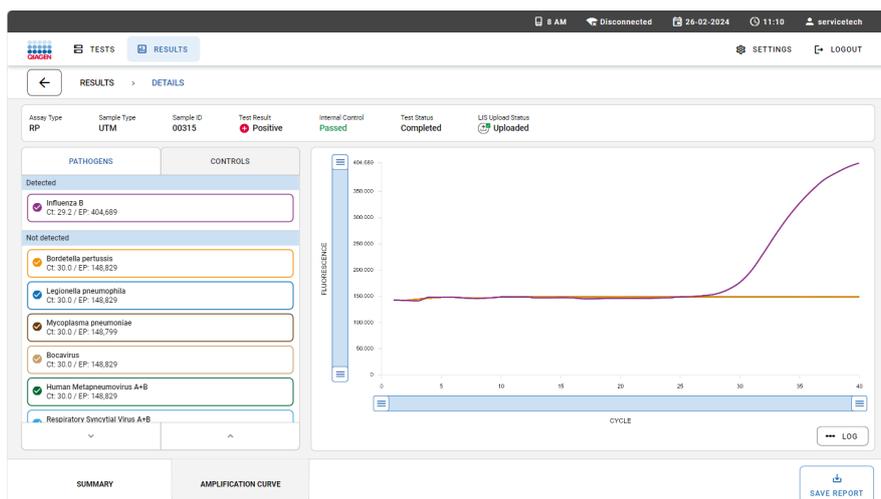


Figure 50. The amplification curves screen.

Tap on the **PATHOGENS** tab on the left side to display the plots corresponding to the tested pathogens. Tap on the pathogen name to select which pathogens are shown in the amplification plot. It is possible to select single, multiple or no pathogens. Each pathogen in the selected list will be assigned a color corresponding to the amplification curve associated with the pathogen. Unselected pathogens will not be shown.

The corresponding C_T and endpoint fluorescence values are shown below each pathogen name. Pathogens are grouped into **detected**, **equivocal**, and **not detected**.

Select the **CONTROLS** tab on the left side to view the controls and select which controls are shown in the amplification plot.

5.8.3. Browsing results from previous tests

To view results from previous tests that are stored in the results repository, use the search functionality in the main results screen (Figure 48).

5.8.4. Exporting results to a USB storage device

To export test results to a USB storage device, follow the steps below:

1. Navigate to the **RESULTS** menu, to export test reports as PDF to a USB storage device.
2. Select the report(s) to export individually or use the **SELECT ALL** button to select all reports. Press the **SAVE REPORTS** button to initiate the export and **CONFIRM** the export.
3. If multiple USB drives are connected, select the desired USB drive (Figure 51). When the export of the reports is completed, the system displays a message in the message bar (Figure 52).

Note: The USB ports are located in the front and on the side of the instrument

Important: Do not remove the USB stick until the data transfer is finished.

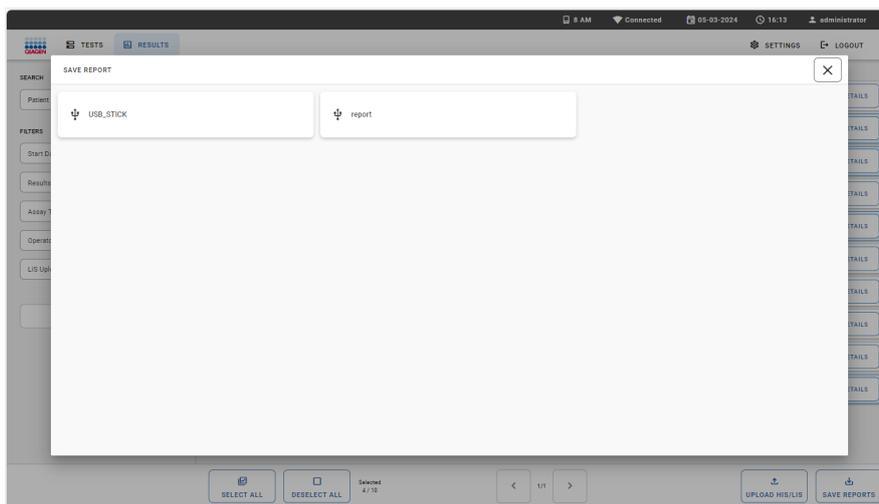


Figure 51. Exporting results to a USB storage device.

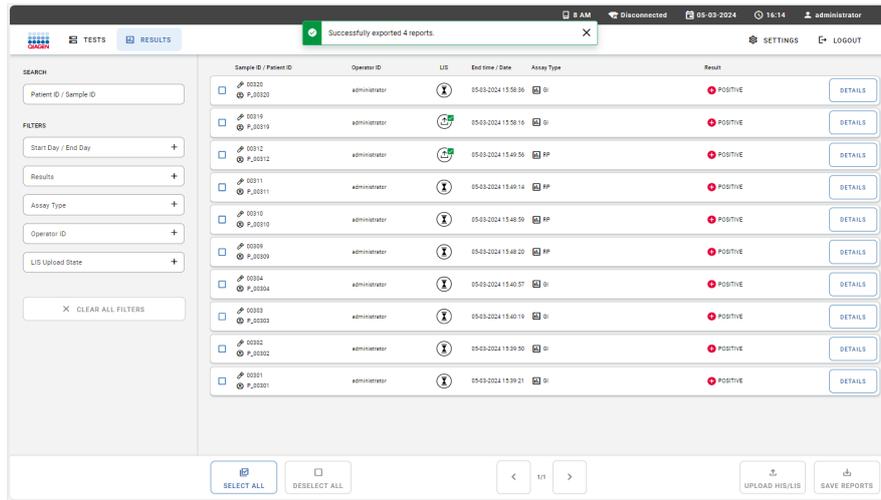


Figure 52. Successful export.

Note: It is recommended to use the USB storage device for short-term data saving and transfer only. The use of a USB storage device is subject to restrictions (e.g., the memory capacity or the risk of overwriting, which should be considered before usage). It is recommended to use USB 3.0 with 64 GB memory capacity and exFAT file system format to decrease the transfer time of files to and from the storage device.

5.9. Creating a support package

If support is required, a support package containing all required run information, system, and technical log files can be created and provided to QIAGEN Technical Services. For creating a support package, tap on the **SETTINGS** and then select **SYSTEM**, go to the **SUPPORT PACKAGE** tab and press **SAVE SUPPORT PACKAGE** button on the bottom right corner of the screen. Save the support package to a USB storage device.

Note: It is recommended to use USB 3.0 with 64 GB memory capacity and exFAT file system format to decrease the transfer time of files to and from the storage device.

The time needed to create a support package depends on the size of the database and the USB stick used. User can continue to operate the instrument while the support package is being generated. Do not remove the USB stick before the process is completed (Save log files screen.). When the download is completed the message “Support package successfully saved” is displayed in the message bar.

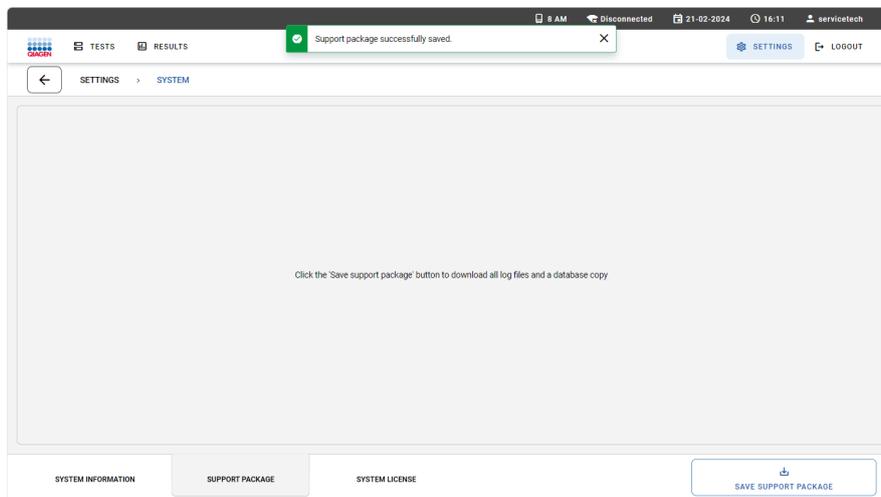


Figure 53. Save log files screen.

6. Operating Procedures

Before proceeding, we recommend that you familiarize yourself with the features of the instrument by referring to Section 3.

Note: The figures shown in this user manual are only examples and may differ from assay to assay.

6.1. Use of the QIAstat-Dx Rise software

This section provides a description of all the available QIAstat-Dx Rise features and options that enable customization of the instrument settings.

Note: If you need to refresh the screen you are working on, switch to another screen and back again.

6.2. Main screen

In the main screen, it is possible to view the status of the instrument and navigate to different sections (Figure 54).

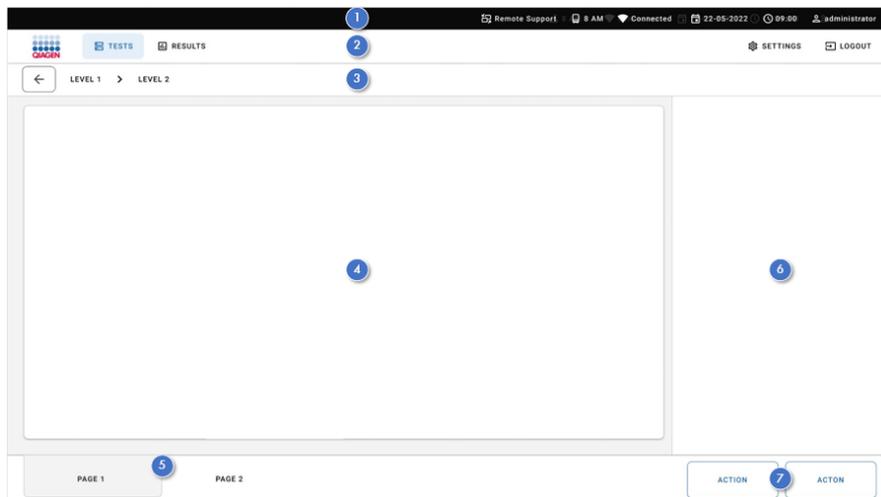


Figure 54. Main screen of the QIAstat-Dx Rise software.

- | | | | |
|---|----------------------|---|----------------------|
| 1 | Status | 5 | View options/details |
| 2 | Main navigation | 6 | View tabs |
| 3 | Secondary navigation | 7 | View actions |
| 4 | View area | | |

6.2.1. Status bar

The status bar provides information about the status of the instrument. The information whether the remote support functionality is enabled (see Section 9.1), number of installed AMs, connection status, instrument date and time, and the user ID of the logged-in user appear on the right status (Figure 55).



Figure 55. Status bar of the QIAstat-Dx Rise.

6.2.2. Main navigation bar

The main navigation bar provides fast access to the following submenus: **TESTS**, **RESULTS** (left side), **SETTINGS** and **LOGOUT** (right side) (Figure 56).



Figure 56. Main navigation bar of the QIAstat-Dx Rise.

Table 3 shows the options that are available to the user through the main navigation bar.

Table 3. Main navigation bar options

Name	Button	Description
Tests	TESTS	Opens the TESTS screen
Results	RESULTS	Opens the view RESULTS screen
Settings	SETTINGS	Opens the SETTINGS submenu
Logout	LOGOUT	Logs the user out

6.2.3. View area

The information displayed in the main view area varies according to the state of the user interface. Results, summaries, configurations, and settings are displayed in this area upon entering different modes and selecting items from the menus described below (Figure 57).

Depending on the content, further options may be available through the view options, view tabs, and view actions menu.



Figure 57. View area of the QIAstat-Dx Rise.

6.2.4. Submenu bar

The submenu bar provides access to context-dependent functions. The content depends on the current submenu (Figure 58).

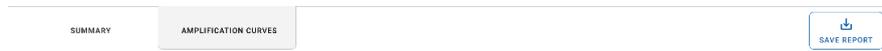


Figure 58. Submenu content area of the QIAstat-Dx Rise.

6.3. Settings menu

The **SETTINGS** menu is accessible from the main menu bar (Figure 59). **Assay Management**, **General Settings**, **Connectivity**, **System**, **User Management**, and **CHANGE PASSWORD** menu can be found under **SETTINGS** menu.

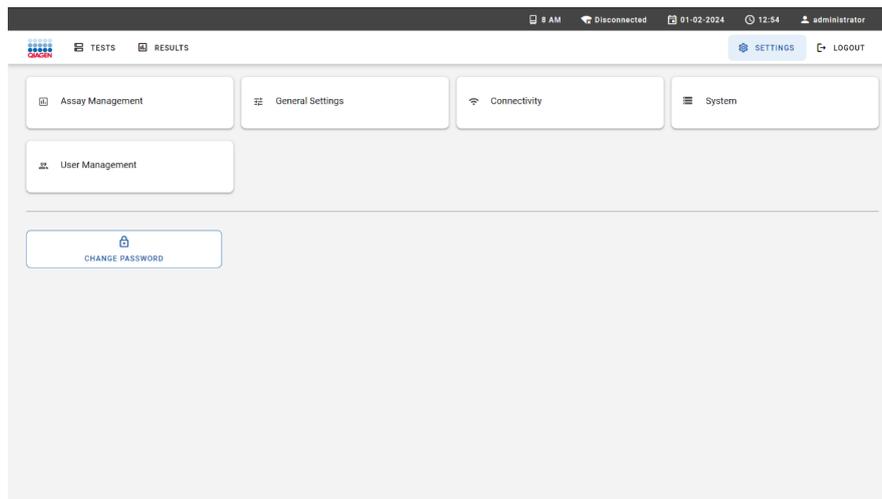


Figure 59. Settings menu screen.

6.3.1. Assay management

The **ASSAY MANAGEMENT** menu provides information about the assays installed on the QIAstat-Dx Rise. Press the **Assay Management** button to see the installed assays (Figure 60). Tap on the assay to view the assay details.

Note: Additional assays can be installed by service technicians remotely (see Section 9.1).



Figure 60. Assay management screen.

The Assay Details screen shows all information for the selected assay. **GENERAL INFO** shows technical information such as name, version, and ID of the assay. **SAMPLE TYPES**, **CONTROLS** (Internal Controls (IC)), and **ANALYTES** are displayed as defined by the assay (Figure 61). The LIS assay name must be unique.

Hide amplification curves

1. Press the **EDIT** button in the **PDF REPORTS** area.
2. Select **Hide amplification curves from PDF reports**, and press the **SAVE** button.

Regional settings

Go to **REGIONAL SETTINGS** to change date, time, time zone, date format, date separator, and time format (Figure 63).

1. Press the **EDIT** button in the **REGIONAL SETTINGS** area.
2. Make changes to the settings listed in Table 4 as needed and press the **SAVE** button.

Table 4. Regional setting

Name	Description
Date	Set the date Note: Even if only the day, month or year are to be modified, they must all be selected together. Otherwise, the date change will not be saved correctly.
Time	Set the time
Time Zone	Choose the time zone. The system automatically shifts to daylight saving time according to the rules of the selected time zone.
Date Format	Choose a date format: <ul style="list-style-type: none">• DD-MM-YYYY (default)• DD-MM-YY• MM-DD-YYYY• YYYY-MM-DD• YY-MM-DD
Date Separator	Choose a date separator: <ul style="list-style-type: none">• (default)• _• /• .• :
Time Format	Choose a time format: <ul style="list-style-type: none">• 24 hours (default)• 12 hours AM/PM

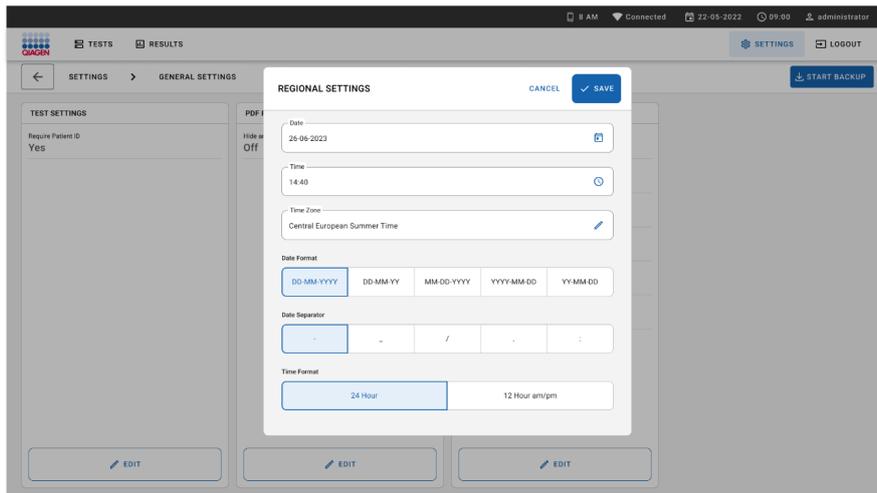


Figure 63. Regional settings.

Important: After changing the time zone, the instrument must be restarted.

6.3.3. Connectivity settings

The **CONNECTIVITY** menu is available to users with the role administrator. In the **CONNECTIVITY** menu, users can configure the **NETWORK ADAPTOR**, enable **REMOTE SUPPORT**, and configure the **HIS/LIS** settings.

Select the **NETWORK** tab to view the **NETWORK ADAPTOR** and **REMOTE SUPPORT** settings (Figure 64). In the **NETWORK ADAPTOR** menu, the following information is displayed (Table 5):

Table 5. Network Adapter setting

Name	Description
MAC ADDRESS	MAC address of the instrument
NETWORK CONFIGURATION	Network configuration ("Automatic" or "Manual")
STATUS	Status ("Connected", "Disconnected", or "Configuring")
IP ADDRESS	IP v4 address with subnet mask, or "Not Assigned" if no IP address is assigned
SUBNET MASK	IP v4 address with subnet mask, or "Not Assigned" if no IP address is assigned
DEFAULT GATEWAY	IP v4 address of Default Gateway
DNS	IP v4 of DNS Server

Additionally, the **REMOTE SUPPORT** functionality can be enabled. For more information about this, refer to Section 9.1.

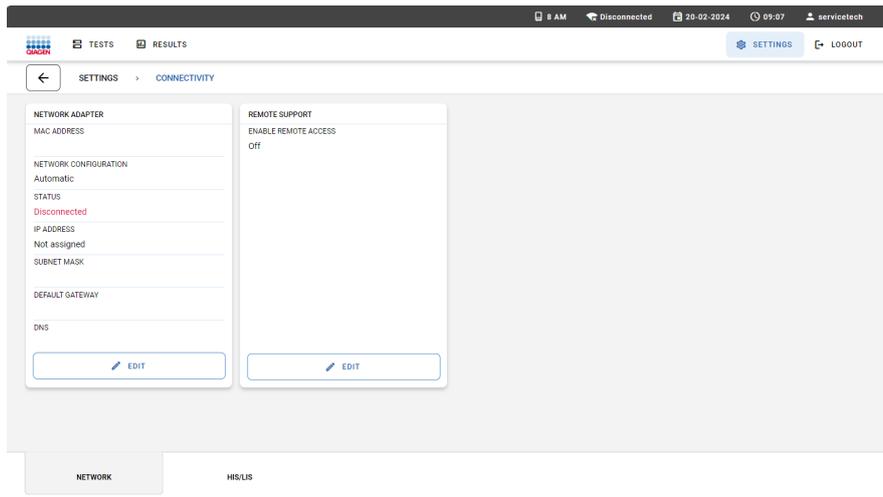


Figure 64. Connectivity screen – Network settings.

Press the **EDIT** button to configure the **NETWORK ADAPTER** settings. Select **AUTOMATIC** (Figure 65) or **MANUAL** (Figure 66) configuration. When **AUTOMATIC** configuration is active, the network settings will be received from your local DHCP server. When **MANUAL** configuration is active, enter the following network settings (Table 6):

Table 6. Manual network setting

Name	Description
NETWORK CONFIGURATION	Network configuration ("Automatic" or "Manual")
STATUS	Status ("Connected", "Disconnected", or "Configuring")
IP ADDRESS	Valid IP address (x.x.x.x where x is an octet and must be a decimal value between 0 and 255. The numbers cannot be 0 prefixed unless they are 0)
SUBNET MASK	Valid network mask in IP address form notation
DEFAULT GATEWAY	Valid IP within the configured network range (IP address and Network mask) or empty.
DNS Server 1	Valid IP or empty
DNS Server 2	Valid IP or empty

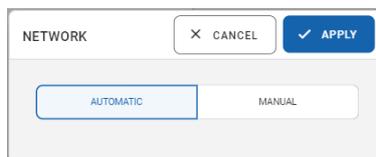


Figure 65. AUTOMATIC network settings.

The screenshot shows a 'NETWORK' dialog box with 'CANCEL' and 'APPLY' buttons. It has two tabs: 'AUTOMATIC' and 'MANUAL', with 'MANUAL' selected. The fields are as follows:

IP Address	192.168.20.2	/24
Subnet Mask	255.255.255.0	
Default Gateway	192.168.20.1	
DNS Server 1	9.9.9.9	DNS Server 2
		8.8.8.8

Figure 66. MANUAL network settings.

Select the **HIS/LIS** tab to view the HIS/LIS settings (Figure 67). For more details about setting up a HIS/LIS connection, please refer to Section 7.

The screenshot shows the 'HIS/LIS' settings screen. At the top, there are navigation tabs for 'TESTS' and 'RESULTS', and a 'SETTINGS' button. Below the navigation, there are four main sections:

- HOST SETTINGS:** Host communication (On), Host Address (10.100.62.97), Host Port (6661), Transfer Protocol (HL7), Log HL7 messages (Off), Hospital Name (MYLIS), Timeout (50). Includes a 'CHECK CONNECTIVITY' button and an 'EDIT' button.
- RESULT UPLOAD SETTINGS:** Result upload (On), Automatic upload (On), PDF Report upload (Off), Expire days (7). Includes an 'EXPIRE ALL' button and an 'EDIT' button.
- MESSAGING:** Message Queue (0). Includes a 'CLEAR QUEUE' button and a 'RETRY' button.
- ORDER SETTINGS:** Test Orders (On), Force Orders (Off). Includes an 'EDIT' button.

At the bottom, there are two tabs: 'NETWORK' and 'HIS/LIS', with 'HIS/LIS' selected.

Figure 67. Connectivity screen – HIS/LIS settings.

6.3.4. System settings

In the **SYSTEM** menu, users can view the **SYSTEM INFORMATION**, create a **SUPPORT PACKAGE**, and view the **SYSTEM LICENSE**. Select the **SYSTEM INFORMATION** tab to view the **SYSTEM VERSION INFORMATION** and the status of the Analytical Modules (Figure 68).

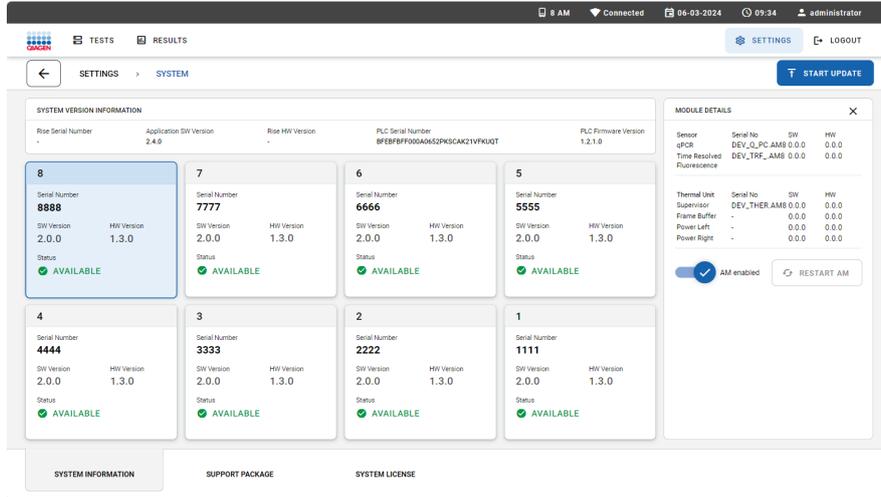


Figure 68. System screen – system information.

In the **SYSTEM VERSION INFORMATION** menu, the following information is displayed (Table 7):

Table 7. System version information

Name	Description
Rise Serial Number	Serial number of the instrument
Application SW Version	Version of the QIAsat-Dx Rise Application Software
Rise HW Version	Hardware version of the instrument
PLC Serial Number	Serial number of the Programmable Logic Controller (PLC)
PLC Firmware Version	Firmware version of the Programmable Logic Controller (PLC)

The Analytical Modules overview shows the following information (Table 8):

Table 8. Analytical modules overview

Name	Description
#	Position of the Analytical Module (AM) in the QIAstat-Dx Rise instrument (1–8)
SW Version	Firmware version of the Analytical Module
HW version	Hardware version of the Analytical Module
Status	Status of the Analytical Module Not installed Initializing Available Test preparation Test running Test finalizing Test done Cartridge ejecting Error Recovering cartridge Excluded

Tap on the Analytical Module (AM) to view the **MODULE DETAILS** (Table 9).

Table 9. Module details

Name	Description
Component name	Name of the AM component: qPCR sensor Time Resolved Fluorescence Sensor Thermal unit supervisor Thermal unit frame buffer Thermal unit power left Thermal unit power right
Serial number	Serial number (for qPCR sensor, Time Resolved Fluorescence Sensor, and Thermal unit supervisor)
Software version	Firmware version of the Analytical Module
Hardware version	Hardware version of the Analytical Module
AM enabled / AM disabled	Toggle button to enable and disable the Analytical Module Users with the role administrator can disable Analytical Modules. This allows to exclude a specific Analytical Module from running samples. This may be useful if a module is suspected of being faulty. In some cases, an Analytical Module is excluded automatically by the system because of an error from which the Analytical Module could not be recovered
Restart AM	Button to restart the Analytical Module without having to restart the entire QIAstat-Dx Rise instrument. The button is only enabled when the selected AM is in an error state.

Note: After excluding a module, the sample queue must be checked and confirmed again, as fewer modules are available, and some samples may run out of onboard stability time.

Select the **SUPPORT PACKAGE** tab to create a **SUPPORT PACKAGE** when you require support from QIAGEN Technical Services (Figure 68). For more details on the **SUPPORT PACKAGE**, please refer to Section 5.9.

Select **SYSTEM LICENSE** tab to view the End User License Agreement for the QIAstat-Dx Rise Software and third-party software components.

6.3.5. User management

The QIAstat-Dx Rise Application Software supports the multiuser mode. Users must log in before performing any action on the QIAstat-Dx Rise. The actions they are allowed to perform are limited and defined according to the user role assigned to their user profile.

The user management option permits users with “administrator” and “laboratory technician” profiles to add new users to the system, define their rights and user profiles, and to activate or inactivate users. Table 10 displays the user profiles that are available.

Table 10. Available user profiles

User role	Rights	Example
Administrator	Full	Instrumentation/IT responsibility
Laboratory Technician	Manage user repository, manage assays, create support packages, view test details, abort and cancel tests, view system information, and restart analytical modules	Microbiologist, laboratory technician

Accessing and managing users

Follow the steps below to access and manage the system users:

1. Press the **SETTINGS** button in the main navigation bar.
2. Select the User Management menu to view the users that can access the QIAstat-Dx Rise (Figure 69). The properties of the user profile are described in Operating Procedures.

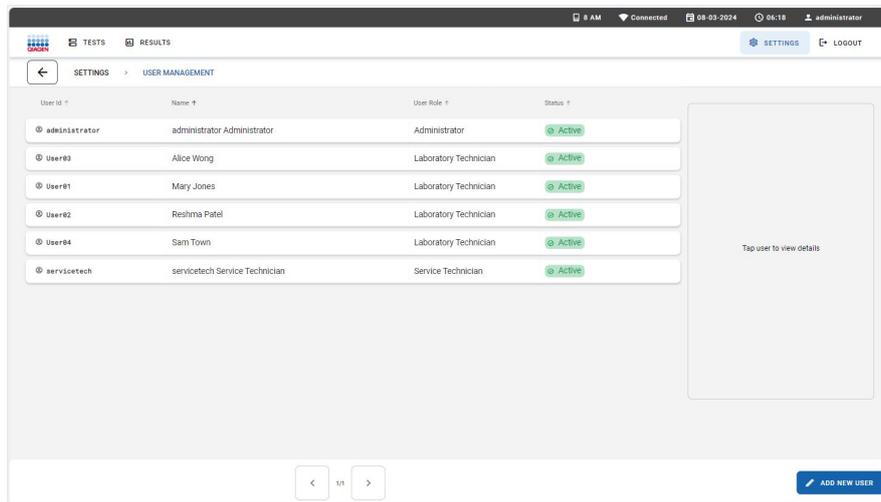


Figure 69. User Management.

Table 11. User Profile Properties

Name	Description
User ID	Unique identifier with which users can log into the system. A user ID must be between 5 and 50 characters long.

Table 11. User Profile Properties (continued)

Name	Description
First Name	The first name of a user. This field is optional.
Last Name	The last name of a user.
User Role	The user role that is assigned to a user determines the privileges that a user has. For an overview of available user roles and rights, refer to Operating Procedures.
Status	By default, newly created users are active. Only active users are able to log into the system.

Adding users

Follow the steps below to add a new user to the system:

1. Press the **ADD NEW USER** button on the bottom right.

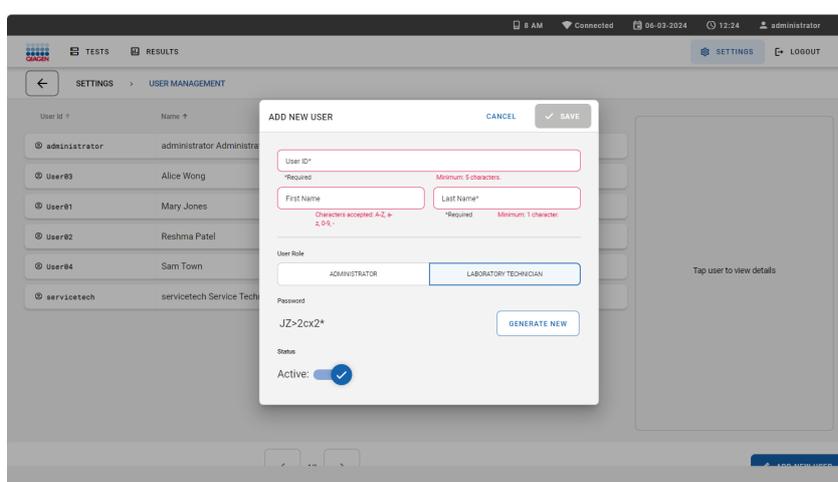


Figure 70. Add new user dialog.

2. Fill out the User ID section. This must be unique.
3. Fill out the First Name section.
4. Fill out the Last Name section.
5. Select one of the user roles. For an overview of available user roles and rights, refer to Table 10.
6. A Password is automatically generated. A new password can be created by pressing the **GENERATE NEW** button. Alternatively, every user can change their own password in the **CHANGE PASSWORD** menu, see Section 6.3.6.
7. Use **Active** button to select whether the user shall be active.
8. Press the **SAVE** button on the upper right corner of the **ADD NEW USER** dialog to persist the changes. Otherwise, press the **CANCEL** button.

Editing users

Follow the steps below to edit an existing user:

1. Select the user to manage from the list of users (Figure 71).
2. Press the **EDIT USER** button in the right panel of the user details.

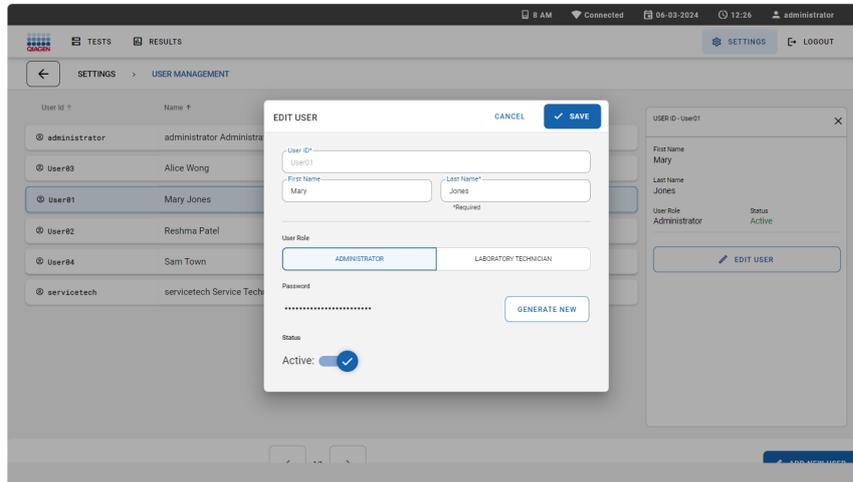


Figure 71. Edit user dialog.

3. Update First Name, Last Name, and User Role as required.
4. Press the **GENERATE NEW** button to generate a new password is automatically. Alternatively, every user can change their own password in the **CHANGE PASSWORD** menu, see Section 6.3.6.
5. Deselect the **Active** button in case you need to disable the user.

Note: The administrator and servicetech user profiles cannot or only to a limited extend be edited.

6.3.6. Change password

Follow the steps below to change the password of a logged in user:

1. Press the **SETTINGS** button in the main navigation bar.
2. Select the **CHANGE PASSWORD** menu.
3. Enter the old password.
4. Enter the new password. The new password must fulfil the following criteria:
 - At least 8 characters long
 - At least one uppercase letter
 - At least one lowercase letter
 - At least one digit
 - At least one special character, e.g., ! @ # ?]

Important: Do not use the “+” symbol when creating a password, in particular not for the Administrator role. Using a “+” symbol will block the user from accessing the system or changing the password.

5. Repeat to enter the new password.
6. Press the **CHANGE PASSWORD** button.

The change password dialog is shown in Figure 72.

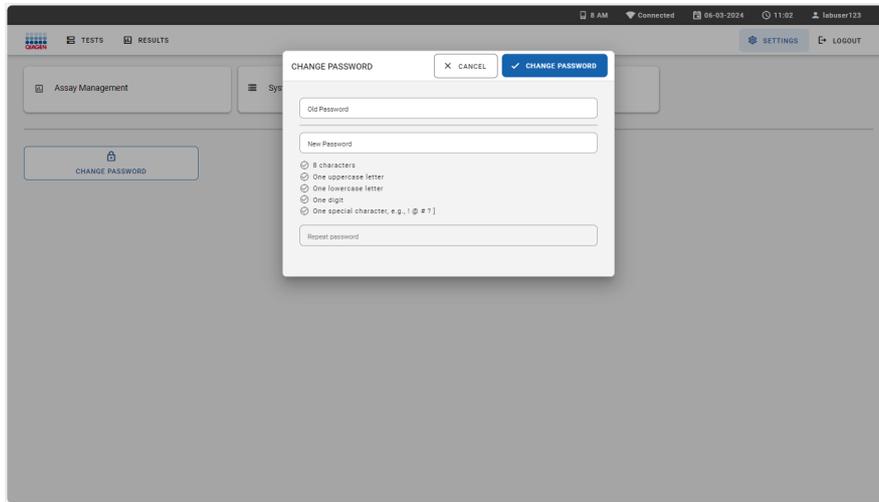


Figure 72. Change password dialog.

6.4. Shutting down the QIAstat-Dx Rise

The QIAstat-Dx Rise is designed to operate continuously. Shutdown the QIAstat-Dx Rise by pressing the on/off button on the front of the instrument. The user needs to be logged on to the system to avoid accidental shutdown of the system. If the instrument is running a test, a dialog will appear indicating that shutdown is currently not possible. Allow the instrument to finish running the test(s) and shut it down upon completion.

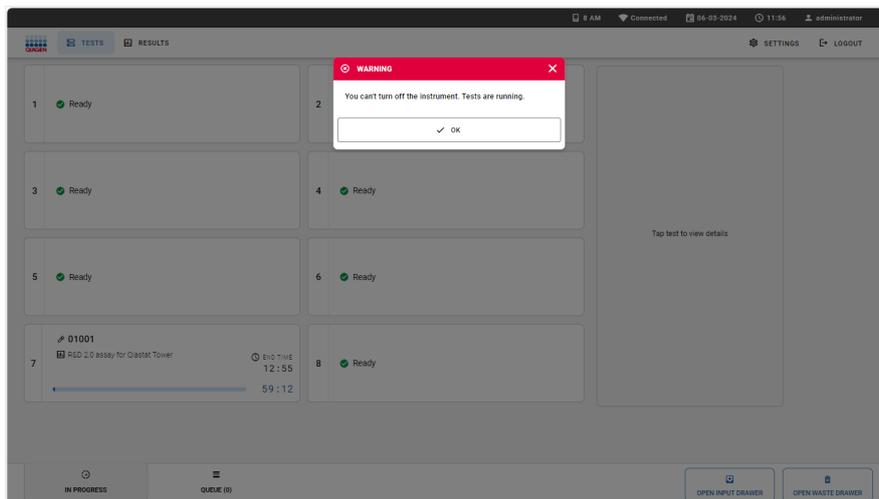


Figure 73. Warning dialog for shutdown while tests are executed.

To power off the instrument for maintenance, shutdown the instrument first and power off the instrument using the power switch on the side of the QIAstat-Dx Rise.

It is recommended to remove all cartridges from the waste drawer prior to shutting down the instrument. Please make sure that both input and waste drawers are closed after loading and wasting the cartridges.

Note: On rare occasions, the instrument may not shut down completely and continuously displays “Instrument is shutting down”. In this case, use the power switch.

In case of an emergency, power off the instrument directly by using the power switch on the side of the QIAstat-Dx Rise.

Note: This will lead to data and sample loss.

6.5. System status of the QIAstat-Dx Rise

The status of the QIAstat-Dx Rise and the Analytical Modules are indicated by the color of the status indicators (LEDs) on the front of the instruments. The QIAstat-Dx Rise and analytical modules can display any of the following status colors (Table 12).

Table 12. System Status of QIAstat-Dx Rise components

Table 12. System Status of QIAstat-Dx Rise components

Instrument	Status indicator colors	Description
QIAstat-Dx Rise	Solid red	One or more AM is in error state.
	Blinking red	Machine is blocked, which can have the following reasons: <ul style="list-style-type: none"> No AM is operational Initialization failed Maintenance mode Waste Tray is full Temperature is too high Manual recovery is required
	Solid blue	<ul style="list-style-type: none"> Admin password has not been set. There are tests in the queue that may/will run out of stability time.
	Blinking blue	<ul style="list-style-type: none"> Initialization procedure is in progress. Power off procedure is in progress. Waste tray is getting full.
	Solid green	The instrument is executing tests
	Blinking green	<ul style="list-style-type: none"> The instrument is idle and ready to execute tests The user is loading test or unloading the drawers.
Analytical Module	Solid red	Malfunction
	Solid green	Executing a test
	Blinking green	Initializing
	Solid blue	Standby
	Solid yellow*	Potential malfunction

* If an AM LED status bar is yellow, and you look from outside through the blue door, it appears green.

7. HIS/LIS Connectivity

This section describes the connectivity of the QIAstat-Dx Rise with a HIS/LIS.

HIS/LIS configuration enables the connection of the QIAstat-Dx Rise to a HIS/LIS to provide such functionalities as:

- Activating and configuring communication with the HIS/LIS
- Running a test based on an order from the HIS/LIS
- Sending the result of a test to the HIS/LIS
- Assay configuration for querying and order and sending results

Note: Please ensure that your local network is sufficiently secured against unauthorized access as communication with HIS/LIS is not encrypted.

7.1. Activating and configuring communication with the HIS/LIS

1. Press the **SETTINGS** button in the main navigation bar.
2. Select the **Connectivity** menu.
3. Select the **HIS/LIS** tab and press the **Edit** button in the **HOST SETTINGS** area to select and define the settings listed in Table 13 as needed.

Table 13. HIS/LIS Host settings

Setting	Description
Host Communication	Enables the HIS/LIS connectivity. This option is disabled by default.
Host address	The host address allows both an IP and a name value of the host. The IP value must be 4 numbers (N.N.N.N) and N must be between 0 and 255.
Host Port	The host port defines on which port the host is listening.
Transfer Protocol	The transfer protocol is compatible with HL7.
Log HL7 messages	Debug logging enables logging specific HL7 debug messages for HIS/LIS uploads. Note: It is strongly recommended to only turn the logging on for analysis during installation and to turn it off afterwards.
Hospital name	Hospital name is an exclusive name to define a DMS or LIS.
Timeout	The default Timeout is configured as 5 seconds and can be extended up to 60 seconds. This is the maximum time the QIAstat-Dx Rise will wait for a message from the host.
Check connectivity	The Check connectivity button validates the connection between the QIAstat-Dx Rise and the host with the IP and port filled.

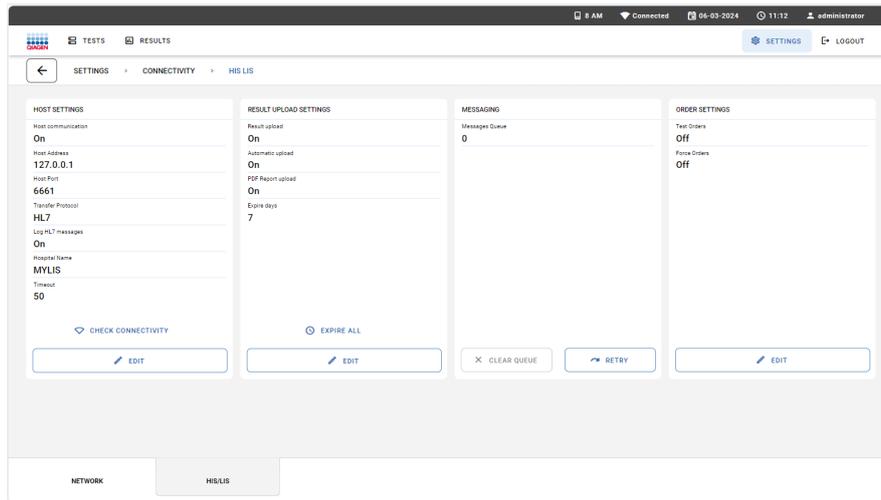


Figure 74. HIS/LIS settings.

7.2. LIS assay name configuration

The assay name in the HIS/LIS may differ from the displayed assay name in the QIAstat-Dx Rise Software. Before using HIS/LIS functions, the following process for confirming/correcting assay names must be performed.

1. Press the **SETTINGS** button in the main navigation bar.
2. Select the **Assay Management** menu.
3. Select the assay from the **Available Assays** menu. Press the **Edit** button next to the LIS name in the General Info area (Figure 61 in Section 6.3.1 Assay management).
4. By default, the LIS name is the same as the assay name. Update the LIS name to the value used as value used as “Universal Service Identifier” in your LIS system and then press the **Apply** button (Update LIS Name dialog.).

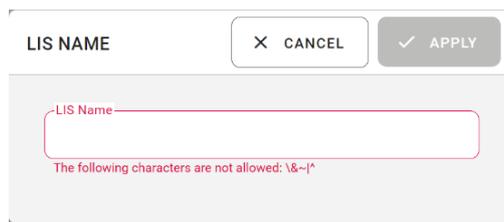


Figure 75. Update LIS Name dialog.

7.3. Querying test orders from HIS/LIS

The QIAstat-Dx Rise can query test orders from a Laboratory Information System (LIS). When **Host Communication** and **Test Orders** are enabled, test orders can be downloaded from the host before a test run.

1. Press the **SETTINGS** button in the main navigation bar.
2. Select the **Connectivity** menu.
3. Select **HIS/LIS** in the submenu.

Configure the **HIS/LIS HOST SETTINGS** as described in Section 7.1. Press the **Edit** button in the **ORDER SETTINGS** area (Figure 74) and define the settings listed in Table 14 as needed.

Table 14. HIS/LIS Order Settings

Setting	Description
Test Orders	Enables the functionality of running a test based on a book order created in the HIS/LIS. This option is disabled by default.
Force Orders	Only active if Test Orders is enabled. Disabling Force Order enables running a test even if communication with the host is unavailable or if there is no book order associated with the entered sample ID. Force Order is disabled by default.

7.4. Uploading a test result to the HIS/LIS

When **Result Upload** and **Results Upload Settings** are enabled, test results can be uploaded to the host either automatically or manually.

7.4.1. Configuration of QIAstat-Dx Rise for uploading test results (automatic)

1. Press the **SETTINGS** button in the main navigation bar.
2. Select the **Connectivity** menu.
3. Select **HIS/LIS** in the submenu.

Configure the HIS/LIS **HOST SETTINGS** as described in Section 7.1. Click on the **Edit** button in the **RESULT UPLOAD SETTINGS** area and define the settings listed in Table 4 as needed.

Table 15. HIS/LIS RESULT UPLOAD SETTINGS

Setting	Description
Result Upload	This enables the possibility to upload a test result manually after the test is completed.
Automatic Upload	If enabled, the result will be automatically uploaded after the test is completed. Note: The result is also automatically uploaded even if the result upload setting above is turned off. If disabled, the user can upload the test result manually to the HIS/LIS.
PDF Report Upload	If enabled, the result upload additionally contains the test report.
Expiry Days	Defines the number of days after which a test result expires and can no longer be uploaded. Set Expiry Days to 0 to never expire the test results.

The QIAstat-Dx Rise shows the number of test results that are currently queued to be uploaded in **MESSAGING** Message Queue (Figure 74).

7.4.2. Viewing the HIS/LIS upload status of a test result

To see the upload status of one or multiple test results, perform the following steps:

1. Press the **RESULTS** button in the main navigation bar.
2. In the result overview, the upload status is shown in the LIS column (Figure 76).

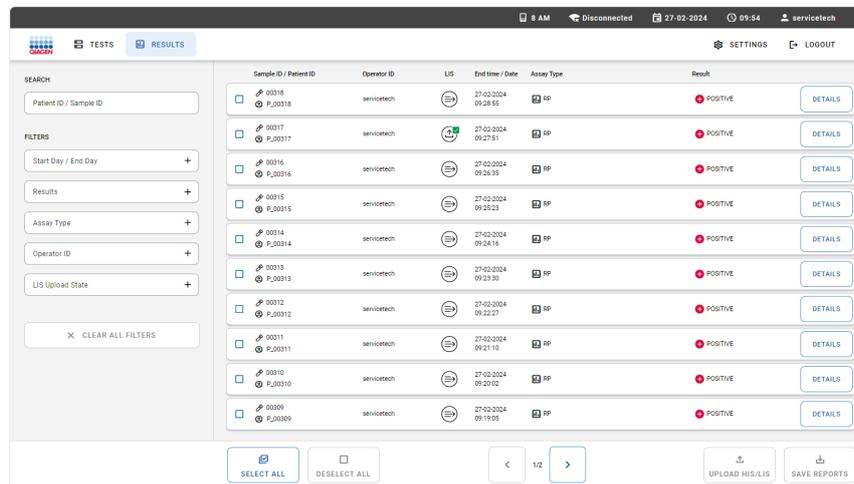


Figure 76. HIS/LIS Upload Status in the result overview.

3. To filter for a specific upload status, select the desired upload status in the LIS Upload State filter in the left menu). Table 16 shows the different upload states a test result may have.

Table 16. LIS Upload State

Name	Icon	Description
Pending		Result not uploaded yet.
Uploading		Result being uploaded.
Uploaded (timestamp)		Result successfully uploaded, with date and time of upload.
Error		Error uploading result (timeout, ...).
Re-Uploading		Result being sent again.
Expired (previously uploaded)		Result cannot be uploaded anymore. It was sent successfully at least once.
Expired (never uploaded)		Result cannot be uploaded anymore. It was never sent.
Disabled		The upload of the result is disabled because the result is not final. The result can neither be uploaded automatically nor manually. This is only applicable for the test status "Canceled".

To see the detailed upload status of a single test results, perform the following steps:

1. Press the **RESULTS** button in the main navigation bar.
2. In the result overview, open a test result by tapping on the details button in the last column.
3. The Upload Status is shown in the upper part of the screen and in the **TEST DETAILS** section. The **TEST DETAILS** also contain additional information such as the upload date and potential errors that occurred during upload (Figure 77).

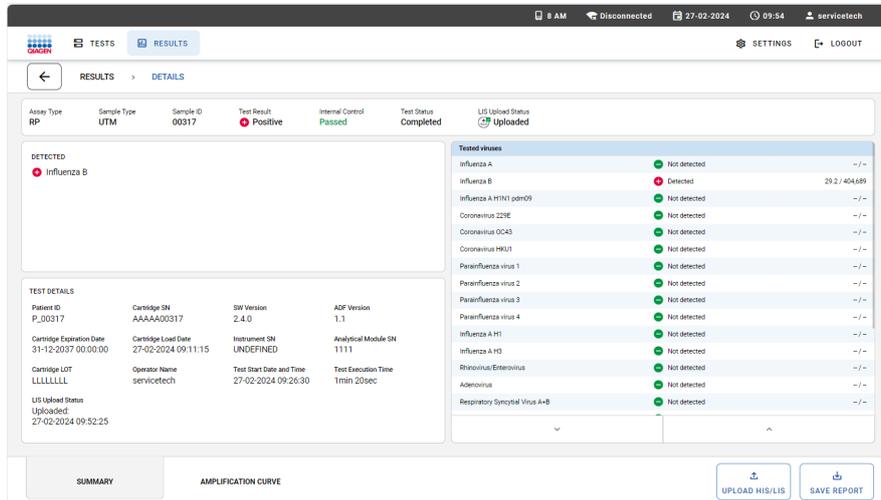


Figure 77. HIS/LIS Upload Status when viewing a test result.

7.4.3. Uploading a test result manually to HIS/LIS

To upload one or multiple test results manually to HIS/LIS, perform the following steps:

1. Press the **RESULTS** button in the main navigation bar.
2. In the result overview, select one or multiple test results by tapping on the checkbox in the first column (Figure 78).
3. Press the **UPLOAD HIS/LIS** button in the submenu bar.

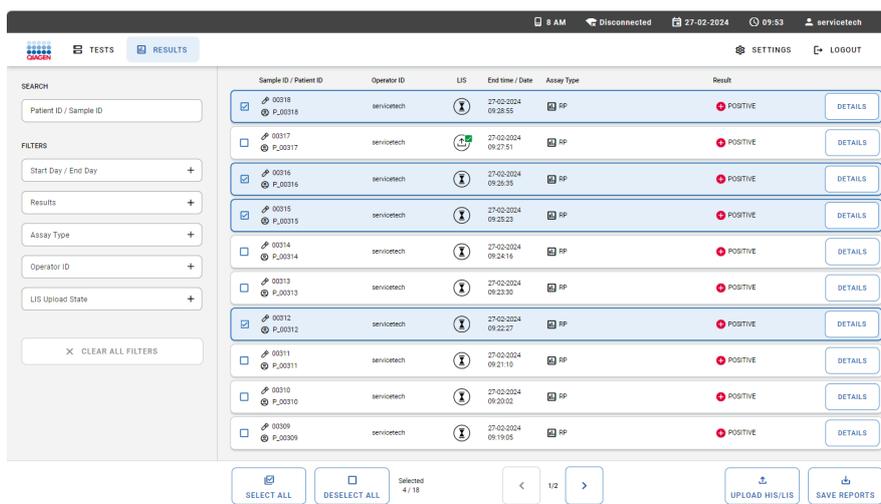


Figure 78. Selecting multiple test results for manual upload to HIS/LIS.

To upload a single test result manually to HIS/LIS, perform the following steps:

1. Press the **RESULTS** button in the main navigation bar.
2. In the result overview, open a test result by clicking the details button in the last column.
3. To upload the result, press the **UPLOAD HIS/LIS** button in the submenu bar (Figure 79).

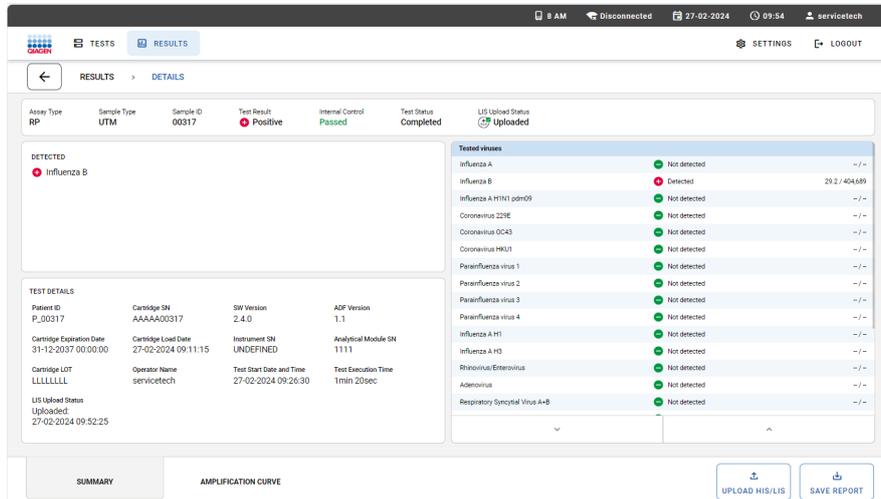


Figure 79. Manually upload a test result to HIS/LIS.

7.5. Troubleshooting host connectivity

To troubleshoot host connectivity issues, see Section 9.

8. Maintenance

This section describes the maintenance tasks required for the QIAstat-Dx Rise.

8.1. Maintenance tasks

Table 17 provides a list of maintenance tasks to be performed on the QIAstat-Dx Rise.

Table 17. Descriptions of maintenance tasks

Task	Frequency
Cleaning or decontaminating the QIAstat-Dx Rise surface	To be performed when liquids, chemicals, or biological specimens (potentially infectious) are spilled on the QIAstat-Dx Rise surface.
Cleaning or decontaminating the QIAstat-Dx Rise and Input tray	To be performed when liquids, chemicals, or biological specimens (potentially infectious) are spilled on the QIAstat-Dx Rise surface.
Exchange of air filter of the QIAstat-Dx Rise and the Analytical Modules	To be performed annually by QIAGEN Technical Services

8.2. Cleaning the QIAstat-Dx Rise surface (including the Analytical Modules)

**WARNING/
CAUTION**



Risk of personal injury and material damage

Wear protective glasses, a lab coat, and gloves when cleaning the instrument to avoid biological and chemical hazards.

**WARNING/
CAUTION**



Risk of personal injury and material damage

Disconnect the QIAstat-Dx Rise from the power outlet before cleaning.

CAUTION



Damage to the instrument

Avoid spilling water or chemicals onto the QIAstat-Dx Rise. Instrument damage caused by water or chemical spillage will void your warranty.

CAUTION



Risk of personal injury and material damage

Avoid spilling liquids on or wetting the touchscreen. To clean the touchscreen, use the screen suede provided with the QIAstat-Dx Rise.

Use the following materials to clean the QIAstat-Dx Rise outside surface:

- Mild detergent
- Paper towels
- Distilled water

Note: Do not use alcohol-based liquids or bleach, as it may damage the door and the touchscreen.

Follow the steps below to clean the QIAstat-Dx Rise and Analytical Module outer surface:

1. Wear laboratory gloves, coat, and protective glasses.
2. Wet a paper towel in mild detergent and wipe down the QIAstat-Dx Rise surface. Take care not to wet the touchscreen. To clean the touchscreen, use the screen suede provided with the QIAstat-Dx Rise.
3. Repeat step 2 three times with fresh paper towels.
4. Wet a paper towel in distilled water and wipe the surface of the QIAstat-Dx Rise to rinse away remaining detergent. Repeat two times.
5. Dry the QIAstat-Dx Rise surface with a fresh paper towel.

8.3. Decontaminating the QIAstat-Dx Rise sample and waste trays

**WARNING/
CAUTION**



Risk of personal injury and material damage

Wear protective glasses, a lab coat, and gloves when cleaning the instrument to avoid biological and chemical hazards.

Bleach is irritating to eyes and skin and may release dangerous gases (chlorine). Wear adequate personal protection equipment.

**WARNING/
CAUTION**



Risk of personal injury and material damage

Disconnect the QIAstat-Dx Rise from the power outlet before cleaning.

CAUTION



Damage to the instrument

Avoid spilling water or chemicals onto the QIAstat-Dx Rise. Instrument damage caused by water or chemical spillage will void your warranty.

CAUTION



Risk of personal injury and material damage

Avoid spilling liquids on or wetting the touchscreen. To clean the touchscreen, use the screen suede provided with the QIAstat-Dx Rise.

Use the following materials to decontaminate the QIAstat-Dx Rise trays:

- 10% bleach solution
- Paper towels
- Distilled water

Follow the steps below to decontaminate the QIAstat-Dx Rise trays:

1. Wear laboratory gloves, coat, and protective glasses.
2. Remove the trays from the instrument, avoiding spillage of liquids in your surroundings.
3. Make sure you keep track of which tray is the input tray and which tray is the waste tray. Place the trays on a flat surface with appropriate measure to collect contaminated liquids. Make sure to remove nearby equipment.
4. Wet a paper towel in 10% bleach solution and wipe down the tray surface, as well as the surrounding workbench area. Wait at least 3 minutes to allow the bleach solution to react with the contaminants.
5. Change into a new pair of gloves.
6. Repeat steps 4 and 5 two additional times with fresh paper towels.
7. Wet a paper tower in distilled water and wipe down the QIAstat-Dx Rise surface to rinse away any remaining bleach solution. Repeat twice.
8. Dry the QIAstat-Dx trays with a fresh paper towel.
9. Place the trays back into their original position. The waste and input tray must not be interchanged. Ensure that the system is only operated with both the input and the waste tray inserted into their respective drawer positions.

Important: Make sure to follow your local and laboratory guidelines for decontamination of the waste.

8.4. QIAstat-Dx Rise repair

The QIAstat-Dx Rise must only be repaired by representatives authorized by QIAGEN. If the QIAstat-Dx Rise is not working as expected, contact QIAGEN Technical Services using the contact information in Section 1.2.1.

**WARNING/
CAUTION**



Risk of personal injury and material damage

Do not open the cover or service flaps of the QIAstat-Dx Rise.

Do not open the side door of the QIAstat-Dx Rise unless prompted by the system for troubleshooting purposes. Do not attempt to repair or modify the QIAstat-Dx Rise.

Attempting to repair or modify the QIAstat-Dx Rise may result in user injury and QIAstat-Dx Rise damage and will void the warranty.

9. Troubleshooting

This section provides information about what to do if an error occurs when using the QIAstat-Dx Rise system.

If further assistance is required, contact QIAGEN Technical Services using the contact information below:

Website: support.qiagen.com

When contacting QIAGEN Technical Services about an error with the QIAstat-Dx Rise, note the steps leading up to the error and any information appearing in any dialog boxes. This information will help the QIAGEN Technical Services solve the problem.

When contacting QIAGEN Technical Services about errors, please have the following information ready:

- QIAstat-Dx Rise serial number, type, and version
- Software version
- Timepoint when the error occurred for the first time
- Frequency of error occurrence (i.e., intermittent or persistent error)
- Detailed description of the error situation
- Photo of the error, if possible
- Support package

This information will help you and your QIAGEN Technical Service Specialist to deal most efficiently with your issue.

Note: Information about the latest software and protocol versions can be found at www.qiagen.com. In some cases, updates may be available for addressing specific problems.

9.1. Remote support

The QIAstat-Dx Rise instrument comes with the capability to provide support for software related issues remotely. This includes troubleshooting procedures as well as certain service procedures such as the installation of assays.

1. To enable the remote support, a user with administrator permissions needs to press the **SETTINGS** button in the main navigation bar.
2. Select the **CONNECTIVITY** menu.
3. Press the **EDIT** button in the **REMOTE SUPPORT** panel (Figure 80).

If a message is displayed stating that “Remote support is not possible on this instrument. Please contact QIAGEN service”, the functionality is not available.

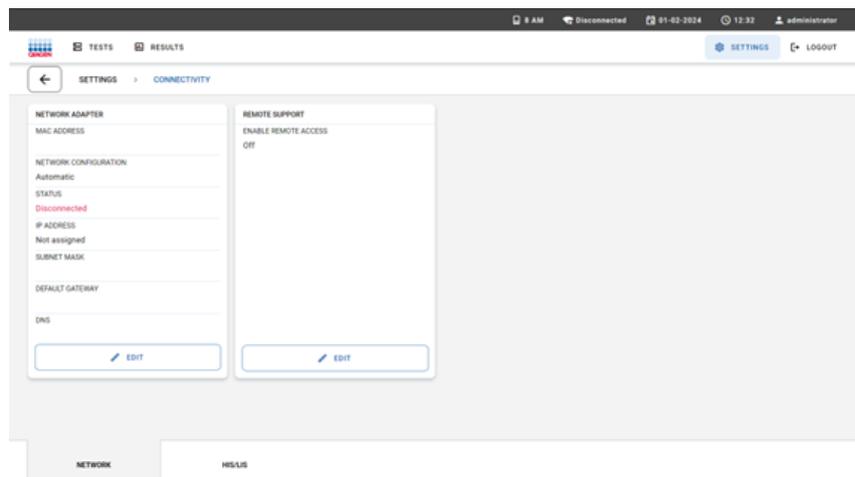


Figure 80. Connectivity settings with remote support setting.

4. Activate the **Enable Remote Access** toggle button (Figure 81).

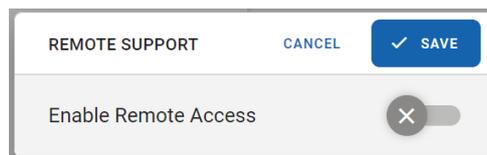


Figure 81. Enable remote access.

5. Press the **SAVE** button.

When **REMOTE SUPPORT** is enabled, the status “Connected” appears in the status bar (Figure 82).



Figure 82. Remote support enabled.

A QIAGEN service technician can now remotely connect to the instrument to deliver the desired support or troubleshooting. Service technicians can access the operating system of the instrument to view logs, backup data, or install new assays. They are not able to see content of the instrument’s screen.

After an instrument reboot, the remote support functionality is automatically disabled. To continue with remote support, enable the functionality again as described above.

Note: The status “Connected” means that it is possible for a QIAGEN service technician to connect to the instrument. It does not necessarily mean that there is an active connection.

9.2. Hardware and software errors

9.2.1. Initialization error

During the initialization, the system checks if there are cartridges in the input/waste drawers, scan station, and analytical modules (AMs). In case that cartridges are detected during the initialization, the software will guide the user through the process to restore the instrument into a safe state (Figure 83).

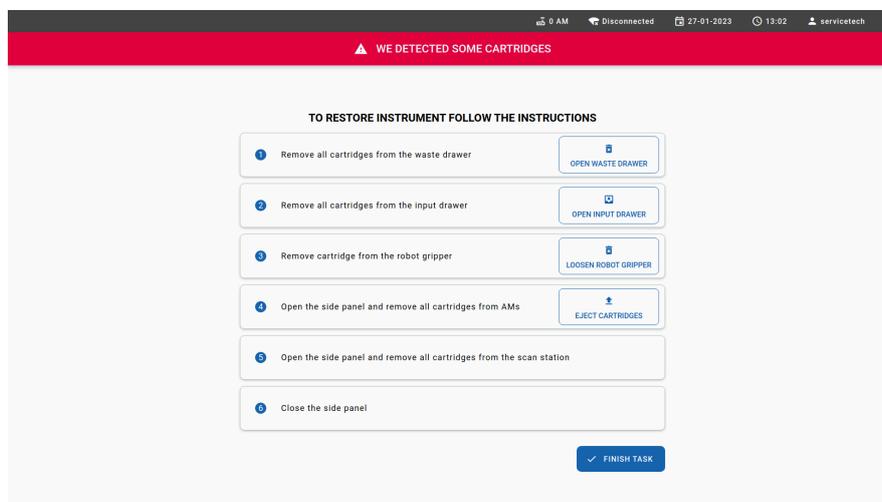


Figure 83. Cartridge recovery screen.

1. Remove all cartridges from the waste drawer by pressing the **OPEN WASTE DRAWER** button. Then pull out the waste drawer, remove all cartridges, and close the drawer again.
2. Remove all cartridges from the input drawer by pressing the **OPEN INPUT DRAWER** button. Then pull out the input drawer, remove all cartridges, and close the drawer again.
3. Press the **LOOSEN ROBOT GRIPPER** button to be able to remove cartridge from the robot gripper.
4. Press the **EJECT CARTRIDGES** button to eject cartridges from AMs which still have a cartridge inside.
5. Open the side door using the door key that was provided with the instrument.
 - a. Remove the ejected cartridges.
 - b. Remove the cartridge from the scan station.
 - c. Remove the cartridge from the robot gripper.
6. Close and lock the side door with the door key.
7. Shut down the instrument and start it up again.

If there are still cartridges detected in the instrument, the process needs to be repeated.

Note: On the recovery screen, if an AM with a cartridge does not eject the cartridge when the **EJECT CARTRIDGES** button is pressed, wait for 60 seconds and then press the button again. You can try pressing the **EJECT CARTRIDGES** button more than once if necessary. If the cartridge is still not ejected restart the instrument.

If an AM that has a cartridge inside was automatically excluded by the system, go to **SETTINGS > SYSTEM** use the toggle button to enable the AM to eject the cartridge.

9.2.2. PLC errors

The Programmable Logic Controller (PLC) is a computer inside the QIAstat-Dx Rise instrument that controls the hardware, in particular the robotic arm movements. Errors on the PLC may result in hardware damage when the robotic arm moves to a faulty position. To prevent hardware damage, the system stops when a PLC error occurs. In this event, the instrument shows a “PLC ERROR OCCURRED” message (Figure 84) and blocks the system.

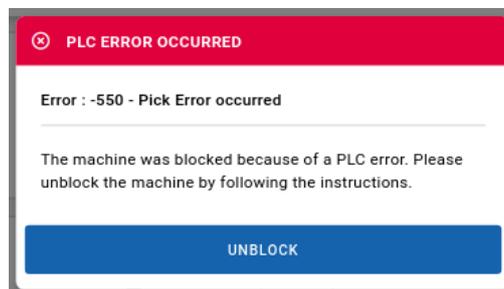


Figure 84. PLC error occurred.

To unblock the system, press the **UNBLOCK** button.

Follow the instructions shown on the screen to remove cartridges from the instrument (Figure 85).

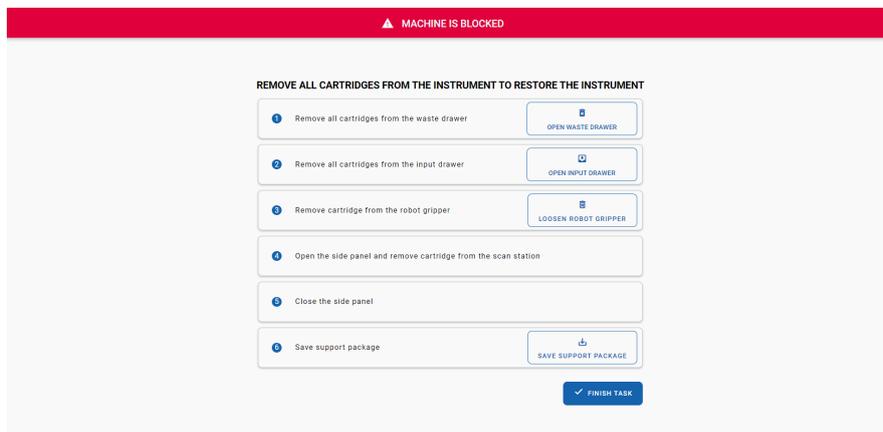


Figure 85. Manual recovery screen.

1. Remove all cartridges from the waste drawer by pressing the **OPEN WASTE DRAWER** button. Then pull out the waste drawer, remove all cartridges, and close the drawer again.
2. Remove all cartridges from the input drawer by pressing the **OPEN INPUT DRAWER** button. Then pull out the input drawer, remove all cartridges, and close the drawer again.
3. Press the **LOOSEN ROBOT GRIPPER** button to be able to remove cartridge from the robot gripper.

4. Open the side door using the door key that was provided with the instrument.
 - a. Remove the cartridge from the scan station.
 - b. Remove the cartridge from the robot gripper.
5. Close and lock the side door with the door key.

Press **SAVE SUPPORT PACKAGE** button to save the support package to a USB stick. Support package is required to be provided to QIAGEN Technical Services to investigate the root cause of the PLC error.

Note: You do not have to wait until the support package generation process to be completed to continue operating the instrument.

6. Press the **FINISH TASK** button.
7. Ensure that all cartridges except those running in the AMs are removed from the system (Figure 86).

Note: There is a high risk to damage the instrument if there are still cartridges somewhere in the instrument which have not been removed.

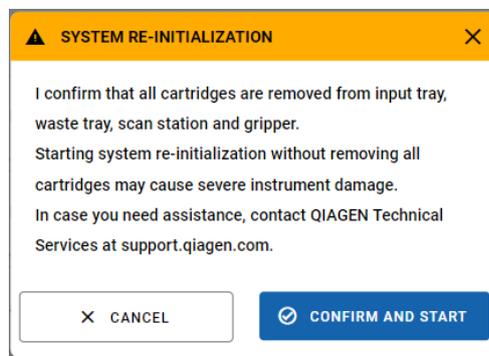


Figure 86. Manual recovery confirmation screen.

Note: No test results are generated for cartridges that are taken out of the instrument during this process. Cartridges can be reloaded again for testing within the onboard stability time.

9.2.3. System freeze

If you encounter the event of a system freeze, the QIAstat-Dx Rise instrument will stop all mechanical movements, (e.g., the robotic arm will not transport cartridges anymore). However, if there are running samples, the analytical modules are still active and will continue to process. **Do not power off the instrument (do not press on/off button on the front or the power switch on the side of the instrument).**

In case of system freeze, follow the instructions below.

1. If samples are running in the analytical modules, please wait until all the runs are completed.
2. Shut down the instrument (by pressing the power switch on the side the instrument) and wait for at least 1 minute.
3. Power on the instrument (by pressing the power switch on the side of the instrument).
4. Press the **on/off** button on the front of the instrument.
5. After restart and login, during initialization, there will be a recovery procedure that can be tracked on the GUI (refer to Section 9.2.1).
6. The unprocessed cartridges can be reintroduced to the instrument following the usual loading procedure. The instrument will reject samples that have exceeded the maximum stability time/onboard time. Please refer to the assay instructions for use for the details.

9.2.4. Analytical Module (AM) errors

In case of an AM error, the status LED of the AM will turn red and an error message is displayed in the GUI.

If such an error occurs, restarting the AM may solve the problem. To do this, go to **SETTINGS > SYSTEM** then tap on the AM that is in the error state and use AM restart button to restart the AM.

If the restart works, the AM will become active again and if there is a cartridge in it, the cartridge will be ejected and wasted. If the cartridge is canceled (due to the AM error), it can be reloaded into the instrument if the onboard stability time is not exceeded.

If the AM error persists, disable the AM and please contact QIAGEN Technical Services for support.

9.3. Error and warning messages

Error Category: MC hardware

Error Code	Message
0x00100000	Generic MC HW Error.
0x00100001	The instrument cannot be initialized, there are doors/panels opened. Make sure that all doors and panels are closed and restart the instrument. Please call Technical Support.
0x00100002	The robotic arm and/or the scan station could not be initialized and cannot be used. Please call Technical Support.
0x00100003	The instrument did not become initialized within max time range. Please call Technical Support.
0x00100004	The instrument does not support AMs configuration: Supported configurations: minimum 2 AMs (must be in slot 3 and 4) or more than 3. Once the Analytical Modules are properly configured, restart the instrument. Please call Technical Support.
0x00100005	Initialization error: cartridge discovered in both Robotic Arm gripper and Scan Station. The cartridge from the Scan Station needs to be removed. Please call Technical Support.

Error Category: MC file system

Error Code	Message
0x00110000	Generic OS Error
0x00110001	Can't save data to USB. Check if space is enough or USB is in read-only status.
0x00110002	No valid USB drive found. Insert a valid USB drive into one of the instrument USB ports to proceed.
0x00110003	An error occurred during report directory creation. Please call Technical Support.

Error Category: Assay management

Error Code	Message
0x00120000	(Reserved for future Generic Error in Assay Management)
0x00120001	An assay has invalid CRC.
0x00120002	No assay definition file found on this drive! Please ensure the .asy file is correctly copied or select a different drive.
0x00120003	No assay in required ADF version.

Error Category: Results and PDF report

Error Code	Message
0x00121000	(Reserved for future Generic Error in Results or PDF Report Generation)
0x00121001	Result details not found.
0x00121002	Could not generate a report. Please call Technical Support.
0x00121003	Result not found during report generation.

Error Category: Assay execution

Error Code	Message
0x00122000	(Reserved for future Generic Assay Execution & Result Processing Error)
0x00122001	The Analytical Module reported that the cartridge is the wrong type.
0x00122002	The Analytical Module reported an AAF CRC error.
0x00122003	The Analytical Module reported an AAF parsing error.
0x00122004	The Analytical Module reported a calibration data length error.
0x00122005	The Analytical Module reported a calibration data CRC error.
0x00122006	The Analytical Module reported that the AAF was too long.
0x00122007	Test run failed: encountered an issue during procedure.
0x00122008	Could not extract cartridge from AM due to an unspecified error.
0x00122009	Analytical Module is not ready for cartridge extraction.
0x0012200A	Analytical Module: Cartridge is already used.
0x0012200B	Analytical Module: Status update timeout exceeded after manual recovery.
0x0012200C	The Analytical Module reported a barcode scan error.
0x0012200D	The Analytical Module reported a test fault error.
0x0012200E	The Analytical Module reported a lid opening error during cartridge insertion. Please call Technical Support.
0x0012200F	The Analytical Module reported a lid closing error during cartridge insertion. Please call Technical Support.
0x00122010	The Analytical Module reported a lid opening error during cartridge extraction. Please call Technical Support.
0x00122011	The Analytical Module reported a lid closing error during cartridge extraction. Please call Technical Support.
0x00122012	The Analytical Module reported a fault error. Please restart the AM. If the error reappears, please call Technical Support.
0x00122013	Test Run could not be started. A recoverable error occurred in Analytical Module.
0x00122014	The Analytical Module reported a homing error. Please restart the AM. If the error reappears, please call Technical Support.
0x00122015	The Analytical Module reported a FW CRC error. Please restart the AM. If the error reappears, please call Technical Support.
0x00122016	The Analytical Module reported a FW Flashing error. Please restart the AM. If the error reappears, please call Technical Support.

Error Category: Cartridge preprocessing and validation

Error Code	Message
0x00123100	(Reserved for future Generic cartridge preprocessing error)
0x00123101	Another cartridge with the given barcode is already in the input drawer.
0x00123102	The cartridge is expired.
0x00123103	Stability time has been exceeded.
0x00123104	There is no assay for given cartridge ID.
0x00123105	The cartridge was already used.
0x00123106	The cartridge's barcode is not valid.
0x00123107	The sample ID is empty.
0x00123108	The sample ID barcode is not valid.

Error Category: Input drawer

Error Code	Message
0x00123200	Input drawer: Unspecified error.
0x00123201	Input drawer error: couldn't read sample id. Remove cartridge <cartridge ID> from the waste drawer and ensure that the sample ID barcode is readable. Then reload cartridge before stability time <timestamp> is exceeded.
0x00123202	Input drawer error: invalid sample id. Remove cartridge <cartridge ID> from the waste drawer and ensure that the sample ID is valid. Then reload cartridge before stability time <timestamp> is exceeded.
0x00123203	Input drawer error: no available assay for cartridge. Remove cartridge <cartridge ID> from the waste drawer and contact QIAGEN service to import the assay.
0x00123204	Input drawer error: cartridge <cartridge ID> is expired. Cartridge is wasted and cannot be reloaded.
0x00123205	Input drawer error: onboard stability time has been exceeded. Cartridge <cartridge ID> is wasted and cannot be reloaded.
0x00123206	Input drawer error: Cartridge <cartridge ID> is already used. A test result for this cartridge should already be available. Cartridge is wasted and cannot be reloaded.
0x00123207	Input drawer error: The cartridge assay does not match with the LIS order. Remove cartridge <cartridge ID> from the waste drawer and ensure that the LIS order matches the cartridge or that the correct cartridge is prepared.
0x00123208	Input drawer error: no LIS order found. Remove cartridge <cartridge ID> from the waste drawer and create a LIS order or disable Force Order. Then reload cartridge before stability time <timestamp> is exceeded.
0x00123209	Input drawer error: Sample type in LIS order does not match the manually entered Sample type. Remove cartridge <cartridge ID> from the waste drawer and correct test data. Then reload cartridge before stability time <timestamp> is exceeded.
0x0012320A	Input drawer error: Patient ID is mandatory but missing in the LIS order. Remove cartridge <cartridge ID> from the waste drawer and ensure that a patient ID is provided in the LIS order. Then reload cartridge before stability time <timestamp> is exceeded.
0x0012320B	Input drawer error: Patient ID in LIS order does not match the manually entered patient ID. Remove cartridge <cartridge ID> from the waste drawer and ensure that the patient ID in the LIS order matches with the test data. Then reload cartridge before stability time <timestamp> is exceeded.
0x0012320C	Input drawer error: No matching assay found in LIS order. Remove Cartridge <cartridge ID> from the waste drawer and create a LIS order with an installed assay, have the assay installed or disable Force Order. Then reload cartridge before stability time <timestamp> is exceeded.
0x0012320D	Input drawer error: No matching sample found in LIS order. Remove Cartridge <cartridge ID> from the waste drawer and create a LIS order with a valid sample or disable Force Order. Then reload cartridge before stability time <timestamp> is exceeded.
0x0012320E	Input drawer error: Timeout while scanning the input tray. Remove all cartridges and contact QIAGEN service

Error Category: Scan station

Error Code	Message
0x00123300	Scan station: Unspecified error.
0x00123301	Scan station error: cartridge was not fully scanned. Remove cartridge <cartridge ID> from the waste drawer and ensure that barcodes are readable. Then reload cartridge before stability time <timestamp> is exceeded.
0x00123302	Scan station error: sample ID is not readable. Remove cartridge <cartridge ID> from the waste drawer and ensure that the sample ID barcode is readable. Then reload cartridge before stability time <timestamp> is exceeded.
0x00123303	
0x00123304	Scan station: unknown sample ID. Remove cartridge <cartridge ID> from the waste drawer. Then reload cartridge before stability time <timestamp> is exceeded.
0x00123305	Scan station: unknown cartridge ID. Remove cartridge from the waste drawer. Then reload cartridge before stability time <timestamp> is exceeded.
0x00123306	Scan station error: cartridge's barcode is not readable or invalid. Remove cartridge <cartridge ID> from the waste drawer and ensure that the cartridge barcode is readable. Then reload cartridge before stability time <timestamp> is exceeded.
0x00123307	Scan station error: cartridge is expired. Cartridge is wasted and cannot be reloaded.
0x00123308	Scan station error: cartridge has already been executed. A test result for this cartridge should already be available. Cartridge is wasted and cannot be reloaded.
0x00123309	Scan station error: detected sample type is incompatible with the used assay. Cartridge is wasted and cannot be reloaded.
0x0012330A	Scan station error: onboard stability time has been exceeded. Cartridge is wasted and cannot be reloaded.
0x0012330B	Scan station error: invalid data after scan detected. Remove cartridge Cartridge <cartridge ID> from the waste drawer and correct the data. Then reload cartridge before stability time <timestamp> is exceeded.
0x0012330C	Scan station error: no available assay for given cartridge. Remove Cartridge <cartridge ID> from the waste drawer and contact QIAGEN service to import the assay. Then reload cartridge before stability time <timestamp> is exceeded.
0x0012330D	Scan station error: no assay in required ADF version. Remove cartridge <cartridge ID> from the waste drawer and contact QIAGEN service to import the assay. Then reload cartridge before stability time <timestamp> is exceeded.
0x0012330E	Scan station error: The cartridge assay does not match with the LIS order. Remove cartridge <cartridge ID> from the waste drawer and ensure that the LIS order matches the cartridge or that the correct cartridge is prepared.

Error Category: Waste drawer

Error Code	Message
0x00123400	Waste drawer error: Unspecified error.
0x00123401	Waste drawer error: There are no available slots in the waste drawer to dispose of a cartridge from Analytical Module.
0x00123402	Waste drawer: only {0} slots left.
0x00123403	Remove cartridges from the waste drawer.
0x00123404	System blocked. Remove cartridges from the waste drawer.

Error Category: Miscellaneous scheduling, pre- and postprocessing

Error Code	Message
0x00123F0A	Unknown test run found in the scan station/gripper.
0x00123F17	Could not insert cartridge to AM due to an unspecified error.
0x00123F18	Test run preparation in AM failed.
0x00123F23	The temperature inside the instrument has been exceeded. Cartridge is wasted and cannot be reloaded.
0x00123F24	Aborted after improper shutdown. Cartridge is wasted and cannot be reloaded.
0x00123F25	The test run execution was manually aborted by the operator {0}. Cartridge is wasted and cannot be reloaded.
0x00123F26	Test Run cannot be aborted. Please try again later.
0x00123F27	The test run execution was manually canceled by the operator <operator> Cartridge <cartridge ID> can be removed from the waste drawer and reloaded before stability time <timestamp> is exceeded.

Error Category: Internal communication

Error Code	Message
0x00124000	Generic internal communication error.
0x00124001	MC not reachable. Please call Technical Support.
0x00124002	Connection error: PLC is not reachable from Master Controller. Please call Technical Support.
0x00124003	PLC firmware version is not compatible with MC Rise application. Please call Technical Support
0x00124004	Scheduled command to PLC has not been processed within max time range. Please call Technical Support.
0x00124005	Scheduled command to PLC has not been accepted.
0x00124006	Scheduled command to PLC returned an error.

Error Category: User management

Error Code	Message
0x00125000	Generic user management error.
0x00125001	The Operator ID or password is incorrect.
0x00125002	The user CRC check for some of the users failed.

Error Category: HIS/LIS

Error Code	Message
0x00126000	Generic HIS/LIS error.
0x00126001	The number of selected results to be uploaded exceeds the maximum size of the upload queue. Please unselect some results.
0x00001001	No connection to HIS/LIS.
0x00001002	No connection to HIS/LIS.
0x00001003	No connection to HIS/LIS.
0x00001010	Upload queue full.
0x00001011	Upload queue cleared.
0x00001020	Message type mismatch.
0x00001021	Processing ID mismatch.
0x00001022	Protocol version mismatch.
0x00001023	Message control id mismatch.
0x00001024	Parse error.
0x00001030	Wrong query tag.
0x00001031	Order not found.
0x00001032	Order not found.
0x00001033	Sample ID mismatch.
0x00001034	Ordered assay not installed.
0x00001035	Unknown sample type.
0x00001036	Assay not in order list.
0x00001037	Sample type mismatch.
0x00001064	Message segments not in proper order.
0x00001065	The required field is missing.
0x00001066	Wrong data type.
0x00001067	Field data identifier mismatch
0x00001068	HIS/LIS internal error.
0x000010C8	Unsupported message type.
0x000010C9	Unsupported event code.
0x000010CA	Unsupported processing ID.
0x000010CB	Unsupported version ID.
0x000010CC	ID not found.
0x000010CD	Order already in process.
0x000010CE	Server not available.
0x000010CF	HIS/LIS internal error.

Error Category: Support package

Error Code	Message
0x00128000	(Reserved for future Generic Support Package Error)
0x00128001	An error occurred during support package directory creation. Please call Technical Support.
0x00128002	Could not generate a support package file. Please call Technical Support.
0x00128003	Could not write results to file for support package. Please call Technical Support.

Error Category: AAF errors

Error Code	Message
0x0Y000067	Failure on cartridge clamping. Cartridge can be reused. If this error persists, please contact QIAGEN Technical Services
0x0Y000068	Failure on cartridge clamping. Cartridge can be reused. If this error persists, please contact QIAGEN Technical Services
0x0Y000069	Atmospheric pressure is out of the analytical module's operational range. Please contact QIAGEN Technical Services
0x0Y0000EF	Failure on PCR readings. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y0000F1	Failure on PCR readings. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y0000F2	Failure on PCR readings. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y0000F3	Failure on PCR readings. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y0000F4	Failure on PCR readings. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y0000F5	Failure on PCR readings. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y0000F6	Failure on PCR readings. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y0000F7	Failure on PCR readings. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y0000F8	Failure on PCR readings. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y0000F9	Failure on PCR readings. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y0000FD	Failure on PCR readings. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y0000FE	Failure on PCR readings. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y0000FF	Failure on PCR readings. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y00012E	Cartridge execution failure : Please retry another cartridge
0x0Y000137	Cartridge execution failure : Please retry another cartridge
0x0Y000138	Cartridge execution failure : Please retry another cartridge
0x0Y000139	Cartridge execution failure : Please retry another cartridge
0x0Y000154	Cartridge execution failure : Please retry another cartridge
0x0Y00016D	Cartridge execution failure : Please retry another cartridge
0x0Y00016E	Cartridge execution failure : Please retry another cartridge
0x0Y00016F	Cartridge execution failure : Please retry another cartridge
0x0Y000170	Cartridge execution failure : Please retry another cartridge
0x0Y000171	Cartridge execution failure : Please retry another cartridge
0x0Y00019B	Cartridge execution failure : Please retry another cartridge and verify that the Swab lid is correctly closed

Error Category: AAF errors

Error Code	Message
0x0Y00019C	Cartridge execution failure : Please retry another cartridge
0x0Y00019D	Cartridge execution failure : Please retry another cartridge and if sample type is Swab follow the IFU for proper swab use and insertion
0x0Y0001B8	Cartridge execution failure : Please retry another cartridge
0x0Y0001F6	Cartridge execution failure : Please retry another cartridge
0x0Y0001FF	Cartridge execution failure : Please retry another cartridge
0x0Y000200	Cartridge execution failure : Please retry another cartridge
0x0Y000201	Cartridge execution failure : Please retry another cartridge and if sample type is Swab follow the IFU for proper swab use and insertion
0x0Y00021C	Cartridge execution failure : Please retry another cartridge
0x0Y00025A	Cartridge execution failure : Please retry another cartridge
0x0Y000263	Cartridge execution failure : Please retry another cartridge and verify that the Swab and Bead Beater lid are properly closed
0x0Y000264	Cartridge execution failure : Please retry another cartridge
0x0Y000265	Cartridge execution failure : Please retry another cartridge
0x0Y000280	Cartridge execution failure : Please retry another cartridge
0x0Y00028A	Cartridge execution failure : Please retry another cartridge
0x0Y00028B	Cartridge execution failure : Please retry another cartridge
0x0Y00028C	Cartridge execution failure : Please retry another cartridge
0x0Y000290	Cartridge execution failure : Please retry another cartridge
0x0Y000291	Cartridge execution failure : Please retry another cartridge
0x0Y000292	Cartridge execution failure : Please retry another cartridge
0x0Y0002BE	Cartridge execution failure : Please retry another cartridge
0x0Y0002C7	Cartridge execution failure : Please retry another cartridge
0x0Y0002C8	Cartridge execution failure : Please retry another cartridge
0x0Y0002C9	Cartridge execution failure : Sample concentration too high. Please dilute and retry another cartridge
0x0Y000322	Cartridge execution failure : Please retry another cartridge
0x0Y00032B	Cartridge execution failure : Please retry another cartridge
0x0Y00032C	Cartridge execution failure : Please retry another cartridge
0x0Y00032D	Cartridge execution failure : Sample concentration too high. Please dilute and retry another cartridge
0x0Y000386	Cartridge execution failure : Please retry another cartridge
0x0Y00038F	Cartridge execution failure : Please retry another cartridge
0x0Y000390	Cartridge execution failure : Please retry another cartridge
0x0Y000391	Cartridge execution failure : Please retry another cartridge
0x0Y0003EA	Cartridge execution failure : Please retry another cartridge
0x0Y0003F3	Cartridge execution failure : Please retry another cartridge
0x0Y0003F4	Cartridge execution failure : Please retry another cartridge

Error Category: AAF errors

Error Code	Message
0x0Y00044E	Cartridge execution failure : Please retry another cartridge
0x0Y000457	Cartridge execution failure : Please retry another cartridge
0x0Y000458	Cartridge execution failure : Please retry another cartridge
0x0Y000459	Cartridge execution failure : Sample concentration too high. Please dilute and retry another cartridge
0x0Y00045A	Cartridge execution failure : Sample concentration too high. Please dilute and retry another cartridge
0x0Y0004B2	Cartridge execution failure : Please retry another cartridge
0x0Y0004BB	Cartridge execution failure : Please retry another cartridge
0x0Y0004BC	Cartridge execution failure : Please retry another cartridge
0x0Y0004BD	Cartridge execution failure : Please retry another cartridge
0x0Y0004BF	Cartridge execution failure : Sample concentration too high. Please dilute and retry another cartridge
0x0Y000516	Cartridge execution failure : Please retry another cartridge
0x0Y00051F	Cartridge execution failure : Please retry another cartridge
0x0Y000520	Cartridge execution failure : Please retry another cartridge
0x0Y000521	Cartridge execution failure : Please retry another cartridge
0x0Y000524	Cartridge execution failure : Sample concentration too high. Please dilute and retry another cartridge
0x0Y00057A	Cartridge execution failure : Please retry another cartridge
0x0Y000583	Cartridge execution failure : Please retry another cartridge
0x0Y000585	Cartridge execution failure : Please retry another cartridge
0x0Y000586	Cartridge execution failure : Please retry another cartridge
0x0Y00058A	Cartridge execution failure : Please retry another cartridge
0x0Y00058B	Cartridge execution failure : Sample concentration too high. Please dilute and retry another cartridge
0x0Y0005DE	Cartridge execution failure : Please retry another cartridge
0x0Y0005E9	Cartridge execution failure : Sample concentration too high. Please dilute and retry another cartridge
0x0Y0005EE	Cartridge execution failure : Please retry another cartridge
0x0Y000642	Cartridge execution failure : Please retry another cartridge
0x0Y00064B	Cartridge execution failure : Please retry another cartridge
0x0Y00064C	Cartridge execution failure : Please retry another cartridge
0x0Y00064D	Cartridge execution failure : Please retry another cartridge
0x0Y0006A6	Cartridge execution failure : Please retry another cartridge
0x0Y0006AF	Cartridge execution failure : Please retry another cartridge
0x0Y0006B0	Cartridge execution failure : Please retry another cartridge
0x0Y0006B1	Cartridge execution failure : Please retry another cartridge
0x0Y00076E	Cartridge execution failure : Please retry another cartridge
0x0Y000777	Cartridge execution failure : Please retry another cartridge
0x0Y000778	Cartridge execution failure : Sample concentration too high. Please dilute and retry another cartridge

Error Category: AAF errors

Error Code	Message
0x0Y00077D	Cartridge execution failure : Sample concentration too high. Please dilute and retry another cartridge
0x0Y0007D2	Cartridge execution failure : Please retry another cartridge
0x0Y0007DB	Cartridge execution failure : Please retry another cartridge
0x0Y0007DC	Cartridge execution failure : Please retry another cartridge
0x0Y0007E1	Cartridge execution failure : Please retry another cartridge
0x0Y0007F8	Cartridge execution failure : Please retry another cartridge
0x0Y000816	Cartridge execution failure : Please retry another cartridge
0x0Y000817	Cartridge execution failure : Please retry another cartridge
0x0Y000818	Failure during PCR preparation. Please retry another cartridge. If this error persists please contact QIAGEN Technical Services
0x0Y000819	Cartridge execution failure : Please retry another cartridge
0x0Y00081F	Cartridge execution failure : Please retry another cartridge
0x0Y000836	Cartridge execution failure : Please retry another cartridge
0x0Y00083F	Cartridge execution failure : Please retry another cartridge
0x0Y00087E	Cartridge execution failure : Please retry another cartridge
0x0Y00087F	Cartridge execution failure : Please retry another cartridge
0x0Y000880	Cartridge execution failure : Please retry another cartridge
0x0Y000881	Cartridge execution failure : Please retry another cartridge
0x0Y000882	Cartridge execution failure : Please retry another cartridge
0x0Y0008A3	Cartridge execution failure : Please retry another cartridge
0x0Y0008DE	Cartridge execution failure : Please retry another cartridge
0x0Y0008E8	Cartridge execution failure : Please retry another cartridge
0x0Y0008E9	Cartridge execution failure : Please retry another cartridge
0x0Y000819	Cartridge execution failure : Please retry another cartridge
0x0Y00081F	Cartridge execution failure : Please retry another cartridge
0x0Y000836	Cartridge execution failure : Please retry another cartridge
0x0Y00083F	Cartridge execution failure : Please retry another cartridge
0x0Y00087E	Cartridge execution failure : Please retry another cartridge
0x0Y00087F	Cartridge execution failure : Please retry another cartridge
0x0Y000880	Cartridge execution failure : Please retry another cartridge
0x0Y000881	Cartridge execution failure : Please retry another cartridge
0x0Y000882	Cartridge execution failure : Please retry another cartridge
0x0Y0008A3	Cartridge execution failure : Please retry another cartridge
0x0Y0008DE	Cartridge execution failure : Please retry another cartridge
0x0Y0008E8	Cartridge execution failure : Please retry another cartridge
0x0Y0008E9	Cartridge execution failure : Please retry another cartridge
0x0Y0008EF	Failure while PCR Preparation (dosing). Please retry another cartridge. If this error persist please contact QIAGEN Technical Services

Error Category: AAF errors

Error Code	Message
0x0Y0008F0	Failure while PCR Preparation (dosing). Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y000907	Cartridge execution failure : Please retry another cartridge
0x0Y000942	Cartridge execution failure : Please retry another cartridge
0x0Y00094D	Failure while PCR Preparation (dosing). Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y00094E	Failure while PCR Preparation (dosing). Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y00094F	Failure while PCR Preparation (dosing). Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y000950	Failure while PCR Preparation (dosing). Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y000951	Failure while PCR Preparation (dosing). Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y000952	Failure while PCR Preparation (dosing). Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y000953	Failure while PCR Preparation (dosing). Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y00096B	Cartridge execution failure : Please retry another cartridge
0x0Y00096C	Cartridge execution failure : Please retry another cartridge
0x0Y000988	Cartridge execution failure : Please retry another cartridge
0x0Y0009B0	Cartridge execution failure : Please retry another cartridge
0x0Y0009CF	Cartridge execution failure : Please retry another cartridge
0x0Y0009EC	Cartridge execution failure : Please retry another cartridge
0x0Y000A1E	Cartridge execution failure : Please retry another cartridge
0x0Y000A1F	Failure while PCR Preparation (dispensing). Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y000A20	Failure while PCR Preparation (dispensing). Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y000A21	Failure while PCR Preparation (dispensing). Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y000A22	Failure while PCR Preparation (dispensing). Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y000A23	Failure while PCR Preparation (dispensing). Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y000A24	Failure while PCR Preparation (dispensing). Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y000A25	Failure while PCR Preparation (dispensing). Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y000AAA	Failure while executing PCR. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y000AAB	Failure while executing PCR. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y000AAC	Failure while executing PCR. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y000AAD	Failure while executing PCR. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y000AAE	Failure while executing PCR. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y000AAF	Failure while executing PCR. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y000AB0	Failure while executing PCR. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services

Error Category: AAF errors

Error Code	Message
0x0Y001A50	Failure while executing PCR. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y001A51	Failure while executing PCR. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y001A52	Failure while executing PCR. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y001A54	Failure while executing PCR. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y001AAE	Failure while executing PCR. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y001AAF	Failure while executing PCR. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y001AB0	Failure while executing PCR. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y001AB1	Failure while executing PCR. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y001AB2	Failure while executing PCR. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y001AB3	Failure while executing PCR. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y001AB4	Failure while executing PCR. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y001AB5	Failure while executing PCR. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y001AB6	Failure while executing PCR. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services
0x0Y0001AB8	Failure while executing PCR. Please retry another cartridge. If this error persist please contact QIAGEN Technical Services

Error Category: AM errors

Error Code	Message
0x0Y008025	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008026	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008027	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008028	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008029	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y00802A	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y00802B	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y00802C	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y00802E	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y00807F	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008080	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008081	Failure on assay execution. Please contact QIAGEN Technical Services
0x0Y0080FF	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008100	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008101	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008102	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008103	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008104	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008105	Failure on analytical module. Please contact QIAGEN Technical Services

Error Category: AM errors

Error Code	Message
0x0Y008106	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008107	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y00813F	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008140	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008141	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y00817F	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008180	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008181	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y0081FF	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008200	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008201	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008202	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008203	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008204	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008205	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008206	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008207	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008208	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008209	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y00820A	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y00820B	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y00822F	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008230	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008231	Failure on qPCR stage. Please contact QIAGEN Technical Services
0x0Y008232	Failure on qPCR stage. Please contact QIAGEN Technical Services
0x0Y008233	Failure on syringe positioning. Please contact QIAGEN Technical Services
0x0Y008234	Failure Thermal Unit motor positioning. Please contact QIAGEN Technical Services
0x0Y008235	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008236	Failure on qPCR stage. Please contact QIAGEN Technical Services
0x0Y008237	Failure on syringe positioning. Please contact QIAGEN Technical Services
0x0Y008238	Failure Thermal Unit motor positioning. Please contact QIAGEN Technical Services
0x0Y008250	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008251	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008252	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008253	Failure on analytical module. Please contact QIAGEN Technical Services

Error Category: AM errors

Error Code	Message
0x0Y008254	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008255	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y0082A0	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y0082A1	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y0082A2	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y0082A3	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y0082FF	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008300	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008301	Motor Failure (TC1). Please contact QIAGEN Technical Services
0x0Y008302	Motor Failure (TC2). Please contact QIAGEN Technical Services
0x0Y008303	Motor Failure (CC). Please contact QIAGEN Technical Services
0x0Y008304	Motor Failure (BB). Please contact QIAGEN Technical Services
0x0Y008305	Motor Failure (Lid). Please contact QIAGEN Technical Services
0x0Y008306	Motor Failure (TC1). Please contact QIAGEN Technical Services
0x0Y008307	Motor Failure (TC2). Please contact QIAGEN Technical Services
0x0Y008308	Motor Failure (CC). Please contact QIAGEN Technical Services
0x0Y008309	Motor Failure (BB). Please contact QIAGEN Technical Services
0x0Y00830A	Motor Failure (Lid). Please contact QIAGEN Technical Services
0x0Y00830B	Motor Failure (TC1). Please contact QIAGEN Technical Services
0x0Y00830C	Motor Failure (TC2). Please contact QIAGEN Technical Services
0x0Y00830D	Motor Failure (CC). Please contact QIAGEN Technical Services
0x0Y00830E	Motor Failure (BB). Please contact QIAGEN Technical Services
0x0Y00830F	Motor Failure (Lid). Please contact QIAGEN Technical Services
0x0Y008310	Motor Failure (TC1). Please contact QIAGEN Technical Services
0x0Y008311	Motor Failure (TC2). Please contact QIAGEN Technical Services
0x0Y008312	Motor Failure (CC). Please contact QIAGEN Technical Services
0x0Y008313	Motor Failure (BB). Please contact QIAGEN Technical Services
0x0Y008314	Motor Failure (Lid). Please contact QIAGEN Technical Services
0x0Y008315	Motor Failure (TC1). Please contact QIAGEN Technical Services
0x0Y008316	Motor Failure (TC2). Please contact QIAGEN Technical Services
0x0Y008317	Motor Failure (CC). Please contact QIAGEN Technical Services
0x0Y008318	Motor Failure (BB). Please contact QIAGEN Technical Services
0x0Y008319	Motor Failure (Lid). Please contact QIAGEN Technical Services
0x0Y00831A	Motor Failure (TC1). Please contact QIAGEN Technical Services
0x0Y00831B	Motor Failure (TC2). Please contact QIAGEN Technical Services

Error Category: AM errors

Error Code	Message
0x0Y00831C	Motor Failure (CC). Please contact QIAGEN Technical Services
0x0Y00831D	Motor Failure (BB). Please contact QIAGEN Technical Services
0x0Y00831E	Motor Failure (Lid). Please contact QIAGEN Technical Services
0x0Y00831F	Motor Failure (TC1). Please contact QIAGEN Technical Services
0x0Y008320	Motor Failure (TC2). Please contact QIAGEN Technical Services
0x0Y008321	Motor Failure (CC). Please contact QIAGEN Technical Services
0x0Y008322	Motor Failure (BB). Please contact QIAGEN Technical Services
0x0Y008323	Motor Failure (Lid). Please contact QIAGEN Technical Services
0x0Y008324	Motor Failure (TC1). Please contact QIAGEN Technical Services
0x0Y008325	Motor Failure (TC2). Please contact QIAGEN Technical Services
0x0Y008326	Motor Failure (CC). Please contact QIAGEN Technical Services
0x0Y008327	Motor Failure (BB). Please contact QIAGEN Technical Services
0x0Y008328	Motor Failure (Lid). Please contact QIAGEN Technical Services
0x0Y008329	Motor Failure (TC1). Please contact QIAGEN Technical Services
0x0Y00832A	Motor Failure (TC2). Please contact QIAGEN Technical Services
0x0Y00832B	Motor Failure (CC). Please contact QIAGEN Technical Services
0x0Y00832C	Motor Failure (BB). Please contact QIAGEN Technical Services
0x0Y00832D	Motor Failure (Lid). Please contact QIAGEN Technical Services
0x0Y00832E	Motor Failure (TC1). Please contact QIAGEN Technical Services
0x0Y00832F	Motor Failure (TC2). Please contact QIAGEN Technical Services
0x0Y008330	Motor Failure (CC). Please contact QIAGEN Technical Services
0x0Y008331	Motor Failure (BB). Please contact QIAGEN Technical Services
0x0Y008332	Motor Failure (Lid). Please contact QIAGEN Technical Services
0x0Y008333	Motor Failure (TC1). Please contact QIAGEN Technical Services
0x0Y008334	Motor Failure (TC2). Please contact QIAGEN Technical Services
0x0Y008335	Motor Failure (CC). Please contact QIAGEN Technical Services
0x0Y008336	Motor Failure (BB). Please contact QIAGEN Technical Services
0x0Y008337	Motor Failure (Lid). Please contact QIAGEN Technical Services
0x0Y008338	Motor Failure (TC1). Please contact QIAGEN Technical Services
0x0Y008339	Motor Failure (TC2). Please contact QIAGEN Technical Services
0x0Y00833A	Motor Failure (CC). Please contact QIAGEN Technical Services
0x0Y00833B	Motor Failure (BB). Please contact QIAGEN Technical Services
0x0Y00833C	Motor Failure (Lid). Please contact QIAGEN Technical Services
0x0Y00833D	Motor Failure (TC1). Please contact QIAGEN Technical Services
0x0Y00833E	Motor Failure (TC2). Please contact QIAGEN Technical Services
0x0Y00833F	Motor Failure (CC). Please contact QIAGEN Technical Services

Error Category: AM errors

Error Code	Message
0x0Y008340	Motor Failure (BB). Please contact QIAGEN Technical Services
0x0Y008341	Motor Failure (Lid). Please contact QIAGEN Technical Services
0x0Y008342	Motor Failure (TC1). Please contact QIAGEN Technical Services
0x0Y008343	Motor Failure (TC2). Please contact QIAGEN Technical Services
0x0Y008344	Motor Failure (CC). Please contact QIAGEN Technical Services
0x0Y008345	Motor Failure (BB). Please contact QIAGEN Technical Services
0x0Y008346	Motor Failure (Lid). Please contact QIAGEN Technical Services
0x0Y008347	Motor Failure (TC1). Please contact QIAGEN Technical Services
0x0Y008348	Motor Failure (TC2). Please contact QIAGEN Technical Services
0x0Y008349	Motor Failure (CC). Please contact QIAGEN Technical Services
0x0Y00834A	Motor Failure (BB). Please contact QIAGEN Technical Services
0x0Y00834B	Motor Failure (Lid). Please contact QIAGEN Technical Services
0x0Y00834C	Motor Failure (TC1). Please contact QIAGEN Technical Services
0x0Y00834D	Motor Failure (TC2). Please contact QIAGEN Technical Services
0x0Y00834E	Motor Failure (CC). Please contact QIAGEN Technical Services
0x0Y00834F	Motor Failure (BB). Please contact QIAGEN Technical Services
0x0Y008350	Motor Failure (Lid). Please contact QIAGEN Technical Services
0x0Y008351	Motor Failure (TC1). Please contact QIAGEN Technical Services
0x0Y008352	Motor Failure (TC2). Please contact QIAGEN Technical Services
0x0Y008353	Motor Failure (CC). Please contact QIAGEN Technical Services
0x0Y008354	Motor Failure (BB). Please contact QIAGEN Technical Services
0x0Y008355	Motor Failure (Lid). Please contact QIAGEN Technical Services
0x0Y008356	Motor Failure (TC1). Please contact QIAGEN Technical Services
0x0Y008357	Motor Failure (TC2). Please contact QIAGEN Technical Services
0x0Y008358	Motor Failure (CC). Please contact QIAGEN Technical Services
0x0Y008359	Motor Failure (BB). Please contact QIAGEN Technical Services
0x0Y00835A	Motor Failure (Lid). Please contact QIAGEN Technical Services
0x0Y00835B	Motor Failure (TC1). Please contact QIAGEN Technical Services
0x0Y00835C	Motor Failure (TC2). Please contact QIAGEN Technical Services
0x0Y00835D	Motor Failure (CC). Please contact QIAGEN Technical Services
0x0Y00835E	Motor Failure (BB). Please contact QIAGEN Technical Services
0x0Y00835F	Motor Failure (Lid). Please contact QIAGEN Technical Services
0x0Y008360	Motor Failure (TC1). Please contact QIAGEN Technical Services
0x0Y008361	Motor Failure (TC2). Please contact QIAGEN Technical Services
0x0Y008362	Motor Failure (CC). Please contact QIAGEN Technical Services

Error Category: AM errors

Error Code	Message
0x0Y008363	Motor Failure (BB). Please contact QIAGEN Technical Services
0x0Y008364	Motor Failure (Lid). Please contact QIAGEN Technical Services
0x0Y008365	Motor Failure (TC1). Please contact QIAGEN Technical Services
0x0Y008366	Motor Failure (TC2). Please contact QIAGEN Technical Services
0x0Y008367	Motor Failure (CC). Please contact QIAGEN Technical Services
0x0Y008368	Motor Failure (BB). Please contact QIAGEN Technical Services
0x0Y008369	Motor Failure (Lid). Please contact QIAGEN Technical Services
0x0Y00836A	Motor Failure (TC1). Please contact QIAGEN Technical Services
0x0Y00836B	Motor Failure (TC2). Please contact QIAGEN Technical Services
0x0Y00836C	Motor Failure (CC). Please contact QIAGEN Technical Services
0x0Y00836D	Motor Failure (BB). Please contact QIAGEN Technical Services
0x0Y00836E	Motor Failure (Lid). Please contact QIAGEN Technical Services
0x0Y00836F	Motor Failure (TC1). Please contact QIAGEN Technical Services
0x0Y008370	Motor Failure (TC2). Please contact QIAGEN Technical Services
0x0Y00837C	Motor Failure (BB). Please contact QIAGEN Technical Services
0x0Y00837D	Motor Failure (Lid). Please contact QIAGEN Technical Services
0x0Y00837E	Motor Failure (TC1). Please contact QIAGEN Technical Services
0x0Y00837F	Motor Failure (TC2). Please contact QIAGEN Technical Services
0x0Y008380	Motor Failure (CC). Please contact QIAGEN Technical Services
0x0Y008381	Motor Failure (BB). Please contact QIAGEN Technical Services
0x0Y008382	Motor Failure (Lid). Please contact QIAGEN Technical Services
0x0Y008383	Motor Failure (BB). Please contact QIAGEN Technical Services
0x0Y008384	Motor Failure (BB). Please contact QIAGEN Technical Services
0x0Y008387	Motor Failure (BB). Please contact QIAGEN Technical Services
0x0Y0083FF	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008400	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008401	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008402	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008403	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008404	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008405	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008406	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008407	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008408	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008409	Failure on analytical module. Please contact QIAGEN Technical Services

Error Category: AM errors

Error Code	Message
0x0Y00840A	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y00840B	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y00840C	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008410	Cartridge can be reused. If error persists please contact QIAGEN Technical Services
0x0Y008411	Cartridge can be reused. If error persists please contact QIAGEN Technical Services
0x0Y008412	Cartridge can be reused. If error persists please contact QIAGEN Technical Services
0x0Y008413	Cartridge can be reused. If error persists please contact QIAGEN Technical Services
0x0Y008414	Cartridge can be reused. If error persists please contact QIAGEN Technical Services
0x0Y008417	Cartridge can be reused. If error persists please contact QIAGEN Technical Services
0x0Y008418	Cartridge can be reused. If error persists please contact QIAGEN Technical Services
0x0Y00841F	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008420	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008421	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008422	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008423	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008424	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008425	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008426	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008427	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008428	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008429	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00842A	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00842B	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00842C	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00842D	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00842E	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00842F	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008430	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008431	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008432	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008433	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008434	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008435	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008436	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008437	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008438	Failure on Thermal Unit. Please contact QIAGEN Technical Services

Error Category: AM errors

Error Code	Message
0x0Y008439	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00843A	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00843B	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00843C	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00843D	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00843E	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00843F	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008440	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008441	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008442	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008443	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008444	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008445	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008446	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008447	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008448	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008449	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00844A	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00844B	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00844C	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00844D	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00844E	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00844F	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008450	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008451	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008452	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008453	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008454	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008455	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008456	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008457	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008458	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008459	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00845A	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00845B	Failure on Thermal Unit. Please contact QIAGEN Technical Services

Error Category: AM errors

Error Code	Message
0x0Y008460	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008461	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008462	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008463	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008464	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008465	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008466	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008467	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008468	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008469	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00846A	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008470	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008471	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008472	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008473	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008474	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008475	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008476	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008477	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008478	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008479	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00847A	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00847B	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00847C	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008480	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008481	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008482	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008483	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008484	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008485	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008486	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008487	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008488	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008489	Failure on Thermal Unit. Please contact QIAGEN Technical Services

Error Category: AM errors

Error Code	Message
0x0Y00848A	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00848B	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00848C	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008490	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008491	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008492	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008493	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008494	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008495	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008496	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008497	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008498	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y008499	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00849A	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00849B	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00849C	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00849D	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00849E	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y00849F	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084A0	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084A1	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084A2	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084A3	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084A4	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084A5	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084A6	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084B0	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084B1	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084B2	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084B3	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084B4	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084B5	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084B6	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084B7	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084B8	Failure on Thermal Unit. Please contact QIAGEN Technical Services

Error Category: AM errors

Error Code	Message
0x0Y0084B9	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084BA	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084BB	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084BC	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084BD	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084BE	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084BF	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084C0	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084C1	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084C2	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084C3	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084C4	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084C5	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084C6	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084C7	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084C8	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084D0	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084D1	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084D2	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084D3	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084D4	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084E0	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084E1	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084E2	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084E3	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084E4	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084E5	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084E6	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084E7	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084E8	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084E9	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084EA	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084EB	Failure on Thermal Unit. Please contact QIAGEN Technical Services
0x0Y0084FF	Failure on Thermal Unit. Please contact QIAGEN Technical Services

Error Category: AM errors

Error Code	Message
0x0Y008500	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008501	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008502	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008504	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008508	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008510	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008520	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008540	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008580	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008581	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y00858F	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008605	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008606	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008607	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008608	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008609	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y00860A	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y00860B	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y00860C	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y00860D	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y00860E	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y00860F	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008610	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008611	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008612	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008613	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008614	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008615	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008616	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008617	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008618	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008619	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y00861A	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y00861B	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y0086EF	Failure on analytical module. Please contact QIAGEN Technical Services

Error Category: AM errors

Error Code	Message
0x0Y0086F0	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y0086FF	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008700	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008701	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008702	Failure on TRF module. Please contact QIAGEN Technical Services
0x0Y008703	Failure on TRF module. Please contact QIAGEN Technical Services
0x0Y008704	Failure on TRF module. Please contact QIAGEN Technical Services
0x0Y008705	Failure on TRF module. Please contact QIAGEN Technical Services
0x0Y008706	Failure on TRF module. Please contact QIAGEN Technical Services
0x0Y008707	Failure on TRF module. Please contact QIAGEN Technical Services
0x0Y008708	Failure on TRF module. Please contact QIAGEN Technical Services
0x0Y008709	Failure on TRF module. Please contact QIAGEN Technical Services
0x0Y00870A	Failure on TRF module. Please contact QIAGEN Technical Services
0x0Y00870B	Failure on TRF module. Please contact QIAGEN Technical Services
0x0Y00870C	Failure on TRF module. Please contact QIAGEN Technical Services
0x0Y00870D	Failure on TRF module. Please contact QIAGEN Technical Services
0x0Y00877F	Failure on TRF module. Please contact QIAGEN Technical Services
0x0Y008780	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y008781	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y008782	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y008783	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008784	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y008785	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y008786	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y008787	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y008788	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y008789	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y00878A	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y00878B	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y00878C	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y00878D	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y00878E	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y00878F	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y008790	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y008791	Failure on qPCR module. Please contact QIAGEN Technical Services

Error Category: AM errors

Error Code	Message
0x0Y008792	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y008793	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y008794	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y008795	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y008796	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y008797	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y008798	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y008799	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y00879A	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y00879B	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y00879C	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y00879D	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y00879E	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y00879F	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y0087FF	Failure on qPCR module. Please contact QIAGEN Technical Services
0x0Y008800	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008801	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008802	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008803	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008804	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008805	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008806	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008807	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008808	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y008809	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y00880A	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y00880B	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y00880C	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y00880D	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y00880E	Failure on analytical module. Please contact QIAGEN Technical Services
0x0Y00881F	Failure on analytical module. Please contact QIAGEN Technical Services

Error Category: RCA errors

Error Code	Message
0x0Y010001	Failure in the instrument, please contact QIAGEN Technical Services
0x0Y010002	Failure in the instrument, please contact QIAGEN Technical Services
0x0Y010003	Failure in the instrument, please contact QIAGEN Technical Services
0x0Y010004	Failure in the instrument, please contact QIAGEN Technical Services
0x0Y010005	Failure in the instrument, please contact QIAGEN Technical Services
0x0Y010006	Failure in the instrument, please contact QIAGEN Technical Services
0x0Y010007	Failure in the instrument, please contact QIAGEN Technical Services
0x0Y010009	Failure in the instrument, please contact QIAGEN Technical Services
0x0Y010010	Failure in the instrument, please contact QIAGEN Technical Services
0x0Y011001	Failure in the instrument, please contact QIAGEN Technical Services
0x0Y011002	Failure in the instrument, please contact QIAGEN Technical Services
0x0Y011003	Failure in the instrument, please contact QIAGEN Technical Services
0x0Y014000	Failure in the Analytical Module, please contact QIAGEN Technical Services
0x0Y014001	Cartridge execution failure. Please retry another cartridge and contact QIAGEN Technical Services
0x0Y014002	Failure in the Analytical Module, please contact QIAGEN Technical Services
0x0Y014003	Cartridge execution failure. Please retry another cartridge and contact QIAGEN Technical Services
0x0Y014004	Abnormal software failure. Please retry another cartridge and contact QIAGEN Technical Services
0x0Y014005	Abnormal software failure. Please retry another cartridge and contact QIAGEN Technical Services

10. Technical Specifications

10.1. Environmental conditions – operating conditions

Table 18. Environmental conditions

Description	Requirement
Power	200–240 VAC
Air temperature	15–27°C
Relative humidity	20–80%
Altitude	0–2200 m
Place of operation	Laboratory (Inside) Instrument operation footprint is 58 cm but, temporary space of 1.5 m is required for installation and service interventions.

10.2. Mechanical data and hardware features

Table 19. Mechanical data

Description	Requirement
Dimensions (door closed)	Height: 1280 mm, depth: 810 mm, width: 580 mm
Dimensions (door open)	Height: 1280 mm, depth: 810 mm, width: 1500 mm
Weight	130 kg
~ Weight with 8 AM	260 kg
Capacity	8 Analytical modules, 18 QIAstat-Dx cartridges

Appendix A

License Terms

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- delay,
- compensation due to defect,
- compensation for wasted expenses.

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For the license texts of third-party software please refer to www.qiagen.com/QIAstat-Dx-Rise-License-Terms

SwiftDecoder™ decoding software licensed by Honeywell; Patent: hsmpats.com

Waste Electrical and Electronic Equipment (WEEE)

This section provides information about disposal of waste electrical and electronic equipment by users.

The crossed-out wheeled bin symbol (see below) indicates that this product must not be disposed of with other waste; it must be taken to an approved treatment facility or to a designated collection point for recycling, according to local laws and regulations.

The separate collection and recycling of waste electronic equipment at the time of disposal helps to conserve natural resources and ensures that the product is recycled in a manner that protects human health and the environment.



Recycling can be provided by QIAGEN upon request at additional cost. In the European Union, in accordance with the specific WEEE recycling requirements and where a replacement product is being supplied by QIAGEN, free recycling of its WEEE-marked electronic equipment is provided.

To recycle electronic equipment, contact your local QIAGEN sales office for the required return form. Once the form is submitted, you will be contacted by QIAGEN either to request follow-up information for scheduling collection of the electronic waste or to provide you with an individual quote.

Liability Clause

QIAGEN shall be released from all obligations under its warranty in the event repairs or modifications are made by persons other than its own personnel, except in cases where the Company has given its written consent to perform such repairs or modifications.

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The QIAstat- Dx Rise is equipped with an Ethernet port. The Purchaser of the QIAstat- Dx Rise is solely responsible for preventing any and all computer viruses, worms, trojans, malware, hacks, or any other type of cybersecurity breaches.

QIAGEN assumes no liability for computer viruses, worms, trojans, malware, hacks, or any other type of cybersecurity breaches.

Appendix B

Glossary

Table 21.

Table 20. Glossary

Term	Description
AAF	Assay Automation File
ADF	Assay Definition File. Is a file necessary for executing an assay on a QIAstat-Dx Rise. The content of the file describes what can be measured, how to measure it and how to evaluate the raw measurement results. The file should be imported to the QIAstat-Dx Rise before executing an assay the first time. Assay files could be uploaded by QIAGEN field service engineer.
AM	Analytical Module. A QIAstat-Dx Rise hardware module, in charge of executing tests on QIAstat-Dx Rise assay cartridges.
GUI	Graphical user interface
MC	Master Controller
PLC	Programmable Logic Controller
RCA	Results Call Algorithm
RF	Radiofrequency
User	A person who operates the QIAstat-Dx Rise in the intended way.

Appendix C

Ordering information

Product	Contents	Cat. no.
QIAstat-Dx Rise		9003163
QIAstat-Dx Analytical Module	Module contains the hardware and software for sample testing and analysis	9002814
Related products		
Air Filter Tray, AM, QSTAT	Air filter	9026189

For up-to-date licensing information and product-specific disclaimers, see the respective QIAGEN kit instructions for use or user manual. QIAGEN kit instructions for use and user manuals are available at www.qiagen.com or can be requested from QIAGEN Technical Services or your local distributor.

Document Revision History

Revision	Changes
R1, February 2022	Release of Instrument
R2, August 2022	Release of SW Version 2.2
R3, February 2023	Release of SW Version 2.3
R4, August 2024	Release of SW Version 2.4

Trademarks: QIAGEN®, Sample to Insight®, QIAstat-Dx® (QIAGEN Group); ACGIH® (American Conference of Government Industrial Hygienists, Inc.); OSHA® (Occupational Safety and Health Administration, U.S. Dept. of Labor). Registered names, trademarks, etc. used in this document, even when not specifically marked as such, are not to be considered unprotected by law.

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