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QIAstat-Dx® Analyzer 2.0 User Manual

Revision 2 For use with software version 1.6.x

IVD

CE

REF

9002828 (QIAstat-Dx Analyzer 2.0, complete system)
9002814 (QIAstat-Dx Analytical Module)
9002826 (QIAstat-Dx Operational Module PRO)

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A printed version of this manual is available upon request.

Table of Contents

1. Introduction

Thank you for choosing the QIAstat-Dx® Analyzer 2.0. We are confident that this system will become an integral part of your laboratory.

This manual describes how to operate the QIAstat-Dx Analyzer 2.0 with software version 1.6.x. Before using the QIAstat-Dx Analyzer 2.0, it is essential that you read this user manual carefully and pay particular attention to the safety information. The instructions and safety information in the user manual must be followed to ensure safe operation of the instrument and to maintain the instrument in a safe condition.

Note: The figures 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 Analyzer 2.0 in the following sections:

- Introduction
- Safety Information
- General Description
- Installation Procedures
- Running a Test and Viewing Results
- System Functions and Options
- HIS/LIS Connectivity
- External Control (EC)
- Maintenance
- Troubleshooting
- Technical Specifications

The appendices contain the following information:

- Printer installation and configuration, including a list of tested printers
- Declaration of Conformity
- Waste Electrical and Electronic Equipment (WEEE)
- Liability Clause
- Software License Agreement
- Disclaimer of warranties
- Glossary

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 Analyzer 2.0 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 at **support.qiagen.com**.

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

- QIAstat-Dx Analyzer 2.0 serial number, type, software version, and installed Assay Definition Files
- Error code (if applicable)
- Timepoint when the error occurred for the first time
- Frequency of error occurrence (i.e., intermittent, or persistent error)
- Photo of error, if possible
- Support package

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 Analyzer 2.0

The QIAstat-Dx Analyzer 2.0 platform 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 indicated for professional use only. It is not a device for self-testing or near-patient testing.

1.3.1. Limitations of use

- The QIAstat-Dx Analyzer 2.0 can only be used with QIAstat-Dx assay cartridges according to the instructions contained in this user manual and in the QIAstat-Dx assay cartridge instructions for use.
- The QIAstat-Dx Analyzer 2.0 can only be used in a Professional healthcare facility environment.
- When connecting the QIAstat-Dx Analyzer 2.0, use only the cables supplied with the system.
- Any service or repairs should be performed only by personnel authorized by QIAGEN.

- The QIAstat-Dx Analyzer 2.0 should only be operated on a flat, horizontal surface 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 at least 10 cm clearance on each side of the QIAstat-Dx Analyzer 2.0 to ensure adequate ventilation.
- Make sure that the QIAstat-Dx Analyzer 2.0 is positioned away from any air conditioning outlets or heat exchangers.
- Do not move the instrument while a test is running.
- Do not change the system configuration during a run.
- Do not use the touchscreen to lift or move the QIAstat-Dx Analyzer 2.0.
- Do not turn off or restart the instrument while a backup, restore, or system update is being performed, or an archive is being created.

2. Safety Information

Before using the QIAstat-Dx Analyzer 2.0, it is essential that you read this user manual carefully and pay particular attention to the safety information. The instructions and safety information in the user manual must be followed to ensure safe operation of the instrument and to maintain the instrument in a safe condition.

Possible hazards that could harm the user or result in damage to the instrument are clearly stated at the appropriate places throughout this user manual.

If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired. The following types of safety information appear throughout this document (*QIAstat-Dx Analyzer 2.0 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.

2.1. Proper use

Use the QIAstat-Dx Analyzer 2.0 according to this user manual. It is highly recommended to carefully read and become acquainted with the instructions for use before using the QIAstat-Dx Analyzer 2.0.

- Follow all safety instructions printed on, or attached to, QIAstat-Dx Analyzer 2.0.
- Improper use of the QIAstat-Dx Analyzer 2.0, or failure to comply with its proper installation and maintenance, may cause personal injuries or damage to the QIAstat-Dx Analyzer 2.0.
- The QIAstat-Dx Analyzer 2.0 must only be operated by qualified and appropriately trained healthcare personnel.
- Servicing of the QIAstat-Dx Analyzer 2.0 must only be performed by representatives authorized by QIAGEN.
- Do not use the QIAstat-Dx Analyzer 2.0 in hazardous environments for which it has not been designed.
- Follow your organization's cybersecurity policies for credential custody.
- Do not move the instrument while a test is running.

WARNING/ CAUTION

Risk of personal injury and material damage

Do not open the housing of the QIAstat-Dx Analyzer 2.0. The housing of the QIAstat-Dx Analyzer 2.0 is designed to protect the operator and to ensure proper operation of the QIAstat-Dx Analyzer 2.0. Using the QIAstat-Dx Analyzer 2.0 without the housing leads to electrical hazards and QIAstat-Dx Analyzer 2.0 malfunction.

WARNING/ CAUTION

Risk of personal injury and material damage

Use caution when the lid of the cartridge entrance port closes to avoid personal injury, such as pinched fingers.

2.2. QIAstat-Dx Analyzer 2.0 transport precautions

WARNING/ CAUTION

Risk of personal injury and material damage

The QIAstat-Dx Analyzer 2.0 is a heavy instrument. To avoid personal injury or damage to the QIAstat-Dx Analyzer 2.0, take care when lifting it and use appropriate lifting methods.

2.3. Electrical safety

Observe all general safety precautions that apply to electrical instruments.

Disconnect the line power cord from the power outlet before servicing.

WARNING

Electrical hazard

Lethal voltages inside theQIAstat-Dx Analyzer 2.0. Do not open the housing of the QIAstat-Dx Analyzer 2.0.

The line power cord must be connected to a line power outlet that has a protective conductor (earth/ground).

Do not touch any switches or power cords with wet hands.

Do not use the instrument outside of the specified power conditions.

2.4. Electromagnetic safety information (EMC)

WARNING

Risk of data and material loss

EM disturbances might cause the QIAstat-Dx Analyzer 2.0 to fail resulting in data loss and/or loss of the sample.

WARNING

Risk of data and material loss

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally..

WARNING

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 QIAGENs service for a replacement.

Other cables might negatively affect the EMC performance of the instrument.

WARNING **Risk of electromagnetic emission**

This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

WARNING **Risk of electromagnetic immunity**

WARNING: Do not use this device in proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with proper operation.

WARNING **Risk of electromagnetic immunity**

WARNING: electromagnetic environment should be evaluated prior to operation of the device.

WARNING **Risk of electromagnetic immunity**

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING **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 %.

WARNING **Risk of electromagnetic immunity**

Main power quality should be that of a typical commercial or hospital environment..

WARNING **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.

WARNING **Risk of electromagnetic immunity**

If the user of QIAstat-Dx Analyzer 2.0 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.

WARNING **Risk of electromagnetic immunity**

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

2.5. Chemical safety

Safety Data Sheets (SDSs) for the cartridge materials are available and can be requested from QIAGEN.

Used QIAstat-Dx assay cartridges must be disposed of in accordance with all national, state, and local health and safety regulations and laws.

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 **Risk of damage to QIAstat-Dx Analyzer 2.0**

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.

2.6. Biological safety

The QIAstat-Dx Analyzer 2.0 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 (**www.cdc.gov/od/ohs/biosfty/biosfty.htm**).

Samples tested on the QIAstat-Dx Analyzer 2.0 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.

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)

Avoid contamination of the QIAstat-Dx Analyzer 2.0 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 QIAstat-Dx Analyzer (see Section 9 Maintenance).

WARNING **Biological hazard**

Use caution when loading or removing QIAstat-Dx assay cartridges containing infectious samples into or from the QIAstat-Dx Analyzer 2.0. A break in the cartridge could contaminate the QIAstat-Dx Analyzer 2.0 and the surrounding area.

All QIAstat-Dx assay cartridges should 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 Analyzer 2.0, refer to Section 9.2 "Cleaning the QIAstat-Dx Analyzer 2.0 surface" on page 104 and 9.3 Maintenance, respectively.

2.7. 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.

For disposal of waste electrical and electronic equipment (WEEE), see Appendix 12.2 Waste Electrical and Electronic Equipment (WEEE).

2.8. Symbols on the QIAstat-Dx Analyzer 2.0

The following symbols appear on the QIAstat-Dx Analyzer 2.0 instrument and/or QIAstat-Dx assay cartridges.

Symbol	Location	Description
	Type plate on the instrument	CE mark for Europe
	Type plate on the instrument	TÜV mark of the TÜV SÜD Product Service for testing
	Type plate on the instrument	CAUTION Hazard – risk of personal injury and material damage
	Type plate on the instrument	WEEE mark for Europe
	Type plate on the instrument	Legal manufacturer
	Type plate on the instrument	In vitro diagnostic medical device
	Type plate on the instrument	Catalog number
	Type plate on the instrument	Instrument serial number
	Type plate on the instrument	Unique Device Identifier
	Type plate on the instrument	Date of manufacturing
 www.qiagen.com	Outer box	Instructions for use available at **www.qiagen.com**

2.9. Data security

Note: It is strongly recommended to perform regular system backups according to your organization's policy for the availability of data and the protection of data from loss.

The QIAstat-Dx Analyzer 2.0 is delivered with a USB storage device, which should preferably be used for short term data storage and general data transfer (e.g., saving results, system backup and archive creations, system updates, or Assay Definition File imports). It is strongly recommended to use another storage location for permanent data storage.

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.)

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 Analyzer 2.0:

- Operate the QIAstat-Dx Analyzer 2.0 in a secured environment and secured network.
- In case of a system update, always compare the checksum of the update package with the checksum provided on the website (**www.qiagen.com**) prior to installation.
- Do not leave the instrument while a system update, system backup, and archive restoration and creation is ongoing, as the automatic log-off feature is turned off during these processes. For more information about the automatic log-off, refer to Section 6.7.4 General settings.
- Perform continuous backups and keep backup files at a secure, ideally offline storage. For more information about backups, refer to Section 6.7.12 System backup.
- Always ensure that you use a malware-free USB storage device.
- Use the Multi-User mode of the QIAstat-Dx Analyzer 2.0. For more information about User management, refer to Section 6.5 User management
- 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 6.5User 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 Analyzer 2.0 unattended. For more information on logging out, refer to Section 6.2.1 Logging out.
- Do not use freely editable fields to enter personal identifiable information (PII) or protected health information (PHI). This includes fields such as the sample ID, patient ID, and result comments.
- Detected events to Cybersecurity are recorded in the System Log (see Section 6.7.8 System log).
- In case you suspect that your QIAstat-Dx Analyzer 2.0 security may have been compromised, please inform your IT or Cybersecurity department immediately 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 Analyzer 2.0 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. Customers can proactively obtain updates from **www.qiagen.com** or contact QIAGEN Technical Service for further support.

In addition, *QIAstat-Dx Analyzer 2.0 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 Analyzer 2.0Security and Privacy Guide* is available on at **www.qiagen.com/QIAstat-Dx**.

3. General Description

3.1. System description

The QIAstat-Dx Analyzer 2.0, in combination with QIAstat-Dx assay cartridges, uses real-time PCR to detect pathogen nucleic acids in human biological samples. The QIAstat-Dx Analyzer 2.0 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 Analyzer 2.0 description

The QIAstat-Dx Analyzer 2.0 consists of an Operational Module and 1 or more (as many as 4) Analytical Modules. The Operational Module includes elements that provide connectivity to the Analytical Module and enable user interaction with the QIAstat-Dx Analyzer 2.0. The Analytical Module contains the hardware and software for sample testing and analysis.

The QIAstat-Dx Analyzer 2.0 includes the following elements:

- Touchscreen for user interaction with the QIAstat-Dx Analyzer 2.0
- Bar code reader for sample, patient, user, and QIAstat-Dx assay cartridge identification
- USB ports for assay and system upgrades, document export and printer connectivity (one in front, three in back)
- Cartridge entrance port for inserting QIAstat-Dx assay cartridges into the QIAstat-Dx Analyzer 2.0
- Ethernet connector for network connectivity

Figure 1 and Figure 2 show the locations of various QIAstat-Dx Analyzer 2.0 features.

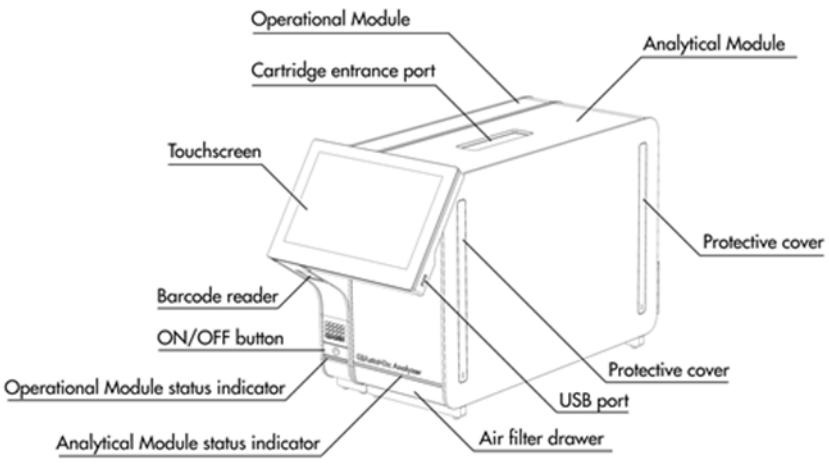


Figure 1. Front view of the QIAstat-Dx Analyzer 2.0. The Operational Module is on the left and the Analytical Module is on the right.

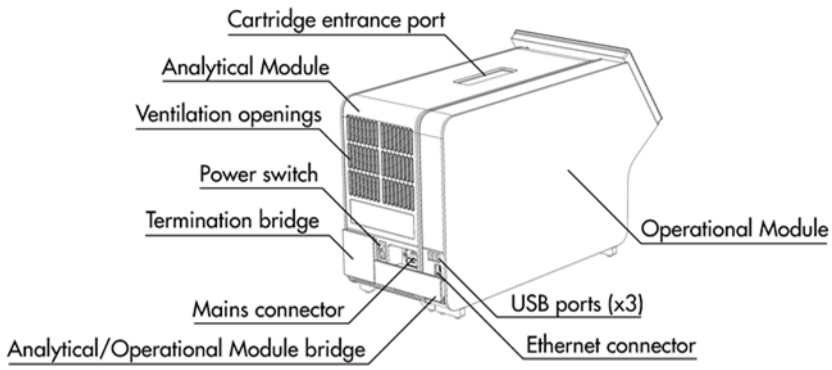


Figure 2. Rear view of the QIAstat-Dx Analyzer 2.0. The Operational Module is on the right and the Analytical Module is on the left.

3.3. QIAstat-Dx assay cartridge description

The QIAstat-Dx assay cartridge is a disposable plastic device that enables performance of fully automated molecular assays. Main features of the QIAstat-Dx assay cartridge include compatibility with various sample types (e.g., fluids, swabs), hermetical containment of all pre-loaded reagents necessary for testing and true walk-away operation. All sample preparation and assay testing steps are performed within the QIAstat-Dx assay cartridge.

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 by pneumatically operated microfluidics and make no direct contact with the QIAstat-Dx Analyzer 2.0 actuators. The QIAstat-Dx Analyzer 2.0 houses air filters for both incoming and outgoing 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 Analyzer 2.0, the following assay steps occur automatically:

- 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 Figure 3.

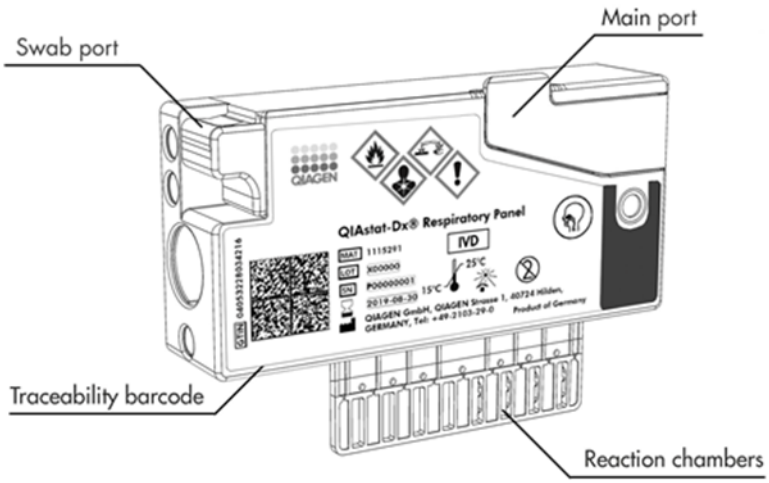


Figure 3. QIAstat-Dx assay cartridge features.

3.4. QIAstat-Dx Analyzer software

The QIAstat-Dx Analyzer's software (SW) is pre-installed on the system. 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, assay management, and hardware/software configuration management)
- Test execution control to perform necessary automated analytical steps that comprise a test execution

4. Installation Procedures

4.1. Site requirements

Select a flat, dry, and clean workbench space for the QIAstat-Dx Analyzer 2.0. 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. Refer to Section 11 for the weight and dimensions of the QIAstat-Dx Analyzer 2.0 and the correct operating conditions (temperature and humidity). The QIAstat-Dx Analyzer 2.0 should have sufficient clearance on all sides to enable proper ventilation and to allow unimpeded access to the cartridge entrance port, the back of the QIAstat-Dx Analyzer 2.0, the power switch, the ON/OFF button, the bar code reader, and the touchscreen.

Note: Before installing and using the QIAstat-Dx Analyzer 2.0, refer to Section 11 Technical Specifications to become familiar with the QIAstat-Dx Analyzer 2.0 operating conditions.

CAUTION **Impeded ventilation**

To ensure proper ventilation, maintain a minimum clearance of 10 cm at the rear of the QIAstat-Dx Analyzer 2.0 and do not block airflow under the unit.

Slits and openings that ensure instrument ventilation must not be covered.

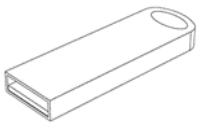
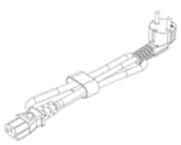
CAUTION **Electromagnetic interference**

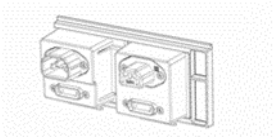
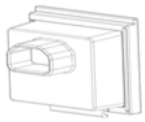
Do not place or use the QIAstat-Dx Analyzer 2.0 in close proximity of sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), as these can interfere with proper operation.

4.2. QIAstat-Dx Analyzer 2.0 delivery and components

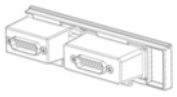
The QIAstat-Dx Analyzer 2.0 is delivered in two separate boxes and includes all the necessary components for setting up and operating the system. The contents of the boxes are described below:

Box 1 contents:

Component	Description
	1x Analytical Module
	1x USB storage device
	1x Power cord

Component	Description
	1x Analytical/Analytical Module Bridge
	1x Termination Bridge
	1x Analytical-Operational Module Assembly Tool
	1x Screen Suede
	1x Protective Cover Removal Tool

Box 2 contents:

Component	Description
	1x Operational Module
	1x Analytical/Operational Module Bridge

4.3. Unpacking and installing the QIAstat-Dx Analyzer 2.0

Carefully unpack the QIAstat-Dx Analyzer 2.0 according to the following steps:

1. Remove the Analytical Module from its box and place it on a level surface. Remove the foam pieces attached to the Analytical Module.

   Note: The Analytical Module must be lifted and handled by taking it from the base with two hands, as shown in Figure 4.

WARNING/ CAUTION

Risk of personal injury and material damage

The QIAstat-Dx Analyzer 2.0 is a heavy instrument. To avoid personal injury or damage to the QIAstat-Dx Analyzer 2.0, take care when lifting it and use appropriate lifting methods.

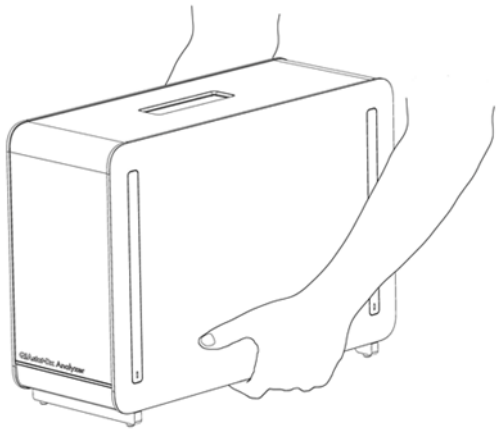


Figure 4. Proper handling of Analytical Module.

2. Remove the protective covers from the side of the Analytical Module using the Protective Cover Removal Tool delivered with the QIAstat-Dx Analyzer 2.0 (Figure 5).

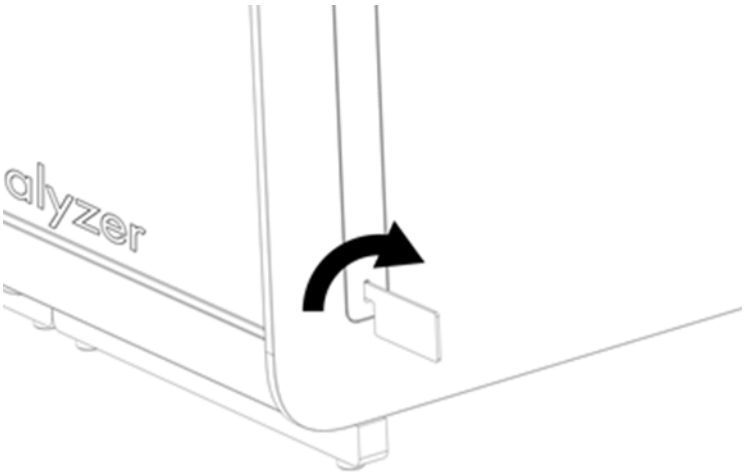


Figure 5. Removing protective covers.

3. Remove the Operational Module from its box and attach it to the left side of the Analytical Module. Tighten the screws using the Analytical-Operational Module Assembly Tool delivered with the QIAstat-Dx Analyzer 2.0 (Figure 6).

CAUTION

Risk of mechanical damage

Do not leave the Operational Module without support or resting on the touchscreen, as this may damage the touchscreen.

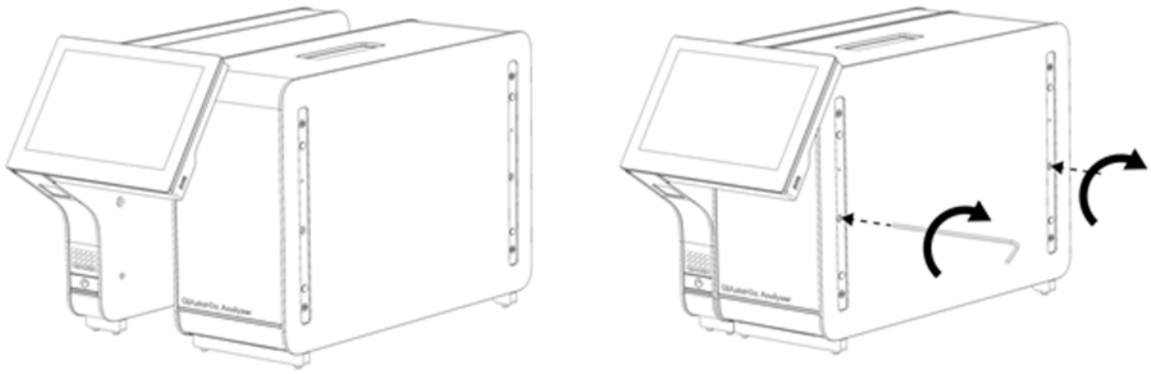


Figure 6. Attaching the Operational Module to the Analytical Module.

4. Reattach the protective covers on the side of the Analytical Module (Figure 7).

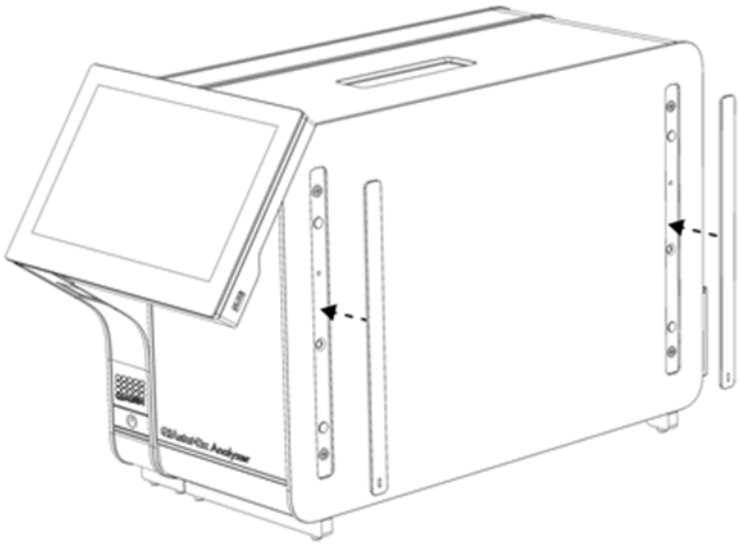


Figure 7. Reattaching the protective covers.

5. Connect the Analytical/Operational Module Bridge at the back of the QIAstat-Dx Analyzer 2.0 to link the Operational and Analytical Modules together (Figure 8).

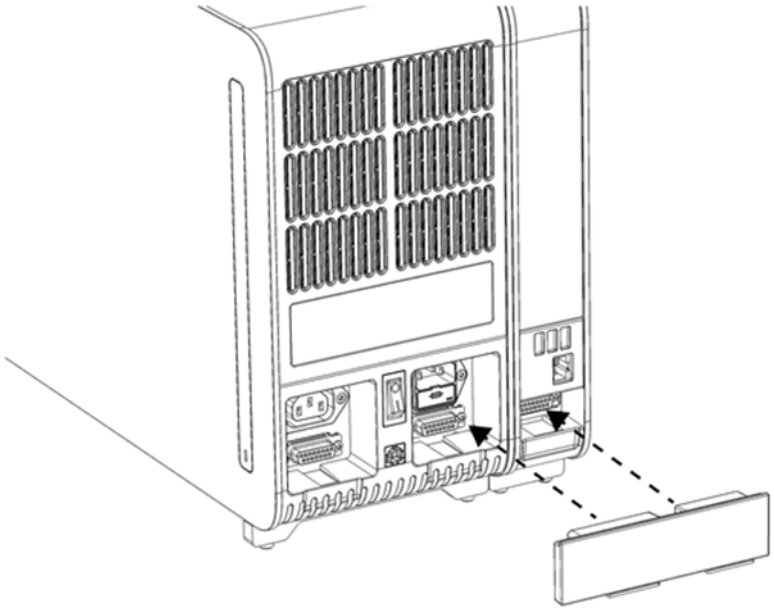


Figure 8. Connecting the Analytical/Operational Module Bridge.

6. Connect the Termination Bridge at the back of the Analytical Module (Figure 9).

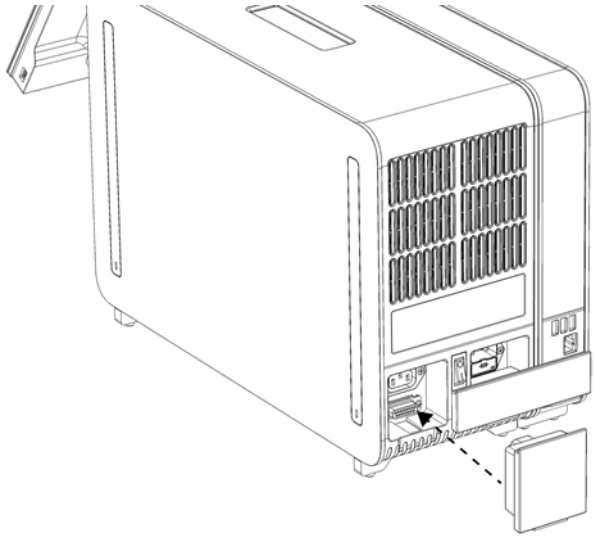


Figure 9. Connecting the Termination Bridge.

7. Connect the power cord that was delivered with the QIAstat-Dx Analyzer 2.0 to the back of the Analytical Module (Figure 10).

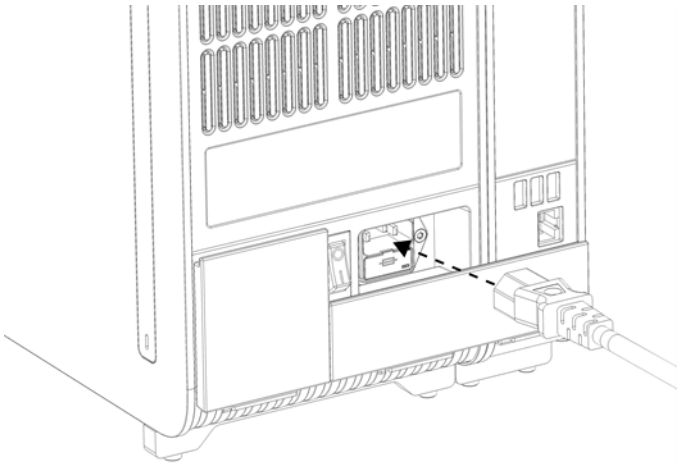


Figure 10. Connecting the power cord.

8. Connect the power cord to a power outlet.
9. Power ON the instrument by pressing the power switch on the back of the Analytical Module to the "I" position (Figure 11). Confirm that the status indicators of the Analytical and Operational Modules are blue.

   Note: If a status indicator is red, there is a malfunction in the Analytical Module. Contact QIAGEN Technical Services using the contact information in Section 10 Troubleshooting for assistance.

   Note: The instrument must not be positioned so that it is difficult to operate the power switch.

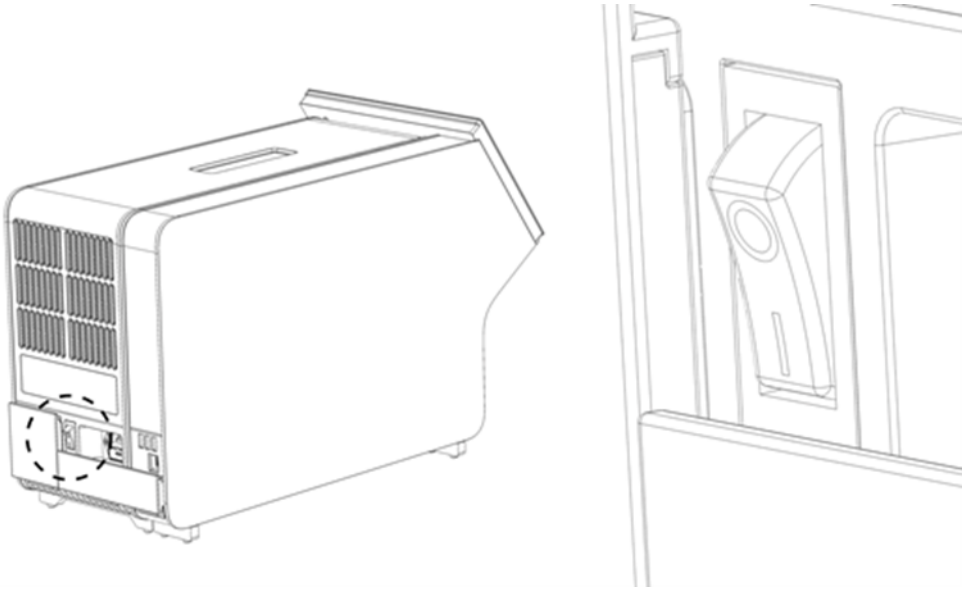


Figure 11. Locating the power switch and setting it to the "I" position.

10. The QIAstat-Dx Analyzer 2.0 is now ready to be configured for its intended use. Refer to Section 6.7 Configuring the QIAstat-Dx Analyzer 2.0 to configure the system parameters, set the system time and date, and configure the network connection.

4.4. Installing additional Analytical Modules

Carefully unpack the additional Analytical Module and install it according to the following steps:

1. Prepare the QIAstat-Dx Analyzer 2.0 for installation of the new module:
   a. Power OFF the system by pressing the ON/OFF button on the front of the QIAstat-Dx Analyzer 2.0.
   b. Power OFF the instrument by pressing the power switch on the back of the Analytical Module to the "O" position.
   c. Remove the power cable.
   d. Remove the Termination Bridge from the back of the Analytical Module (Figure 12).

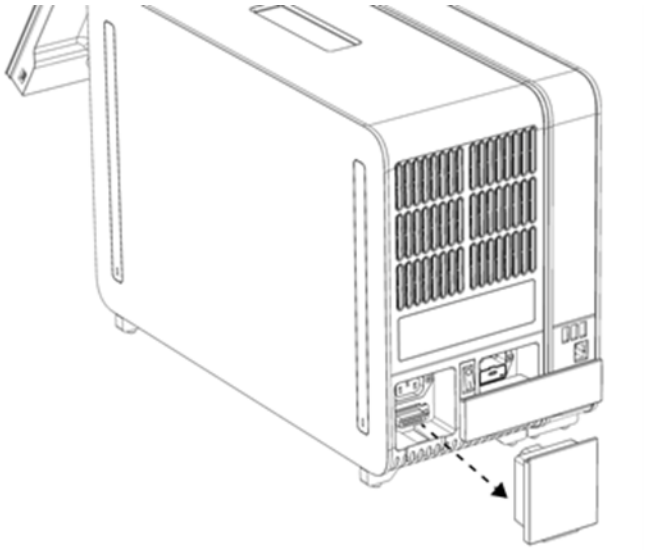


Figure 12. Removing the Termination Bridge.

   e. Remove the protective covers from the side of the Analytical Module, which is where the additional Analytical Module will be attached (Figure 15).

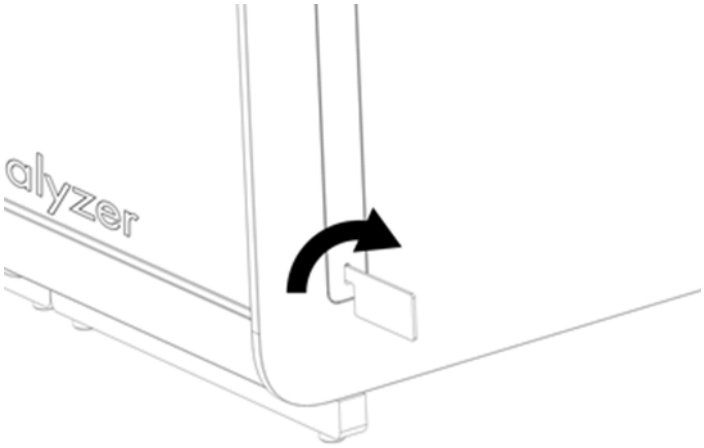


Figure 13. Removing protective covers.

2. Remove the additional Analytical Module from its box and place it on a level surface. Remove the foam pieces attached to the Analytical Module.

   Note: The Analytical Module must be lifted and handled by taking it from the base with two hands, as shown in Figure 14.

WARNING/ CAUTION

Risk of personal injury and material damage

The QIAstat-Dx Analyzer 2.0 is a heavy instrument. To avoid personal injury or damage to the QIAstat-Dx Analyzer 2.0, take care when lifting it and use appropriate lifting methods.

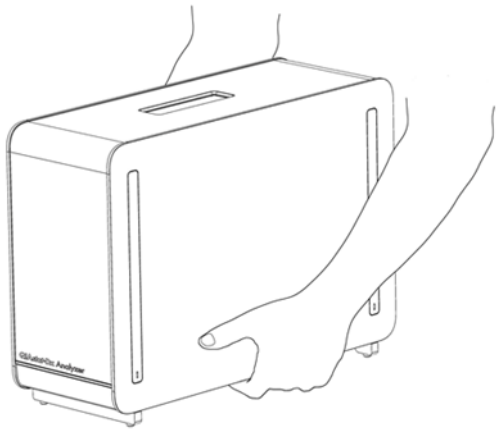


Figure 14. Proper handling of Analytical Module.

3. Remove the protective covers from the side of the Analytical Module using the Protective Cover Removal Tool delivered with the QIAstat-Dx Analyzer 2.0 (Figure 15).

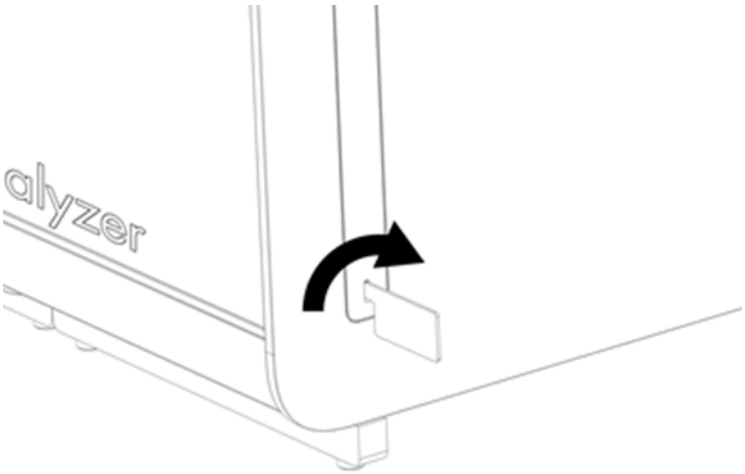


Figure 15. Removing protective covers.

4. Align the additional Analytical Module with the existing Analytical Module. Tighten the screws using the Analytical-Operational Module Assembly Tool delivered with the QIAstat-Dx Analyzer 2.0 (Figure 16).

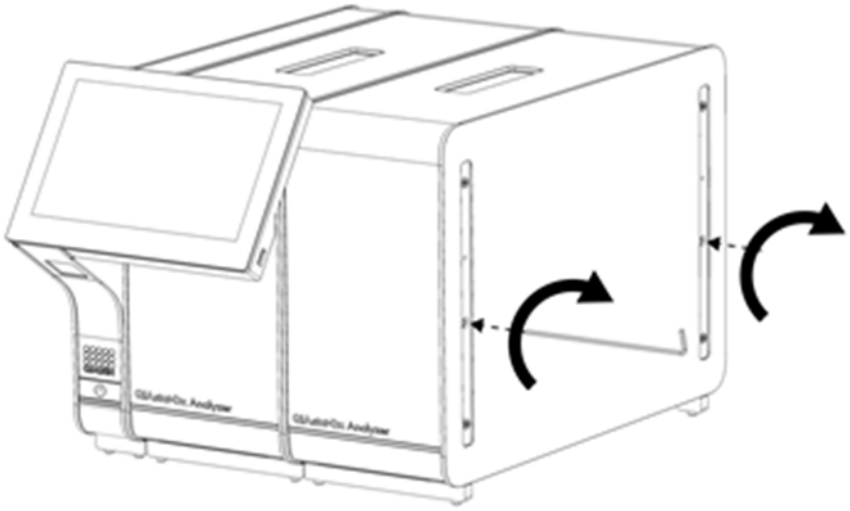


Figure 16. Aligning and attaching the additional Analytical Module.

5. Reattach the protective covers on the side of the additional Analytical Module (Figure 17).

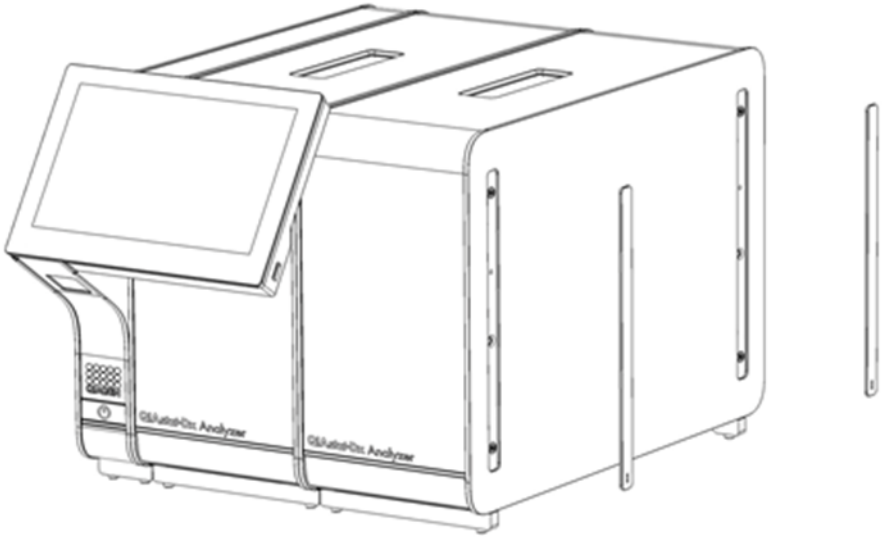


Figure 17. Reattaching protective covers on the additional Analytical Module.

6. Connect the Analytical/Analytical Module Bridge at the back of the QIAstat-Dx Analyzer 2.0 to link the two Analytical Modules together (Figure 18).

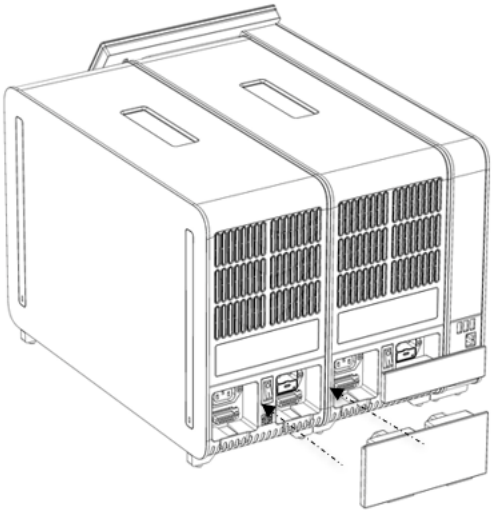


Figure 18. Connecting the Analytical/Analytical Module Bridge.

7. Connect the Termination Bridge at the back of the Analytical Module (Figure 19).

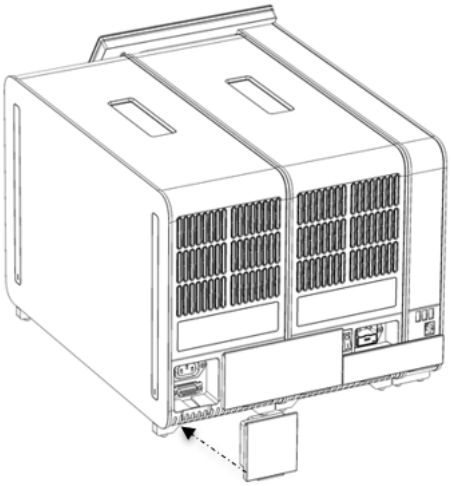


Figure 19. Connecting the Termination Bridge.

8. Connect the power cord that was delivered with the QIAstat-Dx Analyzer 2.0 to the back of the original Analytical Module (Figure 20).

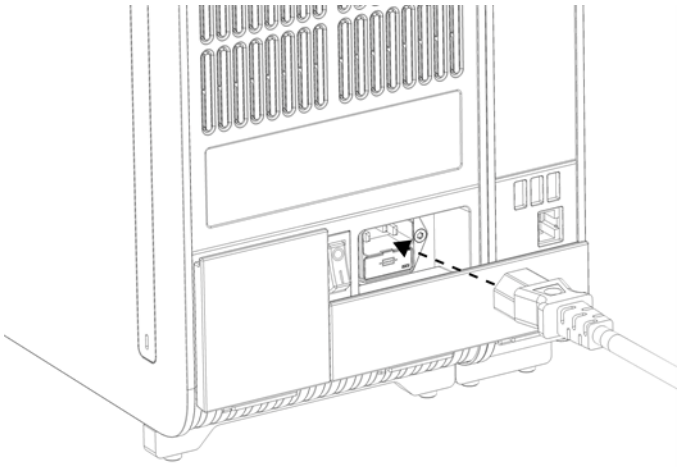


Figure 20. Connecting the power cord.

9. Connect the power cord to a power outlet.
10. Power ON the instrument by pressing the power switch on the back of the Analytical Module to the "I" position (Figure 21). Confirm that the status indicators of the Analytical and Operational Modules are blue.

    Note: If a status indicator is red, there is a malfunction in the Analytical Module. Contact QIAGEN Technical Services using the contact information in Section 10 Troubleshooting for assistance.

    Note: The instrument must not be positioned so that it is difficult to operate the power switch.

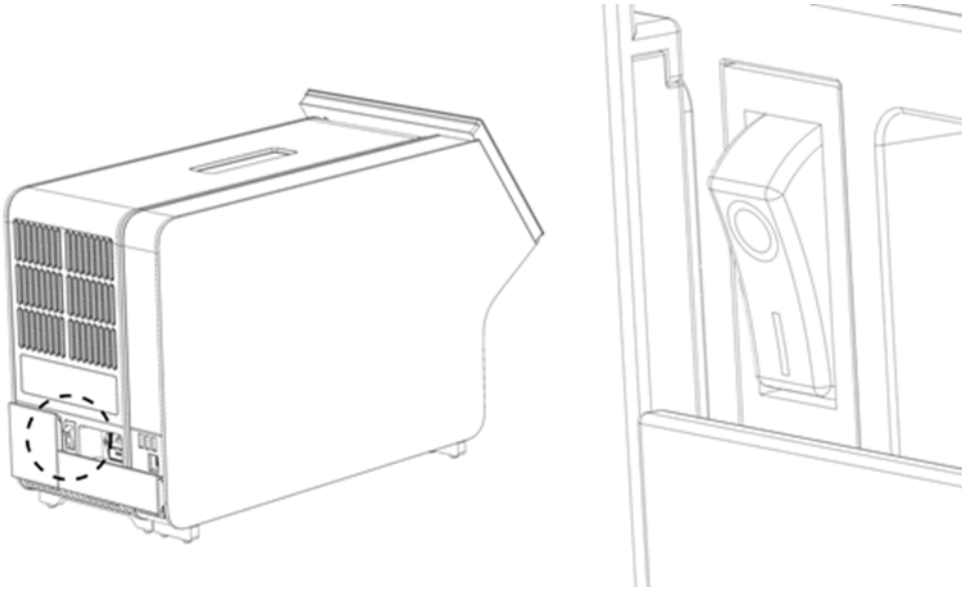


Figure 21. Locating the power switch and setting it to the "I" position.

11. The QIAstat-Dx Analyzer 2.0 is now ready to be configured for its intended use. Refer to Section 6.7 Configuring the QIAstat-Dx Analyzer 2.0 to configure the system parameters, set the system time and date, and configure the network connection.

4.5. Repackaging and shipping the QIAstat-Dx Analyzer 2.0

When repackaging the QIAstat-Dx Analyzer 2.0 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 (see Section 9.2 Cleaning the QIAstat-Dx Analyzer 2.0 surface) prior to packing and that it poses no biological or chemical hazard.

To repackage the instrument:

1. Make sure the instrument is powered OFF (press power switch to the "O" position).
2. Disconnect the power cord from the power outlet.
3. Disconnect the power cord from the back of the Analytical Module.
4. Disconnect the Termination Bridge at the back of the Analytical Module.
5. Disconnect the Analytical/Operational Module bridge linking the Operational and Analytical Modules at the back of the QIAstat-Dx Analyzer 2.0.
6. Remove the protective covers on the side of the Analytical Module using the Protective Cover Removal Tool.
7. Use the Analytical-Operational Module Assembly Tool to loosen the two screws holding the Operational Module to the Analytical Module. Package the Operational Module in its box.
8. Reposition the protective covers on the side of the Analytical Module. Package the Analytical Module, with its foam pieces, in its box.

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 Analyzer 2.0

1. Press the **ON/OFF** button on the front of the QIAstat-Dx Analyzer 2.0 to start the unit (Figure 22).

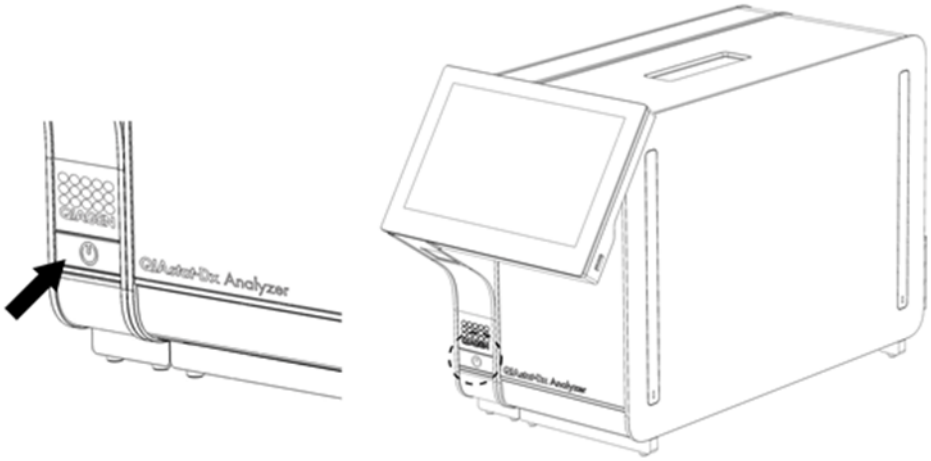


Figure 22. Pressing the ON/OFF button to start the instrument.

2. Wait until the Main screen appears and the Analytical and Operational Module status indicators turn green and stop blinking.

   Note: After initial installation, the Login screen will appear. Refer to Section 6.2 Login screenfor further details.

   Note: After successful initial installation of the QIAstat-Dx Analyzer 2.0, the system administrator needs to log in for the first configuration of the software. For the first-time login, the user ID is “administrator” and the default password is “administrator”. The password must be changed after the first login. The User Access Control is activated automatically. It is strongly recommended to create at least one user account, without an “Administrator” role.

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, (like the sample stability time once loaded into the cartridge), refer to the instructions for use for the specific assay (e.g., QIAstat-Dx Respiratory Panel). Always make sure that both sample lids are firmly closed after adding a sample to the QIAstat-Dx assay cartridge.

5.3. Procedure to run a test

All operators should wear appropriate personal protective equipment, such as gloves, when touching the QIAstat-Dx Analyzer 2.0 touchscreen.

1. Press the **Run Test** button at the top right corner of the Main screen.

   Note: If External Control (EC) is enabled and an EC test is due to be performed, a reminder is shown to run the test with an EC sample. Refer to Section 8 External Control (EC) for further details.

   Note: If EC is enabled and the last EC test performed with the selected module failed, a warning is shown. Users must explicitly choose whether they want to perform a test with the selected module anyway.

2. When prompted, scan the sample ID bar code using the bar code reader that is integrated into the Operational Module (Figure 23).

   Note: Depending on the QIAstat-Dx Analyzer 2.0 configuration, it may also be possible to enter the sample ID using the virtual keyboard of the touchscreen. Refer to Section 6.7.4 General settings for further details.

   Note: Depending on the chosen system configuration, entering patient ID may also be required at this point. Refer to Section 6.7.4 General settings for further details.

   Note: The sample ID and Patient ID should not contain Personally Identifiable Information (PII).

   Note: Depending on the EC configuration, a toggle button labelled EC Test is shown. This button remains in the off position for a test run. For more information about EC, refer to Section 8 External Control (EC)

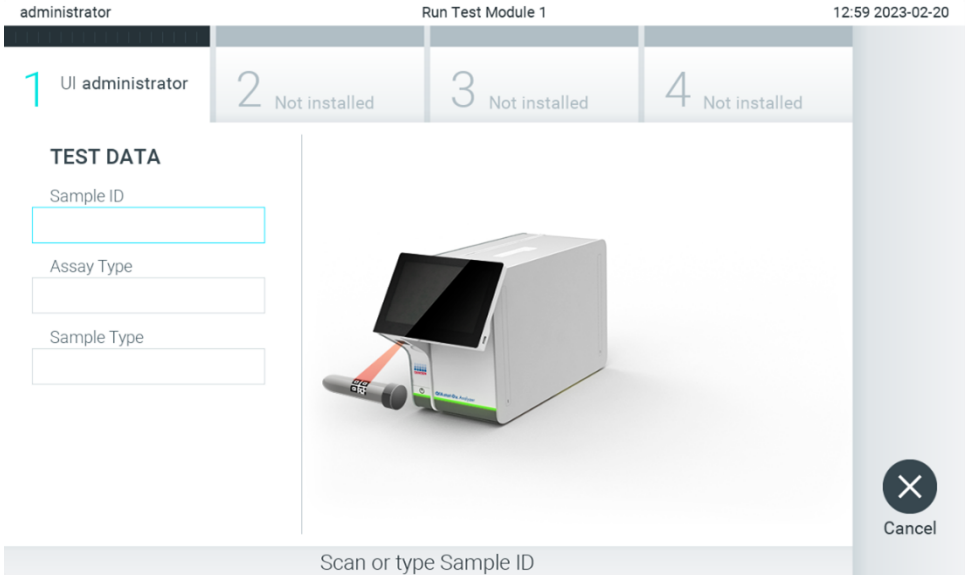


Figure 23. Scanning the sample ID bar code.

3. When prompted, scan the bar code of the QIAstat-Dx assay cartridge to be used. The QIAstat-Dx Analyzer 2.0 automatically recognizes the assay to be run, based on the QIAstat Dx assay cartridge bar code (Figure 24).

   Note: The QIAstat-Dx Analyzer 2.0 will not accept QIAstat-Dx assay cartridges with lapsed expiration dates, previously used cartridges or cartridges for assays that are not installed on the unit. An error message will be shown in these cases. Refer to Section 10.2 Error codes and messages for further details.

   Note: Refer to Section 6.6.3 Importing new assays for instructions on importing and adding assays to the QIAstat-Dx Analyzer 2.0.

   Note: Use the barcode on the side of the cartridge (as indicated in Figure 24) and not the barcode on the packaging of cartridges.

Note: If External Control (EC) is enabled and an EC test is due or the previous one for the selected assay failed on the selected module, a warning is shown. Users need to confirm if they want to proceed, and basic users cannot continue with the test setup. Refer to Section 8 External Control (EC) for further details.

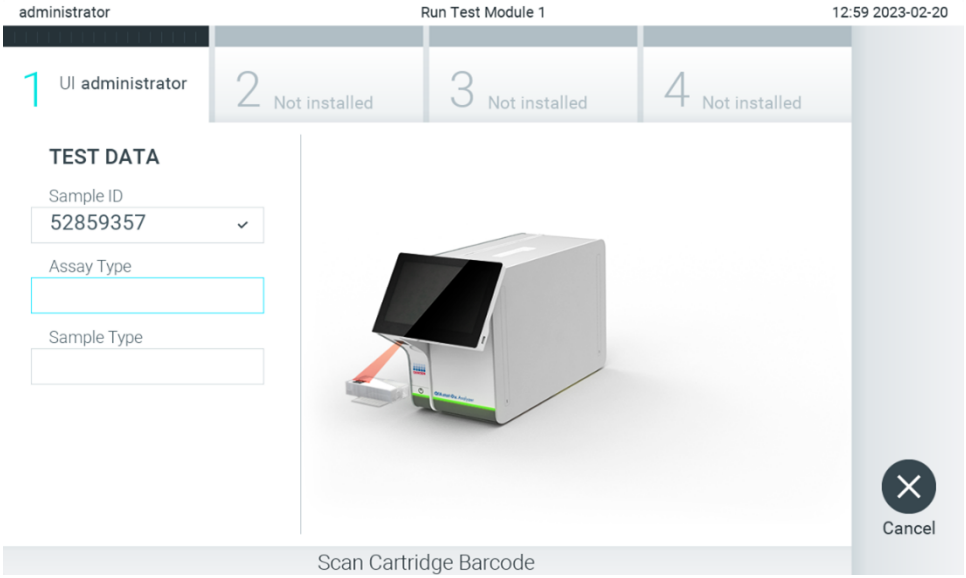


Figure 24. Scanning the QIAstat-Dx assay cartridge bar code.

4. If required, select the appropriate sample type from the list (Figure 25).

   Note: In some rare instances, the sample type list may be empty. In this case, the cartridge needs to be scanned again.

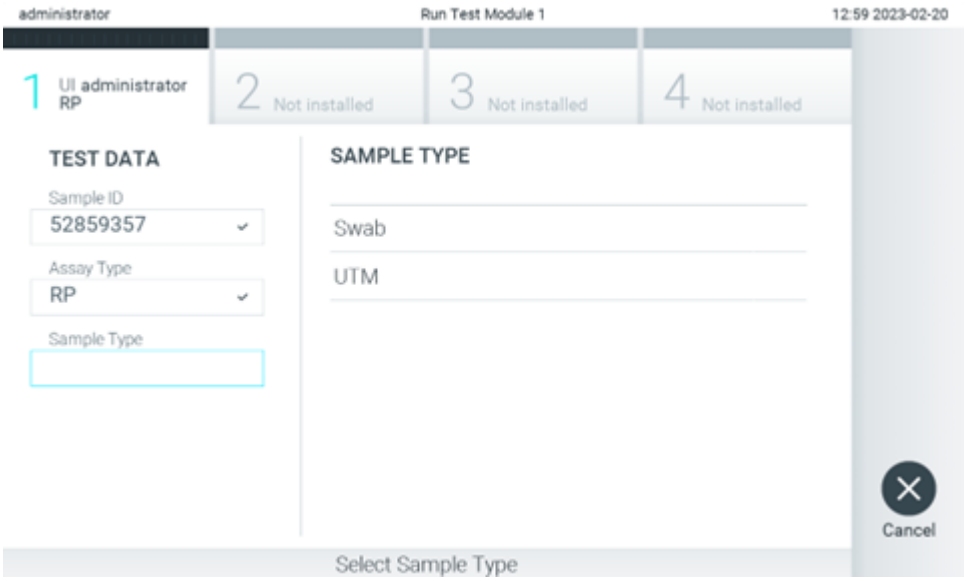


Figure 25. Selecting sample type.

5. The Confirm screen will appear. Review the data entered and make any necessary changes by pressing the relevant fields on the touchscreen and editing the information (Figure 26).

Figure 26. Confirm screen.

6. Press **Confirm** when all the displayed data are correct. If needed, press the appropriate field to edit its content, or press **Cancel** to cancel the test.
7. Make sure that both sample lids of the swab port and main port of the QIAstat-Dx assay cartridge are firmly closed. When the cartridge entrance port on the top of the QIAstat-Dx Analyzer 2.0 automatically opens, insert the QIAstat-Dx assay cartridge with the bar code facing to the left and the reaction chambers facing down (Figure 27).

   Note: When multiple Analytical Modules are connected to an Operational Module, the QIAstat-Dx Analyzer 2.0 automatically selects the Analytical Module in which the test is to be run.

   Note: There is no need to push the QIAstat-Dx assay cartridge into the QIAstat-Dx Analyzer 2.0. Position it correctly into the cartridge entrance port and the QIAstat-Dx Analyzer 2.0 will automatically move the cartridge into the Analytical Module.

Figure 27. Inserting QIAstat-Dx assay cartridge into QIAstat-Dx Analyzer 2.0.

8. Upon detecting the QIAstat-Dx assay cartridge, the QIAstat-Dx Analyzer 2.0 will automatically close the lid of the cartridge entrance port and start the test run. No further action from the operator is required to start the run.

   Note: The QIAstat-Dx Analyzer 2.0 will not accept a QIAstat-Dx assay cartridge other than the one used and scanned during the test setup. If a cartridge other than the one scanned is inserted, an error will be generated, and the cartridge will be automatically ejected.

   Note: Up to this point, it is possible to cancel the test by pressing the **Cancel** button in the bottom-right corner of the screen.

   Note: Depending on the system configuration, the operator may be required to re-enter their password to start the test run.

   Note: The lid of the cartridge entrance port will close automatically after 30 seconds if a QIAstat-Dx assay cartridge is not positioned in the port. If this occurs, repeat the procedure starting with step 5.

9. While the test is running, the remaining run time is displayed on the touchscreen (Figure 28).

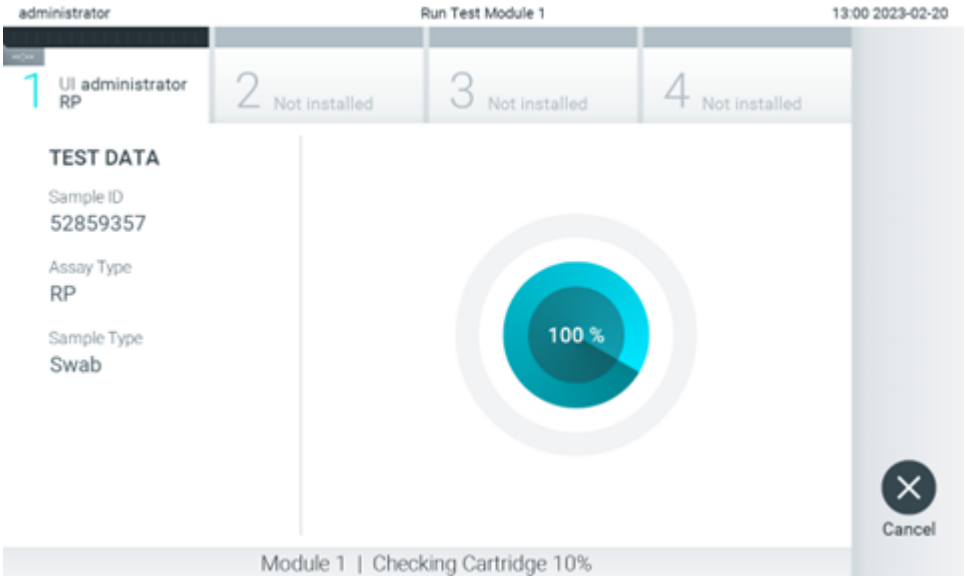


Figure 28. Test execution and remaining run time display.

10. After the test run is completed, the Eject screen will appear (Figure 29).

    Press **Eject** on the touchscreen to remove the QIAstat-Dx assay cartridge and dispose of it as biohazardous waste in accordance with all national, state, and local health and safety regulations and laws.

    Note: The QIAstat-Dx assay cartridge should be removed when the cartridge entrance port opens and ejects the cartridge. If the cartridge is not removed after 30 seconds, it will automatically move back into the QIAstat-Dx Analyzer 2.0 and cartridge entrance port lid will close. If this occurs, press **Eject** to open the lid of the cartridge entrance port again and then remove the cartridge.

    Note: Used QIAstat-Dx assay cartridges must be discarded. It is not possible to reuse cartridges for tests for which the execution was started but then subsequently canceled by the operator, or for which an error was detected.

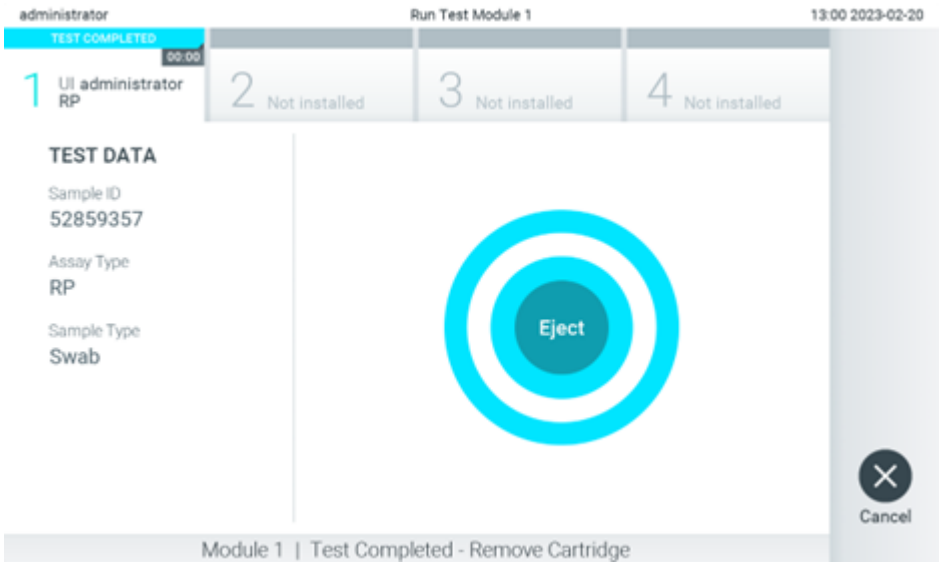


Figure 29. Eject screen display.

11. After the QIAstat-Dx assay cartridge has been ejected, the results Summary screen will appear (Figure 30). Refer to Section 5.5 Viewing results for further details.

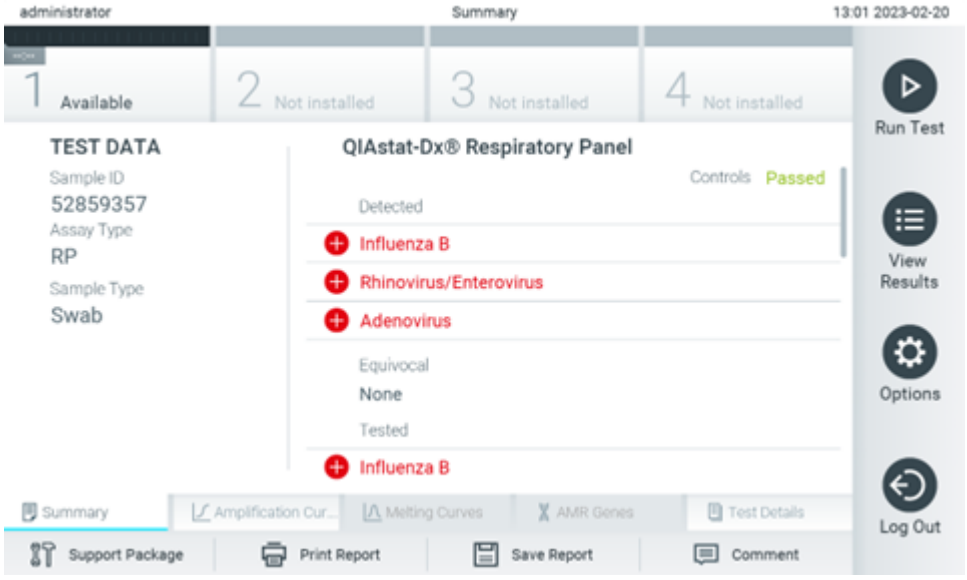


Figure 30. Results Summary screen.

Note: If an error with the analytical module occurred during the run, it may take some time until the run summary is shown, and the run is made visible in the View Results overview.

5.4. Canceling a test run

If a test run is already in progress, pressing **Abort** will stop the execution of the test (Figure 31).

Note: Used QIAstat-Dx assay cartridges must be discarded. It is not possible to reuse cartridges for tests for which the execution was started but then subsequently canceled by the operator, or for which an error was detected.

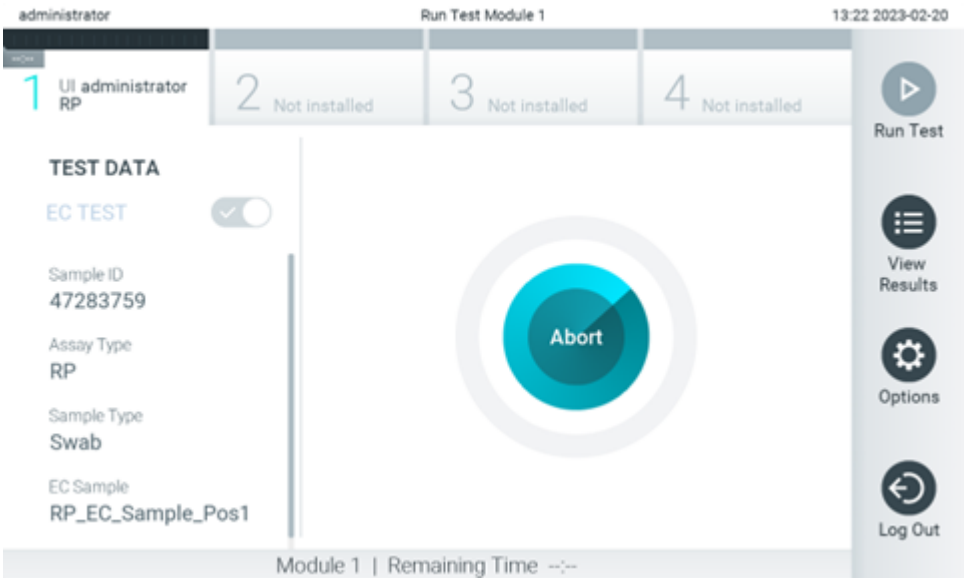


Figure 31. Canceling a test run.

After aborting a test, the QIAstat-Dx assay cartridge can no longer be processed and cannot be re-used. After pressing **Abort**, a dialog box will appear prompting the operator to confirm that the test should be canceled (Figure 32).

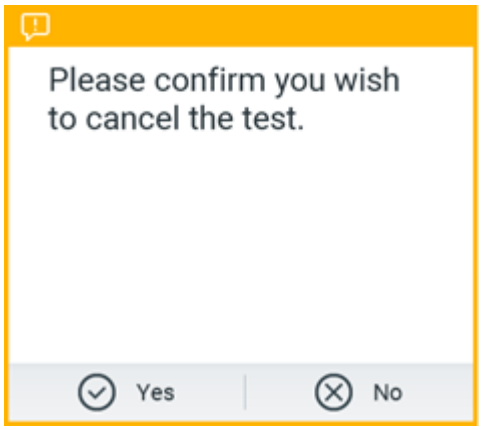


Figure 32. Cancelling a test run confirmation dialog.

5.5. Viewing results

The QIAstat-Dx Analyzer 2.0 automatically interprets and saves test results. After ejecting the QIAstat-Dx assay cartridge, the results Summary screen is automatically displayed (Figure 33).

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

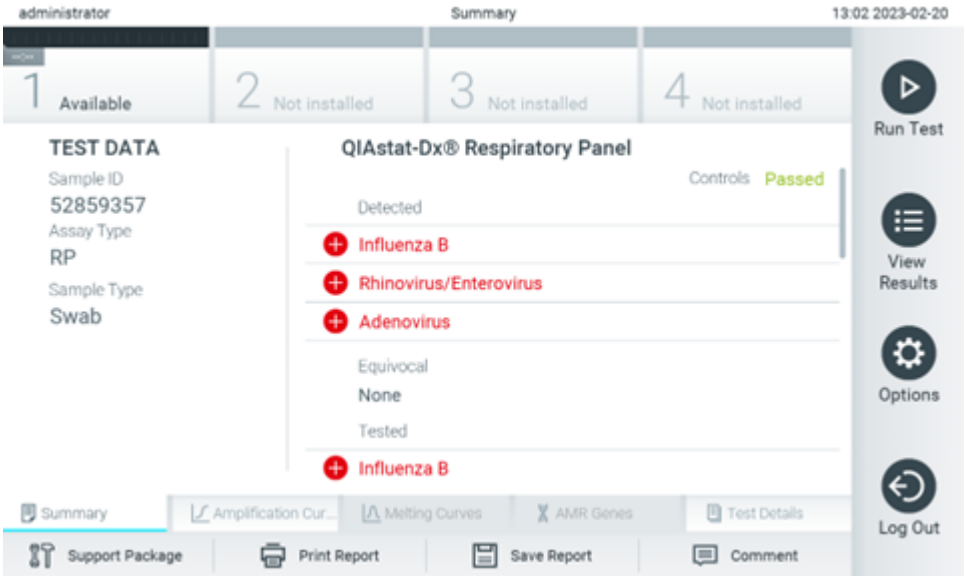


Figure 33. Results Summary screen example showing Test Data in the left panel and test Summary in the main panel.

The main part of the screen provides the following three lists and uses color-coding and symbols to indicate the results:

- The first list includes all pathogens including AMR genes (if supported by the assay) that are detected and identified in the sample, preceded by a sign and are colored red.
- The second list includes all equivocal pathogens, preceded by a question mark and are colored yellow.
- The third list includes all pathogens including AMR genes (if supported by the assay) that are tested in the sample. Pathogens detected and identified in the sample are preceded by a sign and are colored red. Pathogens that were tested but not detected are preceded by a sign and are colored green. Equivocal pathogens are preceded by a question mark and are colored yellow.

  Note: Pathogens detected and identified in the sample are shown in all lists.

  Note: Further details can be found in specific assay instructions for use.

If the test failed to complete successfully, a message will indicate "Failed" followed by the specific Error Code.

The following Test Data are shown on the left side of the screen:

- Sample ID
- Patient ID (if available)
- Assay type
- Sample type
- LIS Upload Status (if applicable)

Further data about the assay is available, depending on the operator's access rights, through the tabs at the bottom of the screen (e.g., amplification plots, melting curves and test details).

Assay data can be exported by pressing **Save Report** in the bottom bar of the screen.

A report can be sent to the printer by pressing **Print Report** in the bottom bar of the screen.

A support package of the selected run or all failed runs can be created by pressing Support Package at the bottom bar of the screen (Figure 34). If support is required, send the support package to the QIAGEN Technical Services.

5.5.1. Viewing amplification curves

To view the test amplification curves, press the Amplification Curves tab (Figure 34). This function may not be available for all assays.

Note: Please be advised that the amplification curves are not meant to interpret test results.

Figure 34. Amplification Curves screen (PATHOGENS tab).

Details about the tested pathogens and internal controls are shown on the left and the amplification curves are shown in the center.

Note: If User Access Control is enabled (refer to section 6.5 User management) on the QIAstat-Dx Analyzer 2.0, the Amplification Curves screen is only available for operators with access rights.

Press the PATHOGENS tab on the left side to display the plots corresponding to the tested pathogens. Press 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 be shown in gray.

The corresponding CT and endpoint fluorescence values are shown below each pathogen name.

Press the **CONTROLS** tab on the left side to view the internal controls and select which internal controls are shown in the amplification plot. Press the circle next to the internal control name to select or deselect it (Figure 35).

Figure 35. Amplification Curves screen (CONTROLS tab) showing internal controls.

The amplification plot displays the data curve for the selected pathogens or internal controls. To alternate between logarithmic or linear scale for the Y-axis, press the **Lin** or **Log** button at the bottom left corner of the plot.

The scale of the X-axis and Y-axis can be adjusted using the blue pickers on each axis. Press and hold a blue picker and then move it to the desired location on the axis. Move a blue picker to the axis origin to return to the default values.

5.5.2. Viewing melting curves

To view the test melting curves, press the **Melting Curves** tab.

Details about the tested pathogens and internal controls are shown on the left and the melting curves are shown in the center.

Note: The **Melting Curves** tab is only available for assays implementing melting analysis.

Note: If User Access Control is enabled (refer to section 6.5 User management) on the QIAstat-Dx Analyzer 2.0, the Melting Curves screen is only available for operators with access rights.

Press the **PATHOGENS** tab on the left side to display the tested pathogens. Press the circle next to the pathogen name to select which pathogen melting curves are shown. It is possible to select single, multiple or no pathogens. Each pathogen in the selected list will be assigned a color corresponding to the melting curve associated with the pathogen. Unselected pathogens will be shown in gray. The melting temperature is shown below each pathogen name.

Press the **CONTROLS** tab on the left side to view the internal controls and select which internal controls are shown in the melting plot. Press the circle next to the control name to select or deselect it.

Internal controls that passed the analysis are shown in green and are labeled "Passed Controls", while those that failed are shown in red and are labeled "Failed Controls".

The scale of the X-axis and Y-axis can be adjusted using the blue pickers on each axis. Press and hold a blue picker and then move it to the desired location on the axis. Move a blue picker to the axis origin to return to the default values.

5.5.3. Viewing AMR genes

To view AMR Genes, press the **AMR genes** tab.

Note: The **AMR Genes** tab is only available for assays containing AMR Genes.

On the left side, there is a list of all detected AMR genes. When selecting one of the detected AMR genes, a list of all associated pathogens is shown in the center. Pathogens detected and identified in the sample are preceded by a sign and are colored red. Pathogens that were tested but not detected are preceded by a sign and are colored green (Figure 36).

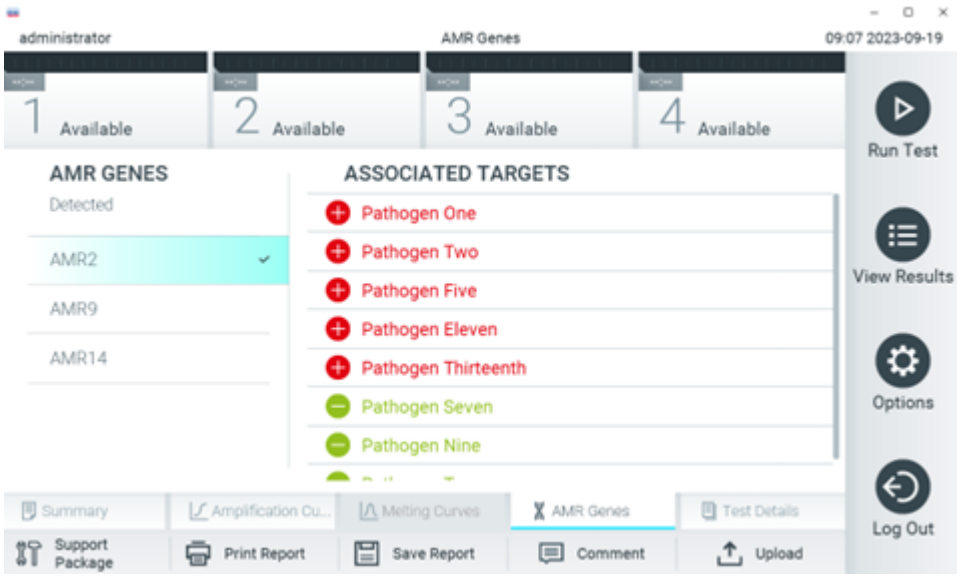


Figure 36. AMR Genes screen.

Note: The data shown in Figure 36 is dummy data and not showing real pathogens.

For more information about AMR genes and a complete overview of all associations between AMR genes and other targets, please refer to the respective assay's instruction for use.

5.5.4. Viewing test details

Press Test Details to review the results in more detail. Scroll down to see the complete report.

The following Test Details are shown in the center of the screen (Figure 37):

- User ID
- Cartridge SN (serial number)
- Cartridge Expiration Date
- Module SN (serial number)
- Test Status (Completed, Failed or Canceled by operator)
- Test Start Date and Time

- Test Execution Time
- Assay Name
- External Control Test (Refer to Section 8 External Control (EC))
- Test ID
- Book Order ID (Visible only if order checking was on when the test was run. Refer to Section 7 HIS/LIS Connectivity)
- Order Time (Visible only if order checking was on when the test was run. Refer to Section 7 HIS/LIS Connectivity)
- HIS/LIS Confirmation (Visible only if order checking was on when the test was run. Refer to Section 7 HIS/LIS Connectivity)
- Error Code (if applicable)
- Error Message (if applicable)
- Last Comment Editor (if applicable, refer to section 5.5.5 Commenting on test results)
- Comment Date and Time (if applicable, refer to section 5.5.5 Commenting on test results)
- Comment (if applicable, refer to section 5.5.5 Commenting on test results)
- Test Result (for every analyte, total result of the test: Positive [pos], Positive with Warning [pos*], Negative [neg], Invalid [inv], Failed [fail] or successful [suc]. Refer to assay-specific instructions for use for details on possible results and their interpretation)
- List of analytes tested in the assay (grouped by Detected Pathogen, Equivocal, Not Detected Pathogens, Invalid, Not Applicable, Out of Range, Passed Controls and Failed Controls), with CT, endpoint fluorescence, and semi-quantification value in cp/mL (copies per milliliter) if available for the assay
- List of internal controls, with CT and endpoint fluorescence (if available for the assay)

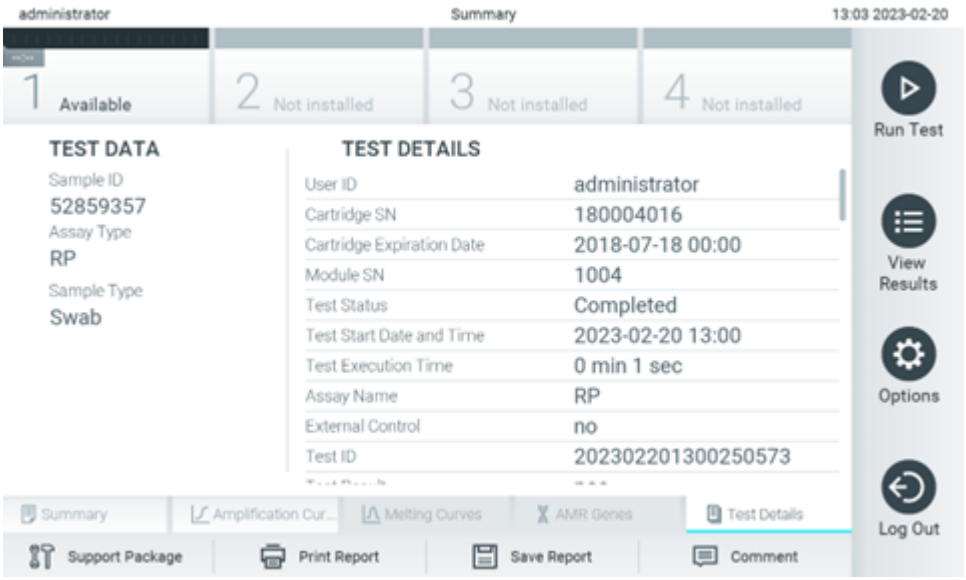


Figure 37. Example screen showing Test Data in the left panel and Test Details in the main panel.

5.5.5. Commenting on test results

From any tab of the Results screen, select **Comment** to add a comment to a test result. When adding a comment, additionally the user that commented on the result as well as the date and time of commenting is saved. Only the last comment, editor and date and time is saved, i.e., when editing an existing comment, the previous comment is not persisted.

A comment can be viewed in the test details tab of a result.

Comments can optionally be hidden from PDF reports. To hide comments from PDF reports, refer to section 6.7.4 General settings.

Note: Adding, editing, and removing comments has no influence on the biological test result.

Note: The comment functionality is not available when the QIAstat-Dx Remote Results Application is used (refer to section 6.7.3 QIAsphere Base settings)

Note: The comment should not contain Personally Identifiable Information (PII) or protected health information (PHI).

5.5.6. Browsing results from previous tests

To view results from previous tests that are stored in the results repository, press View Results on the Main Menu bar (Figure 38).

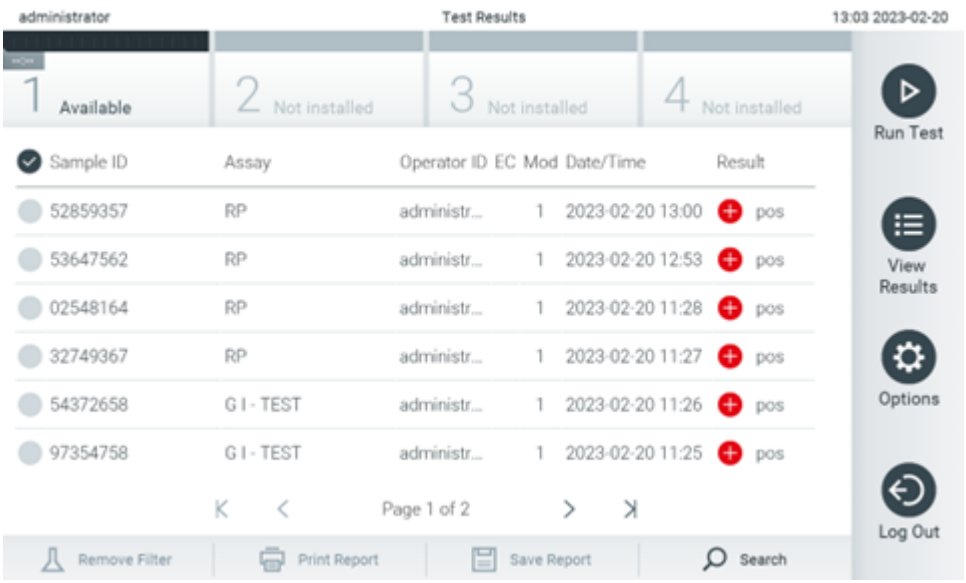


Figure 38. Example View Results screen.

The following information is available for every executed test (Figure 38):

- Sample ID
- Assay (name of test assay)
- Operator ID
- EC (if an EC test was performed)

- Mod (Analytical Module on which the test was executed)
- Upload status (only visible if activated via HIS/LIS settings)
- Date/Time (date and time when the test was finished)
- Result (outcome of the test: positive [pos], pos with warning [pos*], negative [neg], invalid [inv], failed [fail] or successful [suc], EC passed [ecpass], or EC failed [ecfail])

Note: Possible outcomes are assay-specific (i.e., some outcomes may not be applicable for each assay). Refer to the assay-specific instructions for use.

Note: If User Access Control is enabled (refer to section 6.5 User management) on the QIAstat-Dx Analyzer 2.0, the data for which the user has no access rights will be hidden with asterisks.

Note: For viewing previous tests that were either manually or automatically archived, refer to Section 6.12.2 Open archive.

Select one or more test results by pressing the gray circle to left of the sample ID. A checkmark will appear next to selected results. To deselect test results, press the checkmark. The entire list of results can be selected by pressing the checkmark circle in the top row (Figure 39).

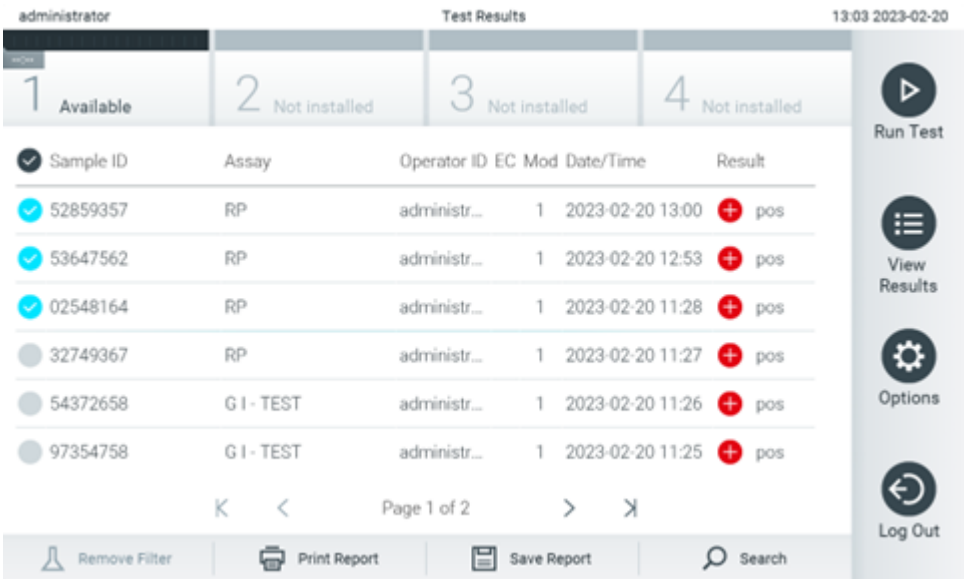


Figure 39. Example of selecting Test Results in the View Results screen.

Press anywhere in the test row to view the result for a particular test. Press a column headline (e.g., Sample ID) to sort the list in ascending or descending order according to that parameter. The list can be sorted according to only one column at a time. The Result column shows the outcome of each test (Table 1).

Note: Possible outcomes are assay-specific (i.e., some outcomes may not be applicable for each assay). Refer to the assay-specific instructions for use.

Table 1. Description of test results

Outcome	Result	Description
Positive	pos	At least one analyte is positive

Table 1. Description of test results (continued)

Outcome	Result	Description
Positive with warning	pos*	At least one analyte is positive, but an assay internal control failed
Negative	neg	No analytes were detected
Failed	fail	The test failed because an error occurred, the test was canceled by the user, or an EC test failed but the user does not have the access rights to view the test results.
Invalid	inv	The test is invalid
Successful	suc	The test is positive, positive with warning, negative, or EC passed but the user does not have the access rights to view the test results
EC Passed	ecpass	The EC test passed, such that all analytes met their expected result.
EC Failed	ecfail	The EC test failed, meaning at least one analyte did not meet its expected result.

Note: Refer to the assay IFU for the test being performed for a detailed description of results.

Make sure a printer is connected to the QIAstat-Dx Analyzer 2.0 and the proper driver is installed (Appendix 12.1 Printer installation and configuration). Press **Print Report** to print the report(s) for the selected result(s).

Press **Save Report** to save the report(s) for the selected result(s) in PDF format to an external USB storage device. Select the report type: **List of Tests** or **Test Reports**.

Note: It is recommended to use the delivered USB storage device for short-term data storage and transfer. 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).

Press **Search** to search the test results by Sample ID, Assay, and Operator ID. Enter the search string using the virtual keyboard and press **Enter** to start the search. Only the records containing the search text will be displayed in the search results. If the results list has been filtered, the search will only apply to the filtered list.

To filter results, press and hold a column headline to apply a filter based on that parameter. For some parameters, such as Sample ID, the virtual keyboard will appear so the search string for the filter can be entered. For other parameters, such as Assay, a dialog will open with a list of assays stored in the repository. Select one or more assays to filter only the tests that were performed with the selected assays.

The symbol to the left of a column headline indicates that the column's filter is active. A filter can be removed by pressing **Remove Filter** in the Submenu bar.

5.5.7. Exporting results to a USB drive

From any tab of the View Results screen, select **Save Report** to export and save a copy of the test results in PDF format to a USB drive. The USB port is located on the front of the QIAstat-Dx Analyzer 2.0 (Figure 40).

Reports can be configured such that amplification curves and comments respectively can be excluded on the export. To configure this, refer to section 6.7.4 General settings.

Note: It is recommended to use the delivered USB storage device for short-term data saving and transfer. 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).

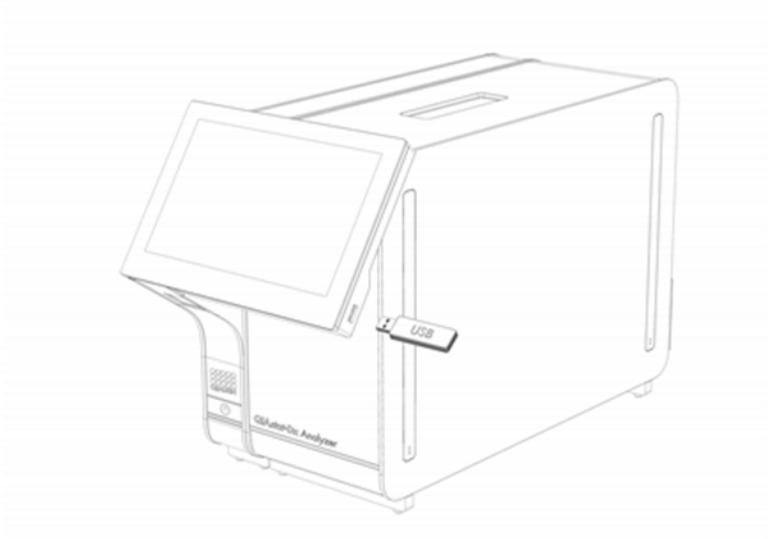


Figure 40. Location of USB port.

5.5.8. Printing results

Make sure a printer is connected to the QIAstat-Dx Analyzer 2.0 and the proper driver is installed (see Appendix 12.1 Printer installation and configuration for more information on driver installation). Press **Print Report** to send a copy of the test results to the printer.

Reports can be configured such that amplification curves and comments respectively can be excluded on the printout. To configure this, refer to section 6.7.4General settings.

Note: With some printers, it may happen that analytes printed in italic are slightly blurred. It is recommended to export the test report in PDF format to a USB drive as described in section 5.5.7 Exporting results to a USB drive and print the PDF document.

5.5.9. 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 Service. For creating a support package, press **Support Package**. A dialog appears and a support package for the selected test or all failed tests can be created (Figure 41). Save the support package to a USB storage device. The USB port is located on the front of the QIAstat-Dx Analyzer 2.0 (Figure 40).

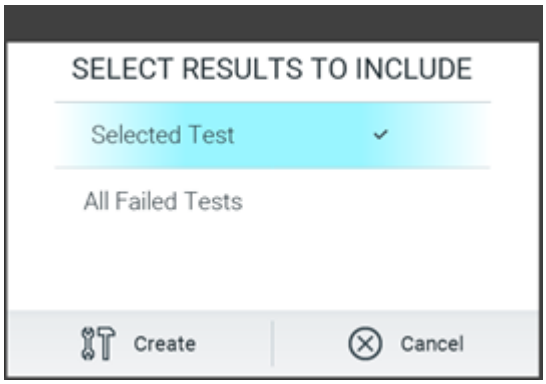


Figure 41. Support Package creation.

Note: It is recommended to use the delivered USB storage device for short-term data storage and transfer. 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.

Note: If support is required, ensure that a support package is created shortly after the problem occurred. Due to limited storage capacity and configuration of the system, system and technical log files of the respective time interval may be deleted automatically when continuing usage of the system.

6. System Functions and Options

This section provides a description of all the available QIAstat-Dx Analyzer 2.0 features and options that enable customization of the instrument settings.

6.1. Main screen

In the Main screen, it is possible to view the status of the Analytical Modules and navigate to different sections (Login, Run Test, View Results, Options, and Log Out) of the user interface (Figure 42).

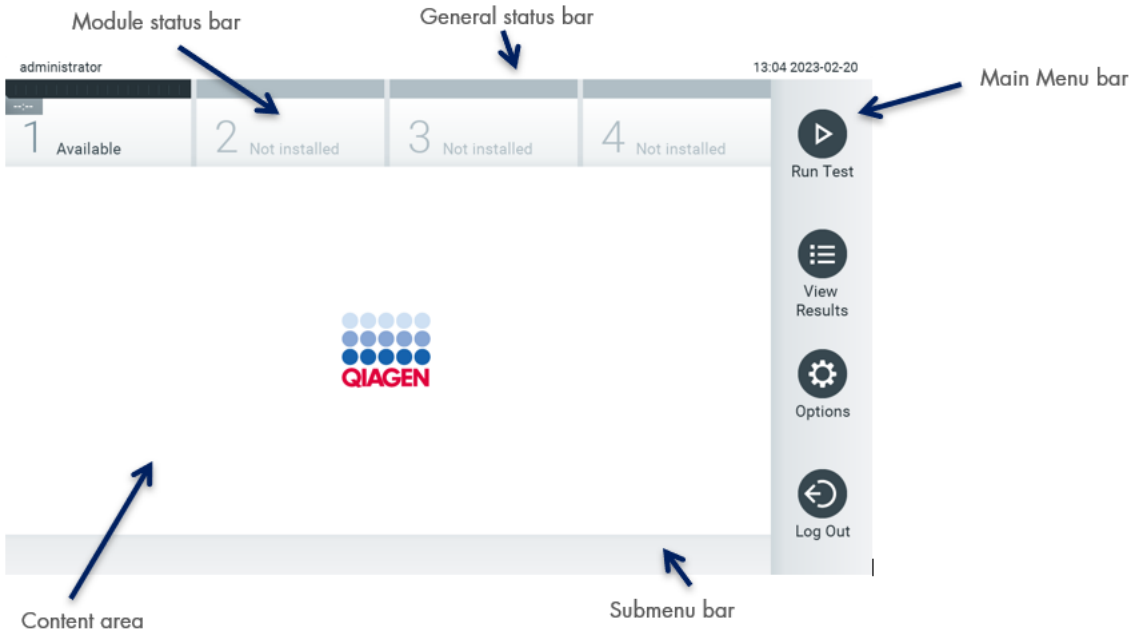


Figure 42. Main screen of the QIAstat-Dx Analyzer 2.0 touchscreen.

The Main screen includes the following elements:

- General status bar
- Module status bar
- Main Menu bar
- Content area
- Tab Menu bar (optionally shown, depends on screen)
- Submenu bar and Instructions bar (optionally shown, depends on screen)

6.1.1. General status bar

The General status bar provides information about the status of the system (Figure 43). The User ID of the logged-in user appears on the left side. The title of the screen appears in the middle, and the system date and time appear on the right.

Figure 43. General status bar.

6.1.2. Module status bar

The Module status bar displays the status of each Analytical Module (1–4) available in the system in corresponding status boxes (Figure 44). The boxes will display "Not Installed" if no Analytical Module is available for that position.

Figure 44. Module status bar.

Click the box corresponding to a particular Analytical Module to access more detailed information (see Module status page). Module states that may be displayed in a status box of the Module status bar are shown in Table 2.

Table 2. Module states that may be displayed in status boxes

State	Description
Not installed	No Analytical Module is installed at that position.
Excluded	The Analytical Module has been excluded by the user via user settings.
Error	The Analytical Module reported a serious error. The Analytical Module is out of order.
Initializing	The Analytical Module is starting up and is performing the self-test.
Available	The Analytical Module is available for a new test. There is no test running in this Analytical Module, no QIAstat-Dx assay cartridge is inserted and the lid of the cartridge entrance port is closed.
Test running 	User "administrator" is currently running the Resp_3018_19c test on Analytical Module 1. There are 32 minutes and 14 seconds remaining to complete the test.
Test completed 	User "administrator" has run the Resp Panel test on Analytical Module 1. The progress bar in the box will show the test status: TEST COMPLETED: the test was completed successfully. TEST FAILED: the test was completed, but an error occurred. TEST CANCELED: the user canceled the test. Once the QIAstat-Dx assay cartridge has been removed and the lid of the cartridge entrance port has closed, the Analytical Module will be available again.
Eject cartridge	The Analytical Module contains a QIAstat-Dx assay cartridge and the lid of the cartridge entrance port is closed, but no test is currently running. This can occur in the following situations: The cartridge was not removed after an ejection due to a canceled or completed test. The system was powered off with a cartridge inside the Analytical Module.

6.1.3. Module status page

The Module status page displays information such as position, serial number, HW revision, and current software version. Additionally, errors concerning the selected Analytical Module are shown as well as information about software and hardware components (Figure 45).

The instruction bar shows a reboot button that can be used to restart the selected Module without having to restart the entire device. The button is only enabled when the selected Module is in an error or "out of order" state.

Note: The **Restart** button might also be disabled after a test finished on the module if post-processing is still ongoing.

Figure 45. Module status page.

The Module status page can be accessed at any time, except when the AM is in the "Not installed", "Not present", or "Initializing" state. During a run and when the cartridge is still inserted, the Module status page will not be shown, instead, it will show the module status bar (introduced in the previous subsection).

Table 3. Main Menu bar options

Name	Button	Description
Run Test		Starts the run test sequence (see Section 5.3). The QIAstat-Dx Software automatically selects an available Analytical Module and starts the test preparation sequence.
View Results		Opens the View Results screen (see Section 5.5).
Options		Displays the Options submenu (see Section 6.4).
Log Out		Logs the user out (See section 6.2.1) Only active when User Access Control is enabled.

6.1.4. Content area

The information displayed in the main content 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 menu described below.

Depending on the content, further options may be available through the Tab Menu bar and Options menu. The Options submenu is accessed by pressing the **Options** button (Figure 46).

Figure 46. Accessing the Options submenu.

6.2. Login screen

When User Access Control is enabled (refer to Section 6.5), users must identify themselves by logging in to access the QIAstat-Dx Analyzer 2.0 functions.

Important: For the first-time login, the user ID is "administrator" and the default password is "administrator". The password must be changed after the first login.

Note: After successful initial installation of the QIAstat-Dx Analyzer 2.0, the User Access Control is activated automatically.

Note: It is strongly recommended to create at least one user account without an "Administrator" role at first login.

The content area of the login screen includes a text box for entering the User ID (Figure 47). If the option Show previous user logins is selected, a list of the previous five users that logged in successfully will also be displayed.

Note: The service technician login icon in the lower right corner of the screen should only be used by personnel authorized by QIAGEN.

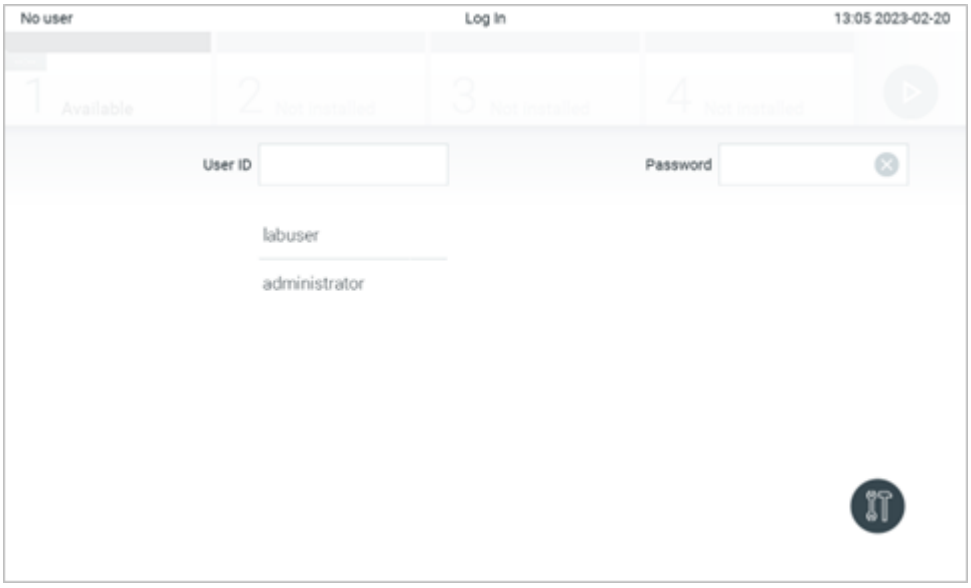


Figure 47. Login screen.

Enter the user name either by clicking on one of the names available in the list or by clicking on the User ID text box and entering the name using the virtual keyboard. Once the user name is entered, confirm by pressing the check mark on the virtual keyboard (Figure 48).

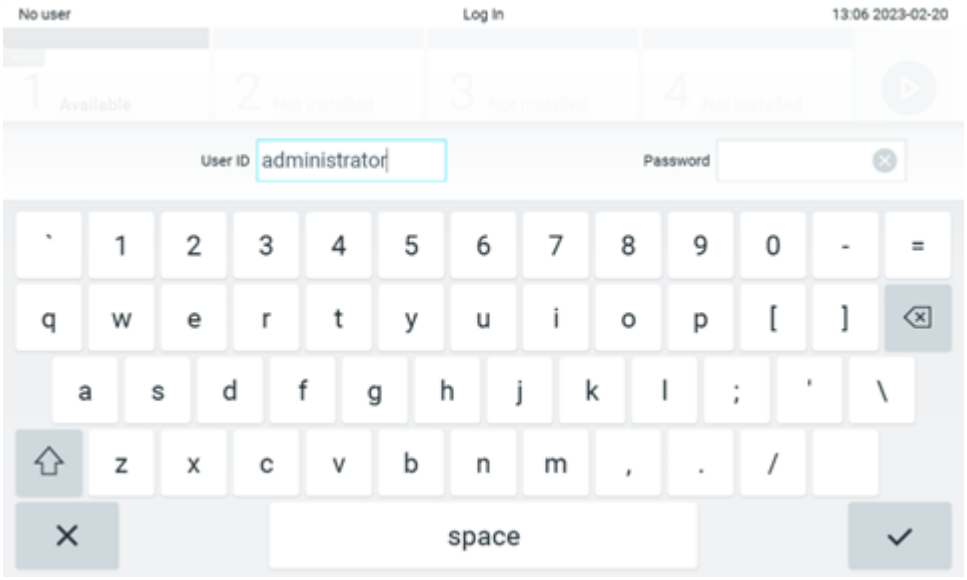


Figure 48. Virtual keyboard on touchscreen.

If the option Require password is selected (refer to Section 6.5), a password text box and the virtual keyboard for entering the password will be shown. If no password is required, the password text box will be grayed out.

If a user forgets his or her password, the system Administrator can reset it.

Note: If the administrator forgets their password, it can only be reset by QIAGEN Technical Services, which requires an on-site visit by a QIAGEN service engineer. Therefore, it is recommended to create an additional administrator account.

For security reasons, if a password is entered incorrectly three times, the system will lock for one minute before the user can try to log in again.

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

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

6.2.1. Logging out

When User Access Control is enabled (refer to Section 6.5), users can log out at any time using the Log Out option in the Main Menu bar.

Users will be automatically logged out when the time for automatic log-off expires. This time can be configured in the General settings of the Options menu (see Section 6.7.4).

6.3. Screen saver

The QIAstat-Dx Analyzer 2.0 screen saver is shown after there has been no user interaction for a pre-defined period of time. This time can be configured in the Options menu (see Section 6.7.4).

The screen saver shows the availability of Analytical Modules and the remaining time until test completion (Figure 49).

Note: During operations such as software update, backup, restore, archive creation, and archive opening, the screen saver and automatic log-off may be disabled. For cybersecurity reasons, it is recommended to not leave the system unattended during this time.

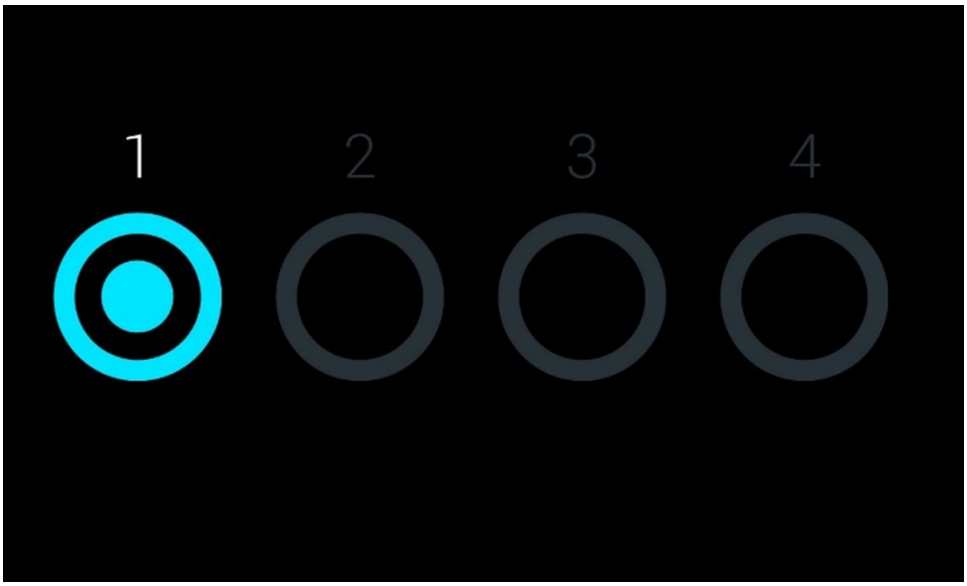


Figure 49. Screen saver showing one available Analytical Module.

6.4. Options menu

The Options menu is accessible from the Main Menu bar. Table 4 shows the options that are available to the user. Options that are not available will be grayed out.

Table 4. Options menu

Name	Button	Description	Reference Section
User Management		Available for users with rights to manage users and user profiles.	6.5
Assay Management		Available for users with rights to manage assays.	6.6
System Configuration		Available for users with the rights to configure the system.	6.7
Change Password		Available if User Access Control is enabled.	6.8
Notifications		Available for all users to view and confirm notifications and to download files.	6.9
Print Queue		Available for all users.	6.10.2
External Control		Available for users with rights to manage External Control settings	8

6.5. User management

The QIAstat-Dx application software is flexible in supporting different usage scenarios. For the management of users and rights, the following modes are available:

- "Single User" mode: User Access Control is disabled and no control of the users that log into the QIAstat-Dx Analyzer 2.0 is performed. All QIAstat-Dx Analyzer 2.0 functions and features will be available without any restrictions to all users.
- "Multi-User" mode: User Access Control is enabled, and users must log in before performing any action on the QIAstat-Dx Analyzer 2.0. The actions they are allowed to perform are limited and defined according to their user profiles.

Note: The User Management option is only available to users with "Administrator" or "Laboratory Supervisor" profiles.

Note: User Access Control can be enabled and disabled in the General settings under System Configuration in the Options menu.

The User Management option permits users with "Administrator" and "Laboratory Supervisor" profiles to add new users to the system, define their rights and user profiles, and to activate or inactivate users.

The User Management can be controlled remotely via QIAsphere when activated in the system configurations. For more information refer to section 6.7.3.

Note: It is strongly recommended to enable the User Access Control. In the single-user mode, the user exhibits all administration rights without control of users that log into the QIAstat-Dx Analyzer 2.0. All functions and features will be available without any restrictions. In addition, it is strongly recommended to create at least one user account without an "Administrator" role at first login. If a single user of QIAstat-Dx Analyzer 2.0 aggregates different user roles, including the "Administrator" role, there is a high risk that access to the software will be completely blocked if this user forgets the password.

Table 5 displays the user profiles that are available in the QIAstat-Dx Analyzer 2.0.

Table 5. User profiles available in the QIAstat-Dx Analyzer 2.0

User Profile	Rights	Example
Administrator	Full	Instrumentation/IT responsibility
Laboratory Supervisor	Add new users, introduce new assays in the assay collection, Running assays and viewing results from all users including saving and printing reports, generating support packages, create and open archives, configure External Control settings, running External Control tests, delete print jobs, viewing and confirming notifications, downloading files from QIAsphere, and commenting on results	Laboratory head
Advanced User	Running assays, Viewing detailed results of own user tests (e.g., amplification plots, etc.) including saving and printing reports, generating support packages, running External Control tests, delete print jobs, viewing and confirming notifications, downloading files from QIAsphere, and commenting on results	Microbiologist, laboratory technician
Basic User	Running assays, Viewing non-detailed results of own user tests (e.g., positive/negative results) including saving and printing reports, generating support packages, viewing and confirming notifications, and downloading files from QIAsphere	Healthcare provider (e.g., nurse, doctor, general practitioner, etc.)

6.5.1. Accessing and managing the list of users

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

1. Press **Options** > **User Management** to configure users. The User Management screen appears in the content area of the display (Figure 50).

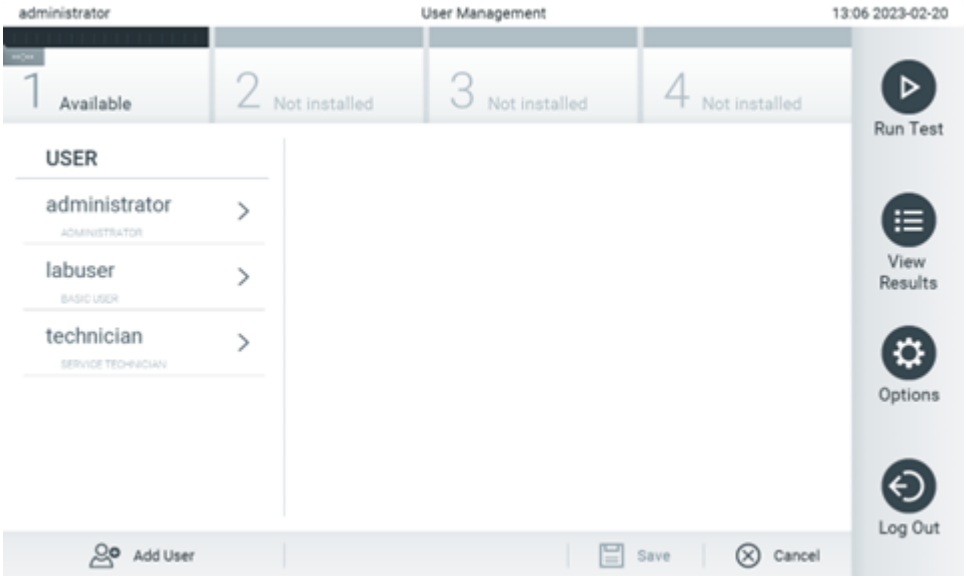


Figure 50. User Management screen.

2. Select the user to manage from the list in the left column of the content area (Figure 51).

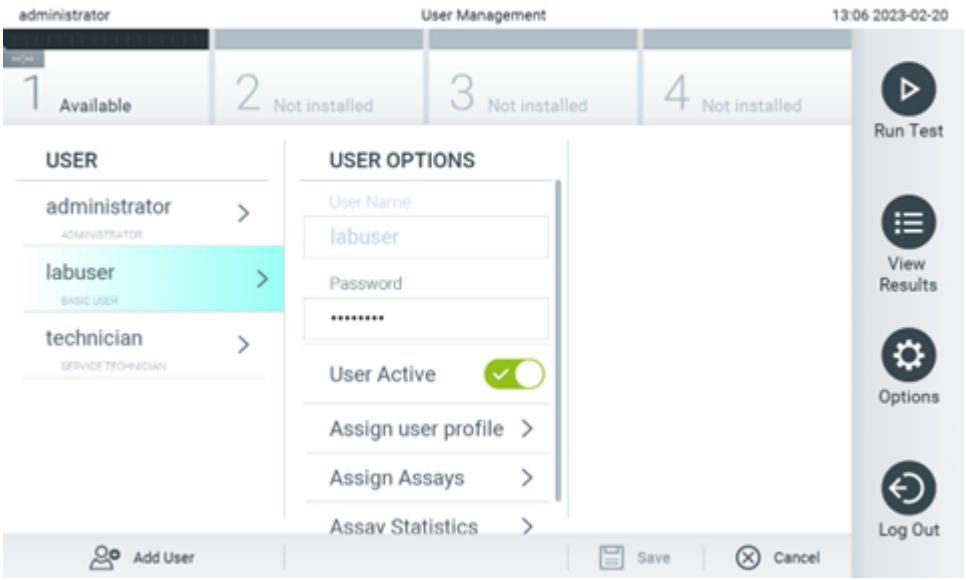


Figure 51. Selecting and managing users.

3. Select and edit the following options as needed:

   - **User Name**: Enables viewing the user name.
   - **Password**: Enables changing the password for that user

     A password must consist of 6-15 characters containing 0-9, a-z, A-Z, and the following special character: _ [ ] ; ' \ , . / - = ~ ! @ # $ % ^ & * ( ) + { } : " | < > ?,<space>.
   - **User Active (yes/no)**: Enables changing whether the user is active or not. Inactive users are not allowed to log in or perform any action on the system.
   - **Assign User Profile**: AllowsEnables assigning a different user profile for that user (e.g., Administrator, Laboratory Supervisor, Advanced User, Basic User). Select the appropriate user profile from the list on the right of the content area (Figure 52).

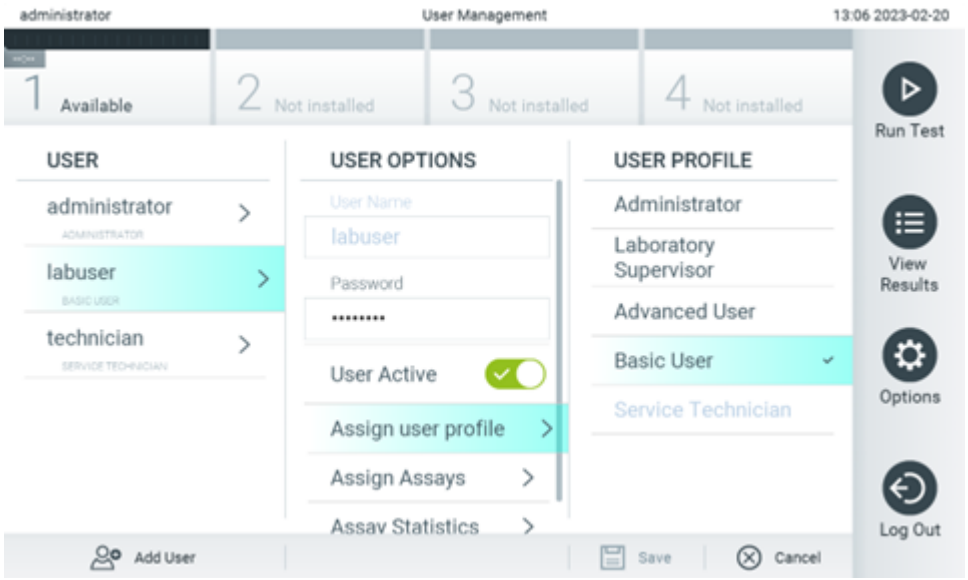


Figure 52. Assigning user profiles to users.

- **Assign Assays**: Enables defining the assays from the assay database that the user is permitted to run. Select the assays from the list on the right of the content area (Figure 53)

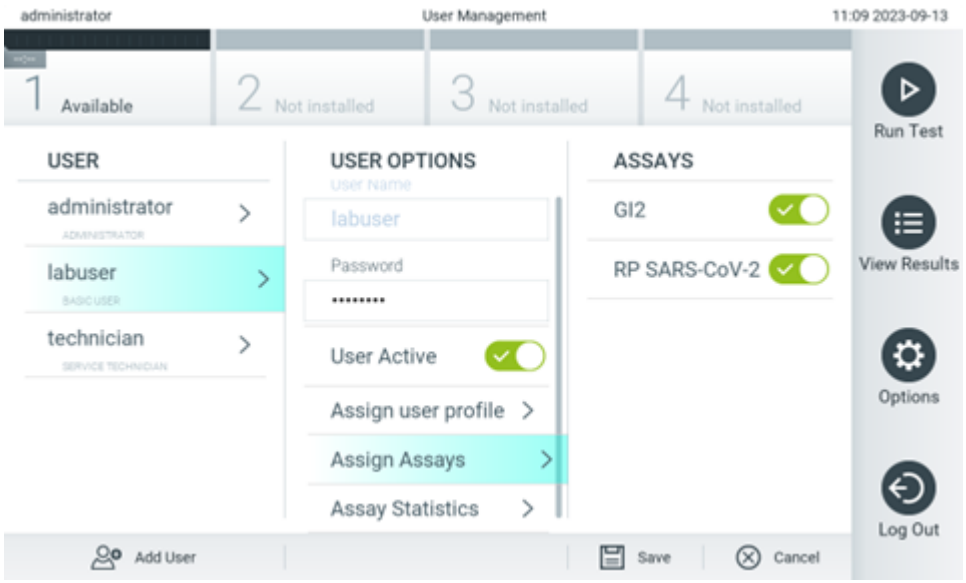


Figure 53. Assigning assays to users.

- **Assay Statistics**: Shows the number of times an assay was run by the selected user (Figure 54).

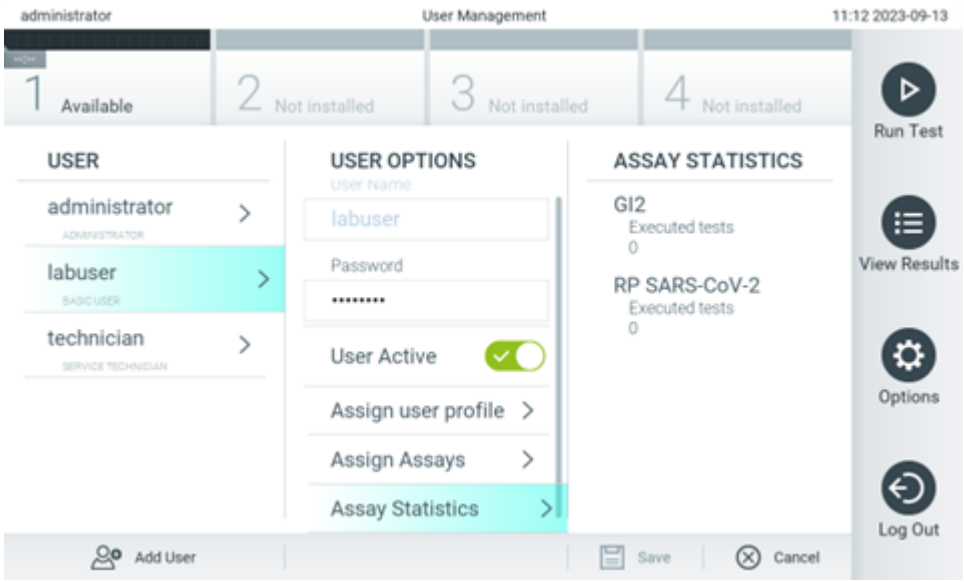


Figure 54. Viewing assay statistics.

4. Press **Save and Confirm** to save the changes. Alternatively, press **Cancel and Confirm** to discard the changes.

6.5.2. Adding users

Follow the steps below to add new users to the QIAstat-Dx Analyzer 2.0:

1. Press **Options** > **User Management** to configure users. The User Management screen appears in the content area of the display (Figure 55).

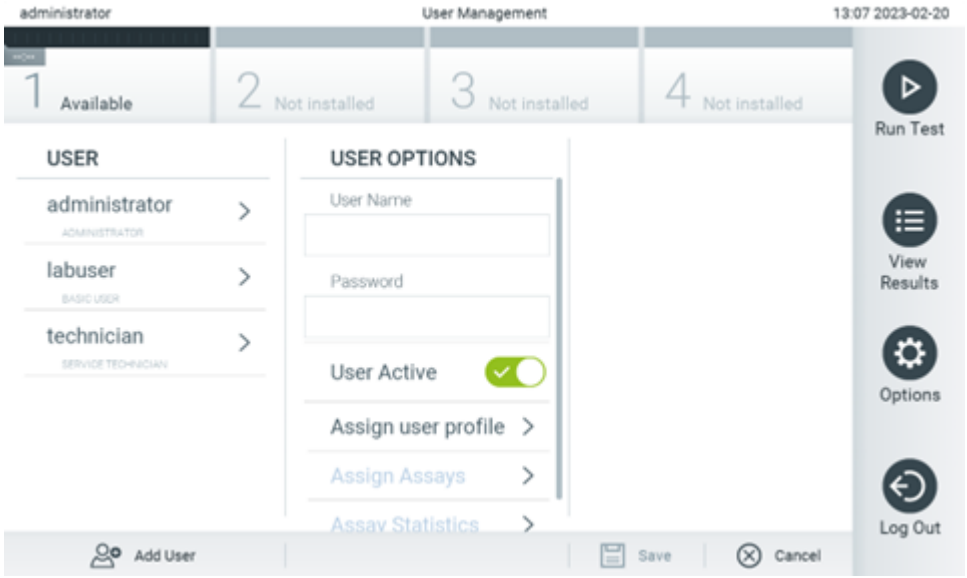


Figure 55. Adding a new user.

2. Press **Add User** located at the bottom left of the screen to add a new user to the system.
3. Use the virtual keyboard to enter specify values in the **User Name** and **Password** fields for the new user.

A User Name must consist of 1-20 characters containing only 0-9, a-z, A-Z, and the following special characters: _, <space>.

A password must consist of 6-15 characters containing 0-9, a-z, A-Z, and the following special character: _ [ ] ; ' \ , . / - = ~ ! @ # $ % ^ & * ( ) + { } : " | < > ?,<space>.

4. Press **Assign User Profile** and assign the appropriate user profile (from the list on the right of the content area) to the new user (Figure 56).

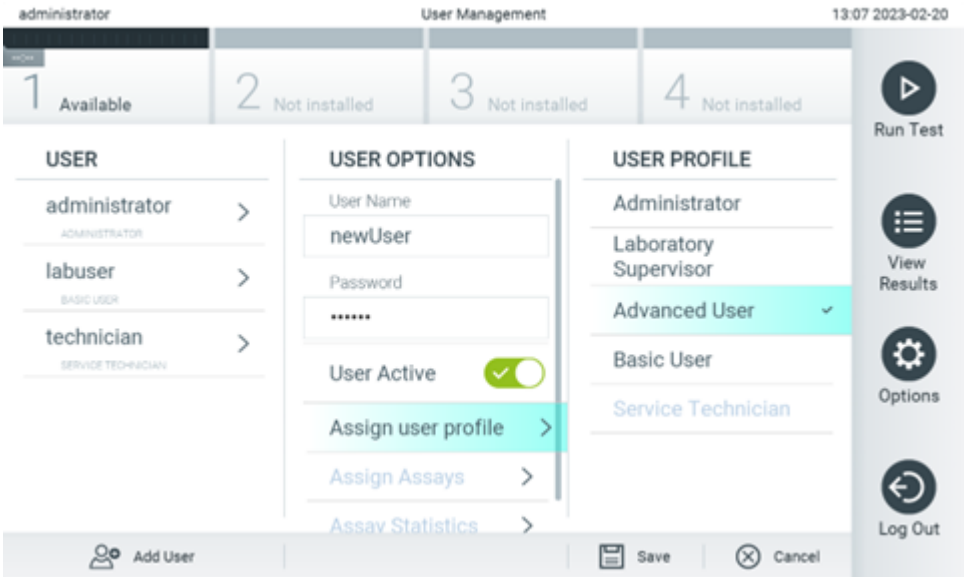


Figure 56. Assigning a user profile to a new user.

5. Press **Assign Assays** and select the assays (from the displayed assay list) that the user is allowed to run.
6. Press **Save and Confirm** to save and store the new information. The new user has been set up and is immediately allowed to log in to the QIAstat-Dx Analyzer 2.0.

6.6. Assay management

From the Assay Management menu, it is possible to manage assays and access assay-related information and statistics.

Note: The Assay Management option is available only to users with "Administrator" or "Laboratory Supervisor" profiles.

6.6.1. Managing available assays

Follow the steps below to manage assays on the QIAstat-Dx Analyzer 2.0:

1. Press **Options** > **Assay Management** to access the Assay Management screen. The available assays are listed in the first column of the content area (Figure 57).

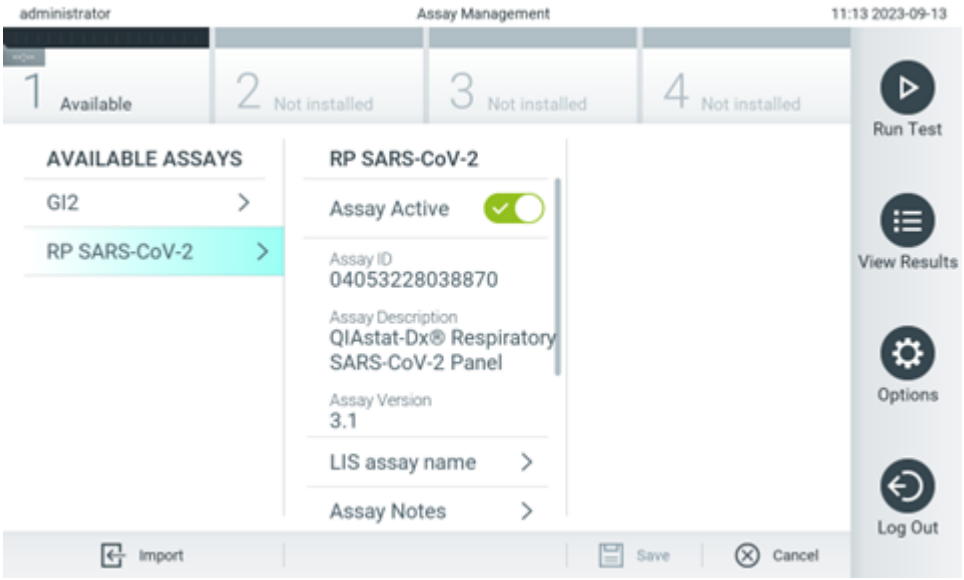


Figure 57. Managing available assays.

2. Press the name of the assay to manage in the left column of the content area.
3. Select one of the options listed in Table 6.

Table 6. Options for managing assays

Option	Description
Assay Active	This button enables setting an assay to active or inactive. Note: It is only possible to test QIAstat-Dx assay cartridges for a particular assay if the assay is active.
Assay ID	Provides the assay identification number.
Assay Description	Provides the assay name.
Assay Version	Provides the assay version.
LIS assay name	Provides information about the LIS assay.
Assay Notes	Provides additional information about the assay.
Type of Samples	Provides a list of the various sample types supported by the assay.
List of Analytes	Provides a list of analytes that are detected and identified by the assay.
List of Controls	Provides the lists of internal control analytes that are implemented in the assay.
Assay Statistics	Provides the number of tests ever run on the QIAstat-Dx Analyzer 2.0 for the selected assay, as well as the number of positive, negative, failed, and canceled tests.
Epidemiology report	Provides the option to create an epidemiology report for a selected date range.

6.6.2. Creating an epidemiology report

An epidemiology report is a report where, for a selected assay and time interval, test results for each pathogen of that assay are counted.

The following information is shown in header of the epidemiology report:

- Assay version
- Selected date
- Serial number of each OM in the data set
- Serial number of each AM in the data set
- Cohort size: total number of distinct patient IDs in tests in the selected data set. If any result in the selected data set is missing a patient ID, then the cohort size shows "n/a"
- Total number of results in the selected data set
- Number of failed or invalid results in the selected data set

The following information is shown in the main section of the epidemiology report:

- Assay name
- Detected results: number of detected results in the selected data set for the given analyte
- Not detected results: number of not detected results in the selected data set for the given analyte
- Equivocal results (if applicable): number of equivocal results in the selected data set for the given analyte
- Other results (if applicable): number of all other results in the selected data set of the given analyte
- Median CT value: the median of all CT values of the given analyte

Note: Results that have previously been archived and removed are not counted in the epidemiology report. For more information about archives, refer to Section 6.12.

Follow the steps below to create an epidemiology report:

1. Follow steps 1 to 3 from Managing available assays.
2. Scroll to the bottom of the options listed in Table 6 and click **Epidemiology Report**.
3. Select the start date from which results are counted in the a **From Date** field, and an an end date until results are counted in the **Until Date** field.

   Note: The from and until date are included in the count.
4. Click **Save Report**.
5. Select a location where the report should be saved.

6.6.3. Importing new assays

Follow the steps below to import new assays to the QIAstat-Dx Analyzer 2.0:

To import new assay(s) to the QIAstat-Dx Analyzer 2.0, assays can either be downloaded via QIAsphere directly onto the instrument (refer to section 6.9) or they must be put into the root folder of a USB storage.

1. When importing assays via a USB storage, insert the USB storage device that contains the Assay Definition File(s) to import into the USB port of the QIAstat-Dx Analyzer 2.0.

Note: It is recommended to use the delivered USB storage device for short-term data storage and transfer. 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.

2. To import the new assay(s) to the QIAstat-Dx Analyzer 2.0, press **Options** > **Assay Management**. The Assay Management screen appears in the content area of the display (Figure 58).

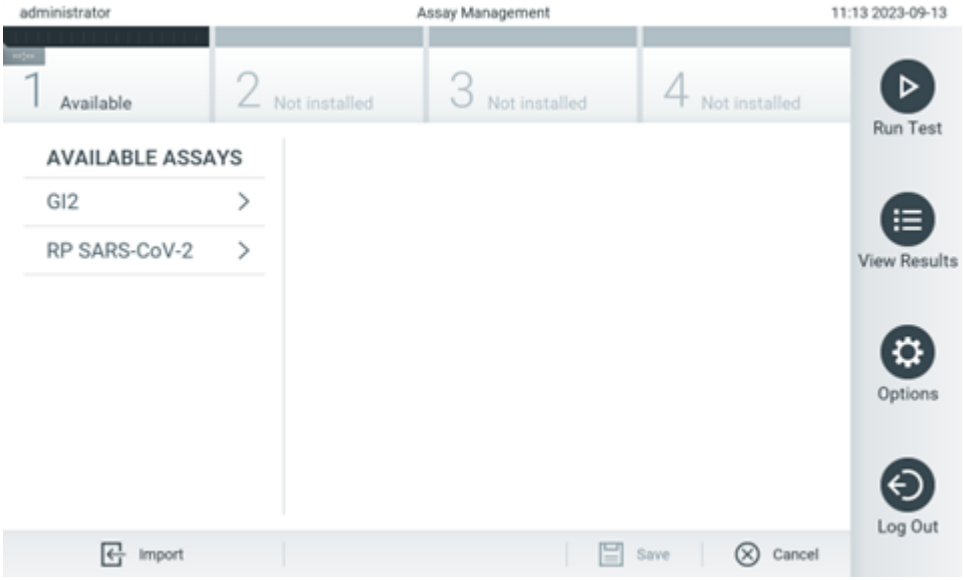


Figure 58. Assay management screen.

3. Press the Import icon located at the bottom left of the screen.
4. Select the Assay Definition File from either QIAsphere or the USB storage device corresponding to the assay to be imported.

   Note: The selection from QIAsphere is currently only possible if any USB storage device was connected after the last startup of the instrument.

5. A dialog box will appear to confirm the import of the file.
6. A dialog box may appear to override the current version by a new one. Press **yes** to override.

   Note: If External Control (EC) samples are linked to an assay that is overwritten by a new version, the EC sample is reset and needs to be reconfigured. For more information refer to Section 6.11.

7. The assay becomes active by selecting Assay Active Figure 59).

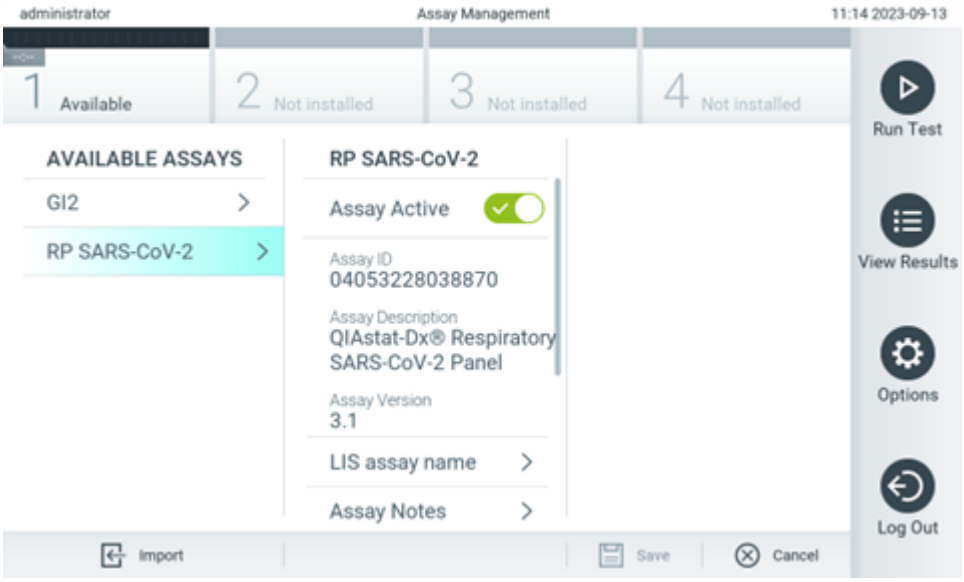


Figure 59. Activating the assay.

6.7. Configuring the QIAstat-Dx Analyzer 2.0

In the System Configuration menu, it is possible to manage the QIAstat-Dx Analyzer 2.0 system and define region-specific parameters.

6.7.1. Regional settings

Follow the steps below to configure the regional settings of the QIAstat-Dx Analyzer 2.0:

1. Press **Options** > **System Configuration**.
2. Select **Regional** from the **Settings** list in the left column. Select and define the settings listed in Table 7 as needed.

Table 7. Available regional settings

Setting	Description
Date	Defines the system date (year, month, day) (Figure 60). This setting is synchronized automatically when the device is connected to a QIAsphere Base.
Time	Defines the system time (hours, minutes). This setting is synchronized automatically when the device is connected to a QIAsphere Base.
Time Zone	Defines the system time zone. This setting might need to be adjusted manually once a connection to a QIAsphere Base is established, as it is currently not automatically synchronized.
Date format	Defines the date format. The following options are available (Figure 61): DD-MM-YYYY, DD-MM-YY, MM-DD-YYYY, YYYY-MM-DD (default), or YY-MM-DD
Date separator	Defines the date separator. The following options are available (Figure 62): “.” “–” (default) “/” “_” “:”

Table 7. Available regional settings (continued)

Setting	Description
Time format	Defines the time format. The following options are available (Figure 63): 24 hours (hh:mm:ss) (default) or 12 hours (hh:mm:ss a.m./p.m.)
Language	Defines the system language (Figure 64). English (default) Spanish (displayed as Español) Mexican Spanish (displayed as Español de México) Finnish (displayed as Suomi) French (displayed as Français) Italian (displayed as Italiano) Norwegian (displayed as Norsk) Portuguese (displayed as Português) Brazilian Portuguese (displayed as Português brasileiro) Swedish (displayed as Svenska) Simplified Chinese (displayed as 简体中文) Traditional Chinese (displayed as 繁體中文)

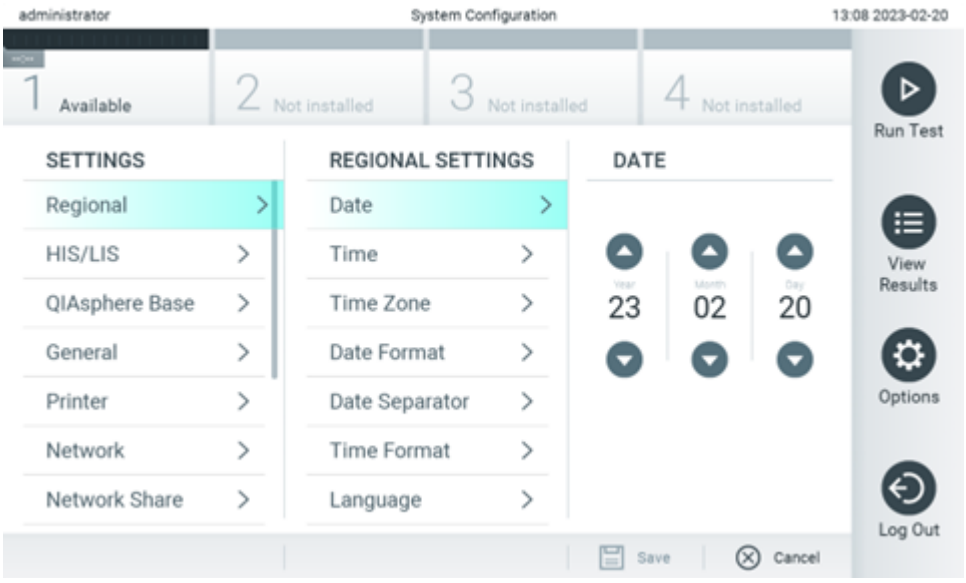


Figure 60. Setting the system date.

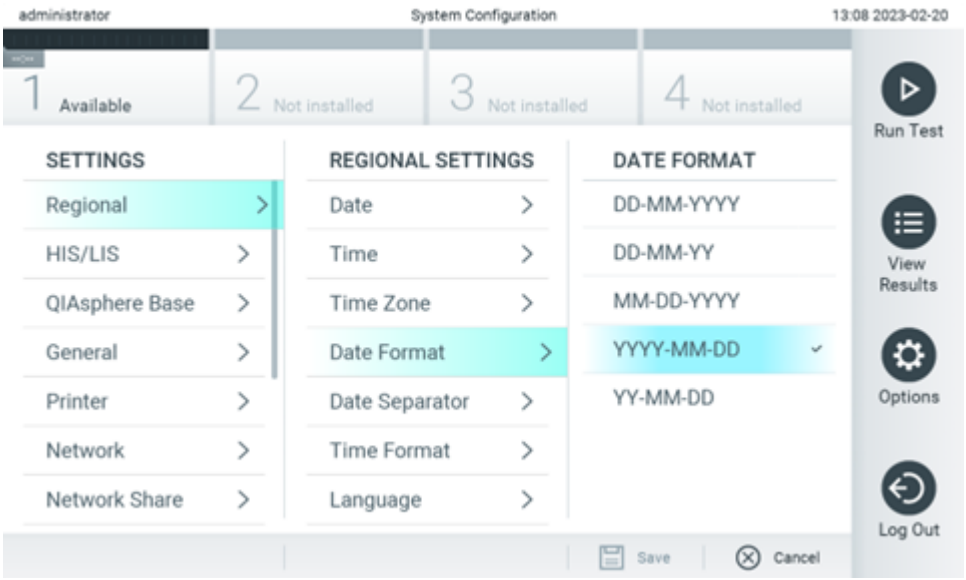


Figure 61. Setting the system date format.

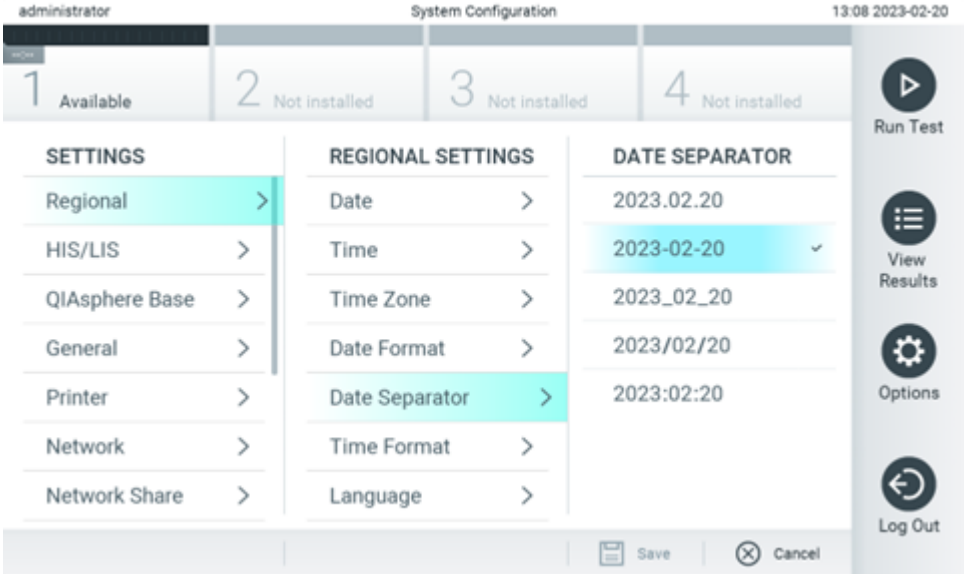


Figure 62. Setting the system date separator.

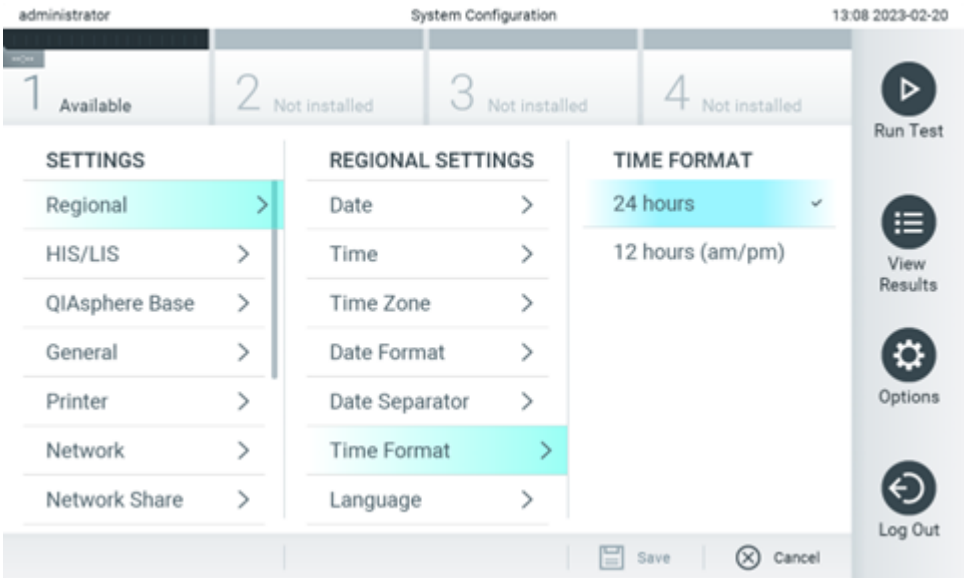


Figure 63. Setting the system time format.

Figure 64. Setting the system language.

6.7.2. HIS/LIS setting

Please refer to Section 7.

6.7.3. QIAsphere Base settings

QIAsphere connects customers with QIAGEN's comprehensive digital ecosystem to deliver a unique user experience and improve laboratory efficiency and safety through cloud-based connectivity. The QIAsphere system consists of the following components:

- QIAsphere-ready Instruments from QIAGEN, which can be connected to the QIAsphere solution
- QIAsphere App for instrument monitoring, available for mobile devices and web browser for desktop use

- QIAsphere Base which is an IoT (Internet of Things) gateway device for secure network communication.

For more information, see **QIAGEN.com/QIAsphere**.

Follow the instructions in the *QIAsphere User Manual* to connect the QIAsphere Base to the same local network that the QIAstat-Dx Analyzer 2.0 is connected to. During this procedure, the QIAsphere Base receives an IP address which is required in the following configuration.

Afterwards, follow the steps below to connect the QIAstat-Dx Analyzer 2.0 to a QIAsphere Base. In order to connect to a QIAsphere Base, ensure that both devices are connected to the same network.

1. Press **Options** > **System Configuration**.
2. Select **QIAsphere Base** from the **Settings** list in the left column (Figure 65).

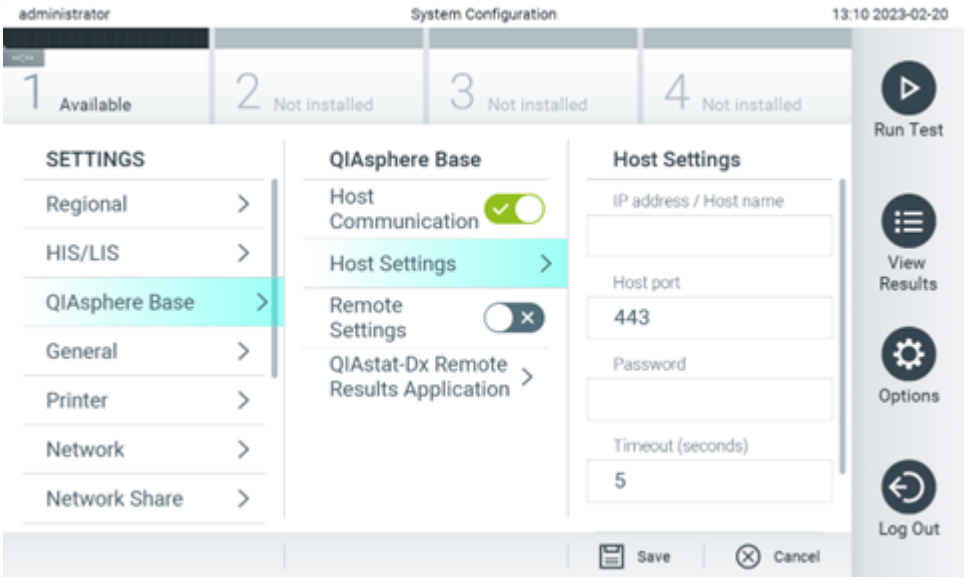


Figure 65. Configuring the QIAsphere Base connection.

3. Select and define the options in Table 8 according to instructions from the network administrator.

Table 8. QIAsphere base settings

Option	Description
Enable Host Communication	Enables the connection to a QIAsphere Base. The submenu Host Settings is only active if "Host Communication" is enabled. Note: Only enable the host communication when also configuring the remaining host settings.
IP address/Host name	Defines the IP address under which the QIAsphere Base can be contacted.
Host port	Defines the host port under which the QIAsphere base can be contacted.
Password	Defines the password which is required to connect to a QIAsphere Base.
Timeout (seconds)	Defines the timeout period in seconds after which a connectivity check is aborted when the QIAsphere Base cannot be contacted.
Check connectivity	A press on the button checks whether a connection to the QIAsphere Base can be established.

Table 8. QIAsphere base settings (continued)

Option	Description
Remote settings	Enables the functionality to remotely change the instrument configuration (HIS/LIS, General, and System Log settings) and user management. The remote configuration tool is accessible through QIAsphere. To be able to edit settings remotely, a user account must exist on the instrument. The same user rights that apply directly on the instrument also reply on the remote site. Remotely changed settings do not impact ongoing test runs and changes are logged in the system log. **Note**: It is possible that changes that were applied remotely are overwritten by local changes on the instrument and vice versa.
QIAstat-Dx Remote Results Application Communication	Enables the connection to the QIAstat-Dx Remote Results application. The QIAstat-Dx Remote Results application itself can be activated via QIAGEN service. For more information, refer to the user manual of the QIAstat-Dx Remote Results application. **Note**: Enabling this feature disables the comment functionality (refer section to 5.5.5).

Note: The current status of the QIAstat-Dx Analyzer 2.0 may not be immediately displayed in the QIAsphere app.

Note: The time and date of the device is synchronized automatically once a connection to a QIAsphere Base is established. The time zone needs to be adjusted manually though.

6.7.4. General settings

Follow the steps below to modify the general settings of the QIAstat-Dx Analyzer 2.0:

1. Press **Options** > **System Configuration**.
2. Select **General** from the **Settings** list in the left column. Select and define the options listed in Table 9 as needed.

Table 9. Available general settings

Setting	Description
User Access Control	Enables the User Access Control, which requires all users to log into the system and limits users to only perform the actions allowed by their user profile. When this option is not enabled, it is not possible to distinguish between users. All features will be available as if they were run by the "Administrator" profile. This option is enabled by default.
Automatic log-off time	Only active if User Access Control is enabled. This setting defines the time interval after which a user is automatically logged out of the system because the QIAstat-Dx Analyzer 2.0 hasn't received user input. The allowed range is 5 minutes up to 99:59 hours. Default: 30 minutes. User input, such as a cursor movement, cursor click, press of a key on an external keyboard or a touch on the touchscreen, resets the automatic log-off time. If a user has entered data (for example, in the Run Test screen) when the automatic log-off occurs, these data will be lost.
Require password before executing assay	Only active if User Access Control is enabled. With this setting activated, all users will be required to enter a password after pressing the Confirm button before executing an assay.
Use Patient ID	With Use Patient ID activated, the QIAstat-Dx Software will provide the option for users to enter a Patient ID or scan a Patient ID when preparing to run a test (see Section 5.3).
Prefer Patient ID Bar Code	Determines if users will be prompted to scan the Patient ID using the bar code reader first. Default: Disabled.

Table 9. Available general settings (continued)

Setting	Description
Patient ID Mandatory	Only active if Use Patient ID is enabled. When activated, users will be required to enter a patient ID before executing an assay. When not activated, users can leave the patient ID data field empty. Default: Disabled.
Sample ID Mandatory	When activated, users will be required to enter a Sample ID before executing an assay. When not activated, users can leave the Sample ID data field empty and a unique Sample ID will be automatically generated by the QIAstat-Dx Analyzer 2.0. Default: Disabled.
Prefer Sample ID Bar Code	Determines if users are prompted to scan the Sample ID using the bar code reader first. Default: Disabled.
Exclude Modules	Enables the possibility to exclude specified Analytical Modules from running tests. This may be useful in the event that a module is suspected of failure. Default: Disabled.
Number of Results Per Page	This setting defines the number of results shown per page in the View Results screen.
Show Previously Logged-in User IDs	Only active if User Access Control is enabled. When this setting is enabled, the list of previously logged-in users will be displayed on the login screen. Default: Enabled.
Require Password to Log In	Only active if User Access Control is enabled. When this setting is enabled, all users must enter their password to log in. When disabled, only the User ID will be required to log in. Default: Enabled.
Max. Number of Technical Log files	Number of technical log files can be changed by the user.
Hide curves in PDF reports	Hides amplification curves from saved and printed PDF reports.
Hide comments in PDF reports	Hides comments from saved and printed PDF reports.
Restore Factory Default	Enables resetting the system back to all factory default settings.

6.7.5. Printer settings

The Printer settings option enables selection of the system printer. The QIAstat-Dx Analyzer 2.0 enables enables the use of network printers or printers connected to the Operational Module via the USB ports on the back of the instrument.

Follow the steps below to modify the printer settings of the QIAstat-Dx Analyzer 2.0:

1. Press **Options** > **System Configuration**.
2. Select **Printer** from the **Settings** list in the left column.
3. Select a printer from the list of available printers (Figure 66).

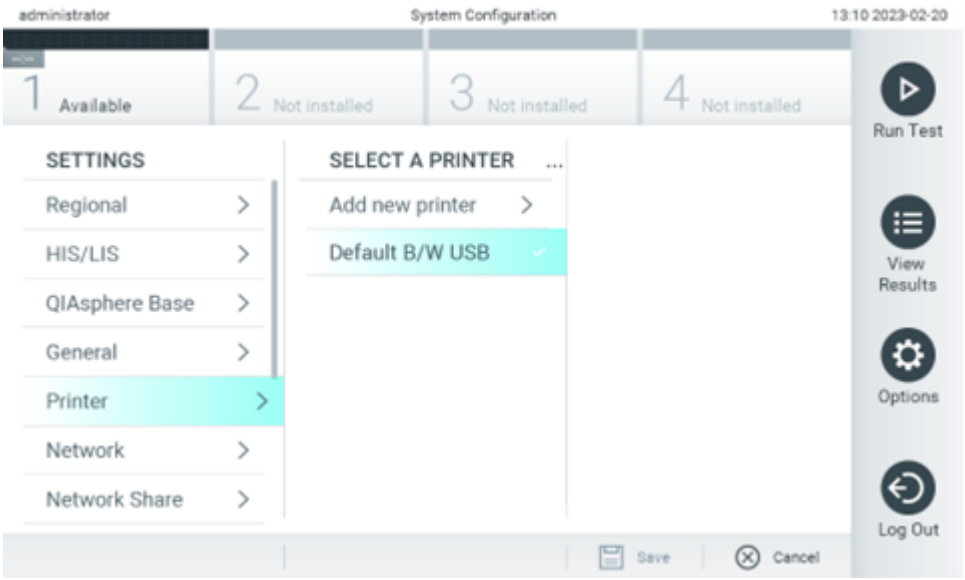


Figure 66. Selecting a system printer.

For USB or network-connected printer installation and deletion, refer to Appendix 12.1.

6.7.6. Network settings

The Network option enables connection of the QIAstat-Dx Analyzer 2.0 to a network, allowsenables enables access to networked printers, and provides connectivity to the HIS/LIS and QIAsphere Base. Contact the network administrator for details on how to configure the network settings.

Note: Do not change the network settings while a test run is ongoing.

Follow these steps to define the network settings:

1. Press **Options** > **System Configuration**.
2. Select **Network** from the **Settings** list in the left column (Figure 67).

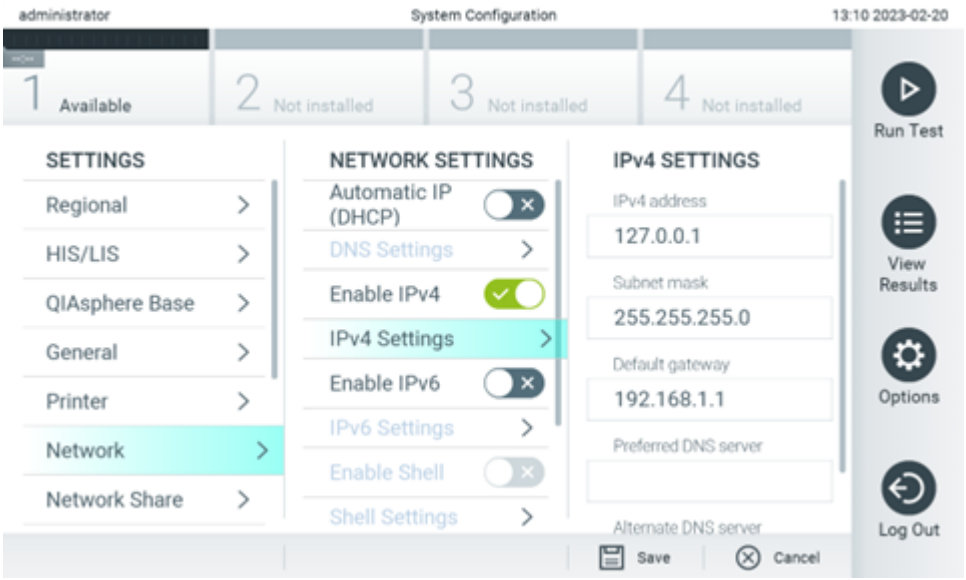


Figure 67. Configuring the network settings.

3. Select and define the options in Table 10 according to instructions from the network administrator.

Table 10. Network settings

Option	Description
Automatic IP (DHCP)	Enables the unit to acquire the IP address from the network using DHCP. The submenu DNS Settings is only active if "Automatic IP (DHCP)" is enabled.
Obtain IPv4 DNS address automatically	Enables the unit to acquire the IPv4 DNS configuration from the network using DHCP. This option is only active if "Automatic IP (DHCP)" is enabled.
Preferred IPv4 DNS Server	Defines the primary IPv4 DNS server. This option can be found either in the DNS Settings or in the IPv4 Settings.
Alternate IPv4 DNS Server	Defines the secondary IPv4 DNS server. This option can be found either in the DNS Settings or in the IPv4 Settings.
Obtain IPv6 DNS address automatically	Enables the unit to acquire the IPv6 DNS configuration from the network using DHCP. This option is only active if "Automatic IP (DHCP)" is enabled. Note that it is possible that multiple IPv6 addresses are assigned simultaneously by the network.
Preferred IPv6 DNS Server	Defines the primary IPv6 DNS server. This option can be found either in the DNS Settings or in the IPv6 Settings.
Alternate IPv6 DNS Server	Defines the secondary IPv6 DNS server. This option can be found either in the DNS Settings or in the IPv6 Settings.
Use IPv4	Enables the use of the IPv4 protocol. This option is only active if "Automatic IP (DHCP)" is enabled. The submenu IPv4 Settings is only active if "Use IPv4" is enabled.
IPv4 address	Defines the manually configured IPv4 address of the Operational Module.
Subnet mask	Defines the IPv4 subnet mask.
Default Gateway	Defines the IPv4 or IPv6 default gateway.
Use IPv6	Enables the use of the IPv6 protocol. This option is only active if "Automatic IP (DHCP)" is enabled. The submenu IPv6 Settings is only active if "Use IPv6" is enabled
IPv6 address	Defines the manually configured IPv6 address of the Operational Module.
Subnet prefix length	Defines the IPv6 subnet prefix length.
Enable Shell	Enables the temporary connection via Shell to the instrument. This option is reserved for QIAGEN service technicians only.
Enable CUPS	Enables the temporary access to the CUPS web interface of the instrument.

6.7.7. Network share

The Network Share option enables selection of network shares. The QIAstat-Dx Analyzer 2.0 enables use of network shares that run on provided by SMB protocol version 2 and 3. Consult with your local IT team to discuss whether this protocol is supported by your local IT infrastructure. Network Shares can be selected as storage locations for backups and automatic archives.

Follow the steps below to add a network share of the QIAstat-Dx Analyzer 2.0:

1. Press **Options** > **System Configuration**.
2. Select **Network Share** from the **Settings** list in the left column.
3. Press **Add new share** (Figure 68).

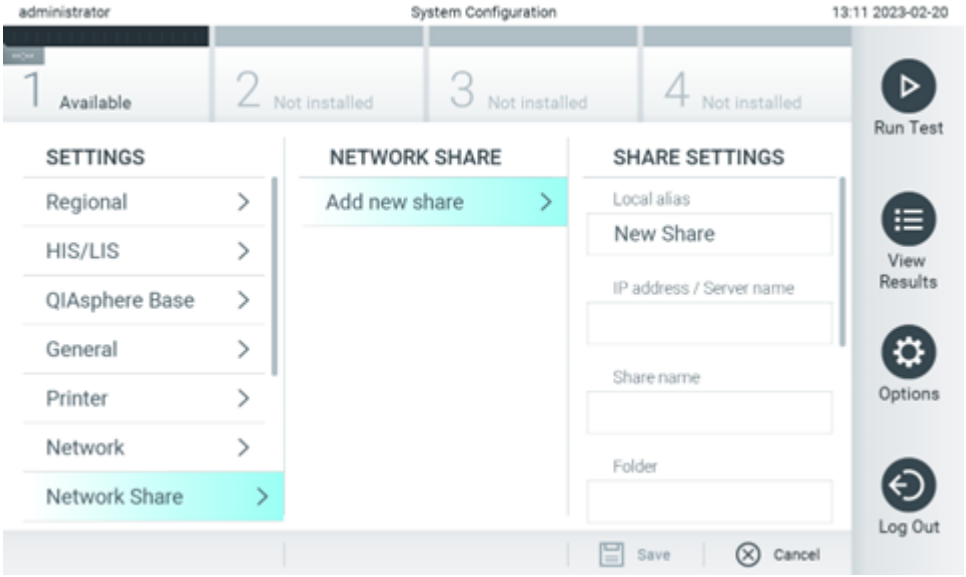


Figure 68. Adding a network share.

4. Select and define the options in Table 11 according to instructions from the network administrator.

Table 11. Network share settings

Option	Description
Local Alias	Defines a name for the entry under which the share can be selected in other menus of the application (e.g., when saving a backup).
IP address/Server name	Defines the server or its IP address that is hosting the network share.
Share name	Defines the name of the network share.
Folder	Defines a path to a specific folder on the network share. A path uses "/" (without quotation marks) to separate folder names, (e.g. "folder/subfolder").
Domain name	Defines the domain to which the server hosting the network share is assigned.
User name	Defines the username that is used to connect to the network share. Please note that the user must have rights to write onto the network share.
Password	Defines the password which is used to authenticate the username.

Table 11. Network share settings (continued)

Option	Description
Check connectivity	Checks whether a connection to the network share can be established. A pop-up with the results of the connection attempt is shown.
Remove Share	Removes the configured Network Share. **Note**: This button is only visible when editing an existing Network Share.

Note: If certain special characters (e.g. \ ) are missing from the current keyboard layout, switch the keyboard layout via the ID button at the bottom to English and find all special characters there.

For an example of a network share configuration, see Table 12.

The path for the example network share is as follows: \\Server123.qiagen.com\ExampleShare\FolderA\SubfolderB

Table 12. Network share example setting

Option	Example
Local Alias	NetworkShare1
IP address/Server name	Server123
Share name	ExampleShare
Folder	FolderA\SubfolderB
Domain name	qiagen.com
User name	user
Password	strongPassword

6.7.8. System log

The system log records general information about the use of the Operational and Analytical Modules, such as adding or removing users and adding or removing assays, logins, logouts, starts of tests, QIAsphere Base connection issues etc. Press **Options** > **System Configuration** > **System Log** to access the system log information. The "System Log Capacity" is shown in the center of the screen followed by the log content. Press **Export Log File** to export the content (Figure 69).

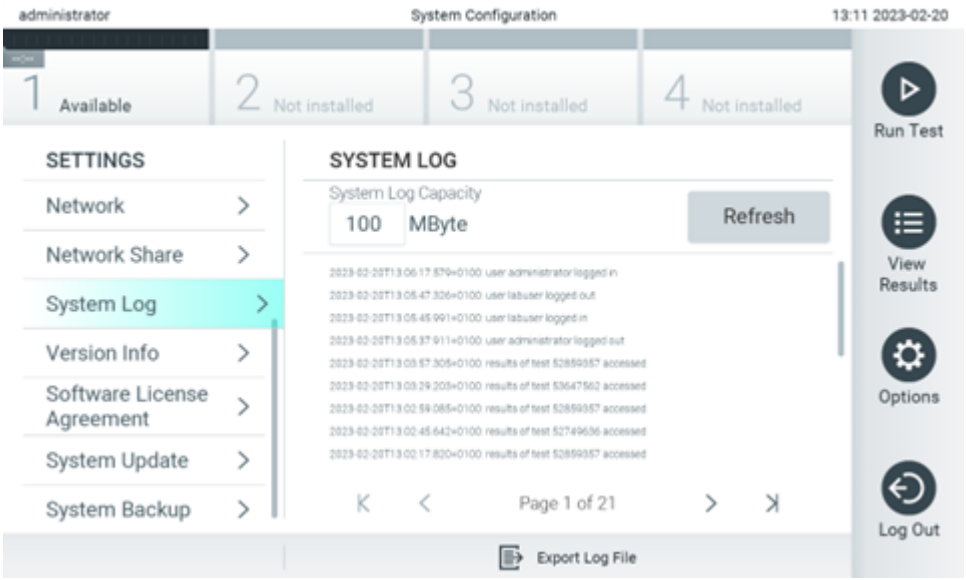


Figure 69. Accessing the system log.

Note: For complete support information of a test or all failed tests, it is recommended to use the support package functionality instead (refer to Section 5.5.9).

6.7.9. Version information

Press **Options** > **System Configuration** > **Version Info** to view the QIAstat-Dx Software version, the serial numbers, the firmware versions for the installed Analytical Modules.

6.7.10. Software license agreement

Press **Options** > **System Configuration** > **Software License Agreement** to view the software license agreement of the application running on the QIAstat-Dx Analyzer 2.0 including licenses of third-party components.

6.7.11. System update

Important: The QIAstat-Dx Analyzer 2.0 is delivered with software version 1.6.x.

To ensure the best performance, please confirm you are using the most up-to-date software version. Contact QIAGEN Technical Services at **support.qiagen.com** for assistance with software upgrades.

To install a new software version on the QIAstat-Dx Analyzer 2.0, software packages can either be downloaded via QIAsphere directly onto the instrument or they must be put into the root folder of a USB storage.

1. When updating the software version via a USB storage, insert the USB storage device that contains the .dup file to import into the USB port of the QIAstat-Dx Analyzer 2.0.

   Note: It is recommended to use the delivered USB storage device for short-term data storage and transfer. The use of a USB storage device is subject to restriction (e.g. the memory capacity or the risk of overwriting), which should be considered before usage.

2. To update the QIAstat-Dx Analyzer 2.0 system, press **Options** > **System Configuration** > **System Update**.

In case the System Update option is greyed outnot available, the instrument is currently in a state where an update is not possible. Please try again later.

A message will appear recommending that a system backup be performed first (refer to Section 6.7.12) (Figure 70).

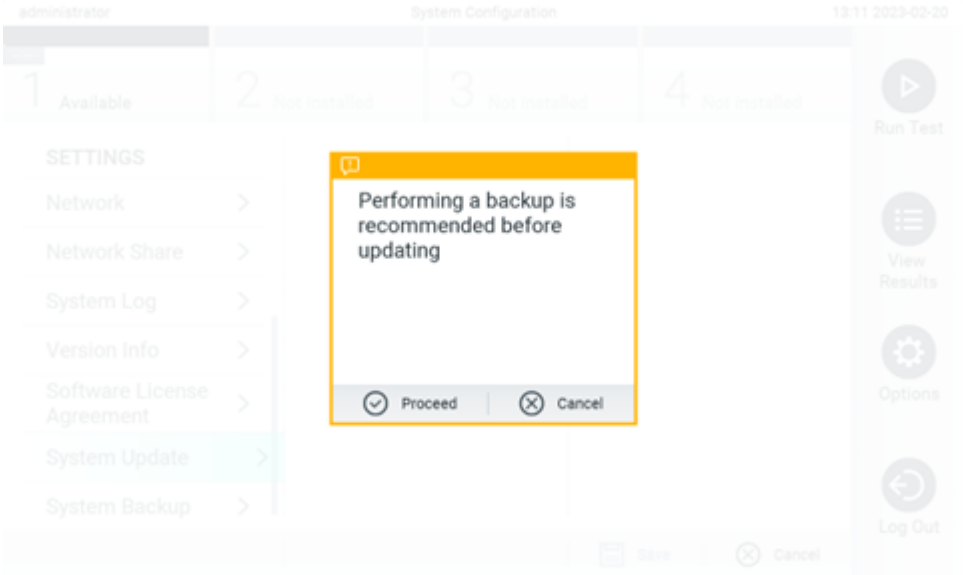


Figure 70. Performing the system update.

3. Select the appropriate .dup file from either QIAsphere or the USB storage device corresponding to the new software version.

   Note: The selection from QIAsphere is currently only possible if any USB storage device was connected after the last startup of the instrument.

4. After the update, the user may be required to shut down the QIAstat-Dx Analyzer 2.0 and restart.

   Note: The screen saver functionality is inactive during a system update. If the User Access Mode is enabled, no re-login for user authentication is enforced. It is recommended to not leave the QIAstat-Dx Analyzer 2.0 unattended during a system update. After the update, the screen saver functionality becomes active again, so it may happen that the information about the success or failure of the update is missed. When in doubt, check the version information (see 6.7.9).

   Note: It is recommended to restart the QIAstat-Dx Analyzer 2.0 after a system update. To shut down the QIAstat-Dx Analyzer 2.0, power OFF the instrument using the power switch on the back of the QIAstat-Dx Analyzer 2.0. Afterwards, power ON the instrument again using the same switch.

6.7.12. System backup

To back up the QIAstat-Dx Analyzer 2.0 system, press **Options** > **System Configuration** > **System Backup** (Figure 71). Insert a USB storage device into the front USB port or configure a network share (See section 6.7.7).

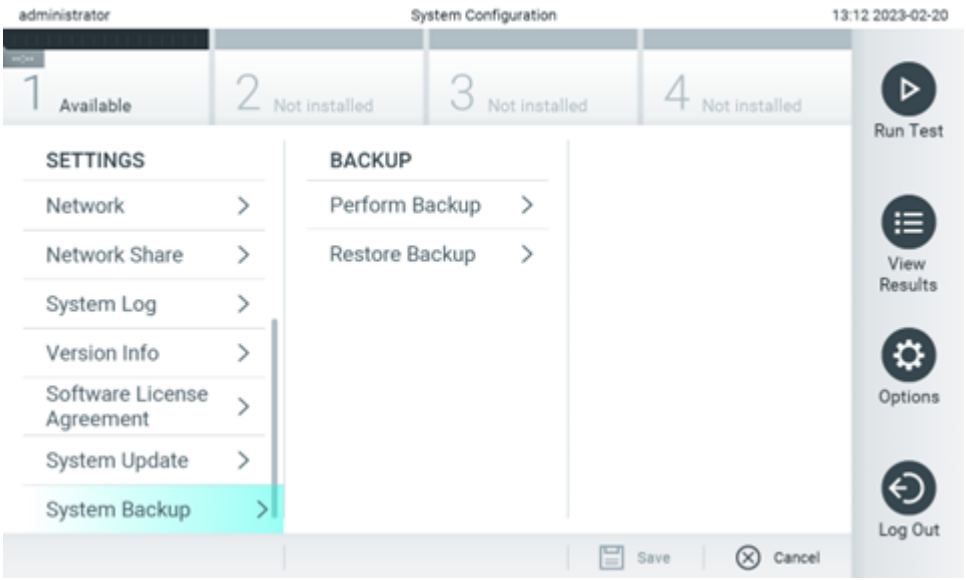


Figure 71. Performing a system backup.

Press **Perform Backup**. A file with the extension .dbk will be generated with a default file name. The file can be saved on either a USB drive or a network share.

To restore a backup, press **Restore Backup** and select the appropriate backup file with a .dbk extension from the connected USB storage device. A message will appear recommending that a backup be created before restoring.

Note: It is strongly recommended to regularly perform system backups according to your organization's policy for the availability of data and the protection of data from loss.

Note: The screen saver functionality is inactive during a system backup creation. If the User Access Mode is enabled, no re-login for user authentication is enforced. It is recommended to not leave the QIAstat-Dx Analyzer 2.0 unattended during a backup creation.

Note: It is recommended to use the delivered USB storage device for short-term data storage and transfer. It is strongly recommended to use another storage location for permanent data storage. 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.

6.8. Change passwords

To change a user password, press **Options** > **Change Password**. First enter the current password in the text field (Figure 72) and then enter the new password into the **New Password** field. Reenter the new password in the **Confirm Password** field (Figure 73).

A password must consist of 6-15 characters containing 0-9, a-z, A-Z, and the following special character: _ [ ] ; ' \ , . / - = ~ ! @ # $ % ^ & * ( ) + { } : " | < > ?,<space>.

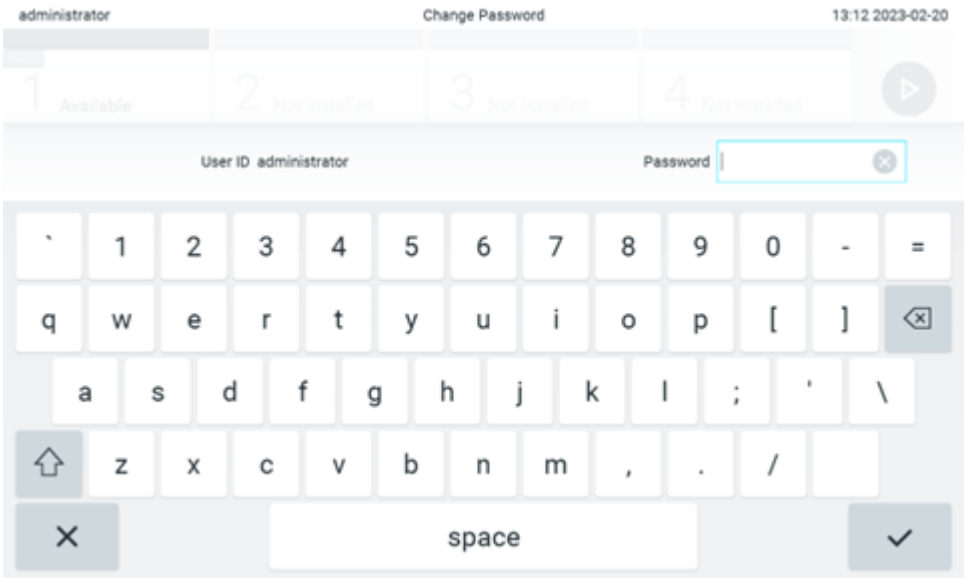


Figure 72. Entering current password.

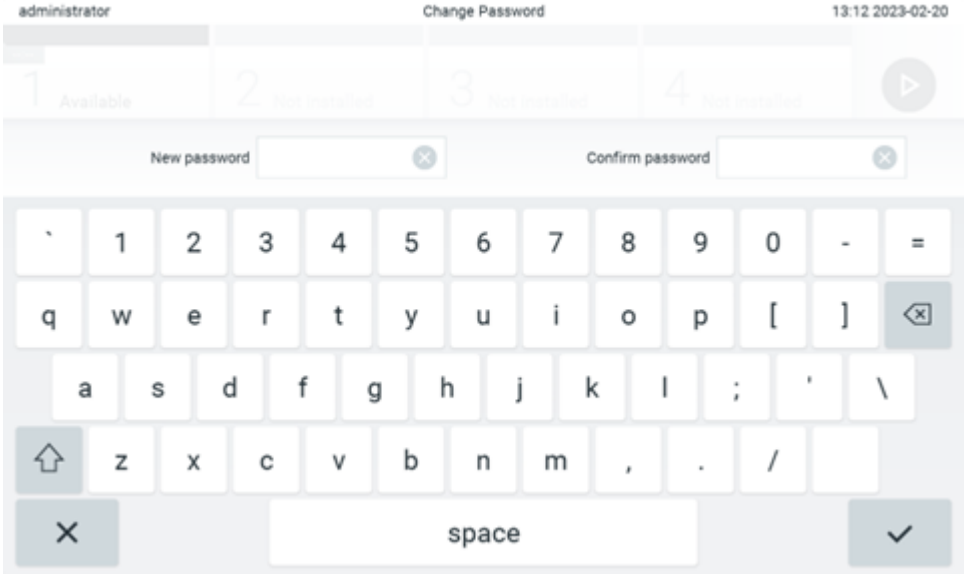


Figure 73. Entering and confirming new password.

After three failed attempts to enter a password, the password entry field will be deactivated for one minute, and a dialog will appear with the message "Password failed, please wait for 1 minute to try it again".

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

6.9. Notifications

The Notifications Center shows important information. To access notifications, press **Options** > **Notifications**. When an unread notification is available, the **Options** button and the **Notifications** button will indicate this as illustrated in Figure 74.

Figure 74. Options and Notifications menu indicating an unread notification.

There are different types of notifications. An overview is shown in Table 13. Once a notification has been addressed (e.g. deleting a notification), it is no longer accessible.

Table 13. Notification types and examples

Notification type	Description
Information	This notification type is of informational nature. For example, if the creation of an automatic archive has failed.
Information to confirm	This notification type requires the confirmation of a user to acknowledge that it has been read. This notification type is only available when the QIAstat-Dx Analyzer 2.0 is connected to QIAsphere (refer to section 6.7.3)
File Download available	This notification type informs about available file downloads directly onto the instrument. This applies to new assay or software version to download directly from QIAsphere. This notification type is only available when the QIAstat-Dx Analyzer 2.0 is connected to QIAsphere (refer to section 6.7.3)

6.10. Printer functionality

This section describes different features related to printer functionality.

6.10.1. Printer installation and deletion

The printer installation and deletion are described in Appendix 12.1.

6.10.2. Viewing print jobs

The printer queue shows active print jobs on the instrument. Reports that have been queued for printing are displayed here. The printer queue is accessible via the options menu.

The print queue shows a table with the name of the printer, job number, and the date and time the print job has been created (Figure 75).

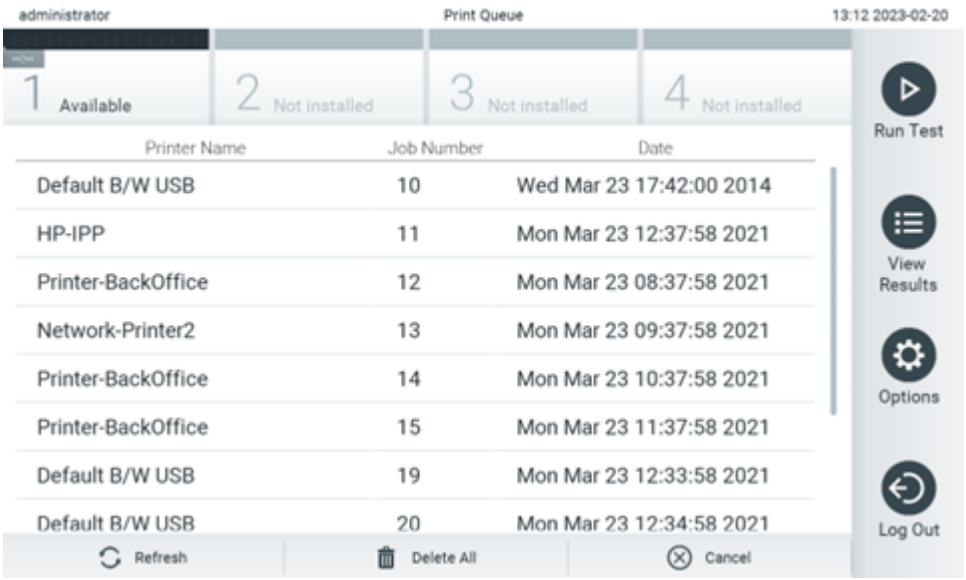


Figure 75. Print queue.

6.10.3. Deleting print jobs

Users with the right to delete print jobs can delete all print jobs in order to clear the queue. This will prevent all reports in queue from being printed. To do this, press **Delete All** at the bottom of the page (Figure 75).

6.11. External Control (EC) settings

From the External Control menu, it is possible to enable the External Control feature and configure its options. For more information about External Control (EC), refer to Section 8.

Follow the steps below to enable the feature and set up intervals and samples for individual assays:

1. Press **Options** in the Main Menu Bar and then **External Control**.
2. Press the **Enable EC** toggle button to activate the feature (Figure 76).

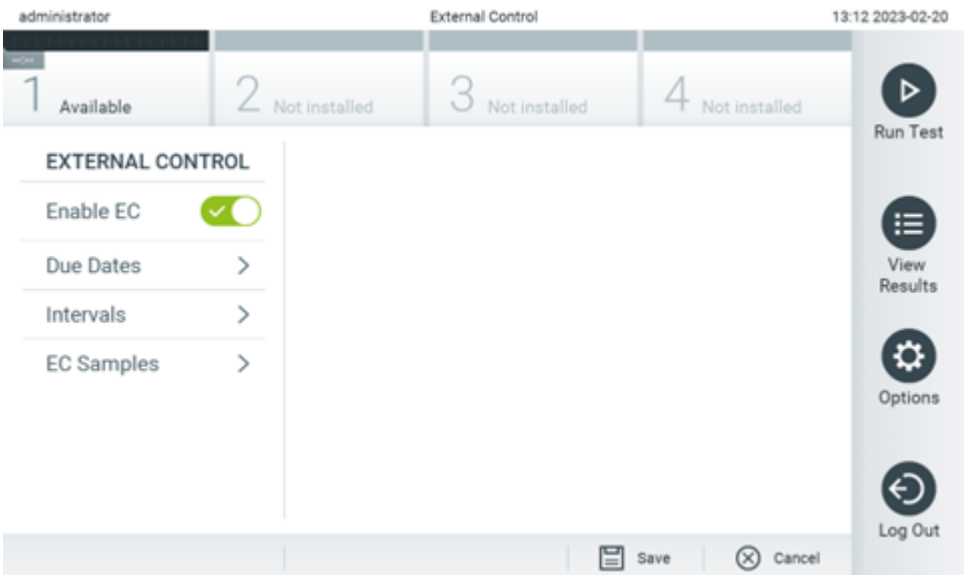


Figure 76. EC screen.

3. Select Due Dates and then an assay from the list to see when the last External Control test was performed per assay and analytical module and when the next External Control test is due (Figure 77).

   Note: If no assays are installed, no due dates can be displayed.

Figure 77. External Control Due Dates screen.

Table 14. External Control Due Dates

Setting	Description
Last EC runs	For the selected assay and each module, the date when the last EC test was performed is shown.
Next EC runs due	For the selected assay and each module, the date or number of tests after which an External Control test needs to be performed is shown. Next EC runs due is only shown if the Enable EC is toggled on. When the interval type for an assay is set to Cartridge lot, next EC runs are not shown.

4. Select **Intervals** and then an assay from the list to configure the interval after. A reminder is shown to remind users that an External Control test needs to be performed for the selected assay if the interval has passed (Figure 78).

   Note: If no assays are installed, intervals cannot be configured.

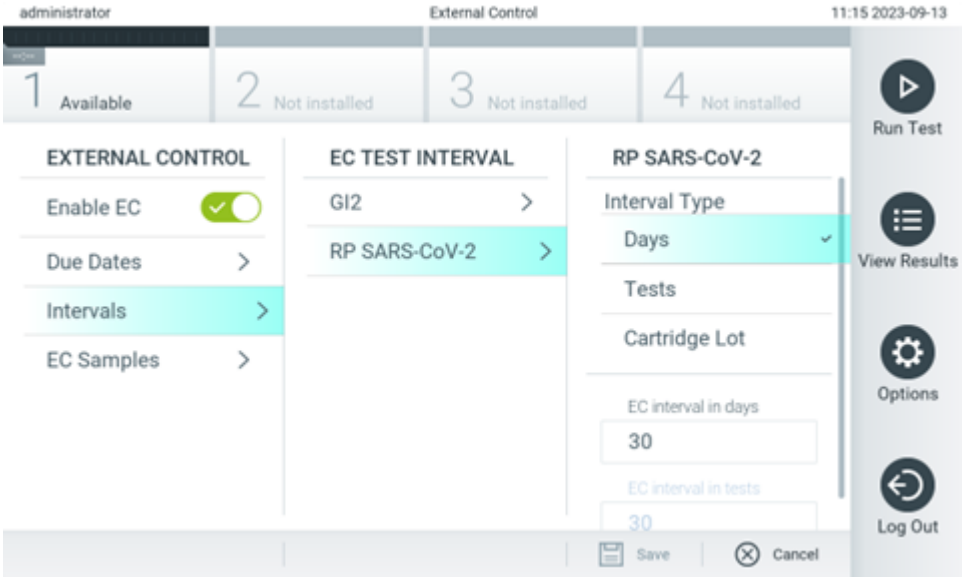


Figure 78. External Control Intervals screen.

Table 15. External Control Intervals settings

Setting	Description
Interval type	The interval type determines if an External Control test needs to be performed after a certain number of days, whether a test needs to be performed after a certain number of tests, or whether a test needs to be performed with each new cartridge lot that is being used.
EC interval in days	Defines the number of days, after which an External Control test needs to be performed. Only active if the interval type is set to “days”.
EC interval in test	Defines the number of tests, after which an External Control test needs to be performed. Only active if the interval type is set to “tests”.

5. Select **EC Samples** to add or edit samples which are used in an External Control test. To add a new EC Sample, press **Add new Sample** and then continue with the configuration in the right column (Figure 79). To edit an EC sample, select an existing one from the middle column and continue with the configuration in the right column.

   Note: It is recommended to specify an appropriate EC Sample name that includes information about the version of the EC sample or similar information that is printed on the respective tube.

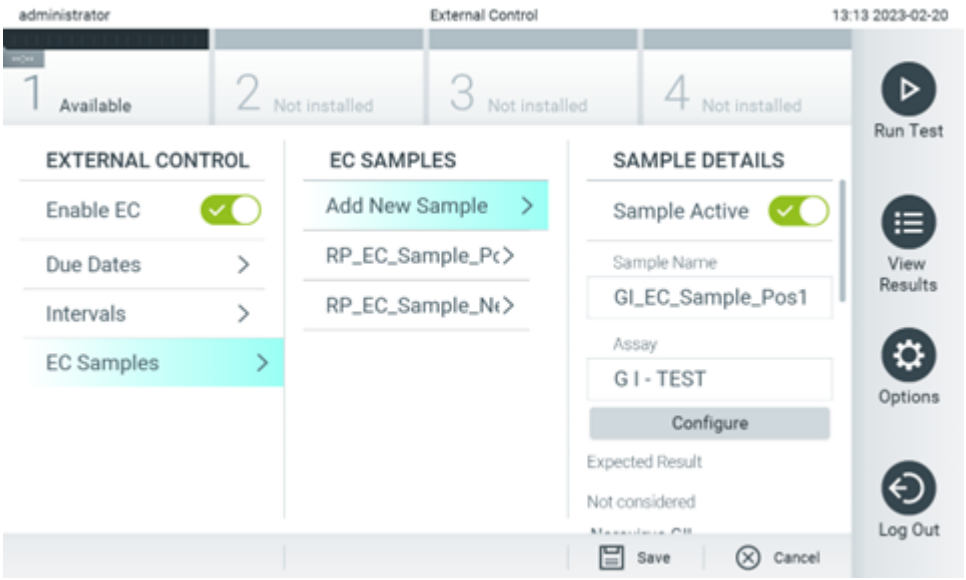


Figure 79. External Control EC Samples screen.

Table 16. External Control EC Samples settings

Setting	Description
Sample Active	Enables the sample so that it can be selected in the External Control test setup.
Sample Name	Defines the sample name, which identifies the sample.
Assay	An EC sample is linked to an assay. An assay can be selected from a list of all installed assays.
Configure	After an assay has been selected, all analytes linked to that assay are loaded. For each analyte, it can be configured whether it should be considered in the external control run or not and whether the analyte is expected to be detected.

6. Select **Configure** to edit the analytes in an External Control test (Figure 79). In the External Control EC Sample configuration, it can be determined whether an analyte is considered for the External Control EC run and whether a detection is expected (Figure 80).

   Note: At least one analyte needs to be considered to save the configuration settings.

Figure 80. External Control EC Sample configuration screen.

Table 17. External Control EC Sample configuration

Setting	Description
Consideration of analyte	For each analyte, it can be configured whether the analyte is considered for the External Control run. If an analyte is considered, the checkbox needs to be checked. Only when an analyte is considered in the external control sample will it be included in the external control result calculation and compared to the actual result of the respective analyte.
Analyte	All analytes linked to that assay are loaded.
Detection Expected	For each considered analyte, it can be configured whether a detection in the External Control run is expected or not. If an analyte is expected to be detected, the toggle button needs to be turned on.

6.12. Archive results

Selected results can be archived with a subsequent removal option to free memory space on the QIAstat-Dx Analyzer 2.0 or to support your organization's policy on data retention. Archived files contain all important data of test runs (e.g., curve data, results of analytes, overall result data, etc.) and can be viewed, saved, and printed at any time on each QIAstat-Dx Analyzer 2.0 instrument (refer to Section 6.12.2).

Note: The Purchaser of the QIAstat-Dx Analyzer 2.0 is solely responsible for compliance to your organization's policy on data retention. Data retention by sole use of archive functionality described in this section might be insufficient to comply with your organization's policy.

The archive functionality is accessible via the Options menu. It is possible to either create archives with or without removal option or loading an archive (See Section 6.12.1). For automatically created archives, results are always removed.

Note: When viewing test results of an archive only limited functionality is available (refer to Section 6.12.2 for more information).

6.12.1. Create archive

Archive file creation without removal function

For archive file creation, filter the results which should be archived. Press **Create Archive** and filter for the desired start date and end date. The selected result number is displayed on the screen. Up to 250 results can be archived within one archive file.

It is possible to select only already HIS/LIS uploaded and expired results for archive file creation. Likewise it is possible to select only already QIAstat-Dx Remote Results Application uploaded result for archive file creation. Press **HIS/LIS Uploaded** to activate this option and press **Create Archive** (Figure 81).

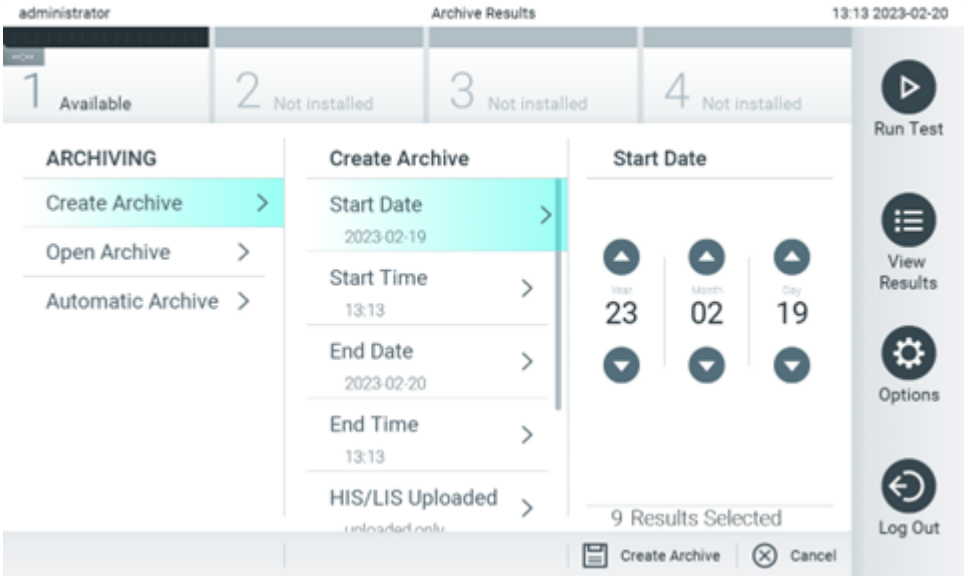


Figure 81. Create archive options.

Note: It is recommended to use the delivered USB storage device for short-term data storage and transfer. It is strongly recommended to use another storage location for permanent data storage. 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.

Note: The screen saver functionality is inactive during an archive creation. If the User Access Mode is enabled, no re-login for user authentication is enforced. It is recommended to not leave the QIAstat-Dx Analyzer 2.0 unattended during archive creation.

Archive file creation with remove function

Important: Archived and removed results are no longer present on the QIAstat-Dx Analyzer 2.0 and will not be part of a system backup file. It is strongly recommended to perform a system backup first before continuing with archive file creation using the removal functionality. Refer to Section 6.7.12 for system backup creation. Removed results are also not counted in epidemiology reports. For more information refer to Section 6.6.2.

If selected results shall be archived and removed from the QIAstat-Dx Analyzer 2.0, proceed with archive file creation as described in below and activate the removal function.

Press **Remove Results** and activate the removal. If the archive file creation was successful, the selected results will be automatically removed from the QIAstat-Dx Analyzer 2.0 (Figure 82).

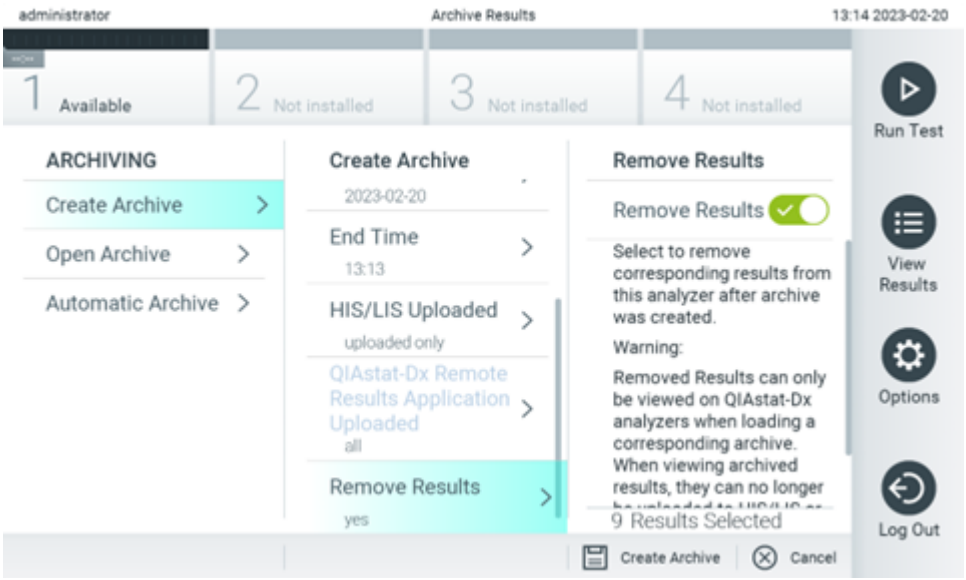


Figure 82. Remove results option screen.

Note: Removed results are no longer present in the QIAstat-Dx Analyzer 2.0. The HIS/LIS upload and QIAstat-Dx Remote Results Application upload are not possible after successful removal.

Note: It is recommended to use the delivered USB storage device for short-term data storage and transfer. It is strongly recommended to use another storage location for permanent data storage. 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.

Note: The screen saver functionality is inactive during an archive creation. If the User Access Mode is enabled, no re-login for user authentication is enforced. It is recommended to not leave the QIAstat-Dx Analyzer 2.0 unattended during an archive creation.

6.12.2. Open archive

Archive files created with the QIAstat-Dx application software can be opened for viewing, saving, and printing results only. Archives can be opened from USB storage devices, as well as preconfigured network shares. Press **Open Archive** and load desired archive file. After successful loading of an archive, press **View Archive**. During the archive results viewing, no new runs can be started. Close the archive file with the **Close Archive** button to regain regular functionality (Figure 83).

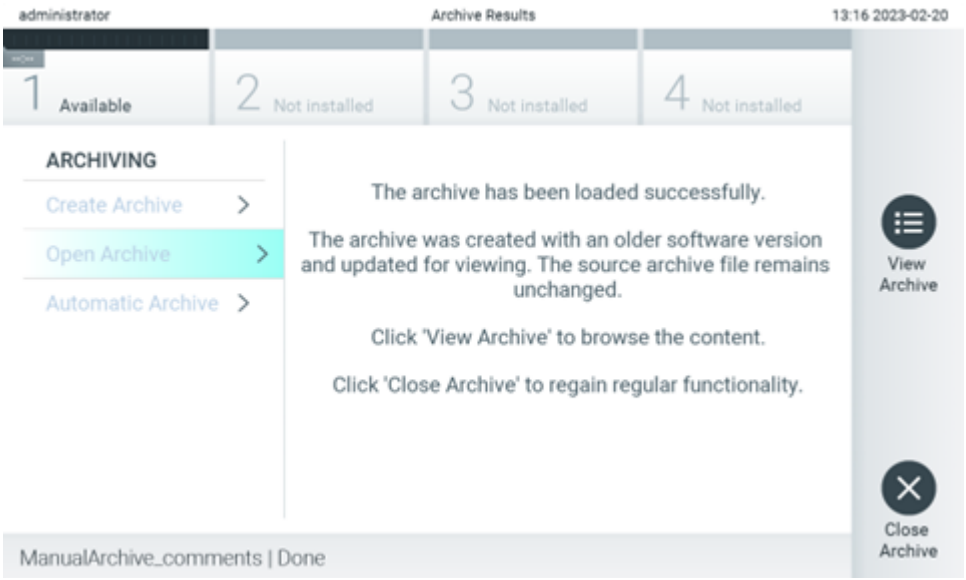


Figure 83. Open archive screen.

Note: It is recommended to use the delivered USB storage device for short-term data storage and transfer. It is strongly recommended to use another storage location for permanent data storage. 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.

6.12.3. Automatic archive

Important: Automatically archived results are removed and are no longer present on the QIAstat-Dx Analyzer 2.0 and will not be part of a system backup file. Refer to Section 6.7.12 for system backup creation. Removed results are also not counted in epidemiology reports. For more information, refer to Section 6.6.2.

Note: Prior to enabling automatic archive file creation, it is recommended to verify the total number of results stored on QIAstat-Dx Analyzer 2.0. If a high number of test results is stored, it is advised to follow instructions in Section 0 first to reduce the number of test results.

For automatic archive file creation, the oldest results stored in the instrument are archived. Follow the steps below to configure the automatic archive process:

1. Press **Options** > **Archive Results**.
2. Press **Automatic Archive** and enable the feature (Figure 84).
3. Select a **Start Time**. This is the time when the automatic archiving takes place every day if the Archive Configuration (Step 4) is met.

   Important: It is highly recommended to configure the start time outside of normal operating hours of the instrument. The automatic archive creation runs in the background and might slow down the software.
4. Select an **Archive Configuration**. The number of results to trigger archiving refers to the total number of results stored in the instrument. The number of results in archive refers to the number of results that are being archived, whereby the oldest results are archived first. Up to 250 results can be archived within one archive file.

   Note: It is recommended to use the default settings for the archive configuration. Increasing the archive size affects the amount of time that the automatic archive creation takes.

5. It is possible to select only HIS/LIS already uploaded and expired results for archive file creation. Press **HIS/LIS Uploaded** to activate this feature.
6. It is possible to select only QIAstat-Dx Remote Results Application already uploaded results for archive file creation. Press **QIAstat-Dx Remote Results Application Uploaded** to activate this feature.
7. Select a **Storage Location**. For the automatic archive it is required to select a pre-configured network share. Refer to Section 6.7.7 for more information on how to configure a network share.

   Note: It is not possible to select a USB storage device as storage location for the automatic archive.
8. Press **Save** and **Confirm** to save and store the configuration.
9. Select **Last archive creation** to view when the last automatic archive was created and whether the previous creation failed.

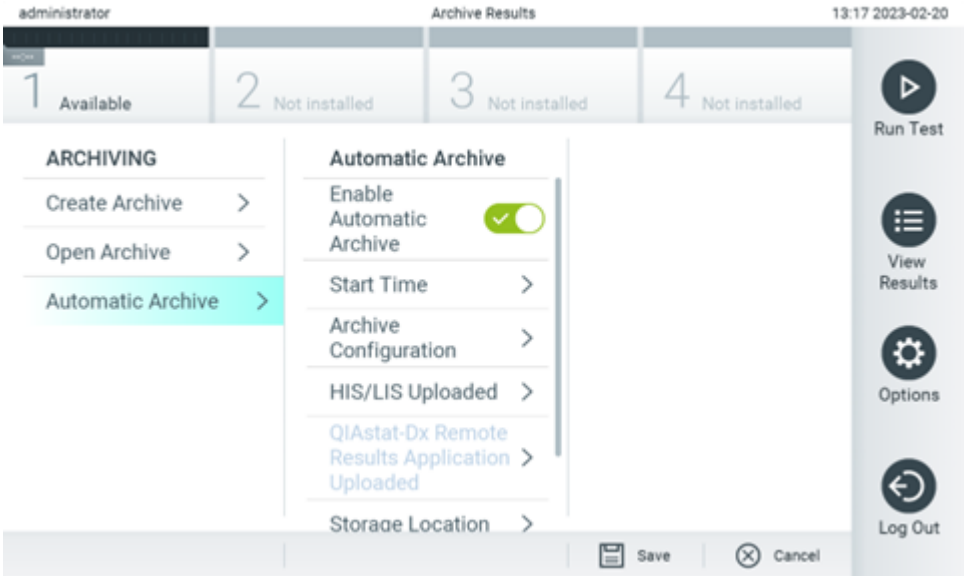


Figure 84. Automatic archive options.

6.13. QIAstat-Dx Analyzer 2.0 system status

The status of the Operational and Analytical Modules is indicated by the color of the status indicators (LEDs) on the front of the QIAstat-Dx Analyzer 2.0.

The Operational Module can display any of the following status colors:

Table 18 explains the status lights that may be displayed on the Operational and Analytical Modules.

Table 18. Descriptions of status lights

Module	Status light	Description
Operational	OFF	QIAstat-Dx Analyzer 2.0 is powered OFF
	Blue	QIAstat-Dx Analyzer 2.0 is in standby mode
	Green	QIAstat-Dx Analyzer 2.0 is running

Table 18. Descriptions of status lights (continued)

Module	Status light	Description
Analytical	OFF	QIAstat-Dx Analyzer 2.0 is powered OFF
	Blue	QIAstat-Dx Analyzer 2.0 is in standby mode
	Green (blinking)	QIAstat-Dx Analyzer 2.0 is initializing
	Green	Analytical Module is running
	Red	Analytical Module malfunction

6.14. Shutting down the QIAstat-Dx Analyzer 2.0

The QIAstat-Dx Analyzer 2.0 is designed to operate continuously. If the unit will not be used for a short time (less than a day), we recommend placing the QIAstat-Dx Analyzer 2.0 in standby mode by pressing the **ON/OFF** button on the front of the instrument. To shut down the QIAstat-Dx Analyzer 2.0 for a longer time period, power OFF the instrument using the power switch on the back of the **QIAstat-Dx Analyzer 2.0**.

If a user attempts to put the QIAstat-Dx Analyzer 2.0 in standby mode while the Analytical Module is running a test, a dialog will appear indicating that shutdown is not currently possible. Allow the instrument to finish running the test(s) and try shutting it down upon completion.

7. HIS/LIS Connectivity

This section describes the connectivity of the QIAstat-Dx Analyzer 2.0 with a HIS/LIS.

HIS/LIS configuration enables the connection of the QIAstat-Dx Analyzer 2.0 to a HIS/LIS to provide such functionalities as:

- Activating and configuring communication with the HIS/LIS
- Assay configuration for sending results and requesting book orders
- Running a test based on a book order
- Sending the result of a test

Note: It is recommended to follow your organization's security measures and policies for your local intranet as communication with HIS/LIS is not encrypted.

7.1. Activating and configuring communication with the HIS/LIS

1. Press **Options** > **System Configuration**.
2. Select **HIS/LIS** from the **Settings** list in the left column. Select and define the settings listed in Table 19 as needed.

Table 19. HIS/LIS settings

Setting	Description
Host Communication	Enables the HIS/LIS connectivity. This option is disabled by default.
Host Settings	Only active if Host Communication is enabled. This setting defines the host address and port of the host. The host address enables 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. The transfer protocol is currently compatible with HL7 Hospital name is an exclusive name to define a DMS or LIS. The default Timeout is configured as 5 seconds and can be extended up to 60 seconds. This is the maximum time QIAstat-Dx Analyzer 2.0QIAstat-Dx Analyzer 2.0 will wait for a message from the host. Messages queued is an indicator of the number of messages waiting in the queue. The Check connectivity button validates the connection between the QIAstat-Dx Analyzer 2.0 and the host with the IP and port filled.
Result Upload	Enables the functionality of sending results from the QIAstat-Dx Analyzer 2.0 to the host. This option is disabled by default.
Results Upload Settings	Only active if Result Upload is enabled. Results uploading can be performed in two modes: automatic and manual. When automatic mode is enabled, as soon as a test is complete the results are sent to the host. If automatic mode is disabled, the results can be sent manually by pressing the Upload button in the Result Summary and View Results screens. Automatic is disabled by default. PDF report upload enables the upload of reports together with the result. Expire Time is the number in days that a test can be sent to the host. When set to zero, this option is disabled so the results will never expire. Reset Uploading clears the queue of messages waiting to be sent. This option can be helpful when many results have been sent but for various reasons the transmission needs to be canceled. Retry resends results that are in upload status "Error". Authorization can be set to a role to allow uploading of results. As default, only the Administrator role has this authorization enabled.

Table 19. HIS/LIS settings (continued)

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.
Order Settings	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.
Debug Logging	Debug logging can only be activated/deactivated as user having administrator rights or as service technician user. It 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.

7.2. Assay name configuration

The displayed assay name in the HIS/LIS may differ from the displayed assay name in the QIAstat-Dx Analyzer 2.0. Before using HIS/LIS functions, the following process for confirming/correcting assay names must be performed.

1. Press **Options** > **Assay Management** to access the Assay Management screen. Available assays are listed in the first column of the content area.
2. Select the assay from the Available Assays menu.
3. Select the **LIS assay name** option. By default, the assay name should be the same for the QIAstat-Dx Analyzer 2.0 and the HIS/LIS. If the assay name in the HIS/LIS is different, it needs to be corrected to match the QIAstat-Dx Analyzer 2.0 assay name. Correct the assay name using the LIS assay name input text field and then press **Save**.

7.3. Creating a test order with host connectivity

When **Host Communication** and **Test Orders** are enabled, test orders can be downloaded from the host before a test run. Scanning or entering the sample ID automatically retrieves the test order from the host.

7.3.1. Configuration of the QIAstat-Dx Analyzer 2.0 with host connectivity

1. Press **Options** > **System Configuration**.
2. Select **HIS/LIS** from the **Settings** list in the left column.
3. Enable **Host Communication** and configure the **Host Settings** with the host details. Press **Check connectivity** to confirm the connection.
4. Enable **Test Orders** and configure the **Order Settings**. There are two modes of working with test orders, with **Force Order** enabled or disabled. When **Force Order** is enabled, if the test order is not successfully retrieved from the host, then the user is not allowed to continue running the test. When **Force Order** is disabled, even if the test order is not retrieved or does not exist in the host, the user can continue with the test and a pop-up dialog box will warn the user.

7.3.2. Running a test based on a test order

1. Press the **Run Test** button located at the top right corner of the Main screen.
2. When prompted, scan the sample ID bar code using the bar code reader that is integrated into the Operational Module (Figure 85).

   Note: Depending on the QIAstat-Dx Analyzer 2.0 configuration, it may also be possible to enter the sample ID using the virtual keyboard of the touchscreen. Refer to Section 6.7.4 for further details.

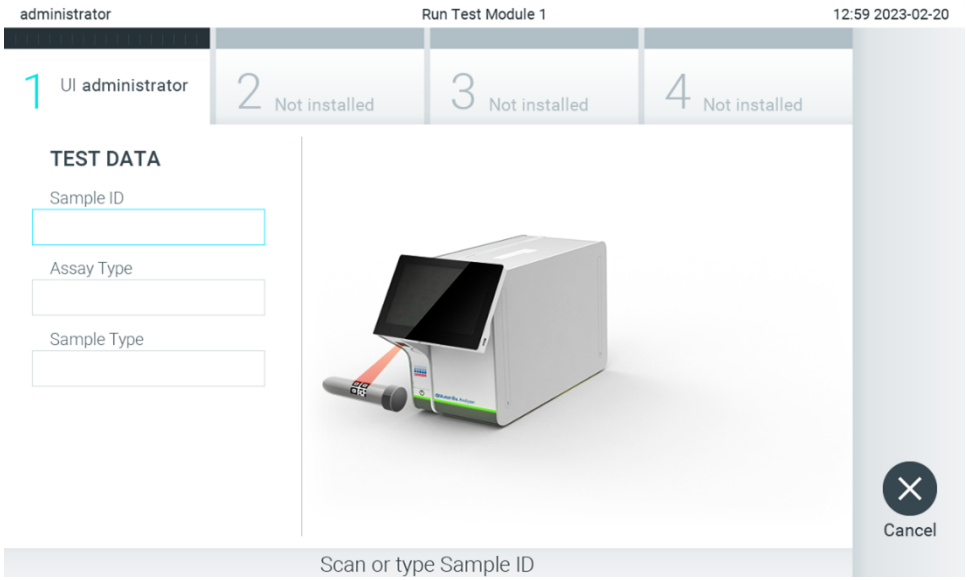


Figure 85. Scanning the sample ID bar code.

3. The sample ID will be sent to the host and while the QIAstat-Dx Analyzer 2.0 waits for a test order, the message "Getting order…" is displayed (Figure 86).

   Note: If the test order is not successfully retrieved from the host, and if **Force Order** is enabled, the user is not allowed to continue running the test. If **Force Order** is disabled, even if the test order is not retrieved, the user can continue with the test (a pop-up dialog box will display a warning message). Refer to Section 10.2 for more information on warnings and errors.

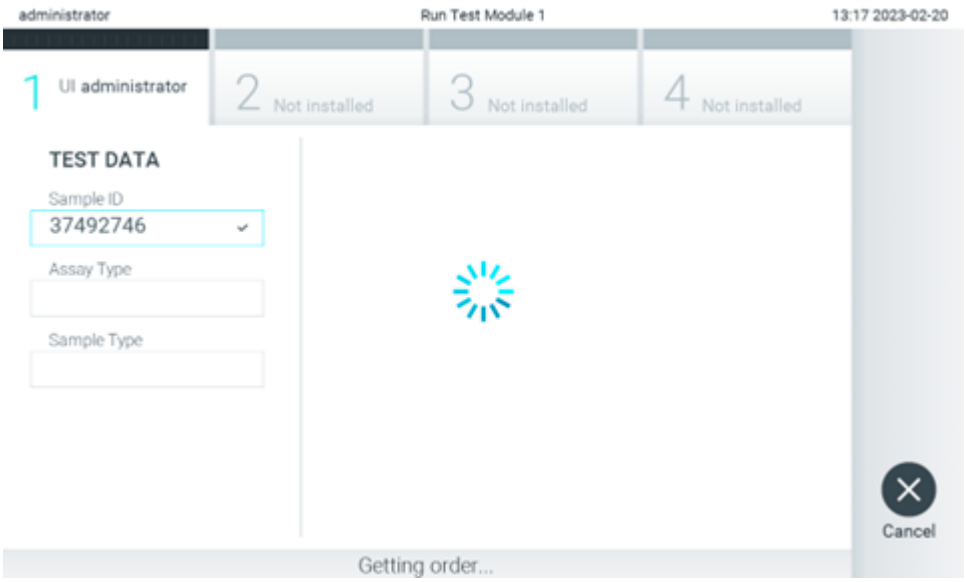


Figure 86. Display during test order retrieval.

4. When the test order has been successfully received from the host, "Scan cartridge for assay <assay_name> and book order <order_number>" is displayed. Scan the bar code of the specified QIAstat-Dx assay cartridge (Figure 87).

   Note: If the host returns more than one test order for a sample ID, the message "Scan cartridge for book order <order_number>" is displayed. If the scanned QIAstat-Dx assay cartridge does not match the book order, the test run cannot continue, and an error will be displayed. Refer to Section 10.2 for more information on warnings and errors.

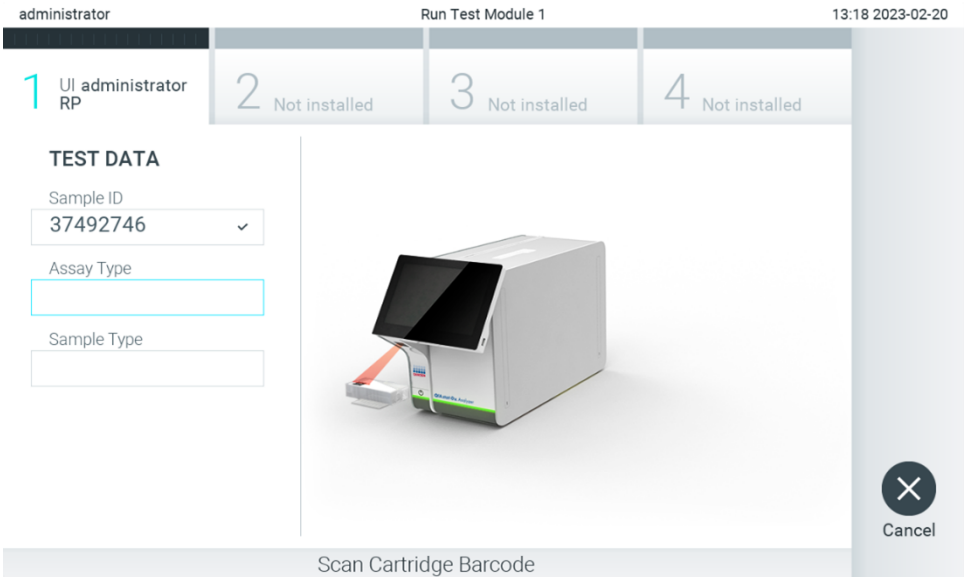


Figure 87. Scanning the QIAstat-Dx assay cartridge bar code.

5. The **Assay Type** field will be automatically entered and, if required, an appropriate Sample Type must be manually selected from the list (Figure 88).

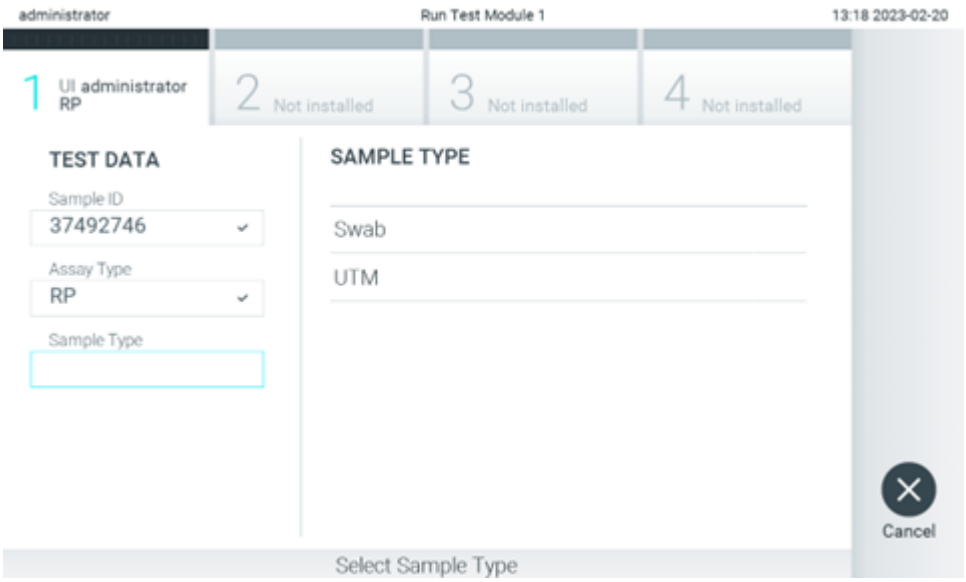


Figure 88. Selecting sample type.

6. Refer to Section 5.3 and complete steps 5–11.

7.4. Uploading a test result to the host

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 Analyzer 2.0 for uploading a test result automatically to the host

1. Press **Options** > **System Configuration**.
2. Select **HIS/LIS** from the **Settings** list in the left column.
3. Enable **Host Communication** and configure the **Host Settings** with the host details. Press **Check connectivity** to confirm the connection.
4. Enable **Result Upload** and configure the **Result Upload Settings**. Enable **Automatic upload**.

7.4.2. Uploading a test result automatically to the host

After the test is completed, the result will be automatically uploaded. The Upload Status is shown in the Test Data section of the results Summary screen and in the Upload column of the View Results screen (Figure 89).

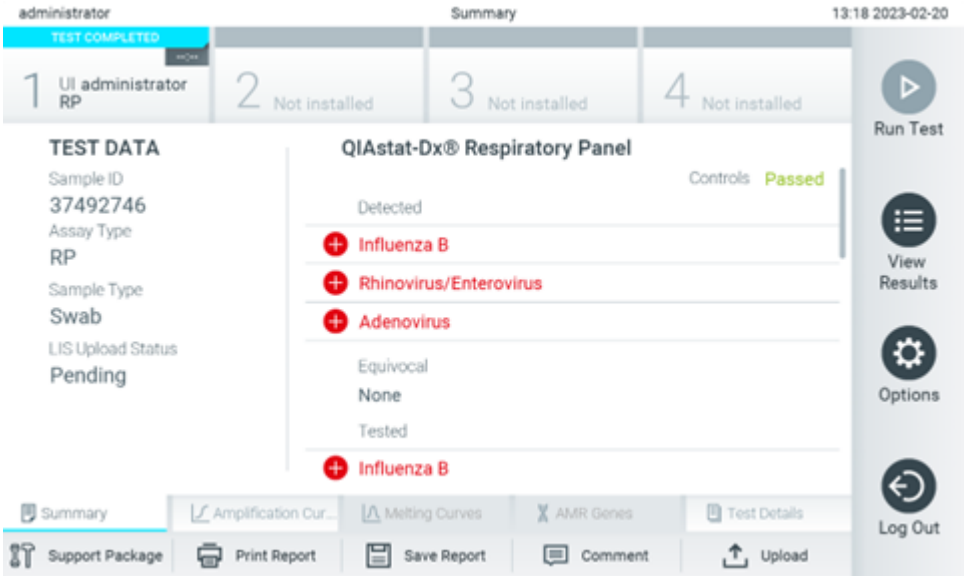


Figure 89. Results Summary screen.

To view the Upload Status for previous tests that are stored in the results repository, press View Results from the Main Menu bar. The Upload column displays the Upload Status (Figure 90).

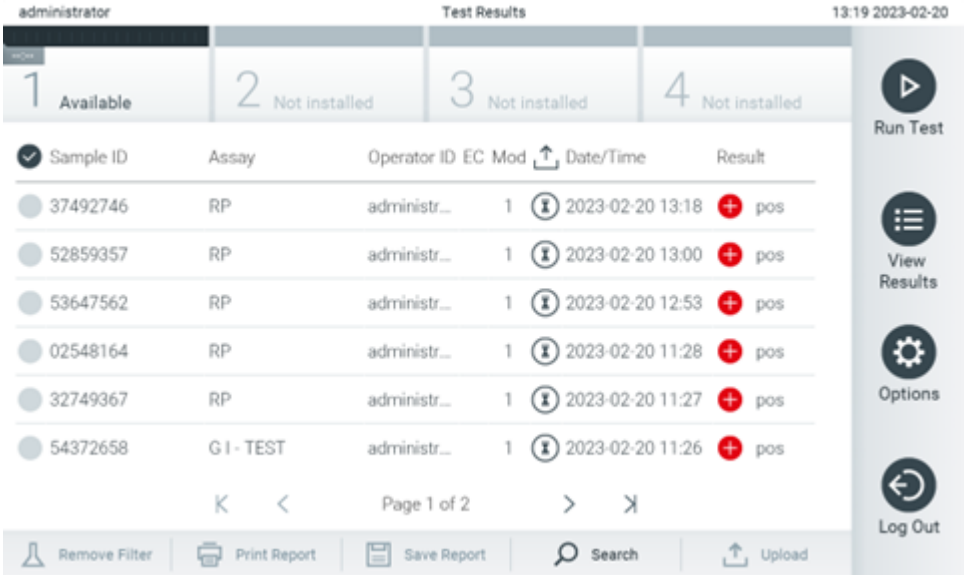


Figure 90. View Results screen.

Possible Upload Statuses that may be displayed are described in Table 20. Upload Status shows the result of the upload, the Name is shown in the result Summary screen and the Icon is displayed in the View Results screen.

Table 20. Description of upload statuses

Name	Icon	Description
Pending		Result not uploaded yet.
Uploading		Result being uploaded.

Table 20. Description of upload statuses (continued)

Name	Icon	Description
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.

7.4.3. Configuration of QIAstat-Dx Analyzer 2.0 for uploading a test result manually to the host

1. Press **Options** > **System Configuration**.
2. Select **HIS/LIS** from the **Settings** list in the left column.
3. Enable **Host Communication** and configure the **Host Settings** with the host details. Press **Check connectivity** to confirm the connection.
4. Enable **Result Upload** and configure the **Result Upload Settings**. Disable **Automatic upload**.

7.4.4. Uploading a test result manually to the host

After the test is completed, the result can be uploaded manually from the result Summary screen or the View Results screen.

To upload the result from the result Summary, screen press the Upload **Upload**.

To upload the result from the View Results screen, select one or more test results by pressing the gray circle to left of the sample ID. A checkmark will appear next to selected results. To deselect test results, press the checkmark. The entire list of results can be selected by pressing the checkmark circle in the top row. After selecting the results for upload, press the Upload **Upload** button (Figure 91).

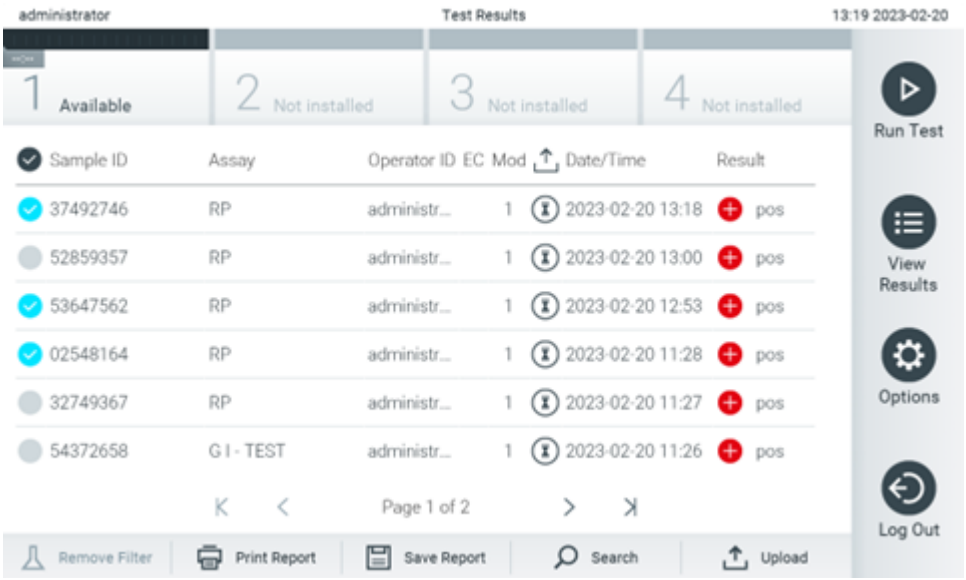


Figure 91. View Results screen.

7.5. Troubleshooting host connectivity

To troubleshoot host connectivity issues, see Section 10.1.

8. External Control (EC)

The QIAstat-Dx Analyzer 2.0 software can be configured, such that it supports laboratories with quality control procedures based on external controls. The purpose of such procedures is to verify that processing a known sample produces expected results on a pathogen level. Follow your organization's policies to ensure that appropriate procedures are established, independent of the use of the functionalities described in this section.

If the feature is enabled, it enables the configuration of intervals after which an EC test has to be performed per assay and module. Users will be reminded if an EC test is due before setting up a test.

When an EC test is performed, an EC sample is selected when setting up the run. The EC sample determines what the expected results for each analyte of a tested assay are. If the expected results configured in an EC sample match the actual results from the test, the EC test passes. If at least one analyte is not meeting its expected result, the EC test fails. A user is warned prior to setting up a test if a module is used for which the previous EC test failed.

8.1. External Control configuration

Refer to Section 6.11 to enable and configure the EC feature.

8.2. Procedure to run an EC test

All operators should wear appropriate personal protective equipment, such as gloves, when touching the QIAstat-Dx Analyzer 2.0 touchscreen.

1. Press the **Run Test** button located at the top right corner of the Main screen.

   Note: If External Control (EC) is enabled and an EC test is due to be performed, a reminder is shown to run the test with an EC sample. Users can choose to perform an EC test or dismiss the reminder.

   Note: If EC is enabled and the last EC test performed with the selected module failed, a warning is shown. Users must explicitly choose whether they want to perform a test with the selected module anyway.

2. Turn on the **EC Test** toggle button (Figure 92).

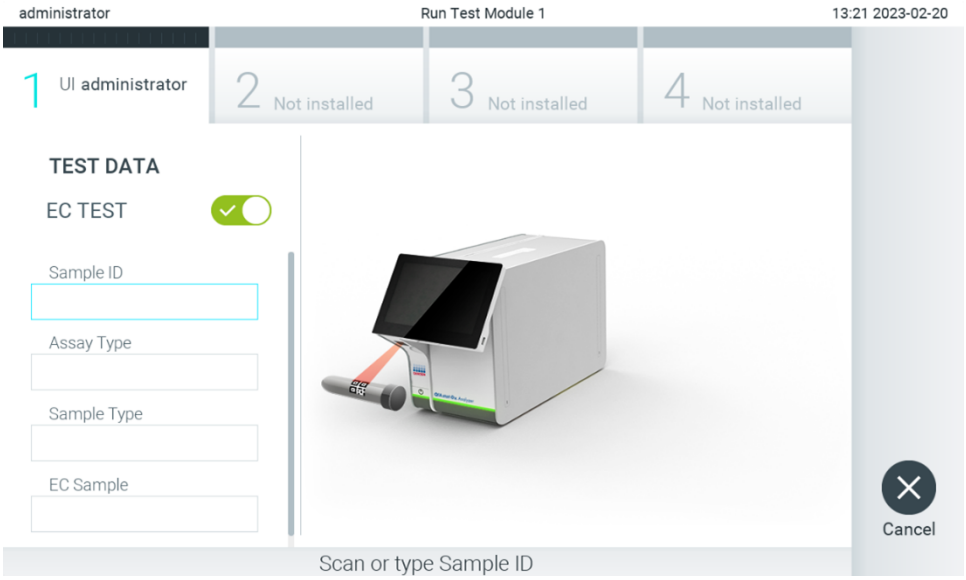


Figure 92. Turning on the EC Test toggle button to enable an EC test.

3. When prompted, scan the sample ID barcode using the bar code reader that is integrated into the Operational Module (Figure 92).

   Note: Depending on the QIAstat-Dx Analyzer 2.0 configuration, it may also be possible to enter the sample ID using the virtual keyboard of the touchscreen. Refer to Section 6.7.4 for further details.

4. When prompted, scan the bar code of the QIAstat-Dx assay cartridge to be used. The QIAstat-Dx Analyzer 2.0 automatically recognizes the assay to be run, based on the QIAstat Dx assay cartridge bar code (Figure 93)

   Note: The QIAstat-Dx Analyzer 2.0 will not accept QIAstat-Dx assay cartridges with lapsed expiration dates, previously used cartridges, or cartridges for assays that are not installed on the unit. An error message will be shown in these cases. Refer to Section 10.2 for further details.

   Note: Refer to Section 6.6.3 for instructions on importing and adding assays to the QIAstat-Dx Analyzer 2.0.

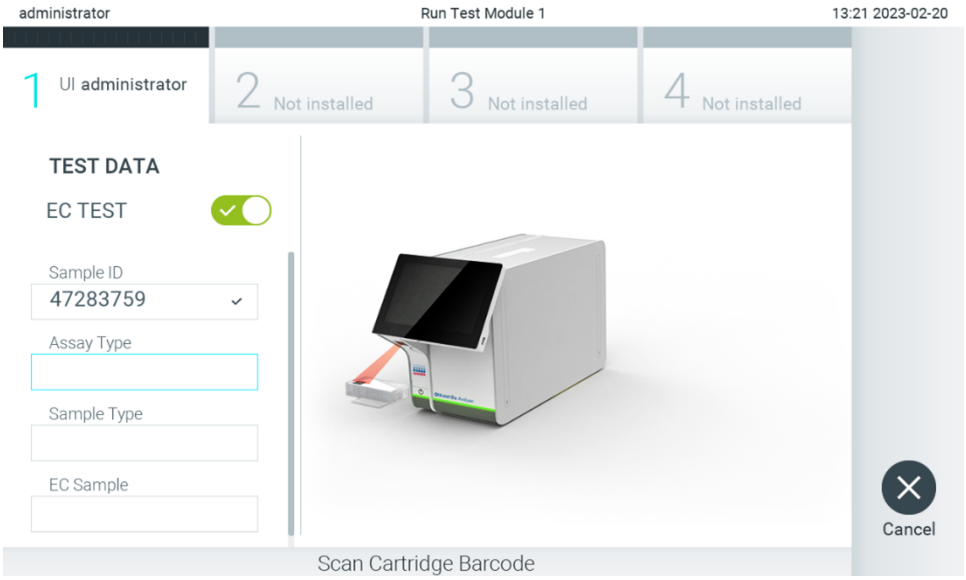


Figure 93. Scanning the QIAstat-Dx assay cartridge bar code.

5. If required, select the appropriate sample type from the list (Figure 94).

   Note: In some rare instances, the sample type list may be empty. In this case, the cartridge needs to be scanned againrescanned.

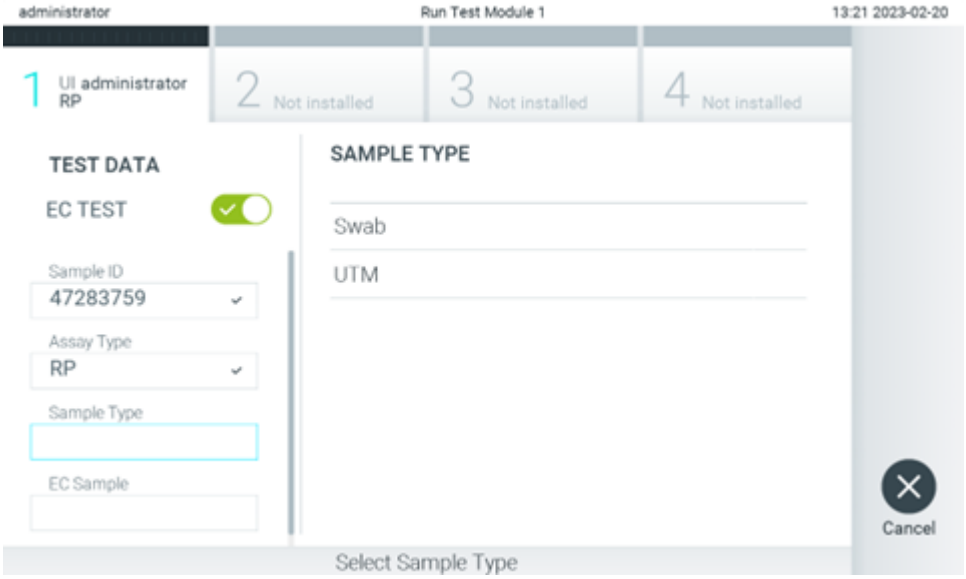


Figure 94. Choosing a sample type.

6. Select the appropriate EC sample from the list. Only EC samples for the selected assay type are shown (Figure 95).

   If no EC samples are configured for the selected assay, the list of EC samples will be empty, and it will not be possible to start an EC test run.

   Note: Refer to Section 6.11 for instructions on configuring EC samples.

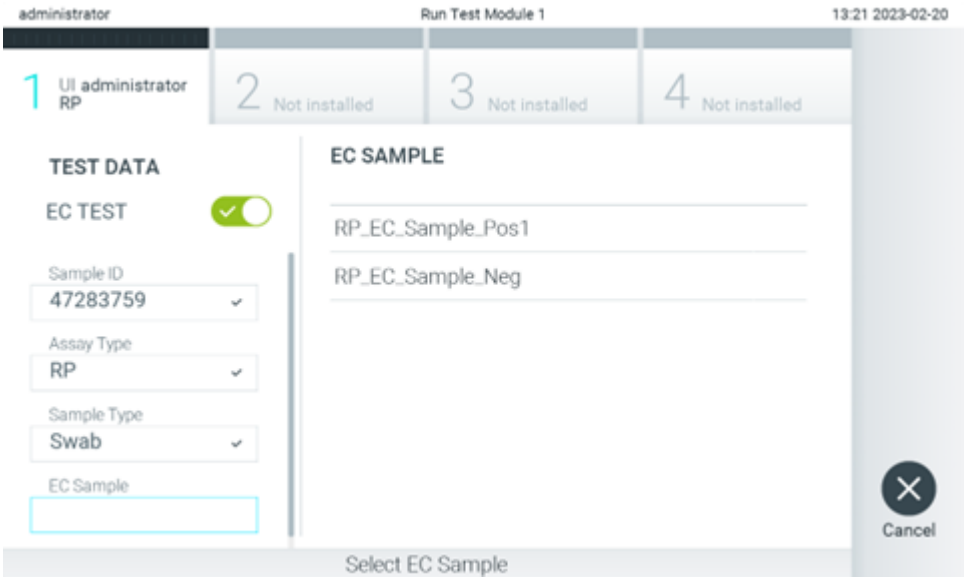


Figure 95. Selecting EC Sample.

7. The Confirm screen will appear. Review the data entered and make any necessary changes by pressing the relevant fields on the touchscreen and editing the information (Figure 96).

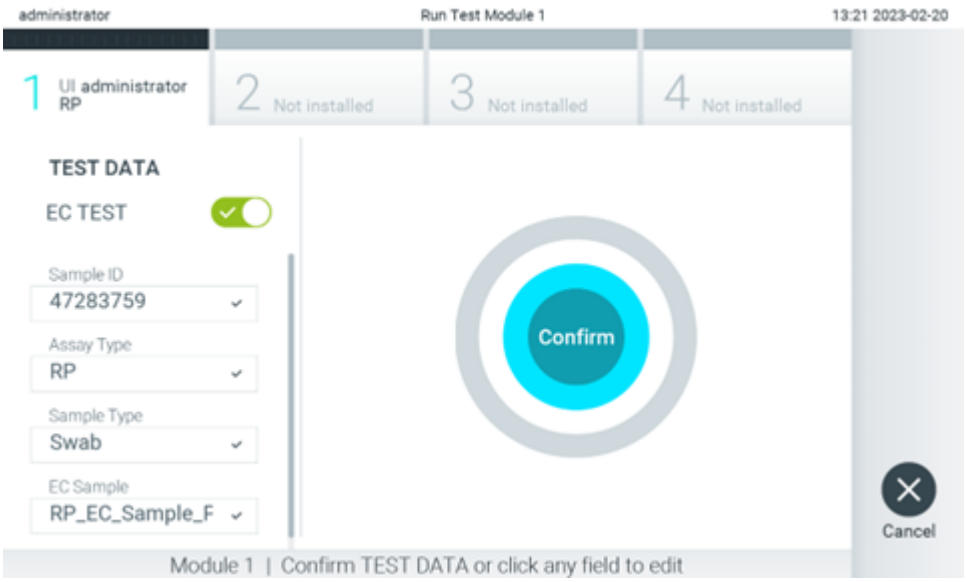


Figure 96. Confirm screen.

8. Press **Confirm** when all the displayed data are correct. If needed, press on the appropriate field to edit its content, or press **Cancel** to abort the test.
9. Make sure that both sample lids of the swab port and main port of the QIAstat-Dx assay cartridge are firmly closed. When the cartridge entrance port on the top of the QIAstat-Dx Analyzer 2.0 automatically opens, insert the QIAstat-Dx assay cartridge with the bar code facing to the left and the reaction chambers facing down (Figure 97).

   Note: When multiple Analytical Modules are connected to an Operational Module, the QIAstat-Dx Analyzer 2.0 automatically selects the Analytical Module in which the test is to be run.

   Note: There is no need to push the QIAstat-Dx assay cartridge into the QIAstat-Dx Analyzer 2.0. Position it correctly into the cartridge entrance port and the QIAstat-Dx Analyzer 2.0 will automatically move the cartridge into the Analytical Module.

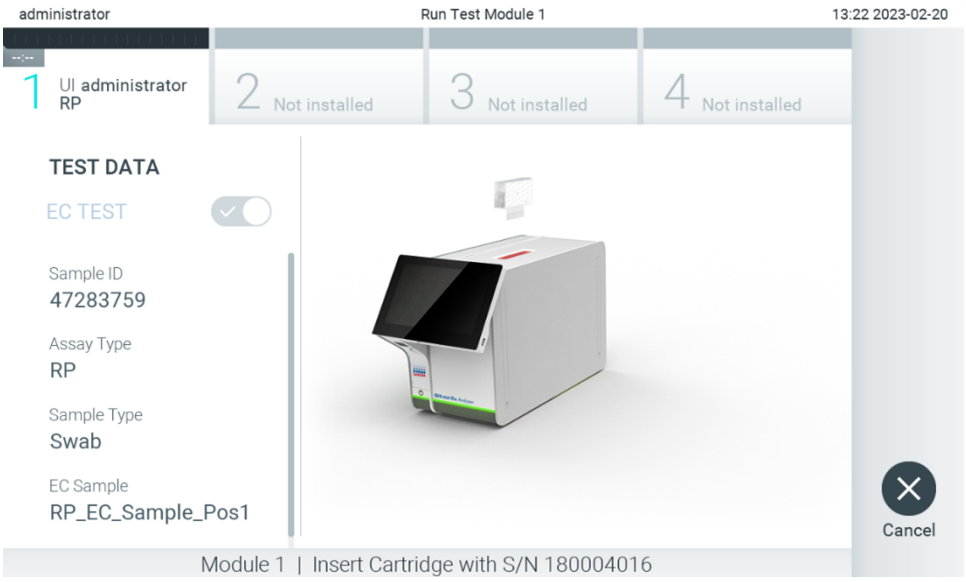


Figure 97. Inserting QIAstat-Dx assay cartridge into QIAstat-Dx Analyzer 2.0.

10. Upon detecting the QIAstat-Dx assay cartridge, the QIAstat-Dx Analyzer 2.0 will automatically close the lid of the cartridge entrance port and start the test run. No further action from the operator is required. While the test is running, the remaining run time is displayed on the touchscreen (Figure 98).

    Note: The QIAstat-Dx Analyzer 2.0 will not accept a QIAstat-Dx assay cartridge other than the one used and scanned during the test setup. If a cartridge other than the one scanned is inserted, an error will be generated, and the cartridge will be automatically ejected.

    Note: Up to this point, it is possible to cancel the test run by pressing the **Cancel** button in the bottom right corner of the touchscreen.

    Note: Depending on the system configuration, the operator may be required to re-enter their user password to start the test run.

    Note: The lid of the cartridge entrance port will close automatically after 30 seconds if a QIAstat-Dx assay cartridge is not positioned in the port. If this occurs, repeat the procedure starting with step 7.

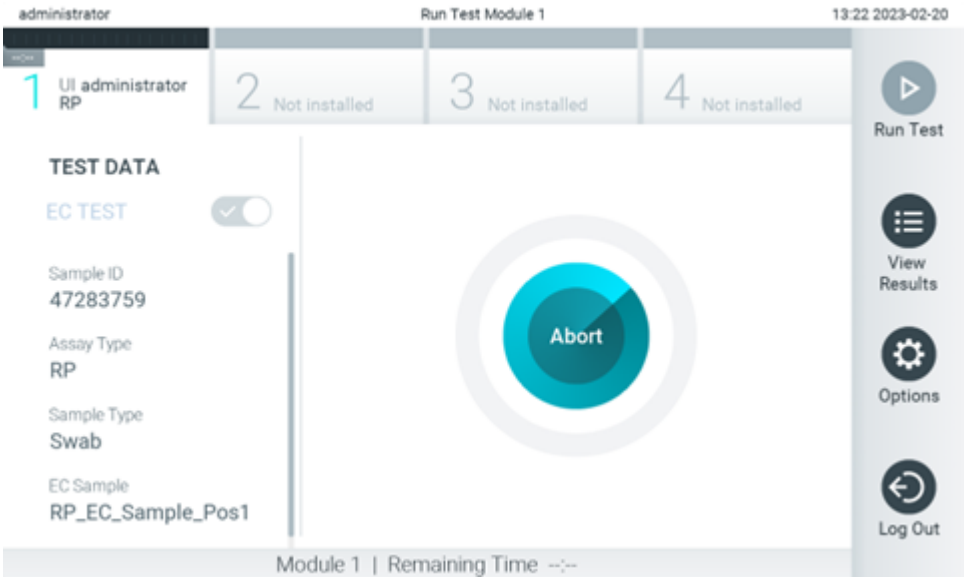


Figure 98. Test execution and remaining run time display.

11. After the test run is completed, the Eject screen will appear (Figure 99). Press **Eject** on the touchscreen to remove the QIAstat-Dx assay cartridge and dispose it as biohazardous waste in accordance with all national, state, and local health and safety regulations and laws.

    Note: The QIAstat-Dx assay cartridge should be removed when the cartridge entrance port opens and ejects the cartridge. If the cartridge is not removed after 30 seconds, it will automatically move back into the QIAstat-Dx Analyzer 2.0 and cartridge entrance port lid will close. If this occurs, press **Eject** to open the lid of the cartridge entrance port again and then remove the cartridge.

    Note: Used QIAstat-Dx assay cartridges must be discarded. It is not possible to reuse cartridges for tests for which the execution was started but then subsequently canceled by the operator, or for which an error was detected.

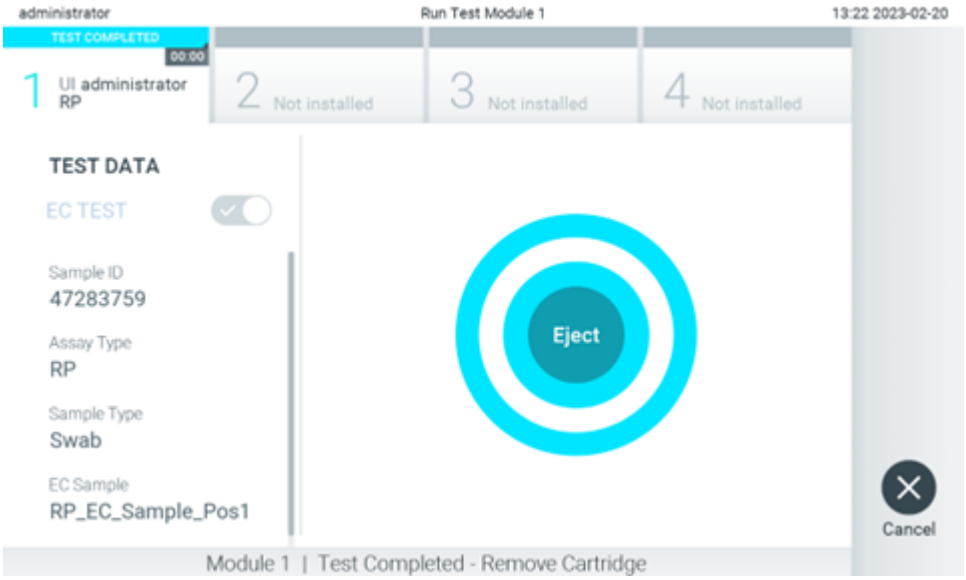


Figure 99. Eject screen display.

12. After the QIAstat-Dx assay cartridge has been ejected, the results Summary screen will appear (Figure 100). Refer to Section 8.3 for further details.

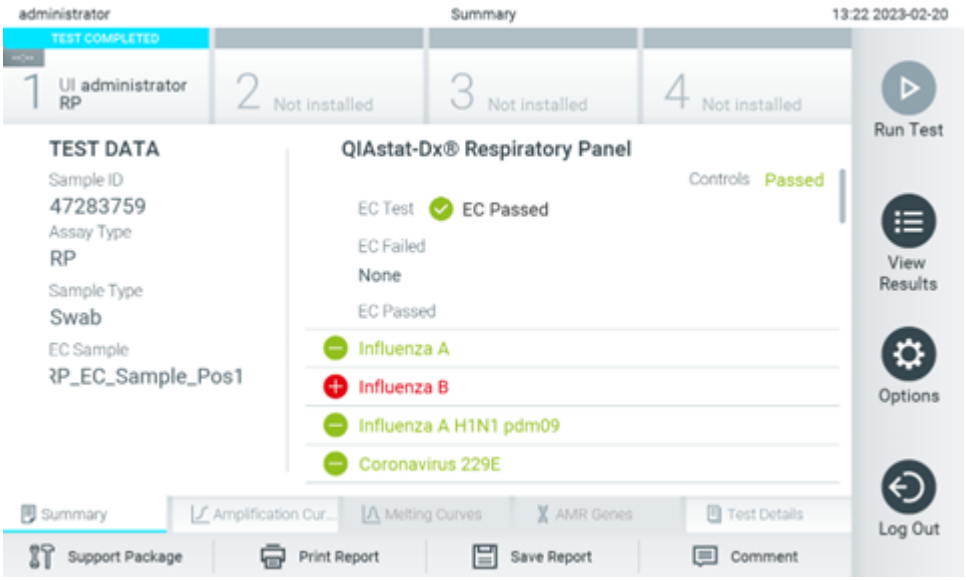


Figure 100. EC Results Summary screen.

Note: If an error with the analytical module occurred during the run, it may take some time until the run results are shown and the run is made visible in the View Results overview.

8.3. Viewing EC test results

The QIAstat-Dx Analyzer 2.0 automatically interprets and saves test results. After ejecting the QIAstat-Dx assay cartridge, the results Summary screen is automatically displayed (Figure 101).

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

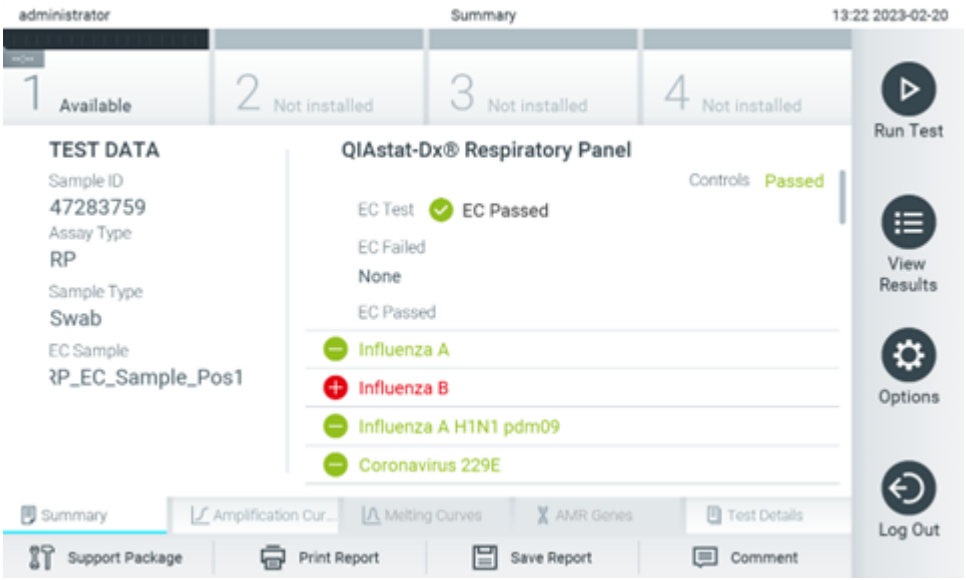


Figure 101. EC Results Summary screen.

The main part of the screen provides the overall EC result (i.e. EC Passed or EC Failed) and the following three lists:

- The first list includes all pathogens tested in the sample where the expected result configured in the EC sample does not match the actual test result, i.e. the EC failed. Only analytes considered in the EC sample are included.

  Pathogens detected and identified in the sample are preceded by a sign and are colored red. Pathogens that were tested but not detected are preceded by a sign and are colored green. Equivocal pathogens are preceded by a question mark and are colored yellow.
- The second list includes all pathogens tested in the sample where the expected result configured in the EC sample does match the actual test result, i.e. the EC passed. Only analytes considered in the EC sample are included.

  Pathogens detected and identified in the sample are preceded by a sign and are colored red. Pathogens that were tested but not detected are preceded by a sign and are colored green.
- The third list includes all pathogens tested in the sample. Pathogens detected and identified in the sample are preceded by a sign and are colored red. Pathogens that were tested but not detected are preceded by a sign and are colored green. Equivocal pathogens are preceded by a question mark and are colored yellow.
- If the test failed to complete successfully, a message will indicate "Failed" followed by the specific Error Code.

The following Test Data are shown on the left side of the screen:

- Sample ID
- Assay Type
- Sample Type
- EC sample
- LIS Upload Status (if applicable)

Further data about the assay is available, depending on the operator's access rights, through the tabs at the bottom of the screen (e.g., amplification plots, melting curves and test details).

Assay data can be exported by pressing **Save Report** in the bottom bar of the screen.

A report can be sent to the printer by pressing **Print Report** in the bottom bar of the screen.

A support package of the selected run or all failed runs can be created by pressing **Support Package** at the bottom bar of the screen. If support is required, send the support package to the QIAGEN Technical Services.

8.3.1. Viewing amplification curves

Interpreting amplification curves does not differ from non-EC tests. Refer to Section 5.5.1 for more information.

8.3.2. Viewing EC melting curves

Interpreting melting curves does not differ from non-EC tests. Refer to Section 5.5.2 for more information.

8.3.3. Viewing EC AMR genes

Viewing AMR genes does not differ from non-EC tests. Refer to Section 5.5.3 for more information.

8.3.4. Viewing EC test details

When viewing an EC test result, press **Test Details** to review the EC results in more detail. Scroll down to see the complete report.

The following Test Details are shown in the screen:

- User ID
- Cartridge SN (serial number)
- Cartridge Expiration Date
- Module SN (serial number)
- Test Status (Completed, Failed or Canceled by operator)
- Test Start Date and Time
- Test Execution Time
- Assay Name
- External Control Test
- Test ID
- Book Order ID (Visible only if order checking was on when the test was run.
- Order Time (Visible only if order checking was on when the test was run.
- HIS/LIS Confirmation (Visible only if order checking was on when the test was run.
- EC Sample

- Test Result (for every analyte, total result of the test: EC Passed [ecpass] and EC Failed [ecfail]).
- Error Code (if applicable)
- Error Message (if applicable)
- Last Comment Editor (if applicable, refer to section 5.5.5)
- Comment Date and Time (if applicable, refer to section 5.5.5)
- Comment (if applicable, refer to section 5.5.5)
- If an EC test passed, the expected results for each pathogen match the detected results.
- List of analytes tested in the assay (grouped by Detected Pathogen, Equivocal, Not Detected Pathogens, Invalid, Not Applicable, Out of Range, Passed Controls and Failed Controls), with CT and endpoint fluorescence (if available for the assay).
- Next to each analyte the expected result and the EC result are shown in separate columns. If an analyte is not considered in the EC run, no expected result and no EC result is shown.
- The expected result column is determined by the configuration of the selected EC sample during the test setup
- The EC result column is a comparison between the actual result of the analyte and the expected result of the considered analytes. The EC result passed, if actual and expected result are the same. The EC result fails, if the actual and expected result are not the same (see Error! Reference source not found.). The analytes not considered in the EC run are not compared to the actual result.

  Note: The expected results are based on the EC sample configuration at the time of the test start.
- List of internal controls, with CT and endpoint fluorescence (if available for the assay)

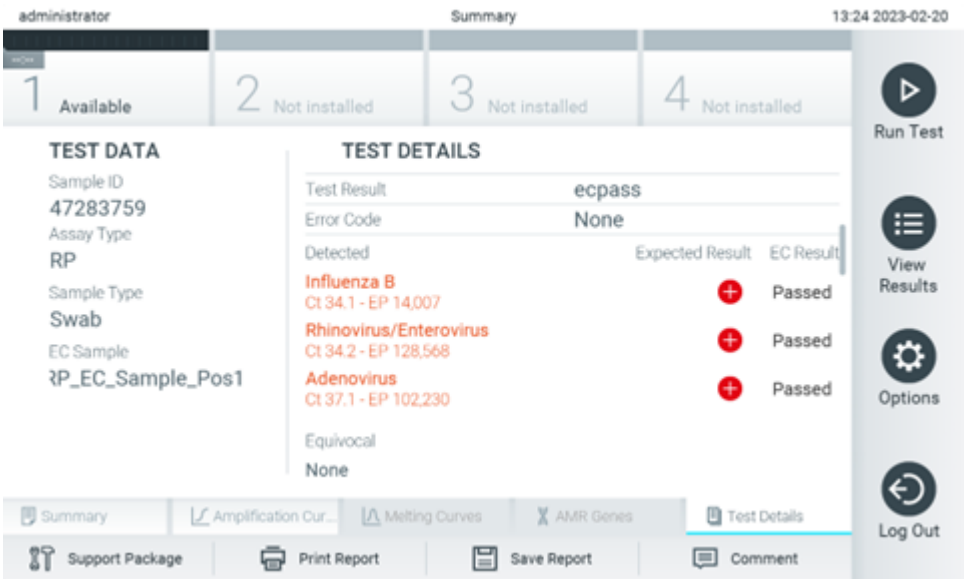


Figure 102. EC test details screen.

9. Maintenance

This section describes the maintenance tasks required for the QIAstat-Dx Analyzer 2.0.

9.1. Maintenance tasks

Table 21 provides a list of maintenance tasks to be performed on the QIAstat-Dx Analyzer 2.0.

Table 21. Descriptions of maintenance tasks

Task	Frequency
Cleaning or decontaminating the QIAstat-Dx Analyzer 2.0 surface	To be performed when liquids, chemicals, or biological specimens (potentially infectious) are spilled on the QIAstat-Dx Analyzer 2.0 surface
Exchange of air filter	To be performed annually

9.2. Cleaning the QIAstat-Dx Analyzer 2.0 surface

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 Analyzer 2.0 from the power outlet before cleaning.

CAUTION

Risk of damage to the QIAstat-Dx Analyzer 2.0

Avoid spilling chemicals or other liquids into or out of theQIAstat-Dx Analyzer 2.0. Damage caused by liquid spillage will void the warranty.

CAUTION

Risk of damage to the QIAstat-Dx Analyzer 2.0

Avoid spilling liquids on or wetting the touchscreen. To clean the touchscreen, use the screen suede provided with the QIAstat-Dx Analyzer 2.0.

Use the following materials to clean the QIAstat-Dx Analyzer 2.0 surface:

- Mild detergent
- Paper towels
- Distilled water

Follow the steps below to clean the QIAstat-Dx Analyzer 2.0 surface:

1. Wear laboratory gloves, coat, and protective glasses.
2. Wet a paper towel in mild detergent and wipe down the QIAstat-Dx Analyzer 2.0 surface, as well as the surrounding workbench area. Take care not to wet the touchscreen. To clean the touchscreen, use the screen suede provided with the QIAstat-Dx Analyzer 2.0.
3. Repeat step 2 three times with fresh paper towels.
4. Wet a paper tower in distilled water and wipe down the QIAstat-Dx Analyzer 2.0 surface to rinse away remaining detergent. Repeat two times.
5. Dry the QIAstat-Dx Analyzer 2.0 surface with a fresh paper towel.

9.3. Decontaminating the QIAstat-Dx Analyzer 2.0 surface

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 Analyzer 2.0 from the power outlet before cleaning.

CAUTION

Risk of damage to the QIAstat-Dx Analyzer 2.0

Avoid spilling chemicals or other liquids into or out of theQIAstat-Dx Analyzer 2.0. Damage caused by liquid spillage will void the warranty.

CAUTION

Risk of damage to the QIAstat-Dx Analyzer 2.0

Avoid spilling liquids on or wetting the touchscreen. To clean the touchscreen, use the screen suede provided with the QIAstat-Dx Analyzer 2.0.

Use the following materials to decontaminate the QIAstat-Dx Analyzer 2.0 surface:

- 10% bleach solution
- Paper towels
- Distilled water

Follow the steps below to decontaminate the QIAstat-Dx Analyzer 2.0 surface:

1. Wear laboratory gloves, coat, and protective glasses.
2. Wet a paper towel in the 10% bleach solution and wipe down the QIAstat-Dx Analyzer 2.0 surface, as well as the surrounding workbench area. Take care not to wet the touchscreen. Wait at least three minutes to allow the bleach solution to react with the contaminants.
3. Change into a new pair of gloves.
4. Repeat steps 2 and 3 two additional times with fresh paper towels.

5. Wet a paper tower in distilled water and wipe down the QIAstat-Dx Analyzer 2.0 surface to rinse away any remaining bleach solution. Repeat twice.
6. Dry the QIAstat-Dx Analyzer 2.0 surface with a fresh paper towel.

9.4. Replacing the filter

The air filter must be exchanged every year to ensure the appropriate airflow rate inside the unit.

The air filter is located below the QIAstat-Dx Analyzer 2.0 and can be accessed by the user at the front of the instrument.

Air filters from QIAGEN must be used as replacement. Catalog number of this material is: 9026189 Air Filter Tray

Follow these steps to exchange the air filter:

1. Set the QIAstat-Dx Analyzer 2.0 in standby mode by pressing the **ON/OFF** button on the front of the instrument.
2. Place a hand below the air filter drawer at the front of the QIAstat-Dx Analyzer 2.0 and use fingers to slightly push up.
3. Pull the air filter back until the filter drawer is completely removed. Dispose the old air filter.
4. Remove the new air filter drawer from its protective bag.
5. Insert the new air filter drawer into the QIAstat-Dx Analyzer 2.0. The unit is now ready for use.

CAUTION **Risk of damage to the QIAstat-Dx Analyzer 2.0**

Only use original parts from QIAGEN. Use of non-authorized parts may result in damage to the unit and will void the warranty.

9.5. QIAstat-Dx Analyzer 2.0 repair

The QIAstat-Dx Analyzer 2.0 must only be repaired by representatives authorized by QIAGEN. If the QIAstat-Dx Analyzer 2.0 is not working as expected, contact QIAGEN Technical Services using the contact information in Section 10.

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

Do not open the QIAstat-Dx Analyzer 2.0 housing. Do not attempt to repair or modify the QIAstat-Dx Analyzer 2.0.

Opening the housing or modifying the QIAstat-Dx Analyzer 2.0 inappropriately may result in user injury and QIAstat-Dx Analyzer 2.0 damage and will void the warranty.

10. Troubleshooting

This section provides information on some issues that may occur with the QIAstat-Dx Analyzer 2.0, along with possible causes and solutions. The information is specific to the instrument. For troubleshooting relevant to a QIAstat-Dx assay cartridge, see the instructions for use for the respective cartridge.

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 Analyzer 2.0, 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 Analyzer 2.0 serial number, type, software version, and installed Assay Definition Files
- Error code (if applicable)
- Timepoint when the error occurred for the first time
- Frequency of error occurrence (i.e., intermittent or persistent error)
- Photo of error, if possible
- Support Package

10.1. Hardware and software errors

Error	Possible cause	Comments and suggestions
The QIAstat-Dx Analyzer 2.0does not start.	The QIAstat-Dx Analyzer 2.0 is not connected to the power outlet. The power switch at the back of the QIAstat-Dx Analyzer 2.0 is not powered ON. The QIAstat-Dx Analyzer 2.00 is in standby mode. There was a brief power loss.	Check that the QIAstat-Dx Analyzer 2.0 is connected to the main power. Power ON using the power switch at the back of QIAstat-Dx Analyzer 2.0. Press the ON/OFF button to take the QIAstat-Dx Analyzer 2.0 out of standby mode. Wait for a few seconds before switching ON the QIAstat-Dx Analyzer 1.0 again. The system might fail to start if the instrument is not allowed to rest for a few seconds before powering ON.
Analytical Module not detected.	Analytical/Operational Module bridge is not properly connected.	Check that the bridge between the Operational Module and the Analytical Module is properly connected.
The Analytical Module status indicator is red.	Hardware failure.	Try to restart the Analytical Module on the Module status page (refer to section 6.1.3) If the issue persists, contact QIAGEN Technical Services.
The touchscreen does not respond.	The QIAstat-Dx Analyzer 2.0 is in standby mode (status indicator is blue). Hardware failure.	Press the ON/OFF button on the Operational Module. Contact QIAGEN Technical Services.
Bar code reader does not scan.	Sample ID bar code feature is not enabled. Bar code reader has a hardware or software problem.	Contact a Laboratory Supervisor or instrument Administrator to configure the bar code feature on the QIAstat-Dx Analyzer 2.0. Contact QIAGEN Technical Services.

Error	Possible cause	Comments and suggestions
The QIAstat-Dx assay cartridge is stuck inside the QIAstat-Dx Analyzer 2.0.	Module mechanical failure.	Contact QIAGEN Technical Services.
Lid of the cartridge entrance port does not open.	Module mechanical failure.	Contact QIAGEN Technical Services.
The Run Test button is not active.	A QIAstat-Dx assay cartridge is still inside the QIAstat-Dx Analyzer 2.0 and must be ejected before the QIAstat-Dx Analyzer 2.0 will allow a new test execution. The module is not available.	The status box of the module in the Module status bar should show the text "Eject cartridge". Press the status box of the module and then press the Eject. Check that the bridge between the Operational Module and the Analytical module is properly connected.
Assay does not run.	The user does not have rights to run the test. The assay is not installed on the QIAstat-Dx Analyzer 2.0.	Contact a Laboratory Supervisor or instrument Administrator. The assay needs to be installed. Contact a Laboratory Supervisor or instrument Administrator.
Result upload status is "Error".	Connectivity with the host has been lost. Communication with the host has timed out. Message rejected from host.	Contact a Laboratory Supervisor or instrument Administrator to check connection details and test connectivity. Contact a Laboratory Supervisor or instrument Administrator to check the Timeout settings value, which can be increased to a maximum value of 60 seconds. If it is already set to the maximum value, then network performance should be reviewed. The host rejected the message for some reason (assay not recognized, semantic issues, etc.). Contact QIAGEN Technical Services.
A result cannot be uploaded.	Result status is expired.	Contact a Laboratory Supervisor or instrument Administrator to check the Expire Time in the HIS/LIS settings.
Cannot run a test because there is no test order.	There is no test order for the sample ID and Force Order is enabled in the HIS/LIS settings. Connectivity issue with the LIS and Force Order is enabled in the HIS/LIS settings.	Contact a LIS administrator to check if there is an order for the specified sample ID in the LIS. Contact a Laboratory Supervisor or instrument Administrator to check connectivity with the host. To run the assay without a test order, disable Force Order in the HIS/LIS settings.
Printer is not setup correctly, or test reports cannot be printed.	There are different causes of printer malfunction.	Visit **QIAGEN.com/QIAStat-Dx_PrinterSetup** for frequently asked questions on troubleshooting for printer setup and guidance to avoid common printer issues.
Time zone change is not applied.	The selected time zone is not recognized by the device.	Select a different time zone with the same offset.

10.2. Error codes and messages

Error Code	Error Message
0x00000001	Analytical Module <Number> Problem with lid.
0x00000002	Analytical Module <Number> Error by closing lid.
0x00000003	Analytical Module <Number> Barcode reading failed.
0x00000004	Analytical Module <Number> Downloading test failed (Crc)
0x00000005	Analytical Module <Number> AAF parse error
0x00000006	Analytical Module <Number> Downloading AAF failed.
0x00000013	Analytical Module <Number> AAF too long

Error Code	Error Message
0x0000010A	Cannot create archive due to existing archives stored on USB device. Remove archives from USB device or use different USB device.
0x0000010D	The selected file: <File Name> , is not supported. Please select a file of type: <File type>
0x00000303	Assay <assay name> requires version <required version>, actual <actual version>.
0x00000304	Assay <assay name> already imported.
0x00000305	Importing <assay name> failed.
0x00000306	Invalid sample type definition found.
0x00000307	Invalid error code detected in file <file name>.
0x00000308	Error loading the assay <assay name>. Please eject the cartridge and insert it again.
0x00000309	Invalid flex data detected in the file <file name>.
0x00000310	Invalid AMR Gene definition in the file <file name>.
0x00000311	Invalid flag for showing Plots and CT/EP values for AMR genes <analyte names>.
0x00000312	Invalid Semi-Quantification data detected in the file <file name>.
0x00000401	Assay <assay name> not available.
0x00000402	Assay <assay name> not active.
0x00000403	This user does not have permission to execute this assay.
0x00000404	Assay <assay name> requires version <version number>.
0x00000405	Analytical Module <Number>: Assay <assay name> requires version <version number>.
0x00000406	A newer version of the assay is required.
0x00000424	Analytical Module <Number>: Eject not possible, cartridge is too hot.
0x00000431	Failed to scan barcode.
0x00000433	Analytical Module <Number>: Different cartridge inserted.
0x00000490	The processing module is not valid.
0x000004F0	Cartridge already used.
0x000004F1	Cartridge expired.
0x00000510	Transmitting barcode failed (Crc)
0x00000511	Transmitting barcode failed (Length)
0x00000516	Invalid identification data (Crc)
0x00000517	Invalid identification data (Length)
0x0000051A	Invalid calibration data (Crc)
0x0000051B	Invalid calibration data (Length)
0x0000051C	Analytical Module <Number>: Calibration Parameters Crc Error
0x0000051D	Analytical Module <Number>: Calibration Parameters Length Error
0x0000051E	Calibration of Analytical Module <Number> required in <number> days.
0x0000051F	Maintenance of Analytical Module <Number> required in <number> days.
0x00000520	Analytical Module <Number>: Test record rejected - test start time is older than 90 minutes.

Error Code	Error Message
0x00000521	Analytical Module <Number>: Test result data lost.
0x00000522	No free module available.
0x00000601 0x00000607 0x00000608 0x00000609	Assay invalid CRC
0x00000602	User data invalid CRC
0x00000603	User profile data invalid CRC
0x00000604	Test record invalid CRC
0x00000605	Database not found.
0x00000606	Database is not compatible.
0x0000060A	An unexpected data base exception happened. Device will restart.
0x0000060B	Failed to rename Database
0x00000805	An error occurred during the deletion of <printer name>.
0x00000902	Error downloading the file <file name> from network share.
0x00001001 0x00001002 0x00001003	No connection to HIS/LIS.
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 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	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.

Error Code	Error Message
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.
0x00002101	The system was not shut down properly last time.
0x0000F001	Unexpected AM found
0x0000F002	Unexpected behavior of Analytical Module <Number>.
0x0000F004	A Process Module error occurred. Please see system log for more information.
0x0067 0x0068	Failure on cartridge clamping. Please retry. If this error persists please contact QIAGEN Technical Services
0x0069	Atmospheric pressure is out of the analyzer operational range. Please contact QIAGEN Technical Services
0x00EF 0x00F1 0x00F2 0x00F3 0x00F4 0x00F5 0x00F6 0x00F7 0x00F8 0x00F9 0x00FD 0x00FE 0x00FF	Failure on PCR readings. Please repeat with another cartridge. If this error persists please contact QIAGEN Technical Services
0x01008000 0x01008001 0x01008002 0x01008003 0x01008004 0x01008005 0x01008006 0x0100800B 0x0100800D 0x0100800E 0x01008010 0x01008011 0x01008012 0x01008013 0x01008014 0x01008015 0x01008016 0x01008017 0x01008021 0x01008022 0x01008023	Switch off the analyzer and restart it again. If this error persists please contact QIAGEN Technical Services

Error Code	Error Message
0x01008007	Analyzer internal temperature below working temperature range. Wait for the analyzer to warm up and then restart the unit. If the error persists please contact QIAGEN Technical Services
0x01008008	Analyzer internal temperature above working temperature range. Verify analyzer placement. Check 'Site Requirements' section in the User manual
0x01008009	Temperature during assay execution too high. Verify analyzer placement. Check 'Site Requirements' section in the User manual
0x0100800A	Analyzer tilted. Verify placement. Check ‘Site Requirements' section in the user manual
0x0100800C	Firmware update needed. Search on QIAGEN website the most recent software version

Error Code	Error Message
0x0100800F	Analyzer failure. Please contact QIAGEN Technical Services
0x0100801A	
0x0100801B	
0x0100801C	
0x0100801D	
0x0100801E	
0x0100801F	
0x01008020	
0x01008025	
0x01008026	
0x01008027	
0x01008028	
0x01008029	
0x0100802A	
0x0100802B	
0x0100802C	
0x0100802E	
0x0100807F	
0x01008080	
0x010080FF	
0x01008100	
0x01008101	
0x01008102	
0x01008103	
0x01008104	
0x01008105	
0x01008106	
0x01008107	
0x0100813F	
0x01008140	
0x01008141	
0x0100817F	
0x01008180	
0x01008181	
0x010081FF	
0x01008200	
0x01008201	
0x01008202	
0x01008203	
0x01008204	
0x01008205	
0x01008206	
0x01008207	
0x01008208	
0x01008209	
0x0100820A	
0x0100820B	
0x0100822F	
0x01008230	
0x01008235	

Error Code	Error Message
0x01008250	
0x01008251	
0x01008252	
0x01008253	
0x01008254	
0x01008255	
0x010082A0	
0x010082A1	
0x010082A2	
0x010082A3	
0x010082FF	
0x01008300	
0x010083FF	
0x01008400	
0x01008401	
0x01008402	
0x01008403	
0x01008404	
0x01008405	
0x01008406	
0x01008407	
0x01008408	
0x01008409	
0x0100840A	
0x0100840B	
0x0100840C	
0x0100841F	
0x01008500	
0x01008501	
0x01008502	
0x01008504	
0x01008508	
0x01008510	
0x01008520	
0x01008540	
0x01008580	
0x01008581	
0x0100858F	
0x01008605	
0x01008606	
0x01008607	
0x01008608	
0x01008609	
0x0100860A	
0x0100860B	
0x0100860C	
0x0100860D	
0x0100860E	
0x0100860F	
0x01008610	

Error Code	Error Message
0x01008611	
0x01008612	
0x01008613	
0x01008614	
0x01008615	
0x01008616	
0x01008617	
0x01008618	
0x01008619	
0x0100861A	
0x0100861B	
0x010086EF	
0x010086F0	
0x010086FF	
0x01008700	
0x01008701	
0x01008783	
0x01008800	
0x01008801	
0x01008802	
0x01008803	
0x01008804	
0x01008805	
0x01008806	
0x01008807	
0x01008808	
0x01008809	
0x0100880A	
0x0100880B	
0x0100880C	
0x0100880D	
0x0100880E	
0x0100881F	
0x01008018	Retry cartridge insertion. If this error persists please contact QIAGEN Technical Services
0x01008410	
0x01008411	
0x01008412	
0x01008413	
0x01008414	
0x01008417	
0x01008418	
0x01008019	Software update failure. Please contact QIAGEN Technical Services
0x01008024	Filter tray not properly closed. Ensure filter tray is correctly closed and switch off/on the Operational Module power button
0x01008081	Assay execution failure. Please contact QIAGEN Technical Services
0x01008231	qPCR stage failure. Please contact QIAGEN Technical Services
0x01008232	
0x01008236	

Error Code	Error Message
0x01008233 0x01008237	Syringe positioning failure. Please contact QIAGEN Technical Services
0x01008234 0x01008238	Failure thermal unit motor positioning. Please contact QIAGEN Technical Services
0x01008301 0x01008306 0x0100830B 0x01008310 0x01008315 0x0100831A 0x0100831F 0x01008324 0x01008329 0x0100832E 0x01008333 0x01008338 0x0100833D 0x01008342 0x01008347 0x0100834C 0x01008351 0x01008356 0x0100835B 0x01008360 0x01008365 0x0100836A 0x0100836F 0x01008374 0x01008379 0x0100837E	Motor failure (TC1). Please contact QIAGEN Technical Services

Error Code	Error Message
0x01008302	Motor failure (TC2). Please contact QIAGEN Technical Services
0x01008307	
0x0100830C	
0x01008311	
0x01008316	
0x0100831B	
0x01008320	
0x01008325	
0x0100832A	
0x0100832F	
0x01008334	
0x01008339	
0x0100833E	
0x01008343	
0x01008348	
0x0100834D	
0x01008352	
0x01008357	
0x0100835C	
0x01008361	
0x01008366	
0x0100836B	
0x01008370	
0x01008375	
0x0100837A	
0x0100837F	

Error Code	Error Message
0x01008303	Motor failure (CC). Please contact QIAGEN Technical Services
0x01008308	
0x0100830D	
0x01008312	
0x01008317	
0x0100831C	
0x01008321	
0x01008326	
0x0100832B	
0x01008330	
0x01008335	
0x0100833A	
0x0100833F	
0x01008344	
0x01008349	
0x0100834E	
0x01008353	
0x01008358	
0x0100835D	
0x01008362	
0x01008367	
0x0100836C	
0x01008371	
0x01008376	
0x0100837B	
0x01008380	

Error Code	Error Message
0x01008304	Motor failure (BB). Please contact QIAGEN Technical Services
0x01008309	
0x0100830E	
0x01008313	
0x01008318	
0x0100831D	
0x01008322	
0x01008327	
0x0100832C	
0x01008331	
0x01008336	
0x0100833B	
0x01008340	
0x01008345	
0x0100834A	
0x0100834F	
0x01008354	
0x01008359	
0x0100835E	
0x01008363	
0x01008368	
0x0100836D	
0x01008372	
0x01008377	
0x0100837C	
0x01008381	
0x01008383	
0x01008384	
0x01008387	

Error Code	Error Message
0x01008305	Motor failure (Lid). Please contact QIAGEN Technical Services
0x0100830A	
0x0100830F	
0x01008314	
0x01008319	
0x0100831E	
0x01008323	
0x01008328	
0x0100832D	
0x01008332	
0x01008337	
0x0100833C	
0x01008341	
0x01008346	
0x0100834B	
0x01008350	
0x01008355	
0x0100835A	
0x0100835F	
0x01008364	
0x01008369	
0x0100836E	
0x01008373	
0x01008378	
0x0100837D	
0x01008382	

Error Code	Error Message
0x01008420	Failure on thermal unit. Please contact QIAGEN Technical Services
0x01008421	
0x01008422	
0x01008423	
0x01008424	
0x01008425	
0x01008426	
0x01008427	
0x01008428	
0x01008429	
0x0100842A	
0x0100842B	
0x0100842C	
0x0100842D	
0x0100842E	
0x0100842F	
0x01008430	
0x01008431	
0x01008432	
0x01008433	
0x01008434	
0x01008435	
0x01008436	
0x01008437	
0x01008438	
0x01008439	
0x0100843A	
0x0100843B	
0x0100843C	
0x0100843D	
0x0100843E	
0x0100843F	
0x01008440	
0x01008441	
0x01008442	
0x01008443	
0x01008444	
0x01008445	
0x01008446	
0x01008447	
0x01008448	
0x01008449	
0x0100844A	
0x0100844B	
0x0100844C	
0x0100844D	
0x0100844E	
0x0100844F	
0x01008450	
0x01008451	

Error Code	Error Message
0x01008452	
0x01008453	
0x01008454	
0x01008455	
0x01008456	
0x01008457	
0x01008458	
0x01008459	
0x0100845A	
0x0100845B	
0x01008460	
0x01008461	
0x01008462	
0x01008463	
0x01008464	
0x01008465	
0x01008466	
0x01008467	
0x01008468	
0x01008469	
0x0100846A	
0x01008470	
0x01008471	
0x01008472	
0x01008473	
0x01008474	
0x01008475	
0x01008476	
0x01008477	
0x01008478	
0x01008479	
0x0100847A	
0x0100847B	
0x0100847C	
0x01008480	
0x01008481	
0x01008482	
0x01008483	
0x01008484	
0x01008485	
0x01008486	
0x01008487	
0x01008488	
0x01008489	
0x0100848A	
0x0100848B	
0x0100848C	
0x01008490	
0x01008491	
0x01008492	

Error Code	Error Message
0x01008493	
0x01008494	
0x01008495	
0x01008496	
0x01008497	
0x01008498	
0x01008499	
0x0100849A	
0x0100849B	
0x0100849C	
0x0100849D	
0x0100849E	
0x0100849F	
0x010084A0	
0x010084A1	
0x010084A2	
0x010084A3	
0x010084A4	
0x010084A5	
0x010084A6	
0x010084B0	
0x010084B1	
0x010084B2	
0x010084B3	
0x010084B4	
0x010084B5	
0x010084B6	
0x010084B7	
0x010084B8	
0x010084B9	
0x010084BA	
0x010084BB	
0x010084BC	
0x010084BD	
0x010084BE	
0x010084BF	
0x010084C0	
0x010084C1	
0x010084C2	
0x010084C3	
0x010084C4	
0x010084C5	
0x010084C6	
0x010084C7	
0x010084C8	
0x010084D0	
0x010084D1	
0x010084D2	
0x010084D3	
0x010084D4	

Error Code	Error Message
0x010084E0	
0x010084E1	
0x010084E2	
0x010084E3	
0x010084E4	
0x010084E5	
0x010084E6	
0x010084E7	
0x010084E8	
0x010084E9	
0x010084EA	
0x010084EB	
0x010084FF	
0x01008702	Failure on TRF module. Please contact QIAGEN Technical Services
0x01008703	
0x01008704	
0x01008705	
0x01008706	
0x01008707	
0x01008708	
0x01008709	
0x0100870A	
0x0100870B	
0x0100870C	
0x0100870D	
0x0100877F	

Error Code	Error Message
0x01008780	Failure on qPCR module. Please contact QIAGEN Technical Services
0x01008781	
0x01008782	
0x01008784	
0x01008785	
0x01008786	
0x01008787	
0x01008788	
0x01008789	
0x0100878A	
0x0100878B	
0x0100878C	
0x0100878D	
0x0100878E	
0x0100878F	
0x01008790	
0x01008791	
0x01008792	
0x01008793	
0x01008794	
0x01008795	
0x01008796	
0x01008797	
0x01008798	
0x01008799	
0x0100879A	
0x0100879B	
0x0100879C	
0x0100879D	
0x0100879E	
0x0100879F	
0x010087FF	

Error Code	Error Message
0x012E	Cartridge execution failure. Please repeat with another cartridge
0x0137	
0x0138	
0x0139	
0x0154	
0x016D	
0x016E	
0x016F	
0x0170	
0x0171	
0x019C	
0x01B8	
0x01F6	
0x01FF	
0x0200	
0x021C	
0x025A	
0x0264	
0x0265	
0x0280	
0x028A	
0x028B	
0x028C	
0x0290	
0x0291	
0x0292	
0x02BE	
0x02C7	
0x02C8	
0x0322	
0x032B	
0x032C	
0x0386	
0x038F	
0x0390	
0x0391	
0x03EA	
0x03F3	
0x03F4	
0x044E	
0x0457	
0x0458	
0x04B2	
0x04BB	
0x04BC	
0x04BD	
0x0516	
0x051F	
0x0520	
0x0521	

Error Code	Error Message
0x057A	
0x0583	
0x0585	
0x0586	
0x058A	
0x05DE	
0x05EE	
0x0642	
0x064B	
0x064C	
0x064D	
0x06A6	
0x06AF	
0x06B0	
0x06B1	
0x076E	
0x0777	
0x07D2	
0x07DB	
0x07DC	
0x07E1	
0x07F8	
0x0816	
0x0817	
0x0819	
0x081F	
0x0836	
0x083F	
0x087E	
0x087F	
0x0880	
0x0881	
0x0882	
0x08A3	
0x08DE	
0x08E8	
0x08E9	
0x0907	
0x0942	
0x096B	
0x096C	
0x0988	
0x09B0	
0x09CF	
0x09EC	
0x0A1E	
0x019B	Cartridge execution failure. Please repeat with another cartridge and verify that the Swab lid is correctly closed
0x019D 0x0201	Cartridge execution failure. Please repeat with another cartridge and if sample type is Swab follow the IFU for proper swab use and insertion

Error Code	Error Message
0x0263	Cartridge execution failure. Please repeat with another cartridge and verify that the Swab and Bead Beater lid are properly closed
0x02C9 0x032D 0x0459 0x045A 0x04BF 0x0524 0x058B 0x05E9 0x0778 0x077D	Cartridge execution failure: Sample concentration too high. Please repeat with another cartridge
0x0818	Failure during PCR preparation. Please repeat with another cartridge. If this error persists please contact QIAGEN Technical Services
0x08EF 0x08F0 0x094D 0x094E 0x094F 0x0950 0x0951 0x0952 0x0953	Failure during PCR preparation (dosing). Please repeat with another cartridge. If this error persists please contact QIAGEN Technical Services
0x0A1F 0x0A20 0x0A21 0x0A22 0x0A23 0x0A24 0x0A25	Failure during PCR preparation (dispensing). Please repeat with another cartridge. If this error persists please contact QIAGEN Technical Services

Error Code	Error Message
0x0AAA	Failure while executing PCR. Please repeat with another cartridge. If this error persists please contact QIAGEN Technical Services
0x0AAB	
0x0AAC	
0x0AAD	
0x0AAE	
0x0AAF	
0x0AB0	
0x0AB1	
0x0AB2	
0x0B18	
0x0B72	
0x0B73	
0x0B74	
0x0B75	
0x0B76	
0x0B77	
0x0B78	
0x0B79	
0x0B7A	
0x0B7C	
0x0BD6	
0x0BD7	
0x0BD8	
0x0BD9	
0x0BDA	
0x0BDB	
0x0BDC	
0x0BDD	
0x0BDE	
0x0BE0	
0x0C3A	
0x0C3B	
0x0C3C	
0x0C3D	
0x0C3E	
0x0C3F	
0x0C40	
0x0C41	
0x0C42	
0x0C44	
0x0C9E	
0x0C9F	
0x0CA0	
0x0CA1	
0x0CA2	
0x0CA3	
0x0CA4	
0x0CA5	
0x0CA6	
0x0CA8	

Error Code	Error Message
0x0D02	
0x0D03	
0x0D04	
0x0D05	
0x0D06	
0x0D07	
0x0D08	
0x0D09	
0x0D0A	
0x0D0C	
0x0D66	
0x0D67	
0x0D68	
0x0D69	
0x0D6A	
0x0D6B	
0x0D6C	
0x0D6D	
0x0D6E	
0x0D70	
0x0DCA	
0x0DCB	
0x0DCC	
0x0DCD	
0x0DCE	
0x0DCF	
0x0DD0	
0x0DD1	
0x0DD2	
0x0DD4	
0x0E2E	
0x0E2F	
0x0E30	
0x0E31	
0x0E32	
0x0E33	
0x0E34	
0x0E35	
0x0E36	
0x0E38	
0x0E92	
0x0E93	
0x0E94	
0x0E95	
0x0E96	
0x0E97	
0x0E98	
0x0E99	
0x0E9A	
0x0E9C	

Error Code	Error Message
0x0EF6	
0x0EF7	
0x0EF8	
0x0EF9	
0x0EFA	
0x0EFB	
0x0EFC	
0x0EFD	
0x0EFE	
0x0F00	
0x0F5A	
0x0F5B	
0x0F5C	
0x0F5D	
0x0F5E	
0x0F5F	
0x0F60	
0x0F61	
0x0F62	
0x0F64	
0x0FBE	
0x0FBF	
0x0FC0	
0x0FC1	
0x0FC2	
0x0FC3	
0x0FC4	
0x0FC5	
0x0FC6	
0x0FC8	
0x1022	
0x1023	
0x1024	
0x1025	
0x1026	
0x1027	
0x1028	
0x1029	
0x102A	
0x102C	
0x1086	
0x1087	
0x1088	
0x1089	
0x108A	
0x108B	
0x108C	
0x108D	
0x108E	
0x1090	

Error Code	Error Message
0x10EA	
0x10EB	
0x10EC	
0x10ED	
0x10EE	
0x10EF	
0x10F0	
0x10F1	
0x10F2	
0x10F4	
0x114E	
0x114F	
0x1150	
0x1151	
0x1152	
0x1153	
0x1154	
0x1155	
0x1156	
0x1158	
0x11B2	
0x11B3	
0x11B4	
0x11B5	
0x11B6	
0x11B7	
0x11B8	
0x11B9	
0x11BA	
0x11BC	
0x1216	
0x1217	
0x1218	
0x1219	
0x121A	
0x121B	
0x121C	
0x121D	
0x121E	
0x1220	
0x127A	
0x127B	
0x127C	
0x127D	
0x127E	
0x127F	
0x1280	
0x1281	
0x1282	
0x1284	

Error Code	Error Message
0x12DE	
0x12DF	
0x12E0	
0x12E1	
0x12E2	
0x12E3	
0x12E4	
0x12E5	
0x12E6	
0x12E8	
0x1342	
0x1343	
0x1344	
0x1345	
0x1346	
0x1347	
0x1348	
0x1349	
0x134A	
0x134C	
0x13A6	
0x13A7	
0x13A8	
0x13A9	
0x13AA	
0x13AB	
0x13AC	
0x13AD	
0x13AE	
0x13B0	
0x140A	
0x140B	
0x140C	
0x140D	
0x140E	
0x140F	
0x1410	
0x1411	
0x1412	
0x1414	
0x146E	
0x146F	
0x1470	
0x1471	
0x1472	
0x1473	
0x1474	
0x1475	
0x1476	
0x1478	

Error Code	Error Message
0x14D2	
0x14D3	
0x14D4	
0x14D5	
0x14D6	
0x14D7	
0x14D8	
0x14D9	
0x14DA	
0x14DC	
0x1536	
0x1537	
0x1538	
0x1539	
0x153A	
0x153B	
0x153C	
0x153D	
0x153E	
0x1540	
0x159A	
0x159B	
0x159C	
0x159D	
0x159E	
0x159F	
0x15A0	
0x15A1	
0x15A2	
0x15A4	
0x15FE	
0x15FF	
0x1600	
0x1601	
0x1602	
0x1603	
0x1604	
0x1605	
0x1606	
0x1608	
0x1662	
0x1663	
0x1664	
0x1665	
0x1666	
0x1667	
0x1668	
0x1669	
0x166A	
0x166C	

Error Code	Error Message
0x16C6	
0x16C7	
0x16C8	
0x16C9	
0x16CA	
0x16CB	
0x16CC	
0x16CD	
0x16CE	
0x16D0	
0x172A	
0x172B	
0x172C	
0x172D	
0x172E	
0x172F	
0x1730	
0x1731	
0x1732	
0x1734	
0x178E	
0x178F	
0x1790	
0x1791	
0x1792	
0x1793	
0x1794	
0x1795	
0x1796	
0x1798	
0x17F2	
0x17F3	
0x17F4	
0x17F5	
0x17F6	
0x17F7	
0x17F8	
0x17F9	
0x17FA	
0x17FC	
0x1856	
0x1857	
0x1858	
0x1859	
0x185A	
0x185B	
0x185C	
0x185D	
0x185E	
0x1860	

Error Code	Error Message
0x18BA	
0x18BB	
0x18BC	
0x18BD	
0x18BE	
0x18BF	
0x18C0	
0x18C1	
0x18C2	
0x18C4	
0x191E	
0x191F	
0x1920	
0x1921	
0x1922	
0x1923	
0x1924	
0x1925	
0x1926	
0x1928	
0x1982	
0x1983	
0x1984	
0x1985	
0x1986	
0x1987	
0x1988	
0x1989	
0x198A	
0x198C	
0x19E6	
0x19E7	
0x19E8	
0x19E9	
0x19EA	
0x19EB	
0x19EC	
0x19ED	
0x19EE	
0x19F0	
0x1A4A	
0x1A4B	
0x1A4C	
0x1A4D	
0x1A4E	
0x1A4F	
0x1A50	
0x1A51	
0x1A52	
0x1A54	

Error Code	Error Message
0x1AAE 0x1AAF 0x1AB0 0x1AB1 0x1AB2 0x1AB3 0x1AB4 0x1AB5 0x1AB6 0x1AB8	
0x0F001001	Backup created with a newer software.
0x0F001009	Opening the archive failed.
0x0F00100A	Opening the archive failed. The archive is corrupted.
0x0F00100B	Opening the archive failed. The database version from the archive is not compatible with the software.
0x0F00100C	Archived results could not be removed. To remove results, create archive again and select to remove results option.
0x0F001010	Could not create the epidemiology report.
0x10001 0x10002 0x10003 0x10004 0x10005 0x10006 0x10007 0x10009 0x10010 0x11001 0x11002 0x11003	Failure in the instrument, please contact QIAGEN Technical Services
0x14000 0x14002	Failure in the analytical module, please contact QIAGEN Technical Services

Error Code	Error Message
0x14001 0x14003 0x14008 0x14009 0x14010 0x14011 0x14012 0x14014 0x14015 0x14016 0x14017 0x14018 0x14019 0x14020 0x14021 0x14022 0x14024 0x14025 0x14026 0x14027 0x14028	Cartridge execution failure. Please retry another cartridge and if this error persists contact QIAGEN Technical Services
0x14004 0x14005 0x14029 0x14030 0x14031 0x14032 0x14033	Abnormal software failure. Please retry another cartridge and if this error persists contact QIAGEN Technical Services
0x14006 0x14007	Cartridge execution failure. Please retry a cartridge from another lot and if this error persists contact QIAGEN Technical Services
0x14013 0x14023	Possible sample concentration too high. Please repeat with another cartridge. If this error persists contact QIAGEN Technical Services

11. Technical Specifications

11.0.1. Operating conditions

Power requirements	100-240 VAC 50–60 Hz IEC 60320-1 C14 socket
Fuse	1x8A time-lag
Temperature	15–30°C (59–86°F)
Humidity	20–80% relative, non-condensing
Altitude	0–3100 m
Light	Up to 4000 lux

11.0.2. Shipping conditions

Temperature	0–55°C (32–131°F), maximum 85% relative humidity, non-condensing

11.0.3. Electromagnetic compatibility (EMC)

EMC requirements

Compliant with class A emission levels and Professional Healthcare Facility Environment immunity levels from IEC 61326 and class A emission levels and Professional Healthcare Facility Environment immunity levels from IEC 60601-1-2 Class A, Group 1

The equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

EMC emissions test levels

Emission test	**Test level / compliance level**	**Electromagnetic environment**
Radiated emissions CISPR 11	Class A, Group 1 emission level	The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Conducted emissions CISPR 11	Class A, Group 1 emissions level	
Harmonic distortion IEC 61000-3-2	As per IEC 61000-3-2	
Voltage fluctuation and flicker IEC 61000-3-3	As per IEC 61000-3-3	

EMC immunity test levels

Immunity test	**Test level / compliance level**	**Electromagnetic environment**

Electrostatic discharge IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air		
Radiated RF EM fields IEC 61000-4-3	3 V/m 80 MHz – 6 GHz (@ 80 % AM at 1 kHz)		
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See table below		
Rated power frequency magnetic fields IEC 61000-4-8	30 A/m (50 Hz or 60 Hz)		
Proximity magnetic fields IEC 61000-4-39	Test frequency 30 kHz, Modulation CW: 8 A/m Test frequency 134.2 kHz, Pulse modulation 2.1 kHz: 65 A/m Test frequency 13.56 MHz, Pulse modulation 50 kHz: 7.5 A/m		Professional healthcare facility environment (Environment where professional healthcare is administered: Locations include hospitals, diagnostic laboratories, blood banks, blood donation centres, physician offices, intensive care units, surgical centres, emergency rooms, surgery rooms, clinics, patient rooms, dental offices, limited care facilities, nursing homes, drugstore with trained operator, and first aid rooms)
Electric fast transients / bursts IEC 61000-4-4	AC Power	± 2 kV (5/50 ns, 100 kHz)	
Electric fast transients / bursts IEC 61000-4-4	I/O Lines	± 1 kV (5/50 ns, 100 kHz)	
Surges Line-to-line Surges Line-to-ground IEC 61000-4-5	AC Power	± 0,5 kV, ± 1 KV ± 0,5 kV, ± 1 kV, ± 2 kV	
Surges Line-to-line Surges Line-to-ground IEC 61000-4-5	I/O Lines	± 2 kV	
Conducted disturbances induced by RF fields IEC 61000-4-6	AC Power	3 V (150 kHz – 80 MHz) 6 V in ISM bands between 150 kHz - 80 MHz (@ 80 % AM at 1 kHz)	

Voltage dips	AC Power	0 % UT; 0,5 cycle (@ 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°)
		0 % UT; 1 cycle
		70 % UT; 25/30 cycles (@ 0°)
Voltage interruptions IEC 61000-4-11		0 % UT; 250/300 cycle

Compliance and test levels, Radiated RF IEC 61000-4-3

Test frequency(MHz)	**Band a) (MHz)**	**Service a)**	**Modulation**	**Immunity test level** (V/m)
385	380 to 390	TETRA 400	Pulse modulation b) 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	28
710				
745				
780	704 to 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	9
810				
870		GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	28
930	800 to 960			
1 720				
1 845		GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	28
1 970	1 700 to 1 990			
2 450	2 400 to 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	28
5 240				
5 500			Pulse modulation b) 217 Hz	9
5 785	5 100 to 5 800	WLAN 802.11 a/n		

If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, the carrier may be pulse modulated using a 50 % duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.

11.0.4. Operational Module PRO

Dimensions	Width: 234 mm Height: 326 mm Depth: 517 mm
Weight	5 kg

11.0.5. Analytical Module

Dimensions	Width: 153 mm Height: 307 mm Depth: 428 mm
Weight	16 kg
Ethernet Interface	1x 10/100 – Base-T Ethernet
USB ports	1 front and 3 rears

12. Appendices

12.1. Printer installation and configuration

There are multiple ways to install a printer on the QIAstat-Dx Analyzer 2.0. After connecting a printer to the Operational Module, printers can be installed using the default driver (Appendix 12.1.3), and by installing the printer via the software (Appendix 12.1.4). It is recommended to try these procedures in the listed order.

12.1.1. Printer connection via USB

Follow the steps below to connect a printer using a USB connection:

1. Connect the USB cable from the printer to one of the USB ports of the Operational Module. There are 4 available USB ports: 1 on the right side of the screen, and 3 at the back of the instrument.
2. Continue with Appendix 12.1.3.

12.1.2. Printer connection via ethernet

Note: For printer connection via ethernet, it is required to have a network printer, a local computer, and QIAstat-Dx Analyzer 2.0 available and located in the same local network.

Note: A local computer is only required if following the steps in Appendix 12.1.5.

Follow the steps below to install a network printer using an ethernet connection:

1. Connect the printer to an ethernet network and power ON the printer.
2. Enable network settings of QIAstat-Dx Analyzer 2.0 (refer to Section 6.7.6).
3. Continue with Appendix 12.1.3.

12.1.3. Printer installation with default driver

In the QIAstat-Dx Analyzer 2.0 software, perform the following steps to install a printer using the default driver:

1. Navigate to the printer settings in the QIAstat-Dx Analyzer 2.0 Operational Module application software under **Options** > **System Config** > **Printer**.
2. Select the default printer called Default B/W USB (Figure 103).
3. Print a report.

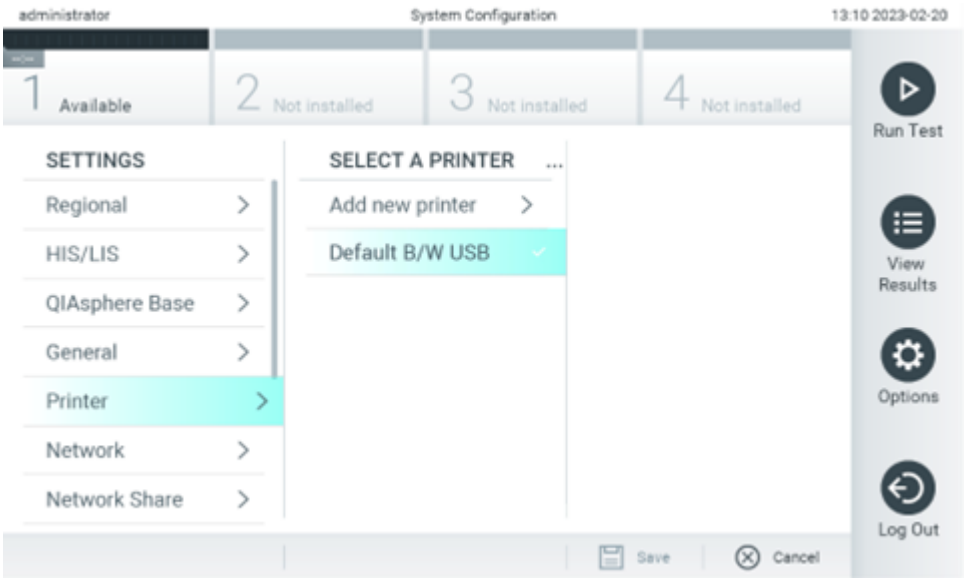


Figure 103. Printer installation with default driver.

12.1.4. Printer installation with driverless installation

In the QIAstat-Dx Analyzer 2.0 software, perform the following steps to install a printer driver via the software:

1. Navigate to the printer settings in the QIAstat-Dx Analyzer 2.0 Operational Module application software under **Options** > **System Config** > **Printer** > **Add new printer**.
2. Enter a printer name.

   The printer name must contain basic English printable characters except: / # ? \ " ' space. Switch the keyboard layout via the ID button at the bottom to find all basic English printable characters there.
3. Click **Select detected Printer**. A list of available printers is loaded.

   Please note that printer names that contain the following characters are not being displayed: < > | { } +. Printers can still be added manually by their IP address regardless of their printer name, please continue with Appendix 12.1.5.
4. Select the desired printer from the list.
5. Click **Add Printer** (Figure 104).
6. Select the newly added printer as the new printer.
7. Save the settings.
8. Print a report.

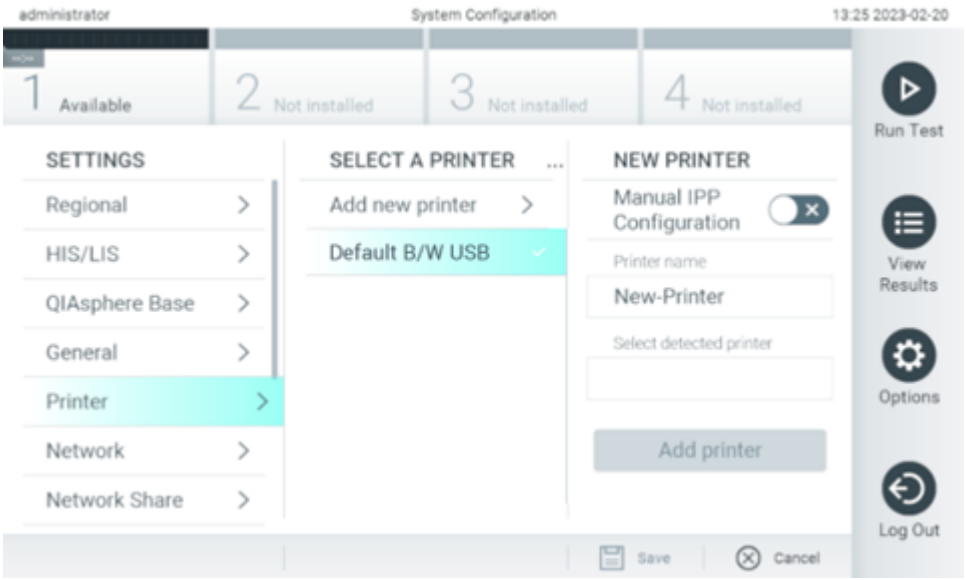


Figure 104. Printer installation with driver installation.

12.1.5. Printer installation with manual IPP configuration

In the QIAstat-Dx Analyzer 2.0 software, perform the following steps to install a printer driver via the software:

1. Navigate to the printer settings in the QIAstat-Dx Analyzer 2.0 Operational Module application software under **Options** > **System Config** > **Printer** > **Add new printer**.
2. Enter a printer name.

   The printer name must contain basic English printable characters except: / # ? \ " ' space. Switch the keyboard layout via the ID button at the bottom to find all basic English printable characters there.
3. Click **Manual IPP Configuration.**
4. Enter the IP address / Host Name of the printer. If the printer is not shown in the list, please continue with an alternative way described in Appendix 12.1.
5. Click **Add Printer** (Figure 105).
6. Select the newly added printer as the new printer.
7. Save the settings.
8. Print a report.

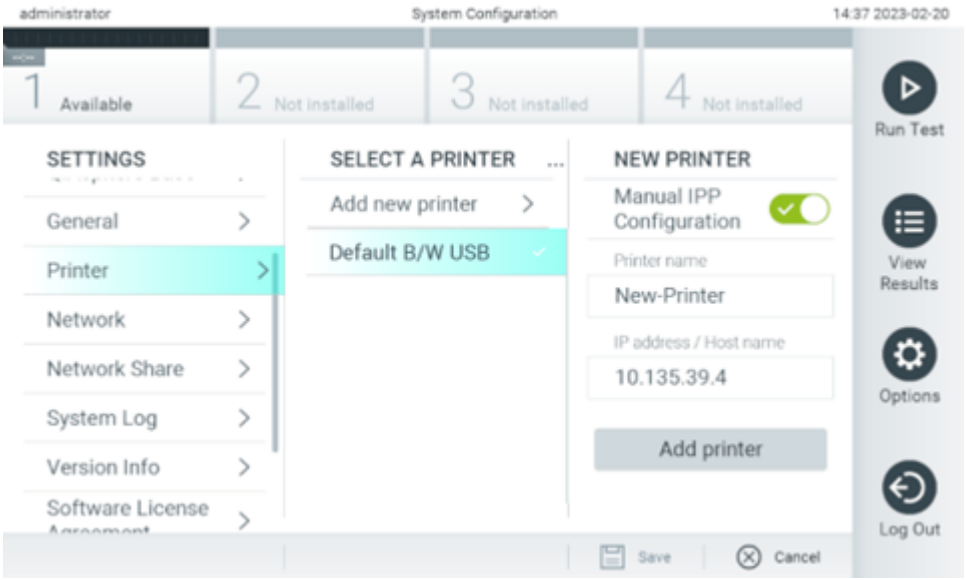


Figure 105. Printer installation with manual IPP configuration.

12.1.6. List of tested printers

At the time this User Manual is released, the following printers have been tested by QIAGEN and are compatible with the QIAstat-Dx Analyzer 2.0, through both USB and Ethernet connections:

- HP® OfficeJet® Pro 6230
- HP Color LaserJet® Pro M254dw
- HP Color LaserJet® MFP M227dw
- HP Laserjet® Pro M404n
- Lexmark MS431dw

Other printers that support IPP Everywhere may be compatible with the QIAstat-Dx Analyzer 2.0 through the procedure outlined in Appendix 12.1.4 and 12.1.5. These printers are listed on **www.pwg.org/printers**.

12.1.7. Printer deletion

In the QIAstat-Dx Analyzer 2.0 software, perform the following steps to delete a printer and its driver via the software:

1. Press **Options** > **System Configuration**.
2. Select **Printer** from the **Settings** list in the left column.
3. Select a printer from the list of available printers.
4. Press **Remove printer** to remove a printer. This will also delete all active print jobs for that printer.

   Note: It is not possible to delete the default printer.

12.2. 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.

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Note: For additional license agreements of third party software included in the QIAstat-Dx Analyzer 2.0, navigate to **Options** > **System Config** > **Version Info**.

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QIAGEN warrants that (a) the SOFTWARE will perform substantially in accordance with the accompanying printed materials for a period of ninety (90) days from the date of receipt. Any implied warranties on the SOFTWARE are limited to ninety (90) days. Some states/jurisdictions do not allow limitations on duration of an implied warranty, so the above limitation may not apply to you.

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QIAGEN entire liability and your exclusive remedy shall be, at QIAGEN's option, either (a) return of the price paid or (b) repair or replacement of the SOFTWARE that does not meet QIAGEN's Limited Warranty and that is returned to QIAGEN with a copy of your receipt. This Limited Warranty is void if failure of SOFTWARE has resulted from accident, abuse, or misapplication. Any replacement of SOFTWARE will be warranted for the remainder of the original warranty period or thirty (30) days, whichever is longer.

7. LIMITED LIABILITY

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The above limitation shall apply accordingly in case of:

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

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If you fail to comply with the terms and conditions of this Agreement, QIAGEN may terminate this Agreement and your right and license to use the SOFTWARE. You may terminate this Agreement at any time by notifying QIAGEN. Upon the termination of this Agreement, you must delete the SOFTWARE from your computer(s) and archives.

YOU AGREE THAT UPON TERMINATION OF THIS AGREEMENT FOR ANY REASON, QIAGEN MAY TAKE ACTIONS SO THAT THE SOFTWARE NO LONGER OPERATES.

10. GOVERNING LAW, VENUE

This Agreement shall be construed and iEXCEPT AS PROVIDED IN QIAGEN TERMS AND CONDITIONS OF SALE FOR THE QIAstat-Dx Analyzer 2.0, QIAGEN ASSUMES NO LIABILITY WHATSOEVER AND DISCLAIMS ANY EXPRESS OR IMPLIED WARRANTY RELATING TO THE USE OF THE QIAstat-Dx Analyzer 2.0 INCLUDING LIABILITY OR WARRANTIES RELATING TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR INFRINGEMENT OF ANY PATENT, COPYRIGHT, OR OTHER INTELLECTUAL PROPERTY RIGHT ANYWHERE IN THE WORLD.

12.5. Disclaimer of warranties

The QIAstat-Dx Analyzer 2.0 is equipped with an Ethernet port. The Purchaser of the QIAstat-Dx Analyzer 2.0 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.

This Agreement shall be construed and interpreted in accordance with the laws of Germany, without giving effect to conflict of laws' provisions. The application of the provisions of the UN Sales Convention is excluded. Notwithstanding any other provision under this Agreement, the parties to this Agreement submit to the exclusive jurisdiction of the Düsseldorf courts.

12.6. Glossary

Analytical Module (AM): The main QIAstat-Dx Analyzer 2.0 hardware module, in charge of executing tests on QIAstat-Dx assay cartridges. It is controlled by the Operational Module (OM).

Assay Definition File: An Assay Definition File is a file necessary for executing an assay on a QIAstat-Dx Analyzer 2.0. 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 Analyzer 2.0 before executing an assay the first time.

GUI: Graphical user interface.

IFU: Instructions for use.

Operational Module (OM): The dedicated QIAstat-Dx Analyzer 2.0 hardware that provides the user interface for 1–4 Analytical Modules (AM).

User: A person who operates the QIAstat-Dx Analyzer 2.0 in the intended way.

13. Document Revision History

Revision	Description
HB-3359-001, V1, R1	Initial release
HB-3359-002,V1, R2	Update on cybersecurity information
HB-3359-003, V1, R2	Updated publishing date on the cover page Formatting and references fix