January 2024

QIAstat-Dx® Respiratory SARS-CoV-2 Panel Instructions for Use (Handbook)

Σ 6

Version 2

IVD

For In Vitro Diagnostic Use

For use with QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise

CE 0197

REF 691214

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R2

Sample to Insight

Table of Contents

Intended Use

The QIAstat-Dx Respiratory SARS-CoV-2 Panel is a qualitative test intended for analyzing nasopharyngeal swab (NPS) samples from patients suspected of respiratory infection for the presence of viral or bacterial nucleic acids. The QIAstat-Dx Respiratory SARS-CoV-2 Panel is able to accept both dry swabs and transport medium liquid samples. The assay is designed for use with the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise for integrated nucleic acid extraction and multiplex real-time RT-PCR detection.

The QIAstat-Dx Respiratory SARS-CoV-2 Panel detects and differentiates* SARS-CoV-2, Influenza A, Influenza A subtype H1N1/2009, Influenza A subtype H1, Influenza A subtype H3, Influenza B, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Respiratory Syncytial virus A/B, human Metapneumovirus A/B, Adenovirus, Bocavirus, Rhinovirus/Enterovirus, *Mycoplasma pneumoniae*, *Chlamydophila pneumoniae*, *Legionella pneumophila*, and *Bordetella pertussis*.

* Enterovirus and Rhinovirus are both detected but not differentiated with the QIAstat-Dx Respiratory SARS-CoV-2 Panel.

The results from the QIAstat-Dx Respiratory SARS-CoV-2 Panel must be interpreted within the context of all relevant clinical and laboratory findings.

Assay performance characteristics have been established only for individuals who have shown respiratory symptoms.

The QIAstat-Dx Respiratory SARS-CoV-2 Panel is intended for professional use only and is not intended for self-testing.

For in vitro diagnostic use.

Summary and Explanation

QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge description

The QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge is a disposable plastic device that allows performance of fully automated molecular assays for the detection of respiratory pathogens. The main features of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge include compatibility with respiratory dry swabs (Copan® FLOQSwabs®, cat. no. 503CS01) and transport medium liquid samples, hermetical containment of the pre-loaded reagents necessary for testing, and true walk-away operation. All sample preparation and assay testing steps are performed within the cartridge.

All reagents required for the complete execution of a test run are pre-loaded and self-contained in the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge. The user does not need to come in contact with and/or manipulate any reagents. During the test, reagents are handled within the cartridge in the Analytical Module of the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0 and QIAstat-Dx Rise by pneumatically operated microfluidics and make no direct contact with the actuators. The QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0 and QIAstat-Dx Rise house air filters for both incoming and outgoing air, further safeguarding the environment. After testing, the cartridge stays hermetically closed at all times, greatly enhancing its safe disposal.

Within the 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 Respiratory SARS-CoV-2 Panel Cartridge containing the sample is introduced into the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise, 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 multiplex real-time RT-PCR testing within each reaction chamber

Note: An increase in fluorescence, indicating detection of the target analyte, is detected directly within each reaction chamber.

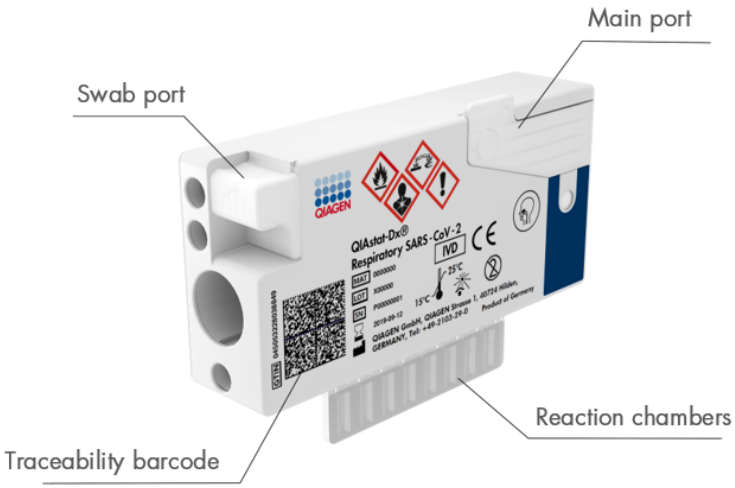

Figure 1. Layout of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge and its features.

Pathogen Information

Acute respiratory infections can be caused by a variety of pathogens, including bacteria and viruses, and generally present with nearly indistinguishable clinical signs and symptoms. The rapid and accurate determination of the presence or absence of potential causative agent(s) helps make timely decisions regarding treatment, hospital admission, infection control, and return of the patient to work and family. It may also greatly support improved antimicrobial stewardship and other important public health initiatives.

The QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge is a single-use cartridge that includes all reagents needed for nucleic acid extraction, nucleic acid amplification, and detection of 23 bacteria and viruses (or their subtypes), including SARS-CoV-2* that cause respiratory symptoms. Testing requires a small sample volume and minimal hands-on time, and the results are available in approximately one hour.

The SARS-CoV-2 target in the QIAstat-Dx Respiratory SARS-CoV-2 Panel was designed in early 2020 upon alignment of the first available 170 genomic sequences in public databases from the SARS-CoV-2 identified as the causative agent of the viral pneumonia (COVID-19) outbreak that originated in Wuhan, Hubei, China. Up to date, a coverage of more than twelve million of available genome sequences support the inclusivity and good performance of the SARS-CoV-2 detection. The SARS-CoV-2 in this panel targets 2 genes of the virus genome (Orf1b poly gen (Rdrp gene) and E genes) detected with the same fluorescent channel.

Pathogens (and subtypes) that can be detected and identified with the QIAstat-Dx Respiratory SARS-CoV-2 Panel are listed in Table 1.

Table 1. Pathogens detected by the QIAstat-Dx Respiratory SARS-CoV-2 Panel

Pathogen	Classification (genome type)
Influenza A	Orthomyxovirus (RNA)
Influenza A, subtype H1N1/2009	Orthomyxovirus (RNA)
Influenza A subtype H1	Orthomyxovirus (RNA)
Influenza A subtype H3	Orthomyxovirus (RNA)
Influenza B	Orthomyxovirus (RNA)
Coronavirus 229E	Coronavirus (RNA)
Coronavirus HKU1	Coronavirus (RNA)
Coronavirus NL63	Coronavirus (RNA)
Coronavirus OC43	Coronavirus (RNA)
SARS-CoV-2	Coronavirus (RNA)
Parainfluenza Virus 1	Paramyxovirus (RNA)
Parainfluenza Virus 2	Paramyxovirus (RNA)
Parainfluenza Virus 3	Paramyxovirus (RNA)
Parainfluenza Virus 4	Paramyxovirus (RNA)
Respiratory Syncytial Virus A/B	Paramyxovirus (RNA)
Human Metapneumovirus A/B	Paramyxovirus (RNA)
Adenovirus	Adenovirus (DNA)
Bocavirus	Parvovirus (DNA)
Rhinovirus/Enterovirus	Picornavirus (RNA)
Mycoplasma pneumoniae	Bacterium (DNA)

Table 1. Pathogens detected by the QIAstat-Dx Respiratory SARS-CoV-2 Panel (continued)

Pathogen	Classification (genome type)
Chlamydophila pneumoniae	Bacterium (DNA)
Legionella pneumophila	Bacterium (DNA)
Bordetella pertussis	Bacterium (DNA)

Note: Enterovirus and Rhinovirus are both detected, but not differentiated, with the QIAstat-Dx Respiratory SARS-CoV-2 Panel.

Principle of the Procedure

Description of the process

Diagnostic tests with the QIAstat-Dx Respiratory SARS-CoV-2 Panel are performed on the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0 and QIAstat-Dx Rise. All of the sample preparation and analysis steps are performed automatically by the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0 and QIAstat-Dx Rise. Samples are collected and loaded manually into the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge, depending on the sample type:

Option 1: Inserting the swab into the swab port when using a dry swab sample type (Figure 2).

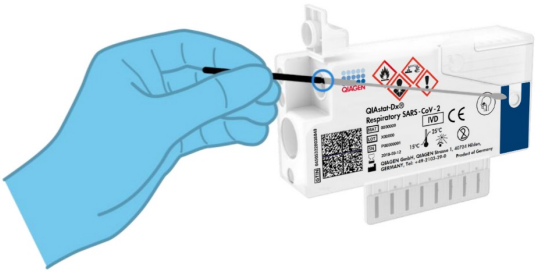

Figure 2. Loading the dry swab sample type into the swab port.

Option 2: A transfer pipette is used for dispensing transport medium liquid sample into the main port (Figure 3).

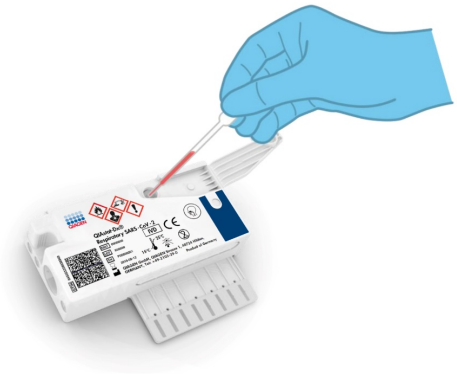

Figure 3. Dispensing transport medium liquid sample into the main port.

Sample collection and cartridge loading

The collection of samples and their subsequent loading into the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge should be performed by personnel trained in safe handling of biological samples.

The following steps are involved and must be executed by the user:

1. A single-use nasopharyngeal swab sample is collected.
2. The nasopharyngeal swab is placed into a single use tube filled with transport medium only in the case of transport medium liquid sample type.
3. The sample information is manually written on or a sample label is affixed to the top of a QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge.
4. Sample is loaded manually into the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge:

- Dry swab sample type: The nasopharyngeal swab sample is inserted into the swab port of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge.
- Transport medium liquid sample type: 300 µL of sample is transferred into the main port of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge using one of the included transfer pipettes.

IMPORTANT: When loading transport medium liquid sample, the user performs a visual check of the sample inspection window (see image below) to confirm that the liquid sample has been loaded (Figure 4).

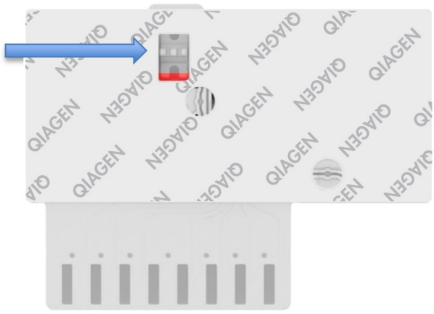

Figure 4. Sample inspection window (blue arrow).

5. The sample bar code and QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge bar code are scanned in the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0 or QIAstat-Dx Rise.
6. The QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge is introduced into the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, or QIAstat-Dx Rise.
7. The test is started on the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, or QIAstat-Dx Rise.

Sample preparation, nucleic acid amplification, and detection

The extraction, amplification, and detection of nucleic acids in the sample are performed automatically by the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise.

1. The liquid sample is homogenized and cells are lysed in the lysis chamber of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge, which includes a rotor that turns at high speed.
2. Nucleic acids are purified from the lysed sample via binding to a silica membrane in the purification chamber of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge in the presence of chaotropic salts and alcohol.
3. The purified nucleic acids are eluted from the membrane in the purification chamber and are mixed with the lyophilized PCR chemistry in the dried-chemistry chamber of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge.
4. The mixture of sample and PCR reagents is dispensed into the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge PCR chambers, which contains lyophilized, assay-specific primers and probes.
5. The QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise creates the optimal temperature profiles to carry out effective multiplex real-time RT-PCR and performs real-time fluorescence measurements to generate amplification curves.
6. The QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise Software interprets the resulting data and process controls, and delivers a test report.

Materials Provided

Kit contents

QIAstat-Dx Respiratory SARS-CoV-2 Panel **Catalog no.** **Number of tests**	 **691214** **6**
QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge*	6
Transfer pipettes†	6

* 6 individually packaged cartridges containing all reagents needed for sample preparation and multiplex real-time RT-PCR, plus Internal Control.

† 6 individually packaged transfer pipettes for dispensing liquid sample into the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge.

Materials Required but not Provided

The QIAstat-Dx Respiratory SARS-CoV-2 Panel is designed for use with the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise. Before beginning a test, make sure the following are available:

- QIAstat-Dx Analyzer 1.0 (at least one Operational Module and one Analytical Module) with software version 1.3 or higher* OR a QIAstat-Dx Rise (at least two Analytical Modules must be inside for the machine to work) with software version 2.2 or higher OR QIAstat-Dx Analyzer 2.0 (at least one Operational Module PRO and one Analytical Module) with software version 1.6 or higher.

  * DiagCORE® Analyzer instruments running QIAstat-Dx software version 1.3 or higher can be used as an alternative to QIAstat-Dx Analyzer 1.0 instruments.

- QIAstat-Dx Analyzer 1.0 User Manual (for use with software version 1.3 or higher) OR QIAstat-Dx Rise User Manual (for use with software version 2.2 or higher) OR QIAstat-Dx Analyzer 2.0 User Manual (for use with software version 1.6 or higher)

- QIAstat-Dx latest Assay Definition File software for Respiratory SARS-CoV-2 Panel installed on the Operational Module or the Operational Module PRO

  Note: Application Software version 1.6 or higher cannot be installed on QIAstat-Dx Analyzer 1.0.

Warnings and Precautions

For in vitro diagnostic use.

The QIAstat-Dx Respiratory SARS-CoV-2 Panel is to be used by laboratory professionals trained in the use of QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and the QIAstat-Dx Rise.

IMPORTANT NOTE: Please be aware that QIAstat-Dx Rise can handle up to 18 QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridges at the same time within the input drawer. Please be also aware, that with software version 2.2 or higher, different panels can be inserted and processed simultaneously in the input drawer.

Safety information

When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, consult the appropriate safety data sheets (SDSs). These are available online in PDF format at **www.qiagen.com/safety** where you can find, view, and print the SDS for each QIAGEN kit and kit component.

Handle all samples, used cartridges, and transfer pipettes as if they are capable of transmitting infectious agents. 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 Guideline* (M29), or other appropriate documents provided by:

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

Follow your institution's safety procedures for handling biological samples. Dispose of samples, QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridges, and transfer pipettes according to the appropriate regulations.

The QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge is a closed, single-use device that contains all reagents needed for sample preparation and multiplex real-time RT-PCR within the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise. Do not use a QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge that is past its expiration date, appears damaged, or leaks fluid. Dispose of used or damaged cartridges in accordance with all national, state, and local health and safety regulations and laws.

Observe standard laboratory procedures for keeping the working area clean and contamination-free. Guidelines are outlined in publications such as the European Centre for Disease Prevention and Control (**https://www.ecdc.europa.eu/en/about-us/networks/disease-and-laboratory-networks/erlinet-biosafety**).

Precautions

The following hazard and precautionary statements apply to components of the QIAstat-Dx Respiratory SARS-CoV-2 Panel.

Contains: ethanol; guanidine hydrochloride; guanidine thiocyanate; isopropanol; proteinase K; t-Octylphenoxypolyethoxyethanol. Danger! Highly flammable liquid and vapour. Harmful if swallowed or if inhaled. May be harmful in contact with skin. Causes severe skin burns and eye damage. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause drowsiness or dizziness. Harmful to aquatic life with long lasting effects. Contact with acids liberates very toxic gas. Corrosive to the respiratory tract. Keep away from heat/sparks/open flames/hot surfaces. No smoking. Avoid breathing dust/fume/gas/mist/vapours/spray. Wear protective gloves/protective clothing/eye protection/face protection. Wear respiratory protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF exposed or concerned: Immediately call a POISON CENTER or doctor/ physician. Remove person to fresh air and keep comfortable for breathing.

Cartridge Storage and Handling

Store the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridges in a dry, clean storage space at room temperature (15–25°C). Do not remove the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridges or the transfer pipettes from their individual packaging until actual use. Under these conditions, QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridges can be stored until the expiration date printed on the individual packaging. The expiration date is also included in the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge bar code and is read by the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, or QIAstat-Dx Rise when the cartridge is inserted into the instrument to run a test.

For handling of damaged cartridges refer to the chapter Safety information.

Specimen Handling, Storage, and Preparation

Transport medium liquid samples

Nasopharyngeal swab samples should be collected and handled according to the manufacturer's recommended procedures.

Recommended storage conditions for NPS (nasopharyngeal swab) resuspended in Universal Transport Medium (UTM) specimens are listed below:

- Room temperature up to 4 hours at 15–25°C
- Refrigerated up to 3 days at 2–8°C
- Frozen up to 30 days at –25°C to –15°C

Dry swab samples

Use freshly collected dry swab specimens for best test performance. If immediate testing is not possible and to maintain best performance, recommended storage conditions for dry swabs are listed below:

- Room temperature up to 45 minutes at 15–25°C
- Refrigerated up to 7 hours at 2–8°C

Internal Control

The QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge includes a full process Internal Control, which is titered MS2 bacteriophage. The MS2 bacteriophage is a single-stranded RNA virus that is included in the cartridge in dried form and is rehydrated upon sample loading. This Internal Control material verifies all steps of the analysis process, including

sample resuspension/homogenization, lysis, nucleic acid purification, reverse transcription, and PCR.

A positive signal for the Internal Control indicates that all processing steps performed by the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge were successful.

A negative signal of the Internal Control does not negate any positive results for detected and identified targets, but it does invalidate all negative results in the analysis. Therefore, the test should be repeated if the Internal Control signal is negative.

Protocol: Dry Swab Samples

Sample collection, transport, and storage

Collect nasopharyngeal swab samples using Copan FLOQSwabs (cat. no. 503CS01) according to the manufacturer's recommended procedures.

Loading a sample into the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge

Note: applicable for both the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise

1. Open the package of a QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge using the tear notches on the sides of the packaging (Figure 5).

   IMPORTANT: After the package is opened, sample should be introduced into the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge and loaded into the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0 within 120 minutes or into QIAstat-Dx Rise within 30 minutes.

Figure 5. Opening the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge.

2. Remove the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge from the packaging and position it so that the bar code on the label faces you.

3. Manually write the sample information or place a sample information label on the top of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge. Make sure that the label is properly positioned and does not block the lid opening (Figure 6). See QIAstat-Dx Rise workflow section for proper cartridge labelling.

Figure 6. Sample information placement on top of QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge.

4. Open the sample lid of the swab port on the left side of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge (Figure 7).

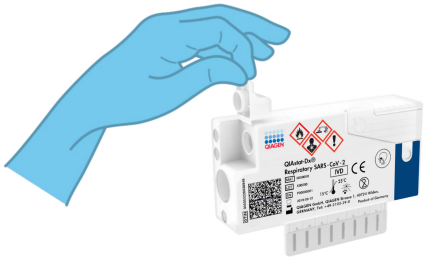

Figure 7. Opening the sample lid of swab port.

5. Insert the swab into the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge until the breakpoint is aligned with the access opening (i.e., the swab will go no further) Figure 8).

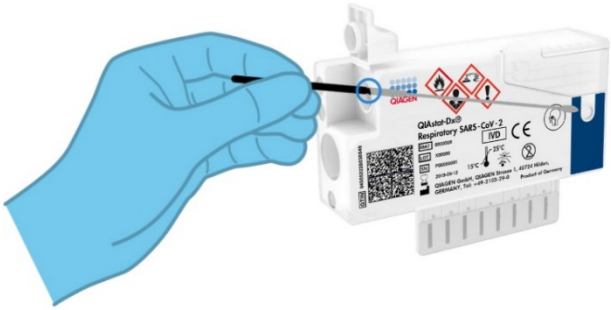

Figure 8. Inserting swab into the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge.

6. Break the swab shaft at the breakpoint, leaving the rest of the swab in the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge (Figure 9).

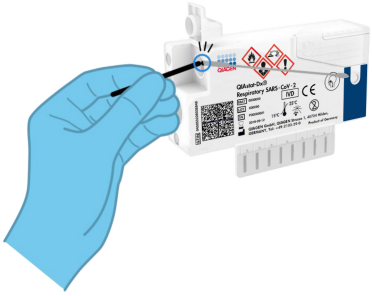

Figure 9. Breaking swab shaft.

7. Firmly close the sample lid of the swab port until it clicks (Figure 10).

IMPORTANT: After the sample is placed inside the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge, the cartridge must be loaded into the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 within 90 minutes or immediately placed on the QIAstat-Dx Rise tray once all samples are loaded into the cartridges. The maximum waiting time for a cartridge that is already loaded into the QIAstat-Dx Rise (on-board stability) is about 300 minutes. The QIAstat-Dx Rise will automatically detect if the cartridge has been placed into the instrument for a longer time than permitted and will automatically warn the user.

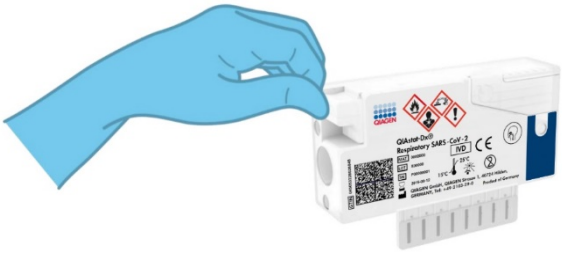

Figure 10. Closing the sample lid of the swab port.

Running a test on the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0

1. Power ON the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 using the On/Off button on the front of the instrument.

   Note: The power switch on the back of the Analytical Module must be set in the "I" position. The QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 status indicators will turn blue.

2. Wait until the Main screen appears and the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 status indicators turn green and stop blinking.

3. Log in to the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 by entering the user name and password.

   Note: The Login screen will appear if **User Access Control** is activated. If the **User Access Control** is disabled, no user name/password will be required, and the Main screen will appear.

4. If the Assay Definition File software has not been installed on the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0, follow the installation instructions prior to running the test (see "Appendix A: Installing the Assay Definition File", for additional information).

5. Press the **Run Test** button in the top right corner of the touchscreen of the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0.

6. When prompted, scan the sample ID bar code on the nasopharyngeal swab sample (located on the swab blister packaging), or scan the specimen information bar code located on the top of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge (see step 3) using the integrated front bar code reader of the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 (Figure 11).

Note: It is also possible to enter the sample ID using the virtual keyboard of the touchscreen by selecting the Sample ID field.

Note: Depending on the chosen system configuration, entering the patient ID may also be required at this point.

Note: Instructions from the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 appear in the Instructions Bar at the bottom of the touchscreen.

Figure 11. Scanning sample ID bar code.

7. When prompted, scan the bar code of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge to be used (Figure 12). The QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 automatically recognizes the assay to be run based on the cartridge bar code.

   Note: The QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 will not accept QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridges with lapsed expiration dates, previously used cartridges, or cartridges for assays that have not been installed on the unit. An error message will be shown in these cases, and the QIAstat-Dx Respiratory

SARS-CoV-2 Panel Cartridge will be rejected. Refer to the *QIAstat-Dx Analyzer 1.0* or the *QIAstat-Dx Analyzer 2.0 User Manual* for further details on how to install assays.

Figure 12. Scanning QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge bar code.

8. Select the appropriate sample type from the list (Figure 13).

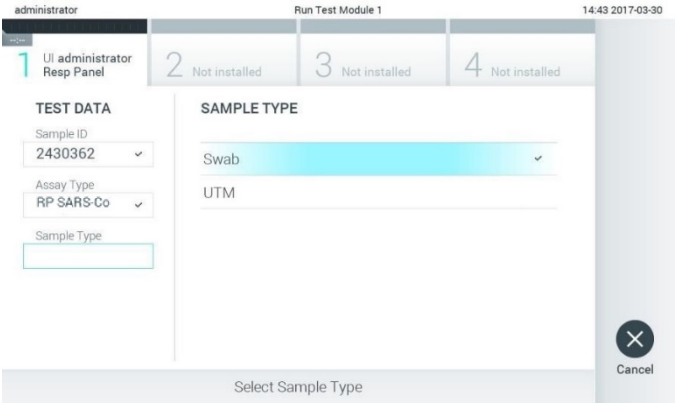

Figure 13. Selecting sample type.

9. The Confirm screen will appear. Review the entered data and make any necessary changes by selecting the relevant fields on the touchscreen and editing the information.

10. Press **Confirm** when all the displayed data are correct. If needed, select the appropriate field to edit its content, or press **Cancel** to cancel the test (Figure 14).

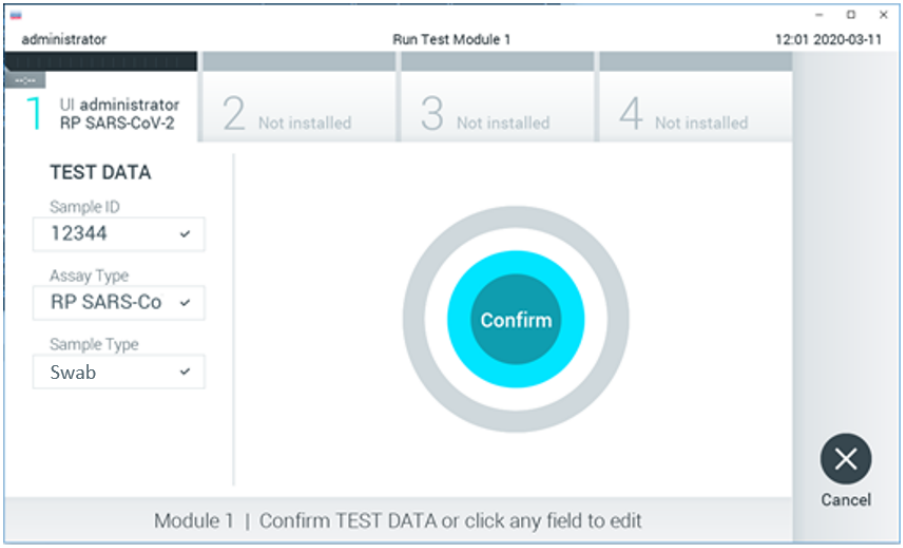

Figure 14. Confirming data entry.

11. Make sure that both sample lids of the swab port and main port of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge are firmly closed. When the cartridge entrance port on the top of the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 automatically opens, insert the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge with the bar code facing to the left and the reaction chambers facing down (Figure 15).

    Note: There is no need to push the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge into the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0. Position it correctly into

the cartridge entrance port and the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 will automatically move the cartridge into the Analytical Module.

Figure 15. Inserting QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge into QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0.

12. Upon detecting the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge, the QIAstat-Dx Analyzer 1.0 or 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 1.0 and the QIAstat-Dx Analyzer 2.0 will not accept a QIAstat-Dx Respiratory SARS-CoV-2 Panel 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 Respiratory SARS-CoV-2 Panel Cartridge is not positioned in the port. If this occurs, repeat the procedure starting with step 16.

13. While the test is running, the remaining run time is displayed on the touchscreen.
14. After the test run is completed, the Eject screen will appear (Figure 16) and the Module status bar will display the test result as one of the following options:

    - **TEST COMPLETED**: The test was completed successfully
    - **TEST FAILED**: An error occurred during the test
    - **TEST CANCELED**: The user canceled the test

    IMPORTANT: If the test fails, refer to the "Troubleshooting" section in the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 User Manual for possible reasons and instructions on how to proceed.

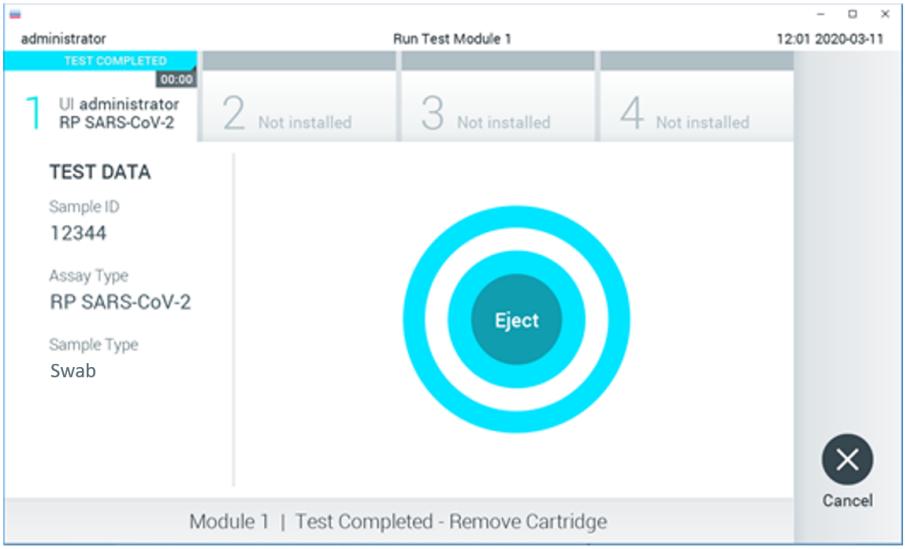

Figure 16. Eject screen display.

15. Press **Eject** on the touchscreen to remove the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge and dispose of it as biohazardous waste in accordance with all national, state, and local health and safety regulations and laws. The QIAstat-Dx Respiratory SARS-CoV-2 Panel 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 1.0 or the QIAstat-Dx Analyzer 2.0 and the 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.

    IMPORTANT: Used QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridges must be discarded. It is not possible to re-use cartridges for tests for which the execution was started but then subsequently cancelled by the operator, or for which an error was detected.

16. After the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge has been ejected, the results Summary screen will appear. Refer to "Interpretation of Results" for further details. To begin the process for running another test, press Run Test.

    Note: For further information on the use of the QIAstat-Dx Analyzer 1.0, refer to the *QIAstat-Dx Analyzer 1.0 User Manual*.

    Note: For further information on the use of the QIAstat-Dx Analyzer 2.0, refer to the *QIAstat-Dx Analyzer 2.0 User Manual*.

Running a test on the QIAstat-Dx Rise

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

Starting the QIAstat-Dx Rise

1. Press the **ON/OFF** button on the front panel of the QIAstat-Dx Rise to start the unit.

    Note: The power switch at the rear-left connection box must be set to the "**I**" position.

2. Wait until the Login screen appears and the LED status indicators turn green.
3. Log in to the system once the login screen appears.

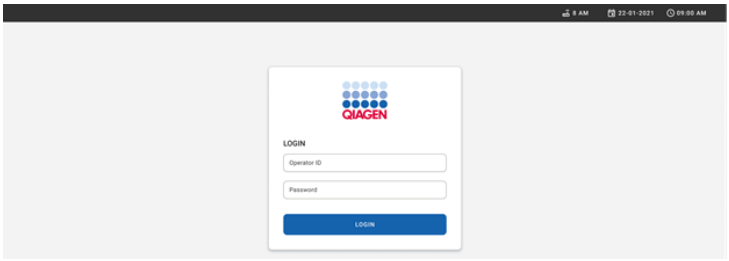

Figure 17. Log in screen

Note: After successful initial installation of the QIAstat-Dx Rise, the system administrator needs to log in for the initial configuration of the software.

Preparing the QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge

Remove the QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge from its packaging. For details about adding the sample to the QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge and for information specific to the assay to be run, refer to "Loading a sample into the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge".

Always make sure that both sample lids are firmly closed after adding a sample to the QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge.

Adding a sample barcode to the QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge

Place a barcode on the top-right side of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge (indicated by the arrow).

Figure 18. Placing sample ID barcode

The maximum barcode size is: 22 mm x 35 mm. The barcode must always be on the right side of the cartridge (as it is shown above with red marked area), as the left side of the cartridge is critical for sample autodetection (Figure 19).

Note: To process samples on the QIAstat-Dx Rise, it is required to provide a machine-readable sample ID barcode on the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge.

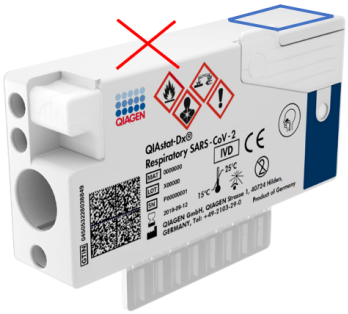

Figure 19. Positioning sample ID barcode

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

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

Procedure to run a test

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

1. Press the **OPEN WASTE DRAWER** button at the lower-right corner of the main test screen (Figure 20).
2. Open the waste drawer and remove used cartridges from previous runs. Check the waste drawer for spilled liquids. If necessary, clean the waste drawer as described in the Maintenance section of the *QIAstat-Dx Rise User Manual*.
3. Close the waste drawer after removal of the cartridges. The system will scan the tray and return to the main screen (Figure 20). If the tray was removed for maintenance purposes, make sure it is correctly inserted before closing the drawer.
4. Press the **OPEN INPUT DRAWER** button on the lower-right corner of the screen (Figure 20).

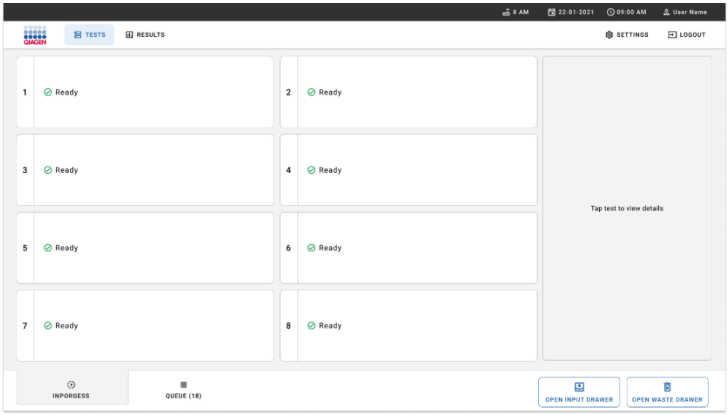

Figure 20. Main test screen.

5. Wait until the input drawer is unlocked (Figure 21).

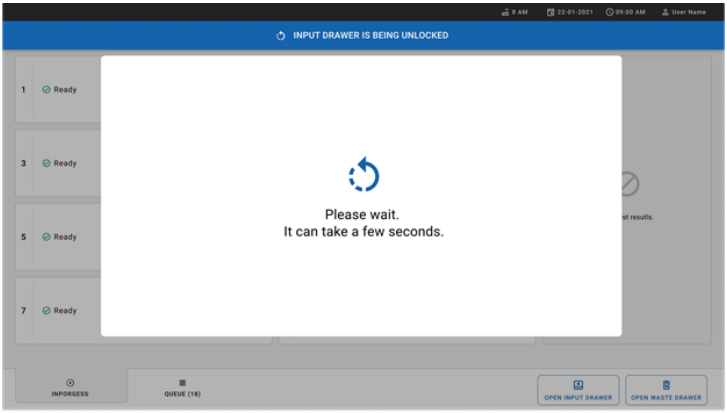

Figure 21. Input drawer waiting dialog box.

6. When prompted, pull the input drawer to open (Figure 22).

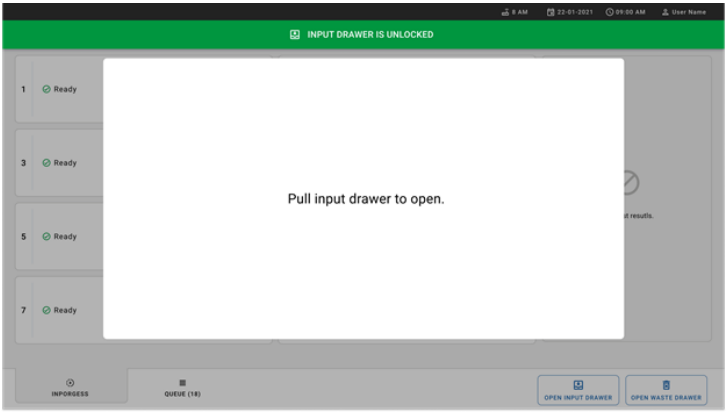

Figure 22. Input drawer open dialog box.

7. The **Add Cartridge** dialog appears and the scanner in front of the instrument will be activated. Scan the sample ID barcode on top of the QIAstat-Dx Respiratory SARS-CoV-2

Panel cartridge in front of the instrument (position indicated by the arrow (Figure 23).

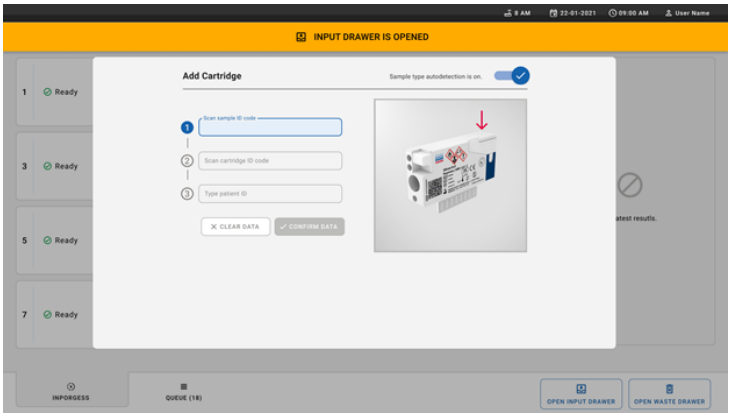

Figure 23. Scan sample ID screen.

8. After entering the sample ID barcode, scan the bar code of the QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge to be used (position indicated by the arrow). The QIAstat-Dx Rise automatically recognizes the assay to be run, based on the QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge barcode (Figure 24).

   Note: Make sure that **Sample type autodetection** is set to **on**. The system will automatically recognize the used sample type,

9. If **Sample type autodetection** is set to **off**, you might need select the appropriate sample type manually (if applicable for the assay used).

   Note: The QIAstat-Dx Rise will not accept QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridges that have lapsed expiration dates, were previously used, or if the QIAstat-Dx Respiratory SARS-CoV-2 Panel assay definition file is not installed on the unit. An error message will be shown in this case.

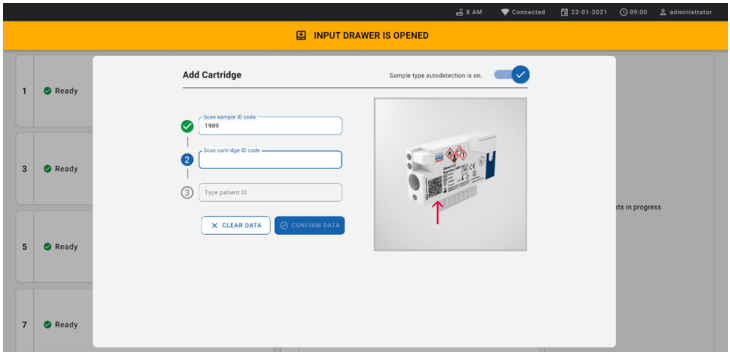

Figure 24. Scan cartridge ID screen

10. Type the patient ID (Patient ID has to be set to **on**) (Figure 25) then confirm the data ().

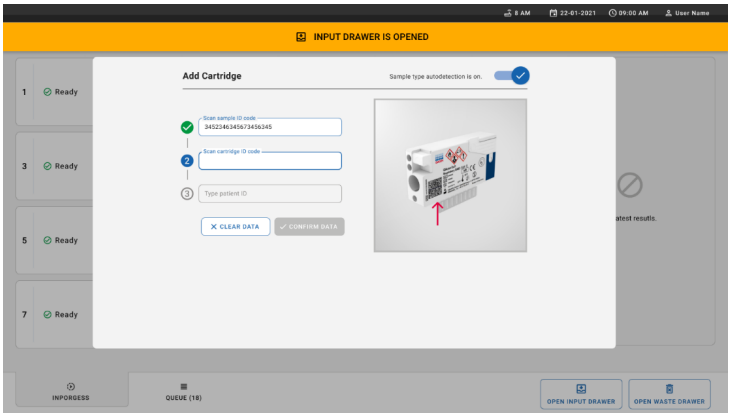

Figure 25. Typing the patient ID.

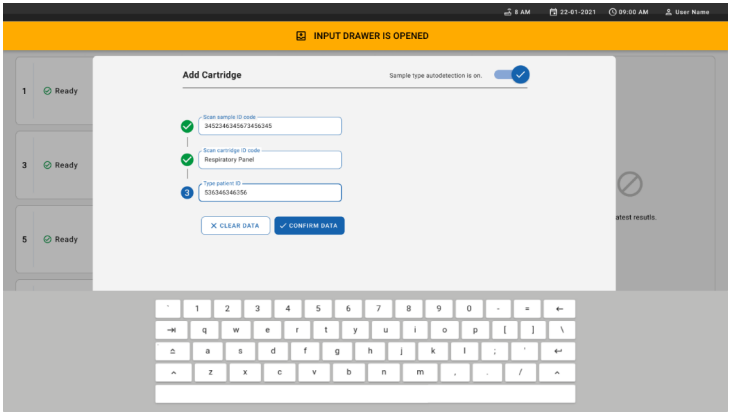

Figure 26. Type patient ID then confirm the data screen.

11. After a successful scan, the following dialog box appears briefly on top of the screen (Figure 27).

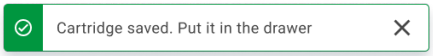

Figure 27. Cartridge saved screen

12. Place the cartridge into the input drawer. Make sure the cartridge is inserted properly into the tray (Figure 28).

13. Continue scanning and inserting cartridges, following previous steps. You can load up to 18 cartridges into the drawer.

    IMPORTANT NOTE: Please be aware that QIAstat-Dx Rise can handle up to 18 QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridges at the same time within the input drawer. Please be also aware, that with software version 2.2, or higher, different panels can be inserted and processed simultaneously in the input drawer.

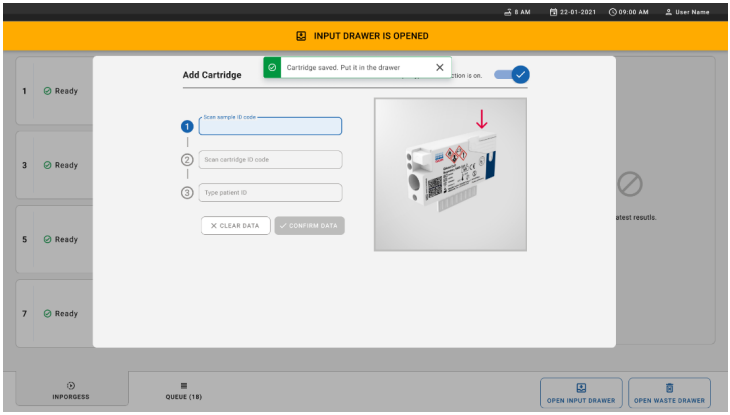

Figure 28. Add cartridge screen.

14. Close the input drawer when all cartridges have been scanned and inserted. The system will scan the cartridges and prepare a queue (Figure 29).

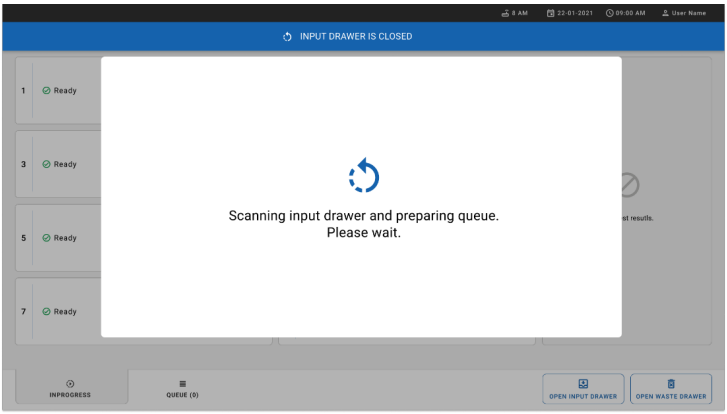

Figure 29. Preparing queue screen.

15. After successful scanning, the queue will be shown (). Review the data shown. In case of an error, press the **OPEN INPUT DRAWER** button, remove the respective cartridge and re-scan the cartridge, following steps 10-13.

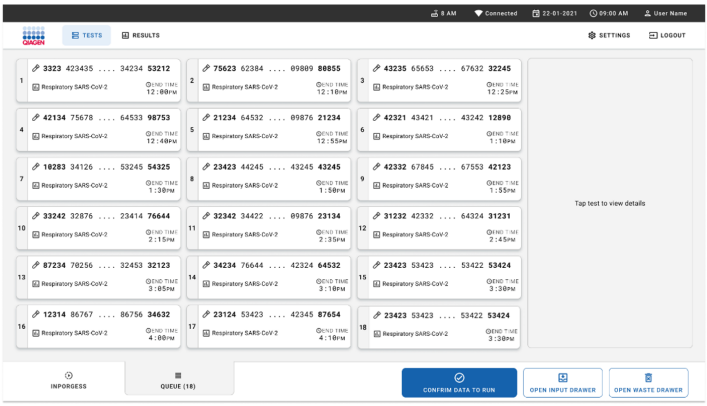

Figure 30. Sample queue screen.

Note: The sample order on the screen may not match the cartridge order in the input drawer (it only matches when all the cartridges are queued together) and cannot be changed without opening the input tray and removing cartridges.

The sample queue/processing order is generated by QIAstat-Dx Rise based on the following rules:

- Stability time: QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridges with the shortest remaining on-board stability time will be prioritized irrespective of the position in the loading tray.
- Within the same assay type, the position in the loading tray determines the order in queue.

If you select a test on the touchscreen, additional information is displayed in the TEST DETAILS section of the screen (Figure 31).

Note: The system will reject cartridges that exceed the maximum on-board stability time within the input drawer (about 300 minutes)

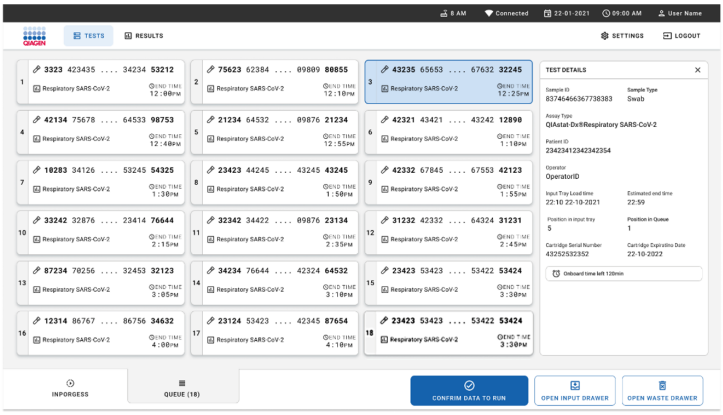

Figure 31. Sample queue screen with selected assay showing additional information.

- The following information is shown in the Test Details section (Figure 32):
- Sample ID
- Sample Type (depends on assay)
- Assay Type
- Patient ID
- Operator ID
- Input Tray Load time
- Estimated end time

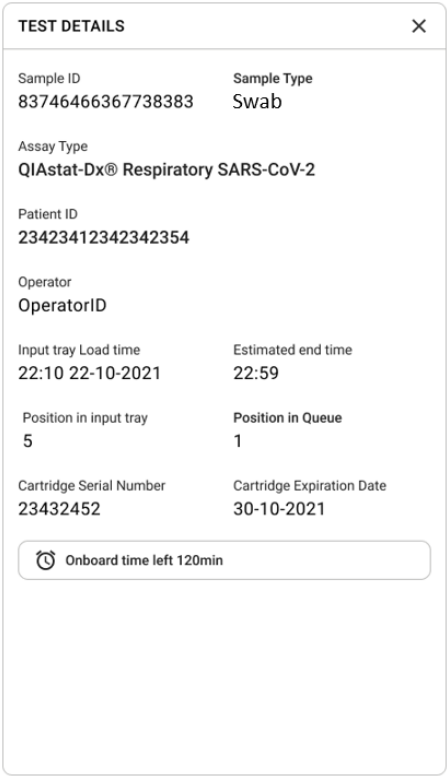

Figure 32. Test details

16. Press the **CONFIRM DATA TO RUN** button at the bottom of the screen when all the displayed data are correct (Figure 31). thereafter, a final confirmation is required from the operator to run the tests.
17. While the tests are running, the remaining run time and other information for all queued tests are displayed on the touchscreen (Figure 33).

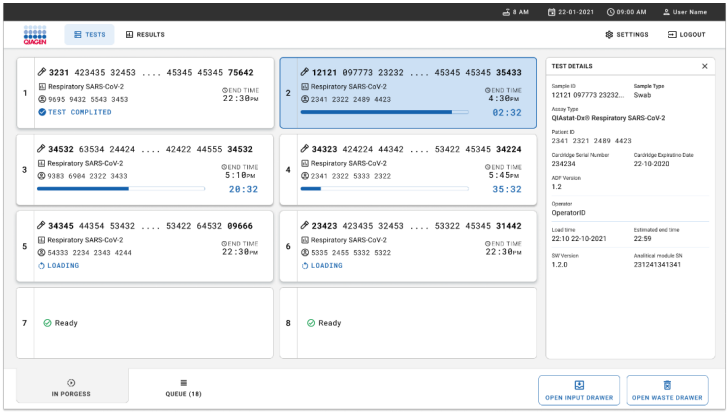

Figure 33. Test execution information on queue screen.

If the cartridge is being loaded into an Analytical Module, a LOADING message and the estimated end time are displayed (Figure 34).

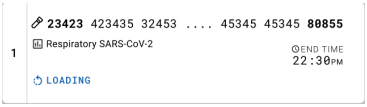

Figure 34. Test loading message and end time.

If the test is running, the elapsed run time and the approximate end time are being displayed (Figure 35).

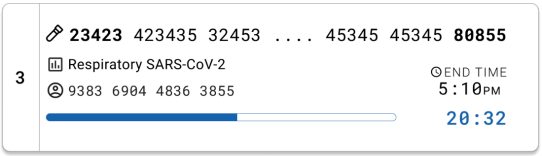

Figure 35. Elapsed run time and approximate end time view.

If the test is completed, a “test completed ” message and the run end time is displayed (Figure 36).

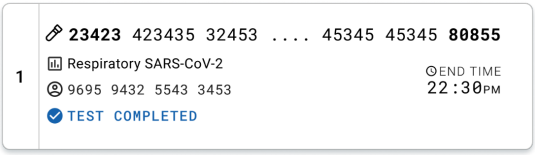

Figure 36. Test completed view .

Protocol: Transport Medium Liquid Samples

Sample collection, transport, and storage

Collect nasopharyngeal swab samples according to the swab manufacturer's recommended procedures and place the swab into UTM.

Loading a sample into the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge

Note: Applicable for the QIAstat-Dx 1.0, QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise.

1. Open the package of a QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge using the tear notches on the sides of the packaging (Figure 37).

   IMPORTANT: After the package is opened, sample should be introduced into the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge and loaded into the QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0 within 120 minutes or into QIAstat-Dx Rise within 30 minutes.

Figure 37. Opening the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge.

2. Remove the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge from the packaging and position it so that the bar code on the label faces you.

3. Manually write the sample information, or place a sample information label, on the top of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge. Make sure that the label is properly positioned and does not block the lid opening (Figure 38).

Figure 38. Sample information placement on top of QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge.

4. Open the sample lid of the main port on the front of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge (Figure 39).

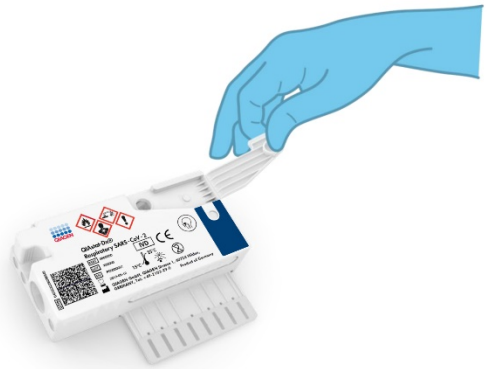

Figure 39. Opening the sample lid of main port.

5. Open the tube with the sample to be tested. Use the supplied transfer pipette to draw up fluid to the third fill line on the pipette (i.e., 300 µL) (Figure 40).

   IMPORTANT: Take care to avoid drawing air into the pipette. If Copan UTM® Universal Transport Medium is used as transport medium, take care not to aspirate any of the beads present in the tube. If air or beads are drawn into the pipette, carefully expel the sample fluid in the pipette back into the sample tube and draw up fluid again. Use alternative sterile and graduated pipettes in case all six pipettes provided with the kit have been used.

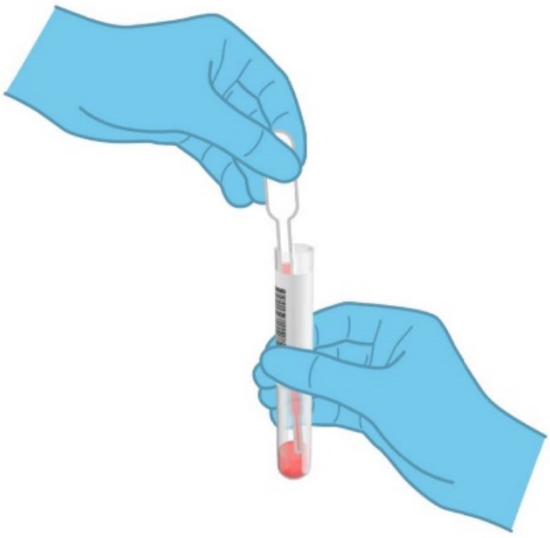

Figure 40. Drawing up sample into the supplied transfer pipette.

Carefully transfer 300 µL of sample volume into the main port of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge using the supplied single-use transfer pipette (Figure 41).

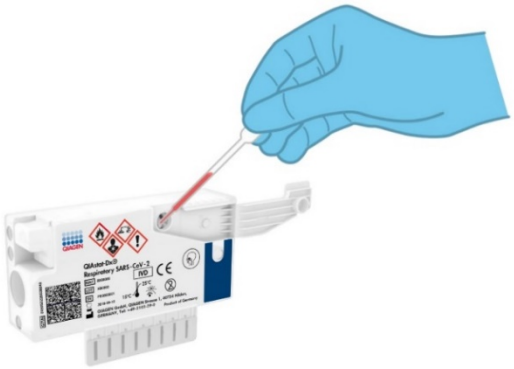

Figure 41. Transferring sample to main port of QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge.

6. Firmly close the sample lid of the main port until it clicks (Figure 42).

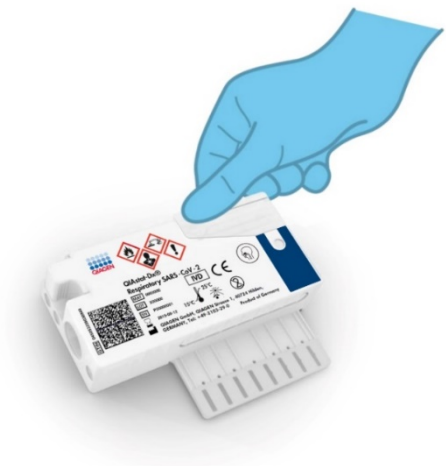

Figure 42. Closing the sample lid of the main port.

7. Visually confirm that the sample has been loaded by checking the sample inspection window of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge (Figure 43).

IMPORTANT: After the sample is placed inside the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge, the cartridge must be loaded into the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 within 90 minutes or immediately placed on the QIAstat-Dx Rise tray once all samples are loaded into the cartridges. The maximum waiting time of a cartridge already loaded in QIAstat-Dx Rise is about 300 minutes. The QIAstat-Dx Rise will automatically detect if the cartridge has been placed into the instrument for a longer time than permitted and will automatically warn the user.

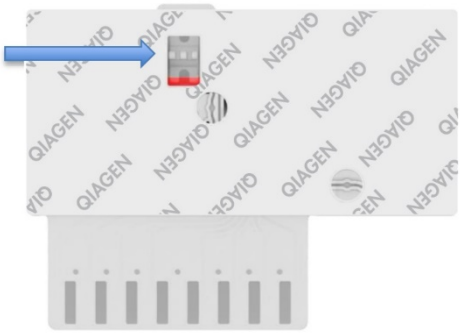

Figure 43. Sample inspection window (blue arrow).

Running a test on the QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0

Note: For further information on the use of the QIAstat-Dx Analyzer 1.0, refer to the QIAstat-Dx Analyzer 1.0 User Manual.

Note: For further information on the use of the QIAstat-Dx Analyzer 2.0, refer to the QIAstat-Dx Analyzer 2.0 User Manual.

1. Power ON the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 using the On/Off button on the front of the instrument.

   Note: The power switch on the back of the Analytical Module must be set in the "I" position. The QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 status indicators will turn blue.

2. Wait until the Main screen appears and the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 status indicators turn green and stop blinking.

3. Log in to the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 by entering the user name and password.

   Note: The Login screen will appear if **User Access Control** is activated. If the User Access Control is disabled, no user name/password will be required and the Main screen will appear.

4. If the Assay Definition File software has not been installed on the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0, follow the installation instructions prior to running the test (see "Appendix A: Installing the Assay Definition File" for additional information).

5. Press the **Run Test** button in the top right corner of the touchscreen of the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0.

6. When prompted, scan the sample ID bar code on the UTM tube containing the sample, or scan the specimen information bar code located on the top of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge (see step 3), using the integrated front bar code reader of the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 (Figure 44).

   Note: It is also possible to enter the sample ID using the virtual keyboard of the touchscreen by selecting the **Sample ID** field.

   Note: Depending on the chosen system configuration, entering the patient ID may also be required at this point.

   Note: Instructions from the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 appear in the Instructions Bar at the bottom of the touchscreen.

Figure 44. Scanning sample ID bar code.

7. When prompted, scan the bar code of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge to be used (Figure 45). The QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 automatically recognizes the assay to be run based on the cartridge bar code.

   Note: The QIAstat-Dx Analyzer 1.0 and the QIAstat-Dx Analyzer 2.0 will not accept QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridges with lapsed expiration dates, previously used cartridges or cartridges for assays that have not been installed on the unit. An error message will be shown in these cases and the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge will be rejected. Refer to the QIAstat-Dx Analyzer 1.0 User Manual or the QIAstat-Dx Analyzer 2.0 User Manual for further details on how to install assays.

Figure 45. Scanning QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge bar code.

8. Select the appropriate sample type from the list (Figure 46).

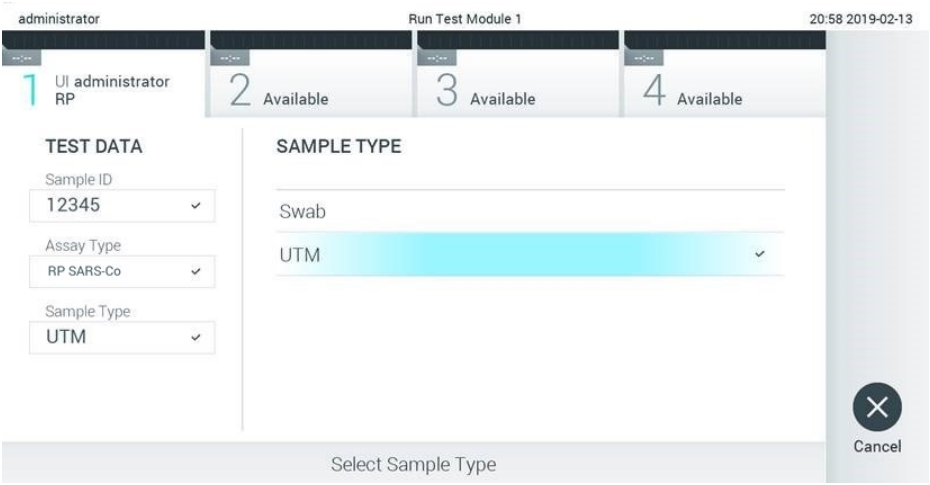

Figure 46. Selecting sample type.

9. The **Confirm** screen will appear. Review the entered data and make any necessary changes by selecting the relevant fields on the touchscreen and editing the information.

10. Press **Confirm** when all the displayed data are correct. If needed, select the appropriate field to edit its content, or press **Cancel** to cancel the test (Figure 47).

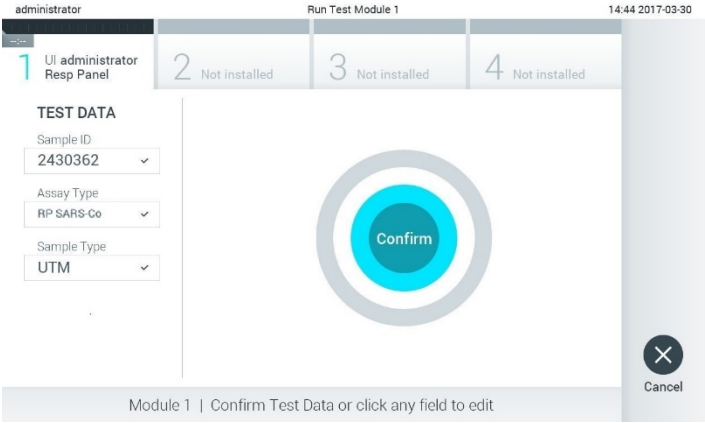

Figure 47. Confirming data entry.

11. Make sure that both sample lids of the swab port and main port of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge are firmly closed. When the cartridge entrance port on the top of the QIAstat-Dx Analyzer 1.0 and the QIAstat-Dx Analyzer 2.0 automatically opens, insert the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge with the bar code facing to the left and the reaction chambers facing down (Figure 48).

    Note: There is no need to push the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge into the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0. Position it correctly into the cartridge entrance port and the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 will automatically move the cartridge into the Analytical Module.

Figure 48. Inserting QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge into QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0.

12. Upon detecting the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge, the QIAstat-Dx Analyzer 1.0 or 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 1.0 or the QIAstat-Dx Analyzer 2.0 will not accept a QIAstat-Dx Respiratory SARS CoV-2 Panel 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 Respiratory SARS-CoV-2 Panel Cartridge is not positioned in the port. If this occurs, repeat the procedure starting with step 17.

13. While the test is running, the remaining run time is displayed on the touchscreen.
14. After the test run is completed, the **Eject** screen will appear (Figure 49) and the Module status bar will display the test result as one of the following options:
    - TEST COMPLETED: The test was completed successfully
    - TEST FAILED: An error occurred during the test
    - TEST CANCELED: The user canceled the test

    IMPORTANT: If the test fails, refer to the "Troubleshooting" section in the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 User Manual for possible reasons and instructions on how to proceed.

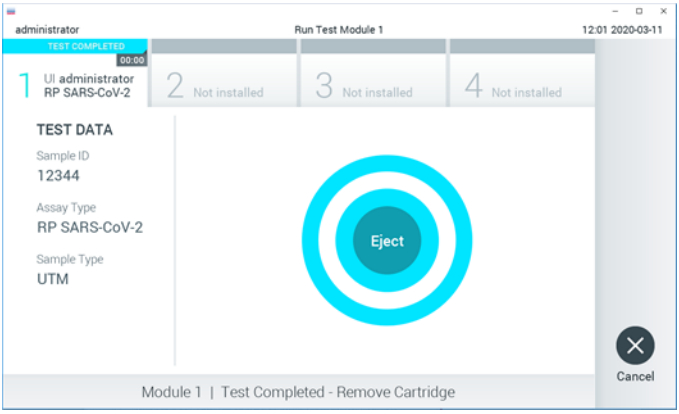

Figure 49. Eject screen display.

15. Press **Eject** on the touchscreen to remove the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge and dispose of it as biohazardous waste in accordance with all national, state and local health and safety regulations and laws. The QIAstat-Dx Respiratory SARS-CoV-2 Panel 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 1.0 or 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.

    IMPORTANT: Used QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridges must be discarded. It is not possible to re-use cartridges for tests for which the execution was started but then subsequently canceled by the operator, or for which an error was detected.

16. After the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge has been ejected, the results Summary screen will appear. Refer to "Interpretation of Results" for further details. To begin the process for running another test, press **Run Test**.

Note: For further information on the use of the QIAstat-Dx Analyzer 1.0, refer to the QIAstat-Dx Analyzer 1.0 User Manual.

Note: For further information on the use of the QIAstat-Dx Analyzer 2.0, refer to the QIAstat-Dx Analyzer 2.0 User Manual.

Running a test on the QIAstat-Dx Rise

Note: For further information on the use of the QIAstat-Dx Rise, refer to the QIAstat-Dx Rise User Manual.

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

Starting the QIAstat-Dx Rise

1. Press the ON/OFF button on the front panel of the QIAstat-Dx Rise to start the unit.

   Note: The power switch at the rear-left connection box must be set to the "I" position.

2. Wait until the Login screen appears and the LED status indicators turn green.
3. Log in to the system once the login screen appears (Figure 50).

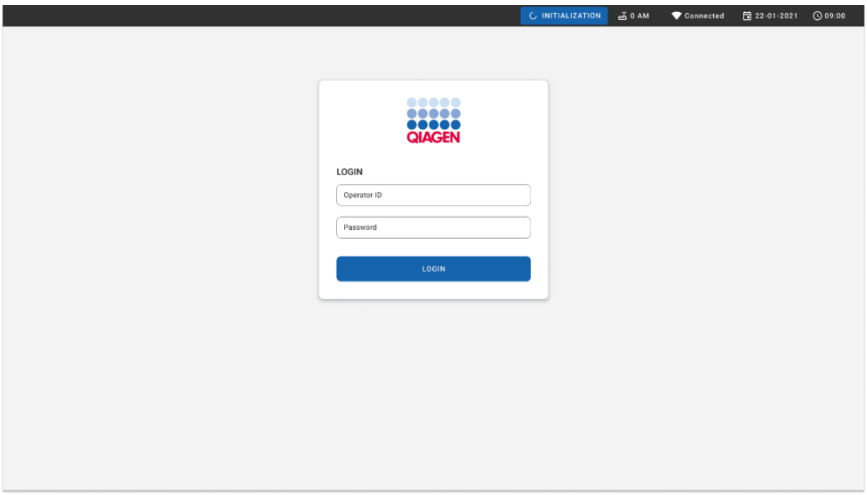

Figure 50. Log in screen

Note: After successful initial installation of the QIAstat-Dx Rise, the system administrator needs to log in for the initial configuration of the software.

Preparing the QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge with universal transport media liquid samples

Remove the QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge from its packaging. For details about adding the sample to the QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge and for information specific to the assay to be run, refer to "Loading a sample into the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge".

Always make sure that both sample lids are firmly closed after adding a sample to the QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge.

Adding a sample barcode to the QIAstat-Dx

Place a barcode on the top right side of the QIAstat-Dx Cartridge (indicated by the arrow) (Figure 51).

Figure 51. Placing sample ID barcode

The maximum barcode size is: 22 mm x 35 mm. The barcode always must always be on the right side of the cartridge (as it is shown above with blue marked area) as left side of the cartridge is critical for sample autodetection (Figure 52).

Note: To process samples on the QIAstat-Dx Rise, it is required to provide a machine-readable sample ID barcode on the QIAstat-Dx Respiratory SARS-CoV-2 Cartridge.

Figure 52. Positioning the sample ID barcode.

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

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

Procedure to run a test

1. Press the OPEN WASTE DRAWER button at the lower-right corner of the main test screen (Figure 53).
2. Open the waste drawer and remove used cartridges from previous runs. Check the waste drawer for spilled liquids. If necessary, clean the waste drawer as described in the Maintenance section of the QIAstat-Dx Rise User Manual.
3. Close the waste drawer after removal of the cartridges. The system will scan the tray and return to the main screen (Figure 53). If the tray was removed for maintenance purposes, make sure it is correctly inserted before closing the drawer.
4. Press the **OPEN INPUT DRAWER** button on the lower-right corner of the screen (Figure 53).

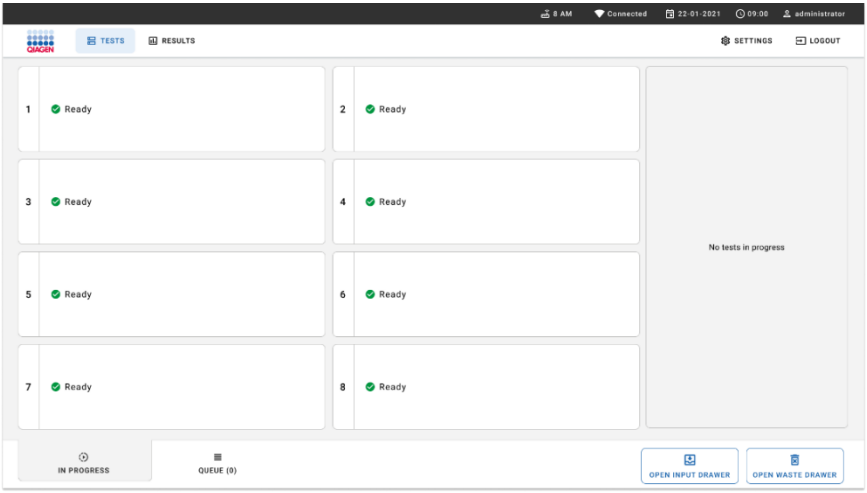

Figure 53. Main test screen.

5. Wait until the input drawer is unlocked (Figure 54).

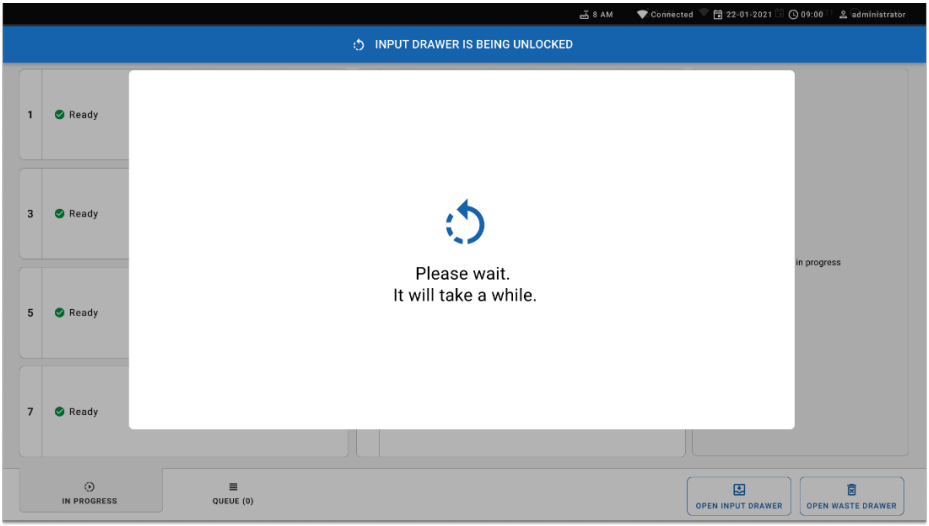

Figure 54. Input tray waiting dialog.

6. When prompted, pull the input drawer to open (Figure 55).

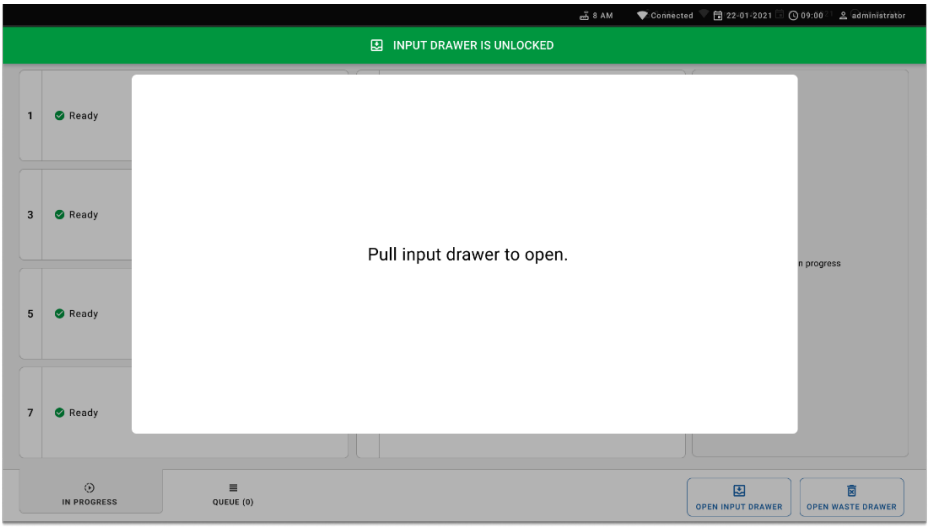

Figure 55. Input drawer open dialog.

7. The **Add cartridge** dialog appears and the scanner at the front will be activated. Scan the sample ID barcode attached to the top of the QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge at the front of the instrument (position indicated by the arrow (Figure 56).

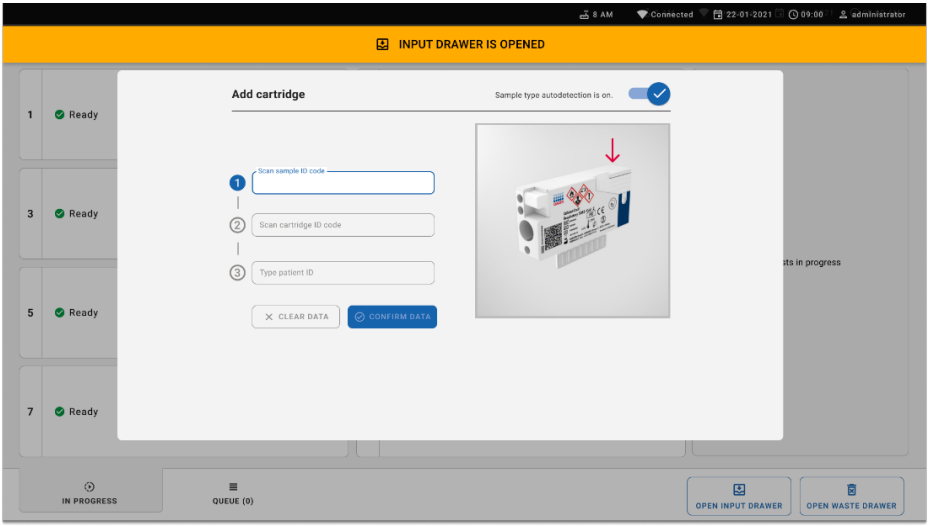

Figure 56. Scan sample ID screen

8. After entering the sample ID barcode, scan the bar code of the QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge to be used (position indicated by the arrow). The QIAstat-Dx Rise automatically recognizes the assay to be run, based on the QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge barcode (Figure 57).

   Note: Make sure that **Sample type autodetection** is set to on. The system will automatically recognize the used sample type (if applicable for the assay used).

   If **Sample type autodetection** is set to off, you might need select the appropriate sample type manually (if applicable for the assay used).

   Note: The QIAstat-Dx Rise will not accept QIAstat-Dx Respiratory SARS-CoV-2 Panel 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.

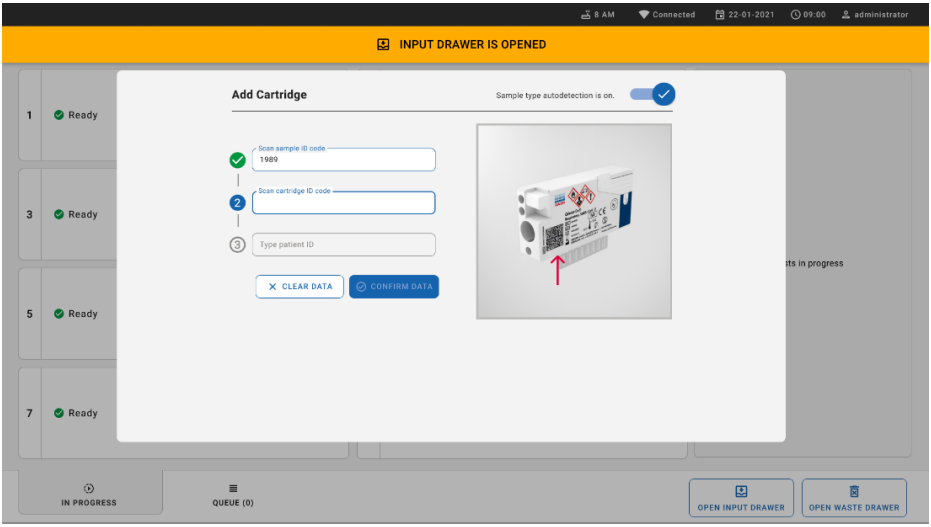

Figure 57. Scan cartridge ID screen

9. Type patient ID (Patient ID has to be set to on) then confirm the data (Figure 58).

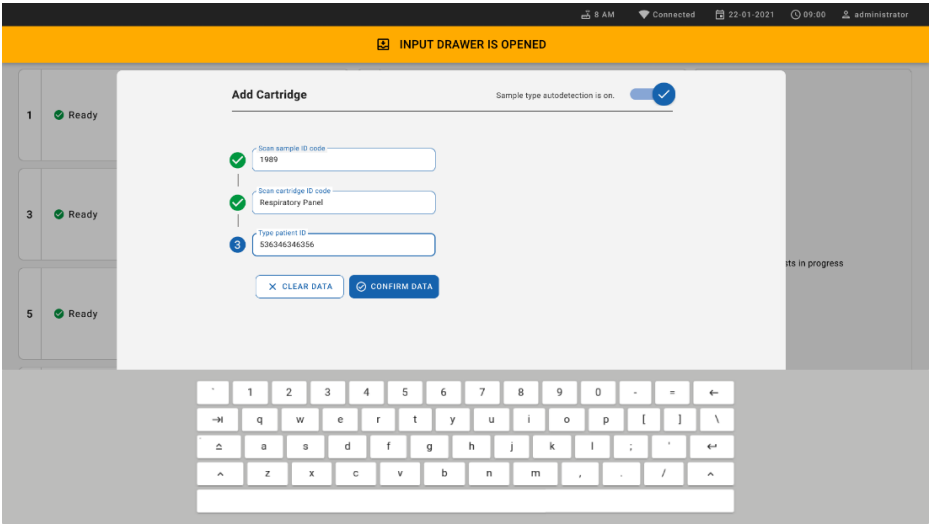

Figure 58. Typing the patient ID

10. After successful scan, the following dialog box appears briefly at the top of the screen (Figure 59)

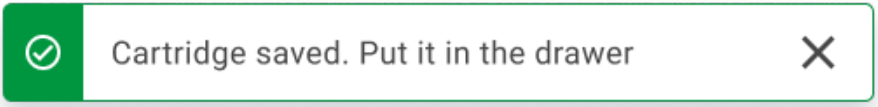

Figure 59. Cartridge saved screen

11. Place the cartridge into the input drawer. Make sure the cartridge is inserted properly into the tray.

12. Continue scanning and inserting cartridges, following previous steps. You can load up to 18 cartridges into the drawer.

IMPORTANT: Please be aware that QIAstat-Dx Rise can handle up to 18 QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridges at the same time within the input drawer. Please be also aware that, with software version 2.2 or higher, different panels can be inserted and processed simultaneously in the input drawer.

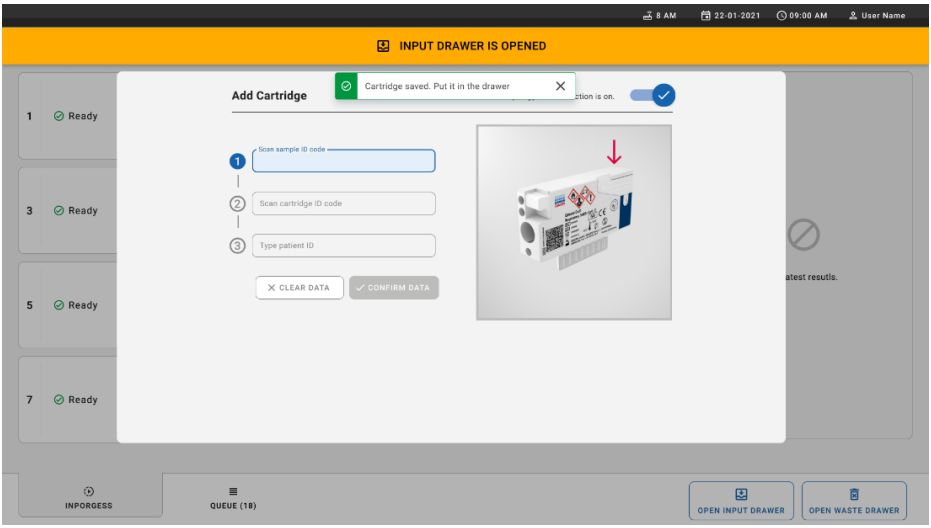

Figure 60. Add cartridge screen.

13. Close the input drawer when all cartridges have been scanned and inserted. The system will scan the cartridges and prepare a queue (Figure 61).

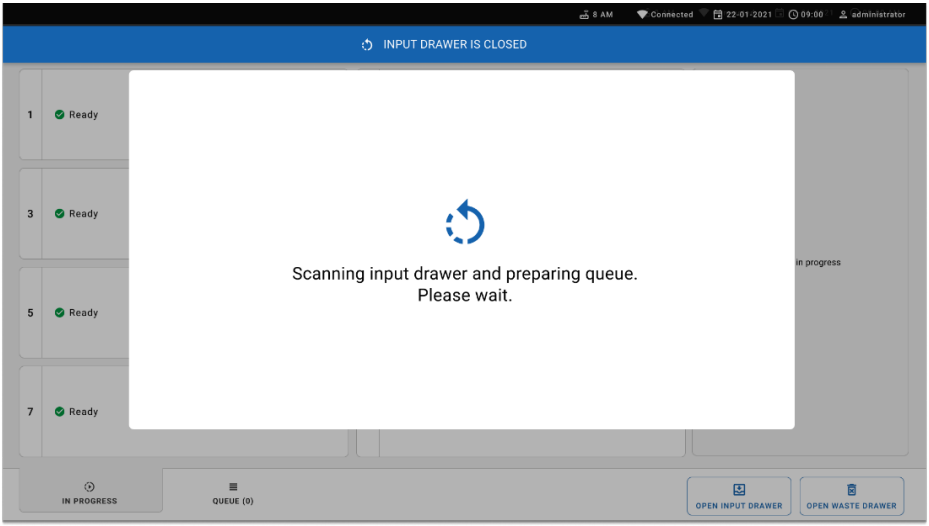

Figure 61. Preparing queue screen.

After successful scanning, the queue will be shown (Figure 62). Review the data shown. In case of an error, press the **Open input drawer** button, remove the respective cartridge and re-scan the cartridge, following steps 10–13.

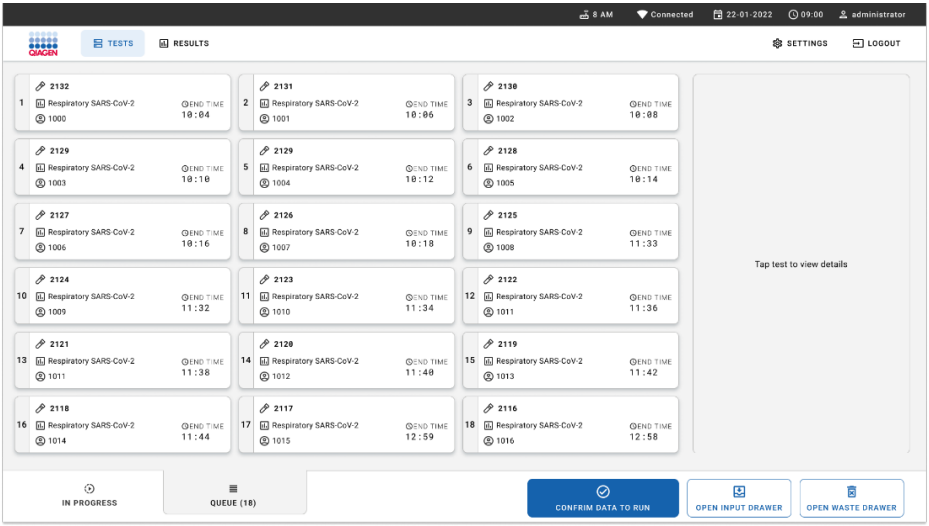

Figure 62. Sample queue screen.

Note: The sample order on the screen may not match the cartridge order in the input drawer (it only matches when all the cartridges are queued together) and cannot be changed without opening the input tray and removing cartridges.

The sample queue/processing order is generated by QIAstat-Dx Rise based on the following rules:

- Stability time: QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridges with the shortest remaining on-board stability time will be prioritized irrespective of the position in the loading tray.
- Within the same assay type the position in the loading tray determines the order in queue.

If you select a test on the touchscreen, additional information is displayed in the view details section of the screen (Figure 63).

Note: The system will reject cartridges that exceed the maximum on-board stability time within the input drawer (about 300 minutes).

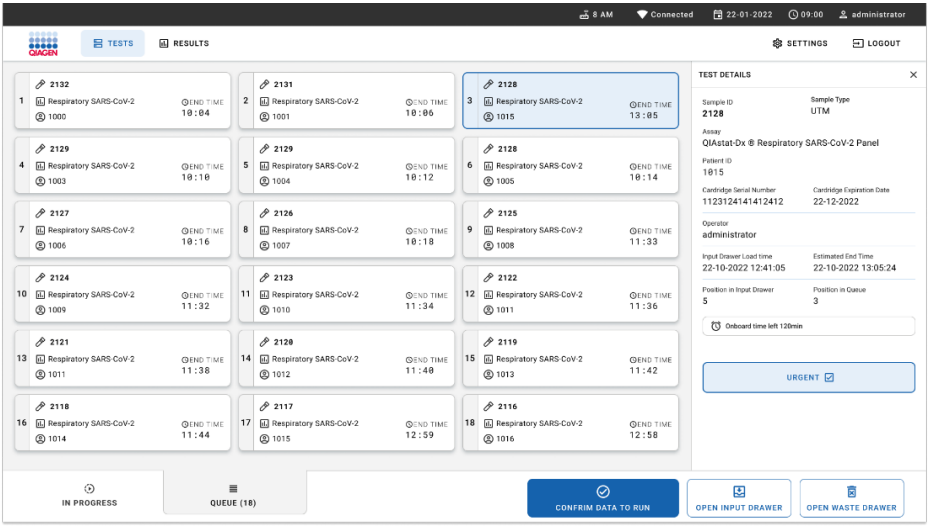

Figure 63. Sample queue screen with selected assay showing additional information.

The following information is shown in the test details section (Figure 64):

- Sample ID
- Sample Type (depends on assay)
- Assay Type
- Patient ID

- Operator ID
- Input Tray Load time
- Estimated end time
- Position in Input drawer
- Position in Queue (Note: the position may differ, based on sample stability time)
- Cartridge serial number
- Cartridge expiration date
- Onboard time left

Note: The on-board time (about 300 minutes) triggers the order of samples in the queue.

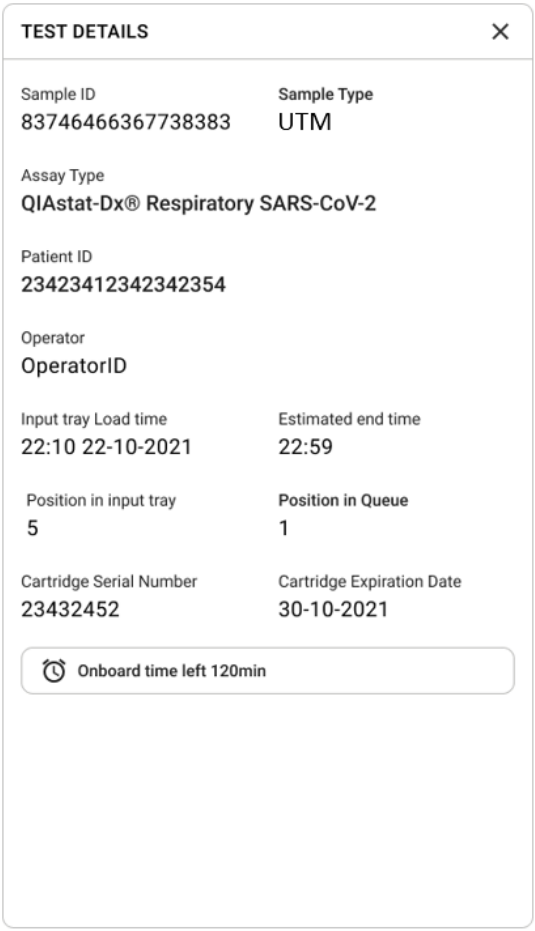

Figure 64. Test details

14. Press the **Confirm data to run** button on the bottom of the screen when all the displayed data are correct (Figure 63). After that, one more confirmation is required from the operator to run the tests (Figure 65).

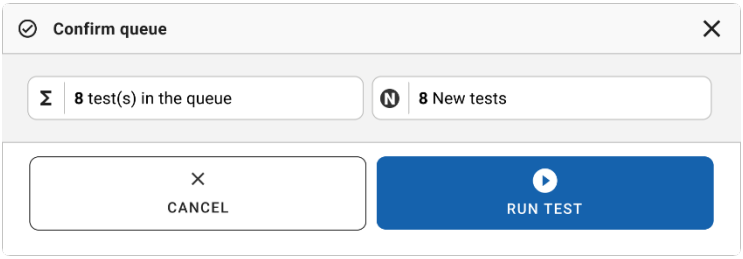

Figure 65. Confirm queue dialog

While the tests are running, the remaining run time and other information for all queued tests is displayed on the touchscreen (Figure 66).

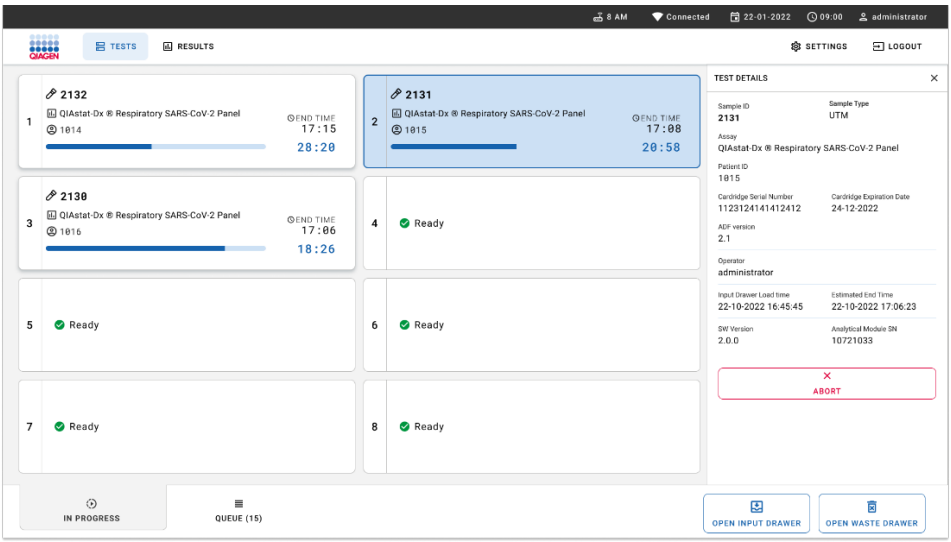

Figure 66. Test execution information on queue screen.

If the cartridge is being loaded into an Analytical Module, a “test loading” message and the estimated end time are displayed (Figure 67).

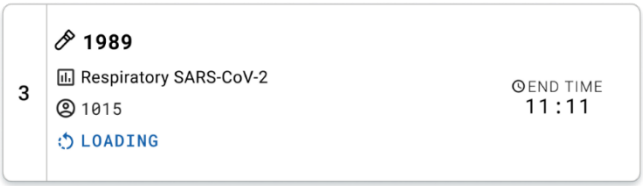

Figure 67. Test loading message and end time.

If the test is running, the elapsed run time and the approximate end time are being displayed (Figure 68).

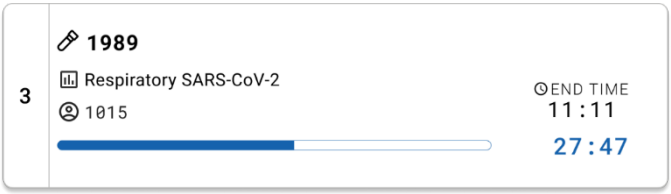

Figure 68. Elapsed run time and approximate end time view.

If the test is completed, a "test completed " message and the run end time is displayed (Figure 69).

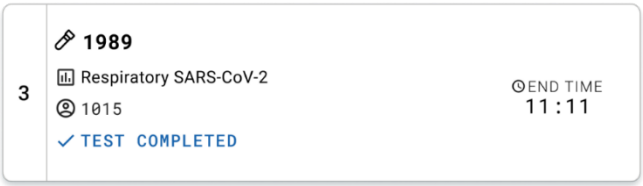

Figure 69. Test completed view

Prioritizing samples

If a sample needs to be run urgently, it is possible to select this sample on the sample queue screen and run as a first sample (Figure 70). Please note that it is not possible to prioritize a sample after confirmation of the queue.

Prioritizing sample before starting run

The urgent sample is selected on the queue screen and marked URGENT from right hand side of the sample queue screen before confirm data to run (Figure 70). Following this, the sample is moved to the first position of the queue (Figure 71). Note that only one sample can be prioritized.

Note: It is required to open and close the input drawer otherwise it is not possible to prioritize a cartridge that has already been confirmed. At this point, if the **Urgent** button is not active, the operator need to switch between QUEUE and IN PROGRESS tabs on the GUI to see the active **Urgent** button.

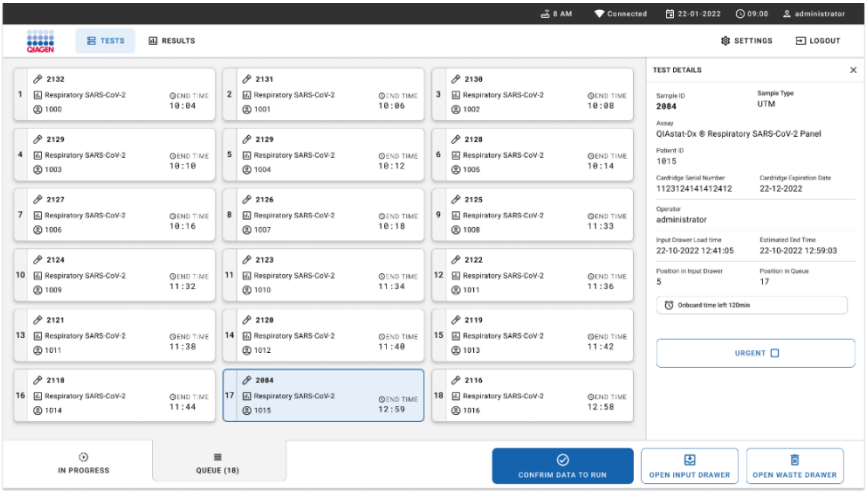

Figure 70. Sample queue screen while selecting sample to be prioritized

Some other samples may run out of stability time due to prioritization of a sample. This warning can be seen on the right corner of the screen (Figure 71).

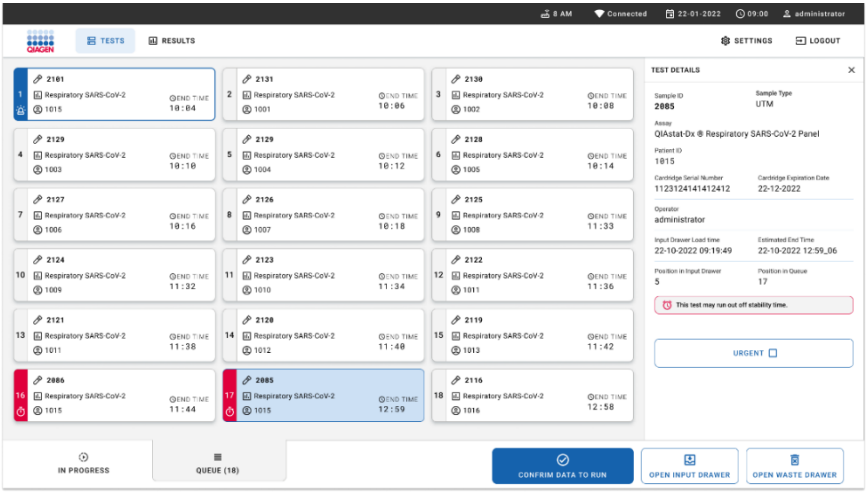

Figure 71. Sample queue screen after a sample is prioritized

After confirmation of the queue the run can be started (Figure 72).

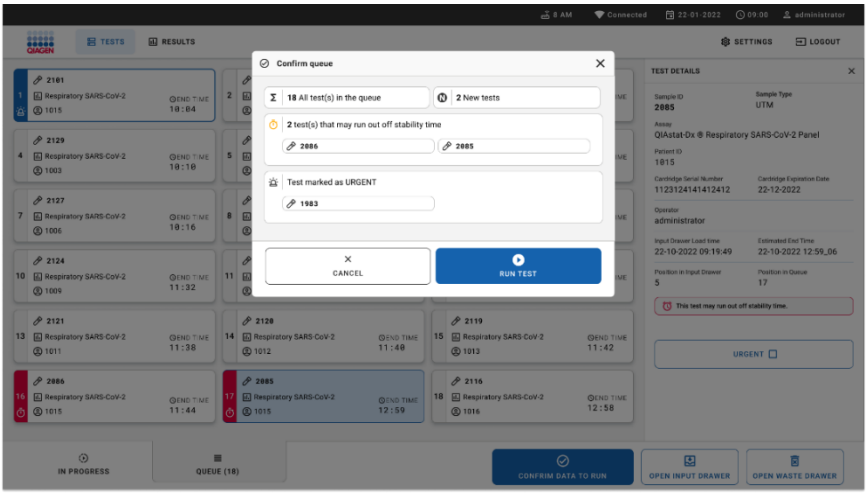

Figure 72. Confirmation of the run screen

Prioritizing samples during run

A sample can be also prioritized for any reason during the run. In this case, if there is no available AM, any other ongoing sample needs to be aborted to perform prioritization (Figure 73).

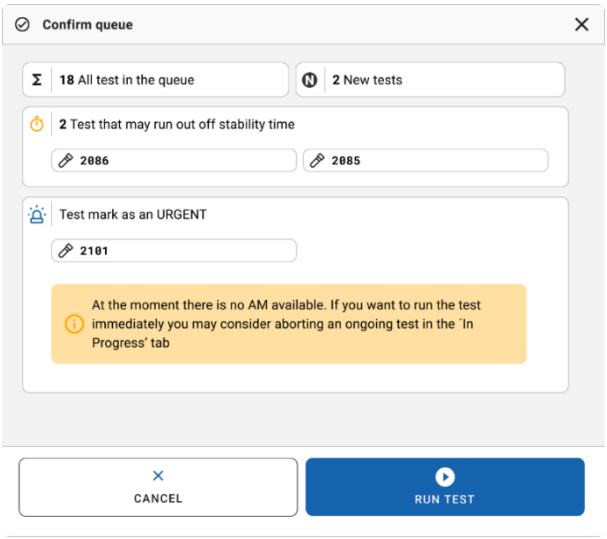

Figure 73. Confirmation dialog during run.

Abortion of running sample

A sample can be aborted during scanning, loading, and running. Please note that, the sample cannot be used again once it is aborted, this is also true for the sample that is aborted during scanning and loading.

To abort a sample, go to **In progress** tab of the screen and select the sample and push "abort" option on the right corner of the screen (Figure 74).

It is not possible to abort a run while a sample is about to load into AM or about to complete to run and the system is retrieving result data or/and technical logs from the respective AM.

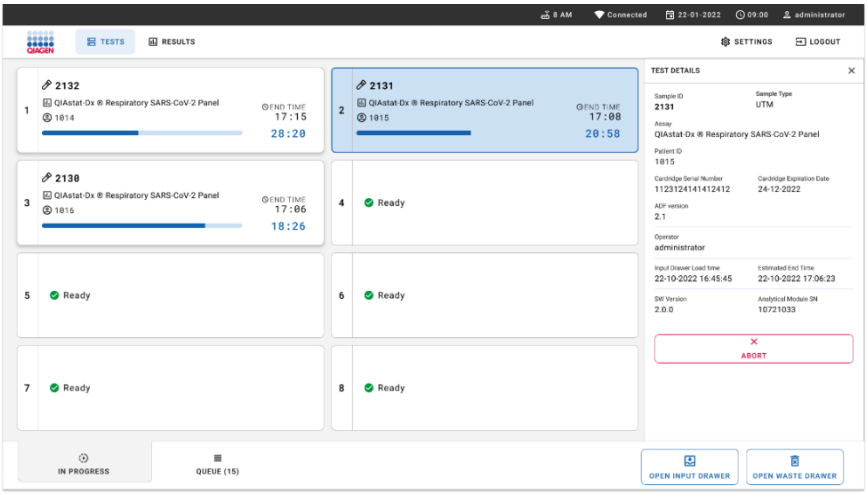

Figure 74. Abortion of a running sample.

The system needs a confirmation to abort the sample (Figure 75).

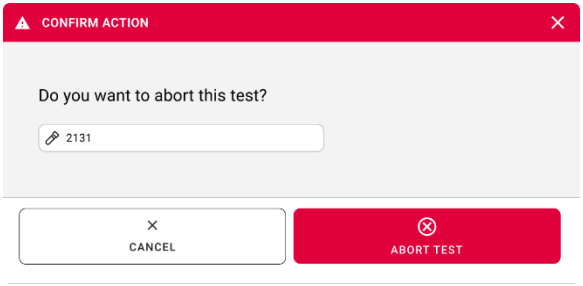

Figure 75. Confirmation dialog to abort running sample.

After a while the sample can be seen as “aborted” on the screen (Figure 76 and 77).

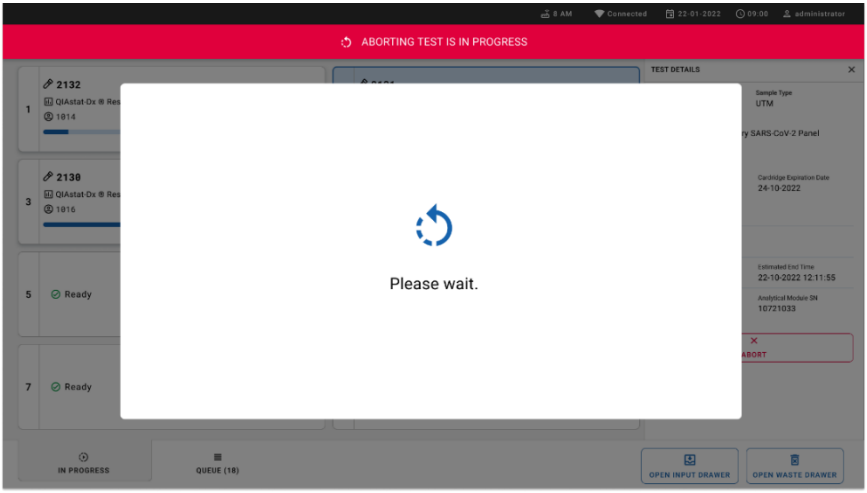

Figure 76. Sample abortion waiting dialog.

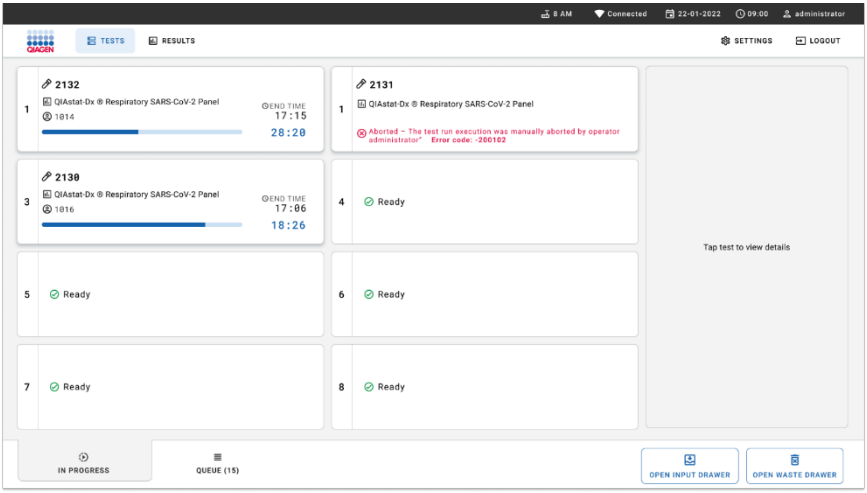

Figure 77. Aborted sample after confirmation of the abortion.

Interpretation of Results

Viewing results with the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0

The QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 automatically interprets and saves test results. After ejecting the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge, the results Summary screen is automatically displayed (Figure 78).

Figure 78 shows the screen for the QIAstat-Dx Analyzer 1.0

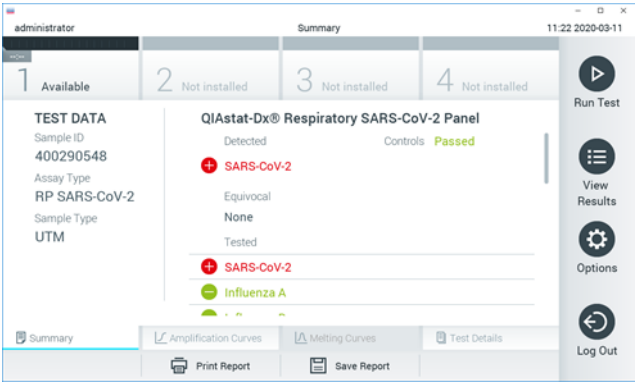

Figure 78. Results Summary screen example showing Test Data on the left panel and Test Summary in the main panel in the QIAstat-Dx Analyzer 1.0.

From this screen, other tabs with more information, which will be explained in the following chapters, are available:

- Amplification Curves
- Melting Curves. This tab is disabled for the QIAstat-Dx Respiratory SARS-CoV-2 Panel.
- Test Details.

Figure 79 shows the screen for the QIAstat-Dx Analyzer 2.0.

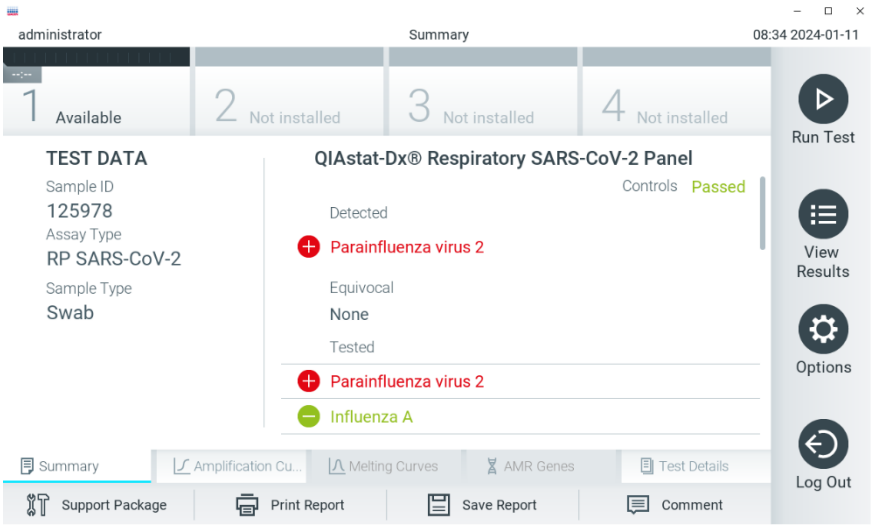

Figure 79. Results Summary screen example showing Test Data on the left panel and Test Summary in the main panel in QIAstat-Dx Analyzer 2.0.

QIAstat-Dx Analyzer 2.0 includes an additional tab:

- AMR Genes. It is disabled for the QIAstat-Dx Respiratory SARS-CoV-2 Panel.

Note: From this point forward, example screen shots will be used when referring to the QIAstat-Dx Analyzer 1.0 and/or QIAstat-Dx Analyzer 2.0 where the functions being explained are the same.

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

- The first list, under the heading “Detected”, includes all pathogens detected and identified in the sample, which are preceded by a  sign and are colored red.
- The second list, under the heading “Equivocal” is not used. “Equivocal” results are not applicable for the QIAstat-Dx Respiratory SARS-CoV-2 Panel. Therefore, the “Equivocal” list will always be empty.
- The third list, under the heading “Tested”, includes all pathogens tested in the sample. Pathogens detected and identified in the sample are preceded by a  sign and are red. Pathogens that were tested but not detected are preceded by a  sign and are green.

Note: Pathogens detected and identified in the sample are shown in both the “Detected” and “Tested” lists.

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

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

- Sample ID
- Assay Type
- Sample Type

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 and test details).

A report with the assay data can be exported to an external USB storage device. Insert the USB storage device into one of the USB ports of the QIAstat-Dx Analyzer 1.0 and press Save Report in the bottom bar of the screen. This report can be exported later at any time by selecting the test from the View Result List.

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

Viewing amplification curves

To view test amplification curves of pathogens detected, press the Amplification Curves tab (Figure 80).

Figure 80. Amplification Curves screen (PATHOGENS tab).

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

Note: If User Access Control is enabled on the QIAstat-Dx Analyzer 1.0 or 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 C_T and endpoint fluorescence (EP) values are shown below each pathogen name.

Press the **CONTROLS** tab on the left side to view the controls in the amplification plot. Press the circle next to the control name to select or deselect it (Figure 81).

Figure 81. Amplification Curves screen (CONTROLS tab).

The amplification plot displays the data curve for the selected pathogens or 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.

Viewing test details

Press Test Details in the Tab Menu bar at the bottom of the touchscreen 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 82):

- User ID
- Cartridge SN (serial number)
- Cartridge Expiration Date
- Module SN (serial number)
- Test Status (Completed, Failed, or Canceled by operator)
- Error Code (if applicable)
- Test Start Date and Time
- Test Execution Time
- Assay Name
- Test ID
- Test Result:
    - Positive (if at least one respiratory pathogen is detected/identified)
    - Negative (no respiratory pathogen is detected)
    - Invalid
- List of analytes tested in the assay, with C_T and endpoint fluorescence in the event of a positive signal
- Internal Control, with C_T and endpoint fluorescence

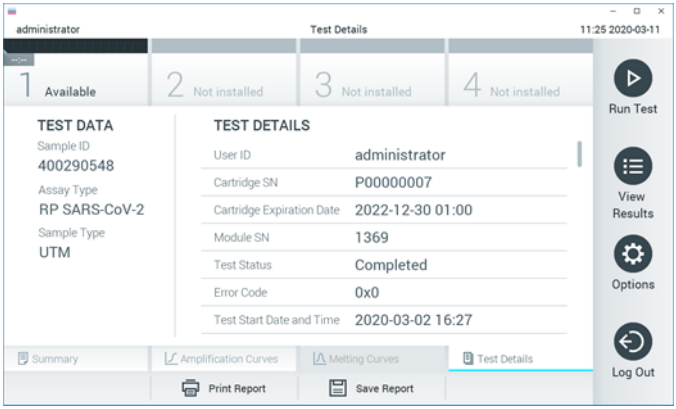

Figure 82. Example screen showing Test Data on the left panel and Test Details in the main panel.

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 83).

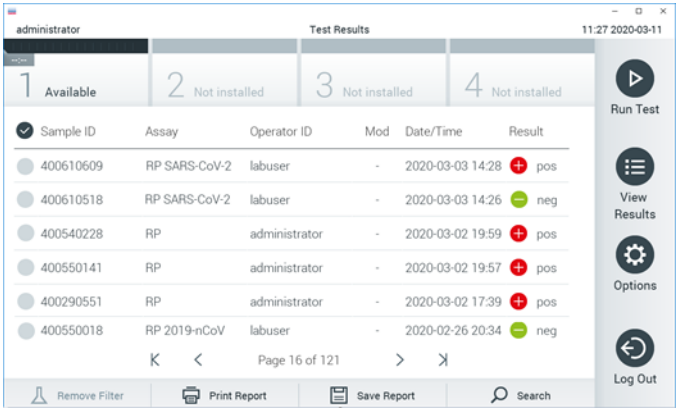

Figure 83. Example View Results screen.

The following information is available for every executed test (Figure 84):

- Sample ID
- Assay (name of test assay, which is “RP” for Respiratory Panel)
- Operator ID
- Mod (Analytical Module on which the test was executed)
- Date/Time (date and time when the test was finished)
- Result (outcome of the test: positive [pos], negative [neg], failed [fail] or successful [suc])

Note: If User Access Control is enabled on the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0, the data for which the user has no access rights will be hidden with asterisks.

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. Unselect test results by pressing this checkmark. The entire list of results can be selected by pressing the ✔ checkmark circle in the top row (Figure 84).

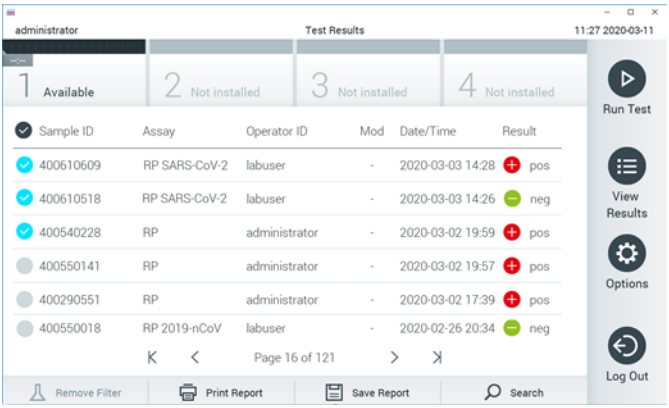

Figure 84. Example of selecting Test Results in the View Results screen.

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 2):

Table 2. Description of Test Results

Outcome	Result	Description
Positive	 pos	At least one pathogen is positive
Negative	 neg	No pathogens were detected
Failed	 fail	The test failed because either an error occurred or the test was canceled by the user
Successful	 suc	The test is either positive or negative, but the user does not have the access rights to view the test results

Make sure a printer is connected to the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 and the proper driver is installed. 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.

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.

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 T 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.

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 1.0 and the QIAstat-Dx Analyzer 2.0.

Printing results

Make sure a printer is connected to the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 and the proper driver is installed. Press Print Report to send a copy of the test results to the printer.

Result interpretation

A result for a respiratory organism is interpreted as "Positive" when the corresponding PCR assay is positive, except for Influenza A. The Influenza A assay in the QIAstat-Dx Respiratory SARS-CoV-2 Panel is designed to detect Influenza A as well as Influenza A subtype H1N1/2009, Influenza A subtype H1 or Influenza A subtype H3. In particular, this means:

If seasonal Influenza A H1 strain is detected by the QIAstat-Dx Respiratory SARS-CoV-2 Panel assay, two signals will be generated and displayed on the QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0 screen: one for Influenza A and a second one for H1 strain.

If seasonal Influenza A H3 strain is detected by the QIAstat-Dx Respiratory SARS-CoV-2 Panel assay, two signals will be generated and displayed on the QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0 screen: one for Influenza A and a second one for H3 strain.

If a pandemic Influenza A/H1N1/2009 strain is detected, two signals will be generated and displayed on the QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0 screen: one for Influenza A and a second one for H1N1/2009.

IMPORTANT: If only an Influenza A signal is present and no additional signal for any of the subtypes is generated, it can be due to either low concentration or, in very rare cases, a new variant or any Influenza A strain other than H1 and H3 (e.g., H5N1, which can infect humans). In cases where only an Influenza A signal is detected and there is a clinical suspicion of non-seasonal Influenza A, retesting is recommended. Likewise, in case only any of the Influenza A subtypes is detected and no additional signal for Influenza A is present, it can also be due to low virus concentration.

For every other pathogen that can be detected with the QIAstat-Dx Respiratory SARS-CoV-2 Panel, only one signal will be generated if the pathogen is present in the sample.

Internal Control interpretation

Internal Control results are to be interpreted according to Table 3.

Table 3. Interpretation of Internal Control results

Control result	Explanation	Action
Passed	The Internal Control amplified successfully	The run was completed with success. All results are valid and can be reported. Detected pathogens are reported as "positive" and undetected pathogens are reported as "negative".
Failed	The Internal Control failed	Positively detected pathogen(s) are reported, but all negative results (tested but not detected pathogen[s]) are invalid. Repeat the testing using a new QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge.

Interpretation of results with QIAstat-Dx Rise

Viewing results with QIAstat-Dx Rise

The QIAstat-Dx Rise automatically interprets and saves test results. After the run completed , the results can be seen in the Results summary screen (Figure 85).

Note: Visible information will be dependent on the operator's access rights.

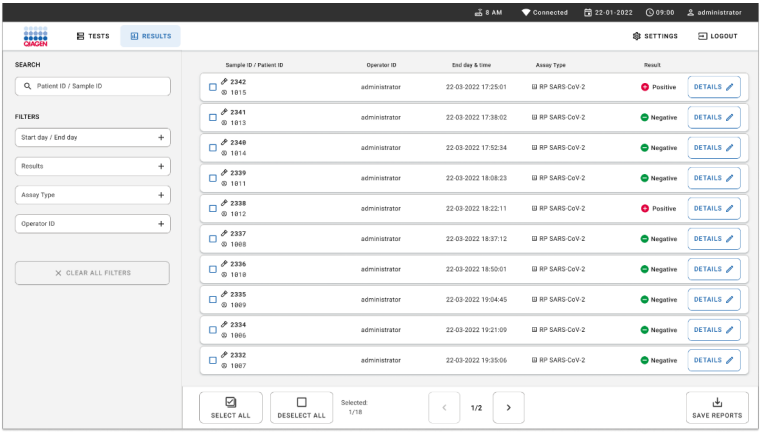

Figure 85. The results summary screen.

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

- If at least one pathogen is detected in the sample, the word Positive is shown in the result column, preceded by a ⊕ sign.
- If no pathogen is detected, and the internal control is valid, the word Negative is shown in the result column, preceded by a ⊖ sign.
- If at least one pathogen is detected in the sample, and the internal control was invalid, the term Positive with warning is shown in the result column, preceded by a ⊕! sign.
- If the test failed to complete successfully, a message will indicate Failed followed by the specific Error Code.

The following Test Data are on the screen (Figure 85)

- Sample ID/Patient ID
- Operator ID
- End day and time
- Assay Type

Viewing test details

Further data about the assay is available, depending on the operator's access rights, through the Details button at the right side of the screen (e.g., amplification plots, and test details (Figure 86).

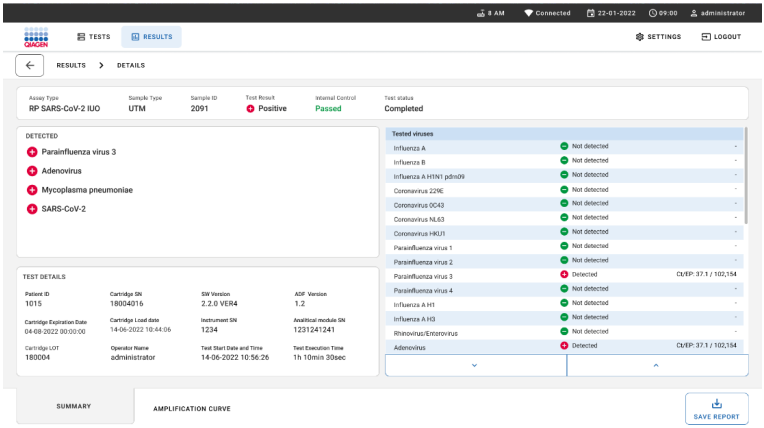

Figure 86. The test details screen.

The upper part of the screen shows general information about the test. It includes assay and sample type, Sample ID, overall test result, status of the internal control, and the test status.

On the left side of the screen, all detected pathogens are shown, the middle part of the screen shows all pathogens that the assay can detect. On the right side of the screen, the following

test details are shown: Sample ID, operator ID, cartridge lot number, cartridge serial number, cartridge expiration date, cartridge load date and time, test execution date and time, test execution duration, Software and ADF version, and the analytical Module serial number.

Viewing amplification curves

To view the test amplification curves, press the Amplification Curves tab at the bottom of the screen (Figure 87).

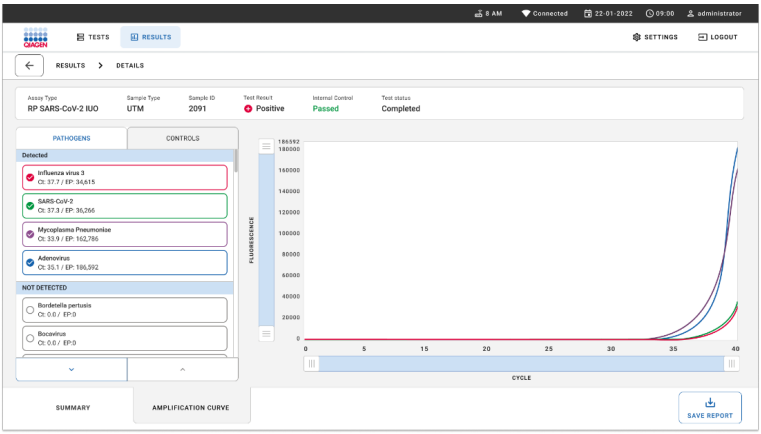

Figure 87. The amplification curves screen.

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 not be shown.

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

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

Browsing results from previous tests

To view results from previous tests that are stored in the results repository, use the search functionality in the main results screen (Figure 88).

Note: The functionality may be restricted or disabled due to user profile settings.

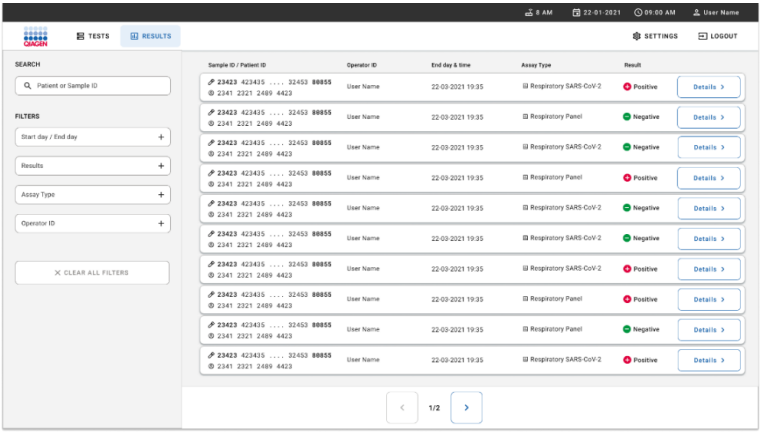

Figure 88. Search functionality in the results screen.

Exporting results to a USB storage device

From the Results screen, select individually or all with Select All button to export and save a copy of the test reports in PDF format to a USB storage device. The USB port is located in front and on the rear of the instrument.

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

Quality Control

In accordance with QIAGEN's ISO-certified Quality Management System, each lot of QIAstat-Dx Respiratory SARS-CoV-2 Panel is tested against predetermined specifications to ensure consistent product quality.

Limitations

- Results from the QIAstat-Dx Respiratory SARS-CoV-2 Panel are not intended to be used as the sole basis for diagnosis, treatment, or other patient management decisions.
- Positive results do not rule out co-infection with organisms not included in the QIAstat-Dx Respiratory SARS-CoV-2 Panel. The agent detected may not be the definitive cause of the disease.
- Negative results do not preclude infection of the upper respiratory tract. Not all agents of acute respiratory infection are detected by this assay and sensitivity in some clinical settings may differ from that described in the package insert.
- A negative result with the QIAstat-Dx Respiratory SARS-CoV-2 Panel does not exclude the infectious nature of the syndrome. Negative assay results may originate from several factors and their combinations, including sample handling mistakes, variation in the nucleic acid sequences targeted by the assay, infection by organisms not included in the assay, organism levels of included organisms that are below the limit of detection for the assay and use of certain medications, therapies, or agents.
- The QIAstat-Dx Respiratory SARS-CoV-2 Panel is not intended for testing of samples other than those described in these Instructions for Use. Test performance characteristics have been established only with nasopharyngeal swab samples collected in transport medium, from individuals with acute respiratory symptoms.
- The QIAstat-Dx Respiratory SARS-CoV-2 Panel is intended to be used in conjunction with standard of care culture for organism recovery, serotyping and/or antimicrobial susceptibility testing where applicable.
- The results from the QIAstat-Dx Respiratory SARS-CoV-2 Panel must be interpreted by a trained healthcare professional within the context of all relevant clinical, laboratory, and epidemiological findings.

- The QIAstat-Dx Respiratory SARS-CoV-2 Panel can be used only with the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise*.

  *DiagCORE Analyzer instruments running QIAstat-Dx software version 1.3 or higher can be used as an alternative to QIAstat-Dx Analyzer 1.0 instruments.

- The QIAstat-Dx Respiratory SARS-CoV-2 Panel is a qualitative assay and does not provide a quantitative value for detected organisms.
- Viral and bacterial nucleic acids may persist in vivo, even if the organism is not viable or infectious. Detection of a target marker does not imply that the corresponding organism is the causative agent of the infection or the clinical symptoms.
- Detection of viral and bacterial nucleic acids depends on proper sample collection, handling, transportation, storage, and loading into the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge. Improper operations for any of the aforementioned processes can cause incorrect results, including false-positive or false-negative results.
- The assay sensitivity and specificity for the specific organisms and for all organisms combined are intrinsic performance parameters of a given assay and do not vary depending on prevalence. In contrast, both the negative and positive predictive values of a test result are dependent on the disease/organism prevalence. Please note that a higher prevalence favors the positive predictive value of a test result, while a lower prevalence favors the negative predictive value of a test result.
- Do not use damaged cartridges. For handling of damaged cartridges, refer to the chapter Safety Information.

Performance Characteristics

The QIAstat-Dx Respiratory SARS-CoV-2 Panel (Cat. no. 691214) assay was developed by introducing the SARS-CoV-2 target in a separate reaction chamber of the QIAstat-Dx Respiratory Panel assay (Cat. No. 691211). It is known that sample preparation and RT-qPCR in the QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge are steps common to all target organisms. In the cartridge, the pooled sample and PCR enzyme mixture is equally allocated to each reaction chamber. As a result of this and/or availability of SARS-CoV-2 clinical samples, certain studies shown below were not done or repeated using the QIAstat-Dx Respiratory SARS-CoV-2 Panel.

Clinical performance

The clinical performance shown below was demonstrated using QIAstat-Dx Analyzer 1.0 and the QIAstat-Dx Analyzer 2.0. The QIAstat-Dx Rise uses the same Analytical Modules as QIAstat-Dx Analyzer 1.0 therefore the performance is not impacted by QIAstat-Dx Rise or QIAstat-Dx Analyzer 2.0.

Transport medium liquid specimens

The performance characteristics of the QIAstat-Dx Respiratory SARS-CoV-2 Panel assay were assessed in a multicenter clinical trial conducted at eight (8) geographically diverse study sites: five (5) U.S. sites and three (3) EU sites. The performance of nasopharyngeal swab specimen was assessed in universal transport medium (UTM) (Copan Diagnostics); MicroTest™ M4®, M4RT®, M5®, and M6™ (Thermo Fisher Scientific); BD™ Universal Viral Transport (UVT) System (Becton Dickinson and Company); HealthLink® Universal Transport Medium (UTM) System (HealthLink Inc.); Universal Transport Medium (Diagnostic Hybrids Inc.); V-C-M Medium (Quest Diagnostics); UniTranz-RT® Universal Transport Media (Puritan Medical Products Company); and dry nasopharyngeal swab specimens (FLOQSwabs,

Copan, cat. no. 503CS01). When using a swab, it is directly inserted into the swab port of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge after collection, avoiding transfer into a liquid medium.

This study was designed as an observational, prospective-retrospective study using leftover samples obtained from subjects with signs and symptoms of an acute respiratory infection. Participating sites were asked to test fresh and/or frozen clinical samples according to a protocol and site/specific instructions.

Samples tested using the QIAstat-Dx Respiratory SARS-CoV-2 Panel were compared with the results of the standard of care (SOC) method(s) at the sites, as well as with a range of validated and commercially available molecular methods. This approach provided results for pathogens not detected by SOC and/or allowed for final discrepancy resolution of discordant results. The QIAstat-Dx Respiratory SARS-CoV-2 Panel assay results were compared against FilmArray® Respiratory Panel 1.7 & 2 and the SARS-CoV-2 RT-PCR assay developed by the **Charité – Universitätsmedizin Berlin Institute of Virology, Berlin, Germany**.

A total of 3,065 clinical UTM patient samples were enrolled into the study. A total of 121 samples did not fulfill the inclusion and exclusion criteria and were therefore excluded from the analysis.

Clinical Sensitivity or Positive Percent Agreement (PPA) was calculated as 100% x (TP/[TP + FN]). True positive (TP) indicates that both the QIAstat-Dx Respiratory SARS-CoV-2 Panel and comparator(s) methods had a positive result for the organism, and false negative (FN) indicates that the QIAstat-Dx Respiratory SARS-CoV-2 Panel result was negative while the comparator methods results were positive. \

Specificity or Negative Percent Agreement (NPA) was calculated as 100% x (TN/[TN + FP]). True negative (TN) indicates that both the QIAstat-Dx Respiratory SARS-CoV-2 Panel and the comparator method had negative results, and a false positive (FP) indicates that the QIAstat-Dx

Respiratory SARS-CoV-2 Panel result was positive but the comparator methods results were negative. For the calculation of the clinical specificity of the individual pathogens, the total available results were used with the concerning true- and false-positive organism results subtracted. The exact binomial two-sided 95% confidence interval was calculated for each point estimate.

Overall Clinical Sensitivity (PPA) and overall Clinical Specificity (NPA) were calculated from 2579 specimen results.

In total, 2575 true positive and 52925 true negative QIAstat-Dx Respiratory Panel and QIAstat-Dx Respiratory SARS CoV-2 Panel results were found, as well as 76 false-negative and 104 false-positive results.

Table 4 displays QIAstat-Dx Respiratory SARS CoV-2 Panel Clinical Sensitivity (or Positive Percent Agreement) and Clinical Specificity (or Negative Percent Agreement) with 95% Confidence Intervals.

Table 4. QIAstat-Dx Respiratory Panel performance data

	TP/(TP+FN)	Sensitivity/PPA (%)	95% CI	TN/(TN+FP)	Specificity/NPA (%)	95% CI
Overall	2575/2651	97.13	96.42-97.73	52925/53029	99.80	99.76-99.84
Viruses						
Adenovirus	136/139	97.84	93.85-99.26	2617/2626	99.66	99.35-99.82
Coronavirus 229E	38/39	97.44	86.82-99.55	2735/2735	100	99.86-100.00
Coronavirus HKU1	73/74	98.65	92.73-99.76	2690/2696	99.78	99.52-99.90
Coronavirus NL63	88/97	90.72	83.30-95.04	2677/2677	100	99.86-100.00

Table 4. QIAstat-Dx Respiratory Panel performance data (continued)

	TP/(TP+FN)	Sensitivity/PPA (%)	95% CI	TN/(TN+FP)	Specificity/NPA (%)	95% CI
Coronavirus OC43	66/66	100	94.50-100.00	2704/2705	99.96	99.79-99.99
Human Metapneumovirus A+B	142/147	96.60	92.29-98.54	2627/2629	99.92	99.72-99.98
Influenza A	327/329	99.39	97.81-99.83	2407/2430	99.05	98.58-99.37
Influenza A H1	0/0	N/A	N/A	2774/2774	100.00	99.86-100.00
Influenza A H1N1 pdm09	124/126	98.41	94.40-99.56	2634/2639	99.81	99.56-99.92
Influenza A H3	210/214	98.13	95.29-99.27	2558/2561	99.88	99.66-99.96
Influenza B	177/184	96.20	92.36-98.15	2591/2591	100.00	99.85-100.00
Parainfluenza Virus 1 (PIV 1)	62/62	100.00	94.17-100.00	2713/2713	100.00	99.86-100.00
Parainfluenza Virus 2 (PIV 2)	8/8	100.00	67.56-100.00	2768/2768	100.00	99.86-100.00
Parainfluenza Virus 3 (PIV 3)	122/123	99.19	95.54-99.86	2648/2649	99.96	99.79-99.99
Parainfluenza Virus 4 (PIV 4)	38/40	95.00	83.50-98.62	2732/2733	99.96	99.79-99.99
Respiratory Syncytial Virus A+B	319/325	98.15	96.03-99.15	2442/2443	99.96	99.77-99.99
Rhinovirus/ Enterovirus	385/409	94.13	91.42-96.03	2317/2339	99.06	98.58-99.38

Table 4. QIAstat-Dx Respiratory Panel performance data (continued)

	TP/(TP+FN)	Sensitivity/PPA (%)	95% CI	TN/(TN+FP)	Specificity/NPA (%)	95% CI
SARS-CoV-2	83 / 88	94.32	87.38-97.55	171/189	90.48	85.45-93.89
			Bacteria			
Bordetella pertussis	43/43	100	91.80-100.00	2716/2726	99.63	99.33-99.80
Mycoplasma pneumoniae	66/66	100	94.50-100.00	2703/2705	99.93	99.73-99.98
Chlamydophila pneumoniae	68 / 72	94.44	86.57-97.82	2701/2701	100.00	99.86-100.00

No evaluable results are available for Legionella pneumophila and Human bocavirus due to low detection (2 and 3 detections, respectively) and absence of comparator method results. Therefore, contrived specimens were used as surrogate clinical specimens to supplement and test the sensitivity and specificity of Bocavirus and Legionella pneumophila. Residual negative clinical specimens were spiked with the pathogens at 2x, 5x and 10x LoD levels (50 of each).

Contrived positive specimens were prepared and randomized along with 50 unspiked negative specimens, such that the analyte status of each contrived specimen was unknown to the users performing the testing in 1 clinical site. Results of the contrived specimen testing are provided in Table 5.

Table 5. QIAstat-Dx SARS-CoV-2 Respiratory Panel performance data on contriving samples

Pathogen	Sample concentration	Detection Frequency	Proportion (%)	95 % CI
Bocavirus	2x LoD	25/25	100.00	86.28-100
	5x LoD	15/15	100.00	78.20-100
	10x LoD	10/10	100.00	69.15-100
	Overall	50/50	100.00	92.89-100
Legionella pneumophila	2x LoD	25/25	100.00	86.28-100
	5x LoD	15/15	100.00	78.20-100
	10x LoD	10/10	100.00	69.15-100
	Overall	50/50	100.00	92.89-100

The QIAstat-Dx Respiratory SARS CoV-2 Panel assay detected multiple organisms in 370 samples. A total of 316 samples were double infections, 46 were triple infections, and the remaining samples had 4 coinfections (8 samples).

Dry swab specimen

A total of 333 paired clinical specimens (NPS in UTM and NPS dry swab) were tested to assess the clinical performance characteristics of the dry swab specimens in comparison to the UTM specimen. This testing was conducted at 4 clinical sites in the EU. The objective was to demonstrate equivalency between performance characteristics of the dry swab and the UTM specimens using the QIAstat-Dx Respiratory SARS-CoV-2 Panel.

Patients enrolled in the studies provided 2 nasopharyngeal swabs (one from each nostril). One swab was directly inserted into the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge, and the other swab was transferred into UTM for comparator testing with a separate QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge (paired samples).

The Clinical Sensitivity (or PPA) was calculated as 100% x (TP/[TP + FN]). True positive (TP) indicates that both the dry swab and the UTM specimen had a positive result for a specific organism and false negative (FN) indicates that the dry swab result was negative while the UTM specimen result was positive for a specific organism. Specificity (or NPA) was calculated as 100% x (TN/[TN + FP]). True negative (TN) indicates that both the dry swab and UTM specimen had negative result for a specific organism and a false positive (FP) indicates that the dry swab result was positive but the UTM specimen result was negative for a specific organism. The exact binomial two-sided 95% confidence interval was calculated for each point estimate.

A total of 319 evaluable paired sample results were available for analysis from the original 333 paired samples enrolled. The remaining 14 paired specimens did not fulfill the inclusion criteria.

Overall Clinical Sensitivity (or PPA) could be calculated from a total 189 positive target results obtained with the UTM specimen. The overall Clinical Specificity (or NPA) was calculated from 6969 individual negative target results were obtained with the UTM specimen. The positive results included different targets in the panel and were representative of the epidemiology of the population tested during the clinical performance study (including SARS-CoV-2 for 2 of the sites).

In total, 179 true-positive and 6941 true-negative dry swab results were found, as well as 10 false- negative (positive for UTM specimen/negative for dry swab specimen) and 28 false-positive (positive for dry swab/negative for UTM specimen) results. Overall, the PPA was

94.71% (95% CI, 90.54%–97.10%) and NPA was 99.60% (95% CI, 99.42%–99.72%), showing a high overall correlation between dry swab and UTM specimen types (Table 6).

Table 6. Agreement Between Overall QIAstat-Dx Respiratory Panel Dry Swab Result and Overall QIAstat-Dx Respiratory Panel UTM Result Overall Sensitivity and Specificity Assessment.

Grouping Variable(s)	Proportion		Two-Sided 95% Confidence Limits	
	Fraction		Percentage	
NPA	6941/6969	99.60	99.42	99.72
PPA	179/189	94.71	90.54	97.10

Specifically, for the SARS-CoV-2 target, 40 true-positive results were found in the comparison between UTM specimens and dry-swab specimens tested using the QIAstat-Dx Respiratory SARS-CoV-2 Panel. No false-negatives were found during this comparison between specimens. Additionally, 181 true-negative and 3 false-positive (dry-swab positive and UTM negative) results were found for SARS-CoV-2.

Differences in results between UTM specimen and dry-swab specimens could be attributable to sampling differences between specimens and the dilution effect of dry swabs in transport media. Dry-swab specimens can only be tested once using the QIAstat-Dx Respiratory SARS-CoV-2 Panel, therefore discordance testing was not possible for this sample type.

Conclusion

Extensive multicenter studies sought to assess the performance of the UTM specimen, as well as the equivalency of the dry swab, with the UTM specimen performance in the QIAstat-Dx Respiratory SARS-CoV-2 Panel assay.

The overall Clinical Sensitivity of the UTM specimen was found to be 97.13% (95% CI, 96.42%–97.73%). The overall Clinical Specificity 99.80% (95% CI, 99.76%–99.84%).

The overall Clinical Sensitivity of the dry swab specimen was found to be 94.71% (95% CI, 90.54%–97.10%). The overall Clinical Specificity for the dry swab specimen was 99.60% (95% CI, 99.42%–99.72%).

Analytical performance

The analytical performance shown below was demonstrated using QIAstat-Dx Analyzer 1.0. The QIAstat-Dx Analyzer 2.0 uses the same Analytical Module as QIAstat-Dx Analyzer 1.0 therefore the performance is not impacted by QIAstat-Dx Analyzer 2.0.

With regards to QIAstat-Dx Rise, specific studies to demonstrate the carryover and the repeatability were executed. The rest of analytical performance parameters shown below was demonstrated using QIAstat-Dx Analyzer 1.0. The QIAstat-Dx Rise uses the same Analytical Module as QIAstat-Dx Analyzer 1.0 therefore the performance is not impacted by QIAstat-Dx Rise.

Sensitivity (Limit of Detection)

The Analytical Sensitivity, or Limit of Detection (LoD), is defined as the lowest concentration at which ≥95% of the tested samples generate a positive call.

The LoD per analyte was determined using selected strains* representing individual pathogens that are possible to detect with the QIAstat-Dx Respiratory SARS-CoV-2 Panel. Simulated NPS sample matrix (cultured human cells in Copan UTM) for transport medium liquid samples and simulated dry swab sample matrix (cultured human cells in artificial NPS) for dry swabs were spiked with one (1) or more pathogens and tested in 20 replicates. Liquid sample workflow uses NPS eluted in UTM and a transfer of 300 µL to the cartridge, whereas dry swab workflow allows transfer of the NPS directly to the cartridge. Dry swab mock swabs were prepared by pipetting 50 µL of each diluted virus stock onto a swab and were left to dry

for a minimum of 20 minutes. Swab was tested following the Dry Swab Sample protocol (page 21).

* Due to limited access to cultured virus, synthetic material (gBlock) was used to determine LoD spiked in clinical negative matrix for the SARS-CoV-2 target and to determine LoD in dry swab for the Bocavirus target.

Individual LoD values for each target are shown in Table 7.

Table 7. LoD values obtained for the different respiratory target strains in NPS sample matrix (cultured human cells in Copan UTM) and/or dry swab (cultured human cells in artificial NPS) tested with the QIAstat-Dx Respiratory SARS CoV 2 Panel

Pathogen	Strain	Source	Concentration	Detection rate
Influenza A H1N1	A/New Jersey/8/76	ATCC® VR-897	28.1 $CEID_{50}$/ml	20/20
	A/Brisbane/59/07	ZeptoMetrix® 0810244CFHI	0.04 $TCID_{50}$/ml	19/20
	A/New Caledonia/20/99	ZeptoMetrix 0810036CFHI	28.7 $TCID_{50}$/mL*	20/20
Influenza A H3N2	A/Virginia/ATCC6/2012	ATCC VR-1811	0.4 PFU/mL	19/20
	A/Wisconsin/67/2005	ZeptoMetrix 0810252CFHI	2.5 $TCID_{50}$/mL	20/20
	A/Port Chalmers/1/73	ATCC VR-810	3000CEID $_{50}$/mL*	20/20
Influenza A, subtype H1N1/2009	A/Virginia/ATCC1/2009	ATCC VR-1736	127 PFU/mL*	20/20
	A/SwineNY/03/2009	ZeptoMetrix 0810249CFHI	14.1 $TCID_{50}$/mL	20/20

Table 7. LoD values obtained for the different respiratory target strains in NPS sample matrix (cultured human cells in Copan UTM) and/or dry swab (cultured human cells in artificial NPS) tested with the QIAstat-Dx Respiratory SARS CoV 2 Panel (continued)

Pathogen	Strain	Source	Concentration	Detection rate
Influenza B	B/Virginia/ATCC5/2012	ATCC VR-1807	0.08 PFU/mL	20/20
	B/FL/04/06	ATCC VR-1804	2050CEID$_{50}$/mL*	19/20
	B/Taiwan/2/62	ATCC VR-295	28.1 CEID$_{50}$/mL	20/20
Coronavirus 229E	–	ATCC VR-740	9.47 TCID$_{50}$/mL*	20/20
Coronavirus OC43	–	ATCC-1558	0.1 TCID$_{50}$/mL	20/20
	–	ZeptoMetrix 0810224CFHI	1.99 TCID$_{50}$/mL	19/20
Coronavirus NL63	–	ZeptoMetrix 0810228CFHI	0.70 TCID$_{50}$/mL*	20/20
Coronavirus HKU1	–	ZeptoMetrix NATRVP-IDI	1/300†	19/20
	–	Clinical, S510	240,000 copies/mL	19/20
SARS-CoV-2	–	IDT (gBlock)	500 copies/mL	19/20
	England/02/2020	NIBSC 20/146	19,000 copies/mL	20/20
Parainfluenza Virus 1 (PIV 1)	C35	ATCC VR-94	23.4 TCID$_{50}$/mL*	20/20
Parainfluenza Virus 2 (PIV 2)	Greer	ATCC VR-92	13.9 TCID$_{50}$/mL*	19/20
Parainfluenza Virus 3 (PIV 3)	C 243	ATCC VR-93	44.1 TCID$_{50}$/mL*	20/20

Table 7. LoD values obtained for the different respiratory target strains in NPS sample matrix (cultured human cells in Copan UTM) and/or dry swab (cultured human cells in artificial NPS) tested with the QIAstat-Dx Respiratory SARS CoV 2 Panel (continued)

Pathogen	Strain	Source	Concentration	Detection rate
Parainfluenza Virus 4 (PIV 4)	M-25	ATCC VR-1378	3.03 $TCID_{50}$/mL*	20/20
Respiratory Syncytial Virus A	A2	ATCC VR-1540	2.8 $TCID_{50}$/mL‡	20/20
	A2	ATCC VR-1540	720 PFU/mL‡	20/20
Respiratory Syncytial Virus B	9320	ATCC VR-955	0.02 $TCID_{50}$/mL	20/20
Human Metapneumovirus	Peru6-2003 (type B2)	ZeptoMetrix 0810159CFHI	1.1 $TCID_{50}$/mL	19/20
	hMPV-16, IA10-2003	ZeptoMetrix 0810161CFHI	3.0 $TCID_{50}$/mL*	20/20
Adenovirus	GB (Adenovirus B3)	ATCC VR-3	94900 $TCID_{50}$/mL	20/20
	RI-67 (Adenovirus E4)	ATCC VR-1572	15.8 $TCID_{50}$/mL	20/20
	Adenoid 75 (Adenovirus C5)	ATCC VR-5	5.0 $TCID_{50}$/mL	20/20
	Adenoid 71 (Adenovirus C1)	ATCC VR-1	5.0 $TCID_{50}$/mL	19/20
	Adenovirus C2	ATCC VR-846	28.1 $TCID_{50}$/mL	20/20
	Adenovirus C6	ATCC VR-6	505.6 $TCID_{50}$/mL	20/20
Enterovirus	/US/IL/14-18952 (Enterovirus D68)	ATCC VR-1824	534.0 $TCID_{50}$·/mL*	20/20
	Echovirus 6 (D-1 (Cox))	ATCC VR-241	0.001 $TCID_{50}$/mL	19/20

Table 7. LoD values obtained for the different respiratory target strains in NPS sample matrix (cultured human cells in Copan UTM) and/or dry swab (cultured human cells in artificial NPS) tested with the QIAstat-Dx Respiratory SARS CoV 2 Panel (continued)

Pathogen	Strain	Source	Concentration	Detection rate
Rhinovirus	1059 (Rhinovirus B14)	ATCC VR-284	28.1 $TCID_{50}$/mL	20/20
	HGP (Rhinovirus A2)	ATCC VR-482	169.0 $TCID_{50}$/mL*	20/20
	11757 (Rhinovirus A16)	ATCC VR-283	8.9 $TCID_{50}$/mL	20/20
	Type 1A	ATCC VR-1559	5.0 $TCID_{50}$/mL	20/20
Chlamydophila pneumoniae	TW183	ATCC VR-2282	0.5 TCID50/mL‡	19/20
Chlamydophila pneumoniae	TW183	ATCC VR-2282	85.3 IFU/mL‡	20/20
Mycoplasma pneumoniae	M129-B7	ATCC 29342	0.1 CFU/mL	20/20
Mycoplasma pneumoniae	PI 1428	ATCC 29085	6.01 CCU/mL	20/20
Legionella pneumophila	CA1	ATCC 700711	5370 copies/mL	19/20
Bordetella pertussis	I028	ATCC BAA-2707	5.13 CFU/mL*	19/20
	A639	ZeptoMetrix NATRVP-IDI	1/10000†	19/20

* Tested with liquid sample and mock dry swab sample type.

†Relative dilution from stock concentration.

‡ Two different lots of the same strain used.

Assay robustness

The verification of robust assay performance was assessed by analyzing the Internal Control performance in clinical nasopharyngeal swab samples. Thirty (30) individual nasopharyngeal swab samples, negative for all pathogens possible to detect, were analyzed with the QIAstat-Dx Respiratory Panel. All samples tested showed a positive result and valid performance for the Internal Control of the QIAstat-Dx Respiratory Panel.

Exclusivity (Analytical Specificity)

The exclusivity study was carried out by in silico analysis and in vitro testing to assess the Analytical Specificity for respiratory or non-respiratory organisms that are not covered by the panel. These organisms included specimens which are related to, but distinct from, respiratory panel organisms or that could be present in specimens collected from the intended test population. Selected organisms are clinically relevant (colonizing the upper respiratory tract or causing respiratory symptoms), are common skin flora or laboratory contaminants, or are microorganisms for which much of the population may have been infected.

Samples were prepared by spiking potential cross-reactive organisms into simulated nasopharyngeal swab sample matrix at the highest concentration possible based on the organism stock, preferably 10^5 $TCID_{50}$/ml for viral targets and 10^6 CFU/mL for bacterial targets.

A certain level of cross-reactivity with Bordetella species was predicted by preliminary sequence analysis and was observed when high concentrations of Bordetella holmesii and some strains of Bordetella bronchiseptica were tested. In accordance with the CDC guidelines for assays that use the IS481 as a target region when using the QIAstat-Dx Respiratory SARS-CoV-2 Panel, if the CT value for Bordetella pertussis is CT >29, a confirmatory specificity test is recommended. No cross-reactivity was observed with Bordetella parapertussis at high concentrations. The target gene used for Bordetella pertussis detection (insertion element

IS481) is a transposon also present in other Bordetella species. Table 8 shows the list of pathogens tested.

Table 8. List of Analytical Specificity pathogens tested

Type	Pathogen	
Bacteria	*Bordetella bronchiseptica* *Bordetella holmesii* *Bordetella parapertussis* *Chlamydia trachomatis* *Enterobacter aerogenes* *Escherichia coli (0157)* *Haemophilus influenzae* *Klebsiella oxytoca* *Klebsiella pneumoniae* *Lactobacillus acidophilus* *Moraxella catarrhalis* *Mycoplasma genitalium* *Mycoplasma hominis*	*Neisseria elongata* *Neisseria gonorrhoeae* *Neisseria meningitidis* *Pseudomonas aeruginosa* *Serratia marcescens* *Staphylococcus aureus* *Staphylococcus epidermidis* *Stenotrophomonas maltophilia* *Streptococcus agalactiae* *Streptococcus pneumoniae* *Streptococcus pyogenes* *Streptococcus salivarus*
Viruses	Cytomeglovirus Epstein-Barr Virus Herpes Simplex Virus 1	Herpes Simplex Virus 2 Measles Virus Mumps
Fungi	*Aspergillus fumigatus* *Candida albicans* *Cryptococcus neoformans*	

All pathogens tested showed a negative result and no cross-reactivity was observed for the organisms tested in the QIAstat-Dx Respiratory SARS-CoV-2 Panel (except for Bordetella holmesii and some strains of Bordetella bronchiseptica as described above).

In silico analysis was performed for all primer/probe designs included in the QIAstat-Dx Respiratory SARS-CoV-2 Panel, proving specific amplification and detection of targets without cross-reactivity.

For the SARS-CoV-2 target, only a limited number of organisms were tested in vitro (Haemophilus influenzae, Streptococcus pyogenes, Chlamydophila pneumoniae, Streptococcus pneumoniae, Mycobacterium tuberculosis, MERS Coronavirus, SARS Coronavirus). No cross-reactivity was observed, both in silico and in vitro, with any clinically relevant pathogens (colonizing the upper respiratory tract or causing respiratory symptoms), or common skin flora or laboratory contaminants, or microorganisms.

Inclusivity (Analytical Reactivity)

An inclusivity study was performed to analyze the detection of a variety of strains that represent the genetic diversity of each respiratory panel target organism ("inclusivity strains"). Inclusivity strains for all analytes were included in the study, representative of the species/types for the different organisms (e.g., a range of Influenza A strains isolated from different geographical areas and in different calendar years were included). Table 9 shows the list of respiratory pathogens tested in this study.

* Not applicable to the SARS-CoV-2 target due to the presence of a single strain at time of study.

Table 9. List of Analytical Reactivity pathogens tested

Pathogen	Subtype/serotype	Strain	Source
Influenza A	H1N1	A/PR/8/34	ATCC VR-1469
		A/New Jersey/8/76	ATCC VR-897
		A/Brisbane/59/07	ZeptoMetrix 0810244CFHI
		A/New Caledonia/20/99	ZeptoMetrix 0810036CFHI

Table 9. List of Analytical Reactivity pathogens tested (continued)

Pathogen	Subtype/serotype	Strain	Source
Influenza A	H3N2	A/Virginia/ATCC6/2012	ATCC VR-1811
		A/Wisconsin/67/2005	ZeptoMetrix 0810252CFHI
		A/Port Chalmers/1/73	ATCC VR-810
		A/Victoria/3/75	ATCC VR-822
		A/Brisbane/10/07	ZeptoMetrix NATRVP-IDI
	H1N1 (pandemic)	A/Virginia/ATCC2/2009	ATCC VR-1737
		A/Virginia/ATCC3/2009	ATCC VR-1738
		A/Virginia/ATCC1/2009	ATCC VR-1736
		A/SwineNY/03/2009	ZeptoMetrix 0810249CFHI
		H1N1/NY/02/09	ZeptoMetrix NATRVP-IDI
Influenza B	Not available	B/Virginia/ATCC5/2012	ATCC VR-1807
		B/FL/04/06	ATCC VR-1804
		B/Taiwan/2/62	ATCC VR-295
		B/Panama/45/90	ZeptoMetrix NATFLUB-ERCM
		B/Florida/02/06	ZeptoMetrix 810037CFHI
		B/Maryland/1/59	ATCC VR-296
Coronavirus 229E	Not available	Not available	ATCC VR-740
		Not available	ZeptoMetrix NATRVP-IDI

Table 9. List of Analytical Reactivity pathogens tested (continued)

Pathogen	Subtype/serotype	Strain	Source
Coronavirus OC43	Not available	Not available	ATCC-1558
		Not available	ZeptoMetrix 0810024CFHI
		Not available	ZeptoMetrix NATRVP-IDI
Coronavirus NL63	Not available	Not available	ZeptoMetrix 0810228CFHI
		Not available	ZeptoMetrix NATRVP-IDI
Coronavirus HKU1	Not available	Not available	ZeptoMetrix NATRVP-IDI
Parainfluenza 1	Not available	C35	ATCC VR-94
		n/a	ZeptoMetrix NATPARA1-ST
		n/a	ZeptoMetrix NATRVP-IDI
Parainfluenza 2	Not available	Greer	ATCC VR-92
		Not available	ZeptoMetrix 0810015CFHI
		Not available	ZeptoMetrix NATRVP-IDI
Parainfluenza 3	Not available	C 243	ATCC VR-93
		Not available	ZeptoMetrix NATPARA3-ST
		Not available	ZeptoMetrix NATRVP-IDI
Parainfluenza 4	A	M-25	ATCC VR-1378
	B	CH 19503	ATCC VR-1377
	B	Not available	ZeptoMetrix NATRVP-IDI

Table 9. List of Analytical Reactivity pathogens tested (continued)

Pathogen	Subtype/serotype	Strain	Source
RSV A	Not available	A2	ATCC VR-1540
		Long	ATCC VR-26
		Not available	ZeptoMetrix NATRVP-IDI
RSV B	Not available	9320	ATCC VR-955
		18537	ATCC VR-1580
		WV/14617/85	ATCC VR-1400
		Not available	ZeptoMetrix NATRSVB-ST
Human Metapneumovirus	B1	Peru2-2002	ZeptoMetrix 0810156CFHI
	B1	IA18-2003	ZeptoMetrix 0810162CFH
	B1	Peru3-2003	ZeptoMetrix 0810158CFHI
	B2	Peru6-2003	ZeptoMetrix 0810159CFHI
	B2	Peru1-2002	ZeptoMetrix 0810157CFHI
	A1	hMPV-16, IA10-2003	ZeptoMetrix 0810161CFHI
	A1	IA3-2002	ZeptoMetrix 0810160CFHI
	A2	IA14-2003	ZeptoMetrix 0810163CFH

Table 9. List of Analytical Reactivity pathogens tested (continued)

Pathogen	Subtype/serotype	Strain	Source
Human Metapneumovirus	B1	Peru2-2002	ZeptoMetrix 0810156CFHI
	B1	IA18-2003	ZeptoMetrix 0810162CFH
	B1	Peru3-2003	ZeptoMetrix 0810158CFHI
	B2	Peru6-2003	ZeptoMetrix 0810159CFHI
	B2	Peru1-2002	ZeptoMetrix 0810157CFHI
	A1	hMPV-16, IA10-2003	ZeptoMetrix 0810161CFHI
	A1	IA3-2002	ZeptoMetrix 0810160CFHI
	A2	IA14-2003	ZeptoMetrix 0810163CFH
C. pneumoniae	Not available	CWL-029	ATCC VR-1310
M. pneumoniae	1	PI 1428	ATCC 29085
	Not available	M129	ZeptoMetrix NATMPN(M129)-ERCM
	Not available	M129-B7	ATCC 29342
	Not available	FH strain of Eaton Agent [NCTC 10119]	ATCC 15531

Table 9. List of Analytical Reactivity pathogens tested (continued)

Pathogen	Subtype/serotype	Strain	Source
L. pneumophila	Not available	CA1	ATCC 700711
		Legionella pneumophila subsp. Pneumophila/169-MN-H	ATCC 43703
		Not available	ZeptoMetrix MB-004 (lot 317955)
		subsp. Pneumophila/Philadelphia-1	ATCC 33152
B. pertussis	Not available	I028	ATCC BAA-2707
		A639	ZeptoMetrix NATRVP-IDI
		18323 [NCTC 10739]	ATCC 9797

All pathogens tested showed positive results at the concentration tested.

Co-Infections

A co-infections study was performed to verify that multiple QIAstat-Dx Respiratory SARS-CoV-2 Panel analytes included in one nasopharyngeal swab sample can be detected.

High and low concentrations of different organisms were combined in one sample. Selection of organisms was made based on relevance, prevalence, and layout of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge (distribution of targets in different reaction chambers).

Analytes were spiked into simulated NPS sample matrix (cultured human cells in UTM) in high (50x LoD concentration) and low concentrations (5x LoD concentration) and tested in different combinations. Table 10 shows the combination of co-infections tested in this study.

Table 10. List of co-infections combinations tested

Pathogens	Strain	Concentration
Influenza A/H3N2 Adenovirus C5	A/Virginia/ATCC6/2012 Adenoid 75	50x LoD 5x LoD
Influenza A/H3N2 Adenovirus C5	A/Virginia/ATCC6/2012 Adenoid 75	5x LoD 50x LoD
Parainfluenza 3 Influenza A/H1N1/2009	C243 NY/03/09	50x LoD 5x LoD
Parainfluenza 3 Influenza A/H1N1/2009	C243 NY/03/09	5x LoD 50x LoD
Respiratory Syncytial Virus A Influenza B	A2 B/FL/04/06	50x LoD 5x LoD
Respiratory Syncytial Virus A Influenza B	A2 B/FL/04/06	5x LoD 50x LoD
Adenovirus C5 Rhinovirus B, Type HRV-B14	Adenoid 75 1059	50x LoD 5x LoD
Adenovirus C5 Rhinovirus B, Type HRV-B14	Adenoid 75 1059	5x LoD 50x LoD
Respiratory Syncytial Virus A Rhinovirus B, Type HRV-B14	A2 1059	50x LoD 5x LoD
Respiratory Syncytial Virus A Rhinovirus B, Type HRV-B14	A2 1059	5x LoD 50x LoD
Respiratory Syncytial Virus B Bocavirus	9320 Not available	50x LoD 5x LoD
Respiratory Syncytial Virus B Bocavirus	9320 Not available	5x LoD 50x LoD
Coronavirus OC43 Rhinovirus B, Type HRV-B14	Not available 1059	50x LoD 5x LoD

Table 10. List of co-infections combinations tested (continued)

Pathogens	Strain	Concentration
Coronavirus OC43 Rhinovirus B, Type HRV-B14	Not available 1059	5x LoD 50x LoD
Human Metapneumovirus B2 Parainfluenza 1	Peru6-2003 C-35	50x LoD 5x LoD
Human Metapneumovirus B2 Parainfluenza 1	Peru6-2003 C-35	5x LoD 50x LoD
Coronavirus 229E Respiratory Syncytial Virus A	Not available A2	50x LoD 5x LoD
Coronavirus 229E Respiratory Syncytial Virus A	Not available A2	5x LoD 50x LoD
Respiratory Syncytial Virus B Coronavirus NL63	9320 Not available	50x LoD 5x LoD
Respiratory Syncytial Virus B Coronavirus NL63	9320 Not available	5x LoD 50x LoD

All co-infections tested gave a positive result for the two pathogens combined at low and high concentrations. No effect in results are observed due to the presence of co-infections.

Interfering substances

The influence of potential interfering substances on the performance of the QIAstat-Dx Respiratory Panel was evaluated in this study. The interfering substances include endogenous as well as exogenous substances that are normally found in the nasopharynx or may be introduced into NPS specimens during specimen collection, respectively.

A set of selected samples that cover all the respiratory pathogens from the panel were used for the interfering substances testing. Interfering substances were spiked into the selected samples at a level predicted to be above the concentration of the substance likely to be found in an

authentic nasopharyngeal swab specimen. The selected samples were tested with and without addition of the potential inhibitory substance for direct sample-to-sample comparison. Additionally, pathogen-negative samples were spiked with the potential inhibitory substances.

None of the tested substances showed interference with the Internal Control or the pathogens included in the combined sample. Table ,11, 12, and 13 show concentrations of the interfering substances tested for the QIAstat-Dx Respiratory Panel.

Table 11. Endogenous substances tested

Substance	Concentration
Human genomic DNA	50 ng/µL
Human whole blood	10% v/v
Human mucin	0.5% v/v

Table 12. Competitive microorganisms tested

Microorganism (source)	Concentration
Staphylococcus aureus (ATCC CRM-6538)	1.70E+08 CFU/mL
Streptococcus pneumoniae (ATCC 6303)	1.25E+07 CFU/mL
Haemophilus influenzae (ATCC 49766)	6.20E+08 CFU/mL
Candida albicans (ATCC CRM-10231)	1.00E+06 CFU/mL
Herpes Simplex Virus 1 (ATCC VR-1789)	1.60E+07 $TCID_{50}$/mL
Human Cytomegalovirus (ATCC NATCMV-0005)	2.0E+04 $TCID_{50}$/mL

Table 13. Exogenous substances tested

Substance	Concentration
Utabon® Nasal spray (decongestant)	10% v/v

Table 13. Exogenous substances tested (continued)

Substance	Concentration
Rhinomer®Nasal spray (salt water solutions)	10% v/v
Tobramycin	6 mg/mL
Mupirocin	2.5% w/v

Carryover

A carryover study was performed to evaluate the potential occurrence of cross-contamination between consecutive runs when using the QIAstat-Dx Respiratory SARS-CoV-2 Panel on the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 and the QIAstat-Dx Rise.

Samples of simulated NPS matrix, with alternating high-positive and negative samples, were conducted on one QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 and two QIAstat-Dx Rise instruments.

No carryover between samples was observed in the QIAstat-Dx Respiratory SARS-CoV-2 Panel.

Reproducibility

To prove reproducible performance of the QIAstat-Dx Respiratory Panel on the QIAstat-Dx Analyzer 1.0, a set of selected samples composed of low-concentrated analytes (3x LoD and 1x LoD) and negative samples was tested in transport medium liquid samples and in dry swab.

Transport medium liquid samples were tested in replicates using different lots of QIAstat-Dx Respiratory Panel Cartridges and tests were executed on different QIAstat-Dx Analyzers 1.0 by different operators on different days.

Reproducibility and repeatability will impact the SARS-CoV-2 target in the same manner as other target organisms verified in the QIAstat-Dx Respiratory Panel.

Table 14. List of respiratory pathogens tested for performance reproducibility in transport medium liquid samples

Pathogen	Strain
Influenza A H1	A/New Jersey/8/76
Influenza A H3	A/Virginia/ATCC6/2012
Influenza A H1N1 pdm	A/SwineNY/03/2009
Influenza B	B/FL/04/06
Coronavirus 229E	Not available
Coronavirus OC43	Not available
Coronavirus NL63	Not available
Coronavirus HKU1	Not available
Parainfluenza Virus 1	C35
Parainfluenza Virus 2	Greer
Parainfluenza Virus 3	C 243
Parainfluenza Virus 4a	M-25
Rhinovirus	A16
Enterovirus	/US/IL/14-18952 (enterovirus D68)
Adenovirus	RI-67 (adenovirus E4)
RSV B	9320
hMPV	Peru6-2003 (type B2)
Bocavirus	Clinical sample
Mycoplasma pneumoniae	M129-B7 (type 1)
Chlamydophila pneumoniae	TW183

Table 14. List of respiratory pathogens tested for performance reproducibility in transport medium liquid samples (continued)

Pathogen	Strain
Legionella pneumophila	CA1
Bordetella pertussis	I028

Table 15. Summary of Positive Agreement/Negative Agreement for reproducibility testing in dry swab samples

Concentration	Pathogen	Expected result	Detection rate	% Agreement with Expected Tesult
3x LoD	Influenza A H1*	Positive	20/20	100
	Coronavirus HKU1	Positive	20/20	100
	PIV-2	Positive	20/20	100
	C. pneumoniae	Positive	20/20	100
	RSVB	Positive	20/20	100
1x LoD	Influenza A H1*	Positive	20/20	100
	Coronavirus HKU1	Positive	19/20	95
	PIV-2	Positive	19/20	95
	C. pneumoniae	Positive	20/20	100
	RSVB	Positive	20/20	100
Negative	Influenza A H1*	Negative	80/80	100
	Coronavirus HKU1	Negative	80/80	100
	PIV-2	Negative	80/80	100
	C. pneumoniae	Negative	80/80	100
	RSVB	Negative	80/80	100
3x LoD	Bocavirus	Positive	20/20	100
1x LoD	Bocavirus	Positive	20/20	100

Table 15. Summary of Positive Agreement/Negative Agreement for reproducibility testing in dry swab samples (continued)

Concentration	Pathogen	Expected result	Detection rate	% Agreement with Expected Tesult
Negative	Bocavirus	Negative	80/80	100
3x LoD	Influenza B	Positive	20/20	100
	Coronavirus 229E	Positive	20/20	100
	PIV-4a	Positive	20/20	100
	Enterovirus D68	Positive	20/20	100
	hMPV B2	Positive	20/20	100
	B. pertussis	Positive	20/20	100
1x LoD	Influenza B	Positive	19/20	95
	Coronavirus 229E	Positive	20/20	100
	PIV-4a	Positive	20/20	100
	Enterovirus D68	Positive	19/20	95
	hMPV B2	Positive	19/20	95
	B. pertussis	Positive	20/20	100
Negative	Influenza B	Negative	80/80	100
	Coronavirus 229E	Negative	80/80	100
	PIV-4a	Negative	80/80	100
	Enterovirus D68	Negative	80/80	100
	hMPV B2	Negative	80/80	100
	B. pertussis	Negative	80/80	100

Table 15. Summary of Positive Agreement/Negative Agreement for reproducibility testing in dry swab samples (continued)

Concentration	Pathogen	Expected result	Detection rate	% Agreement with Expected Tesult
3x LoD	Influenza H1N1 (pdm)†	Positive	20/20	100
	Coronavirus OC43	Positive	20/20	100
	PIV-3	Positive	20/20	100
	Rhinovirus A16	Positive	20/20	100
	M. pneumoniae	Positive	20/20	100
3x LoD	Influenza H1N1 (pdm)†	Positive	20/20	100
	Coronavirus OC43	Positive	20/20	100
	PIV-3	Positive	20/20	100
	Rhinovirus A16	Positive	20/20	100
	M. pneumoniae	Positive	20/20	100
1x LoD	Influenza H1N1 (pdm)†	Positive	20/20	100
	Coronavirus OC43	Positive	20/20	100
	PIV-3	Positive	20/20	100
	Rhinovirus A16	Positive	20/20	100
	M. pneumoniae	Positive	20/20	100
Negative	Influenza H1N1 (pdm)†	Negative	80/80	100
	Coronavirus OC43	Negative	80/80	100
	PIV-3	Negative	80/80	100
	Rhinovirus A16	Negative	80/80	100
	M. pneumoniae	Negative	80/80	100

Table 15. Summary of Positive Agreement/Negative Agreement for reproducibility testing in dry swab samples (continued)

Concentration	Pathogen	Expected result	Detection rate	% Agreement with Expected Tesult
3x LoD	Influenza A H3‡	Positive	20/20	100
	Coronavirus NL63	Positive	20/20	100
	PIV-1	Positive	20/20	100
	Adenovirus E4	Positive	20/20	100
	L. pneumophila	Positive	20/20	100
1x LoD	Influenza A H3‡	Positive	19/20	95
	Coronavirus NL63	Positive	20/20	100
	PIV-1	Positive	20/20	100
	Adenovirus E4	Positive	20/20	100
	L. pneumophila	Positive	20/20	100
Negative	Influenza A H3‡	Negative	80/80	100
	Coronavirus NL63	Negative	80/80	100
	PIV-1	Negative	80/80	100
	Adenovirus E4	Negative	80/80	100
	L. pneumophila	Negative	80/80	100

*Detection rate applies for both targets, Influenza A and H1.

† Detection rate applies for both targets, Influenza A and H1/pandemic.

‡ Detection rate applies for both targets, Influenza A and H3.

Dry swab samples were tested in replicates using different lots of QIAstat-Dx Respiratory Panel Cartridges and tests were executed on different QIAstat-Dx Analyzers 1.0 by different operators, different sites and on different days.

A representative pathogens panel was selected to include at least one RNA virus, one DNA virus and one bacteria covering all (8) Reaction Chambers of the QIAstat-Dx® Respiratory SARS-CoV-2 Panel cartridge

Table 16. List of respiratory pathogens tested for performance reproducibility in dry swab samples

Pathogen	Strain
Influenza B	B/FL/04/06
Coronavirus OC43	Not available
Parainfluenza Virus 3	C 243
Rhinovirus	HGP (rhinovirus A2)
Adenovirus	GB (adenovirus B3)
Mycoplasma pneumoniae	P 1428
SARS-CoV-2	England/02/2020

Table 17. Summary of Positive Agreement/Negative Agreement for reproducibility testing in dry swab samples

Pathogen	Site	Expected result	Detection rate	% Agreement with Expected Result
		3x LoD		
Influenza B	Site 1	Positive	30/30	100
	Site 2	Positive	30/30	100
	Site 3	Positive	30/30	100
	All	Positive	90/90	100
Coronavirus OC43	Site 1	Positive	30/30	100
	Site 2	Positive	30/30	100
	Site 3	Positive	30/30	100
	All	Positive	90/90	100

Table 17. Summary of Positive Agreement/Negative Agreement for reproducibility testing in dry swab samples (continued from previous page)

Pathogen	Site	Expected result	Detection rate	% Agreement with Expected Result
PIV-3	Site 1	Positive	30/30	100
	Site 2	Positive	30/30	100
	Site 3	Positive	30/30	100
	All	Positive	90/90	100
Influenza B	Site 1	Positive	30/30	100
	Site 2	Positive	30/30	100
	Site 3	Positive	30/30	100
	All	Positive	90/90	100
Coronavirus OC43	Site 1	Positive	30/30	100
	Site 2	Positive	30/30	100
	Site 3	Positive	30/30	100
	All	Positive	90/90	100
PIV-3	Site 1	Positive	30/30	100
	Site 2	Positive	30/30	100
	Site 3	Positive	30/30	100
	All	Positive	90/90	100
Rhinovirus	Site 1	Positive	30/30	100
	Site 2	Positive	30/30	100
	Site 3	Positive	30/30	100
	All	Positive	90/90	100

Table 17. Summary of Positive Agreement/Negative Agreement for reproducibility testing in dry swab samples (continued from previous page)

Pathogen	Site	Expected result	Detection rate	% Agreement with Expected Result
Adenovirus	Site 1	Positive	30/30	100
	Site 2	Positive	30/30	100
	Site 3	Positive	30/30	100
	All	Positive	90/90	100
M. pneumoniae	Site 1	Positive	30/30	100
	Site 2	Positive	30/30	100
	Site 3	Positive	30/30	100
	All	Positive	90/90	100
SARS-CoV-2	Site 1	Positive	30/30	100
	Site 2	Positive	30/30	100
	Site 3	Positive	30/30	100
	All	Positive	90/90	100
		1x LoD		
Influenza B	Site 1	Positive	30/30	100
	Site 2	Positive	30/30	100
	Site 3	Positive	30/30	100
	All	Positive	90/90	100
Coronavirus OC43	Site 1	Positive	30/30	100
	Site 2	Positive	30/30	100
	Site 3	Positive	30/30	100
	All	Positive	90/90	100

Table 17. Summary of Positive Agreement/Negative Agreement for reproducibility testing in dry swab samples (continued from previous page)

Pathogen	Site	Expected result	Detection rate	% Agreement with Expected Result
PIV-3	Site 1	Positive	28/30	93.3
	Site 2	Positive	29/30	96.6
	Site 3	Positive	29/30	96.6
	All	Positive	86/90	95.6
Rhinovirus	Site 1	Positive	30/30	100
	Site 2	Positive	30/30	100
	Site 3	Positive	30/30	100
	All	Positive	90/90	100
Adenovirus	Site 1	Positive	30/30	100
	Site 2	Positive	30/30	100
	Site 3	Positive	30/30	100
	All	Positive	90/90	100
M. pneumoniae	Site 1	Positive	30/30	100
	Site 2	Positive	30/30	100
	Site 3	Positive	28/30	93.3
	All	Positive	88/90	97.8
SARS-CoV-2	Site 1	Positive	30/30	100
	Site 2	Positive	30/30	100
	Site 3	Positive	30/30	100
	All	Positive	90/90	100
		Negative		

Table 17. Summary of Positive Agreement/Negative Agreement for reproducibility testing in dry swab samples (continued from previous page)

Pathogen	Site	Expected result	Detection rate	% Agreement with Expected Result
All	Site 1	Negative	690/690	100
	Site 2	Negative	690/690	100
	Site 3	Negative	690/690	100
	All	Negative	2070/2070	100

All samples tested generated the expected result (95–100% agreement) showing reproducible performance of the QIAstat-Dx Respiratory Panel.

Reproducibility testing demonstrated that the QIAstat-Dx Respiratory Panel running in the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 provides highly reproducible test results when the same samples are tested in multiple runs, on multiple days, with multiple sites, with various operators using different QIAstat-Dx Analyzers 1.0, and multiple lots of QIAstat-Dx Respiratory Panel Cartridges.

A repeatability study was conducted on two QIAstat-Dx Rise instruments using a representative set of samples composed of low-concentrated analytes (3x LoD and 1x LoD) spiked into artificial NPS matrix and negative samples. Pathogens included in the positive samples were Influenza B, Coronavirus OC43, PIV3, Rhinovirus, Adenovirus, M. pneumoniae and SARS-CoV-2. Samples were tested in replicates using two lots of cartridges. The study included testing with eight QIAstat-Dx Analyzers for comparison. In total, 183 replicates of 1x LoD positive samples, 189 replicates of 3x LoD positive samples, and 155 replicates of negative samples were run. Overall results showed a 91.1-100.0% and 100.0% detection rate for 1x LoD and 3x LoD samples, respectively. Negative samples showed 100% of negative calls for all panel analytes. QIAstat-Dx Rise performance was shown to be equivalent to the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0.

Sample stability

A sample stability study was executed to analyze storage conditions for clinical samples (simulated sample matrix for transport medium liquid samples and for dry swab sample type) to be tested with the QIAstat-Dx Respiratory SARS-CoV-2 Panel.

Simulated NPS sample matrix (cultured human cells in Copan UTM) was spiked with viral or bacterial culture material of low concentration (e.g., 3x LoD). Samples were stored at the following conditions for testing:

- 15°C to 25°C for 4 hours
- 2°C to 8°C for 3 days
- –15°C to –25°C for 30 days
- –70°C to –80°C for 30 days

All pathogens were successfully detected at the different storage temperatures and durations showing that samples were stable at the indicated storage conditions and durations.

Sample stability in simulated sample matrix for transport medium was not performed for SARS-CoV-2 specifically. However, specimen stability testing was performed with Coronavirus 229E, HKU1, OC43 and NL63, pathogens from the same virus subfamily, with no impact on performance caused by storage of the samples prior to analysis under conditions stated above.

Simulating matrix of artificial NPS and HeLa cells was spiked with viral or bacterial culture material of low concentration (e.g., 1x LoD and 3x LoD) prior to addition on swab (dry swab sample type). Dry swab samples are recommended to be tested immediately after collection. However, additional sample stability testing was performed to allow additional time to take dry swab from collection location to the instrument. Samples were stored at the following conditions for testing:

- 15°C to 25°C for 45 minutes
- 2°C to 8°C for 7 hours

All pathogens were successfully detected at the different storage temperatures and durations showing that samples were stable at the indicated storage conditions and durations.

Appendices

Appendix A: Installing the Assay Definition File

The Assay Definition File of the QIAstat-Dx Respiratory SARS-CoV-2 Panel must be installed on the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 prior to testing with QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridges.

Note: For QIAstat-Dx Rise, please contact Technical Service or your sales representative to upload new assay definition files.

Note: Whenever a new version of the QIAstat-Dx Respiratory SARS-CoV-2 Panel assay is released, the new QIAstat-Dx Respiratory SARS-CoV-2 Panel Assay Definition File must be installed prior to testing.

Note: Assay Definition Files are available at **www.qiagen.com**. The Assay Definition File (**.asy** file type) must be saved onto a USB Drive prior to installation on the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0. This USB Drive must be formatted with a FAT32 file system.

To import new assays from the USB to the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0, proceed with the following steps:

1. Insert the USB stick containing the Assay Definition File into one of the USB ports on the QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0.
2. Press the **Options** button and then select Assay Management. The Assay Management screen appears in the Content area of the display (Figure 89).

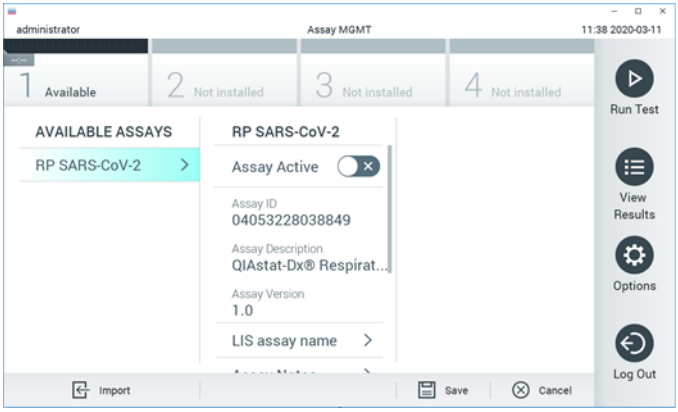

Figure 89. Assay Management screen.

3. Press the **Import** icon in the bottom left of the screen.
4. Select the file corresponding to the assay to be imported from the USB drive.
5. A dialog will appear to confirm upload of the file.
6. A dialog may appear to override the current version by a new one. Press **yes** to override.
7. The assay becomes active by selecting **Assay Active** (Figure 90).

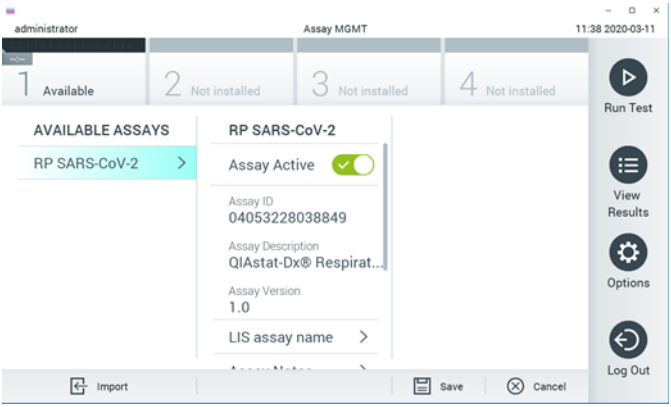

Figure 90. Activating the assay.

8. Assign the active assay to the user by pressing the **Options** button and then the **User Management** button. Select the user who should be allowed to run the assay. Next, select **Assign Assays** from the "User Options". Enable the assay and press the **Save** button (Figure 91).

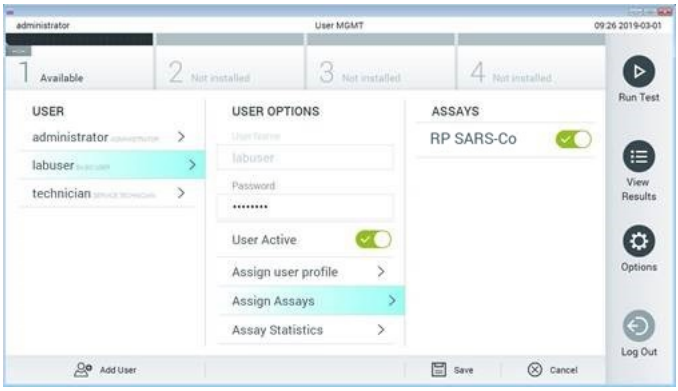

Figure 91. Assigning the active assay.

Appendix B: Glossary

Amplification curve: Graphical representation of the multiplex real-time RT-PCR amplification data.

Analytical Module (AM): The main QIAstat-Dx Analyzer 1.0 or the QIAstat-Dx Analyzer 2.0 hardware module, in charge of executing tests on QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridges. It is controlled by the Operational Module. Several Analytical Modules can be connected to one Operational Module.

QIAstat-Dx Analyzer 1.0: The QIAstat-Dx Analyzer 1.0 consists of an Operational Module and an Analytical Module. The Operational Module or one Operational Module PRO includes elements that provide connectivity to the Analytical Module and enables user interaction with the QIAstat-Dx Analyzer 1.0. The Analytical Module contains the hardware and software for sample testing and analysis.

QIAstat-Dx Analyzer 2.0: The QIAstat-Dx Analyzer 2.0 consists of an Operational Module PRO and an Analytical Module. The Operational Module PRO includes elements that provide connectivity to the Analytical Module and enables user interaction with the QIAstat-Dx Analyzer 2.0. The Analytical Module contains the hardware and software for sample testing and analysis.

QIAstat-Dx Rise: The QIAstat-Dx Rise Base is an in-vitro diagnostic device for use with QIAstat-Dx assays and QIAstat-Dx Analytical Modules, and provides full automation from sample preparation to real-time PCR detection for molecular applications. The system can be operated either in random access and batch testing, and the system throughput can be escalated up to 160 test/day by including up to 8 Analytical Modules. The system also includes a multi-test front drawer that can accommodate up to 18 tests at the same time, and a waste drawer to automatically discard the performed tests, enhancing the walk-away efficiency of the system

QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge: A self-contained disposable plastic device with all pre-loaded reagents required for the complete execution of fully automated molecular assays for the detection of respiratory pathogens.

IFU: Instructions For Use.

Main port: In the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge, inlet for transport medium liquid samples.

Nucleic acids: Biopolymers, or small biomolecules composed of nucleotides, which are monomers made of three components: a 5-carbon sugar, a phosphate group and a nitrogenous base.

Operational Module (OM): The dedicated QIAstat-Dx Analyzer 1.0 hardware that provides the user interface for 1–4 Analytical Modules (AM).

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

PCR: Polymerase Chain Reaction

RT: Reverse Transcription

Swab port: In the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge, inlet for dry swabs.

User: A person who operates the QIAstat-Dx Analyzer 1.0/QIAstat-Dx Analyzer 2.0/QIAstat-Dx Rise and QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge in the intended way.

Appendix C: Disclaimer of warranties

EXCEPT AS PROVIDED IN QIAGEN TERMS AND CONDITIONS OF SALE FOR THE QIAstat-Dx Respiratory SARS- CoV- 2 Panel Cartridge, QIAGEN ASSUMES NO LIABILITY WHATSOEVER AND DISCLAIMS ANY EXPRESS OR IMPLIED WARRANTY RELATING TO THE USE OF THE QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge 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.

References

1. Centers for Disease Control and Prevention (CDC). National Center for Immunization and Respiratory Diseases (NCIRD). Division of Viral Diseases (DVD) web site.
2. World Health Organization. WHO Fact Sheet No. 221, November 2016. Influenza (seasonal). **www.who.int/mediacentre/factsheets/fs211/en/index.html** . Accessed November 2016.
3. Flu.gov web site. About Flu. **www.cdc.gov/flu/about/index.html**
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9. Centers for Disease Control and Prevention (CDC). Diseases & Conditions: Pertussis (Whooping Cough). **www.cdc.gov/pertussis/**
10. Clinical and Laboratory Standards Institute (CLSI) Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline (M29).
11. BLAST: Basic Local Alignment Search Tool. **https://blast.ncbi.nlm.nih.gov/Blast.cgi**

12. Schreckenberger, P.C. and McAdam, A.J. (2015) Point-counterpoint: large multiplex PCR panels should be first-line tests for detection of respiratory and intestinal pathogens. *J Clin Microbiol 53*(10), 3110–3115.

13. Centers for Disease Control and Prevention (CDC). Diseases & Conditions: Coronavirus (COVID-19). **www.cdc.gov/coronavirus/2019-ncov/index.html**

Symbols

This table describes the symbols that may appear on the labeling or in this document.

 <N>	Contains reagents sufficient for <N> reactions
	Use by
	In vitro diagnostic medical device
	Catalog number
	Lot number
	Material number (i.e., component labeling)
	Upper respiratory application
Rn	R is for revision of the Handbook and n is the revision number
	Temperature limitation
	Manufacturer
	Consult instructions for use
	Caution
	CE marking for European Conformity
	Serial number
	Do not reuse
	Keep away from sunlight
	Do not use if package is damaged
	Global Trade Item Number

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1. Centers for Disease Control and Prevention (CDC). National Center for Immunization and Respiratory Diseases (NCIRD). Division of Viral Diseases (DVD) web site.
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10. Clinical and Laboratory Standards Institute (CLSI) Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline (M29).
11. BLAST: Basic Local Alignment Search Tool. **https://blast.ncbi.nlm.nih.gov/Blast.cgi**

12. Schreckenberger, P.C. and McAdam, A.J. (2015) Point-counterpoint: large multiplex PCR panels should be first-line tests for detection of respiratory and intestinal pathogens. *J Clin Microbiol 53*(10), 3110–3115.

13. Centers for Disease Control and Prevention (CDC). Diseases & Conditions: Coronavirus (COVID-19). **www.cdc.gov/coronavirus/2019-ncov/index.html**

Ordering Information

Product	Contents	Cat. no.
QIAstat-Dx Respiratory SARS CoV-2 Panel	For 6 tests: 6 individually packaged QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridges and 6 individually packaged transfer pipettes	691214
Related products		
QIAstat-Dx Analyzer 1.0	1 QIAstat-Dx Analytical Module, 1 QIAstat-Dx Operational Module and related hardware and software to run molecular diagnostic QIAstat-Dx assay cartridges	9002824
QIAstat-Dx Analyzer 2.0	1 QIAstat-Dx Analytical Module, 1 QIAstat-Dx Operational Module PRO and related hardware and software to run molecular diagnostic QIAstat-Dx assay cartridges	9002828
QIAstat-Dx Rise	1 QIAstat-Dx Rise instrument and related accessories and software to run molecular diagnostic QIAstat-Dx assay cartridges	9003163

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

Instructions for Use (Handbook) Document Revision History

Date	Changes
Version 2, Revision 1	Release of SW Version 2.2
Version 2, Revision 2	Inclusion of QIAstat-Dx Analyzer 2.0

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