May 2025

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

Σ 6

Version 1

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 691215

QIAGEN GmbH, QIAGEN Strasse 1, 40724 Hilden, GERMANY

R2 MAT

Sample to Insight

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Intended Use

The QIAstat-Dx® Respiratory SARS-CoV-2 Panel (cat. no. 691215) is a qualitative test intended for analyzing nasopharyngeal swab (NPS) samples taken from symptomatic patients suspected of respiratory infection for the presence of viral or bacterial nucleic acids. The assay is designed for use with the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and the QIAstat-Dx Rise for automated integrated nucleic acid extraction and multiplex real-time RT-PCR detection of nucleic acids in the sample.

QIAstat-Dx Respiratory SARS-CoV-2 Panel detects and differentiates* Adenovirus, Bocavirus, Coronavirus 229E, Coronavirus OC43, Coronavirus NL63, Coronavirus HKU1, SARS-CoV-2, Human Metapneumovirus A+B, Influenza A, Influenza A H1N1/pdm09, Influenza A H1, Influenza A H3, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Respiratory Syncytial Virus A+B, Rhinovirus/Enterovirus, *Bordetella pertussis, Chlamydophila pneumoniae, Legionella pneumophila,* and *Mycoplasma pneumoniae*.

The QIAstat-Dx Respiratory SARS-CoV-2 Panel is an aid in diagnosis of respiratory infections from symptomatic patients.

The results from the QIAstat-Dx Respiratory SARS-CoV-2 Panel must be interpreted within the context of all relevant clinical and laboratory findings. 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 but in conjunction with other clinical, laboratory, and epidemiological data.

Positive results do not rule out co-infection with other organisms not included in the QIAstat-Dx Respiratory SARS-CoV-2 Panel.

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

The agent or agents detected may not be the definite cause of the disease. Negative results do not preclude respiratory infection.

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 use by trained laboratory professionals only and is not intended for self-testing or near-patient testing.

For *in vitro* diagnostic use.

Description and Principle

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 (1). 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. A coverage of more than eleven million of available genome sequences have been analyzed to 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. The two targets are not differentiated, and amplification of either one or both regions leads to a fluorescence signal.

Pathogens (and subtypes) that can be detected and identified with the QIAstat-Dx Respiratory SARS-CoV-2 Panel are listed in Table 1 (2–15).

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

Pathogen	Classification (genome type)
Adenovirus	Adenovirus (DNA)
Bocavirus	Parvovirus (DNA)
Coronavirus 229E	Coronavirus (RNA)
Coronavirus OC43	Coronavirus (RNA)
Coronavirus NL63	Coronavirus (RNA)
Coronavirus HKU1	Coronavirus (RNA)
SARS-CoV-2	Coronavirus (RNA)
Human Metapneumovirus A+B	Paramyxovirus (RNA)
Influenza A	Orthomyxovirus (RNA)
Influenza A H1N1/pdm09	Orthomyxovirus (RNA)
Influenza A H1	Orthomyxovirus (RNA)
Influenza A H3	Orthomyxovirus (RNA)
Influenza B	Orthomyxovirus (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)
Rhinovirus/Enterovirus	Picornavirus (RNA)
Bordetella pertussis	Bacterium (DNA)
Chlamydophila pneumoniae	Bacterium (DNA)
Legionella pneumophila	Bacterium (DNA)

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

Pathogen	Classification (genome type)
Mycoplasma pneumoniae	Bacterium (DNA)

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

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 (16). The main features of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge include compatibility with respiratory NPS directly using dry NPS (e.g. Copan® FLOQSwabs®, cat. no. 503CS01 / 550C) and NPS in universal transport medium (UTM), 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 (17).

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, or 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.

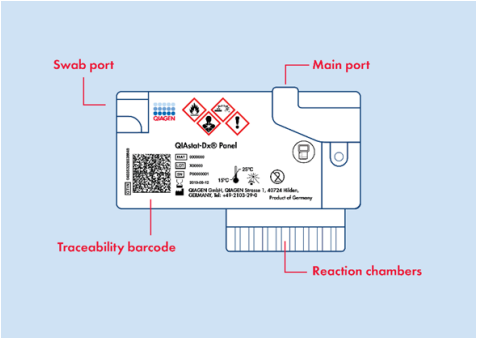


Figure 1. Layout of the QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge and its features.

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, or 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 processing option:

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

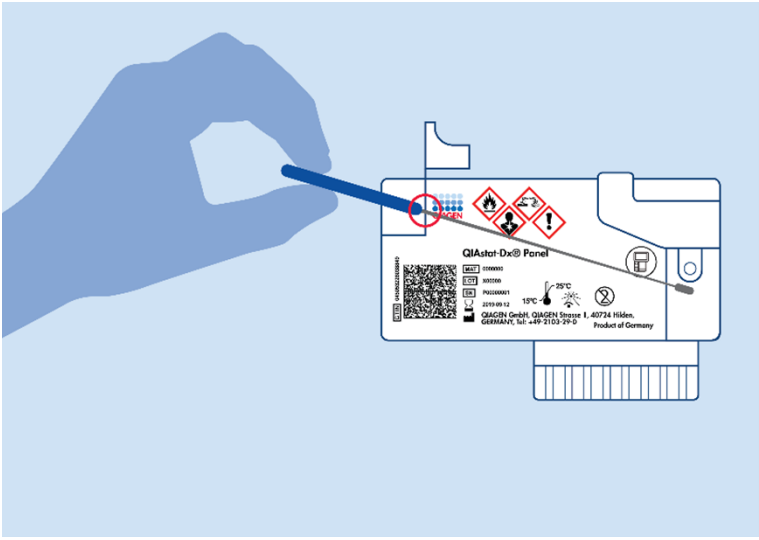


Figure 2. Loading the dry NPS into the swab port.

Option 2: A transfer pipette is used for dispensing NPS in universal transport medium (UTM) into the main port (Figure 3)

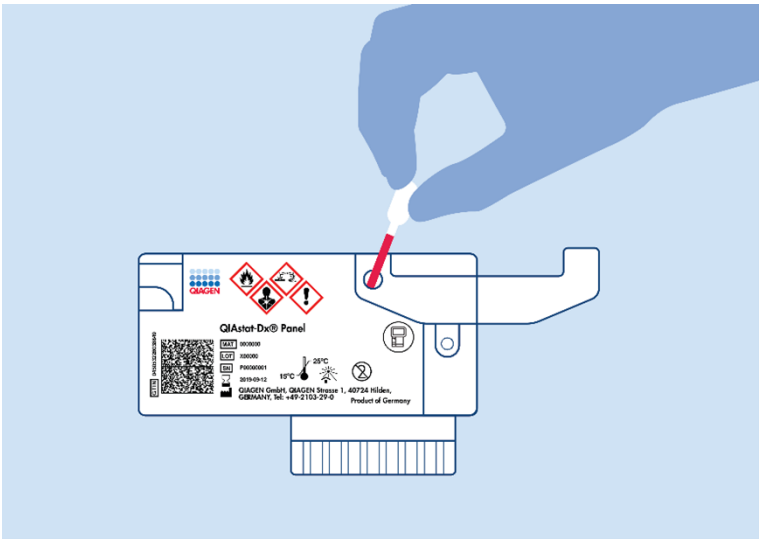


Figure 3. Dispensing NPS in universal transport medium into the main port.

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 universal transport medium only in the case of NPS in universal transport medium processing option.
3. The sample information can either be manually written or a sample label affixed to the top of a in the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge. In case of using QIAstat-Dx Rise, a label with the sample information must be affixed to the top of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge.
4. Sample is loaded manually into the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge:
    - Dry NPS: The nasopharyngeal swab is inserted into the swab port of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge.
    - NPS in Universal Transport medium: 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 NPS in universal transport medium, the user performs a visual check of the sample inspection window (see image below) to confirm that the sample has been loaded (Figure 4).

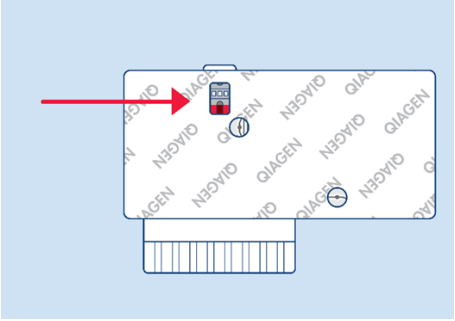


Figure 4. Sample inspection window (red arrow).

5. The sample barcode and the QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge QR code are scanned in the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, or QIAstat-Dx Rise.

   Important: Do not scan the barcode from the cartridge packaging.

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 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 contain 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 preps**	 **691215** **6**
QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge	6*
Transfer pipettes	6†

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

†Individually packaged transfer pipettes for dispensing liquid sample into the QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge.

Components of the cartridge

The principal components of the cartridge are explained below.

Table 2. Active reagents

Reagent	Active Ingredients	Concentration /Range
QIAstat-Dx Respiratory SARS-CoV-2 Cartridge	Internal Control	1000–10000 copies/cartridge
	Guanidine Hydrochloride	≥30%–<50%
	Guanidinium thiocyanate	≥30%–<50%
	t-Octylphenoxypolyethoxyethanol	≥2.5%–<10%
	Proteinase K	≥0.1%–<1%
	Polyethylene glycol	≥1%–<10%
	Ethanol	≥50%–<70%
	Isopropanol	≥30%–<50%
	Reverse Transcriptase	20–100 U/cartridge
	dNTPs	1–5 mM
	DNA Polymerase	10–100 U/cartridge
	Target specific primer	100–1000 µM
	Target specific fluorophore labelled detection Probe	100–1000 µM

Materials Required but Not Provided

Platform and software

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, QIAstat-Dx Analyzer 2.0, or QIAstat-Dx Rise
    - For QIAstat-Dx Analyzer 1.0: at least one Operational Module and one Analytical Module with software version 1.5*
    - For QIAstat-Dx Analyzer 2.0: at least one Operational Module PRO and one Analytical Module with software version 1.6 or later.
    - For QIAstat-Dx Rise: at least two Analytical Modules must be inside for the machine to work, with software version 2.4 or later.
- *QIAstat-Dx Analyzer 1.0 User Manual* (for use with software version 1.5); or *QIAstat-Dx Analyzer 2.0 User Manual* (for use with software version 1.6 or later); or *QIAstat-Dx Rise User Manual* (for use with software version 2.4 or later).
- QIAstat-Dx's latest Assay Definition File software for QIAstat-Dx Respiratory SARS-CoV-2 Panel installed on the Operational Module or Operational Module PRO, or on the QIAstat-Dx Rise.

Note: Application software version 1.6 or later cannot be installed on the QIAstat-Dx Analyzer 1.0.

*DiagCORE® Analyzer instruments running QIAstat-Dx® software version 1.5 can be used as an alternative to QIAstat-Dx® Analyzer 1.0 instruments.

External Control Information

Negative and positive external controls are not necessary but can be used.

All external quality control requirements and testing should be performed in accordance with local, state, and federal regulations or accreditation organizations and should follow the user's laboratory standard quality control procedures.

Warnings and Precautions

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 QIAstat-Dx Rise.

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

Safety information

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

Specimens and samples are potentially infectious. Follow your institution's safety procedures for handling biological samples. Discard sample and assay waste according to your local safety procedures.

Always wear appropriate personal protective equipment, including but not limited to disposable powder-free gloves, a lab coat, and protective eyewear. Protect skin, eyes and mucus membranes. Change gloves often when handling samples.

Handle all samples, 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) [18] or other appropriate documents provided by local authorities. 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.

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 (**www.ecdc.europa.eu/en/about-us/networks/disease-and-laboratory-networks/erlinet-biosafety**).

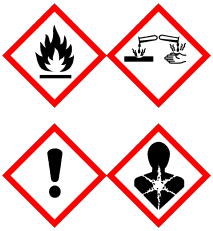
Emergency information

CHEMTREC

Outside USA & Canada +1 703-527-3887

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! Causes severe skin burns and eye damage. Harmful if swallowed or if inhaled. Harmful to aquatic life with long lasting effects. Highly flammable liquid and vapor. May be harmful in contact with skin. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause drowsiness or dizziness. Contact with acids liberates very toxic gas. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep cool. Use only outdoors or in a well-ventilated area. Avoid release to the environment. Wear protective gloves/ protective clothing/ eye protection/ face protection. In case of inadequate ventilation 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/ doctor. Rinse mouth. Do NOT induce vomiting. Remove person to fresh air and keep comfortable for breathing. Wash contaminated clothing before reuse. Store in a well-ventilated place. Keep container tightly closed. Dispose of contents/ container to an approved facility in accordance with local, regional, national and international regulations.

Disposal

Dispose of QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridges as hazardous waste in compliance with local and national regulations. This also applies to unused products. In case of damaged cartridge please refer to "Cartridge Storage and Handling" on the facing page.

Follow recommendations in the Safety Data Sheet (SDS).

Cartridge Storage and Handling

Store the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridges in a clean and dry 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. Once the cartridge is removed from the pouch, it should be protected from sunlight.

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 barcode, and is read by the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise when the cartridge is inserted into the instrument to run a test.

Attention should be paid to expiration dates and storage conditions printed on the box and labels of all components. Do not use expired or incorrectly stored components. In the event of cartridge damage, please refer to "Safety information" on page 19.

In-use stability

After the cartridge package is opened, sample should be introduced into the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge within 30 minutes. Sample-loaded cartridges should be loaded into the QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0 within 90 minutes or immediately into QIAstat-Dx Rise instrument.

Specimen Storage and Handling

The QIAstat-Dx Respiratory SARS-CoV-2 Panel is for use with Nasopharyngeal swab samples. All samples should be treated as potentially infectious. Discard sample and assay waste according to your local safety procedures.

Specimen collection

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

Dry NPS

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

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

NPS in Universal Transport Medium (UTM)

Recommended storage conditions for NPS (nasopharyngeal swab) specimens in Universal Transport Medium (UTM) 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 14 days at –25°C to –15°C

Procedure

Important points before starting

- Ensure all materials required but not provided are available.
- Select the QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge (cat. no. 691215). Respiratory panel cartridge identification is supported by a blue-colored bar on the label and an icon indicating respiratory tract (see "Symbols" on page 170).

  Note: NPS can be processed following two different processing options, either dry NPS or NPS in Universal Transport Medium (UTM) which are referred as Sample type on the Graphical User Interface and Results Report.

Sample collection, transport, and storage

Dry NPS

Collect samples using flocked nasopharyngeal swab (NPS) with 100 mm breaking point (e.g. Copan FLOQSwabs cat. no. 503CS01 / 553C) according to the manufacturer's recommended procedures.

NPS in Universal Transport Medium (UTM)

Collect samples using flocked nasopharyngeal swab (NPS) (e.g. Copan FLOQSwabs cat.no 503CS01 / 553C) 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

Dry NPS

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 or QIAstat-Dx Analyzer 2.0 within 120 minutes or QIAstat-Dx Rise within 30 minutes.

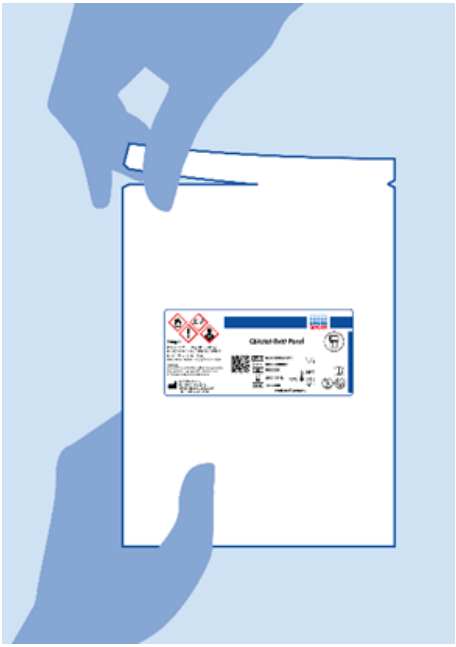


Figure 5. Opening the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge.

2. Remove the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge from the packaging and position it so that the barcode on the label faces you.
3. Manually write the sample information or place a sample barcode 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, if loading the cartridge in QIAstat-Dx Rise.

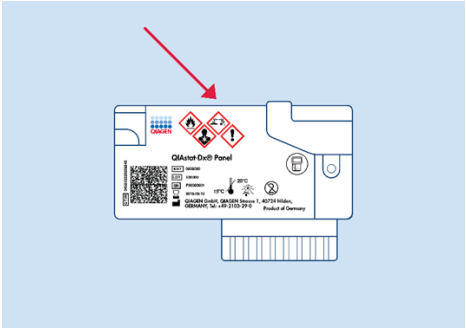


Figure 6. Sample information placement on top of QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge.

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).

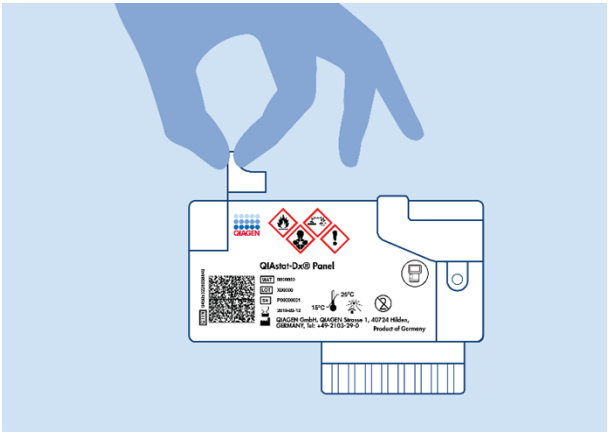


Figure 7. Opening the sample lid of swab port.

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

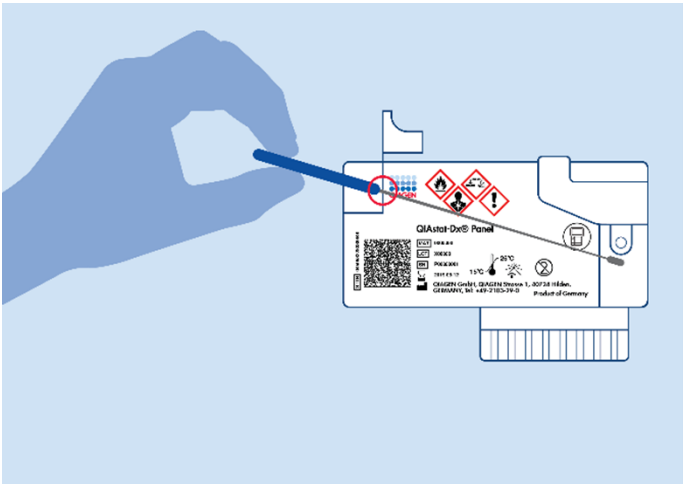


Figure 8. Inserting dry NPS into the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge.

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

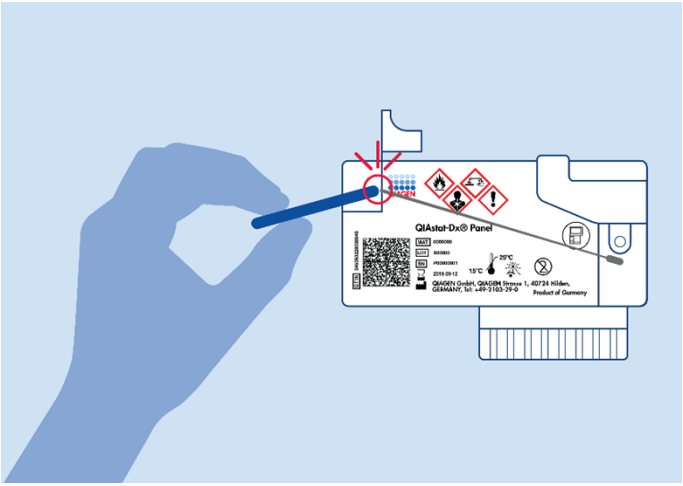


Figure 9. Breaking NPS shaft.

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 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 reject cartridges exceeding the maximum stability time.

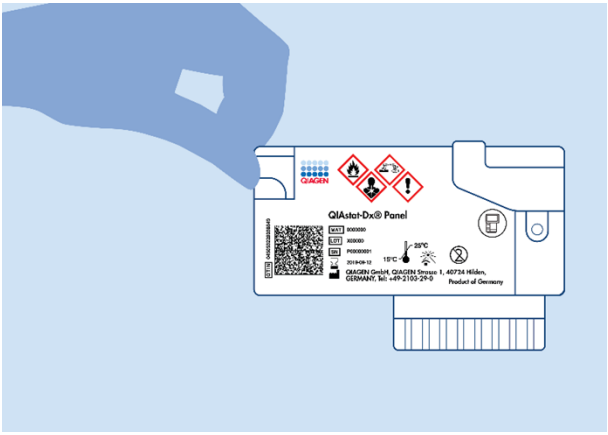


Figure 10. Closing the sample lid of the swab port.

NPS in Universal Transport Medium (UTM)

Note: Applicable for 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 11).

   Important: After the package is open, 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 QIAstat-Dx Rise within 30 minutes.

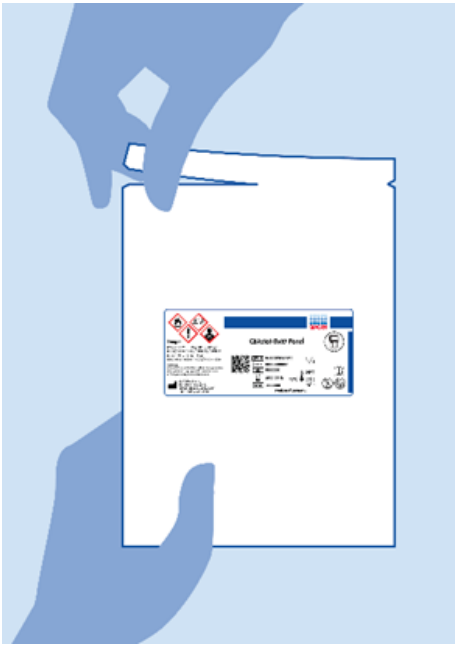


Figure 11. Opening the QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge.

2. Remove the QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge from the packaging and position it so that the QR 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 12). See the QIAstat-Dx Rise workflow section for proper cartridge labelling, if loading the cartridge in QIAstat-Dx Rise.

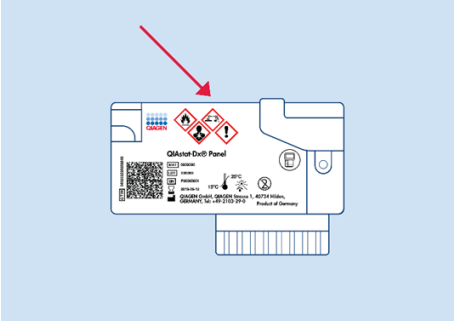


Figure 12. Sample information placement on top of QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge.

4. Open the sample lid of the main port on the front of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge (Figure 13).

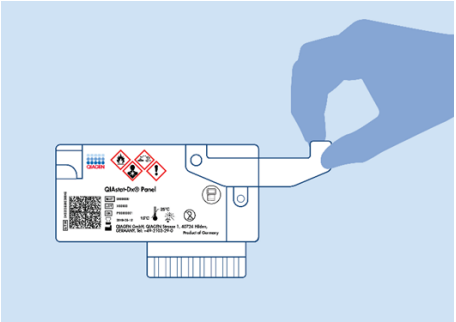


Figure 13. Opening the sample lid of main port.

5. Open the NPS in UTM tube 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 14).

   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 fluid in

the pipette back into the tube and draw up fluid again. Use alternative individually packed graduated pipettes in case all six pipettes provided with the kit have been used.

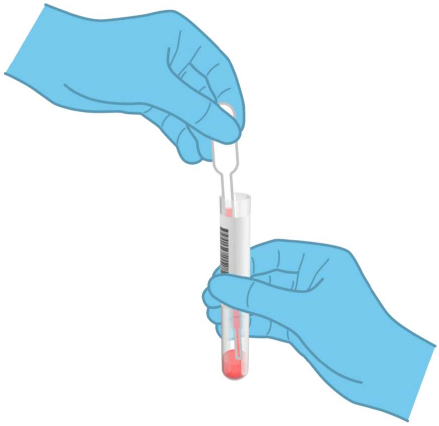


Figure 14. Drawing up sample into the supplied transfer pipette.

6. 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 15).

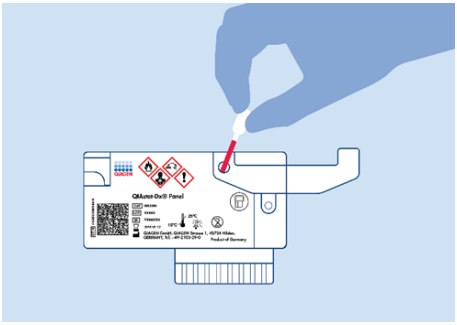


Figure 15. Dispensing universal transport medium into the main port.

7. Firmly close the sample lid of the main port until it clicks (Figure 16).

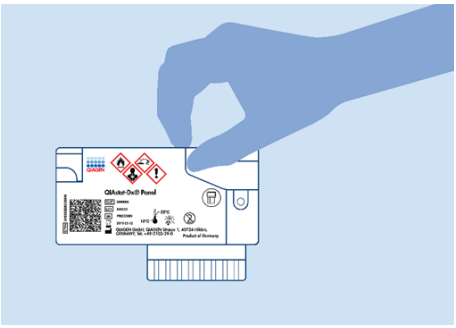


Figure 16. Closing the sample lid of the main port.

8. 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 17).

   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 QIAstat-Dx Analyzer 2.0 within 90 minutes; or immediately placed into the QIAstat-Dx Rise once all samples are loaded into the cartridges. The maximum waiting time of a cartridge that is already loaded in 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 reject cartridges exceeding the maximum stability time.

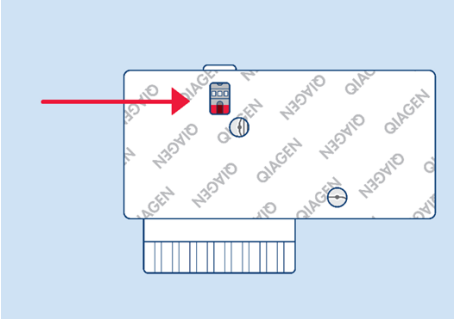


Figure 17. Sample inspection window (red arrow).

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

1. Power ON the QIAstat-Dx Analyzer 1.0 or 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 1.0or 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 QIAstat-Dx Analyzer 2.0 status indicators turn green and stop blinking.

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

   Note: The Login screen will appear if User Access Control is activated. If the User Access Control is disabled, no username/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 QIAstat-Dx Analyzer 2.0, follow the installation instructions prior to running the test (see

"Appendix A: Installing the Assay Definition File" on page 164 for additional information).

5. Press **Run Test** at the top right corner of the touchscreen of the QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0.
6. When prompted, manually type the sample ID or scan the sample ID barcode on nasopharyngeal swab (located on the swab blister packaging), or scan the specimen information barcode located on the top of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge (see step 3 in "Loading a sample into the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge" on page 26) using the integrated front barcode reader of the QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0.

   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 QIAstat-Dx Analyzer 2.0 appear in the Instructions Bar at the bottom of the touchscreen.

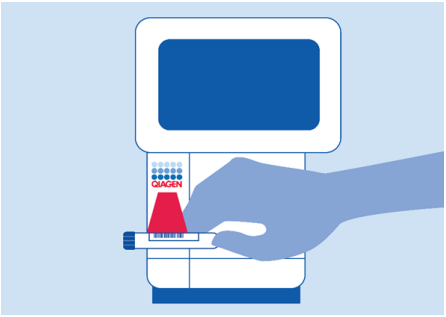


Figure 18. Scanning sample ID barcode.

7. When prompted, scan the barcode of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge to be used (Figure 19). The QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0 automatically recognizes the assay to be run based on the cartridge barcode.

   Note: The QIAstat-Dx Analyzer 1.0 and 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 Appendix A and also the *QIAstat-Dx Analyzer 1.0 User Manual* or *QIAstat-Dx Analyzer 2.0 User Manual* for further details on how to install assays.

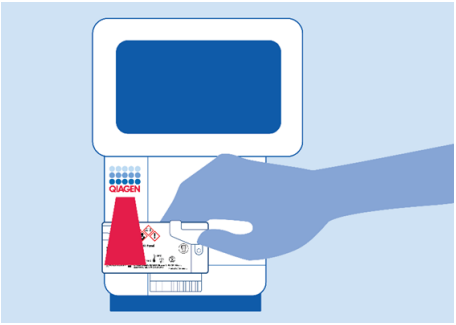


Figure 19. Scanning QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge barcode.

8. Select swab sample type option from the list (Figure 20) for the dry NPS processing option or UTM sample type option for the NPS in UTM processing option.

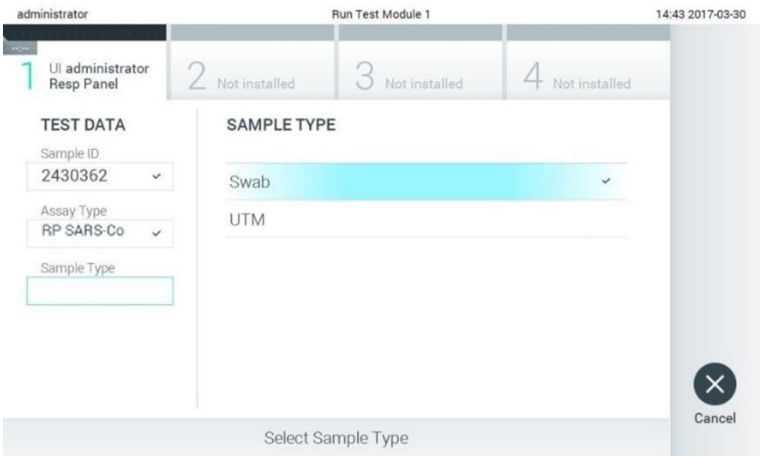


Figure 20. Selecting sample type.

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 21).

Figure 21. Confirming data entry.

11. Make sure that the 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 QIAstat-Dx Analyzer 2.0 automatically opens, insert the QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge with the barcode facing to the left and the reaction chambers facing down (Figure 22 below).

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

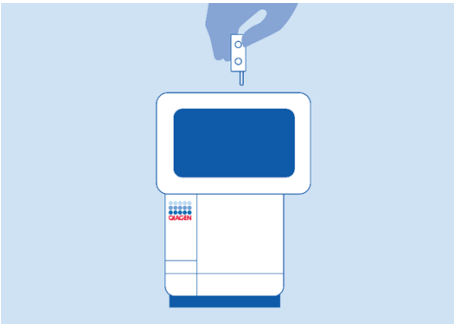


Figure 22. Inserting QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge into QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0.

12. Upon detecting the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge, the QIAstat-Dx Analyzer 1.0 or 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 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 **Cancel** at 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 10.

13. After the test run is completed, the **Eject** screen will appear (Figure 23) 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 User Manual* or *QIAstat-Dx Analyzer 2.0 User Manual* for possible reasons and instructions on how to proceed.

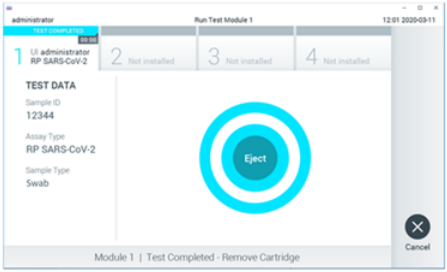


Figure 23. Eject screen display.

14. 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 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 canceled by the operator, or for which an error was detected.

15. After the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge has been ejected, the results Summary screen will appear. Refer to "Interpretation of Results" on page 62 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 or the QIAstat-Dx Analyzer 2.0, refer to the *QIAstat-Dx Analyzer 1.0 User Manual* or the *QIAstat-Dx Analyzer 2.0 User Manual*.

Running a test on the QIAstat-Dx Rise

Starting the QIAstat-Dx Rise

1. First, make sure the power switch at the rear connection box of the instrument is set in the "I" position. Then press the **ON/OFF** button on the front of the QIAstat-Dx Rise to start the unit.
2. Wait until the Login screen appears.
3. Log in to the system once the login screen appears (Figure 24).

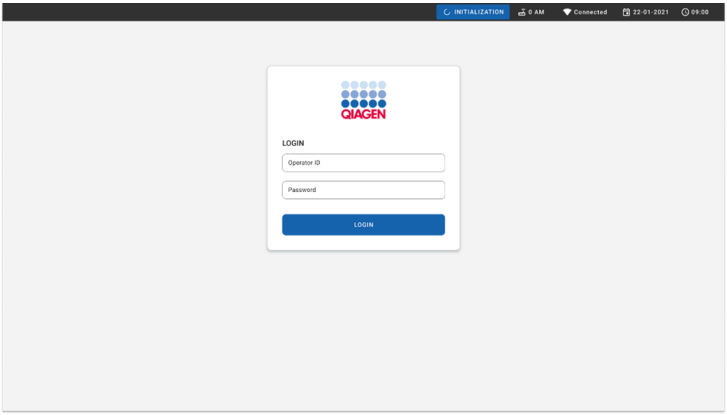


Figure 24. Login screen.

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

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" on page 26.

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 25. Placing sample ID barcode.

Important: 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 below with blue marked area), as the left side of the cartridge is critical for sample auto-detection (Figure 26).

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.

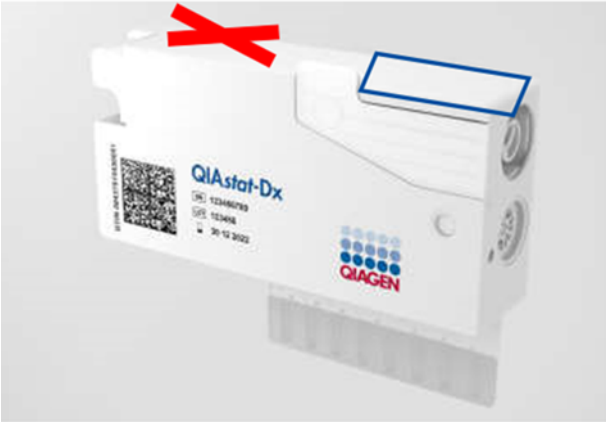


Figure 26. Positioning sample ID barcode.

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.

Note: 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 (1-D linear) or ISO/IEC 15415 (2D).

Procedure to run a test

Important: Check if the correct Assay Definition File software is installed on the QIAstat-Dx Rise, if not, check the *QIAstat-Dx Rise User Manual*.

Make sure that all installed Analytical Modules in the QIAstat-Dx Rise are operational.

1. Press **OPEN WASTE DRAWER** at the lower-right corner of the main test screen (Figure 27).
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 27). If the tray was removed for maintenance purposes, make sure it is correctly inserted before closing the drawer.
4. Press **OPEN INPUT DRAWER** on the lower-right corner of the screen (Figure 27).

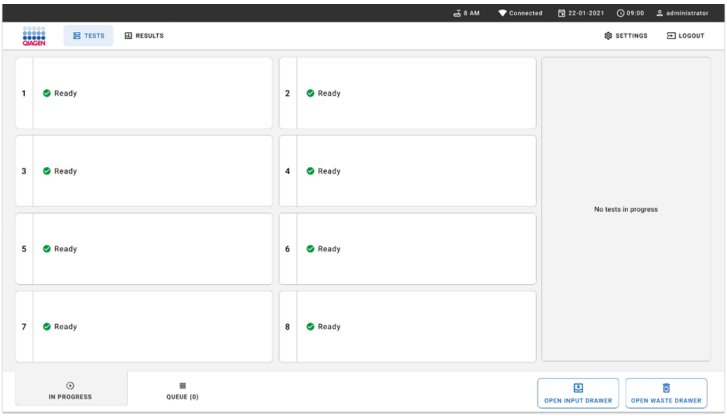


Figure 27. Main test screen.

5. Wait until the input drawer is unlocked (Figure 28).

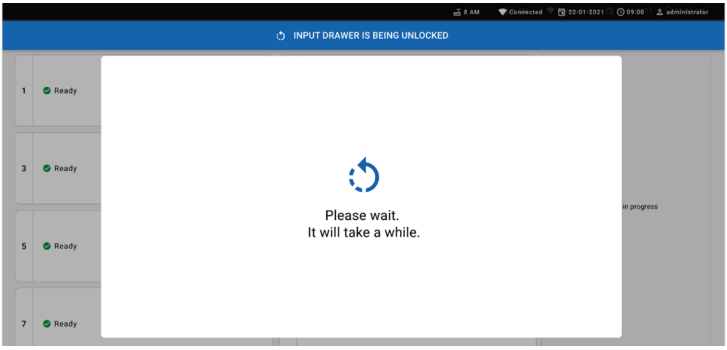


Figure 28. Input drawer waiting dialog box.

6. When prompted, pull the input drawer to open (Figure 29). Depending on instrument status it can take a while for the drawer to unlock.

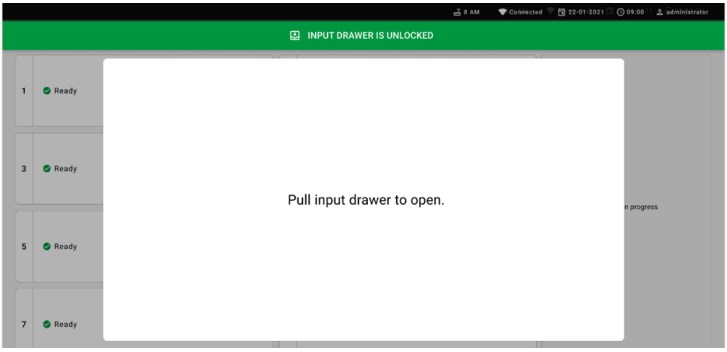


Figure 29. Input drawer open dialog box.

7. The **Add Cartridge** dialog box appears, and the scanner at the front of the instrument will be activated. Scan the sample ID barcode on top of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge (position indicated by the arrow (Figure 30) in front of the instrument.

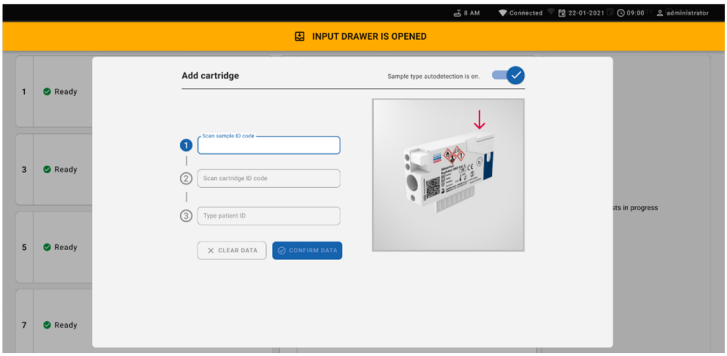


Figure 30. Scan sample ID screen.

8. After entering the sample ID barcode, scan the barcode of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge to be used (position indicated by the arrow) (Figure 31). The QIAstat-Dx Rise automatically recognizes the assay to be run, based on the QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge barcode (Figure 31).

   Important: Do not scan the barcode from the cartridge packaging.

9. If sample type auto-detection is set to on, the system will automatically recognize the sample type used. Sample type will be shown as auto-detected on the test details section of the sample queue screen. If sample type auto-detection is set to off, you might need to select the appropriate sample type manually. Sample type will be shown on the test details section of the sample queue screen.

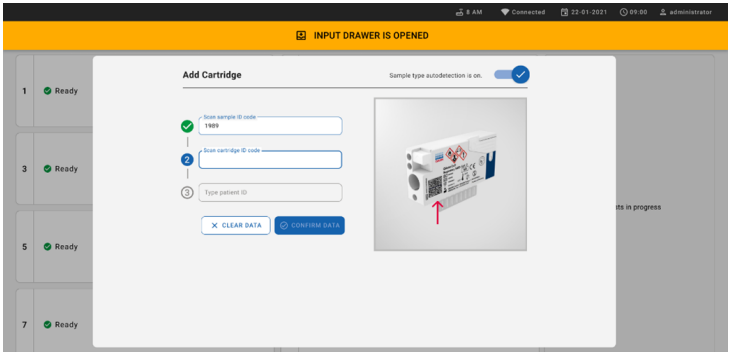


Figure 31. Scan cartridge ID screen.

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 these cases.

10. Type the Patient ID (Patient ID has to be set to **On**) then confirm the data (Figure 32).

    Note: To set Patient ID to on, go to **Settings** > **General Settings** > **Test** > **Edit**. Select **Yes** and press **Save**.

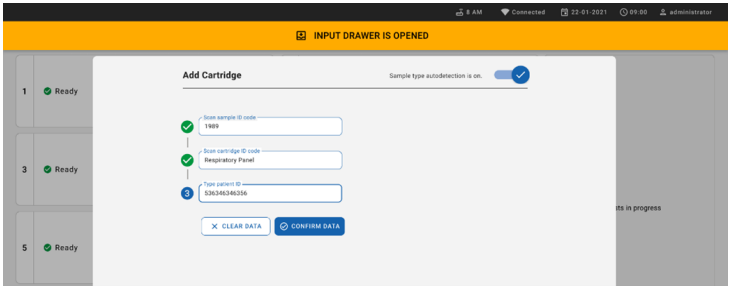


Figure 32. Type patient ID then confirm the data screen.

11. After a successful scan, the following dialog box appears briefly on top of the screen (Figure 33).

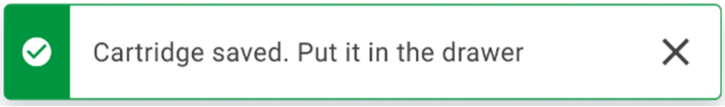


Figure 33. Cartridge saved dialog box.

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

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

    Important: Be aware that QIAstat-Dx Rise can handle multiple QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridges at the same time within the input drawer. Be also aware, that with software version 2.3, or higher, different panels can be inserted and processed simultaneously in the input drawer.

14. Close the input drawer when all cartridges have been manually scanned and inserted. The system will scan the cartridges and prepare a queue (Figure 34).

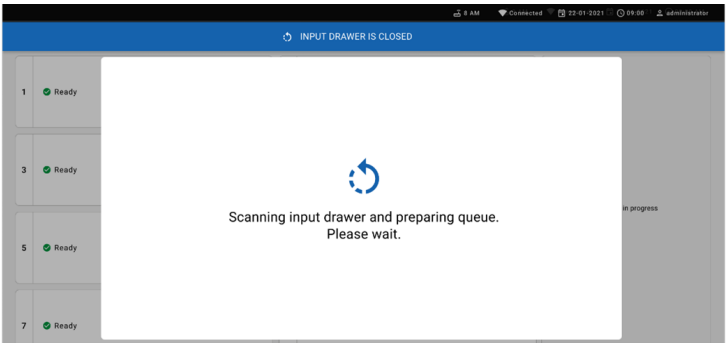


Figure 34. Preparing queue screen.

15. After successful scanning, the queue will be shown (Figure 35). Review the data shown. In case of an error, press the open input drawer button, remove the respective cartridge, and re-scan the cartridge. Already scanned cartridges can be removed or new cartridges can be added once the input drawer is opened.

    Note: During the run, if you need to open the input drawer for any reason (e.g. to load/unload cartridges) the system prepares the queue again so do not forget to confirm data to run again.

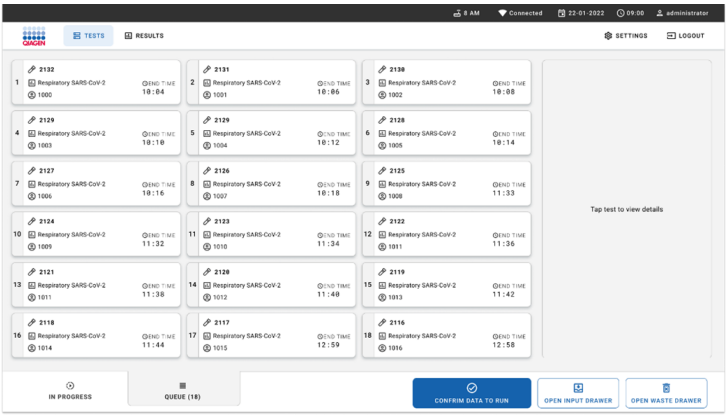


Figure 35. Sample queue screen.

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).

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 36).

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

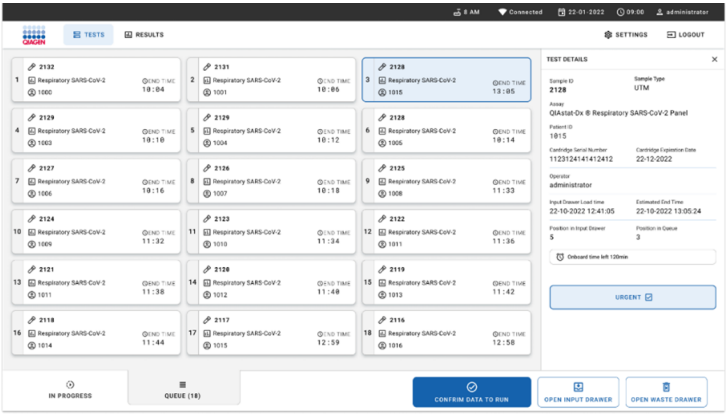


Figure 36. Sample queue screen with selected assay showing additional information.

The following information is shown in the **Test Details** section of the screen:

- Sample ID
- Sample Type (depends on assay and sample autodetection function)
- Assay
- Patient ID (if applicable)

- Cartridge serial number
- Cartridge expiration date
- Operator
- Input Drawer Load time
- Estimated end time
- Position in Input drawer
- Position in Queue (**Note**: the position may differ, based on sample stability time)
- On-board time left
- Urgent icon for prioritization functionality

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

16. Press **CONFIRM DATA TO RUN** at the bottom of the screen when all the displayed data are correct (Figure 36). Thereafter, a final confirmation is required from the operator to run the tests (Figure 37).

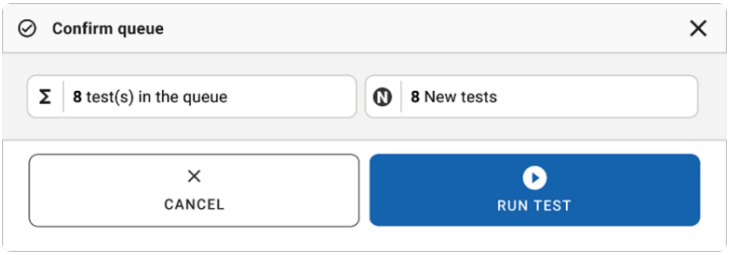


Figure 37. Confirm queue dialog box.

17. While the tests are running, the remaining run time and other information for all queued tests are displayed on the touchscreen (Figure 38).

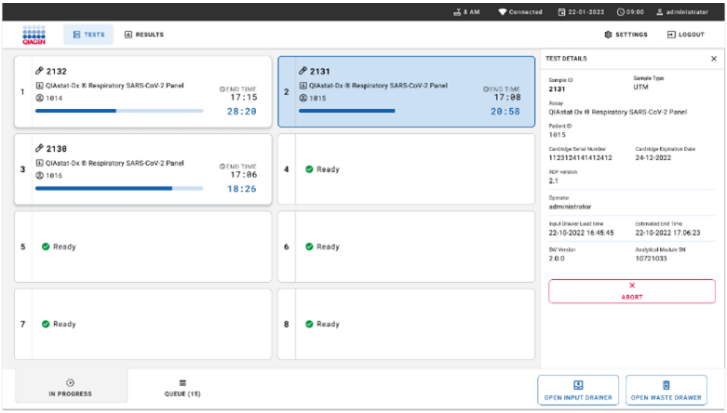


Figure 38. Test execution information on queue screen.

If the cartridge is being loaded into an Analytical Module, a **LOADING** message and the estimated end time are displayed (Figure 39).

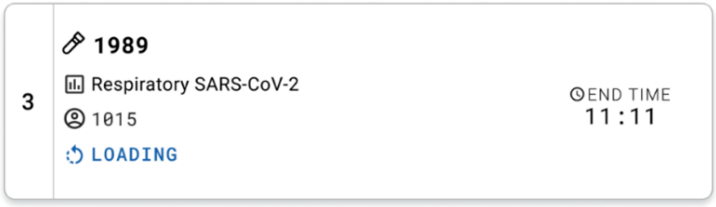


Figure 39. Test loading message and end time.

If the test is running, the elapsed run time and the approximate end time are being displayed (Figure 40).

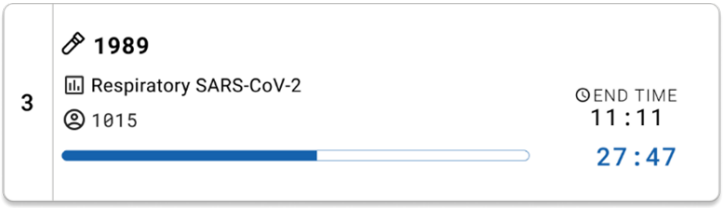


Figure 40. Elapsed run time and approximate end time view.

If the test is completed, a "TEST COMPLETED" message and the run end time is displayed (Figure 41).

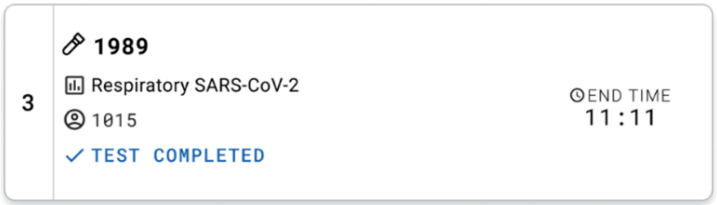


Figure 41. Test completed view.

Important: If the test fails, refer to the "Troubleshooting" section in the *QIAstat-Dx Rise User Manual* for possible reasons and instructions on how to proceed.

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 42). 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** at right-hand side of the sample queue screen before confirm data to run (Figure 42). Following this, the sample is

moved to the first position of the queue (Figure 43).

Note: Only one sample can be prioritized.

Note: If a cartridge has already been previously confirmed, it is required to open and close the input drawer to be able to prioritize the cartridge, 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 needs to switch between QUEUE and IN PROGRESS tabs on the screen to see the active **Urgent** button.

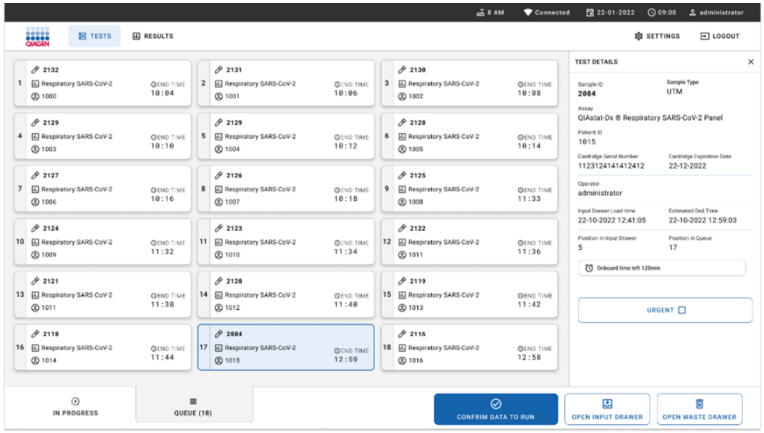


Figure 42. Sample queue screen while selecting sample to be prioritized.

Some other samples may run out of stability time due to prioritization of a sample. This warning is seen on the right corner of the screen (Figure 43) when applicable.

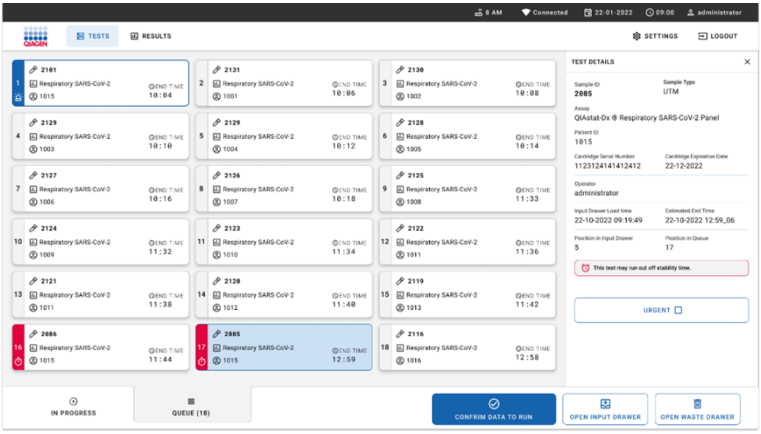


Figure 43. Sample queue screen after a sample is prioritized.

After confirmation of the queue the run can be started (Figure 44).

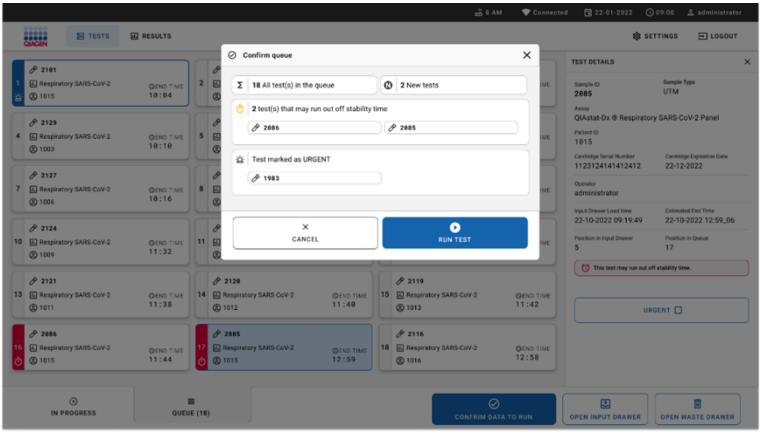


Figure 44. Confirmation of the run screen.

Prioritizing samples during run

A sample can be also prioritized for any reason during the run. In this case, if there is no AM available, any other ongoing sample needs to be aborted to perform prioritization (Figure 45).

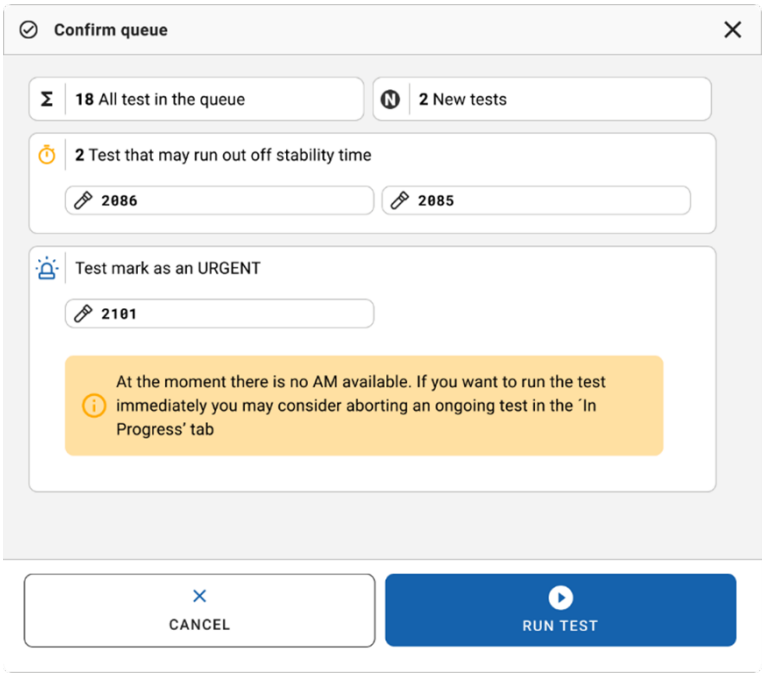


Figure 45. Confirmation dialog box during run.

Abortion of running sample

A sample can be aborted during scanning, loading, and running.

Note: The sample and cartridge cannot be used again once 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 press **Abort** at the right corner of the screen (Figure 46).

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

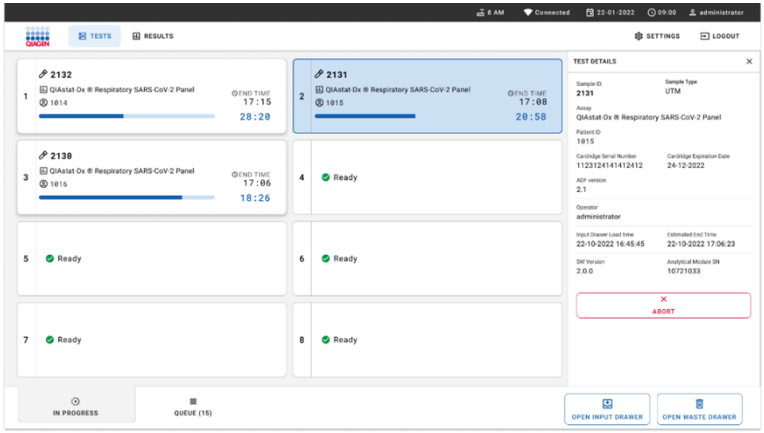


Figure 46. Abortion of a running sample.

The system needs a confirmation to abort the sample (Figure 47).

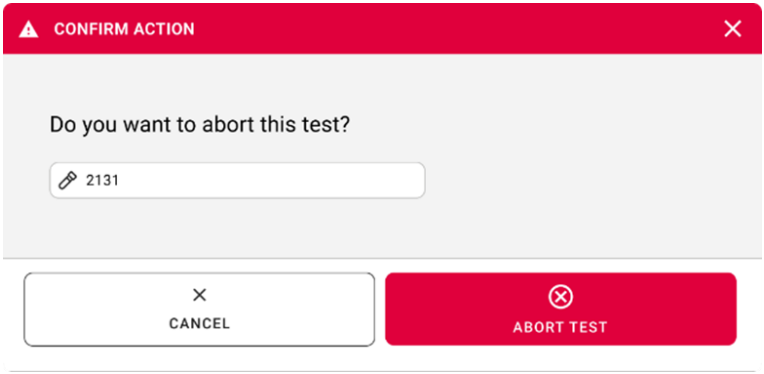


Figure 47. Confirmation dialog box to abort running sample.

After a short while, the sample can be seen as "Aborted" on the screen (Figure 48 and Figure 49).

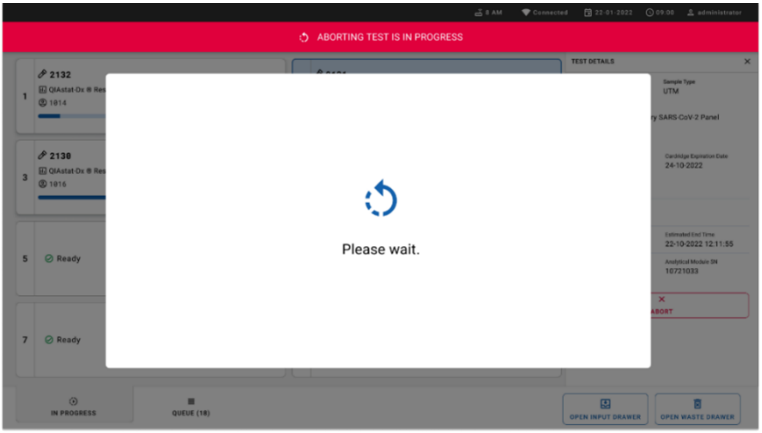


Figure 48. Sample abortion waiting dialog box.

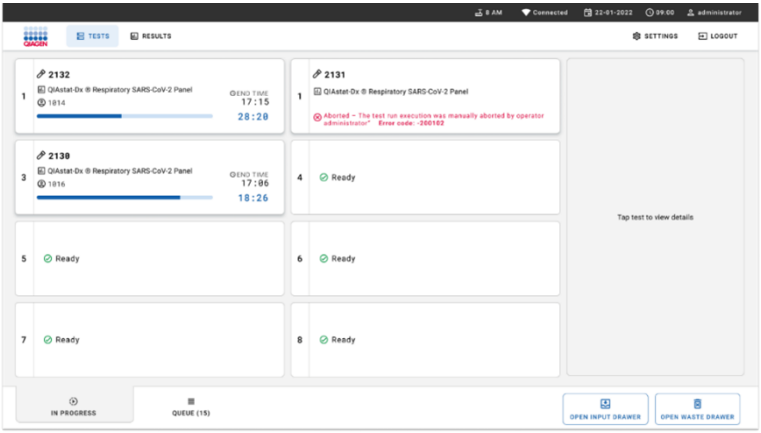


Figure 49. Aborted sample after confirmation of the abortion.

Interpretation of Results

Internal Control interpretation

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.

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.

Pathogen Result Interpretation

Result interpretation information for Influenza A

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/pdm09, 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 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 screen: one for Influenza A and a second one for H3 strain.
- If a pandemic Influenza A H1N1/pdm09 strain is detected, two signals will be generated and displayed on the screen: one for Influenza A and a second one for Influenza A H1N1/pdm09.

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.

Result interpretation for all other pathogens

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.

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

The QIAstat-Dx Analyzer 1.0 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 50).

Figure 50 shows the screen for QIAstat-Dx Analyzer 1.0.

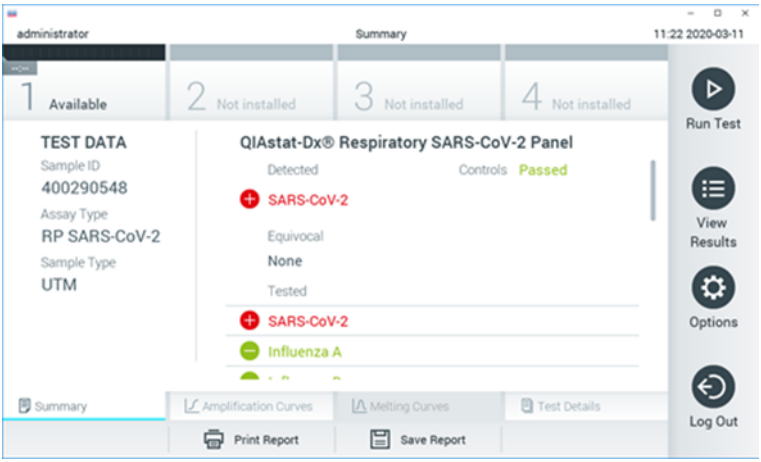


Figure 50. Results Summary screen example showing Test Data on the left panel and Test Summary in the main panel of QIAstat-Dx Analyzer 1.0.

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 51 shows the screen for QIAstat-Dx Analyzer 2.0.

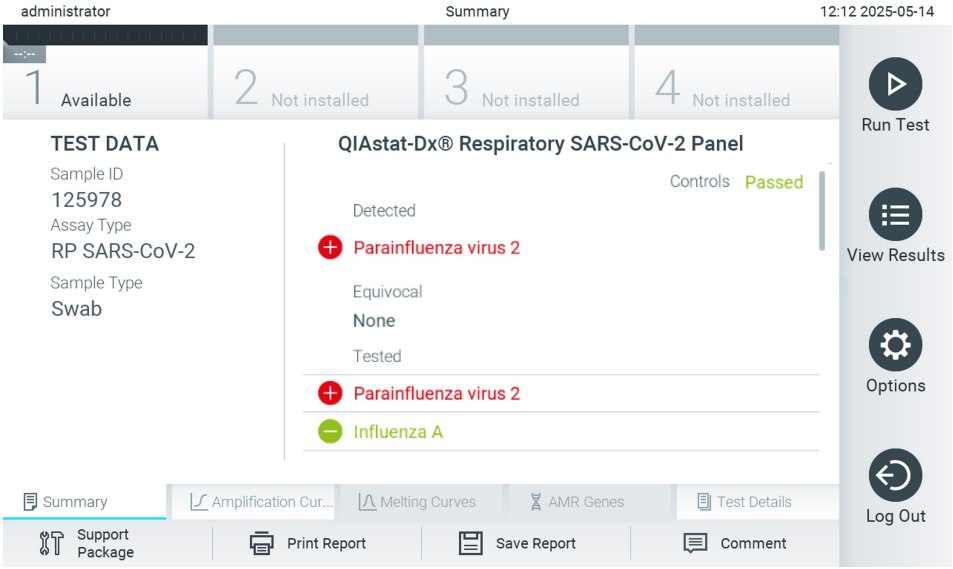


Figure 51. Results Summary screen example showing Test Data on the left panel and Test Summary in the main panel in QIAstat-Dx Analyzer 2.0.

QIAstat-Dx Analyzer 2.0 includes an additional tab:

- AMR genes: This tab is disabled for the QIAstat-Dx Respiratory SARS-CoV-2 Panel.

Note: From this point forward, example screen shots from the QIAstat-Dx Analyzer 1.0 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 or QIAstat-Dx

Analyzer 2.0 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 a 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 52).

Figure 52. 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 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 53).

Figure 53. 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 54):

- 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)
  - Failed (the test failed)
  - Positive with warning (at least one pathogen is positive, but the Internal Control failed)
- 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

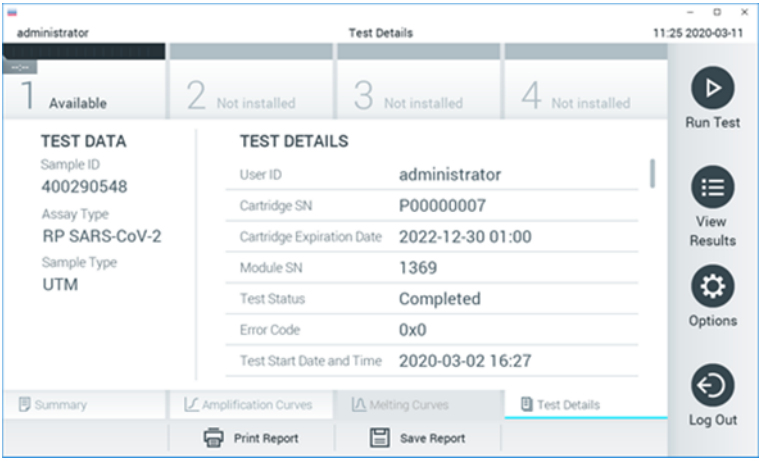


Figure 54. Example screen showing Test Data on the left panel and Test Details in the main panel.

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 55).

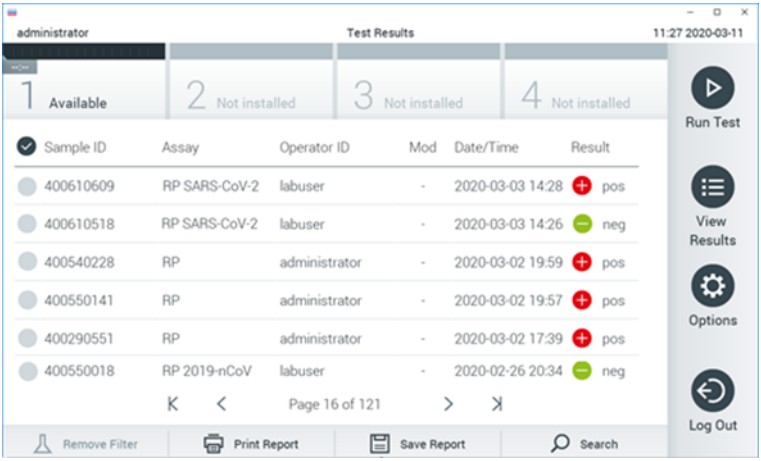


Figure 55. Example View Results screen.

The following information is available for every executed test:

- Sample ID
- Assay name (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], positive with warning [pos*], negative [neg], failed [fail] or successful [suc])

Note: If User Access Control is enabled on the QIAstat-Dx Analyzer 1.0 or 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 56 below).

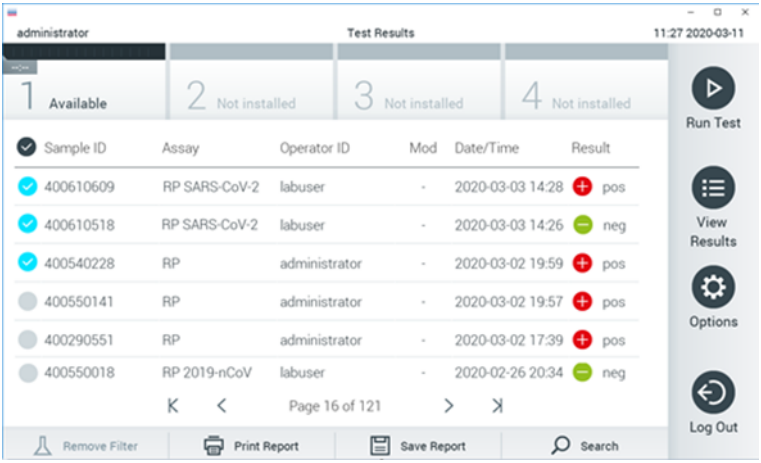


Figure 56. Example of selecting Test Results in the View Results screen.

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 4):

Table 4. Description of the Test Results

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

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 symbol to the left of a column headline indicates that the column's filter is active.

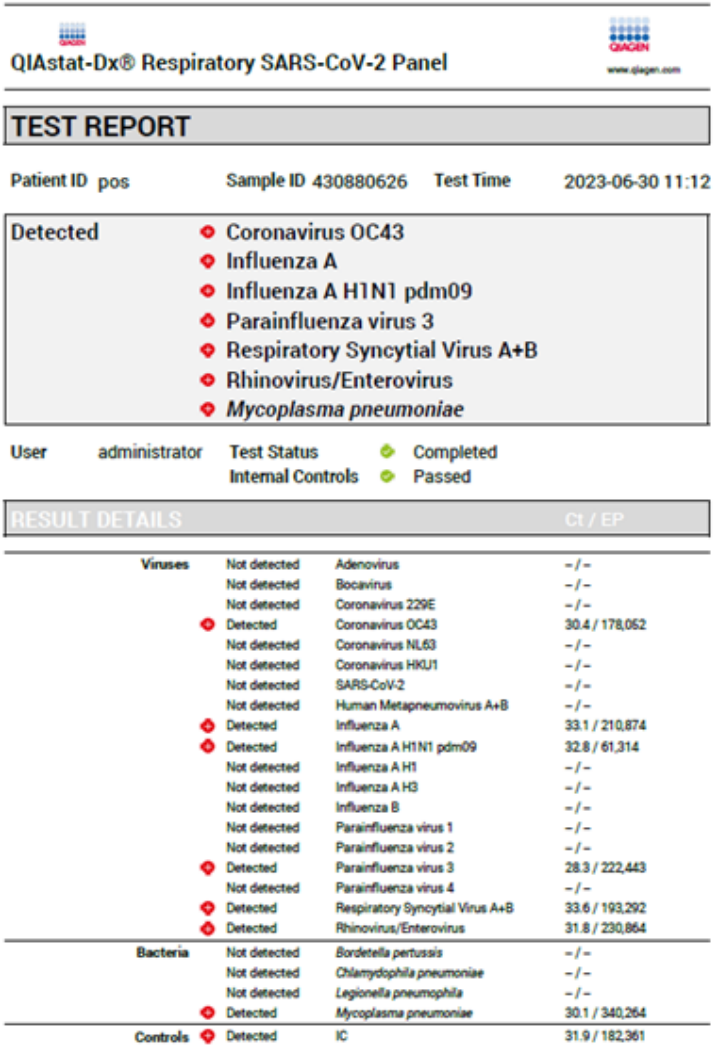
A filter can be removed by pressing **Remove Filter** in the Submenu bar.

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 to a USB drive (Figure 57–Figure 59). The USB port is located on the front of the QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0. The interpretation of the results in the PDF file is shown on Table 5.

Table 5. Interpretation of results on PDF reports

	Outcome	Symbol	Description
Pathogen result	Detected		Pathogen detected
	Not Detected	No symbol	Pathogen not detected
	Invalid	No symbol	The Internal Control failed there is not valid result for this target and the sample should be retested
Test status	Completed		The test was completed and the Internal Control and/or one or more targets were detected
	Failed		The test failed
Internal controls	Passed		The Internal Control passed
	Failed		The Internal Control failed



QIAstat-Dx® Respiratory SARS-CoV-2 Panel

TEST REPORT

Patient ID pos | Sample ID 430880626 | Test Time 2023-06-30 11:12

Detected
- Coronavirus OC43
- Influenza A
- Influenza A H1N1 pdm09
- Parainfluenza virus 3
- Respiratory Syncytial Virus A+B
- Rhinovirus/Enterovirus
- *Mycoplasma pneumoniae*

User administrator | Test Status Completed | Internal Controls Passed

RESULT DETAILS			Ct / EP
Viruses	Not detected	Adenovirus	– / –
	Not detected	Bocavirus	– / –
	Not detected	Coronavirus 229E	– / –
	Detected	Coronavirus OC43	30.4 / 178,052
	Not detected	Coronavirus NL63	– / –
	Not detected	Coronavirus HKU1	– / –
	Not detected	SARS-CoV-2	– / –
	Not detected	Human Metapneumovirus A+B	– / –
	Detected	Influenza A	33.1 / 210,874
	Detected	Influenza A H1N1 pdm09	32.8 / 61,314
	Not detected	Influenza A H1	– / –
	Not detected	Influenza A H3	– / –
	Not detected	Influenza B	– / –
	Not detected	Parainfluenza virus 1	– / –
	Not detected	Parainfluenza virus 2	– / –
	Detected	Parainfluenza virus 3	28.3 / 222,443
	Not detected	Parainfluenza virus 4	– / –
	Detected	Respiratory Syncytial Virus A+B	33.6 / 193,292
	Detected	Rhinovirus/Enterovirus	31.8 / 230,864
Bacteria	Not detected	*Bordetella pertussis*	– / –
	Not detected	*Chlamydophila pneumoniae*	– / –
	Not detected	*Legionella pneumophila*	– / –
	Detected	*Mycoplasma pneumoniae*	30.1 / 340,264
Controls	Detected	IC	31.9 / 182,361

Figure 57. Sample test report.

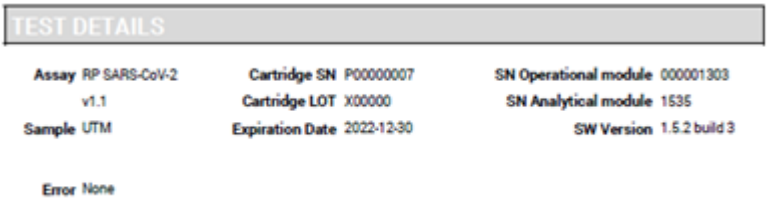


Figure 58. Sample test report showing details about the test.

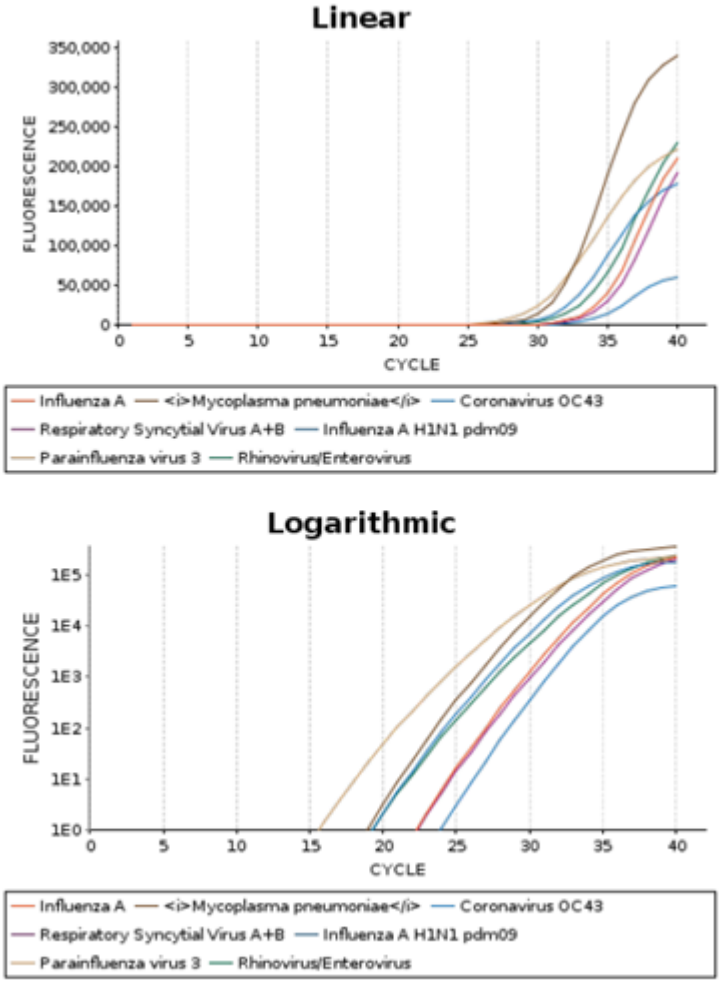


Figure 59. Sample test report showing assay data.

Printing results

Make sure a printer is connected to the QIAstat-Dx Analyzer 1.0 or 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.

Viewing results with the 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 60).

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

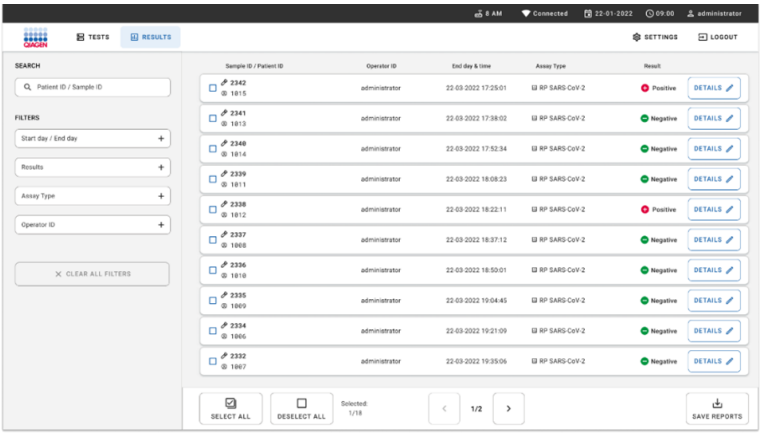


Figure 60. The results summary screen.

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 60):

- 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 61).

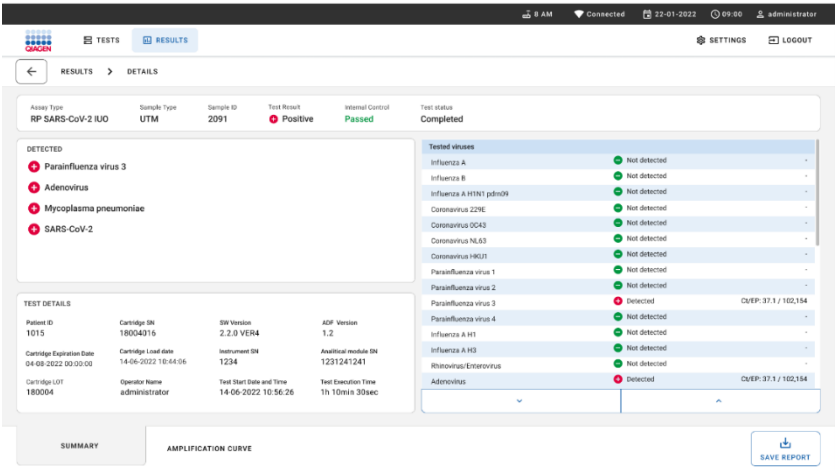


Figure 61. The test details screen.

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 62).

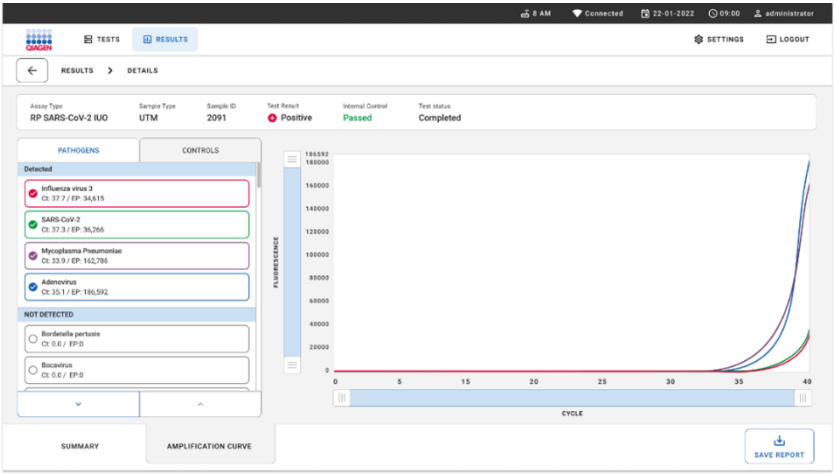


Figure 62. The amplification curves screen.

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 63).

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

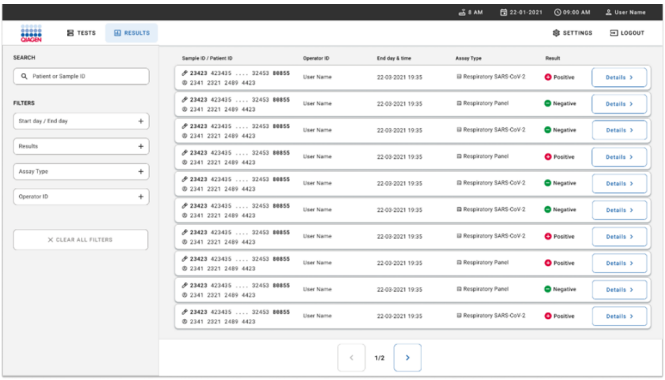


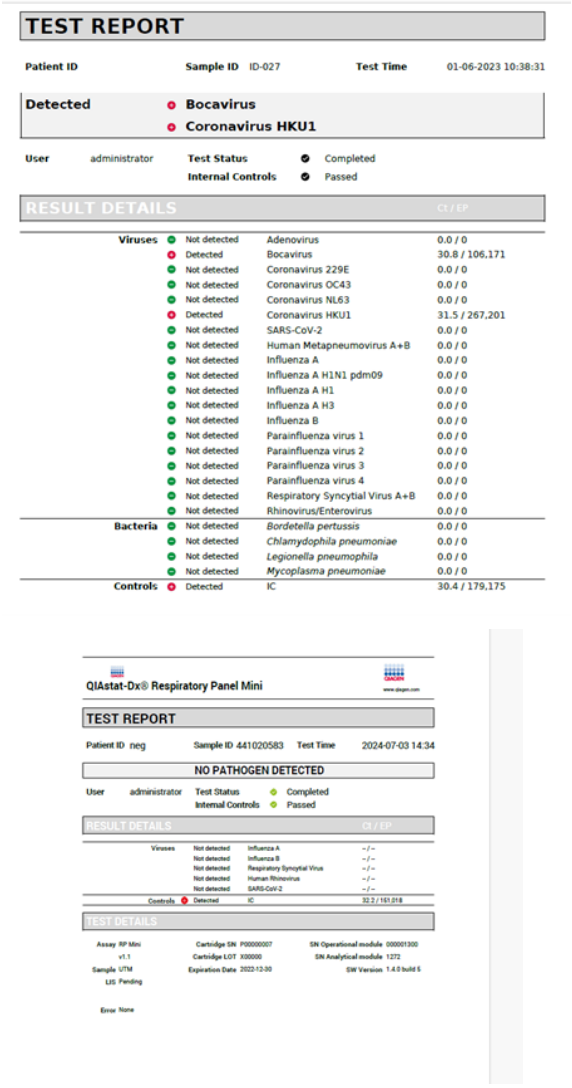
Figure 63. Search functionality in the results screen.

Exporting results to a USB drive

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 (Figure 64–Figure 66). The USB port is located in front and on the rear of the instrument. The interpretation of the results in the PDF file is shown on .

Table 6. Interpretation of results on PDF reports

	Outcome	Symbol	Description
Pathogen result	Detected		Pathogen detected
	Not Detected	No symbol	Pathogen not detected
	Invalid	No symbol	The Internal Control failed there is not valid result for this target and the sample should be retested
Test status	Completed		The test was completed and the Internal Control and/or one or more targets were detected
	Failed		The test failed
Internal controls	Passed		The Internal Control passed
	Failed		The Internal Control failed



TEST REPORT

Patient ID **Sample ID** ID-027 **Test Time** 01-06-2023 10:38:31

Detected
- **Bocavirus**
- **Coronavirus HKU1**

User administrator **Test Status** Completed
Internal Controls Passed

RESULT DETAILS

			Ct / EP
Viruses	Not detected	Adenovirus	0.0 / 0
	Detected	Bocavirus	30.8 / 106,171
	Not detected	Coronavirus 229E	0.0 / 0
	Not detected	Coronavirus OC43	0.0 / 0
	Not detected	Coronavirus NL63	0.0 / 0
	Detected	Coronavirus HKU1	31.5 / 267,201
	Not detected	SARS-CoV-2	0.0 / 0
	Not detected	Human Metapneumovirus A+B	0.0 / 0
	Not detected	Influenza A	0.0 / 0
	Not detected	Influenza A H1N1 pdm09	0.0 / 0
	Not detected	Influenza A H1	0.0 / 0
	Not detected	Influenza A H3	0.0 / 0
	Not detected	Influenza B	0.0 / 0
	Not detected	Parainfluenza virus 1	0.0 / 0
	Not detected	Parainfluenza virus 2	0.0 / 0
	Not detected	Parainfluenza virus 3	0.0 / 0
	Not detected	Parainfluenza virus 4	0.0 / 0
	Not detected	Respiratory Syncytial Virus A+B	0.0 / 0
	Not detected	Rhinovirus/Enterovirus	0.0 / 0
Bacteria	Not detected	*Bordetella pertussis*	0.0 / 0
	Not detected	*Chlamydophila pneumoniae*	0.0 / 0
	Not detected	*Legionella pneumophila*	0.0 / 0
	Not detected	*Mycoplasma pneumoniae*	0.0 / 0
Controls	Detected	IC	30.4 / 179,175

QIAstat-Dx® Respiratory Panel Mini

TEST REPORT

Patient ID neg Sample ID 441020583 Test Time 2024-07-03 14:34

NO PATHOGEN DETECTED

User administrator Test Status Completed
Internal Controls Passed

RESULT DETAILS Ct / EP

Viruses	Not detected	Influenza A	- / -
	Not detected	Influenza B	- / -
	Not detected	Respiratory Syncytial Virus	- / -
	Not detected	Human Rhinovirus	- / -
	Not detected	SARS-CoV-2	- / -
Controls	Detected	IC	32.2 / 161,018

TEST DETAILS

Assay RP Mini v1.1
Sample UTM
LIS Pending
Error None

Cartridge SN P00000007
Cartridge LOT X00000
Expiration Date 2022-12-30

SN Operational module 000001300
SN Analytical module 1272
SW Version 1.4.0 build 5

Figure 64. Sample test report.

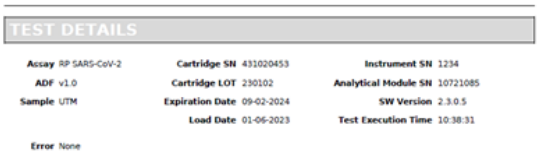


Figure 65. Sample test report showing details about the test.

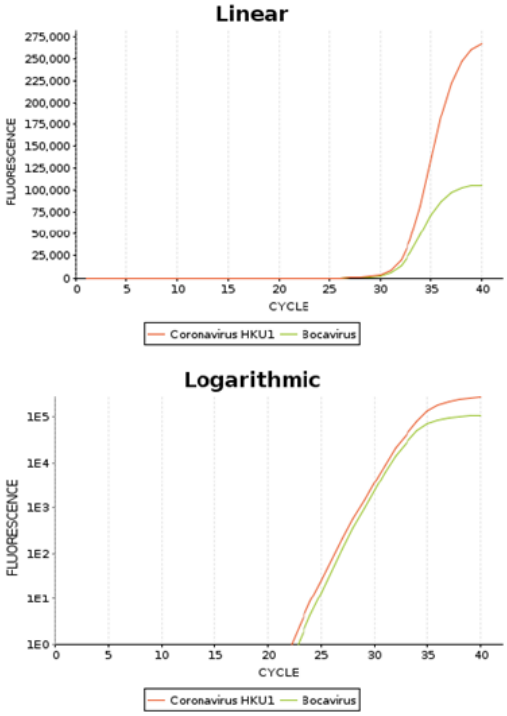


Figure 66. Sample test report showing assay data.

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).

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.
- 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 with NPS samples from individuals with 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.
- 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.
- The performance of this test has not been established in individuals who received Influenza vaccine. Recent administration of a nasal Influenza vaccine may cause false positive results for Influenza A and/or Influenza B.

*DiagCORE Analyzer instruments running QIAstat-Dx software version 1.5 can be used as an alternative to QIAstat-Dx Analyzer 1.0 instruments.

Performance Characteristics

Analytical performance

The analytical performance shown below was demonstrated using the 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 the 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.

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 for each of the QIAstat-Dx Respiratory SARS-CoV-2 Panel target organisms was determined by analyzing serial dilutions of analytical samples prepared from culture isolates from commercial suppliers (e.g. ZeptoMetrix® and ATCC®), confirmed clinical isolates, or artificial samples for commercially unavailable target analytes* on the QIAstat-Dx Analyzer 1.0.

Simulated NPS samples representing both processing options were tested; NPS sample matrix (cultured human cells in Copan UTM) for NPS in UTM and simulated dry swab sample matrix

*Due to limited access to cultured virus, synthetic material (gBlock) was also used to determine LoD spiked in clinical negative matrix for the Bocavirus target.

(cultured human cells in artificial NPS) for dry NPS were spiked with one or more pathogens and tested in at least 20 replicates. The NPS in UTM processing option uses NPS eluted in UTM and a transfer of 300 µL to the cartridge, whereas the dry NPS workflow allows transfer of the NPS directly to the cartridge. Dry NPS mock swabs were prepared by pipetting 50 µL of each diluted virus/bacteria stock onto a swab and were left to dry for a minimum of 20 minutes. Mock swabs were tested following the Dry NPS processing option, page 24. Additional testing of NPS in UTM samples prepared using negative clinical matrix was conducted to assess equivalency. Also, the LoD was demonstrated to be equivalent when one representative pathogen strain for each of the QIAstat-Dx Respiratory SARS-CoV-2 Panel target organisms was tested on the QIAstat-Dx Rise system.

Individual LoD values for each QIAstat-Dx Respiratory SARS-CoV-2 Panel target are shown in Table 7.

Table 7. LoD values obtained for the different respiratory target strains in NPS in UTM and/or dry NPS (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	341.3 $CEID_{50}$/mL	Flu A: 20/20 H1: 20/20
Influenza A H1N1	A/Brisbane/59/07	ZeptoMetrix 0810244CFHI	4.0 $TCID_{50}$/mL	Flu A: 20/20 H1: 20/20
Influenza A H1N1	A/New Caledonia/20/99	ZeptoMetrix 0810036CFHI	28.7 $TCID_{50}$/mL	Flu A: 20/20 H1: 20/20
Influenza A H3N2	A/Virginia/ATCC6/2012	ATCC AV-VR-1811	0.1 PFU/mL	Flu A: 20/20 H3: 20/20
Influenza A H3N2	A/Port Chalmers/1/73	ATCC VR-810	3000 $CEID_{50}$/mL	Flu A: 20/20 H3: 20/20
Influenza A H3N2	A/Wisconsin/67/2005	ZeptoMetrix 0810252CFHI	3.8 $TCID_{50}$/mL	Flu A: 20/20 H3: 20/20
Influenza A/H1N1/pdm09	A/Virginia/ATCC1/2009	ATCC VR-1736	127 PFU/mL	Flu A: 20/20 H1N1: 20/20

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

Pathogen	Strain	Source	Concentration*	Detection rate
Influenza A/H1N1/pdm09	A/SwineNY/03/2009	ZeptoMetrix 0810249CFHI	56.2 $TCID_{50}$/mL	Flu A: 20/20 H1N1: 20/20
Influenza B	B/Virginia/ATCC5/2012	ATCC VR-1807	0.03 PFU/mL	20/20
Influenza B	B/FL/04/06	ATCC VR-1804	2050 $CEID_{50}$/mL	19/20
Influenza B	B/Taiwan/2/62	ATCC VR-295	5000 $CEID_{50}$/mL	19/20
Coronavirus 229E	Not available	ATCC VR-740	9.47 $TCID_{50}$/mL	20/20
Coronavirus 229E	Not available	ZeptoMetrix 0810229CFHI	3.6 $TCID_{50}$/mL	20/20
Coronavirus OC43	Not available	ATCC VR-1558	0.1 $TCID_{50}$/mL	20/20
Coronavirus OC43	Not available	ZeptoMetrix 0810024CFHI	1.99 $TCID_{50}$/mL	20/20
Coronavirus NL63	Not available	ZeptoMetrix 0810228CFHI	0.702 $TCID_{50}$/mL	20/20
Coronavirus HKU1	Not available	ZeptoMetrix NATRVP-IDI	3E+03 copies/mL	20/20
Coronavirus HKU1	Not available	STAT-Dx S510	2.4E+05 copies/mL	20/20
Parainfluenza Virus 1 (PIV1)	C35	ATCC VR-94	9.48 $TCID_{50}$/mL	20/20
Parainfluenza Virus 1 (PIV1)	Not available	ZeptoMetrix 0810014CFHI	0.2 $TCID_{50}$/mL	19/20
Parainfluenza Virus 2 (PIV2)	Greer	ATCC VR-92	13.9 $TCID_{50}$/mL	20/20
Parainfluenza Virus 2 (PIV2)	Not available	ZeptoMetrix 0810015CFHI	1.3 $TCID_{50}$/mL	19/20

Table 7. LoD values obtained for the different respiratory target strains in NPS in UTM and/or dry NPS (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 3 (PIV3)	C 243	ATCC VR-93	44.1 $TCID_{50}$/mL	20/20
Parainfluenza Virus 3 (PIV3)	Not available	ZeptoMetrix 0810016CFHI	11.5 $TCID_{50}$/mL	20/20
Parainfluenza Virus 4a (PIV4a)	M-25	ATCC VR-1378	3.03 $TCID_{50}$/mL	20/20
Parainfluenza Virus 4b (PIV4b)	Not available	ZeptoMetrix 0810060BCFHI	9.5 $TCID_{50}$/mL	20/20
Enterovirus	US/IL/14-18952 (enterovirus D68)	ATCC VR-1824	534 $TCID_{50}$/mL	20/20
Enterovirus	Echovirus 6	ATCC VR-241	0.9 $TCID_{50}$/mL	19/20
Rhinovirus	1059 (rhinovirus B14)	ATCC VR-284	8.9 $TCID_{50}$/mL	20/20
Rhinovirus	HGP (rhinovirus A2)	ATCC VR-482	169 $TCID_{50}$/mL	20/20
Rhinovirus	11757 (rhinovirus C16)	ATCC VR-283	50.0 $TCID_{50}$/mL	20/20
Rhinovirus	Type 1A	ATCC VR-1559	8.9 $TCID_{50}$/mL	20/20
Adenovirus	GB (adenovirus B3)	ATCC VR-3	94900 $TCID_{50}$/mL	20/20
Adenovirus	RI-67 (adenovirus E4)	ATCC VR-1572	15.8 $TCID_{50}$/mL	20/20
Adenovirus	Adenoid 71 (adenovirus C1)	ATCC VR-1	69.5 $TCID_{50}$/mL	20/20
Adenovirus	Adenoid 6 (adenovirus C2)	ATCC VR-846	28.1 $TCID_{50}$/mL	20/20
Adenovirus	Tonsil 99 (adenovirus C6)	ATCC VR-6	88.8 $TCID_{50}$/mL	20/20
Adenovirus	Adenoid 75 (adenovirus C5)	ATCC VR-5	7331.0 $TCID_{50}$/mL	20/20
Respiratory Syncytial virus A (RSV A)	A2	ATCC VR-1540	720 PFU/mL	20/20

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

Pathogen	Strain	Source	Concentration*	Detection rate
Respiratory Syncytial virus A (RSV A)	Long	ATCC VR-26	33.0 PFU/mL	20/20
Respiratory Syncytial virus B (RSV B)	18537	ATCC VR-1580	0.03 PFU/mL	20/20
Respiratory Syncytial virus B (RSV B)	CH93(18)-18	ZeptoMetrix 0810040CFHI	0.4 $TCID_{50}$/mL	19/20
Human Metapneumovirus (hMPV)	Peru6-2003 (type B2)	ZeptoMetrix 0810159CFHI	0.01 $TCID_{50}$/mL	19/20
Human Metapneumovirus (hMPV)	hMPV-16, IA10-2003 (A1)	ZeptoMetrix 0810161CFHI	2.86 $TCID_{50}$/mL	19/20
Human Metapneumovirus (hMPV)	hMPV-20, IA14-2003 (A2)	ZeptoMetrix 0810163CFHI	0.4 $TCID_{50}$/mL	19/20
Human Metapneumovirus (hMPV)	hMPV-3, Peru2-2002 (B1)	ZeptoMetrix 0810156CFHI	1479.9 $TCID_{50}$/mL	19/20
Bocavirus	Not available	IDT (gBLock)	33000 copies/mL	20/20
Bocavirus	Not available	Vall d'hebron hospital	5.5E+04 copies/mL	20/20
Mycoplasma pneumoniae	M129-B7 (type 1)	ATCC 29342	0.1 CCU/mL	20/20
Mycoplasma pneumoniae	PI 1428	ATCC 29085	6.01 CCU/mL	20/20
Chlamydophila pneumoniae	TW183	ATCC VR-2282	85.3 IFU/mL	20/20
Chlamydophila pneumoniae	CWL-029	ATCC VR-1310	120.0 IFU/mL	19/20
Legionella pneumophila	CA1	ATCC 700711	5370 copies/mL	20/20

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

Pathogen	Strain	Source	Concentration*	Detection rate
Bordetella pertussis	I028	ATCC BAA-2707	5.13 CFU/mL	20/20
Bordetella pertussis	18323	ATCC 9797	2.6 CFU/mL	19/20
SARS-CoV-2	Not available	WHO, NIBSC, 20/146	19000 copies/mL (6.8E+04 IU/mL)	112/112
SARS-CoV-2	USA-WA1-2020	ZeptoMetrix 0810587CFH	3160 copies/mL	23/24
SARS-CoV-2	Not available	Vall d'Hebron hospital S1229	1.9E+04 copies/mL	20/20
SARS-CoV-2	Not available	Vall d'Hebron hospital S1231	1.9E+04 copies/mL	24/24
SARS-CoV-2	Not available	STAT-Dx	600 copies/mL	30/30

* The highest LoD is reported.

Assay robustness

The verification of robust assay performance was assessed by analyzing the Internal Control performance in clinical nasopharyngeal swab samples. Fifty individual nasopharyngeal swab samples, negative for all pathogens possible to detect, were analyzed with the QIAstat-Dx Respiratory SARS-CoV-2 Panel. All samples tested showed a positive result and valid performance for the Internal Control of the QIAstat-Dx Respiratory SARS-CoV-2 Panel.

Exclusivity (analytical specificity)

The analytical exclusivity study was carried out by *in silico* analysis and *in vitro* testing to assess the Analytical Specificity of the QIAstat-Dx Respiratory SARS-CoV-2 Panel. On-panel organisms were tested to assess the potential for intra-panel cross-reactivity and off-panel organisms were tested to evaluate panel exclusivity. 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. Both on-panel and off-panel organisms tested are shown in Table 8.

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.

Table 8. List of Analytical Specificity pathogens tested.

On-panel/ Off-panel	Type	Pathogen	Strain	Source
On-panel	Bacteria	*C. pneumoniae*	AR-39 TWAR strain TW-183	ATCC 53592
		B. pertussis	E431	ATCC VR-2282
		M. pneumoniae	M129 UTMB-10P	Zeptometrix 0801460 ATCC 49894
		L. pneumophila	Philadelphia Philadelphia-1	Zeptometrix 0801645 ATCC 33152
	Virus	Influenza A H1N1	A/New Jersey/8/76	ATCC VR-897
		Influenza A H3N2	A/Switzerland/971529/2013 A/Virginia/ATCC6/2012	ATCC VR-1837 ATCC VR-1811
		Influenza A H1N1/2009	A/Virginia/ATCC1/2009 A/California/07/2009 NYMC X-179A	ATCC VR-1736 ATCC VR-1884
		Influenza B	B/Florida/04/06	ATCC VR-1804
		Coronavirus 229E	Not available Not available	Zeptometrix 0810229CF Zeptometrix 0810229CFHI

Table 8. List of Analytical Specificity pathogens tested. (continued)

On-panel/ Off-panel	Type	Pathogen	Strain	Source
		Coronavirus OC43	Not available Not available	ATCC VR-1558 Zeptometrix 0810024CFHI
		Coronavirus NL63	Coronavirus NL63	Bei Resources NR-470
		Coronavirus HKU1	Not available	QIAGEN S506*
		Parainfluenza virus 1	C35	ATCC VR-94
		Parainfluenza virus 2	Greer	ATCC VR-92
		Parainfluenza virus 3	C 243	ATCC VR-93
		Parainfluenza virus 4	PIV4A PIV4B	Zeptometrix 0810060CFHI Zeptometrix 0810060BCFHI
		Respiratory Syncytial virus	A2	ATCC VR-1540
		Human metapneumovirus	A1 (hMPV-16, IA10-2003)	Zeptometrix 0810161CFHI
		Adenovirus C	Adenoid 71 (Adenovirus C1)	ATCC VR-1
		Adenovirus B	Gomen (Adenovirus B7)	ATCC VR-7
		Enterovirus D68	US/IL/14-18952	ATCC VR-1824
		Rhinovirus	2060 (Type 1A)	ATCC VR-1559
		Bocavirus	Type 1	Kansas University*
		SARS-CoV-2	Not available	Hospital Clinic S243*
Off panel	Bacteria	*Acinetobacter calcoaceticus*	Z160	Zeptometrix 0804096
		Bordetella avium	Z338	Zeptometrix 0804316

Table 8. List of Analytical Specificity pathogens tested. (continued)

On-panel/ Off-panel	Type	Pathogen	Strain	Source
		Bordetella bronchiseptica	NRRL B-140	ATCC 4617
		Bordetella hinzii	LMG 13501 Not available	ATCC 51783 Vircell MC089
		Bordetella holmesii	F061 CDC F5101	Zeptometrix 0801464 ATCC 51541
		Bordetella parapertussis	A747	Zeptometrix 0801461
		Chlamydia trachomatis	BOUR	ATCC VR-348-B
		Corynebacterium diphteriae	Z116 48255	Zeptometrix 0801882 ATCC 11913
		Enterobacter aerogenes (Klebisella aerogenes)	NCDC 819-56 Z052	ATCC 13048 Zeptometrix 0801518
		Escherichia coli (0157)	O157:H7; EDL933	Zeptometrix 0801622
		Haemophilus influenzae	L-378	ATCC 49766
		Klebsiella oxytoca	LBM 90.11.033	ATCC 700324
		Klebsiella pneumoniae	NCTC 9633 [NCDC 29853, NCDC 41068]	ATCC 13883
		Lactobacillus acidophilus	Scav [IFO 13951, M. Rogosa 210X, NCIB 8690, P.A. Hansen L 917]	ATCC 4356
		Lactobacillus plantarum	17-5	Zeptometrix 0801507

Table 8. List of Analytical Specificity pathogens tested. (continued)

On-panel/ Off-panel	Type	Pathogen	Strain	Source
		Legionella bozemanii	CIP 103872 (ATCC 33217; CCUG 11880; NCTC 11368)	CECT 7276
		Legionella dumofii	CCUG 11881 (ATCC 33279; CCUG 11881; CIP 103876; NCTC 11370; strain NY 23)	CECT 7349
		Legionella feeleii	Ly166.96 Not available	ATCC 700514 Vircell MC092
		Legionella longbeacheae	Long Beach 4	Zeptometrix 0801577
		Legionella micdadei	Tatlock	Zeptometrix 0801576
		Moraxella catarrhalis *(Branhamella catarrhalis)*	Ne 11 [CCUG 353, LMG 11192, NCTC 11020] N9 [P. Baumann N4]	ATCC 25238 ATCC 25240
		Mycobacterium tuberculosis	Not available	ATCC 25177DQ
		Mycoplasma genitalium	SEA-1	Zeptometrix 0804094-I
		Mycoplasma hominis	Z317 n/a	Zeptometrix 080411 ATCC 27545
		Mycoplasma orale	CH 19299 [NCTC 10112]	ATCC 23714
		Neisseria elongata	Z071	Zeptometrix 0801510
		Neisseria gonorrhoeae	Z017	Zeptometrix 0801482
		Neisseria meningitidis	FAM18 Serogroup Y	ATCC 700532DQ ATCC 35561
		Proteus mirabilis	LRA 08 01 73 [API SA, DSM 6674] Z050	ATCC 35659 Zeptometrix 0801544

Table 8. List of Analytical Specificity pathogens tested. (continued)

On-panel/ Off-panel	Type	Pathogen	Strain	Source
		Pseudomonas aeruginosa	PRD-10 [CIP 103467, NCIB 10421, PCI 812]	ATCC 15442
		Serratia marcescens	PCI 1107	ATCC 14756
		Staphylococcus aureus	Subp. aureus, FDA 209	ATCC CRM-6538
		Staphylococcus epidermidis	FDA strain PCI 1200	ATCC 12228
		Stenotrophomonas maltophilia	810-2 [MDB strain BS 1640, NCIB 9203, NCPPB 1974, NCTC 10257, NRC 729, R.Y. Stanier 67, RH 1168]	ATCC 13637
		Streptococcus agalactiae	NCTC 8181 [G19] Z2019	ATCC 13813 Zeptometrix 0801545
		Streptococcus pneumoniae	Z022, 19F	Zeptometrix 0801439
		Streptococcus pyogenes	Lancefield's group A/C203 S Z018	ATCC 14289 ZeptoMetrix 0801512
		Streptococcus salivarus	Z127 C699 [S30D]	Zeptometrix 0801896 ATCC 13419
		Ureaplasma urealyticum	T-strain 960 (CX8) [960, CIP 103755, NCTC 10177]	ATCC 27618
	Virus	Cytomegalovirus	AD-169 Towne	Zeptometrix NATCMV-0005 Zeptometrix 0810499CFHI
		Epstein-Barr Virus	B958	ATCC VR-1492PQ
		Herpes Simplex Virus 1	ATCC-20111	ATCC VR-1778/ VR-1789
		Herpes Simplex Virus 2	ATCC-2011-2	ATCC VR-1779/ VR-734
		Measles Virus	Edmonston	ATCC VR-24

Table 8. List of Analytical Specificity pathogens tested. (continued)

On-panel/ Off-panel	Type	Pathogen	Strain	Source
	Virus	Middle East Respiratory Syndrome (MERS) Coronavirus	England-1 Not available	Vircell MC121 ATCC VR-3248SD
		Mumps	Enders	ATCC VR-106
		Severe Acute Respiratory Syndrome (SARS)	Not available	IDT (gBlocks)†
	Fungus	*Aspergillus flavus*	Harvard 997 Z013	Vircell MC064 Zeptometrix 0801598
		Aspergillus fumigatus	MCV-C#10 Z014	Vircell MBC002 Zeptometrix 0801716
		Candida albicans	3147 [CBS 6431, CCY 29-3-106, CIP 48.72, DSM 1386, IFO 1594, NCPF 3179, NCYC 1363, NIH 3147, VTT C-85161]	ATCC CRM-10231
		Cryptococcus neoformans	CBS 132 [CCRC 20528, DBVPG 6010, IFO 0608, NRRL Y2534]	ATCC 32045

*Clinical sample obtained in STAT-Dx Life, S.L (a QIAGEN company) (HKU1), Kansas University, US (Bocavirus), and Hospital Clinic, Barcelona (SARS-CoV-2).

†Artificial genomic fragments were used for SARS.

All on-panel pathogens resulted in specific detection, and all off-panel pathogens tested showed a negative result and no cross-reactivity was observed in the QIAstat-Dx Respiratory SARS-CoV-2 Panel. The only exception is Bordetella species since *Bordetella holmesii* and *Bordetella bronchiseptica* cross-reacted with *Bordetella pertussis* assay. The target gene used for *Bordetella pertussis* detection (insertion element IS481) is a transposon also present in other Bordetella species [19,20], and a certain level of cross-reactivity was predicted by preliminary sequence analysis [21] 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 QIAstat-Dx Respiratory SARS-CoV-2 Panel if the C_T value for *Bordetella pertussis* is C_T>29, a confirmatory specificity test is recommended. No cross-reactivity was observed with *Bordetella parapertussis* at high concentrations.

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 (with the only exception described above).

Inclusivity (analytical reactivity)

Analytical Reactivity (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").

A total of 139 Inclusivity strains 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). Based on wet testing and *in silico* analysis, the QIAstat-Dx Respiratory SARS-CoV-2 Panel primers and probes are specific and inclusive for clinically prevalent and relevant strains for each pathogen. Wet testing has been done with the strains listed in Table 9.

Table 9. List of Inclusivity strains tested

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
Influenza A	H1N1	A/Brisbane/59/07	Zeptometrix 0810244CFHI†	1x LoD	Influenza A H1
		A/New Caledonia/20/99	Zeptometrix 0810036CFHI*	0.3x LoD	Influenza A H1
		A/New Jersey/8/76s	ATCC VR-897*	1x LoD	Influenza A H1
		A/Denver/1/57	ATCC VR-546	0.1x LoD	Influenza A H1
		A/Mal/302/54	ATCC VR-98	1x LoD	Influenza A H1
		A/Weiss/43	ATCC VR-96	0.1x LoD	Influenza A H1
		A/PR/8/34	ATCC VR-1469	3x LoD	Influenza A H1
		A/Fort Monmouth/1/1947	ATCC VR-1754	0.1x LoD	Influenza A H1
		A/WS/33	ATCC VR-1520	0.1x LoD	Influenza A H1
		A/Swine/Iowa/15/1930	ATCC VR-333	1x LoD	Influenza A H1

Table 9. List of Inclusivity strains tested (continued)

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
	H3N2	A/Virginia/ATCC6/2012	ATCC VR-1811*	1x LoD	Influenza A H3
		A/Port Chalmers/1/73	ATCC VR-810†	1x LoD	Influenza A H3
		A/Wisconsin/67/2005	Zeptometrix 0810252CFHI*	1x LoD	Influenza A H3
		A/Wisconsin/15/2009	ATCC VR-1882	1x LoD	Influenza A H3
		A/Victoria/3/75	ATCC VR-822	1x LoD	Influenza A H3
		A/Aichi/2/68	ATCC VR-1680	10x LoD	Influenza A H3
		A/Hong Kong/8/68	ATCC VR-1679	10x LoD	Influenza A H3
		A/Alice (recombinant, carries A/England/42/72)	ATCC VR-776	10x LoD	Influenza A H3
		MRC-2 (recombinant A/England/42/72 and A/PR/8/34 strains)	ATCC VR-777	100x LoD	Influenza A H3
		A/Switzerland/9715293/2013	ATCC VR-1837	1x LoD	Influenza A H3
	H1N1/pdm09	A/Virginia/ATCC1/2009	ATCC VR-1736†	1x LoD	Influenza A H1N1/pdm09
		A/SwineNY/03/2009	Zeptometrix 0810249CFHI*	1x LoD	Influenza A H1N1/pdm09
		A/Virginia/ATCC2/2009	ATCC VR-1737	0.1x LoD	Influenza A H1N1/pdm09

Table 9. List of Inclusivity strains tested (continued)

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
		A/Virginia/ATCC3/2009	ATCC VR-1738	100x LoD	Influenza A H1N1/pdm09
		Swine NY/01/2009	Zeptometrix 0810248CFHI	0.3x LoD	Influenza A H1N1/pdm09
		Swine NY/02/2009	Zeptometrix 0810109CFNHI	10x LoD	Influenza A H1N1/pdm09
		A/California/07/2009 NYMC X-179A	ATCC VR-1884	0.1x LoD	Influenza A H1N1/pdm09
		Canada/6294/09	Zeptometrix 0810109CFJHI	3x LoD	Influenza A H1N1/pdm09
		Mexico/4108/09	Zeptometrix 0810166CFHI	0.1x LoD	Influenza A H1N1/pdm09
		Netherlands/2629/2009	BEI Resources NR-19823	0.3x LoD	Influenza A H1N1/pdm09
	H1N2‡	Recombinant Kilbourne F63, A/NWS/1934 (HA) x A/Rockefeller Institute/5/1957 (NA) (nucleic acid)	BEI Resources NR-9677	100x LoD	Influenza A H1
	H1N2‡	Japan/305/1957 (nucleic acid)	BEI Resources NR-2775	1x LoD	Influenza A
		Recombinant Korea/426/1968xPuerto Rico/8/1934 (nucleic acid)	BEI Resources NR-9679	0.3x LoD	

Table 9. List of Inclusivity strains tested (continued)

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
	H2N3‡	Genomic RNA from Influenza A Virus, A/duck/Germany/1215/1973 (H2N3) (nucleic acid)	BEI Resources	Not applicable§	Influenza A
	H5N2‡	Genomic RNA from Influenza A Virus, A/duck/Pennsylvania/10218/1984 (H5N2) (nucleic acid)	BEI Resources	Not applicable§	Influenza A
Influenza A	H5N3‡	A/Duck/Singapore/645/1997 (nucleic acid)	BEI Resources NR-9682	1x LoD	Influenza A
	H7N7‡	Genomic RNA from Influenza A Virus, A/equine/Prague/1956 (H7N7) (nucleic acid)	BEI Resources	Not applicable§	Influenza A
	H10N7‡	Chicken/Germany/N/49 (nucleic acid)	BEI Resources NR-2765	10x LoD	Influenza A
Influenza B	Not available	B/Virginia/ATCC5/2012	ATCC VR-1807†	1x LoD	Influenza B
		B/FL/04/06	ATCC VR-1804*	1x LoD	Influenza B
		B/Taiwan/2/62	ATCC VR-295*	0.3x LoD	Influenza B
		B/Allen/45	ATCC VR-102	Not detected	Negative¶
		B/Hong Kong/5/72	ATCC VR-823	Not detected	Negative¶
		B/Maryland/1/59	ATCC VR-296	0.1x LoD	Influenza B
		B/GL/1739/54	ATCC VR-103	1x LoD	Influenza B

Table 9. List of Inclusivity strains tested (continued)

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
		B/Wisconsin/1/2010	ATCC VR-1883	0.1x LoD	Influenza B
		B/Massachusetts/2/2012	ATCC VR-1813	3x LoD	Influenza B
		B/Florida/02/06	Zeptometrix 0810037CFHI	Impaired detectability	Influenza B or negative**
		B/Brisbane/60/2008	BEI Resources NR-42005	0.1x LoD	Influenza B
		B/Malaysia/2506/2004	BEI Resources NR-9723	0.3x LoD	Influenza B
Coronavirus 229E	Not available	Not available	ATCC VR-740	0.3x LoD	Coronavirus 229
		Not available	Zeptometrix 0810229CFHI†	1x LoD	Coronavirus 229
Coronavirus OC43	Not available	Not available	ATCC VR-1558†	1x LoD	Coronavirus OC43
		Not available	Zeptometrix 0810024CFHI	1x LoD	Coronavirus OC43
Coronavirus NL63	Not available	Not available	Zeptometrix 0810228CFHI†	1x LoD	Coronavirus NL63
		Not available	BEI Resources NR-470	1x LoD	Coronavirus NL63
Coronavirus HKU1	Not available	Not available	Zeptometrix NATRVP-IDI†	1x LoD	Coronavirus HKU1
		Not available	STAT-Dx†† S510	3x LoD	Coronavirus HKU1

Table 9. List of Inclusivity strains tested (continued)

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
		Not available	STAT-Dx†† S501	1x LoD	Coronavirus HKU1
		Not available	STAT-Dx†† S496	1x LoD	Coronavirus HKU1
Parainfluenza Virus 1	Not available	C35	ATCC VR-94*	1x LoD	Parainfluenza Virus 1
		Not available	Zeptometrix 0810014CFHI†	1x LoD	Parainfluenza Virus 1
		Not available	Zeptometrix NATRVP-IDI	10x LoD	Parainfluenza Virus 1
Parainfluenza Virus 2	Not available	Greer	ATCC VR-92†	1x LoD	Parainfluenza Virus 2
		Not available	Zeptometrix 0810015CFHI*	0.3x LoD	Parainfluenza Virus 2
		Not available	Zeptometrix 0810504CFHI	0.1x LoD	Parainfluenza Virus 2
Parainfluenza Virus 3	Not available	C 243	ATCC VR-93*	1x LoD	Parainfluenza Virus 3
		Not available	Zeptometrix 0810016CFHI†	1x LoD	Parainfluenza Virus 3
		Not available	Zeptometrix NATRVP-IDI	0.1x LoD	Parainfluenza Virus 3

Table 9. List of Inclusivity strains tested (continued)

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
Parainfluenza Virus 4	A	M-25	ATCC VR-1378†	1x LoD	Parainfluenza Virus 4
		Not available	Zeptometrix 0810060CFHI	0.1x LoD	Parainfluenza Virus 4
Parainfluenza 4	B	Not available	Zeptometrix 0810060BCFHI*	0.3x LoD	Parainfluenza Virus 4
		CH 19503	ATCC VR-1377	0.3x LoD	Parainfluenza Virus 4
Respiratory Syncytial Virus	A	A2	ATCC VR-1540*	0.3x LoD	Respiratory Syncytial Virus A+B
		Long	ATCC VR-26*	1x LoD	Respiratory Syncytial Virus A+B
		Not available	Zeptometrix 0810040ACFHI	0.1x LoD	Respiratory Syncytial Virus A+B
	B	18537	ATCC VR-1580†	1x LoD	Respiratory Syncytial Virus A+B
		CH93(18)-18	Zeptometrix 0810040CFHI*	1x LoD	Respiratory Syncytial Virus A+B
		B WV/14617/85	ATCC VR-1400	1x LoD	Respiratory Syncytial Virus A+B
Human Metapneumovirus	A1	IA10-2003	Zeptometrix 0810161CFHI†	1x LoD	Human Metapneumovirus A+B

Table 9. List of Inclusivity strains tested (continued)

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
		IA3-2002	Zeptometrix 0810160CFHI	3x LoD	Human Meta-pneumovirus A+B
	A2	IA14-2003	Zeptometrix 0810163CFHI*	1x LoD	Human Meta-pneumovirus A+B
		IA27-2004	Zeptometrix 0810164CFHI	1x LoD	Human Meta-pneumovirus A+B
	B1	Peru2-2002	Zeptometrix 0810156CFHI*	1x LoD	Human Meta-pneumovirus A+B
		Peru3-2003	Zeptometrix 0810158CFHI	1x LoD	Human Meta-pneumovirus A+B
	B2	Peru6-2003	Zeptometrix 0810159CFHI*	1x LoD	Human Meta-pneumovirus A+B
		IA18-2003	Zeptometrix 0810162CFHI	1x LoD	Human Meta-pneumovirus A+B
		Peru1-2002	Zeptometrix 0810157CFHI	10x LoD	Human Meta-pneumovirus A+B
Adenovirus A	12	Not available	ATCC VR-863	0.3x LoD	Adenovirus
Adenovirus B	3	GB	ATCC VR-3*	0.3x LoD	Adenovirus
	7	Not available	ATCC VR-7	0.3x LoD	Adenovirus
	11	Not available	ATCC VR-12	0.1x LoD	Adenovirus

Table 9. List of Inclusivity strains tested (continued)

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
	21	Not available	ATCC VR-256	10x LoD	Adenovirus
	34	Not available	ATCC VR-716	0.3x LoD	Adenovirus
	35	Not available	ATCC VR-718	0.3x LoD	Adenovirus
Adenovirus C	1	Adenoid 71	ATCC VR-1*	1x LoD	Adenovirus
	2	Adenoid 6	ATCC VR-846*	0.3x LoD	Adenovirus
	5	Adenoid 75	ATCC VR-5*	0.3x LoD	Adenovirus
	6	Tonsil 99	ATCC VR-6†	1x LoD	Adenovirus
Adenovirus D	8	Not available	ATCC VR-1815	0.3x LoD	Adenovirus
Adenovirus E	4	RI-67	ATCC VR-1572*	0.3x LoD	Adenovirus
Adenovirus F	40	Not available	ATCC VR-931	0.1x LoD	Adenovirus
	41	Not available	ATCC VR-930	3x LoD	Adenovirus
Enterovirus A	EV-A71	Not available	ATCC VR-1432	1x LoD	Rhinovirus/ Enterovirus
	CV-A10	Not available	ATCC VR-168	10x LoD	Rhinovirus/ Enterovirus
Enterovirus B	E-6	D-1 (Cox)	ATCC VR-241*	0.3x LoD	Rhinovirus/ Enterovirus
	E-11	Not available	ATCC VR-41	10x LoD	Rhinovirus/ Enterovirus

Table 9. List of Inclusivity strains tested (continued)

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
	E-30	Not available	ATCC VR-1660	1x LoD	Rhinovirus/ Enterovirus
	CV-A9	Not available	ATCC VR-1311	0.3x LoD	Rhinovirus/ Enterovirus
	CV-B1	Not available	ATCC VR-28	0.3x LoD	Rhinovirus/ Enterovirus
	CV-B2	Not available	ATCC VR-29	3x LoD	Rhinovirus/ Enterovirus
	CV-B3	Not available	ATCC VR-30	0.3x LoD	Rhinovirus/ Enterovirus
	E-17	Not available	ATCC VR-47	10x LoD	Rhinovirus/ Enterovirus
Enterovirus C	CV-A21	Not available	ATCC VR-850	10x LoD	Rhinovirus/ Enterovirus
Enterovirus D	EV-D68	US/IL/14-18952	ATCC VR-1824†	1x LoD	Rhinovirus/ Enterovirus
Rhinovirus A	1	2060	ATCC VR-1559*	0.1x LoD	Rhinovirus/ Enterovirus
	2	HGP	ATCC VR-482*	1x LoD	Rhinovirus/ Enterovirus
	16	11757	ATCC VR-283*	0.3x LoD	Rhinovirus/ Enterovirus

Table 9. List of Inclusivity strains tested (continued)

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
Rhinovirus B	14	1059	ATCC VR-284†	1x LoD	Rhinovirus/ Enterovirus
	3	Not available	ATCC VR-483	1x LoD	Rhinovirus/ Enterovirus
	17	Not available	ATCC VR-1663	3x LoD	Rhinovirus/ Enterovirus
Bocavirus	Not available	Not available	IDT gBlock†	1x LoD	Bocavirus
		Not available	Clinical Sample††	1x LoD	Bocavirus
		Not available	Zeptometrix 0601178NTS	1x LoD	Bocavirus
		Not available	Zeptometrix MB-004	0.3x LoD	Bocavirus
SARS-CoV-2	Not available	WHO reference material	NIBSC 20/146‡‡	1xLoD	SARS-CoV-2
M. pneumoniae	1	M129-B7	ATCC 29342*	1xLoD	*Mycoplasma pneumoniae*
	1	PI 1428	ATCC 29085†	1xLoD	*Mycoplasma pneumoniae*
	2	Not available	ATCC 15531	0.1xLoD	*Mycoplasma pneumoniae*
B. pertussis	Not available	I028	ATCC BAA-2707†	1xLoD	*Bordetella pertussis*

Table 9. List of Inclusivity strains tested (continued)

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
	Not available	19323	ATCC 9797*	1xLoD	*Bordetella pertussis*
	Not available	n/a	ATCC 10380	0.3xLoD	*Bordetella pertussis*
C. pneumoniae	Not available	TW183	ATCC VR-2282†	1xLoD	*Chlamydophila pneumoniae*
	Not available	CWL-029	ATCC VR-1310*	1xLoD	*Chlamydophila pneumoniae*
	Not available	n/a	ATCC 53592	0.3xLoD	*Chlamydophila pneumoniae*
L. pneumophila	Not available	CA1	ATCC 700711†	1xLoD	*Legionella pneumophila*
	Not available	Legionella pneumophila subsp. Pneumophila/ 169-MN-H	ATCC 43703	3xLoD	*Legionella pneumophila*
	Not available	Not available	Zeptometrix MB-004	1xLoD	*Legionella pneumophila*
	Not available	subsp. Pneumophila / Philadelphia-1	ATCC 33152	1xLoD	*Legionella pneumophila*

* Strains tested in LoD study.

† Strains tested in LoD and used for calculation of sensitivity level (X times LoD).

‡ For all non-human Flu A strains, Influenza A/Brisbane/59/07 (Zeptometrix, 0810244CFHI) taken as reference strain to calculate the x-fold LoD detected.

Table 9. List of Inclusivity strains tested (continued)

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result

§ Three non-human Flu A strains were not available for in vitro testing, and analysis was performed in silico.

¶ Both Flu B strains are derivative from B/Lee/40 ancestral lineage, currently not in circulation.

** Impaired detectability. In silico analysis supports detectability.

†† Clinical samples obtained in STAT-Dx Life, S.L (a QIAGEN company) Q), Spain (HKU1) and University of Kansas, USA (Bocavirus).

‡‡ SARS-CoV-2 WHO reference material was tested in laboratory as representative strain. Additional analysis was run for SARS-CoV-2 to cover all variants and lineages.

In addition, *in silico* analysis was done to characterize inclusivity coverage of on-panel pathogens against available genomic sequences in publicly available databases.

In case of SARS-CoV-2, *in silico* evaluation included a total of 11,323,728 available genomes (since the beginning of the SARS-CoV-2 outbreak (2020, Jan 1st) until 24/April/2023) extracted from GISAID data base. This period includes all major SARS-CoV-2 lineages (Variants of Concern *Alpha, Beta, Gamma, Delta,* and *Omicron;* together with Variants of Interest *Lambda* and *Mu,* plus variants *Kappa, Epsilon, Eta and B.1.617.3*). 11,046,667 (97.55%) of the analyzed sequence genomes showed no evidence of mismatches among the assay's oligonucleotides binding region. For the rest of analyzed genomes, only 35,063 (0.31%) presented any mismatch with potentially critical impact in assay performance with a prevalence of >0.2%. Laboratory validation of those mismatches was performed at LoD level using artificial genomic fragments including corresponding mutations, confirming no loss of performance. This deep analysis covering all main important lineages concluded that the QIAstat-Dx Respiratory SARS-CoV-2 Panel is inclusive for all analyzed SARS-CoV-2 genomes, including all known variants, lineages and sublineages. New sequences and variants are periodically monitored for potential impact on QIAstat-Dx Respiratory SARS-CoV-2 Panel performance.

Also, for those on-panel organisms with known biological subtype differentiation, coverage was analyzed. Inclusivity for Flu A (Table 10), Rhinovirus/Enterovirus (Table 11), and Adenovirus (Table 12) were evaluated based on sequences available in GenBank database. In all cases, the QIAstat-Dx Respiratory SARS-CoV-2 Panel was able to detect all described types or subtypes.

For all other organisms, a BLAST-based homology analysis also confirmed that all available target sequences in GenBank database are predicted to be detected. This applies to Flu B (Victoria and Yamagata lineages), Coronavirus 229E, Coronavirus OC43, Coronavirus NL63, Coronavirus HKU1, PIV1, PIV2, PIV3, PIV4 (including PIV4a and PIV4b), RSV (including RSVA and RSVB), hMPV (including hMPVA1, hMPVA2, hMPB1 and hMPVB2

subtypes), Bocavirus (subtype 1), *Mycoplasma pneumoniae*, *Chlamydophila pneumoniae*, *Bordetella pertussis*, and *Legionella pneumophila* (all described serotypes).

Table 10. Inclusivity of general Influenza A assay

	Detected by BLAST/Sequence alignment*								
H/N serotype combination	**N1**	**N2**	**N3**	**N4**	**N5**	**N6**	**N7**	**N8**	**N9**
H1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
H2	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
H3	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
H4	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
H5	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
H6	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
H7	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
H8	Yes	Yes	Yes	Yes	N/A	Yes	N/A	Yes	N/A
H9	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
H10	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
H11	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
H12	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
H13	N/A	Yes	Yes	N/A	N/A	Yes	N/A	Yes	Yes
H14	N/A	Yes	Yes	Yes	Yes	Yes	Yes	Yes	N/A
H15	N/A	N/A	N/A	Yes	Yes	Yes	Yes	N/A	Yes
H16	N/A	N/A	Yes	N/A	N/A	N/A	N/A	Yes	Yes

* N/A: not applicable (no sequences available in Genbank database).

Table 11. Inclusivity of Rhinovirus/Enterovirus assay

HRV/HEV subtype	Detected by BLAST/Sequence alignment*
Enterovirus A	• Coxsackievirus A10, A12, A14, A16, A2, A3, A4, A5, A6, A7, A8 • Enterovirus A114, A119, A120, A121, A123, A124, A125, A71, A76, A89, A90, A91, A92 • Simian Enterovirus 19
Enterovirus B	• Coxsackievirus A9, B1, B2, B3, B4, B5, B6 • Echovirus E1, E11, E12, E13, E14, E15, E16, E17, E18, E19, E2, E20, E21, E24, E25, E26, E27, E29, E3, E30, E31, E32, E33, E4, E5, E6, E7, E8, E9 • Enterovirus B100, B101, B106, B107, B110, B111, B69, B73, B74, B75, B77, B79, B80, B81, B82, B83, B84, B85, B86, B87, B88, B93, B97, B98 • Enterovirus Yanbian 96-83csf, Yanbian 96-85csf, Simian agent 5, Swine vesicular disease virus
Enterovirus C	• Coxsackievirus A1, A11, A13, A15, A17, A18, A19, A20, A21, A22, A24 • Enterovirus C102, C104, C105, C109, C113, C116, C117, C118, C95, C96, C99 • Human poliovirus 1, 2, 3
Enterovirus D	• Enterovirus D111, D68, D70, D94
Rhinovirus A	• Human rhinovirus A44, A95 • Rhinovirus A1, A10, A100, A101, A103, A105, A106, A11, A12, A13, A15, A16, A18, A19, A1B, A2, A20, A21, A22, A23, A24, A25, A28, A29, A30, A31, A32, A33, A34, A36, A38, A39, A40, A41, A43, A45, A46, A47, A49, A50, A51, A53, A54, A55, A56, A57, A58, A59, A60, A61, A62, A63, A64, A65, A66, A67, A68, A7, A71, A73, A74, A75, A76, A77, A78, A8, A80, A81, A82, A85, A88, A89, A9, A90, A94, A96, A98
Rhinovirus B	• Rhinovirus B100, B101, B102, B103, B14, B17, B26, B27, B3, B35, B37, B4, B42, B48, B5, B52, B6, B69, B70, B72, B79, B83, B84, B86, B91, B92, B93, B97, B99
Rhinovirus C	• Rhinovirus C1, C11, C13, C15, C17, C19, C2, C20, C23, C26, C27, C28, C3, C30, C31, C32, C33, C34, C35, C36, C4, C40. C41, C43, C44, C47, C5, C50, C51, C53, C54, C55, C56, C6, C7, C8, C9

*Rest of Rhinovirus/Enterovirus strains not included in table correspond to no target gene sequences available to corroborate positive detection.

Table 12. Inclusivity of Adenovirus assay

Adenovirus subtype	Detected by BLAST/Sequence alignment
Adenovirus A	• Human Adenovirus A12, A18, A31, A61
Adenovirus B	• Human Adenovirus B3, B3+11p, B3+7, B7, B11, B50, B55, B1, B2
Adenovirus C	• Human Adenovirus C1, C2, C5, C6, C57
Adenovirus D	• Human Adenovirus D15, D15/H9, D17, D19, D20, D22, D23, D24, D25, D26, D27, D28, D29, D30, D32, D33, D36, D38, D39, D42, D43, D44, D45, D46, D47, D48, D49, D51, D53, D54, D58, D60a, D62, D63, D64, D65, D67, D69, D71, D81, D10, D13, D37, D8, D9
Adenovirus E	• Human Adenovirus E4 • Simian Adenovirus 23, 24, 25, 26, 30, 36, 37, 38, 39, E22 • Chimpanzee adenovirus Y25, Gorilla gorilla adenovirus E1
Adenovirus F	• Adenovirus F40, F41
Adenovirus G	• Adenovirus G52

Based on both wet testing and *in silico* analysis, the QIAstat-Dx Respiratory SARS-CoV-2 Panel primers and probes are specific and inclusive for clinically prevalent and relevant strains for each pathogen.

Reproducibility

To prove reproducible performance of the QIAstat-Dx Respiratory SARS-CoV-2 Panel on the QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0, a set of selected samples composed of low-concentrated analytes (3x LoD and 1x LoD) and high negative (0.1x LoD)/negative samples was tested in NPS processed in UTM or dry NPS.

NPS samples processed in UTM were tested in replicates using different lots of QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridges and tests were executed on different QIAstat-Dx Analyzers 1.0 by different operators, different sites and on different days. As SARS-CoV-2 was added as a target to the panel at a later stage, when reproducibility for all other targets

had been confirmed, SARS-CoV-2 testing was conducted in one site to corroborate that it had the expected behaviour. Table 13 contains the list of tested pathogens.

Table 14 and Table 15 summarize the results for 3x and 1x LoD concentration where it is observed that the detection rate for 24 of the 24 targets was ≥95%. Table 16 summarizes the results for high negative/negative concentration where it is observed that the detection rate for 24 of the 24 targets was <95% and 0%, respectively.

Table 13. List of respiratory pathogens tested for reproducibility in NPS in UTM

Pathogen	Strain
Influenza A H1	A/New Jersey/8/76
Influenza A H3	A/Port Chalmers/1/73
Influenza A H1N1/pdm09	A/SwineNY/03/2009
Influenza B	B/Taiwan/2/62
Coronavirus 229E	Not available
Coronavirus OC43	Not available
Coronavirus NL63	Not available
Coronavirus HKU1	Not available
Parainfluenza Virus 1	Not available
Parainfluenza Virus 2	Greer
Parainfluenza Virus 3	C 243
Parainfluenza Virus 4a	M-25
Rhinovirus	HGP (rhinovirus A2)
Enterovirus	US/IL/14-18952 (enterovirus D68)
Adenovirus	GB (adenovirus B3)
RSV B	CH93(18)-18

Table 13. List of respiratory pathogens tested for reproducibility in NPS in UTM (continued)

Pathogen	Strain
RSV A	A2
hMPV	hMPV-16, IA10-2003 (A1)
Bocavirus	Clinical sample
Mycoplasma pneumoniae	PI 1428
Chlamydophila pneumoniae	TW183
Legionella pneumophila	CA1
Bordetella pertussis	I028
SARS-CoV-2	England/02/2020

Table 14. Summary of Agreement for reproducibility at 3x LoD in NPS in UTM.

Target (3x LoD)	Specific signal	Site	Detection Rate (#Positive)	% Detection rate (#Positive)	Lower Two-Sided Exact 90% Confidence Limit	Upper Two-Sided Exact 90% Confidence Limit	% Agreement with expected result
Influenza A H1N1/pdm09 (0810249CFHI)*	Influenza A	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	19 / 19	100.00%	85.41%	100.00%	100.00%
		All Sites (Overall)	58 / 58	100.00%	94.97%	100.00%	100.00%
	H1N1/pdm09	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	19 / 19	100.00%	85.41%	100.00%	100.00%
		All Sites (Overall)	58 / 58	100.00%	94.97%	100.00%	100.00%

Table 14. Summary of Agreement for reproducibility at 3x LoD in NPS in UTM. (continued)

Target (3x LoD)	Specific signal	Site	Detection Rate (#Positive)	% Detection rate (#Positive)	Lower Two-Sided Exact 90% Confidence Limit	Upper Two-Sided Exact 90% Confidence Limit	% Agreement with expected result
Influenza A H1 (ATCC VR-897)*	Influenza A	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	60 / 60	100.00%	95.13%	100.00%	100.00%
	H1	Site 1	19 / 20	95.00%	78.39%	99.74%	95.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 60	98.33%	92.34%	99.91%	98.33%
Influenza H3 (ATCC VR-810)*	Influenza A	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
	H3	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
Influenza B	Not available	Site 1	19 / 20	95.00%	78.39%	99.74%	95.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	58 / 59	98.31%	92.21%	99.91%	98.31%

Table 14. Summary of Agreement for reproducibility at 3x LoD in NPS in UTM. (continued)

Target (3x LoD)	Specific signal	Site	Detection Rate	% Detection rate	Lower Two-Sided Exact 90%	Upper Two-Sided Exact 90%	% Agreement with expected result
			(#Positive)	(#Positive)	Confidence Limit	Confidence Limit	
Coronavirus 229E (ATCC VR-740)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
Coronavirus OC43 (ATCC VR-1558)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	19 / 19	100.00%	85.41%	100.00%	100.00%
		All Sites (Overall)	58 / 58	100.00%	94.97%	100.00%	100.00%
Coronavirus NL63 (0810228CFHI)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
Coronavirus HKU1 (NATRVP-IDI)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	60 / 60	100.00%	95.13%	100.00%	100.00%
Parainfluenza Virus 1 (0810014CFHI)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%

Table 14. Summary of Agreement for reproducibility at 3x LoD in NPS in UTM. (continued)

Target (3x LoD)	Specific signal	Site	Detection Rate	% Detection rate	Lower Two-Sided Exact 90%	Upper Two-Sided Exact 90%	% Agreement with expected result
			(#Positive)	(#Positive)	Confidence Limit	Confidence Limit	
Parainfluenza Virus 2 (ATCC VR-92)	Not available	Site 1	19 / 20	95.00%	78.39%	99.74%	95.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 60	98.33%	92.34%	99.91%	98.33%
Parainfluenza Virus 3 (ATCC VR-93)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	19 / 19	100.00%	85.41%	100.00%	100.00%
		All Sites (Overall)	58 / 58	100.00%	94.97%	100.00%	100.00%
Parainfluenza Virus 4 (ATCC VR-1378)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
Rhinovirus (ATCC VR-482)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	85.41%	100.00%	100.00%
		All Sites (Overall)	58 / 58	100.00%	94.97%	100.00%	100.00%
Enterovirus (ATCC VR-1824)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%

Table 14. Summary of Agreement for reproducibility at 3x LoD in NPS in UTM. (continued)

Target (3x LoD)	Specific signal	Site	Detection Rate	% Detection rate	Lower Two-Sided Exact 90%	Upper Two-Sided Exact 90%	% Agreement with expected result
			(#Positive)	(#Positive)	Confidence Limit	Confidence Limit	
Adenovirus (ATCC VR-3)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
Respiratory Syncytial Virus A (ATCC VR-1540)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	19 / 19	100.00%	85.41%	100.00%	100.00%
		All Sites (Overall)	58 / 58	100.00%	94.97%	100.00%	100.00%
Respiratory Syncytial Virus B (0810040CF)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	60 / 60	100.00%	95.13%	100.00%	100.00%
Human Metapneumovirus (0810161CF)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
M. pneumoniae (ATCC 29085)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	19 / 19	100.00%	85.41%	100.00%	100.00%
		All Sites (Overall)	58 / 58	100.00%	94.97%	100.00%	100.00%

Table 14. Summary of Agreement for reproducibility at 3x LoD in NPS in UTM. (continued)

Target (3x LoD)	Specific signal	Site	Detection Rate (#Positive)	% Detection rate (#Positive)	Lower Two-Sided Exact 90% Confidence Limit	Upper Two-Sided Exact 90% Confidence Limit	% Agreement with expected result
C. pneumoniae (ATCC VR-2282)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 20	95.00%	78.39%	99.74%	95.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 60	98.33%	92.34%	99.91%	98.33%
B. pertussis (ATCC BAA-2707)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
SARS-CoV-2 (NIBSC)†	Not available	Site 1	92/92	100%	96.07%	100%	100%

* Two signals are required (both generic Influenza A and the strain specific target) for the complete results reporting of the pathogen.

† Tested in one site.

Table 15. Summary of Agreement for reproducibility at 1x LoD in NPS in UTM.

Target (1x LoD)	Specific signal	Site	Detection Rate (#Positive)	% Detection rate (#Positive)	Lower Two-Sided Exact 90% Confidence Limit	Upper Two-Sided Exact 90% Confidence Limit	% Agreement with expected result
Influenza A H1N1/pdm09 (0810249CFHI)*	Influenza A	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
	H1N1/pdm09	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	85.41%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	94.97%	100.00%	100.00%
Influenza A H1 (ATCC VR-897)*	Influenza A	Site 1	19 / 20	95.00%	78.39%	99.74%	95.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59/ 60	98.33%	92.34%	99.91%	98.33%
	H1	Site 1	20/ 20	100.00%	86.09%	100.00%	100.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	19/ 20	95.00%	78.39%	99.74%	95.00%
		All Sites (Overall)	59 / 60	98.33%	92.34%	99.91%	98.33%
Influenza H3 (ATCC VR-810)*	Influenza A	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%

Table 15. Summary of Agreement for reproducibility at 1x LoD in NPS in UTM. (continued)

Target (1x LoD)	Specific signal	Site	Detection Rate (#Positive)	% Detection rate (#Positive)	Lower Two-Sided Exact 90% Confidence Limit	Upper Two-Sided Exact 90% Confidence Limit	% Agreement with expected result
	H3	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	18 / 18	100.00%	84.67%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	58 / 58	100.00%	94.97%	100.00%	100.00%
Influenza B	Not available	Site 1	19 / 20	95.00%	78.39%	99.74%	95.00%
		Site 2	20 / 20	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	58 / 59	98.31%	92.21%	99.91%	98.31%
Coronavirus 229E (ATCC VR-740)	Not available	Site 1	18 / 20	90.00%	71.74%	98.19%	90.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	58 / 60	96.67%	89.88%	99.40%	96.67%
Coronavirus OC43 (ATCC VR-1558)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
Coronavirus NL63 (0810228CFHI)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	18 / 18	100.00%	84.67%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	58 / 58	100.00%	94.97%	100.00%	100.00%

Table 15. Summary of Agreement for reproducibility at 1x LoD in NPS in UTM. (continued)

Target (1x LoD)	Specific signal	Site	Detection Rate	% Detection rate	Lower Two-Sided Exact 90%	Upper Two-Sided Exact 90%	% Agreement with expected result
			(#Positive)	(#Positive)	Confidence Limit	Confidence Limit	
Coronavirus HKU1 (NATRVP-IDI)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	60 / 60	100.00%	95.13%	100.00%	100.00%
Parainfluenza Virus 1 (0810014CFHI)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	18 / 18	100.00%	84.67%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	58 / 58	100.00%	94.97%	100.00%	100.00%
Parainfluenza Virus 2 (ATCC VR-92)	Not available	Site 1	19 / 20	95.00%	78.39%	99.74%	95.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	19 / 20	95.00%	78.39%	99.74%	95.00%
		All Sites (Overall)	58 / 60	96.67%	89.88%	99.40%	96.67%
Parainfluenza Virus 3 (ATCC VR-93)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
Parainfluenza Virus 4 (ATCC VR-1378)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	60 / 60	100.00%	95.13%	100.00%	100.00%

Table 15. Summary of Agreement for reproducibility at 1x LoD in NPS in UTM. (continued)

Target (1x LoD)	Specific signal	Site	Detection Rate	% Detection rate	Lower Two-Sided Exact 90%	Upper Two-Sided Exact 90%	% Agreement with expected result
			(#Positive)	(#Positive)	Confidence Limit	Confidence Limit	
Rhinovirus (ATCC VR-482)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
Enterovirus (ATCC VR-1824)	Not available	Site 1	19 / 20	95.00%	78.39%	99.74%	95.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	19 / 20	95.00%	78.39%	99.74%	95.00%
		All Sites (Overall)	58 / 60	96.67%	89.88%	99.40%	96.67%
Adenovirus (ATCC VR-3)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	18 / 18	100.00%	84.67%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	58 / 58	100.00%	94.97%	100.00%	100.00%
Respiratory Syncytial Virus A (ATCC VR-1540)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
Human Metapneumovirus (0810161CF)	Not available	Site 1	19 / 20	95.00%	86.09%	99.74%	95.00%
		Site 2	20 / 20	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 60	98.33%	95.05%	99.91%	98.33%

Table 15. Summary of Agreement for reproducibility at 1x LoD in NPS in UTM. (continued)

Target (1x LoD)	Specific signal	Site	Detection Rate	% Detection rate	Lower Two-Sided Exact 90%	Upper Two-Sided Exact 90%	% Agreement with expected result
			(#Positive)	(#Positive)	Confidence Limit	Confidence Limit	
M. pneumoniae (ATCC 29085)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	19 / 19	100.00%	85.41%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	59 / 59	100.00%	95.05%	100.00%	100.00%
C. pneumoniae (ATCC VR-2282)	Not available	Site 1	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	60 / 60	100.00%	95.13%	100.00%	100.00%
B. pertussis (ATCC BAA-2707)	Not available	Site 1	18 / 20	90.00%	71.74%	98.19%	90.00%
		Site 2	20 / 20	100.00%	86.09%	100.00%	100.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	58 / 60	96.67%	89.88%	99.40%	96.67%
SARS-CoV-2 (NIBSC)†	Not available	Site 1	87/90	96.67%	90.57%	99.31%	96.67%

* Two signals are required (both generic Influenza A and the strain specific target) for the complete results reporting of the pathogen.

† Tested in one site.

Table 16. Summary of Agreement for reproducibility at 0.1x LoD in NPS in UTM.

Target (0.1x LoD)	Specific signal	Site	Detection Rate (#Positive)	% Detection rate (#Positive)	Lower Two-Sided Exact 90% Confidence Limit	Upper Two-Sided Exact 90% Confidence Limit	% Agreement with expected result
Influenza A H1N1/pdm09 (0810249CFHI)*	Influenza A	Site 1	19 / 20	95.00%	78.39%	99.74%	95.00%
		Site 2	18 / 20	90.00%	71.74%	98.19%	90.00%
		Site 3	20 / 20	100.00%	86.09%	100.00%	100.00%
		All Sites (Overall)	57 / 60	95.00%	87.58%	98.62%	95.00%
	H1N1/pdm09	Site 1	14 / 20	70.00%	49.22%	86.04%	70.00%
		Site 2	16 / 20	80.00%	59.90%	92.86%	80.00%
		Site 3	15 / 20	75.00%	54.44%	89.59%	75.00%
		All Sites (Overall)	45 / 60	75.00%	64.15%	83.91%	75.00%
Influenza A H1 (ATCC VR-897)*	Influenza A	Site 1	14 / 20	70.00%	49.22%	86.04%	70.00%
		Site 2	9 / 19	47.37%	27.39%	67.99%	47.37%
		Site 3	12 / 20	60.00%	39.36%	78.29%	60.00%
		All Sites (Overall)	35 / 59	59.32%	47.78%	70.13%	59.32%
	H1	Site 1	13 / 20	65.00%	44.20%	82.27%	65.00%
		Site 2	13 / 19	68.42%	47.00%	85.25%	68.42%
		Site 3	15 / 20	75.00%	54.44%	89.59%	75.00%
		All Sites (Overall)	41 / 59	69.49%	58.19%	79.26%	69.49%
Influenza H3 (ATCC VR-810)*	Influenza A	Site 1	10 / 20	50.00%	30.20%	69.80%	50.00%
		Site 2	9 / 19	47.37%	27.39%	67.99%	47.37%
		Site 3	16 / 19	84.21%	64.06%	95.55%	84.21%
		All Sites (Overall)	35 / 58	60.34%	48.70%	71.17%	60.34%

Table 16. Summary of Agreement for reproducibility at 0.1x LoD in NPS in UTM. (continued)

Target (0.1x LoD)	Specific signal	Site	Detection Rate	% Detection rate	Lower Two-Sided Exact 90%	Upper Two-Sided Exact 90%	% Agreement with expected result
			(#Positive)	(#Positive)	Confidence Limit	Confidence Limit	
	H3	Site 1	13 / 20	65.00%	44.20%	82.27%	65.00%
		Site 2	16 / 19	84.21%	64.06%	95.55%	84.21%
		Site 3	17 / 19	89.47%	70.42%	98.10%	89.47%
		All Sites (Overall)	46 / 58	79.31%	68.64%	87.61%	79.31%
Influenza B (ATCC VR-295)	n/a	Site 1	7 / 20	35.00%	17.73%	55.80%	35.00%
		Site 2	9 / 19	47.37%	27.39%	67.99%	47.37%
		Site 3	8 / 20	40.00%	21.71%	60.64%	40.00%
		All Sites (Overall)	24 / 59	40.68%	29.87%	52.22%	40.68%
Coronavirus 229E (ATCC VR-740)	Not available	Site 1	9 /20	45.00%	25.87%	65.31%	45.00%
		Site 2	12 / 19	63.16%	41.81%	81.25%	63.16%
		Site 3	5 / 20	25.00%	10.41%	45.56%	25.00%
		All Sites (Overall)	26 / 59	44.07%	33.01%	55.58%	44.07%
Coronavirus OC43 (ATCC VR-1558)	Not available	Site 1	13 / 20	65.00%	44.20%	82.27%	65.00%
		Site 2	15 / 20	75.00%	54.44%	89.59%	75.00%
		Site 3	15 / 20	75.00%	54.44%	89.59%	75.00%
		All Sites (Overall)	43 / 60	71.67%	60.58%	81.07%	71.67%
Coronavirus NL63 (0810228CFHI)	Not available	Site 1	13 / 20	65.00%	44.20%	82.27%	65.00%
		Site 2	12 / 19	63.16%	41.81%	81.25%	63.16%
		Site 3	14 / 19	73.68%	52.42%	89.01%	73.68%
		All Sites (Overall)	39 / 58	67.24%	55.74%	77.37%	67.24%

Table 16. Summary of Agreement for reproducibility at 0.1x LoD in NPS in UTM. (continued)

Target (0.1x LoD)	Specific signal	Site	Detection Rate	% Detection rate	Lower Two-Sided Exact 90%	Upper Two-Sided Exact 90%	% Agreement with expected result
			(#Positive)	(#Positive)	Confidence Limit	Confidence Limit	
Coronavirus HKU1 (NATRVP-IDI)	Not available	Site 1	17 / 20	85.00%	65.63%	95.78%	85.00%
		Site 2	10 / 19	52.63%	32.01%	72.61%	52.63%
		Site 3	9 / 20	45.00%	25.87%	65.31%	45.00%
		All Sites (Overall)	36 / 59	61.02%	49.48%	71.69%	61.02%
Parainfluenza Virus 1 (0810014CFHI)	Not available	Site 1	14 / 20	70.00%	49.22%	86.04%	70.00%
		Site 2	12 / 19	63.16%	41.81%	81.25%	63.16%
		Site 3	9 / 19	47.37%	27.39%	67.99%	47.37%
		All Sites (Overall)	35 / 58	60.34%	48.70%	71.17%	60.34%
Parainfluenza Virus 2 (ATCC VR-92)	Not available	Site 1	9 / 20	45.00%	25.87%	65.31%	45.00%
		Site 2	11 / 19	57.89%	36.81%	77.03%	57.89%
		Site 3	12 / 20	60.00%	39.36%	78.29%	60.00%
		All Sites (Overall)	32 / 59	54.24%	42.75%	65.39%	54.24%
Parainfluenza Virus 3 (ATCC VR-93)	Not available	Site 1	13 / 20	65.00%	44.20%	82.27%	65.00%
		Site 2	17 / 20	85.00%	65.63%	95.78%	85.00%
		Site 3	17 / 20	85.00%	65.63%	95.78%	85.00%
		All Sites (Overall)	47 / 60	78.33%	67.78%	86.68%	78.33%
Parainfluenza Virus 4 (ATCC VR-1378)	Not available	Site 1	10 / 20	50.00%	30.20%	69.80%	50.00%
		Site 2	11 / 19	57.89%	36.81%	77.03%	57.89%
		Site 3	9 / 20	45.00%	25.87%	65.31%	45.00%
		All Sites (Overall)	30 / 59	50.85%	39.46%	62.17%	50.85%

Table 16. Summary of Agreement for reproducibility at 0.1x LoD in NPS in UTM. (continued)

Target (0.1x LoD)	Specific signal	Site	Detection Rate (#Positive)	% Detection rate (#Positive)	Lower Two-Sided Exact 90% Confidence Limit	Upper Two-Sided Exact 90% Confidence Limit	% Agreement with expected result
Rhinovirus (ATCC VR-482)	Not available	Site 1	15 / 20	75.00%	54.44%	89.59%	75.00%
		Site 2	15 / 20	75.00%	54.44%	89.59%	75.00%
		Site 3	18 / 20	90.00%	71.74%	98.19%	90.00%
		All Sites (Overall)	48 / 60	80.00%	69.62%	88.03%	80.00%
Enterovirus (ATCC VR-1824)	Not available	Site 1	8 / 20	40.00%	21.71%	60.64%	40.00%
		Site 2	6 / 19	31.58%	14.75%	53.00%	31.58%
		Site 3	7 / 20	35.00%	17.73%	55.80%	35.00%
		All Sites (Overall)	21 / 59	35.59%	25.24%	47.08%	35.59%
Adenovirus (ATCC VR-3)	Not available	Site 1	10 / 20	50.00%	30.20%	69.80%	50.00%
		Site 2	9 / 19	47.37%	27.39%	67.99%	47.37%
		Site 3	10 / 19	52.63%	32.01%	72.61%	52.63%
		All Sites (Overall)	29 / 58	50.00%	38.54%	61.46%	50.00%
Respiratory Syncytial Virus A (ATCC VR-1540)	Not available	Site 1	6 / 20	30.00%	13.96%	50.78%	30.00%
		Site 2	7 / 20	35.00%	17.73%	55.80%	35.00%
		Site 3	9 / 20	45.00%	25.87%	65.31%	45.00%
		All Sites (Overall)	22 / 60	36.67%	26.29%	48.07%	36.67%
Respiratory Syncytial Virus B (0810040CF)	Not available	Site 1	14 / 20	70.00%	49.22%	86.04%	70.00%
		Site 2	15 / 19	78.95%	58.09%	92.47%	78.95%
		Site 3	10 / 20	50.00%	30.20%	69.80%	50.00%
		All Sites (Overall)	39 / 59	66.10%	54.67%	76.28%	66.10%

Table 16. Summary of Agreement for reproducibility at 0.1x LoD in NPS in UTM. (continued)

Target (0.1x LoD)	Specific signal	Site	Detection Rate	% Detection rate	Lower Two-Sided Exact 90%	Upper Two-Sided Exact 90%	% Agreement with expected result
			(#Positive)	(#Positive)	Confidence Limit	Confidence Limit	
Human Meta-pneumovirus (0810161CF)	Not available	Site 1	6 / 20	30.00%	13.96%	50.78%	30.00%
		Site 2	9 / 19	47.37%	27.39%	67.99%	47.37%
		Site 3	9 / 20	45.00%	25.87%	65.31%	45.00%
		All Sites (Overall)	24 / 59	40.68%	29.87%	52.22%	40.68%
M. pneumoniae (ATCC 29085)	Not available	Site 1	13 / 20	65.00%	44.20%	82.27%	65.00%
		Site 2	14 / 20	70.00%	49.22%	86.04%	70.00%
		Site 3	14 / 20	70.00%	49.22%	86.04%	70.00%
		All Sites (Overall)	41 / 60	68.33%	57.08%	78.17%	68.33%
C. pneumoniae (ATCC VR-2282)	Not available	Site 1	11 /20	55.00%	34.69%	74.13%	55.00%
		Site 2	11 / 19	57.89%	36.81%	77.03%	57.89%
		Site 3	14 / 20	70.00%	49.22%	86.04%	70.00%
		All Sites (Overall)	36 / 59	61.02%	49.48%	71.69%	61.02%
B. pertussis (ATCC BAA-2707)	Not available	Site 1	9 / 20	45.00%	25.87%	65.31%	45.00%
		Site 2	7 / 19	36.84%	18.75%	58.19%	36.84%
		Site 3	9 / 20	45.00%	25.87%	65.31%	45.00%
		All Sites (Overall)	25 / 59	42.37%	31.43%	53.91%	42.37%
SARS-CoV-2 (NIBSC)†	Not available	Site 1	90/90‡	100%‡	95.98%	100.00%	100%

* Two signals are required (both generic Influenza A and the strain specific target) for the complete results reporting of the pathogen.

† Tested in one site at negative concentration.

‡ Refers to #Negative

NPS samples processed as dry NPS were also tested in replicates using different lots of QIAstat-Dx Respiratory SARS-CoV-2 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 17).

Table 18 and Table 19 summarize the results for 3x and 1x LoD concentration where it is observed that the detection rate for 8 of the 8 targets was ≥95%. Table 20 summarizes the results for negative concentration where it is observed that the detection rate for 8 of the 8 targets was 0%.

Table 17. List of respiratory pathogens tested for reproducibility in dry NPS.

Pathogen	Strain
Influenza B	B/Florida/4/2006
Coronavirus OC43	Not available
Parainfluenza Virus 3	C 243
Rhinovirus	HGP (rhinovirus A2)
Adenovirus	GB (adenovirus B3)
Mycoplasma pneumoniae	PI 1428
SARS-CoV-2	England/02/2020

Table 18. Summary of Agreement for reproducibility testing at 3x LoD in dry NPS.

Target (3x LoD)	Specific signal	Site	Detection Rate	% Detection rate	% Agreement with expected result
			(#Positive)	(#Positive)	
Influenza B (ATCC VR-295)	Not available	Site 1	30/30	100%	100%
		Site 2	30/30	100%	100%
		Site 3	30/30	100%	100%
		All Sites (Overall)	90/90	100%	100%
Coronavirus OC43 (ATCC VR-1558)	Not available	Site 1	30/30	100%	100%
		Site 2	30/30	100%	100%
		Site 3	30/30	100%	100%
		All Sites (Overall)	90/90	100%	100%
Parainfluenza Virus 3 (ATCC VR-93)	Not available	Site 1	30/30	100%	100%
		Site 2	30/30	100%	100%
		Site 3	30/30	100%	100%
		All Sites (Overall)	90/90	100%	100%
Rhinovirus (ATCC VR-482)	Not available	Site 1	30/30	100%	100%
		Site 2	30/30	100%	100%
		Site 3	30/30	100%	100%
		All Sites (Overall)	90/90	100%	100%
Adenovirus (ATCC VR-3)	Not available	Site 1	30/30	100%	100%
		Site 2	30/30	100%	100%
		Site 3	30/30	100%	100%
		All Sites (Overall)	90/90	100%	100%

Table 18. Summary of Agreement for reproducibility testing at 3x LoD in dry NPS. (continued)

Target (3x LoD)	Specific signal	Site	Detection Rate	% Detection rate	% Agreement with expected result
M. pneumoniae (ATCC 29085)	Not available	Site 1	30/30	100%	100%
		Site 2	30/30	100%	100%
		Site 3	30/30	100%	100%
		All Sites (Overall)	90/90	100%	100%
SARS-CoV-2 (NIBSC)	Not available	Site 1	30/30	100%	100%
		Site 2	30/30	100%	100%
		Site 3	30/30	100%	100%
		All Sites (Overall)	90/90	100%	100%

Table 19. Summary of Agreement for reproducibility testing at 1x LoD in dry NPS.

Target (1x LoD)	Specific signal	Site	Detection Rate	% Detection rate	% Agreement with expected result
			(#Positive)	(#Positive)	
Influenza B (ATCC VR-295)	Not available	Site 1	30/30	100%	100%
		Site 2	30/30	100%	100%
		Site 3	30/30	100%	100%
		All Sites (Overall)	90/90	100%	100%
Coronavirus OC43 (ATCC VR-1558)	Not available	Site 1	28/30	93.3%	100%
		Site 2	29/30	96.6%	100%
		Site 3	29/30	96.6%	100%
		All Sites (Overall)	86/90	95.5%	100%

Table 19. Summary of Agreement for reproducibility testing at 1x LoD in dry NPS. (continued)

Target (1x LoD)	Specific signal	Site	Detection Rate	% Detection rate	% Agreement with expected result
Parainfluenza Virus 3 (ATCC VR-93)	Not available	Site 1	30/30	100%	93.3%
		Site 2	30/30	100%	96.6%
		Site 3	30/30	100%	96.6%
		All Sites (Overall)	90/90	100%	95.6%
Rhinovirus (ATCC VR-482)	Not available	Site 1	30/30	100%	100%
		Site 2	30/30	100%	100%
		Site 3	30/30	100%	100%
		All Sites (Overall)	90/90	100%	100%
Adenovirus (ATCC VR-3)	Not available	Site 1	30/30	100%	100%
		Site 2	30/30	100%	100%
		Site 3	30/30	100%	100%
		All Sites (Overall)	90/90	100%	100%
M. pneumoniae (ATCC 29085)	Not available	Site 1	30/30	100%	100%
		Site 2	30/30	100%	100%
		Site 3	28/30	93.3%	93.3%
		All Sites (Overall)	88/90	97.8%	97.8%
SARS-CoV-2 (NIBSC)	Not available	Site 1	30/30	100%	100%
		Site 2	30/30	100%	100%
		Site 3	30/30	100%	100%
		All Sites (Overall)	90/90	100%	100%

Table 20. Summary of Agreement for reproducibility testing in negative dry NPS.

Target (Negative)	Specific signal	Site	Detection Rate	% Detection rate	% Agreement with expected result
			(#Positive)	(#Positive)	
All	Not available	Site 1	690/690	100%	100%
		Site 2	690/690	100%	100%
		Site 3	690/690	100%	100%
		All Sites (Overall)	2070/2070	100%	100%

Reproducibility testing demonstrated that QIAstat-Dx Respiratory SARS-CoV-2 Panel running in the QIAstat-Dx Analyzer 1.0 provides highly reproducible 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 SARS-CoV-2 Panel Cartridges.

The potential variation introduced by sites, days, replicates, cartridge lots, operators, and QIAstat-Dx Analyzers was assessed during the reproducibility study showing no significant contribution to variability (Coefficient of Variation and Standard Deviation values below 5% and 1.0, respectively) caused by any of the assessed variables.

Repeatability

A repeatability study was conducted on the QIAstat-Dx Analyzer 1.0 instruments using a representative set of NPS in UTM samples composed of low-concentrated analytes spiked into simulated matrix (3x LoD, 1x LoD and 0.1x LoD). Pathogens included in the positive samples were as per the Reproducibility study (see Table 13). Each sample was tested in triplicate per day and cartridge lot (three lots tested in total) in the course of 15 days. In total, at least 45 replicates of each sample concentration were run. High negative samples resulted in <95% detection rate, 1x LoD samples in ≥90% detection rate, and 3x LoD samples in ≥95% of

positive calls for all targets tested. This was also confirmed for Dry NPS samples for which a representative set of low-concentrated analytes (see Table 17) at 3x LoD and 1x LoD, as well as negative samples, were analysed. Samples were tested at least in triplicate per day, over 12 days and using a total of 3 different cartridge lots. In total, 60 replicates of each sample concentration were run. Samples resulted in ≥95.0% and ≥90% detection rate at 3xLoD and 1xLoD, respectively. For negative samples, 99.6% of negative calls were observed.

The potential variation introduced by days, replicates, cartridge lots, and QIAstat-Dx Analyzers was assessed during the repeatability study showing no significant contribution to variability (Coefficient of Variation and Standard Deviation values below 5% and 1.0, respectively) caused by any of the assessed variables.

Repeatability in the QIAstat-Dx Rise instrument was also evaluated in comparison with QIAstat-Dx Analyzers. The 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 two QIAstat-Dx Analyzer 1.0 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 93.3-100.0% 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 QIAstat-Dx Analyzer 1.0.

Whole system failure rate

The whole system failure rate was assessed by analysing SARS-CoV-2 samples tested at 3x LoD concentration (156 with QIAstat-Dx Analyzer 1.0 and 125 with QIAstat-Dx Rise). A 100% detection rate of these samples was demonstrated.

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 and the QIAstat-Dx Rise.

Samples of simulated NPS matrix, with alternating high-positive and negative samples, were tested on two QIAstat-Dx Analyzer 1.0 and one QIAstat-Dx Rise instrument containing eight AMs.

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

Interfering substances (Analytical Specificity)

The effect of potentially interfering substances on the detectability of the QIAstat-Dx Respiratory SARS-CoV-2 Panel organisms was evaluated. 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. Potentially interfering substances were added to contrived samples at a level predicted to be above the concentration of the substance likely to be found in an authentic NPS specimen. The contrived samples (also referred to as combined samples) were each comprised of a mix of organisms tested at a concentration of 3x–5x LoD.

Endogenous substances such as whole blood, human genomic DNA and several pathogens were tested alongside exogenous substances like antibiotics, nasal sprays and different workflow contaminants.

The combined samples were tested with and without addition of an inhibitory substance allowing direct sample-to-sample comparison. Additionally, for substances that may contain

genetic material (such as blood, mucin, DNA and microorganisms), negative specimens (blank artificial NPS sample matrix with no organism mix) were spiked with only the test substance to evaluate the potential for false positive results due to the test substance itself.

Combined samples not spiked with any test substance served as a positive control and blank artificial NPS sample matrix with no organism mix as negative control.

All pathogen-containing samples without spiked interferent generated positive signals for all pathogens present in the respective combined sample. Negative signals were obtained for all pathogens not present in the same sample but detected by the QIAstat-Dx Respiratory SARS-CoV-2 Panel.

None of the substances tested showed inhibition, except for the nasal influenza vaccines. In addition, nasal influenza vaccines (Fluenz Tetra and FluMist®) were predicted to be reactive with the QIAstat-Dx Respiratory SARS-CoV-2 Panel Influenza A (including subtypes) and Influenza B assays. Final dilution without observable interfering effect was 0.000001% v/v for both vaccines.

No impact on performance is expected when clinical NPS samples are examined in the presence of the substances tested.

The results of interfering substance testing are provided in Table 21.

Table 21. Outcome of interfering substances highest concentrations tested

Substance tested	Concentration tested	Results
Endogenous substances		
Human genomic DNA 200 ng/µL	20 ng/µL	No Interference
Human blood (+NaCitrate)	1% v/v	No Interference
Mucin from bovine submaxillary	1% v/v	No Interference

Table 21. Outcome of interfering substances highest concentrations tested (continued)

Substance tested	Concentration tested	Results
Competitive microorganisms		
Staphylococcus aureus	1.00E+06 CFU/mL* 4.50E+08 CFU/mL*	No Interference No Interference
Neisseria meningitidis	5.00E+04 CFU/mL* 1.00E+03 CFU/mL*	No Interference No Interference
Corynebacterium diphtheriae	5.00E+03 CFU/mL* 1.00E+03 CFU/mL*	No Interference No Interference
Human Cytomegalovirus	1.00E+05 TCID50/mL* 1.00E+04 TCID50/mL*	No Interference No Interference
Exogenous substances		
Tobramycin	0.6 mg/ml	No Interference
Mupirocin	2% w/v	No Interference
Saline nasal spray with preservatives	1% v/v	No Interference
Afrin®, severe congestion nasal spray (Oxymetazoline HCl)	1% v/v	No Interference
Analgesic ointment (Vicks® VapoRub®)	1% w/v	No Interference
Petroleum Jelly (Vaseline®)	1% w/v	No Interference
FluMist nasal influenza vaccine†	0.00001% v/v 0.000001% v/v	Interference No Interference
Fluenz Tetra nasal influenza vaccine†	0.00001% v/v 0.000001% v/v	Interference No Interference
Chiroflu Influenza Vaccine (surface antigen inactivated)†	0.000001% v/v	No Interference
Disinfecting/cleaning substances		
Disinfecting wipes	½ inches2/1 ml UTM	No Interference

Table 21. Outcome of interfering substances highest concentrations tested (continued)

Substance tested	Concentration tested	Results
DNAZap	1% v/v	No Interference
RNaseOUT‡	1% v/v	No Interference
ProtectRNA™ RNase Inhibitor 500x Concentrate‡	1% v/v	No Interference
Bleach	5% v/v	No Interference
Ethanol	5% v/v	No Interference
Specimen collection materials		
Swab Copan 168C	1 swab/1 ml UTM	No Interference
Swab Copan FloQ	1 swab/1 ml UTM	No Interference
Swab Copan 175KS01	1 swab/1 ml UTM	No Interference
Swab Puritan 25-801 A 50	1 swab/1 ml UTM	No Interference
VTM Sigma Virocult	100%	No Interference
VTM Remel M4-RT	100%	No Interference
VTM Remel M4§	100%	No Interference
VTM Remel M5§	100%	No Interference
VTM Remel M6§	100%	No Interference
VTM RT§	100%	No Interference
DeltaSwab Virus§	100%	No Interference
BD Universal Viral Transport	100%	No Interference

* Microorganism concentrations tested depending on stock availability.

† Bocavirus, *Legionella pneumophila*, and SARS-CoV-2 were tested with Chiroflu nasal influenza vaccine instead of FluMist and Fluenz Tetra nasal vaccines.

‡ Bocavirus, *Legionella pneumophila*, and SARS-CoV-2 were tested with Protect RNA instead of RNAseOUT.

§ Bocavirus, *Legionella pneumophila*, and SARS-CoV-2 were tested with VTM RT and Delta Swab Virus instead of VTM Remel M4, VTM Remel M5 and VTM Remel M6.

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 (25x-50x LoD concentration) and low concentrations (5x LoD concentration) and tested in different combinations. Table 22 shows the combination of co-infections tested in this study.

Table 22. List of co-infections combinations tested

Pathogens	Strain	Concentration
Influenza A H3N2	A/Port Chalmers/1/73	50x LoD
Adenovirus C2	Adenoid 6	5x LoD
Influenza A H3N2	A/Port Chalmers/1/73	5x LoD
Adenovirus C2	Adenoid 6	50x LoD
Parainfluenza Virus 3	C243	50x LoD
Enterovirus D68	US/IL/14-18952	5x LoD
Influenza A H3N2	A/Port Chalmers/1/73	50x LoD
Adenovirus C2	Adenoid 6	5x LoD
Influenza A H3N2	A/Port Chalmers/1/73	5x LoD
Adenovirus C2	Adenoid 6	50x LoD
Parainfluenza Virus 3	C243	50x LoD
Enterovirus D68	US/IL/14-18952	5x LoD

Table 22. List of co-infections combinations tested (continued)

Pathogens	Strain	Concentration
Parainfluenza 3 Virus	C243	5x LoD
Enterovirus D68	US/IL/14-18952	50x LoD
Respiratory Syncytial Virus A	A2	50x LoD
Influenza B	B/Virginia/ATCC5/2012	5x LoD
Respiratory Syncytial Virus A	A2	5x LoD
Influenza B	B/Virginia/ATCC5/2012	50x LoD
Adenovirus C2	Adenoid 6	50x LoD
Rhinovirus A2	HGP	5x LoD
Adenovirus C2	Adenoid 6	5x LoD
Rhinovirus A2	HGP	50x LoD
Respiratory Syncytial Virus A	A2	50x LoD
Rhinovirus A2	HGP	5x LoD
Respiratory Syncytial Virus A	A2	5x LoD
Rhinovirus A2	HGP	50x LoD
Coronavirus OC43	OC43	50x LoD
Rhinovirus A2	HGP	5x LoD
Coronavirus OC43	OC43	5x LoD
Rhinovirus A2	HGP	50x LoD
Human Metapneumovirus B2	Peru6-2003	50x LoD
Parainfluenza Virus 1	C-35	5x LoD
Human Metapneumovirus B2	Peru6-2003	5x LoD
Parainfluenza Virus 1	C-35	50x LoD
Coronavirus 229E	229E	50x LoD
Respiratory Syncytial Virus A	A2	5x LoD
Coronavirus 229E	229E	5x LoD
Respiratory Syncytial Virus A	A2	50x LoD

Table 22. List of co-infections combinations tested (continued)

Pathogens	Strain	Concentration
Respiratory Syncytial Virus B Coronavirus NL63	18537 Not available	50x LoD 5x LoD
Respiratory Syncytial Virus B Coronavirus NL63	18537 Not available	5x LoD 50x LoD
Influenza A H1N1/pdm09 Influenza B	NY/03/09 B/Virginia/ATCC5/2012	25x LoD* 5x LoD
Influenza A H1N1/pdm09 Influenza B	NY/03/09 B/Virginia/ATCC5/2012	5x LoD 50x LoD
Coronavirus 229E Coronavirus OC43	229E OC43	50x LoD 5x LoD
Coronavirus 229E Coronavirus OC43	229E OC43	5x LoD 50x LoD
Parainfluenza 3 Parainfluenza Virus 4a	C-243 M-25	50x LoD 5x LoD
Parainfluenza 3 Parainfluenza Virus 4a	C-243 M-25	5x LoD 50x LoD
Respiratory Syncytial Virus B Human Metapneumovirus A1	18537 IA 10-2003	5x LoD* 5x LoD
Respiratory Syncytial Virus B Human Metapneumovirus A1	18537 IA 10-2003	5x LoD 50x LoD
Influenza A H3N2 Rhinovirus A2	A/Port Chalmers/1/73 HGP	50x LoD 5x LoD
Influenza A H3N2 Rhinovirus A2	A/Port Chalmers/1/73 HGP	5x LoD 50x LoD
M. pneumoniae *C. pneumoniae*	M129-B7 TW183	50x LoD 5x LoD

Table 22. List of co-infections combinations tested (continued)

Pathogens	Strain	Concentration
M. pneumoniae	M129-B7	5x LoD
C. pneumoniae	TW183	50x LoD
Respiratory Syncytial Virus B	9320	50x LoD
Bocavirus	Clinical sample	5x LoD
Respiratory Syncytial Virus B	9320	5x LoD
Bocavirus	Clinical sample	50x LoD
Influenza A H3N2	A/Virginia/ATCC6/2012	50x LoD
Adenovirus C5	Adenoid 75	5x LoD
Influenza A H3N2	A/Virginia/ATCC6/2012	5x LoD
Adenovirus C5	Adenoid 75	50x LoD
Parainfluenza Virus 3	C243	50x LoD
Influenza A H1N1/pdm09	NY/03/09	5x LoD
Parainfluenza Virus 3	C243	5x LoD
Influenza A H1N1/pdm09	NY/03/09	50x LoD
Adenovirus C5	Adenoid 75	50x LoD
Rhinovirus B, Type HRV-B14	1059	5x LoD
Adenovirus C5	Adenoid 75	5x LoD
Rhinovirus B, Type HRV-B14	1059	50x LoD
Respiratory Syncytial Virus A	A2	50x LoD
Rhinovirus B, Type HRV-B14	1059	5x LoD
Respiratory Syncytial Virus A	A2	5x LoD
Rhinovirus B, Type HRV-B14	1059	50x LoD
Coronavirus OC43	OC43	50x LoD
Rhinovirus B, Type HRV-B14	1059	5x LoD
Coronavirus OC43	OC43	5x LoD
Rhinovirus B, Type HRV-B14	1059	50x LoD

*Final concentration tested that allowed detection of both pathogens in the mix.

Two combinations of pathogens: Influenza A H1N1/pdm09 with Influenza B; and RSV B with hMPV A1, did not produce a positive result for both targets in the mix at the initial concentration tested. After diluting the concentrations of these samples, both targets of the co-infections were successfully detected. Co-infections by Influenza A H1N1/pdm09 and Influenza B are very rare, and circulation of both viruses simultaneously during the same season is unusual ([22] and [23]). Although RSV and hMPV viruses have overlapping seasonality, hMPV is more frequently detected in spring while RSV peak is in winter, decreasing the probability of co-infections. All other co-infections tested, with the exception of the aforementioned combinations, gave a positive result for the two pathogens combined at low and high concentrations. No effect in assay results are observed due to the presence of co-infections.

Clinical performance

The clinical performance was demonstrated using QIAstat-Dx Analyzer 1.0. The QIAstat-Dx Rise and the QIAstat-Dx Analyzer 2.0 use the same Analytical Modules as QIAstat-Dx Analyzer 1.0; therefore the clinical performance is not impacted by use of QIAstat-Dx Rise or QIAstat-Dx Analyzer 2.0. The equivalency on performance between QIAstat-Dx Rise and QIAstat-Dx Analyzer 1.0 was confirmed through a repeatability study (see details on page 142).

Since 2018, multiple studies across EU and USA sites have been conducted generating data which was subsequently used in a meta-analysis. This analysis included a total of 3746 subjects with signs and symptoms of respiratory infection.

Specimens tested in the clinical studies were collected using the Universal Transport Medium (UTM) (Copan Diagnostics [Brescia, Italy and CA, USA]), DeltaSwab Virus (DeltaLab, Spain), MicroTest™ M4®, M4RT®, M5®, M6® (Thermo Fisher Scientific®, MA, USA), BD™ Universal Viral Transport (UVT) System (Becton Dickinson, NJ, USA), Universal Transport Medium (UTM) System (HealthLink® Inc., FL, USA), Universal Transport Medium (Diagnostic Hybrids®, OH,

USA), V-C-M Medium (Quest Diagnostics®, NJ, USA) and UniTranz-RT® Universal Transport Media (Puritan® Diagnostics, ME, USA) collection kits.

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 (CI) was calculated for each point estimate. Table 23 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 prior to discrepant resolution.

Table 23. Agreement Between QIAstat-Dx Respiratory SARS-CoV-2 Panel and Reference Method pre discrepant resolution

	Positive Percent Agreement			Negative Percent Agreement		
Target	**TP/ (TP+FN)**	**%**	**95% CI**	**TN/ (TN+FP)**	**%**	**95% CI**
Viruses						
Adenovirus	124 / 136	91.18%	85.09%–95.36%	2610 / 2642	98.79%	98.29%–99.17%
Bocavirus*	N/A	N/A	N/A	N/A	N/A	N/A

Table 23. Agreement Between QIAstat-Dx Respiratory SARS-CoV-2 Panel and Reference Method pre discrepant resolution (continued)

	Positive Percent Agreement			Negative Percent Agreement		
Target	TP/ (TP+FN)	%	95% CI	TN/ (TN+FP)	%	95% CI
Coronavirus 229E	38 / 42	90.48%	77.38%–97.34%	2734 / 2734	100.00%	99.87%–100.00%
Coronavirus OC43	63 / 67	94.03%	85.41%–98.35%	2704 / 2708	99.85%	99.62%–99.96%
Coronavirus NL63	86 / 98	87.76%	79.59%–93.51%	2674 / 2679	99.81%	99.56%–99.94%
Coronavirus HKU1	73 / 75	97.33%	90.70%–99.68%	2689 / 2701	99.56%	99.23%–99.77%
SARS-CoV-2	396 / 417	94.96%	92.40%–96.86%	535 / 540	99.07%	97.85%–99.70%
Human Meta-pneumovirus A+B	139 / 150	92.67%	87.26%–96.28%	2622 / 2627	99.81%	99.56%–99.94%
Influenza A	267 / 270	98.89%	96.79%–99.77%	2407 / 2495	96.47%	95.67%–97.16%
Influenza A H1N1 pdm09	124 / 128	96.88%	92.19%–99.14%	2634 / 2645	99.58%	99.26%–99.79%
Influenza A H1	0 / 1	0.00%	0.00%–97.50%	2774 / 2774	100.00%	99.87%–100.00%
Influenza A H3	199 / 203	98.03%	95.03%–99.46%	2558 / 2572	99.46%	99.09%–99.70%
Influenza B	175 / 184	95.11%	90.92%–97.74%	2590 / 2592	99.92%	99.72%–99.99%
Parainfluenza virus 1	58 / 59	98.31%	90.91%–99.96%	2713 / 2717	99.85%	99.62%–99.96%
Parainfluenza virus 2	8 / 10	80.00%	44.39%–97.48%	2766 / 2766	100.00%	99.87%–100.00%

Table 23. Agreement Between QIAstat-Dx Respiratory SARS-CoV-2 Panel and Reference Method pre discrepant resolution (continued)

	Positive Percent Agreement			Negative Percent Agreement		
Target	**TP/ (TP+FN)**	**%**	**95% CI**	**TN/ (TN+FP)**	**%**	**95% CI**
Parainfluenza virus 3	121 / 127	95.28%	90.00%–98.25%	2646 / 2652	99.77%	99.51%–99.92%
Parainfluenza virus 4	28 / 31	90.32%	74.25%–97.96%	2732 / 2745	99.53%	99.19%–99.75%
Respiratory Syncytial Virus A+B	313 / 329	95.14%	92.22%–97.20%	2438 / 2447	99.63%	99.30%–99.83%
Rhinovirus/Enterovirus	366 / 403	90.82%	87.57%–93.45%	2313 / 2375	97.39%	96.67%–97.99%
Bacteria						
Bordetella pertussis	41 / 41	100.00%	91.40%–100.00%	2716 / 2735	99.31%	98.92%–99.58%
Chlamydophila pneumoniae	66 / 74	89.19%	79.80%–95.22%	2700 / 2702	99.93%	99.73%–99.99%
*Legionella pneumophila**	N/A	N/A	N/A	N/A	N/A	N/A
Mycoplasma pneumoniae	65 / 65	100.00%	94.48%–100.00%	2703 / 2711	99.70%	99.42%–99.87%
Overall						
Overall	2750 / 2910	94.50%	93.61%–95.30%	53258 / 53559	99.44%	99.37%–99.50%

*not applicable as no clinical specimens seen across full dataset

Following discrepant resolution, 2889 true positive and 53289 true negative QIAstat-Dx Respiratory Panel results were found, as well as 120 false-negative and 162 false-positive results. Table 24 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 following discrepant resolution.

Table 24. Agreement between QIAstat Respiratory SARS-CoV-2 Panel and Reference Method following Discrepant Resolution

	Positive Percent Agreement			Negative Percent Agreement		
Target	**TP/ (TP+FN)**	**%**	**95% CI**	**TN/ (TN+FP)**	**%**	**95% CI**
Viruses						
Adenovirus	136 / 141	96.45%	91.92%–98.84%	2617 / 2637	99.24%	98.83%–99.54%
Bocavirus*	N/A	N/A	N/A	N/A	N/A	N/A
Coronavirus 229E	38 / 41	92.68%	80.08%–98.46%	2735 / 2735	100.00%	99.87%–100.00%
Coronavirus OC43	66 / 70	94.29%	86.01%–98.42%	2704 / 2705	99.96%	99.79%–100.00%
Coronavirus NL63	88 / 97	90.72%	83.12%–95.67%	2677 / 2680	99.89%	99.67%-99.98%
Coronavirus HKU1	73 / 74	98.65%	92.70%–99.97%	2690 / 2702	99.56%	99.23%–99.77%
SARS-CoV-2	397 / 409	97.07%	94.93%–98.47%	544 / 548	99.27%	98.14%–99.80%
Human Meta-pneumovirus A+B	142 / 148	95.95%	91.39%–98.50%	2627 / 2629	99.92%	99.73%–99.99%
Influenza A	327 / 330	99.09%	97.37%–99.81%	2407 / 2435	98.85%	98.34%–99.23%
Influenza A H1N1 pdm09	124 / 128	96.88%	92.19%–99.14%	2634 / 2645	99.58%	99.26%–99.79%
Influenza A H1	0 / 1	0.00%	0.00%–97.50%	2774 / 2774	100.00%	99.87%-100.00%

Table 24. Agreement between QIAstat Respiratory SARS-CoV-2 Panel and Reference Method following Discrepant Resolution (continued)

	Positive Percent Agreement			Negative Percent Agreement		
Target	**TP/ (TP+FN)**	**%**	**95% CI**	**TN/ (TN+FP)**	**%**	**95% CI**
Influenza A H3	210 / 214	98.13%	95.28%–99.49%	2558 / 2561	99.88%	99.66%–99.98%
Influenza B	177 / 185	95.68%	91.66%–98.11%	2591 / 2591	100.00%	99.86%–100.00%
Parainfluenza virus 1	62 / 63	98.41%	91.47%–99.96%	2713 / 2713	100.00%	99.86%–100.00%
Parainfluenza virus 2	8 / 8	100.00%	63.06%–100.00%	2768 / 2768	100.00%	99.87%–100.00%
Parainfluenza virus 3	122 / 126	96.83%	92.07%–99.13%	2648 / 2653	99.81%	99.56%–99.94%
Parainfluenza virus 4	38 / 41	92.68%	80.08%–98.46%	2732 / 2735	99.89%	99.68%–99.98%
Respiratory Syncytial Virus A+B	319 / 331	96.37%	93.75%–98.11%	2442 / 2445	99.88%	99.64%–99.97%
Rhinovirus/Enterovirus	385 / 418	92.11%	89.09%–94.50%	2317 / 2360	98.18%	97.55%-98.68%
Bacteria						
Bordetella pertussis	43 / 43	100.00%	91.78%–100.00%	2716 / 2733	99.38%	99.01%–99.64%
Chlamydophila pneumoniae	68 / 75	90.67%	81.71%–96.16%	2701 / 2701	100.00%	99.86%–100.00%
*Legionella pneumophila**	N/A	N/A	N/A	N/A	N/A	N/A
Mycoplasma pneumoniae	66 / 66	100.00%	94.56%–100.00%	2703 / 2710	99.74%	99.47%–99.90%
Overall						

Table 24. Agreement between QIAstat Respiratory SARS-CoV-2 Panel and Reference Method following Discrepant Resolution (continued)

	Positive Percent Agreement			Negative Percent Agreement		
Target	TP/ (TP+FN)	%	95% CI	TN/ (TN+FP)	%	95% CI
Overall	2889 / 3009	96.01%	95.25%–96.68%	53298 / 53460	99.70%	99.65%–99.74%

* Target not evaluated in clinical specimens.

Contrived specimens were used as surrogate clinical specimens to supplement and test the sensitivity and specificity of Bocavirus, *Legionella pneumophila,* Influenza A H1N1, Parainfluenza 2, Parainfluenza 4, Coronavirus 229E and *Chlamydophila pneumoniae.* Residual negative clinical specimens were spiked with the pathogens at 2x, 5x and 10x LoD levels for Bocavirus and *Legionella pneumophila*, and 3x, 5x and 10x LoD levels for Influenza A H1N1, Parainfluenza 2, Parainfluenza 4, Coronavirus 229E, and *Chlamydophila pneumoniae.*

Results of the contrived specimen testing are provided in Table 25 and Table 26.

Table 25. QIAstat-Dx Respiratory SARS-CoV-2 Panel performance data on contriving samples for Bocavirus, *Legionella pneumophila*

				Exact Two-sided 95% Confidence Interval	
Pathogen	Sample Level	Frequency	Proportion (%)	Lower Limit (%)	Upper Limit (%)
Bocavirus	2xLoD	25 / 25	100.00%	86.28%	100.00%
	5xLoD	15 / 15	100.00%	78.20%	100.00%
	10xLoD	10 / 10	100.00%	69.15%	100.00%
Legionella pneumophila	2xLoD	25 / 25	100.00%	86.28%	100.00%
	5xLoD	15 / 15	100.00%	78.20%	100.00%
	10xLoD	10 / 10	100.00%	69.15%	100.00%

Table 26. QIAstat-Dx Respiratory SARS-CoV-2 Panel performance data on contriving samples for Influenza A H1N1, Parainfluenza 2, Parainfluenza 4, Coronavirus 229E and *Chlamydophila pneumoniae*

				Exact Two-sided 95% Confidence Interval	
Pathogen	**Sample Level**	**Frequency**	**Proportion (%)**	**Lower Limit (%)**	**Upper Limit (%)**
Influenza A , H1	3xLOD	24/24	100%	86.2%	100%
	5xLOD	27/27	100%	87.5%	100%
	10xLOD	24/24	100%	86.2%	100%
Coronavirus 229E	3xLOD	16/16	100%	80.6%	100%
	5xLOD	18/18	100%	82.4%	100%
	10xLOD	16/16	100%	80.6%	100%
Parainfluenza Virus 2	3xLODv	16/16	100%	80.6%	100%
	5xLOD	18/18	100%	82.4%	100%
	10xLOD	16/16	100%	80.6%	100%
Parainfluenza Virus 4	3xLOD	15/16	93.8%	71.7%	100%
	5xLOD	18/18	100%	82.4%	100%
	10xLOD	16/16	100%	80.6%	100%
Chlamydophila pneumoniae	3xLOD	16/16	100%	80.6%	100%
	5xLOD	18/18	100%	82.4%	100%
	10xLOD	16/16	100%	80.6%	100%

Conclusion

Extensive multicenter studies demonstrate the performance of the QIAstat-Dx Respiratory SARS-CoV-2 Panel assay.

The overall Clinical Sensitivity was found to be 95.73% (95% CI, 94.94%–96.42%). The overall Clinical Specificity 99.70% (95% CI, 99.65%–99.74%).

Summary of safety and performance

The summary of safety and performance can be found on the EUDAMED website.

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Troubleshooting guide

In case of damaged cartridge, please refer to the Safety Information section. For technical assistance and more information, please see our Technical Support Center at **www.qiagen.com/Support** (for contact information, visit **www.qiagen.com**). For issues that may occur with the QIAstat-Dx Analyzer 1.0 , QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise, please refer to the corresponding User Manuals which are also available at **www.qiagen.com**.

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 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**) must be saved onto a USB Drive prior to installation on the QIAstat-Dx Analyzer 1.0 or 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 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 QIAstat-Dx Analyzer 2.0.
2. Press **Options** and then select **Assay Management.** The Assay Management screen appears in the Content area of the display (Figure 67).

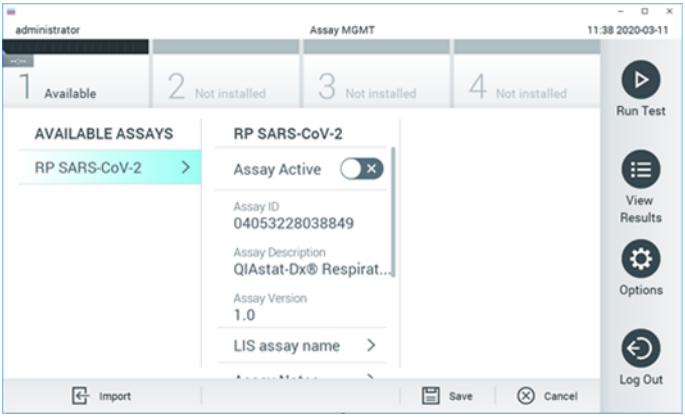

Figure 67. Assay Management screen.

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 68).

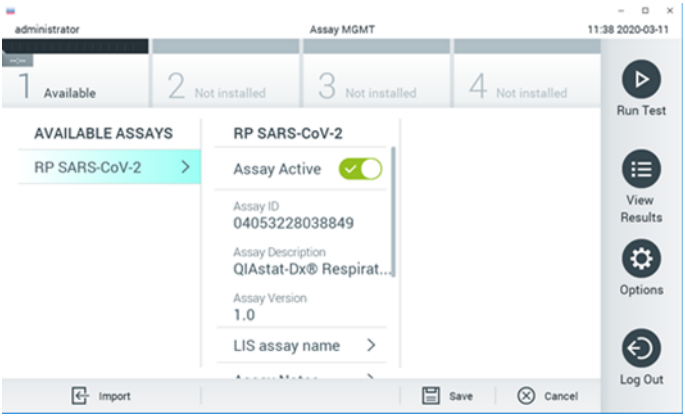

Figure 68. Activating the assay.

8. To assign the active assay to the user, perform the following steps (Figure 69):
   a. Go to **Options** > **User Management**.
   b. Select the user who should be allowed to run the assay.
   c. Select **Assign Assays** from User Options section.
   d. Enable the assay, then press **Save**.

Figure 69. 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, QIAstat-Dx Analyzer 2.0 and QIAstat-Dx Rise hardware module in charge of executing tests on QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridges.
- **QIAstat-Dx Analyzer 1.0**: The QIAstat-Dx Analyzer 1.0 consists of an Operational Module and an Analytical Module. The Operational Module 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 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. The system also includes a multi-test front drawer and a waste drawer to automatically discard the performed tests.
- **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.
- **NPS**: Nasopharyngeal swab.
- **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 NPS.

- **User**: A person who operates the QIAstat-Dx Analyzer 1.0 / QIAstat-Dx Analyzer 2.0 / QIAstat-Dx Rise / QIAstat-Dx Respiratory SARS-CoV-2 Panel cartridge in the intended way.
- **UTM**: Universal Transport Medium. Stands for a generic term referring to liquid transport medium used for collection and preservation of respiratory pathogens.

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.

Symbols

The following symbols may appear in the instructions for use or on the packaging and labeling:

Symbol	Symbol Definition
	Contains reagents sufficient for <N> reactions
	Use by
	This product fulfills the requirements of the European Regulation 2017/746 for in vitro diagnostic medical devices.
	*In vitro* diagnostic medical device
	Catalog number
	Lot number
	Material number (i.e., component labeling)
	Components
	Contains
	Number
	Global Trade Item Number
Rn	R is for revision of the Instructions for Use and n is the revision number
	Temperature limitation
	Manufacturer
	Consult instructions for use
	Keep away from sunlight
	Warning/caution

Contact Information

For technical assistance and more information, please see our Technical Support Center at **www.qiagen.com/Support**, call 00800-22-44-6000, or contact one of the QIAGEN Technical Service Departments or local distributors (see back cover or visit **www.qiagen.com**).

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	691215
Instrument		
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 Base Module with up to 8 QIAstat-Dx Analytical Modules and related hardware and software to run molecular diagnostics on QIAstat-Dx assay cartridges	9003163

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

Document Revision History

Revision	Description
R1, January 2025	Initial release
R2, May 2025	Inclusion of QIAstat-Dx Analyzer 2.0 Update of clinical data for *Chlamydophila pneumoniae*

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