August 2025

QIAstat-Dx® Respiratory Panel Plus Instructions for Use

Σ 6

Version 1

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

℞ Only

IVD

REF 691224

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R3

Sample to Insight

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Intended Use

The QIAstat-Dx® Respiratory Panel Plus is a multiplexed nucleic acid test intended for use with the QIAstat-Dx system for the simultaneous in vitro qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals with clinical signs and symptoms of respiratory tract infections, including Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2).

The following organism types and subtypes are identified using the QIAstat-Dx Respiratory Panel Plus: Adenovirus, Human Coronavirus 229E, Human Coronavirus HKU1, Human Coronavirus NL63, Human Coronavirus OC43, Human Metapneumovirus, Influenza A, Influenza A H1, Influenza A H1N1 pdm09, Influenza A H3, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Respiratory Syncytial Virus, Human Rhinovirus/Enterovirus (not differentiated), SARS-CoV-2, *Bordetella pertussis*, *Chlamydophila pneumoniae*, and *Mycoplasma pneumoniae*.

Nucleic acids from viral and bacterial organisms identified by this test are generally detectable in NPS specimens during the acute phase of infection. Detecting and identifying specific viral and bacterial nucleic acids from individuals presenting with signs and symptoms of a respiratory infection aids in the diagnosis of respiratory infection, if used in conjunction with other clinical, epidemiological and laboratory findings. The results of this test should not be used as the sole basis for diagnosis, treatment or other patient management decisions.

Negative results in the presence of a respiratory illness may be due to infection with pathogens that are not detected by the test, or due to lower respiratory tract infection that is not detected by a NPS specimen.

Conversely, positive results are indicative of the presence of the identified microorganism, but do not rule out co-infection with other pathogens not detected by the QIAstat-Dx Respiratory

Panel Plus. The agent(s) detected by the QIAstat-Dx Respiratory Panel Plus may not be the definite cause of disease.

The use of additional laboratory testing (e.g., bacterial and viral culture, immunofluorescence, and radiography) may be necessary when evaluating a patient with possible respiratory tract infection.

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 Panel Plus Cartridge is a single-use cartridge that includes all reagents needed for nucleic acid extraction, nucleic acid amplification, and detection of 22 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 was designed in early 2020 upon alignment of the first available 170 genomic sequences in public databases from the SARS-CoV-2 identified as the causative agent of the viral pneumonia (COVID-19) outbreak that originated in Wuhan, Hubei, China. Up to date, a coverage of more than sixteen million of available genome sequences support the inclusivity and good performance of the SARS-CoV-2 detection. The SARS-CoV-2 assay 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 Panel Plus are listed in Table 1 (2–15).

Table 1. Pathogens detected by the QIAstat-Dx Respiratory Panel Plus

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

Note: Enterovirus and Rhinovirus are both detected, but not differentiated, with the QIAstat-Dx Respiratory Panel Plus

Summary and explanation

QIAstat-Dx Respiratory Panel Plus Cartridge description

The QIAstat-Dx Respiratory Panel Plus 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 Panel Plus Cartridge include compatibility with nasopharyngeal swabs resuspended in transport medium (liquid samples), hermetical containment of the pre-loaded reagents necessary for testing, and true walk-away operation. All sample preparation and assay testing steps are performed within the cartridge.

All reagents required for the complete execution of a test run are pre-loaded and self-contained in the QIAstat-Dx Respiratory Panel Plus 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, or 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 Panel Plus 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.

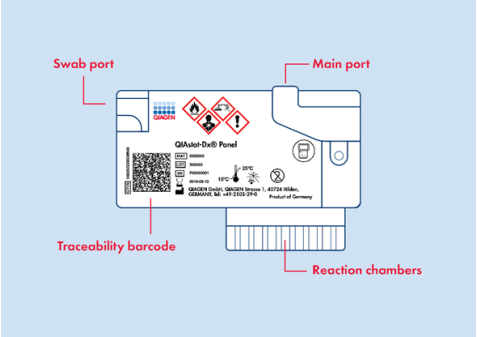


Figure 1. Layout of the QIAstat-Dx Respiratory Panel Plus Cartridge and its features.

Note: The swab port is not used for the QIAstat-Dx Respiratory Panel Plus.

Principle of the Procedure

Description of the process

Diagnostic tests with the QIAstat-Dx Respiratory Panel Plus 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, or QIAstat-Dx Rise. Samples are collected and loaded manually into the QIAstat-Dx Respiratory Panel Plus Cartridge:

A transfer pipette provided with the test kit is used for dispensing transport medium liquid sample into the main port (Figure 2).

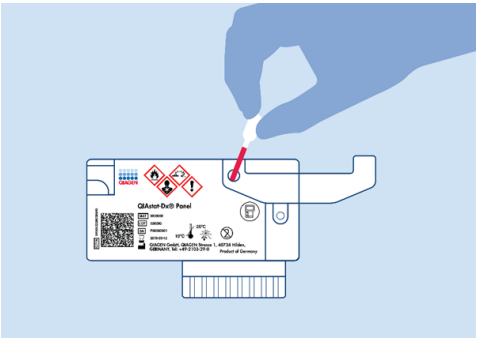


Figure 2. Dispensing transport medium liquid sample into the main port.

Sample collection and cartridge loading

The collection of samples and their subsequent loading into the QIAstat-Dx Respiratory Panel Plus 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 transport medium.
3. The sample information is manually written on a sample label affixed to the top of a QIAstat-Dx Respiratory Panel Plus Cartridge.
4. Transport medium liquid sample is loaded manually into the QIAstat-Dx Respiratory Panel Plus Cartridge.
5. 300 µL of sample is transferred into the main port of the QIAstat-Dx Respiratory Panel Plus Cartridge using one of the included transfer pipettes.

   Note: When loading transport medium liquid sample, the user performs a visual check of the sample inspection window (see image below) to confirm that the liquid sample has been loaded (Figure 3).

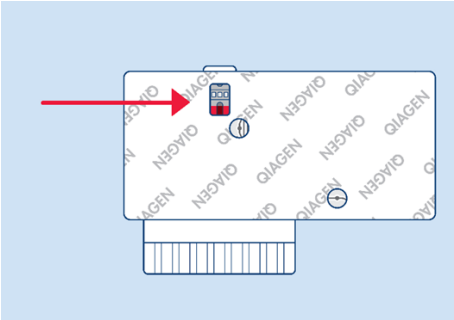


Figure 3. Sample inspection window (red arrow).

6. The sample barcode and the QIAstat-Dx Respiratory Panel Plus 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.

7. The QIAstat-Dx Respiratory Panel Plus Cartridge is introduced into the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, or QIAstat-Dx Rise.

8. 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, or QIAstat-Dx Rise.

1. The liquid sample is homogenized and cells are lysed in the lysis chamber of the QIAstat-Dx Respiratory Panel Plus 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 Panel Plus 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 Panel Plus Cartridge.
4. The mixture of sample and PCR reagents is dispensed into the QIAstat-Dx Respiratory Panel Plus Cartridge PCR chambers, which contain lyophilized, assay-specific primers and probes.
5. The QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, or 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, or QIAstat-Dx Rise software interprets the resulting data and process controls and delivers a test report.

Materials Provided

Kit contents

QIAstat-Dx Respiratory Panel Plus **Catalog no.** **Number of tests**	 **691224** **6**
QIAstat-Dx Respiratory Panel Plus Cartridge	6*
Transfer pipettes	6†
QIAstat-Dx Respiratory Panel Plus Product Information Card	1

*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 Panel Plus Cartridge.

Materials Required but Not Provided

Platform and software

The QIAstat-Dx Respiratory Panel Plus is designed for use with the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, or 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 must be assembled together to work with software version 1.4 or 1.5.
    - For QIAstat-Dx Analyzer 2.0: at least one Operational Module PRO and one Analytical Module must be assembled together to work 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 1.4 or 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 the QIAstat-Dx Respiratory Panel Plus installed on the Operational Module or Operational Module PRO.

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

Warnings and Precautions

For in vitro diagnostic use. The QIAstat-Dx Respiratory Panel Plus is to be used by laboratory professionals trained in the use of the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, or QIAstat-Dx Rise.

This device is restricted to sale by or on the order of a physician, or to a clinical laboratory; its use is restricted to, by, or on the order of a physician.

Pertussis is a nationally notifiable infectious disease in the U.S. If *Bordetella pertussis* is detected, notify state and/or local health departments.

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 at **www.qiagen.com/safety** where you can find, view, and print the SDS for each QIAGEN kit and kit component.

Samples are potentially infectious. 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, used cartridges, and transfer pipettes as if they are capable of transmitting infectious agents. Always observe safety precautions as outlined in relevant guidelines, such as the Clinical and Laboratory Standards Institute® (CLSI) *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline* (M29) [18], or other appropriate documents provided by:

- OSHA®: Occupational Safety and Health Administration (United States of America)
- ACGIH®: American Conference of Government Industrial Hygienists (United States of America)

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

If infection with SARS-CoV-2 is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions.

If infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to a state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

The QIAstat-Dx Respiratory Panel Plus 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, or QIAstat-Dx Rise. Do not use a QIAstat-Dx Respiratory Panel Plus Cartridge that is past its expiration date, appears damaged, or leaks fluid. Dispose of used or damaged cartridges in accordance with all national, state, and local health and safety regulations and laws.

Observe standard laboratory procedures for keeping the working area clean and contamination-free. Guidelines are outlined in publications such as the *Biosafety in Microbiological and Biomedical Laboratories from the Centers for Disease Control and Prevention and the National Institutes of Health* (**www.cdc.gov/labs/BMBL**).

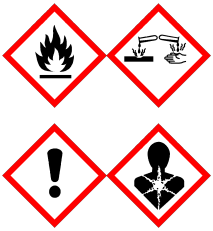
Emergency information

CHEMTREC

USA & Canada 1-800-424-9300

Precautions

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



Contains: ethanol; guanidine hydrochloride; guanidine thiocyanate; isopropanol; proteinase K; t-Octylphenoxypolyethoxyethanol.

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

Cartridge Storage and Handling

Store the QIAstat-Dx Respiratory Panel Plus Cartridges in a clean and dry storage space at room temperature (15–25°C). Do not remove the QIAstat-Dx Respiratory Panel Plus 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, the QIAstat-Dx Respiratory Panel Plus Cartridges can be stored until the expiration date printed on the individual packaging. The expiration date is also included in the QIAstat-Dx Respiratory Panel Plus Cartridge barcode, and is read by the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, or QIAstat-Dx Rise when the cartridge is inserted into the instrument to run a test.

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 16.

In-use stability

After the cartridge package is opened, sample should be introduced into the QIAstat-Dx Respiratory Panel Plus 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.

Specimen Storage and Handling

The QIAstat-Dx Respiratory Panel Plus 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.

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

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

- Room temperature up to 4 hours at 15–25°C;
- Refrigerated up to 3 days at approximately 4°C;
- Frozen up to 14 days at -20°C.

*Specimen collection material (NPS and UTM) is not provided with the QIAstat-Dx Respiratory Panel Plus.

Procedure

Important points before starting

- Ensure all materials required but not provided are available.
- Select the QIAstat-Dx Respiratory Panel Plus Cartridge (cat. no. 691224). Respiratory panel cartridge identification is supported by a blue-colored bar on the label and an icon indicating respiratory tract ().
- All operators should wear appropriate personal protective equipment, such as gloves, lab coat, and protective glasses when handling the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, or QIAstat-Dx Rise touchscreen and cartridges.

Sample collection, transport, and storage

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

Loading a sample into the QIAstat-Dx Respiratory Panel Plus Cartridge

1. Open the package of a QIAstat-Dx Respiratory Panel Plus Cartridge using the tear notches on the sides of the packaging (Figure 4).

   Important: After the package is opened, sample should be introduced into the QIAstat-Dx Respiratory Panel Plus Cartridge within 30 minutes.

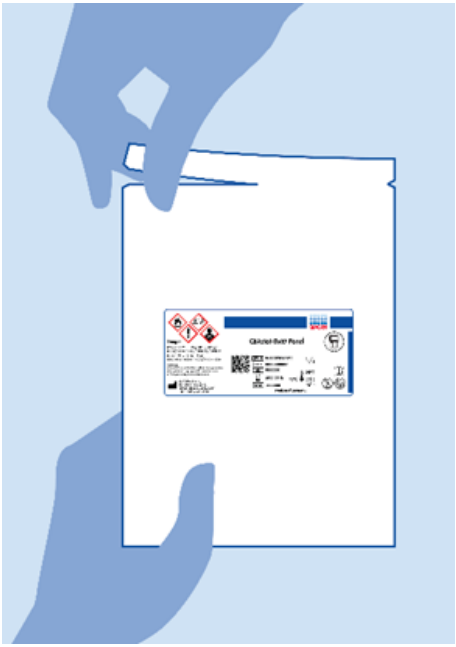


Figure 4. Opening the QIAstat-Dx Respiratory Panel Plus Cartridge.

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

3. For the QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0, manually write the sample information or place a sample information label on the top of the QIAstat-Dx Respiratory Panel Plus Cartridge. Make sure that the label is properly positioned and does not block the lid opening (Figure 5). If loading the cartridge in QIAstat-Dx Rise, see the QIAstat-Dx Rise workflow section for proper cartridge labelling.

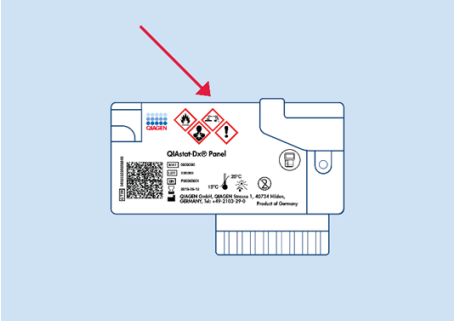


Figure 5. Sample information placement on top of the QIAstat-Dx Respiratory Panel Plus Cartridge.

4. Open the sample lid of the main port on the front of the QIAstat-Dx Respiratory Panel Plus Cartridge (Figure 6).

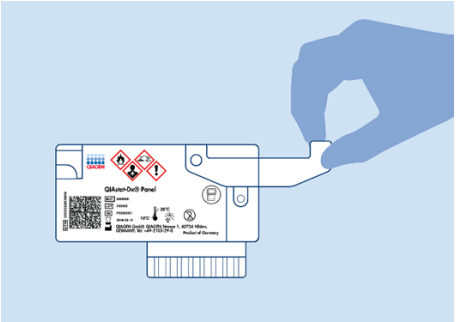


Figure 6. Opening the sample lid of main port.

5. Open the tube with the sample to be tested. Use the supplied transfer pipette to draw up fluid to the third fill line on the pipette (i.e., 300 µL) (Figure 7).

   Important: Avoid drawing air into the pipette. If Copan® UTM®, Universal Transport Medium, is used as transport medium, take care not to aspirate any of the beads present in the tube. If air or beads are drawn into the pipette, carefully expel the sample fluid in

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

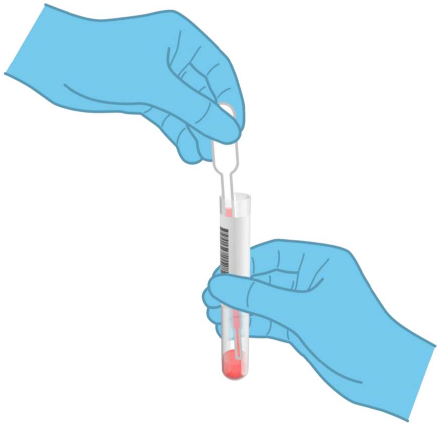


Figure 7. Drawing up sample into the supplied transfer pipette.

6. Carefully transfer 300 µL of sample volume into the main port of the QIAstat-Dx Respiratory Panel Plus Cartridge using the supplied single-use transfer pipette (Figure 8).

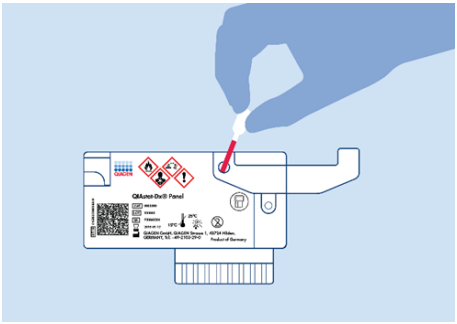


Figure 8. Transferring sample to main port of the QIAstat-Dx Respiratory Panel Plus Cartridge.

7. Firmly close the sample lid of the main port until it clicks (Figure 9).

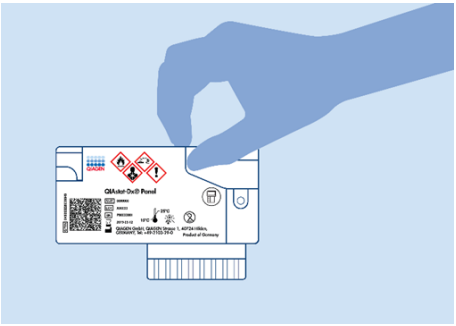


Figure 9. Closing the sample lid of the main port.

8. Visually confirm that the sample has been loaded by checking the sample inspection window of the QIAstat-Dx Respiratory Panel Plus Cartridge (Figure 10).

   Important: After the sample is placed inside the QIAstat-Dx Respiratory Panel Plus Cartridge, the cartridge must be loaded into the QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0 within 90 minutes; or immediately 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 the QIAstat-Dx Rise (onboard stability) is 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 onboard stability time.

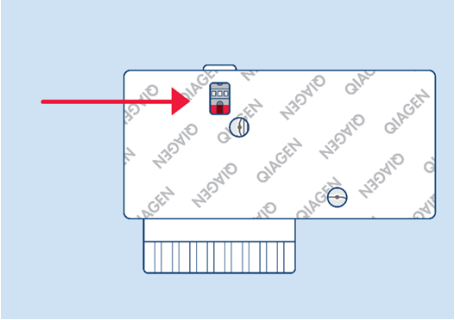


Figure 10. Sample inspection window (red arrow).

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

Starting the QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0

Warning: All operators should wear appropriate personal protective equipment, such as gloves, lab coat, and protective glasses when handling the QIAstat-Dx Analyzer 1.0 / QIAstat-Dx Analyzer 2.0 touchscreen and cartridges.

1. First, make sure the power switch at the back of the Analytical Module is set in the "I" position. Then, press the **ON/OFF** button on the front of the QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0 to start the instrument.

   Note: The QIAstat-Dx Analyzer 1.0 or 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 193 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, scan the sample ID barcode on the UTM tube containing the sample, or scan the specimen information barcode located on the top of the QIAstat-Dx Respiratory Panel Plus Cartridge (see step 3 from the section Procedure - Loading a sample into the QIAstat-Dx Respiratory Panel Plus Cartridge) using the integrated front barcode reader of the QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0 (Figure 11).

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

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

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

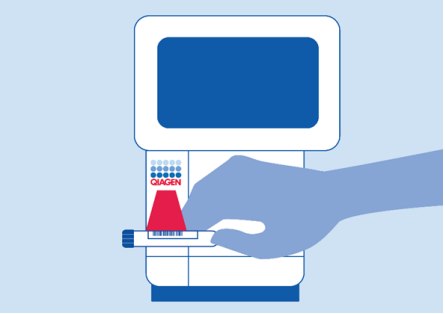


Figure 11. Scanning sample ID barcode.

7. When prompted, scan the barcode of the QIAstat-Dx Respiratory Panel Plus Cartridge to be used (Figure 12). 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 or QIAstat-Dx Analyzer 2.0 will not accept QIAstat-Dx Respiratory Panel Plus 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 Panel Plus Cartridge will be rejected. Refer to the *QIAstat-Dx Analyzer 1.0 User Manual* or *QIAstat-Dx Analyzer 2.0 User Manual* for further details on how to install assays.

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

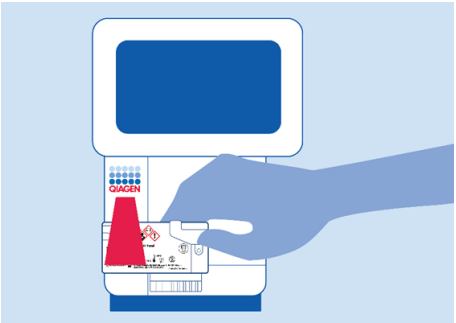


Figure 12. Scanning the QIAstat-Dx Respiratory Panel Plus Cartridge barcode.

8. 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.
9. 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 13).

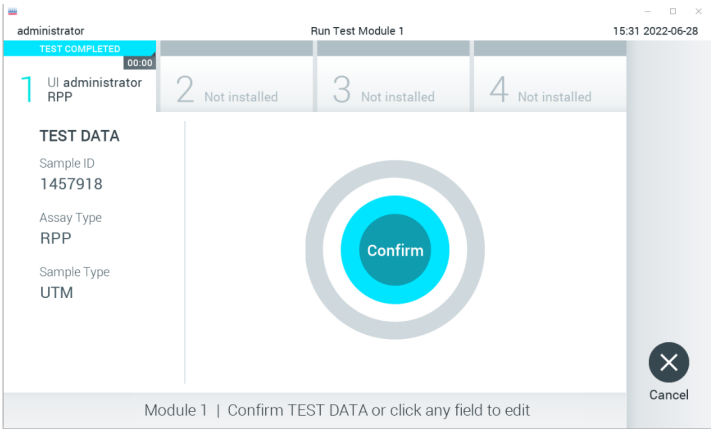


Figure 13. Confirming data entry.

10. Make sure that the lids of the swab port and main port of the QIAstat-Dx Respiratory Panel Plus Cartridge are firmly closed. When the cartridge entrance port on the top of QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0 automatically opens, insert the QIAstat-Dx Respiratory Panel Plus Cartridge with the barcode facing to the left and the reaction chambers facing down (Figure 14 on page 31).

    Note: There is no need to push the QIAstat-Dx Respiratory Panel Plus 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.

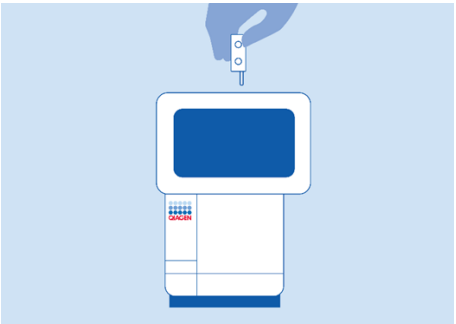


Figure 14. Inserting the QIAstat-Dx Respiratory Panel Plus Cartridge into the QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0.

11. Upon detecting the QIAstat-Dx Respiratory Panel Plus 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 Panel Plus 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 Panel Plus Cartridge is not positioned in the port. If this occurs, please press **Cancel** at the lower-right corner of the screen of the QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0 and repeat the procedure starting with step 13.

12. While the test is running, the remaining run time is displayed on the touchscreen.

13. After the test run is completed, the **Eject** screen will appear (Figure 15) 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.

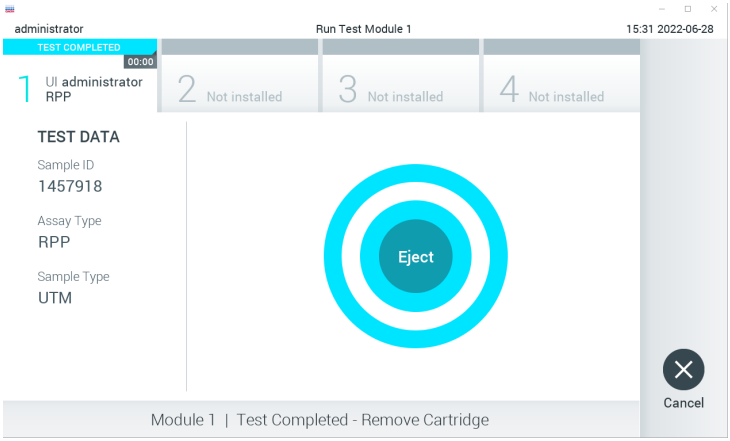


Figure 15. Eject screen display.

14. Press **Eject** on the touchscreen to remove the QIAstat-Dx Respiratory Panel Plus 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 Panel Plus 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 Panel Plus 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 Panel Plus Cartridge has been ejected, the results Summary screen will appear. Refer to "Interpretation of Results" on page 72 for further details. To begin the process for running another test, press **Run Test**.

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

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

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

The QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0 automatically interpret and save test results. After ejecting the QIAstat-Dx Respiratory Panel Plus Cartridge, the results Summary screen is automatically displayed (Figure 16 and Figure 17).

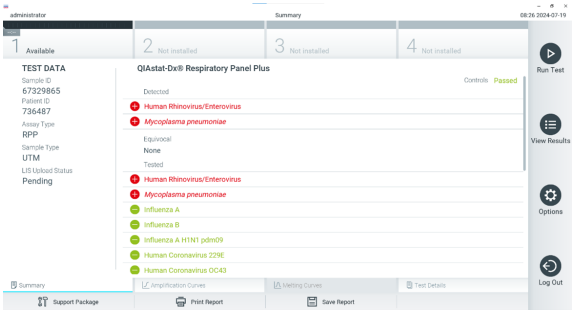


Figure 16. Results Summary screen example showing Test Data on the left panel and Test Summary in the main panel for QIAstat-Dx Analyzer 1.0.

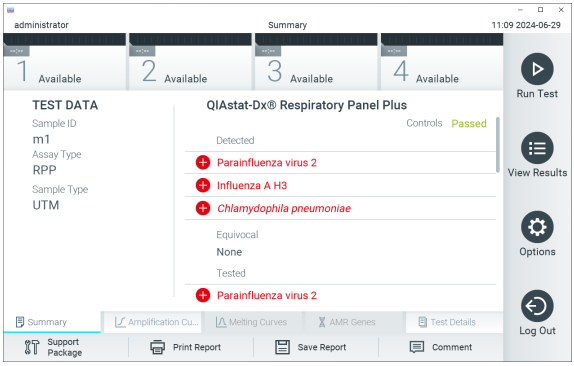


Figure 17. Results summary screen example showing Test Data on the left panel and Test Summary in the main panel for QIAstat-Dx Analyzer 2.0.

The QIAstat-Dx Analyzer 2.0 includes an additional tab:

- AMR Genes. It is disabled for the QIAstat-Dx Respiratory Panel Plus.

Note: From this point forward, example screenshots 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 includes all pathogens detected and identified in the sample, preceded by a  sign and are colored red.
- The second list includes all equivocal pathogens, preceded by a yellow question mark  , in the event any of the subtypes H1, H3 and/or H1N1 pdm09 are detected and identified in the sample, but Influenza A is not detected.

Note: Pathogens detected and identified in the sample are shown in all 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). For additional

details, please see "Viewing amplification curves with the QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0".

Running a test on the QIAstat-Dx Rise

Starting the QIAstat-Dx Rise

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

1. First make sure the power switch at the side connection box of the instrument must be set in the "I" position. Then, press the **ON/OFF** button on the front of the QIAstat-Dx Rise to start the unit (Figure 18).

Figure 18. ON/OFF button on the QIAstat-Dx Rise.

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

2. Log in to the system once the LOGIN screen appears (Figure 19).

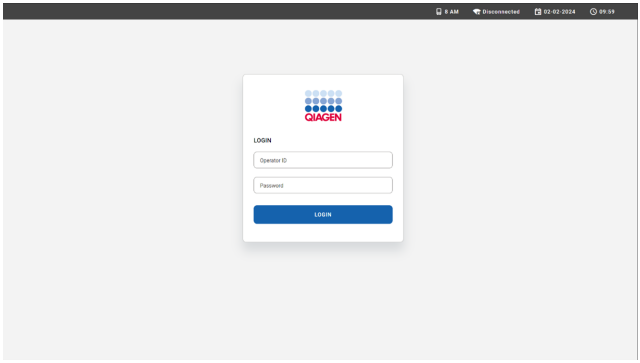


Figure 19. Log in screen.

3. After logging in, wait for initialization to complete. When initialization is complete, please check the following:
    - The QIAstat-Dx Rise is correctly initialized.
    - All installed Analytical Modules (AM) are operational.
    - The connectivity is available.
    - The HIS/LIS Settings are available.
    - Assay Definition File (ADF) is available.
    - Check if time and date settings are correct.
    - Check if patient ID is activated. If the use of patient ID is preferred, it must be enabled in the **SETTINGS** menu. Go to **SETTINGS** > **General Settings** > **TEST SETTINGS** > **Require Patient ID** and tap **EDIT**. Select **Require Patient ID** and press the **SAVE** button (see "General Settings" in the *QIAstat-Dx Rise User Manual*).

Preparing the QIAstat-Dx Respiratory Panel Plus Cartridge

For details about adding the sample to the cartridge, refer to "Loading a sample into the QIAstat-Dx Respiratory Panel Plus Cartridge".

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

Important: After the sample is placed inside the QIAstat-Dx Respiratory Panel Plus Cartridge, the cartridge must be loaded immediately 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 the QIAstat-Dx Rise (onboard stability) is 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 onboard stability time.

Adding a sample barcode to the QIAstat-Dx Respiratory Panel Plus Cartridge

Place a barcode on the top right side of the QIAstat-Dx Respiratory Panel Plus Cartridge indicated by the arrow (Figure 20).

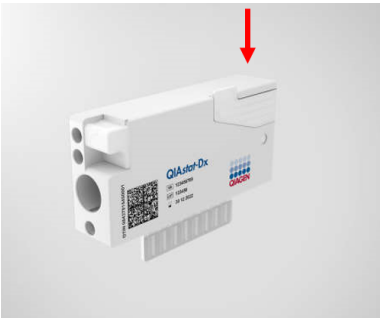


Figure 20. Placing sample ID barcode.

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

Important: The barcode must always be on the right side of the cartridge when looking at it from the side of the label (as it is shown below with blue marked area). The barcode label must not be placed beyond 35 mm from the right side of the cartridge (Figure 21).

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

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

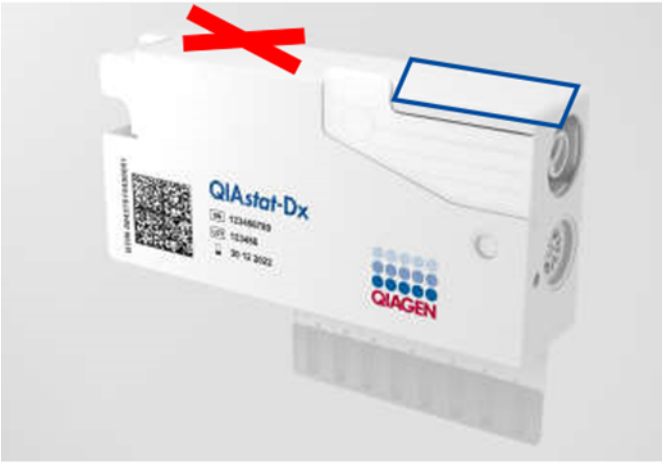


Figure 21. Positioning sample ID barcode.

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

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

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

Procedure to run a test

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

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

When initialization is complete, please check the following:

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

To run a test, follow the steps below:

1. Press the **OPEN WASTE DRAWER** button at the lower right corner of the main test screen (Figure 22). Remove used cartridges from previous runs and dispose of them as biohazardous waste in accordance with all national, state, and local health and safety regulations and laws.
2. Close the waste drawer. The system will scan the tray and return to the main screen. If the waste tray was removed for maintenance purposes, make sure it is correctly inserted before closing the drawer.
3. Press the **OPEN INPUT DRAWER** button at the lower right corner of the main test screen (Figure 22).

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

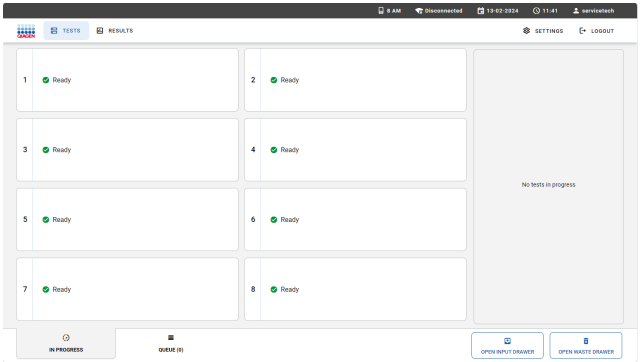


Figure 22. Main test screen.

4. Wait until the input drawer is unlocked (Figure 23).

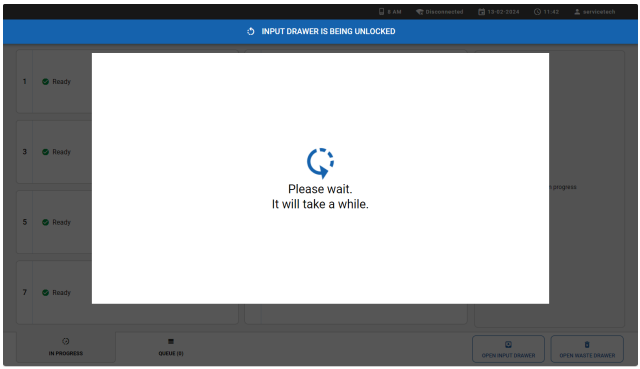


Figure 23. Input drawer waiting dialog box.

5. When prompted, pull the input drawer to open (Figure 24). Depending on instrument status, it can take a moment for the drawer to unlock. Note that the input drawer will be automatically locked if no interaction is performed.

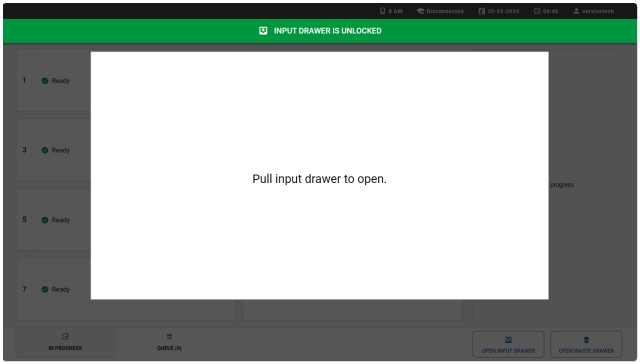


Figure 24. Input drawer open dialog box.

Starting with the cartridge loading step, the test setup in the QIAstat-Dx Rise may differ depending on the HIS/LIS connection status and the **Test Orders** and **Force Orders**

functionality of the HIS/LIS connection (Table 2). The details of the HIS/LIS settings can be found in "HIS/LIS Connectivity" in the *QIAstat-Dx Rise User Manual*. For more information on **Test Orders** and **Force Orders** functionality refer to "Querying test orders from HIS/LIS" in the *QIAstat-Dx Rise User Manual*.

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

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

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

Table 2. Test setup options

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

Manual test setup

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

1. The Add cartridge dialog box appears and the scanner at the front will be activated. Scan the sample ID barcode attached to the top of the QIAstat-Dx assay cartridge (position is indicated by the arrow) (Figure 25).

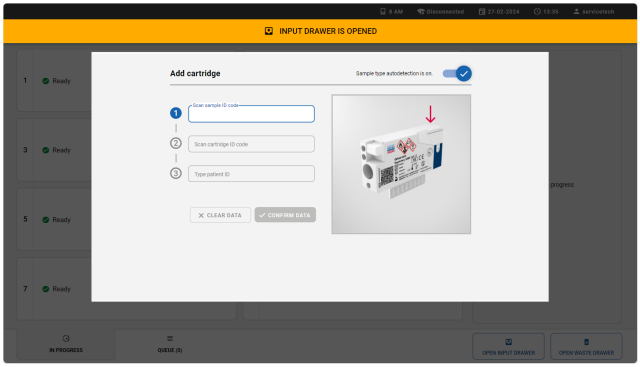


Figure 25. Scan sample ID screen.

2. Scan the cartridge ID barcode. The QIAstat-Dx Rise automatically recognizes the assay to be run, based on the QIAstat-Dx assay cartridge barcode (Figure 26).

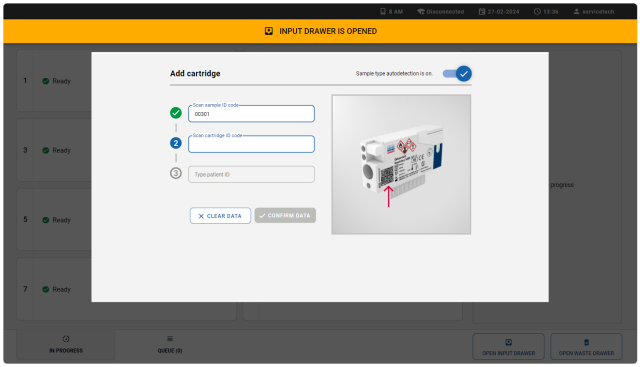


Figure 26. Scan cartridge ID screen.

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

3. Enter the patient ID and press **CONFIRM DATA** (Figure 27).

   Note: To enable the use of the patient ID, refer to "Procedure to run a test".

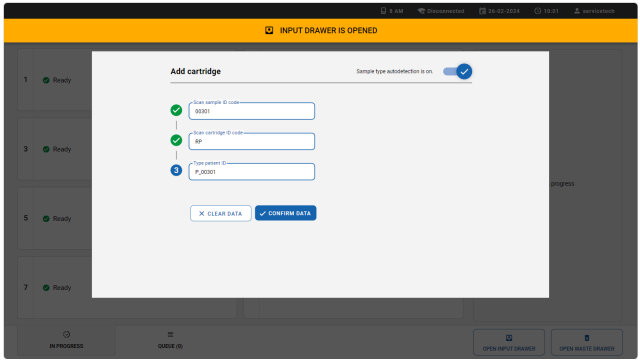


Figure 27. Type patient ID then confirm the data screen.

4. After successful data entry, the following message bar appears briefly at the top of the screen (Figure 28).

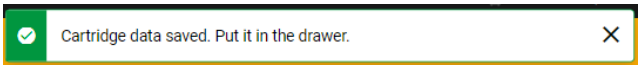


Figure 28. Cartridge saved dialog box.

5. Place the cartridge into the input drawer. Make sure the cartridge is inserted properly into the tray.
6. Continue scanning and inserting cartridges following previous steps. You can load up to 18 cartridges into the drawer.
7. Close the input drawer when all cartridges have been manually scanned and inserted. The system will scan the cartridges and prepare a queue (Figure 29).

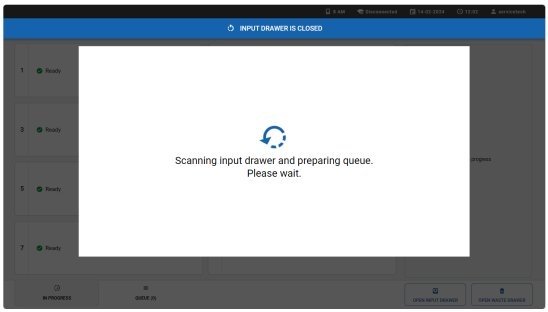


Figure 29. Preparing queue screen.

8. Continue with reviewing the test queue in "Review and confirm the test queue to run".

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

Test setup with HIS/LIS connection

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

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

LIS orders enforced

When **Force Orders** is enabled, the Load Cartridge(s) dialog box appears as seen below (Figure 30).

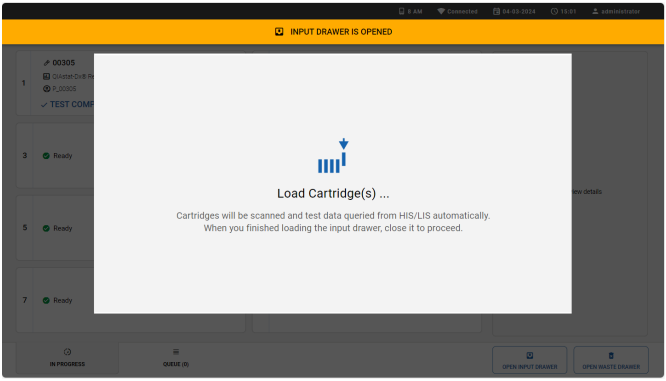


Figure 30. The load cartridge dialog box when both test order and force orders are enabled.

1. Place the cartridges into the input drawer (see "Preparing the QIAstat-Dx Respiratory Panel Plus Cartridge" for correct cartridge preparation). Make sure all the cartridges are inserted properly into the tray and the sample ID barcode is placed correctly.
2. Close the input drawer. The system will scan the sample ID barcode of the cartridges and prepare a queue (Figure 32).
3. Continue with reviewing the test queue in "Review and confirm the test queue to run".

Note: If Force Orders is enabled and the test order is not successfully retrieved from the LIS, the system will issue an error and not run the test. If a sample must be urgently run for which no test order is created yet, an administrator must temporarily turn off the Force Orders functionality as described in "HIS/LIS Connectivity" section in the *QIAstat-Dx Rise User Manual*.

LIS orders optional

When **Force Orders** is disabled, the Load Cartridge(s) dialog box appears as seen below (Figure 31).

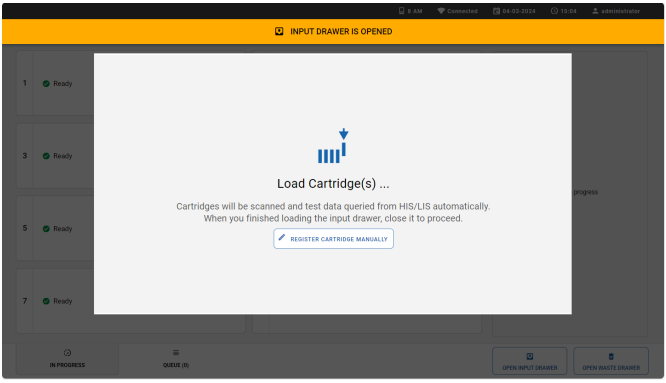


Figure 31. The load cartridge dialog box when the test order functionality is enabled and force order disabled.

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

1. Place the cartridges into the input drawer (see "Preparing the QIAstat-Dx Respiratory Panel Plus Cartridge" for correct cartridge preparation). Make sure all the cartridges are inserted properly into the tray.
2. Close the input drawer. The system will scan the sample ID barcode of the cartridges and prepare a queue (Figure 32).
3. Continue with reviewing the test queue in "Review and confirm the test queue to run".

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

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

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

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

Review and confirm the test queue to run

When calculated, the test queue is shown as below (Figure 32). Review the data shown in the queue. In case of an error, the respective cartridge will be moved to the waste tray after confirming the queue.

Important: If LIS orders are enabled and a cartridge was previously canceled, the onboard stability time cannot be shown correctly by the system during confirmation of the queue. The

correct onboard stability time will only be shown once the cartridge is scanned in the scan station. In this case, it is required that the user tracks the onboard stability time of the sample as cartridges with exceeded onboard stability time might lead to false results.

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

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

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

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

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

It is possible to prioritize a sample at that point (see "Prioritizing samples").

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

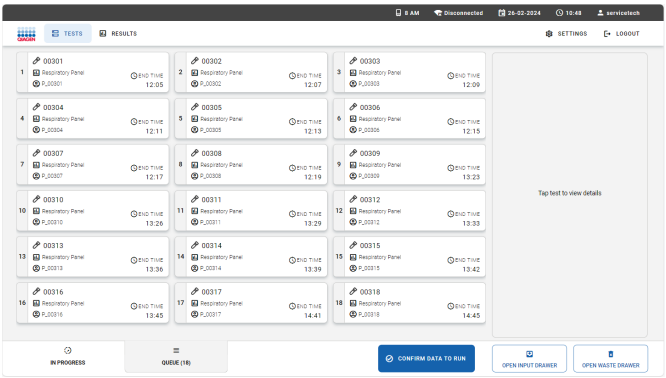


Figure 32. Sample queue screen.

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

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

Note: After the sample is placed inside the QIAstat-Dx Respiratory Panel Plus Cartridge, the cartridge must be loaded immediately 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 the QIAstat-Dx Rise (onboard stability) is 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 onboard stability time.

If you select a test on the touchscreen, additional information is displayed in the view details section of the screen (Figure 33).

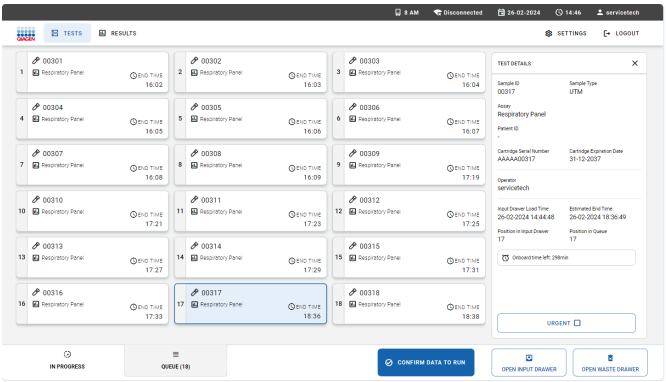


Figure 33. Sample queue screen with selected assay showing additional information.

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

- Sample ID
- Sample Type (depends on assay and sample autodetection function)
- Assay
- Patient ID (if applicable)
- Cartridge Serial Number
- Cartridge Expiration Date
- Operator

- Input Drawer Load Time
- Estimated End Time
- Position in Input drawer
- Position in Queue (**Note**: the position may differ, based on sample or assay stability time/onboard time)
- Onboard time left
- **URGENT** icon for prioritization functionality
- Error messages, warnings (if applicable)

Note: In case that a cartridge was loaded using the automatic test setup (see "Test setup with HIS/LIS connection"), some of the information above (such as the cartridge serial number) may not yet be displayed.

Press the **CONFIRM DATA TO RUN** button on the bottom of the screen when all the displayed data are correct (Figure 33). Thereafter, one final confirmation is required from the operator to run the tests, press **RUN TEST** button. (Figure 34).

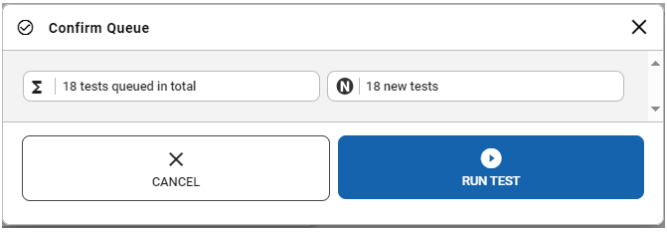


Figure 34. Confirm queue dialog box.

Test execution

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

While the tests are running, the remaining run time and other information for all tests in process are displayed on the touchscreen (Figure 35).

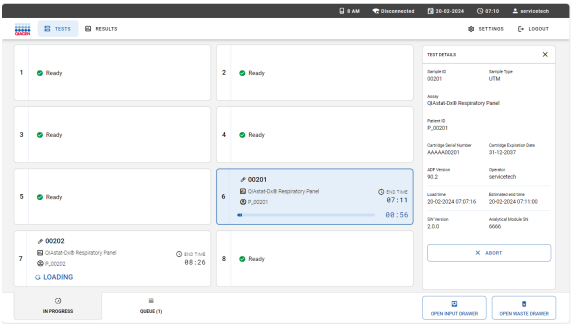


Figure 35. Test execution information on TESTS screen.

When the cartridge is scanned on the scan station, the state "CHECKING" is displayed (Figure 36).

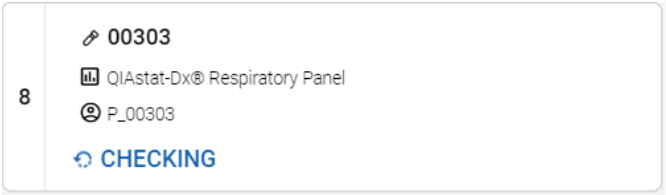


Figure 36. Cartridge checking message.

When the cartridge is being loaded into an AM, a test "LOADING" message and the estimated end time are displayed (Figure 37).

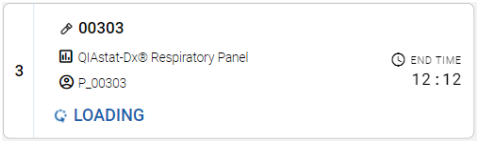


Figure 37. Test loading message and end time.

When the test is running, the elapsed run time and the approximate end time are being displayed (Figure 38).

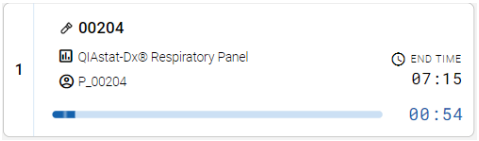


Figure 38. Elapsed run time and approximate end time view.

If the test is completed, a "TEST COMPLETED" message and the run end time are displayed (Figure 39).

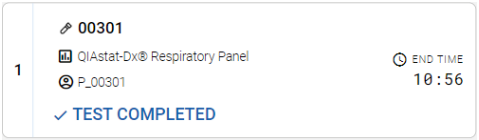


Figure 39. Test completed view.

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

Prioritizing samples

Prioritizing samples before starting the run

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

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

The urgent sample is selected on the queue screen and marked urgent from right-hand side of the sample queue screen before confirm data to run (Figure 40). Following this, the sample is moved to the first position of the queue and will be processed before all other cartridges in the first available AM (Figure 41).

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

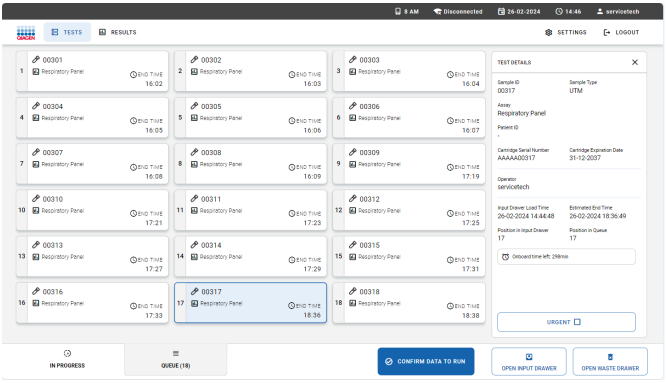


Figure 40. Sample queue screen while selecting sample to be prioritized.

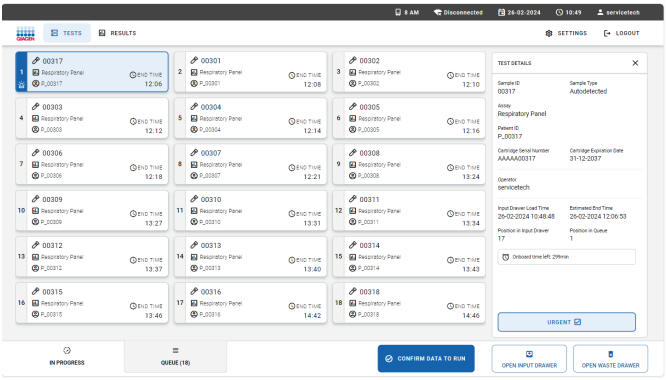


Figure 41. Sample queue screen after a sample is prioritized.

Some other samples may run out of stability time due to prioritization of a sample. The system marks samples that may run out of stability time with a red icon and show the remaining onboard time in the TEST DETAILS area (Figure 42).

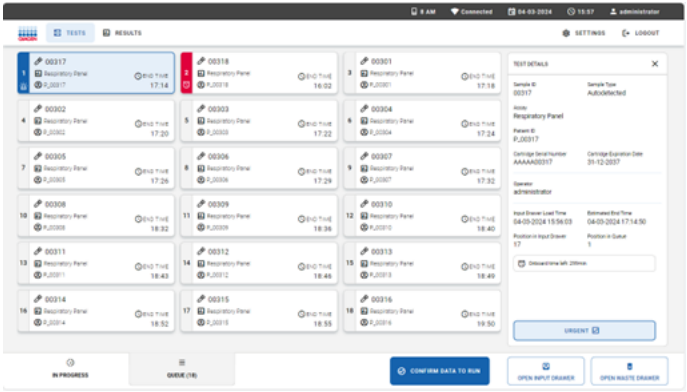


Figure 42. Sample queue screen after a sample is prioritized and one sample may run out of stability time.

After confirmation of the queue the run can be started (Figure 43).

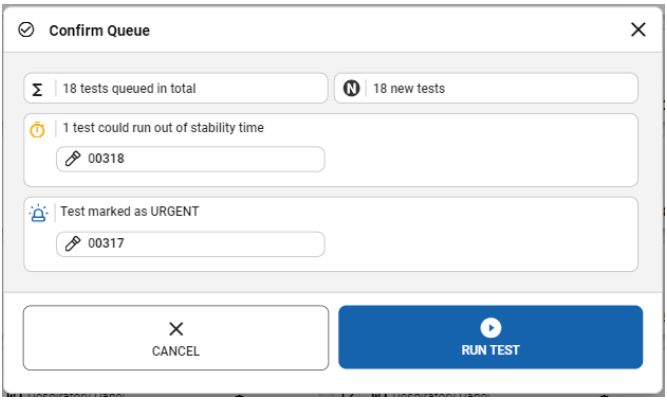


Figure 43. Confirmation of the run screen.

Prioritizing sample during run

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

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

In case the **URGENT** sample needs to be processed immediately and all Analytical Modules are executing tests, any other ongoing test needs to be aborted to start the test execution of the **URGENT** sample (Figure 44).

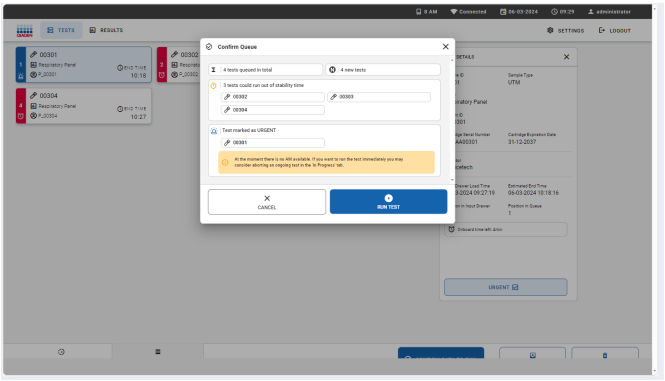


Figure 44. Confirmation when there is no available AM.

Cancelation and abortion of samples

Cancelation and abortion of samples by the system

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

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

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

Result records are created for both canceled (Figure 45) and aborted (Figure 46) cartridges. The test status shows whether a test was canceled or aborted. A detailed error message describes the error. For canceled samples, the message also indicates how to resolve the error

so that the cartridge can be reloaded into the instrument. For aborted samples, the test result is transferred to LIS when the system is setup accordingly. In both cases, the cartridge can be taken out of the instrument from the waste drawer.

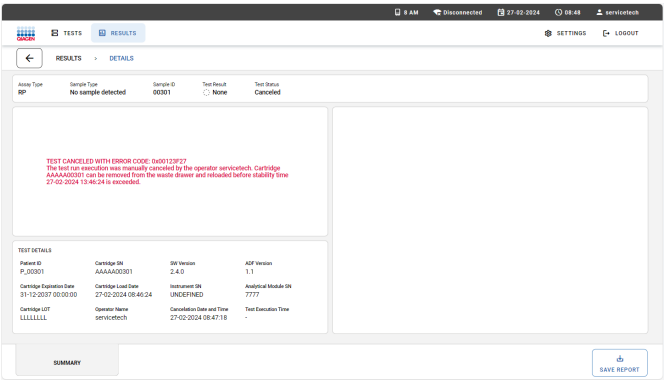


Figure 45. Result of a canceled sample.

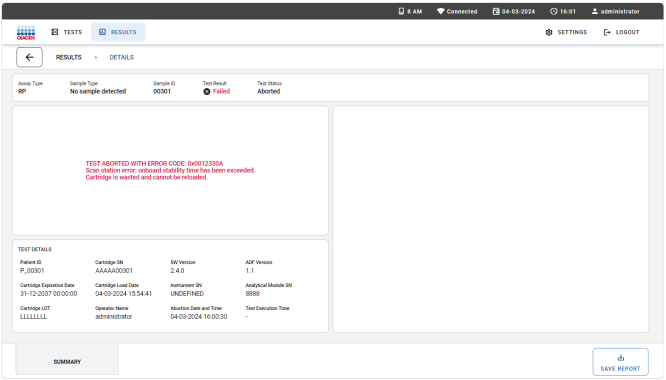


Figure 46. Result of an aborted sample.

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

Cancelation of a sample by user

A sample can be canceled during transfer to the scan station and cartridge check performed in the scan station (Figure 47). Once the sample is loaded into the AM, it is no longer possible to cancel the test and therefore the cancel option is no longer visible on the touchscreen. After this point, the cartridge can only be aborted (see "Cancelation and abortion of samples").

To cancel a sample, go to the **IN PROGRESS** tab of the screen, then select the sample and press the **CANCEL** button on the bottom right corner of the screen (Figure 47).

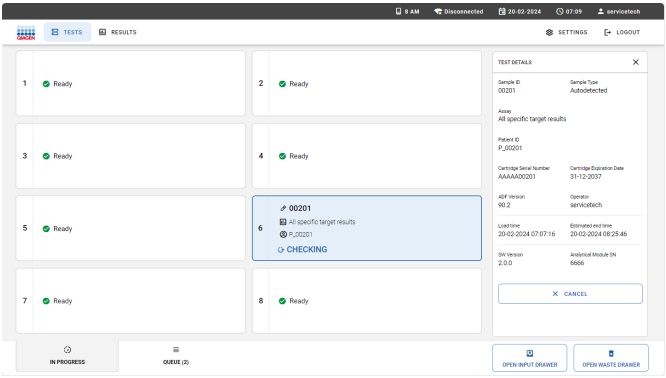


Figure 47. Cancelation of a sample.

Press the **CONFIRM CANCELATION** button to proceed with the cancelation (Figure 48).

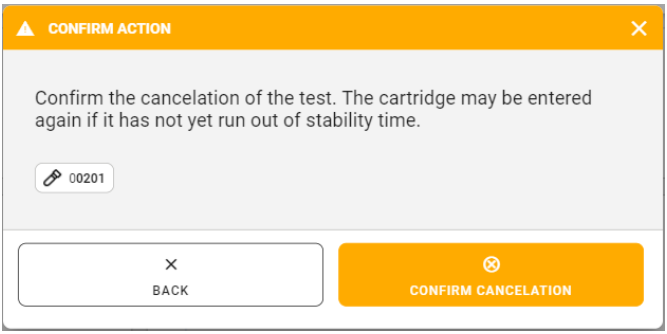


Figure 48. Confirmation dialog box of sample cancelation.

The canceled sample can be reloaded into the instrument if the onboard stability time is not exceeded (Figure 49).

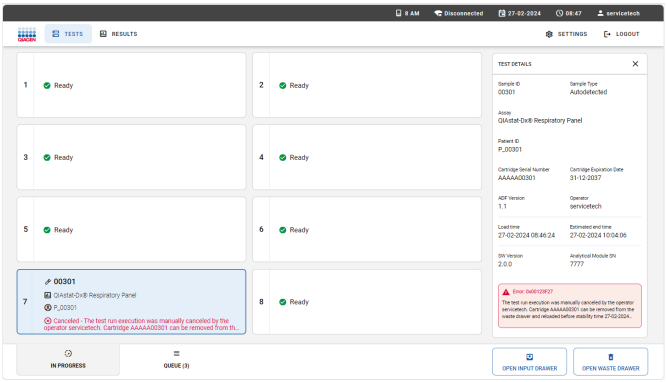


Figure 49. Canceled sample screen.

Abortion of a sample by user

A sample can be aborted while the test is running inside the Analytical Module (AM). To abort a sample, go to the **IN PROGRESS** tab of the **TESTS** screen, then select the sample and press the **ABORT** button on the bottom right corner of the screen (Figure 50).

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

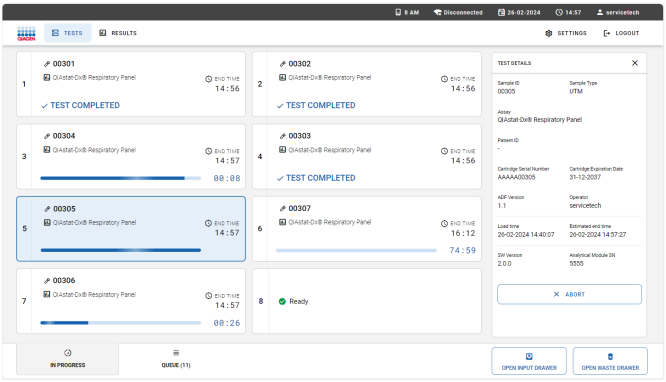


Figure 50. Abortion of a running sample.

Press the **CONFIRM ABORTION** button to proceed with aborting the sample (Figure 51).

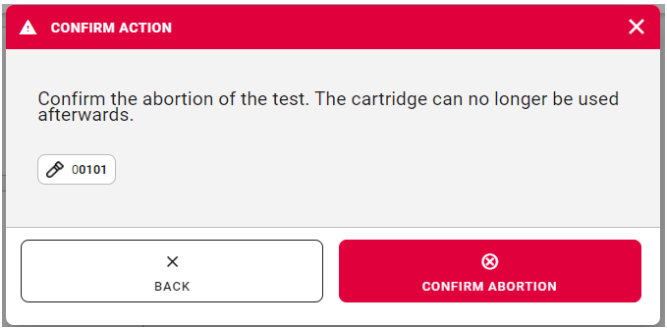


Figure 51. Confirmation dialog box to abort running sample.

After confirmation, the system aborts the run, ejects the cartridge, and moves it to the waste drawer. After a while, the sample can be seen as aborted on the screen (Figure 52 and Figure 53).

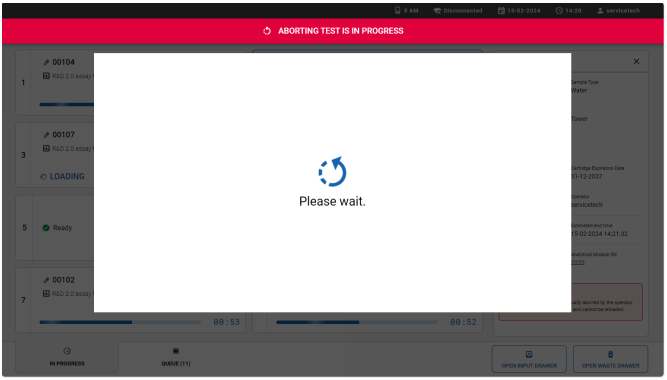


Figure 52. Sample abortion waiting dialog box.

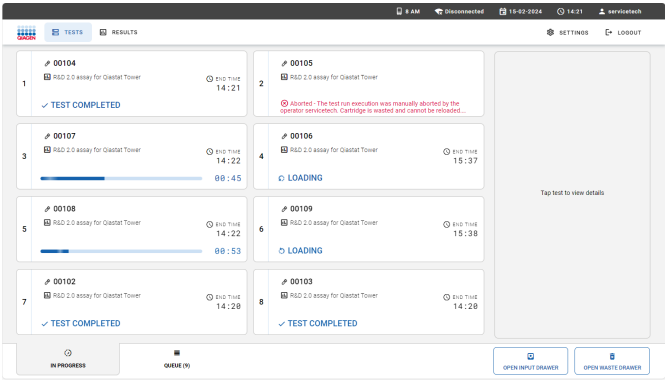


Figure 53. Aborted sample after confirmation of the abortion.

Continuous operation

Continuous loading

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

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

Empty the waste drawer during continuous run

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

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

If the total number of the cartridges exceeds the available slots in the waste drawer and available AM, the QIAstat-Dx Rise will show the "Empty The Waste Drawer" warning dialog box right after the scan of input tray and load check of waste tray. The warning dialog box contains the number of available slots for waste tray and AM and occupied slots for input tray (Figure 54).

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

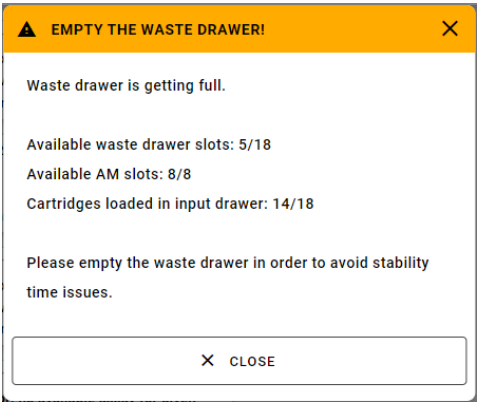


Figure 54. Empty waste drawer dialog box.

When there are 7 empty slots in the waste tray, the warning dialog box appears on the upper side of the screen and the status indicators (LEDs) of the system starts blinking blue. This additional warning is automatically updated by the system, and it is permanent on the screen until the waste drawer is emptied (Figure 55).

Figure 55. Waste drawer warning.

If the waste tray is not emptied, the system will be blocked and the two warning dialog boxes appear on the screen (Figure 56). The user can select **OPEN WASTE DRAWER** option on the warning and empty the waste drawer. Please note that this warning will disappear after a few seconds, but the warning on the upper side (Figure 57) will stay until the waste drawer is emptied. The user can still open the waste drawer and empty at any time.

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

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

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

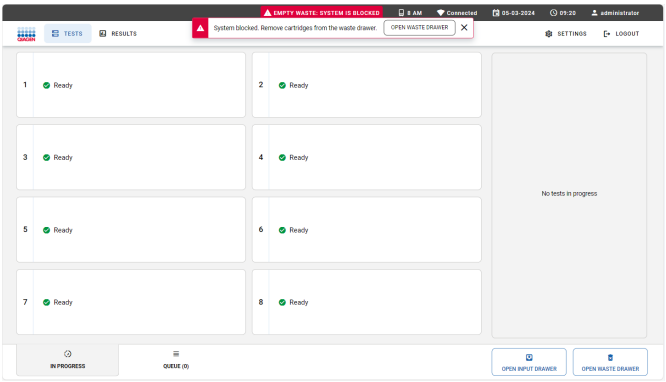


Figure 56. System is blocked warnings.

Figure 57. System is blocked warning.

Viewing results with the QIAstat-Dx Rise

The QIAstat-Dx Rise automatically interprets and saves test results. After the run is completed, the results can be seen in the **RESULTS** summary screen (Figure 58).

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

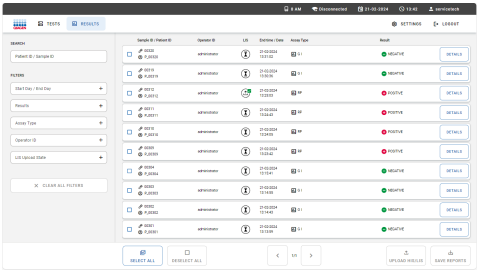


Figure 58. The RESULTS summary screen.

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

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

- If a test is aborted before running in an AM, the term **ABORTED** is shown in the result column, proceeded by a ⊗ sign. When viewing the details of such a test, a specific error message displays the reason for the abortion. The cartridge of an aborted test cannot be reloaded into the instrument.

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

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

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

Viewing test details

For the summary of data, press **DETAILS** at the right side of the screen (Figure 58). The upper part of the screen shows general information about the test. It includes **Assay Type**, **Sample Type**, **Sample ID**, **Test Result**, status of the **Internal Control**, **Test Status** and **LIS Upload Status** (Figure 59).

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

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

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

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

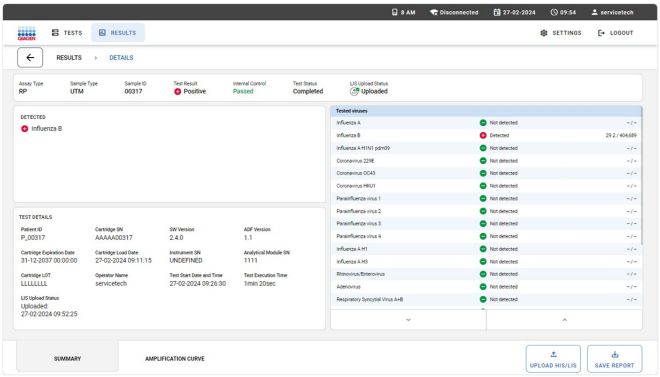


Figure 59. The test details screen.

Interpretation of Results

Internal Control interpretation

This subsection applies to the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise.

The QIAstat-Dx Respiratory Panel Plus 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 Panel Plus 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 Panel Plus Cartridge.

Pathogen result interpretation

Result interpretation information for Influenza A

This subsection applies to the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise.

A result for a respiratory organism is interpreted as "Positive" when the corresponding PCR assay is positive (see exceptions for Influenza A below). The Influenza A assay in the QIAstat-Dx Respiratory Panel Plus 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 Influenza A H1 strain is detected by the QIAstat-Dx Respiratory Panel Plus assay, both Influenza A generic and Influenza A H1 will be detected, but only Influenza A H1 will be displayed on the screen.

  Note: In case only the subtype H1 signal is obtained (and not the generic Influenza A signal), Influenza A H1 will be reported as "equivocal".

- If Influenza A H3 strain is detected by the QIAstat-Dx Respiratory Panel Plus assay, both Influenza A generic and Influenza A H3 will be detected, but only Influenza A H3 will be displayed on the screen.

  Note: In case only the subtype H3 signal is obtained (and not the generic Influenza A signal), Influenza A H3 will be reported as "equivocal".

- If an Influenza A H1N1 pdm09 strain is detected by the QIAstat-Dx Respiratory Panel Plus assay, both Influenza A generic and Influenza A H1N1 pdm09 will be detected, but only Influenza A H1N1 pdm09 will be displayed on the screen.

  Note: In case only the subtype H1N1 pdm09 signal is obtained (and not the generic Influenza A signal), Influenza A H1N1 pdm09 will be reported as "equivocal".

Note: It is acceptable if only the Influenza A signal is obtained, which would be indicated as "Influenza A (no subtype detected)".

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. If the same results are obtained upon retesting, contact the appropriate public health authorities for confirmatory testing.

Result interpretation for all other pathogens

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

Viewing amplification curves with the QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0

To view test amplification curves of pathogens detected, press the Amplification Curves tab (Figure 60).

Figure 60. 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 the pathogen name to select which pathogens are shown in the amplification plot. It is possible to select single, multiple, or no pathogens. Each pathogen in the selected list will be assigned a color corresponding to the amplification curve associated with the pathogen. Unselected pathogens will be shown in gray.

The corresponding Ct and endpoint fluorescence (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 61).

Figure 61. 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 of the QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0

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 62):

- 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)
    - Positive with warning (at least one respiratory pathogen is detected but the Internal Control failed)
    - Negative (no respiratory pathogen is detected)
    - Invalid
- List of analytes tested in the assay, with Ct and endpoint fluorescence in the event of a positive signal
- Internal control, with Ct and endpoint fluorescence

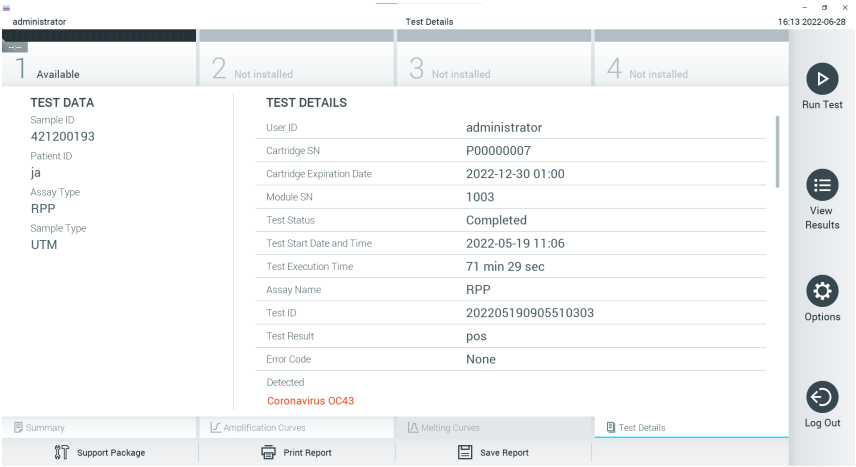


Figure 62. Example screen showing Test Data on the left panel and Test Details in the main panel.

Browsing results from previous tests of the QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0

To view results from previous tests that are stored in the results repository, press View Results on the Main Menu bar (Figure 63).

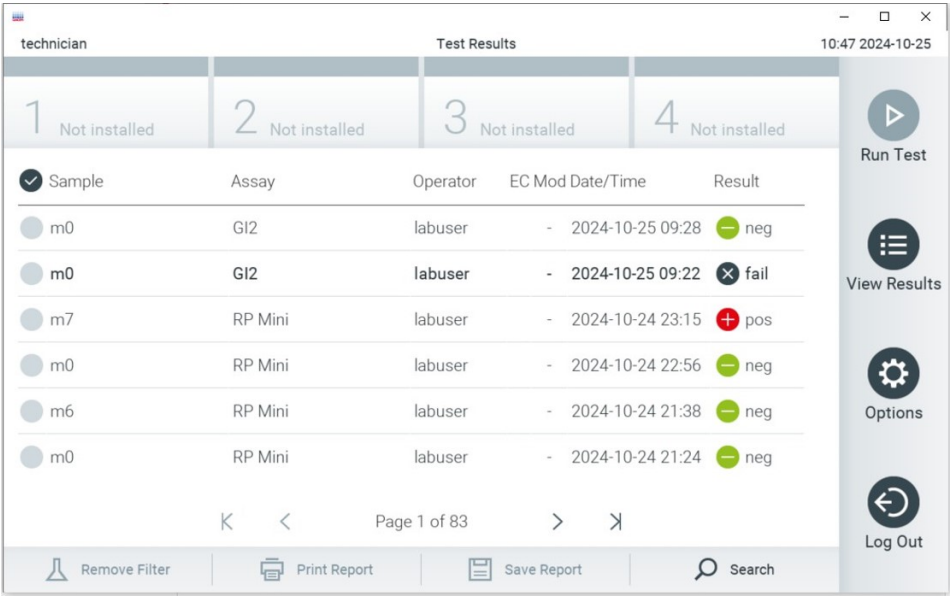


Figure 63. Example View Results screen.

The following information is available for every executed test:

- Sample ID
- Assay (name of test assay)
- 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 the 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 64).

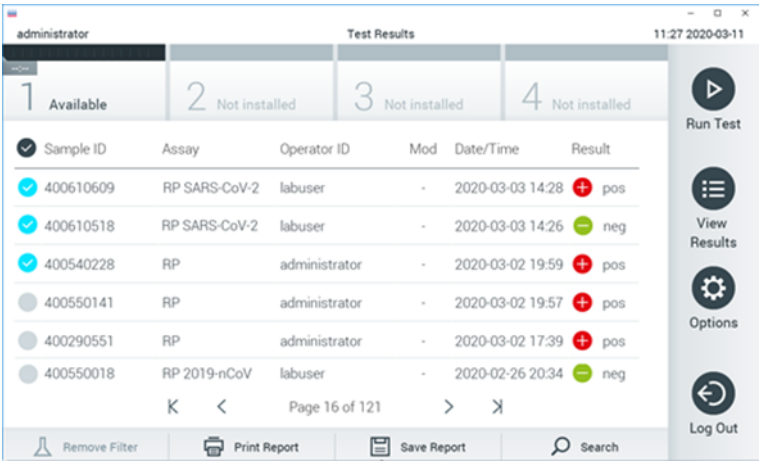


Figure 64. Example of selecting Test Results in the View Results screen.

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 overall test results

Outcome	Result	Description	Action
Positive	pos	At least one pathogen is positive.	Refer to the Summary Result Screen or Result Printout for pathogen specific results.
Positive with warning	pos*	At least one pathogen is positive, but the Internal Control failed.	Refer to the Summary Result Screen or Result Printout for pathogen specific results.
Negative	neg	No pathogens were detected.	Refer to the Summary Result Screen or Result Printout for pathogen specific results.
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.	Repeat the test using a new cartridge. Accept the results of the repeat testing. If the error persists, contact QIAGEN Technical Services for further instructions.
Successful	suc	The test is either positive or negative, but the user does not have the access rights to view the test results.	Login from a user profile with rights to view the 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 box 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 QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0

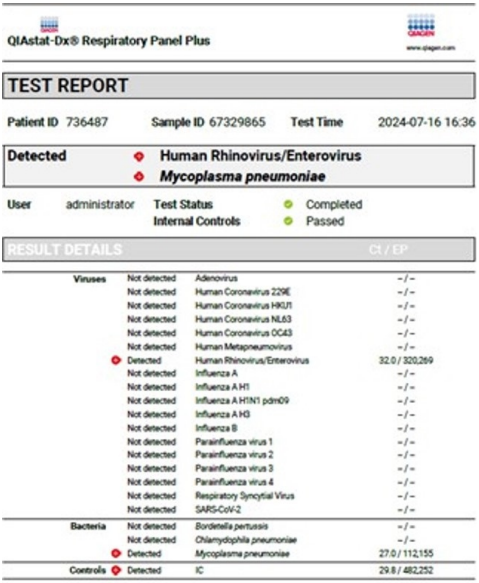
From any tab of the View Results screen, select **Save Report** to export and save a copy of the test results in PDF to a USB drive. The USB port is located on the front of the QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0. The interpretation of the results in the PDF file is shown on Table 5.

Table 5. Interpretation of test results on PDF reports

	Outcome	Symbol	Description
Pathogen result	Detected		Pathogen detected.
	Equivocal		Equivocal result. An Influenza A subtype is detected but not the Influenza A.
	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.

Table 5. Interpretation of test results on PDF reports (continued)

Outcome	Symbol	Description
Failed	✕	The Internal Control failed.



QIAstat-Dx® Respiratory Panel Plus

TEST REPORT

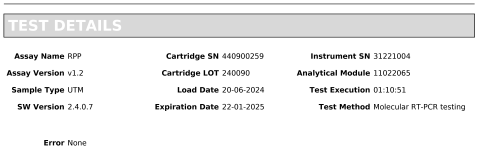
Patient ID 736487 Sample ID 67329865 Test Time 2024-07-16 16:36

Detected
- Human Rhinovirus/Enterovirus
- *Mycoplasma pneumoniae*

User administrator Test Status Completed
Internal Controls Passed

RESULT DETAILS			Ct / EP
Viruses	Not detected	Adenovirus	-/-
	Not detected	Human Coronavirus 229E	-/-
	Not detected	Human Coronavirus HKU1	-/-
	Not detected	Human Coronavirus NL63	-/-
	Not detected	Human Coronavirus OC43	-/-
	Not detected	Human Metapneumovirus	-/-
	Detected	Human Rhinovirus/Enterovirus	32.0 / 320,269
	Not detected	Influenza A	-/-
	Not detected	Influenza A H1	-/-
	Not detected	Influenza A H1N1 pdm09	-/-
	Not detected	Influenza A H3	-/-
	Not detected	Influenza B	-/-
	Not detected	Parainfluenza virus 1	-/-
	Not detected	Parainfluenza virus 2	-/-
	Not detected	Parainfluenza virus 3	-/-
	Not detected	Parainfluenza virus 4	-/-
	Not detected	Respiratory Syncytial Virus	-/-
	Not detected	SARS-CoV-2	-/-
Bacteria	Not detected	*Bordetella pertussis*	-/-
	Not detected	*Chlamydophila pneumoniae*	-/-
	Detected	*Mycoplasma pneumoniae*	27.0 / 112,155
Controls	Detected	IC	29.8 / 482,252

Figure 65. Sample test report.



TEST DETAILS

Assay Name RPP	**Cartridge SN** 440900259	**Instrument SN** 31221004
Assay Version v1.2	**Cartridge LOT** 240090	**Analytical Module** 11022065
Sample Type UTM	**Load Date** 20-06-2024	**Test Execution** 01:10:51
SW Version 2.4.0.7	**Expiration Date** 22-01-2025	**Test Method** Molecular RT-PCR testing

Error None

Figure 66. Sample test report showing details about the test.

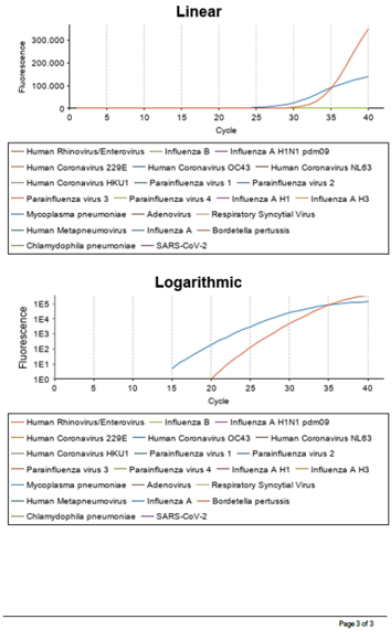


Figure 67. Sample test report showing assay data.

Printing results of QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0

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 amplification curves with QIAstat-Dx Rise

To view the test amplification curves, press the **Amplification Curves** tab at the bottom of the screen (Figure 68).

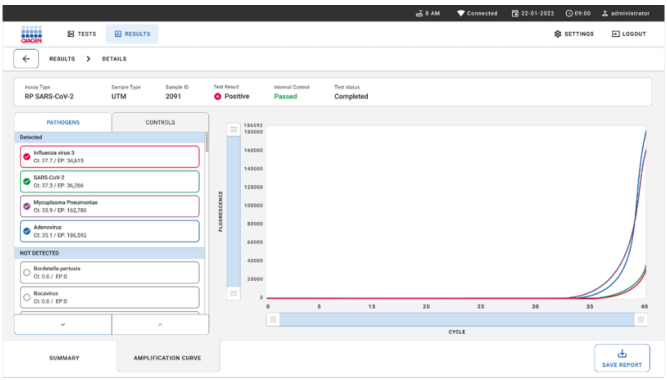


Figure 68. The amplification curves screen.

Press the **PATHOGENS** tab on the left side to display the plots corresponding to the tested pathogens. Press 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 Ct 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 of the QIAstat-Dx Rise

To view results from previous tests that are stored in the results repository, use the search functionality in the main results screen (Figure 69).

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

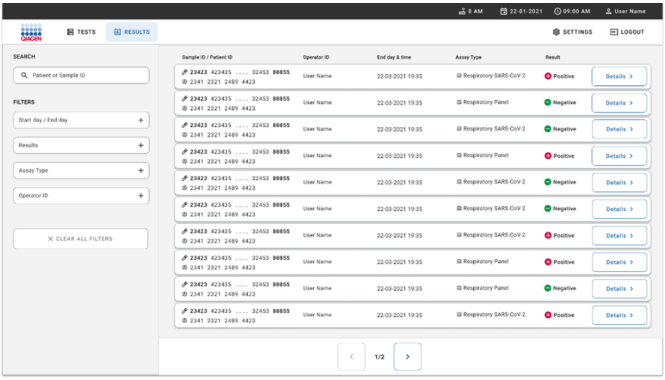


Figure 69. Search functionality in the results screen.

Exporting results to a USB drive from the QIAstat-Dx Rise

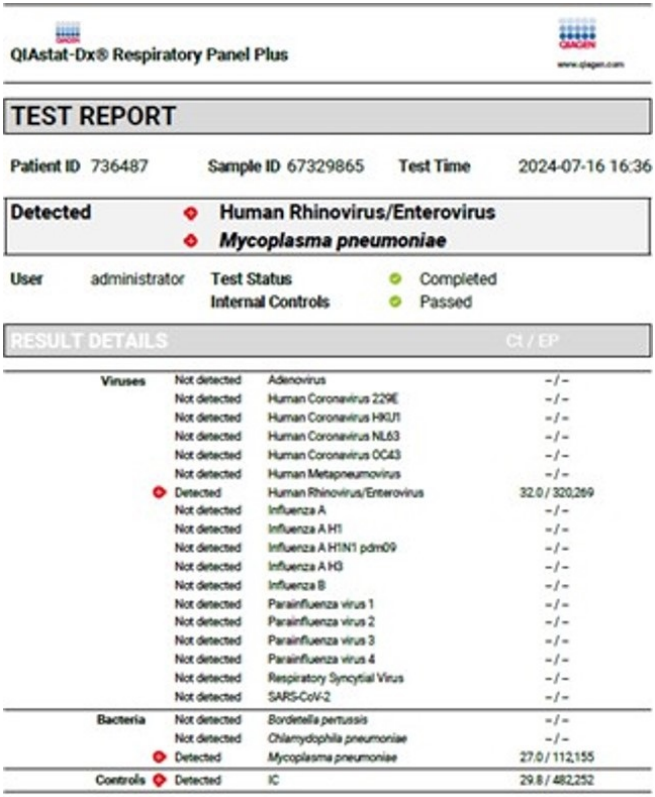
From the **Results** screen, select individually or all with **Select All** button to export and save a copy of the test reports in PDF format to a USB storage device (Figure 70–Figure 71). The USB port is located in front and on the rear of the instrument. The interpretation of the results in the PDF file is shown on Table 6.

Table 6. Interpretation of test results on PDF reports

	Outcome	Symbol	Description
Pathogen result	Detected	+	Pathogen detected.
	Equivocal	?	Equivocal result. An Influenza A subtype is detected but not the Influenza A.
	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.

Table 6. Interpretation of test results on PDF reports (continued)

	Outcome	Symbol	Description
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 Panel Plus

www.qiagen.com

TEST REPORT

Patient ID 736487 **Sample ID** 67329865 **Test Time** 2024-07-16 16:36

Detected
- Human Rhinovirus/Enterovirus
- *Mycoplasma pneumoniae*

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

RESULT DETAILS			Ct / EP
Viruses	Not detected	Adenovirus	– / –
	Not detected	Human Coronavirus 229E	– / –
	Not detected	Human Coronavirus HKU1	– / –
	Not detected	Human Coronavirus NL63	– / –
	Not detected	Human Coronavirus OC43	– / –
	Not detected	Human Metapneumovirus	– / –
	Detected	Human Rhinovirus/Enterovirus	32.0 / 320,269
	Not detected	Influenza A	– / –
	Not detected	Influenza A H1	– / –
	Not detected	Influenza A H1N1 pdm09	– / –
	Not detected	Influenza A H3	– / –
	Not detected	Influenza B	– / –
	Not detected	Parainfluenza virus 1	– / –
	Not detected	Parainfluenza virus 2	– / –
	Not detected	Parainfluenza virus 3	– / –
	Not detected	Parainfluenza virus 4	– / –
	Not detected	Respiratory Syncytial Virus	– / –
	Not detected	SARS-CoV-2	– / –
Bacteria	Not detected	*Bordetella pertussis*	– / –
	Not detected	*Chlamydophila pneumoniae*	– / –
	Detected	*Mycoplasma pneumoniae*	27.0 / 112,155
Controls	Detected	IC	29.8 / 482,252

Figure 70. Sample test report.

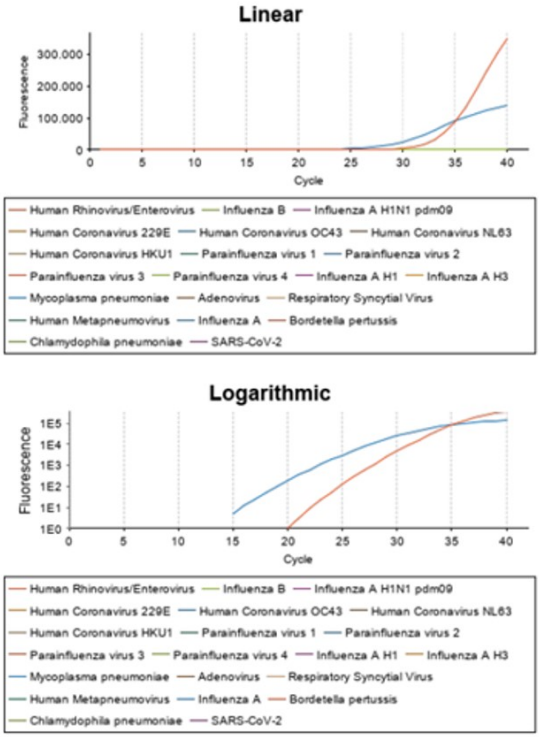


Figure 71. Sample test report showing assay data.

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).

Quality Control

In accordance with QIAGEN's ISO-certified Quality Management System, each lot of QIAstat-Dx Respiratory Panel Plus is tested against predetermined specifications to ensure consistent product quality. External controls are not provided with the QIAstat-Dx Respiratory Panel Plus. Quality control requirements should be performed in conformance with local, state, and/or federal regulations or accreditation requirements and your laboratory's standard quality control procedures.

Limitations

- For prescription use only.
- Results from the QIAstat-Dx Respiratory Panel Plus are not intended to be used as the sole basis for diagnosis, treatment, or other patient management decisions.
- The performance of this test has not been established for immunocompromised individuals.
- The performance of this test has not been established for patients without signs and symptoms of respiratory infection.
- Positive results do not rule out co-infection with organisms not included in the QIAstat-Dx Respiratory Panel Plus. The agent detected may not be the definitive cause of the disease.
- Negative results do not preclude infection of the upper respiratory tract. Not all agents of acute respiratory infection are detected by this assay and sensitivity in some clinical settings may differ from that described in the Instructions for Use.
- A negative result with the QIAstat-Dx Respiratory Panel Plus 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 Panel Plus is not intended for testing of samples other than those described in these Instructions for Use. Test performance characteristics have been established only with nasopharyngeal swab samples collected in universal transport media (UTM), from individuals with acute respiratory symptoms.
- The QIAstat-Dx Respiratory Panel Plus 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 Panel Plus must be interpreted by a trained healthcare professional within the context of all relevant clinical, laboratory, and epidemiological findings.
- The QIAstat-Dx Respiratory Panel Plus can be used only with the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise.
- The QIAstat-Dx Respiratory Panel Plus 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 Panel Plus Cartridge. Improper operations for any of the aforementioned processes can cause incorrect results, including false-positive or false-negative results.
- The performance of this test has not been established for screening of blood or blood products.
- 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.
- The QIAstat-Dx Respiratory Panel Plus Cartridge may not be able to distinguish between existing viral strains and new variants as they emerge. For example, the QIAstat-Dx Respiratory Panel Plus can detect H3N2 Influenza but may not be able to distinguish H3N2 from H3N2 variant (H3N2v).
- The QIAstat-Dx Respiratory Panel Plus detects the multi-copy IS481 insertion sequence present in multiple *Bordetella* species. False positive *B. pertussis* results are possible if the specimen is contaminated with non-pertussis *Bordetella* species.

- 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. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods when prevalence is moderate or low.
- Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.
- Do not attempt viral culture in cases of positive results for SARS-CoV-2 and/or any similar microbial agents, unless a facility with an appropriate level of laboratory biosafety (e.g., BSL-3 or higher) is available to receive and culture specimens.
- If infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL-3+ facility is available to receive and culture specimens.
- Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- Performance characteristics for Influenza A were established when Influenza A/H3 and Influenza A/H1-2009 were the predominant Influenza strains.
- This test has been evaluated for use with human specimen material only.
- The performance of QIAstat-Dx Respiratory Panel Plus has not been validated for the testing of pooled specimens.

- The performance of QIAstat-Dx Respiratory Panel Plus has not been established for monitoring treatment of infection with any of the panel organisms.
- The QIAstat-Dx Respiratory Panel Plus Influenza A/H1 and A/H3 subtyping assays target the Influenza A hemagglutinin (H) gene only; they do not detect or differentiate the Influenza A/H1 and A/H3 neuraminidase (N) subtypes.
- The QIAstat-Dx Respiratory Panel Plus Influenza A/H1N1pdm09 subtyping assay targets the Influenza A neuraminidase (N) gene only; it does not detect or differentiate the Influenza A/H1N1pdm09 hemagglutinin (H) subtype.
- Due to the genetic similarity between Human Rhinovirus and Enterovirus, the QIAstat-Dx Respiratory Panel Plus cannot differentiate them. A QIAstat-Dx Respiratory Panel Plus Human Rhinovirus/Enterovirus Detected result should be followed-up using an alternate method (e.g., cell culture or sequence analysis) if differentiation between the viruses is required.
- If a specimen yields a repeated positive result for Influenza A but produces negative test results for all specific Influenza A subtypes intended to be differentiated (i.e., H1, H1N1pdm09, and H3), this result requires notification of appropriate local, state, or federal public health authorities to determine necessary measures for verification.
- Due to the small number of positive specimens collected during the prospective and the retrospective clinical studies, performance characteristics for Influenza A H1 and Parainfluenza Virus 2 were established primarily using contrived clinical specimens.
- In silico analyses of the SARS-CoV-2 primer/probe sequences indicated that they may cross-react with pangolin and bat coronaviruses, causing a false positive SARS-CoV-2 result. Pangolin and bat coronaviruses are not currently known to circulate in the human population; and thus the risk of a false positive SARS-CoV-2 result due to these organisms in a human specimen is low.

Performance Characteristics

The QIAstat-Dx Respiratory Panel Plus (cat. no. 691224) was developed by introducing the SARS-CoV-2 target in a separate reaction chamber of the QIAstat-Dx Respiratory Panel Plus (Cat. No. 691211). It is known that the introduction of this additional target does not impact the performance of the other targets and as such data generated with the QIAstat-Dx Respiratory Panel Plus can be leveraged.

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 Modules as QIAstat-Dx Analyzer 1.0; therefore, the performance is not impacted by QIAstat-Dx Analyzer 2.0. Likewise, the QIAstat-Dx Rise uses the same Analytical Modules as QIAstat-Dx Analyzer 1.0 and/or QIAstat-Dx Analyzer 2.0; therefore, the analytical performance is not expected to be impacted by use of QIAstat-Dx Rise. Moreover, an analytical equivalency study was completed for representative panel organisms (20 replicates/concentration/organism), which demonstrated equivalent performance between the QIAstat-Dx Analyzer 1.0 and the QIAstat-Dx Rise platforms.

Limit of detection for SARS-CoV-2

A limit of detection study (LoD) was performed to evaluate the analytical sensitivity of the SARS-CoV-2 assay of the QIAstat-Dx Respiratory Panel Plus. For this study, five (5) SARS-CoV-2 strains were evaluated individually by testing serial dilutions prepared in NPS matrix. Testing was broken into two parts: preliminary and confirmatory LoD testing. For the preliminary LoD study, a serial dilution series consisting of four concentrations was tested in replicates of four per dilution. The preliminary LoD for each strain was defined as the lowest concentration at which 100% of replicates were positive for SARS-CoV-2. The confirmed LoD

was established by testing 20 replicates at the concentration determined from the preliminary LoD for each strain. The LoD for each strain was confirmed if ≥ 95% of the replicates were positive. To further confirm the LoD, at least one dilution below the LoD was tested for each strain and was also tested in 20 replicates and was required to result in less than 95% positivity. The confirmed LoD for SARS-CoV-2 is summarized in Table 7.

Table 7. Confirmatory LoD results for SARS-CoV-2 with QIAstat-Dx Respiratory Panel Plus

Pathogen	Strain	Source	Concentration	Detection rate
SARS-CoV-2	Not available	WHO, NIBSC, 20/146	316 copies/mL	19/20
SARS-CoV-2	USA-WA1-2020	ZeptoMetrix 0810587CFH	3160 copies/mL	19/20
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	20/20
SARS-CoV-2	Not available	STAT-Dx 243	600 copies/mL	20/20

In addition, a subset of the original panel analytes (QIAstat-Dx Respiratory Panel Plus, K183597) was tested side-by-side with the QIAstat-Dx Respiratory Panel Plus. It was demonstrated that the addition of the SARS-CoV-2 target does not impact the performance of targets in the other reaction chambers.

Limit of detection for non-SARS-CoV-2 targets

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 Panel Plus pathogen 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.

The LoD concentration was determined for a total of 51 pathogen strains. The LoD of the QIAstat-Dx Respiratory Panel Plus was determined per analyte using selected strains representing individual pathogens that are possible to detect with the QIAstat-Dx Respiratory Panel Plus. Pathogens were spiked into simulated NPS sample matrix (cultured human cells in Copan UTM) and tested in at least 20 replicates, and 300 µL transferred to the cartridge. Additional testing of samples prepared using negative clinical NPS matrix was conducted to assess equivalency.

At least three different cartridge lots and at least three different QIAstat-Dx Analyzers were used for LoD determination for every pathogen.

Individual LoD values for each QIAstat-Dx Respiratory Panel Plus target are shown in Table 8.

Table 8. LoD values obtained for the different respiratory target strains in NPS sample matrix tested with the QIAstat-Dx Respiratory Panel Plus

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	15 $TCID_{50}$/mL	Flu A: 20/20 H1: 19/20
Influenza A H3N2	A/Virginia/ATCC6/2012	ATCC AV-VR-1811	0.1 PFU/mL	Flu A: 20/20 H3: 20/20

Table 8. LoD values obtained for the different respiratory target strains in NPS sample matrix tested with the QIAstat-Dx Respiratory Panel Plus (continued)

Pathogen	Strain	Source	Concentration*	Detection rate
Influenza A H3N2†	A/Port Chalmers/1/73	ATCC VR-810	499.3 $CEID_{50}$/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	67 PFU/mL	Flu A: 20/20 H1N1: 20/20
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	1080 $CEID_{50}$/mL	20/20
Influenza B†‡	B/Taiwan/2/62	ATCC VR-295	5000 $CEID_{50}$/mL	19/20
Coronavirus 229E†	Not available	ATCC VR-740	0.2 $TCID_{50}$/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

Table 8. LoD values obtained for the different respiratory target strains in NPS sample matrix tested with the QIAstat-Dx Respiratory Panel Plus (continued)

Pathogen	Strain	Source	Concentration*	Detection rate
Coronavirus OC43	Not available	ZeptoMetrix 0810024CFHI	0.1 $TCID_{50}$/mL	20/20
Coronavirus NL63†	Not available	ZeptoMetrix 0810228CFHI	0.01 $TCID_{50}$/mL	20/20
Coronavirus HKU1†	Not available	Clinical Sample S510	4E+04 copies/mL	20/20
Parainfluenza Virus 1 (PIV1)	C35	ATCC VR-94	0.2 $TCID_{50}$/mL	19/20
Parainfluenza Virus 1 (PIV1)†	Not available	ZeptoMetrix 0810014CFHI	0.2 $TCID_{50}$/mL	19/20
Parainfluenza Virus 2 (PIV2)†	Greer	ATCC VR-92	7.3 $TCID_{50}$/mL	20/20
Parainfluenza Virus 2 (PIV2)	Not available	ZeptoMetrix 0810015CFHI	1.3 $TCID_{50}$/mL	19/20
Parainfluenza Virus 3 (PIV3)†, ‡	C 243	ATCC VR-93	2.3 $TCID_{50}$/mL	20/20
Parainfluenza Virus 3 (PIV3)	Not available	Zepto-metres 0810016CFHI	11.5 $TCID_{50}$/mL	20/20
Parainfluenza Virus 4a (PIV4a)†	M-25	ATCC VR-1378	0.5 $TCID_{50}$/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	8.9 $TCID_{50}$/mL	19/20
Enterovirus	Echovirus 6	ATCC VR-241	0.9 $TCID_{50}$/mL	19/20

Table 8. LoD values obtained for the different respiratory target strains in NPS sample matrix tested with the QIAstat-Dx Respiratory Panel Plus (continued)

Pathogen	Strain	Source	Concentration*	Detection rate
Rhinovirus	1059 (rhinovirus B14)	ATCC VR-284	8.9 $TCID_{50}$/mL	20/20
Rhinovirus†‡	HGP (rhinovirus A2)	ATCC VR-482	8.9 $TCID_{50}$/mL	19/20
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	4993.0 $TCID_{50}$/mL	19/20
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	12.0 PFU/mL	20/20
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

Table 8. LoD values obtained for the different respiratory target strains in NPS sample matrix tested with the QIAstat-Dx Respiratory Panel Plus (continued)

Pathogen	Strain	Source	Concentration*	Detection rate
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	0.5 $TCID_{50}$/mL	20/20
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
Mycoplasma pneumoniae	M129-B7 (type 1)	ATCC 29342	0.1 CCU/mL	20/20
Mycoplasma pneumoniae†‡	PI 1428	ATCC 29085	1.0 CCU/mL	20/20
Chlamydophila pneumoniae†	TW183	ATCC VR-2282	14.2 IFU/mL	20/20
Chlamydophila pneumoniae	CWL-029	ATCC VR-1310	120.0 IFU/mL	19/20
Bordetella pertussis†	I028	ATCC BAA-2707	0.3 CFU/mL	19/20
Bordetella pertussis	18323	ATCC 9797	2.6 CFU/mL	19/20

*The highest LoD is reported.

†The LoD has been obtained in clinical matrix.

‡Pathogen used as representative panel analyte from the original panel (QIAstat-Dx Respiratory Panel Plus, K183597) to confirm LoD with the QIAstat-Dx Respiratory Panel Plus assay.

Exclusivity (analytical specificity)

The analytical specificity study was carried out by in silico analysis and in vitro testing to assess the cross-reactivity and exclusivity of the QIAstat-Dx Respiratory Panel Plus. 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 those which are related to, but distinct from QIAstat-Dx Respiratory Panel Plus 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 by which much of the population may have been infected. Both on-panel and off-panel organisms tested are shown in Table 9a–Table 9e.

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 and fungal targets.

Table 9a. List of analytical specificity pathogens tested (Bacteria, On-Panel)

Pathogen	Strain	Source
C. Pneumoniae	TWAR strain TW-183 AR-39	ATCC VR-2282 ATCC 53592
B. Pertussis	E431 18323	ZeptoMetrix 0801460 ATCC 9797‡
M. Pneumoniae	UTMB-10P M129	ATCC 49894 ZeptoMetrix 0801579

Table 9b. List of analytical specificity pathogens tested (Virus, On-Panel)

Pathogen	Strain	Source
Influenza A H1N1	A/New Jersey/8/76 New Cal/20/99	ATCC VR-897 ZeptoMetrix 0810036CFHI‡
Influenza A H3N2	A/Switzerland/971529/2013 A/Virginia/ATCC6/2012	ATCC VR-1837 ATCC VR-1811
Influenza A H1N1 pdm09	A/California/07/2009 NYMC X-179A A/Virginia/ATCC1/2009	ATCC VR-1884 ATCC VR-1736
Influenza B	B/Florida/04/06	ATCC VR-1804
Coronavirus 229E	Not available Not available Not available	ZeptoMetrix 0810229CFHI ZeptoMetrix 0810229CF ATCC VR-740‡
Coronavirus OC43	Not available Not available	ZeptoMetrix 0810024CFHI ATCC VR-1558‡
Coronavirus NL63	Not available	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	PIV4B PIV4A	ZeptoMetrix 0810060BCFHI ZeptoMetrix 0810060CFHI
Respiratory Syncytial virus	A2 Long	ATCC VR-1540 ATCC VR-26‡
Human Metapneumovirus	A1 (hMPV-16, IA10-2003)	ZeptoMetrix 0810161CFHI#
Adenovirus A12	Huie	ATCC VR-863‡

Table 9b. List of analytical specificity pathogens tested (Virus, On-Panel) (continued)

Pathogen	Strain	Source
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‡
Echovirus 6	D-1 (Cox)	ATCC VR-241‡
SARS-CoV–2	Not available	Hospital Clinic S243*

Table 9c. List of analytical specificity pathogens tested (Bacteria, Off-Panel)

Pathogen	Strain	Source
Acetinobacter calcoaceticus	Z160	ZeptoMetrix 0804096
Bordetella avium	Z338	ZeptoMetrix 0804316
Bordetella bronchiseptica	NRRL B-140	ATCC 4617
Bordetella hinzii	Not available LMG 13501	Vircell MC089 ATCC 51783
Bordetella holmesii	CDC F5101 F061	ATCC 51541 ZeptoMetrix 0801464
Bordetella parapertussis	A747	ZeptoMetrix 0801461
Chlamydia trachomatis	BOUR	ATCC VR-348-B
Corynebacterium diphteriae	48255 Z116	ATCC 11913‡ ZeptoMetrix 0801882
Enterobacter aerogenes	NCDC 819-56 Z052	ATCC 13048 ZeptoMetrix 0801518
Escherichia coli (0157)	O157:H7; EDL933	ZeptoMetrix 0801622

Table 9c. List of analytical specificity pathogens tested (Bacteria, Off-Panel)

Pathogen	Strain	Source
Haemophilus influenzae	L-378 AMC 36-A-7 AMC 36-A-1	ATCC 49766 ATCC 8142‡ ATCC 10211‡
Klebsiella oxytoca	LBM 90.11.033	ATCC 700324
Klebsiella pneumoniae	NCTC 9633 [NCDC 298-53, 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
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	Not available Ly166.96	Vircell MC092 ATCC 700514
Legionella longbeacheae	Long Beach 4	ZeptoMetrix 0801577
Legionella micdadei	Tatlock	ZeptoMetrix 0801576
Legionella pneumophila	Philadelphia-1 Philadelphia	ATCC 33152‡ ZeptoMetrix 0801645‡
Legionella pneumophila	Los Angeles-1	ATCC 33156‡
Moraxella catarrhalis (Branhamella catarrhalis)	N9 [P. Baumann N4] Ne 11 [CCUG 353, LMG 11192, NCTC 11020]	ATCC 25240 ATCC 25238
Mycobacterium tuberculosis§	Not available	ATCC 25177DQ

Table 9c. List of analytical specificity pathogens tested (Bacteria, Off-Panel)

Pathogen	Strain	Source
Mycoplasma genitalium	SEA-1	ZeptoMetrix 0804094-I
Mycoplasma hominis	Not available Z317	ATCC 27545 ZeptoMetrix 080411
Mycoplasma orale	CH 19299 [NCTC 10112]	ATCC 23714
Neisseria elongata	Z071	ZeptoMetrix 0801510
Neisseria gonorrhoeae	Z017	ZeptoMetrix 0801482
Neisseria meningitidis	Serogroup Y FAM18 Serogroup A	ATCC 35561 ATCC 700532DQ ATCC 13077‡
Proteus mirabilis	Z050 LRA 08 01 73 [API SA, DSM 6674]	ZeptoMetrix 0801544 ATCC 35659
Pseudomonas aeruginosa	PRD-10 [CIP 103467, NCIB 10421, PCI 812]	ATCC 15442‡
Serratia marcescens	PCI 1107	ATCC 14756
Staphylococcus aureus	Subsp. Aureus, FDA 209	ATCC CRM-6538‡
Staphylococcus epidermidis	FDA strain PCI 1200	ATCC 12228
Staphylococcus epidermidis	Fussel	ATCC 14990‡
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	Z2019 NCTC 8181 [G19]	ZeptoMetrix 0801545 ATCC 13813
Streptococcus pneumoniae	Z022, 19F	ZeptoMetrix 0801439#

Table 9c. List of analytical specificity pathogens tested (Bacteria, Off-Panel)

Pathogen	Strain	Source
Streptococcus pyogenes	Lancefield's group A/C203 S Z018	ATCC 14289 ZeptoMetrix 0801512
Streptococcus salivarius	C699 [S30D]	ATCC 13419‡
Streptococcus salivarius	Z127	ZeptoMetrix 0801896‡
Ureaplasma urealyticum	T-strain 960 (CX8) [960, CIP 103755, NCTC 10177]	ATCC 27618

Table 9d. List of analytical specificity pathogens tested (Virus, Off-Panel)

Pathogen	Strain	Source
Bocavirus	Type 1	Kansas University*
Cytomegalovirus	Towne AD-169	ZeptoMetrix 0810499CFHI‡ ZeptoMetrix NATCMV-0005
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
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)†

Table 9e. List of analytical specificity pathogens tested (Fungus, Off-Panel)

Pathogen	Strain	Source
Aspergillus Flavus	Z013 Harvard 997	ZeptoMetrix 0801598 Vircell MC064
Aspergillus fumigatus	Z014 MCV-C#10	ZeptoMetrix 0801716 Vircell MBC002
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
Candida albicans	CBS 562	ATCC 18804‡
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.

‡ Pathogen tested in combination with SARS-CoV-2 at 3xLoD resulting in no impact on assay performance.

§*Mycobacterium tuberculosis* genomic DNA tested

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 Panel Plus.

The only exception is *Bordetella* species (*Bordetella holmesii* and *Bordetella bronchiseptica*). 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 the QIAstat-Dx Respiratory Panel Plus 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.

Inclusivity (analytical reactivity)

The 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 131 inclusivity strains were included in the study, representative of the species/types of the different organisms (e.g., a range of Influenza A strains isolated from different geographical areas and in different calendar years were included). Results of the Inclusivity Strains wet testing are shown in Table 10.

Table 10. 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/8/76	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 10. List of inclusivity strains tested (continued)

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

Table 10. List of inclusivity strains tested (continued)

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

Table 10. List of inclusivity strains tested (continued)

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
Influenza A	H1N2‡	Recombinant Kilbourne F63, A/NWS/1934 (HA) x A/Rockefeller Institute/5/1957 (NA) (nucleic acids)	BEI Resources NR-9677	100x LoD	Influenza A H1
	H2N2‡	Japan/305/1957 (nucleic acid)	BEI Resources NR-2775	1x LoD	Influenza A
		Korea/426/1968 x Puerto Rico/8/1934 (nucleic acid)	BEI Resources NR-9679	0.3x LoD	Influenza A
	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
	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

Table 10. List of inclusivity strains tested (continued)

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

Table 10. List of inclusivity strains tested (continued)

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
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	QIAGEN Barcelona‡‡ S510	3x LoD	Coronavirus HKU1
		Not available	QIAGEN Barcelona‡‡ S501	1x LoD	Coronavirus HKU1
		Not available	QIAGEN Barcelona‡‡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

Table 10. List of inclusivity strains tested (continued)

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
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
Parainfluenza Virus 4	A	M-25	ATCC VR-1378*	1x LoD	Parainfluenza Virus 4
		Not available	ZeptoMetrix 0810060CFHI	0.1x LoD	Parainfluenza Virus 4
	B	Not available	ZeptoMetrix 0810060BCFHI†	0.3x LoD	Parainfluenza Virus 4
		CH 19503	ATCC VR-1377	0.3x LoD	Parainfluenza Virus 4

Table 10. List of inclusivity strains tested (continued)

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

Table 10. List of inclusivity strains tested (continued)

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
Human Metapneumovirus	A1	IA10-2003	ZeptoMetrix 0810161CFHI*	1x LoD	Human Metapneumovirus A+B
		IA3-2002	ZeptoMetrix 0810160CFHI	3x LoD	Human Metapneumovirus A+B
	A2	IA14-2003	ZeptoMetrix 0810163CFHI†	1x LoD	Human Metapneumovirus A+B
		IA27-2004	ZeptoMetrix 0810164CFHI	1x LoD	Human Metapneumovirus A+B
	B1	Peru2-2002	ZeptoMetrix 0810156CFHI†	1x LoD	Human Metapneumovirus A+B
		Peru3-2003	ZeptoMetrix 0810158CFHI	1x LoD	Human Metapneumovirus A+B

Table 10. List of inclusivity strains tested (continued)

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
	B2	Peru6-2003	ZeptoMetrix 0810159CFHI†	1x LoD	Human Metapneumovirus A+B
		IA18-2003	ZeptoMetrix 0810162CFHI	1x LoD	Human Metapneumovirus A+B
		Peru1-2002	ZeptoMetrix 0810157CFHI	10x LoD	Human Metapneumovirus 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	0.1x LoD	Adenovirus
	11	Not available	ATCC VR-12	10x LoD	Adenovirus
	21	Not available	ATCC VR-256	0.3x LoD	Adenovirus
	34	Not available	ATCC VR-716	0.3x LoD	Adenovirus
	35	Not available	ATCC VR-718	0.3x LoD	Adenovirus

Table 10. List of inclusivity strains tested (continued)

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

Table 10. List of inclusivity strains tested (continued)

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

Table 10. List of inclusivity strains tested (continued)

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
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
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
SARS-CoV-2§§	Not available	WHO reference material	NIBSC 20/146	1x LoD	SARS-CoV-2
M. pneumoniae	1	M129-B7	ATCC 29342†	1x LoD	*Mycoplasma pneumoniae*
	1	PI 1428	ACC 29085*	1x LoD	*Mycoplasma pneumoniae*
	2	Not available	ATCC 15531	0.1x LoD	Mycoplasma pneumoniae

Table 10. List of inclusivity strains tested (continued)

Pathogen	Subtype/ Serotype	Strain	Source	x LoD detected	QIAstat-Dx Result
B. pertussis	Not available	I028	ATCC BAA-2707*	1x LoD	*Bordetella pertussis*
		19323	ATCC 9797†	1x LoD	*Bordetella pertussis*
		Not available	ATCC 10380	0.3x LoD	*Bordetella pertussis*
C. pneumoniae	Not available	TW183	ATCC VR-2282*	1x LoD	*Chlamydophila pneumoniae*
		CWL-029	ATCC VR-1310†	1x LoD	*Chlamydophila pneumoniae*
		Not available	ATCC 53592	0.3x LoD	*Chlamydophila pneumoniae*

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

† Strains tested in LoD study.

‡ 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.

§ 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 sample obtained in STAT-Dx Life, S.L , Spain (HKU1).

§§ 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.

SARS-CoV-2 in silico evaluation included a total of 8,118,241 available genomes (since the beginning of the SARS-CoV-2 outbreak (January 01, 2020 until May 06, 2022) 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*). 7,932,071 (97.71%) of the analyzed sequence genomes showed no evidence of mismatches among the assay's oligonucleotides binding region. For the rest of analyzed genomes, only 19,045 (0.23%) 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. As a conclusion, QIAstat-Dx Respiratory Panel Plus was inclusive for all analyzed SARS-CoV-2 genomes, including all known variants, lineages and sublineages. Additional analysis was also performed to include SARS-CoV-2 genomic sequences available until July 07, 2023, with no additional critical mismatch found. New sequences and variants are periodically monitored for potential impact on the QIAstat-Dx Respiratory Panel Plus performance. Refer to QIAGEN website for most recent data (**https://www.qiagen.com/us/applications/infectious-disease/coronavirus**).

For those on-panel organisms with known biological subtype differentiation, coverage was also analyzed. Inclusivity for Influenza A (Table 11), Rhinovirus/Enterovirus (Table 12), and Adenovirus (Table 13) were evaluated based on sequences available in GenBank database. In all cases, the QIAstat-Dx Respiratory Panel Plus was predicted 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 Influenza 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), *Mycoplasma pneumoniae*, *Chlamydophila pneumoniae*, and *Bordetella pertussis*.

Table 11. 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 12. 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
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 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 13. 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 wet testing and in silico analysis, the QIAstat-Dx Respiratory Panel Plus primers and probes are predicted to be inclusive for clinically prevalent and relevant strains for each pathogen.

Reproducibility

Reproducibility testing of contrived samples was performed at three test sites including one internal site (site 1) and two external sites (site 2 and site 3). The study incorporated a range of potential variation introduced by sites, days, replicates, cartridge lots, operators, and QIAstat-Dx Analyzers. For each site, testing was performed across 5 days with 4 replicates per day (leading to a total of 20 replicates per target, concentration, and site), a minimum of 2 different QIAstat-Dx Analyzers per site, and at least 2 operators on each testing day. A total of 12 sample mixes were prepared with at least 3 replicates tested per sample mix. Each pathogen was spiked into HeLa in UTM combined samples in a final concentration of 0.1x

LoD, 1x LoD, or 3x LoD, respectively. Table 14 summarizes the results for 0.1x LoD concentration where it is observed that the detection rate for 24 of the 24 targets was <95%.

Table 14. Detection rate per target at 0.1x LoD concentration for each site of reproducibility study and 2-sided 95% Confidence Interval by target.

Target (0.1x LoD)	Site	Detection rate (# positive)	% detection rate (# positive)	95% Confidence Interval
Adenovirus (ATCC VR-3)	SITE 1	10/20	50.0%	29.9–70.1%
	SITE 2	9/19	47.4%	27.3–68.3%
	SITE 3	10/19	52.6%	31.7–72.7%
	All sites (overall)	29/58	50.0%	37.5–62.5%
B. pertussis (BAA-2707)	SITE 1	9/20	45.0%	25.8–65.8%
	SITE 2	7/19	36.8%	19.1–59.0%
	SITE 3	9/20	45.0%	25.8–65.8%
	All sites (overall)	25/59	42.4%	30.6–55.1%
C. pneumoniae (ATCC VR-2282)	SITE 1	11/20	55.0%	34.2–74.2%
	SITE 2	11/19	57.9%	36.3–76.9%
	SITE 3	14/20	70.0%	48.1–85.5%
	All sites (overall)	36/59	61.0%	48.3–72.4%
Coronavirus 229E (ATCC VR-740)	SITE 1	9/20	45.0%	25.8–65.8%
	SITE 2	12/19	63.2%	41.0–80.9%
	SITE 3	5/20	25.0%	11.2–46.9%
	All sites (overall)	26/59	44.1%	32.2–56.7%

Table 14. Detection rate per target at 0.1x LoD concentration for each site of reproducibility study and 2-sided 95% Confidence Interval by target. (continued)

Target (0.1x LoD)	Site	Detection rate (# positive)	% detection rate (# positive)	95% Confidence Interval
Coronavirus HKU1 (NATRVP-IDI)	SITE 1	17/20	85.0%	64.0–94.8%
	SITE 2	10/19	52.6%	31.7–72.7%
	SITE 3	9/20	45.0%	25.8–65.8%
	All sites (overall)	36/59	61.0%	48.3–72.4%
Coronavirus NL63 (0810228CFHI)	SITE 1	13/20	65.0%	43.3–81.9%
	SITE 2	12/19	63.2%	41.0–80.9%
	SITE 3	14/19	73.7%	51.2–88.2%
	All sites (overall)	39/58	67.2%	54.4–77.9%
Coronavirus OC43 (ATCC VR-1558)	STAT	13/20	65.0%	43.3–81.9%
	SITE 2	15/20	75.0%	53.1–88.8%
	SITE 3	15/20	75.0%	53.1–88.8%
	All sites (overall)	43/60	71.7%	59.2–81.5%
Enterovirus (ATCC VR-1824)	SITE 1	8/20	40.0%	21.9–61.3%
	SITE 2	6/19	31.6%	15.4–54.0%
	SITE 3	7/20	35.0%	18.1–56.7%
	All sites (overall)	21/59	35.6%	24.6–48.3%
Human Metapneumovirus (0810161CF)	SITE 1	6/20	30.0%	14.5–51.9%
	SITE 2	9/19	47.4%	27.3–68.3%
	SITE 3	9/20	45.0%	25.8–65.8%
	All sites (overall)	24/59	40.7%	29.1–53.4%

Table 14. Detection rate per target at 0.1x LoD concentration for each site of reproducibility study and 2-sided 95% Confidence Interval by target. (continued)

Target (0.1x LoD)	Site	Detection rate (# positive)	% detection rate (# positive)	95% Confidence Interval
Influenza A (0810249CFHI)	SITE 1	19/20	95.0%	76.4–99.1%
	SITE 2	18/20	90.0%	69.9–97.2%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	57/60	95.0%	86.3–98.3%
Influenza A (ATCC VR-810)	SITE 1	10/20	50.0%	29.9–70.1%
	SITE 2	9/19	47.4%	27.3–68.3%
	SITE 3	16/19	84.2%	62.4–94.5%
	All sites (overall)	35/58	60.3%	47.5–71.9%
Influenza A (ATCC VR-897)	SITE 1	14/20	70.0%	48.1–85.5%
	SITE 2	9/19	47.4%	27.3–68.3%
	SITE 3	12/20	60.0%	38.7–78.1%
	All sites (overall)	35/59	59.3%	46.6–70.9%
Influenza A H1 (ATCC VR-897)	SITE 1	13/20	65.0%	43.3–81.9%
	SITE 2	13/19	68.4%	46.0–84.6%
	SITE 3	15/20	75.0%	53.1–88.8%
	All sites (overall)	41/59	69.5%	56.9–79.7%
Influenza B (ATCC VR-295)	SITE 1	7/20	35.0%	18.1–56.7%
	SITE 2	9/19	47.4%	27.3–68.3%
	SITE 3	8/20	40.0%	21.9–61.3%
	All sites (overall)	24/59	40.7%	29.1–53.4%

Table 14. Detection rate per target at 0.1x LoD concentration for each site of reproducibility study and 2-sided 95% Confidence Interval by target. (continued)

Target (0.1x LoD)	Site	Detection rate (# positive)	% detection rate (# positive)	95% Confidence Interval
Influenza H1N1 pdm09 (0810249CFHI)	SITE 1	14/20	70.0%	48.1–85.5%
	SITE 2	16/20	80.0%	58.4–91.9%
	SITE 3	15/20	75.0%	53.1–88.8%
	All sites (overall)	45/60	75.0%	62.8–84.2%
Influenza H3 (ATCC VR-810)	SITE 1	13/20	65.0%	43.3–81.9%
	SITE 2	16/19	84.2%	62.4–94.5%
	SITE 3	17/19	89.5%	68.6–97.1%
	All sites (overall)	46/58	79.3%	67.2–87.7%
M. pneumoniae (29085)	SITE 1	13/20	65.0%	43.3–81.9%
	SITE 2	14/20	70.0%	48.1–85.5%
	SITE 3	14/20	70.0%	48.1–85.5%
	All sites (overall)	41/60	68.3%	55.8–78.7%
Parainfluenza Virus 1 (0810014CFHI)	SITE 1	14/20	70.0%	48.1–85.5%
	SITE 2	12/19	63.2%	41.0–80.9%
	SITE 3	9/19	47.4%	27.3–68.3%
	All sites (overall)	35/58	60.3%	47.5–71.9%
Parainfluenza Virus 2 (ATCC VR-92)	SITE 1	9/20	45.0%	25.8–65.8%
	SITE 2	11/19	57.9%	36.3–76.9%
	SITE 3	12/20	60.0%	38.7–78.1%
	All sites (overall)	32/59	54.2%	41.7–66.3%

Table 14. Detection rate per target at 0.1x LoD concentration for each site of reproducibility study and 2-sided 95% Confidence Interval by target. (continued)

Target (0.1x LoD)	Site	Detection rate (# positive)	% detection rate (# positive)	95% Confidence Interval
Parainfluenza Virus 3 (ATCC VR-93)	SITE 1	13/20	65.0%	43.3–81.9%
	SITE 2	17/20	85.0%	64.0–94.8%
	SITE 3	17/20	85.0%	64.0–94.8%
	All sites (overall)	47/60	78.3%	66.4–86.9%
Parainfluenza Virus 4 (ATCC VR-1378)	SITE 1	10/20	50.0%	29.9–70.1%
	SITE 2	11/19	57.9%	36.3–76.9%
	SITE 3	9/20	45.0%	25.8–65.8%
	All sites (overall)	30/59	50.9%	38.4–63.2%
Respiratory Syncytial Virus A (ATCC VR-1540)	SITE 1	6/20	30.0%	14.5–51.9%
	SITE 2	7/20	35.0%	18.1–56.7%
	SITE 3	9/20	45.0%	25.8–65.8%
	All sites (overall)	22/60	36.7%	25.6–49.3%
Respiratory Syncytial Virus B (0810040CF)	SITE 1	14/20	70.0%	48.1–85.5%
	SITE 2	15/19	79.0%	56.7–91.5%
	SITE 3	10/20	50.0%	29.9–70.1%
	All sites (overall)	39/59	66.1%	53.4–76.9%
Rhinovirus (ATCC VR-482)	SITE 1	15/20	75.0%	53.1–88.8%
	SITE 2	15/20	75.0%	53.1–88.8%
	SITE 3	18/20	90.0%	69.9–97.2%
	All sites (overall)	48/60	80.0%	68.2–88.2%

Table 15 summarizes the results for 1x LoD concentration where it is observed that the detection rate for 24 of the 24 targets was ≥95%.

Table 15. Detection rate per target at 1x LoD concentration for each site of reproducibility study and 2-sided 95% Confidence Interval by target

Target (1x LoD)	Site	Detection rate (# positive)	% detection rate (# positive)	95% Confidence Interval
Adenovirus (ATCC VR-3)	SITE 1	20/20	100%	83.9–100%
	SITE 2	18/18	100%	82.4–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	58/58	100%	93.8–100%
B. pertussis (BAA-2707)	SITE 1	18/20	90.0%	69.9–97.2%
	SITE 2	20/20	100%	83.9–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	58/60	96.7%	88.6–99.1%
C. pneumoniae (ATCC VR-2282)	SITE 1	20/20	100%	83.9–100%
	SITE 2	20/20	100%	83.9–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	60/60	100%	94.0–100%
Coronavirus 229E (ATCC VR-740)	SITE 1	18/20	90.0%	69.9–97.2%
	SITE 2	20/20	100%	83.9–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	58/60	96.7%	88.6–99.1%
Coronavirus HKU1 (NATRVP-IDI)	SITE 1	20/20	100%	83.9–100%
	SITE 2	20/20	100%	83.9–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	60/60	100%	94.0–100%

Table 15. Detection rate per target at 1x LoD concentration for each site of reproducibility study and 2-sided 95% Confidence Interval by target (continued)

Target (1x LoD)	Site	Detection rate (# positive)	% detection rate (# positive)	95% Confidence Interval
Coronavirus NL63 (0810228CFHI)	SITE 1	20/20	100%	83.9–100%
	SITE 2	18/18	100%	82.4–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	58/58	100%	93.8–100%
Coronavirus OC43 (ATCC VR-1558)	SITE 1	20/20	100%	83.9–100%
	SITE 2	19/19	100%	83.2–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	59/59	100%	93.9–100%
Enterovirus (ATCC VR-1824)	SITE 1	19/20	95.0%	76.4–99.1%
	SITE 2	20/20	100%	83.9–100%
	SITE 3	19/20	95.0%	76.4–99.1%
	All sites (overall)	58/60	96.7%	88.6–99.1%
Human Metapneumovirus (0810161CF)	SITE 1	19/20	95.0%	76.4–99.1%
	SITE 2	20/20	100%	83.9–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	59/60	98.3%	91.1–99.7%
Influenza A (0810249CFHI)	SITE 1	20/20	100%	83.9–100%
	SITE 2	19/19	100%	83.2–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	59/59	100%	93.9–100%

Table 15. Detection rate per target at 1x LoD concentration for each site of reproducibility study and 2-sided 95% Confidence Interval by target (continued)

Target (1x LoD)	Site	Detection rate (# positive)	% detection rate (# positive)	95% Confidence Interval
Influenza A (ATCC VR-810)	SITE 1	19/20	95.0%	76.4–99.1%
	SITE 2	18/18	100%	82.4–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	57/58	98.3%	90.9–99.7%
Influenza A (ATCC VR-897)	SITE 1	19/20	95.0%	76.4–99.1%
	SITE 2	20/20	100%	83.9–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	59/60	98.3%	91.1–99.7%
Influenza A H1 (ATCC VR-897)	SITE 1	20/20	100%	83.9–100%
	SITE 2	20/20	100%	83.9–100%
	SITE 3	19/20	95.0%	76.4–99.1%
	All sites (overall)	59/60	98.3%	91.1–99.7%
Influenza B (ATCC VR-295)	SITE 1	19/20	95.0%	76.4–99.1%
	SITE 2	20/20	100%	83.9–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	59/60	98.3%	91.1–99.7%
Influenza H1N1 pdm09 (0810249CFHI)	SITE 1	20/20	100%	83.9–100%
	SITE 2	19/19	100%	83.2–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	59/59	100%	93.9–100%

Table 15. Detection rate per target at 1x LoD concentration for each site of reproducibility study and 2-sided 95% Confidence Interval by target (continued)

Target (1x LoD)	Site	Detection rate (# positive)	% detection rate (# positive)	95% Confidence Interval
Influenza H3 (ATCC VR-810)	SITE 1	20/20	100%	83.9–100%
	SITE 2	18/18	100%	82.4–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	58/58	100%	93.8–100%
M. pneumoniae (29085)	SITE 1	20/20	100%	83.9–100%
	SITE 2	19/19	100%	83.2–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	59/59	100%	93.9–100%
Parainfluenza Virus 1 (0810014CFHI)	SITE 1	20/20	100%	83.9–100%
	SITE 2	18/18	100%	82.4–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	58/58	100%	93.8–100%
Parainfluenza Virus 2 (ATCC VR-92)	SITE 1	19/20	95.0%	76.4–99.1%
	SITE 2	20/20	100%	83.9–100%
	SITE 3	19/20	95.0%	76.4–99.1%
	All sites (overall)	58/60	96.7%	88.6–99.1%
Parainfluenza Virus 3 (ATCC VR-93)	SITE 1	20/20	100%	83.9–100%
	SITE 2	19/19	100%	83.2–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	59/59	100%	93.9–100%

Table 15. Detection rate per target at 1x LoD concentration for each site of reproducibility study and 2-sided 95% Confidence Interval by target (continued)

Target (1x LoD)	Site	Detection rate (# positive)	% detection rate (# positive)	95% Confidence Interval
Parainfluenza Virus 4 (ATCC VR-1378)	SITE 1	20/20	100%	83.9–100%
	SITE 2	20/20	100%	83.9–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	60/60	100%	94.0–100%
Respiratory Syncytial Virus A (ATCC VR-1540)	SITE 1	20/20	100%	83.9–100%
	SITE 2	19/19	100%	83.2–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	59/59	100%	93.9–100%
Respiratory Syncytial Virus B (0810040CF)	SITE 1	20/20	100%	83.9–100%
	SITE 2	20/20	100%	83.9–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	60/60	100%	94.0–100%
Rhinovirus (ATCC VR-482)	SITE 1	20/20	100%	83.9–100%
	SITE 2	19/19	100%	83.2–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	59/59	100%	93.9–100%

Table 16 summarizes the results for 3x LoD concentration where it is observed that detection rate for 24 of the 24 targets was ≥95%.

Table 16. Detection rate per target at 3x LoD concentration for each site of reproducibility study and 2-sided 95% Confidence Interval by target.

Target (3x LoD)	Site	Detection rate (# positive)	% detection rate (# positive)	95% Confidence Interval
Adenovirus (ATCC VR-3)	SITE 1	20/20	100%	83.9–100%
	SITE 2	19/19	100%	83.2–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	59/59	100%	93.9–100%
B. pertussis (BAA-2707)	SITE 1	20/20	100%	83.9–100%
	SITE 2	19/19	100%	83.2–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	59/59	100%	93.9–100%
C. pneumoniae (ATCC VR-2282)	SITE 1	20/20	100%	83.9–100%
	SITE 2	19/20	95.0%	76.4–99.1%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	59/60	98.3%	91.1–99.7%
Coronavirus 229E (ATCC VR-740)	SITE 1	20/20	100%	83.9–100%
	SITE 2	19/19	100%	83.2–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	59/59	100%	93.9–100%
Coronavirus HKU1 (NATRVP-IDI)	SITE 1	20/20	100%	83.9–100%
	SITE 2	20/20	100%	83.9–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	60/60	100%	94.0–100%

Table 16. Detection rate per target at 3x LoD concentration for each site of reproducibility study and 2-sided 95% Confidence Interval by target. (continued)

Target (3x LoD)	Site	Detection rate (# positive)	% detection rate (# positive)	95% Confidence Interval
Coronavirus NL63 (0810228CFHI)	SITE 1	20/20	100%	83.9–100%
	SITE 2	19/19	100%	83.2–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	59/59	100%	93.9–100%
Coronavirus OC43 (ATCC VR-1558)	SITE 1	20/20	100%	83.9–100%
	SITE 2	19/19	100%	83.2–100%
	SITE 3	19/19	100%	83.2–100%
	All sites (overall)	58/58	100%	93.8–100%
Enterovirus (ATCC VR-1824)	SITE 1	20/20	100%	83.9–100%
	SITE 2	19/19	100%	83.2–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	59/59	100%	93.9–100%
Human Metapneumovirus (0810161CF)	SITE 1	20/20	100%	83.9–100%
	SITE 2	19/19	100%	83.2–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	59/59	100%	93.9–100%
Influenza A (0810249CFHI)	SITE 1	20/20	100%	83.9–100%
	SITE 2	19/19	100%	83.2–100%
	SITE 3	19/19	100%	83.2–100%
	All sites (overall)	58/58	100%	93.8–100%

Table 16. Detection rate per target at 3x LoD concentration for each site of reproducibility study and 2-sided 95% Confidence Interval by target. (continued)

Target (3x LoD)	Site	Detection rate (# positive)	% detection rate (# positive)	95% Confidence Interval
Influenza A (ATCC VR-810)	SITE 1	20/20	100%	83.9—100%
	SITE 2	19/19	100%	83.2–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	59/59	100%	93.9–100%
Influenza A (ATCC VR-897)	SITE 1	20/20	100%	83.9–100%
	SITE 2	20/20	100%	83.9–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	60/60	100%	94.0–100%
Influenza A H1 (ATCC VR-897)	SITE 1	19/20	95.0%	76.4–99.1%
	SITE 2	20/20	100%	83.9–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	59/60	98.3%	91.1–99.7%
Influenza B (ATCC VR-295)	SITE 1	19/20	95.0%	76.4–99.1%
	SITE 2	19/19	100%	83.2–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	58/59	98.3%	91.0–99.7%
Influenza H1N1 pdm09 (0810249CFHI)	SITE 1	20/20	100%	83.9–100%
	SITE 2	19/19	100%	83.2–100%
	SITE 3	19/19	100%	83.2–100%
	All sites (overall)	58/58	100%	93.8–100%

Table 16. Detection rate per target at 3x LoD concentration for each site of reproducibility study and 2-sided 95% Confidence Interval by target. (continued)

Target (3x LoD)	Site	Detection rate (# positive)	% detection rate (# positive)	95% Confidence Interval
Influenza H3 (ATCC VR-810)	SITE 1	20/20	100%	83.9–100%
	SITE 2	19/19	100%	83.2–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	59/59	100%	93.9–100%
M. pneumoniae (29085)	SITE 1	20/20	100%	83.9–100%
	SITE 2	19/19	100%	83.2–100%
	SITE 3	19/19	100%	83.2–100%
	All sites (overall)	58/58	100%	93.8–100%
Parainfluenza Virus 1 (0810014CFHI)	SITE 1	20/20	100%	83.9–100%
	SITE 2	19/19	100%	83.2–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	59/59	100%	93.9–100%
Parainfluenza Virus 2 (ATCC VR-92)	SITE 1	19/20	95.0%	76.4–99.1%
	SITE 2	20/20	100%	83.9–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	59/60	98.3%	91.1–99.7%
Parainfluenza Virus 3 (ATCC VR-93)	SITE 1	20/20	100%	83.9–100%
	SITE 2	19/19	100%	83.2–100%
	SITE 3	19/19	100%	83.2–100%
	All sites (overall)	58/58	100%	93.8–100%

Table 16. Detection rate per target at 3x LoD concentration for each site of reproducibility study and 2-sided 95% Confidence Interval by target. (continued)

Target (3x LoD)	Site	Detection rate (# positive)	% detection rate (# positive)	95% Confidence Interval
Parainfluenza Virus 4 (ATCC VR-1378)	SITE 1	20/20	100%	83.9–100%
	SITE 2	19/19	100%	83.2–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	59/59	100%	93.9–100%
Respiratory Syncytial Virus A (ATCC VR-1540)	SITE 1	20/20	100%	83.9–100%
	SITE 2	19/19	100%	83.2–100%
	SITE 3	19/19	100%	83.2–100%
	All sites (overall)	58/58	100%	93.8–100%
Respiratory Syncytial Virus B (0810040CF)	SITE 1	20/20	100%	83.9–100%
	SITE 2	20/20	100%	83.9–100%
	SITE 3	20/20	100%	83.9–100%
	All sites (overall)	60/60	100%	94.0–100%
Rhinovirus (ATCC VR-482)	SITE 1	20/20	100%	83.9–100%
	SITE 2	19/19	100%	83.2–100%
	SITE 3	19/19	100%	83.2–100%
	All sites (overall)	58/58	100%	93.8–100%

A representative panel of analytes (Influenza B, Coronavirus HKU1, Parainfluenza virus 3, Rhinovirus, Adenovirus, *Mycoplasma pneumoniae*, and SARS-CoV-2) was tested in one site to confirm that the SARS-CoV-2 analyte had the expected behavior. A set of selected samples composed of low-concentrated analytes (3x LoD and 1x LoD) and negative samples was tested in simulated sample matrix (HeLa cells in UTM). At least 90 replicates per each analyte and concentration were tested. 3x and 1x LoD concentrations showed ≥95% detection rate for all targets, and negative concentration showed 0% detection rate for all targets.

A reproducibility study of the QIAstat-Dx Respiratory Panel Plus and the automated loading in the QIAstat-Dx Rise system was conducted by operators at three sites using panels of representative combined analytes at moderate positive, low positive, and negative concentrations in simulated NPS matrix. The testing was performed across five non-consecutive days using three operators, three instruments (one per site), and three reagent lots. Each operator performed two replicates per analyte at each sample concentration each testing day for a total of 90 datapoints per analyte and concentration (3 operators x 2 replicates x 3 sites x 5 days). All negative, moderate positive, and low positive samples for all analytes exhibited acceptable performance. There were no significant differences observed within run, between lots, between days, between operators, or between sites, demonstrating assay variability within an acceptable range.

Carryover

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

Samples of simulated NPS matrix, with alternating high-positive and negative samples, were tested on two QIAstat-Dx Analyzer 1.0. No carryover between samples was observed in the QIAstat-Dx Respiratory Panel Plus.

Moreover, another study was conducted with eight consecutive alternating runs of high-positive and negative samples (18 cartridges/run) to evaluate carryover between samples when loading the cartridges into the QIAstat-Dx Rise. No carryover between samples was observed in the QIAstat-Dx Respiratory Panel Plus in this study.

Interfering substances (analytical specificity)

The effect of potentially interfering substances on the detectability of the QIAstat-Dx Respiratory Panel Plus 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 or 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 controls.

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 Panel Plus.

None of the substances tested showed inhibition, except for the nasal influenza vaccines. This was due to the fact that the selection of substances concentration was higher than the

concentrations expected to be present in a sample. In addition, nasal influenza vaccines (Fluenz Tetra and FluMist®) were predicted to be reactive with the QIAstat-Dx Respiratory Panel Plus Influenza A (subtype) 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 17.

Table 17. Outcome of potential interfering substances 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
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	Interference
	0.000001% v/v	No Interference

Table 17. Outcome of potential interfering substances tested (continued)

Substance tested	Concentration tested	Results
Fluenz Tetra nasal influenza vaccine*	0.00001% v/v	Interference
	0.000001% v/v	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
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

Table 17. Outcome of potential interfering substances tested (continued)

Substance tested	Concentration tested	Results
VTM RT‡	100%	No Interference
BD Universal Viral Transport	100%	No Interference
Delta Swab Virus	100%	No Interference

* SARS-CoV-2 was tested with Chiroflu nasal influenza vaccine instead of FluMist and Fluenz Tetra nasal vaccines.

† SARS-CoV-2 was tested with Protect RNA instead of RNAseOUT.

‡ SARS-CoV-2 were tested with VTM RT instead of VTM Remel M4, VTM Remel M5 and VTM Remel M6.

Microbial interference

A microbial interference study was conducted to assess the inhibitory effects of select non-target organisms on the ability to detect SARS-CoV-2. Clinically relevant and challenging concentrations (1.00E+06 CFU/mL for bacteria/fungi, 1.00E+05 PFU/mL for viruses unless otherwise noted) of non-target organisms were individually mixed with SARS-CoV-2 at 3x LoD in simulated NPS matrix. Testing was performed in triplicate with two additional tests performed if SARS-CoV-2 was not detected in any one of the original three replicates. All combinations and replicates successfully detected SARS-CoV-2 except for three samples, one *Legionella pneumophila*, one *Streptococcus salivarius* sample, and one *H.influenzae* sample. For these, additional replicates successfully detected SARS-CoV-2. Where available, at least one additional strain of *L. pneumophila, S. salivarius* or *H. influenzae* was also tested in triplicate with all samples successfully detecting SARS-CoV-2. See Table 18 for a list of the strains tested and the result summary.

Table 18. Microbial interference study results

Non-Target Organism	Strain/Isolate	Source/ Catalog #	# SARS-CoV-2 detected/valid runs
*Staphylococcus aureus**	FDA 209	ATCC CRM-6538	3/3
Streptococcus pneumoniae	Z022 19F	ZeptoMetrix 0801439	3/3
Streptococcus salivarius	C699 [S30D]	ATCC 13419	3/3
Streptococcus salivarius	Z127	ZeptoMetrix 0801896	4/5
Haemophilus influenzae	AMC 36-A-7	ATCC 8142	3/3
Haemophilus influenzae	AMC 36-A-1	ATCC 10211	3/3
Candida albicans	CBS 562	ATCC 18804	3/3
Herpes Simplex Virus 1	ATCC-2011-9	ATCC VR-1789	3/3
Staphylococcus epidermidis	Fussel	ATCC 14990	4/5
Pseudomonas aeruginosa	PRD-10	ATCC 15442	3/3
Legionella pneumophila	Philadelphia†	ZeptoMetrix 0801645	3/5
Legionella pneumophila	Philadelphia-1†	ATCC 33152	3/3
Legionella pneumophila	Los Angeles-1	ATCC 33156	3/3
*Neisseria meningitidis**	serogroup A	ATCC 13077	3/3
*Corynebacterium diphtheriae**	48255	ATCC 11913	3/3
Human Cytomegalovirus (CMV)*	Towne	ZeptoMetrix 0810499 CFHI	3/3

* *S. aureus* was evaluated at 4.5x10^8 CFU/mL, *N. meningitidis* at 1.0x10^3 CFU/mL, *C. diphtheriae at* 1.0x10^3 CFU/mL, and CMV at 1.0x10^4 $TCID_{50}$/mL.

† Philadelphia and Philadelphia-1 are both designations of strain Philadelphia serogroup-1, differences in naming are due to supplier.

Competitive inhibition

Clinically relevant co-infections testing demonstrated that when at least two QIAstat-Dx Respiratory Panel Plus pathogens of different concentrations are simultaneously present in one sample, all targets can be detected by the assay. SARS-CoV-2 at 3x LoD has been tested in combination with the on-panel pathogens listed in Table 19 at high concentrations (10E+05 for viral targets, 10E+06 for bacterial targets), with no impact on assay performance.

Table 19. On-panel pathogens tested for competitive inhibition

On-panel pathogen	Concentration tested
Coronavirus 229E	1.00E+05 $TCID_{50}$/mL
Coronavirus OC43	1.00E+05 $TCID_{50}$/mL
Adenovirus A12	1.00E+05 $TCID_{50}$/mL
Parainfluenza Virus 3	1.00E+05 $TCID_{50}$/mL
Bordetella pertussis	1.00E+06 CFU/mL
Enterovirus D68	1.00E+05 $TCID_{50}$/mL
Echovirus 6	1.00E+05 $TCID_{50}$/mL
Respiratory Syncytial Virus	1.00E+05 PFU/mL
Rhinovirus	1.00E+05 PFU/mL
hMPV	1.00E+05 $TCID_{50}$/mL
Influenza A H1N1	1.00E+05 $TCID_{50}$/mL

Clinical Performance

The clinical performance shown below was demonstrated using the QIAstat-Dx Analyzer 1.0. The QIAstat-Dx Analyzer 2.0 uses the same Analytical Modules as QIAstat-Dx Analyzer 1.0; therefore, the performance is not impacted by QIAstat-Dx Analyzer 2.0. Likewise, the QIAstat-Dx Rise uses the same Analytical Modules as QIAstat-Dx Analyzer 1.0 and/or QIAstat-Dx Analyzer 2.0; therefore, the clinical performance is not expected to be impacted by use of the QIAstat-Dx Rise.

The clinical performance of the QIAstat-Dx Respiratory Panel Plus was established in two separate clinical studies. The first study was conducted between December 2017 and April 2019 to establish the performance for all targets excluding SARS-CoV-2. The performance for SARS-CoV-2 was established in a second study conducted between February and May 2023 and February 2024.

Clinical performance for all targets excluding SARS-CoV-2

The clinical performance of the QIAstat-Dx Respiratory Panel was established during a multi-center study conducted at six (6) geographically diverse study sites: five (5) U.S. sites and one (1) international site that covered all targets excluding SARS-CoV-2.

Residual NPS specimens in UTM were tested with the QIAstat-Dx Respiratory Panel and an FDA-cleared molecular comparator, in accordance with product instructions for use. Specimens tested in the clinical study were collected using the Universal Transport Medium (UTM) (Copan Diagnostics [Brescia, Italy and CA, USA]), 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.

A total of 2304 residual NPS specimens (1994 prospective, 310 archived) were tested in this comparison study. Between December 2017 to April 2019, specimens were prospectively collected from all comers meeting the study inclusion criteria and immediately frozen for later testing by the study site as frozen prospective specimens (N=1093). No frozen specimens were distributed amongst sites. At time of testing, specimens were thawed and tested on both the QIAstat-Dx Respiratory Panel and comparator method.

Between February and August 2018, specimens were prospectively collected from all comers meeting the study eligibility criteria and tested fresh (N=901) on both the QIAstat-Dx Respiratory Panel and comparator method in accordance with product instructions as fresh prospective specimens. One specimen was withdrawn from the study due to an incorrect specimen type.

Table 20 provides the summary of demographic information for the 1994 subjects that participated in the first prospective study.

Table 20. Demographic summary for the first prospective study

		Overall	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6
SEX								
	Male	924 (46.3%)	186	0	196	177	170	195
	Female	1070 (53.7%)	232	0	230	271	133	204
AGE								
	≤5 years	627 (31.4%)	126	0	103	49	216	133
	6–21 years	239 (11.9%)	34	0	40	38	79	48
	22–49 years	330 (16.5%)	110	0	56	107	7	50
	50+ years	798 (40.0%)	148	0	227	254	1	168
STATUS								
	Outpatient	788 (39.5%)	272	0	50	44	145	277
	Hospitalized	686 (34.4%)	145	0	318	0	101	122
	Emergency	67 (3.4%)	0	0	9	34	24	0
	ICU	153 (7.7%)	1	0	49	70	33	0
	Not provided/ unknown	300 (15.0%)	0	0	0	300	0	0
	Total	**1994**	**418**	**0**	**426**	**448**	**303**	**399**

A total of 1994 specimens were evaluated for all panel members in the first prospective study. The performance of the QIAstat-Dx was evaluated by comparing the QIAstat-Dx Respiratory Panel test results with those from an FDA-cleared multiplexed respiratory pathogen panel.

Positive Percent Agreement (PPA) for each analyte was calculated as 100% x (TP/[TP+FN]). True Positive (TP) indicates that both the QIAstat-Dx Respiratory Panel and the comparator method yielded a "Detected" result of that specific analyte. A False Negative (FN) indicates that the QIAstat-Dx Respiratory Panel was "Not Detected" while the comparator method was "Detected" for that specific analyte. Negative Percent Agreement (NPA) was calculated as 100% x (TN/[TN+FP]). True Negative (TN) indicates that both the QIAstat-Dx Respiratory Panel and the comparator method resulted in "Not Detected" for that specific analyte. A False Positive (FP) indicates that the QIAstat-Dx Respiratory Panel was "Detected" while the comparator method was "Not Detected" for that specific analyte.

Binomial two-sided 95% Confidence Intervals were calculated using the Wilson Score Method.

The QIAstat-Dx Respiratory Panel prospective performance data in positive percent and negative percent agreements against the comparator methods are presented by analyte in Table 21.

Table 21. QIAstat-Dx Respiratory Panel prospective clinical performance summary

		Positive Percent Agreement			Negative Percent Agreement		
Target	**Sample type**	**TP/ (TP+FN)**	**%**	**95 % CI (%)**	**TN/ (TN+FP)**	**%**	**95 % CI (%)**
			Virus				
Adenovirus*	Fresh	55 / 58	94.8	85.6–98.9	833 / 839	99.3	98.4–99.7
	Frozen	31 / 32	96.9	83.8–99.9	1047 / 1057	99.1	98.3–99.5
	Overall	86 / 90	95.6	89.0–98.8	1880 / 1896	99.2	98.6–99.5
Coronavirus 229E	Fresh	8 / 9	88.9	51.8–99.7	886 / 886	100.0	99.6–100.0
	Frozen	0 / 0	N/A	N/A	1089 / 1089	100.0	99.7–100.0
	Overall	8 / 9	88.9	51.8–99.7	1975 / 1975	100.0	99.8–100.0
Coronavirus HKU1†	Fresh	3 / 3	100.0	29.2–100.0	890 / 892	99.8	99.2–100.0
	Frozen	48 / 49	98.0	89.1–99.9	1035 / 1040	99.5	98.9–99.8
	Overall	51 / 52	98.1	89.7–100.0	1925 / 1932	99.6	99.3–99.9
Coronavirus NL63‡	Fresh	4 / 5	80.0	28.4–99.5	890 / 890	100.0	99.6–100.0
	Frozen	36 / 42	85.7	71.5–94.6	1046 / 1048	99.8	99.3–100.0
	Overall	40 / 47	85.1	71.7–93.8	1936 / 1938	99.9	99.6–100.0

Table 21. QIAstat-Dx Respiratory Panel prospective clinical performance summary (continued)

		Positive Percent Agreement			Negative Percent Agreement		
Target	**Sample type**	**TP/ (TP+FN)**	**%**	**95 % CI (%)**	**TN/ (TN+FP)**	**%**	**95 % CI (%)**
Coronavirus OC43§	Fresh	3 / 3	100.0	29.2–100.0	892 / 892	100.0	99.6–100.0
	Frozen	23 / 26	88.5	69.8–97.6	1059 / 1063	99.6	99.0–99.9
	Overall	26 / 29	89.7	72.6–97.8	1951 / 1955	99.8	99.5–99.9
Human Meta-pneumovirus¶	Fresh	62 / 67	92.5	83.4–97.5	828 / 829	99.9	99.3–100.0
	Frozen	53 / 55	96.4	87.5–99.6	1030 / 1034	99.6	99.0–99.9
	Overall	115 / 122	94.3	88.5–97.7	1858 / 1863	99.7	99.4–99.9
Influenza A	Fresh	132 / 133	99.2	95.9–100.0	752 / 756	99.5	98.7–99.9
	Frozen	111 / 112	99.1	95.1–100.0	971 / 976	99.5	98.8–99.8
	Overall	243 / 245	99.2	97.1–99.9	1723 / 1732	99.5	99.0–99.8
Influenza A H1**	Fresh	0 / 1	0.0	0.0–97.5	894 / 894	100.0	99.6–100.0
	Frozen	0 / 0	N/A	N/A	1089 / 1089	100.0	99.7–100.
	Overall	0 / 1	0.0	0.0–97.5	1983 / 1983	100.0	0 99.8–100.0

Table 21. QIAstat-Dx Respiratory Panel prospective clinical performance summary (continued)

		Positive Percent Agreement			Negative Percent Agreement		
Target	**Sample type**	**TP/ (TP+FN)**	**%**	**95 % CI (%)**	**TN/ (TN+FP)**	**%**	**95 % CI (%)**
Influenza A H1N1 pdm09 ††	Fresh	62 / 63	98.4	91.5–100.0	826 / 831	99.4	98.6–99.8
	Frozen	18 / 18	100.0	81.5–100.0	1071 / 1071	100.0	99.7–100.0
	Overall	80 / 81	98.8	93.3–100.0	1897 / 1902	99.7	99.4–99.9
Influenza A H3‡‡	Fresh	67 / 67	100.0	94.6–100.0	825 / 826	99.9	99.3–100.
	Frozen	89 / 90	98.9	94.0–100.0	992 / 998	99.4	0 98.7–99.8
	Overall	156 / 157	99.4	96.5–100.0	1817 / 1824	99.6	99.2–99.8
Influenza B§§	Fresh	64 / 67	95.5	87.5–99.1	826 / 827	99.9	99.3–100.0
	Frozen	58 / 62	93.5	84.3–98.2	1027 / 1027	100.0	99.6–100.0
	Overall	122 / 129	94.6	89.1–97.8	1853 / 1854	99.9	99.7–100.0
Parainfluenza Virus 1¶¶	Fresh	3 / 3	100.0	29.2–100.0	892 / 892	100.0	99.6–100.0
	Frozen	13 / 14	92.9	66.1–99.8	1072 / 1075	99.7	99.2–99.9
	Overall	16 / 17	94.1	71.3–99.9	1964 / 1967	99.8	99.6–100.0

Table 21. QIAstat-Dx Respiratory Panel prospective clinical performance summary (continued)

		Positive Percent Agreement			Negative Percent Agreement		
Target	**Sample type**	**TP/ (TP+FN)**	**%**	**95 % CI (%)**	**TN/ (TN+FP)**	**%**	**95 % CI (%)**
Parainfluenza Virus 2	Fresh	2 / 2	100.0	15.8–100.0	893 / 893	100.0	99.6–100.0
	Frozen	0 / 0	N/A	N/A	1089 / 1089	100.0	99.7–100.0
	Overall	2 / 2	100.0	15.8–100.0	1982 / 1982	100.0	99.8–100.0
Parainfluenza Virus 3 ***	Fresh	102 / 104	98.1	93.2–99.8	788 / 793	99.4	98.5–99.8
	Frozen	9 / 9	100.0	66.4–100.0	1081 / 1081	100.0	99.7–100.0
	Overall	111 / 113	98.2	93.8–99.8	1869 / 1874	99.7	99.4–99.9
Parainfluenza Virus 4 †††	Fresh	3 / 3	100.0	29.2–100.0	892 / 892	100.0	99.6–100.0
	Frozen	0 / 0	N/A	N/A	1087 / 1089	99.8	99.3–100.0
	Overall	3 / 3	100.0	29.2–100.0	1979 / 1981	99.9	99.6–100.0
Respiratory Syncytial Virus A+B‡‡‡	Fresh	73 / 76	96.1	88.9–99.2	819 / 820	99.9	99.3–100.0
	Frozen	139 / 144	96.5	92.1–98.9	941 / 945	99.6	98.9–99.9
	Overall	212 / 220	96.4	93.0–98.4	1760 / 1765	99.7	99.3–99.9

Table 21. QIAstat-Dx Respiratory Panel prospective clinical performance summary (continued)

		Positive Percent Agreement			Negative Percent Agreement		
Target	**Sample type**	**TP/ (TP+FN)**	**%**	**95 % CI (%)**	**TN/ (TN+FP)**	**%**	**95 % CI (%)**
Rhinovirus/ Enterovirus§§§	Fresh	144 / 157	91.7	86.3–95.5	715 / 739	96.8	95.2–97.9
	Frozen	124 / 137	90.5	84.3–94.9	941 / 953	98.7	97.8–99.3
	Overall	268 / 294	91.2	87.3–94.1	1656 / 1692	97.9	97.1–98.5
		Bacteria					
Bordetella pertussis¶¶¶	Fresh	2 / 2	100.0	15.8–100.0	893 / 893	100.0	99.6–100.0
	Frozen	1 / 1	100.0	2.5–100.0	1082 / 1088	99.4	98.8–99.8
	Overall	3 / 3	100.0	29.2–100.0	1975 / 1981	99.7	99.3–99.9
*Chlamydophila pneumoniae*****	Fresh	4 / 4	100.0	39.8–100.0	891 / 891	100.0	99.6–100.0
	Frozen	1 / 1	100.0	2.5–100.0	1087 / 1088	99.9	99.5–100.0
	Overall	5 / 5	100.0	47.8–100.0	1978 / 1979	99.9	99.7–100.0
Mycoplasma pneumoniae††††	Fresh	18 / 18	100.0	81.5–100.0	875 / 877	99.8	99.2–100.0
	Frozen	1 / 1	100.0	2.5–100.0	1085 / 1088	99.7	99.2–99.9

Table 21. QIAstat-Dx Respiratory Panel prospective clinical performance summary (continued)

		Positive Percent Agreement			Negative Percent Agreement		
Target	**Sample type**	**TP/ (TP+FN)**	**%**	**95 % CI (%)**	**TN/ (TN+FP)**	**%**	**95 % CI (%)**
	Overall	19 / 19	100.0	82.4–100.0	1960 / 1965	99.7	99.4–99.9

* Adenovirus was detected in 3/4 FN specimens using an independent molecular method. Adenovirus was detected in 6/16 FP specimens using an independent molecular method.

† The single FN specimen was negative for Coronavirus HKU1 when tested using an independent molecular method. Coronavirus HKU1 was detected 0/7 FP specimens using an independent molecular method.

‡ Coronavirus NL63 was detected in 7/7 FN specimens using an independent molecular method. Coronavirus NL63 was detected in 1/2 FP specimens using an independent molecular method.

§ The 3 FN specimens were negative for Coronavirus OC43 when tested using an independent molecular method. Coronavirus OC43 was detected in 3/4 FP specimens using an independent molecular method.

¶ Human metapneumovirus (hMPV) was detected in 4/7 FN specimens using an independent molecular method. hMPV was detected in 3/5 FP specimens using an independent molecular method.

** Influenza A H1 was detected in 1/1 FN specimen by an independent molecular method. Note: Non-2009 H1 has not been in circulation since being replaced by the 2009 H1 and thus this discrepancy test result is likely false.

†† Influenza A H1N1 pdm09 was detected in 1/1 FN by an independent molecular method. Influenza A H1 was detected in 3/5 FP specimens by an independent molecular method.

‡‡ Influenza A H3 was detected in 1/1 FN by an independent molecular method. Influenza H3 was detected in 7/7 FP specimens by an independent molecular method.

§§ Influenza B was detected in 6/6 FN specimens available for testing by an independent molecular method; one discordant sample was not tested by an independent molecular method. Influenza B was detected in 1/1 FP specimens available for testing by an independent molecular method.

¶¶ The single FN specimen was negative for Parainfluenza virus 1 by an independent molecular method. Parainfluenza virus 1 was detected in 3/3 FP specimens by an independent molecular method.

*** Parainfluenza virus 3 was detected in 1/2 FN specimens by an independent molecular method. Parainfluenza 3 was detected in 3/5 FP specimens by an independent molecular method.

††† Parainfluenza virus 4 was detected in 2/2 FP specimens by an independent molecular method.

‡‡‡ Respiratory Syncytial Virus was detected in 2/8 FN specimens by an independent molecular method. Respiratory Syncytial Virus was detected in 3/5 FP specimens by an independent molecular method.

§§§ Rhinovirus was detected in 18/26 FN specimens using an independent molecular method. Rhinovirus was detected in 14/36 FP specimens using an independent molecular method

¶¶¶ *Bordetella pertussis* was detected in 1/6 FP specimens by an independent molecular method.

**** *Chlamydophila pneumoniae* was detected in 1/1 FP specimens by an independent molecular method.

†††† *Mycoplasma pneumoniae* was detected in 1/4 specimens by an independent molecular method.

Co-infection summary for all targets excluding SARS-CoV-2

The QIAstat-Dx Respiratory Panel detected a total of 191 specimens with distinctive multiple organism detections (9.6% of all specimens) in the prospective study.

All distinct co-infection combinations, as detected by the QIAstat-Dx Respiratory Panel during prospective study, are presented in Table 22.

Table 22. Distinct co-infection combinations detected by QIAstat-Dx Respiratory Panel for all targets excluding SARS-CoV-2

Analyte 1	Analyte 2	Analyte 3	Analyte 4	Total co-infections	Number of discrepant co-infections	Discrepant analyte(s)
Adenovirus	Rhinovirus / Enterovirus	Coronavirus NL63		2	0	N/A
Adenovirus	Rhinovirus / Enterovirus			12	3	Rhinovirus/Enterovirus (1); Adenovirus (2)
Adenovirus	Respiratory Syncytial Virus			11	1	Respiratory Syncytial Virus (1)
Adenovirus	*Mycoplasma pneumoniae*			2	1	*Mycoplasma pneumoniae* (1)
Adenovirus	Coronavirus HKU1			3	1	Coronavirus HKU1 (1)
Coronavirus HKU1	Adenovirus	Respiratory Syncytial Virus		1	1	Coronavirus HKU1 (1)
Coronavirus HKU1	Human Meta-pneumovirus			3	1	Human Metapneumovirus (1)
Coronavirus HKU1	Parainfluenza Virus 3	Rhinovirus/ Enterovirus		1	0	N/A
Coronavirus HKU1	Parainfluenza Virus 4			1	1	Coronavirus HKU1, Parain-fluenza Virus 4 (1)
Coronavirus HKU1	Respirator Syncytial Virus			8	1	Coronavirus HKU1 (1)

Table 22. Distinct co-infection combinations detected by QIAstat-Dx Respiratory Panel for all targets excluding SARS-CoV-2 (continued)

Analyte 1	Analyte 2	Analyte 3	Analyte 4	Total co-infections	Number of discrepant co-infections	Discrepant analyte(s)
Coronavirus HKU1	Rhinovirus/ Enterovirus	Respiratory Syncytial Virus		1	0	N/A
Coronavirus HKU1	Rhinovirus/ Enterovirus			4	1	Rhinovirus/Enterovirus (1)
Coronavirus NL63	Adenovirus	Respiratory Syncytial Virus		1	0	N/A
Coronavirus NL63	Adenovirus			1	1	Adenovirus (1)
Coronavirus NL63	*Bordetella pertussis*			2	2	*Bordetella pertussis* (2)
Coronavirus NL63	Parainfluenza Virus 1			1	0	N/A
Coronavirus NL63	Respiratory Syncytial Virus			2	0	N/A
Coronavirus NL63	Rhinovirus / Enterovirus			2	0	N/A
Coronavirus OC43	Adenovirus			2	0	N/A
Coronavirus OC43	Human Meta-pneumovirus			2	0	N/A
Coronavirus OC43	Parainfluenza Virus 3	Rhinovirus/ Enterovirus		1	0	N/A
Coronavirus OC43	Respiratory Syncytial Virus			4	0	N/A
Coronavirus OC43	Rhinovirus / Enterovirus	Respiratory Syncytial Virus		2	0	N/A
Coronavirus OC43	Rhinovirus / Enterovirus			2	2	N/A
Coronavirus 229E	Respiratory Syncytial Virus			1	0	N/A

Table 22. Distinct co-infection combinations detected by QIAstat-Dx Respiratory Panel for all targets excluding SARS-CoV-2 (continued)

Analyte 1	Analyte 2	Analyte 3	Analyte 4	Total co-infections	Number of discrepant co-infections	Discrepant analyte(s)
Human Metapneumovirus	Adenovirus			2	1	Adenovirus (1)
Human Metapneumovirus	Respiratory Syncytial Virus			2	0	N/A
Human Metapneumovirus	Rhinovirus / Enterovirus			9	3	Rhinovirus/ Enterovirus (3)
Human Metapneumovirus	Rhinovirus / Enterovirus	Adenovirus	Coronavirus 229E	1	1	Adenovirus, Rhinovirus/Enterovirus (1)
Influenza A (no subtype)	Respiratory Syncytial Virus	Adenovirus		1	1	Influenza A, Adenovirus (1)
Influenza A (no subtype)	Respiratory Syncytial Virus			1	0	N/A
Influenza A H1N1 pdm09	Coronavirus NL63			1	0	N/A
Influenza A H1N1 pdm09	Coronavirus OC43	Adenovirus		1	1	Adenovirus (1)
Influenza A H1N1 pdm09	Rhinovirus / Enterovirus			2	0	N/A
Influenza A H1N1 pdm09	Rhinovirus / Enterovirus	*Bordetella pertussis*		1	0	N/A
Influenza A H1N1 pdm09	Respiratory Syncytial Virus			1	0	N/A
Influenza A H3	Adenovirus			2	1	Adenovirus (1)
Influenza A H3	Coronavirus NL63	Parainfluenza Virus 1		1	0	N/A
Influenza A H3	Coronavirus NL63	*Bordetella pertussis*		1	1	*Bordetella pertussis* (1)

Table 22. Distinct co-infection combinations detected by QIAstat-Dx Respiratory Panel for all targets excluding SARS-CoV-2 (continued)

Analyte 1	Analyte 2	Analyte 3	Analyte 4	Total co-infections	Number of discrepant co-infections	Discrepant analyte(s)
Influenza A H3	Coronavirus NL63			1	1	NL63 (1)
Influenza A H3	Coronavirus OC43	Adenovirus	Respiratory Syncytial Virus	1	1	Coronavirus OC43, Adenovirus (1)
Influenza A H3	Rhinovirus / Enterovirus			4	2	Rhinovirus/Enterovirus (2)
Influenza A H3	Parainfluenza Virus 1			2	0	N/A
Influenza A H3	Parainfluenza Virus 3			2	0	N/A
Influenza A H3	Respiratory Syncytial Virus			1	0	N/A
Influenza A H3	Coronavirus 229E			1	0	N/A
Influenza B	Coronavirus HKU1			3	0	N/A
Influenza B	Coronavirus NL63			1	0	N/A
Influenza B	Respiratory Syncytial Virus			2	0	N/A
Influenza B	Rhinovirus / Enterovirus			7	4	Rhinovirus/Enterovirus (4)
Mycoplasma pneumoniae	Coronavirus HKU1			1	1	Coronavirus HKU1 (1)
Mycoplasma pneumoniae	Rhinovirus / Enterovirus			1	0	N/A
Parainfluenza Virus 1	Adenovirus			1	0	N/A
Parainfluenza Virus 1	Respiratory Syncytial Virus			1	1	Parainfluenza Virus 1 (1)

Table 22. Distinct co-infection combinations detected by QIAstat-Dx Respiratory Panel for all targets excluding SARS-CoV-2 (continued)

Analyte 1	Analyte 2	Analyte 3	Analyte 4	Total co-infections	Number of discrepant co-infections	Discrepant analyte(s)
Parainfluenza Virus 1	Rhinovirus / Enterovirus			2	0	N/A
Parainfluenza Virus 1	Rhinovirus / Enterovirus	*Mycoplasma pneumoniae*		1	1	Rhinovirus/Enterovirus (1)
Parainfluenza Virus 3	Adenovirus			3	2	Adenovirus (2)
Parainfluenza Virus 3	Adenovirus	Rhinovirus/ Enterovirus		3	1	Parainfluenza virus 3 (1)
Parainfluenza Virus 3	Human Metapneumovirus			2	1	Human Metapneumovirus (1)
Parainfluenza Virus 3	Respiratory Syncytial Virus			2	1	Parainfluenza Virus 3 (1)
Parainfluenza Virus 3	Rhinovirus / Enterovirus			14	3	Rhinovirus/ Enterovirus (2), Parainfluenza Virus 3 (1)
Parainfluenza Virus 4	Respiratory Syncytial Virus			1	0	N/A
Parainfluenza Virus 4	Rhinovirus / Enterovirus			2	0	N/A
Respiratory Syncytial Virus	Human Metapneumovirus	Rhinovirus/ Enterovirus		1	0	N/A
Respiratory Syncytial Virus	Human Metapneumovirus	Rhinovirus/ Enterovirus		2	1	Human Metapneumovirus, Rhinovirus / Enterovirus (1)
Respiratory Syncytial Virus	Rhinovirus / Enterovirus			29	6	Rhinovirus/Enterovirus (5), Respiratory Syncytial Virus (1)
Rhinovirus/Enterovirus	Respiratory Syncytial Virus	Adenovirus		2	0	N/A

Table 22. Distinct co-infection combinations detected by QIAstat-Dx Respiratory Panel for all targets excluding SARS-CoV-2 (continued)

Analyte 1	Analyte 2	Analyte 3	Analyte 4	Total co-infections	Number of discrepant co-infections	Discrepant analyte(s)
Total co-infections				**191**	**51**	
Total double infections				**166**	**42**	
Total triple infections				**22**	**7**	
Total quadruple infections				**3**	**2**	

The three organisms most prevalent in multiple detections by the QIAstat-Dx Respiratory Panel in prospective study were Rhinovirus/Enterovirus (108/191, 56.5%), Respiratory Syncytial Virus (77/191, 40.8%), and Adenovirus (53/191, 27.7%). The prevalence of individual organisms in each multiple detection are shown in Table 23.

Table 23. The prevalence of individual organisms in each QIAstat-Dx Respiratory Panel multiple detection from the prospective study

Analyte	Prevalence in multiple detections (N=191)
Viruses	
Adenovirus	53 (27.7%)
Coronavirus 229E	3 (1.6%)
Coronavirus HKU1	26 (13.6%)
Coronavirus NL63	16 (8.4%)
Coronavirus OC43	15 (7.9%)
Human Metapneumovirus	24 (12.6%)
Rhinovirus/Enterovirus	108 (56.5%)
Influenza A H1	0 (0.0%)
Influenza A H1N1 pdm09	6 (3.1%)
Influenza A H3	16 (8.4%)
Influenza B	13 (6.8%)
Parainfluenza Virus 1	9 (4.7%)
Parainfluenza Virus 2	0 (0.0%)
Parainfluenza Virus 3	28 (14.7%)
Parainfluenza Virus 4	4 (2.1%)
Respiratory Syncytial Virus	78 (40.8%)
Bacteria	
Bordetella pertussis	4 (2.1%)
Chlamydophila pneumoniae	0 (0.0%)
Mycoplasma pneumoniae	5 (2.6%)

Additional distinct co-infection combinations detected by the comparator method but not detected by the QIAstat-Dx Respiratory Panel in the first prospective clinical trial are presented in Table 24.

Table 24. Additional distinct co-infection combinations detected by the comparator method but not by the QIAstat-Dx Respiratory Panel in the first prospective study

Distinct co-infection combinations detected by the comparator method

Analyte 1	Analyte 2	Analyte 3	Total Co-infections
Adenovirus	Coronavirus HKU1	Respiratory Syncytial Virus	1
Adenovirus	Coronavirus OC43	Coronavirus NL63	1
Adenovirus	Respiratory Syncytial Virus	Coronavirus NL63	1
Adenovirus	Rhinovirus/Enterovirus	Respiratory Syncytial Virus	1
Coronavirus HKU1	Coronavirus OC43		1
Coronavirus HKU1	Respiratory Syncytial Virus		1
Coronavirus HKU1	Coronavirus NL63	Respiratory Syncytial Virus	1
Coronavirus HKU1	Coronavirus NL63		1
Coronavirus HKU1	Parainfluenza Virus 1	Rhinovirus/Enterovirus	1
Coronavirus NL63	Respiratory Syncytial Virus		1
Coronavirus NL63	Rhinovirus/Enterovirus		1
Coronavirus NL63	Influenza A H3		1
Coronavirus OC43	Respiratory Syncytial Virus		1
Human Metapneumovirus	Parainfluenza virus 3	Rhinovirus/Enterovirus	1
Human Metapneumovirus	Rhinovirus/Enterovirus		1
Rhinovirus/Enterovirus	Adenovirus		1
Rhinovirus/Enterovirus	Influenza A H3		2
Rhinovirus/Enterovirus	Parainfluenza Virus 3		1

Table 24. Additional distinct co-infection combinations detected by the comparator method but not by the QIAstat-Dx Respiratory Panel in the first prospective study (continued)

Distinct co-infection combinations detected by the comparator method

Analyte 1	Analyte 2	Analyte 3	Total Co-infections
Rhinovirus/Enterovirus	Parainfluenza Virus 3	Respiratory Syncytial Virus	1
Rhinovirus/Enterovirus	Parainfluenza Virus 4		2
Influenza A H3	Respiratory Syncytial Virus		1
Influenza B	Influenza A (Equivocal)		1
		Total co-infections	**24**
		Total double infections	**16**
		Total triple infections	**8**

A total of 1994 prospective clinical specimens were tested and analyzed during the first prospective clinical evaluation. Of these, 95.9% (1912/1994) yielded valid results on the first attempt (i.e., first loaded cartridge). Invalid or no result were obtained for the remaining 82 specimens (4.11%). Forty-two (42) specimens were invalid due to cartridge Internal Control failure (2.11%). Of these, 20 (1.00%) provided a result for positively detected targets and 22 (1.10%) had no detections. For 40 (2.00%) specimens, no results were obtained due to incomplete runs. Of these, 1 specimen was aborted by users (0.05%), 21 were due to instrument errors (1.05%) and 18 were due to cartridge-related errors (0.90%). Seventy-two (72) of the 82 initially failed (no result or invalid) specimens yielded valid results after a single retesting using a new cartridge/sample. The remaining 10 specimens failed on the second attempt (2 due to cartridge failures, 1 due to instrument errors and 7 due to Internal Control failures). Of these Internal Control failures, detected pathogens were reported for 4 specimens.

Preselected archived specimens

Some of the analytes on the QIAstat-Dx Respiratory Panel were of low prevalence and were not encountered in sufficiently large numbers during the first prospective study to adequately demonstrate clinical performance. To supplement the results of the first prospective clinical study, an evaluation of preselected frozen archived retrospective specimens was performed. The specimens selected for testing had previously tested positive for one of the following targets at the clinical laboratory by their standard of care method: *Bordetella pertussis*, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Influenza A H1N1 2009, *Mycoplasma pneumoniae*, *Chlamydophila pneumoniae*, Parainfluenza Virus 1, Parainfluenza Virus 2, and Parainfluenza Virus 4. Testing was performed by operators who were blinded to the expected test result. A total of 310 clinical samples were included within the frozen archived retrospective sample tested arm. Samples were tested by both the comparator method and the QIAstat-Dx Respiratory Panel. If the comparator method did not confirm the preselected target as positive, it was excluded from the data analysis for that target.

A summary of the demographic information available for the archived specimens is provided in Table 25.

Table 25. Demographic summary for the retrospective study arm

		Overall (%)
SEX	Male	158 (50.8%)
	Female	152 (49.2%)
AGE	≤5 years	139 (44.9%)
	6–21 years	85 (27.4%)
	22–49 years	53 (17.1%)
	50+ years	33 (10.7%)
STATUS	Outpatient	224 (72.3%)
	Hospitalized	68 (21.9%)
	Emergency	8 (2.6%)
	ICU	8 (2.6%)
	Other	2 (0.6%)
	Total	**310**

The QIAstat-Dx Respiratory Panel retrospective specimens testing performance data against the comparator method are provided in Table 26 by analyte.

Table 26. Overall retrospective clinical study performance

Analyte	TP/(TP+FN)	Sensitivity/PPA	95% CI	TN/(TN+FP)	Specificity/NPA	95% CI
Viruses						
Adenovirus*	9/9	100.0%	70.1–100.0	297/304	97.8%	95.4–98.9
Coronavirus 229E	26/27	96.3%	81.7–99.3	286/286	100.0%	98.7–100.0
Coronavirus HKU1‡	14/14	100.0%	78.5–100.0	298/299	99.7%	98.1–99.9

Table 26. Overall retrospective clinical study performance (continued)

Analyte	TP/(TP+FN)	Sensitivity/PPA	95% CI	TN/(TN+FP)	Specificity/NPA	95% CI
Coronavirus NL63‡	24/24	100.0%	86.2–100.0	286/288	99.3%	97.5–99.8
Coronavirus OC43	28/29	96.6%	82.8–99.4	279/279	100.0%	98.6–100.0
Human Metapneumovirus	2/2	100.0%	34.2–100.0	311/311	100.0%	98.7–100.0
Rhinovirus/ Enterovirus§	44/49	89.8%	78.2–95.5	254/264	96.2%	93.2–97.9
Influenza A	17/17	100.0%	81.5–100.0	296/296	100.0%	98.7–100.0
Influenza A H1	0/0	N/A	N/A	313/313	100.0%	98.8–100.0
Influenza A H1N1 pdm09¶	7/8	87.5%	52.9–97.8	304/304	100.0%	98.8–100.0
Influenza A H3	8/8	100.0%	67.5–100.0	305/305	100.0%	98.8–100.0
Influenza B	1/1	100.0%	20.7–100.0	312/312	100.0%	98.8–100.0
Parainfluenza Virus 1	40/40	100.0%	91.2–100.0	267/267	100.0%	98.6–100.0
Parainfluenza Virus 2	3/3	100.0%	43.8–100.0	309/309	100.0%	98.8–100.0
Parainfluenza Virus 3**	1/4	25.0%	4.6–69.9	309/309	100.0%	98.8–100.0
Parainfluenza Virus 4††	22/24	91.7%	74.2–97.7	278/278	100.0%	98.6–100.0
Respiratory Syncytial Virus (RSV)‡‡	11/12	91.7%	64.6–98.5	300/301	99.7%	98.4–99.9

Table 26. Overall retrospective clinical study performance (continued)

Analyte	TP/(TP+FN)	Sensitivity/PPA	95% CI	TN/(TN+FP)	Specificity/NPA	95% CI
Bacteria						
Bordetella pertussis	33/33	100.0%	89.6–100.0	261/261	100.0%	98.5–100.0
Chlamydophila pneumoniae§§	54/61	88.5%	78.2–94.3	250/250	100.0%	98.5–100.0
Mycoplasma pneumoniae	25/25	100.0%	86.7–100.0	287/288	99.7%	98.1–99.9

* Adenovirus was detected in 3/5 FP specimens using an independent molecular method. 2 FP did not undergo discordant analysis.

† The single FP Coronavirus HKU1 specimen was negative when tested using an independent molecular method.

‡ The single FP Coronavirus NL63 specimen was negative when tested using an independent molecular method.

§ Rhinovirus was detected in 1/2 FN when tested using an independent molecular method. Rhinovirus was detected in 4/10 FP specimens using an independent molecular method.

¶ Influenza H1N1 pdm09 was detected in the single FN specimen.

** Parainfluenza Virus 3 was detected in 1/3 FN specimens by an independent molecular method.

†† Parainfluenza Virus 4 was detected in 1/2 FN specimens by an independent molecular method.

‡‡The single FN Respiratory Syncytial Virus was negative for that target by an independent molecular method. The single FP Respiratory Syncytial Virus was negative for that target by an independent molecular method.

§§ *Chlamydophila pneumoniae* was detected in 4/5 FN specimens by an independent molecular method.

Testing of contrived specimens

Influenza A H1, Parainfluenza Virus 2, Parainfluenza Virus 4, Coronavirus 229E and *Chlamydophila pneumoniae*, despite all prospective and retrospective testing efforts, were insufficient to demonstrate system performance. Therefore, contrived specimens were used as surrogate clinical specimens to supplement and test the sensitivity and specificity of the above analytes. Residual negative clinical specimens were spiked with the pathogens at 3x, 5x, and 10x LoD levels (50 of each).

Contrived samples were provided a unique study identification number and the individual who contrived the samples did not test them therefore the status of each contrived specimen was unknown at the time of testing. Results of contrived specimen testing are provided in Table 27.

Table 27. Contrived specimen results

		Positive Predictive Agreement		
	x LoD	**TP/(TP + FN)**	**%**	**95% CI**
Influenza A H1*	3	24/24	100%	86.2–100
	5	27/27	100%	87.5–100
	10	24/24	100%	86.2–100
Coronavirus 229E	3	16/16	100%	80.6–100
	5	18/18	100%	82.4–100
	10	16/16	100%	80.6–100
Parainfluenza Virus 2	3	16/16	100%	80.6–100
	5	18/18	100%	82.4–100
	10	16/16	100%	80.6–100
Parainfluenza Virus 4	3	15/16	93.8%	71.7–98.9
	5	18/18	100%	82.4–100
	10	16/16	100%	80.6–100
Chlamydophila pneumoniae	3	16/16	100%	80.6–100
	5	18/18	100%	82.4–100
	10	16/16	100%	80.6–100

* One Influenza A H1 strain [VR-897] was initially spiked incorrectly, yielding unexpected results across all LoD concentrations [3x LoD = 4/8 (50%), 5x LoD = 2/9 (22.2%) and 10x LoD = 6/8 (75.0%). A replacement strain [0810244CFHI] was sent to the testing site for spiking and strain VR-897 was also repeated to confirm that the issue was isolated to a procedural error and not an instrument failure.

Expected values for all targets excluding SARS-CoV-2

A total of 1994 eligible prospective nasopharyngeal swab (NPS) specimens were collected and tested at five (5) sites across the US (4) and Europe (1) from December 2017 through June 2018. The number and percentage of positive cases, as determined by the QIAstat-Dx Respiratory Panel, calculated by testing site or by age group are presented in Table 28, Table 29, and Table 30.

Table 28. Expected value (EV) (as determined by the QIAstat Dx Respiratory Panel) summary overall and by site for all targets excluding SARS-CoV-2 (N = number)

	Overall (n=1994)		Site 1 (n=418)		Site 2 (n=426)		Site 3 (n=448)		Site 4 (n=303)		Site 5 (n=399)	
Organism	**N**	**EV**	**N**	**EV**	**N**	**EV**	**N**	**EV**	**N**	**EV**	**N**	**EV**
Viruses												
Adenovirus	102	5.1%	44	10.5%	9	2.1%	12	2.7%	30	9.9%	7	1.8%
Coronavirus 229E	8	0.4%	1	0.2%	0	0.0%	0	0.0%	7	2.3%	0	0.0%
Coronavirus HKU1	58	2.9%	4	1.0%	11	2.6%	14	3.1%	12	4.0%	17	4.3%
Coronavirus NL63	42	2.1%	4	1.0%	1	0.2%	15	3.3%	11	3.6%	11	2.8%
Coronavirus OC43	30	1.5%	0	0.0%	5	1.2%	6	1.3%	12	4.0%	7	1.8%
Human Metapneumovirus	120	6.0%	42	10.0%	24	5.6%	14	3.1%	14	4.6%	26	6.5%
Human Rhinovirus/Enterovirus	304	15.2%	59	14.1%	78	18.3%	39	8.7%	53	17.5%	75	18.8%
Influenza A	251	12.6%	120	28.7%	0	0.0%	58	12.9%	38	12.5%	35	8.8%
Influenza A H1	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Influenza A H1N1 pdm 2009	85	4.3%	67	16.0%	0	0.0%	4	0.9%	10	3.3%	4	1.0%
Influenza H3	163	8.2%	52	12.4%	0	0.0%	52	11.6%	28	9.2%	31	7.8%

Table 28. Expected value (EV) (as determined by the QIAstat Dx Respiratory Panel) summary overall and by site for all targets excluding SARS-CoV-2 (N = number) (continued)

	Overall (n=1994)		Site 1 (n=418)		Site 2 (n=426)		Site 3 (n=448)		Site 4 (n=303)		Site 5 (n=399)	
Influenza B	123	6.2%	58	13.9%	0	0.0%	32	7.1%	7	2.3%	26	6.5%
Parainfluenza Virus 1	19	1.0%	2	0.5%	1	0.2%	2	0.4%	4	1.3%	10	2.5%
Parainfluenza Virus 2	2	0.1%	2	0.5%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Parainfluenza Virus 3	116	5.8%	23	5.5%	19	4.5%	16	3.6%	23	7.6%	35	8.8%
Parainfluenza Virus 4	5	0.3%	1	0.2%	0	0.0%	1	0.2%	0	0.0%	3	0.8%
Respiratory Syncytial Virus	217	10.9%	64	15.3%	40	9.4%	35	7.8%	40	13.2%	38	9.5%
Bacteria												
Bordetella pertussis	9	0.5%	2	0.5%	1	0.2%	0	0.0%	6	2.0%	0	0.0%
Chlamydophila pneumoniae	6	0.3%	2	0.5%	1	0.2%	1	0.2%	1	0.3%	1	0.3%
Mycoplasma pneumoniae	24	1.2%	19	4.5%	0	0.0%	2	0.4%	1	0.3%	2	0.5%

Table 29. Expected value (EV) (as determined by the QIAstat-Dx Respiratory Panel) summary by age category for the prospective clinical evaluation (N = number)

	Overall		≤5 years (n=627)		6–21 years (n=239)		22–49 years (n=330)		>49 years (n=798)	
	N	EV	N	EV	N	EV	N	EV	N	EV
Viruses										
Adenovirus	102	5.1%	78	12.4%	7	2.9%	11	3.3%	6	0.8%
Coronavirus 229E	8	0.4%	4	0.6%	4	1.7%	0	0.0%	0	0.0%

Table 29. Expected value (EV) (as determined by the QIAstat-Dx Respiratory Panel) summary by age category for the prospective clinical evaluation (N = number) (continued)

	Overall		≤5 years (n=627)		6–21 years (n=239)		22–49 years (n=330)		>49 years (n=798)	
	N	EV	N	EV	N	EV	N	EV	N	EV
Coronavirus HKU1	58	2.9%	29	4.6%	5	2.1%	8	2.4%	16	2.0%
Coronavirus NL63	42	2.1%	25	4.0%	3	1.3%	5	1.5%	9	1.1%
Coronavirus OC43	30	1.5%	20	3.2%	2	0.8%	4	1.2%	4	0.5%
Human Metapneumovirus	120	6.0%	46	7.3%	3	1.3%	17	5.2%	54	6.8%
Human Rhinovirus/Enterovirus	304	15.2%	186	29.7%	35	14.6%	22	6.7%	61	7.6%
Influenza A	251	12.6%	47	7.5%	36	15.1%	64	19.4%	104	13.0%
Influenza A H1	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Influenza A H1N1 pdm 2009	85	4.3%	20	3.2%	6	2.5%	30	9.1%	29	3.6%
Influenza H3	163	8.2%	25	4.0%	30	12.6%	35	10.6%	73	9.1%
Influenza B	123	6.2%	11	1.8%	22	9.2%	27	8.2%	63	7.9%
Parainfluenza virus 1	19	1.0%	11	1.8%	0	0.0%	4	1.2%	4	0.5%
Parainfluenza virus 2	2	0.1%	1	0.2%	0	0.0%	0	0.0%	1	0.1%
Parainfluenza virus 3	116	5.8%	70	11.2%	4	1.7%	6	1.8%	36	4.5%
Parainfluenza virus 4	5	0.3%	4	0.6%	0	0.0%	0	0.0%	1	0.1%
Respiratory Syncytial Virus	217	10.9%	135	21.5%	11	4.6%	17	5.2%	54	6.8%
Bacteria										
Bordetella pertussis	9	0.5%	5	0.8%	2	0.8%	0	0.0%	2	0.3%

Table 29. Expected value (EV) (as determined by the QIAstat-Dx Respiratory Panel) summary by age category for the prospective clinical evaluation (N = number) (continued)

	Overall		≤5 years (n=627)		6–21 years (n=239)		22–49 years (n=330)		>49 years (n=798)	
	N	EV	N	EV	N	EV	N	EV	N	EV
Chlamydophila pneumoniae	6	0.3%	1	0.2%	3	1.3%	2	0.6%	0	0.0%
Mycoplasma pneumoniae	24	1.2%	4	0.6%	6	2.5%	11	3.3%	3	0.4%

The number and percentage of co-infection cases, as determined by the QIAstat-Dx Respiratory Panel, calculated by age group are presented in Table 30 below.

Table 30. Expected value (co-infections as determined by the QIAstat-Dx Respiratory Panel for all targets excluding SARS-CoV-2) summary by age group

Co-infection	Number (expected value) overall (n=191)	<6 years (n=151)	6–21 years (n=12)	22–49 years (n=14)	>49 years (n=14)
AdV + HRV/EV + CoV NL63	2 (1.05%)	2	0	0	0
AdV + HRV/EV	12 (6.28%)	9	2	1	0
AdV + RSV	11 (5.82%)	11	0	0	0
AdV + *M. pneumoniae*	2 (1.05%)	1	1	0	0
AdV + CoV HKU1	3 (1.57%)	3	0	0	0
CoV HKU1+ AdV+ RSV	1 (0.52%)	1	0	0	0
CoV HKU1 + HMPV	3 (1.57%)	3	0	0	0
CoV HKU1 + PIV 3 + HRV/EV	1 (0.52%)	1	0	0	0
CoV HKU1 + PIV 4	1 (0.52%)	1	0	0	0
CoV HKU1 + RSV	8 (4.28%)	5	1	1	1
CoV HKU1 + HRV/EV + RSV	1 (0.52%)	1	0	0	0

Table 30. Expected value (co-infections as determined by the QIAstat-Dx Respiratory Panel for all targets excluding SARS-CoV-2) summary by age group (continued)

Co-infection	Number (expected value) overall (n=191)	<6 years (n=151)	6–21 years (n=12)	22–49 years (n=14)	>49 years (n=14)
CoV HKU1 + HRV/EV	4 (2.09%)	2	0	0	2
CoV NL63 + AdV+ RSV	1 (0.52%)	1	0	0	0
CoV NL63 + AdV	1 (0.52%)	1	0	0	0
CoV NL63 + *B. pertussis*	2 (1.05%)	1	1	0	0
CoV NL63 + PIV 1	1 (0.52%)	0	0	1	0
CoV NL63 + RSV	2 (1.05%)	2	0	0	0
CoV NL63 + HRV/EV	2 (1.05%)	2	0	0	0
CoV OC43 + AdV	2 (1.05%)	2	0	0	0
CoV OC43 + HMPV	2 (1.05%)	2	0	0	0
CoV OC43 + PIV 3 + HRV/EV	1 (0.52%)	1	0	0	0
CoV OC43 + RSV	4 (2.09%)	3	1	0	0
CoV OC43 + HRV/EV + RSV	2 (1.05%)	2	0	0	0
CoV OC43 + HRV/EV	2 (1.05%)	1	1	0	0
CoV 229E + RSV	1 (0.52%)	1	0	0	0
HMPV + AdV	2 (1.05%)	1	0	1	0
HMPV + RSV	2 (1.05%)	1	0	0	1
HMPV + HRV/EV + AdV + CoV 229E	1 (0.52%)	1	0	0	0
Influenza A (no subtype) + RSV + AdV	1 (0.52%)	1	0	0	0
Influenza A (no subtype) + RSV	1 (0.52%)	1	0	0	0

Table 30. Expected value (co-infections as determined by the QIAstat-Dx Respiratory Panel for all targets excluding SARS-CoV-2) summary by age group (continued)

Co-infection	Number (expected value) overall (n=191)	<6 years (n=151)	6–21 years (n=12)	22–49 years (n=14)	>49 years (n=14)
Influenza A H1N1 pdm09 + CoV NL63	1 (0.52%)	0	0	1	0
Influenza A H1N1 pdm09 + CoV OC43 + AdV	1 (0.52%)	1	0	0	0
Influenza A H1N1 pdm09 + HRV/EV	2 (1.05%)	1	1	0	0
Influenza A H1N1 pdm09 + HRV/EV + *B. pertussis*	1 (0.52%)	1	0	0	0
Influenza A H1N1 pdm09 + RSV	1 (0.52%)	1	0	0	0
Influenza A H3 + AdV	2 (1.05%)	0	0	1	1
Influenza A H3 + CoV NL63 + PIV 1	1 (0.52%)	1	0	0	0
Influenza A H3 + CoV NL63 + *B. pertussis*	1 (0.52%)	1	0	0	0
Influenza A H3 + CoV NL63	1 (0.52%)	0	0	0	1
Influenza A H3 + CoV OC43 + AdV + RSV	1 (0.52%)	1	0	0	0
Influenza A H3 + HRV/EV	4 (2.09%)	2	0	1	1
Influenza A H3 + PIV 1	2 (1.05%)	2	0	0	0
Influenza A H3 + PIV 3	2 (1.05%)	1	0	0	1
Influenza A H3 + RSV	1 (0.52%)	0	0	1	0
Influenza A H3 + CoV 229E	1 (0.52%)	0	1	0	0
Influenza B + CoV HKU1	3 (1.57%)	1	0	0	2

Table 30. Expected value (co-infections as determined by the QIAstat-Dx Respiratory Panel for all targets excluding SARS-CoV-2) summary by age group (continued)

Co-infection	Number (expected value) overall (n=191)	<6 years (n=151)	6–21 years (n=12)	22–49 years (n=14)	>49 years (n=14)
Influenza B + CoV NL63	1 (0.52%)	0	1	0	0
Influenza B + HRV/EV	7 (3.67%)	4	1	1	1
M. pneumoniae + CoV HKU1	1 (0.52%)	0	1	0	0
M. pneumoniae + HRV/EV	1 (0.52%)	0	0	1	0
PIV 1 + AdV	1 (0.52%)	1	0	0	0
PIV 1 + RSV	1 (0.52%)	1	0	0	0
PIV 1 + HRV/EV	2 (1.05%)	2	0	0	0
PIV 1 + HRV/EV + *M. pneumoniae*	1 (0.52%)	1	0	0	0
PIV 3 + AdV	3 (1.57%)	3	0	0	0
PIV 3 + AdV + HRV/EV	3 (1.57%)	3	0	0	0
PIV 3 + HMPV	2 (1.05%)	2	0	0	0
PIV 3 + RSV	2 (1.05%)	2	0	0	0
PIV 3 + HRV/EV	14 (7.33%)	14	0	0	0
PIV 4 + RSV	1 (0.52%)	1	0	0	0
PIV 4 + HRV/EV	2 (1.05%)	2	0	0	0
RSV + HMPV + HRV/EV + AdV	1 (0.52%)	1	0	0	0
RSV + HMPV + HRV/EV	2 (1.05%)	1	0	0	1
RSV + HRV/EV	29 (15.18%)	26	0	2	1
HRV/EV + RSV + AdV	2 (1.05%)	2	0	0	0

Clinical performance of QIAstat-Dx Respiratory Panel Plus SARS-CoV-2 assay

The clinical performance of the SARS-CoV-2 assay in the QIAstat-Dx Respiratory Panel Plus was established through a multi-center prospective (i.e., all comers) clinical study conducted at five (5) geographically diverse study sites in the US. Nasopharyngeal swab (NPS) specimens in UTM were prospectively collected from individuals with signs and symptoms of respiratory infection, between February and May 2023, and February 21–26, 2024.

The clinical performance of the SARS-CoV-2 assay in the QIAstat-Dx Respiratory Panel Plus was established by comparing results to an FDA-cleared molecular respiratory panel that includes SARS-CoV-2 and was cleared under 21 CFR 866.3981. A total of 616 prospective NPS specimens were enrolled and tested in this clinical study. One specimen was excluded due to failure to meet the inclusion criteria. Overall, 615 evaluable specimens were included in the analysis.

Table 31a–Table 31d provides the summary of demographic information for the 615 subjects that participated in the study.

Table 31a. Demographic summary for the SARS-CoV-2 prospective study (sex)

	Total	
Sex	**N**	**Percentage (%)**
Female	391	63.58
Male	224	36.42
All	**615**	**100.00**

Table 31b. Demographic summary for the SARS-CoV-2 prospective study (age group)

	Total	
Age group	**N**	**Percentage (%)**
<5	23	3.74
5–9	23	3.74
10–13	4	0.65
14–18	31	5.04
19–29	208	33.82
30–49	206	33.50
50–69	102	16.59
70–85	18	2.93
All	**615**	**100.0**

Table 31c. Demographic summary for the SARS-CoV-2 study (race)

Race	Total	
	N	**Percentage (%)**
American Indian or Alaskan Native	2	0.33
American Indian or Alaskan Native, Other	1	0.16
Asian	19	3.09
Asian, White	3	0.49
Black or African American	56	9.11
Black or African American, Native Hawaiian or Other Pacific Islander, White	1	0.16
Black or African American, White	1	0.16

Table 31c. Demographic summary for the SARS-CoV-2 study (race) (continued)

Race	Total	
	N	Percentage (%)
Native Hawaiian or Other Pacific Islander	1	0.16
Native Hawaiian or Other Pacific Islander, White	1	0.16
Not Reported	85	13.82
Other	51	8.29
White	391	63.58
White, Other	3	0.49
All	**615**	**100.00**

Table 31d. Demographic summary for the SARS-CoV-2 study (SARS-CoV-2 vaccination status)

SARS-CoV-2 Vaccination Status	Total	
	N	Percentage (%)
Not vaccinated	132	21.46
Prefer not to say/No information	69	11.22
Vaccinated	414	67.32
All	**615**	**100.00**

The overall performance of the QIAstat-Dx Respiratory Panel Plus SARS-CoV-2 assay only is shown in Table 32.

Table 32. QIAstat-Dx Respiratory Panel Plus prospective clinical performance summary for SARS-CoV-2 target only

		Positive percent agreement			Negative percent agreement		
Target	**Sample Type**	**TP/(TP+FN)**	**%**	**95% CI**	**TN/(TN+FP)**	**%**	**95% CI**
SARS-CoV-2	Fresh	61 / 63*	96.8	89.0-99.6	551 / 552†	99.8	99.0–100.0

TP-True Positive, FP-False Positive, TN-True Negative, FN-False Negative

*The two samples with false negative SARS-CoV-2 results by the QIAstat-Dx Respiratory Panel Plus were both positive by two FDA-EUA molecular SARS-CoV-2 assays.

† The single sample with a false positive SARS-CoV-2 result by the QIAstat-Dx Respiratory Panel Plus was positive by two FDA-EUA molecular SARS-CoV-2 assays. The PPA for SARS-CoV-2 is 96.8% with a two-sided 95% CI of 89.0–99.6%. The NPA for SARS-CoV-2 is 99.8% with a two-sided 95% CI of 99.0–100%.

Co-infection summary for SARS-CoV-2

The QIAstat-Dx Respiratory Panel Plus detected two SARS-CoV-2 positive specimens with distinctive multiple organism detection. The distinct co-infection combinations are presented in Table 33.

Both results were true positive based on the comparator result.

Table 33. Listing of SARS-CoV-2 positive specimens with co-infections based on the QIAstat-Dx Respiratory Panel Plus results from prospective studies

Number of Positive Pathogens Detected	Pathogens Detected	
2	Rhinovirus/Enterovirus	SARS-CoV-2
2	Human Metapneumovirus A+B	SARS-CoV-2

During the QIAstat-Dx Respiratory Panel Plus clinical evaluation a total of 615 prospective clinical specimens were tested. Of these, 98.9% (608/615) yielded valid results on the first attempt (i.e., first loaded cartridge). Of the remaining 7, 5 had invalid results and 2 had

positive with warning results. Testing was repeated for the subjects with invalid or positive with warning results and in all cases a valid result was obtained on re-testing.

Expected values

The number and percentage of positive SARS-CoV-2 cases, as determined by the QIAstat-Dx Respiratory Panel Plus, calculated by age group are presented in Table 34 and Table 35.

Table 34. Summary of Expected values of SARS-CoV-2 by site based on the QIAstat-Dx Respiratory Panel Plus result excluding cartridge failures and positive with warning results

	Overall (n=615)		Site 1 (n=183)		Site 2 (n=33)		Site 3 (n=179)		Site 4 (n=170)		Site 5 (n=50)	
Pathogen	N Positive	% Positive	N Positive	% Positive	N Positive	% Positive	N Positive	% Positive	N Positive	% Positive	N Positive	% Positive
SARS-CoV-2	62	10.8	17	9.3	0	0.0	25	14.0	18	10.6	2	4

Table 35. Summary of expected values of SARS-CoV-2 by age groups based on the QIAstat-Dx Respiratory Panel Plus result

	Overall (n=615)		2-21 yrs. (n=108)		22-49 yrs. (n=387)		>49 yrs. (n=120)	
Analyte	N Positive	% Positive	N Positive	% Positive	N Positive	% Positive	N Positive	% Positive
SARS-CoV-2	62	10.1	2	1.8	36	9.3	24	20.0

Disposal

Dispose of QIAstat-Dx Respiratory Panel Plus 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 "Safety Information" on page 16.

Follow recommendations in the Safety Data Sheet (SDS).

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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, or QIAstat-Dx Rise, please refer to the corresponding User Manuals which are also available at **www.qiagen.com**.

Symbols

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

Symbol	Symbol Definition
 <N>	Contains reagents sufficient for <N> reactions
	Use by
IVD	*In vitro* diagnostic medical device
REF	Catalog number
LOT	Lot number
MAT	Material number (i.e., component labeling)
COMP	Components
CONT	Contains
NUM	Number
GTIN	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
℞ Only	Prescription Use Only

Symbol	Symbol Definition
	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**).

Appendices

Appendix A: Installing the Assay Definition File

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

Assay Definition Files for use on QIAstat-Dx Rise can only be uploaded/installed by a QIAGEN field service engineer. QIAGEN service will inform you whenever there is a new ADF version available.

Note: Whenever a new version of the QIAstat-Dx Respiratory Panel Plus assay is released, the new QIAstat-Dx Respiratory Panel Plus 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 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 72).

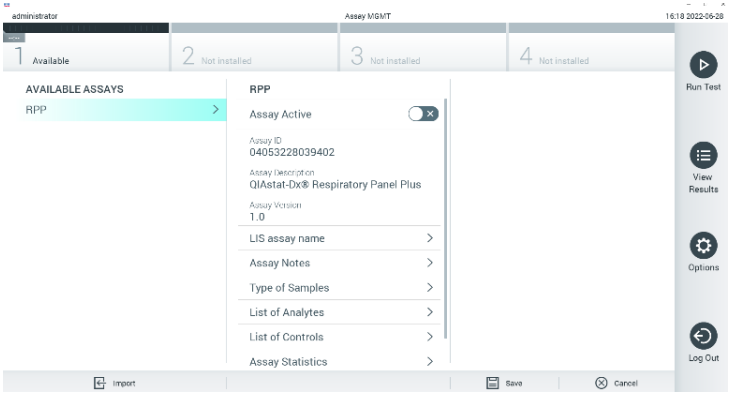

Figure 72. Assay Management screen.

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 73).

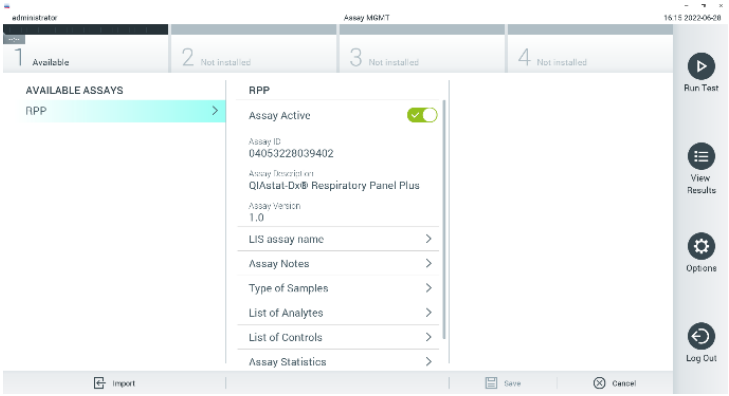

Figure 73. Activating the assay.

Appendix B: Glossary

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

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

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 QIAstat-Dx Analyzer 1.0. 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 Analyzer 2.0: The QIAstat-Dx Analyzer 2.0 consists of an Operational Module PRO and Analytical Module. The Operational Module PRO includes elements that provide connectivity to the Analytical Module and enables user interaction with QIAstat-Dx Analyzer 2.0. The Analytical Module contains the hardware and software for sample testing and analysis.

QIAstat-Dx Respiratory Panel Plus 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 Panel Plus Cartridge, inlet for transport medium liquid samples.

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

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

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

PCR: Polymerase Chain Reaction.

RT: Reverse Transcription.

Swab port: In the QIAstat-Dx Respiratory Panel Plus Cartridge, inlet for dry swabs. The swab port is not used for the QIAstat-Dx Respiratory Panel Plus.

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

Ordering Information

Product	Contents	Cat. no.
QIAstat-Dx Respiratory Panel Plus	For 6 tests: 6 individually packaged QIAstat-Dx Respiratory Panel Plus cartridges and 6 individually packaged transfer pipettes	691224
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, June 2024	Initial release
R2, July 2024	Inclusion of QIAstat-Dx Analyzer 2.0 Updated screenshots in Interpretation of Results to change "rhinovirus" to "human rhinovirus"
R3, August 2025	Inclusion of QIAstat-Dx Rise as an additional instrument to use with the cartridge.

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