February 2020

QIAstat-Dx® Respiratory 2019-nCoV Panel Instructions for Use (Handbook)

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For Research Use Only.
For use with QIAstat-Dx Analyzer 1.0

REF   691212

🏭   QIAGEN GmbH, QIAGEN Strasse 1, D-40724 Hilden

R1

Version 1

Sample to Insight

QIAGEN

Contents

Intended Use

The QIAstat-Dx Respiratory 2019-nCoV Panel is for research use only to detect viral or bacterial nucleic acids from nasopharyngeal swab (NPS) samples by real-time PCR (RT-PCR).

The following pathogens can be detected and differentiated* with the QIAstat-Dx Respiratory 2019-nCoV Panel: Influenza A, Influenza A subtype H1N1/2009, Influenza A subtype H1, Influenza A subtype H3, Influenza B, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Respiratory Syncytial virus A/B, human Metapneumovirus A/B, Adenovirus, Bocavirus, Rhinovirus/Enterovirus, *Mycoplasma pneumoniae*, *Legionella pneumophila*, *Bordetella pertussis*, and 2019-nCoV (SARS-CoV-2).

The assay is designed for use with the QIAstat-Dx Analyzer 1.0 for integrated nucleic acid extraction and multiplex real-time RT-PCR detection.

Summary and Explanation

QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge description

The QIAstat-Dx Respiratory 2019-nCoV Panel cartridge is a disposable plastic device that allows performance of fully automated molecular assays for the detection of respiratory pathogens. Main features of the QIAstat-Dx Respiratory Panel 2019-nCoV Cartridge include compatibility with the respiratory dry swabs (Copan® FLOQSwabs®, cat. no. 503CS01) and transport medium liquid samples and hermetic 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 2019-nCoV Panel Cartridge. The user does not need to come in

* Enterovirus and Rhinovirus are both detected but not differentiated with the QIAstat-Dx Respiratory 2019-nCoV Panel.

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 by pneumatically-operated microfluidics and make no direct contact with the actuators. The QIAstat-Dx Analyzer 1.0 houses air filters for both incoming and outgoing air, further safeguarding the environment. After testing, the cartridge stays hermetically closed at all times, greatly enhancing its safe disposal.

Within the cartridge, multiple steps are automatically performed in sequence using pneumatic pressure to transfer samples and fluids via the transfer chamber to their intended destinations.

After the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge containing the sample is introduced into the QIAstat-Dx Analyzer 1.0, the following assay steps occur automatically:

- Resuspension of the 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.
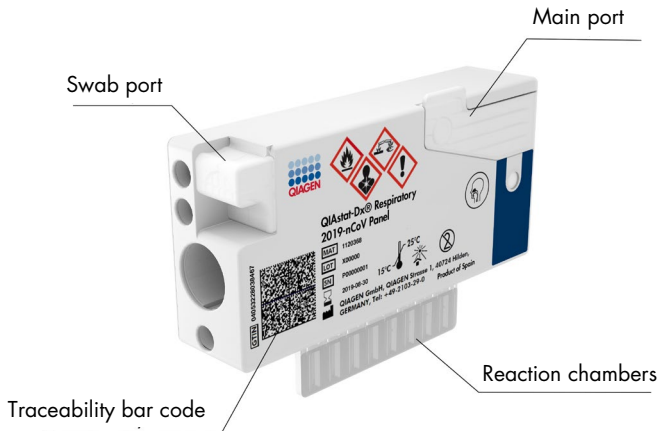
Figure 1. Layout of the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge and its features.

Pathogen Information

The QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge is a single-use cartridge that includes all reagents needed for nucleic acid extraction, nucleic acid amplification, and detection of 23 bacteria and viruses (or their subtypes), including 2019-nCoV (SARS-CoV-2)*. Testing requires a small sample volume and minimal hands-on time, and the results are available in approximately 1 hr.

Pathogens (and subtypes) that can be detected and identified with the QIAstat-Dx Respiratory 2019-nCoV Panel are listed in Table 1 (next page).

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* The 2019-nCoV (SARS-CoV-2) target in the QIAstat-Dx Respiratory 2019-nCoV Panel has been designed upon alignment of more than 170 genomic sequences available in public databases from the SARS-CoV-2 identified as the causative agent of the viral pneumonia (COVID-19) outbreak originated in Wuhan, Hubei, China. The 2019-nCoV (SARS-CoV-2) in the QIAstat-Dx Respiratory 2019-nCoV Panel targets 2 genes of the virus genome (Orf1b poly gen (Rdrp gene) and E genes) detected with the same fluorescent channel.

Table 1. Pathogens detected by the QIAstat-Dx Respiratory 2019-nCoV Panel

Pathogen	Classification (genome type)
Influenza A	Orthomyxovirus (RNA)
Influenza A, subtype H1N1/2009	Orthomyxovirus (RNA)
Influenza A subtype H1	Orthomyxovirus (RNA)
Influenza A subtype H3	Orthomyxovirus (RNA)
Influenza B	Orthomyxovirus (RNA)
Coronavirus 229E	Coronavirus (RNA)
Coronavirus HKU1	Coronavirus (RNA)
Coronavirus NL63	Coronavirus (RNA)
Coronavirus OC43	Coronavirus (RNA)
SARS-CoV-2 (2019-nCoV)	Coronavirus (RNA)
Parainfluenza Virus 1	Paramyxovirus (RNA)
Parainfluenza Virus 2	Paramyxovirus (RNA)
Parainfluenza Virus 3	Paramyxovirus (RNA)
Parainfluenza Virus 4	Paramyxovirus (RNA)
Respiratory Syncytial Virus A/B	Paramyxovirus (RNA)
Human Metapneumovirus A/B	Paramyxovirus (RNA)
Adenovirus	Adenovirus (DNA)
Bocavirus	Parvovirus (DNA)
Rhinovirus/Enterovirus	Picornavirus (RNA)
Mycoplasma pneumoniae	Bacterium (DNA)
Legionella pneumophila	Bacterium (DNA)
Bordetella pertussis	Bacterium (DNA)

Note: Enterovirus and Rhinovirus are both detected, but not differentiated, with the QIAstat-Dx Respiratory 2019-nCoV Panel.

Principle of the Procedure

Description of the process

Samples that are tested with the QIAstat-Dx Respiratory 2019-nCoV Panel are analyzed using the QIAstat-Dx Analyzer 1.0. All of the sample preparation and analysis steps are performed automatically by the QIAstat-Dx Analyzer 1.0. Samples are collected and loaded manually into the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge, depending on the sample type:

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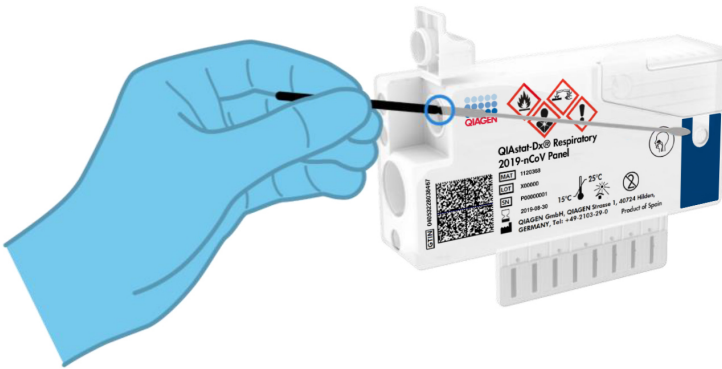

Figure 2. Loading the dry swab sample type into the swab port.

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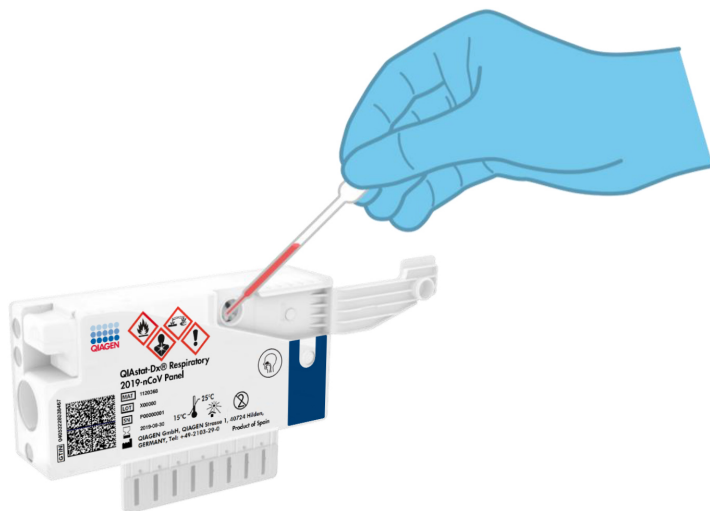

Figure 3. Dispensing transport medium liquid sample into the main port.

Sample collection and cartridge loading

The collection of samples and their subsequent loading into the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge should be performed by personnel trained in safe handling of biological samples.

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

1. A nasopharyngeal swab sample is collected.
2. The nasopharyngeal swab is placed into transport medium only in the case of transport medium liquid sample type.
3. The sample information is manually written on or a sample label is affixed to the top of a QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge.

4. Sample is loaded manually into the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge:

   ○ Dry swab sample type: The nasopharyngeal swab sample is inserted into the swab port of the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge.

   ○ Transport medium liquid sample type: 300 µl of sample is transferred into the main port of the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge using 1 of the included transfer pipettes.

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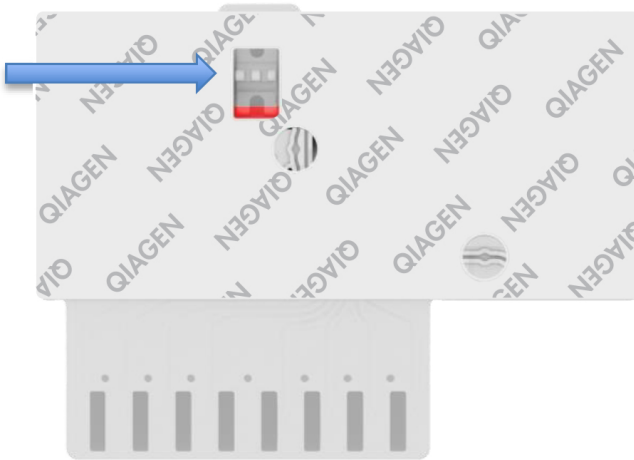

Figure 4. Sample inspection window (blue arrow).

5. The sample bar code and QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge bar code are scanned in the QIAstat-Dx Analyzer 1.0.

6. The QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge is introduced into the QIAstat-Dx Analyzer 1.0.

7. The test is started on the QIAstat-Dx Analyzer 1.0.

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.

1. The liquid sample is homogenized and cells are lysed in the lysis chamber of the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge, which includes a rotor that turns at high speed.
2. Nucleic acids are purified from the lysed sample via binding to a silica membrane in the purification chamber of the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge in the presence of chaotropic salts and alcohol.
3. The purified nucleic acids are eluted from the membrane in the purification chamber and are mixed with the lyophilized PCR chemistry in the dried-chemistry chamber of the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge.
4. The mixture of sample and PCR reagents is dispensed into the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge PCR chambers, which contain lyophilized, assay-specific primers and probes.
5. The QIAstat-Dx Analyzer 1.0 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 Software interprets the resulting data and process controls and delivers a test report.

Materials Provided

Kit contents

QIAstat-Dx Respiratory 2019-nCoV Panel Catalog no. Number of tests	691212 6
QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge*	6
Transfer pipettes†	6

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

† 6 individually packaged transfer pipettes for dispensing liquid sample into the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge.

Materials Required but Not Provided

The QIAstat-Dx Respiratory 2019-nCoV Panel is designed for use with the QIAstat-Dx Analyzer 1.0. Before beginning a test, make sure the following are available:

- QIAstat-Dx Analyzer 1.0 (at least 1 Operational Module and one Analytical Module) with software version 1.2 or higher*
- *QIAstat-Dx Analyzer 1.0 User Manual* (for use with software version 1.2 or higher)
- QIAstat-Dx latest Assay Definition File software for Respiratory Panel installed on the Operational Module

* DiagCORE® Analyzer instruments running QIAstat-Dx software version 1.2 or higher can be used as an alternative to QIAstat-Dx Analyzer 1.0 instruments.

Warnings and Precautions

For Research Use Only.

The QIAstat-Dx Respiratory 2019-nCoV Panel is to be used by laboratory professionals trained in the use of QIAstat-Dx Analyzer 1.0.

Safety information

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

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), or other appropriate documents provided by the following:

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

Follow your institution's safety procedures for handling biological samples. Dispose of samples, QIAstat-Dx Respiratory 2019-nCoV Panel Cartridges, and transfer pipettes according to the appropriate regulations.

The QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge is a closed, single-use device that contains all reagents needed for sample preparation and multiplex real-time RT-PCR within the QIAstat-Dx Analyzer 1.0. Do not use a QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge that is past its expiration date, appears damaged, or leaks fluid. Dispose of used or damaged cartridges in accordance with all national, state, and local health and safety regulations and laws.

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

The following hazard and precautionary statements apply to components of the QIAstat-Dx 2019-nCoV Respiratory Panel.

QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge

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.

Reagent Storage and Handling

Store the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridges in a dry, clean storage space at room temperature (15–25°C). Do not remove the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridges or the transfer pipettes from their individual packaging until actual use. Under these conditions, QIAstat-Dx Respiratory 2019-nCoV Panel Cartridges can be stored until the expiration date printed on the individual packaging. The expiration date is also included in the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge bar code and is read by the QIAstat-Dx Analyzer 1.0 when the cartridge is inserted into the instrument to run a test.

Specimen Handling, Storage and Preparation

Nasopharyngeal swab 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 2–8°C
- Frozen up to 30 days at –15 to –25°C

Procedure

Internal Control

The QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge includes a full process Internal Control which is titered MS2 bacteriophage. The MS2 bacteriophage is a single-stranded RNA virus that is included in the cartridge in dried form and is rehydrated upon sample loading. This Internal Control material verifies all steps of the analysis process, including sample resuspension/homogenization, lysis, nucleic acid purification, reverse transcription and PCR.

A positive signal for the Internal Control indicates that all processing steps performed by the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge were successful.

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

Protocol: Dry Swab Samples

Sample collection, transport and storage

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

Loading a sample into the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge

1. Open the package of a QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge using the tear notches on the sides of the packaging (Figure 5).

   IMPORTANT: After the package is open, sample should be introduced inside the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge and loaded into the QIAstat-Dx Analyzer 1.0 within 120 minutes.

Figure 5. Opening the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge.

2. Remove the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge from the packaging and position it so that the bar code on the label faces you.

3. Manually write the sample information, or place a sample information label, on the top of the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge. Make sure that the label is properly positioned and does not block the lid opening (Figure 6).

Figure 6. Sample information placement on top of QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge.

4. Open the sample lid of the swab port on the left side of the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge (Figure 7).

Figure 7. Opening the sample lid of swab port.

5. Insert the swab into the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge until the breakpoint is aligned with the access opening (i.e., the swab will go no further) (Figure 8).
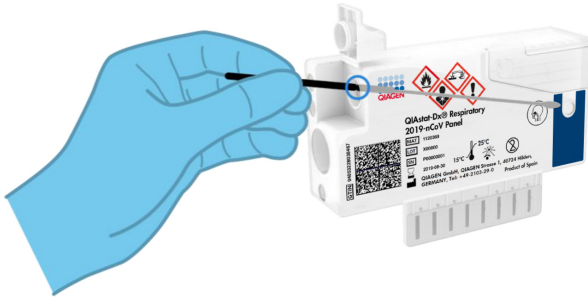

Figure 8. Inserting swab into the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge.

6. Break the swab shaft at the breakpoint, leaving the rest of the swab in the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge (Figure 9).
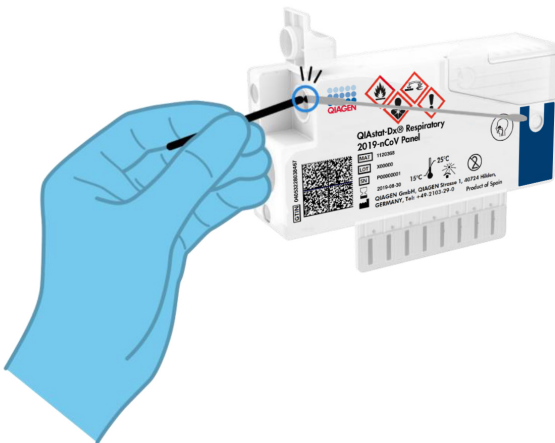

Figure 9.Breaking swab shaft.

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

   IMPORTANT: After the sample is placed inside the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge, the cartridge must be loaded into the QIAstat-Dx Analyzer 1.0 within 90 minutes.
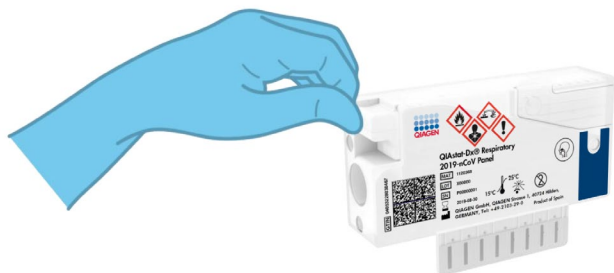

Figure 10. Closing the sample lid of the swab port.

Starting the QIAstat-Dx Analyzer 1.0

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

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

9. Wait until the **Main** screen appears and the QIAstat-Dx Analyzer 1.0 status indicators turn green and stop blinking.

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

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

11. If the Assay Definition File software has not been installed on the QIAstat-Dx Analyzer 1.0, follow the installation instructions prior to running the test (see Appendix A: Installing the Assay Definition File, page 52, for additional information).

Running a test

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

13. When prompted, scan the sample ID bar code on the nasopharyngeal swab sample (located on the swab blister packaging), or scan the specimen information bar code located on the top of the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge (see step 3), using the integrated front bar code reader of the QIAstat-Dx Analyzer 1.0 (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 appear in the **Instructions Bar** at the bottom of the touchscreen.

Figure 11. Scanning sample ID bar code.

14. When prompted, scan the bar code of the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge to be used (Figure 12). The QIAstat-Dx Analyzer 1.0 automatically recognizes the assay to be run based on the cartridge bar code.

    Note: The QIAstat-Dx Analyzer 1.0 will not accept QIAstat-Dx Respiratory 2019-nCoV Panel Cartridges with lapsed expiration dates, previously used cartridges, or cartridges for assays that have not been installed on the unit. An error message will be shown in these cases and the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge will be rejected. Refer to the *QIAstat-Dx Analyzer 1.0 User Manual* for further details on how to install assays.

Figure 12. Scanning QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge bar code.

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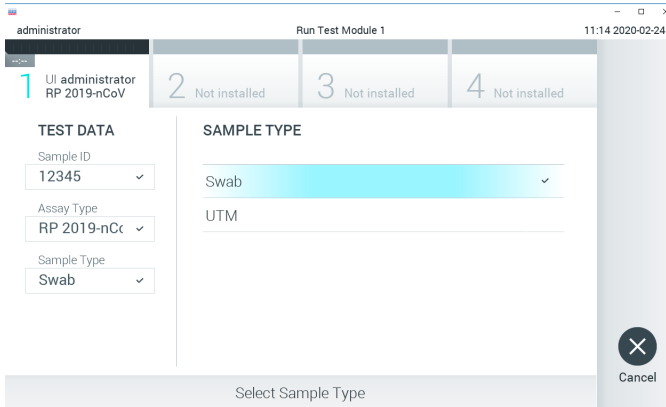

Figure 13.Selecting sample type.

16. 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.

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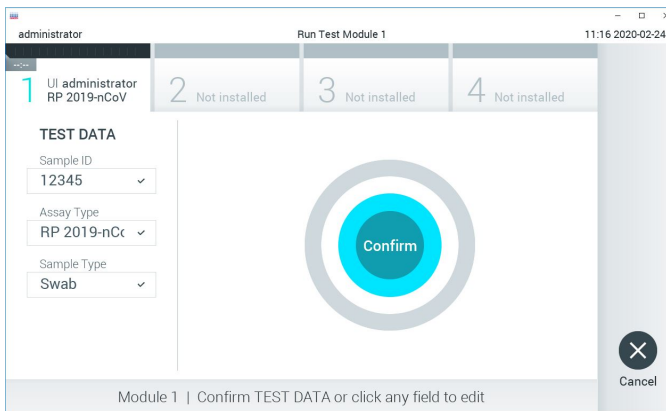

Figure 14.Confirming data entry.

18. Make sure that both sample lids of the swab port and main port of the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge are firmly closed. When the cartridge entrance port on the top of the QIAstat-Dx Analyzer 1.0 automatically opens, insert the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge with the bar code facing to the left and the reaction chambers facing down (Figure 15).

Note: There is no need to push the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge into the QIAstat-Dx Analyzer 1.0. Position it correctly into the cartridge entrance port and the QIAstat-Dx Analyzer 1.0 will automatically move the cartridge into the Analytical Module.

Figure 15. Inserting QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge into QIAstat-Dx Analyzer 1.0.

19. Upon detecting the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge, the QIAstat-Dx Analyzer 1.0 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 will not accept a QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge other than the one used and scanned during the test setup. If a cartridge other than the one scanned is inserted, an error will be generated and the cartridge will be automatically ejected.

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

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

    Note: The lid of the cartridge entrance port will close automatically after 30 seconds if a QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge is not positioned in the port. If this occurs, repeat the procedure starting with step 16.

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

21. After the test run is completed, the **Eject** screen will appear (Figure 16, next page) 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* for possible reasons and instructions on how to proceed.
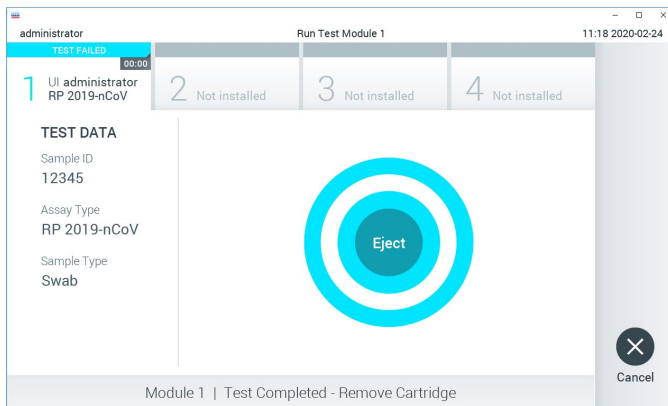
Figure 16. Eject screen display.

22. Press ⦿ **Eject** on the touchscreen to remove the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge and dispose of it as biohazardous waste in accordance with all national, state, and local health and safety regulations and laws. The QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge should be removed when the cartridge entrance port opens and ejects the cartridge. If the cartridge is not removed after 30 seconds, it will automatically move back into the QIAstat-Dx Analyzer 1.0 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 2019-nCoV Panel Cartridges must be discarded. It is not possible to reuse cartridges for tests wherein the execution was started but then subsequently canceled by the operator, or wherein an error was detected.

23. After the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge has been ejected, the results **Summary** screen will appear. Refer to "Interpretation of Results", page 39, 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*.

Protocol: Transport Medium Liquid Samples

Sample collection, transport, and storage

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

Loading a sample into the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge

1. Open the package of a QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge using the tear notches on the sides of the packaging (Figure 17).

   IMPORTANT: After the package is open, sample should be introduced inside the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge and loaded into the QIAstat-Dx Analyzer 1.0 within 120 minutes.

Figure 17. Opening the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge.

2. Remove the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge from the packaging and position it so that the bar code on the label faces you.

3. Manually write the sample information, or place a sample information label, on the top of the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge. Make sure that the label is properly positioned and does not block the lid opening (Figure 18).

Figure 18.Sample information placement on top of QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge.

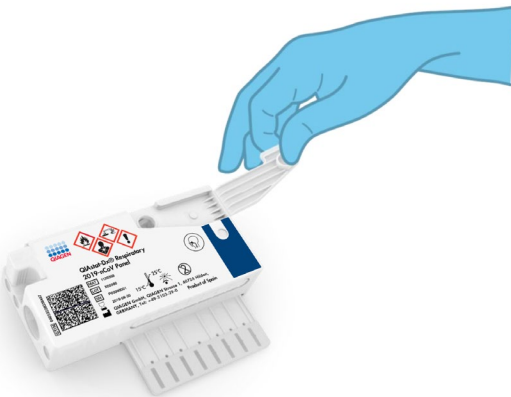4. Open the sample lid of the main port on the front of the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge (Figure 19).

Figure 19.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 20).

   IMPORTANT: Take care to avoid drawing air into the pipette. If Copan UTM®, Universal Transport Medium, is used as transport medium, take care not to aspirate any of the beads present in the tube. If air or beads are drawn into the pipette, carefully expel the sample fluid in the pipette back into the sample tube and draw up fluid again.
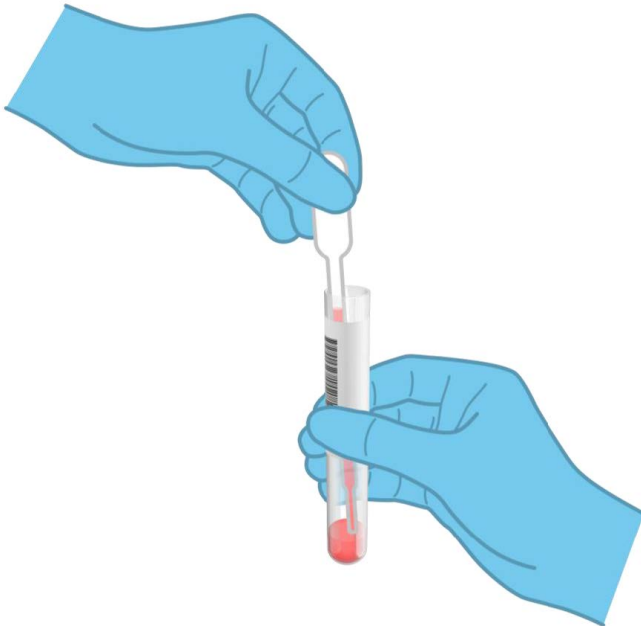

Figure 20.Drawing up sample into the supplied transfer pipette.

6. Carefully transfer 300 μl of sample volume into the main port of the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge using the supplied single-use transfer pipette (Figure 21, next page).
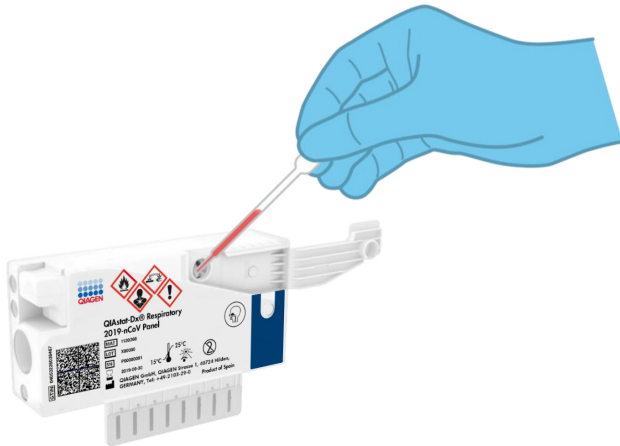
Figure 21. Transferring sample to main port of QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge.

7. Firmly close the sample lid of the main port until it clicks (Figure 22).

Figure 22. 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 2019-nCoV Panel Cartridge (Figure 23).

   IMPORTANT: After the sample is placed inside the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge, the cartridge must be loaded into the QIAstat-Dx Analyzer 1.0 within 90 minutes.
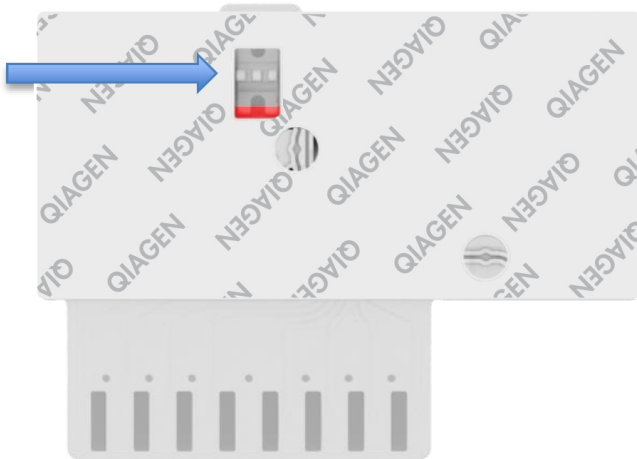

Figure 23.Sample inspection window (blue arrow).

Starting the QIAstat-Dx Analyzer 1.0

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

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

10. Wait until the **Main** screen appears and the QIAstat-Dx Analyzer 1.0 status indicators turn green and stop blinking.

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

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

12. If the Assay Definition File software has not been installed on the QIAstat-Dx Analyzer 1.0, follow the installation instructions prior to running the test (see Appendix A: Installing the Assay Definition File, page 52, for additional information).

Running a test

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

14. When prompted, scan the sample ID bar code on the UTM tube containing the sample, or scan the specimen information bar code located on the top of the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge (see step 3), using the integrated front bar code reader of the QIAstat-Dx Analyzer 1.0 (Figure 24).

    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 appear in the **Instructions Bar** at the bottom of the touchscreen.

Figure 24. Scanning sample ID bar code.

15. When prompted, scan the bar code of the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge to be used (Figure 25). The QIAstat-Dx Analyzer 1.0 automatically recognizes the assay to be run based on the cartridge bar code.

    Note: The QIAstat-Dx Analyzer 1.0 will not accept QIAstat-Dx Respiratory 2019-nCoV Panel Cartridges with lapsed expiration dates, previously used cartridges or cartridges for assays that have not been installed on the unit. An error message will be shown in these cases and the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge will be rejected. Refer to the *QIAstat-Dx Analyzer 1.0 User Manual* for further details on how to install assays.

Figure 25.Scanning QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge bar code.

16. Select the appropriate sample type from the list (Figure 26).
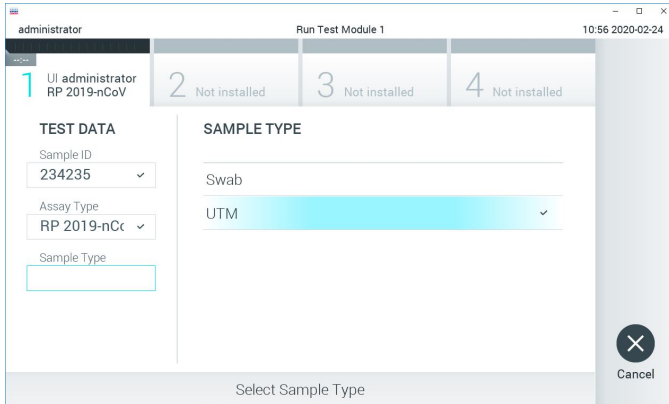

Figure 26. Selecting sample type.

17. 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.

18. 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 27).
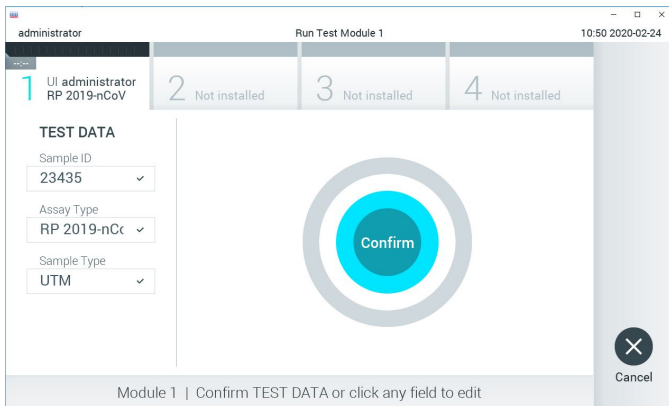

Figure 27. Confirming data entry.

19. Make sure that both sample lids of the swab port and main port of the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge are firmly closed. When the cartridge entrance port on the top of the QIAstat-Dx Analyzer 1.0 automatically opens, insert the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge with the bar code facing to the left and the reaction chambers facing down (Figure 28).

Note: There is no need to push the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge into the QIAstat-Dx Analyzer 1.0. Position it correctly into the cartridge entrance port and the QIAstat-Dx Analyzer 1.0 will automatically move the cartridge into the Analytical Module.

Figure 28. Inserting QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge into QIAstat-Dx Analyzer 1.0.

20. Upon detecting the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge, the QIAstat-Dx Analyzer 1.0 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 will not accept a QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge other than the one used and scanned during the test setup. If a cartridge other than the one scanned is inserted, an error will be generated and the cartridge will be automatically ejected.

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

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

    Note: The lid of the cartridge entrance port will close automatically after 30 seconds if a QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge is not positioned in the port. If this occurs, repeat the procedure starting with step 17.

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

22. After the test run is completed, the **Eject** screen will appear (Figure 29, next page) 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* for possible reasons and instructions on how to proceed.
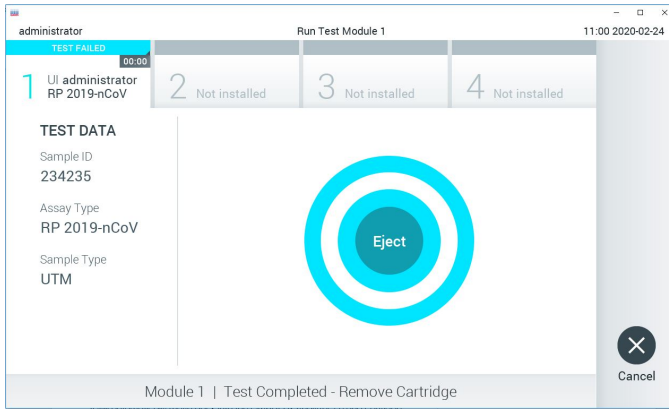
Figure 29. Eject screen display.

23. Press 🔘 **Eject** on the touchscreen to remove the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge and dispose of it as biohazardous waste in accordance with all national, state and local health and safety regulations and laws. The QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge should be removed when the cartridge entrance port opens and ejects the cartridge. If the cartridge is not removed after 30 seconds, it will automatically move back into the QIAstat-Dx Analyzer 1.0 and cartridge entrance port lid will close. If this occurs, press **Eject** to open the lid of the cartridge entrance port again and then remove the cartridge.
    IMPORTANT: Used QIAstat-Dx Respiratory 2019-nCoV Panel Cartridges must be discarded. It is not possible to re-use cartridges for tests for which the execution was started but then subsequently canceled by the operator, or for which an error was detected.

24. After the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge has been ejected, the results **Summary** screen will appear. Refer to "Interpretation of Results", page 39, 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*.

Interpretation of Results

Viewing results

The QIAstat-Dx Analyzer 1.0 automatically interprets and saves test results. After ejecting the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge, the results **Summary** screen is automatically displayed (Figure 30).
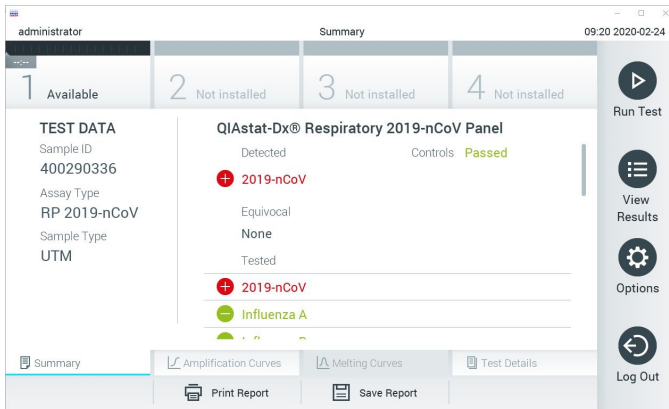

Figure 30. Results Summary screen example showing Test Data on the left panel and Test Summary in the main panel.

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

- The first list, under the heading "Detected", includes all pathogens detected and identified in the sample, which are preceded by a ⊕ sign and are colored red.

- The second list, under the heading "Equivocal" is not used. "Equivocal" results are not applicable for the QIAstat-Dx 2019-nCoV Respiratory Panel. Therefore, the "Equivocal" list will always be empty.

- The third list, under the heading "Tested", includes all pathogens tested in the sample. Pathogens detected and identified in the sample are preceded by a ⊕ sign and are colored red. Pathogens that were tested but not detected are preceded by a ⊖ sign and are colored green.

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

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

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

- Sample ID
- Assay Type
- Sample Type

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

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

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

Viewing amplification curves

To view test amplification curves of pathogens detected, press the ⌇ **Amplification Curves** tab (Figure 31, next page).

Figure 31. 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 the **Amplification Curves** screen is only available for operators with access rights.

Press the **PATHOGENS** tab on the left side to display the plots corresponding to the tested pathogens. Press on the pathogen name to select which pathogens are shown in the amplification plot. It is possible to select single, multiple or no pathogens. Each pathogen in the selected list will be assigned a color corresponding to the amplification curve associated with the pathogen. Unselected pathogens will be shown in gray.

The corresponding C_T and endpoint fluorescence (EP) values are shown below each pathogen name.

Press the **CONTROLS** tab on the left side to view the controls in the amplification plot. Press the circle next to the control name to select or deselect it (Figure 32, next page).

Figure 32.Amplification Curves screen (CONTROLS tab).

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

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

Viewing test details

Press 🗐 **Test Details** in the Tab Menu bar at the bottom of the touchscreen to review the results in more detail. Scroll down to see the complete report.

The following Test Details are shown in the center of the screen (Figure 33, next page):

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

- Error Code (if applicable)
- Test Start Date and Time
- Test Execution Time
- Assay Name
- Test ID
- Test Result:
  - Positive (if at least one respiratory pathogen is detected/identified)
  - Negative (no respiratory pathogen is detected)
  - Invalid
- List of analytes tested in the assay, with C_T and endpoint fluorescence in the event of a positive signal
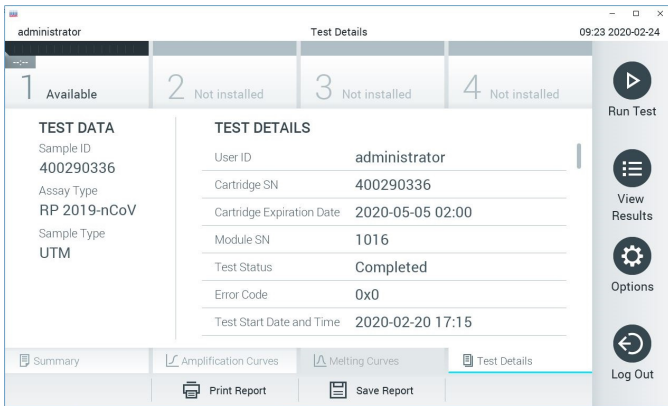- Internal Control, with C_T and endpoint fluorescence

Figure 33. Example screen showing Test Data on the left panel and Test Details in the main panel.

Browsing results from previous tests

To view results from previous tests that are stored in the results repository, press ⊜ **View Results** on the Main Menu bar (Figure 34).
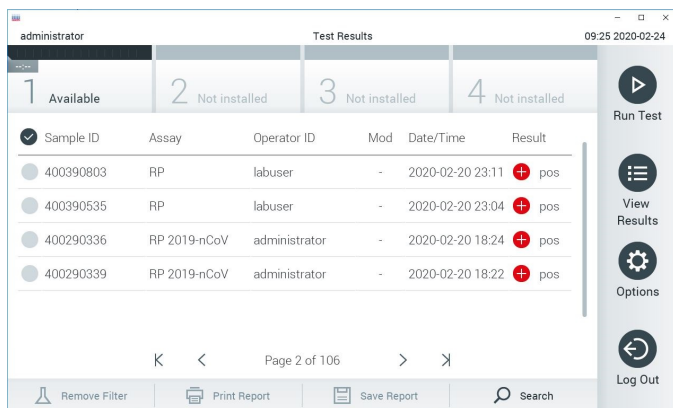

Figure 34.Example View Results screen.

The following information is available for every executed test (Figure 35):

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

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

Select one or more test results by pressing the **gray circle** to left of the sample ID. A **checkmark** will appear next to selected results. Unselect test results by pressing this **checkmark**. The entire list of results can be selected by pressing the ⊘ **checkmark circle** in the top row (Figure 35, next page).
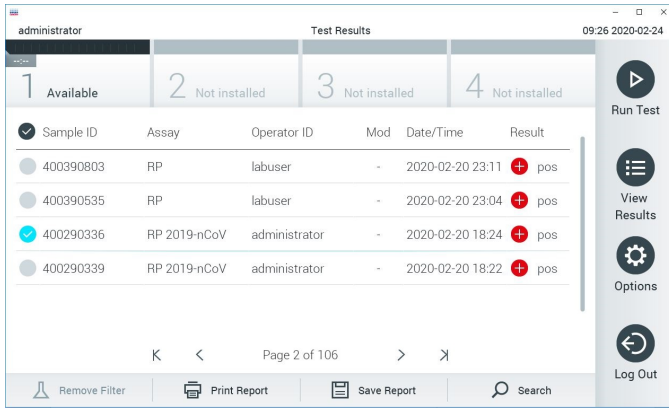
Figure 35.Example of selecting Test Results in the View Results screen.

Press anywhere in the test row to view the result for a particular test.

Press a column headline (e.g., **Sample ID**) to sort the list in ascending or descending order according to that parameter. The list can be sorted according to only one column at a time.

The **Result** column shows the outcome of each test (Table 2):

Table 2. Descriptions of test results

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

Make sure a printer is connected to the QIAstat-Dx Analyzer 1.0 and the proper driver is installed. Press **Print Report** to print the report(s) for the selected result(s).

Press **Save Report** to save the report(s) for the selected result(s) in PDF format to an external USB storage device.

Select the report type: List of Tests or Test Reports.

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

If the results list has been filtered, the search will only apply to the filtered list.

Press and hold a column headline to apply a filter based on that parameter. For some parameters, such as **Sample ID**, the virtual keyboard will appear so the search string for the filter can be entered.

For other parameters, such as **Assay**, a dialog will open with a list of assays stored in the repository. Select one or more assays to filter only the tests that were performed with the selected assays.

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

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

Exporting results to a USB drive

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

Printing results

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

Result interpretation

A result for a respiratory organism is interpreted as "Positive" when the corresponding PCR assay is positive, except for Influenza A. The Influenza A assay in the QIAstat-Dx Respiratory 2019-nCoV Panel is designed to detect Influenza A as well as Influenza A subtype H1N1/2009, Influenza A subtype H1 or Influenza A subtype H3. In particular, this means:

- If seasonal Influenza A H1 strain is detected by the QIAstat-Dx Respiratory 2019-nCoV Panel assay, two signals will be generated and displayed on the QIAstat-Dx Analyzer 1.0 screen: one for Influenza A and a second one for H1 strain.
- If seasonal Influenza A H3 strain is detected by the QIAstat-Dx Respiratory 2019-nCoV Panel assay, two signals will be generated and displayed on the QIAstat-Dx Analyzer 1.0 screen: one for Influenza A and a second one for H3 strain.
- If a pandemic Influenza A/H1N1/2009 strain is detected, two signals will be generated and displayed on the QIAstat-Dx Analyzer 1.0 screen: one for Influenza A and a second one for H1N1/2009.

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

Internal Control interpretation

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

Table 3. Interpretation of Internal Control results

Control result	Explanation	Action
Passed	The Internal Control amplified successfully	The run was completed with success. All results are validated 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 2019-nCoV Panel Cartridge.

Quality Control

In accordance with QIAGEN's ISO-certified Quality Management System, each lot of QIAstat-Dx Respiratory 2019-nCoV Panel is tested against predetermined specifications to ensure consistent product quality.

Limitations

- Results from the QIAstat-Dx Respiratory 2019-nCoV Panel are not intended to be used for diagnosis, treatment or other patient management decisions.
- Positive results do not rule out co-infection with organisms not included in the QIAstat-Dx Respiratory Panel. The agent detected may not be the definitive cause of the disease.
- Negative results do not preclude infection of the upper respiratory tract. Not all agents of acute respiratory infection are detected by this assay.
- A negative result with the QIAstat-Dx Respiratory 2019-nCoV Panel does not exclude the infectious nature of the syndrome. Negative assay results may originate from several factors and their combinations, including sample handling mistakes, variation in the nucleic acid sequences targeted by the assay, infection by organisms not included in the assay, organism levels of included organisms that are below the limit of detection for the assay and use of certain medications, therapies or agents.
- The QIAstat-Dx Respiratory 2019-nCoV Panel is not intended for testing of samples other than those described in these Instructions for Use.
- The QIAstat-Dx Respiratory 2019-nCoV Panel can be used only with the QIAstat-Dx Analyzer 1.0.*
- The QIAstat-Dx Respiratory 2019-nCoV Panel is a qualitative assay and does not provide a quantitative value for detected organisms.
- Detection of viral and bacterial nucleic acids depends on proper sample collection, handling, transportation, storage and loading into the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge. Improper operations for any of the aforementioned processes can cause incorrect results, including false-positive or false-negative results.

* DiagCORE Analyzer instruments running QIAstat-Dx software version 1.2 or higher can be used as an alternative to QIAstat-Dx Analyzer 1.0 instruments.

Analytical Performance

Sensitivity (Limit of Detection)

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

The LoD of the QIAstat-Dx Respiratory 2019-nCoV Panel was determined per analyte using selected strains representing individual pathogens that are possible to detect with the QIAstat-Dx Respiratory 2019-nCoV Panel. Simulated NPS sample matrix (cultured human cells in Copan UTM) was spiked with one (1) or more pathogens and tested in 20 replicates.

Individual LoD values for each QIAstat-Dx Respiratory 2019-nCoV Panel target are shown in Table 4.

Table 4. LoD values obtained for the different respiratory target strains tested with the QIAstat-Dx Respiratory 2019-nCoV Panel

Pathogen	Strain	Source	Concentration	Detection rate
Influenza A H1N1	A/New Jersey/8/76	ATCC® VR-897	28.1 CEID$_{50}$/ml	20/20
	A/Brisbane/59/07	ZeptoMetrix® 0810244CFHI	0.04 TCID$_{50}$/ml	19/20
	A/New Caledonia/20/99	ZeptoMetrix 0810036CFHI	4.6 TCID$_{50}$/ml	19/20
Influenza A H3N2	A/Virginia/ATCC6/2012	ATCC VR-1811	0.4 PFU/ml	19/20
	A/Wisconsin/67/2005	ZeptoMetrix 0810252CFHI	2.5 TCID$_{50}$/ml	20/20
	A/Port Chalmers/1/73	ATCC VR-810	791.1 CEID$_{50}$/ml	20/20
Influenza A, subtype H1N1/2009	A/Virginia/ATCC1/2009	ATCC VR-1736	2.6 PFU/ml	20/20
	A/SwineNY/03/2009	ZeptoMetrix 0810249CFHI	14.1 TCID$_{50}$/ml	20/20
Influenza B	B/Virginia/ATCC5/2012	ATCC VR-1807	0.08 PFU/ml	20/20
	B/FL/04/06	ATCC VR-1804	34.8 CEID$_{50}$/ml	19/20
	B/Taiwan/2/62	ATCC VR-295	28.1 CEID$_{50}$/ml	20/20

continued on next page

Table 4 (continued from previous page)

Pathogen	Strain	Source	Concentration	Detection rate
Coronavirus 229E	–	ATCC VR-740	0.3 TCID$_{50}$/ml	20/20
Coronavirus OC43	–	ATCC-1558	0.1 TCID$_{50}$/ml	20/20
Coronavirus NL63	–	ZeptoMetrix 0810228CFHI	0.01 TCID$_{50}$/ml	20/20
Coronavirus HKU1	–	ZeptoMetrix NATRVP-IDI	1/300*	19/20
SARS-CoV-2 (2019-nCoV)	–	IDT gBlock	400 copies/mL	19/20
Parainfluenza Virus 1 (PIV 1)	C35	ATCC VR-94	23.4 TCID$_{50}$/ml	20/20
Parainfluenza Virus 2 (PIV 2)	Greer	ATCC VR-92	5.0 TCID$_{50}$/ml	19/20
Parainfluenza Virus 3 (PIV 3)	C 243	ATCC VR-93	15.8 TCID$_{50}$/ml	20/20
Parainfluenza Virus 4 (PIV 4)	M-25	ATCC VR-1378	2.8 TCID$_{50}$/ml	20/20
Respiratory Syncytial Virus A	A2	ATCC VR-1540	2.8 TCID$_{50}$/ml	20/20
Respiratory Syncytial Virus B	9320	ATCC VR-955	0.02 TCID$_{50}$/ml	20/20
Human Metapneumovirus	Peru6-2003 (type B2)	ZeptoMetrix 0810159CFHI	1.1 TCID$_{50}$/ml	19/20
	hMPV-16, IA10-2003	ZeptoMetrix 0810161CFHI	3.0 TCID$_{50}$/ml	20/20
Adenovirus	GB (Adenovirus B3)	ATCC VR-3	50.0 TCID$_{50}$/ml	20/20
	RI-67 (Adenovirus E4)	ATCC VR-1572	15.8 TCID$_{50}$/ml	20/20
	Adenoid 75 (Adenovirus C5)	ATCC VR-5	5.0 TCID$_{50}$/ml	20/20
	Adenoid 71 (Adenovirus C1)	ATCC VR-1	5.0 TCID$_{50}$/ml	19/20
	Adenovirus C2	ATCC VR-846	28.1 TCID$_{50}$/ml	20/20
	Adenovirus C6	ATCC VR-6	505.6 TCID$_{50}$/ml	20/20

* Relative dilution from stock concentration.

Table 4 (continued from previous page)

Pathogen	Strain	Source	Concentration	Detection rate
Bocavirus	Clinical sample	–	>1.0 copies/ml	20/20
Enterovirus	/US/IL/14-18952 (Enterovirus D68)	ATCC VR-1824	50.0 $TCID_{50}$/ml	19/20
	Echovirus 6 (D-1 (Cox))	ATCC VR-241	0.001 $TCID_{50}$/ml	19/20
Rhinovirus	1059 (Rhinovirus B14)	ATCC VR-284	28.1 $TCID_{50}$/ml	20/20
	HGP (Rhinovirus A2)	ATCC VR-482	0.3 $TCID_{50}$/ml	19/20
	11757 (Rhinovirus A16)	ATCC VR-283	8.9 $TCID_{50}$/ml	20/20
	Type 1A	ATCC VR-1559	5.0 $TCID_{50}$/ml	20/20
Mycoplasma pneumoniae	M129-B7	ATCC 29342	0.1 CFU/ml	20/20
Legionella pneumophila	CA1	ATCC 700711	>0.01 CFU/ml	20/20
Bordetella pertussis	I028	ATCC BAA-2707	>0.001 CFU/ml	20/20
	A639	ZeptoMetrix NATRVP-IDI	1/10000*	19/20

* Relative dilution from stock concentration.

Appendix A: Installing the Assay Definition File

The Assay Definition File of the QIAstat-Dx Respiratory 2019-nCoV Panel must be installed on the QIAstat-Dx Analyzer 1.0 p9rior to testing with QIAstat-Dx Respiratory 2019-nCoV Panel Cartridges.

Note: Whenever a new version of the QIAstat-Dx Respiratory 2019-nCoV Panel assay is released, the new QIAstat-Dx Respiratory 2019-nCoV Panel Assay Definition File must be installed prior to testing.

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

To import new assays from the USB to the QIAstat-Dx Analyzer 1.0, 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.
2. Press the **Options** button and then select **Assay Management**. The Assay Management screen appears in the Content area of the display (Figure 36 next page).
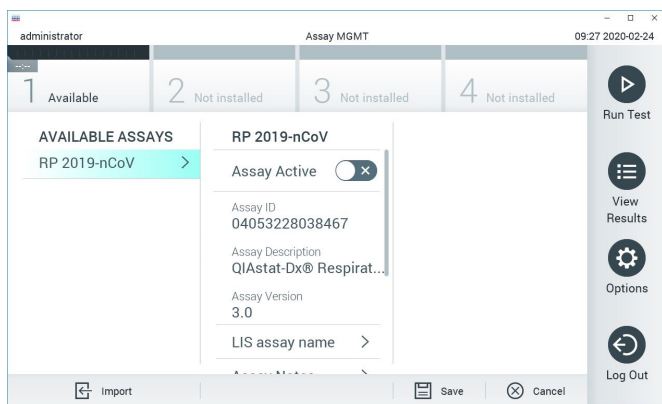
Figure 36. Assay Management screen.

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 37).
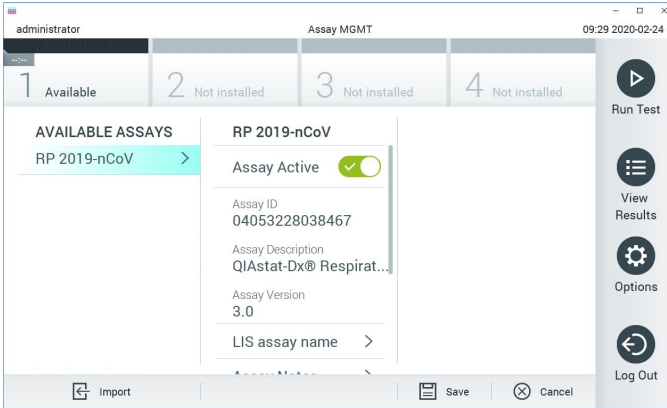
Figure 37. Activating the assay.

8. Assign the active assay to the user by pressing the **Options** button and then the **User Management** button. Select the user who should be allowed to run the assay. Next, select **Assign Assays** from the "User Options". Enable the assay and press the **Save** button (Figure 38).
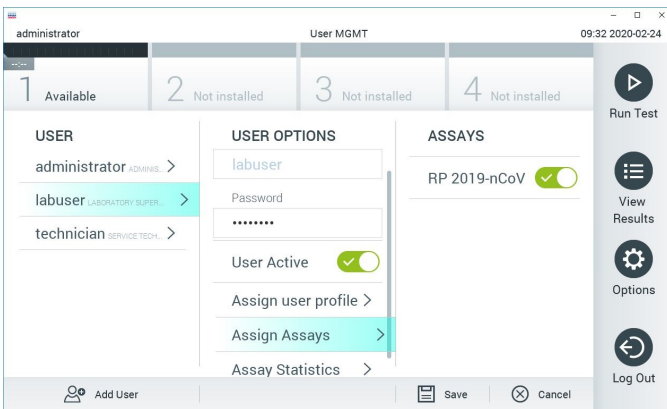
Figure 38. Assigning the active assay.

Appendix B: Glossary

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

Analytical Module (AM): The main QIAstat-Dx Analyzer 1.0 hardware module, in charge of executing tests on QIAstat-Dx Respiratory 2019-nCoV Panel Cartridges. It is controlled by the Operational Module. Several Analytical Modules can be connected to one Operational Module.

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

QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge: A self-contained disposable plastic device with all pre-loaded reagents required for the complete execution of fully automated molecular assays for the detection of respiratory pathogens.

IFU: Instructions For Use.

Main port: In the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge, inlet for transport medium liquid samples.

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

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

PCR: Polymerase Chain Reaction

RT: Reverse Transcription

Swab port: In the QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge, inlet for dry swabs.

User: A person who operates the QIAstat-Dx Analyzer 1.0/QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge in the intended way.

Appendix C: Disclaimer of warranties

EXCEPT AS PROVIDED IN QIAGEN TERMS AND CONDITIONS OF SALE FOR THE QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge, QIAGEN ASSUMES NO LIABILITY WHATSOEVER AND DISCLAIMS ANY EXPRESS OR IMPLIED WARRANTY RELATING TO THE USE OF THE QIAstat-Dx Respiratory 2019-nCoV Panel Cartridge INCLUDING LIABILITY OR WARRANTIES RELATING TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR INFRINGEMENT OF ANY PATENT, COPYRIGHT, OR OTHER INTELLECTUAL PROPERTY RIGHT ANYWHERE IN THE WORLD.

References

1. Centers for Disease Control and Prevention (CDC). National Center for Immunization and Respiratory Diseases (NCIRD). Division of Viral Diseases (DVD) web site.

2. World Health Organization. WHO Fact Sheet No. 221, November 2016. Influenza (seasonal). www.who.int/mediacentre/factsheets/fs211/en/index.html. Accessed November 2016.

3. Flu.gov web site. About Flu. www.cdc.gov/flu/about/index.html

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8. Centers for Disease Control and Prevention (CDC). Diseases & Conditions: *Mycoplasma pneumoniae* Infection. www.cdc.gov/pneumonia /atypical/mycoplasma/index.html

9. Centers for Disease Control and Prevention (CDC). Diseases & Conditions: Pertussis (Whooping Cough). www.cdc.gov/pertussis/

10. Clinical and Laboratory Standards Institute (CLSI) *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline* (M29).

11. BLAST: Basic Local Alignment Search Tool. https://blast.ncbi.nlm.nih.gov/Blast.cgi

Symbols

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

Symbol	Description
Σ \<N\>	Contains reagents sufficient for \<N\> reactions
⧖	Use by
REF	Catalog number
LOT	Lot number
MAT	Material number (i.e., component labeling)
(respiratory symbol)	Upper respiratory application
Rn	R is for revision of the Handbook and n is the revision number
(thermometer symbol)	Temperature limitation
(manufacturer symbol)	Manufacturer
(book symbol)	Consult instructions for use
⚠	Caution
SN	Serial number
(do not reuse symbol)	Do not reuse
(sunlight symbol)	Keep away from sunlight
(damaged package symbol)	Do not use if package is damaged
GTIN	Global Trade Item Number

Ordering Information

Product	Contents	Cat. no.
QIAstat-Dx Respiratory 2019-nCoV Panel	For 6 tests: 6 individually packaged QIAstat-Dx Respiratory 2019-nCoV Panel Cartridges and 6 individually packaged transfer pipettes	691212
Related Products		
QIAstat-Dx Analyzer 1.0	1 QIAstat-Dx Analytical Module, 1 QIAstat-Dx Operational Module and related hardware and software to run molecular diagnostic QIAstat-Dx assay cartridges	9002824

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

Handbook Revision History

Date	Changes
Revision 1 02/2020	Initial release.