QIAstat-Dx® Respiratory Panel

Version 2

The QIAstat-Dx® Respiratory Panel is intended for in vitro diagnostic use.

Further information

- Safety Data Sheets (SDSs): www.qiagen.com/safety
- Technical assistance: support.qiagen.com

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Notes before starting

- Before starting a test, it is required to thoroughly read and understand the *QIAstat-Dx Respiratory Panel Instructions for Use (Handbook)*: www.qiagen.com/HB-2638
- Before starting a test, make sure the following are available:
  - QIAstat-Dx Analyzer 1.0 (at least one Operational Module and one Analytical Module) with software version 1.2 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
- When working with chemicals, always wear a suitable lab coat, disposable gloves and protective goggles.

Setting up a test: dry swab samples

Loading a dry swab sample into the QIAstat-Dx Respiratory Panel Cartridge

1. Remove the QIAstat-Dx Respiratory Panel Cartridge from the package and position it so that the bar code on the label faces you.

2. Write the sample information, or place a sample information label, on the top of the cartridge. Make sure the label is properly positioned and doesn't block the lid opening.

3. Open the swab port sample lid on the left side of the QIAstat-Dx Respiratory Panel Cartridge.

* 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.

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

5. Break the swab shaft at the breakpoint, leaving the rest of the swab in the QIAstat-Dx Respiratory Panel Cartridge.
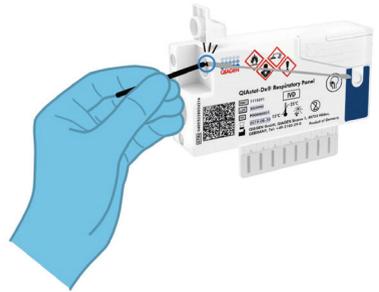
6. Firmly close the sample lid of the swab port until it clicks.

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

Setting up a test: transport medium liquid samples

Loading a transport medium liquid sample into the QIAstat-Dx Respiratory Panel Cartridge

1. Remove the QIAstat-Dx Respiratory Panel Cartridge from the package and position it so that the bar code on the label faces you.

2. Write the sample information, or place a sample information label, on the top of the cartridge. Make sure the label is properly positioned and doesn't block the lid opening.

3. Open the main port sample lid on the front of the QIAstat-Dx Respiratory Panel Cartridge.
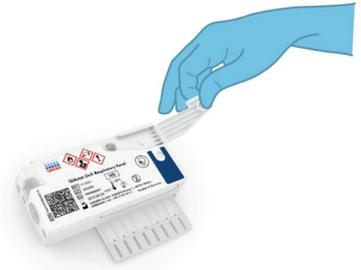
4. Open the sample tube to be tested. Use the supplied transfer pipette to draw up fluid to the third fill line (300 µl). Carefully transfer the 300 µl sample volume into the main port.
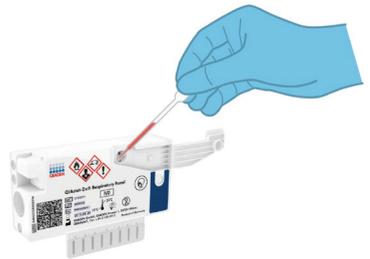
5. Firmly close the main port sample lid until it clicks. Visually confirm the sample is loaded using the sample inspection window of the QIAstat-Dx Respiratory Panel Cartridge.

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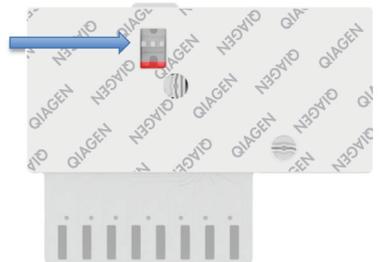
Starting the QIAstat-Dx Analyzer 1.0

1. Power ON the QIAstat-Dx Analyzer 1.0 using the On/Off button on the front of the instrument. The status indicators will turn blue.

2. After the **Main** screen appears and the QIAstat-Dx Analyzer 1.0 status indicators turn green and stop blinking, log in to the instrument.

Running a test

1. Press the **Run Test** button. When prompted, use the bar code reader to scan the sample ID bar code (on the nasopharyngeal swab sample or UTM sample tube, as appropriate) or scan the sample information label bar code on the QIAstat-Dx Respiratory Panel Cartridge.

2. When prompted, scan the bar code of the QIAstat-Dx Respiratory Panel Cartridge.

3. Select the appropriate sample type from the list.

4. The **Confirm** screen will appear. Review the entered data and make any necessary changes. Press **Confirm** when all the displayed data are correct.

5. Make sure that both sample lids of the swab port and main port of the QIAstat-Dx Respiratory Panel Cartridge are closed. Insert the cartridge into the cartridge entrance port of the QIAstat-Dx Analyzer 1.0 with the bar code facing to the left and the reaction chambers facing down. The instrument will automatically close and start the test run.

6. When the test run is completed, the **Eject** screen will appear and one of the following test results will be displayed: TEST COMPLETED, TEST FAILED or TEST CANCELED.
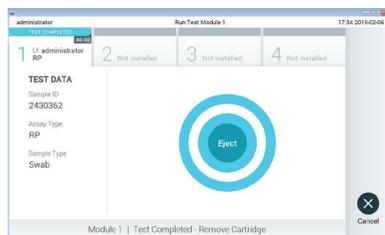
7. Press ⊙ Eject on the touchscreen to remove the QIAstat-Dx Respiratory Panel Cartridge.

Viewing results

The QIAstat-Dx Analyzer 1.0 automatically interprets and saves test results. After ejecting the QIAstat-Dx Respiratory Panel Cartridge, the results **Summary** screen is displayed. The main part of the screen uses color-coding and symbols to indicate the results:
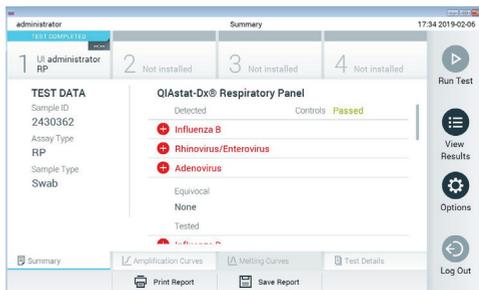
- The first list, under the heading "Detected", includes all pathogens detected and identified in the sample, which are preceded by a red plus sign ⊕.
- The second list, under the heading "Equivocal" is not used. "Equivocal" results are not applicable for the QIAstat-Dx Respiratory Panel. Therefore, 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.
- Press 🗐 Test Details in the Tab Menu bar at the bottom of the touchscreen to review the results in more detail.
- To view test amplification curves of pathogens detected, press the ⌁ Amplification Curves tab.

Document Revision History	
Revision 1 04/2019	Initial release.