

QIAstat-Dx[®] Respiratory Panel

Rx Only.

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

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-2662
- 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
 - *QIAstat-Dx Analyzer 1.0 User Manual* (for use with software version 1.2)
 - 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.



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Setting up a test

Loading a sample into the QIAstat-Dx Respiratory Panel Cartridge

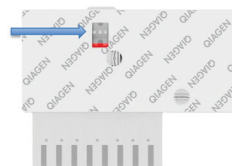
1. Remove the QIAstat-Dx Respiratory Panel Cartridge from the package and position it so that the QR code on the label faces you.
2. Write the sample information, or place a sample information label, on the top of the cartridge. Make sure the label is properly positioned and doesn't block the lid opening.
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

6. 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.
7. 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

8. Press the **Run Test** button. When prompted, use the bar code reader to scan the sample ID bar code on the UTM sample tube or scan the sample information label bar code on the QIAstat-Dx Respiratory Panel Cartridge.



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

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

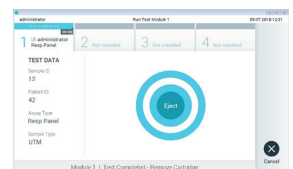


11. Make sure that both sample lids of the swab port and main port of the QIAstat-Dx Respiratory Panel Cartridge are closed. Insert the cartridge into the cartridge entrance port of the QIAstat-Dx Analyzer 1.0 with the bar code facing to the left and the reaction chambers facing down. The instrument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



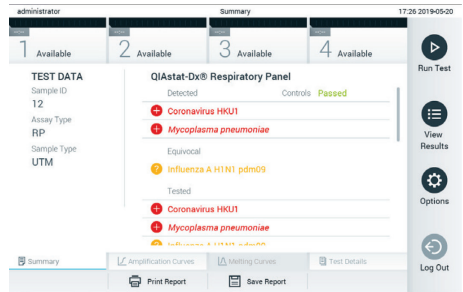
12. When the test run is completed, the **Eject** screen will appear and one of the following test results will be displayed: TEST COMPLETED, TEST FAILED or TEST CANCELED.

13. 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:



- Pathogens detected and identified in the sample are colored red and preceded by a red plus sign **+**.
- Equivocal pathogens are preceded by a yellow question mark **?**.
- Pathogens that were tested but not detected are colored green and preceded by a green minus sign **-**.
- 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.