September 2022

Important Note

NOTE: READ AND FOLLOW THE INSTRUCTIONS OF THIS LETTER BEFORE USING THE QIAstat-Dx Respiratory SARS-CoV-2 Panel with *Chlamydophila pneumoniae*.

Release of new QIAstat-Dx Respiratory SARS-CoV-2 Panel with *Chlamydophila pneumoniae*

Dear laboratory partner,

QIAGEN is dedicated to meeting the needs of our customers, and we continually strive to provide the best value in products and services. As such, we would like to inform you of the updated release of QIAstat-Dx Respiratory SARS-CoV-2 Panel (Cat. No. 691214, V2), which provides the additional target of *Chlamydophila pneumoniae* compared to the previous QIAstat-Dx Respiratory SARS-CoV-2 Panel version (Cat. No. 691214, V1). This updated version of the panel detects and differentiates 23 viral and bacterial targets for common pathogens causing respiratory tract infections. Importantly, this update includes the target of *Chlamydophila pneumoniae*, a type of bacteria that causes such respiratory tract infections such as Pneumonia. This bacteria causes illness by damaging the lining of the respiratory tract including the throat, windpipe, and lungs.

The QIAstat-Dx Respiratory SARS-CoV-2 Panel (Cat. No. 691214, V2) can be run on both the QIAstat-Dx Analyzer 1.0 (Cat. No. 9002824) and the recently released QIAstat-Dx Rise instrument (Cat. No. 9003163). The QIAstat-Dx Rise, with a random access capacity of up to 18 QIAstat-Dx SARS-CoV-2 Panel cartridges, can provide results for up to 56 samples in an eight-hour shift or 160 samples per day when using eight Analytical Modules. Building on the existing technology of the QIAstat-Dx Analyzer 1.0, which houses up to four Analytical Modules, the QIAstat-Dx Rise is a flexible new option for institutions that require increased testing capacity.

In order to use the new QIAstat-Dx Respiratory SARS-CoV-2 Panel with *Chlamydophila pneumoniae*, you will need to import the new QIAstat-Dx Respiratory SARS-CoV-2 Panel ADF version 3.1 onto your QIAstat-Dx Analyzer 1.0. The QIAstat-Dx Respiratory SARS-CoV-2 Panel with *Chlamydophila pneumoniae* ADF is compatible with the QIAstat-Dx Analyzer 1.0 running software version 1.3 and above, and with the QIAstat-Dx Rise running software version 2.2 or higher.

Important note: The new ADF version of the QIAstat-Dx SARS-CoV-2 panel, overrides the existing ADF in the QIAstat-Dx Analyzer. Any existing stock of the QIAstat-Dx SARS-CoV-2 Panel can be used with this ADF version and will have no changes in their reporting.

How to install QIAstat-Dx Respiratory SARS-CoV-2 Panel with *Chlamydophila pneumoniae* ADF Version 3.1 on your QIAstat-Dx Analyzer 1.0

The installation of the QIAstat-Dx Respiratory SARS-CoV-2 Panel ADF version 3.1 can be performed by customers. If you experience any issues during the update, please contact QIAGEN Technical Services at **support.qiagen.com**.

To install the QIAstat-Dx Respiratory SARS-CoV-2 Panel with *Chlamydophila pneumoniae* ADF version 3.1 on your QIAstat-Dx Analyzer 1.0, perform the following steps:

1. Request the ADF file from your QIAGEN sales representative or go to **https://www.qiagen.com/shop/automated-solutions/pcr-instruments/qiastat-dx/**
2. On the **Product Resources** tab, click on **Protocol Files** and download the QIAstat-Dx Respiratory SARS-CoV-2 Panel ADF version 3.10 file. Save and unzip the package. Copy the ***.asy** file to the root folder of the USB storage device (directly on the USB storage device, not in any folder).
3. Insert the USB storage device that contains the corresponding ADF into the USB port of the QIAstat-Dx Analyzer 1.0.
4. Press the **Options** button and then the **Assay Management** button. The Assay Management screen appears in the content area of the display.
5. Press the **Import** icon at the bottom left of the screen.
6. Select the ADF file to be imported from the USB storage device.
7. A dialog box will appear, and you will need to confirm the upload of the files.
8. A dialog box may then appear, which will ask you to overwrite the current version with the new one. Press **Yes** to confirm.
9. Select **Assay Active** to allow the assay to become active.
10. Assign the active assay to a user by pressing the **Options** button and then the **User Management** button.
11. Select the user who should be allowed to run the assay. Select **Assign Assays** from the **User Options**.
12. Enable the assay and press the **Save** button.

For additional information, refer to the instructions for use manual for the specific assay QIAstat-Dx Respiratory SARS-CoV-2 Panel (Cat. No. 691214, V2).

Thank you for your continued support of QIAGEN products and services. If you have questions regarding the points mentioned above, please do not hesitate to contact us via your QIAGEN sales representative or your local QIAGEN Technical Services at **support.qiagen.com**.

Sincerely,
Your QIAGEN team
www.qiagen.com

The QIAstat-Dx Analyzer 1.0, QIAstat-Dx Rise and QIAstat-Dx panels are intended for in vitro diagnostic use.