Important Note

NOTE: READ AND FOLLOW THE INSTRUCTIONS IN THIS LETTER BEFORE USING THE QIAstat-Dx SARS-CoV-2/Flu A/B/RSV PANEL.

QlAstat-Dx SARS-CoV-2/Flu A/B/RSV Panel Assay Definition File (ADF) Update to Version 1.1

Dear valued customer,

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 an Assay Definition File (ADF) update for the QIAstat-Dx SARS-CoV-2/Flu A/B/RSV Panel (Cat No. 691216).

This new ADF enables a new fluidic protocol to enhance testing reliability and mitigate Internal Control false negatives. Additionally, this new ADF enables the assay to be run at higher altitudes up to 3100 m above sea level. Customers are required to install this new ADF in their system before using the QIAstat-Dx SARS-CoV-2/Flu A/B/RSV Panel. This ADF update will not take longer than 1 minute.

In order to use the new ADF, you will need to import the QIAstat-Dx SARS-CoV-2/Flu A/B/RSVADF version 1.1 onto your QIAstat-Dx Analyzer 1.0. The QIAstat-Dx SARS-CoV-2/Flu A/B/RSV Panel ADF is compatible with the QIAstat-Dx Analyzer 1.0 running software version 1.3 and above.

How to update your QIAstat-Dx SARS-CoV-2/Flu A/B/RSV Panel ADF to Version 1.1

- The update to QIAstat-Dx SARS-CoV-2/Flu A/B/RSV Panel ADF version 1.1 can be performed by customers. If you experience any issues during the update, please contact QIAGEN Technical Services at support.giagen.com
- To update your QIAstat-Dx SARS-CoV-2/Flu A/B/RSV Panel ADF to version 1.1 and to import the updated version of the assay to your QIAstat-Dx Analyzer 1.0, perform the following steps:
 - Request for the ADF file from your QIAGEN sales representative or go to https://www.qiagen.com/shop/automated-solutions/pcr-instruments/qiastat-dx/
 - Under the Resources tab, click on Protocol Files and download The QIAstat-Dx SARS-CoV-2/Flu A/B/RSV Panel ADF version 1.1. 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 the user by pressing the **Options** button and then the **User Management** button.

Select the user who should be allowed to run the assay.

Select Assign Assays from the User Options.

Enable the assay and press the Save button.

For additional information, refer to the instructions for use manual for the specific assay (QIAstat-Dx SARS-CoV-2/Flu A/B/RSV Panel).

Please do not hesitate to contact us via your QIAGEN sales representative if you have any further questions regarding the abovementioned points.

Sincerely,

Your QIAGEN team www.qiagen.com