

Get ready to run QIAstat-Dx Respiratory SARS-CoV-2 Panel (cat. no. 691215, IVDR-compliant version)

How to install QIAstat-Dx Respiratory SARS-CoV-2 Panel (IVDR) ADF version 1.2 and later

Dear laboratory partner,

Thank you for your interest in installing the ADF to run the new QIAstat-Dx Respiratory SARS-CoV-2 Panel (IVDR) (cat. no. 691215). The minimum installation requirements are the following:

- **Instrument:** The QIAstat-Dx Respiratory SARS-CoV-2 Panel (IVDR) is a multiplexed nucleic acid test intended for use with the QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0 and QIAstat-Dx Rise.
- **Software version:**
 - For QIAstat-Dx Rise: At least two Analytical Modules must be inside for the machine to work with software version 2.4 or later.
 - For QIAstat-Dx Analyzer 1.0: At least one Operational Module and one Analytical Module is required for the instrument to work with software version 1.5.
 - For QIAstat-Dx Analyzer 2.0: At least one Operational Module PRO and one Analytical Module is required for the instrument to work with software version 1.6 or later.
- **Assay Definition File (ADF):** The QIAstat-Dx Respiratory SARS-CoV-2 Panel (IVDR) requires the ADF version 1.2 or later. You can find the latest version on [qiagen.com/resources](https://www.qiagen.com/resources).

In order to run the panel on your QIAstat-Dx instrument, you will need to import the QIAstat-Dx Respiratory SARS-CoV-2 Panel (IVDR) ADF version 1.2 or later onto your QIAstat-Dx Analyzer 1.0, QIAstat-Dx Analyzer 2.0 or QIAstat-Dx Rise.

How to upload QIAstat-Dx Respiratory SARS-CoV-2 Panel (IVDR) ADF version 1.2 or later

For QIAstat-Dx Rise: Please contact Technical Service or your sales representative to upload new ADFs.

For QIAstat-Dx Analyzer 1.0: Upload of QIAstat-Dx Respiratory SARS-CoV-2 Panel (IVDR) ADF version 1.2 or later can be performed by customers. If you experience any issues during the upload, please contact QIAGEN Technical Services at support.qiagen.com.

To import the latest version of the ADF to 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/product-categories/diagnostics-and-clinical-research/infectious-disease/qiastat-dx-syndromic-testing>.
2. Scroll down to the **Products** section and choose **QIAstat-Dx**.
3. On the **Resources** tab, click on **Protocol Files** and download the QIAstat-Dx Respiratory SARS-CoV-2 Panel (IVDR) ADF version 1.2. Save and unzip the package. Copy the *.asy file to the root folder of a USB storage device (directly on the USB storage device, not in any folder).
4. Insert the USB storage device that contains the corresponding ADF into the USB port of your QIAstat-Dx Analyzer 1.0.
5. Press the **Options** button and then the **Assay Management** button. The Assay Management screen appears in the content area of the display.
6. Press the **Import** icon at the bottom left of the screen.
7. Select the ADF file to be imported from the USB storage device.
8. A dialog box will appear, and you will need to confirm the upload of the files.

9. A dialog box may then appear, which will ask you to overwrite the older ADF version with the new one. Press **Yes** to confirm.
10. Select **Assay Active** to allow the assay to become active.
11. Assign the active assay to a 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 QIAstat-Dx Analyzer 2.0:

Upload of the QIAstat-Dx Respiratory SARS-CoV-2 Panel (IVDR) ADF version 1.2 and later can be performed by customers. If you experience any issues during the upload, please contact QIAGEN Technical Services at support.qiagen.com.

To import the latest version of the ADF to your QIAstat-Dx Analyzer 2.0, you can request the ADF file from your QIAGEN sales representative, download the ADF file directly from QIASphere onto your instrument, or download the ADF from QIAGEN website and save it to a USB storage device.

How to download the ADF from QIASphere:

1. From your QIAstat-Dx Analyzer 2.0, press the **Options** button and then the **Notifications** button.
2. You will receive a notification when a new version ADF is available for download. Confirm download of the ADF.
3. Press the **Import** icon at the bottom left of the screen.
4. Select the ADF file to be imported from QIASphere.
5. A dialog box will appear, and you will need to confirm the upload of the files.
6. A dialog box may then appear, which will ask you to overwrite the older ADF version with the new one. Press **Yes** to confirm.
7. Select **Assay Active** to allow the assay to become active for use.
8. Assign the active assay to a 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.

How to download the ADF from the QIAGEN website and install using a USB storage device:

Follow the same steps above on how to install the ADF on the QIAstat-Dx Analyzer 1.0.

This release confirms that no regression has been introduced in the transition from QIAstat-Dx Respiratory SARS-CoV-2 Panel (IVDD) to QIAstat-Dx Respiratory SARS-CoV-2 Panel (IVDR) as a result of recent updates. The test results demonstrate that both products continue to operate within their defined specifications and meet all established quality and stability criteria. No regression in functionality, performance or user experience has been observed compared to prior certified versions.

If you have any further questions regarding the above-mentioned points, please do not hesitate to contact us via your QIAGEN sales representative or your local QIAGEN Technical Services at support.qiagen.com.

Sincerely,
Your QIAstat-Dx Team
www.qiagen.com

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