Get ready to run QIAstat-Dx Gastrointestinal Panel 2 IVDR

How to upload QIAstat-Dx Gastrointestinal Panel 2 (IVDR) ADF version 1.0 or later

Dear laboratory partner,

Thank you for your interest in installing the ADF to run the new Gastrointestinal Panel 2 (IVDR). The minimum requirements are the following:

- **Instrument:** The QIAstat-Dx Gastrointestinal Panel 2 (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 2.2 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 1.4 or 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 Gastrointestinal Panel 2 (IVDR) requires the ADF version 1.0 or later. You can find the latest version on **www.qiagen.com/resources**.

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

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

For QIAstat-Dx Analyzer 1.0: Upload of the QIAstat-Dx Gastrointestinal Panel 2 (IVDR) ADF version 1.0 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 Gastrointestinal Panel 2 (IVDR) ADF version 1.0 or later. 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 Gastrointestinal Panel 2 (IVDR) ADF version 1.0 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 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 then the **Notifications** button.

2. You will receive a notification when a new version ADF is available for download. Press to download 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. Continue to step 8 on how to install ADF on the QIAstat-Dx Analyzer 1.0

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

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

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