

October 2025

Get ready to run QIAstat-Dx Meningitis/Encephalitis (ME) Panel (cat. no. 691612, IVDR-compliant version)

How to install QIAstat-Dx ME Panel IVDR ADF version 1.2 or later

Dear laboratory partner,

Thank you for your interest in installing the ADF to run the new QIAstat-Dx ME Panel (cat. no. 691612, IVDR-compliant version). The minimum requirements are the following:

- **Instrument:** The QIAstat-Dx ME Panel is a multiplexed nucleic acid test intended for use with the QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0.
- **Software version:**
 - For QIAstat-Dx Analyzer 1.0: At least one Operational Module and one Analytical Module are 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 are required for the instrument to work, with software version 1.6 or later.
- **Assay Definition File (ADF):** The new QIAstat-Dx ME Panel (cat. no. 691612, IVDR-compliant version) requires the QIAstat-Dx ME Panel IVDR ADF version 1.2 or later. You can find the latest version on [qiagen.com/resources](https://www.qiagen.com/resources). Please make sure to select the file that has “IVDR” in its name.

In order to run the panel on your instrument, you will need to install the QIAstat-Dx ME Panel IVDR ADF version 1.2 or later onto your QIAstat-Dx Analyzer 1.0 or QIAstat-Dx Analyzer 2.0.

How to install QIAstat-Dx ME Panel IVDR ADF version 1.2 or later

For QIAstat-Dx Analyzer 1.0: Upload of the QIAstat-Dx ME 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 QIAGEN Technical Services 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 ME Panel IVDR ADF version 1.2 or later. Make sure to select the file that has “IVDR” in its name. 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:

When a new version of the QIAstat-Dx ME Panel ADF becomes available, you will receive a notification directly on your instrument. Follow the instructions on the instrument screen to install the new ADF. If you experience any issues during the update, or would like additional information about the update notification system, please contact QIAGEN Technical Services at support.qiagen.com.

This release confirms that no regression has been introduced in the transition from QIAstat-Dx Respiratory ME Panel (IVDD) to QIAstat-Dx ME 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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