



May 2023

Important Note

It's time to update your QIAstat-Dx system Mandatory upgrade to QIAstat-Dx Meningitis/Encephalitis Panel ADF version 1.2

Dear laboratory partner,

Your satisfaction with the QIAstat-Dx system is our highest priority. That's why we're releasing an updated Assay Definition File (ADF) for the **QIAstat-Dx Meningitis/Encephalitis Panel** (QIAstat-Dx ME Panel, Cat No. 691611).

Please note that this mandatory update will only take 1 minute to complete.

This **mandatory update to ADF version 1.2** (V1.2) will change the LOINC codes associated with two QIAstat-Dx ME Panel targets, HSV1 and HSV2. This change will only affect HIS/LIS connectivity. Previously, both HSV1 and HSV2 shared the same LOINC code. This ADF update to V1.2 will now provide separate LOINC codes for HSV1 and HSV2. To review the LOINC code changes, please refer to the QIAstat-Dx LIS Interface Specification document for the QIAstat-Dx Meningitis/Encephalitis Panel. The LIS Interface Specification document can be provided by your sales representative.

In order to use the new ADF, you will need to import the QIAstat-Dx ME Panel ADF V1.2 onto your QIAstat-Dx Analyzer 1.0. The QIAstat-Dx ME Panel ADF V1.2 is compatible with the QIAstat-Dx Analyzer 1.0 running software version 1.4 and later.

How to update your QIAstat-Dx ME Panel ADF to version 1.2

The update to QIAstat-Dx ME Panel ADF V1.2 can be performed by customers. If you experience any issues during the update, please contact QIAGEN Technical Services at support.qiagen.com.

To update your QIAstat-Dx ME Panel ADF V1.2 and to import the updated version of the assay 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/shop/automated-solutions/pcr-instruments/qiastat-dx/>
2. On the **Resources** tab, click on **Protocol Files** and download the QIAstat-Dx ME Panel ADF V1.2. 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 ME Panel).

If you have any further questions regarding the abovementioned 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

The QIAstat-Dx Analyzer 1.0 is intended for in vitro diagnostic use.

The QIAstat-Dx ME Panel is indicated as an aid in the diagnosis of specific agents that cause meningitis and/or encephalitis, and results must be used in conjunction with other clinical, epidemiological, and laboratory data. Results from the QIAstat-Dx ME Panel are not intended to be used as the sole basis for diagnosis, treatment, or other patient management decisions. Positive results do not rule out co-infection with organisms not included in the QIAstat-Dx ME Panel. The agent or agents detected may not be the definite cause of the disease. Negative results do not preclude central nervous system (CNS) infection. The QIAstat-Dx ME Panel is intended for in vitro diagnostic use by laboratory professionals only.

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