

Importing Assay Definitions

Importing ADFs by CD or the Web
for GeneXpert[®] System with Touchscreen

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Importing Assay Definitions - English

This document explains how to import Assay Definition Files (ADFs) into the GeneXpert® System with Touchscreen.

This document is divided into 2 main sections. Select the appropriate section depending upon the mode of ADF access that you are using:

- Section 1 : Accessing ADFs.
- Section 2 : Importing ADFs on GeneXpert System with Touchscreen.

Important If your system is connected to an LIS or HIS network, you must update your host test codes (after the assay definition file installation), in order to download tests to the system and/or upload test results from the system to the LIS or HIS network. For instructions on updating host test codes, see your system operator manual.

1 Accessing ADFs

1.1 Web-based ADF Files

Note You must be logged in as an administrator to load assay definition files (ADFs). Make sure to log in as an administrator on your system before proceeding with the steps below.

To download the Assay Definition File (ADF) from the Cepheid website there are two options:

- If the GeneXpert system with touchscreen is *internet-connected*, use your touchscreen system to exit the kiosk mode and open a web browser.
 - If the GeneXpert system with touchscreen is *not internet-connected*, use a separate internet-capable computer to open a web browser.
1. Navigate to <https://www.cepheid.com/edoc>.
 2. Select an option under **Select Location/Territory**.
 3. Select an option for **Language**.
 4. Select the **Catalogue Number** for which you are downloading ADF files.
 5. Select the **System** used in your laboratory.
 6. Scroll down to the **ADF Files** section on the left side of the screen and click the ADF file to download.
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Important Be sure to extract the zipped files once you have downloaded them.

7. Copy the decompressed file to a secure folder on your touchscreen system or on an unencrypted USB flash drive if using a separate computer. If using a flash-drive, insert the flash drive (with the saved files) into the touchscreen system to prepare for ADF import. Follow your institution's approved IT policy when downloading ADFs.
8. Import the assay definitions following the procedure in Section 2 : Importing ADFs on GeneXpert System with Touchscreen.

1.2 CD-based ADF Files

CD Contents – The CD contains:

- Importing Assay Definitions document (this document)
- Assay Definition Files

The DVD drive provided with the system may also be used to import the assay definitions from the CD.

1. Locate the DVD drive. The DVD drive, supplied with the system, is shipped in the accessories box and is labeled as an item to save.

2. Plug the DVD drive into one of the available USB ports on the rear of the touchscreen.
3. Press the **Eject** button on the front of the DVD drive to open the door.
4. Insert the assay definitions CD into the DVD drive and close the DVD drive door. The green light on the front of the DVD drive will flash while the drive reads the CD.
5. The assay definitions CD is now ready for assay definition import. Import the assay definitions following the procedure in Section 2 for GeneXpert system with touchscreen.

2 Importing ADFs on GeneXpert System with Touchscreen

On GeneXpert system with touchscreen, you must import the assay definition files. Depending upon your preferences, you may also need to update your LIS test codes if the system is connected to an LIS (Laboratory Information System) or HIS (Hospital Information System).

Note Although *in vitro* diagnostic ADFs can be imported, the GeneXpert software does not allow the ADF to be modified.

To import assay definition files:

1. On the GeneXpert system with touchscreen, tap the **three dots** > **Settings** > **Test Menu**. See Figure 1 and Figure 2.

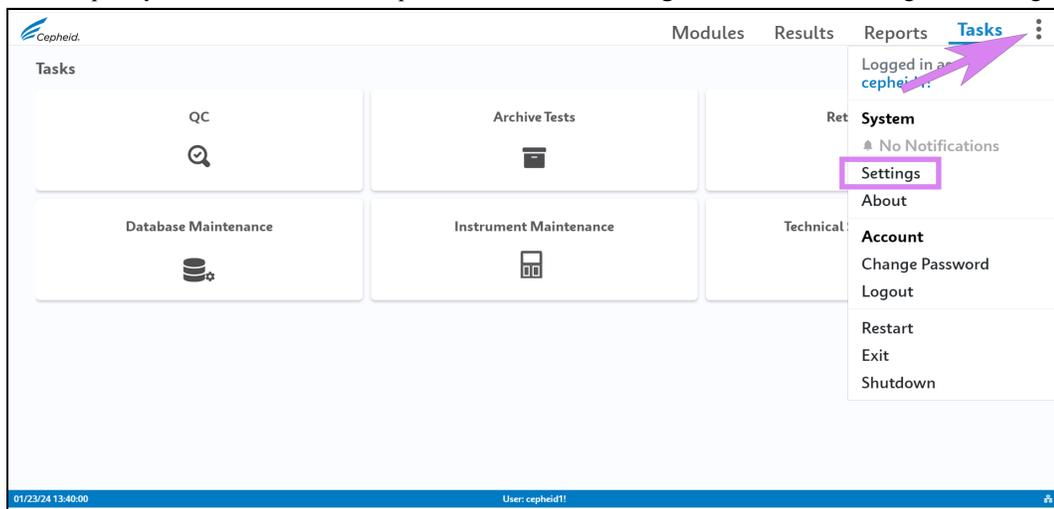


Figure 1. Settings Screen

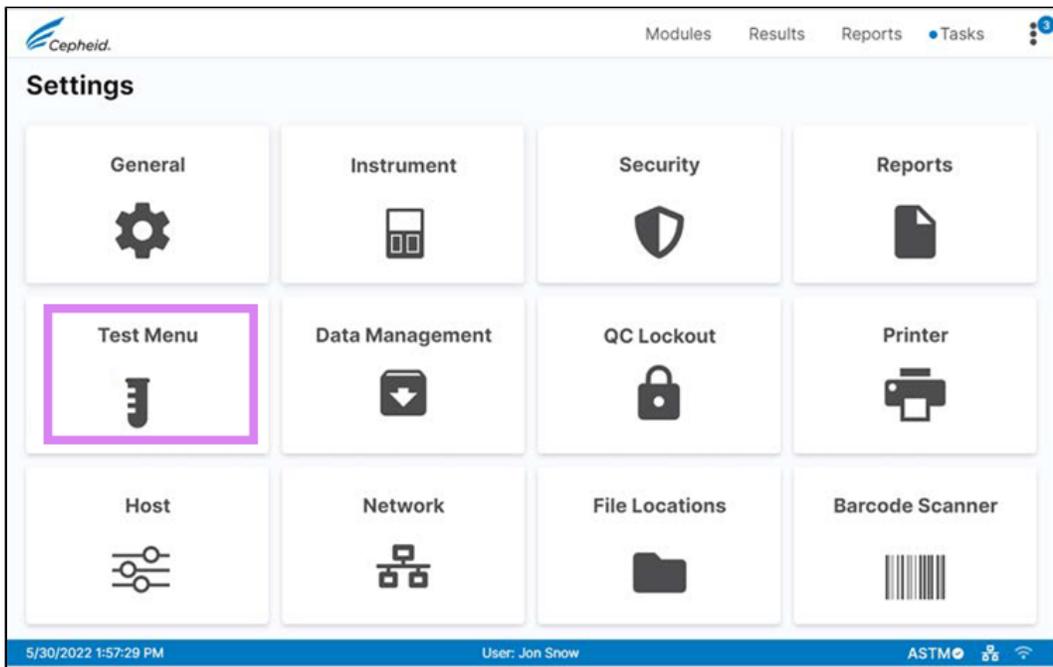


Figure 2. Test Menu

2. In the **Test Menu** screen, tap the **Import Test** button. See Figure 3.

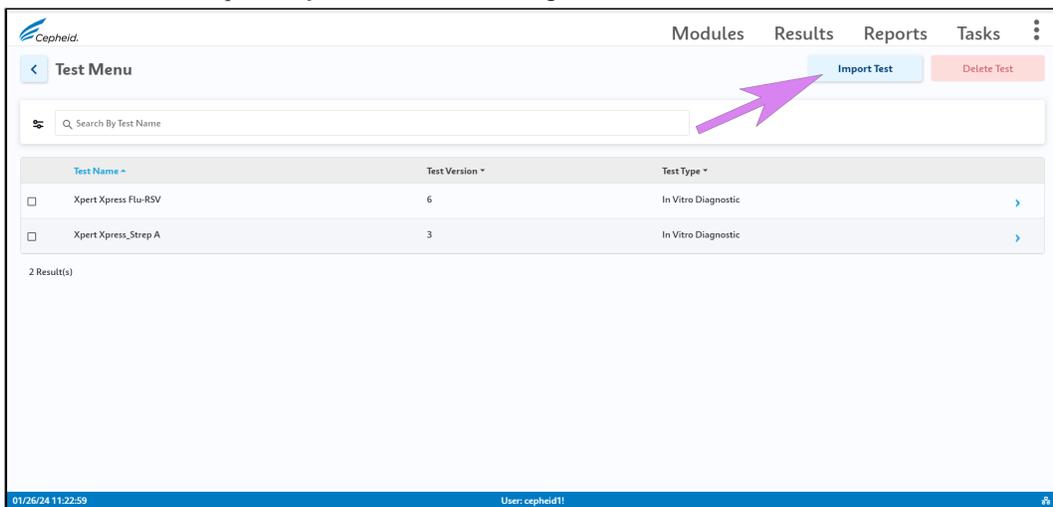


Figure 3. Test Menu Screen

3. Navigate to the folder containing the ADFs (*i.e.*, DVD drive if accessing ADF from a CD or extracted zipped files if downloading ADF from the web).
4. Locate and tap the ADF (.gxa/.nxa) file. The test name appears in the **File Name** field. See Figure 4 as an example. Tap **Open** to import the file into the system.

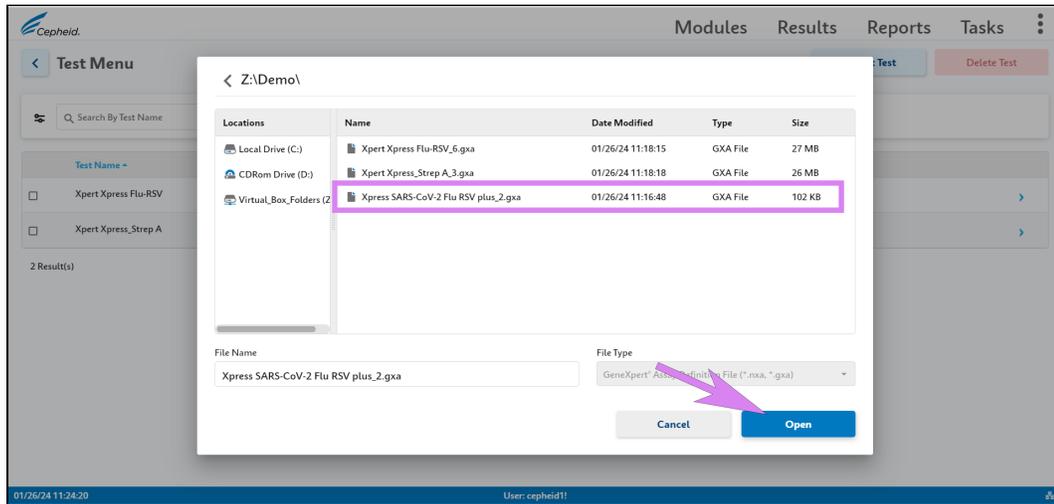


Figure 4. ADF Selected

The new test name and version number appears in the **Test Menu**. See Figure 5.

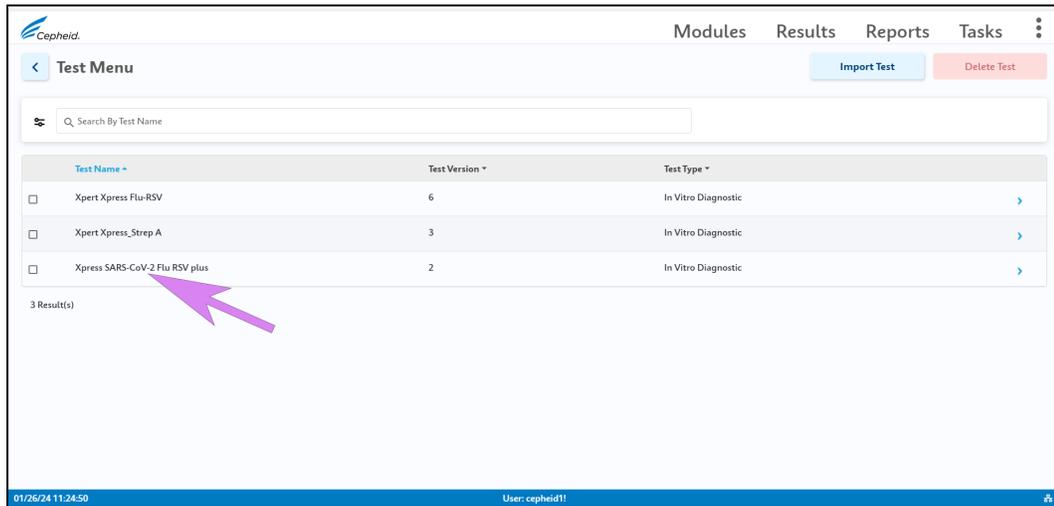


Figure 5. Test Menu showing Imported ADF

5. Check the test name and version number to verify that you have imported the correct assay definitions.
6. Some tests will offer multiple testing options. For example, the Xpert Xpress CoV-2/FLU/RSV *plus* test offers five testing options: 1.) Xpress SARS-CoV-2 Flu RSV plus, 2.) Xpress SARS-CoV-2 Flu plus, 3.) Xpress SARS-CoV-2 plus, 4.) Xpress Flu RSV plus, and 5.) Xpress Flu plus. A unique ADF is required for each testing option, as applicable. If you need to import additional assay definition files, repeat step 3 through step 5.

Note For combination assays that have multiple .gxa/.nxa files, import only the assay definition files that will be performed in your lab.

7. If using a CD, remove the CD from the DVD drive and store the CD in a safe location in the event it is needed in the future. Disconnect the DVD drive from the touchscreen and store it along with the associated cables in the event they are needed in the future.
8. After an ADF has been imported, if your system is connected to an LIS or HIS, for newly imported tests, you must update your host test code(s) in order to download orders to the GeneXpert system with touchscreen and/or upload test results from the GeneXpert system with touchscreen to the LIS or HIS network. For tests with an ADF revision update, confirm that the codes were transferred to the new assay definition file or update as needed based on screenshots. For instructions on updating host test codes, see Section 10.9 of the *GeneXpert System with Touchscreen Operator Manual*.

Cepheid recommends to always confirm that LIS or HIS uploaded results match GeneXpert results after any changes to the GeneXpert or host system, including, but not limited to, changes to the following:

- GeneXpert software version
 - Note** ● GeneXpert assay definition files and version
 - GeneXpert host communication settings
 - Host middleware software or configuration changes
 - LIS software or configuration changes
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