

Importing Assay Definitions

Importing ADFs by CD or the Web

IVD

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1 Importing Assay Definitions - English

This document explains how to import Assay Definition Files (ADFs) into the GeneXpert® Dx Systems and the GeneXpert® Infinity Systems.

Select the appropriate section depending upon the mode of ADF access and the model of system that you are using:

- Section 2: Accessing ADFs from the Cepheid Website or from the ADF Kit CD.
- Section 3: Importing ADFs on GeneXpert Dx Systems.
- Section 4: Importing ADFs on GeneXpert Infinity-48s and GeneXpert Infinity-80 Systems.

Important When performing an ADF update for a test on current test menu, take screenshots of LIS or HIS Host Test codes for all applicable ADFs and ensure after ADF update, the codes carried over to the new ADF. If codes did not carry over, enter the test codes as shown on the screenshots taken for earlier version.

2 Accessing ADFs from the Cepheid Website or from the ADF Kit CD

2.1 Web-based ADF Files

Download the Assay Definition File (ADF) from the Cepheid Website. With an Internet capable computer, navigate to: <https://www.cephheid.com/edoc>.

1. Select an option under **Select Location/Territory**.
2. Select an option for **Language**.
3. Select the **Catalogue Number** for which you are downloading ADF files.
4. Select the **System** used in your laboratory.
5. Scroll down to the **ADF Files** section on the left side of the screen and click the ADF file to download.

Important When using Windows, be sure to extract the zipped files once you have downloaded them.

6. Copy the file to a secure folder from where it can be retrieved based on your institutions approved IT policy.

2.2 CD-based ADF Files

CD Contents – The CD contains the following:

- Importing Assay Definitions document (this document)
- Assay Definition Files for both GeneXpert Dx and Infinity Systems

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

For **GeneXpert® Dx Systems**, insert the assay definition CD into the computer's DVD drive. Skip Step 1 through Step 3 below for GeneXpert Dx Systems.

For **GeneXpert Infinity Systems**, the DVD drive must be plugged into the USB connectors on the side of the monitor.

To plug in the DVD drive and load the assay definition file CD:

1. Locate the DVD drive. The drive is supplied with the system, but customers decide where to store the DVD drive. It may be located on the shelf above the waste container. Contact your lab manager if you cannot locate the DVD drive. The DVD drive supplied is shown in Figure 1.



Figure 1. DVD Drive Supplied with GeneXpert Infinity Systems

2. Place the DVD drive on the kiosk top.
3. On the side of the monitor, locate the two USB connectors and plug both DVD drive connectors into the two USB connectors on the side of the monitor. See Figure 2.

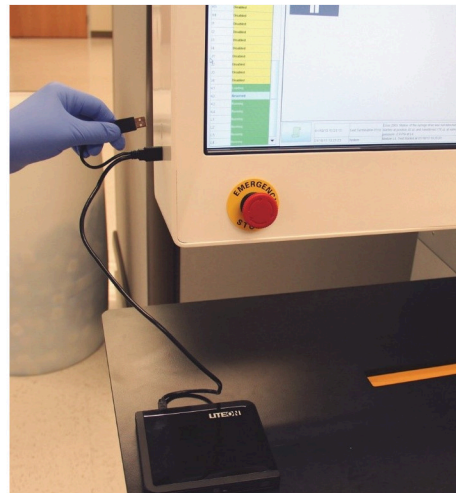
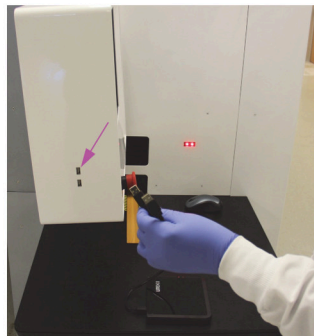


Figure 2. Plugging in the DVD Drive (GeneXpert Infinity only)

4. Press the Eject button on the front of the DVD drive to open the door.
5. 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 DVD. See Figure 3.

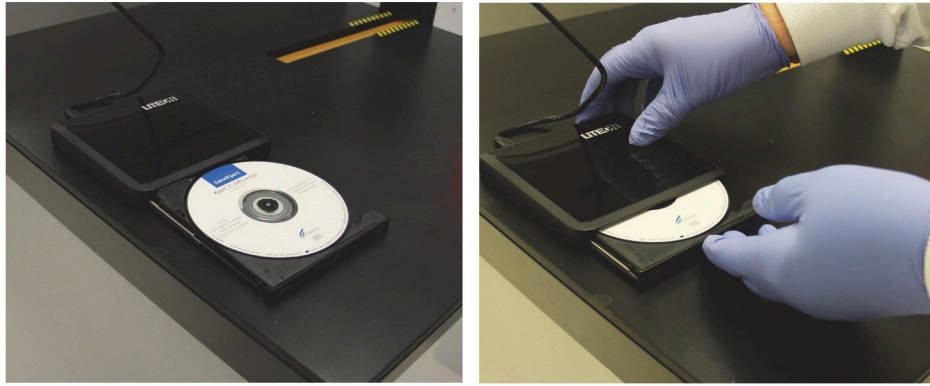


Figure 3. Inserting the Assay Definitions CD into the DVD Drive

6. This completes the installation of the DVD drive and the assay definitions CD. Import the assay definitions following the procedure in *Importing ADFs on GeneXpert Dx Systems* and *Importing ADFs on GeneXpert Infinity-48s and GeneXpert Infinity-80 Systems*.

3 Importing ADFs on GeneXpert Dx Systems

On GeneXpert Dx Systems, 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 Screenshots shown in this section are Windows® 7 screenshots. Windows XP and Windows 10 screens will be very similar.

Note Although you can import assay definitions, the GeneXpert Dx software does not allow you to modify the assay definitions.

To import assay definition files:

1. In the **GeneXpert Dx System** window, click **Define Assays**. See Figure 4.

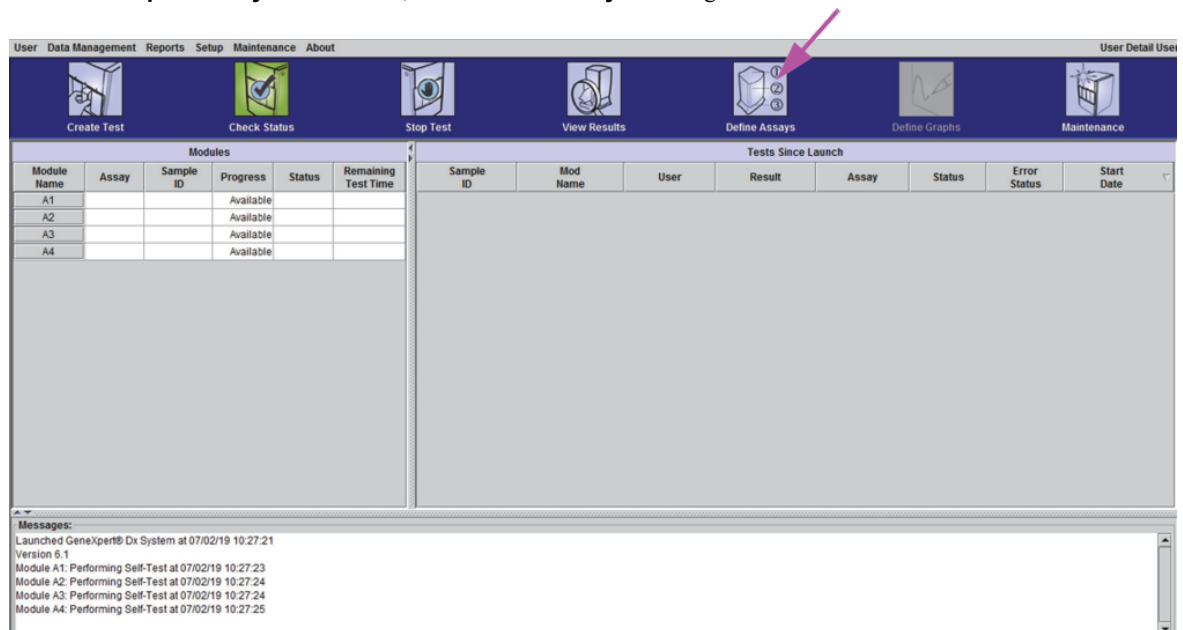


Figure 4. GeneXpert Dx System Window

The **Define Assays** window appears. See Figure 5.

3 Importing ADFs on GeneXpert Dx Systems

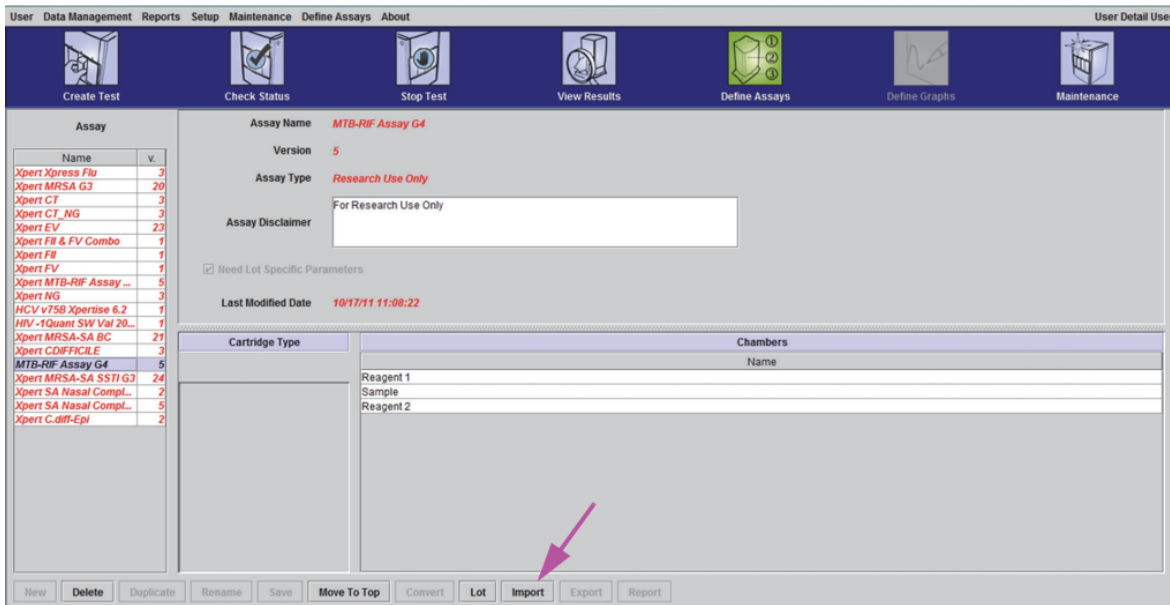


Figure 5. GeneXpert Define Assays Window

2. Click **Import**.

The **Import Assay dialog** box appears. See Figure 6.

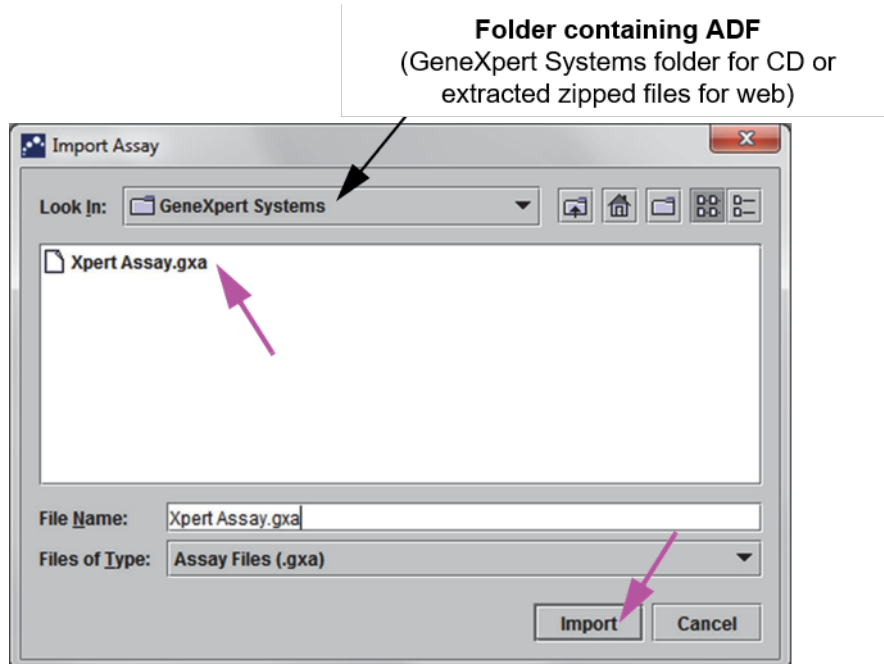


Figure 6. Import Assay Dialog Box (Dx)

3. Under the **Look In:** drop-down, select the folder containing ADF (i.e., GeneXpert Systems folder if accessing ADF from a CD or extracted zipped files if downloading ADF from the web).
4. Under the file directory, select the folder containing the ADF to view the list of assay definition files applicable to the GeneXpert Dx software.

5. Select the assay definition (.gxa/.nxa) file inside the folder containing the ADF, then click the **Import** button on the Import Assay dialog box. The new assay name and version number will appear in the assay list (on the left side of the **Define Assays** window) and the details about the assay will appear to the right of the list. See Figure 5.
6. Check the assay name and version number to verify that you have imported the correct assay definitions.
7. If you need to import additional assay definition files, repeat Step 5 through Step 6.

Note

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

8. 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.
9. **(Optional)** 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 Dx System and/or upload test results from the GeneXpert Dx System to the LIS or HIS network. For tests with an ADF revision update, please confirm that the codes were transferred to new assay definition file or update as needed based on screenshots. For instructions on updating host test codes, see Chapter 5 of the *GeneXpert Dx System 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
-

4 Importing ADFs on GeneXpert Infinity-48s and GeneXpert Infinity-80 Systems

On GeneXpert Infinity-48s and GeneXpert Infinity-80 systems, 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 you can import assay definitions, the GeneXpert Dx software does not allow you to modify the assay definitions.

To import assay definition files:

1. In the Xpertise software, click the **Home** icon to display the **Xpertise Software Home** workspace. See Figure 7.

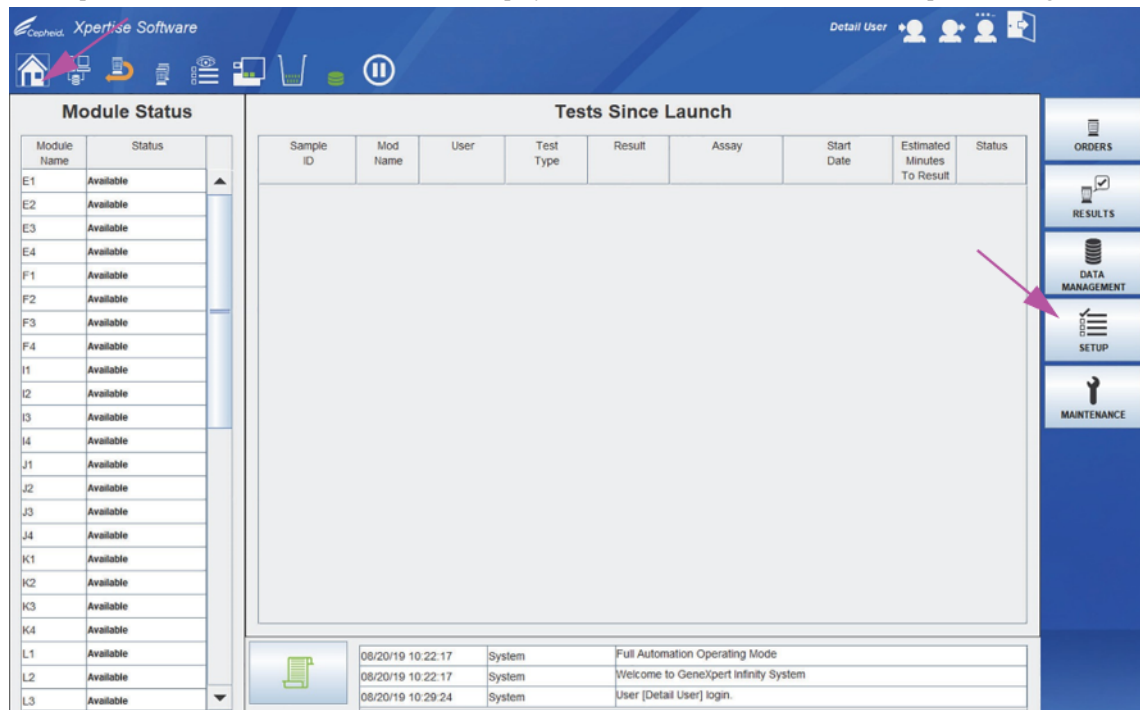


Figure 7. Xpertise Software Home Workspace

2. Press the **SETUP** button.
The **Setup** menu is displayed. See Figure 8.

4 Importing ADFs on GeneXpert Infinity-48s and GeneXpert Infinity-80 Systems

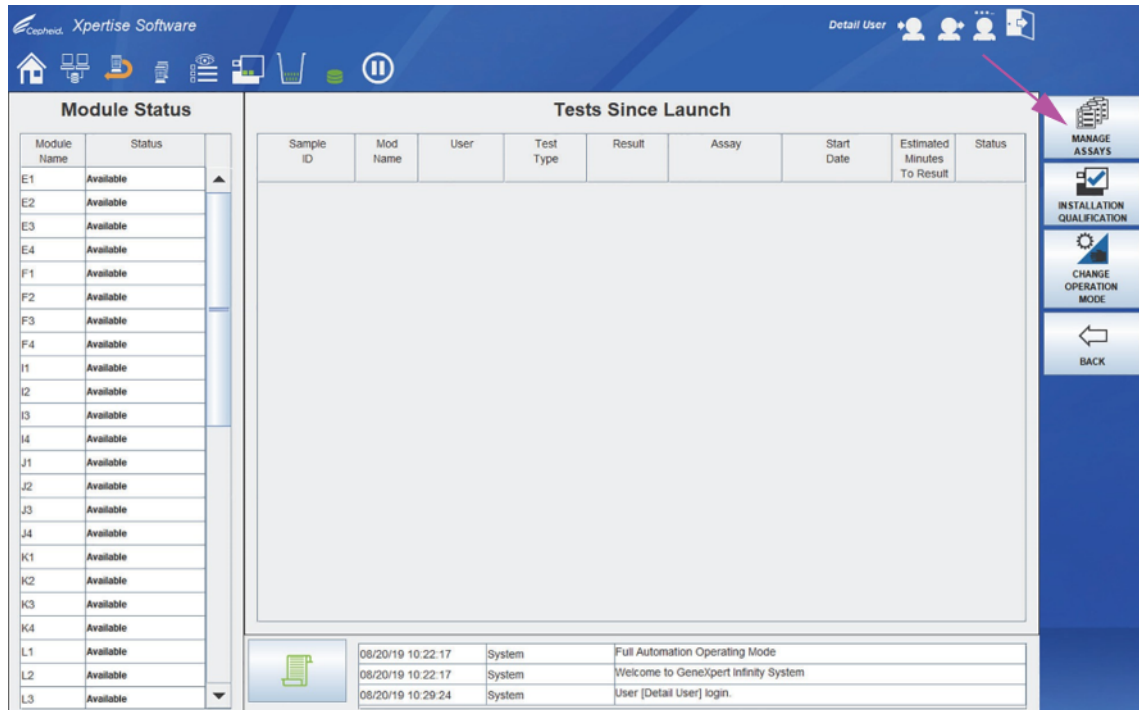


Figure 8. Setup Menu

3. Press the **MANAGE ASSAY** button.
The **Manage Assays** workspace is displayed, showing the list of assays previously imported. See Figure 9.

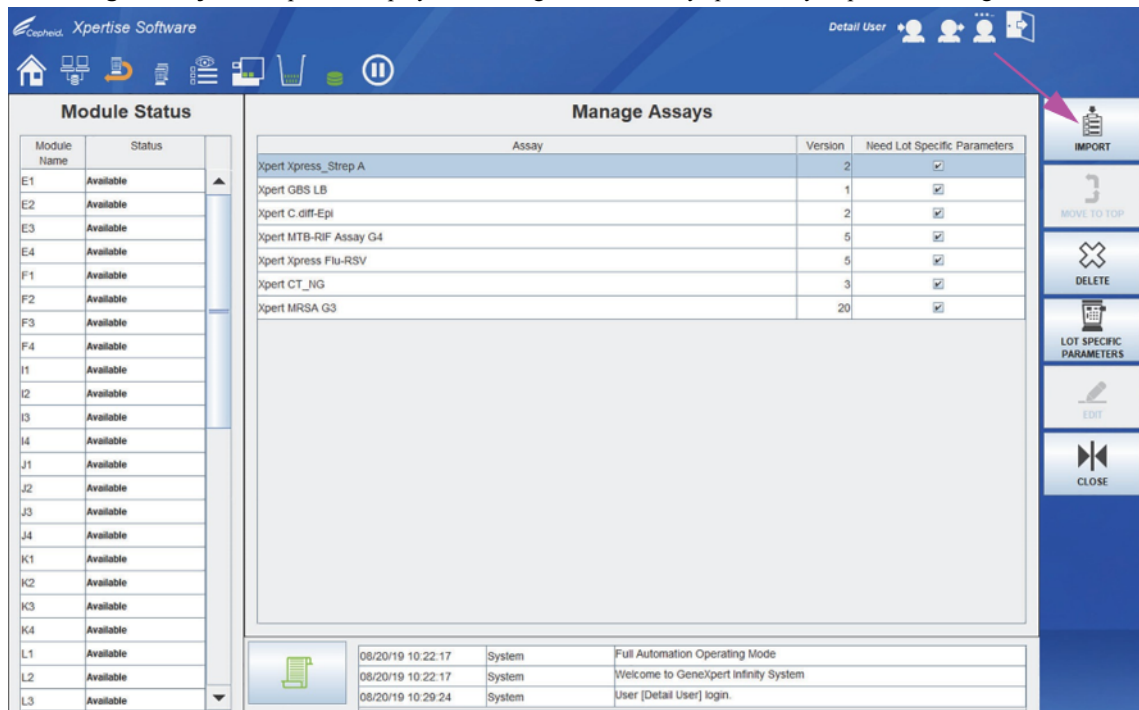


Figure 9. Xpert Manage Assays Workspace

4. Click **IMPORT**.
The **Import Assay** dialog box appears. See Figure 10.

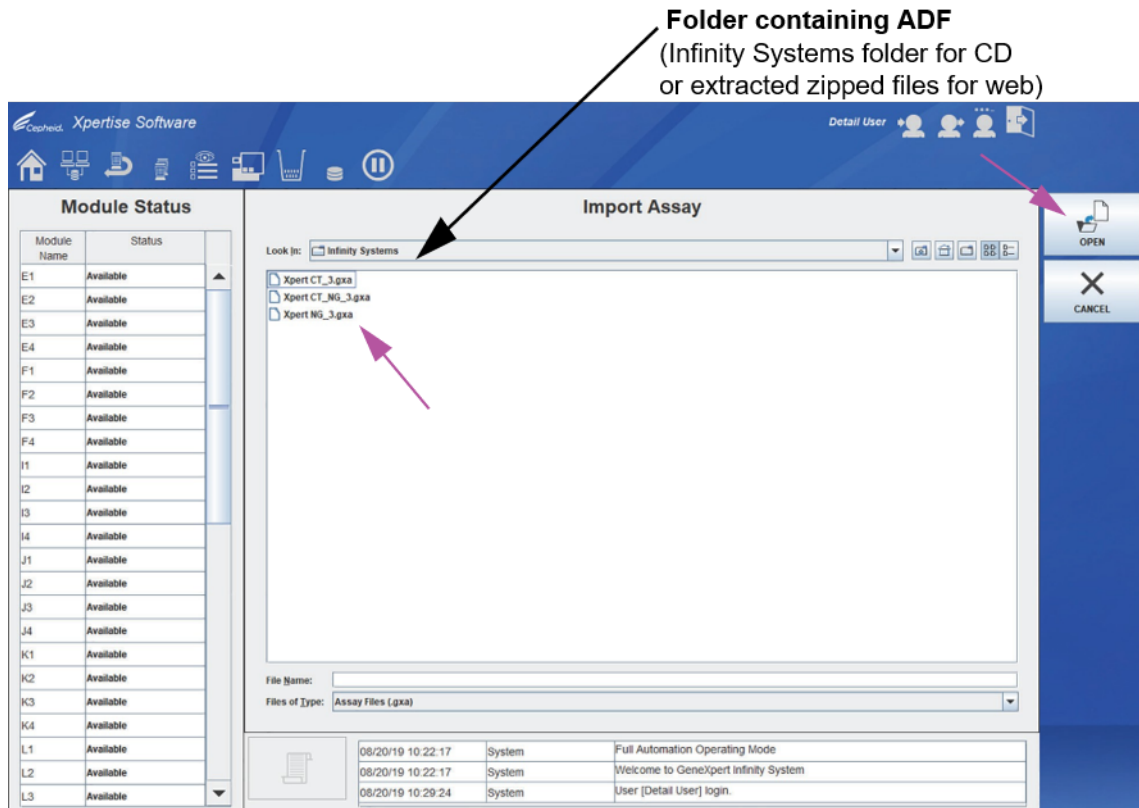


Figure 10. Import Assay Dialog Box (Infinity)

5. Under the **Look In:** drop-down, select the folder containing ADF (i.e., Infinity Systems folder if accessing ADF from a CD or extracted zipped files if downloading ADF from the web). Under the ADF directory, select the folder containing the ADF to view the list of assay definition files applicable to the Xpertise software. See Figure 10.
6. Select the assay definition (.gxa/.nxa) file, then click the **OPEN** button. The new assay name and version number will appear in the assay list in the Manage Assays workspace. Check the assay name and version number to verify that you have imported the correct assay definitions. See Figure 9.
7. If you need to import additional assay definition files, repeat Step 1 through Step 6.

Note

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

8. 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 USB port connectors and store the DVD drive for future use.
9. **(Optional)** You can configure the automation to retain cartridges for this assay for specific conditions, see Chapter 2 of the *GeneXpert Infinity System Operator Manual*.
10. **(Optional)** If your system is connected to an LIS or HIS network, you must update your host test code(s) in order to download orders to the GeneXpert Infinity System to the LIS or HIS network. For tests with an ADF revision update, please confirm that the codes were transferred to new assay definition file or update as needed based on screenshots. For instructions on updating host test codes, see Chapter 5 of the *GeneXpert Infinity System 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