GeneXpert®

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ADF Import Instructions

Importing ADFs by CD or the Web

IVD

Cepheid®

In Vitro Diagnostic Medical Device

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ADF Import Instructions

1 Before You Begin

This document explains how to import an Assay Definition File (ADF) into the GeneXpert® System with Touchscreen, GeneXpert® Hub Systems, GeneXpert Tablet, GeneXpert® Dx Systems and the GeneXpert® Infinity Systems. To perform the procedure, use the assay definition from the CD provided or the Cepheid website.

2 Importing Downloaded Assay Definition Files

This document explains how to import assay definitions for:

- GeneXpert® System with Touchscreen
- GeneXpert® Xpress Hub System
- GeneXpert® Xpress Tablet System
- GeneXpert® Dx System
- GeneXpert® Infinity-48s and Infinity-80 systems.

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

This guide is divided into two main sections. Select the appropriate section depending upon how you will be importing the assay definition files for the system you are using:

- For importing assay definitions by the Cepheid Website, see Section 3, For Web-based ADFs.
- For importing assay definitions using the CD provided, See Section 4, Importing Assay Definitions by CD.

3 For Web-based ADFs

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

   a. Select an option under **Select Location/Territory**.
   b. Select an option for **Language**.
   c. Select the **Catalogue Number** for which you are downloading ADF files.
   d. Select the **System** used in your laboratory.
   e. Scroll down to the **ADF Files** section on the left side of the screen and click the ADF file to download.

Important Screenshots in this document use Xpert Xpress SARS CoV-2/Flu/RSV or Xpert Xpress Flu as an example. The Xpert Xpress SARS CoV-2/Flu/RSV and Xpert Xpress Flu tests may not be available for download on the https://www.cepheid.com/edoc website. Product names and file names will be different depending on the product.
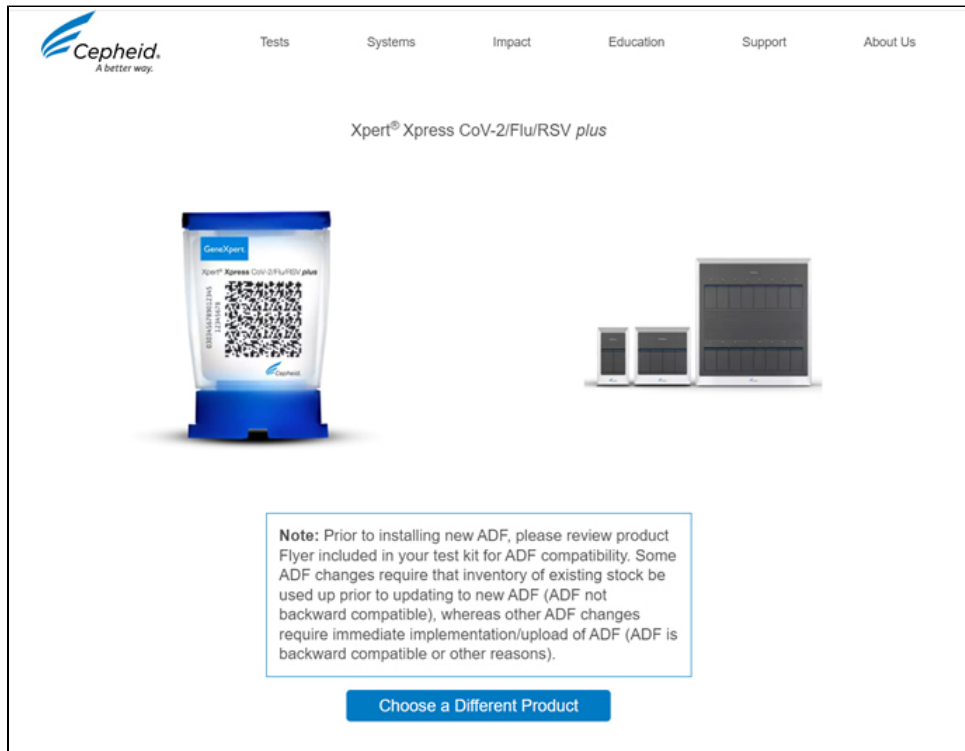
Important	**When using Windows, be sure to extract the zipped files once you have downloaded them.**

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

Important	**Some assays will offer multiple testing options. For example, the Xpert Xpress SARS-CoV-2/FLU/RSV assay offers three testing options: 1.) Xpert Xpress SARS-CoV-2/Flu/RSV, 2.) XpertXpress SARS-CoV-2/FLU, and 3.) Xpert Xpress SARS-CoV-2 only. A unique ADF is required for each testing option, as applicable. Please ensure that all ADF files are downloaded to the GeneXpert instrument.**

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.**

3.1 Identifying Your GeneXpert System

This chapter is divided into four sections. Select the appropriate section depending upon the configuration of the system you are using:

- Section 3.3, Importing Assay Definition Files on GeneXpert System with Touchscreen or GeneXpert Xpress System - Hub Configuration
- Section 3.4, Importing Assay Definition Files on GeneXpert Xpress System - Tablet Configuration
- Section 3.5, Importing Assay Definition Files on GeneXpert Dx Systems
- Section 3.6, Importing Assay Definition Files on GeneXpert Infinity-48s and Infinity-80 Systems

Figure 1. GeneXpert Systems

3.2 Importing Assay Definition Files on GeneXpert System with Touchscreen

1. To import new assay definition files, ensure you are logged in as an administrator, then touch the **Settings > Test Menu**.
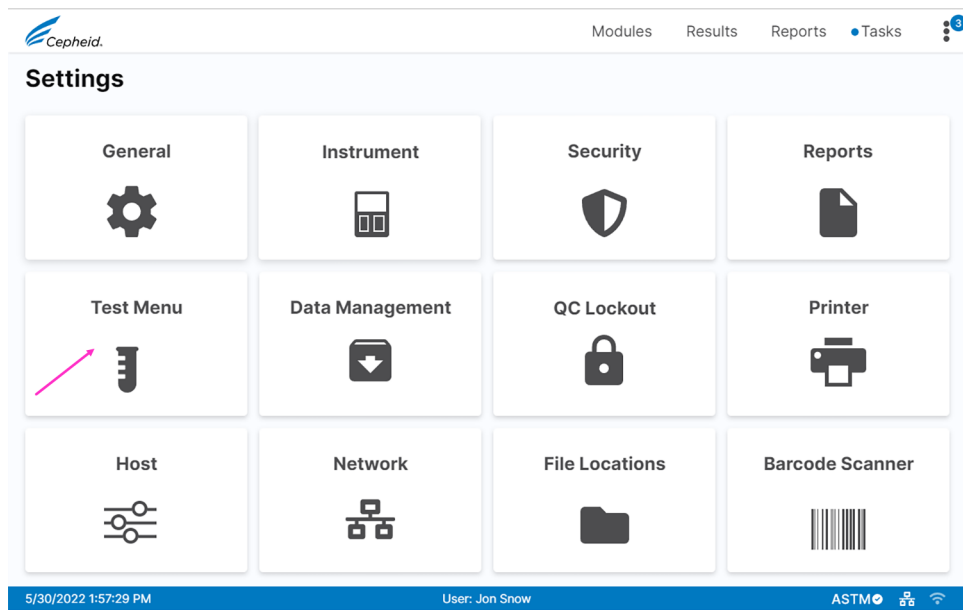

Figure 2. Settings Screen

2. The **Test Menu** screen appears (see Figure 3). To import an assay into the system, touch the **Import Test** button.
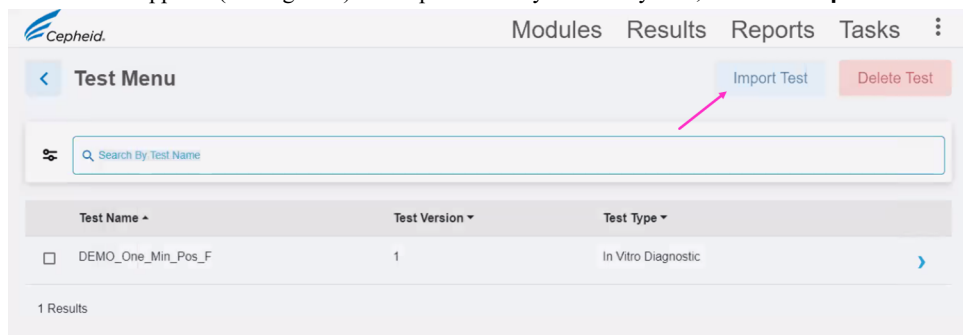

Figure 3. Test Menu Screen, showing the Import Test Function

3. Navigate to the to the folder containing ADF files. A screen appears where you will locate the assay definition file to be imported. Locate and touch the assay definition (.gxa) file (see Figure 4). The graphics show below are an example. Check the assay name and version number to make sure the correct ADF is being imported.
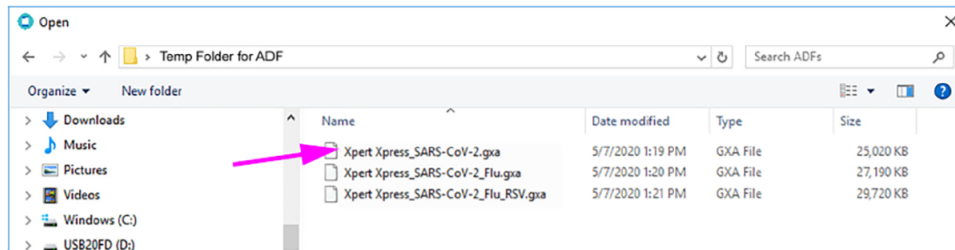
Figure 4. File Screen showing the ADF to be imported

4. The assay name appears in the file name field (see Figure 5). Touch **Open** to import the file into the system.
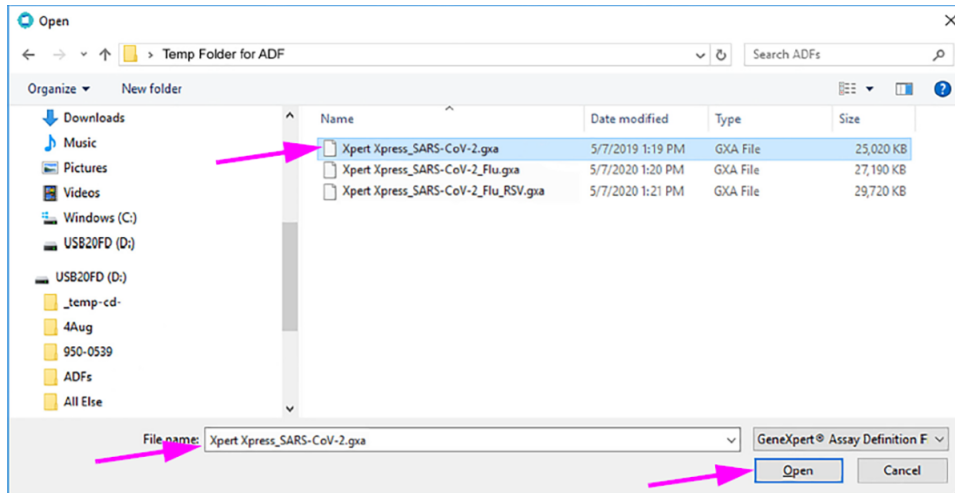

Figure 5. File Screen showing the ADF to be Imported

5. The new assay name and version number appear in the Assay list.
6. Repeat Step 1 - 4 to import additional ADF files, if applicable.
7. Check the assay name and version number to make sure the correct assay definition has been imported.
8. After the ADF has been imported correctly, delete the temporary folder you created on the desktop.

3.3 Importing Assay Definition Files on GeneXpert Xpress System -Hub Configuration

1. To import new assay definitions, ensure you are logged in as an administrator, then touch the **MANAGE ASSAYS** button on the **ADMIN** screen (see Figure 6).
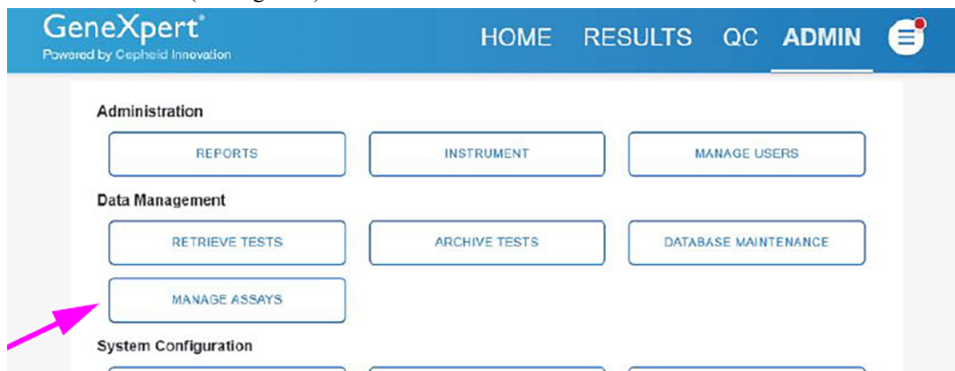

Figure 6. ADMIN Screen

2. The **Manage Assays** screen appears (see Figure 7). To import an assay into the system, touch the **IMPORT ASSAY** button.
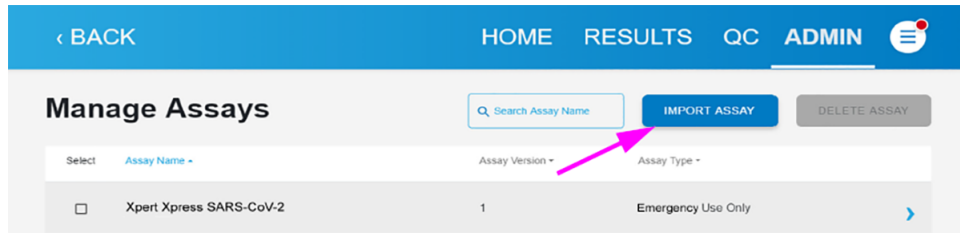
Figure 7. Manage Assays Screen, showing the Import Assay Function

3. Navigate to the to the folder containing ADF files. A screen appears where you will locate the assay definition file to be imported. Locate and touch the assay definition (.gxa) file (see Figure 8). The graphics show below are an example. Check the assay name and version number to make sure the correct ADF is being imported.
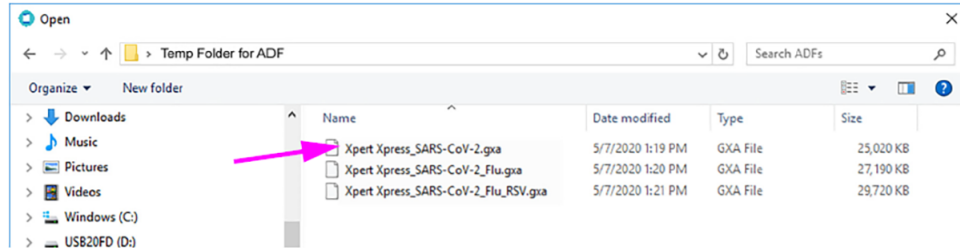

Figure 8. File Screen showing the ADF to be imported

4. The assay name appears in the file name field (see Figure 9). Touch **Open** to import the file into the system.
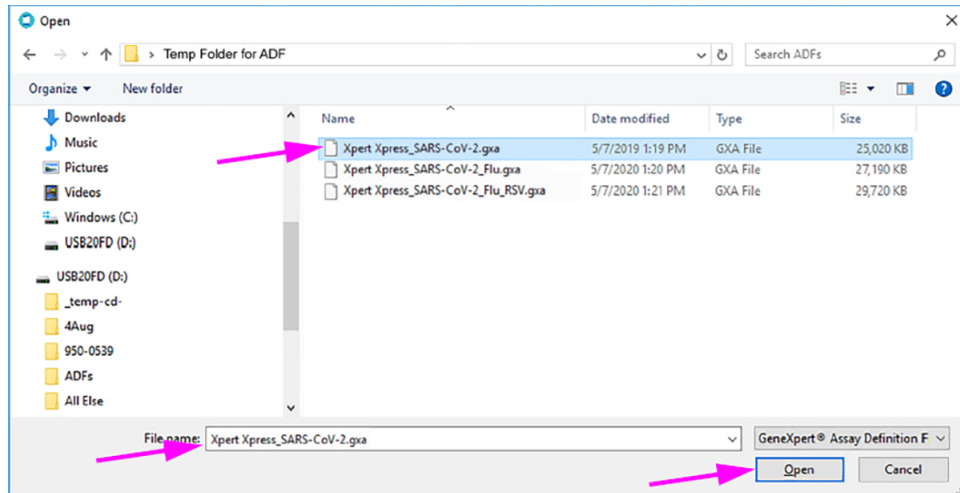

Figure 9. File Screen showing the ADF to be Imported

5. The new assay name and version number appear in the Assay list.
6. Repeat Step 1 - 4 to import additional ADF files, if applicable.
7. Check the assay name and version number to make sure the correct assay definition has been imported.
8. After the ADF has been imported correctly, delete the temporary folder you created on the desktop.

3.4 Importing Assay Definition Files on GeneXpert Xpress System - Tablet Configuration

1. Log in of the GeneXpert Xpress software.
2. Start the GeneXpert Dx software. Ensure you are logged in as an administrator.
3. In the GeneXpert Dx System window, select **Define Assays** on the menu bar. The **Define Assays** window displays (see Figure 10). Select **Import**.
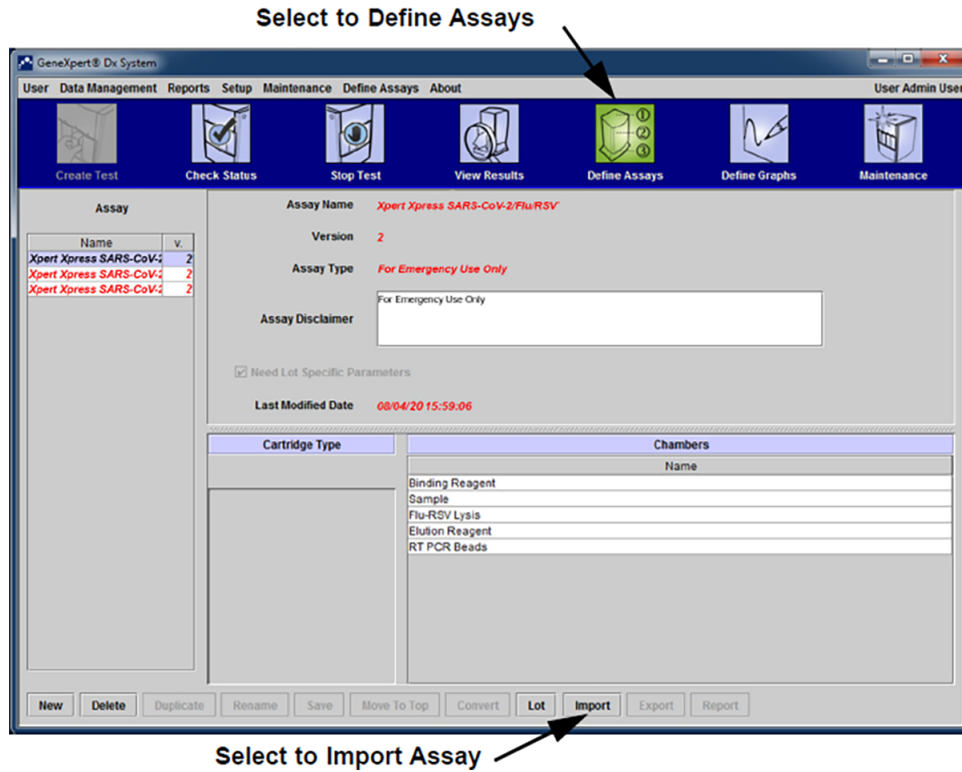
Figure 10. System - Define Assays Window (Administration User View)

4. The **Import Assay** dialog box displays (see Figure 11).
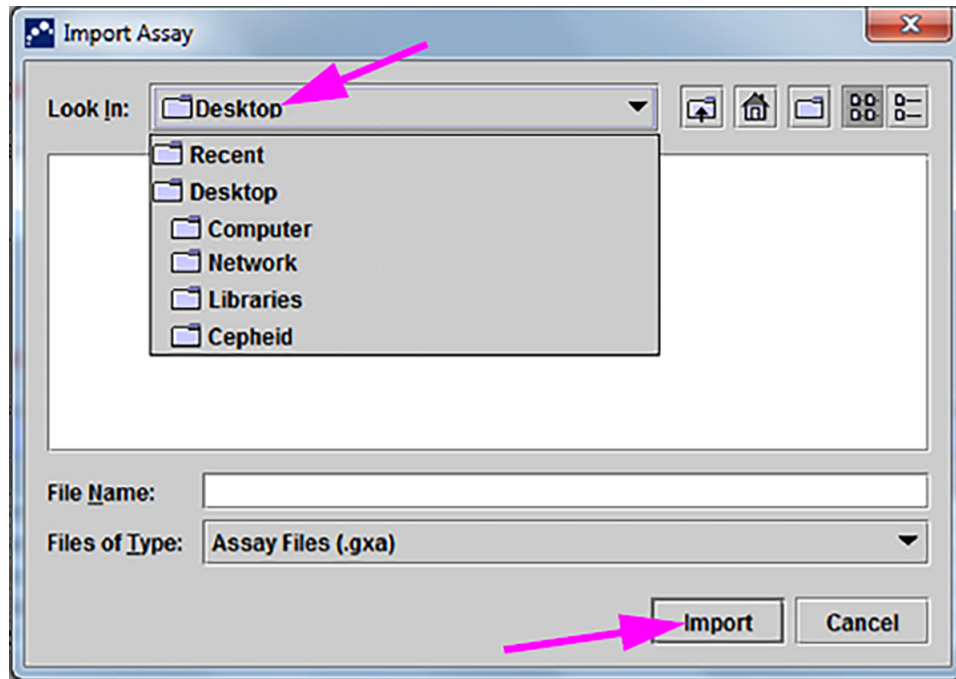

Figure 11. Import Assay Dialog Box

5. Navigate to the temporary folder you created. Locate and select the assay definition (.gxa) file, and then select **Import**. The new assay name and version number appear in the Assay list (on the left side of the window) and details about the assay appear to the right of the list.

6. Repeat Step 1 - 5 to import additional ADF files, if applicable.

7. Check the assay name and version number to make sure the correct assay definition has been imported.

8. After the ADF has been imported correctly, close the GeneXpert Dx software.

9. Delete the temporary folder you created on the desktop.
10. Restart the GeneXpert Xpress software.

3.5 Importing Assay Definition Files on GeneXpert Dx Systems

1. In the GeneXpert Dx System window, click **Define Assays**(see Figure 12). The **Define Assays** window appears. (See Figure 13).
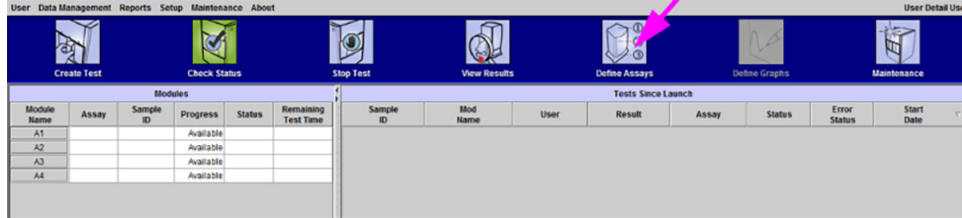

Figure 12. GeneXpert Dx System Window

2. In the **Define Assays** window, click **Import**. The Import Assay dialog box appears (see Section 3.5).
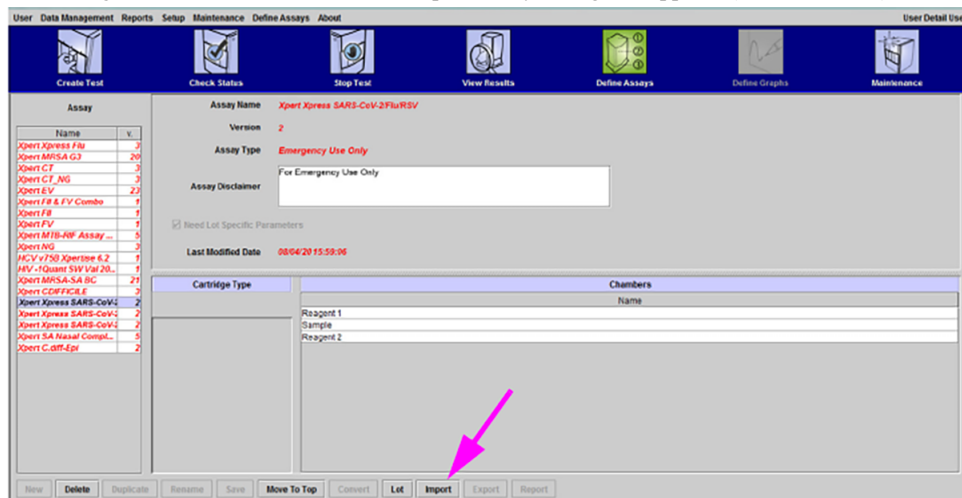

Figure 13. GeneXpert Define Assays Window

3. Under the **Look in:** drop-down, select the desktop. (See Figure 14). Select the temporary folder you created to view the list of ADFs available.
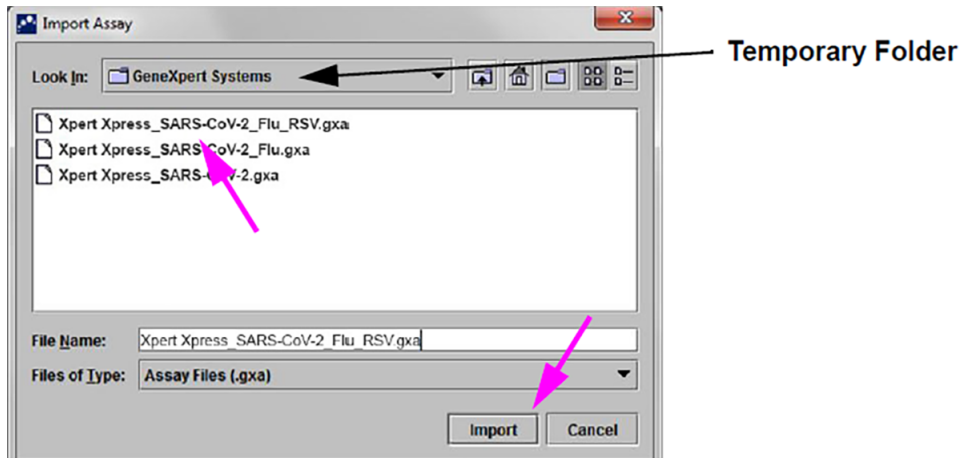

Figure 14. Import Assay Dialog Box

4. Select the assay definition (.gxa) file inside the temporary folder then click the **Import** button on the Import Assay dialog box (see Figure 14).

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 appears to the right of the list as shown in Figure 13.

5. Repeat Step 1 - 4 to import additional ADF files, if applicable.

6. Check the assay name and version number to verify that you have imported the correct assay definitions.

7. After the ADF has been imported correctly, delete the temporary folder you created on the desktop.

3.6 Importing Assay Definition Files on GeneXpert Infinity-48s and Infinity-80 Systems

1. In the Xpertise software, press the **Home** icon to display the Xpertise Software Homework space (see Figure 15).
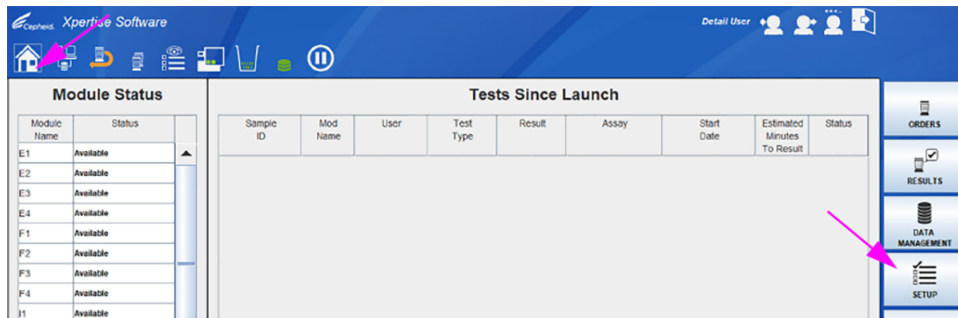

Figure 15. Xpertise Software Home Workspace

2. In the Xpertise Software Home workspace, press the **SETUP** button. The Setup menu is displayed (see Figure 16).
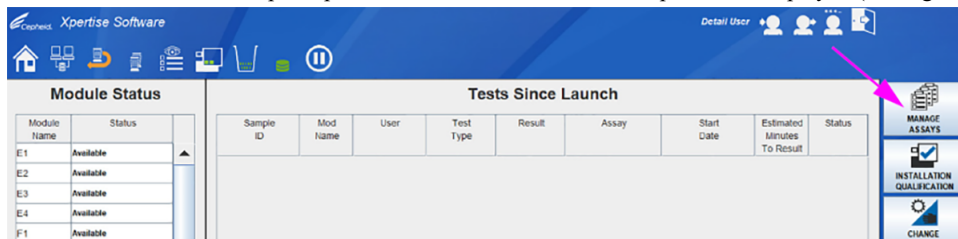

Figure 16. Setup Menu

3. In the Setup menu, press the **MANAGE ASSAYS** button. The Manage Assays workspace is displayed showing the list of assays previously imported (see Figure 17).
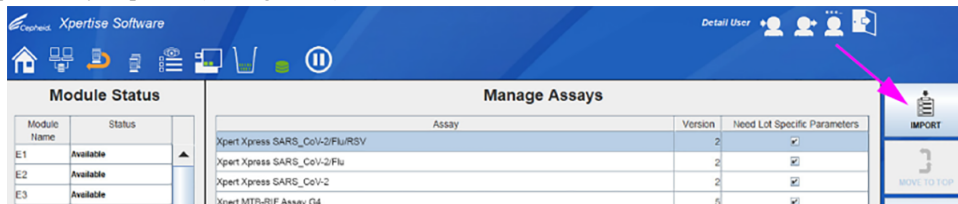

Figure 17. Xpertise Manage Assays Workspace

4. In the Manage Assays workspace, click **IMPORT**. The Import Assay dialog box appears (see Figure 18).
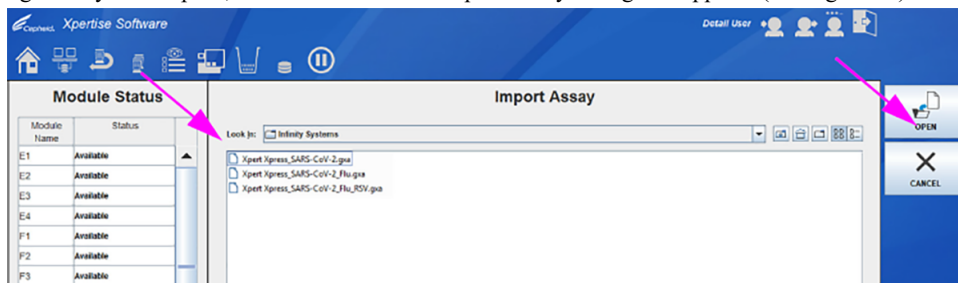

Figure 18. Import Assay Dialog Box

5. Under **Look in**, navigate to the temporary folder to view the list of ADFs applicable to the Xpertise software (see Figure 18).

6. Select the assay definition (.gxa) file, then click the **OPEN** button. See Figure 18.

   The new assay name and version number will appear in the assay list in the Manage Assays workspace (see Figure 13). Check the assay name and version number to verify that you have imported the correct assay definitions.

7. Repeat Step 1 - 4 to import additional ADF files, if applicable.

8. Check the assay name and version number to make sure the correct assay definition has been imported.

9. After the ADF has been imported correctly, delete the temporary folder you created on the desktop.

Note After an assay has been imported, if you would like to configure the automation to retain cartridges for this assay for specific conditions, reference your *GeneXpert Infinity System Operator Manual*.

4 Importing Assay Definitions by CD

An assay definition contains a series of programmed steps that the GeneXpert systems uses to perform sample preparation, amplification and detection procedures. *In vitro* diagnostic assay definition (.gxa/.nxa) files are included on the CD and imported into the software as described in this section. Assay definitions that are no longer in use can also be deleted. Although you can import assay definitions, the GeneXpert Dx software does not allow you to modify the assay definitions.

Cepheid recommends confirming that LIS or HIS uploaded results match GeneXpert result after any changes to the GeneXpert or host system, changes include, but are not limited to, the following:

Note
- GeneXpert software version
- GeneXpert ADFs and version
- GeneXpert host communication settings
- Host middleware software or configuration changes
- LIS software or configuration changes

4.1 Identifying Your GeneXpert System

This chapter is divided into four sections. Select the appropriate section depending upon the configuration of the system you are using:

- Section 4.4, Importing Assay Definition Files on GeneXpert System with Touchscreen or GeneXpert Xpress System - Hub Configuration.
- Section 4.5, Importing Assay Definition Files on GeneXpert Xpress Tablet configuration.
- Section 4.6, Importing Assay Definition Files on GeneXpert Dx systems.
- Section 4.7, Importing Assay Definition Files on GeneXpert Infinity 48s or Infinity 80.

Figure 19. GeneXpert Systems

4.2 Importing Assay Definition Files on GeneXpert System with Touchscreen

1. To import new assay definition files, ensure you are logged in as an admin, then touch the **Settings > Test Menu**.
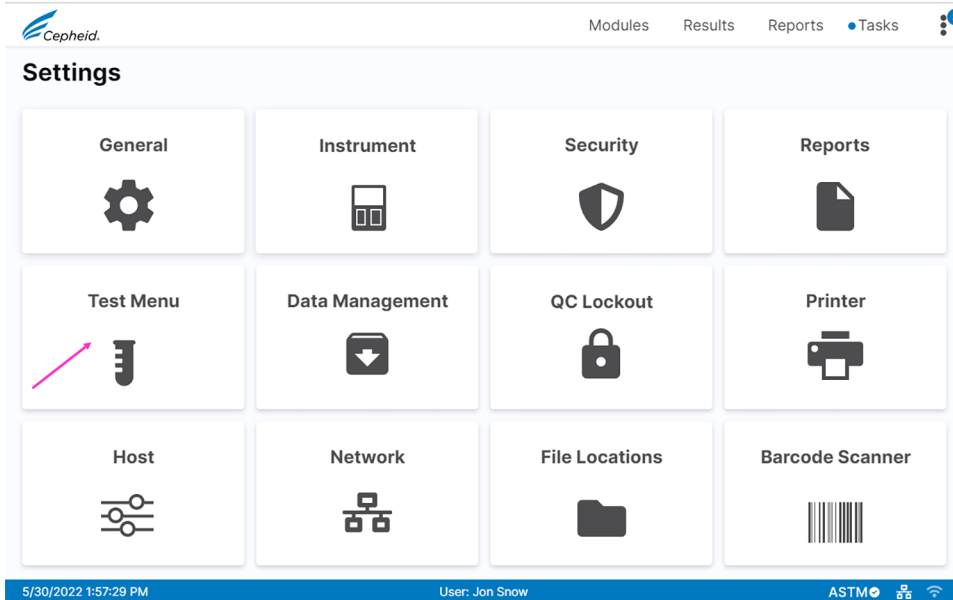

Figure 20. Settings Screen

2. The **Test Menu** screen appears. To import an assay into the system, touch the **Import Test** button.
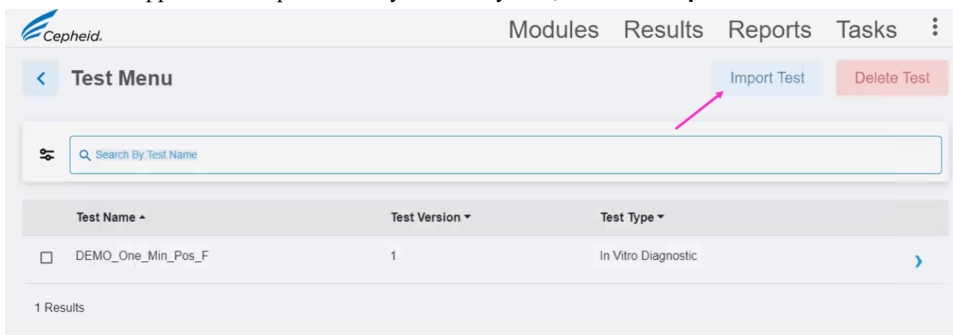

Figure 21. Manage Assays Screen, showing the Import Assay Function

3. Navigate to the DVD and to the folder containing ADF files. A screen appears where you will locate the ADF to be imported. Locate and touch the assay definition (.gxa/.nxa) file (see Figure 22 for an example). What is shown below is an example. Check the assay name and version number to make sure the correct assay definition is being imported.
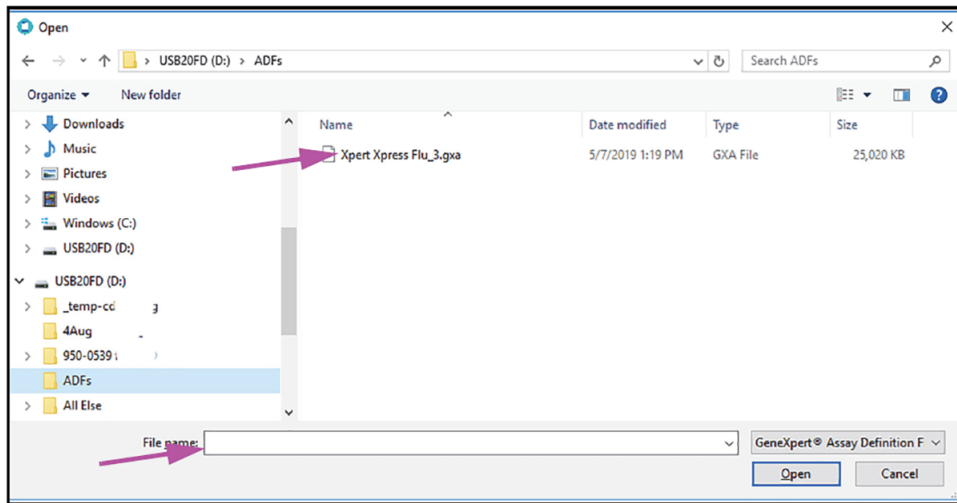
Figure 22. File Screen, showing the Assay Definition File to be Imported

4. The assay name appears in the file name field (see Figure 23). Touch **Open** to import the file into the system.
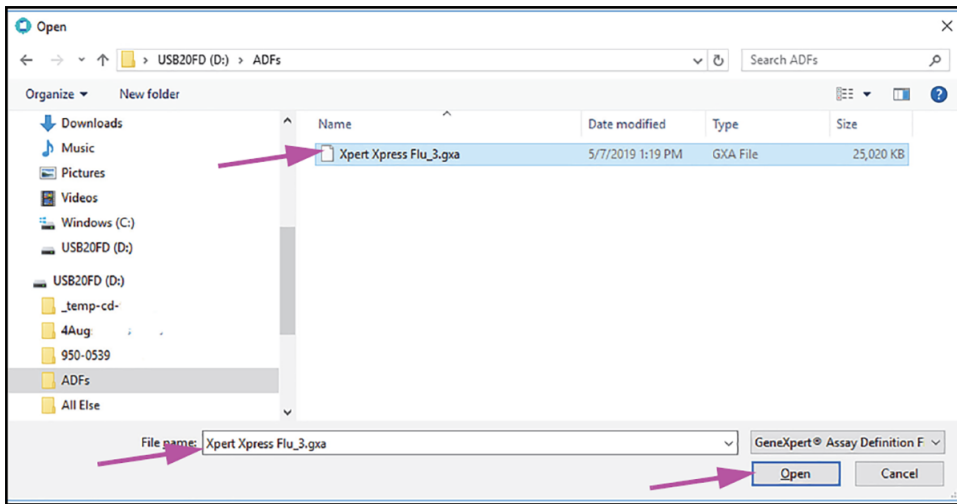

Figure 23. File Screen, showing the Assay Definition File to be Imported

5. The new assay name and version number appear in the Assay list.

6. If you need to import additional ADFs from the same CD, repeat Step 2 through Step 4.

Note   For combination assays that have multiple .gxa/.nxa files, import only the ADFs for assays that will be performed in your lab.
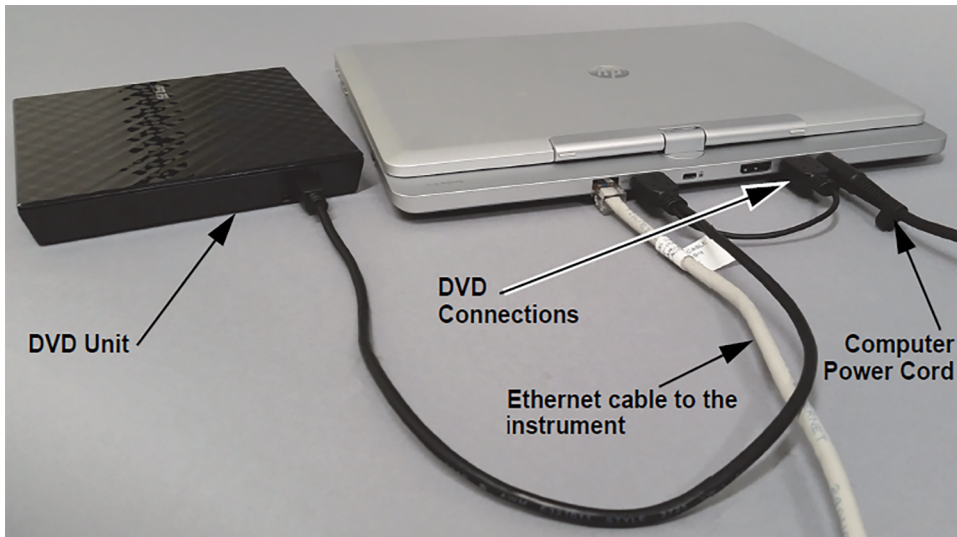
7. Remove the CD from the DVD drive.

8. Disconnect the DVD drive from the touchscreen.

Note   Store the CD, DVD drive, and all cables in a safe location for future use.

4.3 Connecting a DVD Drive to the Xpress System

Depending on the computer supplied with your own system, the DVD drive is connected in one of two ways.

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

2. Plug the DVD drive in (see Figure 24). You will need to disconnect the scanner.
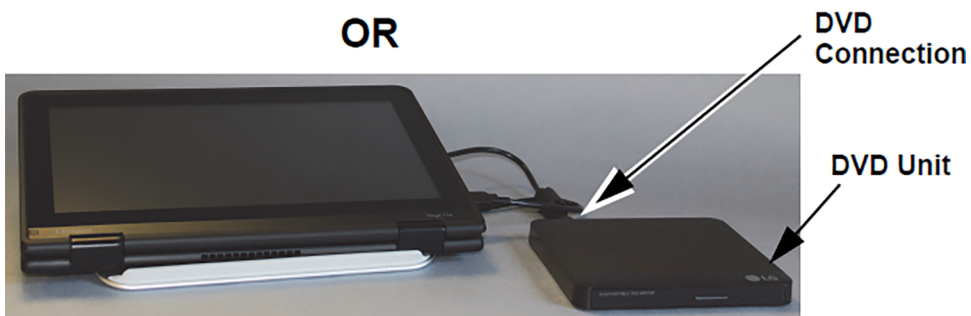
Figure 24. DVD Drive

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.

4.4 Importing Assay Definition Files on GeneXpert Xpress System - Hub Configuration

1. To import new assay definitions, ensure you are logged in as an admin, then touch the **MANAGE ASSAYS** button on the **Admin** screen (see Figure 25).
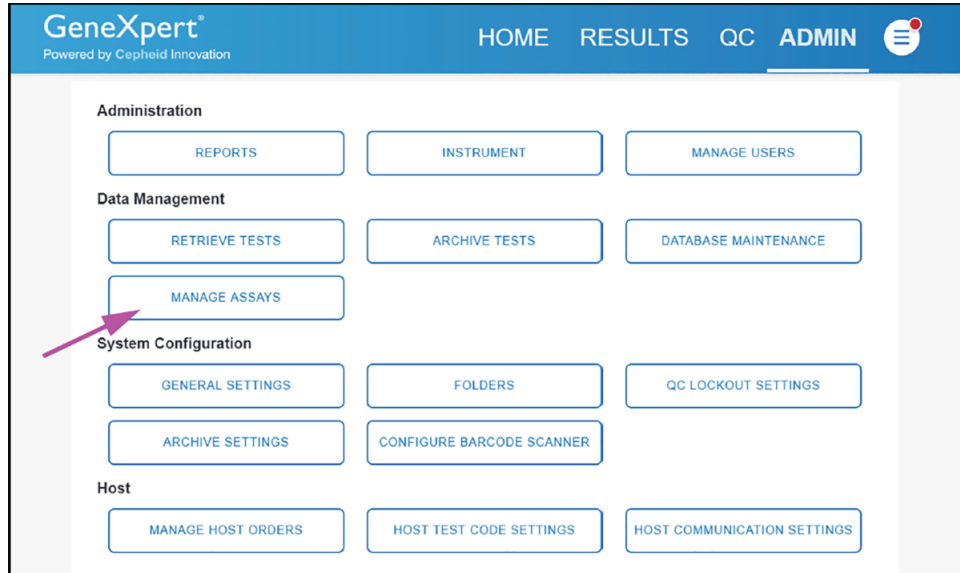

Figure 25. Admin Screen

2. The **Manage Assays** screen appears (see Figure 26). To import an assay into the system, touch the **IMPORT ASSAY** button.
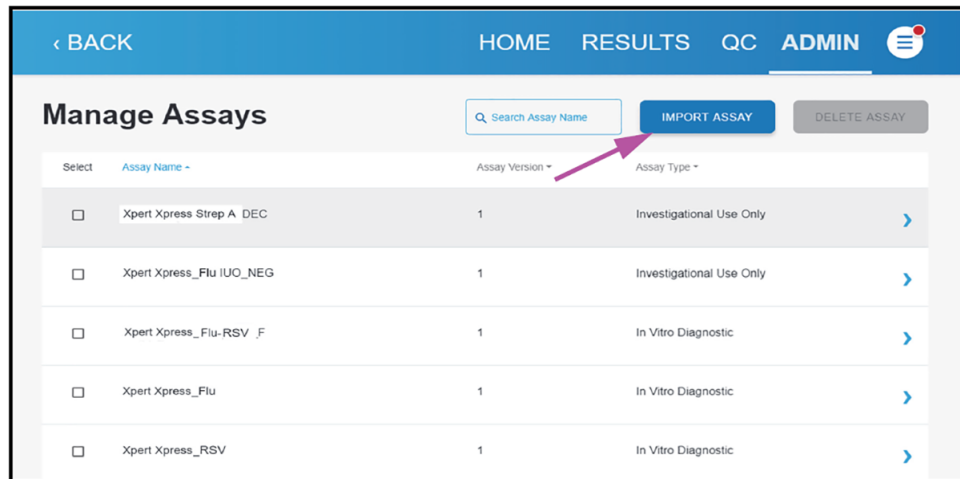

Figure 26. Manage Assays Screen, showing the Import Assay Function

3. Navigate to the DVD and to the folder containing ADF files. A screen appears where you will locate the ADF to be imported. Locate and touch the assay definition (.gxa/.nxa) file (see Figure 27 for an example). What is shown below is an example. Check the assay name and version number to make sure the correct assay definition is being imported.
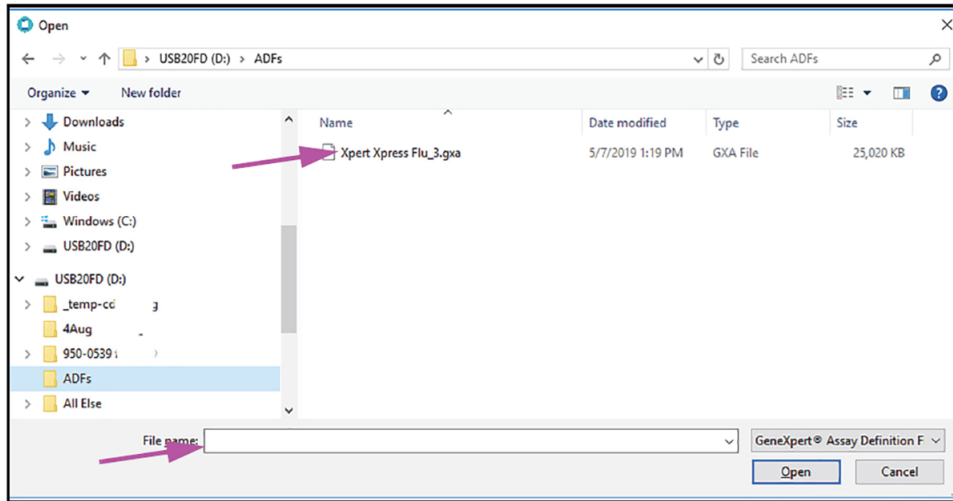
Figure 27. File Screen, showing the Assay Definition File to be Imported

4. The assay name appears in the file name field (see Figure 28). Touch **Open** to import the file into the system.
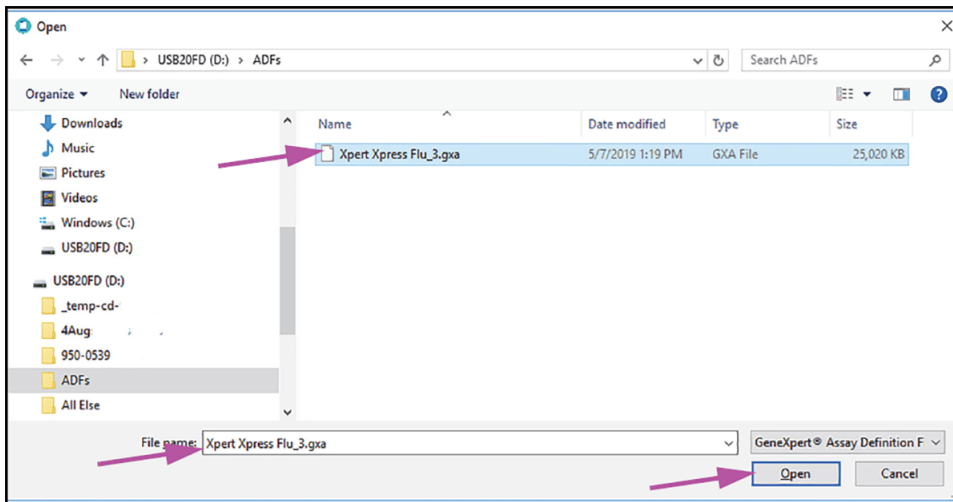

Figure 28. File Screen, showing the Assay Definition File to be Imported

5. The new assay name and version number appear in the Assay list.

6. If you need to import additional ADFs from the same CD, repeat Step 2 through Step 4.

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

7. Remove the CD from the DVD drive.

8. Disconnect the DVD drive from the hub.

Note Store the CD, DVD drive, and all cables in a safe location for future use.

4.5 Importing Assay Definition Files on GeneXpert Xpress System - Tablet Configuration

1. Start the Gx Dx software. Ensure you are logged in as an admin.

2. In the GeneXpert Dx window, select **Define Assays** on the menu bar. The Define Assays window displays (see Figure 1).

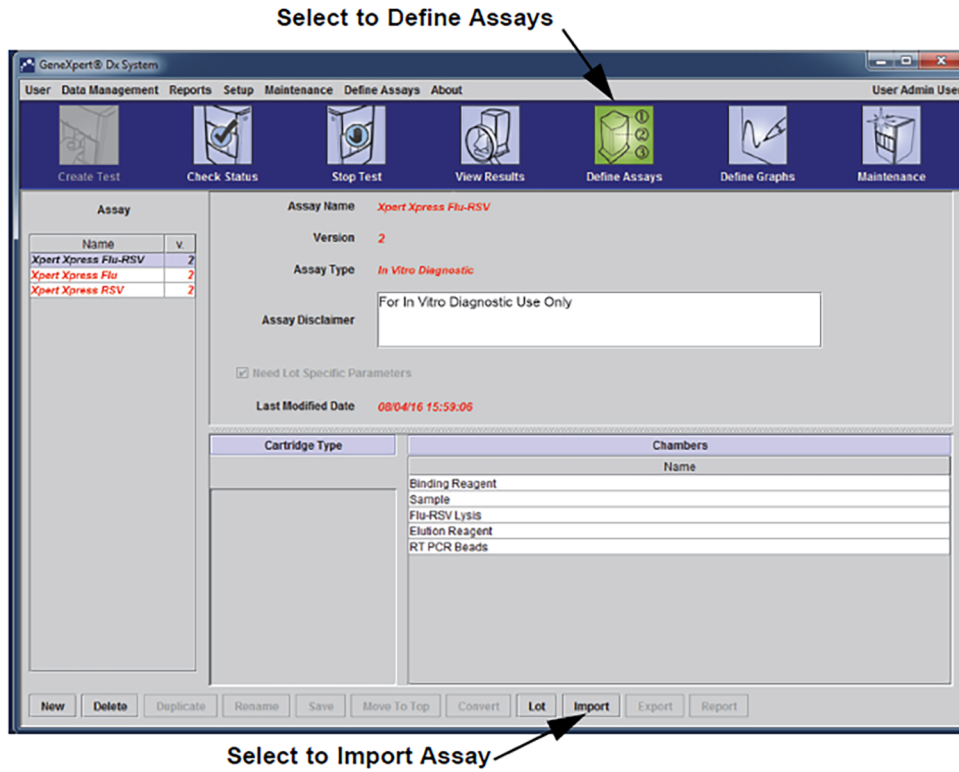3. Select **Import**. The Import Assay dialog box displays (see Figure 2).

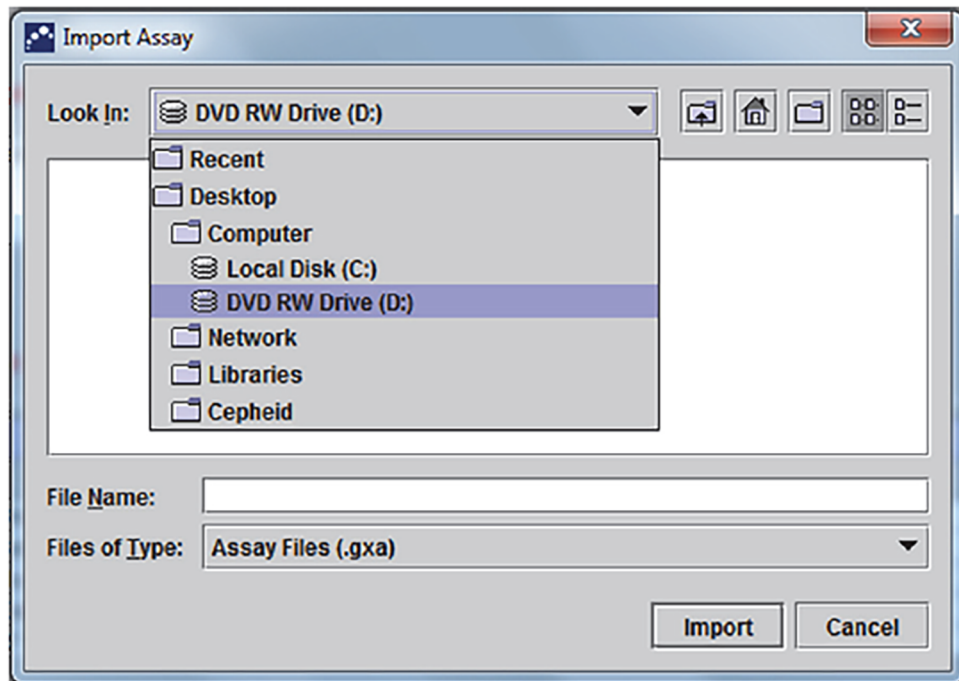**Figure 29. System - Define Assays Window (Admin User View)**

Figure 30. Import Assay Dialog Box

4. Navigate to the DVD folder. Locate and select the assay definition (.gxa/.nxa) file,and then select **Import**.The new assay name and version number are shown in the assay list on the left side of the window. Details about the assay are shown on the right side of the list.

5. Check the assay name and version number to make sure the correct assay definition has been imported.

6. If you need to import additional ADFs from the same CD, repeat Step 2 through Step 5.

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.

7. Remove the CD from the DVD drive and store the CD in a safe location in the event it is needed in the future.

8. Disconnect the DVD drive from the computer and store it and the cables to it in the event they are needed in the future.

4.6 Importing Assay Definition Files on GeneXpert Dx Systems

On GeneXpert Dx Systems, you must import the ADFs. 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).

1. Insert the assay definition CD into the computer's DVD drive.

2. In the GeneXpert Dx System window, click **Define Assays** (see Figure 31). The **Define Assays** window appears (see Figure 32).

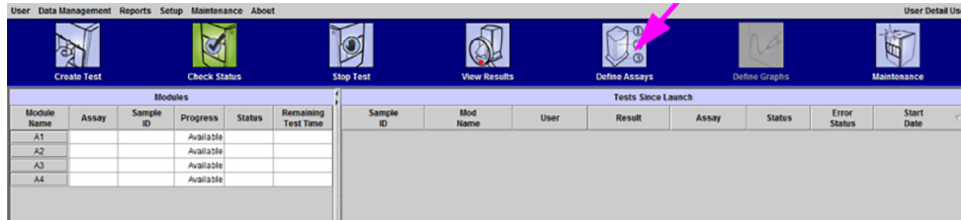3. In the **Define Assays** window, click **Import**. The Import Assay dialog box appears (see Figure 32) .

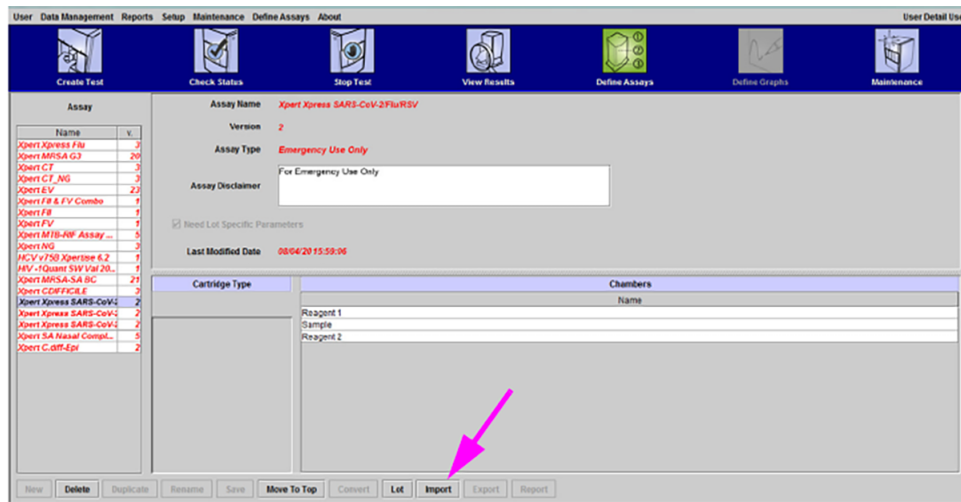**Figure 31. GeneXpert Dx System Window**

Figure 32. GeneXpert Define Assays Window

4. Click **Look in**, in the drop-down, select the **DVD drive**. See Figure 33. Under the CD directory, select the GeneXpert Systems folder to view the list of ADFs applicable to the GeneXpert Dx software.
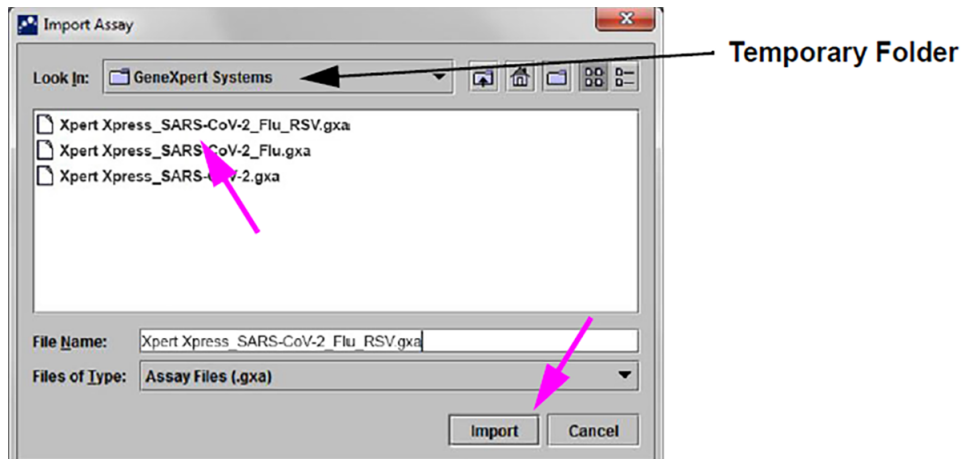
Figure 33. Import Assay Dialog Box

5. Select the assay definition (.gxa/.nxa) file inside the GeneXpert Systems folder then click the **Import** button on the Import Assay dialog box (see Figure 33).

   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 appears to the right of the list as shown in Figure 32.

6. View the assay name and version number to verify that the correct ADFs have been imported.

7. If you need to import additional ADFs from the same CD, repeat Step 4 through Step 6.

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

8. Remove the CD from the DVD drive and store the CD in a safe location in the event it is needed in the future.

4.7 Importing Assay Definition Files on GeneXpert Infinity-48s and Infinity-80 Systems

1. In the Xpertise software, press the **Home** icon to display the Xpertise Software Homework space. See Figure 34.

Figure 34. Xpertise Software Home Workspace

2. In the Xpertise Software Home workspace, press the **SETUP** button. The Setup menu is displayed. See Figure 35.
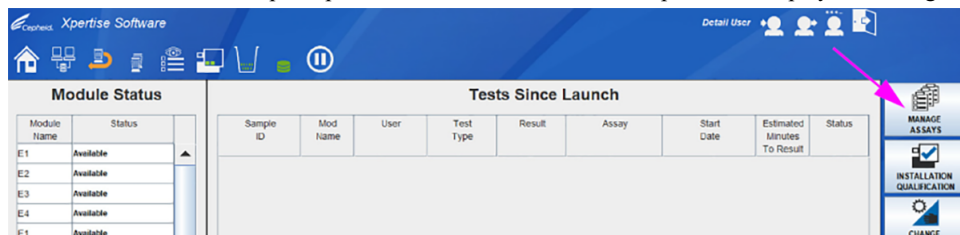

Figure 35. Setup Menu

3. In the Setup menu, press the **MANAGE ASSAYS** button. The Manage Assays workspace is displayed showing the list of previously imported assays. Figure 36.
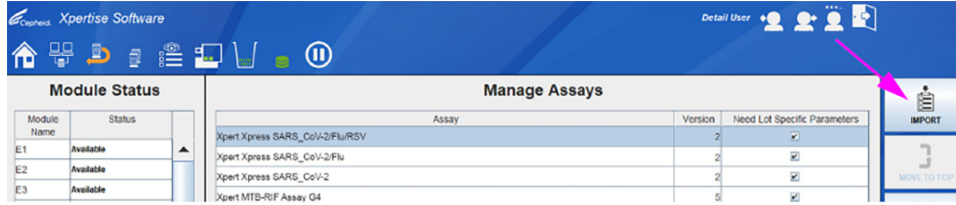

Figure 36. Xpertise Manage Assays Workspace

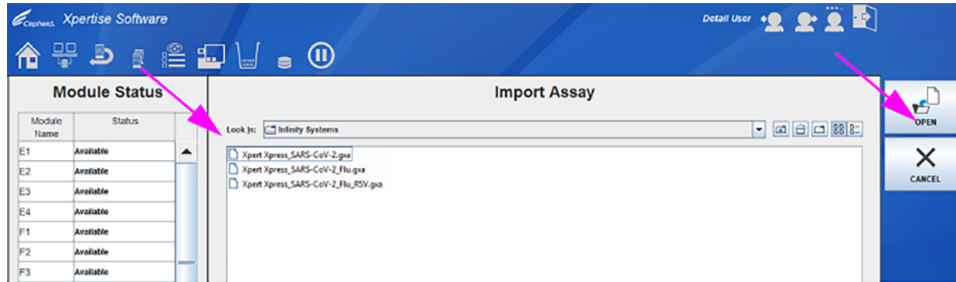4. In the Manage Assays workspace, click **IMPORT**. The Import Assay dialog box appears. See Figure 37.

Figure 37. Xpertise Manage Assays Workspace

5. Under **Look in**, navigate to the temporary folder to view the list of ADFs applicable to the Xpertise software. See Figure 37.

6. Select the assay definition (.gxa) file, then click the **OPEN** button. See Figure 37.

    The new assay name and version number will appear in the assay list in the Manage Assays workspace. See Figure 36. Check the assay name and version number to verify that you have imported the correct assay definitions.

7. Repeat Step 1 - 4 to import additional ADF files, if applicable.

8. Check the assay name and version number to make sure the correct assay definition has been imported.

9. After the ADFs has been imported correctly, delete the temporary folder you created on the desktop.

| **Note** | After an ADF has been imported, if you would like to configure the automation to retain cartridges for this assay for specific conditions, reference your GeneXpert Infinity System Operator Manual |