GeneXpert®
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Importing Assay Definition Files From the Cepheid Website

Cepheid®

In Vitro Diagnostic Medical Device IVD

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Technical Assistance

Before contacting Cepheid Technical Support, collect the following information:

- Product name
- Lot number
- Serial number of the instrument
- Error messages (if any)
- Software version and, if applicable, Computer Service Tag number

Contact Information

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Telephone: + 1 888 838 3222	Telephone: + 33 563 825 319
Email: techsupport@cepheid.com	Email: support@cepheideurope.com

Contact information for all Cepheid Technical Support offices is available on our website: www.cepheid.com/en/CustomerSupport.

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 systems
- GeneXpert® Infinity-48s and Infinity-80 systems.

Important **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.**

1 Before You Begin

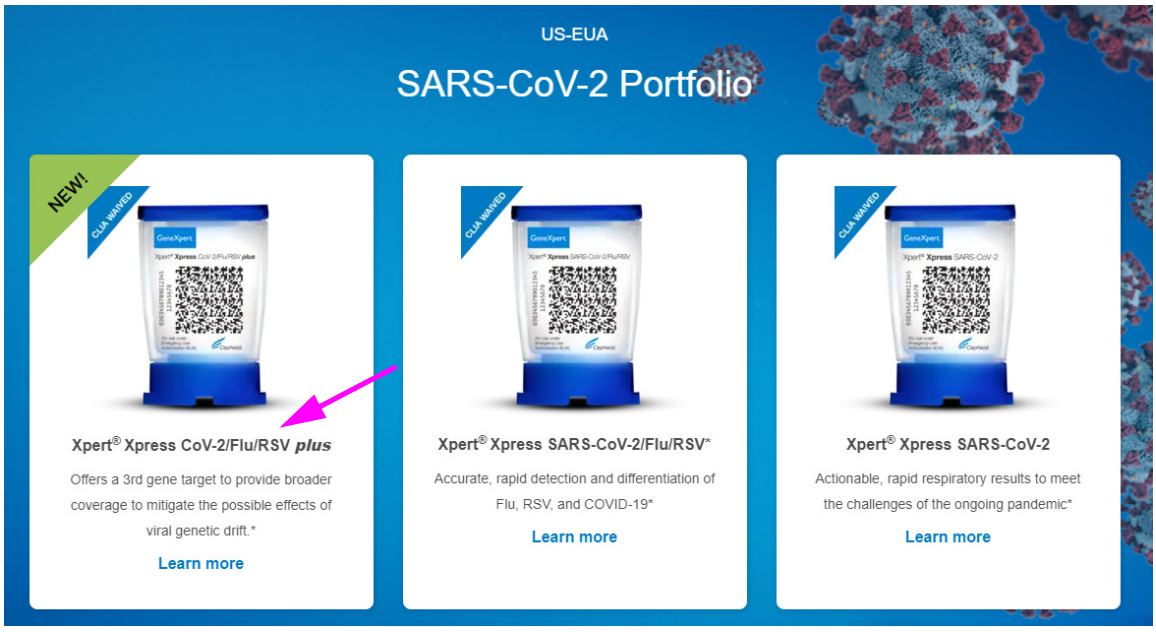
1. Download the Assay Definition File (ADF) from the Cepheid Website.
   With an Internet capable computer, navigate to:
   https://www.cepheid.com/coronavirus-product-resources.

   A) Choose an option under **Select Your Region**.

   B) Select the test for which you are downloading ADF files.

   C) Scroll down to **Product Resources**, locate the **ADF Files** section, and click the **Download ADF** button.

Important **Screenshots in this document use Xpert Xpress SARS CoV-2/Flu/RSV as an example. 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.**

D) 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.) Xpert Xpress 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.**

2 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:

- For the GeneXpert System with Touchscreen or the GeneXpert Xpress *Hub* configuration, see Section 3, Importing Assay Definition Files on GeneXpert System with Touchscreen or GeneXpert Xpress System - Hub Configuration
- For the GeneXpert Xpress *Tablet* configuration, see Section 4, Importing Assay Definition Files on GeneXpert Xpress System - Tablet Configuration
- For any of the GeneXpert *Dx* family of systems, see Section 5, Importing Assay Definition Files on GeneXpert Dx Systems
- For either the GeneXpert *Infinity 48s* or *Infinity 80*, see Section 6, Importing Assay Definition Files on GeneXpert Infinity-48s and Infinity-80 Systems

Figure 1. GeneXpert Systems

3 Importing Assay Definition Files on GeneXpert System with Touchscreen or 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 2).

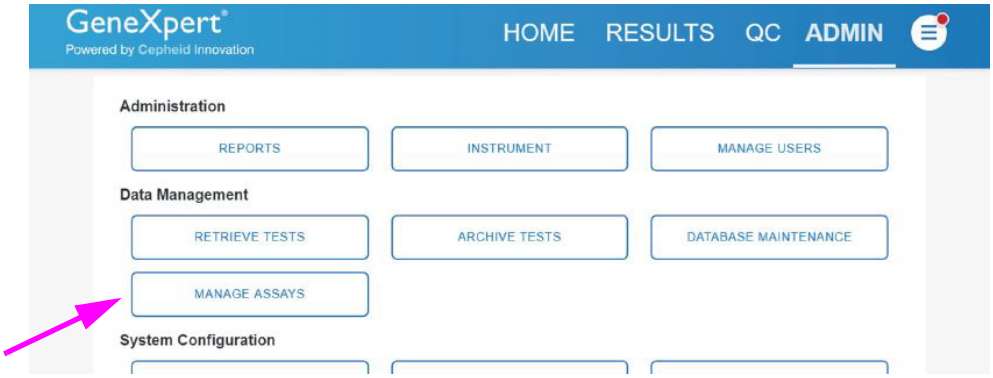


Figure 2. ADMIN Screen

2. The Manage Assays screen appears (see Figure 3). To import an assay into the system, touch the **IMPORT ASSAY** button.

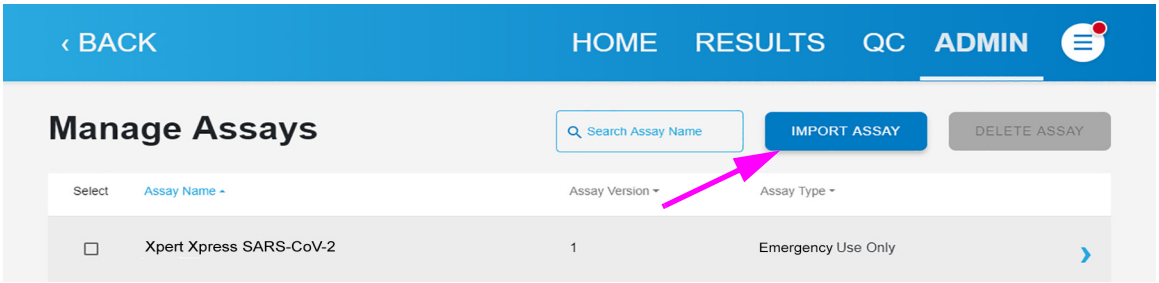


Figure 3. Manage Assays Screen, showing the Import Assay Function

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 4). The graphics show below are an example. Check the assay name and version number to make sure the correct assay definition is being imported.

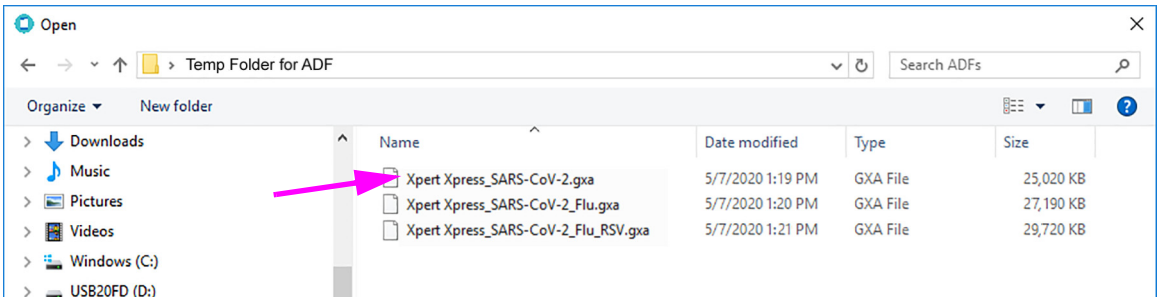


Figure 4. File Screen, showing the Assay File to be Imported

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

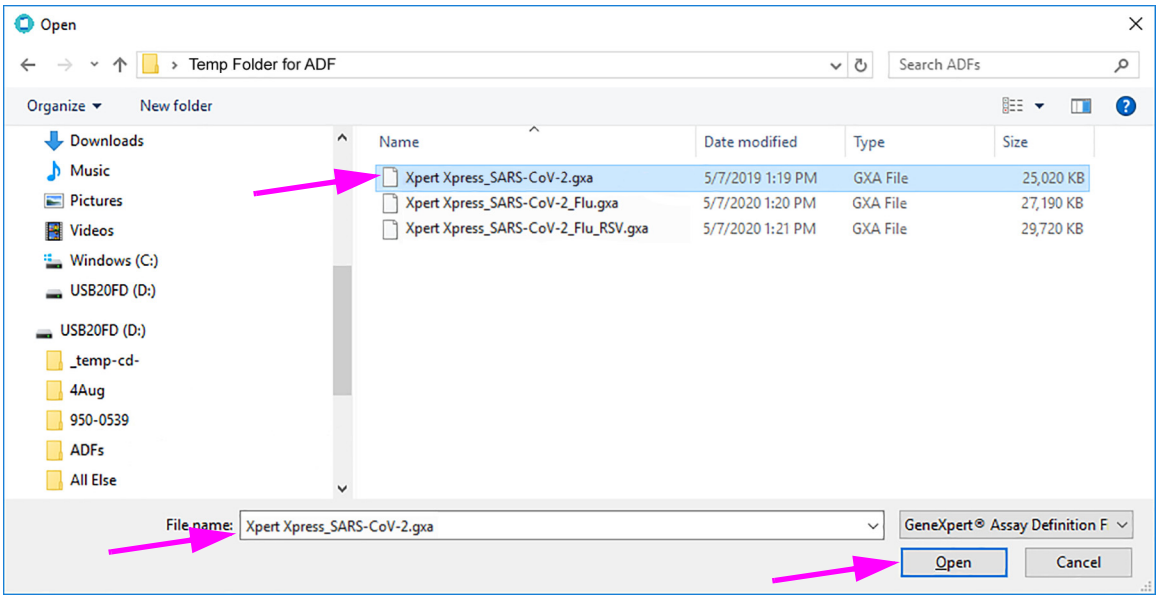


Figure 5. File Screen, showing the Assay File to be Imported

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 assay definition file has been imported correctly, delete the temporary folder you created on the desktop.

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

1. Log out 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 6). Select **Import**.

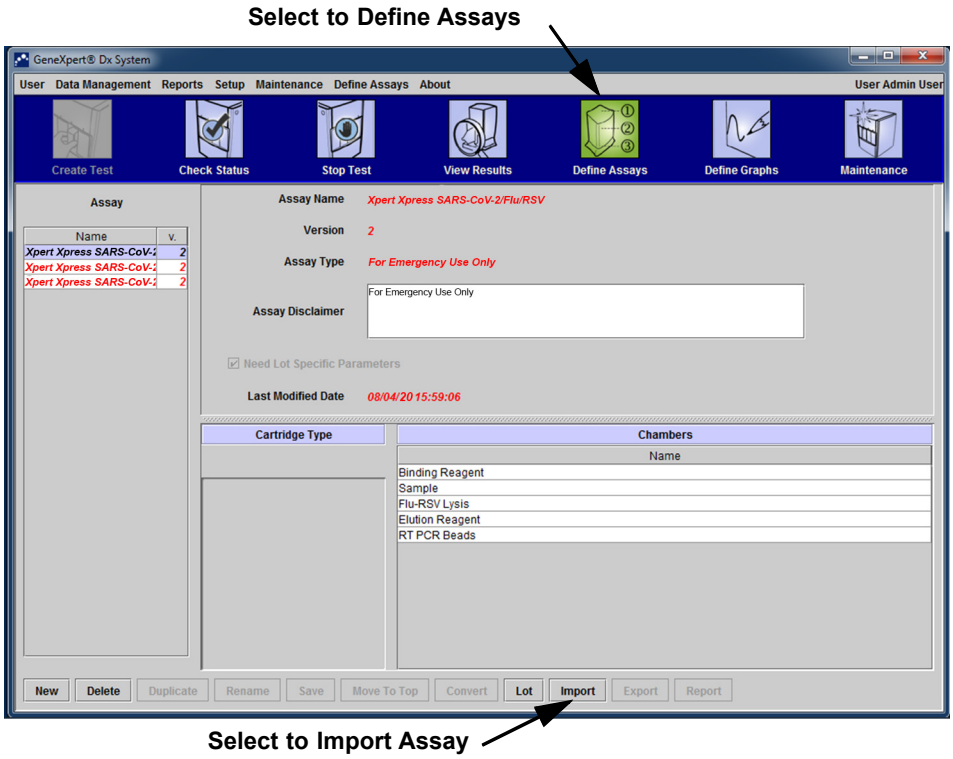


Figure 6. System - Define Assays Window (Administration User View)

4. The Import Assay dialog box displays (see Figure 7).

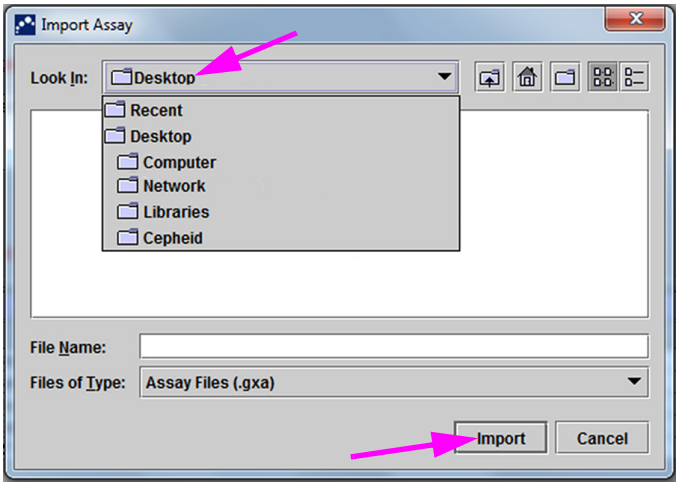


Figure 7. Import Assay Dialog Box

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 assay definition file 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.

5 Importing Assay Definition Files on GeneXpert Dx Systems

1. In the GeneXpert Dx System window, click **Define Assays**. See Figure 8. The Define Assays window appears. See Figure 9.

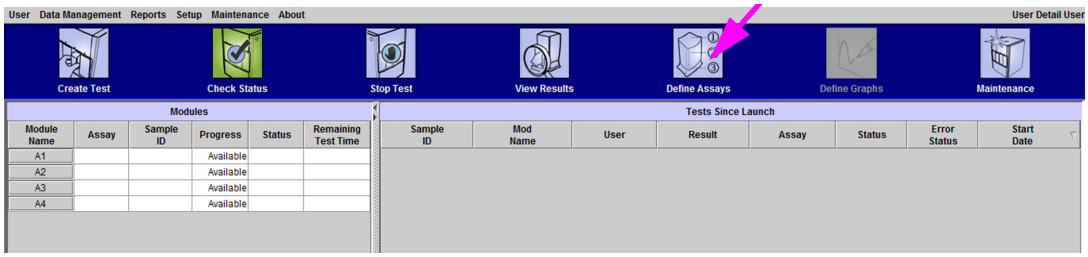


Figure 8. GeneXpert Dx System Window

2. In the Define Assays window, click **Import**. The Import Assay dialog box appears. See Figure 10.

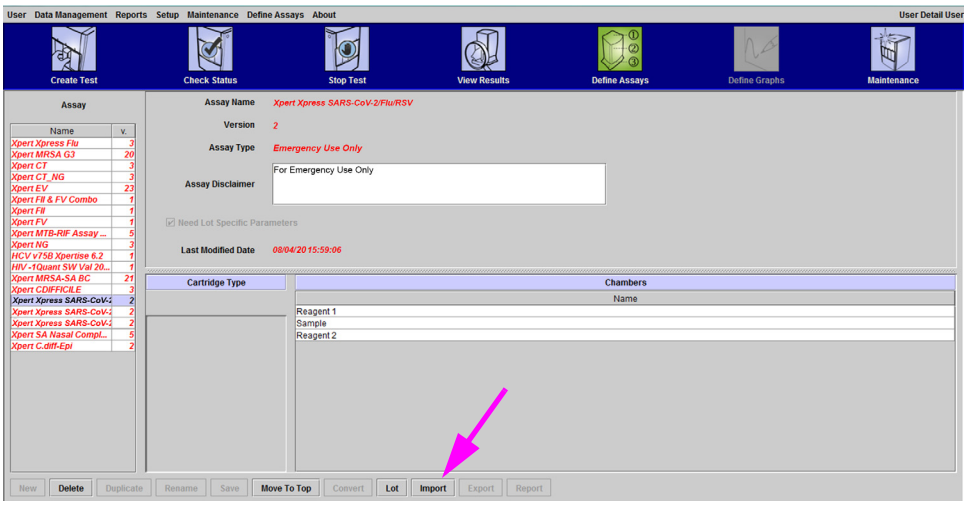


Figure 9. GeneXpert Define Assays Window

3. Under the **Look in:** drop-down, select the desktop. See Figure 10. Select the temporary folder you created to view the list of assay definition files available.

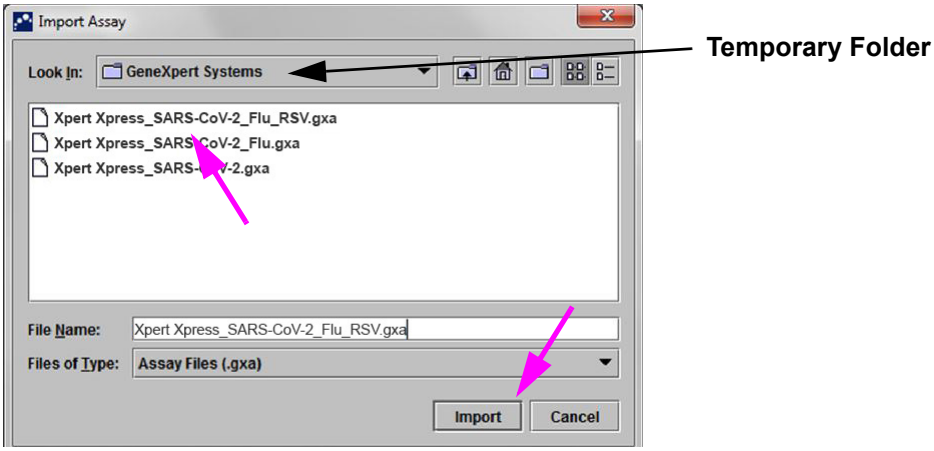


Figure 10. Import Assay Dialog Box

4. Select the assay definition (.gxa) file inside the temporary folder then click the **Import** button on the Import Assay dialog box. See Figure 10.

   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 9.

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 assay definition file has been imported correctly, delete the temporary folder you created on the desktop.

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 Home workspace. See Figure 11.

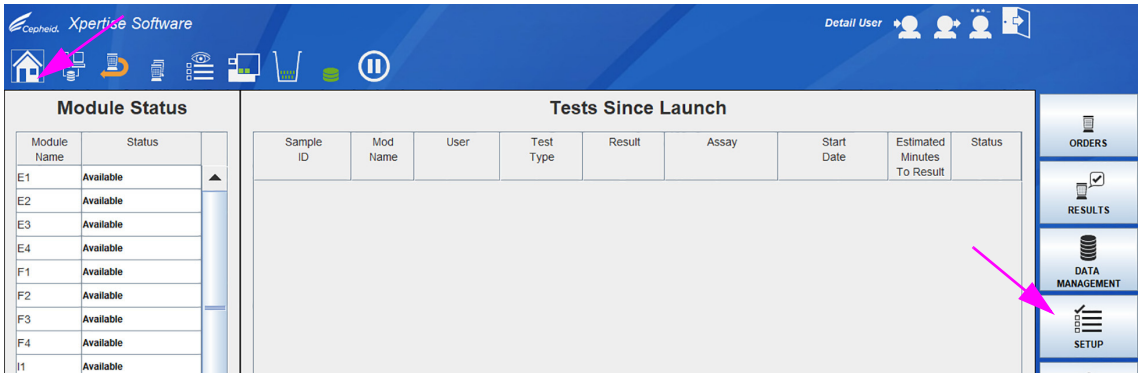


Figure 11. Xpertise Software Home Workspace

2. In the Xpertise Software Home workspace, press the **SETUP** button. The Setup menu is displayed. See Figure 12.

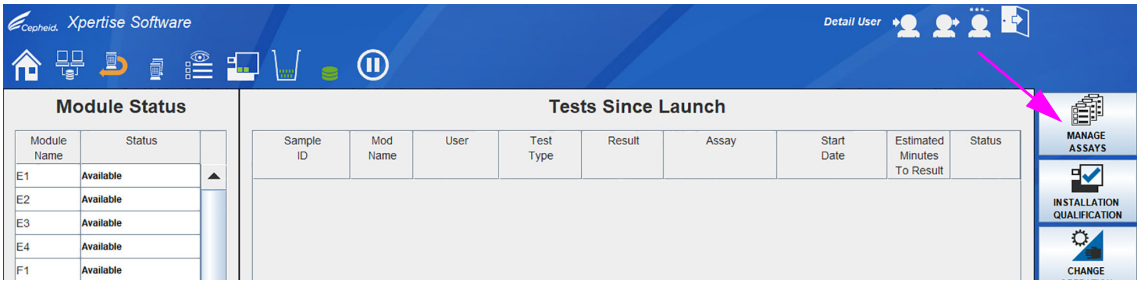


Figure 12. Setup Menu

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 13.

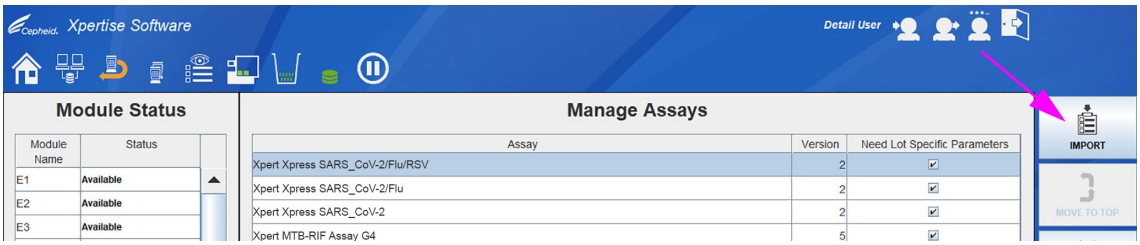


Figure 13. Xpertise Manage Assays Workspace

4. In the Manage Assays workspace, click **IMPORT**. The Import Assay dialog box appears. See Figure 14.

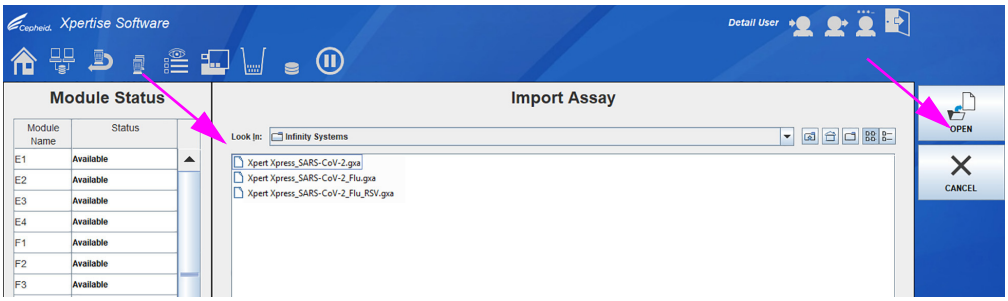


Figure 14. Import Assay Dialog Box

5. Under **Look in,** navigate to the temporary folder to view the list of assay definition files applicable to the Xpertise software. See Figure 14.

6. Select the assay definition (.gxa) file, then click the **OPEN** button.
   See Figure 14.
   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 assay definition file has been imported correctly, delete the temporary folder you created on the desktop.

10. (**Optional**) After an assay has been imported, if you would like to configure the automation to retain cartridges for this assay for specific conditions, see Chapter 2 in your *GeneXpert Infinity System Operator Manual*.