

Importing Assay Definitions

Importing ADFs by CD or the Web



In Vitro Diagnostic Medical Device

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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.

When performing an ADF update for a test on current test menu, take screenshots of LIS or HIS Host Test Important 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.cepheid.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.
- 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.

User Data Management Reports	s Setup Maintenance Defi	ne Assays About				User Detail Use
Create Test	Check Status	Stop Test	View Results	Define Assays	Define Graphs	Maintenance
Assay	Assay Name	MTB-RIF Assay G4				
line la	Version	5				
Voert Voress Elu 3						
Xpert MRSA G3 20	Assay Type	Research Use Only				
Xpert CT 3		For Research Use Only				
Xpert CT_NG 3	Assay Disclaimer					
Xpert EV 23	Produj Discumier					
Xpert Fil & FV Combo 1 Ypert Fil 4						
Xpert FV 1	Need Lot Specific Par					
Xpert MTB-RIF Assay 5						
Xpert NG 3	Last Modified Date	40/47/44 44-00-22				
HCV v75B Xpertise 6.2 1	Last mounied Date	10/11/11/100.22				
HIV -1Quant SW Val 20 1						
Xpert MRSA-SA BC 21	Cartridge Type			Chambers		
MTB-RIF Assav G4 5				Name		
Xpert MRSA-SA SSTI G3 24		Reagent 1				
Xpert SA Nasal Compl 2		Sample				
Xpert SA Nasal Compl 5		Reagent 2				
Xpert C.diff-Epi 2						
			1			
I	J	1				
New Delete Duplicate	Rename Save	Move To Top Convert Lot	Import Export Report			

Figure 5. GeneXpert Define Assays Window

2. Click Import.

The Import Assay dialog box appears. See Figure 6.

		Folder containing ADF (GeneXpert Systems folder for CD o extracted zipped files for web)
Import Assay	GeneXnert Systems	
Xpert Assa	y.gxa	
File <u>N</u> ame: Files of <u>T</u> ype:	Xpert Assay.gxa Assay Files (.gxa)	Import Cancel

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.

Cepheid, X	pertise Software						/		Detail Use	• • 2	: 🛄 💽	
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1	Available	ſ		08/20/10 10:22:4	7 System	1	Full Automa	ation Operating Mode			1	
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1.2	Available	-	-	08/20/19 10:29:2	4 System	1	User [Detai	I User] login.				

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.

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合 문	2 📮 🛔			•					
Mo	odule Status					Manage Assays			自
Module	Status				Assay		Version	Need Lot Specific Parameters	IMPORT
E1	Available		Xpert Xpress_Stre	рА			2	✓	7
E2	Available		Xpert GBS LB				1	×	ت.
E3	Available		Xpert C.diff-Epi				2	×	MOVE TO TOP
E4	Available		Xpert MTB-RIF As	say G4			5	×	\$2
F1	Available		Xpert Xpress Flu-F	RSV			5	×	\sim
F2	Available		Xpert CT_NG				3	×	DELETE
F3	Available	-	Xpert MRSA G3				20	×	
F4	Available								LOT SPECIFIC
11	Available								PARAMETERS
12	Available								1
13	Available								EDIT
14	Available								
J1	Available	1							
J2	Available	1							CLOSE
J3	Available	1							
J4	Available	1							
K1	Available	1							
K2	Available	1							
КЗ	Available	1							
K4	Available								
L1	Available	1	-	08/20/19 10:22:17	System	Full Automation Operating Mode	5	1	
L2	Available		L L	08/20/19 10:22:17	System	Welcome to GeneXpert Infinity S	system		
L3	Available	-		08/20/19 10:29:24	System	User [Detail User] login.			

Figure 9. Xpertise Manage Assays Workspace

4. Click IMPORT.

The Import Assay dialog box appears. See Figure 10.

(Infinity Syste or extracted z							ontaining ADF systems folder for CD ted zipped files for web	taining ADF tems folder for CD zipped files for web)			
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E2	Available		Xpert CT_	VG_3.gxa							
E3	Available	1	Xpert NG_	3.gxa				CANCEL			
E4	Available										
F1	Available										
F2	Available										
F3	Available	-		× *							
F4	Available										
11	Available										
12	Available										
13	Available										
14	Available										
J1	Available										
J2	Available										
J3	Available										
J4	Available	1									
К1	Available										
K2	Available		File Name:								
КЗ	Available		Files of Type:	Assay Files (.gxa)							
К4	Available	1									
L1	Available			08/20/19 10:22:17	System	Full Automation Operating Mod	le				
L2	Available			08/20/19 10:22:17	System	Welcome to GeneXpert Infinity	System				
L3	Available	-		08/20/19 10:29:24	System	User [Detail User] login.					

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*.

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