

ADF Import Instructions

Importing ADFs by CD or the Web



In Vitro Diagnostic Medical Device

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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.

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

If your system is connected to an LIS or HIS network, you must update your host test codes(after the assay Important 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**.

Cepheid.		Modules	Results	Reports	 Tasks 	:
Settings						
General	Instrument	Security		Repo	orts	
\$		V				
Test Menu	Data Management	QC Lockout		Prin	ter	
/]						
Host	Network	File Locations		Barcode	Scanner	
	동					
5/30/2022 1:57:29 PM	User: Jon	Snow		A	STM⊘ 뫎	Ŷ

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.

C Test Menu		
i cot menu	Import Test Dele	te Test
C Search By Test Name		
Test Name A Test Versi	ion • Test Type •	

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.

→ Y ↑ _ > Temp Folder	for ADF		~	ک Sea	erch ADFs		Q
rganize 👻 New folder							?
🕹 Downloads	^ Name	^	Date modified	Туре	Size		
h Music	Xpert	: Xpress_SARS-CoV-2.gxa	5/7/2019 1:19 PM	GXA File	25,0	20 KB	
E Pictures] Xpert	Xpress_SARS-CoV-2_Flu.gxa	5/7/2020 1:20 PM	GXA File	27,1	90 KB	
🛃 Videos	T Xpert	Xpress_SARS-CoV-2_Flu_RSV.gxa	5/7/2020 1:21 PM	GXA File	29,7	20 KB	
Lindows (C:)							
USB20FD (D:)							
USB20FD (D:)							
_temp-cd-							
4Aug							
950-0539							
ADFs							
All Else	~						
	Variate SARS Call 2 and			√ Ge	eneXpert® Assay De	finition	F ~
File name: Xpert	Apress_SARS+COV+2.gxa						

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).

Administration		
REPORTS	INSTRUMENT	MANAGE USERS
Data Management		
RETRIEVE TESTS	ARCHIVE TESTS	DATABASE MAINTENANCE
MANAGE ASSAYS		

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.

< BACK	HOME RESULTS QC ADMIN 📑
Manage Assays	Q Search Assay Name IMPORT ASSAY DELETE ASSAY
Select Assay Name -	Assay Version • Assay Type •
Xpert Xpress SARS-CoV-2	1 Emergency Use Only

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.

🗘 Open					×
← → ∽ ↑ → Temp Folder for	ADF		Search ADFs		٩
Organize 👻 New folder)II • 🔲	?
> 🦊 Downloads	^ Name	Date modified	Туре	Size	
> 🁌 Music	Xpert Xpress_SARS-CoV-2.gxa	5/7/2020 1:19 PM	GXA File	25,020 KB	
> 📰 Pictures	Xpert Xpress_SARS-CoV-2_Flu.gxa	5/7/2020 1:20 PM	GXA File	27, 190 KB	
> 🛃 Videos	Xpert Xpress_SARS-CoV-2_Flu_RSV.gxa	5/7/2020 1:21 PM	GXA File	29,720 KB	
> 🏪 Windows (C:)					
> USB20FD (D:)					

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.

🗘 Open						×
← → × ↑ 📙 > Temp Folde	r for ADF		~	Search ADF		Q
Organize 👻 New folder)II • 🔟	?
🖶 Downloads	^	Name	Date modified	Туре	Size	
Music		Xpert Xpress_SARS-CoV-2.gxa	5/7/2019 1:19 PM	GXA File	25,020 KB	
E Pictures		Xpert Xpress_SARS-CoV-2_Flu.gxa	5/7/2020 1:20 PM	GXA File	27, 190 KB	
🛃 Videos		Xpert Xpress_SARS-CoV-2_Flu_RSV.gxa	5/7/2020 1:21 PM	GXA File	29,720 KB	
Windows (C:)						
USB20FD (D:)						
_						
SB20FD (D:)						
_temp-cd-						
4Aug						
950-0539						
ADFs						
All Else	~					
File.name: Xne	rt Xnress SARS-C	oV-2 ma		GeneXnert	Assay Definition I	FV
The line Ape	n Apress_sans-c	0V-2.9X8		Generger		
			_	<u>O</u> pen	Cancel	

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**.

	Select to	Define Assays	、		
GeneXpert® Dx System					
User Data Management Report	ts Setup Maintenance Defin	e Assays About			User Admin User
Create Test Chr	eck Status Stop Te	st View Results	Define Assays	Define Graphs	Maintenance
Assay	Assay Name	Xpert Xpress SARS-CoV-2/Flu/RSV			
Name v.	Version	2			
Xpert Xpress SARS-CoV-2 Xpert Xpress SARS-CoV-2 Xpert Xpress SARS-CoV-2	Assay Type	For Emergency Use Only			
	Assay Disclaimer	For Energiney out only			
	Last Modified Date	08/04/20 15:59:06	Chamb	ers	
	curringe type		Nam	0	
		Binding Reagent			
		Sample			
		Flu-RSV Lysis Elution Reacent			
		RT PCR Beads			
New Delete Duplicate	Rename Save M	ove To Top Convert Lot	Import Export	Report	
	Select to Imp	ort Assay			

Figure 10. System - Define Assays Window (Administration User View)

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

Import A	Assay
Look in:	□Desktop
	Recent
	🗂 Desktop
	Computer
	Network
	Libraries
	Cepheid
File <u>N</u> ame	к
Files of T	ype: Assay Files (.gxa) 💌
	Import Cancel

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).

User Data	Management	Reports Set	up Maintena	ance Abou	t					/			User Detail User
	reate Test		Check St	atus	9	Stop Test	View Results		Define Assays	De	fine Graphs		Maintenance
		Mode	iles			1			Tests Since L	aunch			
Module Name	Assay	Sample ID	Progress	Status	Remaining Test Time	Sample ID	Mod Name	User	Result	Assay	Status	Error Status	Start T
A1			Available										
A2			Available										
A3			Available										
A4			Available										

Figure 12. GeneXpert Dx System Window

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

User Data Management Report	ts Setup Maintenance Defi	ne Assays About				User Detail User
Create Test	Check Status	Stop Test	Ver Reselts	Define Assays	Define Grephs	Maintenence
Assay	Assay Name	Xpert Xpress SARS-CoV-2FluRSV				
Name	Version	2				
Xpert Xpress Flu 3	Assay Type	Emergency Use Only				
Xpen CT 3		For Emergency Use Only				
Xpert CT_NG J Xpert EV Z3	Assay Disclaimer					
Xpert F8 & FV Combo 1 Xpert F8 1						
Xpert FV 1 Xpert M18-R# Assay 5	Need Lot Specific Par	ameters				
Xpert NG 3	Last Modified Date	08/04/20 15:59:06				
HV-1Quant SW Val 20. 1						
Xpert CD#FFC8LE 3	Cartridge Type			Chambers		
Xpert Xpress SARS-CoV-1 2		Report 1		Name		
Xpert Xpress SARS-CoV-2		Sample				
Xpert SA Nasal Compl 5		Reagent 2				
Xpert C.dtf-Epi 2						
New Delete Duplicate	Rename Save	Nove To Top Convert Lot	Import Export Report			

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.

Mark Import Assay	/	×	Town or on a Folder
Look in:	GeneXpert Systems		Temporary Folder
Xpert Xpr Xpert Xpr Xpert Xpr	ess_SARS-CoV-2_Flu_RSV.gxa ess_SARS`CoV-2_Flu.gxa ess_SARS-1_V-2.gxa		
File <u>N</u> ame:	Xpert Xpress_SARS-CoV-2_Flu_RSV.gxa		
Files of <u>Type</u> :	Assay Files (.gxa)		
	li	mport Cancel	

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).

Ecepteia X	pertise Software							Detail Use	· 9 9	: 🗓 💽]
合 暻	i 🖻 🗳	▣ \/ •	•								
Mo	odule Status				Tes	ts Since L	aunch				l a
Module Name	Status	Sample ID	Mod Name	User	Test Type	Result	Assay	Start Date	Estimated Minutes	Status	MANAGE ASSAYS
E1	Available								To Result		
E2	Available										INSTALLATION
E3	Available										QUALIFICATION
E4	Available										9
F1	Available										CHANGE

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).

Cechnic. X	pertise Software	,				Det	all User + 👥 👥 🛄	
合 쁞	i 🖻 🤹		-] 🖌 🖕 🕕				
M	odule Status		Τ	Manage	Assays			à
Module	Status			Assay		Version	Need Lot Specific Parameters	IMPORT
Name				Xpert Xpress SARS_CoV-2/Flu/RSV		2		
E1	Available	•		Xpert Xpress SARS_CoV-2/Flu		2	R	<u>,</u>
E2	Available			Yeard Yerran SADE Cold-2				NOVE TO TOO
E3	Available			AperApress onNo_corre				MOVE TO TOP
				Xpert MTB-RIF Assay G4		5		

Figure 17. Xpertise Manage Assays Workspace

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

Courses)	Kpertise Softwar	re			Detall User 👷 👥 🖳
1	; b (£	• • •		
M	odule Status	8		Import Assay	
Module Name	Status		Look jn: 🔄 Infinity Systems		
E1	Available		Xpert Xpress_SARS-CoV-2.gua		×
E2	Available		Xpert Xpress_SARS-CoV-2_Flu.gxa		CANCEL
E3	Available		Xpert Xpress_SARS-CoV-2_Flu_RSV.gxa		
E4	Available				
F1	Available				
F2	Available				
F3	Available				



- 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:

- GeneXpert software version
- **Note** 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**.

Cepheid.		Modules	Results Reports •Tasks •3
Settings			
General	Instrument	Security	Reports
Test Menu	Data Management	QC Lockout	Printer
Host	Network	File Locations	Barcode Scanner
5/30/2022 1:57:29 PM	User: Jo	n Snow	ASTM⊘ 뮮 중

Figure 20. Settings Screen

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

Cep	bheid.	ſ	Vodules	Results	Reports	Tasks	:
<	Test Menu				Import Test	Delete Te	est
₽	Q Search By Test Name						
	Test Name +	Test Version -	Te	est Type ▼			
	DEMO_One_Min_Pos_F	1	In	Vitro Diagnostic			>
1 Res	ults						

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.

Open					×
\leftarrow \rightarrow \checkmark \uparrow \square \rightarrow USB20FD (D:) \rightarrow ADFs		~	ල Search ADFs		٩
Organize 👻 New folder				📰 🔹 🛄	?
> 🕹 Downloads 🔷 Name	e ^	Date modified	Туре	Size	
> 👌 Music	pert Xpress Flu_3.gxa	5/7/2019 1:19 PM	GXA File	25,020 KB	
> 💽 Videos > 🟪 Windows (C:) > 🔄 US820FD (D:)					
✓ _ USB20FD (D:) >temp-cci g					
4Aug					
All Else					
File pame:			✓ GeneXpert [®] Open	Assay Definition Cancel	Fi ~

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.

Open						×
\leftarrow \rightarrow \checkmark \uparrow \square \rightarrow USB20FD (D:) \rightarrow λ	ADFs		~	ල් Search ADFs		Q
Organize 👻 New folder					E • 🔟	?
🖶 Downloads	^ Name	^	Date modified	Туре	Size	
h Music	Xpert Xpres	s Flu_3.gxa	5/7/2019 1:19 PM	GXA File	25,020 KB	
Pictures						
Videos						
Windows (C:)						
USB20FD (D:)						
USB20FD (D:)						
temp-cd-						
📙 4Aug: 💈 💈						
950-0539						
ADFs						
📙 All Else	*					
File pame: Xpert Xp	ess Flu_3.gxa			✓ GeneXpert [®]	Assay Definition	F v
				<u>O</u> pen	Cance	

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).

eneXpert [®] ed by Cepheid Innovation	HOME RESULTS QC ADMIN
Administration	
REPORTS	INSTRUMENT MANAGE USERS
Data Management	
RETRIEVE TESTS	ARCHIVE TESTS DATABASE MAINTENANCE
MANAGE ASSAYS	
System Configuration	
GENERAL SETTINGS	FOLDERS QC LOCKOUT SETTINGS
ARCHIVE SETTINGS	CONFIGURE BARCODE SCANNER
Host	
MANAGE HOST ORDERS	HOST TEST CODE SETTINGS HOST COMMUNICATION SETTINGS

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.

< BAC	СК	HOME RES	SULTS QC ADMIN	6
Man	age Assays	Q Search Assay Name	IMPORT ASSAY DELETE	EASSAY
Select	Assay Name ~	Assay Version -	Assay Type -	
	Xpert Xpress Strep A DEC	1	Investigational Use Only	>
	Xpert Xpress_Flu IUO_NEG	1	Investigational Use Only	>
	Xpert Xpress_Flu-RSV _F	1	In Vitro Diagnostic	>
	Xpert Xpress_Flu	1	In Vitro Diagnostic	>
	Xpert Xpress_RSV	1	In Vitro Diagnostic	>

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.

Open					×
\leftarrow \rightarrow \checkmark \Uparrow 📙 \diamond USB20FD (D:) > ADFs	· · · · · · · · · · · · · · · · · · ·	・ ひ Search ADFs		Q
Organize 👻 New folder)III 🕶 🔲	?
> 🕹 Downloads	^ Name ^	Date modified	Туре	Size	
> 🎝 Music	Xpert Xpress Flu_3.gxa	5/7/2019 1:19 PM	GXA File	25,020 KB	
> E Pictures					
> 📑 Videos					
> 🏪 Windows (C:)					
> 👝 USB20FD (D:)					
 USB20FD (D:) 					
> 📙 _temp-cd 🛛 g					
_ 4Aug _					
> 950-0539 i)					
ADFs					
> 📙 All Else	~				
File name:			GeneXpert	Assay Definition	F 🗸
			Open	Cancel	

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 multip	le .gxa/.nxa files	, import only t	the ADFs for assa	ys that will be p	performed in your
Note	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).

Jser Data Management	Reports Setup	Maintenance Defi	ne Assays About	`		User Admir
Create Test	Check Status	s Stop Te	est View Results	Define Assays	Define Graphs	Maintenance
Assay		Assay Name	Xpert Xpress Flu-RSV			
Name	V.	Version	2			
Xpert Xpress Flu-RSV Xpert Xpress Flu	2	Assay Type	In Vitro Diegnostic			
Xpert Xpress RSV	2		For In Vitro Diagnostic Use On	У	1	
		Assay Disclaimer				
	I 1	leed Lot Specific Par	ameters			
		Last Modified Date	08/04/16 15:59:06			
		Cartridge Type	08/04/16 15:59:06	Chamb	ers	
		Cartridge Type	0804/16 15:59:06	Chamb	ers e	
		Cartridge Type	Binding Reagent	Chamb	ers 0	
		Cartridge Type	Binding Reagent Sample Flu-RSV Lysis	Chamb- Name	ers e	
		Cartridge Type	Binding Reagent Sample FlurkSV Lysis Elution Reagent	Chamb Name	ers e	
		Cartridge Type	Binding Reagent Sample Flu-RSV Lysis Elution Reagent RT PCR Beads	Chamb Name	ers e	
		Cartridge Type	Binding Reagent Sample Flu-RSV Lysis Elution Reagent RT PCR Beads	Chamb	ers e	
		Cartridge Type	Binding Reagent Sample Flu-RSV Lysis Elution Reagent RT PCR Beads	Chamb	ers e	
		Cartridge Type	Binding Reagent Sample Flu-RSV Lysis Elution Reagent RT PCR Beads	Chamb	ers e	
		Cartridge Type	Binding Reagent Sample Flu-RSVLysis Elution Reagent RT PCR Beads	Chamb	ers e	
		Cartridge Type	Binding Reagent Sample Flu-RSV Lysis Elution Reagent RT PCR Beads	Chamb Nam	ers e	
		Cartridge Type	Binding Reagent Sample Flu-RSV Lysis Eluton Reagent RT PCR Beads	Chamb	ers 9	

Select to Define Assays

Select to Import Assay ~

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

Import A	Assay	×
Look In:	😂 DVD RW Drive (D:) 🔻	
	Recent	
	C Desktop	
	Computer	
	😂 Local Disk (C:)	
	DVD RW Drive (D:)	
	Network	
	Libraries	
	Cepheid Cepheid	
I		
File <u>N</u> ame	e:	
Files of T	ype: Assay Files (.gxa)	•
	Im	port Cancel

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).

User Data M	anagement	Reports Se	up Mainten	ance Abos	R .					*			User Detail Use
Cre	Create Test Check Status S		Stop Test View Rosellts		Define Assays	De	fine Graphs		Maintenance				
		Mod	ules			1			Tests Since L	aunch			
Module Name	Assay	Sample ID	Progress	Status	Remaining Test Time	Sample ID	Mod Name	User	Result	Assay	Status	Error Status	Start T
A1			Available										
A2			Available										
A3			Available										
A4			Available										

Figure 31. GeneXpert Dx System Window

User Data Management Repo	its Setup Maintenance Den	ne Assays About				User Detail Use
Create Test	Check States	Stop Test	View Resells	Define Asseys	Define Grephs	Maintenense
Assay	Assay Name	Xpert Xpress SARS-CoV-2FluRSV	(
New Ind	Version	2				
Xpert Xpress Flu 3	Assav Type	Emergency Use Only				
Xpert MRSA G3 20 Xpert CT 3		Linight, ore only				
Xpert CT_NG 3	Assay Disclaimer	For Emergency Use Only				
XpertEV 23 XpertF8&FV Combo 1						
Xpert Fil 1 Xpert FV 1	R Read Lot Specific Day	ramahara				
XpertMIB-R# Assay 5	E) need to append to					
HCV v758 Xpertise 6.2 1	Last Modified Date	08/04/20 15:59:06				
HV-1Quant SW Val 20 1 Xbert MRSA-SA BC 21	Castilas Tras			Chambara		
Xperi CD#FICILE 3	Cartridge Type			Nama		
Xpert Xpress SARS-CoV-2 2		Reagent 1		Harre		
Xpert Xpress SARS-CoV: 2		Sample				
Xpert C.dtff-Epi 2		Reagent 2				
			· · · · · ·			
New Delete Duplicat	e Rename Save	Move To Top Convert Lot	Import Export Report			

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.

Look in:	GeneXpert Systems			88 8-	- Temporary Folde
 Xpert Xpre Xpert Xpre Xpert Xpre Xpert Xpre 	ss_SARS-CoV-2_Flu ss_SARS\CoV-2_Flu ss_SARS-1V-2.gxa	_RSV.gxa gxa			
	Ň				
File <u>N</u> ame:	Xpert Xpress_SARS-	CoV-2_Flu_RSV.gxa	/		

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.

Ecepteis)	Kpertise Softwa	re							Detail Us	" 👤 👤	2	
$\mathbf{\hat{n}}$	🖗 🔔 👩	i	. 🖌 🖕	•								
м	odule Status	s				Tes	ts Since L	aunch				
Module	Status		Sample	Mod Name	User	Test Type	Result	Assay	Start	Estimated Minutes	Status	ORDERS
E1	Available									To Result		_
E2	Available											RESULTS
E3	Available											
E4	Available										× 1	
F1	Available											
F2	Available											RANKOERENT
F3	Available											
F4	Available											SETUP
11	Available											

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.

Ecepteia. X	pertise Software								Detail Use	· • 9. 9:	· 🗓 🛃	
合 55	i 🖻 🗳	• • \		•								
Mo	odule Status					Tes	ts Since L	aunch				「「「」」
Module Name	Status	1	Sample	Mod Name	User	Test Type	Result	Assay	Start Date	Estimated Minutes	Status	MANAGE ASSAYS
E1	Available									To Result		-
E2	Available											INSTALLATION
E3	Available											QUALIFICATION
E4	Available											9
F1	Available											CHANGE

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.

Ecepteia X	pertise Software	,		Detail User 👷 👱 💆 💽					
合 문	7 🖻 🛊	e 1	• V • •						
Module Status				Manage Assays			à		
Module	Status			Assay	Version	Need Lot Specific Parameters	IMPORT		
Name			Xpert Xpress SARS_CoV-2/Flu/RSV		2				
E1	Available	•	Xpert Xpress SARS CoV-2/Flu		2	P	<u>,</u>		
E2	Available		Ynet Yness SåRS Col/-2		2	2	MONE TO TOP		
E3	Available		Xpert MTB-RIF Assay G4		5	2	MOTE TO TOP		

Figure 36. Xpertise Manage Assays Workspace

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

Coprace)	Kpertise Softwar	~ ≇∎ 1		Detall User + 👱 👷 💆 🛐	
M	odule Status	s	Import Assay	y .	, , , , ,
Module	Status		Look jn: 🔄 Infinity Systems	- 4 2 1 22 1	OPEN
E1	Available	-	Xpert Xpress_SARS-CoV-2.goa		X
E2	Available		Xpert Xpress_SARS-CoV-2_Flu.gxa		CANCEL
E3	Available		Xpert Xpress_SARS-CoV-2_Flu_RSV.gva		CONCEL
E4	Available				
F1	Available				
F2	Available				
F3	Available	_			

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