

# Importing Assay Definition Files From the Cepheid Website





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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**

United States Telephone: + 1 888 838 3222 Email: techsupport@cepheid.com France Telephone: + 33 563 825 319 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<sup>®</sup> System with Touchscreen
- GeneXpert<sup>®</sup> Xpress Hub System
- GeneXpert<sup>®</sup> Xpress Tablet System
- GeneXpert<sup>®</sup> Dx systems
- GeneXpert<sup>®</sup> 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

- 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.

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

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).

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

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.

< BACK	HOME RESULTS QC ADMI	м 📑
Manage Assays	Q Search Assay Name IMPORT ASSAY DELE	TE ASSAY
Select Assay Name -	Assay Version - Assay Type -	
Xpert Xpress SARS-CoV-2	1 Emergency Use Only	>

#### 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.

🗘 Open					Х
$\leftarrow$ $\rightarrow$ $\checkmark$ $\uparrow$ $\square$ $\rightarrow$ Temp Folder for ADF	ර් Search ADFs		P		
Organize 👻 New folder				☷ ▾ 🔟	?
> 👆 Downloads	^ Name	Date modified	Туре	Size	
> 🁌 Music	Xpert Xpress_SARS-CoV-2.gxa	5/7/2020 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:)					
> 🚰 Videos > 🏪 Windows (C:) > 🔄 USB20FD (D:)	Xpert Xpress_SARS-CoV-2_Flu_RSV.gxa	5/7/2020 1:21 PM	GXA File	29,720 KB	

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.

Open						Х
← → 丶 ↑ 📙 → Temp Fol	der for ADF			Search ADFs		Q
Organize 🔻 New folder					EE ▼ 🛄	?
👆 Downloads	^	Name	Date modified	Туре	Size	
👌 Music		Ypert Xpress_SARS-CoV-2.gxa	5/7/2019 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:)						
🔜 USB20FD (D:)						
_temp-cd-						
4Aug						
950-0539						
ADFs						
All Else	~					
File.name: X	nert Xnress SARS-	CoV-2 gya		GeneXpert®	Assay Definition	F v
	percorpress_owno-	cor Ligna		Senespere		
				<u>O</u> pen	Cance	

#### 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.

Select to Define Assays

- 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**.

		<b>\</b>	
GeneXpert® Dx System			
User Data Management Reports	s Setup Maintenance Defir	e Assays About	User Admin User
Create Test Che	ck Status Stop Te	st View Results Define Assay	vs Define Graphs Maintenance
Assay	Assay Name	Xpert Xpress SARS-CoV-2/Flu/RSV	
	Varsian	2	
Name v.	Version	2	
Xpert Xpress SARS-CoV-2 2 Xpert Xpress SARS-CoV-2 2	Assay Type	For Emergency Use Only	
Xpert Xpress SARS-CoV-2 2		For Emergency Use Only	
	Assay Disclaimer		
	Need Lot Specific Para	meters	
	Last Modified Date	08/04/2015-50-06	
	Last Modified Date	08/04/20 15:59:06	
	Last Modified Date	08/04/20 15:59:06	Chambers
	Last Modified Date	08/04/20 15:59:06	Chambers Name
	Last Modified Date	08/04/20 15:59:06	Chambers Name
	Last Modified Date	08/04/2015:59:06 Binding Reagent Sample	Chambers Name
	Last Modified Date	08/04/2015:59:06 Binding Reagent Sample Fluk-RSV Lysis Elution Beagent	Chambers Name
	Last Modified Date	08/04/20 15:59:06 Binding Reagent Sample Flu-RSV Lysis Elution Reagent RT PCR Beads	Chambers Name
	Last Modified Date	00/04/2015:59:06 Binding Reagent Sample Flu-RSVLysis Elution Reagent RT PCR Beads	Chambers Name
	Last Modified Date	08/04/2015:59:06 Binding Reagent Sample Flu-RSV Lysis Elution Reagent RT PCR Beads	Chambers Name
	Last Modified Date	08/04/2015:59:06	Chambers Name
	Last Modified Date	08/04/20 15:59:06 Binding Reagent Sample Flu-RSV Lysis Elution Reagent RT PCR Beads	Chambers Name
	Last Modified Date	08/04/2015:59:06 Binding Reagent Sample Flu-RSVLysis Elution Reagent RT PCR Beads	Chambers Name
	Last Modified Date	08/04/2015:59:06 Binding Reagent Sample Flu-RSV Lysis Elution Reagent RT PCR Beads	Chambers
	Last Modified Date	08/04/2015:59:06 Binding Reagent Sample Flu-RSV Lysis ELution Reagent RT PCR Beads	Chambers
New Delete Duplicate	Last Modified Date	08/04/2015:59:06 Binding Reagent Sample Flu-RSVLysis Elution Reagent RT PCR Beads ove To Top Convert Lot Import Exc	Chambers Name

Select to Import Assay //

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

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

Import Assay	×
	Desktop  Recent Desktop Computer Network Libraries Cepheid
File <u>N</u> ame: Files of <u>T</u> ype:	Assay Files (.gxa)
	Import

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.

User Data i	anagement	Reports Set	up manitena	ance Abou	•					/			User Detail User
Cr	reate Test		Check St	atus	a	Stop Test	est View Results Define Assays Define Graphs Maint		Maintenance				
Modules									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 Date
A1			Available										
A2			Available										
A3			Available										
A4			Available										

Figure 8. GeneXpert Dx System Window

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

User Data Management Reports	s Setup Maintenance Defin	e Assays About				User Detail Use
Create Test	Check Status	Stop Test	View Results	Define Assays	Define Graphs	Maintenance
Assay	Assay Name	Xpert Xpress SARS-CoV-2/Flu/RSV				
Name	Version	2				
Xpert Xpress Flu 3	Assav Type	Emergency Use Only				
Xpert MRSA G3 20 Xpert CT 3						
Xpert CT_NG 3	Assay Disclaimer	For Emergency Use Only				
Xpert EV 23 Xpert FII & FV Combo 1	,,					
Xpert FII 1	Veed Let Creatific Dave					
Xpert MTB-RIF Assay 5						
Xpert NG 3 HCV v75B Xpertise 6.2 1	Last Modified Date	08/04/20 15:59:06				
HIV -1Quant SW Val 20 1						
Xpert MRSA-SA BC 21	Cartridge Type			Chambers		
Xpert Xpress SARS-CoV-2				Name		
Xpert Xpress SARS-CoV-2 2		Reagent 1				
Xpert Xpress SARS-CoV-2 2		Sample				
Xpert SA Nasal Compl 5		Reagent 2				
Xpert C.diff-Epi 2						
			<b></b>			
New Delete Duplicate	Rename Save M	love To Top Convert Lot	Import Export Report			

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.

Ecepheid. X	pertise Softwar								Detail User 👷 👷 🖳 🖻			
Mo	odule Status	\$				Tes	ts Since L	aunch				
Module Name	Status		Sample ID	Mod Name	User	Test Type	Result	Assay	Start Date	Estimated Minutes	Status	ORDERS
E1	Available									To Result		
E2	Available											RESULTS
E3	Available	_										
E4	Available	_										DATA
F2	Available											MANAGEMENT
F3	Available											
F4	Available											SETUP
11	Available											

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.

Cepheid. Xpertise Software							Detail User					
<b>1</b>	l 📮 🖉		• 1/ •	•								
Mo	odule Status					Tes	ts Since L	aunch				l a
Module Name	Status		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											<u></u>
F1	Available											CHANGE

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.

	ipertise Software	-		Deta	ill User + 👤 👤 🗓 💽			
Mo	odule Status		Manage Assays	Manage Assays				
Module	Status		Assay	Version	Need Lot Specific Parameters	IMPORT		
Name			Xpert Xpress SARS_CoV-2/Flu/RSV	2	<b>v</b>			
E1	Available		Xpert Xpress SARS_CoV-2/Flu	2	<b>v</b>	, j		
E2	Available		Xpert Xpress SARS_CoV-2	2	×	MOVE TO TOP		
E3	Available		Xpert MTB-RIF Assay G4	5	2			

Figure 13. Xpertise Manage Assays Workspace

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

Contract. Xpertise Software						Detail User + 👤 👷 🛄 🕎	
Mc	odule Status				Import Assay		<b>_</b> _D
Module	Status		Look in:	🗂 Infinity Systems			OPEN
E1	Available		Xpert Xp	Xpert Xpress_SARS-CoV-2.gxa			×
E2	Available		Xpert Xp	press_SARS-CoV-2_Flu.gxa			CANCEL
E3	Available		Xpert Xpress_S	press_SARS-CoV-2_Flu_RSV.gxa			
E4	Available						
F1	Available						
F2	Available						
F3	Available						

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*.