

GeneXpert[®] Software

Version 6.2



IVD. In vitro diagnostic medical device. May not be available in all countries.

6-Color and 10-Color Modules

- GeneXpert® Dx Software 6.2 supports an instrument with either 6-color or 10-color modules.
- A 10-color module can be identified by a blue stripe on the upper edge of the module door.
- GeneXpert Dx software version 6.2 is compatible with Microsoft *Windows 7 & Windows 10* operating systems.

6-Color Module
No Identification
Stripe on door



10-Color Module
Blue Identification
Stripe on door



Installation and Setup Workflow

1. Install the GeneXpert® Dx System.
2. Turn on the computer.
3. Start the software.
4. Assign instrument letters. (Optional)
5. Define users and permissions.
6. Configure the system.
7. Manage assay definition files
8. Verify proper installation and setup.

Start the Windows Operating System (Windows7 /Windows 10)

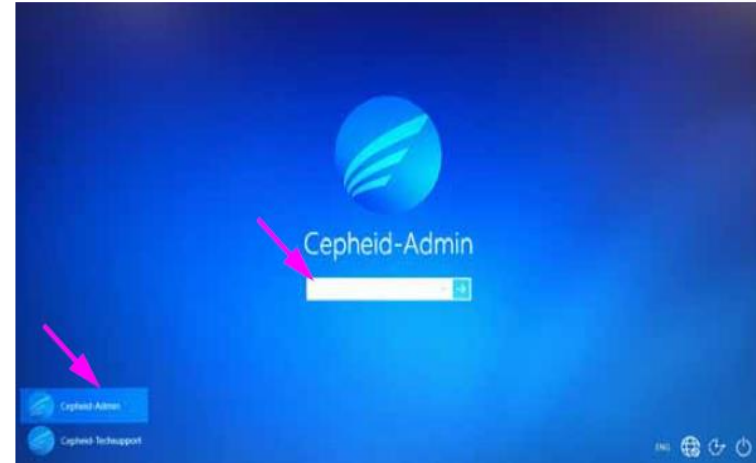
- 1 Switch on the GeneXpert® Dx System : a small blue light will appear at the front panel of the system
- 2 Switch on the Computer
- 3 Open the session:



User-Account: **Cepheid-Admin** Password: **cphd**



With Windows 7



With Windows 10



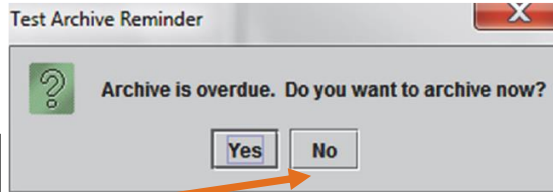
Prepare your system for routine use

4

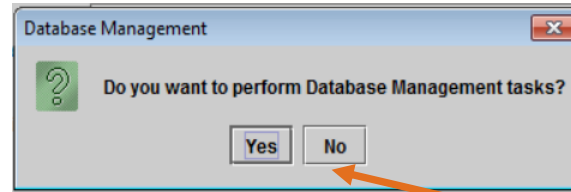
Please wait couple of minutes– the GeneXpert® Dx software will start automatically



GeneXpert Dx icon on the Windows desktop allows for manual software initiation.



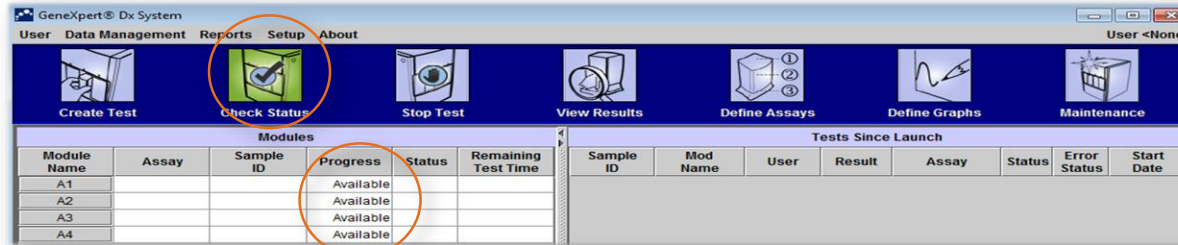
Click on **NO** if Database Management is not required to be archived at this time.



Click on **NO** if Database Management is not required to be done at this time.

5

In the **Check Status** screen, verify that all modules are available



If no modules are available, please refer to Troubleshooting section in the Operator Manual and contact Cepheid Technical Support

Prepare your system for routine use

To re-open the Software manually, double click on the «GeneXpert Dx» icon on the desktop



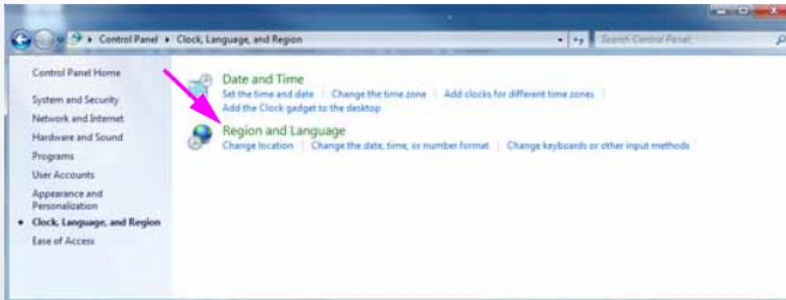
The GeneXpert® Gx Dx Software is available in:



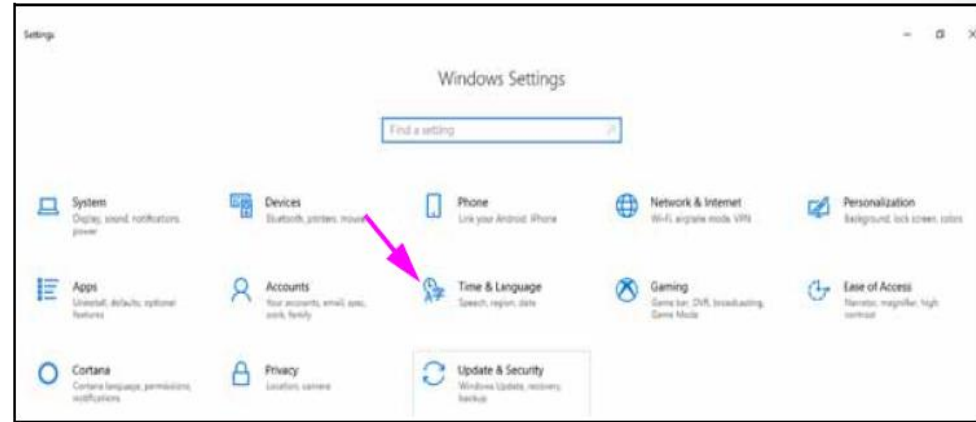
For more information contact : training@cepheid.com.

Source: <http://www.free-country-flags.com/index.php>

Windows 7 & Windows 10 Language Setting

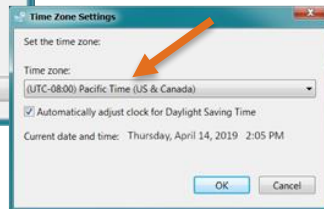
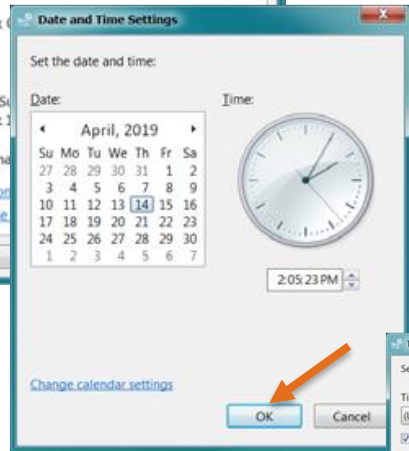
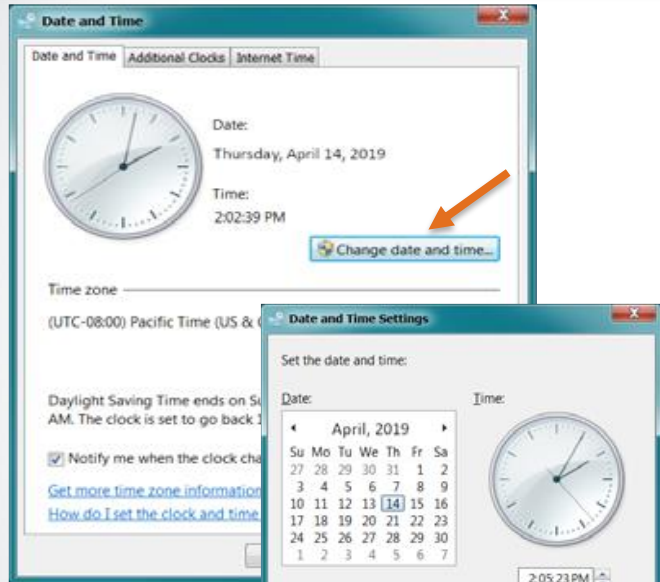


With Windows 7

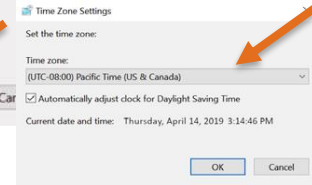
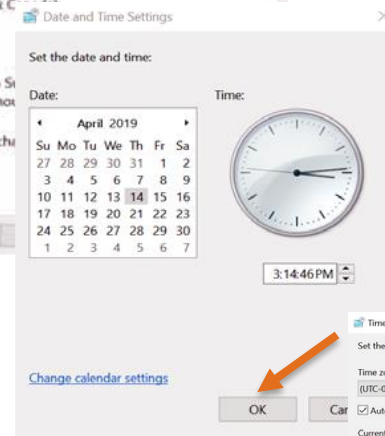


With Windows 10

Local Date and Time Setting



With Windows 7



With Windows 10

How to Assign Instrument Letters



IVD. In vitro diagnostic medical device. May not be available in all countries.

Assign Instrument Letters

1

Click Setup

2

Click Assign instrument letter

3

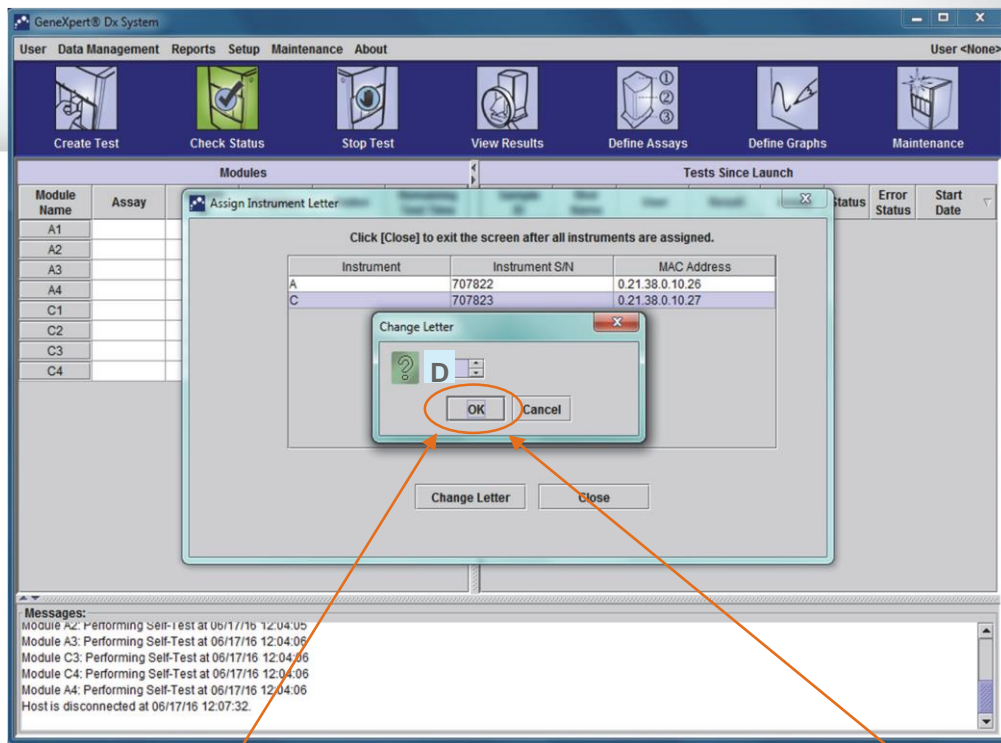
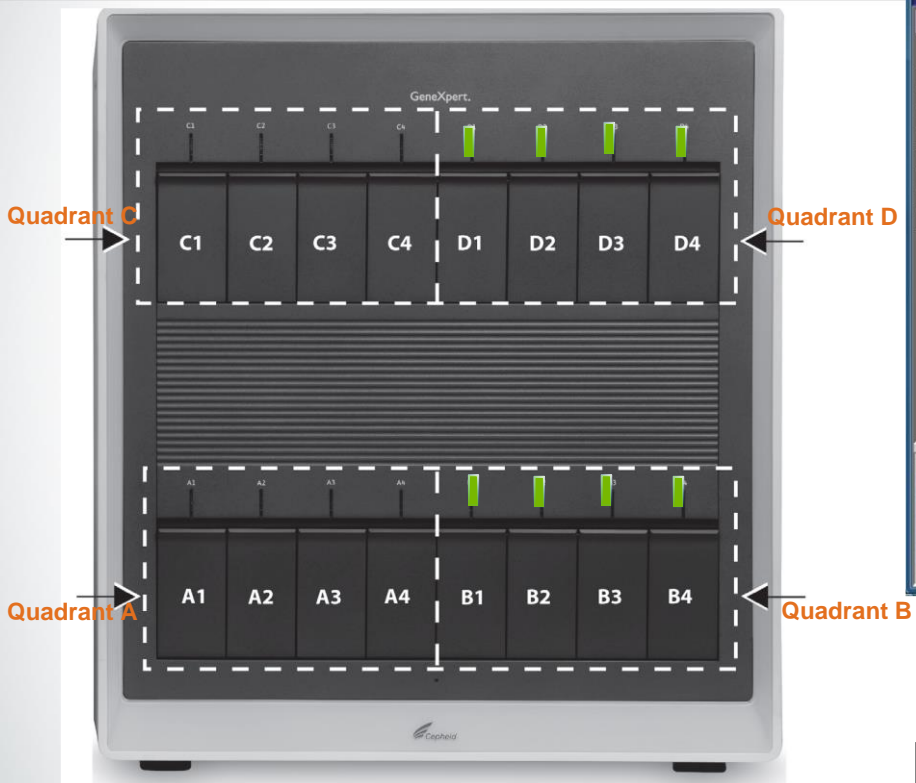
Click Change Letter

The screenshot shows the GeneXpert Dx System interface. The top menu bar includes 'User', 'Data Management', 'Reports', 'Setup', 'Maintenance', 'Define Assays', and 'About'. The 'Setup' menu is open, showing options: 'User Administration', 'User Type Configuration', 'System Configuration', and 'Assign Instrument Letter'. The 'Assign Instrument Letter' option is circled in orange. Below the menu, the 'Assign Instrument Letter' dialog box is displayed. It contains a table with the following data:

Instrument	Instrument S/N	MAC Address
A	707822	0.21.38.0.10.26
C	707823	0.21.38.0.10.27

At the bottom of the dialog box, the 'Change Letter' button is circled in orange. The background interface shows a 'Modules' table with columns 'Module Name' and 'Assay', and a 'Tests Since Launch' table with columns 'Status', 'Error Status', and 'Start Date'. A 'Messages' window at the bottom displays system logs.

Assign Instrument Letters



4

Change the Letter
(A ,B ,C or D etc)

5

Click OK

Assign Instrument Letters

- The GeneXpert® Dx system window will be displayed, showing the updated letter assignments

GeneXpert® Dx System

User <None>

Create Test Check Status Stop Test View Results Define Assays Define Graphs Maintenance

Modules					
Module Name	Assay	Sample ID	Progress	Status	Remaining Test Time
A1				Available	
A2				Available	
A3				Available	
A4				Available	
B1				Available	
B2				Available	
B3				Available	
B4				Available	

Tests Since Launch							
Sample ID	Mod Name	User	Result	Assay	Status	Error Status	Start Date

Messages:

- Module A2: Performing Self-Test at 02/22/19 12:04:06
- Module A3: Performing Self-Test at 02/22/19 12:04:06
- Module C3: Performing Self-Test at 02/22/19 12:04:06
- Module C4: Performing Self-Test at 02/22/19 12:04:06
- Module A4: Performing Self-Test at 02/22/19 12:04:06
- Host is disconnected at 02/22/19 12:07:32.

Verifying Proper Installation and Setup



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Installation Qualification Report

1

Click on Reports & Drop-Down the Menu

GeneXpert@ Dx System

User Data Management Reports Setup Maintenance About

Specimen Report
Patient Report
Control Trend Report
System Log
Assay Statistics Report
Installation Qualification

Module Name Assay Progress Status Remaining Test Time

Module Name	Assay	Progress	Status	Remaining Test Time
A1			Available	
A2			Available	
A3			Available	
A4			Booting	

Tests Since Launch

Sample ID	Mod Name	User	Result	Assay	Status	Error Status	Start Date

Messages:

Launched GeneXpert@ Dx System at 01/02/19 11:13:10
Version 6.1
Module A1: Performing Self-Test at 01/02/19 11:13:12
Module A2: Performing Self-Test at 01/02/19 11:13:12
Module A3: Performing Self-Test at 01/02/19 11:13:13
Module A4: Performing Self-Test at 01/02/19 11:13:14

2

Select Installation Qualification

GeneXpert@ Dx System Installation Qualification Report

This report provides documented evidence of the installation of this GeneXpert@ Dx System.

System Information

Software	Version	Status
GeneXpert@ Dx System	6.2	Pass
Java Runtime Environment	1.8.0_131	Pass
GX_Utils.DLL	0.8.4.0	Pass
SQL Database	Microsoft SQL Server 11.00.6020	Pass
Database	gx_db 3.0.9.0	Pass
Operating System	Windows 7 6.1 Service Pack 1	Pass
GIT Plug-In	1	Pass

Instrument Information

Instrument A

Instrument S/N	Gateway Firmware
803488	2.0.18

Module Name	Module S/N	Module Firmware	Internal Temp °C	Status
A1	628676	3.3.3	31.6	Pass
A2	638430	3.3.3	30.8	Pass
A3	638964	3.3.3	30.0	Pass
A4	641366	3.3.3	30.7	Fail*

Fail* = Ambient temperature too high, incorrect model number or hardware error has been detected. Please generate a System Log with the list of errors for further troubleshooting.

Shaded Modules = Reporter is out of calibration.

GeneXpert PC

02/12/20 14:33:50

GeneXpert@ Dx System Installation Qualification Report

Installation of networked instruments complies with the setup requirements specified in the GeneXpert@ Dx System Operator Manual, 'Installation' section.

Verified by _____

Date _____

This IQ is acceptable if all System Information and Instrument Information are listed as 'Pass'. All instrument modules that are listed as 'Pass' are available for use.

Acceptance: [] Acceptable [] Not Acceptable

Performed by _____

Date _____

Reviewed and approved by _____

Date _____

Page 1 of 2

Configuring the System



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Configuring the System

1

Click **Setup** on the menu bar, then click **System Configuration**

2

Click on **General** Tab

3

Write the Hospital name/ institution name/ system configuration and Serial Number

System Configuration

General | Archive Settings | Folders | Host Communication Settings

System Name: GeneXpert PC

Date Format: MM/DD/YY

Time Format: 24 Hour (HH:mm:ss)

Use Patient ID

- Patient ID
- Patient ID 2
- Patient Name
- Patient Demographics

Scan Patient ID Barcode

Scan Sample ID Barcode

Scan Cartridge Barcode

Require Start Test Login

- Never
- Always
- Start Test Login Timeout (In Minutes): 30

Audio At End Of Test

Print Test Report At End Of Test

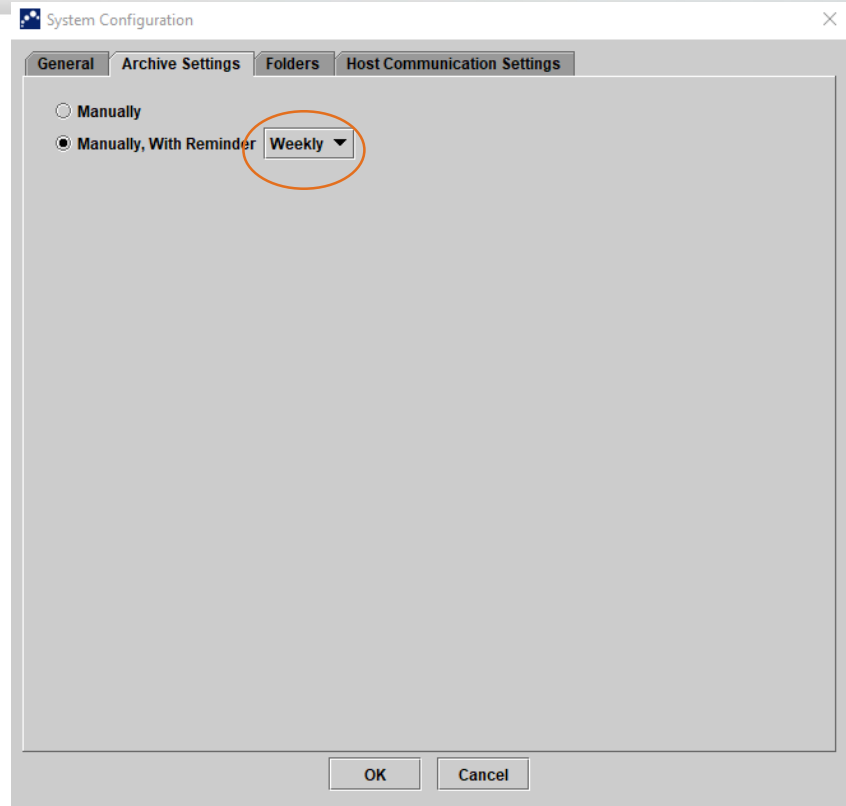
Assay Statistics Deletion Reminder

Database Management Reminders

OK Cancel

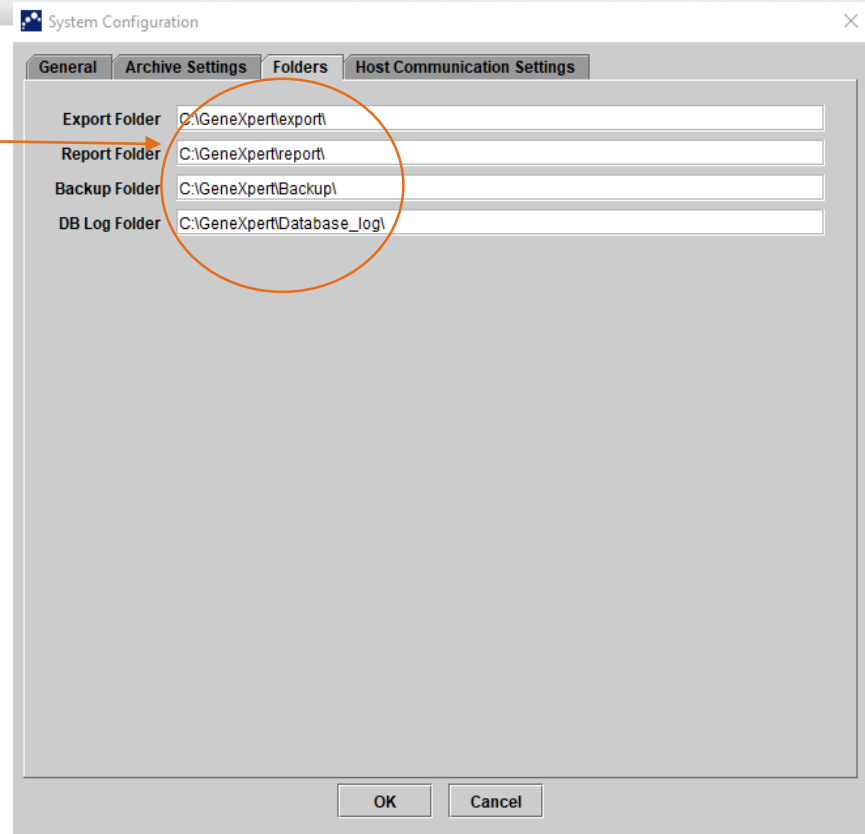
Configuring the System

- The reminder is displayed when:
 - GeneXpert[®] Dx application starts
 - GeneXpert[®] Dx application normally terminates
 - User logs in (excluding start test login)



Configuring the System

- The default locations of each folder on the computer hard drive is indicated here.



Configuring the System

Host Communication Settings Workspace

System Configuration

General Archive Settings Folders Host Communication Settings

Enable Host Communication

Host Setting

Use Cepheid Link (Only check if you have the Cepheid Link middleware solution for sample traceability)

Host ID LX

Automatic Host Query After Sample ID Scan

Automatic Test Order Download

Automatic Result Upload

Use Instrument Specimen ID

Communication Settings

Protocol HL7 ASTM

Run Host As Server Client

Server IP Address

Port # 1234

Order/Result Management

Delete Cancelled Orders

Expire Results

Reset Communication Buffer

Host Test Code

Enable	Assay	Host Test Code	Edit
<input type="checkbox"/>	Xpert BCR-ABL Monitor IS Version 1		Edit
<input checked="" type="checkbox"/>	Xpert CDIFFICILE Version 3		Edit
<input type="checkbox"/>	Xpert CT_NG Version 3		Edit
<input type="checkbox"/>			
<input type="checkbox"/>			
<input type="checkbox"/>			

OK Cancel

The GeneXpert Dx Software Features

The screenshot shows the GeneXpert Dx software interface. At the top, three categories are labeled: **Test**, **Administration**, and **Maintenance**. The **Test** category includes 'Create Test', 'Check Status', and 'Stop Test'. The **Administration** category includes 'View Results' and 'Define Assays'. The **Maintenance** category includes 'Define Graphs' and 'Maintenance'. The interface also features a menu bar with 'User', 'Data Management', 'Reports', 'Setup', 'Maintenance', and 'About'. Below the menu bar is a toolbar with icons for each function. The main window is divided into two panes: 'Modules' and 'Tests Since Launch'. The 'Modules' pane contains a table with columns for Module Name, Assay, Sample ID, Progress, Status, and Remaining Test Time. The 'Tests Since Launch' pane contains a table with columns for Sample ID, Mod Name, User, Result, Assay, Status, Error Status, and Start Date.

Modules					
Module Name	Assay	Sample ID	Progress	Status	Remaining Test Time
A1			Available		
A2			Available		
A3			Available		
A4			Available		

Tests Since Launch							
Sample ID	Mod Name	User	Result	Assay	Status	Error Status	Start Date

Managing Users



IVD. In vitro diagnostic medical device. May not be available in all countries.

Adding new users :

1. Create an Administrator Account (“Admin”)

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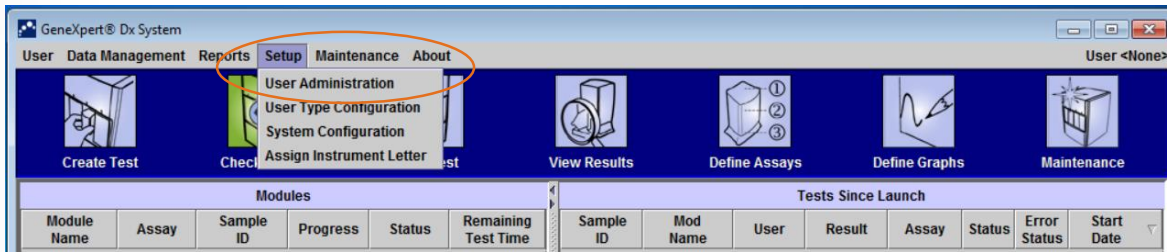


Create an Administrator Account (“Admin”)

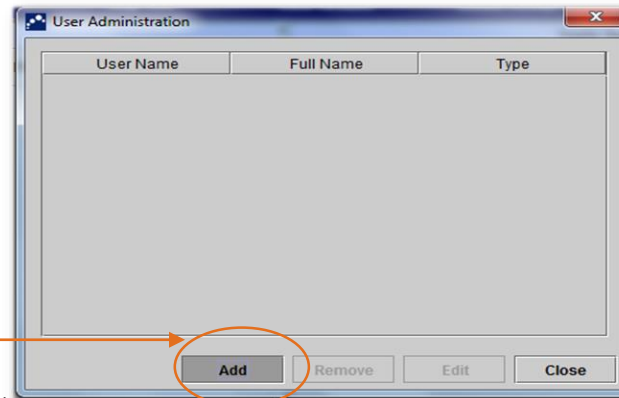
Define the person in the lab that will have full access to the software

The first account to be created **must be an Admin account**. There can be more than one Administrator account per system

1 Setup → User Administration



2 Click Add

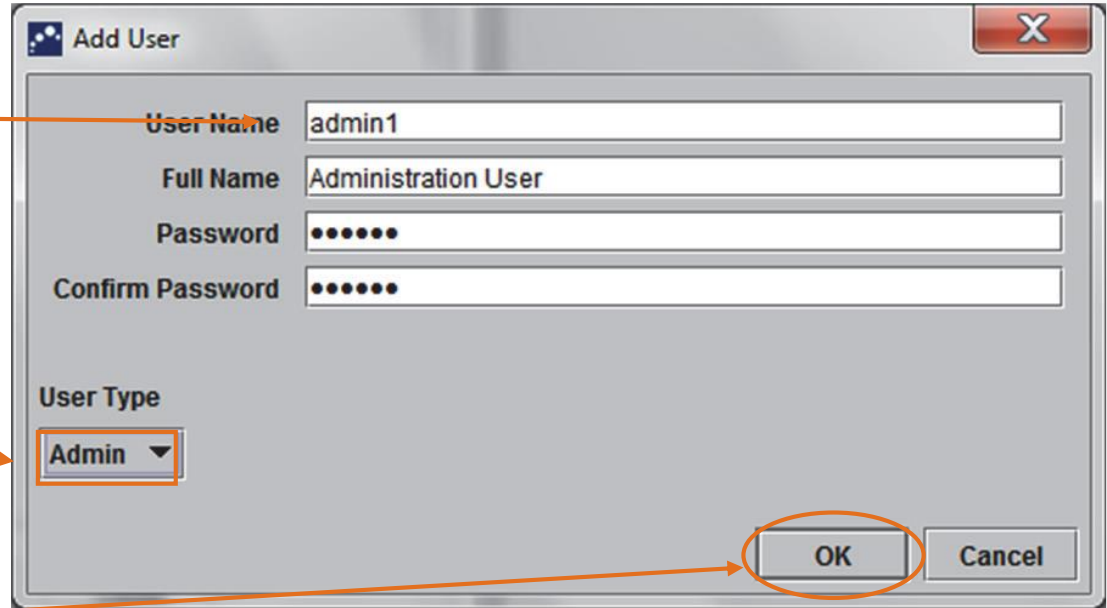


Create an Administrator Account (“Admin”)

3 Enter the Username and Password

4 Choose the User type (Admin)

5 Click OK



The screenshot shows a dialog box titled "Add User" with a close button (X) in the top right corner. The dialog contains the following fields and controls:

- User Name:** A text input field containing "admin1". An orange arrow points from the instruction box to this field.
- Full Name:** A text input field containing "Administration User".
- Password:** A text input field with seven dots representing a masked password.
- Confirm Password:** A text input field with seven dots representing a masked password.
- User Type:** A dropdown menu with "Admin" selected. An orange arrow points from the instruction box to this dropdown.
- Buttons:** "OK" and "Cancel" buttons at the bottom right. The "OK" button is circled in orange, with an arrow pointing from the instruction box to it.

Adding new users :

2. Create a Basic Account

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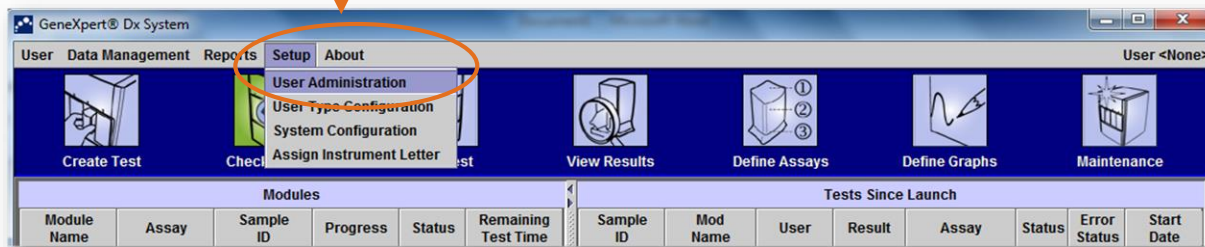


Create a Basic Account

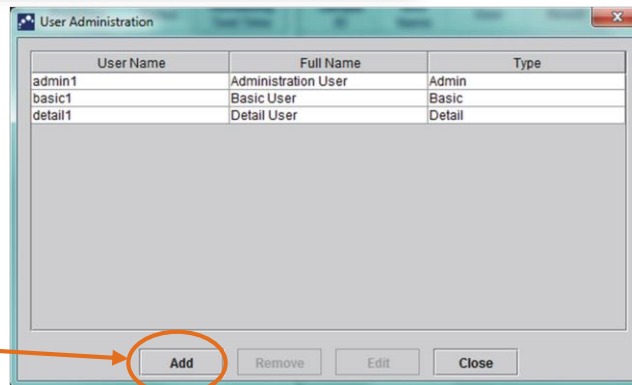
Define the person in the lab that will have limited access to the software

There can be more than one Basic account per system

1 Setup → User administration



2 Click on Add



Create a Basic Account

3 Enter the Username and Password

4 Choose the User type (Basic)

5 Click on OK

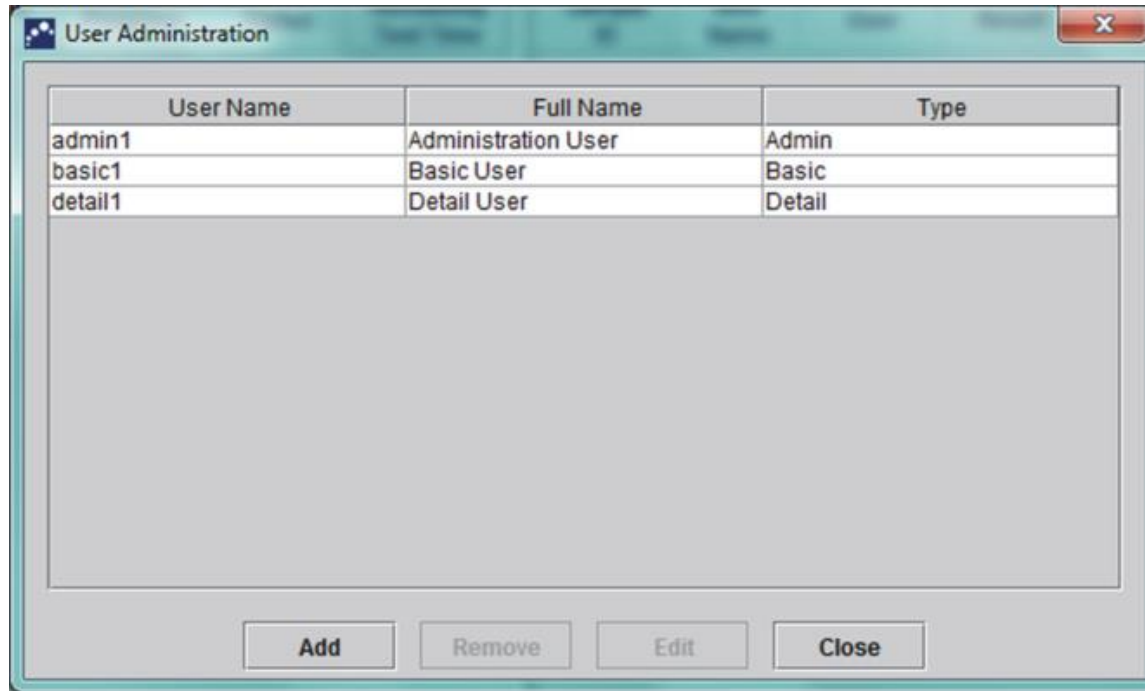
The screenshot shows a 'User Administration' window with an 'Add User' dialog box open. The dialog contains the following fields and controls:

- User Name:** basic1
- Full Name:** Basic User
- Password:** [masked with dots]
- Confirm Password:** [masked with dots]
- User Type:** Basic (dropdown menu)
- Buttons:** OK (circled in orange), Cancel

The main window below the dialog has buttons for Add, Remove, Edit, and Close.

NOTE: There are differences in what Basic account users can see or do

User Administration Dialog Box



User Type Configuration

1

Setup → User Type Configuration

The screenshot shows the GeneXpert Dx System software interface. The 'User Administration' menu is highlighted, and the 'User Type Configuration' dialog box is open. The dialog box contains a list of functions with checkboxes for 'Basic' and 'Detail' permissions.

	Basic	Detail
Create/Start Test	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Stop One Test or All Tests	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
View Detailed Research Assay Test Result and Report	<input type="checkbox"/>	<input checked="" type="checkbox"/>
View Detailed Template Assay Test Result and Report	<input type="checkbox"/>	<input checked="" type="checkbox"/>
View Detailed Reference Assay Test Result and Report	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Edit Test Details	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Create, Rename and Edit Research Assay	<input type="checkbox"/>	<input type="checkbox"/>
Duplicate Research Assay Into Research Assay	<input type="checkbox"/>	<input type="checkbox"/>
Duplicate Template Assay Into Research Assay	<input type="checkbox"/>	<input type="checkbox"/>
Duplicate Reference Assay Into Research Assay	<input type="checkbox"/>	<input type="checkbox"/>
Delete Assay and Lot Specific Parameters	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Manage Assay Definition	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Export Research Assay	<input type="checkbox"/>	<input type="checkbox"/>
Export Template Assay	<input type="checkbox"/>	<input type="checkbox"/>
Export Reference Assay	<input type="checkbox"/>	<input type="checkbox"/>
Convert Research Assay To Reference Assay	<input type="checkbox"/>	<input type="checkbox"/>
Edit Graphs	<input type="checkbox"/>	<input type="checkbox"/>
Archive Test	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Purge Test	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Retrieve Test	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Backup Database	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Restore Database	<input type="checkbox"/>	<input type="checkbox"/>
Compact DB and Run Database Integrity Check	<input type="checkbox"/>	<input type="checkbox"/>
View Specimen, Patient and Patient Trend Reports	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
View Control Trend and Assay Statistics Reports	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Editing User Profile

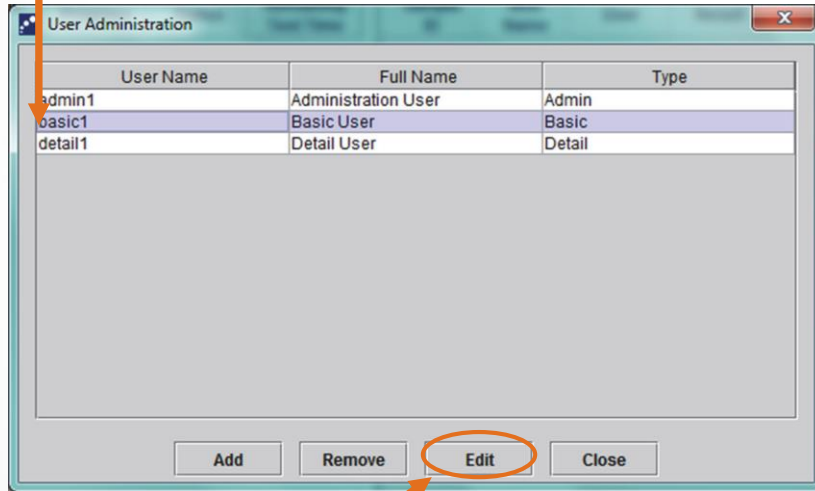


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How to edit user profile

1

Select the user to be edited from the user administration list.

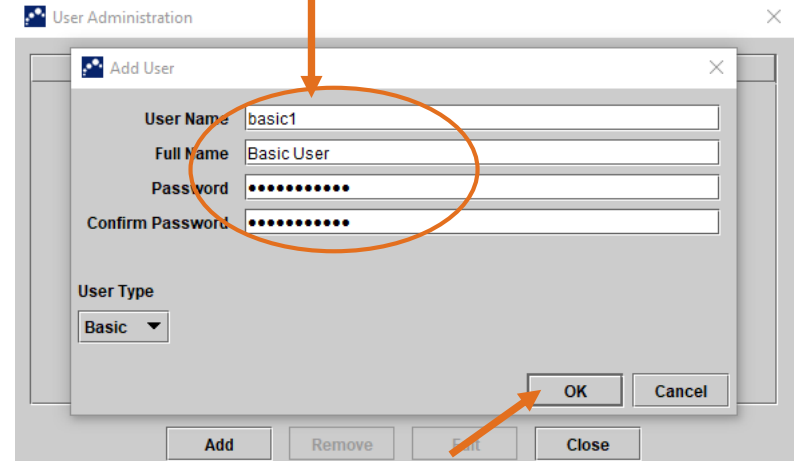


2

Click on **Edit**

3

Revise the information, as desired, and then click **OK** to save the changes and close the Edit User dialog box.



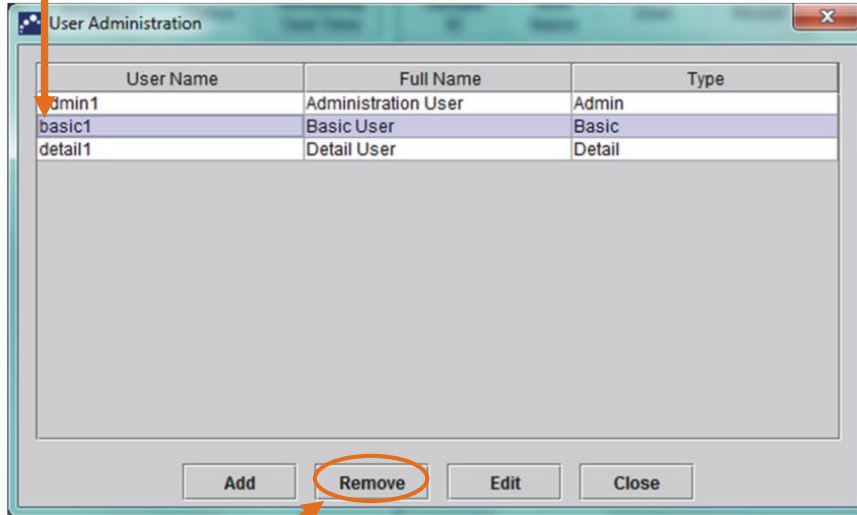
Removing Users



IVD. In vitro diagnostic medical device. May not be available in all countries.

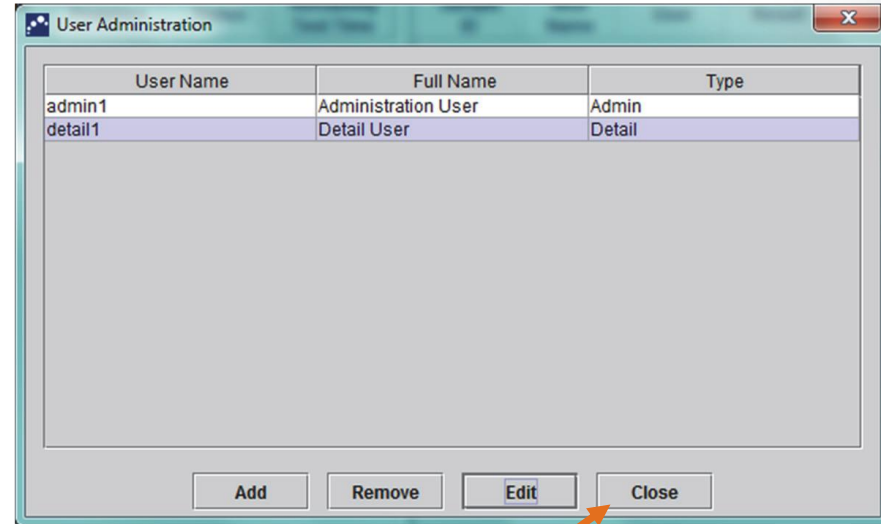
How to remove users

1 Click to select the user to be removed



2 Click on **Remove**

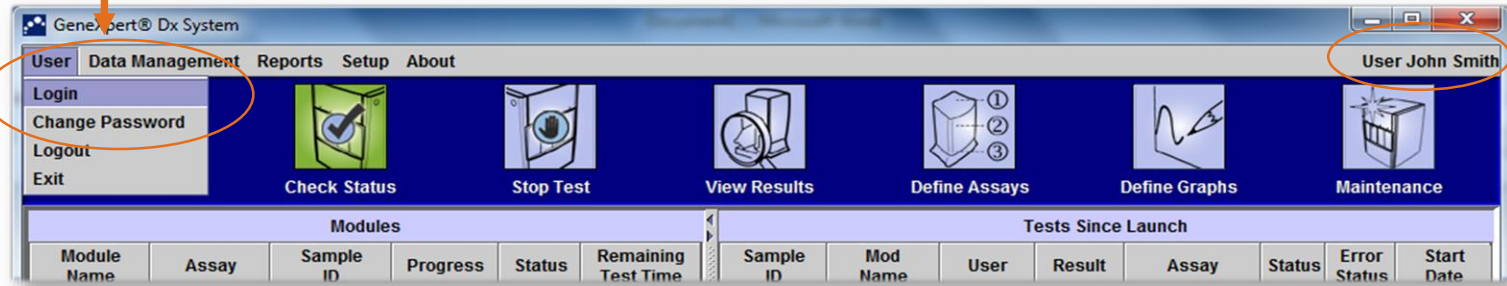
3 To remove additional users, repeat Step 1 and Step 2. If you are done removing users, click **Close**



How to login

1

Select User → Login



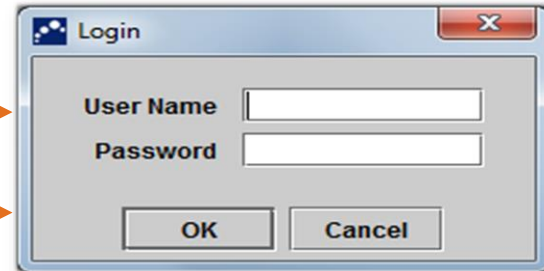
4

2

Enter your User Name and Password

3

Click OK



GeneXpert® Dx System Window

Create and start a test

View the results

Monitor the test progress

Check the list of assays

Module Name	Assay	Sample ID	Progress	Status	Remaining Test Time
A1				Available	
A2				Available	
A3				Available	
A4				Available	
C1				Available	
C2				Available	
C3				Available	
C4				Available	

Sample ID	Mod Name	User	Result	Assay	Status	Error Status	Start Date
-----------	----------	------	--------	-------	--------	--------------	------------

Messages:
Module A2: Performing Self-Test at 05/11/16 12:04:05
Module A3: Performing Self-Test at 05/11/16 12:04:05
Module C3: Performing Self-Test at 05/11/16 12:04:05
Module C4: Performing Self-Test at 05/11/16 12:04:05
Module A4: Performing Self-Test at 05/11/16 12:04:05
Host is disconnected at 05/11/16 12:07:32

Create a Test

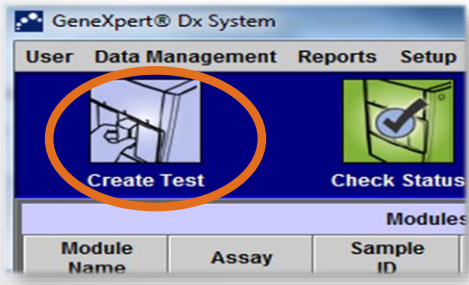


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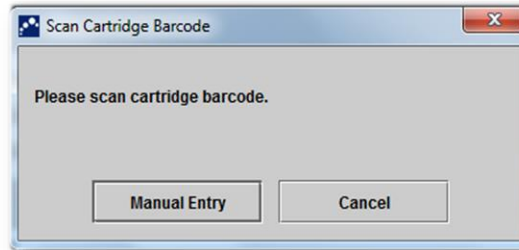
Create a Test

After preparing your cartridge according to the Package insert:

1 Click on **Create Test**



2 A dialogue box appears:
Scan cartridge barcode



3 Scan the barcode by holding the scanner about 8 to 10 inches from the barcode, aligning the laser on the scanner to the barcode image



Create a Test

4 Fill in the Patient ID, Sample ID. Patient Name if available

5 The Module is assigned automatically

6 Click **Start test**

7 A green light will flash on the module: Open the door and place the cartridge in the module.

8 Close the module door completely. The green light will stop flashing and the test will start.

The screenshot shows the 'Create Test' window with the following fields filled in:

- Patient ID: H112874895762R
- Sample ID: SD142231
- Patient ID 2: 1234567
- Last Name: Patient Last Name 1
- First Name: Patient First Name 1
- Date of Birth: YYYY/MM/DD
- Postal Code: [empty]
- Gender: <None>
- Ethnicity: <None>
- Select Assay: Xpert.C. difficile G2
- Version: 2
- Select Module: A2
- Reagent Lot ID*: 08100
- Expiration Date*: 2020/12/25
- Cartridge S/N*: 70462806
- Test Type: Specimen
- Sample Type: Other
- Other Sample Type: [empty]
- Notes: [empty]

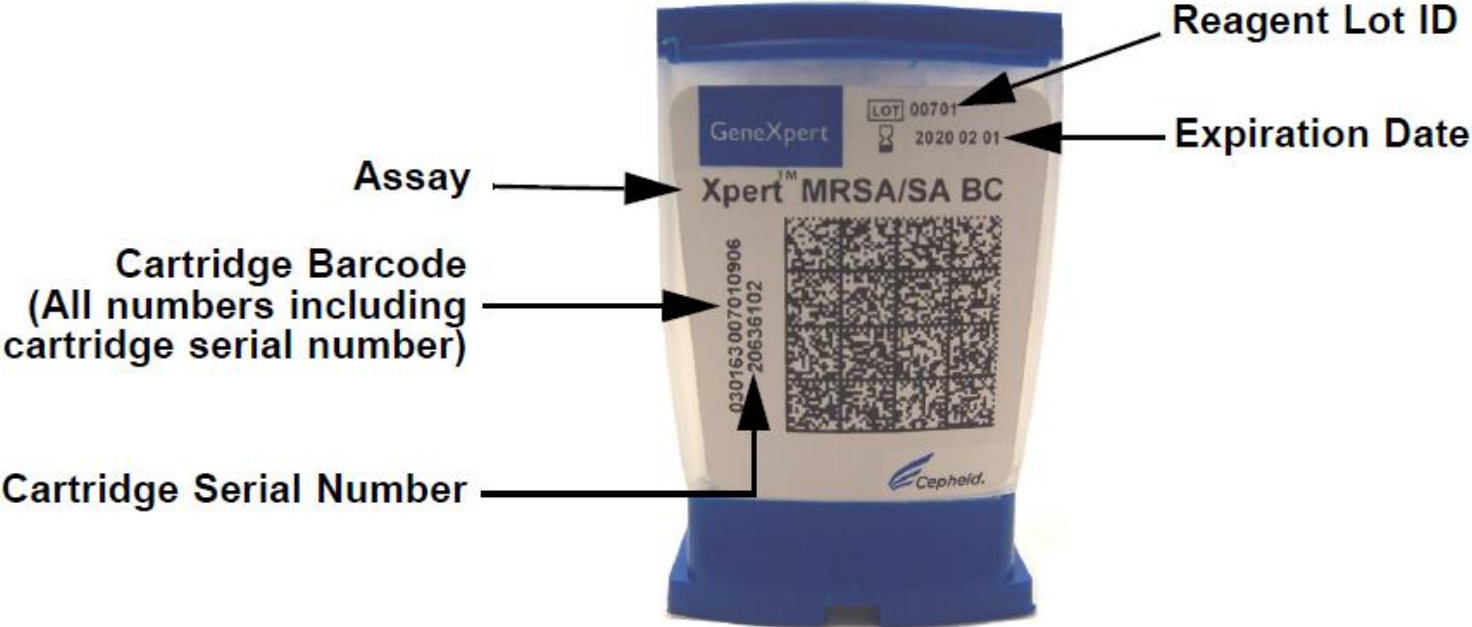
Buttons at the bottom: Start Test (circled), Scan Cartridge Barcode, Cancel.

Manual Entry of the Cartridge Barcode



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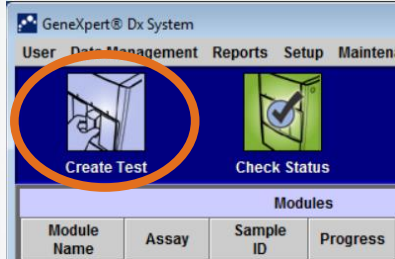
GeneXpert Cartridge



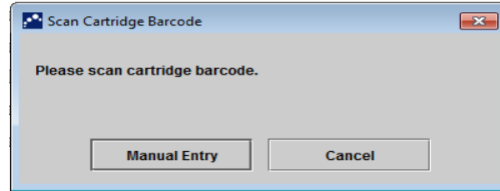
Manual Entry of the cartridge barcode

If the barcode scanner is not working; you can enter the cartridge barcode manually

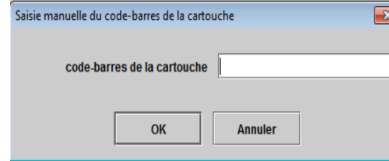
1 Click on **Create Test**



2 A dialogue box will appear:
Click on **Manual Entry**



This window will appear after clicking on **Manuel Entry**



3 Type manually the 2 line numbers of the cartridges – see the picture



Enter the full cartridge number without leaving any spaces

If the barcode scanner fails while using a new lot, creating a test cannot be completed. Please contact Cepheid technical support to request the Lot Specific Parameter (**LSP**)

Create a Test

4 Fill in the Patient ID, Sample ID. Patient Name if available

5 The Module is assigned automatically

6 Click **Start test**

7 A green light will flash on the module: Open the door and place the cartridge in the module.

8 Close the module door completely. The green light will stop flashing and the test will start.

The screenshot shows the 'Create Test' window with the following fields filled in:

- Patient ID: H112874895762R
- Sample ID: SD142231
- Patient ID 2: 1234567
- Last Name: Patient Last Name 1
- First Name: Patient First Name 1
- Date of Birth: YYYY/MM/DD
- Postal Code: [empty]
- Gender: <None>
- Ethnicity: <None>
- Select Assay: Xpert.C. difficile G2
- Select Module: A2
- Reagent Lot ID*: 08100
- Expiration Date*: 2020/12/25
- Cartridge S/N*: 70462806
- Test Type: Specimen
- Sample Type: Other
- Other Sample Type: [empty]

The 'Start Test' button is circled in orange. A blue arrow points from the 'Start Test' button to the photograph of the Cepheid Xpert module, which has a green light flashing on its top surface.

Monitoring the Test Process



IVD. In vitro diagnostic medical device. May not be available in all countries.

Monitoring the Test Process

Check the Module Area for Test Status

The screenshot displays the GeneXpert Dx System software interface. The top menu bar includes 'User', 'Data Management', 'Reports', 'Setup', 'Maintenance', and 'About'. Below the menu is a toolbar with icons for 'Create Test', 'Check Status', 'Stop Test', 'View Results', 'Define Assays', 'Define Graphs', and 'Maintenance'. The main area is divided into two panels: 'Modules' and 'Tests Since Launch'. The 'Modules' panel contains a table with columns for Module Name, Assay, Sample ID, Progress, Status, and Remaining Test Time. The 'Tests Since Launch' panel contains a table with columns for Sample ID, Mod Name, User, Result, Assay, Status, Error Status, and Start Date. A message window at the bottom displays the following text:

```
Message
Module A1: Performing Self-Test at 04/09/19 12:32:53
Module A2: Performing Self-Test at 04/09/19 12:32:54
Module A3: Performing Self-Test at 04/09/19 12:32:55
Module A4: Performing Self-Test at 04/09/19 12:32:55
Please load the cartridge into the module A1.
```

How to Stop a Test and Why

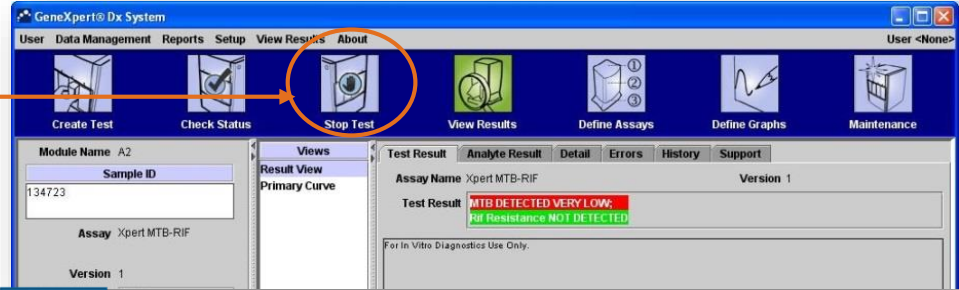


IVD. In vitro diagnostic medical device. May not be available in all countries.

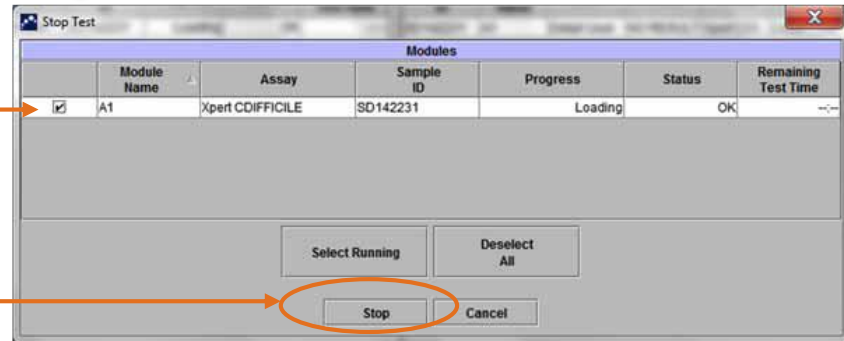
How to stop a test

You might have to stop the test to **avoid waste of time**

1 Click **Stop Test**



2 Select the module(s) that need to be stopped, by marking the tick box

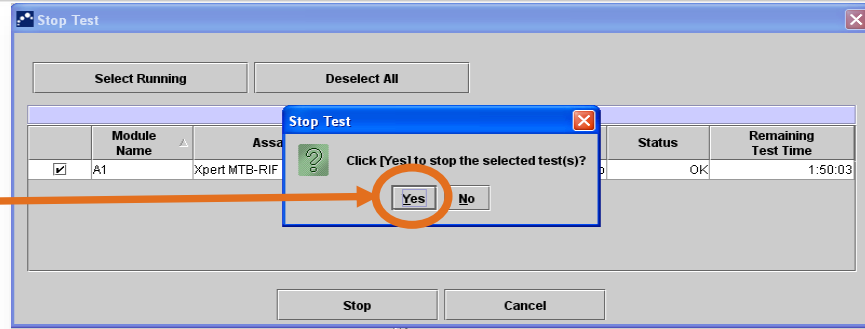


3 After selecting click **Stop**

How to stop a test

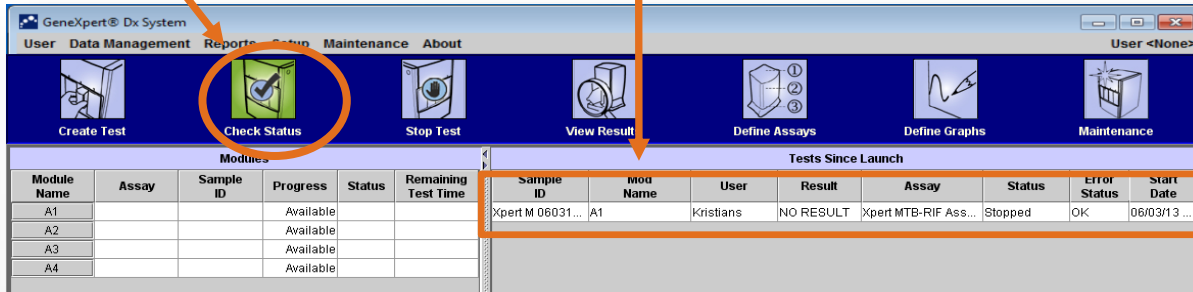
4

Confirm your choice by clicking on **Yes**:
or click **No** to cancel



5

You will see the details about interrupted/stopped tests Under **Check Status** menu; **Tests Since Launch** Section



View Results



IVD. In vitro diagnostic medical device. May not be available in all countries.

View results

1

Click on **View Results**

The screenshot displays the GeneXpert Dx System software interface. The 'View Results' menu item in the top navigation bar is circled in orange. The main window shows test details for Patient ID H351890559777R and Sample ID TZ637890. The assay is Xpert CT_NG, Version 3. The test result is displayed as 'CT NOT DETECTED' and 'NG NOT DETECTED'. A graph at the bottom right shows fluorescence over cycles, with a legend indicating CT1, NG2, NG4, SAC, and SPC. The 'View Test' button at the bottom is also circled in orange.

GeneXpert® Dx System

User Data Management Reports Setup Maintenance View Results About User Detail User

Create Test Check Status Stop Test View Results Define Assays Define Graphs Maintenance

Patient ID
H351890559777R

Sample ID
TZ637890

Assay Xpert CT_NG
Version 3
Test Type Specimen
Sample Type Other

Other Sample Type

Notes

Upload Status NA
Module Name A4
Reagent Lot ID* 05814
Start Time 01/30/19 17:41:03
End Time 01/30/19 19:08:20
Status Done
User Detail User

Views
Result View
Primary Curve

Test Result Analyte Result Detail Errors History Support
Assay Name Xpert CT_NG Version 3
Test Result
CT NOT DETECTED
NG NOT DETECTED

For In Vitro Diagnostic Use Only.

Views
Result View
Primary Curve

Fluorescence

Cycles

Legend
 CT1; Primary
 NG2; Primary
 NG4; Primary
 SAC; Primary
 SPC; Primary

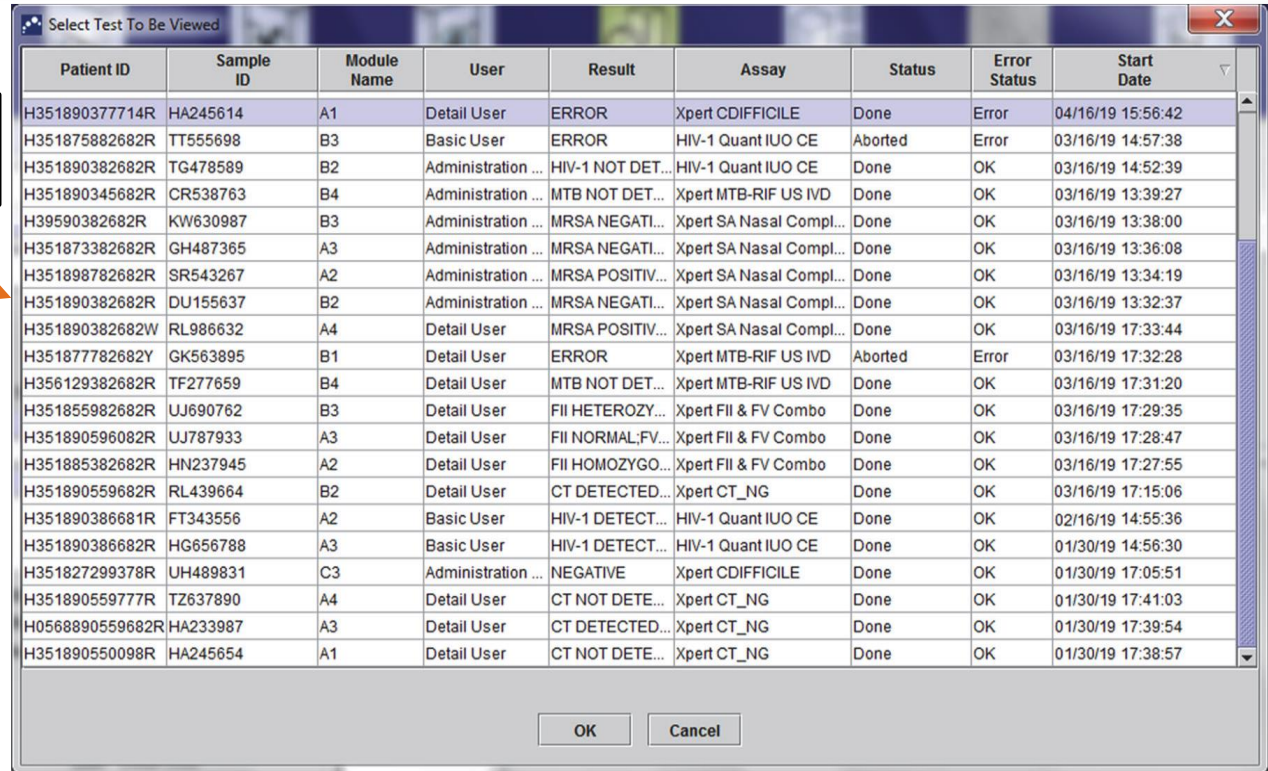
Save Changes Export Report Upload Test Select Graphs View Test

2

To visualize one particular result, click on **View Test**

View results

Double click on the test you want to display



Patient ID	Sample ID	Module Name	User	Result	Assay	Status	Error Status	Start Date
H351890377714R	HA245614	A1	Detail User	ERROR	Xpert CDIFFICILE	Done	Error	04/16/19 15:56:42
H351875882682R	TT555698	B3	Basic User	ERROR	HIV-1 Quant IUO CE	Aborted	Error	03/16/19 14:57:38
H351890382682R	TG478589	B2	Administration ...	HIV-1 NOT DET...	HIV-1 Quant IUO CE	Done	OK	03/16/19 14:52:39
H351890345682R	CR538763	B4	Administration ...	MTB NOT DET...	Xpert MTB-RIF US IVD	Done	OK	03/16/19 13:39:27
H39590382682R	KW630987	B3	Administration ...	MRSA NEGATI...	Xpert SA Nasal Compl...	Done	OK	03/16/19 13:38:00
H351873382682R	GH487365	A3	Administration ...	MRSA NEGATI...	Xpert SA Nasal Compl...	Done	OK	03/16/19 13:36:08
H351898782682R	SR543267	A2	Administration ...	MRSA POSITIV...	Xpert SA Nasal Compl...	Done	OK	03/16/19 13:34:19
H351890382682R	DU155637	B2	Administration ...	MRSA NEGATI...	Xpert SA Nasal Compl...	Done	OK	03/16/19 13:32:37
H351890382682W	RL986632	A4	Detail User	MRSA POSITIV...	Xpert SA Nasal Compl...	Done	OK	03/16/19 17:33:44
H351877782682Y	GK563895	B1	Detail User	ERROR	Xpert MTB-RIF US IVD	Aborted	Error	03/16/19 17:32:28
H356129382682R	TF277659	B4	Detail User	MTB NOT DET...	Xpert MTB-RIF US IVD	Done	OK	03/16/19 17:31:20
H351855982682R	UJ690762	B3	Detail User	FII HETEROZY...	Xpert FII & FV Combo	Done	OK	03/16/19 17:29:35
H351890596082R	UJ787933	A3	Detail User	FII NORMAL;FV...	Xpert FII & FV Combo	Done	OK	03/16/19 17:28:47
H351885382682R	HN237945	A2	Detail User	FII HOMOZYGO...	Xpert FII & FV Combo	Done	OK	03/16/19 17:27:55
H351890559682R	RL439664	B2	Detail User	CT DETECTED...	Xpert CT_NG	Done	OK	03/16/19 17:15:06
H351890386681R	FT343556	A2	Basic User	HIV-1 DETECT...	HIV-1 Quant IUO CE	Done	OK	02/16/19 14:55:36
H351890386682R	HG656788	A3	Basic User	HIV-1 DETECT...	HIV-1 Quant IUO CE	Done	OK	01/30/19 14:56:30
H351827299378R	UH489831	C3	Administration ...	NEGATIVE	Xpert CDIFFICILE	Done	OK	01/30/19 17:05:51
H351890559777R	TZ637890	A4	Detail User	CT NOT DETE...	Xpert CT_NG	Done	OK	01/30/19 17:41:03
H0568890559682R	HA233987	A3	Detail User	CT DETECTED...	Xpert CT_NG	Done	OK	01/30/19 17:39:54
H351890550098R	HA245654	A1	Detail User	CT NOT DETE...	Xpert CT_NG	Done	OK	01/30/19 17:38:57

View results

Basic user view

GeneXpert® Dx System

User Data Management Reports Setup Maintenance View Results About User Basic User

Create Test Check Status Stop Test **View Results** Define Assays Define Graphs Maintenance

Results Errors Support

Patient ID: H351890550098R

Sample ID: HA245654

Assay: Xpert CT_NG Version: 3

Result: **CT NOT DETECTED;**
NG DETECTED

Sample Type: Other

Other Sample Type:

Notes:

User Detail User

Start Time: 02/03/19 17:38:57

End Time: 02/03/19 19:06:02

Status: Done

Upload Status NA

For In Vitro Diagnostic Use Only.

Save Changes Export Report Upload Test Select Graphs View Test

GeneXpert® Dx System

User Data Management Reports Setup Maintenance View Results About User Basic User

Create Test Check Status Stop Test **View Results** Define Assays Define Graphs Maintenance

Results Errors Support

#	Description	Detail	Time
1	Operation terminated	Error 2002: Could not find calibration information for reporter #2	03/09/19 09:57:34

GeneXpert® Dx System

User Data Management Reports Setup Maintenance View Results About User Basic User

Create Test Check Status Stop Test **View Results** Define Assays Define Graphs Maintenance

Results Errors Support

Assay Type: In Vitro Diagnostic

Test Type: Specimen

Reagent Lot ID: 05814

Expiration Date: 04/19/19

Cartridge S/N: 425669558

Error Status: OK

S/W Version: 6.1

Module Name: A1

Instrument S/N: 702162

Module S/N: 629995

Save Changes Export Report Upload Test Select Graphs View Test

View results

Detail Users and Administrator View

Information about the test

The screenshot displays the GeneXpert Dx System interface. At the top, there is a navigation bar with icons for 'Create Test', 'Check Status', 'Stop Test', 'View Results', 'Define Assays', 'Define Graphs', and 'Maintenance'. Below this is a menu bar with options like 'User', 'Data Management', 'Reports', 'Setup', 'Maintenance', 'View Results', and 'About'. The main area is divided into several sections:

- Left Panel:** Contains fields for 'Patient ID' (Patient 1), 'Sample ID' (Sample 1), 'Assay' (Xpert MTB-RIF Ultra), 'Version' (4), 'Test Type' (Specimen), 'Sample Type' (Other), and 'Other Sample Type'. There is also a 'Notes' section and a 'Module Name' (B2) with 'Reagent Lot ID' (15015), 'Start Time' (08/05/20 22:12:42), 'End Time' (08/05/20 23:30:02), 'Status' (Done), and 'User' (<None>).
- Views Area:** A central panel with a 'Views' dropdown menu showing 'Result View' and 'Primary Curve'. An orange box highlights this area with the label 'Views Area'.
- Test Result:** A red box highlights the text 'MTB DETECTED MEDIUM; RIF Resistance NOT DETECTE' with the label 'Interpretation of the Result'.
- Real-Time PCR Curves:** A graph showing 'Fluorescence' on the y-axis (0 to 600) and 'Cycles' on the x-axis (0 to 40). Multiple colored curves represent different targets. A legend on the right lists targets: SPC; Primary, IS1081-IS6110; Primary, rpoB1; Primary, rpoB2; Primary, rpoB3; Primary, and rpoB4; Primary. An orange box highlights the graph with the label 'Real-Time PCR curves'.



View results

Detail Users and Administrator View (tabs)

View Results

Sample ID	Sample Name	CT	EnPI	Analyte Result	Probe Check Result
Sample 1	SPEC	150	400	175	PASS
Sample 1	SI104-06110	213	516	276	PASS
Sample 1	ipqB1	209	548	188	PASS
Sample 1	ipqB2	96	291	83	PASS
Sample 1	ipqB3	123	361	123	PASS
Sample 1	ipqB4	126	268	126	PASS
Sample 1	ipqB5	119	119	119	PASS
Sample 1	ipqB6	0	0	0	NA
Sample 1	ipqB7	0	0	0	NA
Sample 1	ipqB8	0	0	0	NA

View Results

Sample ID	Sample Name	CT	EnPI	Analyte Result	Probe Check Result	2nd Data Flag	2nd Data Hcgt	Cure Ft
Sample 1	SPEC	150	400	175	PASS	0.0	NA	NA
Sample 1	SI104-06110	213	516	276	PASS	0.0	NA	NA
Sample 1	ipqB1	209	548	188	PASS	0.0	PASS	0.0
Sample 1	ipqB2	96	291	83	PASS	0.0	PASS	0.0
Sample 1	ipqB3	123	361	123	PASS	0.0	PASS	0.0
Sample 1	ipqB4	126	268	126	PASS	0.0	PASS	0.0
Sample 1	ipqB5	119	119	119	PASS	0.0	NA	0.0
Sample 1	ipqB6	0	0	0	NA	0.0	NA	0.0
Sample 1	ipqB7	0	0	0	NA	0.0	NA	0.0
Sample 1	ipqB8	0	0	0	NA	0.0	NA	0.0

View Results

Sample ID	Sample Name	CT	EnPI	Analyte Result	Probe Check Result	2nd Data Flag	2nd Data Hcgt	Cure Ft	Hot	Hot
Sample 1	ipqB1	167	167	167	PASS	0.0	NA	0.0	88.1	93.0
Sample 1	ipqB2	167	167	167	PASS	0.0	NA	0.0	72.8	127.6
Sample 1	ipqB3	167	167	167	PASS	0.0	NA	0.0	76.4	107.6
Sample 1	ipqB4	167	167	167	PASS	0.0	NA	0.0	67.4	91.0

View Results

Sample ID	Sample Name	CT	EnPI	Analyte Result	Probe Check Result
Sample 1	SPEC	150	400	175	PASS
Sample 1	SI104-06110	213	516	276	PASS
Sample 1	ipqB1	209	548	188	PASS
Sample 1	ipqB2	96	291	83	PASS
Sample 1	ipqB3	123	361	123	PASS
Sample 1	ipqB4	126	268	126	PASS
Sample 1	ipqB5	119	119	119	PASS
Sample 1	ipqB6	0	0	0	NA
Sample 1	ipqB7	0	0	0	NA
Sample 1	ipqB8	0	0	0	NA

View Results

Sample ID	Sample Name	CT	EnPI	Analyte Result	Probe Check Result	2nd Data Flag	2nd Data Hcgt	Cure Ft
Sample 1	SPEC	150	400	175	PASS	0.0	NA	NA
Sample 1	SI104-06110	213	516	276	PASS	0.0	NA	NA
Sample 1	ipqB1	209	548	188	PASS	0.0	PASS	0.0
Sample 1	ipqB2	96	291	83	PASS	0.0	PASS	0.0
Sample 1	ipqB3	123	361	123	PASS	0.0	PASS	0.0
Sample 1	ipqB4	126	268	126	PASS	0.0	PASS	0.0
Sample 1	ipqB5	119	119	119	PASS	0.0	NA	0.0
Sample 1	ipqB6	0	0	0	NA	0.0	NA	0.0
Sample 1	ipqB7	0	0	0	NA	0.0	NA	0.0
Sample 1	ipqB8	0	0	0	NA	0.0	NA	0.0

View Results

Sample ID	Sample Name	CT	EnPI	Analyte Result	Probe Check Result	2nd Data Flag	2nd Data Hcgt	Cure Ft	Hot	Hot
Sample 1	ipqB1	167	167	167	PASS	0.0	NA	0.0	88.1	93.0
Sample 1	ipqB2	167	167	167	PASS	0.0	NA	0.0	72.8	127.6
Sample 1	ipqB3	167	167	167	PASS	0.0	NA	0.0	76.4	107.6
Sample 1	ipqB4	167	167	167	PASS	0.0	NA	0.0	67.4	91.0

How to Edit Test Information



IVD. In vitro diagnostic medical device. May not be available in all countries.

Editing the Test Information

If necessary, you can edit the test related information and notes after the test is completed or while the test is running

1

All the white fields in this section are editable

2

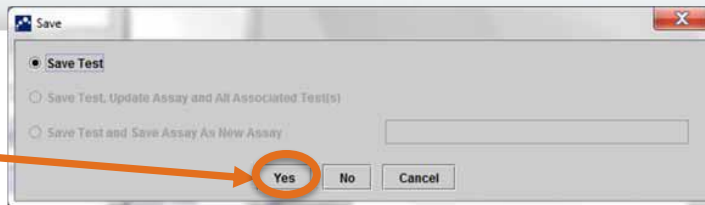
After editing click **Save Changes**

The screenshot shows the GeneXpert Dx System software interface. The top navigation bar includes buttons for 'Create Test', 'Check Status', 'Stop Test', 'View Results', 'Define Assays', 'Define Graphs', and 'Maintenance'. The 'View Results' window is active, displaying test details for 'Xpert CT_NG' version 3. The test result is 'CT NOT DETECTED; NG NOT DETECTED'. A graph shows fluorescence over cycles. A legend lists various assay components. The 'Save Changes' button is highlighted at the bottom.

Editing the Test Information

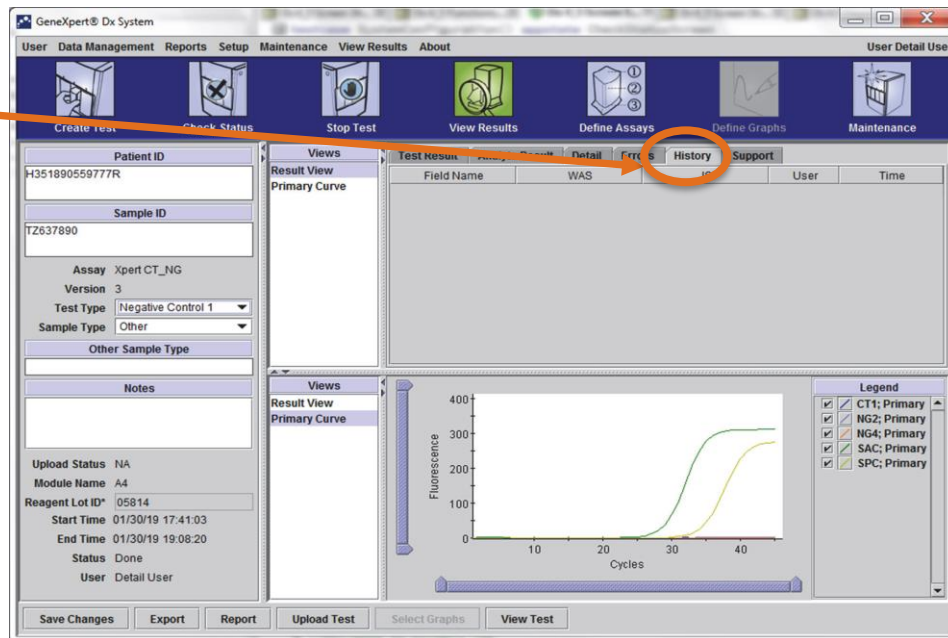
3

Click **Yes** to confirm the changes



4

The history of the changed information is saved under the tab **History**



Editing the Test Information

History tab
showing change

The screenshot displays the GeneXpert Dx System software interface. The main window is titled "GeneXpert Dx System" and includes a menu bar with options: User, Data Management, Reports, Setup, Maintenance, View Results, and About. Below the menu bar is a toolbar with icons for "Create Test", "Check Status", "Stop Test", "View Results", "Define Assays", "Define Graphs", and "Maintenance".

The interface is divided into several sections:

- Left Panel:** Contains fields for "Patient ID" (H351890559777R), "Sample ID" (TZ637890), "Assay" (Xpert_CT_NG), "Version" (3), "Test Type" (Negative Control 1), and "Sample Type" (Other). It also includes a "Notes" section and "Upload Status" (NA), "Module Name" (A4), "Reagent Lot ID" (05814), "Start Time" (04/30/19 17:41:03), "End Time" (04/30/19 19:08:20), "Status" (Done), and "User" (Detail User).
- Views Panel:** Shows "Result View" and "Primary Curve".
- History Tab:** A table with columns: Field Name, WAS, IS, User, and Time. The data row shows: Test Type, Specimen, Negative Control, <None>, and 01/05/19 12:49:54.
- Graphs Panel:** A line graph showing "Fluorescence" (Y-axis, 0 to 400) versus "Cycles" (X-axis, 0 to 40). The graph displays two curves: a green curve (CT1; Primary) and a yellow curve (SPC; Primary). A legend on the right lists the curves with checkboxes.

Buttons at the bottom include "Save Changes", "Export", "Report", "Upload Test", "Select Graphs", and "View Test".

Generate a Result Report in PDF



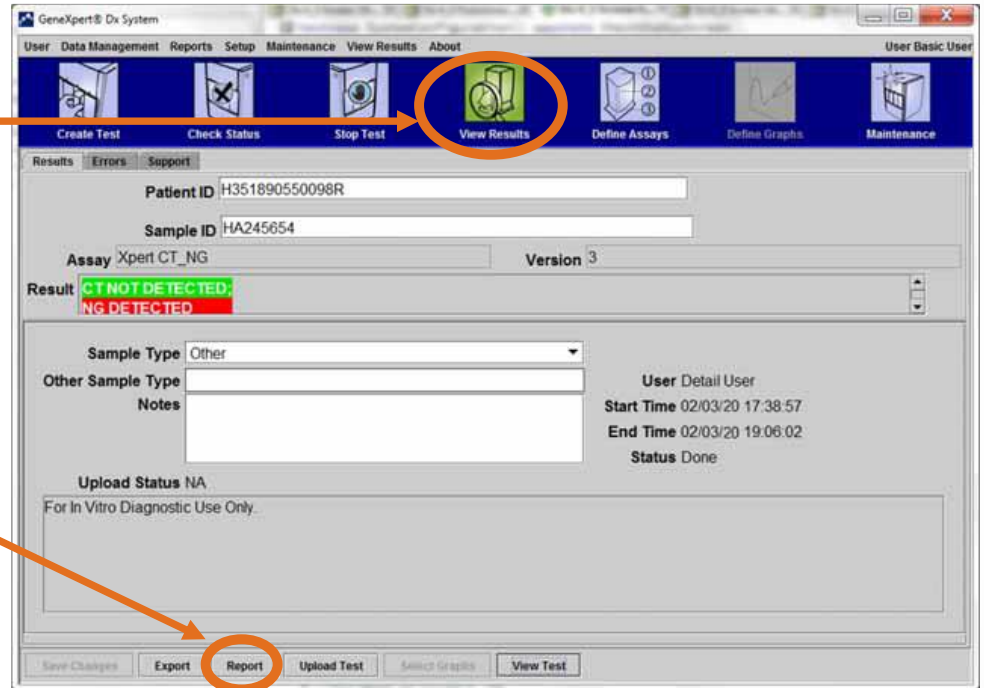
IVD. In vitro diagnostic medical device. May not be available in all countries.

Generate a result report in PDF

Basic user view

1 Click on **View Results**

2 Click on **Report**

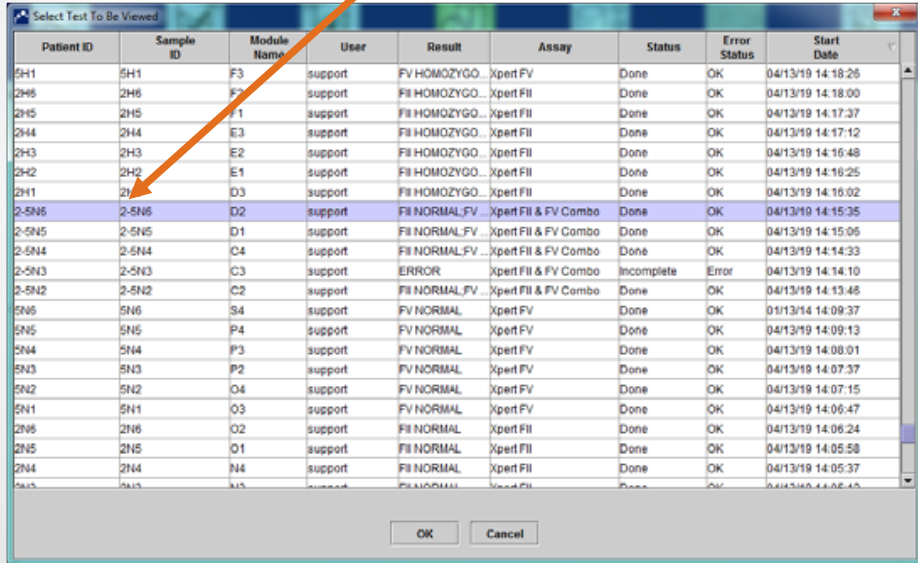


Generate a result report in PDF

Basic user view

3

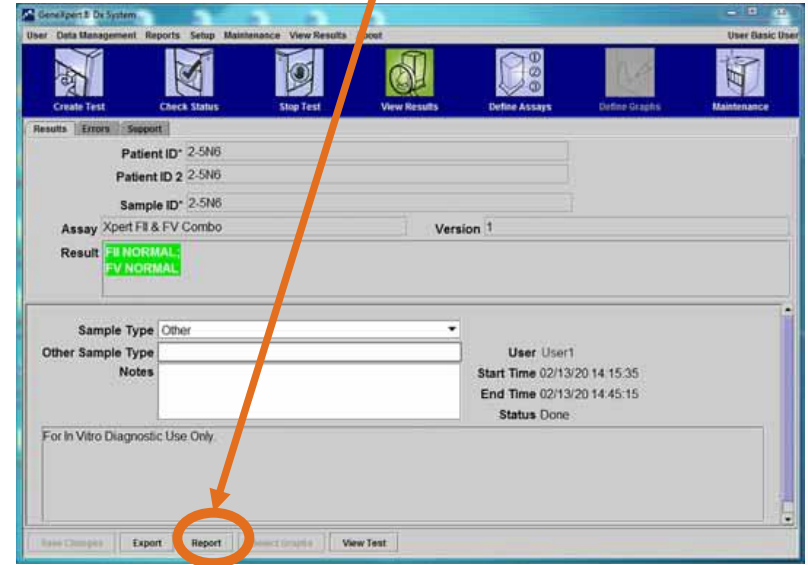
Select Test to Be Viewed



Patient ID	Sample ID	Module Name	User	Result	Assay	Status	Error Status	Start Date
5H1	5H1	F3	support	FV HOMOZYGO	Xpert FV	Done	OK	04/13/19 14:18:25
2H5	2H5	F3	support	Fil HOMOZYGO	Xpert Fil	Done	OK	04/13/19 14:18:00
2H5	2H5	F1	support	Fil HOMOZYGO	Xpert Fil	Done	OK	04/13/19 14:17:37
2H4	2H4	E3	support	Fil HOMOZYGO	Xpert Fil	Done	OK	04/13/19 14:17:12
2H3	2H3	E2	support	Fil HOMOZYGO	Xpert Fil	Done	OK	04/13/19 14:16:48
2H2	2H2	E1	support	Fil HOMOZYGO	Xpert Fil	Done	OK	04/13/19 14:16:25
2H1	2H1	D3	support	Fil HOMOZYGO	Xpert Fil	Done	OK	04/13/19 14:16:02
2-5N6	2-5N6	D2	support	Fil NORMAL FV	Xpert Fil & FV Combo	Done	OK	04/13/19 14:15:35
2-5N5	2-5N5	D1	support	Fil NORMAL FV	Xpert Fil & FV Combo	Done	OK	04/13/19 14:15:05
2-5N4	2-5N4	C4	support	Fil NORMAL FV	Xpert Fil & FV Combo	Done	OK	04/13/19 14:14:33
2-5N3	2-5N3	C3	support	ERROR	Xpert Fil & FV Combo	Incomplete	Error	04/13/19 14:14:10
2-5N2	2-5N2	C2	support	Fil NORMAL FV	Xpert Fil & FV Combo	Done	OK	04/13/19 14:13:48
5N6	5N6	S4	support	FV NORMAL	Xpert FV	Done	OK	01/13/14 14:09:37
5N5	5N5	P4	support	FV NORMAL	Xpert FV	Done	OK	04/13/19 14:09:13
5N4	5N4	P3	support	FV NORMAL	Xpert FV	Done	OK	04/13/19 14:08:01
5N3	5N3	P2	support	FV NORMAL	Xpert FV	Done	OK	04/13/19 14:07:37
5N2	5N2	O4	support	FV NORMAL	Xpert FV	Done	OK	04/13/19 14:07:15
5N1	5N1	O3	support	FV NORMAL	Xpert FV	Done	OK	04/13/19 14:06:47
2N5	2N5	O2	support	Fil NORMAL	Xpert Fil	Done	OK	04/13/19 14:06:24
2N5	2N5	O1	support	Fil NORMAL	Xpert Fil	Done	OK	04/13/19 14:05:58
2N4	2N4	N4	support	Fil NORMAL	Xpert Fil	Done	OK	04/13/19 14:05:37

4

Select Report to generate PDF



General® Dx System

User: Data Management | Reports | Setup | Maintenance | View Results | Logout | User: Basic User

Create Test | Check Status | Stop Test | View Results | Define Assays | Order Graphs | Maintenance

Results | Errors | Support

Patient ID* 2-5N6
Patient ID 2 2-5N6
Sample ID* 2-5N6
Assay Xpert Fil & FV Combo | Version 1
Result **Fil NORMAL**
FV NORMAL

Sample Type Other
Other Sample Type
Notes

User User1
Start Time 02/13/20 14:15:35
End Time 02/13/20 14:45:15
Status Done

For In Vitro Diagnostic Use Only.

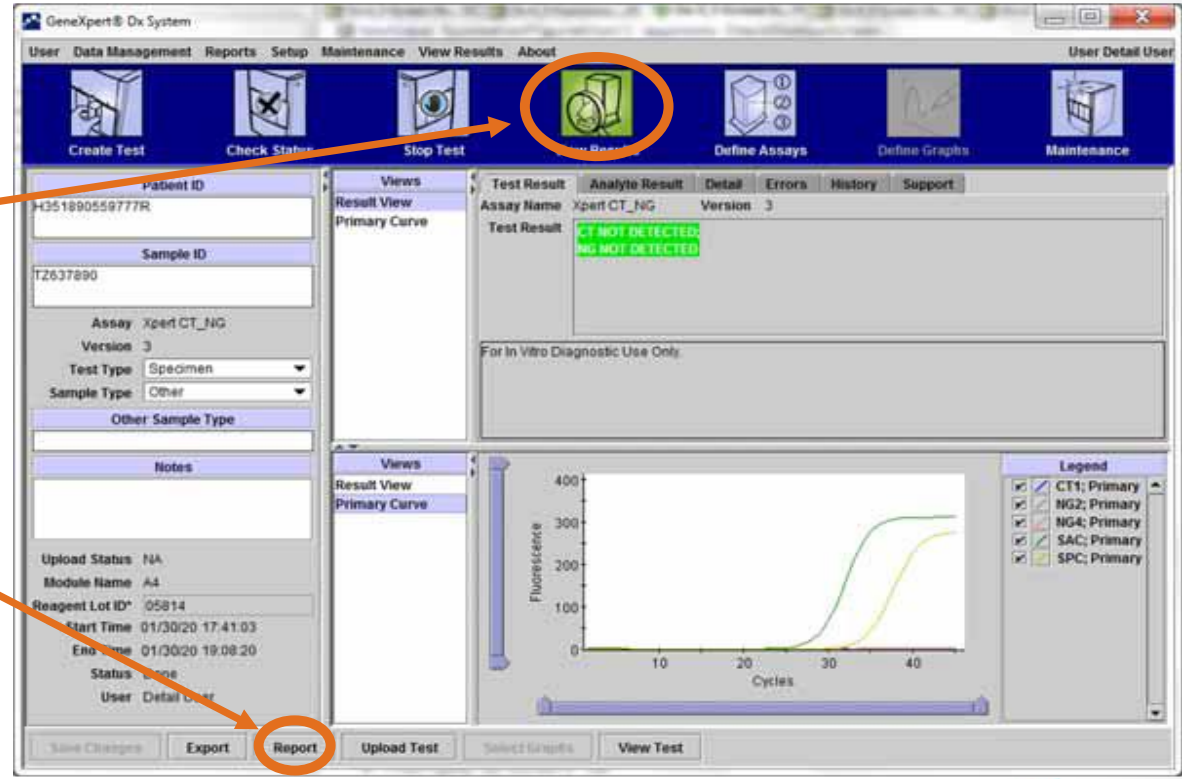
Base Changes | Export | Report | Select Graphs | View Test

How to generate a PDF

Detail Users and Administrator View

1 Click on **View Result**

2 Click on **Report**



How to generate a PDF

Detail Users and Administrator View

3 Select the result you may want to visualize in PDF

Test Report

Analyte Result

- Detail
- Melt Peaks
- Error Details
- Troubleshoot
- Messages
- History
- Replaced Runs

	Patient ID	Sample ID	Module Name	User	Result	Assay	Status	Error Status	Start Date
<input checked="" type="checkbox"/>	2-5N6	2-5N6	D2	support	Flu NORMAL;FV ...	Xpert Flu & FV Combo	Done	OK	04/13/19 14:15:35
<input type="checkbox"/>	2-5N5	2-5N5	D1	support	Flu NORMAL;FV ...	Xpert Flu & FV Combo	Done	OK	04/13/19 14:15:06
<input type="checkbox"/>	2-5N4	2-5N4	C4	support	Flu NORMAL;FV ...	Xpert Flu & FV Combo	Done	OK	04/13/19 14:14:33
<input type="checkbox"/>	2-5N3	2-5N3	C3	support	ERROR	Xpert Flu & FV Combo	Incomplete	Error	04/13/19 14:14:10
<input type="checkbox"/>	2-5N2	2-5N2	C2	support	Flu NORMAL;FV ...	Xpert Flu & FV Combo	Done	OK	04/13/19 14:13:46
<input type="checkbox"/>	5N6	5N6	S4	support	FV NORMAL	Xpert FV	Done	OK	04/13/19 14:09:37
<input type="checkbox"/>	5N5	5N5	P4	support	FV NORMAL	Xpert FV	Done	OK	04/13/19 14:09:13
<input type="checkbox"/>	5N4	5N4	P3	support	FV NORMAL	Xpert FV	Done	OK	04/13/19 14:08:01
<input type="checkbox"/>	5N3	5N3	P2	support	FV NORMAL	Xpert FV	Done	OK	04/13/19 14:07:37
<input type="checkbox"/>	5N2	5N2	O4	support	FV NORMAL	Xpert FV	Done	OK	04/13/19 14:07:15
<input type="checkbox"/>	5N1	5N1	O3	support	FV NORMAL	Xpert FV	Done	OK	04/13/19 14:06:47
<input type="checkbox"/>	2N6	2N6	O2	support	Flu NORMAL	Xpert Flu	Done	OK	04/13/19 14:06:24
<input type="checkbox"/>	2N5	2N5	O1	support	Flu NORMAL	Xpert Flu	Done	OK	04/13/19 14:05:58
<input type="checkbox"/>	2N4	2N4	N4	support	Flu NORMAL	Xpert Flu	Done	OK	04/13/19 14:05:37
<input type="checkbox"/>	2N3	2N3	N3	support	Flu NORMAL	Xpert Flu	Done	OK	04/13/19 14:05:12
<input type="checkbox"/>	2N2	2N2	N1	support	Flu NORMAL	Xpert Flu	Done	OK	04/13/19 14:04:47

Generate Report File Preview PDF Close

In the upper left-hand corner of the dialog box

Select Analyte Result

Available

EndPt

Selected

Analyte Name
Ct
Interpretation Result
Reason
Analyte Result
Probe Check Result
Target Delta Ct

OK Cancel

4 Click on **Preview PDF** for immediate visualisation



Example Test Report

GeneXpert PC 29/08/18 07:00:34

Test Report

Patient ID:
Sample ID: 2D4E3DAEDA481A0830D30140B
Test Type: Specimen
Sample Type:

Assay Information

Assay	Assay Version	Assay Type
Xpert MTB-RIF Ultra	2	In Vitro Diagnostic

Test Result: **MTB DETECTED LOW;
RIF Resistance DETECTED**

Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
SPC	24.1	123	NA	PASS
IS1081- IS6110	20.9	550	NA	PASS
rpoB1	26.5	238	POS	PASS
rpoB2	27.9	140	POS	PASS
rpoB3	36.1	42	POS	PASS
rpoB4	32.6	89	POS	PASS

User: <None>
Status: Done
Expiration Date*: 18/03/18
S/W Version: 4.8
Cartridge S/N*: 411360303
Reagent Lot ID*: 20201
Notes: J3 TUBE 3 LCR
TAJ/AA

Start Time: 13/11/17 11:37:37
End Time: 13/11/17 12:54:33
Instrument S/N: 705498
Module S/N: 625802
Module Name: A1

Error Status: OK

Errors
<None>

For In Vitro Diagnostic Use Only.

GeneXpert PC 02/14/20 09:01:20

Test Report

User: Detail1
Status: Done
Expiration Date*: 11/16/20
S/W Version: 6.2
Cartridge S/N*: 116820908
Reagent Lot ID*: 04701
Notes:
Error Status: OK

Start Time: 02/13/20 14:15:35
End Time: 02/13/20 14:45:15
Instrument S/N: 801225
Module S/N: 607389
Module Name: D2

Errors
<None>

Tech. Initial/Date

Supervisor Initial/Date

* indicates that a particular field is entered using a barcode scanner

For In Vitro Diagnostic Use Only.

Uploading Test Results to the LIS

IVD. In vitro diagnostic medical device. May not be available in all countries.

Uploading Test Results to the LIS

Upload Test Results
to the LIS

The screenshot displays the GeneXpert Dx System software interface. The main window is titled "GeneXpert Dx System" and includes a menu bar with options: User, Data Management, Reports, Setup, Maintenance, View Results, and About. Below the menu bar is a toolbar with icons for "Create Test", "Check Status", "Stop Test", "View Results", "Define Assays", "Define Graphs", and "Maintenance".

The interface is divided into several sections:

- Left Panel:** Contains fields for "Patient ID" (H351890559777R) and "Sample ID" (TZ637890). Below these are fields for "Assay" (Xpert CT_NG), "Version" (3), "Test Type" (Specimen), and "Sample Type" (Other). There is also a "Notes" section and "Upload Status" (NA).
- Top Right Panel:** Shows "Test Result" for "Assay Name" Xpert CT_NG, Version 3. The result is "CT NOT DETECTED; NG NOT DETECTED". Below this is a section for "For In Vitro Diagnostic Use Only".
- Bottom Right Panel:** Displays a graph of "Fluorescence" vs "Cycles". The y-axis ranges from 0 to 400, and the x-axis ranges from 0 to 40. Two curves are shown: a blue curve (CT1; Primary) and a green curve (NG2; Primary). A legend on the right lists: CT1; Primary, NG2; Primary, NG4; Primary, SAC; Primary, and SPC; Primary.

At the bottom of the window, there are buttons for "Save Changes", "Export", "Report", "Upload Test", "Select Graphs", and "View Test". An orange arrow points from the text box on the left to the "Upload Test" button.

Uploading Test Results to the LIS Automatically.

1

click the
**Automatic Result
Upload** check box

2

click **Ok**

The screenshot shows the 'System Configuration' dialog box with the 'Host Communication Settings' tab selected. The 'Enable Host Communication' checkbox is checked. Under 'Host Setting', the 'Automatic Result Upload' checkbox is checked. The 'Communication Settings' section shows 'Protocol' set to HL7 and 'Run Host As' set to Client. The 'Server IP Address' and 'Port #' fields are empty and 1234, respectively. The 'Order/Result Management' section contains three buttons: 'Delete Cancelled Orders', 'Expire Results', and 'Reset Communication Buffer'. The 'Host Test Code' table is visible at the bottom.

Enable	Assay	Host Test Code	
<input type="checkbox"/>	Xpert BCR-ABL Monitor IS Version 1		Edit
<input checked="" type="checkbox"/>	Xpert CDIFFICILE Version 3		Edit
<input type="checkbox"/>	Xpert CT_NG Version 3		Edit
<input type="checkbox"/>			
<input type="checkbox"/>			
<input type="checkbox"/>			

Generate Specimen and Patient Reports in PDF



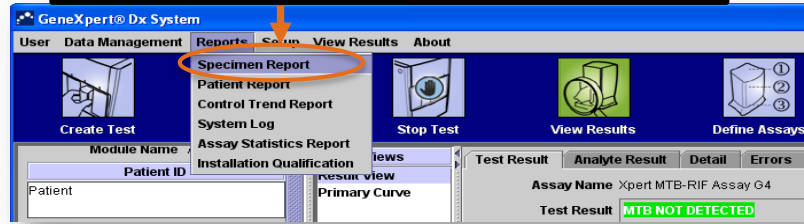
IVD. In vitro diagnostic medical device. May not be available in all countries.

How to generate specimen and patient reports in PDF

1

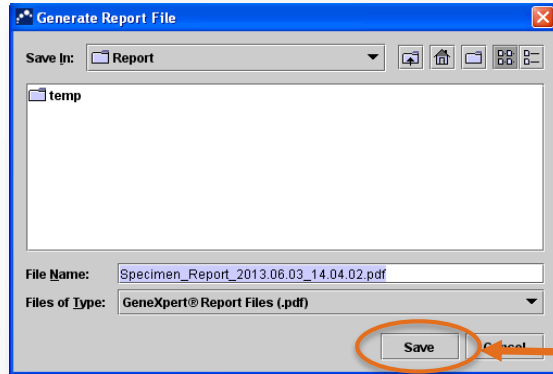
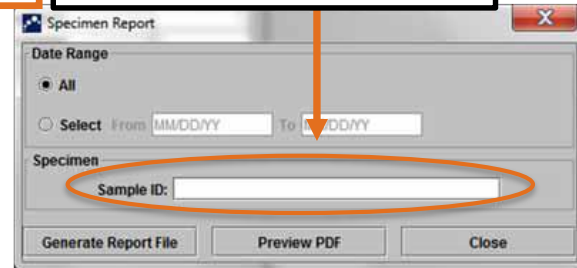
Specimen Report

Click Reports -> Specimen Report



2

Fill in the Sample ID



3a

Generate Report File will save the report in GeneXpert Folder -> Report

3

Preview PDF will open the PDF file

Example Specimen Report

GeneXpert PC

02/17/20 12:55:54

Specimen Report

Found Sample ID #2 = DU155637

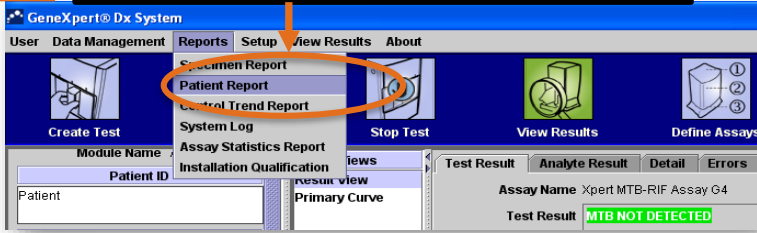
- 1 Test(s) Found -

Patient ID:	H351890382682R
Sample ID:	DU155637
Assay:	Xpert SA Nasal Complete G3
Assay Version:	5
Test Result:	MRSA NEGATIVE; SA POSITIVE
Start Time:	02/16/20 13:32:37
Test Type:	Specimen
User:	Administration User
Status:	Done
Notes:	

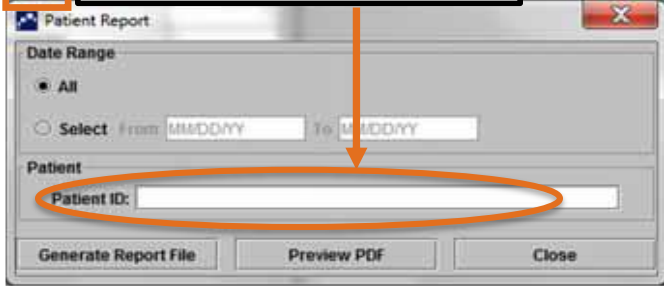
How to generate specimen and patient reports in PDF

1 Click Reports -> Patient Report

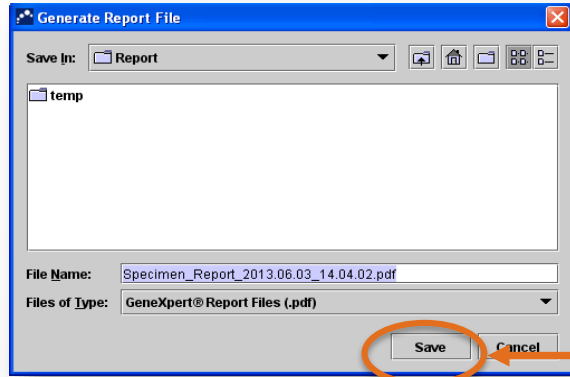
Patient Report



2 Fill in the Patient ID



3a Generate Report File will save the report in GeneXpert Folder -> Report



3 Preview PDF will open the PDF file

Example Patient Report

GeneXpert PC

02/09/20 12:51:40

Patient Report

Found Patient ID #2 = H112874895762R

- 2 Test(s) Found -

Patient ID: H112874895762R
Sample ID: SD142231
Assay: Xpert CDIFFICILE
Assay Version: 3
Test Result: **NEGATIVE**
Start Time: 02/09/20 12:38:42
Test Type: Specimen
User: Detail User
Status: Done
Notes:

Patient ID: H112874895762R
Sample ID: SD142231
Assay: Xpert BCR-ABL Monitor IS
Assay Version: 1
Test Result: **ERROR**
Start Time: 02/09/20 12:41:13
Test Type: Specimen
User: Detail User
Status: Aborted
Notes:

How to Automatically Print a Test Report



IVD. In vitro diagnostic medical device. May not be available in all countries.

How to automatically print a test report

- Connect and install your printer
- This setting allows the system to automatically print a report once the test is completed.

1

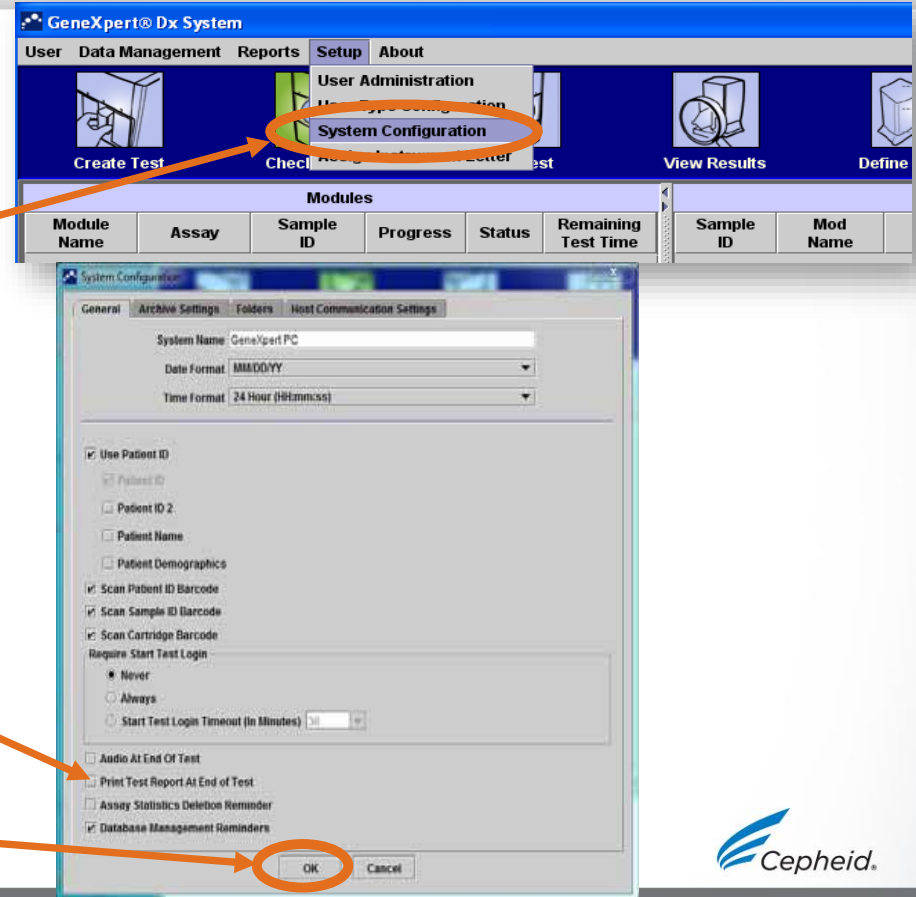
Click on **Setup**, then **System configuration**

2

Select the appropriate option **Print Test Report At End of Test**

3

Click **OK**

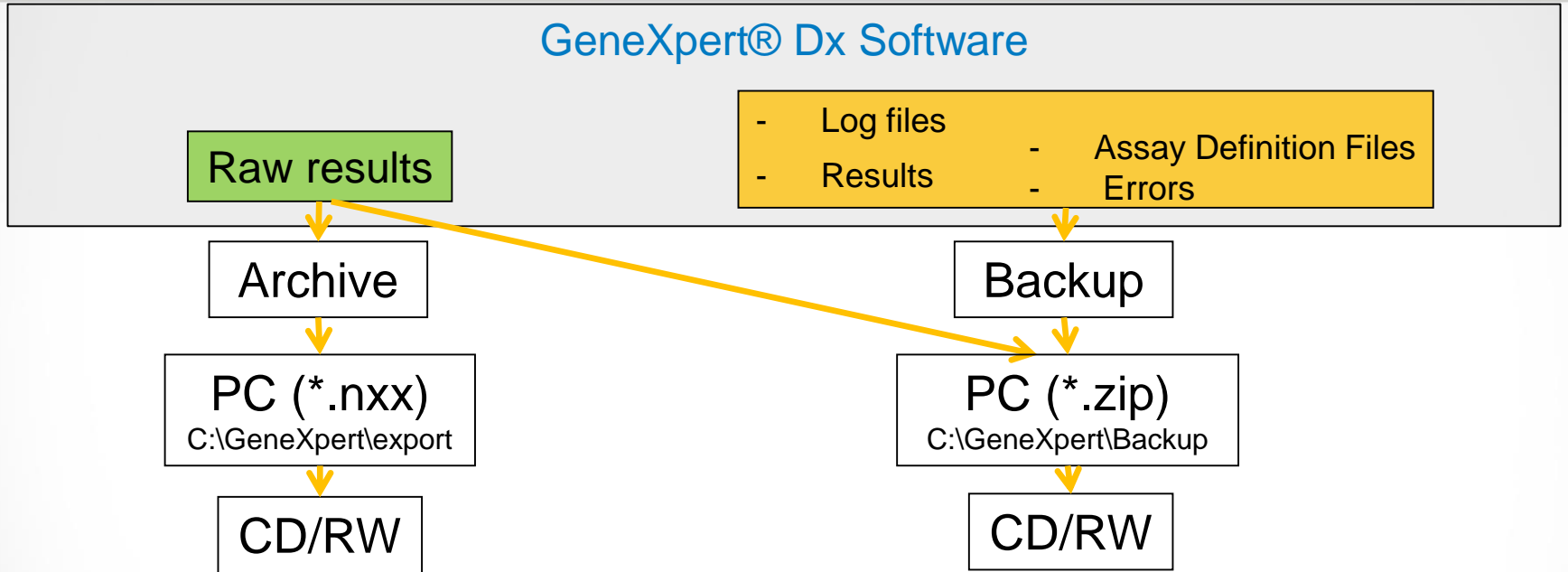


Data Management Tasks



IVD. In vitro diagnostic medical device. May not be available in all countries.

Difference between Archive/Backup



- To be provided to technical Support in case of a complaint
- Can only be retrieved with GeneXpert DX software

- To be used to restore data in GeneXpert® DX software in case of computer failure
- Backup all your data every month on a CD or RW-CD

How to Archive Results

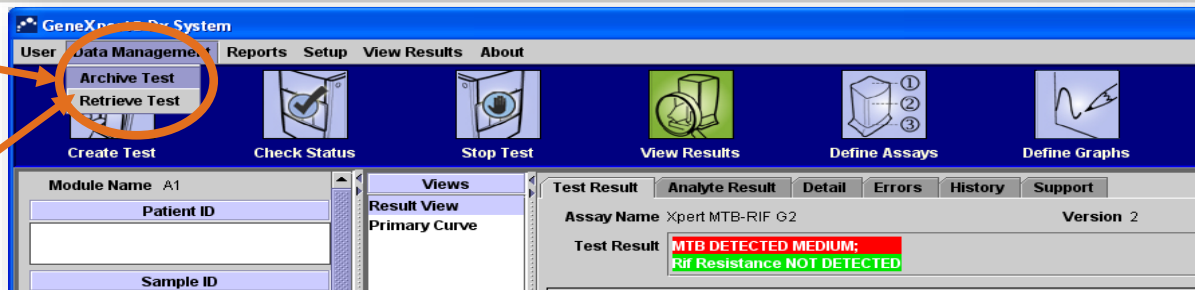


IVD. In vitro diagnostic medical device. May not be available in all countries.

How to archive results

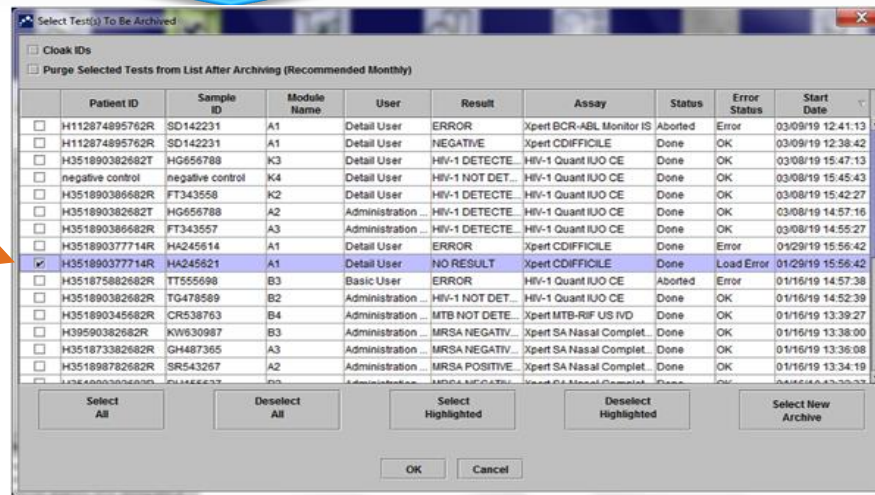
1 Click Data Management

2 Click Archive test



3 Choose the tests that need to be archived Or Select All

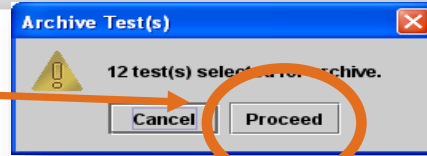
4 You can choose to Purge selected items after archiving



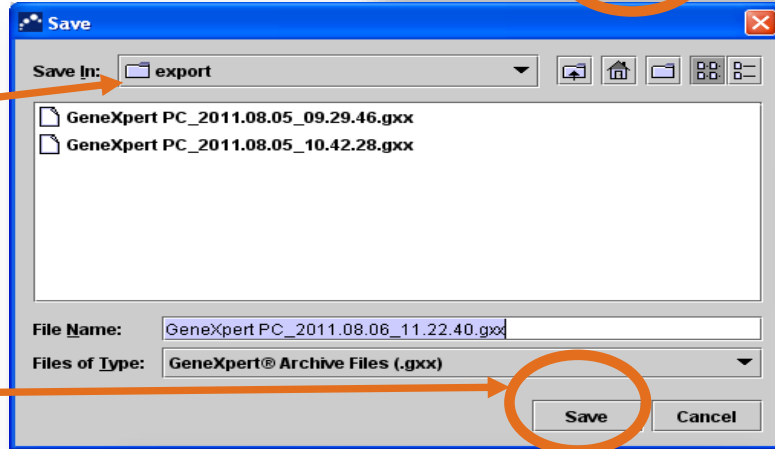
Purged tests will no longer appear in the GX Dx Software

How to archive results

5 In the next dialog box click **Proceed**



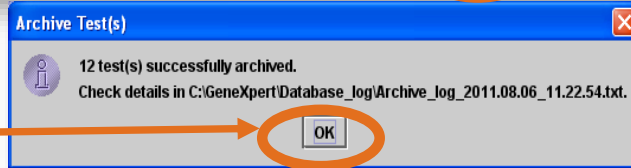
6 The files will be saved in the folder **Export**



Save the archived data to an external device.

7 Click on **SAVE**

8 Click **OK**



The archived file in the folder C:\GeneXpert\export

How to Retrieve Results

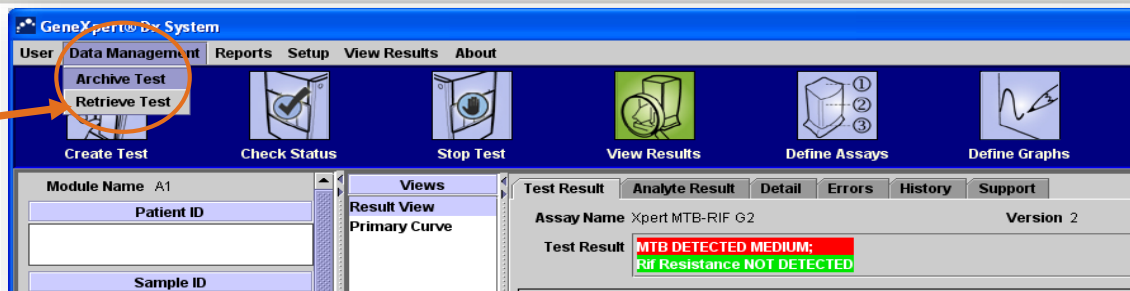


IVD. In vitro diagnostic medical device. May not be available in all countries.

How to retrieve results

1

Click **Data Management** and Click **Retrieve Test**

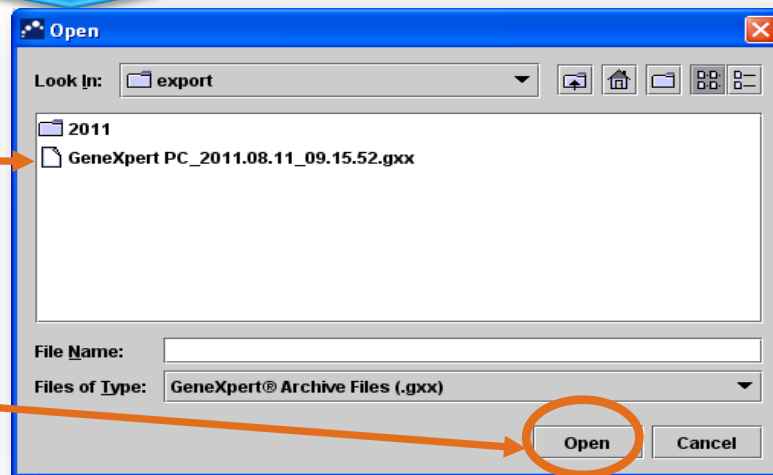


2

Locate and select the archive (.gxx/.nxx) file.

3

Click on **Open**



How to retrieve results

4

Select the test to be retrieved (or Select All)

	Patient ID	Sample ID	Module Name	User	Result	Assay	Status	Error Status	Start Date
<input checked="" type="checkbox"/>	H351890382682T	HG656788	K3	Detail User	HIV-1 DETECTED	HIV-1 Quant IUO CE	Done	OK	02/18/19 15:47:13
<input checked="" type="checkbox"/>	negative control	negative control	K4	Detail User	HIV-1 NOT DETECTED	HIV-1 Quant IUO CE	Done	OK	02/18/19 15:45:43
<input checked="" type="checkbox"/>	H351890386682R	FT343558	K2	Detail User	HIV-1 DETECTED	HIV-1 Quant IUO CE	Done	OK	02/18/19 15:42:27
<input checked="" type="checkbox"/>	H351890382682T	HG656788	A2	Administration U	HIV-1 DETECTED	HIV-1 Quant IUO CE	Done	OK	02/18/19 14:57:16
<input checked="" type="checkbox"/>	H351890386682R	FT343557	A3	Administration U	HIV-1 DETECTED	HIV-1 Quant IUO CE	Done	OK	02/18/19 14:55:27
<input type="checkbox"/>	H35189037782R	TL332298	B1	Basic User	MTB NOT DETECTED	Xpert MTB-RIF US IVD	Done	OK	02/16/19 14:58:50
<input checked="" type="checkbox"/>	H351875882682R	TT555698	B3	Basic User	ERROR	HIV-1 Quant IUO CE	Aborted	Error	02/16/19 14:57:38
<input checked="" type="checkbox"/>	H351890382682R	TG478589	B2	Administration U	HIV-1 NOT DETECTED	HIV-1 Quant IUO CE	Done	OK	02/16/19 14:52:39
<input checked="" type="checkbox"/>	H351890345682R	CR538763	B4	Administration U	MTB NOT DETECTED	Xpert MTB-RIF US IVD	Done	OK	02/16/19 13:39:27
<input checked="" type="checkbox"/>	H39590382682R	KW630987	B3	Administration U	MRSA NEGATIVE	Xpert SA Nasal Complete	Done	OK	02/16/19 13:38:00
<input checked="" type="checkbox"/>	H351873382682R	QH487365	A3	Administration U	MRSA NEGATIVE	Xpert SA Nasal Complete	Done	OK	02/16/19 13:38:08
<input checked="" type="checkbox"/>	H351898782682R	SR543267	A2	Administration U	MRSA POSITIVE	Xpert SA Nasal Complete	Done	OK	02/16/19 13:34:19
<input checked="" type="checkbox"/>	H351890382682R	DU155637	B2	Administration U	MRSA NEGATIVE	Xpert SA Nasal Complete	Done	OK	02/16/19 13:32:37
<input checked="" type="checkbox"/>	H351890382682W	RL986632	A4	Detail User	MRSA POSITIVE	Xpert SA Nasal Complete	Done	OK	02/16/19 17:33:44
<input checked="" type="checkbox"/>	H351877782682Y	GK563895	B1	Detail User	ERROR	Xpert MTB-RIF US IVD	Aborted	Error	02/16/19 17:32:28
<input checked="" type="checkbox"/>	H356129382682R	TF277659	B4	Detail User	MTB NOT DETECTED	Xpert MTB-RIF US IVD	Done	OK	02/16/19 17:31:20
<input checked="" type="checkbox"/>	H351855982682R	UJ890762	B3	Detail User	FI HETEROZYGOUS	Xpert FI & FV Combo	Done	OK	02/16/19 17:29:35
<input checked="" type="checkbox"/>	H351890596082R	UJ787933	A3	Detail User	FI NORMAL FV	Xpert FI & FV Combo	Done	OK	02/16/19 17:28:47
<input checked="" type="checkbox"/>	H351885382682R	HN237945	A2	Detail User	FI HOMOZYGOUS	Xpert FI & FV Combo	Done	OK	02/16/19 17:27:55
<input checked="" type="checkbox"/>	H35189056082R	RL430664	B2	Detail User	CT DETECTED	NO Xpert CT, MR	Done	OK	02/16/19 17:16:06

5

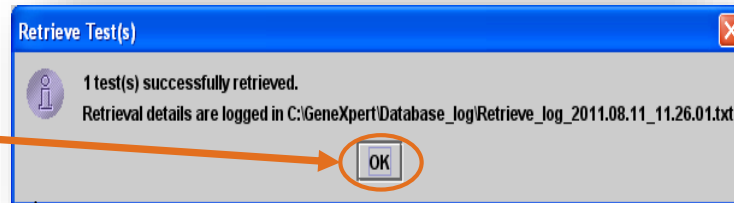
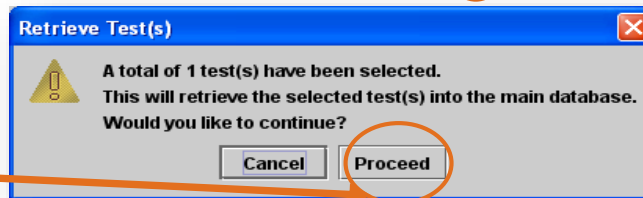
Click OK

6

Click Proceed

7

Click OK



How to Backup the Data

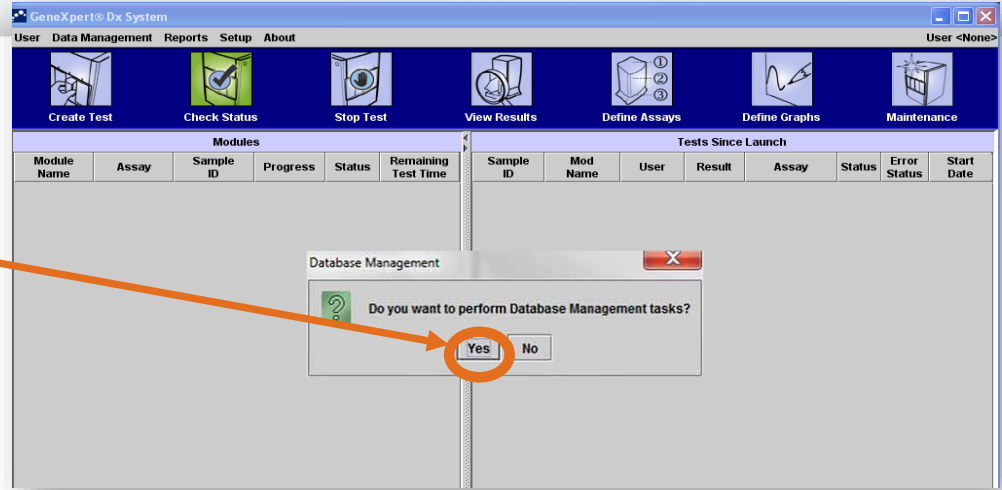
IVD. In vitro diagnostic medical device. May not be available in all countries.



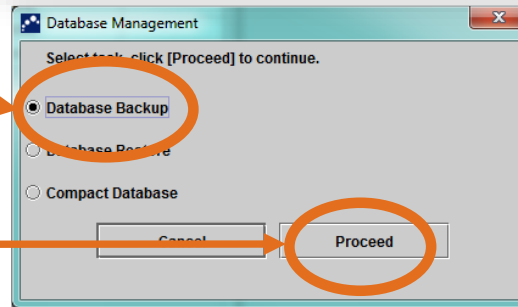
Data management tasks

When closing the GeneXpert software, the following dialog box will appear.

1 Click Yes



2 Click Database Backup

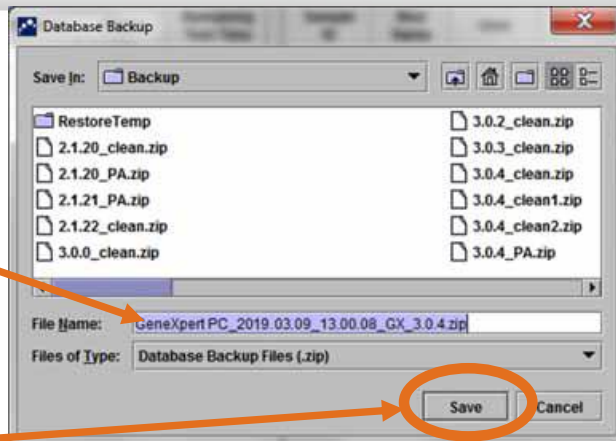


3 Click Proceed

How to Create a Backup

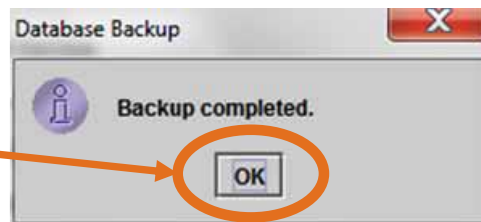
The software will create a zip file with all the results

The file is saved on the desktop, in the GeneXpert folder -> Backup subfolder



4 Click **Save**

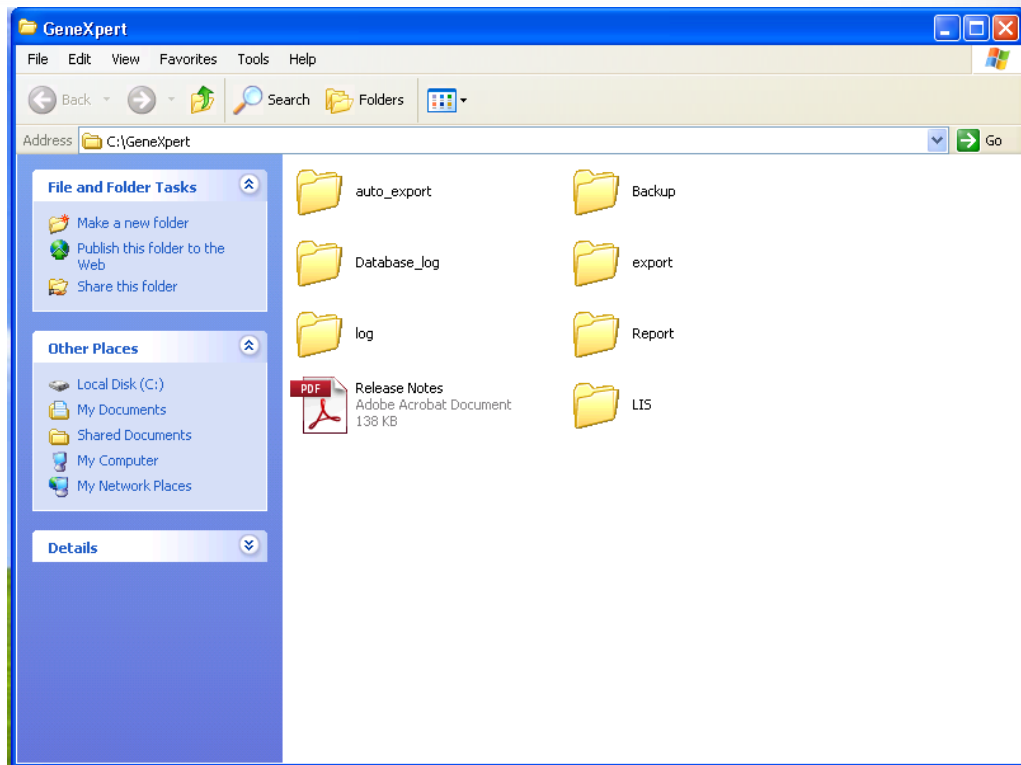
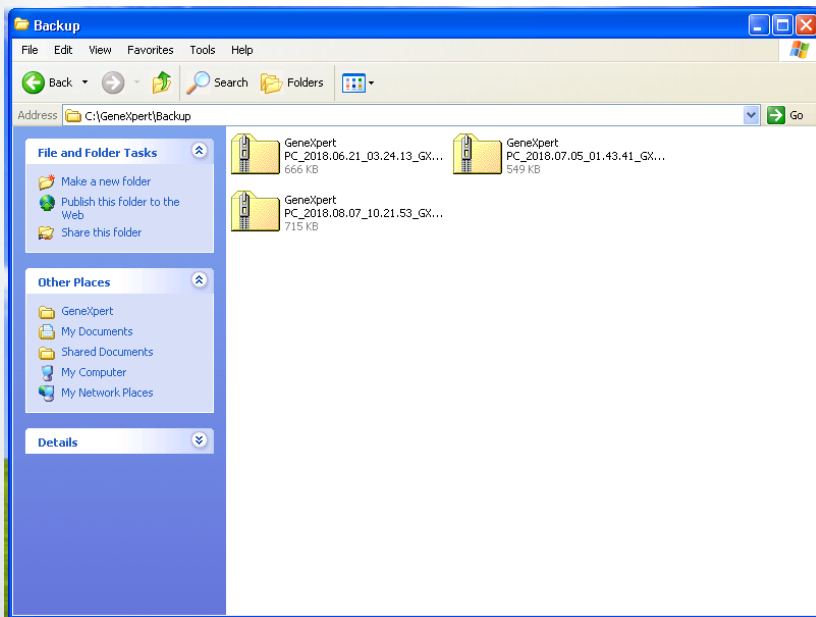
5 Click **OK**



The zip file can only be restored through/ into the GX software. It cannot be unzipped or opened on Windows desktop or folders.

How to Create a Backup

The file is saved on the desktop, in the GeneXpert folder -> Backup subfolder



How to Restore Data from a Backup

IVD. In vitro diagnostic medical device. May not be available in all countries.

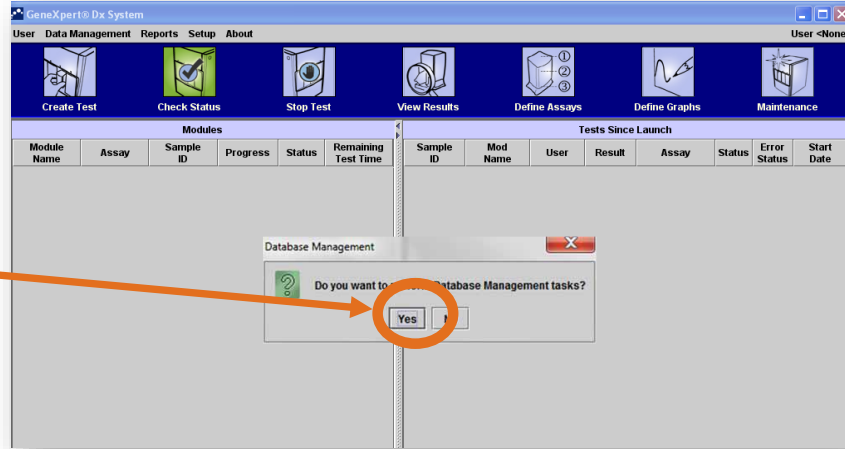


How to restore data

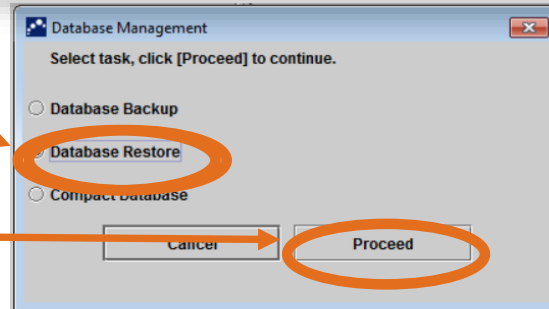
In case of computer failure you might have to restore your data after reinstallation of all system.

By closing the GeneXpert software, The following screen will appear.

1 Click **Yes**



2 Click **Database Restore**

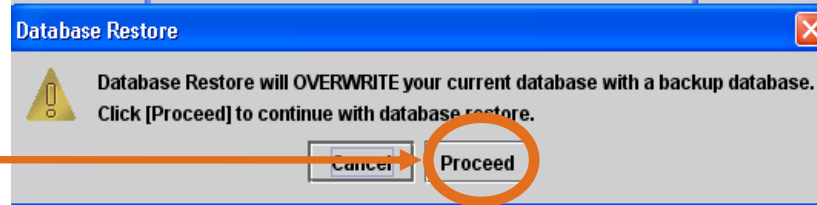


3 Click **Proceed**

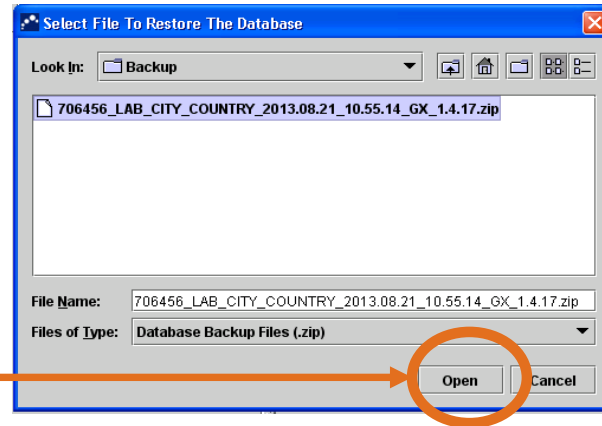
How to restore data

A warning message tells you that the current database will be lost.

Click **Proceed** to continue



Select the database to be restored and Click **Open** to continue

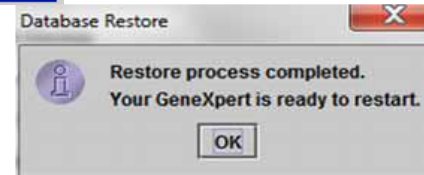
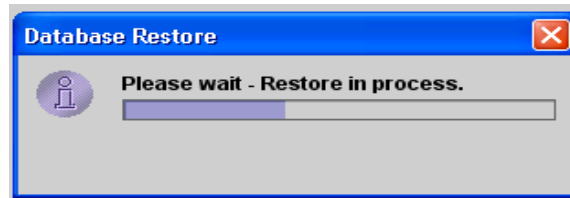
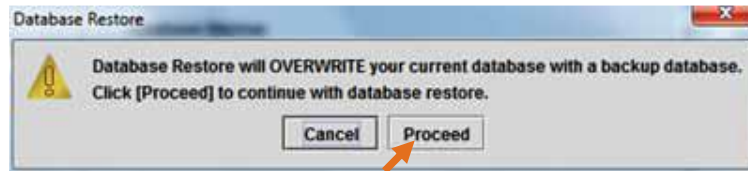


How to restore data

A dialog box appears.

Click **Proceed** to create the backup

Click **Cancel** to continue Backup Restore



Import the Assay Definition File (ADF)



IVD. In vitro diagnostic medical device. May not be available in all countries.

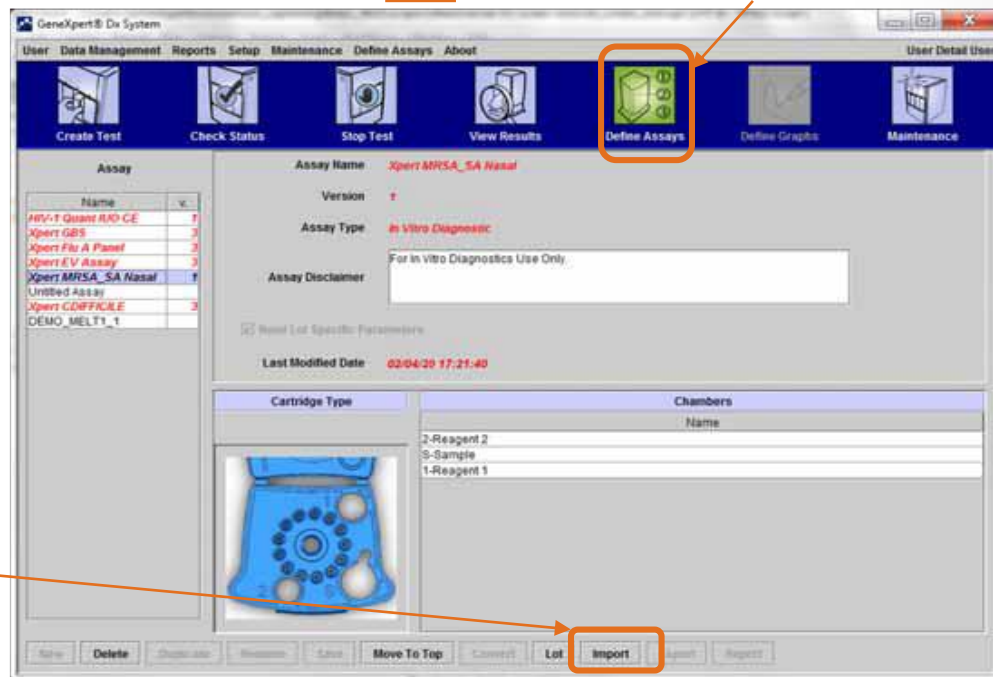
Import the Assay Definition File (ADF)

- In case of test update, the ADF may need to be updated.
- Before using this lot, load the ADF.

1 Insert the CD on the Computer CD drive

2 Click on **Define Assays**

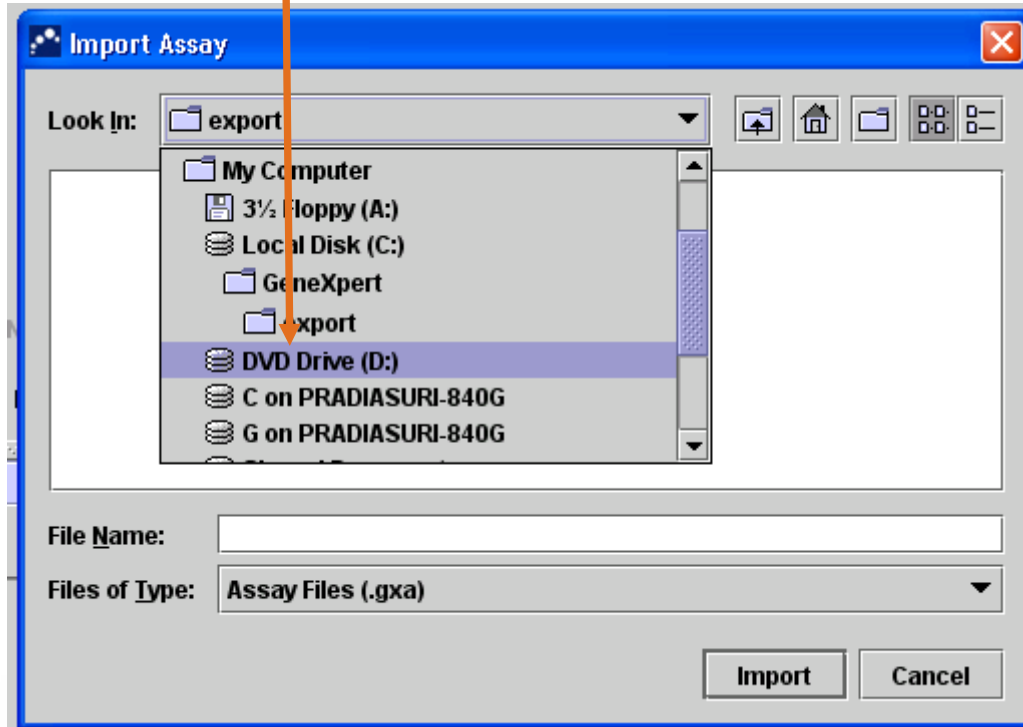
3 Click **Import**



Import the Assay Definition File (ADF)

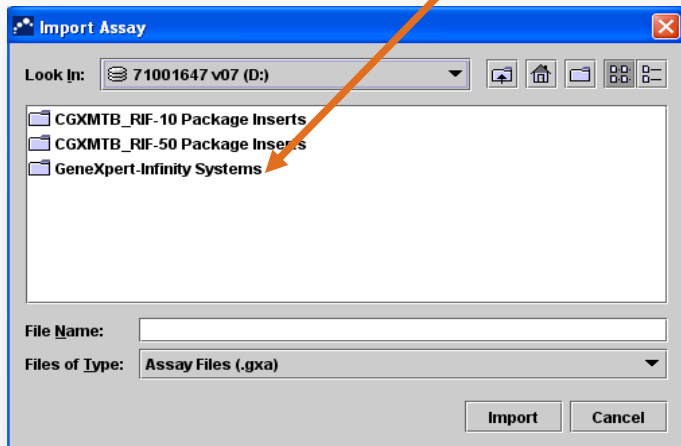
4

locate the file on the computer

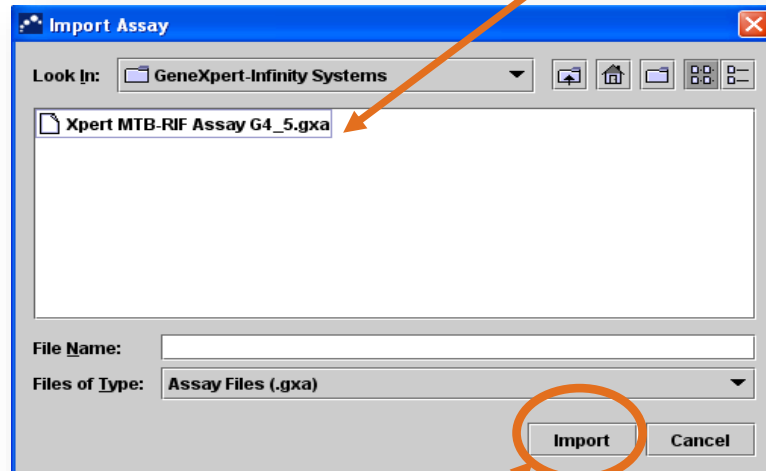


Import the Assay Definition File (ADF)

5 Double click on the GeneXpert Systems folder.



6 Choose the Xpert MTB-RIF.gxa/nxa file



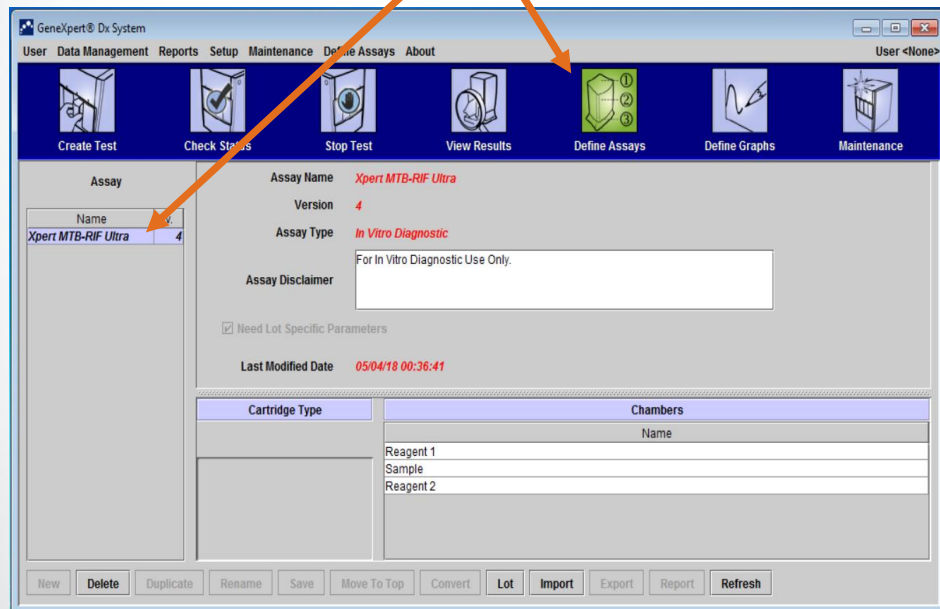
7 Click Import

!!! ATTENTION!!!

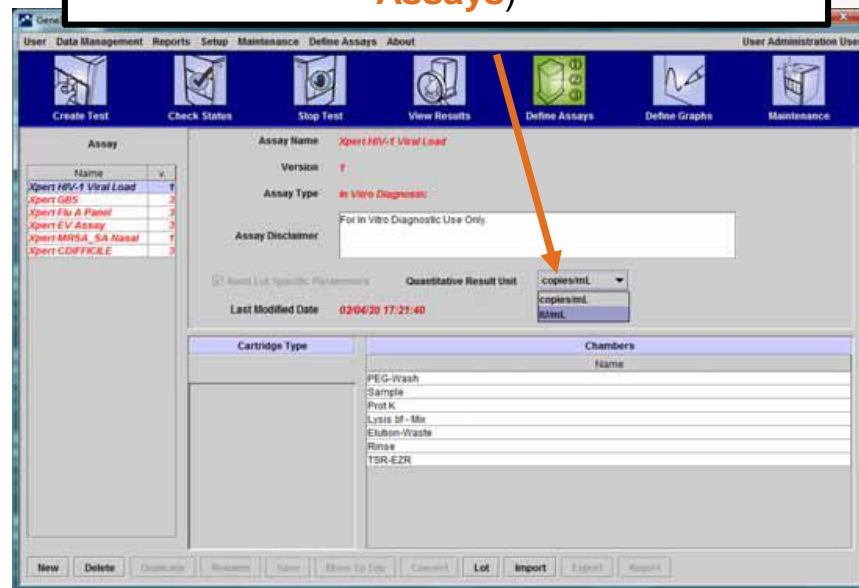
The name of the file may vary from version to version. In any case, load the file with the **.gxa/nxa** extension.

Import the Assay Definition File (ADF)

The Assay Definition Files appears.



NB! After importing a quantitative assay, the Quantitative Result Unit can be changed (**Not applicable on All Xpert Assays**)

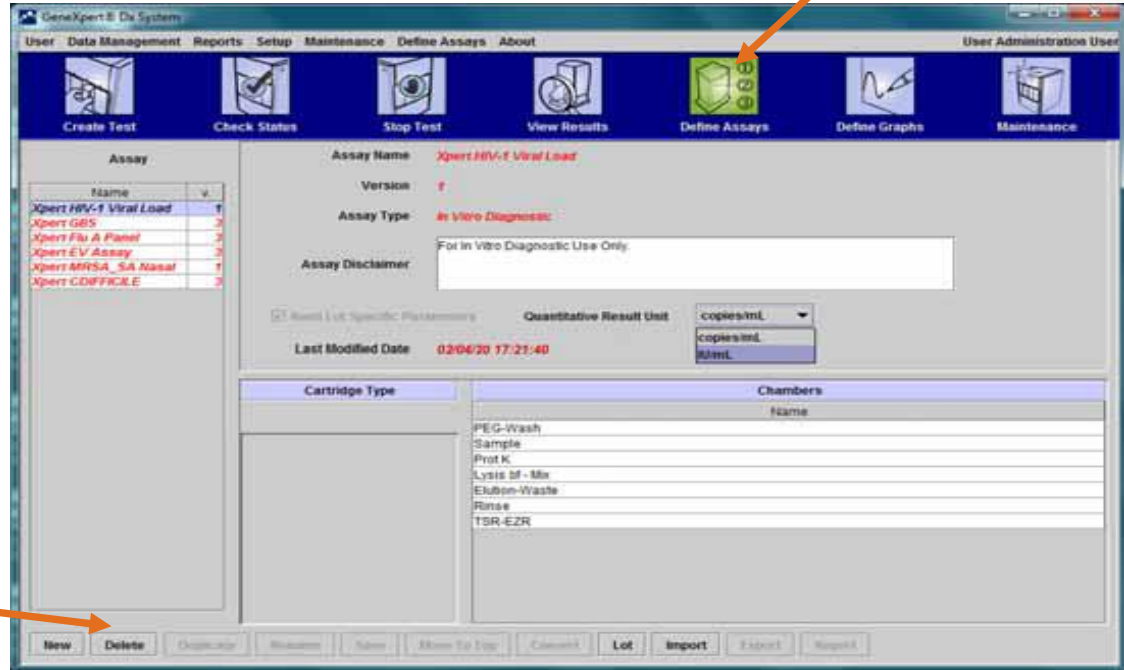


Deleting Assay Definition File (ADF)

- Deleting Assay Definition Files from the system is a permanent operation.
- Make sure that the Assay Definition Files to be deleted are no longer needed.

1

Click **Define Assays**



2

Click **Delete**

Import Lot Specific Parameter (Optional)

IVD. In vitro diagnostic medical device. May not be available in all countries.

Importing Lot Specific Parameters Manually

1

Click to Define Assays

2

select the assay name in the Assay list

GeneXpert® Dx System

User Data Management Reports Setup Maintenance Define Assays About User Detail User

Create Test Check Status Stop Test View Results Define Assays Define Graphs Maintenance

Assay

Name	v.
HIV-1 Quant IUO CE	1
Xpert GBS	3
Xpert Flu A Panel	3
Xpert EV Assay	3
Xpert MRSA_SA Nasal	1
Untitled Assay	
Xpert CDIFFICILE	3
DEMO_MELT1_1	

Assay Name *Xpert MRSA_SA Nasal*

Version 1


Assay Type *In Vitro Diagnostic*

Assay Disclaimer For In Vitro Diagnostics Use Only.

Need Lot Specific Parameters

Last Modified Date 03/04/09 17:21:40

Cartridge Type



Chambers

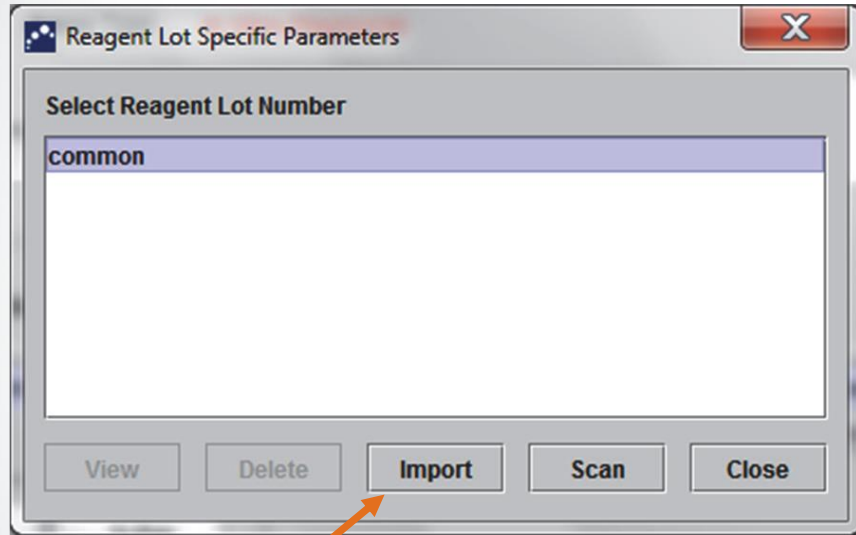
Name	Chambers
2-Reagent 2	
S-Sample	
1-Reagent 1	

New Delete Duplicate Rename Save Move To Top Compare Lot Import Export Report

3

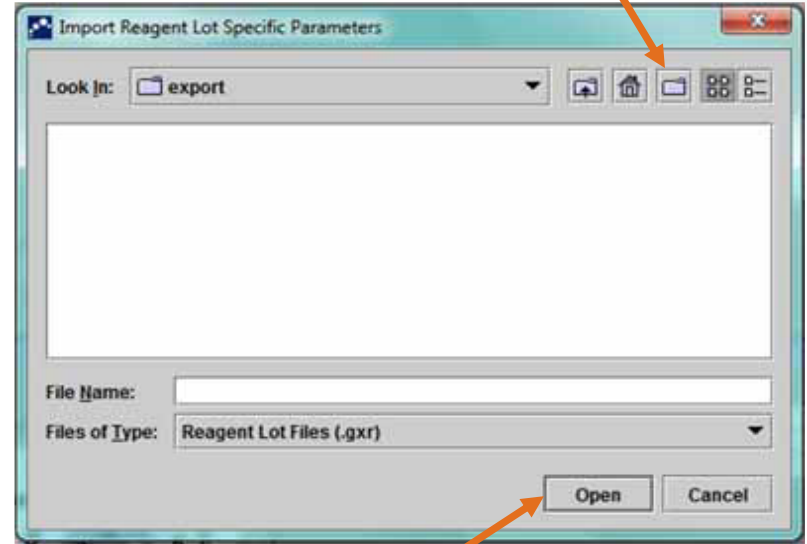
Click to Import Lot Specific Parameters

Importing Lot Specific Parameters Manually



4

Click on **Import**. The Import Reagent Lot Specific Parameters dialog box appears



5

Look In: file viewing area, locate and select the **.gxr/.nrx** file obtained from Technical Support previously, and then click **Open**

Copy/Paste Data to OpenOffice Calc

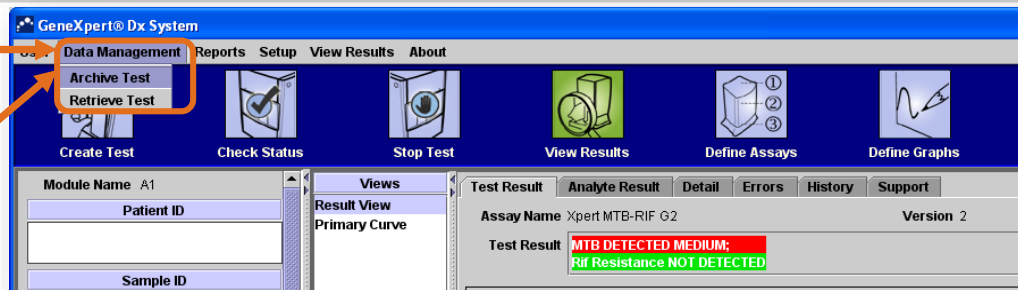
IVD. In vitro diagnostic medical device. May not be available in all countries.



How to copy/paste data to OpenOffice Calc

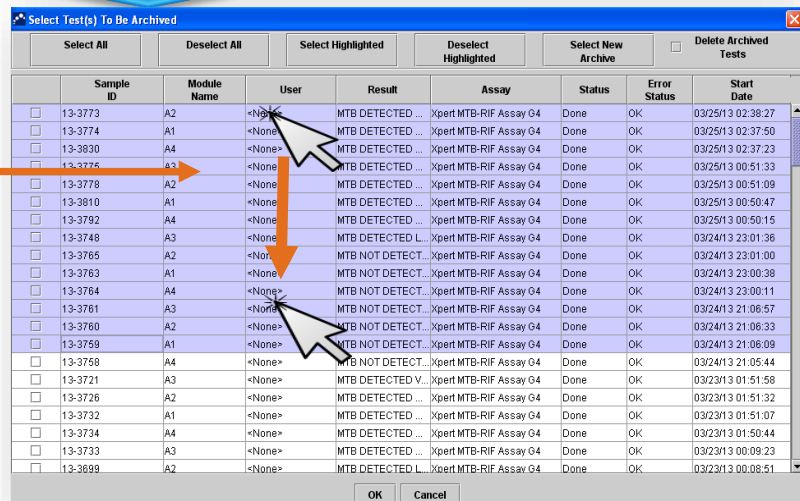
1 Click **Data Management**

2 Click **Archive test**



3 Click/Highlight on the first result you wish to select, Press & hold the **SHIFT** key on your keyboard Click/Highlight on the last line you wish to select. You may also select only certain rows by using **CTRL+Click** key instead of **SHIFT**.

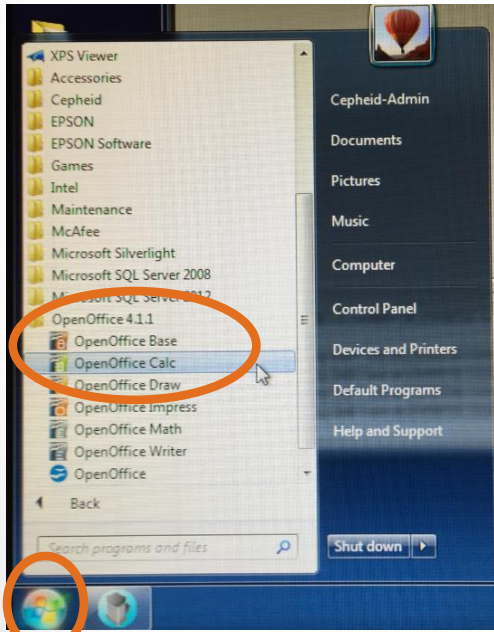
4 While the lines marked press **Ctrl + C** at the same time on your keyboard



How to copy/paste data to OpenOffice Calc

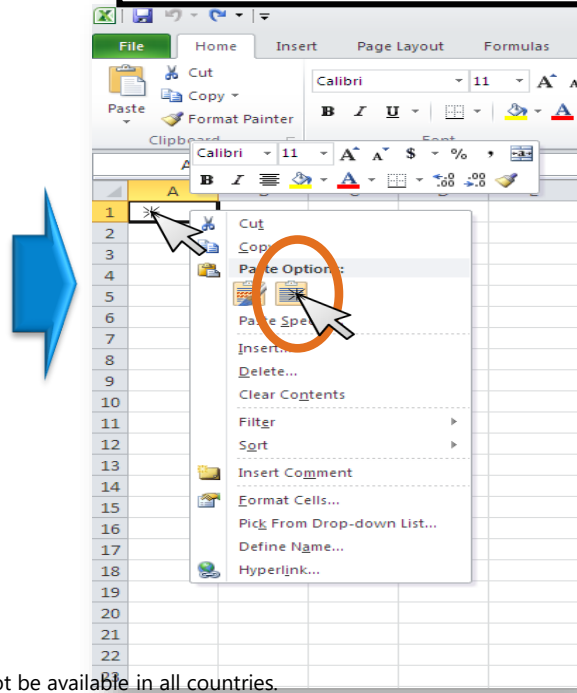
1

OpenOffice Calc by clicking
Start -> All Programs ->
OpenOffice Calc



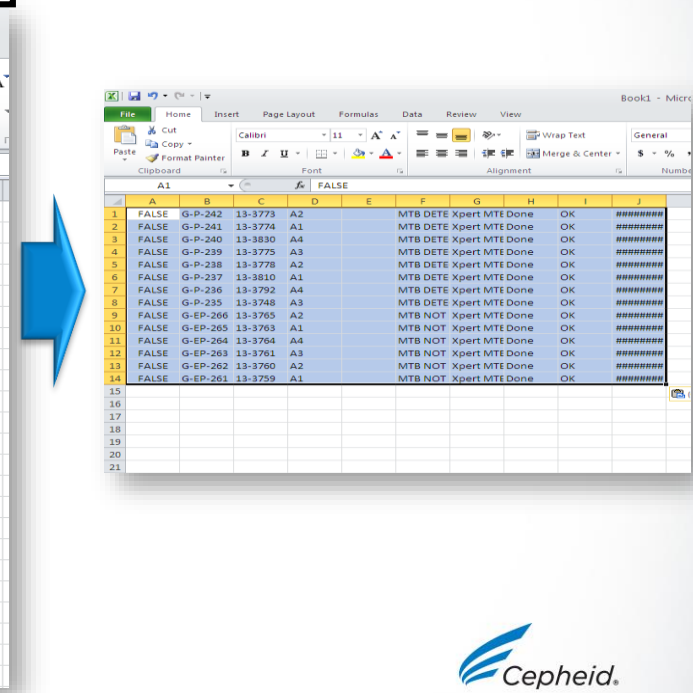
2

Click the right mouse button and in the menu and choose "Match destination Formatting"
→ click on it – see below



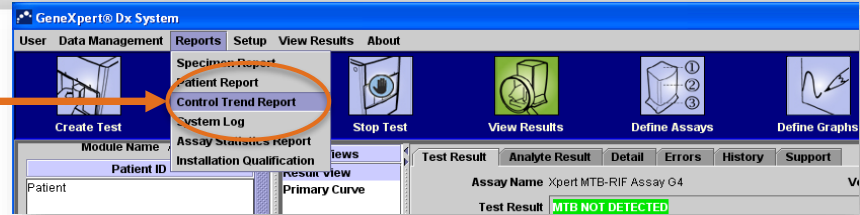
3

The chosen results will be pasted in excel sheet



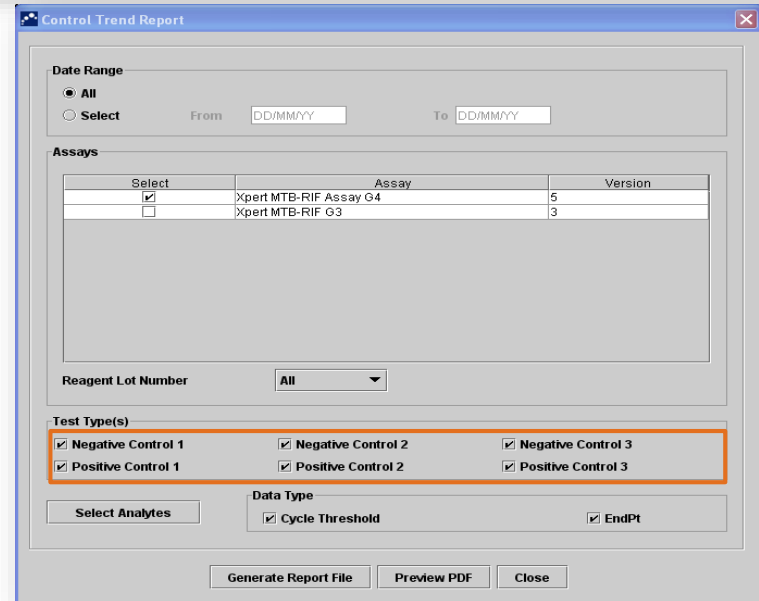
Control Trend Report

Click Reports -> Control Trend Report



To be able to use the control trend report, you need to define these particular samples as positive or negative control on the “create test” screen.

The control trend report will be used to monitor the performance of the internal controls.



For information on GeneXpert® DX Software

GeneXpert Operator Manual , Software Version 6.2

Access to the Operator Manual:

- The Operator Manual is located on a CD that was shipped with the system.
- Log your request online using the following link:
<https://www.cepheid.com/support>

GeneXpert® Dx System



Operator Manual
Software Version 6.2



302-0670, Rev. D April 2020

Technical Assistance

- Before contacting Cepheid Technical Support, collect the following information:
 - Product name
 - Lot number
 - Serial number of the System
 - Error messages (if any)
 - Software version and, if applicable, Computer Service Tag number
- Log your request online using the following link: <https://www.cepheid.com/support>



Thank You.

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123456789012345
12345678



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IVD. In vitro diagnostic medical device. May not be available in all countries.

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