



# GeneXpert® Dx 6.4 Software Technical Training

302-6963 Rev A, June 2021

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"US-IVD and CE-IVD. In Vitro Diagnostic Medical Device. May not be available in all countries."

# 6-Color and 10-Color Modules

- GeneXpert® Dx Software 6.4 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 6.4 is compatible with Microsoft® *Windows® 7 & Windows® 10* operating systems. GeneXpert® Dx software version 6.4 is not compatible with Win XP 32-bit

**6-Color Module**  
**No Identification**  
**Stripe on door**

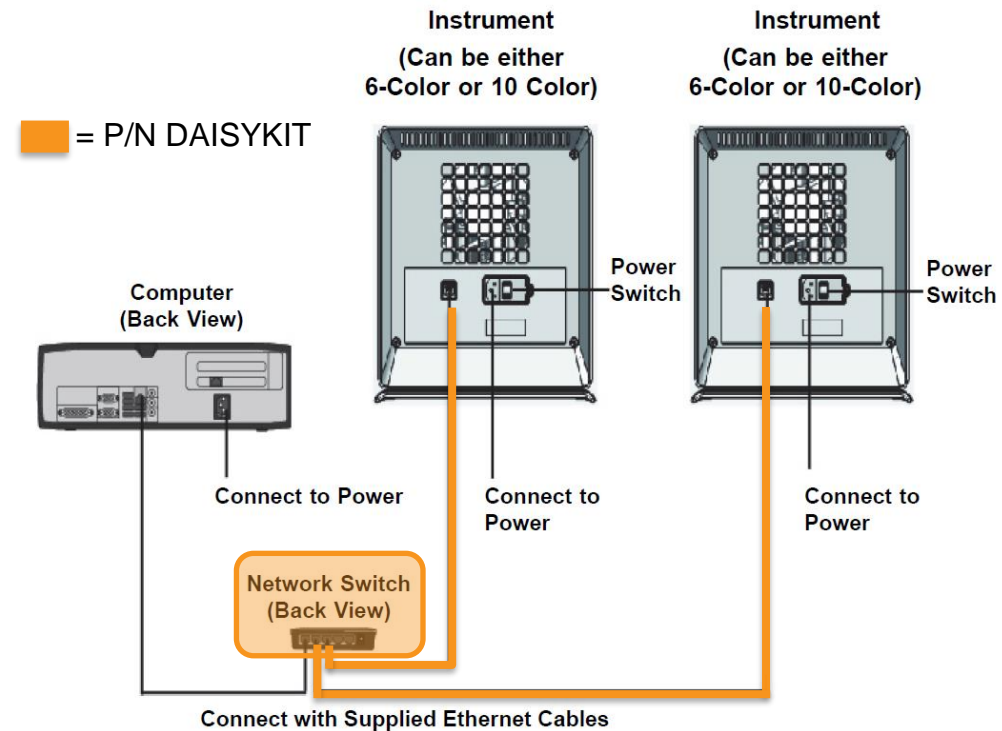


**10-Color Module**  
**Blue Identification**  
**Stripe on door**



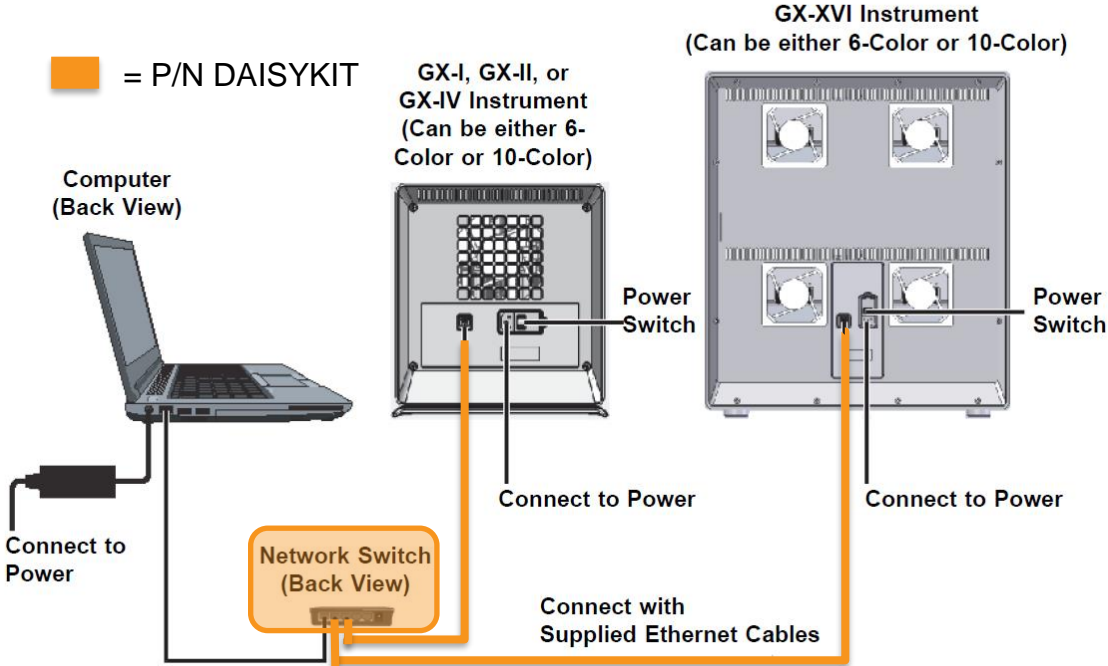
# Connecting Multiple Instruments to the Computer

- Max # of Module is dependent on GeneXpert® DX Software :
  - [GeneXpert Dx Software Version 6.1 and higher](#) Up to **22 GeneXpert modules** (10- or 6-color) in any combination of GeneXpert® GX-I, GeneXpert® GX-II, or GeneXpert GX-IV or GeneXpert® GX-XVI instruments can be connected to a single computer.



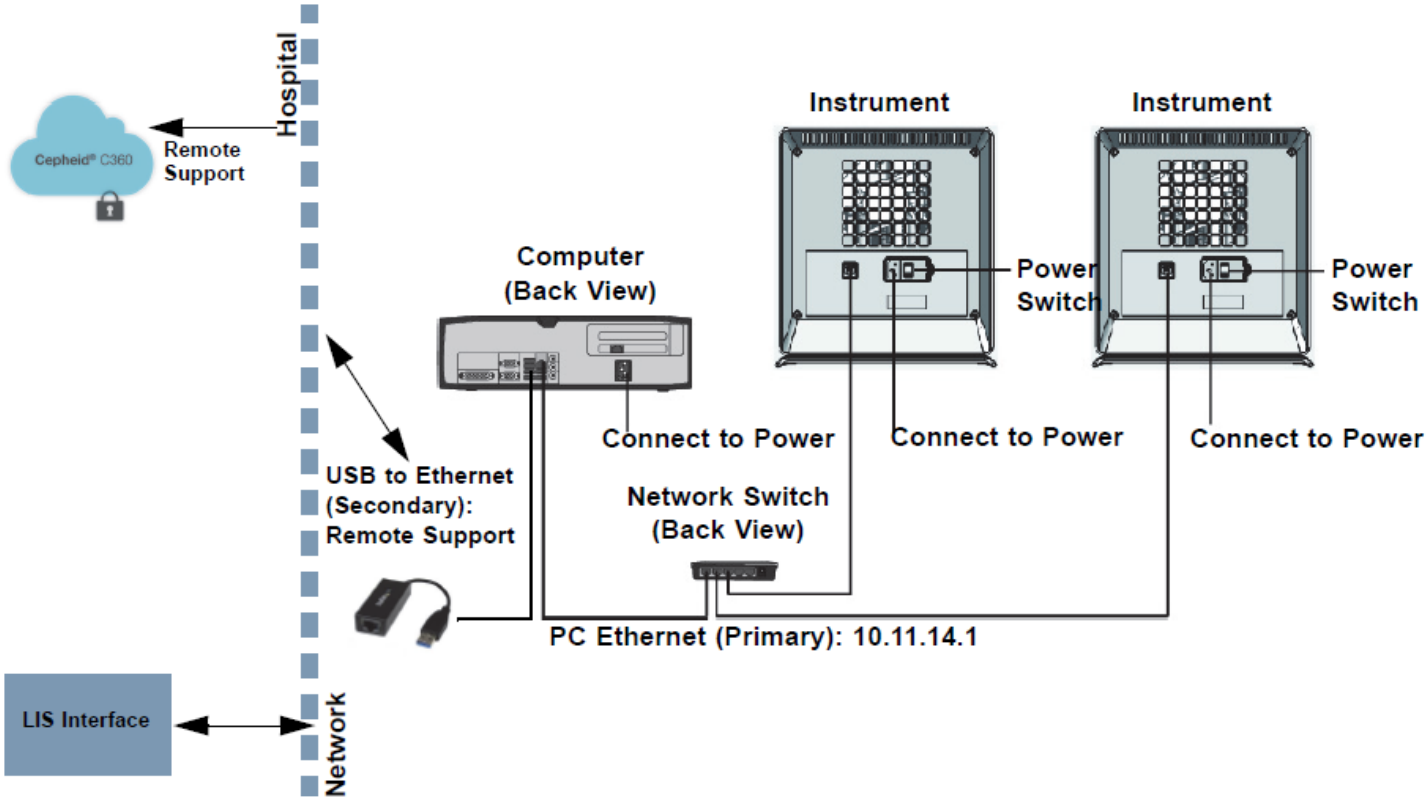
Connecting Multiple GX-IV Instruments to the Desktop Computer

# Connecting Multiple Instruments to the Computer



Connecting Multiple Instruments to the Laptop Computer

# Connecting to Cepheid® C360



Connecting Multiple GX-IV Instruments to C360

# Installation and Setup Workflow

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

# Start the Windows® Operating System (Windows® 7 / 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

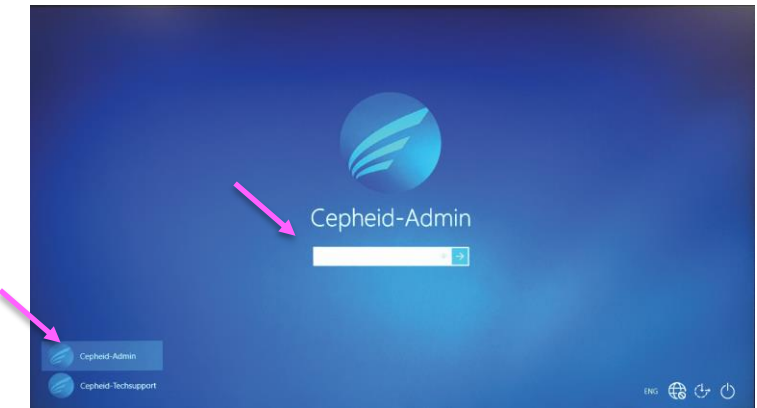
**3** Open the session:

User-Account: **Cepheid-Admin**

Password: **cphd**



*With Windows® 7*



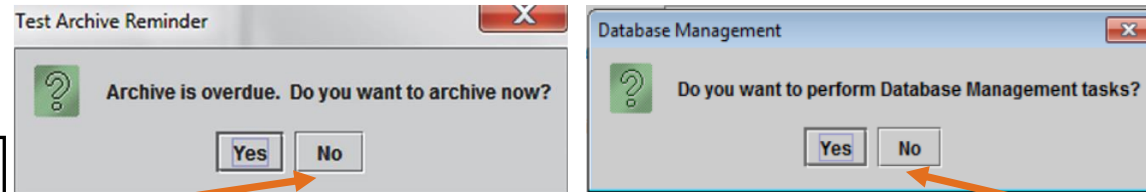
*With Windows® 10*

# 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.

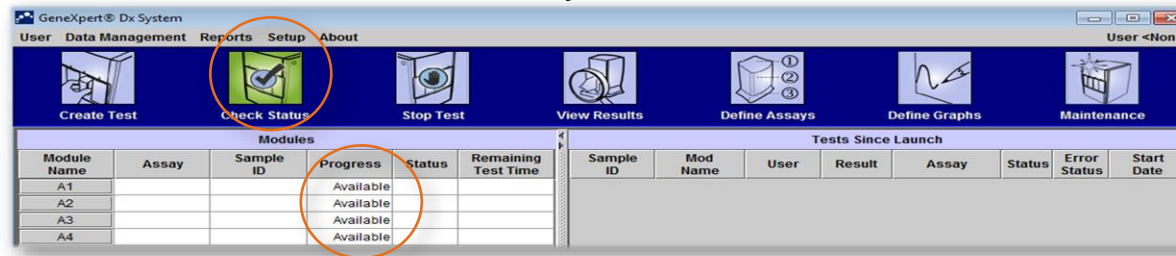


Click on **NO** if Database Management is not required to be archived at this time.

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*

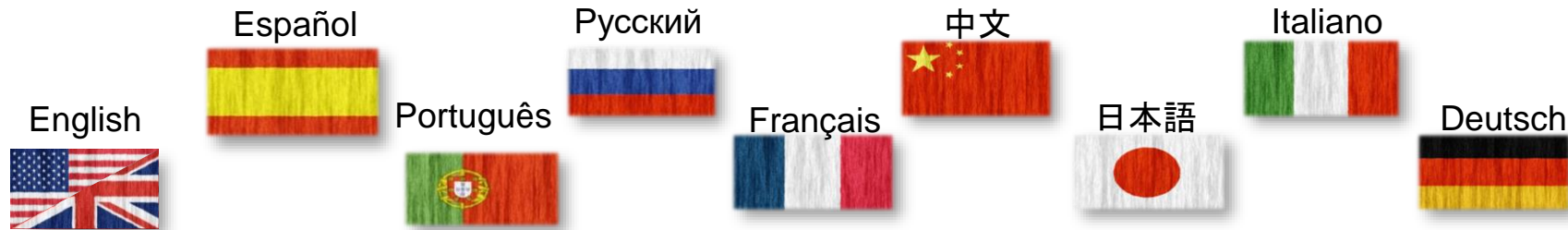


# Prepare your System for Routine Use

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

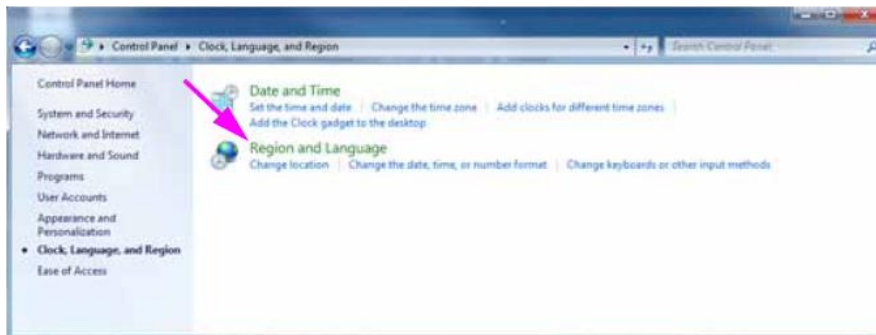


The GeneXpert GX Dx Software is available in:

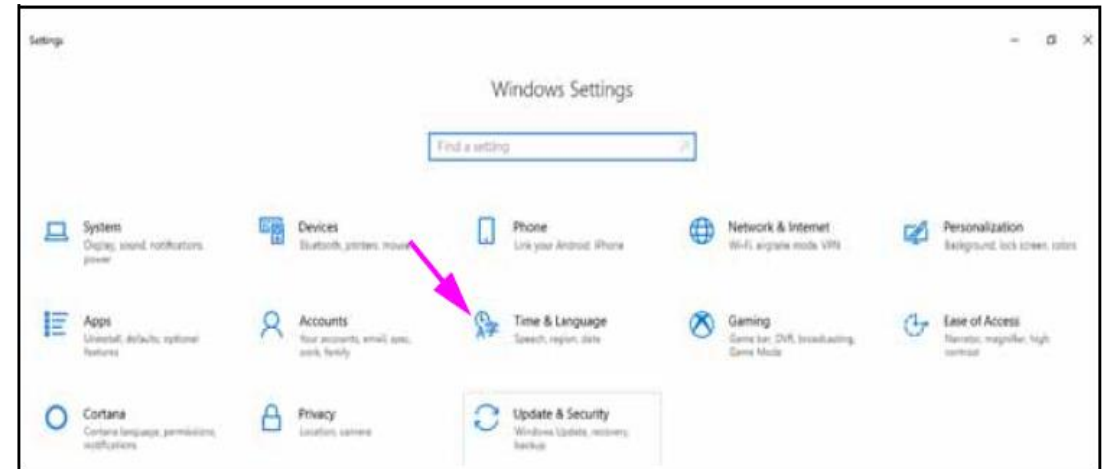


Source: <http://www.free-country-flags.com/index.php>

# Windows® 7 & Windows® 10 Language Setting

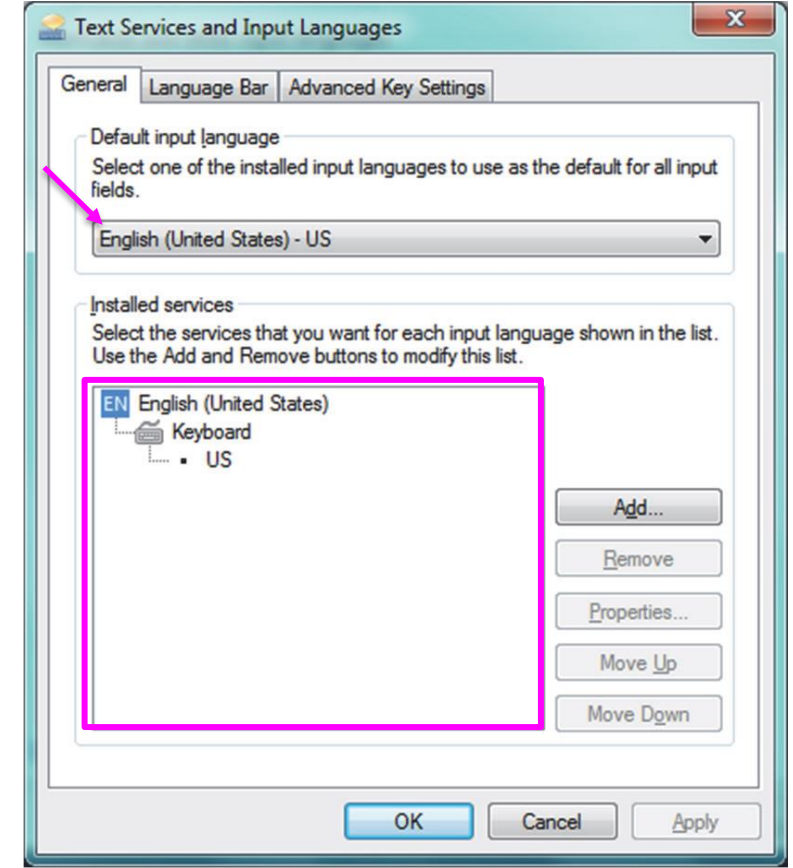
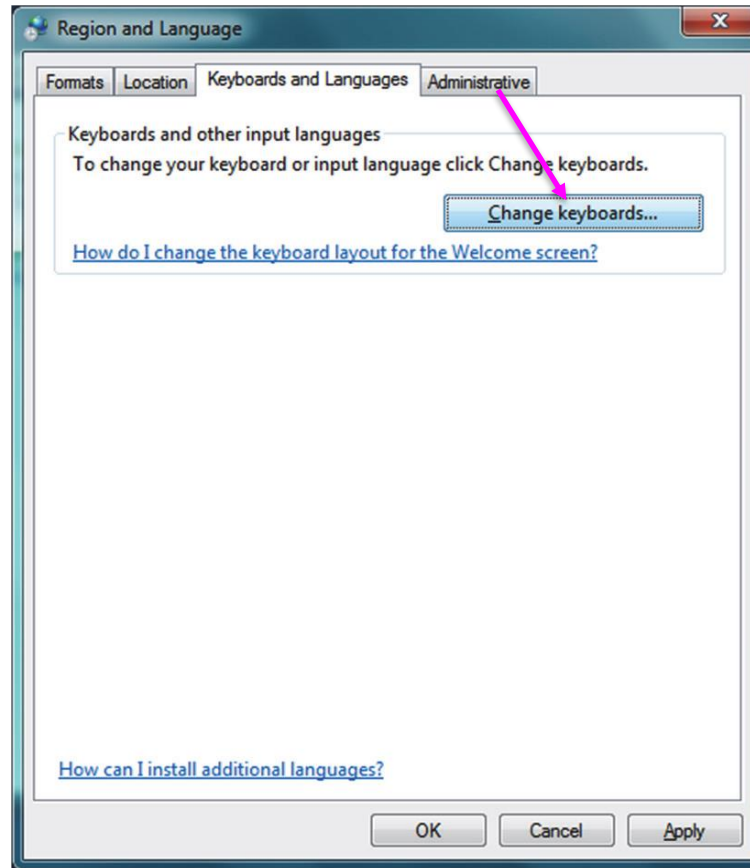
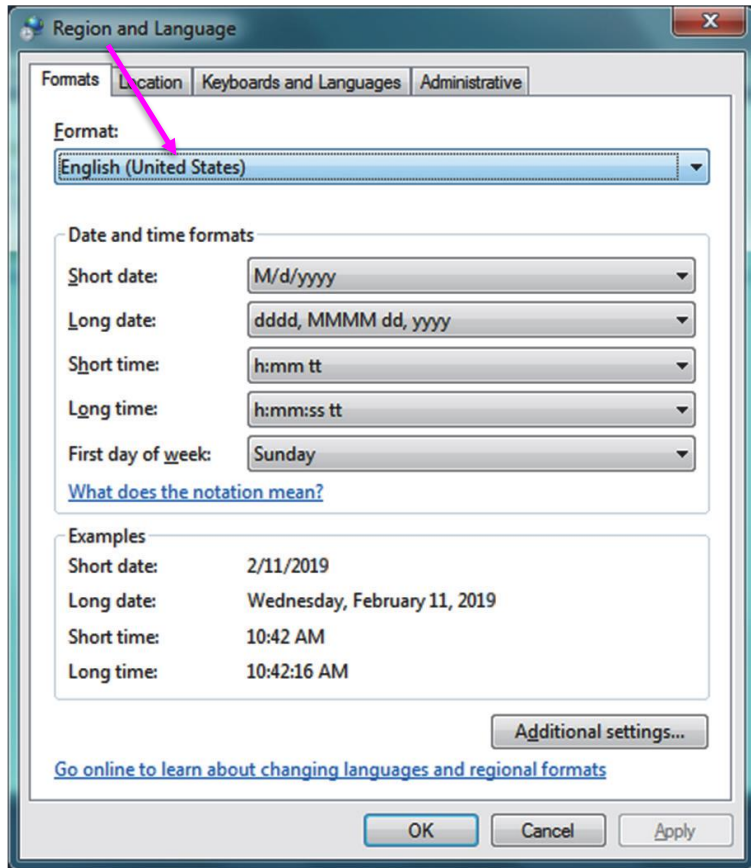


*With Windows® 7*

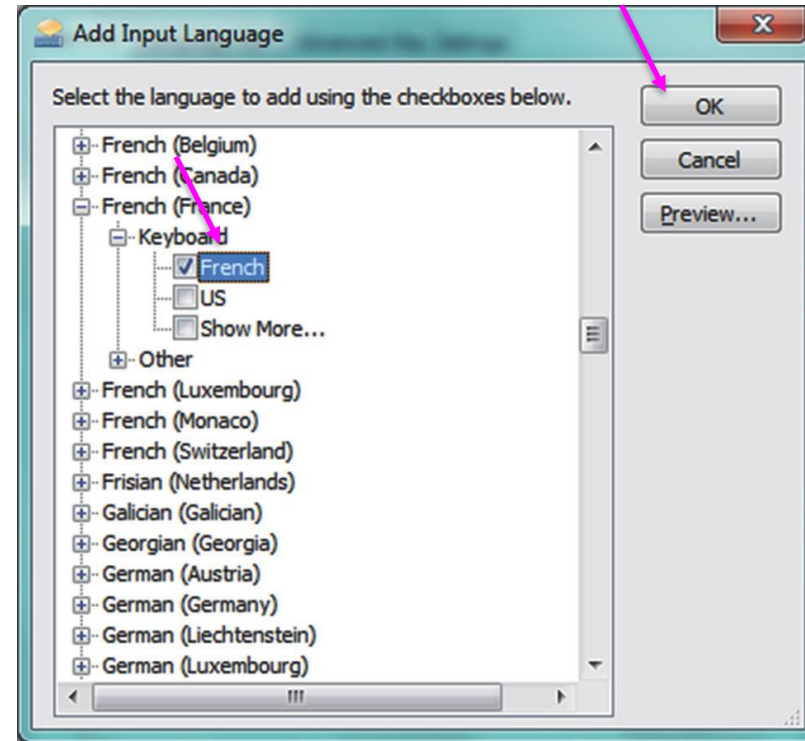
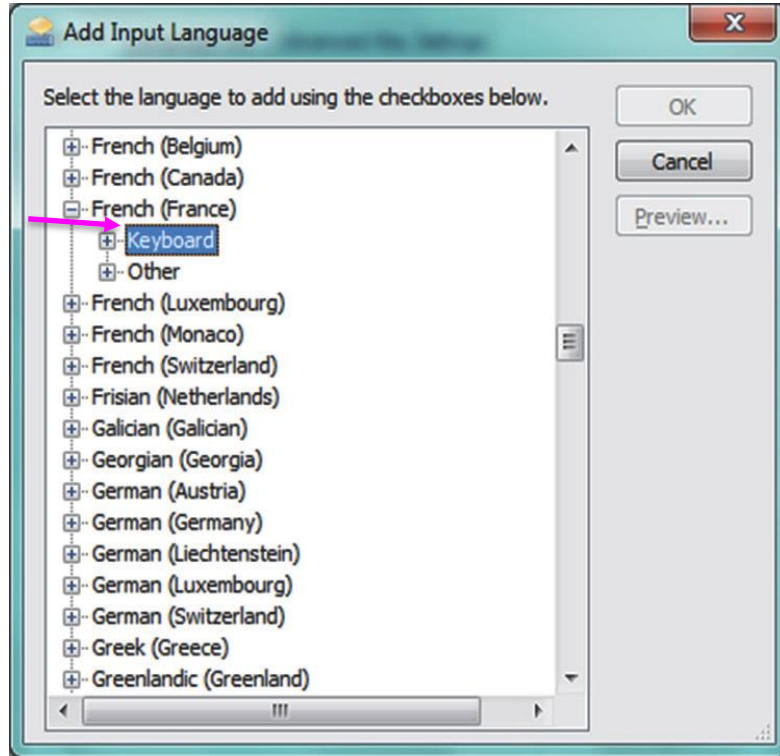


*With Windows® 10*

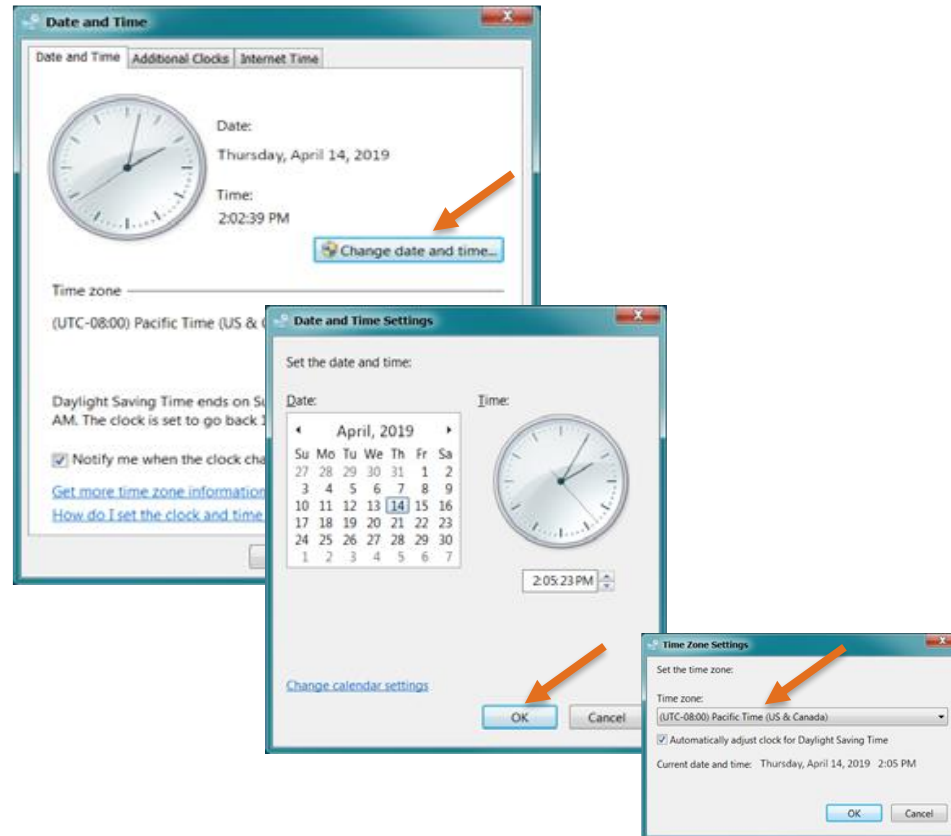
# Configuring the Windows 7 Keyboard



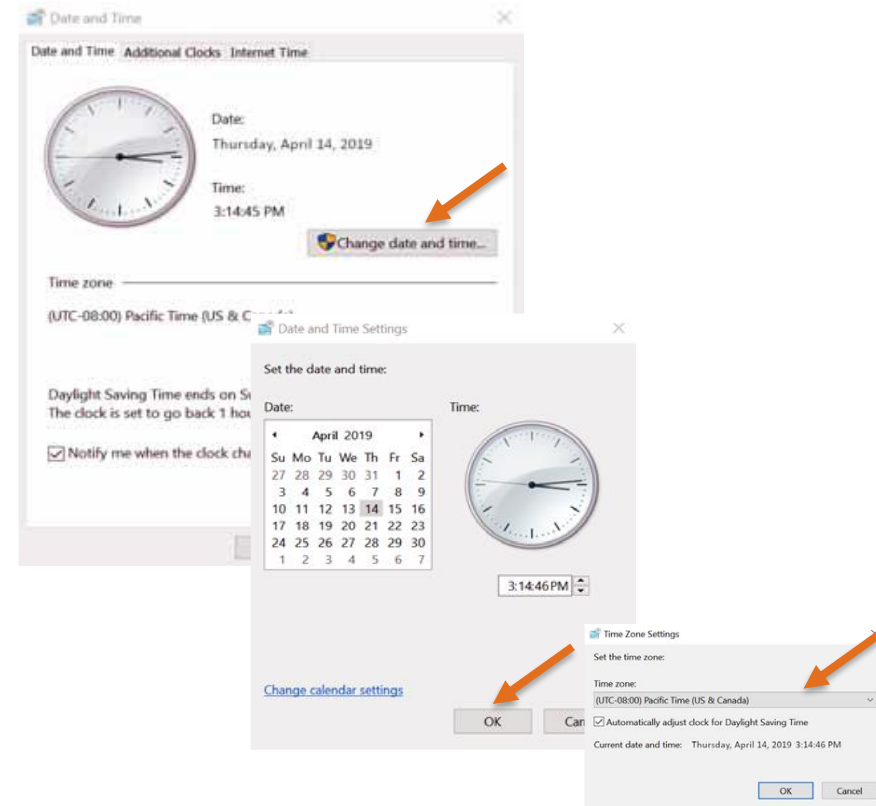
# Configuring the Windows 7 Keyboard ( cont.)



# Local Date and Time Setting



*With Windows 7*



*With Windows 10*

# How to Assign Instrument Letters

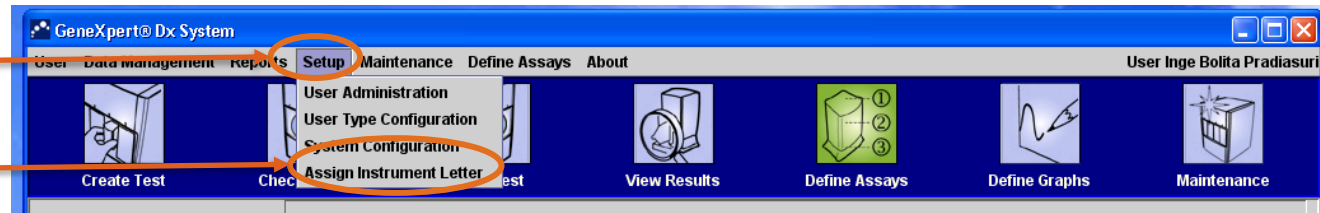
# Assign Instrument Letters

1

Click **Setup**

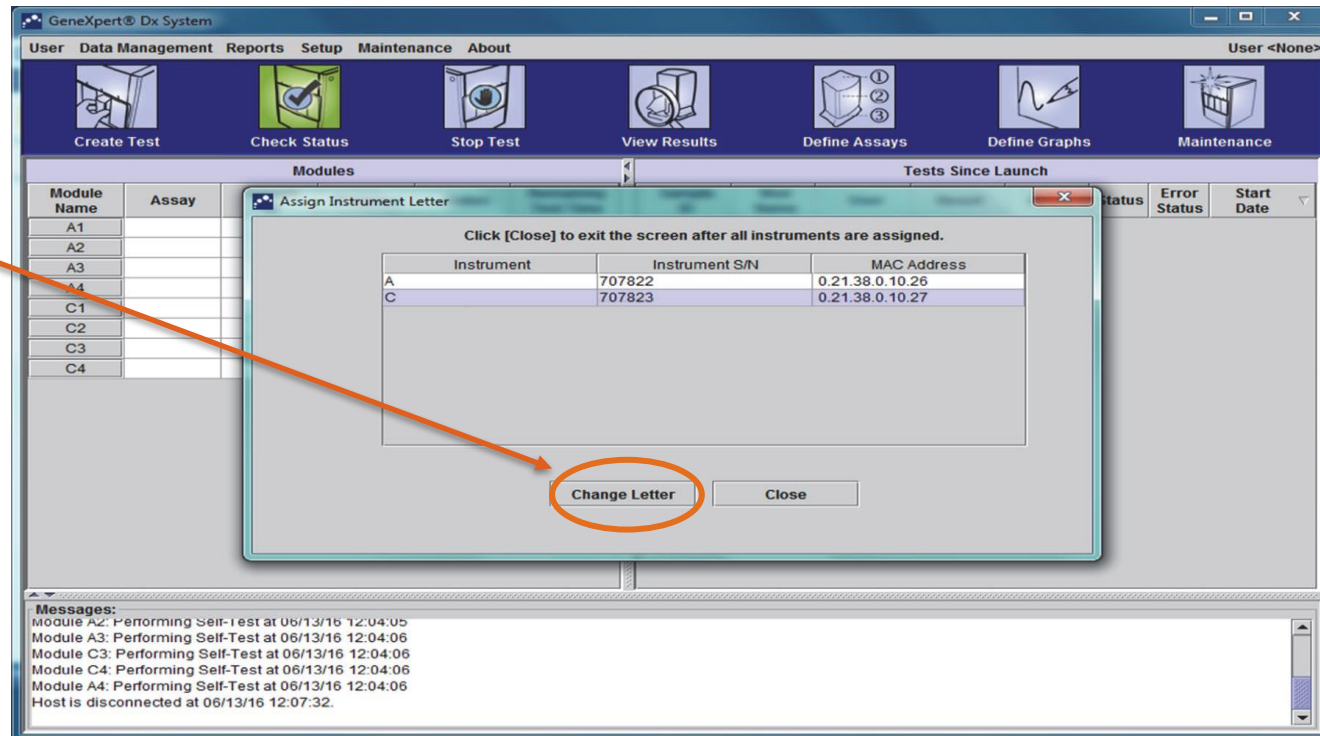
2

Click **Assign instrument letter**

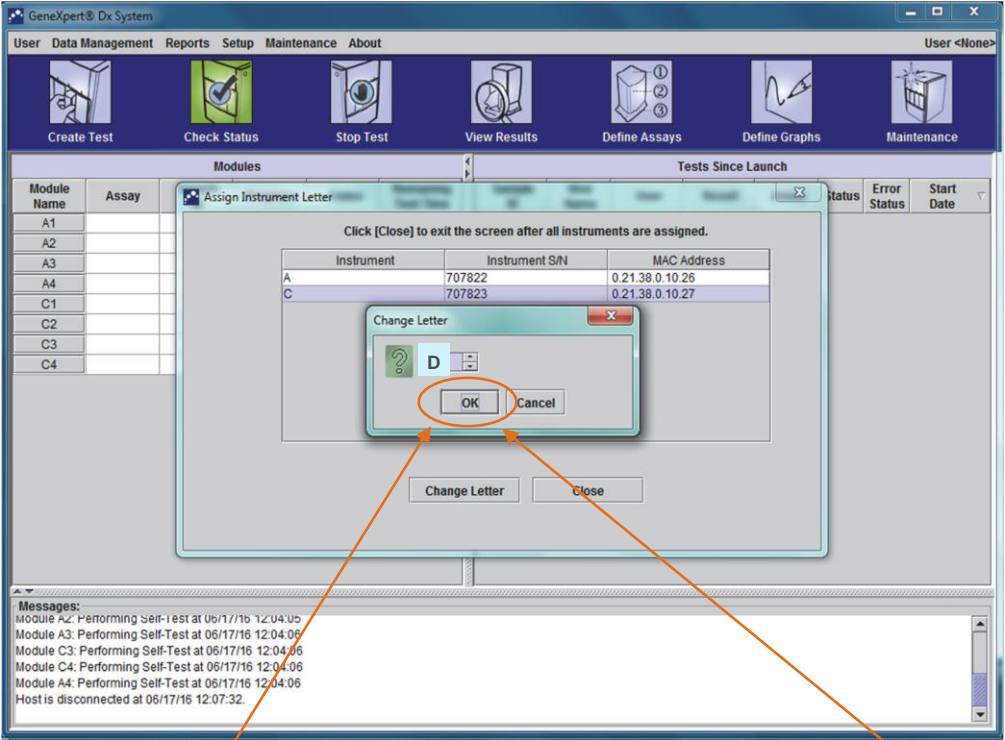
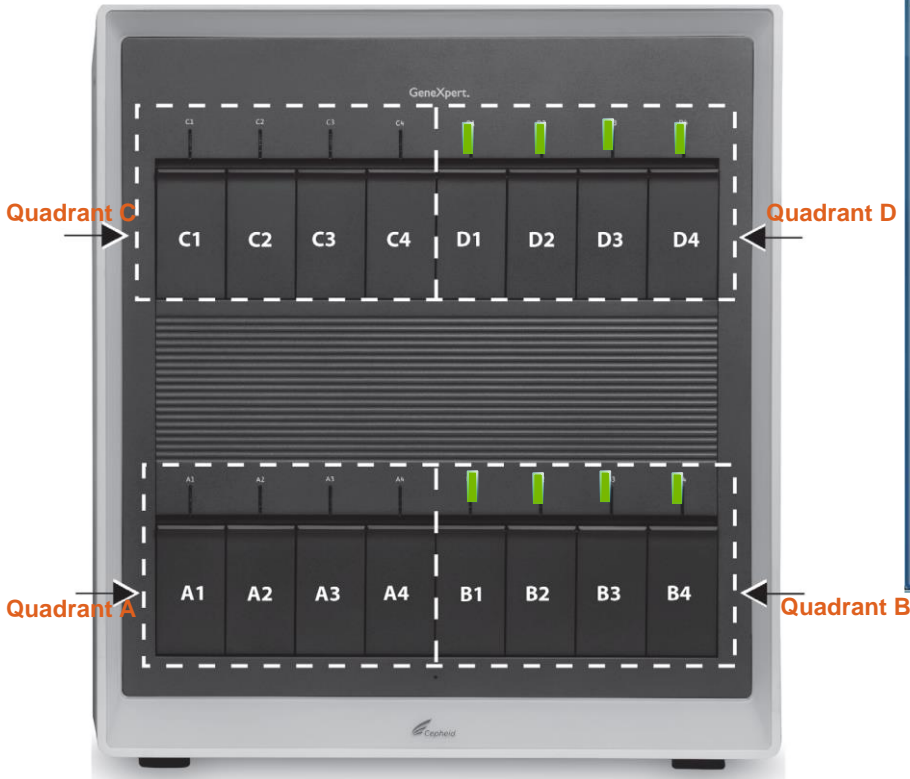


3

Click **Change Letter**



# 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 Data Management Reports Setup Maintenance About 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:

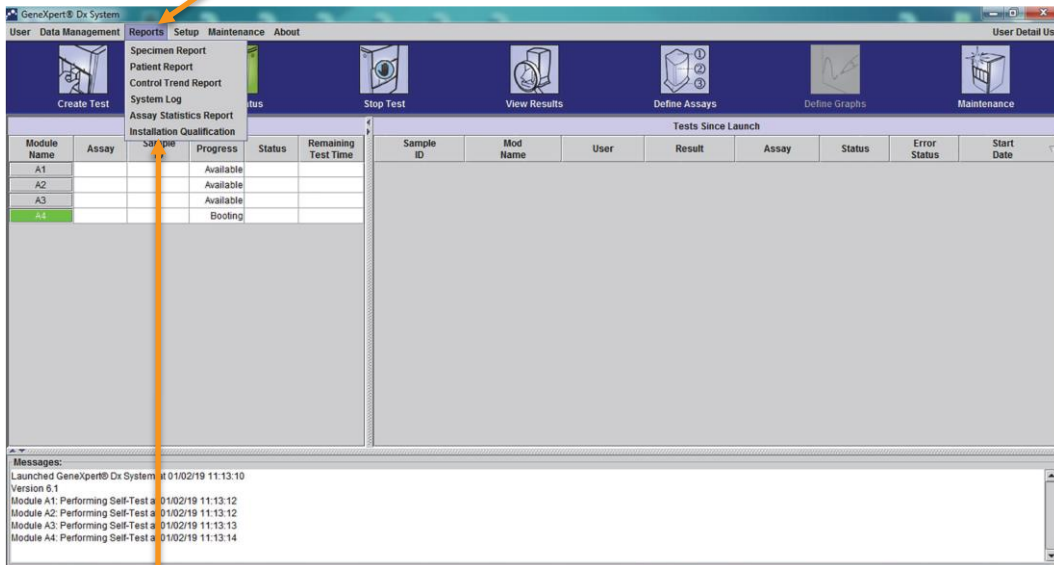
Module A2: Performing Self-Test at 02/22/19 12:04:06  
Module A3: Performing Self-Test at 02/22/19 12:04:06  
Module C3: Performing Self-Test at 02/22/19 12:04:06  
Module C4: Performing Self-Test at 02/22/19 12:04:06  
Module A4: Performing Self-Test at 02/22/19 12:04:06  
Host is disconnected at 02/22/19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



# Verifying Proper Installation and Setup

# Installation Qualification Report

**1** Click on Reports & Drop-Down the Menu



**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   |
| CIT Plug-In              | 1                               | Pass   |

### Instrument Information

| Instrument A             | Gateway Firmware |
|--------------------------|------------------|
| Instrument S/N<br>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.

### Available Assays

| Assay Name                 | Version | Assay Type          |
|----------------------------|---------|---------------------|
| Xpert FII                  | 1       | In Vitro Diagnostic |
| Xpert FII & FV Combo       | 1       | In Vitro Diagnostic |
| Xpert FV                   | 1       | In Vitro Diagnostic |
| Xpert Breast Cancer STRAT4 | NA      | Research            |

## 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 \_\_\_\_\_

# Configuring the System

# Configuring the System

## General

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

**2** Click on **General Tab**

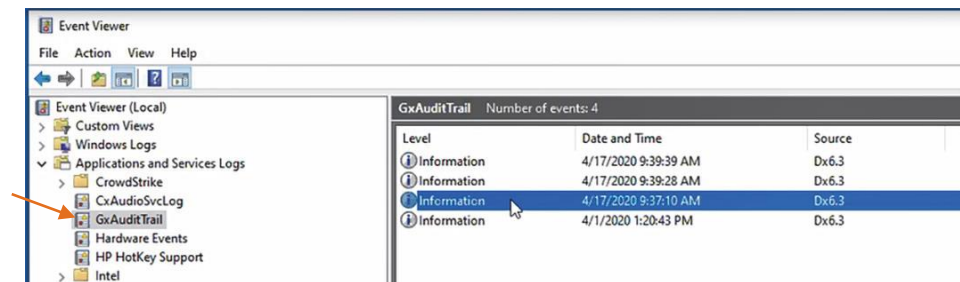
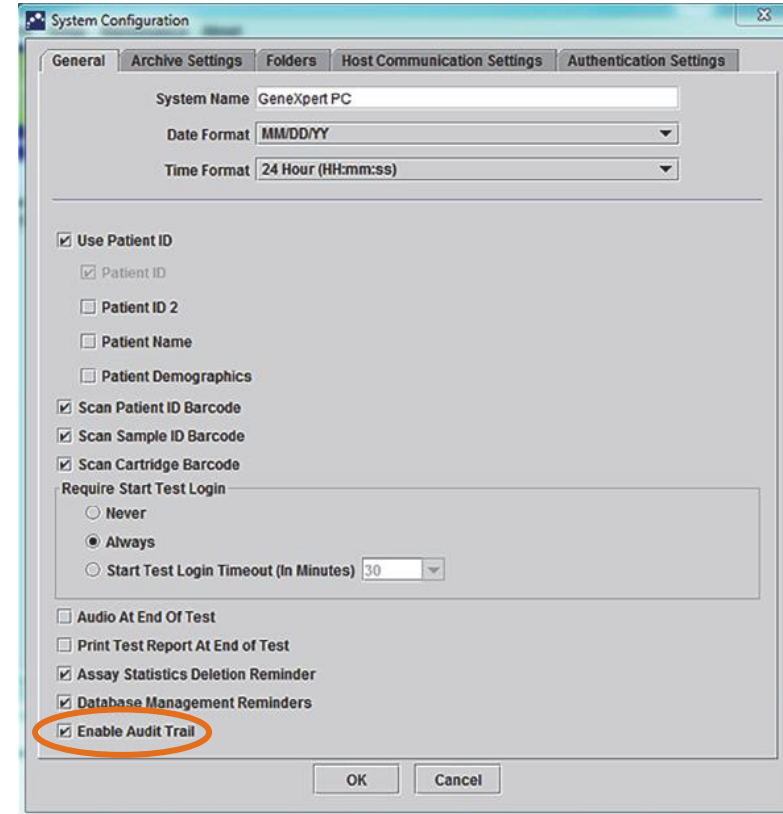
**3** Write Country, Hospital/Institution name, System configuration and GeneXpert® System Serial Number

The screenshot shows the 'System Configuration' dialog box with the 'General' tab selected. The 'System Name' field is highlighted with an orange circle and contains the text 'GeneXpert PC'. Below this, there are dropdown menus for 'Date Format' (set to 'MM/DD/YY') and 'Time Format' (set to '24 Hour (HH:mm:ss)'). The 'Use Patient ID' section is checked, with 'Patient ID' also checked. Other options like 'Patient ID 2', 'Patient Name', and 'Patient Demographics' are unchecked. The 'Scan Patient ID Barcode', 'Scan Sample ID Barcode', and 'Scan Cartridge Barcode' options are all checked. Under 'Require Start Test Login', the 'Always' radio button is selected, and the 'Start Test Login Timeout (In Minutes)' is set to 30. At the bottom, there are 'OK' and 'Cancel' buttons.

# Configuring the System

## General

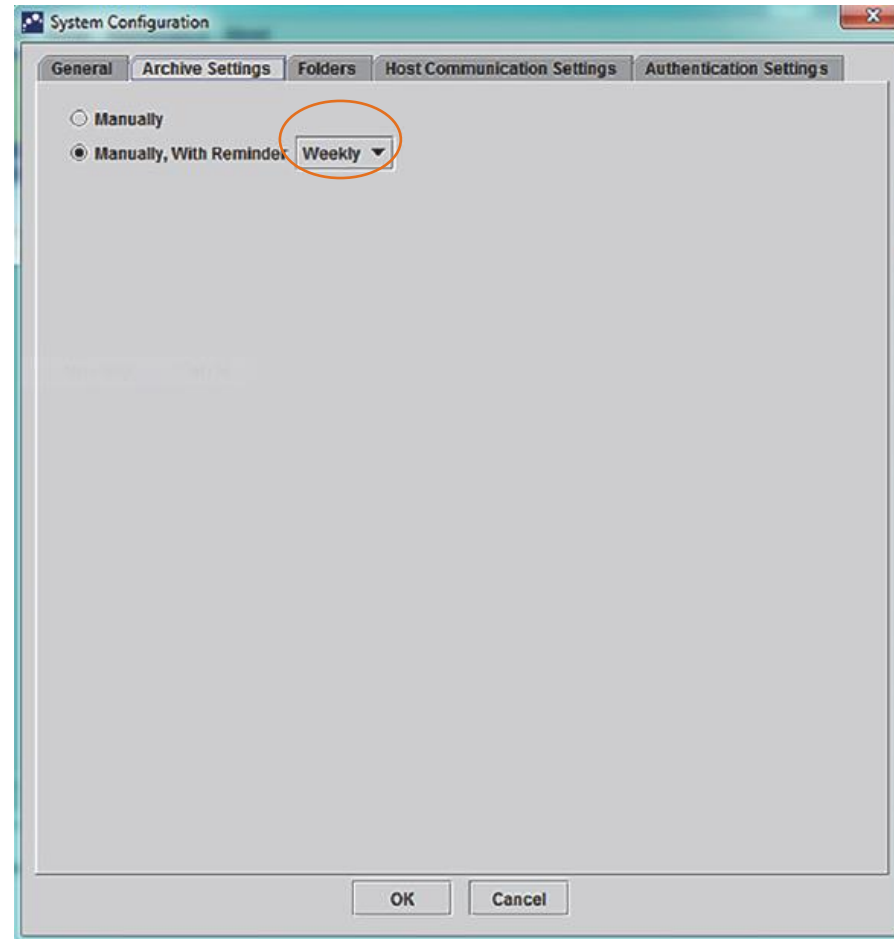
- **Enable Audit Trail**—The user can enable or disable event logging.
- If **Enable Audit Trail** is checked, the system will make a record of user interactions with PHI and PII such as:
  - User Authentication
  - User Administration
  - Creation of Tests
  - Data Import/Export
  - Report Generation
- To access the Event Viewer, click on the Windows Start menu, search for **Event Viewer**, expand **Applications and Service Logs**, then expand **Gx Audit Trail**. By default, this feature is disabled. See Appendix E for detailed information
- Click **OK** to save the changes and close the window.



# Configuring the System

## Archive Settings

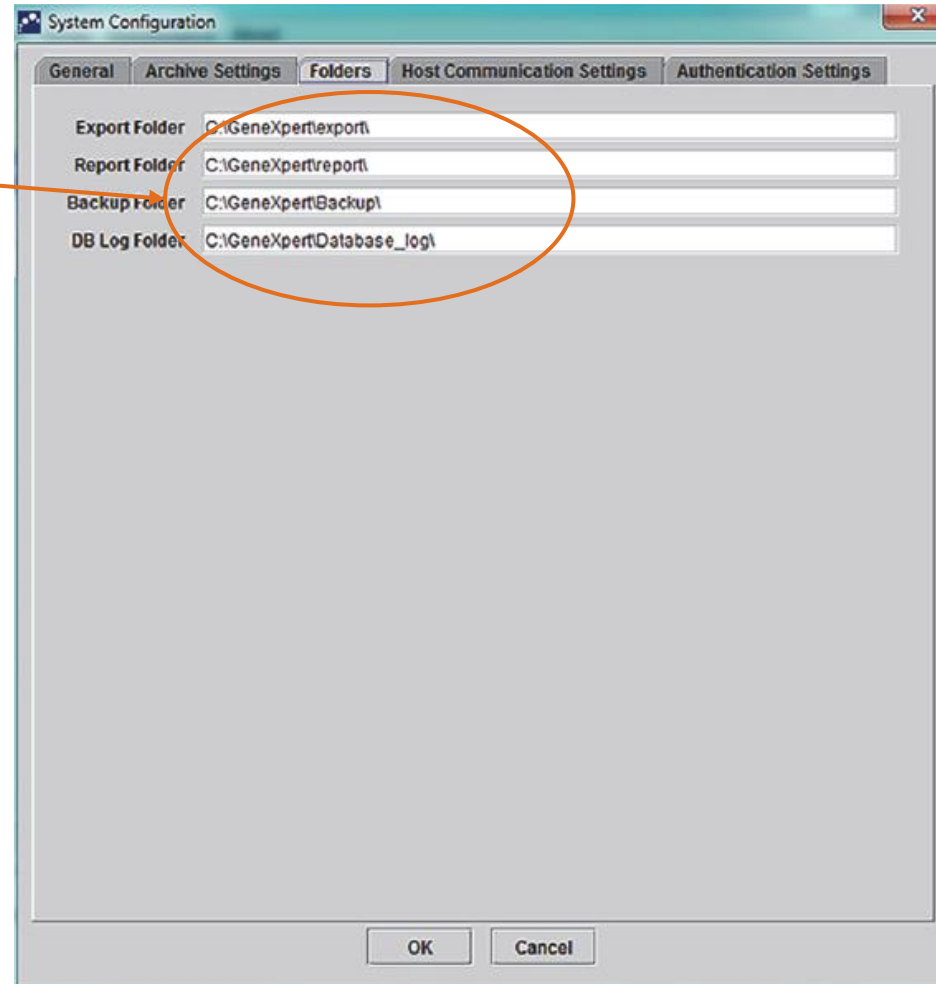
- The reminder is displayed when:
  - GeneXpert® Dx software application starts.
  - GeneXpert® Dx software application normally terminates.
  - User logs in (excluding start test login).



# Configuring the System

## Folders

- 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 Authentication 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 C. diff-Epi Version 2      |                | Edit |
| <input checked="" type="checkbox"/> | Xpert MTB-RIF Assay G4 Version 6 |                | Edit |

OK Cancel

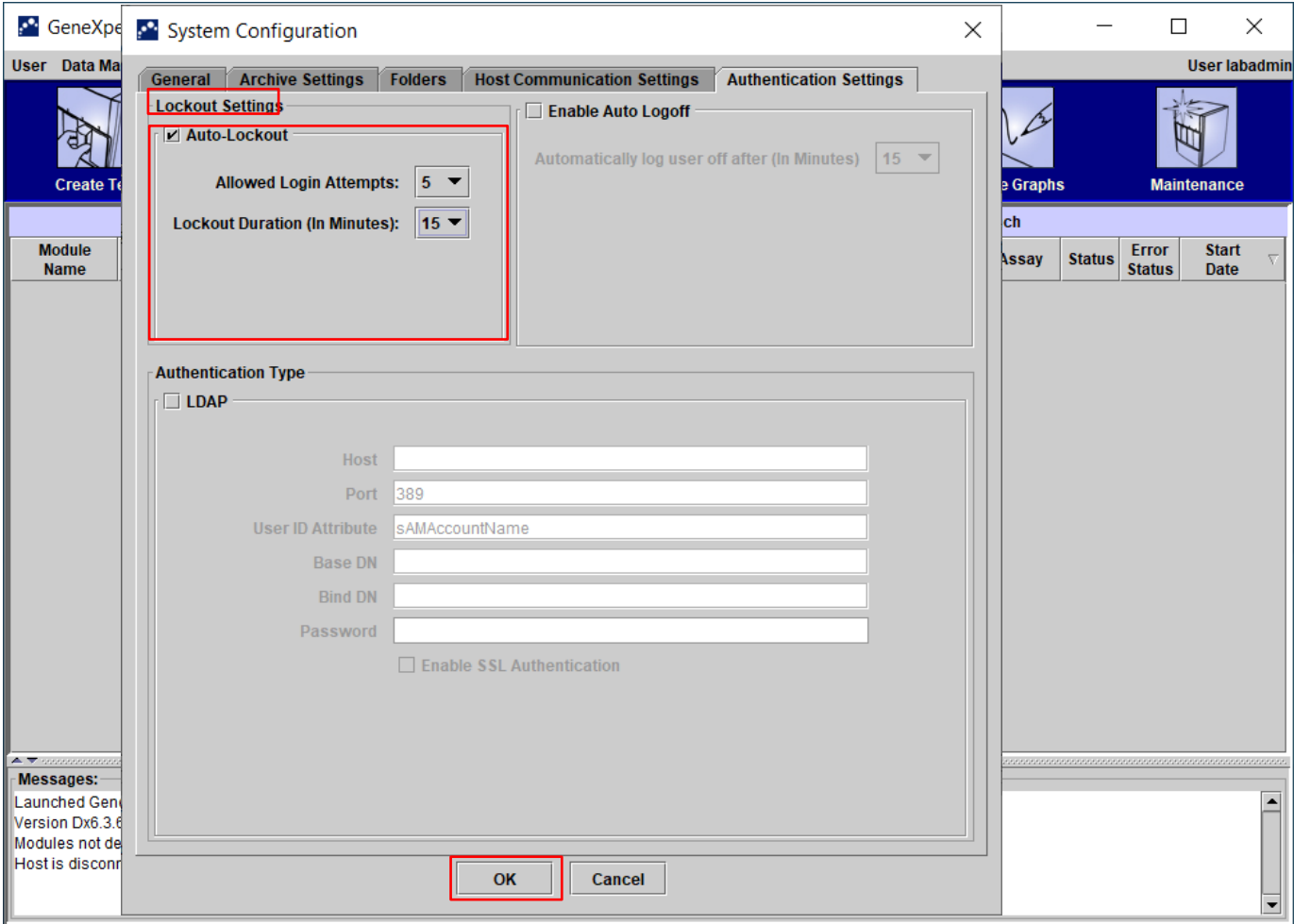


# Account Lockout

# Account Lockout

- Users will be locked out after a configured number of failed login attempts for a set period of time
- The lockout period will be reset on a successful attempt or after the user updates their password
- A GeneXpert® admin cannot circumvent the lockout period unless they disable the feature
- This feature does not apply to users such as support or to remote users integrated with LDAP.

# Configuration



# Mis-type the password 5 times





# Auto Logoff

# Auto Logoff

- The GeneXpert® application will log out a user after a period of inactivity
- However, the OS session will continue, or the lab user will lose tests that are running
- Interacting with the user interface will reset the timer
- The timer is suspended for long running operations like backup/restore, export

# Configuration

The screenshot shows the 'System Configuration' dialog box for GeneXpert Dx. The 'Authentication Settings' tab is active. The 'Lockout Settings' section includes 'Auto-Lockout' (checked), 'Allowed Login Attempts' (5), and 'Lockout Duration (In Minutes)' (15). The 'Enable Auto Logoff' checkbox is checked, and the 'Automatically log user off after (In Minutes)' dropdown is set to 15. The 'Authentication Type' section has 'LDAP' unchecked, with fields for Host, Port (389), User ID Attribute (sAMAccountName), Base DN, Bind DN, and Password. An 'Enable SSL Authentication' checkbox is also present. The 'OK' button is highlighted with a red box. A 'Messages' pane at the bottom left shows system logs.

| Module Name | Assay |
|-------------|-------|
|-------------|-------|

| Status | Error Status | Start Date |
|--------|--------------|------------|
|--------|--------------|------------|

Messages:  
Launched GeneXpert® D  
Version Dx6.3.67\_Demo  
Modules not detected. C  
Host is connected at 07/0



# Confirmation

The screenshot shows the GeneXpert Dx System software interface. At the top, a menu bar includes 'User', 'Data Management', 'Reports', 'Setup', 'Maintenance', and 'About'. A red box highlights a 'User Logged Out' notification in the top right corner. 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'. Both panels contain empty tables with the following headers:

| Module Name | Assay | Sample ID | Progress | Status | Remaining Test Time |
|-------------|-------|-----------|----------|--------|---------------------|
|-------------|-------|-----------|----------|--------|---------------------|

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

At the bottom, a 'Messages' pane displays the following text:

Launched GeneXpert® Dx System at 06/16/20 11:54:39  
Version Dx6.3.67\_Demo  
Modules not detected. Check power switch and computer/GeneXpert cable connections.



# Managing Users

# Adding new users :

1. Create an Administrator Account (“Admin”)

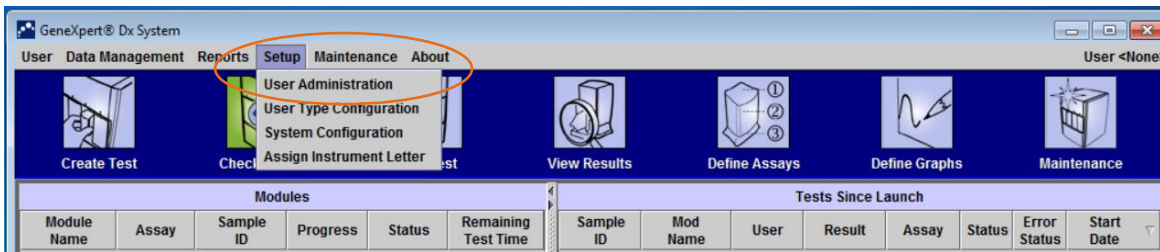
# Create an Administrator Account (“Admin”)

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*

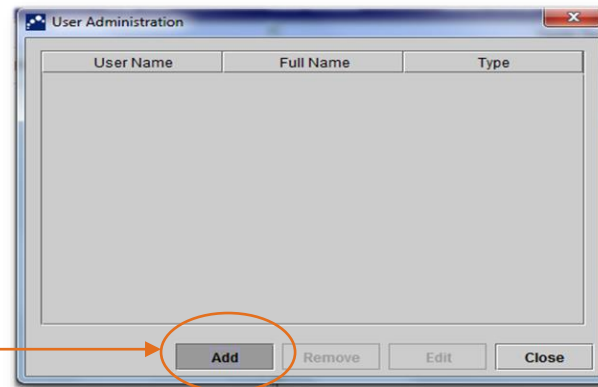
1

Setup → User Administration



2

Click Add

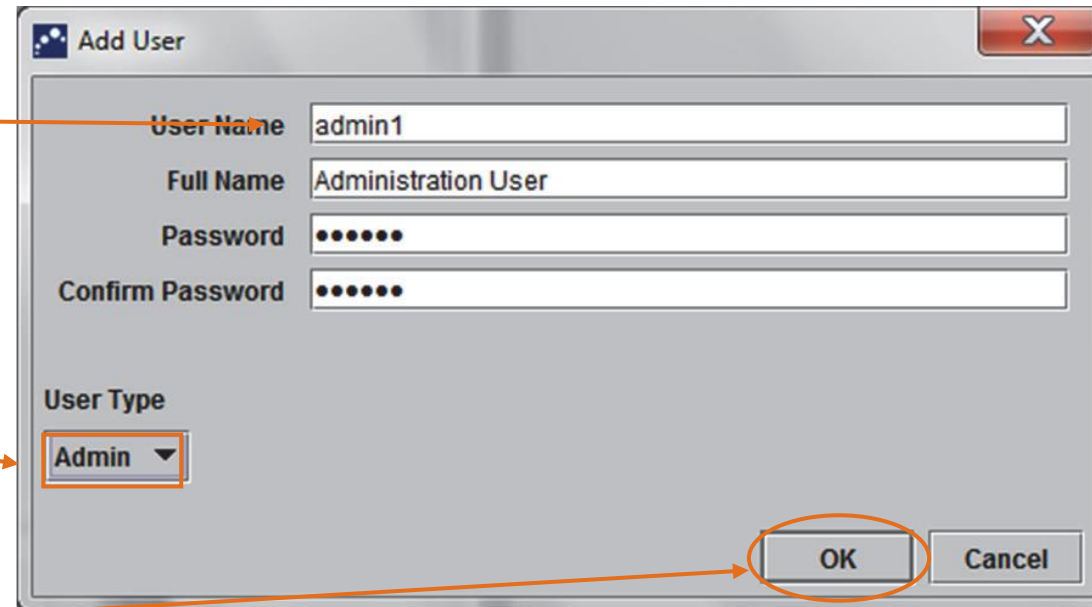


# Create an Administrator Account (“Admin”)

**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 "3" to this field.
- Full Name:** A text input field containing "Administration User".
- Password:** A text input field with six dots representing a masked password.
- Confirm Password:** A text input field with six dots representing a masked password.
- User Type:** A dropdown menu with "Admin" selected. An orange arrow points from the instruction box "4" to this dropdown.
- Buttons:** "OK" and "Cancel" buttons at the bottom right. The "OK" button is circled in orange, and an orange arrow points from the instruction box "5" to it.

# Adding new users :

## 2. Create a Basic Account

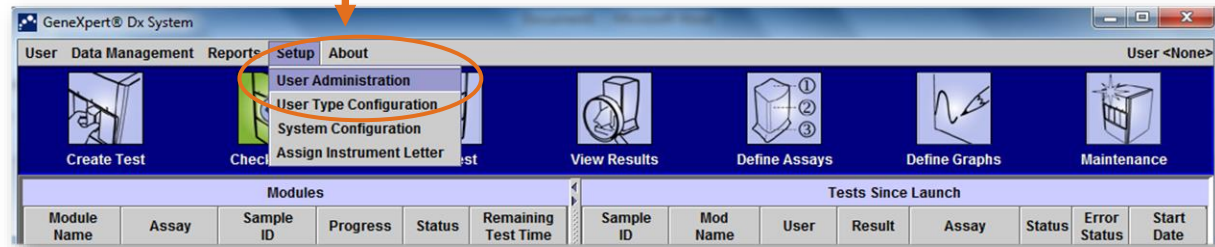


# Create a Basic Account

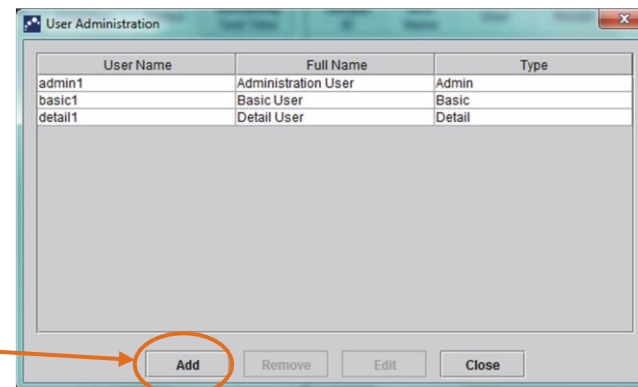
Define the person in the lab that will have limited access to the software

*There can be more than one Basic account per system*

**1** Setup → User administration



**2** Click on Add

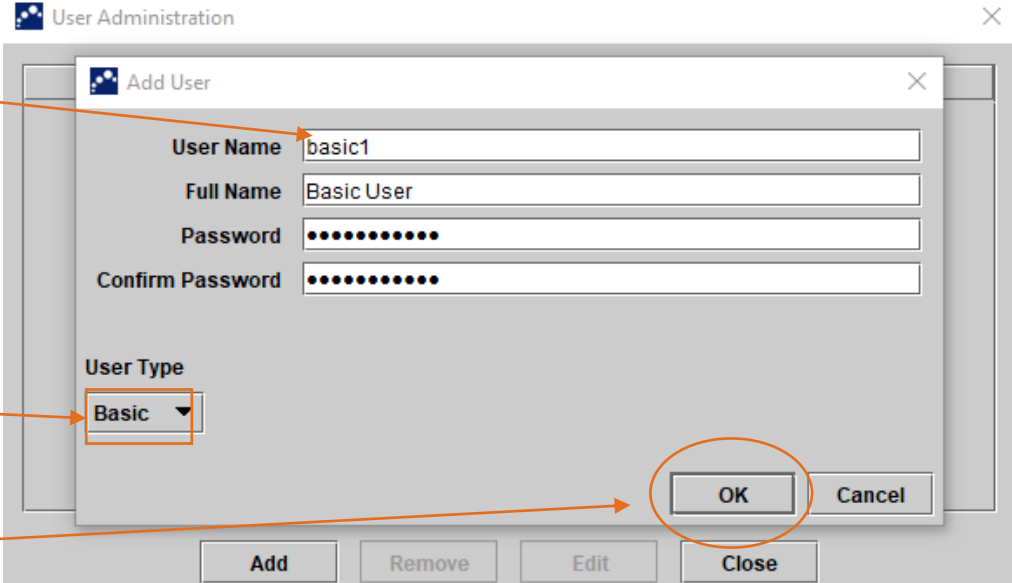


# Create a Basic Account

**3** Enter the Username and Password

**4** Choose the User type (**Basic**)

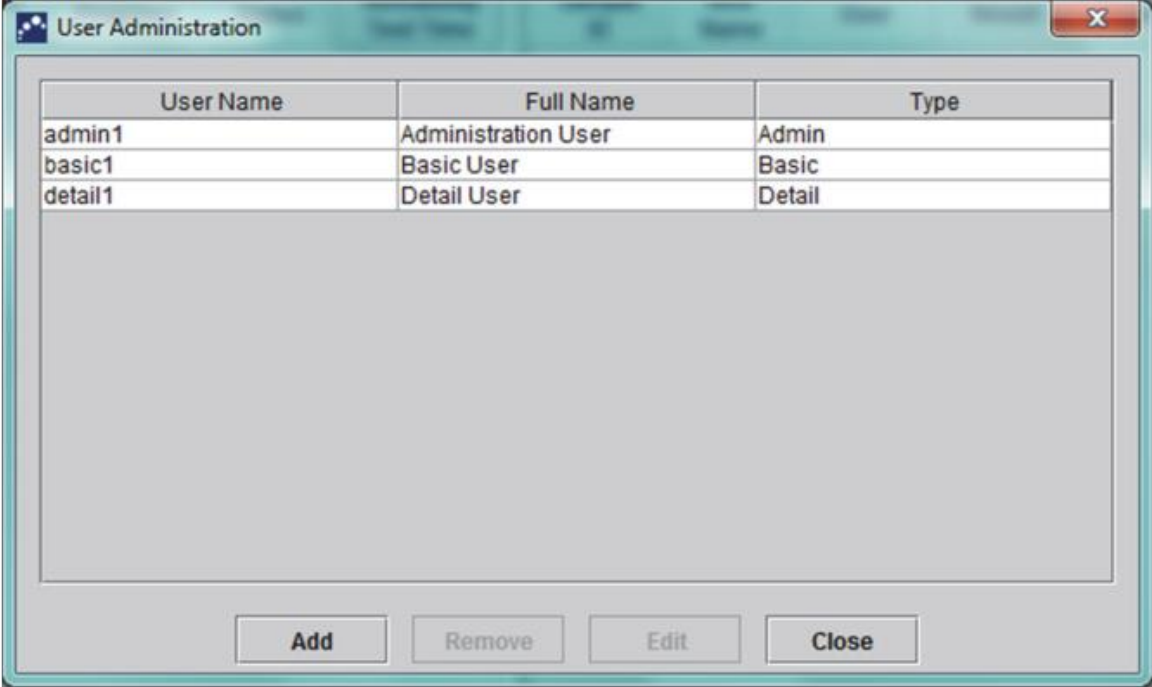
**5** Click on **OK**



*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 displays the GeneXpert Dx System software interface. The main window has a menu bar with 'User', 'Data Management', 'Reports', 'Setup', 'Maintenance', and 'About'. The 'Setup' menu is open, showing options: 'User Administration', 'User Type Configuration' (highlighted with an orange circle), 'System Configuration', and 'Assign Instrument Letter'. Below the menu is a toolbar with icons for 'Create Test', 'Stop Test', 'View Results', 'Define Assays', 'Define Graphs', and 'Maintenance'. The main area is divided into 'Modules' and 'Sample ID', 'Mod Name', and 'User' columns. A 'Messages' pane at the bottom left shows system launch information and a warning: 'Modules not detected. Check power switch and computer/GeneXpert cable connections.'

The 'User Type Configuration' dialog box is open, showing a list of permissions with checkboxes for 'Basic' and 'Detail' access. The permissions listed are:

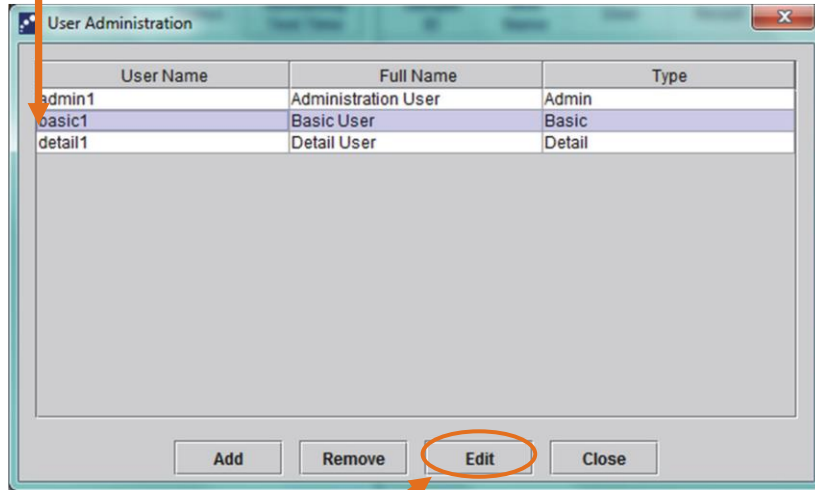
|  | Basic                               | Detail                              |
|--|-------------------------------------|-------------------------------------|
| Delete Assay and Lot Specific Parameters             | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |
| Manage Assay Definition                              | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| View About Box                                       | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| 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"/> |
| 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 Database                                     | <input type="checkbox"/>            | <input type="checkbox"/>            |
| View Specimen and Patient Reports                    | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| View Control Trend and Assay Statistics Reports      | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |
| View System Log                                      | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |
| View IQ Report                                       | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Edit System Configuration                            | <input type="checkbox"/>            | <input type="checkbox"/>            |
| Edit Test Details                                    | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Edit Graphs  | <input type="checkbox"/>            | <input type="checkbox"/>            |
| Assign Instrument Letter                             | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |
| View Module Reporter                                 | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |
| Run Plunger Rod Maintenance                          | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Open Door  | <input type="checkbox"/>            | <input type="checkbox"/>            |
| Run Self-Test  | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Exclude Modules From Test                            | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |

Buttons at the bottom of the dialog: OK, Cancel, Reset to Default.

# Editing User Profile

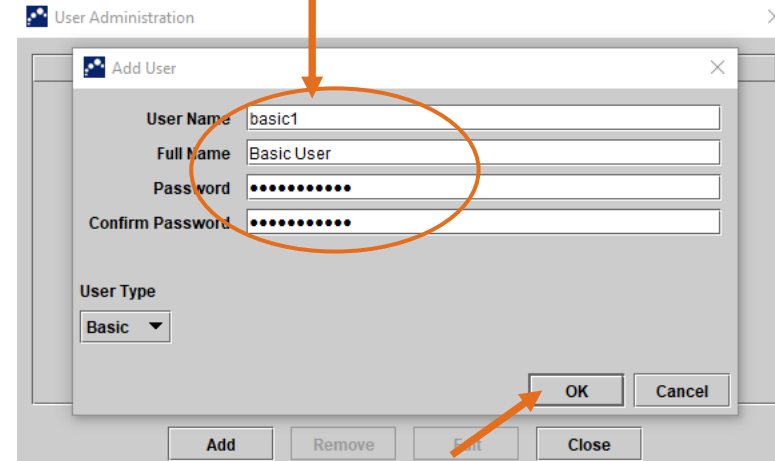
# How to Edit User Profile

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



**2** Click on **Edit**

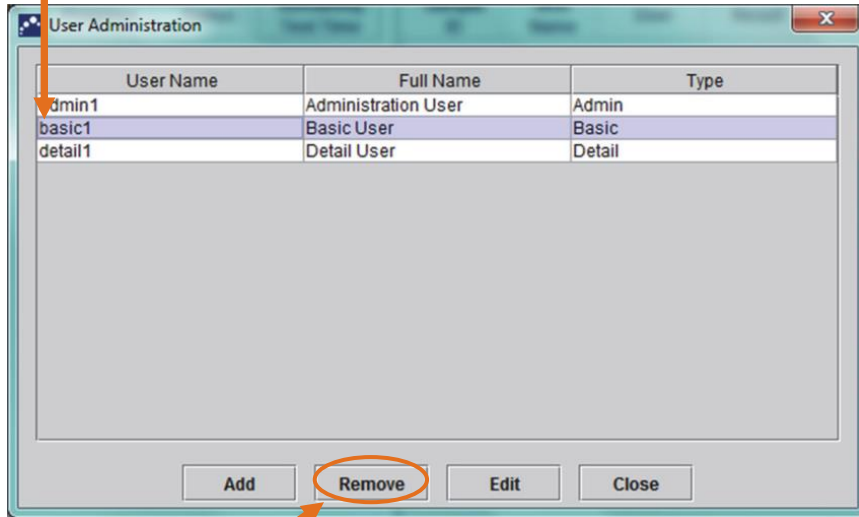
**3** Revise the information, as desired, and then click **OK** to save the changes and close the Edit User dialog box.



# Removing Users

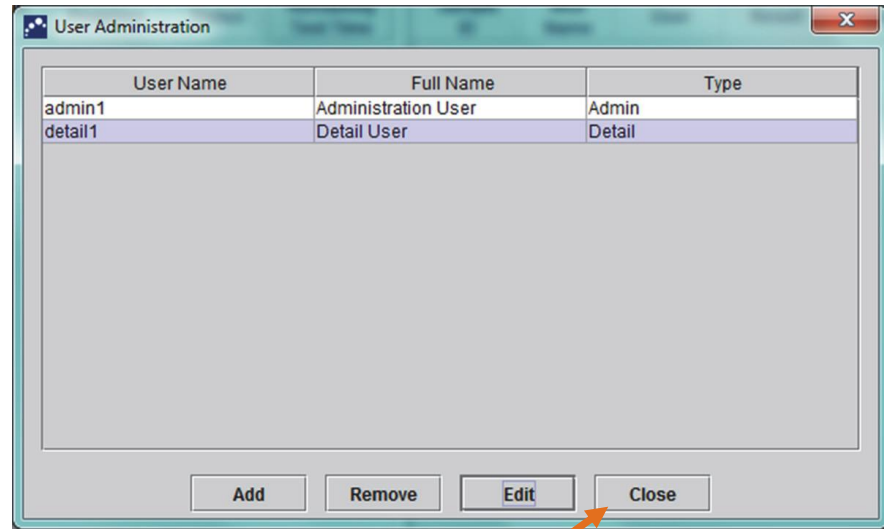
# How to Remove Users

**1** Click to select the user to be removed



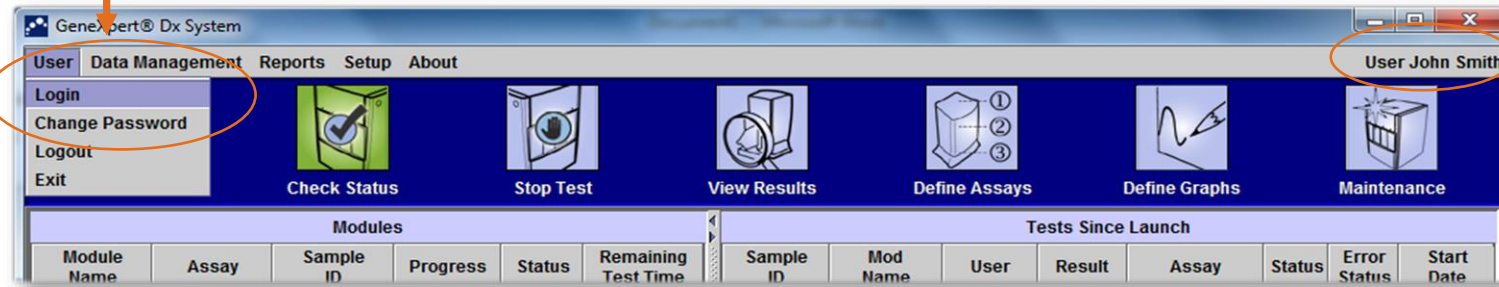
**2** Click on **Remove**

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



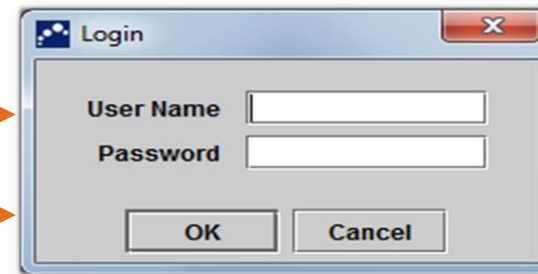
# How to Login

**1** Select User → Login



**2** Enter your User Name and Password

**3** Click OK





# LDAP Integration



# LDAP - Lightweight Directory Access Protocol

- Open, vendor-neutral, industry standard protocol for accessing and maintaining distributed directory information services over an Internet Protocol network
- Based on telephone directories
  - Telecomm companies had ~70 years of producing and managing telephone directories as books.
  - Introduced the concept of directory services to computer networking, culminating in the comprehensive **X.500** specification
  - X.500 directory services were traditionally accessed via **DAP** using OSI protocol
  - LDAP uses lower bandwidth, so it's **Lighter**

# Active Directory

- Microsoft® Active Directory (**AD**) is a Directory Server that ‘speaks’ LDAP
- Provides services such as authentication, group and user management, policy administration, etc...
- LDAP integration will allow a customer’s IT department to centrally manage users on a GeneXpert® system
  - The lab user must now use their network credentials to login to the application
  - The network policy on passwords applies with regard to complexity, duration, reuse, history, etc...
  - If a user is deactivated on the network, then they will not be able to login to the GeneXpert® application

# Implementation

- Allows configuration of an LDAP connection to perform authentication
  - Remote users must be entered in User Administration and assigned a role
  - The connection is established when:
    - Saving new settings
    - Adding/Editing a remote user
    - Sending a login request
  - When LDAP is enabled the users who can log in are:
    - Remote Users (when connected)
    - Internal GeneXper® t Users such as support
    - Local Admin Users

# Configuration

The screenshot shows the 'System Configuration' dialog box for GeneXpert, with the 'Authentication Settings' tab selected. The 'Lockout Settings' section includes 'Auto-Lockout' (checked) with 'Allowed Login Attempts' set to 5 and 'Lockout Duration (In Minutes)' set to 15. 'Enable Auto Logoff' is also checked, with 'Automatically log user off after (In Minutes)' set to 15. Under 'Authentication Type', 'LDAP' is selected. The following fields are highlighted with a red box:

- Host: 10.169.82.112
- Port: 389
- User ID Attribute: sAMAccountName
- Base DN: CN=Users,DC=GeneXpert,DC=local
- Bind DN: CN=Administrator,CN=Users,DC=GeneXpert,DC=local
- Password: [Redacted]

The 'Enable SSL Authentication' checkbox is unchecked. The 'OK' button is highlighted with a red box. The background shows the GeneXpert interface with a 'Messages' pane at the bottom left displaying: 'Launched GeneXp', 'Version Dx6.3.67\_', 'Modules not detec', 'Host is connected'.

# Confirmation

The screenshot shows the GeneXpert Dx System software interface. At the top, there is a menu bar with options: User, Data Management, Reports, Setup, Maintenance, and About. The user is identified as 'User labadmin'. 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 panes:

- Modules:** A table with columns: Module Name, Assay, Sample ID, Progress, Status, Remaining Test Time.
- Tests Since Launch:** A table with columns: Sample ID, Mod Name, User, Result, Assay, Status, Error Status, Start Date.

At the bottom, there is a Messages pane with the following text:

```
Messages:  
Launched GeneXpert® Dx System at 06/30/20 16:53:23  
Version Dx6.3.67_Demo  
Modules not detected. Check power switch and computer/GeneXpert cable connections.  
Host is disconnected at 06/30/20 16:53:50.  
Connection to LDAP successful
```

The message 'Connection to LDAP successful' is highlighted with a red box.

# Confirmation

The screenshot shows the GeneXpert Dx System software interface. At the top, there is a menu bar with 'User', 'Data Management', 'Reports', 'Setup', 'Maintenance', and 'About'. The 'User' menu is open, showing 'User GeneX1'. 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 main area is divided into two panels: 'Modules' and 'Tests Since Launch'. The 'Tests Since Launch' panel displays a large blue text prompt: 'Password: Cepheid123!'. At the bottom, a 'Messages' log shows the following text: 'Launched GeneXpert® Dx System at 06/22/20 07:42:06', 'Version Dx6.3.67\_Demo', 'Modules not detected. Check power switch and computer/GeneXpert cable connections.', and 'Host is disconnected at 06/22/20 07:42:32.'.

| Modules     |       |           |          |        |                     | Tests Since Launch    |          |      |        |       |        |              |            |
|-------------|-------|-----------|----------|--------|---------------------|-----------------------|----------|------|--------|-------|--------|--------------|------------|
| Module Name | Assay | Sample ID | Progress | Status | Remaining Test Time | Sample ID             | Mod Name | User | Result | Assay | Status | Error Status | Start Date |
|             |       |           |          |        |                     | Password: Cepheid123! |          |      |        |       |        |              |            |

**Messages:**  
Launched GeneXpert® Dx System at 06/22/20 07:42:06  
Version Dx6.3.67\_Demo  
Modules not detected. Check power switch and computer/GeneXpert cable connections.  
Host is disconnected at 06/22/20 07:42:32.

# 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 area is divided into two tables: 'Modules' and 'Tests Since Launch'.

| 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 |

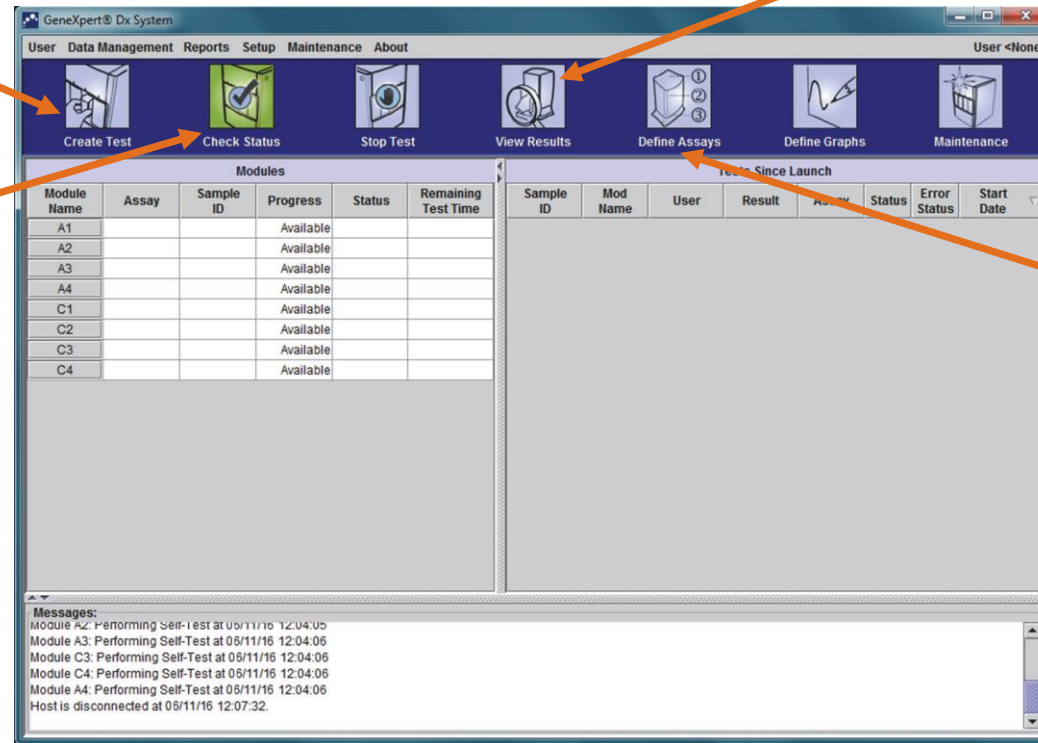
# GeneXpert® Dx System Window

Create and start a test

View the results

Monitor  
the test  
progress

Check  
the list of  
assays





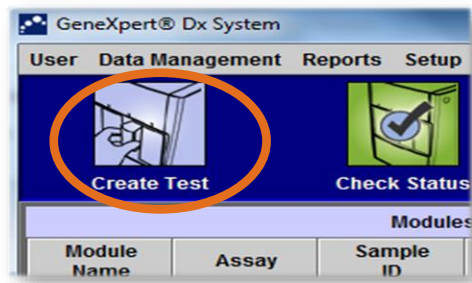


# Create a Test

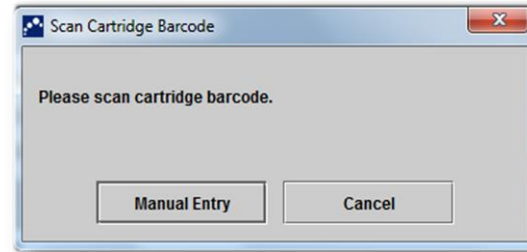
# Create a Test

After preparing the cartridge according to the Package Insert:

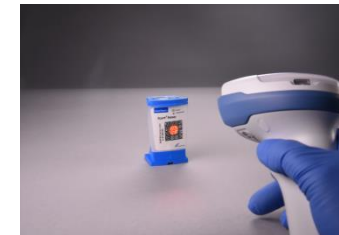
**1** Click on **Create Test**



**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 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

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:   
Gender: <None>      Ethnicity: <None>  
Name: Xpert-C. difficile G2      Version: 2  
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:   
Notes:   
**Start Test**      Scan Cartridge Barcode      Cancel

**6** Click **Start test**

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

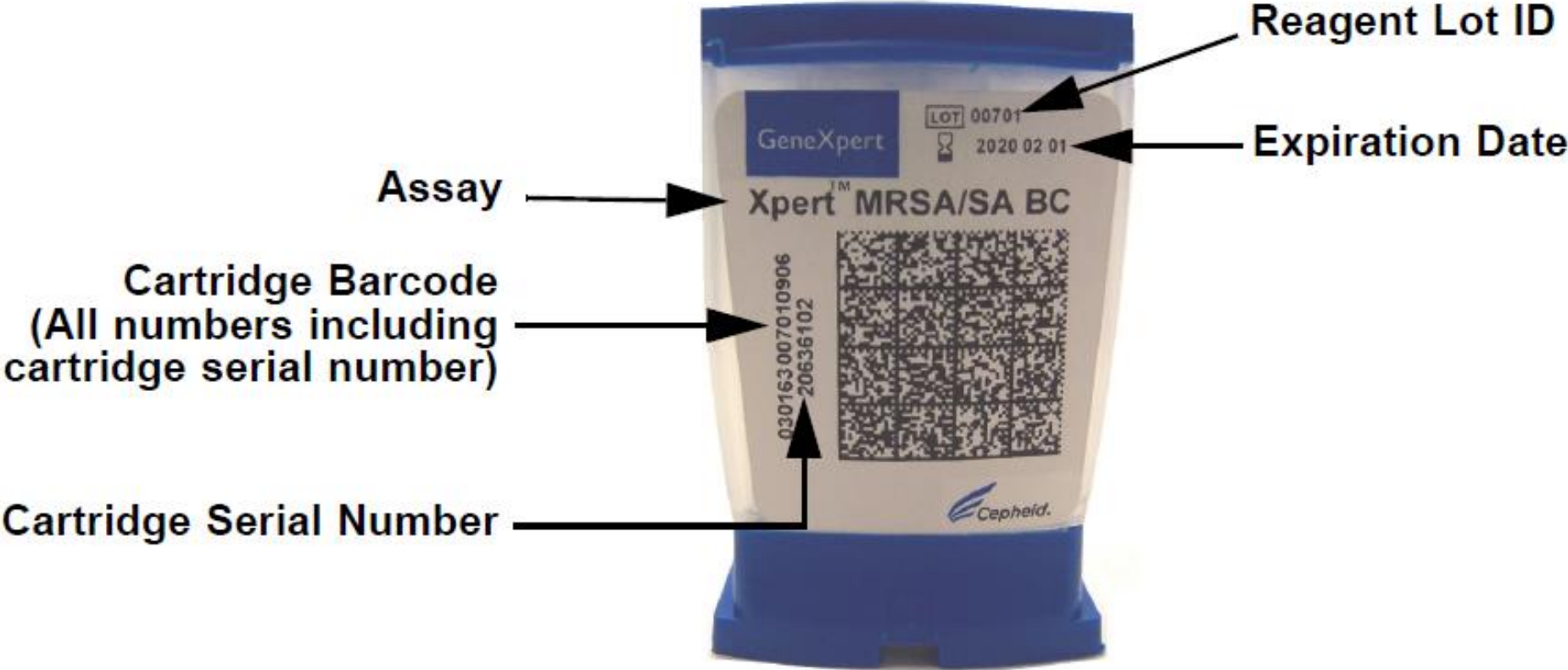


**8** Close the module door completely. The green light will stop flashing and the test will start.



# Manual Entry of the Cartridge Barcode

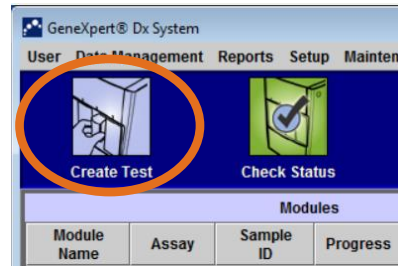
# GeneXpert<sup>®</sup> Cartridge



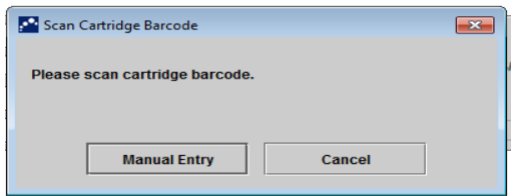
# Manual Entry of the Cartridge Barcode

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

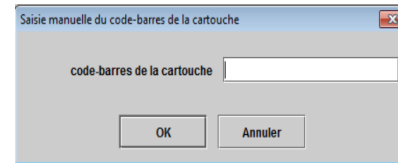
**1** Click on **Create Test**



**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

Form fields and values:

- 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\*: 98100
- Expiration Date\*: 2020/12/25
- Cartridge S/N\*: 70462806
- Test Type: Specimen
- Sample Type: Other
- Other Sample Type: [Empty]

**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.

# Monitoring the Test Process



# Monitoring the Test Process

Check the Module Area for Test Status

The screenshot displays the GeneXpert Dx System software interface. At the top, there is a menu bar with options: 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 system logs.

| Modules     |               |           |           |        |                     |
|-------------|---------------|-----------|-----------|--------|---------------------|
| Module Name | Assay         | Sample ID | Progress  | Status | Remaining Test Time |
| A1          | Xpert CDIF... | SD142231  | Loading   | OK     | --                  |
| A2          |               |           | Available |        |                     |
| A3          |               |           | Available |        |                     |
| A4          |               |           | Available |        |                     |

| Tests Since Launch |          |             |           |              |          |              |                 |
|--------------------|----------|-------------|-----------|--------------|----------|--------------|-----------------|
| Sample ID          | Mod Name | User        | Result    | Assay        | Status   | Error Status | Start Date      |
| SD142231           | A1       | Detail User | NO RESULT | Xpert CDI... | Loadi... | OK           | 04/09/19 12:... |

**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.

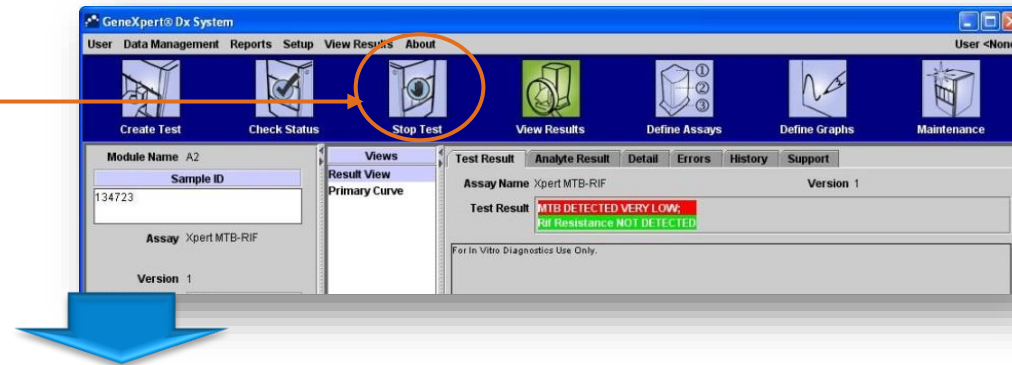


# How to Stop a Test

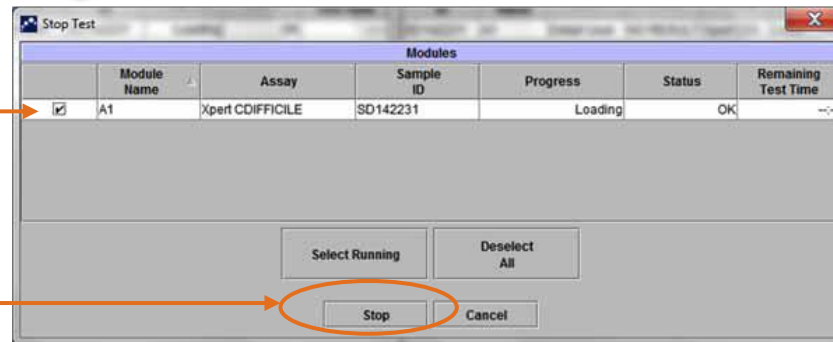
# How to Stop a Test

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

1 Click **Stop Test**



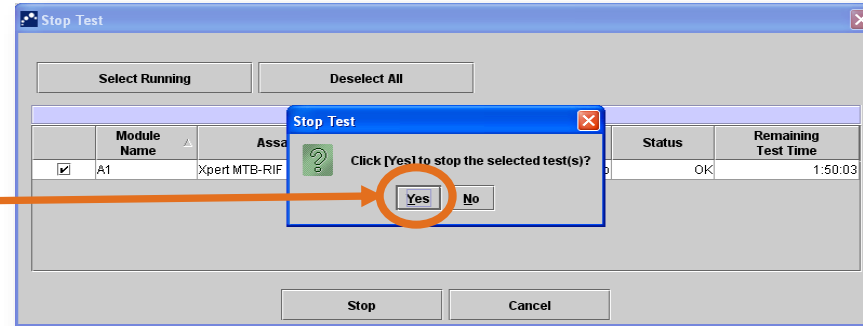
2 Select the module(s) that need to be stopped, by marking the tick box



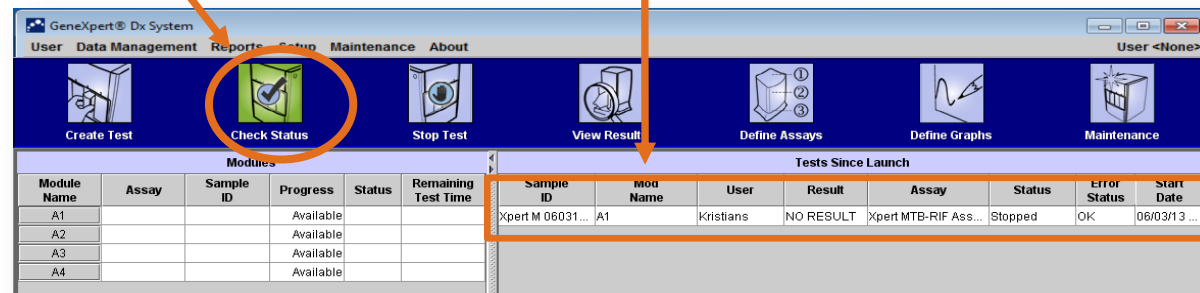
3 After selecting click **Stop**

# 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

# View Results

1

Click on **View Results**

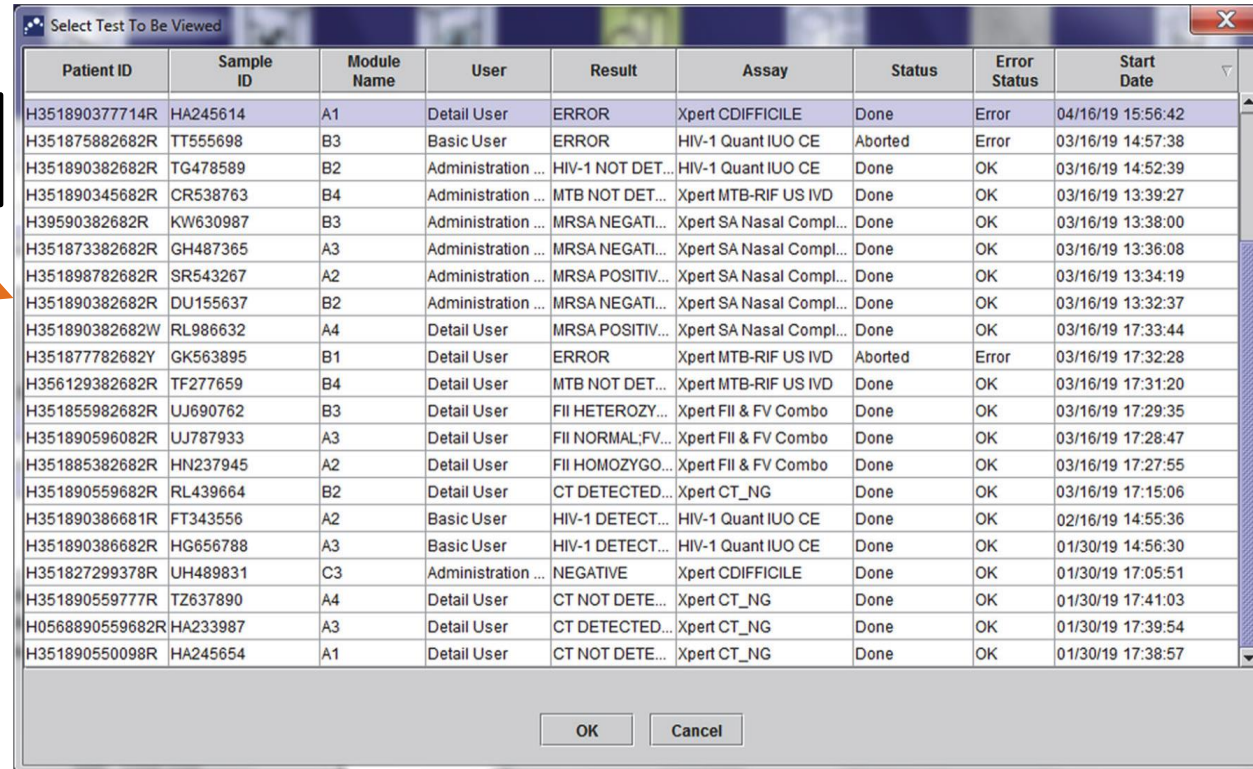
2

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

The screenshot displays the GeneXpert Dx System software interface. The 'View Results' icon 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, with Test Type Specimen and Sample Type Other. The Test Result section shows 'CT NOT DETECTED' and 'NG NOT DETECTED'. Below this, there is a 'Primary Curve' graph showing Fluorescence vs. Cycles. The graph has a y-axis from 0 to 400 and an x-axis from 0 to 40. Two curves are visible: a green curve (CT) and a yellow curve (NG). The legend on the right lists: CT1; Primary, NG2; Primary, NG4; Primary, SAC; Primary, and SPC; Primary. The 'View Test' button at the bottom is also circled in orange.

# 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 |

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

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

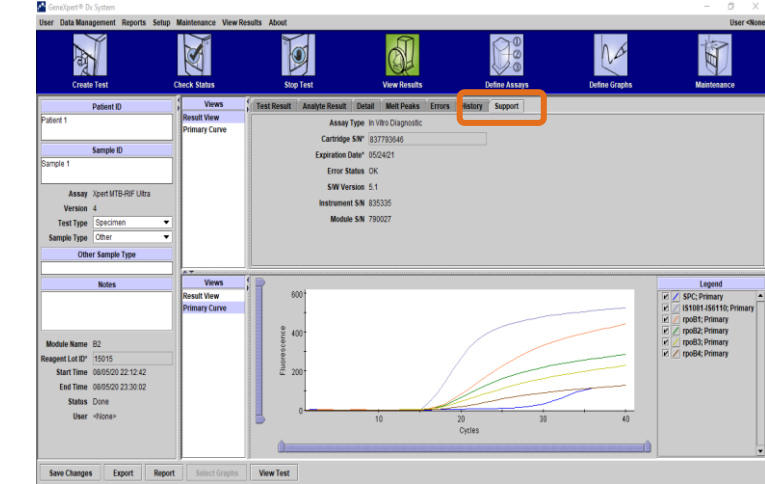
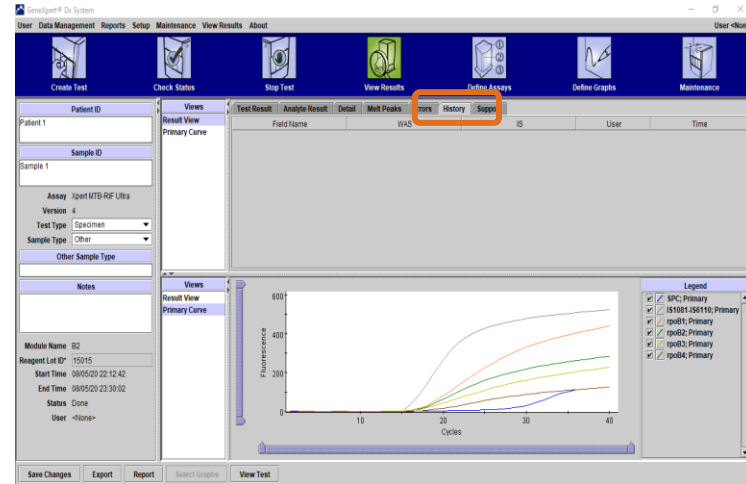
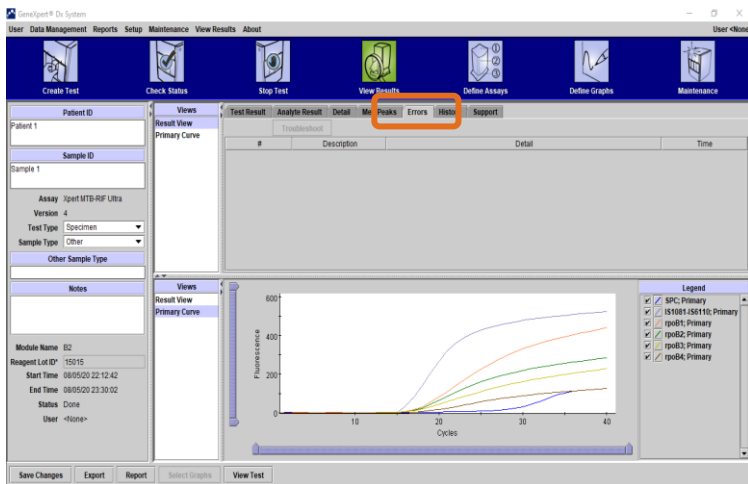
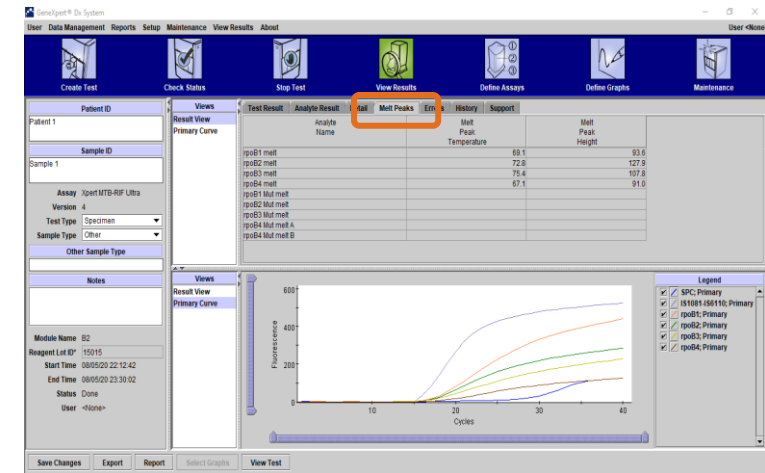
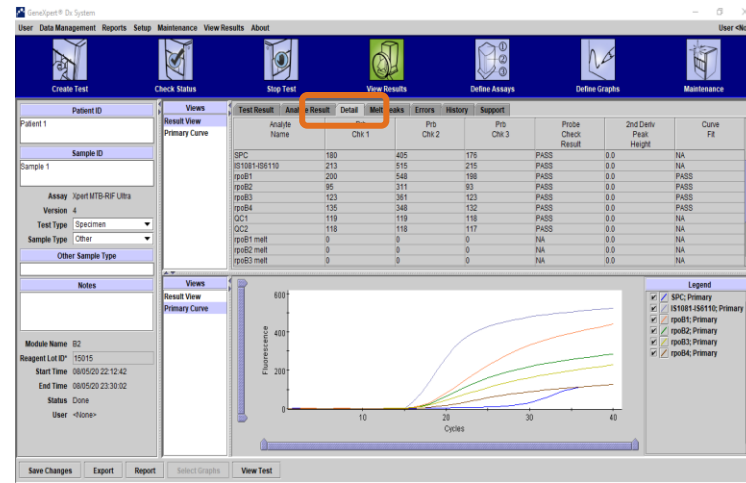
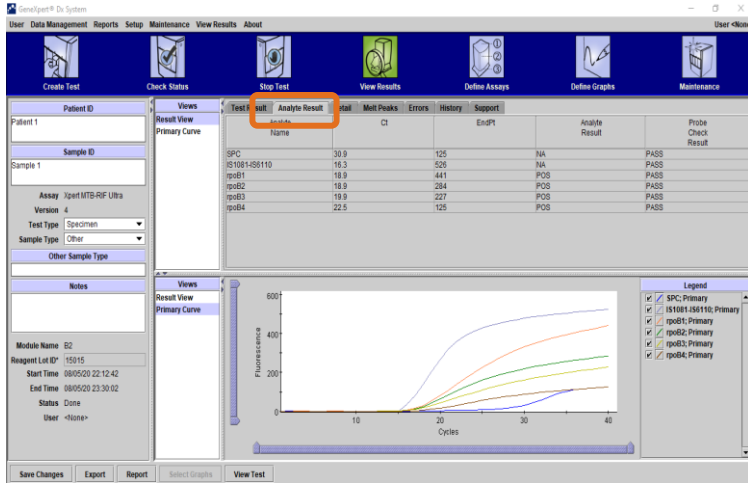
The screenshot displays the GeneXpert Dx System software interface. The top menu bar includes options like User, Data Management, Reports, Setup, Maintenance, View Results, and About. Below the menu is a toolbar with icons for Create Test, Check Status, Stop Test, View Results, Define Assays, Define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

- Information about the test:** A callout box points to the left sidebar containing fields for Patient ID (Patient 1), Sample ID (Sample 1), Assay (Xpert MTB-RIF Ultra, Version 4), Test Type (Specimen), Sample Type (Other), and a Notes section. Below these are fields for Module Name (B2), 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 callout box points to a central 'Views' panel with options for Result View and Primary Curve.
- Interpretation of the Result:** A callout box points to a red and green text box displaying 'MTB DETECTED MEDIUM;' and 'RIF Resistance NOT DETECTE'.
- Real-Time PCR curves:** A callout box points to a graph showing fluorescence over cycles (0 to 40). The graph displays multiple curves for different assays, with a legend on the right listing SPC, IS1081-IS6110, and rpoB1 through rpoB4, all marked as Primary.

At the bottom of the interface, there are buttons for Save Changes, Export, Report, Select Graphs, and View Test.

# View results

## Detail Users and Administrator View (tabs)



# How to Edit Test Information

# How to Edit 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

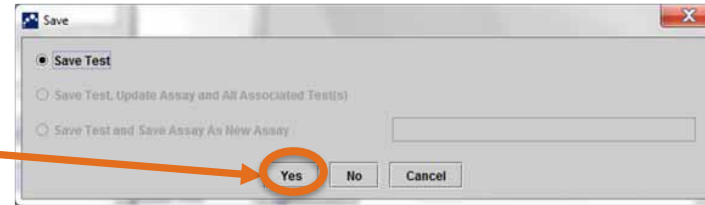
After editing click **Save Changes**

The screenshot displays the GeneXpert Dx System interface. The top navigation bar includes 'User', 'Data Management', 'Reports', 'Setup', 'Maintenance', 'View Results', and 'About'. Below this is a toolbar with icons for 'Create Test', 'Check Status', 'Stop Test', 'View Results', 'Define Assays', 'Define Graphs', and 'Maintenance'. The 'View Results' icon is highlighted with an orange box. An arrow points from the text box '1' to this icon. Below the toolbar, the interface is divided into several sections. On the left, there is a 'Patient ID' field with the value 'H351890559777R', a 'Sample ID' field with 'TZ637890', and an 'Assay' section with 'Xpert CT\_NG' and 'Version 3'. Below this is a 'Notes' field. At the bottom left, there is an 'Upload Status' section with fields for 'Module Name', 'Reagent Lot ID', 'Start Time', 'End Time', 'Status', and 'User'. An arrow points from the text box '2' to the 'Save Changes' button at the bottom of the interface. The main area on the right shows 'Test Result' information, including 'Assay Name: Xpert CT\_NG', 'Version: 3', and 'Test Result: CT NOT DETECTED; NG NOT DETECTED'. Below this is a graph showing 'Fluorescence' vs 'Cycles' with a legend on the right. The legend includes 'CT1; Primary', 'NG2; Primary', 'NG4; Primary', 'SAC; Primary', and 'SPC; Primary'.

# Editing the Test Information

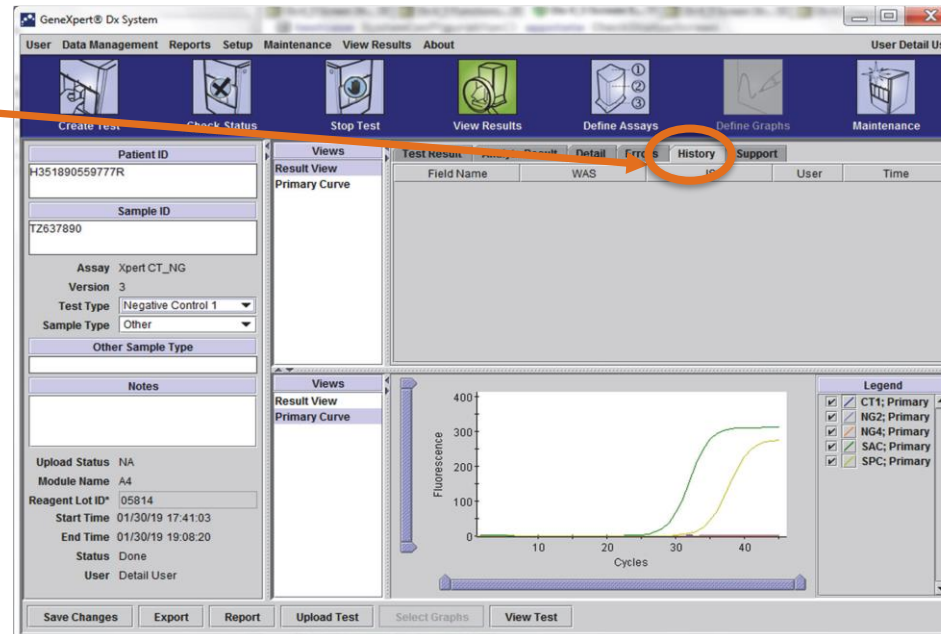
3

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 top menu bar includes 'User', 'Data Management', 'Reports', 'Setup', 'Maintenance', 'View Results', 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 window 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 has a 'Notes' section and a 'User Detail' section with fields for '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' as 'Specimen', 'IS' as 'Negative Control', 'User' as '<None>', and 'Time' as '01/05/19 12:49:54'.
- Graph:** A line graph showing 'Fluorescence' on the y-axis (0 to 400) and 'Cycles' on the x-axis (0 to 40). The curve shows a sigmoidal increase starting around cycle 25.
- Legend:** A list of assay types with checkboxes: CT1; Primary, NG2; Primary, NG4; Primary, SAC; Primary, and SPC; Primary.

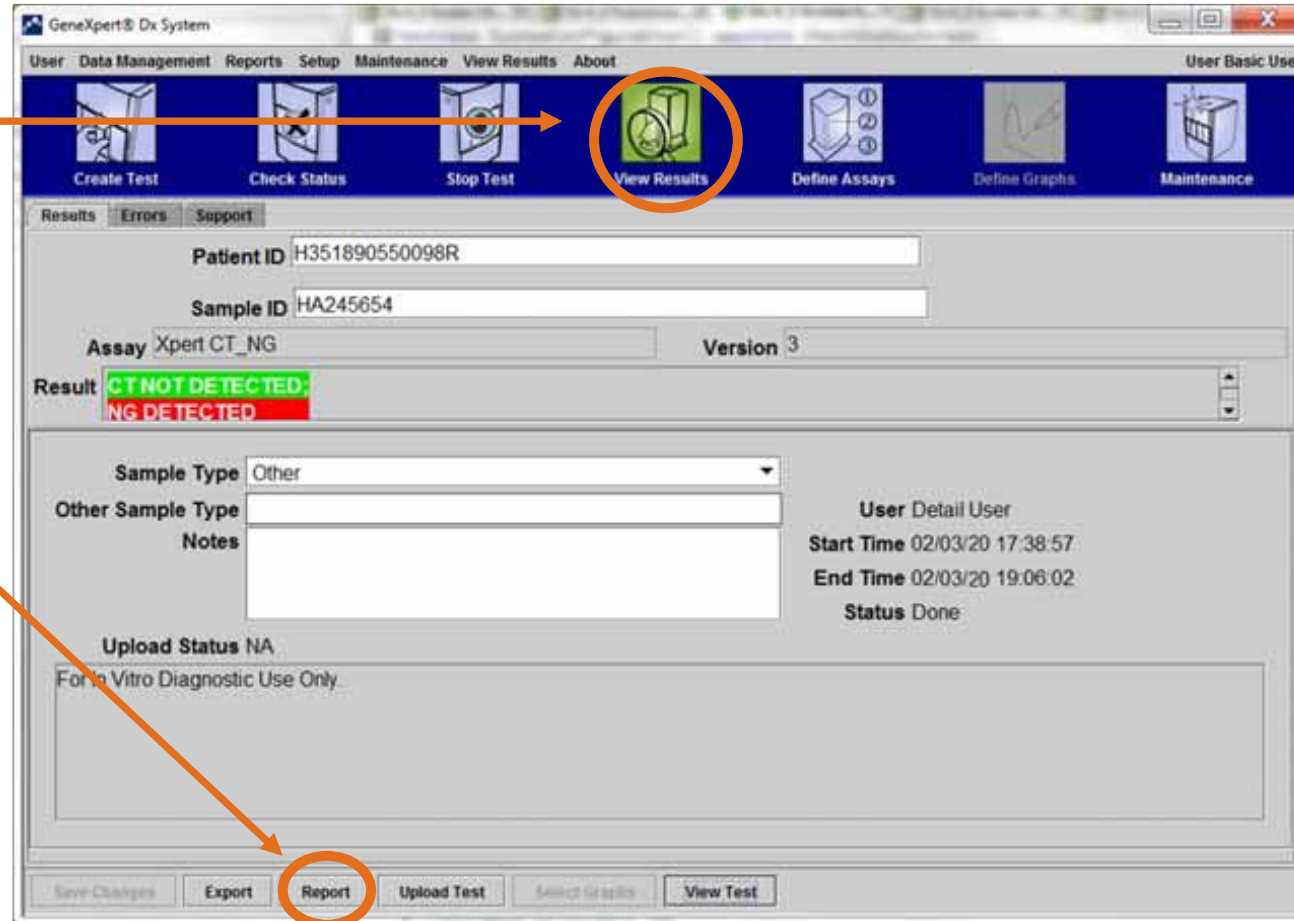
At the bottom of the interface are buttons for 'Save Changes', 'Export', 'Report', 'Upload Test', 'Select Graphs', and 'View Test'.

# Generate a Result Report in PDF

# 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 14:18:26 |
| 2H6        | 2H6       | F7          | 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 14:15:06 |
| 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 14:13:46 |
| 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 |
| 2N6        | 2N6       | 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 |
| 5N5        | 5N5       | K5          | support | Fil NORMAL      | Xpert Fil            | Done       | OK           | 04/13/19 14:05:15 |

**4**

Select Report to generate PDF

Generalist 8 Dx System

User: Data Management Reports Setup Maintenance View Results Report User: Basic User

Create Test Check Status Stop Test View Results Define Assays Define 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

Save Changes Export Report Print Graphs View Test

# How to generate a PDF

## Detail Users and Administrator View

1 Click on View Result

2 Click on Report

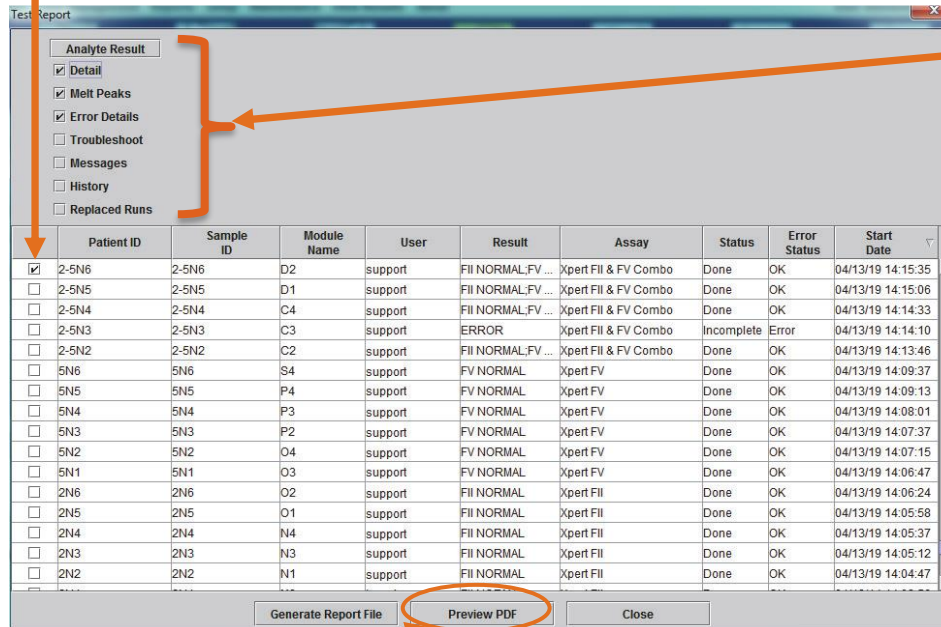
The screenshot displays the GeneXpert Dx System software interface. The top menu bar includes 'User', 'Data Management', 'Reports', 'Setup', 'Maintenance', 'View Results', and 'About'. The 'View Results' menu item is circled in orange, with an arrow pointing to it from the first instruction box. Below the menu bar, there are several icons for 'Create Test', 'Check Status', 'Stop Test', 'View Results', 'Define Assays', 'Define Graphs', and 'Maintenance'. The 'View Results' icon is also circled in orange. The main window is divided into several sections. On the left, there are fields for 'Patient ID' (H351890559777R), 'Sample ID' (T2637890), 'Assay' (Xpert CT\_NG), 'Version' (3), 'Test Type' (Specimen), and 'Sample Type' (Other). Below these are 'Notes' and 'Upload Status' (NA), 'Module Name' (A4), 'Reagent Lot ID' (05814), 'Start Time' (01/30/20 17:41:03), 'End Time' (01/30/20 19:08:20), 'Status' (Done), and 'User' (Detail User). The 'View Results' section shows 'Test Result' (Analyte Result) and 'Assay Name' (Xpert CT\_NG, Version: 3). The 'Test Result' field is highlighted in green and contains the text 'CT NOT DETECTED; NG NOT DETECTED'. Below this is a graph showing 'Fluorescence' (Y-axis, 0 to 400) versus 'Cycles' (X-axis, 0 to 40). The graph displays two curves: a green curve and a yellow curve. The green curve shows a higher fluorescence signal than the yellow curve. A legend on the right side of the graph lists 'CT1; Primary', 'NG2; Primary', 'NG4; Primary', 'SAC; Primary', and 'SPC; Primary', all of which are checked. At the bottom of the interface, there are buttons for 'Save Changes', 'Export', 'Report', 'Upload Test', 'Select Graphs', and 'View Test'. The 'Report' button is circled in orange, with an arrow pointing to it from the second instruction box.

# How to generate a PDF

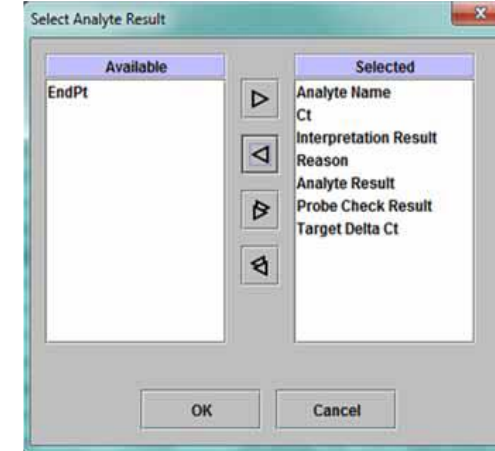
## Detail Users and Administrator View

3

Select the result you may want to visualize in PDF



In the upper left-hand corner of the dialog box



4

Click on **Preview PDF** for immediate visualisation

# Example Test Report

GeneXpert PC 11/14/20 09:01:20

## Test Report

Patient ID\*: H351885382682R  
 Patient ID 2:  
 Sample ID\*: HN237945  
 Test Type: Specimen  
 Sample Type:

| Assay                | Assay Version | Assay Type          |
|----------------------|---------------|---------------------|
| Xpert FII & FV Combo | 1             | In Vitro Diagnostic |

Test Result: **FII NORMAL;  
FV NORMAL**

| Analyte Name | Ct   | EndPt | Analyte Result | Probe Check Result |
|--------------|------|-------|----------------|--------------------|
| FII 20210G   | 24.4 | 461   | POS            | PASS               |
| FII 20210A   | 0.0  | 20    | NEG            | PASS               |
| FV 1691G     | 25.1 | 347   | POS            | PASS               |
| FV 1691A     | 0.0  | 17    | NEG            | PASS               |

| Analyte Name | Prb Chk 1 | Prb Chk 2 | Prb Chk 3 | Probe Check Result | 2nd Deriv Peak Height | Curve Fit |
|--------------|-----------|-----------|-----------|--------------------|-----------------------|-----------|
| FII 20210G   | 125       | 221       | 126       | PASS               | 0.0                   | NA        |
| FII 20210A   | 46        | 179       | 47        | PASS               | 0.0                   | NA        |
| FV 1691G     | 57        | 166       | 58        | PASS               | 0.0                   | NA        |
| FV 1691A     | 40        | 119       | 41        | PASS               | 0.0                   | NA        |

Melt Peaks  
 <Not applicable>

For In Vitro Diagnostic Use Only.

GeneXpert PC

11/14/20 08:54:43

## Test Report

Patient ID\*: H351885382682R  
 Patient ID 2:  
 Sample ID\*: HN237945  
 Test Type: Specimen  
 Sample Type:

| Assay                | Assay Version | Assay Type          |
|----------------------|---------------|---------------------|
| Xpert FII & FV Combo | 1             | In Vitro Diagnostic |

Test Result: **FII NORMAL;  
FV NORMAL**

User: Basic1  
 Status: Done  
 Expiration Date\*: 11/16/20  
 SW Version: 6.4  
 Cartridge S/N\*: 116820908  
 Reagent Lot ID\*: 04701  
 Notes:  
 Errors  
 <None>

Start Time: 11/13/20 14:15:35  
 End Time: 11/13/20 14:45:15  
 Instrument S/N: 801225  
 Module S/N: 607389  
 Module Name: D2

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

# 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 features 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 panels:

- Left Panel:** Contains fields for "Patient ID" (H351890559777R), "Sample ID" (TZ637890), "Assay" (Xpert CT\_NG), "Version" (3), "Test Type" (Specimen), and "Sample Type" (Other). It also includes a "Notes" section and a metadata table with fields like "Upload Status", "Module Name", "Reagent Lot ID", "Start Time", "End Time", "Status", and "User".
- Top-Right Panel:** Shows "Test Result" and "Analyte Result" tabs. The "Test Result" tab displays "CT NOT DETECTED" and "NG NOT DETECTED" in green text.
- Bottom-Right Panel:** Features a "Primary Curve" graph showing "Fluorescence" (0 to 400) versus "Cycles" (0 to 40). The graph displays two curves: a green curve (CT1) and a yellow curve (NG2). A legend on the right lists "CT1; Primary", "NG2; Primary", "NG4; Primary", "SAC; Primary", and "SPC; Primary", all with checked boxes.

At the bottom of the interface, there is a row of buttons: "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 'Host ID' field contains 'LX'. Under 'Communication Settings', 'Protocol' is set to 'HL7' and 'Run Host As' is set to 'Client'. The 'Server IP Address' field is empty and the 'Port #' field contains '1234'. Under 'Order/Result Management', there are buttons for 'Delete Cancelled Orders', 'Expire Results', and 'Reset Communication Buffer'. At the bottom, there is a table for 'Host Test Code' and 'Ok' and 'Cancel' buttons.

| 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"/>            |                                    |                |      |

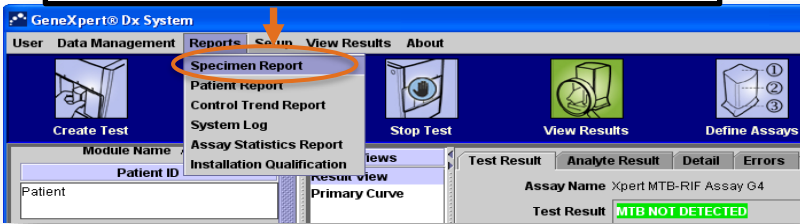


# Generate Specimen and Patient Reports in PDF



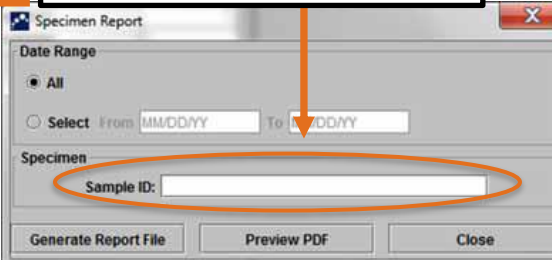
# How to generate specimen and patient reports in PDF

**1** **Specimen Report**  
Click Reports -> Specimen Report

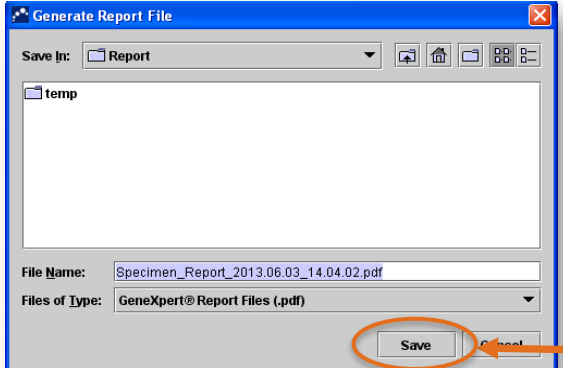


The screenshot shows the GeneXpert Dx System main menu. The 'Reports' dropdown menu is open, and 'Specimen Report' is highlighted with an orange circle. Other options in the menu include Patient Report, Control Trend Report, System Log, Assay Statistics Report, and Installation Qualification. The main window also shows various icons for 'Create Test', 'Stop Test', 'View Results', and 'Define Assays'.

**2** Fill in the Sample ID



The screenshot shows the 'Specimen Report' dialog box. It has a 'Date Range' section with 'All' selected and a 'Select' section with 'From' and 'To' date fields. The 'Specimen' section has a 'Sample ID' field highlighted with an orange circle. At the bottom, there are buttons for 'Generate Report File', 'Preview PDF', and 'Close'.



The screenshot shows the 'Generate Report File' dialog box. It has a 'Save In' dropdown set to 'Report' and a file list containing 'temp'. The 'File Name' field contains 'Specimen\_Report\_2013.06.03\_14.04.02.pdf' and the 'Files of Type' dropdown is set to 'GeneXpert® Report Files (.pdf)'. The 'Save' button is highlighted with an orange circle.

**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 -

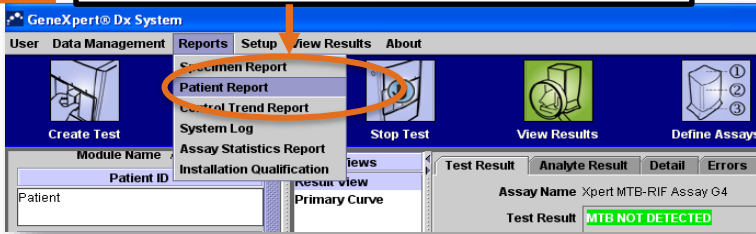
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|                |   |
|----------------|---|
| Patient ID:    | H351890382682R                              |
| Sample ID:     | DU155637                                    |
| Assay:         | Xpert SA Nasal Complete G3                  |
| Assay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

---

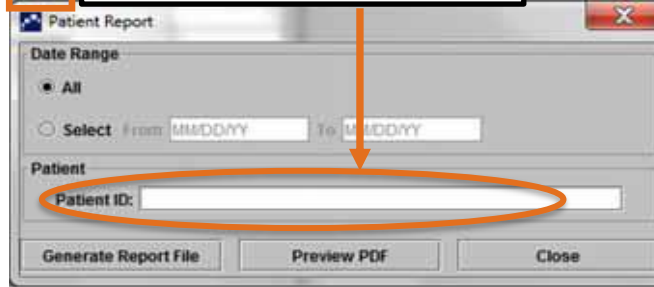
# How to generate specimen and patient reports in PDF

**1** **Patient Report**  
Click Reports -> Patient Report



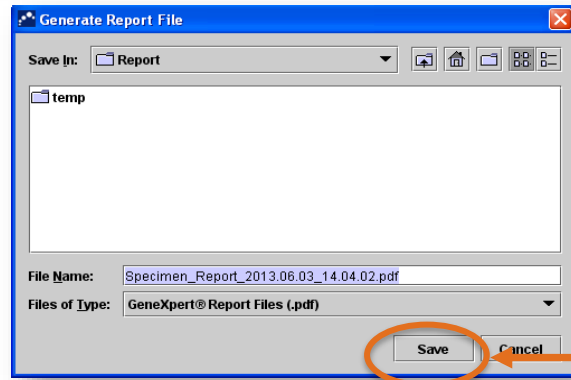
The screenshot shows the GeneXpert software interface. The 'Reports' menu is open, and 'Patient Report' is highlighted. Other menu items include 'Specimen Report', 'Control Trend Report', 'System Log', 'Assay Statistics Report', and 'Installation Qualification'. The main window displays 'Patient ID' and 'Test Result: MTB NOT DETECTED'.

**2** Fill in the Patient ID



The screenshot shows the 'Patient Report' dialog box. The 'Date Range' is set to 'All'. The 'Patient ID' field is highlighted with an orange circle. The 'Generate Report File' button is visible at the bottom.

**3a**



The screenshot shows the 'Generate Report File' dialog box. The 'Save In' location is 'Report'. The 'File Name' is 'Specimen\_Report\_2013.06.03\_14.04.02.pdf'. The 'Files of Type' is 'GeneXpert® Report Files (.pdf)'. The 'Save' button is highlighted with an orange circle.

**3** Preview PDF will open the PDF file

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

# 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:

---



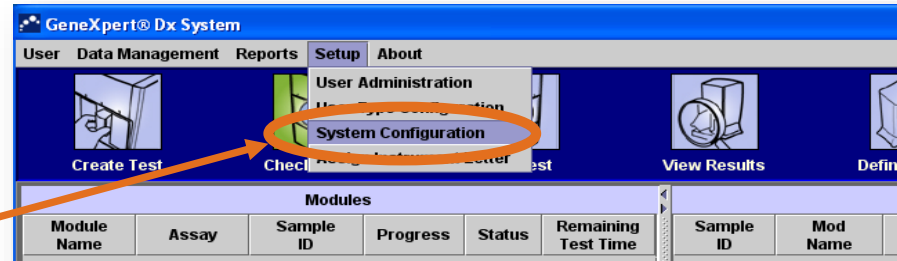
# How to Automatically Print a Test Report



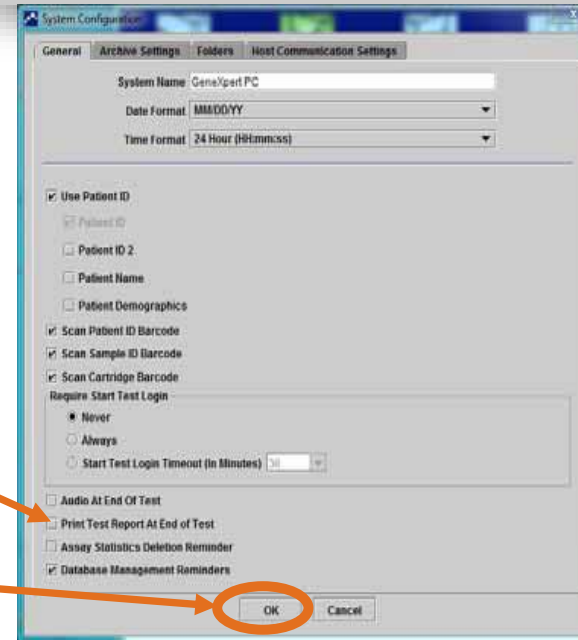
# How to automatically print a test report

- 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**

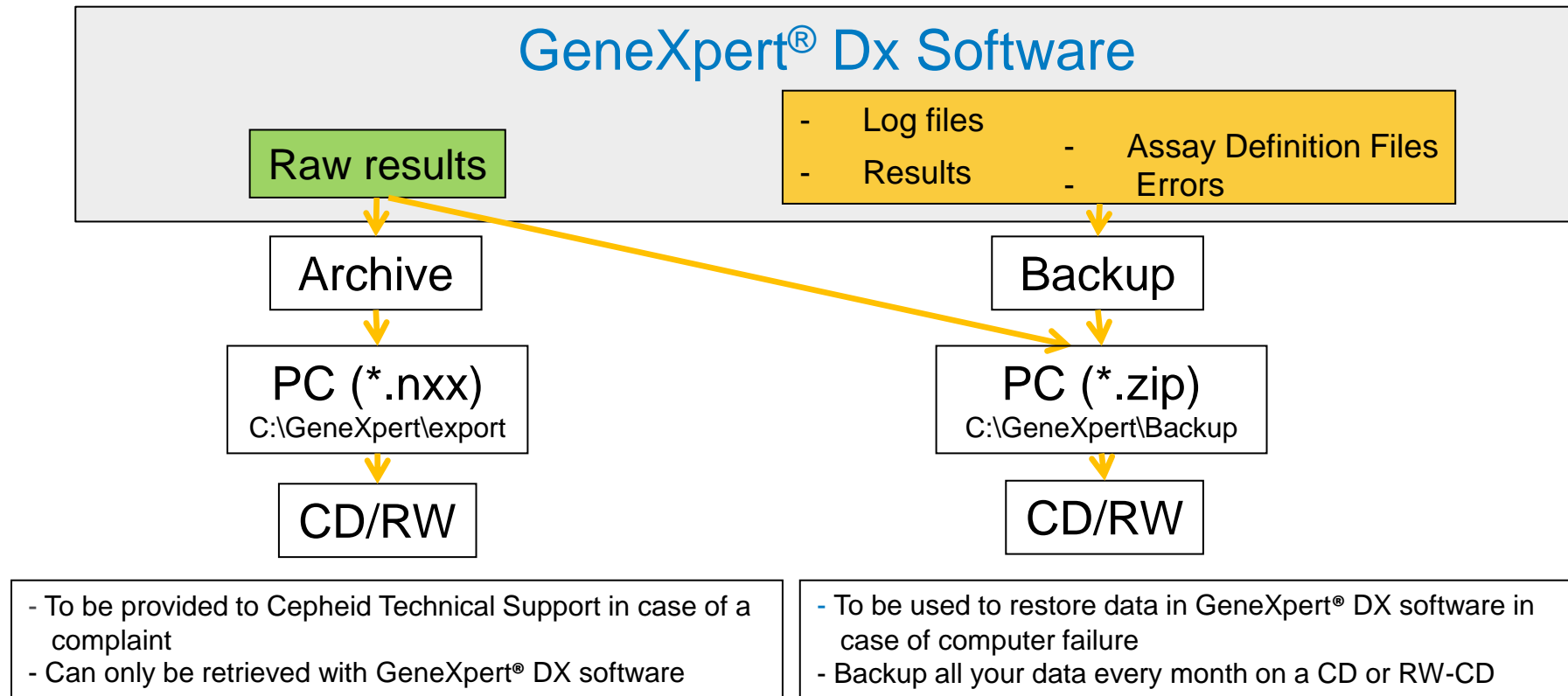


**3** Click **OK**

# Data Management Tasks

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# Difference between Archive/Backup

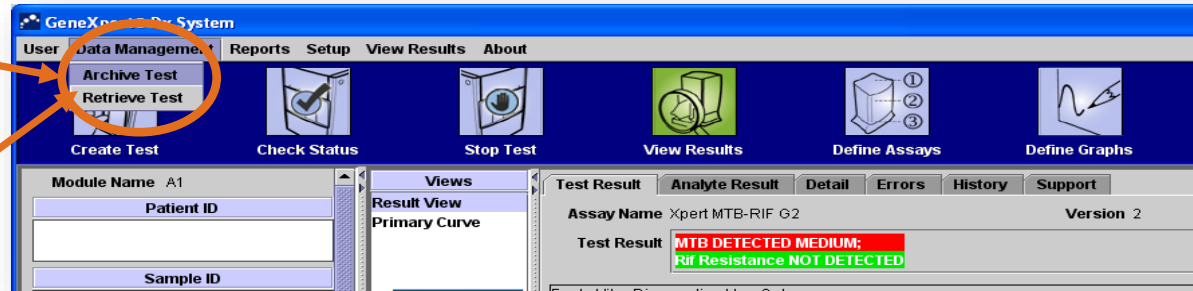




# How to Archive Tests

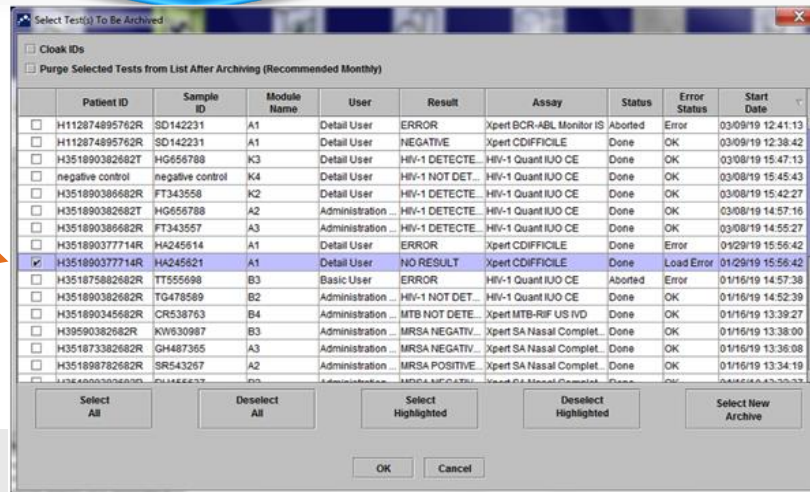
# How to Archive Tests

- 1 Click Data Management
- 2 Click Archive test



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

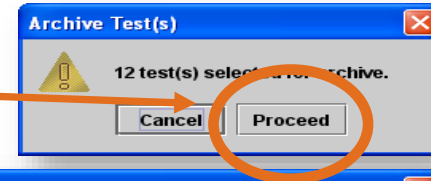
- 4 You can choose to Purge selected items after archiving



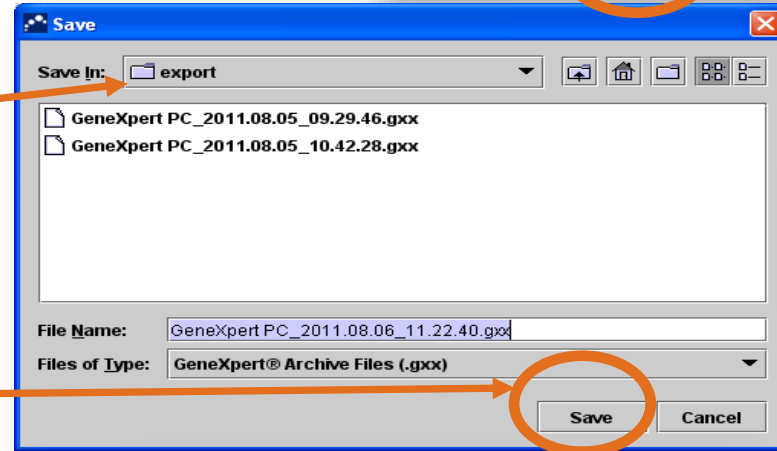
Purged tests will no longer appear in the GeneXpert® Dx Software

# How to Archive Tests

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



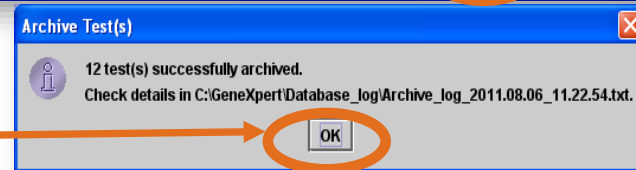
6 The files will be saved in the folder **Export**



Save the archived data to an external device.

7 Click on **SAVE**

8 Click **OK**

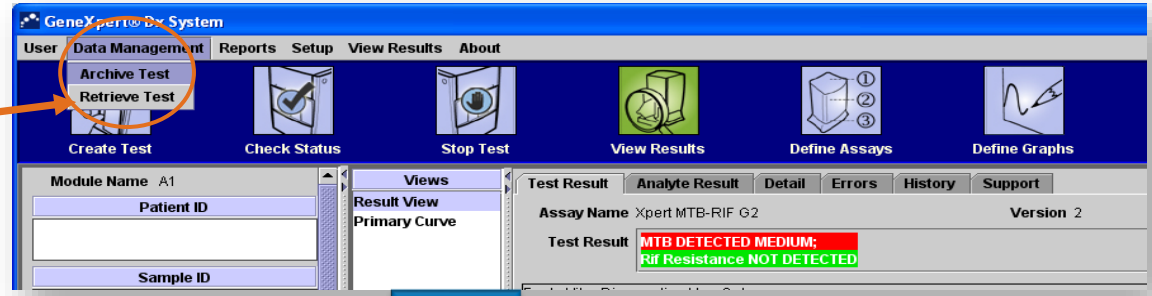


The archived file in the folder C:\GeneXpert\export

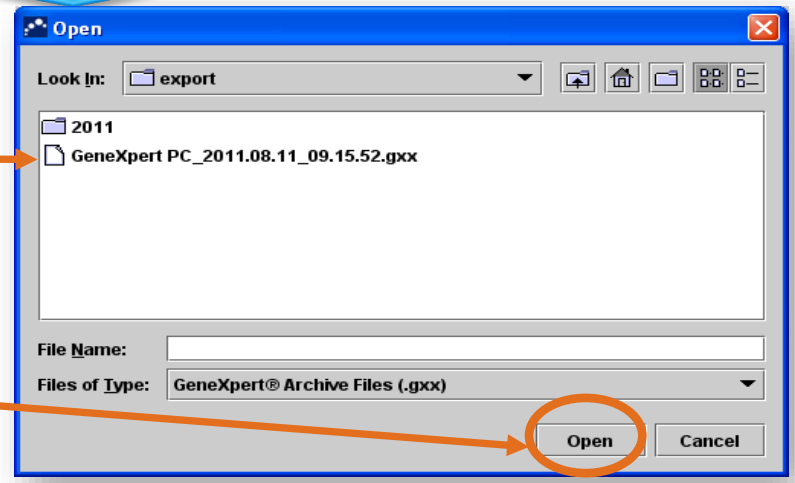
# How to Retrieve Tests

# How to Retrieve Tests

1 Click Data Management and Click Retrieve Test



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



3 Click on Open

# How to Retrieve Tests

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"/>            | H351890377782R   | 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   | TG478569         | 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   | GH487365         | A3   | Administration U | MRSA NEGATIVE      | Xpert SA Nasal Complete   | Done         | OK         | 02/16/19 13:36:08 |
| <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   | LU990782         | B3   | Detail User      | FI HETEROZYGOUS    | Xpert FI & FV Combo       | Done         | OK         | 02/16/19 17:29:35 |
| <input checked="" type="checkbox"/> | H351890596082R   | LU787933         | A3   | Detail User      | FI NORMAL          | FV NO Xpert FI & FV Combo | Done         | OK         | 02/16/19 17:28:47 |
| <input checked="" type="checkbox"/> | H351885382682R   | HR237945         | 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        | MG Xpert CT, MG           | Done         | OK         | 03/16/19 17:15:06 |

5 Click OK

6 Click Proceed

**Retrieve Test(s)**

A total of 1 test(s) have been selected.  
This will retrieve the selected test(s) into the main database.  
Would you like to continue?

Cancel Proceed

7 Click OK

**Retrieve Test(s)**

1 test(s) successfully retrieved.  
Retrieval details are logged in C:\GeneXpert\Database\_log\Retrieve\_log\_2011.08.11\_11.26.01.txt

OK

# How to Backup Database

# Database Management Tasks

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

The image shows a screenshot of the GeneXpert software interface with a 'Database Management' dialog box overlaid. The dialog box contains the question 'Do you want to perform Database Management tasks?' with 'Yes' and 'No' buttons. An orange arrow points from a box labeled '1 Click Yes' to the 'Yes' button. Below this, another 'Database Management' dialog box is shown with the text 'Select task, click [Proceed] to continue.' and three radio button options: 'Database Backup', 'Database Restore', and 'Compact Database'. An orange arrow points from a box labeled '2 Click Database Backup' to the 'Database Backup' radio button. At the bottom of this dialog box are 'Cancel' and 'Proceed' buttons. An orange arrow points from a box labeled '3 Click Proceed' to the 'Proceed' button.

1 Click Yes

2 Click Database Backup

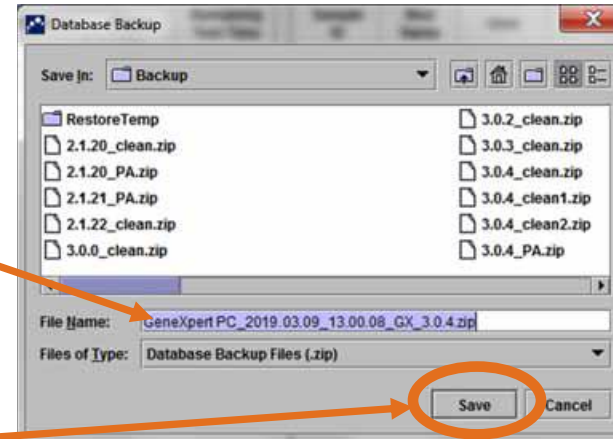
3 Click Proceed



# How to Create a Backup

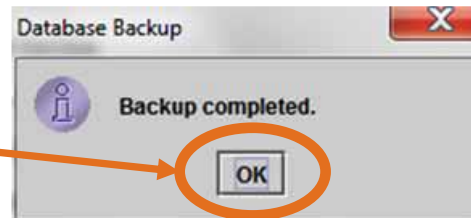
The software will create a zip file with all the results

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



**4** Click "Save"

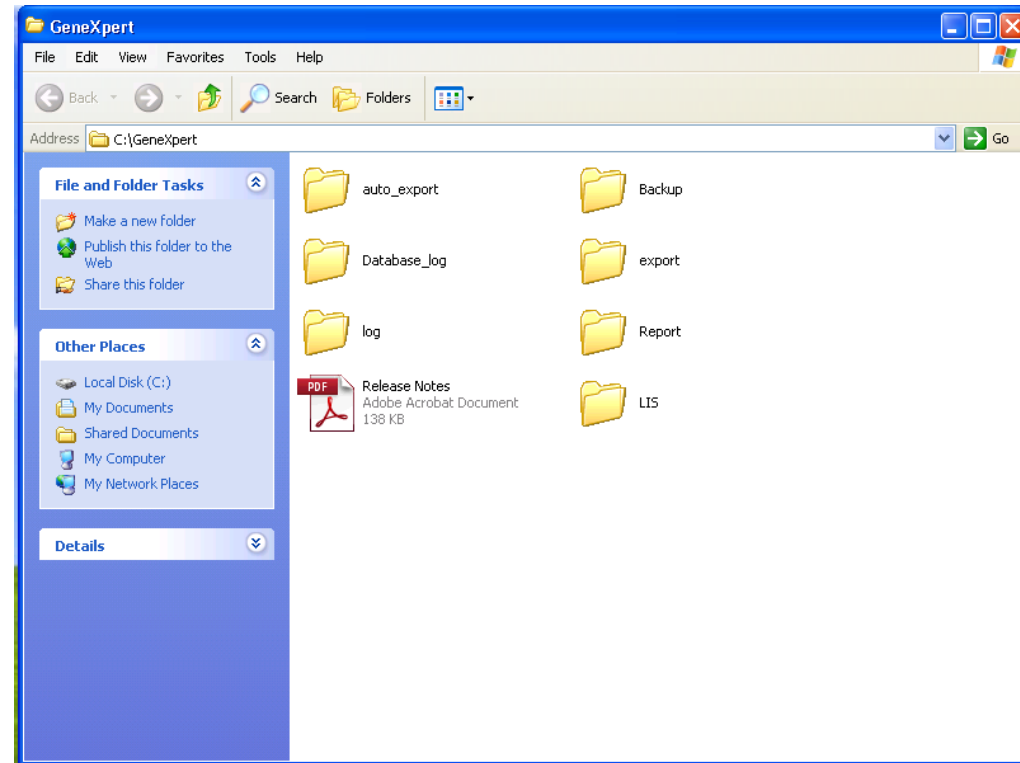
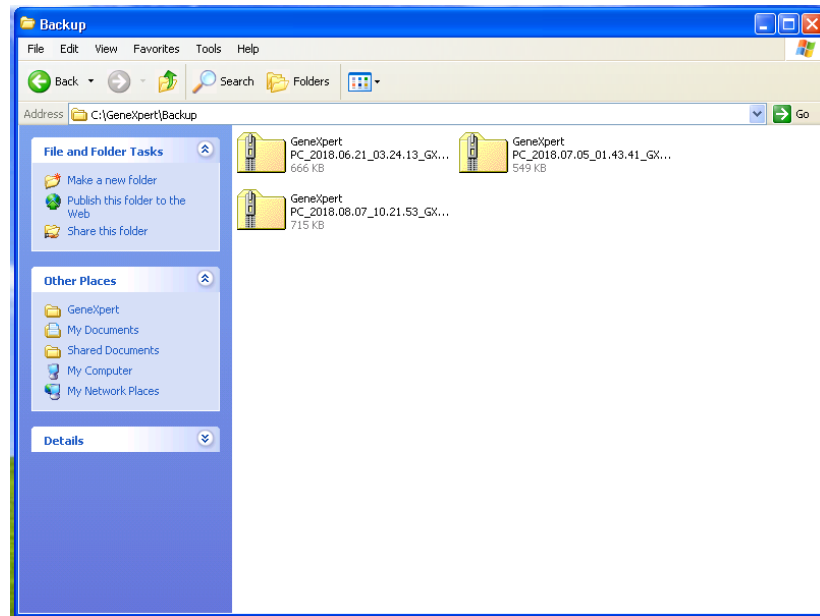
**5** Click OK



The zip file can only be restored through/ into the GeneXpert® Dx 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 Database from a Backup

# How to Restore Database

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

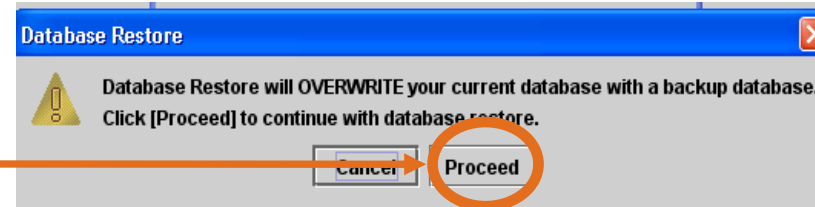
**3** Click Proceed

**4** dialog box appears asking if you want to back up the current database (recommended) before restoring. Click Proceed

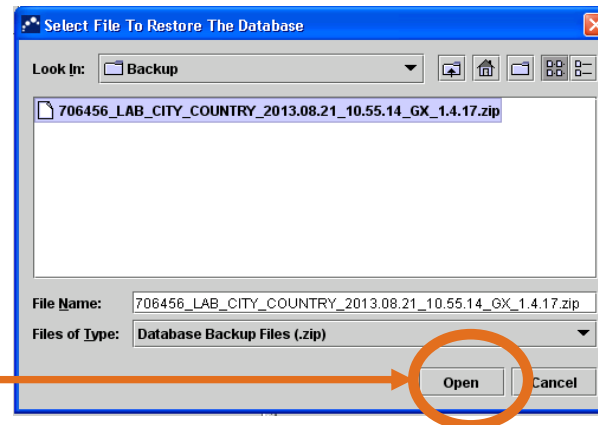
# How to Restore Database

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

Click **Proceed** to continue



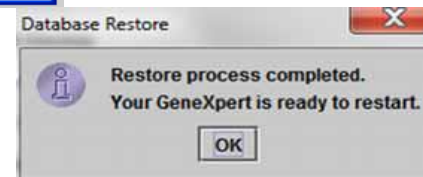
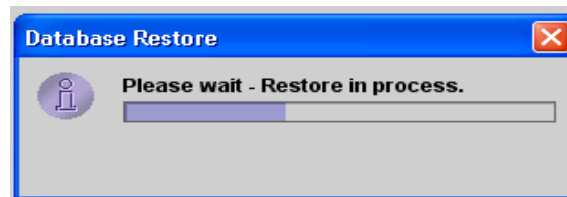
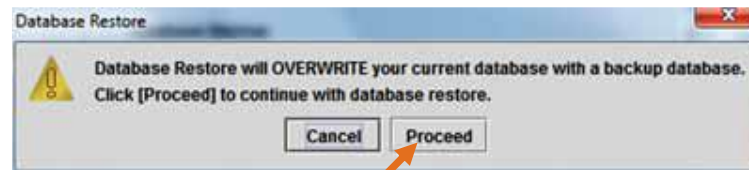
Select the database to be restored and Click **Open** to continue



# How to Restore Database

A dialog box appears.

Click **Proceed** to create the backup  
Click **Cancel** to continue Backup Restore



# Import the Assay Definition File (ADF)

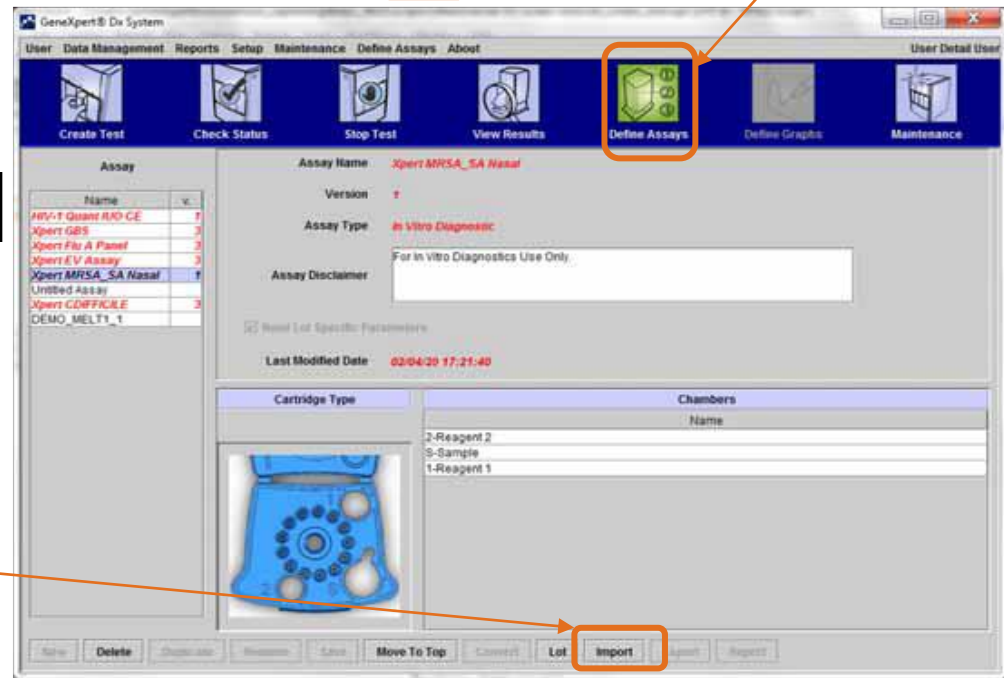
# Import the Assay Definition File (ADF)

- 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**

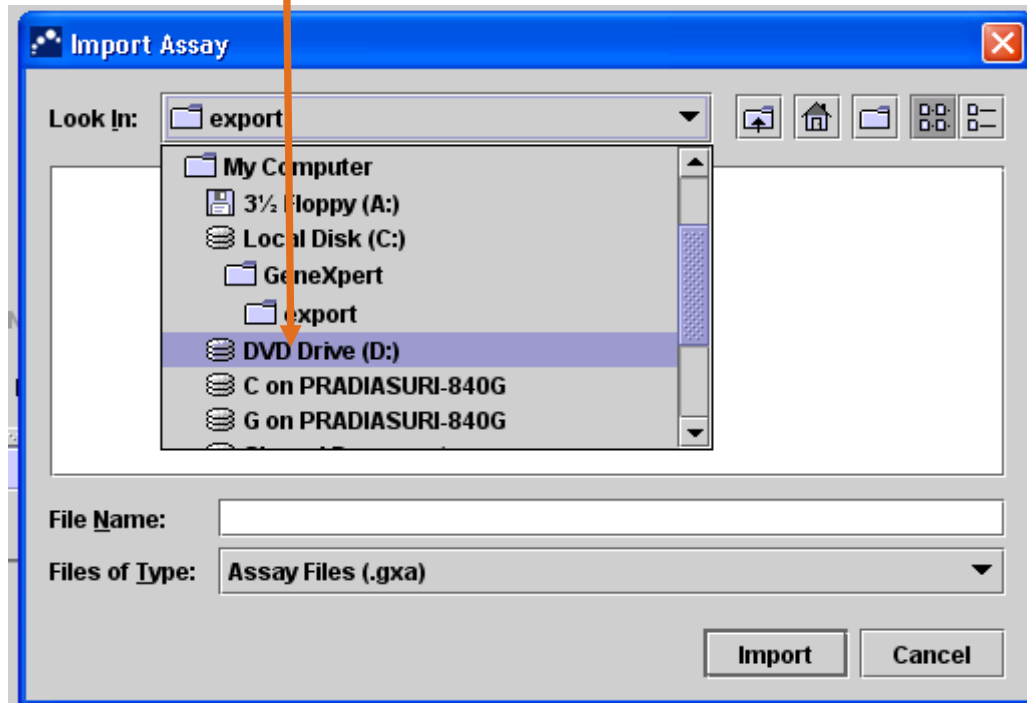




# Import the Assay Definition File (ADF)

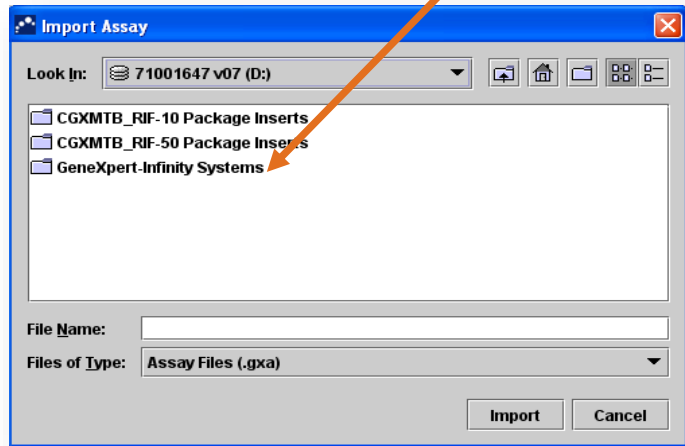
4

locate the file on the computer

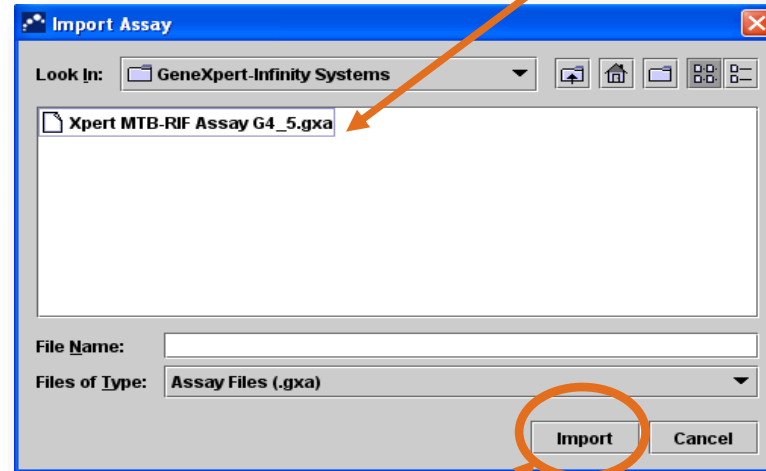


# Import the Assay Definition File (ADF)

**5** Double click on the GeneXpert® Systems folder.



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

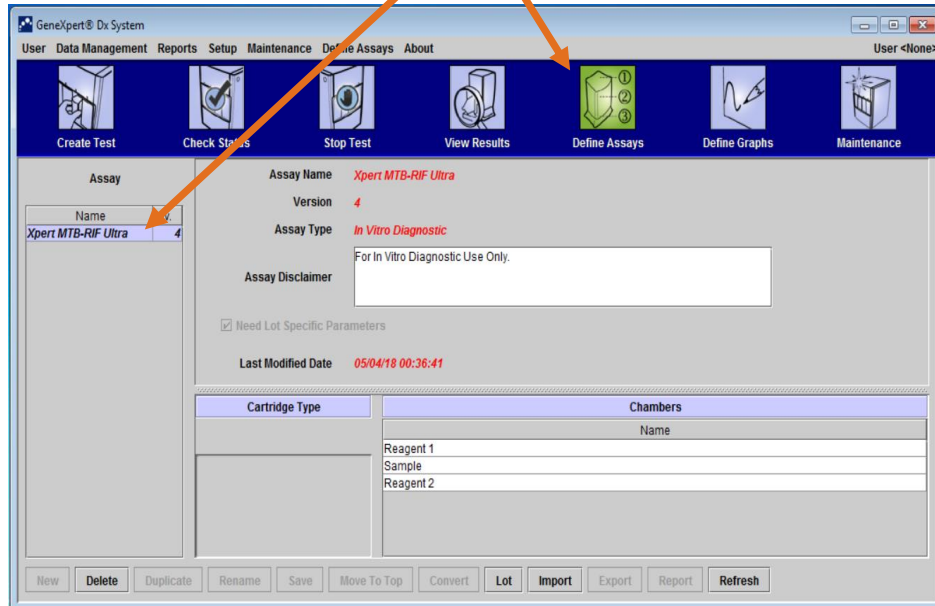


**7** Click Import

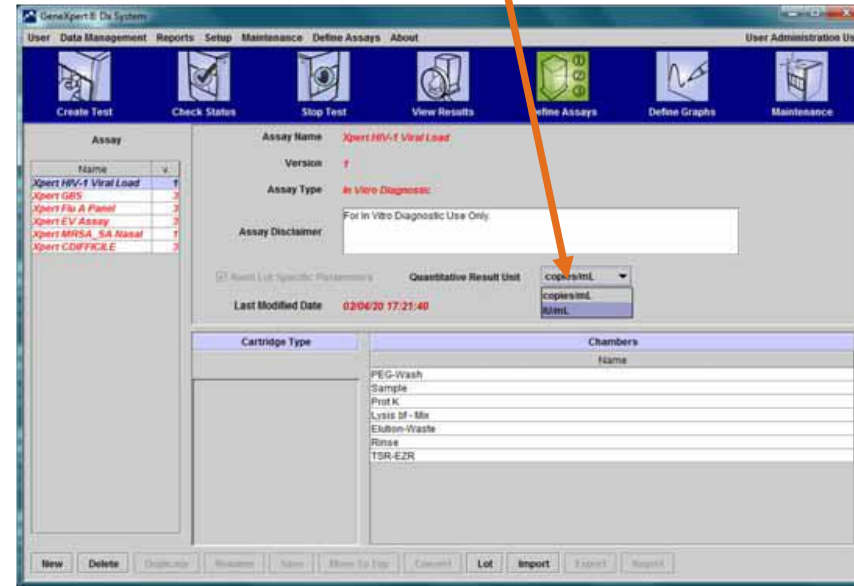
**!!! ATTENTION!!!**  
The name of the file may vary from version to version. In any case, load the file with the **.gxa/nxa** extension.

# Import the Assay Definition File (ADF)

The Assay Definition Files appears.



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



# Deleting Assay Definition File (ADF)

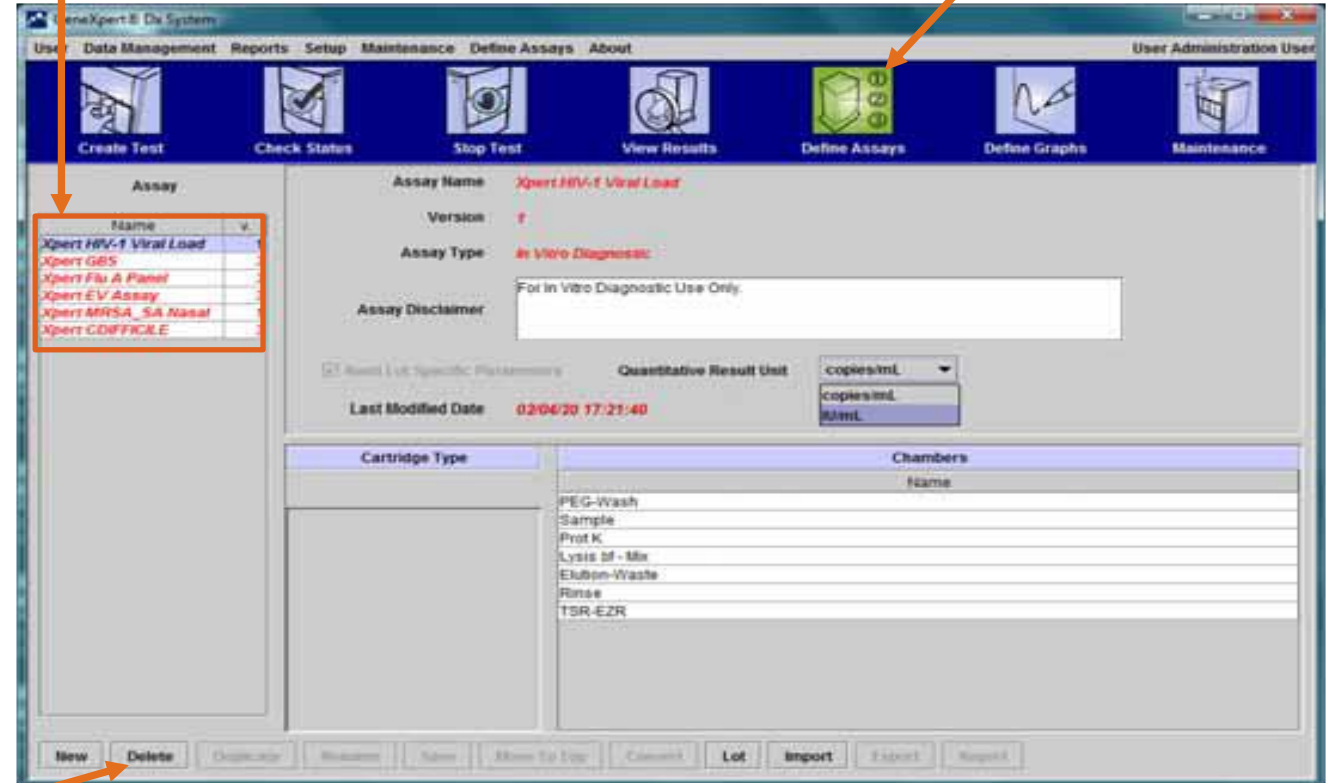
- To delete an assay definition file, in the Define Assays window, select the assay name in the Assay list (on the left side of the window), and then click **Delete**.
- A confirmation message appears. Click **Yes** to delete the assay definition. The assay definition file will be deleted and is removed from the list of assays.
- 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.

2

select the assay name

1

Click **Define Assays**



3

Click **Delete**

# Import Lot Specific Parameter ( Optional )

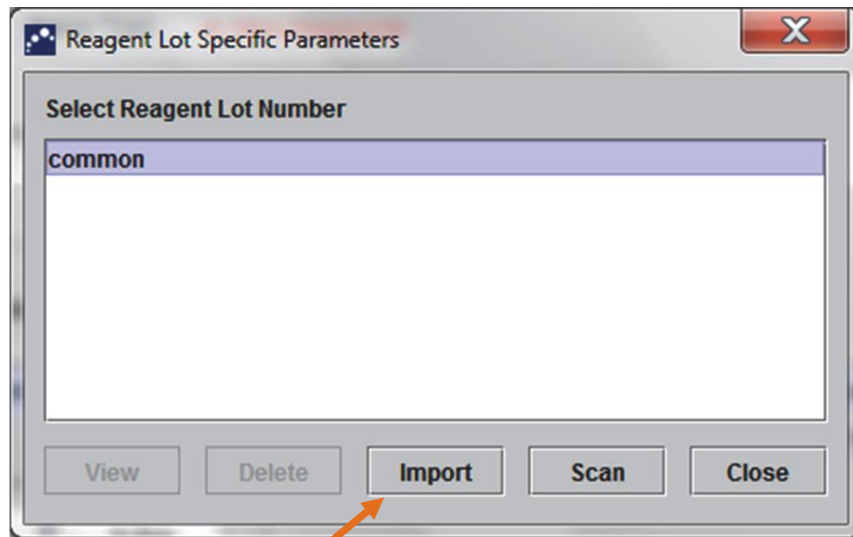
# Importing Lot Specific Parameters Manually

**1** Click to Define Assays

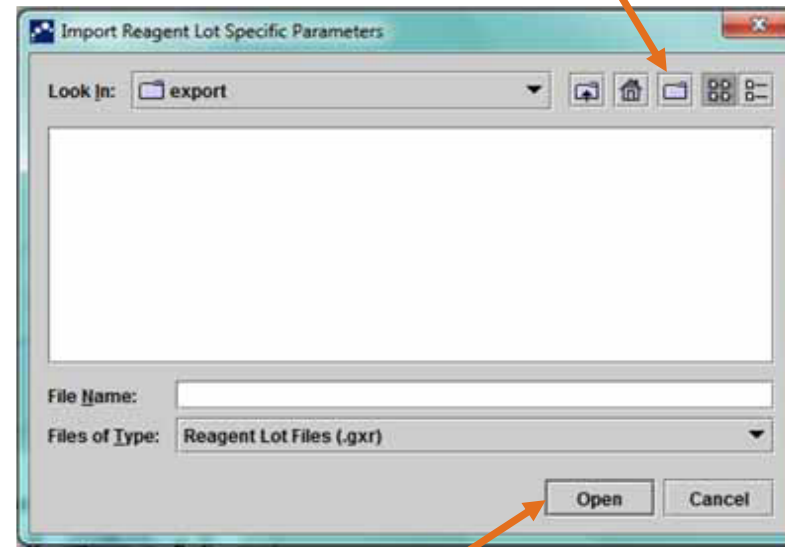
**2** select the assay name in the Assay list

**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



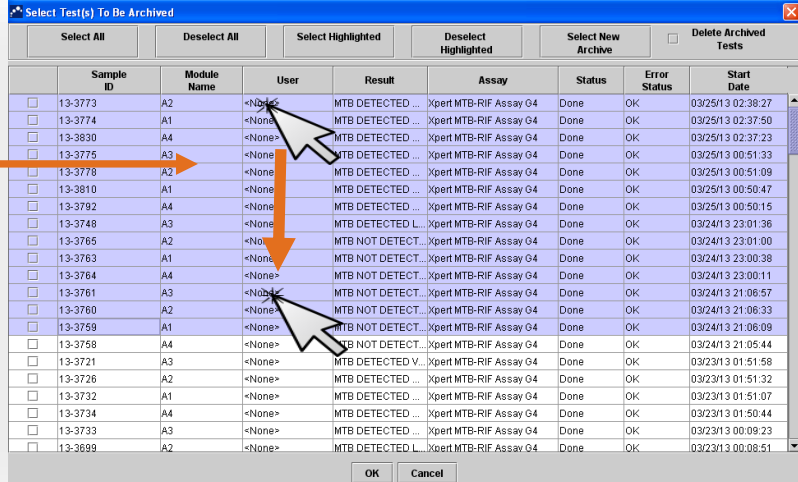
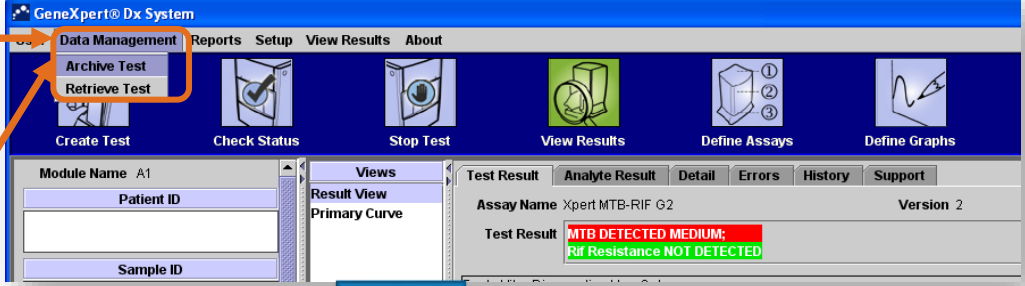
**5** Look In: file viewing area, locate and select the **.gxr/.nrx** file obtained from Technical Support previously, and then click **Open**

# Copy/Paste Data to OpenOffice Calc



# How to Copy/Paste Data to Open Office Calc

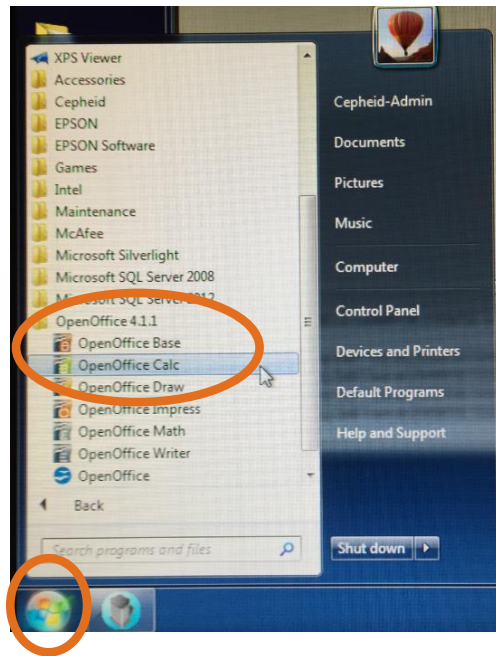
- 1** Click **Data Management**
- 2** Click **Archive test**
- 3** Click/Highlight on the first result you wish to select, Press & hold the **SHIFT** key on your keyboard Click/Highlight on the last line you wish to select. You may also select only certain rows by using **CTRL+Click** key instead of **SHIFT**.
- 4** While the lines marked press **ctrl + C** at the same time on your keyboard



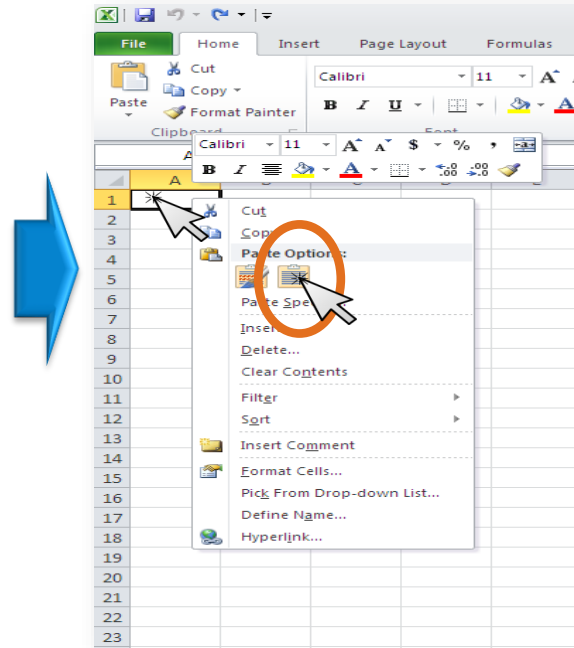
| Sample ID                | Module Name | User | Result | Assay             | Status                 | Error Status | Start Date |                   |
|--------------------------|-------------|------|--------|-------------------|------------------------|--------------|------------|-------------------|
| <input type="checkbox"/> | 13-3773     | A2   | <None> | MTB DETECTED ...  | Xpert MTB-RIF Assay G4 | Done         | OK         | 03/25/13 02:38:27 |
| <input type="checkbox"/> | 13-3774     | A1   | <None> | MTB DETECTED ...  | Xpert MTB-RIF Assay G4 | Done         | OK         | 03/25/13 02:37:50 |
| <input type="checkbox"/> | 13-3830     | A4   | <None> | MTB DETECTED ...  | Xpert MTB-RIF Assay G4 | Done         | OK         | 03/25/13 02:37:23 |
| <input type="checkbox"/> | 13-3775     | A3   | <None> | MTB DETECTED ...  | Xpert MTB-RIF Assay G4 | Done         | OK         | 03/25/13 00:51:33 |
| <input type="checkbox"/> | 13-3778     | A2   | <None> | MTB DETECTED ...  | Xpert MTB-RIF Assay G4 | Done         | OK         | 03/25/13 00:51:09 |
| <input type="checkbox"/> | 13-3810     | A1   | <None> | MTB DETECTED ...  | Xpert MTB-RIF Assay G4 | Done         | OK         | 03/25/13 00:50:47 |
| <input type="checkbox"/> | 13-3792     | A4   | <None> | MTB DETECTED ...  | Xpert MTB-RIF Assay G4 | Done         | OK         | 03/25/13 00:50:15 |
| <input type="checkbox"/> | 13-3748     | A3   | <None> | MTB DETECTED L... | Xpert MTB-RIF Assay G4 | Done         | OK         | 03/24/13 23:01:36 |
| <input type="checkbox"/> | 13-3765     | A2   | <None> | MTB NOT DETECT... | Xpert MTB-RIF Assay G4 | Done         | OK         | 03/24/13 23:01:00 |
| <input type="checkbox"/> | 13-3763     | A1   | <None> | MTB NOT DETECT... | Xpert MTB-RIF Assay G4 | Done         | OK         | 03/24/13 23:00:38 |
| <input type="checkbox"/> | 13-3764     | A4   | <None> | MTB NOT DETECT... | Xpert MTB-RIF Assay G4 | Done         | OK         | 03/24/13 23:00:11 |
| <input type="checkbox"/> | 13-3761     | A3   | <None> | MTB NOT DETECT... | Xpert MTB-RIF Assay G4 | Done         | OK         | 03/24/13 21:06:57 |
| <input type="checkbox"/> | 13-3760     | A2   | <None> | MTB NOT DETECT... | Xpert MTB-RIF Assay G4 | Done         | OK         | 03/24/13 21:06:33 |
| <input type="checkbox"/> | 13-3759     | A1   | <None> | MTB NOT DETECT... | Xpert MTB-RIF Assay G4 | Done         | OK         | 03/24/13 21:06:09 |
| <input type="checkbox"/> | 13-3758     | A4   | <None> | MTB NOT DETECT... | Xpert MTB-RIF Assay G4 | Done         | OK         | 03/24/13 21:05:44 |
| <input type="checkbox"/> | 13-3721     | A3   | <None> | MTB DETECTED V... | Xpert MTB-RIF Assay G4 | Done         | OK         | 03/23/13 01:51:58 |
| <input type="checkbox"/> | 13-3726     | A2   | <None> | MTB DETECTED ...  | Xpert MTB-RIF Assay G4 | Done         | OK         | 03/23/13 01:51:32 |
| <input type="checkbox"/> | 13-3732     | A1   | <None> | MTB DETECTED ...  | Xpert MTB-RIF Assay G4 | Done         | OK         | 03/23/13 01:51:07 |
| <input type="checkbox"/> | 13-3734     | A4   | <None> | MTB DETECTED ...  | Xpert MTB-RIF Assay G4 | Done         | OK         | 03/23/13 01:50:44 |
| <input type="checkbox"/> | 13-3733     | A3   | <None> | MTB DETECTED ...  | Xpert MTB-RIF Assay G4 | Done         | OK         | 03/23/13 00:09:23 |
| <input type="checkbox"/> | 13-3699     | A2   | <None> | MTB DETECTED L... | Xpert MTB-RIF Assay G4 | Done         | OK         | 03/23/13 00:08:51 |

# How to Copy/Paste Data to OpenOffice Calc

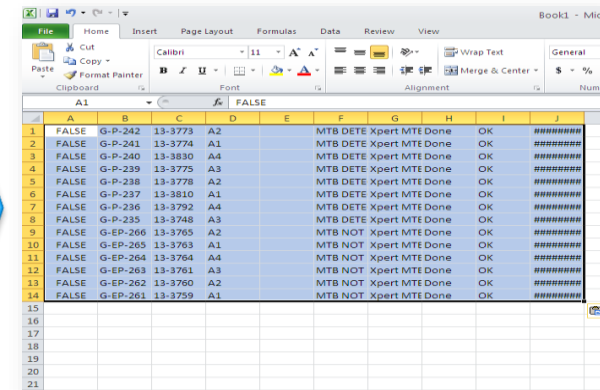
**1** OpenOffice Calc by clicking Start -> All Programs -> OpenOffice Calc



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

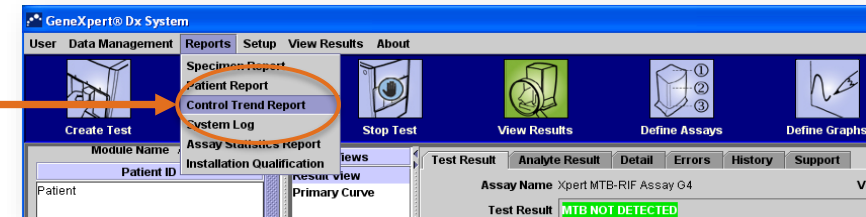


**3** The chosen results will be pasted in excel sheet

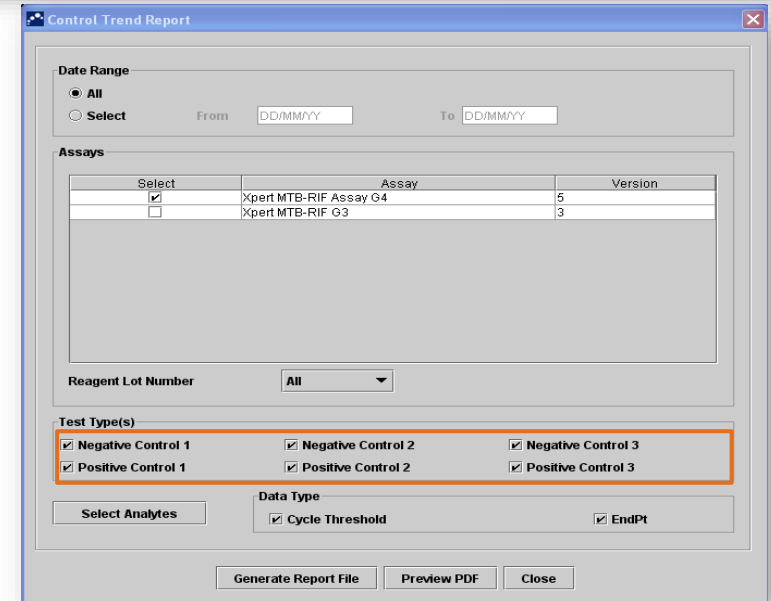


# Control Trend Report

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 6.4

GeneXpert® Dx System



**Operator Manual**  
Software Version 6.4

## 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>



302-4070, Rev. B December 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

[www.cepheid.com](http://www.cepheid.com)