GeneXpert® Dx 6.4 Software
Technical Training

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
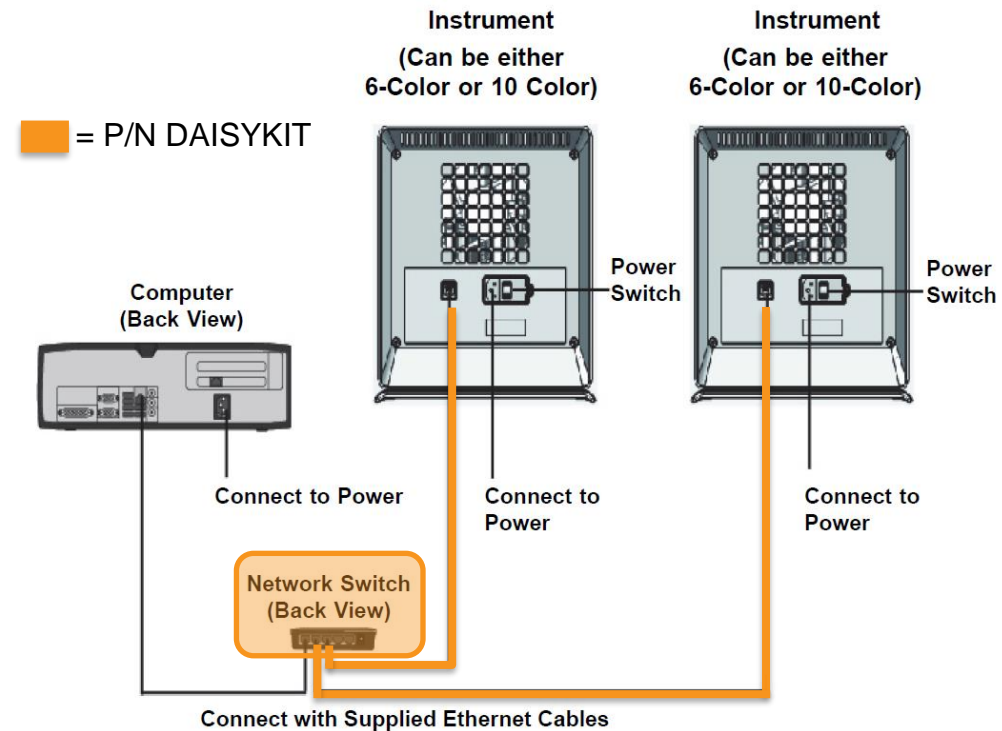**No Identification**
Stripe on door

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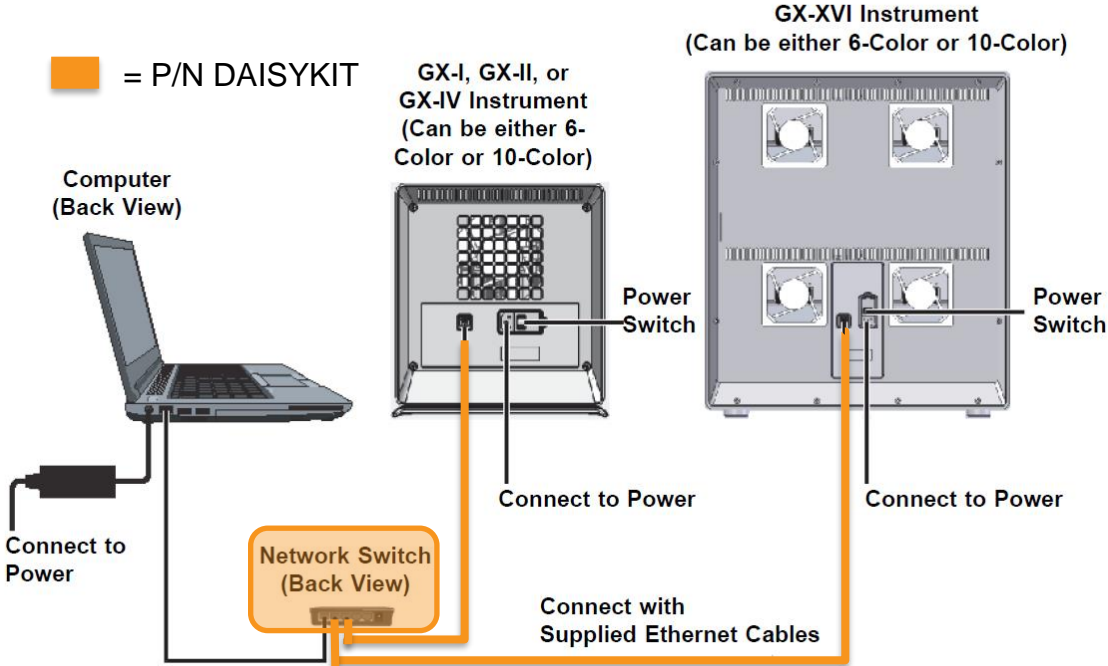**Blue Identification**
Stripe on door

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.

Instrument (Can be either 6-Color or 10 Color)

Instrument (Can be either 6-Color or 10-Color)

= P/N DAISYKIT

Computer (Back View)

Power Switch

Power Switch

Connect to Power

Connect to Power

Connect to Power

Network Switch (Back View)

Connect with Supplied Ethernet Cables

Connecting Multiple GX-IV Instruments to the Desktop Computer

Cepheid®

Connecting Multiple Instruments to the Computer

Connecting Multiple Instruments to the Laptop Computer

Connecting to Cepheid® C360
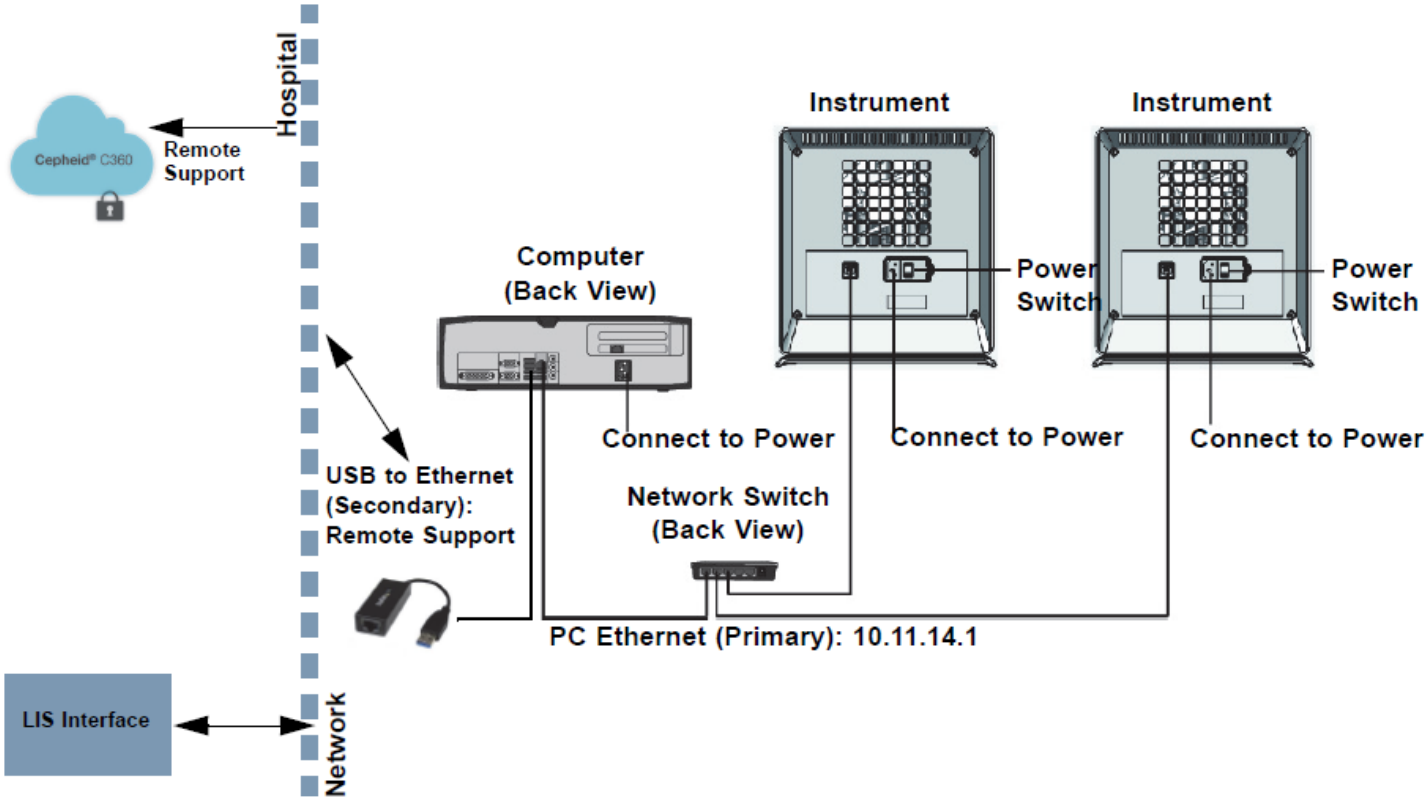
Connecting Multiple GX-IV Instruments to C360

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
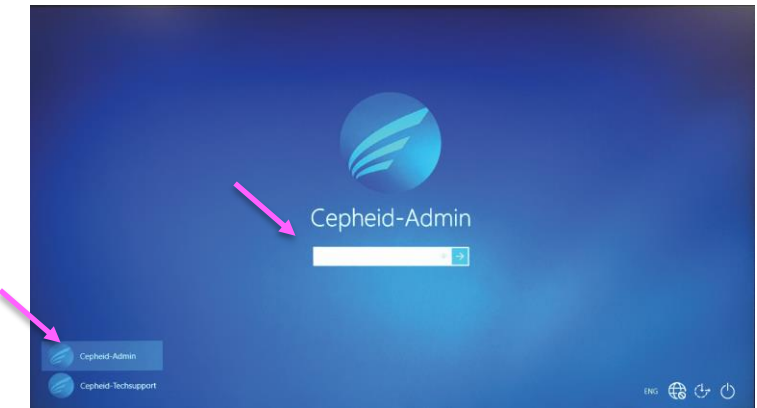
With Windows® 10

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.

Test Archive Reminder

Archive is overdue. Do you want to archive now?

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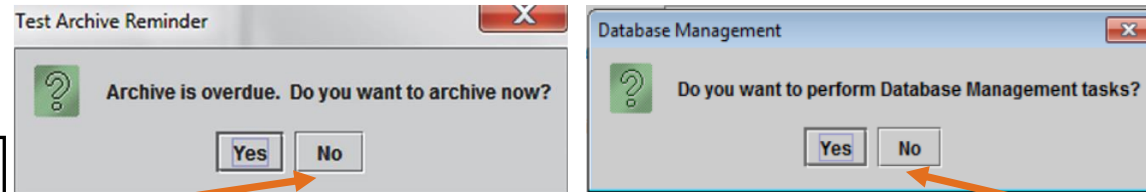
Click on **NO** if Database Management is not required to be archived at this time.

Database Management

Do you want to perform Database Management tasks?

[Yes] [No]

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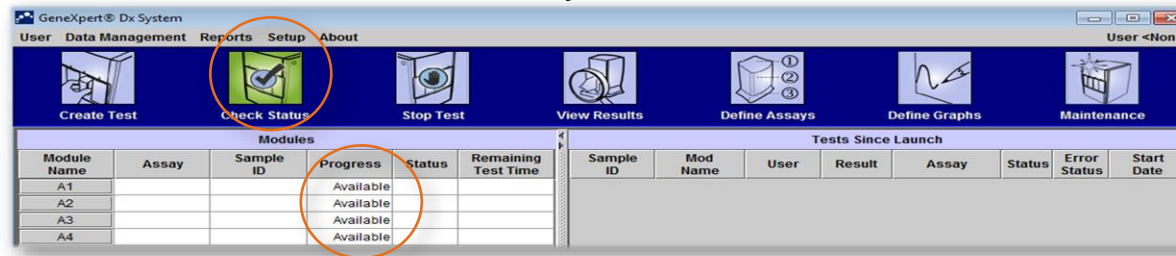
If no modules are available, please refer to Troubleshooting section in the Operator Manual and contact Cepheid Technical Support

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Prepare your System for Routine Use

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

GeneXpert Dx

The GeneXpert GX Dx Software is available in:

English   Español   Português   Русский   Français   中文   日本語   Italiano   Deutsch

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

Cepheid.
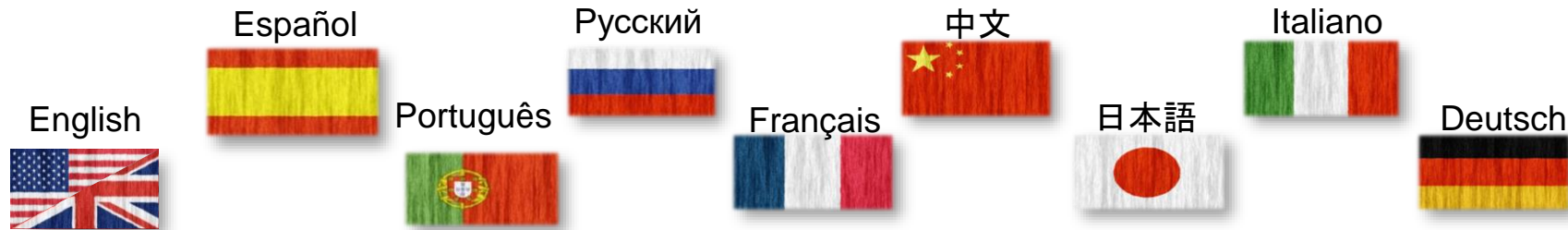
Windows® 7 & Windows® 10 Language Setting

With Windows® 7

With Windows® 10

Cepheid®
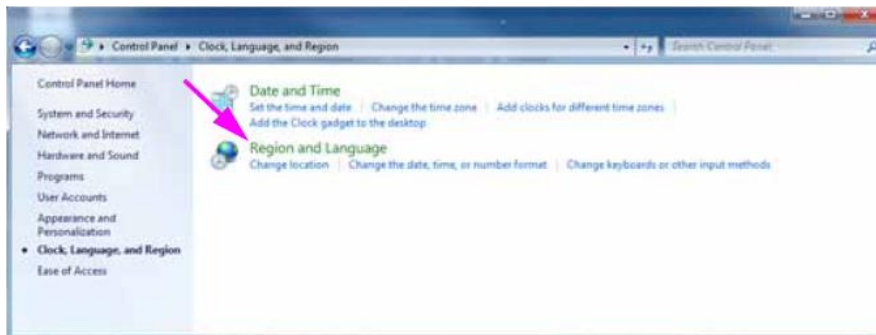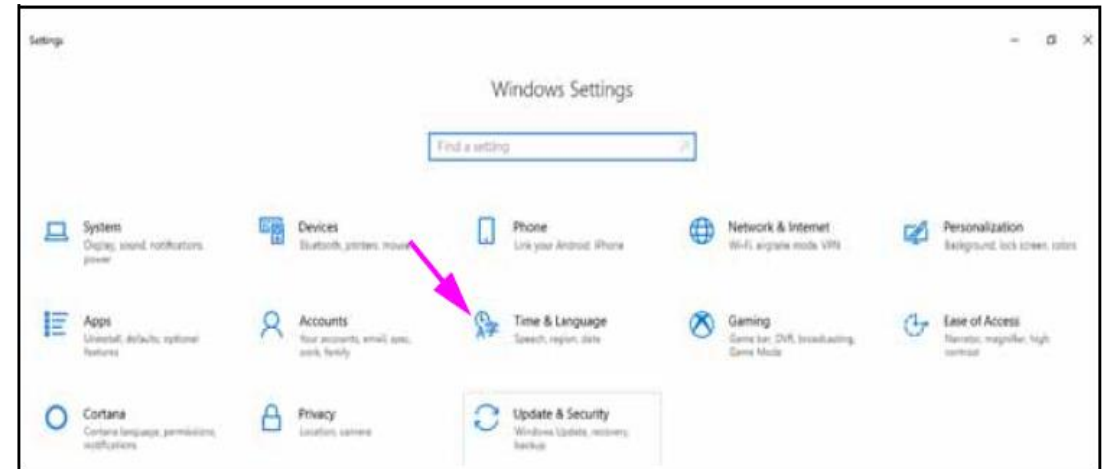
Configuring the Windows 7 Keyboard
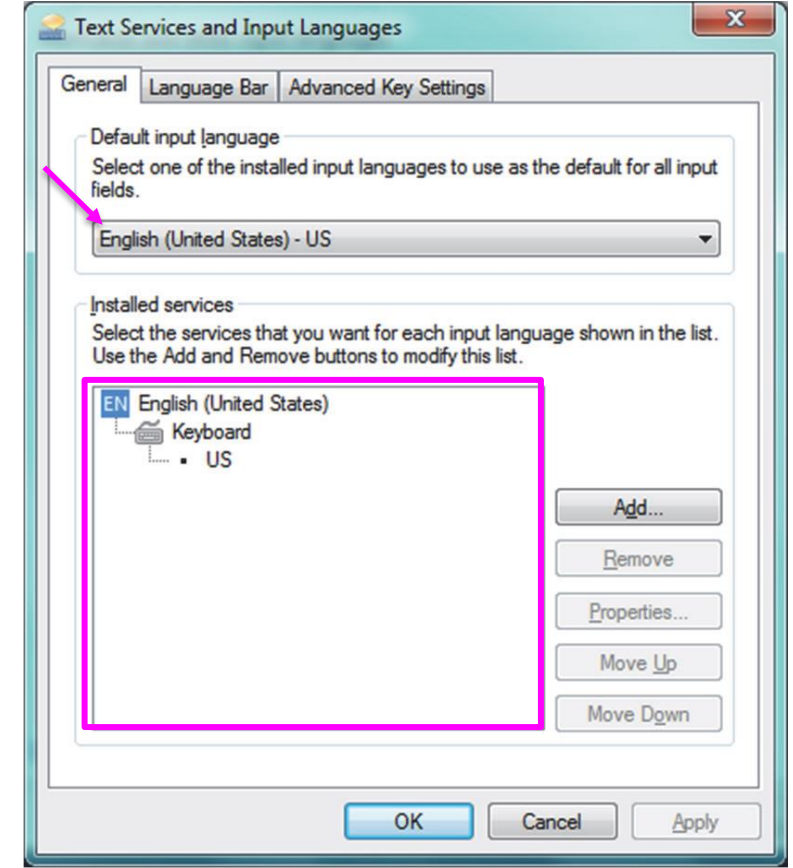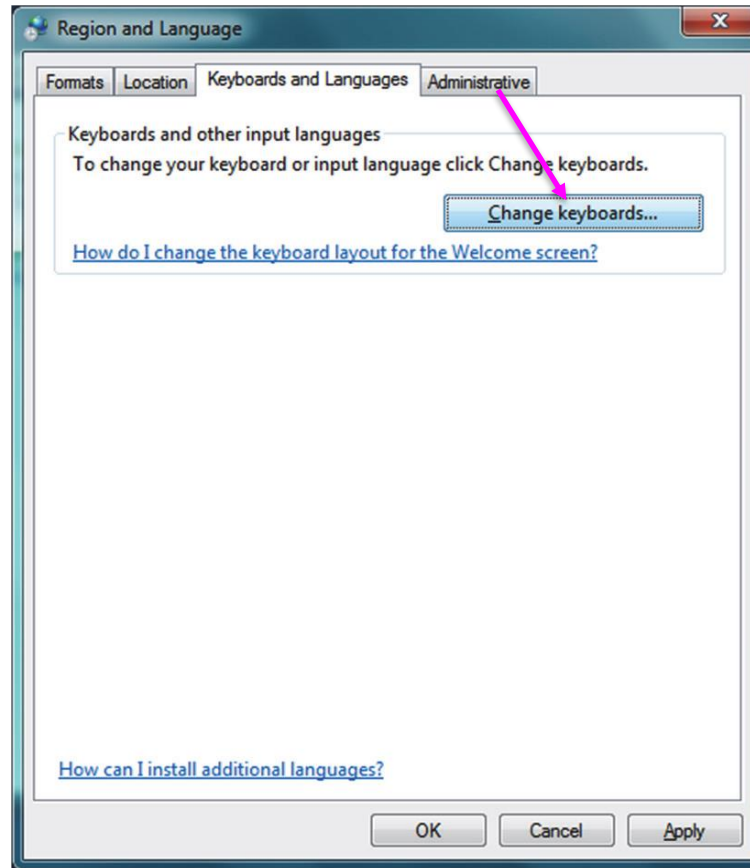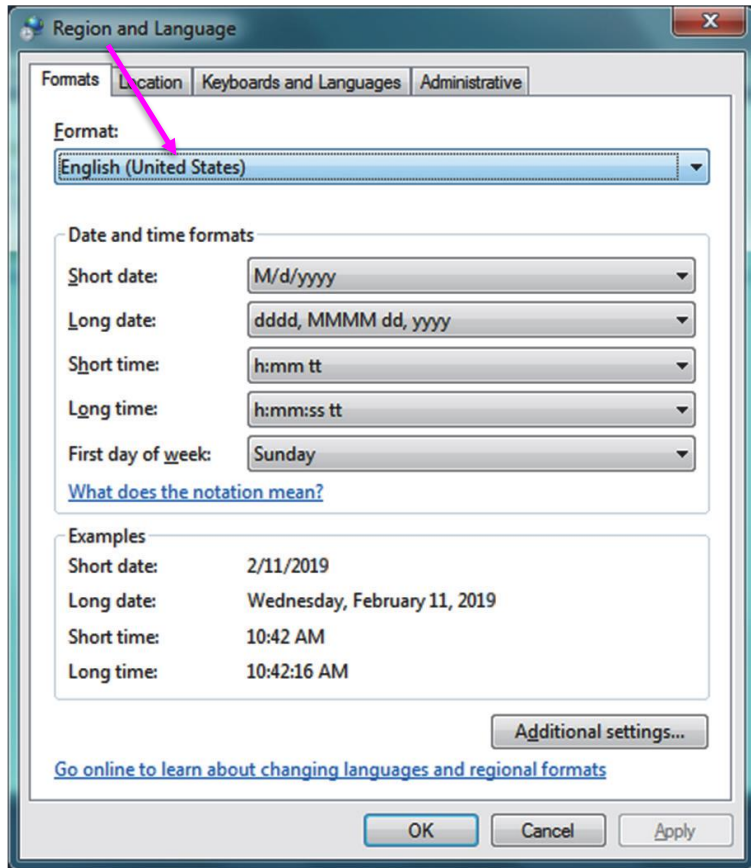
Configuring the Windows 7 Keyboard (cont.)
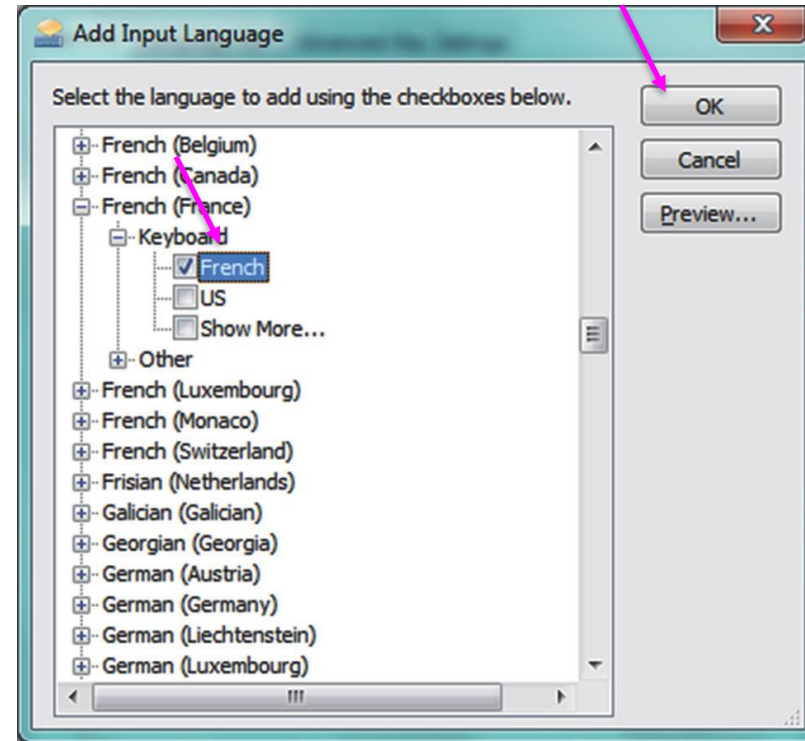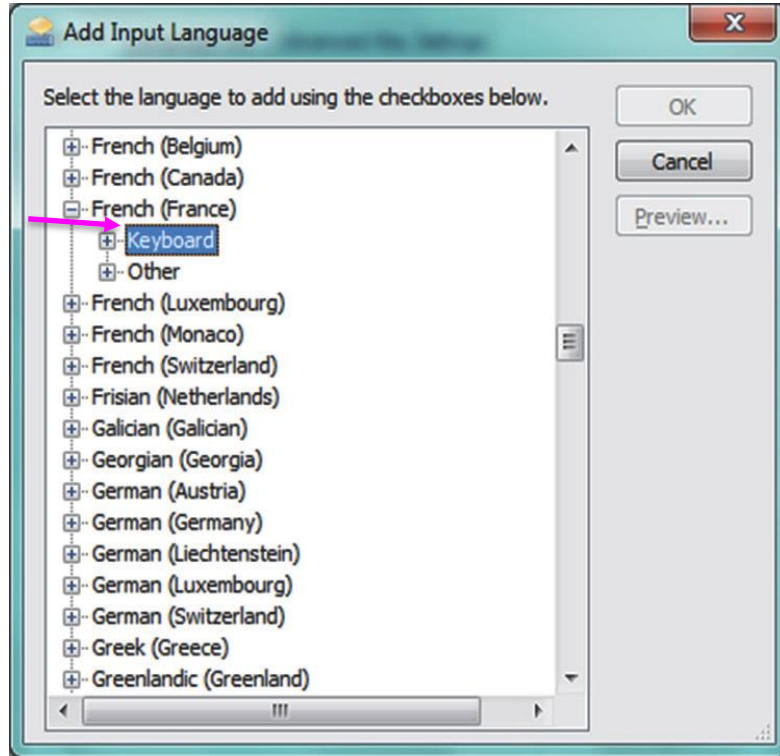
Local Date and Time Setting

With Windows 7

With Windows 10

Cepheid®
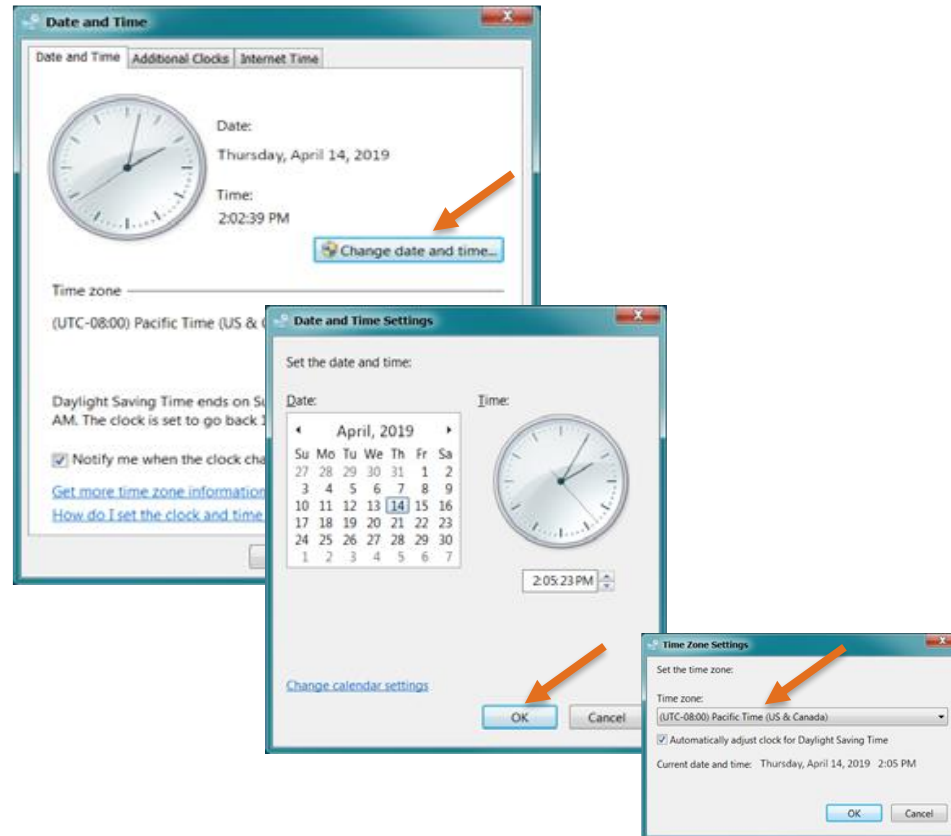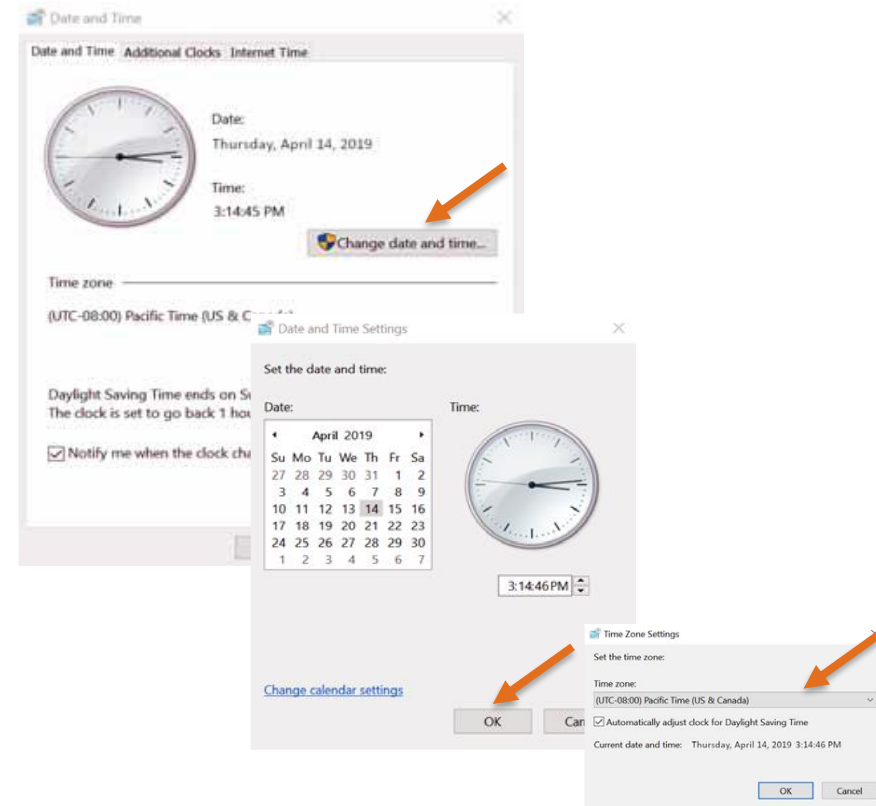
How to Assign Instrument Letters

Assign Instrument Letters

1 Click **Setup**

2 Click **Assign instrument letter**
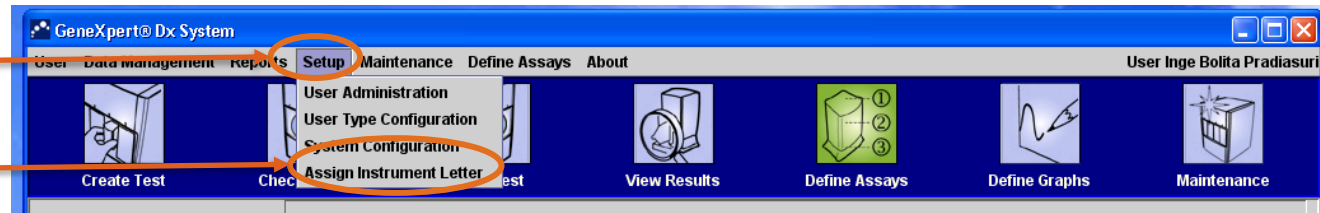
3 Click **Change Letter**
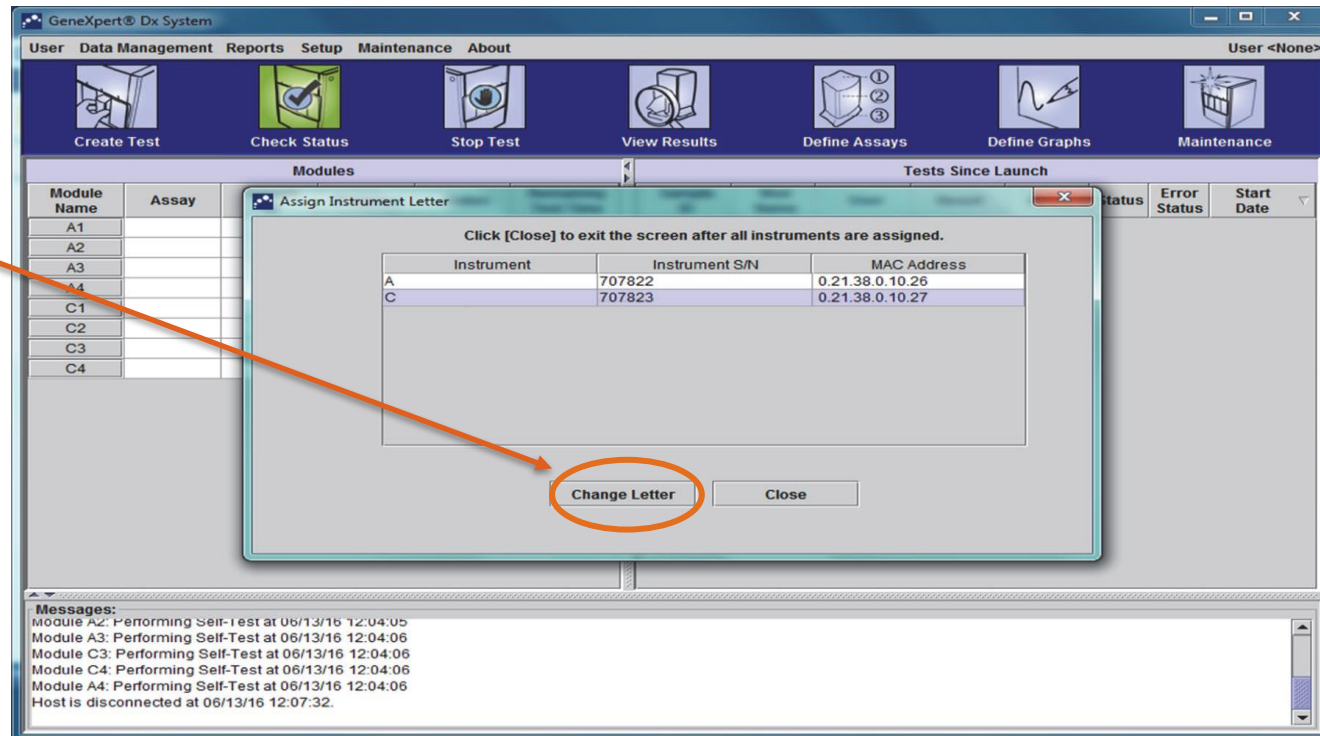
Assign Instrument Letters
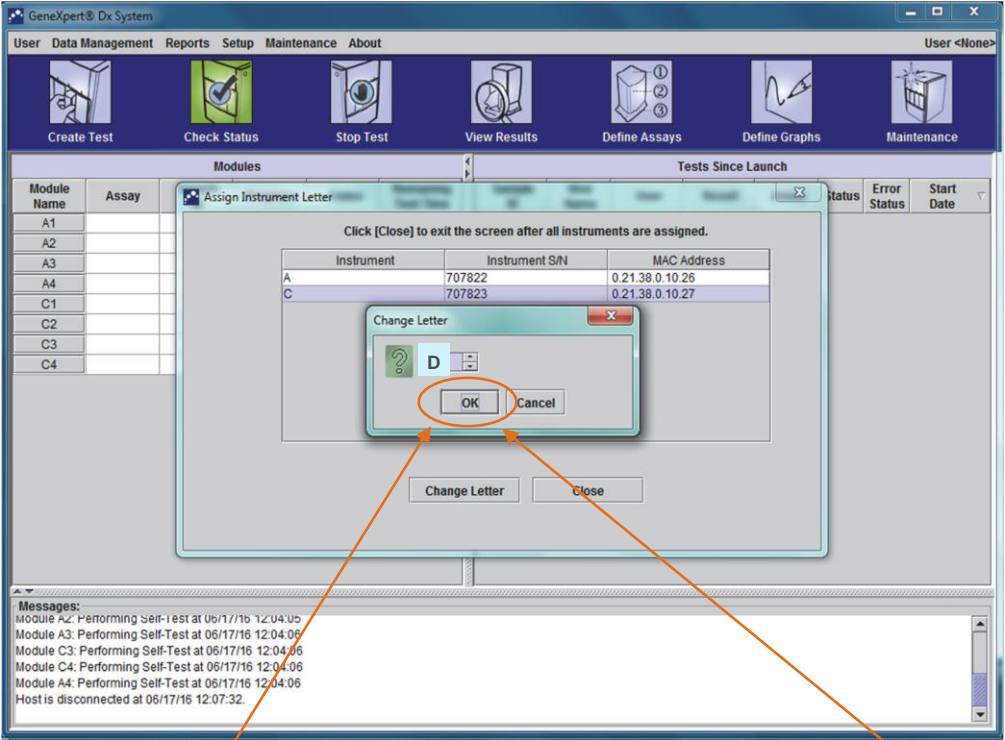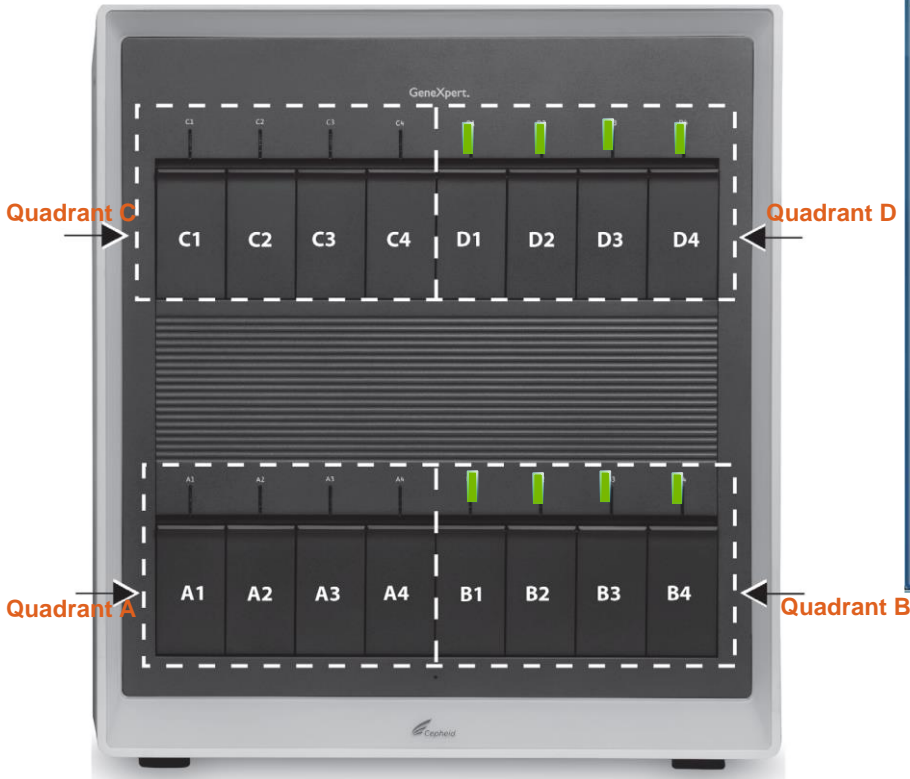
4 — Change the Letter (A ,B ,C or D etc)

5 — Click **OK**

Assign Instrument Letters

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

Verifying Proper Installation and Setup

Installation Qualification Report

1 Click on **Reports** & Drop-Down the Menu
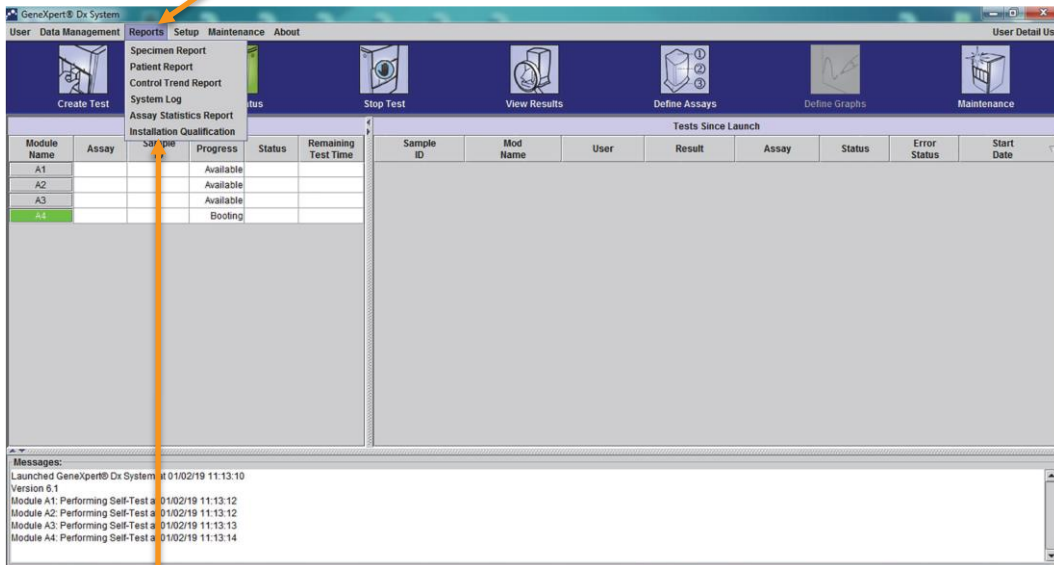
2 Select **Installation Qualification**

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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

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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.
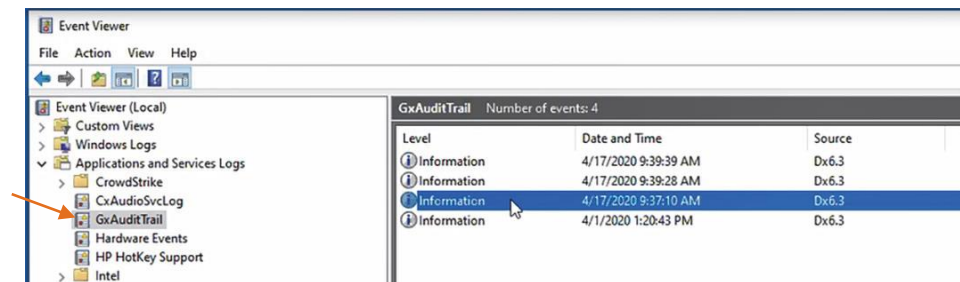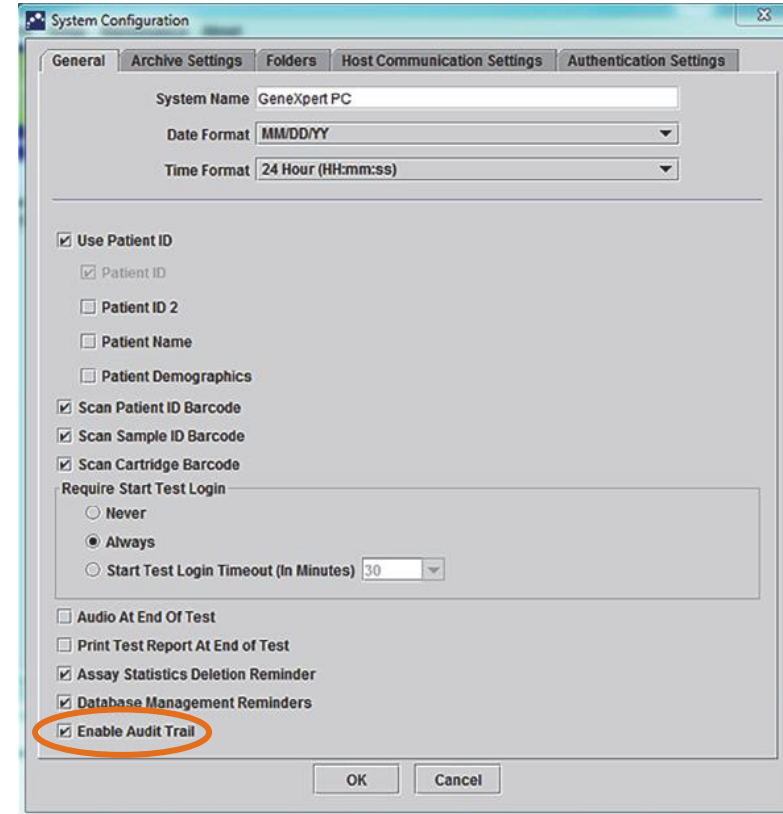
Configuring the System
Archive Settings

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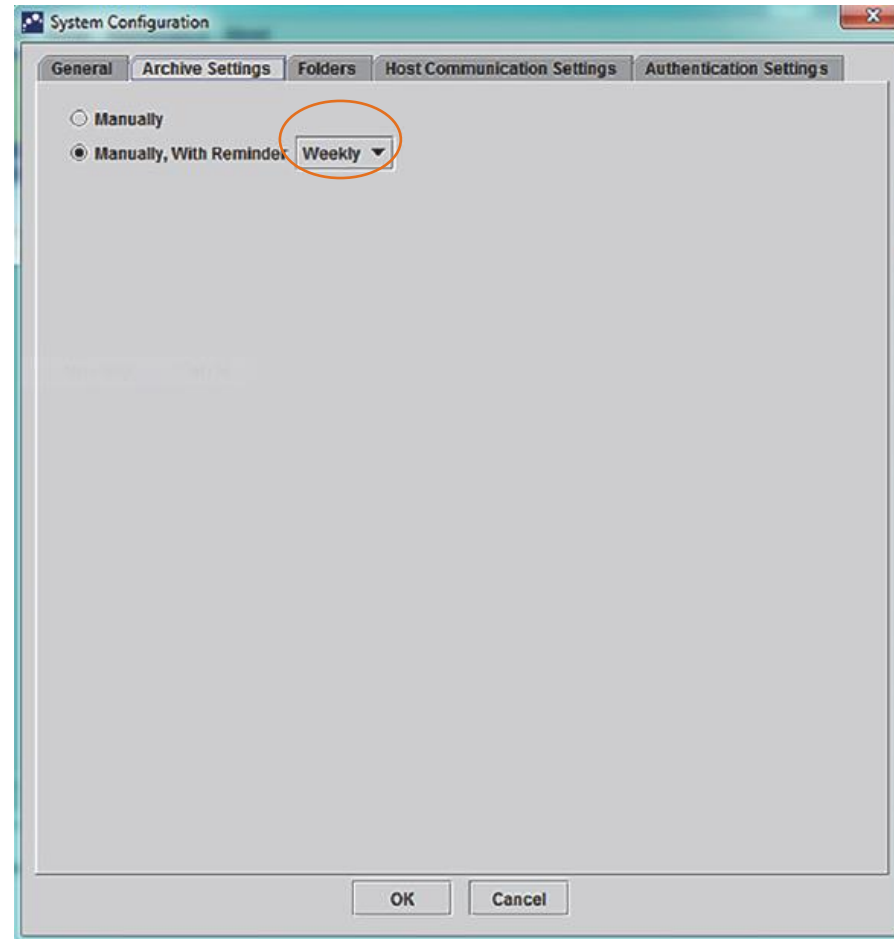
Configuring the System
Folders

- The default locations of each folder on the computer hard drive is indicated here.
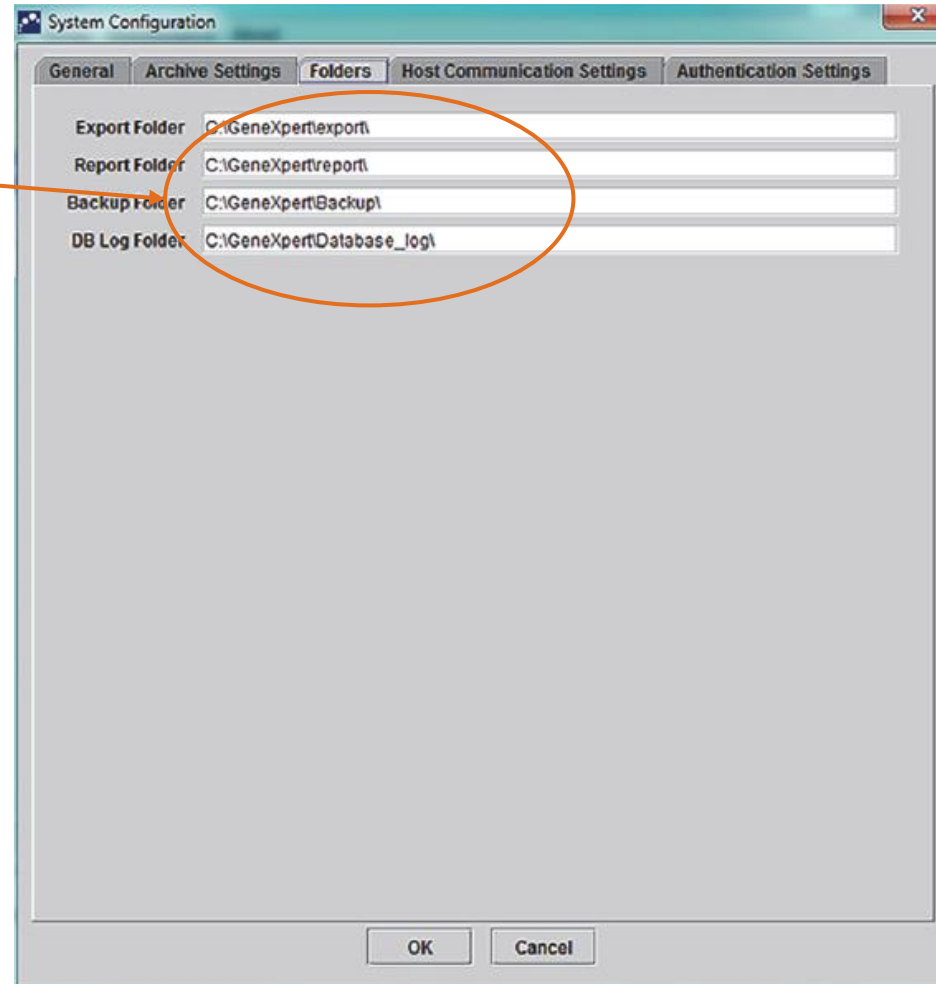
Configuring the System
Host Communication Settings Workspace

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
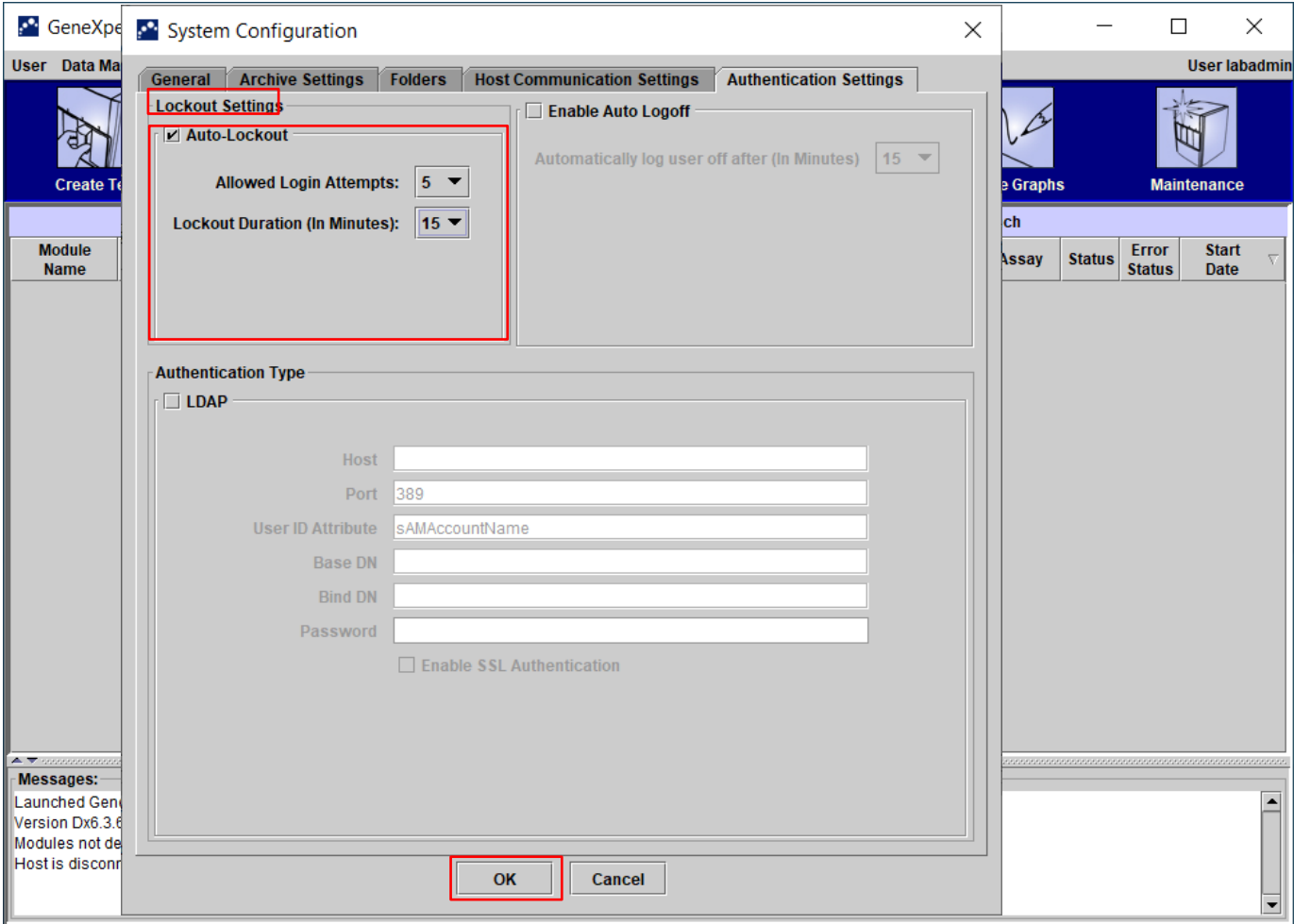
Mis-type the password 5 times

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

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Configuration

Confirmation

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
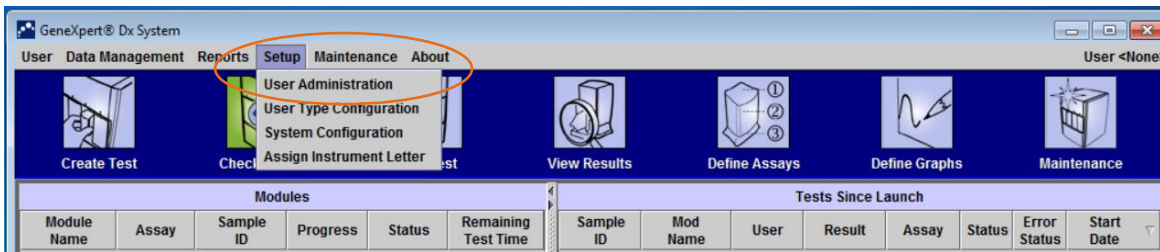
2 | Click **Add**
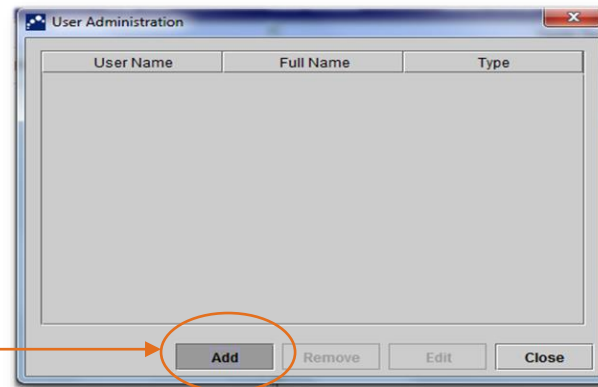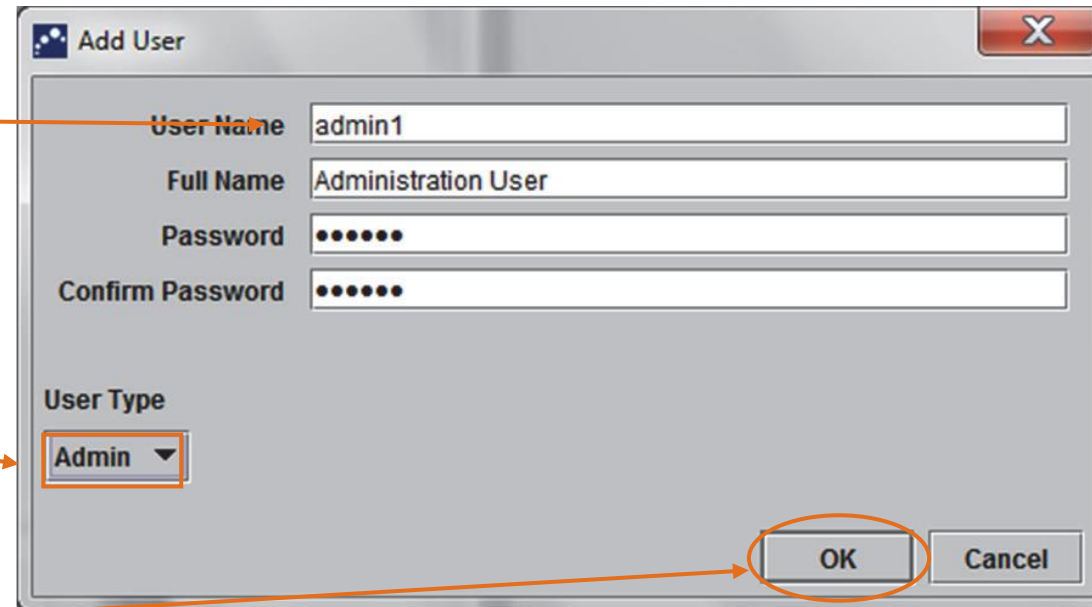
Create an Administrator Account ("Admin")

3 | Enter the Username and Password

4 | Choose the User type (**Admin**)

5 | Click **OK**

Add User

User Name	admin1
Full Name	Administration User
Password	••••••
Confirm Password	••••••

User Type

Admin ▾

OK   Cancel

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**
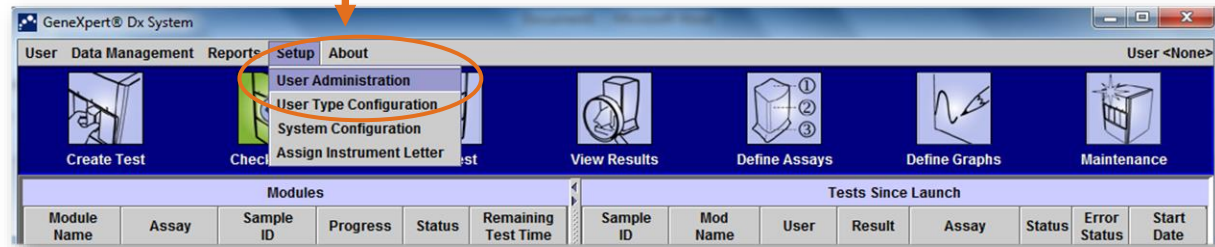
2 Click on **Add**

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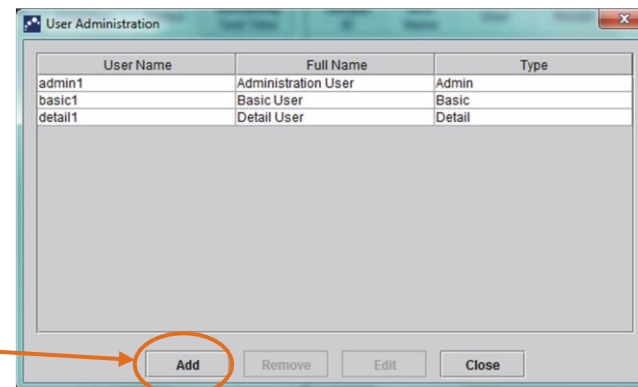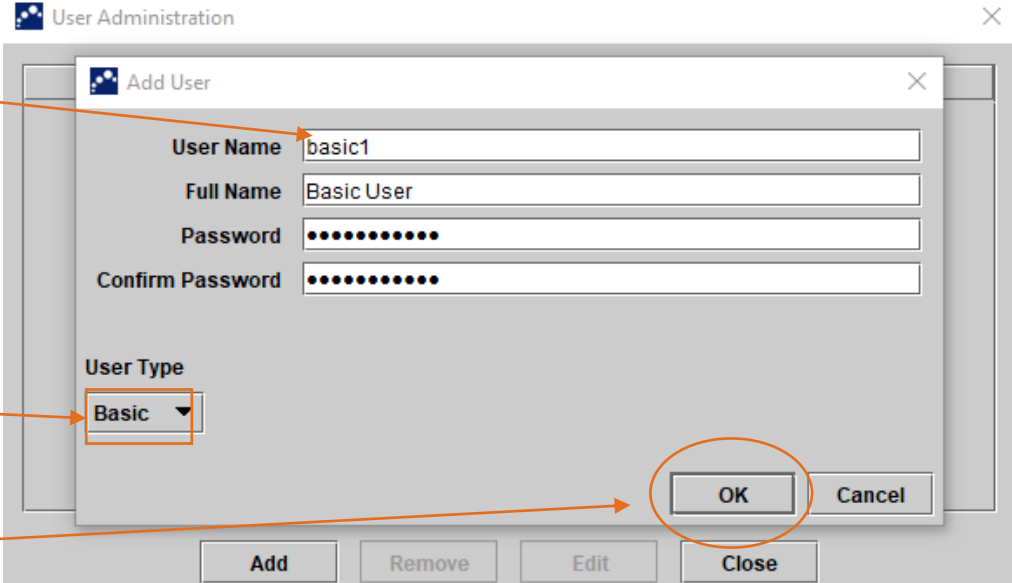
Create a Basic Account

3 Enter the Username and Password

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

5 Click on **OK**

User Administration

Add User

User Name	basic1
Full Name	Basic User
Password	••••••••••
Confirm Password	••••••••••

User Type

Basic

OK   Cancel

Add   Remove   Edit   Close

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

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User Administration Dialog Box

User Type Configuration

1   Setup → **User Type Configuration**

Editing User Profile

How to Edit User Profile

1 Select the user to be edited from the user administration list.
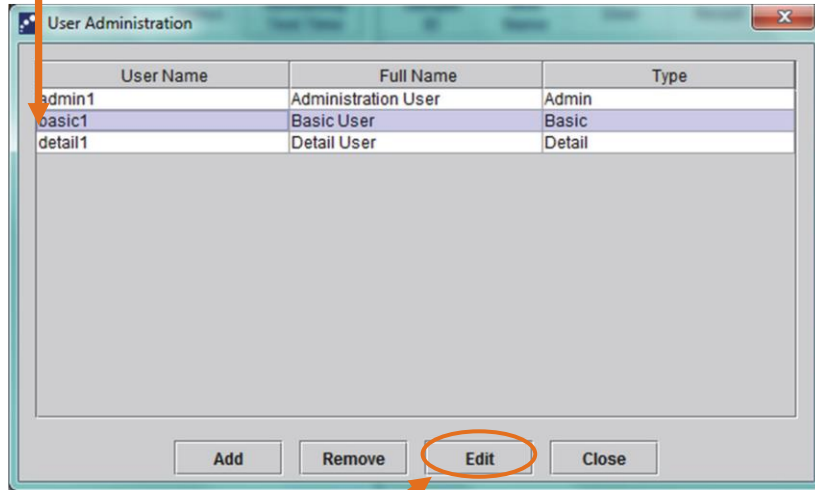
2 Click on **Edit**

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

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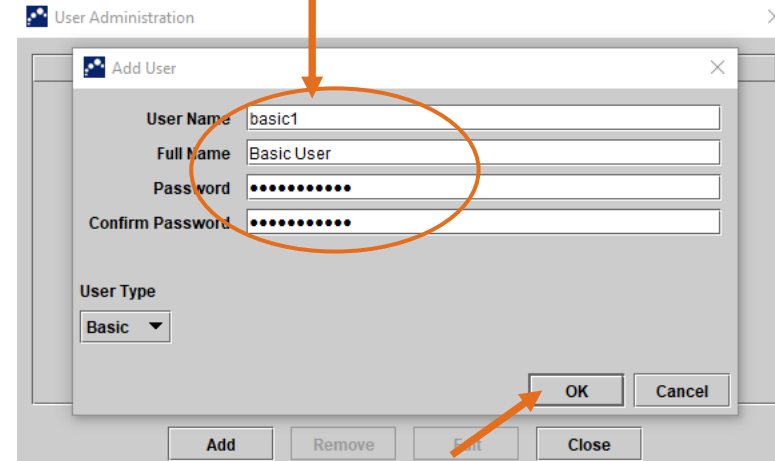
Removing Users

How to Remove Users

1 Click to select the user to be removed
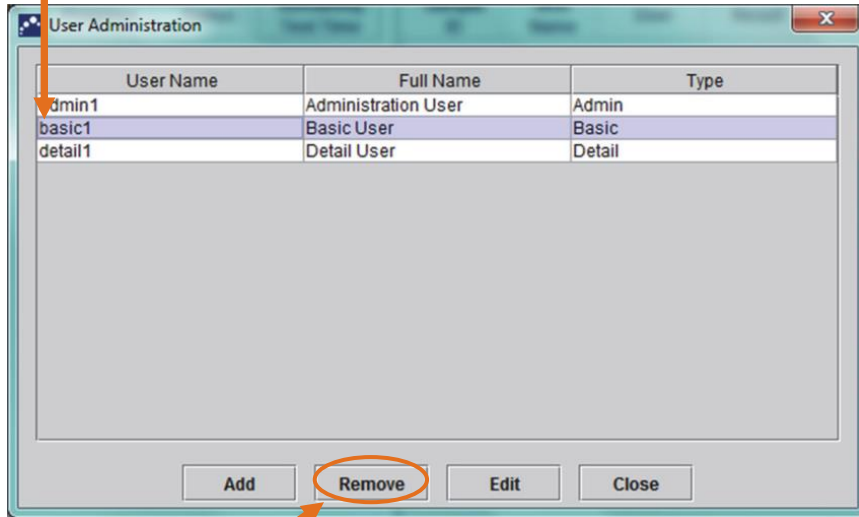
2 Click on **Remove**

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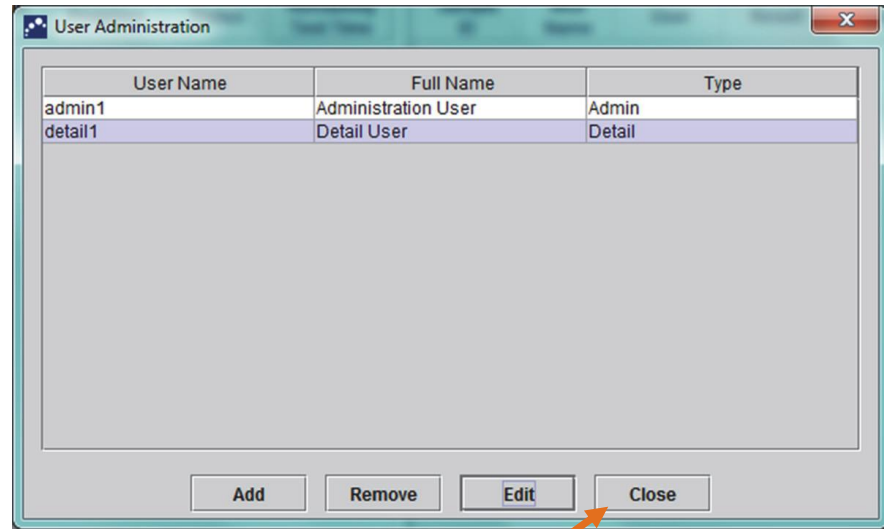
How to Login
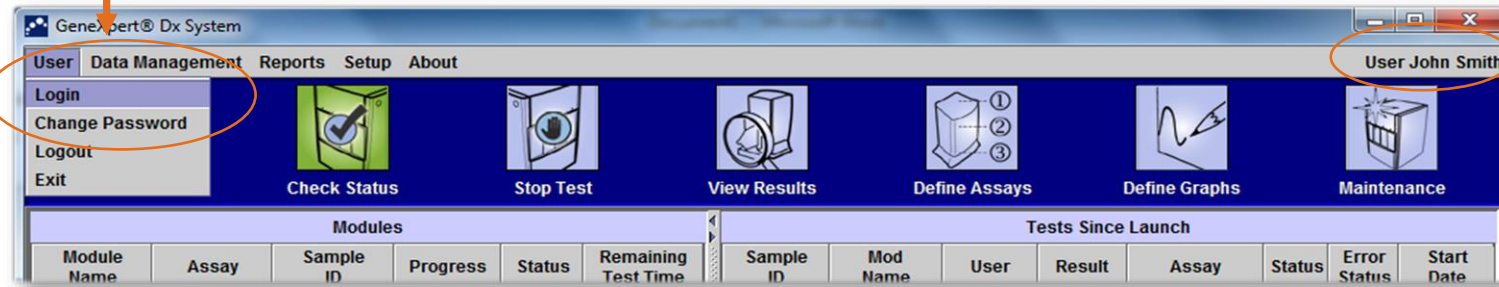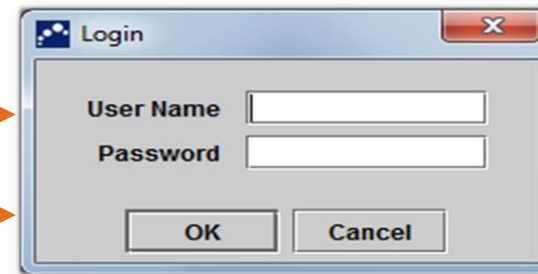
LDAP Integration

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 **L**ighter

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

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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

Confirmation

Confirmation

The GeneXpert® Dx Software Features

GeneXpert® Dx System Window

Create and start a test

View the results

Monitor the test progress

Check the list of assays
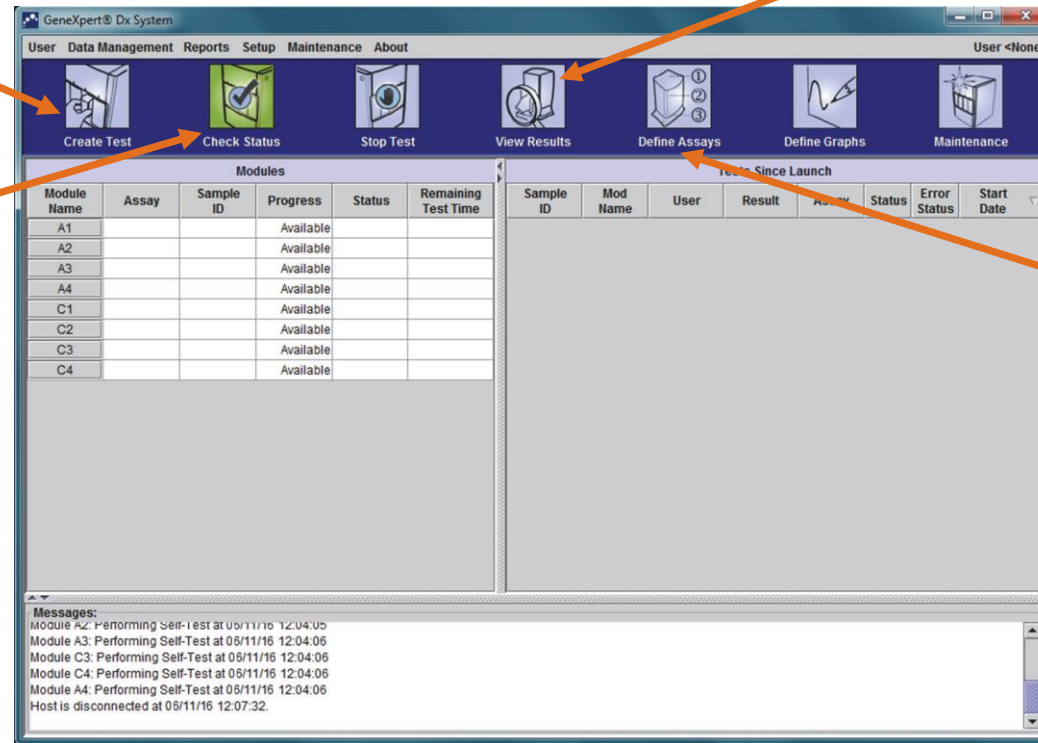
Create a Test

Create a Test

After preparing the cartridge according to the Package Insert:

1 Click on **Create Test**
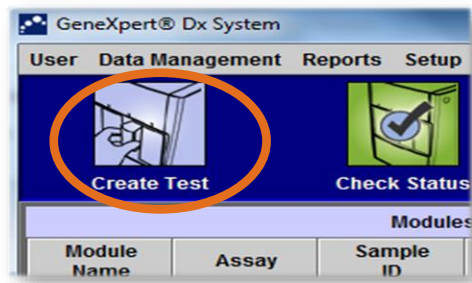
2 A dialogue box appears: **Scan cartridge barcode**
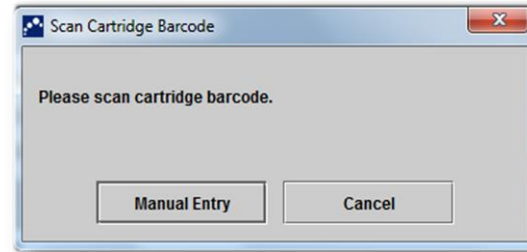
3 Scan the barcode by holding the scanner about 8 to 10 inches from the barcode, aligning the scanner to the barcode image

Create a Test

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

5 — The Module is assigned automatically

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® Cartridge

Reagent Lot ID

Expiration Date

Assay

Cartridge Barcode
(All numbers including
cartridge serial number)

Cartridge Serial Number
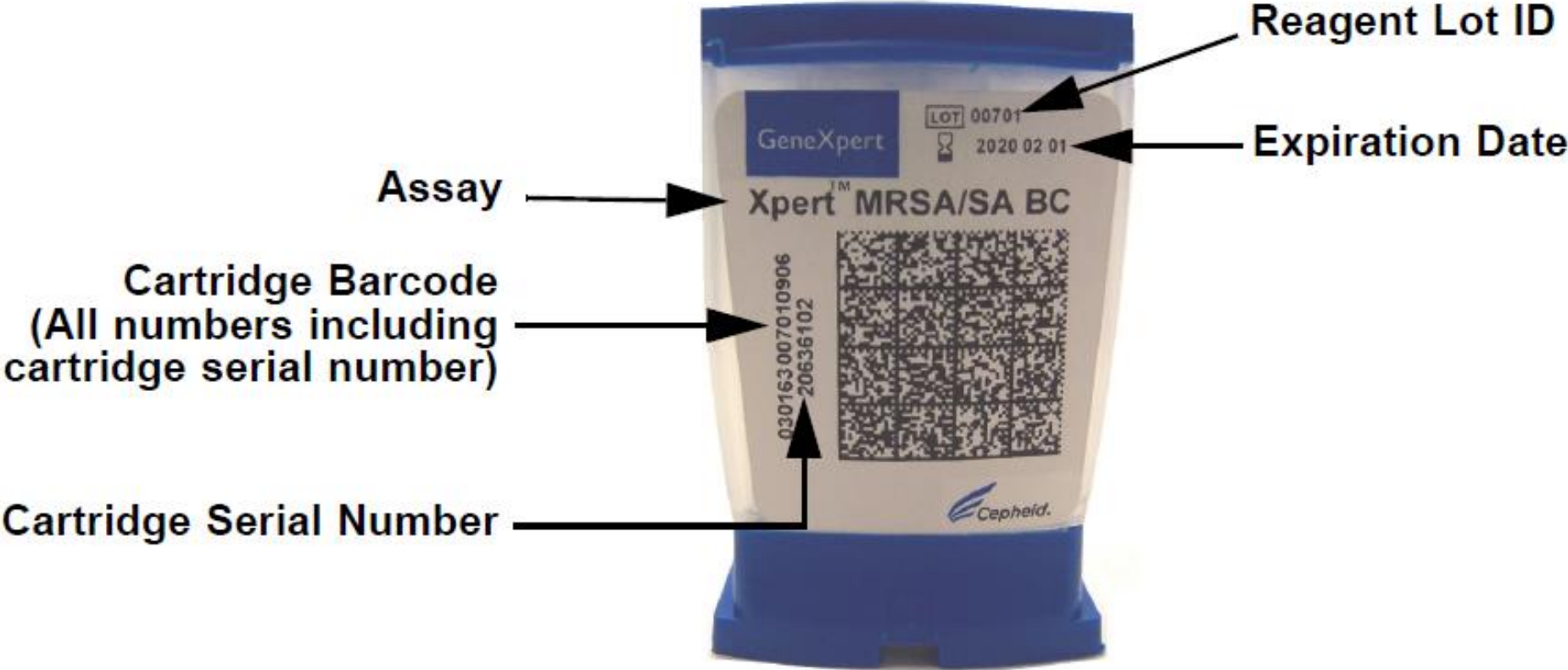
Manual Entry of the Cartridge Barcode

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

1 Click on **Create Test**
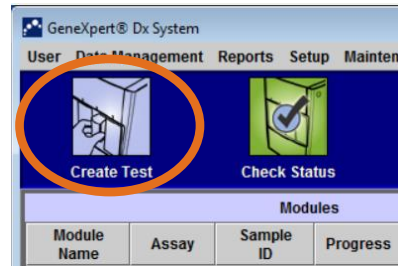
2 A dialogue box will appear: Click on **Manual Entry**
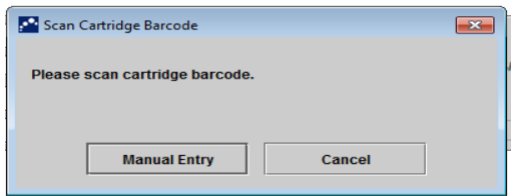
This window will appear after clicking on **Manuel Entry**
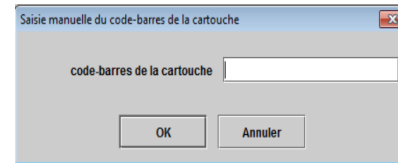
3 Type manually the 2-line numbers of the cartridges – see the picture

Enter the full cartridge number without leaving any spaces

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

Create a Test

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

5 The module is assigned automatically

6 Click **Start test**

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

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

Monitoring the Test Process

Monitoring the Test Process

Check the Module Area for Test Status

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**
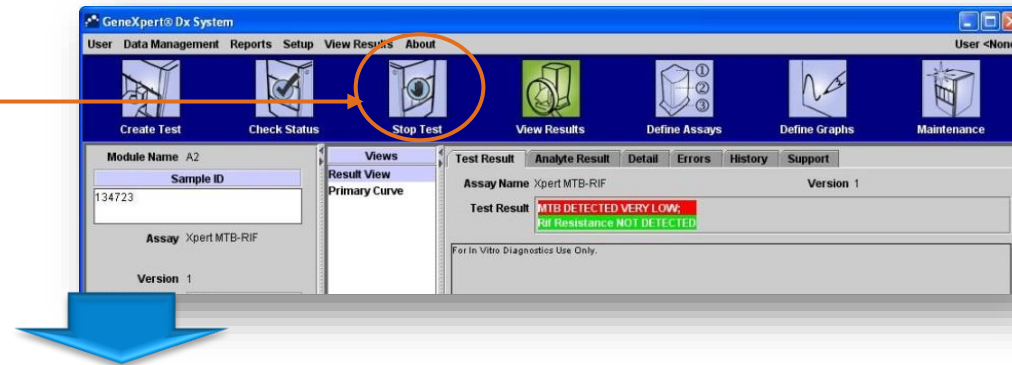
2 Select the module(s) that need to be stopped, by marking the tick box
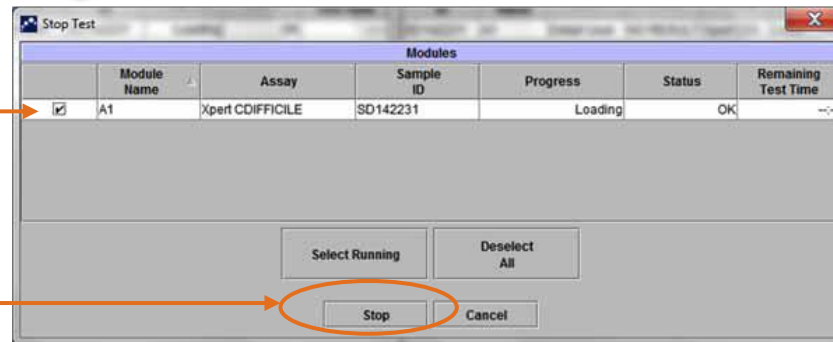
3 After selecting click **Stop**

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How to Stop a Test

4 Confirm your choice by clicking on **Yes**:
*or click **No** to cancel*
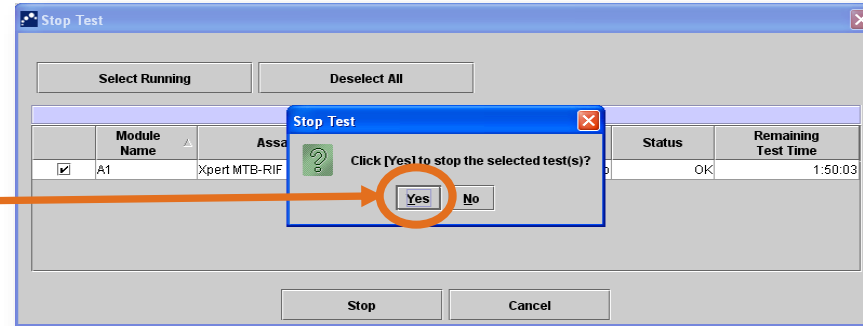
5 You will see the details about interrupted/stopped tests under **Check Status** menu; **Tests Since Launch** Section
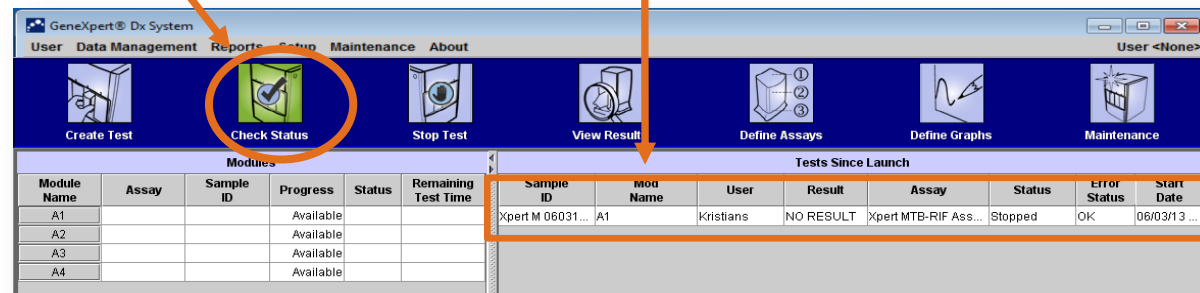
View Results

View Results

1 Click on **View Results**
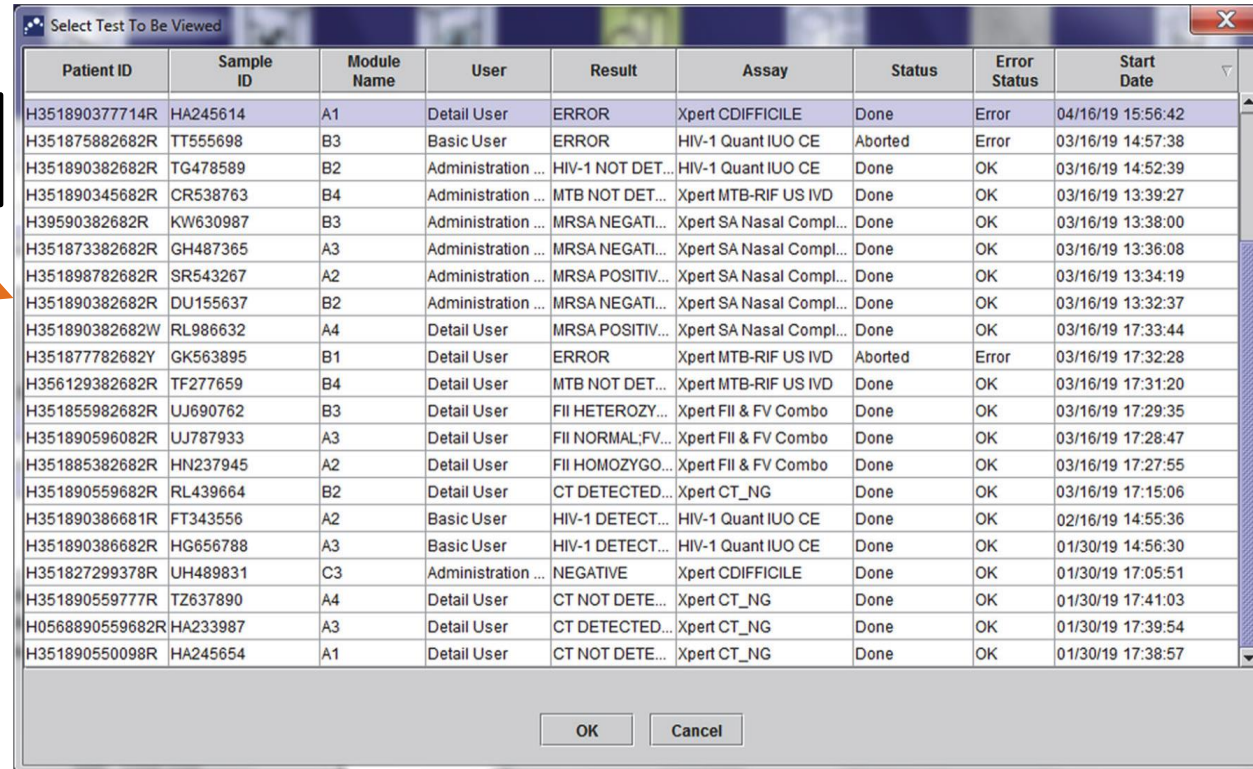
2 To visualize one particular result, click on **View Test**

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View Results

Double click on the test you want to display

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View results
Basic user view

View results
Detail Users and Administrator View

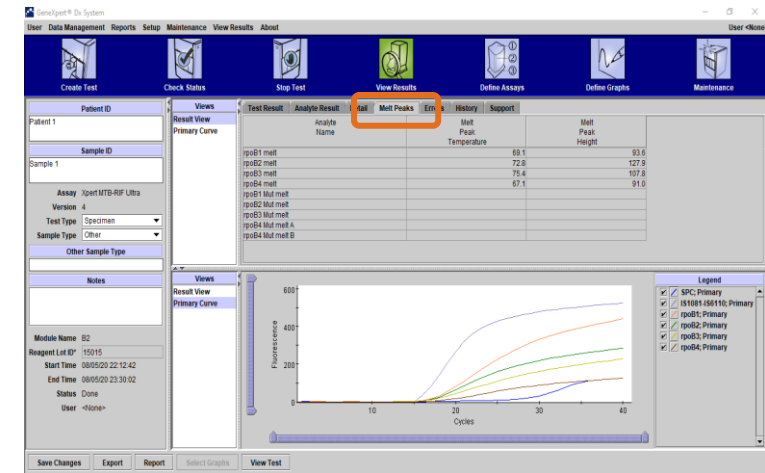© 2021-2022 Cepheid.

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
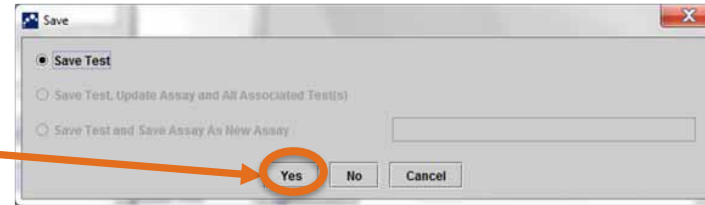

1 All the white fields in this section are editable

2 After editing click **Save Changes**

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Editing the Test Information

3 Click **Yes** to confirm the changes

4 The history of the changed information is saved under the tab **History**
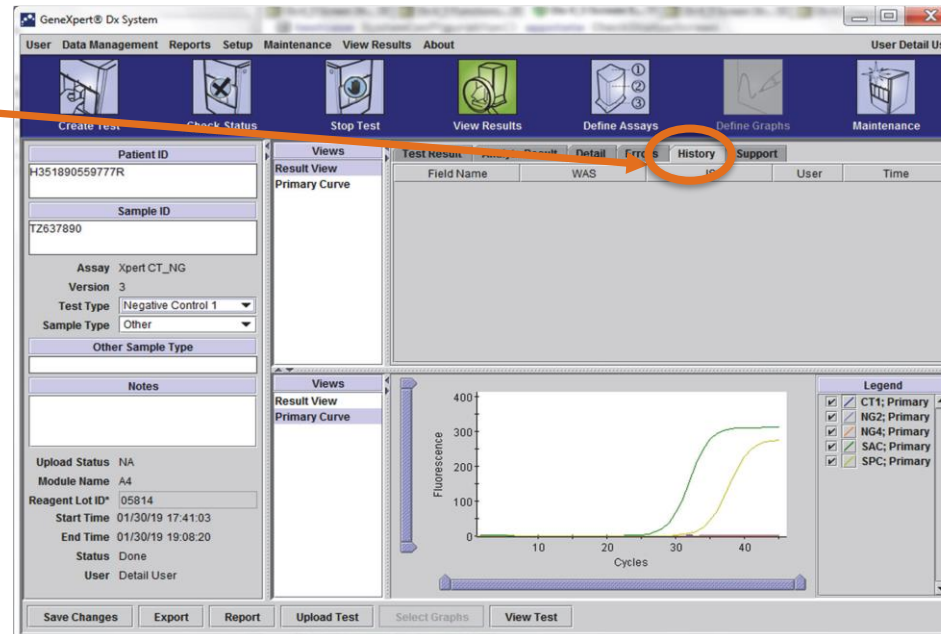
Editing the Test Information

History tab showing change

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Generate a Result Report in PDF

Generate a result report in PDF
Basic user view

1 Click on **View Results**
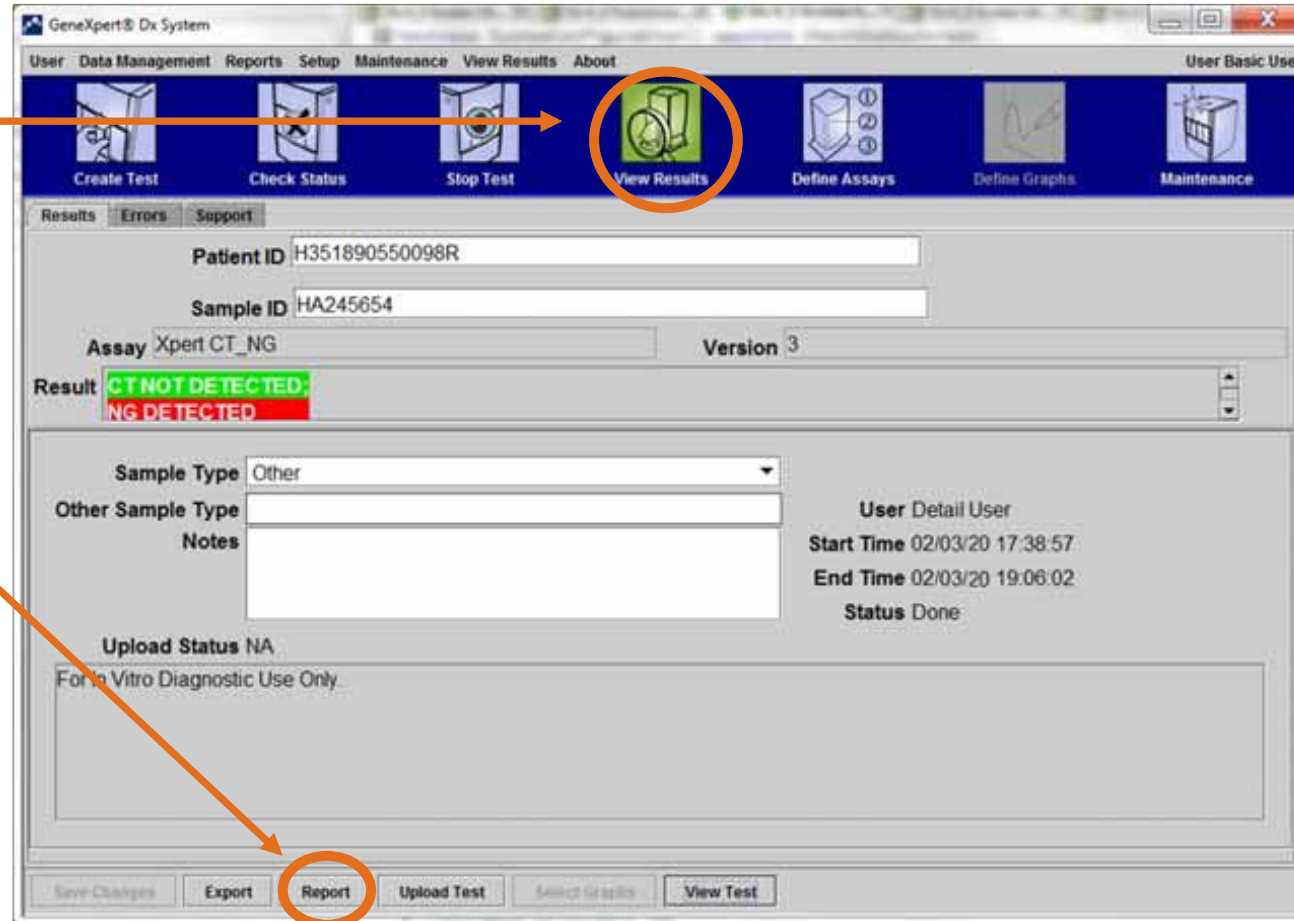
2 Click on **Report**

Generate a result report in PDF
Basic user view

3 Select Test to Be Viewed

4 Select Report to generate PDF

How to generate a PDF
Detail Users and Administrator View

1 Click on **View Result**

2 Click on **Report**

How to generate a PDF
Detail Users and Administrator View

3 Select the result you may want to visualize in PDF
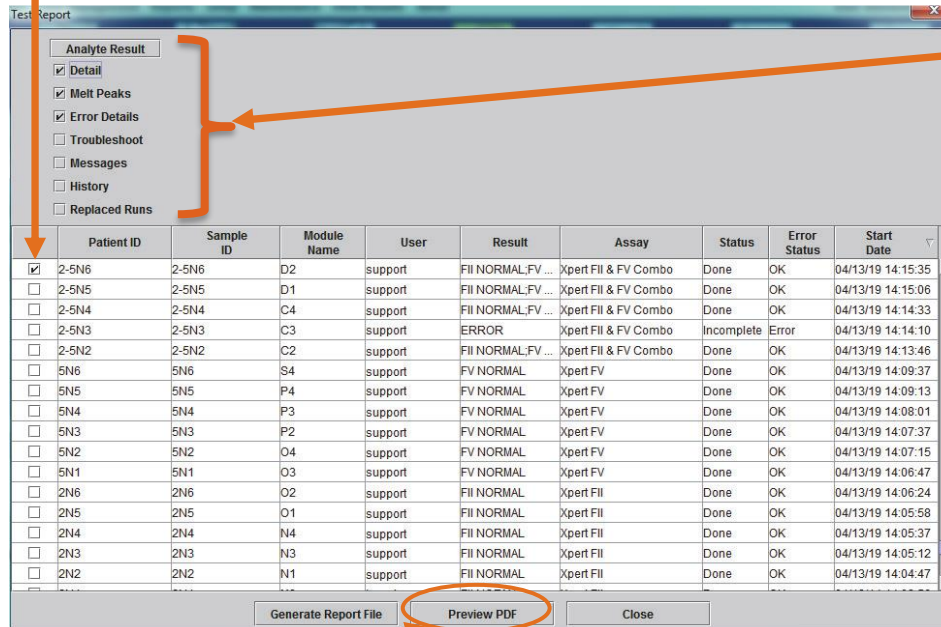
In the upper left-hand corner of the dialog box
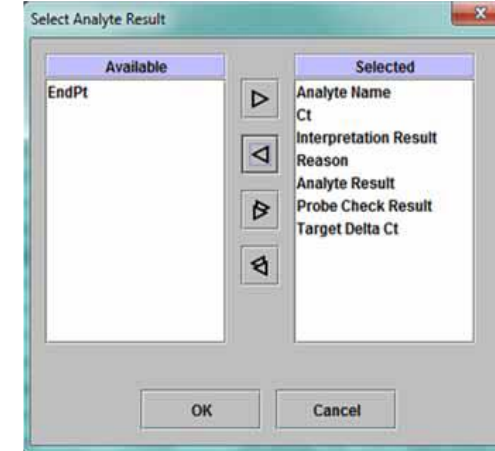
4 Click on **Preview PDF** for immediate visualisation

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Example Test Report

Example Test Report—Detail and Administrator User Page 1 & 2

Example Test Report—Basic User

Uploading Test Results to the LIS

Uploading Test Results to the LIS

Upload Test Results to the LIS

Uploading Test Results to the LIS Automatically.

1 click the **Automatic Result Upload** check box

2 click **Ok**

Generate Specimen and Patient Reports in PDF

How to generate specimen and patient reports in PDF

1 **Specimen Report**

Click **Reports** -> **Specimen Report**
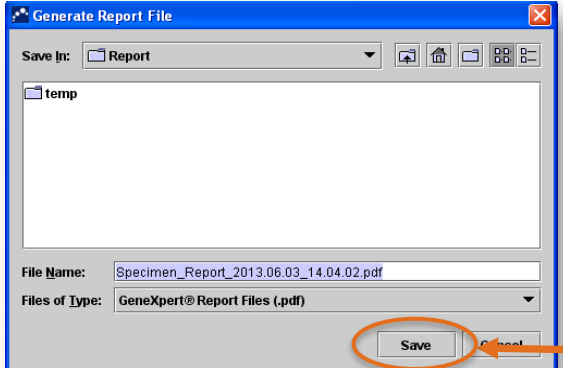
2 Fill in the Sample ID

3a

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

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

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Example Specimen Report

GeneXpert PC   02/17/20 12:55:54

Specimen Report

Found Sample ID #2 = DU155637

- 1 Test(s) Found -
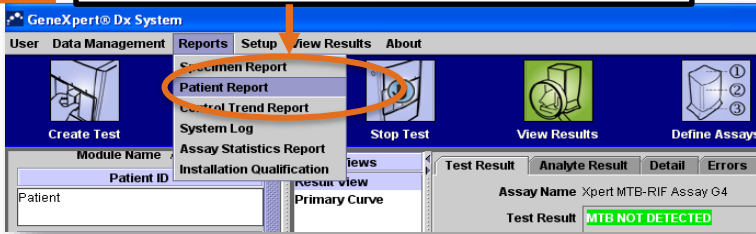
Patient ID: H351890382682R
Sample ID: DU155637
Assay: Xpert SA Nasal Complete G3
Assay Version: 5

Test Result: **MRSA NEGATIVE;**
                   SA POSITIVE

Start Time: 02/16/20 13:32:37
Test Type: Specimen
User: Administration User
Status: Done
Notes:

GeneXpert® Dx System Version 6.2   Cepheid®
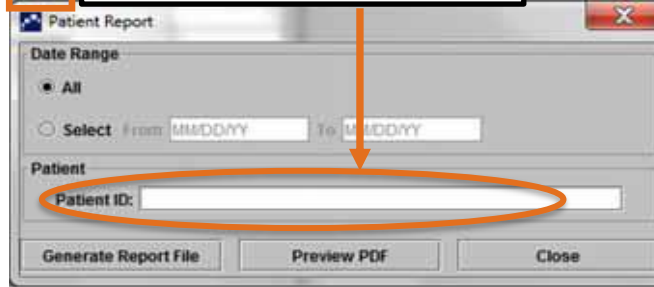
How to generate specimen and patient reports in PDF

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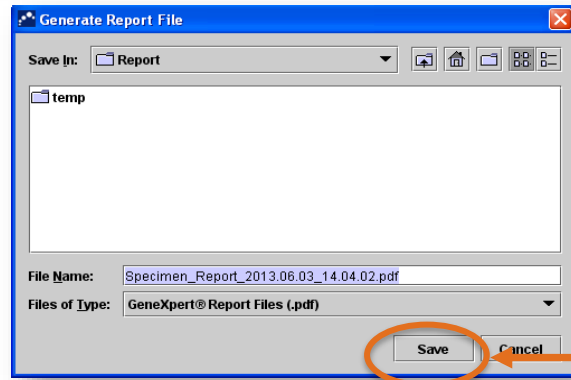
Patient Report

GeneXpert® Dx System

User Data Management Reports Setup View Results About

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

Create Test   Stop Test   View Results   Define Assays

Module Name

Patient ID

Patient

Result View
Primary Curve

Test Result | Analyte Result | Detail | Errors

Assay Name Xpert MTB-RIF Assay G4

Test Result MTB NOT DETECTED

---

2 Fill in the Patient ID

Patient Report

Date Range

○ All

○ Select From MM/DD/YY To MM/DD/YY

Patient

Patient ID:

Generate Report File   Preview PDF   Close

Generate Report File

Save In: Report

temp

File Name: Specimen_Report_2013.06.03_14.04.02.pdf

Files of Type: GeneXpert® Report Files (.pdf)

Save   Cancel

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

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

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Example Patient Report

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**
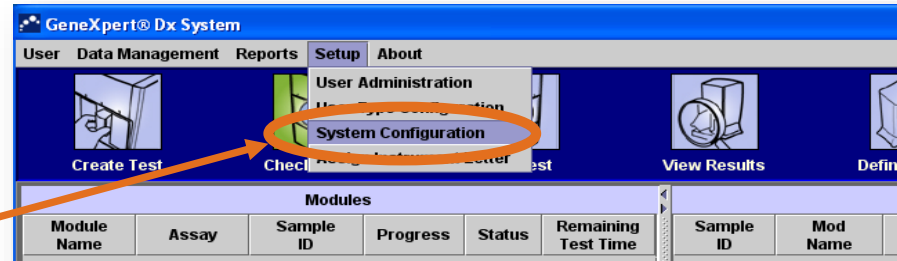
2 Select the appropriate option **Print Test Report At End of Test**
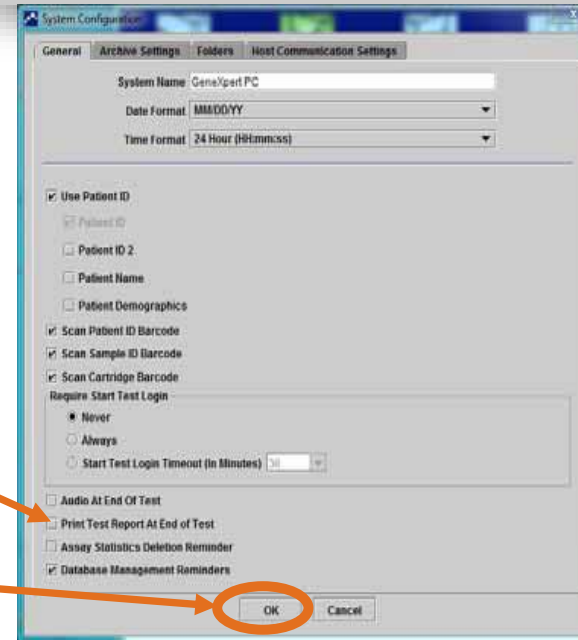
3 Click **OK**

Data Management Tasks

Difference between Archive/Backup

© 2021-2022 Cepheid.
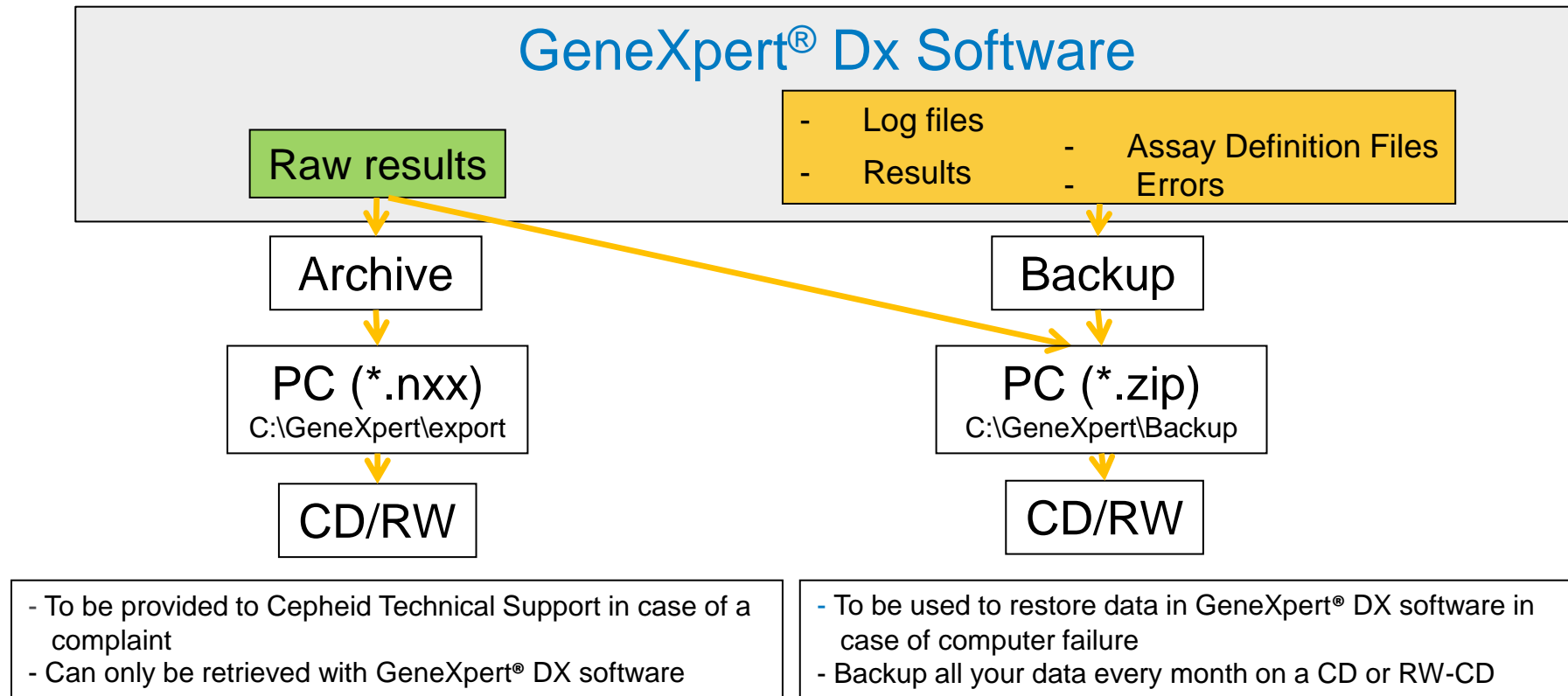
How to Archive Tests

How to Archive Tests

1 Click **Data Management**

2 Click **Archive test**
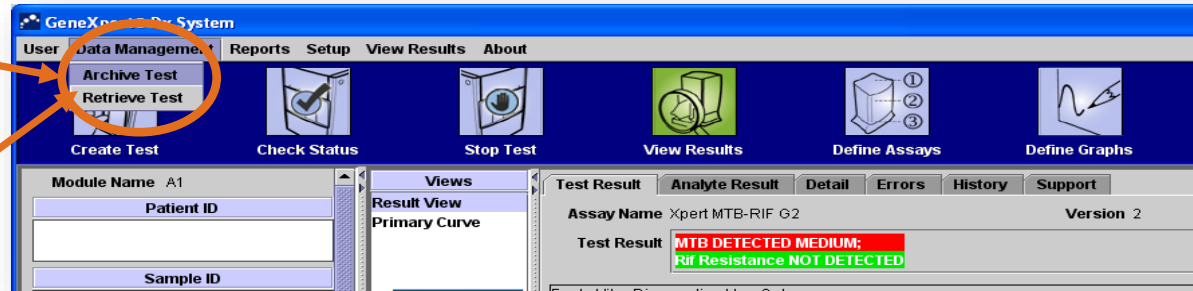
3 Choose the tests that need to be archived Or **Select All**

4 You can choose to Purge selected items after archiving
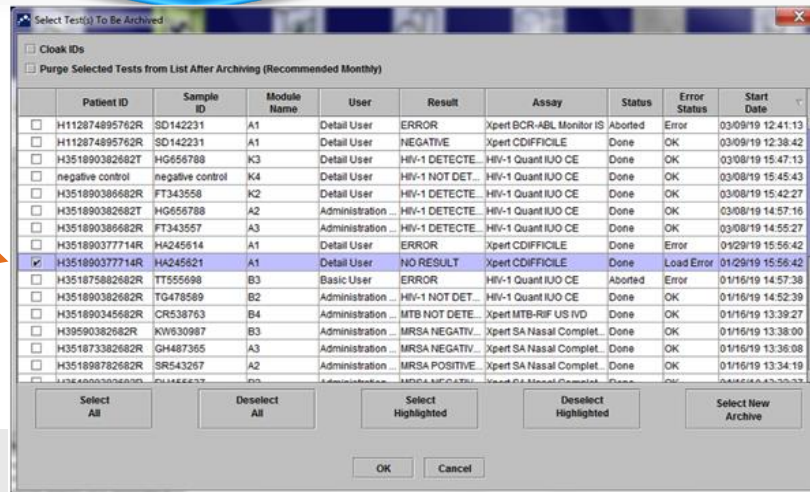
Purged tests will no longer appear in the GeneXpert ® Dx Software

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How to Archive Tests

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

Archive Test(s)

⚠ 12 test(s) selected for archive.

Cancel | Proceed
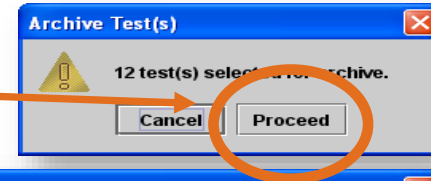
6 The files will be saved in the folder **Export**

Save

Save In: export

GeneXpert PC_2011.08.05_09.29.46.gxx
GeneXpert PC_2011.08.05_10.42.28.gxx

File Name: GeneXpert PC_2011.08.06_11.22.40.gxx
Files of Type: GeneXpert® Archive Files (.gxx)

Save | Cancel
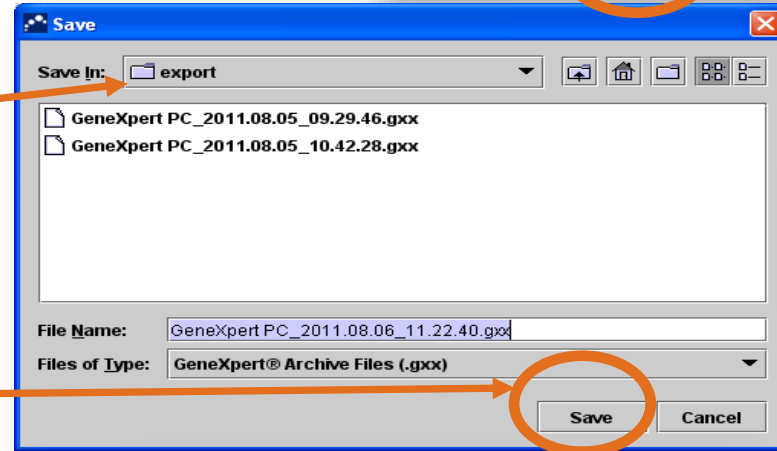
Save the archived data to an external device.

7 Click on **SAVE**

8 Click **OK**

Archive Test(s)

ⓘ 12 test(s) successfully archived.
Check details in C:\GeneXpert\Database_log\Archive_log_2011.08.06_11.22.54.txt.

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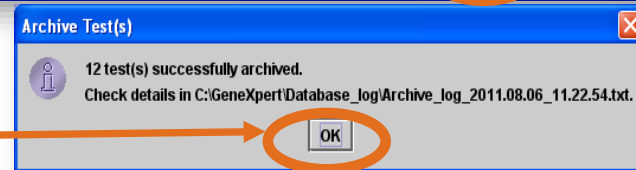
The archived file in the folder C:\GeneXpert\export

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How to Retrieve Tests

How to Retrieve Tests

1 Click **Data Management** and Click **Retrieve Test**
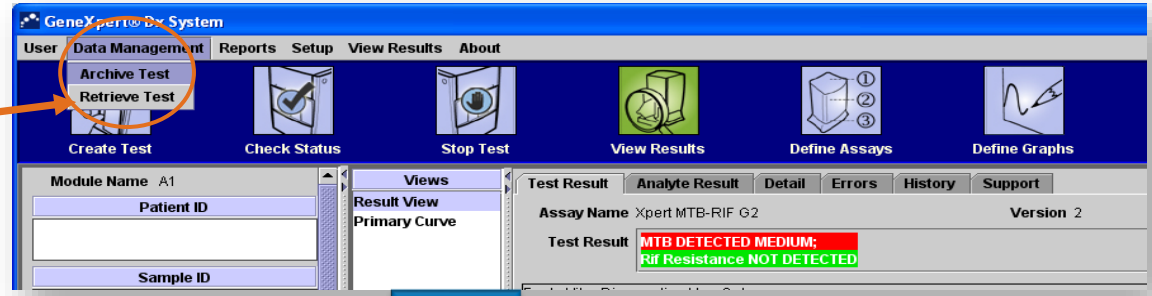
2 Locate and select the archive (**.gxx**/**.nxx**) file.
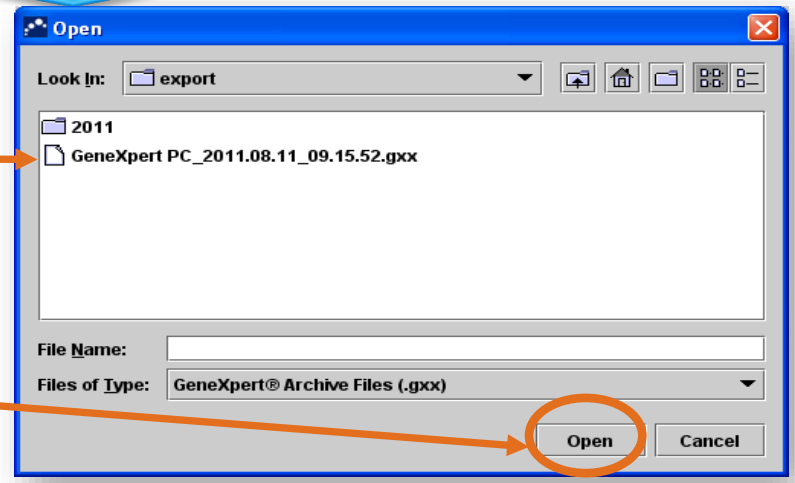
3 Click on **Open**

How to Retrieve Tests

4 Select the test to be retrieved (or Select All)

5 Click **OK**

6 Click **Proceed**

7 Click **OK**

How to Backup Database

Database Management Tasks

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

1 Click **Yes**

2 Click **Database Backup**

3 Click **Proceed**

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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
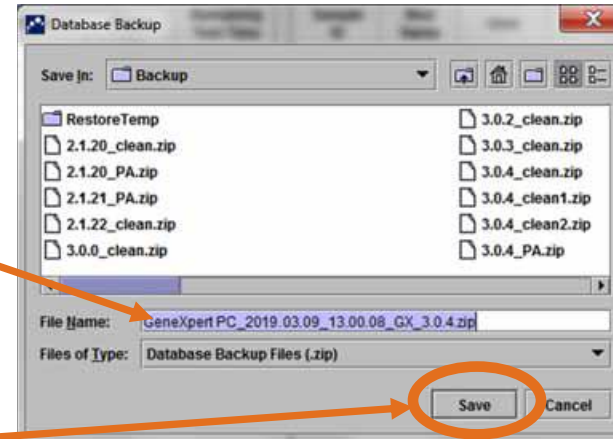
4 Click "**Save**"

5 Click **OK**
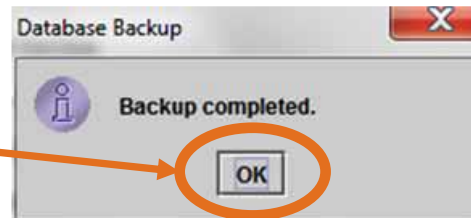
The zip file can only be restored through/ into the GeneXpert® Dx software. It cannot be unzipped or opened on Windows desktop of folders.

How to Create a Backup

The file is saved on the desktop, in the GeneXpert® folder -> Backup subfolder
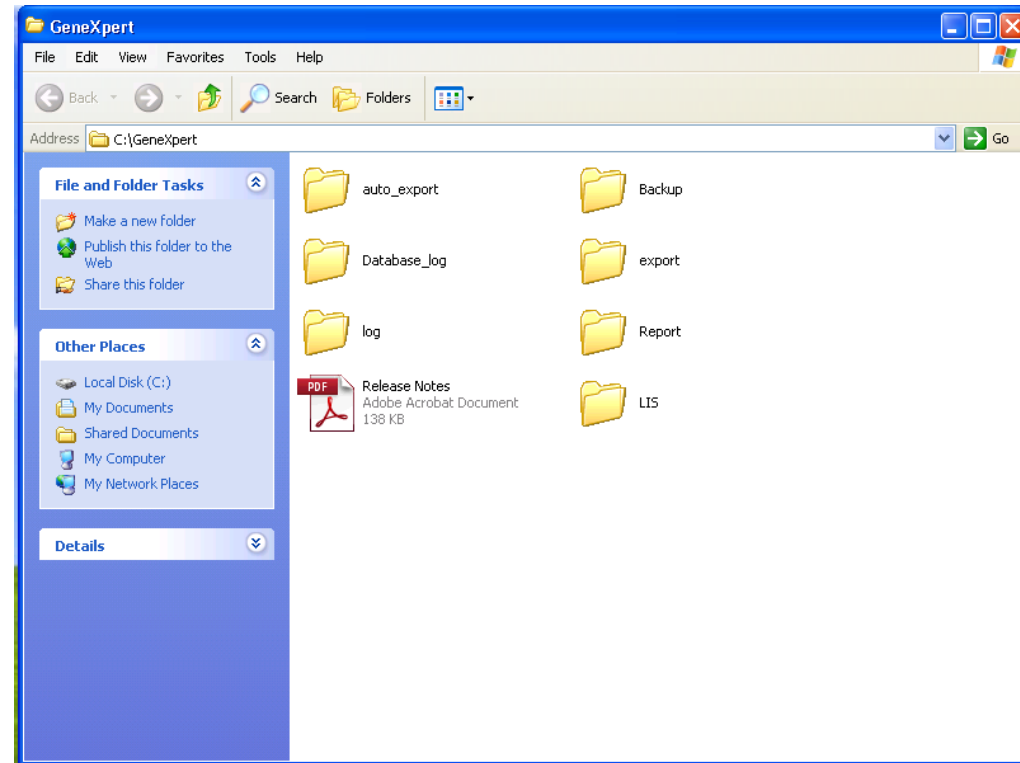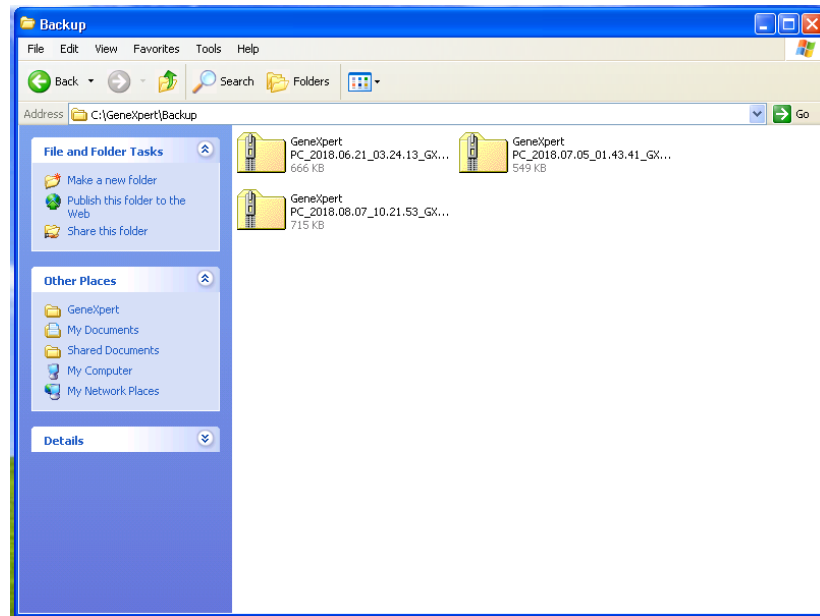
How to Restore Database from a Backup

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

Database Restore

Database Restore will OVERWRITE your current database with a backup database. Click [Proceed] to continue with database restore.

Cancel | Proceed

Select File To Restore The Database

Look In: Backup

706456_LAB_CITY_COUNTRY_2013.08.21_10.55.14_GX_1.4.17.zip

File Name: 706456_LAB_CITY_COUNTRY_2013.08.21_10.55.14_GX_1.4.17.zip

Files of Type: Database Backup Files (.zip)

Open | Cancel

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

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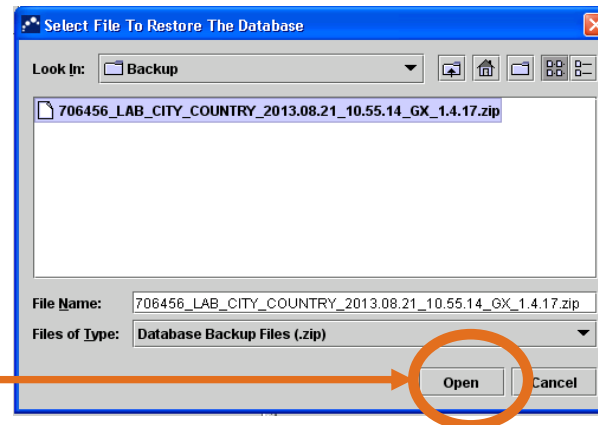
How to Restore Database

A dialog box appears.

Click **Proceed** to create the backup
Click **Cancel** to continue Backup Restore
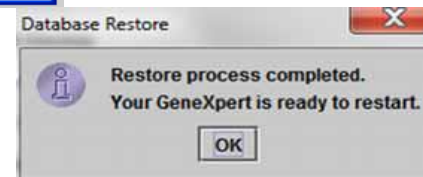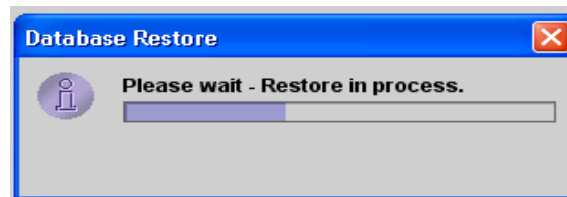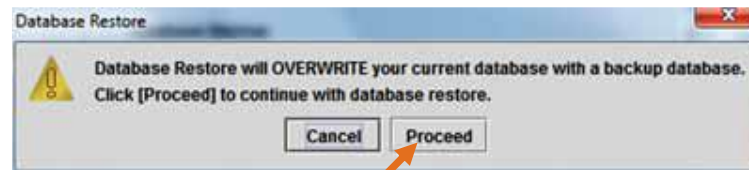
Import the Assay Definition File (ADF)

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.

2 | Click on **Define Assays**

1 | Insert the CD on the Computer CD drive

3 | Click **Import**

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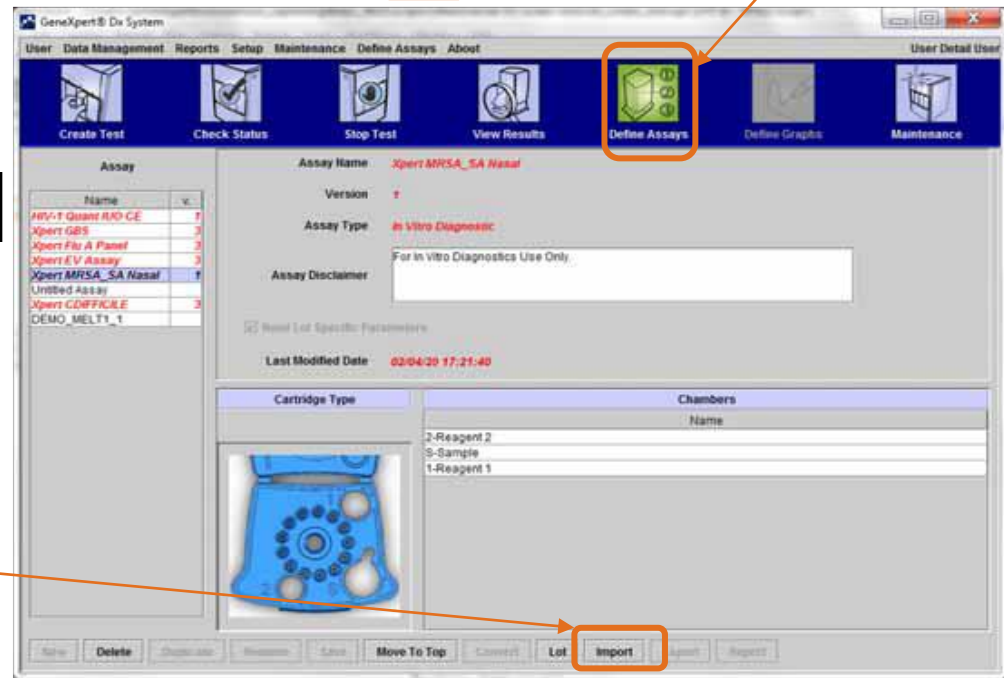
Import the Assay Definition File (ADF)

4 locate the file on the computer
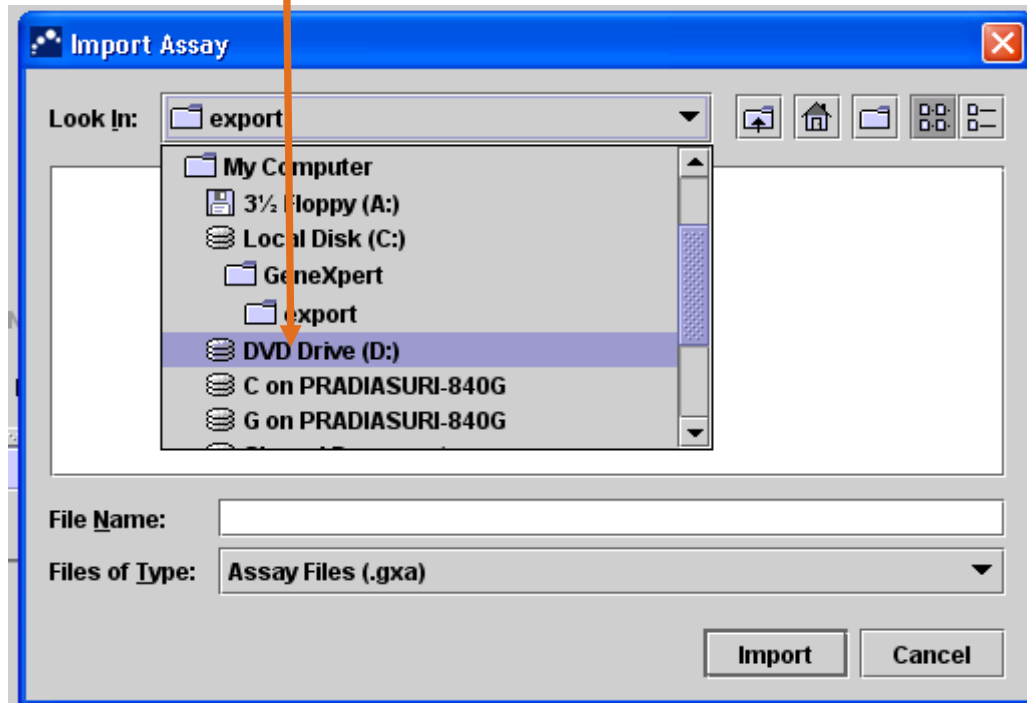
Import the Assay Definition File (ADF)

5 Double click on the GeneXpert® Systems folder.
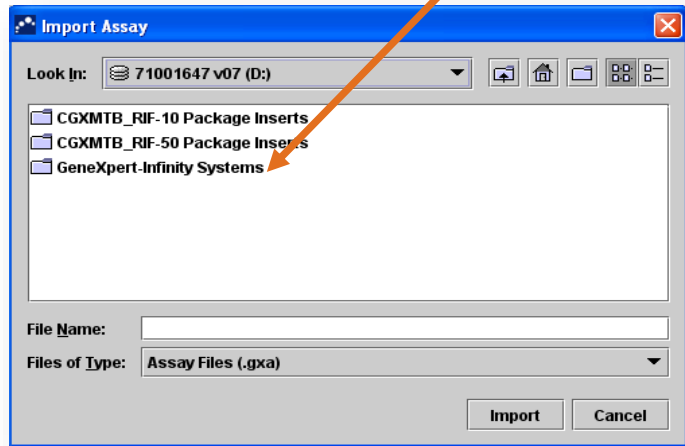
6 Choose the Xpert® MTB-RIF.**gxa/nxa** file

Import Assay

Look In: 71001647 v07 (D:)

- CGXMTB_RIF-10 Package Inserts
- CGXMTB_RIF-50 Package Inserts
- GeneXpert-Infinity Systems

File Name:

Files of Type: Assay Files (.gxa)

Import   Cancel

Import Assay

Look In: GeneXpert-Infinity Systems

Xpert MTB-RIF Assay G4_5.gxa

File Name:

Files of Type: Assay Files (.gxa)

Import   Cancel
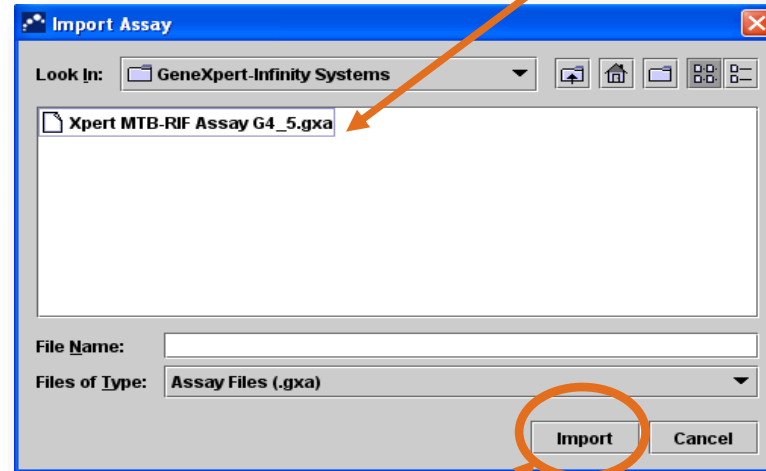
7 Click **Import**

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

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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**)
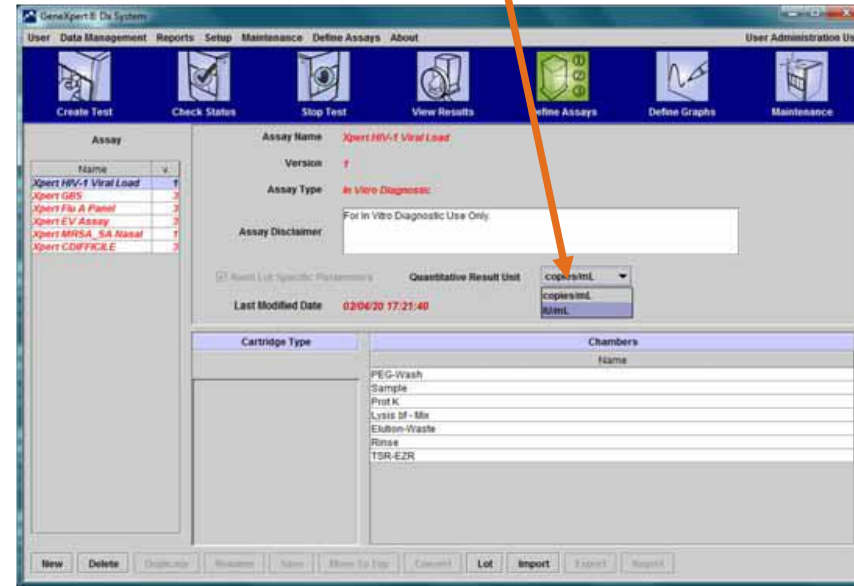
Deleting Assay Definition File (ADF)

- 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.
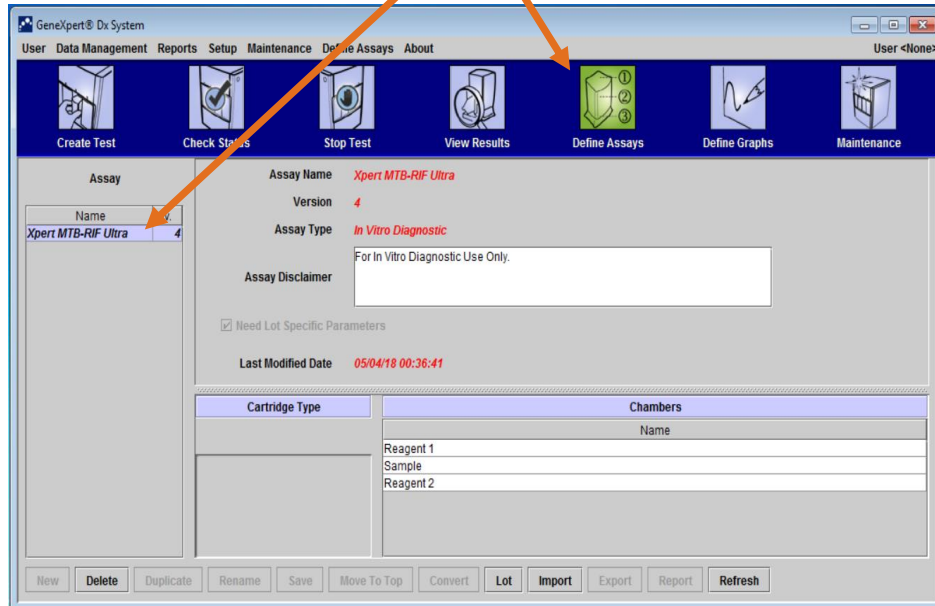
2 select the assay name

1 Click **Define Assays**
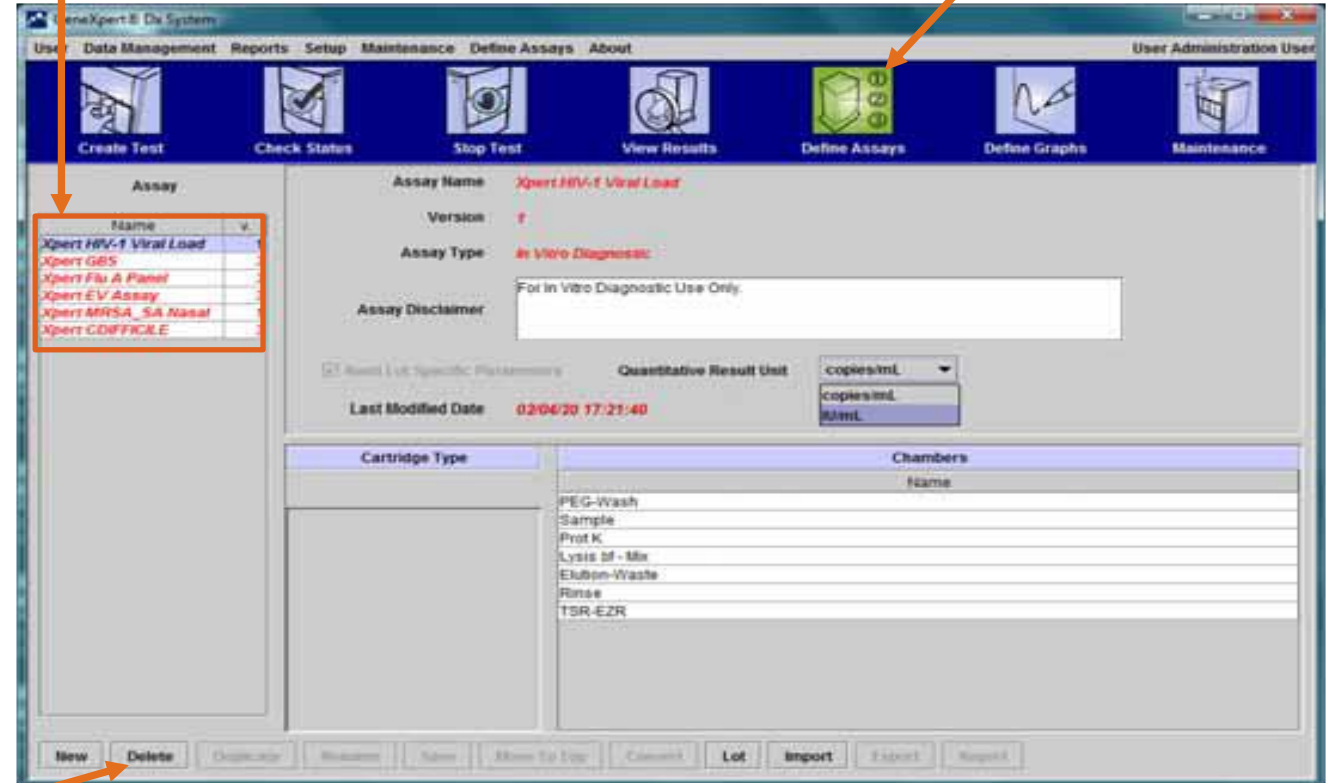
3 Click **Delete**

Import Lot Specific Parameter
(Optional)

Importing Lot Specific Parameters Manually

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Importing Lot Specific Parameters Manually

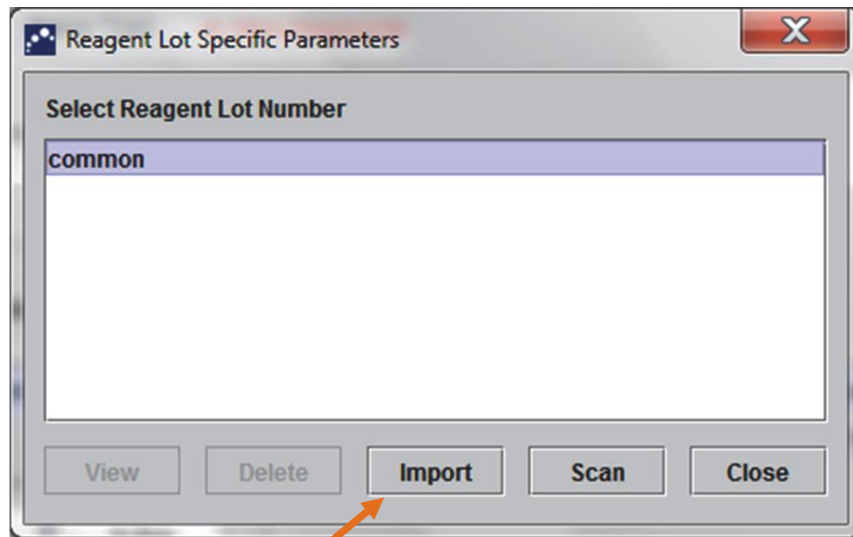**4** Click on **Import**. The Import Reagent Lot Specific Parameters dialog box appears
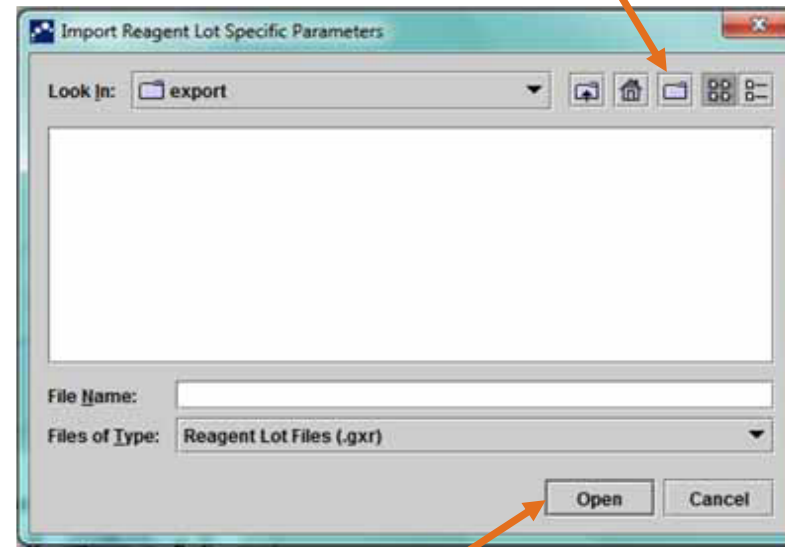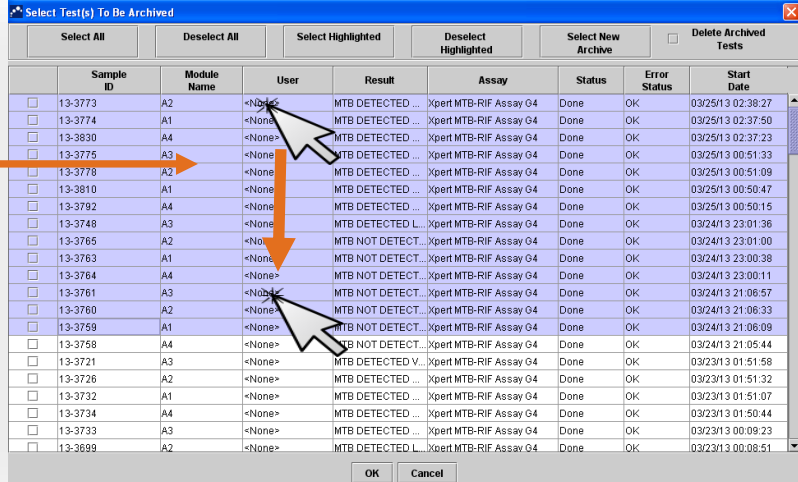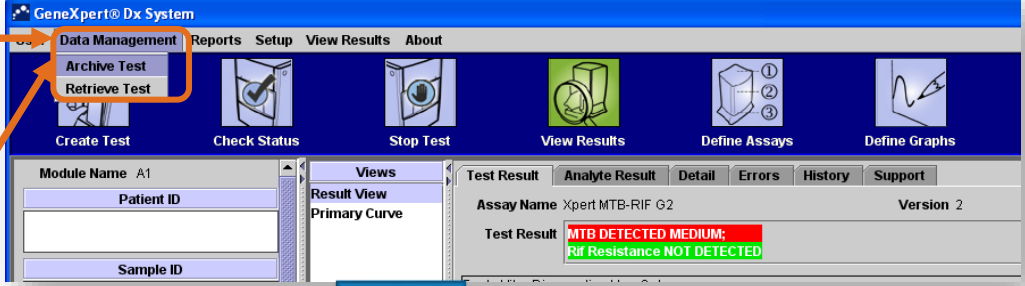
5 Look In: file viewing area, locate and select the **.gxr/.nxr** file obtained from Technical Support previously, and then click **Open**

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.

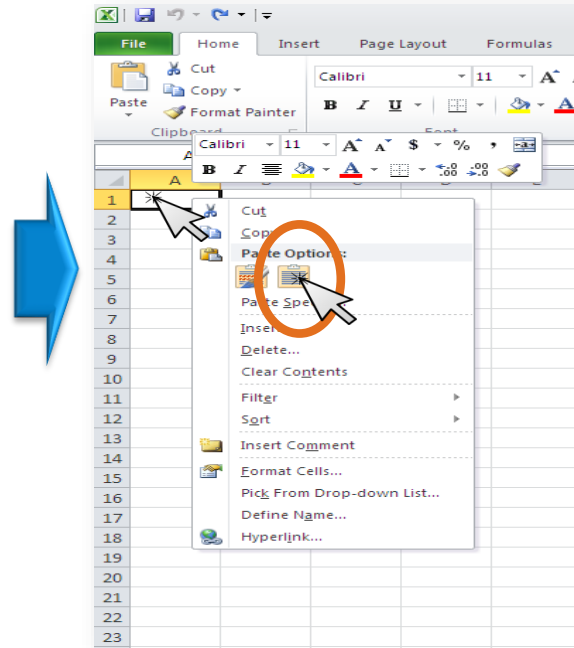**4** While the lines marked press **ctrl + C** at the same time on your keyboard

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How to Copy/Paste Data to OpenOffice Calc

1 | OpenOffice Calc by clicking Start -> All Programs -> OpenOffice Calc
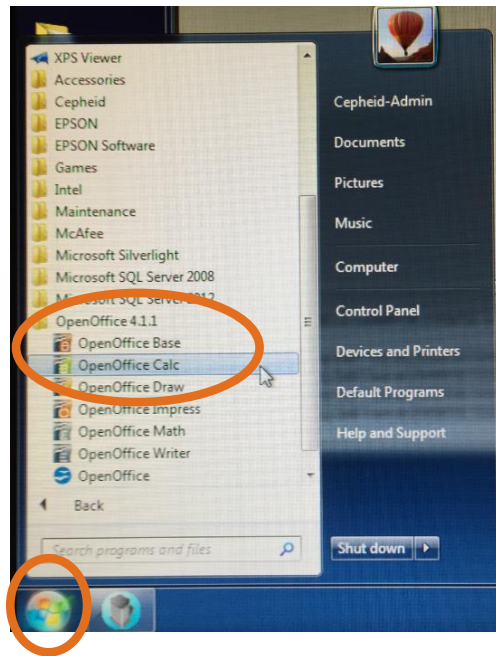
2 | Click the right mouse button and in the menu and choose "Match destination Formatting" → click on it – *see below*

3 | The chosen results will be pasted in excel sheet

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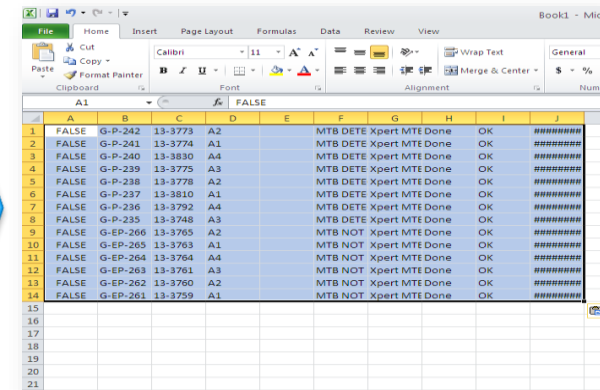
Control Trend Report

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.
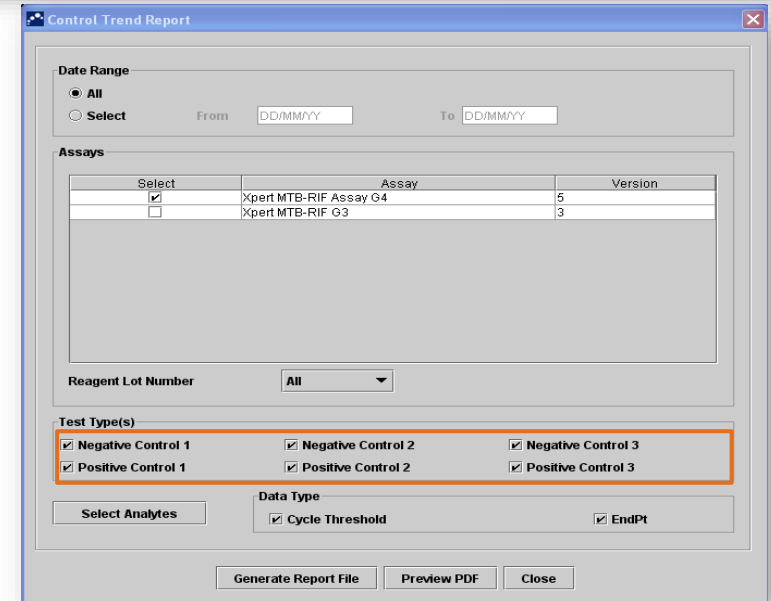
For information on GeneXpert® DX Software

GeneXpert ® Operator Manual ,Software Version 6.4

GeneXpert® Dx System

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
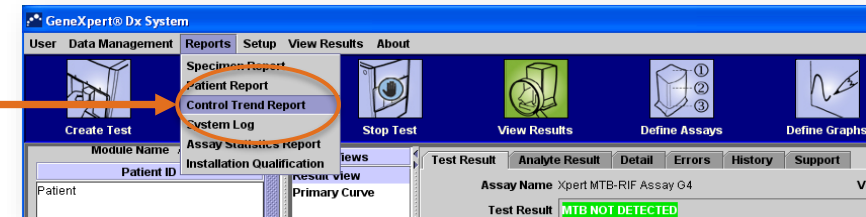
Operator Manual

Software Version 6.4

CE IVD   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

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Thank You

www.cepheid.com