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April 2018

Dear Xpert® MTB/RIF Ultra* Customer,

As part of our on-going product improvement process we are introducing a change to the software (Assay Definition File (ADF)) of the Xpert MTB/RIF Ultra (Catalog No. GXMTB/RIF-ULTRA-10 and GXMTB/RIF-ULTRA-50).

The change indicates the following:

Software

Cepheid implemented a new reflector tube which improves consistency through the manufacturing process. As a result you will need to install a new ADF for Xpert MTB/RIF Ultra.

The new ADF won't be able to co-exist with the existing ADF on GeneXpert® software. For that reason, we would like to **encourage you to clear your existing Xpert MTB/RIF Ultra stock first** before installing the new ADF to avoid wasting unused cartridges.

For installation of the new ADF please refer to the instructions in the GeneXpert DX System and the GeneXpert Infinity System Operator Manuals or to the letter included into the kits that you will receive.

The performance of the assay has not changed. It is the laboratory's responsibility to assess the need for assay re-verification/ re-validation in accordance with country and local laws.

If you are connected to a Laboratory Information System (LIS), please note that LIS result outputs must be verified to be consistent with instrument result outputs.

* CE-IVD. In Vitro Diagnostic Medical Device. Product distribution outside the United States. Product may not be available in all countries



For additional questions regarding this matter, please contact your local Technical Support office at or see contact details in the table below: <http://www.cepheid.com/en/support/support/technical-support-offices>

Region	Telephone	Email
US	+ 1 888 838 3222	techsupport@cepheid.com
Australia and New Zealand	+ 1800 130 821 + 0800 001 028	techsupportANZ@cepheid.com
Brazil and Latin America	+ 55 11 3524 8373	latamsupport@cepheid.com
China	+ 86 021 5406 5387	techsupportchina@cepheid.com
France	+ 33 563 825 319	support@cepheideurope.com
Germany	+ 49 69 710 480 480	support@cepheideurope.com
India, Bangladesh, Bhutan, Nepal, and Sri Lanka	+ 91 11 48353010	techsupportindia@cepheid.com
Italy	+ 39 800 902 567	support@cepheideurope.com
South Africa	+ 27 861 22 76 35	support@cepheideurope.com
United Kingdom	+ 44 3303 332 533	support@cepheideurope.com
Other European, Middle East, and African countries	+ 33 563 825 319 + 971 4 253 3218	support@cepheideurope.com
Other countries not listed	+ 1 408 400 8495	techsupport@cepheid.com

Thank you for your continued business with Cepheid and your patience during this transition.

Kind Regards,

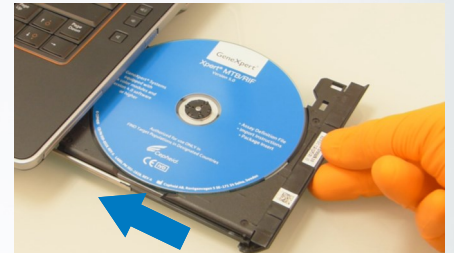


Iain Sharp-Paul
Director, POC & Emerging Markets
Global Marketing
Cepheid

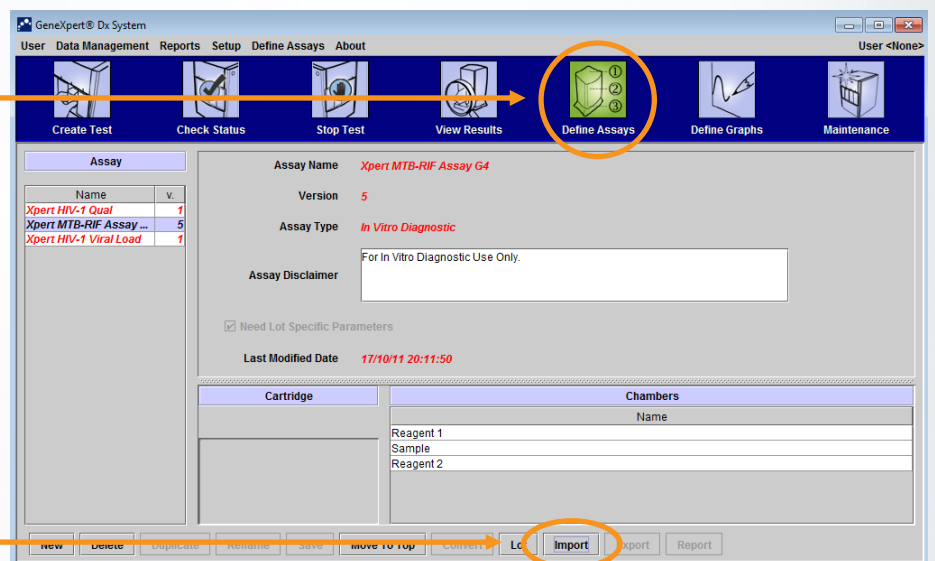
TEST UPDATE

In case of a test update, or if you are starting to use a new assay, the GeneXpert software will request you to import the Assay Definition File (ADF) before running a test. The ADF can be found on the CD-ROM provided in the kit.

- 1 Insert the CD in the computer CD-drive

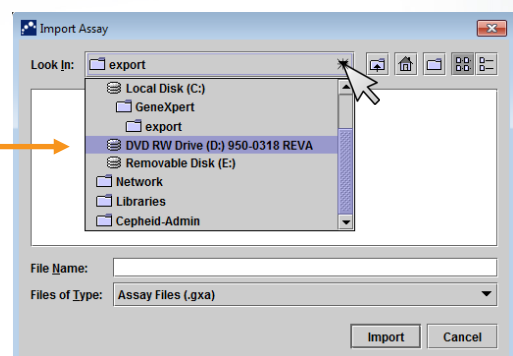


- 2 Click on **Define Assays**



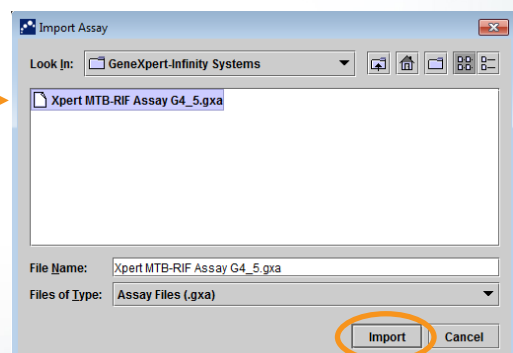
- 3 Click on **Import**

- 4 Locate the DVD RW Drive



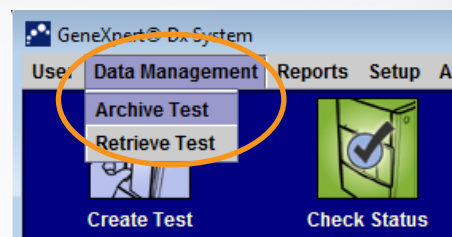
- 5 Import the file

*Note: the file name will vary depending on the assay, the extension must always be *.gxa*

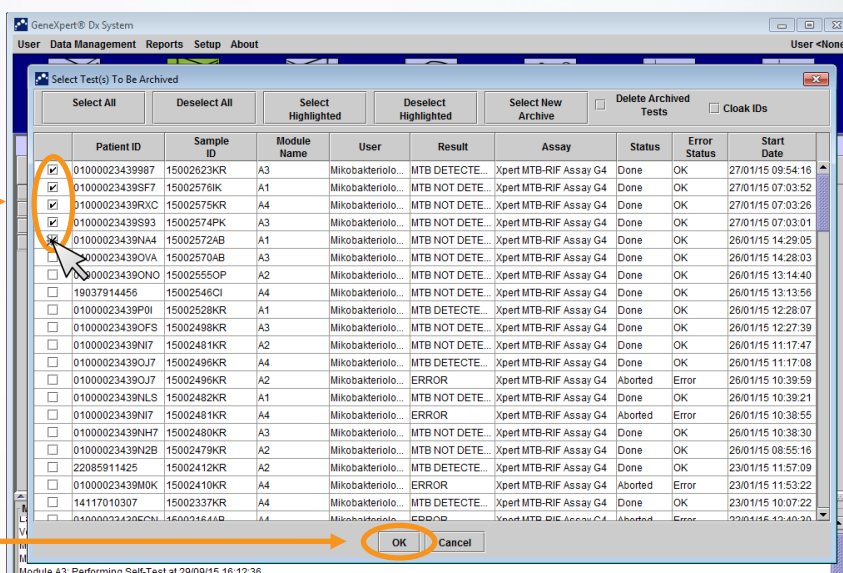


SAVE YOUR DATA

- 1 Choose **Data Management** and **Archive Test**

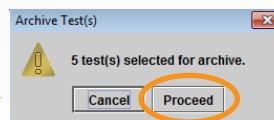


- 2 Choose tests for archiving

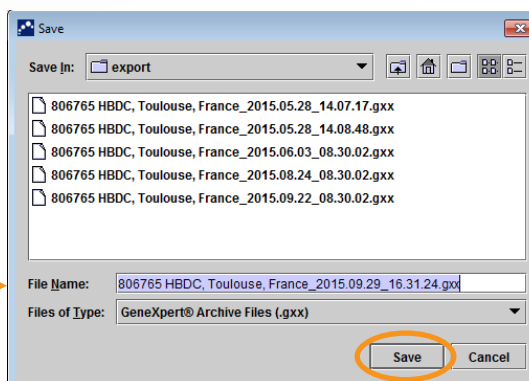


- 3 OK

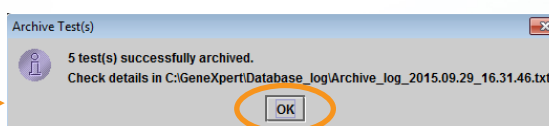
- 4 Proceed



- 5 File name given automatically



- 6 OK

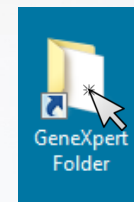


The archived file can be found in the folder C:\GeneXpert\export

It is highly advised to burn (write) your archives on a CD

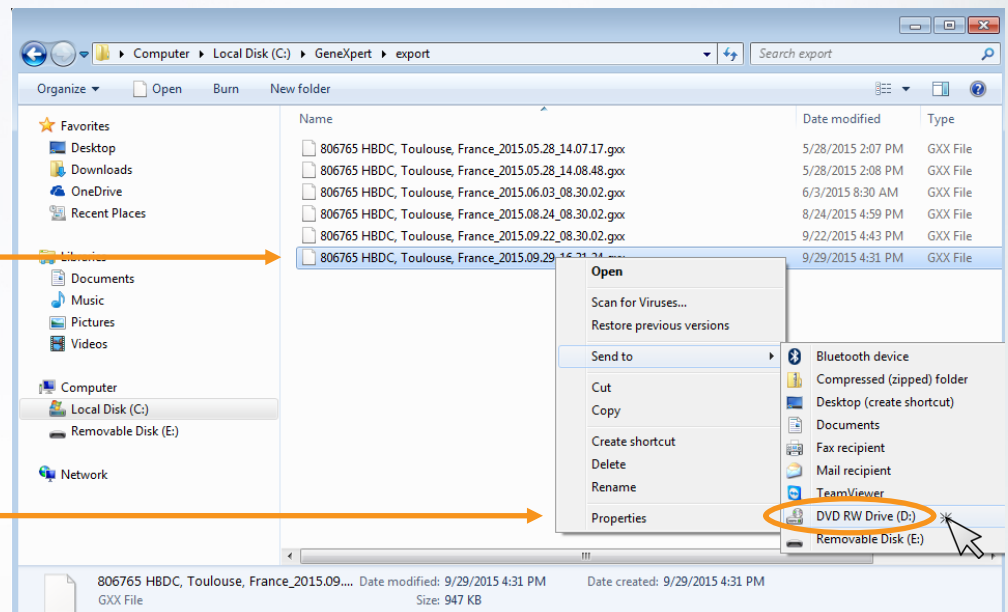
SAVE YOUR DATA ON A CD

- 1 Look up the archived file
GeneXpert folder C:\GeneXpert\export

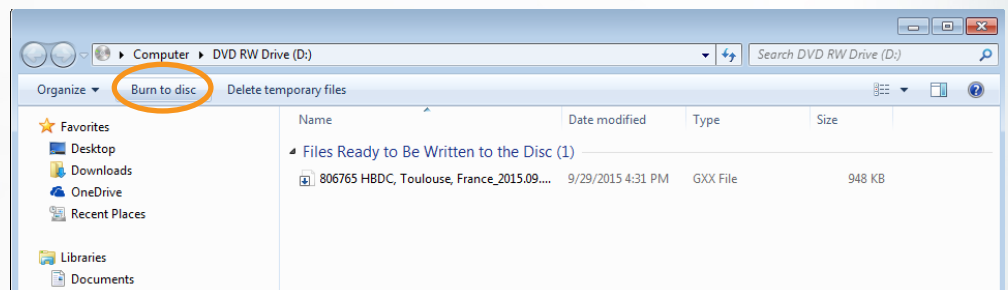


- 2 Right click on the file

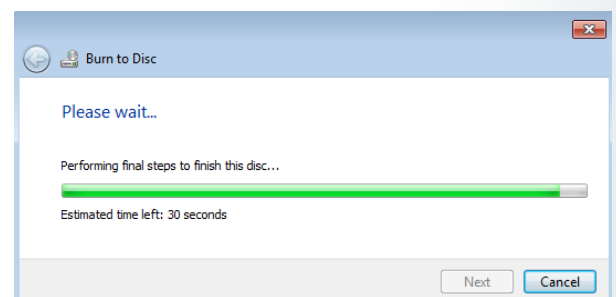
- 3 Send to..
DVD RW Drive



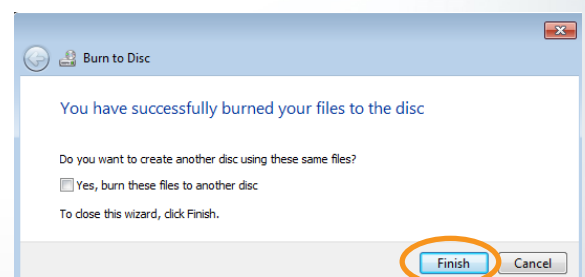
- 4 Choose..
Burn to disc



- 5 Wait...



- 6 Finish



Keep a CD-RW (rewritable) in you institution for this purpose

DO'S AND DON'TS

COMPUTER

DO	DON'T
Install anti-virus software provided by Cepheid or validate your institution's anti-virus with Cepheid	Don't install any non-approved software: this computer is dedicated to GeneXpert
Update the anti-virus regularly	Don't alter the computer, Windows or GxDx software settings
Use CD-RW for transferring data	Don't use USB memory sticks
Verify that the computer's date and time is correct	Don't change the default password "cphd"
Save your data at least once a month	Don't exclude a module from tests without Cepheid's assistance

GENEXPERT

DO	DON'T
Install the GeneXpert on a stable surface	Don't replace any part without Cepheid's assistance
Perform regular maintenance and cleaning	Don't obstruct the fan grid on the back panel of the GX
Wear disposable gloves when working	Don't move the system when tests are in progress
Use the dust cover whenever the system is not working	Don't insert anything in the PCR tube slot except the provided brush for monthly maintenance
Restart the system once a week	Don't put vibrating equipment on the same bench with the GeneXpert

CARTRIDGE

DO	DON'T
Store cartridges at 2-28°C	Don't store cartridges in high or low temperatures
Store cartridges away from daylight	Don't store cartridges containing samples in a fridge
Hold the cartridge by its body	Don't hold the PCR tube when picking up the cartridge
Write the Sample ID on the side of the cartridge	Don't write the Sample ID on the barcode or the lid
Always keep the cartridge on a stable surface	Don't shake the cartridge