

Xpert Check Quick Reference Guide

*For reference only – Refer to the Package Insert for complete details

REQUIREMENTS:

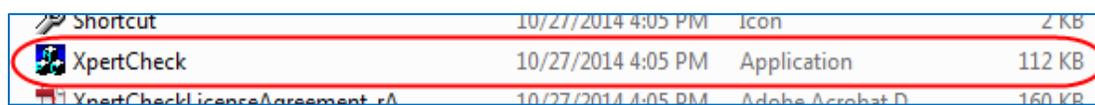
- For use with **6-color modules** and **software versions 4.0 and above**.
- One cartridge is used to check one module.
- Windows Administrator privileges are needed to install the Xpert Check program.
- An **Admin User** login is required on the GxDx software. If your software does not currently require a user to login, you must establish one within the GeneXpert software before starting Xpert Check.
Go to SETUP, USER ADMINISTRATION, select ADD, establish a user and change drop down from **DETAIL to ADMIN**. Refer to Operators Manual.
- Do not run Xpert Check in high temperature environments. The ideal environmental temperature range is **15 – 30°C**. Xpert Check cannot be performed with an internal system temperature > 40°C. Confirm all cooling fans are operating on the GeneXpert system. The internal temperature can be determined as described in the Maintenance section of the Operator Manual.
- Allow the Xpert Check cartridge(s) to come to ambient temperature prior to use. Wait at least 10 minutes after removal from cold storage before using.
- Before running Xpert Check, perform Optics Cleaning according to the Xpert Check Package Insert.
- **Know your Authorized Service Provider (ASP) code**. For example, the ASP code in the United States is **US01**. Contact Cepheid Technical Support if you do not know your ASP code.
- Use the cartridge within 48 hours of opening the foil pouch. Do not use cartridges that have been removed from their foil-wrapped pouches outside of the approved usage interval.
- Do not use cartridges that have passed the expiration date.
- Do not open a cartridge lid until you are ready to perform testing.

INSTRUMENT PREPARATION:

- **GeneXpert:** Exit the Dx software.
- **Xpress:** Exit the Xpress and/or GeneXpert Dx software
- **Infinity-48:** Put instrument into Manual mode and exit the Xpertise software
- **Infinity-80 and 48S:** Exit system software; open the glass doors following the instructions in the user's manual.

XPERT CHECK:

1. Insert Software CD1 into the CD ROM drive; when the pop-up window appears, choose 'Open folder to view files'
 - a. If a pop-up window does not appear, go to the START menu, select COMPUTER, then right-click on the DVD RW Drive and select **Open** to view CD contents.
2. Right-click on the **XPERTCHECK** icon and Choose "**Run as Administrator**". The Xpert Check application will load.



Icon	Name	Date Modified	Type	Size
Shortcut	Shortcut	10/27/2014 4:05 PM	Icon	2 KB
XpertCheck	XpertCheck	10/27/2014 4:05 PM	Application	112 KB
XpertCheckLicenceAgreement_rA	XpertCheckLicenceAgreement_rA	10/27/2014 4:05 PM	Adobe Acrobat D	160 KB

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3. Navigate to the Xpert Check shortcut that has been added to the computer desktop and double-click to open.



4. Read and agree to Terms of Service. CLICK  to proceed. When necessary, CLICK  to go back.
5. Enter Admin User Name and Password credentials for the GeneXpert software to continue.
6. Click on **COLLECT XPERT CHECK DATA** on the Home page.
7. Complete contact information on PAGE 1 (* fields are required).
8. Complete contact information on PAGE 2 (* fields are required). The ASP code is entered here.
9. Open module doors. Wait while modules are being prepared. This may take a few minutes.
10. Select modules for data collection. By default ALL are selected or check marked. It is typical to perform Xpert Check on all modules at the same time. Modules may be de-selected if using Xpert Check for troubleshooting purposes.
11. Confirm module selection.
12. Open Xpert Check cartridge pouch and scan cartridge barcode.
13. Open and close cartridge lid to vent. **THIS IS IMPORTANT.**
14. Wait for light above module to begin blinking green.
15. Load cartridge into appropriate module.
16. Data collection begins after module door is closed and takes approximately 20 minutes.

Note: If all modules are checked at one time, the process will take 20 minutes to complete after the last cartridge is loaded into the last module.

TEST COMPLETION:

1. Xpert Check test completion is successful when all modules are **Green**.
2. If a module Fails (Orange with **RETRY** icon), click on the flashing **RETRY** icon in the lower left and follow the on-screen instructions to use a new cartridge. Be sure to open and close the new cartridge lid.
3. If a module is determined to require service, a **PHONE icon** will be visible in the orange area. Contact CEPHEID Technical Support.

Note: Complete the Xpert Check process if a module retest is requested. This may require loading a second cartridge into a module. Do not abort the Xpert Check process.
4. Xpert Check data analysis occurs automatically for internet-connected systems. If not internet-connected, the software will prompt user to burn data to CD and email/mail to Cepheid for analysis. See steps below.
5. When prompted, remove and discard all used Xpert Check cartridges. Contents of cartridges are non-hazardous. Discard all used and unused materials, including cleaning brushes and cartridges.

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DATA ANALYSIS AND APPLYING ACTIVATION CODE:

INTERNET-CONNECTED

1. Xpert Check data will upload automatically and an ACTIVATION CODE will be returned automatically within 1-2 minutes. ACTIVATION COMPLETE screen will show status.
2. The Xpert Check Summary report can be found at: **C:\GeneXpert\XpertCal\Reports**
3. Restart GeneXpert system and computer. The system will be ready for full operation.

Note: When logging into the GeneXpert software for the first time following Xpert Check, module firmware may be updated.

4. Continue to PRINTING THE XPERT CHECK SUMMARY REPORT section of this guide.

NOT INTERNET-CONNECTED

1. Remove Software CD1.
2. Insert CD2 and write data file to CD2. Follow on screen instructions.
3. Enter system serial number for Disk Title (Example: SN 800000) when prompted.
4. Label the CD with the Date, system SN, Facility, City and State. For fastest turnaround, email the CALIBRATION_INFO.GXC FILE from this CD2 to Service.Calibration@cepheid.com, your ASP, or the local Technical Support office for data quality assurance review and issuance of your Xpert Check code.
 - a. If email is not an option, place the Xpert Check CD2 into the provided CD shipping envelope and mail it to your local Authorized Service Provider (ASP) or the local Cepheid Technical Support office.

NOT INTERNET-CONNECTED – APPLYING ACTIVATION CODE

1. An Activation code will be returned to you via email or mail.
2. Open the Xpert Check application by selecting the icon on the GeneXpert desktop:
3. Click **ENTER XPERT CHECK CODE** to scan barcode or enter code manually.
4. Click the forward arrow at the bottom of the screen to continue. The **Applying Code** screen will appear.

Note: The Xpert Check Activation Code needs to be scanned or entered manually within 45 days after the Xpert Check is performed.

5. After the Xpert Check code has been applied, the **Xpert Check Complete** screen will appear.
6. The Xpert Check Summary report can be found at: **C:\GeneXpert\XpertCal\Reports**

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PRINTING THE XPERT CHECK SUMMARY REPORT:

1. On the computer desktop, open the GeneXpert folder.
2. Open the XpertCal folder, then open the 'reports' folder
3. Open the Summary file (showing date instrument Xpert Check was performed) and print for maintenance records.
4. Modules requiring retesting or service are listed by serial number in Table 1 (examples shown below taken from Xpert Check Package Insert Figure 2-48). When requesting service, provide these listed serial numbers to your ASP or the local Cepheid Technical Support office.

Table 1: Modules Requiring Service

Module Serial Number / Location	Module Status
639563/A2	Skipped and Retest required
639565/A1	Requiring Service

5. 'None' indicates that all modules passed Xpert Check. No further action is required.

Table 1: Modules Requiring Service

Module Serial Number / Location	Module Status
None	Not Applicable

END OF DOCUMENT