

**DECLARAȚIE
privind valabilitatea ofertei**

Către: **CENTRUL PENTRU ACHIZITII PUBLICE CENTRALIZATE IN SANATATE**

Stimați domni,

Ne angajăm să menținem oferta valabilă, **Privind În scopul atribuirii contractelor subsecvente ca urmare a acordului cadru nr. ocds...23328 din 18.10.2024 încheiat prin procedura de achiziție publică nr. ocds-b3wdp1-MD-1720528223328 din 09.07.2024 privind încheierea acordului-cadru - Achiziționarea dispozitivelor medicale conform Programului Național de combaterea hepatitelor virale B, C și D pentru anii 2025-2027**, pentru o durată de 30 (treizeci) zile, respectiv până la data de 10/02/2025 (ziua/luna/anul), și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării 29.11.2024

Digitally signed by Anghel Gabriela-Cristina
Date: 2024.11.29 14:28:28 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ



Cu stimă,
Ofertant/candidat
Gabriela-Cristina Anghel
(semnătura autorizată)

Tip.doc. 1 :

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LEI: Una Suta Douazeci si Noua Mii Doua:

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DECLARAȚIE
privind neîncadrarea în situațiile prevăzute la art. 19 din
Legea nr.131/2015 privind achizițiile publice

Către: **CENTRUL PENTRU ACHIZITII PUBLICE CENTRALIZATE IN SANATATE**

Stimați domni,

Subsemnata Gabriela Anghel, în calitate de ofertant la procedura nr. [ocds-b3wdp1-MD-1731504710848](#), privind **achiziția În scopul atribuirii contractelor subsecvente ca urmare a acordului cadru nr. ocds...23328 din 18.10.2024 încheiat prin procedura de achiziție publică nr. ocds-b3wdp1-MD-1720528223328 din 09.07.2024 privind încheierea acordului-cadru - Achiziționarea dispozitivelor medicale conform Programului Național de combaterea hepatitelor virale B, C și D pentru anii 2025-2027**, declar pe proprie răspundere că:

- Medist Grup SRL, nu se află în niciuna din situațiile de excludere menționate la art.19. În cazul în care situația se va modifica, vom informa imediat autoritatea contractantă.

Data completării 29.11.2024

Cu stimă,
Ofertant/candidat
Gabriela-Cristina Anghel
(semnătura autorizată)

EU DECLARATION OF CONFORMITY

	Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA Single Registration Number (SRN): US-MF-000010979
EC REP	Cepheid Europe SAS Vira Solelh 81470 Maurens-Scopont France Single Registration Number (SRN): FR-AR-000001368
Device Trade Name	Xpert® Check
Basic UDI-DI	081164701-XPERTCHECK-3B
REF	XPRTCHECK-CE-5
Device Intended Purpose	Intended Use Xpert Check is part of a check, verification, and hardware test system for GeneXpert modules. Xpert Check is used in GeneXpert DX, GeneXpert Xpress and Infinity systems, and cannot be used in the GeneXpert Omni system. Xpert Check is used to check the optical system, verify the thermal system and perform a series of system-level tests to ensure full system functionality within Cepheid's instrument servicing specifications. One Xpert Check cartridge is usually used to check a single module in conjunction with the Xpert Check software. In certain cases where a retest is required, multiple cartridges may be necessary to test a module. Intended User / Environment Xpert Check is intended to be performed by trained users where a GeneXpert System is installed

We, as the manufacturer of the device take sole responsibility for and hereby declare that the above mentioned device meets the provisions of the following Regulation:

Regulation EU 2017/746 on <i>in vitro</i> Diagnostic Medical Devices	
Risk Class	A ☒ B ☐ C ☐ D ☐
Classification Rule	Annex VIII, Implementing Rule 1.3. Accessory Annex VIII, Rule: 5 (b) Accessory to instrument

Conformity Assessment Route	☐ Annex IX(I) Quality Management System ☐ Annex IX(II) Technical Documentation ☐ Annex X Type Examination ☐ Annex XI Production Quality Assurance ☒ Annex II & III (class A only)
Common Specification	Not applicable
Notified Body	Not applicable
Notified Body Number	Not applicable
Certificate(s)	Not applicable

Signed on behalf of Cepheid by:



Signature



Date of Issue

Lena KirsellSenior Manager of Regulatory Affairs
Regulatory Affairs**Place of Issue:** Solna, Sweden

EC DECLARATION OF CONFORMITY**Manufacturer:**

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Product name: Xpert® HBV Viral Load
Catalogue number(s): GXHBV-VL-CE-10

We, the manufacturer, hereby declare, under our sole responsibility, that the product(s) stated above conforms to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (IVDD), (LVFS 2001:7).

Product classification: Annex II, list A

Conformity Assessment route: Annex IV

Notified Body: BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands
Notified Body number: 2797

EC Certificate – Full Quality Assurance: CE 708525

EC Design-Examination Certificate: CE 708526

Signed on behalf of Cepheid AB by:



Signature

Lena Kirsal

Senior Manager of Regulatory Affairs



Date of Issue

Place of Issue: Solna, Sweden

EC DECLARATION OF CONFORMITY**Manufacturer:**

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Product name: Xpert® HCV Viral Load
Catalogue number(s): GXHCV-VL-CE-10

We, the manufacturer, hereby declare, under our sole responsibility, that the product(s) stated above conforms to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (IVDD), (LVFS 2001:7).

Product classification: Annex II, list A

Conformity Assessment route: Annex IV

Notified Body: BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands
Notified Body number: 2797

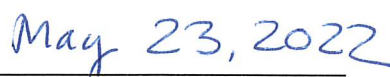
EC Certificate – Full Quality Assurance: CE 708525

EC Design-Examination Certificate: CE 708527

Signed on behalf of Cepheid AB by:



Signature
Lena Kirsell
Senior Manager of Regulatory Affairs



Date of Issue

Place of Issue: Solna, Sweden

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Cepheid
904 Caribbean Drive
Sunnyvale
California
94089
USA

Holds Certificate Number:

MD 774674

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, Development, Manufacture and Distribution of Nucleic Acid Test Kits and Reagents used for Monitoring and Patient Management. Design, Development, Service, Installation, Distribution and Refurbishment of Analyzers, Control of Manufacture of Analyzers used for Monitoring and Patient Management.

Transfer from: LRQA Limited

Certificate identity number: 10454286

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2022-08-02

Latest Revision Date: 2022-08-02

Effective Date: 2022-08-02

Expiry Date: 2024-12-18

Page: 1 of 4



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Certificate No: **MD 774674**

Location	Registered Activities
Cepheid 904 Caribbean Drive Sunnyvale California 94089 USA	Design, Development, Manufacture and Distribution of Nucleic Acid Test Kits and Reagents used for Monitoring and Patient Management. Design, Development, Service, Installation, Distribution and Refurbishment of Analyzers, Control of Manufacture of Analyzers used for Monitoring and Patient Management.
Cepheid 632 Caribbean Drive Sunnyvale California 94089 USA	Distribution of in-vitro diagnostics and Analyzers used for Monitoring and Patient Management.
Cepheid 1339 Moffet Park Drive Sunnyvale California 94089 USA	Service and Support, General Administration of in-vitro diagnostics and Analyzers used for Monitoring and Patient Management.
Cepheid 1327 Chesapeake Terrace Sunnyvale California 94089 USA	Design and Development of in-vitro diagnostics and Analyzers used for Monitoring and Patient Management.
Cepheid 1315 Chesapeake Terrace Sunnyvale California 94089 USA	Design and Development of in-vitro diagnostics and Analyzers used for Monitoring and Patient Management.
Cepheid 918 Caribbean Drive Sunnyvale California 94089 USA	Manufacture of in-vitro diagnostics used for Monitoring and Patient Management.

Original Registration Date: 2022-08-02

Latest Revision Date: 2022-08-02

Effective Date: 2022-08-02

Expiry Date: 2024-12-18

Page: 2 of 4

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Information and Contact:

BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780

BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.

Certificate No: **MD 774674**

Location	Registered Activities
Cepheid 1324 Chesapeake Terrace Sunnyvale California 94089 USA	Design and Development, Purchasing, General Administration of in-vitro diagnostics and Analyzers used for Monitoring and Patient Management.
Cepheid 7000 Gateway Blvd. Newark California 94560 USA	Manufacture of in-vitro diagnostics used for Monitoring and Patient Management.
Cepheid 6601 Overlake Pl. Newark California 94560 USA	Manufacture of in-vitro diagnostics used for Monitoring and Patient Management.
Cepheid 44509 Pacific Commons Blvd. Fremont California 94538 USA	Distribution of in-vitro diagnostics and Analyzers used for Monitoring and Patient Management.
Cepheid AB Röntgenvägen 5 SE-171 54 Solna Sweden	Design, Development, Manufacture and Distribution of Nucleic Acid Test Kits and Reagents used for Monitoring and Patient Management.
Cepheid Mätarvägen 45 196 37 Kungsängen Sweden	Distribution of in-vitro Diagnostics used for Monitoring and Patient Management.
Cepheid 225 North Guild Avenue Lodi California 95240 USA	Manufacture of Plastic Components used for Monitoring and Patient Management

Original Registration Date: 2022-08-02

Latest Revision Date: 2022-08-02

Effective Date: 2022-08-02

Expiry Date: 2024-12-18

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BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.

Certificate No: **MD 774674**

Location	Registered Activities
Cepheid 121 N Guild Ave. Lodi California 95240 USA	Manufacture of in-vitro diagnostics used for Monitoring and Patient Management.
Cepheid 850 East Thurman Road Lodi California 95240 USA	Manufacture of Plastic Components used for Monitoring and Patient Management



Original Registration Date: 2022-08-02
Latest Revision Date: 2022-08-02

Effective Date: 2022-08-02
Expiry Date: 2024-12-18

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BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.

Xpert Check Package Insert

REF **XPERTCHECK-CE-5**

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Xpert Check is a trademark of Cepheid.

Adobe[®] and Reader[®] are registered trademarks of Adobe Systems Incorporated.

Windows[®] is a registered trademark of Microsoft Corporation.



Cepheid
904 Caribbean Drive
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Preface

About This Document

The *Xpert Check Package Insert* provides instructions on running Xpert Check software for checking module performance.

Safety Information

Read and understand any safety information presented in this document before you begin operating the instrument. Make sure you follow the precautionary statements presented in this guide:

Caution



Indicates that damage to the system, loss of data, or invalid results could occur if the user fails to comply with the advice given.

Important

Highlights information that is critical for the completion of a task or the optimal performance of the system.

Note

Identifies information that applies only in special cases.

Related Documents

For other information outside the scope of this document, see the following publications:

- GeneXpert Dx Operator Manual
- GeneXpert Xpress User's Guide
- Infinity Operator Manual

Cepheid Headquarters Locations

Corporate Headquarters	European Headquarters
Cepheid 904 Caribbean Drive Sunnyvale, CA 94089-1189 USA	Cepheid Europe SAS Vira Solelh 81470 Maurens-Scopont France
Telephone: +1 408.541.4191	Telephone: +33.563.825.300
Fax: +1 408.541.4192	Fax: +33.563.825 301
www.cepheid.com	www.cepheidinternational.com

Technical Assistance

Before contacting Cepheid Technical Support, collect the following information:

- Product name
- Serial number of the instrument
- Error messages (if any)
- Software version and, if applicable, Computer Service Tag number

Contact Information

United States

Telephone: + 1 888.838.3222
Email: techsupport@cepheid.com

France

Telephone: + 33 563.825.319
Email: support@cepheideurope.com

Contact information for all Cepheid Technical Support offices is available on our website: www.cepheid.com/en/CustomerSupport.

Table of Symbols

Symbol	Meaning
	Catalog number
	<i>In vitro</i> diagnostic medical device
	Batch code
	Do not reuse
	This type of symbol indicates a Warning or Caution for which there is no other identified symbol. Read the instructions following the symbol to avoid injury or equipment damage.
	Consult instructions for use
	Manufacturer
	Country of manufacture
	Contains sufficient for <n> tests
	Expiration date
	Control
	CE marking - European Conformity
	Authorized representative in the European Community
	Temperature limitation
	This type of warning label indicates a potential biological hazard risk. Biological samples such as tissues, body fluids, and blood of humans and/or animals have the potential to transmit infectious diseases. Follow your local, state/provincial, and national safety regulations for handling and disposing the samples.



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1 Introduction

Important

Read and understand this entire document before performing the data collection procedure.

1.1 Proprietary Name

Xpert Check

1.2 Common or Usual Name

Xpert Check

1.3 Intended Use

The Xpert Check kit is part of a check, verification, and hardware test system for GeneXpert modules. The Xpert Check kit is used in GeneXpert DX, GeneXpert Xpress and Infinity systems, and cannot be used in the GeneXpert Omni system. The Xpert Check kit is used to check the optical system, verify the thermal system and perform a series of system-level tests to ensure full system functionality within Cepheid's instrument servicing specifications. One Xpert Check cartridge is usually used to check a single module in conjunction with the Xpert Check software. In certain cases where a retest is required, multiple cartridges may be necessary to test a module.

1.4 Summary and Explanation

The GeneXpert (GX) module is the basis for all GeneXpert instrument systems worldwide. Cepheid recommends that the system be checked for proper operation on an annual basis. Based upon the usage and care of each system, checks may be recommended more frequently. The system is designed to detect module issues with the internal assay controls.

The Xpert Check kit includes reagents for the optical checking and performance verification of the module. Probe Check Controls (PCCs) verify reagent rehydration, PCR tube filling in the cartridge, probe integrity, and reagent stability. Thermal performance is verified via proprietary thermal probe chemistries, and module hardware performance is tested and verified by a suite of subsystem-specific tests which exercise all critical elements of the GX module.

The Xpert Check process consists of two phases. The first phase is the execution of module testing using the cartridges contained within this kit. The second phase consists of a Cepheid Quality Assurance Review, followed by the issuance of an Xpert Check code to complete the Xpert Check process. **The Xpert Check process is not complete until this code is applied to the system.**

1.5 Reagents and Instruments

1.5.1 Materials Provided

The Xpert Check kit contains the following:

Table 1-1. Kit Contents

Description	Quantity
Xpert Check cartridges with integrated reaction tubes	5 per kit
Each cartridge contains the following materials:	
• Bead 1	1 per cartridge
• Reagent 1	1.0 mL per cartridge
I-CORE Lens Cleaning Brush	4 per kit
PI/Software (P/N 950-0413)	1 per kit
Data CD	1 per kit

Note

Safety Data Sheets (SDS) are available at www.cepheidinternational.com under the **SUPPORT** tab.

1.5.2 Storage and Handling



- Store the Xpert Check cartridges at 2-28 °C. Wait at least 10 minutes after removal from cold storage before using, to allow a cartridge to reach ambient temperature.
- Use the cartridge within 48 hours of opening the foil pouch.
- Discard 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.
- The cartridge lid must be opened (vented) prior to use of the cartridge; however, no sample is required for testing.
- Discard all used and unused materials, including cleaning brushes and cartridges once the Xpert Check session is completed.

Note

Contents of cartridges are non-hazardous.

1.5.3 Materials Required but Not Provided

- GeneXpert Dx, GeneXpert Xpress or Infinity System with Cepheid-supplied computer and barcode scanner.
- GeneXpert instrument.

1.6 Limitations

- For use with GeneXpert modules (running GeneXpert Dx software version 4.4, or higher, GeneXpert Edge v1.0, GeneXpert Xpertise v6.3 or higher and GeneXpert Xpress software version 5.1 or higher). 4-color GeneXpert modules cannot run Xpert Check and must be tested by Cepheid Service. Xpert Check 1.5a is not compatible with systems running Windows XP.
- Use of the Xpert Check kit does not guarantee that the GeneXpert instrument will be free of hardware failures, nor does it take the place of a Cepheid Service Agreement.

1.7 Warnings and Precautions

After January 14, 2020, Microsoft will no longer provide security updates or support for PCs running Windows 7. It is recommended that you upgrade to Windows 10.

Important

Please contact:

<https://www.microsoft.com/en-us/microsoft-365/windows/end-of-windows-7-support> for Windows 7 support information.

In addition, please contact your local Cepheid Technical Support if you have questions about using Windows 7.

- Even though Xpert Check cartridges do not contain hazardous chemicals, you should always follow your institution's safety procedures for working with chemicals.
- Do not add a sample or other reagents to the Xpert Check cartridges.
- Do not use a cartridge that has a damaged reaction tube.
- Do not use cartridges from visibly damaged or compromised foil pouches.
- Contact your local Cepheid Technical Support office for replacement of damaged kit contents.
- Do not use a cartridge if it is dropped.
- Each single-use Xpert Check cartridge is used to process one test. Do not reuse spent cartridges.
- Each cleaning brush is intended for use in a single module. Do not re-use brushes in multiple modules.

②

- Do not open a cartridge package or break the lid seal until you are ready to perform testing.
- Allow the Xpert Check cartridge to come to ambient temperature prior to use if it has been placed in cold storage. Wait at least 10 minutes after removal from cold storage before using.
- Do not store single cartridges. Cartridges left over from an Xpert Check session, including pouched/unopened cartridges should be discarded along with spent cartridges.
- Do not use cartridges whose shelf life has expired. The system will detect expired cartridges and abort the test.
- Once a cartridge barcode has been scanned, do not substitute another cartridge in place of the scanned cartridge.
- If using an internet-enabled Xpert Check, it is recommended that up-to-date anti-virus software be installed on the desktop or laptop computer with updated virus definition files, prior to executing Xpert Check.
- Prior to running Xpert Check, ensure that the environmental operating temperature is within the correct limits (15 °C–30 °C). Xpert Check will render a system's modules unavailable if the internal temperature is above 40 °C. The internal temperature can be verified in the Maintenance section of the GeneXpert DX, Infinity or GeneXpert Xpress software. Do not proceed under these conditions.
- Xpert Check expects the same computer to be used throughout the entire process. The computer installed with the GeneXpert system should be used, and not another computer from a different GeneXpert system.
- The Xpert Check code will expire if not applied within 45 days of completion of running Xpert Check.

1.8 Chemical Hazards

According to the Globally Harmonized System for Classification and Labeling (GHS) Regulation, this material is not considered hazardous.

1.9 Assistance and Contact Information

For a complete listing of Cepheid technical support, service support, sales support, and headquarters contacts, please see [Technical Assistance](#), in the Preface of this document.

1.10 Software Buttons, Icons and Symbols

Table 1-2. Software Buttons, Icons and Symbols

Symbol	Definition
	Information. Touch or click this icon to obtain additional information. Displays the Information Key workspace screen which has an explanation of the various module icon displays.
	Continue. This icon is located at the bottom of most screens. Touch or Click this icon to advance the display to the next screen.
	Continue to End. Touching or clicking this icon moves the user to the last screen.
	Exit. Exits the Xpert Check application.
	About. Brings up the About screen which shows the name of the software, the software version number, copyright notice, etc.
	Home. Go to the Home screen.
	Repeat/Retry. Retry loading an Xpert check cartridge to attempt to check a module that has had an unsuccessful test of a minor nature or if the cartridge has not been vented by the user. Used on the 'Check Test' screen.
	Back. Touching or clicking this icon takes the user to the previous screen.
	Cancel. Cancel the current operation. In most cases this will mean going back to the previous screen. In some cases, it may mean going back to the screen before the one that started the current operation.

Table 1-2. Software Buttons, Icons and Symbols

Symbol	Definition
	Select none of the modules for check. Deselects all modules for checking. If you only want to check a few modules, you may deselect ALL of them, and then reselect only the ones you wish to check.
	Select all of the modules for checking. The default setting for the system.
	Connectivity Status. Indicates the system is able to reach the Xpert Connectivity Center.
	Connectivity Status. Indicates the system is not able to reach the Xpert Connectivity Center.
	Module unsupported for Xpert Check. Skip the current module and do NOT attempt to check the current module.
	Module selected for Xpert Check. Module will be included when Xpert Check is run.
	Skip Current Module. Skip the current module and do not attempt to Xpert Check the current module. Used on the 'Load Xpert Check Cartridges' screen.
	Skip Remaining Modules. Skip all the remaining modules and do NOT attempt to Xpert Check them. Used on the 'Load Xpert Check Cartridges' screen.

Table 1-2. Software Buttons, Icons and Symbols

Symbol	Definition
	Module not selected for Xpert Check. Module will not be included when Xpert Check is run.
	Module unavailable for Xpert Check. Module will not be included when Xpert Check is run.
	Indicates a module with data collection in progress.
	Indicates data collection complete.
	Retest required. Indicates an incomplete Xpert Check data collection. A message will notify the user that the test must be rerun. A further message will indicate if the existing cartridge can be reused for the test or if a new cartridge must be used.
	Service required. Contact the Cepheid Authorized Service Provider (ASP) or your local Cepheid Technical Support office.

Table 1-2. Software Buttons, Icons and Symbols

Symbol	Definition
	Lost communication. Contact the Cepheid Authorized Service Provider (ASP) or your local Cepheid Technical Support office.
	Burn. Burn a CD containing the collected Xpert check information (for users without an active internet connection).
	Collect Xpert Check Data. Leads the user through the Xpert Check data collection process.
	Enter Xpert Check code. Go to the 'Enter Xpert Check Code' screen.
	Xpert Check Status. Go to the Xpert Check Status screen to review Xpert Check status.
	Upload Xpert Check Data File. Go to the 'Upload Xpert Check Code Data File' screen.
	Upload Xpert Check Data CD. Go to the 'Upload Xpert Check Code Data CD' screen.
	Write Xpert Check Code. Write an Xpert Check Code to a file.
	Read Xpert Check Code. Open a file to read the Xpert Check code.
	Scan. Turn the barcode scanner on, and accept the next scanned input.
	View and Print. Launch the Adobe Reader so you can view and then print a PDF file.

2 Procedure

2.1 System Preparation

Note

Prepare the system for Xpert Check by following one of the four procedures listed in this section for the GeneXpert Dx, GeneXpert Xpress, the Infinity-48, Infinity 48s or the Infinity-80.

Important

Authorized Service Providers (ASPs) who perform Xpert Check but won't be on-site when the Xpert Check code numbers come back (non-internet connection sites), should leave the user name and password for the users to log in later to enter the codes (see [section 2.3.2](#)).

2.1.1 GeneXpert Dx Preparation

1. Create an Administrator or Basic level User Name and Password in the GeneXpert software if one does not exist. Xpert Check requires this logon credential to be established prior to starting.
2. Have your Authorized Service Provider (ASP) code available before continuing to the next steps.
3. Exit the GeneXpert Dx software.
4. Go to [Section 2.2, GeneXpert Dx, GeneXpert Xpress and Infinity Optics Cleaning](#).

2.1.2 GeneXpert Xpress Preparation

1. Create an Administrator or Basic level User Name and Password in the GeneXpert Xpress software if one does not exist. Xpert Check requires this logon credential to be established prior to starting.
2. Have your Authorized Service Provider (ASP) code available before continuing to the next steps.
3. Exit the GeneXpert Xpress software.
4. Go to [Section 2.2, GeneXpert Dx, GeneXpert Xpress and Infinity Optics Cleaning](#).

2.1.3 Infinity-48 Preparation

1. Create an Administrator or Basic level User Name and Password in the GeneXpert software if one does not exist. Xpert Check requires this logon credential to be established prior to starting.
2. Have your Authorized Service Provider (ASP) code available before continuing to the next steps.
3. Restart the Xpertise software and switch the system from Automatic mode to Manual mode. Follow the instructions in the GeneXpert Infinity System Operator Manual for the Infinity-48.
4. Go to [Section 2.2, GeneXpert Dx, GeneXpert Xpress and Infinity Optics Cleaning](#).

2.1.4 Infinity-48s or Infinity-80 Preparation

1. Create an Administrator or Basic level User Name and Password in the GeneXpert software if one does not exist. Xpert Check requires this logon credential to be established prior to starting.
2. Have your Authorized Service Provider (ASP) code available before continuing to the next steps.
3. Exit the Infinity System software.
4. Open the glass doors following the instructions in the *Infinity Operator Manual*.
5. Go to [Section 2.2, GeneXpert Dx, GeneXpert Xpress and Infinity Optics Cleaning](#).

2.2 GeneXpert Dx, GeneXpert Xpress and Infinity Optics Cleaning

This procedure describes the method for removing dust and tube debris from the surface of rod lenses of the excite and detect blocks for GeneXpert Dx, GeneXpert Xpress and Infinity modules prior to performing the Xpert Check procedure.

Materials Required or Recommended for Cleaning

- 300-8330 –Applicator brush (Quantity of four Included in the Xpert Check kit)
- Disposable gloves

Estimated Cleaning Time: 30 Seconds per module.

2.2.1 Lens Cleaning Procedure

1. Select the module to be checked and manually open the door of the module.
2. If necessary, remove the cartridge from the module.

Biological Risks



Remove the cartridge from the GeneXpert modules prior to cleaning. Failure to remove a cartridge could result in personnel being exposed to biological hazards and/or liquid biological materials spilling into the instrument and causing damage to the instrument.

3. Locate the brush provided in the Xpert Check kit (see [Figure 2-1](#)).

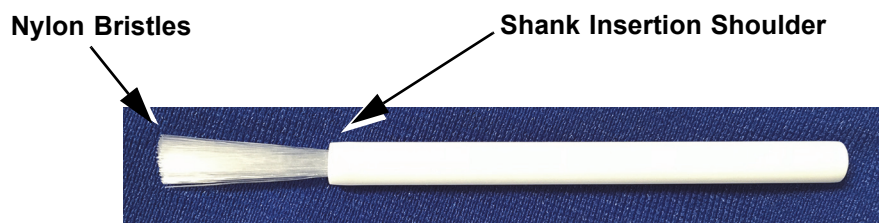


Figure 2-1. Lens Cleaning Brush (300-8330)

Note

The brush is designed so that it will easily insert into the I-CORE slit and make contact with the rod lenses of the excite and detect blocks.

Biological Risks



Make sure you wear disposable gloves for the cleaning process. Wearing gloves prevents you from being exposed to biologically hazardous materials.

4. Wearing disposable gloves, insert the brush into the I-CORE slit in a tilted manner up to the shank insertion shoulder, as shown in [Figure 2-2](#).

Note

Make sure that all the bristles are fully inserted (up to the shoulder of the plastic shank of the brush) so that it does not cause unnecessary damage to the brush.

Caution



Do not insert any objects into the I-CORE slit except the provided brush. Inserting any other object may damage the I-CORE.

Caution



Do not apply any solution (such as ethanol or bleach) onto the brush bristles. The brush must be completely dry when inserting it into the I-CORE slit.

Important

The brush is intended for single-use and should not be used on more than one module. Use a new brush for each module to be cleaned.

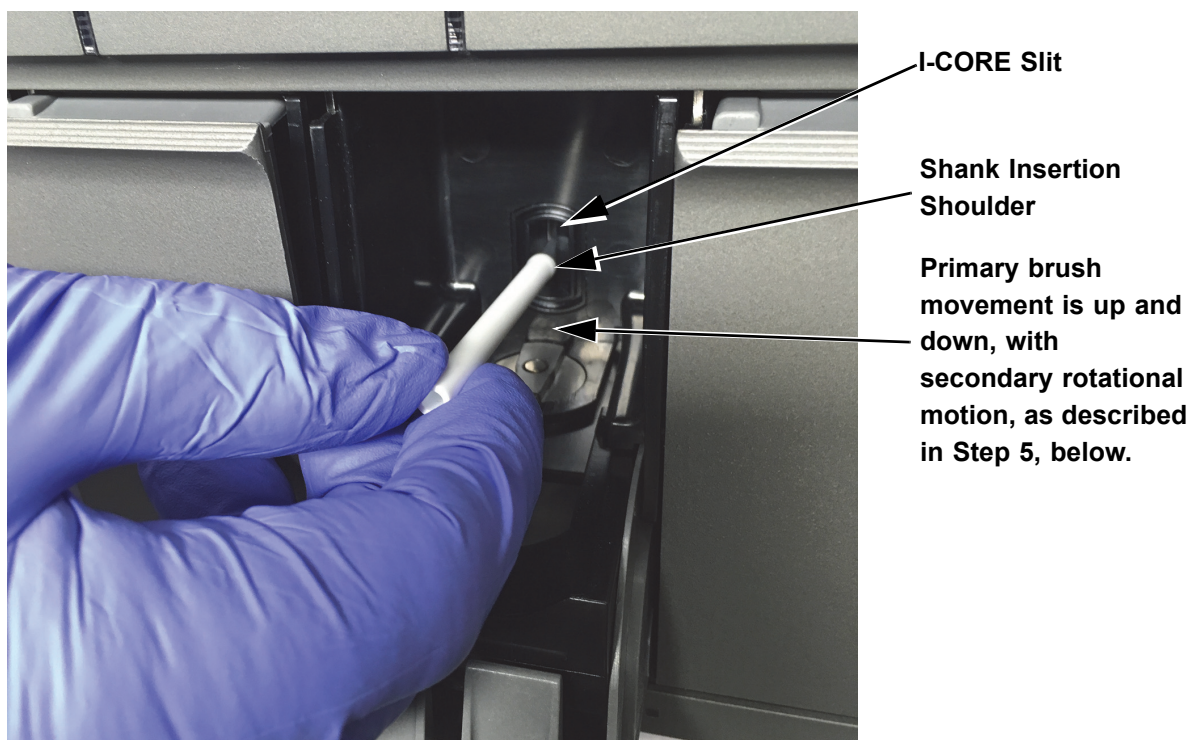


Figure 2-2. Inserting the Cleaning Brush into the I-CORE Slit

5. Insert the brush into the I-CORE slit completely up to the plastic shank (shoulder) of the brush. Hold the brush firmly in the I-CORE slit, and perform cleaning of the rod lenses as described below. The entire cleaning process should take approximately 30 seconds per module.

Note

Cleaning is done by moving the brush in an up and down direction within the I-CORE slit. Brush rotation, even if it has to be done, is not the main action that results in optics cleaning.

- A. Begin by brushing from the top of the I-CORE slit to the bottom, making sure to apply a uniform pressure when brushing from the top to the bottom of the I-CORE slit. This will ensure that most of the tube debris and dust is brushed off from the surface of the lenses.
- B. Rotate the brush from left to right and back again, approximately 180°.
- C. Brush once more from the top of the I-CORE slit to the bottom.
- D. Rotate the brush again from left to right and back again, approximately 180°.
- E. Finally, brush again from the top of the I-CORE slit to the bottom.
6. When lens cleaning is complete, remove and discard the used brush and gloves as hazardous waste.

Important

Dispose of gloves and brushes according to your institution's safety policies and procedures for hazardous waste.

7. Proceed to [Section 2.3, Data Collection Procedure: GeneXpert Dx, GeneXpert Xpress and Infinity](#).

2.3 Data Collection Procedure: GeneXpert Dx, GeneXpert Xpress and Infinity

Important

Before collecting data, be sure to prepare the system for checking as described in [Section 2.1, System Preparation](#). Internet-connected users should verify their system's connectivity status prior to beginning the Xpert Check process.

Note

Throughout this procedure, when making an onscreen button or icon selection, use the touchscreen on the GeneXpert Xpress system by touching the button or icon with your finger. When using the GeneXpert Dx or Infinity system, use a mouse to select, by clicking the desired button or icon.

Note

Use care in inserting CD1 into the DVD drive. Be sure the CD is fully seated in the tray before closing the drive door.

1. Place Software CD1 in the computer connected to the GeneXpert Dx. For the GeneXpert Dx system using an external DVD drive and for the GeneXpert Xpress and Infinity systems, connect the DVD drive following the instructions in the GeneXpert Dx Operator Manual, the GeneXpert Xpress User's Guide or the Infinity Operator Manual, and insert the CD into the DVD drive.
2. For a GeneXpert Xpress system, follow the procedure in Step A., for GeneXpert Dx and Infinity, follow the procedure in Step B.:
 - A. **GeneXpert Xpress** On the computer desktop, touch and hold the **Computer** icon and a drop-down menu will appear. Touch **Open**, then touch and hold the applicable drive letter for your DVD drive. Touch **Open** from the drop-down menu, and the files located on the CD will then be displayed. Find, touch and hold the **XpertCheck.exe** application, and when the drop-down menu appears, touch **Run** to install as administrator. When the software has been installed, a "wrench" icon will appear on the desktop.
 - B. **GeneXpert Dx and Infinity:** On the computer desktop, right-click the

Note

The software may take some time to load from the CD.

Computer icon and a drop-down menu will appear. Click **Open**, then right-click on the applicable drive letter for your DVD drive. Select **Open** from the drop-down menu, and the files located on the CD will then be displayed. Find and right-click the **XpertCheck.exe** application, and when the drop-down menu appears, click **Run** to install as Administrator. When the software has been installed, a "wrench" icon will appear on the desktop.

Note

The software may take some time to load from the CD.

3. Depending on your system, either touch or double-click the "wrench" icon to launch the Xpert Check program.

4. The License Agreement screen appears first. Use the scroll bar to read through the entire document. You will be asked to select (touch or click) the check box (bottom of the screen) to verify that you have read and agree to the License Agreement before continuing. See [Figure 2-3](#).

Note

The Xpert Check software runs on Windows 7 or Windows 10. The screens shown in this manual are from Xpert Check software running on Windows 7. Screens for Xpert Check software running on Windows 10 will be similar.

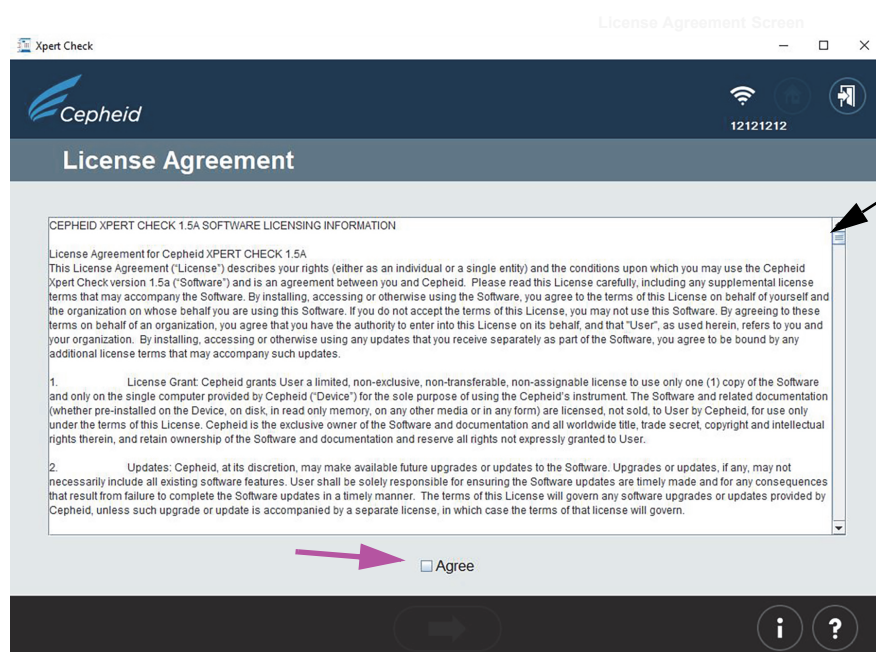
After January 14, 2020, Microsoft will no longer provide security updates or support for PCs running Windows 7. It is recommended that you upgrade to Windows 10.

Important

Please contact:

<https://www.microsoft.com/en-us/microsoft-365/windows/end-of-windows-7-support> for Windows 7 support information.

In addition, please contact your local Cepheid Technical Support if you have questions about using Windows 7.



Scroll down to read the entire document.

Note: A copy of the License Agreement is located on CD1.

Figure 2-3. License Agreement Screen

5. After agreeing to the License Agreement, the Login screen will appear. Log in with your GeneXpert Dx, GeneXpert Xpress or Infinity designated Administrator level **USER NAME** and **PASSWORD** (previously assigned to you by your system administrator). After entering your login information, touch or click the forward arrow button at the bottom of the screen to advance to the Xpert Check Home screen. See [Figure 2-4](#).

Note

On the GeneXpert Xpress system, touching any field for inputting usernames, passwords, text, etc., will cause a virtual keyboard to appear for data entry. To close the keyboard, touch the **X** key in the upper right corner of the keyboard.

Note

The user name and password are the same ones you used for the GeneXpert Dx, GeneXpert Xpress or Xpertise software.

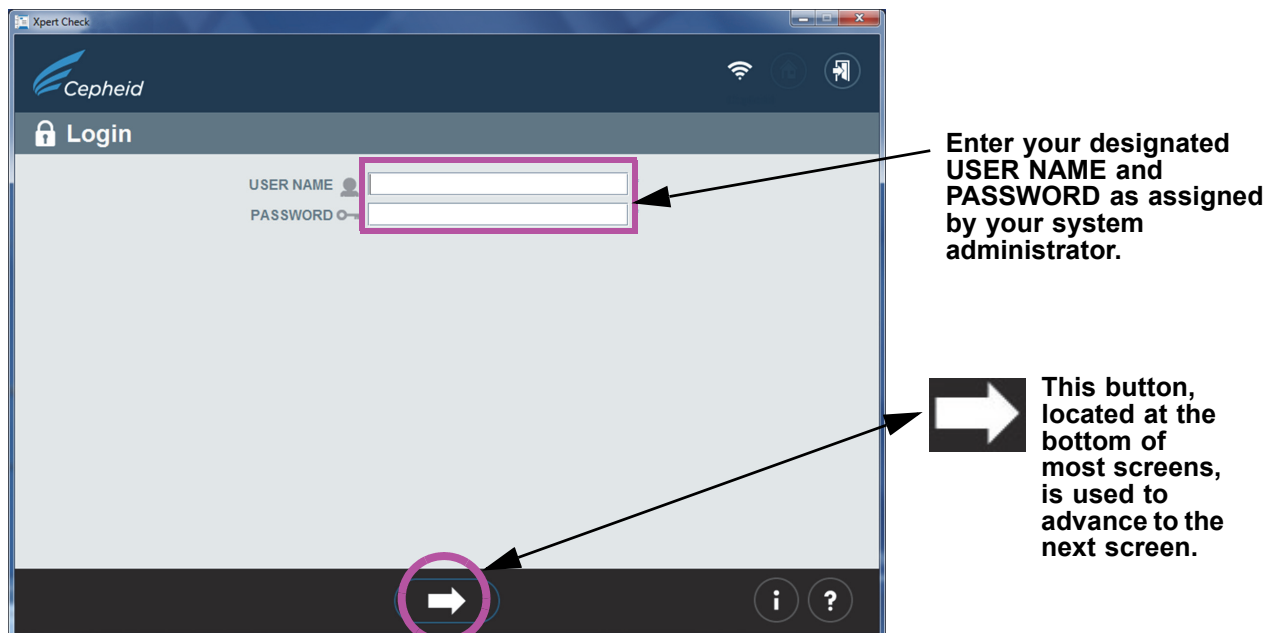


Figure 2-4. Xpert Check Login Screen

In case of a login error, the following screen will appear. See [Figure 2-5](#).

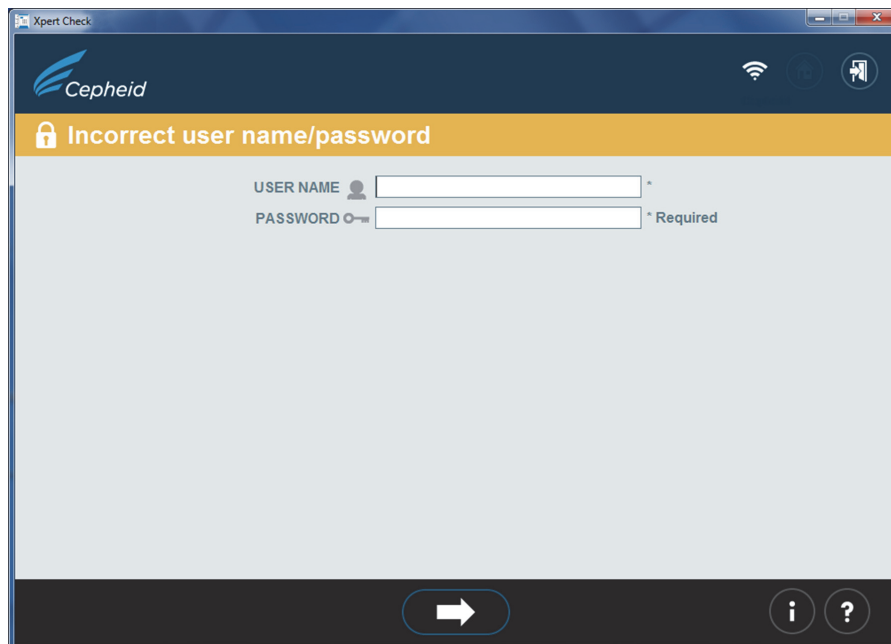


Figure 2-5. Login Error Screen

6. If a login error occurs, examine the **USER NAME** and **PASSWORD** entries for errors. If necessary, reenter the information and retry. After entering your login information, touch or click the forward arrow button at the bottom of the screen to advance to the Xpert Check Home screen.
7. Obtain a sufficient number of cartridges for the number of modules to be tested.

Important

Do not open cartridge packages until you are ready to scan the cartridge barcode (in Step 17).

Note

When determining the number of cartridges that will be needed for this test, the user should be aware of the number of modules that they will be checking.

8. Touch or click the **Collect Xpert Check Data** icon on the Home screen (See Figure 2-6). After a few seconds, the first Contact Information screen (Figure 2-7) will appear.

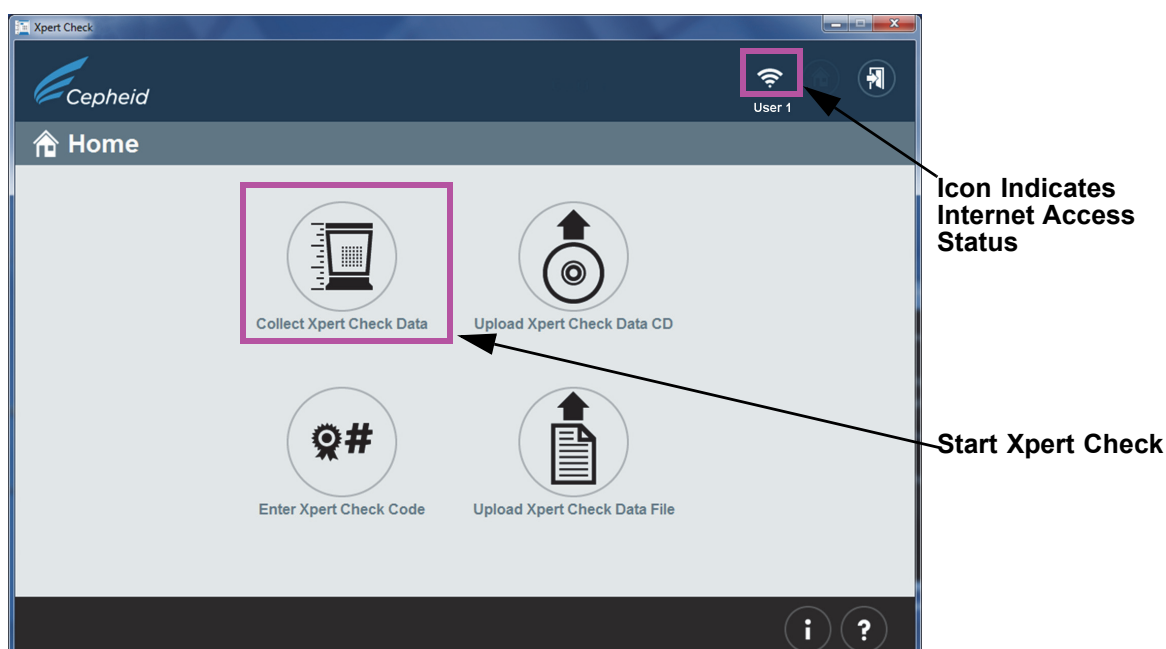


Figure 2-6. Home Screen

9. When the first of two Contact Information screens appear (see Figure 2-7 and Figure 2-8), fill out the fields in the two screens. Use the large navigation arrows at the bottom of the screens to move between the two screens.

Note

GeneXpert Xpress: When you touch a field, an onscreen keyboard appears for entering data.

Note that fields marked with “*” (at the right of the entry area) are mandatory fields.

Figure 2-7. Contact Information Screen - Page 1

In this mandatory field, enter your Authorized Service Provider's ID code. The ID code is four characters, as described in the note below.

Clicking on this icon will take the user back to the first Contact Information screen

Clicking on this icon will take the user to the Open Module Doors screen

Figure 2-8. Contact Information Screen - Page 2

Note

The ASP-provided ID code for the Service Provider on the Contact Information screen consists of four characters. (As examples: US01, 1203, etc.)

10. When all information has been entered, touch or click the forward arrow button at the bottom of page 2 of the Contact Information screen. The Open Module Doors

screen will appear. See [Figure 2-9](#). Manually open all module doors to enable cartridge loading.

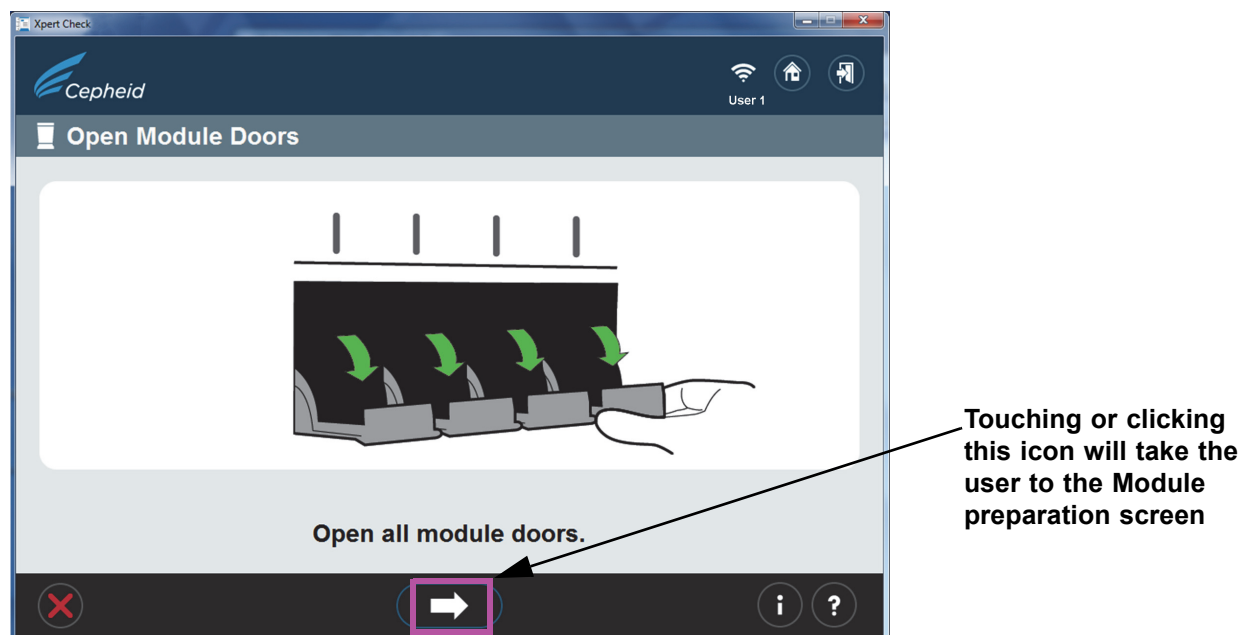


Figure 2-9. Open Module Doors Screen

11. After opening all the module doors, touch or click the forward arrow button at the bottom of the screen. The Module preparation screen may appear, showing the message **Wait while modules are being prepared.** (See [Figure 2-10](#).)

Important

Note that the Module preparation screen will appear only if the firmware in the modules is not 3.0.3. The screen indicates that the software is upgrading/downgrading the firmware to the modules. The next screen you see will be the screen shown in [Figure 2-11](#), the Select Modules screen.

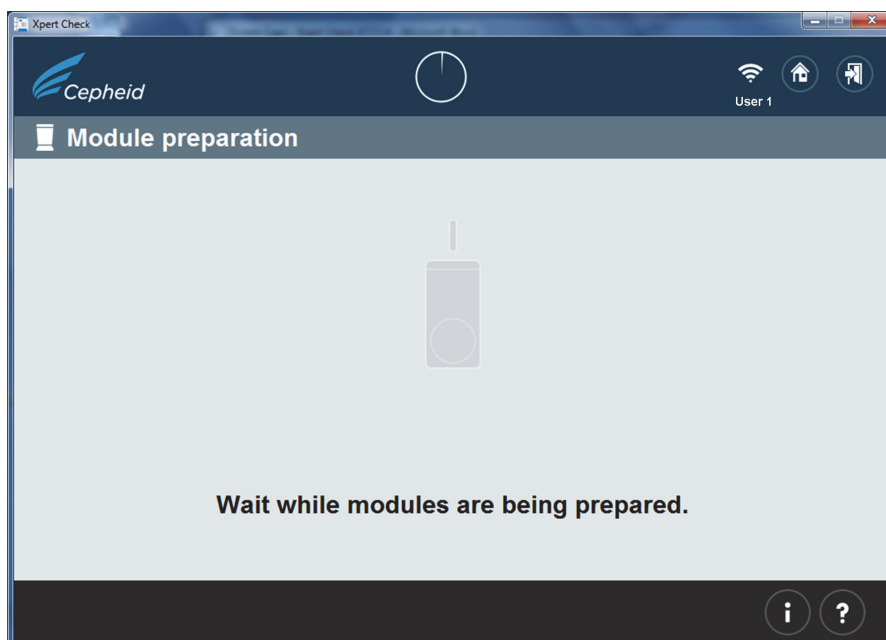


Figure 2-10. Module preparation Screen

12. Follow the on-screen software instructions in [Figure 2-11](#). By default, all detected modules will be marked as selected for checking.

On this screen, the user can touch or click individual module icons to exclude the modules from being checked, if required. The module icons will disappear as they are excluded.

Note

For excluded modules (not selected for checking), the door position (open or closed) does not matter.

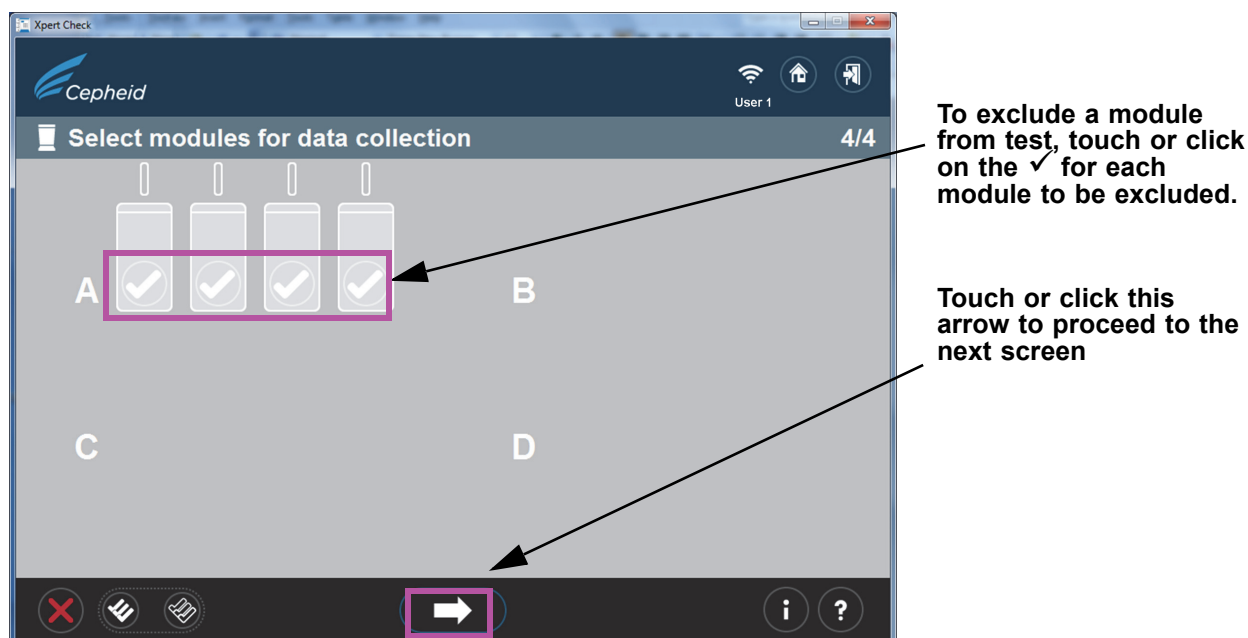
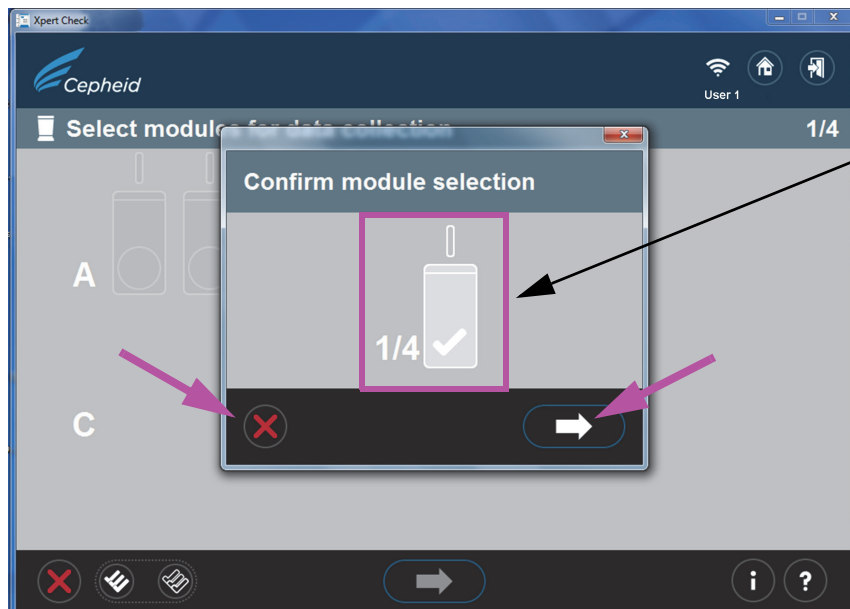


Figure 2-11. Select modules for data collection Screen

Important

GeneXpert-XVI and Infinity systems only: When selecting modules on screen, make a note of which module lights are blinking on the system as you select each bank, to ensure cartridges are placed in the correct modules for testing.

13. After confirming the module selection shown in [Figure 2-11](#), touch or click the white arrow at the bottom of the screen overlay, to begin scanning cartridges. If the module selection shown is incorrect, touch or click the red **X** at the bottom left corner of the screen to return to the Select Modules screen and change your selection. See [Figure 2-12](#).



Module selection is shown here. In this example, one module is selected for checking.

Figure 2-12. Confirm module selection Screen

14. In case of an error in the preceding step, in which either no modules have been selected, or all modules have been excluded, one of the following screens will appear (Figure 2-13). Follow the on-screen instructions to select a module, or start over by returning to the Home screen or exiting the program.

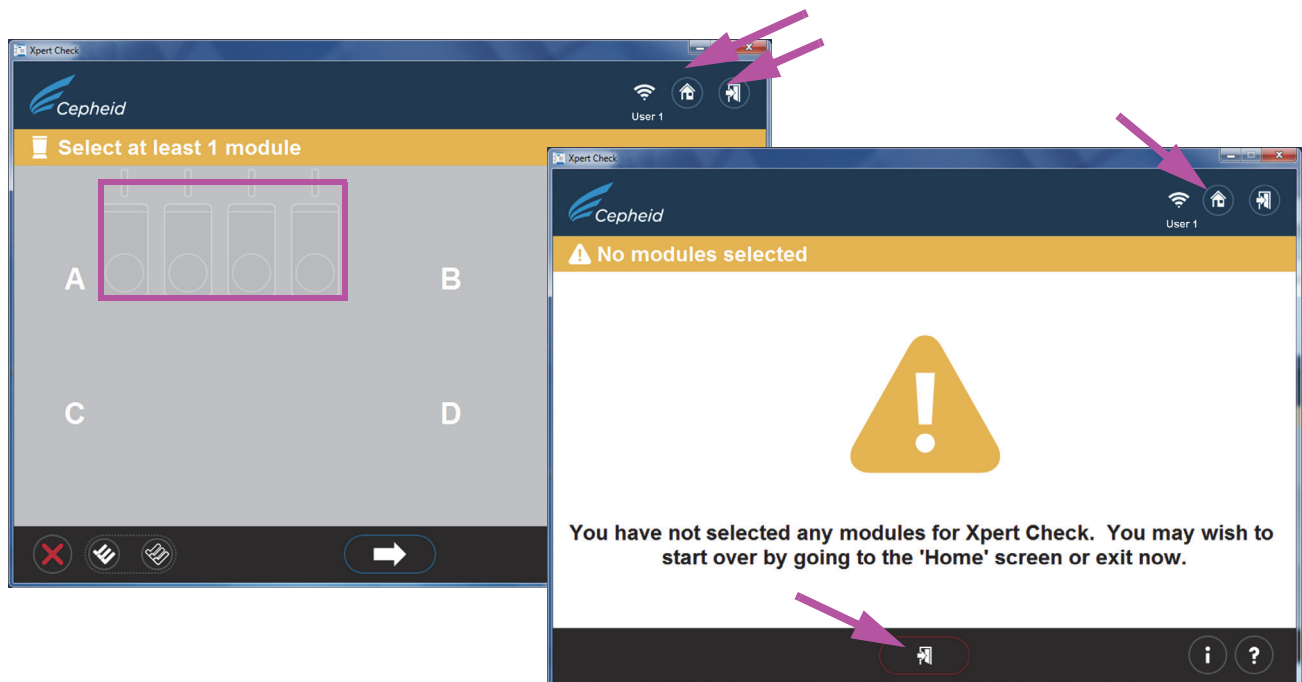


Figure 2-13. Error Screen Examples

15. After confirming your module selection, you will advance to the Scan cartridge screen, where you will be prompted to scan the barcode on the Xpert Check cartridge.

Note

Verify you have enough cartridges on hand to perform the check procedure for the desired number of modules.

16. Remove the test kit cartridge from the package for the module you've previously selected, opening only one cartridge at a time.

Important

Allow the cartridge to reach ambient temperature before proceeding. Do not remove a cartridge from refrigerated storage and immediately use the cartridge to run this test.

17. Scan the cartridge barcode. [Figure 2-14](#) shows a cartridge barcode being scanned. Do not substitute a cartridge with another after it's been scanned.

Note

If the barcode cannot be scanned, skip the cartridge and contact your ASP or local Cepheid Technical Support office for a replacement cartridge, if necessary. If the barcode scanner is damaged, missing or incorrectly configured, contact your ASP or local Cepheid Technical Support office for guidance.

Scanning the cartridge barcode

Note: To avoid inserting a wrong cartridge into a module, do not set the cartridge aside after it has been scanned. In one operation, scan the cartridge barcode, vent the cartridge and insert it into the next available (lighted) module.

SKIP button: Touch or click this icon to skip the cartridge just scanned.

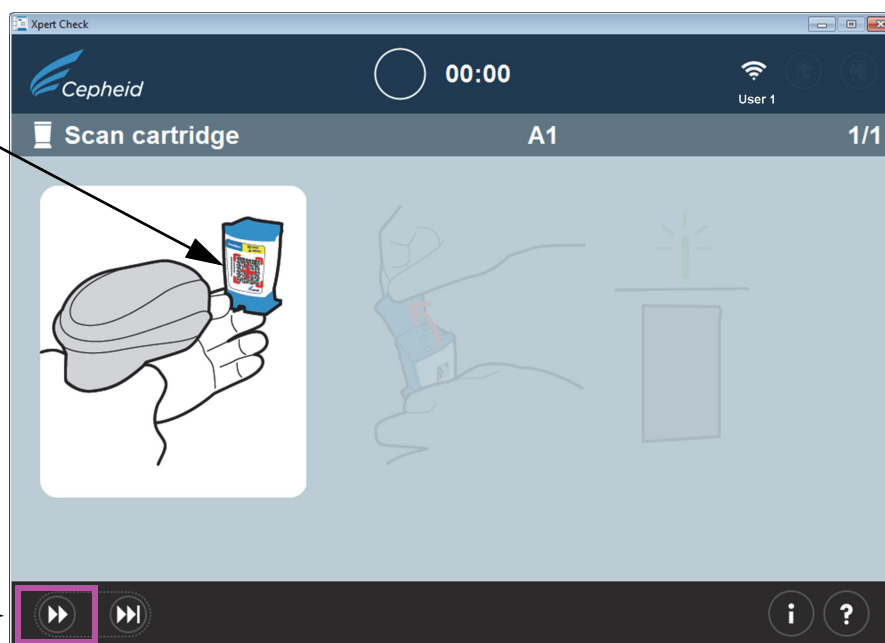


Figure 2-14. Scanning the Cartridge Barcode Screen

- A. After scanning the barcode of the cartridge, ensure you open (vent) the cartridge lid and then close it for each cartridge as directed by the software in [Step B](#) through [Step E](#) below.

Important

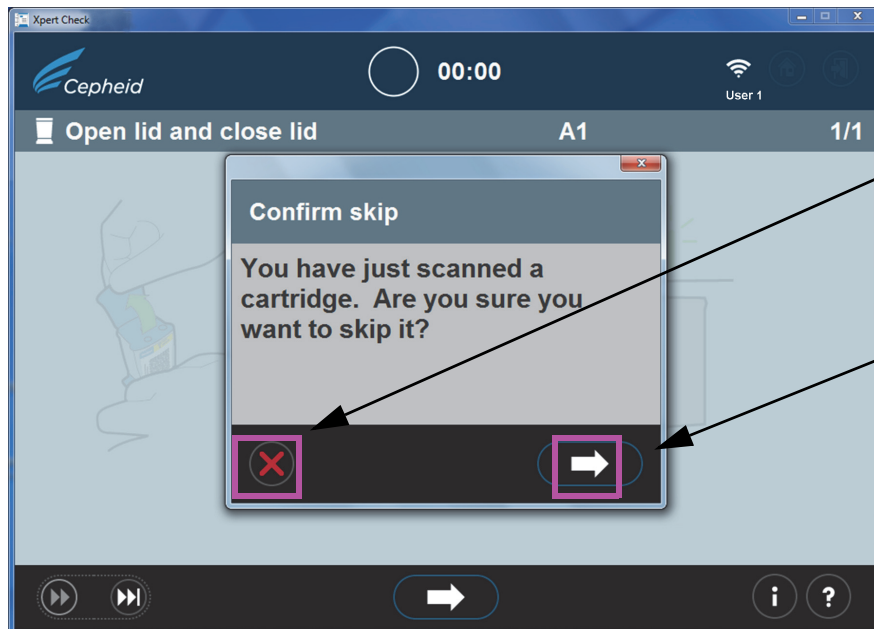
Do Not add a sample or reagent to the cartridge. Use ONLY the cartridges in the Xpert Check kit provided.

Note

After a cartridge barcode is scanned a green light will blink on the system above the module door where the cartridge is to be loaded. (See [Figure 2-17](#).)

Note

If, for some reason, you want to skip the cartridge just scanned, touch or click the **SKIP** button at the bottom of the screen. An overlay, shown in [Figure 2-15](#), will appear, asking for confirmation on skipping the cartridge. To SKIP the cartridge, touch or click the forward arrow at the bottom of the confirmation screen. To proceed without skipping the cartridge, touch or click the **X** icon at the left bottom corner of the screen. You are urged to rescan a cartridge (or substitute a new cartridge if necessary) to ensure a module is not skipped.



Touch or click the X icon to “undo” the SKIP selection and proceed with opening, venting and loading the cartridge into a module.

Touch or click the arrow to confirm you want to skip the cartridge just scanned.

Figure 2-15. Confirm skip Screen

- B. Venting the cartridge (shown in [Figure 2-16](#)), for two seconds is sufficient. This screen is animated, showing the cartridge lid being opened and closed. After venting, touch or click the forward arrow at the bottom of the screen to continue.

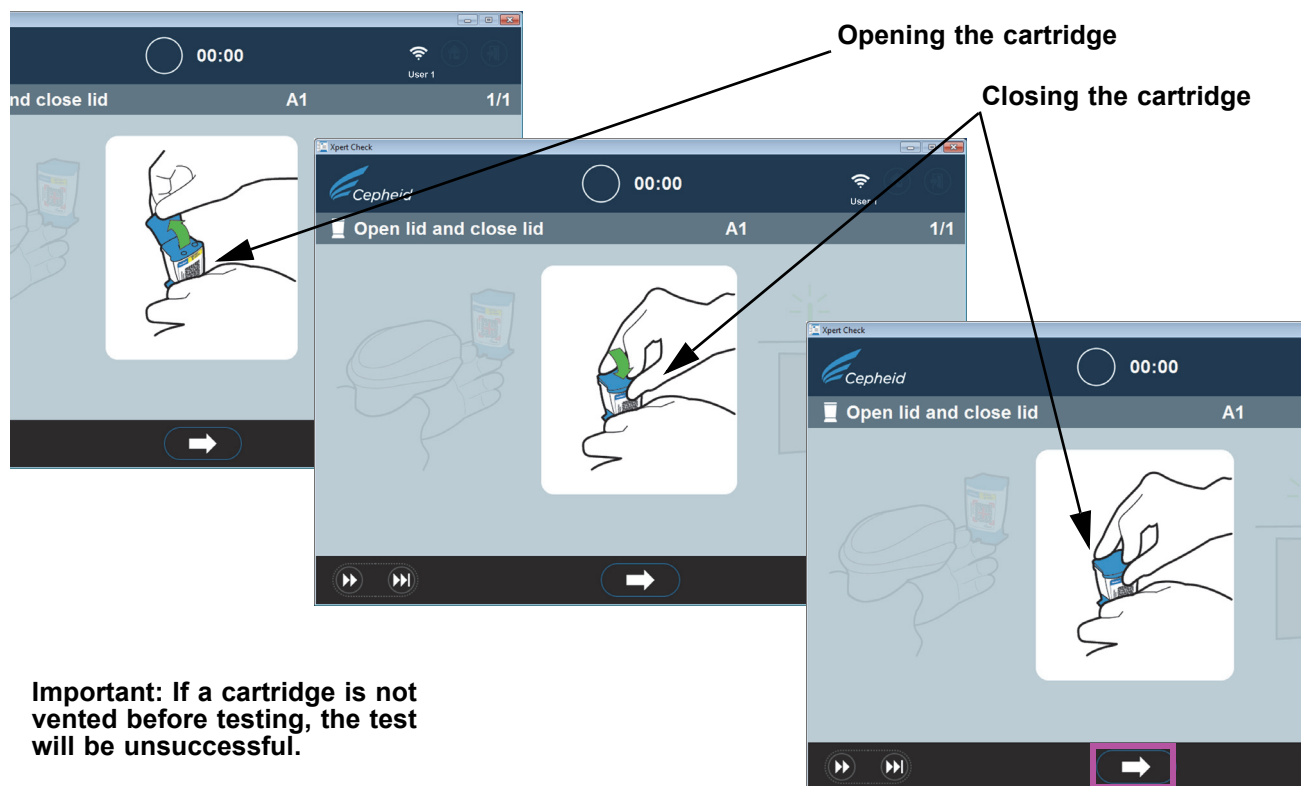


Figure 2-16. Venting the Cartridge by Opening and Closing the Cartridge Lid - Animated Screen

- C. Close the cartridge lid and ensure the module door is fully opened to receive the cartridge.
- D. Load the cartridge into the module (with the cartridge reaction tube (tab) facing away from you), as directed by the animated software screens. See [Figure 2-17](#).

Note

Be sure to load scanned cartridges in sequence in the next available module. This will avoid loading cartridges in the wrong location or leaving modules empty.

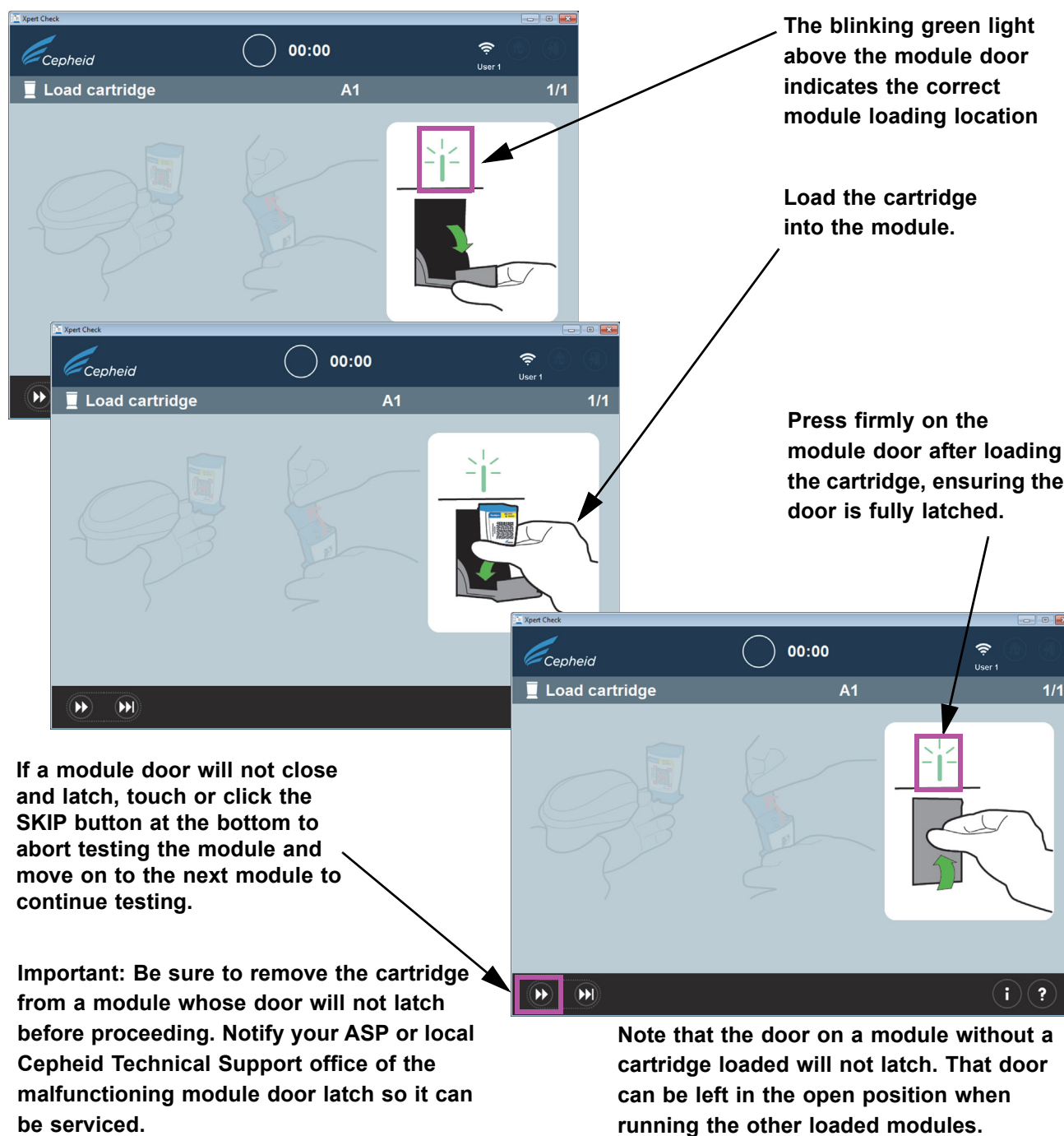


Figure 2-17. Loading the Cartridge into the Module

- E. If you are checking additional modules, continue by scanning the next cartridge. Place each individually scanned cartridge into the next selected open module, pressing the module door securely closed until it latches. **As each module door is closed and latched, data collection will automatically start on that specific module.** The blinking green light above the module will then become steady green, indicating that checking has started.

Important

If a module door is not closed completely (until it latches) after loading a cartridge, the screen will continue to display a message to insert a cartridge, and the check will not run.

If you are unable to close and latch a module door after several tries, touch or click the SKIP button at the bottom of the screen to skip the module with the faulty door and move ahead. Notify your ASP or local Cepheid Technical Support office so the module can be serviced.

18. Checking will take approximately 20 minutes to complete after the final module has been loaded for testing. When checking begins, the Data collection in progress screen appears, as shown in [Figure 2-18](#).

Important

If necessary, a retest of a previously run module may be started without waiting for the present module to complete its test, as described in steps 19b through 19d.

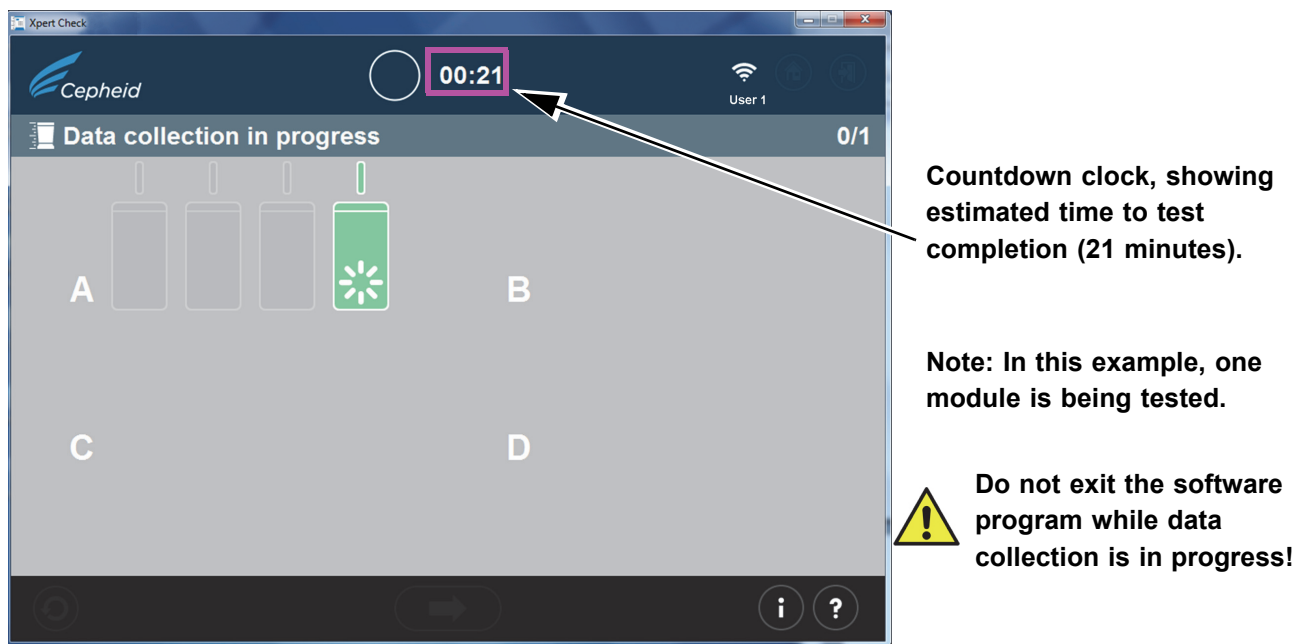


Figure 2-18. Data Collection Screen

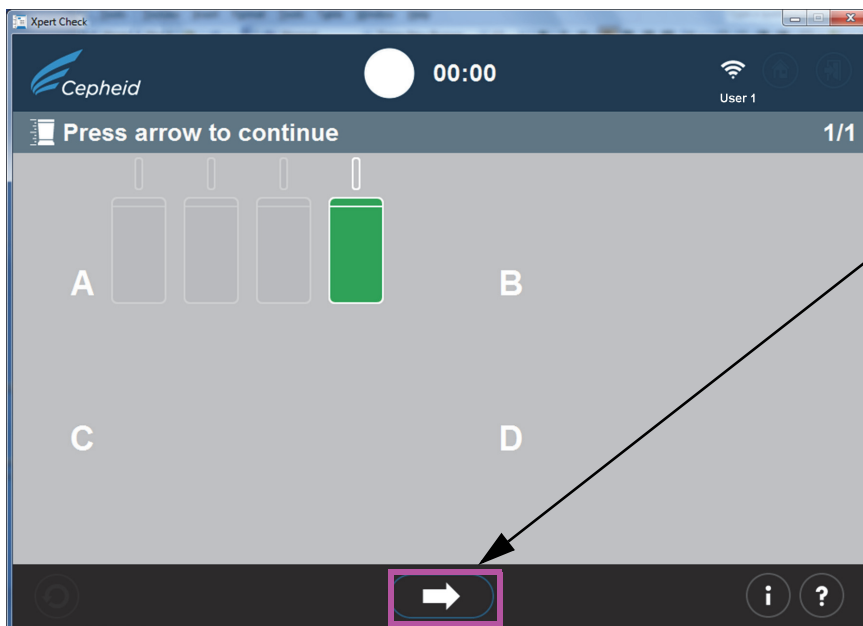
Important

If you do not have an internet connection, skip to section 2.2.1 for the remainder of this procedure. If you have an internet connection, continue with step 19.

19. After test completion, the module door will open and the light above the module door will turn off. Screens similar to those shown in [Figure 2-19](#) or [Figure 2-20](#) will appear. Touch or click the right arrow to continue.
 - A. [Figure 2-19](#) shows the completion of a successful Xpert Check data collection. When the test is complete, touch or click the forward button at the bottom of the screen to begin uploading Xpert Check test results to the Xpert Connectivity Center.

Important

When uploading test results, especially multiple files, verify the selected folder destination is correct.



Touch or click to continue to the next screen.

Note: In this example, one module is being tested.

Figure 2-19. Test Completion Screen - Successful

- B. If the test was unsuccessful, the screen shown in [Figure 2-20](#) will appear, showing module status. A test retry must be performed. Touch or click the **Retry** icon in the lower left-hand corner of the screen.

Module test unsuccessful. Test must be rerun using either the same or a new cartridge, as instructed by the on-screen display.

Continue button. Touch or click to proceed without retesting. See [Figure 2-21](#).

Retry Icon: Touch or click to retest the module.

Note: In this example, one module is being tested.

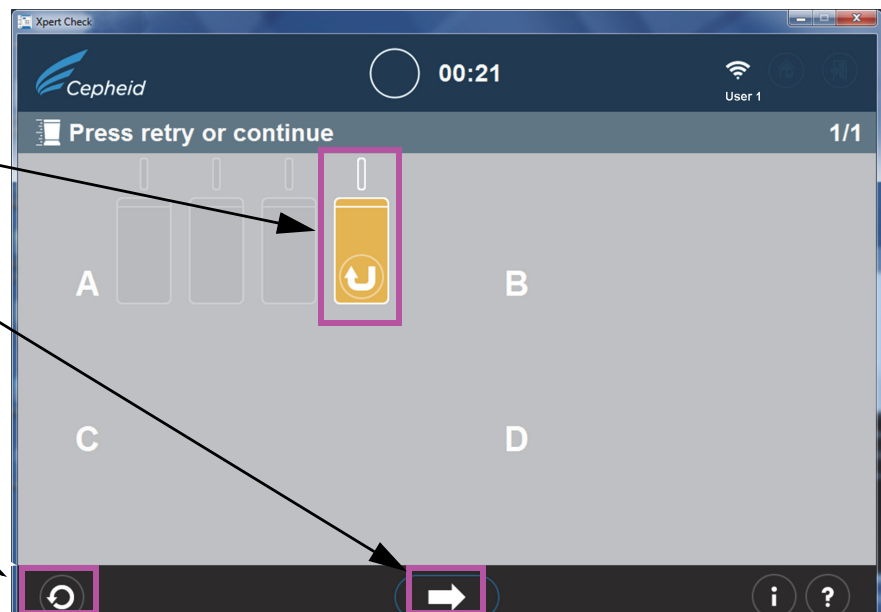


Figure 2-20. Test Completion Screen - Unsuccessful Module Checking Example

- C. If the **Continue** arrow at the bottom of the screen is pressed when there is an unsuccessful module test displayed (as shown in [Figure 2-20](#)), the Confirm continue screen will appear. See [Figure 2-21](#).

To return to the Press retry or continue Screen to retest the flagged module, touch or click the X icon.

To continue without retesting the flagged module, touch or click the right arrow at the bottom of the Confirm continue screen.

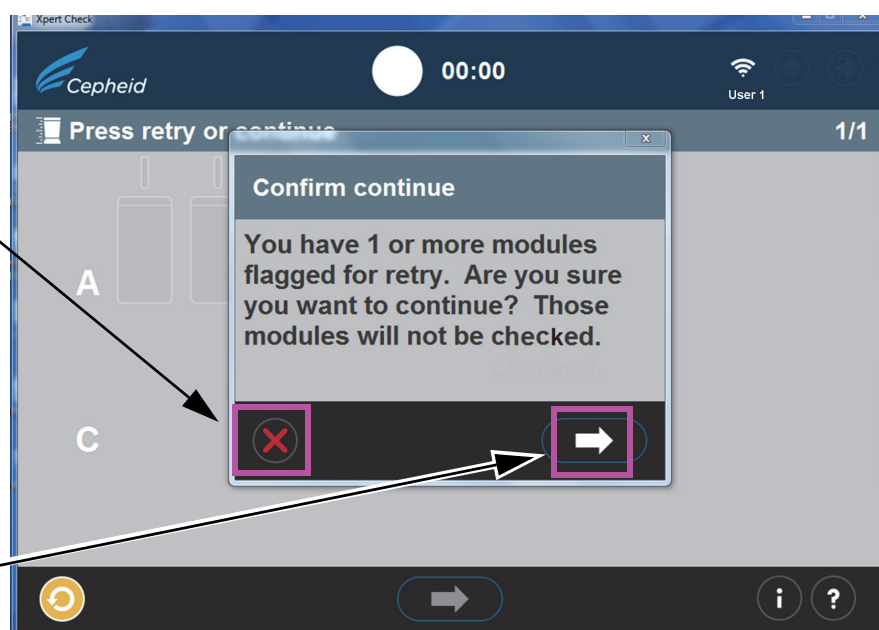


Figure 2-21. Confirm Continue Screen Overlay

You have the option of continuing by touching or clicking the right arrow on the Confirm continue screen overlay. Choosing this option will result in the flagged module not being retested, and you will begin uploading check data as described in [Step 20](#).

Another option is to return to the Press retry or continue screen to Retry (retest) the flagged module by clicking the red X icon at the bottom left of the Confirm continue screen. The Retry procedure is described in [Step D](#) which follows.

- D. If the Retry icon (shown above in [Figure 2-21](#) at the bottom of the screen) appears, touch or click the Retry icon and you will return to the Scan Barcode screen ([Figure 2-14](#)) to complete the retest on the affected module(s).

Note that the retest can be of two possible types:

- 1) Retry with the same cartridge: For example, a message may appear telling you to vent the cartridge, rescan it, and put it back in the module.
- 2) Retry with a new cartridge: If the cartridge was defective, or had already been used, you will be asked to replace it by scanning the barcode on a new cartridge, venting it, and loading it into the module.

Note

During the course of running retests, modules may need to be skipped if the user runs out of Xpert Check cartridges. Please contact your ASP or local Cepheid Technical Support office for additional Xpert Check cartridges. Rerun Xpert Check on any modules that were skipped.

Note

At the completion of the Xpert Check data collection process, modules determined to require service will be flagged with an orange module icon (See [Figure 2-20](#)). Please contact your local ASP or local Cepheid Technical Support office for further assistance in servicing or replacing modules.

20. After successful test completion and Xpert Check data collection, touch or click the forward arrow to display the screen shown in [Figure 2-22](#), if you have an active

internet connection. However, if you have never been internet connected, or have lost your functioning internet connection sometime during the Xpert Check test, a Download Xpert Check code error screen or an Upload incomplete error screen (Figure 2-23) may appear instead, instructing you to write Xpert Check data to a data CD to send to your ASP or local Cepheid Technical Support office. In this case, continue to the instructions beginning at Step 4 (under Section 2.3.1) of this procedure to continue as a user without an internet connection.

Note

With a functioning internet connection, the system should proceed normally (with Step 21), and the Xpert Check code should begin downloading, as shown in Figure 2-24.

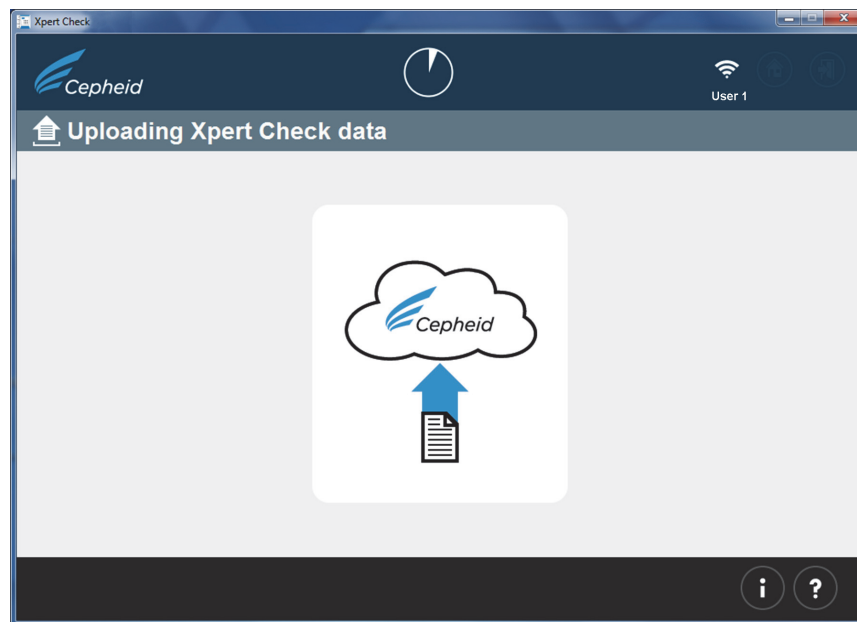


Figure 2-22. Uploading Xpert Check Data Screen

Touch or click this icon to move to the Write Xpert Check Data to CD screen. See Figure 2-31.

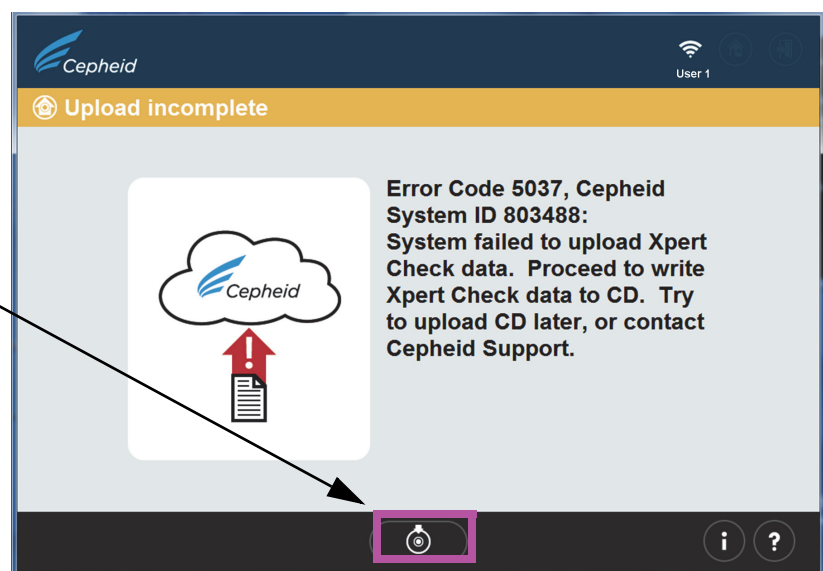


Figure 2-23. Upload incomplete Error Screen

21. When the Xpert Check data has finished uploading, a Quality Assurance check will be performed on the data. If the check is acceptable, the Xpert Check code will automatically download. See [Figure 2-24](#).

If the test is not acceptable, the affected module(s) will require service or replacement and will be flagged with an orange icon. Please contact Cepheid or your local ASP or the local Cepheid Technical Support office for further assistance.

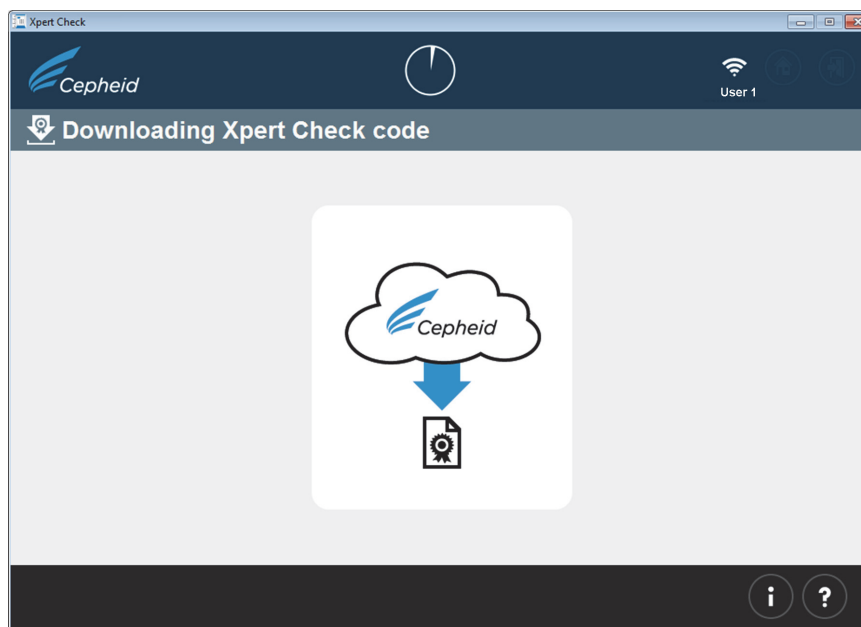


Figure 2-24. Downloading Xpert Check code Screen

22. After the Xpert Check test results have downloaded, the Xpert Check code will be applied to each successfully tested module, and those modules will then be identified with a + symbol. See [Figure 2-25](#). As shown here, one module is being checked.

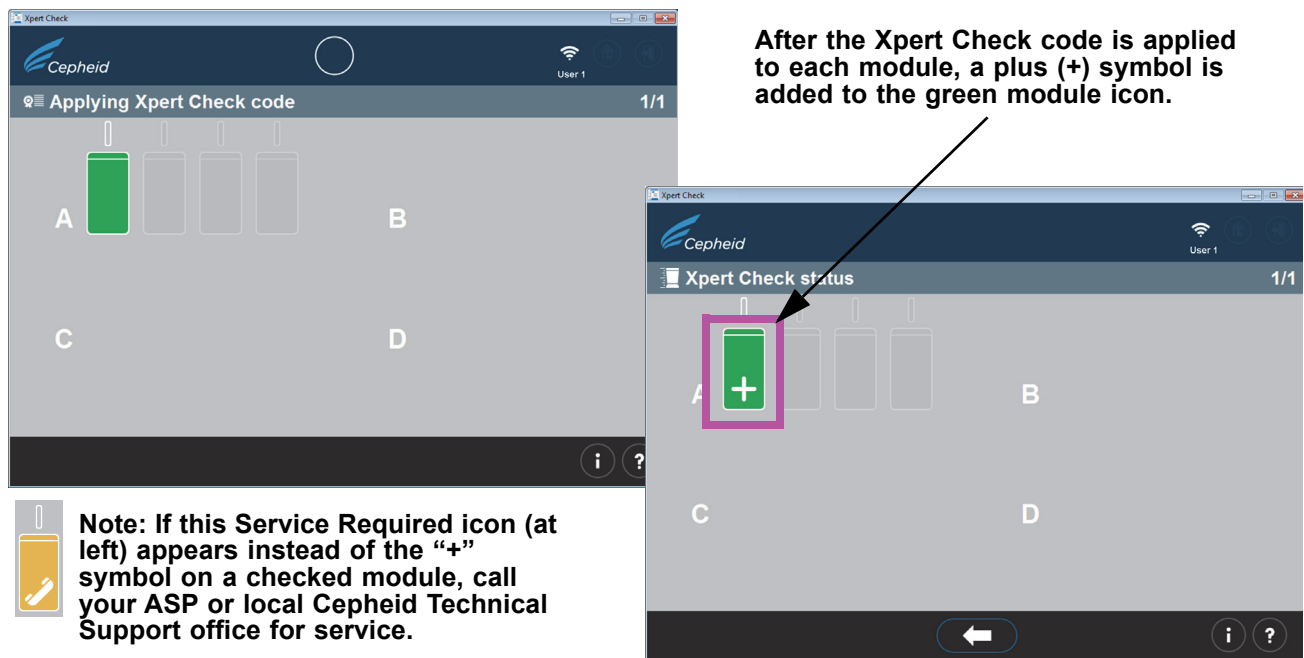


Figure 2-25. Applying Xpert Check code Screen

Note

In the screen shown in [Figure 2-25](#), some modules may display the service required icon or may be grayed out if they were skipped.

23. After all the Xpert Check codes have been applied to the successfully-tested modules (those green modules which appear with the plus symbols applied), the Xpert Check complete screen will appear. See [Figure 2-26](#). This screen shows the location of the Xpert Check Data report, which is available for review, if desired.

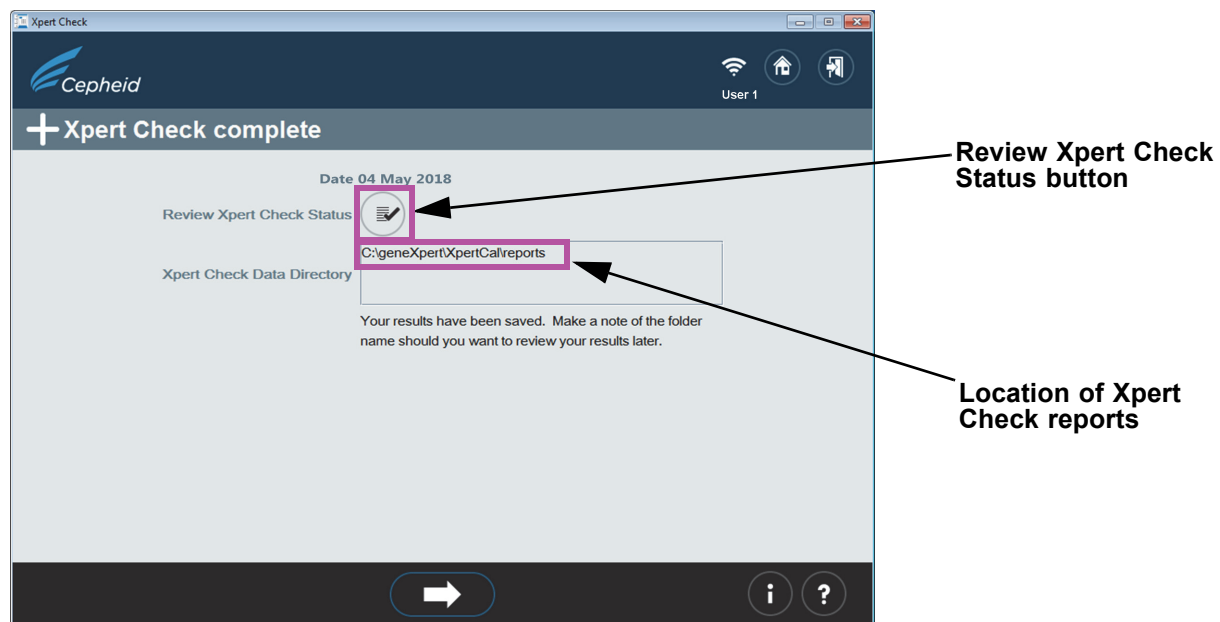


Figure 2-26. Xpert Check complete Screen

24. Remove and discard all Xpert Check cartridges. Do not save partial kits (all unused cartridges must be discarded). When complete, click the **Exit** icon at the top or bottom of the screen to exit the program. See [Figure 2-27](#).

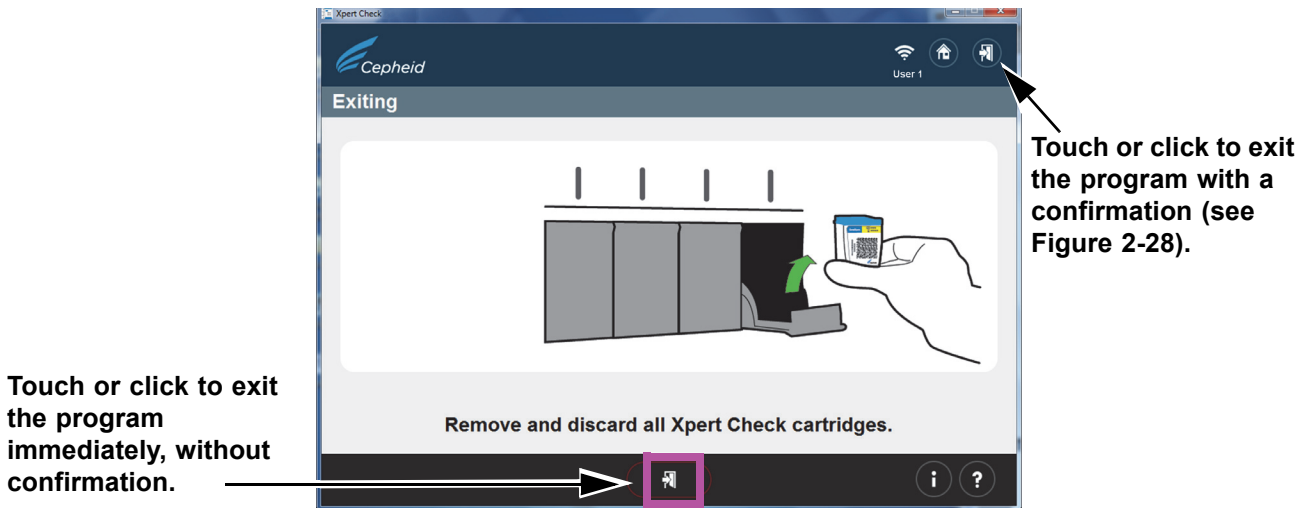


Figure 2-27. Exit the Program

25. The screen shown in [Figure 2-28](#) appears only if you touch or click the exit arrow in the upper right of the screen.

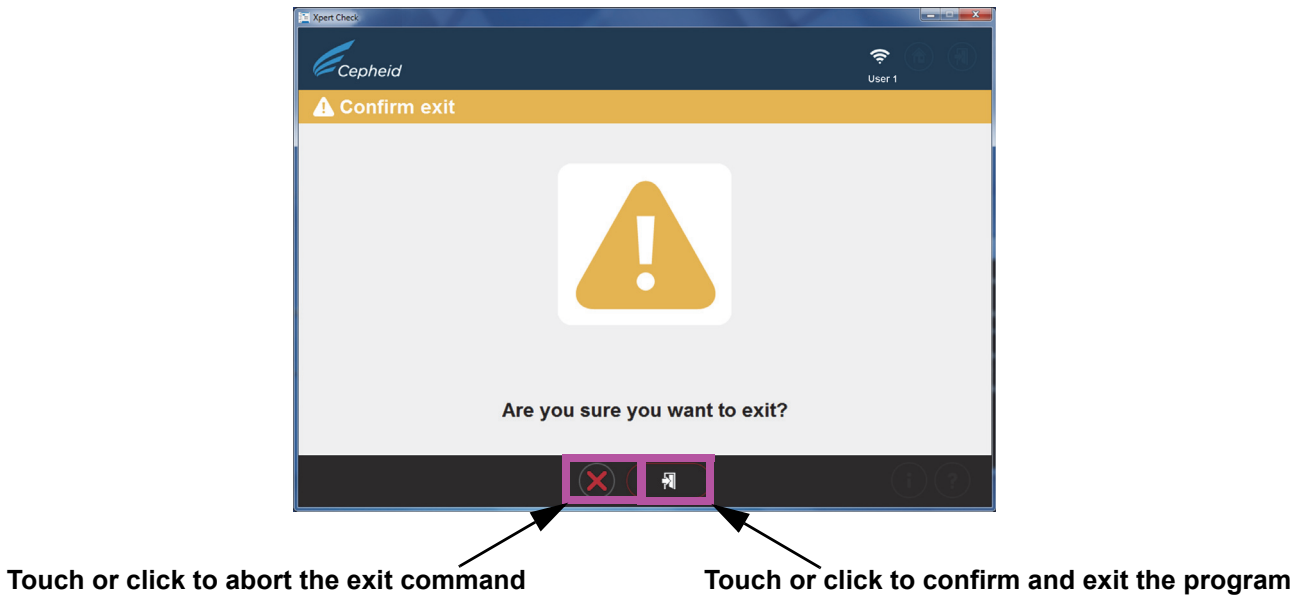


Figure 2-28. Confirm exit Screen

This completes the Xpert Check Test for an internet-connected user.

- Note**

Contact your Authorized Service Provider or the local Cepheid Technical Support office concerning modules requiring service.
- Note**

To view your Xpert Check results, see [Step 23](#) and [Figure 2-26](#), which shows the file path and location of Xpert Check results and the Xpert Check Summary report.

2.3.1 Xpert Check Completion For Non-internet Connected Users

For Non-internet connected users, you should have completed [Step 1](#) through [Step 19](#) of [Section 2.3](#) to collect data before starting this section.

1. This section begins with the Data collection in progress screen, which is similar to [Step 18](#) in [Section 2.3](#), and the screen shown in [Figure 2-18](#) for internet-connected users.

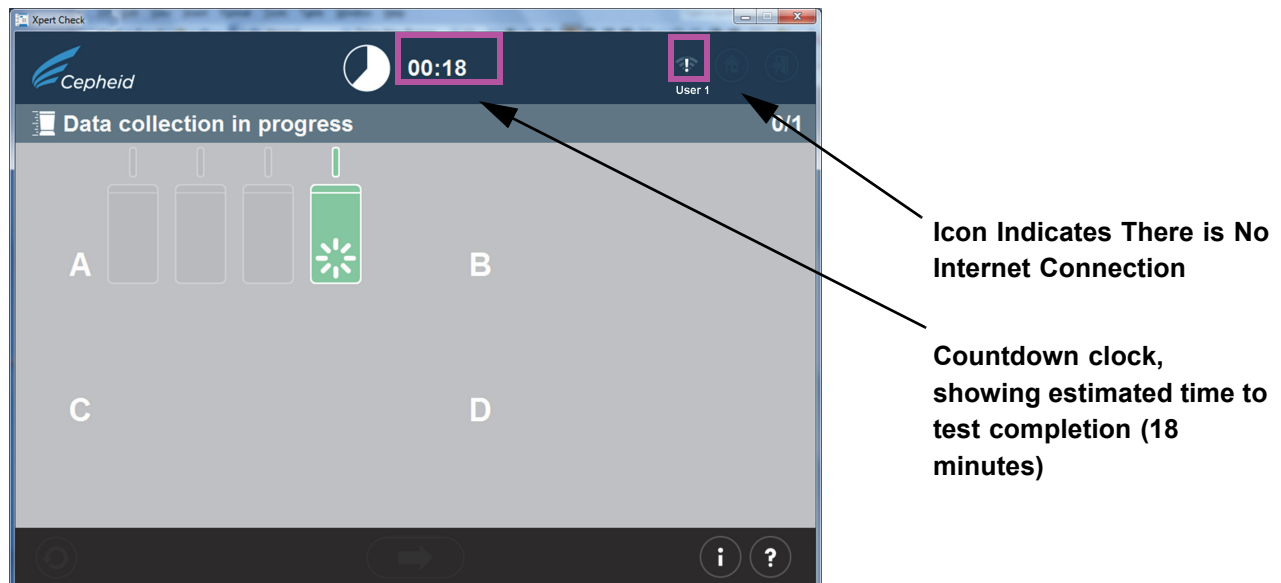


Figure 2-29. Data collection in progress Screen

2. After test completion, the module door will open and the light above the module will turn off. A screen similar to that shown in [Figure 2-30](#) will appear. Touch or click the right arrow at the bottom of the screen to advance to the next screen.

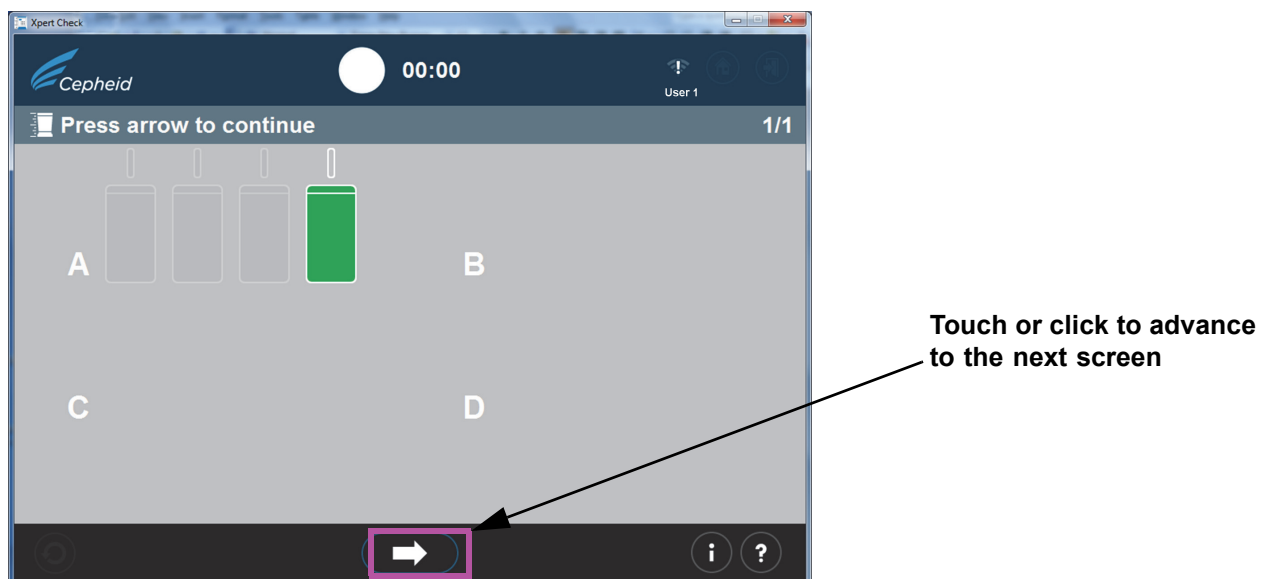


Figure 2-30. Test Completion screen - Successful

3. When the Write Xpert Check data to CD screen appears (Figure 2-31), you will be prompted to press the **Eject** button on the DVD drive to remove the existing Xpert Check Software CD so you can insert the blank data CD.

Note

In the following step, use care in inserting the blank CD into the DVD drive. Be sure the CD is fully seated in the tray before closing the drive door.

Important

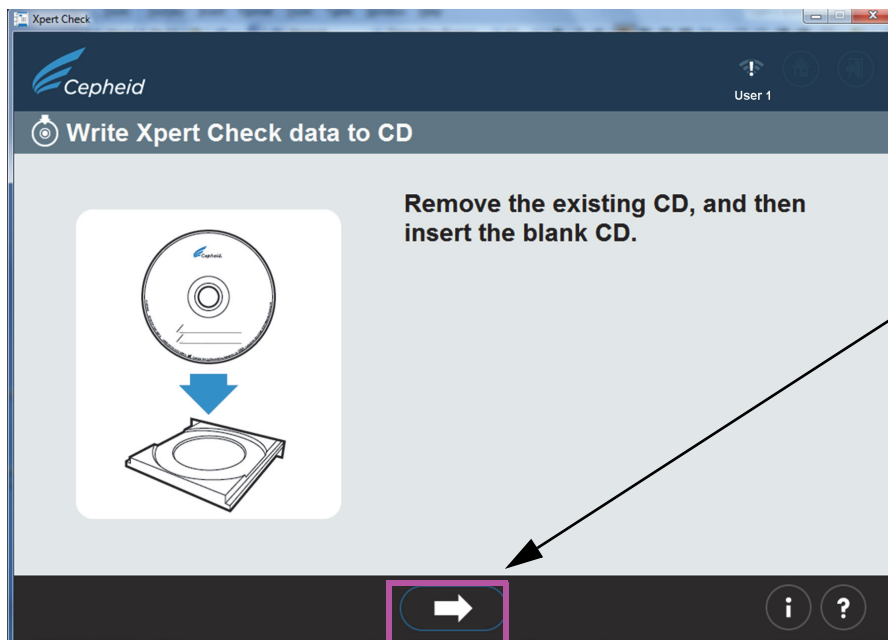
If you have been running this test as an internet-connected user and then lose your internet connection and received an error screen (Figure 2-23), resume your procedure beginning with the following Step 4, continuing through Step 12.

Note

In the following step, pause for 10 seconds after CD insertion and cancel any wizards that auto-open before touching or clicking the forward arrow to proceed. When you either close the wizard or have waited enough time to ensure that a wizard will not auto-open, touch or click the forward button to proceed. This will launch the Windows CD burning screens that the Xpert Check program opens.

4. Insert the blank CD into the DVD drive of the computer and close the DVD drive tray fully to ensure the CD will be recognized.

Pause to allow the launch of any possible CD wizard programs. If wizard programs launch, close them before touching or clicking the forward button to proceed.



Pause 10 seconds after CD insertion and then touch or click to continue to the next screen.

Figure 2-31. Write Xpert Check data to CD Screen - Step 1

5. After inserting the blank CD, the screen will change briefly, indicating the CD has been recognized. See Figure 2-32. This screen will remain displayed until the CD writing process is complete.

Note

It is not necessary for the user to locate the file to write because that process is automatic.

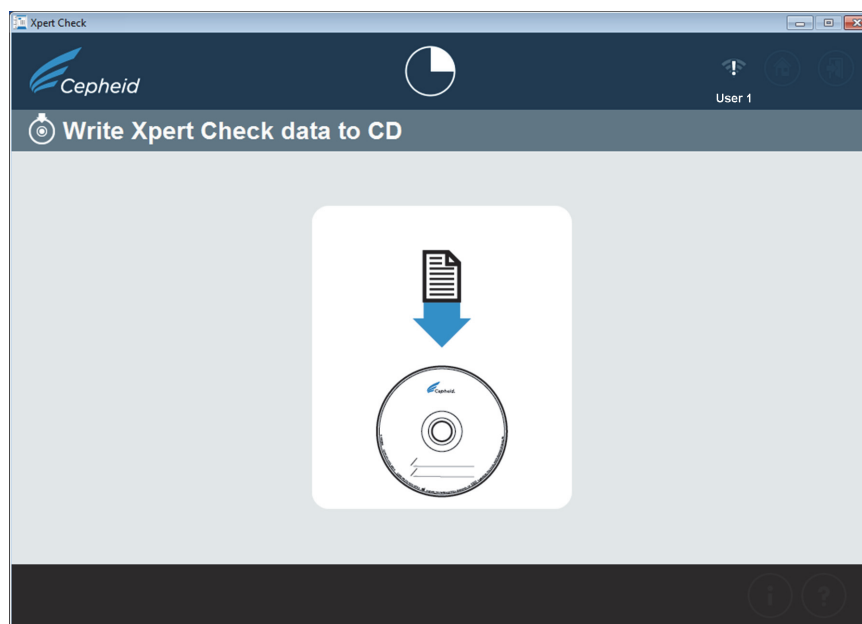


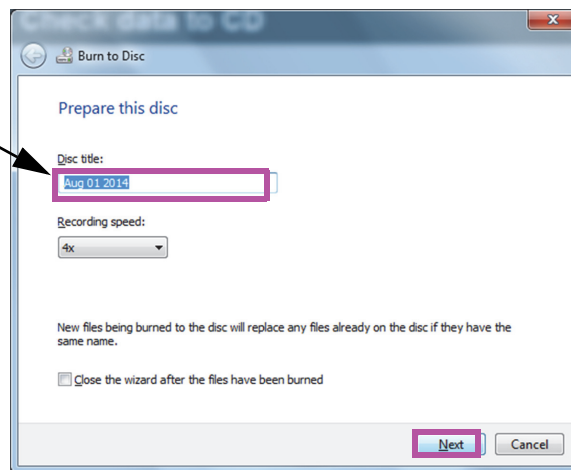
Figure 2-32. Write Xpert Check data to CD screen - Step 2

6. The CD Writing Wizard or Burn to Disc screen (Figure 2-34) will then appear as an overlay of the screen shown above, in Figure 2-32.

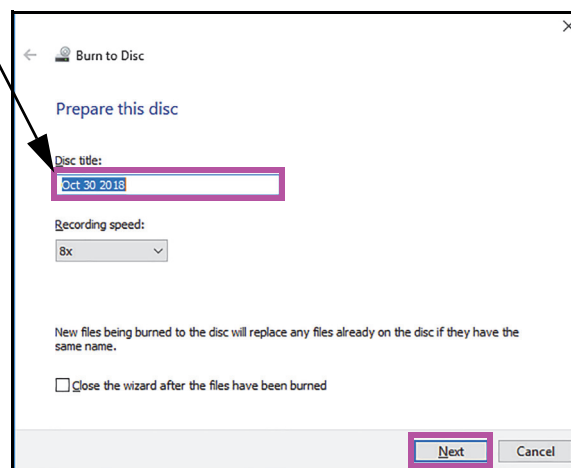
The next screens (Figure 2-33 through Figure 2-37) show the CD writing program screens as you progress through the writing process.

- Windows® 7 users: Follow the screens on the top of the figure.
 - Windows® 10 users: Follow the screens at the bottom of the figure.
- A. On the first screen, after successful recognition of the blank CD, you will be asked to provide a name for the CD that you will be writing. DO NOT simply touch or click the **Next** button to continue the writing process with the default name that appears. Instead, type in your facility's name, such as "XYZ Hospital," in the space provided and touch or click **Next**. See Figure 2-33.

Type in your facility name
for the CD name/Disc title



Opening Screen - Windows 7



Opening Screen - Windows 10

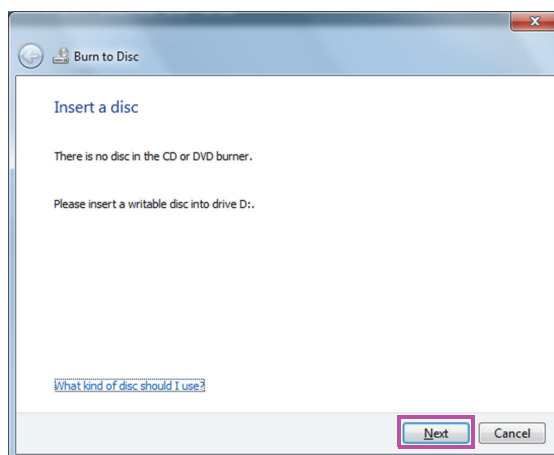
Figure 2-33. CD Writing Program - Opening Screen

- B. If the CD is not recognized, the screen shown in [Figure 2-34](#) may appear, instead of the screen in [Figure 2-35](#), asking you to insert a writable disc to continue. Writable discs, in this case, are CDs on which you can store files. Writable discs can only be written to once, meaning that once any files are copied to the disc, they are there permanently.

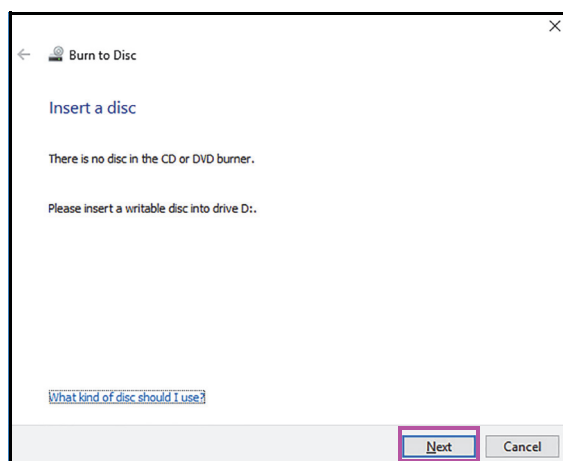
A disc that has data on it is not considered to be a writable disc and will result in an error screen, as shown in [Figure 2-39](#).

Note

If you are unsuccessful with any part of the CD writing process, you may contact your ASP or local Cepheid Technical Support office for assistance. It is safe for you to close the Xpert Check software now because the Xpert Check files have been saved to the hard drive and you will not lose data.



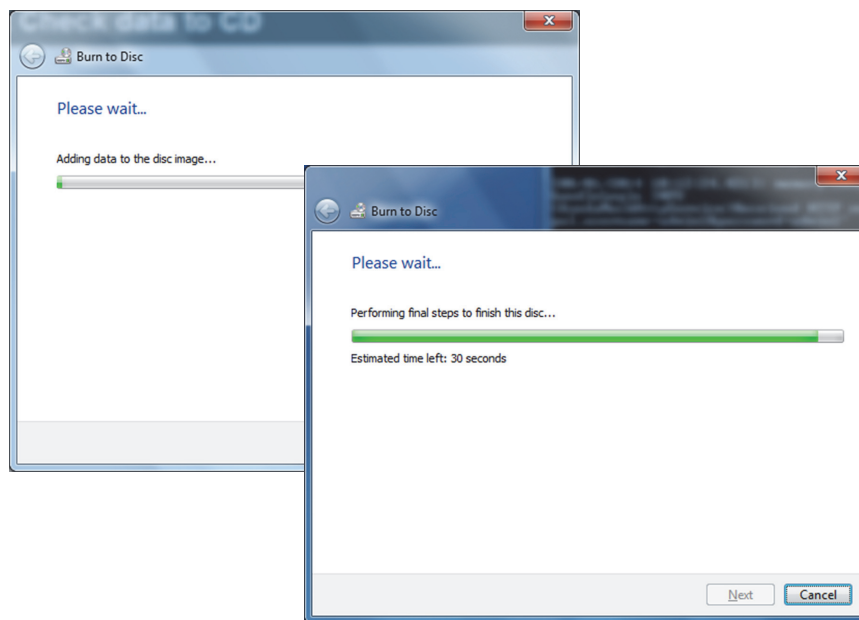
Insert a Disc Screen - Windows 7



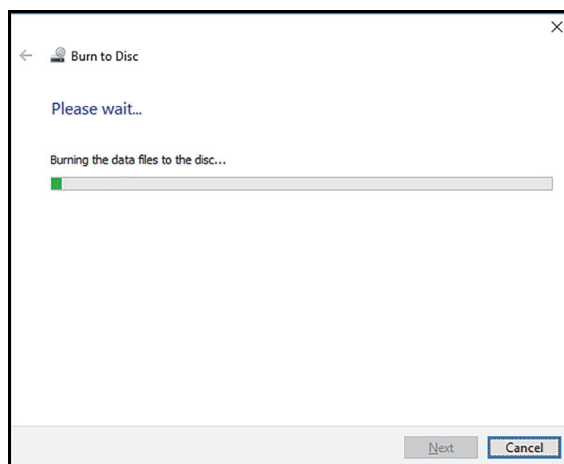
Insert a Disc Screen - Windows 10

Figure 2-34. CD Writing program - Insert a writable disk to continue Screen - Example

- C. After successful recognition and naming of the CD, touch or click the **Next** button to continue. The writing process will begin automatically.
- D. During the writing/burning process, a progress bar will appear on the screen. See [Figure 2-35](#).



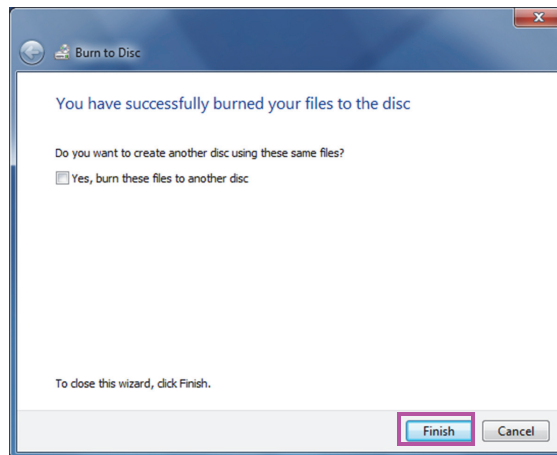
File Burning Progress Screens - Windows 7



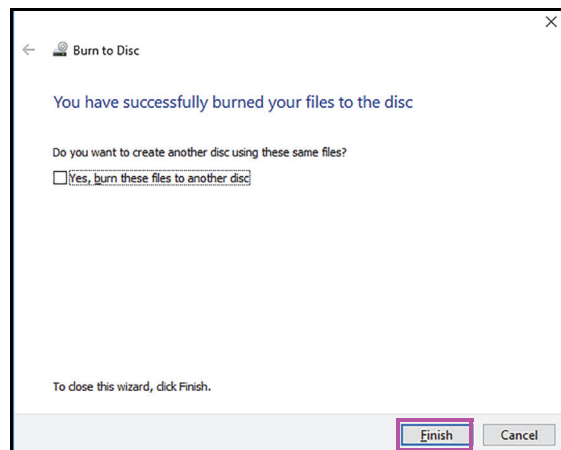
File Burning Progress Screen - Windows 10

Figure 2-35. CD Writing/Burning Progress Screen

- E. When the writing of the CD is complete, the screen shown in [Figure 2-36](#) will appear. Touch or click the **Finish** button to exit the CD writing program.



Completion Screen - Windows 7



Completion Screen - Windows 10

Figure 2-36. CD Writing Completion Screen

- F. On a Windows 7 computer, you may see the screen displayed in [Figure 2-37](#) after a successful CD write. Touch or click the **OK** button as many times as necessary for the screen to disappear, before continuing.

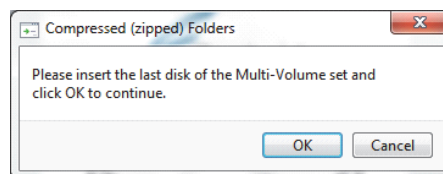


Figure 2-37. Final Screen from Windows 7 After CD Writing has Completed

7. After touching or clicking the **Finish** button on the CD writing screen, the Send the CD to your Authorized Service Provider Screen will appear (see [Figure 2-38](#)). Remove the completed Xpert Check data CD from the disk drive and prepare the label, as described in [Step 10](#).

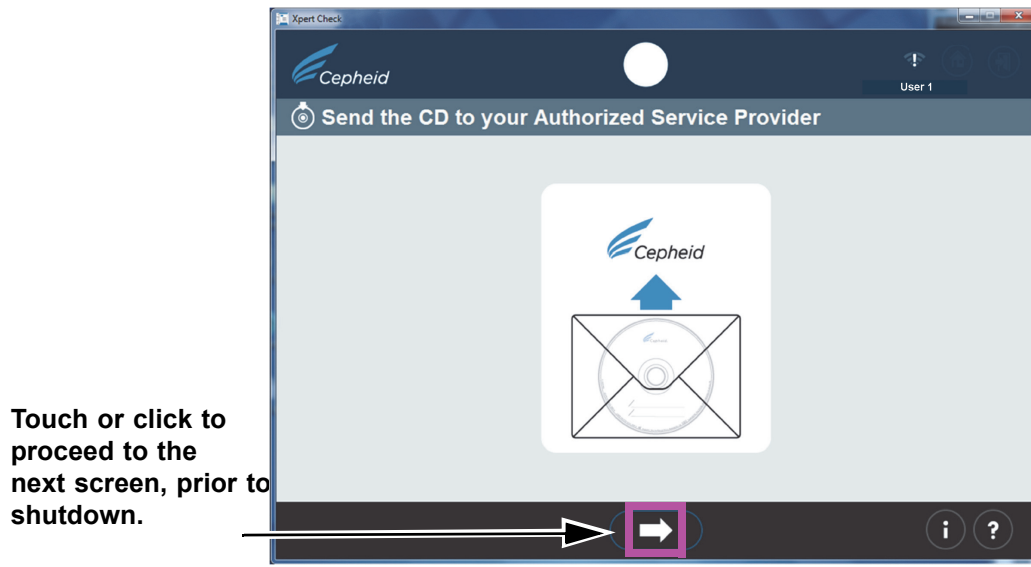
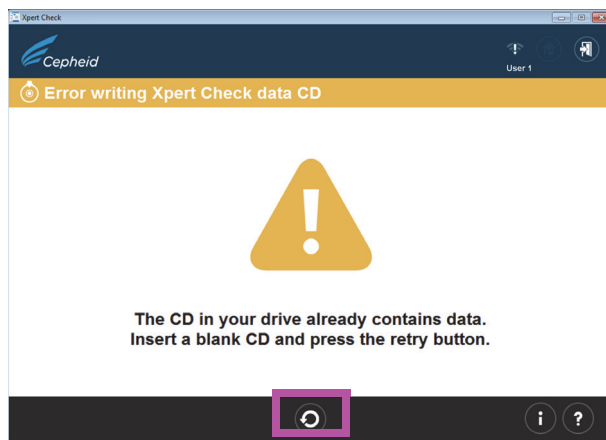


Figure 2-38. Send the CD to your Authorized Service Provider Screen - Step 3

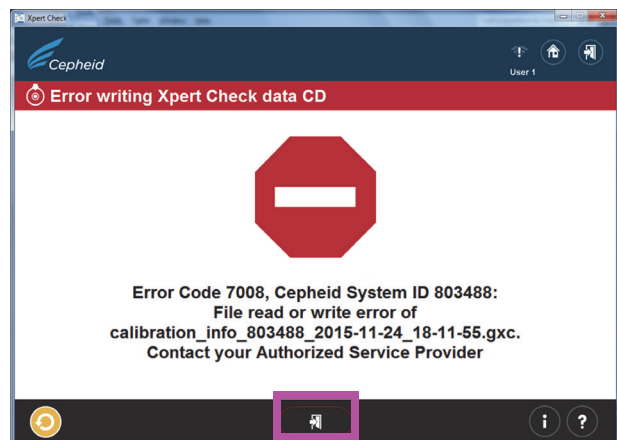
8. If a problem has occurred anytime during the CD writing process, an error code screen may appear. (See [Figure 2-39](#)).
 - If a CD you have inserted already contains data as shown in the error screen below at the left, remove the CD and insert a blank CD, and then touch or click the **Retry** icon.
 - In the case of a read or write error, the screen shown at the right may appear and you must exit the program. Contact your ASP or the local Cepheid Technical Support office for assistance, if necessary.

Disc is not Writable (Already Contains Data)



Retry Button

General Write Failure



Exit the Program

Figure 2-39. Error writing Xpert Check data CD Screens - Two Examples

9. After test completion, the Exiting screen will appear with the message **Remove and discard all Xpert Check cartridges** (see [Figure 2-40](#)).

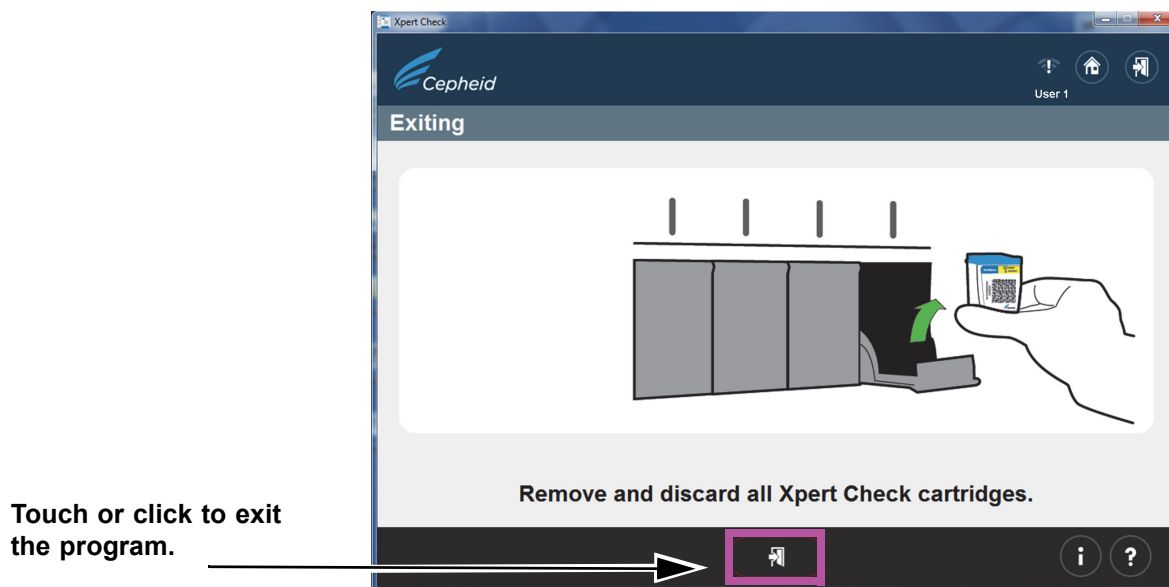


Figure 2-40. Exiting Screen

10. Use a felt-tip pen to write on the label of the Xpert Check data CD you have just created by writing the date, instrument identification and facility/location of the test performed. See a label example in [Figure 2-41](#).

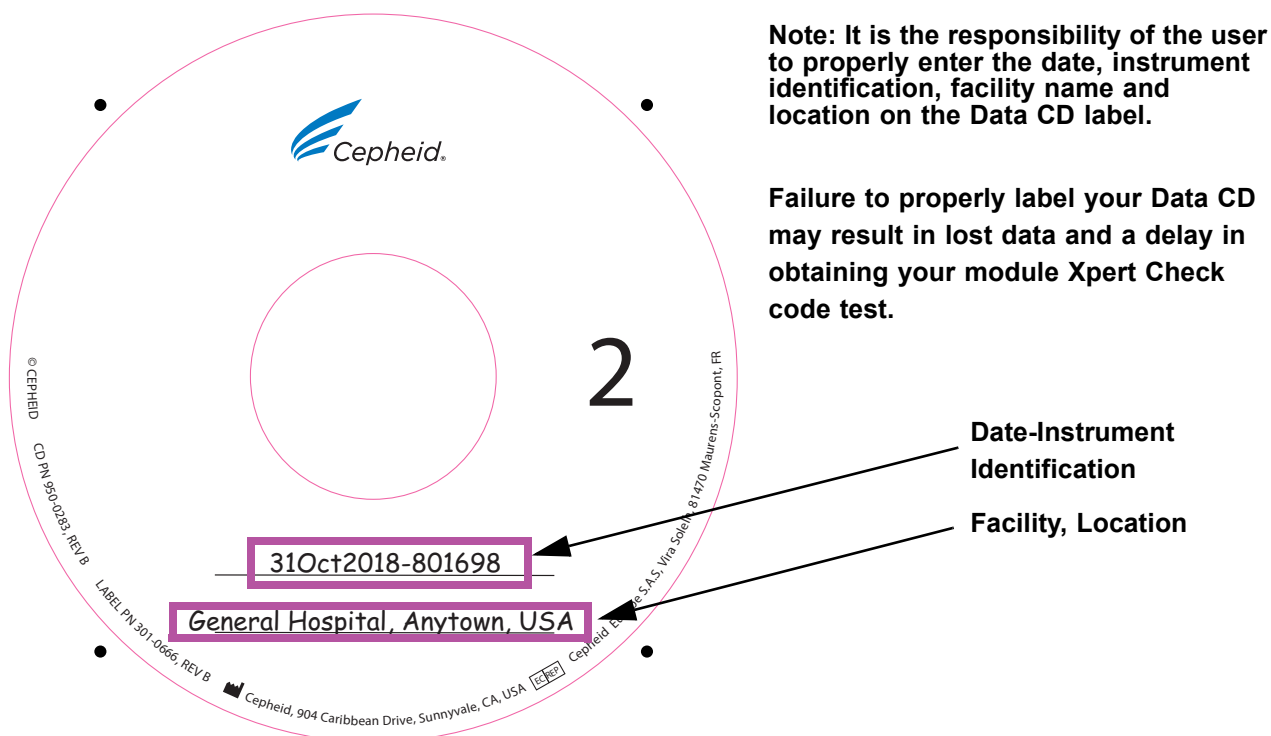


Figure 2-41. Data CD Labeling Example

11. You have the option to copy the calibration_info.gxc data file (located on the Xpert Check data CD just written) and Email the data file directly to your ASP or the local Cepheid Technical Support office instead of mailing the CD. 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 for data quality assurance checking and the issuing of your Xpert Check code.
12. Your ASP or the local Cepheid Technical Support office will perform the quality assurance review and, if successful, send back your Xpert Check code either by Email or regular mail, depending on what method you have previously set up with them.

Note

Discard all remaining materials from the kit. DO NOT save unopened kit pouches for later use. DO NOT discard your Software CD. For users who Emailed their file and have not shipped their data CD: DO NOT discard your Data CD.

13. Restart your GeneXpert Dx, GeneXpert Xpress or Infinity system and computer.

Note

You can continue to use your system while awaiting your Xpert Check code.

2.3.2 Obtaining the Xpert Check Code for Non-Internet Connected Users

Note

Ensure the system is in the same configuration as when Xpert Check was run (i.e., no software updates or changes have been made and no new GeneXpert systems have been moved to or from this computer). In the case of any module servicing and/or replacement that may occur between data collection and application of the Xpert Check Code, new or modified modules will be ignored for the purposes of the Xpert Check testing process.

Note

In the following step, use care in inserting the CD into the DVD drive. Be sure the CD is fully seated in the tray before closing the drive door.

1. Exit the GeneXpert Dx, GeneXpert Xpress or Infinity software.
2. To finish the Xpert Check process, place the Software CD in the DVD drive of the computer connected to the GeneXpert Dx or GeneXpert Xpress instrument or in the kiosk computer for the Infinity.
3. Touch or click on My Computer, then touch and hold or double-click on the applicable drive letter for your DVD drive. The files located on the CD will then be displayed. Find and touch and hold or double-click the **XpertCheck.exe** application/shortcut to launch the software.
4. Log in with your GeneXpert Dx, GeneXpert Xpress or Infinity designated **USER NAME** and **PASSWORD** (see the IMPORTANT note in [Section 2.1](#)). Also see [Figure 2-4](#) for the Login screen.

After entering your login information, touch or click the forward arrow button at the bottom of the screen to advance to the next screen (the Xpert Check Home screen).

Note

The user name and password are the same ones you used for the GeneXpert Dx, GeneXpert Xpress or Xpertise software. If an ASP (FSE) previously performed Xpert Check and is not now on site, the user name and password should have been provided for this step to enter the code. If the user name or password are not now available, contact your ASP or your local Cepheid Technical Support office.

5. Touch or click the **Enter Xpert Check Code** button. See [Figure 2-42](#). The Enter Xpert Check code screen will appear. See [Figure 2-43](#).

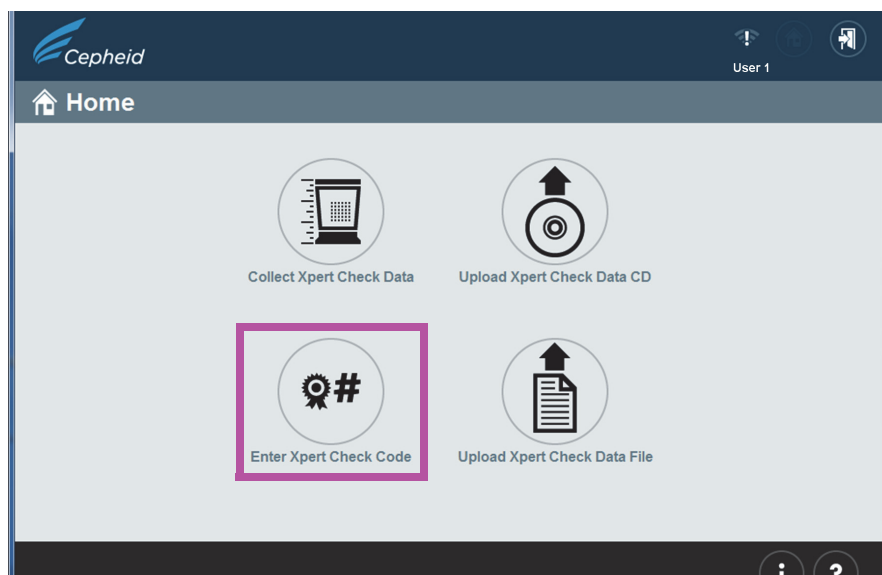


Figure 2-42. Home Screen, showing Enter Xpert Check Code Button

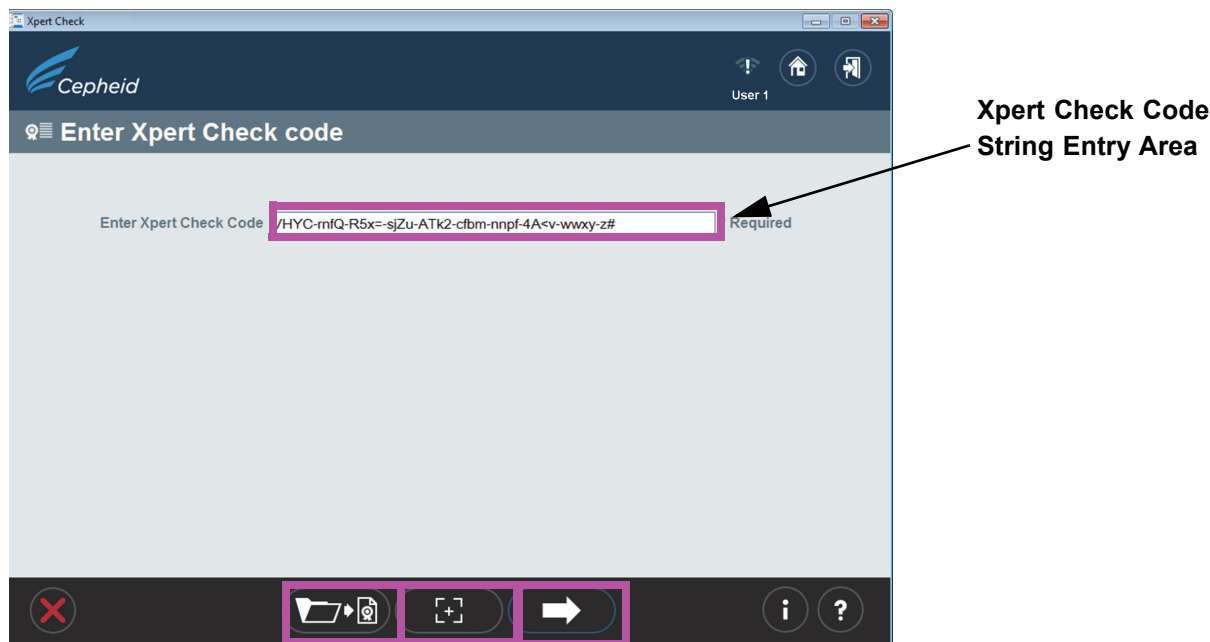


Figure 2-43. Enter Xpert Check code Screen

6. Enter your Xpert Check code as described below.

In this step, there are various ways to enter the Xpert Check code, depending on your system. Your four options are listed below.



- A. Option 1 (For GeneXpert Dx or Infinity systems only): Use your scanner to input the barcode as follows: First, click the icon located in the bottom center of the screen. The Xpert Check Code File ([Figure 2-44](#)) will appear on your screen. Position your scanner to scan the barcode on the Code form, using care to avoid any reflection on the monitor that may interfere with your scanner. See [Figure 2-44](#) for an example of an Xpert Check Code File.
- B. Option 2 (For all systems): Print a copy of the Xpert Check Code File and use your scanner to scan the barcode on the printed page. See [Figure 2-44](#) for an example of an Xpert Check Code File.
- C. Option 3 (For GeneXpert Dx and Infinity systems only): Copy and paste the code string into the Enter code screen from the screen's display. The code string is visible on [Figure 2-44](#).
- D. Option 4 (For all systems): Type in the code string manually using the information on your screen or printed page.

When you have successfully entered the code, touch or click the forward arrow at the bottom of the screen to continue. The Applying Xpert Check code screen will appear. See [Figure 2-45](#).



Xpert Check Code File

Here is the Xpert Check code for the recent data collection of your modules for the system identified below.

Xpert Check data collection performed on 30 September 2020 15:02:31 PST

GX Instrument Name:	My GeneXpert
Cepheid System ID:	123456
Software Version:	Xh1.5a
Data Collected By:	admin1
Institution Name:	Institution1
Laboratory Name:	Lab1
Street Address:	100 Main Street, Suite 202
City:	New York
State/Province:	NY
Postal Code:	10001
Country:	USA
Email:	user@institution.com
Facility Phone Number:	408 400-0000
Extension:	
Mobile:	
ASP Code:	US01

Scan or enter the Xpert Check code to complete the Xpert Check process.

Xpert Check Code String



Barcode

VDQ&-k<4x-Tkq3-@yww-s@DZ-Hgam-nnpA-d88U-xwxy-z#

1. Cepheid recommends that system performance should be evaluated annually using Xpert Check.
2. Cepheid declares that the I-CORE modules in the GeneXpert® Instrument were checked using an Xpert Check product. NIST traceable qualification standards are used to control the parameters for the fluorescence standards of concentration, brightness, and spectrum. Cepheid products are manufactured, quantified and controlled under a Quality System compliant with ISO 13485 and QSR requirements.

GeneXpert® Xpert Check Version: Xh1.5a

Page 1 of 1

Figure 2-44. Xpert Check Code File - Example

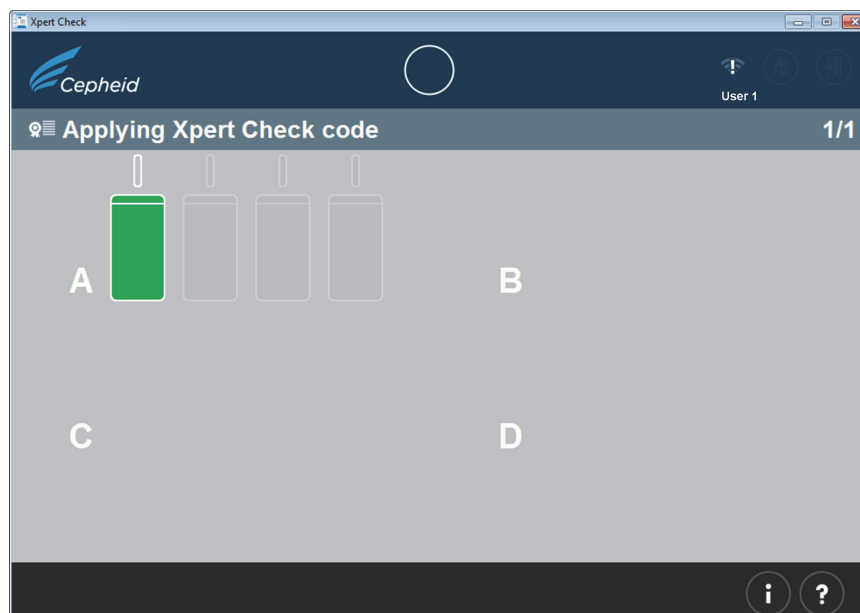


Figure 2-45. Applying Xpert Check code Screen Example

- E. After the Xpert Check code has been applied, the Xpert Check Complete screen will appear with the location of the Xpert Check Report displayed in the **Xpert Check Data Directory** area. Write down the file path and location of the Xpert Check Report file, as shown. See [Figure 2-46](#).

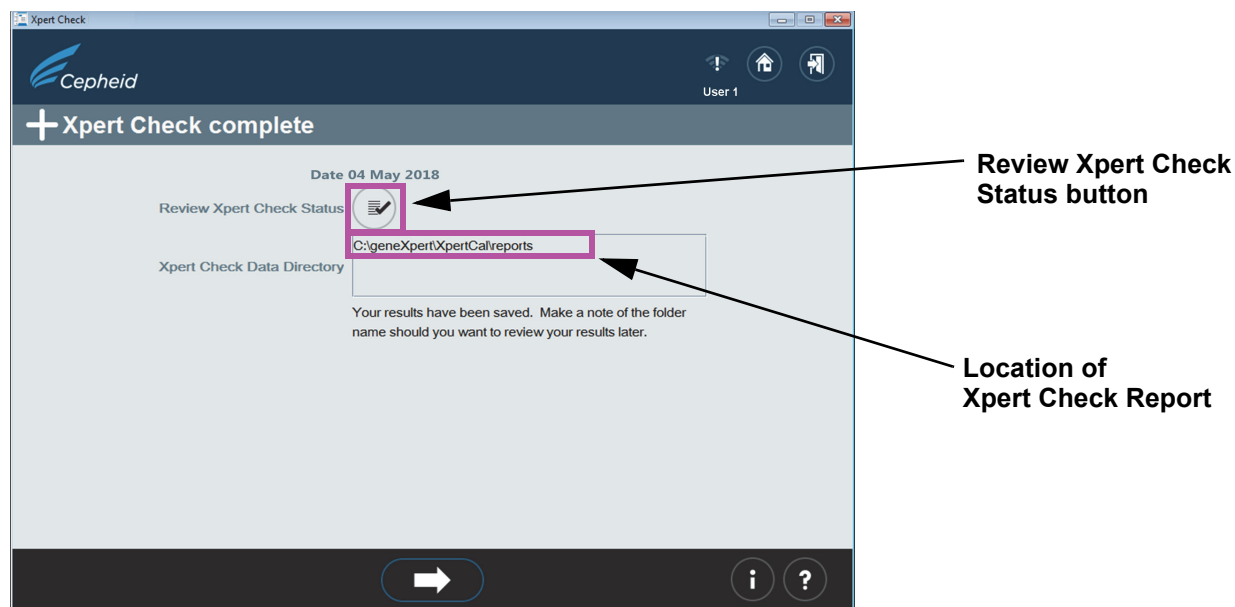


Figure 2-46. Xpert Check complete Screen

- F. Touch or click the **Review Xpert Check Status** button (see [Figure 2-46](#)).
- G. The Xpert Check status screen will appear. See [Figure 2-47](#). In the Xpert Check status screen, the successfully checked modules are indicated by a + symbol on a green module.

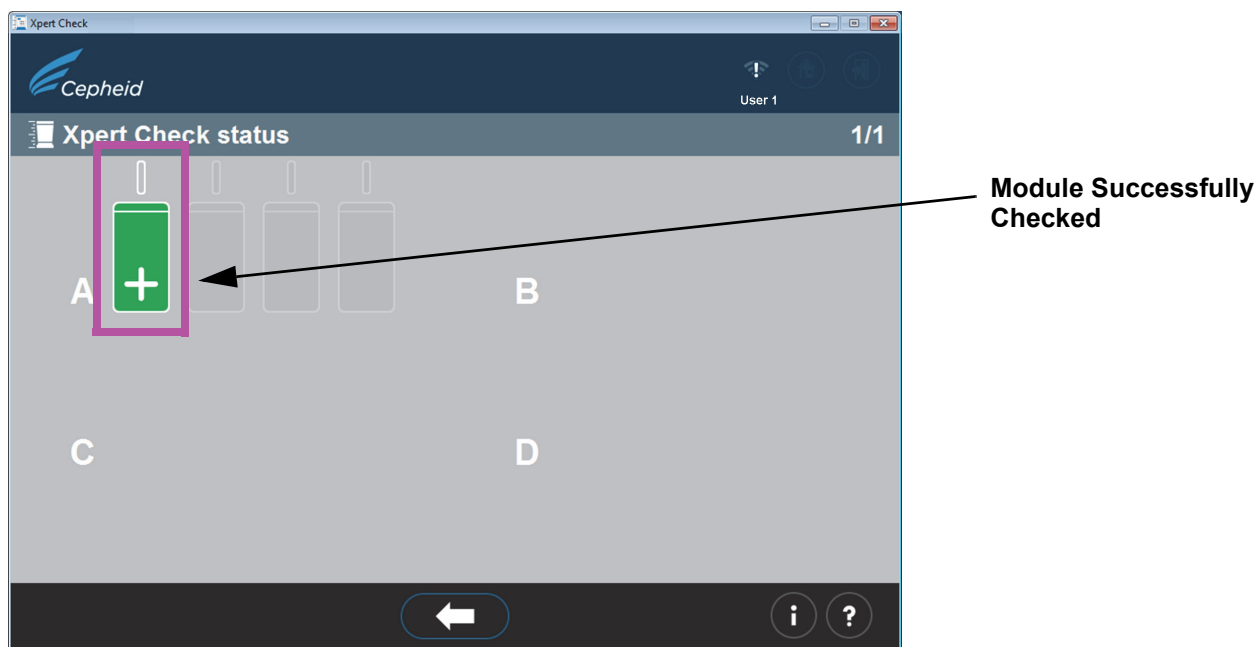


Figure 2-47. Xpert Check status Screen

Note

If the Xpert Check report on the computer has been deleted, contact your ASP or the local Cepheid Technical Support office for assistance.

7. Identify the generated Xpert Check Report file in the folder
C:\GeneXpert\XpertCall\Reports.
8. Identify the generated Xpert Check Summary Report file in the folder
C:\GeneXpert\XpertCall\Reports.
 - A. See [Figure 2-48](#) for an example of a Xpert Check Summary Report.
The Xpert Check Summary Report lists the modules that had an unsuccessful test and require retesting or service.
The modules requiring retesting or service are listed by serial number in Table 1 on the form in [Figure 2-48](#). When requesting service, provide these listed serial numbers to your ASP or the local Cepheid Technical Support office.
Gateway information is provided in Table 2 of the form.



Xpert Check Summary Report

Please Note:

Xpert Check data collection performed on 30 September 2020 09:37:04 PDT
 All modules that DID NOT pass Xpert Check are listed in Table 1: Modules Requiring Service.
 Gateway Informations are provided in Table 2.
 Complete test results for each module are listed in Table 3: Detailed Test Results by Module.

GX Instrument Name:	My 6Color
Cepheid System ID:	12345
Data Collected By:	User1
Institution Name:	Institution1
Laboratory Name:	Laboratory Sunnyvale
Street Address:	123 Main Street
City:	Sunnyvale
State/Province:	CA
Postal Code:	90001
Country:	USA
Email:	User1@Institution1.com
Facility Phone Number:	408-400-XXXX
Extension:	
Mobile:	
ASP Code:	US03

Table 1: Modules Requiring Service

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

Table 2: Gateway Information

Gateway Serial Number	MAC Address
804471	00:21:38:00:2E:1B
804470	00:21:38:00:2E:1A

Figure 2-48. Xpert Check Summary Report Example - Page 1



Xpert Check Summary Report

Table 3: Detailed Test Results by Module Serial Number

The column header will show Module Serial Number, followed by (Location / Cartridge Lot).

If a module undergoes multiple tests, the Module Serial Number will be shown as Module Serial Number : Cartridge -Test Run.

Test	639565 (A1/00402)
Cartridge Load	pass
Module Tests	pass
Ambient Temperature	pass
Motherboard EEPROM	pass
ICORE EEPROM	pass
+12V Power Supply	pass
-12V Power Supply	pass
+24V Power Supply	pass
Valve Drive	pass
Valve Label Dropouts	pass
Valve Home Integrity	pass
Valve Timing	pass
Valve Drift	pass
Pump Drive	pass
Ultrasonic	pass
ICORE Heater	pass
ICORE Fan	pass
Force Sensor	pass
Optical Check	fail
EBF Value	pass
Probe Check	fail

1. Cepheid recommends that system performance should be evaluated annually using Xpert Check.
2. Cepheid declares that the I-CORE modules in the GeneXpert® Instrument were checked using an Xpert Check product. NIST traceable qualification standards are used to control the parameters for the fluorescence standards of concentration, brightness, and spectrum. Cepheid products are manufactured, quantified and controlled under a Quality System compliant with ISO 13485 and QSR requirements.

Figure 2-49. Xpert Check Summary Report Example - Page 2

2.4 Return System to Normal Operation

Note

Return the system to normal operation by following one of the three procedures listed in this section for the GeneXpert Dx, GeneXpert Xpress, the Infinity-48, the Infinity 48s, or the Infinity-80.

2.4.1 GeneXpert Dx

Ensure all Xpert Check cartridges and CDs have been removed from the GeneXpert Dx.

1. Restart your GeneXpert system and computer. Follow the instructions in the GeneXpert Dx System Operator Manual.
2. The system will be ready for full operation.

2.4.2 GeneXpert Xpress

Ensure all Xpert Check cartridges and CDs have been removed from the GeneXpert Xpress.

1. Restart your GeneXpert Xpress system. Follow the instructions in the GeneXpert Xpress User's Guide.
2. The system will be ready for full operation

2.4.3 Infinity-48

Ensure all Xpert Check cartridges and CDs have been removed from the Infinity-48.

1. Restart the Xpertise software and switch the system from Manual mode back to Automation mode. Follow the instructions in the GeneXpert Infinity System Operator Manual for the Infinity-48.
2. The system will be ready for full operation.

2.4.4 Infinity-48s or Infinity-80

Ensure all Xpert Check cartridges and CDs have been removed from the Infinity-48s or Infinity-80.

1. Restart the Xpertise software. Follow the instructions in the GeneXpert Infinity System Operator Manual.

The system will be in Automation mode, ready for full operation.

2.5 Information Key Screen

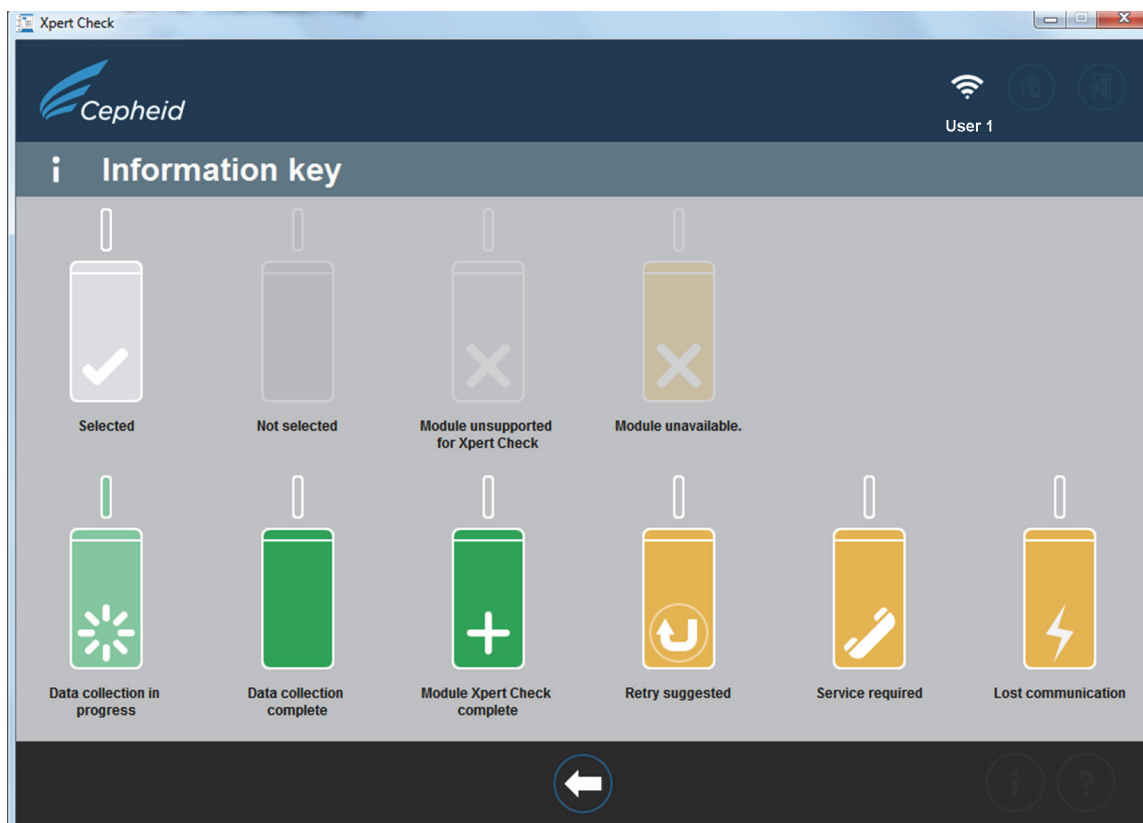


Figure 2-50. Information key Screen

2.5.1 Reasons to Repeat Xpert Check with a New Cartridge

If the onscreen instructions direct you to retest, repeat the test according to the instructions in [Step B.](#) on [page 2-19](#).

2.5.2 Reasons to Repeat Xpert Check with the Same Cartridge

If software reports that the cartridge film seal was not broken, remove the original cartridge, rescan the cartridge barcode, open the lid, close the lid, and reinsert the cartridge. Restart the Xpert Check procedure for the affected module.

2.5.3 Application of Xpert Check Code



Xpert Check is not complete until the Cepheid-supplied Xpert Check code is applied to the system being tested. Upon receipt of the Quality Assurance Xpert Check Code from Cepheid, apply the code to your system using the Xpert Check Software to complete the Xpert Check process.

Xpert[®] HBV Viral Load

REF GXHBV-VL-CE-10

Инструкция по применению теста

CE 2797 **IVD**

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Xpert® HBV Viral Load

Для диагностического применения *in vitro*.

1 Фирменное название

Xpert® HBV Viral Load

2 Наименование медицинского изделия

Xpert HBV VL

3 Целевое использование

Тест Cepheid Xpert® HBV Viral Load (VL) представляет собой тест *in vitro*, выполняемый методом амплификации нуклеиновых кислот для количественного определения ДНК вируса гепатита В (ВГВ) в образцах сыворотки или плазмы (с ЭДТА) человека, полученных у хронически ВГВ-инфицированных лиц, на автоматизированной системе GeneXpert®.

Тест предназначен для использования в контексте общей клинической картины и информации о прочих лабораторных маркерах прогноза заболевания, как вспомогательное средство оценки вирусологического ответа на противовирусную терапию путем определения изменений уровней ДНК ВГВ в плазме или сыворотке.

Тест не предназначен для скрининга на ВГВ доноров или для использования в качестве подтверждающего диагностического теста.

4 Краткие сведения и разъяснения

Вирус гепатита В (ВГВ) представляет собой небольшой ДНК-содержащий вирус с оболочкой из семейства *Нерадnaviridae*, который вызывает острый и хронический гепатит В. Он содержит небольшого размера геном из кольцевой ДНК диаметром 42 нм, двухцепочечной в одних частях и одноцепочечной в других. ВГВ содержит различные антигенные компоненты, включая поверхностный антиген вируса гепатита В (HBsAg), ядерный антиген вируса гепатита В (HBeAg) и е-антиген вируса гепатита В (HBeAg). ВГВ передается при попадании на кожу или слизистые оболочки крови или других биологических жидкостей инфицированного лица, от матери к новорожденному, при тесном бытовом контакте, при переливании крови без надлежащего скрининга или при повторном использовании нестерилизованных шприцев или игл для инъекций в медицинских учреждениях, при употреблении инъекционных наркотиков и половом контакте с инфицированным лицом.

Хронический вирусный гепатит В может быть HBeAg-положительным и HBeAg-отрицательным.

Серораспространенность HBsAg в различных возрастных группах существенно различается в разных географических регионах. Самый высокий (> 5 %) этот показатель является в тропической Африке, в некоторых частях Балканского региона, в Восточной Азии, Океании и в бассейне реки Амазонки (Южная Америка). В Центральной Латинской Америке, Северной Америке и Западной Европе распространенность составляет менее 2 %. В целом почти половина населения земного шара проживает в высокоэндемичных регионах.¹ Заболеваемость хроническим гепатитом В и связанная с ним смертность связаны с персистенцией репликации вируса и развитием цирроза печени и (или) гепатоцеллюлярного рака.² Смертность от вирусного гепатита со временем увеличилась, и будет продолжать расти, если заболевшие лица не будут выявляться и получать лечение.³

Вакцина против ВГВ используется у новорожденных, и это позволило существенно уменьшить число новых случаев хронической инфекции, однако охват вакцинацией составляет всего 39 %.³ В 2015 г. хроническая инфекция ВГВ имела у 3,5 % населения планеты, при этом наибольшая встречаемость заболевания была характерна для Западно-Тихоокеанского региона и Африки.³ Только 9 % инфицированных ВГВ знали о своем диагнозе, и только

8 % из осведомленных о диагнозе пациентов получали лечение.³ Для лечения пациентов в соответствующих случаях применяются аналоги нуклеотидов и нуклеозидов, такие как тенофовир и энтекавир, так как они эффективно подавляют репликацию ВГВ, предотвращают прогрессирование до цирроза и уменьшают смертность, связанную с поражением печени.¹ Лечение ВГВ является пожизненным.¹

5 Принципы проведения процедуры

Тест Xpert® HBV VL – это автоматический тест для количественного определения вируса гепатита В. Этот тест выполняют на анализаторах Cepheid GeneXpert и GeneXpert Infinity.

Система приборов GeneXpert автоматизирует и интегрирует процессы очистки образцов, амплификации нуклеиновых кислот и обнаружения целевой последовательности в простых или сложных образцах с использованием ПЦР в режиме реального времени. Система состоит из прибора, персонального компьютера и предустановленного программного обеспечения для выполнения тестов и просмотра результатов. Для работы с системой требуются одноразовые картриджи GeneXpert, которые содержат реагенты для ПЦР и в которых происходят очистка и процессы ПЦР. Поскольку картриджи представляют собой замкнутые системы, вероятность перекрестной контаминации между образцами сводится к минимуму. Полное описание систем представлено в соответствующем *руководстве оператора GeneXpert Dx* или *руководстве оператора GeneXpert Infinity*.

В комплект теста Xpert® HBV VL входят реагенты для обнаружения ДНК ВГВ в образцах и два внутренних контроля для количественного определения ДНК ВГВ. Внутренние контроли также предназначены для контроля правильности обработки целевой последовательности и для отслеживания присутствия ингибиторов ПЦР. Контроль зондов (Probe Check Control, PCC) предназначен для проверки регидратации реагентов, заполнения пробирки для ПЦР в картридже, целостности зондов и стабильности красителя.

Этот тест стандартизован по 4-му международному стандарту Всемирной организации здравоохранения (ВОЗ) для ДНК ВГВ для методик амплификации нуклеиновых кислот (код NIBSC: 10/266).⁴

6 Реагенты и приборы

6.1 Комплект поставки

Набор реагентов теста Xpert HBV VL содержит реагенты в количестве, достаточном для анализа 10 образцов и (или) образцов контроля качества. В набор входят:

Картриджи HBV VL со встроенными реакционными пробирками	10
- Гранулы 1, 2 и 3 (лиофилизированные) - Реагент для лизирования (гуанидина тиоцианат) - Ополаскивающий реагент - Элюирующий реагент - Реагент связывания - Реагент протеиназа К	по 1 каждого типа в одном картридже 1,7 мл в одном картридже 0,5 мл в каждом картридже 1,5 мл в каждом картридже 1,5 мл в каждом картридже 0,48 мл в каждом картридже
Одноразовые пипетки для переноса, 1 мл	10 в каждом наборе
Компакт-диск	1 в каждом наборе
- Файл описания теста (ADF) - Инструкцию по импортированию файла ADF в программное обеспечение GeneXpert и Infinity - Инструкция по применению (вкладыш-инструкция)	

Прим. Паспорта безопасности вещества (Safety Data Sheet, SDS) можно найти по ссылкам www.cepheid.com или www.cepheidinternational.com на вкладке **ПОДДЕРЖКА (SUPPORT)**.

Прим. Для изготовления бычьего сывороточного альбумина (БСА), входящего в состав гранул данного изделия, использовалась только плазма бычьей крови животных, выращенных в США. В пищу быков не добавлялись белки, полученные из тканей жвачных животных, а также другие белки животного происхождения; всех животных обследовали до и после забоя. Во время производства не происходило смешивания сырья с другими материалами животного происхождения.

7 Хранение и обращение

- Храните картриджи анализа Xpert® HBV VL при температуре 2–35 °C до истечения срока годности, указанного на этикетке.
- Если картриджи хранятся на холоде, доведите их до комнатной температуры перед применением.
- Не используйте картриджи с истекшим сроком годности.
- Не открывайте крышку картриджа до тех пор, пока не будете готовы начать выполнение теста.
- Не используйте картриджи с признаками утечки.

8 Необходимые материалы, не входящие в комплект поставки

- Анализатор GeneXpert® Dx или GeneXpert® Infinity (номер по каталогу зависит от конфигурации): прибор GeneXpert, компьютер с патентованным программным обеспечением GeneXpert версии 4.7b или выше (системы GeneXpert Dx) либо Xpertise версии 6.4b или выше (системы Infinity-80/Infinity-48s), сканер штрих-кодов и соответствующее руководство оператора прибора GeneXpert.
- Принтер: если необходим принтер, обратитесь в службу технической поддержки компании Cepheid, чтобы организовать приобретение рекомендованного принтера.
- Отбеливатель или гипохлорит натрия
- Денатурированный этанол

9 Предупреждения и меры предосторожности

9.1 Общие положения

- Для использования при проведении диагностических тестов *in vitro*.
- При работе со всеми биологическими образцами, в том числе и с использованными картриджами, следует считать их способными к переносу возбудителей инфекционных заболеваний. Поскольку часто невозможно предугадать, что может переносить инфекцию, обращение со всеми биологическими образцами требует соблюдения стандартных мер предосторожности. Методические рекомендации по обращению с образцами предоставляются агентством «Центры по контролю и профилактике заболеваний США» (U.S. Centers for Disease Control and Prevention)⁵ и Институтом клинических и лабораторных стандартов (Clinical and Laboratory Standards Institute).⁶
- С целью избежать контаминации образцов и реагентов рекомендуется следовать принципам надлежащей лабораторной практики, включая правило замены перчаток перед началом работы с образцом следующего пациента.
- Следуйте принятым в учреждении процедурам техники безопасности по работе с химическими веществами и обращению с биологическими образцами.
- Не заменяйте реагенты теста Xpert HBV VL другими реагентами.
- Не открывайте крышку картриджа Xpert HBV VL до тех пор, пока не будете готовы внести образец.
- Не используйте картридж, если он упал после извлечения из упаковки.
- Не встряхивайте картридж. Встряхивание или падение картриджа после вскрытия его крышки может привести к получению недействительных результатов.
- Не используйте картридж с поврежденной реакционной пробиркой.
- Не закрывайте этикетку со штрих-кодом на картридже.

- При помощи пипетки для переноса или прецизионной пипетки внесите образец в картридж. Не переливайте образец в картридж непосредственно из устройства для сбора.
- Каждый одноразовый картридж Xpert HBV VL применяется для проведения только одного теста. Не используйте картриджи повторно.
- Каждая одноразовая пипетка используется для переноса одного образца. Не используйте одноразовые пипетки повторно.
- Пользуйтесь чистым лабораторным халатом и перчатками. Перчатки подлежат замене перед обработкой каждого следующего образца.
- В случае загрязнения рабочей зоны или оборудования образцами или контролями тщательно протрите контактированный участок свежеприготовленным 0,5 % раствором гипохлорита натрия (или разбавленным в соотношении 1:10 хлорсодержащим хозяйственным отбеливателем). Затем протрите поверхность 70 % этиловым спиртом. Перед продолжением работы дайте рабочим поверхностям полностью высохнуть.
- Биологические образцы, устройства для переноса и использованные картриджи следует считать возможными переносчиками возбудителей инфекционных заболеваний, при обращении с ними необходимо соблюдать стандартные меры предосторожности. Для правильного удаления в отходы использованных картриджей и неиспользованных реагентов следуйте принятым в вашем учреждении правилам защиты окружающей среды при обращении с отходами. Эти материалы могут иметь свойства химически опасных отходов и требовать выполнения особых национальных или региональных процедур удаления в отходы. Если принятые в стране или регионе правила не дают ясных указаний по правильному удалению в отходы, биологические образцы и использованные картриджи следует удалять в отходы с соблюдением правил ВОЗ (Всемирной организации здравоохранения) относительно обращения с медицинскими отходами и их удаления.⁷

10 Опасные химические факторы^{8,9}

Реагент для лизирования (гуанидина тиоцианат)

- Сигнальное слово: ПРЕДОСТЕРЕЖЕНИЕ
- Заявления об опасности СГС ООН
 - Вредно при проглатывании
 - Вызывает слабое раздражение кожи
 - Вызывает раздражение глаз
- Предостерегающие заявления СГС ООН
 - Профилактика
 - После использования тщательно вымыть.
 - Реагирование
 - При раздражении кожи: Обратиться за медицинской консультацией/помощью.
 - ПРИ ПОПАДАНИИ В ГЛАЗА: Осторожно промыть водой в течение нескольких минут. Снять контактные линзы, если вы ими пользуетесь, и если это легко сделать. Продолжить промывание.
 - Если раздражение глаз не проходит: Обратиться за медицинской консультацией/помощью.
 - При плохом самочувствии обратиться в ТОКСИКОЛОГИЧЕСКИЙ ЦЕНТР или к врачу-специалисту/терапевту.

11 Образцы: взятие, транспортировка и хранение

Цельную кровь следует собирать в пробирки для сбора образцов с K₂-ЭДТА, пробирки PPT-ЭДТА или пробирки для сбора сыворотки, и центрифугировать для отделения плазмы/сыворотки от эритроцитов, в соответствии с инструкциями изготовителя.

- Для теста Xpert HBV VL требуется не менее 0,6 мл плазмы или сыворотки. Если используется пипетка для переноса, входящая в набор, ее следует заполнить сывороткой или плазмой до четвертой метки (1,0 мл). Либо, при использовании прецизионной пипетки, требуется 0,6 мл плазмы или сыворотки. См. указания в Раздел 12.2, вариант 1 и вариант 2, соответственно.
- Перед получением плазмы или сыворотки цельную кровь можно хранить до 24 часов при температуре 2–35 °C или до 3 дней при температуре 2–8 °C. Центрифугировать в соответствии с инструкциями изготовителя.
- После центрифугирования и отделения плазму и сыворотку можно хранить до исследования в течение до 24 часов при температуре 2–35 °C или до 7 дней при температуре 2–8 °C.

- Стабильность замороженных (от -80 °C до -20 °C) образцов плазмы и сыворотки сохраняется в течение 6 недель.
- Стабильность образцов плазмы и сыворотки сохраняется в течение не более трех циклов замораживания/размораживания.
- До переноса в картридж образцы плазмы и сыворотки следует разморозить и дождаться их согревания до комнатной температуры.
- При транспортировке образцов цельной крови, плазмы и сыворотки следует соблюдать местные, региональные и федеральные нормативные требования по транспортировке возбудителей.

12 Процедура

12.1 Подготовка образца

Прим. Анализ следует начать не позднее чем через 4 часа после того, как образец был помещен в картридж.

1. После центрифугирования образца цельной крови, плазму можно перенести при помощи пипетки непосредственно в картридж. Для получения действительных результатов крайне важно использовать достаточный объем образца (см. указания в Раздел 12.2. Подготовка картриджа).
2. Замороженные образцы перед использованием следует поместить в условия комнатной температуры (20–35 °C) до их полного оттаивания и согревания до комнатной температуры.
3. Образцы плазмы и сыворотки, хранившиеся при температуре 2–8 °C, перед использованием необходимо извлечь из холодильника и дождаться их согревания до комнатной температуры.
4. Образцы плазмы, хранившиеся при температуре 2–8 °C или замороженные и оттаявшие, перед использованием необходимо перемешать на вихревой мешалке в течение 10 секунд. Мутный образец следует осветлить непродолжительным центрифугированием.

12.2 Подготовка картриджа

1. Пользуйтесь одноразовыми защитными перчатками.
2. Если картриджи хранятся на холоде, доведите их до комнатной температуры перед применением.
3. Осмотрите картридж на предмет отсутствия повреждений. В случае повреждения не используйте его.
4. Нанесите на картридж этикетку с идентификатором образца.
5. Откройте крышку картриджа.
6. Внесите образец в картридж.
 - **Способ 1.** Если используется пипетка для переноса, входящая в набор (см. Рисунок 1), ее следует заполнить плазмой или сывороткой (из пробирки для сбора) до четвертой метки (1,0 мл) или несколько выше. Выпустите содержимое пипетки в предназначенную для образца камеру картриджа (см. Рисунок 2).
 - **Способ 2.** При использовании прецизионной пипетки, необходимо перенести 0,6 мл плазмы или сыворотки (из пробирки для сбора) в предназначенную для образца камеру картриджа (см. Рисунок 2).

Прим. Не снимайте тонкую полимерную пленку, покрывающую внутреннее кольцо с 13 портами картриджа.

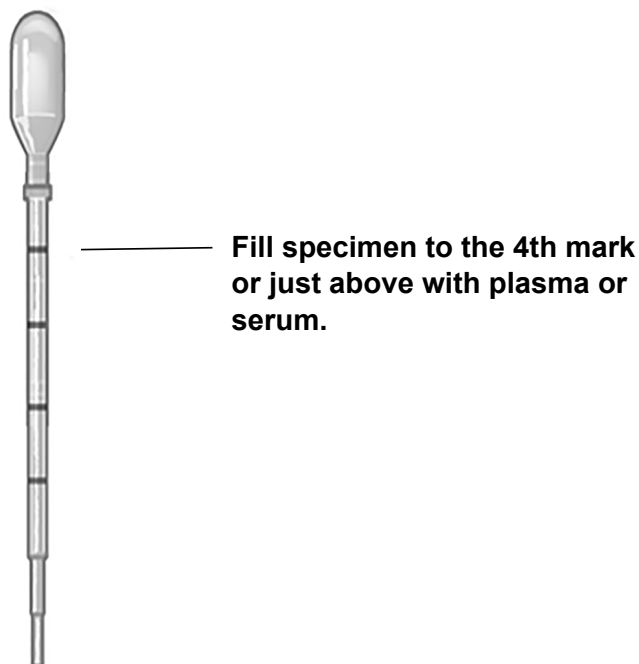


Рисунок 1. Пипетка для переноса теста Xpert HBV VL

7. Закройте крышку картриджа. Убедитесь, что крышка надежно защелкнулась на месте.



Рисунок 2. Картридж Xpert Xpert HBV VL (вид сверху)

12.3 Запуск теста

Важное замечание Прежде чем начинать анализ, убедитесь, что файл с описанием теста (assay definition file, ADF) Xpert HBV VL импортирован в программное обеспечение.

В данном разделе перечислены основные действия при выполнении теста. Подробные инструкции приводятся в *руководстве оператора системы GeneXpert Dx* или *руководстве оператора системы GeneXpert Infinity*, в зависимости от используемой модели прибора.

Прим. Выполняемые действия могут быть другими, если системный администратор изменит установленную по умолчанию рабочую последовательность системы.

1. Включите приборную систему GeneXpert:

- При использовании GeneXpert Dx вначале следует включить прибор, а затем компьютер. Программное обеспечение GeneXpert Dx запустится автоматически, или же может потребоваться двойной щелчок по ярлыку программного обеспечения GeneXpert Dx на рабочем столе Windows®.
 - или
 - При использовании прибора GeneXpert Infinity следует включить прибор. Программное обеспечение GeneXpert запустится автоматически либо после двойного щелчка на ярлыке программного обеспечения Xpertise, находящегося на рабочем столе Windows®.
2. Войдите в программное обеспечение приборной системы GeneXpert, используя свое имя пользователя и пароль.
 3. В окне системы GeneXpert выберите пункт **Создать анализ (Create Test)** (для GeneXpert Dx) или выберите пункт **Команды (Orders)**, а затем **Задать команду на проведение анализа (Order Test)** (для Infinity). Откроется окно **Создать анализ (Create Test)**.
 4. Отсканируйте «ID пациента» (Patient ID) (не обязательно). Если вводится «ID пациента» (Patient ID), то проследите за тем, чтобы он был введен корректно. «ID пациента» (Patient ID) указывается в левой части окна «Просмотреть результаты» (View Results) и связывается с результатами теста.
 5. Отсканируйте «ID образца» (Sample ID) или введите вручную «ID образца» (Sample ID). Если вводится «ID образца» (Sample ID), проследите за тем, чтобы он был введен корректно. «ID образца» (Sample ID) указывается в левой части окна «Просмотреть результаты» (View Results) и связывается с результатами анализа.
 6. Отсканируйте штрихкод на картридже теста Xpert HBV VL. На основе информации, считанной со штрихкода, программным обеспечением автоматически заполняются следующие поля: «ID партии реагента» (Reagent Lot ID), «С/Н картриджа» (Cartridge SN) и «Срок годности» (Expiration Date).

Прим. Если штрихкод картриджа Xpert HBV VL не сканируется, повторите анализ с новым картриджем.

7. Щелкните **Начать анализ (Start Test)** (для GeneXpert Dx) или **Отправить (Submit)** (для Infinity). В появившемся диалоговом окне введите свой пароль.
8. При использовании системы GeneXpert Infinity поместите картридж на конвейерную ленту. Загрузка картриджа произойдет автоматически, будет выполнен тест, а использованный картридж будет удален в контейнер для отходов.

или

Для прибора GeneXpert Dx:

- a) Откройте дверцу модуля прибора с мигающим зеленым индикатором и загрузите картридж.
- b) Закройте дверцу. После этого начинается тест, и зеленая индикаторная лампа перестает мигать. По завершении процесса теста индикаторная лампа выключается.
- c) Перед открытием дверцы модуля и извлечением картриджа дождитесь разблокирования системой замка дверцы.
- d) Удалите использованные картриджи в подходящий контейнер для сбора отходов образцов согласно стандартной практике, принятой в вашем учреждении.

13 Просмотр и печать результатов

В данном разделе перечислены основные действия по просмотру и печати результатов. Более подробные инструкции по просмотру и печати результатов см. в *руководстве оператора системы GeneXpert Dx* или *руководстве оператора системы GeneXpert Infinity*, в зависимости от используемого прибора.

1. Для просмотра результатов выберите ярлык **Просмотреть результаты (View Results)**.
2. По завершении теста нажмите кнопку **Отчет (Report)** в окне **Просмотреть результаты (View Results)** для просмотра и (или) получения отчета в формате PDF.

14 Контроль качества

Каждый тест содержит контроль достаточности объема образца (Sample Volume Adequacy, SVA), внутренние количественные стандарты (Internal Quantitative Standard, IQS) высокой и низкой концентрации (IQS-H и IQS-L), а также специальные параметры партии (Lot Specific Parameters, LSP) и контроль зондов (Probe Check Control, PCC).

- **Контроль достаточности объема образца (SVA)** — предназначен для подтверждения правильности внесения образца в картридж. Контроль SVA позволяет подтвердить, что в камеру для образца внесен надлежащий объем

образца. Контроль SVA считается пройденным, если его результат соответствует валидированным критериям приемлемости. Если контроль SVA не пройден, отображается либо сообщение **Ошибка 2096 (Error 2096)**, если образец не был внесен в картридж, либо сообщение **ОШИБКА 2097 (ERROR 2097)**, если в картридж был внесен недостаточный объем образца. Система не позволит пользователю возобновить тестирование.

- **Внутренние количественные стандарты высокой и низкой концентрации (IQS-H и IQS-L)** — это две линейаризованные плазмиды, последовательность которых не связана с последовательностью ВГВ. Они находятся в каждом картридже и проходят через весь процесс анализа. Эти стандарты используют для расчета концентрации ДНК ВГВ в образце. Кроме того, IQS-H и IQS-L обнаруживают связанное с образцом ингибирование реакции ПЦР в реальном времени, выполняя функцию контролей обработки образца. Контроли IQS-H и IQS-L считаются пройденными, если их результаты соответствуют валидированным критериям приемлемости.
- **Параметры, специфичные для партии (Lot Specific Parameters, LSP), для количественного определения** — каждая партия набора содержит характерные для нее LSP, созданные путем анализа калибровочной панели ВГВ, прослеживаемой до 4-го международного стандарта ВОЗ для ВГВ (код NIBSC: 10/266)⁴, и IQS-H и IQS-L. Эти LSP уникальны для каждой партии реагента и используются для обеспечения правильного количественного определения.
- **Контроль зондов (Probe Check Control, PCC)** — перед запуском ПЦР анализатор GeneXpert измеряет флуоресцентный сигнал от зондов для отслеживания регидратации гранул, заполнения реакционной пробирки, целостности зондов и стабильности красителя. Контроль PCC считается пройденным, если флуоресцентные сигналы соответствуют валидированным критериям приемлемости.
- **Внешние контроли** — в соответствии с принципами надлежащей лабораторной практики, внешние контроли, **не входящие в данный набор**, следует использовать согласно применимым требованиям местных и государственных уполномоченных организаций.

15 Интерпретация результатов

Результаты интерпретируются системой приборов GeneXpert на основании измерений флуоресцентных сигналов и встроенных алгоритмов расчета; они отображаются в окне «Просмотреть результаты» (View Results) (см. Рисунок 3 — Рисунок 8). Возможные результаты показаны в Таблица 1.

Таблица 1. Результаты теста Xpert HBV VL и их интерпретация

Результат	Интерпретация
ВГВ обнаружен, МЕ/мл (log X,XX) (HBV DETECTED IU/mL, log X.XX) См. Рисунок 3.	ДНК ВГВ обнаружена в концентрации XX МЕ/мл (log X,XX). • Титр ДНК ВГВ находится в пределах диапазона количественного определения теста (10–1,00E09 МЕ/мл). • IQS-H и IQS-L: ПРОЙДЕН (PASS). • Контроль зондов — ПРОЙДЕН (PASS); все проверки в рамках контроля зондов успешно пройдены.
ВГВ ОБНАРУЖЕН >1,00E09 МЕ/мл (HBV DETECTED >1.00E09 IU/mL) См. Рисунок 4.	Обнаруженный титр ДНК ВГВ выше границы диапазона количественного определения теста. • IQS-H и IQS-L: ПРОЙДЕН (PASS). • Контроль зондов — ПРОЙДЕН (PASS); все проверки в рамках контроля зондов успешно пройдены.
ВГВ ОБНАРУЖЕН <10 МЕ/мл (HBV DETECTED <10 IU/mL) См. Рисунок 5.	Обнаруженный титр ДНК ВГВ ниже границы диапазона количественного определения теста. • IQS-H и IQS-L: ПРОЙДЕН (PASS). • Контроль зондов — ПРОЙДЕН (PASS); все проверки в рамках контроля зондов успешно пройдены.
ВГВ НЕ ОБНАРУЖЕН (HBV NOT DETECTED) См. Рисунок 6.	ДНК ВГВ не обнаружена. • IQS-H и IQS-L: ПРОЙДЕН (PASS). • Контроль зондов — ПРОЙДЕН (PASS); все проверки в рамках контроля зондов успешно пройдены.

Результат	Интерпретация
НЕДЕЙСТВИТЕЛЬНЫЙ (INVALID) См. Рисунок 7.	Невозможно установить, присутствует или отсутствует в образце ДНК ВГВ. Повторите тест согласно инструкциям, содержащимся в Раздел 16.2. Процедура повторного теста. - IQS-H и (или) IQS-L: НЕ ПРОЙДЕН (FAIL); пороги цикла (Ct) не находятся в действительном диапазоне. - Контроль зондов — ПРОЙДЕН (PASS); все проверки в рамках контроля зондов успешно пройдены.
ОШИБКА (ERROR) См. Рисунок 8.	Невозможно установить, присутствует или отсутствует в образце ДНК ВГВ. Повторите тест согласно инструкциям, содержащимся в Раздел 16.2. Процедура повторного теста. Контроль зондов — НЕ ПРОЙДЕН (FAIL)*; все или один из контролей зондов не пройдены. Если контроль зондов пройден, ошибка вызвана выходом за границы действительного диапазона предельного максимального давления или сбоям компонента системы.
НЕТ РЕЗУЛЬТАТА (NO RESULT)	Невозможно установить наличие или отсутствие ДНК ВГВ. Повторите тест согласно инструкциям, содержащимся в Раздел 16.2. Процедура повторного теста. Сообщение НЕТ РЕЗУЛЬТАТА (NO RESULT) свидетельствует о том, что собрано недостаточно данных. Такое сообщение, например, может появляться, если лаборант прервал текущий процесс анализа.

Прим. Снимки с экранов тестов даны только в качестве примеров. Номер версии может отличаться от показанной на снимках с экрана в этой инструкции по применению.

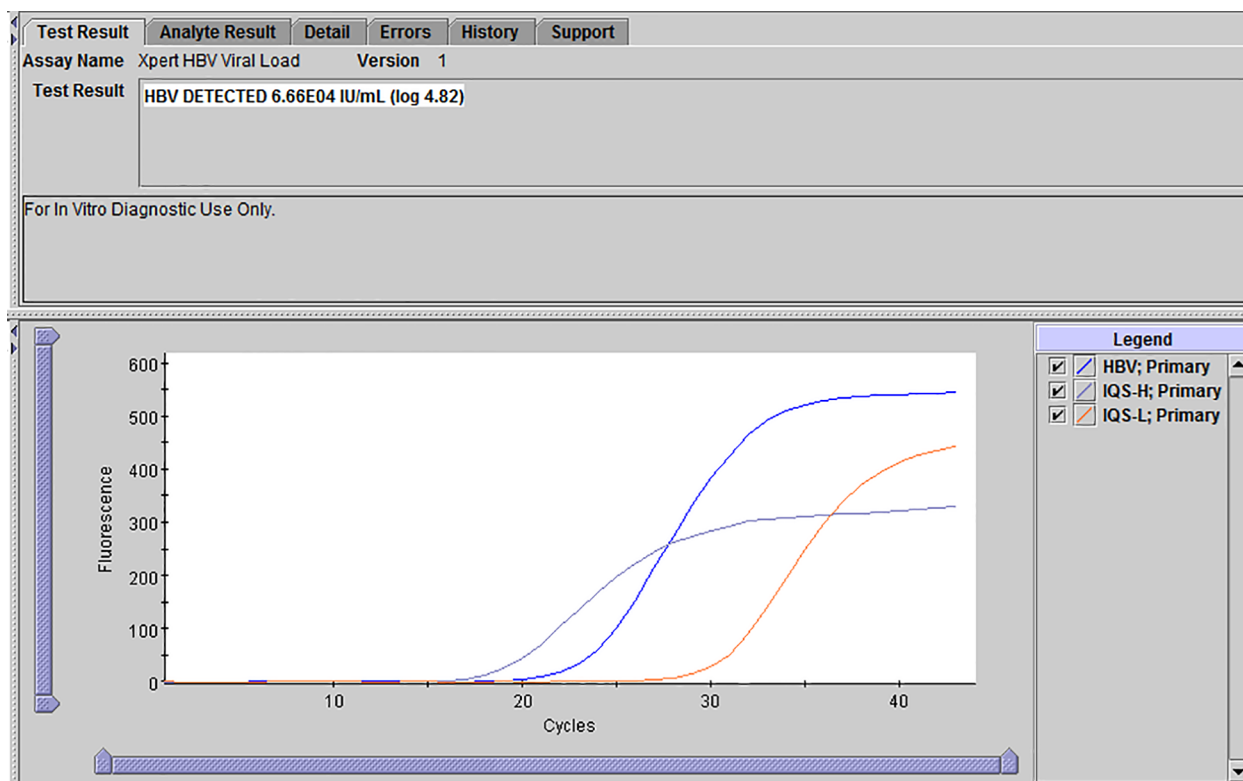


Рисунок 3. Результат: ВГВ обнаружен и количественно определен

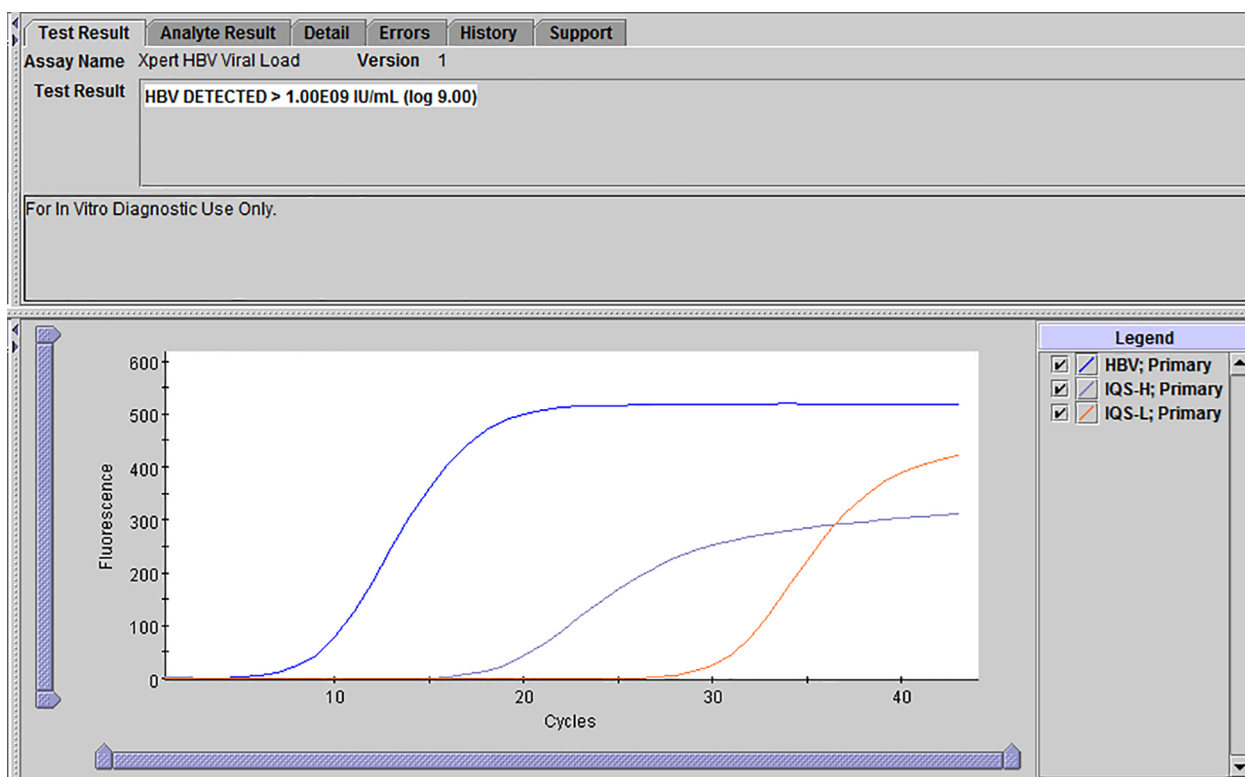


Рисунок 4. Результат: ВГВ обнаружен, но его титр выше границы диапазона количественного определения теста

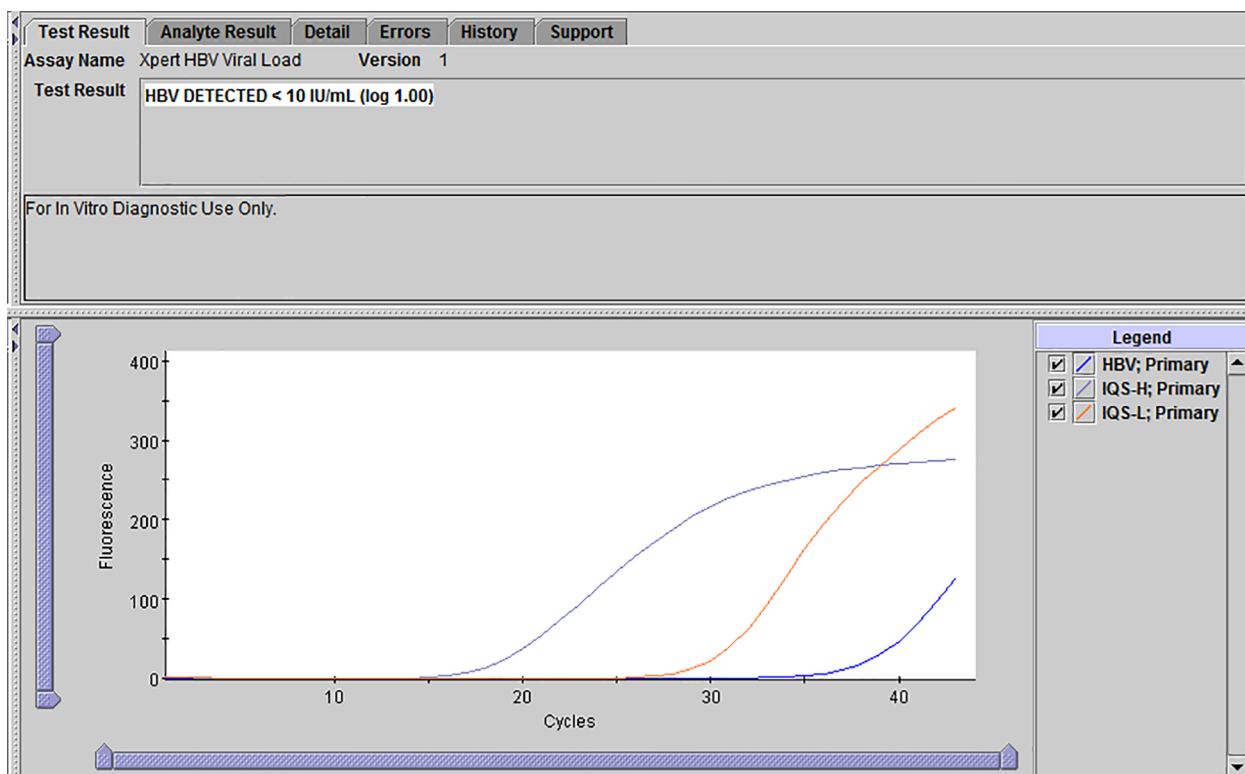


Рисунок 5. Результат: ВГВ обнаружен, но его титр ниже границы диапазона количественного определения теста

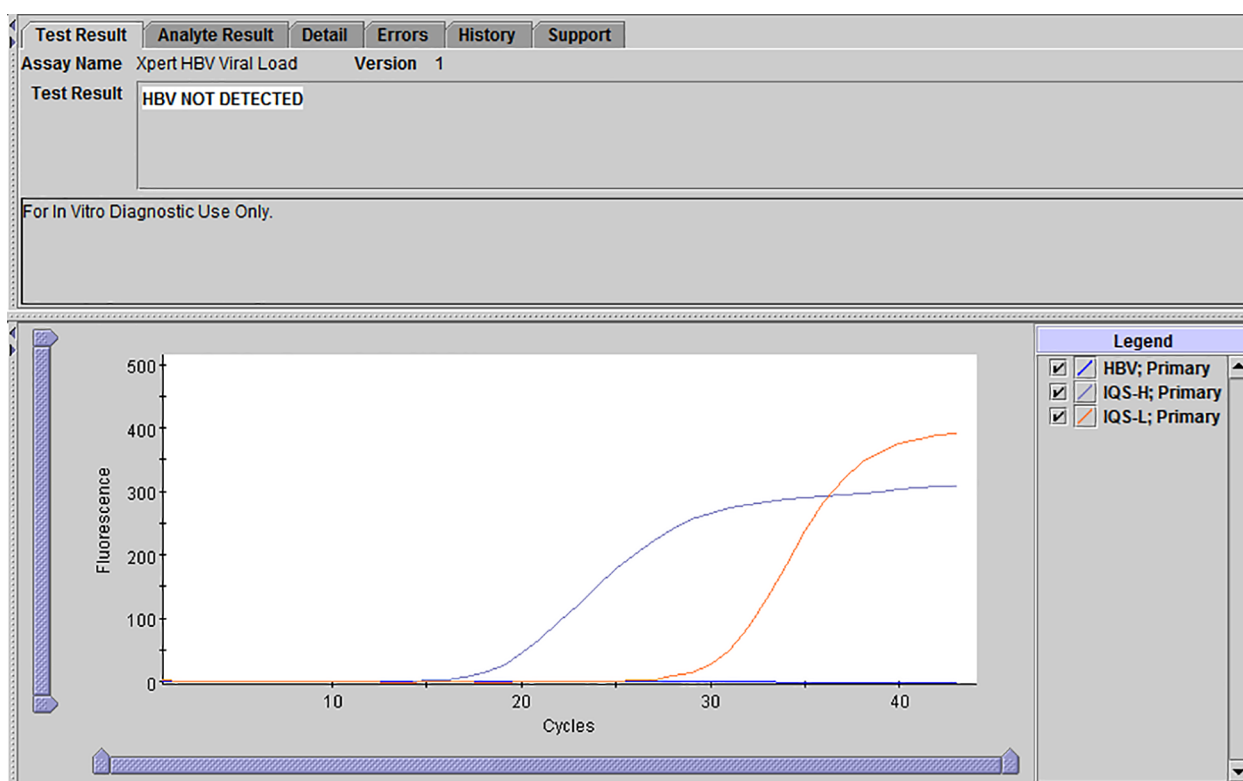


Рисунок 6. Результат: ВГВ не обнаружен

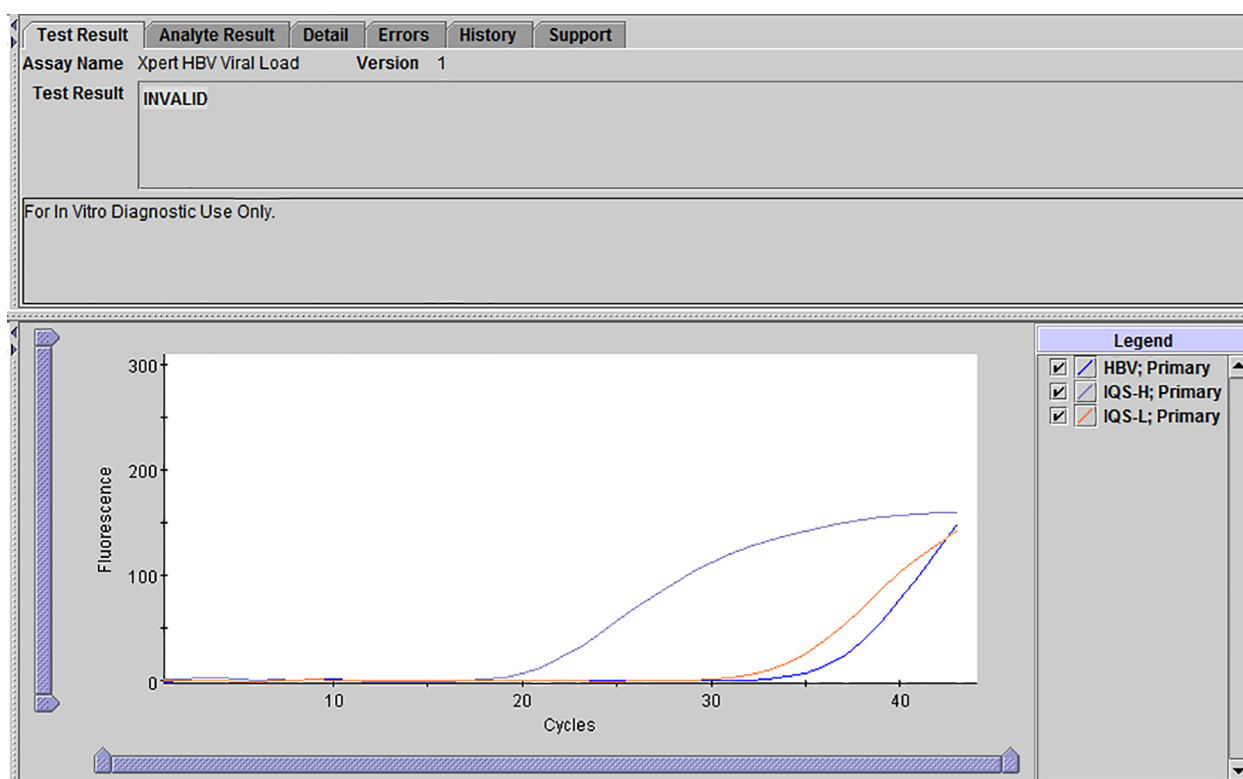


Рисунок 7. Результат: Недействительный результат

Test Result	Analyte Result	Detail	Errors	History	Support
Assay Name	Xpert HBV Viral Load		Version	1	
Test Result	ERROR				
For In Vitro Diagnostic Use Only.					
<No Data Available>					

Рисунок 8. Результат: Ошибка

16 Повторное выполнение теста

16.1 Причины повторного выполнения теста

При получении любого из следующих результатов теста повторите тест в соответствии с указаниями, изложенными в Раздел 16.2. Процедура повторного теста.

- **НЕДЕЙСТВИТЕЛЬНЫЙ (INVALID)** результат может быть связан с одной или более следующих причин:
 - Значения Ct IQS-H и (или) IQS-L не находятся в действительном диапазоне.
 - Образец не был обработан надлежащим образом, или произошло ингибирование ПЦР.
- Результат **ОШИБКА (ERROR)** показывает, что тест был прерван. Возможные причины: внесен недостаточный объем образца, неправильное заполнение реакционной пробирки, обнаружена проблема целостности зонда реагента или превышен максимальный предел давления.
- Сообщение **НЕТ РЕЗУЛЬТАТА (NO RESULT)** свидетельствует о том, что собрано недостаточно данных. Например, если оператор прервал выполняющийся процесс анализа или произошел перебой в подаче электроэнергии.

16.2 Процедура повторного теста

При получении результата **НЕДЕЙСТВИТЕЛЬНЫЙ (INVALID)**, **ОШИБКА (ERROR)** или **НЕТ РЕЗУЛЬТАТА (NO RESULT)** выполните повторное тестирование соответствующего образца с использованием нового картриджа (не допускайте повторного использования картриджа).

1. Извлеките новый картридж из набора.
2. Выполните действия, указанные в Раздел 12. Процедура, включая Раздел 12.2. Подготовка картриджа и Раздел 12.3. Запуск теста.

17 Ограничения

- Во избежание контаминации образцов и реагентов рекомендуется следовать принципам надлежащей лабораторной практики, включая правило замены перчаток перед началом работы с каждым следующим образцом.
- Редкие мутации в целевом регионе теста Xpert HBV VL могут влиять на связывание праймера или зонда, в результате чего концентрация окажется заниженной или вирус не обнаружится.
- Данный тест был валидирован только для использования с образцами сыворотки и плазмы с ЭДТА. Тестирование других типов образцов может привести к получению неточных результатов.
- Отрицательные результаты теста не исключают наличия инфекции ВГВ. Поэтому тест Xpert HBV VL не следует использовать в качестве диагностического для подтверждения инфицирования ВГВ.

18 Функциональные характеристики

18.1 Порог обнаружения

Порог обнаружения теста Xpert HBV VL был определен для генотипа А вируса гепатита В путем тестирования серийных разведений 4^{-го} международного стандарта ВОЗ для ДНК вируса гепатита В (код NIBSC 10/266),⁴ разведенного в сыворотке и плазме с ЭДТА, отрицательных на ВГВ. Панели из образцов сыворотки или плазмы с ЭДТА шести уровней концентрации и отрицательного образца тестировали, соответственно, с использованием реагентов четырех или трех партий. Каждый компонент панели тестировали в течение трех дней, 24 повтора на партию реагентов. Всего каждый компонент панели образцов плазмы был исследован в 96 повторах, а панели образцов сыворотки — в 72 повторах.

Результаты для образцов сыворотки и плазмы с ЭДТА представлены в Таблица 2. Исследование показало, что тест Xpert HBV VL позволяет обнаруживать ДНК ВГВ в международном стандарте ВОЗ в концентрации 3,20 МЕ/мл при исследовании плазмы с ЭДТА и в концентрации 5,99 МЕ/мл при исследовании сыворотки с долей положительных результатов 95% по результатам регрессионного пробит-анализа.

Таблица 2. Порог обнаружения теста Xpert HBV VL при использовании 4^{-го} международного стандарта ВОЗ для ВГВ

Генотип	Материал	Номинальная концентрация ВГВ (МЕ/мл)	Количество действительных повторов	Количество положительных результатов	Доля положительных результатов (%)	95 % LOD по пробит-анализу (95 % доверительный интервал)
А	Плазма	10	95	95	100	3,20 МЕ/мл (2,79–3,60 МЕ/мл)
		5	96	94	98	
		2,5	96	82	85	
		1,25	96	62	65	
		0,625	96	41	43	
		0	96	0	0	
А	Сыворотка	10	72	70	97	5,99 МЕ/мл (5,13–6,86 МЕ/мл)
		5	72	63	88	
		2,5	72	58	81	
		1,25	72	37	51	
		0,625	71	15	21	
		0	72	0	0	

Порог обнаружения для генотипов ВГВ от В до Н определяли путем тестирования панелей из шести или семи компонентов, приготовленных путем внесения ВГВ-положительных образцов, представляющих каждый генотип (генотипы от В до Г из международной референсной панели ВОЗ, код PEI: 5086/08, и генотипа Н в клиническом образце) в плазму с ЭДТА, отрицательную на ВГВ. Каждый компонент панели тестировали в течение трех дней, с использованием трех партий реагентов, всего по 24 повтора на компонент. Результаты представлены в Таблица 3.

Таблица 3. Порог обнаружения для ВГВ генотипов от В до Н в плазме с ЭДТА

Генотип	95 % LOD по пробит-анализу (МЕ/мл)	95 % доверительный интервал (МЕ/мл)
B	1,34	0,98–1,69
C	1,63	1,23–2,03
D	3,96	3,01–4,92
E	3,77	2,76–4,78
F	2,39	1,82–2,96
G	1,21	0,95–1,47
B	3,84	2,91–4,77

Порог обнаружения для ВГВ генотипов от В до Н подтверждали в образцах сыворотки согласно стандарту CLSI EP17-A2¹⁰ в 24 повторях. Если не удавалось достичь доли положительных результатов > 85 %, тестировали образцы более высоких концентраций. Результаты представлены в Таблица 4.

Таблица 4. Подтверждение порога обнаружения (LOD) для генотипов от В до Н в сыворотке

Генотип	Номинальная концентрация ВГВ (МЕ/мл)	Доля положительных результатов (%)
B	1,34	88
C	3,25	96
D	3,96	96
E	3,77	96
F	2,39	92
G	1,21	88
B	3,84	100

Функциональные характеристики теста Xpert HBV VL также оценивали в отношении вируса гепатита В с мутацией в преколовом участке. Для этого тестировали с одной партией реагентов секвенированный клинический образец ВГВ, включавший две мутации в преколовом участке (C1858T и G1896A) и две мутации основного корового промотора (A1762T и G1764A), разведенный до концентрации 10 МЕ/мл в сыворотке и плазме с ЭДТА. Доля положительных результатов, равная 100 %, достигалась для всех 24 повторов для каждого материала.

18.2 Предел количественного определения

Нижний предел количественного определения (lower limit of quantitation LLOQ) — это наименьшая концентрация ДНК ВГВ, которая может быть количественно определена с приемлемой прецизионностью и правильностью, и устанавливаемая путем оценки общей аналитической ошибки (total analytical error, TAE) и подхода, основанного на разности двух измерений. LLOQ определяли с использованием четырех независимых образцов, представляющих генотипы ВГВ от А до D, в плазме с ЭДТА, при концентрации, близкой к порогу обнаружения теста. Каждый образец тестировали с четырьмя партиями реагентов, по 8–24 повтора на партию. Оценка TAE была получена в модели Вестгарда в соответствии с рекомендациями CLSI EP17-A2¹⁰ с критерием, [(абсолютная систематическая ошибка) + 2 CO ≤ 1 log₁₀ МЕ/мл]. Подход с разностью двух измерений оценивался с использованием критерия [(2 × кв. корень (2) × CO) ≤ 1 log₁₀ МЕ/мл].

Результаты определения LLOQ для каждого образца представлены в Таблица 5.

Таблица 5. Определение LLoQ для теста Xpert HBV VL

Генотип ВГВ	Партия	N	Концентрация ВГВ (log ₁₀ МЕ/мл)		Систематическая ошибка	Общее СО	Общая аналитическая ошибка (Total Analytical Error, TAE) ^a	Подход с двумя измерениями ^b
			Ожидаемая	Наблюдаемая				
A	1	24	1,00	1,02	0,02	0,20	0,42	0,57
	2	24	1,00	1,05	0,05	0,16	0,37	0,45
	3	24	1,00	0,94	-0,06	0,20	0,46	0,57
	4	23	1,00	1,02	0,02	0,14	0,30	0,40
B	1	16	1,00	1,18	0,18	0,11	0,39	0,30
	2	24	1,00	1,18	0,18	0,17	0,53	0,49
	3	8	1,00	1,17	0,17	0,19	0,54	0,53
	4	8	1,00	1,25	0,25	0,19	0,64	0,55
C	1	16	1,00	1,10	0,10	0,17	0,44	0,47
	2	24	1,00	1,11	0,11	0,22	0,55	0,61
	3	8	1,00	0,83	-0,17	0,24	0,65	0,68
	4	8	1,00	1,01	0,01	0,18	0,36	0,50
D	1	16	1,00	0,81	-0,19	0,28	0,74	0,78
	2	24	1,00	0,79	-0,21	0,27	0,75	0,76
	3	8	1,00	0,83	-0,14	0,14	0,42	0,39
	4	8	1,00	0,91	-0,09	0,11	0,31	0,32

^a Значения общей аналитической ошибки, вычисленные в модели Вестгарда, где: [TAE = |систематическая ошибка| + (2×СО) ≤ 1 log₁₀ МЕ/мл], что обеспечивает 95 %-ную вероятность того, что измерение будет отличаться от истинного значения менее чем на 1 log₁₀ МЕ/мл.

^b Подход с двумя измерениями [2 × (SQRT(2) × SD) ≤ 1 log₁₀ МЕ/мл] показал, что отличие менее 1 log₁₀ МЕ/мл может объясняться случайной ошибкой измерения.

Эти результаты показывают, что тест Xpert HBV VL позволяет определять ДНК ВГВ в концентрации 10 МЕ/мл с приемлемыми правильностью и прецизионностью.

18.3 Прецизионность/воспроизводимость

Прецизионность и воспроизводимость теста Xpert HBV VL определяли с использованием образцов плазмы с К₂ЭДТА при помощи дисперсионного анализа (ANOVA) для определения общей дисперсии.

Было проведено многоцентровое (3 центра; 2 внешних и 1 внутренний) слепое исследование с целью определения основных компонентов дисперсии теста Xpert HBV VL с применением восьмикомпонентной панели, состоящей из восьми ВГВ-положительных образцов. ВГВ-положительные компоненты панели готовили путем разведения ВГВ-плазмид с хорошо изученными характеристиками или ВГВ-положительного клинического образца в человеческой плазме с ЭДТА. По два оператора (один с опытом выполнения ПЦР, другой без такого опыта) в каждом из трех исследовательских центров исследовали одну панель в двух повторах два раза в день (что равноценно восьми повторам в день) на протяжении шести дней. Всего выполнено 144 повторов на каждый компонент панели. Были использованы три партии теста Xpert HBV VL, каждая на протяжении двух дней исследований. Прецизионность и воспроизводимость определяли в соответствии с CLSI EP05-A3¹¹ и CLSI EP15-A3.¹²

Прецизионность и воспроизводимость теста Xpert HBV VL оценивали методом иерархического дисперсионного анализа, где в качестве факторов использованы следующие: центр/анализатор, партия, день, оператор/серия, в пределах серии. Рассчитывали стандартное отклонение и процент вариабельности концентрации ВГВ, представленной в виде log₁₀, под влиянием каждого фактора, как показано в Таблица 6.

Таблица 6. Прецизионность и воспроизводимость теста Xpert HBV VL

Концентрация ДНК ВГВ (log ₁₀ МЕ/мл)			Влияние на СО общей вариабельности (КВ%)										Общая прецизионность	
			Центр/прибор		Партия		День		Оператор/серия		В пределах цикла			
Ожидаемая	Наблюдаемая	N	СО	(%) ^а	СО	(%) ^а	СО	(%) ^а	СО	(%) ^а	СО	(%) ^а	СО	КВ (%) ^б
9,00	9.13 ^с	144	<0,01	<0,01	0,04	23,4	<0,01	<0,01	0,02	4,9	0,07	71,7	0,08	19,7
8,00	8,17	144	<0,01	<0,01	0,04	26,7	<0,01	<0,01	0,02	5,4	0,06	67,9	0,07	16,9
7,00	7,15	144	0,01	2,2	0,03	12,2	0,01	3,9	<0,01	<0,01	0,07	81,8	0,07	16,8
6,00	6,18	144	<0,01	<0,01	0,04	32,1	0,01	4,3	<0,01	<0,01	0,05	63,6	0,06	14,7
4,70	4,87	144	0,02	4,5	0,03	15,3	<0,01	<0,01	<0,01	<0,01	0,07	80,2	0,07	17,1
3,00	3,19	144	<0,01	<0,01	0,03	28,8	<0,01	<0,01	0,02	11,5	0,04	59,7	0,06	13,2
2,00	2,17	144	<0,01	<0,01	0,02	8,6	<0,01	<0,01	0,01	1,0	0,08	90,5	0,08	19,0
1,00	1,13	144	<0,01	<0,01	<0,01	<0,01	0,05	11,0	0,01	0,3	0,15	88,8	0,16	37,7

^а (%) представляет собой влияние компонента дисперсии на общую дисперсию

^б

$$Lognormal CV(\%) = 100 * \sqrt{10^{(\ln(10) * \sigma_{log10_data}^2)} - 1}$$

«КВ» является логнормальным КВ, полученным по формуле:

^с Наблюдавшееся значение превышает диапазон количественного определения теста Xpert HBV VL.

18.4 Линейный диапазон

Генотип А

Линейный диапазон теста Xpert HBV VL определяли путем анализа панелей из восьми образцов, включавших диапазон концентраций от 1,00 до 9,00 log₁₀ МЕ/мл. Панели готовили путем внесения клинического образца, содержащего ВГВ генотипа А, или архивной ДНК-плазмиды ВГВ в высоком титре, в отрицательную на ВГВ сыворотку и плазму с ЭДТА. Каждый компонент панели исследовали в восьми повторях на партию реагентов, за исключением самых низких разведений, которые исследовали в шестнадцати повторях на партию реагентов. Использовали две партии реагентов. Результаты представлены в Рисунок 9 и Рисунок 10.

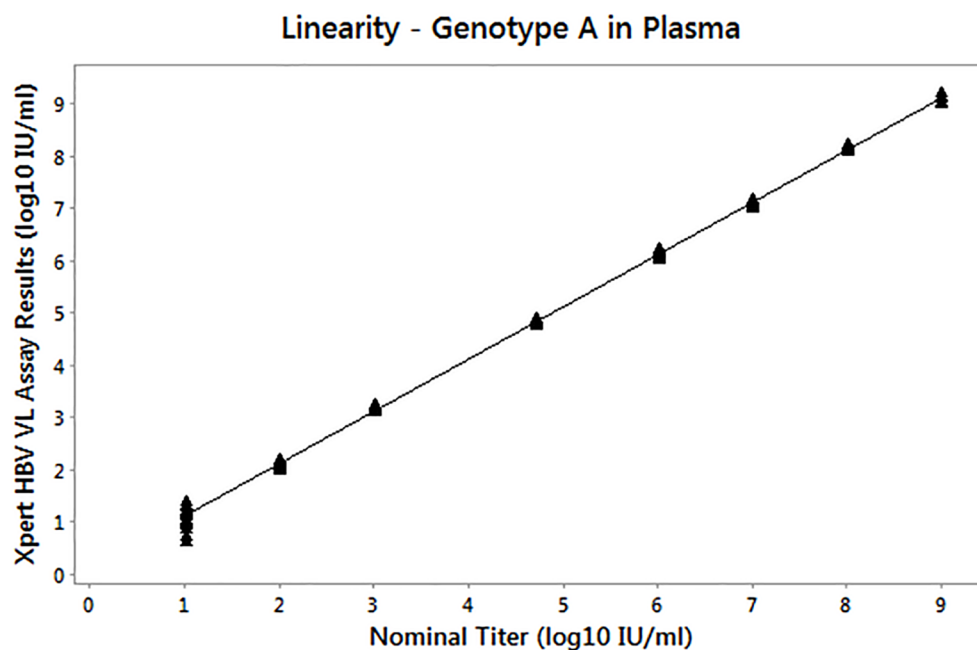


Рисунок 9. Линейность теста Xpert BV VL при исследовании образцов плазмы с ЭДТА

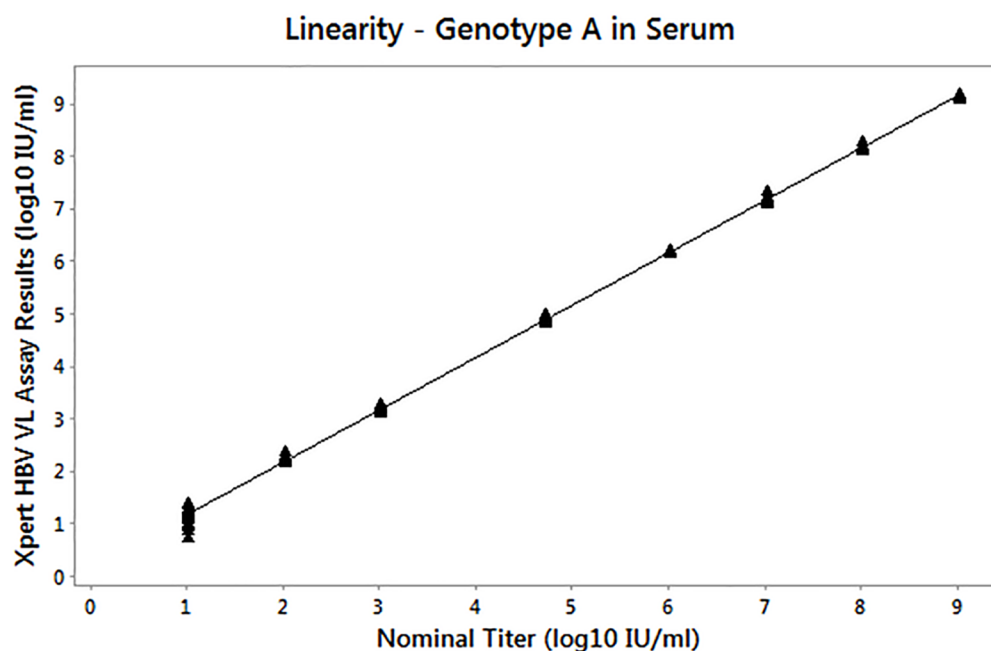


Рисунок 10. Линейность теста Xpert BV VL при исследовании образцов сыворотки с ЭДТА

Генотипы В-Н

Для подтверждения линейности были приготовлены панели разведения с генотипами ВГВ от В до Н, с целью включить как можно более широкий диапазон измерений. Для этого клинические образцы, соответствующие каждому генотипу ВГВ, разводили в отрицательной на ВГВ плазме с ЭДТА. Компоненты панели тестировали с использованием одной партии реагентов, количество повторов на каждый компонент было таким же, как и для ВГВ генотипа А.

Была продемонстрирована линейность в соответствии с рекомендациями CLSI EP06-A¹³ для генотипов А-Н со значением $R^2 > 0,99$. Тест Xpert HBV VL дает линейные результаты в диапазоне 1,00–9,00 $\log_{10}$ МЕ/мл для генотипа А и во всем исследованном диапазоне для генотипов от В до Н (см. Таблица 7).

Таблица 7. Линейность теста Xpert HBV VL по генотипу

Генотип	Уравнение линейной регрессии	R^2	Исследованный диапазон титров ($\log_{10}$ МЕ/мл)
А (плазма)	$y = 1,005x + 0,093$	0,999	1,00–9,00
А (сыворотка)	$y = 1,000x + 0,167$	0,999	1,00–9,00
В	$y = 0,998x - 0,027$	0,995	1,00–6,83
С	$y = 0,998x - 0,119$	0,998	1,00–7,69
Д	$y = 0,993x + 0,101$	0,998	1,00–7,41
Е	$y = 1,010x - 0,149$	0,999	1,00–8,14
Г	$y = 0,994x - 0,068$	0,999	1,00–7,96
Г	$y = 0,990x + 0,538$	0,999	1,00–8,61
В	$y = 0,991x + 0,122$	0,999	1,00–6,35

18.5 Аналитическая специфичность (эксклюзивность)

Аналитическую специфичность теста Xpert HBV VL оценивали путем внесения микроорганизмов и вирусов, способных давать перекрестные реакции, в концентрации 1×10^6 КОЕ/мл для микроорганизмов и 1×10^5 копий/мл или ЦПД₅₀/мл для вирусов в ВГВ-отрицательную плазму с ЭДТА и в плазму с ЭДТА, содержащую около 30 МЕ/мл эталонного материала ВГВ (4-й международный стандарт ВОЗ для ВГВ, код NIBSC: 10/266)⁴. Исследованные микроорганизмы перечислены в Таблица 8. Ни один из исследованных организмов не дал перекрестной реакции и не препятствовал количественному определению в тесте Xpert HBV VL.

Таблица 8. Аналитическая специфичность, микроорганизмы

Вирусы		Бактерии	Дрожжи
Вирус полиомы человека ВК	Вирус иммунодефицита человека 1	<i>Staphylococcus epidermidis</i>	<i>Candida albicans</i>
Цитомегаловирус	Вирус иммунодефицита человека 2	<i>Staphylococcus aureus</i>	
Вирус Эпштейна-Барр	Вирус папилломы человека типа 16		
Вирус гепатита А	Вирус папилломы человека типа 18		
Вирус гепатита С	Т-лимфотропный вирус человека, тип 1		
Вирус простого герпеса, тип 1	Т-лимфотропный вирус человека, тип 2		
Вирус простого герпеса, тип 2	Вирус ветряной оспы		
Вирус герпеса человека 6 типа	Вирус осповакцины		
Вирус герпеса человека типа 8			

18.6 Субстанции, вероятно препятствующие проведению анализа

Оценивали подверженность теста Xpert HBV VL влиянию повышенных уровней эндогенных веществ, маркеров аутоиммунных заболеваний и назначаемых ВГВ-инфицированным пациентам лекарств. Ингибирующий эффект изучали в отсутствие и присутствии около 30 МЕ/мл эталонного материала ДНК ВГВ (4-й международный стандарт ВОЗ для ВГВ, код NIBSC: 10/266).⁴

Было установлено, что повышенные уровни эндогенных веществ, перечисленных в Таблица 9, не препятствуют количественной оценке теста Xpert HBV VL со средним титром $\log_{10}$ каждого из положительных образцов ВГВ, содержащих потенциально мешающие вещества в пределах $\pm 0,10 \log_{10}$ МЕ/мл от значения положительного контроля. Отрицательные результаты были получены для всех образцов, не содержащих ВГВ, что указывает на отсутствие влияния на специфичность теста.

Эндогенные вещества

Таблица 9. Эндогенные субстанции и применявшиеся в анализе концентрации

Субстанция	Концентрация, применявшаяся в анализе
Альбумин	9 г/дл
Билирубин	20 мг/дл
Гемоглобин	500 мг/дл
ДНК человека	0,4 мг/дл
Триглицериды	3000 мг/дл

Лекарственные препараты

Установлено, что перечисленные в Таблица 10 лекарственные препараты в концентрациях, в 3 раза превышающих максимальную концентрацию в плазме (C_{max}), в присутствии или отсутствии ДНК ВГВ, не оказывают влияния на количественные показатели, получаемые при помощи теста Xpert HBV VL, или на его специфичность.

Таблица 10. Пулы препаратов, применявшиеся в анализе

Пул	Лекарственные препараты
1	Зидовудин, саквинавир кларитромицин, интерферон-альфа-2b, ритонавир, омбитасвир, паритапревир, дасабувир, диданозин
2	Абакавира сульфат, фосампренавир, пегинтерферон-альфа-2a, рибавирин, энтекавир, адефовира дипивоксил
3	Тенофовира дизопроксила фумарат, ламивудин, индинавира сульфат, ганцикловир, валганцикловира гидрохлорид, ацикловир, пароксетин, телбивудин
4	Ставудин, эфавиренз, лопинавир, энфувиртид, ципрофлоксацин, флуоксетин
5	Невирапин, нелфинавир, азитромицин, валацикловир, сертралин, тенофовира алафенамид

Маркеры аутоиммунных заболеваний

При исследовании образцов плазмы с K_2 ЭДТА, содержащих маркеры аутоиммунных заболеваний (каждый маркер был взят у пяти положительных пациентов), не было выявлено влияния на функциональные характеристики теста Xpert HBV VL маркеров системной красной волчанки (СКВ), антинуклеарных антител (АНА) или ревматоидного фактора (РФ). Средняя концентрация ДНК ВГВ (представленная в виде $\log_{10}$), которая вносилась в образцы, находилась в пределах $\pm 0,10 \log_{10}$ МЕ/мл относительно положительного контроля. Отрицательные результаты были получены для всех образцов, не содержащих ВГВ, что указывает на отсутствие влияния на специфичность теста.

18.7 Эквивалентность материалов (плазма с K₂ЭДТА, РРТ-ЭДТА и сыворотка)

Исследование эквивалентности материалов для теста Xpert HBV VL было проведено с использованием 32 соответствующих по характеристикам ВГВ-положительных клинических образцов и 23 соответствующих по характеристикам ВГВ-отрицательных клинических образцов, собранных в пробирки для сбора плазмы с K₂-ЭДТА, пробирки для сбора плазмы РРТ-ЭДТА и пробирки для сбора сыворотки. В 23 соответствующих по характеристикам ВГВ-отрицательных клинических образца вносили клинические образцы с ВГВ, соответствующие генотипам от В до G, а также ДНК-плазмиды, экспрессирующие целевую последовательность генома генотипа А, в титрах по всему линейному диапазону.

На исследованных образцах была продемонстрирована эквивалентность материалов (см. Рисунок 11 и Рисунок 12).

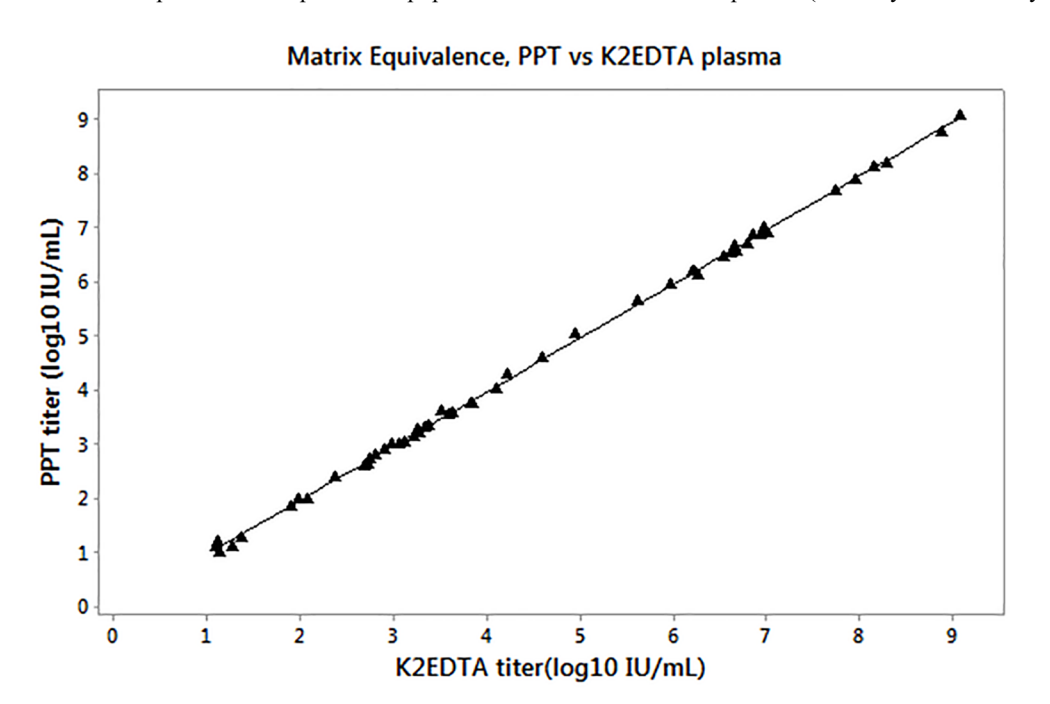


Рисунок 11. График линейной регрессии, плазма в пробирках РРТ-ЭДТА по сравнению с плазмой в пробирках с K₂-ЭДТА

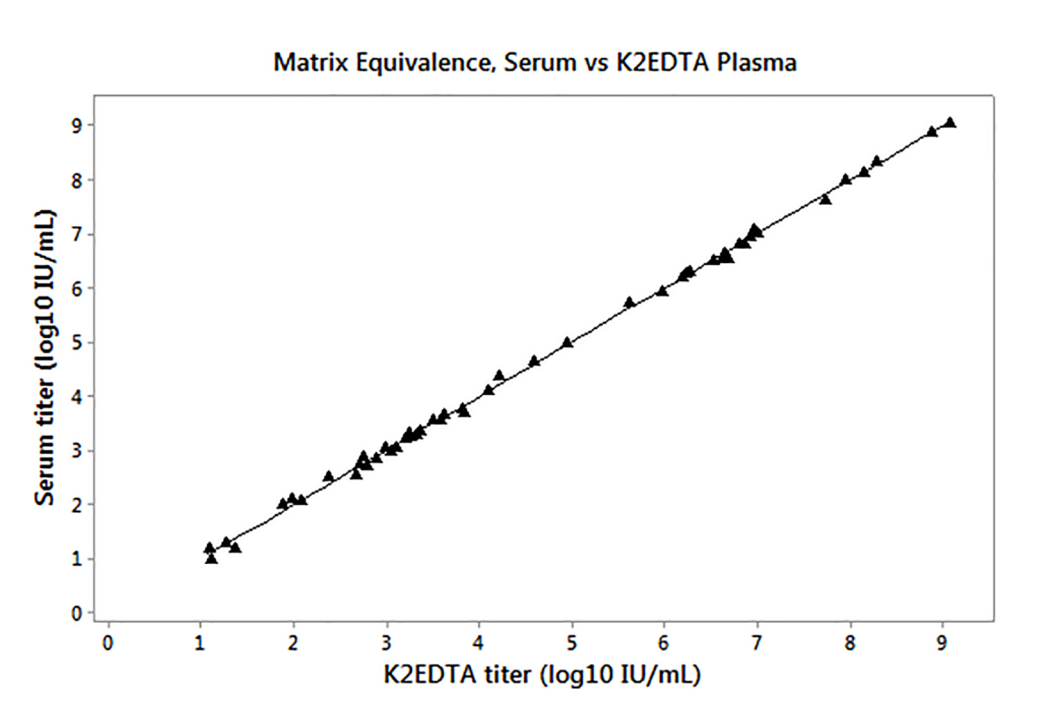


Рисунок 12. График линейной регрессии, сыворотка по сравнению с плазмой в пробирках с К₂-ЭДТА

Результаты показывают, что тест Xpert HBV VL эквивалентно работает в плазме К₂-ЭДТА, плазме PPT-ЭДТА и сыворотке для образцов в диапазоне приблизительно 1,0–9,0 log₁₀ МЕ/мл.

18.8 Отказ всей системы

Частоту отказа всей системы для теста HBV VL определяли путем тестирования в 100 повторах образца плазмы с ЭДТА, в который был внесен ВГВ генотипа А в виде 4-го международного стандарта ВОЗ для ДНК ВГВ (код NIBSC 10/266)⁴. Тестировали образцы с внесенной вирусной ДНК в концентрации около 3 × LLOQ (30 МЕ/мл).

Результаты исследования показали, что все повторы были действительными, с положительным результатом в отношении целевой последовательности ВГВ, а частота отказа всей системы составила 0,0 %

18.9 Контаминация продуктами предыдущей реакции

Выполняли тестирование ВГВ-положительного образца с высоким титром (>1 × 10⁷ МЕ/мл) и сразу после этого тестировали ВГВ-отрицательный образец на том же модуле GeneXpert. Процедуру повторяли двадцать (20) раз на двух модулях. Частота контаминации продуктами предыдущей реакции в тесте Xpert HBV VL составила 0 %.

19 Клинические функциональные характеристики

19.1 Специфичность у здоровых доноров крови

Специфичность теста Xpert HBV VL оценивали с использованием 99 образцов сыворотки и 100 образцов плазмы с ЭДТА, полученных от ВГВ-отрицательных доноров крови. Специфичность теста Xpert HBV VL составила 100,0 % [95 % ДИ: 98,1–100,0 (199/199)].

19.2 Корреляция между методами

Было проведено многоцентровое исследование для сравнения функциональных характеристик теста Xpert HBV VL с методом сравнения, предназначенным для количественного определения ДНК ВГВ. Для этого были использованы оставшиеся образцы сыворотки и плазмы с ЭДТА, полученные в рамках оказания стандартной медицинской помощи у лиц, инфицированных ВГВ.

Из 876 пригодных к анализу пациентов 351 (40,1 %) были женского пола и 489 (55,8%) были мужского пола. Средний возраст составил $47,2 \pm 15,9$ лет, диапазон возраста — от 18 до 89 лет. Из 876 образцов 560 содержали ДНК ВГВ в диапазоне количественного определения обоих тестов — Xpert HBV VL и метода сравнения. Результаты анализа с использованием регрессии Деминга и обычной линейной регрессии представлены в Рисунок 13.

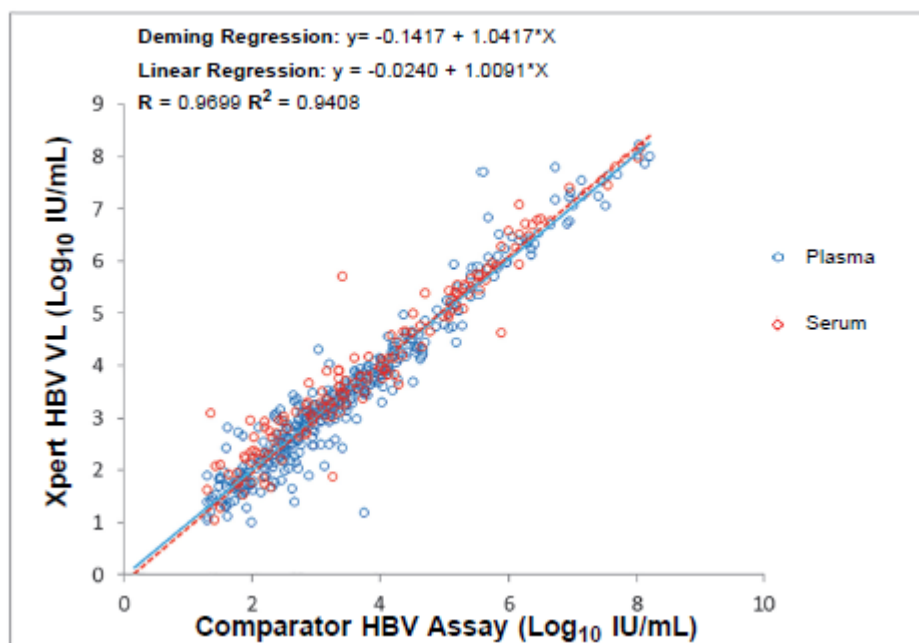


Рисунок 13. Корреляция между результатами теста Xpert HBV VL и метода сравнения при использовании образцов сыворотки и плазмы с ЭДТА

20 Литература

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21 Расположение штаб-квартиры корпорации Cepheid

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22 Техническая поддержка

Прежде чем обращаться в службу технической поддержки компании Cepheid, подготовьте следующую информацию:

- Название изделия
- Номер партии
- Серийный номер прибора
- Сообщения об ошибках (если имеются)
- Версия программного обеспечения и, при наличии, сервисный номер компьютера

Контактная информация

США

Телефон: + 1 888 838 3222

Электронный адрес: techsupport@cepheid.com

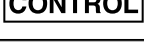
Франция

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Контактная информация всех офисов службы технической поддержки компании Cepheid доступна на нашем веб-сайте: www.cepheid.com/en/CustomerSupport.

23 Условные обозначения

Символ	Значение
	Номер по каталогу
	Медицинское изделие для диагностики <i>in vitro</i>
	Не использовать повторно
	Код партии
	См. инструкцию по применению
	Производитель
	Страна производства
	Содержит достаточное количество для <i>n</i> тестов
	Контроль
	Срок годности
	Маркировка CE – Европейское соответствие
	Температурные ограничения
	Биологические риски
	Предупреждение
	Предупреждение
	Уполномоченный представитель в Швейцарии
	Импортер



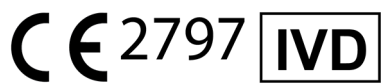
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Xpert® HCV Viral Load

REF **GXHCV-VL-CE-10**
GXHCV-VL-IN-10

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Xpert[®] HCV Viral Load

For *In Vitro* Diagnostic Use Only.

1 Proprietary Name

Xpert[®] HCV Viral Load

2 Common or Usual Name

HCV VL

3 Intended Use

The HCV VL assay, performed on GeneXpert[®] Instrument Systems, is designed for the rapid quantitation of Hepatitis C Virus (HCV) RNA in human serum or plasma (EDTA) from HCV-infected individuals. The test utilizes automated reverse transcriptase polymerase chain reaction (RT-PCR) using fluorescence to detect the RNA of interest for the quantitation of HCV.

The HCV VL assay quantifies HCV genotypes 1–6 over the range of 10 to 100,000,000 IU/mL. The HCV VL assay is intended for use as an aid in the management of HCV infected patients undergoing antiviral therapy. The test measures HCV RNA levels at baseline and during treatment and can be utilized to predict sustained and nonsustained virological responses to HCV therapy.

Results from the HCV VL assay may also be used to confirm HCV infection in anti-HCV positive individuals. In anti-HCV positive individuals who test negative for HCV RNA, use of another HCV antibody assay may be considered for distinction between true HCV exposure and biologic false positivity. Repeat HCV RNA testing may be indicated in cases that have had HCV exposure in the last 6 months or have clinical evidence of HCV disease.

The Xpert HCV VL assay is intended to be used by laboratory professionals or specifically-trained healthcare workers.

The assay is not intended to be used as a donor screening test for HCV.

4 Summary and Explanation

HCV is a member of the Flaviviridae family and has been recognized as the major causative agent of chronic liver disease, including chronic active hepatitis, cirrhosis and hepatocellular carcinoma.¹ The HCV genome is a positive-sense RNA molecule of approximately 9500 nucleotides.¹ HCV is usually transmitted through percutaneous exposure to infected blood, primarily by intravenous drug use and receipt of unscreened donated blood products. Less frequently, HCV has been shown to be transmitted through occupational, perinatal and sexual exposures.²

An estimated 185 million people, or roughly 3% of the world's population, have been infected with HCV, and over 80% live in Low and Middle Income Countries (LMICs).³ The burden of disease is greatest in developing countries; the highest reported prevalence is in China (3.2%)⁴ Pakistan (4.8%)⁴, Nigeria (18.3%)⁵ and Egypt (22%).⁴ About 15 million European adults are infected with HCV and most of these people are unaware of their infection.⁶ Each year, 350,000 to 500,000 people die from HCV-related liver disease.⁷

Antiviral medicines can cure HCV, but access to diagnosis and treatment is low.⁷ A cure for HCV infection is now possible in most patients with highly effective, safe and tolerable combinations of oral direct-acting antivirals (DAAs) taken for 8–24 weeks.⁵ Eradication of HCV is being discussed for the first time.⁵

Quantitation of HCV RNA has proven useful in providing a metric to evaluate the effectiveness of antiviral response to HCV treatment. Guidelines for the management and treatment of HCV recommend quantitative testing for HCV RNA before the start of antiviral therapy, during therapy, and after the conclusion of treatment. The primary objective of treatment is Sustained Virologic Response (SVR), defined as undetectable HCV RNA by a sensitive test 12 or 24 weeks after the end of treatment depending on the anti-HCV therapy.⁸

5 Principle of the Procedure

The GeneXpert Instrument Systems automate and integrate sample purification, nucleic acid amplification, and detection of the target sequence in simple or complex samples using RT-PCR which uses fluorescence to detect the RNA of interest. The systems consist of an instrument, personal computer, and preloaded software for running tests and viewing the results. The systems require the use of single-use disposable GeneXpert cartridges that hold the RT-PCR reagents and host the RT-PCR processes. Because the cartridges are self-contained, cross-contamination between samples is minimized. For a full description of the systems, refer to the appropriate *GeneXpert Dx Operator Manual* or *GeneXpert Infinity Operator Manual*.

The HCV VL assay includes reagents for the detection of HCV RNA in specimens as well as two internal controls used for quantitation of HCV RNA. The internal controls monitor recovery and the presence of inhibitor(s) in the RT and PCR reactions. The Probe Check Control (PCC) verifies reagent rehydration, PCR tube filling in the cartridge, probe integrity, and dye stability.

6 Reagents

6.1 Materials Provided



The HCV VL assay kit contains sufficient reagents to process 10 specimens or quality control samples. The kit contains the following:

HCV VL Assay Cartridges with Integrated Reaction Tubes	10
• Bead 1, Bead 2, and Bead 3 (freeze-dried)	1 of each per cartridge
• Lysis Reagent (Guanidinium Thiocyanate)	2.0 mL per cartridge
• Rinse Reagent	0.5 mL per cartridge
• Elution Reagent	1.5 mL per cartridge
• Binding Reagent	2.4 mL per cartridge
• Proteinase K Reagent	0.48 mL per cartridge
Disposable 1 mL Transfer Pipettes	10 per kit
CD	1 per kit
• Assay Definition File (ADF)	
• Instructions to import ADF into GeneXpert software	
• Instructions for Use (Package Insert)	

Note Safety Data Sheets (SDS) are available at www.cepheidinternational.com under the **SUPPORT** tab.

Note The bovine serum albumin (BSA) in the beads within this product was produced and manufactured exclusively from bovine plasma sourced in the United States. No ruminant protein or other animal protein was fed to the animals; the animals passed ante- and post-mortem testing. During processing, there was no mixing of the material with other animal materials.

7 Storage and Handling



- Store the HCV VL assay cartridges and reagents at 2–28 °C.
- Do not open the cartridge until you are ready to perform the assay.
- Do not use a cartridge that has leaked.
- Do not use HCV VL assay cartridges and reagents that were previously frozen.
- Do not use reagents or cartridges that have passed the expiration date.

8 Materials Required but Not Provided

- GeneXpert Dx System or GeneXpert Infinity Systems (catalog number varies by configuration): GeneXpert Instrument, computer with proprietary GeneXpert Dx Software Version 4.7b or higher (GeneXpert Dx systems); or Xpertise 6.4b or higher (Infinity-80/Infinity-48s), barcode scanner, and operator manual.
- Printer: If a printer is needed, contact Cepheid Technical Support to arrange for the purchase of a recommended printer.
- Bleach or sodium hypochlorite

9 Warnings and Precautions



- Treat all biological specimens, including used cartridges, as if capable of transmitting infectious agents. Because it is often impossible to know which might be infectious, all biological specimens should be treated with standard precautions. Guidelines for specimen handling are available from the U.S. Centers for Disease Control and Prevention⁹ and the Clinical and Laboratory Standards Institute.¹⁰
- Good laboratory practices and changing gloves between handling specimens are recommended to avoid contamination of specimens or reagents.
- Follow your institution's safety procedures for working with chemicals and handling biological samples.
- Do not substitute HCV VL assay reagents with other reagents.
- Do not open the HCV VL assay cartridge lid except when adding sample.
- Do not use a cartridge that has been dropped after removing it from the packaging.
- Do not shake the cartridge. Shaking or dropping the cartridge after opening the lid may yield invalid results.
- Do not use a cartridge that has a damaged reaction tube.
- Do not use a cartridge that has leaked.



- Each single-use HCV VL assay cartridge is used to process one test. Do not reuse cartridges.



- The single-use disposable pipette is used to transfer one specimen. Do not reuse spent disposable pipettes.
- Wear clean lab coats and gloves. Change gloves between processing each sample.
- In the event of contamination of the work area or equipment with samples or controls, thoroughly clean the contaminated area with a solution of 1:10 dilution of household chlorine bleach or sodium hypochlorite and then 70% ethanol or 70% denatured ethanol. Wipe work surfaces dry completely before proceeding.
- Consult your institution's environmental waste personnel on proper disposal of used cartridges and unused reagents. Check state, territorial, or local regulations as they may differ from national disposal regulations. The material may exhibit characteristics of hazardous waste requiring specific disposal requirements. Institutions should check their hazardous waste disposal requirements.
- Biological specimens, transfer devices, and used cartridges should be considered capable of transmitting infectious agents requiring standard precautions. Follow your institution's environmental waste procedures for proper disposal of used cartridges and unused reagents. These materials may exhibit characteristics of chemical hazardous waste requiring specific disposal. If country or regional regulations do not provide clear direction on proper disposal, biological specimens and used cartridges should be disposed per WHO [World Health Organization] medical waste handling and disposal guidelines.

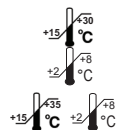
10 Chemical Hazards^{11,12}

- Signal Word: WARNING
- **UN GHS Hazard Statements:**
 - Harmful if swallowed
 - Causes mild skin irritation
 - Causes eye irritation
- **UN GHS Precautionary Statements:**
 - **Prevention:**
 - Wash thoroughly after handling.
 - **Response:**
 - Call a POISON CENTER or doctor/physician if you feel unwell.
 - If skin irritation occurs: Get medical advice/attention.
 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
 - If eye irritation persists: Get medical advice/attention.

11 Specimen Collection, Storage, and Transport

Whole blood should be collected in K2-EDTA tubes, EDTA-PPT or serum collection tubes and centrifuged to separate the plasma/serum and red blood cells per the manufacturer's instructions.

- A minimum of 1 mL plasma or serum is required for the HCV VL assay. If using the transfer pipette included in the kit, a minimum of 1.2 mL plasma or serum is required. Alternatively, if using a precision pipette, a minimum of 1 mL plasma or serum is required.



- Whole blood may be held at 15–30 °C for up to 24 hours or at 2–8 °C for up to 3 days prior to plasma/serum preparation. Centrifugation should be performed according to the manufacturer instructions.

- After centrifugation and separation, plasma and serum may be held at 15–35 °C for up to 24 hours or at 2–8 °C for up to 3 days prior to testing.



- Plasma and serum specimens are stable frozen (-70 to -18 °C) for 6 weeks.

- Plasma and serum specimens are stable for up to three freeze/thaw cycles.

- Plasma and serum specimens must be thawed and equilibrated to room temperature prior to transfer to the cartridge.



- Ship whole blood, plasma or serum specimens at 2–8 °C.

- Transportation of whole blood, plasma or serum specimens must comply with country, federal, state and local regulations for the transportation of etiologic agents.

12 Procedure

12.1 Preparing the Specimen

- Following centrifugation of whole blood samples, 1 mL of plasma can be pipetted directly into the cartridge. Sufficient volume is critical to obtaining valid test results (see instructions in Section 12.2, Preparing the Cartridge Option 1 below).



- If using frozen specimens, place the specimens at room temperature (20–35 °C) until completely thawed and equilibrated to room temperature before use.



- Plasma and serum samples stored at 2–8 °C should be removed from the refrigerator and equilibrated to room temperature before use.



- Plasma samples stored at 2–8 °C or frozen and thawed should be vortexed for 15 seconds before use, if the specimen is cloudy, clarify by a quick centrifugation.

12.2 Preparing the Cartridge

- Wear protective disposable gloves.
 - Inspect the test cartridge for damage. If damaged, do not use it.
 - Open the lid of the test cartridge.
- Option 1:** If using the transfer pipette included in the kit (Figure 1), fill to just below the bulb but above the line to transfer at least 1 mL plasma or serum from the collection tube into the sample chamber of the test cartridge (Figure 2). Do **NOT** pour the specimen into the chamber!
 - Option 2:** If using an automatic pipette, transfer at least 1 mL of plasma or serum into the sample chamber of the test cartridge (Figure 2). Do **NOT** pour the specimen into the chamber!

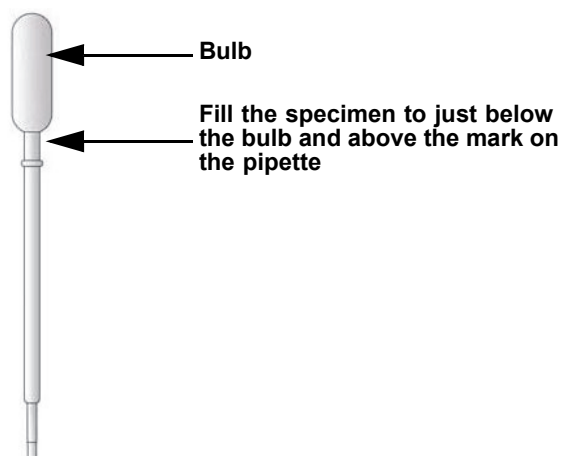


Figure 1. HCV VL Assay Transfer Pipette

4. Close the cartridge lid.
5. Load the cartridge into the GeneXpert Dx instrument or Infinity system.

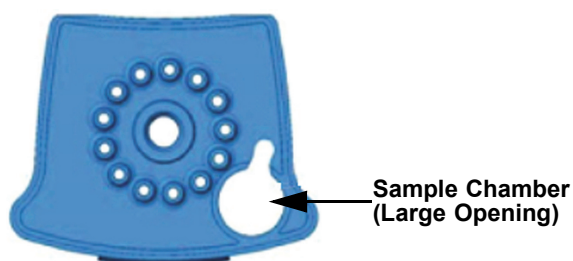


Figure 2. HCV VL Assay Cartridge (Top View)

12.3 Starting the Test

Important Before you start the test, make sure the HCV VL Assay Definition File (ADF) is imported into the software.

Note The steps you follow can be different if the system administrator changed the default workflow of the system.

This section lists the basic steps for running the test. For detailed instructions, see the *GeneXpert Dx System Operator Manual* or the *GeneXpert Infinity System Operator Manual*, depending on the model that is being used.

1. Turn on the GeneXpert instrument:
 - If using the GeneXpert Dx instrument, first turn on the instrument and then turn on the computer. The GeneXpert software will launch automatically. If it doesn't, double-click the GeneXpert Dx software shortcut icon on the Windows® desktop.
 - or
 - If using the GeneXpert Infinity instrument, power up the instrument. The GeneXpert software will launch automatically. If it doesn't, double-click the Xpertise software shortcut icon on the Windows® desktop.
2. Log on to the GeneXpert Instrument System software using your user name and password.
3. In the GeneXpert System window, click **Create Test** (GeneXpert Dx) or **Orders** and **Order Test** (Infinity).
4. Scan in the Patient ID (optional). If typing the Patient ID, make sure the Patient ID is typed correctly. The Patient ID is associated with the test results and is shown in the View Results window.
5. Scan or type in the Sample ID. If typing the Sample ID, make sure the Sample ID is typed correctly. The Sample ID is associated with the test results and is shown in the View Results window and all reports. The Scan Cartridge dialog box appears.
6. Scan the barcode on the HCV VL assay cartridge. The Create Test window appears. Using the barcode information, the software automatically fills the boxes for the following fields: Select Assay, Reagent Lot ID, Cartridge SN, and Expiration Date.
7. Click **Start Test** (GeneXpert Dx) or **Submit** (Infinity). Enter your password, if requested.
8. For the GeneXpert Infinity System, place the cartridge on the conveyor belt. The cartridge will be automatically loaded, the test will run, and the used cartridge will be placed into the waste container.

or

For the GeneXpert Dx Instrument:

- A. Open the instrument module door with the blinking green light and load the cartridge.
- B. Close the door. The test starts and the green light stops blinking. When the test is finished, the light turns off.
- C. Wait until the system releases the door lock before opening the module door and removing the cartridge.
- D. The used cartridges should be disposed in the appropriate specimen waste containers according to your institution's standard practices.

13 Viewing and Printing Results

This section lists the basic steps for viewing and printing results. For more detailed instructions on how to view and print the results, see the *GeneXpert Dx System Operator Manual* or the *GeneXpert Infinity System Operator Manual*, depending on the instrument used.

1. Click the **View Results** icon to view results.
2. Upon completion of the test, click the **Report** button of the View Results window to view and/or generate a PDF report file.

14 Quality Control

CONTROL

Each test includes a Sample Volume Adequacy (SVA), Internal Quantitative Standard High and Low (IQS-H and IQS-L, also acts a specimen processing control [SPC]) and Probe Check Control (PCC).

- **Sample Volume Adequacy (SVA)** – Ensures the sample was correctly added to the cartridge. The SVA verifies that the correct volume of sample has been added in the sample chamber. The SVA passes if it meets the validated acceptance criteria. If the SVA does not pass, an **ERROR 2096** will be displayed if there is no sample or an **ERROR 2097** will be displayed if there is not enough sample. The system will prevent the user from resuming the test.
- **Internal Quantitative Standard High and Low (IQS-H and IQS-L)** – IQS-H and IQS-L are two Armored RNA® constructs in the form of a dry bead that goes through the whole assay process. The IQS-H and IQS-L are standards calibrated against the WHO 4th International standard for HCV. They are used for quantification by using lot specific parameters for the calculation of HCV RNA concentration in the sample. Additionally IQS-H and IQS-L detect specimen-associated inhibition of the RT-PCR reaction. The IQS-H and IQS-L pass if they meet the validated acceptance criteria.
- **Probe Check Control (PCC)** – Before the start of the PCR reaction, the GeneXpert Instrument System measures the fluorescence signal from the probes to monitor bead rehydration, reaction tube filling, probe integrity and dye stability. The PCC passes if it meets the validated acceptance criteria.
- **External Controls** – Following good laboratory practices, external controls, not available in the kit, should be used in accordance with local, state, and federal accrediting organizations' requirements as applicable.

15 Interpretation of Results

The results are interpreted automatically by the GeneXpert Instrument System from measured fluorescent signals and embedded calculation algorithms and are clearly shown in the View Results window (Figure 3 and Figure 5). Possible results are shown in Table 1.

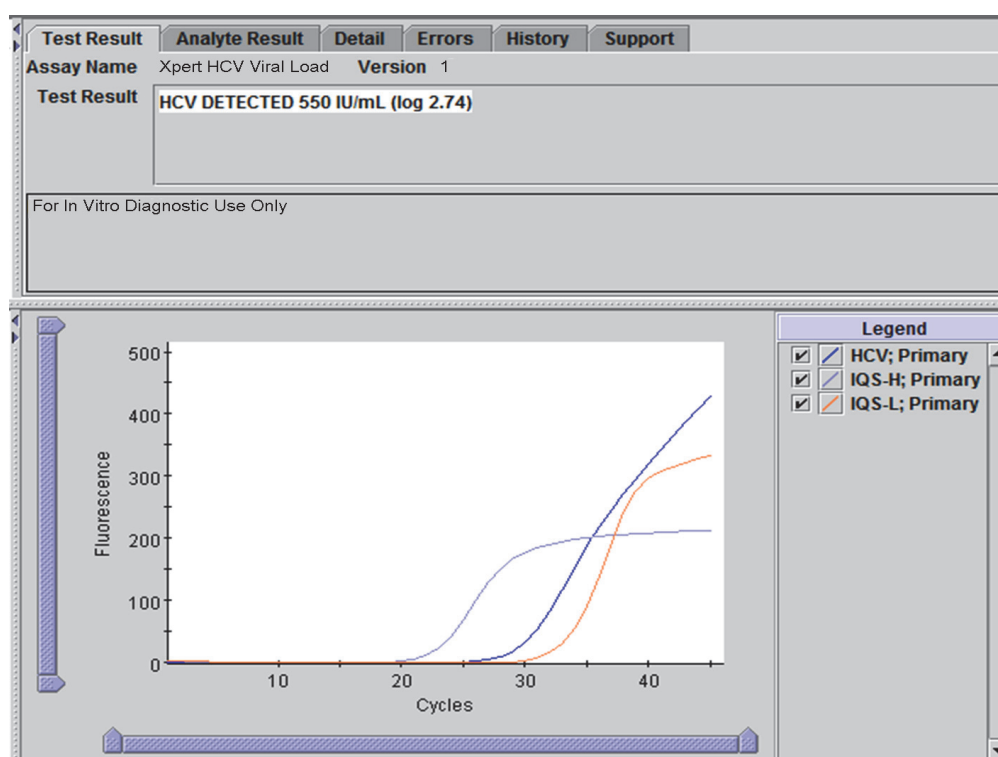
Table 1. HCV VL Assay Results and Interpretation

Result	Interpretation
HCV DETECTED XX IU/mL (log X.XX) See Figure 3.	The HCV RNA is detected at XX IU/mL. • The HCV RNA has a titer within the linear range setting of the assay and the endpoint above the minimum. • IQS-H and IQS-L: PASS. • Probe Check: PASS; all probe check results pass.
HCV DETECTED > 1.00E08 IU/mL See Figure 4.	The HCV RNA is detected above the quantitative range of the assay. • IQS-H and IQS-L: PASS. • Probe Check: PASS; all probe check results pass.
HCV DETECTED < 10 IU/mL See Figure 5.	The HCV RNA is detected below the quantitative range of the assay. • IQS-H and IQS-L: PASS. • Probe Check: PASS; all probe check results pass.
HCV NOT DETECTED See Figure 6.	The HCV RNA is not detected. • HCV RNA is not detected. • IQS-H and IQS-L: PASS. • Probe Check: PASS; all probe check results pass.
INVALID See Figure 7.	Presence or absence of the HCV RNA cannot be determined. Repeat test according to the instructions in Section 16.2, Retest Procedure. • IQS-H and/or IQS-L: FAIL; Cycle thresholds (Cts) are not within valid range and the endpoint is below the minimum setting. • Probe Check: PASS; all probe check results pass.

Table 1. HCV VL Assay Results and Interpretation (Continued)

Result	Interpretation
ERROR See Figure 8.	Presence or absence of HCV RNA cannot be determined. Repeat test according to the instructions in Section 16.2, Retest Procedure. Probe Check: FAIL*; all or one of the probe check results fail. * If the probe check passed, the error is caused by the maximum pressure limit exceeding the acceptable range or by a system component failure.
NO RESULT	Presence or absence of HCV RNA cannot be determined. Repeat test according to the instructions in Section 16.2, Retest Procedure. A NO RESULT indicates that insufficient data were collected. For example, the operator stopped a test that was in progress.

Note Assay screenshots are for example only. Assay name and version number may vary from the screenshots shown in this package insert.


Figure 3. HCV Detected and Quantified

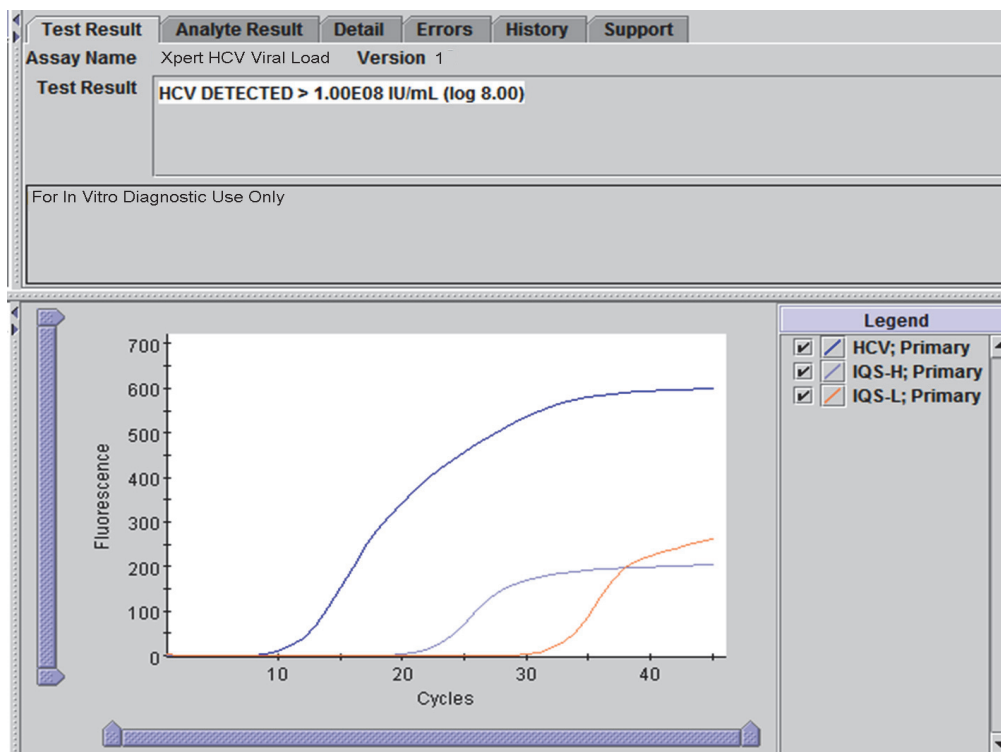


Figure 4. HCV Detected

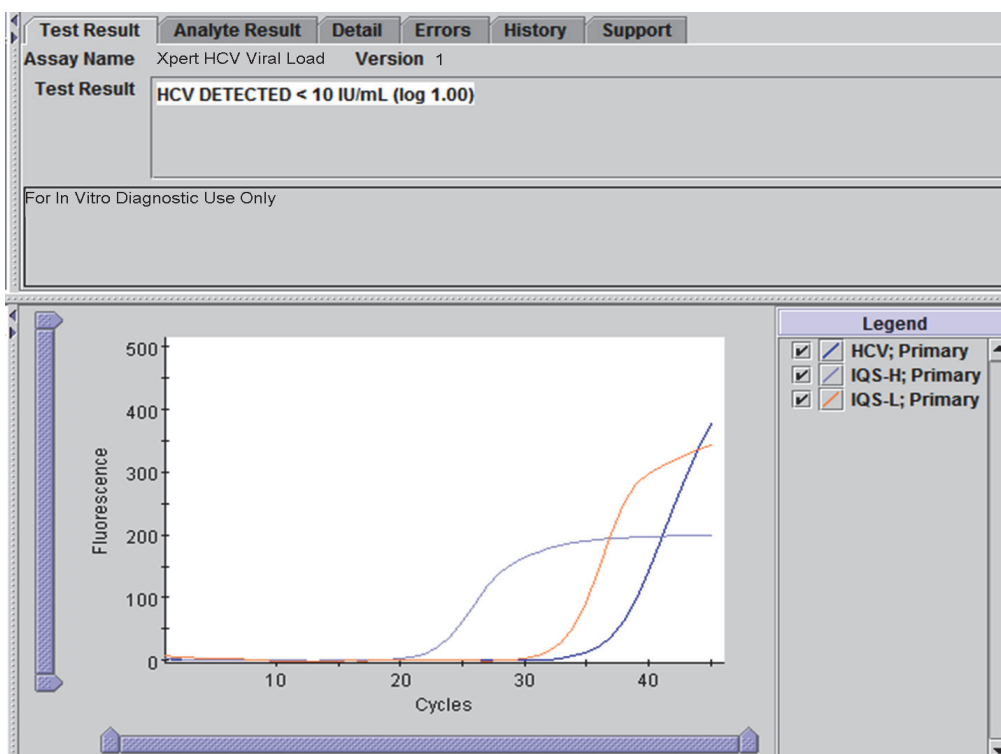


Figure 5. HCV Detected

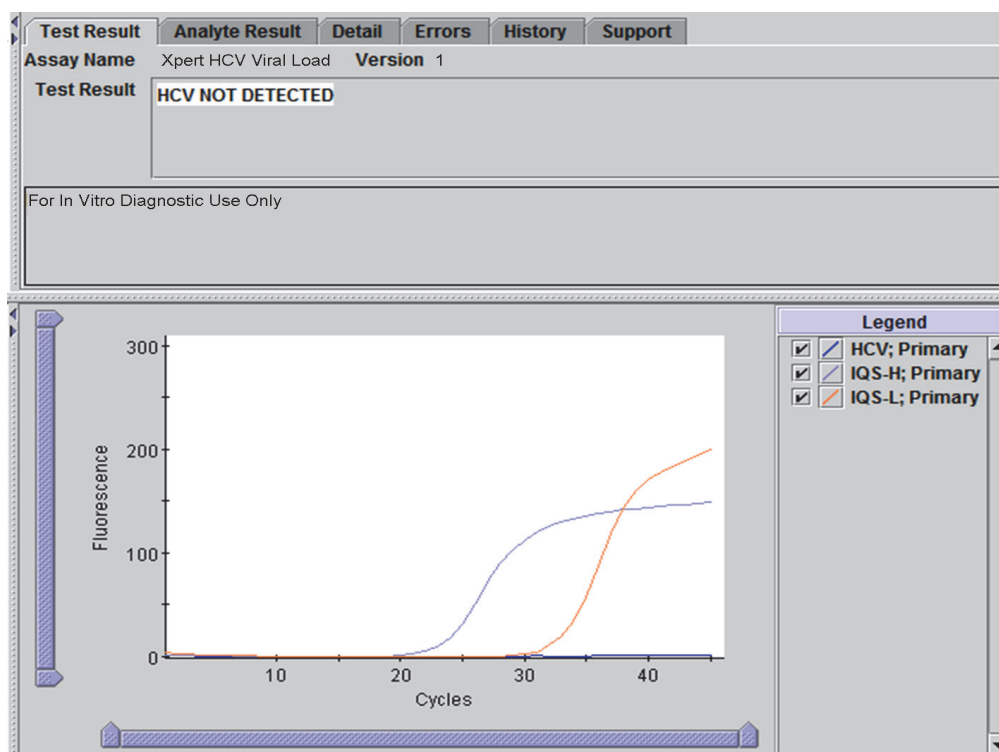


Figure 6. HCV Not Detected

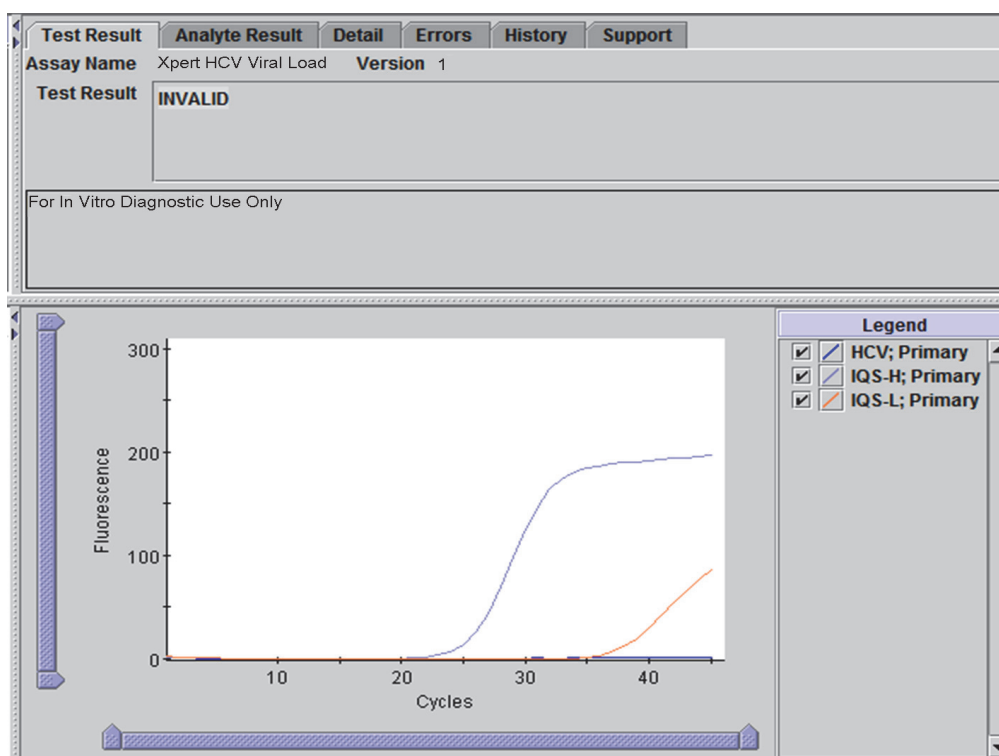


Figure 7. Invalid

The screenshot shows the Xpert HCV Viral Load software interface. At the top, there are tabs: Test Result, Analyte Result, Detail, Errors, History, and Support. The 'Test Result' tab is selected. Below the tabs, the 'Assay Name' is 'Xpert HCV Viral Load' and the 'Version' is '1'. The 'Test Result' field displays 'ERROR' in a yellow box. Below this, there is a section labeled 'For In Vitro Diagnostic Use Only'. The main area of the interface is a large grey rectangle with the text '<No Data Available>' centered in it.

Figure 8. Error

16 Retests

16.1 Reasons to Repeat the Assay

If any of the test results mentioned below occur, repeat the test according to the instructions in Section 16.2, Retest Procedure.

- An **INVALID** result indicates one or more of the following:
 - The IQS-H and/or IQS-L Cts are not within valid range.
 - The sample was not properly processed or PCR was inhibited.
- An **ERROR** result indicates that the assay was aborted. Possible causes include: insufficient volume of sample was added, the reaction tube was filled improperly, a reagent probe integrity problem was detected, or the maximum pressure limit was exceeded.
- A **NO RESULT** indicates that insufficient data were collected. For example, the operator stopped a test that was in progress, or a power failure occurred.

16.2 Retest Procedure

For retest of a **NO RESULT**, **INVALID**, or **ERROR** result, use a new cartridge (do not re-use the cartridge) and new reagents.

1. Remove a new cartridge from the kit.
2. See Section 12, Procedure, including Section 12.1, Preparing the Specimen, Section 12.2, Preparing the Cartridge, and Section 12.3, Starting the Test.

17 Limitations

Good laboratory practices and changing gloves between handling specimens are recommended to avoid contamination of reagents.

Mutations or polymorphisms in primer or probe binding regions may affect detection of new or unknown HCV variants resulting in a false negative result.

18 Performance Characteristics

18.1 Limit of Detection

The limit of detection (LOD) of the HCV VL assay was determined by testing eight different dilutions prepared from a HCV genotype 1 reference standard in HCV negative EDTA plasma and serum. The HCV genotype 1 material used in the LOD study was the WHO 4th International standard, NIBSC code 06/102. The limit of detection was determined for three reagent lots and a total of 72 or 73 replicates per concentration level were tested. One additional low concentration level was included for both sample types after the first day of testing. The number of tested replicates for this level was thus smaller (49 in plasma and 53 in serum). The evaluation was performed according to CLSI guideline E17-A2. The HCV RNA concentration that can be detected with a positivity rate of greater than 95% was determined by Probit regression analysis and the results for the individual lots and specimens are shown in Table 2. The maximum observed LOD with Probit analysis for HCV genotype 1 in EDTA plasma is 4.0 IU/mL (95% CI 2.8 – 5.2). The maximum observed LOD with Probit analysis for HCV genotype 1 in serum is 6.1 IU/mL (95% CI 4.2 – 7.9).

Table 2. HCV VL LOD Estimates with Probit Regression and 95% Upper and Lower Confidence Intervals for HCV Genotype 1 Specimens in Plasma and Serum per Kit Lot

Specimen	Lot	LOD 95% (IU/mL)	95% CI (IU/mL)
WHO (Plasma)	1	3.3	2.4 - 4.2
	2	4.0	2.7 - 5.2
	3	4.0	2.8 - 5.2
WHO (Serum)	1	6.1	4.2 - 7.9
	2	2.6	1.9 - 3.3
	3	2.3	1.8 - 2.9

Hit rate analysis shows a positivity of > 95% at 6 IU/mL for the HCV genotype 1 material tested as shown in Table 3.

Table 3. HCV VL LOD for HCV Genotype 1 in EDTA Plasma and Serum

Specimen	Concentration (IU/mL)	No. Replicates	No. Positives	Positivity Rate (%)
WHO (Plasma)	0.5 ^a	49	24	49
	1	72	47	65
	2	72	61	85
	3	72	69	96
	4	72	67	93
	6	72	71	99
	8	73	73	100
	10	72	72	100
WHO (Serum)	0.5 ^a	53	21	40
	1	73	47	64
	2	73	64	88
	3	72	69	96
	4	73	71	97
	6	72	71	99
	8	72	70	97
	10	72	72	100

a. 0.5 IU/mL was added day 2 due to the high positivity rate observed at 1 IU/mL after day 1

In addition, dilutions of clinical specimens representing HCV genotype 1a, 2b, 3a, 4a, 5a and 6a in negative human EDTA plasma were analyzed with one reagent lot and 24 replicates per concentration level. The assignment of the nominal concentration of clinical specimens was determined by Abbott RealTime HCV™ assay. Hit rate analysis shows a positivity of >95% for all genotypes at 10 IU/mL as shown in Table 4.

Table 4. HCV VL LOD Hit Rate Analysis for HCV Genotype 1 – 6 Specimens in EDTA Plasma

Genotype	Lowest Concentration Level > 95% Hit Rate (IU/mL)	Hit Rate (%)
1a	10	100
2b	4	100
3a	6	100
4a	4	100
5a	2	96
6a	4	96

18.2 Limit of Quantitation

The total analytical error (TAE) was calculated using estimates determined through analysis of data from LOD study (WHO standard) and the Precision/Reproducibility study according to CLSI guideline E17-A2. The TAE for the dilutions that had an observed concentration at or near the assay limit of detection 10 IU/mL ($1.0 \log_{10}$) are presented in Table 5. TAE was estimated by two different methods.

Table 5. HCV VL TAE Analysis for Determination of LOQ

Specimen (Study)	DL Lot	N	Concentration (Log10 IU/mL)		Bias	Total SD	TAE ^a Absolute Bias + 2xSD	TAE ^b 2xSQRT (2)xSD
			Expected	Observed				
Acrometrix (Precision)	DL1	72	1.40	1.31	0.09	0.15	0.38	0.41
	DL2	72	1.40	1.29	0.11	0.14	0.40	0.41
	DL3	72	1.40	1.24	0.16	0.12	0.41	0.35
Acrometrix (Precision)	DL1	72	1.00	0.92	0.08	0.22	0.52	0.62
	DL2	72	1.00	0.82	0.18	0.18	0.54	0.51
	DL3	72	1.00	0.75	0.25	0.19	0.63	0.54
WHO, Plasma (LOD)	DL1	24	1.00	0.91	0.09	0.21	0.51	0.59
	DL2	24	1.00	0.82	0.18	0.30	0.78	0.86
	DL3	24	1.00	0.86	0.14	0.17	0.48	0.48
WHO, Serum (LOD)	DL1	24	1.00	0.96	0.04	0.13	0.30	0.37
	DL2	24	1.00	0.88	0.12	0.23	0.58	0.66
	DL3	24	1.00	0.80	0.20	0.18	0.57	0.52

a. TAE calculated according to the Westgard model in CLSI EP17-A2 (Section 6.2)

b. TAE based upon the difference between two measurements approach

The results of the TAE analysis demonstrate that the HCV VL assay can determine 10 IU/mL ($1.0 \log_{10}$) with an acceptable trueness and precision.

18.3 Precision/Reproducibility

The precision/reproducibility of the HCV VL assay was determined by analysis of parallel dilutions of HCV reference materials in HCV negative EDTA plasma. The nominal concentration of the reference material used was calibrated to the WHO 4th HCV International Standard (06/102). The study was a two site, blinded, comparative study using a seven-member panel of HCV reference material in HCV negative EDTA plasma with RNA concentrations that span the HCV VL assay quantitation range. Two operators at each of the two study sites tested one panel of twenty-one samples once per day over six testing days per lot. One site used an Infinity-80 instrument and the other site used GeneXpert Dx instruments. Three lots of HCV VL assay reagents were used for the study. Precision/reproducibility was evaluated in accordance with “Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline” CLSI document EP5-A2. The precision results for each reagent lot are shown in Table 6.

Table 6. HCV VL Precision per Lot

Expected HCV RNA Concentration log ₁₀ IU/mL	Total Precision per Lot					
	Lot 1		Lot 2		Lot 3	
	SD	CV ^a	SD	CV ^a	SD	CV ^a
1.0	0.23	55.8%	0.18	44.2%	0.20	48.1%
1.4	0.15	35.1%	0.15	35.8%	0.13	29.6%
2.7	0.09	20.7%	0.09	20.6%	0.09	20.2%
4.2	0.07	16.4%	0.08	18.9%	0.07	15.3%
5.4	0.12	28.3%	0.09	19.9%	0.07	16.2%
6.9	0.13	31.8%	0.09	20.9%	0.07	17.0%
8.2	0.10	22.7%	0.10	23.7%	0.08	17.8%

a. “CV” is lognormal CV, as obtained using the formula:

$$CV(\text{of the lognormal dist}) = \sqrt{10^{\ln(10)^2 \sigma^2} - 1}$$

The reproducibility and precision of the HCV VL assay was evaluated by using nested ANOVA with terms for Site/Instrument, Lot, Day, Operator/Run and Within-Run. The standard deviation and the percentage of variability due to each component of the log₁₀ HCV transformed concentrations were calculated, see Table 7.

Table 7. Standard Deviation and Contributable Percentage of Variability for Each Term and Total Precision

HCV RNA Concentration log ₁₀ IU/mL			Contribution to Total Variance SD (CV%)										Total Precision			
			Site/Inst		Lot		Day		Operator/Run		Within-Run		Total			
Expected	Actual	N	SD	(%) ^a	SD	(%) ^a	SD	(%) ^a	SD	(%) ^a	SD	(%) ^a	SD	Lower CI	Upper CI	CV ^b
1.0	0.83	216	0.03	1.8%	0.08	13.2%	0.04	3.5%	0.00	0.0%	0.19	81.6%	0.21	0.18	0.25	51.7%
1.4	1.28	216	0.00	0.0%	0.04	7.1%	0.00	0.0%	0.00	0.0%	0.14	92.9%	0.14	0.13	0.16	34.1%
2.7	2.66	216	0.00	0.0%	0.04	17.2%	0.00	0.0%	0.02	3.2%	0.08	79.5%	0.09	0.08	0.11	22.1%
4.2	4.18	215	0.00	0.0%	0.05	30.9%	0.01	2.6%	0.00	0.0%	0.07	66.5%	0.09	0.07	0.12	20.6%
5.4	5.44	216	0.00	0.0%	0.06	26.5%	0.00	0.0%	0.01	1.3%	0.09	72.2%	0.11	0.09	0.14	25.8%
6.9	6.86	216	0.00	0.0%	0.07	34.0%	0.02	3.4%	0.00	0.0%	0.10	62.5%	0.13	0.10	0.17	29.8%
8.2	8.11	216	0.00	0.0%	0.09	47.9%	0.00	0.0%	0.02	2.6%	0.09	49.5%	0.13	0.10	0.19	30.5%

a. (%) is contribution of variance component to overall lognormal CV

b. “CV” is lognormal CV, as obtained using the formula:

$$CV(\text{of the lognormal dist}) = \sqrt{10^{\ln(10)^2 \sigma^2} - 1}$$

18.4 Linear Range and Inclusivity

The linear range of the HCV VL assay was determined by analysis of a twelve member panel covering a range from ~ 5 ($0.75 \log_{10}$) to $\sim 1 \times 10^8$ ($8 \log_{10}$) IU/mL. Panels were prepared by parallel dilutions of HCV reference material (Armored RNA[®] genotype 1 and clinical specimen genotype 1) in HCV negative EDTA plasma and serum. The nominal concentration of the reference material used was calibrated to the WHO 4th HCV International Standard (06/102). Each panel member was tested in replicates of four on each of three testing days using two kit lots. Totally, 24 replicates per panel member and sample type were tested. The linearity analysis was performed according to CLSI guideline EP06-A. The combined results for both lots are shown in Figure 9 and Figure 10. The HCV VL assay is linear within a range 0.8 – $8.0 \log_{10}$ IU/mL with a R^2 value of >0.997 .

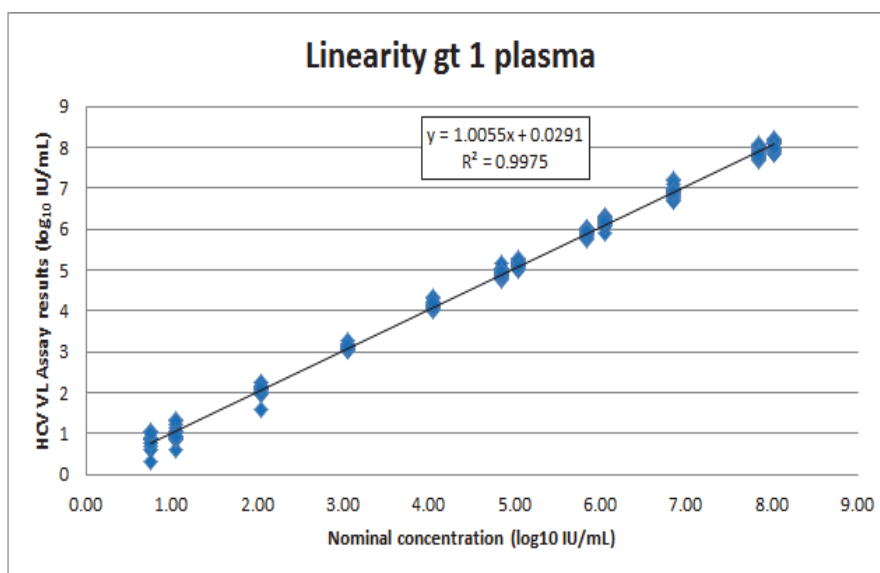


Figure 9. Linearity Genotype 1 in EDTA Plasma for the HCV VL Assay

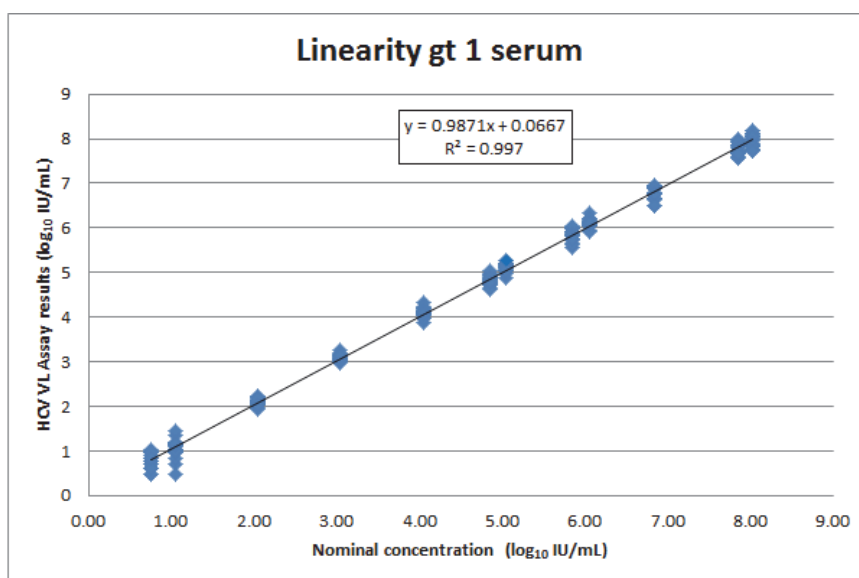


Figure 10. Linearity Genotype 1 in Serum for the HCV VL Assay

To confirm the linear range and evaluate the inclusivity of the HCV VL assay, panels consisting of clinical specimens representing HCV genotype 2 – 6 and Armored RNA® when available (genotypes 2 and 3 only) were prepared in negative human EDTA plasma. 7 – 13 panel members per genotype covering as wide a range as possible, varying from ~ 0.9 – 6 log₁₀ IU/mL for genotype 5 to ~ 0.9 – 8.3 log₁₀ for genotype 3, were prepared and analyzed in replicates of four on each of three testing days using two kit lots. For each genotype, 24 replicates per panel member were tested. The nominal concentrations of the reference materials used were calibrated to the WHO 4th HCV International Standard (06/102). All genotypes responded linearly with R² values ranging from 0.994 – 0.998.

18.5 Analytical Specificity (Exclusivity)

The analytical specificity of the HCV VL assay was evaluated by adding potentially cross-reacting organisms at 1 x 10⁵ CFU/mL, copies/mL or TCID₅₀/mL input concentration into HCV negative EDTA plasma and in plasma that contained ~25 IU/mL HCV reference material (clinical specimen genotype 1). Tested organisms are listed in Table 8.

Table 8. Analytical Specificity Organisms

Human Immunodeficiency virus 1
Human Immunodeficiency virus 2
Human T-cell lymphotropic virus I
Human T-cell lymphotropic virus II
<i>Candida albicans</i>
Cytomegalovirus
Epstein-Barr virus
Hepatitis A virus
Hepatitis B virus
Herpes simplex virus 1
Herpes simplex virus 2
Human herpes virus 6
Human herpes virus 8
Varicella Zoster virus
BK Human polyoma virus
Banji virus
Ilheus virus
West Nile virus
Zika virus
Human papilloma virus 16
Human papilloma virus 18
<i>Staphylococcus epidermidis</i>
<i>Staphylococcus aureus</i>

None of the tested organisms showed cross reactivity and all positive replicates resulted in concentrations of HCV RNA within ± 0.5 log from a HCV positive control when tested using the HCV VL assay. In addition to the species listed in Table 8, Dengue virus and vaccinia virus were analyzed *in silico* since material representing the viruses could not be obtained for testing. No practical significant sequence similarity was found between the analyzed viruses and the primers and probes of the Xpert HCV VL assay.

18.6 Potentially Interfering Substances

The susceptibility of the HCV VL assay to interference by elevated levels of endogenous substances, by drugs prescribed to HCV infected patients and by autoimmune disease markers was evaluated. HCV negative EDTA plasma and plasma that contained ~25 IU/mL HCV reference material (clinical specimen genotype 1) were tested.

Elevated levels of the endogenous substances listed in Table 9 were shown not to interfere with the quantification of the HCV VL assay or impact the assay specificity.

Table 9. Endogenous Substances and Concentration Tested

Substance	Tested Concentration
Albumin	9 g/dL
Bilirubin	20 mg/dL
Hemoglobin	500 mg/dL
Human DNA	0.4 mg/dL
Triglycerides	3000 mg/dL

The drug components as presented in Table 10 were shown not to interfere with the quantification of the HCV VL assay or impact the assay specificity when tested at three times peak level concentration in five drug pools.

Table 10. Drug Pools Tested

Pool	Drugs
Control	N/A
1	Zidovudine, Saquinavir, Ritonavir, Interferon alfa-2b, Clarithromycin
2	Abacavir sulfate, Fosampervir Calcium, Peginterferon 2b, Ribavirin
3	Tenofovir disoproxil fumarate, Lamivudine (3TC), Indinavir sulfate, Ganciclovir, Valganciclovir HCl, Acyclovir
4	Stavudine (d4T), Efavirenz, Lopinavir, Enfuvirtide (T-20), Ciprofloxacin
5	Nevirapine, Nelfinavir mesylate, Azithromycin, Valacyclovir HCl

Testing of specimens from ten individuals per autoimmune disease marker shows no interference with the autoimmune disease markers systemic lupus erythematosus (SLE), anti-nuclear antibody (ANA), or rheumatoid factor (RF) using the HCV VL assay.

18.7 Seroconversion Sensitivity

The sensitivity of the HCV VL Assay was evaluated by testing sequential plasma specimens from ten seroconversion panels with a total of 59 panel members. Each seroconversion panel consisted of undiluted plasma specimens collected from a single donor during development of HCV infection and subsequent immune response. The HCV VL assay detected HCV RNA in 51 out of 57 tested specimens with valid test result as compared to 21 of the 59 tested that were detected by at least one of the HCV antibody tests (Abbott ARCHITECT HCV Ab, Abbott PRISM HCV Ab, Ortho® Ver. 3.0 ELISA HCV Ab, Ortho HCV 3.0 ELISA Test System with Enhanced SAvE, Ortho Vitros Eci, Siemens ADIVA Centaur). HCV RNA was detected by the HCV VL Assay prior to antibody tests in nine seroconversion panels and at the same time point for one seroconversion panel. The result is presented in Table 11.

Table 11. Seroconversion Sensitivity of the HCV VL Assay

Panel No	No. of Specimens in Panel	Days Spanned	No. of Reactive Panel Members		Days to First Reactive Result		Days Between First Reactive Result with Xpert HCV VL and Any Ab Test
			Xpert HCV VL	Antibody (Ab) Test ^a	Xpert HCV VL	Antibody (Ab) Test ^a	
PHV913	4	9	4	2	0 ^b	7	7
PHV915	4	14	3 ^c	2	5 ^c	12	7
PHV920	9	35	9	7	0 ^b	13	13
PHV922	6	17	5 ^c	5	3 ^c	3	0
PHV924	6	88	6	3	0 ^b	59	59
PHV925	5	27	5	1	0 ^b	27	27
PHV926	5	14	5	1	0 ^b	14	14
PHV927	5	17	4	0	4	17 ^d	13
PHV928	9	50	7	0	29	50 ^d	21
PHV929	6	22	3	0	14	22 ^d	8

a. Antibody test based on vendor data: Abbott ARCHITECT HCV Ab, Abbott PRISM HCV Ab, Ortho Ver. 3.0 ELISA HCV Ab, Ortho Enhanced SAVE HCV Ab, Ortho Vitros Eci, Siemens ADIVA Centaur.

b. All bleeds were detected with the Xpert HCV VL Assay.

c. All test results of Xpert HCV VL is presented, first panel member caused an invalid test result.

d. All bleeds were non-reactive for HCV Antibodies (based on vendor information). The last bleed day is used as "Days to First Reactive Result"

18.8 Sample Collection Media Equivalence (EDTA, PPT-EDTA and Serum)

For each sample collection media (EDTA, PPT-EDTA and serum) specimens from 50 matched HCV positive individuals and 25 matched HCV negative specimens were collected and tested using one kit lot of the HCV VL assay.

As shown in Figure 11 and Figure 12 equivalent performance of the HCV VL assay was shown for EDTA plasma versus serum samples and EDTA plasma versus PPT-EDTA plasma samples. All HCV positive specimens collected in serum or PPT-EDTA plasma produced concentrations of HCV RNA within $\pm 0.5 \log_{10}$ IU/mL of the HCV positive specimen collected in EDTA plasma when tested using the HCV VL assay.

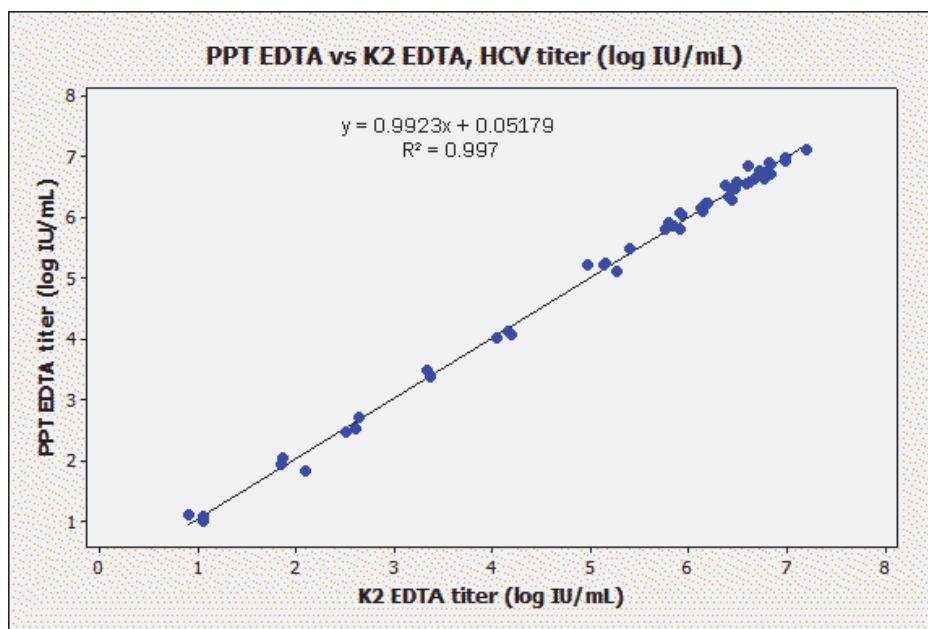


Figure 11. Scatterplot of Log IU/mL PPT-EDTA versus Log IU/mL EDTA

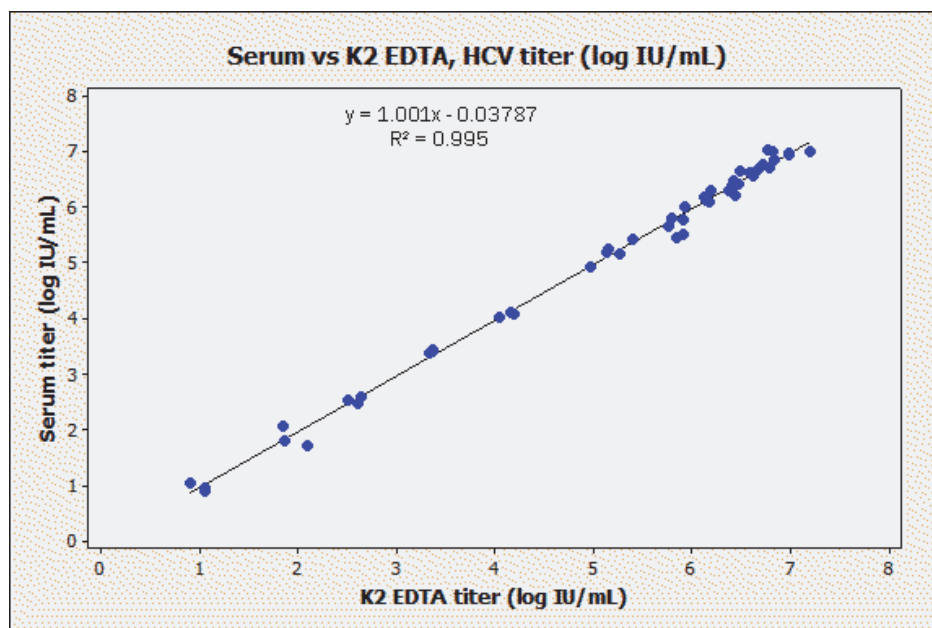


Figure 12. Scatterplot of Log IU/mL Serum versus Log IU/mL EDTA Plasma

19 Performance Characteristics – Clinical Performance

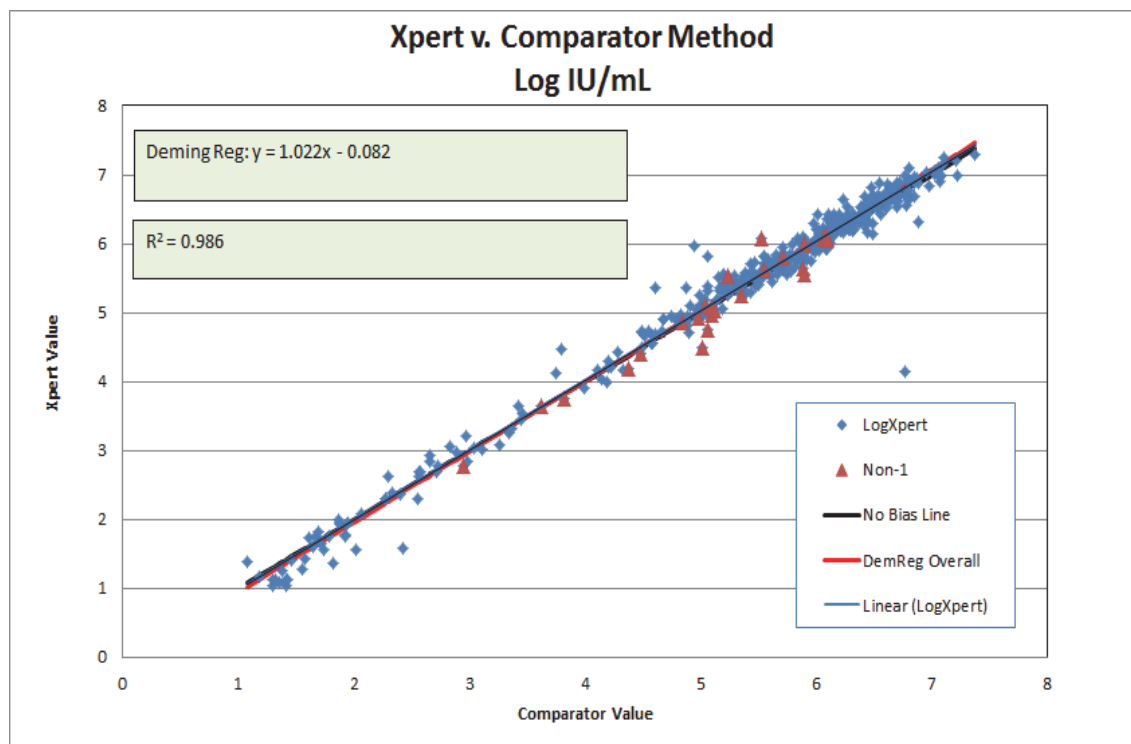
Specificity

The specificity of the HCV VL assay was evaluated using 501 EDTA plasma specimens from HCV negative blood donors. HCV RNA was not detected in any of the 501 specimens tested by the Xpert HCV VL assay demonstrating 100% specificity (95% CI: 99.2-100.0).

Method Correlation

A multi-site study was conducted to evaluate the performance of the HCV VL assay relative to a comparator method using fresh and frozen human plasma or serum specimens collected from HCV infected individuals. Of the 607 eligible specimens, each from unique individuals, 408 (67.2%) were collected from male subjects. The average age was 50.2 ± 13.2 years with an age range of 21 to 86 years.

Of the 607 specimens, 389 were within the quantitation range of both assays including 23 specimens that were HCV non-1 genotypes (2, 2a, 2b, 2c, 3, 3a, 4 & 6) and one mixed genotype (HCV 1 & 6). The Deming regression shows very good correlation between the HCV VL and the comparator method with a slope of 1.022 and intercept of 0.082. The R^2 was 0.986.



*HCV non-1 genotypes are represented as triangles. A single outlier was not included in the analysis.

Figure 13. Xpert v. Comparator Method

20 References

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11. REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on the classification labeling and packaging of substances and mixtures amending and repealing, List of Precautionary Statements, Directives 67/548/EEC and 1999/45/EC (amending Regulation (EC)).
12. Occupational Safety and Health Standards, Hazard Communication, Toxic and Hazard Substances (March 26, 2012) (29 C.F.R., pt. 1910, subpt. Z).

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22 Technical Assistance

Before contacting Cepheid Technical Support, collect the following information:

- Product name
- Lot number
- Serial number of the instrument
- Error messages (if any)
- Software version and, if applicable, Computer Service Tag number

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Contact information for all Cepheid Technical Support offices is available on our website:
www.cepheid.com/en/CustomerSupport.

23 Table of Symbols

Symbol	Meaning
	Catalog number
	<i>In vitro</i> diagnostic medical device
	Do not reuse
	Batch code
	Caution
	Manufacturer
	Country of manufacture
	Contains sufficient for <n> tests
	Control
	Expiration date
	CE marking – European Conformity
	Temperature limitation
	Biological risks
	Warning
	Authorized representative in Switzerland
	Importer



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Xpert[®] Check Instructions for Use

REF **XPERTCHECK-CE-5**

Trademark Information

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See Revision History for a description of changes.

Revision History

Description of changes: 301-3985, Rev. J to 302-6125, Rev A

Purpose: To align with the requirements of Regulation (EU) 2017/746

Section	Description of Change
Front Section	Updated Copyright Information
Preface	Added EU/Switzerland Importer Information
Preface	Added CH REP symbol to Table of Symbols
1.3	Revised Intended Use section structure and added Intended Usage/Environment.
1.5.1	Added new Note regarding bovine serum albumin in the beads.
1.7	Corrected typo. Changed "DX" to Dx" in 2 places.



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Preface

About This Document

The *Xpert Check Package Insert* provides instructions on running Xpert Check software for checking module performance.

Safety Information

Read and understand any safety information presented in this document before you begin operating the instrument. Make sure you follow the precautionary statements presented in this guide:

Caution



Indicates that damage to the system, loss of data, or invalid results could occur if the user fails to comply with the advice given.

Important

Highlights information that is critical for the completion of a task or the optimal performance of the system.

Note

Identifies information that applies only in special cases.

Related Documents

For other information outside the scope of this document, see the following publications:

- *GeneXpert Dx Operator Manual*
- *GeneXpert Xpress User's Guide*
- *GeneXpert Infinity Operator Manual*

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Technical Assistance

Before contacting Cepheid Technical Support, collect the following information:

- Product name
- Serial number of the instrument
- Error messages (if any)
- Software version and, if applicable, Computer Service Tag number

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Contact information for all Cepheid Technical Support offices is available on our website: www.cepheid.com/en/CustomerSupport.

Table of Symbols

Symbol	Meaning
	Catalog number
	<i>In vitro</i> diagnostic medical device
	Batch code
	Do not reuse
	This type of symbol indicates a Warning or Caution for which there is no other identified symbol. Read the instructions following the symbol to avoid injury or equipment damage.
	Consult instructions for use
	Manufacturer
	Country of manufacture
	Contains sufficient for <n> tests
	Expiration date
	Control
	CE marking - European Conformity
	Authorized representative in the European Community
	Authorized representative in Switzerland
	Temperature limitation
	This type of warning label indicates a potential biological hazard risk. Biological samples such as tissues, body fluids, and blood of humans and/or animals have the potential to transmit infectious diseases. Follow your local, state/provincial, and national safety regulations for handling and disposing the samples.



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1 Introduction

Important

Read and understand this entire document before performing the data collection procedure.

1.1 Proprietary Name

Xpert[®] Check

1.2 Common or Usual Name

Xpert Check

1.3 Intended Purpose

1.3.1 Intended Use

Xpert[®] Check is part of a check, verification, and hardware test system for GeneXpert[®] modules. Xpert Check is used in GeneXpert Dx, GeneXpert Xpress and GeneXpert Infinity systems. Xpert Check is used to check the optical system, verify the thermal system and perform a series of system-level tests to ensure full system functionality within Cepheid's instrument servicing specifications. One Xpert Check cartridge is usually used to check a single module in conjunction with the Xpert Check software. In certain cases where a retest is required, multiple cartridges may be necessary to test a module.

1.3.2 Intended User/Environment

Xpert[®] Check is intended to be performed by trained users where a GeneXpert System is installed.

1.4 Summary and Explanation

The GeneXpert module is the basis for all GeneXpert instrument systems worldwide. Cepheid recommends that the system be checked for proper operation on an annual basis. Based upon the usage and care of each system, checks may be recommended more frequently. The system is designed to detect module issues with the internal assay controls.

Xpert Check is an accessory to GeneXpert systems. Xpert Check includes reagents for the optical checking and performance verification of the module. Probe Check Controls (PCCs) verify reagent rehydration, PCR tube filling in the cartridge, probe integrity, and reagent stability. Thermal performance is verified via proprietary thermal probe chemistries, and module hardware performance is tested and verified by a suite of subsystem-specific tests which exercise all critical elements of the GX module.

The Xpert Check process consists of two phases. The first phase is the execution of module testing using the cartridges. The second phase consists of a Cepheid Quality Assurance Review, followed by the issuance of an Xpert Check code to complete the Xpert Check process. **The Xpert Check process is not complete until this code is applied to the system.**

1.5 Reagents and Instruments

1.5.1 Materials Provided

The Xpert Check kit contains the following:

Table 1-1. Kit Contents

Description	Quantity
Xpert Check cartridges with integrated reaction tubes	5 per kit
Each cartridge contains the following materials:	
• Bead 1	1 per cartridge
• Reagent 1	1.0 mL per cartridge
I-CORE Lens Cleaning Brush	4 per kit
PI/Software (P/N 950-0413)	1 per kit
Data CD	1 per kit

Note Safety Data Sheets (SDS) are available at www.cepheidinternational.com under the **SUPPORT** tab.

Note The bovine serum albumin (BSA) in the beads within this product was produced and manufactured exclusively from bovine plasma sourced in the United States. No ruminant protein or other animal protein was fed to the animals; the animals passed ante- and postmortem testing. During processing, there was no commingling of the material with other animal materials.

1.5.2 Storage and Handling



- Store the Xpert Check cartridges at 2-28 °C. Wait at least 10 minutes after removal from cold storage before using, to allow a cartridge to reach ambient temperature.
- Use the cartridge within 48 hours of opening the foil pouch.
- Discard 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.
- The cartridge lid must be opened (vented) prior to use of the cartridge; however, no sample is required for testing.
- Discard all used and unused materials, including cleaning brushes and cartridges once the Xpert Check session is completed.

Note

Contents of cartridges are non-hazardous.

1.5.3 Materials Required but Not Provided

- GeneXpert Dx, GeneXpert Xpress or GeneXpert Infinity System with Cepheid-supplied computer and barcode scanner.
- GeneXpert instrument.

1.6 Limitations

- For use with GeneXpert modules (running GeneXpert Dx software version 4.0 and above or GeneXpert Xpress software version 6.2 and above). 4-color GeneXpert modules (including Bio-threat modules) and Dual-Cal modules cannot run Xpert Check and must be tested by Cepheid Service.
- Use of the Xpert Check kit does not guarantee that the GeneXpert instrument will be free of hardware failures, nor does it take the place of a Cepheid Service Agreement.

1.7 Warnings and Precautions

After January 14, 2020, Microsoft will no longer provide security updates or support for PCs running Windows 7. It is recommended that you upgrade to Windows 10.

Important

Please contact:
<https://www.microsoft.com/en-us/microsoft-365/windows/end-of-windows-7-support> for Windows 7 support information.

In addition, please contact your local Cepheid Technical Support if you have questions about using Windows 7.

- Even though Xpert Check cartridges do not contain hazardous chemicals, you should always follow your institution's safety procedures for working with chemicals.
- Do not add a sample or other reagents to the Xpert Check cartridges.
- Do not use a cartridge that has a damaged reaction tube.
- Do not use cartridges from visibly damaged or compromised foil pouches.

②

- Contact your local Cepheid Technical Support office for replacement of damaged kit contents.
- Do not use a cartridge if it is dropped.
- Each single-use Xpert Check cartridge is used to process one test. Do not reuse spent cartridges.
- Each cleaning brush is intended for use in a single module. Do not re-use brushes in multiple modules.
- Do not open a cartridge package or break the lid seal until you are ready to perform testing.
- Allow the Xpert Check cartridge to come to ambient temperature prior to use if it has been placed in cold storage. Wait at least 10 minutes after removal from cold storage before using.
- Do not store single cartridges. Cartridges left over from an Xpert Check session, including pouched/unopened cartridges should be discarded along with spent cartridges.
- Do not use cartridges whose shelf life has expired. The system will detect expired cartridges and abort the test.
- Follow your institution's environmental waste procedures/consult your institution's environmental waste personnel for proper disposal of cartridges. If necessary, reference the WHO's [World Health Organization's] waste handling and disposal guidelines for the proper disposal of cartridges.
- Once a cartridge barcode has been scanned, do not substitute another cartridge in place of the scanned cartridge.
- If using an internet-enabled Xpert Check, it is recommended that up-to-date anti-virus software be installed on the desktop or laptop computer with updated virus definition files, prior to executing Xpert Check.
- Prior to running Xpert Check, ensure that the environmental operating temperature is within the correct limits (15 °C–30 °C). Xpert Check will render a system's modules unavailable if the internal temperature is above 40 °C. The internal temperature can be verified in the Maintenance section of the GeneXpert Dx, GeneXpert Infinity or GeneXpert Xpress software. Do not proceed under these conditions.
- Xpert Check expects the same computer to be used throughout the entire process. The computer installed with the GeneXpert system should be used, and not another computer from a different GeneXpert system.
- The Xpert Check code will expire if not applied within 45 days of completion of running Xpert Check.

1.8 Chemical Hazards

According to the Globally Harmonized System for Classification and Labeling (GHS) and the Classification, Labeling and Packaging (CLP) Regulation, this material is not considered hazardous.

1.9 Assistance and Contact Information

For a complete listing of Cepheid technical support, service support, sales support, and headquarters contacts, please see [Technical Assistance](#), in the Preface of this document.

1.10 Software Buttons, Icons and Symbols

Table 1-2. Software Buttons, Icons and Symbols

Symbol	Definition
	Information. Touch or click this icon to obtain additional information. Displays the Information Key workspace screen which has an explanation of the various module icon displays.
	Continue. This icon is located at the bottom of most screens. Touch or Click this icon to advance the display to the next screen.
	Continue to End. Touching or clicking this icon moves the user to the last screen.
	Exit. Exits the Xpert Check application.
	About. Brings up the About screen which shows the name of the software, the software version number, copyright notice, etc.
	Home. Go to the Home screen.

Table 1-2. Software Buttons, Icons and Symbols

Symbol	Definition
	Repeat/Retry. Retry loading an Xpert check cartridge to attempt to check a module that has had an unsuccessful test of a minor nature or if the cartridge has not been vented by the user. Used on the 'Check Test' screen.
	Back. Touching or clicking this icon takes the user to the previous screen.
	Cancel. Cancel the current operation. In most cases this will mean going back to the previous screen. In some cases, it may mean going back to the screen before the one that started the current operation.
	Select none of the modules for check. Deselects all modules for checking. If you only want to check a few modules, you may deselect ALL of them, and then reselect only the ones you wish to check.
	Select all of the modules for checking. The default setting for the system.
	Connectivity Status. Indicates the system is able to reach the Xpert Connectivity Center.
	Connectivity Status. Indicates the system is not able to reach the Xpert Connectivity Center.
	Module unsupported for Xpert Check. Skip the current module and do NOT attempt to check the current module.
	Module selected for Xpert Check. Module will be included when Xpert Check is run.

Table 1-2. Software Buttons, Icons and Symbols

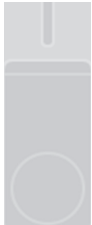
Symbol	Definition
	Skip Current Module. Skip the current module and do not attempt to Xpert Check the current module. Used on the 'Load Xpert Check Cartridges' screen.
	Skip Remaining Modules. Skip all the remaining modules and do NOT attempt to Xpert Check them. Used on the 'Load Xpert Check Cartridges' screen.
	Module not selected for Xpert Check. Module will not be included when Xpert Check is run.
	Module unavailable for Xpert Check. Module will not be included when Xpert Check is run.
	Indicates a module with data collection in progress.
	Indicates data collection complete.
	Retest required. Indicates an incomplete Xpert Check data collection. A message will notify the user that the test must be rerun. A further message will indicate if the existing cartridge can be reused for the test or if a new cartridge must be used.

Table 1-2. Software Buttons, Icons and Symbols

Symbol	Definition
	Service required. Contact the Cepheid Authorized Service Provider (ASP) or your local Cepheid Technical Support office.
	Lost communication. Contact the Cepheid Authorized Service Provider (ASP) or your local Cepheid Technical Support office.
	Burn. Burn a CD containing the collected Xpert check information (for users without an active internet connection).
	Collect Xpert Check Data. Leads the user through the Xpert Check data collection process.
	Enter Xpert Check code. Go to the 'Enter Xpert Check Code' screen.
	Xpert Check Status. Go to the Xpert Check Status screen to review Xpert Check status.
	Upload Xpert Check Data File. Go to the 'Upload Xpert Check Code Data File' screen.
	Upload Xpert Check Data CD. Go to the 'Upload Xpert Check Code Data CD' screen.
	Write Xpert Check Code. Write an Xpert Check Code to a file.
	Read Xpert Check Code. Open a file to read the Xpert Check code.
	Scan. Turn the barcode scanner on, and accept the next scanned input.

Table 1-2. Software Buttons, Icons and Symbols

Symbol	Definition
	View and Print. Launch the Adobe Reader so you can view and then print a PDF file.

2 Procedure

2.1 System Preparation

Note

Prepare the system for Xpert Check by following one of the four procedures listed in this section for the GeneXpert Dx, GeneXpert Xpress, the GeneXpert Infinity-48s, or the GeneXpert Infinity-80.

Important

Authorized Service Providers (ASPs) who perform Xpert Check but won't be on-site when the Xpert Check code numbers come back (non-internet connection sites), should leave the user name and password for the users to log in later to enter the codes (see [section 2.3.2](#)).

2.1.1 GeneXpert Dx Preparation

1. Create an Administrator or Basic level User Name and Password in the GeneXpert software if one does not exist. Xpert Check requires this logon credential to be established prior to starting.
2. Have your Authorized Service Provider (ASP) code available before continuing to the next steps.
3. Exit the GeneXpert Dx software.
4. Go to [Section 2.2, GeneXpert Dx, GeneXpert Xpress and GeneXpert Infinity Optics Cleaning](#).

2.1.2 GeneXpert Xpress Preparation

1. Create an Administrator or Basic level User Name and Password in the GeneXpert Xpress software if one does not exist. Xpert Check requires this logon credential to be established prior to starting.
2. Have your Authorized Service Provider (ASP) code available before continuing to the next steps.
3. Exit the GeneXpert Xpress software.
4. Go to [Section 2.2, GeneXpert Dx, GeneXpert Xpress and GeneXpert Infinity Optics Cleaning](#).

2.1.3 GeneXpert Infinity-48s or GeneXpert Infinity-80 Preparation

1. Create an Administrator or Basic level User Name and Password in the GeneXpert software if one does not exist. Xpert Check requires this logon credential to be established prior to starting.

2. Have your Authorized Service Provider (ASP) code available before continuing to the next steps.
3. Exit the GeneXpert Infinity System software.
4. Open the glass doors following the instructions in the *GeneXpert Infinity System Operator Manual*.
5. Go to [Section 2.2, GeneXpert Dx, GeneXpert Xpress and GeneXpert Infinity Optics Cleaning](#).

2.2 GeneXpert Dx, GeneXpert Xpress and GeneXpert Infinity Optics Cleaning

This procedure describes the method for removing dust and tube debris from the surface of rod lenses of the excite and detect blocks for GeneXpert Dx, GeneXpert Xpress and GeneXpert Infinity modules prior to performing the Xpert Check procedure.

Materials Required or Recommended for Cleaning

- I-CORE Lens Cleaning brush (Quantity of four Included in the Xpert Check kit)
- Disposable gloves

Estimated Cleaning Time: 30 Seconds per module.

2.2.1 I-CORE Lens Cleaning Procedure

1. Select the module to be checked and manually open the door of the module.
2. If necessary, remove the cartridge from the module.

Biological Risks



Remove the cartridge from the GeneXpert modules prior to cleaning. Failure to remove a cartridge could result in personnel being exposed to biological hazards and/or liquid biological materials spilling into the instrument and causing damage to the instrument.

3. Locate the brush provided in the Xpert Check kit (see [Figure 2-1](#)).

Figure 2-1. I-CORE Lens Cleaning Brush

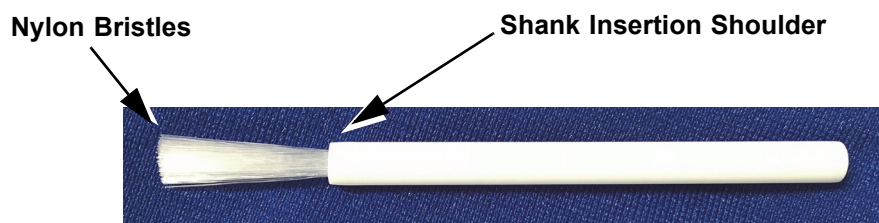


Figure 2-1. I-CORE Lens Cleaning Brush

Note

The brush is designed so that it will easily insert into the I-CORE slit and make contact with the rod lenses of the excite and detect blocks.

Biological Risks



Make sure you wear disposable gloves for the cleaning process. Wearing gloves prevents you from being exposed to biologically hazardous materials.

4. Wearing disposable gloves, insert the brush into the I-CORE slit in a tilted manner up to the shank insertion shoulder, as shown in [Figure 2-2](#).

Note

Make sure that all the bristles are fully inserted (up to the shoulder of the plastic shank of the brush) so that it does not cause unnecessary damage to the brush.

Caution



Do not insert any objects into the I-CORE slit except the provided brush. Inserting any other object may damage the I-CORE.

Caution



Do not apply any solution (such as ethanol or bleach) onto the brush bristles. The brush must be completely dry when inserting it into the I-CORE slit.

Important

The brush is intended for single-use and should not be used on more than one module. Use a new brush for each module to be cleaned.



Figure 2-2. Inserting the Cleaning Brush into the I-CORE Slit

5. Insert the brush into the I-CORE slit completely up to the plastic shank (shoulder) of the brush. Hold the brush firmly in the I-CORE slit, and perform cleaning of the rod lenses as described below. The entire cleaning process should take approximately 30 seconds per module.

Note

Cleaning is done by moving the brush in an up and down direction within the I-CORE slit. Brush rotation, even if it has to be done, is not the main action that results in optics cleaning.

- A. Begin by brushing from the top of the I-CORE slit to the bottom, making sure to apply a uniform pressure when brushing from the top to the bottom of the I-CORE slit. This will ensure that most of the tube debris and dust is brushed off from the surface of the lenses.
 - B. Rotate the brush from left to right and back again, approximately 180°.
 - C. Brush once more from the top of the I-CORE slit to the bottom.
 - D. Rotate the brush again from left to right and back again, approximately 180°.
 - E. Finally, brush again from the top of the I-CORE slit to the bottom.
6. When lens cleaning is complete, remove and discard the used brush and gloves as hazardous waste.

Important

Dispose of gloves and brushes according to your institution's safety policies and procedures for hazardous waste.

7. Proceed to [Section 2.3, Data Collection Procedure: GeneXpert Dx, GeneXpert Xpress and GeneXpert Infinity](#).

2.3 Data Collection Procedure: GeneXpert Dx, GeneXpert Xpress and GeneXpert Infinity

Important

Before collecting data, be sure to prepare the system for checking as described in [Section 2.1, System Preparation](#). Internet-connected users should verify their system's connectivity status prior to beginning the Xpert Check process.

Note

Throughout this procedure, when making an onscreen button or icon selection, use the touchscreen on the GeneXpert Xpress system by touching the button or icon with your finger. When using the GeneXpert Dx or GeneXpert Infinity system, use a mouse to select, by clicking the desired button or icon.

Note

Use care in inserting CD1 into the DVD drive. Be sure the CD is fully seated in the tray before closing the drive door.

1. Place Software CD1 in the computer connected to the GeneXpert Dx. For the GeneXpert Dx system using an external DVD drive and for the GeneXpert Xpress and GeneXpert Infinity systems, connect the DVD drive following the instructions in the *GeneXpert Dx Operator Manual*, the *GeneXpert Xpress User's Guide* or the *GeneXpert Infinity System Operator Manual*, and insert the CD into the DVD drive.

2. For a GeneXpert Xpress system, follow the procedure in [Step A](#); for GeneXpert Dx and GeneXpert Infinity, follow the procedure in [Step B](#).

- A. **GeneXpert Xpress** On the computer desktop, touch and hold the **Computer** icon and a drop-down menu will appear. Touch **Open**, then touch and hold the applicable drive letter for your DVD drive.
Touch **Open** from the drop-down menu, and the files located on the CD will then be displayed.
Find, touch and hold the **XpertCheck.exe** application, and when the drop-down menu appears, touch **Run** to install as administrator. When the software has been installed, a “wrench” icon will appear on the desktop.

Note

The software may take some time to load from the CD.

- B. **GeneXpert Dx and GeneXpert Infinity:** On the computer desktop, right-click the **Computer** icon and a drop-down menu will appear. Click **Open**, then right-click on the applicable drive letter for your DVD drive.
Select **Open** from the drop-down menu, and the files located on the CD will then be displayed.
Find and right-click the **XpertCheck.exe** application, and when the drop-down menu appears, click **Run** to install as Administrator. When the software has been installed, a “wrench” icon will appear on the desktop.

Note

The software may take some time to load from the CD.

3. Depending on your system, either touch or double-click the “wrench” icon to launch the Xpert Check program.
4. The Terms of Service screen appears first. Use the scroll bar to read through the entire document. You will be asked to select (touch or click) the check box (bottom of the screen) to verify that you have read and agree to the Terms of Service before continuing. See [Figure 2-3](#).

Note

The Xpert Check software runs on Windows 7 or Windows 10. The screens shown in this manual are from Xpert Check software running on Windows 7. Screens for Xpert Check software running on Windows 10 will be similar.

After January 14, 2020, Microsoft will no longer provide security updates or support for PCs running Windows 7. It is recommended that you upgrade to Windows 10.

Important

Please contact:
<https://www.microsoft.com/en-us/microsoft-365/windows/end-of-windows-7-support> for Windows 7 support information.

In addition, please contact your local Cepheid Technical Support if you have questions about using Windows 7.

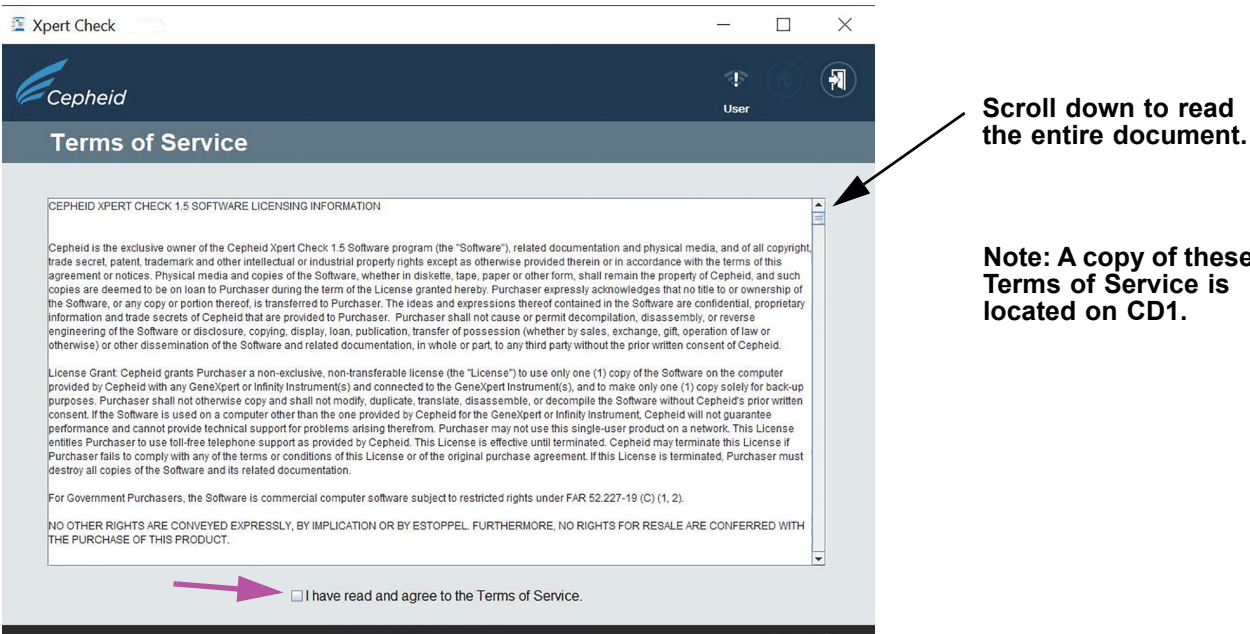


Figure 2-3. Terms of Service Screen

5. After agreeing to the Terms of Service, the Login screen will appear. Log in with your GeneXpert Dx, GeneXpert Xpress or GeneXpert Infinity designated Administrator level **USER NAME** and **PASSWORD** (previously assigned to you by your system administrator). After entering your login information, touch or click the forward arrow button at the bottom of the screen to advance to the Xpert Check Home screen. See [Figure 2-4](#).

Note	On the GeneXpert Xpress system, touching any field for inputting usernames, passwords, text, etc., will cause a virtual keyboard to appear for data entry. To close the keyboard, touch the X key in the upper right corner of the keyboard.
Note	The user name and password are the same ones you used for the GeneXpert Dx, GeneXpert Xpress or GeneXpert Xpertise software.

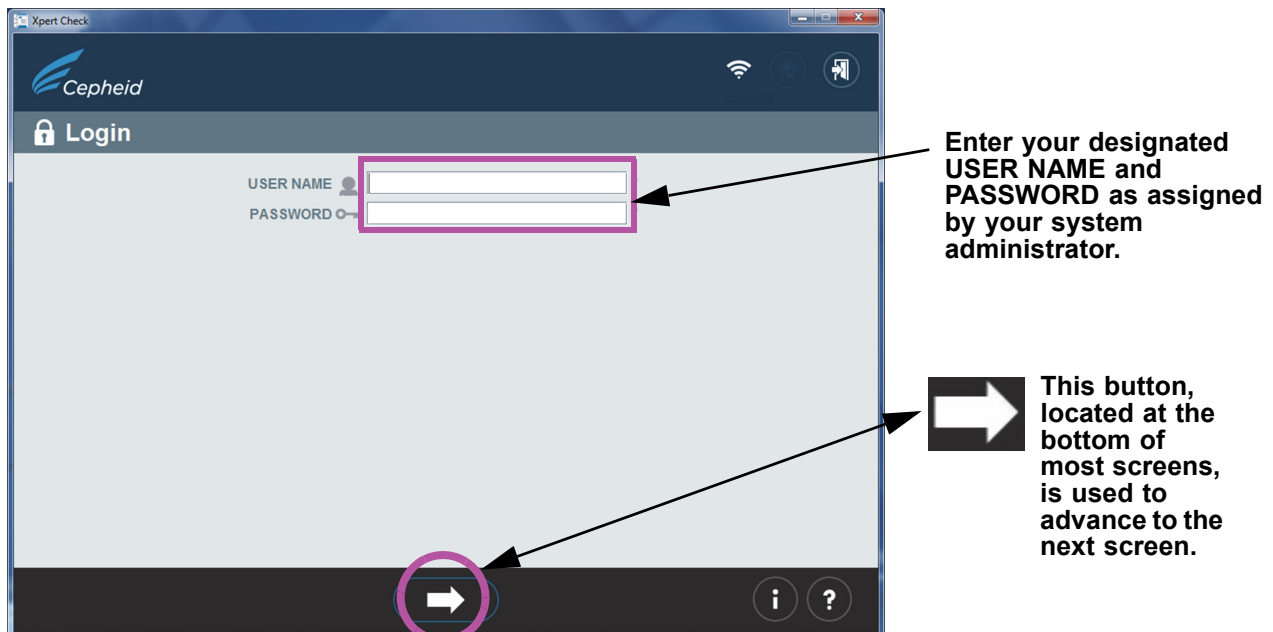


Figure 2-4. Xpert Check Login Screen

In case of a login error, the following screen will appear. See [Figure 2-5](#).

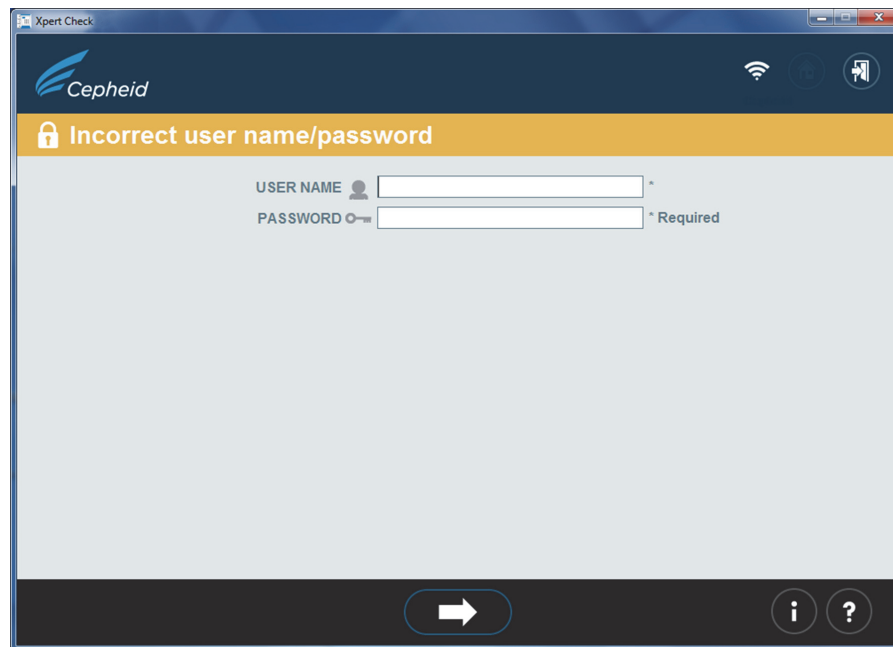


Figure 2-5. Login Error Screen

6. If a login error occurs, examine the **USER NAME** and **PASSWORD** entries for errors. If necessary, reenter the information and retry. After entering your login information, touch or click the forward arrow button at the bottom of the screen to advance to the Xpert Check Home screen.
7. Obtain a sufficient number of cartridges for the number of modules to be tested.

Important

Do not open cartridge packages until you are ready to scan the cartridge barcode (in Step 17).

Note

When determining the number of cartridges that will be needed for this test, the user should be aware of the number of modules that they will be checking.

8. Touch or click the **Collect Xpert Check Data** icon on the Home screen (See Figure 2-6). After a few seconds, the first Contact Information screen (Figure 2-7) will appear.

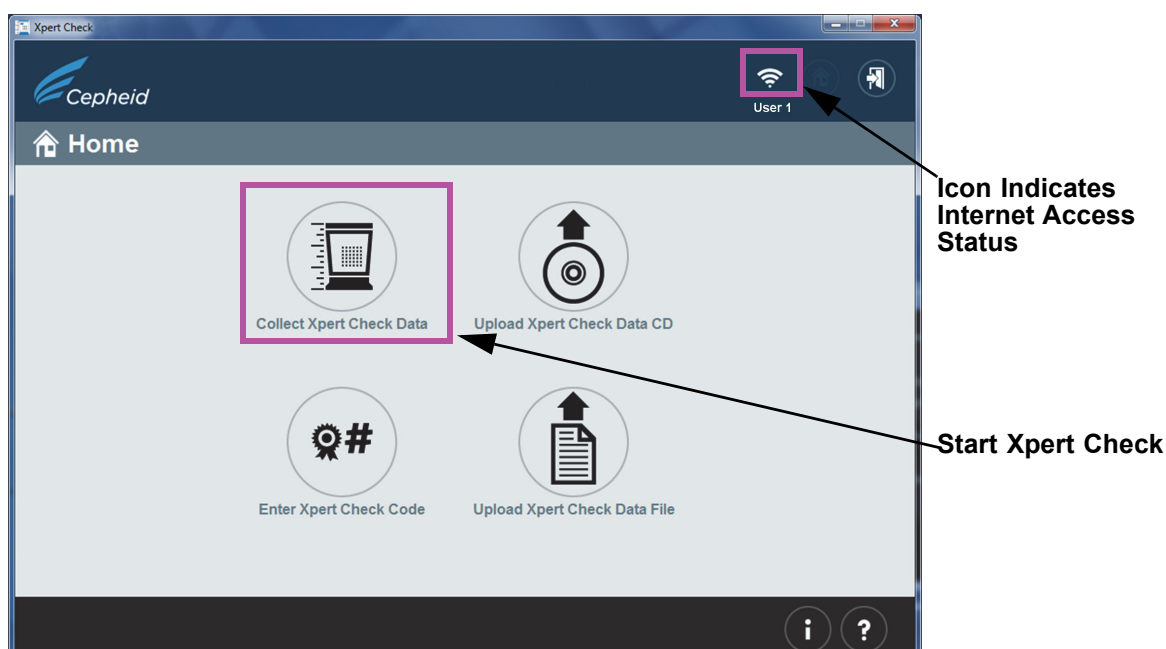


Figure 2-6. Home Screen

9. When the first of two Contact Information screens appear (see Figure 2-7 and Figure 2-8), fill out the fields in the two screens. Use the large navigation arrows at the bottom of the screens to move between the two screens.

Note

GeneXpert Xpress: When you touch a field, an onscreen keyboard appears for entering data.

Note that fields marked with “*” (at the right of the entry area) are mandatory fields.

Xpert Check

Cepheid

User1

Contact Information

Instrument Name My GeneXpert *

Serial Number # 123456 *

User User1 *

Institution institution1 *

Laboratory Lab 1 *

Address 100 Main Street *

Address (line 2) Suite 202 *

City New York *

State/Province NY *

Postal Code 10001 *

Country USA *

Navigation icons: Red X, Right Arrow, Information, Help

Figure 2-7. Contact Information Screen - Page 1

Xpert Check

Cepheid

User1

Contact Information

Email user1@institution.com *

Phone 408-400-XXXX *

Ext. X *

Mobile *

Service Provider US01 *

Navigation icons: Red X, Left Arrow, Right Arrow, Information, Help

In this mandatory field, enter your Authorized Service Provider's ID code. The ID code is four characters, as described in the note below.

Clicking on this icon will take the user back to the first Contact Information screen

Clicking on this icon will take the user to the Open Module Doors screen

Figure 2-8. Contact Information Screen - Page 2

Note

The ASP-provided ID code for the Service Provider on the Contact Information screen consists of four characters. (As examples: US01, 1203, etc.)

- When all information has been entered, touch or click the forward arrow button at the bottom of page 2 of the Contact Information screen. The Open Module Doors screen will appear. See [Figure 2-9](#). Manually open all module doors to enable cartridge loading.

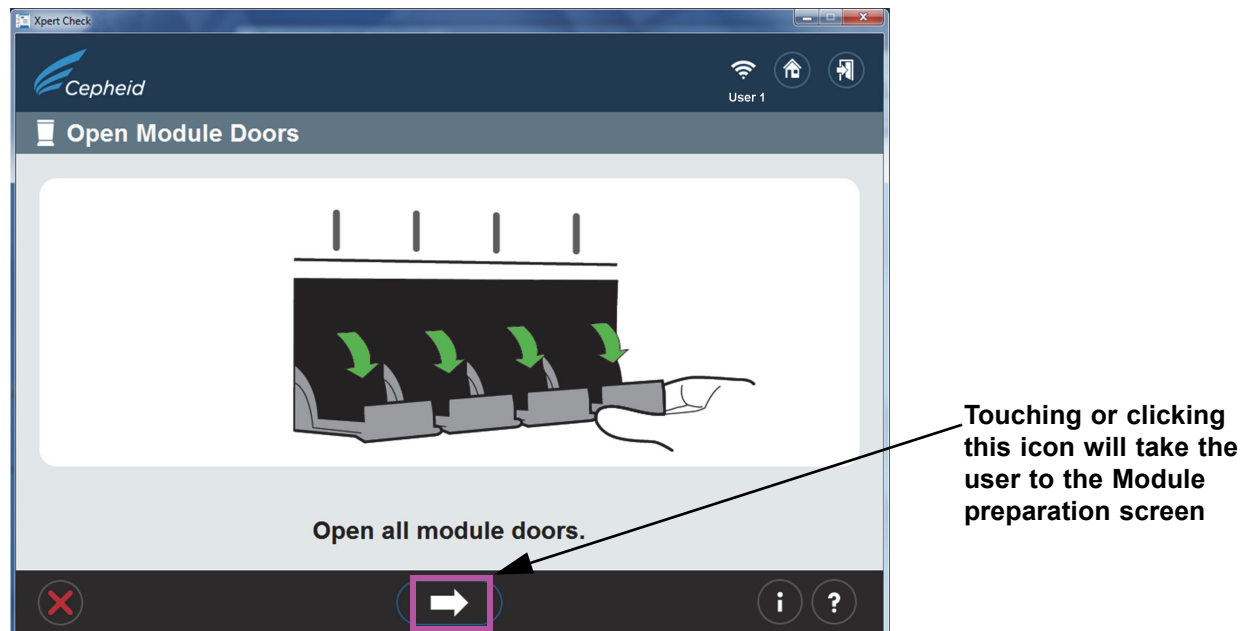


Figure 2-9. Open Module Doors Screen

- After opening all the module doors, touch or click the forward arrow button at the bottom of the screen. The Module preparation screen may appear, showing the message **Wait while modules are being prepared.** (See [Figure 2-10](#).)

Important

Note that the Module preparation screen will appear only if the firmware in the modules is not 3.0.3. The screen indicates that the software is upgrading/downgrading the firmware to the modules. The next screen you see will be the screen shown in [Figure 2-11](#), the Select Modules screen.

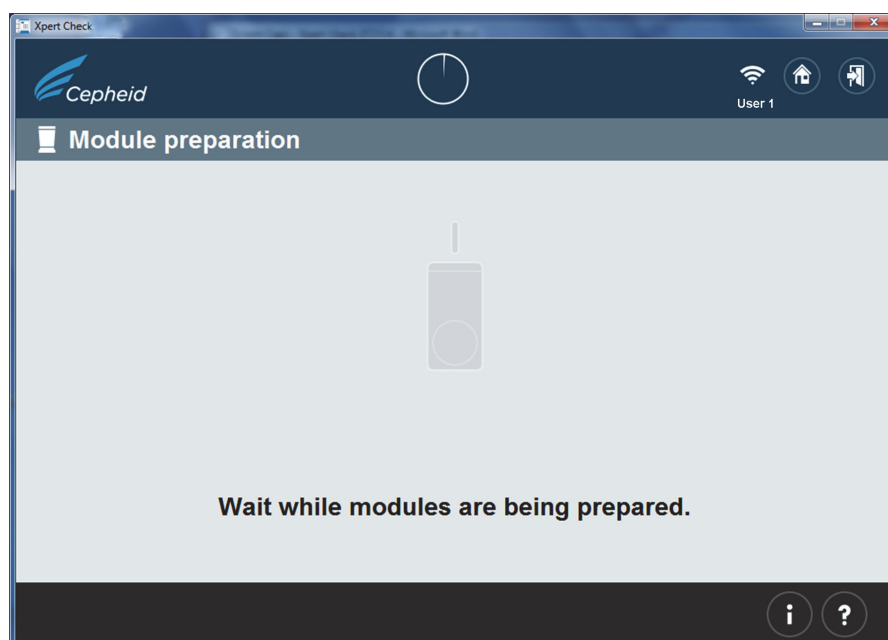


Figure 2-10. Module preparation Screen

12. Follow the on-screen software instructions in [Figure 2-11](#). By default, all detected modules will be marked as selected for checking.

On this screen, the user can touch or click individual module icons to exclude the modules from being checked, if required. The module icons will disappear as they are excluded.

Note

For excluded modules (not selected for checking), the door position (open or closed) does not matter.

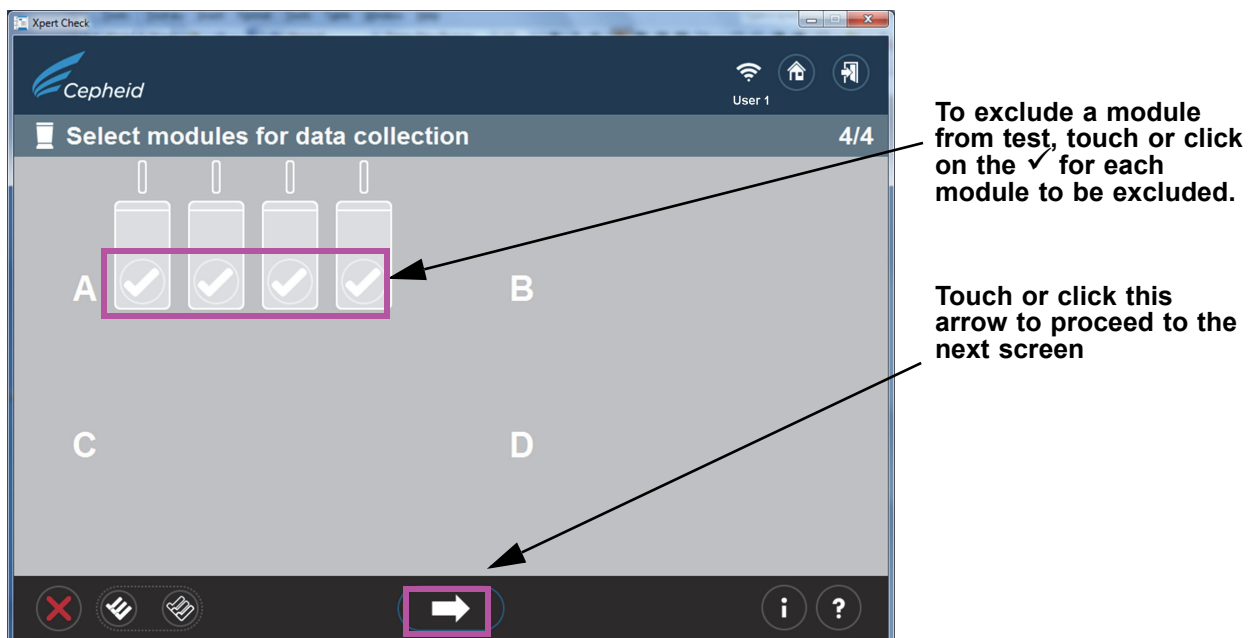


Figure 2-11. Select modules for data collection Screen

Important

GeneXpert-XVI and GeneXpert Infinity systems only: When selecting modules on screen, make a note of which module lights are blinking on the system as you select each bank, to ensure cartridges are placed in the correct modules for testing.

13. After confirming the module selection shown in [Figure 2-11](#), touch or click the white arrow at the bottom of the screen overlay, to begin scanning cartridges. If the module selection shown is incorrect, touch or click the red **X** at the bottom left corner of the screen to return to the Select Modules screen and change your selection. See [Figure 2-12](#).

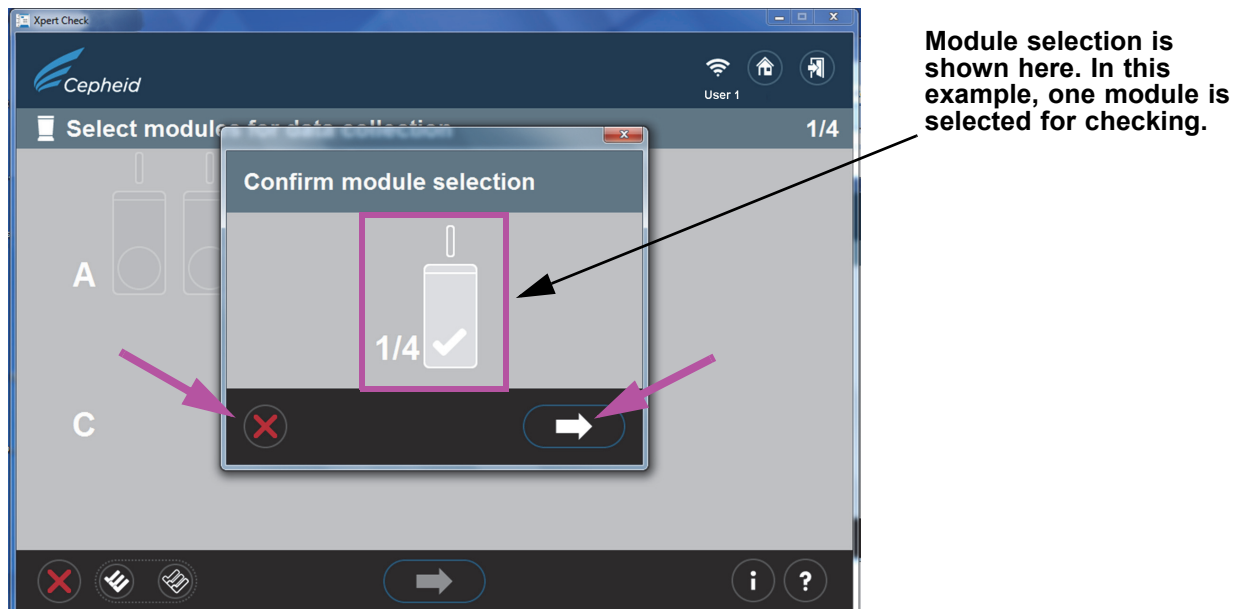


Figure 2-12. Confirm module selection Screen

14. In case of an error in the preceding step, in which either no modules have been selected, or all modules have been excluded, one of the following screens will appear (Figure 2-13). Follow the on-screen instructions to select a module, or start over by returning to the Home screen or exiting the program.

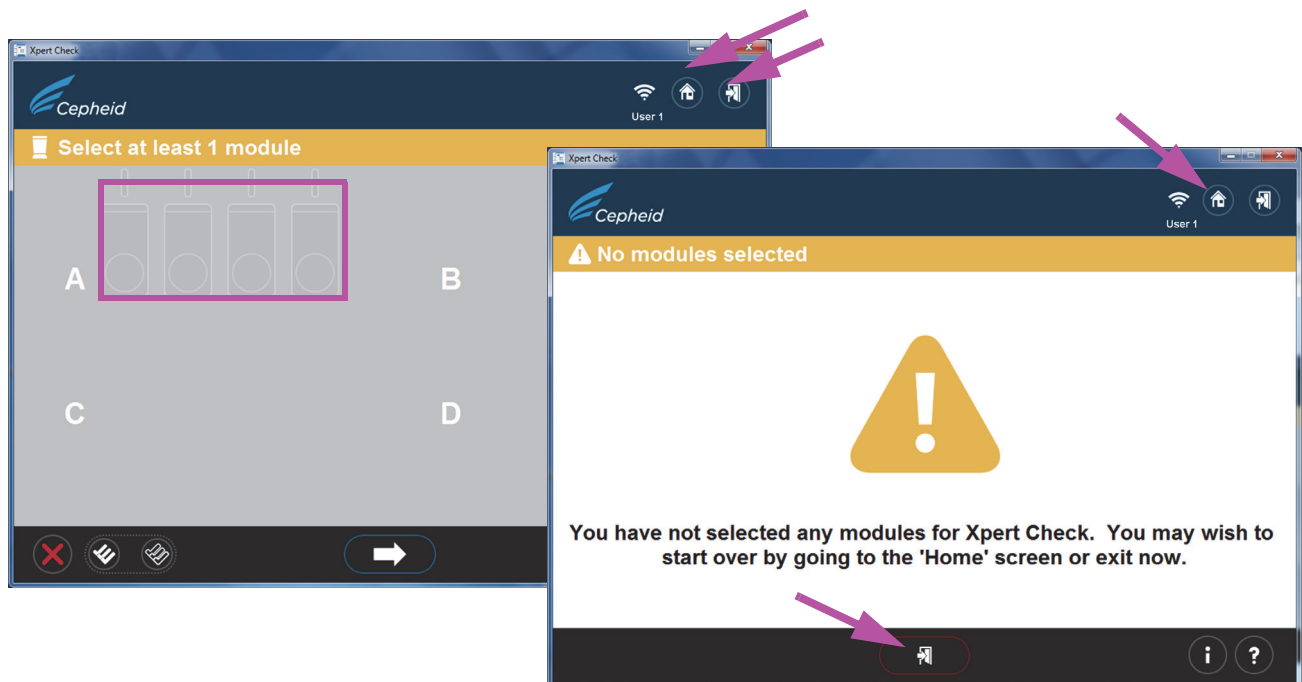


Figure 2-13. Error Screen Examples

15. After confirming your module selection, you will advance to the Scan cartridge screen, where you will be prompted to scan the barcode on the Xpert Check cartridge.

Note

Verify you have enough cartridges on hand to perform the check procedure for the desired number of modules.

16. Remove the test kit cartridge from the package for the module you've previously selected, opening only one cartridge at a time.

Important

Allow the cartridge to reach ambient temperature before proceeding. Do not remove a cartridge from refrigerated storage and immediately use the cartridge to run this test.

17. Scan the cartridge barcode. [Figure 2-14](#) shows a cartridge barcode being scanned. Do not substitute a cartridge with another after it's been scanned.

Note

If the barcode cannot be scanned, skip the cartridge and contact your ASP or local Cepheid Technical Support office for a replacement cartridge, if necessary. If the barcode scanner is damaged, missing or incorrectly configured, contact your ASP or local Cepheid Technical Support office for guidance.

Scanning the cartridge barcode

Note: To avoid inserting a wrong cartridge into a module, do not set the cartridge aside after it has been scanned. In one operation, scan the cartridge barcode, vent the cartridge and insert it into the next available (lighted) module.

SKIP button: Touch or click this icon to skip the cartridge just scanned.

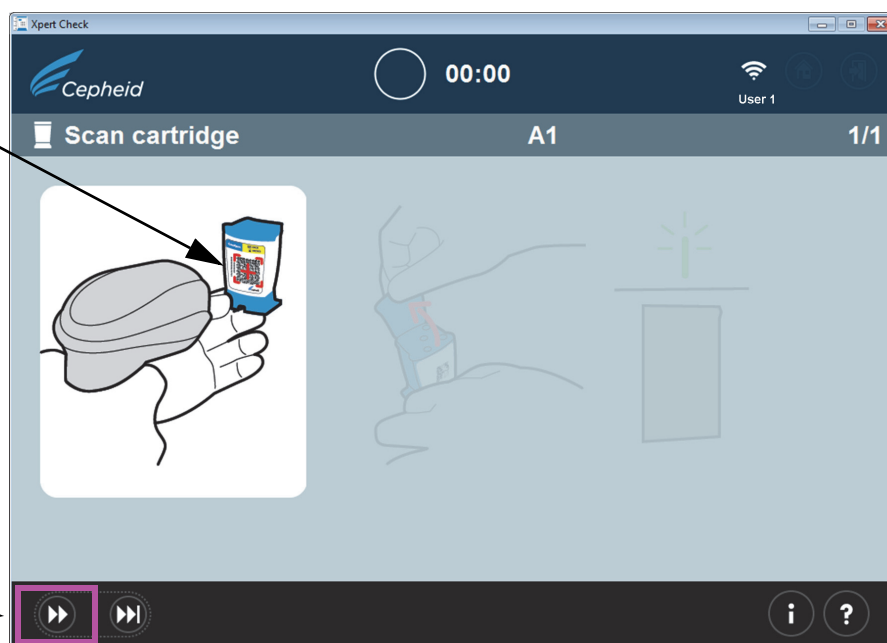


Figure 2-14. Scanning the Cartridge Barcode Screen

- A. After scanning the barcode of the cartridge, ensure you open (vent) the cartridge lid and then close it for each cartridge as directed by the software in [Step B](#) through [Step E](#) below.

Important

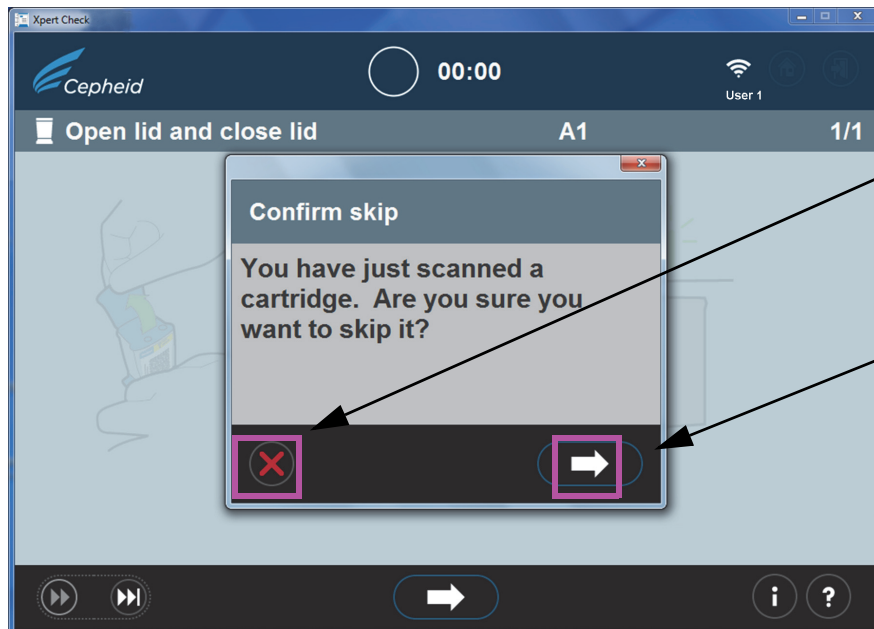
Do Not add a sample or reagent to the cartridge. Use ONLY the cartridges in the Xpert Check kit provided.

Note

After a cartridge barcode is scanned a green light will blink on the system above the module door where the cartridge is to be loaded. (See [Figure 2-17](#).)

Note

If, for some reason, you want to skip the cartridge just scanned, touch or click the **SKIP** button at the bottom of the screen. An overlay, shown in [Figure 2-15](#), will appear, asking for confirmation on skipping the cartridge. To SKIP the cartridge, touch or click the forward arrow at the bottom of the confirmation screen. To proceed without skipping the cartridge, touch or click the **X** icon at the left bottom corner of the screen. You are urged to rescan a cartridge (or substitute a new cartridge if necessary) to ensure a module is not skipped.



Touch or click the X icon to “undo” the SKIP selection and proceed with opening, venting and loading the cartridge into a module.

Touch or click the arrow to confirm you want to skip the cartridge just scanned.

Figure 2-15. Confirm skip Screen

- B. Venting the cartridge (shown in [Figure 2-16](#)), for two seconds is sufficient. This screen is animated, showing the cartridge lid being opened and closed. After venting, touch or click the forward arrow at the bottom of the screen to continue.

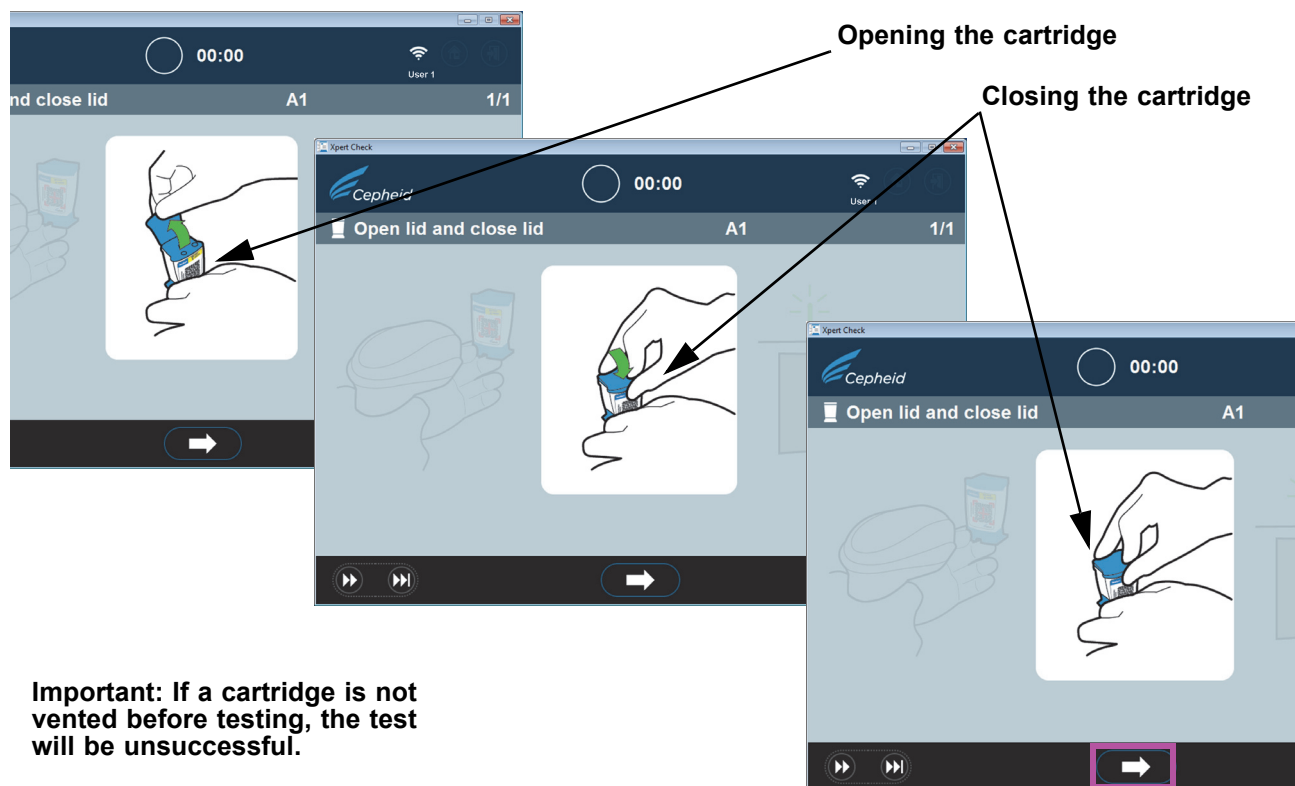


Figure 2-16. Venting the Cartridge by Opening and Closing the Cartridge Lid - Animated Screen

- C. Close the cartridge lid and ensure the module door is fully opened to receive the cartridge.
- D. Load the cartridge into the module (with the cartridge reaction tube (tab) facing away from you), as directed by the animated software screens. See [Figure 2-17](#).

Note

Be sure to load scanned cartridges in sequence in the next available module. This will avoid loading cartridges in the wrong location or leaving modules empty.

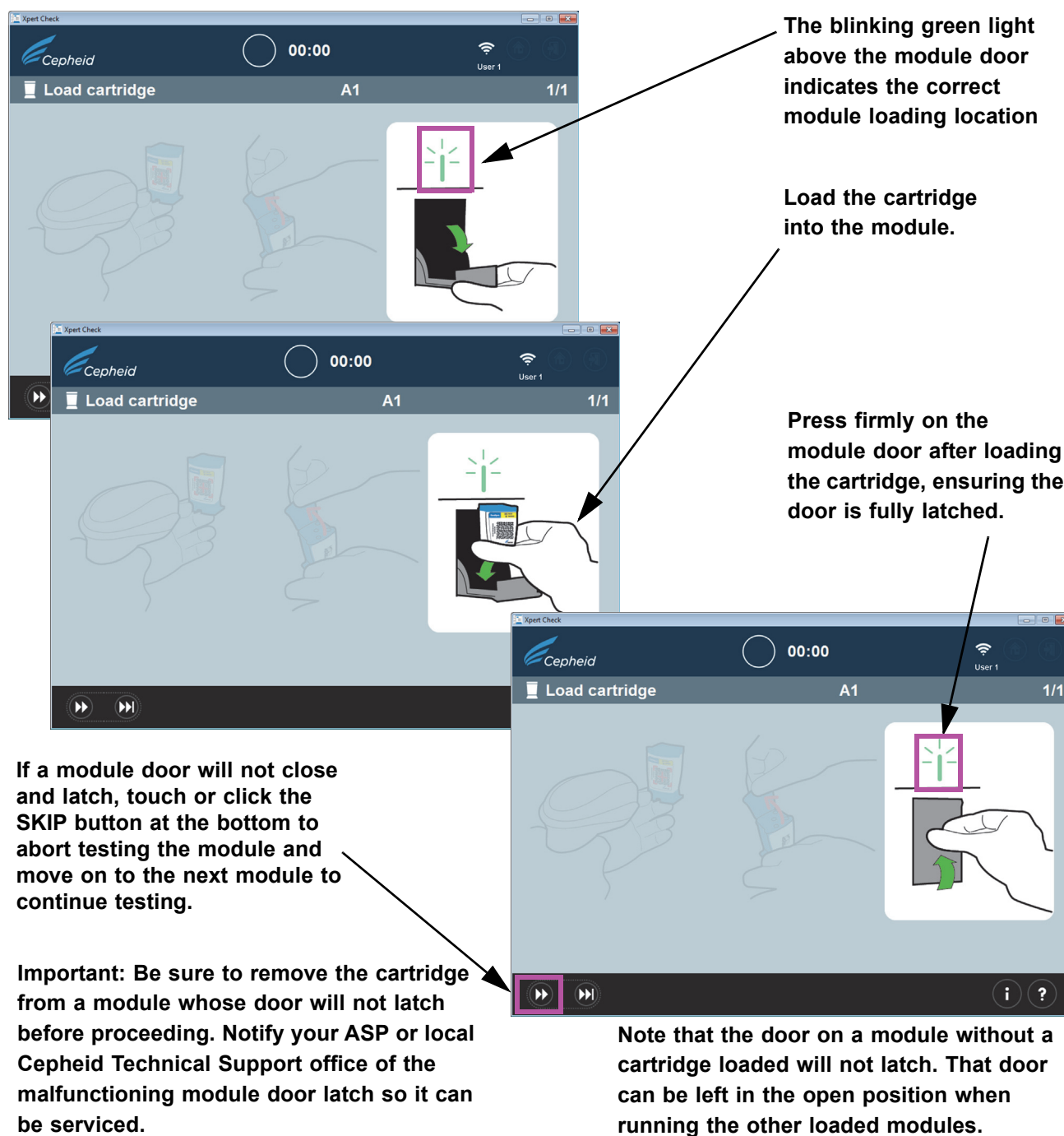


Figure 2-17. Loading the Cartridge into the Module

- E. If you are checking additional modules, continue by scanning the next cartridge. Place each individually scanned cartridge into the next selected open module, pressing the module door securely closed until it latches. **As each module door is closed and latched, data collection will automatically start on that specific module.** The blinking green light above the module will then become steady green, indicating that checking has started.

Important

If a module door is not closed completely (until it latches) after loading a cartridge, the screen will continue to display a message to insert a cartridge, and the check will not run.

If you are unable to close and latch a module door after several tries, touch or click the SKIP button at the bottom of the screen to skip the module with the faulty door and move ahead. Notify your ASP or local Cepheid Technical Support office so the module can be serviced.

18. Checking will take approximately 20 minutes to complete after the final module has been loaded for testing. When checking begins, the Data collection in progress screen appears, as shown in [Figure 2-18](#).

Important

If necessary, a retest of a previously run module may be started without waiting for the present module to complete its test, as described in steps 19b through 19d.

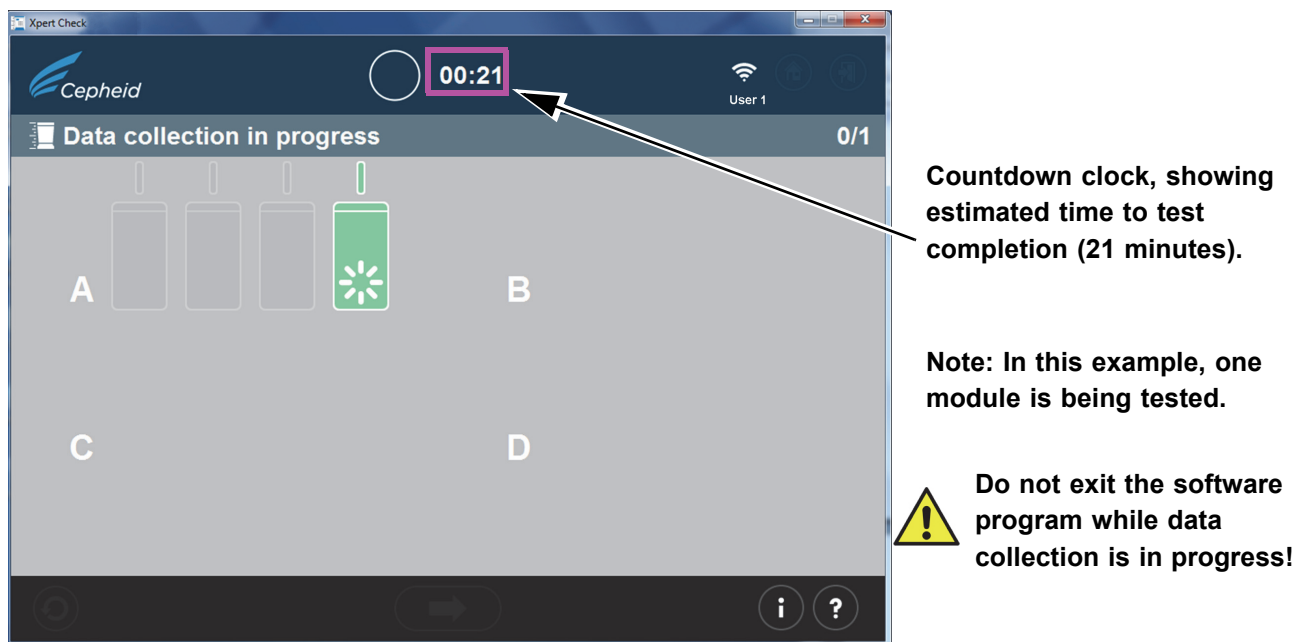


Figure 2-18. Data Collection Screen

Important

If you do not have an internet connection, skip to section 2.2.1 for the remainder of this procedure. If you have an internet connection, continue with step 19.

19. After test completion, the module door will open and the light above the module door will turn off. Screens similar to those shown in [Figure 2-19](#) or [Figure 2-20](#) will appear. Touch or click the right arrow to continue.
 - A. [Figure 2-19](#) shows the completion of a successful Xpert Check data collection. When the test is complete, touch or click the forward button at the bottom of the screen to begin uploading Xpert Check test results to the Xpert Connectivity Center.

Important

When uploading test results, especially multiple files, verify the selected folder destination is correct.

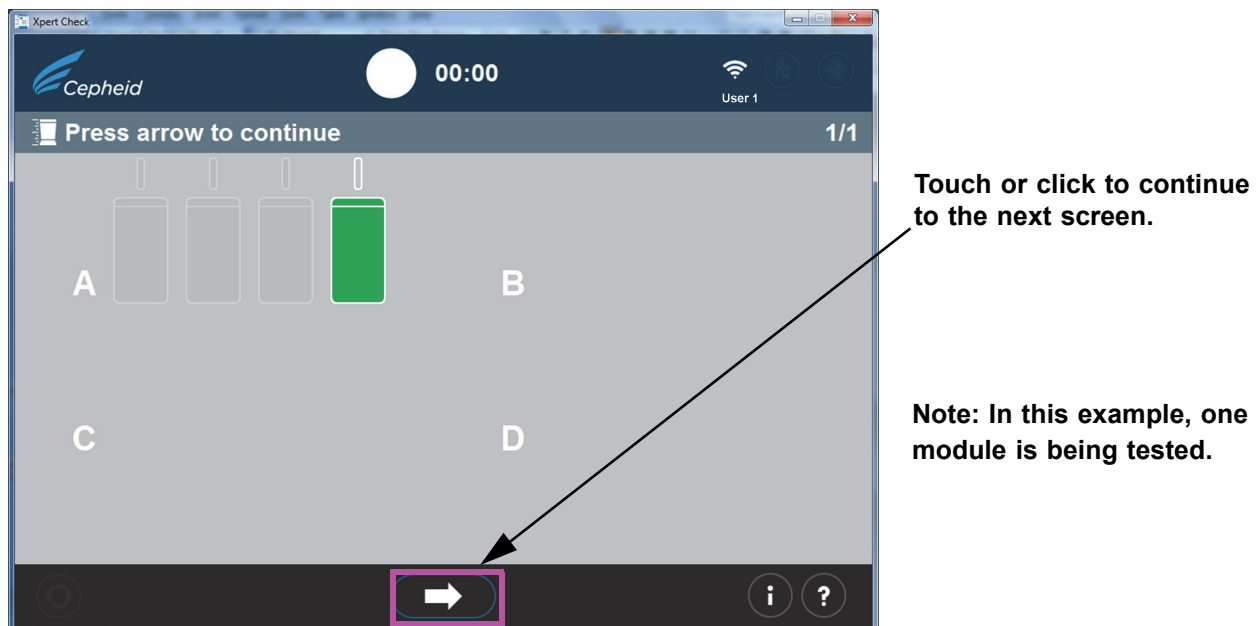


Figure 2-19. Test Completion Screen - Successful

- B. If the test was unsuccessful, the screen shown in [Figure 2-20](#) will appear, showing module status. A test retry must be performed. Touch or click the **Retry** icon in the lower left-hand corner of the screen.

Module test unsuccessful.
Test must be rerun using either the same or a new cartridge, as instructed by the on-screen display.

Continue button. Touch or click to proceed without retesting. See [Figure 2-21](#).

Retry Icon: Touch or click to retest the module.

Note: In this example, one module is being tested.

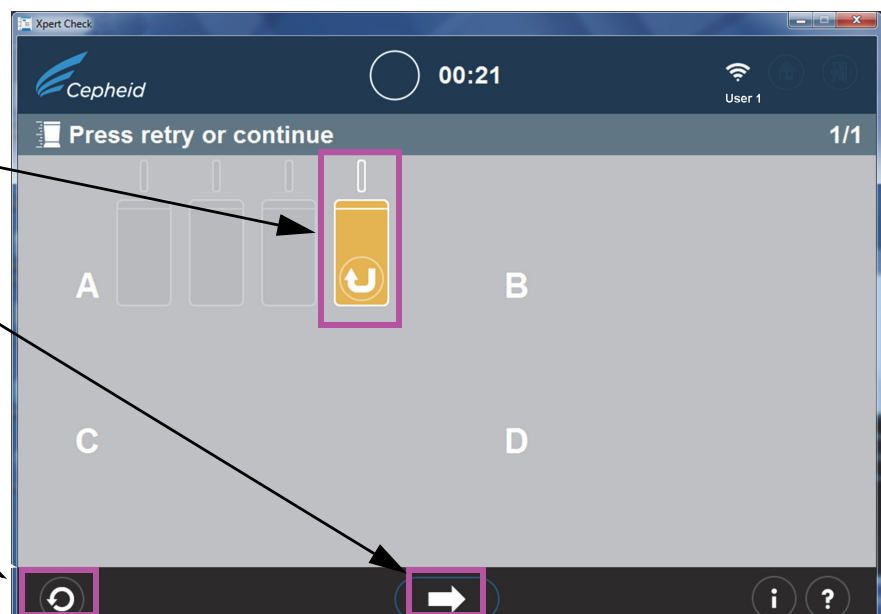


Figure 2-20. Test Completion Screen - Unsuccessful Module Checking Example

- C. If the **Continue** arrow at the bottom of the screen is pressed when there is an unsuccessful module test displayed (as shown in [Figure 2-20](#)), the Confirm continue screen will appear. See [Figure 2-21](#).

To return to the Press retry or continue Screen to retest the flagged module, touch or click the X icon.

To continue without retesting the flagged module, touch or click the right arrow at the bottom of the Confirm continue screen.

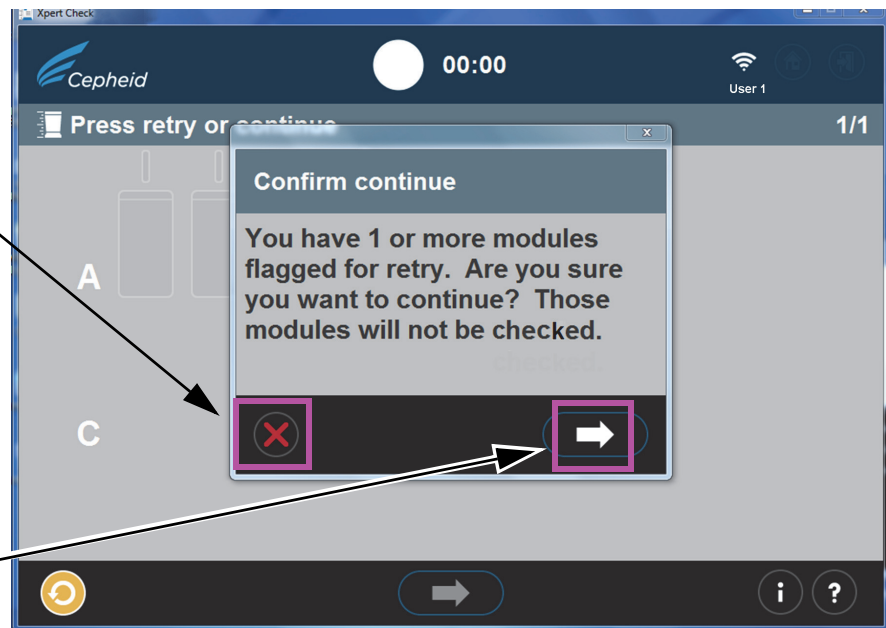


Figure 2-21. Confirm Continue Screen Overlay

You have the option of continuing by touching or clicking the right arrow on the Confirm continue screen overlay. Choosing this option will result in the flagged module not being retested, and you will begin uploading check data as described in [Step 20](#).

Another option is to return to the Press retry or continue screen to Retry (retest) the flagged module by clicking the red X icon at the bottom left of the Confirm continue screen. The Retry procedure is described in [Step D](#) which follows.

- D. If the Retry icon (shown above in [Figure 2-21](#) at the bottom of the screen) appears, touch or click the Retry icon and you will return to the Scan Barcode screen ([Figure 2-14](#)) to complete the retest on the affected module(s).

Note that the retest can be of two possible types:

- 1) Retry with the same cartridge: For example, a message may appear telling you to vent the cartridge, rescan it, and put it back in the module.
- 2) Retry with a new cartridge: If the cartridge was defective, or had already been used, you will be asked to replace it by scanning the barcode on a new cartridge, venting it, and loading it into the module.

Note

During the course of running retests, modules may need to be skipped if the user runs out of Xpert Check cartridges. Please contact your ASP or local Cepheid Technical Support office for additional Xpert Check cartridges. Rerun Xpert Check on any modules that were skipped.

Note

At the completion of the Xpert Check data collection process, modules determined to require service will be flagged with an orange module icon (See [Figure 2-20](#)). Please contact your local ASP or local Cepheid Technical Support office for further assistance in servicing or replacing modules.

20. After successful test completion and Xpert Check data collection, touch or click the forward arrow to display the screen shown in [Figure 2-22](#), if you have an active

internet connection. However, if you have never been internet connected, or have lost your functioning internet connection sometime during the Xpert Check test, a Download Xpert Check code error screen or an Upload incomplete error screen (Figure 2-23) may appear instead, instructing you to write Xpert Check data to a data CD to send to your ASP or local Cepheid Technical Support office. In this case, continue to the instructions beginning at Step 4 (under Section 2.3.1) of this procedure to continue as a user without an internet connection.

Note

With a functioning internet connection, the system should proceed normally (with Step 21), and the Xpert Check code should begin downloading, as shown in Figure 2-24.

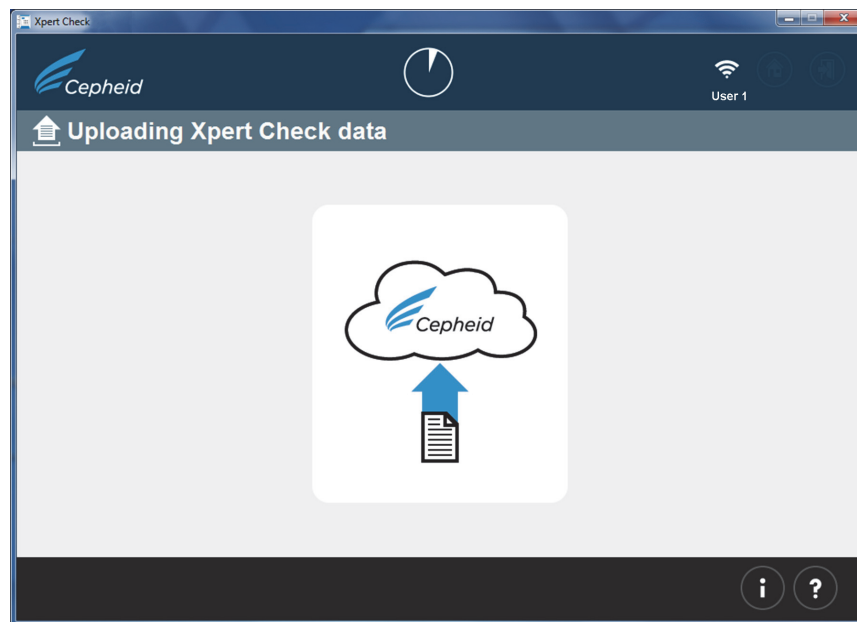


Figure 2-22. Uploading Xpert Check Data Screen

Touch or click this icon to move to the Write Xpert Check Data to CD screen. See Figure 2-31.

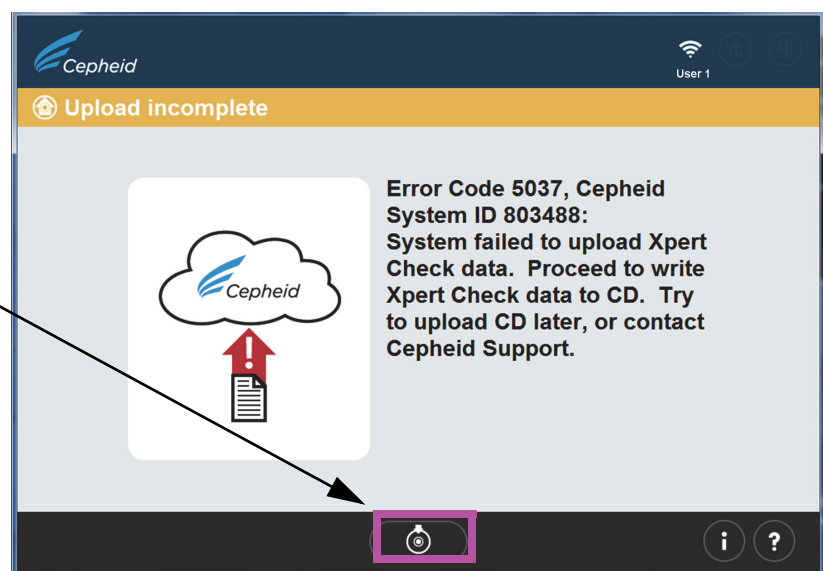


Figure 2-23. Upload incomplete Error Screen

21. When the Xpert Check data has finished uploading, a Quality Assurance check will be performed on the data. If the check is acceptable, the Xpert Check code will automatically download. See [Figure 2-24](#).

If the test is not acceptable, the affected module(s) will require service or replacement and will be flagged with an orange icon. Please contact Cepheid or your local ASP or the local Cepheid Technical Support office for further assistance.

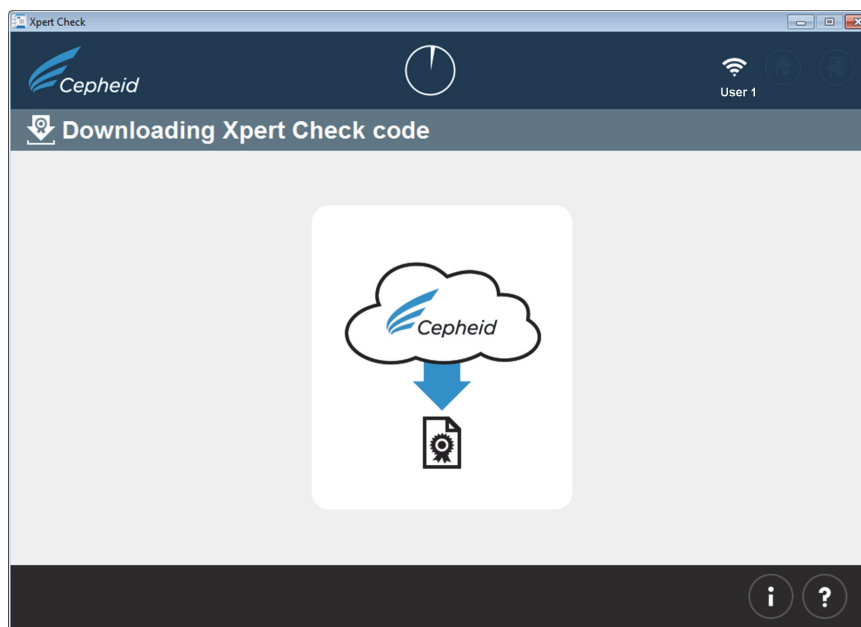


Figure 2-24. Downloading Xpert Check code Screen

22. After the Xpert Check test results have downloaded, the Xpert Check code will be applied to each successfully tested module, and those modules will then be identified with a + symbol. See [Figure 2-25](#). As shown here, one module is being checked.

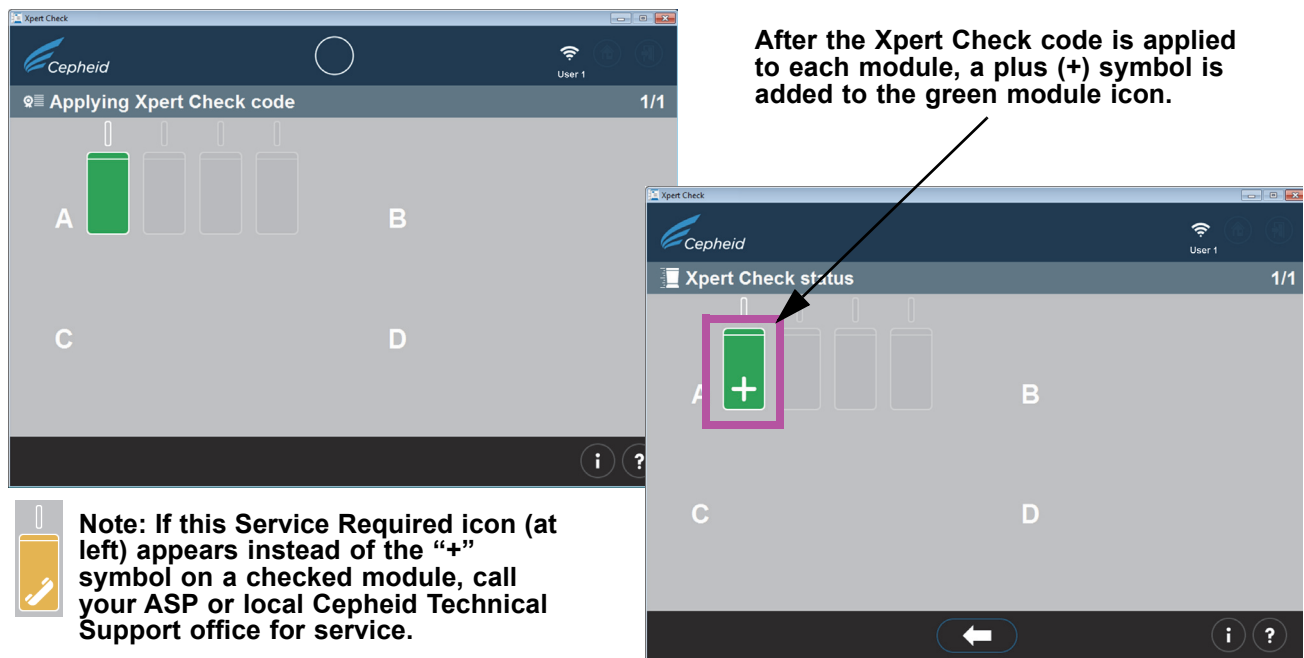


Figure 2-25. Applying Xpert Check code Screen

Note

In the screen shown in [Figure 2-25](#), some modules may display the service required icon or may be grayed out if they were skipped.

23. After all the Xpert Check codes have been applied to the successfully-tested modules (those green modules which appear with the plus symbols applied), the Xpert Check complete screen will appear. See [Figure 2-26](#). This screen shows the location of the Xpert Check Data report, which is available for review, if desired.

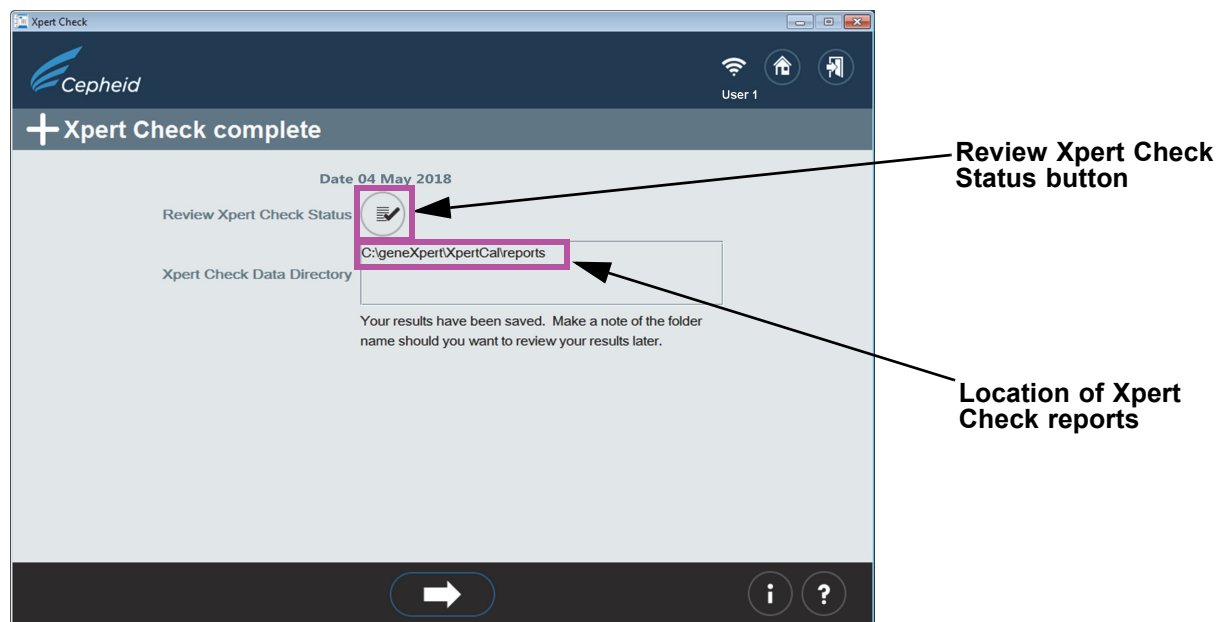


Figure 2-26. Xpert Check complete Screen

24. Remove and discard all Xpert Check cartridges. Do not save partial kits (all unused cartridges must be discarded). When complete, click the **Exit** icon at the top or bottom of the screen to exit the program. See [Figure 2-27](#).

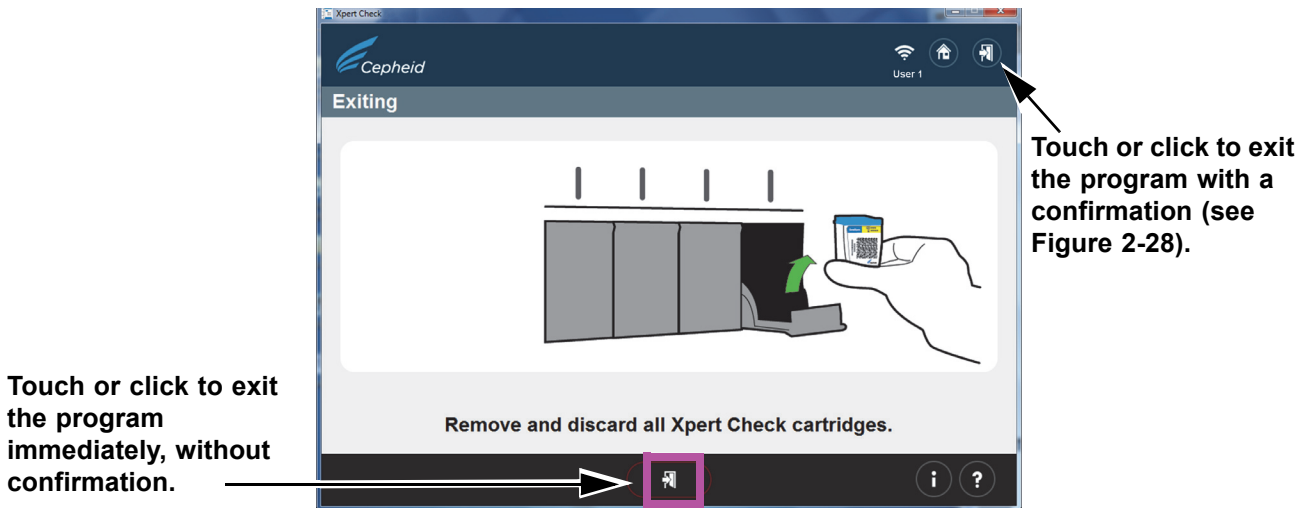


Figure 2-27. Exit the Program

25. The screen shown in [Figure 2-28](#) appears only if you touch or click the exit arrow in the upper right of the screen.

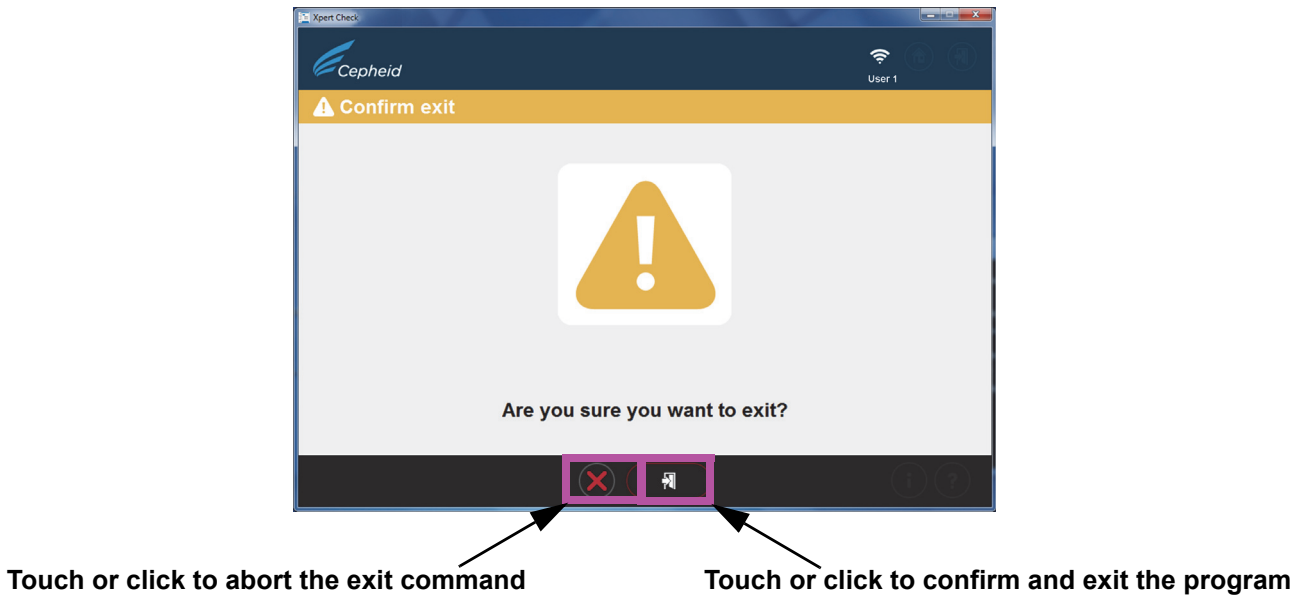


Figure 2-28. Confirm exit Screen

This completes the Xpert Check Test for an internet-connected user.

- Note**

Contact your Authorized Service Provider or the local Cepheid Technical Support office concerning modules requiring service.
- Note**

To view your Xpert Check results, see [Step 23](#) and [Figure 2-26](#), which shows the file path and location of Xpert Check results and the Xpert Check Summary report.

2.3.1 Xpert Check Completion For Non-internet Connected Users

For Non-internet connected users, you should have completed [Step 1](#) through [Step 19](#) of [Section 2.3](#) to collect data before starting this section.

1. This section begins with the Data collection in progress screen, which is similar to [Step 18](#) in [Section 2.3](#), and the screen shown in [Figure 2-18](#) for internet-connected users.

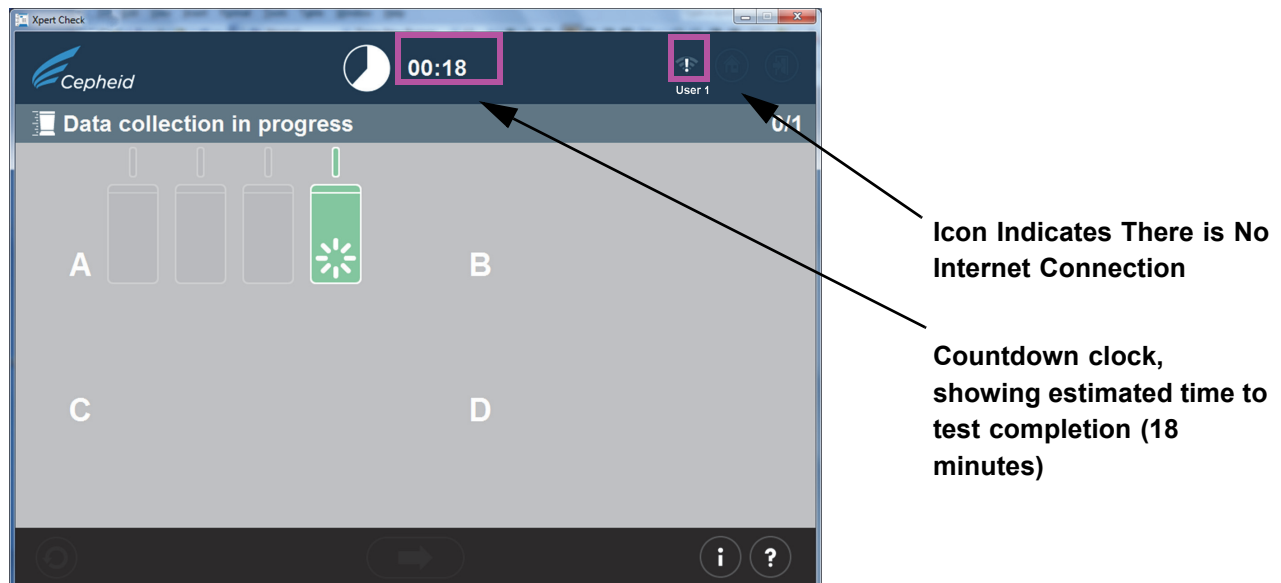


Figure 2-29. Data collection in progress Screen

2. After test completion, the module door will open and the light above the module will turn off. A screen similar to that shown in [Figure 2-30](#) will appear. Touch or click the right arrow at the bottom of the screen to advance to the next screen.

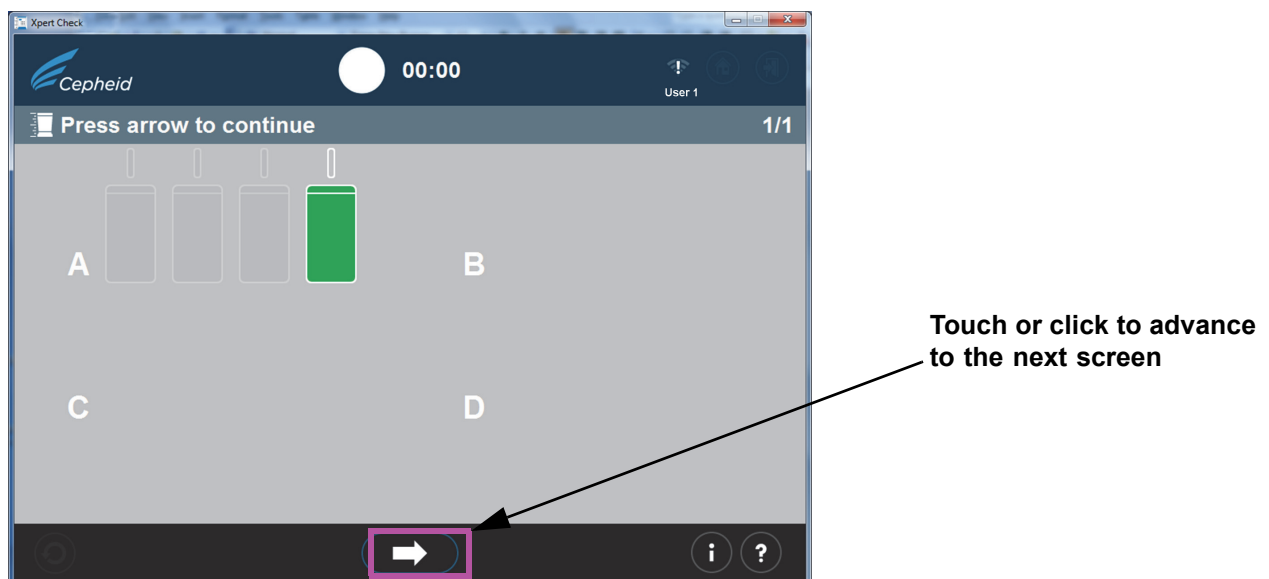


Figure 2-30. Test Completion screen - Successful

3. When the Write Xpert Check data to CD screen appears (Figure 2-31), you will be prompted to press the **Eject** button on the DVD drive to remove the existing Xpert Check Software CD so you can insert the blank data CD.

Note

In the following step, use care in inserting the blank CD into the DVD drive. Be sure the CD is fully seated in the tray before closing the drive door.

Important

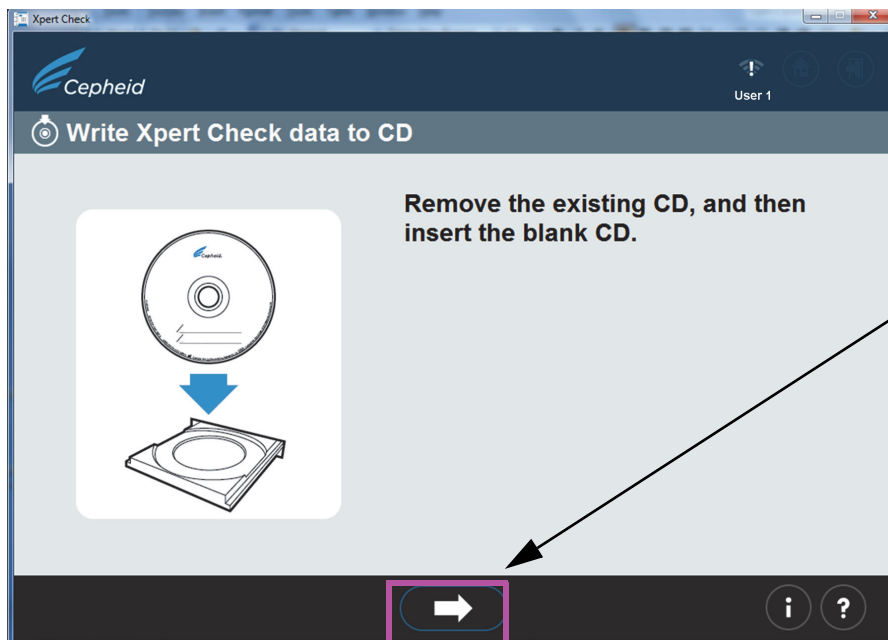
If you have been running this test as an internet-connected user and then lose your internet connection and received an error screen (Figure 2-23), resume your procedure beginning with the following Step 4, continuing through Step 12.

Note

In the following step, pause for 10 seconds after CD insertion and cancel any wizards that auto-open before touching or clicking the forward arrow to proceed. When you either close the wizard or have waited enough time to ensure that a wizard will not auto-open, touch or click the forward button to proceed. This will launch the Windows CD burning screens that the Xpert Check program opens.

4. Insert the blank CD into the DVD drive of the computer and close the DVD drive tray fully to ensure the CD will be recognized.

Pause to allow the launch of any possible CD wizard programs. If wizard programs launch, close them before touching or clicking the forward button to proceed.



Pause 10 seconds after CD insertion and then touch or click to continue to the next screen.

Figure 2-31. Write Xpert Check data to CD Screen - Step 1

5. After inserting the blank CD, the screen will change briefly, indicating the CD has been recognized. See Figure 2-32. This screen will remain displayed until the CD writing process is complete.

Note

It is not necessary for the user to locate the file to write because that process is automatic.

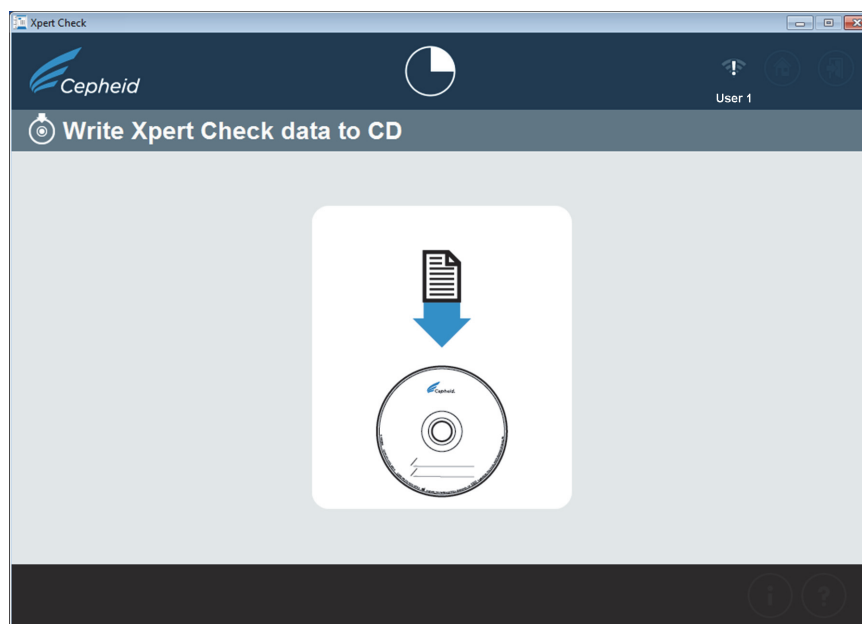


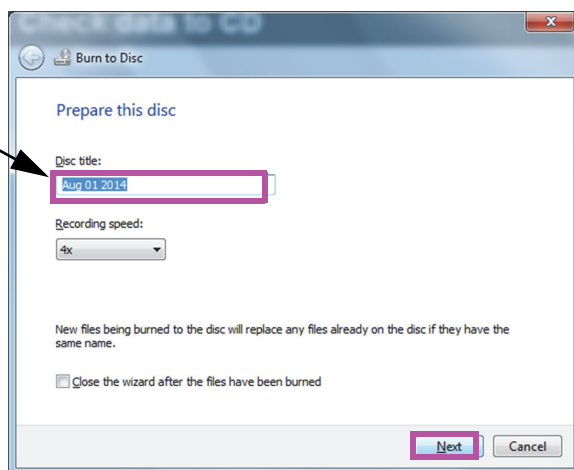
Figure 2-32. Write Xpert Check data to CD screen - Step 2

6. The CD Writing Wizard or Burn to Disc screen (Figure 2-34) will then appear as an overlay of the screen shown above, in Figure 2-32.

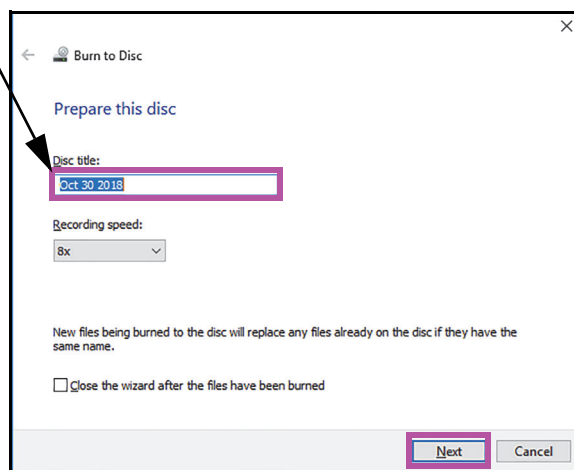
The next screens (Figure 2-33 through Figure 2-37) show the CD writing program screens as you progress through the writing process.

- Windows® 7 users: Follow the screens on the top of the figure.
 - Windows® 10 users: Follow the screens at the bottom of the figure.
- A. On the first screen, after successful recognition of the blank CD, you will be asked to provide a name for the CD that you will be writing. DO NOT simply touch or click the **Next** button to continue the writing process with the default name that appears. Instead, type in your facility's name, such as "XYZ Hospital," in the space provided and touch or click **Next**. See Figure 2-33.

Type in your facility name
for the CD name/Disc title



Opening Screen - Windows 7



Opening Screen - Windows 10

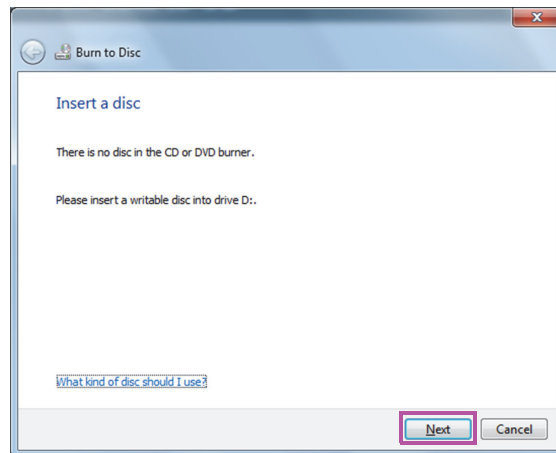
Figure 2-33. CD Writing Program - Opening Screen

- B. If the CD is not recognized, the screen shown in [Figure 2-34](#) may appear, instead of the screen in [Figure 2-35](#), asking you to insert a writable disc to continue. Writable discs, in this case, are CDs on which you can store files. Writable discs can only be written to once, meaning that once any files are copied to the disc, they are there permanently.

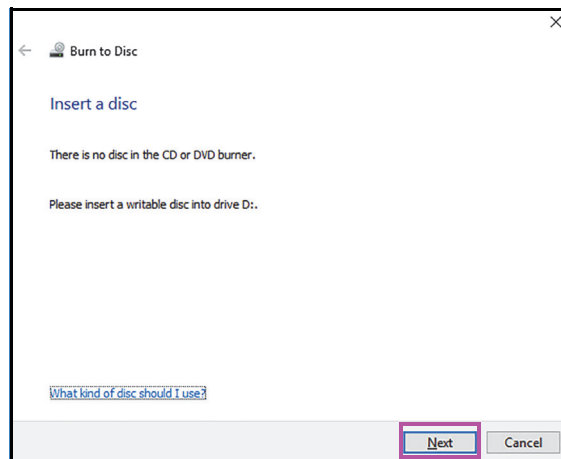
A disc that has data on it is not considered to be a writable disc and will result in an error screen, as shown in [Figure 2-39](#).

Note

If you are unsuccessful with any part of the CD writing process, you may contact your ASP or local Cepheid Technical Support office for assistance. It is safe for you to close the Xpert Check software now because the Xpert Check files have been saved to the hard drive and you will not lose data.



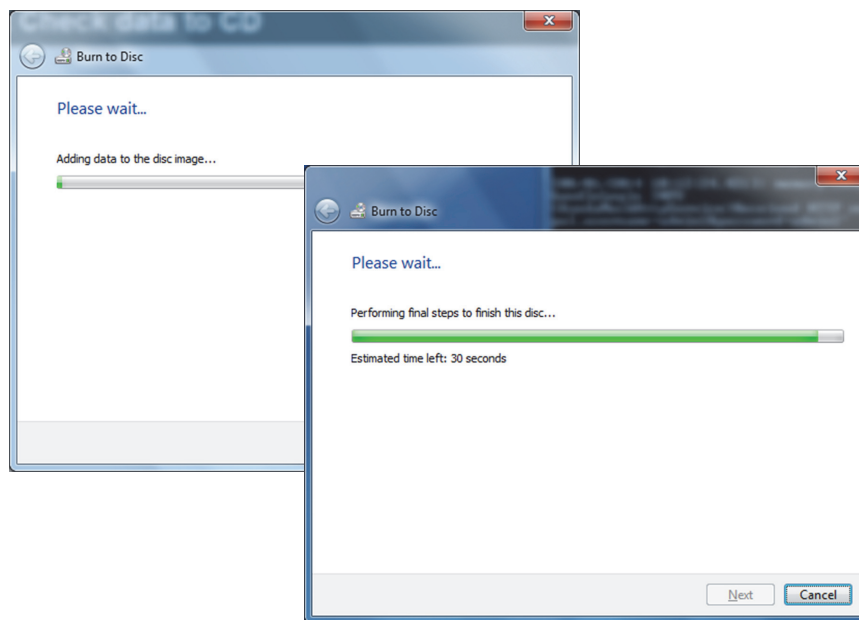
Insert a Disc Screen - Windows 7



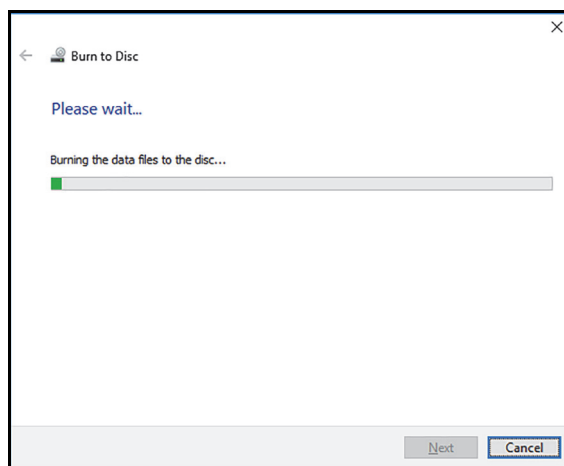
Insert a Disc Screen - Windows 10

Figure 2-34. CD Writing program - Insert a writable disk to continue Screen - Example

- C. After successful recognition and naming of the CD, touch or click the **Next** button to continue. The writing process will begin automatically.
- D. During the writing/burning process, a progress bar will appear on the screen. See [Figure 2-35](#).



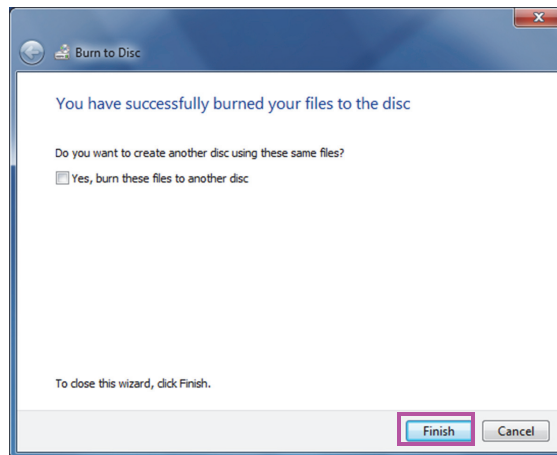
File Burning Progress Screens - Windows 7



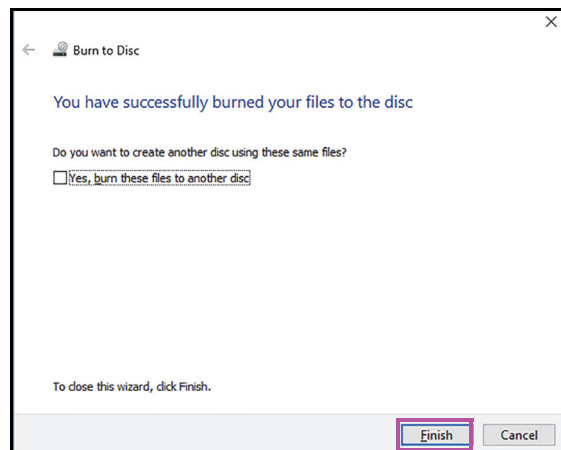
File Burning Progress Screen - Windows 10

Figure 2-35. CD Writing/Burning Progress Screen

- E. When the writing of the CD is complete, the screen shown in [Figure 2-36](#) will appear. Touch or click the **Finish** button to exit the CD writing program.



Completion Screen - Windows 7



Completion Screen - Windows 10

Figure 2-36. CD Writing Completion Screen

- F. On a Windows 7 computer, you may see the screen displayed in [Figure 2-37](#) after a successful CD write. Touch or click the **OK** button as many times as necessary for the screen to disappear, before continuing.

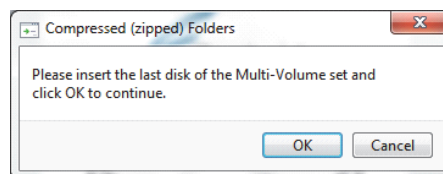


Figure 2-37. Final Screen from Windows 7 After CD Writing has Completed

7. After touching or clicking the **Finish** button on the CD writing screen, the Send the CD to your Authorized Service Provider Screen will appear (see [Figure 2-38](#)). Remove the completed Xpert Check data CD from the disk drive and prepare the label, as described in [Step 10](#).

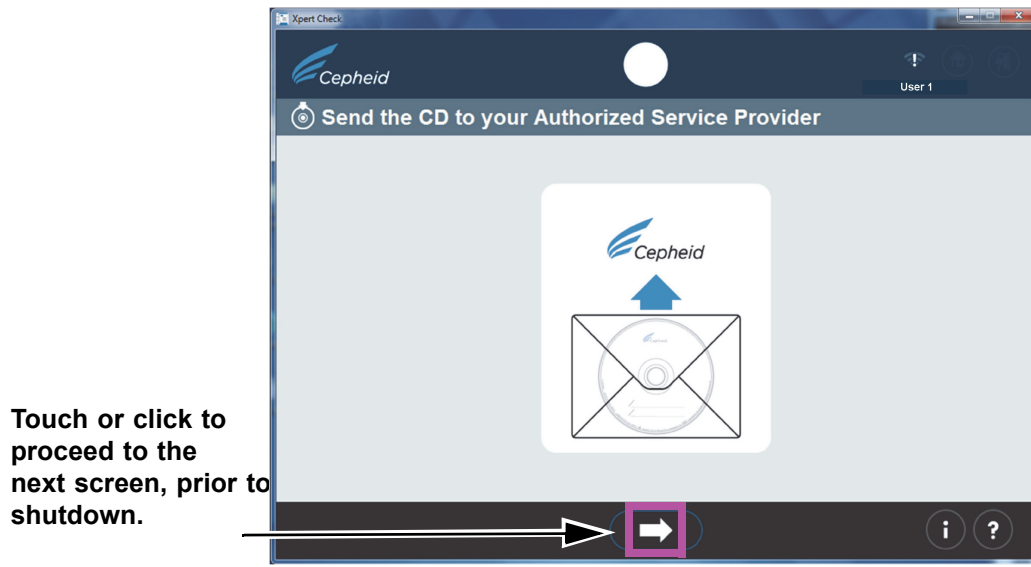
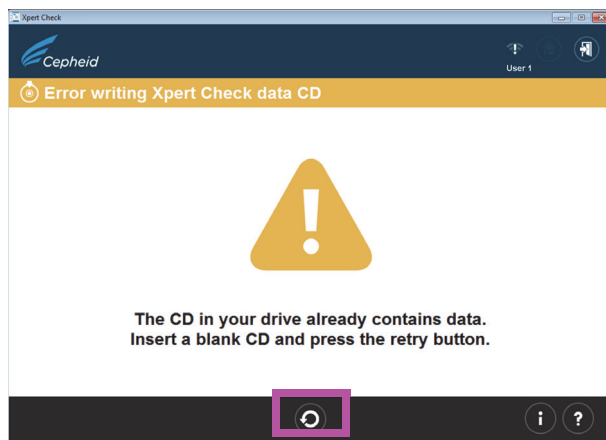


Figure 2-38. Send the CD to your Authorized Service Provider Screen - Step 3

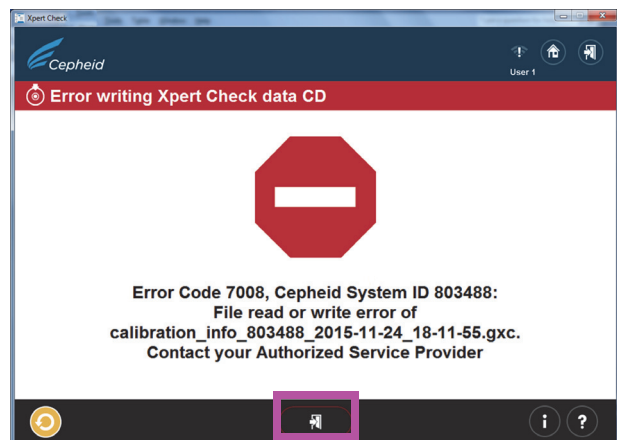
8. If a problem has occurred anytime during the CD writing process, an error code screen may appear. (See [Figure 2-39](#)).
 - If a CD you have inserted already contains data as shown in the error screen below at the left, remove the CD and insert a blank CD, and then touch or click the **Retry** icon.
 - In the case of a read or write error, the screen shown at the right may appear and you must exit the program. Contact your ASP or the local Cepheid Technical Support office for assistance, if necessary.

Disc is not Writable (Already Contains Data)



Retry Button

General Write Failure



Exit the Program

Figure 2-39. Error writing Xpert Check data CD Screens - Two Examples

9. After test completion, the Exiting screen will appear with the message **Remove and discard all Xpert Check cartridges** (see [Figure 2-40](#)).

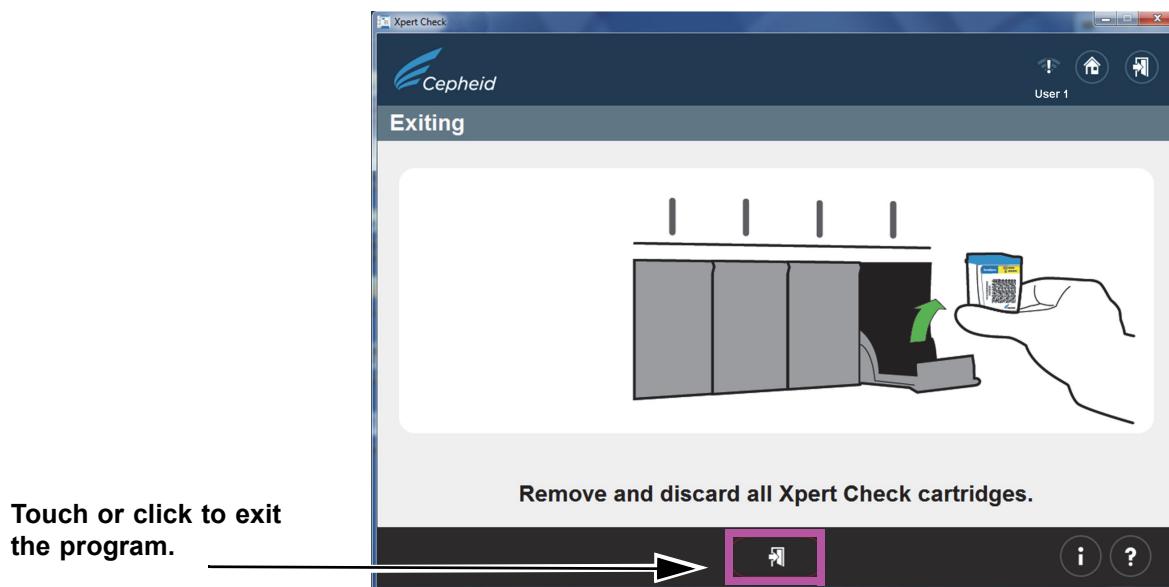


Figure 2-40. Exiting Screen

10. Use a felt-tip pen to write on the label of the Xpert Check data CD you have just created by writing the date, instrument identification and facility/location of the test performed. See a label example in [Figure 2-41](#).

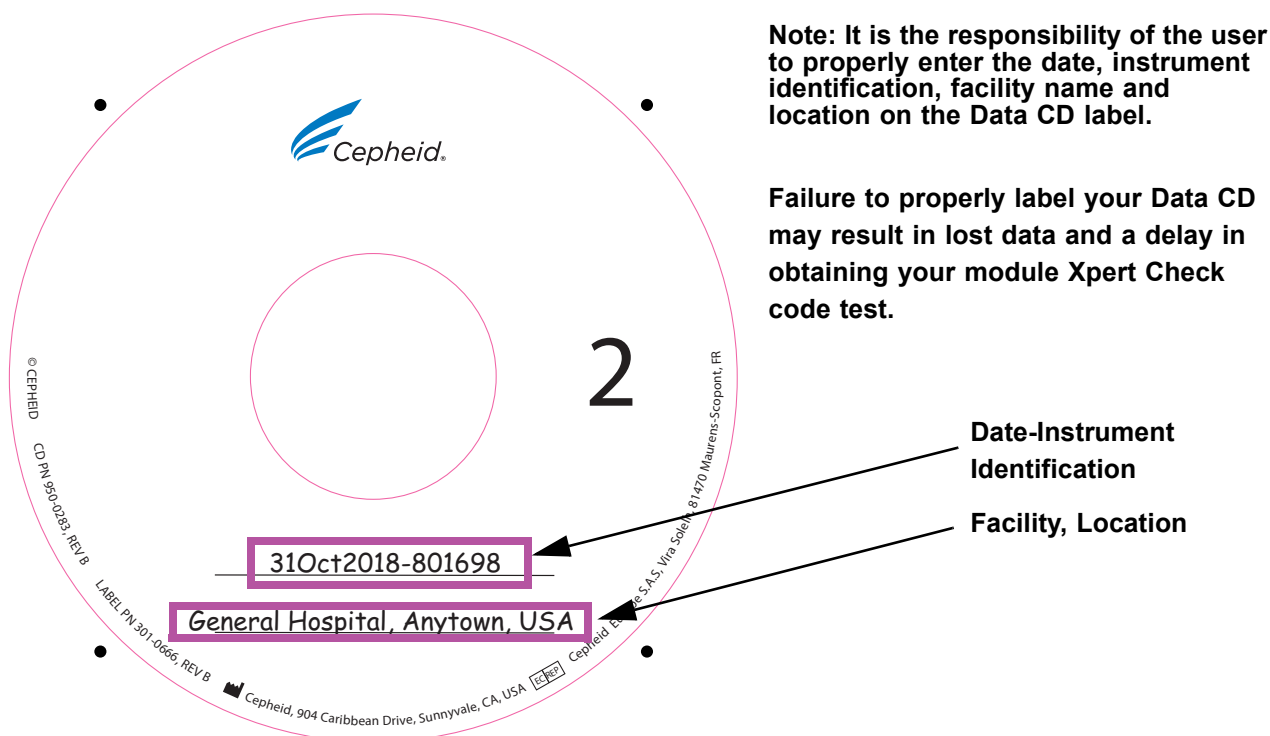


Figure 2-41. Data CD Labeling Example

11. You have the option to copy the calibration_info.gxc data file (located on the Xpert Check data CD just written) and Email the data file directly to your ASP or the local Cepheid Technical Support office instead of mailing the CD. 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 for data quality assurance checking and the issuing of your Xpert Check code.
12. Your ASP or the local Cepheid Technical Support office will perform the quality assurance review and, if successful, send back your Xpert Check code either by Email or regular mail, depending on what method you have previously set up with them.

Note

Discard all remaining materials from the kit. DO NOT save unopened kit pouches for later use. DO NOT discard your Software CD. For users who Emailed their file and have not shipped their data CD: DO NOT discard your Data CD.

13. Restart your GeneXpert Dx, GeneXpert Xpress or GeneXpert Infinity system and computer.

Note

You can continue to use your system while awaiting your Xpert Check code.

2.3.2 Obtaining the Xpert Check Code for Non-Internet Connected Users

Note

Ensure the system is in the same configuration as when Xpert Check was run (i.e., no software updates or changes have been made and no new GeneXpert systems have been moved to or from this computer). In the case of any module servicing and/or replacement that may occur between data collection and application of the Xpert Check Code, new or modified modules will be ignored for the purposes of the Xpert Check testing process.

Note

In the following step, use care in inserting the CD into the DVD drive. Be sure the CD is fully seated in the tray before closing the drive door.

1. Exit the GeneXpert Dx, GeneXpert Xpress or GeneXpert Infinity software.
2. To finish the Xpert Check process, place the Software CD in the DVD drive of the computer connected to the GeneXpert Dx or GeneXpert Xpress instrument or in the kiosk computer for the GeneXpert Infinity.
3. Touch or click on My Computer, then touch and hold or double-click on the applicable drive letter for your DVD drive. The files located on the CD will then be displayed. Find and touch and hold or double-click the **XpertCheck.exe** application/shortcut to launch the software.
4. Log in with your GeneXpert Dx, GeneXpert Xpress or GeneXpert Infinity designated **USER NAME** and **PASSWORD** (see the IMPORTANT note in [Section 2.1](#)). Also see [Figure 2-4](#) for the Login screen.

After entering your login information, touch or click the forward arrow button at the bottom of the screen to advance to the next screen (the Xpert Check Home screen).

Note

The user name and password are the same ones you used for the GeneXpert Dx, GeneXpert Xpress or Xpertise software. If an ASP (FSE) previously performed Xpert Check and is not now on site, the user name and password should have been provided for this step to enter the code. If the user name or password are not now available, contact your ASP or your local Cepheid Technical Support office.

5. Touch or click the **Enter Xpert Check Code** button. See [Figure 2-42](#). The Enter Xpert Check code screen will appear. See [Figure 2-43](#).

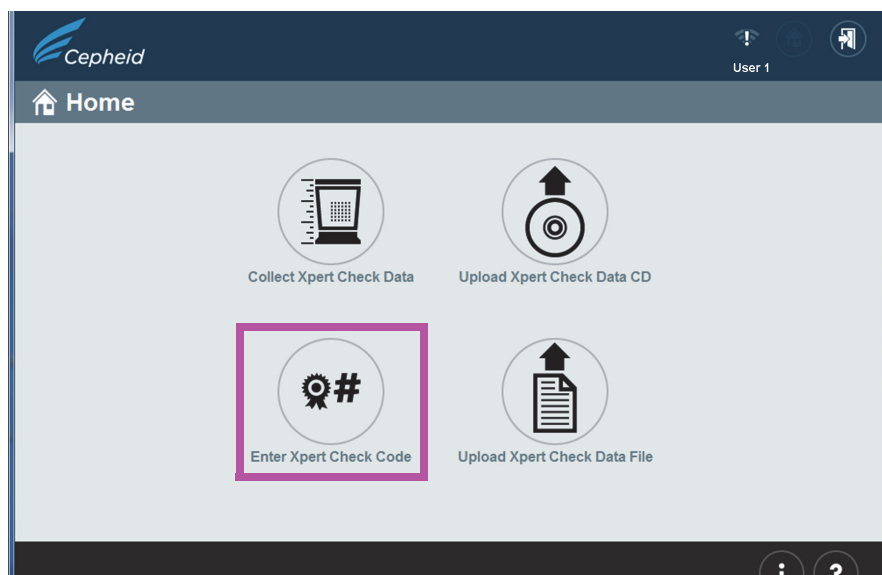


Figure 2-42. Home Screen, showing Enter Xpert Check Code Button

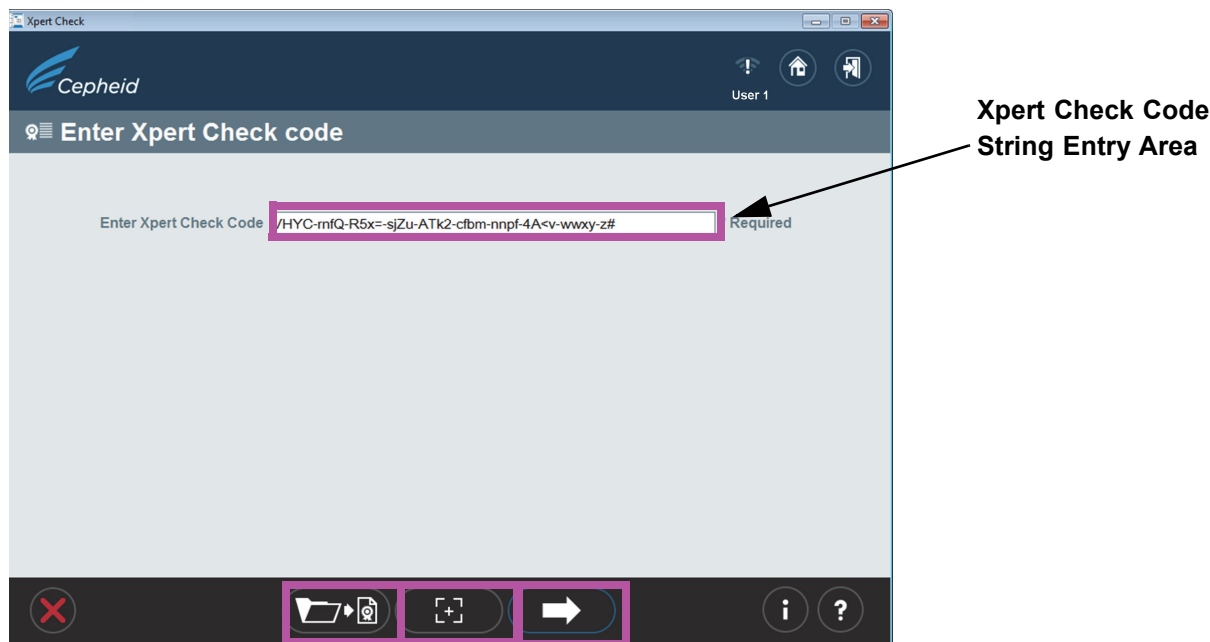


Figure 2-43. Enter Xpert Check code Screen

6. Enter your Xpert Check code as described below.

In this step, there are various ways to enter the Xpert Check code, depending on your system. Your four options are listed below.



- A. Option 1 (For GeneXpert Dx or GeneXpert Infinity systems only): Use your scanner to input the barcode as follows: First, click the icon located in the bottom center of the screen. The Xpert Check Code File ([Figure 2-44](#)) will appear on your screen. Position your scanner to scan the barcode on the Code form, using care to avoid any reflection on the monitor that may interfere with your scanner. See [Figure 2-44](#) for an example of an Xpert Check Code File.
- B. Option 2 (For all systems): Print a copy of the Xpert Check Code File and use your scanner to scan the barcode on the printed page. See [Figure 2-44](#) for an example of an Xpert Check Code File.
- C. Option 3 (For GeneXpert Dx and GeneXpert Infinity systems only): Copy and paste the code string into the Enter code screen from the screen's display. The code string is visible on [Figure 2-44](#).
- D. Option 4 (For all systems): Type in the code string manually using the information on your screen or printed page.

When you have successfully entered the code, touch or click the forward arrow at the bottom of the screen to continue. The Applying Xpert Check code screen will appear. See [Figure 2-45](#).



Xpert Check Code File

Here is the Xpert Check code for the recent data collection of your modules for the system identified below.

Xpert Check data collection performed on 30 September 2020 15:02:31 PST

GX Instrument Name:	My GeneXpert
Cepheid System ID:	123456
Software Version:	Xh1.5
Data Collected By:	admin1
Institution Name:	Institution1
Laboratory Name:	Lab1
Street Address:	100 Main Street, Suite 202
City:	New York
State/Province:	NY
Postal Code:	10001
Country:	USA
Email:	user@institution.com
Facility Phone Number:	408 400-0000
Extension:	
Mobile:	
ASP Code:	US01

Scan or enter the Xpert Check code to complete the Xpert Check process.

Xpert Check Code String



Barcode

/DQ&-k<4x-Tkq3-@yww-s@DZ-Hgam-nnpA-d88U-xwxy-z#

1. Cepheid recommends that system performance should be evaluated annually using Xpert Check.
2. Cepheid declares that the I-CORE modules in the GeneXpert® Instrument were checked using an Xpert Check product. NIST traceable qualification standards are used to control the parameters for the fluorescence standards of concentration, brightness, and spectrum. Cepheid products are manufactured, quantified and controlled under a Quality System compliant with ISO 13485 and QSR requirements.

Figure 2-44. Xpert Check Code File - Example

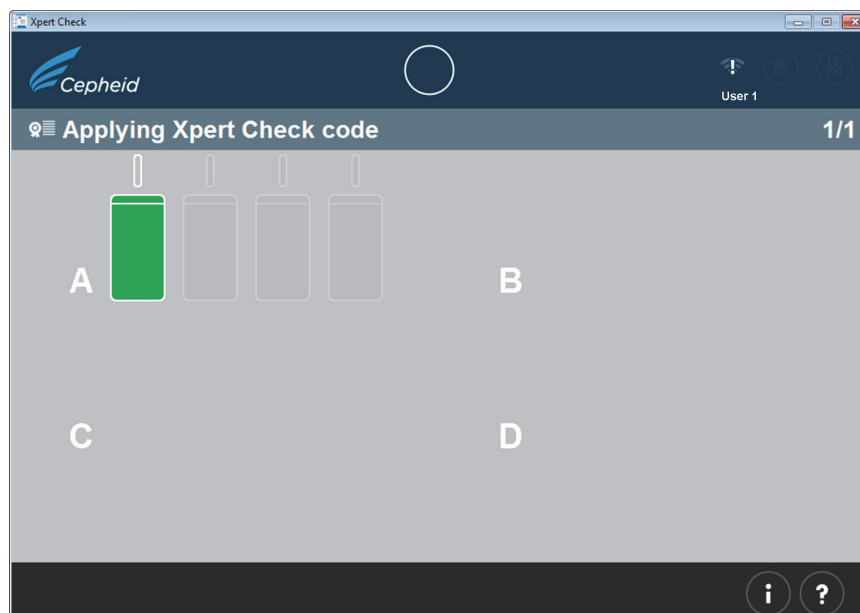


Figure 2-45. Applying Xpert Check code Screen Example

- E. After the Xpert Check code has been applied, the Xpert Check Complete screen will appear with the location of the Xpert Check Report displayed in the **Xpert Check Data Directory** area. Write down the file path and location of the Xpert Check Report file, as shown. See [Figure 2-46](#).

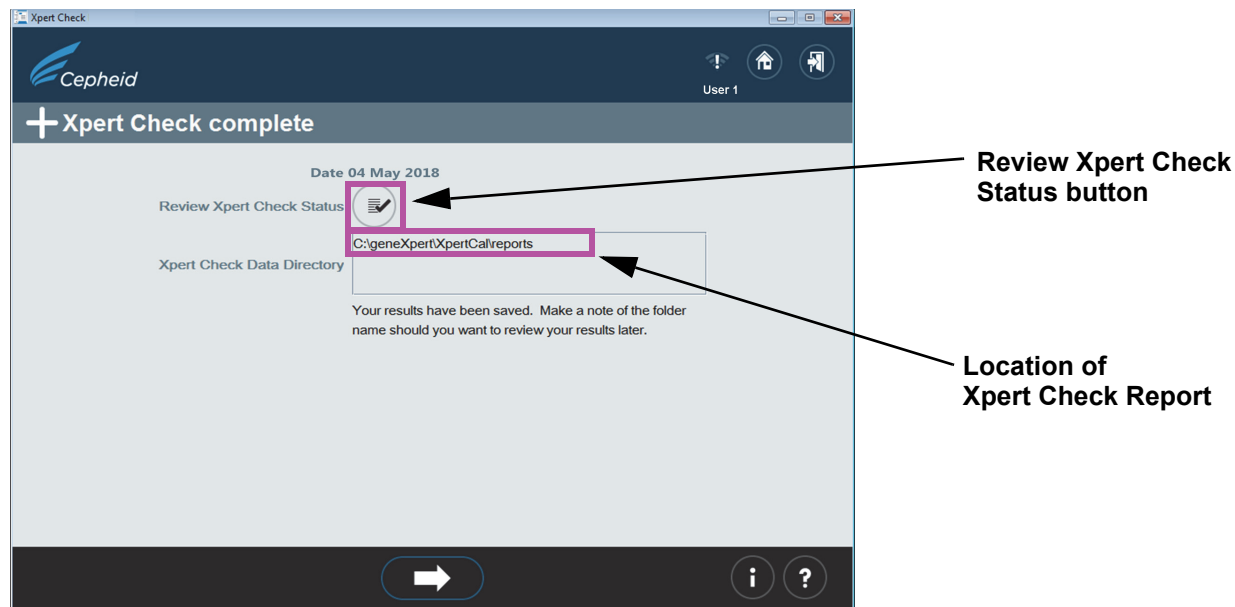


Figure 2-46. Xpert Check complete Screen

- F. Touch or click the **Review Xpert Check Status** button (see [Figure 2-46](#)).
- G. The Xpert Check status screen will appear. See [Figure 2-47](#). In the Xpert Check status screen, the successfully checked modules are indicated by a + symbol on a green module.

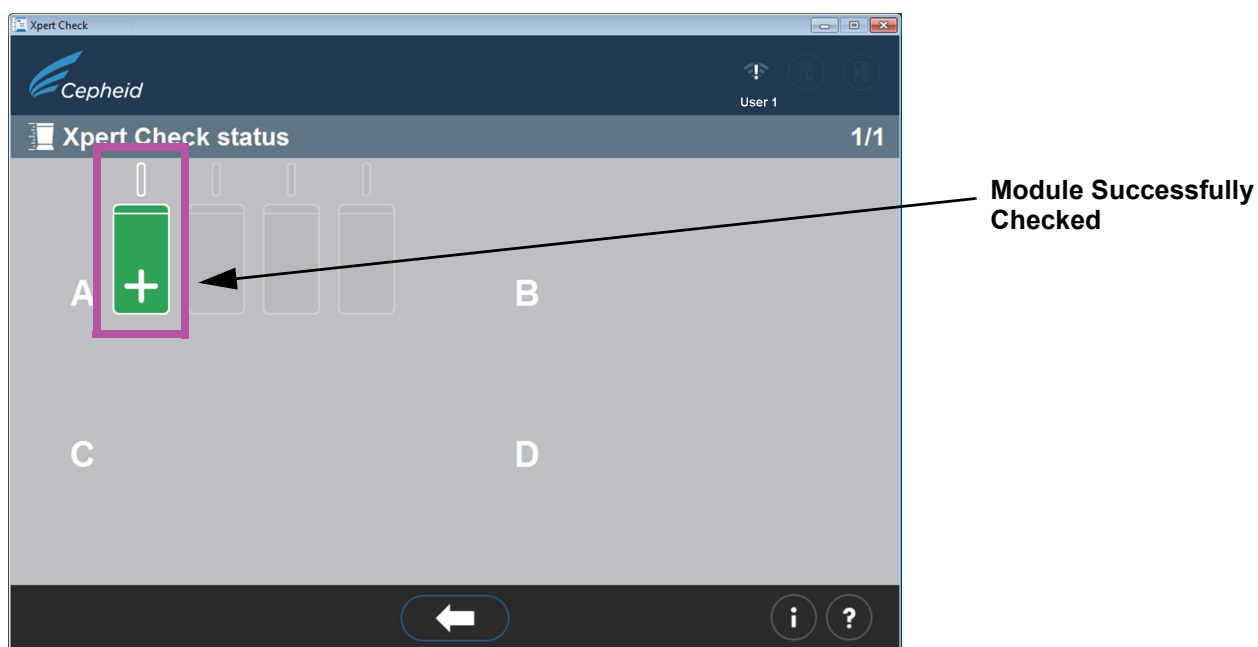


Figure 2-47. Xpert Check status Screen

Note

If the Xpert Check report on the computer has been deleted, contact your ASP or the local Cepheid Technical Support office for assistance.

7. Identify the generated Xpert Check Report file in the folder **C:\GeneXpert\XpertCall\Reports**.
8. Identify the generated Xpert Check Summary Report file in the folder **C:\GeneXpert\XpertCall\Reports**.
 - A. See [Figure 2-48](#) for an example of a Xpert Check Summary Report.
 The Xpert Check Summary Report lists the modules that had an unsuccessful test and require retesting or service.
 The modules requiring retesting or service are listed by serial number in Table 1 on the form in [Figure 2-48](#). When requesting service, provide these listed serial numbers to your ASP or the local Cepheid Technical Support office.
 Gateway information is provided in Table 2 of the form.



Xpert Check Summary Report

Please Note:

Xpert Check data collection performed on 30 September 2020 09:37:04 PDT
 All modules that DID NOT pass Xpert Check are listed in Table 1: Modules Requiring Service.
 Gateway Informations are provided in Table 2.
 Complete test results for each module are listed in Table 3: Detailed Test Results by Module.

GX Instrument Name:	My 6Color
Instrument Serial Number:	12345
Data Collected By:	User1
Institution Name:	Institution1
Laboratory Name:	Laboratory Sunnyvale
Street Address:	123 Main Street
City:	Sunnyvale
State/Province:	CA
Postal Code:	90001
Country:	USA
Email:	User1@Institution1.com
Facility Phone Number:	408-400-XXXX
Extension:	
Mobile:	
ASP Code:	US03

Table 1: Modules Requiring Service

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

Table 2: Gateway Information

Gateway Serial Number	MAC Address
804471	00:21:38:00:2E:1B
804470	00:21:38:00:2E:1A

Figure 2-48. Xpert Check Summary Report Example - Page 1



Xpert Check Summary Report

Table 3: Detailed Test Results by Module Serial Number

The column header will show Module Serial Number, followed by (Location / Cartridge Lot).

If a module undergoes multiple tests, the Module Serial Number will be shown as Module Serial Number : Cartridge -Test Run.

Test	639565 (A1/00402)
Cartridge Load	pass
Module Tests	pass
Ambient Temperature	pass
Motherboard EEPROM	pass
ICORE EEPROM	pass
+12V Power Supply	pass
-12V Power Supply	pass
+24V Power Supply	pass
Valve Drive	pass
Valve Label Dropouts	pass
Valve Home Integrity	pass
Valve Timing	pass
Valve Drift	pass
Pump Drive	pass
Ultrasonic	pass
ICORE Heater	pass
ICORE Fan	pass
Force Sensor	pass
Optical Check	fail
EBF Value	pass
Probe Check	fail

1. Cepheid recommends that system performance should be evaluated annually using Xpert Check.
2. Cepheid declares that the I-CORE modules in the GeneXpert® Instrument were checked using an Xpert Check product. NIST traceable qualification standards are used to control the parameters for the fluorescence standards of concentration, brightness, and spectrum. Cepheid products are manufactured, quantified and controlled under a Quality System compliant with ISO 13485 and QSR requirements.

Figure 2-49. Xpert Check Summary Report Example - Page 2

2.4 Return System to Normal Operation

Note

Return the system to normal operation by following one of the three procedures listed in this section for the GeneXpert Dx, GeneXpert Xpress, the GeneXpert Infinity 48s, or the GeneXpert Infinity-80.

2.4.1 GeneXpert Dx

Ensure all Xpert Check cartridges and CDs have been removed from the GeneXpert Dx.

1. Restart your GeneXpert system and computer. Follow the instructions in the GeneXpert Dx System Operator Manual.
2. The system will be ready for full operation.

2.4.2 GeneXpert Xpress

Ensure all Xpert Check cartridges and CDs have been removed from the GeneXpert Xpress.

1. Restart your GeneXpert Xpress system. Follow the instructions in the GeneXpert Xpress User's Guide.
2. The system will be ready for full operation

2.4.3 GeneXpert Infinity-48s or GeneXpert Infinity-80

Ensure all Xpert Check cartridges and CDs have been removed from the GeneXpert Infinity-48s or GeneXpert Infinity-80.

1. Restart the Xpertise software. Follow the instructions in the *GeneXpert Infinity System Operator Manual*.

The system will be in Automation mode, ready for full operation.

2.5 Information Key Screen

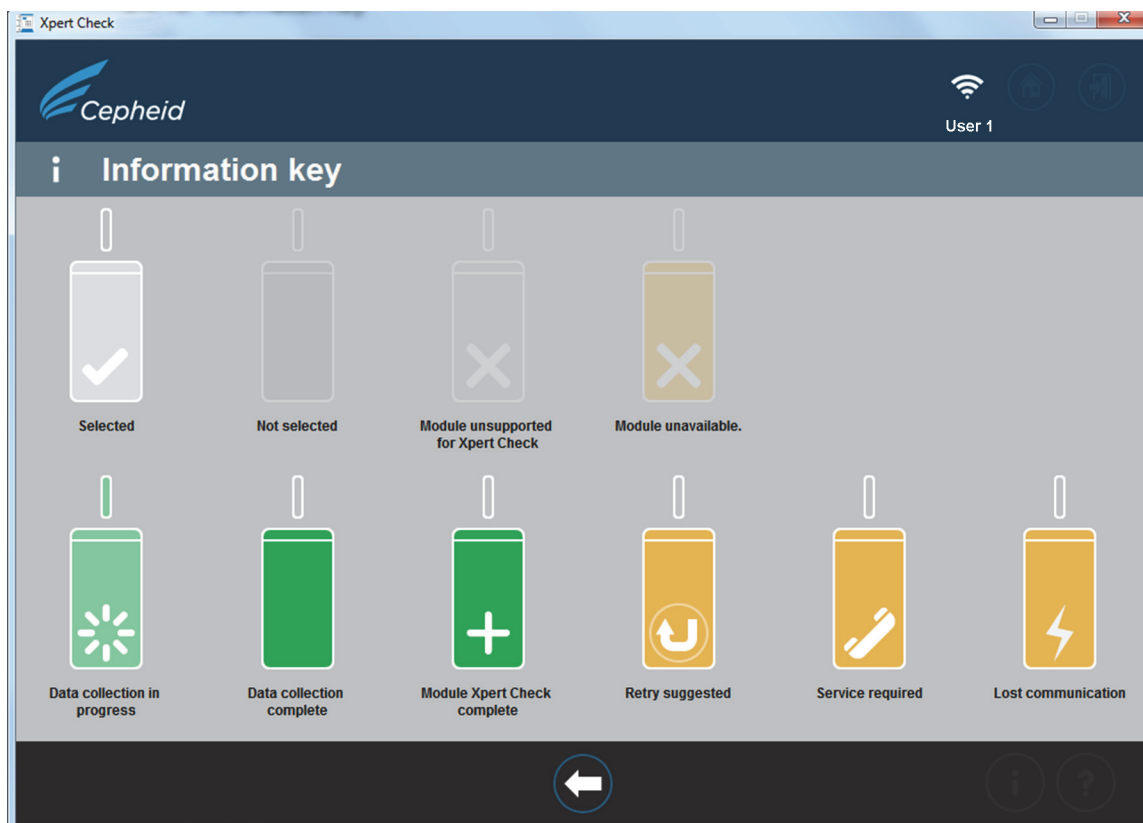


Figure 2-50. Information key Screen

2.5.1 Reasons to Repeat Xpert Check with a New Cartridge

If the onscreen instructions direct you to retest, repeat the test according to the instructions in [Step B.](#) on [page 2-19](#).

2.5.2 Reasons to Repeat Xpert Check with the Same Cartridge

If software reports that the cartridge film seal was not broken, remove the original cartridge, rescan the cartridge barcode, open the lid, close the lid, and reinsert the cartridge. Restart the Xpert Check procedure for the affected module.

2.5.3 Application of Xpert Check Code



Xpert Check is not complete until the Cepheid-supplied Xpert Check code is applied to the system being tested. Upon receipt of the Quality Assurance Xpert Check Code from Cepheid, apply the code to your system using the Xpert Check Software to complete the Xpert Check process.



Simplify Hepatitis B Treatment Management

Xpert® HBV Viral Load





“

In order to expand treatment of Hepatitis B, simplified and easy to use core service interventions are needed to implement effective HBV DNA Testing. Xpert® HBV Viral Load has the potential to simplify disease management by offering a flexible workflow for any testing setting and quality results in approximately an hour.”

Professor Pietro Lampertico, MD, PhD
Fondazione IRCCS Ca' Granda, Ospedale Maggiore Policlinico, Milan, Italy

The Goal

Elimination of Hepatitis by 2030

Viral hepatitis is one of the leading causes of death globally with 1.4 million deaths per year, as many as HIV/AIDS, tuberculosis or malaria. Hepatitis B and C viruses cause 95% of those deaths in the world.¹

The WHO global health sector strategy to eliminate Viral Hepatitis as a major public health threat by 2030 requires considerable efforts from governments, healthcare authorities and communities.

Service delivery must be expanded to better manage the number of people living with Hepatitis B Virus (HBV).¹



The Need

Efficient Treatment Delivery

- Although a vaccine for HBV exists, there is still no cure and lifelong treatment is needed for individuals already chronically infected with Hepatitis B Virus
- HBV rapid antibody testing is mainly done at point of care or in community based programmes but HBV viral load testing and monitoring is traditionally done in the laboratory with long turnaround times, which can result in more patients being lost to follow up and care
- Service coverage of core interventions are needed to expand prevention, testing and treatment for HBV



The Solution

Xpert HBV Viral Load on the GeneXpert® system

- Accurate and reliable quantification of HBV DNA in human serum or plasma
- Flexible throughput for any testing setting with round the clock, on-demand results
- Simplify disease management with the possibility of having sample to viral load results less than one hour

Coverage, plus
Accuracy, plus
Peace of mind

That's the **PCR***plus* advantage.
From Cepheid.

The Impact

- **Improve Patient Care:** Same day results support better clinical decisions
- **Increase Efficiency:** High quality HBV viral load quantitative results for accurate treatment delivery
- **Patient Centered Diagnostics:** Simplify testing for multiple diseases using a single platform

▀ Designed to simplify testing in low and high volume settings

No Waiting

- Deliver rapid individual patient results in a single visit

Simple and Organised

- True 24/7 random access accommodates other urgent test requests — i.e., Xpert® HCV Viral Load, Xpert® HIV-1 Viral Load, Xpert® MTB/RIF Ultra can run simultaneously on the same system

Improved Service

- Modular system can adapt to any throughput requirement from Health Clinics to National Reference Centers

Workflow: 2 Easy Steps

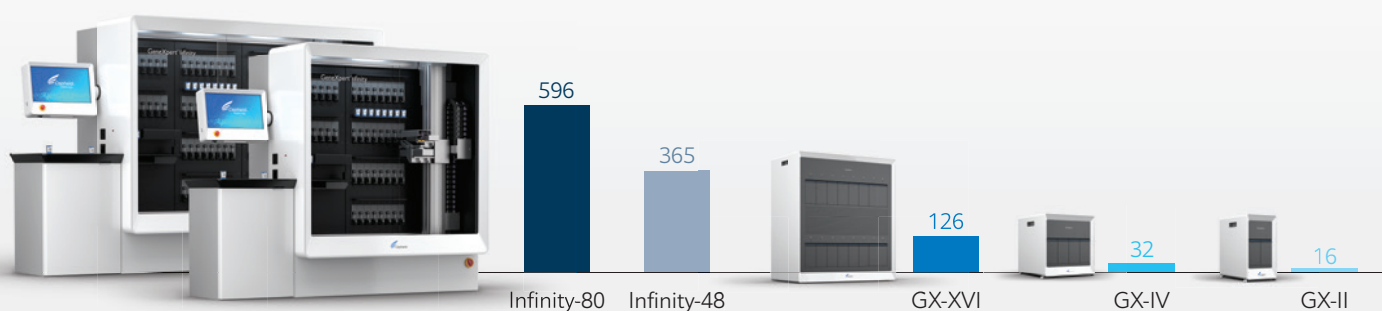
- 1 Transfer at least 0.6 mL of plasma or serum into the cartridge



- 2 Scan, load cartridge and start test



System Throughput* 8-hr shift



* Operational throughput per 8-hr shift based on HBV Viral Load testing, internal analysis.

Catalog Information

Xpert® HBV Viral Load	10 tests	GXHBV-VL-CE-10
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Reference:

- 1 WHO. Global Health Sector Strategy on Viral Hepatitis 2016–2021. 2016 June. Accessed Aug 2020. <https://apps.who.int/iris/bitstream/handle/10665/246177/WHO-HIV-2016.06-eng.pdf;jsessionid=E5D2C86E67F6CAC0258DDC6892B5A5E8?sequence=1>

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