Technical Training
Xpert® HIV-1 Viral Load XC

Catalog Number (GXHIV-VL-XC-CE-10)
For CE-IVD Only

302-3909 Rev.C January 2023

Training Agenda

1. Reagents
2. Sample collection
3. Kit storage and handling
4. Preparing the cartridge
5. Quality controls
6. Results analysis
7. Discussion

Training Objectives

At the end of the training, users will be able to:

- Properly store and handle the Xpert® HIV-1 Viral Load XC cartridge kit and sample collection
- Follow proper laboratory safety precautions
- Collect and transport appropriate specimen
- Prepare a cartridge and run the Xpert® HIV-1 Viral Load XC test
- Report the various software generated results
- Understand the Xpert® HIV-1 Viral Load XC control strategy

The Cepheid Solution

- Simultaneous detection
  - Detects and quantifies HIV-1 RNA
  - Reliable results with a linear range from 40 -10,000,000 HIV-1 RNA copies/mL
- On-board internal controls for each sample
  - Sample Volume Adequacy (SVA)
  - Probe Check Control (PCC)
  - Internal Quantitative Standards (IQS) High (H) and Low (L)
- Results in 91 minutes
- Closed cartridge system minimizes risk of contamination
- On-demand results
- Random access

Intended Use

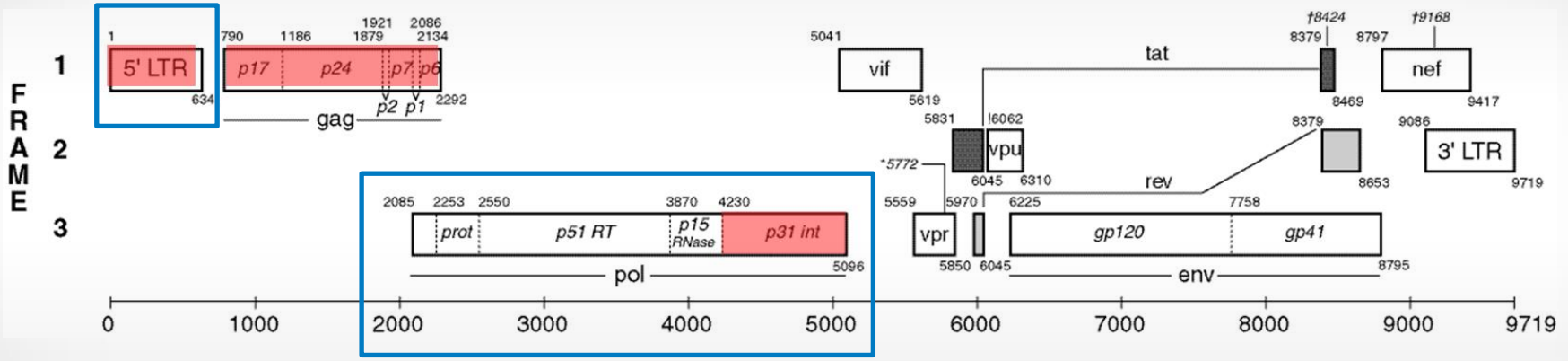
- Xpert® HIV-1 Viral Load XC (Extended Coverage) is an in vitro reverse transcription polymerase chain reaction (RTPCR) test for the quantification of human immunodeficiency virus type 1 (HIV-1) RNA in human EDTA plasma using the automated GeneXpert® System.
- It is intended for use as an aid in clinical management of patients infected with HIV-1.

- Xpert® HIV-1 Viral Load XC is intended for use in conjunction with clinical presentation and other laboratory markers for disease prognosis and for use as an aid in assessing viral response to antiretroviral treatment as measured by changes in plasma HIV-1 RNA levels from HIV-1 infected individuals.

Intended Use continued

- Xpert® HIV-1 Viral Load XC is intended to be performed by trained professional users or trained healthcare workers in laboratory or near-patient testing environments.
- Xpert® HIV-1 Viral Load XC is not intended to be used as a donor screening test for HIV-1 infection.

Targets and Probes



Targets

- Dual independent HIV-1 target:
  - LTR region (highly conserved)
  - POL gene (polymerase gene)

Probes

- 1 probe binds to IQS-H
- 1 probe binds to IQS-L
- 2 probes for Dual HIV-1 Target (LTR & POL gene)

Courtesy of Dr. M. Obermeier, MiB, Berlin
Source: http://www.hiv.lanl.gov/content/hiv-db/MAP/landmark.html

CE-IVD. In Vitro Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

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Xpert® HIV-1 Viral Load XC Requirements

GeneXpert® Systems

- GeneXpert® Dx software **v4.7b** or higher
- Xpertise® software **v6.4b** or higher
- GeneXpert Edge Software **v1.0** or higher

Test Kits

- Catalog Number (GXHIV-VL-XC-CE-10)

Sample Collection

- K2 EDTA tube or BD Vacutainer® PPT™ Plasma Preparation Tubes

Other Materials

- Personal Protective Equipment (PPE)
- 10% Bleach / Sodium Hypochlorite
- 70% ethanol or denatured ethanol
- Vortex
- Centrifuge for plasma preparation

Other Materials

- Uninterruptible Power Supply /Surge Protector
- Printer

Good Laboratory Practice Review

Personal Protective Equipment (PPE)	• Wear clean lab coats, safety glasses, and gloves • Change gloves between processing samples
Lab Bench Area	• Clean work surfaces routinely with: ✓ 1:10 dilution of household bleach* ✓ 70% Ethanol Solution • After cleaning, ensure work surfaces are dry
Specimens, Samples, and Kits Storage	• Store specimens and samples away from kit to prevent contamination
Equipment	• Use filtered pipette tips when recommended • Follow the manufacturer's requirements for calibration and maintenance of equipment

* Final active chlorine concentration should be 0.5% regardless of the household bleach concentration in your country.

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Kit Handling

Xpert® HIV-1 Viral Load XC Kit Contents

Catalog Number	GXHIV-VL-XC-CE-10
Cartridges* Per Kit	10
Kit CD	Assay Definition File (ADF) Assay Import Instructions Package Insert (PDF)
Storage	2-28 °C

Note: Sample Reagent contains guanidinium thiocyanate, which is harmful if swallowed (H303) and Irritating to eyes and skin (H315, H319).

* *Cartridges contain chemically hazardous substances - please see Package Insert and Safety Data Sheet for more detailed information.*

Kit Storage and Handling

- Store the Xpert® HIV-1 Viral Load XC cartridges at 2–28˚C
- It is very important to bring Xpert® HIV-1 Viral Load XC cartridges to 15-30˚C prior to use if they have been stored cold
- Do not open the cartridge lid until you are ready to perform the test.
- Do not use Collection Reagent tubes that have not been validated by Cepheid other than those stated in the Package insert
- Open the test cartridge lid only when adding the sample. After sample addition, close the lid and proceed with processing
- Do not use a cartridge that has leaked
- Use cartridge within 4 hours after opening the cartridge lid and adding sample.
- Do not use cartridges that previously have been frozen.
- Do not use a cartridge past the expiration date.

Test Limitations

- Good laboratory practice and changing gloves between handling samples are recommended to avoid contamination of samples or reagents.
- Rare mutations, deletions or insertions within the target regions of the HIV-1 VL XC test may affect primer and/or probe binding resulting in under-quantitation or failure to detect the virus.
- Patients who have received CAR-T therapies may display positive results with Xpert (HIV-1 Qual XC, HIV-1 VL,etc.) as the result of the presence of the LTR target within certain chimeric antigen receptor T-cell (CAR-T) products. Additional confirmatory testing should be performed to determine the patient's HIV status in people who have received CAR-T treatment.
- The HIV-1 VL XC test has been validated only for use with K2 EDTA and PPT-EDTA plasma. Testing of other sample types may lead to inaccurate results.
- A negative test result does not preclude HIV-1 infection. Results from the HIV-1 VL XC test should be interpreted in conjunction with clinical presentation and other laboratory markers.

Test Limitations continued

- Prior to switching from one technology to the next, Cepheid recommends that users perform method correlation studies in their laboratory to qualify technology differences.
- Reliable results are dependent on adequate sample collection, transport, storage and processing.
- Quantitation of HIV-1 RNA is dependent on the number of virus particles present in a sample and may be affected by sample collection methods, patient factors (i.e. age, presence of symptoms), and/or stage of infection.
- A sample that yields an **INVALID** result twice may contain an inhibitor; retesting is not recommended

Specimen Collection, Storage and Transport

Specimen Collection

- Whole blood
  - Collect whole blood specimens in BD Vacutainer® PPT™ Plasma Preparation Tubes for Molecular Diagnostic Test Methods OR sterile collection tubes containing K2 EDTA as an anticoagulant as per manufacturer's instructions

EDTA tube

BD® Vacutainer tube

Heparin tube

- **Plasma**
  - Centrifuge to separate the plasma and red blood cells per the manufacturer's instructions
  - A minimum of 1.0 mL of plasma is required for theHIV-1 VL XC test

Specimen Collection, Transport and Storage

	Prior to testing	Temperature (°C)	Storage Time
	Whole blood	2 - 30°C	24 hours

Plasma specimens are stable up to **5 freeze/thaw cycles**. Thaw sample at 15–30 °C.

	Prior to testing (After Plasma Separation)	Temperature (°C)	Storage Time
	Plasma	2 - 35°C	24 hours
		2 - 8°C	7 days
		≤ -18 °C & ≤ -70 °C	6 weeks

Specimen collection, Storage and transport

Specimen Type	Prior to testing	Temperature (°C)	Storage Time
	**Whole blood**	2 - 30°C	24 hours
 Following centrifugation of whole blood samples, plasma may be pipetted directly into the test cartridge. Sufficient volume is critical to obtaining valid test results	**Plasma** (Plasma specimens are stable up to **5 freeze/thaw cycles**. Thaw sample at 15–30 °C)	2 - 35°C OR 2 - 8°C OR ≤ -18 °C & ≤ -70 °C	24 hours OR 7 days OR 6 weeks

Cartridge Preparation

Warnings and Precautions

- Do not substitute HIV-1 VL XC test reagents with other reagents.
- 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 place the sample ID label on the cartridge lid or on the barcode label.
- Each single-use HIV-1 VL XC test cartridge is used to process one sample. Do not reuse spent cartridges.
- Do not use a cartridge that has a damaged reaction tube.
- Each single-use disposable pipette is used to transfer one sample.
- Do not reuse spent disposable pipettes.
- If using a precision pipette: Each single use disposable pipette tip is used to transfer one sample. Do not reuse spent pipette tips.
- Wear clean lab coats and gloves. Change gloves between processing each sample.

Proper Cartridge Handling Techniques

Correct

- Do not touch the reaction tube
- Keep the cartridge upright
- Do not tilt after sample is added

Incorrect

Cartridge Preparation Card: Cepheid - supplied pipette

Xpert® HIV-1 Viral Load XC Cartridge Preparation *using a Cepheid-supplied pipette*

- Xpert® HIV-1 Viral Load XC

Refer to the package insert for detailed instructions, precautions, and warnings.

For a copy of the SDS, visit www.cepheid.com or www.cepheidinternational.com

Cepheid Technical Support

US office
(888) 838-3222, Option 2
techsupport@cepheid.com

European office
+33 563 825 319
support@cepheideurope.com

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A better way.

NOTE: Allow HIV-1 VL XC test cartridges and sample to equilibrate to 15–30 °C prior to pipetting plasma into the cartridge. Do not pipette plasma into a cartridge that is cold (below 15°C).

1 Take one Xpert cartridge and tube of plasma.

2 Open the cartidge lid.

3 Fill the pipette to just below the bulb to transfer at least 1 mL plasma from the tube. Make sure no large air bubbles are created in the pipette tip while filling the pipette.

4 Empty the contents of the pipette into the sample chamber of the cartridge.

5 Close the cartridge lid.

6 Start the test within the timeframe specified in the package insert.

CE IVD *In Vitro* Diagnostic Use

In vitro medical diagnostic device. May not be available in all countries.

302-4987 Rev. A February 2021

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Cartridge Preparation Card – Precision pipette

Xpert® HIV-1 Viral Load XC Cartridge Preparation *using a precision pipette*

- Xpert® HIV-1 Viral Load XC

Refer to the package insert for detailed instructions, precautions, and warnings.

For a copy of the SDS, visit www.cepheid.com or www.cepheidinternational.com

Cepheid Technical Support

US office
(888) 838-3222, Option 2
techsupport@cepheid.com

European office
+33 563 825 319
support@cepheideurope.com

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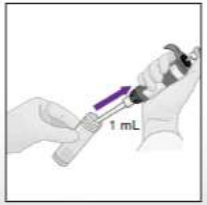
NOTE: Allow HIV-1 VL XC test cartridges and sample to equilibrate to 15–30 °C prior to pipetting plasma into the cartridge. Do not pipette plasma into a cartridge that is cold (below 15°C).

1 Take one Xpert cartridge and tube of plasma.

2 Open the cartridge lid.

3 Pre-wet the pipette tip once by filling the pipette tip with plasma and emptying it into the tube. Then fill the pipette with 1 mL plasma from the tube.



4 Empty the contents of the pipette into the sample chamber of the cartridge.

5 Close the cartridge lid.

6 Start the test within the timeframe specified in the package insert.

CE IVD *In Vitro Diagnostic Use*

In vitro medical diagnostic device. May not be available in all countries.

302-4987 Rev. A February 2021

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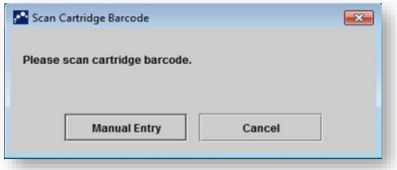
Run a Test on GeneXpert® Dx

1 Create a test.

Start the test within 4 hours after adding the sample to the cartridge.

2 Scan barcode for Patient and/or Sample ID.



Do not click on Manual Entry or Cancel.

3 Scan the cartridge.

For complete details on how to run a test, refer to the Package Insert and the GeneXpert Dx Operator Manual.

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Run a Test on GeneXpert® Dx (continued)

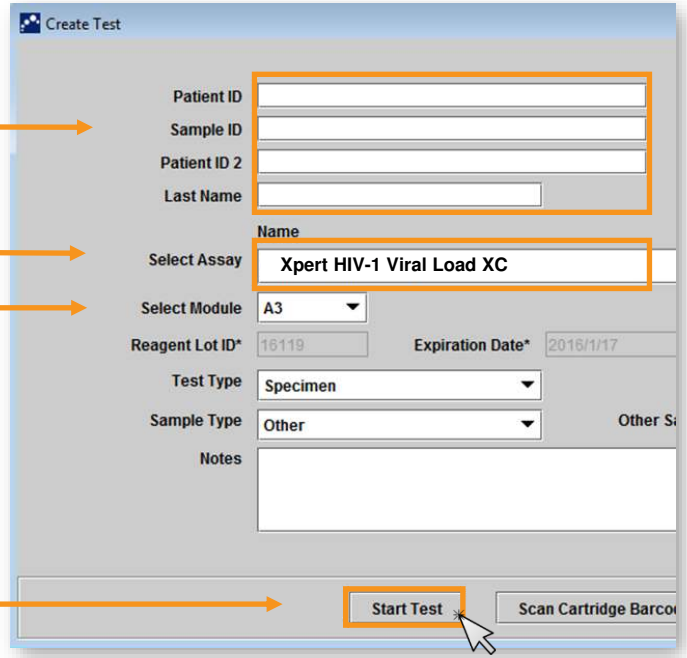
4 Complete the fields as required.

5 Xpert® HIV-1 VL XC test is selected automatically.

6 The module is selected automatically.

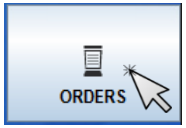
7 Click on Start Test.

8 A green light will flash on the module.
Load the cartridge into module and close the door.



Run a Test on GeneXpert® Infinity

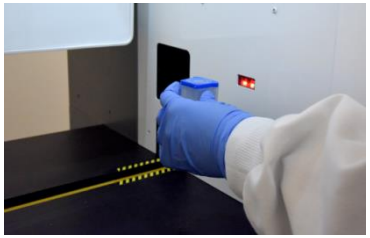
1 Create a test.



Place the cartridge on the conveyor within 30 minutes of after adding the sample into the cartridge .

2 Scan barcode for Patient and/or Sample ID.

3 Scan the cartridge.



For complete details on how to run a test, refer to the Package Insert and the Xpertise Operator Manual.

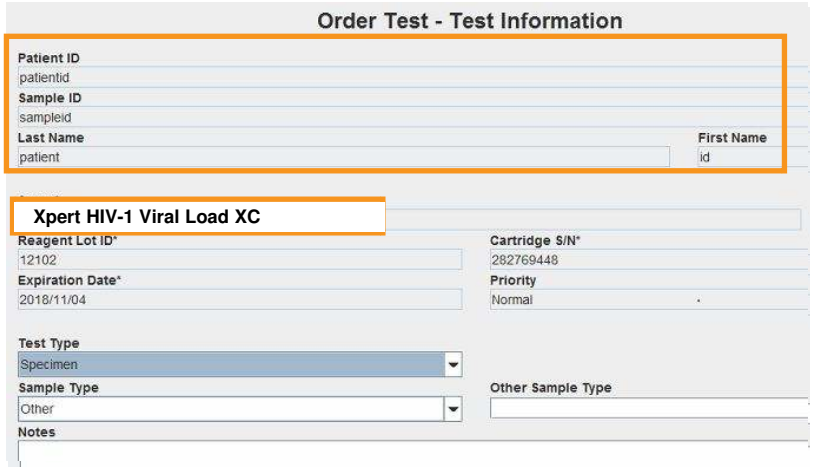
Run a Test on GeneXpert® Infinity (continued)

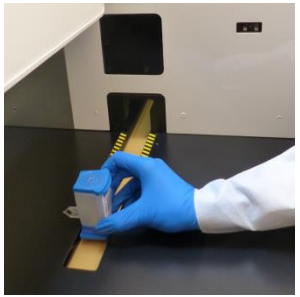
4 Complete the fields as required.

5 Xpert® HIV-1 VL XC test is selected automatically.

6 Click SUBMIT.

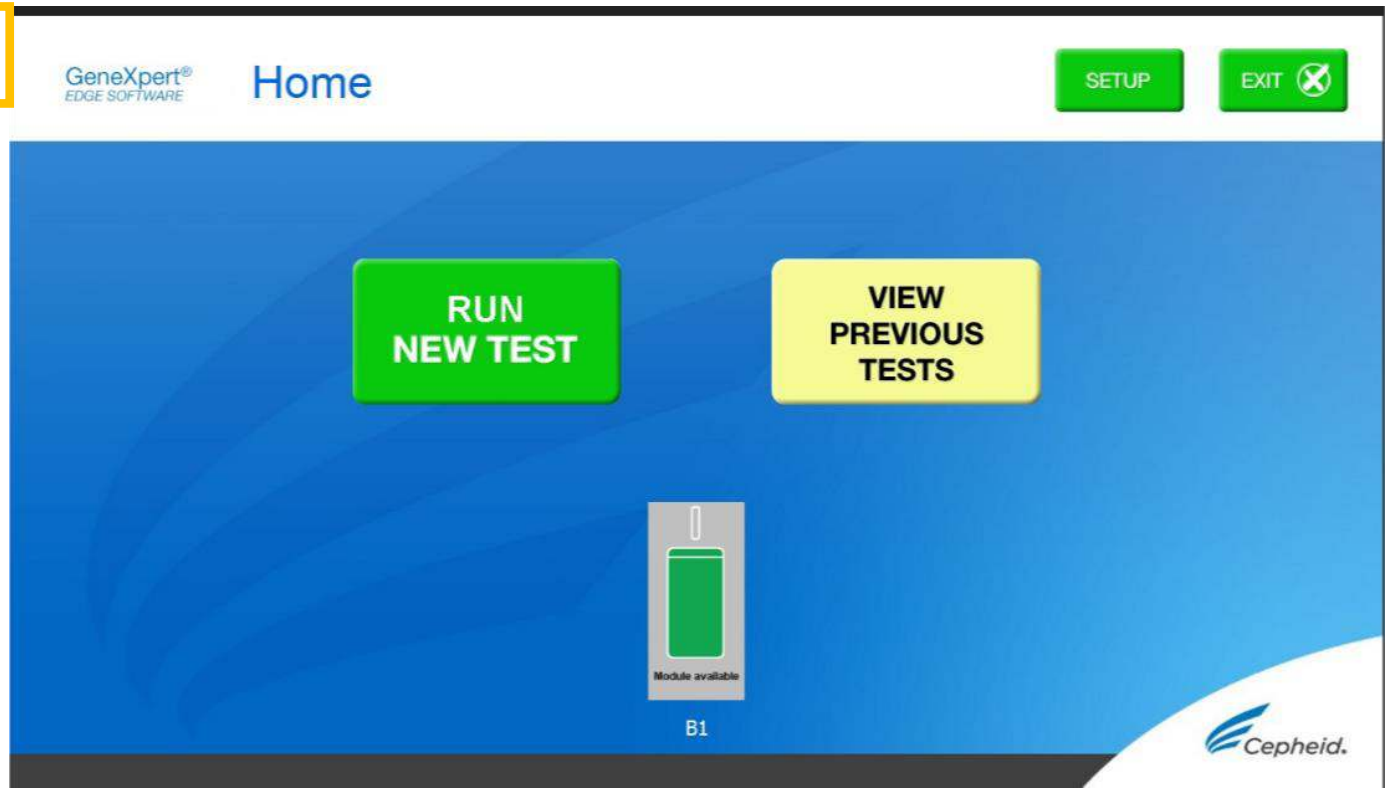
7 Place the cartridge onto the conveyor belt.





Create a Test on GeneXpert® Edge System

1



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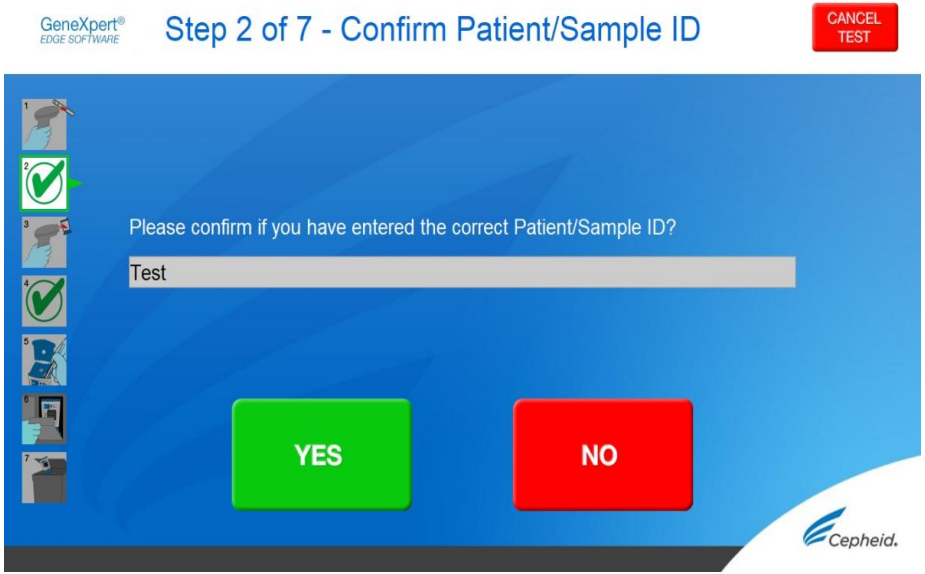
Create a Test on GeneXpert® Edge

2



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Create a Test on GeneXpert® Edge

3

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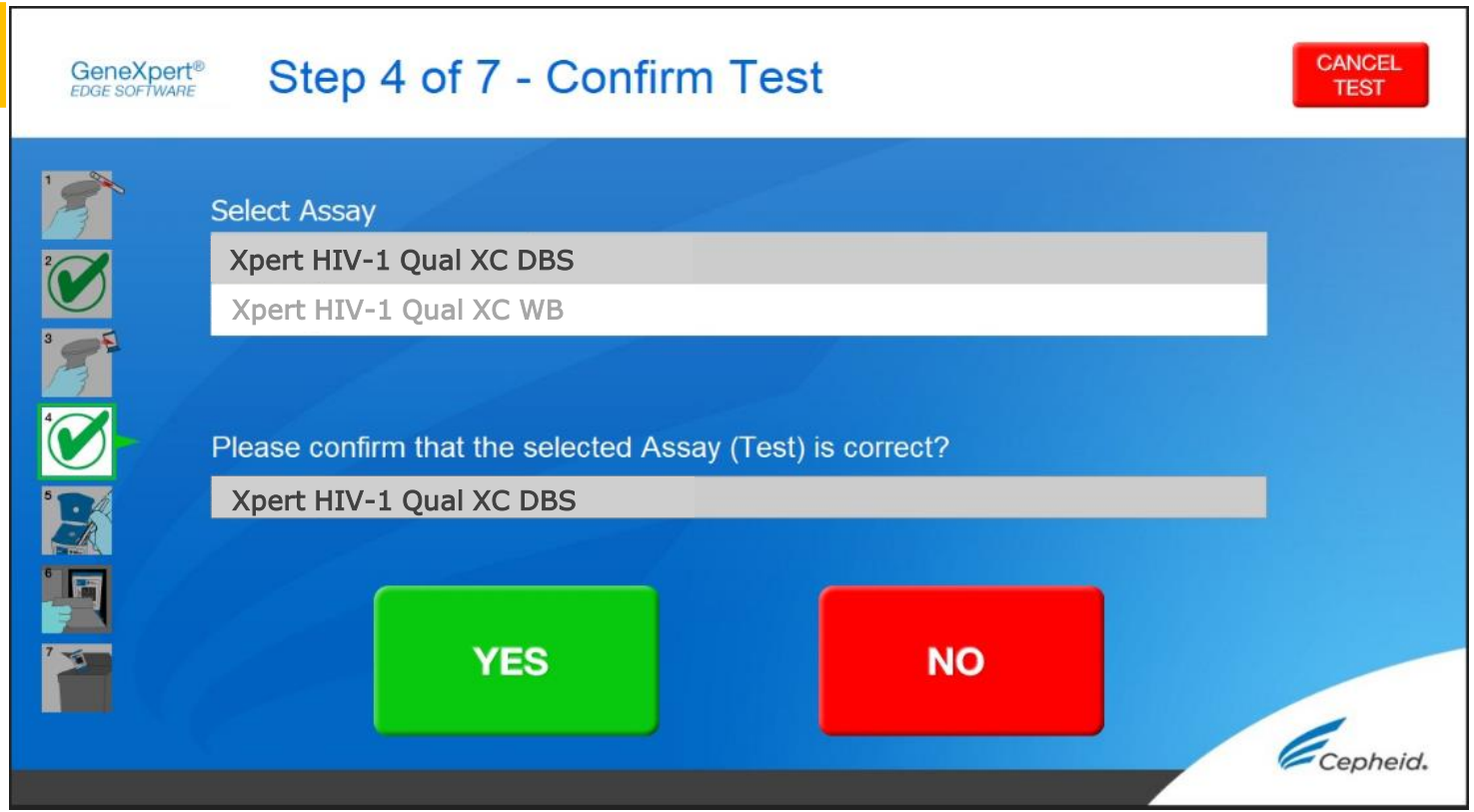
Create a Test on GeneXpert® Edge

4



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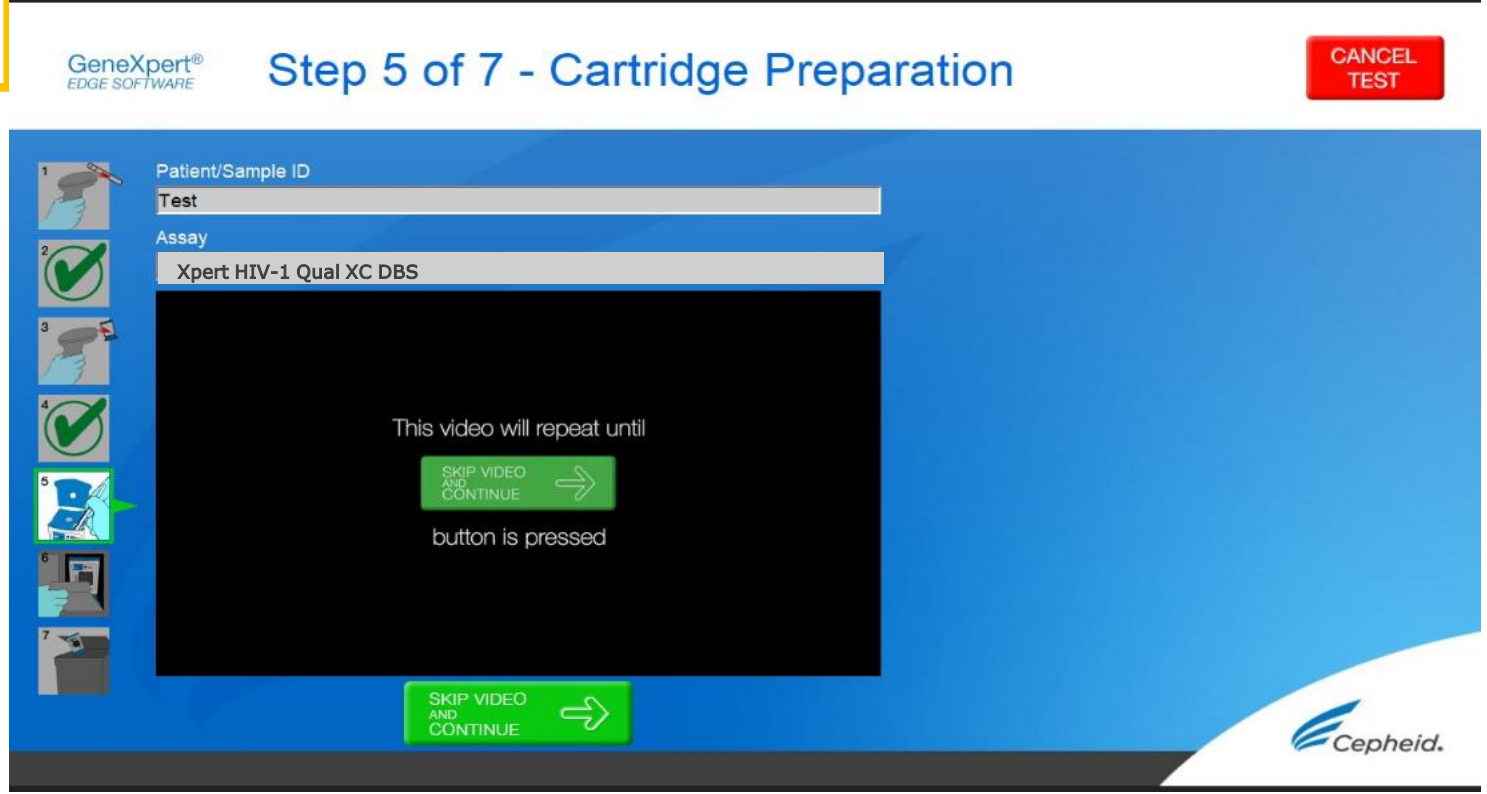
Create a Test on GeneXpert® Edge

5



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Create a Test on GeneXpert® Edge

6

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Automated Xpert® HIV-1 Viral Load XC Protocol

1 Sample is added to the cartridge

2 The cartridge is loaded into the System

3 Nucleic acids are purified

4 Purified nucleic acids mix with the PCR reagents

5 Simultaneous amplification and detection occurs

6 Results are ready to view

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Warnings and Precautions

- For in vitro diagnostic use only.
- 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 samples should be treated with standard precautions. Guidelines for samples handling are available from the U.S. Centers for Disease Control and Prevention and the Clinical and Laboratory Standards Institute (CLSI)
- Follow your institution's safety procedures for working with chemicals and handling biological samples.
- Appropriate safety measures should be taken in the event of a splash that may occur using bleach and facilities for adequate eye washing or skin rinsing are advised to care for such events.

Warnings and Precautions continued

- Biological samples, 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 samples and used cartridges should be disposed per WHO [World Health Organization] medical waste handling and disposal guidelines[6].
- Do not substitute HIV-1 VL XC test reagents with other reagents.
- Wear clean lab coats and gloves. Change gloves between processing each sample.

6. World Health Organization. Safe management of wastes from health-care activities. 2nd Edition. WHO, 2014.Accessed July 24, 2020 at http://www.who.int/water_sanitation_health/publications/wastemanag/en/

Warnings and Precautions continued

- In the event of contamination of the work area or equipment with samples, thoroughly clean the contaminated area with a freshly prepared solution of 0.5% sodium hypochlorite (or a 1:10 dilution of household chlorine bleach). Follow by wiping the surface with 70% ethanol. Let the work surfaces dry completely before proceeding.
- For Instrument System cleaning and disinfecting instructions, refer to the appropriate GeneXpert Dx System Operator Manual or GeneXpert Infinity System Operator Manual or GeneXpert Infinity System Operator Manual..

Quality Controls

Xpert® Xpert® HIV-1 Viral Load XC Control Strategy

CONTROL

- Xpert® Xpert® HIV-1 Viral Load XC Quality Controls
  - Each Xpert cartridge is a self-contained test device
  - Cepheid designed specific molecular methods to include internal controls that enable the system to detect specific failure modes within each cartridge:
    - Sample Volume Adequacy (SVA)
    - Probe Check Controls (PCC)
    - Internal Quantitative Standard High and Low (IQS-H and IQS-L)
    - Lot Specific Parameters (LSP)

Refer to 301-4868 GeneXpert® Quality Control Features for all Cepheid Xpert tests.

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Internal Quality Controls

- **Sample Volume Adequacy (SVA)**
  - Ensures that 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 acceptance criteria.
  - If the SVA does not pass, an ERROR 2096 will display if there is no sample or an ERROR 2097 if there is not enough sample.
  - The system will prevent the test to be processed.

- **Probe Check Controls (PCC)**
  - Before the PCR step, the fluorescence signal is measured from all probes and compared with default settings to monitor
    - bead rehydration
    - reaction tube filling
    - probe integrity
    - dye stability

Internal Quality Controls

- **Internal Quantitative Standard High and Low (IQS-H and IQS-L)**
  - IQS-H and IQS-L are two Armored RNA® controls unrelated to HIV that are included in each cartridge and go through the whole test process
  - They are used for quantification by using lot specific parameters for the calculation of HIV-1 RNA concentration in the sample
  - Verifies that sample was correctly processed
  - Detect specimen-associated inhibition of the RT-PCR reaction, thereby acting as sample processing controls.
  - IQS Low and IQS High Ct values must always be within the valid range

- **Lot Specific Parameters (LSP)**
  - Each kit lot has built-in LSP generated from an HIV-1 calibration panel, traceable to the 4th WHO International Standard for HIV-1 (NIBSC code 16/194), and the IQS-H and IQS-L.
  - The LSP are unique for each kit lot and are used to ensure correct quantitation

Commercially Available External Controls

Vendor	Catalog #	Description	Configuration	Storage
Zeptometrix	NATHIV1-ERCM (order quantity of 2)	HIV-1 Medium positive control (50000 IU/mL)	1.0 mL x 6 vials	2-8°C
Zeptometrix	NATHIV1-ERCL (order quantity of 2)	HIV-1 Low/Medium positive control (1000 IU/mL)	1.0 mL x 6 vials	2-8°C
Zeptometrix	NATHIV-LIN	Linearity panel	0.25 mL x 6 vials	2-8°C
Seracare	AccuSpan™ HIV-1 RNA Linearity panel (2410-0221)	Different series available 150 to 500 copies/ml	1.2mL x 10 vials	2-8°C

Note: The conversion factor is 2.06 IU equals 1 copy

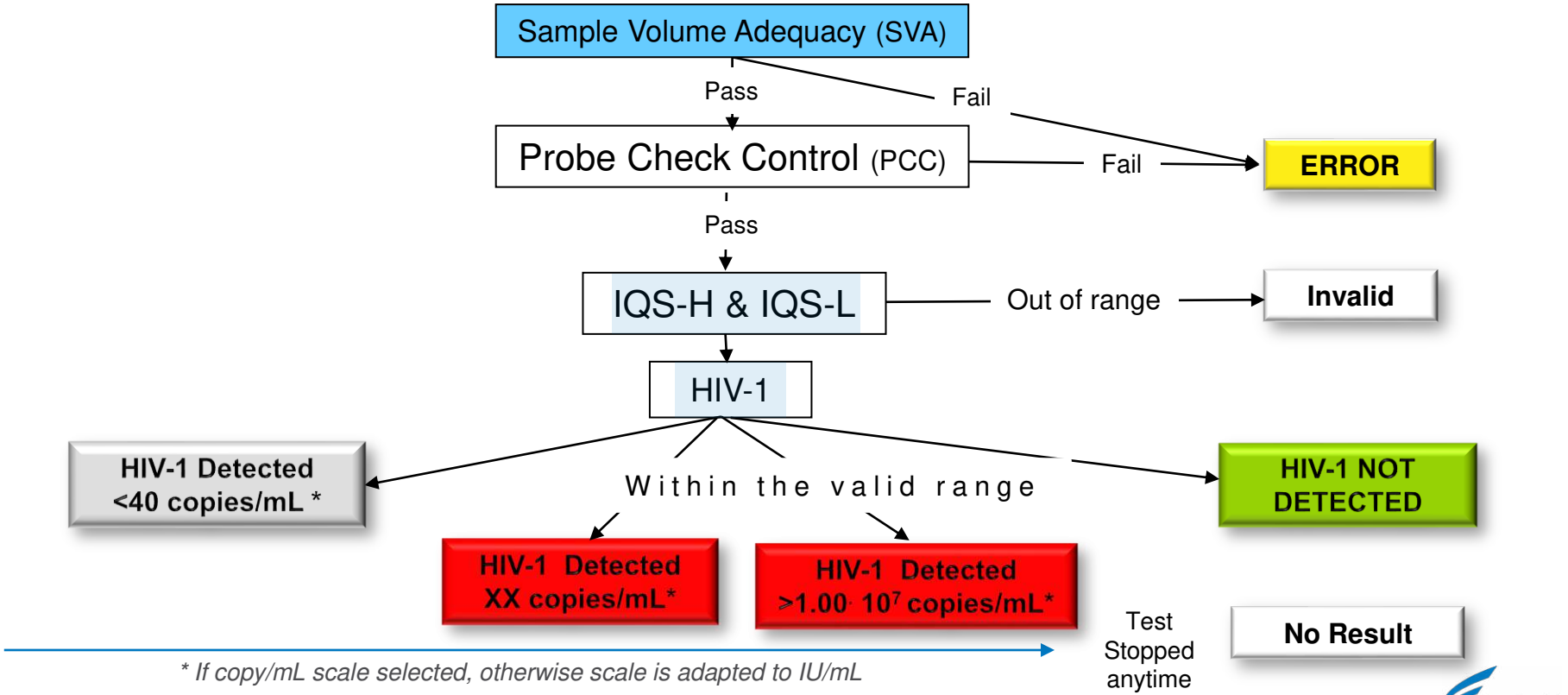
**** For more information, visit:***
Zeptometrix: http://www.zeptometrix.com/
Seracare: https://www.seracare.com/

- *1 lot of each control were evaluated with up to 2 lots of the Xpert HIV-1 VL XC. Performance has not been determined with other lots.*
- *List of lots evaluated available upon request.*

- Many other vendors for quality control material are also available in addition to the ones outline above.
- External controls should be used in accordance with local, state accrediting organizations, as applicable

Result Interpretation

Result Interpretation Algorithm



** If copy/mL scale selected, otherwise scale is adapted to IU/mL*

Copies/mL or IU

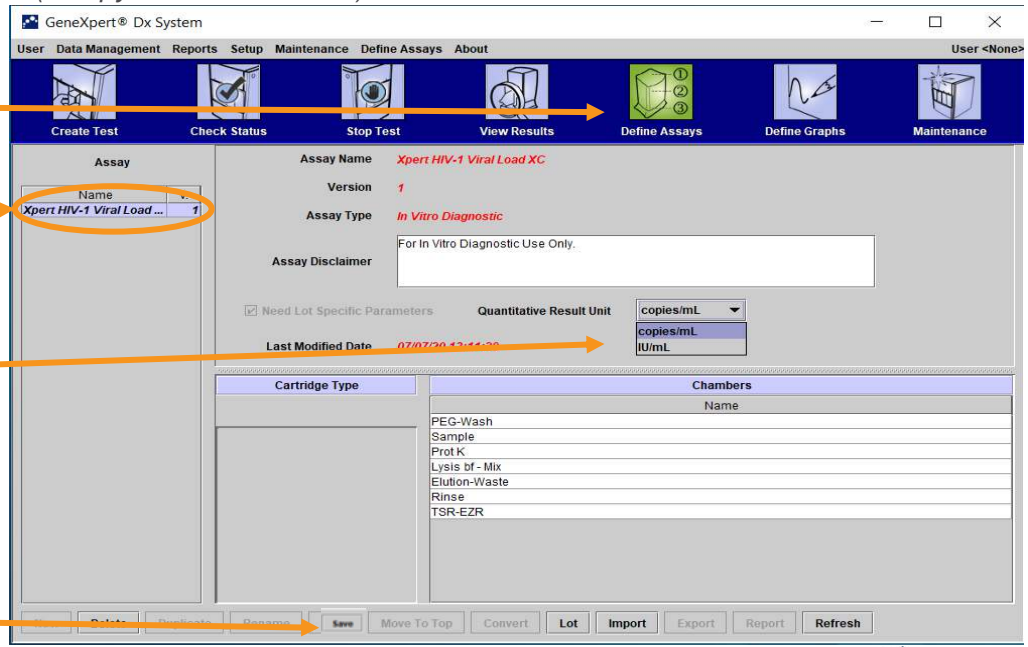
- **choose units to be displayed**
  - Copies/mL or International Units/mL *(1 copy/mL = 2.06 IU/mL)*

1 Select Define Assays

2 Highlight Xpert® HIV-1 Viral Load XC Test

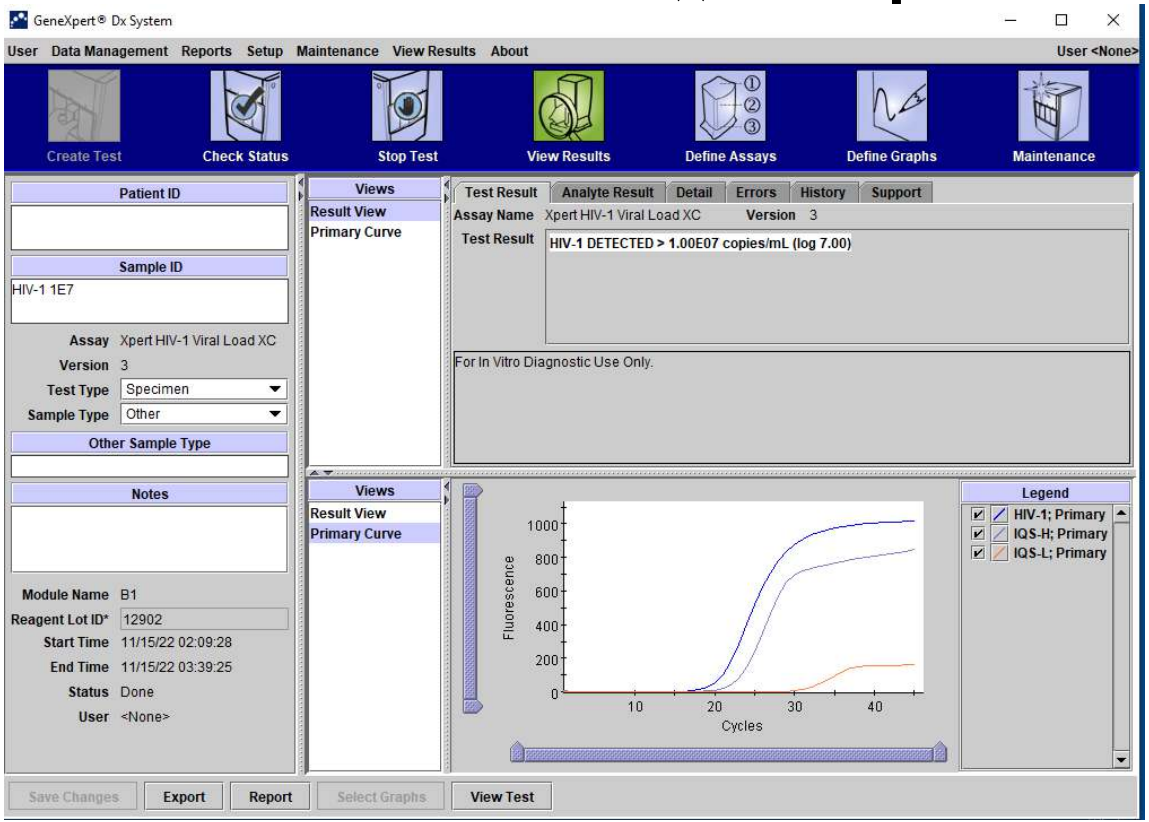
3 Choose units

4 Save your settings



HIV-1 DETECTED

HIV-1 DETECTED >1 x 10 copies/mL



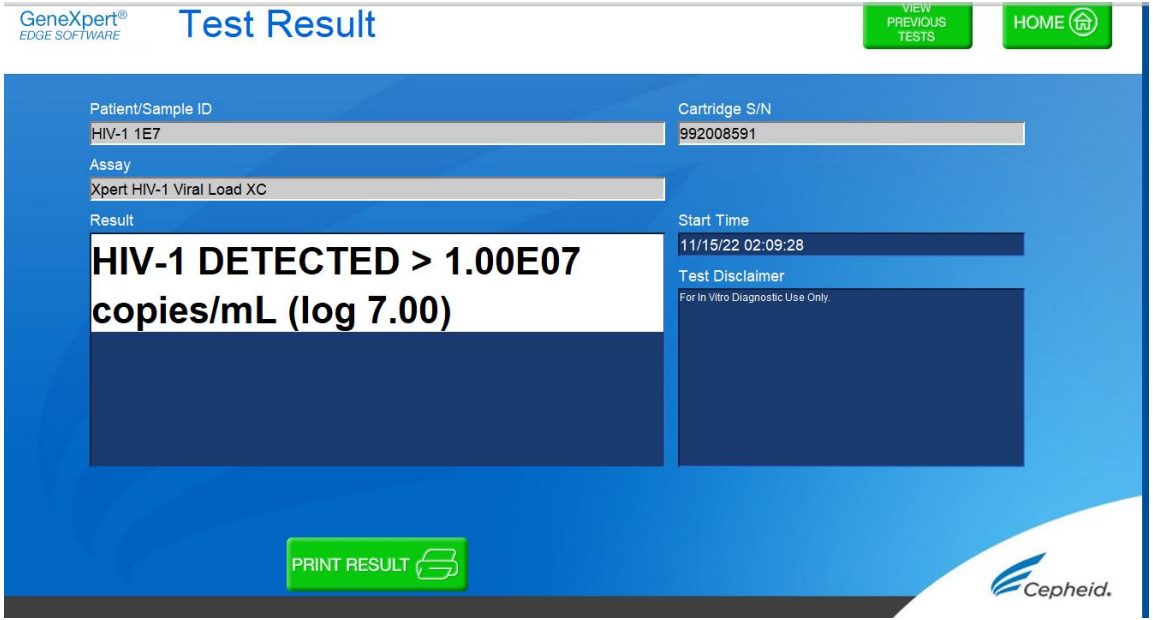
- The target HIV-1 is detected above the analytical measurement range
- IQS-H: PASS
  - IQS-H has a Ct value within the valid range
- IQS-L: PASS
  - IQS-L has a Ct value within the valid range
- Probe Check: PASS

Example calculation:

$1x10^7$ = 10 000 000 (million) copies/mL

HIV-1 DETECTED >1 x 10 copies/mL

GeneXpert® Edge



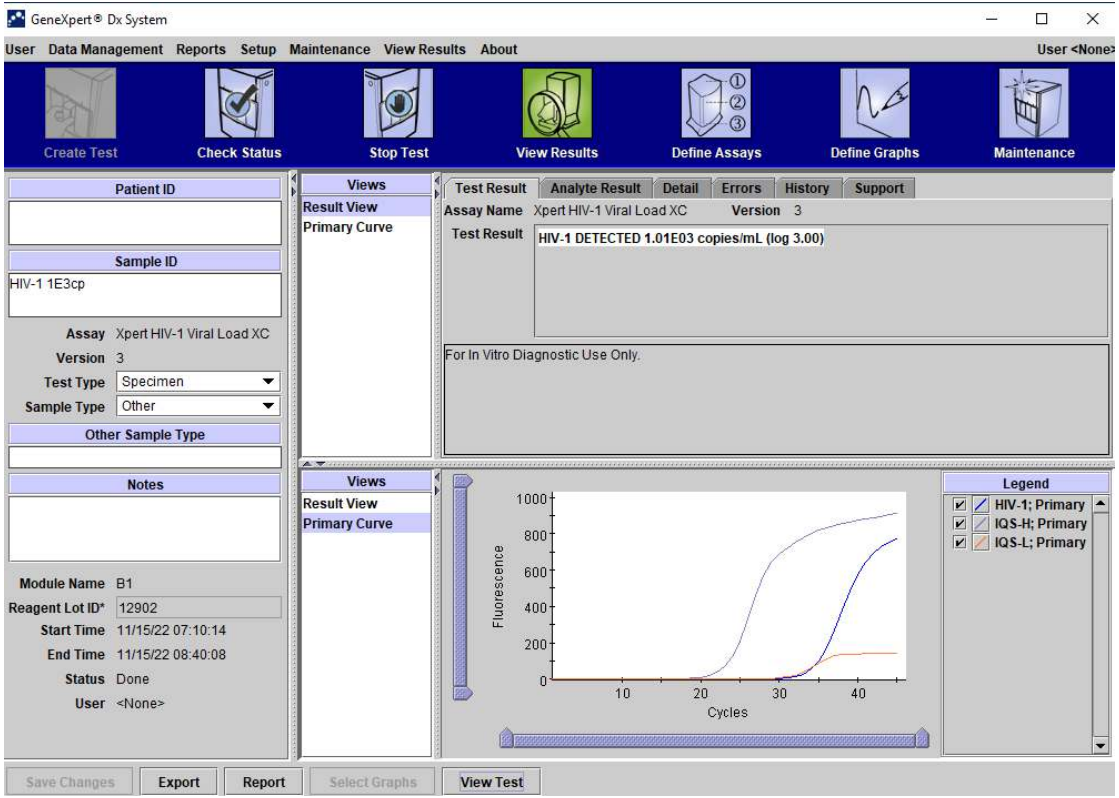
- The target HIV-1 is detected above the analytical measurement range
- IQS-H: PASS
  - IQS-H has a Ct value within the valid range
- IQS-L: PASS
  - IQS-L has a Ct value within the valid range
- Probe Check: PASS

Example calculation:

$1x10^7$ = 10 000 000 (million) copies/mL

HIV-1 DETECTED

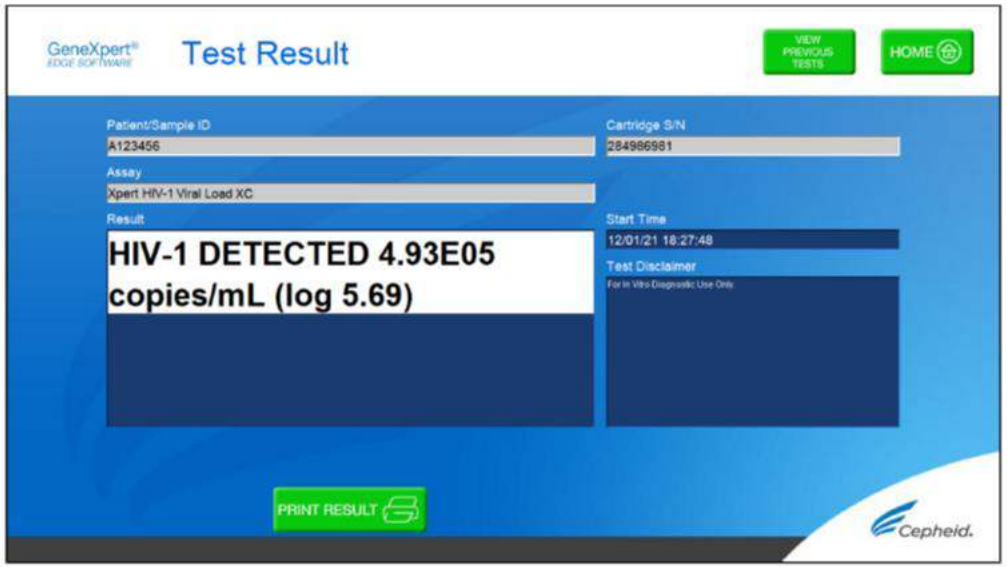
HIV-1 DETECTED xx copies/mL



- The target HIV-1 is detected at a quantitative value
- IQS-H: PASS
  - IQS-H has a Ct value within the valid range
- IQS-L: PASS
  - IQS-L has a Ct value within the valid range
- Probe Check: PASS

HIV-1 DETECTED xx copies/mL

GeneXpert® Edge



- The target HIV-1 is detected at a quantitative value
- IQS-H: PASS
  - IQS-H has a Ct value within the valid range
- IQS-L: PASS
  - IQS-L has a Ct value within the valid range
- Probe Check: PASS

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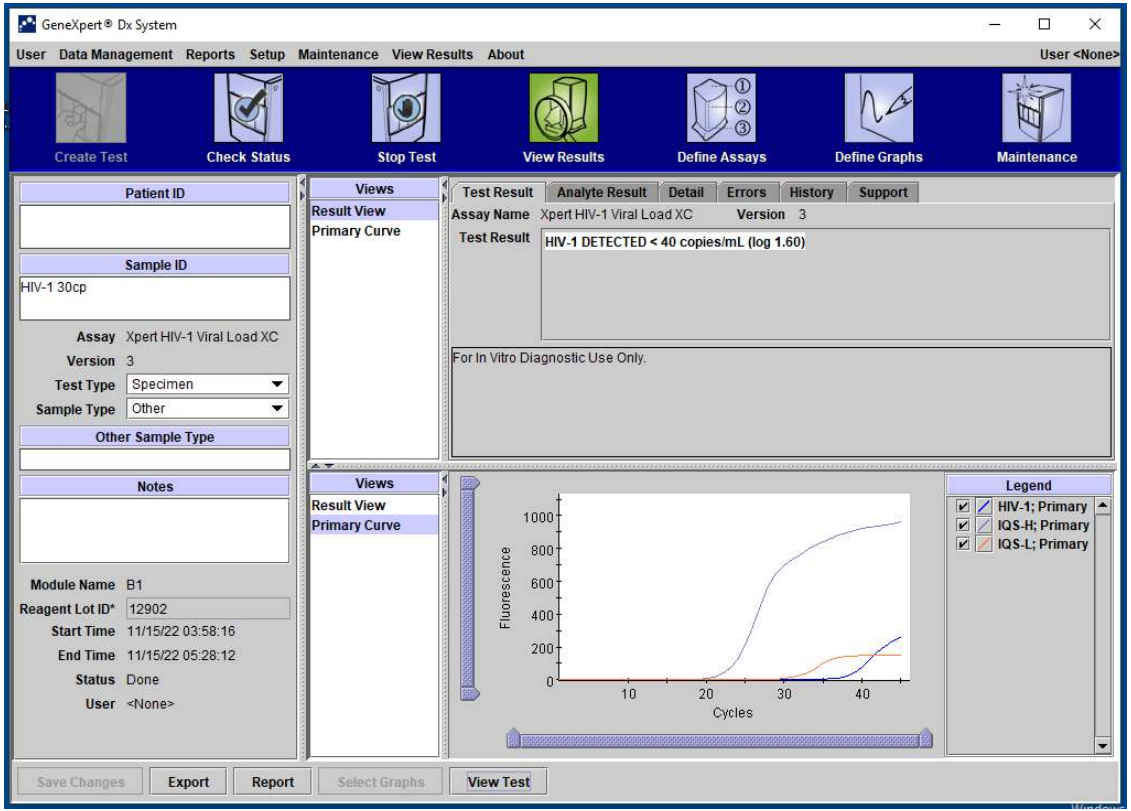
HIV-1 DETECTED

HIV-1 DETECTED < 40 copies/mL



- The target HIV-1 is detected below the analytical measurement range
- IQS-H: PASS
  - IQS-H has a Ct value within the valid range
- IQS-L: PASS
  - IQS-L has a Ct value within the valid range
- Probe Check: PASS

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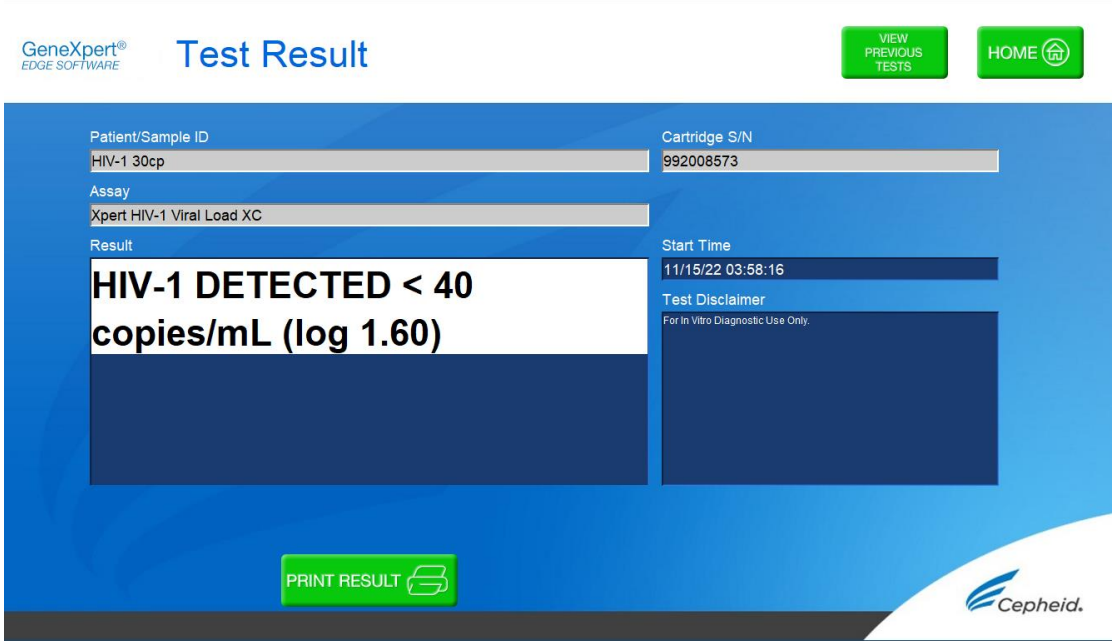
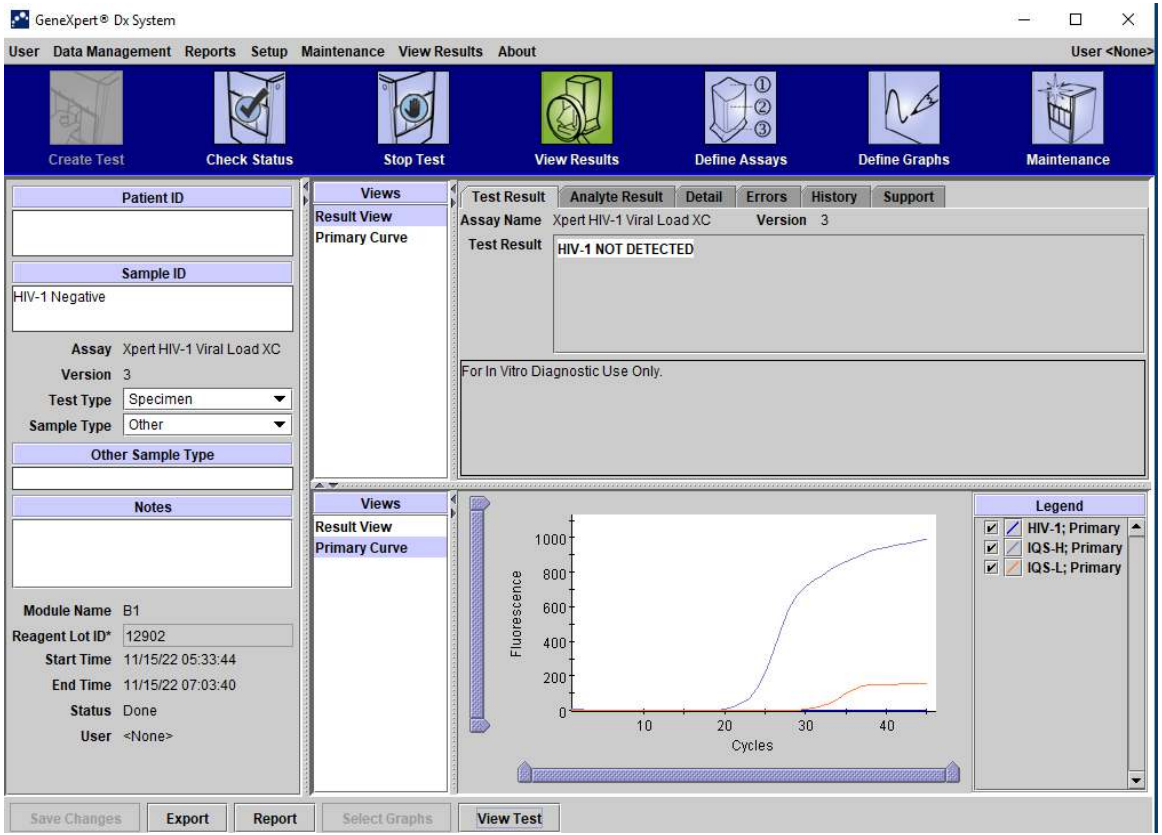
HIV-1 DETECTED < 40 copies/mL



- The target HIV-1 is detected below the analytical measurement range
- IQS-H: PASS
  - IQS-H has a Ct value within the valid range
- IQS-L: PASS
  - IQS-L has a Ct value within the valid range
- Probe Check: PASS

HIV-1 NOT DETECTED

HIV-1 NOT DETECTED



- The target HIV-1 is NOT detected
- IQS-H: PASS
  - IQS-H has a Ct value within the valid range
- IQS-L: PASS
  - IQS-L has a Ct value within the valid range
- Probe Check: PASS

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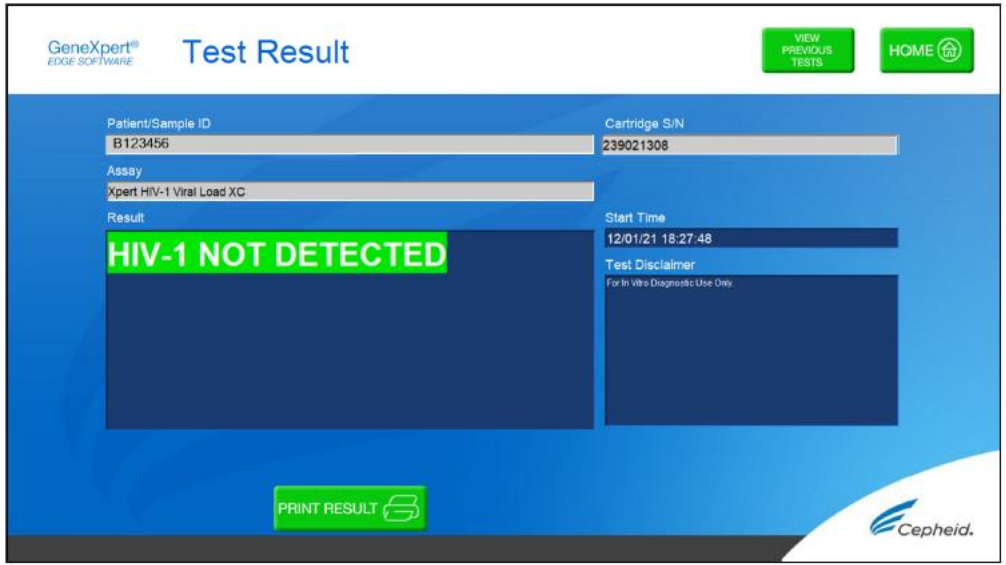
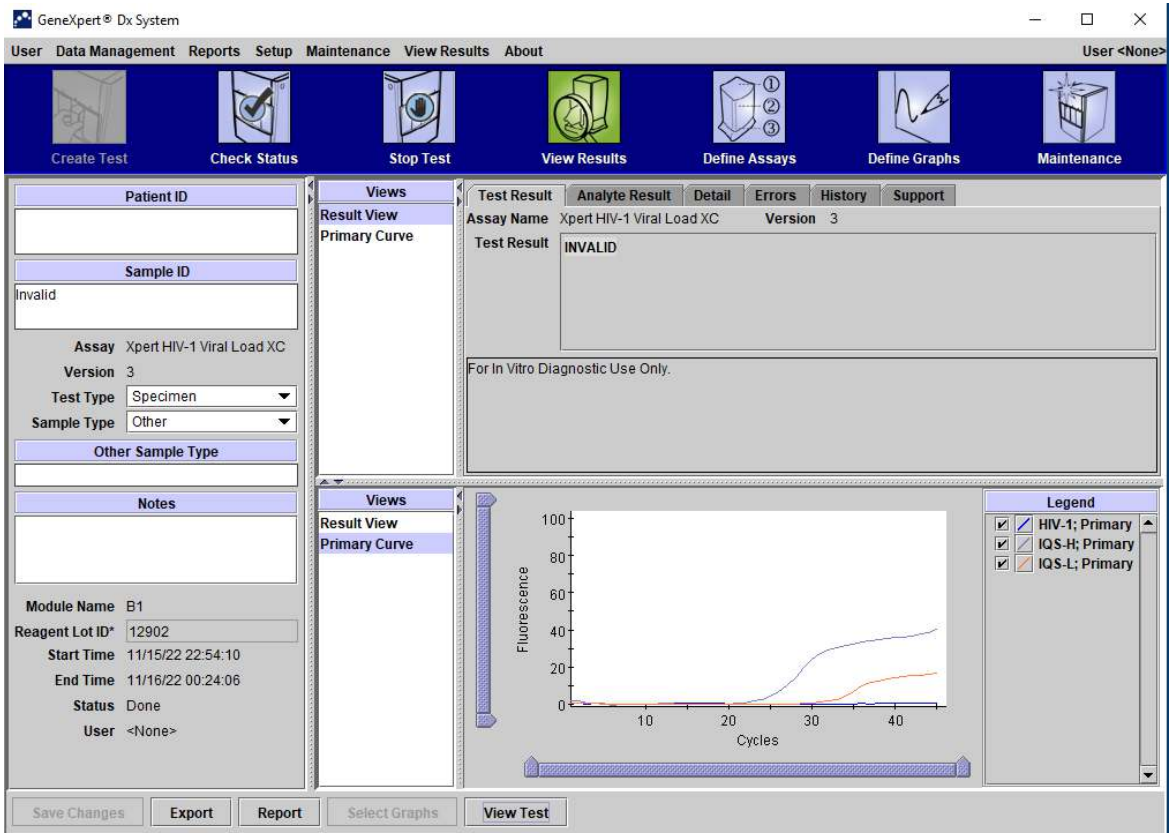
HIV-1 NOT DETECTED



- The target HIV-1 is NOT detected
- IQS-H: PASS
  - IQS-H has a Ct value within the valid range
- IQS-L: PASS
  - IQS-L has a Ct value within the valid range
- Probe Check: PASS

Troubleshooting

INVALID Result



Presence or absence of the HIV-1 target can not be determined

- IQS-H and or IQS-L: FAIL

  Internal Quantitative Control Cycle thresholds are not within the valid range

- Probe Check: PASS

Test Interference

- Potentially Interfering Substances
  - A total of 5 endogenous substances were evaluated
  - Elevated levels of those endogenous substances were shown not to impact the test specificity or interfere with the detection of HIV-1

Substance	Tested Concentration
Albumin	9 g/dL
Bilirubin	40 mg/dL
Hemoglobin	1000 mg/dL
Human DNA	0.4 mg/dL
Triglycerides	3000 mg/dL

Test Interference continued

– The drug components below were shown not to interfere with the quantitation or the specificity of the Xpert® HIV-1 Viral Load XC test

Pool	Drugs
1	Zidovudine, Clarithromycin, Interferon alfa-2b, Maraviroc, Rilpivirine, Ganciclovir
2	Abacavir sulfate, Peginterferon 2a, Ribavirin, Emtricitabine, Adefovir dipivoxil, Entecavir, Valganciclovir HCl
3	Tenofovir disoproxil fumarate, Lamivudine, 3TC, Raltegravir, Etravirine
4	Stavudine, d4T, Efavirenz, Lopinavir, Ciprofloxacin, Indinavir sulfate, Acyclovir
5	Nevirapine, Azithromycin, Telbivudine, Foscarnet[a], Cidofovir
6	Fosamprenavir calcium, Elvitegravir, Darunavir, Cobicistat, Atazanavir
7	Paritaprevir, Simeprevir
8	Daclatasvir, Elbasvir, Ledipasvir, Ombitasvir, Glecaprevir, Velpatasvir, Dasabuvir
9	Dolutegravir, Bictegravir, Doravirine, Maraviroc
10	Acetaminophen, Acetylsalicylic acid, Atorvastatin, Loratadine
11	Nadolol, Ascorbic acid, Phenylephrine, Ibuprofen
12	Artemether, Desethylamodiaquine, Mefloquine, Quinine
13	Primaquine, Chloroquine, Doxycycline
14	Rifampin, INH, Ethambutol, Pyrazinamide
15	Moxifloxacin, Levofloxacin, Amikacin, Bedaquiline[a]
16	Trimethoprim/Sulfamethoxazole, Gentamicin, Metronidazole, Ceftriaxone

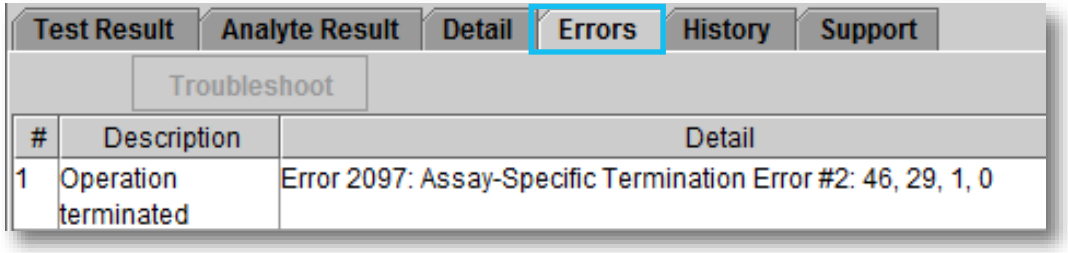
[a] Tested individually instead of in combination with other drug components

Testing of K2 EDTA plasma specimens from five individuals positive for each of the autoimmune disease markers; systemic lupus erythematosus (SLE), anti-nuclear antibodies (ANA) or rheumatoid factor (RF) were shown to not interfere with the quantification of the HIV-1 VL XC test or impact the specificity of the test when tested in presence and absence of HIV-1 RNA.

ERROR Result

ERROR

- The Sample Volume Adequacy (SVA) passes if it meets the validated acceptance criteria.
- An ERROR indicates that the test 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.



Error Code	Cause	Solution
2096	No sample added	– Ensure the Sample is added to cartridge – Ensure cartridge is loaded within 4 hours after adding sample
2097	Not enough sample added	– Ensure the minimum sample volume is added to the cartridge – Ensure cartridge is loaded within 4 hours after adding sample

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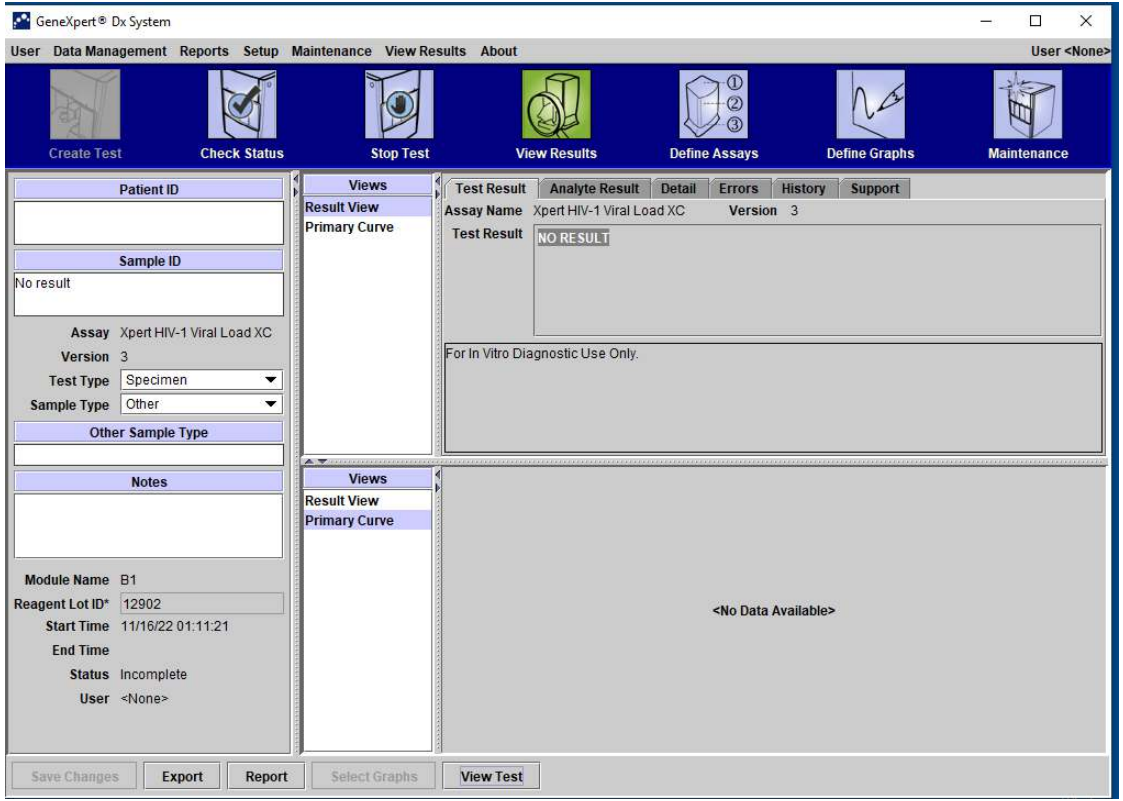
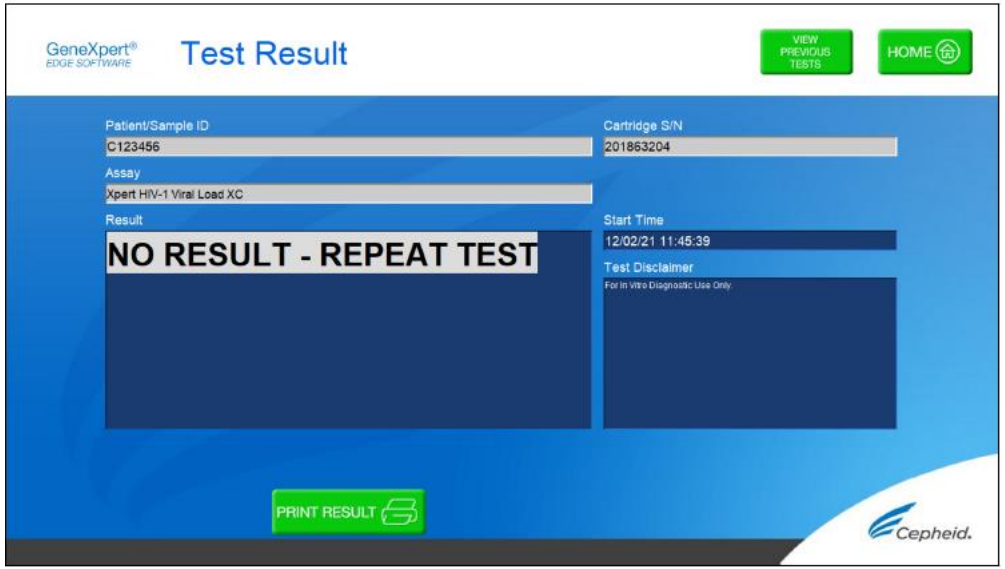
NO RESULT



- The presence or absence of HIV-1 cannot be determined.
- A NO RESULT indicates that insufficient data were collected.
- IQS-H or IQS-L: NO RESULT
- Probe Check: NA (not applicable)
- **Cause**
  - Test was stopped with stop test button
  - Electrical failure
- **Solution**
  - Secure the power
  - Repeat the test with a new cartridge

NO RESULT



- The presence or absence of HIV-1 cannot be determined.
- A NO RESULT indicates that insufficient data were collected.
- IQS-H or IQS-L: NO RESULT
- Probe Check: NA (not applicable)
- **Cause**
  - Test was stopped with stop test button
  - Electrical failure
- **Solution**
  - Secure the power
  - Repeat the test with a new cartridge

Re-test Procedure

1

Discard used cartridge

Follow your institution's safety guidelines for disposal of cartridges

2

Obtain the residual sample, mix according to Package Insert

If the leftover sample volume is insufficient, or the retest continues to return an INVALID, ERROR, or NO RESULT, collect a new sample

3

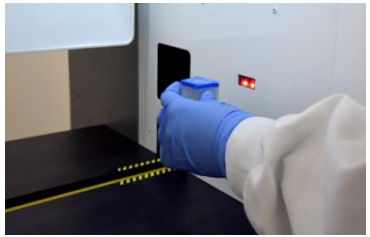
Obtain a new cartridge

Label appropriately as retest on the new cartridge

Process the sample per the package insert

4

Run the test on the GeneXpert® System



Technical Assistance

- Before contacting Cepheid Technical Support, collect the following information:
  - Product name
  - Lot number
  - Serial number of the System
  - Error messages (if any)
  - Software version

- Log your complaint online using the following link ***http://www.cepheid.com/en/support:*** *Create a Support Case*

Cepheid
A better way.

Thank You

www.Cepheid.com