Test Technical Training : Xpert® HIV-1 Qual XC

GXHIV-QA-XC-CE-10
For CE-IVD Only

CE 2797 IVD In Vitro Diagnostic Medical Device

302-3910 Rev. B September 2023

May not be available in all countries. Not available in the United States

Training Agenda

Xpert® HIV-1 Qual XC

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

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Training Objectives

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

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

The Cepheid Solution

- Simultaneous Detection
- **Dual targets for HIV-1 detection**
- On-board controls for each sample
- Sample Adequacy Control (SAC)
- Probe Check Control (PCC)
- Specimen Processing Control (SPC)
- Results in approximately:
- **79 minutes for Whole Blood**
- **91 minutes for DBS**
- Closed cartridge system minimizes risk of contamination
- On-demand results
- Random access

Intended Use

- Xpert® HIV-1 Qual XC (Extended Coverage) is an in vitro nucleic acid amplification test for the qualitative detection of human immunodeficiency virus type 1 (HIV-1) total nucleic acids, on the automated GeneXpert® System. The test is used to detect HIV-1 in **human dried blood spots (DBS)** and **EDTA capillary or venous whole blood (WB)** specimens from individuals suspected of HIV-1 infection.
- Xpert® HIV-1 Qual XC is intended to aid in the diagnosis of HIV-1 infection in conjunction with clinical presentation and other laboratory markers in **infant, adolescent and adult populations.**
- Xpert® HIV-1 Qual XC is intended to be used by laboratory professionals, trained health care professionals or other health care workers receiving appropriate training on the use of the device. This test may be used in **laboratory** or **near-patient** testing environments.

Intended Use continued

- The test is not intended to be used as a blood, organ or tissue donor screening test for HIV-1.

Targets and Probes

Targets

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

Probes

- 2 probes for Dual HIV-1 Target (LTR & POL gene)
- 1 probe for the Sample Adequacy Control (SAC)
- 1 probe for Specimen Processing Control (SPC)

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

Assay Requirements

GeneXpert Systems

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

Test Kits (CE-IVD)

- GXHIV-QA-XC-CE-10

Sample Collection

- K2 EDTA tube
- DBS filter paper cards for 12 mm spots, e.g., Whatman™ 903, Munktell or equivalent

Other materials

- Personal Protective Equipment (PPE)
- 10% Bleach / Sodium Hypochlorite
- 70% ethanol or denatured ethanol
- Lancets, Serviettes/Wipes, plastic sealable bags
- Antiseptic

Optional

- Uninterruptible Power Supply /Surge Protector
- Printer

Good Laboratory Practice

Personnel Protective Equipment (PPE)	• Wear clean lab coats 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 sample away from kit to prevent contamination
Equipment(s)	• Use filtered tips when recommended • Follow the manufacturer's requirements for calibration and maintenance of equipment(s)

Kit Storage and Handling

Xpert® HIV-1 Qual Kit Contents

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

Note: Sample Reagent contains guanidinium hydrochloride, which is harmful if swallowed (H302) and Irritating to eyes and skin (H313/H320).

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

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Xpert® HIV-1 Qual XC Kit Storage and Handling

- Store the Xpert® HIV-1 Qual XC cartridges at **2–28° C**
- Bring Xpert® HIV-1 Qual XC test 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.
- Use cartridge within **4 hours** after opening the cartridge lid and adding sample.
- Do not use a cartridge that has leaked.
- Do not use cartridges that previously have been frozen.
- Do not use a cartridge past the expiration date.
- Store cartridges in the kit boxes until time for use and avoid exposure of direct sunlight.

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Test Limitations

- Good laboratory practice and changing gloves between handling samples are recommended to avoid contamination of samples or reagents.
- The performance of the HIV-1 Qual XC was validated using the procedures provided in this package insert only. Modifications to these procedures may alter the performance of the test.
- Rare mutations, deletions or insertions within the target region of the Xpert® HIV-1 Qual XC test may affect primer and/or probe binding resulting in failure to detect the virus.
- The Xpert® HIV-1 Qual XC test has been validated only for use with capillary and venous whole blood and with DBS specimens. Testing of other specimen types with this test may lead to inaccurate results.
- The Xpert® HIV-1 Qual XC test has been validated only for use with K2 EDTA tubes. Usage of other tubes than K2 EDTA tubes may lead to inaccurate results.

Test Limitations continued

- Proper performance of this test requires appropriate specimen collection, storage, handling, and transport to the test site.
- A negative test result with the Xpert® HIV-1 Qual XC test does not preclude HIV-1 infection. Results from the Xpert® HIV-1 Qual XC test should be interpreted in conjunction with clinical presentation and other laboratory markers.
- The Xpert® HIV-1 Qual XC test is not intended for the screening of blood, plasma, serum, or tissue donations for HIV-1.
- False negative results may occur if virus is present at levels below the analytical limit of detection.
- The effect of interfering substances has only been evaluated for those listed within the labeling. Interference by substances other than those described can lead to erroneous results.

Test Limitations continued

- Detection of HIV-1 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.
- Whole blood that has clotted or coagulated may lead to errors or invalid results.
- The Xpert® HIV-1 Qual XC test has not been evaluated in those receiving pre-exposure prophylaxis (PrEP).
- HIV may be undetectable by the HIV-1 Qual XC test in those receiving ART.
- The Xpert® HIV-1 Qual XC test is intended to aid in the diagnosis of HIV-1 infection and should not be used in isolation but in conjunction with clinical presentation and other laboratory markers.

Test Limitations continued

- 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.

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 specimens should be treated with standard precautions. Guidelines for specimen handling are available from the U.S. Centers for Disease Control and Prevention[14] and the Clinical and Laboratory Standards Institute.[15]
- Wear protective disposable gloves, laboratory coats and eye protection when handling specimens and reagents. Wash hands thoroughly after handling specimens and test reagents.
- 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.

14. Centers for Disease Control and Prevention. Biosafety in Microbiological and Biomedical Laboratories. Richmond JY and McKinney RW (eds) (1993). HHS Publication number (CDC) 93-8395.
15. Clinical and Laboratory Standards Institute. Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline. Document M29 (refer to latest edition).

Warnings and Precautions continued

- Follow your institution's safety procedures for working with chemicals and handling biological samples.
- When processing more than one sample at a time, open only one cartridge; add sample and close the cartridge before processing the next sample.
- Good laboratory practices, including changing gloves between handling patient specimens, are recommended to avoid contamination of specimens or reagent.
- 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.

Warnings and Precautions continued

❖ DO NOT :

- Substitute Xpert® HIV-1 Qual XC test reagents with other reagents.
- Open the Xpert® HIV-1 Qual XC test cartridge lid except when adding the WB or DBS sample.
- Use a cartridge if it appears wet or if the lid seal appears to have been broken.
- Use a cartridge that has been dropped after removing it from the packaging.
- Shake the cartridge. Shaking or dropping the cartridge after opening the cartridge lid may yield invalid results
- Use a cartridge that has a damaged reaction tube.
- Place the sample ID label on the cartridge lid or on the barcode label.
- Each single-use Xpert HIV-1 Qual XC test cartridge is used to process one specimen. Do not reuse spent cartridges.
- The single-use disposable pipette is used to transfer one specimen. Do not reuse spent disposable pipettes.
- Always keep the Xpert® HIV-1 Qual XC test cartridge in an upright position to avoid leakage.

Warnings and Precautions continued

- 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.[17]

- For Instrument System cleaning and disinfecting instructions, refer to the appropriate *GeneXpert® Dx System Operator Manual, GeneXpert® Infinity System Operator Manual or GeneXpert® Edge System User's Guide.*

17. World Health Organization. Safe management of wastes from health-care activities. 2nd Edition. WHO, 2014. Accessed April 20, 2018 at http://www.who.int/water_sanitation_health/publications/wastemanag/en/

Automated Xpert 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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Specimen Collection, Storage and Handling

Venous Whole Blood (WB) Collection

- **Venous Whole Blood**
  - Collect venous WB in sterile K2 EDTA tube as per manufacturer's instructions
  - a minimum of 100ul whole blood(WB) is required

Capillary Whole Blood (WB) Collection

- Collect in K2 EDTA-coated collection tubes for small volumes as per manufacturer's instructions
- Collect more than 100ul (e.g.150ul) to compensate volume loss on tube surfaces
- If possible, collect enough WB volume for retests, either in the same collection tube or in a separate tube, depending on tube volume

Capillary Whole Blood (WB) Collection continued

❖Heel Stick collection

- It is suggested that the child is comfortable and if possible, calm, and in a secure position so the heel can be stabilized.
- Use a new pair of gloves for each patient.
- Locate the site of the heel for the skin prick and clean the site using a sterilizing wipe. The site should be dry before puncture. The sides of the bottom of the heel may provide the best sites for collection.
- Using a sterile lancet appropriate for infants, puncture the skin and allow for adequate blood flow. Do not squeeze or repeatedly press the site but gentle pressure of the heel may help the blood to flow more freely.
- The first drops of blood may be small and of inadequate volume, so these can be wiped off until larger blood drops are seen.
- Allow blood to flow freely from the site directly into the K2 EDTA coated collection tube. Do not allow the blood to clot or coagulate as this may interfere with testing.
- Cover the heel site with a bandage after the blood has been collected.

Capillary Whole Blood (WB) Collection continued

❖Fingerstick collection

- Use a new pair of gloves for every patient.
- Locate an appropriate site for the puncture. The sides of the third or fourth fingers with adequate soft tissue often work well. Avoid the very tip of the fingers and the center of the finger pad.
- Warming of the hands and fingers and holding the downwards may assist with proper blood flow.
- Clean the site using a sterilizing wipe and ensure that it is dry before attempting the puncture.

Capillary Whole Blood (WB) Collection continued

- Using a sterile lancet, puncture the finger slightly to the side of the center of the finger pad. It is advised to use a lancet that will provide free blood flow. Do not squeeze or repeatedly press the site but gentle pressure to the tip of the finger may help the blood to flow more freely.
- The first drops of blood may be small and of inadequate volume, so these can be wiped off until larger blood drops are seen.
- Allow blood to flow freely from the site directly into the K2 EDTA coated collection tube. Cover the site with a plaster or adhesive dressing after the blood has been collected.

Dried Blood Spot (DBS) Collection

- Collect dried blood spot (DBS) specimen
- DBS should be prepared using Whatman 903, Munktell filter paper cards or equivalent from blood collected in K2 EDTA obtained from:
  - a heel-stick
  - finger-stick
  - toe-stick
  - an EDTA-tube
- Ensure that the entire circle is covered with blood (approximately 60–70 µL). A minimum of **two circles** should be made from each sample to allow for retesting.
- Air-dry the card at room temperature for a minimum of 4 hours. Package each card in an individual resealable bag with a desiccant sachet in each bag.

https://www.spotonsciences.com/knowledge-center/dbs-technology/

For further details about DBS preparation and packaging please refer to related chapter in "WHO DBS drug resistance testing Manual"

Sample Transport and Storage

Sample type	Collection device	Volume	Storage temperature
Venous blood	K2 EDTA	100ul	○ 2-8°C for 96 hours OR ○ 2-35°C 24 hours
Capillary blood	K2 EDTA	More than 100ul	○ 2-35°C for 60 minutes
Dried blood spots	Whatman 903, Munktell filter paper cards or equivalent	Entire circle (approximately 60-70ul)	○ 2-25°C/ Frozen @ -15°C or Colder 16 weeks ○ 2-35°C up to 8 weeks

Cartridge Preparation

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 - Whole Blood

Xpert® HIV-1 Qual XC Cartridge Preparation *using whole blood*

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

Before starting the procedure, allow the cartridge and sample to equilibrate to room temperature (15–30 °C).

Cepheid. A better way.

1 Mix the EDTA whole blood by inverting the vial at least 7 times.

2 Label the side of the cartridge with the patient ID.

3 Open the cartridge lid.

4 Fill the pipette with 100 µL of EDTA whole blood by squeezing the bulb, ensuring there are no bubbles.

5 Immediately transfer the EDTA whole blood into the sample chamber.

6 Close the cartridge lid.

7 Start the test within 4 hours.

CE IVD *In Vitro* Diagnostic Use *In vitro* medical diagnostic device. May not be available in all countries.

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Cartridge Preparation – Dried Blood Spots

Xpert® HIV-1 Qual XC Cartridge Preparation *using dried blood spots*

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

Before starting the procedure:
- Allow the cartridge and sample to equilibrate to room temperature (15–30 °C).
- Make sure that the card is air-dried at room temperature (15–30 °C) for a minimum of 4 hours.
- Clean the scissors/tweezers using 10% bleach and allow to dry between each sample.

Cepheid. *A better way.*

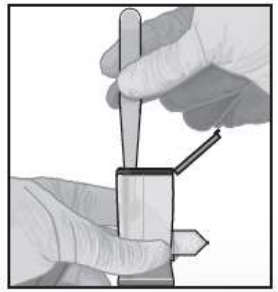
1 Label the side of the cartridge with the sample ID.

2 Open the cartidge lid.

3 Using sterilized scissors, cut out one DBS from the filter paper card following the dashed line. If the dashed line is perforated, use tweezers to detach the DBS.

4 Using tweezers, insert the DBS into the sample chamber.

5 Push DBS down until it reaches the bottom of the chamber with tweezers.



6 Close the cartridge lid.

7 Start the test within 4 hours after adding the sample.

CE IVD *In Vitro* Diagnostic Use *In vitro* medical diagnostic device. May not be available in all countries.

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Create a Test : GeneXpert® System / GeneXpert® Infinity

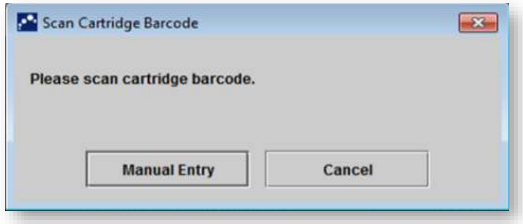
1 Create Test

GeneXpert®

Start the test in **4hours** after adding the sample to the cartridge

2 Scan barcode messages:

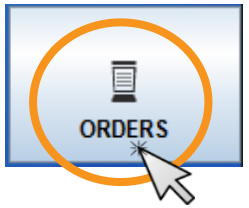
Cartridge/ Patient and/or Sample ID



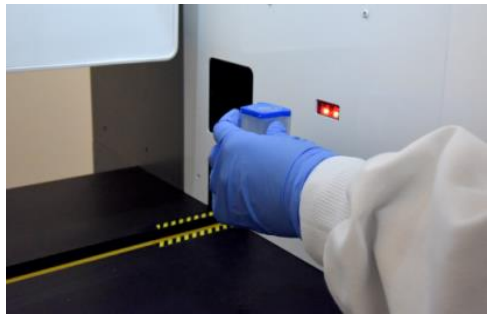
By default, do not click on **Manual Entry** or **Cancel**

3 Scan the cartridge

GeneXpert® Infinity



Place the cartridge on the conveyor within **4hours** of adding the sample.



"For complete details on how to run a test, refer to the Package Insert and the GeneXpert® Dx or Xpertise Operator Manuals."

Create a Test on Dx Software

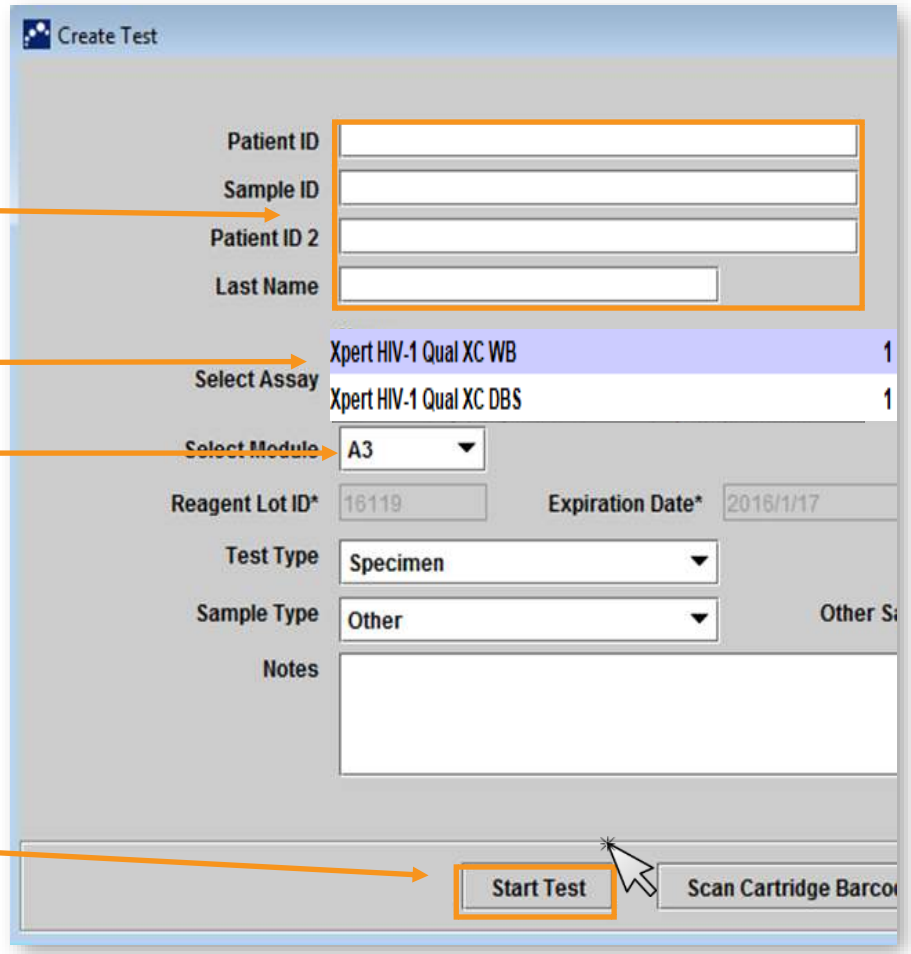
4 Complete the fields as required

5 **Chose appropriate ADF according to sample type**

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



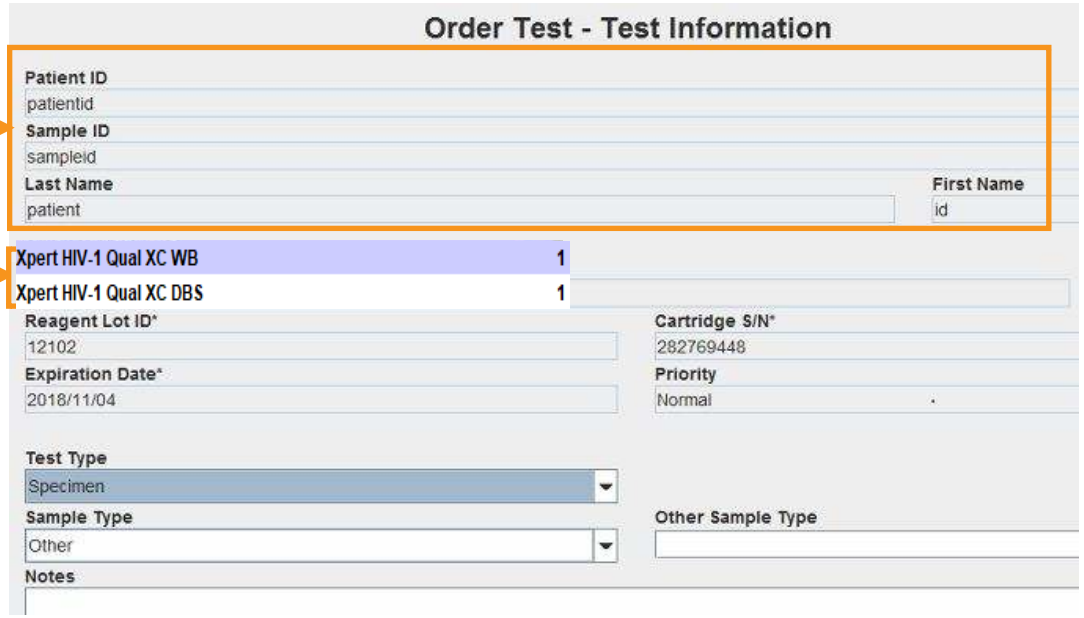
Create a Test on Xpertise Software

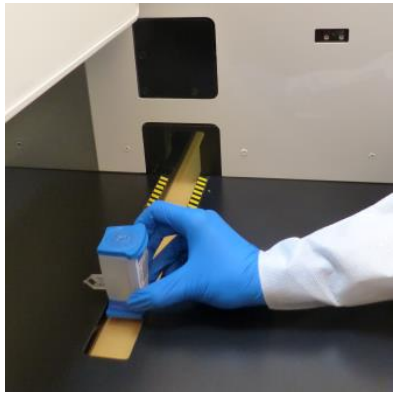
4 Complete the fields as required

☐ **Chose appropriate ADF according to sample type**

6 Click on SUBMIT

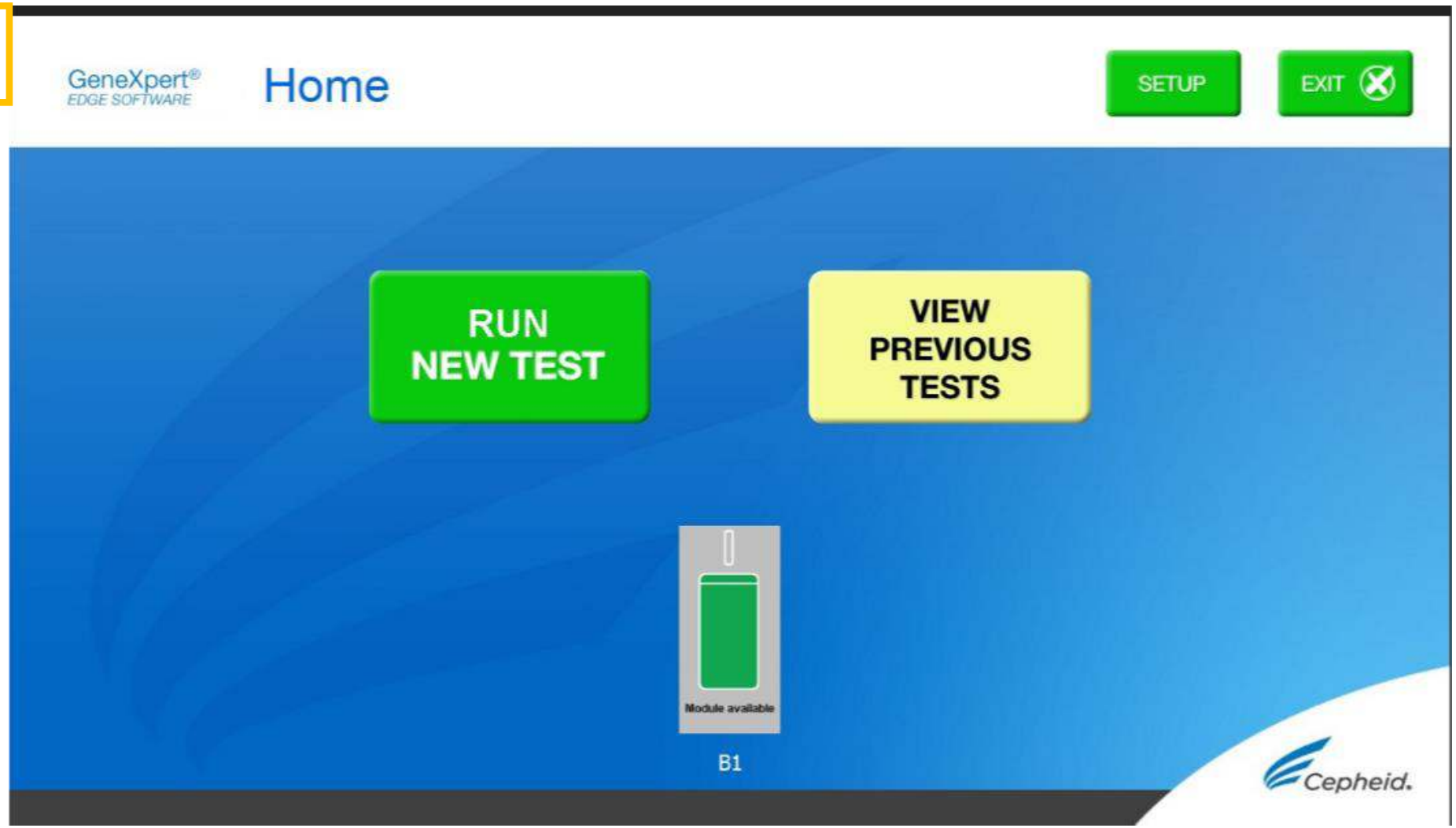
7 Place the cartridge into the conveyor belt





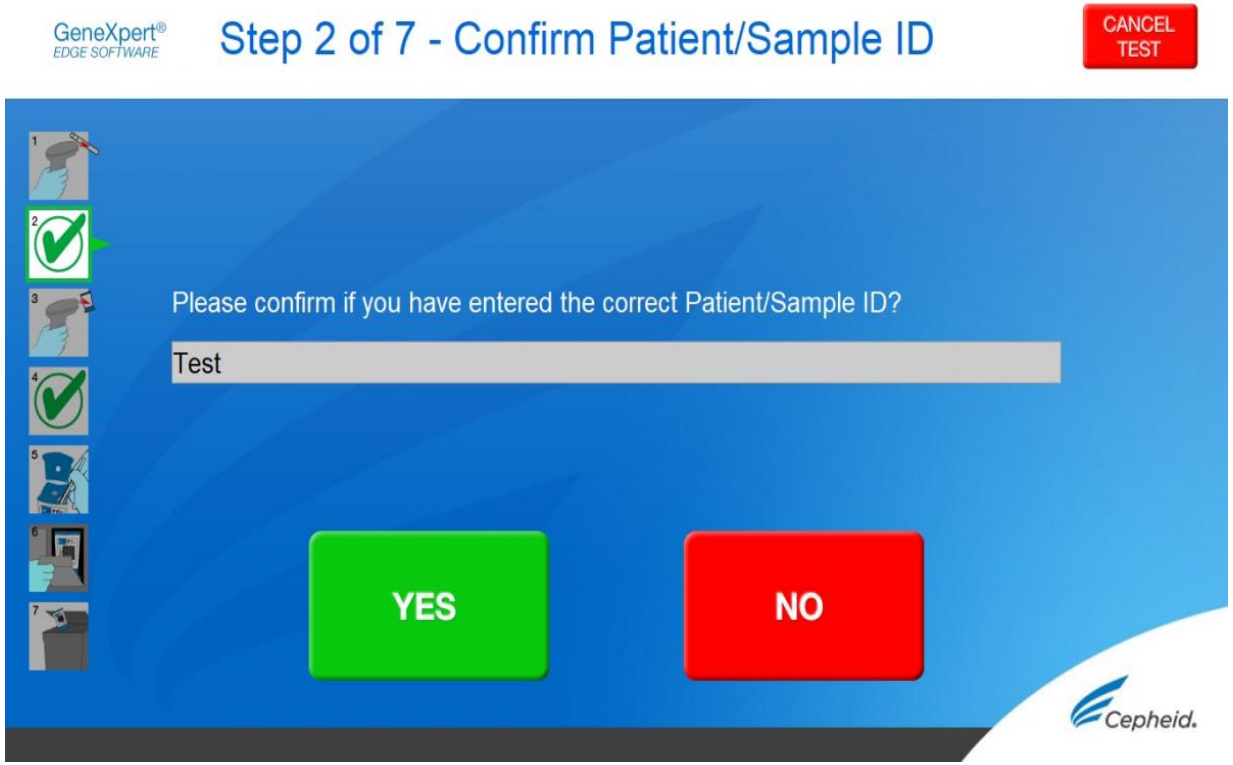
Create a Test on GeneXpert® Edge System

1



Create a Test on GeneXpert® Edge

2



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Create a Test on GeneXpert® Edge

3

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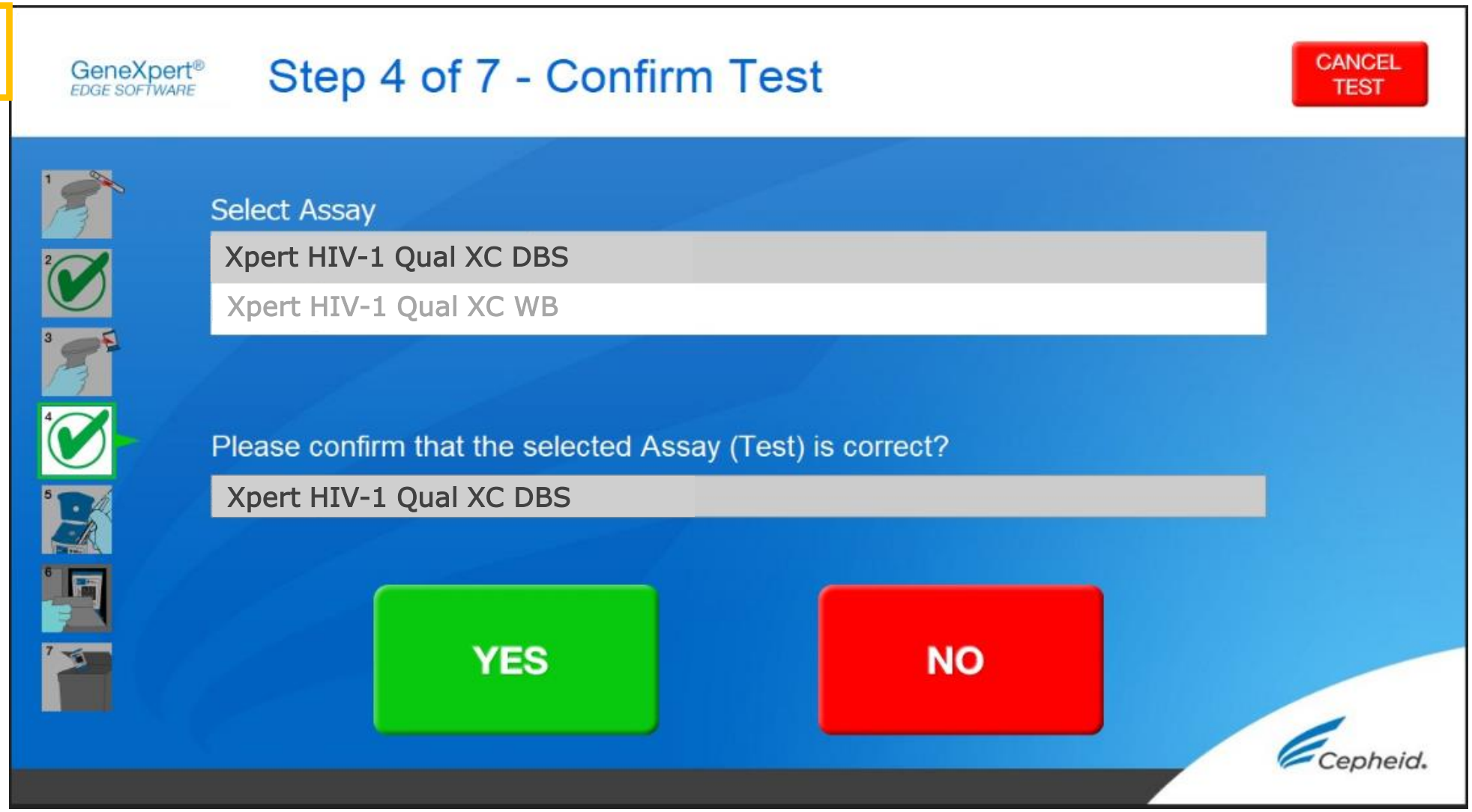
Create a Test on GeneXpert® Edge

4



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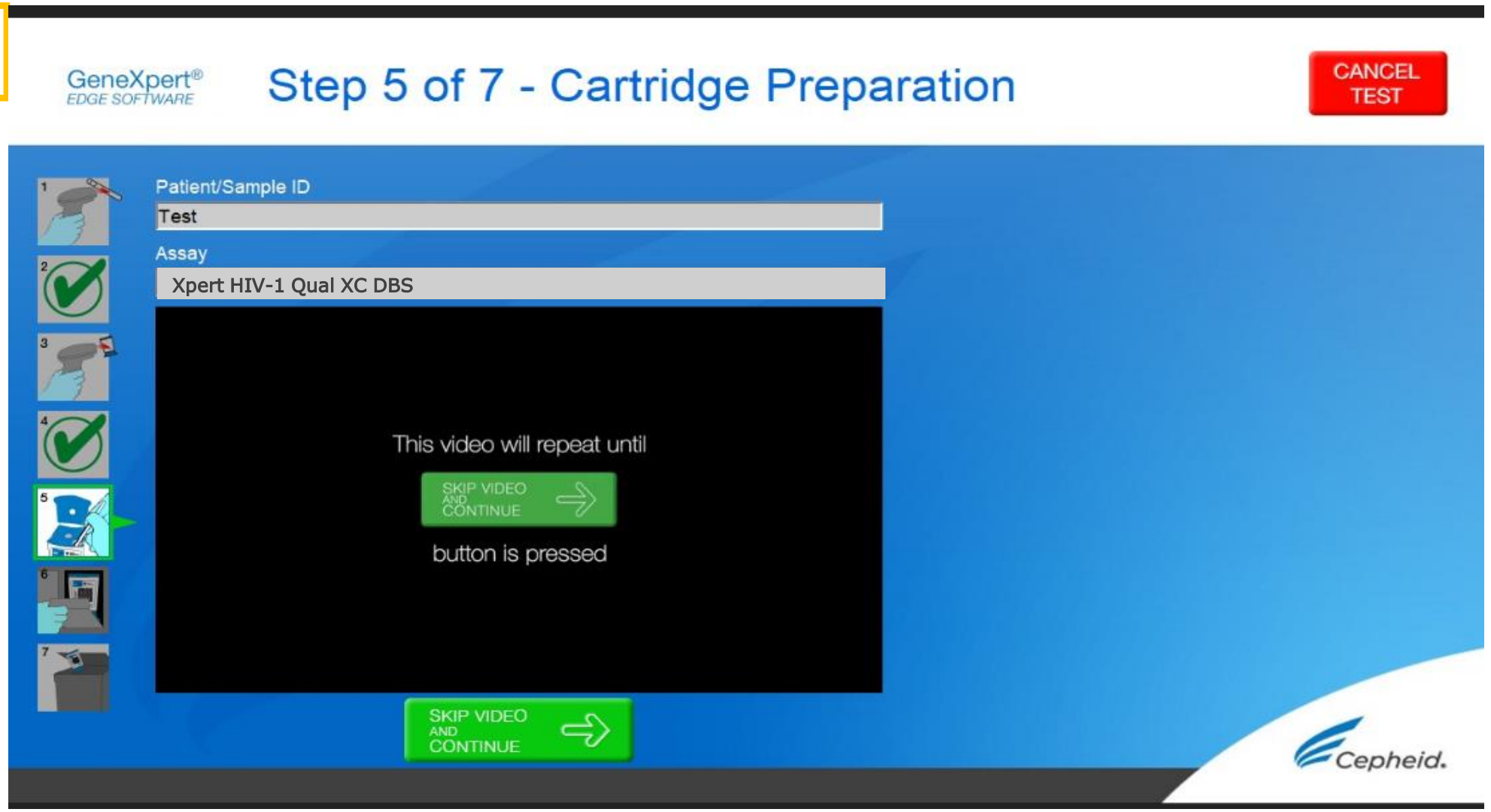
Create a Test on GeneXpert® Edge

5



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Create a Test on GeneXpert® Edge

6

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Automated Xpert® Protocol

1 Sample is added to the cartridge

2 The cartridge is loaded into the instrument

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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Quality Controls

Cepheid Control Strategy

CONTROL

- **Xpert® HIV-1 Qual 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 Adequacy Control (SAC)
    - Probe Check Controls (PCC)
    - Specimen Processing Control (SPC)

Internal Quality Controls

- **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

- **Sample Processing Controls (SPC)**
  - Synthetic Armoured RNA® control
    - Verifies adequate sample processing
    - Detects specimen-associated inhibition of the RT-PCR
    - Should be positive in a negative sample
    - Can be positive or negative in a positive sample

Internal Quality Controls

- **Sample Adequacy Control (SAC)**
  - Ensure that sample added is a human sample
  - If a volume has been added that is not a human sample, an insufficient volume or if an empty DBS has been inserted into the cartridge, an INVALID result will be displayed after the run.
  - If WB ADF instead of DBS ADF is chosen, an INVALID result will be displayed after the run.
  - The SAC should be positive in a negative sample and can be negative or positive in a positive sample.
  - If the SAC doesn't meet the validated acceptance criteria, the test result will show INVALID

Commercially Available External Controls

These are QC and verification panel suggestions for Xpert® HIV-1 Qual XC.

Vendor	Catalog #	Description	Configuration	Storage
Zeptometrix®	NATHIV1-ERCL	Low positive control (1000 IU/mL)	1.0 mL x 6 vials	2-8°C
Zeptometrix®	NATHIV1-ERCM	Medium positive control (50000 IU/mL)	1.0 mL x 6 vials	2-8°C
SmartSpot	SSQ-XHIVQD-V16	16 Dried Blood Spots (DBS) Precision Verification Panel	6x DBS High Positive 6x DBS Low Positive 4x DBS Negative	ambient
SmartSpot	SSQ-XHIVQD-V28	Liquid Control Verification Panel	2x 1.0mL High Positive 2x 1.0mL Low Positive 2x 1.0mL Negative	ambient

**** For more information, visit:***
ZeptoMetrix® : http://www.zeptometrix.com/
SmartSpot: https://www.smartspotq.com

Commercially Available External Controls

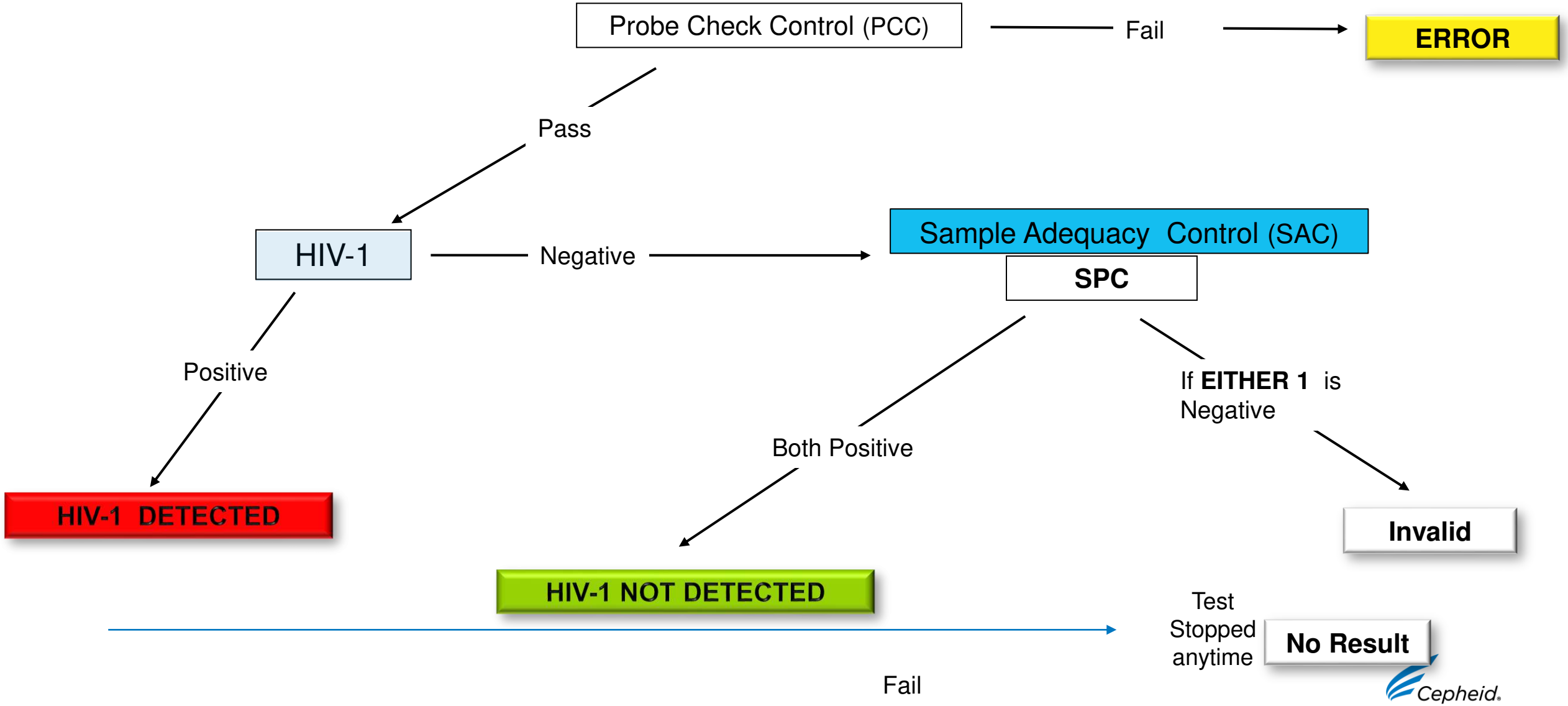
Vendor	Panel	Sample format
NHLS South Africa	Proficiency Testing Scheme – Early Infant Diagnosis	DBS
SmartSpot	EQA Panels appropriate for use with Xpert® HIV-1 Qual XC	DBS and Liquid

- *"These are PT/EQA suggestions for Xpert HIV-1 Qual XC. There may be additional PT/EQA Panels compatible with Xpert® HIV-1 Qual XC that are not listed above"*

- *External controls should be used in accordance with local, state accrediting organizations, as applicable*

Result Interpretation

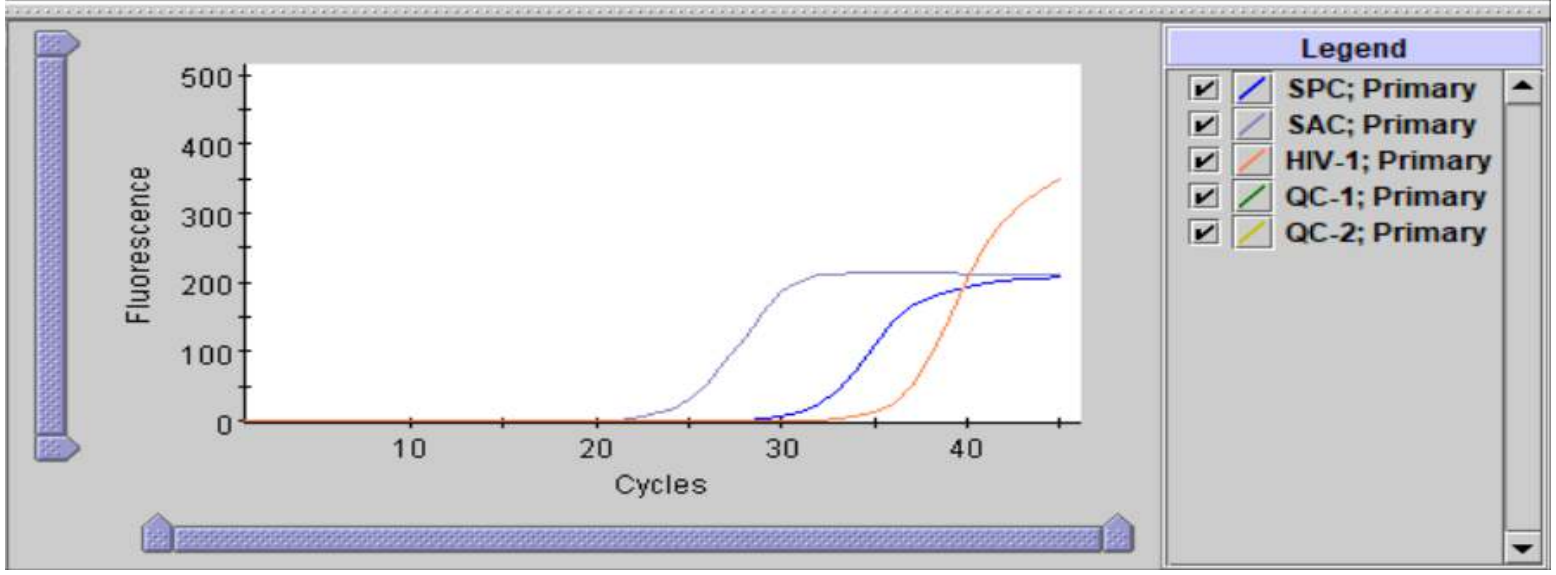
Result Interpretation



HIV-1 DETECTED

Test Result | Analyte Result | Detail | Errors | History | Support

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
SPC	32.1	208	NA	PASS
SAC	24.6	212	NA	PASS
HIV-1	37.3	351	POS	PASS
QC-1	0.0	0	NEG	PASS
QC-2	0.0	0	NEG	PASS



The target HIV-1 is detected

- SPC: NA (Not Applicable) SPC is ignored when HIV-1 target amplified
- SAC: NA (Not Applicable) SAC is ignored when HIV-1 target amplified
- Probe Check: PASS

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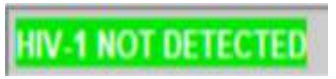
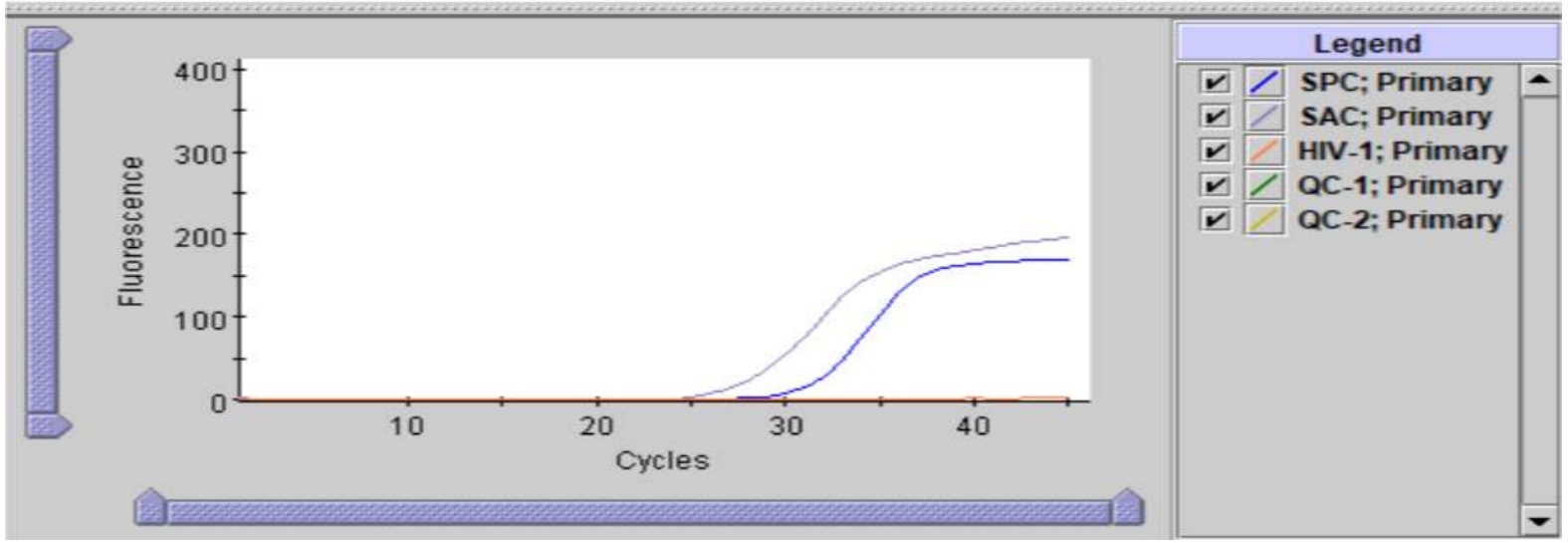
HIV-1 NOT DETECTED



Test Result | Analyte Result | Detail | Errors | History | Support

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
SPC	31.8	170	PASS	PASS
SAC	28.2	197	PASS	PASS
HIV-1	0.0	2	NEG	PASS
QC-1	0.0	0	NEG	PASS
QC-2	0.0	0	NEG	PASS



The target HIV-1 is NOT detected

- SPC: PASS

SPC has a Ct value within the valid range

- SAC : PASS

SAC has a Ct value within the valid range

- Probe Check: PASS

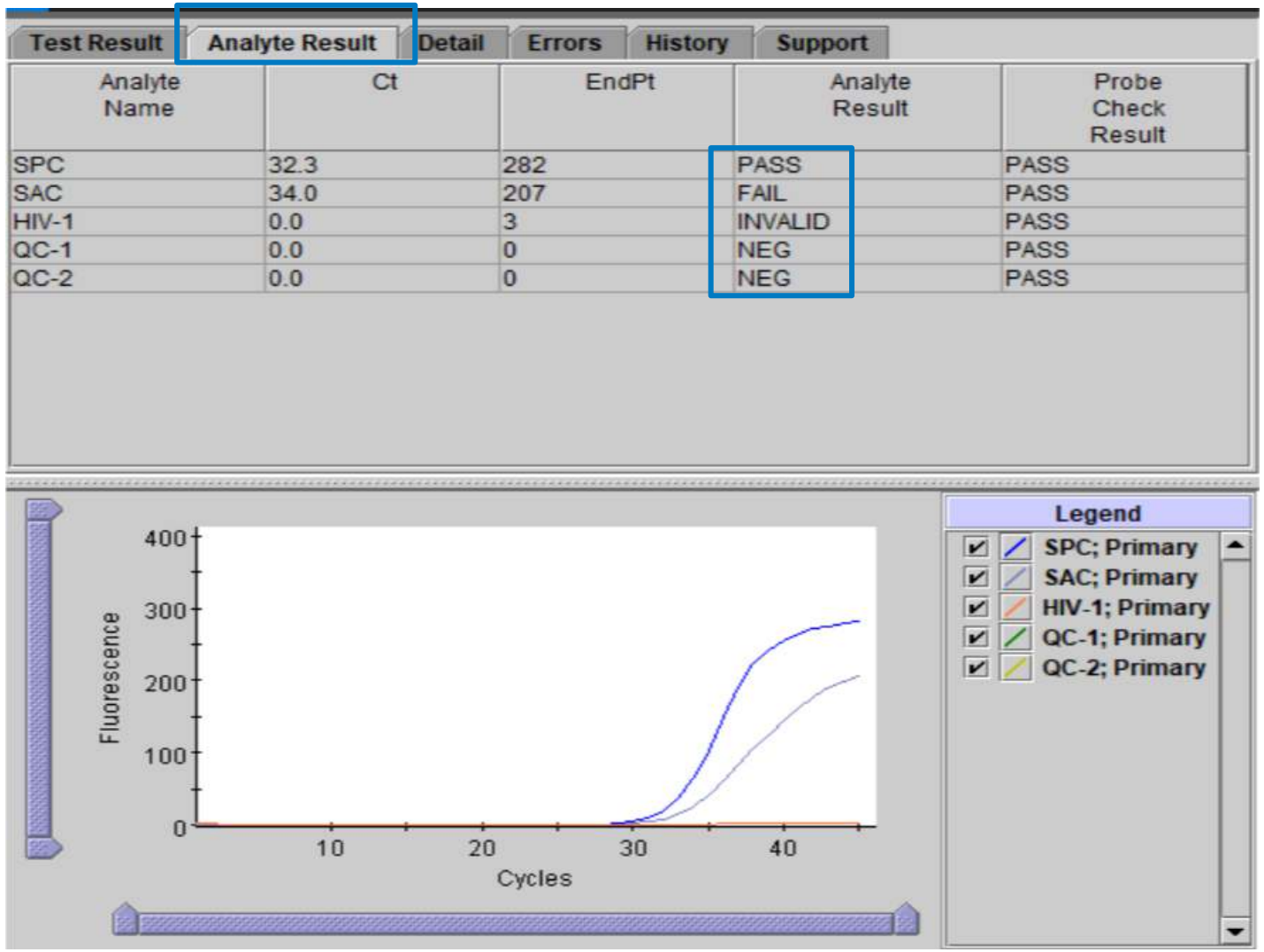
Troubleshooting

Factors That Negatively Affect Results

- Improper specimen collection
  - Performance with other collection devices and specimen types has not been assessed
- Improper transport or storage of collected specimen
  - Refer to the Package Insert for the appropriate handling instructions
- Improper testing procedure
  - Modification to the testing procedures, technical error and sample mix-up may impact the test results
  - Careful compliance with the package insert is necessary to avoid erroneous results
- Improper selection of the ADF for the test order
  - Accidentally selecting WB ADF for test order with a DBS sample.

INVALID

INVALID Result



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

- SPC/ SAC : FAIL
  - SPC / SAC Ct value is not within the valid range
- Probe Check: PASS

– Possible Causes
  – Improper sample collection (using heparin tube for e.g)
  – Incorrect sample preparation (Plasma)
  – Improper storage of the kit
  – Inefficient sample processing in cartridge
  – Presence of inhibitors in the sample
  – Incorrect ADF selected (WB ADF chosen instead of DBS ADF)
– Solution
  – Repeat the test with a new cartridge and new sample

Assay Interference (Endogenous Substances and Concentration Tested)

- Potentially Interfering Substances (Please refer Package Insert for more details)
  - **A total of 6 endogenous substances were evaluated**
  - **Elevated levels of those endogenous substances were shown not to interfere with the detection of HIV-1 or impact the specificity of the HIV-1 Qual test when tested in the presence/absence of HIV-1.**

Substance	Tested Concentration
Albumin	9.6 g/dL
Bilirubin	62 mg/dL
Hemoglobin	20 g/L
Human DNA	0.4 mg/dL
Triglycerides	3200 mg/dL
White blood Cells (WBCs)	1.70E+09 cells/dL

Assay Interference (Drug Pools Tested)

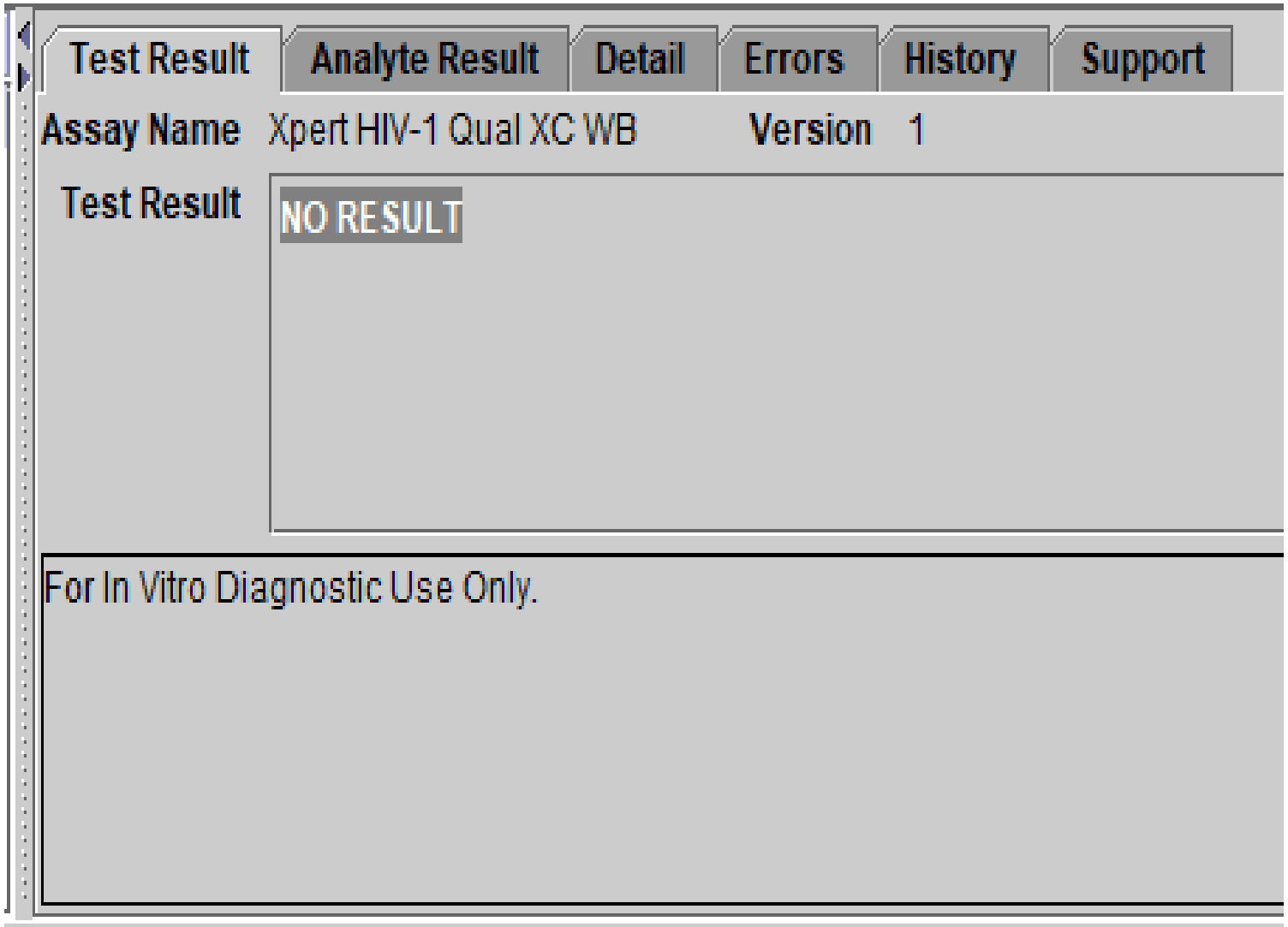
- The drug components were shown to not interfere with the detection of HIV-1 or impact the specificity of the HIV-1 Qual XC test when tested at 3 times peak level concentration (C_{max}) in the presence and absence of HIV-1.

Pool	Drugs
1	Atazanavir, Abacavir sulfate, Bictegravir, Cidofovir
2	Darunavir, Dolutegravir, Doravirine, Efavirenz
3	Emtricitabine, Lamivudine. 3TC, Lopinavir, Maraviroc
4	Nevirapine , Raltegravir, Tenofovir disoproxil fumarate, Zidovudine
5	Daclatasvir, Dasabuvir. ABT-333, Grazoprevir, Pibrentasvir, Sofosbuvir
6	Ombitasvir, Paritaprevir, Ribavirin, Simeprevir, Velpatasvir
7	Interferon alfa-2b, Peginterferon 2a, Adefovir dipivoxil, Entecavir, Telbivudine
8	Acyclovir, Foscarnet, Ganciclovir, Valganciclovir HCl
9	Azithromycin, Ciprofloxacin, Clarithromycin
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 separately
Testing of whole blood specimens from 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 detection of HIV-1 or impact the specificity of the HIV-1 Qual XC test when tested in presence and absence of HIV-1.

NO RESULT

NO RESULT



- The presence or absence of HIV-1 target nucleic acids cannot be determined.
  - HIV-1 : NO RESULT
  - CONTROLS: NO RESULT
- Probe Check: NA (not applicable)

Possible Causes

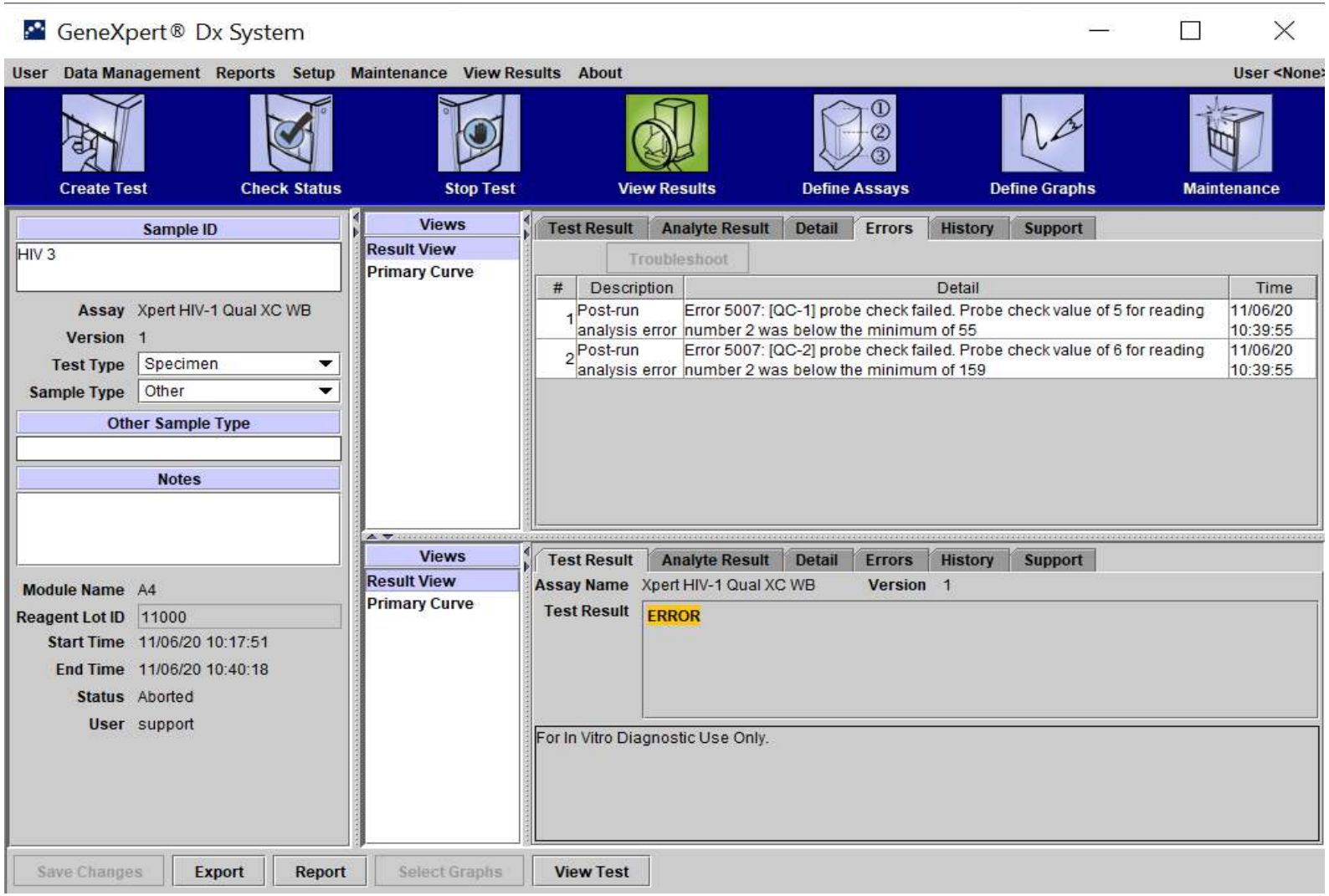
A NO RESULT indicates that insufficient data were collected.

- Test was stopped with stop test button
- Electrical failure

Solution

- Secure the power
- Repeat the test with a new cartridge

Error Result



- The presence or absence of HIV-1 target nucleic acids cannot be determined.
  - HIV-1: NO RESULT
  - SPC: NO RESULT
- 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

Re-test Procedure

1

Discard used cartridge

Follow your institution's safety guidelines for disposal of cartridges

2

For EDTA WB/ DBS: follow procedure 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 and, if applicable, Computer Service Tag number

- Log your complaint online using the following link ***: http://www.cepheid.com/us/support :***

- *Create a Support Case*

Q&A

Thank You

www.cepheid.com

