Test Training
Xpert® HPV v2

For use with:
GeneXpert® Dx
GeneXpert® Infinity Systems

Catalog Number : GXHPV2-CE-10
For CE-IVD Only
CE-marked in accordance with IVDR (Regulation (EU) 2017/746)

CE 2797 IVD In Vitro Diagnostic Medical Device

303-3860 Rev B October 2024

Training Objectives

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

- Properly store and handle the Xpert® HPV v2 cartridge kit
- Follow proper laboratory safety precautions
- Collect, transport and store appropriate specimens
- Prepare a cartridge, samples and run the Xpert® HPV v2 test
- Explain the Xpert® HPV v2 control strategy
- Interpret the patient results report

Training Agenda

1. Overview
2. Kit Handling
3. Specimen Collection, Transport and Storage
4. Cartridge Preparation
5. Quality Controls
6. Results Interpretation
7. Troubleshooting

AGENDA

Overview

The Cepheid Solution

- Qualitative detection of the E6/E7 region of the viral DNA genome from high-risk Human Papillomavirus (HPV)
- On-board internal controls for each sample
  - Probe Check Control (PCC)
  - Sample Adequacy Control (SAC)
- Closed cartridge system minimizes risk of contamination
- On-demand results
- Random access

Intended Use

- The Xpert® HPV v2 test is a qualitative in vitro test for the detection of the E6/E7 region of the viral DNA genome from high-risk Human Papillomavirus (HPV) in patient specimens. The test carries out multiplexed amplification of target DNA by real-time Polymerase Chain Reaction (PCR) of 14 high risk HPV types in a single analysis. Xpert® HPV v2 specifically identifies types HPV 16 and HPV 18/45 in two distinct detection channels, and reports 11 other high-risk types (31, 33, 35, 39, 51, 52, 56, 58, 59, 66 and 68) in a pooled result.
- Specimens are limited to cervical cells collected in PreservCyt® Solution (Hologic Corp.). Cervical specimens collected in PreservCyt Solution that have been pretreated with Glacial Acetic Acid (GAA) to lyse excess red blood cells for cytology review have also been validated for use with the Xpert® HPV v2 test.
- The Xpert® HPV v2 test can be used with a Pap specimen to assess the presence or absence of genotypes 16 and 18/45 and other high risk HPV genotypes in adult females who are at increased risk of developing cervical cancer or the presence of high-grade disease.
- The Xpert® HPV v2 test can be used as a first-line primary screening test to identify adult females who are at increased risk of developing cervical cancer or the presence of high-grade disease.

This information, together with the physician's assessment of the patient's medical history, other risk factors, and professional guidelines, may be used to guide patient management.

Intended User/Environment

- The Xpert® HPV v2 test is intended to be performed by healthcare professionals trained on the use of the test. This test is for use in a laboratory environment.

	HPV Types Detected
HPV 16	HPV 16
HPV 18_45	HPV {18 and 45}
P3	HPV {31,35,33,52,58}
P4	HPV {51,59}
P5	HPV {39,68,56,66}

Xpert® HPV v2 Requirements

GeneXpert Software	• GeneXpert Dx software **v4.3** or higher • Xpertise software **v6.1** or higher
Test Kits	• GXHPV2-CE-10
Sample Collection	• Cervical specimen collected in PreservCyt with either a broom-like device or an endocervical brush/spatula combination
Other Materials	• Personal Protective Equipment (PPE) • 1:10 dilution bleach • 70% ethanol or denatured ethanol
Optional	• Uninterruptible Power Supply /Surge Protector • Printer • Vortex

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Kit Handling

Good Laboratory Practice Review

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Personnel Protective Equipment (PPE)

- Wear clean lab coats, safety glasses, and gloves
- Change gloves between processing specimens

Lab Bench Area

- Clean work surfaces routinely with:
  - ✓ 1:10 dilution of household bleach*
  - ✓ 70% ethanol solution
- After cleaning, ensure work surfaces are dry and gloves are changed

Specimens, and Kits Storage

- Store specimens and sample away from kit to prevent contamination

Equipment

- Follow the manufacturer's requirements for instrument maintenance
- Setup samples away from the instrument

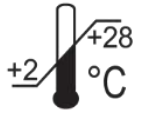
*Final Active Chlorine concentration should be 0.5% regardless of the household bleach concentration

Cepheid

Xpert® HPV v2 Kit Components

Catalog Number	**GXHPV2-CE-10**
Cartridges Per Kit	10
Kit CD	Xpert® HPV v2 Assay Definition Files (ADF) Instructions to import ADF into GeneXpert software Instructions for Use (IFU)
Storage	2-28 °C
Transfer Pipettes	10 (1 mL transfer pipettes)

Xpert® HPV v2 Kit Storage and Handling



- Store the Xpert® HPV v2 cartridges at 2–28 °C.
- Do not open a cartridge until ready to perform test.
- Do not use a cartridge that has leaked.
- Do not use a cartridge that previously has been frozen.
- Do not use a cartridge pass the expiry date.

Warning and Precautions

General

- For *In Vitro* Diagnostic Use
- Pathogenic microorganisms, including hepatitis viruses and human immunodeficiency virus (HIV), may be present in clinical samples. Treat all biological samples, 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 sample handling are available from the U.S. Center for Disease Control and Prevention and the Clinical and Laboratory Standards Institute.6,7
- Follow your institution's safety procedures for working with chemicals and handling biological samples.
- Good laboratory practices and changing gloves between handling patient specimens are recommended to avoid contamination of specimens.

6. Centers for Disease Control and Prevention. Biosafety in microbiological and biomedical laboratories. (Refer to latest edition.)
7. CLSI Publication M29. Protection of laboratory workers from occupationally acquired infections; Approved Guideline. (Refer to latest edition.)

Warning and Precautions

General 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 national or regional disposal procedures. If national 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.
- Do not substitute Xpert® HPV v2 reagents with other reagents.
- Do not open the Xpert® HPV v2 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 cartridge may yield invalid results.
- Do not place the sample ID label on the cartridge lid or on the barcode label.
- Do not use a cartridge that has a damaged reaction tube.

Warning and Precautions

General Continued

- Each single-use Xpert® HPV v2 cartridge is used to process one test. Do not reused processed cartridges.
- The single-use disposable pipette is used to transfer one specimen. Do not reuse spent disposable pipettes.
- Do not use cartridge which has been knocked over after adding sample.
- 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 concentration of 1:10 dilution of household chlorine bleach or sodium hypochlorite and then a 70% ethanol or 70% isopropanol solution. Whip work surfaces dry completely before proceeding.
- 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.
- For Instrument System cleaning and disinfecting instructions, refer to the appropriate GeneXpert Dx System Operator Manual or GeneXpert Infinity System Operator Manual.

AGENDA

Specimen Collection, Transport and Storage

Specimen Collection, Transport and Storage

AGENDA

❖ Specimen Collection

- Cervical specimens collected in PreservCyt Solution have been validated for use with the Xpert® HPV v2 test. Follow the manufacturer's instructions for collecting cervical specimens.

❖ Specimen Transport

- Cervical specimens collected in PreservCyt Solution can be transported at 2–30 °C. Transportation of cervical specimens must comply with country, federal, state and local regulations for the transport of etiologic agents.

❖ Specimen Storage

- Cervical specimens collected in PreservCyt Solution may be stored at 2–30 °C for up to six months after the date of collection.

Specimen Transport and Storage

AGENDA

Follow the manufacturer's instructions for collecting cervical specimens.

Specimen Type	Transport and Storage
Cervical specimens collected in PreservCyt solution	2-30°C Up to 6 months after date of collection

AGENDA

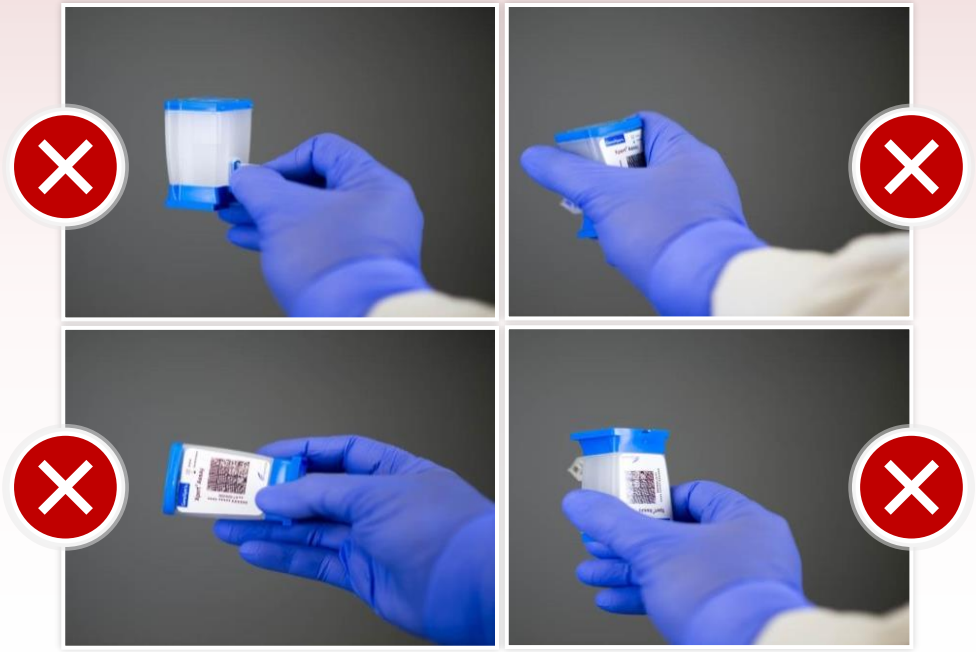
Cartridge Preparation

Proper Cartridge Handling Techniques

Correct

- Do not touch the reaction tube
- Keep the cartridge upright after seal has been broken
- Do not tilt when scanning the cartridge

Incorrect

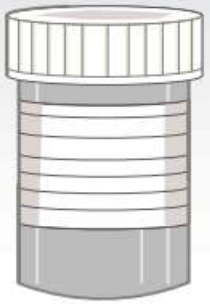


Xpert® HPV v2 Cartridge Preparation

Xpert® HPV v2 Cartridge Preparation

Refer to the Instructions for Use for detailed instructions, precautions, and warnings.

1 Obtain one appropriately collected and labeled test sample.



2 Obtain one Xpert HPV v2 cartridge and transfer pipette (provided). The line on the pipette indicates 1mL fill volume. Label the cartridge with sample identification.

3 Inspect the test cartridge for damage. If damaged, do not use it. Open the cartridge lid.

4 Mix the sample by gently inverting the sample vial 8 to 10 times, or by vortexing briefly with a vortex mixer at half-speed continuously for 5 seconds.

5 Unwrap the transfer pipette. Open the sample vial lid, compress the transfer pipette bulb, insert the pipette into the vial, and release the bulb to fill the transfer pipette to the 1 mL line. Ensure the pipette is filled, with no bubbles present.

6 Expel the pipette's contents into the sample chamber of the cartridge.Avoid adding excess mucus to the catridge

7 Close the cartridge lid and start the test within the timeframe specified in the IFU.

CE 2797 IVD

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Which GeneXpert® System Do You Have?

1 GX Dx

GX Dx Click Here

2 Infinity

Infinity Click Here

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

Run a Test on GeneXpert® Dx

1 Start a test.

Start the test within 30 minutes after adding the sample to the cartridge.

2 Scan barcode for Patient and/or Sample ID.

3 Scan the cartridge.

To Scan do not click on Manual Entry or Cancel.

Run a Test on GeneXpert® Dx (Continued)

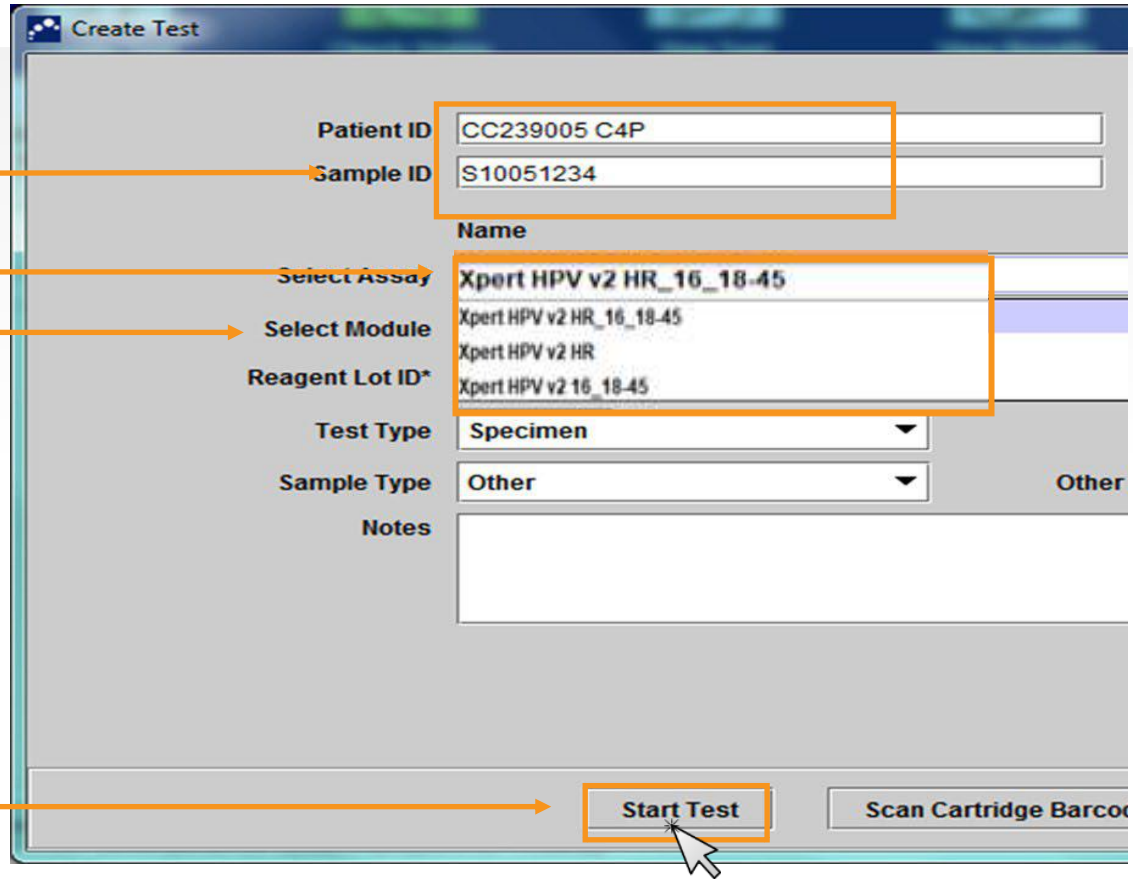
4 Complete the fields as required.

5 Select the assay protocol

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.

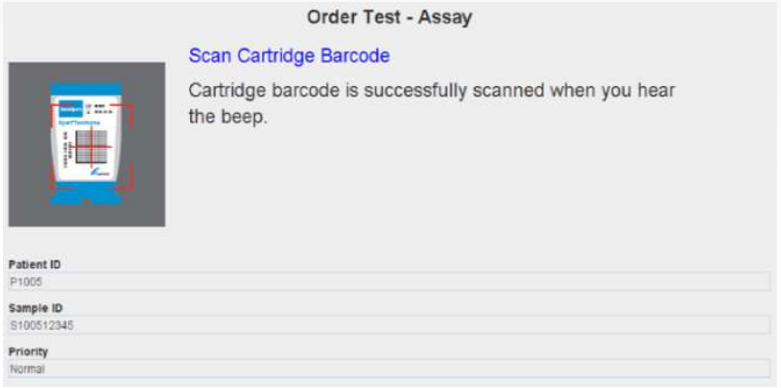


Run a Test on GeneXpert® Infinity

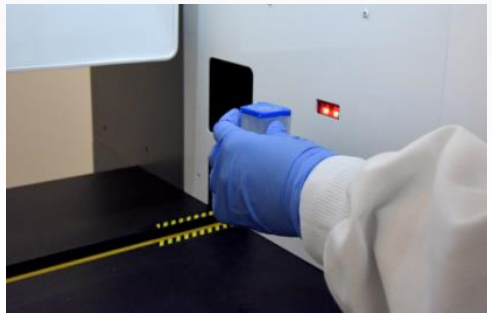
1 Start a test.

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

2 Scan barcode for Patient and/or Sample ID.



3 Scan the cartridge.

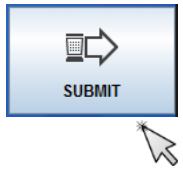


Run a Test on GeneXpert® Infinity (Continued)

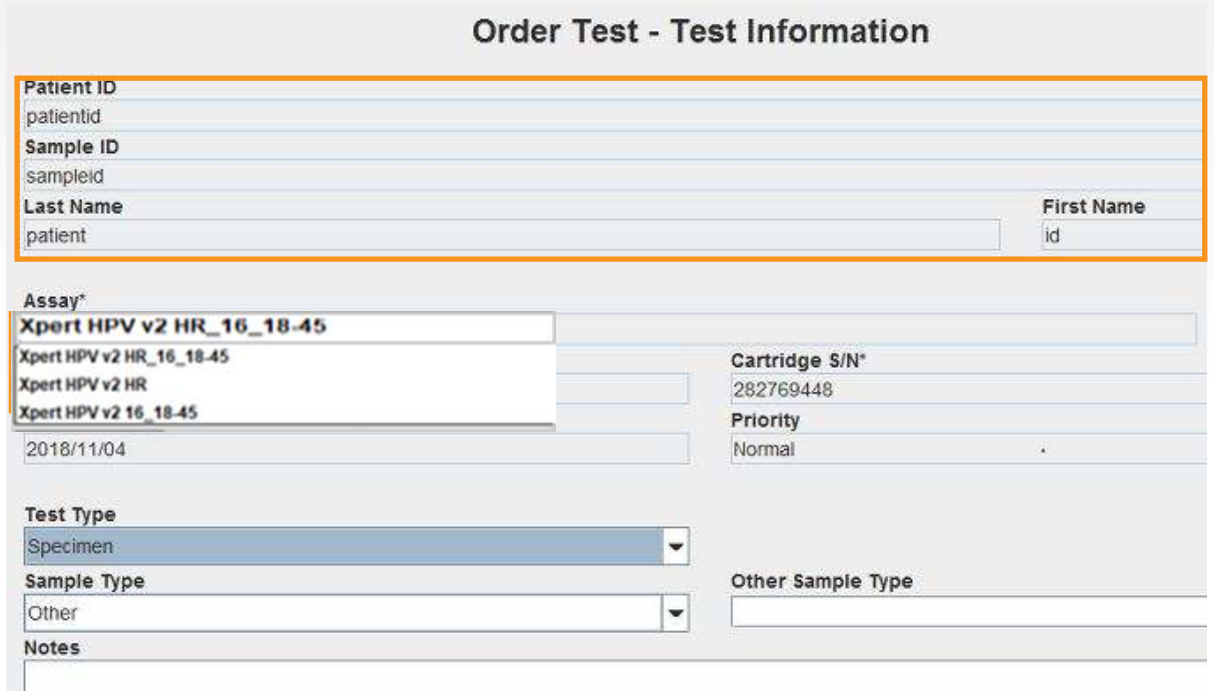
4 Complete the fields as required.

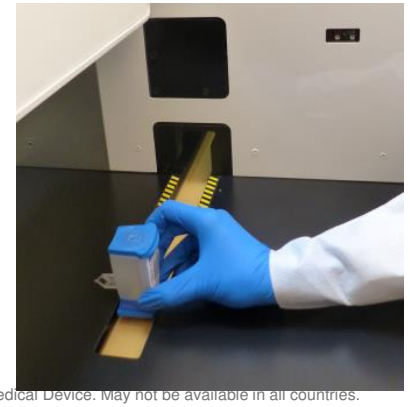
5 Select the assay protocol

6 Click SUBMIT.



7 Place the cartridge into the conveyor belt.





Automated Xpert® HPV v2 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

Waste Disposal Warnings and Precautions

AGENDA

Biological specimens, transfer devices, and used cartridges should be considered capable of transmitting infectious agents and require use of 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 national or regional disposal procedures.

Please Note: Used cartridges may contain potentially infectious materials, as well as highly amplified PCR target(s). Do not open or attempt to alter any part of the cartridge for disposal.

If national 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.

AGENDA

Quality Controls

Xpert® HPV v2 Control Strategy

- Xpert® HPV v2 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:
    - Probe Check Control (PCC)
    - Sample Adequacy Control (SAC)

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

Internal Quality Controls

Probe Check Controls (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. PCC passes if it meets the validated acceptance criteria.

Sample Adequacy Control (SAC)

- The SAC reagents detect the presence of a single copy human gene present in one copy per cell and monitor whether the sample contains human DNA.

AGENDA

Results Interpretation

Results Summary

Result	Interpretation
HR HPV POS	High-risk HPV DNA is detected as positive.
HPV 16 POS	HPV 16 DNA is detected as positive
HPV 18_45 POS	HPV 18_45 DNA is detected as positive
OTHER HR HPV POS	Other high-risk HPV DNA is detected as positive.
HR HPV NEG	High risk HPV DNA is below the level of detection
HPV 16 NEG	HPV 16 DNA is below the level of detection.
HPV 18_45 NEG	HPV 18-45 DNA is below the level of detection
OTHER HR HPV NEG	Other high-risk HPV DNA is below the level of detection
INVALID	Presence or absence of HPV target DNA cannot be determined. Repeat the test according to the instructions in the Retest Procedure.
ERROR	Presence or absence of HPV target DNA cannot be determined. Repeat the test according to the instructions in the Retest Procedure
NO RESULT	Presence or absence of HPV target DNA cannot be determined. Repeat the test according to the instructions in Section 14. Retest Procedure. 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.

NOTE: Only the test results for the selected ADF will be collected once the test is started

Three different Assay Definition Files (ADF's)

High risk HPV only test: select **Xpert® HPV v2 HR**

- Reports a positive or a negative overall result for the presence of any of the 14 high risk HPV types detected

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HPV 16, 18/45 genotyping test: select **Xpert® HPV v2 16_18_45**

- Reports a positive or a negative result for:
  - HPV 16, and for
  - HPV 18 or HPV 45 genotype
  - Specific results of all other HPV types are neither collected nor displayed

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A combined high-risk HPV an HPV genotype test: select **Xpert® HPV v2 HR_16_18-45**

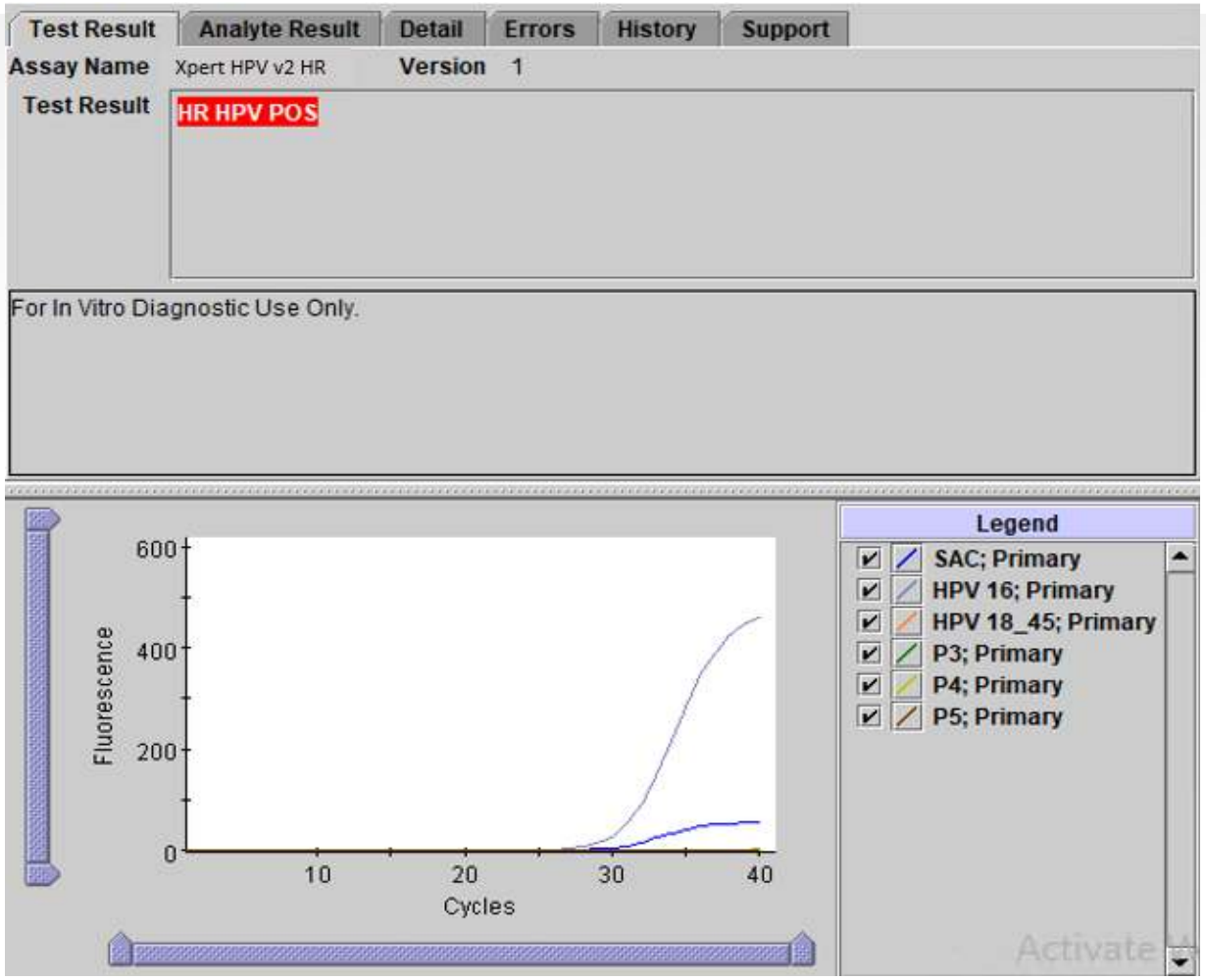
- Reports a positive or a negative test result for:
  - HPV 16, for HPV 18/45, and for the presence of any of the remaining 11 other high-risk types as "Other HR HPV."

NOTE: Only the test results for the selected ADF will be collected once the test is started

AGENDA

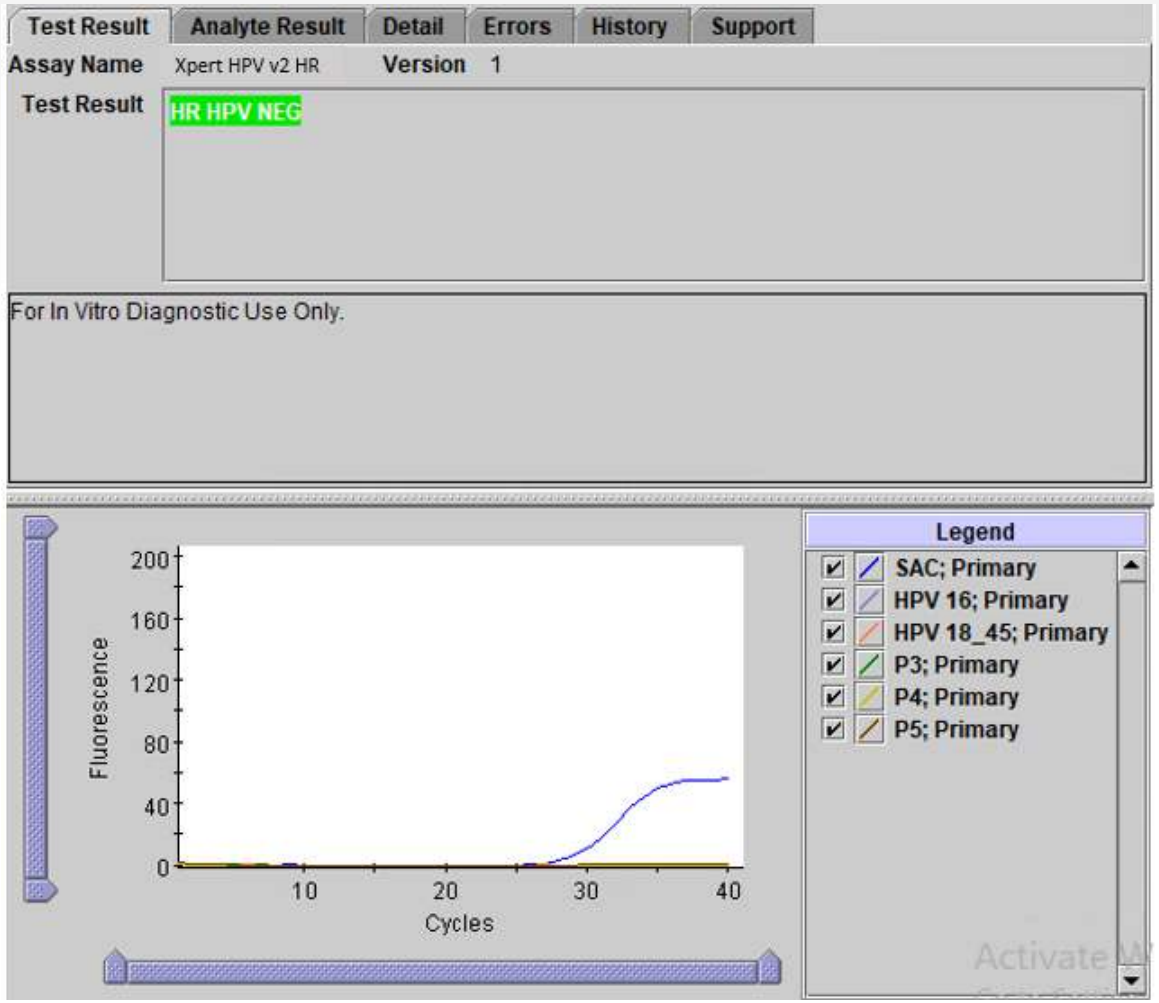
Xpert HPV v2 HR ADF Results Output

HR HPV POS



- **High risk HPV DNA is detected as positive**
  - The targeted high-risk HPV DNA has a Ct within the valid range and a fluorescence endpoint above the threshold setting.
  - SAC: Not Applicable. The SAC is ignored because HPV target amplification can compete within this control.
  - PCC PASS; All probe check results pass

HR HPV NEG



- **High risk HPV DNA is below the level of detection**

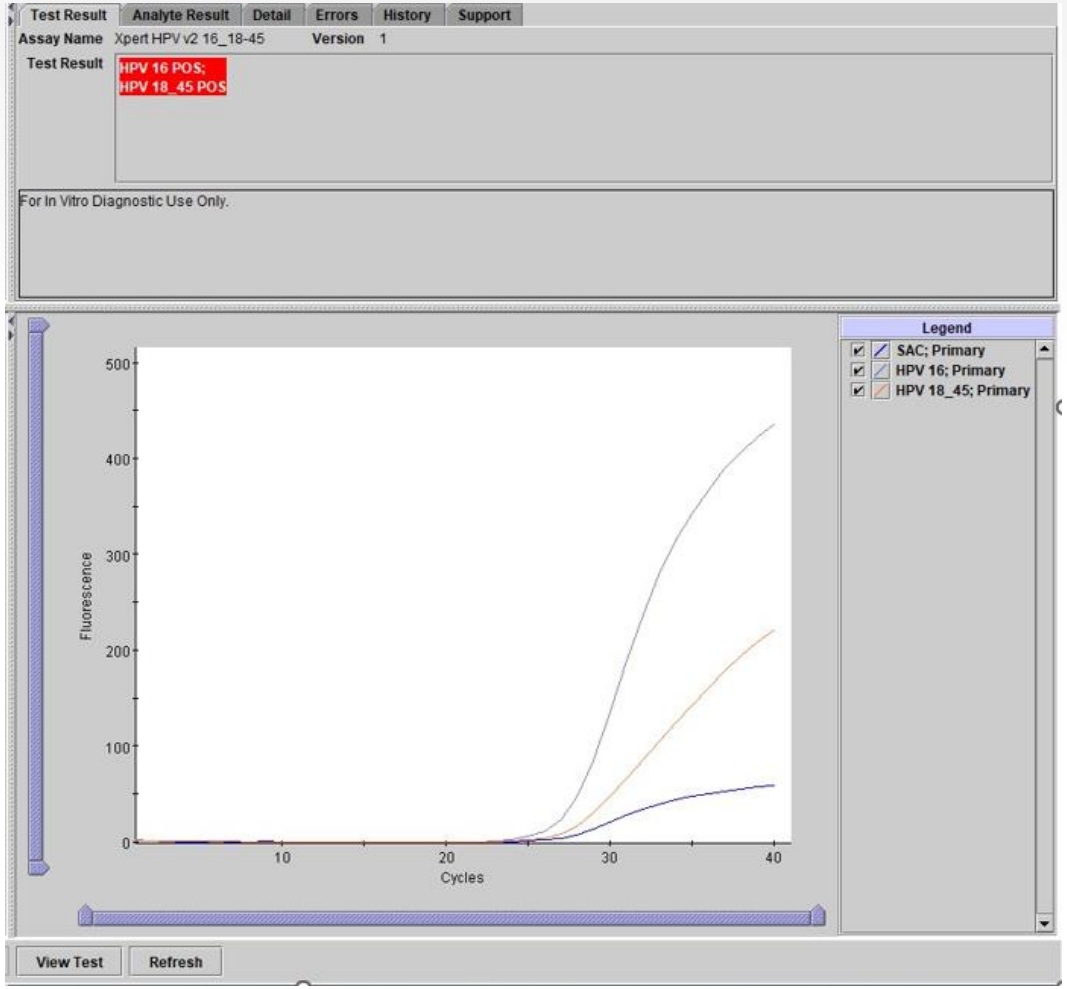
  - The targeted high-risk HPV DNA has a Ct not within the valid range and/or a fluorescence endpoint below the threshold setting.

  - SAC : PASS; PCR amplification of the SAC target gives a Ct within the valid range and a fluorescence endpoint above the threshold setting.

  - PCC : PASS; All probe check results pass

Xpert HPV v2 16_18_45 ADF Results Output

HPV 16, HPV 18_45 POS



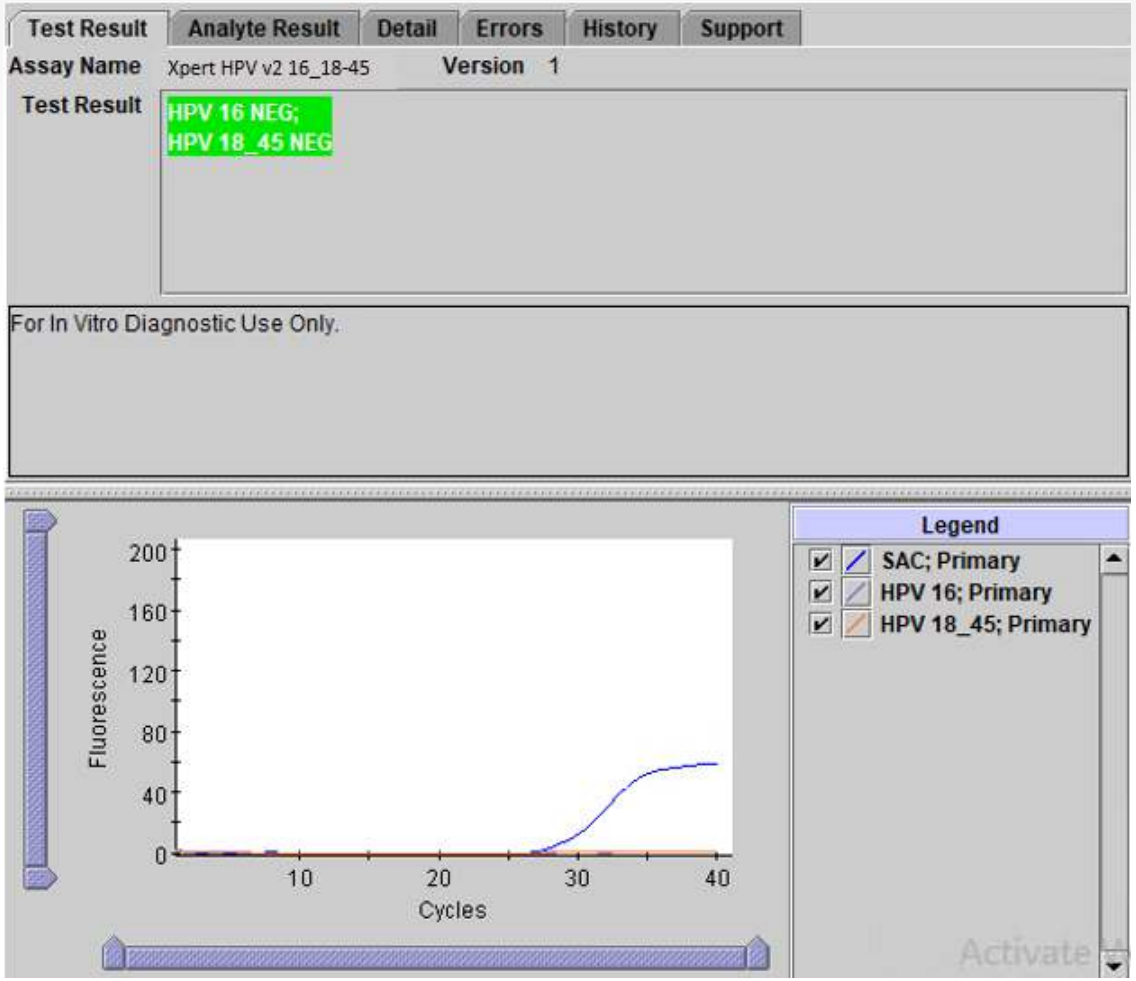
- **HPV 16 DNA is detected as positive**
- **HPV 18_45 DNA is detected as positive**

  - The targeted HPV 16 DNA & HPV 18_45 DNA has a Ct within the valid range and a fluorescence endpoint above the threshold setting.

- SAC: Not Applicable. The SAC is ignored because HPV target amplification can compete within this control.

- PCC PASS; All probe check results pass

HPV 16, HPV 18_45 NEG



- **HPV 16 DNA & HPV18_45 DNA is below the level of detection.**

  - The targeted HPV 16 DNA & HPV 18_45 DNA has a Ct not within the valid range and/or a fluorescence endpoint below the threshold setting.

  - SAC : PASS; PCR amplification of the SAC target gives a Ct within the valid range and a fluorescence endpoint above the threshold setting.

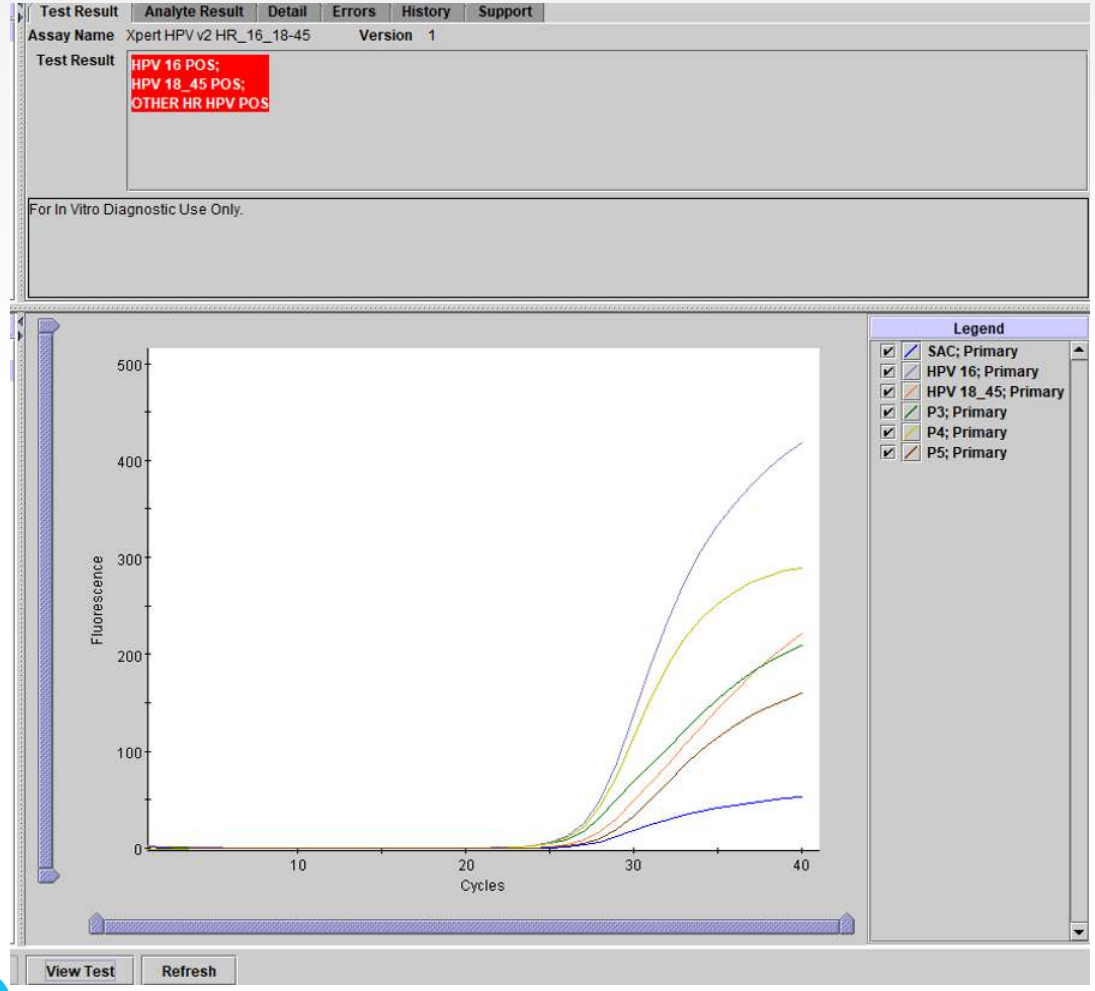
  - PCC PASS; All probe check results pass

Xpert HPV v2 16_18_45 - Other Possible Test Results Combinations

Displayed Results	HPV 16	HPV 18_45
HPV 16 POS	+	-
HPV 18_45 NEG		
HPV 16 NEG	-	+
HPV 18_45 POS		

Xpert HPV v2 HR 16_18_45 ADF Results Output

HPV 16, HPV 18_45, OTHER HR HPV POS



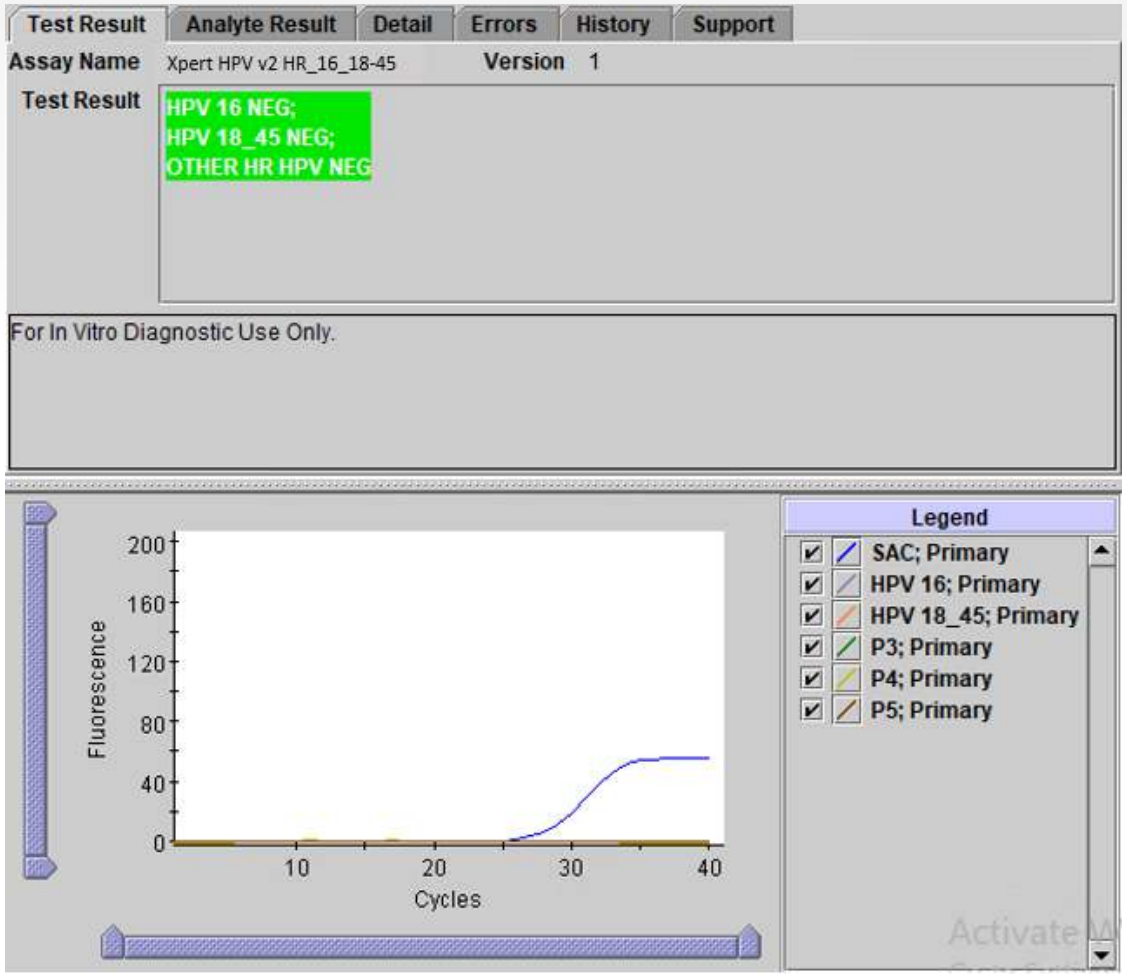
- **HPV 16 DNA detected as positive**
- **HPV 18_45 DNA is detected as positive**
- **Other high-risk HPV DNA is detected as positive**

- The targeted HPV 16 DNA, HPV 18/45 DNA & Other high-risk HPV DNA has a Ct within the valid range and a fluorescence endpoint above the threshold setting.

- SAC: Not Applicable. The SAC is ignored because HPV target amplification can compete within this control.

- PCC PASS; All probe check results pass

HPV 16, HPV 18_45, OTHER HR HPV NEG



- **HPV 16 DNA is below the level of detection**
- **HPV 18_45 DNA is below the level of detection**
- **Other high-risk HPV DNA is below the level of detection**

- The targeted HPV 16 DNA, HPV 18/45 DNA & Other high-risk HPV DNA has a Ct not within the valid range and/or a fluorescence endpoint below the threshold setting.

- SAC: PASS; PCR amplification of the SAC target gives a Ct within the valid range and a fluorescence endpoint above the threshold setting.

- PCC PASS; All probe check results pass

Xpert HPV v2 HR_16_18_45: Other Possible Test Results Combinations

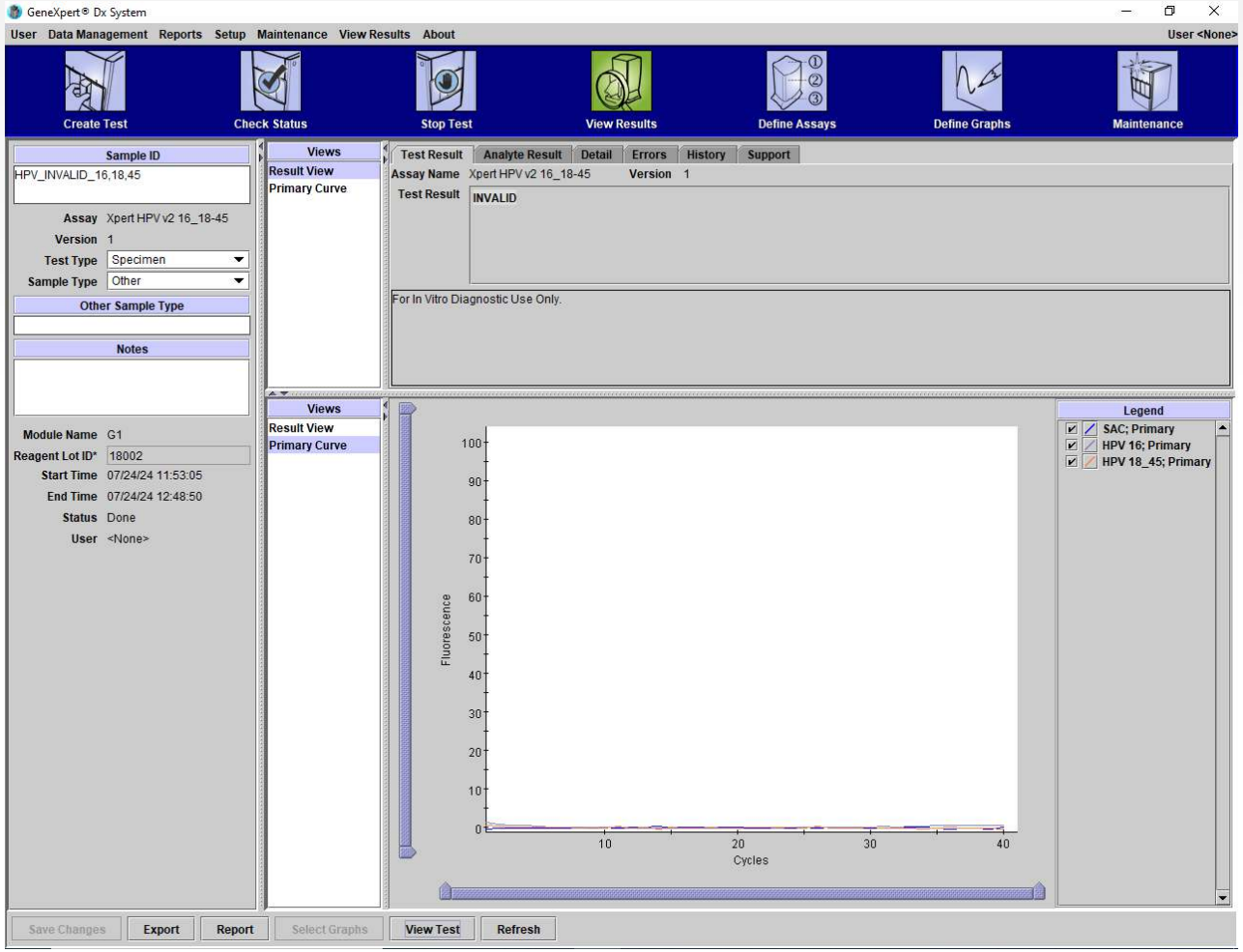
Displayed Results	HPV 16	HPV 18_45	Other HR HPV
HPV 16 POS HPV 18_45 POS OTHER HPV NEG	+	+	-
HPV 16 POS HPV 18_45 NEG OTHER HPV NEG	+	-	-
HPV 16 POS HPV 18_45 NEG OTHER HPV POS	+	-	+
HPV 16 NEG HPV 18_45 POS OTHER HPV NEG	-	+	-

Xpert HPV v2 HR_16_18_45: Other Possible Test Results Combinations

Displayed Results	HPV 16	HPV 18_45	Other HR HPV
HPV 16 NEG HPV 18_45 POS OTHER HPV POS	-	+	+
HPV 16 NEG HPV 18_45 NEG OTHER HPV POS	-	-	+

Applies to All ADF's

INVALID

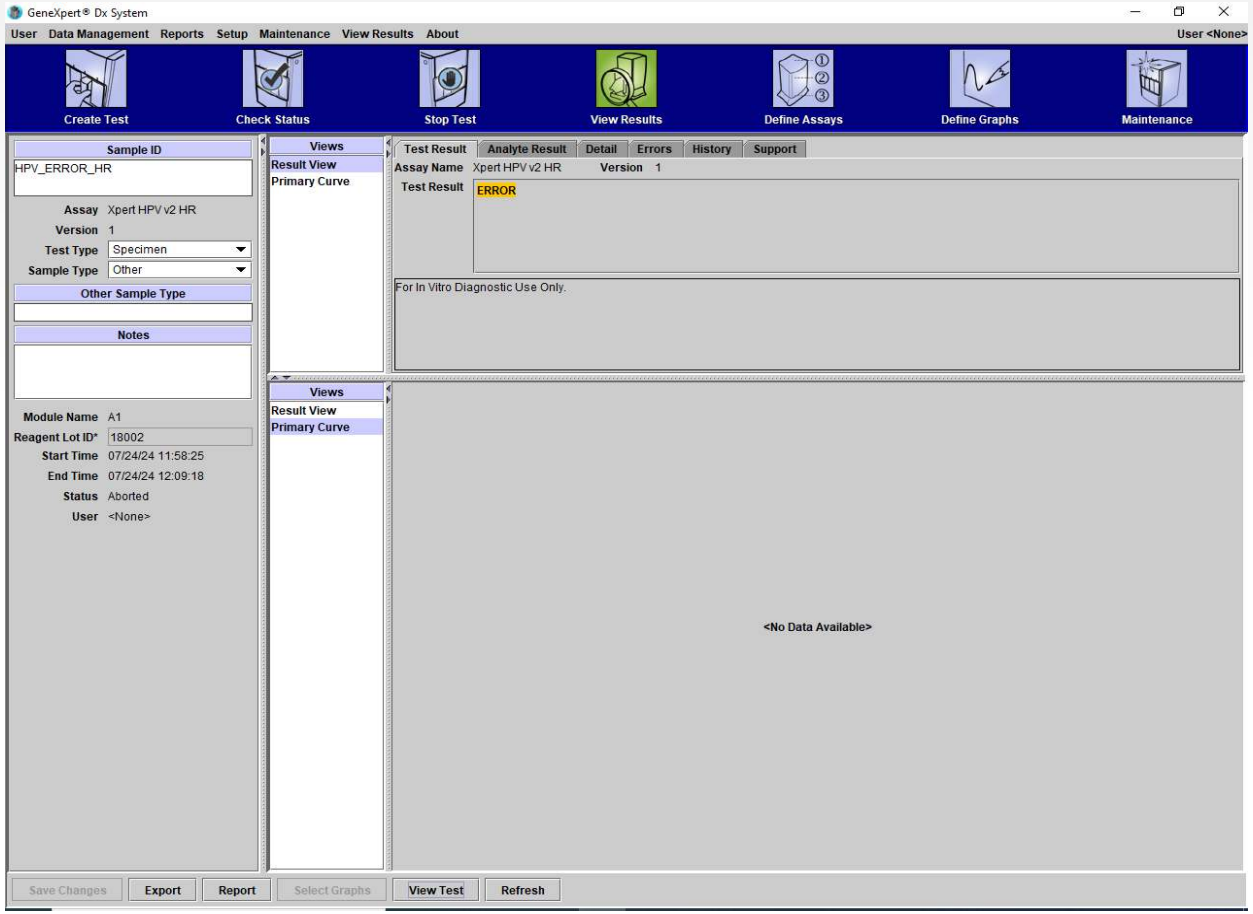


- Presence or absence of HPV target DNA cannot be determined. Repeat the test according to the instructions in Retest Procedure.

- SAC: FAIL; SAC Ct is not within the valid range and/or a fluorescence endpoint below the threshold setting

- PCC: PASS; all probe check results pass.

ERROR

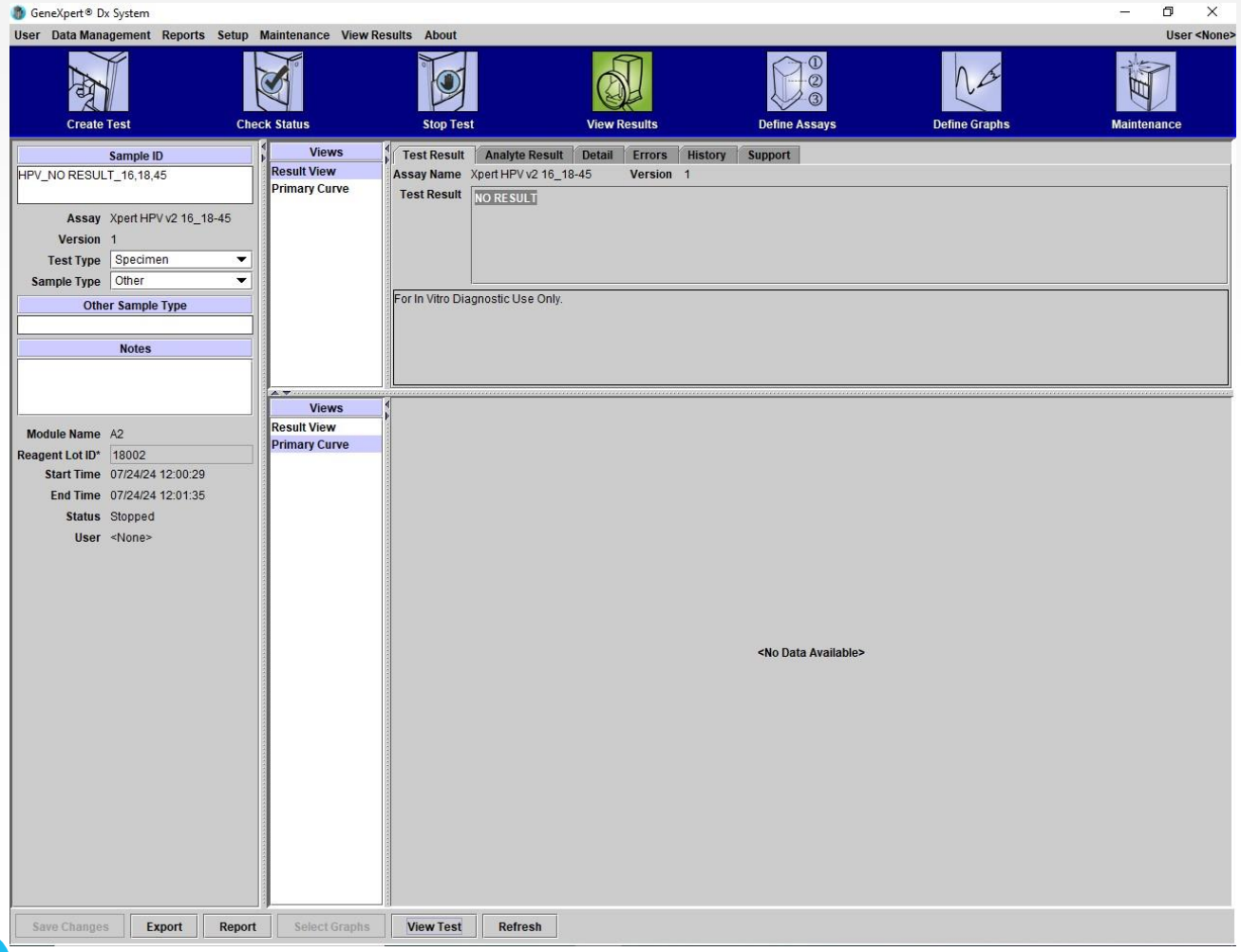


- Presence or absence of HPV target DNA cannot be determined. Repeat the test according to the instructions in Retest Procedure.

- SAC: No result
- PCC: 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 HPV target DNA cannot be determined. Repeat the test according to the instructions in Retest Procedure. 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

- HPV : NO RESULT
- SAC: NO RESULT
- PCC: PCC: PASS; all probe check results pass.

Troubleshooting

Reasons to Repeat the Test

- An INVALID result indicates that the SAC failed. The sample was not properly processed, PCR is inhibited, or the sample was inadequate.
- An ERROR result indicates that the test was aborted, possibly because the reaction tube was filled improperly, a reagent probe integrity problem was detected, pressure limits were exceeded, a valve positioning error was detected.
- 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.

Retest Procedure

1

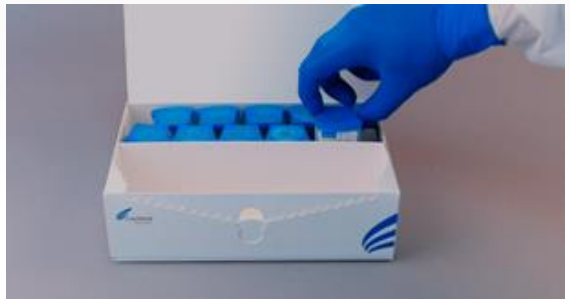
Discard used cartridge. Follow your institution's safety guidelines for disposal of cartridges.

2

Obtain the residual specimen. Prepare according to Instructions For Use.

If insufficient, or the retest continues to return an INVALID, ERROR, or NO RESULT, collect a new sample and repeat the test with a new cartridge

3



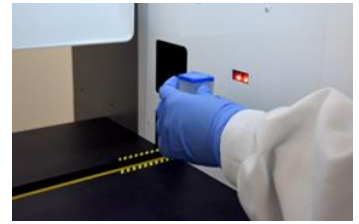
Obtain a new cartridge.

Label appropriately as retest on the new cartridge

Process the specimen per the Instructions For Use.

4

Run the test on the system.



Technical Assistance

Before contacting Cepheid Technical Support, collect the following GeneXpert® information:

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

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

→ Create a Support Case

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Thank You

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End Show