Assay Technical Training: Xpert® CT/NG

For CE-IVD and US-IVD Use

IVD In Vitro Diagnostic Medical Device

CE IVD In Vitro Diagnostic Medical Device

301-1883 Rev. E, June 2019

Training Agenda

- **Xpert® CT/NG Training**
  - Intended use
  - Reagents
  - Sample collection
  - Kit storage and handling
  - Preparing the cartridge
  - Quality Controls
  - Results Analysis
- **Discussion**

CE-IVD and US-IVD. For *in vitro* diagnostic use

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Training Objectives

- **At the end of the training, users will be able to:**
  - Store and handle the Xpert® CT/NG cartridge kit and Sample collection kits
  - Follow proper laboratory safety precautions
  - Collect appropriate specimen types and transport specimens
  - Perform the cartridge set up and run the assay
  - Report the various software-generated results
  - Understand the assay control strategy

The Cepheid Solution

- Simultaneous detection of CT and a dual target NG (NG2/NG4)
- On-board controls for each individual sample
  - Probe Check Control (PCC)
  - Specimen Processing Control (SPC)
  - Sample Adequacy Control (SAC)
- Results in approximately 90 minutes
- Closed cartridge system minimizes risk of contamination
- On-demand results
- Random access

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Intended Use

The Xpert ® CT/NG Assay is an automated in vitro diagnostic test for qualitative detection and differentiation of DNA from *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG).

The assay may be used to test the following specimens from asymptomatic and symptomatic individuals:

- **Specimen**
  - Urine Specimen (male and female)
  - Pharyngeal Swab Specimen (male and female)
  - Rectal Specimen (male and female)
  - Patient-collected Vaginal Specimen (collected in a clinical setting)
  - Endocervical Specimen
- **Detects:**
  - CT target sequence
  - NG (NG2/NG4) target sequences

Targets

5 targets are detected:

- CT1 located on genomic DNA (also present in the genome of the swedish variant strains of *Chlamydia trachomatis)*
- NG2 independent and unique target of *Neisseria gonorrhoeae*
- NG4 independent and unique target of *Neisseria gonorrhoeae*
- SPC
- SAC

Assay Requirements

GeneXpert® Systems

- GeneXpert® Dx Software **v4.3** or higher/ Xpertise™ Software **v6.0** or higher

Test Kits

- GXCT/NG-10 and GXCT/NG-120 (US-IVD)
- GXCT/NGX-CE-10 and GXCT/NGX-CE-120 (CE-IVD)

Sample Collection

- SWAB/A-50
- URINE/A-50
- SWAB/G-50

Other materials

- Personal Protective Equipment (PPE)
- 1:10 dilution of household bleach
- 70% ethanol or denatured ethanol

Optional

- Uninterruptible Power Supply /Surge Protector
- Printer

Good Laboratory Practice

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

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

Specimens, Samples, and Kits Storage	• Store specimens and sample away from kit to prevent contamination
Equipment	• Use filtered tips when recommended • Follow the manufacturer's requirements for calibration and maintenance of equipment(s)

Kit Handling

Xpert® CT/NG Assay Kit Contents

Catalog Number	GXCT/NG-10 or GXCT/NGX-CE-10 GXCT/NG-120 or GXCT/NGX-CE-120
Tests Per Kit	10 or 120
Kit CD	Assay Definition File (ADF)
	Assay Import Instructions
	Package Insert (PDF)
Transfer Pipettes	10 or 120
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.

Warnings and Precautions

- Store the Xpert® CT/NG Assay cartridges and reagents at 2–28°C

- Follow your institution's safety procedures for working with chemicals and handling biological samples
- Do not use Collection Reagent tubes that have not been validated by Cepheid
- Open the Assay cartridge lid only when adding the Sample, close the lid and proceed with processing
- With the GeneXpert System, start the test within 30 minutes after adding the sample to the cartridge
- With the Infinity System, place the cartridge on the conveyor within 30 minutes of adding the sample.

Warnings and Precautions

- Do not shake the cartridge
- Do not use a cartridge that…:
  - appears wet, has leaked or if the lid seal appears to have been broken
  - appears damaged
  - has been dropped after removing it from packaging
  - has been dropped or shaken after adding the sample to it
  - has a damaged reaction tube
  - has been used: each cartridge is single-use to process one test
  - is expired
  - do not reuse disposable pipettes

Dispose Xpert® CT/NG Assay cartridges and reagents according to your institution's and country's guidelines for disposal of hazardous materials

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Warnings and Precautions

- 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.

Xpert® CT/NG Assay Limitations

- The Xpert CT/NG test has been validated with the following specimen types, collected with the Xpert Swab Specimen Collection Kit, Xpert CT/NG Urine Specimen Collection Kit or Xpert Urine Specimen Collection Kit.
  - Endocervical swabs
  - Patient-collected vaginal swabs
  - Male and female pharyngeal swabs
  - Male and female rectal swabs
  - Male and female urine
- Presence of vaginal discharge, tampons, douching, and Cepheid non-validated specimen collection have not been determined.
- Collection and testing of urine specimens with the Xpert® CT/NG Assay is not intended to replace a cervical exam and endocervical sampling for diagnosis of urogenital infections. Other genitourinary tract infections can be caused by other infectious agents.
- The performance of Xpert® CT/NG has not been evaluated for patients less than 14 years of age or in patients with a history of hysterectomy.

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For detailed information, refer to the current Package Insert

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Specimen Collection, Storage and Transport

Urine Specimen Collection

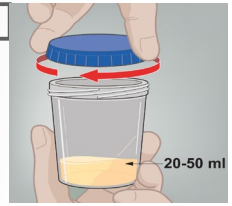
- **Urine**
  - Refer to urine specimen collection package insert
  - 20 to 50 ml of first-catch urine should be collected in a sterile urine collection cup with no preservative (not provided by Cepheid), from which 7 mL is transferred to the Urine Sample tube containing the preservative
  - Use only Xpert Urine Sample Collection kit for processing male and female urine prior to testing in the GeneXpert CT/NG assay
  - Urine specimen must be collected and tested before the expiration date of the Xpert Urine Sample Collection kit

Cepheid catalog # URINE/A-50

URINE/A-50 is designed to preserve and transport CT and NG DNA in first-catch male and female urine specimens

Urine Specimen Collection (First Catch)

1

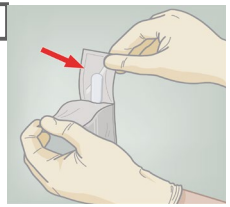


Direct patient to provide first catch urine (20-50 mL) into a urine collection cup.
Note: The patient should not have urinated for at least 1 hour before. Patient should not cleanse the genital area prior to collecting specimen.

2

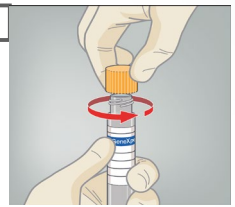
The Xpert® Urine Specimen Collection kit contains
Ⓐ Large transfer pipette
Ⓑ Urine Transport Reagent tube

3



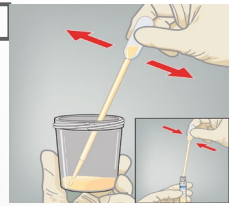
Open the package of disposable transfer pipette.

4



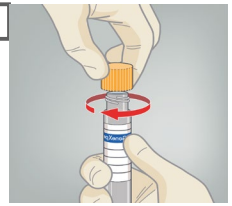
Remove the yellow cap from the transportation tube.

5



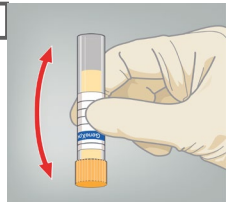
Transfer approximately 7 mL of urine into the transport tube, using the disposable transfer pipette. The correct volume is marked by the black dashed line on the pipette.

6



Replace the yellow cap on the transport tube and tighten securely.

7



Invert the transport tube 3-4 times to ensure that the specimen and reagent are well mixed.

8

Return the tube as instructed by your doctor, nurse or health care provider.

Under or over dispensing of urine into the Xpert Urine Transport Reagent tubes may affect assay performance

Adapted from document 301-5611

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Specimen Collection, Transport and Storage

- **Unprocessed Urine samples**

		Temperature (°C)	Storage Time
	Female urine ♀	Room temperature	24 hours
	Male urine ♂		3 days
	Male or Female Urine ♀ ♂	+2 +4 °C	8 days

Pictures :greencrossvet.com

Specimen Collection, Transport and Storage

- **Urine samples transferred to Xpert® CT/NG Urine transport tube**

  Cepheid catalog # URINE/A-50

		Temperature (˚C)	Storage Time
	Female urine sample ♀	+15 ±2 °C	45 days
	Female urine sample ♀	+30 ±2 °C	3 days
	Male urine sample ♂	+30 ±2 °C	45 days

Vaginal and Endocervical Collection

- **Swab**
  - Pharyngeal, rectal, vaginal and endocervical specimens are collected from patients using flocked swabs included in the kit
  - Vaginal samples are collected by the patient. Conversely, endocervical samples are collected by a clinician
  - Swabs are broken off into the transport reagent tubes to elute organisms and stabilize DNA
  - Swab specimens are then transported to the laboratory for testing on the GeneXpert® Instrument

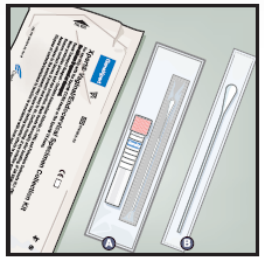
Volume of transport medium: 2,4 mL

**Cepheid catalog # SWAB/A-50 for vaginal & endocervical samples*

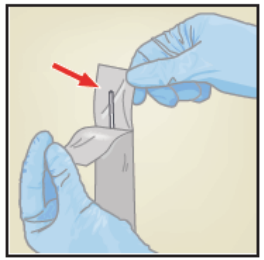
or Cepheid catalog # SWAB/G-50 kits for pharyngeal, rectal, vaginal & endocervical sample

SWAB/A-50 and SWAB/G-50 kits are designed to collect, preserve and transport endocervical and vaginal specimens from symptomatic and asymptomatic individuals to the lab prior to analysis with the Xpert® CT/NG Assay

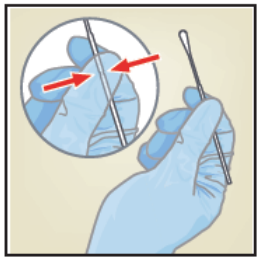
Pharyngeal Collection



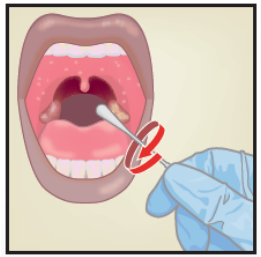
Open the individual rectal specimen collection package that contains the pink-capped swab transport tube and individually wrapped collection swab. Discard the larger swab



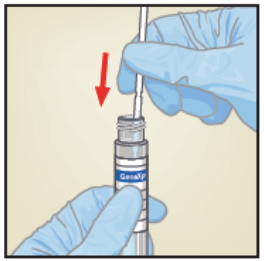
Open the collection swab wrapper by peeling the top of the wrapper



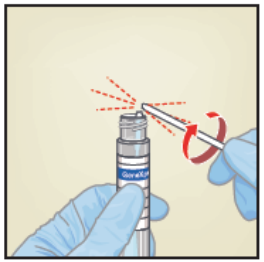
Hold the swab in your hand, placing your thumb and forefinger in the middle of the swab shaft across the scoreline.



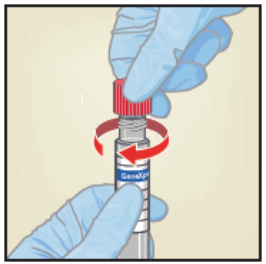
Instruct the patient to open mouth widely. Position the tongue toward the bottom of the mouth. Swab areas of the pharynx (tonsil, posterior wall, uvula, posterior wall).



While holding the swab in the same hand, unscrew the cap from the Xpert Swab Transport Reagent tube.



Carefully break the swab shaft against the side of the tube at the scoreline

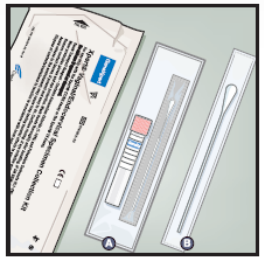


Re-cap the transport tube and tighten the cap securely.

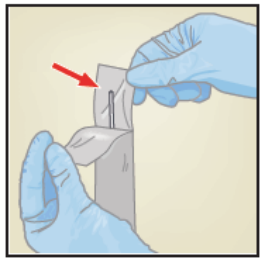
Invert or gently shake the tube 3-4 times to elute material from the swab. Avoid foaming. Label the transport tube with the sample ID, including date of the collection, as required.

Avoid splashing contents of the transport tube on the skin. Wash with soap and water if exposed.

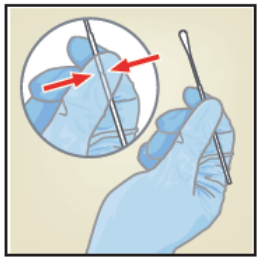
Rectal Collection



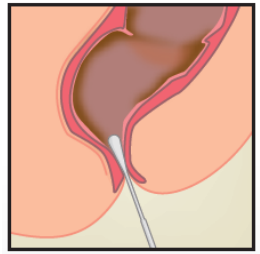
Open the individual rectal specimen collection package that contains the pink-capped swab transport tube and individually wrapped collection swab. Discard the larger swab



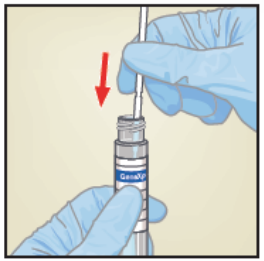
Open the collection swab wrapper by peeling the top of the wrapper



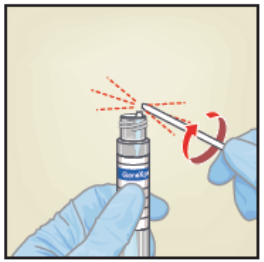
Hold the swab in your hand, placing your thumb and forefinger in the middle of the swab shaft across the scoreline.



Carefully insert the swab approximately 1 cm beyond the anal sphincter, so that the fiber tips are no longer visible and rotate the swab.



While holding the swab in the same hand, unscrew the cap from the Xpert Swab Transport Reagent tube.



Carefully break the swab shaft against the side of the tube at the scoreline

Re-cap the transport tube and tighten the cap securely.

Invert or gently shake the tube 3-4 times to elute material from the swab. Avoid foaming. Label the transport tube with the sample ID, including date of the collection, as required.

Avoid splashing contents of the transport tube on the skin. Wash with soap and water if exposed.

Assessing a correct sample

Figure 1. Examples of Acceptable Rectal Swabs

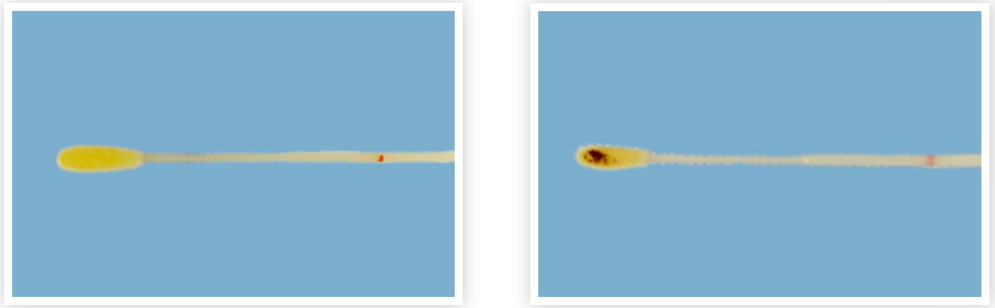
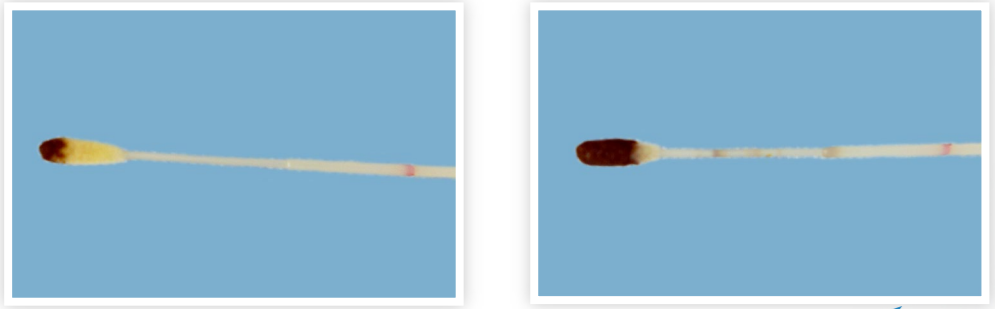
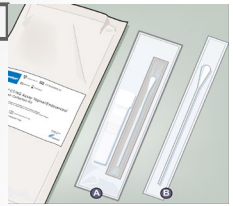


Figure 2. Examples of Unacceptable Rectal Swabs



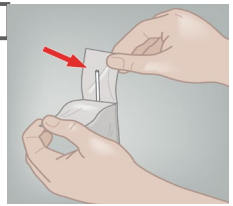
Vaginal Collection (Patient Collected)

1



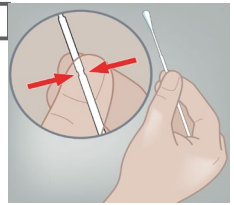
Open the individual vaginal/endocervical specimen collection package (A) that contains the pink-capped swab transport tube and individually wrapped collection swab. Set the tube aside. Discard the larger (B) swab

2



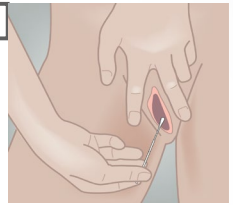
Open the collection swab by peeling open the top of the wrapper.
Remove the swab, taking care not to touch the tip or lay it down.

3



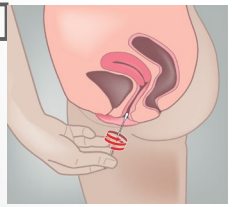
Hold the swab in your hand, placing your thumb and forefinger in the middle of the swab shaft across the scoreline.

4



Carefully insert the swab into your vagina about 2 inches/5cm inside the opening of the vagina

5

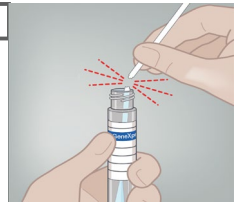


Gently rotate the swab for 10-30 seconds. Ensure the swab touches the walls of the vagina so that the moisture is absorbed by the swab.
Withdraw the swab and continue to hold it in your hand.

6

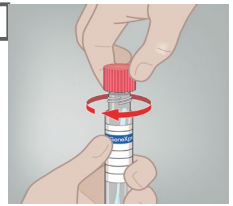
Unscrew the cap from the transport tube.
Immediately place the collection swab into the transport tube.

7



Identifying the scoreline, break the swab shaft against the side of the tube. Discard the top portion of the swab shaft.
Avoid splashing contents on the skin. Wash with soap and water if exposed.

8



Re-cap the transport tube and tighten the cap securely.
Return the tube as instructed by your doctor, nurse or health care provider.

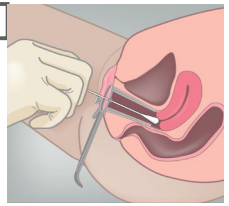
Adapted from document 301-1790

Endocervical Collection (Clinician-collected)

1

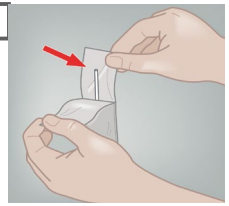
The Vaginal /Endocervical Specimen Collection kit contains
A Individual Collection swab
B Cleaning Swab

2



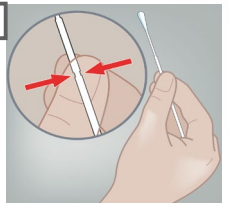
Remove excess mucus from the cervix and surrounding area using the large individually wrapped cleaning swab
Discard the swab. B

3



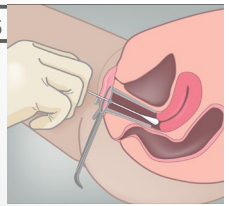
Open the package that contains the pink-capped Xpert Swab Transport tube and individually wrapped collection swab.
Open the collection swab wrapper by peeling the top of the wrapper

4



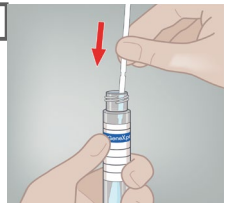
Hold the swab in your hand, placing your thumb and forefinger in the middle of the swab shaft.

5



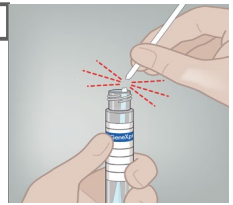
Insert the collection swab into the endocervical canal. Rotate the swab for 30 seconds in the endocervical canal.
Withdraw the swab carefully.

6



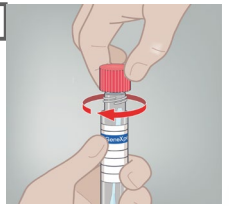
Unscrew the cap from the transport tube.
Immediately place the collection swab into the transport tube.

7



Align the small groove against the edge (rim) of the tube and break it off. If needed, gently rotate the shaft to complete the breakage. Discard the top part of the swab shaft.

8



Re-cap the transport tube and tighten the cap securely.
Label the transport tube with the sample ID and date of collection, as required.

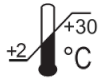
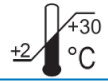
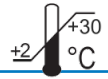
Adapted from document 301-1790

Specimen Collection, Transport and Storage

- **Swab samples transferred to Xpert® CT/NG swab transport tube**

  Cepheid catalog # SWAB/A-50

  or Cepheid catalog # SWAB/G-50 kits

	Swab Samples	Validated Collection Tool	Temperature (˚C)	Storage Time
	Endocervical collection Swab	*SWAB/A-50* *SWAB/G-50 kits*		60 days
	Vaginal collection Swab	*SWAB/A-50* *SWAB/G-50 kits*		60 days
	Pharyngeal collection Swab	*SWAB/G-50 kits*		60 days
	Rectal collection Swab	*SWAB/G-50 kits*		60 days

  CE-IVD and US-IVD. For *in vitro* diagnostic use

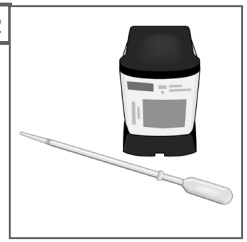
Cartridge Preparation

Cartridge Preparation – Urine or Swab

1

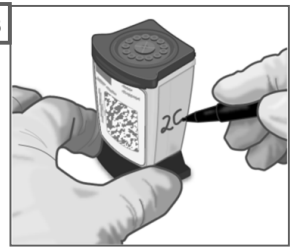
Obtain appropriately collected urine or swab specimen in Xpert Sample Collection Kit

2



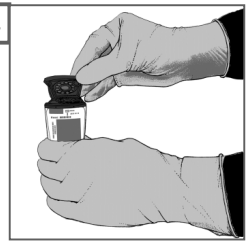
Take one Xpert CT/NG cartridge and the provided transfer pipette

3



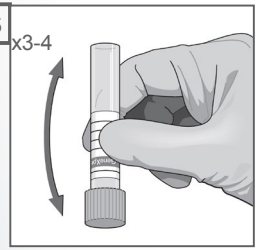
Label the side of the cartridge with the same ID as the collection tube

4



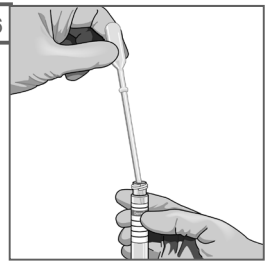
Open the cartridge lid

5



Gently mix by inverting the transport tube 3-4 times

6



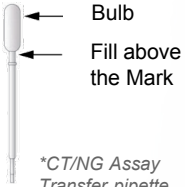
Pipette at least 1 mL of the sample using the provided pipette*

7

Slowly empty the pipette into the sample chamber of the cartridge

8

Close the lid firmly.
Start the test within the time frame specified in the package insert.



CT/NG Assay Transfer pipette

Adapted from document 301-1811

  CE-IVD and US-IVD. For *in vitro* diagnostic use

Cepheid

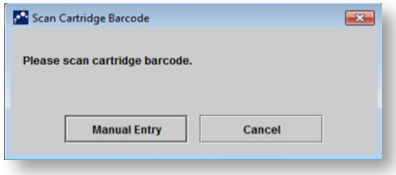
Run a Test

1 Create Test

GeneXpert

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

2 Scan cartridge barcode message

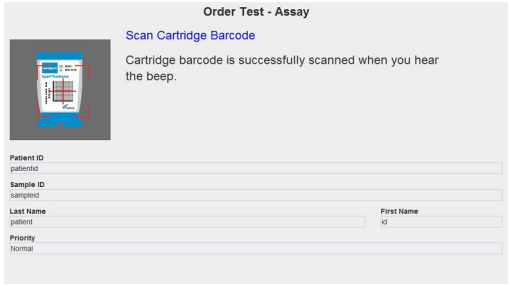


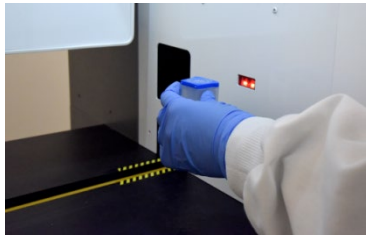
By default, do not click on **Manual Entry** or **Cancel**

3 Scan the cartridge

GeneXpert Infinity

Place the cartridge on the conveyor within 30 minutes 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 GeneXpert® Dx Software

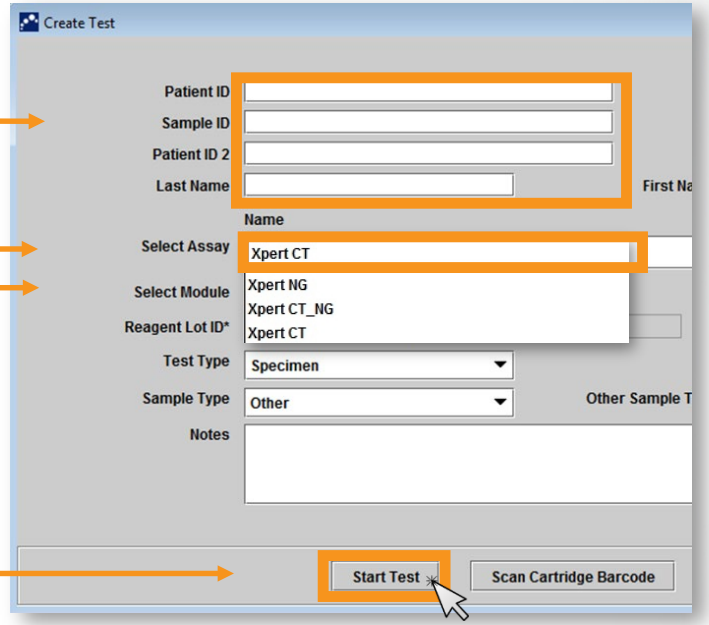
4 Complete the fields as required

5 Select the appropriate Assay Protocol from the drop-down list: you will get only the assay related result

6 The module is selected automatically

7 Click on Start Test

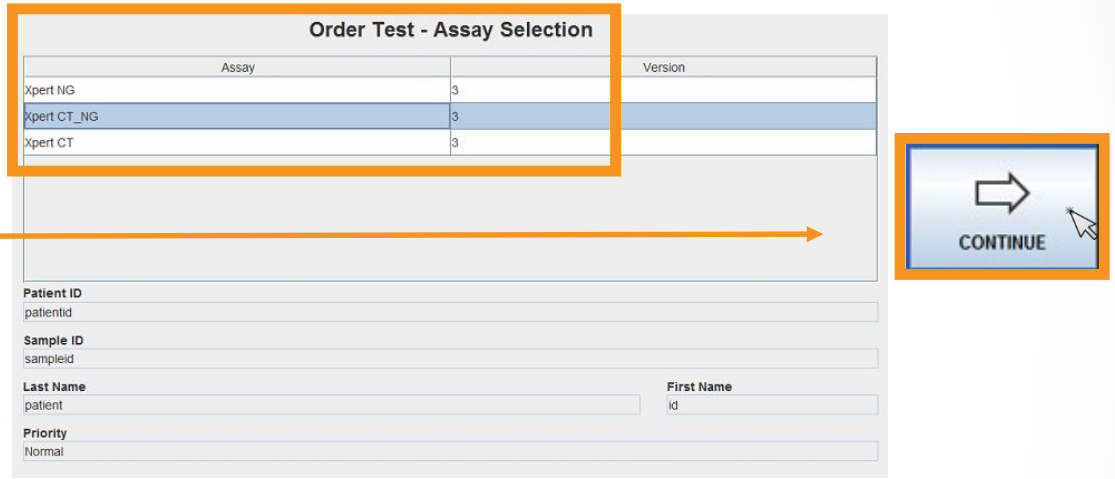
8 A green light will flash on the module
Load the cartridge into module and close the door



Create a Test on Xpertise™ Software – Assay Selection

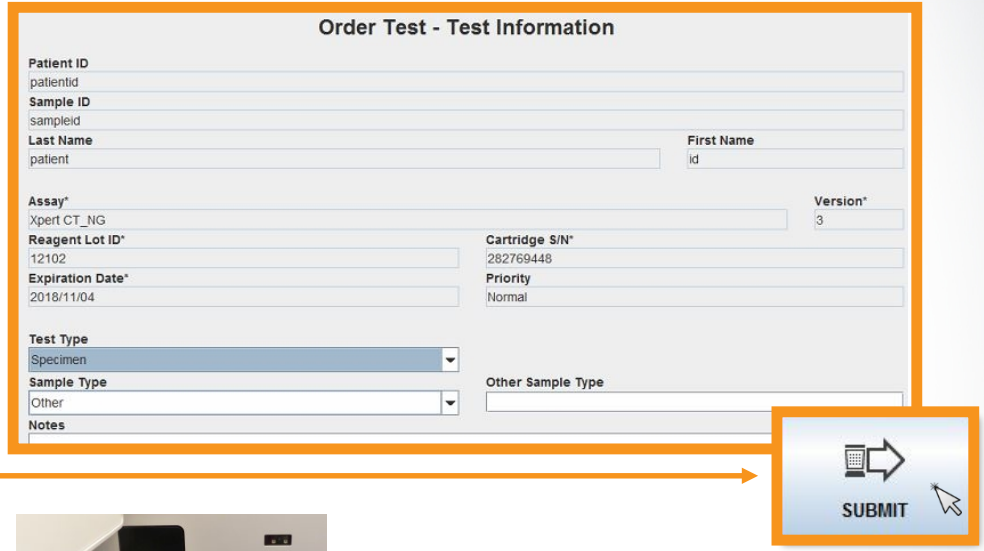
4 Select the appropriate Assay Protocol from the drop-down list: you will get only the assay related result

5 Click on Continue



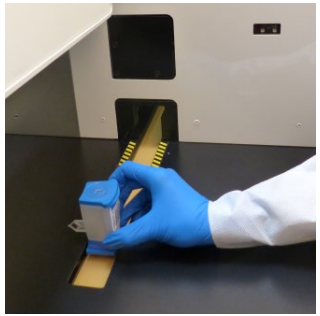
Create a Test on Xpertise™ Software – Test Information

6 Review and complete the test information



7 Click on SUBMIT

8 Place the cartridge on the conveyor belt



  CE-IVD and US-IVD. For *in vitro* diagnostic use

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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

  CE-IVD and US-IVD. For *in vitro* diagnostic use

Cepheid

Quality Controls

Cepheid Control Strategy

- **Instrument System Control – Check Status**
  - System control checks the optics, temperature of the module and mechanical integrity of each cartridge.
  - If the system controls fail, an ERROR test result will be reported.

- **Assay 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)
    - Specimen Processing Control (SPC)
    - Probe Check Controls (PCC)

Internal Quality Controls

- **Sample Adequacy Control (SAC)** HMBS (Hydroxymethylbilane synthase)
  - Verifies that human cells are present in the sample
- **Probe Check Controls (PCC)**
  - Before the PCR step, fluorescence signal is measured on all probes and compared with pre-established factory settings to monitor
    - bead rehydration
    - reaction tube filling
    - probe integrity
    - dye stability
- **Sample Processing Controls (SPC)**
  - Genomic DNA of *Bacillus globigii* in each cartridge
    - Verifies adequate sample processing
    - Verifies lysis, presence of the organism and detects PCR inhibition
    - Must be positive in a negative sample
    - Can be positive or negative in a positive sample

Commercially Available External Controls

Part Number	Description	Configuration	Storage
NATCT(434)-6MC	CT positive control	1 mL x 6 vials	2-8°C
NATNG-6MC	NG positive control	1 mL x 6 vials	2-8°C
NATCT/NGNEG-6MC	CT and NG Negative controls	1 mL x 6 vials	2-8°C

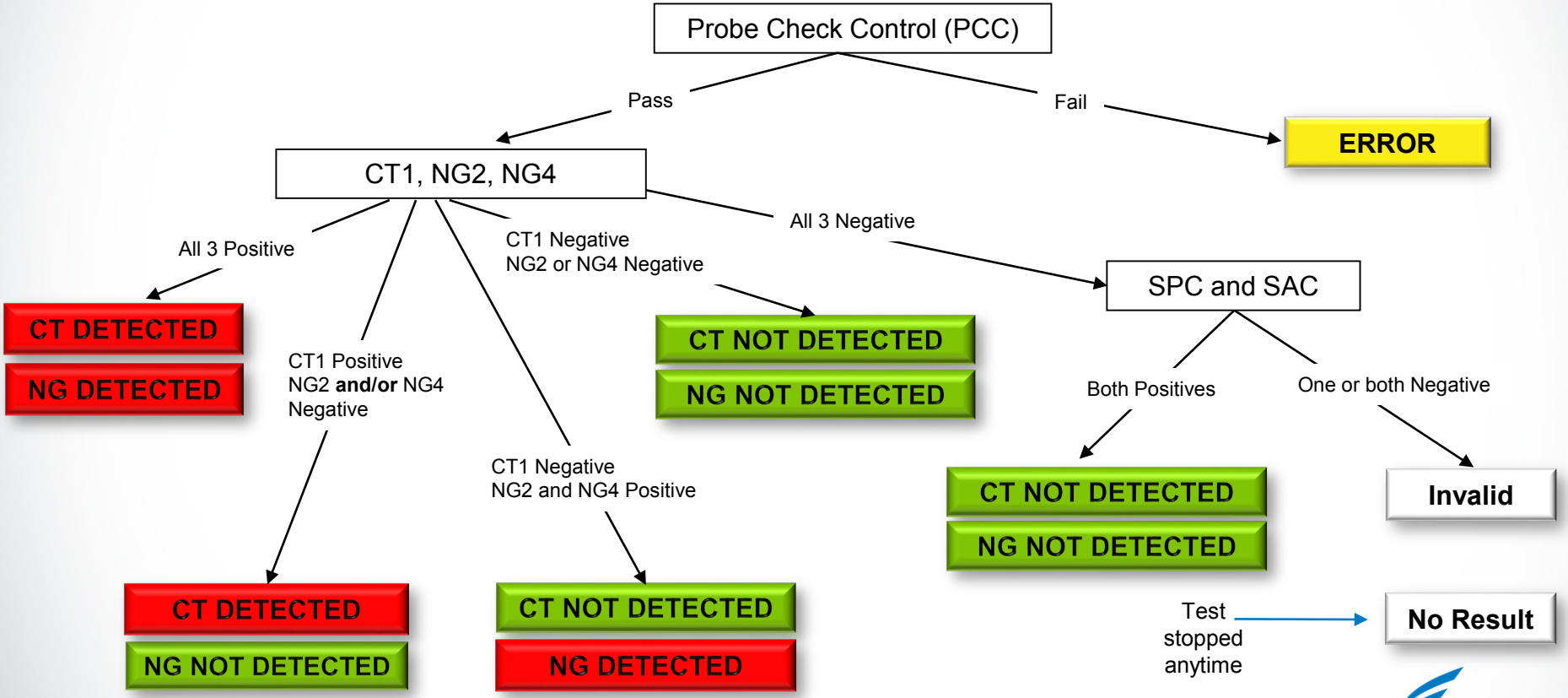
http://www.zeptometrix.com

1. *Take 1 vial of the control material*
2. *Vortex for 10 seconds*
3. *Using the kit pipette, aspirate control mix to the mark (1mL) and add it to the sample chamber of the cartridge*
4. *Close the lid and launch the test on the GeneXpert®*

- External controls should be used in accordance with local, state accrediting organizations, as applicable
- NATtrol™ products are Research Use Only and not for in-vitro diagnostic use.

Result Interpretation

Result Interpretation Algorithm



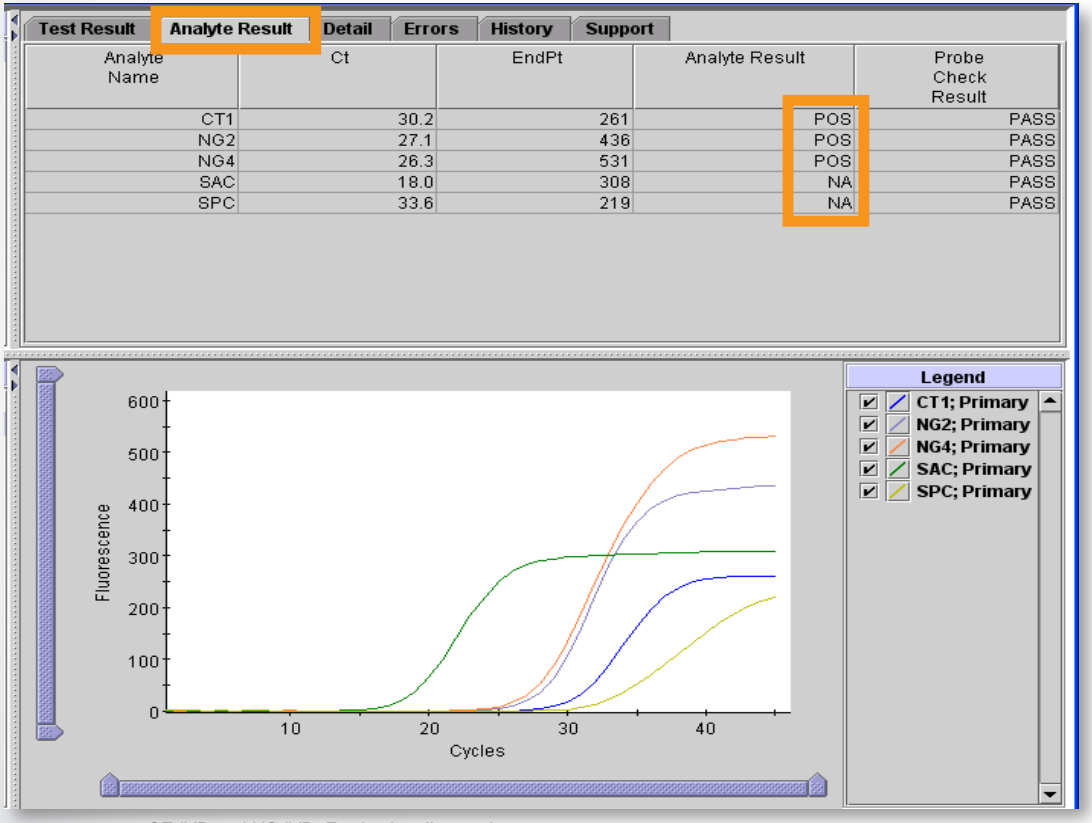
  CE-IVD and US-IVD. For *in vitro* diagnostic use

Xpert® CT/NG – All possible results

Result displayed	CT1	NG2	NG4	SPC	SAC
CT DETECTED NG DETECTED	+	+	+	+/-	+/-
CT DETECTED NG NOT DETECTED	+	+	-	+/-	+/-
CT DETECTED NG NOT DETECTED	+	-	+	+/-	+/-
CT NOT DETECTED NG DETECTED	-	+	+	+/-	+/-
CT NOT DETECTED NG NOT DETECTED	-	-	+	+/-	+/-
CT NOT DETECTED NG NOT DETECTED	-	-	-	+	+
INVALID	-	-	-	-	+/-
INVALID	-	-	-	+/-	-

CT DETECTED
NG DETECTED

CT DETECTED;
NG DETECTED



- The targets CT1, NG2 and NG4 are detected and the Ct values are within the valid range
- SAC: NA (not applicable)
  - SAC is ignored because a target amplification occurred
- SPC: NA (not applicable)
  - SPC is ignored because a target amplification occurred
- Probe Check: PASS

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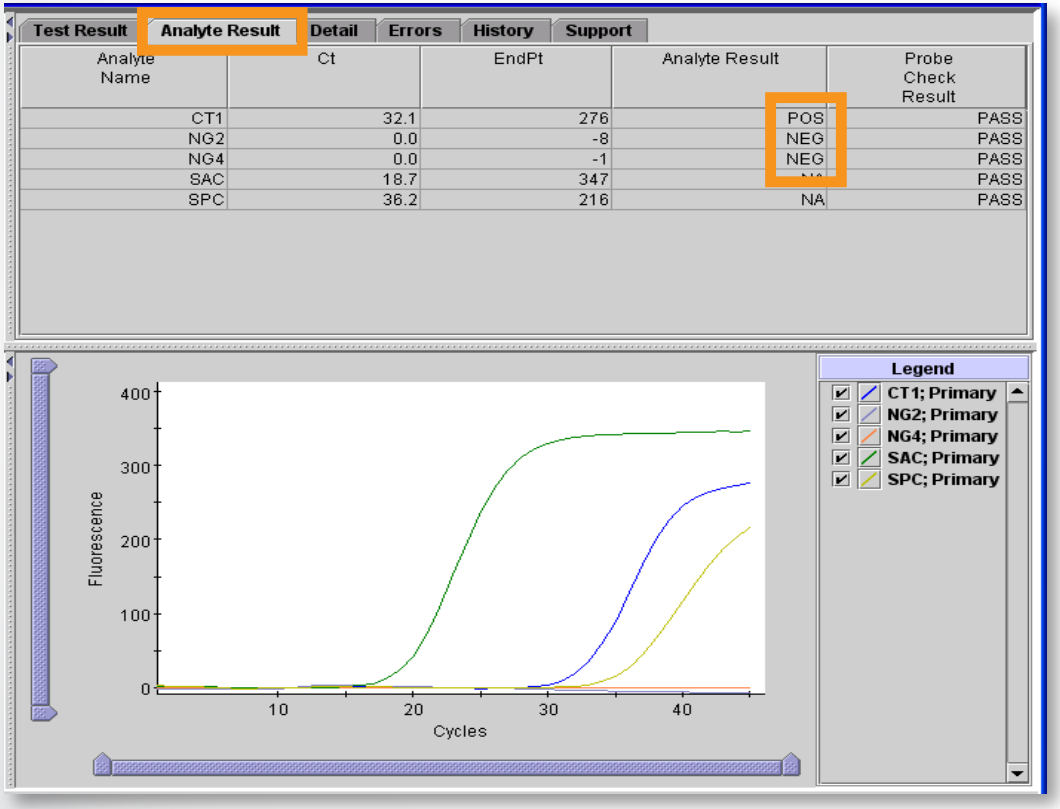
CT DETECTED; NG NOT DETECTED

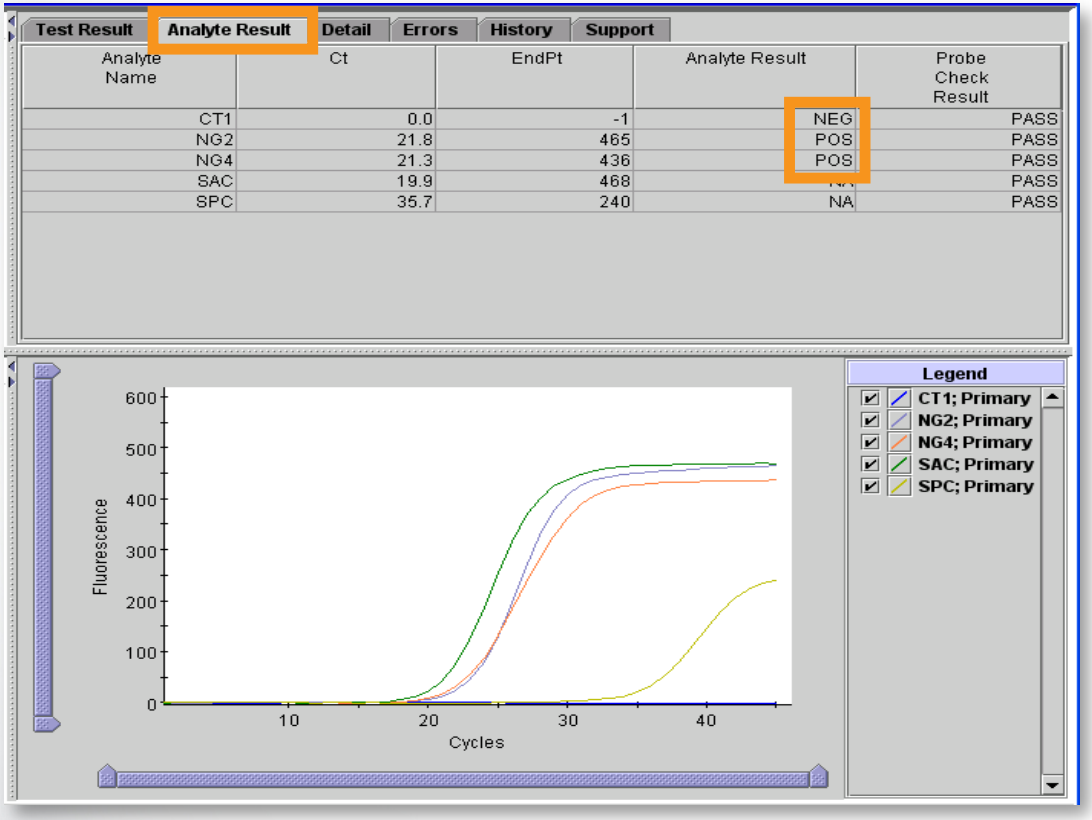
CT DETECTED;
NG NOT DETECTED



- The target CT1 is detected and the Ct value is within the valid range
- None of the NG targets are detected
- SAC: NA (not applicable)
  - SAC is ignored because an amplification occurred
- SPC: NA (not applicable)
  - SPC is ignored because the CT1 target amplification occurred
- Probe Check: PASS

CT NOT DETECTED; NG DETECTED

CT NOT DETECTED;
NG DETECTED

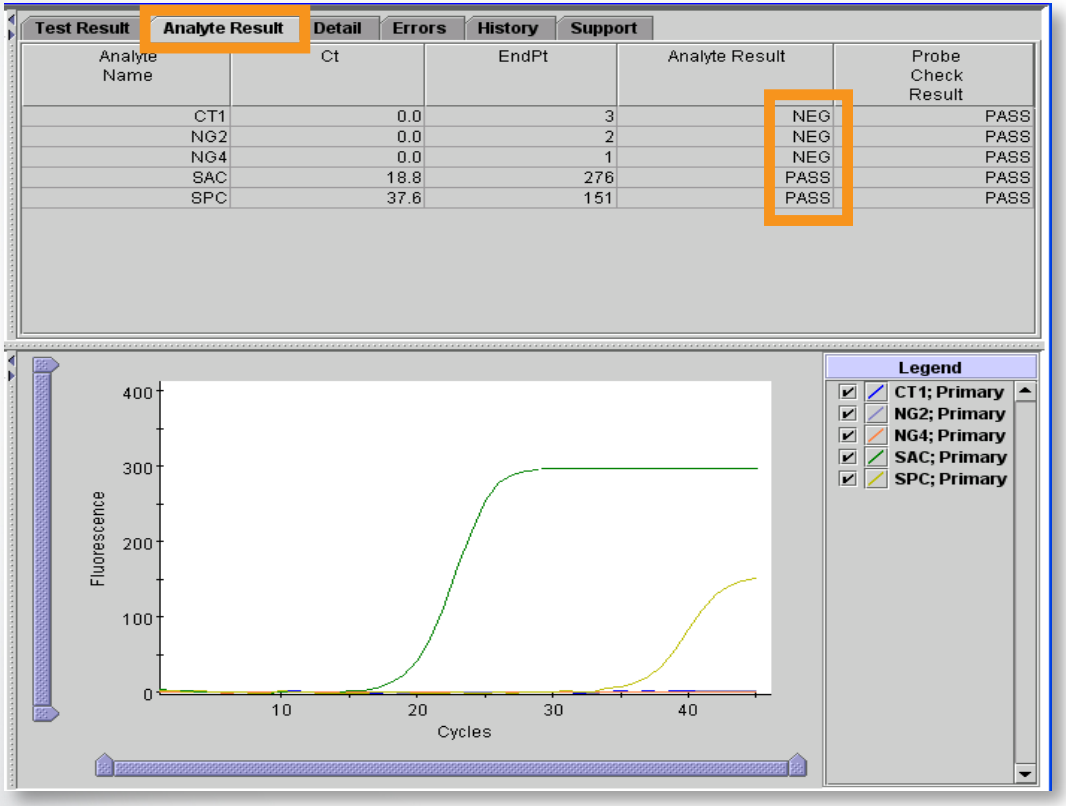


- The targets NG2 and NG4 are detected and the Ct values are within the valid range
- The target CT1 is not detected
- SAC: NA (not applicable)
  - SAC is ignored because the NG target amplification occurred
- SPC: NA (not applicable)
  - SPC is ignored because the NG target amplification occurred
- Probe Check: PASS

Cepheid

CT NOT DETECTED; NG NOT DETECTED

CT NOT DETECTED; NG NOT DETECTED



- The targets CT1, NG2 and NG4 are NOT detected
- SAC: PASS
  - SAC has a Ct value within the valid range
- SPC: PASS
  - SPC has a Ct value within the valid range
- Probe Check: PASS

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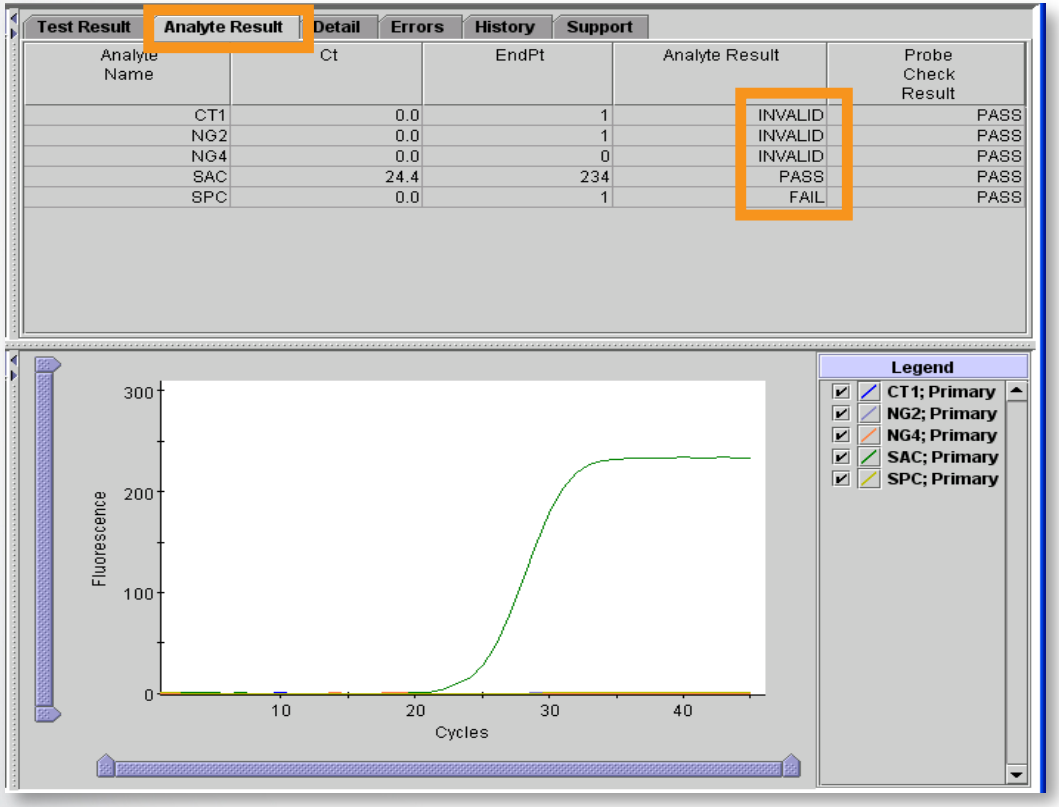
Troubleshooting

Factors That Negatively Affect Results

- Improper specimen collection
  - The number of organisms in the specimen is below the detection limit of the test
  - Performance with other collection devices and specimen types has not been assessed
- Improper transport or storage of collected specimen
  - Storage and transport conditions are specimen specific
  - Refer to the Package Insert for the appropriate handling instructions
- Improper testing procedure
  - Modification to the testing procedures may alter the performance of the test.
  - Careful compliance with the package insert is necessary to avoid erroneous results

INVALID

INVALID

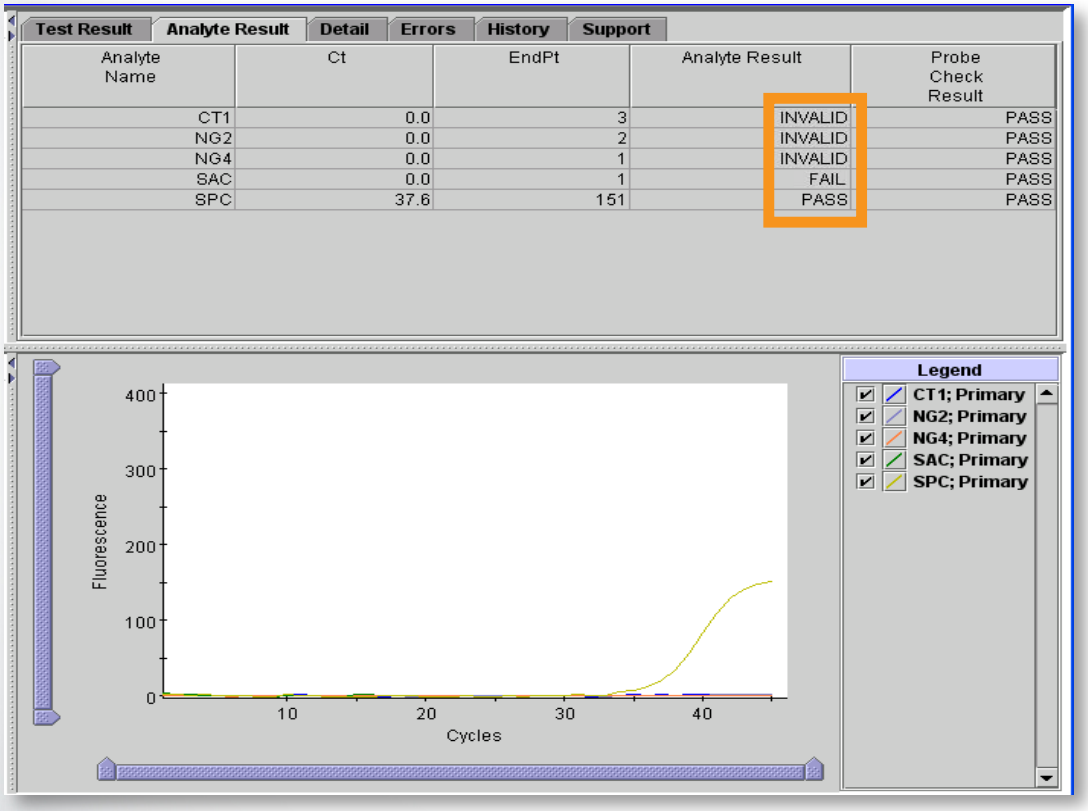


- Presence or absence of the CT1 and NG2/4 targets can not be determined
- SAC: PASS
  - SPC has a Ct value within the valid range
- SPC: FAIL
  - SAC Ct value is not within the valid range
- Probe Check: PASS

Cepheid

INVALID

INVALID

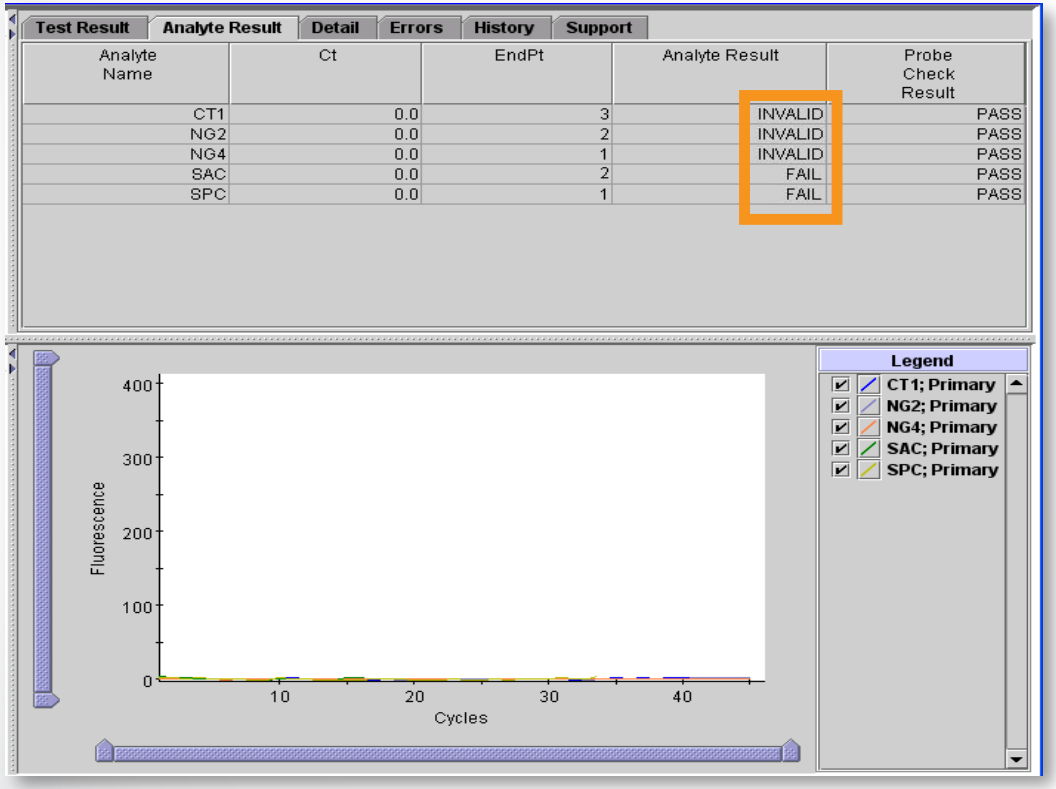


- Presence or absence of the CT1 and NG2/4 targets can not be determined
- SAC: FAIL
  - SAC Ct value is not within the valid range
- SPC: PASS
  - SPC has a Ct value within the valid range
- Probe Check: PASS

Cepheid

INVALID

INVALID



- Presence or absence of the CT1 and NG2/4 targets can not be determined
- SAC: FAIL
  - SPC Ct value is not within the valid range
- SPC: FAIL
  - SAC Ct value is not within the valid range
- Probe Check: PASS

INVALID

- INVALID result with failing SPC and/or SAC

  Origin(s)

  – PCR was inhibited due to interfering substances
  – Inadequate sample was used
  – Improper specimen storage/collection/preparation
  – Improper kit storage conditions

  Solution(s)

  – Use the correct specimen type
  – Check the sample quality (Blood, Mucin, topical medication…)
  – Follow recommended instructions on sample collection, preparation and storage
  – Check kit storage conditions and shelf life
  – Collect a new sample when necessary and retest

INVALID

- INVALID result with failing SAC only

  Origin(s)

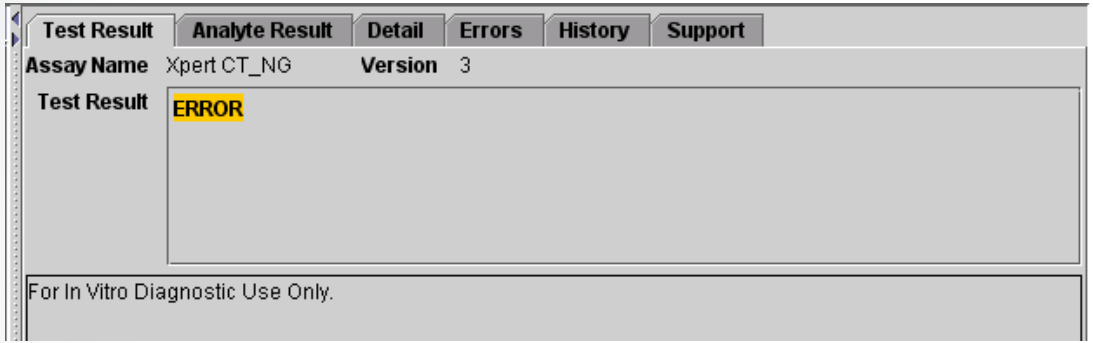
  – Inadequate sample was used
  – Improper specimen collection
  – Improper sample storage or preparation
  – Improper kit storage conditions

  Solution(s)

  – Use the correct specimen type
  – Check the collection: Urine first catch must be collected to ensure a proper epithelial cell concentration – Proper swabbing must be performed (according to illustrated collection instructions)
  – Follow recommended instructions on sample collection, preparation and storage
  – Check kit storage conditions and shelf life
  – Collect a new sample in the appropriate conditions, when necessary, and retest

ERROR

ERROR



- The Test result tab displays “ERROR”
- The error code and description can be found in the “Errors” Tab
- The test must be re-run, after corrective actions

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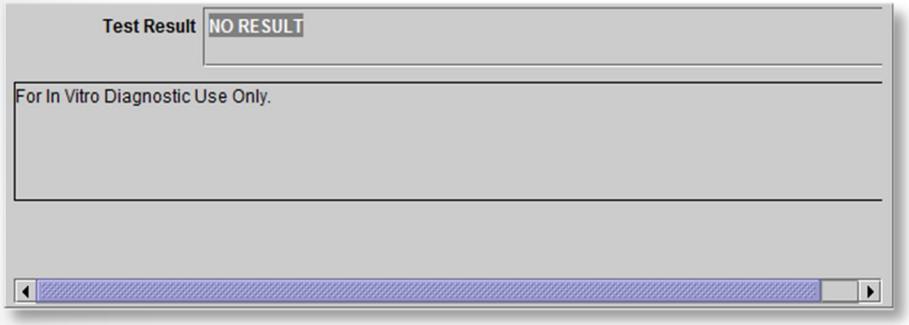
NO RESULT

NO RESULT



NO RESULT

- Test could not be completed and insufficient data was collected

ORIGIN(S)

- Power failure during test
- “Stop Test” function was used.
- Computer freeze or crash during test

Re-test Procedure

1

Discard used cartridge

Follow your institution's safety guidelines for disposal of cartridges

2

Obtain the residual treated sample from either

- Swab Transport Reagent or
- Urine Transport Reagent tube

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

3

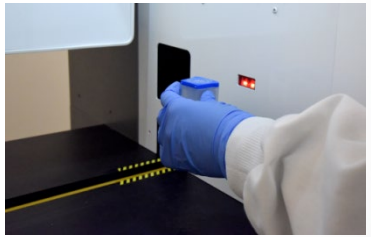
Obtain a new cartridge

Label appropriately as retest on the new cartridge

Process the sample per the package insert

4

Run the test on the GeneXpert® System



Cepheid

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 using the following link ***http://www.cepheid.com/us/support***

Region	Telephone	Technical Support Email
US	+ 1 888 838 3222	techsupport@cepheid.com
Australia and New Zealand	+ 1800 130 821 + 0800 001 028	techsupportANZ@cepheid.com
Brazil and Latin America	+ 55 11 3524 8373	latamsupport@cepheid.com
China	+ 86 400 821 0728	techsupportchina@cepheid.com
France	+ 33 563 825 319	support@cepheideurope.com
Germany	+ 49 69 710 480 480	support@cepheideurope.com
India, Bangladesh, Bhutan, Nepal and Sri Lanka	+ 91 11 48353010	techsupportindia@cepheid.com
Italy	+ 39 800 902 567	support@cepheideurope.com
South Africa	+ 27 861 22 76 35	support@cepheideurope.com
United Kingdom	+ 44 3303 332 533	support@cepheideurope.com
Belgium, Luxembourg and Netherlands	+33 563 825 3319	support@cepheideurope.com
Other European, Middle East, and African countries	+ 33 563 825 319 + 971 4 253 3218	support@cepheideurope.com
Other countries not listed	+1 408 400 8495	techsupport@cepheid.com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