Cepheid®

Instructions For Use

Xpert® CT/NG

For use with GeneXpert® System with Touchscreen

Catalog Numbers

REF GXCT/NG-10

REF GXCT/NG-120

303-0941 | Rev. A | 2023-07

℞only IVD *In Vitro* Diagnostic Medical Device

Trademark, Patents and Copyright Statements

See Revision History for a description of changes.

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Product Information

Proprietary Name

Xpert® CT/NG

Common or Usual Name

Xpert CT/NG

Intended Use, Summary, and Principle of Procedure

Intended Use

The Xpert CT/NG test, performed on the GeneXpert® Instrument Systems, is a qualitative *in vitro* real-time PCR test for the automated detection and differentiation of genomic DNA from *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (NG) to aid in the diagnosis of chlamydial and gonorrheal disease in the urogenital tract and extragenital sites (pharynx and rectum). The test may be used to test the following specimens from asymptomatic and symptomatic individuals: female and male urine, patient-collected vaginal swabs (collected in a clinical setting), clinician-collected endocervical swabs, and female and male pharyngeal and rectal swabs.

Summary and Explanation

Chlamydia trachomatis (CT) are Gram-negative, non-motile, bacteria that exist as obligate intracellular parasites of eukaryotic cells due to their inability to synthesize ATP. The CT species is comprised of at least fifteen serovars that can cause disease in humans; serovars D through K are the major cause of genital chlamydial infections in men and women[1] . Left untreated, CT can cause non-gonococcal urethritis, epididymitis, proctitis, cervicitis, and acute salpingitis. In women, untreated CT can lead to pelvic inflammatory disease (PID) in more than 40% of the infected population and render up to 20% infertile. PID can manifest as endometritis, salpingitis, pelvic peritonitis, and tubo-ovarian abscesses.[2,3,4,5]

Neisseria gonorrhoeae (NG) are non-motile, Gram-negative diplococci, and the causative agent of gonorrheal disease. Gonorrhea is the second most commonly reported bacterial sexually transmitted disease (STD). The majority of urethral infections caused by NG among men produce symptoms that cause them to seek curative treatment, but among women, infections often do not produce recognizable symptoms until complications (e.g., PID) have occurred.[6]

NG and CT infections are not limited to the genital tract but include extragenital sites, such as the pharynx and rectum.[7] This is particularly true for men who have sex with men, where disease may be limited to the pharynx or rectum and may go undetected if only genital sites are tested.[8] However, extragenital disease has also been reported in women.[9] Improved detection of extragenital NG is critical for identifying patients who require treatment and may prevent development of drug resistance due to inadequate treatment regimens that do not cover extragenital sites.[10]

Principle of the Procedure

The Xpert CT/NG test is an automated *in vitro* diagnostic test for qualitative detection and differentiation of DNA from CT and NG. The test is performed on the Cepheid GeneXpert Instrument Systems.

The GeneXpert Instrument Systems automate and integrate sample purification, nucleic acid amplification, and detection of the target sequences in simple or complex samples using real-time PCR and RT-PCR tests. The systems consist of an instrument, personal computer, and preloaded software for running tests on collected samples and viewing the results. The systems require the use of single-use disposable cartridges that hold the PCR reagents and host the PCR process. Because the cartridges are self-contained, cross-contamination between cartridges during the testing process is minimized. For a full description of the systems, refer to the appropriate *GeneXpert Instrument System Operator Manual*.

The Xpert CT/NG test includes reagents for the 5' exonuclease real-time PCR detection of CT and NG. Reagents for the detection of a Sample Processing Control (SPC), a Sample Adequacy Control (SAC), and a Probe Check Control (PCC) are also included in the cartridge. The SPC is present to control for adequate processing of the target bacteria and to monitor the presence of inhibitors in the PCR reaction.

The SAC reagents detect the presence of a single copy human gene and monitor whether the sample contains human DNA. The PCC verifies reagent rehydration, PCR tube filling in the cartridge, probe integrity, and dye stability. The primers and probes in the Xpert CT/NG test detect chromosomal sequences in the bacteria. One target is detected for CT (CT1) and two different targets are detected for NG (NG2 and NG4). Both NG targets need to be positive for the Xpert CT/NG test to return a positive NG result.

The Xpert CT/NG test is designed for use with the following specimens collected from symptomatic and asymptomatic individuals: female and male urine, patient-collected vaginal swabs (collected in a clinical setting), clinician-collected endocervical swabs, and female and male pharyngeal and rectal swabs. The urine and swab transport reagents are designed to preserve patient specimens to allow transport to the laboratory prior to analysis with the Xpert CT/NG test and are included in the following specimen collection kits: the Xpert Urine Specimen Collection Kit, the Xpert Vaginal/Endocervical Specimen Collection Kit, and the Xpert Swab Specimen Collection Kit.

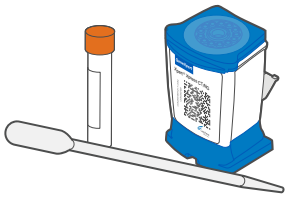
The specimen is briefly mixed by inverting the collection tube several times and/or aspirating with a transfer pipette. Using the supplied transfer pipette, the sample is pipetted above the fill mark on the transfer pipette and transferred to the sample chamber of the Xpert CT/NG cartridge. The GeneXpert cartridge is loaded onto the GeneXpert Instrument System platform, which performs hands-off, automated sample processing, and real-time PCR for detection of DNA. Summary and detailed test results are obtained in approximately 90 minutes and are displayed in tabular and graphic formats.

Reagents, Instruments, and Materials

Reagents

Materials Provided

The Xpert CT/NG kit (GXCT/NG-10) contains sufficient reagents to process 10 specimens or quality control samples, and the Xpert CT/NG kit (GXCT/NG-120) contains sufficient reagent to process 120 specimens or quality control samples.



The kits contain the following:

Xpert CT/NG cartridges with integrated reaction tubes	**10 per kit**	**120 per kit**
Bead 1, 2, and 3	1 of each per cartridge	1 of each per cartridge
Elution Reagent	2.0 mL per cartridge	2.0 mL per cartridge
Lysis Reagent (Guanidinium thiocyanate)	2.5 mL per cartridge	2.5 mL per cartridge
Wash Reagent	0.5 mL per cartridge	0.5 mL per cartridge
Binding Reagent	3.0 mL per cartridge	3.0 mL per cartridge
Transfer pipettes (1 mL)	**10 per kit**	**125 per kit**
CD	**1 per kit**	**1 per kit**

- Assay Definition Files (ADF)
- Instructions to import ADF into GeneXpert software
- Instructions for Use (Package Insert)

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

Note The bovine serum albumin (BSA) in the beads within this product was produced and manufactured exclusively from bovine plasma sourced in the United States. No ruminant protein or other animal protein

was fed to the animals; the animals passed ante- and post-mortem testing. During processing, there was no mixing of the material with other animal materials.

Materials Required but Not Provided

- Primary samples must be collected and treated with the appropriate kit:
  - Xpert Vaginal/Endocervical Specimen Collection Kit (SWAB/A-50) or Xpert Swab Specimen Collection Kit (SWAB/G-50)
  - Xpert Urine Specimen Collection Kit (URINE/A-50)
- GeneXpert system with touchscreen: GeneXpert instrument, touchscreen unit with built-in scanner, Cepheid OS software version 2.0 or higher, and operator manual.
- Printer: If a printer is required, contact Cepheid Technical support to arrange for the purchase of a recommended printer.

Materials Available but Not Provided

- ZeptoMetrix® NATtrol™ CT/NG External Run Controls (catalog # NATCT/NGNEG-6MC) as negative control.
- ZeptoMetrix® NATtrol™ CT/NG External Run Controls (catalog # NATCT(434)-6MC and NATNG-6MC) as positive controls.

Warnings and Precautions

General

- For *in vitro* diagnostic use. ℞only
- Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. 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. Center for Disease Control and Prevention and the Clinical and Laboratory Standards Institute.[11] ,[12]
- Follow your institution's safety procedures for working with chemicals and handling biological samples.
- 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.

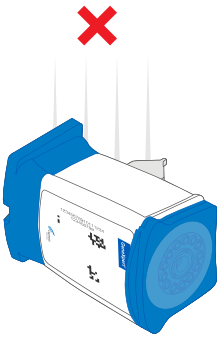
Specimen

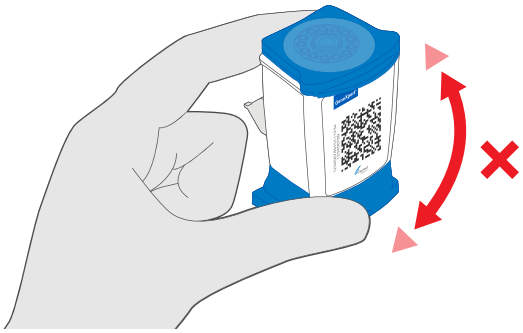
- For collection of endocervical swab specimens and patient-collected vaginal swab specimens, use only the Xpert Vaginal/Endocervical Specimen Collection Kit.
- For collection of endocervical swab specimens, patient-collected vaginal swab specimens, pharyngeal swab specimens and rectal swab specimens, use the Xpert Swab Specimen Collection Kit.

- For urine specimens, use only the Xpert Urine Specimen Collection Kit or unpreserved (neat) urine.
- Under or over dispensing of urine into Urine Transport Reagent tubes may affect test performance.
- Endocervical and patient-collected vaginal swab specimens must be collected and tested before the expiration date of the Swab Transport Reagent tube.
- Urine specimens must be tested before the expiration date of the Urine Transport Reagent tube.
- For rectal swab collection, highly soiled fecal swabs should not be used as they may result in errors.
- Maintain proper storage conditions during specimen transport to ensure the integrity of the specimen. Specimen stability under shipping conditions other than those recommended has not been evaluated.

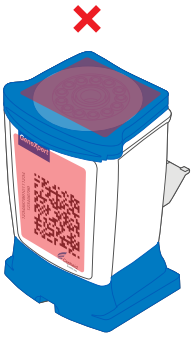
Test/Reagent

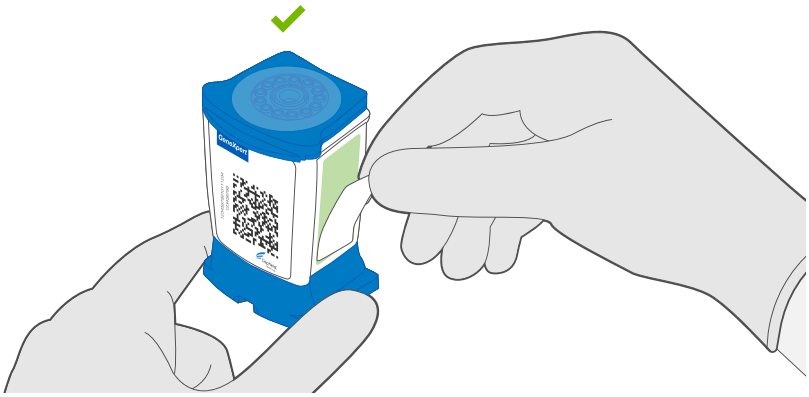
- Do not substitute Xpert CT/NG reagents with other reagents.
- Do not open the Xpert CT/NG cartridge lid except when adding the sample.
- Do not use a cartridge that has been dropped or shaken.



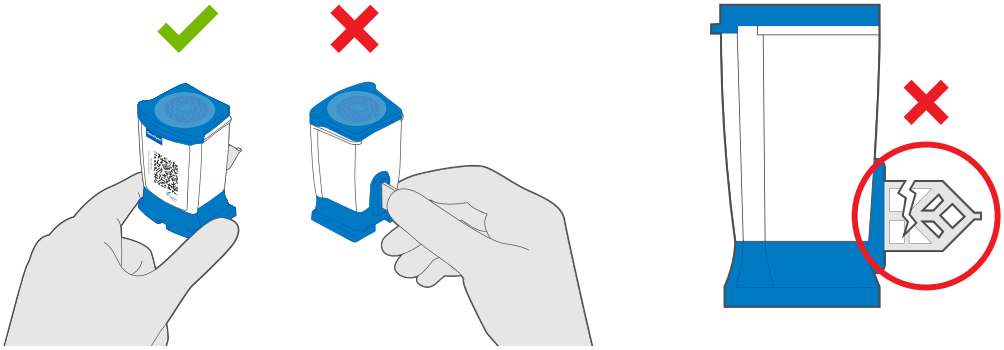


- Do not place the sample ID label on the cartridge lid or on the barcode label.





- Hold the cartridge by the base. Do not touch the reaction tube at the rear of the cartridge, as this could cause damage that would interfere with the light passing through it during the test. Do not use a cartridge that has a damaged reaction tube.



- Each single-use Xpert CT/NG cartridge is used to process one test. Do not reuse processed cartridges.
- Use of CT positive controls in the NG only test mode may lead to invalid control results.
- Use of NG positive controls in the CT only test mode may lead to invalid control results.
- Do not test the endocervical or patient-collected vaginal specimens received in the laboratory without the swab present. A false negative test result may occur.
- CHANGE GLOVES if they come in contact with specimen or appear to be wet, to avoid contaminating other specimens. Change gloves before leaving work area and upon entry into work area.
- In the event of a spill of specimens or controls, wear gloves and absorb the spill with paper towels. Then, thoroughly clean the contaminated area with a 1:10 dilution of freshly prepared household chlorine bleach. Final active chlorine concentration should be 0.5% regardless of the household bleach concentration in your country. Allow a minimum of two minutes of contact time. Ensure the work area is dry before using 70% denatured ethanol to remove bleach residue. Allow surface to dry completely before proceeding. Or, follow your institution's standard procedures for a contamination or spill event. For equipment, follow the manufacturer's recommendations for decontamination of equipment.

Chemical Hazards, Storage and Handling

Chemical Hazards[13,14]

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

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Storage and Handling

- Store the Xpert CT/NG cartridges and reagents at 2 °C – 28 °C until the expiration date provided on the label.
- Do not use reagents or cartridges that have passed the expiration date.
- Do not open a cartridge until ready to test. Use cartridges within 30 minutes after opening the cartridge lid.
- Do not use a cartridge that has leaked.

Specimen Collection, Testing, and Results

Specimen Collection

Specimen Collection, Transport and Storage

Collect specimens only with a Cepheid collection kit:

Xpert CT/NG Urine Specimen Collection Kit (CT/NGURINE-50) or Xpert Urine Specimen Collection Kit (URINE/A-50)

- First catch female urine specimen must be transferred to the Xpert Urine Transport Reagent or Xpert CT/NG Urine Transport Reagent tube within 24 hours of primary collection if shipped and/or stored at room temperature.
- First catch male urine specimen must be transferred to the Xpert Urine Transport Reagent or Xpert CT/NG Urine Transport Reagent tube within 3 days of primary collection if shipped and/or stored at room temperature.
- First catch male and female urine specimen NOT transferred to the Xpert Urine Transport Reagent or Xpert CT/NG Urine Transport Reagent tube (unpreserved urine specimen) can be shipped and/or stored for up to 8 days at 4 °C ± 2°C.
- First catch female urine specimen that is transferred to the Xpert Urine Transport Reagent or Xpert CT/NG Urine Transport Reagent tube (preserved female urine specimen) can be shipped and/or stored up to 45 days at 2 °C to 15 °C, or up to 3 days at 2 °C to 30 °C before testing with the Xpert CT/NG test.
- First catch male urine specimen that is transferred to the Xpert Urine Transport Reagent or Xpert CT/NG Urine Transport Reagent tube (preserved male urine specimen) can be shipped and/or stored up to 45 days at 2 °C to 30 °C before testing with the Xpert CT/NG test.

Note Urine must transferred to the Xpert Urine Transport Reagent or Xpert CT/NG Urine Transport Reagent tube prior to adding sample to the Xpert CT/NG cartridge.

Xpert CT/NG Vaginal/Endocervical Specimen Collection Kit (CT/NGSWAB-50) or Xpert Vaginal/Endocervical Specimen Collection Kit (SWAB/A-50) or Xpert Swab Specimen Collection Kit (SWAB/G-50)

For collection of endocervical swab specimens and patient-collected vaginal swab specimens, use the Xpert CT/NG Vaginal/Endocervical Specimen Collection Kit or the Xpert Vaginal/Endocervical Specimen Collection

Kit.

For collection of endocervical swab specimens, patient-collected vaginal swab specimens, pharyngeal swab specimens and rectal swab specimens, use the Xpert Swab Specimen Collection Kit.

- Swab samples stored in Xpert Swab Transport Reagent or Xpert CT/NG Swab Transport Reagent tubes should be transported to the laboratory at 2 °C to 30 °C.
- Swab samples in Xpert Swab Transport Reagent or Xpert CT/NG Swab Transport Reagent tubes are stable up to 60 days at 2 °C to 30 °C before testing with the Xpert CT/NG test.

Refer to the appropriate specimen collection kit IFU for collection and transport instructions.

Procedure

Preparing the Cartridge

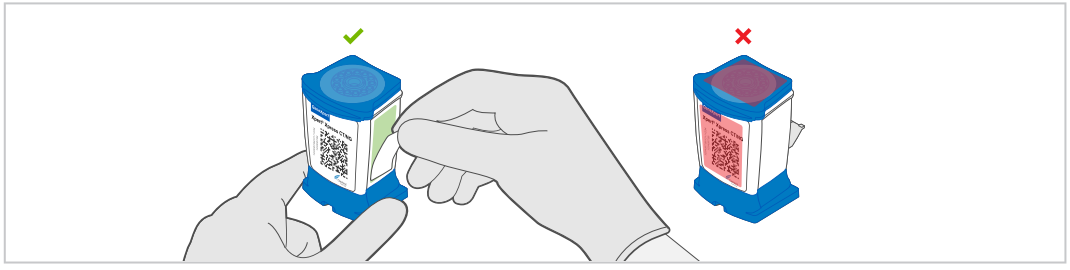
Important Start the test within 30 minutes of adding the sample to the cartridge.

To add the sample to the Xpert® CT/NG cartridge:

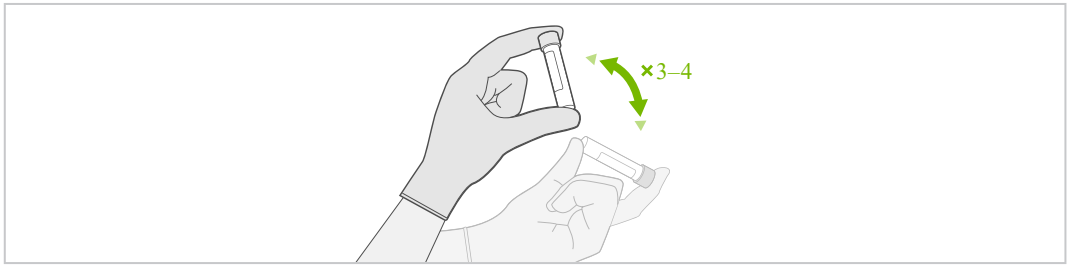
1. Obtain the following items:

   - Xpert® CT/NG cartridge

   - Transfer pipette (provided)
   - Appropriately collected and labeled test sample



2. Open the cartridge lid.
3. Gently invert the transport tube 3 to 4 times to ensure adequate mixing of sample and transport matrix.



4. Unwrap the transfer pipette.
5. Open the transport tube lid, compress the bulb of the transfer pipette, insert the pipette into the transport tube, and release the bulb to fill the transfer pipette above the mark on the pipette shaft (Figure 1). Ensure the pipette is filled with no air bubbles present.

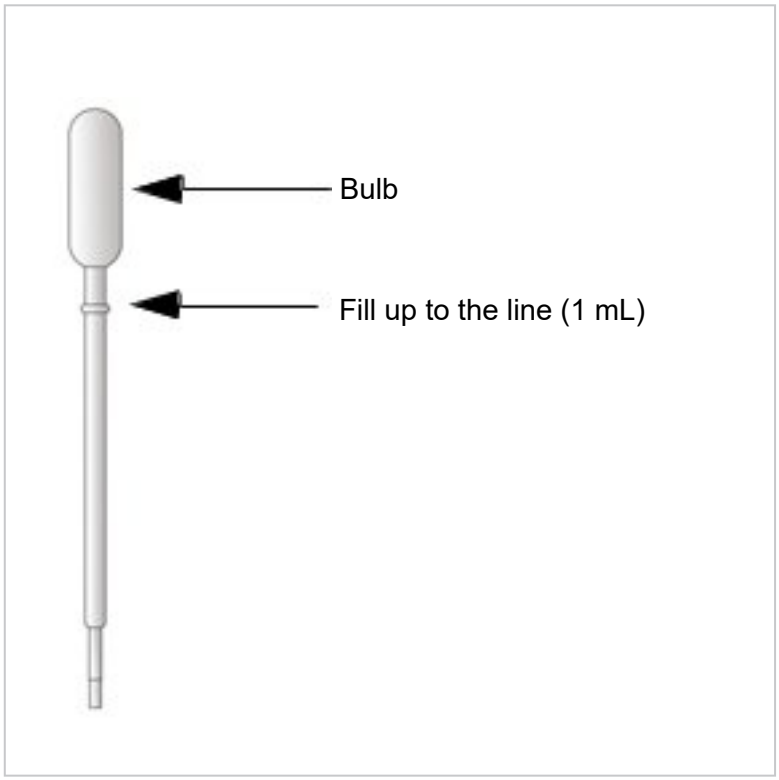
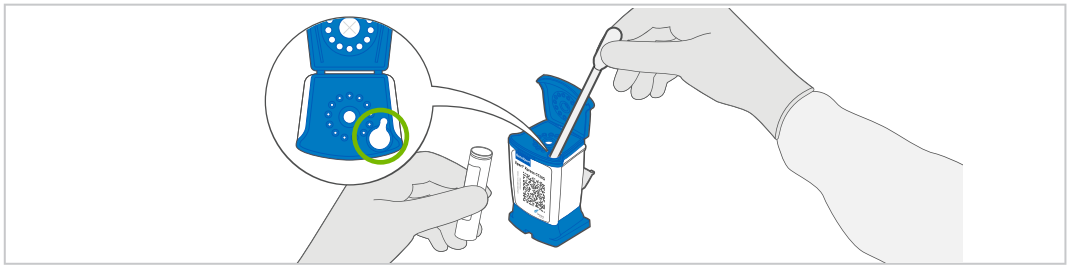
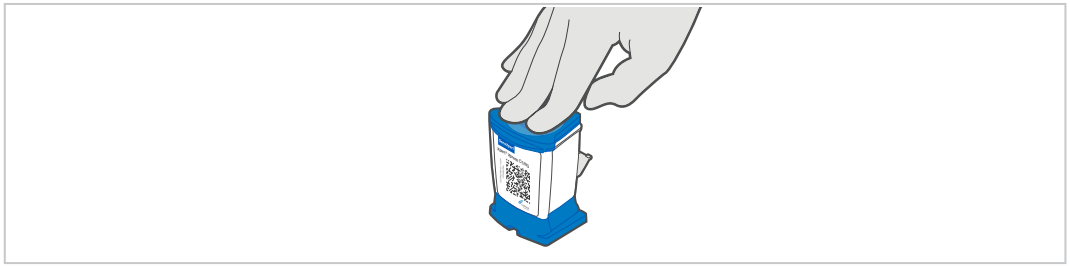


Figure 1 Transfer Pipette and Fill Mark

6. Empty the pipette's content into the sample chamber of the cartridge.



7. Close the cartridge lid.



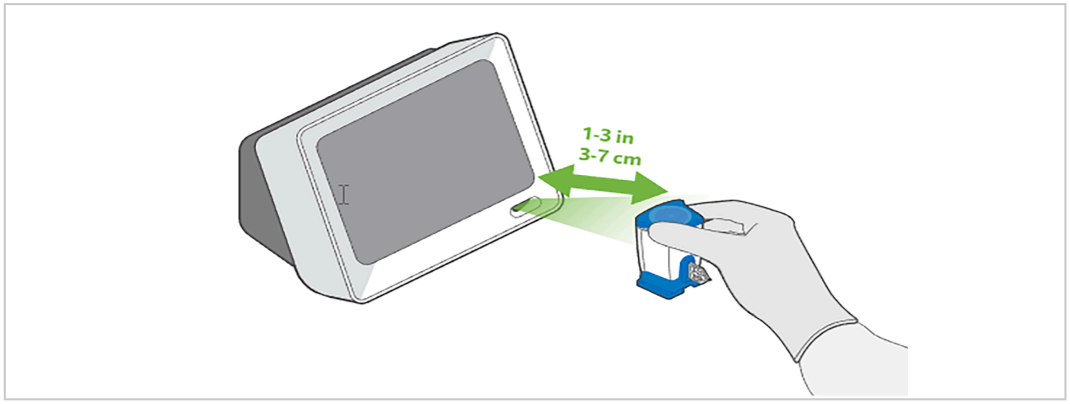
Starting the Test: GeneXpert System with Touchscreen

Important **Before you start the test, make sure that:**

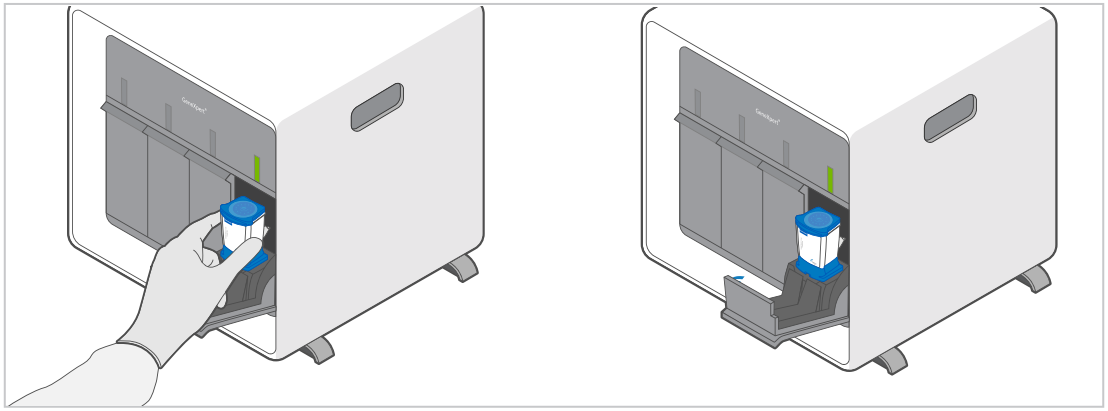
- **The system is running the correct Cepheid OS software version shown in section - Materials Required but Not Provided.**
- **The correct assay definition file is imported into the software.**

Note The default workflow is shown. Your system administrator may alter the workflow.

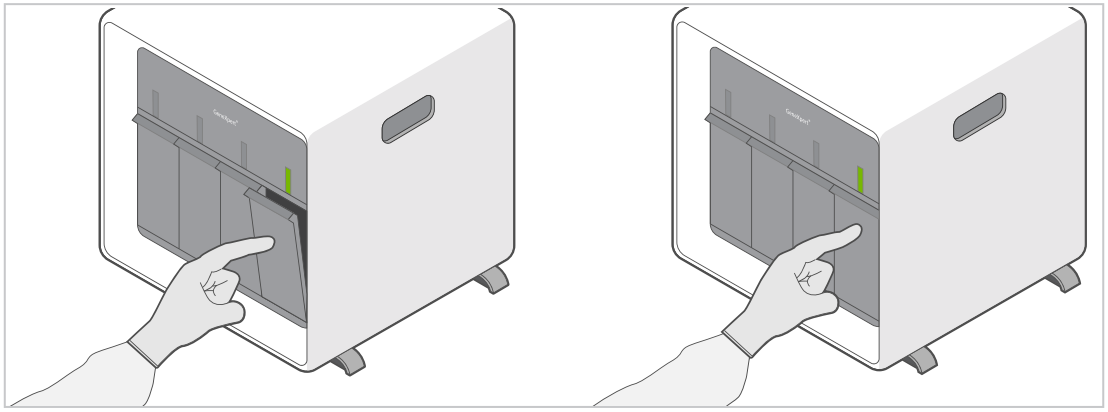
1. Turn on GeneXpert system with touchscreen.
2. Log on to system software using your username and password.
3. On the Modules tab, touch **Start Test**.
4. Follow onscreen prompts to create new test and enter patient and sample information.
5. Scan or manually input the cartridge serial number. If scanning, hold the cartridge about 1-3 inches (3-7 cm) away from the scanner. The scanner projects a green crosshair, which you center on the barcode. Scanning is complete when you hear an audible beep. Touch **Continue**.



6. Select the desired test and touch **Continue**.
7. Watch the cartridge preparation video, if needed.
8. On the Confirm screen, review all data and touch **Confirm**.
9. Open the module door under flashing green light and insert the cartridge.



10. Close cartridge module door completely by pressing until it latches. The test starts.



11. When the test completes, the **Results Summary** screen appears. Open the module door and remove cartridge.
12. Dispose of used cartridge in appropriate waste container according to your institution's standard practices.

Viewing Results: GeneXpert System with Touchscreen

The GeneXpert system with touchscreen results screen will automatically interpret test results for you and clearly show them in the **View Results** window.

1. Tap **Results**.
2. Tap the test to be viewed in the Results screen.
3. Click **OK**.
4. To generate a PDF report file, touch **View Report**. More detailed instructions for viewing and uploading results are available in your system operator manual.

Quality Control

Each test includes a Sample Processing Control (SPC), a Sample Adequacy Control (SAC) and a Probe Check Control (PCC).

- **Sample Processing Control (SPC)**—Ensures the sample was correctly processed. The SPC verifies that binding and elution of target DNA have occurred if the organisms are present and verifies that sample processing is adequate. Additionally this control detects sample-associated inhibition of the real-time PCR

test. The SPC should be positive in an analyte negative sample and can be negative or positive in an analyte positive sample. The SPC passes if it meets the validated acceptance criteria.

- **Sample Adequacy Control (SAC)**—Ensures that the sample contains human cells or human DNA. This multiplex test includes primers and probes for the detection of a single copy human gene. The SAC signal is only to be considered in an analyte negative sample. A negative SAC indicates that no human cells are present in the sample due to insufficient mixing of the sample or because of an inadequately taken sample.
- **Probe Check Control (PCC)**—Before the PCR reaction starts, the GeneXpert instrument 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.
- **External Controls**—External controls (one positive and one negative) may be used in accordance with local, state, and/or federal accrediting organizations, as applicable.

Results

The results are interpolated by the GeneXpert Instrument System from measured fluorescent signals and embedded calculation algorithms and will be shown in the **`View Results`** window. The Xpert CT/NG test provides test results for CT and NG targets, according to the algorithms shown in Table 1.

Table 1. Possible Final Test Results for CT/NG Selected Test

Result Text	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`	-	-	-	+/-	-

See Table 2 to interpret test result statements for the CT/NG test. The format of the test results shown will vary depending on the user's choice to run either a CT/NG, CT, or NG test.

Table 2. Xpert CT/NG Results and Interpretations

Result	Interpretation
CT DETECTED; NG DETECTED	CT target and NG target DNA sequences are detected. • PCR amplification of the CT target and the two NG targets give Cts within the valid range and fluorescence endpoints above the minimum setting. • SPC: Not applicable. The SPC is ignored because CT and NG target amplification can compete with this control. • SAC: Not applicable. The SAC is ignored because CT and NG target amplification can compete with this control. • PCC: PASS; all probe check results pass.
CT NOT DETECTED; NG DETECTED	CT target DNA sequence is not detected; NG target DNA sequences are detected. • CT is absent or below the test detection level; PCR amplification of the two NG targets give Cts within the valid range and fluorescence endpoints above the minimum setting. • SPC: Not applicable. The SPC is ignored because CT and NG target amplification can compete with this control. • SAC: Not applicable. The SAC is ignored because CT and NG target amplification can compete with this control. • PCC: PASS; all probe check results pass.
CT DETECTED;NG NOT DETECTED	CT target DNA sequence is detected; NG target DNA sequences are not detected. • PCR amplification of the CT target gives a Ct within the valid range and a fluorescence endpoint above the minimum setting; NG is absent or below the test detection level. • SPC: Not applicable. The SPC is ignored because CT and NG target amplification can compete with this control. • SAC: Not applicable. The SAC is ignored because CT and NG target amplification can compete with this control. • PCC: PASS; all probe check results pass.
CT NOT DETECTED; NG NOT DETECTED	Neither CT nor NG target DNA sequences are detected. • CT and NG are absent or below the test detection level. • SPC: PASS; PCR amplification of the SPC target gives a Ct within the valid range and a fluorescence endpoint above the minimum setting. • SAC: PASS; PCR amplification of the SAC target gives a Ct within the valid range and a fluorescence endpoint above the minimum setting. • PCC: PASS; all probe check results pass.

Result	Interpretation
INVALID	Presence or absence of CT and NG target DNA cannot be determined. Use the instructions in the Retest Procedure section to repeat the test. • SPC: FAIL; SPC target result is negative and the SPC Ct is not within valid range and endpoint below minimum setting. • SAC: PASS; SAC has a Ct within the valid range and fluorescence endpoint above the minimum setting. • PCC: PASS; all probe check results pass. Or • SPC: PASS; SPC has a Ct within the valid range and fluorescence endpoint above the minimum setting. • SAC: FAIL; SAC target result is negative. The SAC Ct is not within valid range and fluorescence endpoint is below the minimum setting. • PCC: PASS; all probe check results pass. Or • SPC: FAIL; SPC target result is negative, the SPC Ct is not within valid range and fluorescence endpoint is below the minimum setting. • SAC: FAIL; SAC target result is negative. The SAC Ct is not within valid range and fluorescence endpoint is below the minimum setting. • PCC: PASS; all probe check results pass.
ERROR	Presence or absence of CT and NG target DNA cannot be determined. Use the instructions in the Retest Procedure section to repeat the test. • SPC: NO RESULT • SAC: NO RESULT • PCC: FAIL*; all or one of the probe check results fail. The PCC probably failed because the reaction tube was filled improperly or a probe integrity problem was detected. * If the probe check passed, the error is caused by a system component failure.
NO RESULT	Presence or absence of CT and NG target DNA cannot be determined. Use the instructions in the Retest Procedure section to repeat the test. Insufficient data were collected to produce a test result (for example, the operator stopped a test that was in progress). • SPC: NO RESULT • SAC: NO RESULT • PCC: Not applicable

Reasons to Repeat the Test

If any of the following test results occur, repeat the test according to instructions in the Retest Procedure.

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

Retest Procedure

Obtain the leftover treated sample from the CT/NG Swab Transport Reagent, Swab Transport Reagent, CT/NG Urine Transport Reagent or Urine Transport Reagent tube. Repeat the test with a new cartridge. If the

leftover treated sample volume is 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.

Limitations

Limitations of the Procedure

- The Xpert CT/NG test has been validated with the following specimen types, collected with the Cepheid Xpert Vaginal/Endocervical Collection Kit:
  - Endocervical swabs
  - Patient-collected vaginal swabs
- The Xpert CT/NG test has been validated with the following specimen types, collected with the Xpert Swab 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
- Erroneous test results might occur from improper specimen collection, technical error, sample mix-up, or because the number of organisms are below the limit of detection of the test.
- Careful compliance with the instructions in this insert and to the Swab and Urine Collection Kit instruction documents are necessary to avoid erroneous results.
- False negative results may occur if the organism(s) is present at levels below the analytical limit of detection.
- The Xpert CT/NG test has been validated using the procedures provided in this IFU only. Modification to these procedures may alter the performance of the test.
- Because the detection of CT and NG is dependent on the DNA present in the sample, reliable results are dependent on proper sample collection, handling and storage.
- With endocervical and patient-collected vaginal specimens, test interference may be observed in the presence of: blood (>1% v/v) or mucin (>0.8% w/v).
- With urine specimens, test interference may be observed in the presence of: blood (>0.3% v/v), mucin (>0.2% w/v), bilirubin (>0.2 mg/mL), or Vagisil feminine powder (>0.2% w/v).
- Collection and testing of urine specimens with the Xpert CT/NG test is not intended to replace cervical exams and endocervical sampling for diagnosis of urogenital infection. Other genitourinary tract infections can be caused by other infectious agents.
- The effects of other potential variables such as vaginal discharge, use of tampons, douching, and specimen collection variables have not been determined.
- A negative test result does not exclude the possibility of infection because test results may be affected by improper specimen collection, technical error, specimen mix-up, concurrent antibiotic therapy, or the number of organisms in the specimen which may be below the sensitivity of the test.
- The Xpert CT/NG test should not be used for the evaluation of suspected sexual abuse or for other medico-legal indications. Additional testing is recommended in any circumstance when false positive or false negative results could lead to adverse medical, social, or psychological consequences.
- The Xpert CT/NG test provides qualitative results. No correlation can be drawn between the magnitude of the Ct value and the number of cells in an infected sample.

- The predictive value of a test depends on the prevalence of the disease in any particular population. See Table 3 through Table 8 for hypothetical predictive values when testing varied populations.
- Positive results may be observed after successful antibiotic treatment due to target nucleic acids from residual non-viable chlamydia.
- The Xpert CT/NG performance has not been evaluated in patients less than 14 years of age.
- The Xpert CT/NG performance has not been evaluated in patients with a history of hysterectomy.
- The patient-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated.
- The Xpert CT/NG test has not been validated for use with vaginal swab specimens collected by patients at home. The patient-collected vaginal swab specimen application is limited to healthcare facilities where support/counseling is available to explain procedures and precautions.
- The Xpert CT/NG test has not been evaluated with patients who are currently being treated with antimicrobial agents active against CT or NG.
- As with many diagnostic tests, results from the Xpert CT/NG test should be interpreted in conjunction with other laboratory and clinical data available to the clinician.
- Mutations or other changes within the regions of the bacterial genomes covered by the primers and/or probes in the Xpert test may result in failure to detect the target organisms.

Expected Values

The prevalence of infection with CT and/or NG in patient populations depend on risk factors such as age, gender, the presence or absence of symptoms, the type of clinic, and the sensitivity of the test used to detect infections. During the clinical evaluation of Xpert CT/NG for urogenital specimens, the observed CT prevalence rates in females were 5.3% and 5.4% for vaginal and endocervical swab specimens, respectively; the observed CT prevalence rates were 5.6% and 5.7% for female and male urine specimens, respectively (Table 9). The observed NG prevalence rates in females were 1.4% for both vaginal and endocervical swab specimens; the observed NG prevalence rates were 1.4% and 3.5% for female and male urine specimens, respectively (Table 10). During the clinical evaluation of Xpert CT/NG for extragenital specimens, the observed CT prevalence rates were 1.9% for pharyngeal swab specimens and 9.0% for rectal swab specimens, respectively (Table 15). The observed NG prevalence rates were 8.0% for pharyngeal swab specimens and 8.1% for rectal swab specimens, respectively (Table 16).

Positive and Negative Predictive Values

Hypothetical estimated positive and negative predictive values (PPV and NPV) for different prevalence rates using Xpert CT/NG are shown in Table 3 through Table 8 below. These calculations are based on a hypothetical prevalence and the overall sensitivity and specificity (compared to the patient infected status and the anatomical site infected status) observed during the Xpert CT/NG multi-center clinical studies (Table 9, Table 10, Table 15, and Table 16).

In patient-collected vaginal swab specimens, the overall sensitivity and specificity for CT were 99.5 and 99.1%, respectively (Table 9). The overall sensitivity and specificity for NG were 100% and 99.9%, respectively (Table 10). Table 3 shows PPV and NPV for patient-collected vaginal swab specimens using hypothetical prevalence rates.

Table 3. Hypothetical PPV and NPV– Patient-collected Vaginal Swabs

Prevalence Rate (%)	CT				NG			
	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
1	99.5	99.1	53.6	100	100	99.9	92.6	100
2	99.5	99.1	70.0	100	100	99.9	96.2	100
5	99.5	99.1	85.8	100	100	99.9	98.5	100
10	99.5	99.1	92.7	99.9	100	99.9	99.3	100
15	99.5	99.1	95.3	99.9	100	99.9	99.5	100
20	99.5	99.1	96.6	99.9	100	99.9	99.7	100
25	99.5	99.1	97.4	99.8	100	99.9	99.8	100
30	99.5	99.1	98.0	99.8	100	99.9	99.8	100
50	99.5	99.1	99.1	99.5	100	99.9	99.9	100

In endocervical swab specimens, the overall sensitivity and specificity for CT were 96.0% and 99.6%, respectively (Table 9). The overall sensitivity and specificity for NG were 100% and >99.9%, respectively (Table 10). Table 4 shows PPV and NPV for endocervical swab specimens using hypothetical prevalence rates.

Table 4. Hypothetical PPV and NPV– Endocervical Swabs

Prevalence Rate (%)	CT				NG			
	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
1	96.0	99.6	68.3	100	100	>99.9	97.4	100
2	96.0	99.6	81.3	99.9	100	>99.9	98.7	100
5	96.0	99.6	91.8	99.8	100	>99.9	99.5	100
10	96.0	99.6	96.0	99.6	100	>99.9	99.8	100
15	96.0	99.6	97.4	99.3	100	>99.9	99.8	100
20	96.0	99.6	98.2	99.0	100	>99.9	99.9	100
25	96.0	99.6	98.6	98.7	100	>99.9	99.9	100
30	96.0	99.6	98.9	98.3	100	>99.9	99.9	100
50	96.0	99.6	99.5	96.2	100	>99.9	100	100

In female urine specimens, the overall sensitivity and specificity for CT were 98.1% and 99.8%, respectively (Table 9). The overall sensitivity and specificity for NG were 94.4% and >99.9%, respectively (Table 10). Table 5 shows PPV and NPV for female urine specimens using hypothetical prevalence rates.

Table 5. Hypothetical PPV and NPV– Female Urine

Prevalence Rate (%)	CT				NG			
	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
1	98.1	99.8	85.5	100	94.4	>99.9	97.3	99.9
2	98.1	99.8	92.2	100	94.4	>99.9	98.6	99.9
5	98.1	99.8	96.8	99.9	94.4	>99.9	99.5	99.7
10	98.1	99.8	98.5	99.8	94.4	>99.9	99.7	99.4
15	98.1	99.8	99.0	99.7	94.4	>99.9	99.8	99.0

Prevalence Rate (%)	CT				NG			
	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
20	98.1	99.8	99.3	99.5	94.4	>99.9	99.9	98.6
25	98.1	99.8	99.5	99.4	94.4	>99.9	99.9	98.2
30	98.1	99.8	99.6	99.2	94.4	>99.9	99.9	97.7
50	98.1	99.8	99.8	98.1	94.4	>99.9	100	94.7

In male urine specimens, the overall sensitivity and specificity for CT were 98.5% and 99.8%, respectively (Table 9). The overall sensitivity and specificity for NG were 98.3% and 99.9%, respectively (Table 10). Table 6 shows PPV and NPV for male urine specimens using hypothetical prevalence rates.

Table 6. Hypothetical PPV and NPV– Male Urine

Prevalence Rate (%)	CT				NG			
	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
1	98.5	99.8	82.2	100	98.3	99.9	91.7	100
2	98.5	99.8	90.3	100	98.3	99.9	95.7	100
5	98.5	99.8	96.0	99.9	98.3	99.9	98.3	99.9
10	98.5	99.8	98.1	99.8	98.3	99.9	99.2	99.8
15	98.5	99.8	98.8	99.7	98.3	99.9	99.5	99.7
20	98.5	99.8	99.1	99.6	98.3	99.9	99.6	99.6
25	98.5	99.8	99.3	99.5	98.3	99.9	99.7	99.4
30	98.5	99.8	99.5	99.3	98.3	99.9	99.8	99.3
50	98.5	99.8	99.8	98.5	98.3	99.9	99.9	98.3

In pharyngeal swab specimens, the overall sensitivity and specificity for CT were 95.9% and 99.7%, respectively (Table 15). The overall sensitivity and specificity for NG were 94.7% and 98.8%, respectively (Table 16). Table 7 shows PPV and NPV for pharyngeal swab specimens using hypothetical prevalence rates.

Table 7. Hypothetical PPV and NPV– Pharyngeal Swabs

Prevalence Rate (%)	CT				NG			
	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
1	95.9	99.7	75.2	100.0	94.7	98.8	43.9	99.9
2	95.9	99.7	85.9	99.9	94.7	98.8	61.3	99.9
5	95.9	99.7	94.0	99.8	94.7	98.8	80.3	99.7
10	95.9	99.7	97.1	99.5	94.7	98.8	89.6	99.4
15	95.9	99.7	98.1	99.3	94.7	98.8	93.2	99.1
20	95.9	99.7	98.7	99.0	94.7	98.8	95.1	98.7
25	95.9	99.7	99.0	98.7	94.7	98.8	96.3	98.2
30	95.9	99.7	99.2	98.3	94.7	98.8	97.1	97.7
50	95.9	99.7	99.7	96.1	94.7	98.8	98.7	94.9

In rectal swab specimens, the overall sensitivity and specificity for CT were 86.0% and 99.4%, respectively (Table 15). The overall sensitivity and specificity for NG were 91.2% and 99.6%, respectively (Table 16). Table 8 shows PPV and NPV for rectal swab specimens using hypothetical prevalence rates.

Table 8. Hypothetical PPV and NPV– Rectal Swabs

Prevalence Rate (%)	CT				NG			
	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
1	86.0	99.4	57.2	99.9	91.2	99.6	70.3	99.9
2	86.0	99.4	73.0	99.7	91.2	99.6	82.7	99.8
5	86.0	99.4	87.4	99.3	91.2	99.6	92.5	99.5
10	86.0	99.4	93.6	98.5	91.2	99.6	96.3	99.0
15	86.0	99.4	95.9	97.6	91.2	99.6	97.6	98.5
20	86.0	99.4	97.1	96.6	91.2	99.6	98.3	97.8
25	86.0	99.4	97.8	95.5	91.2	99.6	98.7	97.1
30	86.0	99.4	98.3	94.3	91.2	99.6	99.0	96.4
50	86.0	99.4	99.3	87.7	91.2	99.6	99.6	91.9

Specific Performance Characteristics

Clinical Performance – Urine, Endocervical Swabs and Vaginal Swabs

Performance characteristics of Xpert CT/NG were determined in a multi-site prospective investigational study at 36 US and UK institutions by comparing Xpert CT/NG to a patient infected status (PIS) algorithm based on combined results from two currently marketed NAAT tests.

Study participants included consenting asymptomatic and symptomatic, sexually active males and females, including pregnant women, seen at locations including, but not limited to: OB/GYN, sexually transmitted disease (STD), teen, public health, and family planning clinics. The average age among female study participants was 30.3 years (range = 14 to 83 years); the average age among male study participants was 37.7 years (range = 17 to 74 years).

The study specimens consisted of prospectively collected male urine, female urine, endocervical swabs, urethral swabs and patient-collected vaginal swabs (collected in a clinical setting).

A female study participant was categorized as infected (I) by PIS for CT or NG if at least one positive result was reported from each reference NAAT test. If both NAAT tests resulted in equivocal results for both sample types (swab and urine), the PIS status was defined as equivocal (EQ). This is the only scenario for an overall PIS of EQ; no study participants fell into this category for this study. Female study participants with positive results on both reference urine specimens and negative results on both reference swab specimens were categorized as infected (I) for urine and not infected (NI) for the swab specimen. Any other combination of results was categorized as not infected (NI).

A male study participant was categorized as infected (I) by PIS for CT or NG if at least one positive result was reported from each reference NAAT test. If both NAAT tests resulted in equivocal results for both sample types (swab and urine), the PIS status was defined as equivocal (EQ). This is the only scenario for an overall PIS of EQ; no study participants fell into this category for this study. Any other combination of results was categorized as not infected (NI).

Performance of Xpert CT/NG was calculated relative to the PIS for each of the three female sample types (endocervical swabs, patient-collected vaginal swabs and urine), and male urine.

During the clinical evaluation of Xpert CT/NG, a total of 212 female subjects were infected with CT. Symptoms were reported in 41.0% (87/212) of infected and 34.1% (1221/3579) non-infected female subjects. A total of 54 female subjects were infected with NG. Symptoms were reported in 53.7% (29/54) of infected and 34.1% (1273/3729) non-infected female subjects. A total of 196 male subjects were infected with CT. Symptoms were reported in 62.8% (123/196) of infected and 18.0% (584/3248) non-infected male subjects. A total of 119 male subjects were infected with NG. Symptoms were reported in 89.1% (106/119) of infected

and 18.1% (601/3325) non-infected male subjects.

Among the 14,790 tests performed, 416 had to be retested due to **ERROR**, **INVALID** or **NO RESULT** outcomes (2.81%, 95% CI 2.56-3.09). Of those, 355 specimens yielded valid results upon repeat test (18 specimens were not retested). The overall valid reporting rate of the test was 99.6% (14,729/14,790).

Chlamydia Trachomatis Performance Results

Results from Xpert CT/NG were compared to the patient infected status (PIS) algorithm for determination of sensitivity, specificity, and predictive values. Sensitivity and specificity for CT by gender, specimen type, and symptom status are shown in Table 9.

Table 9. Xpert CT/NG vs. Patient Infected Status for CT Detection- Urine, Endocervical Swabs and Vaginal Swabs

Specimen		Sx Status	n	TP	FP	TN	FN	Prev%	Sensitivity% (95 CI)	Specificity% (95 CI)	PPV% (95 CI)	NPV% (95 CI)
Female	PC-VS	Sym	1294	79	20	1195	0	6.1	100 (95.4-100)	98.4 (97.5-99.0)	79.8 (70.5-87.2)	100 (99.7-100)
		Asym	2472	121	11	2339	1	4.9	99.2 (95.5-100)	99.5 (99.2-99.8)	91.7 (85.6-95.8)	>99.9 (99.8-100)
		All	3766	200	31	3534	1	5.3	99.5 (97.3-100)	99.1 (98.8-99.4)	86.6 (81.5-90.7)	>99.9 (99.8-100)
	ES	Sym	1293	76	5	1209	3	6.1	96.2 (89.3-99.2)	99.6 (99.0-99.9)	93.8 (86.2-98.0)	99.8 (99.3-99.9)
		Asym	2464	117	11	2331	5	5.0	95.9 (90.7-98.7)	99.5 (99.2-99.8)	91.4 (85.1-95.6)	99.8 (99.5-99.9)
		All	3757	193	16	3540	8	5.4	96.0 (92.3-98.3)	99.6 (99.3-99.7)	92.3 (87.9-95.6)	99.8 (99.6-99.9)
	Urine	Sym	1292	84	4	1203	1	6.6	98.8 (93.6-100)	99.7 (99.2-99.9)	95.5 (88.8-98.7)	99.9 (99.5-100)
		Asym	2475	123	2	2347	3	5.1	97.6 (93.2-99.5)	99.9 (99.7-100)	98.4 (94.3-99.8)	99.9 (99.6-100)
		All	3767	207	6	3550	4	5.6	98.1 (95.2-99.5)	99.8 (99.6-99.9)	97.2 (94.0-99.0)	99.9 (99.7-100)
Male	Urine	Sym	706	120	2	581	3	17.4	97.6 (93.0-99.5)	99.7 (98.8-100)	98.4 (94.2-99.8)	99.5 (98.5-99.9)
		Asym	2730	73	5	2652	0	2.7	100.0 (95.1-100)	99.8 (99.6-99.9)	93.6 (85.7-97.9)	100 (99.9-100)
		All	3436	193	7	3233	3	5.7	98.5 (95.6-99.7)	99.8 (99.6-99.9)	96.5 (92.9-98.6)	99.9 (99.7-100)

TP=true positive, FP=false positive, TN=true negative, FN=false negative, ES=endocervical swab, PC-VS=patient collected vaginal swab

Neisseria Gonorrhoeae Performance Results

Results from Xpert CT/NG were compared to the patient infected status (PIS) algorithm for determination of sensitivity, specificity, and predictive values. Sensitivity and specificity for NG by gender, specimen type, and symptom status are shown in Table 10.

Table 10. Xpert CT/NG vs. Patient Infected Status for NG Detection- Urine, Endocervical Swabs and Vaginal Swabs

Specimen		Sx Status	n	TP	FP	TN	FN	Prev%	Sensitivity% (95 CI)	Specificity% (95 CI)	PPV% (95 CI)	NPV% (95 CI)
Female	PC-VS	Sym	1294	27	2	1265	0	2.1	100 (87.2-100)	99.8 (99.4-100)	93.1 (77.2-99.2)	100 (99.7-100)
		Asym	2472	25	1	2446	0	1.0	100 (86.3-100)	>99.9 (99.8-100)	96.2 (80.4-99.9)	100 (99.8-100)
		All	3766	52	3	3711	0	1.4	100 (93.2-100)	99.9 (99.8-100)	94.5 (84.9-98.9)	100 (99.9-100)
	ES	Sym	1293	27	1	1265	0	2.1	100 (87.2-100)	99.9 (99.6-100)	96.4 (81.7-99.9)	100 (99.7-100)
		Asym	2464	25	0	2439	0	1.0	100 (86.3-100)	100 (99.8-100)	100 (86.3-100)	100 (99.8-100)
		All	3757	52	1	3704	0	1.4	100 (93.2-100)	>99.9 (99.8-100)	98.1 (89.9-100)	100 (99.9-100)
	Urine	Sym	1292	28	0	1263	1	2.2	96.6 (82.2-99.9)	100 (99.7-100)	100 (87.7-100)	99.9 (99.6-100)
		Asym	2475	23	1	2449	2	1.0	92.0 (74.0-99.0)	>99.9 (99.8-100)	95.8 (78.9-99.9)	99.9 (99.7-100)
		All	3767	51	1	3712	3	1.4	94.4 (84.6-98.8)	>99.9 (99.9-100)	98.1 (89.7-100)	99.9 (99.8-100)
Male	Urine	Sym	706	105	0	600	1	15.0	99.1 (94.9-100)	100 (99.4-100)	100 (96.5-100)	99.8 (99.1-100)
		Asym	2730	12	3	2714	1	0.5	92.3 (64.0-99.8)	99.9 (99.7-100)	80.0 (51.9-95.7)	>99.9 (99.8-100)
		All	3436	117	3	3314	2	3.5	98.3 (94.1-99.8)	99.9 (99.7-100)	97.5 (92.9-99.5)	99.9 (99.8-100)

TP=true positive, FP=false positive, TN=true negative, FN=false negative, ES=endocervical swab, PC-VS=patient collected vaginal swab

Cycle Threshold (Ct) Frequency Distribution

Patient-collected vaginal swabs, endocervical swabs and urine specimens were collected from 3781 females and urine specimens were collected from 3444 males at 36 collection sites in the US and the UK. A total of 212 females and 196 males were infected with CT and a total of 54 females and 119 males were infected with NG. The frequency distribution of Xpert CT/NG positive results for CT and NG infected study subjects are shown in Figure 2 and Figure 3, respectively.

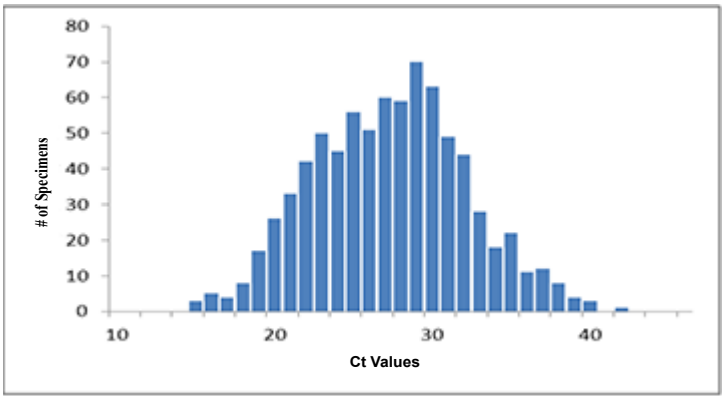


Figure 2 Ct Distribution of Patients Designated as Positive for CT Based on PIS Algorithm

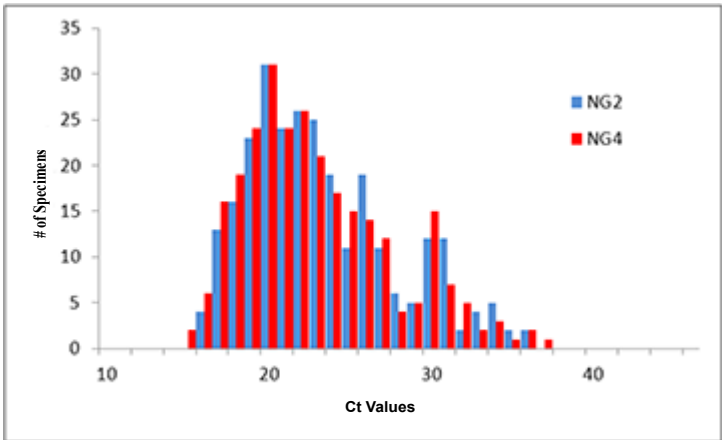


Figure 3 Ct Distribution of Patients Designated as Positive for NG Based on PIS Algorithm

Table 11 shows the number of results from symptomatic and asymptomatic females designated as infected or not infected with CT based on the PIS algorithm.

Table 11. Patient Infected Status – Female CT

PIS[a]	NAAT1		NAAT2		Xpert			Symptom Status		Total
	SW[a]	UR[a]	SW	UR	PC-VS[a]	ES[a]	UR	Symp	Asymp	
NI[b]	-	-	-	-	-	-	-	1160	2269	3429
NI	-	-	-	-	IND	-	-	6	8	14
NI	-	-	-	-	-	IND[c]	-	6	16	22
NI	-	-	-	-	-	-	IND	5	6	11
NI	-	-	-	-	+	+	-	0	1	1
NI	-	-	-	-	+	-	-	6	4	10
NI	-	-	-	-	-	+	-	3	5	8
NI	-	-	-	-	-	-	+	1	0	1
NI	-	-	-	EQ[d]	-	-	-	6	20	26
NI	-	-	-	EQ	IND	IND	-	1	0	1
NI	-	-	EQ	-	-	-	-	3	4	7
NI	-	-	EQ	-	-	-	IND	1	0	1
NI	-	-	-	+	-	-	-	0	7	7
NI	-	-	+	-	-	-	-	3	0	3
NI	-	-	+	-	-	+	-	0	1	1
NI[e]	-	+	-	+	+	-	+	7	1	8
NI[e]	-	+	-	+	+	-	-	0	1	1
NI[e]	-	+	-	+	-	-	+	0	1	1
NI	-	+	-	-	-	-	-	1	0	1
NI	-	+	-	-	+	-	+	1	0	1
NI	+	-	-	-	-	-	-	4	8	12
NI	+	-	-	-	+	-	-	2	1	3

PIS[a]	NAAT1		NAAT2		Xpert			Symptom Status		Total
	SW[a]	UR[a]	SW	UR	PC-VS[a]	ES[a]	UR	Symp	Asymp	
NI	+	-	-	-	+	+	-	1	2	3
NI	+	-	-	-	-	+	-	0	1	1
NI	+	+	-	-	-	-	-	1	0	1
NI	+	+	-	-	-	-	+	0	1	1
NI	+	+	-	-	+	+	+	1	1	2
NI	+	+	-	-	+	-	+	1	0	1
NI	+	+	-	-	+	-	-	1	0	1
Total Non-Infected								**1221**	**2358**	**3579**
I[f]	+	+	+	+	+	+	+	65	104	169
I	+	+	+	+	IND	+	+	0	1	1
I	+	+	+	+	+	IND	+	0	1	1
I	+	+	+	+	+	+	IND	1	0	1
I	+	+	+	+	-	+	+	0	1	1
I	+	+	+	+	+	-	+	0	1	1
I[f]	-	+	-	+	+	-	+	7	1	8
I[f]	-	+	-	+	+	-	-	0	1	1
I[f]	-	+	-	+	-	-	+	0	1	1
I	-	+	+	+	+	+	+	0	2	2
I	+	-	+	+	+	+	+	1	0	1
I	+	-	+	+	+	-	+	0	1	1
I	+	-	+	+	+	+	+	1	0	1
I	+	+	-	+	+	-	+	3	2	5
I	+	+	-	+	+	+	+	4	2	6
I	+	+	+	-	+	+	+	3	4	7
I	+	+	+	-	+	+	-	1	1	2
I	+	+	+	-	+	-	+	0	1	1
I	+	-	+	-	+	+	+	1	0	1
I	+	-	EQ	+	+	+	+	0	1	1
Total Infected								**87**	**125**	**212**

a. **PIS** = Patient Infected Status; **SW** = swab; **UR** = urine; **PC-VS** = patient-collected vaginal swab; **ES** = endocervical swab

b. **NI** = Non-infected

c. **IND** = Indeterminate – **ERROR**, **INVALID** or **NO RESULT** by Xpert CT/NG; specimens with IND results by Xpert are not included in the performance tables for that specimen type.

d. **EQ** = Equivocal result for this individual specimen type only; PIS status determined based on remaining specimens.

e. These samples are infected for urine and non-infected for swabs. In this table, they appear twice.

f. **I** = Infected

Table 12 shows the number of results from symptomatic and asymptomatic females designated as infected or not infected with NG based on the PIS algorithm.

Table 12. Patient Infected Status – Female NG

PIS[a]	NAAT1		NAAT2		Xpert			Symptom Status		Total
	SW[a]	UR[a]	SW	UR	PC-VS[a]	ES[a]	UR	Symp	Asymp	
NI[b]	-	-	-	-	-	-	-	1229	2390	3619
NI	-	-	-	-	IND[c]	-	-	6	9	15
NI	-	-	-	-	-	IND	-	6	17	23
NI	-	-	-	-	-	-	IND	6	6	12
NI	-	-	-	-	+	-	+	0	1	1
NI	-	-	-	-	+	-	-	1	0	1
NI	-	-	EQ[d]	-	-	-	-	2	5	7
NI	-	-	-	EQ	-	-	-	9	20	29
NI	-	-	-	+	-	-	-	1	3	4
NI	-	-	+	-	-	-	-	7	4	11
NI[e]	-	+	-	+	+	+	+	1	0	1
NI[e]	-	+	-	+	-	-	+	1	0	1
NI	-	-	+	+	-	-	-	1	0	1
NI	+	-	-	-	-	-	-	1	1	2
NI	-	-	EQ	-	-	-	IND	1	0	1
NI	-	-	-	EQ	-	IND	IND	1	0	1
Total Non-Infected								**1273**	**2456**	**3729**
I[f]	+	+	+	+	+	+	+	19	19	38
I	+	+	+	-	+	+	+	2	2	4
I	+	-	+	+	+	+	+	1	1	2
I[f]	-	+	-	+	+	+	+	1	0	1
I[f]	-	+	-	+	-	-	+	1	0	1
I	+	-	+	-	+	+	-	1	2	3
I	+	-	+	-	+	+	+	1	0	1
I	+	+	-	+	+	+	+	1	0	1
I	+	+	+	EQ	+	+	+	0	1	1
I	+	+	EQ	+	+	+	+	1	0	1
I	+	EQ	+	-	+	+	+	1	0	1
Total Infected								**29**	**25**	**54**

a. **PIS** = Patient Infected Status; **SW** = swab; **UR** = urine; **PC-VS** = patient-collected vaginal swab; **ES** = endocervical swab

b. **NI** = Non-infected

c. **IND** = Indeterminate – **ERROR**, **INVALID** or **NO RESULT** by Xpert CT/NG; specimens with IND results by Xpert are not included in the performance tables for that specimen type.

d. **EQ** = Equivocal result for this individual specimen type only; PIS status determined based on remaining specimens.

e. These samples are infected for urine and non-infected for swabs. In this table, they appear twice.

f. **I** = Infected

Table 13 shows the number of results from symptomatic and asymptomatic males designated as infected or

not infected with CT based on the PIS algorithm.

Table 13. Patient Infected Status – Male CT

PIS[a]	NAAT1		NAAT2		GX	Symptom Status		Total
	SW[a]	UR[a]	SW	UR	UR	Symp	Asymp	
NI[b]	-	-	-	-	-	568	2621	3189
NI	-	-	-	EQ[c]	-	0	19	19
NI	-	-	+	-	-	2	1	3
NI	+	-	-	-	-	6	1	7
NI	+	+	-	-	-	1	1	2
NI	-	-	-	+	-	2	7	9
NI	-	+	-	-	-	2	1	3
NI	-	-	EQ	-	-	0	1	1
NI	+	+	-	-	+	2	4	6
NI	-	-	-	-	+	0	1	1
NI	-	-	-	-	IND[d]	1	6	7
NI	-	-	-	EQ	IND	0	1	1
Total Non-Infected						**584**	**2664**	**3248**
I[e]	+	+	+	+	+	104	50	154
I	+	+	-	+	+	8	10	18
I	-	+	-	+	+	4	7	11
I	+	+	+	-	+	2	2	4
I	+	-	+	-	+	1	0	1
I	+	-	-	+	+	1	0	1
I	-	+	+	+	+	0	1	1
I	+	+	+	EQ	+	0	2	2
I	EQ	+	-	+	+	0	1	1
I	+	-	+	-	-	2	0	2
I	+	+	+	-	-	1	0	1
Total Infected						**123**	**73**	**196**

a. **PIS**= Patient Infected Status; **SW** = Swab; **UR** = urine,

b. **NI** = Non-infected

c. **EQ** = Equivocal result for this individual specimen type only; PIS status determined based on remaining specimens.

d. **IND** = Indeterminate – **ERROR**, **INVALID** or **NO RESULT** by Xpert CT/NG; specimens with IND results by Xpert are not included in the performance tables for that specimen type.

e. **I** = Infected

Table 14 shows the number of results from symptomatic and asymptomatic males designated as infected or not infected with NG based on the PIS algorithm.

Table 14. Patient Infected Status – Male NG

PIS[a]	NAAT1		NAAT2		GX	Symptom Status		Total
	SW[a]	UR[a]	SW	UR	UR	Symp	Asymp	
NI[b]	-	-	-	-	-	597	2680	3277
NI	-	-	-	EQ[c]	-	0	21	21
NI	-	-	EQ	-	-	0	1	1
NI	EQ	EQ	-	-	-	1	0	1
NI	-	-	+	-	-	0	3	3
NI	-	-	-	+	-	0	3	3
NI	-	+	-	-	-	0	1	1
NI	+	-	-	-	-	2	5	7
NI	-	EQ	-	-	+	0	1	1
NI	EQ	-	+	-	+	0	1	1
NI	-	-	-	-	+	0	1	1
NI	-	-	-	-	IND[d]	1	6	7
NI	-	-	-	EQ	IND	0	1	1
Total Non-Infected						**601**	**2724**	**3325**
I[e]	+	+	+	+	+	105	11	116
I	+	+	+	-	+	0	1	1
I	+	-	+	-	-	0	1	1
I	+	-	-	+	-	1	0	1
Total Infected						**106**	**13**	**119**

a. **PIS** = Patient Infected Status; **SW** = Swab; **UR** = urine.

b. **NI** = Non-infected

c. **EQ** = Equivocal result for this individual specimen type only; PIS status determined based on remaining specimens.

d. **IND** = Indeterminate – **ERROR**, **INVALID** or **NO RESULT** by Xpert CT/NG; specimens with IND results by Xpert are not included in the performance tables for that specimen type.

e. **I** = Infected

Clinical Performance – Pharyngeal Swabs and Rectal Swabs

Performance characteristics of Xpert CT/NG were determined in a multi-site prospective investigational study at 9 US institutions by comparing Xpert CT/NG to the anatomic site infected status (ASIS) algorithm based on combined results from two NAAT tests, with a tiebreaker NAAT test if applicable.

The anatomic site was considered to be infected if both of the reference test results were positive. The anatomic site is considered to be not infected when both reference test results were negative. If there was discordance between the reference tests, an additional NAAT was tested as a tiebreaker. In this case, agreement of 2/3 of the reference NAATs determined the ASIS result. If two tests were equivocal or one equivocal and one not run, the third test result stood as the ASIS if positive or negative. If two tests were not run, the ASIS was considered invalid and excluded from the analysis. The tiebreaker test was run by the lab if any NAAT was not concordant with the others and interpreted only in the case of discordant results between the two planned reference tests for each test. As the tiebreaker test was not a combination test, the tiebreaker was only run for the organism with disagreement (e.g., if NG disagrees and CT agrees, the tiebreaker was only

run for NG).

Study participants included consenting adults seeking sexually transmitted disease (STD) testing at the participating clinics, which included clinics focused on sexually transmitted diseases, women's health, student health and family planning, as well as clinics specializing in lesbian, gay, bisexual, and transgender (LGBT) health. Potential subjects were identified, assessed for eligibility and approached for informed consent. Both symptomatic and asymptomatic individuals were included in the study population. The study specimens consisted of prospectively collected rectal and pharyngeal swabs. Performance of Xpert CT/NG was calculated relative to the ASIS for each of the two sample types.

A total of 2767 study participants were enrolled in the study, of which 2577 pharyngeal swab and 2538 rectal swab specimens were eligible for inclusion in the data analyses. One hundred and ninety (190) pharyngeal specimens were excluded from the data analyses due to the following reasons: 167 for temperature excursions during shipment, 4 participants withdrew consent, 2 specimens shipment errors, 2 post-swab collection errors, 1 specimen not collected, 1 participant receiving antibiotics, and 13 specimens with Xpert results not available or non-determinate. Two hundred and twenty-nine (229) rectal specimens were excluded from the data analyses due to the following reasons: 167 for temperature excursions during shipment, 6 participants withdrew consent, 5 specimens shipment errors, 2 post-swab collection errors, 1 specimen not collected, 1 participant receiving antibiotics, and 46 specimens with Xpert results not available or non-determinate.

Among the study participants included in the data analyses for pharyngeal swab performance 20.8% were female at birth and 79.2% were male at birth. The average age was 33.8 years (range = 18 to 76 years).

Among the study participants included in the data analyses for rectal swab performance 20.9% were female at birth and 79.1% were male at birth. The average age was 33.7 years (range = 18 to 76 years).

Of the 2572 study participants eligible for inclusion in the pharyngeal and rectal swab analyses for CT detection, 0.9% (22/2572) were positive for CT by pharyngeal swab and rectal swab by ASIS. Of the 2573 study participants eligible for inclusion in the pharyngeal and rectal swab analyses for NG detection, 3.7% (95/2573) were positive for NG by pharyngeal swab and rectal swab.

Among the 5163 tests performed, 198 (3.8%) had to be retested due to **ERROR**, **INVALID** or **NO RESULT** outcomes. Of those, 151 specimens yielded valid results upon repeat test (2 specimens were not retested). The overall valid reporting rate of the test was 99.1% (5116/5163).

Chlamydia Trachomatis Performance Results – Pharyngeal and Rectal Swabs

Results from Xpert CT/NG were compared to the ASIS algorithm for determination of sensitivity and specificity. Results for CT by symptomatic status are shown in Table 15.

Table 15. Xpert CT/NG vs. ASIS for CT Detection by Symptomatic Status– Pharyngeal Swabs and Rectal Swabs

Specimen	Status	n	TP	FP	TN	FN	Prev %	Sensitivity% (95 CI)	Specificity% (95 CI)
PS	Sym	306	9	0	297	0	2.9	100.0% (70.1-100.0)	100.0% (98.7-100.0)
	Asym	2269	38	8	2221	2	1.8	95.0% (83.5-98.6)	99.6% (99.3-99.8)
	All	2575	47	8	2518	2	1.9	95.9% (86.3-98.9)	99.7% (99.4-99.8)
RS	Sym	188	22	1	160	5	14.4	81.5% (63.3-91.8)	99.4% (96.6-99.9)

Specimen	Status	n	TP	FP	TN	FN	Prev %	Sensitivity% (95 CI)	Specificity% (95 CI)
	Asym	2347	175	14	2131	27	8.6	86.6% (81.3-90.7)	99.4% (98.9-99.6)
	All	2535	197	15	2291	32	9.0	86.0% (80.9-89.9)	99.4% (98.9-99.6)

TP=true positive**, FP**=false positive, **TN**=true negative, **FN**=false negative, **PS**=pharyngeal swab, **RS**=rectal swab

Neisseria gonorrhoeae Performance Results – Pharyngeal and Rectal Swabs

Results from Xpert CT/NG were compared to the ASIS algorithm for determination of sensitivity and specificity. Results for NG by symptomatic status are shown in Table 16.

Table 16. Xpert CT/NG vs. ASIS for NG Detection by Symptomatic Status – Pharyngeal Swabs and Rectal Swabs

Specimen	Status	n	TP	FP	TN	FN	Prev%	Sensitivity% (95 CI)	Specificity% (95 CI)
PS	Sym	306	39	3	261	3	13.7	92.9% (81.0-97.5)	98.9% (96.7-99.6)
	Asym	2269	156	26	2079	8	7.2	95.1% (90.7-97.5)	98.8% (98.2-99.2)
	All	2575	195	29	2340	11	8.0	94.7% (90.7-97.0)	99.7% (99.4-99.8)
RS	Sym	188	38	0	149	1	20.7	97.4% (86.8-99.6)	99.4% (96.6-99.9)
	Asym	2347	149	9	2173	17	7.1	89.8% (84.2-93.5)	99.4% (98.9-99.6)
	All	2535	187	9	2322	18	8.1	91.2% (86.6-94.4)	99.6% (98.9-99.6)

TP=true positive**, FP**=false positive, **TN**=true negative, **FN**=false negative, **PS**=pharyngeal swab, **RS**=rectal swab

Table 17 and Table 18 show the number of results designated as infected or not infected with CT based on the ASIS algorithm for pharyngeal and rectal specimens, respectively.

Table 17. Anatomic Site Infected Status – Pharyngeal CT

ASIS[a]	NAAT1	NAAT2	Tiebreaker NAAT	Xpert	Total
NI	-	-	NA[b]	-	2504
NI	NR[c]	-	-	-	6
NI	-	-	NA	+	4
NI	-	+	-	-	5
NI	+	-	-	-	2
NI	-	+	-	+	1
NI	+	-	-	+	1
NI	EQ[d]	-	-	-	1
IND[e]	+	-	EQ	+	1

ASIS[a]	NAAT1	NAAT2	Tiebreaker NAAT	Xpert	Total
IND	NR	-	+	+	1
				Total Not Infected	2526
I	+	+	NA	+	40
I	-	+	+	+	5
I	+	-	+	+	2
I	+	+	NA	-	1
I	-	+	+	-	1
				Total Infected	49

a. **ASIS** = Anatomic Site Infected Status: **NI**=Not Infected; **I**=Infected; **IND**=indeterminate, considered not infected.

b. **NA**=Not applicable; both reference NAAT tests agreed.

c. **NR** = Not run

d. **EQ**=Equivocal

e. **IND**=Indeterminate. Considered infected if Xpert negative and not infected if Xpert positive to evaluate under worst-case scenario.

Table 18. Anatomic Site Infected Status – Rectal CT

ASIS[a]	NAAT1	NAAT2	Tiebreaker NAAT	Xpert	Total
NI	-	-	NA[b]	-	2221
NI	NR[c]	-	-	-	47
NI	-	-	NA	+	12
NI	+	-	-	-	11
NI	-	+	-	-	10
NI	-	+	-	+	2
NI	-	EQ[d]	-	-	2
IND[e]	+	EQ	-	+	1
				Total Not Infected	2306
I	+	+	NA	+	172
I	-	+	+	+	14
I	-	+	+	-	11
I	+	+	NA	-	9
I	+	-	+	+	6
I	+	-	+	-	5
I	+	EQ	+	+	3
I	-	EQ	+	-	2
I	NR	+	+	+	2
I	+	EQ	+	-	1
I	+	EQ	NR	-	1
I	NR	E	+	-	1
IND	-	NR	+	-	1
IND	+	-	NR	-	1
				Total Infected	229

a. **ASIS** = Anatomic Site Infected Status: **NI**=Not Infected; **I**=Infected; **IND**=indeterminate, considered not infected.

b. **NA**=Not applicable; both reference NAAT tests agreed.

c. **NR** = Not run

d. **EQ**=Equivocal

e. **IND**=Indeterminate. Considered infected if Xpert negative and not infected if Xpert positive to evaluate under worst-case scenario.

Table 19 and Table 20 show the number of results designated as infected or not infected with NG based on the ASIS algorithm for pharyngeal and rectal specimens, respectively.

Table 19. Anatomic Site Infected Status – Pharyngeal NG

ASIS[a]	NAAT1	NAAT2	Tiebreaker NAAT	Xpert	Total
NI	-	-	NA[b]	-	2317
NI	-	-	NA	+	19
NI	-	+	-	-	14

ASIS[a]	NAAT1	NAAT2	Tiebreaker NAAT	Xpert	Total
NI	-	+	-	+	4
NI	+	-	-	-	4
NI	+	-	-	+	4
NI	NR[c]	-	-	-	5
NI	-	EQ[d]	-	+	1
IND[e]	-	+	EQ	+	1
				Total Not Infected	2369
I	+	+	NA	+	175
I	+	+	NA	-	4
I	-	+	+	+	16
I	-	+	+	-	5
I	+	-	+	+	2
I	NR	+	+	+	2
IND	+	EQ	-	-	1
IND	-	EQ	+	-	1
				Total Infected	206

a. **ASIS** = Anatomic Site Infected Status: **NI**=Not Infected; **I**=Infected; **IND**=indeterminate, considered not infected.

b. **NA**=Not applicable; both reference NAAT tests agreed.

c. **NR** = Not run

d. **EQ**=Equivocal

e. **IND**=Indeterminate. Considered infected if Xpert negative and not infected if Xpert positive to evaluate under worst-case scenario.

Table 20. Anatomic Site Infected Status – Rectal NG

ASIS[a]	NAAT1	NAAT2	Tiebreaker NAAT	Xpert	Total
NI	-	-	NA[b]	-	2261
NI	NR[c]	-	-	-	49
NI	-	-	NA	+	6
NI	+	-	-	-	5
NI	-	+	-	-	4
NI	+	-	-	+	2
NI	-	EQ[d]	-	-	2
NI	-	NR	-	-	1
IND[e]	+	EQ	-	+	1
				Total Not Infected	2331
I	+	+	NA	+	172
I	-	+	+	+	13
I	+	+	NA	-	8
I	-	+	+	-	8
I	+	-	+	+	1

ASIS[a]	NAAT1	NAAT2	Tiebreaker NAAT	Xpert	Total
I	+	EQ	+	+	1
I	NR	+	+	-	1
IND	-	EQ	+	-	1
				Total Infected	205

a. **ASIS** = Anatomic Site Infected Status: **NI**=Not Infected; **I**=Infected; **IND**=indeterminate, considered not infected.

b. **NA**=Not applicable; both reference NAAT tests agreed.

c. **NR** = Not run

d. **EQ**=Equivocal

e. **IND**=Indeterminate. Considered infected if Xpert negative and not infected if Xpert positive to evaluate under worst-case scenario.

Analytical Performance

Analytical Sensitivity (Limit of Detection)

Studies were performed to determine the analytical limit of detection (LoD) of Xpert CT/NG with purified CT elementary bodies seeded into negative natural human pooled clinical vaginal swab, pooled clinical male urine, pooled clinical pharyngeal swab, and pooled clinical rectal swab matrices and NG cells seeded into negative pooled simulated swab and pooled male urine matrices.

Pooled Vaginal Swab Matrix

Elementary bodies from two CT serovars, ATCC vr885 serovar D and ATCC vr879 serovar H, were purified by centrifugation through a 30% sucrose cushion and titered by enumeration of elementary bodies by transmission electron microscopy. Each serovar was diluted into pooled negative clinical vaginal swab matrix and tested with Xpert CT/NG. Replicates of 20 were evaluated at eight concentrations for CT serovar D and at seven concentrations for CT serovar H and LoDs were estimated by probit analysis. The claimed LoDs were confirmed by analyzing at least 20 replicate samples with elementary bodies diluted to the estimated LoD concentrations. For this study, the claimed LoD is defined as the lowest concentration at which 95% of at least 20 replicates are positive.

The claimed LoD for purified CT serovar D elementary bodies (EB) in vaginal swab matrix is 84 EB/mL. The claimed LoD for purified CT serovar H elementary bodies in vaginal swab matrix is 161 EB/mL (Table 21). In this study, LoDs for the remaining purified CT serovars (in EB/mL) are A (600), B (6), Ba (1900), C (34), E (6), F (202), G (96), I (21), J (150), K (117), LGV I (31), LGV II (20) and LGV III (210) EB/mL.

Table 21. LoD of Two CT Serovars in Pooled Clinical Vaginal Swab Matrix

Organism	LoD
CT ATCC vr885 serovar D (EB/mL)	84
CT ATCC vr879 serovar H (EB/mL)	161

Two NG strains (ATCC 19424 and ATCC 49226) were tested. Replicates of 20 were evaluated at six concentrations. The LoD was estimated by probit analysis.

The LoD for NG, estimated by probit analysis, is 1.5 – 1.6 CFU/mL in a simulated swab matrix background (Table 22). An additional 30 NG strains were tested in a simulated matrix and the LoD was confirmed by testing replicates of three at or near the LoD.

Table 22. LoD of Two NG Strains in Pooled Vaginal Swab Matrix

Organism	LoD
NG ATCC 19424 (CFU/mL)	1.5
NG ATCC 49226 (CFU/mL)	1.6

Pooled Male Urine Matrix

Purified and titered elementary bodies from two CT serovars, ATCC vr885 serovar D and ATCC vr879 serovar H, were each tested in a sample matrix of negative pooled clinical male urine. Replicates of 20 were evaluated at eight concentrations for CT serovar D and at seven concentrations for CT serovar H and LoDs were estimated by probit analysis. The claimed LoDs were confirmed by analyzing at least 20 replicate samples with elementary bodies diluted to the estimated LoD concentrations. For this study, the claimed LoD is defined as the lowest concentration at which 95% of at least 20 replicates are positive.

The claimed LoD for purified CT serovar D elementary bodies in male urine matrix is 75 EB/mL. The claimed LoD for purified CT serovar H elementary bodies in male urine matrix is 134 EB/mL (Table 23). In this study, LoDs for the remaining purified CT serovars (in EB/mL) are A (900), B (11), Ba (3037), C (34), E (12), F (151), G (48), I (43), J (112), K (88), LGV I (31), LGV II (40) and LGV III (157).

Table 23. LoD of Two CT Serovars in Pooled Clinical Male Urine Matrix

Organism	LoD
CT ATCC vr885 serovar D (EB/mL)	75
CT ATCC vr879 serovar H (EB/mL)	134

Two NG strains, ATCC 19424 and ATCC 49226, were tested in a sample matrix of negative pooled male urine. Replicates of 20 were evaluated at six concentrations. The LoD was estimated by probit analysis.

The LoD for NG, estimated by probit analysis, is 1.2 – 2.7 CFU/mL in a male urine matrix background (Table 24). LoD for 30 additional NG strains was confirmed by testing replicates of three at or near the LoD.

Table 24. LoD of Two NG Strains in Pooled Male Urine Matrix

Organism	LoD
NG ATCC 19424 (CFU/mL)	2.7
NG ATCC 49226 (CFU/mL)	1.2

Pooled Pharyngeal Swab Matrix

Purified and titered elementary bodies from two CT serovars, ATCC vr885 serovar D and ATCC vr879 serovar H, were each tested in a sample matrix of negative pooled clinical pharyngeal swab matrix. Replicates of 20 were evaluated at five concentrations for CT serovar D and for CT serovar H and LoDs were estimated by probit analysis. The claimed LoDs were confirmed by analyzing at least 20 replicate samples with elementary bodies diluted to the estimated LoD concentrations. For this study, the claimed LoD is defined as the lowest concentration at which 95% of at least 20 replicates are positive.

The claimed LoD for purified CT serovar D elementary bodies (EB) in pharyngeal swab matrix is 161 EB/mL (Table 25). The claimed LoD for purified CT serovar H elementary bodies in pharyngeal swab matrix is 225 EB/

mL (Table 25).

Table 25. LoD of Two CT Serovars in Pooled Pharyngeal Swab Matrix

Organism	LoD
CT ATCC vr885 serovar D (EB/mL)	161
CT ATCC vr879 serovar H (EB/mL)	225

Two NG strains (ATCC 19424 and ATCC 49226) were tested. Replicates of 20 were evaluated at five concentrations. The LoD was estimated by probit analysis.

The LoD for NG, estimated by probit analysis, is 6.4 – 7.1 CFU/mL in a pooled pharyngeal swab matrix (Table 26).

Table 26. LoD of Two NG Strains in Pooled Pharyngeal Swab Matrix

Organism	LoD
NG ATCC 19424 (CFU/mL)	7.1
NG ATCC 49226 (CFU/mL)	6.4

Pooled Rectal Swab Matrix

Purified and titered elementary bodies from two CT serovars, ATCC vr885 serovar D and ATCC vr879 serovar H, were each tested in a sample matrix of negative pooled clinical rectal swab matrix. Replicates of 20 were evaluated at five concentrations for CT serovar D and for CT serovar H and LoDs were estimated by probit analysis. The claimed LoDs were confirmed by analyzing at least 20 replicate samples with elementary bodies diluted to the estimated LoD concentrations. For this study, the claimed LoD is defined as the lowest concentration at which 95% of at least 20 replicates are positive.

The claimed LoD for purified CT serovar D elementary bodies (EB) in rectal swab matrix is 88 EB/mL (Table 27). The claimed LoD for purified CT serovar H elementary bodies in rectal swab matrix is 161 EB/mL (Table 27).

Table 27. LoD of Two CT Serovars in Pooled Rectal Swab Matrix

Organism	LoD
CT ATCC vr885 serovar D (EB/mL)	88
CT ATCC vr879 serovar H (EB/mL)	161

Two NG strains (ATCC 19424 and ATCC 49226) were tested. Replicates of 20 were evaluated at five concentrations. The LoD was estimated by probit analysis.

The LoD for NG, estimated by probit analysis, is 4.9 – 5.3 CFU/mL in a pooled rectal swab matrix (Table 28).

Table 28. LoD of Two NG Strains in Pooled Rectal Swab Matrix

Organism	LoD
NG ATCC 19424 (CFU/mL)	4.9
NG ATCC 49226 (CFU/mL)	5.3

Analytical Reactivity (Inclusivity)

Fourteen CT serovars and twenty NG strains were tested in this study. Testing was performed using CT and NG cultures that were diluted in pooled clinical pharyngeal and pooled clinical rectal swab matrices at levels near the analytical LoD. Three replicates were tested for each strain. Results are shown in Table 29 and Table 30 for CT serovars and NG strains, respectively. All 14 CT serovars and all 20 NG strains were correctly reported using the Xpert CT/NG test.

Table 29. Analytical Reactivity Results of Xpert CT/NG with CT Serovars in Pooled Pharyngeal and Rectal Swab Matrices

C. trachomatis serovar	Concentration Tested in Pharyngeal Swab Matrix	Concentration Tested in Rectal Swab Matrix	Test Result	
			CT	NG
A	1800 EB/mL	1800 EB/mL	POS	NEG
B	9 EB/mL	8.1 EB/mL	POS	NEG
Ba	0.9 EB/mL	0.81 EB/mL	POS	NEG
C	900 EB/mL	322 EB/mL	POS	NEG
E	450 EB/mL	322 EB/mL	POS	NEG
E/SW2	0.9 IFU/mL[a]	0.81 IFU/mL[a]	POS	NEG
F	450 EB/mL	322 EB/mL	POS	NEG
G	900 EB/mL	644 EB/mL	POS	NEG
I	0.18 EB/mL	0.16 EB/mL	POS	NEG
J	900 EB/mL	644 EB/mL	POS	NEG
K	900 EB/mL	644 EB/mL	POS	NEG
LGV I	450 EB/mL	322 EB/mL	POS	NEG
LGV II	450 EB/mL	322 EB/mL	POS	NEG
LGV III	450 EB/mL	644 EB/mL	POS	NEG

a. IFU/mL = Infectious units per mL

Table 30. Analytical Reactivity Results of Xpert CT/NG with NG Strains in Pharyngeal and Rectal Swab Matrices

N. gonorrhoeae Strain	Concentration Tested in Pharyngeal Swab Matrix (CFU/mL)	Concentration Tested in Rectal Swab Matrix (CFU/mL)	Test Result	
			CT	NG
9793	14.2	10.6	NEG	POS
9830	14.2	10.6	NEG	POS

N. gonorrhoeae Strain	Concentration Tested in Pharyngeal Swab Matrix (CFU/mL)	Concentration Tested in Rectal Swab Matrix (CFU/mL)	Test Result	
			CT	NG
19999	14.2	10.6	NEG	POS
27629	14.2	10.6	NEG	POS
27630	14.2	10.6	NEG	POS
27631	14.2	10.6	NEG	POS
31148	14.2	10.6	NEG	POS
31397	14.2	10.6	NEG	POS
31399	14.2	10.6	NEG	POS
31400	14.2	10.6	NEG	POS
1170	14.2	42.4	NEG	POS
6395	14.2	10.6	NEG	POS
13281	14.2	10.6	NEG	POS
34447	14.2	10.6	NEG	POS
37541	14.2	10.6	NEG	POS
10226	14.2	10.6	NEG	POS
10227	14.2	10.6	NEG	POS
10932	14.2	10.6	NEG	POS
11472	14.2	10.6	NEG	POS
50348	14.2	10.6	NEG	POS

Analytical Specificity (Cross-Reactivity and Competitive Interference)

Endocervical Swab, Vaginal Swab, and Urine Specimens

One hundred and one (101) different microorganisms were tested at a concentration of at least 10^6 CFU/mL or 10^5 genome copies/mL in replicates of three (Table 31). All isolates were reported **CT NOT DETECTED**; **NG NOT DETECTED**; none of the organisms were detected by Xpert CT/NG. Positive and negative controls were included in the study. The analytical specificity was 100%.

Table 31. Potential Cross-reacting Microorganisms in Xpert CT/NG

Acinetobacter calcoaceticus	Herpes simplex virus I[a]	Neisseria sicca (3)
Acinetobacter lwoffi	Herpes simplex virus II[a]	Neisseria subflava (2)
Aerococcus viridans	Human papilloma virus[a]	Paracoccus denitrificans
Aeromonas hydrophila	*Kingella denitrificans*	Peptostreptococcus anaerobius
Alcaligenes faecalis	*Kingella kingae*	Plesiomonas shigelloides
Arcanobacterium pyogenes	Klebsiella oxytoca	Propionibacterium acnes
Bacteriodes fragilis	Klebsiella pneumoniae	Proteus mirabilis
Bifidobacterium adolescentis	Lactobacillus acidophilus	Proteus vulgaris
Branhamella catarrhalis	Lactobacillus brevis	Providencia stuartii
Brevibacterium linens	Lactobacillus jensonii	Pseudomonas aeruginosa

Candida albicans	*Lactobacillus lactis*	*Pseudomonas fluorescens*
Candida glabrata	*Legionella pneumophila*	*Pseudomonas putida*
Candida parapsilosis	*Leuconostoc paramensenteroides*	*Rahnella aquatilis*
Candida tropicalis	*Listeria monocytogenes*	*Saccharomyces cerevisiae*
Chlamydia pneumoniae	*Micrococcus luteus*	*Salmonella minnesota*
Chromobacterium violaceum	*Moraxella lacunata*	*Salmonella typhimurium*
Citrobacter freundii	*Moraxella osloensis*	*Serratia marcescens*
Clostridium perfringens	*Morganella morganii*	*Staphylococcus aureus*
Corynebacterium genitalium	*Mycobacterium smegmatis*	*Staphylococcus epidermidis*
Corynebacterium xerosis	*N. meningiditis*	*Staphylococcus saprophyticus*
Cryptococcus neoformans	*N. meningitidis Serogroup A*	*Streptococcus agalactiae*
Cytomegalovirus[a]	*N. meningitidis Serogroup B*	*Streptococcus bovis*
Eikenella corrodens	*N. meningitidis Serogroup C*	*Streptococcus mitis*
Entercoccus avium	*N. meningitidis Serogroup D*	*Streptococcus mutans*
Entercoccus faecalis	*N. meningitidis Serogroup W135*	*Streptococcus pneumoniae*
Entercoccus faecium	*N. meningitidis Serogroup Y*	*Streptococcus pyogenes*
Enterobacter aerogenes	*Neisseria cinerea*	*Streptococcus salivarius*
Enterobacter cloacae	*Neisseria dentrificans*	*Streptococcus sanguis*
Erysipelothrix rhusiopathiae	*Neisseria elongata (3)*	*Streptococcus griseinus*
Escherichia coli	*Neisseria flava*	*Vibrio parahaemolyticus*
Elizabethkingia meningoseptica[b]	*Neisseria flavescens (2)*	*Yersinia enterocolitica*
Fusobacterium nucleatum	*Neisseria lactamica (5)*	
Gardnerella vaginalis	*Neisseria mucosa (3)*	
Gemella haemolysans	*Neisseria perflava*	
Haemophilus influenzae	*Neisseria polysaccharea*	
(n) number of strains tested		

a. Tested at 1 x 10^5 genome copies/mL

b. Previously known as Flavobacterium meningosepticum

Pharyngeal Swab and Rectal Swab Specimens

Forty-one microorganisms potentially present in pharyngeal flora (Table 32) and forty-three microorganisms potentially present in rectal flora (see Table 33) were tested using Xpert CT/NG. The microorganisms were tested in the presence (competitive interference) and absence (cross-reactivity) of 2X LoD CT (Serovar D) and NG (ATCC 49226) organisms and were diluted into pooled clinical negative pharyngeal swab matrix or pooled clinical negative rectal swab matrix for testing. Bacterial strains were tested in triplicate at a concentration of at least 10^6 CFU/mL except for *Treponema denticola*, which was tested at 1.92 x 10^6 genome equivalents/mL. Parasites were tested at 1 x 10^6 cells/mL except for *Entamoeba histolytica*, which was tested at 1 x 10^5 CFU/mL and viruses were tested at 1 x 10^5 $TCID_{50}$/ml or 1 x 10^5 IFU/mL. Positive and negative controls were included in the study. All CT and NG positive samples remained positive and all CT and NG negative samples remained negative, indicating that there was no interference or cross-reactivity with the results of the Xpert CT/NG test for these microorganisms.

Table 32. Potential Cross-reacting/Competitive Interfering Microorganisms in Pooled Pharyngeal Swab Matrix

Actinobacillus actinomycetemcomitans	*Klebsiella pneumoniae*	*Staphylococcus aureus*
Adenovirus	*Lactobacillus acidophilus*	*Staphylococcus epidermidis*
Arcanobacterium haemolyticum	*Lactobacillus lactis*	*Streptococcus anginosus*
Bordetella pertussis	*Moraxella catarrhalis*	*Streptococcus dysgalactiae*
Campylobacter rectus	*Mycoplasma pneumoniae*	*Streptococcus mitis*
Candida albicans	*Neisseria flavescens*	*Streptococcus mutans*
Coronavirus	*Peptostreptococcus micros*	*Streptococcus pneumoniae*
Corynebacterium diphtheriae	*Porphyromonas gingivalis*	*Streptococcus pyogenes*
Fusobacterium necrophorum	*Prevotella bivia*	*Streptococcus salivarius*
Haemophilus influenzae	*Prevotella oralis*[a]	*Streptococcus sanguinis*
Herpes virus	*Pseudomonas aeruginosa*	*Tannerella forsythia*[b]
Human influenza virus A	*Respiratory syncytial virus*	*Treponema denticola*[c]
Human influenza virus B	Rhinovirus	*Veillonella parvula*
Human metapneumovirus	*Saccharomyces cerevisiae*	

a. Bacteroides oralis is Prevotella oralis.

b. Bacteriodes forsythus is Tannerella forsythia.

c. Genomic DNA tested.

Table 33. Potential Cross-reacting /Competitive Interfering Microorganisms in Pooled Rectal Swab Matrix

Acinetobacter baumannii	*Fusobacterium necrophorum*	*Providencia stuartii*
Anaerococcus tetradius	*Fusobacterium nucleatum*	*Pseudomonas aeruginosa*
Anaerococcus hydrogenalis	*Giardia lamblia*	*Salmonella enterica sb enterica sv minnesota*
Bacteroides fragilis	*Helicobacter pylori*	*Salmonella enterica sb enterica sv typhimurium*
Bifidobacterium adolescent	*Klebsiella oxytoca*	*Shigella flexneri*
Campylobacter jejuni	*Lactobacillus acidophilus*	*Shigella sonnei*
Candida albicans	*Lactobacillus delbreueckii*	*Staphylococcus aureus*
Citrobacter freundii	*Listeria monocytogenes*	*Staphylococcus epidermidis*
Clostridiodes difficile	*Morganella morganii*	*Streptococcus agalactiae*
Entamoeba histolytica	Norovirus	*Streptococcus dysgalactiae*
Enterobacter cloacae	*Peptostreptococcus anaerobius*	*Vibrio cholerae*
Enterococcus faecalis	*Plesiomonas shigelloides*	*Vibrio parahaemolyticus*
Enterococcus faecium	*Prevotella bivia*	*Yersinia enterocolitica*
Enterovirus	*Prevotella oralis*	
Escherichia coli	*Proteus mirabilis*	

Interfering Substances Study

Performance of the Xpert CT/NG test was evaluated in the presence of potentially interfering substances. The evaluated substances were diluted into vaginal/endocervical swab simulated matrix and urine matrix

containing either 5x LoD CT serovar D and NG strain ATCC 49226 or 5x LoD CT serovar H and NG strain ATCC 19424.

There was no test interference in the presence of the substances at the concentrations for vaginal/endocervical matrix (Table 34) and urine matrix (Table 35).

Table 34. Potentially Interfering Substances in Vaginal/Endocervical Matrix

Substance	Concentration
Blood	1.0% v/v
Mucin	0.8% w/v
Seminal Fluid	5.0% v/v
Hormones	7 mg/mL Progesterone + 0.07 mg/mL Beta Estradiol
LGV II (CT EB)	10^6EB/mL
Vagisil Anti-Itch Cream	0.25% w/v
Clotrimazole Vaginal Cream	0.25% w/v
Preparation H Hemorroidal Cream	0.25% w/v
Miconazole 3	0.25% w/v
Monistat 1	0.25% w/v
Zovirax Cold Sore Cream	0.25% w/v
Vagisil Moisturizer	0.25% w/v
Vagi Gard Moisturizing Gel	0.25% w/v
KY Jelly Personal Lubricant	0.25% w/v
Yeast Gard Douche	0.25% w/v
Delfen Vaginal Contraceptive Foam	0.25% w/v
VH Essentials Povidone-Iodine Medicated Douche	0.25% v/v
Leukocytes	10^6cells/mL

Table 35. Potentially Interfering Substances in Urine Matrix

Substance	Concentration
Blood	0.3% v/v
Mucin	0.2% v/v
Seminal Fluid	5.0% v/v
Hormones	7 mg/mL Progesterone + 0.07 mg/mL Beta Estradiol
LGV II (CT EB)	10^6EB/mL
Leukocytes	10^6cells/mL
Norforms Deodorant Suppositories	0.25% w/v
BSA	10 mg/ml
Glucose	10 mg/mL
Bilirubin	0.2 mg/mL
Aspirin	40 mg/mL

Substance	Concentration
Azithromycin	1.8 mg/mL
Doxycycline	3.6 mg/mL
Organisms - UTI *Candida albicans/Staphylococcus aureus/Escherichia coli*	2.9 x 10^4CFU/mL
Acetaminophen	3.2 mg/mL
Vagisil Feminine Powder	0.25% w/v
Acidic Urine	pH 4.0
Alkaline Urine	pH 9.0

With vaginal/endocervical specimens, test interference may be observed in the presence of:

- Blood at a concentration greater than 1% v/v;
- Mucin at a concentration greater than 0.8% w/v.

With urine specimens, test interference may be observed in the presence of:

- Blood at a concentration greater than 0.3% v/v;
- Mucin at a concentration greater than 0.2% w/v;
- Bilirubin at a concentration greater than 0.2 mg/mL (20 mg/dL);
- Vagisil feminine powder at a concentration greater than 0.2% w/v.

Pharyngeal Swab and Rectal Swab Specimens

Potentially interfering exogenous substances were diluted in pooled clinical pharyngeal swab and pooled clinical rectal swab matrices containing two different mixtures of CT and NG cells. The first mixture contained 3x LoD CT serovar D and NG strain ATCC 49226. The second mixture contained 3x LoD CT serovar H and NG strain ATCC 19424.

There was no test interference in the presence of the substances at the concentrations tested for pharyngeal swab matrix (Table 36) and rectal swab matrix (Table 37).

Table 36. Potentially Interfering Substances Tested in Pooled Pharyngeal Swab Matrix

Potentially Interfering Substances to be Evaluated	Concentration Tested
Mucin (pig gastric mucin)	25 mg/mL
Whole human blood	5% v/v
Mouthwash (Cool Mint Listerine, antiseptic)	5% v/v
Cough Medicine Guaifenesin (Guaiacol glyceryl)	5 mg/mL
Cough Medicine Dextromethorphan HBr	100 µg/mL
Antibiotic (Penicillin G)	1.2 mg/mL
Antibiotic (Erythromycin)	15 µg/mL
Sugar-containing cold and flu remedies (Acetaminophen)	5% v/v
Chloraseptic	5% v/v

Potentially Interfering Substances to be Evaluated	Concentration Tested
Salt-modifying remedy (sodium chloride)	50% v/v
Foods/drinks that increase salivary viscosity (milk)	5% v/v
pH Modifying Remedy (orange juice)	5% v/v
Cold Sore medication Abreva	5% v/v

Table 37. Potentially Interfering Substances Tested in Pooled Rectal Swab Matrix

Potentially Interfering Substances to be Evaluated	Concentration Tested
Barium sulfate	0.25% w/v
Ciprofloxacin	0.25% w/v
Condom	1 condom (#)
Cortizone	0.25% w/v
ExLax	0.25% w/v
Fecal fat (Stearic acid/Palmitic acid/Cholesterol)	0.25% w/v
Imodium	0.25% w/v
K-Y Jelly	0.25% w/v
Milk of Magnesia	0.25% w/v
Mineral Oil	0.25% w/v
Neosporin (Polymixin B/ Neomycin/Bacitracin)	0.25% w/v
Nystatin	0.25% w/v
Pepcid	0.25% w/v
Pepto-Bismol	0.25% w/v
Preparation H	0.25% w/v
Prilosec	0.25% w/v
Saline	0.25% w/v
Tagamet	0.25% w/v
Vagisil	0.25% w/v

Carry-Over Contamination Study

A study was conducted to demonstrate that single-use, self-contained GeneXpert cartridges prevent carry-over contamination in negative samples run following very high positive samples in the same GeneXpert module. The study consisted of a negative sample processed in the same GeneXpert module immediately following a sample with high CT spike (1.9 x 10^4 EB/mL) and high NG spike (5.2 x 10^5 CFU/mL). Two sample types were used for this testing: a) known pooled negative urine samples; and b) known pooled negative swab samples. Each sample type was tested in each of four GeneXpert modules for a total of 44 runs resulting in 20 positives and 24 negatives. All 40 positive samples were correctly reported as **CT DETECTED**; **NG DETECTED**. All 48 negative samples were correctly reported as **CT NOT DETECTED**; **NG NOT DETECTED**.

Reproducibility

Reproducibility of Xpert CT/NG was evaluated at three sites using specimens comprised of CT and NG

organisms seeded into pooled, negative male urine or pooled, negative female vaginal swab samples. The specimens were prepared at concentration levels representing low positive (1X LoD), moderate positive (2-3X LoD), and high positive (>20X LoD) for each organism. Negative panel members were also included, and were comprised of pooled, negative male urine and pooled, negative vaginal swab samples. A panel of 22 specimens (11 in urine matrix and 11 in swab matrix) was tested on five different days by two different operators four times per day at three sites (22 specimens x 2 operators x 5 days x 4 replicates per day x 3 sites). Three lots of Xpert CT/NG reagents were included in the study, with two lots being tested at each site. Xpert CT/NG tests were performed according to the Xpert CT/NG procedure. The rate of agreement with expected results of CT and NG for each panel member is shown by site in Table 38 and Table 39.

Table 38. Summary of Reproducibility Results by Study Site; Percent Agreement Swab Samples

Sample		Site 1 (GeneXpert Dx)	Site 2 (Infinity-80)	Site 3 (Infinity-48)	% Total Agreement by Sample
CT >20X LoD; NG >20X LoD	CT	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)
	NG	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)
CT >20X LoD; NG 1X LoD	CT	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)
	NG	87.5% (35/40)	97.5% (39/40)	95.0% (38/40)	93.3% (112/120)
CT >20X LoD; NG neg	CT	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)
	NG	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)
CT 1X LoD; NG >20X LoD	CT	90.0% (36/40)	97.5% (39/40)	95.0% (38/40)	94.2% (113/120)
	NG	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)
CT 1X LoD; NG 1X LoD	CT	97.5% (39/40)	100% (40/40)	100% (40/40)	99.2% (119/120)
	NG	92.5% (37/40)	90.0% (36/40)	90.0% (36/40)	90.8% (109/120)
CT 1X LoD; NG neg	CT	97.5% (39/40)	90.0% (36/40)	90.0% (36/40)	92.5% (111/120)
	NG	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)
CT 2-3X LoD; NG neg	CT	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)
	NG	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)
CT neg; NG >20X LoD	CT	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)
	NG	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)
CT neg; NG 1X LoD	CT	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)
	NG	100% (40/40)	97.5% (39/40)	97.5% (39/40)	98.3% (118/120)
CT neg; NG 2-3X LoD	CT	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)
	NG	97.5% (39/40)	100% (40/40)	100% (40/40)	99.2% (119/120)
CT neg; NG neg	CT	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)
	NG	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)

Table 39. Summary of Reproducibility Results by Study Site; Percent Agreement Urine Samples

Sample		Site 1 (GeneXpert Dx)	Site 2 (Infinity-80)	Site 3 (Infinity-48)	% Total Agreement by Sample
CT >20X LoD; NG >20X LoD	CT	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)
	NG	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)
CT >20X LoD; NG 1X LoD	CT	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)
	NG	92.5% (37/40)	97.5% (39/40)	97.5% (39/40)	95.8% (115/120)
CT >20X LoD; NG neg	CT	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)

Sample		Site 1 (GeneXpert Dx)	Site 2 (Infinity-80)	Site 3 (Infinity-48)	% Total Agreement by Sample
	NG	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)
CT 1X LoD; NG >20X LoD	CT	92.5% (37/40)	95.0% (38/40)	90.0% (36/40)	92.5% (111/120)
	NG	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)
CT 1X LoD; NG 1X LoD	CT	95.0% (38/40)	80.0% (32/40)	87.5% (35/40)	87.5% (105/120)
	NG	95.0% (38/40)	85.0% (34/40)	87.5% (35/40)	89.2% (107/120)
CT 1X LoD; NG neg	CT	87.5% (35/40)	97.5% (39/40)	97.5% (39/40)	94.2% (113/120)
	NG	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)
CT 2-3X LoD; NG neg	CT	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)
	NG	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)
CT neg; NG >20X LoD	CT	97.5% (39/40)	100% (40/40)	100% (40/40)	99.2% (119/120)
	NG	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)
CT neg; NG 1X LoD	CT	100% (40/40)	100% (40/40)	97.5% (39/40)	99.2% (119/120)
	NG	100% (40/40)	97.5% (39/40)	100% (40/40)	99.2% (119/120)
CT neg; NG 2-3X LoD	CT	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)
	NG	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)
CT neg; NG neg	CT	100% (40/40)	100% (40/40)	97.5% (39/40)	99.2% (119/120)
	NG	100% (40/40)	100% (40/40)	100% (40/40)	100% (120/120)

The reproducibility of the test was also evaluated in terms of the fluorescence signal expressed in Ct values for each target detected. The mean, standard deviation (SD), and coefficient of variation (CV) between-sites, between-lots, between-days, and between-runs for each panel member are shown in Table 40 through Table 42.

Table 40. Summary of Reproducibility Data for Swab and Urine Specimens – CT1 Target

Type	Target Conc.					Between-Site		Between-Lot		Between-Day		Between-Run[a]		Within-Run		Total	
	CT (LoD)	NG (LoD)	Agree/ N	Agrmt (%)	Mean Ct	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
Swab	>20X	>20X	120/120	100	20.67	0.21	1.0	0.11	0.5	0.11	0.5	0.00	0.0	0.29	1.4	0.39	1.9
	>20X	1X	112/120	93.3	20.73	0.29	1.4	0.37	1.8	0.00	0.0	0.00	0.0	1.59	7.7	1.66	8.0
	>20X	NEG	120/120	100	20.59	0.00	0.0	0.21	1.0	0.06	0.3	0.08	0.4	0.26	1.3	0.35	1.7
	1X	>20X	113/120	94.2	37.20	0.10	0.3	0.21	0.6	0.00	0.0	0.00	0.0	1.15	3.1	1.18	3.2
	1X	1X	106/120	88.3	37.04	0.17	0.5	0.00	0.0	0.00	0.0	0.12	0.3	1.08	2.9	1.10	3.0
	1X	NEG	111/120	92.5	37.04	0.06	0.2	0.00	0.0	0.00	0.0	0.00	0.0	1.12	3.0	1.12	3.0
	2-3X	NEG	120/120	100	35.63	0.13	0.4	0.00	0.0	0.15	0.4	0.10	0.3	0.77	2.2	0.80	2.3
	NEG	>20X	120/120	100	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	NEG	1X	118/120	98.3	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	NEG	2-3X	119/120	99.2	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	NEG	NEG	120/120	100	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Urine	>20X	>20X	120/120	100	21.46	0.23	1.0	0.00	0.0	0.12	0.5	0.02	0.1	0.31	1.4	0.40	1.9
	>20X	1X	115/120	95.8	21.33	0.13	0.6	0.05	0.2	0.13	0.6	0.00	0.0	0.43	2.0	0.47	2.2

Type	Target Conc.					Between-Site		Between-Lot		Between-Day		Between-Run[a]		Within-Run		Total	
	CT (LoD)	NG (LoD)	Agree/N	Agrmt (%)	Mean Ct	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
	>20X	NEG	120/120	100	21.36	0.19	0.9	0.00	0.0	0.12	0.6	0.02	0.1	0.47	2.2	0.52	2.4
	1X	>20X	111/120	92.5	37.24	0.36	1.0	0.00	0.0	0.00	0.0	0.00	0.0	1.33	3.6	1.38	3.7
	1X	1X	97/120	80.8	37.15	0.40	1.1	0.18	0.5	0.17	0.4	0.00	0.0	1.02	2.8	1.13	3.0
	1X	NEG	113/120	94.2	37.39	0.10	0.3	0.32	0.9	0.00	0.0	0.00	0.0	1.38	3.7	1.42	3.8
	2-3X	NEG	120/120	100	35.26	0.24	0.7	0.00	0.0	0.30	0.9	0.00	0.0	0.80	2.3	0.89	2.5
	NEG	>20X	119/120	99.2	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	NEG	1X	118/120	98.3	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	NEG	2-3X	120/120	100	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	NEG	NEG	119/120	99.2	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

a. A run is defined as the four samples per panel member run by one operator at one site on one day.

Agrmt=Agreement, Conc=concentration, CV=coefficient of variation, N/A=Not Applicable for negative samples, SD=standard deviation

Note Variability from some factors may be numerically negative, which can occur if the variability due to those factors is very small. When this occurs, the variability as measured with SD and CV is set to 0.

Table 41. Summary of Reproducibility Data for Swab and Urine Specimens – NG2 Target

Type	Target Conc.					Between-Site		Between-Lot		Between-Day		Between-Run [a]		Within-Run		Total	
	CT (LoD)	NG (LoD)	Agree/N	Agrmt (%)	Mean Ct	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
Swab	>20X	>20X	120/120	100	19.65	0.03	0.1	0.09	0.4	0.07	0.3	0.02	0.1	0.24	1.2	0.26	1.3
	>20X	1X	112/120	93.3	35.38	0.22	0.6	0.00	0.0	0.00	0.0	0.00	0.0	1.98	5.6	1.99	5.6
	>20X	NEG	120/120	100	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	1X	>20X	113/120	94.2	19.69	0.12	0.6	0.00	0.0	0.19	1.0	0.00	0.0	0.43	2.2	0.49	2.5
	1X	1X	106/120	88.3	35.61	0.00	0.0	0.53	1.5	0.00	0.0	0.80	2.2	1.37	3.9	1.67	4.7
	1X	NEG	111/120	92.5	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	2-3X	NEG	120/120	100	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	NEG	>20X	120/120	100	19.60	0.10	0.5	0.07	0.4	0.00	0.0	0.07	0.4	0.20	1.0	0.25	1.3
	NEG	1X	118/120	98.3	35.43	0.39	1.1	0.00	0.0	0.04	0.1	0.22	0.6	0.94	2.6	1.04	2.9
	NEG	2-3X	119/120	99.2	33.97	0.00	0.0	0.15	0.4	0.00	0.0	0.15	0.4	0.71	2.1	0.74	2.2
	NEG	NEG	120/120	100	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Urine	>20X	>20X	120/120	100	20.34	0.06	0.3	0.09	0.4	0.00	0.0	0.07	0.3	0.23	1.1	0.26	1.3
	>20X	1X	115/120	95.8	35.41	0.00	0.0	0.00	0.0	0.19	0.5	0.30	0.8	1.15	3.3	1.20	3.4
	>20X	NEG	120/120	100	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	1X	>20X	111/120	92.5	20.40	0.06	0.3	0.07	0.3	0.00	0.0	0.00	0.0	0.39	1.9	0.40	2.0
	1X	1X	97/120	80.8	35.57	0.20	0.6	0.00	0.0	0.13	0.4	0.10	0.3	1.28	3.6	1.31	3.7
	1X	NEG	113/120	94.2	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	2-3X	NEG	120/120	100	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Type	Target Conc.					Between-Site		Between-Lot		Between-Day		Between-Run [a]		Within-Run		Total	
	CT (LoD)	NG (LoD)	Agree/N	Agrmt (%)	Mean Ct	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
	NEG	>20X	119/120	99.2	20.39	0.00	0.0	0.07	0.4	0.14	0.7	0.05	0.3	0.26	1.3	0.31	1.5
	NEG	1X	118/120	98.3	35.35	0.00	0.0	0.11	0.3	0.00	0.0	0.36	1.0	0.92	2.6	0.99	2.8
	NEG	2-3X	120/120	100	33.80	0.00	0.0	0.18	0.5	0.00	0.0	0.00	0.0	0.54	1.6	0.57	1.7
	NEG	NEG	119/120	99.2	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

a. A run is defined as the four samples per panel member run by one operator at one site on one day.

Agrmt=Agreement, Conc=concentration, CV=coefficient of variation, N/A=Not Applicable for negative samples, SD=standard deviation

Note Variability from some factors may be numerically negative, which can occur if the variability due to those factors is very small. When this occurs, the variability as measured with SD and CV is set to 0.

Table 42. Summary of Reproducibility Data for Swab and Urine Specimens – NG4 Target

Type	Target Conc.					Between-Site		Between-Lot		Between-Day		Between-Run[a]		Within-Run		Total	
	CT (LoD)	NG (LoD)	Agree/N	Agrmt (%)	Mean Ct	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
Swab	>20X	>20X	120/120	100	19.34	0.00	0.0	0.12	0.6	0.11	0.6	0.00	0.0	0.39	2.0	0.42	2.2
	>20X	1X	112/120	93.3	35.00	0.41	1.2	0.00	0.0	0.00	0.0	0.32	0.9	1.89	5.4	1.96	5.6
	>20X	NEG	120/120	100	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	1X	>20X	113/120	94.2	19.41	0.07	0.4	0.00	0.0	0.14	0.7	0.03	0.2	0.49	2.5	0.52	2.7
	1X	1X	106/120	88.3	35.47	0.32	0.9	0.00	0.0	0.00	0.0	0.70	2.0	0.90	2.5	1.19	3.3
	1X	NEG	111/120	92.5	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	2-3X	NEG	120/120	100	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	NEG	>20X	120/120	100	19.35	0.02	0.1	0.04	0.2	0.00	0.0	0.07	0.4	0.28	1.5	0.29	1.5
	NEG	1X	118/120	98.3	35.05	0.00	0.0	0.16	0.5	0.00	0.0	0.00	0.0	1.00	2.9	1.01	2.9
	NEG	2-3X	119/120	99.2	33.57	0.14	0.4	0.17	0.5	0.00	0.0	0.00	0.0	0.78	2.3	0.81	2.4
	NEG	NEG	120/120	100	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Urine	>20X	>20X	120/120	100	20.06	0.12	0.6	0.12	0.6	0.09	0.4	0.00	0.0	0.39	1.9	0.43	2.1
	>20X	1X	115/120	95.8	35.27	0.17	0.5	0.13	0.4	0.00	0.0	0.00	0.0	1.04	2.9	1.06	3.0
	>20X	NEG	120/120	100	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	1X	>20X	111/120	92.5	20.16	0.00	0.0	0.08	0.4	0.00	0.0	0.12	0.6	0.56	2.8	0.58	2.9
	1X	1X	97/120	80.8	35.25	0.00	0.0	0.00	0.0	0.41	1.2	0.00	0.0	1.17	3.3	1.24	3.5
	1X	NEG	113/120	94.2	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	2-3X	NEG	120/120	100	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	NEG	>20X	119/120	99.2	20.12	0.09	0.5	0.10	0.5	0.06	0.3	0.00	0.0	0.41	2.0	0.43	2.2
	NEG	1X	118/120	98.3	35.05	0.24	0.7	0.00	0.0	0.15	0.4	0.12	0.4	1.09	3.1	1.13	3.2
	NEG	2-3X	120/120	100	33.67	0.00	0.0	0.33	1.0	0.00	0.0	0.16	0.5	0.83	2.5	0.91	2.7
	NEG	NEG	119/120	99.2	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

a. A run is defined as the four samples per panel member run by one operator at one site on one day.

Agrmt=Agreement, Conc=concentration, CV=coefficient of variation, N/A=Not Applicable for negative samples, SD=standard deviation

Note Variability from some factors may be numerically negative, which can occur if the variability due to those factors is very small. When this occurs, the variability as measured with SD and CV is set to 0.

Instrument System Precision

An in-house precision study was conducted to compare the performance of the GeneXpert Dx and the Infinity-80 Instrument Systems using specimens comprised of CT and NG organisms seeded into negative urine (urine matrix) or diluent for Xpert CT/NG (swab matrix). Negative urine and negative diluent were used for the negative specimens. A panel of 20 specimens (10 in urine matrix and 10 in swab matrix) was tested on 12 different days by two operators. Each operator conducted four runs of each panel specimen per day on each of the two instrument systems (20 specimens x 4 times/ day x 12 days x 2 operators x 2 instrument systems). One lot of Xpert CT/NG was used for the study. Xpert CT/NG tests were performed according to the Xpert CT/NG procedure. The rate of agreement of CT and NG for each panel member is shown by instrument in Table 43 and Table 44.

Table 43. Summary of Instrument System Precision Results; Percent Agreement Swab Matrix

Sample		GeneXpert Dx	Infinity-80	% Total Agreement by Sample
CT >20X LoD; NG >20X LoD	CT	100% (96/96)	100% (95/95)[a]	100% (191/191)
	NG	100% (96/96)	100% (95/95)	100% (191/191)
CT >20X LoD; NG 0.25-0.5X LoD	CT	100% (96/96)	100% (96/96)	100% (192/192)
	NG	62.5% (60/96)	52.1% (50/96)	57.3% (110/192)
CT >20X LoD; NG neg	CT	100% (96/96)	100% (95/95)[b]	100% (191/191)
	NG	100% (96/96)	100% (95/95)	100% (191/191)
CT 0.25-0.5X LoD; NG >20X LoD	CT	46.9% (45/96)	42.7% (41/96)	44.8% (86/192)
	NG	100% (96/96)	100% (96/96)	100% (192/192)
CT 0.25-0.5X LoD; NG 0.25-0.5X LoD	CT	55.2% (53/96)	60.4% (58/96)	57.8% (111/192)
	NG	50.0% (48/96)	66.7% (64/96)	58.3% (112/192)
CT 0.25-0.5X LoD; NG neg	CT	61.5% (59/96)	62.1% (59/95)[c]	61.8% (118/191)
	NG	100% (96/96)	100% (95/95)	100% (191/191)
CT 2-3X LoD; NG 2-3X LoD	CT	100% (96/96)	100% (96/96)	100% (192/192)
	NG	100% (96/96)	100% (96/96)	100% (192/192)
CT neg; NG >20X LoD	CT	100% (96/96)	100% (96/96)	100% (192/192)
	NG	100% (96/96)	100% (96/96)	100% (192/192)
CT neg; NG 0.25-0.5X LoD	CT	100% (95/95)	100% (96/96)	100% (191/191)
	NG	58.9% (56/95)	62.5% (60/96)	60.7% (116/191)
CT neg; NG neg	CT	100% (96/96)	100% (96/96)	100% (192/192)
	NG	100% (96/96)	100% (96/96)	100% (192/192)

a. One sample was indeterminate after initial and retest.

b. One sample each of CT >20X LoD; NG neg sample and CT neg; NG 0.25-0.5X LoD resulted in ERROR on initial test and were not retested.

c. One sample mistakenly not tested.

Table 44. Summary of Instrument System Precision Results; Percent Agreement Urine Matrix

Sample		GeneXpert Dx	Infinity-80	% Total Agreement by Sample
CT >20X LoD; NG >20X LoD	CT	100% (96/96)	100% (96/96)	100% (192/192)
	NG	100% (96/96)	100% (96/96)	100% (192/192)
CT >20X LoD; NG 0.25-0.5X LoD	CT	100% (96/96)	100% (96/96)	100% (192/192)
	NG	46.9% (45/96)	49.0% (47/96)	47.9% (92/192)
CT >20X LoD; NG neg	CT	100% (96/96)	100% (96/96)	100% (192/192)
	NG	100% (96/96)	100% (96/96)	100% (192/192)
CT 0.25-0.5X LoD; NG >20X LoD	CT	50.0% (48/96)	52.1% (50/96)	51.0% (98/192)
	NG	100% (96/96)	100% (96/96)	100% (192/192)
CT 0.25-0.5X LoD; NG 0.25-0.5X LoD	CT	44.8% (43/96)	39.6% (38/96)	42.2% (81/192)
	NG	62.5% (60/96)	58.3% (56/96)	60.4% (116/192)
CT 0.25-0.5X LoD; NG neg	CT	46.9% (45/96)	46.9% (45/96)	46.9% (90/192)
	NG	100% (96/96)	100% (96/96)	100% (192/192)
CT 2-3X LoD; NG 2-3X LoD	CT	100% (96/96)	100% (96/96)	100% (192/192)
	NG	100% (96/96)	100% (96/96)	100% (192/192)
CT neg; NG >20X LoD	CT	100% (96/96)	100% (96/96)	100% (192/192)
	NG	100% (96/96)	100% (96/96)	100% (192/192)
CT neg; NG 0.25-0.5X LoD	CT	100% (96/96)	100% (96/96)	100% (192/192)
	NG	36.5% (35/96)	33.3% (32/96)	34.9% (67/192)
CT neg; NG neg	CT	100% (96/96)	100% (96/96)	100% (192/192)
	NG	100% (96/96)	100% (96/96)	100% (192/192)

The within lab precision of Xpert CT/NG was also evaluated in terms of the fluorescence signal expressed in Ct values for each target detected. The mean, standard deviation (SD), and coefficient of variation (CV) between-instruments, between-days, and between-runs for each panel member are shown in Table 45 through Table 47.

Table 45. Summary of Precision Data for Swab and Urine Specimens – CT1 Target

Type	Target Conc.					Between-Instrument		Between-Day		Between-Run[a]		Within-Run		Total	
	CT (LoD)	NG (LoD)	Agree/N	Agrmt (%)	Mean Ct	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
Swab	>20X	>20X	191/191	100	23.52	0.05	0.2	0.02	0.1	0.00	0.0	0.25	1.1	0.26	1.1
	>20X	0.25-0.5X	110/192	57.3	23.52	0.00	0.0	0.00	0.0	0.08	0.3	0.18	0.7	0.19	0.8
	>20X	NEG	191/191	100	23.55	0.03	0.1	0.00	0.0	0.00	0.0	0.22	0.9	0.22	0.9
	0.25-0.5X	>20X	86/192	44.8	38.77	0.00	0.0	0.00	0.0	0.32	0.8	1.38	3.6	1.42	3.7
	0.25-0.5X	0.25-0.5X	59/192	30.7	38.46	0.00	0.0	0.30	0.8	0.00	0.0	1.35	3.5	1.39	3.6
	0.25-0.5X	NEG	118/191	61.8	38.05	0.08	0.2	0.00	0.0	0.00	0.0	1.26	3.3	1.26	3.3
	2-3X	2-3X	192/192	100	31.49	0.04	0.1	0.00	0.0	0.06	0.2	0.24	0.8	0.25	0.8
	NEG	>20X	192/192	100	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	NEG	0.25-0.5X	116/191	60.7	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Type	Target Conc.					Between-Instrument		Between-Day		Between-Run[a]		Within-Run		Total	
	CT (LoD)	NG (LoD)	Agree/N	Agrmt (%)	Mean Ct	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
	NEG	NEG	192/192	100	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Urine	>20X	>20X	192/192	100	24.35	0.05	0.2	0.20	0.8	0.10	0.4	0.30	1.2	0.38	1.6
	>20X	0.25-0.5X	92/192	47.9	24.25	0.00	0.0	0.06	0.3	0.00	0.0	0.62	2.6	0.62	2.6
	>20X	NEG	192/192	100	24.12	0.00	0.0	0.15	0.6	0.19	0.8	0.34	1.4	0.41	1.7
	0.25-0.5X	>20X	98/192	51.0	38.33	0.12	0.3	0.00	0.0	0.84	2.2	1.03	2.7	1.33	3.5
	0.25-0.5X	0.25-0.5X	48/192	25.0	38.26	0.00	0.0	0.00	0.0	0.56	1.5	1.05	2.7	1.19	3.1
	0.25-0.5X	NEG	90/192	46.9	38.39	0.00	0.0	0.00	0.0	0.00	0.0	1.09	2.8	1.09	2.8
	2-3X	2-3X	192/192	100	31.85	0.00	0.0	0.11	0.4	0.18	0.6	0.32	1.0	0.39	1.2
	NEG	>20X	192/192	100	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	NEG	0.25-0.5X	67/192	34.9	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	NEG	NEG	192/192	100	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

a. A run is defined as the four samples per panel member run by one operator at one site on one day.

Agrmt=Agreement, Conc=concentration, CV=coefficient of variation, N/A=Not Applicable for negative samples, SD=standard deviation

Note Variability from some factors may be numerically negative, which can occur if the variability due to those factors is very small. When this occurs, the variability as measured with SD and CV is set to 0.

Table 46. Summary of Precision Data for Swab and Urine Specimens – NG2 Target

Type	Target Conc.					Between-Instrument		Between-Day		Between-Run[a]		Within-Run		Total	
	CT (LoD)	NG (LoD)	Agree/N	Agrmt (%)	Mean Ct	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
Swab	>20X	>20X	191/191	100	19.03	0.01	0.0	0.02	0.1	0.00	0.0	0.21	1.1	0.21	1.1
	>20X	0.25-0.5X	110/192	57.3	37.63	0.07	0.2	0.46	1.2	0.00	0.0	1.55	4.1	1.62	4.3
	>20X	NEG	191/191	100	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	0.25-0.5X	>20X	86/192	44.8	19.08	0.00	0.0	0.00	0.0	0.10	0.5	0.31	1.6	0.32	1.7
	0.25-0.5X	0.25-0.5X	59/192	30.7	36.78	0.00	0.0	0.24	0.6	0.00	0.0	1.47	4.0	1.49	4.0
	0.25-0.5X	NEG	118/191	61.8	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	2-3X	2-3X	192/192	100	31.35	0.00	0.0	0.00	0.0	0.00	0.0	0.33	1.1	0.33	1.1
	NEG	>20X	192/192	100	19.02	0.00	0.0	0.00	0.0	0.07	0.4	0.22	1.2	0.23	1.2
	NEG	0.25-0.5X	116/191	60.7	36.77	0.00	0.0	0.46	1.2	0.00	0.0	1.65	4.5	1.71	4.7
	NEG	NEG	192/192	100	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Urine	>20X	>20X	192/192	100	19.85	0.00	0.0	0.15	0.7	0.00	0.0	0.34	1.7	0.37	1.8
	>20X	0.25-0.5X	92/192	47.9	36.72	0.15	0.4	0.00	0	0.00	0.0	1.36	3.7	1.37	3.7
	>20X	NEG	192/192	100	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	0.25-0.5X	>20X	98/192	51.0	19.51	0.00	0.0	0.00	0.0	0.00	0.0	1.20	6.1	1.20	6.1
	0.25-0.5X	0.25-0.5X	48/192	25.0	36.38	0.26	0.7	0.00	0.0	1.98	5.5	1.13	3.1	2.30	6.3
	0.25-0.5X	NEG	90/192	46.9	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Type	Target Conc.					Between-Instrument		Between-Day		Between-Run[a]		Within-Run		Total	
	CT (LoD)	NG (LoD)	Agree/N	Agrmt (%)	Mean Ct	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
	2-3X	2-3X	192/192	100	31.53	0.00	0.0	0.09	0.3	0.16	0.5	0.42	1.3	0.46	1.4
	NEG	>20X	192/192	100	19.26	0.14	0.7	0.00	0.0	0.17	0.9	0.43	2.3	0.49	2.4
	NEG	0.25-0.5X	67/192	34.9	36.88	0.00	0.0	0.31	0.8	0.00	0	1.45	3.9	1.48	7.5
	NEG	NEG	192/192	100	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

a. A run is defined as the four samples per panel member run by one operator at one site on one day.

Agrmt=Agreement, Conc=concentration, CV=coefficient of variation, N/A=Not Applicable for negative samples, SD=standard deviation

Note Variability from some factors may be numerically negative, which can occur if the variability due to those factors is very small. When this occurs, the variability as measured with SD and CV is set to 0.

Table 47. Summary of Precision Data for Swab and Urine Specimens – NG4 Target

Type	Target Conc.					Between-Instrument		Between-Day		Between-Run[a]		Within-Run		Total	
	CT (LoD)	NG (LoD)	Agree/N	Agrmt (%)	Mean Ct	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
Swab	>20X	>20X	191/191	100	18.67	0.00	0.0	0.00	0.0	0.19	1.0	0.34	1.8	0.39	2.1
	>20X	0.25-0.5X	110/192	57.3	36.94	0.49	1.3	0.00	0.0	0.10	0.3	1.63	4.4	1.71	4.6
	>20X	NEG	191/191	100	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	0.25-0.5X	>20X	86/192	44.8	18.72	0.06	0.3	0.00	0.0	0.21	1.1	0.41	2.2	0.46	2.5
	0.25-0.5X	0.25-0.5X	59/192	30.7	36.57	0.00	0.0	0.50	1.4	0.00	0.0	1.55	4.3	1.63	4.5
	0.25-0.5X	NEG	118/191	61.8	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	2-3X	2-3X	192/192	100	31.06	0.00	0.0	0.05	0.2	0.00	0.0	0.42	1.4	0.43	1.4
	NEG	>20X	192/192	100	18.69	0.00	0.0	0.00	0.0	0.22	1.2	0.38	2.0	0.44	2.3
	NEG	0.25-0.5X	116/191	60.7	36.31	0.08	0.2	0.13	0.4	0.00	0.0	1.24	3.4	1.25	3.4
	NEG	NEG	192/192	100	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Urine	>20X	>20X	192/192	100	19.44	0.01	0.1	0.10	0.5	0	0	0.45	2.3	0.46	2.4
	>20X	0.25-0.5X	92/192	47.9	36.31	0	0	0.04	0.1	0.17	0.5	1.18	3.2	1.19	6.1
	>20X	NEG	192/192	100	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	0.25-0.5X	>20X	98/192	51.0	19.08	0	0	0	0	0	0	1.35	7.1	1.35	6.9
	0.25-0.5X	0.25-0.5X	48/192	25.0	36.16	0	0	0.24	0.7	0	0	1.98	5.5	2.00	10.3
	0.25-0.5X	NEG	90/192	46.9	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	2-3X	2-3X	192/192	100	31.09	0	0	0.16	0.5	0.11	0.4	0.49	1.6	0.53	2.7
	NEG	>20X	192/192	100	18.80	0.04	0.2	0	0	0.14	0.7	0.47	2.5	0.50	2.6
	NEG	0.25-0.5X	67/192	34.9	36.58	0.18	0.5	0	0	0.74	2.0	1.40	3.8	1.60	8.2
	NEG	NEG	192/192	100	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

a. A run is defined as the four samples per panel member run by one operator at one site on one day.

Agrmt=Agreement, Conc=concentration, CV=coefficient of variation, N/A=Not Applicable for negative samples, SD=standard deviation

Note Variability from some factors may be numerically negative, which can occur if the variability due to those factors is very small. When this occurs, the variability as measured with SD and CV is set to 0.

Appendix

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Table of Symbols

Symbol	Meaning
	Catalog number
	*In vitro* diagnostic medical device
	Do not reuse
	Batch code
	Consult instructions for use
	Caution
	Manufacturer
	Country of manufacture
	Contains sufficient for *n* tests
	Control
	Expiration date
	Temperature limitation
	Biological risks
	Warning
	For prescription use only

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