Lab Dept: Microbiology

Test Name: CHLAMYDIA & GONORRHOEAE PCR

General Information

Lab Order Codes:	CGPCR
Synonyms:	Chlamydia trachomatis/Neisseria gonorrhoeae by Nucleic Acid Amplification; CT/GC PCR; CT/NG; Nucleic Acid Amplification Test (NAAT)
CPT Codes:	87491 – Chlamydia trachomatis, amplified probe technique 87591 – Neisseria gonorrhoeae, amplified probe technique
Test Includes:	Detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) DNA by PCR (Real time Polymerase Chain Reaction) in first catch urine specimens, endocervical, vaginal, anal/rectal, throat and conjunctival swabs.

Logistics

Test Indications:	Detection of Chlamydia trachomatis and Neisseria gonorrhoeae in FDA-approved specimen types
Lab Testing Sections:	Microbiology (Performed on Mpls campus)
Phone Numbers:	MIN Lab: 612-813-6280 STP Lab: 651-220-6550
Test Availability:	Daily, 24 hours
Turnaround Time:	3 hours from receipt in Minneapolis lab
Special Instructions:	● This test is approved for endocervical swabs, vaginal swabs, anal/rectal swabs, throat swabs, conjunctival swabs utilizing special collection kits obtainable on patient units. ● Obtain special collection supplies based on type of specimen to be collected. Supplies are stocked on patient units. ● Specimen site, date/time of collection and collector's initials are required for processing.

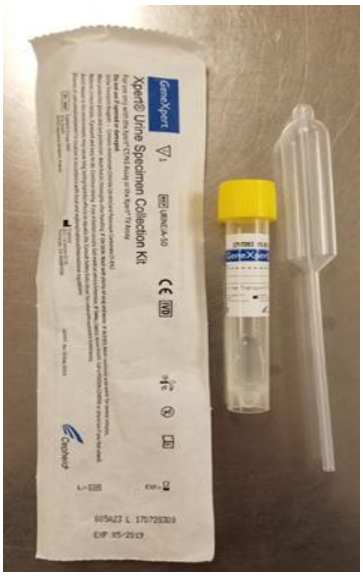
Specimen

Specimen Type:	Endocervical swabs, vaginal swabs, anal/rectal swabs, throat swabs, conjunctival swabs, NEAT urine

Container:

Obtain one of the following (stocked on patient units)
Clinics: order in PeopleSoft

Urine:
Sterile screw-cap urine cup
and
CHC Supply#31655
Xpert Urine Collect Kit



Swabs:
CHC Supply# 31654
Xpert Swab Specimen Collection Kit

Draw Volume:

Urine (NEAT): 20-50 mL urine

Other sources: 1 swab

Collection:

Urine: Screw-capped urine cup and Supply #31655-Xpert Urine Collection Kit

● The patient should not have urinated for at least 1 hour prior to specimen collection.
● Female patients should not cleanse the labial area prior to collecting the specimen.
● Male patients should not cleanse the tip of the penis area prior to collecting the specimen.

1. Direct patient to provide first-catch urine (approximately 20-50 mL of the initial urine stream) into a urine cup free of any preservatives. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity.
2. Wearing gloves, swirl urine cup to mix well.
3. Open the packaging of the disposable transfer pipette provided in the kit.
4. Remove the cap from the Xpert CT/NG Urine Transport Reagent tube and from the urine collection cup.
5. Insert the transfer pipette into the urine cup so that the tip is near the bottom of the cup. Transfer approximately 7 mL of urine to the Xper CT/NG Urine Transport reagent tube. Under or overfilling the tube may affect assay performance.

6. Replace the cap on the Xpert CT/NG Urine Transport Reagent tube and tighten securely.
7. Invert the Xpert CT/NG Urine Transport reagent tube 3-4 times to ensure that the specimen and reagent are well-mixed.
8. Recap the urine cup securely.
9. Label the transport tube with the patient label including the date/time of collection and the collector's initials. Take care not to obscure the fill line on the transport tube.
10. Transport the sample to the lab.

Endocervical swab:
Supply # 31654 - Xpert Swab Specimen Collection Kit

1. Open the Swab Specimen Collection Kit.
2. Use the large cleaning swab to remove excess mucus from endocervix and surrounding mucosa and discard.
3. Open the package that contains the pink-capped Xpert Swab Transport Reagent tube and the individually wrapped collection swab. Set the tube aside before proceeding.
4. Remove the swab, taking care not to touch the tip or lay it down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Xpert Swab Specimen Collection Kit.
5. Insert collection swab into endocervical canal, and rotate swab gently for 30 seconds. Avoid touching vaginal wall when removing swab.
6. Immediately place collection swab into Xpert Swab Transport Reagent Tube (pink cap) provided in collection kit. Snap off swab at score line so swab fits into closed tube.
7. Cap tube securely and invert the tube 3-4 times to elute material from

the swab. Avoid foaming.
8. Label the transport tube with the patient label including date of collection, specimen type and collector's initials.
9. Transport and store swab container at 2 to 30 degrees C (refrigerate is preferred temperature) within 3 days of collection.

● Do not spill the contents of the tube. If the contents of the tube are spilled, use a new collection kit.

● **Warning:** If the contents of the tube are spilled on your skin, wash the affected area with soap and water. If the contents of the tube are splashed in your eyes, immediately flush your eyes with water.

Vaginal Swab:
Supply # 31654 - Xpert Swab Specimen Collection Kit

1. Open the Xpert Swab Specimen collection kit.
2. Discard the large cleaning swab.
3. Open the package that contains the pink-capped Xpert Swab Transport Reagent tube and the individually wrapped collection swab. Set the tube aside before proceeding.
4. Remove the swab, taking care not to touch the tip or lay it down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Xpert Swab Specimen Collection Kit.
5. Insert collection swab about 5 cm past introitus and rotate gently for 30 seconds.
6. Immediately place collection swab into Xpert Swab Transport Reagent Tube (pink cap) provided in collection kit. Snap off swab at score line so swab fits into closed tube.
7. Cap tube securely and invert the tube 3-4 times to elute material from the swab. Avoid foaming.
8. Label the transport tube with the patient label including date of collection, specimen type and collector's initials.
9. Transport and store swab container at 2 to 30 degrees C (refrigerate is preferred temperature) within 3 days of collection.

● Do not spill the contents of the tube. If the contents of the tube are spilled, use a new collection kit.

● **Warning:** If the contents of the tube are spilled on your skin, wash the affected area with soap and water. If the contents of the tube are splashed in your eyes, immediately flush your eyes with water.

Patient-collected Vaginal Swab:
Supply # 31654 - Xpert Swab Specimen Collection Kit

Caution: Do NOT expose swab to Xpert Swab Transport Reagent prior to collection.

STEPS FOR PATIENT TO PERFORM

Wash your hands before starting.

1. Open the outer peel pack (which contains the two-package kit) and identify the larger cleaning swab and discard it.
2. Open the package that contains the pink-capped Xpert Swab Transport Reagent tube and individually wrapped collection swab. Set the tube aside before beginning to collect the sample.
3. Open the collection swab wrapper by peeling open the top of the wrapper.
4. Remove the swab, taking care not to touch the tip or lay it down.
If the soft tip is touched, the swab is laid down, or the swab is dropped, request a new collection kit.
5. Hold the swab in your hand, placing your thumb and forefinger in the middle of the swab shaft across the scoreline.
6. Carefully insert the swab into your vagina about 5 cm (two inches) inside the opening of the vagina and gently rotate the swab for 10 to 30 seconds. Ensure the swab touches the walls of the vagina so that moisture is absorbed by the swab.
7. Withdraw the swab carefully and continue to hold it in your hand.
8. While holding the swab in the same hand, unscrew the pink cap from the Xpert Swab Transport Reagent tube.
9. Do not spill the contents of the tube. If the contents of the tube are spilled, request a new collection kit.

● **Warning:** If the contents of the tube are spilled on your skin, wash the affected area with soap and water. If the contents of the tube are splashed in your eyes, immediately flush your eyes with water. Notify your doctor, nurse or care-provider if irritation develops. If the contents of the tube are spilled, your test result may be invalidated. Do not take internally.

10. Immediately place the specimen collection swab into the transport reagent tube.
11. Identify the score line on the collection swab shaft. Carefully break the swab shaft against the side of the tube at the scoreline and discard the top portion of the swab shaft.
12. Re-cap the swab transport reagent tube and tighten the cap securely.
13. Return the tube as instructed by your doctor, nurse, or care provider to complete the following steps.

STEPS FOR CAREGIVER TO PERFORM

14. Invert the tube 3-4 times to elute material from the swab. Avoid foaming.
15. Label the transport tube with the patient label including date of collection and specimen type.
16. Transport and store swab container at 2 to 30 degrees C (refrigerate is preferred temperature) within 3 days of collection.

Throat Swab Specimen Collection
Supply # 31654
1. Open the outer peel pack of the Xpert swab collection kit and discard the larger cleaning swab.
2. Partially peel open the top of the collection swab wrapper.
3. Remove the swab, taking care not to touch the tip or lay it down.
4. Instruct the patient to open mouth widely. Position the tongue toward the bottom of the mouth. Swab areas of the pharynx (tonsil, posterior wall, and

uvula).
5. While holding the swab in the same hand, unscrew the cap from the Xpert Swab Transport Reagent Tube and immediately place the swab into the tube.
6. Identify the score line on the swab shaft and carefully break the swab shaft off; use care to avoid splashing contents.
7. Re-cap the transport tube, tighten cap, and invert the tube 3-4 times. Avoid foaming.
8. Label the transport tube with the patient label including date of collection, specimen type and collector's initials.

Anal/Rectal Swab Specimen Collection
Supply # 31654
1. Open the outer peel pack of the Xpert swab collection kit and discard the larger cleaning swab.
2. Partially peel open the top of the collection swab wrapper.
3. Remove the swab, taking care not to touch the tip or lay it down.
4. Carefully insert the swab approximately 1 cm beyond the anal sphincter (so that the fiber tip is no longer visible) and rotate gently. See Figure 1 and Figure 2 below for acceptable and unacceptable swab specimens.

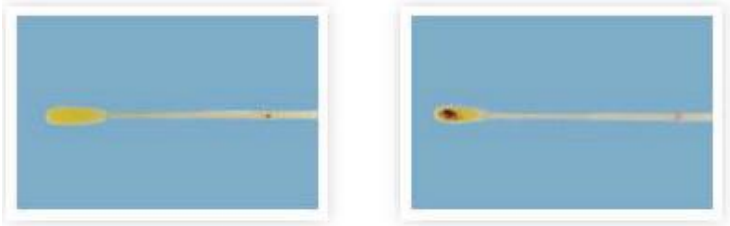


Figure 1. Examples of Acceptable Rectal Swabs

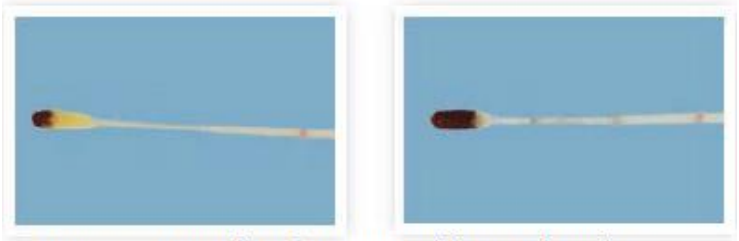


Figure 2. Examples of Unacceptable Rectal Swabs

5. While holding the swab in the same hand, unscrew the cap from the Xpert Swab Transport Reagent Tube and immediately place the swab into the tube.
6. Identify the score line on the swab shaft and carefully break the swab shaft off; use care to avoid splashing contents.
7. Re-cap the transport tube, tighten cap, and invert the tube 3-4 times. Avoid foaming.
8. Label the transport tube with the patient label including date of collection, specimen type and collector's initials.

Conjunctival Swab Specimen Collection
Supply # 31654

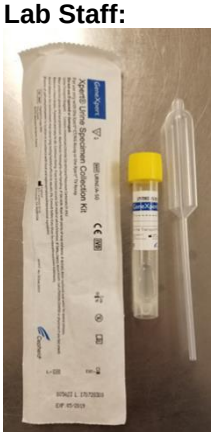
1. Open the outer peel pack of the Xpert swab collection kit and discard the larger cleaning swab.
2. Partially peel open the top of the collection swab wrapper.
3. Remove the swab, taking care not to touch the tip or lay it down.
4. With sterile gloved hands, open patient's eye lid and hold head still. Swab areas of the conjunctiva.
5. While holding the swab in the same hand, unscrew the cap from the Xpert Swab Transport Reagent Tube and immediately place the swab into the tube.
6. Identify the score line on the swab shaft and carefully break the swab shaft off; use care to avoid splashing contents.
7. Re-cap the transport tube, tighten cap, and invert the tube 3-4 times. Avoid foaming.
8. Label the transport tube with the patient label including date of collection, specimen type and collector's initials

Transport/Storage:

Specimen	**Transport/Storage Temperature**	**Specimen Stability**
Conjunctival swab in Xpert Transport Tube	Refrigerate or Room temperature	7 Days
Endocervical/Vaginal/ Rectal/Throat Swab in Xpert Transport Tube	Refrigerated or Room temperature	60 Days
Endocervical/Vaginal Swab in Xpert Transport tube	Refrigerated or Room temperature	60 Days
Urine, Unprocessed (NEAT) Female	Refrigerated	8 Days
	Room Temperature	24 Hours
Urine, Unprocessed (NEAT) Male	Refrigerated	8 Days
	Room Temperature	3 Days
Urine in Xpert Transport Tube, Female	Refrigerated	45 Days
	Room Temperature	3 Days
Urine in Xpert Transport Tube, Male	Refrigerated or Room temperature	45 Days

Special Processing:

Lab Staff:



Neat Urine processing in the lab:

1. Process urine in the hood.
2. Put on clean gloves
3. Place Sunquest large bar code test label aligned vertically on the Xpert CT/NG Urine Transport Reagent tube with the patient's name and medical record number closest to the opening of the container. Take care not to obscure the fill line on the transport tube. Compare patient's name, medical record number, accession number and test information with the original specimen container label. Write your tech code on the bar code label.
4. Swirl urine cup to mix well.
5. Open the packaging of the disposable transfer pipette provided in the kit.
6. Remove the cap from the Xpert CT/NG Urine Transport Reagent tube and from the urine collection cup.
7. Insert the transfer pipette into the urine cup so that the tip is near the bottom of the cup. Transfer approximately 7 mL of urine to the Xpert CT/NG Urine Transport Reagent tube. The correct volume of urine has been added when the level reaches the black dashed line on the label of the Xpert CT/NG Urine Transport Reagent tube. Under or overfilling the tube may affect assay performance.
8. Replace the cap on the Xpert CT/NG Urine Transport Reagent tube and tighten securely.
9. Invert the Xpert CT/NG Urine Transport reagent tube 3-4 times to ensure that the specimen and reagent are well mixed.
10.Recap the urine cup securely.
11. Change gloves to process another sample.

Note:

● Transfer one sample at a time with only one tube open at once.
● Previously aliquoted samples should not be returned to an original container to avoid the possibility of contamination.

Sample Rejection:

Large white swab included in Xpert Swab Specimen Collection Kit is for preparatory cleaning of the endocervix and is unacceptable for testing. Specimens in any transport media other than indicated above. Specimens in swab transport media without a swab. Specimen not submitted in appropriate transport container; improperly labeled specimen; midstream urine; cath urine, vaginal drainage, urethral swabs; insufficient volume; external contamination; specimens exceeding acceptable transport time. If an unacceptable specimen is received, the physician or nursing station will

be notified and another specimen requested before the specimen is discarded.

Interpretive

Reference Range: Negative

Unresolved results due to PCR inhibition are inconclusive. Consider repeat collection if clinically indicated.

Critical Values: Positive results in patients 12 years of age and under are considered semi-urgent.

Positive results from conjunctival samples are considered semi-urgent.

Limitations:

● This assay is intended for use in clinical monitoring or management of patients; it is not intended for use in medico-legal applications. Additional testing is recommended in any circumstance when false positive or false negative results could lead to adverse medical, social, or psychological consequences.
● 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, assay interference may be observed in the presence of: blood (>1% v/v) or mucin (>0.8% w/v).
● 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. Improper specimen collection, concurrent antibiotic therapy, presence of inhibitors, or low numbers of organisms in the specimen (i.e., below the sensitivity of the test) may cause false-negative results.
● In low prevalence populations, positive results must be interpreted carefully as false-positive results may occur more frequently than true positive results in this setting.
● This assay cannot be used to monitor therapeutic success as residual target nucleic acid may persist for up to three weeks.
● Xpert CT/NG Assay performance has not been evaluated in patients less than 14 years of age. During validation testing a total of nine patients under the age of 14 had samples submitted for testing (6 urine, 2 vaginal, 1 conjunctival). All sample results were negative and in agreement with the comparator method, with the exception of one that was invalid. Due to a low frequency of testing this population and availability of resources, a more thorough evaluation was not possible.
● Assay performance has not been evaluated in pregnant women, or in patients with a history of hysterectomy.
● This assay 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.
● Results should be interpreted in conjunction with other laboratory and clinical information.
● Erroneous test results might occur from improper specimen collection,

technical error, or sample mix-up.
● 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 not been evaluated with patients who are currently being treated with antimicrobial agents active against CT or NG.
● Mutations or other changes within the regions of the bacterial genomes covered by the primers and/or probes in the Xpert assay may result in failure to detect the target organisms.
● The performance and characteristics of the assay to perform testing on conjunctival swabs have been evaluated and verified by Children's MN Laboratory.

Methodology: Real time Polymerase Chain reaction (PCR) performed on the Cepheid GeneXpert platform

References:

Cepheid. Xpert CT/NG Assay Package Insert (2019), 301-0234, Rev J. Sunnyvale, CA

Cepheid. Xpert Swab Collection Kit Package Insert (2019), 302-0175, Rev B, HPC135A Rev. 01. Sunnyvale, CA

GeneXpert Dx System Operator Manual: Software Version 4.8 (2016) 3010045, Rev. K. In. Sunnyvale, CA: Cepheid Inc

Centers for Disease Control and Prevention: Sexually Transmitted Diseases Treatment Guidelines (2015). MMWR Morb Mortal Wkly Rep 2015; 64:RR3

Updates:

12/6/2018: Update specimen rejection criteria
8/20/2019: Added new validated specimen sources
8/5/2020: Removed urine references. No longer performed by this method internally.
11/18/2020: Added urine references.
5/11/2021: Updated acceptable swab types.
8/3/2021: Updated information for urine collection and processing.