Lab Dept: Microbiology/Virology

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.

For oral/throat, ocular, anal/rectal, and peritoneal fluid sources refer to Chlamydia trachomatis Amplified RNA Assay, Misc. Sites and Neisseria gonorrhoeae Amplified RNA Assay, Misc. Sites

Logistics

Test Indications: Detection of Chlamydia trachomatis and Neisseria gonorrhoeae in FDA-approved specimen types

Lab Testing Sections: Virology (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 and male and female urine 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.

● Patients should not have urinated for at least 1 hour prior to urine specimen collection.
The first 50mls of a voided urine is used because it has the highest concentration of organisms, midstream urine is unacceptable.

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, the first 20-50ml of voided urine specimens

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

**Swabs:**
Supply# 31654- Xpert Vaginal/Endocervical Specimen Collection Kit

Urine:
Standard sterile screw-cap urine cup
and
Supply #31655 - Xpert Urine Collection Kit

**Draw Volume:** 50 mL (Minimum: 20 mL) urine or 1 swab

**Collection:**  Endocervical swab:

Supply # 31654 - Xpert Vaginal/Endocervical Specimen Collection Kit

1. Open the swab 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 Vaginal/Endocervical 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 Vaginal/Endocervical Specimen Collection Kit

1. Open the Xpert Vaginal/Endocervical 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 Vaginal/Endocervical 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 Vaginal/Endocervical Specimen Collection Kit

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

1. Open the outer peelpack (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 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.

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.

**Urine specimens – 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 specimen.

1. Direct patient to provide first-catch urine (approximately 20 to 50ml of the initial urine stream) into a urine collection 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 a disposable transfer pipette provided in the kit.
4. Remove the cap from the Xpert GT/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 7ml of urine to the Xpert CT/NG Urine Transport Reagent tube using the disposable transfer pipette. 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 tube may affect assay performance.

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

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Transport/Storage Temperature</th>
<th>Specimen Stability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urine, Unprocessed (neat) Female</td>
<td>Refrigerated</td>
<td>8 Days</td>
</tr>
<tr>
<td></td>
<td>Room temperature</td>
<td>24 Hours</td>
</tr>
<tr>
<td>Urine, Unprocessed (neat) Male</td>
<td>Refrigerated</td>
<td>8 Days</td>
</tr>
<tr>
<td></td>
<td>Room temperature</td>
<td>3 Days</td>
</tr>
<tr>
<td>Urine in Xpert Transport Tube, Female</td>
<td>Refrigerated</td>
<td>45 Days</td>
</tr>
<tr>
<td></td>
<td>Room temperature</td>
<td>3 days</td>
</tr>
<tr>
<td>Urine in Xpert Transport Tube, Male</td>
<td>Refrigerated or Room temperature</td>
<td>45 Days</td>
</tr>
<tr>
<td>Conjunctival swab in Xpert Transport Tube</td>
<td>Refrigerate or Room temperature</td>
<td>7 Days</td>
</tr>
<tr>
<td>Endocervical/Vaginal/ Rectal/Throat Swab in Xpert Transport Tube</td>
<td>Refrigerated or Room temperature</td>
<td>60 Days</td>
</tr>
</tbody>
</table>

### 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 Xpert GT/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 a disposable transfer pipette provided in the kit.
6. Remove the cap from the Xpert GT/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 7ml 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 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:
1. Transfer one sample at a time with only one tube open at once.
2. 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.

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**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).

- With urine specimens, assay 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).

- 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.

• 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 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.

**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


Updates:

12/6/2018: Update specimen rejection criteria
8/20/2019: Added new validated specimen sources