North Memorial Health Laboratory utilizes the Roche Cobas PCR molecular test system for Chlamydia trachomatis & Neisseria gonorrhoeae for testing.

**Limitations of testing:**
Molecular testing should not be used as an assessment of therapeutic success or failure as it can detect non-viable DNA causing false positive results.

Molecular testing of suspected sexual abuse or other medico-legal indications may be helpful in treatment of the victim/patient; however it may not be legally acceptable as evidence in a court of law.

**Specimen Types**
- Female or male urine, preferably a "First Catch Urine" sample.
- Physician assisted endocervical swabs.
- Physician assisted vaginal swabs.
- Self-collected vaginal swabs.

**Unacceptable Specimen**
- Urine samples filled above or below the acceptable lines on the Cobas PCR Media tube are unacceptable.
- Female swab specimens with two swabs or no swab in them.
- Swabs not transported to the Lab in the Cobas PCR Media.
- Any specimen collected with any swab other than that provided in the Cobas Female Swab Sample Packet.
- All male swabs are unacceptable.

**Material Required:**

<table>
<thead>
<tr>
<th>For:</th>
<th>Use:</th>
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</thead>
<tbody>
<tr>
<td>Physician assisted endocervical or vaginal specimens:</td>
<td>Cobas PCR Dual Swab Sample Packet</td>
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<tr>
<td>Self-collected vaginal swabs:</td>
<td>Cobas PCR Female Uni Swab Sample Packet</td>
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<tr>
<td>Female or male urine:</td>
<td>Cobas PCR Urine Sample Packet</td>
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* Cobas PCR Sample Packets are available from North Memorial Health Hospital Laboratory

**Specimen Collection**
Follow instructions for type of specimen to be collected.

**Urine:**
1. Prior to sampling the patient should not have urinated for at least 1 hour.
2. Provide patient with a sterile, plastic, preservative-free, screw cap specimen collection cup.
3. Direct the patient to collect the first 15 – 50 mL of the initial urine stream in the cup provided. First-catch urine specimens are preferred due to the fact that collection of larger volumes of urine may reduce test sensitivity.
4. Make sure patient tightly screwed the lid back on the container.
5. Immediately transfer urine into the Cobas PCR Media tube using the provided disposable pipette. Fill the Cobas PCR Media tube to within the acceptable lines. Filling either above or below is unacceptable.
6. Label Cobas PCR Media tube with patient identification; date/time collected, and include the source as "First Catch Urine" to differentiate it from a midstream urine.
   - Note: A separate midstream urine specimen should be collected for either UA and/or UC testing.
7. Invert tube 5 times to mix.
8. Specimen can be stored and transported at 2-30 ºC to North Memorial Health Hospital.
Physician assisted Endocervical Swab:

1. Remove excess mucus from cervical os and surrounding mucosa with the larger woven swab provided in the Cobas PCR Dual Swab Sample Packet. Then discard the swab.
2. Insert second flocked swab from collection kit into cervical canal and rotate for 15-30 sec. Use only enclosed swabs. No other swab type is validated for testing.
3. Withdraw swab carefully. Avoid contact with vaginal mucosa and immediately place the swab into the Cobas PCR Media yellow cap tube. Break off swab at the dark line.
4. Make sure the cap is tightly secured to the tube.
5. Label with patient identification and date/time collected.
6. Specimen can be stored and transported at 2-30 °C to North Memorial Health Hospital Laboratory.

Physician assisted Vaginal Swab:

Use only one of the two enclosed swabs provided. No other swab type is validated for testing.

To collect the specimen:

1. Insert the flocked swab about 5 cm (2 inches) into the vaginal opening.
2. Gently turn the swab for about 30 seconds while rubbing the swab against the walls of the vagina.
3. Withdraw swab carefully. Do not let the swab touch any surface before placing it into the Cobas PCR Media yellow cap tube. Break off swab at the dark line.
4. Make sure the cap is tightly secured to the tube.
5. Label with patient identification and date/time collected.
6. Specimen can be stored and transported at 2-30 °C to North Memorial Health Hospital Laboratory.

Patient Self-Collected Vaginal Swab:

Use only Cobas PCR Female Uni Swab Sample Packet. No other swab type is validated for testing.

1. **POSITION:** Hold the swab in one hand and with the other hand separate the folds of the skin around the vaginal opening (labia). Do not touch the swab tip or lay it down. If you touch the tip or lay the swab down, ask for a new swab.
2. **COLLECT:** Insert the swab about 5 cm (2 inches) into the vaginal opening. Gently turn the swab for about 30 seconds while rubbing the swab against the walls of the vagina. Remove the swab carefully. Do not let the swab touch any surface before placing it into the Cobas PCR Media yellow cap tube.
3. **OPEN TUBE:** While holding the swab in the same hand remove the yellow cap from the tube.
4. **ALIGN:** Lower the swab into the tube until the visible dark line on the swab shaft is lined up with the tube rim. The tip of the swab should be just above the liquid in the tube.
5. **BREAK:** Carefully lean the swab against the tube rim to break the swab shaft at the dark line; discard the top portion of the swab leaving the tip of the swab in the tube with the liquid media.
6. **CLOSE:** Tightly close the yellow cap cobas PCR Media Tube. Wash hands after collect.
7. Label with patient full name and date/time collected.
8. Specimen can be stored and transported at 2-30 °C to North Memorial Health Hospital Laboratory.