LABSTRACT – Updated November 2021

*Chlamydia trachomatis* and *Neisseria gonorrhoeae* - Nucleic Acid Amplification Testing – change in test assay and collection kits

**Audience**

Health care providers submitting specimens to Public Health Ontario’s (PHO) laboratory for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by nucleic acid amplification testing.

**Update**

As of December 1, 2021, PHO’s laboratory is changing their testing assay to the Roche cobas® CT/NG assay from the Hologic® Aptima Combo 2® assay. This means that new collection kits will be required for health care providers when submitting clinical specimens for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) testing by the nucleic acid amplification test (NAAT) method. Test Information Sheets with a complete NAAT menu are available on the PHO website at [publichealthontario.ca/en/laboratory-services/test-information-index](http://publichealthontario.ca/en/laboratory-services/test-information-index). Testing will be available with both assays for one month from December 1 to December 31, 2021 to allow clients to transition to the new specimen collection kits. After December 31, 2021 testing with the previous collection kits will no longer be available. Clients that are unable to meet this timeline should contact our Laboratory Customer Service Centre (contact information below).

The following information is provided in this Labstract:

- Overview
- Specimen Collection Kits
- Limitations
- Medico-legal Investigations
- Confirmatory Testing
- Test of Cure
- Reporting
- Sensitivity and Specificity Data
Overview

PHO’s laboratory accepts male or female urine, clinician-collected endocervical, clinician and patient-collected vaginal, rectal and pharyngeal site specimens for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) for testing by NAAT. A limited validation of rectal and pharyngeal specimens was performed at PHO to support NAAT for these collections as the Roche cobas® CT/NG assay is currently not approved by Health Canada for testing of extragenital sites. Urethral and penile meatal swabs are not included as part of the Roche cobas® assay and will not be accepted. NAAT is the recommended method for initial screening or testing of CT and NG collected from the approved anatomical sites listed above.

Testing from all other anatomical sites require a CT or NG culture collection kit to be submitted. Specimens submitted for culture using a NAAT collection kit will be rejected. Specimens submitted using a NAAT collection kit for anatomical sites not listed above will be rejected.

Rectal and/or pharyngeal testing is recommended for individuals who have had unprotected sexual exposures at these sites and are in specific at-risk groups or have risk factors, including:

- gay, bisexual, and men who have sex with men, including trans women;
- individuals engaged in sex work or who have had sexual contact with someone engaging in sex work;
- individuals who are known contacts of those infected with CT or NG;
- individuals who have signs or symptoms of rectal or pharyngeal infection

Rectal and/or pharyngeal testing in individuals who have had exposures at these sites and are not in specific risk groups above may be considered in individual circumstances based on clinical evaluation or local epidemiology.


Rectal bacterial sexually transmitted infections, including CT and NG, have been associated with increased risk of HIV infection in gay, bisexual, and other men who have sex with men, and transgender women. Screening for HIV is highly recommended in these individuals. Details about HIV serology testing at PHO can be found here: HIV Serology Test Information Sheet. Consider initiation of Pre-Exposure Prophylaxis (PrEP) for HIV-negative individuals. For more information on PrEP visit ontarioprep.ca.

Specimen Collection Kits: NAAT for CT and NG at PHO’s laboratory is performed using the Roche cobas® CT/NG assay and two collection kits are available for specimen collection and submission.

- The Roche cobas® Media Dual Swab Sample Kit contains two swabs, a flocked swab and a woven swab. The flocked swab is only to be used for female endocervical swab collection and the woven swab for all other swab collections as outlined below. Incoming primary swab specimen tubes with no swabs or with two swabs have not been collected according to the collection instructions and therefore will not be tested.
• The Roche cobas® Urine Sample Kit is used for urine specimen collection. Neat urine specimens will not be accepted and clients must transfer the appropriate amount of specimen to the approved collection kit (fill to between indicated lines on tube).

• Collection instructions using the Roche cobas® kits can be found here: Roche Educational Resources

Table 1: Acceptable Specimen Collection Sites and Associated Collection Kits for CT and NG NAAT

<table>
<thead>
<tr>
<th>Collection Site</th>
<th>Collection Kit</th>
<th>Collection Kit - swab</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female endocervical</td>
<td>Roche cobas® PCR Media Dual Swab Sample Kit</td>
<td>Flocked swab</td>
</tr>
<tr>
<td>Clinician or patient-collected specimens in a clinical setting</td>
<td>Roche cobas® PCR Media Dual Swab Sample Kit</td>
<td>Woven swab</td>
</tr>
<tr>
<td>• Female vaginal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Rectal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Pharyngeal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male and female urine</td>
<td>Roche cobas® PCR Urine Sample Kit</td>
<td></td>
</tr>
</tbody>
</table>

**Note:** Patient-collected specimen collection for women is not designed to replace cervical exams and endocervical specimens for the diagnosis of female urogenital infections. Patients may have cervicitis, urethritis, urinary tract infections, or vaginal infections due to other causes or concurrent infections with other agents. Women who have symptoms suggesting pelvic inflammatory disease (PID) should not use a self-collected swab to obtain patient-collected vaginal swab specimens as a replacement for a pelvic exam. The patient-collected swab specimen collection is limited to health care facilities where support or counseling is available to explain the procedures and precautions. PHO’s laboratory does not accept at-home patient self-collection.
Limitations: The following specimens should be recollected at the time of specimen collection or they will be rejected if received in the laboratory.

- Swab specimens grossly contaminated with blood or feces.
- Swab specimen tubes with no swabs or with two swabs.
- Urine specimens with volumes outside the two black lines on the tube label.

Medico-legal investigations: CT and NG culture is the preferred and recommended method for medico-legal investigations; however, NAAT specimens will also be accepted. A positive NAAT result requires confirmation by another NAAT using a different set of primers as per the current Public Health Agency of Canada (PHAC) Canadian Guidelines on Sexually Transmitted Infections. Specimens received on patients <14 years of age have not been validated by the manufacturer; however, they will be tested by PHO with a disclaimer added.

Confirmatory testing:

- NG confirmatory testing will be performed on NG-positive specimens for extragenital sites, children <12 years of age, cases of sexual abuse/sexual assault, and medico-legal investigations. Confirmatory testing for NG is performed using the Roche cobas® omni Utility Channel with the PivNG Assay V2 (IDT). This assay is not currently approved by Health Canada but has been validated for use at PHO’s laboratory.
CT confirmatory testing will be performed on CT positive specimens for children <12 years of age, cases of sexual abuse/sexual assault, and medico-legal investigations. CT confirmatory testing is performed using the Cepheid Xpert® CT/NG assay.

**Test of cure:** Test of cure by culture testing is recommended for all cases of pharyngeal gonorrhea, suspected rectal/pharyngeal gonorrhea treatment failures, if first line treatment was not used, for CT and NG infections during pregnancy, and in cases of sexual abuse/sexual assault. Refer to the PHAC Canadian Guidelines on Sexually Transmitted Infections for additional information.

- Culture testing for NG should be performed 3 – 7 days after completion of treatment. If culture is not available, test of cure by NAAT will also be accepted. NAAT for NG should be performed 2 – 3 weeks after completion of treatment.

- In rare cases where test of cure is recommended for CT infection, NAAT should be performed 3 – 4 weeks after completion of treatment. In rare circumstances, CT genetic material may persist for longer than 4 weeks and therefore must be considered when interpreting positive test of cure results.

Test Information Sheets for NAAT and culture testing are available by accessing PHO’s Laboratory Test Information Index.

**Reporting:** Positive CT or NG laboratory test results are reported to the Medical Officer of Health at the local public health unit.

**Assay Sensitivity and Specificity**
Table 2 below provides sensitivity and specificity information for the Roche cobas® assay for the detection of CT and NG at urogenital sites for females and males.

Clinic-based patient-collected swabbing at vaginal, rectal and pharyngeal sites has the same performance characteristics as clinician-collected swabbing when performed correctly. For collection instructions on patient-collected swabbing, refer to the following link: Roche Educational Resources.
Table 2: Manufacturer reported test performance of the Roche cobas® assay for CT and NG (% (95% CI))

<table>
<thead>
<tr>
<th></th>
<th>Chlamydia trachomatis</th>
<th>Neisseria gonorrhoeae</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sensitivity</td>
<td>Specificity</td>
</tr>
<tr>
<td>Female: Urine</td>
<td>100%</td>
<td>99.1%</td>
</tr>
<tr>
<td></td>
<td>(98.7%-100%)</td>
<td>(98.6%-99.5%)</td>
</tr>
<tr>
<td>Female: Clinician-collected vaginal swab</td>
<td>100%</td>
<td>98.6%</td>
</tr>
<tr>
<td></td>
<td>(95.8%-100%)</td>
<td>(97.7%-99.2%)</td>
</tr>
<tr>
<td>Female: Self-collected vaginal swab</td>
<td>100%</td>
<td>98.7%</td>
</tr>
<tr>
<td></td>
<td>(96.0%-100%)</td>
<td>(97.8%-99.3%)</td>
</tr>
<tr>
<td>Female: Endocervical swab</td>
<td>100%</td>
<td>99.2%</td>
</tr>
<tr>
<td></td>
<td>(96.8%-100%)</td>
<td>(98.6%-99.5%)</td>
</tr>
<tr>
<td>Male: Urine</td>
<td>100%</td>
<td>99.6%</td>
</tr>
<tr>
<td></td>
<td>(96.8%-100%)</td>
<td>(98.8%-99.9%)</td>
</tr>
</tbody>
</table>

References

1 cobas® CT/NG, Qualitative nucleic acid test for use on the cobas® 6800/8800 Systems, Package Insert 08978905001-01EN. Doc Rev 1.0. 05/2019
For further information

- Contact PHO’s Laboratory Customer Service Centre at 416-235-6556 or 1-877-604-4567 (toll-free), or by email at customerservicecentre@oahpp.ca

- For specimen collection information and previous Labstracts, refer to publichealthontario.ca/en/laboratory-services/test-information-index

- The current version of PHO’s Laboratory General Test Requisition and other forms are available at publichealthontario.ca/Requisitions

- To subscribe to future Labstracts, register on our website

- To register for Autofax and receive laboratory reports by fax directly from our laboratory information system as soon as they are released, contact the PHO’s Laboratory Customer Service Centre.

Public Health Ontario is an agency of the Government of Ontario.