Public Health Ontario | Santé publique Ontario

LABSTRACT – Updated May 2022

Chlamydia trachomatis and *Neisseria gonorrhoeae* - Nucleic Acid Amplification Testing

Audience

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

Update

In December 2021, PHO's laboratory changed CT/NG NAAT to the Roche cobas® CT/NG assay from the Hologic® Aptima Combo 2® assay. Since the change in assays was implemented, additional information have been updated:

1. Rectal and pharyngeal collections with the Roche cobas® CT/NG assay are now Health Canada approved. Performance data have been included in Table 2: Manufacturer reported test performance of the Roche cobas® assay for CT and NG. Performance data is for clinician collected specimens only. Results must be interpreted with caution if clinicians request patients to perform self-collection of rectal and pharyngeal specimens outside of a clinical setting.

2. The Canadian STI guidelines have been updated to recommend test of cure (TOC) testing for all *Neisseria gonorrhoeae* positive sites.

Test Information Sheets with a complete NAAT menu are available on the PHO website at publichealthontario.ca/test directory.

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 when collected in a clinical setting for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) for testing by NAAT. 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.

Neisseria gonorrhoeae (NG) culture is recommended plus NAAT when suspecting antimicrobial resistance, test of cure, symptomatic patients, pelvic inflammatory disease (PID), pregnancy, and sexual abuse/sexual assault.

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.

Please refer to PHO's Bacterial STI Testing: Quick Reference Guide for guidance on testing based on risk factors and clinical presentation.

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).

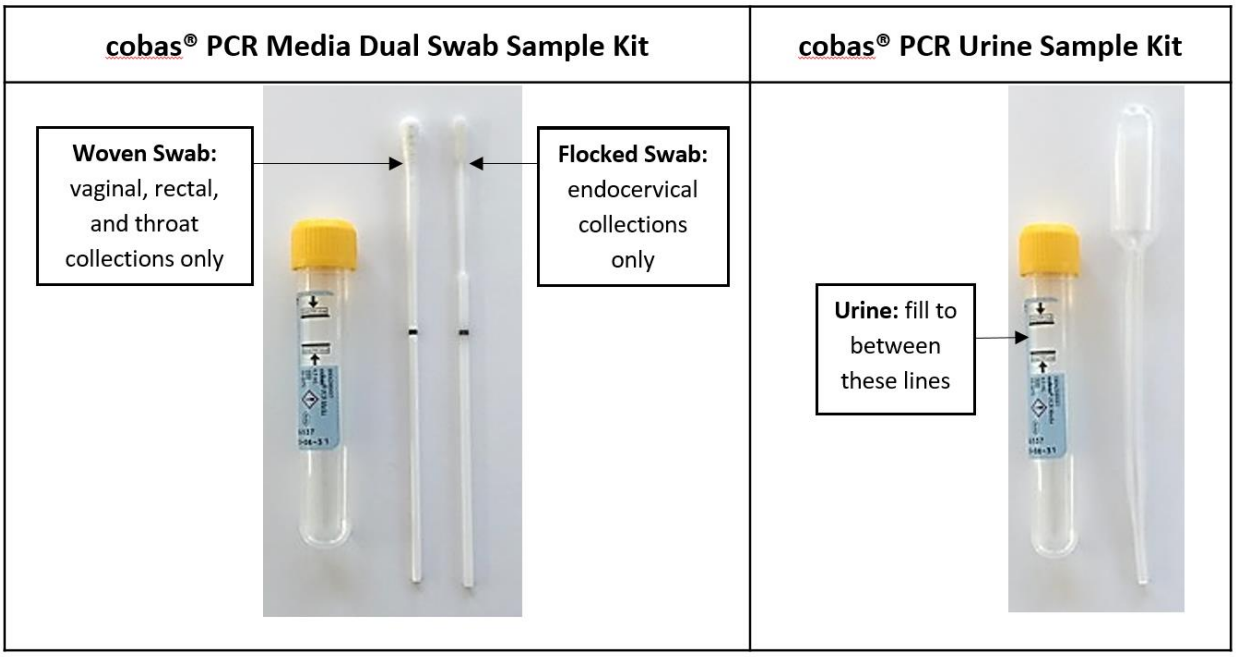
- Collection instructions using the Roche cobas® kits can be found here: Roche Educational Resources

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

Collection Site	Collection Kit	Collection Kit - swab
Female endocervical	Roche cobas® PCR Media Dual Swab Sample Kit	Flocked swab
Clinician or patient-collected specimens in a clinical setting 1. Female vaginal 2. Rectal 3. Pharyngeal	Roche cobas® PCR Media Dual Swab Sample Kit	Woven swab
Male and female urine	Roche cobas® PCR Urine Sample Kit	

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.

Figure 1: Acceptable Specimen Collection Kits for CT/NG NAAT



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 (TOC): General guidelines for NG and CT are described below. Refer to the PHAC Canadian Guidelines on Sexually Transmitted Infections for detailed information.

- **NG:** TOC is recommended for all positive sites and culture is the preferred method. Obtain cultures 3 to 7 days after treatment is complete. If culture is not available and NAAT is used as a TOC, it should be performed 2 to 3 weeks after completion of treatment. Repeat screening is recommended 6 months post-treatment for all individuals with NG infection.

- **CT:** TOC by NAAT is recommended 3 to 4 weeks after completion of treatment when compliance to treatment is suboptimal, an alternative treatment regimen is used, for those with persisting signs or symptoms post-treatment, or the individual is prepubertal or pregnant. For LGV, TOC is recommended 3 weeks after completion of treatment. Follow LGV-infected individuals until TOC for CT is negative and symptoms have resolved. In rare circumstances, CT DNA may persist for longer than 4 weeks and therefore must be considered when interpreting positive TOC results. Repeat screening is recommended 3 months post-treatment for all individuals with CT infection.

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 and extragenital sites.

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))[1,2]

	CT Sensitivity	CT Specificity	NG Sensitivity	NG Specificity
Female: Urine	100% (98.7%-100%)	99.1% (98.6%-99.5%)	100% (85.2%-100%)	99.8% (99.6%-100%)
Female: Clinician-collected vaginal swab	100% (95.8%-100%)	98.6% (97.7%-99.2%)	100% (83.2%-100%)	99.9% (99.5%-100%)
Female: Self-collected vaginal swab	100% (96.0%-100%)	98.7% (97.8%-99.3%)	100% (81.5%-100%)	99.7% (99.2%-99.9%)
Female: Endocervical swab	100% (96.8%-100%)	99.2% (98.6%-99.5%)	95.7% (78.1%-99.9%)	99.9% (99.7%-100%)
Male: Urine	100% (96.8%-100%)	99.6% (98.8%-99.9%)	96.8% (83.3%-99.9%)	100% (99.5%-100%)
Pharyngeal	100% (87.9%-100%)	99.8% (99.6%-99.9%)	100% (96.2%-100%)	98.9% (98.4%-99.2%)
Rectal	95.1% (90.2%-97.6%)	99.2% (98.8%-99.5%)	99.0% (94.6%-99.8%)	99.3% (98.9%-99.6%)

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

[2] cobas® CT/NG, Qualitative nucleic acid test for use on the cobas® 6800/8800 Systems, Package Insert 07997981001-03EN. Doc Rev 3.0. 11/2021

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/test directory
- 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.

Ontario

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