Public Health Ontario | Santé publique Ontario

LABSTRACT – Updated June 2019

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

Audience

Health Care Providers submitting specimens to the Public Health Ontario (PHO) Laboratory for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by nucleic acid amplification testing.

Update

As of June 27, 2019, the PHO Laboratory has added the vaginal swab to their test menu for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) for testing with their current nucleic acid amplification test (NAAT) method. Test Information Sheets with a complete NAA test menu are available on the PHO website at publichealthontario.ca/test directory.

The collection device for the vaginal swab is now available and is the Hologic® Aptima® Multitest Swab Specimen Collection Kit. The Test Information Sheet for CT/GC testing also includes details for ordering the correct collection kits for the various approved clinical sites. Vaginal swabs may be clinician or patient collected only in a clinical setting. Specimens collected outside of a clinic setting will not be accepted as they are not recommended by the manufacturer. Specimens collected from pregnant women or patients less than 16 years of age have not been validated, but will be accepted. (Aptima® Combo 2® Assay package insert, 502487 Rev. 002 2019-02.)

Overview

PHO Laboratory accepts urine, urethral, penile meatal, clinician and patient collected vaginal, endocervical, rectal and pharyngeal site specimens for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) by NAAT. NAAT is the recommended method for initial screening or testing of chlamydia and gonorrhea collected from the approved anatomical sites listed above.

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

Rectal and pharyngeal testing is recommended in the case of unprotected sexual exposure at oral and anal sites only for the following groups:

- men who have sex with men (MSM);
- sex workers and their contacts;
- patients who are known contacts of those infected with CT or GC.

At present, for women, there is insufficient evidence to support a policy of routine screening of rectal and pharyngeal sites for chlamydia and gonorrhea. However, this may represent a relative lack of studies examining extragenital transmission in this group. As a result, if there is clinical concern regarding rectal or pharyngeal infection with chlamydia or gonorrhea in a woman presenting to care, testing at these sites can be offered.

Specimen Collection Kits: NAAT for CT and GC at PHO Laboratory is performed using the Hologic® Aptima Combo 2® Assay.

- Two different swab collection kits are provided by the manufacturer: the smaller tipped Aptima® Unisex Swab Specimen Collection Kit, and the larger tipped Aptima® Multitest Swab Specimen Collection Kit. Note: each kit contains a cleaning swab and a collection swab; only the collection swab is optimized and validated for testing.
- The Hologic® Aptima® Urine Specimen Collection Kit should be used for urine specimen collection.

Table 1: PHO Laboratory Acceptable Specimen Collection Sites and Associated Collection Kits for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Nucleic Acid Amplification Testing

Collection Site	Collection Kit
Male urethral and female endocervical specimens	Hologic® Aptima® Unisex Swab Specimen Collection Kit
Clinician or patient collected vaginal specimens (in a clinical setting) Penile meatal specimens	Hologic® Aptima® Multitest Swab Specimen Collection Kit
Rectal and pharyngeal specimens	Hologic® Aptima® Unisex Swab Specimen Collection Kit OR Hologic® Aptima® Multitest Swab Specimen Collection Kit
Male and female urine specimens	Hologic® Aptima® Urine Specimen Collection Kit

Table 2: PHO Laboratory Acceptable Specimen Collection Kits for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Nucleic Acid Amplification Testing

Hologic® Aptima® Multitest Swab Specimen Collection Kit	Hologic® Aptima® Urine Specimen Collection Kit	Hologic® Aptima® Unisex Swab Specimen Collection Kit
		

Medico-legal investigations: CT and GC 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.

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, as well as for chlamydia and gonorrhea infections during pregnancy. The optimal specimen for test of cure is culture and should be performed at 1 - 2 weeks after completion of treatment. If culture is not available, test of cure by NAAT will also be accepted. Test of cure for GC by NAAT should be performed 2 - 3 weeks after completion of treatment and for CT should be performed 3 – 4 weeks after completion of treatment. Chlamydia genetic material may persist for longer than 4 weeks and therefore must be considered when interpreting positive test of cure results. Refer to the PHAC Canadian Guidelines on Sexually Transmitted Infections for additional information.

Limitations: Use of the Multitest swab for patient-collected vaginal specimen collection is not designed to replace cervical exams and endocervical specimens for 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 the Multitest swab to obtain patient-collected vaginal swab specimens as a replacement for a pelvic exam.

The patient-collected Multitest swab specimen application is limited to health care facilities where support or counseling is available to explain the procedures and precautions.

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

Test information sheets for NAAT and culture testing are available by accessing the PHO Laboratory Test Information Index.

Tables 3 & 4 below provide updated sensitivity and specificity information for the Hologic® Aptima Combo 2® Assay for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* at urogenital sites for males and females.
Table 5 describes the sensitivity and specificity information for the Hologic® Aptima Combo 2® Assay for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* at rectal and pharyngeal sites by NAAT performed at the PHO Laboratory.

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 for vaginal, penile meatal, rectal and pharyngeal swabs, refer to the following link: Hologic® Aptima® Multitest Swab Specimen Collection Kit for Patient Collected Specimens. Performance characteristics are not available for penile meatal swabs.

Table 3: Comparison of Hologic® Aptima Combo 2® Assay Specimens vs. Patient Infected Status in Males for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Nucleic Acid Amplification Testing [1]

	Sensitivity	Specificity
Chlamydia trachomatis Urethral Swab	95.9 %	97.5 %
Chlamydia trachomatis Urine	97.9 %	98.5 %
Neisseria gonorrhoeae Urethral Swab	99.1 %	97.8 %
Neisseria gonorrhoeae Urine	98.5 %	99.6 %

[1] Hologic® Aptima Combo 2® Assay package insert. San Diego, CA Hologic, Inc.; 2019-02.

Table 4: Comparison of Hologic® Aptima Combo 2® Assay Specimens vs. Patient Infected Status in Females for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Nucleic Acid Amplification Testing [1]

	Sensitivity	Specificity
Chlamydia trachomatis Endocervical Swab	94.2 %	97.6 %
Chlamydia trachomatis Urine	94.7 %	98.9 %
Chlamydia trachomatis Clinician-collected Vaginal Swab	96.6 %	96.8 %
Chlamydia trachomatis Patient-collected Vaginal Swab	98.4%	96.8%
Neisseria gonorrhoeae Endocervical Swab	99.2 %	98.7 %
Neisseria gonorrhoeae Urine	91.3 %	99.3 %
Neisseria gonorrhoeae Clinician-collected Vaginal Swab	96.0 %	99.2 %
Neisseria gonorrhoeae Patient-collected Vaginal Swab	100%	99.5%

[1] Hologic® Aptima Combo 2® Assay package insert. San Diego, CA Hologic, Inc.; 2019-02.

Table 5. Performance Characteristics of clinician collected Hologic® Aptima Combo 2® CT/GC NAAT from Rectal and Pharyngeal Sites as Compared to Culture for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Nucleic Acid Amplification Testing (PHO Laboratory Data)

	Sensitivity	Specificity
Chlamydia trachomatis Rectal	99.4%	99.9%
Chlamydia trachomatis Pharyngeal	92.2%	99.9%
Neisseria gonorrhoeae Rectal	100%	99.0%
Neisseria gonorrhoeae Pharyngeal	100%	98.2%

For further information

- Contact the PHO Laboratory Customer Service Centre at 416-235-6556 or 1-877-604-4567 (toll-free), or by email at customerservicecentre@oahpp.ca
- For PHO Laboratory specimen collection information and previous Labstracts, refer to publichealthontario.ca/test directory
- The current version of the PHO 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 Laboratory Customer Service Centre.