Specimen collection and transport for Chlamydia trachomatis and Neisseria gonorrhoeae testing

Overview

Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) infections are two of the most common sexually transmitted infections in the United States.

Chlamydia Trachomatis

In 2010, 1.3 million cases of Chlamydia trachomatis infection were reported to the Centers for Disease Control and Prevention (CDC), the largest number of cases ever reported to the CDC for any condition.\(^1\) Prevalence of CT is highest in persons 25 years of age or younger. In women, chlamydial infections can result in Pelvic Inflammatory Disease (PID), a major cause of infertility, ectopic pregnancy, chronic pelvic pain, and increased risk of becoming infected with HIV. Pregnant women infected with chlamydia can pass the infection to their infants during delivery, potentially resulting in eye and lung complications. Screening programs can lead to as much as a 60% reduction in the incidence of PID.\(^1\)

Complications among men are rare. Infection sometimes spreads to the epididymis (the tube that carries sperm from the testis), causing pain, fever, and, rarely, sterility.\(^2\)

Neisseria gonorrhoeae

The most common site of Neisseria gonorrhoeae infection is the urogenital tract. Men may experience dysuria with penile discharge (usually symptomatic), and women may have mild vaginal discharge, severe pelvic pain, or no symptoms. Women with gonorrhea can develop ascending infection that causes acute salpingitis and /or PID. PID can lead to tubal infertility, ectopic pregnancy, and chronic pelvic pain. In addition, epidemiologic and biologic studies provide strong evidence that gonococcal infections facilitate the transmission of HIV infection.

Chlamydia trachomatis infections in the US continue to rise

- Chlamydia trachomatis (CT) is the most frequently reported bacterial STD in the US
- 1.3 million cases of Chlamydia and 300,000 cases of Neisseria gonorrhoeae (NG) were reported in 2009\(^1\)
- Untreated Chlamydia infection can cause:
  - Pelvic inflammatory disease (PID)
  - Infection and inflammation of the uterus, fallopian tubes, ovaries, or adjacent peritoneum
  - Ectopic pregnancy, which is potentially fatal, and infertility in women
  - Epididymitis, infertility in men
Why self-collected specimens?
New guidelines encourage movement towards more progressive self-collected specimen types.

Self-collected specimens such as vaginal swabs and urine reduce barriers to testing by offering convenience, increasing comfort, and eliminating the “fear factor.” Women find it easy and prefer to collect their own swabs.3

- For female screening, vaginal swab specimens are the preferred specimen type. Vaginal swab specimens are as sensitive as cervical swab specimens, and there is no difference in specificity. Cervical samples are acceptable when pelvic examinations are done, but vaginal swab specimens are an appropriate sample type even when a full pelvic exam is being performed.4
- When using Nucleic Acid Amplification Tests (NAATS), self-collected vaginal swab specimens perform at least as well as other approved specimens, and women find this screening strategy highly acceptable.5
- Urine is the preferred sample type for testing or screening men using nucleic acid amplification technology (NAAT). There is little need for urethral swab specimens, and in some studies, these samples are less sensitive than urine. Urethral swab specimens and male urine were equivalent in specificity.4

Specimen types recommended by the CDC for CT/NG testing4

For women: Vaginal swab is the preferred specimen type for women when a NAAT is used for testing.
- Vaginal swab (provider-collected or self-collected)
- Endocervical swab
- Urine
- Liquid-based cytology

For men: Urine is the preferred specimen type for men when a NAAT is used for testing.
- Urine specimen
- Urethral swab

Note: The cobas® CT/NG v2.0 test is not cleared for use with urethral swab specimens.
# Specimen collection for specimen types recommended by the CDC for CT/NG testing

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| **Urine** (male or female) | • Collecting urine specimens for CT/NG NAAT testing requires collection of the specimen at the beginning of the urine stream or so called “first catch” urine.  
• Manufacturers often require that patients not urinate for a specified period of time prior to specimen collection, usually at least 1 hour.  
• Once the patient has collected the “first catch” urine specimen in a urine cup, the patient should tightly cap the container.  
• The urine can then be carefully transferred to a secondary collection tube containing nucleic acid stabilizing agents. This is often done by transferring a specified amount of urine with a transfer pipette to the secondary tube followed by capping tightly and mixing. | First-catch urine is expected to contain the greatest concentration of chlamydial elementary bodies, which results in a higher likelihood of pathogen identification in an infected individual, thus yielding the best test sensitivity.  
Collection of a large volume of urine can reduce test sensitivity so manufacturers typically limit the amount of urine to be collected (between 10-50 mLs for example). |
| **Vaginal Swab** (self- or clinician-collected) | • If two swabs are provided, discard second swab as only one swab is required for specimen collection.  
• Vaginal collection typically includes careful insertion of a swab approximately 2 inches into the vaginal opening and gently turning/rubbing the swab against the vaginal wall followed by swab removal and insertion into the collection tube (being careful not to touch the swab to any surface prior to placing into the collection tube).  
• The swab shaft is broken at an indicated height and the top portion of the shaft is discarded while the bottom portion is included in the specimen collection tube.  
• Once the specimen tube is sealed, the specimen is typically mixed to ensure the collected specimen has been thoroughly exposed to the transport media which contains nucleic acid stabilizing agents. | While both *C. trachomatis* and *N. gonorrhoeae* infect columnar epithelial cells of the endocervix and urethra, it has been postulated that exfoliated organisms and debris from the infected cervix and urethra are detected by vaginal specimens.  
According to the CDC, Vaginal swabs are the preferred specimen type for female screening. |
### Specimen collection for specimen types recommended by the CDC for CT/NG testing

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| **Endocervical Swab** | • Collecting an endocervical swab specimen for use in NAAT testing procedures involves the use of a speculum and includes the use of two swabs, one for initial cleaning of the cervix to remove excess mucus from the cervical os and surrounding mucosa (this swab should be discarded), and a second for specimen collection.  
  • Once the cleaning swab has been used and discarded, the second swab is used to collect the specimen by insertion of the swab into the endocervical canal followed by gentle rotation of the swab.  
  • The swab is then withdrawn while avoiding contact with the vaginal mucosa.  
  • Similar to the vaginal swab collection procedure, the swab shaft is typically broken at an indicated height and the top portion of the shaft is discarded while the bottom portion is included in the specimen collection tube.  
  • Once the specimen tube is sealed, the specimen is mixed to ensure the collected specimen has been thoroughly exposed to the transport media which contains nucleic acid stabilizing agents. | Cervical mucus is secreted as a result of hormonal changes in the normal female reproductive cycle, and thus, may vary from woman to woman. Other factors that influence the production of cervical mucus include the use of hormonal contraceptives, breastfeeding, sexually transmitted infections, and perimenopause. Thorough cleaning of excess cervical mucus prior to specimen collection is necessary to avoid potential interference with testing. |
| **Male Urethral Swab** | • Manufacturers often require that patients not urinate for a specified period of time prior to specimen collection.  
  • A small sterile swab provided in the manufacturer’s collection kit is typically inserted 2-4 cm into the urethra and rotated briefly.  
  • The swab is then placed in the transport tube and the swab shaft is typically broken at an indicated height and the top portion of the shaft is discarded while the bottom portion is included in the specimen collection tube.  
  • Once the specimen tube is sealed, the specimen is mixed to ensure the collected specimen has been thoroughly exposed to the transport media which contains nucleic acid stabilizing agents. | Urinating just prior to specimen collection may wash away much of the accessible bacteria from the urethra. Lack of urination prior to collection increases the odds that the specimen will contain the greatest concentration of pathogen. This results in a higher likelihood of pathogen identification in an infected individual and yields the best test performance. |

Note: The cobas® CT/NG v2.0 test is not cleared for use with urethral swab specimens.
| Specimen Type               | Specimen Collection                                                                                                                                                           | Rationale                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Liquid-based cytology      | - This specimen type is typically collected primarily for cytology testing (the Pap test), but this specimen can also be used for molecular testing.  
- Clinicians collecting cytology specimens for CT/NG NAAT testing should follow the same protocol established for collecting specimens for cytology testing. | Several sexually transmitted infections occur in same region where HPV (the causative agent of cervical cancer) infects.  
This allows Pap cytology specimens to be used to detect various STIs using molecular methods. Please follow established laboratory procedures/instructions for specific tests.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |

**Specimen collection for specimen types recommended by the CDC for CT/NG testing**

The cobas® CT/NG v2.0 test is cleared for use with male or female urine, self-collected vaginal swab specimens (collected in a clinical setting) clinician collected vaginal swab specimens, and endocervical swab specimens, all collected in cobas® PCR Media, and cervical specimens collected in PreservCyt® solution.

Collection guides in English and Spanish are available upon request for the collection of Endocervical, vaginal and urine specimens with the cobas® PCR Female Swab and cobas® PCR Urine collection and transport kits.
cobas PCR Female Swab and cobas PCR Urine collection and transport kits

The cobas PCR Female swab and urine kits are the specimen collection kits that have been validated for the cobas CT/NG v2.0 test.

cobas PCR Female swab specimen collection kit

Two swabs
- 1 cleaning swab
- 1 collection swab

Note: the cleaning swab is not used when collecting a vaginal swab sample, dispose of the second swab

cobas PCR Media tube

After collecting the specimen, place the swab in the PCR media tube and carefully lean the swab against the tube rim to break the swab shaft at the dark line.

Specimens in the cobas PCR media tube are stable at room temperature (2 - 30°C) for up to 1 year.

Vaginal Specimen collection

When collecting a self-collected vaginal swab specimen female patients are instructed to discard one swab, collect one swab and place the swab directly into the cobas PCR Media tube. See the collection guide for additional details.

cobas PCR urine specimen collection kit

Patients should not urinate 1 hour prior to specimen collection. Approximately 10 - 15 mL of urine should be collected from the beginning of the stream. Once collected the urine should be transferred to the cobas PCR media tube within 24 hrs.

Fill lines

Use transfer pipette to add urine to the cobas PCR tube. Final volume of the tube should be between fill lines.

Replace and tighten the cap and invert the tube 5 times to mix. This specimen is now stable at room temperature for one year.

This document is intended for educational use only.
References:

1 CDC STD Surveillance 2009
2 CDC Chlamydia Fact Sheet; CS226060A, Division of STD Prevention (DSTDP) Centers for Disease Control and Prevention
5 Sexually Transmitted Diseases Treatment Guidelines, 2010; CDC, December 17, 2010.
7 cobas CT/NG package insert, Roche Molecular Systems, 12/2013 Doc Rev. 1.0.
8 cobas® PCR Urine Sample Kit, Roche Molecular Systems, 03/2013 Doc Rev. 6.0.
9 cobas® PCR Female Swab Sample Kit, Roche Molecular Systems, 11/2013 Doc Rev. 4.0.

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