

Overview

Useful For

Detection of *Chlamydia trachomatis* or *Neisseria gonorrhoeae*

Profile Information

Test ID	Reporting Name	Available Separately	Always Performed
CTRNA	Chlamydia trachomatis Amplified RNA	Yes	Yes
GCRNA	Neisseria gonorrhoeae Amplified RNA	Yes	Yes

Method Name

Transcription Mediated Amplification

NY State Available

Yes

Specimen

Specimen Type

Varies

Necessary Information

Specimen source is required.

Specimen Required

Submit only 1 of the following specimens:

Swab specimen must be collected using an Aptima Collection Unisex Swab (T583) or Aptima Collection Multitest Swab (T584, formerly called Aptima Vaginal Swab Specimen Collection Kit). These swabs are contained in the Aptima Collection Kit.

Supplies: Swab, Aptima Male/Female Collection (T583)

Specimen Type: Endocervix

Container/Tube: Aptima Collection Unisex Swab (T583)

Specimen Volume: Swab

Collection Instructions:

1. Use cleaning swab (white shaft) to remove excess mucus from endocervix and discard.

-
2. Insert second swab (blue shaft) 1 to 1.5 cm into endocervical canal, and rotate swab gently for 30 seconds. Avoid touching vaginal wall when removing swab.
 3. Place second swab into transport tube provided in collection kit. Snap off swab at score line so swab fits into closed tube.
 4. Cap tube securely, and label tube with patient's entire name, and date and time of collection.
 5. Transport and store swab container at 2 to 30 degrees C (refrigerate is preferred temperature) within 60 days of collection. If longer storage is needed, freeze at -20 to -70 degrees C for 12 months.

Supplies: Swab, Aptima Multitest Swab Specimen Collection Kit (T584)

Specimen Type: Vaginal

Container/Tube: Aptima Collection Multitest Swab (T584)

Specimen Volume: Swab

Collection Instructions:

1. Insert swab (pink shaft) about 5 cm past introitus and rotate gently for 30 seconds.
2. Place swab into transport tube provided in collection kit. Snap off swab at score line so swab fits into closed tube.
3. Cap tube securely, and label tube with patient's entire name, and date and time of collection.
4. Transport and store swab container at 2 to 30 degrees C (refrigerate is preferred temperature) within 60 days of collection. If longer storage is needed, freeze at -20 to -70 degrees C for 12 months.

Supplies: Swab, Aptima Male/Female Collection (T583)

Specimen Type: Urethra (Males Only)

Container/Tube: Aptima Collection Unisex Swab (T583)

Specimen Volume: Swab

Collection Instructions:

1. Patient should not have urinated for at least 1 hour prior to collection.
2. With a rotating movement, insert swab (blue shaft) 2 to 4 cm into urethra.
3. Once inserted, rotate swab gently at least 1 full rotation using sufficient pressure to ensure swab comes into contact with all urethral surfaces. Allow swab to remain inserted for 2 to 3 seconds.
4. Place swab in transport tube provided in collection kit. Snap off swab at score line so swab fits into closed tube.
5. Cap tube securely, and label tube with patient's entire name, and date and time of collection.

6. Transport and store swab container at 2 to 30 degrees C (refrigerate is preferred temperature) within 60 days of collection. If longer storage is needed, freeze at -20 to -70 degrees C for 12 months.

Supplies: Aptima Urine Transport Tube (T582)

Specimen Type: Urine (Males and Females)

Container/Tube: Aptima Urine Specimen Transport Tube (T582)

Specimen Volume: 15-20 mL

Collection Instructions:

1. Patient should not have urinated for at least 1 hour prior to specimen collection.
2. Patient should collect first portion of random voided urine (first part of stream) into a sterile, plastic, preservative-free container.
3. Transfer 2 mL of urine into the urine specimen transport tube using the disposable pipette provided within 24 hours of collection. The correct volume of urine has been added when the fluid level is between the black fill lines on the urine transport tube. Place the labels on the transport tube so the black fill lines are still visible for volume confirmation at Mayo Clinic Laboratories.
4. Transport and store urine specimen transport container at 2 to 30 degrees C (refrigerate is preferred temperature) within 30 days of collection. If longer storage is needed, freeze at -20 to -70 degrees C for 12 months.

Supplies: Aptima Thin Prep Transport Tube (T652)

Specimen Type: ThinPrep Specimen (Endocervix)

Container/Tube: ThinPrep (also called PreservCyt) Collection Kit

Specimen Volume: 1 mL

Collection Instructions:

1. Aliquot ThinPrep specimen for *Chlamydia* and/or *Neisseria* testing before processing for Pap smear. For each specimen, use a new pair of clean gloves.
2. Vortex ThinPrep/PreservCyt vial 3 to 10 seconds. Within 1 minute of vortexing:
 - a. Transfer 1 mL of specimen into the Aptima Specimen Transfer Tube (T652) using a disposable transfer pipette or a pipette tip containing a filter (aerosol barrier or hydrophobic plug).
 - b. Process only 1 ThinPrep and transfer tube set at a time.
 - c. Recap Aptima Specimen Transfer Tube tightly and gently invert 3 times to mix.
3. Label Aptima transfer tube with appropriate label.

4. Use remainder of ThinPrep specimen for Pap testing.
5. Transport and store specimen transfer container at 2 to 30 degrees C (refrigerate is preferred temperature) within 60 days of collection. If longer storage is needed, freeze at -20 to -70 degrees C for 12 months.

Forms

If not ordering electronically, complete, print, and send a [Microbiology Test Request](#) (T244) with the specimen.

Specimen Minimum Volume

Endocervical in PreservCyt: 1mL
 Urine: 2 mL
 Swabs (Endocervical, Urethral, Vaginal): Entire Collection

Reject Due To

Other	Midstream urine specimen Overfilled or underfilled urine transport tubes Specimen collected into a SurePath device Transport tubes containing a cleaning swab or more than 1 swab
-------	---

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Refrigerated (preferred)		APTIMA VIAL
	Ambient		APTIMA VIAL
	Frozen		APTIMA VIAL

Clinical and Interpretive

Clinical Information

[Chlamydia is caused by the obligate intracellular bacterium *Chlamydia trachomatis* and is the most prevalent sexually transmitted bacterial infection \(STI\) in the United States.\(1,2\) In 2010, 1.3 million documented cases were reported to the CDC.\(2\) Given that 3 out of 4 infected women and 1 out of 2 infected men will be asymptomatic initially, the actual prevalence of disease is thought to be much greater than reported.\(2\) The organism causes genitourinary infections in women and men and may be associated with dysuria and vaginal, urethral, or rectal discharge. In women, complications include pelvic inflammatory disease, salpingitis, and infertility. Approximately 25% to 30% of women who develop acute salpingitis become infertile.\(2\)](#) Complications among men are rare, but include epididymitis and sterility. Rarely, genital chlamydial infection can cause arthritis with associated skin lesions and ocular inflammation (Reiter syndrome). *C trachomatis* can be transmitted from the mother during delivery and is associated with conjunctivitis and pneumonia. Finally, *C trachomatis* may cause hepatitis and pharyngitis in adult.

Once detected, the infection is easily treated by a short course of antibiotic therapy.(2) Annual *Chlamydia* screening is now recommended for all sexually active women age 25 years and younger, and for older women with risk factors for infection, such as a new sex partner or multiple sex partners.(2) The CDC also recommends that all pregnant women be given a screening test for chlamydia infection.(2) Repeat testing for test-of-cure is **not** recommended after treatment with a standard treatment regimen unless patient compliance is in question, reinfection is suspected, or the patient's symptoms persist. Repeat testing of pregnant women, 3 weeks after completion of therapy, is also recommended to ensure therapeutic cure.(2)

Gonorrhea is caused by the bacterium *Neisseria gonorrhoeae*. It is also a very common STI, with 301,174 cases of gonorrhea reported to CDC in 2009.(1,2) Like *Chlamydia*, many infections in women are asymptomatic, and the true prevalence of gonorrhea is likely much higher than reported.(1,2) The organism causes genitourinary infections in women and men and may be associated with dysuria and vaginal, urethral, or rectal discharge. Complications include pelvic inflammatory disease in women and gonococcal epididymitis and prostaticitis in men. Gonococcal bacteremia, pharyngitis, and arthritis may also occur. Infection in men is typically associated with symptoms that would prompt clinical evaluation. Given the risk for asymptomatic infection in women, screening is recommended for women at increased risk of infection (eg, women with previous gonorrhea or other STI, inconsistent condom use, new or multiple sex partners, and women in certain demographic groups such as those in communities with high STI prevalence.)⁽²⁾ The CDC currently recommends dual antibiotic treatment due to emerging antimicrobial resistance.⁽²⁾

Culture was previously considered to be the gold standard test for diagnosis of *C trachomatis* and *N gonorrhoeae* infection. However, these organisms are labile in vitro, and precise specimen collection, transportation, and processing conditions are required to maintain organism viability, which is necessary for successful culturing. In comparison, nucleic acid amplification testing (NAAT) provides superior sensitivity and specificity and is now the recommended method for diagnosis in most cases.⁽²⁻⁵⁾ Immunoassays and nonamplification DNA tests are also available for *C trachomatis* and *N gonorrhoeae* detection, but these methods are significantly less sensitive and less specific than NAATs.⁽²⁻⁵⁾

Improved screening rates and increased sensitivity of NAAT testing have resulted in an increased number of accurately diagnosed cases.⁽²⁻⁵⁾ Improved detection rates result from both the increased performance of the assay and the patients' easy acceptance of urine testing. Early identification of infection enables sexual partners to seek testing and/or treatment as soon as possible and reduces the risk of disease spread. Prompt treatment reduces the risk of infertility in women.

Reference Values

Chlamydia trachomatis

Negative

Neisseria gonorrhoeae

Negative

Interpretation

A positive result indicates that rRNA of *Chlamydia trachomatis* or *Neisseria gonorrhoeae* is present in the specimen tested and strongly supports a diagnosis of chlamydial or gonorrheal infection.

A negative result indicates that rRNA for *C trachomatis* or *N gonorrhoeae* was not detected in the specimen.

The predictive value of an assay depends on the prevalence of the disease in any particular population. In settings with a high prevalence of sexually transmitted disease, positive assay results have a high likelihood of being true-positives. In settings with a low prevalence of sexually transmitted disease, or in any setting in which a patient's clinical signs and symptoms or risk factors are inconsistent with gonococcal or chlamydial urogenital infection, positive results should be carefully assessed and the patient retested by other methods (eg, culture for *N gonorrhoeae*), if appropriate.

A negative result does not exclude the possibility of infection. If clinical indications strongly suggest gonococcal or chlamydial infection, additional specimens should be collected for testing. A result of indeterminate indicates that a new specimen should be collected.

This test has not been shown to cross react with commensal (nonpathogenic) *Neisseria* species present in the oropharynx.

Cautions

Care must be taken to avoid cross-contamination during handling of PreservCyt solution liquid Pap specimens. If testing PreservCyt specimens processed with the ThinPrep 2000 processor, it is important to follow procedures to reduce the risk for cross-contamination during Pap processing such as bleaching of the PreservCyt filter cap and changing gloves between each sample. Refer to the ThinPrep 2000 Processor Operator's Manual and the Aptima specimen for more guidance.

The performance of endocervical, vaginal, and male urethral swab specimens, male and female urine specimens, and PreservCyt solution liquid Pap specimens has not been evaluated in adolescents younger than 16 years of age. The performance of vaginal swab specimens has not been evaluated in pregnant women.

This report is intended for use in clinical monitoring or management of patients; it is not intended for use in medico-legal applications.

Appropriate specimen collection and handling is necessary for optimal assay performance.

Results should be interpreted in conjunction with other laboratory and clinical information.

A negative test result does not exclude the possibility of infection. Improper specimen collection, concurrent antibiotic therapy, presence of inhibitors, or low numbers of organisms in the specimen (ie, below the sensitivity of the test) may cause false-negative test results.

In low-prevalence populations, positive results must be interpreted carefully as false-positive results may occur more frequently than true-positive results in this setting.

In general, this assay should not be used to assess therapeutic success or failure, since nucleic acids from these organisms may persist for 3 weeks or more following antimicrobial therapy.

The presence of mucous does not interfere with this assay. However, this test requires endocervical cells, and if excess mucous is not removed prior to collection, adequate numbers of these cells may not be obtained.

No interference is expected due to:

-Blood

-Lubricants and spermicides

The effects of use of tampons, douching, specimen types other than those listed in Specimen Required, and specimen collection variable have not been determined.

Testing of urine specimens with this method is not intended to replace cervical exam and endocervical sampling for diagnosis of urogenital infection; infections may result from other causes or concurrent infections may occur.

Testing urine specimens as the sole test for identifying female patients with chlamydial or gonococcal infections may miss some infected individuals.

Performance estimates for urine specimens are based on evaluation of urine obtained from the first part of the urine stream; performance on midstream collections has not been determined.

This assay **does** detect plasmid-free variants of *Chlamydia trachomatis*.

This assay **does not** detect *C pneumoniae*.

This assay has not been shown to cross-react with commensal (nonpathogenic) *Neisseria* species in the oropharynx.

Clinical Reference

- Centers for Disease Control and Prevention. 2002. Reporting of laboratory-confirmed chlamydial infection and gonorrhea by providers affiliated with three large Managed Care Organizations-United States, 1995-1999. MMWR Morb Mortal Wkly Rep 2002;51:256-259
- Centers for Disease Control and Prevention: Sexually Transmitted Diseases Treatment Guidelines, 2010. MMWR Morb Mortal Wkly Rep 2010;59:RR12
- Crotchfelt KA, Pare B, Gaydos C, Quinn TC: Detection of *Chlamydia trachomatis* by the GEN-PROBE AMPLIFIED *Chlamydia trachomatis* Assay (AMP CT) in urine specimens from men and women and endocervical specimens from women. J Clin Microbiol 1998 Feb;36(2):391-394
- Gaydos CA, Quinn TC, Willis D, et al: Performance of the APTIMA Combo 2 assay for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in female urine and endocervical swab specimens. J Clin Microbiol 2003 Jan;41(1):304-309
- Chernesky MA, Jang DE: APTIMA transcription-mediated amplification assays for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. Expert Rev Mol Diagn 2006 Jul;6(4):519-525

Performance

Method Description

The HOLOGIC APTIMA Combo 2 Assay combines the technologies of target capture, transcription-mediated amplification, and dual kinetic assay. The detection of the rRNA amplification product sequences (amplicon) is achieved using nucleic acid hybridization. Single-stranded chemiluminescent DNA probes are labeled and combine with amplicon to form stable RNA:DNA hybrids. Light emitted from the labeled RNA:DNA hybrids is measured as photon signals in a luminometer. (Package insert: HOLOGIC APTIMA Combo 2 Assay 501798 002 2017-03)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Saturday; Varies

Analytic Time

1 day

Maximum Laboratory Time

4 days

Specimen Retention Time

7 days

Performing Laboratory Location

Rochester

Fees and Codes

Fees

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact [Customer Service](#).

Test Classification

This test has been cleared or approved by the U.S. Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

87491-*Chlamydia trachomatis*

87591-*Neisseria gonorrhoeae*

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
CGRNA	Chlamydia/Gonorrhoeae Amplified RNA	64017-7

Result ID	Test Result Name	Result LOINC Value
SRC14	SOURCE:	31208-2
SRC17	SOURCE:	31208-2
34875	Neisseria gonorrhoeae amplified RNA	43305-2
34874	Chlamydia trachomatis amplified RNA	43304-5