MAYO CLINIC LABORATORIES

Test Definition: CTCON

Chlamydia trachomatis Confirmation, Nucleic Acid Amplification, Varies

Overview

Useful For

Detecting *Chlamydia trachomatis*

This test is **not intended for use** in medico-legal applications.

This test is **not useful for** the detection of other *Chlamydia* species.

Highlights

This test is used to confirm positive *Chlamydia trachomatis* results from the Hologic Aptima Combo 2 Assay (Hologic Inc.) or another *C trachomatis* molecular assay.

Method Name

Transcription-Mediated Amplification

NY State Available

Yes

Specimen

Specimen Type

Varies

Ordering Guidance

This test should be ordered only on prior *Chlamydia trachomatis* positive samples or on a new collection from a patient who previously tested positive for *C trachomatis* by the Hologic Aptima Combo 2 assay (eg, CGRNA / *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, Nucleic Acid Amplification, Varies; CTRNA / *Chlamydia trachomatis*, Nucleic Acid Amplification, Varies; MCTGC / *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, Miscellaneous Sites, Nucleic Acid Amplification, Varies; MCRNA / Chlamydia trachomatis, Miscellaneous Sites, Nucleic Acid Amplification, Varies) or by an alternative *C trachomatis* molecular assay.

Additional Testing Requirements

A prior positive *Chlamydia trachomatis* result from the Hologic Aptima Combo 2 assay or another *C trachomatis* molecular assay is required prior to performing this test.

Shipping Instructions

If submitting a previously tested specimen that resulted as positive for *Chlamydia trachomatis*, ensure that the specimen is tightly capped with a non-penetrable cap on the specimen transport tube. Maintain recommended storage and shipping requirements indicated below.

Necessary Information

Specimen source is required.

Specimen Required

If testing is being performed on a previously tested specimen that resulted as positive, submit that specimen.

If testing is being performed on a newly collected specimen, submit only 1 of the following specimens:

Specimen Type: Ocular (corneal/conjunctiva)
Supplies:
-Aptima Unisex Swab Collection Kit (T583)
-Aptima Multitest Swab Specimen Collection Kit (T584)
Container/Tube: Aptima Multitest Swab or Aptima Collection Unisex Swab
Specimen Volume: 1 Swab
Collection Instructions:
1. Swab site using Aptima Multitest Swab or Aptima Collection Unisex Swab. Specimens must be collected using either of these options.
Note: The white swab provided within the collection kit is a cleaning swab and should not be used for collection. Discard the white cleaning swab.
2. Place collection swab in transport tube provided in collection kit.
3. Snap off swab at score line so it fits into closed tube.
4. Cap tube securely and label tube with patient's entire name and collection date and time.
5. Maintain swab container at 2 to 30 degrees C (refrigerated temperature is preferred) or -20 to -70 degrees C and transport within 14 days of collection.

Specimen Type: Vaginal
Supplies: Aptima Multitest Swab Specimen Collection Kit (T584)
Container/Tube: Aptima Multitest Swab
Specimen Volume: 1 Swab
Collection Instructions:
1. Specimen must be collected using the Aptima Multitest Swab Specimen Collection Kit.
2. Insert swab (pink shaft) about 5 cm past introitus and rotate gently for 30 seconds.
3. Place pink swab into transport tube provided in collection kit.
4. Snap off pink swab at score line so it fits into closed tube.
5. Cap tube securely, and label tube with patient's entire name and collection date and time.
6. Maintain swab container at 2 to 30 degrees C (refrigerated temperature is preferred) and transport within 60 days of collection. If longer storage is needed, freeze at -20 to -70 degrees C for 12 months.

Specimen Type: Urine
Supplies: Aptima Urine Transport Tube (T582)
Container/Tube: Aptima urine specimen transport tube
Specimen Volume: 15 to 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. Within 24 hours of collection. transfer 2 mL of urine into the urine specimen transport tube using the disposable pipette provided. The correct volume of urine has been added when the fluid level is between the black fill lines on the urine transport tube.
4. Place the labels on the transport tube so the black fill lines are still visible for volume confirmation at Mayo Clinic Laboratories.
5. Maintain urine specimen transport tube at 2 to 30 degrees C (refrigerated temperature is preferred) and transport within 30 days of collection. If longer storage is needed, freeze at -20 to -70 degrees C for 12 months.

Specimen Type: Oropharynx/Pharynx/Throat
Supplies: Aptima Multitest Swab Collection Kit (T584)
Container/Tube: Aptima Collection Multitest Swab
Specimen Volume: Swab
Collection Instructions:
1. Specimens must be collected using Aptima Multitest Swab Specimen Collection Kit.
2. Swab site using Aptima Collection Multitest Swab (pink shaft).
3. Place pink swab in transport tube provided in collection kit.
4. Snap off pink swab at score line so it fits into closed tube.
5. Cap tube securely and label tube with patient's entire name and collection date and time.
6. Maintain swab container at either 2 to 30 degrees C (refrigerated temperature is preferred) or -20 to -70 degrees C and transport within 14 days of collection.

Specimen Type: Rectal/Anal
Supplies: Aptima Multitest Swab Collection Kit (T584)
Container/Tube: Aptima Multitest Swab
Specimen Volume: Swab
Collection Instructions:
1. Specimens must be collected using Aptima Multitest Swab Specimen Collection Kit.
2. Insert swab into rectum about 3 to 5 cm past anal margin and gently rotate swab for 10 seconds.
3. Place collection swab in transport tube provided in collection kit.
4. Snap off swab at score line so it fits into closed tube.
5. Cap tube securely and label tube with patient's entire name and collection date and time.
6. Maintain swab container at either 4 to 30 degrees C (refrigerated temperature is preferred) or -20 to -70 degrees C and transport within 14 days of collection.

Specimen Minimum Volume

See Specimen Required

Reject Due To

Midstream urine specimen	Reject

Clean catch urine specimen	Reject
Overfilled urine transport tubes	Reject
Multiple sources on single tube	Reject
Transport tubes containing a cleaning swab or more than 1 swab	Reject

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information

Chlamydia is caused by the obligate intracellular bacterium *Chlamydia trachomatis* and is the most prevalent sexually transmitted infection (STI) caused by bacteria in the United States. In 2020, over 1.5 million documented cases were reported to the Centers for Disease Control and Prevention (CDC). Given that 3 out of 4 infected women and 1 out of 2 infected men are initially asymptomatic, the actual prevalence of disease is thought to be much greater than reported. *C trachomatis* causes genitourinary infections in women and men and may be associated with dysuria as well as 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. 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 in the newborn. Finally, *C trachomatis* may cause hepatitis and pharyngitis in adults.

Once detected, the infection is easily treated by a short course of antibiotic therapy. Annual chlamydia screening is now recommended for all sexually active women aged 25 years or younger and for older women with risk factors for infection, such as a new sex partner or multiple sex partners. The CDC also recommends that all pregnant women be given a screening test for chlamydia infection. 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, although residual nucleic acid may remain in the absence of active infection.

Improved screening rates and increased sensitivity of nucleic acid amplification testing have resulted in an increased number of accurately diagnosed cases. Improved detection rates result from improved performance characteristics of the assays and patients' easy acceptance of urine testing. Early identification of infection enables sexual partners to seek testing and treatment as soon as possible and reduces the risk of disease spread. Prompt treatment reduces the risk of infertility in women.

Per CDC guidance, a positive *C trachomatis* result in a child undergoing evaluation for an STI should be confirmed because of the risk of a false positive result due to the overall low prevalence of STIs in this patient population. An initial positive result should be confirmed by re-testing the sample using an assay targeting an alternative *C trachomatis* gene region, or by collecting and testing a new sample.

Reference Values

Negative

Interpretation

A positive result indicates the presence of nucleic acid from *Chlamydia trachomatis* and strongly supports the diagnosis of chlamydial infection.

A negative result indicates that nucleic acid from *C trachomatis* was not detected in the specimen. A negative result does not exclude the possibility of infection. If clinical indications strongly suggest chlamydial infection, additional specimens should be collected for testing.

A result of inconclusive indicates that a new specimen should be collected.

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

Cautions

This report is intended for 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.

No interference is expected in swab specimens due to:
-Blood
-Lubricants and spermicides

The effects of tampon use, douching, specimen types other than those listed in Specimen Required, and specimen collection variables 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 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 detects plasmid-free variants of *Chlamydia trachomatis*.

This assay does not detect *Chlamydia pneumoniae* or other *Chlamydia* species.

Clinical Reference

1. Workowski KA, Bachmann LH, Chan PA, et al. Sexually transmitted infections treatment guidelines, 2021. MMWR Recomm Rep. 2021;70(4):1-187. doi:10.15585/mmwr.rr7004a1
2. Adamson PC, Klausner JD. Diagnostic test for detecting chlamydia trachomatis and neisseria gonorrhoeae in rectal and pharyngeal specimens. J Clin Microbiol. 2022;60(4):e0021121. doi:10.1128/JCM.00211-21

Performance

Method Description

The Aptima Chlamydia trachomatis assay is a nucleic acid amplification test (NAAT) that employs target capture, Transcription-Mediated Amplification TMA, and Hybridization Protection Assay HPA technologies. The detection of the ribosomal RNA amplification product sequences (amplicon) is achieved using nucleic acid hybridization. Single-stranded chemiluminescent DNA probes are labeled and combined 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: Aptima Chlamydia trachomatis Assay, AW-28328-001. Hologic, Inc; Rev 001, 01/2024)

Test Definition: CTCON

Chlamydia trachomatis Confirmation, Nucleic Acid Amplification, Varies

PDF Report
No

Day(s) Performed
Monday through Sunday

Report Available
1 to 4 days

Specimen Retention Time
7 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Superior Drive

Fees & 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 account representative. For assistance, contact Customer Service.

Test Classification
This test has been modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information
87491

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
CTCON	C trachomatis Confirm, RNA, Varies	43304-5

Result ID	Test Result Name	Result LOINC® Value
SRC20	SOURCE:	31208-2
623155	C trachomatis Confirm, RNA, Varies	43304-5