Test Definition: MCRNA

Chlamydia trachomatis, Miscellaneous Sites, Nucleic Acid Amplification, Varies

Overview

Useful For

Detecting *Chlamydia trachomatis* in non-US Food and Drug Administration-approved specimen types

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

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

Method Name

Transcription Mediated Amplification

NY State Available

Yes

Specimen

Specimen Type

Varies

Ordering Guidance

This test is used for specimens that **are not** US Food and Drug Administration (FDA) approved for this assay. Acceptable non-FDA-approved specimen types are ocular swabs, nasopharyngeal swabs, and peritoneal fluid.

For FDA-approved specimen types, order CTRNA / *Chlamydia trachomatis*, Nucleic Acid Amplification, Varies.

Necessary Information

Specimen source is required.

Specimen Required

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 Unisex Swab
Specimen Volume: 1 Swab
Collection Instructions:
1. Swab site using Aptima Multitest Swab or Aptima Unisex Swab. **Specimens must be collected using either of these**

Aptima swabs.
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 (refrigerate temperature is preferred); transport within 60 days of collection.

Pediatric Specimen Type: Nasopharyngeal (NP) (**only accepted for patients aged 6 months or younger**)
Supplies: Aptima Unisex Swab Collection Kit (T583)
Container/Tube: Aptima Unisex Swab
Specimen Volume: 1 Swab
Collection Instructions:
1. Swab site using NP Swab or Aptima Unisex Swab. **Specimens must be collected using either one of these swabs**.
Note: The white swab provided within the Aptima Unisex Swab Collection kit is a cleaning swab and should not be used during this collection process. This white swab should be discarded.
2. Place NP swab in Aptima Specimen Transfer Tube.
3. If using the Aptima Unisex Swab collection kit, place the unisex swab in the Aptima Collection kit tube. 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 (refrigerate temperature is preferred); transport within 60 days.

Specimen Type: Peritoneal fluid (pelvic wash, cul-de-sac fluid)
Supplies: Aptima Specimen Transfer Kit (T652)
Container/Tube: Aptima specimen transfer tube
Specimen Volume: 1 mL
Collection Instructions:
1. Transfer 1mL of peritoneal fluid directly into the Aptima specimen transfer tube within 24 hours of collection.
2. Cap tube securely and label tube with patient's entire name and collection date and time.
3. Maintain Aptima specimen transfer tube at 2 to 30 degrees C (refrigerate temperature is preferred); transport within 30 days of collection.

Forms

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

Specimen Minimum Volume

See Specimen Required

Reject Due To

REGULAR HOURS: Transport Ambient to testing lab. OFF HOURS: Refrigerate and send to testing lab next working day.

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.

Reference Values

Negative

Interpretation

A positive result indicates the presence of nucleic acid from *Chlamydia trachomatis*.

A negative result indicates the absence of *C trachomatis* nucleic acid. 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 this organism may persist for 3 weeks or more following antimicrobial therapy.

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

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 Hologic Aptima Combo 2 Assay combines the technologies of target capture, transcription-mediated amplification,

and dual kinetic assay. 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 Combo 2 Assay, AW-25929-001. Hologic, Inc; Rev 002, 06/2023)

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
MCRNA	C. trach, Misc, Amplified RNA	43304-5

Result ID	Test Result Name	Result LOINC® Value
SRC11	SOURCE:	31208-2
34507	C. trach, Misc, Amplified RNA	43304-5