Lab Dept: Microbiology/Virology

Test Name: CHLAMYDIA AMPLIFIED RNA ASSAY

General Information

Lab Order Codes: CTRN

Synonyms: Chlamydia trachomatis by Nucleic Acid Amplification (Gen-Probe)

CPT Codes: 87491 – Chlamydia trachomatis, amplified probe technique

Test Includes: Target capture, transcription-mediated amplification, and dual kinetic assay. The detection of 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.

Logistics

Test Indications: Chlamydia trachomatis infection is the most prevalent sexually transmitted disease (STD) in the United States. The organism causes genitourinary infections in men and women, and some infected individuals may be asymptomatic. An estimated 3 out of 4 infected women and 1 out of 2 infected men will be asymptomatic initially. Chlamydial infection is the most common cause of acute salpingitis, and about 25% of women who develop acute salpingitis become infertile. Once detected, the infection is easily treated by a short course of antibiotic therapy.

Lab Testing Sections: Virology - Sendouts

Referred to: Mayo Medical Laboratories (MML Test#: CTRNA)

Phone Numbers: MIN Lab: 612-813-5806

STP Lab: 651-220-6555

Test Availability: Daily, 24 hours

Turnaround Time: 1 - 2 days, performed daily

Special Instructions:

● This test is approved for endocervical swabs, vaginal swabs, male urethral swabs and male and female urine utilizing special collection kits obtainable on patient units.

● **Obtain special collection supplies based on type of specimen to be collected. Supplies are stocked on patient units.**

● Swabs of vaginal drainage and female urethral swabs will be rejected.

● The first portion of voided urine is used because it has the highest concentration of organisms, midstream urine is unacceptable.

● **Specimen site** and **date/time of collection** are required for processing.

Specimen

Specimen Type: Endocervical swabs, male urethral swabs, vaginal swabs, the first portion of voided urine specimens

Container:

Obtain one of the following (stocked on patient units):	
Endocervix (Females) Uretha (Males)	Supply T583 – Aptima Unisex swab specimen collection system 
Vaginal (Females)	Supply T584 – Aptima Vaginal swab specimen collection system 

Urine (Males and Females)	Collect in standard sterile screw-cap urine cup.

Volume: 15 - 20 mL of urine or 1 swab based on supply kit for specimen type

Collection:

Endocervical swab (Female) specimens – Supply T583:
a. Remove excess mucus from the cervical os and surrounding mucosa using the cleaning swab (white shaft). Discard this Swab.
b. Insert the specimen collection swab (blue shaft) 1 to 1.5 cm into the endocervical canal.
c. Gently rotate the swab clockwise for 30 seconds in the endocervical canal to ensure adequate sampling.
d. Withdraw the swab carefully; avoid any contact with the vaginal mucosa.
e. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
f. Carefully break the swab shaft at the score line; use care to avoid splashing of contents.
g. Re-cap the swab specimen transport tube tightly.
h. Label tube with patient identifiers, specimen type and date and time of collection.

Urethral swab (Male) specimens – Supply T583:
a. The patient should not have urinated for at least one hour prior to sample collection.
b. Insert the specimen collection swab (blue shaft) 2 to 4 cm into the urethra.
c. Gently rotate the swab clockwise for 2 to 3 seconds in the urethra to ensure adequate sampling.
d. Withdraw the swab carefully.
e. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
f. Carefully break the swab shaft at the score line; use care to avoid splashing of contents.
g. Re-cap the swab specimen transport tube tightly.
h. Label tube with patient identifiers, specimen type and date and time of collection.

Vaginal Swab specimens – Supply T584:
a. Insert swab (pink shaft) about 5 cm past introitus and rotate gently for 30 seconds.
b. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
c. Carefully break the swab shaft at the score line; use care to avoid splashing of contents.
d. Re-cap the swab specimen transport tube tightly.
e. Label tube with patient identifiers, specimen type and date and time of collection.

Urine specimens – Screw-capped urine cup:
a. The patient should not have urinated for at least one hour prior to sampling.
b. Direct patient to provide a first-catch urine (approximately 20 to 30 mL of the initial urine stream) into a urine collection cup. Minimum amount is 2 mL urine. Collection of larger volumes of urine may reduce test sensitivity.

Female patients should not cleanse the labial area prior to providing the specimen.
c. Label the urine sample with patient identifiers and date and time of collection.
d. Send sample to the laboratory.

Transport/Storage: Transport swabs at 2-27ºC to the Laboratory. Once in the lab, refrigerate swab and forward to Mayo.

Transport urine at 2-8ºC to the Laboratory for processing.

Special Processing: Lab staff:

Urine specimens – Supply T582:
a. Transfer 2 mL of urine into the urine specimen transport tube from Supply T582 using the disposable pipette provided within 24 hours of collection. The correct volume has been added when the fluid level is between the black fill lines on the urine transport tube.
b. Label with patient identifiers and date and time of collection.
c. Store at refrigerated temperatures.
d. Forward to Mayo for testing.

Endocervical, Urethral and Vaginal swab specimens: Store at refrigerated temperatures and forward to Mayo for testing.

Sample Rejection: Specimen not submitted in appropriate transport container; improperly labeled specimen; midstream urine; insufficient volume; external contamination; swabs of vaginal drainage and female urethral swabs. If an unacceptable specimen is received, the physician or nursing station will be notified and another specimen requested before the specimen is discarded.

Interpretive

Reference Range: No *Chlamydia trachomatis* detected

Interpretation: A negative result indicates that rRNA for *Chlamydia trachomatis* was not detected in the specimen.

A positive result indicate the presence of rRNA *Chlamydia trachomatis*.

The predictive value of an assay depend 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 chlamydial or gonococcal urogenital infection, positive results should be carefully assessed and the patient retested by other methods, if appropriate.

Limitations:

- 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 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.
- This assay cannot be used to assess therapeutic success or failure, since nucleic acids from these organisms may persist 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 (urine and swab) specimens or lubricants and spermicides (swab).
- The effects of use of tampons, douching, specimen types other than those listed 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 does detect plasmid-free variants of Chlamydia trachomatis.
- This assay does not detect Chlamydia pneumoniae.

Methodology: Transcription Mediated Amplification (Gen-Probe)

References:

Mayo Medical Laboratories January 2014