GENETRACKDiagnostics

Chlamydia

WHAT IS CHLAMYDIA?

Chlamydia is a common sexually transmitted disease (STD) caused by infection with the obligate intracellular bacterium *Chlamydia trachomatis*. Chlamydia is transmitted through sexual contact with the penis, vagina, mouth, or anus of an infected individual. It can also be transmitted from a mother with an untreated chlamydial cervical infection to her newborn during childbirth (1).

C. trachomatis are a non-motile, gram-negative bacterial species of at least 15 serovars that can cause disease in humans. *C. trachomatis* has two distinct forms during its life cycle. Reticulate bodies are found only within host cells, while smaller elementary bodies surrounded by a rigid cell wall allow the bacteria to survive (but not replicate) outside a host cell, enabling the initiation of a new infection when it comes into contact with a susceptible host cell (2).

SYMPTOMS

Most individuals infected with chlamydia remain asymptomatic, with only an estimated 10% of infected males showing symptoms and 5-30% of infected females (3). *C. trachomatis* initially infects the cervix of females and sometimes the urethra. In symptomatic females this can result in abnormal vaginal discharge, endocervical bleeding, increased urinary frequency, and dysuria.

Symptomatic males generally develop urethritis resulting in urethral discharge, dysuria, and testicular pain. Chlamydia infections of the rectum may lead to rectal pain, discharge and/or bleeding (4). Sexually acquired chlamydial conjunctivitis can also occur in both males and females (5).

Untreated chlamydial infections in females can lead to pelvic inflammatory disease (PID), and PID-associated infertility, ectopic pregnancy, and chronic pelvic pain. Untreated chlamydia during pregnancy has been associated with preterm delivery (6). Chlamydial infections can be passed to newborns during delivery, increasing the risk of conjunctivitis (18-44% of cases) and pneumonia (3-16% of cases) (7; 8).

Complications in untreated males are rare, but can include epididymitis and infertility. Chlamydial infections can also facilitate the transmission of HIV infection, and in rare cases can cause reactive arthritis (1).

PREVALENCE

Any sexually active individual is at risk of chlamydial infection, with an increased risk among younger individuals. This is due to less consistent condom use (9), increased sexual partners (10), and reduced access to STD prevention services due to a lack of transportation, cost, and perceived stigma (10). In addition, cervical ectopy is more common among younger women, which may increase the susceptibility to chlamydial infection (11).

Chlamydia is one of the most prevalent STDs in the United States with 1,758,668 cases reported to CDC in 2018, corresponding to a rate of 539.9 cases per 100,000 population (1). However, due to many individuals remaining asymptomatic and not undergoing testing, annual cases are estimated to be closer to 2.86 million (12).

Approximately 60% of new chlamydia infections occur in individuals aged between 15 and 24 years, with reported chlamydia rates in females being approximately two times the rate among males (likely reflecting the larger number of females being screened for this STD).

The prevalence of chlamydial infections varies between racial and ethnic groups, with a significantly higher rate among non-Hispanic blacks compared to non-Hispanic whites (13).

DIAGNOSIS

Historically, cell culture was considered the "gold standard" for detection of *C. trachomatis*, as it is quite specific. Nowadays, modern nucleic acid amplification testing (NAAT) provides the most sensitivity and specificity for chlamydia diagnosis. These can be performed on vaginal swabs (either clinician- or patient-collected) or urine.

TREATMENT

Chlamydia is easily cured with antibiotics; however, repeat chlamydial infections from sexual contact with an infected partner are common, which increase the risk of serious reproductive health complications (14). Antibiotics do not repair any permanent damage done by the disease. Condom use reduces, but does not eliminate, the risk of chlamydia.

TESTING RECOMMENDATIONS

The CDC recommends that sexually active young females aged 25 years and younger should be tested annually for chlamydia. Annual testing is recommended in females over 25 years of age who have risk factors for chlamydia, such as a new partner or multiple sexual partners (15).

The CDC also recommends chlamydia screening in all pregnant women. Routine screening is not recommended for males, aside from sexually active men who have sex with men, or in clinical settings with a high prevalence of chlamydia.

TEST PROCEDURE

Correct specimen collection and handling is required for optimal assay performance.

This test requires a first-void urine specimen collected at least 1 hour after previous urination. All supplies for sample collection are provided in this kit.

Collect 20-30 mL of first-void urine in the sterile urine collection container and transfer 2 mL to the urine specimen transport container using the disposable pipette provided. Transfer to the urine transport container must occur within 24 hours of collection, and liquid level must fall between the two black indicator lines on the tube label. Re-cap the urine transport container tightly. Seal in the transport bag and return to the laboratory in the provided prepaid return shipping envelope.

Maintain specimen at temperatures between 2°C and 30°C during storage and transport.

Upon receipt at the laboratory, the urine sample is analyzed by a fully automated nucleic acid amplification testing procedure. *C. trachomatis* rRNA is detected using nucleic acid hybridization, where single-stranded chemiluminescent DNA probes are combined with the rRNA amplicon to form stable RNA:DNA hybrids. Light emitted from the labeled RNA:DNA hybrids is measured as photon signals in a luminometer.

SPECIAL INSTRUCTIONS

- Repeat urine collection (at least 1 hour after previous urination) if more than 60ml of first-void urine is collected.
- Females should not clean the labial area prior to urine collection.
- Do not apply the transport medium directly to skin or mucous membranes or take internally.

TEST INTERPRETATION

- A positive result indicates that *C. trachomatis* nucleic acid (rRNA) is present in the specimen tested and strongly supports a chlamydia diagnosis.
- A negative result indicates that *C. trachomatis* nucleic acid (rRNA) was not detected in the specimen tested. Additional specimens should be collected for testing if clinical symptoms strongly suggest a chlamydial infection.
- An indeterminate result indicates that a new specimen should be tested.

DISCLAIMERS/LIMITATIONS

This report is not intended for use in medico-legal applications. These results are intended for screening and monitoring for chlamydia and should be interpreted in conjunction with other laboratory and clinical information.

Correct specimen collection and handling is required for optimal assay performance. Blood, lubricants, spermicides, anti-fungal creams, human feces, cold sore medication, lip balm, toothpaste, anti-diarrheal medication, and antacids are not expected to cause interference in this assay.

The effects of tampon use, douching, and specimen collection variables have not been assessed for their impact on the detection of chlamydia.

A negative result does not exclude the possibility of infection. Falsenegative test results may occur due to improper specimen collection, concurrent antibiotic therapy, presence of inhibitors, or organism levels below the sensitivity of this assay (which is common within 2 weeks postexposure).

False-positive results are rare, but may be more frequent in lowprevalence populations. A false-positive result may also occur directly after successful antimicrobial therapy, as *C. trachomatis* nucleic acids may persist for 3 weeks or more. For this reason, this test cannot be used for determining therapeutic success or failure.

The performance of this assay has not been evaluated in adolescents less than 14 years of age.

Female urine specimens may detect up to 10% fewer chlamydia infections when compared with vaginal and endocervical swab specimens.

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