GENETRACK Diagnostics

Gonorrhea

WHAT IS GONORRHEA?

Gonorrhea is a common sexually transmitted disease (STD) caused by infection with the bacterium *Neisseria gonorrhoeae*. Gonorrhea 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 untreated gonorrheal infection to her newborn during childbirth (1).

N. gonorrhoeae are gram-negative diplococci, which are capable of moving using twitching motility. A process called antigenic variation enables *N. gonorrhoeae* to alter antigenic determinants on its surface to evade the immune system (2). This also contributes to the lack of an effective vaccine for gonorrhea (3).

SYMPTOMS

Males may exhibit symptoms of gonorrheal infection; however, most infected females remain asymptomatic, with an estimated 85-90% of infected males showing symptoms and only ~20% of infected females (4). In males, *N. gonorrhoeae* causes genitourinary infections resulting in dysuria, frequent urination, abnormal urethral discharges, and testicular pain and swelling (5).

In symptomatic females, symptoms may be so mild that they are mistaken for a bladder or vaginal infection (6). Symptoms can include dysuria, abnormal vaginal discharge and endocervical bleeding.

Rectal infections (in males and females) can lead to discharge from the rectum, itching, bleeding, or painful bowel movements (7), while pharyngeal infections are generally asymptomatic but may cause a sore throat (8).

Untreated gonorrheal infections in females can lead to pelvic inflammatory disease (PID), and PID-associated infertility, ectopic pregnancy, and chronic pelvic pain. Complications in males include epididymitis and prostatitis. Gonococcal bacteremia, pharyngitis, and arthritis may also occur.

Untreated gonorrhea during pregnancy increases the risk of miscarriage and inflammation of the lining of the uterus (9). Gonorrheal infections can be passed to newborns during delivery, increasing the risk of eye infections (which may lead to blindness) and sepsis (which can lead to meningitis) (10). Gonorrheal infections can also facilitate the transmission of HIV infection (11).

PREVALENCE

Any sexually active individual is at risk of gonorrheal infection, with an increased risk among younger individuals. Gonorrhea is a common STD in the United States with 583,405 cases reported to the CDC in 2018, corresponding to a rate of 179.1 cases per 100,000 population (12).

Approximately 50% of cases occur in individuals between 15 and 24 years (5), with higher rates observed in males compared to females (12). The prevalence of gonorrheal infections varies between racial and ethnic groups, with a significantly higher rate among blacks compared to whites (12).

DIAGNOSIS

Historically, gonorrhea was diagnosed by isolation of *N. gonorrhoeae* on selective media or observation of diplococci in Gram stained smears. However, culture methods are highly dependent on stringent specimen handling, as improper specimen storage and transport can lead to false negative results.

Nowadays, modern nucleic acid amplification testing (NAAT) provides the most sensitivity and specificity for gonorrhea diagnosis, and can be performed on vaginal swabs (either clinician- or patient-collected) or urine (13).

TREATMENT

Antibiotic treatment is generally effective for gonorrheal infections. Often individuals infected with gonorrhea are also infected with chlamydia, so chlamydia treatment may be prescribed concurrently. Repeat gonorrheal infections from sexual contact with an infected partner can occur, which increase the risk of serious reproductive health complications. Antibiotics do not repair any permanent damage done by the disease. Condom use reduces, but does not eliminate, the risk of gonorrhea.

TESTING RECOMMENDATIONS

The CDC recommends that sexually active young individuals (25 years and younger) should be tested annually for gonorrhea. Annual testing is also recommended in individuals over 25 years of age who have risk factors for gonorrhea, such as a new partner or multiple sexual partners (10).

The CDC also recommends gonorrhea screening in pregnant women less than 25 years of age and in older pregnant women at increased risk.

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. *N. gonorrhoeae* 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 *N. gonorrhoeae* nucleic acid (rRNA) is present in the specimen tested and strongly supports a gonorrhea diagnosis.

- A negative result indicates that *N. gonorrhoeae* nucleic acid (rRNA) was not detected in the specimen tested. Additional specimens should be collected for testing if clinical symptoms strongly suggest a gonorrheal 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 gonorrhea 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 gonorrhea.

A negative result does not exclude the possibility of infection. False-negative 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 post-exposure).

False-positive results are rare, but may be more frequent in low-prevalence populations. A false-positive result may also occur directly after successful antimicrobial therapy, as *N. gonorrhoeae* 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 gonorrhea infections when compared with vaginal and endocervical swab specimens.

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